North Dakota Medicaid

Drug Utilization Review Board Meeting

March 6th, 2024

Conference Room 210/212

NORTH Dakota | Health & Human Services

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Meeting Notice

North Dakota Medicaid Drug Use Review Board

Wednesday, March 6th, 2024
1 to 4 p.m. Central Time

In-Person Information

Conference Room 210/212, 2nd Floor, Judicial Wing, State Capitol
600 E. Boulevard Ave., Bismarck

Virtual Information

Join virtually: Click here to join the meeting
Join by phone: 701-328-0950, Conference ID: 245 967 869 #

Agenda

1. Call to Order
2. Roll Call
3. Review and Approval of Minutes
4. Reports from Department
    - Administrative Report: COVID-19 treatment (Lagevrio & Paxlovid)
    - Financial Report: Budget, Top Drugs
    - Retrospective DUR Report
    - Clinical Report:
        - Prior authorization update
        - Criteria updates: Corticosteroids – Inhaled Criteria, Tardive Dyskinesia, Phenylketonuria
5. Unfinished business
    - Update to Hyperkalemia Criteria, Prophylaxis to Migraine, Eczema / Atopic Dermatitis, Cholestatis Pruritis
6. New business
    - First Review of potassium-competitive acid blockers (Voquezna)
    - First Review of Seborrheic Dermatitis (Zoryve)
    - First Review of Primary Hyperoxaluria Tyle 1 (Rivfloza)
    - First Review of Myasthenia Gravis (Ziibrysq)
    - First Review of Duchenne Muscular Dystrophy (Emflaza, Agamree)
    - First Review of Paroxysmal Nocturnal Hemoglobinuria (Empaveli, Fabhalta)
    - Review of retrospective DUR criteria recommendations
7. Announcements
    - Next Meeting (June 5, 2024)
8. Adjourn

Individuals with disabilities who need accommodations, including appropriate auxiliary aids to participate, can contact Ashley Gerving at 701-328-2354, toll-free 800-755-2604, 711 (TTY) or gervingashley@nd.gov.

Meeting Minutes
North Dakota Medicaid Drug Use Review (DUR) Board
Meeting Date: December 6th, 2023
Time and Location: 1:00 pm CST in Bismarck, North Dakota

Call to Order:
A regular quarterly meeting of the North Dakota Medicaid Drug Use Review (DUR) Board meeting was convened at 1:06 pm CST. Motion moved by A. Werremeyer to have pro tem Presiding Officer K. Martian presiding and seconded by T. Schmidt. **Motion carried.**
DUR Board Coordinator, C. Stauter recording minutes.

Roll Call:
Board Members Voting:
Present: Stephanie Antony, Josh Askvig, Gabriela Balf, Kurt Datz, Andrea Honeyman, Laura Kroetsch, Kevin Martian, Kristen Peterson, Tanya Schmidt, Amy Werremeyer
Absent: Jennifer Iverson
Quorum Present: Yes

Board Members Non-Voting:
Absent: Kathleen Traylor

Medicaid Pharmacy Department:
Present: Brendan Joyce, Alexi Murphy, LeNeika Roehrich
Absent: Jeff Hostetter

Approval of Meeting Minutes:
Motion: Moved by L. Kroetsch to approve the minutes of the September 6th, 2023 meeting, motion was seconded by K. Peterson. **Motion carried.**
The minutes of the September 6th, 2023, meeting were approved as distributed.

Reports:
*Administrative Report***:** Rebates by A. Murphy
A. Murphy shared with the Board changes to rebate calculations. This information can be found in the handout.

Financial Report: Budget provided by B. Joyce
B. Joyce shared with the Board trends of pharmacy claims costing over $5000 from August 2023. This information can be found in the handout.

Financial Report: Top Drugs provided by B. Joyce
B. Joyce presented the quarterly review of the top 25 drugs based on total number and cost of claims and the top 15 therapeutic classes based on number and cost of claims. This report can be found in the handout.

Retrospective Drug Utilization Review (RDUR) Report by C. Stauter
C. Stauter reviewed the quarterly RDUR criteria that were selected for review of each month, including a special mailing letter from July 2023. This material can be found in the handout.

Clinical Report: Annual PDL Review and Criteria Updates by C. Stauter
C. Stauter discussed updates to the Preferred Drug List (PDL) throughout the year 2023, with emphasis on the following sections in the PDL: cholestasis pruritis, diabetes, and Hepatitis C. The presented information can be found in the handout. Testimony was provided by the following: Phong Pham from Ipsen Biopharmaceuticals on Bylvay; Shawn Hansen from Novo Nordisk on Ozempic and Rybelsus; Erin Nowak from Abbvie on Mavyret, Rinvoq, Skyrizi, and Ubrelvy; Phil Wettestad from Novartis on Leqvio and Cosentyx; Christine Dubé from Astrazeneca on Brilinta, Lokelma, and Fasenra; John Deason from Neurocrine Biosciences on Ingrezza.

New business:
Second Reviews provided by C. Stauter
C. Stauter presented group prior authorization criteria for diuretics and menopause. The presented material can be found in the handout.
Motion: Moved by K. Peterson to place diuretics on prior authorization, motion was seconded by K. Martian. **Motion carried.**
Motion: Moved by T. Schmidt to place agents for menopause on prior authorization, motion was seconded by A. Werremeyer. **Motion carried.**

Retrospective Drug Utilization Review (RDUR) Criteria Recommendations:
RDUR criteria recommendations were reviewed. The presented material can be found in the handout.
Motion: Moved by K. Martian to approve the RDUR criteria, motion was seconded by T. Schmidt. **Motion carried.**

Announcements:
Next meeting is March 6th, 2024.

Adjournment:
Meeting adjourned by K. Martian at 2:32 pm CST.

Date of Minutes Approval:
Minutes submitted by: Claire Stauter, Acentra Health

Administrative Report:

COVID-19 treatments:
https://aspr.hhs.gov/COVID-19/Therapeutics/Pages/COVID19-Tx-Transition-Guide.aspx
COVID-19 Therapeutics Transition to Commercial Distribution: Frequently Asked Questions | HHS/ASPR

Under the American Rescue Plan, Medicaid plans must cover COVID-19 oral antivirals until the end of the third quarter of calendar year 2024.

On November 1, 2023, the manufacturers of Lagevrio and Paxlovid began a transition from distribution by the US Government to distribution through the commercial channel. To aid in this transition, the manufacturers have created patient assistance programs.

- **Paxlovid:** Through December 31, 2024, Medicaid members can obtain Paxlovid directly at the pharmacy *without having to enroll in the patient assistance program (PAP).*
  - How it works:
    1. Pharmacy bills commercial supply to Medicaid.
    2. The state collects a Pfizer calculated state-specific rebate to reimburse the Medicaid program for the cost of Paxlovid. To facilitate this, pharmacies may not use 340b stock.
  - For information on the Paxlovid PAP and to obtain Paxlovid at no cost: https://www.paxlovid.com/paxcess or call 1-877-219-7225 (1-877-C19-PACK).

- **Lagevrio:** Approved under emergency use authorization (EUA), Lagevrio should only be used in cases where Paxlovid is not an option, and the use of Lagevrio is a medically urgent need. Prior authorization will be used to verify that the FDA approved Paxlovid cannot be utilized.
  - Medicaid members cannot receive Lagevrio through the PAP operated by the manufacturer. Merck has published program information at https://www.merckhelps.com/LAGEVRIO or 1-800-727-5400.
  - For more information on use of EUA drugs during the COVID-19 pandemic - see Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1)

PDMP Use Survey:
- In accordance with the SUPPORT ACT under Section 5042 (effective October 1, 2021), all Medicaid providers authorized to prescribe controlled substances are required to assess qualified prescription drug monitoring programs (PDMPs) before prescribing controlled substances to most Medicaid members.
- A survey was sent to providers to assess their use of the PDMP to facilitate federally required reporting on PDMP utilization in February 2024.

Antipsychotic Weight Gain:
- Metformin is already allowed in the system and per the compendia
- Victoza has been added, and will be covered by using diagnosis code T43.505A

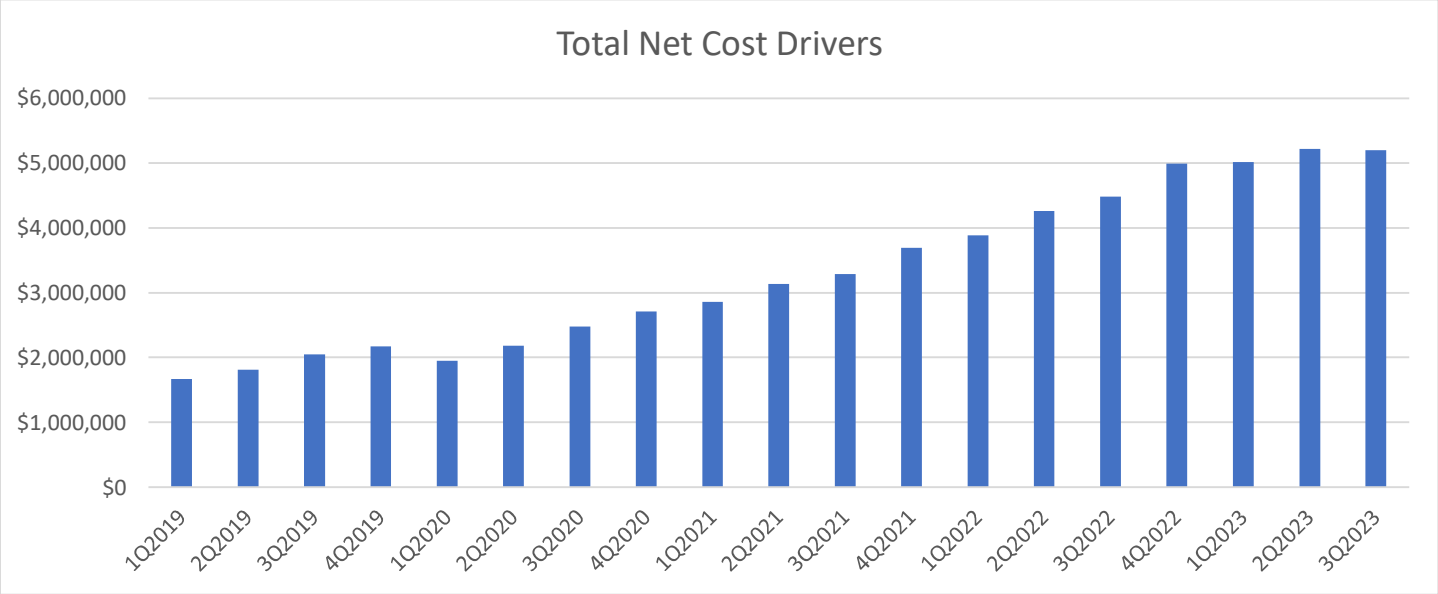
Cost Drivers:

- **Antipsychotics (more injectable use)**
  - 98.9% growth 1Q19 to 1Q23
  - $954,000 quarterly spend
- **Cystic Fibrosis (newest drugs are very effective)**
  - 268.7% growth 1Q19 to 1Q23
  - $621,000 quarterly spend
- **Eczema (Dupixent)**
  - 1,714% growth 1Q19 to 1Q23
  - $343,000 quarterly spend
- **Hemophilia (member no longer has TPL)**
  - 909.4% growth 3Q22 to 3Q23
  - $216,000 quarterly spend
- **Hepatitis C**
  - 14.6% growth 1Q19 to 1Q23
  - $212,000 quarterly spend
- **HIV**
  - 116.7% growth 1Q19 to 1Q23
  - $283,000 quarterly spend
- **Immunomodulators (Enbrel, Humira, etc)**
  - 574.4% growth 1Q19 to 1Q23
  - $1.1 million quarterly spend
- **Migraine**
  - 244.3% growth 1Q19 to 1Q23
  - $72,000 quarterly spend
- **Multiple Sclerosis**
  - 35.1% growth 1Q19 to 1Q23
  - $100,000 quarterly spend
- **Narcotic Treatment (more injectable use)**
  - 104.7% growth 1Q19 to 1Q23
  - $294,000 quarterly spend
- **Oncology**
  - 169.8% growth 1Q19 to 1Q23
  - $878,000 quarterly spend
- **Pulmonary HTN**
  - 779.4% growth 1Q19 to 1Q23
  - $200,000 quarterly spend
- **Tardive dyskinesia**
  - 720.2% growth 3Q19 to 3Q23
  - $140,000 quarterly spend

Summary:

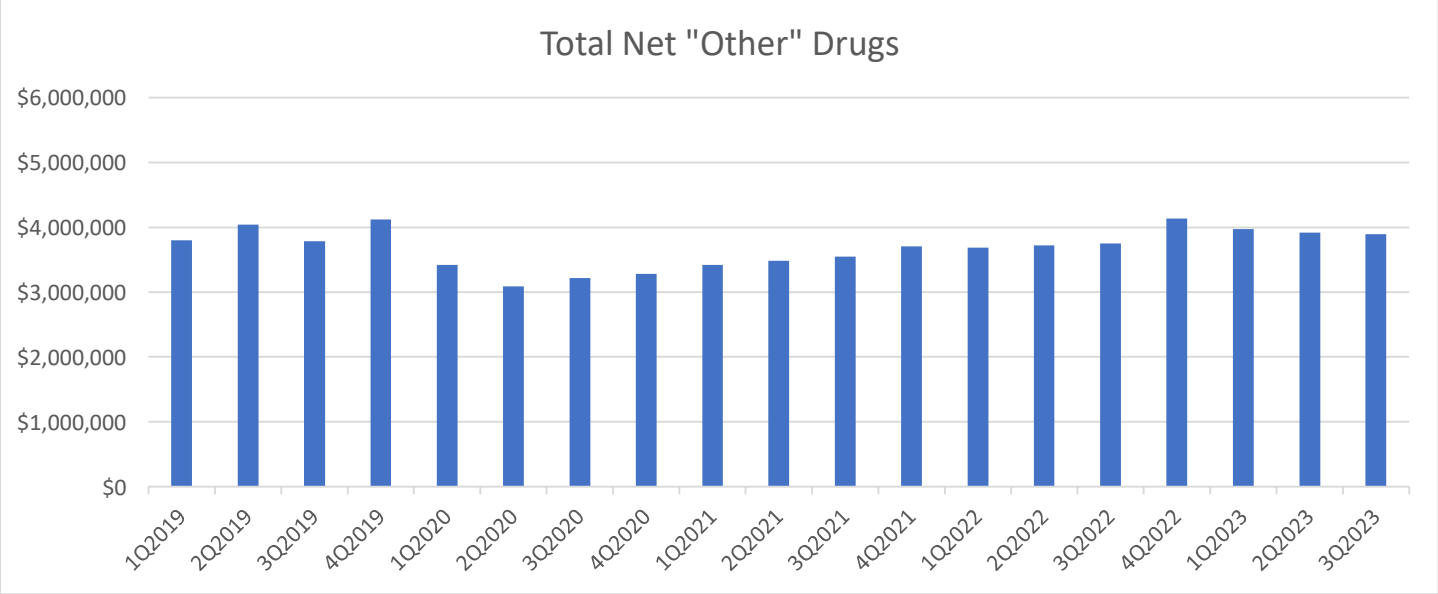
Cost Driver drug classes

- 200.7% growth 1Q19 to 1Q23
- $5.2 million quarterly spend



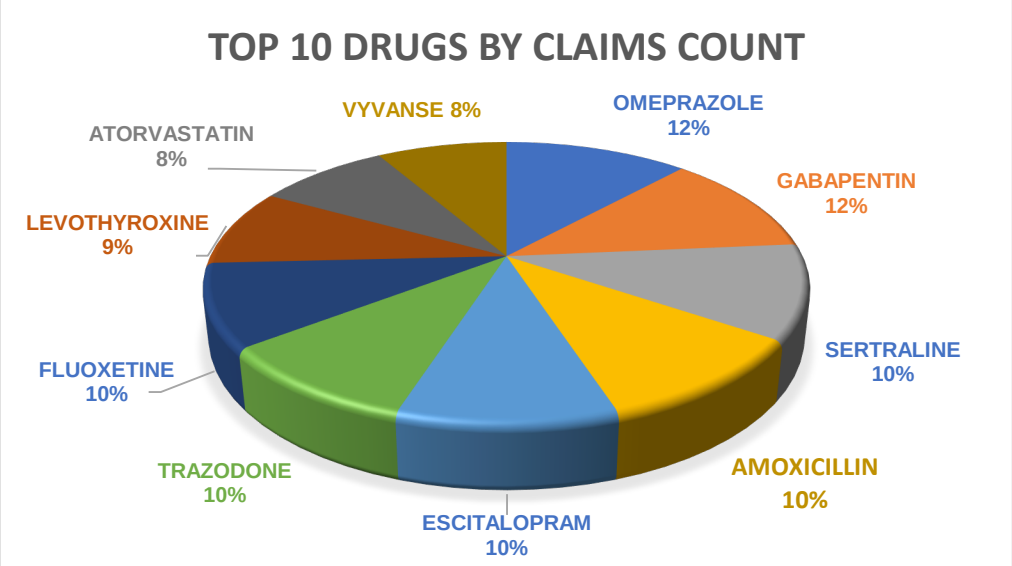
ALL OTHER DRUGS / ALL OTHER DRUG CLASSES

- 4.4% growth 1Q19 to 1Q23
- $3.9 million quarterly spend



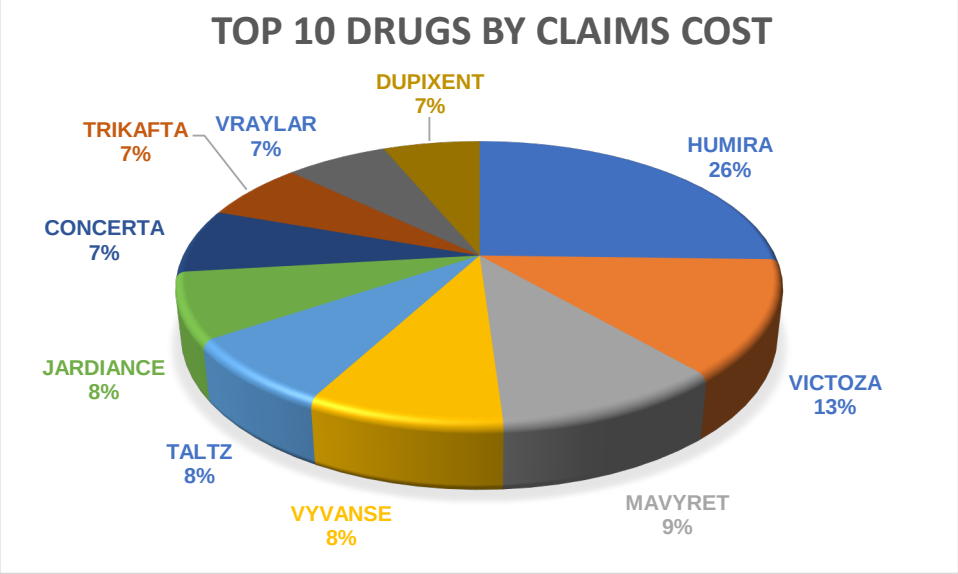
Top 25 Drugs Based on Number of Claims from 10/01/2023 – 12/31/2023

Drug	Claims	Claims Cost	Patients	Cost / Claim	% Total Claims	Dif.
1. GABAPENTIN	4,395	$64,864.30	1,899	$14.76	1.7%	↑1
2. OMEPRAZOLE	4,320	$55,568.18	2,134	$12.86	1.7%	↓1
3. SERTRALINE	3,820	$52,081.13	2,164	$13.63	1.5%	NC
4. AMOXICILLIN	3,799	$54,196.46	3,547	$14.27	1.5%	↑15
5. ESCITALOPRAM	3,661	$49,533.77	2,111	$13.53	1.4%	↓1
6. TRAZODONE	3,624	$49,004.33	1,890	$13.52	1.4%	↓1
7. FLUOXETINE	3,598	$48,039.16	1,957	$13.35	1.4%	↓1
8. LEVOTHYROXINE	3,189	$47,948.67	1,675	$15.04	1.3%	↓1
9. ATORVASTATIN	3,017	$42,944.04	1,808	$14.23	1.2%	NC
10. VYVANSE	3,009	$816,556.71	1,256	$271.37	1.2%	NC
11. VENTOLIN HFA	3,005	$194,077.31	2,970	$64.58	1.2%	NC
12. LISINOPRIL	3,003	$38,668.47	1,817	$12.88	1.2%	↓4
13. BUPROPION XL	2,917	$47,951.63	1,580	$16.44	1.2%	↓1
14. PANTOPRAZOLE	2,829	$39,259.28	1,420	$13.88	1.1%	↑1
15. AMOXICILLIN-CLAV	2,690	$47,483.81	2,506	$17.65	1.1%	↑16
16. PREDNISONE	2,666	$31,242.69	2,148	$11.72	1.1%	↑4
17. CLONIDINE	2,577	$31,882.66	1,280	$12.37	1.0%	↓2
18. NORCO	2,522	$37,413.25	1,560	$14.83	1.0%	↓4
19. DULOXETINE HCL	2,488	$40,954.73	1,311	$16.46	1.0%	↓3
20. LAMOTRIGINE	2,488	$35,557.37	1,043	$14.29	1.0%	↓3
21. CYCLOBENZAPRINE	2,420	$28,811.61	1,541	$11.91	1.0%	↓3
22. HYDROXYZINE	2,402	$33,371.03	1,498	$13.89	1.0%	↓1
23. BUSPIRONE	2,225	$33,601.71	1,204	$15.10	0.9%	NC
24. ONDANSETRON ODT	2,198	$30,962.28	1,739	$14.09	0.9%	↑8
25. ARIPIPRAZOLE	2,171	$32,296.35	1,052	$14.88	0.9%	↑1
Total Claims						**252,760**



Top 25 Drugs Based on Total Claims Cost from 10/01/2023 – 12/31/2023

Drug	Claims	Claims Cost	Patients	Cost / Patient	% Total Cost	Dif.
1. HUMIRA	293	$2,547,367.57	136	$18,730.64	7.3%	NC
2. VICTOZA	1,391	$1,254,889.13	688	$1,823.97	3.6%	NC
3. MAVYRET	52	$933,214.98	44	$21,209.43	2.7%	↑12
4. VYVANSE	3,009	$816,556.71	1,256	$650.12	2.3%	↓1
5. TALTZ	99	$749,738.54	39	$19,224.07	2.1%	↑2
6. JARDIANCE	1,100	$741,963.92	569	$1,303.98	2.1%	↓2
7. CONCERTA	2,070	$732,463.05	883	$829.52	2.1%	↓2
8. DUPIXENT	214	$726,444.93	101	$7,192.52	2.1%	↑1
9. TRIKAFTA	36	$703,839.86	14	$50,274.28	2.0%	↑3
10. VRAYLAR	700	$669,062.18	281	$2,381.00	1.9%	↓2
11. LANTUS	1,219	$633,244.71	772	$820.27	1.8%	↓1
12. BIKTARVY	258	$592,016.46	114	$5,193.13	1.7%	↓5
13. INVEGA SUSTENNA	204	$541,292.70	86	$6,294.10	1.5%	↓2
14. STELARA	20	$486,263.52	13	$37,404.89	1.4%	↑3
15. NORDITROPIN	82	$470,124.89	37	$12,706.08	1.3%	↑8
16. ADDERALL XR	2,164	$390,369.22	920	$424.31	1.1%	NC
17. ELIQUIS	680	$378,363.60	332	$1,139.65	1.1%	↓4
18. SYMBICORT	1,009	$363,704.15	578	$629.25	1.0%	NC
19. INGREZZA	47	$340,892.02	20	$17,044.60	1.0%	↑5
20. ENBREL	50	$316,541.07	24	$13,189.21	0.9%	NC
21. NOVOLOG	474	$314,345.38	303	$1,037.44	0.9%	↓7
22. ADVAIR DISKUS	796	$303,212.96	460	$659.16	0.9%	↓3
23. INSULIN ASPART	744	$298,030.93	453	$657.90	0.8%	NC
24. ABILIFY MAINTENA	123	$287,162.79	51	$5,630.64	0.8%	↓3
25. SUBLOCADE	146	$282,212.16	69	$4,090.03	0.8%	↓3
Total Claims Cost						**$35,100,930.83**



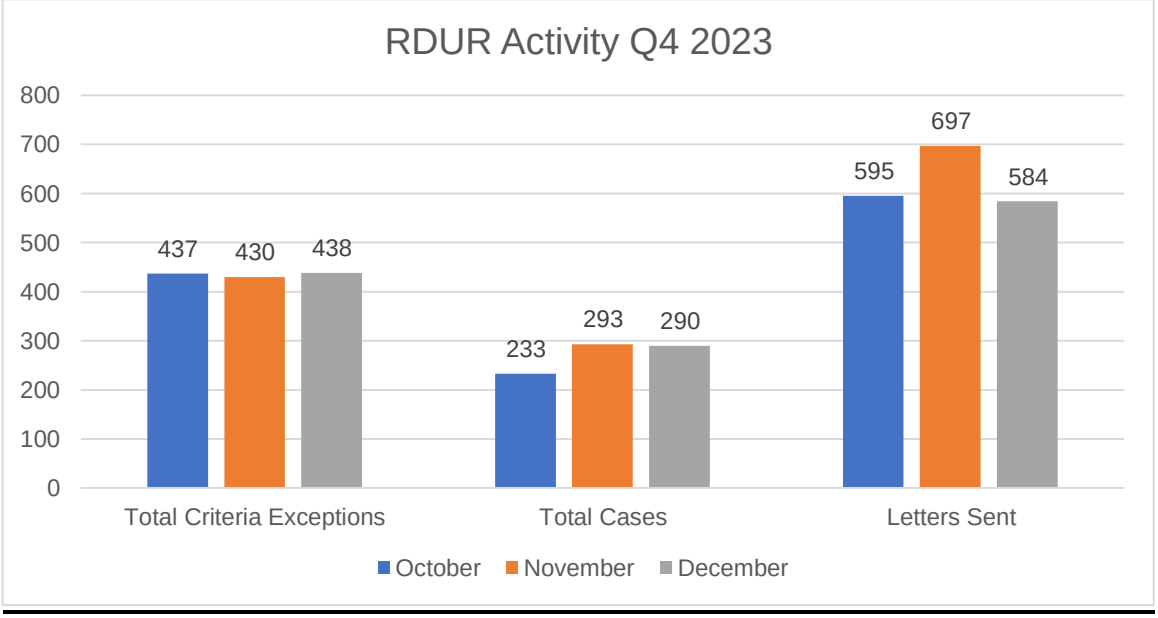
Top 15 Therapeutic Classes Based on Number of Claims from 10/01/2023 – 12/31/2023

Therapeutic Class Description	Claims	Claims Cost	Patients	Cost/Claim	% Total Claims	Dif.
1. ANTIDEPRESSANTS	27,364	$631,049.98	11,545	$23.06	10.8%	NC
2. ANTICONVULSANTS	13,231	$547,643.21	4,725	$41.39	5.2%	NC
3. ANTIPSYCHOTIC AGENTS	9,314	$2,512,358.06	3,689	$269.74	3.7%	NC
4. PPI'S	7,598	$165,525.72	3,729	$21.79	3.0%	NC
5. ANXIOLYTICS, SEDATIVES, HYPNOTICS	7,159	$104,901.98	3,680	$14.65	2.8%	NC
6. PENICILLIN ANTIBIOTICS	6,816	$107,096.35	6,028	$15.71	2.7%	↑6
7. AMPHETAMINES	6,810	$1,275,024.87	2,790	$187.23	2.7%	↓1
8. OPIATE AGONISTS	6,137	$98,341.35	3,179	$16.02	2.4%	↓1
9. NSAIDS	5,807	$79,769.80	3,867	$13.74	2.3%	↓1
10. RESP/CNS STIMULANTS	5,629	$976,379.37	2,144	$173.46	2.2%	NC
11. STATINS	5,414	$78,757.39	3,191	$14.55	2.1%	↓2
12. BETA BLOCKING AGENTS	4,998	$81,987.75	2,813	$16.40	2.0%	↓1
13. ADRENALS	4,548	$61,530.06	3,574	$13.53	1.8%	↑1
14. BETA AGONISTS	4,249	$251,818.70	3,890	$59.27	1.7%	↓1
15. BIGUANIDES	3,769	$53,049.25	2,217	$14.08	1.5%	↑1

Top 15 Therapeutic Classes Based on Claims Cost from 10/01/2023 – 12/31/2023

Therapeutic Class Description	Claims	Claims Cost	Patients	Cost/Patient	% Total Cost	Dif.
1. DMARDS	594	$3,585,936.02	248	$14,459.42	10.2%	NC
2. ANTIPSYCHOTIC AGENTS	9,314	$2,512,358.06	3,689	$681.04	7.2%	NC
3. SKIN AGENTS	650	$2,170,574.91	376	$5,772.81	6.2%	NC
4. INSULINS	3,201	$1,630,598.49	1,309	$1,245.68	4.6%	NC
5. INCRETIN MIMETICS	1,585	$1,424,354.23	715	$1,992.10	4.1%	NC
6. ANTINEOPLASTIC AGENTS	585	$1,406,890.82	246	$5,719.07	4.0%	↑1
7. AMPHETAMINES	6,810	$1,275,024.87	2,790	$457.00	3.6%	↓1
8. HCV ANTIVIRALS	68	$1,198,396.74	57	$21,024.50	3.4%	↑7
9. ANTIRETROVIRALS	709	$1,072,509.75	265	$4,047.21	3.1%	NC
10. CORTICOSTEROIDS (RESP)	3,462	$1,037,976.26	2,064	$502.90	3.0%	↓2
11. SGLT2 INHIBITORS	1,511	$1,004,789.63	781	$1,286.54	2.9%	↓1
12. RESP/CNS STIMULANTS	5,629	$976,379.37	2,144	$455.40	2.8%	↓1
13. CFTR CORRECTORS	36	$703,839.86	14	$50,274.28	2.0%	↑5
14. ANTIDEPRESSANTS	27,364	$631,049.98	11,545	$54.66	1.8%	↓2
15. PITUITARY	372	$609,256.69	149	$4,088.97	1.7%	↑2

RDUR Report: Q4 2023



October Cases by Type of Criteria		
Criteria Description	**# of Cases**	**% of Cases**
Clinical Appropriateness	7	3.0%
Drug-Disease Conflicts	38	16.3%
Drug-Drug Conflicts	188	80.7%

November Cases by Type of Criteria		
Criteria Description	**# of Cases**	**% of Cases**
Clinical Appropriateness	110	37.5%
Drug-Disease Conflicts	4	1.4%
Drug-Drug Conflicts	176	60.1%
Therapeutic Duplication	3	1.0%

December Cases by Type of Criteria		
Criteria Description	**# of Cases**	**% of Cases**
Clinical Appropriateness	268	92.4%
Drug-Disease Interactions	22	7.6%
Drug-Drug Conflicts	2	0.7%

Clinical Report

Prior Authorization Updates

Drug Name	PA Status	Class
Agamree	PA	Non-Preferred Dosage Forms
Betaseron	PA	Multiple Sclerosis - Interferons
Coxanto	PA	NSAIDs
Jesduvroq	PA	Chronic Kidney Disease
Jylamvo	PA	Non-Preferred Dosage Forms
Ogsiveo	PA	Medications Over $3000
Omvoh	PA	Ulcerative Colitis
Perseris	PA	Antipsychotics – Long Acting Injectable (LAI)
Rivfloza	PA	Medications Over $3000
Rykindo ER	PA	Antipsychotics – Long Acting Injectable (LAI)
Triamterene	PA	Diuretics
Veozah	PA	Menopause – Vasomotor Symptoms
Vevye	PA	Dry Eye Syndrome
Welireg	PA	Medications Over $3000
Xphozah	PA	Chronic Kidney Disease and Ulcerative Colitis
Zilbrysq	PA	Medications Over $3000
Zituvio	PA	Diabetes - DPP4 Inhibitors
Zimhi	Remove PA	Opioid Reversal Medications

Corticosteroids - Inhaled Summary of Changes:
Due to Medicaid Rebate CAP removal, Flovent Diskus and Flovent HFA are being discontinued. Because of this, Arnuity Ellipta has been moved to a preferred agent. PA criteria was added to Asmanex HFA, QVAR Redihaler, and fluticasone HFA to accommodate requests where the relatively higher inspiratory flow is required for preferred agents.

Corticosteroids – Inhaled

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ARNUITY ELLIPTA (fluticasone)	ALVESCO (ciclesonide)
ASMANEX (mometasone) TWISTHALER	ARMONAIR DIGIHALER (fluticasone)
budesonide suspension	ASMANEX HFA (mometasone)
PULMICORT FLEXHALER (budesonide)	fluticasone HFA
	fluticasone diskus
	PULMICORT RESPULES (budesonide)
	QVAR REDIHALER (beclomethasone)

GINA and EPR-3 Guidelines – SMART:
- For steps 3-5, ICS-formoterol is preferred for use as an as needed and regular daily treatment
- Please consider SMART therapy instead of single agent inhaled corticosteroid.
    - Both Symbicort and Dulera are available as HFA products

Quantity Limits to accommodate SMART therapy:
- 2 Symbicort or Dulera inhalers per 30-day supply not to exceed a total of 9 inhalers per 365 days without prior approval.

References:

1. Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention, 2023. Updated July 2023. Available from: www.ginasthma.org
2. Cloutier, Michelle M., et al. "2020 focused updates to the asthma management guidelines: a report from the National Asthma Education and Prevention Program Coordinating Committee Expert Panel Working Group." Journal of Allergy and Clinical Immunology 146.6 (2020): 1217-1270. Available at: https://www.epa.gov/sites/default/files/2021-05/documents/_sites_default_files_publications_asthmamanagementguidelinesreport-2-4-21.pdf

Electronic Age Verification:
- Fluticasone HFA does not require PA for ages 4 and under

Electronic Duration Verification:
- Budesonide Suspension 1 mg/2 mL is payable for 30 days every 75 days. For diluted nasal rinses, please use 0.5 mg/2 mL instead of 1 mg/2 mL for doses 1 mg per day or higher.
- Guidelines recommend that once control is achieved, dose should be titrated down to minimum dose required to maintain control. For doses 1.5 mg per day or lower, please use 0.5 mg/2 mL strength.

Prior Authorization
Initial Criteria – Approval Duration: 12 months
- The member must have failed a 30-day trial of each preferred inhaler of a unique active ingredient, as evidenced by paid claims or pharmacy printouts.
- Armonair Digihaler Only:
    - The member must have failed a 30-day trial of Asmanex HFA, as evidenced by pharmacy claims or pharmacy printouts.
    - Clinical justification must be provided explaining why the member is unable to use the preferred products (subject to clinical review).

- Asmanex HFA and QVAR Redihaler Only:
  - Preferred agent trials may be bypassed if member meets one of the following criteria:
    - Member is unable to achieve inspiratory flow rate of 40 L/min.
    - Member is unable to achieve inspiratory flow rate of 60 L/min and has previously had adrenal insufficiency with fluticasone.
    - Permanent disability preventing use of a dry powder inhaler
- fluticasone HFA only:
  - Preferred agent trials may be bypassed if member meets one of the following criteria:
    - Member is unable to achieve inspiratory flow rate of 40 L/min.
    - Permanent disability preventing use of a dry powder inhaler

References:

1. Sannarangappa V, Jalleh R. Inhaled corticosteroids and secondary adrenal insufficiency. Open Respir Med J. 2014 Jan 31;8:93-100. doi: 10.2174/1874306401408010093. PMID: 25674179; PMCID: PMC4319207.
2. Saag KG, Furst DE, Barnes PJ . Major side effects of inhaled glucocorticoids In: *UpToDate*, Post TW (Ed), UpToDate, Waltham, MA, 2023

Tardive Dyskinesia - Summary of Changes:
With the requirement for specialist consulting on the diagnosis, removed diagnosis criteria to be able to use the general form instead of require attestation specific form to collect the information.

Tardive Dyskinesia

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AUSTEDO (deutetrabenazine)	tetrabenazine 25 mg
AUSTEDO XR (deutetrabenazine)	XENAZINE (tetrabenazine)
INGREZZA (valbenazine)	
tetrabenazine 12.5 mg	

Electronic Step Therapy Required

- The Initiation Pack or 40 mg x 7 days is required for titration to 80 mg capsules.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The requested medication must be prescribed by, or in consult with, a neurologist or psychiatrist.
- The member must have a history of treatment with dopamine receptor blocking agent (DRBA).
- ~~The member must have a diagnosis of tardive dyskinesia, including the following:~~
    - ~~Involuntary athetoid or choreiform movements~~
    - ~~History of treatment with dopamine receptor blocking agent (DRBA)~~
    - ~~The member must have symptom duration lasting longer than 4-8 weeks~~

Phenylketonuria - Summary of Changes:
With the addition of Palynziq, there is an option available for those with two null mutations in trans. Sapropterin is not effective in those with two null mutations in trans.

Phenylketonuria	
PREFERRED AGENTS (CLINICAL PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**
JAVYGTOR (sapropterin)	KUVAN (sapropterin)
sapropterin	PALYNZIQ (pegvaliase-pqpz)

Underutilization

- Sapropterin and Palynziq must be used adherently and will reject on point of sale for late fill

Prior Authorization Criteria

Prior Authorization Form - Phenylketonuria

Initial Criteria - Approval Duration: 2 months (sapropterin); 12 months (Palynziq)

- The member must have been compliant with a PHE restricted diet for past 6 months (documentation must be attached).
- The requested medication must be prescribed by, or in consult with, a geneticist or endocrinologist.
- Baseline PHE levels must be attached
  - For members of childbearing potential and children ≤ 12 years old: PHE levels must be above 360 µmoles/liter (6 mg/dL)
  - For members without childbearing potential, and children > 12 years old: PHE levels must be above 600 µmoles/liter 10 mg/dL)
- Sapropterin Only:
  - The member's weight must be provided. Requested initial dose must be 10 mg/kg
  - The member must not have two null mutations in trans
- Palynziq Only: One of the following must be met:
  - PHE levels must be attached documenting the member was unable to achieve a PHE level less than 600 µmoles/liter (10 mg/dL) despite a 3-month trial of 20 mg/kg dose of sapropterin with good compliance, as evidenced by paid claims or pharmacy printouts.
  - The member is known to have two null mutations in trans

Renewal Criteria:

- For same or reduced dose from previous trial:
  Approval Duration: 12 months - if dose is the same or less than previous trial
  - PHE level must be between 60 and 600 µmoles per liter
  - Sapropterin Only: The member's weight must be provided.

- For a dose increase from previous trial
  Approval Duration: 4 months - for a dose increase from previous trial
  - PHE level must be attached that were taken after previous trial (1 month for Kuvan, 4 months for Palynziq)
    - For members of childbearing potential and children ≤ 12 years old: PHE levels must be above 360 µmoles/liter (6mg/dL)
    - For members without childbearing potential, and children > 12 years old: PHE levels must be above 600 µmoles/liter 10mg/dL)
  - Sapropterin Only: The member's weight must be provided.

Unfinished Business:

Hyperkalemia - Summary of Changes:
The KDIGO guidelines recommend that NSAIDs be discontinued with hyperkalemia. Renin–angiotensin–aldosterone system inhibitors (RAASi) and mineralocorticoid receptor antagonists (MRAs) should be continued unless other measures, including potassium binders, fail to lower potassium.

Hyperkalemia (Chronic)	
PREFERRED AGENTS (CLINICAL PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**
LOKELMA (sodium zirconium cyclosilicate)	VELTASSA (patiromer)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 3 months
- The requested medication must be prescribed by, or in consult with, a nephrologist.
- If member is on renal dialysis, Medicare eligibility must be ruled out *(6-month approval may be allowed to determine eligibility)*.
- The member's current serum potassium level must be exceeding the upper limit of normal, as evidenced by documentation from at least two separate lab values, submitted with the request.
- The member must have failed 30-day trials with at least two of the following products:
  - bumetanide, chlorothiazide, fludrocortisone, furosemide, hydrochlorothiazide, indapamide, metolazone, torsemide
- The member must not be receiving nonsteroidal anti-inflammatory drugs (NSAIDs)
  - ~~the medications known to cause hyperkalemia listed below, OR medical justification must be provided explaining why discontinuation of these agents would be clinically inappropriate in this member:~~
  - ~~angiotensin-converting enzyme inhibitor~~
  - ~~angiotensin II receptor blocker~~
  - ~~aldosterone antagonist~~
  - ~~nonsteroidal anti-inflammatory drugs (NSAIDs)~~

Non-Preferred Agent Criteria:
- The member must have failed a 30-day trial with Lokelma, as evidenced with paid claims or pharmacy print outs.

Renewal Criteria – Approval Duration: 12 months
- The member's current serum potassium level is within normal limits or has been significantly reduced from baseline, as evidenced by lab documentation submitted with the request.

Reference:

1. Rossing, Peter, et al. "KDIGO 2022 clinical practice guideline for diabetes management in chronic kidney disease." *Kidney International* 102.5 (2022): S1-S127.

Prophylaxis of Migraine - Summary of Changes
Timolol removed from qualifying trial medications. Although some references cite it as an effective medication, it does not have the level of support required for inclusion in the compendia.

Migraine

Prophylaxis of Migraine

Calcitonin Gene-Related Peptide (CGRP) Receptor Antagonist

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AJOVY (fremanezumab-vfrm) INJECTION	AIMOVIG (erenumab-aooe) INJECTION
EMGALITY (galcanazumab-gnlm) INJECTION	NURTEC ODT (rimegepant) TABLETS
	QULIPTA (atogepant) TABLETS
	VYEPTI (eptinezumab-jjmr) – *Medical Billing Only*

Prior Authorization Criteria
Prior Authorization Form – Migraine Prophylaxis/Treatment

Initial Criteria – Approval Duration: *6 months*
- The member must experience 3 or more migraine days per month.
- The member must have failed 2-month trials of at least two of the following agents from different therapeutic classes, as evidenced by paid claims or pharmacy printouts:
    - amitriptyline, atenolol, divalproex sodium, metoprolol, nadolol, propranolol, ~~timolol,~~ topiramate, venlafaxine

Non-Preferred Agents Criteria:
- The member must have failed a 3-month trial of two self-administered CGRPs (Ajovy, Emgality, and Aimovig), as evidenced by paid claims or pharmacy printouts.
- *Vyepti Only:*
    - The member must have failed a 3-month trial of Nurtec ODT, as evidenced by paid claims or pharmacy printouts.

Renewal Criteria – Approval Duration: *12 months*
- The member must have experienced at least a 50% reduction in migraine frequency, pain intensity, or duration from baseline.

Eczema / Atopic Dermatitis - Summary of Changes
Required length of trial for dupilumab was changed from 6 months to 4 months. Clinical trials SOLO-1 and SOLO-2 assessed dupilumab efficacy after 16 weeks. The following source recommends discontinuation if efficacy is not seen after 16 weeks: Dupilumab | Eczema Treatment | Eczema.org

Eczema / Atopic Dermatitis

Systemic

Interleukin (IL)-4/13 Inhibitor

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
DUPIXENT (dupilumab) INJECTION	

Interleukin (IL)-13 Inhibitor

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ADBRY (tralokinumab-idrm) INJECTION	

Janus Kinase (JAK) inhibitor

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
CIBINQO (abrocitinib) TABLET	
OLUMIANT (baricitinib)	
RINVOQ ER (upadacitinib) TABLET	

Prior Authorization Criteria
Prior Authorization Form - Atopic Dermatitis

Initial Criteria - Approval Duration: 3 months
- Member must have failed a 6-week trial of tacrolimus or pimecrolimus as evidenced by paid claims or pharmacy printouts:
- One of the following must be met:
  - The member has failed a two 2-week trials of topical corticosteroids of medium or higher potency, as evidenced by paid claims or pharmacy printouts.
  OR
  - The member meets both of the following (1 AND 2):
    1. Affected area is on face, groin, axilla, or under occlusion.
    2. Member must have failed two 2-week trials of topical corticosteroids of low or higher potency, as evidenced by paid claims or pharmacy printouts.

Janus Kinase (JAK) Inhibitors Only:
- The member must have had a 4~~6~~-month trial with dupilumab.

Cholestatic Pruritis – Summary of Changes
Ileal bile acid transport inhibitors - Length of Therapy:
Long-term treatment (mean treatment duration 4.7 years) with maralixibat has been studied and shown to reduce event-free survival (EFS). EFS being variceal bleeding, ascites requiring therapy, surgical biliary diversion, liver transplantation, or death. Predictors of EFS include >1 point improvement in pruritus score, serum bilirubin <6.5 mg/dL, and bile acids <200 micromol/L. Long-term follow-up studies of odevixibat are ongoing (NCT05035030).

Cholestasis Pruritis

Alagille Syndrome (ALGS):

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED (PA REQUIRED)
LIVMARLI (maralixibat)	BYLVAY (odevixibat)

Progressive Familial Intrahepatic Cholestasis (PFIC):

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED (PA REQUIRED)
BYLVAY (odevixibat)	

Prior Authorization Criteria

Initial Criteria - Approval Duration: 6 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a hepatologist or gastroenterologist.
- Documentation must be provided to support the presence of moderate to severe pruritis.
- The member must have cholestasis, as evidenced by ≥ 1 of the following:
  - Serum bile acid > 3x upper limit of normal as defined by the reporting laboratory
  - Conjugated bilirubin > 1mg/dL
  - Fat soluble vitamin deficiency otherwise unexplainable
  - Gamma-glutamyl transferase > 3x the upper limit of normal
  - Intractable pruritus explainable only by liver disease
- The member must not have a history of liver transplant or decompensated cirrhosis.
- The member must not have history of biliary diversion surgery within the past 6 months.
- The member must have failed at least a 3-month trial of both of the following, as evidenced by paid claims or pharmacy printouts:
  - Ursodiol
  - agents to treat pruritis: cholestyramine, rifampin, antihistamines
- Bylvay Only:
  - ALGS:
    - Genetic testing confirms pathogenic variant (e.g., *JAG1* and *NOTCH2).*
    - The member has had a 6-month trial with Livmarli.
  - PFIC:
    - Genetic testing confirms pathogenic variant (e.g., ATP8B1, ABCB11, ABCB4, TJP2, NR1H4, and MYO5B).
    - Genetic testing does not indicate PFIC Type 2 with ABCB11 variants that predict complete absence of BSEP-3 protein.
- Livmarli Only:
  - Genetic testing confirms pathogenic variant of JAG1 or NOTCH1

Renewal Criteria - Approval Duration: 12 months

- The member has experienced an improvement in pruritis, as evidenced by clinical documentation.
- The member must have experienced a reduction in ~~serum bile acid as defined as a bile acid reduction ≥ 70% or reaching a bile acid level ≤ 70 micromol/L~~ bilirubin < 6.5mg/dL and bile acids < 200 micromol/L.

References

1. Sokol RJ, Gonzales EM, Kamath BM, et al. Predictors of 6-year event-free survival in Alagille syndrome patients treated with maralixibat, an ileal bile acid transporter inhibitor. Hepatology 2023; 78:1698.
2. Shneider BL, Spino CA, Kamath BM, Magee JC, Ignacio RV, Huang S, Horslen SP, Molleston JP, Miethke AG, Kohli R, Leung DH, Jensen MK, Loomes KM, Karpen SJ, Mack C, Rosenthal P, Squires RH, Baker A, Rajwal S, Kelly D, Sokol RJ, Thompson RJ; for ChiLDReN and UK IMAGO/IMAGINE Investigators. Impact of long-term administration of maralixibat on children with cholestasis secondary to Alagille syndrome. Hepatol Commun. 2022 Aug;6(8):1922-1933. doi: 10.1002/hep4.1992. Epub 2022 Jun 7. PMID: 35672955; PMCID: PMC9315125.

New Business:

FIRST REVIEW OF ACID BLOCKERS (VOQUEZNA)

Acid blockers are used in various disease states such as ulcer treatment, H. pylori, hypersecretory conditions, and gastroesophageal reflux disease (GERD). GERD can be classified as nonerosive reflux disease (NERD), erosive esophagitis (EE), and Barrett's esophagus (BE). Voquezna is a first-in-class potassium competitive acid blocker (PCAB) that has been FDA approved for the treatment of H. pylori and EE. Proton pump inhibitors (PPIs) are first line agents for EE.

	Histamine H_2 Receptor Antagonist (H_2RA)	**PPIs**	**PCAB**
Drugs within the category	• Cimetidine • Famotidine • Nizatidine	• dexlansoprazole (Dexilant) • esomeprazole (Nexium) • lansoprazole (Prevacid) • omeprazole (Prilosec) • omeprazole-sodium bicarb (Zegerid) • pantoprazole (Protonix) • rabeprazole (Aciphex)	Voquezna (vonoprazan)
Difference in Mechanism	Inhibits H_2 receptors	Inhibits H+, K+-ATPase enzyme system	inhibits H+, K+-ATPase enzyme system by reversibly binding to K+
Prodrug	No	Yes: must be taken 30-60 minutes prior to food to create an acidic environment	No
Onset	1 hour	1-3 hours	2-3 hours
Maximal acid suppression after dosing	10-12 hours	3-5 days	1 day
Duration of treatment	Twice daily up to 12 weeks	• Healing: daily for 8 weeks, an additional 8 weeks of treatment may be considered • Maintenance: various durations	• Healing: daily for 8 weeks • Maintenance: daily for 6 months
Warnings	Risk of delirium	Carry similar warnings such as C difficile infection, bone fractures, hypomagnesemia, vitamin B12 deficiency, gastric malignancy, etc.	
Cost per **year**	~$36	~$20±	$7,800

Based on adult dosing for EE maintenance at lowest per unit WAC cost. ± omeprazole or pantoprazole, comparing solid dosage forms.

FDA Approval

Voquezna (vonoprazan): 505(b) New Drug Application (NDA) pathway

- Triple Pak (vonoprazan tablets; amoxicillin capsules; clarithromycin tablets): Type 1 New Molecular Entity and Type 4 New Combination, PRIORITY
- Dual Pak (vonoprazan tablets; amoxicillin capsules): Type 5 New formulation (Dual Pack) – New Molecular Entity, PRIORITY
- Voquezna (vonoprazan): STANDARD

**Initial approval 5/3/22 for H. pylori, amendment 5/19/23 due to response from 2/7/23 action letter (impurities); new indication approval 11/1/23 for EE*

Clinical Trials

Approval was based on results from Phase 3 PHALCON-EE study (NCT04124926). The trial was a randomized, double-blind, multicenter study that enrolled 1,024 patients with EE in U.S. and Europe. The study compared Voquezna to lansoprazole.

Primary Endpoint:

- Healing phase:
  - Results showed that Voquezna 20 mg was non-inferior with healing rate of all grades of EE of 93% compared to 85% for lansoprazole 30 mg by week 8 (P<0.0001)
- Maintenance phase
  - Results showed that Voquezna 20 mg was non-inferior to lansoprazole for maintaining healing of EE through week 24 (79.2% for Voquezna vs 72% for lansoprazole) (P<0.0001)

Secondary Endpoints:

- Healing phase:
  - Demonstrated superior rates of healing in patients with moderate-to-severe disease (LA Grade C/D) at Week 2 with Voquezna 20 mg (70%) compared to lansoprazole 30 mg (53%) (P=0.0008)
  - Voquezna 20 mg also demonstrated non-inferiority to lansoprazole 30 mg in mean percentage of 24-hour heartburn free days over the healing period
- Maintenance phase:
  - Voquezna 10 mg (79%) was superior to lansoprazole 15 mg (72%) in all randomized patients as well as a subset of patients with moderate to severe EE (75% for Voquezna 10 mg compared to 61% for lansoprazole 15 mg) (P=0.0490)
  - Voquezna 10 mg demonstrated non-inferiority to lansoprazole 15 mg for relief of heartburn

Safety: Adverse advents were comparable to lansoprazole in the trial.

Place in Therapy

Voquezna is a potential option in patients with severe erosive esophagitis (LA Class C/D) and PPI-refractory patients.

Advantages	Disadvantages
• Alternative for patients who do not respond to first line agents or with severe EE • Voquezna does not depend on gastric acid activation to inhibit acid secretion and binds to active and inactive proton pumps while PPIs only inhibit active proton pumps. • Does not require formulation to protect from gastric acid. • Can be administered without regard to meals.	• Cost • Non-inferiority designed trials compared use of Voquezna to lansoprazole only; one study did not compare to compendia supported lansoprazole dosing • Long term safety is unknown • Does not have alternative dosage forms, cannot be crushed/chewed

Current Utilization

	Quarter 1 2023			Quarter 2 2023		
Medication	**Rx Count**	**% of Rx**	**Reimb Amount**	**Rx Count**	**% of Rx**	**Reimb Amount**
cimetidine	26	0.3%	$844.33	29	0.3%	$890.57
cimetidine HCl	5	0.0%	$210.95	1	0.0%	$22.54
dexlansoprazole	108	1.1%	$31,107.28	108	1.1%	$31,308.80
esomeprazole	129	1.3%	$7,383.80	125	1.2%	$7,691.18
famotidine	1,087	10.9%	$19,313.87	1,122	11.1%	$19,908.84
lansoprazole	129	1.3%	$2,519.34	148	1.5%	$4,112.76
nizatidine	0	0.0%	$ -	1	0.0%	$24.47
omeprazole	5,177	51.8%	$67,175.16	5,131	50.8%	$65,739.63
omeprazole/Na bicarbonate	0	0.0%	$ -	26	0.3%	$8,260.43
pantoprazole	3,327	33.3%	$49,760.50	3,402	33.7%	$50,794.56
rabeprazole	15	0.1%	$272.85	14	0.1%	$254.51
Voquezna	0	0.0%	$ -	0	0.0%	$ -
TOTALS	10,003		$178,588.08	10,107		$189,008.29
	Quarter 3 2023			**Quarter 4 2023**		
Medication	**Rx Count**	**% of Rx**	**Reimb Amount**	**Rx Count**	**% of Rx**	**Reimb Amount**
cimetidine	28	0.3%	$904.72	20	0.2%	$691.40
cimetidine HCl	0	0.0%	$ -	113	0.0%	$34,313.91
dexlansoprazole	111	1.2%	$32,559.51	113	1.3%	$34,313.91
esomeprazole	110	1.2%	$6,286.60	101	1.2%	$6,062.66
famotidine	1,043	11.1%	$17,959.25	1,044	12.1%	$18,414.72
lansoprazole	122	1.3%	$3,134.73	136	1.6%	$3,616.81
nizatidine	0	0.0%	$ -	0	0.0%	$ -
omeprazole	4,759	50.9%	$60,845.25	4,316	49.9%	$55,390.54
omeprazole/Na bicarbonate	33	0.4%	$9,902.83	71	0.8%	$22,157.53
pantoprazole	3,123	33.4%	$45,733.56	2,835	32.8%	$42,169.08
rabeprazole	28	0.3%	$509.32	16	0.2%	$301.77
Voquezna	0	0.0%	$ -	0	0.0%	$ -
TOTALS	9,357		$177,835.77	8,765		$217,432.33

References:

1. *Vonoprazan. In-Depth Answers and Red Book. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. January 11, 2024. https://www.micromedexsolutions.com*
2. *Vonoprazan. Drug Facts and Comparisons. Wolters Kluwer Health, Inc. Riverwoods, IL. January 25, 2024. http://online.factsandcomparisons.com*
3. *Voquezna (vonoprazan oral tablets). [prescribing information]. Buffalo Grove, IL: Phathom Pharmaceuticals Inc; 2023.*
4. *U.S. Food and Drug Administration, Center for Drug Evaluation and Research. Voquezna NDA 215151 approval letter, November 1, 2023. https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2023/215151Orig1s000ltr.pdf*
5. *Voquezna: A New Treatment for Erosive GERD. IPD Analytics. Aventura, FL. November 2023. https://www.ipdanalytics.com*
6. *Proton Pump Inhibitors. Drug Facts and Comparisons. Wolters Kluwer Health, Inc. Riverwoods, IL. January 31, 2024. http://online.factsandcomparisons.com*
7. *Histamine H2 Antagonists. Drug Facts and Comparisons. Wolters Kluwer Health, Inc. Riverwoods, IL. January 31, 2024. http://online.factsandcomparisons.com*
8. *Cimetidine. Quick Answers and Red Book. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. January 24, 2024. https://www.micromedexsolutions.com*

9. *Famotidine. Quick Answers and Red Book. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. January 24, 2024. https://www.micromedexsolutions.com*
10. *Nizatidine. Quick Answers and Red Book. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. December 28, 2023. https://www.micromedexsolutions.com*
11. *Dexlansoprazole. Quick Answers and Red Book. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. January 25, 2024. https://www.micromedexsolutions.com*
12. *Esomeprazole. Quick Answers and Red Book. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. January 25, 2024. https://www.micromedexsolutions.com*
13. *Lansoprazole. Quick Answers and Red Book. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. January 25, 2024. https://www.micromedexsolutions.com*
14. *Omeprazole. Quick Answers and Red Book. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. January 25, 2024. https://www.micromedexsolutions.com*
15. *Omeprazole/sodium bicarbonate. Quick Answers and Red Book. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. February 5, 2024. https://www.micromedexsolutions.com*
16. *Pantoprazole. Quick Answers and Red Book. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. January 25, 2024. https://www.micromedexsolutions.com*
17. *Rabeprazole. Quick Answers and Red Book. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. January 25, 2024. https://www.micromedexsolutions.com*
18. *Laine L, Sharma P, Mulford DJ, et al. Pharmacodynamics and pharmacokinetics of the potassium-competitive acid blocker vonoprazan and the proton pump inhibitor lansoprazole in US subjects. Am J Gastroenterol 2022;117:1158-1161.*
19. *Lundell L, Vieth M, Gibson F, et al. Systematic review: The effects of long-term proton pump inhibitor use on serum gastrin levels and gastric histology. Aliment Pharmacol Ther 2015;42:649-663.*

FIRST REVIEW OF SEBORRHEIC DERMATITIS (ZORYVE)

Seborrheic dermatitis is a chronic relapsing condition involving sebaceous glands; although the cause is unknown, *Malassezie* species is oftentimes associated with the condition. Symptoms range from mild, such as dandruff, to severe involving widespread yellowish scales.

Treatment is dependent on the severity and location of the condition, but may consist of topical antifungals, anti-inflammatories, Eucrisa (crisaborole), or Zoryve (roflumilast); refractory seborrheic dermatitis may require oral antifungal treatment. Topical corticosteroids (TCS) are considered first or second line agents depending on the severity.

General key notes for treatment options:

- Some agents are used off-label for seborrheic dermatitis
- Most products share similar dermatologic side effects: erythema, pruritis, burning
- Age limitations on various products from ingredients that are not safe for certain ages (e.g., propylene glycol)
- Most products have various formulations

Topical Antifungals:	
Rationale for use	• Decrease *Malassezie* and mild anti-inflammatory activity • **Place in therapy:** Considered first line for mild severity
Agents per guidelines	Azoles: • Ketoconazole 2% cream, 2% gel, 2% shampoo • Miconazole 2 % cream • Terbinafine 1% solution/cream
	Ciclopirox 0.77% gel, 1% shampoo
Mechanism	• Azoles: inhibits cytochrome P450 and alters cell wall permeability • Ciclopirox: exact mechanism of action is unknown, inhibits transport of substrates to fungal cells
Frequency	• Shampoos are often used twice weekly for treatment and once weekly for maintenance • Topical skin agents are used once to twice daily
Key notes	• Multiple formulations • Slower onset than TCS • Some agents have limited data: miconazole, terbinafine
Cost per **gram**	$~1.00
Topical Anti-Inflammatory Agents:	
Rationale for use	• TCS and calcineurin inhibitors are used due to their anti-inflammatory effects • **Place in therapy:** o TCS considered first line for moderate to severe cases and second line for no improvement after antifungal use in mild cases o Calcineurin inhibitors used in cases with frequent relapse
Mechanism	• TCS: induce phospholipase A2 inhibitory proteins and inhibit release of arachidonic acid • Calcineurin inhibitors (tacrolimus, pimecrolimus): inhibits transport of agents required for synthesis of DNA, RNA, and protein
Key Points	• TCS: limitations of use due to side effects (e.g., adrenal suppression, Cushing syndrome, hyperglycemia, skin atrophy, etc.) • Relapse occurs more often with TCS • Calcineurin inhibitor with the most data: pimecrolimus 1% cream
Cost per **gram**	• Topical corticosteroid: $~1 • Tacrolimus: $2.33 • Pimecrolimus: $8.13

Topical Phosphodiesterase-4 (PDE4) Inhibitors	
Drugs within the class	• Eucrisa (crisaborole) • Zoryve (roflumilast): foam is FDA approved for seborrheic dermatitis
Rationale for use	• Mechanism for therapeutic effect is not well defined • **Place in therapy:** considered after frequent use of steroids
Mechanism	Phosphodiesterase-4 (PDE4) inhibitor, increases intracellular cyclic adenosine monophosphate (cAMP) levels
Key Points	• High cost
Cost per **gram**	• Eucrisa: $10.73 • Zoryve: $14.30

Based on lowest per unit WAC cost; cost per gram provided since cost of therapy will depend on extent/location of dermatitis
**Other agents are available such as over-the-counter products (i.e., selenium sulfide, zinc pryithione, tar shampoo) and steroidal device Promiseb*

FDA Approval

Zoryve (roflumilast): December 15, 2023; 505(b) New Drug Application (NDA) pathway Type 3 New Dosage Form and Type 4 New Combination, STANDARD

Clinical Trials

Approval was based on two randomized, double blind, vehicle-controlled trials STRATUM (NCT04973228) and Trial 203 (NCT04091646). Enrolled total was 683 adult and pediatric patients with seborrheic dermatitis involving the scalp, face, and/or body with Investigator Global Assessment (IGA) of moderate or severe (IGA of 3 or 4 on a 5-point scale from 0 to 4) were randomized to receive Zoryve foam or vehicle once daily for 8 weeks.

Primary Endpoints: Proportion of subjects who achieved IGA treatment success at week 8. Success was defined as score of clear (0) or almost clear (1), plus a 2-grade improvement from baseline.

- In STRATUM, patients randomized to Zoryve foam achieved a 79.5% IGA success compared to 58% IGA success with vehicle foam. There was a higher percentage of subjects who achieved a reduction of at least 4 points on the Worst Itch-Numeric Rating Scale (WI-NRS), among subjects with at least 4 from baseline, at week 8 in the group who received Zoryve foam (62.8%) vs vehicle foam (40.6%).
- In Trial 203, patients randomized to Zoryve foam achieved 73.1% IGA success compared to 40.5% IGA success with vehicle foam.

Safety: Adverse effects reported were similar among groups

Place in Therapy

May be considered after frequent use of steroids and non-response to other treatment options.

Advantages	Disadvantages
• Option for patients who do not response to other agents • Avoid TCS side effects	• High cost • Age limitations (9 years and older) • One formulation (foam) option is FDA approved for seborrheic dermatitis • Clinical trial did not have an active comparator

Current Utilization

	Quarter 1 2023			Quarter 2 2023		
Medication	**Rx Count**	**% of Rx**	**Reimb Amount**	**Rx Count**	**% of Rx**	**Reimb Amount**
alclometasone dipropionate	8	0.2%	$373.96	1	0.0%	$40.68
betamethasone dipropionate	90	2.8%	$4,801.74	99	3.0%	$3,238.19
betamethasone valerate	35	1.1%	$2,314.77	27	0.8%	$959.05
betamethasone/prop glyc	15	0.5%	$513.32	21	0.6%	$634.10
ciclopirox	6	0.2%	$148.42	10	0.3%	$327.89
clobetasol propionate	222	6.8%	$5,702.73	226	6.9%	$4,963.06
clobetasol propionate/emoll	3	0.1%	$124.09	2	0.1%	$54.83
desonide	92	2.8%	$3,651.94	91	2.8%	$2,929.72
desoximetasone	1	0.0%	$32.79	2	0.1%	$58.49
Eucrisa (crisaborole)	3	0.1%	$2,129.88	1	0.0%	$356.18
fluocinolone acetonide	69	2.1%	$2,273.74	57	1.7%	$1,929.94
fluocinolone/shower cap	23	0.7%	$791.44	13	0.4%	$372.24
fluocinonide	137	4.2%	$3,522.99	131	4.0%	$3,762.04
fluocinonide/emollient base	1	0.0%	$61.38	1	0.0%	$70.08
fluticasone propionate	3	0.1%	$75.78	9	0.3%	$198.21
halobetasol propionate	3	0.1%	$75.58	1	0.0%	$24.10
hydrocortisone	512	15.6%	$14,179.23	490	14.9%	$7,877.91
hydrocortisone acetate	0	0.0%	$-	0	0.0%	$ -
hydrocortisone butyrate	1	0.0%	$68.78	1	0.0%	$79.06
hydrocortisone valerate	3	0.1%	$ 109.85	5	0.2%	$180.15
hydrocortisone/pramoxine	7	0.2%	$1,100.85	8	0.2%	$1,240.55
ketoconazole	505	15.4%	$12,987.18	511	15.5%	$10,370.62
miconazole nitrate	1	0.0%	$-	2	0.1%	$ -
mometasone furoate	65	2.0%	$1,862.16	43	1.3%	$825.69
pimecrolimus	34	1.0%	$14,564.44	28	0.8%	$14,086.65
tacrolimus	119	3.6%	$9,888.15	106	3.2%	$8,542.11
terbinafine	0	0.0%	$-	0	0.0%	$ -
triamcinolone acetonide	1314	40.2%	$30,445.29	1411	42.8%	$21,938.97
Zoryve (roflumilast)	0	0.0%	$-	0	0.0%	$ -
TOTALS	3272		$111,800.48	3297		$85,060.51
	Quarter 3 2023			**Quarter 4 2023**		
Medication	**Rx Count**	**% of Rx**	**Reimb Amount**	**Rx Count**	**% of Rx**	**Reimb Amount**
alclometasone dipropionate	3	0.1%	$91.36	4	0.1%	$120.44
betamethasone dipropionate	94	3.1%	$3,240.90	67	2.4%	$2,214.46
betamethasone valerate	26	0.8%	$737.24	25	0.9%	$914.76
betamethasone/prop glyc	18	0.6%	$496.94	20	0.7%	$580.76
ciclopirox	7	0.2%	$258.27	11	0.4%	$439.97
clobetasol propionate	202	6.6%	$4,511.46	194	7.0%	$4,204.26
clobetasol propionate/emoll	0	0.0%	$ -	2	0.1%	$62.39

desonide	80	2.6%	$2,221.88	69	2.5%	$1,965.07
desoximetasone	4	0.1%	$299.31	2	0.1%	$123.26
Eucrisa (crisaborole)	0	0.0%	$ -	0	0.0%	$ -
fluocinolone acetonide	61	2.0%	$1,888.10	55	2.0%	$1,797.77
fluocinolone/shower cap	19	0.6%	$615.10	21	0.8%	$735.79
fluocinonide	118	3.8%	$3,019.66	116	4.2%	$2,970.08
fluocinonide/emollient base	0	0.0%	$ -	0	0.0%	$ -
fluticasone propionate	6	0.2%	$132.49	5	0.2%	$110.12
halobetasol propionate	3	0.1%	$121.35	4	0.1%	$124.90
hydrocortisone	424	13.8%	$6,706.38	425	15.2%	$6,807.32
hydrocortisone acetate	0	0.0%	$ -	0	0.0%	$ -
hydrocortisone butyrate	0	0.0%	$ -	0	0.0%	$ -
hydrocortisone valerate	1	0.0%	$22.94	2	0.1%	$42.17
hydrocortisone/pramoxine	6	0.2%	$949.93	5	0.2%	$435.68
ketoconazole	512	16.6%	$10,152.77	458	16.4%	$9,300.72
miconazole nitrate	0	0.0%	$ -	0	0.0%	$ -
mometasone furoate	45	1.5%	$867.32	36	1.3%	$731.42
pimecrolimus	26	0.8%	$12,806.03	27	1.0%	$9,615.48
tacrolimus	112	3.6%	$7,967.57	116	4.2%	$8,096.75
terbinafine	0	0.0%	$ -	0	0.0%	$ -
triamcinolone acetonide	1311	42.6%	$20,741.75	1124	40.3%	$17,496.10
Zoryve (roflumilast)	0	0.0%	$ -	0	0.0%	$ -
TOTALS	3078		$77,848.75	2788		$68,889.67

References:

1. *Zoryve (roflumilast topical foam, 0.3%). [prescribing information]. Westlake Village, CA: Arcutis Biotherapeutics Inc; December 2023.*
2. *U.S. Food and Drug Administration, Center for Drug Evaluation and Research. Zoryve NDA 217242 approval letter, December 15, 2023. https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2023/217242Orig1s000ltr.pdf*
3. *Del Rosso JQ. Adult seborrheic dermatitis: a status report on practical topical management. J Clin Aesthet Dermatol. 2011 May;4(5):32-8. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3100109/pdf/jcad_4_5_32.pdf.*
4. *Sasseville D. Seborrheic dermatitis in adolescents and adults. UpToDate, Fowler J, Corona R (Ed) [Internet]. Waltham, MA: UptoDate; January 12, 2024. Available from: www.uptodate.com*
5. *Roflumilast. Drug Facts and Comparisons. Wolters Kluwer Health, Inc. Riverwoods, IL. January 9, 2024. http://online.factsandcomparisons.com*
6. *Roflumilast. In-Depth Answers and Red Book. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. January 11, 2024. https://www.micromedexsolutions.com*
7. *Identifier NCT04973228, Trial of PDE4 Inhibition With Roflumilast for the Management of Seborrheic Dermatitis (STRATUM). ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). March 10, 2023. Available from: http://clinicaltrials.gov*
8. *Identifier NCT04091646, Safety and Efficacy of ARQ-154 Foam in Subjects With Seborrheic Dermatitis. ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). July 3, 2023. Available from: http://clinicaltrials.gov*
9. *Corticosteroids, topical. Drug Facts and Comparisons. Wolters Kluwer Health, Inc. Riverwoods, IL. January 31, 2024. http://online.factsandcomparisons.com*
10. *Tacrolimus. Quick Answers and Red Book. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. February 1, 2024. https://www.micromedexsolutions.com*
11. *Pimecrolimus. Quick Answers and Red Book. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. December 13, 2023. https://www.micromedexsolutions.com*
12. *Crisaborole. Quick Answers and Red Book. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. April 14, 2023. https://www.micromedexsolutions.com*

FIRST REVIEW OF PRIMARY HYPEROXALURIA TYPE 1 (RIVFLOZA)

Primary hyperoxaluria Type 1 (PH1) is a rare disease that can lead to kidney damage and failure. Patients with PH1 have an excess production of oxalate causing kidney and urinary stones; over time as kidney function decreases, stones can be deposited elsewhere.

Management of PH1 includes increasing fluid intake, urinary alkalization, and high-dose vitamin B6 (pyridoxine). Patients are evaluated for the need of dialysis and transplant as well. There are two FDA approved ribonucleic acid interference (RNAi) medications (Rivloza and Oxlumo) for the treatment of PH1 that work by targeting various stages of oxalate production; there is no evidence to support using these agents together. Both Rivfloza and Oxlumo's most reported side effects are injection site reactions.

	Rivfloza (nedosiran)	Oxlumo (lumasiran)
Mechanism	• Inhibits expression of hepatic lactate dehydrogenase (LDH) • LDH is the enzyme for the last step of oxalate production	• Targets hydroxyacid oxidase 1 (HAO1) which decreases glycolate oxidate (GO) enzyme • This leads to a decrease in glyoxylate, a substrate for oxalate production
Administration	• Subcutaneous by a healthcare professional (HCP), caregiver, or patient • Once monthly	• Subcutaneous by a HCP • Three monthly loading doses, then every 3 months
Labeled indication	• PH1, 9 years of age and older, adults • Relatively preserved kidney function (e.g., eGFR ≥30 mL/minute/1.73 m^2)	• PH1, pediatric and adults
Cost per **dose**	$62,880.00	$104,698.00
Cost per **year**	$754,560.00	$628,188.00

Based on dosing for adult weighing 60 kg at lowest per unit WAC cost. Does not include cost of administration by healthcare provider.

FDA Approval

Rivfloza (nedosiran sodium): September 29, 2023; 505(b) New Drug Application (NDA) pathway; Type 1 New Molecular Entity, STANDARD; orphan

Clinical Trials

Rivfloza was approved based on the randomized, double-blind phase 2 PHYOX2 trial (NCT03847909) which compared Rivfloza (N=23) and placebo (N=12) in patients aged 6 years or older with PH1 or PH2 and relatively preserved kidney function. Efficacy was not evaluated for PH2 population due to low enrollment in the trial, so Rivfloza is only indicated for PH1.

After 6 months of treatment in PHY0X2, patients could enroll in the single-arm extension study, PHY0X3 (NCT04042402). All patients were treated with Rivfloza and the reduction in urinary oxalate was maintained in the 13 patients with PH1 for an additional 6 months of treatment.

Primary Endpoint:
Area under the curve, from days 90 to 180, of the % change from baseline in 24-hour urinary oxalate excretion: least-squared (LS) mean $AUC_{24\text{-hour Uox}}$ was -3486 (95% CI: -5025, -1947) in the Rivfloza group compared to 1490 (95% CI: 781, 3761) in the placebo group (P<0.0001). Among patients with PH1, the between group difference was 56% (95% CI: 33%, 80%) corrected for BSA in patients < 18 years of age averaged over days 90, 120, 150, and 180.

Secondary Endpoint: Percent of patients to achieve normal or near-normal 24-hour UOx excretion at two consecutive visits (50% vs 0%, P=0.002)

Safety: Injection site reactions most reported

Place in Therapy

Unknown: Long term studies needed to assess efficacy and safety; patients still may require transplant and/or dialysis

Advantages	Disadvantages
• Second approved medication for PH1 with a slightly different mechanism of action • Can be self-administered	• High cost • No head-to-head studies comparing approved products • Smaller population for labeled indication • More frequent dosing • Small enrollment in studies

Current Utilization

	Quarter 1-4 2023		
Medication	**Rx Count**	**% of Rx**	**Reimb Amount**
Oxlumo	0	0	0
Rivfloza	0	0	0

Rivfloza billed with unspecified diagnosis code, not reportable for PH1 use

References:

1. *Rivfloza (nedosiran injection, for subcutaneous use). [prescribing information]. Costa Mesa, CA: Pyramid Laboratories; September 2023.*
2. *U.S. Food and Drug Administration, Center for Drug Evaluation and Research. Rivfloza NDA 215842 approval letter, September 29, 2023. https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2023/215842Orig1s000ltr.pdf*
3. *Rivfloza (nedosiran): New Drug Review. IPD Analytics. Aventura, FL. October 2023. https://www.ipdanalytics.com*
4. *Nedosiran injection. Drug Facts and Comparisons. Wolters Kluwer Health, Inc. Riverwoods, IL. January 26, 2024. http://online.factsandcomparisons.com*
5. *Nedosiran. In-Depth Answers and Red Book. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. October 17, 2023. https://www.micromedexsolutions.com*
6. *Lumasiran. In-Depth Answers and Red Book. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. October 14, 2022. https://www.micromedexsolutions.com*

FIRST REVIEW OF MYASTHENIA GRAVIS (ZILBRYSQ)

Myasthenia gravis (MG) is an autoimmune disorder that occurs when antibodies attack proteins in the neuromuscular junction membrane; most patients have anti-acetylcholine receptor antibody positive disease (AChR Ab+).

Treatment goals are to improve muscle strength, limit symptoms, and prevent crises. Cholinesterase inhibitors are used in mild to moderate MG for symptom management. Patients oftentimes need immunosuppressive therapy as well; biologics are usually reserved for refractory disease and guidelines do not give preference to certain agents. Rapid immunotherapy agents are used to treat crises.

ORAL AGENTS			
Cholinesterase Inhibitors: Pyridostigmine			
Indication	• Can cause significant cholinergic, cardiac, respiratory, and gastric side effects • Overdosage may cause cholinergic crisis: rare, muscle weakness • Inconsistent response from patient to patient		
Cost per **year**	$1,836		
Immunosuppressive Agents:			
Agents	• Glucocorticoids: typically used initially, have a warning that they can worsen MG within the first 2 weeks of treatment Other agents are used for maintenance and to limit long term steroid use; have warnings for risk of malignancy • Azathioprine • Mycophenolate mofetil • Cyclosporine • Tacrolimus		
Cost per **year**	$192 (azathioprine) - $540 (tacrolimus)		
INJECTABLE AGENTS			
Complement Inhibitors:			
Indication	AChR Ab+		
Agents	**Zilbrysq (zilucoplan)** • Subcutaneous (SC) • Self-administered • Once daily • Can be administered with IVIG and plasma exchange (PE) without requiring dose adjustments	Soliris (eculizumab) • Intravenous (IV) • HCP administered • Once every 2 weeks	Ultomiris (ravulizumab) • IV • HCP administered • Once every 8 weeks
Warnings	• Black box warning (BBW) and risk evaluation mitigation strategy (REMS) due to risk of meningococcal infections • Risk for other infections, including Neisseria meningitis • Pancreatitis and pancreatic cysts		
Cost per **year**	• Zilbrysq: $381,108 • Soliris: $730,576 • Ultomiris: $550,743.93		
FcRn Antagonists:			
Indication	AChR Ab+ *Rystiggo also approved for muscle-specific tyrosine kinase (MuSK) Ab+		
Agents	• Vyvgart (ergartigimod alfa) • Vyvgart Hytrulo (efgartigimod alfa/hyaluronidase) • Rystiggo (rozanolixizumab-noli)		

Key notes	• All are administered by a HCP (Vyvgart IV, others SC) • Frequency is weekly and cyclic • Do not have BBW and REMS requirements but do carry risk of infections
Cost per **cycle**	• Vyvgart: $48,552 • Vyvgart Hytrulo: $63,092 • Rystiggo: $72,600
Anti-B-cell Therapy	
Indication	Refractory MG and/or MuSK antibody-positive disease
Agents	Rituximab (Riabni, Rituxan, Ruxience, Truxima)
Key notes	• IV weekly or biweekly • Labeled warnings for bowel obstruction/perforation, cytopenia, renal toxicity, and tumor lysis syndrome
Cost per **year**	$22,548.48-73,282.56 (depending on dosing frequency)
Rapid Immunotherapy: plasmapheresis and IVIG	
Indication	• MG crisis • Severe or rapidly worsening disease • Can be used to bridge therapy when starting agents with a slower onset

Based on dosing for adult weighing 60 kg (body surface area 1.6 m2) at lowest per unit WAC cost.

FDA Approval

Zilbrysq (zilucoplan): October 17, 2023; 505(b) New Drug Application (NDA) pathway Type 1 New Molecular Entity, STANDARD; orphan

Clinical Trials

Zilbrysq was approved based on a 12-week, multicenter, randomized, double-blind placebo-controlled phase 3 RAISE trial (NCT04115293). 174 patients were randomized to receive either Zilbrysq or placebo.

Primary Endpoint: Patients assigned to Zilbrysq achieved a -4.39 (-5.28, -3.50) change from baseline in the Myasthenia Gravis-Specific Activities of Daily Living scale (MG-ADL) total score vs. -2.30 (-5.28, -3.50) in the placebo group ($P < 0.001$) after twelve weeks of treatment.

Secondary Endpoint:

- Zilbrysq achieved a -6.19 (-7.29, -5.08) change from baseline in the quantitative Myasthenia Gravis (QMG) total score vs. placebo -3.25 (-4.32, -2.17) ($P<0.001$).
- The proportion of MG-ADL responders with at least a 3-point improvement at week 12 was greater for Zilbrysq (73.1%) compared to placebo (46.1%) ($P<0.001$).
- The proportion of QMG responders with at least a 5-point improvement was also greater for Zilbrysq (58%) compared to placebo (33%) at week 12 ($P= 0.0012$)

Safety: Most reported adverse effects were injection site reactions, upper respiratory tract infections, diarrhea but were similar among groups

**In both MG-ADL and QMG scales, higher scores indicate more severe impairment.*

Place in Therapy

Unknown: may be used as early therapy in place of glucocorticoids, as bridge therapy until immunotherapy takes effect, or as chronic maintenance therapy for refractory disease. Clinical experience for refractory MG is limited compared to other biologic agents.

Advantages	Disadvantages
• First approved complement inhibitor that can be given SC and self-administered • Do not have to stop IVIG or PE	• High cost • No head-to-head studies vs other agents • BBW and REMS requirements • Require daily administration

Current Utilization

	Quarter 1 2023			Quarter 2 2023		
Medication	**Rx Count**	**% of Rx**	**Reimb Amount**	**Rx Count**	**% of Rx**	**Reimb Amount**
azathioprine	86	2.3%	$2,296.57	77	2.0%	$1,990.53
cyclosporine	0	0.0%	$ -	0	0.0%	$ -
methylprednisolone	557	14.6%	$8,403.52	602	15.9%	$8,814.20
mycophenolate mofetil	97	2.5%	$8,006.95	93	2.5%	$7,451.39
prednisone	2856	74.8%	$32,761.11	2799	73.9%	$34,111.48
tacrolimus	168	4.4%	$8,590.11	159	4.2%	$6,877.02
Zilbrysq	0	0.0%	$ -	0	0.0%	$-
Soliris	1	0.0%	$7,940.78	7	0.2%	$71,467.02
Ultomiris	1	0.0%	$47,932.66	2	0.1%	$95,864.44
Vyvgart, Vyvgart Hytrulo	0	0.0%	$ -	7	0.2%	$63,117.61
Rystiggo	0	0.0%	$ -	0	0.0%	$-
Rituxan and biosimilars	51	1.3%	$70,953.89	39	1.0%	$43,662.49
TOTALS	3817		$186,885.59	3785		$274,111.56
	Quarter 3 2023			**Quarter 4 2023**		
Medication	**Rx Count**	**% of Rx**	**Reimb Amount**	**Rx Count**	**% of Rx**	**Reimb Amount**
azathioprine	72	2.0%	$2,047.95	64	1.7%	$1,774.88
cyclosporine	0	0.0%	$ -	0	0.0%	$ -
methylprednisolone	517	14.5%	$7,606.84	584	15.6%	$8,574.50
mycophenolate mofetil	107	3.0%	$8,553.27	98	2.6%	$7,575.38
prednisone	2646	74.3%	$30,577.61	2808	75.2%	$32,937.00
tacrolimus	174	4.9%	$12,660.89	168	4.5%	$14,309.80
Zilbrysq	0	0.0%	$ -	0	0.0%	$ -
Soliris	7	0.2%	$83,378.19	0	0.0%	$ -
Ultomiris	2	0.1%	$95,705.28	1	0.0%	$47,932.66
Vyvgart, Vyvgart Hytrulo	0	0.0%	$ -	2	0.1%	$18,207.00
Rystiggo	0	0.0%	$ -	0	0.0%	$ -
Rituxan and biosimilars	37	1.0%	$70,040.51	10	0.3%	$13,871.70
TOTALS	3562		$310,570.54	3735		$145,182.92

References:

1. *Bird SJ. Overview of the treatment of myasthenia gravis. In: Shefner JM, Goddeau RP, editor. UpToDate. [Internet]. Waltham, Mass.: UpToDate; August 17, 2023. Available from: www.uptodate.com*
2. *U.S. Food and Drug Administration, Center for Drug Evaluation and Research. Zilbrysq NDA 216834 approval letter, October 17, 2023.* https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2023/216834Orig1s000ltr.pdf

3. *Zilbrysq (zilocuplan injection, for subcutaneous use). [prescribing information]. Smyrna, GA: UCB, Inc; October 2023.*
4. *Zilbrysq: New Drug Review. IPD Analytics. Aventura, FL. November 2023. https://www.ipdanalytics.com*
5. *Zilucoplan Injection. Drug Facts and Comparisons. Wolters Kluwer Health, Inc. Riverwoods, IL. February 5, 2024. http://online.factsandcomparisons.com*
6. *Zilucoplan. In-Depth Answers and Red Book. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. November 18, 2023. https://www.micromedexsolutions.com*
7. *Glucocorticoids. Drug Facts and Comparisons. Wolters Kluwer Health, Inc. Riverwoods, IL. January 31, 2024. http://online.factsandcomparisons.com*
8. *Pyridostigmine. Quick Answers and Red Book. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. January 30, 2024. https://www.micromedexsolutions.com*
9. *Azathioprine. Quick Answers and Red Book. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. December 7, 2023. https://www.micromedexsolutions.com*
10. *Mycophenolate mofetil. Quick Answers and Red Book. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. January 23, 2024. https://www.micromedexsolutions.com*
11. *Cyclosporine. Quick Answers and Red Book. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. February 1, 2024. https://www.micromedexsolutions.com*
12. *Tacrolimus. Quick Answers and Red Book. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. February 1, 2024. https://www.micromedexsolutions.com*
13. *Eculizumab. Quick Answers and Red Book. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. June 28, 2023. https://www.micromedexsolutions.com*
14. *Ravulizumab-cwvz. Quick Answers and Red Book. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. December 13, 2023. https://www.micromedexsolutions.com*
15. *Efgartigimod alfa-fcab. Quick Answers and Red Book. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. December 26, 2023. https://www.micromedexsolutions.com*
16. *Efgartigimod alfa/hyaluronidase-qvfc. Quick Answers and Red Book. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. December 26, 2023. https://www.micromedexsolutions.com*
17. *Rozanolixizumab-noli. Quick Answers and Red Book. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. July 18, 2023. https://www.micromedexsolutions.com*
18. *Rituximab. Quick Answers and Red Book. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. January 3, 2024. https://www.micromedexsolutions.com*

FIRST REVIEW OF DUCHENNE MUSCULAR DYSTROPHY (EMFLAZA, AGAMREE)

Duchenne Muscular Dystrophy (DMD) is a rare X-linked disease caused by mutations in the DMD gene which encodes for dystrophin, a protein required for proper muscular function. Patients with DMD experience muscle weakness leading to loss of ambulation, respiratory failure, and cardiac failure. Treatment of DMD targets improving muscle function with the use of corticosteroids and/or improving dystrophin function with exon skipping or gene therapies.

CORTICOSTEROIDS: IMPROVE MUSCULAR FUNCTION		
• Rationale for use: decrease inflammation, improve motor and pulmonary function, postpone loss of ambulation and cardiomyopathy, increase survival • Side effects: weight gain, decreased growth, delayed puberty, bone fractures, behavioral effects, adrenal suppression, immunosuppression, hyperglycemia		
Corticosteroids		
Agents per guidelines	Prednisone or prednisolone	
Cost per **year**	$75.60 (tablets) - $3,720 (suspension)	
Emflaza (deflazacort) and Agamree (vamorolone)		
Similarities	• 2 years and up • Similar efficacy to prednisone • Derivatives of prednisone with more favorable side effects	
	Emflaza (deflazacort)	**Agamree (vamorolone)**
Formulation	Suspension and tablets	Suspension
Compared to prednisone	Less weight gain and behavioral effects; more likely to delay growth	Less growth delay, bone fractures, and behavioral effects
Cost per **year**	$54,620.64 (tablets) – $79,961.76 (suspension)	$114,000
IMPROVE DYSTROPHIN FUNCTION		
• Used in addition to corticosteroid treatment • Have not shown clinically significant benefit but may slow progression		
Exon Skipping Therapy:		
Key notes	• Binds to mRNA to omit exon during processing • Agents: Exondys 51, Vyondys 53, Amondys 45, Viltepso	
Cost per **year**	$460,800 (Exondys, Vyondys 53, Amondys 45) - $473,760 (Viltepso)	
Gene Therapy: Elevidys		
Indication	Introduces shortened version of DMD gene to muscle tissue, one time infusion	
Cost per **infusion**	$3,200,000.00	

Based on pediatric dosing for a 5-year-old patient weighing 20 kg at the lowest per unit WAC cost.

FDA Approval

Emflaza (deflazacort): February 9, 2017; 505(b)(2) New Drug Application (NDA) pathway Type 1 New Molecular Entity, PRIORITY; orphan

Agamree (vamorolone): October 26, 2023; 505(b) New Drug Application (NDA) pathway Type 1 New Molecular Entity, STANDARD; orphan

Clinical Trials

Emflaza

Approval of Emflaza for DMD was based on a multicenter, randomized, double-blind, placebo-controlled, 52-week study (MP-104-NM-001). 196 male patients aged 5 to 15 years of age were enrolled in the study. Patients were randomized to Emflaza, prednisone, or placebo. After 12 weeks, placebo patients were re-randomized to either Emflaza or the active comparator for an additional 40 weeks. Emflaza 1.2mg/kg/day was also analyzed but not included in the results as it is not a recommended dosage due to a higher side effect rate vs. 0.9mg/kg/day.

Primary Endpoint: All groups showed statistically significant improvements in muscle strength score vs placebo from baseline to week 12. Change was greater compared to placebo but not greater than prednisone.

- Emflaza 0.9 mg/kg/day (n = 48): 0.15 (0.01, 0.28); p = 0.0173
- Prednisone 0.75 mg/kg/day (n = 45): 0.27 (0.13, 0.41); p = 0.0002
- Placebo (n = 50): -0.10 (-0.23, 0.03)

Secondary Endpoints: Emflaza maintained greater muscular strength improvement from baseline to week 52.

- Emflaza 0.9 mg/kg/day (n = 41): 0.39 (0.25, 0.54)
- Prednisone 0.75 mg/kg/day (n = 37): 0.23 (0.07, 0.38)

Safety: More adverse events, including serious adverse events and discontinuations, for prednisone

Agamree

Approval of Agamree for the treatment of DMD was based on a multicenter, randomized, double-blind, parallel-group, placebo- and active-controlled, multinational 24-week study (VISION-DMD; NCT03439670). The study enrolled 121 male patients to Agamree, prednisone, or placebo for 24 weeks. After 24 weeks, patients on prednisone or placebo received Agamree at either 2 mg/kg/day or 6 mg/kg/day for an additional 20 weeks.

Primary Endpoint: Change from baseline to Week 24 in Time to Stand Test (TTSTAND) for Agamree compared to placebo.

- TTSTAND velocity (rises/sec) mean change from baseline was -0.012 in the placebo group, 0.033 in the Agamree 2 mg/kg/day group (P=0.017), and 0.048 in the Agamree 6 mg/kg/day group (P=0.002).

Secondary Endpoints: Change from baseline to Week 24 in TTSTAND velocity, 6 Minute Walk Test (6MWT) distance, and Time to Run/Walk 10 meters (TTRW) velocity.

- 6MWT distance (meters) mean change from baseline was -14 in the placebo group, 27 in the Agamree 2 mg/kg/d group (P=0.004), and 29 in the Agamree 6 mg/kg/day group (P=0.002).
- TTRW velocity (meter/second) mean change from baseline was 0.014 in the placebo group, 0.141 in the Agamree 2 mg/kg/d group (P=0.103), and 0.258 in the Agamree 6 mg/kg/day group (P=0.002).

**The primary endpoint and key secondary endpoints were met for the Agamree 6 mg/kg/day treatment group. The Agamree 2 mg/kg/day treatment group was statistically significant vs. placebo for TTSTAND and 6MWT but was not statistically significant vs. placebo for TTRW.*

Safety: Changes in height percentile and decline of serum biomarkers of bone formation were seen in prednisone treated patients but not Agamree

Place in Therapy

Glucocorticoids should be started for children with DMD whose motor skills have plateaued or have started to decline, prior to substantial decline. Glucocorticoid treatment is beneficial for improving motor function, strength, and pulmonary function, delaying the loss of ambulation, and reducing the risk of scoliosis.

Advantages	Disadvantages
• Improved side effect profile compared to prednisone • Offer an option for patients who are unable to tolerate prednisone • Agamree is a novel steroid acting as a potent mineralocorticoid antagonist, which prevents negative mineralocorticoid effects and glucocorticoid receptor binding elements which may contribute to prednisone's side effects.	• High cost • Similar efficacy to low-cost prednisone • No head-to-head trials comparing Agamree and Emflaza

Current Utilization

	Quarter 1 2023			Quarter 2 2023		
Medication	**Rx Count**	**% of Rx**	**Reimb Amount**	**Rx Count**	**% of Rx**	**Reimb Amount**
prednisolone	170	5.6%	$2,814.65	86	3.0%	$1,390.00
prednisone	2856	94.4%	$32,761.11	2799	97.0%	$34,111.48
Emflaza	0	0.0%	$ -	0	0.0%	$ -
Agamree	0	0.0%	$ -	0	0.0%	$ -
Exondys 51	0	0.0%	$ -	0	0.0%	$ -
Vyondys 53	0	0.0%	$ -	0	0.0%	$ -
Amondys 45	0	0.0%	$ -	0	0.0%	$ -
Viltepso	0	0.0%	$ -	0	0.0%	$ -
Elevidys	0	0.0%	$ -	0	0.0%	$ -
TOTALS	3026		$35,575.76	2885		$35,501.48
	Quarter 3 2023			**Quarter 4 2023**		
Medication	**Rx Count**	**% of Rx**	**Reimb Amount**	**Rx Count**	**% of Rx**	**Reimb Amount**
prednisolone	25	0.9%	$465.06	49	1.7%	$816.47
prednisone	2646	99.1%	$30,577.61	2808	98.3%	$32,937.00
Emflaza	0	0.0%	$-	0	0.0%	$-
Agamree	0	0.0%	$-	0	0.0%	$-
Exondys 51	0	0.0%	$-	0	0.0%	$-
Vyondys 53	0	0.0%	$-	0	0.0%	$-
Amondys 45	0	0.0%	$-	0	0.0%	$-
Viltepso	0	0.0%	$-	0	0.0%	$-
Elevidys	0	0.0%	$-	0	0.0%	$-
TOTALS	2671		$31,042.67	2857		$33,753.47

References:

1. *Darras BT. Duchenne and Becker muscular dystrophy: management and prognosis. UpToDate, Patterson MC, Dashe JF (Ed) [Internet]. Waltham, MA: UpToDate; October 12, 2023. Available from: www.uptodate.com*
2. *Emflaza (deflazacort tablets and oral suspension). [prescribing information]. Northbrook, IL: Marathon Pharmaceuticals; February 2017.*
3. *U.S. Food and Drug Administration, Center for Drug Evaluation and Research. Emflaza NDA 208684 and 208685 approval letter, February 9, 2017. https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2017/208684Orig1s000,208685Orig1s000ltr.pdf*
4. *U.S. Food and Drug Administration, Center for Drug Evaluation and Research. Application Number: 208684Orig1s000 Medical Review(s). January 17, 2017. https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/208684,208685Orig1s000MedR.pdf*

5. *Emflaza (deflazacort)/Marathon: summary of issues and management in patients with DMD. IPD Analytics. Aventura, FL. February 2017. https://www.ipdanalytics.com*
6. *Deflazacort. Drug Facts and Comparisons. Wolters Kluwer Health, Inc. Riverwoods, IL. February 5, 2024.* http://online.factsandcomparisons.com
7. *Deflazacort. In-Depth Answers and Red Book. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI.December 5, 2024. https://www.micromedexsolutions.com*
8. *Agamree (vamorolone oral suspension). [prescribing information]. Burlington, MA: Santhera Pharmaceuticals (USA), Inc; October 2023.*
9. *U.S. Food and Drug Administration, Center for Drug Evaluation and Research. Agamree NDA 215239 approval letter, October 26, 2023. https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2023/215239Orig1s000ltr.pdf*
10. *Agamree (vamorolone): New Drug Review. IPD Analytics. Aventura, FL. November 2023. https://www.ipdanalytics.com*
11. *Vamorolone. Drug Facts and Comparisons. Wolters Kluwer Health, Inc. Riverwoods, IL. October 27, 2023.*http://online.factsandcomparisons.com
12. *Vamorolone. In-Depth Answers and Red Book. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI.December 8, 2023. https://www.micromedexsolutions.com*
13. *Glucocorticoids. Drug Facts and Comparisons. Wolters Kluwer Health, Inc. Riverwoods, IL. January 31, 2024. http://online.factsandcomparisons.com*
14. *Eteplirsen. Quick Answers and Red Book. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. August 11, 2023. https://www.micromedexsolutions.com*
15. *Golodirsen. Quick Answers and Red Book. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. December 12, 2023. https://www.micromedexsolutions.com*
16. *Casimersen. Quick Answers and Red Book. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. April 12, 2023. https://www.micromedexsolutions.com*
17. *Viltolarsen. Quick Answers and Red Book. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. August 12, 2023. https://www.micromedexsolutions.com*
18. *Delandistrogene Moxeparvovec-rokl. Quick Answers and Red Book. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. November 14, 2023. https://www.micromedexsolutions.com*
19. *Griggs, Robert C., et al. "Efficacy and safety of deflazacort vs prednisone and placebo for Duchenne muscular dystrophy." Neurology 87.20 (2016): 2123-2131.*

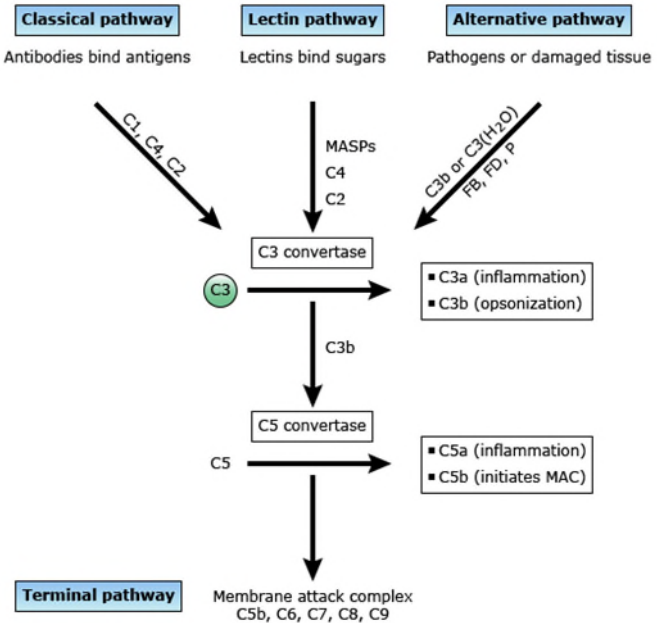
FIRST REVIEW OF PAROXYSMAL NOCTURNAL HEMOGLOBINURIA (EMPAVELI, FABHALTA)

Paroxysmal nocturnal hemoglobinuria (PNH) is a rare hematopoietic stem cell disorder where cells lack surface complementary inhibitor proteins. These cells undergo hemolysis by the complement system, leading to hemolytic anemia. Hemolysis can occur inside (intravascular hemolysis, IVH) or outside of blood vessels (extravascular hemolysis, EVH). Patients with PNH can experience thrombosis, pain, fatigue, dyspnea, and bone marrow suppression.

Treatment of PNH is guided by severity of symptoms, bone marrow suppression, and hemolysis to limit thrombosis. C5 complement inhibitors are the mainstay of treatment; patients who experience breakthrough hemolysis are treated with Empaveli or Fabhalta.

Similarities among all treatment options:

- Agents inhibit various stages of the complement activation system
- BBW for meningococcal infections: require participation in REMS program and vaccination prior to use, may consider antibiotic prophylaxis
  - Empaveli and Fabhalta also require vaccination for all encapsulated bacteria



https://www.uptodate.com/contents/complement-pathways#topicGraphics

C5 Inhibitors		
• Mainstay of treatment • **Hemolysis:** affects IVH only (1/3 of patients will require transfusions) • Can cause infusion reactions **Made by the same company, 80% of patients have been switched over from Soliris to Ultomiris*		
Medication	**Soliris (eculizumab)**	**Ultomiris (ravulizumab)**
Key notes	• IV infusion weekly for 5 weeks then every 2 weeks thereafter, fixed dose	• IV infusion every 8 weeks starting 2 weeks after loading dose, weight based • Adult and pediatric patients ≥1 month of age • Less breakthrough hemolysis
Cost per **year**	$541,409	$550,743.93

C3 Inhibitor	
Empaveli (pegcetacoplan)	
Administration	• Self-administered, subcutaneous twice weekly infusion • Given via commercially available pump or on-body injector
Hemolysis	Affects IVH and EVH
Clinical studies	Superiority evidenced vs Soliris in improvement of hemoglobin levels and decreased need of transfusions
Warnings	Infections, infusion reaction, can interfere with aPTT tests
Cost per **year**	$488,250.88

Factor B Inhibitor	
Fabhalta (iptacopan)	
Administration	• Oral, twice daily • Concerns of hemolysis from nonadherence due to the agent's short half-life
Hemolysis	Affects IVH and EVH
Clinical Studies	Superiority evidenced vs C5 inhibitors in improvement of hemoglobin levels and decreased need of transfusions
Warning	Hyperlipidemia, some patients have required cholesterol lowering medications
Cost per year	$542,465.76

Based on dosing for adult weighing 60 kg at lowest per unit WAC cost.

FDA Approval

Empaveli (pegcetacoplan): May 14, 2021; 505(b) New Drug Application (NDA) pathway Type 1 New Molecular Entity, PRIORITY; orphan

Fabhalta (iptacopan): December 5, 2023; 505(b) New Drug Application (NDA) pathway Type 1 New Molecular Entity, PRIORITY; orphan

Clinical Trials

Empaveli

Approval based on Phase 3 PEGASUS study (NCT03500549). The trial was a randomized, head-to-head, multicenter, open-label study of 80 patients with PNH and hemoglobin levels <10.5 g/dL after Soliris treatment.

Interventions:

- Run-in (4 weeks): continued current Soliris dose alongside self-administered Empaveli
- Randomized, controlled (16 weeks): Empaveli or Soliris
- Open-label (32 weeks): all who completed randomized control period received open-label Empaveli

Primary Endpoint: Results of hemoglobin change from baseline at week 16 showed superiority to Soliris (P<0.001) with an adjusted mean change on 2.37 g/dL for Empaveli vs –1.47 g/dL for Soliris.

Secondary Endpoints: Results showed non-inferiority for transfusion avoidance (85% Empaveli, 15% Soliris, P<0.001) and change in reticulocyte count. Non-inferiority was not evidenced in the change of LDH levels and was not assessed for the Functional Assessment of Chronic Illness Therapy-Fatigue (FACIT-F) scores.

Safety: Injection-site reactions, infections, diarrhea, fatigue, breakthrough hemolysis

Fabhalta

Approval based on Phase 3 APPLY-PNH study (NCT04558918) and Phase 3 APPOINT-PNH study (NCT04820530).

APPLY-PNH (NCT04558918): The trial was a randomized, multicenter study of 97 patients with PNH and anemia after prior complement C5 inhibitor treatment (Soliris or Ultomiris).

Co-Primary Endpoints: Superiority was shown by an increase in hemoglobin ≥2 g/dL (Fabhalta 82.3%, C5 inhibitors 2.0%, P<0.0001) and ≥12 g/dL (Fabhalta 68.8%, C5 inhibitors 1.8%, P<0.0001) without need for transfusions

Secondary Endpoints: Results showed superiority of transfusion avoidance, change of hemoglobin from baseline, FACIT-F score, change of absolute reticulocyte count, and rate of hemolysis.

Safety: Fabhalta had more reports of headache and diarrhea. C5 inhibitors had more reports of infections and hemolysis.

APPOINT-PNH (NCT04820530): The trial was open-label, single arm, multicenter study of 40 patients with complement inhibitor naïve PNH.

Primary Endpoints: 92.2% of patients experienced an increase in hemoglobin ≥2 g/dL without need for transfusions

Secondary Endpoints: 62.8% of patients experienced an increase in hemoglobin ≥12 without need for transfusions, and 97.6% of patients avoided transfusions. No patients experienced hemolysis or major adverse vascular events.

Safety: Most reported were infections, headache, and rash; serious adverse events reported were COVID-19 and bacterial pneumonia; no discontinuations

Place in Therapy

Potential option for patients experiencing breakthrough hemolysis on treatment with C5 inhibitors.

Advantages	Disadvantages
• First oral agent • Another treatment option for patients who require transfusions despite C5 inhibitor therapy	• No head-to-head trials comparing Empaveli and Fabhalta

Current Utilization

	Quarter 1 2023			Quarter 2 2023		
Medication	**Rx Count**	**% of Rx**	**Reimb Amount**	**Rx Count**	**% of Rx**	**Reimb Amount**
Soliris	1	50.00%	$7,940.78	7	77.78%	$71,467.02
Ultomiris	1	50.00%	$7,940.78	2	22.22%	$95,864.44
Empaveli	0	0.00%	$ -	0	0.00%	$ -
Fabhalta	0	0.00%	$ -	0	0.00%	$-
TOTALS	2		$15,881.56	9		$167,331.46
	Quarter 3 2023			**Quarter 4 2023**		
Medication	**Rx Count**	**% of Rx**	**Reimb Amount**	**Rx Count**	**% of Rx**	**Reimb Amount**
Soliris	7	77.78%	$83,378.19	0	0.00%	$ -
Ultomiris	2	22.22%	$95,705.28	1	100.00%	$47,932.66
Empaveli	0	0.00%	$ -	0	0.00%	$ -
Fabhalta	0	0.00%	$ -	0	0.00%	$ -
TOTALS	9		$179,083.47	1		$47,932.66

References:

1. *Brodsky RA. Treatment and prognosis of paroxysmal nocturnal hemoglobinuria. UpToDate, Larson RA, Rosmarin AG (Ed) [Internet]. Waltham, MA: UptoDate; November 27, 2023. Available from: www.uptodate.com*
2. *Hillmen P, Szer J, Weitz I, Röth A, Höchsmann B, Panse J, Usuki K, Griffin M, Kiladjian JJ, de Castro C, Nishimori H, Tan L, Hamdani M, Deschatelets P, Francois C, Grossi F, Ajayi T, Risitano A, Peffault de la Tour R. Pegcetacoplan versus Eculizumab in Paroxysmal Nocturnal Hemoglobinuria. N Engl J Med. 2021 Mar 18;384(11):1028-1037. doi: 10.1056/NEJMoa2029073. PMID: 33730455.*

3. *Empaveli (pegcetacoplan injection, for subcutaneous use). [prescribing information]. Waltham, MA: Apellis Pharmaceuticals, Inc. May 2021.*
4. *U.S. Food and Drug Administration, Center for Drug Evaluation and Research. Empaveli NDA 215014 approval letter, May 14, 2021. https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2021/215014Orig1s000ltr.pdf*
5. *Empaveli (pegcetacoplan): New Drug Review. IPD Analytics. Aventura, FL. May 2021. https://www.ipdanalytics.com*
6. *Pegcetacoplan injection. Drug Facts and Comparisons. Wolters Kluwer Health, Inc. Riverwoods, IL. January 2, 2024. http://online.factsandcomparisons.com*
7. *Pegcetacoplan. In-Depth Answers and Red Book. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. October 4, 2023. https://www.micromedexsolutions.com*
8. *Fabhalta (iptacopan, oral capsules). [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation. December 2023.*
9. *U.S. Food and Drug Administration, Center for Drug Evaluation and Research. Fabhalta NDA 218276 approval letter, December 5, 2023. https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2023/218276Orig1s000ltr.pdf*
10. *Fabhalta (iptacopan): New Drug Review. IPD Analytics. Aventura, FL. January 2024. https://www.ipdanalytics.com*
11. *Iptacopan. Drug Facts and Comparisons. Wolters Kluwer Health, Inc. Riverwoods, IL. December 28, 2023. http://online.factsandcomparisons.com*
12. *Latour RP, Roeth A, Kulasekararaj A, Scheinberg P, Ueda Y, Castro CM, Bona ED, Schrezenmeier H, Langemeijer SM, Barcellini W, Tavitian S, Panse J, Schafhausen P, Mauad VA, Kerloeguen C, Levitch R, RKumar R, Thorburn C, Maitra S, Dahlke M, Risitano AM; Oral Monotherapy with Iptacopan, a Proximal Complement Inhibitor of Factor B, Has Superior Efficacy to Intravenous Terminal Complement Inhibition with Standard of Care Eculizumab or Ravulizumab and Favorable Safety in Patients with Paroxysmal Nocturnal Hemoglobinuria and Residual Anemia: Results from the Randomized, Active-Comparator-Controlled, Open-Label, Multicenter, Phase III Apply-PNH Study. Blood 2022; 140 (Supplement 2): LBA–2. doi: https://doi.org/10.1182/blood-2022-171469*
13. *Iptacopan. In-Depth Answers and Red Book. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. December 21, 2023. https://www.micromedexsolutions.com*
14. *Eculizumab. Quick Answers and Red Book. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. June 28, 2023. https://www.micromedexsolutions.com*
15. *Ravulizumab-cwvz. Quick Answers and Red Book. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. December 13, 2023. https://www.micromedexsolutions.com*
16. *Liszewski MK, Atkinson JP. Complement pathways. UpToDate, Schur PH, Orange JS, Feldweg AM (Ed) [Internet]. Waltham, MA: UpToDate; November 11, 2022. Available from:* www.uptodate.com

NORTH DAKOTA MEDICAID
RETROSPECTIVE DRUG UTILIZATION REVIEW
CRITERIA RECOMMENDATIONS
1st QUARTER 2024

Criteria Recommendations ***Approved*** ***Rejected***

1. Sotagliflozin / Overuse _____ _____

Alert Message: Inpefa (sotagliflozin) may be over-utilized. The recommended maintenance dose of sotagliflozin is 400 mg once daily.

Drugs/Diseases

Util A	Util B	Util C
Sotagliflozin		

Max Dose: 400 mg/day

References:
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Inpefa Prescribing Information, May 2023, Lexicon Pharmaceuticals, Inc.

2. Sotagliflozin / Therapeutic Appropriateness _____ _____

Alert Message: The safety and effectiveness of Inpefa (sotagliflozin) in pediatric patients under 18 years of age have not been established.

Drugs/Diseases

Util A	Util B	Util C
Sotagliflozin		

Age Range: 0 – 17 yoa

References:
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Inpefa Prescribing Information, May 2023, Lexicon Pharmaceuticals, Inc.

3. Sotagliflozin / Therapeutic Appropriateness _____ _____

Alert Message: Inpefa (sotagliflozin) can cause intravascular volume depletion, which may sometimes manifest as symptomatic hypotension or acute transient changes in creatinine. Patients with impaired renal function (eGFR < 60 mL/min/1.73 m2), elderly patients, or patients on loop diuretics may be at increased risk for volume depletion or hypotension. Before initiating sotagliflozin in patients with one or more of these characteristics, assess volume status and renal function. Monitor for signs and symptoms of hypotension and renal function after initiating therapy.

Drugs/Diseases

Util A	Util B	Util C
Sotagliflozin	CKD Stage 3	
	CKD Stage 4	
	CKD Stage 5	

References:
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Inpefa Prescribing Information, May 2023, Lexicon Pharmaceuticals, Inc.

Criteria Recommendations ***Approved*** ***Rejected***

4. Sotagliflozin / Loop Diuretics _____ _____

Alert Message: Inpefa (sotagliflozin) can cause intravascular volume depletion, which may sometimes manifest as symptomatic hypotension or acute transient changes in creatinine. Patients with impaired renal function (eGFR < 60 mL/min/1.73 m2), elderly patients, or patients on loop diuretics may be at increased risk for volume depletion or hypotension. Before initiating sotagliflozin in patients with one or more of these characteristics, assess volume status and renal function. Monitor for signs and symptoms of hypotension and renal function after initiating therapy.

Drugs/Diseases

Util A	Util B	Util C
Sotagliflozin	Bumetanide	
	Ethacrynic Acid	
	Furosemide	
	Torsemide	

References:

Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Inpefa Prescribing Information, May 2023, Lexicon Pharmaceuticals, Inc.

5. Sotagliflozin / Urinary Tract Infection _____ _____

Alert Message: Treatment with SGLT2 inhibitors, including Inpefa (sotagliflozin), increases the risk for urinary tract infections. Serious urinary tract infections, including urosepsis and pyelonephritis, requiring hospitalization have been reported. Evaluate patients for signs and symptoms of urinary tract infections, and promptly treat if indicated.

Drugs/Diseases

Util A	Util B	Util C
Sotagliflozin	Pyelonephritis	
	Urinary Tract Infection	

References:

Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Inpefa Prescribing Information, May 2023, Lexicon Pharmaceuticals, Inc.

6. Sotagliflozin / Genital Mycotic Infections _____ _____

Alert Message: Inpefa (sotagliflozin) use increases the risk of genital mycotic infections. Patients with a history of genital mycotic infections were more likely to develop genital mycotic infections. Monitor and treat appropriately.

Drugs/Diseases

Util A	Util B	Util C
Sotagliflozin	Candida Balanitis	
	Candidiasis of vulva and vagina	
	Urogenital Candidiasis	

References:

Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Inpefa Prescribing Information, May 2023, Lexicon Pharmaceuticals, Inc.

7. Sotagliflozin / Insulin and Insulin Secretagogues _____ _____

Alert Message: Insulin and insulin secretagogues are known to cause hypoglycemia. Inpefa (sotagliflozin) may increase the risk of hypoglycemia when combined with insulin or an insulin secretagogue. A lower dose of insulin or insulin secretagogue may be required to minimize the risk of hypoglycemia when these agents are used in combination with sotagliflozin.

Drugs/Diseases

Util A	Util B	Util C
Sotagliflozin	Insulin	
	Insulin Secretagogues	

References:

Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Inpefa Prescribing Information, May 2023, Lexicon Pharmaceuticals, Inc.

Criteria Recommendations ***Approved*** ***Rejected***

8. Sotagliflozin / Digoxin _____ _____

Alert Message: The concurrent use of Inpefa (sotagliflozin) with digoxin may increase digoxin serum concentrations and the risk of digoxin-related adverse effects. Patients taking sotagliflozin with digoxin should be monitored appropriately. Sotagliflozin is a P-gp efflux transport inhibitor, and digoxin is a P-gp substrate.

Drugs/Diseases

Util A	Util B	Util C
Sotagliflozin	Digoxin	

References:
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Inpefa Prescribing Information, May 2023, Lexicon Pharmaceuticals, Inc.

9. Sotagliflozin / Rifampin _____ _____

Alert Message: The concurrent use of Inpefa (sotagliflozin) with rifampin may decrease sotagliflozin serum concentrations and result in decreased sotagliflozin efficacy. Rifampin is a UGT1A9 inducer, and sotagliflozin is a UGT1A9 substrate. Patients taking sotagliflozin with rifampin should be monitored appropriately.

Drugs/Diseases

Util A	Util B	Util C
Sotagliflozin	Rifampin	

References:
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Inpefa Prescribing Information, May 2023, Lexicon Pharmaceuticals, Inc.

10. Sotagliflozin / Lithium _____ _____

Alert Message: The concurrent use of Inpefa (sotagliflozin) with lithium may decrease lithium serum concentrations and result in decreased lithium efficacy. Monitor serum lithium concentration more frequently during sotagliflozin initiation and dosage changes.

Drugs/Diseases

Util A	Util B	Util C
Sotagliflozin	Lithium	

References:
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Inpefa Prescribing Information, May 2023, Lexicon Pharmaceuticals, Inc.

11. Sotagliflozin / Pregnancy / Pregnancy Negating _____ _____

Alert Message: Based on animal data showing renal effects, Inpefa (sotagliflozin) is not recommended during the second and third trimesters of pregnancy. In rats, renal changes were observed when sotagliflozin was administered during a period of renal development corresponding to the late second and third trimesters of human pregnancy.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Sotagliflozin	Pregnancy	Abortion
		Delivery
		Miscarriage

Gender: Female
Age Range: 11 – 50 yoa

References:
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Inpefa Prescribing Information, May 2023, Lexicon Pharmaceuticals, Inc.

Criteria Recommendations ***Approved*** ***Rejected***

12. Sotagliflozin / Lactation _____ _____

Alert Message: There are no data on the presence of Inpefa (sotagliflozin) in human milk, the effects on the breastfed infant, or the effects on milk production. Sotagliflozin is present in rat milk. When a drug is present in animal milk, it is likely to be present in human milk. Since human kidney maturation occurs in utero and during the first 2 years of life when lactational exposure may occur, there may be risk to the developing human kidney. Because of the potential for serious adverse reactions in a breastfed infant, advise women that breastfeeding is not recommended while taking sotagliflozin.

Drugs/Diseases

Util A	Util B	Util C
Sotagliflozin	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Inpefa Prescribing Information, May 2023, Lexicon Pharmaceuticals, Inc.

13. Sotagliflozin / Non-adherence _____ _____

Alert Message: Based on refill history, your patient may be under-utilizing Inpefa (sotagliflozin). Nonadherence to the prescribed dosing regimen may result in subtherapeutic effects, which may lead to decreased patient outcomes and additional healthcare costs.

Drugs/Diseases

Util A	Util B	Util C
Sotagliflozin		

References:
Osterberg L, Blaschke T. Adherence to Medication. N Engl J Med 2005; 353:487- 497.
Kim J, Combs K, Downs J, Tillman F., Medication Adherence: The Elephant in the Room. US Pharm. 2018;43(1)30-34.

Kleinsinger, Fred. The Unmet Challenge of Medication Nonadherence. The Permanente Journal. Vol. 22 (2018): 18-033. doi:10.7812/TPP/18-033.

14. Tafamidis Meglumine / Overuse _____ _____

Alert Message: Vyndaqel (tafamidis meglumine) may be over-utilized. The recommended dosage of tafamidis meglumine is 80 mg (four 20 mg tafamidis meglumine capsules) once daily.

Drugs/Diseases

Util A	Util B	Util C
Tafamidis Meglumine		

Max Dose: 80 mg/day

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.

Vyndaqel and Vyndamax Prescribing Information, Oct. 2023, Pfizer Inc.

Criteria Recommendations ***Approved*** ***Rejected***

15. Tafamidis Meglumine / Therapeutic Appropriateness _____ _____

Alert Message: The safety and effectiveness of Vyndaqel (tafamidis meglumine) have not been established in pediatric patients.

Drugs/Diseases

Util A	Util B	Util C
Tafamidis Meglumine		

Age Range: 0 – 17 yoa

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.

Vyndaqel and Vyndamax Prescribing Information, Oct. 2023, Pfizer Inc.

16. Tafamidis Meglumine / BCRP Substrates _____ _____

Alert Message: Vyndaqel (tafamidis meglumine) inhibits breast cancer resistant protein (BCRP) in humans. Coadministration of tafamidis and drugs that are BCRP substrates may increase the exposure of the BCRP substrates (e.g., methotrexate, rosuvastatin, and imatinib) and the risk of substrate-related toxicities. Monitor for signs of BCRP substrate-related toxicities and modify the dosage of the substrate if appropriate.

Drugs/Diseases

Util A	Util B		Util C
Tafamidis Meglumine	Alpelisib	Prazosin	
	Berotralstat	Rosuvastatin	
	Dolutegravir	Talazoparib	
	Glyburide	Tenofovir	
	Methotrexate	Topotecan	
	Pazopanib	Ubrogepant	
	Pibrentasvir	Vemurafenib	

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.

Vyndaqel and Vyndamax Prescribing Information, Oct. 2023, Pfizer Inc.

Criteria Recommendations ***Approved*** ***Rejected***

17. Tafamidis Meglumine / Pregnancy / Pregnancy Negating _____ _____

Alert Message: Based on findings from animal studies, Vyndaqel (tafamidis meglumine) may cause fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to a fetus. Report pregnancies to the Pfizer reporting line at 1-800-438-1985.

Drugs/Diseases

Util A	Util B	Util C (Negating)
Tafamidis Meglumine	Pregnancy	Abortion
	Delivery	
	Miscarriage	

Gender: Female

Age Range: 11 – 50 yoa

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.

Vyndaqel and Vyndamax Prescribing Information, Oct. 2023, Pfizer Inc.

18. Tafamidis Meglumine / Therapeutic Appropriateness _____ _____

Alert Message: There are no available data on the presence of Vyndaqel (tafamidis meglumine) in human milk, the effect on the breastfed infant, or the effect on milk production. Tafamidis is present in rat milk. When a drug is present in animal milk, it is likely the drug will be present in human milk. Based on findings from animal studies that suggest the potential for serious adverse reactions in the breastfed infant, advise patients that breastfeeding is not recommended during treatment with tafamidis meglumine.

Drugs/Diseases

Util A	Util B	Util C
Tafamidis Meglumine	Lactation	

Gender: Female

Age Range: 11 – 50 yoa

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.

Vyndaqel and Vyndamax Prescribing Information, Oct. 2023, Pfizer Inc.

Criteria Recommendations ***Approved*** ***Rejected***

19. Tafamidis Meglumine / Non-adherence _____ _____

Alert Message: Based on refill history, your patient may be under-utilizing Vyndaqel (tafamidis meglumine). Nonadherence to the prescribed dosing regimen may result in subtherapeutic effects, which may lead to decreased patient outcomes and additional healthcare costs.

Drugs/Diseases

Util A	Util B	Util C
Tafamidis Meglumine		

References:

Osterberg L, Blaschke T. Adherence to Medication. N Engl J Med 2005; 353:487- 497.
Kim J, Combs K, Downs J, Tillman F., Medication Adherence: The Elephant in the Room. US Pharm. 2018;43(1)30-34.

Kleinsinger, Fred. The Unmet Challenge of Medication Nonadherence. The Permanente Journal. Vol. 22 (2018): 18-033. doi:10.7812/TPP/18-033.

20. Lacosamide XR / Overuse _____ _____

Alert Message: Motpoly XR (lacosamide extended-release) may be over-utilized. The maximum recommended maintenance dose of extended-release lacosamide is 400 mg once daily.

Drugs/Diseases

Util A	Util B	Util C (Negating)
Lacosamide XR		CKD Stage 5 ESRD Hepatic Impairment

Max Dose: 400 mg/day

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Motpoly XR Prescribing Information, May 2023, Aucta Pharmaceuticals, Inc.

21. Lacosamide XR / Overuse – Severe Renal Impairment _____ _____

Alert Message: Motpoly XR (lacosamide extended-release) may be over-utilized. For patients with severe renal impairment [creatinine clearance (CLcr) less than 30 mL/min as estimated by the Cockcroft-Gault equation for adults; CLcr less than 30 mL/min/1.73m2 as estimated by the Schwartz equation for pediatric patients] or end-stage renal disease, the maximum recommended dosage is 300 mg. For patients with mild or moderate renal impairment, no dosage is necessary.

Drugs/Diseases

Util A	Util B	Util C (Include)
Lacosamide XR		CKD Stage 5 ESRD

Max Dose: 300 mg/day

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Motpoly XR Prescribing Information, May 2023, Aucta Pharmaceuticals, Inc.

Criteria Recommendations ***Approved*** ***Rejected***

22. Lacosamide XR / Overuse – Hepatic Impairment _____ _____

Alert Message: Motpoly XR (lacosamide extended-release) may be over-utilized. For patients with mild or moderate hepatic impairment, the maximum recommended dosage is 300 mg. The dose initiation and titration should be based on clinical response and tolerability in patients with hepatic impairment. Extended-release lacosamide use is not recommended in patients with severe hepatic impairment.

Drugs/Diseases

Util A	Util B	Util C (Include)
Lacosamide XR		Hepatic Impairment

Max Dose: 300 mg/day

References:

Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Motpoly XR Prescribing Information, May 2023, Aucta Pharmaceuticals, Inc.

23. Lacosamide / Drugs Effecting Cardiac Conduction _____ _____

Alert Message: Motpoly XR (lacosamide extended-release) should be used with caution in patients on concomitant medications that affect cardiac conduction (sodium channel blockers, beta-blockers, calcium channel blockers, potassium channel blockers), including those that prolong PR interval (including sodium channel blocking AEDs), because of a risk of AV block, bradycardia, or ventricular tachyarrhythmia. In such patients, obtaining an ECG before beginning lacosamide and after lacosamide is titrated to steady-state is recommended.

Drugs/Diseases

Util A	Util B	Util C
Lacosamide XR	Beta-Blockers	
	Calcium Channel Blockers	
	Potassium Channel Blockers	
	Sodium Channel Blockers	

References:

Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.

24. Lacosamide XR / Non-adherence _____ _____

Alert Message: Based on refill history, your patient may be under-utilizing Motpoly XR (lacosamide extended-release). Non-adherence to the prescribed dosing regimen may result in sub-therapeutic effects, which may lead to decreased patient outcomes and additional healthcare costs.

Drugs/Diseases

Util A	Util B	Util C
Lacosamide XR		

References:

Osterberg L, Blaschke T. Adherence to Medication. N Engl J Med 2005; 353:487- 497.
Faught E, Duh MS, Weiner JR, et al. Nonadherence to Antiepileptic Drugs and Increased Mortality, Findings from the RANSOM Study. Neurology 2008;71(20): 1572-1578.
Faught RE, Weiner JR, Guerin A, et al. Impact of Nonadherence to Antiepileptic Drugs on Health Care Utilization and Costs: Findings from the RANSOM Study. Epilepsia 2009;50(3):501-509.

Criteria Recommendations ***Approved*** ***Rejected***

25. Risperidone ER Suspension / Therapeutic Appropriateness _____ _____
Alert Message: The safety and effectiveness of Rykindo (risperidone extended-release suspension) in pediatric patients have been established.

Drugs/Diseases

Util A	Util B	Util C
Risperidone ER Suspension		

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Rykindo Prescribing Information, Jan. 2023, Shandong Luye Pharmaceutical Co., Ltd.

26. Risperidone ER Suspension / Strong CYP2D6 Inhibitor _____ _____
Alert Message: Concomitant use of Rykindo (risperidone extended-release suspension) with strong CYP2D6 inhibitors may increase the plasma concentration of risperidone and lower the concentration of 9-hydroxyrisperidone, a major active metabolite of risperidone. Refer to the official prescribing information for dosage adjustment for risperidone when initiating or discontinuing concurrent use of a strong CYP2D6.

Drugs/Diseases

Util A	Util B		Util C
Risperidone ER Suspension	Bupropion	Paroxetine	
	Fluoxetine	Quinidine	

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Rykindo Prescribing Information, Jan. 2023, Shandong Luye Pharmaceutical Co., Ltd.

27. Risperidone ER Suspension / Strong CYP3A3 Inducers _____ _____
Alert Message: Concomitant use of Rykindo (risperidone extended-release suspension) with strong CYP3A4 inducers may decrease the combined plasma concentrations of risperidone and 9-hydroxyrisperidone, which could lead to decreased efficacy of risperidone treatment. Refer to the official prescribing information for dosage adjustment for risperidone when initiating or discontinuing concurrent CYP3A4 inducers.

Drugs/Diseases

Util A	Util B		Util C
Risperidone ER Suspension	Apalutamide	Phenobarbital	
	Carbamazepine	Phenytoin	
	Enzalutamide	Primidone	
	Mitotane		

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Rykindo Prescribing Information, Jan. 2023, Shandong Luye Pharmaceutical Co., Ltd.

Criteria Recommendations ***Approved*** ***Rejected***

28. Etrasimod / Overuse _____ _____

Alert Message: Velsipity (etrasimod) may be over-utilized. The recommended dosage of etrasimod is 2 mg once daily.

Drugs/Diseases

Util A	Util B	Util C
Etrasimod		

Max Dose: 2 mg/day

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Velsipity Prescribing Information, Oct. 2023, Pfizer Inc.

29. Etrasimod / Therapeutic Appropriateness _____ _____

Alert Message: The safety and effectiveness of Velsipity (etrasimod) in pediatric patients have not been established.

Drugs/Diseases

Util A	Util B	Util C
Etrasimod		

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Velsipity Prescribing Information, Oct. 2023, Pfizer Inc.

30. Etrasimod / Contraindication _____ _____

Alert Message: Velsipity (etrasimod) is contraindicated in patients who, in the last 6 months, have experienced a myocardial infarction, unstable angina pectoris, stroke, transient ischemic attack (TIA), decompensated heart failure requiring hospitalization, or Class III or IV heart failure.

Drugs/Diseases

Util A	Util B	Util C
Etrasimod	Class III or IV Heart Failure	
	Decompensated Heart Failure	
	Myocardial Infarction	
	Stroke	
	Transient Ischemic Attack	
	Unstable Angina	

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Velsipity Prescribing Information, Oct. 2023, Pfizer Inc.

Criteria Recommendations ***Approved*** ***Rejected***

31. Etrasimod / Contraindication _____ _____

Alert Message: Velsipity (etrasimod) is contraindicated in patients who have a history or presence of Mobitz type II second-degree or third-degree AV block, sick sinus syndrome, or sino-atrial block unless the patient has a functioning pacemaker.

Drugs/Diseases

Util A	Util B	Util C (Negating)
Etrasimod	Mobitz type II 2nd Degree	Pacemaker
	Mobitz type II 3rd Degree	
	Sick Sinus Syndrome	
	Sino-atrial Block	

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Velsipity Prescribing Information, Oct. 2023, Pfizer Inc.

32. Etrasimod / Infection _____ _____

Alert Message: Velsipity (etrasimod) may increase the risk of infections. Obtain a complete blood count (CBC) before initiation of etrasimod treatment. Monitor for infection during treatment and for 5 weeks after discontinuation. Consider interruption of etrasimod treatment if a serious infection develops. Avoid the use of live attenuated vaccines during and for up to 5 weeks after treatment.

Drugs/Diseases

Util A	Util B	Util C
Etrasimod	Serious Infections	

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Velsipity Prescribing Information, Oct. 2023, Pfizer Inc.

33. Etrasimod / Decreased Heart Rate _____ _____

Alert Message: Initiation of Velsipity (etrasimod) may result in a transient decrease in heart rate and AV conduction delays. Obtain an electrocardiogram (ECG) to assess for preexisting cardiac conduction abnormalities before starting treatment. Consider cardiology consultation for conduction abnormalities or concomitant use with other drugs that decrease heart rate.

Drugs/Diseases

Util A	Util B	Util C
Etrasimod	Bradycardia	
	QT Prolongation	
	Atrioventricular Block 1st Degree	

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Velsipity Prescribing Information, Oct. 2023, Pfizer Inc.

Criteria Recommendations ***Approved*** ***Rejected***

34. Etrasimod / Liver Injury _____ _____

Alert Message: Elevations of aminotransferases may occur in patients receiving Velsipity (etrasimod). Obtain transaminase and bilirubin levels, if not recently available (i.e., within last 6 months), before initiation of etrasimod. Obtain transaminases and bilirubin in patients who develop symptoms suggestive of hepatic dysfunction, such as unexplained nausea, vomiting, abdominal pain, fatigue, anorexia, or jaundice and/or dark urine. Discontinue etrasimod if significant liver injury is confirmed.

Drugs/Diseases

Util A	Util B	Util C
Etrasimod	Elevated Serum Enzyme Levels	

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Velsipity Prescribing Information, Oct. 2023, Pfizer Inc.

35. Etrasimod / Macular Edema _____ _____

Alert Message: Sphingosine 1-phosphate (S1P) receptor modulators, including Velsipity (etrasimod), have been associated with an increased risk of macular edema. Obtain a baseline evaluation of the fundus, including the macula, near the start of treatment with etrasimod. Periodically conduct an evaluation of the fundus, including the macula, while on therapy and any time there is a change in vision. Macular edema over an extended period of time (i.e., 6 months) can lead to permanent visual loss. Consider discontinuing etrasimod if macular edema develops.

Drugs/Diseases

Util A	Util B	Util C
Etrasimod	Macular Edema	

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Velsipity Prescribing Information, Oct. 2023, Pfizer Inc.

36. Etrasimod / Malignancies _____ _____

Alert Message: Cases of malignancies (including skin malignancies) have been reported in patients treated with S1P receptor modulators. Skin examinations are recommended prior to or shortly after the start of treatment and periodically thereafter for all patients, particularly those with risk factors for skin cancer. Providers and patients are advised to monitor for suspicious skin lesions. If a suspicious skin lesion is observed, it should be promptly evaluated.

Drugs/Diseases

Util A	Util B	Util C
Etrasimod	Malignancies	

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Velsipity Prescribing Information, Oct. 2023, Pfizer Inc.

Criteria Recommendations ***Approved*** ***Rejected***

37. Etrasimod / Moderate to Strong CYP2C9 & Moderate 3A4 Inhibitor _____ _____

Alert Message: Concomitant use of Velsipity (etrasimod) with a drug that is a moderate to strong inhibitor of CYP2C9 and a moderate to strong inhibitor of CYP3A4 is not recommended. In pharmacokinetic studies, increased exposure of etrasimod was observed with concomitant use with a drug that is a moderate inhibitor of CYP2C9 and a moderate inhibitor of CYP3A4 (i.e., fluconazole).

Drugs/Diseases

Util A	Util B	Util C
Etrasimod	Adagrasib	
	Fluconazole	

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Velsipity Prescribing Information, Oct. 2023, Pfizer Inc.

38. Etrasimod / Drugs Causing Decreased HR or QT Prolongation _____ _____

Alert Message: A transient decrease in heart rate and AV conduction delays may occur when initiating Velsipity (etrasimod). Because of the potential additive effect on heart rate, etrasimod may increase the risk of QT prolongation and Torsades de Pointes with concomitant use of Class Ia and Class III anti-arrhythmic drugs and QT-prolonging drugs. Seek the advice of a cardiologist before initiating etrasimod treatment with Class Ia (e.g., quinidine, procainamide), Class III anti-arrhythmic drugs (e.g., amiodarone, sotalol), or other drugs that prolong the QT interval.

Drugs/Diseases

Util A	Util B	Util C
Etrasimod	Class 1A Antiarrhythmics	
	Class III Antiarrhythmics	
	Agents Causing QT Prolongation	

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Velsipity Prescribing Information, Oct. 2023, Pfizer Inc.

39. Etrasimod / Pregnancy / Pregnancy Negating _____ _____

Alert Message: Based on animal studies, Velsipity (etrasimod) may cause fetal harm when administered to a pregnant woman. In animal reproduction studies conducted in rats and rabbits, embryofetal toxicity was observed with administration of etrasimod at clinically relevant doses. Advise pregnant women and females of reproductive potential of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception to avoid pregnancy during and for one week after stopping etrasimod.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Etrasimod	Pregnancy	Abortion
		Delivery
		Miscarriage

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Velsipity Prescribing Information, Oct. 2023, Pfizer Inc.

Criteria Recommendations ***Approved*** ***Rejected***

40. Etrasimod / Lactation _____ _____

Alert Message: There are no data on the presence of Velsipity (etrasimod) in human milk, the effects on the breastfed infant, or the effects of the drug on milk production. When etrasimod was orally administered to female rats during pregnancy and lactation, etrasimod was detected in the plasma of the offspring, suggesting excretion of etrasimod in milk. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for etrasimod and any potential adverse effects on the breastfed infant from etrasimod or the underlying maternal condition.

Drugs/Diseases

Util A	Util B	Util C
Etrasimod	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Velsipity Prescribing Information, Oct. 2023, Pfizer Inc.

41. Etrasimod / Non-adherence _____ _____

Alert Message: Based on refill history, your patient may be under-utilizing Velsipity (etrasimod). Nonadherence to the prescribed dosing regimen may result in subtherapeutic effects, which may lead to decreased patient outcomes and additional healthcare costs.

Drugs/Diseases

Util A	Util B	Util C
Etrasimod		

References:
Osterberg L, Blaschke T. Adherence to Medication. N Engl J Med 2005; 353:487- 497.
Kleinsinger, Fred. The Unmet Challenge of Medication Nonadherence. The Permanente Journal. Vol. 22 (2018): 18-033. doi:10.7812/TPP/18-033.

Martin LR, Williams SL, Haskard KB, DiMatteo MR. The Challenge of Patient Adherence. Ther Clin Risk Manag. 2005 Sep.1(3):189-199.

42. Colchicine / Overuse _____ _____

Alert Message: Lodoco (colchicine) may be over-utilized. The recommended dosage of colchicine in adult patients is 0.5 mg.

Drugs/Diseases

Util A	Util B	Util C
Colchicine		

Max Dose: 0.5 mg/day

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Lodoco Prescribing Information, June 2023, Agepha Pharma FZ LLC.

Criteria Recommendations	*Approved*	*Rejected*

43. Colchicine / Therapeutic Appropriateness _____ _____

Alert Message: The safety and effectiveness of Lodoco (colchicine) have not been established in pediatric patients.

Drugs/Diseases

Util A	Util B	Util C
Colchicine		

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Lodoco Prescribing Information, June 2023, Agepha Pharma FZ LLC.

44. Colchicine / Strong CYP3A4 Inhibitors & P-gp Inhibitors _____ _____

Alert Message: Concurrent use of strong CYP3A4 inhibitors or P-glycoprotein inhibitors with Lodoco (colchicine) is contraindicated because life-threatening and fatal colchicine toxicity has been reported in these patients with colchicine taken in therapeutic doses.

Drugs/Diseases

Util A	Util B		Util C
Colchicine	Amiodarone	Nefazodone	
	Clarithromycin	Nelfinavir	
	Cobicistat	Posaconazole	
	Cyclosporine	Quinidine	
	Dronedarone	Ranolazine	
	Erythromycin	Ritonavir	
	Itraconazole	Verapamil	
	Ketoconazole	Voriconazole	
	Lapatinib		

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Lodoco Prescribing Information, June 2023, Agepha Pharma FZ LLC.

45. Colchicine / Severe Renal Failure _____ _____

Alert Message: Lodoco (colchicine) use is contraindicated in patients with renal failure (creatinine clearance < 15 mL/minute).

Drugs/Diseases

Util A	Util B	Util C
Colchicine	CKD Stage 5	

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Lodoco Prescribing Information, June 2023, Agepha Pharma FZ LLC.

Criteria Recommendations ***Approved*** ***Rejected***

46. Colchicine / Severe Hepatic Impairment _____ _____

Alert Message: Lodoco (colchicine) use is contraindicated in patients with severe hepatic impairment.

Drugs/Diseases

Util A	Util B	Util C
Colchicine	Cirrhosis	
	Hepatic Failure	

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Lodoco Prescribing Information, June 2023, Agepha Pharma FZ LLC.

47. Colchicine / Blood Dyscrasias _____ _____

Alert Message: Lodoco (colchicine) use is contraindicated in patients with blood dyscrasias. Colchicine can cause myelosuppression, leukopenia, granulocytopenia, thrombocytopenia, pancytopenia, and aplastic anemia, which can be life-threatening or fatal. Gastrointestinal symptoms often are the first sign of colchicine toxicity, so new symptoms should prompt an evaluation for toxicity. Concomitant use of drugs that reduce the metabolism of colchicine or the presence of hepatic or renal impairment increases the risk of developing blood dyscrasias.

Drugs/Diseases

Util A	Util B	Util C
Colchicine	Myelosuppression	
	Leukopenia	
	Granulocytopenia	
	Aplastic anemia	

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Lodoco Prescribing Information, June 2023, Agepha Pharma FZ LLC.

48. Colchicine / Moderate CYP3A4 Inhibitors _____ _____

Alert Message: The concurrent use of Lodoco (colchicine) with a moderate CYP3A4 inhibitor may result in significant increases in colchicine plasma concentrations and should be avoided. If concurrent use is warranted, monitor patients receiving moderate CYP3A4 inhibitors for signs of colchicine toxicity. Avoid the use of colchicine with a moderate CYP3A4 inhibitor in patients with existing renal or hepatic impairment.

Drugs/Diseases

Util A	Util B		Util C
Colchicine	Aprepitant	Fluconazole	
	Ciprofloxacin	Fluvoxamine	
	Crizotinib	Imatinib	
	Diltiazem		

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Lodoco Prescribing Information, June 2023, Agepha Pharma FZ LLC.

Criteria Recommendations ***Approved*** ***Rejected***

49. Colchicine / Drugs Causing Myotoxicity _____ _____

Alert Message: Concomitant use of a colchicine-containing product and agents that are associated with myotoxicity (e.g., atorvastatin, simvastatin, pravastatin, fluvastatin, gemfibrozil, and fenofibrate) may potentiate the development of myopathy and rhabdomyolysis. Patients on concurrent therapy should be monitored for signs and symptoms of myotoxicity.

Drugs/Diseases

Util A	Util B		Util C
Colchicine	Atorvastatin	Simvastatin	
	Fluvastatin	Gemfibrozil	
	Lovastatin	Fenofibrate	
	Pravastatin		
	Pitavastatin		

References:

Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Lodoco Prescribing Information, June 2023, Agepha Pharma FZ LLC.

50. Colchicine / Digoxin _____ _____

Alert Message: Concurrent use of a colchicine-containing product and digoxin may result in myopathy and/or rhabdomyolysis. If concomitant use of these two drugs is necessary, the patient should be monitored for signs and symptoms of rhabdomyolysis (dark-colored urine and/or muscle pain, tenderness, or weakness).

Drugs/Diseases

Util A	Util B	Util C
Colchicine	Digoxin	

References:

Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Lodoco Prescribing Information, June 2023, Agepha Pharma FZ LLC.

51. Colchicine / Pregnancy / Pregnancy Negating _____ _____

Alert Message: Although animal reproduction and developmental studies were not conducted with Lodoco (colchicine), published animal reproduction and development studies indicate that colchicine causes embryofetal toxicity and altered postnatal development at exposures within or above the clinical therapeutic range. Colchicine crosses the human placenta. Colchicine should be used during pregnancy only if the potential benefit to the mother justifies the potential risk to the fetus.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Colchicine	Pregnancy	Abortion
		Delivery
		Miscarriage

Gender: Female
Age Range: 11 – 50 yoa

References:

Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.

Criteria Recommendations ***Approved*** ***Rejected***

52. Colchicine / Lactation _____ _____

Alert Message: Lodoco (colchicine) is present in human milk. Adverse events in breastfed infants have not been reported in the published literature after administration of colchicine to lactating women. There are no data on the effects of colchicine on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for colchicine and any potential adverse effects on the breastfed infant from colchicine or the underlying maternal condition.

Drugs/Diseases

Util A	Util B	Util C
Colchicine	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.

53. Colchicine / Non-adherence _____ _____

Alert Message: Based on refill history, your patient may be under-utilizing Lodoco (colchicine). Nonadherence to the prescribed dosing regimen may result in subtherapeutic effects, which may lead to decreased patient outcomes and additional healthcare costs.

Drugs/Diseases

Util A	Util B	Util C
Colchicine		

References:
Osterberg L, Blaschke T. Adherence to Medication. N Engl J Med 2005; 353:487- 497.
Kleinsinger, Fred. The Unmet Challenge of Medication Nonadherence. The Permanente Journal. Vol. 22 (2018): 18-033. doi:10.7812/TPP/18-033.

Brown MT, Bussell J, Supmarna D, et al. Medication Adherence: Truth and Consequences. Am J Med Sci. 2016 Apr;351(4):387-399.

Kim J, Combs K, Downs J, Tillman F., Medication Adherence: The Elephant in the Room. US Pharm. 2018;43(1)30-34.

54. Pexidartinib / Overuse Hepatic Impairment _____ _____

Alert Message: Turalio (pexidartinib) may be over-utilized. The recommended dosage of pexidartinib for patients with moderate hepatic impairment (total bilirubin greater than 1.5 and up to 3 times upper limit of normal (ULN), not due to Gilbert's syndrome, with any AST) is 125 mg twice daily with a low-fat meal. Pexidartinib has not been studied in patients with severe hepatic impairment (total bilirubin >3 to 10 × ULN and any AST).

Drugs/Diseases

Util A	Util B	Util C (Include)
Pexidartinib		Hepatic Impairment

Max Dose: 250 mg/day

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Turalio Prescribing Information, Nov. 2023, Daiichi Sankyo, Inc.

Criteria Recommendations	*Approved*	*Rejected*

55. Tepotinib / Overuse _____ _____

Alert Message: Tepmetko (tepotinib) may be over-utilized. The recommended dosage of tepotinib is 450 mg orally once daily with food until disease progression or unacceptable toxicity.

Drugs/Diseases

Util A	Util B	Util C
Tepotinib		

Max Dose: 450 mg/day

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Tepmetko Prescribing Information, March 2023, EMD Serono.

56. Tepotinib / Therapeutic Appropriateness _____ _____

Alert Message: The safety and efficacy of Tepmetko (tepotinib) in pediatric patients have not been established.

Drugs/Diseases

Util A	Util B	Util C
Tepotinib		

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Tepmetko Prescribing Information, March 2023, EMD Serono.

57. Tepotinib / Interstitial Lung Disease (ILD)/Pneumonitis _____ _____

Alert Message: ILD/pneumonitis, which can be fatal, occurred in patients treated with Tepmetko (tepotinib). ILD/pneumonitis occurred in 2.2% of patients treated with tepotinib, with one patient experiencing a Grade 3 or higher event; this event resulted in death. Four patients (0.9%) discontinued tepotinib due to ILD/pneumonitis. Monitor patients for new or worsening pulmonary symptoms indicative of ILD/pneumonitis (e.g., dyspnea, cough, fever). Immediately withhold tepotinib in patients with suspected ILD/pneumonitis and permanently discontinue if no other potential causes of ILD/pneumonitis are identified.

Drugs/Diseases

Util A	Util B	Util C
Tepotinib	ILD	
	Pneumonitis	

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Tepmetko Prescribing Information, March 2023, EMD Serono.

Criteria Recommendations ***Approved*** ***Rejected***

58. Tepotinib / Hepatotoxicity _____ _____

Alert Message: Hepatotoxicity occurred in patients treated with Tepmetko (tepotinib). Increased alanine aminotransferase (ALT)/increased aspartate aminotransferase (AST) occurred in 13% of patients treated with tepotinib. Grade 3 or 4 increased ALT/AST occurred in 4.2% of patients. A fatal adverse reaction of hepatic failure occurred in one patient (0.2%). Monitor liver function tests (including ALT, AST, and total bilirubin) prior to the start of tepotinib, every 2 weeks during the first 3 months of treatment, then once a month or as clinically indicated, with more frequent testing in patients who develop increased transaminases or bilirubin. Based on the severity of the adverse reaction, withhold, dose reduce, or permanently discontinue tepotinib.

Drugs/Diseases

Util A	Util B	Util C
Tepotinib	Abnormal Liver Studies	
	Abnormal Liver Transaminase Levels	

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Tepmetko Prescribing Information, March 2023, EMD Serono.

59. Tepotinib / Certain P-gp Substrates _____ _____

Alert Message: Tepmetko (tepotinib) is a P-gp inhibitor. Concomitant use of tepotinib with a P-gp substrate increases the concentration of P-gp substrates, which may increase the incidence and severity of adverse reactions of these substrates. Avoid concomitant use of tepotinib with certain P-gp substrates where minimal concentration changes may lead to serious or life-threatening toxicities. If concomitant use is unavoidable, reduce the P-gp substrate dosage if recommended in its approved product labeling.

Drugs/Diseases

Util A	Util B	Util C
Tepotinib	Dabigatran	
	Digoxin	
	Edoxaban	

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Tepmetko Prescribing Information, March 2023, EMD Serono.

60. Tepotinib / Pregnancy / Pregnancy Negating _____ _____

Alert Message: Based on findings in animal studies and its mechanism of action Tepmetko (tepotinib) can cause fetal harm when administered to a pregnant woman. Oral administration of tepotinib to pregnant rabbits during the period of organogenesis resulted in malformations (teratogenicity) and anomalies at exposures less than the human exposure based on area under the curve (AUC) at the 450 mg daily clinical dose. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential or males with female partners of reproductive potential to use effective contraception during treatment with tepotinib and for one week after the final dose.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Tepotinib	Pregnancy	Abortion
		Delivery
		Miscarriage

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Tepmetko Prescribing Information, March 2023, EMD Serono.

Criteria Recommendations ***Approved*** ***Rejected***

61. Tepotinib / Lactation _____ _____
Alert Message: There are no data regarding the secretion of Tepmetko (tepotinib) or its metabolites in human milk or its effects on the breastfed infant or milk production. Advise women not to breastfeed during treatment with (tepotinib and for one week after the final dose.

Drugs/Diseases

Util A	Util B	Util C
Tepotinib	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Tepmetko Prescribing Information, March 2023, EMD Serono.

62. Tepotinib / Therapeutic Appropriateness _____ _____
Alert Message: Advise females of reproductive potential to use effective contraception during Tepmetko (tepotinib) treatment and for one week after the final dose. Based on findings in animal studies and its mechanism of action, tepotinib can cause fetal harm when administered to a pregnant woman.

Drugs/Diseases

Util A	Util B	Util C
Tepotinib		

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Tepmetko Prescribing Information, March 2023, EMD Serono.

63. Tepotinib / Therapeutic Appropriateness _____ _____
Alert Message: Advise male patients with female partners of reproductive potential to use effective contraception during Tepmetko (tepotinib) treatment and for one week after the final dose. Based on findings in animal studies and its mechanism of action, tepotinib can cause fetal harm when administered to a pregnant woman.

Drugs/Diseases

Util A	Util B	Util C
Tepotinib		

Gender: Male

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Tepmetko Prescribing Information, March 2023, EMD Serono.

Criteria Recommendations ***Approved*** ***Rejected***

64. Tepotinib / Non-adherence _____ _____
Alert Message: Based on refill history, your patient may be under-utilizing Tepmetko (tepotinib). Nonadherence to the prescribed dosing regimen may result in subtherapeutic effects, which may lead to decreased patient outcomes and additional healthcare costs.

Drugs/Diseases
Util A Util B Util C
Tepotinib

References:
Osterberg L, Blaschke T. Adherence to Medication. N Engl J Med 2005; 353:487- 497.
Ruddy K, Mayer E, Partridge A. Patient Adherence and Persistence With Oral Anticancer Treatment. CA Cancer J Clin 2009;59:56-66.
Barillet M, Prevost V, Joly F, Clarisse B. Oral Antineoplastic Agents: How do We Care About Adherence?. Br J Clin Pharmacol. 2015;80(6):1289–1302. doi:10.1111/bcp.12734
Greer JA, Amoyal N, Nisotel L, et al. Systemic Review of Adherence to Oral Antineoplastic Therapies. The Oncologist. 2016;21:354-376.

65. Ritlecitinib / Overuse _____ _____
Alert Message: Litfulo (ritlecitinib) may be over-utilized. The recommended dosage of ritlecitinib is 50 mg orally once daily, with or without food.

Drugs/Diseases
Util A Util B Util C
Ritlecitinib

Max Dose: 50 mg/da

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Litfulo Prescribing Information, June 2023, Pfizer, Inc.

66. Ritlecitinib / Therapeutic Appropriateness _____ _____
Alert Message: The safety and efficacy of Litfulo (ritlecitinib) have not been established in pediatric patients under 12 years of age.

Drugs/Diseases
Util A Util B Util C
Ritlecitinib

Age Range: 0 – 12 yoa

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Litfulo Prescribing Information, June 2023, Pfizer, Inc.

Criteria Recommendations ***Approved*** ***Rejected***

67. Ritlecitinib / Serious Infections (Box Warning) _____ _____

Alert Message: Serious infections have been reported in patients receiving Litfulo (ritlecitinib). The most frequent serious infections have been appendicitis, COVID-19 infection (including pneumonia), and sepsis. Avoid use of ritlecitinib in patients with an active, serious infection. Closely monitor patients for the development of signs and symptoms of infection during and after treatment with ritlecitinib. Interrupt ritlecitinib if a patient develops a serious or opportunistic infection.

Drugs/Diseases

Util A	Util B	Util C
Ritlecitinib	Serious Infections	

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Litfulo Prescribing Information, June 2023, Pfizer, Inc.

68. Ritlecitinib / Tuberculosis (Box Warning) _____ _____

Alert Message: Serious infections have been reported in patients receiving Litfulo (ritlecitinib), including tuberculosis (TB). Ritlecitinib should not be given to patients with active TB. Test for latent TB before and during therapy; treat latent TB prior to use. Monitor all patients for active TB during treatment, even patients with initial negative, latent TB test.

Drugs/Diseases

Util A	Util B	Util C
Ritlecitinib	Tuberculosis Infection	
	Personal History of Tuberculosis	
	Personal History of Latent Tuberculosis	

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Litfulo Prescribing Information, June 2023, Pfizer, Inc.

69. Ritlecitinib / Malignancies (Black Box) _____ _____

Alert Message: Malignancies, including non-melanoma skin cancer (NMSC), were observed in clinical trials of Litfulo (ritlecitinib). The risks and benefits of ritlecitinib treatment should be considered prior to initiating or continuing therapy in patients with a known malignancy other than a successfully treated NMSC or cervical cancer.

Drugs/Diseases

Util A	Util B	Util C
Ritlecitinib	Active Diagnosis of Malignant Neoplasm	

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Litfulo Prescribing Information, June 2023, Pfizer, Inc.

Criteria Recommendations ***Approved*** ***Rejected***

70. Ritlecitinib / Thrombosis & Embolism (Black Warning) _____ _____

Alert Message: Thrombosis has occurred in patients treated with Litfulo (ritlecitinib). Avoid ritlecitinib in patients who may be at increased risk of thrombosis. If symptoms of thrombosis or embolism occur, patients should interrupt ritlecitinib and be evaluated promptly and treated appropriately.

Drugs/Diseases

Util A	Util B	Util C
Ritlecitinib	Arterial Thrombosis & Embolism	
	Venous Thrombosis & Embolism	
	Pulmonary Thrombosis & Embolism	

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.

71. Ritlecitinib / Major Cardiovascular Events (Black Warning) _____ _____

Alert Message: Consider the benefits and risks for the individual patient prior to initiating or continuing therapy with Litfulo (ritlecitinib), particularly in patients who are current or past smokers and patients with other cardiovascular risk factors. In a large, randomized, postmarketing safety study of another JAK inhibitor in RA patients 50 years of age and older with at least one cardiovascular risk factor, a higher rate of major adverse cardiovascular events (MACE) defined as cardiovascular death, non-fatal myocardial infarction (MI), and non-fatal stroke was observed with the JAK inhibitor compared to those treated with TNF blockers. Patients who are current or past smokers are at additional increased risk. Patients should be informed about the symptoms of serious cardiovascular events and the steps to take if they occur. Discontinue ritlecitinib in patients who have experienced a myocardial infarction or stroke.

Drugs/Diseases

Util A	Util B	Util C
Ritlecitinib	Myocardial Infarction	
	Stroke	
	Nicotine Dependence, Cigarette Use	
	Tobacco Use	

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Litfulo Prescribing Information, June 2023, Pfizer, Inc.

72. Ritlecitinib / Cirrhosis and Hepatic Failure _____ _____

Alert Message: Litfulo (ritlecitinib) use is not recommended in patients with severe (Child-Pugh C) hepatic impairment.

Drugs/Diseases

Util A	Util B	Util C
Ritlecitinib	Cirrhosis	
	Hepatic Failure	

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Litfulo Prescribing Information, June 2023, Pfizer, Inc.

Criteria Recommendations	*Approved*	*Rejected*

73. Ritlecitinib / Sensitive CYP3A Substrates _____ _____

Alert Message: Litfulo (ritlecitinib) is a CYP3A inhibitor. Concomitant use of ritlecitinib increases the AUC and Cmax of CYP3A substrates, which may increase the risk of adverse reactions of the CYP3A substrates. Consider additional monitoring and dosage adjustment in accordance with approved product labeling of CYP3A substrates where small concentration changes may lead to serious adverse reactions when used with ritlecitinib.

Drugs/Diseases

Util A	Util B					Util C
Ritlecitinib	Avanafil	Eletriptan	Lurasidone	Simvastatin	Vardenafil	
	Budesonide	Eplerenone	Maraviroc	Sirolimus		
	Buspirone	Everolimus	Midazolam	Tacrolimus		
	Conivaptan	Felodipine	Naloxegol	Ticagrelor		
	Darifenacin	Ibrutinib	Nisoldipine	Tipranavir		
	Darunavir	Lomitapide	Quetiapine	Tolvaptan		
	Dronedarone	Lovastatin	Sildenafil	Triazolam		

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Litfulo Prescribing Information, June 2023, Pfizer, Inc.

74. Ritlecitinib / Sensitive CYP1A2 Substrates _____ _____

Alert Message: Litfulo (ritlecitinib) is a CYP1A2 inhibitor. Concomitant use of ritlecitinib increases AUC and Cmax of CYP1A2 substrates, which may increase the risk of adverse reactions of CYP1A2 substrates. Consider additional monitoring and dosage adjustment in accordance with the approved product labeling of CYP1A2 substrates where small concentration changes may lead to serious adverse reactions when used concomitantly with ritlecitinib.

Drugs/Diseases

Util A	Util B		Util C
Ritlecitinib	Alosetron	Theophylline	
	Duloxetine	Tizanidine	
	Ramelteon		
	Tasimelteon		

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Litfulo Prescribing Information, June 2023, Pfizer, Inc.
FDA: Drug Development and Drug Interactions: Tables of Substrates, Inhibitors, and Inducers. Available at:
https://www.fda.gov/drugs/drug-interactions-labeling/drug-development-and-drug-interactions-table-substrates-inhibitors-and-inducers

Criteria Recommendations ***Approved*** ***Rejected***

75. Ritlecitinib / Strong CYP3A Inducers _____ _____

Alert Message: Coadministration of Litfulo (ritlecitinib) with strong inducers of CYP3A is not recommended. Concomitant use with a strong CYP3A inducer may decrease the AUC and Cmax of ritlecitinib, which may result in loss of or reduced clinical response.

Drugs/Diseases

Util A	Util B		Util C
Ritlecitinib	Apalutamide	Phenobarbital	
	Carbamazepine	Phenytoin	
	Enzalutamide	Primidone	
	Mitotane	Rifampin	

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Litfulo Prescribing Information, June 2023, Pfizer, Inc.

76. Ritlecitinib / Pregnancy / Pregnancy Negating _____ _____

Alert Message: Available data from clinical trials with Litfulo (ritlecitinib) use in pregnant women are insufficient to identify a drug-associated risk of major birth defects, miscarriage or other adverse maternal or fetal outcomes. In animal reproduction studies, oral administration of ritlecitinib to pregnant rats and rabbits during organogenesis caused fetotoxicity and fetal malformations. If a patient becomes pregnant while receiving ritlecitinib, healthcare providers should report ritlecitinib exposure by calling 1-877-390-2940.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Ritlecitinib	Pregnancy	Abortion
		Delivery
		Miscarriage

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Litfulo Prescribing Information, June 2023, Pfizer, Inc.

77. Ritlecitinib / Lactation _____ _____

Alert Message: There are no data on the presence of Litfulo (ritlecitinib) in human milk, the effects on the breastfed infant, or the effects on milk production. Ritlecitinib is present in the milk of lactating rats. When a drug is present in animal milk, it is likely that it will be present in human milk. Because of the serious adverse effects in adults, including risks of serious infection and malignancy, advise women not to breastfeed during treatment with ritlecitinib and for approximately 14 hours after the last dose (approximately 6 elimination half-lives).

Drugs/Diseases

Util A	Util B	Util C
Ritlecitinib	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Litfulo Prescribing Information, June 2023, Pfizer, Inc.

78. Ritlecitinib / Non-adherence _____ _____

Alert Message: Based on refill history, your patient may be under-utilizing Litfulo (ritlecitinib). Nonadherence to the prescribed dosing regimen may result in subtherapeutic effects, which may lead to decreased patient outcomes and additional healthcare costs.

Drugs/Diseases

Util A	Util B	Util C
Ritlecitinib		

References:

Osterberg L, Blaschke T. Adherence to Medication. N Engl J Med 2005; 353:487- 497.
Kleinsinger, Fred. The Unmet Challenge of Medication Nonadherence. The Permanente Journal. Vol. 22 (2018): 18-033. doi:10.7812/TPP/18-033.

Brown MT, Bussell J, Suparna D, et al. Medication Adherence: Truth and Consequences. Am J Med Sci. 2016 Apr;351(4):387-399.

79. Fluticasone/Vilanterol / Overuse _____ _____

Alert Message: Breo Ellipta (fluticasone/vilanterol) may be over-utilized. The recommended maintenance dose of fluticasone/vilanterol for the treatment of asthma in adults is one 200 mcg fluticasone/25 mcg vilanterol inhalation once daily.

Drugs/Diseases

Util A	Util B	Util C (Include)
Fluticasone/Vilanterol		Asthma

Max Dose: 200mcg/25mcg per day
Age Range: 18 – 999 yoa

References:

Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Breo Ellipta Prescribing Information, May 2023, GlaxoSmithKline.

80. Fluticasone/Vilanterol / Overuse _____ _____

Alert Message: Breo Ellipta (fluticasone/vilanterol) may be over-utilized. The recommended maintenance dose of fluticasone/vilanterol for the treatment of asthma in patients 12 to 17 years of age is one 100 mcg fluticasone/25 mcg vilanterol inhalation once daily.

Drugs/Diseases

Util A	Util B	Util C (Include)
Fluticasone/Vilanterol		Asthma

Max Dose: 100mcg/25mcg per day
Age Range: 12 – 17 yoa

References:

Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Breo Ellipta Prescribing Information, May 2023, GlaxoSmithKline.

Criteria Recommendations ***Approved*** ***Rejected***

81. Fluticasone/Vilanterol / Overuse _____ _____

Alert Message: Breo Ellipta (fluticasone/vilanterol) may be over-utilized. The recommended maintenance dose of fluticasone/vilanterol for the treatment of asthma in patients 5 to 11 years of age is one 50 mcg fluticasone/25 mcg vilanterol inhalation once daily.

Drugs/Diseases

Util A	Util B	Util C (Include)
Fluticasone/Vilanterol		Asthma

Max Dose: 50mcg/25mcg per day
Age Range: 5 – 11 yoa

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Breo Ellipta Prescribing Information, May 2023, GlaxoSmithKline.

82. Tirzepatide / Oral Contraceptives _____ _____

Alert Message: The use of Mounjaro (tirzepatide) may reduce the efficacy of oral hormonal contraceptives due to delayed gastric emptying. This delay is largest after the first dose and diminishes over time. Advise patients using oral hormonal contraceptives to switch to a non-oral contraceptive method or add a barrier method of contraception for 4 weeks after initiation and for 4 weeks after each dose escalation with tirzepatide.

Drugs/Diseases

Util A	Util B	Util C
Tirzepatide	Oral Contraceptives	

Gender: Female

Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Mounjaro Prescribing Information, July 2023, Eli Lilly and Company

North Dakota Medicaid

Drug Utilization Review Board Meeting

June 5, 2024

Conference Room 210/212

NORTH Dakota Be Legendary. | Health & Human Services

NORTH Dakota | Health & Human Services
Be Legendary.

Meeting Notice

North Dakota Medicaid Drug Use Review Board

Wednesday, June 5th, 2024
1 to 4 p.m. Central Time

In-Person Information

Conference Room 210/212, 2nd Floor, Judicial Wing, State Capitol
600 E. Boulevard Ave., Bismarck

Virtual Information

Join virtually: Click here to join the meeting
Join by phone: 701-328-0950, Conference ID: 876 672 920 #

Agenda

1. Call to Order
2. Roll Call
3. Review and Approval of Minutes
4. Reports from Department
    - Administrative Report: Utilization Review
    - Financial Report: Top Drugs
    - Retrospective DUR Report
    - Clinical Report:
        - Prior Authorization Update
        - Criteria updates: Food Allergy (Xolair), Peanut Allergy (Palforzia), Reduce Risk of Major Adverse Cardiovascular Events (Wegovy), Pulmonary Hypertension (Winrevair), Tardive Dyskinesia (Ingrezza, Austedo)
5. Special Orders: Presiding Officer and Vice-Presiding Officer Elections
6. Unfinished Business: Update to Hyperkalemia
7. New business
    - Second Review of Acid Blockers (Voquezna)
    - Second Review of Seborrheic Dermatitis (Zoryve)
    - Second Review of Primary Hyperoxaluria Type 1 (Rivfloza)
    - Second Review of Myasthenia Gravis (Zilbrysq)
    - Second Review of Duchenne Muscular Dystrophy (Emflaza, Agamree)
    - Second Review of Paroxysmal Nocturnal Hemoglobinuria (Empaveli, Fabhalta)
    - First Review of Molluscum Contagiosum (Ycanth and Zelsuvmi)
    - First Review of Epidermolysis Bullosa (Filsuvez)
    - First Review of Metabolic Dysfunction–Associated Steatohepatitis (Rezdiffra)
    - Review of retrospective DUR criteria recommendations
8. Announcements: Next Meeting (September 4, 2024)
9. Adjourn

Individuals with disabilities who need accommodations, including appropriate auxiliary aids to participate, can contact Ashley Gerving at 701-328-2354, toll-free 800-755-2604, 711 (TTY) or gervingashley@nd.gov.

Meeting Minutes
North Dakota Medicaid Drug Use Review (DUR) Board
Meeting Date: March 6th, 2024
Time and Location: 1:00 pm CST in Bismarck, North Dakota

Call to Order:
A regular quarterly meeting of the North Dakota Medicaid Drug Use Review (DUR) Board meeting was convened at 1:04 pm CST with A. Honeyman presiding as Presiding Officer. DUR Board Coordinator, C. Stauter recording minutes.

Roll Call:
Board Members Voting:
Present: Stephanie Antony, Gabriela Balf, Amanda Dahl, Kurt Datz, Andrea Honeyman, Laura Kroetsch, Kevin Martian, Kristen Peterson
Absent: Josh Askvig, Jennifer Iverson, Tanya Schmidt, Amy Werremeyer
Quorum Present: Yes

Board Members Non-Voting:
Absent: Kathleen Traylor

Medicaid Pharmacy Department:
Present: Jeff Hostetter, Brendan Joyce, Alexi Murphy, LeNeika Roehrich

Approval of Meeting Minutes:
Motion: Moved by K. Martian to approve the minutes of the December 6th, 2023 meeting, motion was seconded by K. Peterson. **Motion carried.**
The minutes of the December 6th, 2023 meeting were approved as distributed.

Reports:
*Administrative Report***:** *Member Update* provided by C. Stauter
C. Stauter introduced the new Board Member A. Dahl.

*Administrative Report***:** by A. Murphy
A. Murphy shared with the Board changes to distribution and patient assistance programs for COVID-19 treatments (Lagevrio and Paxlovid), information regarding a special mailing for prescriber PDMP utilization, and updated to covered agents for antipsychotic induced weight gain. This information can be found in the handout.

Financial Report: Budget provided by B. Joyce
B. Joyce shared with the Board trends of pharmacy claims from Quarter 1 2019 until Quarter 1 2023 for cost drivers and other classes. This information can be found in the handout.

Financial Report: Top Drugs provided by B. Joyce
B. Joyce presented the quarterly review of the top 25 drugs based on total number and cost of claims and the top 15 therapeutic classes based on number and cost of claims. This report can be found in the handout.

Retrospective Drug Utilization Review (RDUR) Report by C. Stauter
C. Stauter reviewed the quarterly RDUR criteria that were selected for review of each month. This material can be found in the handout.

Clinical Report: Prior Authorization and Criteria Updates by C. Stauter
C. Stauter presented prior authorization and criteria updates with emphasis on the following sections in the PDL: inhaled corticosteroids, tardive dyskinesia, and phenylketonuria. The presented information can be found in the handout.

Unfinished business:
Criteria Updates provided by C. Stauter
C. Stauter presented criteria updates with emphasis on the following sections in the PDL: hyperkalemia, prophylaxis to migraine, eczema/atopic dermatitis, and cholestatic pruritis. The presented material can be found in the handout. Testimony was provided by the following: Christine Dubé from Astrazeneca on Lokelma, Erin Nowak from Abbvie on Rinvoq, and Phong Pham from Ipsen Biopharmaceuticals on Bylvay.

New business:
First Reviews presented by C. Stauter
C. Stauter presented an overview of acid blockers (Voquezna), seborrheic dermatitis (Zoryve), primary hyperoxaluria type 1 (Rivfloza), myasthenia gravis (Zilbrysq), Duchenne muscular dystrophy (Emflaza, Agamree), and paroxysmal nocturnal hemoglobinuria (Empaveli, Fabhalta). The presented material can be found in the handout. Testimony was provided by Jamie Tobitt from Apellis Pharmaceuticals on Empaveli and Shirley Quach from Novartis on Fabhalta.
Motion: Moved by K. Peterson to draft prior authorization for acid blockers, motion was seconded by A. Dahl. **Motion carried.**
Motion: Moved by K. Martian to draft prior authorization for seborrheic dermatitis, motion was seconded by A. Honeyman. **Motion carried.**
Motion: Moved by K. Peterson to draft prior authorization for primary hyperoxaluria type 1, motion was seconded by K. Martian. **Motion carried.**
Motion: Moved by K. Martian to draft prior authorization for myasthenia gravis, motion was seconded by G. Balf. **Motion carried.**
Motion: Moved by A. Honeyman to draft prior authorization for Duchenne muscular dystrophy, motion was seconded by K. Martian. **Motion carried.**
Motion: Moved by K. Martian to draft prior authorization for paroxysmal nocturnal hemoglobinuria, motion was seconded by K. Datz. **Motion carried.**

Retrospective Drug Utilization Review (RDUR) Criteria Recommendations:
RDUR criteria recommendations were reviewed. The presented material can be found in the handout.
Motion: Moved by K. Martian to approve the RDUR criteria, motion was seconded by A. Honeyman. **Motion carried.**

Announcements:
Next meeting is June 5th, 2024.

Adjournment:
Meeting adjourned by A. Honeyman at 2:22 pm CST.

Date of Minutes Approval:
Minutes submitted by: Claire Stauter, Acentra Health

Administrative Report

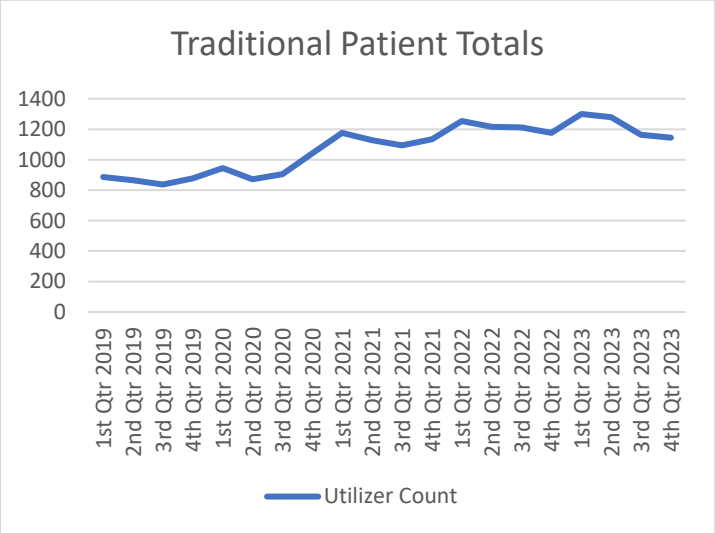
Utilization Review

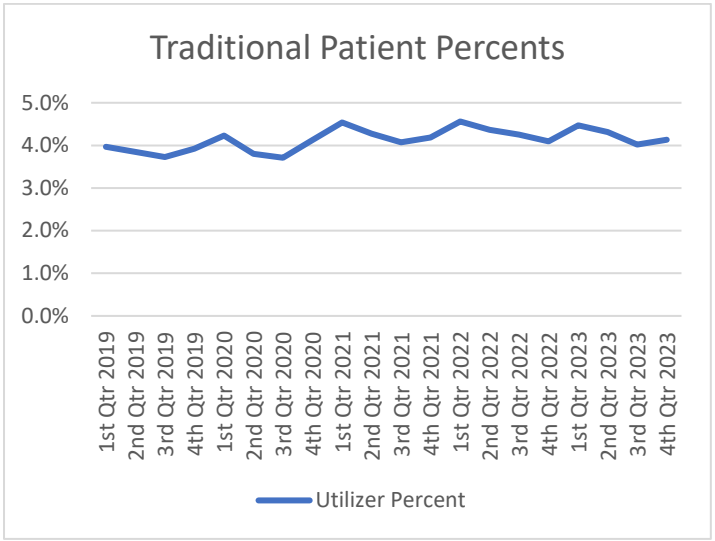
The following graphs depict pharmacy claims utilization of various agents for the specified indications. Pharmacy data is not available for expansion members in 2019.

Antidepressants: Pediatric Females (Ages 0-17)

Chua, Kao-Ping, et al. "Antidepressant dispensing to US adolescents and young adults: 2016–2022." *Pediatrics* 153.3 (2024).

- Data assessed antidepressant prescribing trends in teens and young adults from 2016 to 2022.
- After March 2020, the prescribing rate of antidepressants among female adolescents ages 12-17 increased 130% faster than prior to March 2020.





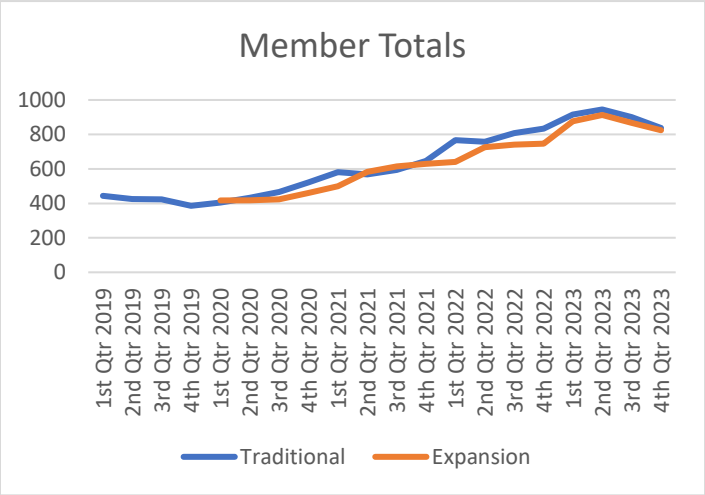
Quarter	Eligible Members	Number of Patients	Percent of Patients
2019 Q1	22,332	886	4.0%
2019 Q2	22,468	865	3.8%
2019 Q3	22,455	837	3.7%
2019 Q4	22,351	877	3.9%
2020 Q1	22,360	945	4.2%
2020 Q2	22,959	872	3.8%
2020 Q3	24,396	905	3.7%
2020 Q4	25,257	1,042	4.1%
2021 Q1	25,890	1,175	4.5%
2021 Q2	26,400	1,128	4.3%
2021 Q3	26,904	1,095	4.1%
2021 Q4	27,099	1,135	4.2%
2022 Q1	27,496	1,254	4.6%
2022 Q2	27,845	1,216	4.4%
2022 Q3	28,457	1,211	4.3%
2022 Q4	28,746	1,176	4.1%
2023 Q1	29,093	1,300	4.5%
2023 Q2	29,706	1,280	4.3%
2023 Q3	28,961	1,164	4.0%
2023 Q4	27,689	1,145	4.1%

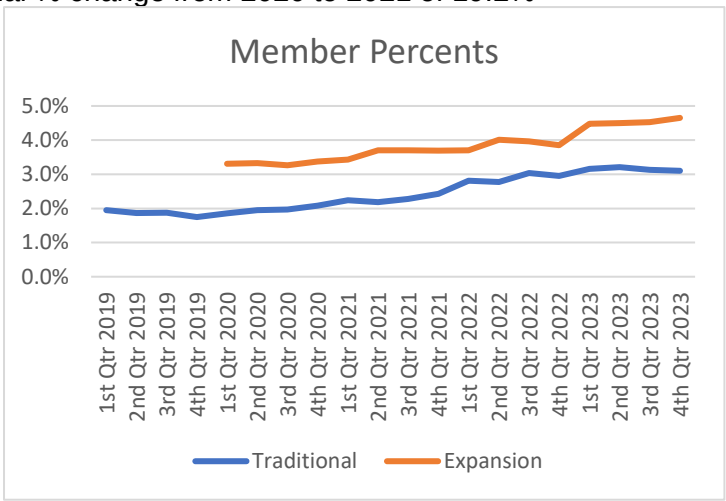
Eligible members: females aged 0-17 years old with traditional Medicaid

Attention-Deficit Hyperactivity Disorder: Adult Females (Ages 18+)

Danielson ML, Bohm MK, Newsome K, et al. Trends in Stimulant Prescription Fills Among Commercially Insured Children and Adults — United States, 2016–2021. MMWR Morb Mortal Wkly Rep 2023;72:327–332. DOI: http://dx.doi.org/10.15585/mmwr.mm7213a1

- Data published by the CDC evidences a rise in ADHD prescriptions during the COVID-19 pandemic, particularly in females aged 15 to 54 and males aged 30 to 39.
- For example, the average annual % change for females aged 20-24 saw an average annual % change from 2016 to 2020 of -1.8% in contrast to the annual % change from 2020 to 2021 of 19.2%





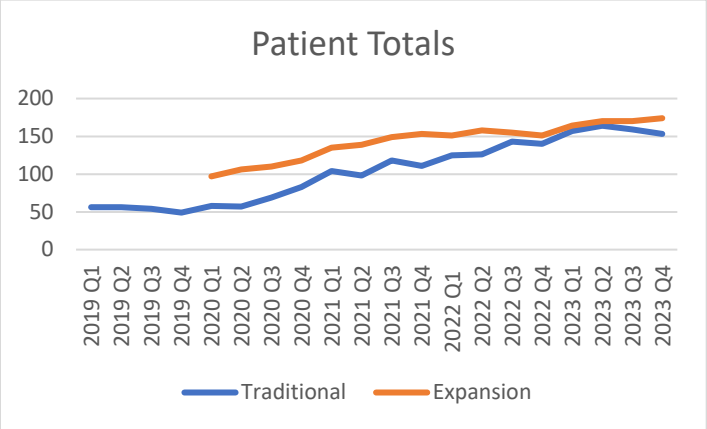
Quarter	Exp Eligible Members	Exp Number of Members	Exp Percent of Members	Trad Eligible Members	Trad Number of Members	Trad Percent of Members
2019 Q1	12,448			22,773	444	1.9%
2019 Q2	12,609			22,807	426	1.9%
2019 Q3	12,580			22,561	423	1.9%
2019 Q4	12,726			22,093	386	1.7%
2020 Q1	12,588	417	3.3%	21,872	405	1.9%
2020 Q2	12,567	418	3.3%	22,260	433	1.9%
2020 Q3	12,992	424	3.3%	23,750	467	2.0%
2020 Q4	13,650	461	3.4%	25,075	521	2.1%
2021 Q1	14,539	499	3.4%	25,910	581	2.2%
2021 Q2	15,759	583	3.7%	25,977	568	2.2%
2021 Q3	16,571	614	3.7%	26,171	595	2.3%
2021 Q4	17,055	629	3.7%	26,573	646	2.4%
2022 Q1	17,298	640	3.7%	27,214	766	2.8%
2022 Q2	18,122	726	4.0%	27,368	758	2.8%
2022 Q3	18,686	741	4.0%	26,573	807	3.0%
2022 Q4	19,396	747	3.9%	28,244	834	3.0%
2023 Q1	19,564	877	4.5%	28,967	915	3.2%
2023 Q2	20,281	913	4.5%	29,448	945	3.2%
2023 Q3	19,163	867	4.5%	28,714	900	3.1%
2023 Q4	17,715	824	4.7%	27,003	837	3.1%

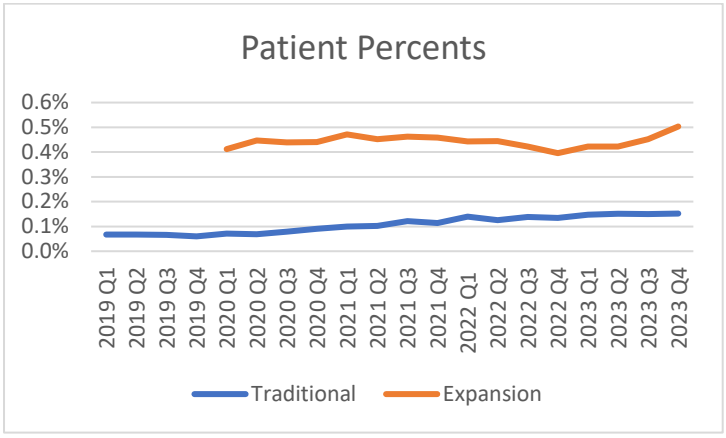
Eligible members: females aged 18+ years old

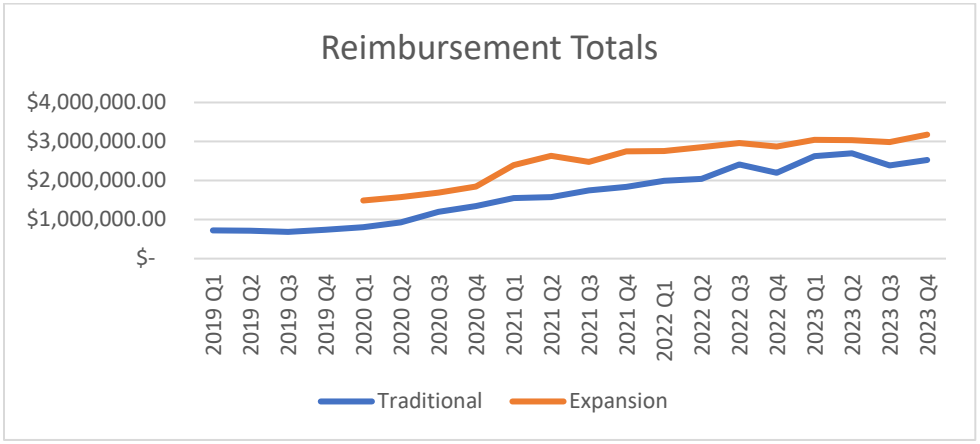
Cost Drivers

- Jornay PM - $75,745 (34% of methylphenidate spend) / 373 scripts (7.5% of methylphenidate utilization) = $203.07 per script (avg. $44.32/script for methylphenidate)

Biologics


Patient Totals
200
150
100
50
0
2019 Q1
2019 Q2
2019 Q3
2019 Q4
2020 Q1
2020 Q2
2020 Q3
2020 Q4
2021 Q1
2021 Q2
2021 Q3
2021 Q4
2022 Q1
2022 Q2
2022 Q3
2022 Q4
2023 Q1
2023 Q2
2023 Q3
2023 Q4
Traditional
Expansion


Patient Percents
0.6%
0.5%
0.4%
0.3%
0.2%
0.1%
0.0%
2019 Q1
2019 Q2
2019 Q3
2019 Q4
2020 Q1
2020 Q2
2020 Q3
2020 Q4
2021 Q1
2021 Q2
2021 Q3
2021 Q4
2022 Q1
2022 Q2
2022 Q3
2022 Q4
2023 Q1
2023 Q2
2023 Q3
2023 Q4
Traditional
Expansion


Reimbursement Totals
$4,000,000.00
$3,000,000.00
$2,000,000.00
$1,000,000.00
$-
2019 Q1
2019 Q2
2019 Q3
2019 Q4
2020 Q1
2020 Q2
2020 Q3
2020 Q4
2021 Q1
2021 Q2
2021 Q3
2021 Q4
2022 Q1
2022 Q2
2022 Q3
2022 Q4
2023 Q1
2023 Q2
2023 Q3
2023 Q4
Traditional
Expansion

Quarter	Exp Eligible Members	Exp Number of Members	Exp Percent of Members	Trad Eligible Members	Trad Number of Members	Trad Percent of Patients
2019 Q1	23,066			82,630	56	0.07%
2019 Q2	23,332			82,814	56	0.07%
2019 Q3	23,265			82,456	54	0.07%
2019 Q4	23,549			81,716	49	0.06%
2020 Q1	23,538	97	0.41%	81,479	58	0.07%
2020 Q2	23,730	106	0.45%	83,007	57	0.07%
2020 Q3	25,055	110	0.44%	87,997	69	0.08%
2020 Q4	26,774	118	0.44%	91,726	83	0.09%
2021 Q1	28,663	135	0.47%	104,590	104	0.10%
2021 Q2	30,783	139	0.45%	95,587	98	0.10%
2021 Q3	32,259	149	0.46%	96,987	118	0.12%
2021 Q4	33,358	153	0.46%	98,028	111	0.11%
2022 Q1	34,074	151	0.44%	89,583	125	0.14%
2022 Q2	35,545	158	0.44%	100,977	126	0.12%
2022 Q3	36,736	155	0.42%	103,217	143	0.14%
2022 Q4	38,149	151	0.40%	104,533	140	0.13%
2023 Q1	38,879	164	0.42%	106,361	157	0.15%
2023 Q2	40,269	170	0.42%	108,369	164	0.15%
2023 Q3	37,649	170	0.45%	105,759	159	0.15%
2023 Q4	34,569	174	0.50%	100,691	153	0.15%

New Cost Drivers:

4Q23

- Stelara - $454,415 for 20 scripts / 13 members = $22,720 per script (every 2-3 months)
- Skyrizi - $257,467 for 14 scripts / 14 members = $18,390 per script (every 2-3 months)
- Tremfya - $116,857 for 9 scripts / 5 members = $12,984 per script (every 2 months)
- **= $828,739 per quarter for 43 scripts / 32 members**

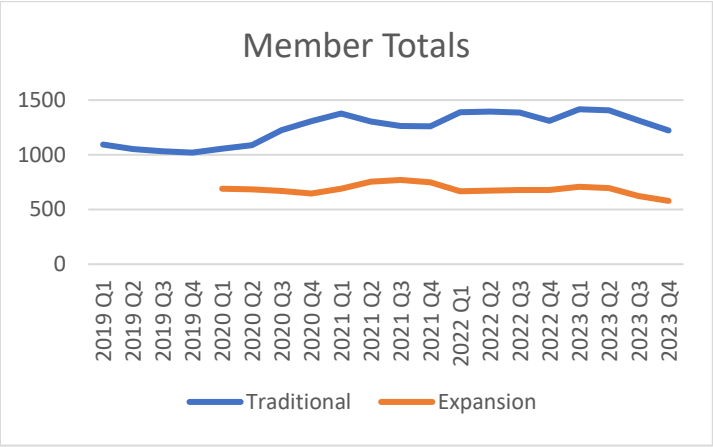
1Q20

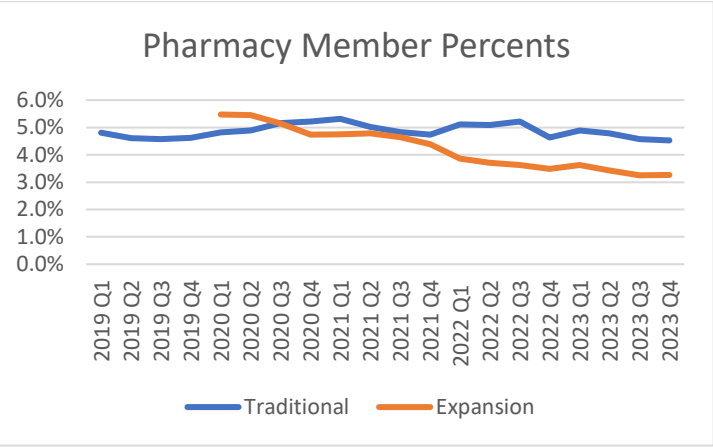
- Stelara – $73,107 for 5 scripts / 4 members = $14,621 per script (every 2-3 months)
- Skyrizi - 0 scripts / 0 members
- Tremfya – $11,404 for 1 script / 1 member = $11,404 for 1 script (every 2 months)
- **= $84,511 per quarter for 6 scripts / 5 members**

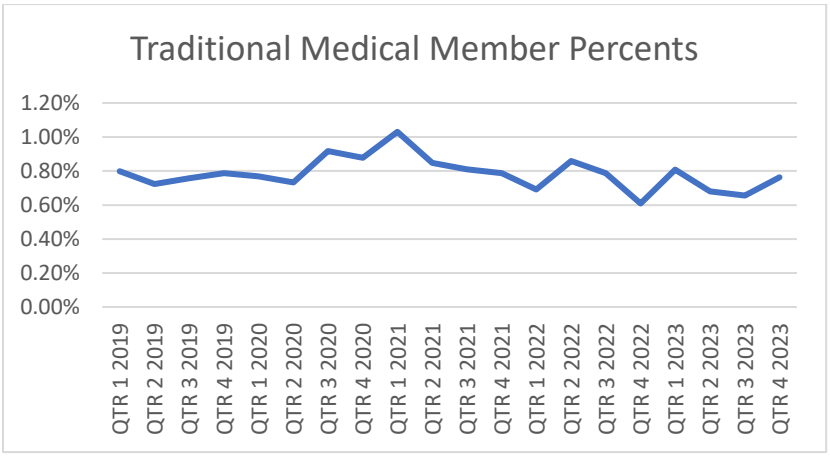
Contraceptives

Steenland, Maria W., et al. "Declines in contraceptive visits in the United States during the COVID-19 pandemic." *Contraception* 104.6 (2021): 593-599.

- Data has shown that the % decline in contraceptive visits between 2019 and April 2020 decreased and remained low through December 2020.
- Comparing levels in December 2019 with those in December 2020, the change in contraceptive visits was -18% for tubal ligation -11% for injectable contraceptives, -6% for LARC, and -5% for pill, patch and ring visits







Pharmacy Utilization

Quarter	Exp Eligible Members	Exp Number of Members	Exp Percent of Members	Trad Eligible Members	Trad Number of Members	Trad Percent of Members
2019 Q1	12,448			22,773	1,095	4.8%
2019 Q2	12,609			22,807	1,052	4.6%
2019 Q3	12,580			22,561	1,032	4.6%
2019 Q4	12,726			22,093	1,020	4.6%
2020 Q1	12,588	689	5.5%	21,872	1,055	4.8%
2020 Q2	12,567	685	5.5%	22,260	1,089	4.9%
2020 Q3	12,992	669	5.1%	23,750	1,224	5.2%
2020 Q4	13,650	646	4.7%	25,075	1,307	5.2%
2021 Q1	14,539	690	4.7%	25,910	1,377	5.3%
2021 Q2	15,759	754	4.8%	25,977	1,304	5.0%
2021 Q3	16,571	770	4.6%	26,171	1,264	4.8%
2021 Q4	17,055	749	4.4%	26,573	1,260	4.7%
2022 Q1	17,298	667	3.9%	27,214	1,390	5.1%

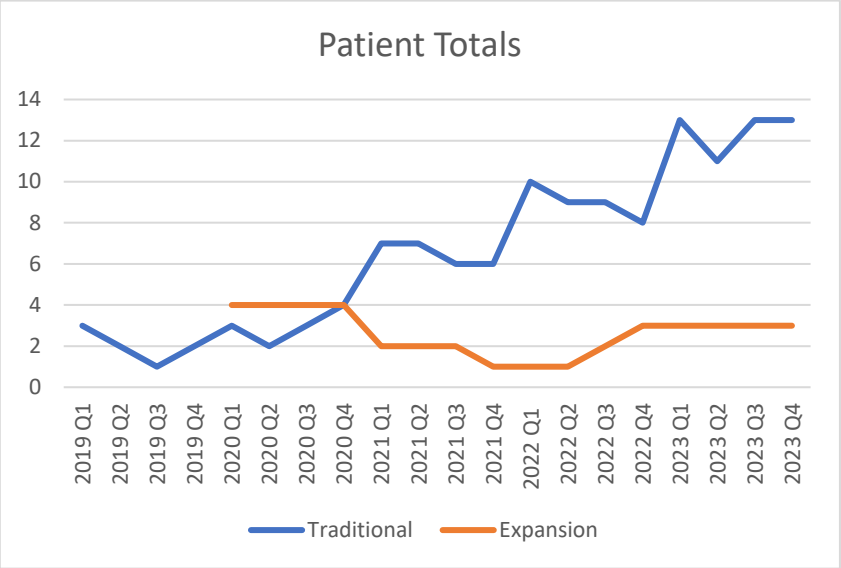
2022 Q2	18,122	673	3.7%	27,368	1,394	5.1%
2022 Q3	18,686	677	3.6%	26,573	1,386	5.2%
2022 Q4	19,396	677	3.5%	28,244	1,309	4.6%
2023 Q1	19,564	709	3.6%	28,967	1,416	4.9%
2023 Q2	20,281	696	3.4%	29,448	1,408	4.8%
2023 Q3	19,163	623	3.3%	28,714	1,314	4.6%
2023 Q4	17,715	579	3.3%	27,003	1,222	4.5%

Eligible members: females aged 18+ years old; IUD's included

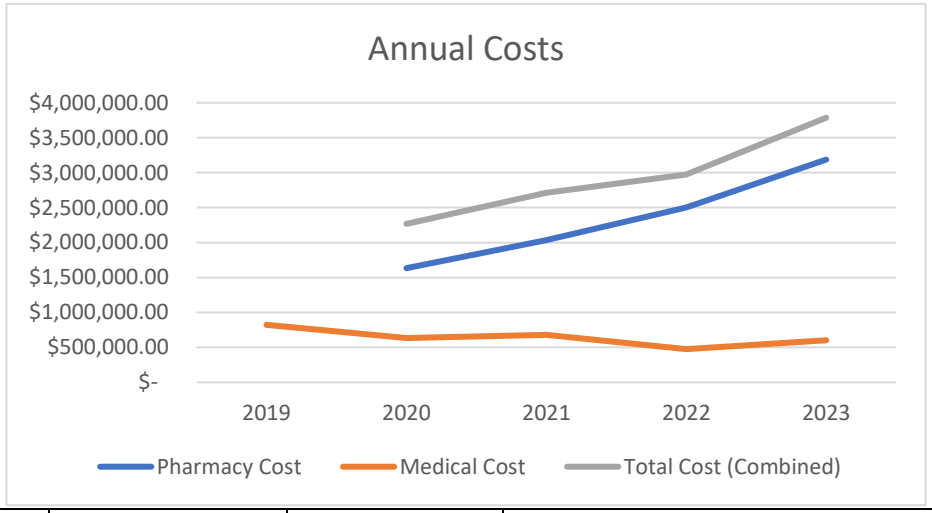
Medical Utilization

Quarter	Service Count	Trad Number of Members	Trad Percent of Members
QTR 1 2019	182	22,773	0.80%
QTR 2 2019	165	22,807	0.72%
QTR 3 2019	171	22,561	0.76%
QTR 4 2019	174	22,093	0.79%
QTR 1 2020	168	21,872	0.77%
QTR 2 2020	163	22,260	0.73%
QTR 3 2020	218	23,750	0.92%
QTR 4 2020	220	25,075	0.88%
QTR 1 2021	267	25,910	1.03%
QTR 2 2021	220	25,977	0.85%
QTR 3 2021	212	26,171	0.81%
QTR 4 2021	209	26,573	0.79%
QTR 1 2022	188	27,214	0.69%
QTR 2 2022	235	27,368	0.86%
QTR 3 2022	209	26,573	0.79%
QTR 4 2022	172	28,244	0.61%
QTR 1 2023	234	28,967	0.81%
QTR 2 2023	200	29,448	0.68%
QTR 3 2023	188	28,714	0.65%
QTR 4 2023	206	27,003	0.76%

Cystic Fibrosis



	Exp Number of Patients	Trad Number of Patients
2019 Q1		3
2019 Q2		2
2019 Q3		1
2019 Q4		2
2020 Q1	4	3
2020 Q2	4	2
2020 Q3	4	3
2020 Q4	4	4
2021 Q1	2	7
2021 Q2	2	7
2021 Q3	2	6
2021 Q4	1	6
2022 Q1	1	10
2022 Q2	1	9
2022 Q3	2	9
2022 Q4	3	8
2023 Q1	3	13
2023 Q2	3	11
2023 Q3	3	13
2023 Q4	3	13

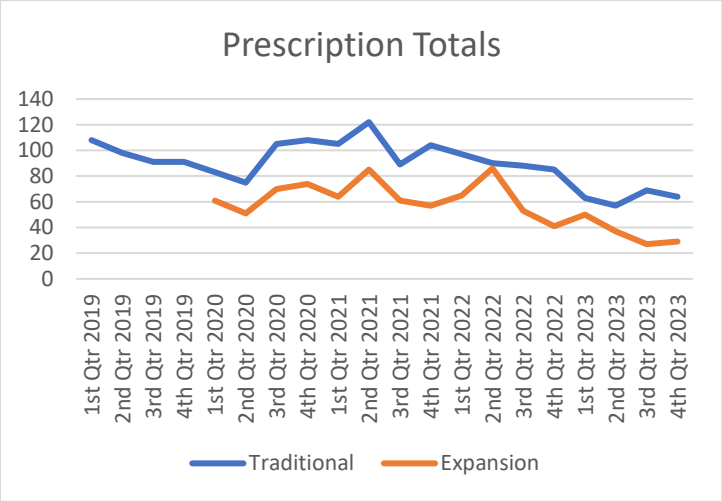


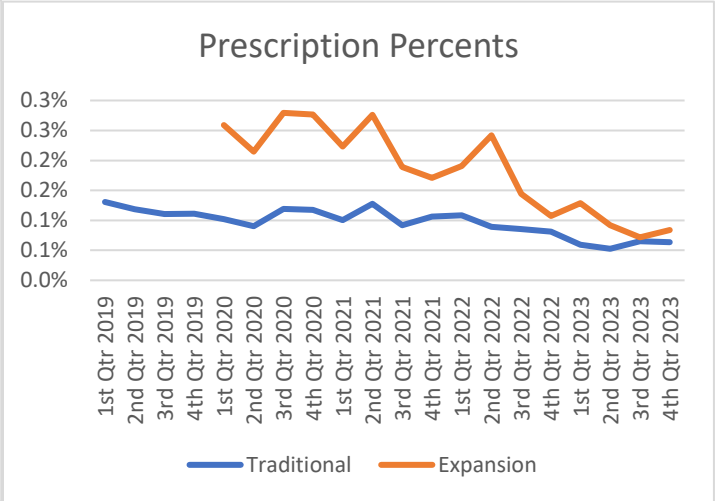
	Pharmacy Cost	Medical Cost	Total Cost (Pharmacy and Medical)
2019		$822,730.61	
2020	$1,633,456.80	$633,385.61	$2,266,842.41
2021	$2,033,262.88	$681,236.36	$2,714,499.24
2022	$2,500,280.01	$474,927.74	$2,975,207.75
2023	$3,186,849.04	$599,749.13	$3,786,598.17

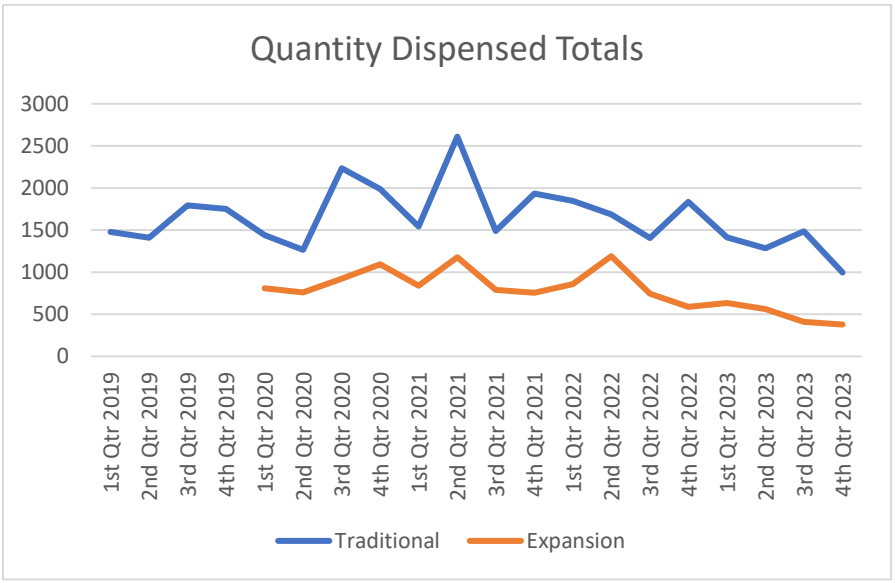
Pharmacy costs do not include costs for expansion members in 2019, so pharmacy claims have been omitted for 2019. Cost data includes both traditional and expansion members.

Dentist Prescribed Opioid Analgesics

- Okunev, Ilya, Julie Frantsve-Hawley, and Eric Tranby. "Trends in national opioid prescribing for dental procedures among patients enrolled in Medicaid." *The Journal of the American Dental Association* 152.8 (2021): 622-630.
- “Although the trends revealed in the analysis show declining opioid prescription patterns, these results suggest that the overall rate is still too high and prescriptions are being written unnecessarily”







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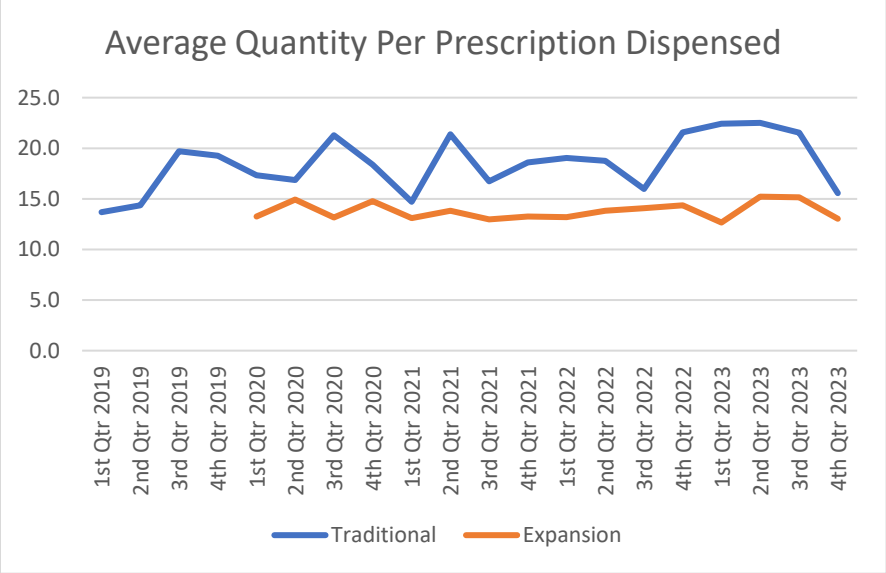
2019 Q3	23,265			82,456	91	0.1%
2019 Q4	23,549			81,716	91	0.1%
2020 Q1	23,538	61	0.3%	81,479	83	0.1%
2020 Q2	23,730	51	0.2%	83,007	75	0.1%
2020 Q3	25,055	70	0.3%	87,997	105	0.1%
2020 Q4	26,774	74	0.3%	91,726	108	0.1%
2021 Q1	28,663	64	0.2%	104,590	105	0.1%
2021 Q2	30,783	85	0.3%	95,587	122	0.1%
2021 Q3	32,259	61	0.2%	96,987	89	0.1%

2021 Q4	33,358	57	0.2%	98,028	104	0.1%
2022 Q1	34,074	65	0.2%	89,583	97	0.1%
2022 Q2	35,545	86	0.2%	100,977	90	0.1%
2022 Q3	36,736	53	0.1%	103,217	88	0.1%
2022 Q4	38,149	41	0.1%	104,533	85	0.1%
2023 Q1	38,879	50	0.1%	106,361	63	0.1%
2023 Q2	40,269	37	0.1%	108,369	57	0.1%
2023 Q3	37,649	27	0.1%	105,759	69	0.1%
2023 Q4	34,569	29	0.1%	100,691	64	0.1%

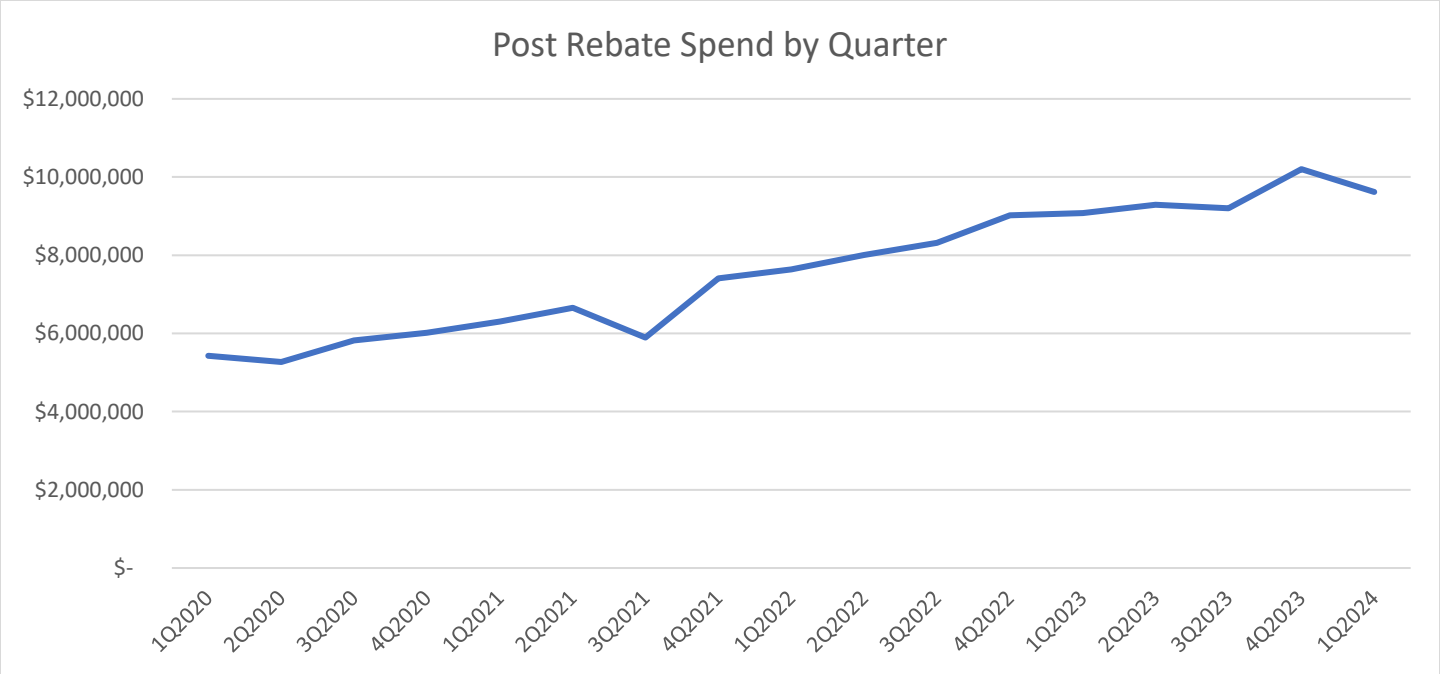
	Exp Quantity Dispensed	Exp Quantity Per Rx	Trad Quantity Dispensed	Trad Quantity Per Rx
2019 Q1			1,478	13.7
2019 Q2			1,408	14.4
2019 Q3			1,793	19.7
2019 Q4			1,753	19.3
2020 Q1	808	13.2	1,438	17.3
2020 Q2	761	14.9	1,265	16.9
2020 Q3	921	13.2	2,235	21.3
2020 Q4	1,092	14.8	1,985	18.4
2021 Q1	839	13.1	1,543	14.7
2021 Q2	1,176	13.8	2,610	21.4
2021 Q3	791	13.0	1,488	16.7
2021 Q4	755	13.2	1,934	18.6
2022 Q1	858	13.2	1,846	19.0
2022 Q2	1,190	13.8	1,687	18.7
2022 Q3	746	14.1	1,407	16.0
2022 Q4	589	14.4	1,833	21.6
2023 Q1	633	12.7	1,413	22.4
2023 Q2	563	15.2	1,283	22.5
2023 Q3	409	15.1	1,487	21.6
2023 Q4	378	13.0	996	15.6

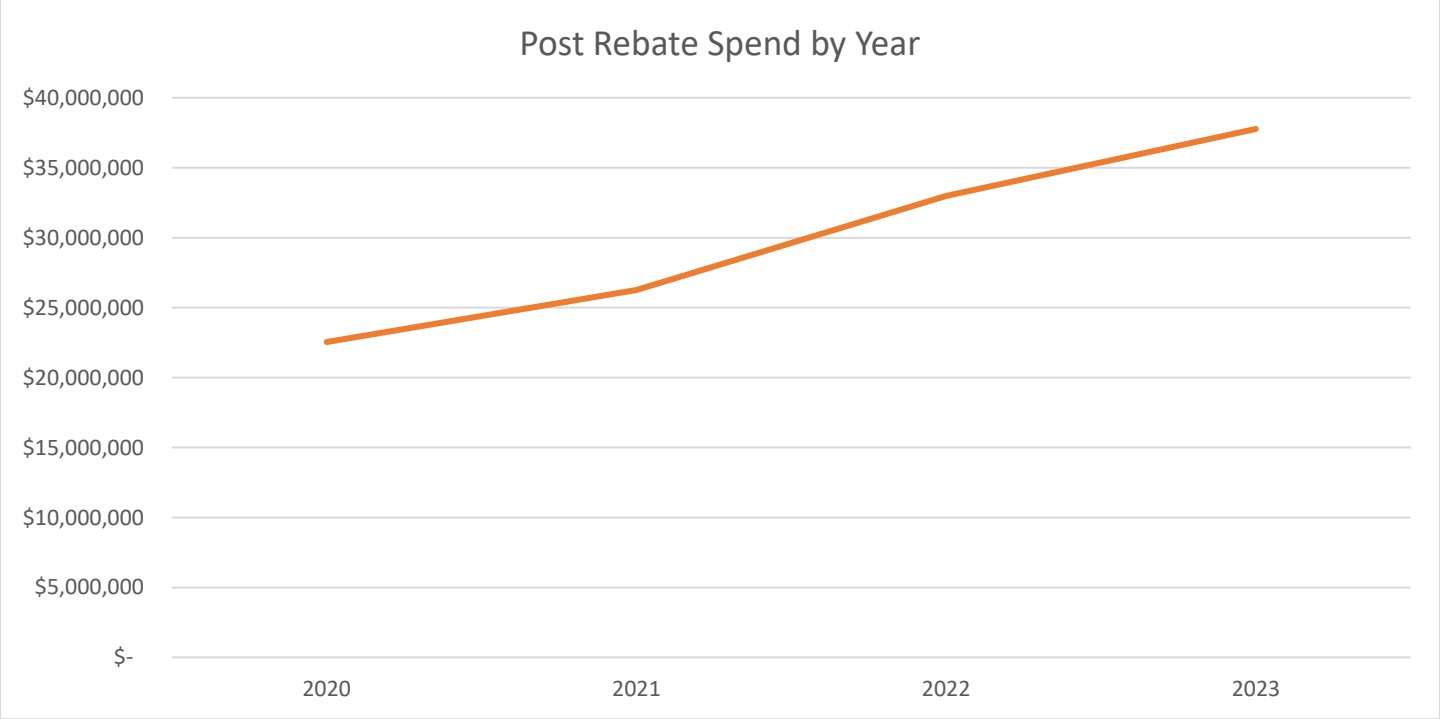


Financial Report

All graphs are only for traditional and expansion pharmacy claims.
ND Medicaid has experienced 67% growth in post rebate spend the past 4 years which equates to an increase of:

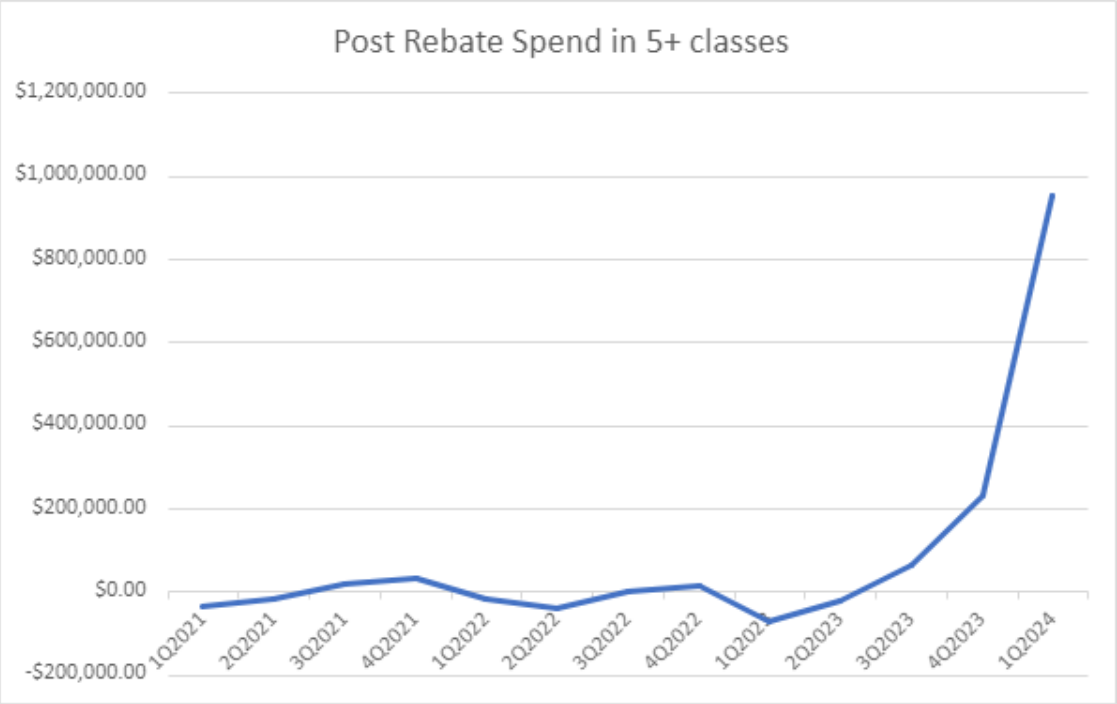
- $4.2 million dollar per quarter or $15.2 million per year



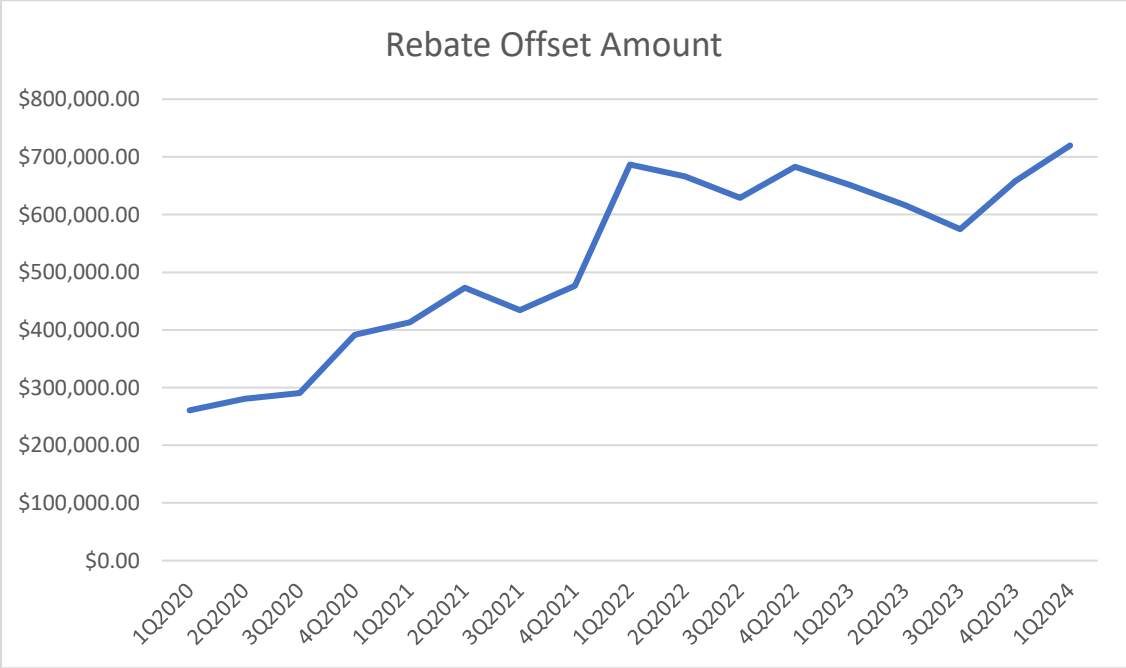


In addition to the long-term trend in growth due to increasing utilization of costly medication, there is additional increase in expenditure not fully captured in the above graphs due to rebate calculation changes.

AMP cap removal effect

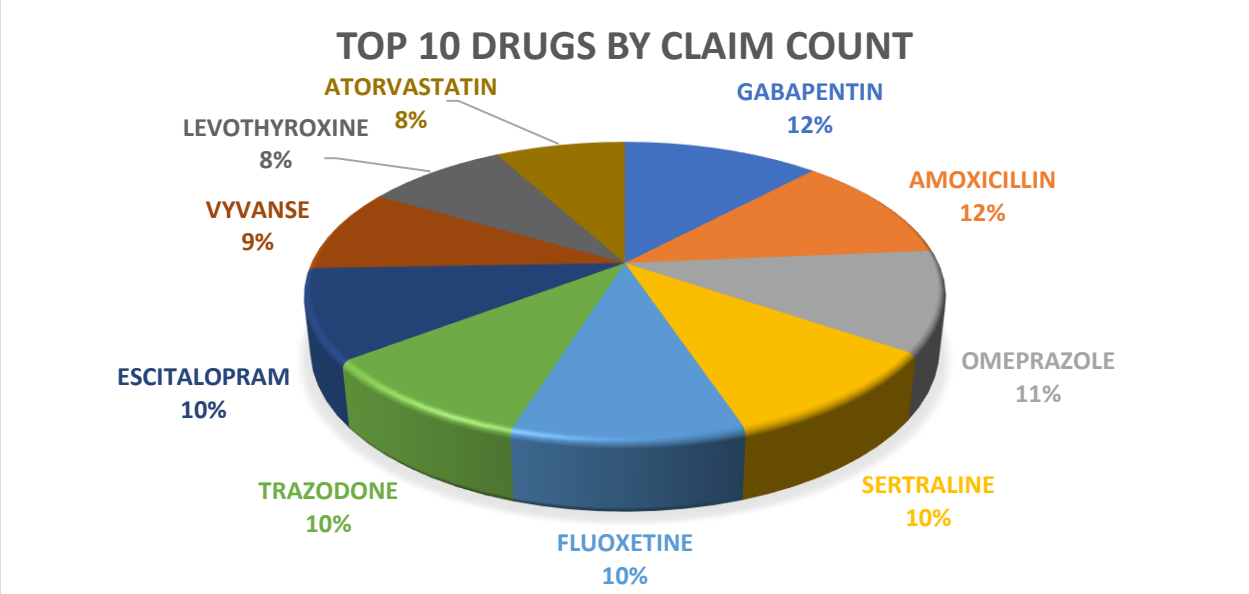


Offset Amount – Line Extension



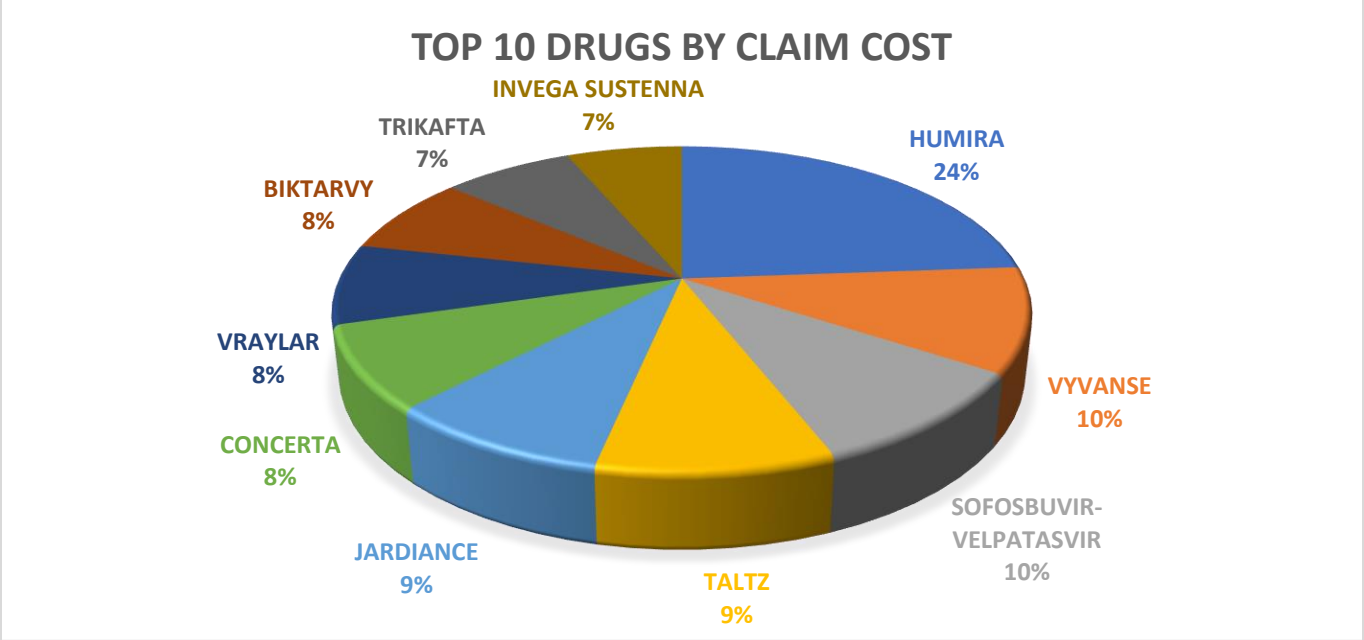
Top 25 Drugs Based on Number of Claims from 01/01/2024 – 03/31/2024

Drug	Claims	Claims Cost	Patients	Cost / Claim	% Claims	Dif.
1. GABAPENTIN	4,239	$62,373.24	1,828	$14.71	1.8%	NC
2. AMOXICILLIN	4,114	$62,936.07	3,844	$15.30	1.7%	↑2
3. OMEPRAZOLE	3,871	$49,806.16	2,048	$12.87	1.6%	↓1
4. SERTRALINE HCL	3,654	$49,168.72	2,091	$13.46	1.5%	↑1
5. FLUOXETINE HCL	3,530	$46,171.21	1,949	$13.08	1.5%	↑2
6. TRAZODONE HCL	3,471	$46,509.94	1,843	$13.40	1.5%	NC
7. ESCITALOPRAM	3,464	$46,348.87	1,984	$13.38	1.5%	↓2
8. VYVANSE	3,190	$916,793.04	1,318	$287.40	1.3%	↑2
9. LEVOTHYROXINE	3,049	$45,058.21	1,631	$14.78	1.3%	↓1
10. ATORVASTATIN	2,806	$40,698.63	1,696	$14.50	1.2%	↓1
11. LISINOPRIL	2,801	$37,352.72	1,755	$13.34	1.2%	↑1
12. BUPROPION XL	2,789	$45,312.46	1,529	$16.25	1.2%	↑1
13. VENTOLIN HFA	2,745	$175,538.27	2,718	$63.95	1.2%	↓2
14. CLONIDINE HCL	2,563	$31,530.10	1,299	$12.30	1.1%	↑3
15. PANTOPRAZOLE	2,493	$35,334.20	1,377	$14.17	1.0%	↑1
16. AMOXICILLIN-CLAV	2,491	$43,725.62	2,327	$17.55	1.0%	↓1
17. PREDNISONE	2,417	$28,013.17	1,943	$11.59	1.0%	↓1
18. LAMOTRIGINE	2,360	$33,408.82	995	$14.16	1.0%	↑2
19. DULOXETINE HCL	2,338	$38,576.15	1,290	$16.50	1.0%	NC
20. HYDROXYZINE HCL	2,311	$33,312.81	1,450	$14.41	1.0%	↑2
21. ONDANSETRON ODT	2,278	$32,090.57	1,828	$14.09	1.0%	↑3
22. ARIPIPRAZOLE	2,261	$33,381.55	1,120	$14.76	0.9%	↑3
23. HYDROCODONE-APAP	2,252	$33,166.82	1,435	$14.73	0.9%	↓5
24. CYCLOBENZAPRINE	2,226	$25,759.01	1,404	$11.57	0.9%	↓3
25. ADDERALL XR	2,112	$379,800.94	917	$179.83	0.9%	↑1
Total Claims						**238,051**



Top 25 Drugs Based on Total Claims Cost from 01/01/2024 – 03/31/2024

Drug	Claims	Claims Cost	Patients	Cost / Patient	% Cost	Dif.
1. HUMIRA	250	$2,103,532.98	114	$18,452.04	6.8%	NC
2. VYVANSE	3,190	$916,793.04	1,318	$695.59	2.9%	↑2
3. SOFOS-VELPATASVIR	37	$864,957.79	37	$23,377.24	2.8%	↑24
4. TALTZ	97	$823,407.50	50	$16,468.15	2.6%	↑1
5. JARDIANCE	1,054	$784,159.53	588	$1,333.60	2.5%	↑1
6. CONCERTA	2,045	$729,103.17	882	$826.65	2.3%	↑1
7. VRAYLAR	699	$704,788.32	294	$2,397.24	2.3%	↑3
8. BIKTARVY	309	$688,521.12	138	$4,989.28	2.2%	↑4
9. TRIKAFTA	33	$643,163.49	14	$45,940.25	2.1%	NC
10. INVEGA SUSTENNA	208	$568,689.32	91	$6,249.33	1.8%	↑3
11. NORDITROPIN	94	$540,683.17	41	$13,187.39	1.7%	↑4
12. DUPIXENT	150	$529,830.65	73	$7,257.95	1.7%	↓4
13. ENBREL	63	$436,395.60	28	$15,585.56	1.4%	↑7
14. ELIQUIS	661	$383,918.81	325	$1,181.29	1.2%	↑3
15. ADDERALL XR	2,112	$379,800.94	917	$414.18	1.2%	↑1
16. INGREZZA	47	$362,703.02	21	$17,271.57	1.2%	↑3
17. STELARA	16	$359,933.56	13	$27,687.20	1.2%	↓3
18. SKYRIZI	16	$319,976.58	14	$22,855.47	1.0%	↑8
19. SUBLOCADE	123	$247,649.47	66	$3,752.26	0.8%	↑6
20. ABILIFY MAINTENA	98	$242,013.93	43	$5,628.23	0.8%	↑4
21. SYMBICORT	981	$230,267.48	599	$384.42	0.7%	↓3
22. INVEGA TRINZA	27	$221,071.71	27	$8,187.84	0.7%	↑4
23. FARXIGA	333	$215,214.27	186	$1,157.07	0.7%	↑6
24. JIVI	2	$183,730.52	1	$183,730.52	0.6%	↑12
25. VENTOLIN HFA	2,745	$175,538.27	2,718	$64.58	0.6%	↑9
Total Claims Cost						**$31,129,344.12**



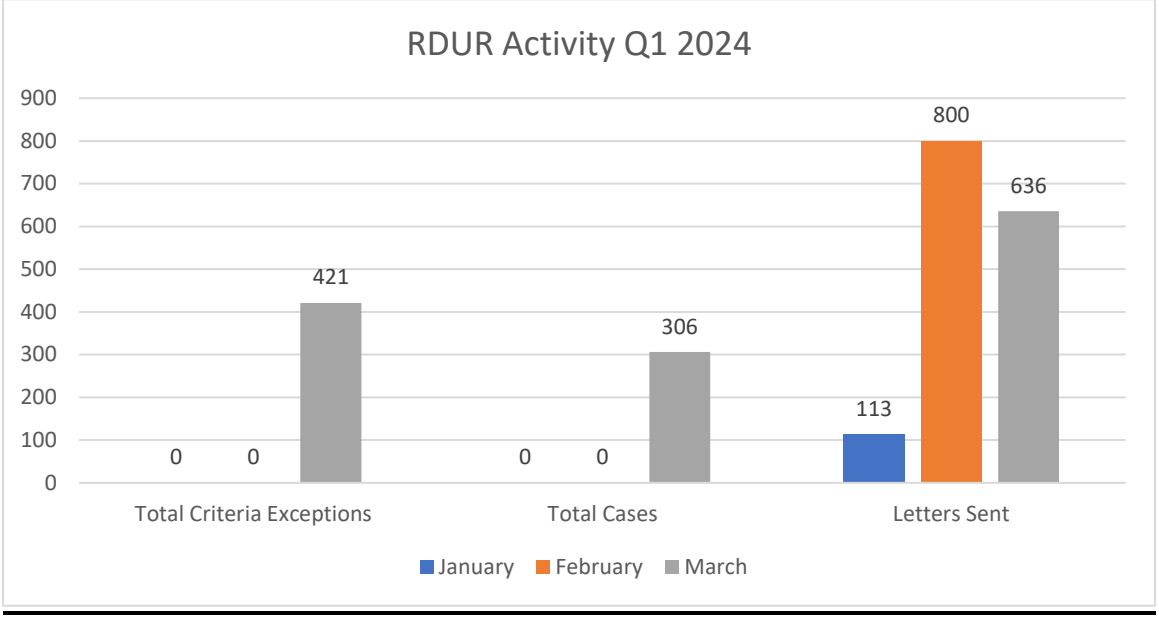
Top 15 Therapeutic Classes Based on Number of Claims from 01/01/2024 – 03/31/2024

Therapeutic Class Description	Claims	Claims Cost	Patients	Cost/Claim	% Claims	Dif.
1. ANTIDEPRESSANTS	25,951	$601,006.96	11,151	$23.16	10.9%	NC
2. ANTICONVULSANTS	12,924	$562,766.38	4,685	$43.54	5.4%	NC
3. ANTIPSYCHOTIC AGENTS	9,337	$2,405,679.06	3,802	$257.65	3.9%	NC
4. PENICILLIN ANTIBIOTICS	6,885	$111,290.27	6,116	$16.16	2.9%	↑2
5. ANXIOLYTICS, SEDATIVES, HYPNOTICS	6,828	$101,318.20	3,540	$14.84	2.9%	NC
6. PROTON-PUMP INHIBITORS	6,807	$161,366.00	3,610	$23.71	2.9%	↓2
7. AMPHETAMINES	6,737	$1,348,461.20	2,849	$200.16	2.8%	NC
8. RESP/CNS STIMULANTS	5,714	$997,464.73	2,183	$174.57	2.4%	↑2
9. OPIATE AGONISTS	5,652	$96,501.24	2,966	$17.07	2.4%	↓1
10. NSAIDS	5,590	$76,196.87	3,789	$13.63	2.3%	↓1
11. STATINS	5,046	$74,749.79	3,051	$14.81	2.1%	NC
12. BETA BLOCKING AGENTS	4,299	$71,517.60	2,462	$16.64	1.8%	NC
13. BETA AGONISTS	4,102	$231,639.81	3,718	$56.47	1.7%	↑1
14. ADRENALS	4,071	$55,788.34	3,242	$13.70	1.7%	↓1
15. BIGUANIDES	3,479	$48,266.58	2,055	$13.87	1.5%	NC

Top 15 Therapeutic Classes Based on Claims Cost from 01/01/2024 – 03/31/2024

Therapeutic Class Description	Claims	Claims Cost	Patients	Cost/Patient	% Cost	Dif.
1. DMARDS	492	$3,241,945.15	210	$15,437.83	10.4%	NC
2. ANTIPSYCHOTIC AGENTS	9,337	$2,405,679.06	3,802	$632.74	7.7%	NC
3. SKIN AGENTS	524	$1,788,798.46	297	$6,022.89	5.7%	NC
4. AMPHETAMINES	6,737	$1,348,461.20	2,849	$473.31	4.3%	↑3
5. ANTIRETROVIRALS	813	$1,307,586.66	308	$4,245.41	4.2%	↑4
6. ANTINEOPLASTIC AGENTS	548	$1,273,829.43	245	$5,199.30	4.1%	NC
7. INCRETIN MIMETICS	1,431	$1,065,462.24	705	$1,511.29	3.4%	↓2
8. SGLT2 INHIBITORS	1,474	$1,048,828.27	810	$1,294.85	3.4%	↑3
9. RESP/CNS STIMULANTS	5,714	$997,464.73	2,183	$456.92	3.2%	↑3
10. HCV ANTIVIRALS	38	$869,552.84	38	$22,882.97	2.8%	↓2
11. INSULINS	3,144	$669,578.43	1,307	$512.30	2.2%	↓7
12. CFTR CORRECTORS	33	$643,163.49	14	$45,940.25	2.1%	↑1
13. CORTICOSTEROIDS (RESP)	3,033	$628,082.92	1,863	$337.14	2.0%	↓3
14. PITUITARY	362	$627,479.21	158	$3,971.39	2.0%	↑1
15. ANTIDEPRESSANTS	25,951	$601,006.96	11,151	$53.90	1.9%	↓1

RDUR Report: Q1 2024



Exception Types:

Drug-drug conflicts: • Drug-drug interaction • Therapeutic duplication	**Overutilization:** • Overuse • High dose	**Clinical Appropriateness** • Therapeutic appropriateness
Drug-disease conflicts: • Drug-disease precaution, actual and inferred • Drug-drug and/or diagnosis	**Underutilization:** • Underuse	

January Special Mailing
113 letters sent to prescribers

Introduction

At the bottom of this report, you will see patients receiving multiple psychotropic medications concurrently in the past 120 days per pharmacy claims data. If multiple prescribers are involved, each will receive this information.

- *Please be aware that the North Dakota Medicaid Psychotropic Monitoring Program was created in response to the SUPPORT (Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment) for Patients and Communities Act; this act requires the state to monitor and manage safe and effective use of psychotropic agents, especially for pediatric patients in foster care.* [1]

Psychotropic Polypharmacy

Prior to considering the use of multiple agents, prescribers should implement non-pharmacological interventions and consider alternative monotherapy or non-psychotropic combinations. Polypharmacy can worsen adverse effects, increase the risk of drug interactions, decrease medication adherence, lead to therapy duplication, and may increase healthcare costs. Although psychotropic polypharmacy is commonly used in clinical practice, it is not supported by the literature and many agents are used off-label; there is insufficient data to assess the safety and efficacy of using multiple agents concurrently. [2]

Safe and effective psychotropic treatment should include evaluation of guideline recommendations, considerations of appropriate indications for use, implementation of non-pharmacological interventions including cognitive behavior therapy, patient education, and continuous monitoring.[3] To properly assess for medication efficacy and safety, prescribers should counsel patients and caregivers regarding their treatment regimen, monitoring plan, and expected outcomes; oftentimes, a medication is considered ineffective despite the inability of the medication to affect the assessed behavior.[4] Proper assessment of side effects is vital to decrease the risk of prescribing cascades to treat adverse effects. [5] The appropriateness of the patient's regimen should also be routinely assessed as well. [6]

For example, despite minimal data and no FDA approved medications for the treatment of Disruptive Behavior Disorders, psychotropic medication use has increased significantly in this patient population.[10] The strongest evidence for management of these disorders is the implementation of behavioral therapy for patients, parents, families, and teachers. These programs aim to implement consistent responses to behaviors, provide aggression and problem-solving training, and improve social skills.[11]

Monitoring for Metabolic Effects

The risk of metabolic effects from psychotropic medications increases with younger age, antipsychotic naïve patients, and longer duration of therapy; despite this increased risk, studies have shown that metabolic monitoring occurs less frequently during antipsychotic treatment for pediatric patients. [3]

Baseline and regular monitoring should include:

- Personal and familial history
- Modifiable risk factors
- Weight
- Body mass index
- Waist circumference
- Blood pressure
- Heart rate
- Fasting glucose
- Hemoglobin A1c
- Fasting lipid profiles

Key Takeaways:

Safe and effective psychotropic treatment should include:

- Evaluation of guideline recommendations and appropriate indications for use
- Considerations of alternative monotherapy or non-psychotropic combinations if current regimen is ineffective
- Implementation of non-pharmacological interventions including cognitive behavior therapy
- Patient and caregiver education regarding their treatment regimen, monitoring plan, and expected outcomes
- Continuous monitoring, especially for metabolic effects in pediatric patients [2, 3, 4]

References:

1. *North Dakota Health and Human Services. Monitoring Program for Psychotropic Medications [Internet]. Bismarck (ND): Medical Services Division; 2023 April. Available from: http://hidesigns.com/assets/files/ndmedicaid/2023/ND_Psychotropic%20Monitoring%20Program_042023.pdf*
2. *Gallego JA, Nielsen J, De Hert M, Kane JM, Correll CU. Safety and Tolerability of Antipsychotic Polypharmacy. Expert Opin Drug Saf. 2012;11(4):527-542. doi:10.1517/14740338.2012.683523*
3. *Libowitz MR, Nurmi EL. The burden of antipsychotic-induced weight gain and metabolic syndrome in children. Front Psychiatry [Internet]. 2021 Mar 12. 12:623681. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7994286/*
4. *McLaren JL, Lichtenstein JD. The Pursuit of the Magic Pill: The Overuse of Psychotropic Medications in Children with Intellectual and Development Disabilities in the USA. Epidemiol Psychiatr Sci. 2019 Aug;28(4):365-368.*
5. *Kukreja S, Kalra G, Shah N, Shrivastava A. Polypharmacy in psychiatry: a review. Mens Sana Monogr. 2013 Jan;11(1):82-99. doi: 10.4103/0973-1229.104497. PMID: 23678240; PMCID: PMC3653237.*
6. *Walkup J, Bernet W, Work Group on Quality Issues, et al. Practice Parameter on the use of Psychotropic Medication in Children and Adolescents. Journal of the American Academy of Child and Adolescent Psychiatry. 2009;48(9):961-973.*
7. *Wolraich ML, Hagan JF, Allan C, et al. AAP Subcommittee on Children and Adolescents with Attention-Deficit/Hyperactive Disorder. Clinical Practice Guideline for the Diagnosis, Evaluation, and Treatment of Attention-Deficit/Hyperactivity Disorder in Children and Adolescents. Pediatrics. 2019;144(4):e20192528*
8. *Solmi M et al. Safety of 80 Antidepressants, Antipsychotics, Anti-attention-deficit/hyperactivity Medications and Mood Stabilizers in Children and Adolescents with Psychiatric Disorders: A Large Scale Systematic Meta-Review of 78 Adverse Effects. World Psychiatry 2020 Jun; 19:214. (https://doi.org/10.1002/wps.20765)*
9. *Walkup J, Bernet W, Work Group on Quality Issues, et al. Practice Parameter on the use of Psychotropic Medication in Children and Adolescents. Journal of the American Academy of Child and Adolescent Psychiatry. 2009;48(9):961-973.*
10. *Agency for Healthcare Research and Quality. Research Protocol: Psychosocial and Pharmacologic Interventions for Disruptive Behavior Disorder [Internet]. Rockville, MD: Effective Health Care Program; 2014 July 1. Available from: https://effectivehealthcare.ahrq.gov/products/disruptive-behavior-disorder/research-protocol*
11. *Agency for Healthcare Research and Quality. Consumer Summary: Treating Disruptive Behavior Disorders in Children and Teens [Internet]. Rockville, MD: Effective Health Care Program; 2016 Aug 31. Available from: https://effectivehealthcare.ahrq.gov/products/disruptive-behavior-disorder/consumer*

February Special Mailing
800 letters sent to prescribers

In accordance with the SUPPORT ACT under Section 5042 (effective October 1, 2021), all Medicaid providers authorized to prescribe controlled substances are required to assess the prescription drug history from a qualified prescription drug monitoring program (PDMP) before prescribing controlled substances to Medicaid members. Exclusions to this requirement include prescriptions written for the following members:

- Receiving hospice, palliative care, or cancer treatment
- Resident of a long-term care facility or facility with a single pharmacy contract[1,2]

A recent review of claims data indicated that you have written a prescription for a controlled substance from October 1, 2022 until September 30, 2023 for a Medicaid member. If there appears to be an error in the information provided, please note the discrepancy.

The PDMP should be checked prior to prescribing controlled substances for Medicaid members (except excluded member categories). State Medicaid programs are required to report provider PDMP use percentages to CMS annually. **Please respond to the attached questionnaire regarding your use of the PDMP for the period of October 1, 2022 through September 30, 2023 and fax it to 866-798-4904.**

References:

1. *Library of Congress. H.R.6 – SUPPORT for Patients and Communities Act (2017-2018). [Internet}. Available from: https://www.congress.gov/bill/115th-congress/house-bill/6/text*
2. *Department of Health and Human Services. Frequently Asked Questions: SUPPORT for Patients and Communities Act, Section 5042 – Medicaid PARTNERSHIP Act [Internet]. Baltimore (MD): Centers for Medicare & Medicare Services. Available from: https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/faq051519_199.pdf*

March Cases by Type of Criteria		
Criteria Description	**# of Cases**	**% of Cases**
Underuse	305	99.7%
High-dose	1	0.3%

Clinical Report

Prior Authorization Updates

Drug Name	PA Status	Class
Alvaiz	PA	Thrombocytopenia
Novolog	PA	Insulins
Opsynvi	PA	Pulmonary Hypertension
Revivasil Kit	PA	Kits
Rezdiffra	PA	Medications Over $3000
Symbicort	PA	Steroid/LABA
Spevigo	PA	Medications Over $3000
Voydeya	PA	Medications Over $3000
Winrevair	PA	Pulmonary Hypertension
Zymfentra	PA	Cytokine Modulators
Bivigam	Remove PA	Immune Globulins
Fiasp	Remove PA, electronic step	Insulins
Flebogamma Dif	Remove PA	Immune Globulins
Gammagard	Remove PA	Immune Globulins
Gammagard S-D	Remove PA	Immune Globulins
Gammaked	Remove PA	Immune Globulins
Gamunex-C	Remove PA	Immune Globulins
Hizentra	Remove PA	Immune Globulins
Hyqvia	Remove PA	Immune Globulins
Octagam	Remove PA	Immune Globulins
Privigen	Remove PA	Immune Globulins

Criteria Updates

Summary of Changes:

Xolair received a new indication of Food Allergy.

Allergy severity is defined since specifically we are looking to treat allergy that may result in anaphylaxis.

What constitutes a positive IgE test varies greatly depending on food specific allergen and age. The size of the skin test does not correlate with severity of clinical allergic reaction. IgE testing also does not correlate well with the severity of a reaction. IgE results also vary based on immunoassay used. A positive skin test to a particular food only indicates the possibility that the patient has a true allergy because of the low specificity of the test, as low as 50% with some foods. A positive IgE tests is indicative of a sensitization, not necessarily of an allergy. It is common to have a positive SPT or IgE test to a tolerated food. Both IgE and SPT is useful for excluding IgE-mediated food allergy.

Further studies are needed to evaluate ways to predict the risk of severe reactions. Although reviewing a patient's history of previous reactions and allergen-specific IgE levels can help provide patient-centered care, these methods are not good predictors of future anaphylaxis.

Resources:

1. *Muraro et al. World Allergy Organization Journal (2022) 15:100687 http://doi.org/10.1016/j.waojou.2022.100687*
2. *Ansotegui, Ignacio J., et al. "IgE allergy diagnostics and other relevant tests in allergy, a World Allergy Organization position paper." World allergy organization journal 13.2 (2020): 100080.*
3. *Sicherer, Scott H., et al. "Allergy testing in childhood: using allergen-specific IgE tests." Pediatrics 129.1 (2012): 193-197.*
4. *Burks, Wesley. "Diagnostic evaluation of IgE-mediated food allergy." Uptodate. Available online: https:// https://www.uptodate.com/contents/diagnostic-evaluation-of-ige-mediated-food-allergy (2023).*
5. *Stokes, Jeff, and Thomas B. Casale. "The relationship between IgE and allergic disease." Uptodate. Available online: https://www.uptodate.com/contents/the-relationship-between-ige-and-allergic-disease (2022).*

Food Allergy

Eosinophil-directed biologics

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
XOLAIR (omalizumab) SYRINGES	
XOLAIR (omalizumab) VIAL – *Medical Billing Only*	

Oral Immunotherapy

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
PALFORZIA (peanut allergen powder)	

Prior Authorization Criteria

Initial Criteria - Approval Duration: 6 months

- The requested medication must be prescribed by, or in consult with, an allergist/immunologist.
- The provider must attest that the member has access to injectable epinephrine, and that the member/caregiver has been instructed and trained on its appropriate use.
- The member has one of the following:
    A. The member has a history of severe (type 1) allergic response requiring the use of epinephrine, an ER visit, or hospitalization.
    B. Allergic reaction produced during a provider observed intake of food allergen and attestation that food allergy is likely to produce anaphylaxis as determined by allergist/immunologist.
    C. The member has all the following:
        - History of urticaria, angioedemia, or wheeze
        - Skin prick wheal of at least 3 mm or positive IgE test as determined by allergist/immunologist (at least 0.35 kUA/L for Palforzia and at least 30 IU/mL for Xolair)
        - Attestation that food allergy is likely to produce anaphylaxis as determined by allergist/immunologist.

Renewal Criteria (Palforzia Only) - Approval Duration: 6 months for continued up-titration or 12 months for maintenance the 300 mg dose.

- The member must have been adherent with therapy (last 6 fills must have been on time).
- One of the following must be met:
    A. The member has been able to tolerate the maintenance dose of Palforzia (300 mg daily)
    OR
    B. An up-titration plan to a final dose of 300 mg daily by week 40 and this is a first request for an up-titration renewal.

Summary of Changes

GLP-1 Agonist semaglutide has received a new indication. Criteria is derived from the SELECT trial's confidence intervals for efficacy.

Age: Age inclusion criteria ≥ 55 years. Hazard ratio for ≥ 75 (0.67 to 1.25) was not statistically significant, so the age was set at ≥ 55 and <75, additionally most people > 65 will be on Medicare.

BMI: BMI inclusion criteria ≥ 27 kg/m^2. Hazard ratios for BMI ≥ 35 to <40 (0.74 to 1.18), BMI ≥ 40 to <45 (0.55 to 1.26) and ≥ 45 (0.51 to 1.65) were not statistically significant, so criteria was set at BMI that performed better than placebo: ≥ 27 kg/m^2 and < 35 kg/m^2

Established Cardiovascular Disease (CVD): Indication requires established CV disease. CV inclusion criteria requires one of the following: prior myocardial infarction (MI), prior stroke, or symptomatic peripheral arterial disease (PAD) as evidenced by intermittent claudication with ankle-brachial index >0.85, peripheral arterial revascularization procure, or amputation due to atherosclerotic disease. Hazard ratios for only stroke (0.75 to 1.27) and only PAD (0.36 to 1.48) were not statistically significant. Only MI and ≥ 2 CVD had statistically significant hazard ratios and are included in the criteria.

Lipid lowering and antiplatelet treatment: Lipid lowering therapy and antiplatelet therapy are indicated for reduction of cardiovascular events, as well as recommended therapy in each of the required co-morbid conditions.

Titration of semaglutide: The semaglutide molecule is marketed under two different brand names, Ozempic and Wegovy. The cost to the department is very different based on the marketed brand name for the exact same molecule. Semaglutide has a relatively high risk of adverse effects, so there is significant likelihood that a titration will not be tolerated. The only strength of semaglutide that is indicated for MACE is 2.4 mg which is only marketed under the brand name Wegovy. There is a required titration to reach the 2.4 mg dose, so we will use the most cost effective semaglutide NDCs for titration (this is congruent with other cost containment strategies similarly made for many other exact same molecules that are marketed under various brand names, e.g., non-preferred dosage forms, biosimilars).

Reduction of Major Adverse Cardiovascular Events (MACE)

Oral Agents

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
See Lipid-Lowering Agents	
See Platelet Aggregation Inhibitors	

Injectable Agents - GLP-1 Agonists

CLINICAL PA REQUIRED
WEGOVY (semaglutide)

Prior Authorization Criteria

For reduction of MACE in members with diabetes, please see diabetes category for criteria on indicated agents.

Initial Criteria - Approval Duration: 12 months

- The member is ages of ≥ 55 and < 75.
- The member does not have diabetes.
- The member has an initial BMI of ≥ 27 kg/m^2 and < 35 kg/m^2

- The member has one of the following:
  - Prior myocardial infarction (MI)
  - Prior stroke and symptomatic peripheral arterial disease (PAD), as evidenced by intermittent claudication with ankle-brachial index >0.85, peripheral arterial revascularization procure, or amputation due to atherosclerotic disease.
- The member is concurrently taking lipid-lowering and antiplatelet therapy
- If the member qualifies for Wegovy, a dose escalation to 2 mg of Ozempic (semaglutide) must be tolerated before Wegovy will be authorized (2.4 mg is the only strength indicated for reduction of MACE)

Summary of Changes

Winrevair has been approved for pulmonary hypertension with a novel mechanism of action.

Pulmonary Hypertension

Activin Signaling Inhibitor

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
WINREVAIR (sotatercept-csrk)	

Electronic Diagnosis Verification

- Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale.

Prior Authorization Criteria

Initial Criteria - Approval Duration: 6 months

- The requested medication must be prescribed by, or in consult with, a pulmonologist or cardiologist.
- The member must currently be on a dual therapy combination regimen.

Renewal Criteria - Approval Duration: 12 months

- Documentation of a therapeutic response as evidenced by stabilization or improvement from baseline in each of the following:
  - 6MWT (≤ 15% decline)
  - WHO functional class

Endothelin Receptor Antagonists

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ambrisentan	LETAIRIS (ambrisentan)
bosentan	OPSUMIT (macitentan)
TRACLEER (bosentan) SUSPENSION	OPSYNVI (macitentan/tadalafil)
	TRACLEER (bosentan) TABLETS

Electronic Diagnosis Verification

- Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale.

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

- The member must have failed a 30-day trial of ambrisentan, as evidenced by paid claims or pharmacy printouts.

PDE-5 Inhibitors

Solid Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
sildenafil tablet	ADCIRCA (tadalafil) TABLET
tadalafil tablet	ALYQ (tadalafil)
	OPSYNVI (macitentan/tadalafil)
	REVATIO (sildenafil) TABLET

Non-Solid Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
REVATIO (sildenafil) SUSPENSION – *Brand Required*	LIQREV (sildenafil) SUSPENSION
	sildenafil suspension
	TADLIQ (tadalafil) SUSPENSION

Electronic Age Verification

- Sildenafil/tadalafil: Prior authorization is not required for ages less than 18 years old.
- Revatio suspension: Prior authorization is not required for ages less than 9 years old.

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

- The request must include medical documentation (e.g., clinical notes) to verify diagnosis.

Non-Preferred Agents Criteria

- The member must have failed a 30-day trial of a preferred product, as evidenced by paid claims or pharmacy printouts.
- Liqrev Only: See Preferred Dosage Form criteria

Prostacyclins

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ORENITRAM ER (treprostinil) TABLET	
REMODULIN (treprostinil) INJECTION – *Brand Co-Preferred*	
treprostinil injection	
TYVASO (treprostinil) DPI	
TYVASO (treprostinil) INHALATION	
UPTRAVI (selexipag) TABLET	
UPTRAVI (selexipag) VIAL	
VENTAVIS (iloprost) INHALATION	

Electronic Diagnosis Verification

- Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale.

Soluble Guanylate Cyclase Stimulators

NO PA REQUIRED
ADEMPAS (riociguat)

Electronic Diagnosis Verification

- Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale.

Summary of Changes

APA recommends that patients who have moderate to severe or disabling tardive dyskinesia associated with antipsychotic therapy be treated with a reversible inhibitor of the vesicular monoamine transporter 2 (VMAT2).

APA also recommends regular assessment of patients for tardive syndromes, including the use of structured evaluative tools such as the clinician-administered Abnormal Involuntary Movement Scale (AIMS). Although AIMS is recommended for assessment of efficacy, there is not an established minimal clinically important difference (MCID). Clinicians may evaluate a change in AIMS score value or percentage from baseline. A change of 2 or 3 points from baseline may be indicative of efficacy. Clinical studies have defined efficacy as 30-50% reduction from baseline.
**AIMS: Item 8 is used to determine overall severity (3 = moderate). Item 9 is used to determine incapacitation due to abnormal movements (3 = moderate).*

Patients with more severe TD (AIMS total score ≥ 6) exhibit better clinical response. A review of the ARM-TD and AIM-TD studies evaluated the change in AIMS scores for patients with mild TD (AIMS score < 6) and more severe TD (AIMS score ≥ 6) who were treated with deutetrabenazine versus placebo:

- For mild TD, the change in AIMS score from baseline at week 12 was not statistically significant versus placebo (mean difference from placebo = -0.92; p = 0.08).
- For more severe TD, the change in AIMS score from baseline at week 12 was statistically significant (mean difference from placebo = -1.79; p < 0.0001).

North Dakota Medicaid paid $360,000 for 59 prescriptions in 2023 Quarter 4 for Ingrezza and Austedo.

Resources:

1. *Hauser RA, Barkay H, Anderson KE, et al. Efficacy and Safety of Deutetrabenazine in Patients With Mild Tardive Dyskinesia: Analysis of the ARM-TD and AIM-TD Studies. Presentation; June 16-19, 2019.*
2. *Kane JM, Correll CU, Nierenberg AA, et al. Revisiting the Abnormal Involuntary Movement Scale: proceedings from the Tardive Dyskinesia Assessment Workshop. J Clin Psychiatry. 2018;79(3):17cs11959.*

Tardive Dyskinesia

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AUSTEDO (deutetrabenazine)	tetrabenazine 25 mg
AUSTEDO XR (deutetrabenazine)	XENAZINE (tetrabenazine)
INGREZZA (valbenazine)	
tetrabenazine 12.5 mg	

Electronic Step Therapy Required

- The Initiation Pack or 40 mg x 7 days is required for titration to 80 mg capsules.

Prior Authorization Criteria

Prior Authorization Form – Tardive Dyskinesia

Initial Criteria – Approval Duration: 12 months
- The requested medication must be prescribed by, or in consult with, a psychiatric or neurology specialist.
- The member must have a history of treatment with dopamine receptor blocking agent (DRBA).
- The member must have a total AIMS score (items 1-7) of ≥ 6 or AIMS score on item 8 or item 9 ≥ 3

Renewal Criteria – Approval Duration: 12 months
- The member must have had improvement in AIMS score from baseline

Special Orders: Elections

Presiding Officer and Vice-Presiding Officer Elections

Unfinished Business

Summary of Changes

Cardiologist has been added as a specialist able to prescribe Lokelma and Veltassa. SPS has been added to PDL as a preferred drug not requiring prior authorization.

Hyperkalemia (Chronic)

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
SPS (sodium polystyrene sulfonate) SUSPENSION	
PREFERRED AGENTS (CLINICAL PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**
LOKELMA (sodium zirconium cyclosilicate)	VELTASSA (patiromer)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 3 months

- The requested medication must be prescribed by, or in consult with, a nephrologist or cardiologist.
- If member is on renal dialysis, Medicare eligibility must be ruled out *(6-month approval may be allowed to determine eligibility)*.
- The member's current serum potassium level must be exceeding the upper limit of normal, as evidenced by documentation from at least two separate lab values, submitted with the request.
- The member must have failed 30-day trials with at least two of the following products:
  - bumetanide, chlorothiazide, fludrocortisone, furosemide, hydrochlorothiazide, indapamide, metolazone, torsemide
- The member must not be receiving nonsteroidal anti-inflammatory drugs (NSAIDs)

Non-Preferred Agent Criteria:

- The member must have failed a 30-day trial with Lokelma, as evidenced with paid claims or pharmacy print outs.

Renewal Criteria – Approval Duration: 12 months

- The member's current serum potassium level is within normal limits or has been significantly reduced from baseline, as evidenced by lab documentation submitted with the request.

Reference:

1. *Rossing, Peter, et al. "KDIGO 2022 clinical practice guideline for diabetes management in chronic kidney disease." Kidney International 102.5 (2022): S1-S127.*

New Business:

Second Reviews

Acid Blockers

Proton Pump Inhibitors

Solid Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	PREFERRED STEP 1 AGENTS (ELECTRONIC STEP)	NON-PREFERRED STEP 2 AGENTS (PA REQUIRED)
DEXILANT (dexlansoprazole) *– Brand Required*	esomeprazole magnesium	ACIPHEX (rabeprazole)
Lansoprazole		dexlansoprazole
Omeprazole		NEXIUM (esomeprazole)
Pantoprazole		omeprazole-sodium bicarbonate
Rabeprazole		PREVACID (lansoprazole)
		PRILOSEC (omeprazole)
		PROTONIX (pantoprazole)
		ZEGERID (omeprazole/sodium bicarbonate)

Electronic Step Therapy Required

- Preferred Step 1 Agents: Member must have failed 14-day trial of at least 2 preferred agents at max dose within 365 days.

Prior Authorization Criteria

Initial Criteria - Approval Duration: 6 months

- Non-Preferred Agents Criteria - Step 2 Agents:
  - Member must have failed a 30-day trial with all preferred agents (including Step 1 Agents), as evidenced by paid claims or pharmacy printouts.
  - Clinical justification must be provided explaining why the member is unable to use the other agents (subject to clinical review).

Non-Solid Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED (PA REQUIRED)
lansoprazole ODT	esomeprazole solution packet
NEXIUM (esomeprazole) PACKET- *Brand Required*	KONVOMEP (omeprazole/sodium bicarbonate)
PROTONIX (pantoprazole) PACKET *– Brand Required*	omeprazole-sodium bicarbonate packet
	pantoprazole packet
	PREVACID (lansoprazole) SOLUTAB
	PRILOSEC SUSPENSION (omeprazole)
	ZEGERID (omeprazole-sodium bicarbonate) PACKET

Prior Authorization Criteria

Initial Criteria - Approval Duration: 6 months

- Member must have failed a 30-day trial with all preferred agents, as evidenced by paid claims or pharmacy printouts.
- Clinical justification must be provided explaining why the member is unable to use the other agents (subject to clinical review).

Electronic Age Verification

- Nexium 2.5 mg and 5 mg Packet: The member must be less than 1 years old (or less than 7.5 kg)

Therapeutic Duplication

- One strength of one medication is allowed at a time.
- Proton Pump Inhibitors is not allowed with:
  - Esomeprazole or omeprazole are not covered with clopidogrel.
    - Other PPIs such as pantoprazole are covered with clopidogrel. Clopidogrel is a substrate for 2C19 and esomeprazole and omeprazole are strong 2C19 inhibitors and can decrease effectiveness of clopidogrel.
  - Dextroamphetamine/Amphetamine ER:
    - Proton Pump Inhibitors increase blood levels and potentiate the action of amphetamine. Co-administration of Adderall XR and gastrointestinal or urinary alkalizing agents should be avoided.
  - H2 Blockers: If either of the following circumstances apply, please call for an override by calling provider relations at 1-800-755-2604:
    - Member is experiencing nocturnal symptoms after compliance with nighttime dose of proton pump inhibitor. A two-month override may be approved for concurrent H2 blocker use.
    - H2 blocker is being used concurrently with a H1 blocker for severe allergy prophylaxis, unrelated to PPI use for GI symptoms.

References

1. Katz PO, Gerson LB, Vela MF. Guidelines for the diagnosis and management of gastroesophageal reflux disease. Am J Gastroenterol 2013;108:308-28.
2. Fackler WK, Ours TM, Vaezi MF, Richter JE. Long-term effect of H2RA therapy on nocturnal gastric breakthrough. Gastroenterology. 2002;122:625-632.

Potassium Competitive Acid Blocker

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
VOQUEZNA (vonoprazan)	

Prior Authorization Criteria

Initial Criteria - Approval Duration: 6 months

- The member must meet one of the following criteria (A or B):
  A. The member has a diagnosis of erosive esophagitis and have failed an 8-week trial of each of the following:
     - Omeprazole twice daily
     - Rabeprazole or esomeprazole daily.
  B. The member has severe esophagitis (LA Grade C/D disease)

Paroxysmal Nocturnal Hemoglobinuria (PNH)

C5 inhibitors

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ULTOMIRIS (ravulizumab)	SOLIRIS (eculizumab) – *Medical Billing Only*
ULTOMIRIS (ravulizumab) – *Medical Billing Only*	

C3 Inhibitors

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
EMPAVELI (pegcetacoplan)	

Factor B Inhibitors

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	FABHALTA (iptacopan)

Factor D Inhibitors

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	VOYDEYA (danicopan)

Prior Authorization Criteria

Initial Criteria - Approval Duration: 6 months

- The requested medication must be prescribed by, or in consult with, a hematologist.
- Diagnosis must be confirmed by flow cytometry demonstrating that the member's peripheral blood cells are deficient in glycosylphosphatidylinositol (GPI) – linked proteins (e.g., CD55, CD59)
- One of the following criteria must be met (A, B, or C):
  A. The member has had at least 1 transfusion in the past 6 months
  B. The member has symptoms of PNH (e.g., abdominal pain, anemia, shortness of breath, hemolysis, organ dysfunction, debilitating fatigue) and one of the following:
     - granulocyte PNH clone size > 10%
     - hemoglobin < 10 g/dL
  C. LDH level of 1.5 times the upper limit of normal (must include at least 2 different reagents tested on at least 2 cell lineages)

Non-Preferred Agent Criteria:

Fabhalta Only:

- The member must have failed a 6-month trial with Empaveli, as evidenced by paid claims or printouts, with one of the following criteria being met (A, B, C):
  A. The member has had at least 1 transfusion in the past 6 months
  B. The member has symptoms of PNH (e.g., abdominal pain, anemia, shortness of breath, hemolysis, organ dysfunction, debilitating fatigue) and one of the following:
     - granulocyte PNH clone size > 10%
     - hemoglobin < 10 g/dL
  C. LDH level of 1.5 times the upper limit of normal (must include at least 2 different reagents tested on at least 2 cell lineages)

Voydeya Only:

- The member must have failed a 6-month trial with Ultomiris, with at least one transfusion, persistent anemia (Hb < 9.5 g/dL) and absolute reticulocyte count ≥ 120 × 109 /L, as evidenced by paid claims or printouts.

Soliris Only:
- The member must have failed a 6-month trial with Ultomiris with Voydeya, as evidenced by paid claims or printouts, with at least one transfusion, persistent anemia (Hb < 9.5 g/dL) and absolute reticulocyte count ≥ 120 × 109 /L, as evidenced by paid claims or printouts.

Renewal Criteria - Approval Duration: 12 months
- The member must have experienced meaningful clinical benefit since starting treatment with the requested medication, as evidenced by one of the following:
  - Member has not required transfusion in the past 6 months
  - Increase in hemoglobin by ≥ 2 g/dL from baseline
  - Normal LDH levels ≤ 280 U/L

Non-Preferred Agent Criteria:
Fabhalta Only:
- The member must have experienced one of the clinical benefit metrics defined in the renewal criteria that was not met Empaveli.

Voydeya Only:
- The member must have experienced one of the clinical benefit metrics defined in the renewal criteria that was not met Ultomiris.

Soliris Only:
- The member must have experienced one of the clinical benefit metrics defined in the renewal criteria that was not met Ultomiris with Voydeya.

References:

1. Parker, Charles J. "Update on the diagnosis and management of paroxysmal nocturnal hemoglobinuria." Hematology 2014, the American Society of Hematology Education Program Book 2016.1 (2016): 208-216.

Duchenne Muscular Dystrophy

Corticosteroids

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AGAMREE (vamorolone)	deflazacort
EMFLAZA (deflazacort) – *Brand Required*	

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months
- Diagnosis must be confirmed by the documented presence of abnormal dystrophin or a confirmed mutation of the dystrophin gene
- The requested medication must be prescribed by, or in consult with, a neurologist

- Onset of weakness must have occurred before 2 years of age
- The member must have serum creatinine kinase activity of at least 10 times the upper limit of normal (ULN) prior to initiating treatment
- The member must have failed a 6-month trial of prednisone, as evidenced by paid claims or pharmacy printouts
- The provider must submit baseline assessment results from the following assessments (the member does not have to meet all of these parameters, but each assessment must be submitted, and provider must indicate which parameters are met and being preserved, must be at least one):
    - Stable cardiac function LVEF > 40% by ECHO
    - Scoliosis not requiring surgery
    - Stable respiratory function – FVC predicted > 50%, not requiring ventilatory assistance
    - The provider must submit baseline motor milestone score results from at least ONE the following assessments:
        - 6-minute walk test (6MWT)
        - North Star Ambulatory Assessment (NSAA)
        - Motor Function Measure (MFM)
        - Hammersmith Functional Motor Scale (HFMS)
        - Performance of Upper Limb (PUL)
- The member must have ONE of the following significant intolerable adverse effects supported by documentation:
    i. Cushingoid appearance
    ii. Central (truncal) obesity
    iii. Severe behavioral adverse effect
    iv. Undesirable weight gain (>10% of body weight gain increase over 6-month period)
    v. Diabetes and/or hypertension that is difficult to manage

Renewal Criteria – Approval Duration: 12 months

- The member must have experienced stabilization, slowing of disease progression, or improvement of the condition since starting treatment with the requested medication, as evidenced by medical documentation (e.g., chart notes) attached to the request (subject to clinical review) including the following assessments (the member does not have to meet all of these parameters, but each assessment must be submitted, and provider must indicate which parameters are met and being preserved, must be at least one):
    - Stable cardiac function LVEF > 40% by ECHO
    - Scoliosis not requiring surgery
    - Stable respiratory function – FVC predicted > 50%, not requiring ventilatory assistance
    - Motor function assessment
        - 6MWT – improvement of 20 meters from baseline
        - NSAA – improvement of 2 points from baseline
        - MFM – improvement of 2 points from baseline
        - HFMS – improvement of 2 points from baseline
        - PUL – improvement of 4 points from baseline
- The member must have had improvement of adverse effects experienced on prednisone supported by documentation:
    i. Cushingoid appearance
    ii. Central (truncal) obesity
    iii. Severe behavioral adverse effect
    iv. Undesirable weight gain (>10% of body weight gain increase over 6-month period)
    v. Diabetes and/or hypertension that is difficult to manage

Genetic Therapies

Exon 45 Skipping

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)

AMONDYS 45 (casimersen) – *Medical Billing Only*	

Exon 51 Skipping

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
EXONDYS 51 (eteplirsen) – *Medical Billing Only*	

Exon 53 Skipping

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
VILTEPSO (viltolarsen) – *Medical Billing Only*	VYONDYS 53 (golodirsen) – *Medical Billing Only*

High-Cost Drug:
Amondys 45, Exondys 51, and Vyondys 53 cost $758,000 per year for a 30 kg child.
Viltepso cost $733,200 per year for a 30 kg child.

- Amondys 45 is awaiting verification of clinical benefit in confirmatory trials. In Study 1 (NCT02500381), individuals treated with Amondys 45 observed an increase in mean dystrophin protein levels of 0.81%, while the placebo arm observed a mean increase of 0.22%.
- Exondys 51 is awaiting verification of clinical benefit in confirmatory trials. In Study 1, there was no significant difference in change in 6MWD in patients treated with Exondys 51 and placebo. All 12 individuals enrolled in Study 1, continued treatment with open-label Exondys 51 and were compared to an external control group. Study 2 failed to provide evidence of a clinical benefit of Exondys 51 compared to the external control group. In Study 3, the median increase in dystrophin level was 0.1% in 12 evaluable individuals receiving open-label Exondys 51.
- Viltepso is awaiting verification of clinical benefit in confirmatory trials. In Study 1 (NCT02740972), 8 individuals treated with Viltepso observed a mean increase in dystrophin of 5.3% of normal levels.
- Vyondys 53 is awaiting verification of clinical benefit in confirmatory trials. In Study 1 (NCT02310906), 25 individuals treated with Vyondys 53 observed a mean increase in dystropin of 0.92% of normal levels.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 8 weeks

- The member must be assigned male at birth between ages of 4 and 19 years old
- Diagnosis must be confirmed by the documented presence of abnormal dystrophin or a confirmed mutation of the dystrophin gene
- The requested medication must be prescribed by, or in consult with, a neurologist
- The member has had an inadequate treatment response with standard corticosteroid therapy for a minimum of 6 months with adherence, as evidenced by paid claims or pharmacy printouts
- Medical records must be provided confirming the member has:
  - A baseline 6-Minute Walk Time (6MWT) ≥ 300 meters while walking independently (e.g., without side-by-side assist, cane, walker, wheelchair, etc.)
  - Stable respiratory function – FVC predicted > 50%, not requiring ventilatory assistance
  - Stable cardiac function – LVEF > 40 % by ECHO
- Weight and calculated dose must be provided consistent with approved FDA dose
- The member must not be taking any other RNA antisense agent or any other gene therapy

Non-Preferred Agent Criteria (Initial)

- Please provide explanation with the request why the preferred agent cannot be used (subject to clinical review)

Renewal Criteria – Approval Duration: 12 months

- Medical records must be provided confirming the member has maintained:

- A 6MWT ≥ 300 meters while walking independently (e.g., without side-by-side assist, cane, walker, wheelchair, etc.)
- Stable respiratory function – FVC predicted > 50%, not requiring ventilatory assistance
- Stable cardiac function – LVEF > 40 % by ECHO

Primary Hyperoxaluria Type 1 (PH1)

RNA interference (RNAi)

CLINICAL PA REQUIRED
OXLUMO (lumasiran) – *Medical Billing Only*
RIVFLOZA (nedosiran)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a nephrologist, urologist or geneticist
- The member's diagnosis must be documented by one of the following:
  - Mutation in the alanine: glyoxylate aminotransferase (AGXT) gene confirmed by genetic testing
  - Liver enzyme analysis confirming absent or significant deficiency in alanine: glyoxylate aminotransferase (AGT) activity
- The member has a failed to achieve at least a 30% reduction in urinary oxalate excretion after a 90-day trial of pyridoxine (vitamin B6) of maximally tolerated doses (maximum dose, 20 mg/kg per day)
- The member has not received a liver transplant
- Documentation of the one of the following must be submitted:
  - Elevated urinary oxalate excretion > 1 mmol/1.73 m^2 per day or 90 mg/1.73 m^2 per day
  - Elevated urinary oxalate: creatinine ratio as defined by age defined laboratory reference range

Renewal Criteria – Approval Duration: 12 months

- The member must have experienced meaningful clinical benefit since starting treatment with the requested medication, as evidenced by medical documentation (e.g., chart notes) attached to the request (subject to clinical review) including one of the following scores and symptoms:
  - Reduced signs and symptoms of PH1 (e.g., nephrocalcinosis, formation of renal stones, renal impairment)
  - Decrease of 30% from baseline or normalization of urinary oxalate excretion
  - Decreased or normalized urinary oxalate: creatinine ratio relative to normative values for age

Myasthenia Gravis

Glucocorticoid-Sparing Therapy

Oral Agents

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
azathioprine	
cyclosporine	
mycophenolate mofetil	

tacrolimus	

Biologic Agents

Acetylcholine Receptor (AChR) Antibody Positive

PREFERRED AGENTS (NO PA REQUIRED)	PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
RIABNI (rituximab-arrx) *– Medical Billing Only*	ULTOMIRIS (ravulizumab) *– Medical Billing Only*	SOLIRIS (eculizumab) *– Medical Billing Only*
RITUXAN (rituximab) *– Medical Billing Only*	RYSTIGGO (rozanolixizumab-noli) *– Medical Billing Only*	
RUXIENCE (rituximab-pvvr) *– Medical Billing Only*	VYVGART (ergartigimod alfa) *– Medical Billing Only*	
TRUXIMA (rituximab-abbs) *– Medical Billing Only*	VYVGART HYTRULO (efgartigimod alfa/hyaluronidase) *– Medical Billing Only*	
	ZILBRYSQ (zilucoplan)	

Muscle Specific Kinase (MuSK) Positive

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
RIABNI (rituximab-arrx) – *Medical Billing Only*	RYSTIGGO (rozanolixizumab-noli) *– Medical Billing Only*
RITUXAN (rituximab) – *Medical Billing Only*	
RUXIENCE (rituximab-pvvr) – *Medical Billing Only*	
TRUXIMA (rituximab-abbs) – *Medical Billing Only*	

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months (1 year total for bridge therapy)

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational).
- The requested medication must be prescribed by, or in consult with, a neurologist or neuromuscular specialist.
- The member must have all of the following:
  - Myasthenia Gravis Foundation of America (MGFA) clinical classification class of II, III, or IV
  - Positive serological lab test for one of the following (A or B):
    A. Anti-AchR antibodies
    B. Anti-MuSK antibodies
- The member must have Myasthenia Gravis-specific Activities of Daily Living (MG-ADL) total score of one of the following:
  - For Zilbrysq (zilucoplan), Soliris (eculizumab), or Ultomiris (ravulizumab-cwvz) requests: ≥ 6
  - For Vyvgart (efgartigimod alfa-fcab) or Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc) requests: ≥ 5
  - For Rystiggo (rozanolixizumab-noli) requests: ≥ 3 (with at least 3 points from non-ocular symptoms

Acetylcholine Receptor (AChR) Antibody Positive

- One of the following (A or B):
  A. The member is unable to complete glucocorticoid bridge therapy (e.g., diabetes) while waiting for efficacy of oral immunosuppressive therapies (e.g., azathioprine, cyclosporine, mycophenolate mofetil, tacrolimus)
  B. The member required chronic intravenous immunoglobulin (IVIG) or chronic plasmapheresis/plasma exchange (i.e., at least every 3 months over 12 months without symptom control), despite a 12-month

trial (total duration) of immunosuppressive therapies (e.g., azathioprine, cyclosporine, mycophenolate mofetil, tacrolimus)

Muscle Specific Kinase (MuSK) Positive

- The member required chronic intravenous immunoglobulin (IVIG) or chronic plasmapheresis/plasma exchange (i.e., at least every 3 months over 12 months without symptom control), despite a 90-day trial of rituximab.

Soliris Only:

- The member required chronic intravenous immunoglobulin (IVIG) or chronic plasmapheresis/plasma exchange (i.e., at least every 3 months over 12 months without symptom control), despite a 90-day trial or recommended cycle duration of each of the following:
  A. Rituximab
  B. Ultomiris
  C. Vyvgart or Rystiggo

Renewal Criteria – Approval Duration: 12 months

- The member must have experienced meaningful clinical benefit since starting treatment with the requested medication, as evidenced by one of the following scores and symptoms (subject to clinical review):
  - Decreased rate of Myasthenia Gravis exacerbations
  - A 2-point improvement in the member's total MG-ADL score

Seborrheic Dermatitis

See Antifungals – Topical

See Steroids - Topical

Topical Phosphodiesterase-4 (PDE-4) Inhibitors

CLINICAL PA REQUIRED
ZORYVE (roflumilast) FOAM

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- The member must have had a 4-week trial of concurrent use of a topical antifungal (shampoo or foam) AND a high potency topical corticosteroid (foam, spray or shampoo).

FIRST REVIEW OF MOLLUSCUM CONTAGIOSUM

Molluscum contagiosum is a viral skin infection consisting of skin lesions or Mollusca. This skin infection can be contracted by contact with infected persons and inanimate objects. Symptoms are self-limiting and usually resolve within 6-12 months but can last 4-5 years. Since symptoms are self-limiting, treatment is optional for immunocompetent patients. Treatment is recommended for those who are immunocompromised or who contract the infection by sexual contact.

Population: 6 million Americans (5% of children), primarily pediatrics but can occur in adults as well

Treatment: Lack of clinical guideline or consensus recommendations for treatment

- In office procedures: ablation, cryotherapy, laser
- Off label use of various medications (tretinoin, imiquimod, podophyllotoxin cream, OTC products) have been proven to be efficacious
- FDA approved medications: Ycanth and Zelsuvmi
- If dermatitis is present, the use of short-term topical corticosteroids can prevent spreading

General key notes for treatment options:

- For topical use only
- Both have risk of skin reactions

Ycanth (cantharidin)	
Labeled population	Adults and pediatrics ≥ 2 years old
Mechanism	Vesicant: blistering agent leads to the disappearance of lesion and healing without scarring
Administration	• Delivered by healthcare provider (HCP) with a single use applicator over 2-4 visits every 3 weeks • Not for ophthalmic, mucosal, or oral use
Key Points	• Ocular contact toxicities: corneal necrosis, ocular perforation, deep ocular injuries • Oral contact toxicities: renal failure, blistering/damage to GI tract, coagulopathy, seizures
Cost	$1370-5480; would be billed on medical side
Zelsuvmi (berdazimer)	
Labeled population	Adults and pediatrics ≥ 1 year old
Mechanism	Nitric oxide releasing agent, exact mechanism for treatment of molluscum contagiosum is unknown
Administration	• Applied by patient or caregiver at home once daily to each lesion up to 12 weeks • Not for ophthalmic, intravaginal, or oral use
Key notes	Possible challenges regarding storage and delivery to ensure stability
Cost	Estimated $2740 per treatment course; would be billed on pharmacy side

Based on lowest per unit WAC cost

FDA Approval

Ycanth (cantharidin): July 21, 2023; 505(b) New Drug Application (NDA) pathway Type 5 New Formulation of New Manufacturer, STANDARD

Zelsuvmi (berdazimer): January 5, 2024; 505(b) New Drug Application (NDA) pathway Type 1 New Molecular Entity, STANDARD

Clinical Trials

Zelsuvmi: Approval was based on three B-SIMPLE Phase 3 multicenter, randomized, double-blind, parallel-group, vehicle-controlled trial consisting of a total of 1598 patients. Eligible patients included those ≥ 6 months of age in generally good health with 3-70 lesions. Trials: B-SIMPLE 4 (NCT04535531), B-SIMPLE 2 (NCT03927703), B-SIMPLE 1 (NCT03927716)

Primary Endpoint: Complete clearance at week 12 in B-SIMPLE 4 showed 32.4% Zelsuvmi (n = 144) vs 19.7% vehicle (n = 88) (p <0.001)
**Efficacy was not statistically significant in B-SIMPLE 1 and 2*

Secondary Endpoint: Complete clearance at week 8 in B-SIMPLE 4 showed 19.6% Zelsuvmi (n = 87) vs 11.6% vehicle (n = 88) (p=0.001) and B-SIMPLE 2 showed 13.9% Zelsuvmi (n = 33) vs 5.9% vehicle (n = 7) (p=0.028)

Safety: Main adverse effects were application pain and erythema

**Only included Zelsuvmi clinical trials; Ycanth would be billed on the medical side*

Place in Therapy

Recommended for immunocompromised members or who contract the infection by sexual contact; optional for immunocompetent patients.

Advantages	Disadvantages
• Data supporting use and FDA approval • Zelsuvmi: at home treatment	• High cost • No head-to-head comparisons • Painful treatment that may lead to scarring

Current Utilization

	Quarter 3 2023 – Quarter 1 2024		
Medication	**Rx Count**	**Rx Count**	**% of Rx**
Ycanth	0	0%	$0
Zelsuvmi	0	0%	$0

References:

1. *Zelsuvmi (berdazimer) topical gel. [prescribing information]. Wilmington, Delaware: EPIH SPV, LLC; January 2024.*
2. *U.S. Food and Drug Administration, Center for Drug Evaluation and Research. Zelsuvmi NDA 217424 approval letter, January 5, 2024. https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2024/217424Orig1s000ltr.pdf*
3. *Zelsuvmi (berdazimer): New Drug Review. IPD Analytics. Aventura, FL. February 2024. https://www.ipdanalytics.com*
4. *Zelsuvmi. Quick Answers and Red Book. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. January 17, 2024. https://www.micromedexsolutions.com*
5. *Ycanth* (cantharidin) topical solution. *[prescribing information]. West Chester, PA: Verrica Pharmaceuticals, Inc; July 2023.*
6. *U.S. Food and Drug Administration, Center for Drug Evaluation and Research. Ycanth NDA 212905 approval letter, July 21, 2023. https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2023/212905Orig1s000ltr.pdf*
7. *Ycanth. Quick Answers and Red Book. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. December 8, 2023. https://www.micromedexsolutions.com*
8. *Isaacs SN. Molluscum contagiosum. UpToDate, Hirsch MS, Levy ML, Rosen T (Ed) [Internet]. Waltham, MA: UptoDate; January 10, 2024. Available from: www.uptodate.com*

FIRST REVIEW OF EPIDERMOLYSIS BULLOSA

Epidermolysis bullosa (EB) is a rare genetic disorder which leads to impaired skin structural proteins and fragile skin. Mild friction can cause painful and chronic blisters, erosions, ulcers, and fibrosis; these wounds may take years to heal. Patients can also experience damage to mucosal tissues of the gastrointestinal, respiratory, and urinary tract and develop further complications such as malnutrition, electrolyte abnormalities, anemia, and strictures. The 4 types of EB are classified by their gene mutation and level of blistering: EB simplex (EBS), dystrophic EB (DEB), junctional EB (JEB), and kindler EB (KEB). There are FDA approved wound treatments for DEB and JEB which are the more severe subtypes.

Population: Estimated 1100 patients with DEB and less than 200 patients with JEB in the United States

Treatment: Individualized, multidisciplinary treatment should address wound care, infection control, nutritional needs, and prevention/treatment of complications

- **Wound Treatment:** FDA approved medications are Vyjuvek and Filsuvez; locally acting and not curative
  - Patients with mild disease may not require treatment with these agents

Vyjuvek (beremagene geperpavec-svdt)	
Labeled population	Adults and pediatrics ≥ 6 months old with DEB
Mechanism	Topical gene therapy that delivers copies of the COL7A1 gene, the mutation that causes DEB
Administration	• Applied once weekly to open wounds by HCP • Max specified weekly dosing
Cost (annual)	Up to $1,271,400; billed on medical side
Filsuvez (birch triterpenes)	
Labeled population	Adults and pediatrics ≥ 6 months old with DEB and JEB
Mechanism	Keratinocyte activator that is thought to promote wound healing; exact mechanism for treatment in DEB is unknown
Administration	• Applied by patient or caregiver at home to open partial-thickness wounds at dressing changes until healing occurs • Each tube is for one time use only • Topical use; not for oral, intravaginal, intra-anal, or ophthalmic use
Key notes	• Main adverse reaction is application site reactions • Cannot use with active infection present
Cost (annual)	$583,200 (based on average use of 27 tubes per month in studied patients); billed on pharmacy side

Based on lowest per unit WAC cost; cost will vary based on frequency of administrations and extent of wounds

FDA Approval

Filsuvez (birch triterpenes): December 18, 2023; 505(b) New Drug Application (NDA) pathway Type 1 New Molecular Entity, PRIORITY, Orphan

Clinical Trials

Approval was based on Phase 3 EASE (NCT03068780) double-blind, randomized, vehicle-controlled trial consisting of 223 patients with DEB and JEB. Patients included in the trial were at least 6 months old and had a target wound present for 21 days to 9 months.

Primary Endpoint: First complete closure of target wound within 45 days showed 41.3% Filsuvez vs. 28.9% placebo (p = 0.01)
*Only shown to be efficacious in patients with DEB

Secondary Endpoints: Secondary endpoints were not met except for greater reduction in pain in patients ≥ 4 years of age at day 14 (p=0.022).

Safety: Similar to placebo, mainly application site reactions

Place in Therapy

Patients with DEB requiring wound treatment. The agent was not shown to be efficacious for patients with JEB.

Advantages	Disadvantages
• First FDA approved treatment option for JEB • Second FDA approved treatment option for DEB	• High cost • No evidence showing efficacy in patients with JEB • No head-to-head comparisons or data showing use alongside Vyjuvek • Frequent administrations • Lack of long-term data • Cannot use with active infection • Did not meet secondary endpoints

Current Utilization

	Quarter 2 2023 – Quarter 1 2024		
Vyjuvek	0	0%	$0
Filsuvez	0	0%	$0

References:

1. *Filsuvez (birch triterpenes) topical gel. [prescribing information]. Wahlstedt Germany: Lichtenheldt GmbH; December 2023.*
2. *U.S. Food and Drug Administration, Center for Drug Evaluation and Research. Filsuvez NDA 215064 approval letter, December 18, 2023. https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2024/215064Orig1s000correctedltr.pdf*
3. *Filsuvez (birch triterpenes). New Drug Review. IPD Analytics. Aventura, FL. March 2024. https://www.ipdanalytics.com*
4. *Filsuvez. Quick Answers. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. April 15, 2024. https://www.micromedexsolutions.com*
5. *Vyjuvek. Quick Answers. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. August 11, 2023. https://www.micromedexsolutions.com*
6. *Murrell DF. Overview of the management of epidermolysis bullosa. UpToDate, Hand JL, Corona R (Ed) [Internet]. Waltham, MA: UptoDate; January 8, 2024. Available from: www.uptodate.com*

FIRST REVIEW OF METABOLIC DYSFUNCTION–ASSOCIATED STEATOHEPATITIS

Metabolic dysfunction-associated steatohepatitis (MASH) is the most severe form of metabolic dysfunction-associated steatotic liver disease (MASLD); these conditions are associated with hepatic steatosis without heavy alcohol use. MASH can lead to the development of cirrhosis and/or liver cancer.

Population: 1.5-6.5% adults in the United States

Treatment:

- Modifying risk factors including elimination of alcohol use, management of cardiovascular disease risk factors (e.g., hypertension, dyslipidemia, diabetes)
- Patients who are unable to meet weight loss goals and have developed moderate to severe fibrosis may require liver targeted therapy
    - Rezdiffra is the first FDA approved treatment for MASH that is to be used in combination with lifestyle modifications
    - Vitamin E and pioglitazone have been used off-label but there is minimal data to support the use of these agents

MASH and MASLD were formerly known as non-alcoholic steatohepatitis (NASH) and nonalcohol-associated fatty liver disease (NAFLD) respectively.

Rezdiffra (resmetirom)	
Labeled population	Adults, MASH with moderate to severe fibrosis (F2-F3) in conjunction with diet and exercise
Mechanism	Thyroid hormone receptor-beta partial agonist
Administration	Oral, once daily (weight-based dosing)
Key Points	• Cannot be used in patients with decompensated cirrhosis • Warnings/precautions due to the risk of hepatotoxicity and gallbladder adverse effects (cholelithiasis, acute cholecystitis, obstructive pancreatitis) • Drug interactions: CYP2C8 inhibitors and substrates, OAT1B1 and OAT1B3 inhibitors, statins
Cost (annual)	$48,058

Based on lowest per unit WAC cost for a patient weighing 100 kg

FDA Approval

Rezdiffra (resmetirom): March 14, 2024; 505(b) New Drug Application (NDA) pathway Type 1 New Molecular Entity, PRIORITY

Clinical Trials

Approval was based on MAESTRO-NASH (NCT03900429), a Phase 3 randomized, double-blind, placebo-controlled trial consisting of 888 patients with biopsy confirmed MASH. Eligible patients included those with F2 and F3 fibrosis, NAFLD Activity Score (NAS) ≥ 4, and metabolic risk factors. Patients were randomized 1:1:1 to receive Rezdiffra 80 mg, Rezdiffra 100 mg, and placebo daily.

Primary Endpoints:

- Resolution of steatohepatitis without fibrosis worsening: 25.9% Rezdiffra 80 mg, 29.9% Rezdiffra 100 mg, vs 9.7% placebo ($p<0.001$ for Rezdiffra 80 and 100 mg)
- Improvement of fibrosis by ≥1 stage without worsening of steatohepatitis at 12 months: 24.2% Rezdiffra 80 mg, 25.9% Rezdiffra 100 mg, vs 14.2% placebo ($p<0.001$ for Rezdiffra 80 and 100 mg)

Secondary endpoint:
Reduction of LDL-C level at 24 weeks: -13.6% Rezdiffra 80 mg, -16.3% Rezdiffra 100 mg, 0.1% placebo (p=<0.001 for Rezdiffra 80 and 100 mg)

Safety: main adverse effects were gastrointestinal (nausea, vomiting, diarrhea, constipation, abdominal pain), pruritis, and dizziness

Place in Therapy

May be considered for patients that have developed moderate to severe fibrosis

Advantages	Disadvantages
• First FDA approved agent for MASH	• Adverse effects may decrease adherence

Current Utilization

	Quarter 1 2024		
Medication	**Rx Count**	**% of Rx**	**Reimb Amount**
Rezdiffra	0	0%	$0

References:

1. *Rezdiffra (resmetirom) tablets, for oral use. [prescribing information]. West Conshohocken, PA: Madrigal Pharmaceuticals, Inc; March 2024.*
2. *U.S. Food and Drug Administration, Center for Drug Evaluation and Research. Rezdiffra NDA 217785 approval letter, March 14, 2024. https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2024/217785Orig1s000ltr.pdf*
3. *Rezdiffra (resmetirom): New Drug Review. IPD Analytics. Aventura, FL. March 2024. https://www.ipdanalytics.com*
4. *Harrison SA, Bedossa P, Guy, CD, Schattenberg JM, Loomba R, et al. A Phase 3, randomized, controlled trial of resmetirom in NASH with liver fibrosis. N Eng J Med. 2024; 390(6):497-509. doi:10.1056/NEJMoa2309000*
5. *Rezdiffra. Quick Answers and Red Book. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. April 2, 2024. https://www.micromedexsolutions.com*
6. *Chopra S, Lai M. Management of metabolic dysfunction-associated steatotic liver disease (nonalcoholic fatty liver disease) in adults. UpToDate, Lindor K, Robson KM (Ed) [Internet]. Waltham, MA: UptoDate; February 28, 2024. Available from: www.uptodate.com*
7. *Tendler DA. Pathogenesis of metabolic dysfunction-associated steatotic liver disease (nonalcoholic fatty liver disease). UpToDate, Lindor K, Robson KM (Ed) [Internet]. Waltham, MA: UptoDate; August 23, 2022. Available from: www.uptodate.com*

NORTH DAKOTA MEDICAID
RETROSPECTIVE DRUG UTILIZATION REVIEW
CRITERIA RECOMMENDATIONS
DUR BOARD MEETING MARCH 2024

1. Antipsychotics / ND Drugs Covered for Weight Gain (Negating)
Alert Message: The use of antipsychotics has been associated with the development of metabolic disturbances. All patients receiving antipsychotic treatment should have baseline weight and metabolic parameter levels obtained at initiation and regular monitoring of metabolic parameters throughout therapy. Products covered for antipsychotic-induced weight gain can be found in the PDL.

Drugs/Diseases

Util A	Util B	Util C (Negating)
Antipsychotics		Victoza
		Metformin
		Phentermine

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Zeier K, Connell R, Resch W, et al. Recommendations for Lab Monitoring of Atypical Antipsychotics. Current Psychiatry. 2013;12(No. 9):51-54.
Pillinger T, McCutcheon RA, Vano L, et.al., Comparative Effects of 18 Antipsychotics on Metabolic Function in patients with Schizophrenia, Predictors of Metabolic Dysregulation, and Association with Psychopathology: A Systematic Review and Network Meta-Analysis. Lancet Psychiatry. 2020 Jan;7(1):64-77.

2. Antibiotics / Viral Infections / Bacterial Infections
Alert Message: Based on a review of the patient's medical history, the patient has received antibiotic therapy and has a diagnosis of a viral infection but no diagnosis of a bacterial infection. Inappropriate antibiotic use is a contributor to antibiotic resistance, as well as putting the patient at risk for antibiotic-related adverse events.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Oral Antibiotics	Viral Infections	Bacterial Infections

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Centers for Disease Control and Prevention, Core Elements of Outpatient Antibiotic Stewardship (Department of Health and Human Services) last Reviewed 2021. www.cdc.gov/antibiotic-use/core-elements/outpatient.html#print Accessed March 2024.
The Pew Charitable Trusts, "Study Shows That Inappropriate Antibiotic Prescribing for Children Leads to Increased Costs, Complications" (2022), https://www.pewtrusts.org/en/research-and-analysis/fact-sheets/2022/05/study-shows-that-inappropriate-antibiotic-prescribing-for-children-leads-to-increased-complications. Accessed March 2024.

NORTH DAKOTA MEDICAID
RETROSPECTIVE DRUG UTILIZATION REVIEW
CRITERIA RECOMMENDATIONS
DUR BOARD MEETING JUNE 2024

NORTH DAKOTA MEDICAID
RETROSPECTIVE DRUG UTILIZATION REVIEW
CRITERIA RECOMMENDATIONS
2ND QUARTER 2024

Criteria Recommendations	***Approved***	***Rejected***

1. Sitagliptin / Overuse _____ _____

Alert Message: Zituvio (sitagliptin) may be over-utilized. The manufacturer's recommended maximum dose is 100 mg once daily.

Drugs/Diseases

Util A	Util B	Util C
Sitagliptin		

Max Dose: 100 mg/day

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Zituvio Prescribing Information, Oct. 2023, Zydus Pharmaceuticals, Inc.

2. Sitagliptin / Therapeutic Appropriateness _____ _____

Alert Message: The safety and effectiveness of Zituvio (sitagliptin) have not been established in pediatric patients.

Drugs/Diseases

Util A	Util B	Util C
Sitagliptin		

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Zituvio Prescribing Information, Oct. 2023, Zydus Pharmaceuticals, Inc.

3. Sitagliptin / Moderate Renal Impairment _____ _____

Alert Message: The recommended dose of Zituvio (sitagliptin) in patients with moderate renal impairment (CrCl >/= 30mL/min/1.73m2 to < 45 mL/min/1.73m2) is 50 mg once daily. Patients with more severe renal insufficiency (CrCl < 30 mL/min/1.73m2) or with end-stage renal disease on hemodialysis or peritoneal dialysis should be dosed at 25 mg once daily. Assessment of renal function is recommended prior to initiation of sitagliptin therapy and periodically thereafter.

Drugs/Diseases

Util A	Util B	Util C
Sitagliptin	CKD 3	

Max Dose: 50 mg/day

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Zituvio Prescribing Information, Oct. 2023, Zydus Pharmaceuticals, Inc.

4. Sitagliptin / Moderate Renal Impairment _____ _____

Alert Message: The recommended dose of Zituvio (sitagliptin) in patients with severe renal insufficiency (CrCl < 30mL/min/1.73m2) or with end-stage renal disease on hemodialysis or peritoneal dialysis is 25 mg once daily. In patients with moderate renal impairment (CrCl >/=30 mL/min/1.73m2 to < 45mL/min/1.73m2) sitagliptin should be dosed at 50 mg once daily. Assessment of renal function is recommended prior to initiation of sitagliptin therapy and periodically thereafter.

Drugs/Diseases

Util A	Util B	Util C
Sitagliptin	CKD 4 & 5	
	ESRD	
	Dialysis	

Max Dose: 25 mg/day

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Zituvio Prescribing Information, Oct. 2023, Zydus Pharmaceuticals, Inc.

5. Sitagliptin / Type 1 Diabetes _____ _____

Alert Message: Zituvio (sitagliptin) should not be used in patients with type 1 diabetes mellitus.

Drugs/Diseases

Util A	Util B	Util C
Sitagliptin	Type 1 Diabetes	

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Zituvio Prescribing Information, Oct. 2023, Zydus Pharmaceuticals, Inc.

6. Sitagliptin / Insulin & Insulin Secretagogues _____ _____

Alert Message: The concurrent use of Zituvio (sitagliptin) with insulin and insulin secretagogues can increase the risk of hypoglycemia. A lower dose of insulin or insulin secretagogue may be required to minimize the risk of hypoglycemia when used in combination with ertugliflozin/sitagliptin.

Drugs/Diseases

Util A	Util B	Util C
Sitagliptin	Insulin	
	Insulin Secretagogues	

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Zituvio Prescribing Information, Oct. 2023, Zydus Pharmaceuticals, Inc.

Criteria Recommendations ***Approved Rejected***

7. Sitagliptin / Pregnancy / Pregnancy Negating _____ _____

Alert Message: There are no adequate and well-controlled studies of Zituvio (sitagliptin) in pregnant women. During pregnancy, consider appropriate alternative therapies. Sitagliptin should be used during pregnancy only if clearly needed.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Sitagliptin	Pregnancy	Abortion
		Delivery
		Miscarriage

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Zituvio Prescribing Information, Oct. 2023, Zydus Pharmaceuticals, Inc.
American Diabetes Association (ADA). 15. Management of Diabetes in Pregnancy. In Standards of Medical Care in Diabetes - 2023. Diabetes Care. 2023;46(Suppl. 1):S254-S266.

8. Sitagliptin / Lactation _____ _____

Alert Message: There is no information regarding the presence of Zituvio (sitagliptin) in human milk, the effects on the breastfed infant, or the effects on milk production. Sitagliptin is present in rat milk and, therefore, possibly present in human milk. The developmental and health benefits of breastfeeding should be considered, along with the mother's clinical need for sitagliptin and any potential adverse effects on the breastfed infant from sitagliptin or the underlying maternal condition.

Drugs/Diseases

Util A	Util B	Util C
Sitagliptin	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Zituvio Prescribing Information, Oct. 2023, Zydus Pharmaceuticals, Inc.

Criteria Recommendations	*Approved*	*Rejected*

9. Sitagliptin / Non-adherence _____ _____

Alert Message: Based on refill history, your patient may be under-utilizing Zituvio (sitagliptin). Nonadherence to the prescribed dosing regimen may result in subtherapeutic effects, which may lead to decreased patient outcomes and additional healthcare costs.

Drugs/Diseases

Util A	Util B	Util C
Sitagliptin		

References:

Osterberg L, Blaschke T. Adherence to Medication. N Engl J Med 2005; 353:487- 497.

Ho PM, Rumsfeld JS, Masoudi FA, et al., Effect of Medication Nonadherence in Diabetes Mellitus. Cardiology Review, April 2007, Vol. 24 No. 4. p.18-22.

Currie CJ, Peyrot M, Morgan CL, et al. The Impact of Treatment Noncompliance on Mortality in People With Type 2 Diabetes. Diabetes Care 35:1279-1284, June 2012.

Butler RJ, Davis TK, Johnson WL, et al. Effects of Nonadherence with Prescription Drugs Among Older Adults. Am J Manag Care. 2011 Feb; 17(2):153-60.

10. Tafamidis / Overuse _____ _____

Alert Message: Vyndamax (tafamidis) may be over-utilized. The recommended dosage of tafamidis is 61 mg once daily.

Drugs/Diseases

Util A	Util B	Util C
Tafamidis		

Max Dose: 61 mg/day

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.

Vyndaqel and Vyndamax Prescribing Information, Oct. 2023, Pfizer Inc.

Criteria Recommendations	*Approved*	*Rejected*

11. Tafamidis / Therapeutic Appropriateness _____ _____

Alert Message: The safety and effectiveness of Vyndamax (tafamidis) have not been established in pediatric patients.

Drugs/Diseases

Util A	Util B	Util C
Tafamidis		

Age Range: 0 – 17 yoa

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.

Vyndaqel and Vyndamax Prescribing Information, Oct. 2023, Pfizer Inc.

12. Tafamidis / BCRP Substrates _____ _____

Alert Message: Vyndamax (tafamidis) inhibits breast cancer resistant protein (BCRP) in humans. Coadministration of tafamidis and drugs that are BCRP substrates may increase the exposure of the BCRP substrates (e.g., methotrexate, rosuvastatin, and imatinib) and the risk of substrate-related toxicities. Monitor for signs of BCRP substrate-related toxicities and modify the dosage of the substrate if appropriate.

Drugs/Diseases

Util A	Util B		Util C
Tafamidis	Alpelisib	Prazosin	
	Berotralstat	Rosuvastatin	
	Dolutegravir	Talazoparib	
	Glyburide	Tenofovir	
	Methotrexate	Topotecan	
	Pazopanib	Ubrogepant	
	Pibrentasvir	Vemurafenib	

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.

Vyndaqel and Vyndamax Prescribing Information, Oct. 2023, Pfizer Inc.

Criteria Recommendations	*Approved*	*Rejected*

13. Tafamidis / Pregnancy / Pregnancy Negating _____ _____

Alert Message: Based on findings from animal studies, Vyndamax (tafamidis) may cause fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to a fetus. Report pregnancies to the Pfizer reporting line at 1-800-438-1985.

Drugs/Diseases

Util A	Util B	Util C (Negating)
Tafamidis	Pregnancy	Abortion
	Delivery	
	Miscarriage	

Gender: Female

Age Range: 11 – 50 yoa

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.

Vyndaqel and Vyndamax Prescribing Information, Oct. 2023, Pfizer Inc.

14. Tafamidis / Therapeutic Appropriateness _____ _____

Alert Message: There are no available data on the presence of Vyndamax (tafamidis) in human milk, the effect on the breastfed infant, or the effect on milk production. Tafamidis is present in rat milk. When a drug is present in animal milk, it is likely the drug will be present in human milk. Based on findings from animal studies that suggest the potential for serious adverse reactions in the breastfed infant, advise patients that breastfeeding is not recommended during treatment with tafamidis.

Drugs/Diseases

Util A	Util B	Util C
Tafamidis	Lactation	

Gender: Female

Age Range: 11 – 50 yoa

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.

Vyndaqel and Vyndamax Prescribing Information, Oct. 2023, Pfizer Inc.

Criteria Recommendations ***Approved Rejected***

15. Tafamidis / Non-adherence _____ _____

Alert Message: Based on refill history, your patient may be under-utilizing Vyndamax (tafamidis). Nonadherence to the prescribed dosing regimen may result in subtherapeutic effects, which may lead to decreased patient outcomes and additional healthcare costs.

Util A Util B Util C

Tafamidis

References:

Osterberg L, Blaschke T. Adherence to Medication. N Engl J Med 2005; 353:487- 497.
Kim J, Combs K, Downs J, Tillman F., Medication Adherence: The Elephant in the Room. US Pharm. 2018;43(1)30-34.

Kleinsinger, Fred. The Unmet Challenge of Medication Nonadherence. The Permanente Journal. Vol. 22 (2018): 18-033. doi:10.7812/TPP/18-033.

16. Levodopa Inhalation / Overuse _____ _____

Alert Message: Inbrija (levodopa inhalation) may be overutilized. The maximum recommended dose of levodopa inhalation per OFF period is 420 mg daily (2 capsules inhaled up to 5 times a day).

Drugs/Diseases

Util A Util B Util C

Levodopa Inhalation

Max Dose:

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.

Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.

Criteria Recommendations	*Approved*	*Rejected*

17. Levodopa Inhalation / Therapeutic Appropriateness _____ _____

Alert Message: The safety and effectiveness of Inbrija (levodopa inhalation) has not been established in pediatric patients.

Drugs/Diseases

Util A	Util B	Util C
Levodopa Inhalation		

Age Range: 0 – 17 yoa

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.

Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.

18. Levodopa Inhalation / Respiratory Disorders _____ _____

Alert Message: Because of the risk of bronchospasm, use of Inbrija (levodopa inhalation) in patients with asthma, COPD, or another chronic underlying lung disease is not recommended.

Drugs/Diseases

Util A	Util B	Util C
Levodopa Inhalation	Asthma	
	Bronchiectasis	
	Chronic Bronchitis	
	COPD	
	Cystic Fibrosis	
	Emphysema	
	Pulmonary Fibrosis	

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.

Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.

Criteria Recommendations	*Approved*	*Rejected*

19. Tirzepatide / Overuse _____ _____

Alert Message: Zepbound (tirzepatide) may be over-utilized. The maximum recommended dose of tirzepatide is 15 mg injected subcutaneously once weekly.

Drugs/Diseases

Util A	Util B	Util C
Tirzepatide		

Max Dose: 15 mg q weekly

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Zepbound Prescribing Information, Nov. 2023, Eli Lilly and Company.

20. Tirzepatide / Therapeutic Appropriateness _____ _____

Alert Message: The safety and effectiveness of Zepbound (tirzepatide) have not been established in pediatric patients younger than 18 years of age.

Drugs/Diseases

Util A	Util B	Util C
Tirzepatide		

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Zepbound Prescribing Information, Nov. 2023, Eli Lilly and Company.

21. Tirzepatide / Therapeutic Appropriateness _____ _____

Alert Message: Zepbound (tirzepatide) is contraindicated in patients with a personal or family history of MTC or patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2). Counsel patients regarding the potential risk of MTC and symptoms of thyroid tumors (e.g., a mass in the neck, dysphagia, dyspnea, persistent hoarseness).

Drugs/Diseases

Util A	Util B	Util C (Include)
Tirzepatide		Medullary Thyroid Carcinoma
		HX of Medullary Thyroid Carcinoma
		Multiple Endocrine Neoplasia Syndrome 2

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Zepbound Prescribing Information, Nov. 2023, Eli Lilly and Company.

Criteria Recommendations	*Approved*	*Rejected*

22. Tirzepatide / Therapeutic Appropriateness _____ _____

Alert Message: Zepbound (tirzepatide) causes a statistically significant increase in thyroid C-cell tumors in rats. It is unknown whether tirzepatide causes thyroid C-cell tumors, including medullary thyroid carcinoma (MTC) in humans, as the human relevance of tirzepatide-induced rodent thyroid C-cell tumors has not been determined.

Drugs/Diseases

Util A	Util B	Util C (Include)
Tirzepatide		

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Zepbound Prescribing Information, Nov. 2023, Eli Lilly and Company.

23. Tirzepatide / Pancreatitis _____ _____

Alert Message: Acute pancreatitis, including fatal and non-fatal hemorrhagic or necrotizing pancreatitis, has been observed in patients treated with GLP-1 receptor agonists, including Zepbound (tirzepatide). Tirzepatide has not been studied in patients with a prior history of pancreatitis. It is unknown if patients with a history of pancreatitis are at higher risk for the development of pancreatitis on tirzepatide. After initiation of tirzepatide, observe patients carefully for signs and symptoms of pancreatitis (including persistent severe abdominal pain, sometimes radiating to the back and which may or may not be accompanied by vomiting). If pancreatitis is suspected, discontinue tirzepatide and initiate appropriate management.

Drugs/Diseases

Util A	Util B	Util C
Tirzepatide	Pancreatitis	

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Zepbound Prescribing Information, Nov. 2023, Eli Lilly and Company.

24. Tirzepatide / Kidney Injury _____ _____

Alert Message: In patients treated with GLP-1 receptor agonists, including Zepbound (tirzepatide), there have been postmarketing reports of acute kidney injury and worsening of chronic renal failure, which may sometimes require hemodialysis. Some of these events have been reported in patients without known underlying renal disease. A majority of the reported events occurred in patients who had experienced nausea, vomiting, diarrhea, or dehydration. Monitor renal function when initiating or escalating doses of tirzepatide in patients with renal impairment reporting severe gastrointestinal adverse reactions.

Drugs/Diseases

Util A	Util B	Util C
Tirzepatide	Renal Impairment	

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Zepbound Prescribing Information, Nov. 2023, Eli Lilly and Company.

Criteria Recommendations	*Approved*	*Rejected*

25. Tirzepatide / Gastroparesis _____ _____

Alert Message: Use of Zepbound (tirzepatide) has been associated with gastrointestinal adverse reactions, sometimes severe. Tirzepatide has not been studied in patients with severe gastrointestinal disease, including severe gastroparesis, and is therefore not recommended in these patients.

Drugs/Diseases

Util A	Util B	Util C
Tirzepatide	Gastroparesis	

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Zepbound Prescribing Information, Nov. 2023, Eli Lilly and Company.

26. Tirzepatide / Diabetic Retinopathy _____ _____

Alert Message: Rapid improvement in glucose control has been associated with a temporary worsening of diabetic retinopathy. Zepbound (tirzepatide) has not been studied in patients with non-proliferative diabetic retinopathy requiring acute therapy, proliferative diabetic retinopathy, or diabetic macular edema. Patients with a history of diabetic retinopathy should be monitored for the progression of diabetic retinopathy.

Drugs/Diseases

Util A	Util B	Util C
Tirzepatide	Diabetic Retinopathy	

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Zepbound Prescribing Information, Nov. 2023, Eli Lilly and Company.

27. Tirzepatide / Gallbladder Disease _____ _____

Alert Message: Acute events of gallbladder disease, such as cholelithiasis or cholecystitis, have been reported in GLP-1 receptor agonist (including tirzepatide) trials and postmarketing. If cholelithiasis is suspected, gallbladder diagnostic studies and appropriate clinical follow-up are indicated.

Drugs/Diseases

Util A	Util B	Util C
Tirzepatide	Cholelithiasis	
	Biliary Colic	
	Cholecystitis	

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Zepbound Prescribing Information, Nov. 2023, Eli Lilly and Company.

28. Tirzepatide / Insulin & Insulin Secretagogues _____ _____

Alert Message: Patients receiving Zepbound (tirzepatide) in combination with an insulin secretagogue (e.g., sulfonylurea) or insulin may have an increased risk of hypoglycemia, including severe hypoglycemia. The risk of hypoglycemia may be lowered by a reduction in the dose of sulfonylurea (or other concomitantly administered insulin secretagogue) or insulin. Inform patients using these concomitant medications of the risk of hypoglycemia and educate them on the signs and symptoms of hypoglycemia.

Drugs/Diseases

Util A	Util B	Util C
Tirzepatide	Insulin	
	Insulin Secretagogues	

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Zepbound Prescribing Information, Nov. 2023, Eli Lilly and Company.

29. Tirzepatide / Oral Drugs with NTI _____ _____

Alert Message: Zepbound (tirzepatide) delays gastric emptying, and thereby has the potential to impact the absorption of concomitantly administered oral medications. Caution should be exercised when oral medications are concomitantly administered with tirzepatide. Monitor patients on oral medications dependent on threshold concentrations for efficacy and those with a narrow therapeutic index (e.g., warfarin) when concomitantly administered with tirzepatide.

Drugs/Diseases

Util A	Util B		Util C
Tirzepatide	Carbamazepine	Phenytoin	
	Cyclosporine	Procainamide	
	Digoxin	Tacrolimus	
	Ethosuximide	Theophylline	
	Levothyroxine	Warfarin	
	Lithium		

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Zepbound Prescribing Information, Nov. 2023, Eli Lilly and Company.

30. Tirzepatide / Oral Contraceptives _____ _____

Alert Message: The use of Zepbound (tirzepatide) may reduce the efficacy of oral hormonal contraceptives due to delayed gastric emptying. Advise patients using oral hormonal contraceptives to switch to a non-oral contraceptive method or add a barrier method of contraception for 4 weeks after initiation and 4 weeks after each dose escalation with tirzepatide.

Drugs/Diseases

Util A	Util B	Util C
Tirzepatide	Oral Contraceptives	

Gender: Female

Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Zepbound Prescribing Information, Nov. 2023, Eli Lilly and Company.

Criteria Recommendations	*Approved*	*Rejected*

31. Tirzepatide / Pregnancy / Pregnancy Negating _____ _____

Alert Message: Available data with Zepbound (tirzepatide) in pregnant patients are insufficient to evaluate for a drug-related risk of major birth defects, miscarriage, or other adverse maternal or fetal outcomes. Advise pregnant patients that weight loss is not recommended during pregnancy and to discontinue tirzepatide when a pregnancy is recognized. Weight loss offers no benefit to a pregnant patient and may cause fetal harm.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Tirzepatide	Pregnancy	Abortion
		Delivery
		Miscarriage

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Zepbound Prescribing Information, Nov. 2023, Eli Lilly and Company.

32. Tirzepatide / Therapeutic Appropriateness _____ _____

Alert Message: There are no data on the presence of Zepbound (tirzepatide) in animal or human milk, the effects on the breastfed infant, or the effects on milk production. The developmental and health benefits of breastfeeding should be considered, along with the mother's clinical need for tirzepatide and any potential adverse effects on the breastfed infant from tirzepatide or the underlying maternal condition.

Drugs/Diseases

Util A	Util B	Util C
Tirzepatide	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Zepbound Prescribing Information, Nov. 2023, Eli Lilly and Company.

33. Quizartinib / Therapeutic Appropriateness _____ _____

Alert Message: The safety and effectiveness of Vanflyta (quizartinib) have not been established in pediatric patients.

Drugs/Diseases

Util A	Util B	Util C
Quizartinib		

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Vanflyta Prescribing Information, July 2023, Daiichi Sankyo, Inc.

Criteria Recommendations	*Approved*	*Rejected*

34. Quizartinib / Box Warning _____ _____

Alert Message: Vanflyta (quizartinib) use is contraindicated in patients with severe hypokalemia or severe hypomagnesemia.

Drugs/Diseases

Util A	Util B	Util C
Quizartinib	Hypokalemia	
	Hypomagnesemia	

References:

Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Vanflyta Prescribing Information, July 2023, Daiichi Sankyo, Inc.

35. Quizartinib / Box Warning _____ _____

Alert Message: Vanflyta (quizartinib) use is contraindicated in patients with long QT syndrome or with a history of ventricular arrhythmias or torsades de pointes. Quizartinib prolongs the QT interval in a dose- and concentration-dependent manner. Torsades de pointes, ventricular fibrillation, cardiac arrest, and sudden death have occurred in patients treated with quizartinib. Do not initiate treatment with quizartinib or escalate the quizartinib dose if the QT interval corrected by Fridericia's formula (QTcF) is greater than 450 ms.

Drugs/Diseases

Util A	Util B	Util C
Quizartinib	QT Prolongation	
	Torsades de Pointes	
	Ventricular Arrhythmias	

References:

Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Vanflyta Prescribing Information, July 2023, Daiichi Sankyo, Inc.

Criteria Recommendations	*Approved*	*Rejected*

36. Quizartinib / QT prolongation Medications (Box Warning) _____ _____

Alert Message: Vanflyta (quizartinib) prolongs the QT/QTc interval. Coadministration of quizartinib with other drugs that prolong the QT interval may further increase the incidence of QT prolongation. Monitor patients more frequently with ECG if coadministration of quizartinib with drugs known to prolong the QT interval is required.

Drugs/Diseases

Util A	Util B				Util C
Quizartinib	Abiraterone	Efavirenz	Lithium	Rilpivirine	
	Alfuzosin	Eliglustat	Lofexidine	Risperidone	
	Amiodarone	Encorafenib	Loperamide	Ritonavir	Amitriptyline
	Entrectinib	Maprotiline	Romidepsin		
	Amoxapine	Eribulin	Methadone	Sertraline	
	Anagrelide	Erythromycin	Metoclopramide	Siponimod	
	Aripiprazole	Escitalopram	Midostaurin	Solifenacin	
	Arsenic Trioxide	Ezogabine	Mifepristone	Sotalol	
	Artemether/Lum	Famotidine	Mirabegron	Sunitinib	
	Asenapine	Felbamate	Mirtazapine	Tacrolimus	
	Atazanavir	Fingolimod	Moexipril	Tamoxifen	
	Atomoxetine	Flecainide	Moxifloxacin	Telavancin	
	Azithromycin	Fluconazole	Nelfinavir	Tetrabenazine	
	Bedaquiline	Fluoxetine	Nilotinib	Thioridazine	
	Bortezomib	Fluvoxamine	Nortriptyline	Tizanidine	
	Bendamustine	Foscarnet	Ofloxacin	Tolterodine	
	Bosutinib	Galantamine	Ondansetron	Toremifene	
	Buprenorphine	Ganciclovir	Osimertinib	Tramadol	
	Ceritinib	Gemifloxacin	Oxaliplatin	Trazodone	
	Chloroquine	Gilteritinib	Paliperidone	Tranylcypromine	
	Chlorpromazine	Glasdegib	Palonosetron	Trimipramine	
	Cilostazol	Granisetron	Panobinostat	Valbenazine	
	Ciprofloxacin	Haloperidol	Paroxetine	Vandetanib	
	Citalopram	Hydroxychloroquine	Pasireotide	Vemurafenib	
	Clarithromycin	Hydroxyzine	Pazopanib	Venlafaxine	
	Clomipramine	Ibutilide	Pentamidine	Voriconazole	
	Clozapine	Iloperidone	Pimavanserin		
	Crizotinib	Imipramine	Pimozide		
	Dabrafenib	Indapamide	Pitolisant		
	Dasatinib	Isocarboxazid	Phenelzine		
	Desipramine	Itraconazole	Posaconazole		
	Deutetrabenazine	Ivosidenib	Procainamide		
	Diphenhydramine	Ivabradine	Promethazine		
	Disopyramide	Ketoconazole	Propafenone		
	Dofetilide	Lapatinib	Protriptyline		
	Dolasetron	Lefamulin	Quetiapine		
	Donepezil	Lenvatinib	Quinidine		
	Doxepin	Leuprolide	Quinine		
	Dronedarone		Ranolazine		

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Vanflyta Prescribing Information, July 2023, Daiichi Sankyo, Inc.

Criteria Recommendations	*Approved*	*Rejected*

37. Quizartinib / Strong CYP3A4 Inhibitors _____ _____

Alert Message: The coadministration of Vanflyta (quizartinib) with a strong CYP3A4 inhibitor increases quizartinib systemic exposure, which may increase the risk of quizartinib adverse reactions. If concurrent use is warranted, reduce the quizartinib dose according to the official prescribing information.

Drugs/Diseases

Util A	Util B	Util C
Quizartinib	Clarithromycin	Nelfinavir
	Cobicistat	Posaconazole
	Itraconazole	Ritonavir
	Ketoconazole	Voriconazole
	Nefazodone	

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Vanflyta Prescribing Information, July 2023, Daiichi Sankyo, Inc.

38. Quizartinib / Moderate & Strong CYP3A4 Inducers _____ _____

Alert Message: The concurrent use of Vanflyta (quizartinib) with strong CYP3A4 inducers should be avoided. Inhibitor decreases quizartinib systemic exposure, which may decrease quizartinib efficacy.

Drugs/Diseases

Util A	Util B	Util C
Quizartinib	Clarithromycin	Nelfinavir
	Cobicistat	Posaconazole
	Itraconazole	Ritonavir
	Ketoconazole	Voriconazole
	Nefazodone	

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Vanflyta Prescribing Information, July 2023, Daiichi Sankyo, Inc.

39. Quizartinib / Pregnancy / Pregnancy Negating _____ _____

Alert Message: Based on findings in animals and its mechanism of action, Vanflyta (quizartinib) can cause fetal harm when administered to a pregnant woman. In animal reproduction studies, administration of quizartinib to pregnant rats during organogenesis at exposures 3 times the maximum recommended human dose (MRHD) of 53 mg/day caused structural abnormalities and alterations to growth. Advise pregnant women of the potential risk to a fetus.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Quizartinib	Pregnancy	Abortion
		Delivery
		Miscarriage

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Vanflyta Prescribing Information, July 2023, Daiichi Sankyo, Inc.

40. Quizartinib / Lactation _____ _____

Alert Message: There are no data on the presence of Vanflyta (quizartinib) or its metabolites in human milk, or the effects on the breastfed child or milk production. Because of the potential for serious adverse reactions in a breastfed child, advise women not to breastfeed during treatment with quizartinib and for one month after the last dose.

Drugs/Diseases

Util A	Util B	Util C
Quizartinib	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Vanflyta Prescribing Information, July 2023, Daiichi Sankyo, Inc.

41. Quizartinib / Therapeutic Appropriateness _____ _____

Alert Message: Advise females of reproductive potential to use effective contraception during treatment with Vanflyta (quizartinib) and for 7 months after the last dose. Based on findings in animals and its mechanism of action, quizartinib can cause fetal harm when administered to a pregnant woman.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Quizartinib		Contraceptives

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Vanflyta Prescribing Information, July 2023, Daiichi Sankyo, Inc.

42. Quizartinib / Therapeutic Appropriateness _____ _____

Alert Message: Based on genotoxicity findings, advise male patients with female partners of reproductive potential to use effective contraception during treatment with Vanflyta (quizartinib) and for 4 months after the last dose.

Drugs/Diseases
Util A Util B Util C
Quizartinib

Gender: Male

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Vanflyta Prescribing Information, July 2023, Daiichi Sankyo, Inc.

43. Ofatumumab / Overuse _____ _____

Alert Message: Kesimpta (ofatumumab) may be over-utilized. The recommended maintenance dose for ofatumumab is one 20 mg subcutaneous injection once a month.

Drugs/Diseases
Util A Util B Util C
Ofatumumab

Max Dose: 20 mg/month

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Kesimpta Prescribing Information, Jan. 2024, Novartis Pharmaceuticals Corporation.

44. Ofatumumab / Therapeutic Appropriateness _____ _____

Alert Message: The safety and effectiveness of Kesimpta (ofatumumab) in pediatric patients have not been established.

Drugs/Diseases
Util A Util B Util C
Ofatumumab

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Kesimpta Prescribing Information, Jan. 2024, Novartis Pharmaceuticals Corporation.

45. Ofatumumab / Active Hepatitis B _____ _____

Alert Message: Kesimpta (ofatumumab) is contraindicated in patients with active hepatitis B. There were no reports of HBV reactivation in patients with MS treated with ofatumumab. However, HBV reactivation, in some cases resulting in fulminant hepatitis, hepatic failure, and death, has occurred in patients being treated with ofatumumab for chronic lymphocytic leukemia (CLL) (at higher intravenous doses than the recommended dose in MS but for a shorter duration of treatment) and in patients treated with other anti-CD20 antibodies.

Drugs/Diseases

Util A	Util B	Util C
Ofatumumab	Hepatitis B	

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Kesimpta Prescribing Information, Jan. 2024, Novartis Pharmaceuticals Corporation.

46. Ofatumumab / Infections _____ _____

Alert Message: Serious, including life-threatening or fatal, bacterial, fungal, and new or reactivated viral infections have been observed during and following completion of treatment with anti-CD20 B-cell depleting therapies, including Kesimpta (ofatumumab). Delay ofatumumab administration in patients with an active infection until the infection is resolved. Vaccination with live-attenuated or live vaccines is not recommended during treatment and after discontinuation until B-cell repletion.

Drugs/Diseases

Util A	Util B	Util C
Ofatumumab	Serious Infection	

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Kesimpta Prescribing Information, Jan. 2024, Novartis Pharmaceuticals Corporation.

47. Ofatumumab / Pregnancy / Pregnancy Negating _____ _____

Alert Message: Based on animal data, Kesimpta (ofatumumab) can cause fetal harm due to B-cell lymphopenia and reduce antibody response in offspring exposed to ofatumumab in utero. Transient peripheral B-cell depletion and lymphocytopenia have been reported in infants born to mothers exposed to other anti-CD20 B-cell depleting antibodies during pregnancy. Advise females of reproductive potential to use effective contraception while receiving ofatumumab and for at least 6 months after the last dose.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Ofatumumab	Pregnancy	Abortion
		Delivery
		Miscarriage

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Kesimpta Prescribing Information, Jan. 2024, Novartis Pharmaceuticals Corporation.

Criteria Recommendations	*Approved*	*Rejected*

48. Ofatumumab / Lactation _____ _____

Alert Message: There are no data on the presence of Kesimpta (ofatumumab) in human milk, the effects on the breastfed infant, or the effects of the drug on milk production. Human IgG is excreted in human milk, and the potential for absorption of ofatumumab to lead to B-cell depletion in the infant is unknown. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for ofatumumab and any potential adverse effects on the breastfed infant from ofatumumab or the underlying maternal condition.

Drugs/Diseases

Util A	Util B	Util C
Ofatumumab	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Kesimpta Prescribing Information, Jan. 2024, Novartis Pharmaceuticals Corporation.

49. Ofatumumab / Adverse Fetal Effects _____ _____

Alert Message: Females of childbearing potential should use effective contraception while receiving Kesimpta (ofatumumab) and for 6 months after the last treatment of ofatumumab.

Drugs/Diseases

Util A	Util B	Util C (Negating)
Ofatumumab		Contraceptives

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Kesimpta Prescribing Information, Jan. 2024, Novartis Pharmaceuticals Corporation.

50. Ofatumumab / Non-adherence _____ _____

Alert Message: Based on refill history, your patient may be under-utilizing Kesimpta (ofatumumab). Nonadherence to the prescribed dosing regimen may result in subtherapeutic effects, which may lead to decreased patient outcomes and additional healthcare costs.

Drugs/Diseases

Util A	Util B	Util C
Ofatumumab		

References:
Osterberg L, Blaschke T. Adherence to Medication. N Engl J Med 2005; 353:487- 497.
McKay KA, Tremlett H, Patten SB, et al. Determinants of Non-Adherence to Disease-Modifying Therapies in Multiple Sclerosis: A Cross-Canada Prospective Study. Mult Scler. 2016;23(4):588-596.

Higuera L, Carlin CS, Anderson S. Adherence to Disease-Modifying Therapies for Multiple Sclerosis. J Manag Care Spec Pharm. 2016;22(12):1394-1401.

51. Omaveloxolone / Overuse _____ _____

Alert Message: Skyclarys (omaveloxolone) may be over-utilized. The recommended dosage of omaveloxolone is 150 mg (3 capsules) once daily.

Drugs/Diseases

Util A	Util B	Util C (Negating)
Omaveloxolone		Hepatic Impairment

Max Dose: 150 mg/day

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Skyclarys Prescribing Information, Jan. 2024, Reata Pharmaceuticals, Inc.

52. Omaveloxolone / Overuse – Moderate Hepatic Impairment _____ _____

Alert Message: Skyclarys (omaveloxolone) may be over-utilized. The recommended dosage of omaveloxolone in patients with moderate hepatic impairment is 100 mg once daily, with close monitoring for adverse reactions. If adverse reactions emerge, consider lowering the dose to 50 mg once daily.

Drugs/Diseases

Util A	Util B	Util C (Include)
Omaveloxolone		Moderate Hepatic Impairment

Max Dose: 100 mg/day

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Skyclarys Prescribing Information, Jan. 2024, Reata Pharmaceuticals, Inc.

53. Omaveloxolone / Severe Hepatic Impairment _____ _____

Alert Message: Skyclarys (omaveloxolone) use should be avoided in patients with severe hepatic impairment. In clinical studies, subjects with severe hepatic impairment (Child-Pugh Class C) receiving omaveloxolone had significantly reduced clearance.

Drugs/Diseases

Util A	Util B	Util C (Include)
Omaveloxolone		Cirrhosis
		Hepatic Failure

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Skyclarys Prescribing Information, Jan. 2024, Reata Pharmaceuticals, Inc.

54. Omaveloxolone / Hypercholesterolemia _____ _____

Alert Message: Treatment with Skyclarys (omaveloxolone) can cause changes in cholesterol. In a clinical study (Study 1), 29% of patients treated with omaveloxolone reported elevated cholesterol above ULN at one or more time points. Mean increases were observed within 2 weeks of initiation of omaveloxolone and returned to baseline within 4 weeks of discontinuing treatment. A total of 16% of patients treated with omaveloxolone had an increase in low-density lipoprotein cholesterol (LDL-C) from baseline, compared to 8% of patients who received placebo. The mean increase in LDL-C for all omaveloxolone-treated patients was 23.5 mg/dL at 48 weeks. A total of 6% of patients treated with omaveloxolone had decreases in high-density lipoprotein cholesterol (HDL-C) from baseline compared to 4% of patients who received placebo. Assess lipid parameters prior to initiation of omaveloxolone and monitor periodically during treatment. Manage lipid abnormalities according to clinical guidelines.

Drugs/Diseases

Util A	Util B	Util C
Omaveloxolone	Hypercholesterolemia	

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Skyclarys Prescribing Information, Jan. 2024, Reata Pharmaceuticals, Inc.

55. Omaveloxolone / Therapeutic Appropriateness _____ _____

Alert Message: The safety and effectiveness of Skyclarys (omaveloxolone) have not been established in pediatric patients less than 16 years of age.

Drugs/Diseases

Util A	Util B	Util C
Omaveloxolone		

Age Range: 0 – 15 yoa

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Skyclarys Prescribing Information, Jan. 2024, Reata Pharmaceuticals, Inc.

56. Omaveloxolone / Hormonal Contraceptives _____ _____

Alert Message: Skyclarys (omaveloxolone) is a weak CYP3A4 inducer. Concomitant use with omaveloxolone may reduce the efficacy of hormonal contraceptives. Advise patients to avoid concomitant use with combined hormonal contraceptives (e.g., pill, patch, ring), implants, and progestin-only pills. Counsel females using hormonal contraceptives to use an alternative contraceptive method (e.g., non-hormonal intrauterine system) or additional non-hormonal contraceptive (e.g., condoms) during concomitant use and for 28 days after discontinuation of omaveloxolone.

Drugs/Diseases

Util A	Util B	Util C
Omaveloxolone	Hormonal Contraceptives	

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Skyclarys Prescribing Information, Jan. 2024, Reata Pharmaceuticals, Inc.

57. Omaveloxolone / Strong or Moderate CYP3A4 Inhibitors _____ _____

Alert Message: Skyclarys (omaveloxolone) is a CYP3A4 substrate. Concomitant use of omaveloxolone with moderate or strong CYP3A4 inhibitors is expected to result in clinically significant increased exposure to omaveloxolone, which may increase the risk of adverse reactions. Avoid concomitant use of omaveloxolone with moderate or strong CYP3A4 inhibitors. If use cannot be avoided, reduce the dose of omaveloxolone to 100 mg once daily and monitor for adverse reactions. If adverse reactions emerge, reduce the dose to 50 mg once daily.

Drugs/Diseases

Util A	Util B		Util C
Omaveloxolone	Atazanavir	Idelalisib	
	Aprepitant	Itraconazole	
	Clarithromycin	Ketoconazole	
	Cobicistat	Nefazodone	
	Crizotinib	Nelfinavir	
	Diltiazem	Posaconazole	
	Dronedarone	Ritonavir	
	Erythromycin	Tipranavir	
	Fluconazole	Verapamil	
	Fluvoxamine	Voriconazole	
	Fosamprenavir		

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Skyclarys Prescribing Information, Jan. 2024, Reata Pharmaceuticals, Inc.

58. Omaveloxolone / Strong or Moderate CYP3A4 Inducers _____ _____

Alert Message: Skyclarys (omaveloxolone) is a CYP3A4 substrate. Concomitant use of omaveloxolone with moderate or strong CYP3A4 inducers may significantly decrease omaveloxolone exposure, which may reduce the effectiveness of omaveloxolone. Avoid concomitant use of omaveloxolone with moderate or strong CYP3A4 inducers.

Drugs/Diseases

Util A	Util B			Util C
Omaveloxolone	Apalutamide	Etravirine	Rifabutin	
	Bosentan	Phenobarbital	Rifampin	
	Carbamazepine	Phenytoin	Rifapentine	
	Efavirenz	Primidone		

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Skyclarys Prescribing Information, Jan. 2024, Reata Pharmaceuticals, Inc.

Criteria Recommendations	*Approved*	*Rejected*

59. Omaveloxolone / Pregnancy / Pregnancy Negating _____ _____

Alert Message: There are no adequate data on the developmental risks associated with the use of Skyclarys (omaveloxolone) in pregnant women. In animal studies, administration of omaveloxolone during pregnancy or throughout pregnancy and lactation produced evidence of developmental toxicity (embryofetal mortality and growth impairment, and mortality, growth impairment, and neurobehavioral deficits in offspring) at plasma exposures similar to or less than exposures in humans.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Omaveloxolone	Pregnancy	Abortion
		Delivery
		Miscarriage

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Skyclarys Prescribing Information, Jan. 2024, Reata Pharmaceuticals, Inc.

60. Omaveloxolone / Lactation _____ _____

Alert Message: There are no data on the presence of Skyclarys (omaveloxolone) or its metabolites in human milk. The effects on milk production and the breastfed infant are unknown. Omaveloxolone was excreted in the milk of lactating rats following oral administration. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for omaveloxolone and any potential adverse effects on the breastfed infant from omaveloxolone or the underlying maternal condition.

Drugs/Diseases

Util A	Util B	Util C
Omaveloxolone	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Skyclarys Prescribing Information, Jan. 2024, Reata Pharmaceuticals, Inc.

61. Omaveloxolone / Non-adherence _____ _____

Alert Message: Based on refill history, your patient may be under-utilizing Skyclarys (omaveloxolone). Nonadherence to the prescribed dosing regimen may result in subtherapeutic effects, which may lead to decreased patient outcomes and additional healthcare costs.

Drugs/Diseases

Util A	Util B	Util C
Omaveloxolone		

References:

Osterberg L, Blaschke T. Adherence to Medication. N Engl J Med 2005; 353:487- 497.
Brown MT, Bussell J, Suparna D, et al. Medication Adherence: Truth and Consequences. Am J Med Sci. 2016 Apr;351(4):387-399.

Marcum ZA, Sevick MA, Handler SM. Medication Nonadherence: A Diagnosable and Treatable Medical Condition. JAMA. 2013;309(20):2105-2106. doi:10.1001/jama.2013.4638.

Kim J, Combs K, Downs J, Tillman F., Medication Adherence: The Elephant in the Room. US Pharm. 2018;43(1)30-34.

62. Reslizumab / Therapeutic Appropriateness _____ _____

Alert Message: The safety and effectiveness of Cinqair (reslizumab) in pediatric patients less than 18 years of age have not been established.

Drugs/Diseases

Util A	Util B	Util C
Reslizumab		

Age Range: 0 – 17 yoa

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.

63. Reslizumab / Pregnancy / Pregnancy Negating _____ _____

Alert Message: The data on pregnancy exposure to Cinqair (reslizumab) from the clinical trials are insufficient to inform on drug associated risk. Monoclonal antibodies, such as reslizumab, are transported across the placenta in a linear fashion as pregnancy progresses; therefore, potential effects on a fetus are likely to be greater during the second and third trimester of pregnancy. Reslizumab has a long half-life. This should be taken into consideration.

Drugs/Diseases

Util A	Util B	Util C (Negate)
	Pregnancy	Abortion
		Delivery
		Miscarriage

Gender: Female
Age Range: 11 – 50 yoa

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.

Criteria Recommendations	*Approved*	*Rejected*

64. Reslizumab / Lactation _____ _____

Alert Message: It is not known whether Cinqair (reslizumab) is present in human milk, and the effects of reslizumab on the breast fed infant and on milk production are not known. However, human IgG is known to be present in human milk. Reslizumab was present in the milk of lactating mice following dosing during pregnancy. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for reslizumab and any potential adverse effects on the breast-fed child from reslizumab or the underlying maternal condition.

Drugs/Diseases

Util A	Util B	Util C
Reslizumab	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.

65. Reslizumab / Helminth Infection _____ _____

Alert Message: Eosinophils may be involved in the immunological response to some helminth infections. It is unknown if Cinqair (reslizumab) will influence the immune response against parasitic infections. Treat patients with pre-existing helminth infections before initiating reslizumab. If patients become infected while receiving treatment with reslizumab and do not respond to anti-helminth treatment, discontinue treatment with reslizumab until infection resolves.

Drugs/Diseases

Util A	Util B	Util C
Reslizumab	Helminth Infection	

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.

North Dakota Medicaid
Drug Utilization Review Board Meeting
September 4, 2024
Conference Room 210/212

NORTH Dakota Be Legendary. | Health & Human Services

NORTH Dakota | Health & Human Services
Be Legendary.

Meeting Notice

North Dakota Medicaid Drug Use Review Board

Wednesday, September 4th, 2024
1 to 4 p.m. Central Time

In-Person Information

Conference Room 210/212, 2nd Floor, Judicial Wing, State Capitol
600 E. Boulevard Ave., Bismarck

Virtual Information

Join virtually: Click here to join the meeting
Join by phone: 701-328-0950, Conference ID: 506 213 519 #

Agenda

1. Call to Order
2. Roll Call
3. Review and Approval of Minutes
4. Reports from Department
    - Administrative Report
    - Financial Report: Top Drugs
    - Retrospective DUR Report
    - Clinical Report:
        - Prior Authorization Update
        - Criteria updates: asthma/COPD, chronic kidney disease, Duchenne muscular dystrophy, growth hormone, heart failure, hereditary angioedema, hypertrophic cardiomyopathy, lipid-lowering treatment, plaque psoriasis, medications over $3000, dry eye disease
5. Unfinished Business
6. New business
    - Second Review of Molluscum Contagiosum (Ycanth and Zelsuvmi)
    - Second Review of Epidermolysis Bullosa (Filsuvez)
    - Second Review of Metabolic Dysfunction–Associated Steatohepatitis (Rezdiffra)
    - First Review of Attention-Deficit Hyperactivity Disorder Stimulants
    - Review of retrospective DUR criteria recommendations
7. Announcements: Next Meeting (December 4, 2024)
8. Adjourn

Individuals with disabilities who need accommodations, including appropriate auxiliary aids to participate, can contact Ashley Gerving at 701-328-2354, toll-free 800-755-2604, 711 (TTY) or gervingashley@nd.gov.

Meeting Minutes
North Dakota Medicaid Drug Use Review (DUR) Board
Meeting Date: June 5th, 2024
Time and Location: 1:00 pm CST in Bismarck, North Dakota

Call to Order:
A regular quarterly meeting of the North Dakota Medicaid Drug Use Review (DUR) Board meeting was convened at 1:03 pm CST with T. Schmidt presiding as Presiding Officer. DUR Board Coordinator, C. Stauter recording minutes.

Roll Call:
Board Members Voting:
Present: Stephanie Antony, Gabriela Balf, Amanda Dahl, Kurt Datz, Andrea Honeyman, Jennifer Iverson, Laura Kroetsch, Kevin Martian, Tanya Schmidt, Amy Werremeyer
Absent: Kristen Peterson, Josh Askvig
Quorum Present: Yes

Board Members Non-Voting:
Absent: Kathleen Traylor

Medicaid Pharmacy Department:
Present: Brendan Joyce, Alexi Murphy, LeNeika Roehrich
Absent: Jeff Hostetter

Approval of Meeting Minutes:
Motion: Moved by A. Werremeyer to approve the minutes of the March 6th, 2024 meeting, motion was seconded by K. Datz. **Motion carried.**
The minutes of the March 6th, 2024 meeting were approved as distributed.

Reports:
*Administrative Report***:** by A. Murphy
A. Murphy shared with the Board reports reviewing drug utilization in the following: antidepressants in pediatric females, attention-deficit hyperactivity disorder in adult females, biologics, contraceptives, cystic fibrosis, and opioid analgesics prescribed by dentists. This information can be found in the handout.

Financial Report: Budget provided by A. Murphy
A. Murphy shared with the Board trends of post rebate spend since 2020 and the financial effects from AMP cap removal. This information can be found in the handout.

Financial Report: Top Drugs provided by C. Stauter
C. Stauter presented the quarterly review of the top 25 drugs based on total number and cost of claims and the top 15 therapeutic classes based on number and cost of claims. This report can be found in the handout.

Retrospective Drug Utilization Review (RDUR) Report by C. Stauter
C. Stauter reviewed the quarterly RDUR criteria that were selected for review of each month. This material can be found in the handout.

Clinical Report: Prior Authorization and Criteria Updates by C. Stauter
C. Stauter presented prior authorization and criteria updates with emphasis on the following sections in the PDL: food allergy, reduction of major adverse cardiovascular events (MACE), pulmonary hypertension, and

tardive dyskinesia. The presented information can be found in the handout. Testimony was provided by Jeremy Whalen from Genentech on Xolair, Mary Claire Wohletz from Merck on Winrevair, and Jasmine Inman from Teva on Austedo.

Special Orders:
Elections
T. Schmidt nominated to serve as Presiding Officer. Moved by T. Schmidt, motion was seconded by A. Honeyman. **Motion carried.**
K. Martian nominated to serve as Vice-Presiding Officer. Moved by K. Datz, motion was seconded by A. Honeyman. **Motion carried.**

Unfinished business:
Criteria Updates provided by C. Stauter
C. Stauter presented criteria updates with emphasis on hyperkalemia. The presented material can be found in the handout.

New business:
Second Reviews presented by C. Stauter
C. Stauter presented group prior authorization criteria for acid blockers, paroxysmal nocturnal hemoglobinuria, Duchenne muscular dystrophy, primary hyperoxaluria type 1, myasthenia gravis, and seborrheic dermatitis. The presented material can be found in the handout. Testimony was provided by Kristin Duffey from Novartis on Fabhalta and Colleen Stoyas from UCB on Zilbrysq.
Motion: Moved by K. Martin to place acid blockers on prior authorization, motion was seconded by A. Werremeyer. **Motion carried.**
Motion: Moved by K. Datz to place paroxysmal nocturnal hemoglobinuria on prior authorization, motion was seconded by K. Martian. **Motion carried.**
Motion: Moved by K. Datz to place Duchenne muscular dystrophy on prior authorization, motion was seconded by A. Honeyman. **Motion carried.**
Motion: Moved by K. Martian to place primary hyperoxaluria type 1 on prior authorization, motion was seconded by K. Datz. **Motion carried.**
Motion: Moved by K. Datz to place myasthenia gravis on prior authorization, motion was seconded by A. Dahl. **Motion carried.**
Motion: Moved by K. Martian to place seborrheic dermatitis on prior authorization, motion was seconded by K. Datz. **Motion carried.**

First Reviews presented by C. Stauter
C. Stauter presented an overview of molloscum cantagiosum, epidermolysis bullosa, and metabolic dysfunction-associated steatohepatitis. The presented material can be found in the handout. Testimony was provided by Tara McKinley from Madrigal on Rezdiffra.
Motion: Moved by K. Datz to draft prior authorization for molloscum cantagiosum, motion was seconded by A. Honeyman. **Motion carried.**
Motion: Moved by K. Martian to draft prior authorization for epidermolysis bullosa, motion was seconded by K. Datz. **Motion carried.**
Motion: Moved by K. Martian to draft prior authorization for metabolic dysfunction-associated steatohepatitis, motion was seconded by K. Datz. **Motion carried.**

Retrospective Drug Utilization Review (RDUR) Criteria Recommendations:
RDUR criteria recommendations were reviewed. The presented material can be found in the handout.

Motion: Moved by K. Datz to approve the RDUR criteria, motion was seconded by K. Martian. **Motion carried.**

Announcements:
Next meeting is September 4th, 2024.

Adjournment:
Meeting adjourned by T. Schmidt at 2:56 pm CST.

Date of Minutes Approval:
Minutes submitted by: Claire Stauter, Acentra Health

Administrative Report

Biosimilars:

2024 Plan for Biosimilars:

Adalimumab

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
adalimumab-adaz	ABRILADA (adalimumab-afzb)
adalimumab-adbm – labeler 00597	adalimumab-aacf
CYLTEZO (adalimumab-abdm)	adalimumab-aaty
HUMIRA (adalimumab)	adalimumab-adbm – labeler 82009
SIMLANDI (adalimumab-ryvk)	adalimumab-fkjp
YUSIMRY (adalimumab-aqvh)	adalimumab-ryvk
	AMJEVITA (adalimumab-atto)
	HADLIMA (adalimumab-bwwd)
	HULIO (adalimumab-fkjp)
	HYRIMOZ (adalimumab-adaz)
	IDACIO (adalimumab-aacf)
	YUFLYMA (adalimumab-aaty)

Infliximab

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AVSOLA (infliximab-axxq) – *Medical Billing Only*	INFLECTRA (infliximab-dyyb) – *Medical Billing Only*
RENFLEXIS (infliximab-abda) – *Medical Billing Only*	infliximab – *Medical Billing Only*
	REMICADE (infliximab) – *Medical Billing Only*

2025 Plan for Biosimilars:

Adalimumab

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
adalimumab-adaz	ABRILADA (adalimumab-afzb)
adalimumab-adbm – labeler 00597	adalimumab-aacf
CYLTEZO (adalimumab-abdm)	adalimumab-aaty
HUMIRA (adalimumab)	adalimumab-adbm – labeler 82009
SIMLANDI (adalimumab-ryvk)	adalimumab-fkjp
YUSIMRY (adalimumab-aqvh)	adalimumab-ryvk
	AMJEVITA (adalimumab-atto)
	HADLIMA (adalimumab-bwwd)
	HULIO (adalimumab-fkjp)
	HYRIMOZ (adalimumab-adaz)
	IDACIO (adalimumab-aacf)
	YUFLYMA (adalimumab-aaty)

Bevacizumab

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
MVASI (bevacizumab – awwb)	ALYMSYS (bevacizumab – maly)

ZIRABEV (bevacizumab – bvzr)	AVASTIN (bevacizumab)
	VEGZELMA (bevacizumab – acdc)

Infliximab

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AVSOLA (infliximab-axxq) – *Medical Billing Only*	infliximab – *Medical Billing Only*
INFLECTRA (infliximab-dyyb) – *Medical Billing Only*	RENFLEXIS (infliximab-abda) – *Medical Billing Only*
	REMICADE (infliximab) – *Medical Billing Only*

Rituximab

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
RIABNI (rituximab-arrx) – *Medical Billing Only*	RITUXAN (rituximab) – *Medical Billing Only*
RUXIENCE (rituximab-pvvr) – *Medical Billing Only*	
TRUXIMA (rituximab-abbs) – *Medical Billing Only*	

Tocilizumab

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
TYENNE (tocilizumab-aazg) AUTOINJECTOR, SYRINGE	ACTEMRA (tocilizumab) ACTPEN, SYRINGE
TYENNE (tocilizumab-aazg) VIAL – *Medical Billing Only*	ACTEMRA (tocilizumab) VIAL – *Medical Billing Only*
	TOFIDENCE (tocilizumab-aazg) VIAL – *Medical Billing Only*

Trastuzumab

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
KANJINTI (trastuzuamb – anns) – *Medical Billing Only*	HERZUMA (trastuzumab – pkrb) – *Medical Billing Only*
TRAZIMERA (trastuzumab – qyyp) – *Medical Billing Only*	HERCEPTIN (trastuzumab) – *Medical Billing Only*
	OGIVRI (trastuzumab – dkst) – *Medical Billing Only*
	ONTRUZANT (trastuzumab – dttb) – *Medical Billing Only*

Filgrastim

Medical Billing

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
GRANIX (TBO-filgrastim) – *Medical Billing Only*	NEUPOGEN (filgrastim) – *Medical Billing Only*
NIVESTYM (filgrastim-aafi) – *Medical Billing Only*	RELEUKO (filgrastim-ayow) – *Medical Billing Only*
ZARXIO (filgrastim-sndz) – *Medical Billing Only*	

Pharmacy Billing

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
NEUPOGEN (filgrastim)	GRANIX (TBO-filgrastim)
RELEUKO (filgrastim-ayow)	NIVESTYM (filgrastim-aafi)
	ZARXIO (filgrastim-sndz)

Pegfilgrastim

Medical Billing

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
NEULASTA (pegfilgrastim) *– Medical Billing Only*	FULPHILA (pegfilgrastrim-jmdb) *– Medical Billing Only*
NEULASTA ONPRO (pegfilgrastim) *– Medical Billing Only*	FYLNETRA (pegfilgrastim -pbbk) *– Medical Billing Only*
NYVEPRIA (pegfilgrastrim–apgf) *– Medical Billing Only*	STIMUFEND (pegfilgrastim-fpgk) *– Medical Billing Only*
UDENYCA ONBODY (pegfligrastim-cbqv) *– Medical Billing Only*	UDENYCA (pegfligrastim-cbqv) *– Medical Billing Only*
	ZIEXTENZO (pegfilgrastim-bmez) *– Medical Billing Only*

Pharmacy Billing

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
FULPHILA (pegfilgrastrim-jmdb)	NEULASTA (pegfilgrastim)
FYLNETRA (pegfilgrastim -pbbk)	NYVEPRIA (pegfilgrastrim–apgf)
NEULASTA ONPRO (pegfilgrastim)	STIMUFEND (pegfilgrastim-fpgk)
UDENYCA ONBODY (pegfligrastim-cbqv)	UDENYCA (pegfligrastim-cbqv)
	ZIEXTENZO (pegfilgrastim-bmez)

Sargramostim

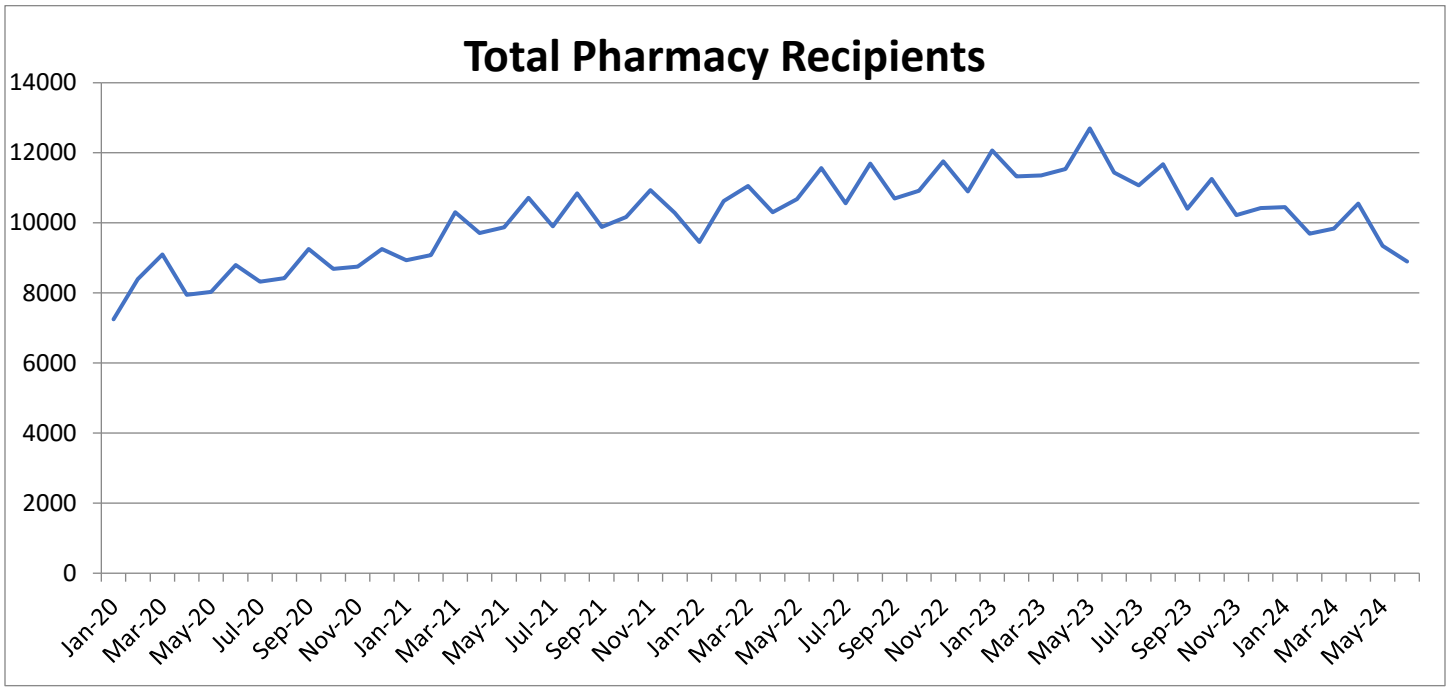
PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
LEUKINE (sargramostim)	
LEUKINE (sargramostim) *– Medical Billing Only*	

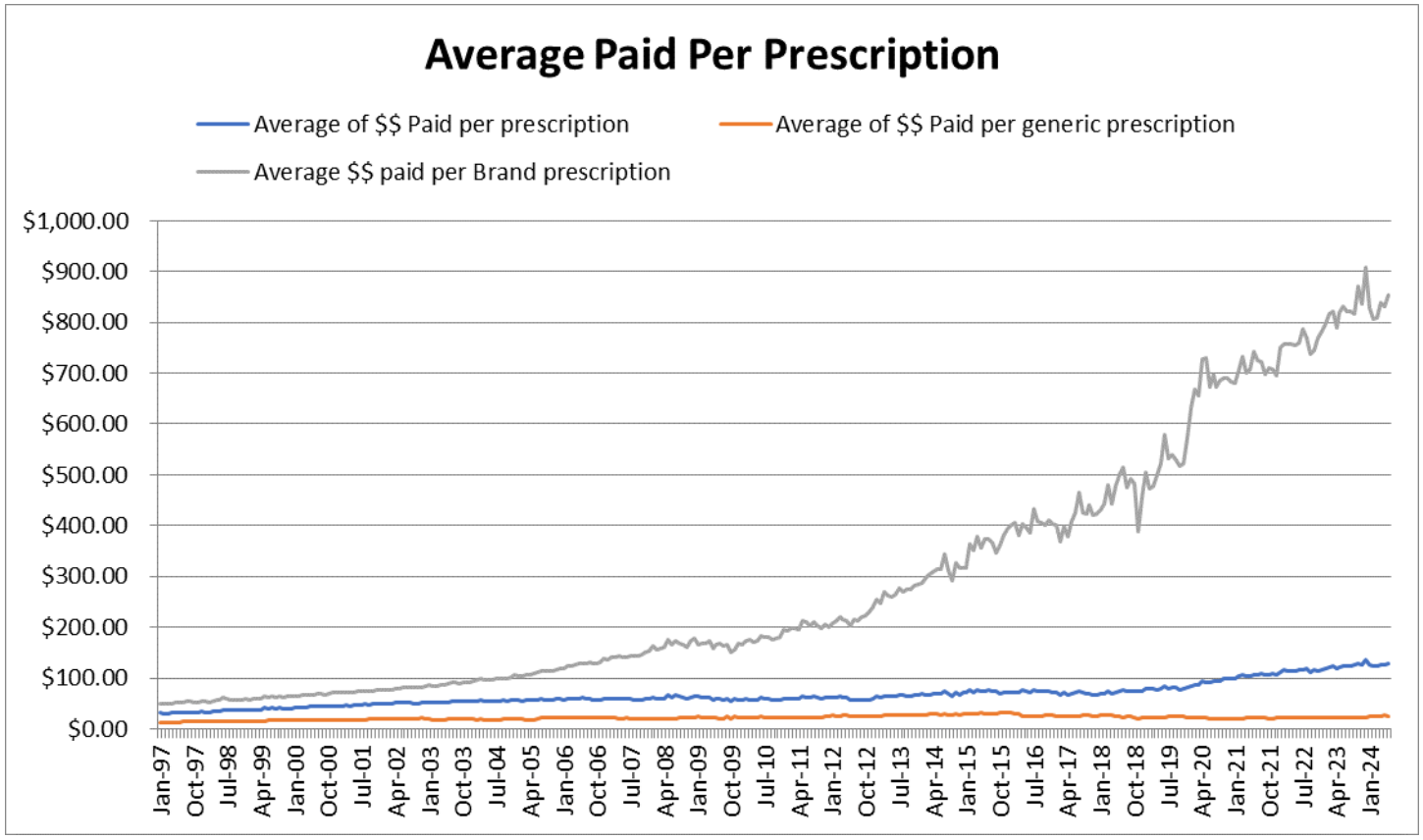
Eflapegrastim-xnst

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	ROLVEDON (eflapegrastim-xnst)
	ROLVEDON (eflapegrastim-xnst) *– Medical Billing Only*

Hepatitis C Update	
Quarter	**Members Treated**
QTR 1 2023	34
QTR 2 2023	28
QTR 3 2023	29
QTR 4 2023	47
QTR 1 2024	41
QTR 2 2024	43

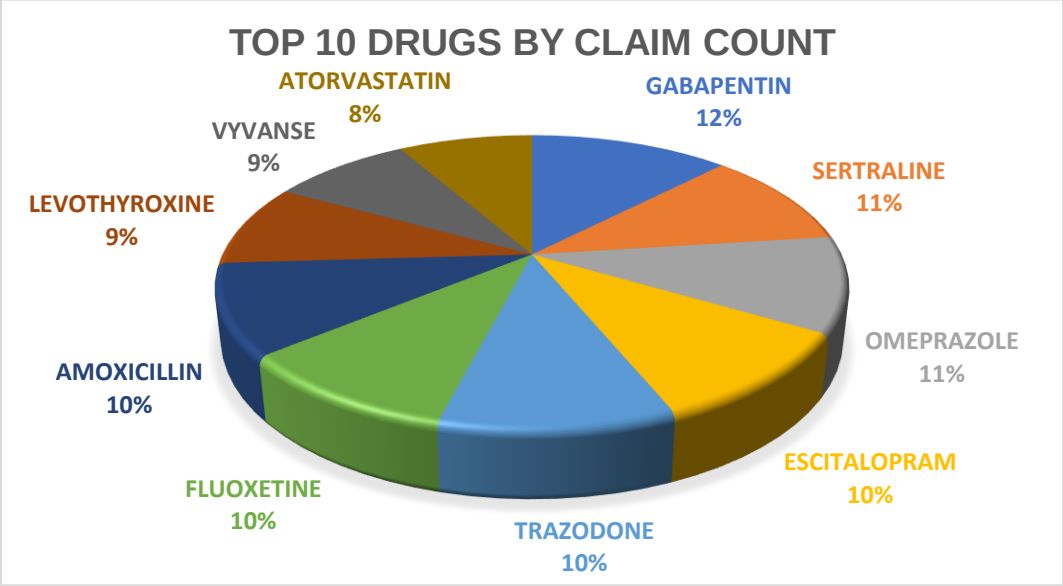
Financial Report





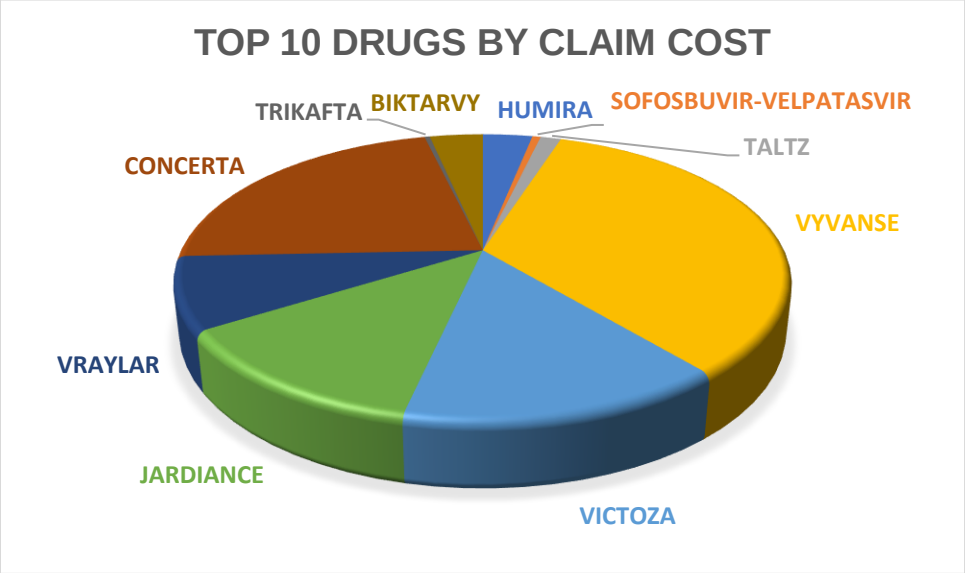
Top 25 Drugs Based on Number of Claims from 04/01/2024 – 06/30/2024

Drug	Claims	Claims Cost	Patients	Cost / Claim	% Claims	Dif.
1. GABAPENTIN	4,053	$59,734.86	1,781	$14.74	1.8%	NC
2. SERTRALINE	3,513	$47,744.65	1,972	$13.59	1.5%	↑2
3. OMEPRAZOLE	3,456	$46,054.06	1,881	$13.33	1.5%	NC
4. ESCITALOPRAM	3,385	$45,436.37	1,929	$13.42	1.5%	↑3
5. TRAZODONE	3,374	$45,299.86	1,780	$13.43	1.5%	↑1
6. FLUOXETINE	3,297	$43,987.95	1,813	$13.34	1.4%	↓1
7. AMOXICILLIN	3,295	$50,569.62	3,130	$15.35	1.4%	↓5
8. LEVOTHYROXINE	2,963	$42,112.61	1,568	$14.21	1.3%	↑1
9. VYVANSE	2,848	$832,301.64	1,224	$292.24	1.2%	↓1
10. ATORVASTATIN	2,729	$38,135.69	1,613	$13.97	1.2%	NC
11. VENTOLIN HFA	2,623	$169,239.72	2,596	$64.52	1.1%	↑2
12. BUPROPION XL	2,619	$42,909.59	1,420	$16.38	1.1%	NC
13. LISINOPRIL	2,595	$33,480.54	1,600	$12.90	1.1%	↓2
14. CLONIDINE	2,548	$31,252.27	1,270	$12.27	1.1%	NC
15. HYDROXYZINE	2,364	$35,601.28	1,458	$15.06	1.0%	↑5
16. PREDNISONE	2,348	$27,109.49	1,887	$11.55	1.0%	↑1
17. AMOXICILLIN-CLAV	2,344	$40,755.77	2,194	$17.39	1.0%	↓1
18. HYDROCODONE-APAP	2,252	$33,432.99	1,455	$14.85	1.0%	↑5
19. LAMOTRIGINE	2,231	$31,016.96	932	$13.90	1.0%	↓1
20. DULOXETINE	2,201	$36,432.73	1,204	$16.55	1.0%	↓1
21. PANTOPRAZOLE	2,180	$30,326.24	1,227	$13.91	0.9%	↓6
22. ARIPIPRAZOLE	2,176	$32,931.90	1,074	$15.13	0.9%	NC
23. BUSPIRONE	2,073	$30,769.54	1,102	$14.84	0.9%	↑3
24. CYCLOBENZAPRINE	2,061	$24,553.78	1,297	$11.91	0.9%	NC
25. CLONAZEPAM	1,994	$26,415.61	855	$13.25	0.9%	↑3
Total Claims						**231,545**



Top 25 Drugs Based on Total Claims Cost from 04/01/2024 – 06/30/2024

Drug	Claims	Claims Cost	Patients	Cost / Patient	% Cost	Dif.
1. HUMIRA	264	$2,117,356.79	120	$17,644.64	6.7%	NC
2. SOFOS-VELPATASVIR	44	$938,637.88	43	$21,828.79	2.9%	↑1
3. TALTZ	109	$903,260.65	53	$17,042.65	2.8%	↑1
4. VYVANSE	2,848	$832,301.64	1,224	$ 679.99	2.6%	↓2
5. VICTOZA	1224	$827,915.83	699	$ 1,184.42	2.6%	↓2
6. JARDIANCE	1,060	$788,073.57	587	$ 1,342.54	2.5%	↓1
7. VRAYLAR	690	$735,100.93	281	$ 2,616.02	2.3%	NC
8. CONCERTA	1,844	$666,901.77	808	$ 825.37	2.1%	↓2
9. TRIKAFTA	28	$622,563.28	11	$56,596.66	2.0%	NC
10. BIKTARVY	282	$617,828.19	142	$4,350.90	1.9%	↓2
11. INVEGA SUSTENNA	192	$528,568.90	84	$6,292.49	1.7%	↓1
12. DUPIXENT	147	$528,235.35	69	$7,655.58	1.7%	NC
13. NORDITROPIN	82	$487,655.96	35	$13,933.03	1.5%	↓2
14. ELIQUIS	640	$391,199.66	327	$1,196.33	1.2%	NC
15. STELARA	16	$390,069.62	12	$32,505.80	1.2%	↑2
16. ADDERALL XR	1,904	$350,515.04	861	$407.10	1.1%	↓1
17. ENBREL	51	$350,081.11	22	$15,912.78	1.1%	↓4
18. INGREZZA	40	$302,686.87	16	$18,917.93	1.0%	↓2
19. SUBLOCADE	143	$286,292.42	70	$4,089.89	0.9%	NC
20. ABILIFY MAINTENA	99	$258,923.34	43	$6,021.47	0.8%	NC
21. DAYBUE	6	$235,979.28	3	$78,659.76	0.7%	↑18
22. TREMFYA	17	$231,125.93	9	$25,680.66	0.7%	↑40
23. INVEGA TRINZA	24	$205,691.85	23	$8,943.12	0.6%	↓1
24. SKYRIZI	10	$203,519.53	9	$22,613.28	0.6%	↓6
25. FARXIGA	314	$185,255.66	169	$1,096.19	0.6%	↓2
Total Claims Cost						**$31,842,570.20**



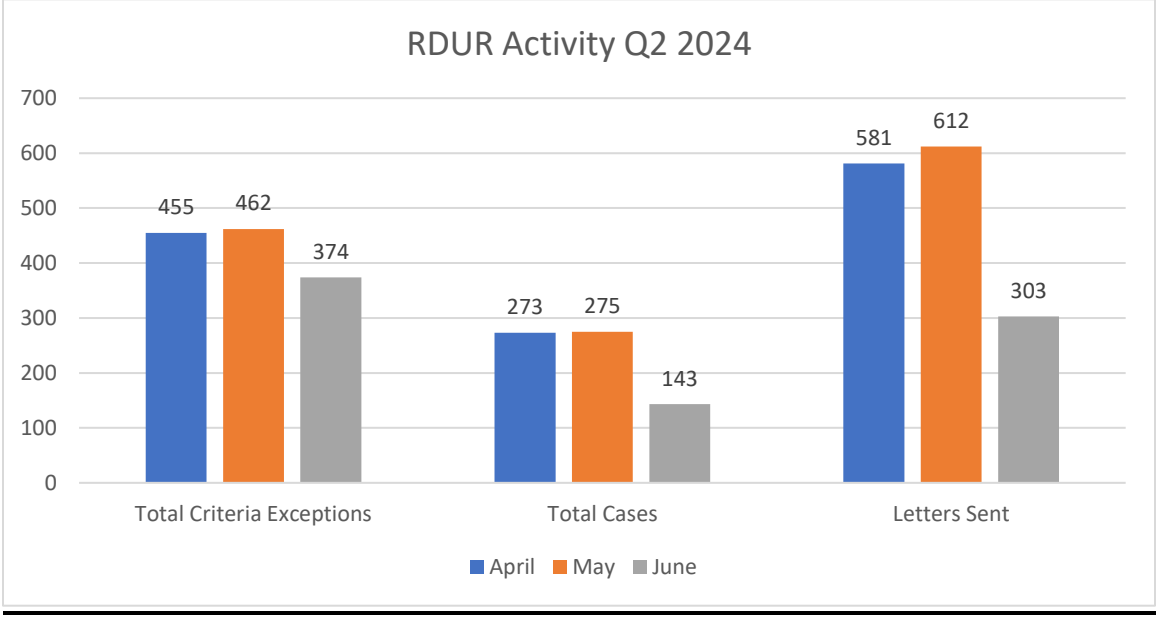
Top 15 Therapeutic Classes Based on Number of Claims from 04/01/2024 – 06/30/2024

Therapeutic Class Description	Claims	Claims Cost	Patients	Cost/Claim	% Claims	Dif.
1. ANTIDEPRESSANTS	24,816	$591,266.06	10,500	$23.83	10.7%	NC
2. ANTIPSYCHOTIC AGENTS	9,099	$2,500,799.63	3,645	$274.84	3.9%	NC
3. AMPHETAMINES	6,382	$1,248,191.69	2,704	$195.58	2.8%	↑3
4. RESP AND CNS STIMULANTS	6,210	$923,310.50	2,488	$148.68	2.7%	↑1
5. GABA ANTICONVULSANTS	6,199	$124,102.76	2,604	$20.02	2.7%	↑2
6. PROTON-PUMP INHIBITORS	5,981	$126,905.92	3,259	$21.22	2.6%	↓2
7. ADRENALS	5,931	$557,401.34	4,021	$93.98	2.6%	↑1
8. PENICILLIN ANTIBIOTICS	5,893	$95,376.68	5,293	$16.18	2.5%	↓5
9. OPIOID AGONISTS	5,662	$102,353.39	2,963	$18.08	2.4%	NC
10. NSAIDS	5,275	$75,779.63	3,599	$14.37	2.3%	NC
11. ANTICONVULSANTS	5,147	$277,034.90	2,044	$53.82	2.2%	NC
12. STATINS	4,891	$70,924.96	2,879	$14.50	2.1%	NC
13. CENTRAL ALPHA-AGONISTS	4,843	$69,593.07	2,206	$14.37	2.1%	NC
14. BETA BLOCKING AGENTS	3,936	$67,911.59	2,232	$17.25	1.7%	NC
15. BETA AGONISTS	3,731	$216,398.28	3,385	$58.00	1.6%	NC

Top 15 Therapeutic Classes Based on Claims Cost from 04/01/2024 – 06/30/2024

Therapeutic Class Description	Claims	Claims Cost	Patients	Cost/Patient	% Cost	Dif.
1. TNF INHIBITORS	338	$2,617,807.48	146	$17,930.19	8.2%	NC
2. ANTIPSYCHOTIC AGENTS	9,099	$2,500,799.63	3,645	$686.09	7.9%	NC
3. INTERLEUKIN AGENTS	152	$1,475,976.72	64	$23,062.14	4.6%	NC
4. AMPHETAMINES	6,382	$1,248,191.69	2,704	$461.61	3.9%	NC
5. ANTINEOPLASTIC AGENTS	511	$1,211,016.00	222	$5,455.03	3.8%	↑1
6. ANTIRETROVIRALS	710	$1,153,012.39	297	$3,882.20	3.6%	↓1
7. SGLT2 INHIBITORS	1,450	$1,017,827.46	792	$1,285.14	3.2%	↑1
8. HCV ANTIVIRALS	45	$1,010,780.17	44	$22,972.28	3.2%	↑2
9. INCRETIN MIMETICS	1,401	$991,937.44	698	$1,421.11	3.1%	↓2
10. RESP AND CNS STIMULANTS	6,210	$923,310.50	2,488	$371.11	2.9%	↓1
11. CFTR CORRECTORS	28	$622,563.28	11	$56,596.66	2.0%	NC
12. ANTIDEPRESSANTS	24,816	$591,266.06	10,500	$56.31	1.9%	↑2
13. INSULINS	2,884	$568,377.78	1,237	$459.48	1.8%	↓1
14. ADRENALS	5,931	$557,401.34	4,021	$138.62	1.8%	↑1
15. PITUITARY	336	$545,590.98	146	$3,736.92	1.7%	↓2

RDUR Report: Q2 2024



April Cases by Type of Criteria		
Criteria Description	**# of Cases**	**% of Cases**
Drug-Disease Interaction	267	97.8%
Underuse	5	1.8%
Therapeutic Appropriateness	1	0.4%

May Cases by Type of Criteria		
Criteria Description	**# of Cases**	**% of Cases**
Drug-Disease Interaction	273	99.3%
Therapeutic Appropriateness	2	0.7%

June Cases by Type of Criteria		
Criteria Description	**# of Cases**	**% of Cases**
Drug-Disease Interaction	125	87.4%
Therapeutic Appropriateness	18	12.6%

Clinical Report

Prior Authorization Updates

September-24	PA Status	Class
Acthar	PA	Medications Over $3000 Criteria
Cimzia	PA	Cytokine Modulators
ciprofloxacin/dexamethasone	PA	ophthalmic anti-infectives
Dexlansoprazole	PA	PPIs
Freshkote	PA	Dry Eye Syndrome
Invokamet	PA	Diabetes
Invokana	PA	Diabetes
Katerzia	PA	non-preferred dosage form
Libervant	PA	non-preferred dosage form
Myhibbin	PA	non-preferred dosage form
Ohtuvayre	PA	Agents Used to Treat COPD
pimecrolimus	PA	Eczema/Atopic Dermatitis
pitavastatin	PA	Lipid-Lowering Therapy
Sentia	PA	Dry Eye Syndrome
tolvaptan	PA	Heart Failure/CKD
Vafseo	PA	Chronic Kidney Disease
verapamil ER PM	PA	non-preferred dosage form
Vetiva	PA	Dry Eye Syndrome
Vigafyde	PA	non-preferred dosage form
Lotronex	remove PA	Irritable Bowel Syndrome
tazarotene cream	remove PA	Acne

Summary of Changes

Ohtuvayre criteria added. ICS/LABA criteria modified to include step 1 and step 2 criteria.

Asthma/COPD

Therapeutic Duplication

- One medication from each class is allowed at time.
  - One inhaled steroid
  - Long-acting anticholinergic
  - Leukotriene pathway inhibitor
  - One short-acting beta agonist
  - One long-acting beta agonist

Electronic Concurrent Medication Required

- Roflumilast: A total of 90 days of an inhaled short or long-acting anticholinergic must be paid within 115 days prior to roflumilast's date of service.
  - According to the Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines, roflumilast is a recommended add-on therapy to members experiencing exacerbations while on antimuscarinic therapy.

Albuterol / Levalbuterol Rescue Inhalers

PREFERRED AGENTS (NO PA REQUIRED)	PREFERRED STEP 1 AGENTS (ELECTRONIC STEP REQUIRED)	NON-PREFERRED STEP 2 AGENTS (PA REQUIRED)
VENTOLIN (albuterol) HFA *– Brand Required*	levalbuterol HFA	albuterol HFA
	PROAIR RESPICLICK (albuterol)	PROVENTIL (albuterol) HFA
		XOPENEX (levalbuterol) HFA

According to the GINA guidelines:

- A low dose ICS should be taken whenever SABA taken for step 1 control of asthma.
- Dispensing ≥ 3 SABA canisters/year is associated with higher risk of emergency department presentations.
- Dispensing ≥ 12 SABA canisters/year is associated with higher risk of death.

Electronic Step Therapy Required

- Levalbuterol HFA:
  A. PA Not Required Criteria: A 30-day supply of albuterol HFA has been paid within 180 days prior to levalbuterol HFA's date of service.
  B. PA Required Criteria: The member must have failed a 30-day trial of albuterol HFA, as evidenced by paid claims or pharmacy printouts.

Electronic Concurrent Medications Required

- ProAir Respiclick: A total of 30 days of steroid inhaler must be paid within 40 days prior to ProAir Respiclick's date of service.
  A. The quantity limit for Ventolin HFA is set to 2 canisters per 6 months (2 puffs per day). If more is needed, member must switch to ProAir Respiclick HFA and be on a steroid inhaler to control asthma.

If the following conditions apply, please call for an override by calling provider relations at 1-800-755-2604:
- If primary insurance will only pay for ProAir Respiclick and member is well-controlled without steroid inhaler (i.e., uses less than 2 canisters per 6 months).

Therapeutic Duplication

- Short acting beta agonist nebulizers and inhalers are not payable together.

A. Inhalers and Nebulizers work equally well whether used at home, in school, or otherwise outside of the home. If member receives multiple forms of rescue medication, the risk of unidentified uncontrolled asthma and rescue inhaler dependence is increased.

If the following conditions apply, please call for an override by calling provider relations at 1-800-755-2604:
- Maximally treated members with end-stage COPD will be allowed an ongoing override (compliance with inhaled steroid, long-acting beta agonist, long-acting muscarinic antagonist, and Daliresp)
- Members with cystic fibrosis will be allowed an ongoing override.
- Acutely ill children will be allowed a one-time override.

References:

1. Albuterol Overuse: A Marker of Psychological Distress? Joe K. Gerald, Tara F. Carr, Christine Y. Wei, Janet T. Holbrook, Lynn B. Gerald. J Allergy Clin Immunol Pract. 2015 Nov-Dec; 3(6): 957–962. Published online 2015 Sep 1. Doi: 10.1016/j.jaip.2015.06.021. PMCID: PMC4641773
2. Global Initiative for Asthma. Global strategy for asthma management and prevention. 2019 GINA Main Report. Available from: www.ginasthma.org. (Accessed February 5, 2020)
3. National Asthma Education and Prevention Program, Third Expert Panel on the Diagnosis and Management of Asthma. Expert Panel Report 3: Guidelines for the Diagnosis and Management of Asthma. Bethesda (MD): National Health, Lung, and Blood Institute (US); 2007 Aug. Available from: https://www.ncbi.nlm.nih.gov/books/NBK7232
4. High-Dose Albuterol by Metered-Dose Inhaler Plus a Spacer Device Versus Nebulization in Preschool Children With Recurrent Wheezing: A Double-Blind, Randomized Equivalence Trial Dominique Ploin, François R. Chapuis, Didier Stamm, Jacques Robert, Louis David, Pierre G. Chatelain, Guy Dutau and Daniel Floret Pediatrics. August 2000, 106 (2) 311-317; DOI: https://doi.org/10.1542/peds.106.2.311

Anticholinergics/Beta Agonists Combinations – Short Acting

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
albuterol/ipratropium	DUONEB (albuterol/ipratropium)
COMBIVENT RESPIMAT (albuterol/ipratropium)	

Anticholinergics/Beta Agonists Combinations – Long Acting

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED STEP 1 AGENTS (PA REQUIRED)	NON-PREFERRED STEP 2 AGENTS (PA REQUIRED)
ANORO ELLIPTA (umeclidinium/vilanterol)	BEVESPI AEROSPHERE (glycopyrrolate/formoterol)	DUAKLIR PRESSAIR (aclidinium/formoterol)
STIOLTO RESPIMAT (tiotropium/olodaterol)		

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

Non-Preferred Step 1 Agents
- The member must have failed a 30-day trial of 2 preferred agents, as evidenced by paid claims or pharmacy printouts

Non-Preferred Step 2 Agents:

- The member must have failed a 30-day trial of Bevespi Aerosphere and 2 preferred agents, as evidenced by paid claims or pharmacy printouts
- Clinical justification must be provided explaining why the member is unable to use the preferred products (subject to clinical review).

Anticholinergics – Long-Acting

PREFERRED AGENTS (NO PA REQUIRED)	PREFERRED STEP 1 AGENTS (ELECTRONIC STEP REQUIRED)	NON-PREFERRED STEP 2 AGENTS (PA REQUIRED)
INCRUSE ELLIPTA (umeclidinium)	SPIRIVA RESPIMAT 1.25 MCG (tiotropium)	LONHALA MAGNAIR (glycopyrrolate)
SPIRIVA HANDIHALER (tiotropium)		tiotropium handihaler
SPIRIVA RESPIMAT 2.5 MCG (tiotropium)		TUDORZA PRESSAIR (aclidinium)
		YUPELRI (revefenacin)

Electronic Concurrent Medications Required

- Spiriva Respimat 1.25 mg: A total of 30 days of a long-acting beta agonist (ICS should be used with LABA as combination or single ingredient inhalers) must be paid within 40 days prior to the Spiriva Respimat 1.25 mg date of service.

Electronic Diagnosis Verification

- Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale.
  - Spiriva Respimat 1.25 mg is indicated for asthma.
  - Spiriva Respimat 2.5 mg is indicated for COPD.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must have failed a 30-day trial of at least 2 preferred long-acting anticholinergic agents of unique ingredients (in combination or alone), as evidenced by paid claims or pharmacy printouts.
- Lonhala Magnair (glycopyrrolate) only:
  - The member must have failed a 30-day trial of Yupelri, as evidenced by paid claims or pharmacy printouts.

Therapeutic Duplication

- Anticholinergic medications are not covered with acetylcholinesterase inhibitors.
  A. The effects of an anticholinergic (blocks the effect of acetylcholine) and acetylcholinesterase inhibitors (prevents breakdown of acetylcholine) oppose each other, and the therapeutic effect of both products is diminished.

Beta Agonists – Long-Acting

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
arformoterol	BROVANA (arformoterol)
formoterol	PERFOROMIST (formoterol)
SEREVENT DISKUS (salmeterol)	
STRIVERDI RESPIMAT (olodaterol)	

Biologics

Anti-IL-5 biologics

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
CINQAIR (reslizumab) – *Medical Billing Only*	NUCALA (mepolizumab) SYRINGE, AUTOINJECTOR
FASENRA (benralizumab)	NUCALA (mepolizumab) VIAL – *Medical Billing Only*

Anti-IL-4/13 biologics

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
DUPIXENT (dupilumab)	

Eosinophil-directed biologics

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
XOLAIR (omalizumab) SYRINGE, AUTOINJECTOR	
XOLAIR (omalizumab) VIAL – *Medical Billing Only*	

Thymic Stromal Lymphopoietin (TSLP) blocker

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
TEZSPIRE (tezepelumab-ekko) PENS	
TEZSPIRE (tezepelumab-ekko) VIAL and SYRINGES – *Medical Billing Only*	

Prior Authorization Criteria

Prior Authorization Form – Asthma

Initial Criteria – Approval Duration: 3 months

- The requested medication must be prescribed by, or in consult with, an allergist/immunologist or pulmonologist
- The member must have had at least one exacerbation requiring use of oral corticosteroids in the previous year despite continued compliant use of a high dose inhaled steroid in combination with a long-acting beta agonist (LABA) and long-acting muscarinic antagonist (LAMA) as evidenced by paid claims or pharmacy printouts

Anti-IL-5 biologics:

- The member has eosinophilic phenotype with eosinophil count ≥ 150 cells/mcL within the past 90 days
- Nucala: The member must have failed a 3-month trial of a preferred Anti-IL-5 biologic, as evidenced by paid claims or pharmacy printouts

Eosinophil-directed biologics:

- The member has a serum total IgE level, measured before the start of treatment, of ≥ 30 IU/mL and ≤ 700 IU/mL in members age ≥ 12 years or ≥ 30 IU/mL and ≤ 1300 IU/mL in members ages 6 to < 12 years.
- The member has had a positive skin test or in vitro reactivity to a perennial aeroallergen

Renewal Criteria – Approval Duration: 12 months

- The member must have achieved a significant reduction in asthma exacerbations and utilization of rescue medications since treatment initiation since starting treatment with the requested medication, as evidenced by medical documentation (e.g., chart notes) attached to the request (subject to clinical review).

Corticosteroids – Inhaled

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ARNUITY ELLIPTA (fluticasone)	ALVESCO (ciclesonide)

ASMANEX (mometasone) TWISTHALER	ASMANEX HFA (mometasone)
budesonide suspension	fluticasone HFA
PULMICORT FLEXHALER (budesonide)	fluticasone diskus
	PULMICORT RESPULES (budesonide)
	QVAR REDIHALER (beclomethasone)

GINA and EPR-3 Guidelines – SMART:

- For steps 3-5, ICS-formoterol is preferred for use as an as needed and regular daily treatment
- Please consider SMART therapy instead of single agent inhaled corticosteroid.
  - Both Symbicort and Dulera are available as HFA products

Quantity Limits to accommodate SMART therapy:

- 2 Symbicort or Dulera inhalers per 30-day supply not to exceed a total of 9 inhalers per 365 days without prior approval.

References:

1. Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention, 2023. Updated July 2023. Available from: www.ginasthma.org
2. Cloutier, Michelle M., et al. "2020 focused updates to the asthma management guidelines: a report from the National Asthma Education and Prevention Program Coordinating Committee Expert Panel Working Group." *Journal of Allergy and Clinical Immunology* 146.6 (2020): 1217-1270. Available at: https://www.epa.gov/sites/default/files/2021-05/documents/_sites_default_files_publications_asthmamanagementguidelinesreport-2-4-21.pdf

Electronic Age Verification:

- Fluticasone HFA does not require PA for ages 4 and under

Electronic Duration Verification:

- Budesonide Suspension 1 mg/2 mL is payable for 30 days every 75 days. For diluted nasal rinses or oral use, please use 0.5 mg/2 mL instead of 1 mg/2 mL for doses 1 mg per day or higher.
  - Guidelines recommend that once control is achieved, dose should be titrated down to minimum dose required to maintain control. For doses 1.5 mg per day or lower, please use 0.5 mg/2 mL strength.

Prior Authorization

Initial Criteria – Approval Duration: 12 months

- The member must have failed a 30-day trial of each preferred inhaler of a unique active ingredient, as evidenced by paid claims or pharmacy printouts.
- *Asmanex HFA and QVAR Redihaler Only:*
  - Preferred agent trials may be bypassed if member meets one of the following criteria:
    - Member is unable to achieve inspiratory flow rate of 40 L/min.
    - Member is unable to achieve inspiratory flow rate of 60 L/min and has previously had adrenal insufficiency with fluticasone.
    - Permanent disability preventing use of a dry powder inhaler
- *fluticasone HFA only:*
  - Preferred agent trials may be bypassed if member meets one of the following criteria:
    - Member is unable to achieve inspiratory flow rate of 40 L/min.
    - Permanent disability preventing use of a dry powder inhaler

References:

1. Sannarangappa V, Jalleh R. Inhaled corticosteroids and secondary adrenal insufficiency. Open Respir Med J. 2014 Jan 31;8:93-100. doi: 10.2174/1874306401408010093. PMID: 25674179; PMCID: PMC4319207.
2. Saag KG, Furst DE, Barnes PJ . Major side effects of inhaled glucocorticoids In: *UpToDate*, Post TW (Ed), UpToDate, Waltham, MA, 2023

Corticosteroid/Long-Acting Beta Agonist (LABA) Combination Inhalers

Solid Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED STEP 1 AGENTS (PA REQUIRED)	NON-PREFERRED STEP 2 AGENTS (PA REQUIRED)
ADVAIR DISKUS (fluticasone/salmeterol) *– Brand Required*	BREO ELLIPTA (fluticasone/vilanterol) *– Brand Required*	budesonide/formoterol
ADVAIR HFA (fluticasone/salmeterol) *– Brand Required*		fluticasone/salmeterol
AIRDUO RESPICLICK (fluticasone/salmeterol) *– Brand Required*		fluticasone/vilanterol
DULERA (mometasone/formoterol)		SYMBICORT (budesonide/formoterol) *– Brand Required*
		WIXELA INHUB (fluticasone/salmeterol)

GINA Guidelines – SMART:

- For mild asthma, ICS-formoterol is the preferred reliever medication for as needed symptom relief
- For steps 3-5, ICS-formoterol is preferred for use as an as needed and regular daily treatment
  Quantity Limits to accommodate SMART therapy:
  - 2 Symbicort or Dulera inhalers per 30-day supply not to exceed a total of 9 inhalers per 182 days without prior approval.

Electronic Diagnosis Verification

- Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

Non-Preferred Step 1 Agents:

- The member must have failed a 30-day trial of each preferred agent of a unique ingredient, as evidenced by paid claims or pharmacy printouts.
- For COPD diagnosis only: The member must currently be taking a long acting antimuscarinic agent.

Non-Preferred Step 2 Agents:

- The member must have failed a 30-day trial of each preferred and non-preferred step 1 agent of a unique ingredient, as evidenced by paid claims or pharmacy printouts.
- For COPD diagnosis only: The member must currently be taking a long acting antimuscarinic agent.

Corticosteroid/Anticholinergics/Long-Acting Beta Agonists Combinations

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
TRELEGY ELLIPTA (fluticasone/umeclidinium/vilanterol)	BREZTRI AEROSPHERE (budesonide/glycopyrrolate/formoterol)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must have blood eosinophil of ≥ 100
- The member must have experienced an exacerbation while adherent to a 60-day trial of fluticasone inhaler + umeclidinium + vilanterol which have the same active ingredients as Trelegy Ellipta, as evidenced by paid claims or pharmacy printouts. Clinical justification must also be provided why Trelegy Ellipta is expected to improve outcomes versus using fluticasone inhaler + umeclidinium + vilanterol combination therapy (subject to clinical review).
    - available combination products to achieve this are fluticasone + Anoro Ellipta (umedclidium/vilanterol) and Breo Ellipta (fluticasone/vilanterol) + Incluse Ellipta (umeclidinium)
- The member must have experienced an exacerbation while adherent to a 60-day trial of triple therapy (Steroid/Long-Acting Beta Agonist/Long-Acting Anticholinergic) that has at least one ingredient different from fluticasone inhaler + umeclidinium + vilanterol combination therapy, as evidenced by paid claims or pharmacy printouts.

Non-Preferred Agents Criteria:

- The member must have failed a 30-day trial of the preferred product, as evidenced by paid claims or pharmacy printouts:

Phosphodiesterase-3 (PDE3) and Phosphodiesterase-4 (PDE4) Inhibitor

PREFERRED AGENTS (CLINICAL PA REQUIRED)
OHTUVAYRE (ensifentrine)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must meet one of the following criteria:
    - The member has a blood eosinophil of ≥ 100 and has experienced an exacerbation while adherent to a 60-day trial of a triple combination regimen consisting of an inhaled steroid, long-acting beta agonist, and long-acting anticholinergic.
    - The member has a blood eosinophil of < 100 and has experienced an exacerbation while adherent to a 60-day trial of a dual combination regimen consisting of a long-acting beta agonist and long-acting anticholinergic.
    - The member has experienced an exacerbation while adherent to a 60-day trial of a long-acting anticholinergic and has a contraindication or intolerance to a long-acting beta agonist (subject to clinical review)
    - The member has experienced an exacerbation while adherent to a 60-day trial of a long-acting beta agonist and has a contraindication or intolerance to a long-acting anticholinergic (subject to clinical review)

Summary of Changes

Kerendia Criteria Updated: Kerendia criteria updated to specify UACR and albuminuria labs must be collected while on ACE or ARB therapy based on KDIGO clinical practice guidelines and renewal criteria was updated to allow for stabilization of eGFR based on clinical trial primary endpoint.

Tovlaptan criteria added.

Chronic Kidney Disease

Therapeutic Duplication

- Medication classes not payable together:
  - Filspari, ACE Inhibitors, ARBs, and Renin Inhibitors are not allowed with each other.

Dual endothelin angiotensin receptor antagonist

CLINICAL PA REQUIRED
FILSPARI (sparsentan)

Kappa-opioid agonist

CLINICAL PA REQUIRED
KORSUVA (difelikefalin) – *Medical Billing Only*

Non-steroidal selective mineralocorticoid receptor antagonist (MRA)

CLINICAL PA REQUIRED
KERENDIA (finerenone)

Renin-Angiotensin-Aldosterone System (RAAS) Inhibitors

NO PA REQUIRED
ACE (angiotensin-converting enzyme) inhibitors – *all oral agents preferred*
ARBs (angiotensin receptor blockers) – *all oral agents preferred*
TEKTURNA (aliskiren)

SGLT-1/SGLT-2 Inhibitor

CLINICAL PA REQUIRED
INPEFA (sotagliflozin)

SGLT-2 Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
FARXIGA (dapagliflozin) – *Brand Required*	dapagliflozin
INVOKANA (canagliflozin)	
JARDIANCE (empagliflozin)	

Sodium/Hydrogen Exchanger 3 (NHE3)

CLINICAL PA REQUIRED
XPHOZAH (tenapanor)

Systemic Corticosteroids

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
methylprednisolone	TARPEYO (budesonide-targeted release)
prednisone	

Vasopressin V2-receptor (V2R) Antagonist

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
JYNARQUE (tolvaptan)	

Electronic Duration Verification:

- Tarpeyo is payable for 9 months every 3 years.
- tolvaptan is payable for 30 days every year.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

Inpefa Only:

- The requested medication must be prescribed by, or in consult with, a cardiologist or nephrologist.
- If member is on renal dialysis, Medicare eligibility must be ruled out. *(6-month approval allowed to determine eligibility)*
- The member has type 2 diabetes and chronic kidney disease.
- The member has a history of a cardiovascular event (e.g., heart failure, myocardial infarction, cerebrovascular event) or two or more risk factors (e.g., elevated cardiac and inflammatory biomarker, obesity, hyperlipidemia, hypertension)
- The member is receiving concurrent Entresto, a beta-blocker, a SGLT-2 Inhibitor, and a mineralocorticoid receptor antagonist.
- Clinical justification must be provided explaining why the member is unable to use a preferred SGLT-2 inhibitor (subject to clinical review)

Kerendia Only

- The member must have history of diabetes.
- The member must be on the following at the target or maximally tolerated dose, as evidenced by paid claims or pharmacy printouts:
  - An ACE-inhibitor or an ARB
  - A SGLT-2 inhibitor
- The member has an estimated glomerular filtration rate (eGFR) ≥ 25 mL/min/1.73 m^2
- The member has one of the following (1 or 2) despite a 3-month trial with an ACE inhibitor or a 6-month trial with an ARB:
  1. urinary albumin-to-creatinine ratio (UACR) ≥ 30 mg/g (≥3 mg/mmol)
  2. albuminuria ≥ 300 mg/day

Korsuva Only

- If member is on renal dialysis, Medicare eligibility must be ruled out *(6-month approval may be allowed to determine eligibility)*.
- The member must have failed a 90-day trial of pregabalin or gabapentin, as evidenced by paid claims or pharmacy printouts.

Filspari and Tarpeyo Only

- The member must have eGFR ≥ 30.
- If member is on renal dialysis, Medicare eligibility must be ruled out *(6-month approval may be allowed to determine eligibility)*.
- The member must be experiencing proteinuria > 1 gram/day or UPCR ≥ 1.5 g/g (documentation must be attached) despite 3-month trials with good compliance of the following at the target or maximally tolerated dose, as evidenced by paid claims or pharmacy printouts:
  - ACE inhibitor or an ARB
  - A SGLT-2 inhibitor
  - prednisone or methylprednisolone

Tolvaptan Only

- The requested medication must be prescribed by, or in consult with, a nephrologist.
- The member does not have liver disease.
- The member has eGFR ≥ 25
- The prescriber has provided clinical justification that the member is at high risk of kidney progression such as one of the following (subject to clinical review):
  - Autosomal dominant polycystic kidney disease mayo classes 1C, 1D, or 1E
  - Kidney length > 16.5 cm (by ultrasound, MRI, or CT scan)
  - An annual eGFR decline of at least 5 mL/min/1.73 m2 in one year
  - An annual eGFR decline of at least 2.5 mL/min/1.73 m2 per year over a period of five years
  - A greater than 5 % increase in total kidney volume per year on at least three repeated measurements (via MRI or CT (computed tomography), each at least 6 months apart

Xphozah Only

- If member is on renal dialysis, Medicare eligibility must be ruled out *(6-month approval may be allowed to determine eligibility)*.
- The member must have failed 30-day trials of sevelamer carbonate and sucroferric oxyhydroxide, as evidenced by paid claims or pharmacy printouts.

<u>Renewal Criteria – Approval Duration:</u> 12 months

- If member is on renal dialysis, Medicare eligibility must be ruled out *(6-month approval may be allowed to determine eligibility)*.
- The member must have experienced meaningful clinical benefit since starting treatment with the requested medication, as evidenced by medical documentation (e.g., chart notes) attached to the request (subject to clinical review) including the following scores and symptoms:
  - *Filspari and Tarpeyo Only*: proteinuria <1 gram/day or UPCR < 1.5 g/g or reduction of 30% from baseline
  - *Kerendia Only*: The member has experienced a stabilization in eGFR or one of the following:
    - albuminuria <1 gram/day or reduction of 30% from baseline
    - UACR < 1.5 g/g or reduction of 30% from baseline

References:

1. Stevens, Paul E., et al. "KDIGO 2024 Clinical practice guideline for the evaluation and management of chronic kidney disease." Kidney international 105.4 (2024): S117-S314.
2. de Boer, Ian H., et al. “Diabetes management in chronic kidney disease: a consensus report by the American Diabetes Association (ADA) and Kidney Disease: Improving Global Outcomes (KDIGO).” *Diabetes care* 45.12 (2022): 3075-3090.

Summary of Changes

Added criteria for new drug Duvyzet. Study 1; NCT02851797 included male patients 6 years of age and older with a confirmed diagnosis of DMD who were ambulatory and on a stable dosage of corticosteroids.

Duchenne Muscular Dystrophy

Corticosteroids

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AGAMREE (vamorolone)	deflazacort
EMFLAZA (deflazacort) – *Brand Required*	

Prior Authorization Criteria

Prior Authorization Form – Duchenne Muscular Dystrophy

Initial Criteria – Approval Duration: 6 months

(approval may be granted for tapering if all initial criteria are not met)

- Diagnosis must be confirmed by the documented presence of abnormal dystrophin or a confirmed mutation of the dystrophin gene
- The requested medication must be prescribed by, or in consult with, a physician who specializes in the treatment of Duchenne Muscular Dystrophy (DMD) and/or neuromuscular disorders
- Onset of weakness must have occurred before 2 years of age
- The member must have serum creatinine kinase activity of at least 10 times the upper limit of normal (ULN) prior to initiating treatment
- The member must have failed a 6-month trial of prednisone, as evidenced by paid claims or pharmacy printouts
- The provider must submit baseline assessment results from the following assessments (the member does not have to meet all of these parameters, but each assessment must be submitted, and provider must indicate which parameters are met and being preserved, must be at least one):
    i. Stable cardiac function LVEF > 40% by echo
    ii. Scoliosis not requiring surgery
    iii. Stable respiratory function – FVC predicted > 50%, not requiring ventilatory assistance
    iv. The provider must submit baseline motor milestone score results from at least ONE the following assessments:
        - 6-minute walk test (6MWT)
        - North Star Ambulatory Assessment (NSAA)
        - Motor Function Measure (MFM)
        - Hammersmith Functional Motor Scale (HFMS)
        - Performance of Upper Limb (PUL)
- The member must have ONE of the following significant intolerable adverse effects supported by documentation:
    i. Cushingoid appearance
    ii. Central (truncal) obesity
    iii. Severe behavioral adverse effect
    iv. Undesirable weight gain (>10% of body weight gain increase over 6-month period)
    v. Diabetes and/or hypertension that is difficult to manage

Renewal Criteria – Approval Duration: 12 months

- The member must have experienced stabilization, slowing of disease progression, or improvement of the condition since starting treatment with the requested medication, as evidenced by medical documentation

(e.g., chart notes) attached to the request (subject to clinical review) including the following assessments (the member does not have to meet all of these parameters, but each assessment must be submitted, and provider must indicate which parameters are met and being preserved, must be at least one):
    i. Stable cardiac function LVEF > 40% by ECHO
    ii. Scoliosis not requiring surgery
    iii. Stable respiratory function – FVC predicted > 50%, not requiring ventilatory assistance
    iv. Motor function assessment
        - 6MWT – improvement of 20 meters from baseline
        - NSAA – improvement of 2 points from baseline
        - MFM – improvement of 2 points from baseline
        - HFMS – improvement of 2 points from baseline
        - PUL – improvement of 4 points from baseline
- The member must have had improvement of adverse effects experienced on prednisone supported by documentation:
    i. Cushingoid appearance
    ii. Central (truncal) obesity
    iii. Severe behavioral adverse effect
    iv. Undesirable weight gain (>10% of body weight gain increase over 6-month period)
    v. Diabetes and/or hypertension that is difficult to manage

Histone Deacetylase Inhibitor

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
DUVYZAT (givinostat)	

Prior Authorization Criteria

Prior Authorization Form – Duchenne Muscular Dystrophy

Initial Criteria – Approval Duration: 6 months

- The requested medication must be prescribed by, or in consult with, a physician who specializes in the treatment of Duchenne Muscular Dystrophy (DMD) and/or neuromuscular disorders.
- The member must be assigned male at birth.
- The diagnosis must be confirmed by the documented presence of abnormal dystrophin or a confirmed mutation of the dystrophin gene.
- Medical records must be provided confirming the member has a baseline 6-Minute Walk Time (6MWT) ≥ 300 meters while walking independently (e.g., without side-by-side assist, cane, walker, wheelchair, etc.)
- Weight and calculated dose must be provided consistent with approved FDA dose.
- The provider must submit baseline motor milestone score results from at least ONE the following assessments:
    - North Star Ambulatory Assessment (NSAA)
    - 4-stair claim (4SC)
- The member is on a stable dose of corticosteroids for the past 3 months, as evidenced by paid claims and pharmacy print outs.

Renewal Criteria – Approval Duration: 12 months

- Medical records must be provided confirming the member has maintained a 6MWT ≥ 300 meters while walking independently (e.g., without side-by-side assist, cane, walker, wheelchair, etc.)
- The member must have experienced stabilization, slowing of disease progression, or improvement of the condition since starting treatment with the requested medication, as evidenced by medical documentation (e.g., chart notes) attached to the request (subject to clinical review) including:
    - North Star Ambulatory Assessment (NSAA)
    - 4-stair claim (4SC)

Genetic Therapies

Exon 45 Skipping

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AMONDYS 45 (casimersen) – *Medical Billing Only*	

Exon 51 Skipping

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
EXONDYS 51 (eteplirsen) – *Medical Billing Only*	

Exon 53 Skipping

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
VILTEPSO (viltolarsen) – *Medical Billing Only*	VYONDYS 53 (golodirsen) – *Medical Billing Only*

High-Cost Drug:
Amondys 45, Exondys 51, and Vyondys 53 cost $758,000 per year for a 30 kg child.
Viltepso cost $733,200 per year for a 30 kg child.

- Amondys 45 is awaiting verification of clinical benefit in confirmatory trials. In Study 1 (NCT02500381), individuals treated with Amondys 45 observed an increase in mean dystrophin protein levels of 0.81%, while the placebo arm observed a mean increase of 0.22%.
- Exondys 51 is awaiting verification of clinical benefit in confirmatory trials. In Study 1, there was no significant difference in change in 6MWD in patients treated with Exondys 51 and placebo. All 12 individuals enrolled in Study 1, continued treatment with open-label Exondys 51 and were compared to an external control group. Study 2 failed to provide evidence of a clinical benefit of Exondys 51 compared to the external control group. In Study 3, the median increase in dystrophin level was 0.1% in 12 evaluable individuals receiving open-label Exondys 51.
- Viltepso is awaiting verification of clinical benefit in confirmatory trials. In Study 1 (NCT02740972), 8 individuals treated with Viltepso observed a mean increase in dystrophin of 5.3% of normal levels.
- Vyondys 53 is awaiting verification of clinical benefit in confirmatory trials. In Study 1 (NCT02310906), 25 individuals treated with Vyondys 53 observed a mean increase in dystropin of 0.92% of normal levels.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 8 weeks

- The member must be assigned male at birth between ages of 4 and 19 years old
- Diagnosis must be confirmed by the documented presence of abnormal dystrophin or a confirmed mutation of the dystrophin gene
- The requested medication must be prescribed by, or in consult with, a physician who specializes in the treatment of Duchenne Muscular Dystrophy (DMD) and/or neuromuscular disorders
- The member has had an inadequate treatment response with standard corticosteroid therapy for a minimum of 6 months with adherence, as evidenced by paid claims or pharmacy printouts
- Medical records must be provided confirming the member has:
  - A baseline 6-Minute Walk Time (6MWT) ≥ 300 meters while walking independently (e.g., without side-by-side assist, cane, walker, wheelchair, etc.)
  - Stable respiratory function – FVC predicted > 50%, not requiring ventilatory assistance
  - Stable cardiac function – LVEF > 40 % by ECHO
- Weight and calculated dose must be provided consistent with approved FDA dose
- The member must not be taking any other RNA antisense agent or any other gene therapy

Non-Preferred Agent Criteria (Initial)

- Please provide explanation with the request why the preferred agent cannot be used (subject to clinical review)

Renewal Criteria – Approval Duration: 12 months

- Medical records must be provided confirming the member has maintained:
  - A 6MWT ≥ 300 meters while walking independently (e.g., without side-by-side assist, cane, walker, wheelchair, etc.)
  - Stable respiratory function – FVC predicted > 50%, not requiring ventilatory assistance
  - Stable cardiac function – LVEF > 40 % by ECHO

Summary of Changes

Changes for Prader – Willi Syndrome due to the following warning:

Somatropin is contraindicated in patients with Prader-Willi syndrome who are severely obese, have a history of upper airway obstruction or sleep apnea, or have severe respiratory impairment. There have been reports of sudden death when somatropin was used in such patients

- GH will not be covered until the BMI is less than 120% of the 95th percentile.
- If member has obesity 95th percentile or greater but below 120% of the 95th percentile, rule out of comorbidities and to meet with dietician every 3 months is required.
- If member does not have obesity 95th percentile or greater, the initial and renewal requests will fall under the 12-month approval period with no additional criteria.

Growth Hormone

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
NORDITROPIN FLEXPRO (somatropin)	GENOTROPIN (somatropin)
NUTROPIN AQ (somatropin)	GENOTROPIN MINIQUICK (somatropin)
	HUMATROPE (somatropin)
	NGENLA (somatrogon-ghla)
	OMNITROPE (somatropin)
	SAIZEN (somatropin)
	SKYTROFA (lonapegsomatropin-tcgd)
	SOGROYA (somapacitan-beco)
	ZOMACTON (somatropin)

Prior Authorization Criteria

Prior Authorization Form – Growth Hormone

Initial Criteria – Approval Duration: 12 months (except 6 months if criteria met in Prader-Willi Syndrome)

- Member must have one of the following covered diagnoses (listed below):
  - Multiple pituitary hormone deficiencies caused by a known hypothalamic-pituitary disease or its treatment (brain surgery and/or radiation)
  - Turner's syndrome

- SHOX syndrome
- Noonan syndrome
- Chronic renal insufficiency
- Prader–Willi syndrome
- Endogenous growth hormone deficiency

- The requested medication must be prescribed by, or in consult annually with, an endocrinologist or nephrologist.
- The member must not have active malignancy.
- The member must not have epiphyseal closure and must still be growing, unless one of the below exceptions is present:
  - The member has a diagnosis of Prader-Willi syndrome.
  - The member has a diagnosis of endogenous growth hormone deficiency and is experiencing hypoglycemic episodes without growth hormone and growth hormone is needed to maintain proper blood glucose.

Chronic Renal Insufficiency

- The member must not have received a renal transplant.
- The member must consult with a dietitian annually to maintain a nutritious diet.

Endogenous Growth Hormone Deficiency

- ONE of below criteria must be met:
  - The member has multiple pituitary hormone deficiencies caused by a known hypothalamic-pituitary disease or its treatment (brain surgery and/or radiation) and must have an IGF-1 or IGFBP-3 level of less than SDS -1.3.
  - The member has had GH stimulation testing by at least two different stimuli (e.g., insulin, levodopa, L-arginine, propranolol, clonidine, or glucagon) with a maximum peak of < 10 ng/mL after stimulation no more than 6 months apart.

Prader-Willi Syndrome (PWS)

See covered medications for weight loss

- The member must not have severe obesity (class 2) defined as ≥ 120% of the 95th percentile for age and gender
- If the member has obesity ≥ 95th percentile and < 120% of the 95th percentile for age and gender, all the following must be met (*6-month approval criteria*):
  - The prescriber must attest that member will meet with a dietician every 3 months
  - The member must have had a sleep study to rule out sleep apnea
  - The member must not have non-alcoholic fatty liver disease
  - The member must not have an A1c > 5.7%

Non-Preferred Agent Criteria:

- The member must have failed a 30-day trial of all preferred agents, as evidenced by paid claims or pharmacy printouts.
- Clinical justification must be provided explaining why the member is unable to use the preferred agents (subject to clinical review).

Renewal Criteria – Approval Duration: 12 months (6 months if criteria below for PWS is met)

- The member must have been compliant with growth hormone (last 6 fills must have been on time).

Prader-Willi Syndrome

- If the member has obesity ≥ 95th percentile and < 120% of the 95th percentile for age and gender, initial criteria must be met in addition to the following *(6-month approval criteria)*:
  - The member must have met with a dietician at least 2 times in the past 6 months

Summary of Changes

Tolvaptan and Entresto Sprinkle were added to prior authorization with criteria.

Heart Failure

First Line Agents

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ACE (angiotensin-converting enzyme) inhibitors – *all oral agents preferred*	dapagliflozin
ARBs (angiotensin receptor blockers) – *all oral agents preferred*	INPEFA (sotagliflozin)
Beta blockers – *all oral agents preferred*	SAMSCA (tolvaptan)
Diuretics	tolvaptan
ENTRESTO (sacubitril/valsartan)	
FARXIGA (dapagliflozin) – *Brand Required*	
JARDIANCE (empagliflozin)	

Second Line Agents

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
CORLANOR (ivabradine)	
VERQUVO (vericiguat)	

Non-Solid Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
enalapril oral solution	ENTRESTO (sacubitril/valsartan) SPRINKLE
	EPANED (enalapril) SOLUTION

Electronic Diagnosis Verification

- Corlanor, Entresto, and Verquvo: Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale.

Electronic Duration Verification:

- tolvaptan is payable every year.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- Corlanor Only:
  - The requested medication must be prescribed by, or in consult with, a cardiologist.
  - The member must have a resting HR ≥ 70 beats per minute on maximally tolerated or target beta blocker dose in sinus rhythm.
- Entresto Sprinkle
  - See Non-Solid Dosage Form criteria
  - The member has a diagnosis of heart failure with left ventricular ejection fraction of ≤ 45 %
  - The member has failed a 3 month trial of enalapril, as evidenced by paid claims or pharmacy printouts.
- Inpefa Only:

- The requested medication must be prescribed by, or in consult with, a cardiologist or nephrologist.
- The member is receiving concurrent Entresto, a beta-blocker, a SGLT-2 Inhibitor, and a mineralocorticoid receptor antagonist.
- The member has been admitted to the hospital, a heart failure unit, infusion center, or emergency department for worsening heart failure within the past 3 months.
- Clinical justification must be provided explaining why the member is unable to use Farxiga and Jardiance (subject to clinical review)

- Tolvaptan Only:
  - The requested medication must be prescribed by, or in consult with, a cardiologist or nephrologist.
  - The member is experiencing sodium levels less than 125 mEq/L despite a 30-day trial of an ACE inhibitor or ARB.
  - The member does not have liver disease.
- Verquvo Only:
  - The requested medication must be prescribed by, or in consult with, a cardiologist.
  - The member must have left ventricular ejection fraction (LVEF) < 45% at initiation.
  - The member must have had a hospitalization or need for IV diuretics within the past 3 months
  - The member is receiving concurrent Entresto, a beta-blocker, a SGLT-2 Inhibitor, and a mineralocorticoid receptor antagonist.

Summary of Changes

Berinert moved non-preferred but allowed bypass for members who are pregnant, breastfeeding, or under 18 years old upon request due to more evidence in these populations.

Prophylaxis criteria added for situations likely to require prophylaxis. Renewal criteria added inline with clinical trial endpoints.

Hereditary Angioedema (HAE)

Acute Attack

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
icatibant	BERINERT (plasma derived C1 Esterase Inhibitor)
	BERINERT (plasma derived C1 Esterase Inhibitor) – *Medical Billing Only*
	FIRAZYR (icatibant)
	KALBITOR (ecallantide) – *Medical Billing Only*
	RUCONEST (recombinant C1 Esterase Inhibitor)
	RUCONEST (recombinant C1 Esterase Inhibitor) – *Medical Billing Only*

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

- The requested medication must be prescribed by, or in consult with, an allergist/immunologist or rheumatologist.

Non-Preferred Agent Criteria:

- The member must have a contraindication to or failed a trial of all preferred agents, as evidenced by paid claims or pharmacy printouts.

A. Berinert Only: The preferred agent trial may be bypassed for members who are pregnant, breastfeeding, or under 18 years old upon request.

B. Ruconest Only: The member must have a contraindication to or failed a trial of Berinert, as evidenced by paid claims or pharmacy printouts.

Prophylaxis

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
HAEGARDA (plasma derived C1 Esterase Inhibitor)	CINRYZE (plasma derived C1 Esterase Inhibitor)
TAKHZYRO (lanadelumab-flyo)	ORLADEYO (berotrlastat)

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

- The requested medication must be prescribed by, or in consult with, an allergist/immunologist or rheumatologist.
- The member's weight and dose are provided.
- One of the following must be met (A, B, or C):
  - A. The member has had at least 1 moderate to severe acute attack in the past 3 months (e.g., airway swelling, facial swelling, severe abdominal pain)
  - B. The member is using short-term prophylaxis for one of the following:
    - a procedure related to pregnancy
    - oral cavity or invasive procedures
    - stressful life event at high risk for precipitating HAE attack (clinical justification subject to clinical review)
  - C. Estrogen treatment is required, and member is at high risk for estrogen-precipitated HAE attack (clinical justification subject to clinical review)

Non-Preferred Agent Criteria:

- The member must have a contraindication to or failed a 3-month trial of all preferred agents with the same indication for use (prophylaxis or acute treatment), as evidenced by paid claims or pharmacy printouts.

Renewal Criteria – Approval Duration: 12 months

- The member must have experienced meaningful clinical benefit since starting treatment with the requested medication, as evidenced by at least a 50% reduction in the number of HAE attacks.

Quantity Override Request

- Takhyzro: The number of attacks in the last 6 months must be included if the requested dosing frequency is every 2 weeks (must be more than 0).

References

1. Busse, Paula J., et al. "US HAEA medical advisory board 2020 guidelines for the management of hereditary angioedema." *The Journal of Allergy and Clinical Immunology: In Practice* 9.1 (2021): 132-150.

Summary of Changes

Camzyos criteria was updated to reflect parameters used in the Explorer-HCM and VALOR-HCM trials

Hypertrophic Cardiomyopathy

CLINICAL PA REQUIRED
CAMZYOS (mavacamten)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The requested medication must be prescribed by, or in consult with, a cardiologist.
- The member must have all of the following:
  - left ventricular ejection fraction (LVEF) ≥ 55%
  - NYHA class II or III
  - Resting oxygen saturation of ≥ 90%
  - Valsava left ventricular outflow tract (LVOT) gradient ≥ 50 mmHg at rest or with provocation.
- The member must have persistent symptoms despite maximally tolerated therapy with each of the following:
  - Non-dihydropyridine calcium channel blocker
  - beta blocker

Renewal Criteria – Approval Duration: 12 months

- The member has one of the following:
  - an improved pVO_2 by ≥ 1.5 mL/kg/min plus improvement in NYHA class by at least 1
  - an improvement of pVO_2 by ≥ 3 mL/kg/min and no worsening in NYHA class.
  - NYHA class I or II without exertion-induced syncope
  - Valsalva LVOT gradient < 50 mmHg at rest or with provocation.

References

1. Olivotto, Iacopo, et al. "Mavacamten for treatment of symptomatic obstructive hypertrophic cardiomyopathy (EXPLORER-HCM): a randomised, double-blind, placebo-controlled, phase 3 trial." The Lancet 396.10253 (2020): 759-769.
2. Desai, Milind Y., et al. “Mavacamten in patients with hypertrophic cardiomyopathy referred for septal reduction: week 56 results From the VALOR-HCM randomized clinical trial.” JAMA cardiology 8.10 (2023): 968-977.

Summary of Changes

Non-Preferred Criteria added for Atorvaliq. Pitavastatin moved to non-preferred, criteria added.

Lipid-Lowering Agents

ACL (ATP Citrate Lyase) Inhibitors

PREFERRED AGENTS (ELECTRONIC STEP REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
NEXLETOL (bempedioc acid)	
NEXLIZET (bempedoic acid and ezetimibe)	

Electronic Step Therapy Required

- Nexletol or Nexlizet:
  - PA Not Required Criteria: A total of 90-day supply of rosuvastatin or atorvastatin has been paid within 120 days prior to Nexletol or Nexlizet’s date of service.
  - PA Required Criteria: The member must have failed a 90-day trial of rosuvastatin or atorvastatin, as evidenced by paid claims or pharmacy printouts.

Cholesterol Absorption Inhibitor – 2-Azetidinone

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ezetimibe	ZETIA (ezetimibe)

Eicosapentaenoic acid (ESA) Ethyl Ester

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
VASCEPA (icosapent ethyl) – *Brand Required*	icosapent ethyl

Fenofibrate

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
fenofibrate, micronized 43 mg, 67 mg, 134 mg, 200mg	ANTARA (fenofibrate, micronized)
fenofibrate, nanocrystallized	fenofibrate capsules 50 mg, 150 mg
fenofibrate tablets 54 mg, 160 mg	fenofibrate, micronized 90 mg, 130 mg
fenofibric acid DR 45 mg, 135 mg	fenofibrate tablets 40 mg, 120 mg
	fenofibric acid 105 mg
	FENOGLIDE (fenofibrate)
	LIPOFEN (fenofibrate)
	TRICOR (fenofibrate, nanocrystalized)
	TRIGLIDE (fenofibrate)
	TRILIPIX (fenofibric acid)

Prior Authorization Criteria

- See Preferred Dosage Form criteria

MTP (Microsomal Triglyceride Transfer Protein) Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	JUXTAPID (lomitapide)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 3 months

- Clinical justification must be provided explaining why the member is unable to use all other products to lower their cholesterol (subject to clinical review)

PCSK9 (Proprotien Convertase Subtilisin/Kexin Type 9) Inhibitors

PREFERRED AGENTS (ELECTRONIC STEP REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
PRALUENT PEN (alirocumab)	
REPATHA PUSHTRONEX (evolocumab)	
REPATHA SURECLICK (evolocumab)	
REPATHA SYRINGE (evolocumab)	

Underutilization

- Praluent and Repatha must be used adherently and will reject on point of sale for late fill.

Electronic Step Therapy Required

- Praluent and Repatha:

- PA Not Required Criteria: A total of 90-day supply of rosuvastatin or atorvastatin has been paid within 120 days prior to Praluent and Repatha's date of service.
- PA Required Criteria: The member must have failed a 90-day trial of rosuvastatin or atorvastatin, as evidenced by paid claims or pharmacy printouts.

Statins (HMG-CoA (3-hydroxy-3-methylglutaryl-CoA Reductase Inhibitors))

Solid Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
atorvastatin	ALTROPREV (lovastatin)
CADUET (amlodipine/atorvastatin) – *Brand Required*	amlodipine/atorvastatin
ezetimibe/simvastatin	CRESTOR (rosuvastatin)
fluvastatin	fluvastatin ER
lovastatin	LESCOL XL (fluvastatin ER)
pravastatin	LIPITOR (atorvastatin)
rosuvastatin	LIVALO (pitavastatin)
simvastatin	pitavastatin
	PRAVACHOL (pravastatin)
	VYTORIN (ezetimibe/simvastatin)
	ZOCOR (simvastatin)
	ZYPITAMAG (pitavastatin)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- Pitavastatin Only –
  - One of the following criteria must be met:
    - The member is receiving treatment with anti-retroviral therapy for HIV
    - The member is receiving treatment with a strong CYP3A4 inhibitor and is experiencing muscle toxicity despite 90-day trials with fluvastatin, rosuvastatin, and pravastatin.
- All other agents: See Preferred Dosage Form criteria

Non-Solid Dosage Forms

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
EZALLOR SPRINKLE (rosuvastatin)	ATORVALIQ (atorvastatin) SOLUTION

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- See Non-Solid Dosage Form criteria

Non-Preferred Agent Criteria

- The member has an LDL-C level greater than 100 mg/dL despite a 90-day trial with Ezallor Sprinkle.

Renewal Criteria – Approval Duration: 12 months

- The member has an LDL-C level less than 100 mg/dL or has achieved a 40% reduction.

Angiopoietin-like 3 (ANGPTL3) Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	EVKEEZA (evinacumab-dgnb) – *Medical Billing Only*

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a cardiologist, endocrinologist, or lipid specialist.
- Documentation of one of the following must be provided:
  - Genetic testing confirming two mutant alleles at the low-density lipoprotein receptor (LDLR), apolipoprotein B (apo B), proprotein convertase subtilisin kexin type 9 (PCSK9) or low-density lipoprotein receptor adaptor protein 1 (LDLRAP1) gene locus
  - Untreated total cholesterol of > 500 mg/dL with one of the following:
    - Cutaneous or tendon xanthoma before age 10 years
    - Evidence of total cholesterol > 250 in both parents
  - Low-density lipoprotein cholesterol (LDL-C) level greater than 100 mg/dL after a 90-day trial of each of the following, as evidenced by paid claims or pharmacy printouts or clinical justification as to why a treatment is unable to be used (subject to clinical review):
    - PCSK9 inhibitor and ezetimibe combined with rosuvastatin ≥20 mg or atorvastatin ≥ 40 mg
    - Nexlizet and ezetimibe combined with rosuvastatin ≥20 mg or atorvastatin ≥ 40 mg

Renewal Criteria – Approval Duration: 12 months

- The member has an LDL-C level less than 100 mg/dL or has achieved a 40% reduction.

siRNA (small interfering RNA) therapy

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	LEQVIO (inclisiran) – *Medical Billing Only*

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- The member must have failed a 90-day trial of both of the following, as evidenced by paid claims or pharmacy printouts:
  - Praluent combined with rosuvastatin ≥20 mg or atorvastatin ≥ 40 mg
  - Nexlizet combined with rosuvastatin ≥20 mg or atorvastatin ≥ 40 mg

Renewal Criteria – Approval Duration: 12 months

- The member has an LDL-C level less than 100 mg/dL or has achieved a 40% reduction.
- The member must currently be receiving a maximally tolerated statin (HMG-CoA reductase inhibitor) agent, as evidenced by paid claims or pharmacy printouts.

Summary of Changes

Vtama criteria added

Plaque Psoriasis

Biologics

Interleukin (IL)-12/IL-23 Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	STELARA (ustekinumab)
	WEZLANA (ustekinumab-auub)

Interleukin (IL)-17A Inhibitor

PREFERRED AGENTS (ELECTRONIC STEP REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
TALTZ (ixekizumab)	COSENTYX (secukinumab)
	COSENTYX (secukinumab) – *Medical Billing Only*

Interleukin (IL)-17A and IL-17F inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	BIMZELX (bimekizumab-bkzx)

Interleukin (IL)-17 Receptor Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	SILIQ (brodalumab)

Interleukin (IL)-23p19 Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	ILUMYA (tildrakizumab-asmn) – *Medical Billing Only*
	SKYRIZI (risankizumab-rzaa)
	TREMFYA (guselkumab)

TNF Inhibitors

Adalimumab

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
adalimumab-adaz	ABRILADA (adalimumab-afzb)
adalimumab-adbm – labeler 00597	adalimumab-aacf
CYLTEZO (adalimumab-abdm)	adalimumab-aaty
HUMIRA (adalimumab)	adalimumab-adbm – labeler 82009
SIMLANDI (adalimumab-ryvk)	adalimumab-fkjp
YUSIMRY (adalimumab-aqvh)	adalimumab-ryvk
	AMJEVITA (adalimumab-atto)
	HADLIMA (adalimumab-bwwd)
	HULIO (adalimumab-fkjp)
	HYRIMOZ (adalimumab-adaz)
	IDACIO (adalimumab-aacf)

	YUFLYMA (adalimumab-aaty)

Infliximab

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AVSOLA (infliximab-axxq) – *Medical Billing Only*	INFLECTRA (infliximab-dyyb) – *Medical Billing Only*
RENFLEXIS (infliximab-abda) – *Medical Billing Only*	infliximab – *Medical Billing Only*
	REMICADE (infliximab) – *Medical Billing Only*

Other TNF

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ENBREL (etanercept)	CIMZIA (certolizumab) SYRINGE
	CIMZIA (certolizumab) VIAL – *Medical Billing Only*

Electronic Diagnosis Verification

- Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale.

Electronic Step Therapy Required

- Taltz:
  - PA Not Required Criteria: A total of 84-day supply of a TNF Inhibitor has been paid within 120 days prior to Taltz's date of service.
  - PA Required Criteria: The member must have failed a 3-month trial of a TNF inhibitor, as evidenced by paid claims or pharmacy printouts.

Prior Authorization

Initial Criteria – Approval Duration: 12 months

- The member must have failed a 3-month trial of a TNF inhibitor (adalimumab, certolizumab pegol or infliximab) and an Interleukin (IL)-17A Inhibitor, as evidenced by paid claims or pharmacy printouts.
- Remicade, infliximab, and Inflectra Only: See Preferred Dosage Form criteria.
- Stelara, Tremfya, and Wezlana Only: The member must have failed a 3-month trial of an TNF inhibitor (adalimumab, certolizumab pegol or infliximab), an Interleukin (IL)-17A Inhibitor, and Siliq, as evidenced by paid claims or pharmacy printouts.
- Medical billing only agents: Clinical justification must be provided why a self-administered agent cannot be used (subject to clinical review).

Oral

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
acitretin 10 mg, 25 mg	acitretin 17.5 mg
cyclosporine	OTEZLA (apremilast) 20 MG
methotrexate	SOTYKTU (deucravacitinib)
OTEZLA (apremilast) 30 MG	

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- Acitretin 17.5 mg Only: See Preferred Dosage Form criteria

- Otezla 20 mg Only: The member must have failed a 3-month trial of adalimumab, as evidenced by paid claims or pharmacy printouts.
- Sotyktu Only: The member must have failed a trial of each of the following, as evidenced by paid claims or pharmacy printouts:
    - 30-day trial of Otezla
    - 3-month trial of an TNF inhibitor (adalimumab, certolizumab pegol or infliximab)

Topical

Foams, Gel, Solution, Suspension

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
calcipotriene solution	calcipotriene/betamethasone suspension
calcipotriene foam	SORILUX (calcipotriene) FOAM
ENSTILAR (calcipotriene/betamethasone) FOAM	tazarotene gel
TACLONEX (calcipotriene/betamethasone) SUSPENSION – *Brand Required*	

Cream, Lotion

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
calcipotriene cream	DUOBRII (halobetasol/tazarotene) LOTION
	tazarotene cream
	VTAMA (tapinarof) 1% CREAM
	ZORYVE (roflumilast) 0.3% CREAM

Ointment

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
calcipotriene ointment	calcitriol ointment
calcipotriene/betamethasone ointment	

Electronic Diagnosis Verification

- Zoryve: Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must have failed a 30-day trial of each preferred agent of a unique active ingredient(s) within same route/dosage form category, as evidenced by paid claims or pharmacy printouts.
- Zoryve Only:
    - The member has had a 30-day trial of each of the following, as evidenced by paid claims or pharmacy printouts.
        - calcipotriene/betamethasone
        - halobetasol/tazarotene combination
- Vtama Only:
    - The member has had a 30-day trial of each of the following, as evidenced by paid claims or pharmacy printouts.
        - calcipotriene/betamethasone
        - halobetasol/tazarotene combination
    - The member has had a 2-month trial of Zoryve, as evidenced by paid claims or pharmacy printouts.

Summary of Changes

Added criteria to follow recommendations in available guidelines or expert consensus.

Medications that cost over $3000/month

Prior Authorization Criteria

Initial Criteria - Approval Duration: 6 months

- Both of the following must be met:
  - The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational).
  - The medication must be used as recommended in available guidelines or expert consensus statements, including medication trials that are recommended prior to use of requested medication.
- The requested medication must be prescribed by, or in consult with, a specialist in the member's treated diagnosis.
- As applicable, documentation must be attached to confirm serum marker or pathogenic gene variants amenable to treatment.
- Documentation of the baseline labs, signs or symptoms that can be utilized for comparison to show member has experienced clinical benefit upon renewal has been submitted with request.

Summary of Changes

Criteria and PA added to high cost lubricants; persistent symptoms category was added and split into step 1 and step 2 agents.

Dry Eye Syndrome

Initial Management – Eye Lubricants

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ARTIFICIAL TEARS (dextran/hypromellose/glycerin)	FRESHKOTE (polyvinyl alcohol/povidone)
ARTIFICIAL TEARS (polyvinyl alcohol/povidone)	SENTIA (propylene glycol)
BION TEARS EYE DROPS (dextran 70/hypromellose)	VENTIVA (propylene glycol)
carboxymethylcellulose	VENTIVA (carboxymethylcellulose)
DRY EYE RELIEF (peg 400/Hypromellose/glycerin)	
GENTEAL TEARS (dextran/hypromellose/glycerin)	
GENTEAL TEARS (dextran 70/hypromellose)	
GENTEAL TEARS (hypromellose)	
LUBRICANT EYE DROPS (carboxymethylcellulose)	
LUBRICANT EYE DROPS (propylene glycol/peg 400)	
REFRESH (carboxymethylcellulose)	
REFRESH (polyvinyl alcohol/povidone)	
REFRESH (carboxymethylcellulose/glycerin)	
REFRESH (carboxymethylcellulose/glycerin/poly80)	
SYSTANE (hypromellose)	
SYSTANE (propylene glycol)	
SYSTANE (propylene glycol/peg 400)	

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must have failed a 1-month trial of each preferred agent of a unique ingredient, as evidenced by paid claims or pharmacy printouts.
- See Preferred Dosage Form Criteria

Persistent Symptoms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED STEP 1 AGENTS (PA REQUIRED)	NON-PREFERRED STEP 2 AGENTS (PA REQUIRED)
RESTASIS (cyclosporine) DROPPERETTE – *Brand Required*	TYRVAYA (varenicline) NASAL SPRAY	CEQUA (cyclosporine)
XIIDRA (lifitegrast)		cyclosporine dropperette
		MIEBO (perfluorohexyloctane)
		RESTASIS MULTIDOSE (cyclosporine)
		VEVYE 0.1% EYE DROP (cyclosporine)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

Non-Preferred Step 1 Agents

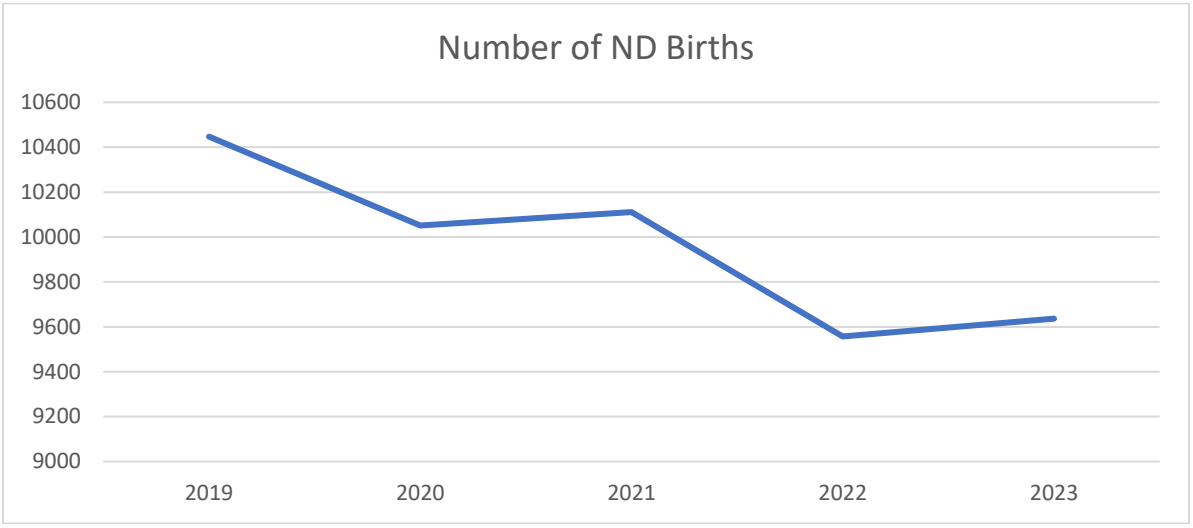
- The requested medication must be prescribed by, or in consult with, an ophthalmologist.
- The member must have failed a 6-month trial of Restasis (cyclosporine) and a 2-month trial of Xiidra (lifitegrast)t, as evidenced by paid claims or pharmacy printouts.

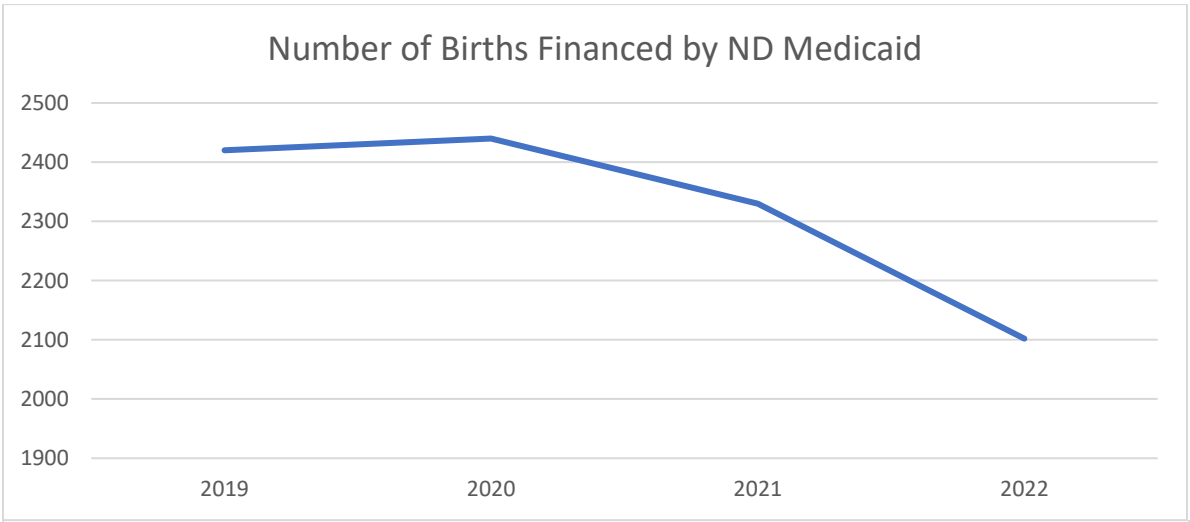
Non-Preferred Step 2 Agents:

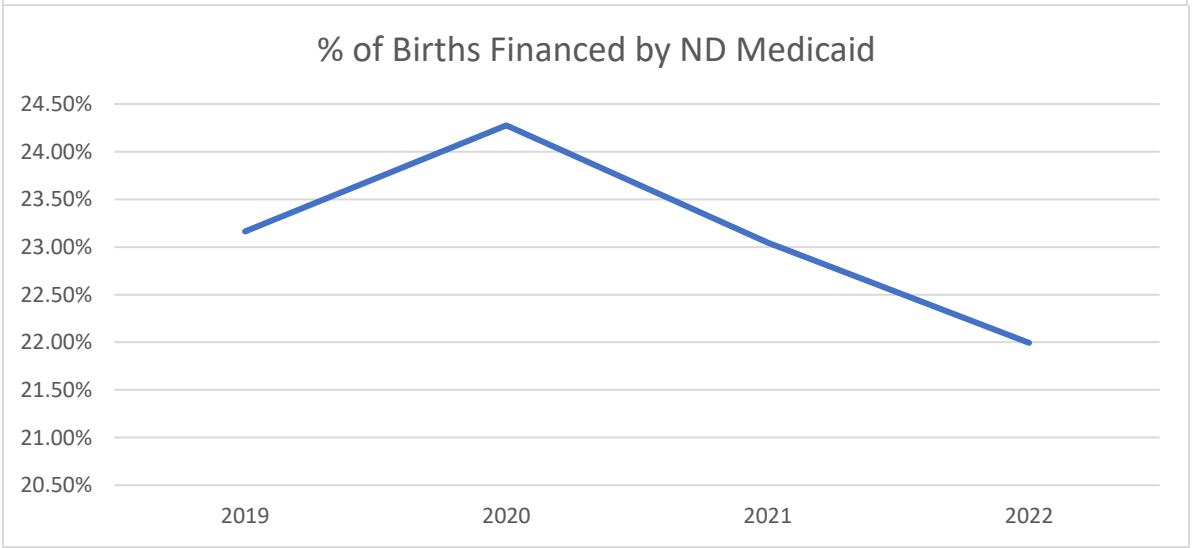
- The requested medication must be prescribed by, or in consult with, an ophthalmologist.
- The member must have failed a 6-month trial of Restasis (cyclosporine) and a 2-month trial of Xiidra (lifitegrast), and a 1-month trial of Tyrvaya (varenicline) as evidenced by paid claims or pharmacy printouts.
- Cyclosporine products: See Preferred Dosage Form criteria

Unfinished Business

Birth Rates:





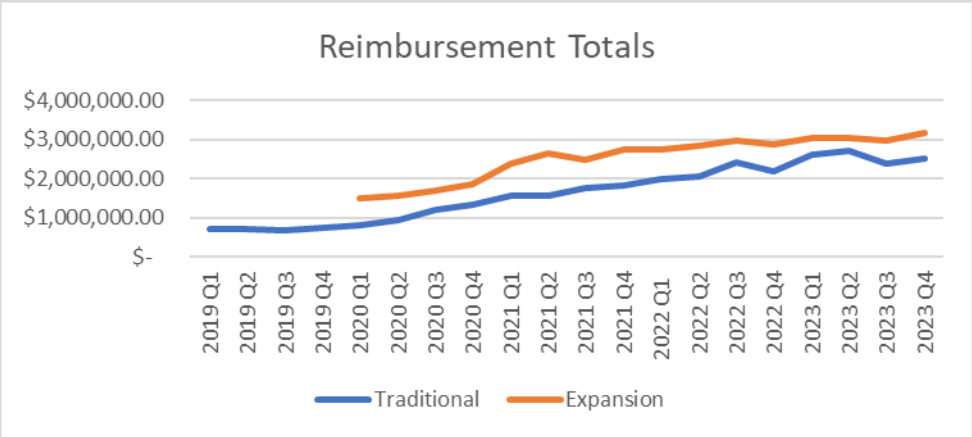


Alternative RDUR Communication Tools:
- Provider and pharmacy online response form
- Investigation of faxing letters

Dentist Prescribed Opioids
- Future targeted mailing

Biologics Breakout Cost
Identified 7 areas of substantial cytokine modulator competition:
- Calculated cost per day by quantity and day supply.
- Broken out by indication, age, and place of administration.

Added additional steps for agents that are much more expensive than competitors and for clinical justification on use of physician administered drugs instead of pharmacy administered drugs. Available evidence was weighed in addition to cost.



New Cost Drivers:

4Q23

- Stelara - $454,415 for 20 scripts / 13 members = $22,720 per script (every 2-3 months)
- Skyrizi - $257,467 for 14 scripts / 14 members = $18,390 per script (every 2-3 months)
- Tremfya - $116,857 for 9 scripts / 5 members = $12,984 per script (every 2 months)
- **= $828,739 per quarter for 43 scripts / 32 members**

1Q20

- Stelara – $73,107 for 5 scripts / 4 members = $14,621 per script (every 2-3 months)
- Skyrizi - 0 scripts / 0 members
- Tremfya – $11,404 for 1 script / 1 member = $11,404 for 1 script (every 2 months)
- **= $84,511 per quarter for 6 scripts / 5 members**

New Business:

Second Reviews

Molluscum Contagiosum

PREFERRED AGENTS (CLINICAL PA REQUIRED)
ZELSUVMI (berdazimer) GEL
YCANTH (cantharidin) SOLUTION – *Medical Billing Only*

Initial Criteria - Approval Duration: 12 months

- The requested medication must be prescribed by, or in consult with, a dermatologist or pediatrician.
- One of the following must be present (1 or 2):
  - The member is immunocompromised.
  - The member is immunocompetent but experiences severe bleeding, intense itching, recurring infection, or severe pain for greater than 6 months.

Epidermolysis Bullosa

PREFERRED AGENTS (CLINICAL PA REQUIRED)
FILSUVEZ (birch triterpenes)
VYJUVEK (beremagene geperpavec-svdt) – *Medical Billing Only*

Initial Criteria - Approval Duration: 12 months

- The member has dystrophic epidermolysis bullosa.
- The requested medication must be prescribed by, or in consult with, a dermatologist or wound care specialist.
- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational).
- As applicable, documentation must be attached to confirm serum marker or pathogenic gene variants amenable to treatment.
- Documentation of the baseline symptoms (e.g., extensive skin blistering, number and size of wounds) that can be utilized for comparison to show member has experienced clinical benefit upon renewal has been submitted with request.

Metabolic Dysfunction-Associated Steatohepatitis (MASH)

PREFERRED AGENTS (CLINICAL PA REQUIRED)
REZDIFFRA (resmetirom)

Initial Criteria - Approval Duration: 12 months

- The requested medication must be prescribed by, or in consult with, a gastroenterologist or hepatologist.
- The member has moderate to severe fibrosis (F2 or F3) as determined by one of the following (1-5):
  1. Biopsy
  2. Vibration-controlled transient elastography (VCTE; e.g. Fibroscan)
  3. Enhanced Liver Fibrosis (ELF)
  4. Magnetic Resonance Imaging Proton Density Fat Fraction (MRI-PDFF).
  5. Magnetic resonance elastography (MRE)
- If the member has a history of alcohol use, one of the following must be met (1, 2 or 3):
  1. The member has a carbohydrate-deficient transferrin (CDT) level < 3% within the past 3 months.

2. The member has a phosphatidylethanol (PEth) level < 20 ng/mL.
3. The member has submitted two negative alcohol tests with the most recent alcohol test within the past 3 months.

- The member must not have a concomitant terminal diagnosis where life expectancy is less than 1 year.

Renewal Criteria – Approval Duration: 12 months

- The member must have experienced stabilization or improvement of fibrosis and steatohepatitis, as determined by one of the following (1-4):
  1. Biopsy
  2. Vibration-controlled transient elastography (VCTE; e.g. Fibroscan)
  3. Enhanced Liver Fibrosis (ELF)
  4. Magnetic Resonance Imaging Proton Density Fat Fraction (MRI-PDFF)
  5. Magnetic resonance elastography (MRE)

FIRST REVIEW OF ATTENTION-DEFICIT HYPERACTIVITY DISORDER (ADHD)

ADHD is a common neurodevelopmental disorder that leads to impairment of occupational, academic, and social functioning. Symptoms consist of inattention, impulsivity, restlessness, and emotional dysregulation.[1]

Population:

- 2.6% adults globally and 4.4% 18–44-year-olds in US[1]
- 9-15% school-age children[2]

Treatment:

- Preschool-Aged Children (4-5 years of age):
  - First line: behavioral therapy
  - Second line: methylphenidate
- School-Aged Children (6-11 years of age):
  - First line: behavioral therapy and/or methylphenidate
  - Second line: Vyvanse
  - Third line: dextroamphetamine and/or amphetamine OR atomoxetine or guanfacine
- Adolescents (12-18 years of age):
  - First line: long-acting stimulants with less abuse potential (Daytrana, Concerta, Vyvanse) and behavior therapy
  - Second line: atomoxetine > guanfacine > clonidine
- Adults:
  - First line: stimulants and behavior therapy

General key notes for treatment options:

- Mechanism of action: block reuptake of norepinephrine and dopamine
- Effects are seen immediately; medication trials can be accomplished in 3-7 days
- Alternative dosage forms/administration methods* can make easier to swallow and minimize risk of abuse
- Adverse effects: increase heart rate/blood pressure, vascular problems (priapism, Raynaud's), psychosis, mania, lower seizure threshold, decreased appetite, serotonin syndrome[1]
- Boxed warnings due to the risk of abuse and dependence

Amphetamine					
Drug	**Generic**	**Formulation**	**Time to Peak**	**DOA**	**Cost/month ($)**
Adderall	Yes	IR tablet	3 hours	4 hours	• Generic: 15.15 • Brand: 321.69
Adderall XR*	Yes	ER capsule, beaded delivery system (IR:DR of 50:50)	7 hours	10 hours	• Generic: 6.95 • Brand: 213.69
Adzenys XR ODT	No	ER orally disintegrating tablet, contains IR:DR of 50:50	5 hours	10-12 hours	502.18
Dexedrine Spansule **FDA approved for pediatrics*	Yes	SR capsule, initial dose released immediately, remainder released gradually	8 hours	10 hours	• Generic: 43.74 • Brand: 703.24
Dyanavel XR	No	ER tablet and oral suspension; IR and ER components, ER component coated in pH independent polymer	4 hours	12-13 hours	236.00
Evekeo **FDA approved for pediatrics*	No	IR tablet	3 hours	4-6 hours	239.26
Mydayis	Yes	ER capsule, triple-bead delivery system of one IR and two DR types	7-10 hours	~16 hours	• Generic: 22.37 • Brand: 338.82
Procentra **FDA approved for pediatrics*	Yes	Oral solution	3 hours	4-6 hours	• Generic: 45.60 • Brand: 50.74
Vyvanse*	Yes	Capsule and chewable tablet, prodrug	1-3.5 hours	10 hours	• Generic: 55.20 • Brand: 387.78
Xelstrym	No	Transdermal system, worn 9 hours	9 hours	9 hours	486.16
Zenzedi **FDA approved for pediatrics*	Yes	IR tablet	3 hours	4-6 hours	• Generic: 12.89 • Brand: 303.23
Methylphenidate					
Drug	**Generic**	**Formulation**	**Time to Peak**	**DOA**	**Cost/month ($)**
Aptensio XR*	Yes	Capsule with multilayered beads (IR:CR of 40:60)	First: 2 hours Second: 8 hours	~16 hours	• Generic: 51.59 • Brand: 250.12
Azstarys	No	Capsule, prodrug	2 hours	5-12 hours	418.58
Concerta	Yes	Osmotic-release oral system (OROS), tri-layer core with an IR overcoat	6-10 hours	~12 hours	• Generic: 21.60 • Brand: 386.96
Cotempla XR-ODT **FDA approved for pediatrics*	No	ER orally disintegrating tablet (IR:ER of 25:75)	5 hours	4 hours	513.24
Daytrana **FDA approved for pediatrics*	Yes	Adhesive-based matrix transdermal patch	8 hours	12 hours	180.57
Focalin	Yes	IR tablet	1 hour	4 hours	• Generic: 12 • Brand: 40.66
Focalin XR*	Yes	Isomer product dexmethylphenidate, beaded delivery system (IR:ER of 50:50)	First: 1.5 hours Second: 6.5	9-12 hours	• Generic: 39 Brand: 147.53
Jornay PM	Yes	ER capsule, bead delivery system with two film coatings surrounding drug core	14 hours	11-12 hours	455.89
Metadate CD	Yes	ER capsule, bead delivery system (IR:ER of 30:70)	First: 1.5 hours Second: 4.5 hours	6-8 hours	• Generic: 42.60 • Brand: 599
Methylin	Yes	IR solution, chewable tablet, and tablet	1-2 hours	3-5 hours	• Generic: 126.60 • Brand: 357.55
QuilliChew ER	No	ER chewable tablet (IR:ER of 30:70)	5 hours	~12 hours	372.77
Quillivant XR	No	ER suspension (IR: ER of 20:80)	2-4 hours	~6 hours	677.86
Relexxii	Yes	ER tablet, OROS delivery system, bilayer core with IR drug overcoat	First: 1.5 hours Second: 5.5	8 hours	• Generic: 21.60 • Brand: 355.23
Ritalin	Yes	IR tablet	1-2 hours	3-5 hours	• Generic: 7.20 • Brand: 71.26
Ritalin LA*	Yes	SODAS encapsulated biphasic release beads (IR:DR of 50:50)	First: 1.5-3 hours Second: 4.5 – 6.5 hours	6-8 hours	• Generic: 46.50 • Brand: 378.62

Based on lowest per unit WAC cost

Current Utilization

	Quarter 1 2023			Quarter 2 2023		
Medication	**Rx Count**	**% of Rx**	**Reimb Amount**	**Rx Count**	**% of Rx**	**Reimb Amount**
amphetamine	5	0.0%	$1,331.97	7	0.1%	$3,155.10
dexmethylphenidate HCl	899	6.1%	$69,154.88	863	6.3%	$36,597.46
dextroamphetamine sulfate	108	0.7%	$5,288.36	95	0.7%	$3,954.53
dextroamphetamine/amphetamine	4044	27.5%	$487,458.49	3889	28.2%	$489,401.47
lisdexamfetamine dimesylate	4031	27.4%	$1,078,473.03	3713	26.9%	$1,034,676.39
methylphenidate	21	0.1%	$8,341.34	14	0.1%	$4,171.73
methylphenidate HCl	5598	38.1%	$1,034,289.93	5213	37.8%	$986,288.55
serdexmethylphen/dexmethylphen	3	0.0%	$1,156.67	2	0.0%	$767.46
TOTALS	14709		$2,685,494.67	13796		$2,559,012.69
	Quarter 3 2023			**Quarter 4 2023**		
Medication	**Rx Count**	**% of Rx**	**Reimb Amount**	**Rx Count**	**% of Rx**	**Reimb Amount**
amphetamine	3	0.0%	$1,604.08	6	0.0%	$2,743.59
dexmethylphenidate HCl	804	6.4%	$37,119.07	819	6.5%	$37,523.60
dextroamphetamine sulfate	83	0.7%	$3,820.08	89	0.7%	$3,748.33
dextroamphetamine/amphetamine	3617	28.9%	$450,342.40	3561	28.1%	$450,687.19
lisdexamfetamine dimesylate	3167	25.3%	$831,425.36	3154	24.9%	$855,919.07
methylphenidate	16	0.1%	$5,782.31	28	0.2%	$7,004.34
methylphenidate HCl	4817	38.5%	$936,317.20	5032	39.6%	$977,748.96
serdexmethylphen/dexmethylphen	1	0.0%	$141.17	3	0.0%	$307.35
TOTALS	12508		$2,266,551.67	12692		$2,335,682.43

References:

1. *Bukstein OG. Attention deficit hyperactivity disorder in adults: Epidemiology, clinical features, assessment, and diagnosis. UpToDate, Brent D, Friedman M (Ed) [Internet]. Waltham, MA: UptoDate; Nov 27, 2023. Available from: www.uptodate.com*
2. *Chan, E. Attention deficit hyperactivity disorder in children and adolescents: Epidemiology and pathogenesis. UpToDate, Augustyn M, Tehrani N (Ed) [Internet]. Waltham, MA: UptoDate; July 1, 2024. Available from: www.uptodate.com*
3. *Brent D, Bukstein OG, Solanto MV. Attention deficit hyperactivity disorder in adults: Treatment overview. UpToDate, Stein MB, Friedman M (Ed) [Internet]. Waltham, MA: UptoDate; April 17, 2024. Available from: www.uptodate.com*
4. *Chan, E. Attention deficit hyperactivity disorder in children and adolescents: Overview of treatment and prognosis. UpToDate, Augustyn M, Tehrani N (Ed) [Internet]. Waltham, MA: UptoDate; June 25, 2024. Available from: www.uptodate.com*
5. *Stimulant agents used for ADHD. Drug Facts and Comparisons. Wolters Kluwer Health, Inc. Riverwoods, IL. May 25, 2024. http://online.factsandcomparisons.com*
6. *Wolraich ML, Hagan JF Jr, Allan C, et al. Clinical Practice Guideline for the Diagnosis, Evaluation, and Treatment of Attention-Deficit/Hyperactivity Disorder in Children and Adolescents [published correction appears in Pediatrics. 2020 Mar;145(3):].*
7. *Pediatrics. 2019;144(4):e20192528. doi:10.1542/peds.2019-2528 Methylphenidate or Dexmethylphenidate (Concerta, Ritalin and others).*
8. *College of Pediatric and Neurologic Pharmacists (CPNP) and the National Alliance on Mental Illness (NAMI). August 2019. https://www.nami.org/About-Mental-Illness/Treatments/Mental-Health-Medications/Types-ofMedication/Methylphenidate-or-Dexmethylphenidate-(Concerta-R [accessed 09/21/2021]. Markowitz, John & Straughn, Arthur & Patrick, Kennerly. (2003).*
9. *Advances in the Pharmacotherapy of Attention-Deficit–Hyperactivity Disorder: Focus on Methylphenidate Formulations. Pharmacotherapy. 23. 1281-99. 10.1592/phco.23.12.1281.32697.*
10. *Pliszka, S. MD, (July 2007). Practice Parameter for the Assessment and Treatment of Children and Adolescents With Attention-Deficit/Hyperactivity Disorder. Journal of the American Academy of Child Adolescent Psychiatry, 46(7):894-921. DOI: 10.1097/chi.0b013e318054e724*
11. *Walkup, J. MD, (September 2009). Practice Parameter on the Use of Psychotropic Medication in Children and Adolescents. Journal of the American Academy of Child Adolescent Psychiatry, 48(9):961-973. DOI: 10.1097/CHI.0b013e3181ae0a08*
12. *NICE (March 2018). Attention deficit hyperactivity disorder: diagnosis and management. Available from www.nice.org.uk/guidance/ng87/chapter/Recommendations#medication.*
13. *Key Findings: Treatment of Attention-Deficit/Hyperactivity Disorder (ADHD) among Children with Special Health Care Needs. CDC.gov. Available from https://www.cdc.gov/ncbddd/adhd/features/adhd-keyfindings-treatment-special-needs-children.html*
14. *Adderall (Dextroamphetamine Saccharate, Amphetamine Aspartate, Dextroamphetamine Sulfate and Amphetamine Sulfate Tablets) [prescribing information]. Horsham, PA: Teva Pharmaceuticals; January 2017.*
15. *Adderall XR (mixed salts of a single-entity amphetamine product) dextroamphetamine sulfate, dextroamphetamine saccharate, amphetamine aspartate monohydrate, amphetamine sulfate capsules [prescribing information]. Wayne, PA: Shire US Inc; November 2013.*
16. *Adderall. Red Book. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. https://www.micromedexsolutions.com*
17. *Adderall XR. Red Book. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. https://www.micromedexsolutions.com*
18. *Dextroamph sacc-amph asp-dextroam sulf- amphet sulf. Red Book. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. https://www.micromedexsolutions.com*

19. *Adzenys XR-ODT (amphetamine extended-release) orally disintegrating tablets [prescribing information]. Grand Prairie, TX: Neos Therapeutics; January 2017.*
20. *Adzenys XR-ODT. Red Book. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. https://www.micromedexsolutions.com*
21. *Dexedrine (dextroamphetamine sulfate) Spansule sustained-release capsules [prescribing information]. Tringle Park, NC: GlaxoSmithKline; March 2007.*
22. *Dexedrine Spansule. Red Book. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. https://www.micromedexsolutions.com*
23. *Dyanavel XR (amphetamine) extended-release tablets and oral suspension [prescribing information]. Monmouth Junction, NJ: Tris Pharma, Inc; November 2021.*
24. *Dyanavel XR. Red Book. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. https://www.micromedexsolutions.com*
25. *Evekeo (amphetamine sulfate) tablets [prescribing information]. Atlanta, GA: Adare Pharmaceuticals, Inc; April 2021.*
26. *Evekeo. Red Book. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. https://www.micromedexsolutions.com*
27. *Mydayis (mixed salts of single-entity amphetamine product) extended-release capsules [prescribing information]. Lexington, MA: Shire US, Inc; June 2017.*
28. *Mydayis. Red Book. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. https://www.micromedexsolutions.com*
29. *Procentra (dextroamphetamine sulfate) oral solution [prescribing information]. Newport, KY: Independence Pharmaceuticals; September 2023.*
30. *Procentra. Red Book. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. https://www.micromedexsolutions.com*
31. *Vyvanse (lisdexamfetamine dimesylate) capsules and chewable tablets [prescribing information]. Lexington, MA: Shire Pharmaceuticals; January 2017.*
32. *Vyvanse. Red Book. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. https://www.micromedexsolutions.com*
33. *Xelstrym (dextroamphetamine) transdermal system [prescribing information]. Miami, FL: Noven Pharmaceuticals; March 2022.*
34. *Xelstrym. Red Book. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. https://www.micromedexsolutions.com*
35. *Zenzedi (dextroamphetamine sulfate) tablets [prescribing information]. Atlanta, GA: Arbor Pharmaceuticals; October 2023.*
36. *Zenzedi. Red Book. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. https://www.micromedexsolutions.com*
37. *Metadate ER (methylphenidate) [prescribing information]. Smyrna, GA: UCB Inc; February 2016.*
38. *Metadate. Red Book. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. https://www.micromedexsolutions.com*
39. *Methylin oral solution [prescribing information]. Florham Park, NJ: Shionogi Inc; July 2021.*
40. *Methylin. Red Book. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. https://www.micromedexsolutions.com*
41. *Metadate CD (methylphenidate) [prescribing information]. Philadelphia, PA: Lannett Company Inc; June 2021.*
42. *Metadate CD. Red Book. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. https://www.micromedexsolutions.com*
43. *Concerta (methylphenidate) [prescribing information]. Titusville, NJ: Janssen Pharmaceuticals; June 2021.*
44. *Concerta. Red Book. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. https://www.micromedexsolutions.com*
45. *Ritalin LA (methylphenidate) [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals; June 2021.*
46. *Ritalin/Ritalin SR (methylphenidate) [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corp; June 2021.*
47. *Quillivant XR (methylphenidate) [prescribing information]. Monmouth Junction, NJ: Tris Pharma Inc; June 2021.*
48. *Quillivant XR. Red Book. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. https://www.micromedexsolutions.com*
49. *Jornay PM (methylphenidate) [prescribing information]. Cherry Hill, NJ: Ironshore Pharmaceuticals Inc; June 2021.*
50. *Jornay PM. Red Book. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. https://www.micromedexsolutions.com*
51. *Daytrana (methylphenidate) [prescribing information]. Miami, FL: Noven Therapeutics LLC; June 2021.*
52. *Daytrana. Red Book. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. https://www.micromedexsolutions.com*
53. *Aptensio XR (methylphenidate) extended-release capsules [prescribing information]. Greenville, NC: Patheon; June 2021.*
54. *Aptensio XR. Red Book. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. https://www.micromedexsolutions.com*
55. *QuilliChew ER (methylphenidate) extended-release chewable tablets [prescribing information]. Monmouth Junction, NJ: Tris Pharma Inc; June 2021.*
56. *QuilliChew. Red Book. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. https://www.micromedexsolutions.com*
57. *Cotempla XR-ODT (methylphenidate) [prescribing information]. Grand Prairie, TX: Neos Therapeutics Brands LLC; June 2021.*
58. *Cotempla XR-ODT. Red Book. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. https://www.micromedexsolutions.com*
59. *Azstarys (serdexmethylphenidate and dexmethylphenidate) [prescribing information]. Grand Rapids, MI: Corium, Inc; June 2021.*
60. *Azstarys. Red Book. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. https://www.micromedexsolutions.com*
61. *Focalin (dexmethylphenidate hydrochloride) tablets [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals; January 2012.*
62. *Focalin XR (dexmethylphenidate hydrochloride) Extended-Release Capsules [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals; January 2017.*
63. *Focalin. Red Book. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. https://www.micromedexsolutions.com*
64. *Relexxii (methylphenidate hydrochloride) extended-release tablets [prescribing information]. Alpharetta, GA: Vertical Pharmaceuticals; June 2022.*
65. *Relexxii. Red Book. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. https://www.micromedexsolutions.com*

NORTH DAKOTA MEDICAID
RETROSPECTIVE DRUG UTILIZATION REVIEW
CRITERIA RECOMMENDATIONS
DUR BOARD MEETING SEPTEMBER 2024

NORTH DAKOTA MEDICAID
RETROSPECTIVE DRUG UTILIZATION REVIEW
CRITERIA RECOMMENDATIONS
3RD QUARTER 2024

Criteria Recommendations	***Approved***	***Rejected***

1. Zuranolone / Overuse _____ _____

Alert Message:Zurzuvae (zuranolone) may be over-utilized.The recommended dosage of zuranolone is 50 mg once daily in the evening for 14 days.If the patient experiences CNS depressant effects within the 14-day period, consider reducing the dosage to 40 mg once daily in the evening within the 14-day period.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Zuranolone		CKD 3 & 4
		Cirrhosis
		Hepatic Failure

Max Dose: 50 mg/day

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Zurzuvae Prescribing Information, Aug. 2024, Sage Therapeutics, Inc.

2. Zuranolone / Overuse – Severe Hepatic Impairment _____ _____

Alert Message:Zurzuvae (zuranolone) may be over-utilized.The recommended dosage of zuranolone in patients with severe hepatic impairment (Child-Pugh C) is 30 mg once daily in the evening for 14 days.No dosage adjustment is required in patients with mild (Child-Pugh A) or moderate (Child-Pugh B) hepatic impairment.

Drugs/Diseases

Util A	Util B	Util C (Include)
Zuranolone		Cirrhosis
		Hepatic Failure

Max Dose: 30 mg/day

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Zurzuvae Prescribing Information, Aug. 2024, Sage Therapeutics, Inc.

3. Zuranolone / Overuse – Severe Hepatic Impairment _____ _____

Alert Message:Zurzuvae (zuranolone) may be over-utilized.The recommended dosage of zuranolone in patients with moderate or severe renal impairment (eGFR 15 to 59 mL/min/1.73m2) is 30 mg once daily in the evening for 14 days.No dosage adjustment is required in patients with mild (eGFR 60 to 89 mL/min/1.73m2) renal impairment.Zuranolone has not been studied in patients with an eGFR of < 15 mL/min/1.73m2 or patients requiring dialysis.

Drugs/Diseases

Util A	Util B	Util C (Include)
Zuranolone		CKD 3
		CKD 4

Max Dose: 30 mg/day

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Zurzuvae Prescribing Information, Aug. 2024, Sage Therapeutics, Inc.

Criteria Recommendations	*Approved*	*Rejected*

4. Zuranolone / Therapeutic Appropriateness _____ _____

Alert Message:The safety and effectiveness of Zurzuvae (zuranolone) in pediatric patients have not been established.

Drugs/Diseases

Util A	Util B	Util C
Zuranolone		

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Zurzuvae Prescribing Information, Aug. 2024, Sage Therapeutics, Inc.

5. Zuranolone / Therapeutic Appropriateness _____ _____

Alert Message:The safety and effectiveness of Zurzuvae (zuranolone) use beyond 14 days in a single treatment course have not been established.

Drugs/Diseases

Util A	Util B	Util C
Zuranolone		

Duration: > 14 days

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Zurzuvae Prescribing Information, Aug. 2024, Sage Therapeutics, Inc.

6. Zuranolone / Therapeutic Appropriateness _____ _____

Alert Message:The safety and effectiveness of Zurzuvae (zuranolone) in geriatric patients have not been established.

Drugs/Diseases

Util A	Util B	Util C
Zuranolone		

Age Range: ≥ 65 yoa

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Zurzuvae Prescribing Information, Aug. 2024, Sage Therapeutics, Inc.

7. Zuranolone / CNS Depression _____ _____

Alert Message:Zurzuvae (zuranolone) can cause CNS depressant effects such as somnolence and confusion.If patients develop CNS depressant effects, consider dosage reduction or discontinuation of zuranolone.

Drugs/Diseases

Util A	Util B	Util C
Zuranolone	Confusion	
	Gait Disturbances	
	Somnolence	

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Zurzuvae Prescribing Information, Aug. 2024, Sage Therapeutics, Inc.

Criteria Recommendations	*Approved*	*Rejected*

8. Zuranolone / CNS Depressant _____ _____

Alert Message:Caution should be used when Zurzuvae (zuranolone) is administered in combination with other CNS drugs or alcohol due to additive pharmacological effects.If use with another CNS depressant is unavoidable, consider zuranolone dosage reduction.

Drugs/Diseases

Util A	Util B	Util C
Zuranolone	CNS Depressants	

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Zurzuvae Prescribing Information, Aug. 2024, Sage Therapeutics, Inc.

9. Zuranolone / Strong CYP3A4 Inhibitors _____ _____

Alert Message:The concurrent use ofZurzuvae (zuranolone) with a strong CYP3A4 inhibitor will result in increased zuranolone exposure and may increase the risk of zuranolone-associated adverse reactions.Reduce the zuranolone dosage to 30 mg orally once daily in the evening for 14 days when used concomitantly with a strong CYP3A4 inhibitor.

Drugs/Diseases

Util A	Util B		Util C
Zuranolone	Clarithromycin	Nelfinavir	
	Cobicistat	Posaconazole	
	Itraconazole	Ritonavir	
	Ketoconazole	Voriconazole	
	Nefazodone		

Max Dose: 30 mg/day

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Zurzuvae Prescribing Information, Aug. 2024, Sage Therapeutics, Inc.

10. Zuranolone / CYP3A4 Inducers _____ _____

Alert Message:The concurrent use ofZurzuvae (zuranolone) with CYP3A4 inducers should be avoided.Zuranolone is a CYP3A4 substrate, and concomitant use with a CYP3A4 inducer will decrease zuranolone exposure which may reduce zuranolone efficacy.

Drugs/Diseases

Util A	Util B	Util C
Zuranolone	Apalutamide	
	Carbamazepine	
	Enzalutamide	
	Mitotane	
	Phenobarbital	
	Phenytoin	
	Primidone	
	Rifampin	

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Zurzuvae Prescribing Information, Aug. 2024, Sage Therapeutics, Inc.

Criteria Recommendations	*Approved*	*Rejected*

11. Zuranolone / Pregnancy / Pregnancy Negating _____ _____

Alert Message:Based on findings from animal studies, Zurzuvae (zuranolone) may cause fetal harm.Advise pregnant women of the potential risk to a fetus.Available data on zuranolone use in pregnant women from the clinical development program are insufficient to evaluate for a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Zuranolone	Pregnancy	Abortion
		Delivery
		Miscarriage

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Zurzuvae Prescribing Information, Aug. 2024, Sage Therapeutics, Inc.

12. Zuranolone / Lactation _____ _____

Alert Message:Available data from a clinical lactation study in 14 women indicate that Zurzuvae (zuranolone) is present in low levels in human milk. There are no data on the effects of zuranolone on a breastfed infant and limited data on the effects on milk production.The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for zuranolone and any potential adverse effects on the breastfed child from zuranolone or the underlying maternal condition.

Drugs/Diseases

Util A	Util B	Util C
Zuranolone	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Zurzuvae Prescribing Information, Aug. 2024, Sage Therapeutics, Inc.

13. Zuranolone / Reproductive Potential _____ _____

Alert Message:Advise female patients of reproductive potential to use effective contraception during treatment with Zurzuvae (zuranolone) and for one week after the final dose.Based on animal studies, zuranolone may cause embryo-fetal harm when administered to a pregnant woman.

Drugs/Diseases

Util A	Util B	Util C (Negating)
Zuranolone		Contraceptives

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Zurzuvae Prescribing Information, Aug. 2024, Sage Therapeutics, Inc.

Criteria Recommendations	*Approved*	*Rejected*

14. Macitentan/Tadalafil / Overuse _____ _____

Alert Message:Opsynvi (macitentan/tadalafil) may be over-utilized.The maximum recommended dose of macitentan/tadalafil is one 10 mg/40 mg tablet once daily.

Drugs/Diseases

Util A	Util B	Util C
Macitentan/Tadalafil		

Max Dose: 10mg/40 mg per day

References:
Opsynvi Prescribing Information, March 2024, Janssen.
Clinical Pharmacology, 2024 Elsevier/Gold Standard.

15. Macitentan/Tadalafil / Therapeutic Appropriateness _____ _____

Alert Message:The safety and efficacy of Opsynvi (macitentan/tadalafil) in children have not been established.

Drugs/Diseases

Util A	Util B	Util C
Macitentan/Tadalafil		

Age Range: 0 – 17 yoa

References:
Opsynvi Prescribing Information, March 2024, Janssen.
Clinical Pharmacology, 2024 Elsevier/Gold Standard.

16. Macitentan/Tadalafil / Hepatic _____ _____

Alert Message:The macitentan component of Opsynvi (macitentan/tadalafil) is an endothelin receptor antagonist (ERA), and other ERAs have been shown to cause elevated hepatic enzymes, hepatotoxicity, and liver failure.Obtain liver enzyme tests prior to initiation of macitentan/tadalafil and repeat during treatment as clinically indicated.If clinically relevant aminotransferase elevations occur, or if elevations are accompanied by an increase in bilirubin > 2 x ULN, or by clinical symptoms of hepatotoxicity, discontinue macitentan/tadalafil.Do not initiate macitentan/tadalafil in patients with elevated aminotransferases (> 3 x upper limit of normal [ULN]) at baseline.

Drugs/Diseases

Util A	Util B	Util C
Macitentan/Tadalafil	Elevated Liver Transaminase Levels	

References:
Opsynvi Prescribing Information, March 2024, Janssen.
Clinical Pharmacology, 2024 Elsevier/Gold Standard.

Criteria Recommendations	*Approved*	*Rejected*

17. Macitentan/Tadalafil / Severe Hepatic Impairment _____ _____

Alert Message:The macitentan component of Opsynvi (macitentan/tadalafil) is an endothelin receptor antagonist (ERA), and other ERAs have been shown to cause elevated hepatic enzymes, hepatotoxicity, and liver failure.Patients with severe hepatic cirrhosis (Child-Pugh Class C) have not been studied, and, therefore, avoid the use of macitentan/tadalafil in these patients.

Drugs/Diseases

Util A	Util B	Util C
Macitentan/Tadalafil	Cirrhosis	

References:
Opsynvi Prescribing Information, March 2024, Janssen.
Clinical Pharmacology, 2024 Elsevier/Gold Standard.

18. Macitentan/Tadalafil / Pulmonary Edema _____ _____

Alert Message:The macitentan component of Opsynvi (macitentan/tadalafil) is a pulmonary vasodilator and may significantly worsen the cardiovascular status of patients with pulmonary veno-occlusive disease (PVOD).Should signs of pulmonary edema occur, the possibility of PVOD should be considered and, if confirmed, discontinue treatment with macitentan/tadalafil.

Util A	Util B	Util C
Macitentan/Tadalafil	Pulmonary Edema	

References:
Opsynvi Prescribing Information, March 2024, Janssen.
Clinical Pharmacology, 2024 Elsevier/Gold Standard.

19. Macitentan/Tadalafil / Dual CYP3A4 & 2C9 Inhibitors _____ _____

Alert Message:Avoid concomitant use of Opsynvi (macitentan/tadalafil) with moderate dual inhibitors of CYP3A4 and CYP2C9 (such as fluconazole and amiodarone).Concomitant use of moderate dual inhibitors of CYP3A4 and CYP2C9 such as fluconazole is predicted to increase macitentan exposure approximately 4-fold.

Drugs/Diseases

Util A	Util B	Util C
Macitentan/Tadalafil	Amiodarone Fluconazole	

References:
Opsynvi Prescribing Information, March 2024, Janssen.
Clinical Pharmacology, 2024 Elsevier/Gold Standard.

Criteria Recommendations	*Approved*	*Rejected*

20. Macitentan/Tadalafil / Strong CYP3A4 Inducers _____ _____

Alert Message:The use of Opsynvi (macitentan/tadalafil) with strong CYP3A4 inducers should be avoided.Concurrent use of macitentan/tadalafil with strong inducers of CYP3A4 significantly reduces macitentan exposure.

Drugs/Diseases

Util A	Util B	Util C
Macitentan/Tadalafil	Apalutamide	
	Carbamazepine	
	Enzalutamide	
	Mitotane	
	Phenobarbital	
	Phenytoin	
	Primidone	
	Rifampin	

References:
Opsynvi Prescribing Information, March 2024, Janssen.
Clinical Pharmacology, 2024 Elsevier/Gold Standard.

21. Macitentan/Tadalafil / Strong CYP3A4 Inhibitors _____ _____

Alert Message:Avoid concomitant use of Opsynvi (macitentan/tadalafil) with strong CYP3A4 inhibitors such as ritonavir, ketoconazole and itraconazole.Concomitant use with a strong CYP3A4 inhibitor increases exposure to both macitentan and tadalafil.Use other PAH treatment options when strong CYP3A4 inhibitors are needed.

Drugs/Diseases

Util A	Util B		Util C
Macitentan/Tadalafil	Clarithromycin	Nelfinavir	
	Cobicistat	Posaconazole	
	Itraconazole	Ritonavir	
	Ketoconazole	Voriconazole	
	Nefazodone		

References:
Opsynvi Prescribing Information, March 2024, Janssen.
Clinical Pharmacology, 2024 Elsevier/Gold Standard.

Criteria Recommendations	*Approved*	*Rejected*

22. Macitentan/Tadalafil / Alpha-1 Adrenergic Blockers _____ _____

Alert Message:Caution should be exercised when Opsynvi (macitentan/tadalafil) is co-administered with an alpha-1 adrenergic blocker.Tadalafil and alpha-adrenergic blocking agents are both vasodilators with blood-pressure-lowering effects.In patients who are taking alpha-1 blockers, concomitant administration of tadalafil may lead to symptomatic hypotension.

Drugs/Diseases

Util A	Util B	Util C
Macitentan/Tadalafil	Alfuzosin	
	Doxazosin	
	Prazosin	
	Silodosin	
	Tamsulosin	
	Terazosin	

References:
Opsynvi Prescribing Information, March 2024, Janssen.
Clinical Pharmacology, 2024 Elsevier/Gold Standard.

23. Macitentan/Tadalafil / Pregnancy / Pregnancy Negating (Box Warning) _____ _____

Alert Message:Opsynvi (macitentan/tadalafil) may cause fetal harm when administered to a pregnant woman.The use of macitentan/tadalafil is contraindicated in females who are pregnant.The macitentan component of the combination product was consistently shown to have teratogenic effects when administered to animals.If macitentan/tadalafil is used during pregnancy, advise the patient of the potential risk to a fetus.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Macitentan/Tadalafil	Pregnancy	Abortion
	Delivery	
	Miscarriage	

Gender: Female
Age Range: 11 – 50 yoa

References:
Opsynvi Prescribing Information, March 2024, Janssen.
Clinical Pharmacology, 2024 Elsevier/Gold Standard.

24. Macitentan/Tadalafil / Lactation (Box Warning) _____ _____

Alert Message:Because of the potential for serious adverse reactions in breastfed infants from Opsynvi (macitentan/tadalafil), advise women not to breastfeed during treatment with macitentan/tadalafil.There are no data on the presence of tadalafil, macitentan, and/or their metabolites in human milk, the effects on the breastfed infant, or the effect on milk production. Tadalafil and/or its metabolites are present in the milk of lactating rats.When a drug is present in animal milk, it is likely that the drug will be present in human milk.

Drugs/Diseases

Util A	Util B	Util C
Macitentan/Tadalafil	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Opsynvi Prescribing Information, March 2024, Janssen.
Clinical Pharmacology, 2024 Elsevier/Gold Standard.

Criteria Recommendations	*Approved*	*Rejected*

25. Macitentan/Tadalafil / Contraceptives (Negating) _____ _____

Alert Message:In females of reproductive potential, exclude pregnancy prior to initiation of Opsynvi (macitentan/tadalafil) therapy, ensure the use of acceptable contraceptive methods and obtain monthly pregnancy tests.Macitentan/tadalafil may cause fetal harm when administered during pregnancy and is contraindicated for use in females who are pregnant.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Macitentan/Tadalafil		Contraceptives

Gender: Female
Age Range: 11 – 50 yoa

References:
Opsynvi Prescribing Information, March 2024, Janssen.
Clinical Pharmacology, 2024 Elsevier/Gold Standard.

26.Macitentan/Tadalafil / Non-adherence _____ _____

Alert Message:Based on refill history, your patient may be under-utilizing Opsynvi (macitentan/tadalafil).Nonadherence to the prescribed dosing regimen may result in subtherapeutic effects, which may lead to decreased patient outcomes and additional healthcare costs.

Drugs/Diseases

Util A	Util B	Util C
Macitentan/Tadalafil		

References:
Osterberg L, Blaschke T. Adherence to Medication. N Engl J Med 2005; 353:487- 497.
Roebuck MC, Liberman JN, Gemmill-Toyama M, Brennan TA. Medication Adherence Leads to Lower Health Care Use and Costs Despite Increased Spending. Health Affairs No. 1 (2011):91-99.
Dean BB, Saundankar V, Stafkey-Mailey D, Anguiano RH, Nelsen AC, Gordon K, Classi P. Medication Adherence and Healthcare Costs Among Patients with Pulmonary Arterial Hypertension Treated with Oral Prostacyclins: A Retrospective Cohort Study. Drugs Real World Outcomes. 2020 Sep;7(3):229-239. doi: 10.1007/s40801-020-00183-x. Erratum in: Drugs Real World Outcomes. 2020 Jun 5;: PMID: 32144746; PMCID: PMC7392967.
Ho PM, Bryson CL, Rumsfeld JS. Medication Adherence: Its Importance in Cardiovascular Outcomes. Circulation. 2009 Jun 16;119(23):3028-3035.

27. Mepolizumab / Therapeutic Appropriateness - CRSwNP _____ _____

Alert Message:The safety and effectiveness of Nucala (mepolizumab) in patients less than 18 years of age with chronic rhinosinusitis with nasal polyps (CRSwNP) have not been established.

Drugs/Diseases

Util A	Util B	Util C (Include)
Mepolizumab		Nasal Polyps

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.

Criteria Recommendations	*Approved*	*Rejected*

28. Mepolizumab / Therapeutic Appropriateness - HES _____ _____

Alert Message:The safety and effectiveness of Nucala (mepolizumab) in pediatric patients less than 12 years of age with hypereosinophilic syndrome (HES) have not been established.

Drugs/Diseases

Util A	Util B	Util C(Include)
Mepolizumab		Hypereosinophilic Syndrome

Age Range: 0 – 11 yoa

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.

29.Mepolizumab / Overutilization -HES _____ _____

Alert Message:The manufacturer's recommended dose of Nucala (mepolizumab) for hypereosinophilic syndrome (HES) is 300 mg administered once every 4 weeks by subcutaneous injection.

Drugs/Diseases

Util A	Util B	Util C (Include)
Mepolizumab		Hypereosinophilic Syndrome

Max Dose: 3 injections/4 weeks

Age Range:≥ 12 yoa

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.

30. Elagolix/Estradiol/Norethindrone / Overuse _____ _____

Alert Message:Oriahnn (elagolix/estradiol/norethindrone) may be over-utilized. The recommended dosage of elagolix/estradiol/norethindrone is one capsule in the morning and one capsule in the evening.The use of elagolix/estradiol/norethindrone should be limited to 24 months due to the risk of continued bone loss, which may not be reversible.

Drugs/Diseases

Util A	Util B	Util C
Elagolix/Estradiol/Norethindrone		

Max Dose: 2 caps/day

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Oriahnn Prescribing Information, June 2023, AbbVie Inc.

31. Elagolix/Estradiol/Norethindrone / Therapeutic Appropriateness _____ _____

Alert Message:The safety and effectiveness of Oriahnn (elagolix/estradiol/norethindrone) in pediatric patients have not been established.

Util A	Util B	Util C
Elagolix/Estradiol/Norethindrone		

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Oriahnn Prescribing Information, June 2023, AbbVie Inc.

32. Elagolix/Estradiol/Norethindrone / Thrombotic Disorders _____ _____

Alert Message:Oriahnn (elagolix/estradiol/norethindrone) is contraindicated in women with a current or a history of thrombotic or thromboembolic disorders and in women at increased risk for these events. In general, the risk is greatest among women over 35 years of age who smoke and women with uncontrolled hypertension, dyslipidemia, vascular disease, or obesity.

Drugs/Diseases

Util A	Util B	Util C
Elagolix/Estradiol/Norethindrone	Deep Vein Thrombosis	
	Dyslipidemia	
	Migraine with Aura	
	Myocardial Infarction	
	Obesity	
	Pulmonary Embolism	
	Stroke	
	Vascular Disease	

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Oriahnn Prescribing Information, June 2023, AbbVie Inc.

33. Elagolix/Estradiol/Norethindrone / Pregnancy / Pregnancy Negating _____ _____

Alert Message:Oriahnn (elagolix/estradiol/norethindrone) is contraindicated in women who are pregnant.Exposure to elagolix/estradiol/norethindrone in early pregnancy may increase the risk of early pregnancy loss.

Drugs/Diseases

Util A	Util B	Util C (Negating)
Elagolix/Estradiol/Norethindrone	Pregnancy	Abortion
		Delivery
		Miscarriage

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Oriahnn Prescribing Information, June 2023, AbbVie Inc.

Criteria Recommendations	*Approved*	*Rejected*

33. Elagolix/Estradiol/Norethindrone / Pregnancy / Pregnancy Negating _____ _____

Alert Message:Oriahnn (elagolix/estradiol/norethindrone) is contraindicated in women who are pregnant.Exposure to elagolix/estradiol/norethindrone in early pregnancy may increase the risk of early pregnancy loss.

Drugs/Diseases

Util A	Util B	Util C (Negating)
Elagolix/Estradiol/Norethindrone	Pregnancy	Abortion
		Delivery
		Miscarriage

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Oriahnn Prescribing Information, June 2023, AbbVie Inc.

34. Elagolix/Estradiol/Norethindrone / Osteoporosis _____ _____

Alert Message:Oriahnn (elagolix/estradiol/norethindrone) is contraindicated in women with known osteoporosis because of the risk of further bone loss.Elagolix/estradiol/norethindrone may cause a decrease in bone mineral density (BMD) in some patients.BMD loss is greater with increasing duration of use and may not be completely reversible after stopping treatment.

Drugs/Diseases

Util A	Util B	Util C (Include)
Elagolix/Estradiol/Norethindrone		Osteoporosis

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Oriahnn Prescribing Information, June 2023, AbbVie Inc.

35. Elagolix/Estradiol/Norethindrone / Hormonally-Sensitive Malignancies _____ _____

Alert Message:Oriahnn (elagolix/estradiol/norethindrone) is contraindicated in women with breast cancer, a history of breast cancer or other hormonally-sensitive malignancies, and who are at increased risk for hormonally-sensitive malignancies.

Drugs/Diseases

Util A	Util B	Util C (Include)
Elagolix/Estradiol/Norethindrone		Breast Cancer
		Endometrial Cancer
		Ovarian Cancer
		Uterine Cancer

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Oriahnn Prescribing Information, June 2023, AbbVie Inc.

Criteria Recommendations	*Approved*	*Rejected*

36. Elagolix/Estradiol/Norethindrone / Hepatic Impairment _____ _____

Alert Message:Oriahnn (elagolix/estradiol/norethindrone) is contraindicated in women with known hepatic impairment or disease.Instruct patients to promptly seek medical attention if they develop symptoms or signs that may reflect liver injury, such as jaundice.

Util A	Util B	Util C
Elagolix/Estradiol/Norethindrone	Cirrhosis	
	Chronic Hepatitis	
	Fibrosis of Liver	
	Inflammatory Liver Disease	
	Jaundice	
	Hepatic Failure	
	Hepatic Impairment	

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Oriahnn Prescribing Information, June 2023, AbbVie Inc.

37. Elagolix/Estradiol/Norethindrone / OATP1B1 Inhibitors _____ _____

Alert Message:Oriahnn (elagolix/estradiol/norethindrone) is contraindicated in women taking inhibitors of organic anion transporting polypeptide (OATP)1B1 that are known or expected to significantly increase elagolix plasma concentration.

Drugs/Diseases

Util A	Util B		Util C
Elagolix/Estradiol/Norethindrone	Asciminib	Enasidenib	
	Cobicistat	Fostemsavir	
	Cyclosporine	Gemfibrozil	
	Darolutamide	Glecaprevir	
	Eltrombopag	Velpatasvir	
	Clarithromycin	Encorafenib	

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Oriahnn Prescribing Information, June 2023, AbbVie Inc.

38. Elagolix/Estradiol/Norethindrone / Suicidal Ideation& Depression _____ _____

Alert Message:In clinical trials Oriahnn (elagolix/estradiol/norethindrone)-treated women had a higher incidence of depression, depressed mood, and tearfulness compared to placebo-treated women.Suicidal ideation and behavior, including a completed suicide, occurred in women treated with lower doses of elagolix in clinical trials conducted for a different indication. Promptly evaluate patients with psychiatric symptoms to determine whether the risks of continued therapy outweigh the benefits.

Drugs/Diseases

Util A	Util B	Util C
Elagolix/Estradiol/Norethindrone	Anxiety	
	Depression	
	Mood Disorders	
	Suicidal Ideation	

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Oriahnn Prescribing Information, June 2023, AbbVie Inc.

39. Elagolix/Estradiol/Norethindrone / Gallbladder Disease _____ _____

Alert Message:Oriahnn (elagolix/estradiol/norethindrone) may increase the risk of gallbladder disease.For women, with a history of cholestatic jaundice associated with past estrogen use or when pregnant, assess the risk-benefit of continuing therapy.Discontinue elagolix/estradiol/norethindrone if jaundice occurs.

Drugs/Diseases

Util A	Util B	Util C (Include)
Elagolix/Estradiol/Norethindrone		Diseases of Gallbladder

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Oriahnn Prescribing Information, June 2023, AbbVie Inc.

40. Elagolix/Estradiol/Norethindrone / Digoxin _____ _____

Alert Message:Concurrent use of Oriahnn (elagolix/estradiol/norethindrone) with digoxin may result in increased digoxin concentrations.Increase monitoring of digoxin concentrations and potential signs and symptoms of digoxin toxicity.Digoxin is a P-gp substrate, and the elagolix component of the combination product is a P-gp efflux transport inhibitor.Digoxin dosage adjustment may be required.

Drugs/Diseases

Util A	Util B	Util C
Elagolix/Estradiol/Norethindrone	Digoxin	

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Oriahnn Prescribing Information, June 2023, AbbVie Inc.

41. Elagolix/Estradiol/Norethindrone / Rosuvastatin _____ _____

Alert Message:Concurrent use of Oriahnn (elagolix/estradiol/norethindrone) with a rosuvastatin-containing product may result in decreased rosuvastatin exposure and loss of therapeutic effect.Monitor the patient for rosuvastatin efficacy.Dosage adjustment of rosuvastatin may be necessary during elagolix/estradiol/norethindrone therapy.

Drugs/Diseases

Util A	Util B	Util C
Elagolix/Estradiol/Norethindrone	Rosuvastatin	

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Oriahnn Prescribing Information, June 2023, AbbVie Inc.

42. Elagolix/Estradiol/Norethindrone / Midazolam _____ _____

Alert Message:Concurrent use of Oriahnn (elagolix/estradiol/norethindrone) with midazolam may result in decreased midazolam exposure. Monitor the patient for altered response to midazolam therapy.Consider increasing the dose of midazolam by no more than 2-fold and individualize midazolam therapy based on the patient’s response.

Drugs/Diseases

Util A	Util B	Util C
Elagolix/Estradiol/Norethindrone	Midazolam	

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Oriahnn Prescribing Information, June 2023, AbbVie Inc.

Criteria Recommendations	*Approved*	*Rejected*

43. Elagolix/Estradiol/Norethindrone / Strong CYP3A4 Inducers _____ _____

Alert Message: Concomitant use of Oriahnn (elagolix/estradiol/norethindrone) with a strong CYP3A inducer is not recommended.Elagolix, estradiol, and norethindrone are CYP3A4 substrates, and concurrent use with a CYP3A4 inducer may decrease plasma concentrations of all substrates and efficacy.

Drugs/Diseases

Util A	Util B	Util C
Elagolix/Estradiol/Norethindrone	Apalutamide	
	Carbamazepine	
	Enzalutamide	
	Mitotane	
	Phenobarbital	
	Phenytoin	
	Primidone	

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Oriahnn Prescribing Information, June 2023, AbbVie Inc.

44. Elagolix/Estradiol/Norethindrone / Strong CYP3A4 Inhibitors _____ _____

Alert Message:Concomitant use of Oriahnn (elagolix/estradiol/norethindrone) with strong CYP3A inhibitors is not recommended.Elagolix, estradiol, and norethindrone are CYP3A4 substrates, and concurrent use with a strong CYP3A4 inhibitor may increase plasma concentrations of all substrates, increasing the risk of adverse reactions.

Drugs/Diseases

Util A	Util B		Util C
Elagolix/Estradiol/Norethindrone	Clarithromycin	Nelfinavir	
	Cobicistat	Posaconazole	
	Itraconazole	Ritonavir	
	Ketoconazole	Voriconazole	
	Nefazodone		

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Oriahnn Prescribing Information, June 2023, AbbVie Inc.

45. Elagolix/Estradiol/Norethindrone / Rifampin _____ _____

Alert Message:Concomitant use of Oriahnn (elagolix/estradiol/norethindrone) with rifampin is not recommended.The concurrent use of rifampin with an elagolix-containing agent may result in increased elagolix plasma concentrations, increasing the risk of adverse reactions.

Drugs/Diseases

Util A	Util B	Util C
Elagolix/Estradiol/Norethindrone	Rifampin	

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Oriahnn Prescribing Information, June 2023, AbbVie Inc.

Criteria Recommendations	*Approved*	*Rejected*

46. Elagolix/Estradiol/Norethindrone / Lactation _____ _____

Alert Message:The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Oriahnn (elagolix/estradiol/norethindrone) and any potential adverse effects on the breastfed child from elagolix/estradiol/norethindrone or the underlying maternal condition.There is no information on the presence of elagolix or its metabolites in human milk, the effects on the breastfed child, or the effects on milk production. Estrogen administration to nursing women has been shown to decrease the quantity and quality of breast milk.Detectable amounts of estrogen and progestin have been identified in the breast milk of women receiving estrogen and progestin combinations.

Drugs/Diseases

Util A	Util B	Util C
Elagolix/Estradiol/Norethindrone	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Oriahnn Prescribing Information, June 2023, AbbVie Inc.

47. Oteseconazole / Therapeutic Appropriateness _____ _____

Alert Message:The safety and effectiveness of Vivjoa (oteseconazole) have not been established in pre-menarchal pediatric females.

Drugs/Diseases

Util A	Util B	Util C
Oteseconazole		

Age Range: 0 – 10 yoa

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.

48. Oteseconazole / Therapeutic Appropriateness _____ _____

Alert Message:Vivjoa (oteseconazole) use is contraindicated in females of reproductive potential and pregnant or lactating women.Based on animal studies, oteseconazole may cause fetal harm.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Oteseconazole		Hysterectomy
		Postmenopausal
		Salpingo-oophorectomy
		Tubal Ligation
		Pregnancy
		Lactation

Age Range: 11– 50 yoa
Gender: Female

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Vivjoa Prescribing Information, April 2024, Mycovia Pharmaceuticals, Inc.

Criteria Recommendations	*Approved*	*Rejected*

49. Oteseconazole / Pregnancy / Pregnancy Negating _____ _____

Alert Message:Vivjoa (oteseconazole) use is contraindicated in pregnant women.Based on animal studies, oteseconazole may cause fetal harm.Ocular abnormalities were observed in a pre- and postnatal animal study in the offspring of rats administered oteseconazole.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Oteseconazole	Pregnancy	Abortion
		Delivery
		Miscarriage

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Vivjoa Prescribing Information, April 2024, Mycovia Pharmaceuticals, Inc.

50. Oteseconazole / Lactation _____ _____

Alert Message:Vivjoa (oteseconazole) use is contraindicated in lactating women.Ocular abnormalities were observed in the offspring of pregnant rats dosed at 7.5 mg/kg/day during organogenesis through lactation in pre- and postnatal developmental studies.

Drugs/Diseases

Util A	Util B	Util C
Oteseconazole	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Vivjoa Prescribing Information, April 2024, Mycovia Pharmaceuticals, Inc.

51. Oteseconazole / BRCP Substrates _____ _____

Alert Message:Vivjoa (oteseconazole) is a BCRP inhibitor.Concomitant use of oteseconazole with a BCRP substrate may increase the exposure of the BCRP substrate, which may increase the risk of adverse reactions associated with the substrate.Use the lowest possible starting dose of the BCRP substrate or consider reducing the dose of the substrate drug and monitor for adverse reactions.

Drugs/Diseases

Util A	Util B	Util C
Oteseconazole	Atorvastatin	
	Alpelisib	
	Dolutegravir	
	Pazopanib	
	Rosuvastatin	
	Sulfasalazine	
	Talazoparib	
	Tenofovir ala	
	Tenofovir dis	
	Topotecan	
	Ubrogepant	

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Vivjoa Prescribing Information, April 2024, Mycovia Pharmaceuticals, Inc.

52. Vonoprazan / Therapeutic Appropriateness _____ _____

Alert Message:The safety and effectiveness of Voquezna (vonoprazan) in pediatric patients have not been established.

Drugs/Diseases

Util A	Util B	Util C
Vonoprazan		

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Voquezna Prescribing Information, November 2023, Phantom Pharmaceuticals.

53. Vonoprazan / Rilpivirine-Containing Drugs _____ _____

Alert Message:Concurrent use of Voquezna (vonoprazan) with rilpivirine-containing products is contraindicated.Vonoprazan reduces intragastric acidity, which may alter the absorption of rilpivirine, leading to changes in safety and/or effectiveness.The inhibitory effect of vonoprazan on acid secretion increases with repeated daily dosing.

Drugs/Diseases

Util A	Util B	Util C
Vonoprazan	Rilpivirine	
	Rilpivirine/Cabotegravir	
	Rilpivirine/Dolutegravir	
	Rilpivirine/Emtricitabine/Tenofovir ala	
	Rilpivirine/Emtricitabine/Tenofovir dis	

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Voquezna Prescribing Information, November 2023, Phantom Pharmaceuticals.

54. Vonoprazan / Atazanavir-Containing Drugs _____ _____

Alert Message:Concurrent use of Voquezna (vonoprazan) with an atazanavir-containing product should be avoided.Vonoprazan reduces intragastric acidity, which may alter the absorption of atazanavir, leading to changes in safety and/or effectiveness.The inhibitory effect of vonoprazan on acid secretion increases with repeated daily dosing.

Drugs/Diseases

Util A	Util B	Util C
Vonoprazan	Atazanavir	
	Atazanavir Cobicistat	

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Voquezna Prescribing Information, November 2023, Phantom Pharmaceuticals.

55. Vonoprazan / Nelfinavir _____ _____

Alert Message:Concurrent use of Voquezna (vonoprazan) with nelfinavir should be avoided. Vonoprazan reduces intragastric acidity, which may alter the absorption of nelfinavir, leading to changes in safety and/or effectiveness.The inhibitory effect of vonoprazan on acid secretion increases with repeated daily dosing.

Drugs/Diseases

Util A	Util B	Util C
Vonoprazan	Nelfinavir	

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Voquezna Prescribing Information, November 2023, Phantom Pharmaceuticals.

56. Vonoprazan / Strong or Moderate CYP3A4 Inducers _____ _____

Alert Message:Voquezna (vonoprazan) is a CYP3A substrate.Concomitant use of vonoprazan with strong or moderate CYP3A inducers may decrease vonoprazan exposure, which may reduce the effectiveness of the vonoprazan.The concurrent use of vonoprazan with strong or moderate CYP3A inducers should be avoided.

Drugs/Diseases

Util A	Util B	Util C
Vonoprazan	Apalutamide	
	Bosentan	
	Carbamazepine	
	Efavirenz	
	Etravirine	
	Phenobarbital	
	Phenytoin	
	Primidone	
	Rifabutin	
	Rifampin	
	Rifapentine	

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Voquezna Prescribing Information, November 2023, Phantom Pharmaceuticals.

57. Vonoprazan / CYP3A4 Substrates w/ NTI _____ _____

Alert Message:Voquezna (vonoprazan) is a weak CYP3A inhibitor.Concurrent use of vonoprazan with CYP3A substrates where minimal concentration changes may lead to serious toxicities should be done with caution.Frequent monitoring of substrate concentrations and/or adverse reactions related to the substrate drugs is recommended when used with vonoprazan.

Drugs/Diseases

Util A	Util B	Util C
Vonoprazan	Cyclosporine	
	Sirolimus	
	Tacrolimus	

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Voquezna Prescribing Information, November 2023, Phantom Pharmaceuticals.

58. Vonoprazan / Clopidogrel _____ _____

Alert Message:Voquezna (vonoprazan) is a CYP2C19 inhibitor.Concurrent use of vonoprazan with clopidogrel, a CYP2C19 substrate, may result in reduced clopidogrel efficacy.Vonoprazan may reduce plasma concentrations of the active metabolite of clopidogrel and may cause a reduction in platelet inhibition.Carefully monitor the efficacy of clopidogrel and consider alternative anti-platelet therapy.

Drugs/Diseases

Util A	Util B	Util C
Vonoprazan	Clopidogrel	

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Voquezna Prescribing Information, November 2023, Phantom Pharmaceuticals.

59. Vonoprazan / Citalopram _____ _____

Alert Message:Voquezna (vonoprazan) is a CYP2C19 inhibitor.Concurrent use of vonoprazan with citalopram, a CYP2C19 substrate, may result in increased citalopram exposure, increasing the risk for citalopram adverse reactions.The dose of citalopram should be limited to 20 mg/day when co-administered with vonoprazan.

Drugs/Diseases

Util A	Util B	Util C
Vonoprazan	Citalopram	

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Voquezna Prescribing Information, November 2023, Phantom Pharmaceuticals.

60. Vonoprazan / Cilostazol _____ _____

Alert Message:Voquezna (vonoprazan) is a CYP2C19 inhibitor.Concurrent use of vonoprazan with cilostazol, a CYP2C19 substrate, may result in increased cilostazol exposure, increasing the risk for cilostazol-related adverse reactions.The dose of cilostazol should be limited to 50 mg twice daily when co-administered with vonoprazan.

Drugs/Diseases

Util A	Util B	Util C
Vonoprazan	Cilostazol	

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Voquezna Prescribing Information, November 2023, Phantom Pharmaceuticals.

61. Vonoprazan / Severe Renal Impairment / Erosive Esophagitis _____ _____

Alert Message:The Voquezna (vonoprazan) dose should not exceed 10 mg once daily for the healing of erosive esophagitis in patients with severe renal impairment (eGFR less than 30 mL/minute).In pharmacokinetic studies, patients with severe renal impairment had increased systemic exposure (2.4 times greater) to vonoprazan compared to subjects with normal renal function.

Drugs/Diseases

Util A	Util B	Util C (Include)
Vonoprazan	CKD Stage 4	Erosive Esophagitis
	CKD Stage 5	
	ESRD	

Max Dose: 10 mg/day

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Voquezna Prescribing Information, November 2023, Phantom Pharmaceuticals.

62. Vonoprazan / Severe Renal Impairment / H. pylori _____ _____

Alert Message:The use of Voquezna (vonoprazan) is not recommended for the treatment of Helicobacter pylori in patients with severe renal impairment (eGFR less than 30 mL/minute). In pharmacokinetic studies, patients with severe renal impairment had increased systemic exposure (2.4 times greater) to vonoprazan compared to subjects with normal renal function.

Drugs/Diseases

Util A	Util B	Util C (Include)
Vonoprazan 20 mg	CKD Stage 4	H. Pylori
	CKD Stage 5	
	ESRD	

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Voquezna Prescribing Information, November 2023, Phantom Pharmaceuticals.

63. Vonoprazan / Moderate to Severe Hepatic Impairment / H. pylori _____ _____

Alert Message:The use of Voquezna (vonoprazan) for the treatment of Helicobacter pylori infection in patients with moderate to severe hepatic impairment (Child-Pugh Class B or C) is not recommended.In pharmacokinetic studies, patients with moderate and severe hepatic impairment exhibited increased systemic exposure to vonoprazan (2.4 and 2.6 times greater, respectively) as compared to subjects with normal hepatic function.

Drugs/Diseases

Util A	Util B	Util C (Include)
Vonoprazan	Cirrhosis	H. Pylori
	Hepatic Failure	
	Toxic Liver	
	Fatty Liver	

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Voquezna Prescribing Information, November 2023, Phantom Pharmaceuticals.

64. Vonoprazan / Pregnancy / Pregnancy Negating _____ _____

Alert Message:There are no adequate and well-controlled studies of Voquezna (vonoprazan) in pregnant women to evaluate for drug-associated risks of major birth defects, miscarriage, or other adverse maternal or fetal outcomes.Avoid the use of vonoprazan during pregnancy unless other treatments are not clinically appropriate.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Vonoprazan	Pregnancy	Abortion
		Delivery
		Miscarriage

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Voquezna Prescribing Information, November 2023, Phantom Pharmaceuticals.

65. Vonoprazan / Lactation _____ _____

Alert Message:There are no data regarding the presence of Voquezna (vonoprazan) in human milk, the effects on the breastfed infant, or the effects on milk production.Vonoprazan and its metabolites are present in rat milk.Liver injury occurred in offspring from pregnant and lactating rats administered oral vonoprazan.When a drug is present in animal milk, it is likely that the drug will be present in human milk.Because of the potential risk of adverse liver effects shown in animal studies with vonoprazan, a woman should pump and discard human milk for the duration of vonoprazan therapy and for 2 days after therapy ends and feed her infant stored human milk (collected prior to therapy) or formula.

Drugs/Diseases

Util A	Util B	Util C
Vonoprazan	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Voquezna Prescribing Information, November 2023, Phantom Pharmaceuticals.

66. Fezolinetant / Overuse _____ _____

Alert Message:Veozah (fezolinetant) may be over-utilized.The recommended daily dose of fezolinetant is one 45 mg tablet once daily.

Drugs/Diseases

Util A	Util B	Util C
Fezolinetant		

Max Dose: 45 mg/day

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Veozah Prescribing Information, May 2023, Astellas Pharma US, Inc.

67. Fezolinetant / Therapeutic Appropriateness _____ _____

Alert Message:The efficacy and safety of Veozah (fezolinetant) in individuals less than 18 years of age have not been established.

Drugs/Diseases

Util A	Util B	Util C
Fezolinetant		

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Veozah Prescribing Information, May 2023, Astellas Pharma US, Inc.

Criteria Recommendations	*Approved*	*Rejected*

68. Fezolinetant / Therapeutic Appropriateness _____ _____

Alert Message:Veozah (fezolinetant) is contraindicated in women with cirrhosis. Fezolinetant has not been studied in this patient population.In pharmacokinetics studies, patients with Child-Pugh Class A or B hepatic impairment receiving fezolinetant experienced increased fezolinetant exposure compared to patients with normal hepatic function.Perform baseline bloodwork to evaluate for hepatic function and injury prior to fezolinetant initiation.Do not start fezolinetant if the concentration of ALT or AST is equal to or exceeds two times the ULN or if the total bilirubin is elevated (for example, equal to or exceeds two times the ULN) for the evaluating laboratory.

Drugs/Diseases

Util A	Util B	Util C
Fezolinetant	Cirrhosis	

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Veozah Prescribing Information, May 2023, Astellas Pharma US, Inc.

69. Fezolinetant / Severe Renal Impairment & ESRD _____ _____

Alert Message:Veozah (fezolinetant) is contraindicated in women with severe renal impairment (eGFR 15 to < 30 mL/min/1.73m2) or end-stage renal disease (eGFR < 15 mL/min/1.73m2). In pharmacokinetics studies, following oral administration of fezolinetant 30 mg, the AUC of the major metabolite increased by approximately 75% and 380% in patients with moderate and severe renal impairment, respectively.

Drugs/Diseases

Util A	Util B	Util C
Fezolinetant	CKD Stage 4	
	CKD Stage 5	
	ESRD	

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Veozah Prescribing Information, May 2023, Astellas Pharma US, Inc.

70. Fezolinetant / CYP1A2 Inhibitors _____ _____

Alert Message:Coadministration of Veozah (fezolinetant) with a CYP1A2 inhibitor is contraindicated.Fezolinetant is a substrate of CYP1A2.Concomitant use of fezolinetant with drugs that are weak, moderate, or strong CYP1A2 inhibitors significantly increases the plasma Cmax and AUC of fezolinetant.

Drugs/Diseases

Util A	Util B		Util C
Fezolinetant	Acyclovir	Methoxsalen	
	Allopurinol	Mexiletine	
	Amiodarone	Obeticholic Acid	
	Cannabidiol	Osilodrostat	
	Capmatinib	Pacritinib	
	Cimetidine	Peginterferon Alfa-2b	
	Ciprofloxacin	Ritlecitinib	
	Deferasirox	Rucaparib	
	Disulfiram	Ticlopidine	
	Enasidenib	Verapamil	
	Fluvoxamine	Vemurafenib	
	Givosiran	Viloxazine	
	Leniolisib	Zileuton	
	Meropenem		

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Veozah Prescribing Information, May 2023, Astellas Pharma US, Inc.

71. Fezolinetant / Pregnancy / Pregnancy Negating _____ _____

Alert Message:There are no data on Veozah (fezolinetant) use in pregnant women to evaluate for a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes.Fezolinetant is indicated for the treatment of moderate to severe vasomotor symptoms due to menopause.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Fezolinetant	Pregnancy	Abortion
		Delivery
		Miscarriage

Gender: Female
Age Range: 11 – 50 yoa

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Veozah Prescribing Information, May 2023, Astellas Pharma US, Inc.

Criteria Recommendations	*Approved*	*Rejected*

72. Fezolinetant / Lactation _____ _____

Alert Message:There are no data on the presence of fezolinetant in human milk, the effects on the breastfed child, or the effects on milk production. It is not known if fezolinetant is present in human milk.Fezolinetant is indicated for the treatment of moderate to severe vasomotor symptoms due to menopause.

Drugs/Diseases

Util A	Util B	Util C
Fezolinetant	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Veozah Prescribing Information, May 2023, Astellas Pharma US, Inc.

73. Fezolinetant / Non-adherence _____ _____

Alert Message:Based on refill history, your patient may be under-utilizing Veozah (fezolinetant). Nonadherence to the prescribed dosing regimen may result in subtherapeutic effects, which may lead to decreased patient outcomes and additional healthcare costs.

Drugs/Diseases

Util A	Util B	Util C
Fezolinetant		

References:
Osterberg L, Blaschke T. Adherence to Medication. N Engl J Med 2005; 353:487- 497.
Kim J, Combs K, Downs J, Tillman F., Medication Adherence: The Elephant in the Room. US Pharm. 2018;43(1)30-34.

Kleinsinger, Fred. The Unmet Challenge of Medication Nonadherence. The Permanente Journal. Vol. 22 (2018): 18-033. doi:10.7812/TPP/18-033.

74. Loxapine Inhalation / Therapeutic Appropriateness _____ _____

Alert Message:The use of Adasuve (loxapine inhalation) is contraindicated in patients with a current diagnosis of asthma, COPD, or other lung diseases associated with bronchospasm.

Drugs/Diseases

Util A	Util B	Util C
Loxapine Inhalation	Asthma	
	COPD	
	Chronic Bronchitis	
	Emphysema	

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.

75. Loxapine Inhalation / Drugs to Treat Airway Disease _____ _____

Alert Message:The use of Adasuve (loxapine inhalation) is contraindicated in patients with current use of medications to treat airway disease, such as asthma or COPD.Loxapine inhalation can cause bronchospasm that has the potential to lead to respiratory distress and respiratory arrest.

Drugs/Diseases

Util A	Util B		Util C
Loxapine Inhalation	Albuterol	Terbutaline	Montelukast
	Aclidinium	Theophylline	Zafirlukast
	Arformoterol	Tiotropium	Zileuton
	Formoterol	Umeclidinium	Roflumilast
	Glycopyrrolate	Vilanterol	Beclomethasone
	Indacaterol	Benralizumab	Budesonide
	Ipratropium	Dupilumab	Ciclesonide
	Levalbuterol	Mepolizumab	Fluticasone
	Olodaterol	Omalizumab	Mometasone
	Revefenacin	Reslizumab	Cromolyn
	Salmeterol	Tezepelumab	

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.

76. Apremilast / Overuse _____ _____

Alert Message:Otezla (apremilast) may be over-utilized.The recommended maintenance dose of apremilast (after the 5-day titration schedule) for the treatment of moderate to severe plaque psoriasis in pediatric patients 6 years of age and older and weighing at least 50 kg is 30 mg twice a day.The recommended maintenance dose in pediatric patients weighing 20 kg to less than 50 kg is 20 mg twice daily.

Drugs/Diseases

Util A	Util B	Util C (Negating)
Apremilast		CKD Stage 4 & 5

Max Dose: 60 mg/day
Age Range: 6 – 17 yoa

References:
Otezla Prescribing Information, April 2024, Amgen Inc.

77. Apremilast / Overuse - Severe Renal Impairment _____ _____

Alert Message:Otezla (apremilast) may be over-utilized.The recommended maintenance dose of apremilast (after the 5-day titration schedule) for the treatment of moderate to severe plaque psoriasis in pediatric patients 6 years of age and older and weighing at least 50 kg with severe renal impairment is 30 mg once daily.The recommended maintenance dose in pediatric patients weighing 20 kg to less than 50 kg is 20 mg once daily.

Drugs/Diseases

Util A	Util B	Util C (Include)
Apremilast		CKD Stage 4 & 5

Max Dose: 30 mg/day
Age Range: 6 – 17 yoa

References:
Otezla Prescribing Information, April 2024, Amgen Inc.

Criteria Recommendations	*Approved*	*Rejected*

78. Apremilast / Therapeutic Appropriateness _____ _____

Alert Message:The safety and effectiveness of Otezla (apremilast) have not been established in pediatric patients below the age of 6 years or weighing less than 20 kg with moderate to severe plaque psoriasis.

Drugs/Diseases

Util A	Util B	Util C (Include)
Apremilast		Plaque Psoriasis

Age Range: 0 – 5 yoa

References:
Otezla Prescribing Information, April 2024, Amgen Inc.

79. Apremilast / Therapeutic Appropriateness _____ _____

Alert Message:The safety and effectiveness of Otezla (apremilast) have not been established in pediatric patients with psoriatic arthritis or oral ulcers associated with Behcet's Disease.

Drugs/Diseases

Util A	Util B	Util C (Include)
Apremilast		Psoriatic Arthritis
		Behcet's Disease

Age Range: 0 – 17 yoa

References:
Otezla Prescribing Information, April 2024, Amgen Inc.

North Dakota Medicaid
Drug Utilization Review Board Meeting
December 4, 2024
Conference Room 210/212

NORTH Dakota Be Legendary. | Health & Human Services

NORTH Dakota | Health & Human Services
Be Legendary.

Meeting Notice

North Dakota Medicaid Drug Use Review Board

Wednesday, December 4th, 2024
1 to 4 p.m. Central Time

In-Person Information

Conference Room 210/212, 2nd Floor, Judicial Wing, State Capitol
600 E. Boulevard Ave., Bismarck

Virtual Information

Join virtually: Click here to join the meeting
Join by phone: 701-328-0950, Conference ID: 394 833 97 #

Agenda

1. Call to Order
2. Roll Call
3. Review and Approval of Minutes
4. Reports from Department
    - Administrative Report
    - Financial Report: Top Drugs
    - Retrospective DUR Report
    - Clinical Report:
        - Prior Authorization Update
        - Criteria updates: Amyloidosis, COPD / Asthma, and Secondary Hyperparathyroidism
        - Annual PDL Review
5. Unfinished Business: Alternative RDUR Communication
6. New business
    - Second Review of Attention-Deficit Hyperactivity Disorder Stimulants
    - First Review of Migraine Prophylaxis and Treatment
    - First Review of Nonsteroidal Anti-Inflammatory Drugs
    - First Review of Primary Biliary Cholangitis
    - Review of retrospective DUR criteria recommendations
7. Announcements: Next Meeting (March 5, 2025)
8. Adjourn

Individuals with disabilities who need accommodations, including appropriate auxiliary aids to participate, can contact Ashley Gerving at 701-328-2354, toll-free 800-755-2604, 711 (TTY) or gervingashley@nd.gov.

Meeting Minutes
North Dakota Medicaid Drug Use Review (DUR) Board
Meeting Date: September 4th, 2024
Time and Location: 1:00 pm CST in Bismarck, North Dakota

Call to Order:
A regular quarterly meeting of the North Dakota Medicaid Drug Use Review (DUR) Board meeting was convened at 1:01 pm CST with T. Schmidt presiding as Presiding Officer. DUR Board Coordinator, C. Stauter recording minutes.

Roll Call:
Board Members Voting:
Present: Stephanie Antony, Amanda Dahl, Kurt Datz, Andrea Honeyman, Laura Kroetsch, Kevin Martian, Kristen Peterson, Tanya Schmidt, Amy Werremeyer
Absent: Gabriela Balf
Quorum Present: Yes

Board Members Non-Voting:
Present: Kathleen Traylor

Medicaid Pharmacy Department:
Present: Brendan Joyce, Alexi Murphy
Absent: Jeff Hostetter, LeNeika Roehrich

Approval of Meeting Minutes:
Motion: Moved by K. Datz to approve the minutes of the June 5th, 2024 meeting, motion was seconded by K. Martian. **Motion carried.**
The minutes of the June 5th, 2024 meeting were approved as distributed.

Reports:
*Administrative Report***:** by A. Murphy
A. Murphy shared with the Board North Dakota Medicaid's biosimilar plan for 2024-2025 and data regarding hepatitis C treatment. This information can be found in the handout. Appreciation for Josh Askvig and Jennifer Iverson's service to the Board was expressed as their appointments have ended. Katie Steig will be starting as the new pharmacist on September 9th.

Financial Report: by B. Joyce
B. Joyce shared with the Board trends of pharmacy recipients and payments per prescription. B. Joyce also presented the quarterly review of the top 25 drugs based on total number and cost of claims and the top 15 therapeutic classes based on number and cost of claims. This report can be found in the handout.

Retrospective Drug Utilization Review (RDUR) Report by C. Stauter
C. Stauter reviewed the quarterly RDUR criteria that were selected for review of each month. This material can be found in the handout.

Clinical Report: Prior Authorization and Criteria Updates by C. Stauter
C. Stauter presented prior authorization and criteria updates with emphasis on the following sections in the PDL: asthma/COPD, chronic kidney disease, Duchenne muscular dystrophy, growth hormone, heart failure, hereditary angioedema, hypertrophic cardiomyopathy, lipid-lowering treatment, plaque psoriasis, medications over $3000, and dry eye disease. The presented information can be found in the handout. Testimony was provided by Christine Dube from Astrazeneca on Fasenra, Giuseppe Miranda from BioCryst on Orladeyo, Sandy Kosmaczeski from Dermavent on Vtama, and Erin Nowak from Abbvie on Skyrizi.

Unfinished business by C. Stauter*:*

C. Stauter presented information regarding birth rates, alternative RDUR communication tools, dentist prescribed opioids, and biologics breakout cost. The presented material can be found in the handout.

New business:
Second Reviews presented by C. Stauter
C. Stauter presented group prior authorization criteria for molluscum contagiosum, epidermolysis bullosa, and metabolic dysfunction-associated steatohepatitis. The presented material can be found in the handout. Testimony was provided by Tara McKinley from Madrigal on Rezdiffra.
Motion: Moved by K. Martin to place molluscum contagiosum on prior authorization, motion was seconded by K. Datz. **Motion carried.**
Motion: Moved by K. Datz to place epidermolysis bullosa on prior authorization, motion was seconded by A. Werremeyer. **Motion carried.**
Motion: Moved by K. Martin to place metabolic dysfunction-associated steatohepatitis on prior authorization, motion was seconded by K. Datz. **Motion carried.**

First Reviews presented by C. Stauter
C. Stauter presented an overview of attention-deficit hyperactivity disorder stimulants. The presented material can be found in the handout.
Motion: Moved by K. Datz to draft prior authorization for attention-deficit hyperactivity disorder stimulants, motion was seconded by A. Werremeyer. **Motion carried.**

Retrospective Drug Utilization Review (RDUR) Criteria Recommendations:
RDUR criteria recommendations were reviewed. The presented material can be found in the handout.
Motion: Moved by K. Martian to approve the RDUR criteria, motion was seconded by A. Honeyman. **Motion carried.**

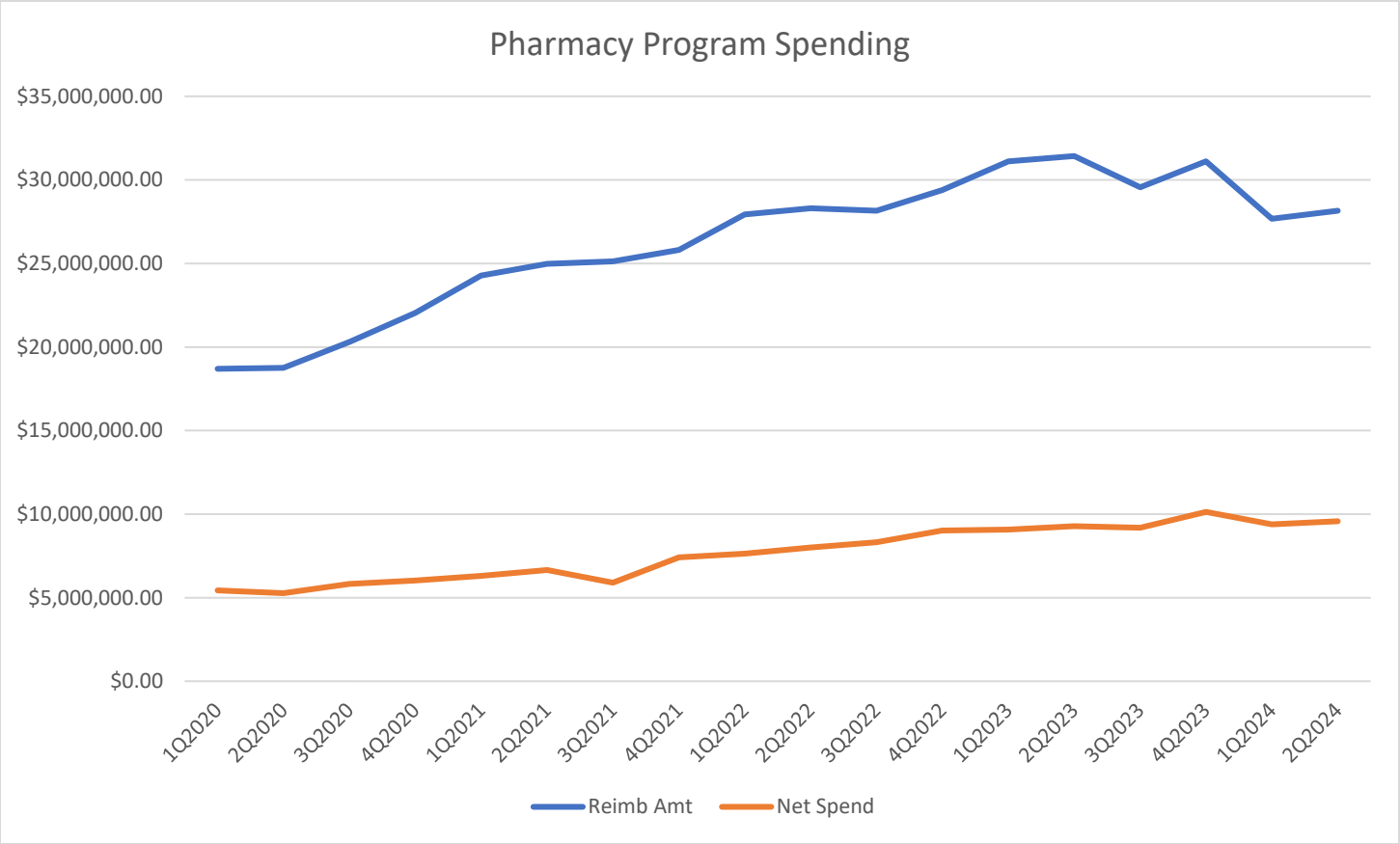
Announcements:
Next meeting is December 4th, 2024.

Adjournment:
Meeting adjourned by T. Schmidt at 2:08 pm CST.

Date of Minutes Approval:
Minutes submitted by: Claire Stauter, Acentra Health

Financial Report

The following graphs are pharmacy drug claims and do not include diabetic supplies, medical drugs (J-codes), or claims paid to Indian Health Services.

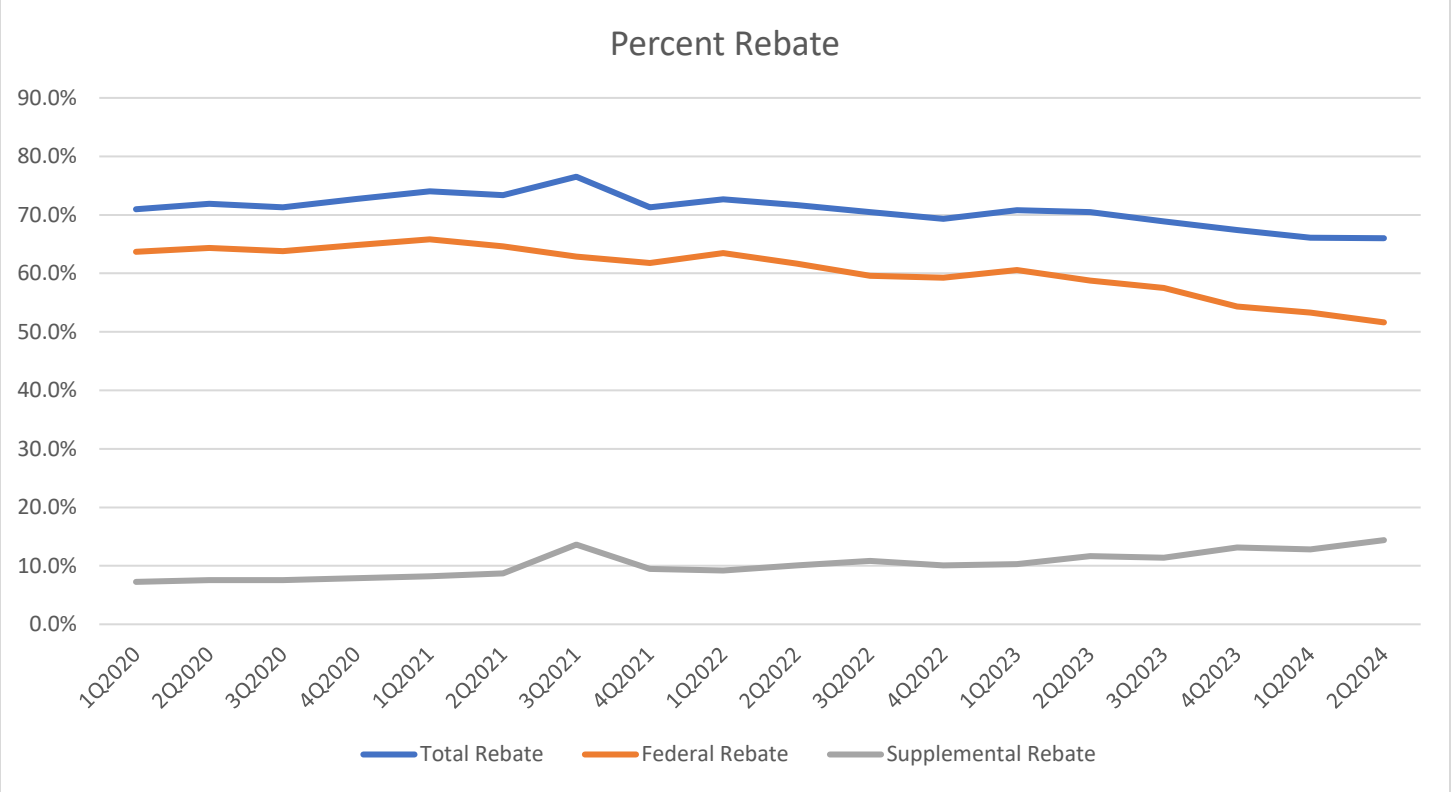


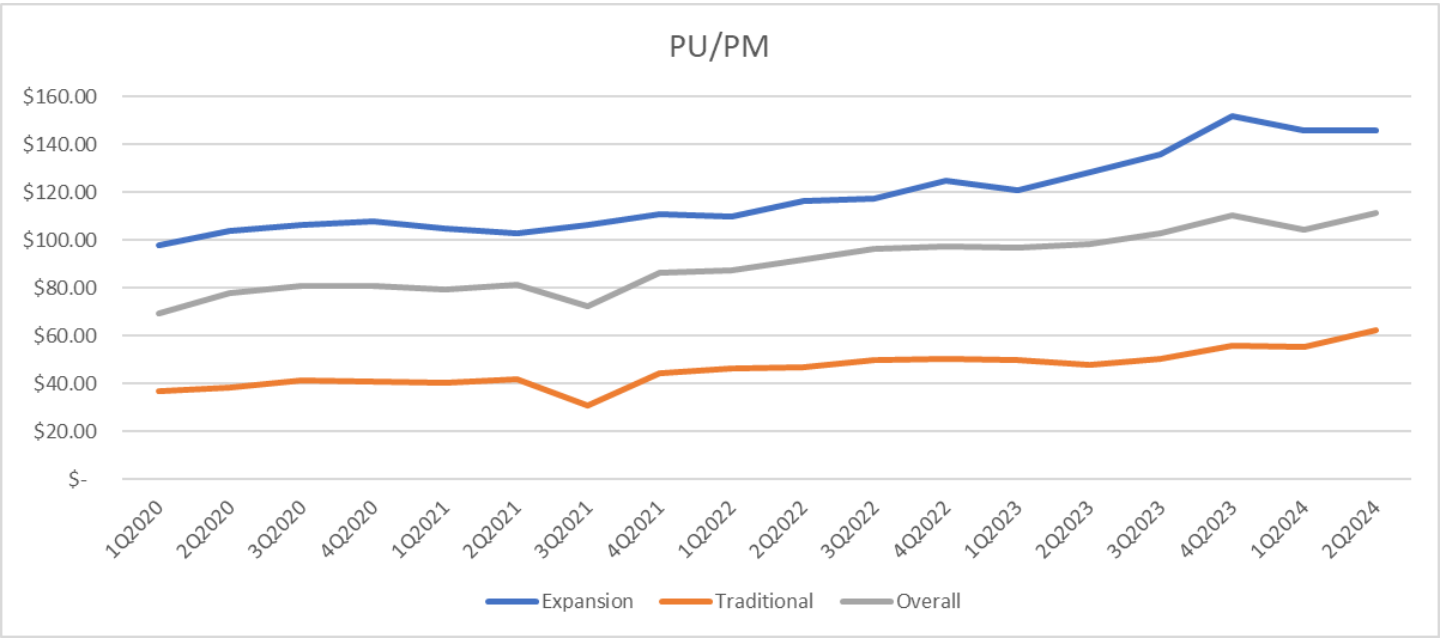
Decrease in reimbursement trend timeline:

2Q23 - Insulin prices start to decrease

1Q24 – AMP cap is removed (some manufacturers choose to decrease price of their drugs to avoid the rebate increasing above AMP)

These changes in reimbursement do not reflect directly into net spend (which is increasing) as rebate % is decreasing during this same time period and net spend per utilizer is going up.





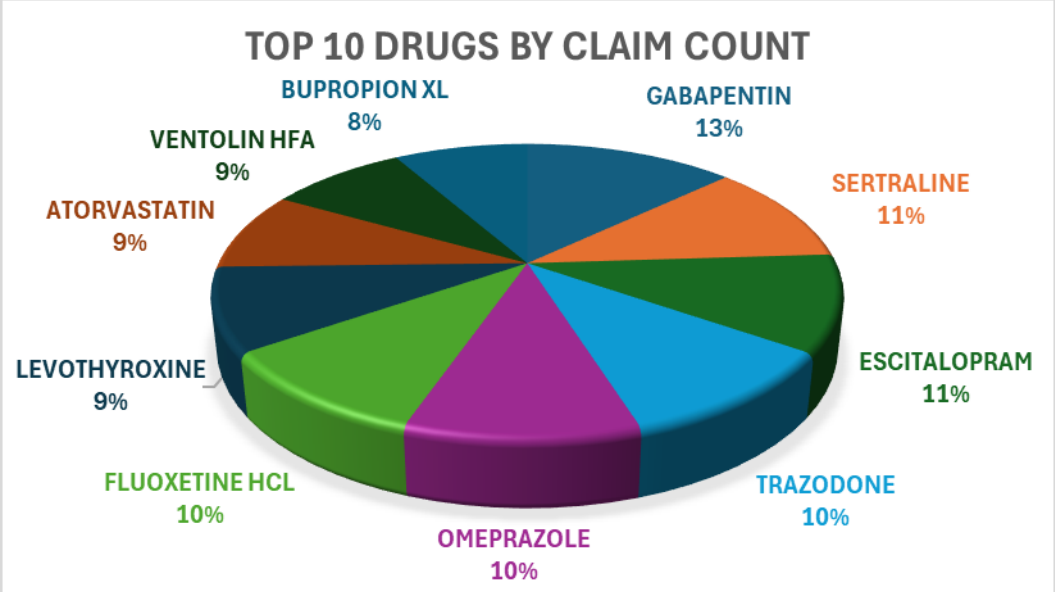
Between 1Q19 and 1Q23: Primary Cost Drivers

Antipsychotics (long acting injectables), cystic fibrosis (CFTR modulators), biologics (574.4% growth, Dupixent 1,714% growth), hepatitis C, HIV, migraine CGRPs and gepants, multiple sclerosis, narcotic treatment (long acting injectables), oncology, pulmonary hypertension, tardive dyskinesia, and hemophilia (loss of primary insurance payments on members).

These classes alone contribute to about 57% of our net spend and 200.7% of net spend growth, while all other drug classes account for 4.4% of net spend growth.

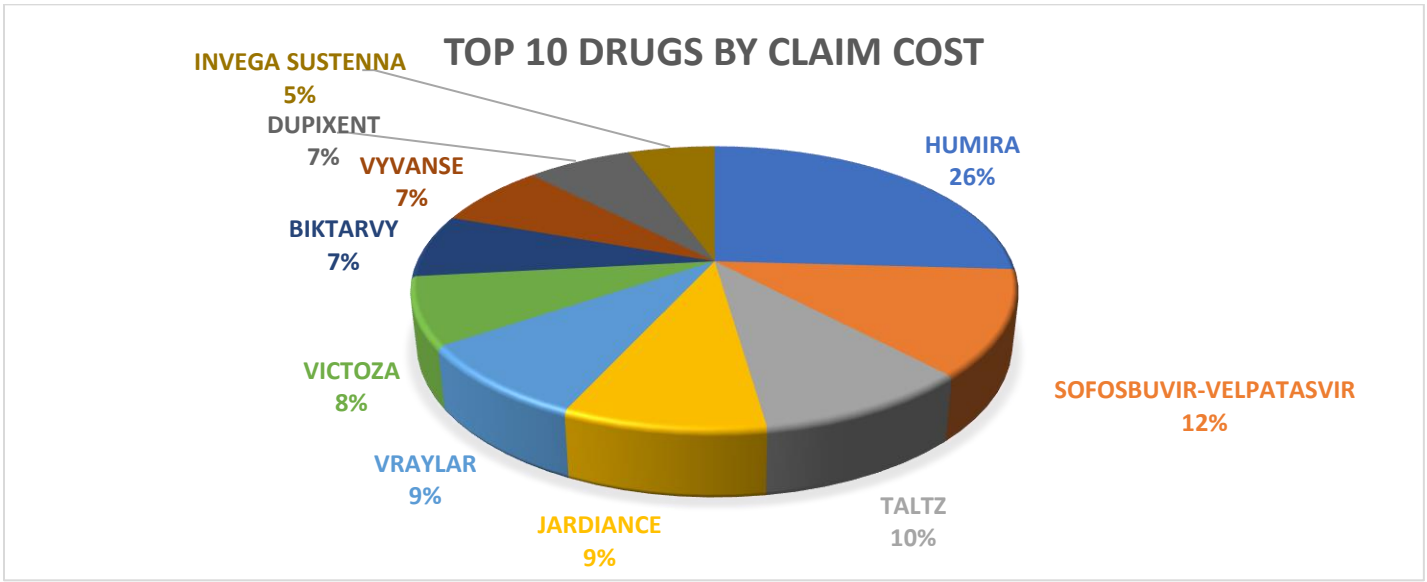
Top 25 Drugs Based on Number of Claims from 07/01/2024 – 09/30/2024

Drug	Claims	Claims Cost	Patients	Cost / Claim	% Claims	Dif.
1. GABAPENTIN	4,001	$59,134.68	1,755	$14.78	1.8%	NC
2. SERTRALINE HCL	3,392	$45,885.98	1,937	$13.53	1.5%	NC
3. ESCITALOPRAM	3,274	$43,957.21	1,920	$13.43	1.5%	↑1
4. TRAZODONE HCL	3,226	$43,436.63	1,750	$13.46	1.5%	↑1
5. OMEPRAZOLE	3,152	$41,762.80	1,812	$13.25	1.4%	↓2
6. FLUOXETINE HCL	3,103	$41,175.56	1,748	$13.27	1.4%	NC
7. LEVOTHYROXINE	2,835	$40,782.06	1,522	$14.39	1.3%	↑1
8. ATORVASTATIN	2,646	$36,989.06	1,564	$13.98	1.2%	↑2
9. VENTOLIN HFA	2,623	$170,091.54	2,598	$64.85	1.2%	↑2
10. BUPROPION XL	2,551	$41,710.02	1,423	$16.35	1.1%	↑2
11. CLONIDINE HCL	2,542	$31,200.49	1,294	$12.27	1.1%	↑3
12. LISINOPRIL	2,523	$32,586.27	1,546	$12.92	1.1%	↑1
13. HYDROXYZINE HCL	2,352	$34,906.37	1,505	$14.84	1.1%	↑2
14. HYDROCODONE-APAP	2,280	$33,812.88	1,438	$14.83	1.0%	↑4
15. AMOXICILLIN	2,181	$33,429.90	2,078	$15.33	1.0%	↓8
16. VYVANSE	2,164	$644,069.16	1,022	$297.63	1.0%	↓7
17. ARIPIPRAZOLE	2,144	$32,153.96	1,073	$15.00	1.0%	↑5
18. PANTOPRAZOLE	2,134	$30,195.23	1,247	$14.15	1.0%	↑3
19. LAMOTRIGINE	2,126	$30,060.97	882	$14.14	1.0%	NC
20. PREDNISONE	2,117	$24,550.50	1,702	$11.60	1.0%	↓4
21. DULOXETINE HCL	2,115	$34,897.67	1,143	$16.50	1.0%	↓1
22. CYCLOBENZAPRINE	2,054	$24,345.34	1,328	$11.85	0.9%	↑2
23. CLONAZEPAM	2,048	$27,630.47	871	$13.49	0.9%	↑2
24. BUSPIRONE HCL	1,914	$28,413.57	1,090	$14.85	0.9%	↓1
25. AMLODIPINE BESYLATE	1,890	$23,977.36	1,174	$12.69	0.8%	↑1
Total Claims						**222,444**



Top 25 Drugs Based on Total Claims Cost from 07/01/2024 – 09/30/2024

Drug	Claims	Claims Cost	Patients	Cost / Patient	% Cost	Dif.
1. HUMIRA	281	$2,316,865.42	129	$17,960.20	7.4%	NC
2. SOFOS-VELPATASVIR	48	$1,077,627.16	48	$22,450.57	3.4%	NC
3. TALTZ	110	$873,207.22	50	$17,464.14	2.8%	NC
4. JARDIANCE	1,088	$820,597.45	605	$ 1,356.36	2.6%	↑2
5. VRAYLAR	756	$778,143.13	312	$ 2,494.05	2.5%	↑2
6. VICTOZA	1040	$690,750.44	619	$ 1,115.91	2.2%	↓1
7. BIKTARVY	278	$644,429.86	133	$ 4,845.34	2.0%	↑3
8. VYVANSE	2,164	$644,069.16	1,022	$ 630.20	2.0%	↓4
9. DUPIXENT	171	$607,688.37	76	$ 7,995.90	1.9%	↑3
10. INVEGA SUSTENNA	178	$493,788.64	77	$ 6,412.84	1.6%	↑1
11. TRIKAFTA	22	$469,369.32	11	$42,669.94	1.5%	↓2
12. NORDITROPIN FLEXPRO	73	$454,257.24	34	$13,360.51	1.4%	↑1
13. STELARA	18	$444,353.62	14	$31,739.54	1.4%	↑2
14. ELIQUIS	628	$387,498.38	327	$ 1,185.01	1.2%	NC
15. INGREZZA	44	$326,791.79	19	$17,199.57	1.0%	↑3
16. SUBLOCADE	152	$308,404.96	77	$ 4,005.26	1.0%	↑3
17. JIVI	3	$282,644.82	1	$282,644.82	0.9%	↑9
18. ABILIFY MAINTENA	103	$264,554.88	45	$ 5,879.00	0.8%	↑2
19. COSENTYX	28	$258,618.66	11	$23,510.79	0.8%	↑10
20. ENBREL	38	$257,061.03	19	$13,529.53	0.8%	↓3
21. CONCERTA	627	$221,995.27	464	$478.44	0.7%	↓13
22. DULERA	654	$210,447.62	395	$532.78	0.7%	↑31
23. FARXIGA	324	$205,149.70	176	$1,165.62	0.7%	↑2
24. XIFAXAN	79	$204,582.90	35	$5,845.23	0.7%	↑9
25. ADDERALL XR	1,059	$195,393.46	597	$327.29	0.6%	↑8
Total Claims Cost						**$31,455,890.38**



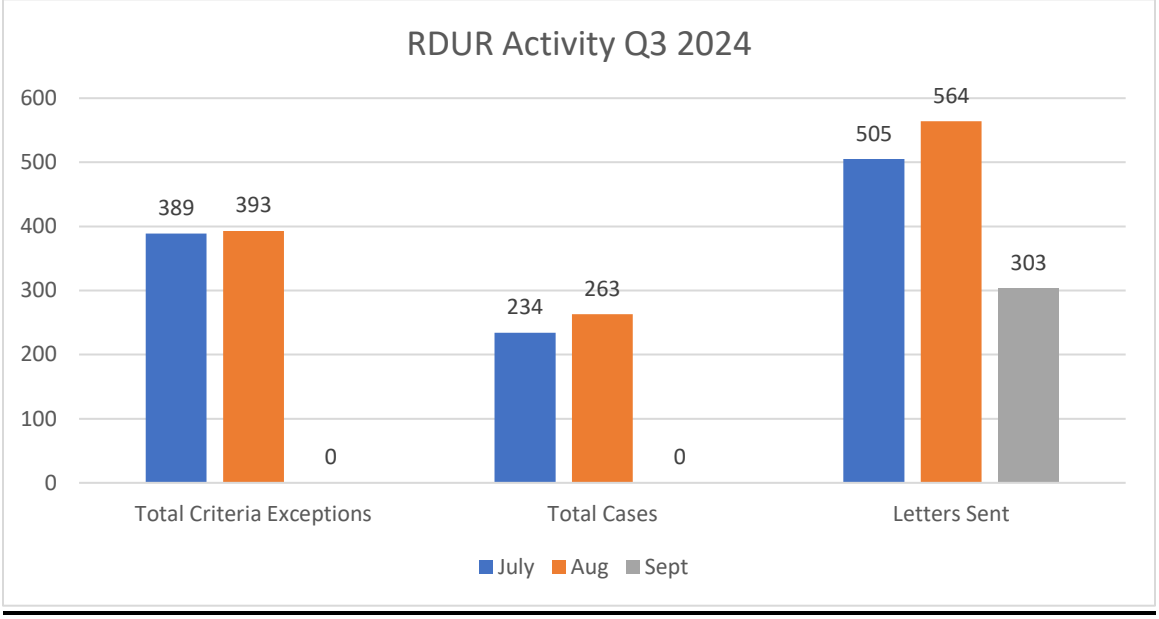
Top 15 Therapeutic Classes Based on Number of Claims from 07/01/2024 – 09/30/2024

Therapeutic Class Description	Claims	Claims Cost	Patients	Cost/Claim	% Claims	Dif.
1. ANTIDEPRESSANTS	24,003	$564,513.14	10,366	$23.52	10.8%	NC
2. ANTIPSYCHOTIC AGENTS	8,949	$2,395,961.66	3,706	$267.74	4.0%	NC
3. AMPHETAMINES	6,444	$989,228.11	2,719	$153.51	2.9%	NC
4. GABA ANTICONVULSANTS	6,321	$131,008.56	2,646	$20.73	2.8%	↑1
5. RESP AND CNS STIMULANTS	5,883	$536,916.93	2,408	$91.27	2.6%	↓1
6. OPIOID AGONISTS	5,622	$97,328.86	2,910	$17.31	2.5%	↑3
7. PROTON-PUMP INHIBITORS	5,594	$97,046.92	3,178	$17.35	2.5%	↓1
8. BETA AGONISTS	5,313	$708,637.71	3,654	$133.38	2.4%	↑7
9. NSAIDS	5,214	$74,067.87	3,552	$14.21	2.3%	↑1
10. CENTRAL ALPHA-AGONISTS	4,771	$69,558.18	2,205	$14.58	2.1%	↑3
11. ANTICONVULSANTS	4,741	$273,588.78	1,952	$57.71	2.1%	NC
12. STATINS	4,741	$68,552.25	2,795	$14.46	2.1%	NC
13. BETA BLOCKING AGENTS	4,557	$79,756.39	2,642	$17.50	2.0%	↑1
14. PENICILLIN ANTIBIOTICS	4,146	$68,604.93	3,735	$16.55	1.9%	↓6
15. ADRENALS	4,102	$199,060.73	2,996	$48.53	1.8%	↓8

Top 15 Therapeutic Classes Based on Claims Cost from 07/01/2024 – 09/30/2024

Therapeutic Class Description	Claims	Claims Cost	Patients	Cost/Patient	% Cost	Dif.
1. TNF INHIBITORS	342	$2,724,267.33	148	$18,407.21	8.7%	NC
2. ANTIPSYCHOTIC AGENTS	8,949	$2,395,961.66	3,706	$646.51	7.6%	NC
3. INTERLEUKIN AGENTS	162	$1,599,842.84	72	$22,220.04	5.1%	NC
4. ANTINEOPLASTIC AGENTS	513	$1,268,314.77	214	$5,926.70	4.0%	↑1
5. ANTIRETROVIRALS	699	$1,205,276.19	275	$4,382.82	3.8%	↑1
6. HCV ANTIVIRALS	48	$1,077,627.16	48	$22,450.57	3.4%	↑2
7. SGLT2 INHIBITORS	1,477	$1,062,808.29	808	$1,315.36	3.4%	NC
8. AMPHETAMINES	6,444	$989,228.11	2,719	$363.82	3.1%	↓4
9. INCRETIN MIMETICS	1,256	$881,154.41	637	$1,383.29	2.8%	NC
10. BETA AGONISTS	5,313	$708,637.71	3,654	$193.93	2.3%	↑15
11. SKIN AGENTS	203	$610,126.49	101	$6,040.86	1.9%	↑5
12. INSULINS	2,826	$582,199.50	1,187	$490.48	1.9%	↑1
13. ANTIDEPRESSANTS	24,003	$564,513.14	10,366	$54.46	1.8%	↓1
14. RESP AND CNS STIMULANTS	5,883	$536,916.93	2,408	$ 222.97	1.7%	↓4
15. CFTR MODULATORS	24	$515,872.20	12	$42,989.35	1.6%	↓4

RDUR Report: Q3 2024



July Cases by Type of Criteria		
Criteria Description	**# of Cases**	**% of Cases**
Therapeutic Appropriateness	233	99.6%
Drug-Disease Interaction	1	0.4%

Aug Cases by Type of Criteria		
Criteria Description	**# of Cases**	**% of Cases**
Therapeutic Appropriateness	263	100%

September Special Mailing

50 letters sent to prescribers

Introduction

At the bottom of this report, you will see patients receiving at least one attention-deficit-hyperactivity disorder (ADHD) stimulant medication above the maximum compendia recommended dose in the past 120 days per pharmacy claims data. If multiple prescribers are involved, each will receive this information.

High-Dose Stimulants

Stimulant medications are oftentimes used in the management of ADHD and narcolepsy.[1] Stimulants are available in a variety of dosage formulations, allowing prescribers to meet patient-specific needs.[2] Prescribers should follow compendia or FDA label supported use (e.g., diagnosis, age, dosage, frequency, route) and routinely monitor treatment response to adjust the patient's regimen as needed. [1]

Stimulants can cause hypertension, gastrointestinal side effects, headache, insomnia, and a loss of appetite. [2] They also have warnings for cardiovascular events (e.g., acute myocardial infarction, stroke, sudden cardiac death), serotonin syndrome, growth suppression, and psychotic or manic symptoms. Risks of these side effects are increased when used at higher than recommended doses.[3]

Stimulant medications have a boxed warning for potential dependence and abuse, and overutilization of stimulants may increase the risk of misuse. [2] Misuse occurs when using a medication differently than instructed, without a prescription, or for recreational use; this has become a major health concern in the United States. Prescribers can help limit the risk of misuse by carefully choosing the medication (e.g., type, formulation), monitoring prescription drug monitoring programs (PDMP) when prescribing refills, requiring patient signed agreements, and educating patients on appropriate use and risks associated with dependence and abuse. [3]

Key Takeaways:

- Reference compendia or FDA label for safe and supported prescribing (e.g., diagnosis, age, dosage, frequency, route)
- Routinely monitor treatment response to adjust the patient's regimen as needed[1]
- Prescribers can help limit the risk of misuse by carefully choosing the medication (e.g., type, formulation), monitoring prescription drug monitoring programs (PDMP) when prescribing refills, requiring patient signed agreements, and educating patients on appropriate use and risks associated with dependence and abuse. [3]

References:

1. *Agency for Healthcare Research and Quality. Evidence-based Practice Center Systematic Review Protocol Project Title: ADHD Diagnosis and Treatment in Children and Adolescents. Effective Healthcare Program. Available from: https://effectivehealthcare.ahrq.gov/sites/default/files/product/pdf/deficit-hyperactivity-protocol.pdf?_gl=1*g41jnf*_ga*NDczODIwNzE3LjE3MjA3MjIwNTQ.*_ga_45NDTD15CJ*MTcyMDcyMjA2My4xLjAuMTcyMDcyMjA2My42MC4wLjA.*
2. *U.S. Department of Health and Human Services. Stimulant and Related Medications: Use in Adults. Centers for Medicare and Medicaid Servies. October 2015. Available from: https://www.cms.gov/medicare-medicaid-coordination/fraud-prevention/medicaid-integrity-education/pharmacy-education-materials/downloads/stim-adult-factsheet11-14.pdf*
3. *Substance Abuse and Mental Health Services Administration (SAMHSA). Prescription Stimulant Misuse and Prevention Among Youth and Young Adults. Publication No. PEP21-06-01-003. Rockville, MD: National Mental Health and Substance Use Policy Laboratory. Substance Abuse and Mental Health Services Administration, 2021. Available from: https://store.samhsa.gov/sites/default/files/pep21-06-01-003.pdf*

Clinical Report

Prior Authorization Updates

Drug	PA Status	Class	
Bethkis	PA	Cystic Fibrosis	Starting with 2025 PDL
Nivestym	PA	Preferred Dosage Forms - figrastim	Starting with 2025 PDL
Nyvepria	PA	Preferred Dosage Forms - pegfilgrastim	Starting with 2025 PDL
Praluent	PA	cholesterol lowering drugs/PCSK9 inhibitors	Starting with 2025 PDL
Stimufend	PA	Preferred Dosage Forms - pegfilgrastim	Starting with 2025 PDL
Udenyca	PA	Preferred Dosage Forms - pegfilgrastim	Starting with 2025 PDL
Ziextenzo	PA	Preferred Dosage Forms - pegfilgrastim	Starting with 2025 PDL
Zimhi	PA	Preferred Dosage Forms - naloxone	Starting with 2025 PDL
Abrilada	Remove PA	Cytokine Modulators	Starting with 2025 PDL
Eysuvis	Remove PA	Dry Eye Syndrome	Starting with 2025 PDL
Hadlima	Remove PA	Cytokine Modulators	Starting with 2025 PDL
Rykindo ER	Remove PA	Preferred Dosage Forms - risperidone	Starting with 2025 PDL
Suflave	remove PA	Bowel Prep agents	Starting with 2025 PDL
Sutab	remove PA	Bowel Prep agents	Starting with 2025 PDL
Xaciato	Remove PA	Vaginal Infections	Starting with 2025 PDL
Akynzeo	PA	Nausea and Vomiting	
clobetasol 0.05% eye drops	PA	ophthalmic corticosteroids	
Crexont	PA	Parkinsons's Agents / Preferred Dosage Forms	
Ebglyss	PA	Atopic Dermatitis	
Elyxyb	PA	Migraine	
Iqirvo	PA	Medications > $3000	
Neffy	PA	Epinephrine	
Nemluvio	PA	Prurigo Nodularis	
Tyenne	PA	Cytokine Modulators	
Vyalev	PA	Parkinson's Disease	
Yorvipath	PA	Secondary Hypoparathyroidism	
Zituvimet XR	PA	DPP-4 inhibitors	
aprepitant	remove PA	Nausea and Vomiting	
Dificid	remove PA	Clostridioides difficile - associated diarrhea (CDAD)	

Criteria Updates

Summary of Changes

RNA – targeted therapies

1. Guideline recommends genetic documentation as well as a positive amyloid biopsy for confirmation of diagnosis.
2. Added additional screening options as used in HELIO-A Trial (NCT03759379) and as indicated in the guidelines.
3. Updated signs and symptoms to correspond with initial symptoms as indicated in guidelines.

TTR – stabilizers

1. Updated diagnostic confirmation and heart failure history criteria based on NCT01994889 inclusion criteria
2. Updated exclusion criteria based on exclusion criteria from NCT01994889 and results that were not statistically significant for class III HF.

References:

1. Ando Y, Coelho T, Berk JL, Cruz MW, Ericzon BG, Ikeda S, Lewis WD, Obici L, Planté-Bordeneuve V, Rapezzi C, Said G, Salvi F. Guideline of transthyretin-related hereditary amyloidosis for clinicians. Orphanet J Rare Dis. 2013 Feb 20;8:31. doi: 10.1186/1750-1172-8-31. PMID: 23425518; PMCID: PMC3584981.

Amyloidosis

RNA – targeted therapies

TTR-specific small interfering RNA (siRNA)

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ONPATTRO (patisiran) – *Medical Billing Only*	

Transhyretin-directed small interfering RNA (siRNA)

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AMVUTTRA (vutrisiran) – *Medical Billing Only*	

Antisense Oligonucleotide (ASO)

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
TEGSEDI (inotersen)	
WAINUA (eplontersen)	

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a neurologist, geneticist, or specialist in the treatment of amyloidosis.
- The diagnosis must be confirmed by both of the following:
  - Genetic testing confirming a pathogenic TTR mutation (e.g., V30M)
  - Amyloid deposits via tissue biopsy
- Documentation of one of the following must be provided:

- Baseline polyneuropathy disability (PND) score ≤ IIIb
- Baseline Coutinho staging system stage 1 or 2
- Baseline Neuropathy Impairment Score [NIS] of 5–130
- Karnofsky Performance Status score of ≥60%

- The member has not had a liver transplant.
- The member has clinical signs and symptoms of the disease (e.g., peripheral neuropathy, numbness, altered pain and temperature sensation, decreased pinprick sensation)
- The member is not receiving any other TTR reducing agent (i.e., vutrisiran, patisiran, tafamidis, inotersen, eplontersen).

Renewal Criteria – Approval Duration: 12 months

- Documentation of a therapeutic response as evidenced by stabilization or improvement (e.g., improved neurologic impairment, motor function, quality of life, slowing of disease progression, etc.) from baseline in one of the following:
  - PND score ≤ IIIb
  - Coutinho staging system stage 1 or 2
  - Baseline Neuropathy Impairment Score [NIS] of 5–130
  - Karnofsky Performance Status score of ≥60%

TTR Stabilizers

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
VYNDAQEL (tafamidis)	
VYNDAMAX (tafamidis)	

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a cardiologist, geneticist, or specialist in the treatment of amyloidosis.
- Documentation of confirmation of the diagnosis by both of the following must be provided:
  - genetic testing confirming a pathogenic TTR mutation (e.g., V30M)
  - amyloid deposits via tissue biopsy
- The member must have heart failure class I or II with at least 1 prior hospitalization for heart failure or with symptoms of volume overload or elevated intracardiac pressures (e.g., elevated jugular venous pressure, shortness of breath or signs of pulmonary congestion on x-ray or auscultation, peripheral edema) despite 6-months of adherent use of a diuretic.
- The member has an end-diastolic interventricular septal wall thickness of at least 12 mm.
- The member must not have any of the following:
  - NYHA class IV symptoms or severe aortic stenosis
  - Previous heart transplant or implanted cardiac mechanical assist device
  - Previous liver transplant
- Documentation of baseline 6MWT > 100 meters must be submitted.
- The member is not receiving any other TTR reducing agent (i.e., vutrisiran, patisiran, tafamidis, inotersen)

Renewal Criteria – Approval Duration: 12 months

- Documentation of a therapeutic response as evidenced by stabilization or improvement from baseline in both of the following:
  - 6MWT > 100 meters
  - NYHA class

Summary of Changes

1. Ohtuvayre is a new to market drug.
    a. Global Initiative for Chronic Obstructive Lung Disease (GOLD) 2024 report recommend LABA + LAMA + ICS for patients who develop exacerbations on LABA + LAMA and have a blood eosinophil count of ≥ 100.
2. Dupixent received a new indication of COPD.
    a. Biologics
3. Additional criteria added for Dupixent for asthma based on the QUEST trial, subjects with baseline blood eosinophil count <150 cells/mcL and FeNO <25 ppb, similar severe exacerbation rates were observed between Dupixent and placebo
4. Tobacco cessation counseling requirement was added for Asthma/COPD indicated drugs were treatment is being escalated as listed below.

Asthma/COPD

Biologics

Anti-IL-5 biologics

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
FASENRA (benralizumab)	CINQAIR (reslizumab) – *Medical Billing Only*
	NUCALA (mepolizumab) SYRINGE, AUTOINJECTOR
	NUCALA (mepolizumab) VIAL – *Medical Billing Only*

Anti-IL-4/13 biologics

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
DUPIXENT (dupilumab)	

Allergic Asthma-directed biologics

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
XOLAIR (omalizumab) SYRINGE, AUTOINJECTOR	
XOLAIR (omalizumab) VIAL – *Medical Billing Only*	

Thymic Stromal Lymphopoietin (TSLP) blocker

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	TEZSPIRE (tezepelumab-ekko) PENS
	TEZSPIRE (tezepelumab-ekko) VIAL and SYRINGES – *Medical Billing Only*

Prior Authorization Criteria

Prior Authorization Form – Asthma

Initial Criteria – Approval Duration: 6 months

For Asthma Only

- The requested medication must be prescribed by, or in consult with, an allergist/immunologist or pulmonologist
- If the member is a current tobacco user, the member must have received tobacco cessation counseling in the past year
- The member must have had at least one exacerbation requiring use of oral corticosteroids in the past year despite continued compliant use of a high dose inhaled steroid in combination with a long-acting beta agonist (LABA) for at least 3 months prior to the exacerbation, as evidenced by paid claims or pharmacy printouts

Dupixent Only:

- The member must have an eosinophil count of ≥ 150 cells/mcL or FeNO ≥ 25 ppb within the past year

Xolair Only:

- The member has a serum total IgE level, measured before the start of treatment within the past year, of ≥ 30 IU/mL and ≤ 700 IU/mL in members age ≥ 12 years or ≥ 30 IU/mL and ≤ 1300 IU/mL in members ages 6 to < 12 years.
- The member has had a positive skin test or in vitro reactivity to a perennial aeroallergen

Anti-IL-5 biologics:

- The member has an eosinophil count ≥ 150 cells/mcL within the past year
- *Nucala and Cinqair Only*:
    - The member must have had at least one exacerbation requiring use of oral corticosteroids in the past year despite continued compliant use of a triple therapy regimen (high dose inhaled steroid + long-acting beta agonist (LABA) + long-acting muscarinic antagonist (LAMA)) in combination with each of the following for at least 4 months, as evidenced by paid claims or pharmacy printouts: Dupixent, Fasenra, and Tezspire

Tezspire Only:

- The member must have had at least one exacerbation requiring use of oral corticosteroids in the past year despite continued compliant use of a triple therapy regimen (high dose inhaled steroid + long-acting beta agonist (LABA) + long-acting muscarinic antagonist (LAMA)) in combination with each of the following for at least 4 months, as evidenced by paid claims or pharmacy printouts: Dupixent and Fasenra

For COPD Only

Dupixent Only:

- The requested medication must be prescribed by, or in consult with, an allergist/immunologist or pulmonologist
- If the member is a current tobacco user, the member must have received tobacco cessation counseling in the past year
- The member must have had at least one exacerbation requiring use of oral corticosteroids in the previous year despite continued compliant use of an inhaled steroid AND long-acting beta agonist (LABA) AND long-acting muscarinic antagonist (LAMA) as evidenced by paid claims or pharmacy printouts
- The member has an eosinophil count of ≥ 300 cells/mcL within the past year

<u>Renewal Criteria – Approval Duration:</u> 12 months

- The member must have achieved a significant reduction in exacerbations and utilization of systemic steroids and rescue medications since treatment initiation since starting treatment with the requested medication (subject to clinical review).

Phosphodiesterase-3 (PDE3) and Phosphodiesterase-4 (PDE4) Inhibitor

PREFERRED AGENTS (CLINICAL PA REQUIRED)
OHTUVAYRE (ensifentrine)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The requested medication must be prescribed by, or in consult with, a pulmonologist
- If the member is a current tobacco user, the member must have received tobacco cessation counseling in the past year
- The member must meet one of the following criteria:
    - The member has a blood eosinophil of ≥ 100 cells/mcL and has experienced an exacerbation while adherent to a 60-day trial of a triple combination regimen consisting of an inhaled steroid, long-acting beta agonist, and long-acting anticholinergic.
    - The member has a blood eosinophil of < 100 cells/mcL and has experienced an exacerbation while adherent to a 60-day trial of a dual combination regimen consisting of a long-acting beta agonist and long-acting anticholinergic.

Corticosteroid/Anticholinergics/Long-Acting Beta Agonists Combinations

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
TRELEGY ELLIPTA (fluticasone/umeclidinium/vilanterol)	BREZTRI AEROSPHERE (budesonide/glycopyrrolate/formoterol)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must have blood eosinophil of ≥ 100 cells/mcL within the past 90 days
- If the member is a current tobacco user, the member must have received tobacco cessation counseling in the past year
- The member must have experienced an exacerbation while adherent to a 60-day trial of fluticasone inhaler + umeclidinium + vilanterol which have the same active ingredients as Trelegy Ellipta, as evidenced by paid claims or pharmacy printouts. Clinical justification must also be provided why Trelegy Ellipta is expected to improve outcomes versus using fluticasone inhaler + umeclidinium + vilanterol combination therapy (subject to clinical review).
    - available combination products to achieve this are fluticasone + Anoro Ellipta (umedclidium/vilanterol) and Breo Ellipta (fluticasone/vilanterol) + Incluse Ellipta (umeclidinium)
- The member must have experienced an exacerbation while adherent to a 60-day trial of triple therapy (Steroid/Long-Acting Beta Agonist/Long-Acting Anticholinergic) that has at least one ingredient different from fluticasone inhaler + umeclidinium + vilanterol combination therapy, as evidenced by paid claims or pharmacy printouts.

Non-Preferred Agents Criteria:

- The member must have failed a 30-day trial of the preferred product, as evidenced by paid claims or pharmacy printouts:

Anticholinergics – Long-Acting

PREFERRED AGENTS (NO PA REQUIRED)	PREFERRED STEP 1 AGENTS (ELECTRONIC STEP REQUIRED)	NON-PREFERRED STEP 2 AGENTS (PA REQUIRED)

INCRUSE ELLIPTA (umeclidinium)	SPIRIVA RESPIMAT 1.25 MCG (tiotropium)	tiotropium handihaler
SPIRIVA HANDIHALER (tiotropium)		TUDORZA PRESSAIR (aclidinium)
SPIRIVA RESPIMAT 2.5 MCG (tiotropium)		YUPELRI (revefenacin)

Electronic Concurrent Medications Required

- Spiriva Respimat 1.25 mg: A total of 30 days of a long-acting beta agonist (ICS should be used with LABA as combination or single ingredient inhalers) must be paid within 40 days prior to the Spiriva Respimat 1.25 mg date of service.

Electronic Diagnosis Verification

- Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale.
  - Spiriva Respimat 1.25 mg is indicated for asthma.
  - Spiriva Respimat 2.5 mg is indicated for COPD.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must have failed a 30-day trial of at least 2 preferred long-acting anticholinergic agents of unique ingredients (in combination or alone), as evidenced by paid claims or pharmacy printouts.
- If the member is a current tobacco user, the member must have received tobacco cessation counseling in the past year

Corticosteroid/Long-Acting Beta Agonist (LABA) Combination Inhalers

Solid Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED STEP 1 AGENTS (PA REQUIRED)	NON-PREFERRED STEP 2 AGENTS (PA REQUIRED)
ADVAIR DISKUS (fluticasone/salmeterol) *– Brand Required*	BREO ELLIPTA (fluticasone/vilanterol) *– Brand Required*	BREYNA (budesonide/formoterol)
ADVAIR HFA (fluticasone/salmeterol) *– Brand Required*		budesonide/formoterol
AIRDUO RESPICLICK (fluticasone/salmeterol) *– Brand Required*		fluticasone/salmeterol
DULERA (mometasone/formoterol)		fluticasone/vilanterol
		SYMBICORT (budesonide/formoterol) *– Brand Required*
		WIXELA INHUB (fluticasone/salmeterol)

GINA Guidelines – SMART:

- For mild asthma, ICS-formoterol is the preferred reliever medication for as needed symptom relief
- For steps 3-5, ICS-formoterol is preferred for use as an as needed and regular daily treatment
  Quantity Limits to accommodate SMART therapy:
  - 2 Symbicort or Dulera inhalers per 30-day supply not to exceed a total of 9 inhalers per 182 days without prior approval.

Electronic Diagnosis Verification

- Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

Non-Preferred Step 1 Agents:
- The member must have failed a 30-day trial of each preferred agent of a unique ingredient, as evidenced by paid claims or pharmacy printouts.
- For COPD diagnosis only: The member must currently be taking a long acting antimuscarinic agent.

Non-Preferred Step 2 Agents:
- The member must have failed a 30-day trial of each preferred and non-preferred step 1 agent of a unique ingredient, as evidenced by paid claims or pharmacy printouts.
- If the member is a current tobacco user, the member must have received tobacco cessation counseling in the past year
- For COPD diagnosis only, the member must currently be taking a long acting antimuscarinic agent.

Summary of Changes

1. Yorvipath is a new to market drug. Calcium, magnesium, and vitamin D levels are based on the inclusion criteria for Study 1 (NCT04701203)

Secondary Hyperparathyroidism

Oral

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
calcitriol	cinacalcet
paricalcitol	doxercalciferol capsule
	HECTOROL (doxercalciferol) CAPSULE
	RAYALDEE ER (calcifediol)
	ROCALTROL (calcitriol)
	SENSIPAR (cinacalcet)
	ZEMPLAR (paricalcitol)

++ cinacalcet is associated with hypocalcemia, increased urinary calcium excretion, and increased serum phosphate levels

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months
Cinacalcet only:

- If member is on renal dialysis, Medicare eligibility must be ruled out *(6-month approval may be allowed to determine eligibility)*

All other agents:

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The member must have failed a 30-day trial of paricalcitol
- Clinical justification must be provided explaining why the member is unable to use the preferred agents (subject to clinical review)

References:

1. Quarles LD. Management of secondary hyperparathyroidism in adult non-dialysis patients with chronic kidney disease. In: *UpToDate*, Post TW (Ed), UpToDate, Waltham, MA, 2023

Subcutaneous

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	YORVIPATH (palopegteriparatide)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The requested medication must be prescribed by, or in consult with, an endocrinologist
- The member must have persistent hypoparathyroidism as evidenced by one of the following symptoms despite a 6-month trial of calcitriol or equivalent oral agent:
    - Symptomatic hypocalcemia
    - Hyperphosphatemia
    - Hypercalciuria
- The member must have an albumin-corrected serum calcium concentration must be ≥ 7.8 mg/dL
- The member must have a magnesium concentration ≥ 1.3 mg/dL
- The member must have a 25 (OH) vitamin D concentration between 20 and 80 ng/mL

Renewal Criteria – Approval Duration: 12 months

- The member no longer requires active vitamin D or has experienced a significant reduction in required dosage and is still titrating Yorvipath
- The member has an albumin-corrected serum calcium in the lower-half of the normal reference range or just below the reference range (~8-9 mg/dL)

Pharmacy Coverage Policy Manual

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Preferred Drug List (PDL)

This contains coverage rules for medications including prior authorization criteria for medications billed by pharmacy point of sale systems and for HCPCS codes billed by a physician/clinic through an 837P transactions.

Preferred Diabetes Supply List (PDSL)

This is a list of diabetes supplies billed by pharmacy point of sale systems.

Prior Authorization Review Dates

Please see DUR Board found at https://ndmedicaid.acentra.com/

Preferred Drug List (PDL)

Rules

1. Requests for non-preferred brand name agents with a generic formulation available must meet the Dispense as Written (DAW1) criteria for approval in addition to as any other applicable coverage criteria/rule (unless otherwise noted).
2. Non-solid dosage preparations must meet Non-Solid Dosage Preparations prior authorization criteria even if they are preferred in the clinical category.
3. Renewal Request Criteria must be met for all renewal requests.
4. The use of all preferred and non-preferred agents must meet recommendations found in the FDA label or compendia (e.g., diagnosis, age, dosage, frequency, route). Compendia supported use is defined as at least of level of IIa efficacy rating and IIb recommendation. ND Medicaid uses DrugDex ® compendia. Requests outside of FDA approved or compendia supported use are not reviewable by prior authorization and the request will be dismissed on PA review. Sec. 1927. [42 U.S.C. 1396r-8] (d).
5. Clinical justification may be provided when criteria does not encompass a standard of care or guideline supported therapy or a member's unique scenario, by faxing supporting chart notes and evidence using the General Prior Authorization Form.
6. Grandfathering may be allowed in cases where the clinical condition has been verified by a specialist, member is currently receiving FDA or compendia approved medication, and there is clinical evidence for decompensation of member's condition if agent is switched (subject to clinical review).
7. A trial will be considered a failure if a product was not effective at the maximum therapeutic dose with good compliance with most recent trial within the past 6 months, as evidenced by paid claims or pharmacy print outs. If unable to titrate dose to maximum therapeutic dose due to contraindication, intolerance, or lack of effect; trial requirements must be met with alternative preferred product(s) when applicable. Mitigation efforts must be provided, as applicable, with a request to bypass a trial for a preferred product(s) due to intolerance (subject to clinical review).
8. The use of pharmaceutical samples will not be considered when evaluating the member's medical condition or prior prescription history for drugs that require prior authorization.
9. Unless otherwise specified, the listing of a brand or generic name includes all legend formulations of that drug. OTC drugs are not covered unless specified. All drugs are pharmacy billed medications unless otherwise specified.
10. Please use the following forms unless otherwise indicated:
    - Pharmacy Point of Sale: General Prior Authorization Form
    - Medical Office Billing: Provider Administered Drug (Medical Billing) PA Form
    - Requested product is same active ingredient as preferred product: MedWatch Form
11. For pharmacy billed medication: please use the prior authorization website https://ndmedicaid.acentra.com/ to access PA forms, NDC Drug Lookup, quantity limits, and prior authorization information for all medications.
12. For medical billed medications: Please see the full list of medical drugs that require PA at https://www.hhs.nd.gov/human-services/medicaid/provider under the "Codes Requiring Service Authorization" tab at the bottom of the page.
13. All requirements outlined in the Pharmacy Provider Manual and any other federal or ND Medicaid manuals, policies, or guidance still apply. For example, when the PDL says a drug is covered without prior authorization, that does not imply that ND Medicaid will pay for that drug if someone has Medicare coverage.
14. If member is 65 years or older, on renal dialysis or has had a kidney transplant within the past 3 years, Medicare eligibility must be ruled out (6-month approval may be allowed to determine eligibility)

Prior Authorization Updates

Drug name	PA Status	Class
Akynzeo	PA	Nausea and Vomiting
Bethkis	PA	Cystic Fibrosis

Nivestym	PA	Preferred Dosage Forms - figrastim
Nyvepria	PA	Preferred Dosage Forms - pegfilgrastim
Praluent	PA	cholesterol lowering drugs/PCSK9 inhibitors
Stimufend	PA	Preferred Dosage Forms - pegfilgrastim
Udenyca	PA	Preferred Dosage Forms - pegfilgrastim
Vyalev	PA	Parkinson's Disease
Ziextenzo	PA	Preferred Dosage Forms - pegfilgrastim
Zimhi	PA	Preferred Dosage Forms - naloxone
Zituvimet XR	PA	DPP-4 inhibitors
Abrilada	Remove PA	Cytokine Modulators
aprepitant	Remove PA	Nausea and Vomiting
Eysuvis	Remove PA	Dry Eye Syndrome
Hadlima	Remove PA	Cytokine Modulators
Rykindo ER	Remove PA	Preferred Dosage Forms - risperidone
Suflave	Remove PA	Bowel Prep agents
Sutab	Remove PA	Bowel Prep agents
Xaciato	Remove PA	Vaginal Infections

Version Changes

Category	Change
Amyloidosis	Criteria updated
Antidepressants	Category added
Anti-infectives - Resistance Prevention	Criteria updated
Antipsychotics - Long Acting Injectable	Preferred products updated
Asthma / COPD	Criteria updated - Biologics
Biosimilars	Category added
Bowel Prep Agents	Preferred products updated
Chronic Rhinosinusitis with Nasal Polyps	Preferred products & criteria updated
Cystic Fibrosis	Preferred products updated
Diabetic Supplies - Continous Glucose Monitors	Criteria & FAQ updated - Non-Preferred Guardian CGM added
Diabetic Supplies - Ketone Strips	Preferred products updated
Diabetic Supplies - Meters	Preferred products updated
Diabetic Supplies - Pen Needles	Preferred products updated
Diabetic Supplies - Syringes	Preferred products updated
Diabetic Supplies - Test Strips	Preferred products updated
Dry Eye Syndrome	Preferred products and criteria updated
Eczema / Atopic Dermatitis	Preferred products updated
Growth Hormone	Preferred products & criteria updated
Hematopoietic, Colony Stimulating Factors	Preferred products updated
Hemophilia	Criteria updated - gene therapy
Influenza	Criteria updated
Lipid Lowering Agents	PCSK9 inhibitors criteria updated - Praluent moved to non-preferred

Migraine - Prophylaxis	Preferred products and criteria updated
Omnipod	Criteria updated - Type 2 diabetes coverage added
Opioid Reveral Medications	Preferred products updated
Parkinson's Disease	Criteria updated and rearranged & Vyalev added
Plaque Psoriasis	Criteria updated for Otezla 20 mg and Tremfya
Psoriatic Arthritis	Criteria updated - Tremfya
Sickle Cell Disease	Criteria and preferred products updated
Stimulants	Preferred products & criteria updated
Vaginal Anti-infectives	Preferred products updated

General Policies

Dispense as Written (DAW1)

Member or prescriber preference is NOT criteria considered for approval.

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

- Request must meet one of the following (A or B):
  - A. Primary insurance requires a ND Medicaid non-preferred branded product.
  - B. All the following are met (1-4):
    1. The requested brand-name product must not have an authorized generic available.
    2. The member must have failed a 30-day trial of each pharmaceutically equivalent generic product at maximum tolerated dose from each available manufacturer, as evidenced by paid claims or pharmacy print outs.
    3. Clinical justification is provided for the different clinical outcome expected for the requested brand and other alternatives (e.g., medications in same class) are not an option for the member (subject to clinical review)
    4. A MedWatch form for each trial of each NDC from the available manufacturer(s) is filled out and attached to request.

Generic Non-Preferred Requests

Member or prescriber preference is NOT criteria considered for approval.

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months (1 month for short-term request)

- Request must meet one of the following (A, B, or C):
  - A. Primary insurance requires a ND Medicaid non-preferred generic product.
  - B. Pharmacy requests a short-term approval due to dose titration or supply issue.
  - C. All the following are met (1-3):
    1. The member must have failed a 30-day trial of preferred brand product, as evidenced by paid claims or pharmacy print outs.
    2. Clinical justification is provided for the different clinical outcome expected for the requested generic and other alternatives (e.g., medications in same class) are not an option for the member (subject to clinical review)

3. A MedWatch form for each trial of each product from the available manufacturer(s) is filled out and attached to request.

Medications that cost over $3000/month

Prior Authorization Criteria

Initial Criteria - Approval Duration: 6 months

- Both of the following must be met:
  - The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational).
  - The medication must be used as recommended in available guidelines or expert consensus statements, including medication trials that are recommended prior to use of requested medication.
- The requested medication must be prescribed by, or in consult with, a specialist in the member's treated diagnosis.
- As applicable, documentation must be attached to confirm serum marker or pathogenic gene variants amenable to treatment.
- Documentation of the baseline labs, signs or symptoms that can be utilized for comparison to show member has experienced clinical benefit upon renewal has been submitted with request.

CLINICAL PA REQUIRED
ABECMA (idecabtagene vicleucel) – *Medical Billing Only*
ACTHAR (corticotropin) SELF-INJECTOR
BLINCYTO (blinatumomab) – *Medical Billing Only*
BREYANZI (lisocabtagene maraleucel) – *Medical Billing Only*
CARVYKTI (ciltacabtagene autoleucel) – *Medical Billing Only*
CYSTADROPS (cysteamine)
CYSTARAN (cysteamine)
DANYELZA (naxitamab-gqgk) – *Medical Billing Only*
DAYBUE (trofinetide)
DOJOVI (triheptanoin)
EPKINLY (epcoritamab-bysp) – *Medical Billing Only*
FIRDAPSE (amifampridine)
FUROSCIX (furosemide)
FUROSCIX (furosemide) – *Medical Billing Only*
FYARRO (sirolimus protein-bound particles) – *Medical Billing Only*
GATTEX (teduglutide)
INCRELEX (mecasermin)
IQIRVO (elafibranor)
JOENJA (leniolisib)
KIMMTRAK (tebentafusp-tebn) – *Medical Billing Only*
KYMRIAH (tisagenlecleucel) – *Medical Billing Only*
LIVDELZI (seldelpar lysine)
MYCAPSSA (octreotide)
NULIBRY (fosdenopterin)
OCALIVA (obeticholic acid)
OXERVATE (cenegermin-bkbj)
PYRUKYND (mitapivat)
REZUROCK (belumosudil)

SKYCLARYS (omaveloxolone)
SPEVIGO (spesolimab-sbzo)
SOHONOS (palovarotene)
TAVNEOS (avacopan)
TECARTUS (brexucabtagene autoleucel) – *Medical Billing Only*
TECVAYLI (Inj teclistamab cqyv 0.5 mg) – *Medical Billing Only*
TIVDAK (tisotumab vedotin-tftv) – *Medical Billing Only*
VIJOICE (alpelisib)
VYJUVEK (beremagene geperpavec-svdt) – *Medical Billing Only*
WELIREG (belzutifan)
XENPOZYME (olipudase alfa) – *Medical Billing Only*
XOLREMDI (mavorixafor)
YESCARTA (axicabtagene ciloleucel) – *Medical Billing Only*
ZOKINVY (lonafamib)
ZYNLONTA (loncastuximab tesirine-lpyl) – *Medical Billing Only*

Non-Solid Dosage Forms

Electronic Age Verification

- Non-Solid Dosage Forms that do not require prior authorization for clinical criteria will reject at the point of sale for members 10 years and older to verify they meet Non-Solid Dosage Form prior authorization criteria.

Prior Authorization Criteria

Initial Criteria - Approval Duration: 3 years (1 month for short-term restriction)

- One of the following criteria is met:
  - The member has a feeding tube placed and the medication is not available in a dosage form that can be crushed or poured into the tube.
  - The member does not have a feeding tube placement but one of the following apply:
    - Swallow study documentation has been submitted showing inability to swallow.
    - Permanent disability of swallowing solid dosage forms
    - Short-term restriction (e.g., mouth surgery)

Renewal Requests

Prior Authorization Criteria

Renewal Criteria

- The member must have experienced and maintained clinical benefit since starting treatment with the requested medication (subject to clinical review).
- The member must continue to meet applicable initial criteria. Additional renewal criteria may apply as indicated under specific category.
- One of the following must be met (1 or 2):
  1. *Approval Duration: regular renewal approval duration or 1 year*
     - The member was at least 80% adherent to medication, excluding any claim gaps due to hospitalization or eligibility.
  2. *Approval Duration: 3 months*
     - All the following must be met -
       - Clinical justification must be provided for the non-adherence.

- A method to improve adherence must be provided such as addressing adherence barriers, implementing a treatment plan, medication therapy management (MTM), etc.
- Clinical justification must be provided to continue treatment and how efficacy is assessed despite non-adherence.

Allergy/Immunology

Therapeutic Duplication

- One strength of one medication is allowed at a time.

Chronic Idiopathic Urticaria

Biologic Agents

CLINICAL PA REQUIRED
XOLAIR (omalizumab) SYRINGE, AUTOINJECTOR
XOLAIR (omalizumab) VIALS – *Medical Billing Only*

Prior Authorization Criteria

Initial Criteria - Approval Duration: 3 months

- The requested medication must be prescribed by, or in consult with, an allergist/immunologist.
- The member must have failed a 30-day trial of a dose of fourfold normal dosing of second-generation H_1 antihistamine (e.g., cetirizine, desloratadine, fexofenadine, levocetirizine, loratadine) in addition to the following:
  A. Leukotriene receptor antagonist (e.g., montelukast, zafirlukast, zileuton)
  B. Histamine H_2-receptor (e.g., ranitidine, famotidine, nizatidine, cimetidine)

References

1. Khan DA. Chronic spontaneous urticaria: Treatment of refractory symptoms. In: *UpToDate*, Post TW (Ed), UpToDate, Waltham, MA, 2023
2. Schaefer P. Acute and Chronic Urticaria: Evaluation and Treatment. Am Fam Physician. 2017 Jun 1;95(11):717-724. PMID: 28671445
3. Zuberbier, Torsten, et al. "The international EAACI/GA²LEN/EuroGuiDerm/APAAACI guideline for the definition, classification, diagnosis, and management of urticaria." *Allergy* 77.3 (2022): 734-766.

Chronic Rhinosinusitis with Nasal Polyps

Steroids – Nasal Spray

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
fluticasone	XHANCE (fluticasone)

Initial Criteria - Approval Duration: 12 months

- Xhance (fluticasone) Only: See Preferred Dosage Form criteria

Biologics

Anti-IL-4/13 biologics

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
DUPIXENT (dupilumab)	

Anti-IL-5 biologics

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	NUCALA (mepolizumab) SYRINGE, AUTOINJECTOR
	NUCALA (mepolizumab) VIAL – *Medical Billing Only*

Eosinophil-directed biologics

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
XOLAIR (omalizumab) SYRINGE, AUTOINJECTOR	
XOLAIR (omalizumab) VIAL – *Medical Billing Only*	

Prior Authorization Criteria

Prior Authorization Form - Nasal Polyps

Initial Criteria - Approval Duration: 3 months

- The requested medication must be prescribed by, or in consult with, an ear/nose/throat specialist or allergist/immunologist.
- The member must have failed a 12-week trial of intranasal corticosteroids.
- The member must have trialed at least two courses of a 10-day trial of oral glucocorticoids in the past year.
- The member must have bilateral polyps confirmed by sinus CT, anterior rhinoscopy, or nasal endoscopy.

Non-Preferred Agent Criteria:

- The member must have failed a 90-day trial with each preferred agent, as evidenced by paid claims or pharmacy printouts. Dupixent trial may be bypassed if the member has eosinophilic granulomatosis with polyangiitis

Renewal Criteria - Approval Duration: 12 months

- Documentation must be provided including that the member has achieved a significant reduction in nasal polyp size and symptoms since treatment initiation.
- The member must be receiving intranasal steroids.

References:

1. Rank, Matthew A., et al. "The Joint Task Force on Practice Parameters GRADE guidelines for the medical management of chronic rhinosinusitis with nasal polyposis." *Journal of Allergy and Clinical Immunology* 151.2 (2023): 386-398.

Cytokine Release Syndrome

Biologic Agents

Tocilizumab

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
TYENNE (tocilizumab-aazg) AUTOINJECTOR, SYRINGE	ACTEMRA (tocilizumab) ACTPEN, SYRINGE

TYENNE (tocilizumab-aazg) VIAL – *Medical Billing Only*	ACTEMRA (tocilizumab) VIAL – *Medical Billing Only*
	TOFIDENCE (tocilizumab-aazg) VIAL – *Medical Billing Only*

Prior Authorization Criteria

Initial Criteria - Approval Duration: 4 doses

- The member must have grade 3 or 4 Cytokine Release Syndrome resulting in hypotension and/or hypoxia.
- Non-preferred agents only: See biosimilar agent criteria

References

- Porter DL, Maloney DG. Cytokine Release Syndrome. In: *UpToDate*, Post TW (Ed), UpToDate, Waltham, MA, 2024

Deficiency of IL-A Receptor Antagonists (DIRA)

Biologic Agents

Interleukin (IL) -1 Receptor Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
KINERET (anakinra)	ARCALYST (rilonacept)

Prior Authorization Criteria

Initial Criteria - Approval Duration: 6 months

- The member must have failed a 3-month trial of a preferred agent, as evidenced by paid claims or pharmacy printouts.

References

- Nigrovic PA. Cryopyrin-associated periodic syndromes and related disorders. In: *UpToDate*, Post TW (Ed), UpToDate, Waltham, MA, 2023

Eosinophilic Granulomatosis with Polyangiitis (EGPA)

Biologic Agents

Anti-B-cell Therapy

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
RIABNI (rituximab-arrx) – *Medical Billing Only*	RITUXAN (rituximab) – *Medical Billing Only*
RUXIENCE (rituximab-pvvr) – *Medical Billing Only*	
TRUXIMA (rituximab-abbs) – *Medical Billing Only*	

Anti-IL-5 Biologics

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
FASENRA (benralizumab)	NUCALA (mepolizumab) SYRINGE, AUTOINJECTOR
	NUCALA (mepolizumab) VIAL – *Medical Billing Only*

Prior Authorization Criteria

Initial Criteria - Approval Duration: 6 months

- The requested medication must be prescribed by, or in consult with, a pulmonologist, rheumatologist, or allergy/immunology specialist.
- The member must not have severe disease defined as vasculitis with life- or organ-threatening manifestations (e.g., alveolar hemorrhage, glomerulonephritis, central nervous system vasculitis, mononeuritis multiplex, cardiac involvement, mesenteric ischemia, limb/digit ischemia)
- The member must have received at least 4 weeks of an oral corticosteroid dose ≥ 7.5 mg/day to control relapsing or refractory disease.
- The member must have asthmatic manifestations on a combination of high doses of inhaled glucocorticoids and long acting β2-agonist.
- The member must have blood eosinophil count of ≥ 1000 cells/mcL and/or ≥10 percent of leukocytes within the previous 6 weeks.

Non-Preferred Agents Criteria

- The member must have failed a 3-month trial of Fasenra, as evidenced by paid claims or pharmacy printouts.
- Rituxan Only: See Biosimilar Agents criteria

Renewal Criteria - Approval Duration: 12 months (one time renewal except in history of multiple relapses)

- The member must have experienced a decrease in relapses* and corticosteroid dose, and an increase of time of remission since starting treatment with the requested medication, as evidenced by medical documentation (e.g., chart notes) attached to the request (subject to clinical review).

  *Relapse is defined as active vasculitis, active asthma symptoms, active nasal or sinus disease requiring the use of glucocorticoids or immunosuppressants.

References

1. Chung SA, Langford CA, Maz M, Abril A, Gorelik M, Guyatt G, et al. 2021 American College of Rheumatology/Vasculitis Foundation guideline for the management of antineutrophil cytoplasmic antibody–associated vasculitis. *Arthritis Care Res (Hoboken)* 2021; 73: 1088– 1105.
2. Jennette, J.C., Falk, R.J., Bacon, P.A., Basu, N., Cid, M.C., Ferrario, F., Flores-Suarez, L.F., Gross, W.L., Guillevin, L., Hagen, E.C., Hoffman, G.S., Jayne, D.R., Kallenberg, C.G.M., Lamprecht, P., Langford, C.A., Luqmani, R.A., Mahr, A.D., Matteson, E.L., Merkel, P.A., Ozen, S., Pusey, C.D., Rasmussen, N., Rees, A.J., Scott, D.G.I., Specks, U., Stone, J.H., Takahashi, K. and Watts, R.A. (2013), 2012 Revised International Chapel Hill Consensus Conference Nomenclature of Vasculitides. Arthritis & Rheumatism, 65: 1-11. https://doi.org/10.1002/art.37715
3. King, Jr. TE. Eosinophilic granulomatosis with polyangiitis (Churg-Strauss): Treatment and prognosis. In: *UpToDate*, Post TW (Ed), UpToDate, Waltham, MA, 2023
4. Emmi, Giacomo, et al. "Evidence-Based Guideline for the diagnosis and management of eosinophilic granulomatosis with polyangiitis." *Nature reviews Rheumatology* 19.6 (2023): 378-393.

Food Allergy

Eosinophil-directed biologics

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
XOLAIR (omalizumab) SYRINGE, AUTOINJECTOR	
XOLAIR (omalizumab) VIAL – *Medical Billing Only*	

Oral Immunotherapy

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
PALFORZIA (peanut allergen powder)	

Prior Authorization Criteria

Initial Criteria - Approval Duration: 6 months

- The requested medication must be prescribed by, or in consult with, an allergist/immunologist.

- The provider must attest that the member has access to injectable epinephrine, and that the member/caregiver has been instructed and trained on its appropriate use.
- The member has one of the following (A, B, or C):
    A. The member has a history of severe (type 1) allergic response requiring the use of epinephrine, an ER visit, or hospitalization.
    B. Allergic reaction produced during a provider observed intake of food allergen and attestation that food allergy is likely to produce anaphylaxis as determined by allergist/immunologist.
    C. The member has all the following:
    - History of urticaria, angioedemia, or wheeze
    - Skin prick wheal of at least 3 mm or positive IgE test as determined by allergist/immunologist (at least 0.35 kUA/L for Palforzia and at least 30 IU/mL for Xolair)
    - Attestation that food allergy is likely to produce anaphylaxis as determined by allergist/immunologist.

Renewal Criteria (Palforzia Only) - Approval Duration: 6 months for continued up-titration or 12 months for maintenance the 300 mg dose.

- The member must have been adherent with therapy (last 6 fills must have been on time).
- One of the following must be met (A or B)
    A. The member has been able to tolerate the maintenance dose of Palforzia (300 mg daily) OR
    B. An up-titration plan to a final dose of 300 mg daily by week 40 and this is a first request for an up-titration renewal.

Hypereosinophilic Syndrome (HES)

Biologic Agents

CLINICAL PA REQUIRED
NUCALA (mepolizumab) SYRINGE, AUTOINJECTOR
NUCALA (mepolizumab) VIAL – *Medical Billing Only*

Prior Authorization Criteria

Initial Criteria - Approval Duration: 6 months

- The requested medication must be prescribed by, or in consult with, a hematologist, or allergy/immunology specialist.
- The member must be FIP1L1-PDGFRα kinase-negative.
- The member must have experienced at least 2 HES flares within the past 12 months despite a 3-month trial with oral corticosteroid ≥ 7.5 mg/day
- The member must have a blood eosinophil count of 1000 cells/mcL or higher.

Renewal Criteria - Approval Duration: 12 months

- The member must have experienced and maintained clinical benefit (e.g., reduction in flares, decreased blood eosinophilic count, reduction in corticosteroid dose or steroid sparing therapy) since starting treatment with the requested medication, as evidenced by medical documentation (e.g., chart notes) attached to the request (subject to clinical review)

Gout

Flare Treatment

Oral agents

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
colchicine tablet	colchicine capsule
NSAIDs	GLOPERBA (colchicine) ORAL SOLUTION
Oral Corticosteroids	MITIGARE (colchicine) CAPSULE

Prior Authorization Criteria

- See applicable Preferred Dosage Form or Non-Solid Oral Dosage Form criteria.

Biologic Agents

Interleukin (IL) -1 Receptor Inhibitors

PREFERRED AGENTS (CLINICAL PA REQUIRED)
ILARIS (canakinumab) – *Medical Billing Only*

Prior Authorization Criteria

Initial Criteria - Approval Duration: 6 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a rheumatologist or nephrologist.
- The member is concurrently taking a medication for prophylaxis of gout flares
- The member must have failed a 7-day trial of each of the following, as evidenced by paid claims or pharmacy printouts:
  A. colchicine
  B. NSAIDs
  C. corticosteroids

Urate Lowering Therapy

Uricosuric Drugs

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
probenecid-colchicine tablets	
probenecid tablets	

Xanthine Oxidase Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
6-mercaptopurine (6-MP)	AZASAN (azathioprine)
allopurinol 100 mg, 300 mg tablet	allopurinol 200 mg tablet
azathioprine 50 mg	azathioprine 75 mg, 100 mg tablet

	++febuxostat
	IMURAN (azathioprine)
	++ULORIC (febuxostat) TABLET
	ZYLOPRIM (allopurinol) TABLET

++Clinically Non-Preferred: In clinical trials, febuxostat had a higher incidence of thromboembolic cardiovascular events and hepatic abnormalities compared to allopurinol.

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months
The member must meet one of the following criteria:

- The member must have failed a 30-day trial of allopurinol, as evidenced by paid claims or pharmacy printouts.
- The member is HLA-B*5801 positive

Uricase

PREFERRED AGENTS (CLINICAL PA REQUIRED)
KRYSTEXXA (pegloticase) – *Medical Billing Only*

Prior Authorization Criteria

Initial Criteria - Approval Duration: 6 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a rheumatologist or nephrologist.
- The member must have failed a 3-month trial of two of the following, as evidenced by paid claims or pharmacy printouts:
  A. allopurinol
  B. febuxostat
  C. allopurinol or febuxostat in combination with probenecid
- The failure of previous trials must be documented by both of the following (A and B):
  A. A. Serum uric acid level ≥ 6 mg/dL within the past month
  B. One of the following (i, ii, or iii):
    i. At least 3 gout flares in the previous 18 months that were inadequately controlled.
    ii. At least 1 gouty tophus
    iii. Chronic gouty arthropathy/arthritis

Renewal Criteria - Approval Duration: 12 months

- The member is not experiencing infusion reactions.
- The member must have experienced and maintained clinical benefit since starting treatment with the requested medication, as evidenced by medical documentation (e.g., chart notes) attached to the request (subject to clinical review) including both of the following:
  - Serum uric acid level < 6 mg/dL within the past month
  - Decrease in gout flares or nonrevolving tophaceous deposits

Hereditary Angioedema (HAE)

Acute Attack

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
icatibant	BERINERT (plasma derived C1 Esterase Inhibitor)
	BERINERT (plasma derived C1 Esterase Inhibitor)

	– Medical Billing Only
	FIRAZYR (icatibant)
	KALBITOR (ecallantide) *– Medical Billing Only*
	RUCONEST (recombinant C1 Esterase Inhibitor)
	RUCONEST (recombinant C1 Esterase Inhibitor) *– Medical Billing Only*

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

- The requested medication must be prescribed by, or in consult with, an allergist/immunologist or rheumatologist.

Non-Preferred Agent Criteria:

- The member must have a contraindication to or failed a trial of all preferred agents, as evidenced by paid claims or pharmacy printouts.
  A. Berinert Only: The preferred agent trial may be bypassed for members who are pregnant, breastfeeding, or under 18 years old upon request.
  B. Ruconest Only: The member must have a contraindication to or failed a trial of Berinert, as evidenced by paid claims or pharmacy printouts.

Prophylaxis

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
HAEGARDA (plasma derived C1 Esterase Inhibitor)	CINRYZE (plasma derived C1 Esterase Inhibitor)
TAKHZYRO (lanadelumab-flyo)	ORLADEYO (berotrlastat)

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

- The requested medication must be prescribed by, or in consult with, an allergist/immunologist or rheumatologist.
- The member's weight and dose are provided.
- One of the following must be met (A, B, or C):
  A. The member has had at least 1 moderate to severe acute attack in the past 3 months (e.g., airway swelling, facial swelling, severe abdominal pain)
  B. The member is using short-term prophylaxis for one of the following:
    - a procedure related to pregnancy
    - oral cavity or invasive procedures
    - stressful life event at high risk for precipitating HAE attack (clinical justification subject to clinical review)
  C. Estrogen treatment is required, and member is at high risk for estrogen-precipitated HAE attack (clinical justification subject to clinical review)

Non-Preferred Agent Criteria:

- The member must have a contraindication to or failed a 3-month trial of all preferred agents with the same indication for use (prophylaxis or acute treatment), as evidenced by paid claims or pharmacy printouts.

Renewal Criteria – Approval Duration: 12 months

- The member must have experienced meaningful clinical benefit since starting treatment with the requested medication, as evidenced by at least a 50% reduction in the number of HAE attacks.

Quantity Override Request

- Takhyzro: The number of attacks in the last 6 months must be included if the requested dosing frequency is every 2 weeks (must be more than 0).

References

1. Busse, Paula J., et al. "US HAEA medical advisory board 2020 guidelines for the management of hereditary angioedema." *The Journal of Allergy and Clinical Immunology: In Practice* 9.1 (2021): 132-150.

Immune Globulins

IM

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
GAMASTAN (immune globul G (IgG)/glycine)	
GAMASTAN (immune globul G (IgG)/glycine) – *Medical Billing Only*	

IVIG

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
BIVIGAM (human immunoglobulin G)	ALYGLO (human immunoglobulin G - stwk)
BIVIGAM (human immunoglobulin G) – *Medical Billing Only*	ALYGLO (human immunoglobulin G - stwk) – *Medical Billing Only*
GAMMAGARD S-D (human immunoglobulin G)	ASCENIV (human immune globulin G- slra)
GAMMAPLEX (human immunoglobulin G)	ASCENIV (human immune globulin G- slra) – *Medical Billing Only*
GAMMAPLEX (human immunoglobulin G) – *Medical Billing Only*	PANZYGA (human immune globulin G- ifas)
OCTAGAM (human immunoglobulin G)	PANZYGA (human immune globulin G - ifas) – *Medical Billing Only*
OCTAGAM (human immunoglobulin G) – *Medical Billing Only*	
PRIVIGEN (human immunoglobulin G)	
PRIVIGEN (human immunoglobulin G) – *Medical Billing Only*	

IVIG/SCIG

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
GAMMAGARD LIQUID (human immunoglobulin gamma)	
GAMMAKED (human immunoglobulin gamma)	
GAMMAKED (human immunoglobulin gamma) – *Medical Billing Only*	
GAMUNEX-C (human immunoglobulin gamma)	
GAMUNEX-C (human immunoglobulin gamma) – *Medical Billing Only*	

SCIG

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
CUTAQUIG (human immune globulin G - hipp)	CUVITRU (human immunoglobulin gamma)

CUTAQUIG (human immune globulin G - hipp) – *Medical Billing Only*	CUVITRU (human immunoglobulin gamma) – *Medical Billing Only*
HIZENTRA (human immunoglobulin gamma)	HYQVIA (human immune globulin G and hyaluronidase)
HIZENTRA (human immunoglobulin gamma) – *Medical Billing Only*	HYQVIA (human immune globulin G and hyaluronidase) – *Medical Billing Only*
XEMBIFY (immune globulin,gamma(IgG)klhw)	
XEMBIFY (immune globulin,gamma(IgG)klhw) – *Medical Billing Only*	

Electronic Diagnosis and Quantity Verification

- For medical billing only: the following Local Coverage Determination applies to applicable preferred and non-preferred agents: Article - Billing and Coding: Immune Globulin Intravenous (IVIg) (A57187) (cms.gov)

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

- If the member's BMI > 30, adjusted body weight must be provided along with the calculated dose.
- The member must meet one of the following criteria:
  - The member must have failed a trial of each of the preferred products, as evidenced by paid claims or pharmacy printouts.
  - The member is stable on current therapy (have had a paid claim for requested therapy in the past 45 days)

Steroids – Nasal Spray

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
DYMISTA (azelastine-fluticasone) – *Brand Required*	azelastine-fluticasone
fluticasone	BECONASE AQ (beclomethasone)
mometasone – labeler 60605	flunisolide
OMNARIS (ciclesonide)	mometasone – labeler 65152
QNASL (beclomethasone)	QNASL CHILDREN (beclomethasone)
ZETONNA (ciclesonide)	RYALTRIS (olopatadine/mometasone)
	XHANCE (fluticasone)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must have failed a 30-day trial of each preferred agent, as evidenced by paid claims or pharmacy printouts.
- Xhance (fluticasone) Only: See Preferred Dosage Form Criteria

Cardiology

Therapeutic Duplication

- One Strength of one medication is allowed at a time
  A. Exceptions:
    - carvedilol IR 25 mg allowed with all other strengths
    - warfarin strengths are allowed together

    - prazosin strengths are allowed together
- Medication classes not payable together:
    - Entresto, ACE Inhibitors, ARBs, and Renin Inhibitors are not allowed with each other.
    - sildenafil, tadalafil, Adempas, nitrates are not allowed with each other.
    - carvedilol and labetalol are not allowed with other non-selective alpha blockers (Alfuzosin ER, doxazosin, prazosin, and terazosin)
        - carvedilol and labetalol are non-selective beta blockers with alpha 1 blocking activity
    - tizanidine is not allowed with other alpha 2 agonists (clonidine, clonidine/chlorthalidone, guanfacine, methyldopa)
        - tizanidine is also an alpha 2 agonist
    - clopidogrel is not covered with esomeprazole or omeprazole. Other PPIs such as pantoprazole are covered with clopidogrel.
        - clopidogrel is a substrate for 2C19 and esomeprazole and omeprazole are strong 2C19 inhibitors and can decrease effectiveness of clopidogrel.
    - clopidogrel, prasugrel, ticagrelor, and ticlopidine are not covered with morphine. Other opioid analgesics are covered with clopidogrel, prasugrel, ticagrelor, and ticlopidine.
        - Morphine may diminish the antiplatelet effect and serum concentrations of P2Y12 Inhibitor antiplatelet agents (clopidogrel, prasugrel, ticagrelor, and ticlopidine).

Alpha and/or Beta Blockers Therapeutic Duplication – Override Request

Overrides may be available for alpha and/or beta blockers for use within the cardiac or nephrology specialties if they have a difference in mechanism of action (e.g., non-selective or selective beta blocking activity, with or without alpha-1 blocker activity). Please request an override by calling provider relations at 1-800-755-2604.

- The prescribers of each medication must be aware of each other.
- The requested medications must be prescribed by, or in consult with, a cardiologist or nephrologist.

Anticoagulants

Anticoagulants - Direct Oral Anticoagulants (DOACs)

Solid oral dosage forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ELIQUIS (apixaban)	dabigatran capsule
PRADAXA (dabigatran) capsule – *Brand Required*	SAVAYSA (edoxaban)
XARELTO (rivaroxaban)	

Non-solid oral dosage forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
XARELTO (rivaroxaban) SUSPENSION	PRADAXA (dabigatran) PELLET

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must have failed a 30-day trial of each preferred agent and warfarin, as evidenced by paid claims or pharmacy printouts.

Reduction of Risk of Major Cardiovascular Events in Chronic CAD or PAD

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
XARELTO (rivaroxaban) 2.5 mg	

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- Xarelto 2.5 mg: The diagnosis must be provided with the request.

Anticoagulants - Injectables

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
enoxaparin	ARIXTRA (fondaparinux)
	fondaparinux – *No PA required for HIT diagnosis**
	FRAGMIN (dalteparin)
	LOVENOX (enoxaparin)

Electronic Diagnosis Verification

- Fondaparinux: Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale*

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must have failed a 30-day trial of enoxaparin, as evidenced by paid claims or pharmacy printouts.

Calcium Channel Blockers

Non-solid oral dosage forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
NORLIQVA (amlodipine) SOLUTION	KATERZIA (amlodipine) SUSPENSION
NYMALIZE (nimodipine) SOLUTION	

Electronic Diagnosis Verification

- Nymalize: Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale

Solid oral dosage forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
amlodipine	ADALAT CC (nifedipine)
CARTIA XR (diltiazem)	CALAN SR (verapamil)
diltiazem	CARDIZEM (diltiazem)
diltiazem ER	CARDIZEM CD (diltiazem)
DILT-XR (diltiazem)	levamlodipine
felodipine ER	nisoldipine ER 20 mg, 30 mg, 40 mg
isradipine	NORVASC (amlodipine)
MATZIM LA (diltiazem) ER	PROCARDIA XL (nifedipine)
nicardipine	SULAR ER (nisoldipine)
nifedipine	TIAZAC (diltiazem)
nifedipine ER	TIAZAC ER (diltiazem)
nimodipine	verapamil ER PM
nisoldipine ER 8.5 mg, 17 mg, 25.5 mg, 34 mg	VERELAN (verapamil)
TAZTIA XT (diltiazem)	VERELAN PM (verapamil)

TIADYLT ER (diltiazem)	
verapamil	
verapamil ER	

Prior Authorization Criteria

- Katerzia, Verapamil ER PM, Nisoldipine ER 20 mg, 30 mg, 40 mg, levamlopidine:
  - See Preferred Dosage Form criteria

Diuretics

Diuretics – Loop

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
furosemide	ethacrynic acid
bumetanide	
torsemide	

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- Ethacrynic acid: One of the following must be met:
  1. The member must have a documented sulfa allergy.
  2. The member must have failed a 30-day trial of each preferred agent, as evidenced by paid claims or pharmacy print outs.

Diuretics – Potassium Sparing / Sodium channel blocker

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
amiloride	triamterene

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must have failed a 30-day trial of each preferred agent of an unique ingredient, as evidenced by paid claims or pharmacy print outs.

Diuretics – Potassium Sparing / Aldosterone Antagonist

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
amiloride	ALDACTONE (spironolactone) TABLET
eplerenone	CAROSPIR (spironolactone) SUSPENSION
spironolactone suspension	INSPRA (eplerenone)
spironolactone tablet	

Heart Failure

Solid Dosage Forms

First Line Agents

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)

ACE (angiotensin-converting enzyme) inhibitors – *all oral agents preferred*	dapagliflozin
ARBs (angiotensin receptor blockers) – *all oral agents preferred*	INPEFA (sotagliflozin)
Beta blockers – *all oral agents preferred*	SAMSCA (tolvaptan)
Diuretics	tolvaptan
ENTRESTO (sacubitril/valsartan)	
FARXIGA (dapagliflozin) – *Brand Required*	
JARDIANCE (empagliflozin)	

Second Line Agents

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
CORLANOR (ivabradine)	
VERQUVO (vericiguat)	

Non-Solid Dosage Forms

First Line Agents

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
enalapril oral solution	ENTRESTO (sacubitril/valsartan) SPRINKLE
	EPANED (enalapril) SOLUTION

Electronic Diagnosis Verification

- Corlanor, Entresto, and Verquvo: Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale.

Electronic Duration Verification:

- tolvaptan is payable for 30 days every year.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- Corlanor Only:
  - The requested medication must be prescribed by, or in consult with, a cardiologist.
  - The member must have a resting HR ≥ 70 beats per minute on maximally tolerated or target beta blocker dose in sinus rhythm.
- Entresto Sprinkle
  - See Non-Solid Dosage Form criteria
  - The member has a diagnosis of heart failure with left ventricular ejection fraction of ≤ 45 %
  - The member has failed a 3-month trial of enalapril, as evidenced by paid claims or pharmacy printouts.
- Inpefa Only:
  - The requested medication must be prescribed by, or in consult with, a cardiologist or nephrologist.
  - The member is receiving concurrent Entresto, a beta-blocker, a SGLT-2 Inhibitor, and a mineralocorticoid receptor antagonist.
  - The member has been admitted to the hospital, a heart failure unit, infusion center, or emergency department for worsening heart failure within the past 3 months.

- Clinical justification must be provided explaining why the member is unable to use Farxiga and Jardiance (subject to clinical review)

- Tolvaptan Only:
  - The requested medication must be prescribed by, or in consult with, a cardiologist
  - The member is experiencing sodium levels less than 125 mEq/L despite a 30-day trial of an ACE inhibitor or ARB.
  - The member does not have liver disease.
- Verquvo Only:
  - The requested medication must be prescribed by, or in consult with, a cardiologist.
  - The member must have left ventricular ejection fraction (LVEF) < 45% at initiation.
  - The member must have had a hospitalization or need for IV diuretics within the past 3 months
  - The member is receiving concurrent Entresto, a beta-blocker, a SGLT-2 Inhibitor, and a mineralocorticoid receptor antagonist.

Hypertrophic Cardiomyopathy

CLINICAL PA REQUIRED
CAMZYOS (mavacamten)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The requested medication must be prescribed by, or in consult with, a cardiologist.
- The member must have all the following:
  - left ventricular ejection fraction (LVEF) ≥ 55%
  - NYHA class II or III
  - Resting oxygen saturation of ≥ 90%
  - Valsava left ventricular outflow tract (LVOT) gradient ≥ 50 mmHg at rest or with provocation.
- The member must have persistent symptoms despite maximally tolerated therapy with each of the following:
  - Non-dihydropyridine calcium channel blocker
  - beta blocker

Renewal Criteria – Approval Duration: 12 months

- The member has one of the following:
  - an improved pVO_2 by ≥ 1.5 mL/kg/min plus improvement in NYHA class by at least 1
  - an improvement of pVO_2 by ≥ 3 mL/kg/min and no worsening in NYHA class.
  - NYHA class I or II without exertion-induced syncope
  - Valsalva LVOT gradient < 50 mmHg at rest or with provocation.

References

1. Olivotto, Iacopo, et al. "Mavacamten for treatment of symptomatic obstructive hypertrophic cardiomyopathy (EXPLORER-HCM): a randomised, double-blind, placebo-controlled, phase 3 trial." The Lancet 396.10253 (2020): 759-769.
2. Desai, Milind Y., et al. “Mavacamten in patients with hypertrophic cardiomyopathy referred for septal reduction: week 56 results From the VALOR-HCM randomized clinical trial.” JAMA cardiology 8.10 (2023): 968-977.

Inappropriate Sinus Tachycardia

CLINICAL PA REQUIRED
CORLANOR (ivabradine)

Electronic Diagnosis Verification

- Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The diagnosis must be provided on the request.

Lipid-Lowering Agents

ACL (ATP Citrate Lyase) Inhibitors

PREFERRED AGENTS (ELECTRONIC STEP REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
NEXLETOL (bempedioc acid)	
NEXLIZET (bempedoic acid and ezetimibe)	

Electronic Step Therapy Required

- Nexletol or Nexlizet:
  - PA Not Required Criteria: A total of 90-day supply of rosuvastatin or atorvastatin has been paid within 120 days prior to Nexletol or Nexlizet's date of service.
  - PA Required Criteria: The member must have failed a 90-day trial of rosuvastatin or atorvastatin, as evidenced by paid claims or pharmacy printouts.

Cholesterol Absorption Inhibitor – 2-Azetidinone

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ezetimibe	ZETIA (ezetimibe)

Eicosapentaenoic acid (ESA) Ethyl Ester

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
VASCEPA (icosapent ethyl) – *Brand Required*	icosapent ethyl

Fenofibrate

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
fenofibrate, micronized 43 mg, 67 mg, 134 mg, 200mg	ANTARA (fenofibrate, micronized)
fenofibrate, nanocrystallized	fenofibrate capsules 50 mg, 150 mg
fenofibrate tablets 54 mg, 160 mg	fenofibrate, micronized 90 mg, 130 mg
fenofibric acid DR 45 mg, 135 mg	fenofibrate tablets 40 mg, 120 mg
	fenofibric acid 105 mg
	FENOGLIDE (fenofibrate)
	LIPOFEN (fenofibrate)
	TRICOR (fenofibrate, nanocrystalized)
	TRIGLIDE (fenofibrate)
	TRILIPIX (fenofibric acid)

Prior Authorization Criteria

- See Preferred Dosage Form criteria

MTP (Microsomal Triglyceride Transfer Protein) Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	JUXTAPID (lomitapide)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 3 months

- Clinical justification must be provided explaining why the member is unable to use all other products to lower their cholesterol (subject to clinical review)

PCSK9 (Proprotien Convertase Subtilisin/Kexin Type 9) Inhibitors

PREFERRED AGENTS (ELECTRONIC STEP REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
REPATHA PUSHTRONEX (evolocumab)	PRALUENT PEN (alirocumab)
REPATHA SURECLICK (evolocumab)	
REPATHA SYRINGE (evolocumab)	

Underutilization

- Praluent and Repatha must be used adherently and will reject on point of sale for late fill.

Electronic Step Therapy Required

- Repatha:
  - PA Not Required Criteria: A total of 90-day supply of rosuvastatin or atorvastatin has been paid within 120 days prior to Repatha's date of service.
  - PA Required Criteria: The member must have failed a 90-day trial of rosuvastatin or atorvastatin, as evidenced by paid claims or pharmacy printouts.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- The member must have failed a 90-day trial of the preferred PCSK9 inhibitor agent, as evidenced by paid claims or pharmacy printouts

Renewal Criteria – Approval Duration: 12 months

- The member has an LDL-C level less than 100 mg/dL or has achieved a 40% reduction.

Statins (HMG-CoA (3-hydroxy-3-methylglutaryl-CoA Reductase Inhibitors))

Solid Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
atorvastatin	ALTROPREV (lovastatin)
CADUET (amlodipine/atorvastatin) – *Brand Required*	amlodipine/atorvastatin
ezetimibe/simvastatin	CRESTOR (rosuvastatin)
fluvastatin	fluvastatin ER
lovastatin	LESCOL XL (fluvastatin ER)
pravastatin	LIPITOR (atorvastatin)
rosuvastatin	LIVALO (pitavastatin)
simvastatin	pitavastatin
	PRAVACHOL (pravastatin)

	VYTORIN (ezetimibe/simvastatin)
	ZOCOR (simvastatin)
	ZYPITAMAG (pitavastatin)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- Pitavastatin Only –
  - One of the following criteria must be met:
    - The member is receiving treatment with anti-retroviral therapy for HIV
    - The member is receiving treatment with a strong CYP3A4 inhibitor and is experiencing muscle toxicity despite 90-day trials with fluvastatin, rosuvastatin, and pravastatin.
- All other agents: See Preferred Dosage Form criteria

Non-Solid Dosage Forms

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
EZALLOR SPRINKLE (rosuvastatin)	ATORVALIQ (atorvastatin) SOLUTION

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- See Non-Solid Dosage Form criteria

Non-Preferred Agent Criteria

- The member has an LDL-C level greater than 100 mg/dL despite a 90-day trial with Ezallor Sprinkle.

Renewal Criteria – Approval Duration: 12 months

- The member has an LDL-C level less than 100 mg/dL or has achieved a 40% reduction.

Angiopoietin-like 3 (ANGPTL3) Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	EVKEEZA (evinacumab-dgnb) – *Medical Billing Only*

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a cardiologist, endocrinologist, or lipid specialist.
- Documentation of one of the following must be provided:
  - Genetic testing confirming two mutant alleles at the low-density lipoprotein receptor (LDLR), apolipoprotein B (apo B), proprotein convertase subtilisin kexin type 9 (PCSK9) or low-density lipoprotein receptor adaptor protein 1 (LDLRAP1) gene locus
  - Untreated total cholesterol of > 500 mg/dL with one of the following:
    - Cutaneous or tendon xanthoma before age 10 years
    - Evidence of total cholesterol > 250 in both parents
  - Low-density lipoprotein cholesterol (LDL-C) level greater than 100 mg/dL after a 90-day trial of each of the following, as evidenced by paid claims or pharmacy printouts or clinical justification as to why a treatment is unable to be used (subject to clinical review):

- PCSK9 inhibitor and ezetimibe combined with rosuvastatin ≥20 mg or atorvastatin ≥ 40 mg
- Bempedoic acid and ezetimibe combined with rosuvastatin ≥20 mg or atorvastatin ≥ 40 mg

Renewal Criteria – Approval Duration: 12 months

- The member has an LDL-C level less than 100 mg/dL or has achieved a 40% reduction.

siRNA (small interfering RNA) therapy

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	LEQVIO (inclisiran) – *Medical Billing Only*

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- The member must have failed a 90-day trial of both of the following, as evidenced by paid claims or pharmacy printouts:
  - PCSK9 inhibitor combined with rosuvastatin ≥20 mg or atorvastatin ≥ 40 mg
  - Bempedoic acid and ezetimibe combined with rosuvastatin ≥20 mg or atorvastatin ≥ 40 mg

Renewal Criteria – Approval Duration: 12 months

- The member has an LDL-C level less than 100 mg/dL or has achieved a 40% reduction.
- The member must currently be receiving a maximally tolerated statin (HMG-CoA reductase inhibitor) agent, as evidenced by paid claims or pharmacy printouts.

Platelet Aggregation Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
aspirin	clopidogrel 300 mg
aspirin/dipyridamole ER	EFFIENT (prasugrel)
BRILINTA (ticagrelor)	PLAVIX (clopidogrel)
clopidogrel 75 mg	ZONTIVITY (vorapaxar)
dipyridamole	
prasugrel	

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must have failed 30-day trials of at least 3 preferred platelet aggregation inhibitor agents, as evidenced by paid claims or pharmacy printouts.

Pulmonary Hypertension

Activin Signaling Inhibitor

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
WINREVAIR (sotatercept-csrk)	

Electronic Diagnosis Verification

- Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- The requested medication must be prescribed by, or in consult with, a pulmonologist or cardiologist.
- The member must currently be on a dual therapy combination regimen.

Renewal Criteria – Approval Duration: 12 months

- Documentation of a therapeutic response as evidenced by stabilization or improvement from baseline in each of the following:
  - 6MWT (≤ 15% decline)
  - WHO functional class

Endothelin Receptor Antagonists

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ambrisentan	LETAIRIS (ambrisentan)
bosentan	OPSUMIT (macitentan)
TRACLEER (bosentan) SUSPENSION	OPSYNVI (macitentan/tadalafil)
	TRACLEER (bosentan) TABLETS

Electronic Diagnosis Verification

- Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must have failed a 30-day trial of ambrisentan, as evidenced by paid claims or pharmacy printouts.

PDE-5 Inhibitors

Solid Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ALYQ (tadalafil)	ADCIRCA (tadalafil) TABLET
sildenafil tablet	OPSYNVI (macitentan/tadalafil)
tadalafil tablet	REVATIO (sildenafil) TABLET

Non-Solid Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
sildenafil suspension – all other labelers	LIQREV (sildenafil) SUSPENSION
	REVATIO (sildenafil) SUSPENSION
	sildenafil suspension – labeler 59762
	TADLIQ (tadalafil) SUSPENSION

Electronic Age Verification

- Sildenafil/tadalafil: Prior authorization is not required for ages less than 18 years old.
- Sildenafil suspension: Prior authorization is not required for ages less than 9 years old.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The request must include medical documentation (i.e., clinical notes) to verify diagnosis.

Non-Preferred Agents Criteria

- The member must have failed a 30-day trial of a preferred product, as evidenced by paid claims or pharmacy printouts.
- Liqrev Only: See Preferred Dosage Form criteria

Prostacyclins

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
epoprostenol	
FLOLAN (epoprostenol)	
ORENITRAM ER (treprostinil) TABLET	
REMODULIN (treprostinil) INJECTION – *Brand Co-Preferred*	
treprostinil injection – *Generic Co-Preferred*	
TYVASO (treprostinil) DPI	
TYVASO (treprostinil) INHALATION	
UPTRAVI (selexipag) TABLET	
UPTRAVI (selexipag) VIAL	
VELETRI (epoprostenol)	
VENTAVIS (iloprost) INHALATION	

Electronic Diagnosis Verification

- Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale.

Soluble Guanylate Cyclase Stimulators

NO PA REQUIRED
ADEMPAS (riociguat)

Electronic Diagnosis Verification

- Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale.

References:

1. Humbert, Marc, et al. "2022 ESC/ERS Guidelines for the diagnosis and treatment of pulmonary hypertension: Developed by the task force for the diagnosis and treatment of pulmonary hypertension of the European Society of Cardiology (ESC) and the European Respiratory Society (ERS). Endorsed by the International Society for Heart and Lung Transplantation (ISHLT) and the European Reference Network on rare respiratory diseases (ERN-LUNG)." *European heart journal* 43.38 (2022): 3618-3731.

Reduction of Major Adverse Cardiovascular Events (MACE)

Oral Agents

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
See Lipid-Lowering Agents	
See Platelet Aggregation Inhibitors	

Injectable Agents

PCSK9 (Proprotien Convertase Subtilisin/Kexin Type 9) Inhibitors

PREFERRED AGENTS (ELECTRONIC STEP REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
PRALUENT PEN (alirocumab)	

REPATHA PUSHTRONEX (evolocumab)	
REPATHA SURECLICK (evolocumab)	
REPATHA SYRINGE (evolocumab)	

Electronic Step Therapy Required

- Praluent and Repatha:
  - PA Not Required Criteria: A total of 90-day supply of rosuvastatin or atorvastatin has been paid within 120 days prior to Praluent and Repatha's date of service.
  - PA Required Criteria: The member must have failed a 90-day trial of rosuvastatin or atorvastatin, as evidenced by paid claims or pharmacy printouts.

GLP-1 Agonists

CLINICAL PA REQUIRED
WEGOVY (semaglutide)

Prior Authorization Criteria

For reduction of MACE in members with diabetes, please see diabetes category for criteria on indicated agents.

Initial Criteria – Approval Duration: 12 months

- The member is ages of ≥ 55 and < 75.
- The member does not have diabetes, as evidenced by A1c within normal range without diabetes medication.
- The member has an initial BMI of ≥ 27 kg/m^2 and < 35 kg/m^2
- The member has one of the following:
  - Prior myocardial infarction (MI)
  - Prior stroke and peripheral arterial disease (PAD), as evidenced by intermittent claudication with ankle-brachial index < 0.85, peripheral arterial revascularization procure, or amputation due to atherosclerotic disease.
- The member is concurrently taking lipid-lowering and antiplatelet therapy
- If the member is a current tobacco user, the member must have received tobacco cessation counseling in the past year
- If the member qualifies for Wegovy, a dose escalation to 2mg of Ozempic (semaglutide) must be tolerated before Wegovy will be authorized (2.4mg is the only strength indicated for reduction of MACE)

Dermatology

Acne

Electronic Age Verification

- The member must be between 12 and 35 years of age for treatment of diagnosis of acne.

Adapalene

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
adapalene cream	CABTREO (adapalene/benzoyl peroxide/clindamycin) 1.2%-0.15%-3.15% GEL
adapalene gel	

adapalene gel with pump	
adapalene/benzoyl peroxide 0.1%-2.5%	
adapalene/benzoyl peroxide 0.3%-2.5%	

Therapeutic Duplication

- One strength of one benzoyl peroxide containing medication is allowed at a time.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- See Preferred Dosage Form criteria

Androgen Receptor Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	WINLEVI (clascoterone) CREAM

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must have failed a 3-month trial of each of the following, as evidenced by paid claims or pharmacy printouts:
  - Topical antibiotics (erythromycin, clindamycin, minocycline, or dapsone) in combination with benzoyl peroxide
  - Topical retinoids in combination with benzoyl peroxide

Clindamycin

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
clindamycin capsule	CLEOCIN T (clindamycin) GEL
clindamycin gel	CLEOCIN T (clindamycin) LOTION
clindamycin lotion	CLEOCIN T (clindamycin) PLEDGETS
	CLINDACIN (clindamycin) FOAM
clindamycin solution	CLINDACIN P (clindamycin) PLEDGETS
ZIANA (clindamycin-tretinoin 1.2%-0.025%) – *Brand Required*	CLINDACIN ETZ (clindamycin) PLEDGETS
	CLINDAGEL (clindamycin) GEL DAILY
	clindamycin gel daily
	clindamycin foam
	clindamycin pledgets
	clindamycin-tretinoin 1.2%-0.025%
	EVOCLIN (clindamycin) FOAM

Clindamycin-Benzoyl Peroxide

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
clindamycin-benzoyl peroxide 1.2%-2.5%	ACANYA (clindamycin-benzoyl peroxide) 1.2%-2.5%
clindamycin-benzoyl peroxide 1%-5% with pump	BENZACLIN (clindamycin/benzoyl peroxide without pump) 1%-5%
clindamycin-benzyl peroxide 1.2%-5%	BENZACLIN (clindamycin/benzoyl peroxide with pump) 1%-5%

clindamycin/benzoyl peroxide 1%-5% without pump	CABTREO (adapalene/benzoyl peroxide/clindamycin) 1.2%-0.15%-3.15% GEL
ONEXTON (clindamycin/benzoyl peroxide) 1.2%-3.75% - *Brand Required*	clindamycin/benzoyl peroxide 1.2%-3.75%
	NEUAC (clindamycin/benzoyl peroxide) 1.2%-5%

Therapeutic Duplication

- One strength of one benzoyl peroxide containing medication is allowed at a time.

Retinoid

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ALTRENO (tretinoin) LOTION	ATRALIN (tretinoin) 0.05% GEL
RENOVA WITHOUT PUMP (tretinoin/emollient base)	ARAZLO (tazarotene) 0.045% LOTION
RENOVA WITH PUMP (tretinoin/emollient base)	clindamycin-tretinoin 1.2%-0.025%
RETIN-A MICRO GEL PUMP (tretinoin microsphere) 0.04%, 0.1% - *Brand Required*	FABIOR (tazarotene) 0.1% FOAM
RETIN-A MICRO (tretinoin microsphere) GEL WITHOUT PUMP – *Brand Required*	RETIN-A (tretinoin) CREAM
tazarotene 0.1% cream	RETIN-A (tretinoin) GEL
tretinoin cream	RETIN-A MICRO GEL PUMP (tretinoin microsphere) 0.06%, 0.08%
tretinoin gel	tazarotene 0.05% cream
ZIANA (clindamycin-tretinoin 1.2%-0.025%) – *Brand Required*	tazarotene 0.1% foam
	tazarotene gel
	tretinoin microsphere gel with pump 0.04%, 0.1%
	tretinoin microsphere gel without pump

Therapeutic Duplication

- One strength of one retinoid medication is allowed at a time.
- One strength of one benzoyl peroxide containing medication is allowed at a time.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- See Preferred Dosage Form criteria

Tetracyclines

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
doxycycline hyclate capsule	demeclocycline
doxycycline hyclate tablet 20 mg, 100 mg	DORYX (doxycycline hyclate) TABLET DR
doxycycline monohydrate 25 mg/5 mL suspension	DORYX MPC (doxycycline hyclate) TABLET DR
doxycycline monohydrate tablet 50 mg, 75 mg, 100 mg	doxycycline monohydrate capsule 75 mg, 150 mg
doxycycline monohydrate capsule 50 mg, 100 mg	doxycycline hyclate tablet 50 mg, 75 mg, 150 mg
minocycline capsule	doxycycline monohydrate tablet 150 mg
tetracycline	doxycycline hyclate tablet DR

	MINOCIN (minocycline) CAPSULE
	minocycline tablet
	minocycline tablet ER
	MINOLIRA ER (minocycline) TABLET
	MORGIDOX (doxycycline hyclate) CAPSULE

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- See Preferred Dosage Form criteria

Sulfonamide

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
BP 10-1 (sodium sulfacetamide/sulfur cleanser) 10%-1%	ACZONE (dapsone) GEL WITH PUMP 7.5%
BP CLEANSING WASH (sulfacetamide sodium/sulfur/urea) 10%-4%-10%	BP 10-1 (sulfacetamide sodium/sulfur) CLEANSER
dapsone gel pump 7.5%	KLARON (sulfacetamide sodium)
dapsone gel without pump 5%	SSS 10-5 (sulfacetamide) CLEANSER
sulfacetamide 10% cleansing gel	SSS 10-5 (sulfacetamide) FOAM
sulfacetamide 10% lotion	sodium sulfacetamide/sulfur pads 10%-4%
sulfacetamide 10% suspension	sodium sulfacetamide/sulfur cream 10%-2%
sulfacetamide 10% wash	SUMADAN (sodium sulfacetamide/sulfur) WASH 9%-4.5%
sodium sulfacetamide/sulfur cleanser 10%-5% (W/W)	SUMAXIN (sodium sulfacetamide/sulfur) WASH 9%-4%
sodium sulfacetamide/sulfur cleanser 9%-4%	SUMAXIN (sodium sulfacetamide/sulfur pads) PADS 10%-4%
sodium sulfacetamide/sulfur cleanser 9%-4.5%	SUMAXIN TS (sodium sulfacetamide/sulfur) SUSPENSION 8%-4%
sodium sulfacetamide/sulfur cleanser 9.8% -4.8%	ZMA CLEAR (sulfacetamide sodium/sulfur) SUSPENSION 9%-4.5%
sodium sulfacetamide/sulfur cleanser 10%-2%	
sodium sulfacetamide/sulfur cleanser 10%-5%-10%	
sodium sulfacetamide/sulfur cream 10%-5% (W/W)	
sodium sulfacetamide/sulfur suspension 8%-4%	
SUMAXIN (sodium sulfacetamide/sulfur) CLEANSER 9%-4%	

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- See Preferred Dosage Form criteria

Actinic Keratosis

Fluorouracil

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
CARAC (fluorouracil) 0.5% CREAM – *Brand Required*	EFUDEX (fluorouracil) 5% CREAM

fluorouracil 5% cream	fluorouracil 0.5% cream
fluorouracil 2% solution	
fluorouracil 5% solution	

Imiquimod

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
imiquimod 5% cream packet	imiquimod 3.75% cream packet
ZYCLARA (imiquimod) 3.75% CREAM PUMP – *Brand Required*	imiquimod 3.75% cream pump
	ZYCLARA (imiquimod) 3.75% CREAM PACKET
	ZYCLARA (imiquimod) 2.5% CREAM PUMP

Diclofenac

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
diclofenac 3% sodium gel	

Electronic Diagnosis Verification

- Diclofenac 3% sodium gel: Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must have failed a 6-month trial of each preferred agent of a unique active ingredient, as evidenced by paid claims or pharmacy printouts.
- If requested product has preferred option with same active ingredient, see Preferred Dosage Form criteria

Antifungals – Topical

Cream

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
butenafine cream	CICLODAN (ciclopirox) CREAM
ciclopirox cream	ERTACZO (sertraconazole) CREAM
clotrimazole cream	EXELDERM (sulconazole) CREAM
econazole cream	LOPROX (ciclopirox) CREAM
ketoconazole cream	luliconazole cream
miconazole cream	LUZU (luliconazole) CREAM
NAFTIN (naftifine) CREAM	MENTAX (butenafine) CREAM
nystatin cream	naftifine cream
nystatin – triamcinolone cream	oxiconazole cream
	sulconazole cream

Foam

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
EXTINA (ketoconazole) FOAM – *Brand Required*	KETODAN (ketoconazole) FOAM
	ketoconazole foam

Gel

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ciclopirox gel	NAFTIN (naftifine) GEL

Lotion

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	OXISTAT (oxiconazole) LOTION

Ointment

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ALEVAZOL (clotrimazole) OINTMENT	miconazole/zinc oxide/white petrolatum ointment
nystatin ointment	
nystatin – triamcinolone ointment	
VUSION (miconazole/zinc/white petrolatum) OINTMENT – *Brand Required*	

Powder

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
KLAYESTA (nystatin) POWDER	
nystatin powder	
NYAMYC (nystatin) POWDER	
NYSTOP (nystatin) POWDER	

Shampoo

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ciclopirox shampoo	LOPROX (ciclopirox) SHAMPOO
ketoconazole shampoo	

Solution

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ciclopirox solution	CICLODAN (ciclopirox) SOLUTION
clotrimazole solution	EXELDERM (sulconazole) SOLUTION
	JUBLIA (efinaconazole) SOLUTION
	KERYDIN (tavaborole) SOLUTION
	tavaborole solution

Suspension

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ciclopirox suspension	LOPROX (ciclopirox) SUSPENSION

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- Onychomycosis Only:
  - Diagnosis must be confirmed by potassium hydroxide (KOH) preparation.
  - The member must have had a trial of one oral agent (terbinafine, fluconazole, or itraconazole), for the length of recommended treatment time for member's particular infection, as evidenced by paid claims or pharmacy printouts.

- Adequate time must have passed since treatment cessation to accurately assess healthy toenail outgrow (at least 6 months)
- One of the following must be met (A or B):
  - Preferred Dosage Form Criteria
  - The active ingredient of the requested product is not available in a preferred formulation.

- Other Diagnoses:
  - The member must have failed a trial of 3 preferred agents, for the length of recommended treatment time for member's particular infection, as evidenced by paid claims or pharmacy printouts.
  - One of the following must be met (A or B):
    - Preferred Dosage Form Criteria
    - The active ingredient of the requested product is not available in a preferred formulation.

Eczema / Atopic Dermatitis

Oral

First Line Agents

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
azathioprine 50 mg	azathioprine 75 mg
cyclosporine	azathioprine 100 mg
methotrexate	
systemic oral corticosteroids	

Prior Authorization Criteria

- Azathioprine: See Preferred Dosage Forms Criteria – Use enough 50 mg to make correct dosage

Topical

Calcineurin Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
tacrolimus 0.03%	ELIDEL (pimecrolimus) CREAM
tacrolimus 0.1%	pimecrolimus

Janus Kinase (JAK) inhibitor

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
OPZELURA (ruxolitinib) 1.5% CREAM	

Phosphodiesterase 4 (PDE-4) inhibitor

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
EUCRISA (crisaborole) OINTMENT	ZORYVE (roflumilast) 0.15% CREAM

Topical Corticosteroids

Please see the Preferred Drug List of Topical Corticosteroids

Systemic

Interleukin (IL)-4/13 Inhibitor

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
DUPIXENT (dupilumab) INJECTION	

Interleukin (IL)-13 Inhibitor

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ADBRY (tralokinumab-idrm) INJECTION	
EBGLYSS (lebrikizumab-lbkz) INJECTION	

Janus Kinase (JAK) inhibitor

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
CIBINQO (abrocitinib) TABLET	
OLUMIANT (baricitinib) TABLET	
RINVOQ ER (upadacitinib) TABLET	

Electronic Age Verification

- Tacrolimus ointment 0.1%: The member must be 16 years of age or older.

Electronic Diagnosis Verification

- Zoryve: Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale.

Prior Authorization Criteria

Prior Authorization Form – Atopic Dermatitis

Initial Criteria – Approval Duration: 3 months

- The member must have failed a 6-week trial of tacrolimus or pimecrolimus as evidenced by paid claims or pharmacy printouts:
- One of the following must be met:
  - The member has failed a two 2-week trials of topical corticosteroids of medium or higher potency, as evidenced by paid claims or pharmacy printouts.
    OR
  - The member meets both of the following (1 AND 2):
    1. Affected area is on face, groin, axilla, or under occlusion.
    2. Member must have failed two 2-week trials of topical corticosteroids of low or higher potency, as evidenced by paid claims or pharmacy printouts.

Zoryve Only:

- The member must have had a 28-day trial with Eucrisa, as evidenced by paid claims or pharmacy printouts

Epidermolysis Bullosa

PREFERRED AGENTS (CLINICAL PA REQUIRED)
FILSUVEZ (birch triterpenes)
VYJUVEK (beremagene geperpavec-svdt) – *Medical Billing Only*

Initial Criteria - Approval Duration: 12 months

- The member has dystrophic epidermolysis bullosa.
- The requested medication must be prescribed by, or in consult with, a dermatologist or wound care specialist.
- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational).
- As applicable, documentation must be attached to confirm serum marker or pathogenic gene variants amenable to treatment.
- Documentation of the baseline symptoms (e.g., extensive skin blistering, number and size of wounds) that can be utilized for comparison to show member has experienced clinical benefit upon renewal has been submitted with request.

Hidradenitis Suppurativa

TNF Inhibitors

Adalimumab

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
adalimumab-adaz	ABRILADA (adalimumab-afzb)
adalimumab-adbm – labeler 00597	adalimumab-aacf
CYLTEZO (adalimumab-abdm)	adalimumab-aaty
HUMIRA (adalimumab)	adalimumab-adbm – labeler 82009
SIMLANDI (adalimumab-ryvk)	adalimumab-fkjp
YUSIMRY (adalimumab-aqvh)	adalimumab-ryvk
	AMJEVITA (adalimumab-atto)
	HADLIMA (adalimumab-bwwd)
	HULIO (adalimumab-fkjp)
	HYRIMOZ (adalimumab-adaz)
	IDACIO (adalimumab-aacf)
	YUFLYMA (adalimumab-aaty)

Interleukin (IL) – 17 Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	COSENTYX (secukinumab)
	COSENTYX (secukinumab) – *Medical Billing Only*

Electronic Diagnosis Verification

- Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- Cosentyx and Simponi Aria Only: The member must have failed a 90-day trial of a TNF inhibitor, as evidenced by paid claims or pharmacy printouts.
- Other agents: See Preferred Dosage Form criteria

Infantile Hemangioma

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
propranolol oral solution	HEMANGEOL (propranolol) ORAL SOLUTION
	timolol gel forming solution (used topically)

Electronic Age Verification

- Hemangeol: The patient must be less than 1 years of age.

Electronic Diagnosis Verification

- Hemangeol: Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must have failed a 6-month trial of the preferred agent, as evidenced by paid claims or pharmacy printouts.
- Hemangeol Only:
  - The member must have failed a 6-month trial of timolol gel forming solution, as evidenced by paid claims or pharmacy printouts.

Molluscum Contagiosum

PREFERRED AGENTS (CLINICAL PA REQUIRED)
ZELSUVMI (berdazimer) GEL
YCANTH (cantharidin) SOLUTION – *Medical Billing Only*

Initial Criteria - Approval Duration: 12 months

- The requested medication must be prescribed by, or in consult with, a dermatologist or pediatrician.
- One of the following must be present (1 or 2):
  - The member is immunocompromised.
  - The member is immunocompetent but experiences severe bleeding, intense itching, recurring infection, or severe pain for greater than 6 months.

Lice / Scabies

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
LICE KILLING SHAMPOO (piperonyl butoxide/pyrethrins)	CROTAN (crotamiton)
ivermectin	malathion
NATROBA (spinosad) – *Brand Required Only*	SKLICE (ivermectin)
permethrin 5% cream	spinosad
LICE TREATMENT (permethrin) 1% CRÈME RINSE LIQUID	
VANALICE (piperonyl butoxide/pyrethrins) GEL	

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- One of the following must be met:
  - The member must have failed a 28-day/2-application trial of each preferred agent, as evidenced by paid claims or pharmacy printouts.
  - There is a documented community breakout of a strain that is not susceptible to the preferred agents.

Plaque Psoriasis

Biologics

Interleukin (IL)-12/IL-23 Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	STELARA (ustekinumab)
	WEZLANA (ustekinumab-auub)

Interleukin (IL)-17A Inhibitor

PREFERRED AGENTS (ELECTRONIC STEP REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
TALTZ (ixekizumab)	COSENTYX (secukinumab)
	COSENTYX (secukinumab) – *Medical Billing Only*

Interleukin (IL)-17A and IL-17F inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	BIMZELX (bimekizumab-bkzx)

Interleukin (IL)-17 Receptor Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	SILIQ (brodalumab)

Interleukin (IL)-23p19 Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	ILUMYA (tildrakizumab-asmn) – *Medical Billing Only*
	SKYRIZI (risankizumab-rzaa)
	TREMFYA (guselkumab)

TNF Inhibitors

Adalimumab

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
adalimumab-adaz	ABRILADA (adalimumab-afzb)
adalimumab-adbm – labeler 00597	adalimumab-aacf
CYLTEZO (adalimumab-abdm)	adalimumab-aaty
HUMIRA (adalimumab)	adalimumab-adbm – labeler 82009
SIMLANDI (adalimumab-ryvk)	adalimumab-fkjp
YUSIMRY (adalimumab-aqvh)	adalimumab-ryvk
	AMJEVITA (adalimumab-atto)
	HADLIMA (adalimumab-bwwd)
	HULIO (adalimumab-fkjp)
	HYRIMOZ (adalimumab-adaz)
	IDACIO (adalimumab-aacf)
	YUFLYMA (adalimumab-aaty)

Infliximab

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AVSOLA (infliximab-axxq) – *Medical Billing Only*	INFLECTRA (infliximab-dyyb) – *Medical Billing Only*
RENFLEXIS (infliximab-abda) – *Medical Billing Only*	infliximab – *Medical Billing Only*
	REMICADE (infliximab) – *Medical Billing Only*

Other TNF

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ENBREL (etanercept)	CIMZIA (certolizumab) SYRINGE
	CIMZIA (certolizumab) VIAL – *Medical Billing Only*

Electronic Diagnosis Verification

- Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale.

Electronic Step Therapy Required

- Taltz:
  - PA Not Required Criteria: A total of 84-day supply of a TNF Inhibitor has been paid within 120 days prior to Taltz's date of service.
  - PA Required Criteria: The member must have failed a 3-month trial of a TNF inhibitor, as evidenced by paid claims or pharmacy printouts.

Prior Authorization

Initial Criteria – Approval Duration: 12 months

- The member must have failed a 3-month trial of a TNF inhibitor (adalimumab, certolizumab pegol or infliximab) and an Interleukin (IL)-17A Inhibitor, as evidenced by paid claims or pharmacy printouts.
- Stelara, and Wezlana Only: The member must have failed a 3-month trial of an TNF inhibitor (adalimumab, certolizumab pegol or infliximab), an Interleukin (IL)-17A Inhibitor, and Siliq, as evidenced by paid claims or pharmacy printouts.
- Remicade, infliximab, and Inflectra Only: See Biosimilar Agents criteria
- Medical billing only agents: In addition to above criteria, clinical justification must be provided why a self-administered agent cannot be used (subject to clinical review).

Oral

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
acitretin 10 mg, 25 mg	acitretin 17.5 mg
cyclosporine	OTEZLA (apremilast) 20 MG
methotrexate	SOTYKTU (deucravacitinib)
OTEZLA (apremilast) 30 MG	

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- Acitretin 17.5 mg Only: See Preferred Dosage Form criteria
- Otezla 20 mg Only:
  - The member must weigh ≥ 20 kg and < 50 kg

- The member must have failed a 3-month trial of adalimumab and an interleukin 17A inhibitor, as evidenced by paid claims or pharmacy printouts.

- Sotyktu Only: The member must have failed a trial of each of the following, as evidenced by paid claims or pharmacy printouts:
  - 30-day trial of Otezla
  - 3-month trial of an TNF inhibitor (adalimumab, certolizumab pegol or infliximab)

Topical

Foams, Gel, Solution, Suspension

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
calcipotriene solution	calcipotriene/betamethasone suspension
calcipotriene foam	SORILUX (calcipotriene) FOAM
ENSTILAR (calcipotriene/betamethasone) FOAM	tazarotene gel
TACLONEX (calcipotriene/betamethasone) SUSPENSION – *Brand Required*	

Cream, Lotion

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
calcipotriene cream	DUOBRII (halobetasol/tazarotene) LOTION
	tazarotene cream
	VTAMA (tapinarof) 1% CREAM
	ZORYVE (roflumilast) 0.3% CREAM

Ointment

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
calcipotriene ointment	calcitriol ointment
calcipotriene/betamethasone ointment	

Electronic Diagnosis Verification

- Zoryve: Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must have failed a 30-day trial of each preferred agent of a unique active ingredient(s) within same route/dosage form category, as evidenced by paid claims or pharmacy printouts.
- Zoryve Only:
  - The member has had a 30-day trial of each of the following, as evidenced by paid claims or pharmacy printouts.
    - calcipotriene/betamethasone
    - halobetasol/tazarotene combination
- Vtama Only:
  - The member has had a 30-day trial of each of the following, as evidenced by paid claims or pharmacy printouts.
    - calcipotriene/betamethasone
    - halobetasol/tazarotene combination
  - The member has had a 2-month trial of Zoryve, as evidenced by paid claims or pharmacy printouts.

Prurigo Nodularis

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
DUPIXENT (dupilumab)	NEMLUVIO (nemolizumab-ilto)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- The requested medication must be prescribed by, or in consult with, a dermatologist.
- The member is experiencing nodular lesions that produce itch for greater than 6 weeks that has significantly diminished quality of life, including sleep disturbances.
- The member has failed a 2-week trial of a topical corticosteroid of at least high potency, as evidenced by paid claims or pharmacy printouts.

Non-Preferred Agent Criteria

- The member must have failed a 3-month trial of Dupixent, as evidenced by paid claims or pharmacy printouts.

Seborrheic Dermatitis

See Antifungals – Topical
See Steroids – Topical

Topical Phosphodiesterase-4 (PDE-4) Inhibitors

CLINICAL PA REQUIRED
ZORYVE (roflumilast) FOAM

Electronic Diagnosis Verification

- Zoryve: Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- The member must have had a 4-week trial of concurrent use of a topical antifungal (shampoo or foam) AND a high potency topical corticosteroid (foam, spray or shampoo).

Steroids – Topical

Super-High Potency (Group 1)

Dosage Form	PREFERRED AGENTS (NO PA REQUIRED)		NON-PREFERRED AGENTS (PA REQUIRED)	
Cream	clobetasol emollient	0.05%		
	clobetasol propionate	0.05%		
	fluocinonide	0.10%		
	halobetasol propionate	0.05%		
Lotion	betamethasone dipropionate, augmented	0.05%	IMPEKLO (clobetasol)	0.05%
	clobetasol propionate	0.05%	ULTRAVATE (halobetasol) MDP	0.05%

Ointment	betamethasone dipropionate, augmented	0.05%		
	clobetasol propionate	0.05%		
	clobetasol propionate foam	0.05%		
	halobetasol propionate	0.05%		
Foam, Gel, Shampoo, Solution, Spray	clobetasol propionate shampoo	0.05%	betamethasone dipropionate, augmented gel	0.05%
	clobetasol propionate solution	0.05%	clobetasol emulsion foam	0.05%
	clobetasol propionate spray	0.05%	STEP 2* halobetasol propionate foam	0.05%
	clobetasol propionate gel	0.05%		

Electronic Diagnosis Verification

- Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale.

Electronic Duration Verification

Group 1 topical steroids are covered for 30 days every 90 days. Group 1 steroids are covered with group 2 steroids to facilitate an alternating schedule.

- If the following conditions apply, please call for an override by calling provider relations at 1-800-755-2604:
  Approval: 1 year
  A. Location of application: palms, soles, or psoriatic crusts
  B. Indication: psoriasis
  C. Close monitoring for side effects

Reference:
Joint AAD-NFP guidelines for management and treatment of psoriasis recommend limiting the use of Group 1 topical steroids to no more than twice daily up to 4 weeks. Transitions to lower potent agents, intermittent therapy, and combination treatment with non-steroids are recommended to minimize side effects.

High Potency (Group 2)

Dosage Form	PREFERRED AGENTS (NO PA REQUIRED)		NON-PREFERRED AGENTS (PA REQUIRED)	
Cream	betamethasone dipropionate, augmented	0.05%	APEXICON E (diflorasone emollient)	0.05%
	desoximetasone	0.25%		
	fluocinonide	0.05%		
	HALOG (halcinonide)– *Brand Required*	0.10%		
Lotion			BRYHALI (halobetasol) LOTION	0.01%
Ointment	betamethasone dipropionate	0.05%	diflorasone diacetate	0.05%
	desoximetasone	0.25%		
	fluocinonide	0.05%		
	fluticasone propionate	0.01%		
	HALOG (halcinonide)	0.10%		
Gel, Solution, Spray	desoximetasone spray	0.25%	desoximetasone gel	0.05%
	fluocinonide gel	0.05%	HALOG (halcinonide) SOLUTION	0.10%
	fluocinonide solution	0.05%		

High Potency (Group 3)

Dosage Form	PREFERRED AGENTS (NO PA REQUIRED)		NON-PREFERRED AGENTS (PA REQUIRED)	
Cream	betamethasone dipropionate	0.05%	STEP2*amcinonide	0.10%
	triamcinolone acetonide	0.50%	desoximetasone	0.05%
			STEP2*diflorasone diacetate	0.05%
			fluocinonide-E	0.05%
Lotion			amcinonide	0.10%
Ointment	betamethasone valerate	0.10%	desoximetasone	0.05%
	fluticasone propionate	0.01%		
	mometasone furoate	0.10%		
	triamcinolone acetonide	0.50%		
Foam	betamethasone valerate foam	0.12%		

Medium Potency (Group 4)

Dosage Form	PREFERRED AGENTS (NO PA REQUIRED)		NON-PREFERRED AGENTS (PA REQUIRED)	
Cream	clocortolone pivalate	0.10%	PANDEL (hydrocortisone probutate)	0.1%
	fluticasone propionate	0.05%		
	mometasone furoate	0.10%		
	triamcinolone acetonide	0.10%		
Ointment	fluocinolone acetonide	0.025%	hydrocortisone valerate	0.20%
	triamcinolone acetonide	0.10%	STEP2*flurandrenolide	0.05%
	triamcinolone acetonide	0.05%		
Aerosol, Paste Solution	mometasone furoate solution	0.10%	triamcinolone acetonide aerosol	0.147 MG/G
	triamcinolone acetonide paste	0.10%		

Lower-Mid Potency (Group 5)

Dosage Form	PREFERRED AGENTS (NO PA REQUIRED)		NON-PREFERRED AGENTS (PA REQUIRED)	
Cream	betamethasone valerate	0.10%	fluocinolone acetonide	0.025%
	hydrocortisone valerate	0.20%	prednicarbate	0.10%
			STEP2*flurandrenolide	0.05%
			hydrocortisone butyrate	0.10%
			hydrocortisone butyrate emollient	0.10%
Lotion	betamethasone dipropionate	0.05%	STEP2*flurandrenolide	0.05%
	LOCOID (hydrocortisone butyrate) *– Brand Required*	0.10%	fluticasone propionate	0.05%
	triamcinolone acetonide	0.10%		
Ointment	desonide	0.05%	hydrocortisone butyrate	0.10%
	triamcinolone acetonide	0.025%	prednicarbate	0.10%

Gel, Solution	hydrocortisone butyrate solution	0.10%	desonide gel	0.05%

Low Potency (Group 6)

Dosage Form	PREFERRED AGENTS (NO PA REQUIRED)		NON-PREFERRED AGENTS (PA REQUIRED)	
Cream	alclometasone dipropionate	0.05%	fluocinolone acetonide	0.01%
	desonide	0.05%		
	triamcinolone acetonide	0.03%		
Lotion	betamethasone valerate lotion	0.10%		
	desonide lotion	0.05%		
	triamcinolone acetonide lotion	0.025%		
Ointment	alclometasone dipropionate	0.05%		
Oil, Solution	fluocinolone acetonide oil	0.01%		
	fluocinolone acetonide solution	0.01%		

Least Potent (Group 7)

Dosage Form	PREFERRED AGENTS (NO PA REQUIRED)		NON-PREFERRED AGENTS (PA REQUIRED)	
Cream	hydrocortisone	1.00%		
	hydrocortisone	2.50%		
Lotion	hydrocortisone	2.50%		
Ointment	hydrocortisone	1.00%		
	hydrocortisone	2.50%		
Solution			TEXACORT (hydrocortisone) SOLUTION	2.50%

Prior Authorization

Initial Criteria – Approval Duration: 12 months

- The member must have failed a 2-week trial of all preferred drug entities within the same potency category and dosage form group within the last 3 months, as evidenced by paid claims or pharmacy printouts.

Agents labeled as "STEP 2"

- The member must have failed a 2-week trial of all preferred and non-preferred drug entities not labeled "STEP 2" within the same potency category and dosage form group within the last 3 months.

Endocrinology

Androgens

Injectable

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
testosterone cypionate injection	AVEED (testosterone undecanoate)
testosterone enanthate injection	AVEED (testosterone undecanoate) *– Medical Billing Only*
	DEPO-TESTOSTERONE (testosterone cypionate)

	XYOSTED (testosterone enanthate)

Oral

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
JATENZO (testosterone undecanoate)	methyltestosterone
TLANDO (testosterone undecanoate)	METHITEST (methyltestosterone)

Topical

Gel Packet

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
testosterone 1% (50mg/5g) gel packet	ANDROGEL (testosterone) GEL PACKET
testosterone 1% (25mg/2.5g) gel packet	testosterone 1.62% (20.25mg/1.25g) gel packet
	testosterone 1.62% (40.5mg/2.5g) gel packet
	VOGELXO (testosterone) GEL PACKET

Gel Pump

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ANDROGEL (testosterone) GEL MD PUMP – *Brand Co-Preferred*	testosterone 2% (10mg/0.5g) gel MD PMP bottle
FORTESTA (testosterone) 2% (10mg/0.5g) GEL MD PMP – *Brand Required*	VOGELXO (testosterone) GEL PMP
testosterone 1% (12.5mg/1.25g) gel MD PMP bottle	
testosterone 1.62% (20.25mg/1.25g) gel MD PMP bottle	
testosterone 2% (30mg/1.5g) solution MD PMP	

Gel Tube

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
TESTIM (testosterone) GEL TUBE – *Brand Co-Preferred*	VOGELXO (testosterone) GEL TUBE
testosterone 1% (50mg/5g) gel tube	

Nasal Gel

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	NATESTO (testosterone) GEL MD PMP

Patch

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ANDRODERM (testosterone) PATCH	

Solution MDP

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
testosterone (30mg/1.5mL)	

Pellet

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
TESTOPEL (testosterone) PELLET – *Medical Billing Only*	

Electronic Diagnosis Verification

- Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale.

Prior Authorization

Initial Criteria – Approval Duration: 12 months

- The member must have failed a 30-day trial of each preferred agent with a comparable route of administration, as evidenced by paid claims or pharmacy printouts.
- See Preferred Dosage Form Criteria

Cushing Syndrome

Adrenal Enzyme Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ketoconazole	ISTURISA (osilodrostat)
LYSODREN (mitotane)	RECORLEV (levoketoconazole)
METOPIRONE (metyrapone)	

Electronic Diagnosis Verification

- Isturisa and Recorlev: Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale.

Prior Authorization

Initial Criteria – Approval Duration: 6 months

- The requested medication must be prescribed by, or in consult with, an endocrinologist or specialist in the treatment of endogenous Cushing's syndrome.
- The member must have failed a 3-month trial of combination treatment with ketoconazole tablets and metyrapone.
- The member is not a candidate for surgery or surgery has not been curative; or is waiting for surgery or effect of pituitary radiation.
- The member must have a mean (at least two measurements) 24-hour urine free cortisol (UFC) level that is 3 x above the normal range per the reporting laboratory reference range.

Renewal Criteria – Approval Duration: 12 months

- The member has normalization of 24-hour urine free cortisol (UFC) level per the reporting laboratory reference range.

Glucocorticoid Receptor Antagonist

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
mifepristone 200 mg	KORLYM (mifepristone) – *Brand Required*
	mifepristone 300 mg

Electronic Diagnosis Verification

- Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale.

Prior Authorization

Initial Criteria – Approval Duration: 6 months

- The requested medication must be prescribed by, or in consult with, an endocrinologist or specialist in the treatment of endogenous Cushing's syndrome.
- The member must have failed a 3-month trial of combination treatment with ketoconazole tablets and metyrapone, as evidenced by paid claims or pharmacy print outs.
- The member is not a candidate for surgery or surgery has not been curative; or is waiting for surgery or effect of pituitary radiation.
- The member has uncontrolled hyperglycemia (type 2 diabetes or glucose intolerance) as defined by a hemoglobin A1c > 7% or TIR < 70%, despite adherence to an anti-diabetes regimen.
- See Preferred Dosage Form Criteria

Renewal Criteria – Approval Duration: 12 months

- The member must have experienced and maintained an improvement in cushingoid appearance, acne, hirsutism, striae, psychiatric symptoms, or excess total body weight.
- The member has improved hyperglycemia as a hemoglobin A1c decrease of 1% or greater or increase in TIR of 10% not attributed to an increase in medications, dosages, or adherence to an anti-diabetes regimen.

References:

- Fleseriu, Maria, et al. "Consensus on diagnosis and management of Cushing's disease: a guideline update." *The lancet Diabetes & endocrinology* 9.12 (2021): 847-875.

Diabetes

References:

1. American Diabetes Association Diabetes Care 2020 Jan; 43(Supplement 1): S98-S110. https://doi.org/10.2337/dc20-S009

Covered options in combination with Insulin therapy:

- GLP-1 agonists, DPP-4 inhibitors, SGLT-2 inhibitors, TZDs, and metformin
  - GLP-1 Agonist and SGLT-2 inhibitors are recommended first line treatments for every pathway indicated in the guidelines (ASCVD, HF, CKD, hypoglycemia risk, and to minimize weight gain)
  - TZDs increase insulin sensitivity and hypoglycemia risk should be monitored.
  - Metformin is recommended throughout treatment escalation.

Therapeutic Duplication

- One Strength of one medication is allowed at a time.
- Medication classes not payable together:
  - DPP-4 Inhibitors and GLP-1 Agonists
    - GLP-1 and DPP-4 Inhibitors should not be used concurrently due to similar mechanisms of action.
  - Sulfonylureas and Insulins
    - When initiating injectable therapy, sulfonylureas and DPP-4 inhibitors are typically discontinued.
  - Humulin R U-500 is not allowed with any other insulin (basal or prandial)
    - Humulin R U-500 is indicated for monotherapy. It acts differently than regular insulin (U-100). It provides both basal and prandial coverage. Injections can be increased to 3 times per day for prandial coverage.

Underutilization

- Toujeo, Tresiba, and Metformin 1000 mg must be used adherently and will reject on point of sale for late fill.

Biologics

CLINICAL PA REQUIRED

TZIELD (teplizumab-mzwv) – *Medical Billing Only*

High-Cost Drug:
This 14-day treatment course costs $193,900.

- In study TN-10; 72 people were enrolled – 44 in active treatment group and 32 in placebo group. By month 36, 63.7% (28) in the active treatment group and 71.9% (23) in the placebo group had experienced Stage 3 Type 1 Diabetes onset.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The requested medication must be prescribed by, or in consult with, an endocrinologist.
- The member has a family history of Type 1 Diabetes
- The member has at least two of the following pancreatic islet cell autoantibodies:
  A. Glutamic acid decarboxylase 65 (GAD) autoantibodies
  B. Insulin autoantibody (IAA)
  C. Insulinoma-associated antigen 2 autoantibody (IA-2A)
  D. Zinc transporter 8 autoantibody (ZnT8A)
  E. Islet cell autoantibody (ICA)
- The member has no symptoms of Type 1 Diabetes (e.g., polyuria, polydipsia, weight loss, fatigue, DKA)
- The member has abnormal blood sugar levels determined by an oral glucose tolerance test.

DPP-4 Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
JANUMET (sitagliptin/metformin)	alogliptan/pioglitazone
JANUMET XR (sitagliptin/metformin)	alogliptin
JANUVIA (sitagliptin)	alogliptin/metformin
JENTADUETO (linagliptin/metformin)	KAZANO (alogliptin/metformin)
JENTADUETO XR (linagliptin/metformin)	NESINA (alogliptin)
TRADJENTA (linagliptin)	ONGLYZA (saxagliptin)
	OSENI (alogliptin/pioglitazone)
	saxagliptin
	saxagliptin/metformin
	sitagliptin/metformin
	ZITUVAMET XR (sitagliptin/metformin)
	ZITUVIO (sitagliptin)

++Clinically Non-Preferred: Alogliptin and saxagliptan have a potentially higher risk for heart failure.

Electronic Age Verification

- The member must be 18 years or older for Januvia, Janumet, or Janumet XR

Electronic Concurrent Medications Required

- A total of 28-day supply of metformin must be paid within 100 days prior to the DPP-4 Inhibitor's date of service. Members with GI intolerances to high dose IR metformin must trial at minimum a dose of 500 mg ER.
  - Metformin is recommended to be continued with therapy with DPP-4 Inhibitors**.** If metformin is not tolerated, SGLT2 inhibitor and GLP-1 Agonists are recommended as part of the glucose-lowering regimen independent of A1C or TIR and are first line alternatives.

* GI intolerances (typically will not be considered to bypass trial requirements):
  - If on high dose IR metformin, member must trial at minimum a dose of 500 mg ER.
  - Patient experiencing GI side effects should be counseled: reduction in meal size, eating slower, decreased intake of greasy, high-fat or spicy food, refrain from laying down after eating.

References:

1. American Diabetes Association Diabetes Care 2020 Jan; 43(Supplement 1): S98-S110. https://doi.org/10.2337/dc20-S009

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member has been unable to achieve goal A1C (≤ 7%) or TIR (>70%) despite two 90-day trials of triple combination therapy, as evidenced by paid claims or pharmacy printouts.
- Zituvio and sitagliptin/metformin only: See Preferred Dosage Form Criteria

DPP-4 Inhibitors / SGLT2 Inhibitors Combination

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
TRIJARDY XR (empagliflozin/linagliptan/metformin)	GLYXAMBI (empagliflozin/linagliptin)
	STEGLUJAN (ertugliflozin/sitagliptin)
	++QTERN (dapagliflozin/saxagliptin)

++Clinically Non-Preferred: Saxagliptan has a potentially higher risk for heart failure.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- See Preferred Dosage Form Criteria
- Clinical justification must be provided explaining why the member cannot use individual preferred products separately or preferred agent.

GLP-1 Agonists^

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (STEP 1 – PA REQUIRED)	NON-PREFERRED AGENTS (STEP 2 – PA REQUIRED)
VICTOZA (liraglutide) *- Brand Required*	BYDUREON BCISE (exenatide microspheres)	++BYETTA (exenatide)
	OZEMPIC (semaglutide)	liraglutide
	RYBELSUS (semaglutide)	TRULICITY (dulaglutide)

++Clinically Non-Preferred: Byetta is less effective than other available agents.
^ See GIP/GLP-1 Agonists section for Mounjaro (tirzepatide) criteria

Clinical information: dose comparison recommendations for switching between GLP-1 agonists

- For GI side effects (start titration at lowest available dose)
- For any other reason, may consider starting at equivalent dose to minimize disruption to glycemic control
  - Victoza 1.2 mg = Trulicity 0.75 mg = Ozempic 0.25 mg = Rybelsus 7 mg
  - Victoza 1.8 mg = Trulicity 1.5 mg = Ozempic 0.5 mg = Rybelsus 14 mg = Mounjaro 2.5 mg
  - Trulicity 3 mg = Ozempic 0.5 mg or 1 mg
  - Trulicity 4.5 mg = Ozempic 1 mg
  - Mounjaro 5 mg = Ozempic 2 mg

References:

1. Almandoz JP, Lingvay I, Morales J, Campos C. Switching Between Glucagon-Like Peptide-1 Receptor Agonists: Rationale and Practical Guidance. Clin Diabetes. 2020 Oct;38(4):390-402. Doi: 10.2337/cd19-0100. PMID: 33132510; PMCID: PMC7566932.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- Step 1: Ozempic, Rybelsus, Bydureon Bcise:
  - The member has been unable to achieve goal A1C (≤ 7%) or TIR (>70%) despite a 90-day trial of triple combination therapy with Victoza, metformin, SGLT-2 inhibitor or insulin, as evidenced by paid claims or pharmacy printouts.
    - If triple therapy cannot be met with Victoza, clinical justification must be provided (subject to clinical review*), and triple therapy must be met with SGLT-2 inhibitor + DPP4 inhibitor + another agent (metformin must be used as tolerated).
    - If triple therapy cannot be met because of inability to use metformin, SGLT-2 inhibitor or insulin, clinical justification must be provided why product cannot be used (subject to clinical review*), and triple therapy must be met with Victoza + two other agents (metformin, SGLT-2 inhibitor or insulin must be used as tolerated).
- Step 2:
  - The member has been unable to achieve goal A1C (≤ 7%) or TIR (>70%) despite two 90-day trials of triple combination therapy (one trial with Victoza and one with Ozempic, subject to clinical review*) along with metformin, SGLT-2 inhibitor or insulin, as evidenced by paid claims or pharmacy printouts.
    - If triple therapy cannot be met with Victoza or Ozempic, clinical justification must be provided (subject to clinical review*), and triple therapy must be met with SGLT-2 inhibitor + DPP4 inhibitor + another agent.
    - If triple therapy cannot be met because of inability to use metformin, SGLT-2 inhibitor or insulin, clinical justification must be provided why product cannot be used (subject to clinical review*), and triple therapy must be met with Victoza or Ozempic + two other agents (metformin, SGLT-2 inhibitor, or insulin must be used as tolerated).
  - One of the following have been met:
    - The requested medication must be prescribed by, or in consult with, an endocrinologist or diabetes specialist.
    - The member has received diabetes education from a diabetic specialist, diabetic educator, or pharmacist (may be accomplished through the MTM program).

*GI intolerances (typically will not be considered to bypass trial requirements):

- If on high dose IR metformin, member must trial at minimum a dose of 500 mg ER.
- If on Victoza or Ozempic, member should be evaluated on potential for GI side effects, with GI effects being common across all GLP-1 agonist agents and transient in nature, typically lessoning with ongoing treatment.
- Patient experiencing GI side effects, mitigation efforts should be trialed for at least two months: reduction in meal size, eating slower, decreased intake of greasy, high-fat or spicy food, refrain from laying down after eating.

GIP/GLP-1 Agonists

CLINICAL PA REQUIRED
MOUNJARO (tirzepatide)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member has been unable to achieve goal A1C (≤ 7%) or TIR (>70%) despite two 90-day trials of triple combination therapy (one trial with Victoza and one with Ozempic, subject to clinical review*) along with metformin, SGLT-2 inhibitor or insulin, as evidenced by paid claims or pharmacy printouts.

- If triple therapy cannot be met with Victoza or Ozempic, clinical justification must be provided (subject to clinical review*), and triple therapy must be met with SGLT-2 inhibitor + DPP4 inhibitor + another agent.
- If triple therapy cannot be met because of inability to use metformin, SGLT-2 inhibitor or insulin, clinical justification must be provided why product cannot be used (subject to clinical review*), and triple therapy must be met with Victoza or Ozempic + two other agents (metformin, SGLT-2 inhibitor, or insulin must be used as tolerated).

- One of the following have been met:
  - The requested medication must be prescribed by, or in consult with, an endocrinologist or diabetes specialist.
  - The member has received diabetes education from a diabetic specialist, diabetic educator, or pharmacist (may be accomplished through the MTM program).

*GI intolerances (typically will not be considered to bypass trial requirements):

- If on high dose IR metformin, member must trial at minimum a dose of 500 mg ER.
- If on Victoza or Ozempic, member should be evaluated on potential for GI side effects, with GI effects being common across all GLP-1 agonist agents and transient in nature, typically lessoning with ongoing treatment.
- Patient experiencing GI side effects, mitigation efforts should be trialed for at least two months: reduction in meal size, eating slower, decreased intake of greasy, high-fat or spicy food, refrain from laying down after eating.

Gastroparesis

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
metoclopramide tablet	GIMOTI (metoclopramide nasal spray)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 3 months

- Clinical justification must be provided explaining why the member is unable to use an oral dosage formulation (including solution formulations) with relevant medical documentation attached to the request, subject to clinical review.

Glucose Rescue Medications

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
BAQSIMI (glucagon) SPRAY – Labeler 00548	BAQSIMI (glucagon) SPRAY – Labeler 00002
GLUCAGEN (glucagon) HYPOKIT – *Brand Required*	glucagon kit
ZEGALOGUE (dasiglucagon) AUTOINJECTOR	GVOKE (glucagon) INJECTION

Electronic Duration Verification

- 4 doses are covered every 60 days without an override.

If one of the following criteria are met (A or B), please request an override by calling provider relations at 1-800-755-2604 or emailing medicaidpharmacy@nd.gov:

A. The previous dose has expired.
B. The dose was used by member for a hypoglycemic episode. (In this case, it is recommended to follow up with prescriber to discuss frequency of use and potential regimen review/adjustments)

Insulin/GLP-1 Agonist Combination

CLINICAL PA REQUIRED

SOLIQUA (insulin glargine/lixisenatide)
XULTOPHY (insulin degludec/liraglutide)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- Clinical justification must be provided explaining why the member is unable to use the preferred products (subject to clinical review).

Insulin

Rapid Acting Insulin

Insulin Lispro

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
HUMALOG U-100 (insulin lispro) *–Kwikpen: Brand Co-Preferred*	ADMELOG (insulin lispro)
HUMALOG U-100 (insulin lispro) JUNIOR KWIKPEN *– Brand Co-Preferred*	HUMALOG U-200 (insulin lispro)
HUMALOG U-100 (insulin lispro) TEMPO PEN	insulin lispro vial
insulin lispro U-100 junior syringe	LYUMJEV U-100 (insulin lispro-aabc)
insulin lispro U-100 insulin pen	LYUMJEV U-200 (insulin lispro-aabc)
	LYUMJEV U-100 TEMPO PEN (insulin lispro-aabc)

Insulin Aspart

PREFERRED AGENTS (ELECTRONIC STEP REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
FIASP (insulin aspart)	insulin aspart
	NOVOLOG (insulin aspart)
	RELION NOVOLOG (insulin aspart)

Insulin Glulisine

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	APIDRA (insulin glulisine)

Insulin Regular, Human

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	++AFREZZA (insulin regular, human)
	++HUMULIN R (insulin regular, human) VIAL
	++NOVOLIN R (insulin regular, human)
	++ RELION NOVOLIN R (insulin regular, human)

++Clinically Non-Preferred: ACOG (American College of Obstetricians and Gynecologists) guidelines prefer insulin analogues (insulin aspart and lispro) over regular insulin due to better compliance, better glycemic control, and overall fewer hypoglycemic episodes.

Electronic Step Therapy Required

- Fiasp

- PA Not Required Criteria: A 3-month supply of Humalog has been paid within 180 days prior to Fiasp's date of service.
- PA Required Criteria: The member must have failed a 3-month trial from Humalog, as evidenced by paid claims or pharmacy printouts.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- Apidra: The member must have failed a 3-month trial of each of the following agents, as evidenced by paid claims or pharmacy printouts:
  - Humalog
  - Fiasp
- Humalog U-200: Request must not be for use in an insulin pump: HUMALOG® (insulin lispro) 200 Units/mL: Do Not Use in a Pump (lillymedical.com)
  - Doses ≤ 200 units/day: Clinical justification must be provided why member cannot tolerate the volume of insulin required to use Humalog U-100 or tolerate two injections per dose.
  - Doses > 200 units/day: Clinical justification must be provided why member is not a candidate for Humulin R U-500.
- Regular Insulin (Humulin R / Novolin R / Afrezza): The member must have failed a 3-month trial of each of the following agents, as evidenced by paid claims or pharmacy printouts:
  - Humalog and Fiasp
- Non-Preferred Agents: See Preferred Dosage Form Criteria

Intermediate Acting Insulin

PREFERRED AGENTS (NO PA REQUIRED)	PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
HUMULIN R U-500 (insulin regular, human)	++ NOVOLIN N (insulin NPH human isophane)	++ HUMULIN N (insulin NPH human isophane)
	++ RELION NOVOLIN N (insulin NPH human isophane)	

++ Clinically non-preferred: Lantus and Levemir have been demonstrated to reduce the risk of symptomatic and nocturnal hypoglycemia compared with NPH insulin.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months (6 months or until due date, if known, for gestational diabetes)

- One of the following must be met:
  - The member must be pregnant or breastfeeding.
  - The member must be tube feedings.
  - The member must be post-solid organ transplant.
    - For kidney transplant – Medicare eligibility must be ruled out *(6-month approval may be allowed to determine eligibility)*
  - Clinical justification explaining why the member is unable to use Lantus or Levemir (subject to clinical review)

Non-Preferred Agent Criteria

- See Preferred Dosage Form Criteria

Long-Acting Insulin

Insulin Glargine

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
LANTUS U-100 (insulin glargine)	BASAGLAR KWIKPEN U-100 (insulin glargine)

– Brand Required	
TOUJEO U-300 (insulin glargine) *No PA required for doses 100 unit/day to 200 unit/day *– Brand Required*	BASAGLAR TEMPO PEN U-100 (insulin glargine)
	insulin glargine U-100 (generic Toujeo)
	insulin glargine-yfgn U-100 (generic Semglee)
	REZVOGLAR U-100 (insulin glargine-aglr)
	SEMGLEE U-100 (insulin glargine) YFGN

Insulin Degludec

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
TRESIBA (insulin degludec) FLEXTOUCH U-200 *No PA required for doses 100 unit/day to 200 unit/day *- Brand Required*	insulin degludec U-100 and U-200
	TRESIBA (insulin degludec) U-100 VIAL

Quantity Override Request

- Toujeo Solostar 300 unit/mL, Toujeo Max Solostar 300 unit/mL and Tresiba 200 unit/mL:
  - Doses > 200 units/day:
    - Clinical justification must be provided explaining why the member is not a candidate for U-500R + Toujeo and Tresiba are not intended as replacements for U-500R insulin
  - Doses >100 units/day to ≤ 200 units/day: No prior authorization required.
    - Please call for an override by calling provider relations at 1-800-755-2604 if the day supply is less than 30 days and dose is between 100 units/day and 200 units/day (e.g., short-cycle filling).
  - Doses ≤ 100 units/day:
    - Must meet Prior Authorization Criteria below

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The requested medication must be prescribed by, or in consult with, an endocrinologist or diabetes specialist.
- The member has had a 90-day trial of Lantus with good compliance, as evidenced by paid claims or pharmacy printouts.
- One of the following must be met, as evidenced by provided clinical notes or labs:
  - The member experiences recurrent episodes of hypoglycemia despite adjustments to current regimen (prandial insulin, interacting drugs, meal, and exercise timing).
  - The member must be experiencing inconsistent blood sugars.
- Biosimilar Agents: See Preferred Dosage Form Criteria

Renewal Criteria – Approval Duration: 12 months

- The member must have experienced at least one of the following, as evidenced by provided clinical notes or labs:
  - Reduction in frequency and/or severity of hypoglycemia
  - Improved glycemic control (evidenced by A1c or TIR)

Mixed Insulin

Insulin NPL/Insulin Lispro

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)

HUMALOG MIX 50/50 (insulin NPL/insulin lispro) VIAL	HUMALOG MIX 50/50 (insulin NPL/insulin lispro) KWIKPEN
insulin lispro mix 75/25 kwikpen	HUMALOG MIX 75/25 (insulin NPL/insulin lispro)

Insulin Aspart Protamine/Insulin Aspart

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
insulin aspart protamine/insulin aspart 70/30	NOVOLOG MIX 70/30 (insulin aspart protamine/insulin aspart) – *Brand Required*
	RELION NOVOLOG MIX 70/30 (insulin aspart protamine/insulin aspart)

Insulin NPH Human/Regular Insulin Human

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
HUMULIN MIX 70/30 (insulin NPH human/regular insulin human)	NOVOLIN MIX 70-30 (insulin NPH human/regular insulin human)
	RELION NOVOLIN MIX 70-30 (insulin NPH human/regular insulin human)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months (6 months or until due date, if known, for gestational diabetes)

- Humulin 70/30 and Novolin 70/30 only:
  - One of the following must be met:
    - Member must be pregnant or breastfeeding.
    - Member must be on tube feedings.
    - Member must be post-solid organ transplant.
      - For kidney transplant – Medicare eligibility must be ruled out *(6-month approval may be allowed to determine eligibility)*

Non-Preferred Agent Criteria

- See Preferred Dosage Form Criteria
- Clinical justification must be provided explaining why the member is unable to use the preferred products or a long acting plus short acting regimen (subject to clinical review).

SGLT2 Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
FARXIGA (dapagliflozin) – *Brand Required*	dapagliflozin
JARDIANCE (empagliflozin)	dapagliflozin/metformin XR 5mg-1000mg, 10mg-1000mg
SYNJARDY (empagliflozin/metformin)	INVOKANA (canagliflozin)
XIGDUO XR (dapagliflozin/metformin) 5 MG-500 MG, 5 MG-1000 MG, 10 MG-500 MG, 10 MG-1000 MG – *Brand Required*	INVOKAMET (canagliflozin/metformin)
	INVOKAMET XR (canagliflozin/metformin)
	STEGLATRO (ertugliflozin)
	STEGLATROMET (ertugliflozin/metformin)
	SYNJARDY XR (empagliflozin/metformin)
	XIGDUO XR (dapagliflozin/metformin) 2.5 MG – 1000 MG

++ Canagliflozin has shown an increase in the risk of lower limb amputations and fractures in studies.

++ Dapagliflozin did not reduce atherosclerotic cardiovascular morbidity or mortality in a primary analysis, however it decreased cardiovascular in the sub analysis of prior myocardial infarction.
++ Ertugliflozin was not superior to placebo in reducing the primary composite cardiovascular endpoint.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must have failed a 30-day trial of each preferred SGLT2 inhibitor of a unique active ingredient, as evidenced by paid claims or pharmacy printouts.
- Clinical justification must be provided explaining why the member is unable to use the preferred agents and other classes of medication (subject to clinical review).

References:

1. DeSantis A. Sodium-glucose cotransporter 2 inhibitors for the treatment of hyperglycemia in type 2 diabetes mellitus. In: *UpToDate*, Post TW (Ed), UpToDate, Waltham, MA, 2023

Sulfonylureas

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
glimepiride 1 mg, 2 mg, and 4 mg	glimepiride 3 mg
glipizide IR 5 mg, 10 mg	glipizide 2.5 mg
glipizide ER	++glyburide
glipizide/metformin	++glyburide/metformin
glipizide ER	++glyburide, micronized

++Clinically Non-preferred: Glyburide is not recommended due to hypoglycemia.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must have failed a 30-day trial of glipizide and glimepiride, as evidenced by paid claims or pharmacy printouts.
- See Preferred Dosage Form Criteria

Growth Hormone

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
GENOTROPIN (somatropin)	HUMATROPE (somatropin)
GENOTROPIN MINIQUICK (somatropin)	NGENLA (somatrogon-ghla)
NORDITROPIN FLEXPRO (somatropin)	NUTROPIN AQ NUSPIN (somatropin)
PREFERRED AGENTS (PA REQUIRED)	OMNITROPE (somatropin)
SKYTROFA (lonapegsomatropin-tcgd)	SAIZEN (somatropin)
	SOGROYA (somapacitan-beco)
	ZOMACTON (somatropin)

Prior Authorization Criteria

Prior Authorization Form – Growth Hormone

Initial Criteria – Approval Duration: 12 months (except 6 months if criteria met in Prader-Willi Syndrome)

- Member must have one of the following covered diagnoses (listed below):
  - Panhypopituitarism OR multiple pituitary hormone deficiencies caused by a known hypothalamic-pituitary disease treatment (brain surgery and/or radiation)

- Turner's syndrome
- SHOX syndrome
- Noonan syndrome
- Chronic renal insufficiency
- Prader–Willi syndrome
- Endogenous growth hormone deficiency

- The requested medication must be prescribed by, or in consult annually with, an endocrinologist or nephrologist.
- The member must not have active malignancy.
- The member must not have epiphyseal closure and must still be growing, unless one of the below exceptions is present:
  - The member has a diagnosis of Prader-Willi syndrome.
  - The member has a diagnosis of endogenous growth hormone deficiency and is experiencing hypoglycemic episodes without growth hormone and growth hormone is needed to maintain proper blood glucose.

Chronic Renal Insufficiency

- The member must not have received a renal transplant.
- The member must consult with a dietitian annually to maintain a nutritious diet.

Endogenous Growth Hormone Deficiency and Panhypopituitarism

2. ONE of below criteria must be met:
   - The member has multiple pituitary hormone deficiencies caused by a known hypothalamic-pituitary disease or its treatment (brain surgery and/or radiation) and must have an IGF-1 or IGFBP-3 level of less than SDS -1.3.
   - The member has had GH stimulation testing by at least two different stimuli (e.g., insulin, levodopa, L-arginine, propranolol, clonidine, or glucagon) with a maximum peak of < 10 ng/mL after stimulation no more than 6 months apart.
   - For infants less than 18 months old, both of the following criteria are met:
     - The member has a plasma glucose level less than 70 mg/dL
     - The member has GH level < 5 mcg/L

Prader-Willi Syndrome (PWS)

See covered medications for weight loss

3. The member must not have severe obesity (class 2) defined as ≥ 120% of the 95th percentile for age and gender
4. If the member has obesity ≥ 95th percentile and < 120% of the 95th percentile for age and gender, all the following must be met (*6-month approval criteria*):
   - The prescriber must attest that member will meet with a dietician every 3 months
   - The member must have had a sleep study to rule out sleep apnea
   - The member must not have non-alcoholic fatty liver disease
   - The member must not have an A1c > 5.7%

Non-Preferred Agent Criteria:

- Skytrofa and Omnitrope Only: The member must have failed a 30-day trial of one preferred agent, as evidenced by paid claims or pharmacy printouts.
- All other agents: See Preferred Dosage Form Criteria

Renewal Criteria – Approval Duration: 12 months (6 months if criteria below for PWS is met)

- The member must have been compliant with growth hormone (last 6 fills must have been on time).

Prader-Willi Syndrome

- If the member has obesity ≥ 95th percentile and < 120% of the 95th percentile for age and gender, initial criteria must be met in addition to the following *(6-month approval criteria)*:
  - The member must have met with a dietician at least 2 times in the past 6 months

References:

1. Deal et al,. Growth hormone research society workshop summary: consensus guidelines for recombinant human growth hormone therapy in Prader Will syndrome. J Clin Endocrin Metab. 2013. doi: 10.1210/jc.2012-3888

Serostim

CLINICAL PA REQUIRED
SEROSTIM (somatropin)

Prior Authorization Criteria

Prior Authorization Form – Growth Hormone

Initial Criteria – Approval Duration: 3 months

- The member must not have an active malignancy.
- The requested medication must be prescribed by, or in consult with, and infectious disease specialist or a specialist in the diagnosis and management of HIV infection.
- The member must be on concomitant antiretroviral therapy.
- The member must have failed a 3-month trial with megestrol, as evidenced by paid claims or pharmacy printouts.
- Lean body mass and body weight must be provided.
- Documentation of physical endurance must be provided.

Renewal Criteria – Approval Duration: 8 months (one time)

- Lean body mass and body weight must have increased from baseline.
- Physical endurance must have increased from baseline.

Imcivree

CLINICAL PA REQUIRED
IMCIVREE (setmelanotide)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 4 months

- The member must have a diagnosis of obesity (BMI > 30 kg/m2 for adults or > 95th percentile using growth chart assessments for pediatric members)
- The member's weight and body mass index (BMI) must be provided within the last 60 days.
- The requested medication must be prescribed by, or in consult with, endocrinologist or medical geneticist.
- The member's obesity must be due to one of the following:
  - Genetic testing confirms one of the following variants that is pathogenic, likely pathogenic, or of unknown significance:
    - Proopiomelanocortin (POMC)
    - Proprotein convertase subtilisin/kexin type 1 (PCSK1)
    - Leptin receptor (LEPR) deficiency
  - Bardet-Biedl syndrome as evidenced by three or more of the following:
    - Rod-cone dystrophy
    - Polydactyly
    - Genital anomalies

- Renal anomalies
- Intellectual impairment

Renewal Criteria – Approval Duration: 12 months

- One of the following must be met since starting treatment with Imcivree, as evidenced by medical documentation (e.g., chart notes) attached to the request:
  - Members ≥ 18 years old:
    - First renewal – a 5% weight reduction has been achieved or maintained.
    - Subsequent renewal – a 10% weight reduction has been achieved or maintained.
  - Members < 18 years old: a 5% reduction in BMI has been achieved or maintained.

Hypothyroidism

Solid Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
levothyroxine tablet	EUTHYROX (levothyroxine) TABLET
	levothyroxine capsule
	LEVO-T (levothyroxine) TABLET
	LEVOXYL (levothyroxine) TABLET
	SYNTHROID (levothyroxine) TABLET
	UNITHROID (levothyroxine) TABLET

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- Levothyroxine capsule only: The member must have documented celiac disease, yellow dye allergy, or lactose/milk protein allergy.
- All other agents: See Preferred Dosage Form criteria

Non-Solid Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ERMEZA (levothyroxine) SOLUTION	THYQUIDITY (levothyroxine) ORAL SOLUTION

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- All other agents: See Preferred Dosage Form criteria

Secondary Hyperparathyroidism

Oral

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
calcitriol	cinacalcet
paricalcitol	doxercalciferol capsule
	HECTOROL (doxercalciferol) CAPSULE
	RAYALDEE ER (calcifediol)
	ROCALTROL (calcitriol)
	SENSIPAR (cinacalcet)

	ZEMPLAR (paricalcitol)

++ cinacalcet is associated with hypocalcemia, increased urinary calcium excretion, and increased serum phosphate levels

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

Cinacalcet only:

- If member is on renal dialysis, Medicare eligibility must be ruled out *(6-month approval may be allowed to determine eligibility)*

All other agents:

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The member must have failed a 30-day trial of paricalcitol
- Clinical justification must be provided explaining why the member is unable to use the preferred agents (subject to clinical review)

References:

1. Quarles LD. Management of secondary hyperparathyroidism in adult non-dialysis patients with chronic kidney disease. In: *UpToDate*, Post TW (Ed), UpToDate, Waltham, MA, 2023

Subcutaneous

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	YORVIPATH (palopegteriparatide)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The requested medication must be prescribed by, or in consult with, an endocrinologist
- The member must have persistent hypoparathyroidism as evidenced by one of the following symptoms despite a 6-month trial of calcitriol or equivalent oral agent:
    - Symptomatic hypocalcemia
    - Hyperphosphatemia
    - Hypercalciuria
- The member must have an albumin-corrected serum calcium concentration must be ≥ 7.8 mg/dL
- The member must have a magnesium concentration ≥ 1.3 mg/dL
- The member must have a 25 (OH) vitamin D concentration between 20 and 80 ng/mL

Renewal Criteria – Approval Duration: 12 months

- The member no longer requires active vitamin D or has experienced a significant reduction in required dosage and is still titrating Yorvipath
- The member has an albumin-corrected serum calcium in the lower-half of the normal reference range or just below the reference range (~8-9 mg/dL)

Precocious Puberty

NO PA REQUIRED	
FENSOLVI (leuprolide) – *Medical Billing Only*	SUPPRELIN LA (histrelin) – *Medical Billing Only*
LUPRON PED DEPOT (leuprolide) – *Medical Billing Only*	
SYNAREL (nafarelin) – *Medical Billing Only*	
TRIPTODUR (triptorelin) – *Medical Billing Only*	

Prior Authorization Criteria

Initial Criteria – Approval Duration: 1 month

- Clinical justification must be provided explaining why the member is unable to use the preferred agents (subject to clinical review).

Thyroid Eye Disease

CLINICAL PA REQUIRED
TEPEZZA (teprotumumab-trbw) – *Medical Billing Only*

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months (8 infusions per lifetime)

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult annually with, an endocrinologist, ophthalmologist, or specialist in the treatment of Thyroid Eye Disease (TED)
- The provider must submit documentation of each of the following:
  - Thyroxine (FT4) and free triiodothyronine (FT3) levels less than 50% above or below normal limits
  - Must have a Clinical Activity Score of greater than or equal to 4
- The member has had a one-month trial of a maximally tolerated indicated dose of systemic glucocorticoids.
- The member has not required prior surgical ophthalmologic intervention.
- The member does not have any of the following:
  - A decrease in best corrected visual acuity (BVCA) due to optic neuropathy within the previous six months (i.e., decrease in vision of 2 lines on the Snellen chart, new visual field defect, or color defect secondary to optic nerve involvement)
  - Corneal decompensation that is unresponsive to medical management
  - Poorly controlled diabetes or diabetes must be maximally treated by, or in consult with, an endocrinologist with good adherence.

X-linked Hypophosphatemia (XLH) or Tumor-Induced Osteomalacia

CLINICAL PA REQUIRED
CRYSVITA (burosumab) – *Medical Billing Only*

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months (one-time 6-month approval for adult with planned orthopedic surgical

- Documentation to confirm the diagnosis must be submitted, as evidenced by the following:
  - Genetic testing confirming phosphate regulating gene with homology to endopeptidases on the X chromosome (PHEX-gene) mutation
  - Increased (FGF23) level based on laboratory reference range with unresectable phosphaturic mesenchymal tumor
- The requested medication must be prescribed by, or in consult with, nephrologist, endocrinologist, geneticist, or specialist experienced in the treatment of metabolic bone disorders.
- Documentation must be submitted confirming the member is experiencing the following:
  - Phosphate manifestations *(must have one)*
    - Fasting serum phosphate is below provided age adjusted reference range.
    - Low tubular resorption of phosphate corrected for glomerular filtration rate (TmP/GFR) based on age
  - Bone manifestations *(must have one)*

- Epiphyseal plate has not fused
- Bone fractures
- Planned orthopedic surgical procedure

Renewal Criteria – Approval Duration: 12 months

- Documentation must be submitted demonstrating that the member has demonstrated a disease stability or beneficial response to therapy from baseline as shown by one or more of the following:
  - Normalization of phosphate levels as defined by laboratory
  - Decrease in serum alkaline phosphatase activity
  - Improvement of renal phosphate wasting
  - Normalization of growth velocity
  - Reduction or healing of fractures
  - Improvement of Thacher Rickets Severity Score (TRSS)

Weight Loss

Antipsychotic Induced Weight Gain

- Metformin is covered without prior authorization.
- Victoza is covered without prior authorization by submitting diagnosis code T43.505A

Obesity

- The following drugs are covered without prior authorization by submitting a corresponding diagnosis code for the indication:
  - phentermine, bupropion, naltrexone, topiramate

GI – Gastroenterology

Acid Blockers

Proton Pump Inhibitor

Solid Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	PREFERRED STEP 1 AGENTS (ELECTRONIC STEP)	NON-PREFERRED STEP 2 AGENTS (PA REQUIRED)
lansoprazole	esomeprazole magnesium	ACIPHEX (rabeprazole)
omeprazole		DEXILANT (dexlansoprazole)
pantoprazole		dexlansoprazole
rabeprazole		NEXIUM (esomeprazole)
		omeprazole-sodium bicarbonate
		PREVACID (lansoprazole)
		PRILOSEC (omeprazole)
		PROTONIX (pantoprazole)
		ZEGERID (omeprazole/sodium bicarbonate)

Electronic Step Therapy Required

- Preferred Step 1 Agents:
  - PA Not Required Criteria: A 14-day supply from at least 1 preferred agent at max dose has been paid within 365 days prior to preferred step 1 agent's date of service.
  - PA Required Criteria: The member must have failed a 14-day trial from at least 1 preferred agent at max dose, as evidenced by paid claims or pharmacy printouts.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- Non-Preferred Agents Criteria – Step 2 Agents:
  - Member must have failed a 30-day trial with all preferred agents (including Step 1 Agents), as evidenced by paid claims or pharmacy printouts.

Non-Solid Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED (PA REQUIRED)
lansoprazole ODT	esomeprazole solution packet
NEXIUM (esomeprazole) PACKET- *Brand Required*	KONVOMEP (omeprazole/sodium bicarbonate)
PROTONIX (pantoprazole) PACKET *– Brand Required*	omeprazole-sodium bicarbonate packet
	pantoprazole packet
	PREVACID (lansoprazole) SOLUTAB
	PRILOSEC SUSPENSION (omeprazole)
	ZEGERID (omeprazole-sodium bicarbonate) PACKET

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- Member must have failed a 30-day trial with all preferred agents, as evidenced by paid claims or pharmacy printouts.
- Clinical justification must be provided explaining why the member is unable to use the other agents (subject to clinical review).

Electronic Age Verification

- Nexium 2.5 mg and 5 mg Packet: The member must be less than 1 years old (or less than 7.5 kg)

Therapeutic Duplication

- One strength of one medication is allowed at a time.
- Proton Pump Inhibitors is not allowed with:
  - Esomeprazole or omeprazole are not covered with clopidogrel.
    - Other PPIs such as pantoprazole are covered with clopidogrel. Clopidogrel is a substrate for 2C19 and esomeprazole and omeprazole are strong 2C19 inhibitors and can decrease effectiveness of clopidogrel.
  - Dextroamphetamine/Amphetamine ER:
    - Proton Pump Inhibitors increase blood levels and potentiate the action of amphetamine. Co-administration of Adderall XR and gastrointestinal or urinary alkalizing agents should be avoided.
  - H2 Blockers: If either of the following circumstances apply, please call for an override by calling provider relations at 1-800-755-2604:

- Member is experiencing nocturnal symptoms after compliance with nighttime dose of proton pump inhibitor. A two-month override may be approved for concurrent H2 blocker use.
- H2 blocker is being used concurrently with a H1 blocker for severe allergy prophylaxis, unrelated to PPI use for GI symptoms.

References

1. Katz PO, Gerson LB, Vela MF. Guidelines for the diagnosis and management of gastroesophageal reflux disease. Am J Gastroenterol 2013;108:308-28.
2. Fackler WK, Ours TM, Vaezi MF, Richter JE. Long-term effect of H2RA therapy on nocturnal gastric breakthrough. Gastroenterology. 2002;122:625-632.

Potassium Competitive Acid Blocker

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
VOQUEZNA (vonoprazan)	

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- The member must meet one of the following criteria (A, B, or C):
  - A. The member has a diagnosis of erosive esophagitis and have failed an 8-week trial of each of the following:
    - Omeprazole twice daily
    - Rabeprazole or esomeprazole daily.
  - B. The member has severe esophagitis (LA Grade C/D disease)
  - C. Member must have failed a 30-day trial with all preferred proton pump inhibitors (including Step 1 Agents), as evidenced by paid claims or pharmacy printouts.

Acute Hepatic Porphyria (AHP)

CLINICAL PA REQUIRED
GIVLAARI (givosiran) – *Medical Billing Only*

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a geneticist, hepatologist, hematologist, gastroenterologist, or specialist in acute hepatic porphyria (AHP)
- The member must have a diagnosis of AHP (i.e., acute intermittent porphyria (AIP), variegate porphyria (VP), hereditary coproporphyria (HCP), delta-aminolevulinic acid dehydratase deficient porphyria (ADP)) with the following as defined by laboratory reference range (evidenced with submitted documentation):
  - Elevated urine porphobilinogen (PBG)
  - Increased aminolevulinic acid (ALA)
  - Genetic testing confirming a mutation
- The member has addressed identifiable lifestyle triggers (e.g., certain drugs, smoking, stress)
- The member has had two documented porphyria attacks within the past 6 months requiring hospitalization, urgent healthcare visit, or intravenous hemin administration (number of attacks and days of hemin are documented)
- The member has not had a liver transplant.

Renewal Criteria – Approval Duration: 12 months

- The member has had a meaningful reduction (e.g., 30%) in each of the following:
  - Number of porphyria attacks
  - Days of Hemin Use
  - Reduction in urinary ALA

Bowel Prep Agents

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
GAVILYTE-C	CLENPIQ
GAVILYTE-G	PEG 3350/SOD SUL/NACL/KCL/ASB/C
GAVILYTE-N	PLENVU
GOLYTELY 236-22.74G – *Brand Co-Preferred*	
MOVIPREP – *Brand Required*	
PEG-3350 AND ELECTROLYTES 236-22.74G	
PEG 3350-ELECTROLYTE 420 G	
PEG 3350-ELECTROLYTE SOLUTION	
SOD SOL-POTASS SUL-MAG SUL	
SUFLAVE	
SUPREP – *Brand Co-Preferred*	
SUTAB	

Prior Authorization Criteria

Initial Criteria – Approval Duration: 1 month

- Clinical justification must be provided explaining why the member is unable to use the preferred agents (subject to clinical review).

Cholestatic Pruritis

Alagille Syndrome (ALGS):

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED (PA REQUIRED)
BYLVAY (odevixibat)	
LIVMARLI (maralixibat)	

Progressive Familial Intrahepatic Cholestasis (PFIC):

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED (PA REQUIRED)
BYLVAY (odevixibat)	LIVMARLI (maralixibat)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a hepatologist or gastroenterologist.
- The member is experiencing itch for greater than 6 weeks that has significantly diminished quality of life, including sleep disturbances.
- The member must have cholestasis, as evidenced by ≥ 1 of the following:
  - Serum bile acid > 3x upper limit of normal as defined by the reporting laboratory
  - Conjugated bilirubin > 1mg/dL
  - Fat soluble vitamin deficiency otherwise unexplainable
  - Gamma-glutamyl transferase > 3x the upper limit of normal
  - Intractable pruritus explainable only by liver disease

- The member must not have a history of liver transplant or decompensated cirrhosis.
- The member must not have history of biliary diversion surgery within the past 6 months.
- The member must have failed at least a 3-month trial of both of the following, as evidenced by paid claims or pharmacy printouts:
  - Ursodiol
  - agents to treat pruritis: cholestyramine, rifampin, antihistamines
- Bylvay Only:
  - ALGS:
    - Genetic testing confirms pathogenic variant (e.g., *JAG1* and *NOTCH2).*
    - The member has had a 6-month trial with Livmarli.
  - PFIC:
    - Genetic testing confirms pathogenic variant (e.g., *ATP8B1, ABCB11, ABCB4, TJP2, NR1H4, and MYO5B*).
    - Genetic testing does not indicate PFIC Type 2 with *ABCB11* variants that predict complete absence of BSEP-3 protein.
- Livmarli Only:
  - Genetic testing confirms pathogenic variant of *JAG1* or *NOTCH1*

Renewal Criteria – Approval Duration: 12 months
- The member has experienced an improvement in pruritis, as evidenced by clinical documentation.
- The member must have experienced a reduction in serum bilirubin < 6.5mg/dL and bile acids < 200 micromol/L

Clostridioides difficile-associated diarrhea (CDAD)

Prevention

Fecal Microbiota

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
REBYOTA (fecal microbiota, live–jslm) SUSPENSION *– Medical Billing Only*	
VOWST (fecal microbiota spores, live-brpk) CAPSULE	

Monoclonal Antibody

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ZINPLAVA (bezlotaoxumab) *– Medical Billing Only*	

Electronic Duration Verification:

- Vowst is payable every 6 months.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months
- The member has one of the following (1 or 2):
  1. The member has had at least two episodes of diarrhea with a positive stool test for *C.difficile* toxin within the last year
  2. The member has had at least one previous episodes of diarrhea with a positive stool test for *C.difficile* toxin within the last year AND one of the following
     - *C. difficile* infection was severe (defined as ZAR score ≥ 2)
     - Member is immunocompromised

Treatment

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
DIFICID (fidaxomicin) 40 MG/ML SUSPENSION	FIRVANQ (vancomycin) SOLUTION
DIFICID (fidaxomicin) TABLET	VANCOCIN (vancomycin) CAPSULE
vancomycin capsule	
vancomycin solution	

Prior Authorization Criteria

Initial Criteria – Approval Duration: 1 month

5. See Preferred Dosage Form Criteria

Crohn's Disease

Biologic Agents

α4 Integrin Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	TYSABRI (natalizumab) – *Medical Billing Only*

++ Clinically Non-Preferred: Tysabri is associated with a risk of developing progressive multifocal leukoencephalopathy (PML), a rare, potentially fatal neurologic disease caused by reactivation of JC virus (JCV) infection.

A4β7 Integrin Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	ENTYVIO (vedolizumab) – *Medical Billing Only*

Janus Kinase (JAK) Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	RINVOQ ER (upadacitinib)

Interleukin (IL) 12/IL-23 Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	STELARA (ustekinumab)
	STELARA (ustekinumab) – *IV Induction Medical Billing Only*
	WEZLANA (ustekinumab-auub)
	WEZLANA (ustekinumab-auub) – *IV Induction Medical Billing Only*

Interleukin (IL)-23p19 Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	SKYRIZI (risankizumab-rzaa)
	SKYRIZI (risankizumab-rzaa) – *IV Induction Medical Billing Only*

TNF Inhibitors

Adalimumab

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ABRILADA (adalimumab-afzb)	adalimumab-aacf
adalimumab-adbm – labeler 00597	adalimumab-aaty
adalimumab-fkjp	adalimumab-adaz
CYLTEZO (adalimumab-abdm)	adalimumab-adbm – labeler 82009
HADLIMA (adalimumab-bwwd)	adalimumab-ryvk
HULIO (adalimumab-fkjp)	AMJEVITA (adalimumab-atto)
HUMIRA (adalimumab)	HYRIMOZ (adalimumab-adaz)
SIMLANDI (adalimumab-ryvk)	IDACIO (adalimumab-aacf)
YUSIMRY (adalimumab-aqvh)	YUFLYMA (adalimumab-aaty)

Infliximab

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AVSOLA (infliximab-axxq) – *Medical Billing Only*	INFLECTRA (infliximab-dyyb) – *Medical Billing Only*
RENFLEXIS (infliximab-abda) – *Medical Billing Only*	infliximab – *Medical Billing Only*
	REMICADE (infliximab) – *Medical Billing Only*
	ZYMFENTRA (infliximab-dyyb)

Other TNF

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	CIMZIA (certolizumab) SYRINGE
	CIMZIA (certolizumab) VIAL – *Medical Billing Only*

Electronic Diagnosis Verification

- Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must have failed a 3-month trial of a TNF inhibitor, as evidenced by paid claims or pharmacy printouts:

Stelara and Wezlana Only:

- The member has failed a 3-month trial of an TNF inhibitor, Rinvoq ER, Entyvio and Skyrizi, as evidenced by paid claims or printouts.

Tysabri Only:

- The requested medication must be prescribed by, or in consult with, an gastroenterologist

Non-Preferred Biosimilars Only:

- See Biosimilar Agents criteria

Constipation

Therapeutic Duplication

- One medication is allowed at a time.

Chronic Idiopathic Constipation

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
LINZESS (linaclotide)	AMITIZA (lubiprostone)
lubiprostone	MOTEGRITY (prucalopride)
TRULANCE (plecanatide)	

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- Motegrity:
  1. The member must have had a 30-day trial with each of the following, as evidenced by paid claims or pharmacy printouts:
     - Linzess or Trulance
     - lubiprostone

Functional Constipation

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
LINZESS (linaclotide) 72 mcg	

Irritable Bowel Syndrome with Constipation (IBS-C)

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
LINZESS (linaclotide)	AMITIZA (lubiprostone)
lubiprostone	IBSRELA (tenapanor)
TRULANCE (plecanatide)	XPHOZAH (tenapanor)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- Ibsrela Only:
  a. The member must have had a 30-day trial with each of the following, as evidenced by paid claims or pharmacy printouts:
     - Linzess or Trulance
     - lubiprostone for members assigned female at birth
- Xphozah Only:
  a. The member must have had a 30-day trial with each of the following, as evidenced by paid claims or pharmacy printouts:
     - Linzess or Trulance
     - lubiprostone for members assigned female at birth
     - Ibsrela

Opioid-Induced Constipation

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
lubiprostone	AMITIZA (lubiprostone)
MOVANTIK (naloxegol)	RELISTOR (methylnaltrexone) TABLET
RELISTOR (methylnaltrexone) SYRINGE	
RELISTOR (methylnaltrexone) VIAL	
SYMPROIC (naldemedine)	

Electronic Concurrent Medications Required

- A total of 28 days of opioid analgesics must be paid within 40 days prior to requested Movantik, Symproic, or Relistor's date of service.
  - Medications indicated for opioid-induced constipation should be discontinued when opioids are stopped.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

a. The member must have had a 30-day trial with each of the following, as evidenced by paid claims or pharmacy printouts:
   - Movantik
   - Symproic

Diarrhea

Irritable Bowel Syndrome

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
antispasmotic (e.g., dicyclomine, hyoscyamine)	alosetron
loperamide	VIBERZI (eluxadoline)
LOTRONEX (alosetron) – *Brand Required*	XIFAXAN (rifaximin) 550 mg tablet
tricyclic antidepressants (e.g., amitriptyline)	

Electronic Diagnosis Verification

- Xifaxan: Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale

Electronic Concurrent Medications Required

- Xifaxan does not require prior authorization for hepatic encephalopathy if used concurrently with lactulose
  - A total of 30 days of lactulose must be paid within 65 days prior to Xifaxan's date of service
  - An override may be available after an adequate trial of lactulose where lactulose is not tolerated

Prior Authorization Criteria

Initial Criteria – Approval Duration: 3 months

- Infectious and medication-induced etiologies of diarrhea must have been ruled out.
- The member must have failed a 30-day trial of a product in each preferred class, as evidenced by paid claims or pharmacy printouts.

HIV / AIDS

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
antimotility agent (e.g., loperamide, diphenoxylate/atropine)	MYTESI (crofelemer)
octreotide	

Prior Authorization Criteria

Initial Criteria – Approval Duration: 3 months

- Infectious and medication-induced etiologies of diarrhea must have been ruled out.

- The member must have failed a 30-day trial of an agent in each preferred class, as evidenced by paid claims or pharmacy printouts.

Digestive Enzymes

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
CREON (lipase/protease/amylase)	PERTZYE (lipase/protease/amylase)
ZENPEP (lipase/protease/amylase)	VIOKACE (lipase/protease/amylase)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months
- A 30-day trial of all preferred agents will be required before a non-preferred agent will be authorized unless member stable on a pancreatic enzyme written by a gastroenterologist or pancreas disease specialist.

Eosinophilic Esophagitis

CLINICAL PA REQUIRED
DUPIXENT (dupilumab)

Prior Authorization Criteria

Prior Authorization Form – Eosinophilic Esophagitis

Initial Criteria – Approval Duration: 6 months
- The requested medication must be prescribed by, or in consult with, a gastroenterologist.
- The member must have ≥15 intraepithelial eosinophils per high-power field (eos/hpf).
- The member must have failed a 3-month trial of a swallowed inhaled respiratory corticosteroid (budesonide or fluticasone).

Renewal Criteria – Approval Duration: 12 months
- The member has achieved a significant reduction in dysphagia symptoms since treatment initiation.
- The member must have achieved an esophageal intraepithelial eosinophil count of ≤6 eos/hp.

Ulcerative Colitis

Biologic Agents

α4β7 Integrin Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	ENTYVIO (vedolizumab)
	ENTYVIO (vedolizumab) – *Medical Billing Only*

Interleukin (IL)-23p19 Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	OMVOH (mirikizumab)
	OMVOH (mirikizumab) *– IV Induction Medical Billing Only*
	SKYRIZI (risankizumab-rzaa)
	SKYRIZI (risankizumab-rzaa) *– IV Induction Medical Billing Only*

Interleukin (IL) 12/IL-23 Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	STELARA (ustekinumab)
	STELARA (ustekinumab) *– IV Induction Medical Billing Only*
	WEZLANA (ustekinumab-auub)
	WEZLANA (ustekinumab-auub) *– IV Induction Medical Billing Only*

Interleukin (IL)-23p19 Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	TREMFYA (guselkumab) – *Medical Billing Only*
	TREMFYA (guselkumab)

TNF Inhibitors

Adalimumab

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ABRILADA (adalimumab-afzb)	adalimumab-aacf
adalimumab-adbm – labeler 00597	adalimumab-aaty
adalimumab-fkjp	adalimumab-adaz
CYLTEZO (adalimumab-abdm)	adalimumab-adbm – labeler 82009
HADLIMA (adalimumab-bwwd)	adalimumab-ryvk
HULIO (adalimumab-fkjp)	AMJEVITA (adalimumab-atto)
HUMIRA (adalimumab)	HYRIMOZ (adalimumab-adaz)
SIMLANDI (adalimumab-ryvk)	IDACIO (adalimumab-aacf)
YUSIMRY (adalimumab-aqvh)	YUFLYMA (adalimumab-aaty)

Infliximab

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AVSOLA (infliximab-axxq) – *Medical Billing Only*	INFLECTRA (infliximab-dyyb) – *Medical Billing Only*
RENFLEXIS (infliximab-abda) – *Medical Billing Only*	infliximab – *Medical Billing Only*
	REMICADE (infliximab) – *Medical Billing Only*

Other TNF

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
SIMPONI (golimumab)	

Electronic Diagnosis Verification

- Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The requested medication must be prescribed by, or in consult with, a gastroenterologist.
- Non-Preferred Biosimilars Only: See Biosimilar Agents criteria
- Entyvio Only: The member must have failed a 3-month trial of a TNF inhibitor, as evidenced by paid claims or pharmacy printouts.

- Skyrizi and Tremfya Only: The member must have failed a 3-month trial of a TNF inhibitor and Entyvio, as evidenced by paid claims or pharmacy printouts.
- Omvoh, Stelara, and Wezlana Only: The member must have failed a 3-month trial of a TNF inhibitor, Entyvio, and Skyrizi, as evidenced by paid claims or pharmacy printouts.

5-Aminosalicylic Acid (5-ASA)

Oral

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
APRISO ER (mesalamine) CAPSULE – *Brand Required*	AZULFIDINE (sulfasalazine)
balsalazide capsule	AZULFIDINE ENTAB (sulfasalazine)
DIPENTUM (olsalazine)	COLAZAL (balsalazide)
mesalamine 1.2 mg DR tablet	LIALDA (mesalamine) TABLET
PENTASA (mesalamine) – *Brand Required*	mesalamine ER 375 mg, 500 mg ER capsule
sulfasalazine DR tablet	mesalamine 400 mg DR capsule, 800 mg DR tablet
sulfasalazine tablet	

Topical

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
hydrocortisone enema	budesonide rectal foam
mesalamine enema	CANASA (mesalamine) SUPPOSITORY
mesalamine rectal suppository	mesalamine enema kit
	ROWASA (mesalamine) ENEMA KIT
	SF ROWASA (mesalamine) ENEMA
	UCERIS (budesonide) RECTAL FOAM

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must have failed a 3-month trial of mesalamine, as evidenced by paid claims or pharmacy printouts.
- Mesalamine HD: See Preferred Dosage Form criteria

Janus Kinase (JAK) Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
XELJANZ IR (tofacitinib) 5 mg, oral solution	RINVOQ ER (upadacitinib)
	XELJANZ IR (tofacitinib) 10 mg
	XELJANZ XR (tofacitinib)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- Xeljanz IR 10 mg, Xeljanz XR Only: See Preferred Dosage Form criteria
- Rinvoq ER Only:
  - The member must have failed a 3-month trial of a TNF inhibitor and a 30-day trial of Xeljanz, as evidenced by paid claims or pharmacy printouts.

Sphingosine 1-Phosphate (S1P) Receptor Modulator

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	VELSIPITY (etrasimod)
	ZEPOSIA (ozanimod)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must have had a 3-month trial of a TNF inhibitor, and 30-day trials of Xeljanz and Rinvoq ER as evidenced by paid claims or pharmacy printouts.

Wilson's Disease

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
CUPRIMINE (penicillamine) CAPSULE – *Brand Required*	CUVRIOR (trientine tetrahydrochloride)
DEPEN (penicillamine) TITRATAB – *Brand Required*	penicillamine capsule
trientine hydrochloride 250 mg	penicillamine tablet
	SYPRINE (trientine hydrochloride)
	trientine hydrochloride 500 mg

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- See Preferred Dosage Form Criteria

Genetic and Rare Disease

Amyloidosis

RNA – targeted therapies

TTR-specific small interfering RNA (siRNA)

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ONPATTRO (patisiran) – *Medical Billing Only*	

Transhyretin-directed small interfering RNA (siRNA)

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AMVUTTRA (vutrisiran) – *Medical Billing Only*	

Antisense Oligonucleotide (ASO)

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
TEGSEDI (inotersen)	
WAINUA (eplontersen)	

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a neurologist, geneticist, or specialist in the treatment of amyloidosis.
- The diagnosis must be confirmed by both of the following:
  - Genetic testing confirming a pathogenic TTR mutation (e.g., V30M)
  - Amyloid deposits via tissue biopsy
- Documentation of one of the following must be provided:
  - Baseline polyneuropathy disability (PND) score ≤ IIIb
  - Baseline Coutinho staging system stage 1 or 2
  - Baseline Neuropathy Impairment Score [NIS] of 5–130
  - Karnofsky Performance Status score of ≥60%
- The member has not had a liver transplant.
- The member has clinical signs and symptoms of the disease (e.g., peripheral neuropathy, numbness, altered pain and temperature sensation, decreased pinprick sensation)
- The member is not receiving any other TTR reducing agent (i.e., vutrisiran, patisiran, tafamidis, inotersen, eplontersen).

Renewal Criteria – Approval Duration: 12 months

- Documentation of a therapeutic response as evidenced by stabilization or improvement (e.g., improved neurologic impairment, motor function, quality of life, slowing of disease progression, etc.) from baseline in one of the following:
  - PND score ≤ IIIb
  - Coutinho staging system stage 1 or 2
  - Baseline Neuropathy Impairment Score [NIS] of 5–130

Karnofsky Performance Status score of ≥60%

TTR Stabilizers

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
VYNDAQEL (tafamidis)	
VYNDAMAX (tafamidis)	

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a cardiologist, geneticist, or specialist in the treatment of amyloidosis.
- Documentation of confirmation of the diagnosis by both of the following must be provided:
  - genetic testing confirming a pathogenic TTR mutation (e.g., V30M)
  - amyloid deposits via tissue biopsy
- The member must have heart failure class I or II with at least 1 prior hospitalization for heart failure or with symptoms of volume overload or elevated intracardiac pressures (e.g., elevated jugular venous pressure, shortness of breath or signs of pulmonary congestion on x-ray or auscultation, peripheral edema) despite 6-months of adherent use of a diuretic.
- The member has an end-diastolic interventricular septal wall thickness of at least 12 mm.
- The member must not have any of the following:
  - NYHA class IV symptoms or severe aortic stenosis
  - Previous heart transplant or implanted cardiac mechanical assist device
  - Previous liver transplant
- Documentation of baseline 6MWT > 100 meters must be submitted.
- The member is not receiving any other TTR reducing agent (i.e., vutrisiran, patisiran, tafamidis, inotersen)

Renewal Criteria – Approval Duration: 12 months

- Documentation of a therapeutic response as evidenced by stabilization or improvement from baseline in both of the following:
  - 6MWT > 100 meters
  - NYHA class

Late Infantile Neuronal Ceroid Lipofuscinosis Type 2 (CLN2)

CLINICAL PA REQUIRED
BRINEURA (cerliponase alfa) – *Medical Billing Only*

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- The member must be between 3 and 8 years of age.
- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a metabolic specialist, geneticist, or pediatric neurologist.
- Documentation of the diagnosis must be submitted, as evidenced by the following:
  - Molecular analysis that has detected two pathogenic variants/mutations in the TPP1/CLN2 gene.
  - An enzyme assay confirming deficiency of tripeptidyl peptidase 1 (TPP1)
- The member must not have ventriculoperitoneal shunts
- Baseline results of motor and language domains of the Hamburg CLN2 Clinical Rating Scale must be submitted and meet the following parameters:
  - Results must show a combined score of less than 6 in the motor and language domains.
  - Results must show a score of at least 1 in each of these domains.

Renewal Criteria – Approval Duration: 12 months

- The member must not have acute, unresolved localized infection on or around the device insertion site or suspected or confirmed CNS infection.
- The member maintains at a score of at least 1 in the motor domain on the Hamburg CLN2 Clinical Rating Scale
- The member has responded to therapy compared to pretreatment baseline with stability/lack of decline* in motor function/milestones.

  ** Decline is defined as having an unreversed (sustained) 2-category decline or an unreversed score of 0 in the Motor domain of the CLN2 Clinical Rating Scale*

References:

1. Ando Y, Coelho T, Berk JL, Cruz MW, Ericzon BG, Ikeda S, Lewis WD, Obici L, Planté-Bordeneuve V, Rapezzi C, Said G, Salvi F. Guideline of transthyretin-related hereditary amyloidosis for clinicians. Orphanet J Rare Dis. 2013 Feb 20;8:31. doi: 10.1186/1750-1172-8-31. PMID: 23425518; PMCID: PMC3584981.

Fabry Disease

Alpha-Galactosidase A Pharmacological Chaperone

PREFERRED AGENTS (CLINICAL PA REQUIRED)
GALAFOLD (migalastat)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- The requested medication must be prescribed by, or in consult with, a metabolic specialist, geneticist, cardiologist, or specialist in Fabry disease.
- The member must be assigned male at birth.
- Baseline value for plasma or urinary globotriosylceramide (GL-3) levels ≥ 5 ng/mcL or GL-3 inclusions ≥ 0.3 per kidney interstitial capillary (KIC) as measured in kidney biopsy.
- The member's diagnosis must be confirmed to be caused by a pathologic galactosidase alpha gene (GLA) variant that is amenable to treatment with Galafold interpreted from a clinical geneticist professional, as evidenced by medical documentation attached to the request.
- The medication must not be used in conjunction with enzyme replacement therapy.
- The member must not have significant renal impairment (eGFR <30 mL/minute/1.73 m2)

Renewal Criteria – Approval Duration: 12 months

- The member must have a decreased Gb3 level or Cb3 inclusion per KIC level and experienced and maintained improvement in one of the following symptoms since starting treatment with requested product, as evidenced by medical documentation (e.g., chart notes) attached to the request (subject to clinical review):
  - Acroparesthesias (burning pain in the extremities)
  - Angiokeratomas (cutaneous vascular lesions)
  - Hypo- or anhidrosis (diminished perspiration)
  - Corneal and lenticular opacities
  - Left ventricular hypertrophy (LVH), hypertrophic cardiomyopathy, or arrythmia of unknown etiology
  - Chronic kidney disease (CKD), multiple renal cysts, and/or proteinuria of unknown etiology

Enzyme Replacement Therapy

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
FABRAZYME (agalsidase beta) *– Medical Billing Only*	ELFABRIO (pegunigalsidase alfa) *– Medical Billing Only*

Initial Criteria – Approval Duration: 6 months

- The requested medication must be prescribed by, or in consult with, a metabolic specialist, geneticist, cardiologist, or specialist in Fabry disease.
- The member will not be concurrently treated with Galafold (migalastat)
- The member must have a diagnosis of Fabry disease with the one of the following (as evidenced with submitted documentation):
  - In males assigned at birth:
    - Deficiency of less than 35% of mean normal alpha-galactosidase A (α-Gal A) enzyme activity
    - Diagnosis is confirmed to be caused by a pathologic galactosidase alpha gene (GLA)
  - In females assigned at birth and males assigned at birth with α-Gal A enzyme activity > 35 percent:
    - Diagnosis must be confirmed to be caused by a pathologic galactosidase alpha gene (GLA)
    - Baseline value for plasma or urinary globotriosylceramide (GL-3) levels ≥ 5 ng/mcL or GL-3 inclusions ≥ 0.3 per kidney interstitial capillary (KIC) as measured in kidney biopsy
    - The member is experiencing one of the following symptoms:
      - Acroparesthesias (burning pain in the extremities)
      - Angiokeratomas (cutaneous vascular lesions)
      - Hypo- or anhidrosis (diminished perspiration)
      - Corneal and lenticular opacities
      - Left ventricular hypertrophy (LVH), hypertrophic cardiomyopathy, or arrythmia of unknown etiology
      - Chronic kidney disease (CKD), multiple renal cysts, and/or proteinuria of unknown etiology

Non-Preferred Agent Criteria:

- The member must have failed a trial of each of the preferred products, as evidenced by paid claims or pharmacy printouts
- Please provide explanation with the request why the preferred agent cannot be used (subject to clinical review)

Renewal Criteria – Approval Duration: 12 months

- The member must have a decreased Gb3 level or Cb3 inclusion per KIC level and experienced and maintained improvement in one of the following symptoms since starting treatment with requested product, as evidenced by medical documentation (e.g., chart notes) attached to the request (subject to clinical review):
  - Acroparesthesias (burning pain in the extremities)
  - Angiokeratomas (cutaneous vascular lesions)
  - Hypo- or anhidrosis (diminished perspiration)
  - Corneal and lenticular opacities
  - Left ventricular hypertrophy (LVH), hypertrophic cardiomyopathy, or arrythmia of unknown etiology
  - Chronic kidney disease (CKD), multiple renal cysts, and/or proteinuria of unknown etiology

Gaucher's Disease

Enzyme Replacement Therapy

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ELELYSO (taliglucerase alfa) – *Medical Billing Only*	CEREZYME (imiglucerase) – *Medical Billing Only*
	VPRIV (velaglucerase alfa) – *Medical Billing Only*

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a geneticist, an endocrinologist, or a physician who specializes in the treatment of lysosomal storage disorders.
- The member must have a diagnosis of Gaucher disease Type I or Type III with the one of the following (as evidenced with submitted documentation):
  - Deficiency in beta-glucocerebrosidase enzyme activity in peripheral leukocytes
  - Genetic testing confirming biallelic pathogenic variants in the GBA1 gene
- The member must be experiencing one or more of the following (as evidenced with submitted documentation):
  - Anemia with hemoglobin less than or equal to the laboratory reported low for patient age and gender
  - Thrombocytopenia with platelet count less than 100,000/mm^3
  - Bone disease (T-score below -1.0 [DXA], height SDS <-2.25 with decreased growth velocity, bone crisis)
  - Hepatomegaly (liver size 1.25 or more times normal)
  - Splenomegaly (spleen size five (5) or more times normal)

Non-Preferred Agent Criteria:

- Please provide explanation with the request why the preferred agent cannot be used (subject to clinical review)

Renewal Criteria – Approval Duration: 12 months

- Documentation has been submitted that member has experienced a disease stability or beneficial response to therapy from baseline as shown by one or more of the following:
  - Reduction in liver volume to normal size or by 10%
  - Reduction in spleen volume by 15%
  - Increase in hemoglobin levels by 1 g/dL
  - Increase in platelet levels by 15%
  - Increased T-score [DXA] by 0.3, normalized growth velocity, or decrease in bone crisis

Substrate Replacement Therapy

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ZAVESCA (miglustat) – *Brand Required*	miglustat
PREFERRED AGENTS (CLINICAL PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**
CERDELGA (eliglustat)	

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- Cerdelga: See Medications that cost over $3000/month criteria

Lysosomal Acid Lipase (LAL) deficiency

CLINICAL PA REQUIRED
KANUMA (sebelipase alfa) – *Medical Billing Only*

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a specialist in the treatment of lysosomal acid lipase (LAL) such as a lipidologist, endocrinologist, cardiologist, or hepatologist.
- Documentation of the member's diagnosis must be submitted, as evidenced by the following:
  - Genetic testing confirming 2 mutations in the LIPA gene
  - Deficiency of the LAL in peripheral blood leukocytes, fibroblasts, or dried blood spots

Renewal Criteria – Approval Duration: 12 months

- The member must have experienced and maintained clinical benefit since starting treatment with the requested medication, as evidenced by medical documentation (e.g., chart notes) attached to the request (subject to clinical review) including improvement in weight for age Z-scores for individuals with growth failure, improved LDL, HDL, AST, ALT and/or triglycerides.

Alpha-Mannosidosis

CLINICAL PA REQUIRED
LAMZEDE (velmanase alfa-tycv) – *Medical Billing Only*

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- Documentation of the member's diagnosis must be submitted, as evidenced by one of the following:

- Deficiency of alpha-mannosidase activity in leukocytes or fibroblasts < 10% of normal activity
- Detection of biallelic pathogenic variants in the *MAN2B1* gene by molecular genetic testing

- The requested medication must be prescribed by, or in consult with, a specialist in lysosomal storage diseases
- Documentation of all of the following must be submitted:
  - Non-central nervous system manifestations (e.g., progressive motor function disturbances, physical disability, hearing and speech impairment, skeletal abnormalities, and immune deficiency)
  - Elevated level of serum oligosaccharide concentration, as defined by being above the upper limit of normal by the laboratory reference range
  - If 6 years of age or older, must be able to walk without support
  - Motor function as measured by one of the following:
    - 6-minute walk test (6-MWT) for 4 years of age and older
    - 2-minute walk test (2-MWT) for under 4 years of age
    - 3-minute stair climb test
    - Forced Vital Capacity (FVC) via Pulmonary Function Test

Renewal Criteria – Approval Duration: 12 months

- The member must have experienced meaningful clinical benefit since starting treatment with the requested medication, as evidenced in medical documentation (e.g., chart notes) attached to the request (subject to clinical review) by both of the following:
  - Reduction in serum oligosaccharide concentration
  - Stability or improvement in the one of the following scores and symptoms:
    - 6-MWT for 4 years of age and older
    - 2-MWT for under 4 years of age
    - 3-minute stair climb test
    - FVC via Pulmonary Function Test

Mucopolysaccharidosis I (MPS I)

CLINICAL PA REQUIRED
ALDURAZYME (laronidase) – *Medical Billing Only*

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, an expert in lysosomal storage diseases.
- Documentation of the member's diagnosis must be submitted, as evidenced by the following:
  - Genetic testing confirming biallelic pathogenic mutations in the IDUA gene
  - Deficiency in activity of the lysosomal enzyme α-L-iduronidase (IDUA) in fibroblast or leukocyte
- Documentation of the member's current motor function must be submitted, as evidenced by scores from the following assessments:
  - 6-minute walk test (6MWT)
  - Forced Vital Capacity (FVC) via Pulmonary Function Test

Renewal Criteria – Approval Duration: 12 months

- The member must have experienced and maintained clinical benefit since starting treatment with the requested medication, as evidenced by medical documentation (e.g., chart notes) attached to the request (subject to clinical review) including improvement in the following scores and symptoms:
  - 6-minute walk test (6MWT)
  - Forced Vital Capacity (FVC) via Pulmonary Function Test

Mucopolysaccharidosis II (MPS II) – Hunter Syndrome

CLINICAL PA REQUIRED
ELAPRASE (idursulfase) – *Medical Billing Only*

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- Documentation of the member's diagnosis must be submitted, as evidenced by the following:
  - Deficiency in iduronate-2sulfatase (I2S) enzyme activity in white cells, fibroblasts, or plasma in the presence of normal activity of at least one other sulfatase
  - Genetic testing confirming pathogenic mutations in the IDS gene
- The requested medication must be prescribed by, or in consult with, an expert in lysosomal storage diseases.
- The member does not have severe cognitive or neurologic impairment (e.g., inability to swallow)
- Documentation of one of the following must be submitted:
  - The Forced Vital Capacity (FVC) via Pulmonary Function Test
  - Urinary glycosaminoglycan (uGAG) levels are elevated defined by laboratory reference range
  - 6-minute walk test (6MWT)
  - Hepatomegaly (liver size 1.25 or more times normal)
  - Splenomegaly (spleen size five (5) or more times normal)

Renewal Criteria – Approval Duration: 12 months

- Documentation must be submitted confirming improvement of one of the following:
  - The Forced Vital Capacity (FVC) via Pulmonary Function Test relative improvement of 10% over baseline
  - Urinary glycosaminoglycan (uGAG) levels normalization defined by laboratory reference range
  - 6-minute walk test (6MWT) increase
  - Reduction in liver volume to normal size or by 10%
  - Reduction in spleen volume by 15%

Mucopolysaccharidosis IVA (MPS IVA) – Morquio A syndrome

CLINICAL PA REQUIRED
VIMIZIM (elosulfase alfa) – *Medical Billing Only*

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- Documentation of the member's diagnosis must be submitted, as evidenced by the following:
  - Genetic testing confirming biallelic pathogenic mutations in the GALNS gene
  - Deficiency in activity of the n N-acetylgalactosamine 6-sulfatase (GALNS) enzyme
- The requested medication must be prescribed by, or in consult with, a geneticist, metabolic specialist, or specialist in mucopolysaccharidoses (MPS)
- The member is experiencing musculoskeletal signs and symptoms of MSP-IVA such as knee deformity, kyphosis, hip dysplasia, arthralgia, etc.
- Documentation of one of the following must be submitted:
  - Forced Vital Capacity (FVC) via Pulmonary Function Test
  - 6-minute walk test (6MWT)

- 3-minute stair climb test (3-MSCT)

Renewal Criteria – Approval Duration: 12 months

- The member must have experienced and maintained clinical benefit since starting treatment with the requested medication, as evidenced by medical documentation (e.g., chart notes) attached to the request (subject to clinical review) by one of the following scores:
  - Forced Vital Capacity (FVC) via Pulmonary Function Test
  - 6-minute walk test (6MWT)
  - 3-minute stair climb test (3-MSCT)
  - Reduced Urine Keratan Sulfate (KS) levels

Mucopolysaccharidosis VI (MPS VI) – Maroteaux-Lamy syndrome

CLINICAL PA REQUIRED
NAGLAZYME (galsulfase) – *Medical Billing Only*

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- Documentation of the member's diagnosis must be submitted, as evidenced by the following:
  - Deficiency of N-acetylgalactosamine 4-sufatase (arylsulfatase B or ASB) enzyme activity of <10% of the lower limit of normal
  - Detection of pathogenic variants in the ARSB gene by molecular genetic testing
- The requested medication must be prescribed by, or in consult with, an expert in lysosomal storage diseases.
- Documentation of both of the following must be submitted:
  - Elevated level of urinary excretion of glycosaminoglycans (GAGs) such as chondroitin sulfate and dermatan sulfate, as defined by being above the upper limit of normal by the laboratory reference range
  - Motor function as measured by one of the following:
    - 6 or 12-minute walk test (6-MWT or 12-MWT)
    - 3-minute stair climb test
    - Forced Vital Capacity (FVC) via Pulmonary Function Test

Renewal Criteria – Approval Duration: 12 months

- The member must have experienced meaningful clinical benefit since starting treatment with the requested medication, as evidenced by medical documentation (e.g., chart notes) attached to the request (subject to clinical review) including improvement in the one of the following scores and symptoms:
  - Reduction in urinary excretion of glycosaminoglycans (GAGs)
  - Stability or improvement in 6 or 12-minute walk test (6-MWT or 12-MWT)
  - Stability or improvement in 3-minute stair climb test
  - Stability or improvement in Forced Vital Capacity (FVC) via Pulmonary Function Test

Mucopolysaccharidosis VII (MPS VII) – Sly Syndrome

CLINICAL PA REQUIRED
MEPSEVII (vestronidase alfa-vjbk) – *Medical Billing Only*

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)

- Documentation of the member's diagnosis must be submitted, as evidenced by the following:
  - Deficiency of beta-glucuronidase enzyme
  - Detection of pathogenic variants in the GUSB gene by molecular genetic testing.
- The requested medication must be prescribed by, or in consult with, an expert in lysosomal storage diseases.
- One or more of the following documentations must be submitted:
  - Skeletal abnormalities
  - Elevated level of urinary excretion of glycosaminoglycans (GAGs) such as chondroitin sulfate and dermatan sulfate, as defined by being above the upper limit of normal by the laboratory reference range
  - Liver and/or spleen volume
  - 6-minute walk test (6MWT)
  - Motor function test (e.g., Bruininks-Oseretsky Test of Motor Proficiency (BOT-2))
  - Forced Vital Capacity (FVC) via Pulmonary Function Test

Renewal Criteria – Approval Duration: 12 months

- The member must have experienced meaningful clinical benefit since starting treatment with the requested medication, as evidenced by medical documentation (e.g., chart notes) attached to the request (subject to clinical review) including improvement in the one of the following scores and symptoms:
  - Stability or improvement in skeletal abnormalities shown on x-ray, short stature, macrocephaly
  - Reduction in urinary excretion of glycosaminoglycans (GAGs)
  - Reduction in liver and/or spleen volume
  - Stability or improvement in 6-minute walk test (6MWT)
  - Stability or improvement in Forced Vital Capacity (FVC) via Pulmonary Function Test

Phenylketonuria

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
JAVYGTOR (sapropterin)	KUVAN (sapropterin)
sapropterin	PALYNZIQ (pegvaliase-pqpz)

Underutilization

- Sapropterin and Palynziq must be used adherently and will reject on point of sale for late fill

Prior Authorization Criteria

Prior Authorization Form – Phenylketonuria

Initial Criteria – Approval Duration: 2 months (sapropterin); 12 months (Palynziq)

- The member must have been compliant with a PHE restricted diet for past 6 months (documentation must be attached).
- The requested medication must be prescribed by, or in consult with, a geneticist or endocrinologist.
- Baseline PHE levels must meet one of the following:
  - For members of childbearing potential and children ≤ 12 years old: PHE levels must be above 360 µmoles/liter (6 mg/dL)
  - For members without childbearing potential, and children > 12 years old: PHE levels must be above 600 µmoles/liter 10 mg/dL)
- Sapropterin Only:
  - The member's weight must be provided. Requested initial dose must be 10 mg/kg
  - The member must not have two null mutations in trans
- Palynziq Only: One of the following must be met:

- PHE levels must be attached documenting the member was unable to achieve a PHE level less than 600 µmoles/liter (10 mg/dL) despite a 3-month trial of 20 mg/kg dose of sapropterin with good compliance, as evidenced by paid claims or pharmacy printouts.
- The member is known to have two null mutations in trans

Renewal Criteria:

- For same or reduced dose from previous trial:
  Approval Duration: 12 months – if dose is the same or less than previous trial
  - PHE level must be between 60 and 600 µmoles per liter
  - Sapropterin Only: The member's weight must be provided.

- For a dose increase from previous trial
  Approval Duration: 4 months – for a dose increase from previous trial
  - PHE level must be attached that were taken after previous trial (1 month for Kuvan, 4 months for Palynziq)
    - For members of childbearing potential and children ≤ 12 years old: PHE levels must be above 360 µmoles/liter (6mg/dL)
    - For members without childbearing potential, and children > 12 years old: PHE levels must be above 600 µmoles/liter 10mg/dL)
  - Sapropterin Only: The member's weight must be provided.

Pompe Disease

CLINICAL PA REQUIRED
LUMIZYME (alglucosidase alpha) – *Medical Billing Only*
NEXVIAZYME (avalglucosidase alfa-ngpt) – *Medical Billing Only*

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- Documentation of the member's diagnosis must be submitted, as evidenced by the following:
  - Deficiency of acid alpha-glucosidase enzyme activity (2% to 40% partial deficiency of GAA non-classic infantile forms or late onset forms) of the lab specific normal mean value
  - Detection of pathogenic variants in the GAA gene by molecular genetic testing.
- The requested medication must be prescribed by, or in consult with, a cardiologist, neurologist or geneticist or specialist in Pompe disease.
- The member must not have permanent invasive ventilation.
- Documentation must be submitted of the member's current motor function such as motor function, respiratory function, cardiac involvement (infantile onset) and scores from at least two of the following assessments:
  A. Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorder (CHOP-INTEND)
  B. Hammersmith Infant Neurological Examination (HINE) Section 2 motor milestone score
  C. Hammersmith Functional Motor Scale Expanded (HFMSE)
  D. Motor Function Measure – 32 items (MFM-32)
  E. Revised Upper Limb Module (RULM)
  F. 6-minute walk test (6MWT)
  G. Forced Vital Capacity (FVC) via Pulmonary Function Test

Renewal Criteria – Approval Duration: 12 months

- The member must have experienced and maintained clinical benefit since starting treatment with the requested medication, as evidenced by medical documentation (e.g., chart notes) attached to the request (subject to clinical review) including stabilization or improvement of the following:
  - Motor function, respiratory function, cardiac involvement (infantile onset)

- CHOP-INTEND, HINE, HFMSE, MFM-32, 6MWT, or RULM scores
- Forced Vital Capacity (FVC) via Pulmonary Function Test (ages 5 and older)

Urea Cycle Agents

Hyperammonemia

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
BUPHENYL (sodium phenylbutyrate) – *Brand Required*	sodium phenylbutyrate
PREFERRED AGENTS (CLINICAL PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**
PHEBURANE (sodium phenylbutyrate)	OLPRUVA (sodium phenylbutyrate)
	RAVICTI (glycerol phenylbutyrate)

N-acetylglutamate synthase (NAGS) deficiency

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
CARBAGLU (carglumic acid) – *Brand Required*	carglumic acid

Electronic Diagnosis Verification

- Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- See Medications that cost over $3000/month criteria.

Non-Preferred Agents Criteria:

- See Preferred Dosage Form criteria.
- *Ravicti Only:* The member is unable to tolerate sodium phenylbutyrate due to sodium content or GI distress.

Therapeutic Duplication

- One strength of one medication is allowed at a time.

Hematology/Oncology

Anemia

Disease-Modifying Agents

PREFERRED AGENTS (CLINICAL PA REQUIRED)
REBLOZYL (luspatercept) – *Medical Billing Only*

Initial Criteria – Approval Duration: 6 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a hematologist or oncologist, or prescriber specializing in the treatment of beta thalassemia or myelodysplastic syndrome/myeloproliferative neoplasm.
- The member must have a diagnosis of anemia due to beta thalassemia or myelodysplastic syndrome/myeloproliferative neoplasm with ring sideroblasts.

- Documentation must be submitted of a pretreatment hemoglobin of less than 11 g/dL.
- Other causes of anemia (e.g., hemolysis, bleeding, recent major surgery, vitamin deficiency, etc.) have been ruled out.
- Member must not have any of the following:
  - Deep vein thrombosis or stroke within the past 24 weeks
  - Platelet count greater than 1000 x 109 per liter

For anemia due to myelodysplastic syndrome/myeloproliferative neoplasm:
- Documentation must be submitted that the member requires 2 or more RBC units over an 8-week period as evidenced by the following:
  - One of the following:
    - Ring sideroblasts greater than or equal to 15%
    - Ring sideroblasts greater than or equal to 5% and less than 15% with an SF3B1 mutation
  - One of the following:
    - Serum erythropoietin greater than 500 mU/mL
    - Serum erythropoietin less than or equal to 500 mU/mL with inadequate response after a 3-month trial with a combination of an ESA (e.g., epoetin alfa) and granulocyte-colony stimulating factor (G-CSF)
  - Member has very low to intermediate risk disease defined as one of the following:
    - Revised International Prognostic Scoring System (IPSS-R); very low, low, or intermediate (Score of 0 to 4.5);
    - IPSS: low/intermediate-1 (Score 0 to 1)
    - WHO-Based Prognostic Scoring System (WPSS): WPSS: very low, low, or intermediate (Score 0 to 2)

For anemia due to beta thalassemia:
- No prior gene therapy
- No prior HSCT
- Documentation must be submitted confirming the following:
  - The member has required at least 6 red blood cell (RBC) transfusions in the previous 24 weeks.
  - The member has not had a transfusion-free period for ≥ 35 days during the most recent 24 weeks.

Renewal Criteria – Approval Duration: 12 months
- The member must have experienced stabilization, slowing of disease progression, or improvement of the condition since starting treatment with the requested medication, as evidenced by medical documentation (e.g., chart notes) attached to the request (subject to clinical review) including:
  - Reduction in transfusion requirements from pretreatment baseline achieving one of the following:
    - At least 2 units packed red blood cells
    - By one-half
    - Complete transfusions independence
- The member continues to have pretreatment hemoglobin of less than 11 g/dL.
- Dose will be increased to 1.25 mg/kg daily.

Cell-based Gene Therapy

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
CASGEVY (exagamglogene autotemcel) – *Medical Billing Only*	ZYNTEGLO (betibeglogene autotemcel) – *Medical Billing Only*

Initial Criteria – Approval Duration: 12 months
- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)

- The requested medication must be prescribed by, or in consult with, a hematologist or prescriber specializing in the treatment of beta thalassemia
- The member must have a transfusion-dependent beta thalassemia requiring one of the following:
  - At least 100 mL/kg/year of packed red blood cells (pRBCs) in the preceding 2 years
  - At least 8 transfusions of pRBCs per year in the preceding 2 years
- Other causes of anemia (e.g., hemolysis, bleeding, recent major surgery, vitamin deficiency, etc.) have been ruled out.
- Member must not have any of the following:
  - Prior receipt of gene therapy
  - Prior HSCT
  - Severely elevated iron in the heart as evidenced by any of the following:
    - Cardiac T2* < 10 msec by MRI
    - LVEF < 45%
  - Advanced liver disease as evidenced by any of the following:
    - AST or ALT > 3 times the upper limit of normal
    - Direct bilirubin value > 2.5 times the upper limit of normal
    - Liver iron content ≥ 15 mg/g (per MRI) with liver biopsy, VCTE, ELF, or MRE demonstrating bridging fibrosis or cirrhosis

Chelating Agents

Iron Chelators

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
deferasirox tablet for suspension	EXJADE (deferasirox tablet for suspension)
deferasirox tablet	deferasirox sprinkle
deferoxamine mesylate vial – *Medical Billing Only*	DESFERAL (deferoxamine) MESYLATE VIAL – *Medical Billing Only*
	FERRIPROX (deferiprone)
	JADENU (deferasirox) SPRINKLE
	JADENU (deferasirox) TABLET

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The member must have failed a trial duration of 30 days (or less if duration is FDA approved) of each preferred agent of a unique ingredient, as evidenced by paid claims or pharmacy printouts.
- Clinical justification must be provided explaining why the member is unable to use the preferred agents (subject to clinical review).

Cold Agglutin Disease (CAD)

Anti-B-cell Therapy

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
RIABNI (rituximab-arrx) – *Medical Billing Only*	RITUXAN (rituximab) – *Medical Billing Only*
RUXIENCE (rituximab-pvvr) – *Medical Billing Only*	
TRUXIMA (rituximab-abbs) – *Medical Billing Only*	

Anti-Complement Therapy

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	ENJAYMO (sutimlimab-jome) – *Medical Billing Only*

Initial Criteria – Approval Duration: 6 months

- The requested medication must be prescribed by, or in consult with, a hematologist or specialist in cold agglutinin disease (CAD)
- The member must have all of the following:
  - Evidence of chronic hemolysis (e.g., high lactated dehydrogenase [LDH], low haptoglobin, high reticulocyte count)
  - Direct antiglobin (Coombs) test is positive for C3d
  - Cold agglutinin titer ≥ 64 at 4°C
- Cold agglutinin syndrome secondary to other factors has been ruled out (e.g., infection, rheumatologic disease, systemic lupus erythematosus, or overt hematologic malignancy)
- The member has a baseline hemoglobin level ≤ 10 g/dL
- The member has a baseline bilirubin level above normal reference range of the reporting laboratory
- The member has one or more of the following symptoms:
  - Symptomatic anemia
  - Acrocyanosis
  - Raynaud's phenomenon
  - Hemoglobinuria
  - Disabling circulatory symptoms
  - Major adverse vascular event
- The member must have been unresponsive to previous rituximab-based therapy or one of the following must be documented:
  - Member has a medical reason why rituximab-based therapy is not appropriate or is contraindicated.
  - Member has severe anemia or acute exacerbations of hemolysis and needs a bridge therapy awaiting the effects of a rituximab-based therapy.
- Rituxan Only: See Biosimilar Agents Criteria

Renewal Criteria – Approval Duration: 12 months

- Documentation must be submitted that the member has had a beneficial response to therapy from baseline as shown by one or more of the following:
  - Decrease in transfusions from baseline
  - Increase in hemoglobin (Hgb) by ≥ 2 g/dL from baseline or Hgb level ≥ 12 g/dL
  - Normalization of bilirubin levels to less than 1.2 mg/dL
- Therapy continues to be necessary due to ongoing cold agglutinin production and inability to use rituximab.

Cytokine Release Syndrome

Interleukin (IL) -6 Receptor Inhibitors

Tocilizumab

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
TYENNE (tocilizumab-aazg) AUTOINJECTOR, SYRINGE	ACTEMRA (tocilizumab) ACTPEN, SYRINGE
TYENNE (tocilizumab-aazg) VIAL – *Medical Billing Only*	ACTEMRA (tocilizumab) VIAL – *Medical Billing Only*
	TOFIDENCE (tocilizumab-aazg) VIAL – *Medical Billing Only*

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- See Medications that cost over $3000/month criteria
- Non-preferred agents: See biosimilar agents criteria

Hemophagocytic Lymphohistiocytosis (HLH)

PREFERRED AGENTS (CLINICAL PA REQUIRED)
GAMIFANT (emapalumab-lzsg) – *Medical Billing Only*

Initial Criteria – Approval Duration: 3 months or up to the hematopoietic stem cell transplantation (HSCT) date

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a hematologist, oncologist, immunologist, or transplant specialist.
- The member has refractory, recurrent or progressive disease or intolerance with conventional HLH therapy (i.e., etoposide + dexamethasone, cyclosporine A, or Anti-thymocyte globulin)
- The member must be a candidate for stem cell transplant.
- Documentation must be submitted confirming the diagnosis, as evidenced by the following:
  - Confirmation of a gene mutation known to cause primary HLH (e.g., PRF1, UNC13D, STX11 RAB27A, STXBP2)
  - Confirmation of 5 of the following clinical characteristics:
    - Fever ≥ 101.3F for over 7 days
    - Splenomegaly
    - Two of the following cytopenias in the peripheral blood:
      - Hemoglobin < 9 g/dL (or < 10 g/dL in infants less than 4 weeks of age)
      - Platelet count < 100,000/microL
      - ANC <1000/microL
    - One of the following:
      - Hypertriglyceridemia defined as fasting triglycerides ≥ 265 mg/dL (2 mmol/L)
      - Hypofibrinogenemia defined as fibrinogen ≤ 1.5 g/L
    - Hemophagocytosis in bone marrow or spleen or lymph nodes with no evidence of malignancy
    - Low or absent natural killer cell activity
    - Ferritin ≥ 500 mg/L
    - Soluble CD25 (i.e., soluble IL-2 receptor) ≥ 2,400 U/mL
- The requested medication must be administered with dexamethasone as part of the induction or maintenance phase of stem cell transplant, which is to be discontinued at the initiation of conditioning for stem cell transplant.

Category Criteria (Renewal): *Approval Duration: 3 months or up to the HSCT date*

- At least 3 HLH abnormalities must be improved by at least 50% from baseline.

Hemophilia

Clotting Factor Products

Hemophilia A Prophylaxis

Factor VIII – Non-Extended Half Life

Plasma Derived

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)

HEMOFIL M (factor VIII plasma derived; mAb-purified)	
KOATE (factor VIII plasma derived, chromatography purified)	

First Generation – Recombinant

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	RECOMBINATE (factor VIII recombinant)

Second Generation – Recombinant

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
KOGENATE FS (factor VIII recombinant)	

Third Generation – Recombinant

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
NOVOEIGHT (factor VIII recombinant)	ADVATE (factor VIII recombinant)
KOVALTRY (factor VIII recombinant)	
XYNTHA (factor VIII recombinant)	
XYNTHA SOLOFUSE (factor VIII recombinant)	

Fourth Generation – Recombinant

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AFSTYLA (factor VIII recombinant, single chain)	
NUWIQ (factor VIII recombinant)	

Factor VIII Extended Half Life

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ADYNOVATE (factor VIII recombinant, PEGylated)	ELOCTATE (factor VIII recombinant, Fc fusion protein)
ALTUVIIIO (antihemophilic factor (recombinant), Fc-VWF-XTEN fusion protein-ehtl)	ESPEROCT (factor VIII recombinant, glycoPEGylated – exei)
JIVI (factor VIII recombinant, pegylated-aucl)	

Recombinant humanized bispecific monoclonal antibody

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
HEMLIBRA (emicizumab-kxwh)	

Factor VII deficiency or Hemophilia A and B with Inhibitors

Factor VIIa

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
NOVOSEVEN RT (coagulation Factor VIIa recombinant)	
SEVENFACT (coagulation Factor VIIa recombinant)	

B domain-deleted porcine – Recombinant

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
OBIZUR (recombinant, B domain-deleted porcine (pig) factor VIII)	

Hemophilia B Prophylaxis

Factor IX – Non-Extended Half Life

Plasma Derived

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ALPHANINE SD (factor IX, plasma-derived)	
MONONINE (factor IX, plasma-derived mAb purified)	

Recombinant

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
BENEFIX (factor IX recombinant)	
IXINITY (factor IX recombinant)	
RIXUBIS (factor IX recombinant)	

Factor IX – Extended Half Life

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ALPROLIX (factor IX recombinant, Fc fusion)	
IDELVION (factor IX recombinant, albumin fusion)	
REBINYN (factor IX recombinant, glycol-PEGylated)	

Prothrombin Complex Concentrates

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
FEIBA NF (Anti-Inhibitor coagulant complex)	
KCENTRA (hum prothrombin cplx(PCC)4fact)	
PROFILNINE (factor IX cplx(pcc)no4,3factor)	

Von Willebrand disease

Factor VIII/vWF

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ALPHANATE (antihemophilic factor/Von Willebrand Factor Complex (Human))	
HUMATE-P (factor VIII/von Willebrand Factor (human))	
WILATE (factor VIII/von Willebrand Factor (human))	

Von Willebrand Factor

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
VONVENDI (recombinant human vWF)	

Factor X Deficiency

Factor X – Plasma Derived

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
COAGADEX (coagulation factor X (human))	

Factor XIII Deficiency

Factor XIII – Plasma Derived

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
CORIFACT (factor XIII concentrate (human))	

Factor XIII A – Subunit, Recombinant

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
TRETTEN (Factor XIII A-Subunit, recombinant)	

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The date of the member's last appointment with a Hemophilia Treatment Center must be within the past year.
- The contact information for Hemophilia Treatment Center must be provided.

Non-Preferred Agents Criteria:

- Clinical justification must be provided explaining why the member is unable to use a preferred agent (subject to clinical review).
- The member may qualify for non-preferred product if they are stable on current therapy (have had a paid claim for requested therapy in the past 45 days)

Gene Therapy

PREFERRED AGENTS (CLINICAL PA REQUIRED)
BEQVEZ (fidanacogene elaparvovec-dzkt) – *Medical Benefit Only*
HEMGENIX (etranacogene dezaparvovec) – *Medical Benefit Only*

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The Medicaid Member must meet FDA-approved label for use
- The member has completed Factor IX inhibitor testing demonstrating the absence of a Factor IX inhibitor
- The member has completed liver health assessment including all of the following:
    - Enzyme testing [alanine aminotransferase (ALT), aspartate aminotransferase (AST), alkaline phosphatase (ALP) and total bilirubin
    - Hepatic ultrasound and elastography
    - In case of patients with either radiological liver abnormalities or sustained liver enzyme elevations, a consulting hepatologist has assessed the that the member is eligible to receive the gene therapy
- Beqvez Only:
    - The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
    - The requested medication must be prescribed by, or in consult with, a hematologist at a dose of 5 × 1011 vector genomes per kg (vg/kg) of body weight.
    - The date of the member's last appointment with a Hemophilia Treatment Center must be within the past year.
    - The contact information for Hemophilia Treatment Center must be provided.
    - The member was assigned male at birth.

- The member must currently be treated with routine Factor IX prophylaxis therapy for at least 12 months.
- The member must have had a life-threatening hemorrhage, or have repeated, serious spontaneous bleeding episodes.
- The member has had HIV testing that confirms that member does not have a CD4+ cell count <200 mm^3 or viral load ≥20 copies/mL
- Clinical justification must be provided why Hemgenix cannot be used (subject to clinical review)

Hematopoietic, Colony Stimulating Factors

Filgrastim

Medical Billing

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
GRANIX (TBO-filgrastim) – *Medical Billing Only*	NEUPOGEN (filgrastim) – *Medical Billing Only*
NIVESTYM (filgrastim-aafi) – *Medical Billing Only*	RELEUKO (filgrastim-ayow) – *Medical Billing Only*
ZARXIO (filgrastim-sndz) – *Medical Billing Only*	

Pharmacy Billing

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
NEUPOGEN (filgrastim)	GRANIX (TBO-filgrastim)
RELEUKO (filgrastim-ayow)	NIVESTYM (filgrastim-aafi)
	ZARXIO (filgrastim-sndz)

Pegfilgrastim

Medical Billing

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
NEULASTA (pegfilgrastim) – *Medical Billing Only*	FULPHILA (pegfilgrastrim-jmdb) – *Medical Billing Only*
NEULASTA ONPRO (pegfilgrastim) – *Medical Billing Only*	FYLNETRA (pegfilgrastim -pbbk) – *Medical Billing Only*
NYVEPRIA (pegfilgrastrim–apgf) – *Medical Billing Only*	STIMUFEND (pegfilgrastim-fpgk) – *Medical Billing Only*
UDENYCA ONBODY (pegfligrastim-cbqv) – *Medical Billing Only*	UDENYCA (pegfligrastim-cbqv) – *Medical Billing Only*
	ZIEXTENZO (pegfilgrastim-bmez) – *Medical Billing Only*
Pharmacy Billing**PREFERRED AGENTS (NO PA REQUIRED)**	**NON-PREFERRED AGENTS (PA REQUIRED)**
FULPHILA (pegfilgrastrim-jmdb)	NEULASTA (pegfilgrastim)
FYLNETRA (pegfilgrastim -pbbk)	NYVEPRIA (pegfilgrastim–apgf)
NEULASTA ONPRO (pegfilgrastim)	STIMUFEND (pegfilgrastim-fpgk)
UDENYCA ONBODY (pegfligrastim-cbqv)	UDENYCA (pegfligrastim-cbqv)
	ZIEXTENZO (pegfilgrastim-bmez)

Sargramostim

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
LEUKINE (sargramostim)	

LEUKINE (sargramostim) – *Medical Billing Only*	

Eflapegrastim-xnst

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	ROLVEDON (eflapegrastim-xnst)
	ROLVEDON (eflapegrastim-xnst) – *Medical Billing Only*

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- See Preferred Dosage Form criteria.

Nausea/Vomiting

Chemo-Induced

NK1 Receptor Antagonists

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
aprepitant tripack	AKYNZEO (netupitant/palonosetron) CAPSULE
EMEND (aprepitant) SUSPENSION	aprepitant capsules
	EMEND (aprepitant) 125 MG-80 MG CAPSULE TRIPACK
	EMEND (aprepitant) CAPSULES

5-HT3 Receptor Antagonists

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
granisetron tablet	AKYNZEO (netupitant/palonosetron) CAPSULE
granisetron vial – *Medical Billing Only*	SANCUSO (granisetron) PATCH
SUSTOL (granisetron) SYRINGE – *Medical Billing Only*	ZOFRAN (ondansetron)

Cannabinoids

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
dronabinol capsule	MARINOL (dronabinol) CAPSULE

Electronic Diagnosis Verification

- Dronabinol Only: Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months or until last day of chemotherapy

- The requested medication must be prescribed by, or in consult with, an oncologist.
- The member must be receiving a moderately or highly emetogenic chemotherapy.
- The final date of chemotherapy treatment must be provided with the request.

- The member must have failed a 3-day trial of each preferred product(s) in the same class within the last 6 months, as evidenced by paid claims or pharmacy printouts.
- The member must not have failed preferred chemical entity with same active ingredient as requested product due to side effects.

Paroxysmal Nocturnal Hemoglobinuria (PNH)

C5 inhibitors

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ULTOMIRIS (ravulizumab)	PIASKY (crovalimab-akkz) – *Medical Billing Only*
ULTOMIRIS (ravulizumab) – *Medical Billing Only*	SOLIRIS (eculizumab) – *Medical Billing Only*

C3 Inhibitors

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
EMPAVELI (pegcetacoplan)	

Factor B Inhibitors

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	FABHALTA (iptacopan)

Factor D Inhibitors

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	VOYDEYA (danicopan)

Prior Authorization Criteria

Prior Authorization Form – Paroxysmal Nocturnal Hemoglobinuria

Initial Criteria – Approval Duration: 6 months

- The requested medication must be prescribed by, or in consult with, a hematologist.
- Diagnosis must be confirmed by flow cytometry demonstrating that the member's peripheral blood cells are deficient in glycosylphosphatidylinositol (GPI) – linked proteins (e.g., CD55, CD59)
- One of the following criteria must be met (A or B):
  - The member has had at least 1 transfusion in the past 6 months
  - The member has symptoms of PNH (e.g., abdominal pain, anemia, shortness of breath, hemolysis, organ dysfunction, debilitating fatigue) and one of the following:
    - granulocyte PNH clone size > 10%
    - hemoglobin < 10 g/dL
    - LDH level of 1.5 times the upper limit of normal (must include at least 2 different reagents tested on at least 2 cell lineages)

Non-Preferred Agent Criteria:

Fabhalta Only:

- The member must have failed a 6-month trial with Empaveli, as evidenced by paid claims or printouts, with one of the following criteria being met (A or B):
  - The member has had at least 1 transfusion in the past 6 months
  - The member has symptoms of PNH (e.g., abdominal pain, anemia, shortness of breath, hemolysis, organ dysfunction, debilitating fatigue) and one of the following:
    - granulocyte PNH clone size > 10%

- hemoglobin < 10 g/dL
- LDH level of 1.5 times the upper limit of normal (must include at least 2 different reagents tested on at least 2 cell lineages)

Voydeya Only:
- The member must have failed a 6-month trial with Ultomiris, with at least one transfusion, persistent anemia (Hb < 9.5 g/dL) and absolute reticulocyte count ≥ 120 × 109 /L, as evidenced by paid claims or printouts.

Piasky and Soliris Only:
- The member must have failed a 6-month trial with Ultomiris with Voydeya, as evidenced by paid claims or printouts, with at least one transfusion, persistent anemia (Hb < 9.5 g/dL) and absolute reticulocyte count ≥ 120 × 109 /L, as evidenced by paid claims or printouts.

Renewal Criteria – Approval Duration: 12 months
- The member must have experienced meaningful clinical benefit since starting treatment with the requested medication, as evidenced by one of the following:
  - Member has not required transfusion in the past 6 months
  - Increase in hemoglobin by ≥ 2 g/dL from baseline
  - Normal LDH levels ≤ 280 U/L

Non-Preferred Agent Criteria:

Fabhalta Only:
- The member must have experienced one of the clinical benefit metrics defined in the renewal criteria that was not met with Empaveli.

Voydeya Only:
- The member must have experienced one of the clinical benefit metrics defined in the renewal criteria that was not met with Ultomiris.

Piasky and Soliris Only:
- The member must have experienced one of the clinical benefit metrics defined in the renewal criteria that was not met Ultomiris with Voydeya

References:

1. Parker, Charles J. “Update on the diagnosis and management of paroxysmal nocturnal hemoglobinuria.” Hematology 2014, the American Society of Hematology Education Program Book 2016.1 (2016): 208-216.

Plasminogen Deficiency Type 1 (Hypoplasminogenemia)

CLINICAL PA REQUIRED
RYPLAZIM (plasminogen, human-tvmh) – *Medical Billing Only*

Prior Authorization Criteria

Initial Criteria – Approval Duration: 3 months
- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a hematologist or specialist in treated condition

- Documentation of the diagnosis must be submitted, as evidenced by the following:
  - Baseline plasminogen activity level ≤ 45% *(If the patient is receiving plasminogen supplementation with fresh frozen plasma, allow for a 7-day washout period before obtaining baseline plasminogen activity level.)*
  - Documented history of lesions (e.g., ligneous conjunctivitis, ligneous gingivitis, occlusive hydrocephalus, abnormal wound healing)
  - Genetic testing to confirm biallelic pathogenic *PLG* mutation

Renewal Criteria – Approval Duration: 12 months, a one-time 6-month approval for dose adjustment allowed for members not meeting renewal criteria upon request

- The member must have experienced meaningful clinical benefit since starting treatment with the requested medication, as evidenced by medical documentation (e.g., chart notes) attached to the request (subject to clinical review) including the following:
  - The member has demonstrated a 50% resolution of lesions, with no active or recurrent lesions.
  - Trough plasminogen activity levels are >10% above baseline.

Sickle Cell Disease

Disease-Modifying Agents

First Line Agents

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
DROXIA (hydroxyurea) capsule	HYDREA (hydroxyurea) CAPSULE
hydroxyurea capsule	SIKLOS (hydroxyurea) tablet

Second Line Agents

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ENDARI (glutamine) – *Brand Required*	+ADAKVEO (crizanlizumab-tmca) – *Medical Billing Only*
	L-glutamine

+ Based on results of the STAND clinical trial, the efficacy of Adakveo in the prevention of vaso-occlusive crisis (VOC) is unclear.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The requested medication must be prescribed by, or in consult with, a hematologist, oncologist, or immunology specialist.
- The member has experienced at least one sickle cell-related VOC within past 12 months while adherent with hydroxyurea (documentation required) at the maximum (35 mg/kg/day) or maximally tolerated dose (mild myelosuppression is expected), as evidenced by paid claims or pharmacy printouts.
- Adakveo Only:
  - The member must have had a 30-day trial of a Endari, as evidenced by paid claims or pharmacy printouts.
- Siklos Only:
  - Baseline hemoglobin (Hb) ≤ 10.5 g/dL
  - See Preferred Dosage Form Criteria

Renewal Criteria – Approval Duration: 12 months

- Adakveo Only:

- The member must have experienced and/or maintained clinical benefit since starting treatment with the requested product, as evidenced by medical documentation (e.g., chart notes) attached to the request (subject to clinical review) by the reduction in sickle cell-related VOCs

- All Other Products:
  - The member must have experienced and/or maintained clinical benefit since starting treatment with the requested product, as evidenced by medical documentation (e.g., chart notes) attached to the request (subject to clinical review) by one of the following:
    - Increase in hemoglobin (Hb) by ≥ 1 g/dL from baseline
    - Decrease in indirect bilirubin from baseline
    - Decrease in percent reticulocyte count from baseline
    - Reduction in sickle cell-related vaso-occlusive crisis

Cell-based Gene Therapy

PREFERRED AGENTS (CLINICAL PA REQUIRED)
CASGEVY (exagamglogene autotemcel) – *Medical Billing Only*
LYFGENIA (lovotibeglogene autotemcel) – *Medical Billing Only*

Initial Criteria – Approval Duration: 12 months

- The member is ≥ 12 and ≤ 50 years of age
- The member has a diagnosis of sickle cell disease (SCD), with either βS/βS or βS/β0 or βS/β+ genotype
- The member has experienced at least four (4) sickle cell-related VOCs or priapism within past 24 months that required pain medications or RBC transfusion at a medical facility while on hydroxyurea at the maximum (35 mg/kg/day) or maximally tolerated dose (mild myelosuppression is expected), as evidenced by paid claims or pharmacy printouts.
- The member does not have human immunodeficiency virus type 1 or 2 (HIV-1 and HIV-2), hepatitis B virus (HBV), or hepatitis C (HCV)
- The member does not have inadequate bone marrow function, as defined by an absolute neutrophil count of < 1000/µL (< 500/µL for members on hydroxyurea treatment) or a platelet count < 100,000/µL
- The member must not be a recipient of a previous allogeneic transplant or gene therapy
- The member must not have a matched allogeneic transplant donor.

Lyfgenia Only:

- The member must not have more than two α-globin gene deletions (−α3.7/−α3.7)

Thrombocytopenia

Immune Thrombocytopenic Purpura (ITP)

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
NPLATE (romiplostim)	ALVAIZ (eltrombopag choline)
PROMACTA (eltrombopag)	DOPTELET (avatrombopag)
PROMACTA (eltrombopag) POWDER PACK	TAVALISSE (fostamatinib)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 4 months

- The member has diagnosis of immune thrombocytopenic purpura (ITP) lasting >3 months.
- Documentation of platelet count of less than 30 x 10^9/L
- The member must have experienced an inadequate response after one of the following (A, B or C):

A. The member must have failed a trial of appropriate duration of a corticosteroid or immunoglobulins, as evidenced by paid claims or pharmacy printouts.
B. Rituximab
C. The member must have undergone a splenectomy.

Non-Preferred Agents Criteria:

- The member must have failed trials with eltrombopag (at the recommended dose and duration) with each preferred agent, as evidenced by paid claims or pharmacy printouts.

Renewal Criteria – Approval Duration: 12 months

- Platelet counts must have achieved greater than or equal to 50 x 10^9/L in response to therapy (supported by documentation)

References:

1. Neunert, Cindy, et al. "American Society of Hematology 2019 guidelines for immune thrombocytopenia." *Blood advances* 3.23 (2019): 3829-3866.

Chronic Liver Disease-Associated Thrombocytopenia

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
DOPTELET (avatrombopag)	MULPLETA (lusutrombopag)

Prior Authorization Criteria

Initial Criteria – Approval Duration: The 2 weeks prior to procedure

- The member must have platelet count of less than 50 x 10^9/L
- The member must be scheduled to undergo a procedure that puts the member at risk of bleeding (documentation must include name and scheduled date of procedure)
- Documentation must include the date therapy will be initiated and discontinued:
  - Doptelet: Member must undergo procedure 5-8 days after last dose.
  - Mulpleta: Member must undergo procedure 2-8 days after last dose.

Non-Preferred Agents Criteria:

- The member must have failed trials with the preferred agent (at the recommended dose and duration) with each preferred agent, as evidenced by paid claims or pharmacy printouts.

Chronic Hepatitis C Infection-Associated Thrombocytopenia

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
PROMACTA (eltrombopag)	ALVAIZ (eltrombopag choline)
PROMACTA (eltrombopag) POWDER PACK	

Prior Authorization Criteria

Initial Criteria – Approval Duration: 4 months

- The member is unable to receive direct acting antivirals for hepatitis C.
- The member's degree of thrombocytopenia must prevent initiation or continuation of interferon-based therapy.

Renewal Criteria – Approval Duration: 12 months

- Platelet counts must have achieved greater than or equal to 50 x 10^9/L in response to therapy (supported by documentation)
- The member is currently receiving interferon-based therapy.

Aplastic Anemia

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
PROMACTA (eltrombopag)	ALVAIZ (eltrombopag choline)
PROMACTA (eltrombopag) POWDER PACK	

Prior Authorization Criteria

Initial Criteria – Approval Duration: 4 months

- The member must have platelet count of less than 30 x 10^9/L
- The member must have failed therapy or be receiving concurrent therapy with immunosuppressive therapy (e.g., corticosteroid, Atgam, cyclosporine)

Renewal Criteria – Approval Duration: 12 months

- Platelet counts must have achieved greater than or equal to 50 x 10^9/L in response to therapy (supported by documentation)

Hepatology

Metabolic Dysfunction-Associated Steatohepatitis (MASH)

PREFERRED AGENTS (CLINICAL PA REQUIRED)
REZDIFFRA (resmetirom)

Initial Criteria - Approval Duration: 12 months

- The requested medication must be prescribed by, or in consult with, an endocrinologist, gastroenterologist or hepatologist.
- The member has moderate to severe fibrosis (F2 or F3) as determined by one of the following (1-5):
  1. Biopsy
  2. Vibration-controlled transient elastography (VCTE; e.g. Fibroscan)
  3. Enhanced Liver Fibrosis (ELF)
  4. Magnetic Resonance Imaging Proton Density Fat Fraction (MRI-PDFF).
  5. Magnetic resonance elastography (MRE)
- If the member has a history of alcohol use, one of the following must be met (1, 2 or 3):
  1. The member has a carbohydrate-deficient transferrin (CDT) level < 3% within the past 3 months.
  2. The member has a phosphatidylethanol (PEth) level < 20 ng/mL.
  3. The member has submitted two negative alcohol tests with the most recent alcohol test within the past 3 months.
- The member must not have a concomitant terminal diagnosis where life expectancy is less than 1 year.

Renewal Criteria – Approval Duration: 12 months

A. The member must have experienced stabilization or improvement of fibrosis and steatohepatitis, as determined by one of the following (1-5):
   1. Biopsy
   2. Vibration-controlled transient elastography (VCTE; e.g. Fibroscan)
   3. Enhanced Liver Fibrosis (ELF)
   4. Magnetic Resonance Imaging Proton Density Fat Fraction (MRI-PDFF)
   5. Magnetic resonance elastography (MRE)

Infectious Disease

Anti-infectives – Resistance Prevention

Antifungals – Aspergillus and Candidiasis Infections

Solid Dosage Form

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
clotrimazole	CRESEMBA (isavuconazonium)
clotrimazole troche	DIFLUCAN (fluconazole)
fluconazole	NOXAFIL (posaconazole)
itraconazole	SPORANOX (itraconazole)
nystatin	VFEND (voriconazole)
ORAVIG (miconazole)	
posaconazole	
terbinafine	
voriconazole	

Non-Solid Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
fluconazole suspension	DIFLUCAN (fluconazole) SUSPENSION
itraconazole solution	NOXAFIL (posaconazole) POWDERMIX SUSPENSION
NOXAFIL (posaconazole) SUSPENSION	SPORANOX (itraconazole) SOLUTION
	TOLSURA (itraconazole) DISPERSE CAPSULE
	voriconazole suspension

Community-Acquired Pneumonia

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
amoxicillin	BAXDELA (delafloxacin)
amoxicillin-clavulanate	FACTIVE (gemifloxacin)
azithromycin	XENLETA (lefamulin)
cefpodoxime	
cefuroxime	
clarithromycin	
doxycycline	
levofloxacin	
linezolid	
moxifloxacin	

Cytomegalovirus infection

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
valganciclovir	LIVTENCITY (maribavir)

Methicillin-Resistant *Staphylococcus aureus* (MRSA):

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)

clindamycin	BAXDELA (delafloxacin)
doxycycline	NUZYRA (omadacycline)
linezolid	SIVEXTRO (tedizolid)
minocycline	
trimethoprim-sulfamethoxazole	

Helicobacter pylori

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
lansoprazole/amoxicillin/clarithromycin	bismuth subcitrate potassium/metronidazole/tetracycline
PYLERA (bismuth subcitrate potassium/metronidazole/tetracycline) – *Brand Required*	OMECLAMOX-PAK (omeprazole/clarithromycin/amoxicillin)
	TALICIA (omeprazole/amoxicillin/rifabutin)
	VOQUEZNA DUAL PAK (vonoprazan/amoxicillin)
	VOQUEZNA TRIPLE PAK (vonoprazan/amoxicillin/clarithromycin)

Tuberculosis

PREFERRED AGENTS (NO PA REQUIRED)	PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ethambutol	isoniazid	cycloserine
PRIFTIN (rifapentine)		MYCOBUTIN (rifabutin)
pyrazinamide		RIFADIN (rifampin)
rifabutin		SIRTURO (bedaquiline)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 5 days or as supported in compendia for indication

- The requested medication must be prescribed by, or in consult with, an infection disease specialist, an antibiotic stewardship program, or protocol.
- Diagnosis must be proven to be caused by a susceptible microorganism by culture and susceptibility testing
  - For Voquezna Dual or Triple Pak – member must have a clarithromycin or amoxicillin resistant strain of *H. Pylori*)
- One of the following criteria must be met (A or B):
  A. The member is continuing treatment upon discharge from an acute care facility.
  B. Clinical justification must be provided explaining why the preferred antibiotics are not an option due to susceptibility, previous failed trials, or other contraindications (subject to clinical review)

Tuberculosis Only:

6. Isoniazid: The ND Division of Disease Control Tuberculosis Prevention and Control program provides isoniazid for no cost through the UND Center for Family Medicine Pharmacy. Please contact 701-328-2378 to obtain supply.

Renewal Criteria – Approval Duration: 5 days

- It is medically necessary to continue treatment course after re-evaluation of the member's condition.
- The total requested duration of use must not be greater than manufacturer labeling or treatment guideline recommendations (whichever is greater).

Human Immunodeficiency Virus (HIV)

Antiretrovirals – Pre-exposure Prophylaxis (PrEP)

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
APRETUDE (cabtegravir)	TRUVADA (emtricitabine/tenofovir disoproxil fumarate)
DESCOVY (emtricitabine/tenofovir alafenamide)	
emtricitabine/tenofovir disoproxil fumarate	

Antiretrovirals – Treatment

References:

Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV. Department of Health and Human Services. Available at https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/adult-adolescent-arv/guidelines-adult-adolescent-arv.pdf Accessed (October 9, 2020)

Integrase Strand Transfer Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
BIKTARVY (bictegravir/emtricitabine/tenofovir)	
CABENUVA (cabotegravir/rilprivirine) – *Medical Billing Only*	
DOVATO (dolutegravir/lamivudine)	
GENVOYA (elvitegravir/cobicistat/emtricitabine/tenofovir)	
ISENTRESS (raltegravir)	
JULUCA (dolutegravir/rilpivirine)	
STRIBILD (elvitegravir/cobicistat/emtricitabine/tenofovir)	
TIVICAY (dolutegravir)	
TRIUMEQ (abacavir/dolutegravir/lamivudine)	
TRIUMEQ PD (abacavir/dolutegravir/lamivudine)	

Non-Nucleoside Reverse Transcriptase Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
COMPLERA (emtricitabine/rilpivirine/tenofovir)	ATRIPLA (efavirenz/emtricitabine/tenofovir)
efavirenz	EDURANT (rilpivirine)
efavirenz/emtricitabine/tenofovir	efavirenz/lamivudine/tenofovir
JULUCA (dolutegravir/rilpivirine)	rilpivirine
ODEFSEY (emtricitabine/rilpivirine/tenofovir)	
PIFELTRO (doravirine)	
SYMFI (efavirenz/lamivudine/tenofovir) – *Brand Required*	
SYMFI LO (efavirenz/lamivudine/tenofovir) – *Brand Required*	
Not Recommended for First Line Use	
etravirine	INTELENCE (etravirine)

nevirapine	nevirapine ER

- Etravirine – Guidelines do not recommend for treatment-naïve members due to insufficient data. FDA indication is for treatment experienced members and so should be reserved for salvage therapy, pretreated members with NNRTI resistance and PI exposure or who have ongoing adverse effects with first line therapies.
- Nevirapine – Guidelines no longer recommend nevirapine for initial treatment of HIV infection in treatment-naïve members. In resource limited settings, it can be considered as a third agent. Nevirapine demonstrated inferiority relative to efavirenz and is associated with serious and fatal hepatic and rash events.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- See Preferred Dosage Form criteria

Nucleoside Reverse Transcriptase Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
abacavir	ATRIPLA (efavirenz/emtricitabine/tenofovir)
abacavir/lamivudine	efavirenz/lamivudine/tenofovir
BIKTARVY (bictegravir/emtricitabine/tenofovir)	emtricitabine capsule
CIMDUO (lamivudine/tenofovir)	EMTRIVA (emtricitabine) CAPSULE
COMPLERA (emtricitabine/rilpivirine/tenofovir)	EPIVIR (lamivudine)
DELSTRIGO (doravirine/lamivudine/tenofovir)	lamivudine
DESCOVY (emtricitabine/tenofovir alafenamide)	TRIZIVIR (abacavir/lamivudine)
efavirenz/emtricitabine/tenofovir	TRUVADA (emtricitabine/tenofovir disoproxil fumarate)
emtricitabine solution	VIREAD (tenofovir)
emtricitabine/tenofovir disoproxil fumarate	ZIAGEN (abacavir)
GENVOYA (elvitegravir/cobicistat/emtricitabine/tenofovir)	
ODEFSEY (emtricitabine/rilpivirine/tenofovir)	
SYMFI (efavirenz/lamivudine/tenofovir) – *Brand Required*	
SYMFI LO (efavirenz/lamivudine/tenofovir) – *Brand Required*	
STRIBILD (elvitegravir/cobicistat/emtricitabine/tenofovir)	
SYMTUZA (darumavir/cobicistat/emtricitabine/tenofovir)	
tenofovir	
TEMIXYS (lamivudine/tenofovir)	
TRIUMEQ (abacavir/dolutegravir/lamivudine)	
TRIUMEQ PD (abacavir/dolutegravir/lamivudine)	
Not Recommended for First Line Use	
abacavir/lamivudine/zidovudine	RETROVIR (zidovudine)
didanosine	TRIZIVIR (abacavir/lamivudine/zidovudine)
lamivudine/zidovudine	ZERIT (stavudine) CAPSULE
stavudine	zidovudine capsule and tablet

zidovudine syrup	

- abacavir/lamivudine/zidovudine – Guidelines do not recommend ABC/3TC/ZDU (as either a triple-NRTI combination regimen or in combination with tenofovir (TDF) as a quadruple-NRTI combination regimen) due to inferior virologic efficacy.
- didanosine **–** Guidelines do not recommend ddI/3TC or ddI/FTC regimens due to inferior virologic efficacy, limited trial experience in ART-naïve members, and ddI toxicities (including pancreatitis and peripheral neuropathy). Ddi/TDF regimens are not recommended due to high rate of early virologic failure, rapid selection of resistance mutations, potential for immunologic nonresponse/CD4 cell decline, and increased ddI drug exposure and toxicities.
- lamivudine/zidovudine **–** Guidelines do not recommend ZDV/3TC due to greater toxicities than recommended NRTIs (including bone marrow suppression, GI toxicities, skeletal muscle myopathy, cardiomyopathy, and mitochondrial toxicities such as lipoatrophy, lactic acidosis and hepatic steatosis).
- stavudine – Guidelines do not recommend d4T/3TC due to significant toxicities (including lipoatrophy, peripheral neuropathy) and hyperlactatemia (including symptomatic and life-threatening lactic acidosis, hepatic steatosis, and pancreatitis)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months
- See Preferred Dosage Form criteria

Post-Attachment Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
TROGARZO (Ibalizumab-uiyk)	

Protease Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
atazanavir	darunavir
EVOTAZ (atazanavir/cobicistat)	NORVIR (ritonavir)
NORVIR (ritonavir) POWDER PACKET	REYATAZ (atazanavir)
PREZCOBIX (darunavir/cobicistat)	
PREZISTA (darunavir) – *Brand Required*	
REYATAZ (atazanavir) POWDER PACK	
ritonavir	
SYMTUZA (darumavir/cobicistat/emtricitabine/tenofovir)	
Not Recommended for First Line Use	
APTIVUS (tipranavir)	KALETRA (lopinavir/ritonavir)
fosamprenavir	
INVIRASE (saquinavir)	
lopinavir/ritonavir	
VIRACEPT (nelfinavir)	

- Fosamprenavir – Guidelines do not recommend use of unboosted FPV or FPV/r due to virologic failure with unboosted FPV-based regimens that may result in selection of mutations that confer resistance to FPV and DRV. There is also less clinical trial data for FPV/r than other RTV-boosted PIs.
- Lopinavir/ritonavir – Guidelines do not recommend LPV/r due to GI intolerance, higher pill burden and higher RTV dose than other PI-based regimens
- Nelfinavir – Guidelines do not recommend use of NFV due to inferior virologic efficacy and diarrhea.

- Saqinavir – Guidelines do not recommend use of unboosted SQV due to inadequate bioavailability and inferior virologic efficacy or SQV/r due to high bill burden and QT and PR prolongation.
- Tipranavir – Guidelines do not recommend TPV/r due to inferior virologic efficacy, higher dose of RTV and higher rate of adverse events than other RTV-boosted Pis.

Capsid Function Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
Not Recommended for First Line Use	
SUNLENCA (lenacapavir) INJECTION – *Medical Billing Only*	
SUNLENCA (lenacapavir) TABLET	

- lenacapavir – SUNLENCA, in combination with other antiretroviral(s), is indicated for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in heavily treatment-experienced adults with multidrug resistant HIV-1 infection failing their current antiretroviral regimen due to resistance, intolerance, or safety considerations.

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
Not Recommended for First Line Use	
FUZEON (enfuvirtide)	
SELZENTRY (maraviroc)	

- Enfuvirtide (Fusion Inhibitor)– Guidelines do not recommend T20 for initial therapy due to twice daily injections, high rate of injection site reactions, and it has only been studied in members with virologic failure
- Maraviroc (CCR5 Antagonist) – Guidelines do not recommend MVC for initial therapy due to twice daily dosing, no virologic benefit compared to recommended regimens, and required CCR5 tropism testing.

Diarrhea

Mytesi: Jump to Criteria

Loss of Appetite

Dronabinol: Jump to Criteria

Wasting Cachexia

Serostim: Jump to Criteria

Hepatitis C Antiviral Treatments

Direct Acting Antivirals

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
HARVONI (ledipasvir/sofosbuvir) 45 mg/200 mg tablet	EPCLUSA (sofosbuvir/velpatasvir)
sofosbuvir/velpatasvir	HARVONI (ledipasvir/sofosbuvir) 90mg/400mg tablet
SOVALDI (sofosbuvir) 200 MG TABLET	HARVONI (ledipasvir/sofosbuvir) ORAL PALLET
	ledipasvir/sofosbuvir 90mg/400mg tablet
	MAVYRET (glecaprevir/pibrentasvir)
	SOVALDI (sofosbuvir) 400MG TABLET
	SOVALDI (sofosbuvir) ORAL PALLET
	VIEKIRA PAK (dasabuvir/ombitasvir/paritaprevir/ritonavir)

	ZEPATIER (elbasvir/grazoprevir)

Electronic Concurrent Medication Required

- Epclusa (and its generic): A total of 84 days of ribavirin must be billed within the previous 14 days of a sofosbuvir/velpatasvir claim if member has decompensated cirrhosis (Child Pugh B or C).

First Fill

- Epclusa (and its generic) and Vosevi: The entire treatment course must be dispensed at the initial fill.
    A. Please call pharmacy provider relations (1-701-328-4086) if a member has already partially completed their treatment course and needs less than a full course of therapy for their current fill.

Prior Authorization Criteria

Prior Authorization Form – Hepatitis C

Initial Criteria – Approval Duration: Based on label recommendations

- The member must have life expectancy greater than 12 months.
- One of the following must be met (1-4):
    1. The member has no history of alcohol use disorder or IV illicit drug use.
    2. The member has maintained sobriety for the past 12 months.
    3. The member has completed or be currently enrolled in a treatment program within the past 12 months.
    4. The Harm Reduction Program Participation Attestation Form is attached indicating one of the following (a or b):
        a. The member participates in a Syringe Service Program
        b. The member participates in at least 2 Harm Reduction Pathway appointments as defined in Appendix D (may be completed by any qualified healthcare provider)

Non-Solid Dosage Form Agents Criteria:

- Epclusa pellet packs: Members that weigh 30 kg or greater must meet Non-Solid Dosage Preparations criteria in addition to Hepatitis C criteria.
- Mavyret pellet packs: Members that weigh 45 kg or greater must meet Non-Solid Dosage Preparations criteria in addition to Hepatitis C criteria.

Non-Preferred Agents Criteria:

- Clinical justification must be provided explaining why the member is unable to use the preferred product (subject to clinical review).

For FIRST TIME or RE-INFECTION Treatment with Direct Acting Antivirals or incomplete therapy after receiving < 28 days:

- Chronic Hepatitis C must be documented by one of the following (most recent test within the last 24 months):
    - No liver fibrosis or unknown (one of the following):
        - 2 positive HCV RNA levels at least 3 months apart
        - 1 positive HCV RNA test with the last likely HCV exposure occurring at least 6 months before the most recent positive test
    - Liver fibrosis or cirrhosis:1 positive HCV RNA test
- For incomplete therapy, the following criteria is met:

Due to incomplete therapy (defined as a medication possession ratio (MPR) of less than 80%)	The member has participated in 1 visit focused on addressing adherence barriers within the past 180 days.

	Adherence education may be provided by a pharmacist (may be billed through the MTM program) or clinic-based E&M billed service (provided by a nurse or independent practitioner).

For RE-TREATMENT after Direct Acting Antiviral failure or incomplete therapy after receiving ≥ 28 days:

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ribavirin	MAVYRET (glecaprevir/pibrentasvir)
VOSEVI (sofosbuvir/velpatasvir/voxilaprevir)	SOVALDI (sofosbuvir) 400MG TABLET

- The requested medication must be prescribed by, or in consult with, a hepatology, gastroenterology, or infectious disease specialist (including via Project ECHO)
- Chronic Hepatitis C must be documented by 1 HCV RNA test since most recent DAA treatment (HCV RNA level must be within the last 24 months)
- The following criteria is met (as applicable due to reason for retreatment):

Reason for retreatment:	
Due to incomplete therapy (defined as a medication possession ratio (MPR) of less than 80%)	The member has participated in 1 visit focused on addressing adherence barriers within the past 180 days. Adherence education may be provided by a pharmacist (may be billed through the MTM program) or clinic-based E&M billed service (provided by a nurse or independent practitioner).
Resistance	• **FIRST TIME treatment with Direct Acting Antivirals** criteria must be met

Non-Preferred Agents Criteria:

- The member has had a failed treatment course with Vosevi.

Influenza

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
oseltamivir	TAMIFLU (oseltamivir)
	XOFLUZA (baloxavir marboxil)

Electronic Age Verification

- Xofluza: The member must be 5 years of age or older

Prior Authorization Criteria

Initial Criteria – Approval Duration: 5 days

- The member must have failed a 5-day trial of oseltamivir, as evidenced by paid claims or pharmacy printouts.
- Clinical justification must be provided explaining why the member is unable to use the preferred product (subject to clinical review).

Malaria

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)

hydroxychloroquine	atovaquone/proguanil
quinine	chloroquine
	COARTEM (artemether/lumefantrine)
	KRINTAFEL (tafenoquine)
	MALARONE (atovaquone/proguanil)
	mefloquine
	primaquine
	QUALAQUIN (quinine)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 7 days

- The member must have had a trial of a generic quinine in the last 30 days, as evidenced by paid claims or pharmacy print outs
- The request must be for treatment of malaria (*NOT covered for prophylaxis)*

Respiratory Syncytial Virus (RSV) Prophylaxis

CLINICAL PA REQUIRED
SYNAGIS (palivizumab) – *Medical Billing Only*

Prior Authorization Criteria

Prior Authorization Form – RSV Prophylaxis

Initial Criteria – Approval Duration: Up to 5 weight-based doses within 6 months of season onset. No further prior authorization requests will be approved following season offset. An SA will only be approved until age 2 or through the second season, whichever occurs first.

Respiratory Syncytial Virus (RSV) Season defined as onset (1st of 2 consecutive weeks when percentage of PCR tests positive for RSV is > 3% and offset (Last of 2 consecutive weeks when percentage of PCR tests positive for RSV is < 3%) as reported by The National Respiratory and Enteric Virus Surveillance System (NREVSS) Region 8 Interactive Dashboard | NREVSS | CDC
North Dakota data specific data is available at: Respiratory Syncytial Virus (RSV) | Health and Human Services North Dakota

If a post-season spike occurs (defined as season onset criteria met within 3 months of season offset), infants may be approved for doses until the age of 3 months old if they meet clinical criteria and have not already received 5 doses during the defined season.

- Clinical justification must be provided addressing why nirsevimab could not be given from VFC (subject to clinical review)
- The member had not received another monoclonal antibody for RSV prophylaxis during the current RSV season.
- The member must not have received immunity through a maternal Respiratory Syncytial Virus Vaccine.
- The member must have one of the following diagnoses and the additional criteria outlined for diagnosis:
  - **Prematurity:**
    - < 29 weeks, 0 days gestational age
      - ≤ 12 months of age at start of RSV season
    - ≥ 29 weeks, 0 days gestational age to ≤ 35 weeks, 0 days gestational age

        - ≤ 6 months of age at start of RSV season
        - One of the following:
            - Neuromuscular disease or pulmonary abnormality that impairs ability to clear secretions from the upper airway because of ineffective cough
            - Profoundly immunocompromised receiving chemotherapy, solid organ transplantation, hematopoietic stem cell transplantation, or require colony stimulating factors
    - **Chronic Lung Disease of Prematurity (CLD)**
        - < 32 weeks, 0 days gestational age
            - ≤12 months of age at start of RSV season
            - Requires supplemental oxygen > 21% for at least the first 28 days after birth
        - < 32 weeks, 0 days gestational age
            - 13-24 months of age at start of RSV season
            - Requires supplemental oxygen > 21% for at least the first 28 days after birth
            - Continues to receive medical support within six months before the start of RSV season with supplemental oxygen, diuretic, or chronic corticosteroid therapy
    - **Congenital Heart Disease**
        - ≤12 months of age at start of RSV season
            - Hemodynamically significant cyanotic or acyanotic congenital heart disease with medical therapy required

References:

1. American Academy of Pediatrics. Updated Guidance: Use of Palivizumab Prophylaxis to Prevent Hospitalization From Severe Respiratory Syncytial Virus Infection During the 2022-2023 RSV Season. American Academy of Pediatrics; July 2022. Available at: https://www.aap.org/en/pages/2019-novel-coronavirus-covid-19-infections/clinical-guidance/interim-guidance-for-use-of-palivizumab-prophylaxis-to-prevent-hospitalization/
2. Midgley CM, Haynes AK, Baumgardner JL, et al. Determining the seasonality of respiratory syncytial virus in the United States: the impact of increased molecular testing. J Infect Dis 2017;216:345–55
3. Rose EB, Wheatley A, Langley G, Gerber S, Haynes A. Respiratory Syncytial Virus Seasonality — United States, 2014–2017. MMWR Morb Mortal Wkly Rep 2018;67:71–76. DOI: http://dx.doi.org/10.15585/mmwr.mm6702a4external icon

Nephrology/Urology

Complement-mediated Thrombotic Microangiopathy (TMA) / Complement-mediated Hemolytic Uremic Syndrome

CLINICAL PA REQUIRED
SOLIRIS (eculizumab) – *Medical Billing Only*
ULTOMIRIS (ravulizumab-cwvz)
ULTOMIRIS (ravulizumab-cwvz) – *Medical Billing Only*

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a hematologist or nephrologist.
- The member has all the following (as evidenced by submitted documentation):
    - Low platelet count, as defined by laboratory reference range or member requires dialysis.

- Evidence of hemolysis such as an elevation in serum lactate dehydrogenase (LDH), elevated indirect bilirubin, reduced haptoglobin, or increased reticulocyte, as defined by laboratory reference range or member requires dialysis.
- Serum creatinine above the upper limits of normal, as defined by laboratory reference range or member requires dialysis.

- The member does not have bloody diarrhea.

Renewal Criteria – Approval Duration: 12 months

- The member must have experienced meaningful clinical benefit since starting treatment with the requested medication, as evidenced by medical documentation (e.g., chart notes) attached to the request (subject to clinical review) including one of the following scores and symptoms:
  - Normalization of platelet count, as defined by laboratory reference range.
  - Normalization of lactate dehydrogenase (LDH), as defined by laboratory reference range.
  - ≥ 25% improvement in serum creatinine from baseline or ability to discontinue dialysis.

Benign Prostatic Hyperplasia

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
alfuzosin ER	AVODART (dutasteride)
CARDURA XL (doxazosin)	CARDURA (doxazosin)
doxazosin	ENTADFI (finasteride/tadalafil)
dutasteride	FLOMAX (tamsulosin)
finasteride	MINIPRESS (prazosin)
prazosin	PROSCAR (finasteride)
silodosin	RAPAFLO (silodosin)
tamsulosin	sildenafil
terazosin	tadalafil

Electronic Diagnosis Verification

- Finasteride, sildenafil, and tadalafil: Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must have failed a 30-day trial of each preferred agent, as evidenced by paid claims or pharmacy printouts.
- Sildenafil/tadalafil: Documentation (e.g., chart notes) must be provided confirming the diagnosis.

Chronic Kidney Disease

Therapeutic Duplication

- Medication classes not payable together:
  - Filspari, ACE Inhibitors, ARBs, and Renin Inhibitors are not allowed with each other.

Dual endothelin angiotensin receptor antagonist

CLINICAL PA REQUIRED
FILSPARI (sparsentan)

Factor B Inhibitors

CLINICAL PA REQUIRED
FABHALTA (iptacopan)

Kappa-opioid agonist

CLINICAL PA REQUIRED
KORSUVA (difelikefalin) – *Medical Billing Only*

Non-steroidal selective mineralocorticoid receptor antagonist (MRA)

CLINICAL PA REQUIRED
KERENDIA (finerenone)

Renin-Angiotensin-Aldosterone System (RAAS) Inhibitors

NO PA REQUIRED
ACE (angiotensin-converting enzyme) inhibitors – *all oral agents preferred*
ARBs (angiotensin receptor blockers) – *all oral agents preferred*
TEKTURNA (aliskiren)

SGLT-1/SGLT-2 Inhibitor

CLINICAL PA REQUIRED
INPEFA (sotagliflozin)

SGLT-2 Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
FARXIGA (dapagliflozin) – *Brand Required*	dapagliflozin
INVOKANA (canagliflozin)	
JARDIANCE (empagliflozin)	

Sodium/Hydrogen Exchanger 3 (NHE3)

CLINICAL PA REQUIRED
XPHOZAH (tenapanor)

Systemic Corticosteroids

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
methylprednisolone	TARPEYO (budesonide-targeted release)
prednisone	

Vasopressin V2-receptor (V2R) Antagonist

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
JYNARQUE (tolvaptan)	

Electronic Duration Verification:

- Tarpeyo is payable for 9 months every 3 years.

- tolvaptan is payable for 30 days every year.

Prior Authorization Criteria

<u>Initial Criteria – Approval Duration:</u> 12 months

Inpefa Only:

- The requested medication must be prescribed by, or in consult with, a cardiologist or nephrologist.
- If member is on renal dialysis, Medicare eligibility must be ruled out. *(6-month approval allowed to determine eligibility)*
- The member has type 2 diabetes and chronic kidney disease.
- The member has a history of a cardiovascular event (e.g., heart failure, myocardial infarction, cerebrovascular event) or two or more risk factors (e.g., elevated cardiac and inflammatory biomarker, obesity, hyperlipidemia, hypertension)
- The member is receiving concurrent Entresto, a beta-blocker, a SGLT-2 Inhibitor, and a mineralocorticoid receptor antagonist.
- Clinical justification must be provided explaining why the member is unable to use a preferred SGLT-2 inhibitor (subject to clinical review)

Kerendia Only

- The member must have history of diabetes.
- The member must be on the following at the target or maximally tolerated dose, as evidenced by paid claims or pharmacy printouts:
  - An ACE-inhibitor or an ARB
  - A SGLT-2 inhibitor
- The member has an estimated glomerular filtration rate (eGFR) ≥ 25 mL/min/1.73 m^2
- The member has one of the following (1 or 2) despite a 3-month trial with an ACE inhibitor or a 6-month trial with an ARB:
  1. urinary albumin-to-creatinine ratio (UACR) ≥ 30 mg/g (≥3 mg/mmol)
  2. albuminuria ≥ 300 mg/day

Korsuva Only

- If member is on renal dialysis, Medicare eligibility must be ruled out *(6-month approval may be allowed to determine eligibility)*.
- The member must have failed a 90-day trial of pregabalin or gabapentin, as evidenced by paid claims or pharmacy printouts.

Fabhalta, Filspari and Tarpeyo Only

- The member must have eGFR ≥ 30.
- If member is on renal dialysis, Medicare eligibility must be ruled out *(6-month approval may be allowed to determine eligibility)*.
- The member must be experiencing proteinuria > 1 gram/day or UPCR ≥ 1.5 g/g despite 3-month trials with good compliance of the following at the target or maximally tolerated dose, as evidenced by paid claims or pharmacy printouts:
  - ACE inhibitor or an ARB
  - A SGLT-2 inhibitor
  - prednisone or methylprednisolone

Tolvaptan Only

- The requested medication must be prescribed by, or in consult with, a nephrologist.
- The member does not have liver disease.
- The member has eGFR ≥ 25

- The prescriber has provided clinical justification that the member is at high risk of kidney progression such as one of the following (subject to clinical review):
  - Autosomal dominant polycystic kidney disease mayo classes 1C, 1D, or 1E
  - Kidney length > 16.5 cm (by ultrasound, MRI, or CT scan)
  - An annual eGFR decline of at least 5 mL/min/1.73 m2 in one year
  - An annual eGFR decline of at least 2.5 mL/min/1.73 m2 per year over a period of five years
  - A greater than 5 % increase in total kidney volume per year on at least three repeated measurements (via MRI or CT (computed tomography), each at least 6 months apart

Xphozah Only

- If member is on renal dialysis, Medicare eligibility must be ruled out *(6-month approval may be allowed to determine eligibility)*.
- The member must have failed 30-day trials of sevelamer carbonate and sucroferric oxyhydroxide, as evidenced by paid claims or pharmacy printouts.

Renewal Criteria – Approval Duration: 12 months

- If member is on renal dialysis, Medicare eligibility must be ruled out *(6-month approval may be allowed to determine eligibility)*.
- The member must have experienced meaningful clinical benefit since starting treatment with the requested medication, as evidenced by the following scores and symptoms:
  - *Fabhalta, Filspari and Tarpeyo Only*: proteinuria <1 gram/day or UPCR < 1.5 g/g or reduction of 30% from baseline
  - *Kerendia Only*: The member has experienced a stabilization in eGFR or one of the following:
    - albuminuria <1 gram/day or reduction of 30% from baseline
    - UACR < 1.5 g/g or reduction of 30% from baseline

References:

1. Stevens, Paul E., et al. "KDIGO 2024 Clinical practice guideline for the evaluation and management of chronic kidney disease." Kidney international 105.4 (2024): S117-S314.
2. de Boer, Ian H., et al. “Diabetes management in chronic kidney disease: a consensus report by the American Diabetes Association (ADA) and Kidney Disease: Improving Global Outcomes (KDIGO).” *Diabetes care* 45.12 (2022): 3075-3090.

Anemia

Hematopoietic, Erythropoiesis Stimulating Agents

Pharmacy Billing

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ARANESP (darbepoetin alfa)	PROCRIT (epoetin alfa)
EPOGEN (epoetin alfa)	RETACRIT (epoetin alfa – epbx) – Labelers 59353
MIRCERA (methoxy polyethylene glycol-epoetin beta)	
RETACRIT (epoetin alfa – epbx) – Labeler 00069	

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must have had a 4-week trial of each preferred agent, as evidenced by paid claims or pharmacy printouts.
- If member is on renal dialysis, Medicare eligibility must be ruled out *(6-month approval may be allowed to determine eligibility)*.

HIF-PHIs (Hypoxia-Inducible Factor-Prolyl Hydroxylase Inhibitors)

PREFERRED AGENTS (CLINICAL PA REQUIRED)
JESDUVROQ (daprodustat)
VAFSEO (vadadustat)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- If member is on renal dialysis, Medicare eligibility must be ruled out *(6-month approval may be allowed to determine eligibility)*.

Hematopoietic Syndrome of Acute Radiation Syndrome

PREFERRED AGENTS (CLINICAL PA REQUIRED)
NPLATE (romiplostim)

Prior Authorization Criteria

Initial Criteria – Approval Duration: treatment plan must be documented in request

- The requested medication must be prescribed by, or in consult with, a hematologist or oncologist.
- The member meets one of the following:
    - The member has had a ≥ 2 gray exposure to radiation
    - The member has had exposure to radiation and experiencing one of the following:
        - Gross blood loss
        - > 10% decrease in hemoglobin
        - Platelet count < 50,000/microL
        - Absolute neutrophil count < 1000 cells/microL
        - Absolute lymphocyte count < 1000 cells/microL

Hyperkalemia (Chronic)

PREFERRED AGENTS (CLINCIAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
LOKELMA (sodium zirconium cyclosilicate)	VELTASSA (patiromer)
SPS (sodium polystyrene sulfonate) SUSPENSION+	

+ SPS can cause intestinal necrosis which may be fatal. Concomitant use of additional sorbitol is not recommended.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 3 months

- The requested medication must be prescribed by, or in consult with, a nephrologist or cardiologist.
- If member is on renal dialysis, Medicare eligibility must be ruled out *(6-month approval may be allowed to determine eligibility)*.
- The member's current serum potassium level must be exceeding the upper limit of normal, as evidenced by documentation from at least two separate lab values, submitted with the request.
- The member must have failed 30-day trials with at least two of the following products:
    - bumetanide, chlorothiazide, fludrocortisone, furosemide, hydrochlorothiazide, indapamide, metolazone, torsemide
- The member must not be receiving nonsteroidal anti-inflammatory drugs (NSAIDs)

Non-Preferred Agent Criteria:

- The member must have failed a 30-day trial with Lokelma, as evidenced with paid claims or pharmacy print outs.

Renewal Criteria – Approval Duration: 12 months

- The member's current serum potassium level is within normal limits or has been significantly reduced from baseline, as evidenced by lab documentation submitted with the request.

Reference:

1. Rossing, Peter, et al. "KDIGO 2022 clinical practice guideline for diabetes management in chronic kidney disease." *Kidney International* 102.5 (2022): S1-S127.

Primary Hyperoxaluria Type 1 (PH1)

RNA interference (RNAi)

CLINICAL PA REQUIRED
OXLUMO (lumasiran) – *Medical Billing Only*
RIVFLOZA (nedosiran)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a nephrologist, urologist or geneticist
- The member's diagnosis must be documented by one of the following:
  - Mutation in the alanine: glyoxylate aminotransferase (AGXT) gene confirmed by genetic testing
  - Liver enzyme analysis confirming absent or significant deficiency in alanine: glyoxylate aminotransferase (AGT) activity
- The member has a failed to achieve at least a 30% reduction in urinary oxalate excretion after a 90-day trial of pyridoxine (vitamin B6) of maximally tolerated doses (maximum dose, 20 mg/kg per day)
- The member has not received a liver transplant
- Documentation of the one of the following must be submitted:
  - Elevated urinary oxalate excretion > 1 mmol/1.73 m^2 per day or 90 mg/1.73 m^2 per day
  - Elevated urinary oxalate: creatinine ratio as defined by age defined laboratory reference range

Renewal Criteria – Approval Duration: 12 months

- The member must have experienced meaningful clinical benefit since starting treatment with the requested medication, (subject to clinical review) including one of the following scores and symptoms:
  - Reduced signs and symptoms of PH1 (e.g., nephrocalcinosis, formation of renal stones, renal impairment)
  - Decrease of 30% from baseline or normalization of urinary oxalate excretion
  - Decreased or normalized urinary oxalate: creatinine ratio relative to normative values for age

Lupus Nephritis

First Line Agents

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
cyclophosphamide	
mycophenolate	
systemic oral corticosteroids	

Anti-CD20 Monoclonal Antibodies

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
RIABNI (rituximab-arrx) – *Medical Billing Only*	RITUXAN (rituximab) – *Medical Billing Only*

RUXIENCE (rituximab-pvvr) – *Medical Billing Only*	
TRUXIMA (rituximab-abbs) – *Medical Billing Only*	

B-Lymphocyte Stimulator (BlyS) – Specific Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
BENLYSTA (belimumab) – *Medical Billing Only*	

Calcineurin Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
cyclosporine	LUPKYNIS (voclosporin)
tacrolimus	

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- The requested medication must be prescribed by, or in consult with, a nephrologist or rheumatologist
- If member is on renal dialysis, Medicare eligibility must be ruled out *(6-month approval may be allowed to determine eligibility)*.
- The member has an eGFR > 45
- The member must be using concurrently with mycophenolate and a systemic corticosteroid for 3 months, as evidenced by paid claims or pharmacy printouts.
- Rituxan Only: See Biosimilar Agents criteria

Renewal Criteria – Approval Duration: 12 months

- The provider must submit documentation showing that the member has experienced clinical benefit since starting treatment, as evidenced by documentation of one of the following:
  - Improvement of proteinuria (UPCR decreased by 50% and/or below 0.5 to 0.7 g/day)
  - Improvement of serum creatinine (SCr ≤ 1.4 mg/dl)
  - Chronic steroid use to ≤ 7.5 mg/day

Overactive Bladder

Topical Formulations

PREFERRED AGENTS (NO PA REQUIRED)
GELNIQUE (oxybutynin) GEL
OXYTROL (oxybutynin) PATCH

Oral Solid Dosage Formulations

PREFERRED AGENTS (NO PA REQUIRED)	PREFERRED STEP 1 AGENTS (ELECTRONIC STEP)	NON-PREFERRED STEP 2 AGENTS (PA REQUIRED)
MYRBETRIQ (mirabegron) – *Brand Required*	fesoterodine ER	darifenacin ER
oxybutynin ER	tolterodine	DETROL (tolterodine)
oxybutynin tablet	tolterodine ER	DETROL LA (tolterodine)
solifenacin		DITROPAN XL (oxybutynin)
tamsulosin		dutasteride/tamsulosin
trospium		fesoterodine
		flavoxate
		FLOMAX (tamsulosin)
		GEMTESA (vibegron)

		JALYN (dutasteride/tamsulosin)
		mirabegron ER
		TOVIAZ ER (fesoterodine)
		trospium ER
		VESICARE (solifenacin)

Therapeutic Duplication

- One strength of one of the following medications is allowed at a time: dutasteride, Jalyn, or finasteride
- Non-selective alpha 1 blockers (doxazosin, prazosin, and terazosin) are not allowed with carvedilol or labetalol
  - Carvedilol and labetalol are non-selective beta blockers with alpha 1 blocking activity

Electronic Diagnosis Verification

- Oxybutynin 2.5 mg: Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale

Electronic Step Therapy Required

- Preferred Step 1 Agents:
  - PA Not Required Criteria: A 30-day supply of a preferred agent at max dose has been paid within 100 days prior to step 1 agent's date of service.
  - PA Required Criteria: The member must have failed A 30-day trial of a preferred agent at max dose, as evidenced by paid claims or pharmacy printouts.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months
- The member must have had a 30-day trial of solifenacin and Myrbetriq, as evidenced by paid claims or pharmacy printouts.

Non-Solid Dosage Form

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
oxybutynin syrup	MYRBETRIQ (mirabegron) SUSPENSION
	VESICARE (solifenacin) LS SUSPENSION

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months
- The member must have had a 30-day trial of a preferred agent, as evidenced by paid claims or pharmacy printouts.
- Must meet Non-Solid Dosage Forms criteria

Therapeutic Duplication

- Anticholinergic medications (tolterodine, oxybutynin, trospium, fesoterodine) are not covered with Acetylcholinesterase Inhibitors.
  - The effects of an anticholinergic (blocks the effect of acetylcholine) and acetylcholinesterase inhibitors (prevents breakdown of acetylcholine) oppose each other, and the therapeutic effect of both products is diminished.

Phosphate Binders

Solid Dosage Form

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
calcium acetate	AURYXIA (ferric citrate) TABLET
sevelamer carbonate tablet	RENAGEL (sevelamer HCl) TABLET
	RENVELA (sevelamer carbonate) TABLET
	sevelamer HCl

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- If member is on renal dialysis, Medicare eligibility must be ruled out *(6-month approval may be allowed to determine eligibility)*.
- The member must have failed a 30-day trial of sevelamer carbonate, as evidenced by paid claims or pharmacy printouts.

Non-Solid Dosage Form

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
FOSRENOL (lanthanum) CHEWABLE TABLET – *Brand Required*	FOSRENOL (lanthanum) POWDER PACK
RENVELA (sevelamer carbonate) POWDER PACK – *Brand Required*	lanthanum chew tab
	sevelamer carbonate powder pack
	VELPHORO (sucroferric oxyhydroxide)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- If member is on renal dialysis, Medicare eligibility must be ruled out *(6-month approval may be allowed to determine eligibility).*
- The member must have failed a 30-day trial of sevelamer carbonate and lanthanum, as evidenced by paid claims or pharmacy printouts.
- Must meet Preferred Dosage Forms criteria
- Must meet Non-Solid Dosage Forms criteria

Neurology

Alzheimer's Disease

Cholinesterase Inhibitors

Solid Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
donepezil 5 mg, 10 mg tablet	ARICEPT (donepezil)
galantamine tablet	donepezil 23 mg tablet
galantamine ER	donepezil ODT
rivastigmine capsule	RAZADYNE (galantamine)

	RAZADYNE ER (galantamine)

Non-Solid Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
EXELON (rivastigmine) PATCH – *Brand Required*	ADLARITY (donepezil) PATCH
	galantamine oral solution
	rivastigmine patch

NMDA Receptor Antagonists

Solid Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
memantine	NAMENDA (memantine)

Non-Solid Dosage Forms

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
memantine ER capsule sprinkle	memantine oral solution
	NAMENDA XR (memantine) CAPSULE SPRINKLE

Cholinesterase Inhibitors / NMDA Receptor Antagonist Combinations

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	NAMZARIC (memantine/donepezil)

Therapeutic Duplication

- One memantine medication is allowed at a time
- Anticholinergic medications are not covered with acetylcholinesterase inhibitors (donepezil, rivastigmine, galantamine, pyridostigmine).
  A. The effects of an anticholinergic (blocks the effect of acetylcholine) and acetylcholinesterase inhibitors (prevents breakdown of acetylcholine) oppose each other, and the therapeutic effect of both products is diminished.

Electronic Diagnosis Verification

- Memantine: Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale

Electronic Age Verification

- Submit chart notes to verify diagnosis for members less than 30 years old

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must have failed a 30-day trial of a pharmaceutically equivalent preferred agent, as evidenced by paid claims or pharmacy printouts.
- The member must not reside in facility where medications are managed such as skilled nursing care.
- Donepezil 23 mg: Clinical justification must be provided explaining why the member is unable to use the preferred products (subject to clinical review).
- Memantine ER capsule sprinkle: Must meet Non-Solid Dosage Forms criteria

Amyloid Beta-Directed Monoclonal Antibody

CLINICAL PA REQUIRED

LEQEMBI (lecanemab-irmb) – *Medical Billing Only*

Prior Authorization Criteria

Initial Criteria – Approval Duration: 1 year
Leqembi Only:

- The member must have been diagnosed with mild cognitive impairment or mild Alzheimer's disease dementia, with documented evidence of beta-amyloid plaque on the brain.
- The member has a physician who participates in a qualifying registry with an appropriate clinical team and follow-up care.

Amyotrophic Lateral Sclerosis (ALS)

PREFERRED AGENTS (NO PA REQUIRED)	PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
riluzole tablet	EXSERVAN (riluzole) FILM	RILUTEK (riluzole) TABLET
	QALSODY (tofersen) + *– Medical Billing Only*	
	RADICAVA (edaravone) *– Medical Billing Only*	
	RADICAVA ORS (edaravone)	
	TIGLUTIK (riluzole) ORAL SUSPENSION	

+ Qalsody failed to demonstrate statistically significant benefit over placebo on the primary efficacy endpoint, the change from baseline to Week 28 in the Amyotrophic Lateral Sclerosis Functional Rating Scale – Revised (ALSFS-R) in the Phase 3 VALOR trial (NCT02623699 or clinical secondary endpoints. Continued approval of Qalsody for this indication may be contingent upon verification of clinical benefit in the ATLAS study (NCT04856982).

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a neurologist or neuromuscular specialist.
- The member has had ALS symptoms present for less than 2 years.
- The member must have both of the following:
  - Forced vital capacity (FVC) > 80 percent of predicted.
  - ALS Function Rating Scale-Revised (ALSFRS-R) with a score of 2 or greater on each individual item of the scale
- The member must not have permanent invasive ventilation.

Exservan and Tiglutik Only: Must meet Non-Solid Dosage Forms criteria

Renewal Criteria – Approval Duration: 12 months

- The member must have both of the following:
  - Forced Vital Capacity (FVC) > 60 percent of predicted
  - Documentation of a therapeutic response (e.g., improved neurologic impairment, motor function, quality of life, slowing of disease progression, etc.) from baseline as evidenced by a score decline of less than 6 on the ALSFRS-R.

Anticonvulsant Prevention

Narrow Spectrum:

Carbamazepine

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
carbamazepine 100 mg chewable tablet	carbamazepine 200 mg chewable tablet
carbamazepine oral suspension	carbamazepine ER capsule
carbamazepine tablet	carbamazepine XR tablet
CARBATROL (carbamazepine) – *Brand Required*	EPITOL (carbamazepine)
EQUETRO (carbamazepine)	TEGRETOL (carbamazepine oral suspension)
TEGRETOL XR (carbamazepine) – *Brand Required*	TEGRETOL (carbamazepine)

Ethosuximide

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ethosuximide capsule	ZARONTIN (ethosuximide)
ethosuximide oral solution	ZARONTIN (ethosuximide) ORAL SOLUTION

Gabapentin

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
gabapentin capsule	NEURONTIN (gabapentin) CAPSULE
gabapentin oral solution	NEURONTIN (gabapentin) ORAL SOLUTION
gabapentin tablet	NEURONTIN (gabapentin) TABLET

Lacosamine

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
lacosamide oral solution	MOTPOLY XR (lacosamide) CAPSULE
lacosamide tablet	VIMPAT (lacosamide) ORAL SOLUTION
	VIMPAT (lacosamide) TABLET

Oxcarbazepine

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
oxcarbazepine oral solution	oxcarbazepine ER
oxcarbazepine tablet	OXTELLAR XR (oxcarbazepine) – *Brand Required*
	TRILEPTAL (oxcarbazepine)
	TRILEPTAL (oxcarbazepine) ORAL SUSPENSION

Pregabalin

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
pregabalin	LYRICA (pregabalin)
pregabalin oral solution	LYRICA (pregabalin) ORAL SOLUTION
	LYRICA CR (pregabalin)
	pregabalin ER

Phenytoin

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
phenytoin chewable tablet	DILANTIN (phenytoin) CHEWABLE TABLET
phenytoin sodium ER	DILANTIN (phenytoin) ORAL SUSPENSION
phenytoin suspension	DILANTIN ER (phenytoin)
	PHENYTEK (phenytoin)

Primidone

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
primidone	MYSOLINE (primidone)

Tiagabine

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
tiagabine	

Vigabatrin

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
SABRIL (vigabatrin) TABLET – *Brand Required*	SABRIL (vigabatrin) POWDER PACK
vigabatrin powder pack	vigabatrin tablet
	VIGADRONE (vigabatrin)
	VIGAFYDE (vigabatrin)
	VIGPODER (vigabatrin)

Other

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
APTIOM (eslicarbazepine)	methsuximide
CELONTIN (methsuximide) – *Brand Name Required*	
DIACOMIT (stiripentol)	
EPIDIOLEX (cannabidiol)	
FINTEPLA (fenfluramine) ORAL SOLUTION	
phenobarbital elixir	
phenobarbital tablet	
XCOPRI (cenobamate)	
ZTALMY (ganaxolone) SUSPENSION	

Electronic Diagnosis Verification

- Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale for Diacomit, Epidiolex, and Fentepla

Electronic Concurrent Medications Required

- A total of 28 days of clobazam must be paid within 45 days prior to Diacomit.
  A. Diacomit is FDA approved to be used in combination with clobazam.

Quantity Limit Override

- Gabapentin: 2400 mg max dose per day
  Please call for an override by calling provider relations at 1-800-755-2604 if dose exceeds 2400 mg per day and the indication is adjuvant seizure (if monotherapy, please send chart notes to verify indication)

Prior Authorization Criteria:

- See Preferred Dosage Form Criteria

Therapeutic Duplication

- One Vimpat strength is allowed at a time
- Lyrica and gabapentin are not allowed together.
- Lyrica and gabapentin oral solutions are not allowed with benzodiazepines, muscle relaxants (except baclofen), or narcotic solid dosage forms. If a member can swallow, they should be transitioned to a solid dosage form.

  Please call for an override by calling provider relations at 1-800-755-2604 if the member's medications are dispensed in solid formulations are being crushed or opened to administer because member is unable to swallow

Broad Spectrum:

Clobazam

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
clobazam	ONFI (clobazam)
clobazam oral solution	ONFI (clobazam) ORAL SOLUTION
	SYMPAZAN (clobazam) FILM

Divalproex/Valproic Acid

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
DEPAKOTE SPRINKLE (divalproex sodium) – *Brand Co-Preferred*	DEPAKENE (valproic acid) CAPSULE
divalproex sodium ER	DEPAKENE (valproic acid) ORAL SOLUTION
divalproex sodium sprinkle	DEPAKOTE (divalproex sodium) TABLET
divalproex sodium tablet	DEPAKOTE ER (divalproex sodium)
valproic acid capsule	
valproic acid oral solution	

Felbamate

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
felbamate oral suspension	felbamate tablet
FELBATOL (felbamate) TABLET– *Brand Required*	

Lamotrigine

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
lamotrigine chewable tablet	LAMICTAL (lamotrigine) CHEWABLE TABLET
lamotrigine ER	LAMICTAL (lamotrigine) DOSE PACK
lamotrigine ODT	LAMICTAL (lamotrigine) TABLET
lamotrigine ODT dose pack	lamotrigine dose pack
lamotrigine tablet	LAMICTAL ODT (lamotrigine)
SUBVENITE (lamotrigine)	LAMICTAL ODT (lamotrigine) DOSE PACK
	LAMICTAL XR (lamotrigine)
	LAMICTAL XR (lamotrigine) DOSE PACK
	SUBVENITE (lamotrigine) DOSE PACK

Levetiracetam

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
levetiracetam ER	ELEPSIA XR (levetiracetam)
levetiracetam oral solution	KEPPRA (levetiracetam)
levetiracetam tablet	KEPPRA (levetiracetam) ORAL SOLUTION
	KEPPRA XR (levetiracetam)
	SPRITAM (levetiracetam) SUSPENSION

Rufinamide

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
BANZEL (rufinamide) ORAL SUSPENSION – *Brand Co-Preferred*	
BANZEL (rufinamide) TABLET – *Brand Co-Preferred*	
rufinamide suspension	
rufinamide tablet	

Topiramate

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
EPRONTIA (topiramate) SOLUTION	TOPAMAX (topiramate)
QUDEXY XR (topiramate) SPRINKLE CAPSULE – *Brand Required*	TOPAMAX (topiramate) SPRINKLE CAPSULE
topiramate sprinkle capsule	topiramate ER sprinkle cap
topiramate tablet	
TROKENDI XR (topiramate) – *Brand Required*	

Other

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
BRIVIACT (brivaracetam)	
FYCOMPA (perampanel)	
FYCOMPA (perampanel) ORAL SUSPENSION	
zonisamide	

Anticonvulsant Rescue Therapies

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
diazepam pediatric rectal gel	LIBERVANT (diazepam) FILM
diazepam rectal gel	
NAYZILAM (midazolam) NASAL SPRAY	
VALTOCO (diazepam) NASAL SPRAY	

Electronic Duration Verification

- 4 doses are covered every 60 days without an override

If one of the following criteria are met (A or B), please request an override by calling provider relations at 1-800-755-2604 or emailing medicaidpharmacy@nd.gov:

A. The previous dose has expired
B. The dose was used by member for a seizure (in this case, it is recommended to follow up with prescriber to discuss frequency of use and potential regimen review/adjustments)

Prior Authorization Criteria:

- See Preferred Dosage Form criteria

Duchenne Muscular Dystrophy

Corticosteroids

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AGAMREE (vamorolone)	deflazacort
EMFLAZA (deflazacort) – *Brand Required*	

Prior Authorization Criteria

Prior Authorization Form – Duchenne Muscular Dystrophy

Initial Criteria – Approval Duration: 6 months
(approval may be granted for tapering if all initial criteria are not met)

- Diagnosis must be confirmed by the presence of abnormal dystrophin or a confirmed mutation of the dystrophin gene
- The requested medication must be prescribed by, or in consult with, a physician who specializes in the treatment of Duchenne Muscular Dystrophy (DMD) and/or neuromuscular disorders
- Onset of weakness must have occurred before 2 years of age
- The member must have serum creatinine kinase activity of at least 10 times the upper limit of normal (ULN) prior to initiating treatment
- The member must have failed a 6-month trial of prednisone, as evidenced by paid claims or pharmacy printouts
- The provider must submit baseline assessment results from the following assessments (the member does not have to meet all of these parameters, but each assessment must be submitted, and provider must indicate which parameters are met and being preserved, must be at least one):
    - Stable cardiac function LVEF > 40% by echo
    - Scoliosis not requiring surgery
    - Stable respiratory function – FVC predicted > 50%, not requiring ventilatory assistance
    - The provider must submit baseline motor milestone score results from at least ONE the following assessments:
        - 6-minute walk test (6MWT)
        - North Star Ambulatory Assessment (NSAA)
        - Motor Function Measure (MFM)
        - Hammersmith Functional Motor Scale (HFMS)
        - Performance of Upper Limb (PUL)
        - 4 stair climb (4SC)
- The member must have ONE of the following significant intolerable adverse effects to prednisone supported by documentation:
    i. Cushingoid appearance
    ii. Central (truncal) obesity
    iii. Severe behavioral adverse effect
    iv. Undesirable weight gain (>10% of body weight gain increase over 6-month period)
    v. Diabetes and/or hypertension that is difficult to manage

Renewal Criteria – Approval Duration: 12 months

- The member must have experienced stabilization, slowing of disease progression, or improvement of the condition since starting treatment with the requested medication, including the following assessments (the member does not have to meet all of these parameters, but each assessment must be submitted, and provider must indicate which parameters are met and being preserved, must be at least one):
    - Stable cardiac function LVEF > 40% by ECHO

- Scoliosis not requiring surgery
- Stable respiratory function – FVC predicted > 50%, not requiring ventilatory assistance
- Motor function assessment
  - 6MWT – improvement of 35 meters from baseline
  - NSAA – improvement of 2 points from baseline
  - MFM – improvement of 2 points from baseline
  - HFMS – improvement of 2 points from baseline
  - PUL – improvement of 4 points from baseline
  - 4SC – improvement of 1 second from baseline

- The member must have had improvement of adverse effects experienced on prednisone supported by documentation:
  i. Cushingoid appearance
  ii. Central (truncal) obesity
  iii. Severe behavioral adverse effect
  iv. Undesirable weight gain (>10% of body weight gain increase over 6-month period)
  v. Diabetes and/or hypertension that is difficult to manage

References:

1. Muntoni, Francesco, et al. "Meaningful changes in motor function in Duchenne muscular dystrophy (DMD): A multi-center study." *PloS one* 19.7 (2024): e0304984.

Histone Deacetylase Inhibitor

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
DUVYZAT (givinostat)	

Prior Authorization Criteria

Prior Authorization Form – Duchenne Muscular Dystrophy

Initial Criteria – Approval Duration: 6 months

- The requested medication must be prescribed by, or in consult with, a physician who specializes in the treatment of Duchenne Muscular Dystrophy (DMD) and/or neuromuscular disorders.
- The member must be assigned male at birth.
- The diagnosis must be confirmed by the presence of abnormal dystrophin or a confirmed mutation of the dystrophin gene.
- The member must have a baseline 6-Minute Walk Time (6MWT) ≥ 300 meters while walking independently (e.g., without side-by-side assist, cane, walker, wheelchair, etc.)
- Weight and calculated dose must be provided consistent with approved FDA dose.
- The provider must submit baseline motor milestone score results from at least ONE the following assessments:
  - North Star Ambulatory Assessment (NSAA)
  - 4-stair claim (4SC)
- The member is on a stable dose of corticosteroids for the past 3 months, as evidenced by paid claims and pharmacy print outs.

Renewal Criteria – Approval Duration: 12 months

- The member must have maintained a 6MWT ≥ 300 meters while walking independently (e.g., without side-by-side assist, cane, walker, wheelchair, etc.)
- The member must have experienced stabilization, slowing of disease progression, or improvement of the condition since starting treatment with the requested medication, as evidenced by medical documentation (e.g., chart notes) attached to the request (subject to clinical review) including:
  - North Star Ambulatory Assessment (NSAA)
  - 4-stair claim (4SC)

Genetic Therapies

Exon 45 Skipping

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AMONDYS 45 (casimersen) – *Medical Billing Only*	

Exon 51 Skipping

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
EXONDYS 51 (eteplirsen) – *Medical Billing Only*	

Exon 53 Skipping

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
VILTEPSO (viltolarsen) – *Medical Billing Only*	VYONDYS 53 (golodirsen) – *Medical Billing Only*

High-Cost Drug:
Amondys 45, Exondys 51, and Vyondys 53 cost $758,000 per year for a 30 kg child.
Viltepso cost $733,200 per year for a 30 kg child.

- Amondys 45 is awaiting verification of clinical benefit in confirmatory trials. In Study 1 (NCT02500381), individuals treated with Amondys 45 observed an increase in mean dystrophin protein levels of 0.81%, while the placebo arm observed a mean increase of 0.22%.
- Exondys 51 is awaiting verification of clinical benefit in confirmatory trials. In Study 1, there was no significant difference in change in 6MWD in patients treated with Exondys 51 and placebo. All 12 individuals enrolled in Study 1, continued treatment with open-label Exondys 51 and were compared to an external control group. Study 2 failed to provide evidence of a clinical benefit of Exondys 51 compared to the external control group. In Study 3, the median increase in dystrophin level was 0.1% in 12 evaluable individuals receiving open-label Exondys 51.
- Viltepso is awaiting verification of clinical benefit in confirmatory trials. In Study 1 (NCT02740972), 8 individuals treated with Viltepso observed a mean increase in dystrophin of 5.3% of normal levels.
- Vyondys 53 is awaiting verification of clinical benefit in confirmatory trials. In Study 1 (NCT02310906), 25 individuals treated with Vyondys 53 observed a mean increase in dystropin of 0.92% of normal levels.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 8 weeks

- The member must be assigned male at birth between ages of 4 and 19 years old
- Diagnosis must be confirmed by the presence of abnormal dystrophin or a confirmed mutation of the dystrophin gene
- The requested medication must be prescribed by, or in consult with, a physician who specializes in the treatment of Duchenne Muscular Dystrophy (DMD) and/or neuromuscular disorders
- The member has had an inadequate treatment response with standard corticosteroid therapy for a minimum of 6 months with adherence, as evidenced by paid claims or pharmacy printouts
- The member must meet the following parameters:
  - A baseline 6-Minute Walk Time (6MWT) ≥ 300 meters while walking independently (e.g., without side-by-side assist, cane, walker, wheelchair, etc.)
  - Stable respiratory function – FVC predicted > 50%, not requiring ventilatory assistance
  - Stable cardiac function – LVEF > 40 % by ECHO
- Weight and calculated dose must be provided consistent with approved FDA dose
- The member must not be taking any other RNA antisense agent or any other gene therapy

Non-Preferred Agent Criteria (Initial)

- Please provide explanation with the request why the preferred agent cannot be used (subject to clinical review)

Renewal Criteria – Approval Duration: 12 months
- The member must meet the following parameters:
  - A 6MWT ≥ 300 meters while walking independently (e.g., without side-by-side assist, cane, walker, wheelchair, etc.)
  - Stable respiratory function – FVC predicted > 50%, not requiring ventilatory assistance
  - Stable cardiac function – LVEF > 40 % by ECHO

Huntington's Disease

CLINICAL PA REQUIRED
AUSTEDO (deutetrabenazine)
AUSTEDO XR (deutetrabenazine)
INGREZZA (valbenazine)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months
- The requested medication must be prescribed by, or in consult with, a neurologist or psychiatrist.
- The member must have failed a 3-month trial of tetrabenazine, as evidenced by paid claims or pharmacy printouts.

Hypersomnolence (Narcolepsy and Idiopathic Hypersomnia)

PREFERRED AGENTS (NO PA REQUIRED)	PREFERRED STEP 1 AGENTS (ELECTRONIC STEP)	NON-PREFERRED AGENTS (PA REQUIRED)
armodafinil	SUNOSI (solriamfetol)	NUVIGIL (armodafinil)
modafinil	XYREM (sodium oxybate) *– Brand Required*	PROVIGIL (modafinil)
		sodium oxybate
		WAKIX (pitolisant)
		XYWAV (sodium, calcium, magnesium, potassium oxybate)

Electronic Step Therapy Required

- Sunosi and Xyrem:
  A. PA Not Required Criteria: A 30-day supply of armodafinil or modafinil has been paid within 60 days prior to preferred step 1 agent's date of service.
  B. PA Required Criteria: The member must have failed a 30-day trial of armodafinil or modafinil, as evidenced by paid claims or pharmacy printouts.
- Wakix requires titration to 17.8 mg dose with 4.45 mg tablets.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months
- The member must have failed 30-day trials of each preferred agent (except Sunosi for idiopathic hypersomnia) and at least 1 additional CNS stimulant indicated for treatment of narcolepsy, as evidenced by paid claims or pharmacy printouts
- Documentation of each treatment failure must be provided, as evidenced by one of the following:

- Multiple Sleep Latency Test (MSLT) <8 minutes
- EPWORTH sleepiness scale score ≥10

- Xywav Only:
  - The member must have failed a 30-day trial with Wakix
  - Clinical justification must be provided explaining why the member is unable to Xyrem due to sodium content (subject to clinical review).

Renewal Criteria – Approval Duration: 12 months

- Provider must submit documentation of symptom improvement, as evidenced by documentation of one of the following, while on prior treatments:
  - Multiple Sleep Latency Test (MSLT) <8 minutes
  - EPWORTH sleepiness scale score ≥10

Therapeutic Duplication

- Sunosi and Wakix are not allowed together.
- Provigil and Nuvigil are not allowed together.
- Xyrem and, Xywav are not allowed with each other, sleeping medication or benzodiazepines.

Underutilization

- Wakix, Sunosi, and Xywav must be used adherently and will reject on point of sale for late fill.

Migraine

Prophylaxis of Migraine

Calcitonin Gene-Related Peptide (CGRP) Receptor Antagonist

PREFERRED AGENTS (CLINICAL PA REQUIRED)	PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AIMOVIG (erenumab-aooe)	NURTEC ODT (rimegepant) TABLETS	QULIPTA (atogepant) TABLETS
AJOVY (fremanezumab-vfrm)		VYEPTI (eptinezumab-jjmr) – *Medical Billing Only*
EMGALITY (galcanazumab-gnlm)		

Prior Authorization Criteria

Prior Authorization Form – Migraine Prophylaxis/Treatment

Initial Criteria – Approval Duration: 6 months

- The member must experience 3 or more migraine days per month.
- The member must have failed 2-month trials of at least two of the following agents from different therapeutic classes, as evidenced by paid claims or pharmacy printouts:
  - amitriptyline, atenolol, candesartan, divalproex sodium, metoprolol, nadolol, propranolol, topiramate, venlafaxine, zonisamide
- *Nurtec ODT Only:*
  - The member must have failed a 3-month trial of Ajovy and Emgality, as evidenced by paid claims or pharmacy printouts.

Non-Preferred Agents Criteria:

- *Qulipta Only:*
  - The member must have failed a 3-month trial of Ajovy, Emgality, Aimovig, and Nurtec ODT, as evidenced by paid claims or pharmacy printouts.
- *Vyepti Only:*
  - The member must have failed a 3-month trial of Ajovy, Emgality, Aimovig, Qulipta and Nurtec ODT, as evidenced by paid claims or pharmacy printouts.

Renewal Criteria – Approval Duration: 12 months

- The member must have experienced at least a 50% reduction in migraine frequency, pain intensity, or duration from baseline.

Treatment of Migraine

Calcitonin Gene-Related Peptide (CGRP) Receptor Antagonist

Therapeutic Duplication

7. One strength of one medication for treatment of migraine is allowed at a time.

Oral

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
NURTEC ODT (rimegepant)	UBRELVY (ubrogepant)

Prior Authorization Criteria

Prior Authorization Form – Migraine Prophylaxis/Treatment

Initial Criteria – Approval Duration: 3 months

- The member must have failed a 30-day trial of two triptans (5HT-1 Agonists) of unique ingredients, as evidenced by paid claims or pharmacy printouts.

Non-Preferred Agents Criteria:

- The member must have failed a 30-day trial of the preferred agent, as evidenced by paid claims or pharmacy printouts.

Nasal

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	ZAVZPRET NASAL SPRAY (zavegepant)

Prior Authorization Criteria

Prior Authorization Form – Migraine Prophylaxis/Treatment

Initial Criteria – Approval Duration: 3 months

Non-Preferred Agents Criteria:

- The member must have failed a 30-day trial of two triptans (5HT-1 Agonists), one of which must be nasal route, of unique ingredients, as evidenced by paid claims or pharmacy printouts.
- The member must have failed a 30-day trial of Nurtec ODT, Ubrelvy, and Reyvow, as evidenced by paid claims or pharmacy printouts.

Non-Steroidal Anti-inflammatory Drugs (NSAIDS)

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)

NSAIDS	ELYXYB (celecoxib)

Prior Authorization Criteria:

- See Preferred Dosage Form criteria

Serotonin (5-HT) 1F Receptor Agonist

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	REYVOW (lasmiditan)

Prior Authorization Criteria

Prior Authorization Form – Migraine Prophylaxis/Treatment

Initial Criteria – Approval Duration: 3 months

- The member must have failed a 30-day trial of two triptans (5HT-1 Agonists) of unique ingredients, as evidenced by paid claims or pharmacy printouts.
- The member must have failed a 30-day trial of Nurtec ODT and Ubrelvy, as evidenced by paid claims or pharmacy printouts.

Therapeutic Duplication

8. One strength of one medication for treatment of migraine is allowed at a time

Therapeutic Duplication

9. One strength of one medication for treatment of migraine is allowed at a time

Ergot Alkaloids

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	D.H.E.45 (dihydroergotamine) INJECTION
	dihydroergotamine injection
	dihydroergotamine nasal spray
	ERGOMAR (ergotamine) SL TABLET
	MIGERGOT (ergotamine/caffeine) RECTAL SUPPOSITORY
	TRUDHESA (dihydroergotamine)

Prior Authorization Criteria

Prior Authorization Form – Migraine Prophylaxis/Treatment

Initial Criteria – Approval Duration: 3 months

- The member must have failed a 30-day trial of two triptans (5HT-1 Agonists) of unique ingredients, as evidenced by paid claims or pharmacy printouts.
- The member must have failed a 30-day trial of a treatment CGRP receptor agonist, as evidenced by paid claims or pharmacy printouts.

Therapeutic Duplication

10. One strength of one medication for treatment of migraine is allowed at a time

Triptans (5HT-1 Agonists)

Solid Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED STEP 1 AGENTS (PA REQUIRED)	NON-PREFERRED STEP 2 AGENTS (PA REQUIRED)
RELPAX (eletriptan) – *Brand Required*	FROVA (frovatriptan) TABLET – *Brand Required*	almotriptan tablet
rizatriptan tablet	naratriptan tablet	AMERGE (naratriptan) TABLET
sumatriptan tablet	zolmitriptan tablet	eletriptan tablet
		frovatriptan tablet
		IMITREX (sumatriptan) TABLET
		MAXALT (rizatriptan) TABLET
		sumatriptan/naproxen tablet
		TREXIMET (sumatriptan/naproxen) TABLET
		ZOMIG (zolmitriptan) TABLET

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

Non-Preferred Step 1 Agents:

- The member must have failed a 30-day trial of rizatriptan, as evidenced by paid claims or pharmacy printouts.
- Members over 18 years old: The member must also have failed a 30-day trial of sumatriptan and eletriptan, as evidenced by paid claims or pharmacy printouts.

Non-Preferred Step 2 Agents:

- The member must have failed a 30-day trial of each available preferred and non-preferred step 1 triptan agent, as evidenced by paid claims or pharmacy printouts

Therapeutic Duplication

11. One strength of one medication for treatment of migraine is allowed at a time

Non-Solid Oral Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
rizatriptan ODT	MAXALT MLT (rizatriptan)
	zolmitriptan ODT

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

12. The member must have failed a 30-day trial of rizatriptan ODT, as evidenced by paid claims or pharmacy printouts.

Therapeutic Duplication

13. One strength of one medication for treatment of migraine is allowed at a time

Nasal Spray

PREFERRED AGENTS (NO PA REQUIRED)	PREFERRED STEP 1 AGENTS (PA REQUIRED)	NON-PREFERRED STEP 2 AGENTS (PA REQUIRED)
ZOMIG (zolmitriptan) NASAL SPRAY *– Brand Required*	sumatriptan spray	TOSYMRA (sumatriptan) NASAL SPRAY
		zolmitriptan spray

Injectable

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
IMITREX (sumatriptan) 6 MG/0.5 ML CARTRIDGE *– Brand Required*	IMITREX (sumatriptan) 4 MG/0.5 ML CARTRIDGE
IMITREX (sumatriptan) 6 MG/0.5 ML PEN INJECTOR *– Brand Required*	IMITREX (sumatriptan) 4 MG/0.5 ML PEN INJECTOR
	sumatriptan cartridge
	sumatriptan pen injector
	sumatriptan vial
	ZEMBRACE SYMTOUCH (sumatriptan)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

14. The member must be unable to take oral medications (subject to clinical review).

Non-Preferred Agent Criteria:

- See Preferred Dosage Form criteria

Therapeutic Duplication

15. One strength of one medication for treatment of migraine is allowed at a time

Cluster Headache

Cluster Headache Prevention

CLINICAL PA REQUIRED
EMGALITY (galcanazumab-gnlm)

- Emgality is to be used as preventative treatment during episodic cluster headache episodes (cluster periods usually last between 2 weeks and 3 months with pain-free periods lasting at least 3 months), as it is not indicated for chronic use

Prior Authorization Criteria

Prior Authorization Form – Migraine Prophylaxis/Treatment

Initial Criteria – Approval Duration: 3 months

- The member has had at least five attacks fulfilling criteria A-C
  - *A.* Severe or very severe unilateral orbital, supraorbital and/or temporal pain lasting at least 15 minutes
  - *B.* Occurring with a frequency of at least every other day
  - *C.* The member must have at least one of the following:
    - A sense of restlessness or agitation

    - Any of the following symptoms or signs, ipsilateral to the headache:
        - Conjunctival injection and/or lacrimation
        - Nasal congestion and/or rhinorrhea
        - Eyelid edema
        - Forehead and facial swelling
        - Miosis and/or ptosis
- The member must have had a 2-month trial with verapamil.

Myasthenia Gravis

Glucocorticoid-Sparing Therapy

Oral Agents

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
azathioprine	
cyclosporine	
mycophenolate mofetil	
tacrolimus	

Biologic Agents

Acetylcholine Receptor (AChR) Antibody Positive

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
RIABNI (rituximab-arrx) – *Medical Billing Only*	RITUXAN (rituximab) – *Medical Billing Only*
RUXIENCE (rituximab-pvvr) – *Medical Billing Only*	SOLIRIS (eculizumab) – *Medical Billing Only*
TRUXIMA (rituximab-abbs) – *Medical Billing Only*	
PREFERRED AGENTS (CLINICAL PA REQUIRED)	
ULTOMIRIS (ravulizumab) – *Medical Billing Only*	
RYSTIGGO (rozanolixizumab-noli) – *Medical Billing Only*	
VYVGART (ergartigimod alfa) – *Medical Billing Only*	
VYVGART HYTRULO (efgartigimod alfa/hyaluronidase) – *Medical Billing Only*	
ZILBRYSQ (zilucoplan)	

Muscle Specific Kinase (MuSK) Positive

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
RIABNI (rituximab-arrx) – *Medical Billing Only*	RITUXAN (rituximab) – *Medical Billing Only*
RUXIENCE (rituximab-pvvr) – *Medical Billing Only*	RYSTIGGO (rozanolixizumab-noli) – *Medical Billing Only*
TRUXIMA (rituximab-abbs) – *Medical Billing Only*	

Prior Authorization Criteria

<u>Initial Criteria – Approval Duration:</u> 6 months (1 year total for bridge therapy)

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational).
- The requested medication must be prescribed by, or in consult with, a neurologist or neuromuscular specialist.
- The member must have all of the following:
    - Myasthenia Gravis Foundation of America (MGFA) clinical classification class of II, III, or IV

- Positive serological lab test for one of the following (A or B):
  A. Anti-AchR antibodies
  B. Anti-MuSK antibodies

- The member must have Myasthenia Gravis-specific Activities of Daily Living (MG-ADL) total score of one of the following:
  - For Zilbrysq (zilucoplan), Soliris (eculizumab), or Ultomiris (ravulizumab-cwvz) requests: ≥ 6
  - For Vyvgart (efgartigimod alfa-fcab) or Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc) requests: ≥ 5
  - For Rystiggo (rozanolixizumab-noli) requests: ≥ 3 (with at least 3 points from non-ocular symptoms)
- Rituxan Only: See Biosimilar Agents Criteria

Acetylcholine Receptor (AChR) Antibody Positive

- One of the following (A or B):
  A. The member is unable to complete glucocorticoid bridge therapy (e.g., diabetes) while waiting for efficacy of oral immunosuppressive therapies (e.g., azathioprine, cyclosporine, mycophenolate mofetil, tacrolimus)
  B. The member required chronic intravenous immunoglobulin (IVIG) or chronic plasmapheresis/plasma exchange (i.e., at least every 3 months over 12 months without symptom control), despite a 12-month trial (total duration) of immunosuppressive therapies (e.g., azathioprine, cyclosporine, mycophenolate mofetil, tacrolimus)
- Soliris Only:
  - The member required chronic intravenous immunoglobulin (IVIG) or chronic plasmapheresis/plasma exchange (i.e., at least every 3 months over 12 months without symptom control), despite a 90-day trial or recommended cycle duration of each of the following:
    A. Rituximab
    B. Ultomiris
    C. Vyvgart or Rystiggo

Muscle Specific Kinase (MuSK) Positive

- The member required chronic intravenous immunoglobulin (IVIG) or chronic plasmapheresis/plasma exchange (i.e., at least every 3 months over 12 months without symptom control), despite a 90-day trial of rituximab.

Renewal Criteria – Approval Duration: 12 months

- The member must have experienced meaningful clinical benefit since starting treatment with the requested medication, as evidenced by one of the following scores and symptoms (subject to clinical review):
  - Decreased rate of Myasthenia Gravis exacerbations
  - A 2-point improvement in the member's total MG-ADL score

Multiple Sclerosis

Injectable Agents

B-cell and T-cell Therapies

PREFERRED AGENTS (NO PA REQUIRED)	PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
BRIUMVI (ublituximab-xiiy) *– Medical Billing Only*	TYSABRI (natalizumab) *– Medical Billing Only*	MAVENCLAD (cladribine)
KESIMPTA (ofatumumab)		LEMTRADA (alemtuzumab) *– Medical Billing Only*
OCREVUS (ocrelizumab) *– Medical Billing Only*		

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months
Tysabri Only:
- The requested medication must be prescribed by, or in consult with, a neurologist

Non-Preferred Agents:
- The member must have failed a 3-month trial of two agents in the class of the requested product, as evidenced by paid claims or pharmacy print outs.

Interferons

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AVONEX (interferon beta-1A) PEN	BETASERON (interferon beta-1B)
AVONEX (interferon beta-1A) SYRINGE	EXTAVIA (interferon beta-1B)
AVONEX (interferon beta-1A) VIAL	PLEGRIDY (peginterferon beta-1A) PEN
	PLEGRIDY (peginterferon beta-1A) SYRINGE
	REBIF (interferon beta-1A)
	REBIF REBIDOSE (interferon beta-1A)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months
- The member must have failed a 3-month trial of the preferred agent in the class of the requested product, as evidenced by paid claims or pharmacy print outs.

Non-Interferons

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
COPAXONE (glatiramer) 20 MG/ML – *Brand Required*	COPAXONE (glatiramer) 40 MG/ML
	glatiramer 20 mg/ml
	glatiramer 40 mg/ml
	GLATOPA (glatiramer)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months
- Copaxone: See Preferred Dosage Form criteria

Oral Agents

Fumerates

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
dimethyl fumarate	BAFIERTAM (monomethyl fumarate)
	TECFIDERA (dimethyl fumarate)
	VUMERITY (diroximel fumarate)

Pyrimidine Synthesis Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
Teriflunomide	AUBAGIO (teriflunomide)

Sphingosine 1-Phosphate (S1P) Receptor Modulators

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
fingolimod 0.5 mg	GILENYA (fingolimod) 0.5 MG
GILENYA (fingolimod) 0.25 MG	MAYZENT (siponimod)
TASCENSO ODT (fingolimod)	PONVORY (ponesimod)
	ZEPOSIA (ozanimod)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must have failed a 3-month trial of all oral preferred agents of an unique ingredient, as evidenced by paid claims or pharmacy print outs.

Neuromyelitis Optica Spectrum Disorder

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ENSPRYNG (satralizumab-mwge)	SOLIRIS (eculizumab) – *Medical Billing Only*
ULTOMIRIS (ravulizumab-cwvz) – *Medical Billing Only*	
UPLIZNA (inebilizumab) – *Medical Billing Only*	

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational).
- The requested medication must be prescribed by, or in consult with, a neurologist
- The member has positive serologic test for anti-AQP4 antibodies.
- The member has a history of ≥ 1 relapses that required rescue therapy within the past 12 months
- The member has an Expanded Disability Status Score (EDSS) of ≤ 6.5
- The member must have one of the core clinical characteristics from the following:
  - Optic neuritis
  - Acute myelitis
  - Area postrema syndrome: episode of otherwise unexplained hiccups or nausea and vomiting
  - Acute brainstem syndrome
  - Symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions
  - Symptomatic cerebral syndrome with NMOSD-typical brain lesions

Non-Preferred Agents Criteria

- The member must have had a 3-month trial with Enspryng, Ultomiris and Uplizna, as evidenced by paid claims or pharmacy print outs:

Renewal Criteria – Approval Duration: 12 months

- The member must have experienced stabilization, slowing of disease progression, or improvement of the condition since starting treatment with the requested medication, as evidenced by medical documentation (e.g., chart notes) attached to the request (subject to clinical review) including:
  - Reduction in relapse rate
  - Reduction in symptoms (such as pain, fatigue, motor function)

Pseudobulbar Affect (PBA)

CLINICAL PA REQUIRED
NUEDEXTA (dextromethorphan/quinidine)

Prior Authorization Criteria

Prior Authorization Form – Nuedexta

Initial Criteria – Approval Duration: 3 months

- The member must not have a diagnosis of any of the following: prolonged QT interval, heart failure, or complete atrioventricular (AV) block.
- The following must be provided:
  - Baseline Center for Neurological Studies lability (CNS-LS) score
  - Baseline weekly PBA episode count
- The member must have diagnosis of pseudobulbar affect (PBA) due to one of the following neurologic conditions and meet additional criteria for diagnosis:
  - Amytrophic Lateral Sclerosis (ALS)
  - Multiple Sclerosis (MS)
  - Alzheimer's Disease
  - Stroke
- For diagnosis of PBA due to Alzheimer's disease or stroke only:
  - Neurologic condition must have been stable for at least 3 months
  - Member must have failed a 3-month trial of at least one medication from each of the following classes, as evidenced by paid claims or pharmacy print outs:
    - SSRIs: sertraline, fluoxetine, citalopram and paroxetine
    - Tricyclic Antidepressants: nortriptyline and amitriptyline
  - Documentation of each treatment failure of SSRI and tricyclic antidepressant must be provided, as evidenced by a PBA episode count and CNS-LS score before and after each trial showing one of the following:
    - PBA count has not decreased by more than 75 percent from baseline
    - CNS-LS score has not decreased by more than 7 points from baseline

Renewal Criteria – Approval Duration: 6 months

- Benefit of continued therapy must be assessed.
  - Spontaneous improvement of PBA occurs and should be ruled out periodically before continuing medication.
- For diagnosis of PBA due to Alzheimer's disease or stroke only:
  - Current CNS-LS score must be reduced by at least 30% from baseline
- For all other indications:
  - Current PBA episode must be reduced by at least 75% from baseline

Parkinson's disease

Parkinson's Agents – First Line Therapy

Parkinson's Agents – Levodopa

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
carbidopa-levodopa-entacapone 25 mg/100 mg, 37.5 mg/150 mg, 50 mg/200 mg	carbidopa-levodopa-entacapone 12.5 mg/50 mg, 18.75 mg/75 mg, 31.25 mg/125 mg
carbidopa-levodopa	CREXONT (carbidopa-levodopa ER)
carbidopa-levodopa ER	DHIVY (carbidopa-levodopa)
carbidopa-levodopa ODT	SINEMET (carbidopa-levodopa) TABLET
RYTARY (carbidopa-levodopa) ER CAPSULE	STALEVO (carbidopa-levodopa-entacapone)

Prior Authorization Criteria

- See Preferred Dosage Form criteria

Parkinson's Agents – Adjunctive Therapy

Parkinson's Agents – Adenosine Receptor Agonists

Oral

CLINICAL PA REQUIRED
NOURIANZ (Istradefylline)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 3 months

- The requested medication must be prescribed by, or in consult with, a neurologist
- The member has a minimum of 3 hours of "off" time per day despite a 3-month trial of combination therapy with a carbidopa/levodopa, a dopamine agonist, a COMT inhibitor, a MOA-B inhibitor, and amantadine.
- The member has had a previous response to levodopa.

Renewal Criteria – Approval Duration: 12 months

- The member has had either a 50% reduction or 3-hour reduction in hours per day of "off" time.

Parkinson's Agents - Amantadine

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
amantadine IR capsule	amantadine IR tablet
amantadine solution	GOCOVRI (amantadine ER)
	OSMOLEX ER (amantadine ER)

Electronic Age Verification:

- Amantadine: Member must be 18 years old or older

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must not reside in facility where medications are managed such as skilled nursing care.
- See Preferred Dosage Form Criteria

Parkinson's Agents – Anticholinergics

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
benztropine	COGENTIN (benztropine)
trihexyphenidyl	

Parkinson's Agents – COMT inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
entacapone	COMTAN (entacapone)

TASMAR (tolcapone) – *Brand Required*	ONGENTYS (opicapone)
	tolcapone

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must have failed a 30-day trial of each of the preferred agents, as evidenced by paid claims or pharmacy printouts.

Parkinson's Agents – Ergot Dopamine Receptor Agonists

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
bromocriptine	PARLODEL (bromocriptine)

Parkinson's Agents – MAO-B Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
rasagiline	AZILECT (rasagiline)
selegiline	EMSAM (selegiline) PATCH
ZALAPAR ODT (selegiline)	XADAGO (safinamide)

Prior Authorization Criteria

Emsam Only:

- See Preferred Dosage Form and Non-Solid Oral Dosage Form criteria

Xadago Only:

- *Initial Criteria – Approval Duration: 3 months*
  - The requested medication must be prescribed by, or in consult with, a neurologist
  - The member has a minimum of 3 hours of "off" time per day despite a 3-month trial of combination therapy with a carbidopa/levodopa, a dopamine agonist, a COMT inhibitor, a MOA-B inhibitor, and amantadine.
  - The member has had a previous response to levodopa.

- *Renewal Criteria – Approval Duration: 12 months*
  - The member has had either a 50% reduction or 3-hour reduction in hours per day of "off" time.

Parkinson's Agents – Non-ergot Dopamine Receptor Agonists

Oral

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
pramipexole IR	MIRAPEX (pramipexole)
ropinirole IR	MIRAPEX ER (pramipexole)
ropinirole ER	pramipexole ER
	REQUIP (ropinirole)

Topical

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	NEUPRO (rotigotine) PATCH

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must not reside in facility where medications are managed such as skilled nursing care.
- Clinical justification must be provided explaining why the member is unable to use the preferred agents (subject to clinical review).
- Pramipexole ER: See Preferred Dosage Form criteria

Parkinson' Agents – Device-Assisted Refractory Therapies

Enteral Suspension

CLINICAL PA REQUIRED
DUOPA (levodopa/carbidopa)

Subcutaneous

CLINICAL PA REQUIRED
VYALEV (foscarbidopa/foslevodopa)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 3 months

- The requested medication must be prescribed by, or in consult with, a neurologist.
- The member is currently taking at least 2 g/day of levodopa in combination with carbidopa.
- The member has a minimum of 3 hours of "off" time per day despite a 3-month trial of at least two of the following: a dopamine agonist, a COMT inhibitor, a MOA-B inhibitor, and amantadine.
- The member has had a previous response to levodopa.

Renewal Criteria – Approval Duration: 12 months

- The member has had either a 50% reduction or 3-hour reduction in hours per day of "off" time.

Parkinson's Agents – On-Demand Rescue for "Off" Episodes

Subcutaneous

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
APOKYN (apomorphine) – *Brand Required*	apomorphine

Inhalation

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
INBRIJA (levodopa)	

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The requested medication must be prescribed by, or in consult with, a neurologist
- The member must be currently taking carbidopa – levodopa, as evidenced by paid claims or pharmacy printouts, and will continue taking carbidopa – levodopa concurrently with requested agent
- Documentation must be provided of intermittent hypomobility or off episodes (number and frequency)
- At least one of the following criteria must be met:
  - The member is experiencing unpredictable off periods, morning off, delayed on, no on or failure of on response

- The member is experiencing wearing off episodes or other levodopa dose cycle related dystonias or akathisias, and a treatment adjustment plan is attached (e.g., levodopa dose and interval adjustments, bedtime dose of CR or ER levodopa/ carbidopa, addition of adjunctive therapy)

Spinal Muscular Atrophy (SMA)

SMN2 Gene Splicing Modifiers

CLINICAL PA REQUIRED
EVRYSDI (risdiplam)
SPINRAZA (nusinersen) – *Medical Billing Only*

Prior Authorization Criteria

Prior Authorization Form – Evrysdi

Initial Criteria – Approval Duration: 12 months

- The member must have a diagnosis of spinal muscular atrophy (SMA) with each of the following:
  - Bi-allelic deletions or mutations of SMN1 as confirmed by genetic testing, reported as one of the following:
    - Homozygous deletions of exon 7
    - Compound heterozygous mutations
  - One of the following:
    - The member has number of SMN2 gene copies ≥ 1 but ≤ 4 as confirmed by genetic testing
    - The member is symptomatic (e.g., loss of reflexes, motor delay, motor weakness, abnormal EMG/neuromuscular ultrasound)
- The requested medication must be prescribed by, or in consult with, a neuromuscular neurologist or neuromuscular physiatrist (medical geneticist may be allowed for initial request)
- The member must visit with a neuromuscular clinic - clinic name and contact information and date of last visit must be provided, and date of last visit must be within the last year (short term 6-month bypass of this criteria may be granted to allow time for appointment scheduling if genetic test showing 0 copies of SMN1 and SMN2 gene copies ≥ 1 but ≤ 4 is provided):
- The member must not require continuous intubation > 3 weeks
- The member must not have received gene therapy (i.e., Zolgensma)
- The member's weight and prescribed dose must be provided and within dosing recommendations per the manufacturer label
- The member's baseline motor milestone score results must be provided from at least two of the following assessments (short term 6-month bypass of this criteria may be granted to allow time for appointment scheduling if genetic test showing 0 copies of SMN1 and SMN2 gene copies ≥ 1 but ≤ 4 is provided):
  - Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorder (CHOP-INTEND)
  - Hammersmith Infant Neurological Examination (HINE) Section 2 motor milestone score
  - Hammersmith Functional Motor Scale Expanded (HFMSE)
  - Motor Function Measure – 32 items (MFM-32)
  - Revised Upper Limb Module (RULM)
  - 6-minute walk test (6MWT)
  - Forced Vital Capacity (FVC and FEV1) via Pulmonary Function Test
- Spinraza Only: The member must not have severe contractures or severe scoliosis

Renewal Criteria – Approval Duration: 12 months

- The member's weight and prescribed dose must be provided and within dosing recommendations per the manufacturer label
- The member must visit with a neuromuscular clinic - clinic name, contact information, and date of last visit must be provided, and date of last visit must be within the last year

- The provider must submit motor milestone score results showing that the member has experienced clinical benefit (defined as maintenance of baseline motor function or significant slowed rate of decline vs expected natural course of the disease) since starting treatment, as evidenced by documentation of one of the following:
  - Current Forced Vital capacity (FVC and FEV1) via Pulmonary Function Test
  - CHOP-INTEND, HINE, HFMSE, MFM-32, 6MWT, or RULM scores

Gene Therapy

CLINICAL PA REQUIRED
ZOLGENSMA (onasemnogene abeparvovec) – *Medical Billing Only*

Prior Authorization Criteria

Initial Criteria – Approval Duration: 1 month (Approval is limited to a single intravenous infusion per lifetime)
- The member is less than 2 years of age
- The diagnosis is spinal muscular atrophy (SMA) with genetic testing confirming bi-allelic deletions or mutations in the *SMN1 gene*
- The medication is prescribed per the dosing guidelines in the package insert (recommended dose is 1.1 x 10^{14} vector genomes per kilogram)
- Baseline Documentation has been provided confirming anti-adeno-associated virus serotype 9 (anti-AAV9) antibody titer is ≤ 1:50 measured by Enzyme-linked Immunosorbent Assay (ELISA) binding immunoassay
- Member must not have advanced SMA evidenced by one of the following
  - Complete paralysis of limbs
  - Permanent ventilator dependence (defined as requiring invasive ventilation (tracheostomy) or respiratory assistance for 16 of more hours per day (including noninvasive ventilatory support) continuously for 14 or more days in the absence of an acute reversible illness, excluding perioperative ventilation.

Tardive Dyskinesia

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AUSTEDO (deutetrabenazine)	tetrabenazine 25 mg
AUSTEDO XR (deutetrabenazine)	XENAZINE (tetrabenazine)
INGREZZA (valbenazine)	
tetrabenazine 12.5 mg	

Electronic Step Therapy Required

- The Initiation Pack or 40 mg x 7 days is required for titration to 80 mg capsules.

Prior Authorization Criteria

Prior Authorization Form – Tardive Dyskinesia

Initial Criteria – Approval Duration: 12 months
- The requested medication must be prescribed by, or in consult with, a psychiatric or neurology specialist.
- The member must have a history of treatment with dopamine receptor blocking agent (DRBA).
- The member must have a total AIMS score (items 1-7) of ≥ 6 or AIMS score on item 8 or item 9 ≥ 3

Renewal Criteria – Approval Duration: 12 months
- The member must have had improvement in AIMS score from baseline

Obstetrics/Gynecology

Endometriosis Pain

CLINICAL PA REQUIRED
MYFEMBREE (relugolix, estradiol, and norethindrone acetate)
ORILISSA (elagolix)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- The member must have failed the following trials (A and B), as evidenced by paid claims or pharmacy printouts:
  A. A 3-menstrual cycle trial of mefenamic acid or meclofenamate, celecoxib, ibuprofen 1800 mg/day or equivalent high dose NSAID
  B. A 3-menstrual cycle trial of an oral estrogen-progestin or progestin contraceptives

Renewal Criteria – Approval Duration: 18 months

- Documentation must be submitted of improvement in pain score from baseline

Electronic Diagnosis Verification

- Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale.

Estrogens

Injectable

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
DELESTROGEN (estradiol valerate) INJECTION – Brand Required	estradiol valerate injection
DEPO-ESTRADIOL (estradiol cypionate) INJECTION	PREMARIN (estrogens, conjugated) INJECTION

Oral

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
estradiol tablet	ACTIVELLA (estradiol-norethindrone) TABLET
estradiol-norethindrone tablet	AMABELZ (estradiol-norethindrone) TABLET
norethindrone-ethinyl estradiol tablet	BIJUVA (estradiol-progesterone) CAPSULE
PREMARIN (estrogens, conjugated) TABLET	ESTRACE (estradiol) TABLET
PREMPHASE (estrogen, conj. M-progest) TABLET	FEMHRT (norethindrone-ethyl estradiol) TABLET
PREMPRO (estrogen, conj. M-progest) TABLET	FYAVOLV (norethindrone-ethinyl estradiol) TABLET
	MENEST (estrogens, esterified) TABLET
	JINTELI (norethindrone-ethinyl estradiol) TABLET
	MIMVEY (estradiol-norgestimate) TABLET
	PREFEST (estradiol-norgestimate) TABLET

Topical Gel/Spray

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ELESTRIN (estradiol) GEL MDP	DIVIGEL (estradiol) GEL PACKET
EVAMIST (estradiol) SPRAY	estradiol gel

Topical Patch

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ALORA (estradiol) PATCH TWICE WEEKLY *- Brand Required*	CLIMARA (estradiol) PATCH WEEKLY
CLIMARA PRO (estradiol-levonorgestrel) PATCH - ONCE WEEKLY	DOTTI (estradiol) PATCH TWICE WEEKLY
COMBIPATCH (estradiol- norethindrone) PATCH - TWICE WEEKLY	estradiol patch twice weekly
estradiol patch weekly	LYLLANA (estradiol) PATCH TWICE WEEKLY
MENOSTAR (estradiol) PATCH ONCE WEEKLY	
MINIVELLE (estradiol) PATCH TWICE WEEKLY *- Brand Required*	
VIVELLE-DOT (estradiol) PATCH TWICE WEEKLY *- Brand Required*	

Vaginal

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
estradiol vaginal cream	ESTRACE (estradiol) CREAM
ESTRING (estradiol)	estradiol vaginal tablet
FEMRING (estradiol)	YUVAFEM (estradiol) VAGINAL TABLET
PREMARIN (estrogens, conjugated) CREAM	
VAGIFEM (estradiol) VAGINAL TABLET *– Brand Required*	

Electronic Diagnosis Verification

- Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must have failed 30-day trials of at least two preferred products, as evidenced by paid claims or pharmacy printouts.

Long-Acting Contraception

Therapeutic Duplication

- One strength of one medication is allowed at a time

Menopause – Vasomotor Symptoms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
citalopram	BRISDELLE (paroxetine mesylate)
clonidine	paroxetine mesylate 7.5mg capsules
desvenlafaxine	VEOZAH (fezolinetant)
escitalopram	
estrogen products	
gabapentin	
oxybutynin	
paroxetine hydrochloride tablets	

venlafaxine	

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

- BOTH of the following must be met (1 and 2):
  1. One of the following must be met (a or b):
     a. The member must have failed a 90-day trial of estrogen therapy, as evidenced by paid claims or pharmacy printouts
     b. The member has prior history of stroke, myocardial infarction, venous thromboembolism, coronary artery disease, or breast cancer.
  2. The member must have failed a 30-day trial of each of the following, as evidenced by paid claims or pharmacy printouts:
     - SNRI: Venlafaxine or desvenlafaxine
     - SSRI: citalopram, escitalopram, or paroxetine
- Paroxetine mesylate: See Preferred Dosage Form Criteria

References:

1. Khan SJ, Kapoor E, Faubion SS, Kling JM. Vasomotor Symptoms During Menopause: A Practical Guide on Current Treatments and Future Perspectives. Int J Womens Health. 2023 Feb 14;15:273-287. doi: 10.2147/IJWH.S365808. PMID: 36820056; PMCID: PMC9938702.

Mifepristone

Electronic Diagnosis Verification

- Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale.

Prior Authorization Form – Mifepristone

Initial Criteria – Approval Duration: 1 month

- Gestational age must be less than or equal to 70 days
- One of the following criteria must be met (A or B):
  - **A. Pregnancy must have resulted from an act of rape or incest, and one of the following (I or II)**
    - I. A written statement signed by the provider must be submitted stating that the rape or act of incest has been reported to the appropriate law enforcement agency, or in the case of a minor who is a victim of incest, to an agency authorized to receive child abuse and neglect reports and it must be indicated to whom the report was made.
    - II. A written statement signed by the member and the provider must be submitted stating that the member's pregnancy resulted from rape or incest and by professional judgement, the provider agrees with the statement.
  - **B. Both of the following must be met (I and II)**
    - I. The member must suffer from a physical disorder, physical injury, or physical illness, including a life-endangering physical condition caused by or arising from the pregnancy itself, that would as certified by a provider, place the member in danger of death unless an abortion is performed
    - II. A written statement signed by the provider must be provided indicating why, in the provider's professional judgement, the life of the member would be endangered if the fetus were carried to term

Nausea/Vomiting – Pregnancy

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)

DICLEGIS (doxylamine/vitamin B6) – *Brand Required*	BONJESTA (doxylamine/vitamin B6)
meclizine	doxylamine/vitamin B6
metoclopramide	
ondansetron	

Prior Authorization Criteria

Initial Criteria – Approval Duration: until due date

- Member's due date must be provided
- See Preferred Dosage Form criteria

Progesterone

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
progesterone capsule	

Electronic Diagnosis Verification

- Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale.

Uterine Fibroids

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
MYFEMBREE (relugolix, estradiol, and norethindrone acetate)	ORIAHNN (elagolix, estradiol, and norethindrone acetate)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- The member must have failed the following trials (A and B), as evidenced by paid claims or pharmacy printouts:
  A. A 3-menstrual cycle trial of mefenamic acid or meclofenamate, celecoxib, ibuprofen 1800 mg/day or equivalent high dose NSAID
  B. A 3-menstrual cycle trial of an oral estrogen-progestin or progestin contraceptives

Renewal Criteria – Approval Duration: 18 months

- Documentation must be submitted of improvement in pain score from baseline

Electronic Diagnosis Verification

- Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale.

Vaginal Infections

Bacterial Infections

Oral

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
metronidazole tablet	

Vaginal

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
CLEOCIN (clindamycin) SUPPOSITORY	CLINDESSE (clindamycin) CREAM

clindamycin cream	VANDAZOLE (metronidazole) GEL
metronidazole gel	
NUVESSA (metronidazole) GEL	
XACIATO (clindamycin phosphate) GEL	

Fungal Infections

Oral

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
fluconazole tablet	BREXAFEMME (ibrexafungerp) TABLETS
tinidazole tablet	VIVJOA (oteseconazole) CAPSULES

Vaginal

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
terconazole cream	GYNAZOLE 1 (butoconazole) CREAM
terconazole suppository – labeler 00713	terconazole suppository – labeler 45802

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must have failed 30-day trials of all preferred agents of unique ingredients, as evidenced by paid claims or pharmacy printouts.
- Vivjoa Only:
  - The member must have failed a six-month trial of oral fluconazole maintenance prophylaxis treatment
  - The member must not be of reproductive potential defined as:
    - The member is postmenopausal
    - The member is known to not be of reproductive potential (e.g., history of tubal ligation, salpingo-oophorectomy, or hysterectomy)

Ophthalmology

Antihistamines

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
azelastine	ALOCRIL (nedocromil)
BEPREVE (bepotastine) – *Brand Required*	ALOMIDE (lodoxamide)
cromolyn	bepotastine
olopatadine 0.1%	epinastine
PAZEO (olopatadine)	olopatadine 0.2%
	ZERVIATE (cetirizine)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must have failed 30-day trials of olopatadine and bepotastine, as evidenced by paid claims or pharmacy printouts.

Anti-infectives

Drops

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
BESIVANCE (besifloxacin) DROPS	AZASITE (azithromycin) DROPS
ciprofloxacin drops	CILOXAN (ciprofloxacin) DROPS
gentamicin sulfate drops	gatifloxacin drops
moxifloxacin drops (generic Vigamox)	moxifloxacin drops (generic Moxeza)
neomycin SU/polymyxin B/gramicidin drops	NATACYN (natamycin) DROPS
ofloxacin drops	OCUFLOX (ofloxacin) DROPS
polymyxin B/trimethoprim drops	POLYTRIM (polymyxin B/trimethoprim) DROPS
sulfacetamide drops	VIGAMOX (moxifloxacin) DROPS
tobramycin drops	
ZYMAXID (gatifloxacin) DROPS – *Brand Required*	

Ointment

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
bacitracin/polymyxin B ointment	bacitracin ointment
CILOXAN (ciprofloxacin) OINTMENT	NEO-POLYCIN (neomycin SU/bacitracin/polymyxin B) OINTMENT
erythromycin ointment	POLYCIN (bacitracin/polymyxin B) OINTMENT
GENTAK (gentamicin sulfate) OINTMENT	sulfacetamide ointment
neomycin SU/bacitracin/polymyxin B ointment	
TOBREX (tobramycin) OINTMENT	

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must have failed a 5-day trial of a preferred agent in each unique therapeutic class, as evidenced by paid claims or pharmacy printouts.

Anti-infectives/Anti-inflammatories

Drops

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
neomycin/polymyxin b/dexamethasone drops	MAXITROL (neomycin/polymyxin b/dexamethasone) DROPS
sulfacetamide/prednisolone drops	neomycin/polymyxin b/hydrocortisone drops
tobramycin/dexamethasone drops	
TOBRADEX ST (tobramycin/dexamethasone) DROPS	
ZYLET (tobramycin/lotepred etab) DROPS	

Ointment

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
neomycin/polymyxin b/dexamethasone ointment	MAXITROL (neomycin/polymyxin b/dexamethasone) OINTMENT
TOBRADEX (tobramycin/dexamethasone) OINTMENT	neomycin/bacitracin/polymyxin b/hydrocortisone ointment
	NEO-POLYCIN HC (neomycin SU/bacitracin/

	polymyxin B/hydrocortisone) OINTMENT

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must have failed a 5-day trial of a preferred agent in each unique therapeutic class, as evidenced by paid claims or pharmacy printouts.

Anti-inflammatories

Corticosteroids

Drops

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ALREX (loteprednol) DROPS – *Brand Required*	clobetasol 0.05% drops
FLAREX (fluorometholone) DROPS	dexamethasone sodium phosphate drops
fluorometholone drops	difluprednate drops
FML FORTE (fluorometholone) DROPS	DUREZOL (difluprednate) DROPS
LOTEMAX (loteprednol) DROPS – *Brand Required*	INVELTYS (loteprednol) DROPS
LOTEMAX (loteprednol) GEL DROPS – *Brand Required*	FML (fluorometholone) DROPS
MAXIDEX (dexamethasone) DROPS	LOTEMAX SM (loteprednol) DROPS
PRED MILD 0.12% (prednisolone acetate) DROPS	loteprednol eye drops
prednisolone acetate 1% drops	loteprednol gel eye drops
prednisolone sodium phosphate 1% drops	PRED FORTE 1% (prednisolone acetate) DROPS

Ointment

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
FML S.O.P. (fluorometholone) OINTMENT	
LOTEMAX (loteprednol) OINTMENT	

Non-Steroidal Anti-inflammatory Drugs (NSAIDS)

Drops

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ACUVAIL (ketorolac) DROPS	ACULAR (ketorolac) DROPS
diclofenac sodium drops	ACULAR LS (ketorolac) DROPS
ILEVRO (nepafenac) DROPS	bromfenac sodium drops
ketorolac tromethaminedrops	BROMSITE (bromfenac sodium) DROPS
NEVANAC (nepafenac) DROPS	
PROLENSA (bromfenac) DROPS – *Brand Required*	

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must have failed a 5-day trial of each preferred agent in the respective therapeutic class, as evidenced by paid claims or pharmacy printouts.

Dry Eye Syndrome

Initial Management - Lubricants

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ARTIFICIAL TEARS (dextran/hypromellose/glycerin)	FRESHKOTE (polyvinyl alcohol/povidone)
ARTIFICIAL TEARS (polyvinyl alcohol/povidone)	SENTIA (propylene glycol)
BION TEARS EYE DROPS (dextran 70/hypromellose)	VENTIVA (propylene glycol)
carboxymethylcellulose	VENTIVA (carboxymethylcellulose)
DRY EYE RELIEF (peg 400/Hypromellose/glycerin)	
GENTEAL TEARS (dextran/hypromellose/glycerin)	
GENTEAL TEARS (dextran 70/hypromellose)	
GENTEAL TEARS (hypromellose)	
LUBRICANT EYE DROPS (carboxymethylcellulose)	
LUBRICANT EYE DROPS (propylene glycol/peg 400)	
REFRESH (carboxymethylcellulose)	
REFRESH (polyvinyl alcohol/povidone)	
REFRESH (carboxymethylcellulose/glycerin)	
REFRESH (carboxymethylcellulose/glycerin/poly80)	
SYSTANE (hypromellose)	
SYSTANE (propylene glycol)	
SYSTANE (propylene glycol/peg 400)	

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must have failed a 1-month trial of each preferred agent of a unique ingredient, as evidenced by paid claims or pharmacy printouts.
- See Preferred Dosage Form Criteria

Persistent Symptoms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED STEP 1 AGENTS (PA REQUIRED)	NON-PREFERRED STEP 2 AGENTS (PA REQUIRED)
EYSUVIS (loteprednol) DROPS	TYRVAYA (varenicline) NASAL SPRAY	CEQUA (cyclosporine)
RESTASIS (cyclosporine) DROPPERETTE – *Brand Required*		cyclosporine dropperette
XIIDRA (lifitegrast)		MIEBO (perfluorohexyloctane)
		RESTASIS MULTIDOSE (cyclosporine)
		VEVYE 0.1% EYE DROP (cyclosporine)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

Non-Preferred Step 1 Agents

- The requested medication must be prescribed by, or in consult with, an ophthalmologist.

- The member must have failed a 1-month trial of Eysuvis, a 6-month trial of Restasis and a 2-month trial of Xiidra, as evidenced by paid claims or pharmacy printouts.

Non-Preferred Step 2 Agents:

- The requested medication must be prescribed by, or in consult with, an ophthalmologist.
- The member must have failed a 6-month trial of Restasis and a 2-month trial of Xiidra, and a 1-month trial of Eysuvis and Tyrvaya as evidenced by paid claims or pharmacy printouts.
- Cyclosporine products: See Preferred Dosage Form criteria

Glaucoma

Alpha Adrenergic

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ALPHAGAN P 0.1% (brimonidine) DROPS – *Brand Required*	apraclonidine 0.5% drops
ALPHAGAN P 0.15% (brimonidine) DROPS – *Brand Required*	brimonidine 0.1% drops
brimonidine 0.2% drops	brimonidine 0.15% drops
COMBIGAN (brimonidine-timolol) DROPS – *Brand Required*	brimonidine-timolol 0.2%-0.5% drops
LUMIFY (brimonidine) 0.03% DROPS	IOPIDINE (apraclonidine) 1% DROPS
SIMBRINZA (brinzolamide/brimonidine) DROPS	

Beta Blockers

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
BETOPTIC S (betaxolol) 0.25% DROPS	betaxolol 0.5% drops
carteolol drops	BETIMOL (timolol) DROPS
COMBIGAN (brimonidine/timolol) DROPS – *Brand Name Required*	brimonidine/timolol drops
dorzolamide/timolol drops	COSOPT (dorzolamide/timolol) PF DROPS
ISTALOL (timolol maleate) DROPS ONCE DAILY – *Brand Required*	timolol drops once daily
levobunolol drops	timolol gel forming solution
timolol maleate drops	TIMOPTIC (timolol maleate) DROPS
timolol maleate/PF drops 0.5%	TIMOPTIC OCUDOSE 0.5% (timolol) PF DROPS
TIMOPTIC OCUDOSE 0.25% (timolol) PF DROPS	TIMOPTIC-XE (timolol gel forming solution)

Prior Authorization Criteria

- See Preferred Dosage Form criteria

Carbonic Anhydrase Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AZOPT (brinzolamide) – *Brand Required*	brinzolamide
dorzolamide	COSOPT (dorzolamide/timolol)
dorzolamide/timolol	TRUSOPT (dorzolamide)
SIMBRINZA (brinzolamide/brimonidine)	

Prostaglandins

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
latanoprost	bimatoprost 0.03%
LUMIGAN (bimatoprost) 0.01%	IYUZEH (latanoprost/pf)
ROCKLATAN (netarsudil/latanoprost)	tafluprost/pf
	TRAVATAN Z (travoprost)
	travoprost
	VYZULTA (latanoprostene)
	XALATAN (latanoprost)
	XELPROS (latanoprost)
	ZIOPTAN (tafluprost/pf)

Prior Authorization Criteria

- The member must have failed a 14-day trial of each of the preferred agents, as evidenced by paid claims or pharmacy printouts.

Rho Kinase Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
RHOPRESSA (netarsudil)	
ROCKLATAN (netarsudil/latanoprost)	

Presbyopia

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
pilocarpine	ISOPTO CARPINE (pilocarpine)
	VUITY (pilocarpine hydrochloride)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- See Preferred Dosage Form criteria
- The requested medication must be prescribed by, or in consult with, an optometrist or ophthalmologist.
- Documentation of medical necessity must be provided, including contraindication to the use of corrective lenses and how activities of daily living are adversely impacted due to inability to correct vision with corrective lenses.

Renewal Criteria – Approval Duration: 12 months

- Documentation must be provided including activities of daily living are positively impacted by drug therapy.

Inherited Retinal Dystrophy

CLINICAL PA REQUIRED
LUXTURNA (alglucosidase alfa) – *Medical Billing Only*

Prior Authorization Criteria

Initial Criteria – Approval Duration: Approval Duration: 1 month (once per lifetime per eye)

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational).

- The requested medication must be prescribed by, or in consult with, an ophthalmologist or retinal surgeon with experience providing subretinal injections
- The member must have a diagnosis of inherited retinal dystrophy (i.e., Leber's congenital amaurosis [LCA], retinitis pigmentosa [RP]); confirmed by biallelic pathogenic variants in the RPE65 gene by molecular genetic testing (as evidenced with submitted documentation)
- The member has sufficient viable retinal cells as measured by OCT (optical coherence tomography) defined as one of the following:
  - retinal thickness greater than 100 microns within the posterior pole
  - ≥ 3-disc areas of the retina without atrophy or pigmentary degeneration within the posterior pole
  - remaining visual field within 30 degrees of fixation as measured by a III4e isopter or equivalent
- The member has remaining light perception in the eye(s) that will receive treatment.
- The member has not previously received RPE65 gene therapy in intended eye.

Uveitis

Adalimumab

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ABRILADA (adalimumab-afzb)	adalimumab-aacf
adalimumab-adbm – labeler 00597	adalimumab-aaty
adalimumab-fkjp	adalimumab-adaz
CYLTEZO (adalimumab-abdm)	adalimumab-adbm – labeler 82009
HADLIMA (adalimumab-bwwd)	adalimumab-ryvk
HULIO (adalimumab-fkjp)	AMJEVITA (adalimumab-atto)
HUMIRA (adalimumab)	HYRIMOZ (adalimumab-adaz)
SIMLANDI (adalimumab-ryvk)	IDACIO (adalimumab-aacf)
YUSIMRY (adalimumab-aqvh)	YUFLYMA (adalimumab-aaty)

Vernal Keratoconjunctivitis

CLINICAL PA REQUIRED
VERKAZIA (cyclosporine) 0.1%

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- The requested medication must be prescribed by, or in consult with, an allergist or ophthalmologist.
- The member has failed* a 3-month trial of combination of each of the following:
  - Topical dual-acting mast cell stabilizers/antihistamines (e.g., olopatadine, azelastine hydrochloride, epinastine, pemirolast potassium, or ketotifen fumarate)
  - Second- and third-generation oral antihistamines (e.g., fexofenadine, loratadine, desloratadine, cetirizine, or levocetirizine)
  - Cyclosporine ophthalmic emulsion 0.05%

*Failure is defined as requiring frequent or prolonged courses of topical ophthalmic corticosteroids include prednisone acetate 1% and dexamethasone 0.1% for severe cases and prednisolone acetate 0.12%, fluorometholone, medrysone, loteprednol, etabonate 0.2 or 0.5%, and rimexolone 1% or compromised corneal epithelium

Ophthalmology Injection- VEGF Inhibitor

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
BEOVU (brolucizumab-dbll) – *Medical Billing Only*	BYOOVIZ (ranibizumab -nuna) – *Medical Billing Only*

CIMERLI (ranibizumab-eqrn) – *Medical Billing Only*	LUCENTIS (ranibizumab) – *Medical Billing Only*
EYLEA (aflibercept) – *Medical Billing Only*	SUSVIMO (ranibizumab) – *Medical Billing Only*
PAVBLU (aflibercept-ayyh) – *Medical Billing Only*	
VABYSMO (faricimab-svoa) – *Medical Billing Only*	

For the indication:

1. Retinopathy of prematurity

Prior Authorization Criteria

- See Medications that cost over $3000/month Criteria

For the indications:

1. diabetic macular edema
2. macular edema following central retinal vein occlusion
3. macular edema following branch retinal vein occlusion
4. neovascular (wet) age-related macular degeneration

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational).
- The requested medication must be prescribed by, or in consult with, an ophthalmologist or retina specialist with experience providing intraocular injections and implants
- The member must have a mean visual acuity letter score (VALS) of 70 or Best Corrected Visual Acuity of 20/40 or worse at baseline
- The member must have failed a trial consisting of at least 2 doses of a bevacizumab agent

Non-Preferred Agent Criteria:

- Byooviz, Lucentis and Susvimo Only: See Preferred Dosage Form Criteria

Renewal Criteria – Approval Duration: 12 months

- The member must have experienced meaningful clinical benefit since starting treatment with the requested medication, as evidenced by medical documentation (e.g., chart notes) attached to the request (subject to clinical review) including improvement or stabilization in VALS, defined as a loss of not more than 5 letters compared to baseline.
- The member must have at least a mean VALS of 20 or BCVA of 20/400

Otic

Anti-infectives/Anti-inflammatories – Fluoroquinolones

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
CIPRO HC (ciprofloxacin/hydrocortisone)	ciprofloxacin/dexamethasone otic drops++
	ciprofloxacin/fluocinolone

++ Please note, for otitis externa with non-intact tympanic membrane, ciprofloxacin (eye drops) and ofloxacin (eye and ear drops) are required preferred agents.

If all the following conditions apply, please request an override for ciprofloxacin/dexamethasone by calling provider relations at 1-800-755-2604 or emailing medicaidpharmacy@nd.gov:

- The member has tympanostomy tubes
- The member has otitis media
- There is granulation tissue present

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must meet one of the following:
  - The member must have failed a 7-day trial of each of the preferred agent, as evidenced by paid claims or pharmacy printouts.

Pain

Lidocaine Patch

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
lidocaine 5% patch	LIDODERM (lidocaine) 5% PATCH
PREFERRED AGENTS (PA REQUIRED)	
ZTLIDO (lidocaine) 1.8% PATCH	

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must have failed a 30-day trial of lidocaine 5% patch, as evidenced by paid claims or pharmacy printouts.

Lidocaine Topical Cream

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The request must be for injection pain from a medically necessary procedure

NSAIDS

Oral Solid Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
celecoxib	ARTHROTEC (diclofenac/misoprostol)
diclofenac potassium 50 mg tablet	COXANTO (oxaprozin)
diclofenac sodium DR 50 mg, 75 mg	CELEBREX (celecoxib)
etodolac	DAYPRO (oxaprozin)
flurbiprofen	diclofenac potassium 25 mg tablet
ibuprofen	diclofenac potassium 25 mg capsule
indomethacin	diclofenac sodium 25 mg DR
indomethacin ER	diclofenac sodium 100 mg ER tablet
ketoprofen IR	diclofenac/misoprostol
ketorolac	DUEXIS (famotidine/ibuprofen)

meclofenamate	etodolac ER
mefenamic acid	famotidine/ibuprofen
meloxicam	FELDENE (piroxicam)
nabumetone	fenoprofen
naproxen	INDOCIN (indomethacin)
piroxicam	ketoprofen ER 200 mg
sulindac	LOFENA (diclofenac potassium)
tolmetin	meloxicam, submicronized
VIMOVO (naproxen/esomeprazole) – *Brand Required*	MOBIC (meloxicam)
	NALFON (fenoprofen)
	NAPRELAN (naproxen)
	naproxen ER 500 mg
	naproxen/esomeprazole
	oxaprozin
	RELAFEN DS (nabumetone)
	SEGLENTIS (celecoxib/tramadol)
	VIVLODEX (meloxicam, submicronized)
	ZORVOLEX (diclofenac, submicronized)

Electronic Diagnosis Verification

- Mefenamic acid and Meclofenamate: Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale for

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- *Non-preferred agents with no same active ingredient preferred:*
  - The member must have failed a 30-day trial of 3 different oral generic NSAIDs including a COX-2 inhibitor if member has experienced GI intolerances, as evidenced by paid claims or pharmacy print outs
- *Non-preferred agents with same active ingredient preferred*:
  - See Preferred Dosage Form Criteria

Therapeutic Duplication

- One strength of one medication is allowed at a time (topical and oral formulations are not allowed together)

If the following conditions apply, please call for an override by calling provider relations at 1-800-755-2604:

- The member is prescribed ketorolac and will stop regular NSAID therapy during course of ketorolac

Oral Non-Solid Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ibuprofen suspension	indomethacin solution
naproxen suspension	

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must have failed a 30-day trial of each preferred agent, as evidenced by paid claims or pharmacy print outs.

Nasal Dosage Forms

CLINICAL PA REQUIRED
ketorolac nasal spray

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must have failed a 30-day trial of 3 different oral generic NSAIDs including a COX-2 inhibitor if member has experienced GI intolerances, as evidenced by paid claims or pharmacy print outs
- Clinical justification must be provided explaining why the member is unable to use another dosage form (subject to clinical review).

Topical Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
diclofenac gel	diclofenac 1.3% patch
diclofenac topical solution (all other labelers)	diclofenac 2% pump
FLECTOR (diclofenac) 1.3% PATCH – *Brand Required*	diclofenac topical solution (labeler 59088)
	LICART (diclofenac) PATCH 1.3%

Prior Authorization Criteria

- See Preferred Dosage Form Criteria

Opioid Analgesics

The Centers for Disease Control (CDC) have published guidelines for the prescribing of opioids for pain.

Therapeutic Duplication

- One extended-release product/strength is allowed at a time
- One immediate release product is allowed (single ingredient or combination)
- Opioid-acetaminophen combination products are not allowed with acetaminophen
- Carisoprodol: The “Holy Trinity” consists of an opioid, a benzodiazepine, and carisoprodol and is a highly abused dangerous combination that can lead to additive CNS depression, overdose, and death. It is not covered.
- Methadone is not allowed with opioids, benzodiazepines, or opioid use disorder medications
- Morphine is not covered with clopidogrel, prasugrel, ticagrelor, and ticlopidine (does not include other opioid analgesics)
  - Morphine may diminish the antiplatelet effect and serum concentrations of P2Y12 Inhibitor antiplatelet agents (clopidogrel, prasugrel, ticagrelor, and ticlopidine).
- Tramadol immediate release with tramadol extended release

Opioids and Benzodiazepine Concurrent Use

Opioid and Benzodiazepines Concurrent Use Form

- Due to guidance in The SUPPORT for Members and Communities Act (H.R. 6) on CNS depression, this includes long-acting opioids over 90 MME/day or immediate release opioids over 15 MME/dose in combination with benzodiazepines.

Initial Criteria – Approval Duration: 12 months

- The member has access to an opioid reversal medication and has been counseled on overdose risk.
- The member has been counseled on the risks of utilizing opioids and benzodiazepines in combination with each other and other CNS depressing medications, including antipsychotics and sedatives.
- The member must currently be on long-acting opioid therapy or must not have achieved therapeutic goal with non-narcotic medication (NSAIDs, TCAs, SNRIs, corticosteroids, etc.) and non-medication alternatives (weight loss, physical therapy, cognitive behavioral therapy, etc.)
- One of the following criteria must be met:
  - The member resides in a facility with skilled nursing care.
  - The member must have taper plan of one or both agents.
  - The opioid medication must be prescribed by, or in consult with, with a palliative care, oncologist OR pain management specialist with a treatment plan including goals for pain and function, and urine and/or blood screens if the cumulative daily dose of opioids exceeds 90 MME/day (specialist requirement not applicable to skilled nursing facility residents or tapering requests).
- The prescriber(s) of both agents have provided reasons why opioid analgesics and benzodiazepines cannot be avoided, or lower doses be used (subject to clinical review).
- The past 3 months of the member's North Dakota PDMP reports must have been reviewed.

Greater than 90 Morphine Milligram Equivalents (MME) per Day:

Prior Authorization Form – Opioid Analgesics

- A cumulative maximum of 90 MME will be allowed without authorization: an MME calculator may be found at https://www.mdcalc.com/calc/10170/morphine-milligram-equivalents-mme-calculator

Initial Criteria – Approval Duration: 12 months

- One of the following criteria must be met:
  - The member resides in a facility with skilled nursing care.
  - The member must have taper plan of one or both agents.
  - The opioid medication must be prescribed by, or in consult with, with a palliative care, oncologist OR pain management specialist with a pain management contract with a treatment plan including goals for pain and function, and urine and/or blood screens

Opioid Analgesics – Long Acting

Partial Agonist/Antagonist Opioids

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
BELBUCA (buprenorphine)	buprenorphine patches
Butorphanol	
BUTRANS (buprenorphine) PATCHES *- Brand Required*	

Abuse Deterrent Formulations/Unique Mechanisms from Full Agonists Opioids

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
OXYCONTIN (oxycodone) – *Brand Required*	CONZIP (tramadol ER) CAPSULES
tramadol ER Tablets	hydrocodone ER tablets
	HYSINGLA ER (hydrocodone)
	levorphanol
	methadone
	MORPHABOND ER (morphine)
	tramadol ER capsules

Full Agonist Opioids Without Abuse Deterrent Formulations

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
fentanyl 12 mcg/hr, 25 mcg/hr, 50 mcg/hr, 75 mcg/hr, 100 mcg/hr	fentanyl patch 37.5 mcg/hr, 62.5 mcg/hr, 87.5 mcg/hr
morphine ER tablets	hydrocodone ER capsules
	hydromorphone ER tablets
	morphine ER capsules
	MS CONTIN (morphine)
	oxycodone ER
	oxymorphone ER tablets

Prior Authorization Criteria

Prior Authorization Form – Opioid Analgesics

Initial Criteria – Approval Duration: 12 months

- The past 3 months of the member's North Dakota PDMP reports must have been reviewed.
- One of the following criteria must be met:
  - The member has access to an opioid reversal medication and has been counseled on overdose risk.
  - The member resides in a facility with skilled nursing care.
- One of the following criteria must be met:
  - The member is currently on a long-acting opioid therapy.
  - The member must have been established on opioid therapy during hospitalization
  - Both of the following are met:
    - The member must have a diagnosis of cancer pain, palliative care, or sickle cell disease.
    - The member must currently be on around-the-clock opioid therapy of at least 30 Morphine Milligram equivalents (MME) for at least a week, as evidenced by paid claims or pharmacy printouts.
      - If member is unable to swallow (e.g., mucositis, head/neck radiation, head/neck cancers, uncontrollable vomiting) and has severe pain (>6/10), fentanyl patch 12 mcg/hr may be considered for approval for opioid naïve members (subject to clinical review).
  - Both of the following are met:
    - The member must currently be on around-the-clock opioid therapy of at least 30 Morphine Milligram equivalents (MME) for at least a week, as evidenced by paid claims or pharmacy printouts.
    - The member has not achieved therapeutic goal with non-narcotic medication (NSAIDs, TCAs, SNRIs, corticosteroids, etc.) and non-medication alternatives (weight loss, physical therapy, cognitive behavioral therapy, etc.).
- One of the following criteria must be met:
  - The member resides in a facility with skilled nursing care.
  - The member must have taper plan
  - The member must have with treatment plan including goals for pain and function, and urine and/or blood screens.

Fentanyl Patch:

- The member must have a BMI ≥17.

Non-Preferred Agents Criteria:

- Clinical justification must be provided explaining why the member is unable to use other opioid and non-opioid analgesic agents (subject to clinical review).

Renewal Criteria – Approval Duration: 12 months

- One of the following must be met:
  - Progress toward therapeutic goal must be included with request (e.g., improvement in pain level, quality in life, or function).
  - The member must be stable on long-acting opioid medication for 2 years or longer.

Underutilization

- Long-acting opioid analgesics must be used adherently and will reject on point of sale for late fill.

Opioid Analgesic – Short Acting

Fentanyl Products

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
fentanyl citrate effervescent tablet	ACTIQ (fentanyl) LOZENGE
fentanyl lozenge	FENTORA (fentanyl) EFFERVESCENT TABLET

Opioid Combination Solid Oral Products

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
acetaminophen-codeine tablets	ENDOCET (oxycodone-acetaminophen)
benzhydrocodone-acetaminophen	hydrocodone-acetaminophen 2.5-325 MG
hydrocodone-acetaminophen 5-325 MG	hydrocodone-acetaminophen 10-300 MG
hydrocodone-acetaminophen 7.5-325 MG	hydrocodone-acetaminophen 5-300 MG
hydrocodone-acetaminophen 10-325 MG	hydrocodone-acetaminophen 7.5-300 MG
oxycodone-acetaminophen 5-325 MG, 7.5-325 MG, 10-325 MG	hydrocodone-ibuprofen 5-200 MG and 10-200 MG
tramadol-acetaminophen tablets	LORCET (hydrocodone-acetaminophen)
hydrocodone-ibuprofen 7.5-200 MG	NALOCET (oxycodone-acetaminophen)
	NORCO (hydrocodone-acetaminophen)
	oxycodone-acetaminophen 2.5-325 MG
	PERCOCET (oxycodone/acetaminophen)
	PRIMLEV (oxycodone/acetaminophen)
	PROLATE (oxycodone/acetaminophen)
	SEGLENTIS (celecoxib/tramadol)
	ULTRACET (tramadol/acetaminophen)
	VICODIN (hydrocodone/acetaminophen)

Opioid – Acetaminophen Combination Non-Solid Oral Products

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
acetaminophen-codeine solution	hydrocodone-acetaminophen 5-163 mg/7.5 mL solution
hydrocodone-acetaminophen 7.5-325/15 ml solution	hydrocodone-acetaminophen 10-325/15 ml solution
	LORTAB (hydrocodone-acetaminophen) SOLUTION

Opioid Single Agent Solid Oral Products

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
codeine tablets	butalbital-codeine tablet
hydromorphone tablet	DEMEROL (meperidine) TABLET
meperidine tablet	DILAUDID (hydromorphone) TABLET
morphine tablet	OXAYDO (oxycodone) TABLET

oxycodone 5 mg, 10 mg tablet	oxycodone tablet (Roxybond generic)
oxymorphone tablet	oxycodone 15 mg, 20 mg, 30 mg tablet
tramadol 50 mg tablet	ROXICODONE (oxycodone) TABLET
	ROXYBOND (oxycodone) TABLET
	tramadol 25mg tablet
	tramadol 100 mg tablet
	ULTRAM (tramadol) TABLET

Opioid Single Agent Non-Solid Oral Products

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
hydromorphone liquid	
morphine solution	
oxycodone solution	

First Fill

- Short acting opioid analgesics must be filled with a 7-day supply if no previous fill within past 34 days
  - If member is filling prescription less than every 34 days due to decreased utilization, please get a new prescription for a lower quantity that reflects actual utilization within a 34-day window.

Prior Authorization Criteria

Prior Authorization Form – Opioid Analgesics

Initial Criteria – Approval Duration: 12 months
Fentanyl Only:
- The member must currently be on around-the-clock opioid therapy of at least 60 Morphine Milligram equivalents (MME) for at least a week, as evidenced by paid claims or pharmacy printouts

Meperidine and Butalbital-Codeine Only:
- Clinical justification must be provided explaining why the member is unable to use other opioid and non-opioid analgesic products (subject to clinical review).

Oxycodone IR Only
- The past 3 months of the member's North Dakota PDMP reports must have been reviewed.
- The member must currently be on a long-acting opioid analgesic that provides a daily Morphine Milligram Equivalent (MME) which meets requirements below (based on requested strength), as evidenced by paid claims or pharmacy printouts (Please use an Opioid Dose Calculator to find the MME for specific products):
  - Oxycodone 15 mg tablet: long-acting opioid must provide ≥150 mg MME per day
  - Oxycodone 20 mg tablet: long-acting opioid must provide ≥200 mg MME per day
  - Oxycodone 30 mg tablet: long-acting opioid must provide ≥300 mg MME per day

Non-preferred agents with same active ingredient preferred:
- See Preferred Dosage Form Criteria

Member with a History of Opioid Use Disorder
If 1 and 2 are met, please call for an override by calling provider relations at 1-800-755-2604 (chart notes will be required for requests beyond one fill):
1. The request is for one of the following:
   - A one-time fill request where pain cannot be reasonably treated with non-opioid therapy (e.g., surgery)
   - A request exceeding a one-time fill and a treatment plan has been provided with expected duration of use and why non-opioid therapy is not an option (subject to clinical review) or a taper plan is provided

2. One of the following is met:
   - Prescribers of both opioid prescription and MOUD (medication for opioid use disorder) are aware of each other and agree to opioid therapy
   - MOUD has been discontinued, and the prescriber of the opioid is aware of previous MOUD treatment and confirms opioid therapy is required

Renewal Criteria – Approval Duration: 12 months

- Progress toward therapeutic goal must be included with request (e.g., improvement in pain level, quality in life, or function).

Qutenza (capsaicin patch)

CLINICAL PA REQUIRED
QUTENZA (capsaicin patch) – *Medical Billing Only*

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a pain specialist
- The member must have failed a 3-month treatment of topical lidocaine patch

Skeletal Muscle Relaxants

Solid Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
baclofen	AMRIX (cyclobenzaprine) TAB 24 HR
chlorzoxazone 500 mg	chlorzoxazone 375 mg and 750 mg
cyclobenzaprine 5 mg and 10 mg	cyclobenzaprine 7.5 mg
dantrolene	cyclobenzaprine ER
methocarbamol	carisoprodol
orphenadrine ER	carisoprodol-aspirin
tizanidine tablets	carisoprodol-aspirin-codeine
	DANTRIUM (dantrolene)
	LORZONE (chlorzoxazone)
	METAXALL (metaxalone)
	metaxalone
	NORGESIC FORTE (orphenadrine/aspirin/caffeine)
	ROBAXIN (methocarbamol)
	SKELAXIN (metaxalone)
	SOMA (carisoprodol)
	tizanidine capsules
	ZANAFLEX (tizanidine)

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months (carisoprodol = 1 week)

- Carisoprodol products only:
  - The member must be undergoing dose tapering
- Metaxalone

- The member must have failed two 30-day trials of other skeletal muscle relaxants, including methocarbamol, as evidenced by paid claims or pharmacy printouts.

- All other products:
  - See Preferred Dosage Form Criteria

Therapeutic Duplication

- One strength of one medication is allowed at a time
  - If the following conditions apply, please call for an override by calling provider relations at 1-800-755-2604:
    - The member has cerebral palsy or another chronic spastic disorder
    - The prescriber is a physiatrist
    - The requested combination is baclofen and tizanidine
- Carisoprodol is not allowed with opioids, benzodiazepines, or opioid use disorder medications
  - The "Holy Trinity" consists of an opioid, a benzodiazepine, and carisoprodol and is a highly abused dangerous combination that can lead to additive CNS depression, overdose, and death. It is not covered.
- Tizanidine is not allowed with other alpha 2 agonists (clonidine, clonidine/chlorthalidone, guanfacine, methyldopa)
  - tizanidine is also an alpha 2 agonist

Non-Solid Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
baclofen solution 5 mg/5 mL	baclofen 25mg/5mL suspension
LYVISPAH (baclofen) GRANULE PACKET	FLEQSUVY (baclofen) 25mg/5mL SUSPENSION

Prior Authorization Criteria

- See Preferred Dosage Form Criteria

Psychiatry

ADHD

Non-Stimulants

Alpha 2 Agonists

PREFERRED AGENTS (NO PA REQUIRED)	PREFERRED STEP 1 AGENTS (ELECTRONIC STEP)	NON-PREFERRED STEP 2 AGENTS (PA REQUIRED)
clonidine	clonidine ER 0.1 mg	clonidine ER 0.17 mg
ONYDA XR (clonidine)		INTUNIV (guanfacine ER)
guanfacine		
guanfacine ER		

First Fill

- Clonidine ER and guanfacine ER must be filled with a 14-day supply (or less) if no previous fill within past 99 days

Therapeutic Duplication

Please see the **Psychotropic Monitoring Program** document for detailed information regarding clinical criteria for Therapeutic Duplication Requests.

- One strength of one medication is allowed at a time. Guanfacine 4 mg IR or ER can be combined with other strengths to form dosages up to 7 mg per day. Guanfacine IR and ER cannot be combined.
- Clonidine and guanfacine are not allowed with each other or other alpha 2 agonists (clonidine/chlorthalidone, methyldopa, or tizanidine)

Electronic Step Therapy Required

- Clonidine ER:
  A. PA Not Required Criteria: A 30-day supply of clonidine IR has been paid within 90 days prior to clonidine ER's date of service.
  B. PA Required Criteria: The member must have failed a 30-day trial of clonidine IR, as evidenced by paid claims or pharmacy printouts.

Norepinephrine Reuptake Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
atomoxetine	STRATTERA (atomoxetine)
PREFERRED AGENTS (CLINICAL PA REQUIRED)	
QELBREE (viloxazine)	

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must meet one of the following:
  - The member has failed a 14-day trial of two stimulants, as evidenced by paid claims or pharmacy printouts.
  - The member has failed a 30-day trial of atomoxetine, as evidenced by paid claims or pharmacy printouts.

Therapeutic Duplication

- One strength of one medication is allowed at a time.

Stimulants

Amphetamines

Solid Dosage Forms

Extended Release

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
dextroamphetamine/amphetamine ER (generic Adderall XR)	ADDERALL XR (dextroamphetamine/amphetamine)
dextroamphetamine ER	DEXEDRINE SPANSULE ER (dextroamphetamine)
lisdexamfetamine	dextroamphetamine/amphetamine ER (generic Mydayis ER
	DYANAVEL XR (amphetamine)

	MYDAYIS ER (dextroamphetamine/amphetamine)
	VYVANSE (lisdexamfetamine)

Immediate Release

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
amphetamine	ADDERALL (dextroamphetamine/amphetamine)
dextroamphetamine 2.5 mg, 5 mg, 10 mg	dextroamphetamine 7.5 mg, 15 mg, 20 mg, 30 mg
dextroamphetamine/amphetamine	EVEKEO (amphetamine)
	methamphetamine
	ZENZEDI (dextroamphetamine)

Non-Solid Dosage Forms

Extended Release

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
DYANAVEL XR (amphetamine) SUSPENSION	ADZENYS XR – ODT (amphetamine)
lisdexamfetamine chew	amphetamine ER suspension
	VYVANSE (lisdexamfetamine) CHEW TABLET
	XELSTRYM (dextroamphetamine) PATCH

Immediate Release

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
dextroamphetamine 5 mg/5 ml	PROCENTRA (dextroamphetamine) SOLUTION

Methylphenidate

Solid Dosage Forms

Extended Release

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
FOCALIN XR (dexmethylphenidate)	APTENSIO XR (methylphenidate)
methylphenidate CD 30-70	AZSTARYS (serdexmethylphenidate/dexmethylphenidate)
methylphenidate ER tablet (generic Concerta)	CONCERTA (methylphenidate)
methylphenidate ER tablet (generic Metadate CD)	dexmethylphenidate ER
RITALIN LA (methylphenidate LA capsules – 50-50) *Brand Name Required*	JORNAY PM (methylphenidate)
	methylphenidate ER 45 mg, 63 mg, 72 mg tablet (generic Relexxii ER)
	methylphenidate ER capsule (generic Aptensio XR)
	methylphenidate LA capsules – 50-50 (generic Ritalin LA) – 60 mg
	methylphenidate LA capsules – 50-50 (generic Ritalin LA) – 10 mg, 20 mg, 30 mg, 40 mg
	RELEXXII ER (methylphenidate)

Immediate Release

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
dexmethylphenidate	FOCALIN (dexmethylphenidate)
methylphenidate tablet	RITALIN (methylphenidate)

Non-Solid Dosage Forms

Extended Release

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
DAYTRANA (methylphenidate) PATCH – *Brand Required*	COTEMPLA XR – ODT (methylphenidate)
QUILLICHEW ER (methylphenidate)	methylphenidate patch
QUILLIVANT XR (methylphenidate)	

Immediate Release

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
methylphenidate chew tablet	METHYLIN (methylphenidate) SOLUTION
methylphenidate solution	

Electronic Age Verification

- The member must be age 6 or older or must meet prior authorization criteria for ages 5 and under listed below.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- For members ages 5 and under:
  - There is a moderate-severe continuing disturbance in the child's function in both home and other settings (e.g., preschool or daycare) despite a 9-month trial of parent and/or teacher-administered behavior therapy which helps parents learn age-appropriate developmental expectation, specific management skills for problem behaviors, and behaviors that strengthen the parent-child relationship (subject to clinical review).

Non-Preferred Agent Criteria:

- Amphetamine Non-Preferred Dosage Forms Only:
  - The member must have had a two 7-day trials of a methylphenidate non-solid dosage form.
- Aptensio XR Only:
  - The member must have a wearing off effect where late afternoon/evening functioning performance has been impacted despite a 7-day trial with a long-acting methylphenidate medication with an afternoon short acting booster.
  - The member must have a wearing off effect where late afternoon/evening functioning performance has been impacted despite a 7-day trial with Concerta or its generic alternative.
- Jornay PM Only:
  - The member must have had two 7-day trials of a fast onset to peak methylphenidate medication (i.e., Concerta, Focalin XR, Metadate CD, Methylin, Ritalin and their generic alternatives).
  - The member must have the inability to time the administration of medication where the peak is occurring at the start of work or school and early morning performance has been impacted at school or work due to the approximate 1-hour delay to peak after administration (subject to clinical review).

16. All Other Agents: See Preferred Dosage Form Criteria

References:

2. Wolraich, Mark L., et al. "Clinical practice guideline for the diagnosis, evaluation, and treatment of attention-deficit/hyperactivity disorder in children and adolescents." *Pediatrics* 144.4 (2019).
3. Hulkower RL, Kelley M, Cloud LK, Visser SN. Medicaid Prior Authorization Policies for Medication Treatment of Attention-Deficit/Hyperactivity Disorder in Young Children, United States, 2015. Public Health Rep. 2017 Nov/Dec;132(6):654-659. doi: 10.1177/0033354917735548. Epub 2017 Oct 26. PMID: 29072963; PMCID: PMC5692165.

Therapeutic Duplication

Please see the **Psychotropic Monitoring Program** document for detailed information regarding clinical criteria for therapeutic duplication requests.

For all stimulants, the following are not payable:
- multiple strengths of a single medication
- amphetamine agent + methylphenidate agent
- multiple long-acting agents
- multiple short acting agents
- non-solid dosage + solid dosage forms

These long-acting products are not allowed with short-acting products:
- Aptensio XR (methylphenidate)
- Adhansia XR (methylphenidate)
- Azstarys (serdexmethylphenidate/dexmethylphenidate)
- Cotempla XR-ODT (methylphenidate)
- Daytrana (methylphenidate)
- Jornay PM (methylphenidate)
- Adderall XR (mixed salts of a single-entity amphetamine product)
- Adzenys XR ODT (amphetamine suspension, extended release)
- Adzenys ER (amphetamine suspension, extended release)
- Dyanavel XR (amphetamine)
- Mydayis (mixed salts of a single-entity amphetamine product)
- Quillivant XR (methylphenidate)
- Vyvanse (lisexamfetamine)
- Vyvanse Chewable (lisexamfetamine)

Amphetamines: One product will be allowed at a time. The following are not payable regimens:
- Dextroamphetamine/Amphetamine ER with Proton Pump Inhibitors
  - Proton pump inhibitors increase blood levels and potentiate the action of amphetamine. Co-administration of Adderall XR and gastrointestinal or urinary alkalizing agents should be avoided.
- Concurrent use of Mydayis and Dyanavel XR with sedatives
  - Members reporting insomnia can use a shorter acting product that does not reach steady state.

Methylphenidates: The following are not payable regimens:
- Concurrent use of dexmethylphenidate and methylphenidate
- Concurrent use of Adhansia XR and Azstarys with sedatives
  - Members reporting insomnia can use a shorter acting product that does not reach steady state.

Electronic Diagnosis Verification

- Adderall, Azstarys, Jornay PM, Mydayis: Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale.

First Fill

- Long-acting stimulants must be filled with a 14-day supply (or less) if no previous fill within past 99 days

Antidepressants

Oral

Solid Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)

amitriptyline	APLENZIN ER (bupropion)
amoxapine	CELEXA (citalopram)
AUVELITY (dextromethorphan/bupropion)	citalopram capsule 30 mg
bupropion	CYMBALTA (duloxetine)
bupropion ER	EFFEXOR XR (venlafaxine)
bupropion SR	LEXAPRO (escitalopram)
citalopram tablet	PAXIL (paroxetine)
clomipramine	PAXIL CR (paroxetine)
desipramine	PRISTIQ ER (desvenlafaxine)
desvenlafaxine ER	PROZAC (fluoxetine)
doxepin	REMERON (mirtazapine)
duloxetine	sertraline capsule
escitalopram	VIIBRYD (vilazodone)
fluoxetine	WELLBUTRIN (bupropion)
fluvoxamine	WELLBUTRIN SR (bupropion)
mirtazapine	WELLBUTRIN XL (bupropion)
nefazodone	ZOLOFT (sertraline)
nortriptyline	
paroxetine	
paroxetine ER	
protriptyline	
sertraline tablet	
trazodone	
venlafaxine	
venlafaxine ER	
vilazodone	
High-Cost Options	
FETZIMA (levomilnacipran)	
fluoxetine weekly	
fluvoxamine ER	
imipramine	
trimipramine	
TRINTELLIX (vortioxetine)	

Non-Solid Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
citalopram oral solution	DRIZALMA (duloxetine) SPRINKLE CAPSULE
duloxetine sprinkle capsule	LEXAPRO (escitalopram) ORAL SOLUTION
escitalopram oral solution	PAXIL (paroxetine) ORAL SUSPENSION
fluoxetine solution	REMERON (mirtazapine) SOLTAB
mirtazapine ODT	ZOLOFT (sertraline) ORAL CONCENTRATE
sertraline oral concentrate	
High-Cost Options	
paroxetine oral suspension	

Electronic Step Therapy Required

- Trintellix Only: Initiation with 10 mg must be used for 10 days prior to continuing therapy with 20 mg.
  - Trintellix recommended starting dose is 10 mg once daily.

- Desvenlafaxine ER Only: 30 days of 50 mg must be paid within 40 days of 25 mg date of service.
  - 25 mg is intended only for gradual titration before discontinuation. It is not a therapeutic dose.

First Fill

- Viibryd and Trintellix must be filled with a 10-day supply if no previous fill within past 99 days

Therapeutic Duplication

Please see **Appendix B** for antidepressant cross tapering coverage guidance.

- One strength of one medication per therapeutic class is allowed at a time
  - Therapeutic classes:
    - SSRIs
    - SNRIs
    - Tricyclic Antidepressants
    - Bupropion
    - Mirtazapine
    - Selegiline
- Fetzima, Viibryd, or Trintellix are not allowed with other SSRIs or SNRIs (exceptions: trazodone)
- Fluvoxamine, a strong 1A2 inhibitor, is not covered with Ramelteon, a 1A2 Substrate.

Antipsychotics

Oral

Solid Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
aripiprazole	ABILIFY (aripiprazole)
clozapine	CLOZARIL (clozapine)
FANAPT (iloperidone)	GEODON (ziprasidone)
lurasidone	INVEGA ER (paliperidone)
olanzapine	LATUDA (lurasidone)
quetiapine	RISPERDAL (risperidone)
quetiapine ER	SEROQUEL (quetiapine)
paliperidone ER	SEROQUEL XR (quetiapine)
risperidone	ZYPREXA (olanzapine)
ziprasidone	
High-Cost Options	
CAPLYTA (lumateperone)	olanzapine/fluoxetine
COBENFY (xanomeline/trospium)	SYMBYAX (olanzapine/fluoxetine)
LYBALVI (olanzapine/samidorphan)	
REXULTI (brexpiprazole)	
VRAYLAR (cariprazine)	

Non-Solid Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
asenapine	RISPERDAL (risperidone) ORAL SOLUTION
clozapine ODT	RISPERDAL M-TAB (risperidone)
olanzapine ODT	SAPHRIS (asenapine) 2.5 MG
risperidone ODT	ZYPREXA ZYDIS (olanzapine)

risperidone oral solution	
SAPHRIS (asenapine) 5 MG, 10 MG *– Brand Co-Preferred*	
High-Cost Options	
aripiprazole ODT	ABILIFY DISCMELT (aripiprazole)
aripiprazole solution	
SECUADO (asenapine) PATCH	

Electronic Step Therapy Required

Vraylar requires initiation titration:
- For 3 mg dose: Initiation pack or 1 day of the 1.5 mg tablet is required
- For 4.5 mg dose: Initiation pack or 1 day of the 1.5 mg tablet plus 6 days of 3 mg tablets is required

Cobenfy requires initiation titration:
- For 100 mg/20 mg dose: Initiation pack or 2 days of the 50 mg/20 mg capsules is required
- For 125 mg/30 mg dose: Initiation pack or 5 days of the 100 mg/20 mg capsules is required

Therapeutic Duplication

Prior Authorization Form - Concurrent Antipsychotics

Please see **Appendix A** for clinical criteria for multiple oral antipsychotics and oral and injectable antipsychotic requests

- One strength of one medication is allowed at a time with the following exceptions:
  - risperidone 0.25 mg, 0.5 mg and 1 mg are allowed with other strengths of risperidone
  - quetiapine 25 mg and 50 mg are allowed with other strengths of quetiapine IR
  - quetiapine 50 mg ER is allowed with other strengths of quetiapine ER
  - olanzapine 2.5 mg is allowed with 10 mg, 15 mg, and 20 mg
  - olanzapine 5 mg is allowed with 7.5 mg and 20 mg

Underutilization

- Caplyta, Cobenfy, Fanapt, Latuda, Paliperidone ER, Rexulti, Saphris, Sacuado, and Vraylar must be used adherently and will reject on point of sale for late fill

First Fill

- Caplyta, Cobenfy, Fanapt, Paliperidone ER, Rexulti, Saphris, Sacuado, and Vraylar must be filled with a 10-day supply if no previous fill within past 99 days

Long Acting Injectable (LAI)

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ABILIFY ASIMTUFII (aripiprazole)	risperidone ER (risperidone microspheres)
ABILIFY MAINTENA (aripiprazole)	
ARISTADA (aripiprazole lauroxil)	
ARISTADA INITIO (aripiprazole lauroxil)	
INVEGA HAFYERA (paliperidone)	
INVEGA SUSTENNA (paliperidone)	

INVEGA TRINZA (paliperidone)	
PERSERIS (risperidone)	
RISPERDAL CONSTA (risperidone microspheres) *– Brand Required*	
RYKINDO ER (risperidone microspheres)	
UZEDY (risperidone)	
ZYPREXA RELPREVV (olanzapine)	

Electronic Step Therapy Required

- Oral formulations must be used prior to injectable formulations to establish tolerability and achieve steady state.

  If the following conditions apply, please call for an override by calling provider relations at 1-800-755-2604:
  - There is a history of tolerability to active ingredient and no requirement for oral overlap for missed dose / initiation of long-acting injectable antipsychotic.
  - Invega Sustenna is being initiated (234 mg x 7 days requires an override for correct billing)

- Aristada Initio: Requires Aristada claim to be billed first.

Therapeutic Duplication

Prior Authorization Form - Concurrent Antipsychotics

Please see **Appendix A** for clinical criteria for multiple oral antipsychotics and oral and injectable antipsychotic requests

- One strength of one medication is allowed at a time.

Prior Authorization Criteria

- See Preferred Dosage Form Criteria

Benzodiazepines

Therapeutic Duplication

- One short acting medication is allowed at a time: alprazolam, lorazepam, oxazepam.
- One long-acting medication is allowed at a time: chlordiazepoxide, clonazepam, diazepam, alprazolam ER
- Benzodiazepines are not covered with:
  - Opioids: Override Criteria Available
  - Xyrem, Xywav
  - Mydayis
    - Insomnia has been reported in 25-56% of members receiving Mydayis. Members reporting insomnia should use a shorter acting product that does not reach steady state.
- For benzodiazepines only indicated for insomnia: see Insomnia

Insomnia

Non-addictive (Non-DEA scheduled) medications

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
Hydroxyzine	doxepin

Mirtazapine	ROZEREM (ramelteon)
Ramelteon	SILENOR (doxepin)
Trazodone	

Addictive (DEA scheduled) Medications

PREFERRED AGENTS (NO PA REQUIRED)	PREFERRED STEP 1 AGENTS (ELECTRONIC STEP)	NON-PREFERRED STEP 2 AGENTS (PA REQUIRED)
eszopiclone	BELSOMRA (suvorexant)	AMBIEN (zolpidem)
zaleplon	zolpidem 10 mg	AMBIEN CR (zolpidem)
zolpidem 5 mg		DAYVIGO (lemborexant)
zolpidem ER		EDLUAR (zolpidem)
		estazolam
		flurazepam
		LUNESTA (eszopiclone)
		QUVIVIQ (daridorexant)
		SECONAL SODIUM (secobarbital)
		temazepam
		triazolam
		zolpidem 7.5 mg
		zolpidem SL tab

Electronic Step Therapy Required

- Belsomra:
  A. PA Not Required Criteria: A 7-day supply of eszopiclone has been paid within 90 days prior to Belsomra's date of service.
  B. PA Required Criteria: The member must have failed 7-day trial of eszopiclone, as evidenced by paid claims or pharmacy printouts.
- Zolpidem:
  A. PA Not Required Criteria: A 7-day supply of zolpidem 5mg has been paid within 90 days prior to zolpidem 10mg's date of service.
  B. PA Required Criteria: The member must have failed 7-day trial of zolpidem 5mg, as evidenced by paid claims or pharmacy printouts.

Prior Authorization Criteria

Prior Authorization Form – Sedative/Hypnotic

Initial Criteria – Approval Duration: 3 months

- Doxepin only
  - The member must have failed a 25-day trial with ramelteon with the most recent failure within the last 90 days, as evidenced by paid claims or pharmacy printouts.
  - Clinical justification must be provided explaining why the member is unable to use mirtazapine, hydroxyzine, or trazodone (subject to clinical review)
- Edluar (zolpidem) only
  - The member's insomnia must be characterized by difficulty with sleep onset.
  - The member must have failed a 25-day trial of each of the following with the most recent failure within the last 90 days, as evidenced by paid claims or pharmacy printouts.
    - eszopiclone
    - zolpidem IR
    - zaleplon

- temazepam, zolpidem SL, Dayvigo, Quviviq only
  - The member's insomnia must be characterized by difficulty with sleep onset and maintenance.
  - The member must have failed a 25-day trial of each of the following with the most recent failure within the last 90 days, as evidenced by paid claims or pharmacy printouts.
    - eszopiclone
    - zolpidem ER
    - Belsomra
- triazolam, fluazepam, estazolam, seconal sodium, zolpidem 7.5mg only
  - Clinical justification must be provided explaining why the member is unable to use the preferred agents (subject to clinical review)

*Renewal Criteria – Approval Duration: 6 months (2 weeks for b*enzodiazepines)

- Other conditions causing sleep issues have been ruled out
- benzodiazepines (temazepam, triazolam, flurazepam, estazolam) only:
  - The member must be undergoing dose tapering

Therapeutic Duplication

- One strength of one medication is allowed at a time
  - Benzodiazepines indicated only for insomnia are not covered with other non-barbiturate insomnia medications or other benzodiazepines
- Sedative/hypnotics are not covered with:
  - Xyrem
  - Mydayis
    - Insomnia has been reported in 25-56% of members receiving Mydayis. Members reporting insomnia should use a shorter acting product that does not reach steady state.
  - Long-acting benzodiazepines. Belsomra and Dayvigo are not covered with short or long-acting benzodiazepines.
    - Concomitant use can lead to CNS depression.
- Ramelteon, a 1A2 Substrate, is not covered with fluvoxamine, a strong 1A2 inhibitor
- Mirtazapine is not allowed with other alpha 2 agonists (clonidine, clonidine/chlorthalidone, guanfacine, methyldopa)
  - Mirtazapine is also an alpha 2 agonist
- Sedating benzodiazepines are not covered with opioids

Non-24-hour Sleep-Wake Disorder

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ramelteon	HETLIOZ (tasimelteon) – *Brand Required*
	ROZEREM (ramelteon)
	tasimelteon

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a specialist in sleep disorders.
- The member must have had a 30-day trial of ramelteon, as evidenced by paid claims or pharmacy printouts.
- One of the following must be met:
  - Member must be unable to perceive light in either eye.

- Sighted members must confirm diagnosis by documentation submitted of self-reported sleep diaries or actigraphy for at least 14 days demonstrating a gradual daily drift (typically later) in rest-activity patterns not better explained by sleep hygiene, substance, or medication use, or other neurological or mental disorders.

Underutilization

- Hetlioz/tasimelteon must be used compliantly and will reject on point of sale for late fill.

Smith-Magenis Syndrome

CLINICAL PA REQUIRED
HETLIOZ (tasimelteon) – *Brand Required*
Tasimelteon

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a specialist in sleep disorders.
- Documentation is submitted of genetic testing confirming deletion 17p11.2 (cytogenetic analysis or microarray) or RAI1 gene mutation.
- Documentation of self-reported sleep diaries or actigraphy must be submitted for at least 14 days must be submitted.

Underutilization

- Hetlioz/tasimelteon must be used compliantly and will reject on point of sale for late fill.

Pulmonary

Asthma/COPD

Therapeutic Duplication

- One medication from each class is allowed at time.
  - One inhaled steroid
  - Long-acting anticholinergic
  - Leukotriene pathway inhibitor
  - One short-acting beta agonist
  - One long-acting beta agonist

Electronic Concurrent Medication Required

- Roflumilast: A total of 90 days of an inhaled short or long-acting anticholinergic must be paid within 115 days prior to roflumilast's date of service.
  - According to the Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines, roflumilast is a recommended add-on therapy to members experiencing exacerbations while on antimuscarinic therapy.

Albuterol / Levalbuterol Rescue Inhalers

PREFERRED AGENTS	PREFERRED STEP 1 AGENTS	NON-PREFERRED STEP 2 AGENTS

(NO PA REQUIRED)	(ELECTRONIC STEP REQUIRED)	(PA REQUIRED)
VENTOLIN (albuterol) HFA *– Brand Required*	levalbuterol HFA	albuterol HFA
	PROAIR RESPICLICK (albuterol)	PROVENTIL (albuterol) HFA
		XOPENEX (levalbuterol) HFA

According to the GINA guidelines:

- A low dose ICS should be taken whenever SABA taken for step 1 control of asthma.
- Dispensing ≥ 3 SABA canisters/year is associated with higher risk of emergency department presentations.
- Dispensing ≥ 12 SABA canisters/year is associated with higher risk of death.

Electronic Step Therapy Required

- Levalbuterol HFA:
  A. PA Not Required Criteria: A 30-day supply of albuterol HFA has been paid within 180 days prior to levalbuterol HFA's date of service.
  B. PA Required Criteria: The member must have failed a 30-day trial of albuterol HFA, as evidenced by paid claims or pharmacy printouts.

Electronic Concurrent Medications Required

- ProAir Respiclick: A total of 30 days of steroid inhaler must be paid within 40 days prior to ProAir Respiclick's date of service.

A. The quantity limit for Ventolin HFA is set to 2 canisters per 6 months (2 puffs per day). If more is needed, member must switch to ProAir Respiclick HFA and be on a steroid inhaler to control asthma.

If the following conditions apply, please call for an override by calling provider relations at 1-800-755-2604:

- If primary insurance will only pay for ProAir Respiclick and member is well-controlled without steroid inhaler (i.e., uses less than 2 canisters per 6 months).

Therapeutic Duplication

- Short acting beta agonist nebulizers and inhalers are not payable together.
  A. Inhalers and Nebulizers work equally well whether used at home, in school, or otherwise outside of the home. If member receives multiple forms of rescue medication, the risk of unidentified uncontrolled asthma and rescue inhaler dependence is increased.

If the following conditions apply, please call for an override by calling provider relations at 1-800-755-2604:

- Maximally treated members with end-stage COPD will be allowed an ongoing override (compliance with inhaled steroid, long-acting beta agonist, long-acting muscarinic antagonist, and Daliresp)
- Members with cystic fibrosis will be allowed an ongoing override.
- Acutely ill children will be allowed a one-time override.

References:

1. Albuterol Overuse: A Marker of Psychological Distress? Joe K. Gerald, Tara F. Carr, Christine Y. Wei, Janet T. Holbrook, Lynn B. Gerald. J Allergy Clin Immunol Pract. 2015 Nov-Dec; 3(6): 957–962. Published online 2015 Sep 1. Doi: 10.1016/j.jaip.2015.06.021. PMCID: PMC4641773
2. Global Initiative for Asthma. Global strategy for asthma management and prevention. 2019 GINA Main Report. Available from: www.ginasthma.org. (Accessed February 5, 2020)
3. National Asthma Education and Prevention Program, Third Expert Panel on the Diagnosis and Management of Asthma. Expert Panel Report 3: Guidelines for the Diagnosis and Management of Asthma. Bethesda (MD): National Health, Lung, and Blood Institute (US); 2007 Aug. Available from: https://www.ncbi.nlm.nih.gov/books/NBK7232

4. High-Dose Albuterol by Metered-Dose Inhaler Plus a Spacer Device Versus Nebulization in Preschool Children With Recurrent Wheezing: A Double-Blind, Randomized Equivalence Trial Dominique Ploin, François R. Chapuis, Didier Stamm, Jacques Robert, Louis David, Pierre G. Chatelain, Guy Dutau and Daniel Floret Pediatrics. August 2000, 106 (2) 311-317; DOI: https://doi.org/10.1542/peds.106.2.311

Anticholinergics/Beta Agonists Combinations – Short Acting

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
albuterol/ipratropium	DUONEB (albuterol/ipratropium)
COMBIVENT RESPIMAT (albuterol/ipratropium)	

Anticholinergics/Beta Agonists Combinations – Long Acting

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED STEP 1 AGENTS (PA REQUIRED)	NON-PREFERRED STEP 2 AGENTS (PA REQUIRED)
ANORO ELLIPTA (umeclidinium/vilanterol)	BEVESPI AEROSPHERE (glycopyrrolate/formoterol)	DUAKLIR PRESSAIR (aclidinium/formoterol)
STIOLTO RESPIMAT (tiotropium/olodaterol)		

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

Non-Preferred Step 1 Agents

- The member must have failed a 30-day trial of 2 preferred agents, as evidenced by paid claims or pharmacy printouts

Non-Preferred Step 2 Agents:

- The member must have failed a 30-day trial of Bevespi Aerosphere and 2 preferred agents, as evidenced by paid claims or pharmacy printouts
- Clinical justification must be provided explaining why the member is unable to use the preferred products (subject to clinical review).

Anticholinergics – Long-Acting

PREFERRED AGENTS (NO PA REQUIRED)	PREFERRED STEP 1 AGENTS (ELECTRONIC STEP REQUIRED)	NON-PREFERRED STEP 2 AGENTS (PA REQUIRED)
INCRUSE ELLIPTA (umeclidinium)	SPIRIVA RESPIMAT 1.25 MCG (tiotropium)	tiotropium handihaler
SPIRIVA HANDIHALER (tiotropium)		TUDORZA PRESSAIR (aclidinium)
SPIRIVA RESPIMAT 2.5 MCG (tiotropium)		YUPELRI (revefenacin)

Electronic Concurrent Medications Required

- Spiriva Respimat 1.25 mg: A total of 30 days of a long-acting beta agonist (ICS should be used with LABA as combination or single ingredient inhalers) must be paid within 40 days prior to the Spiriva Respimat 1.25 mg date of service.

Electronic Diagnosis Verification

- Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale.

- Spiriva Respimat 1.25 mg is indicated for asthma.
- Spiriva Respimat 2.5 mg is indicated for COPD.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must have failed a 30-day trial of at least 2 preferred long-acting anticholinergic agents of unique ingredients (in combination or alone), as evidenced by paid claims or pharmacy printouts.
- If the member is a current tobacco user, the member must have received tobacco cessation counseling in the past year

Beta Agonists – Long-Acting

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
arformoterol	BROVANA (arformoterol)
formoterol	PERFOROMIST (formoterol)
SEREVENT DISKUS (salmeterol)	
STRIVERDI RESPIMAT (olodaterol)	

Biologics

Anti-IL-5 biologics

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
FASENRA (benralizumab)	CINQAIR (reslizumab) – *Medical Billing Only*
	NUCALA (mepolizumab) SYRINGE, AUTOINJECTOR
	NUCALA (mepolizumab) VIAL – *Medical Billing Only*

Anti-IL-4/13 biologics

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
DUPIXENT (dupilumab)	

Allergic Asthma-directed biologics

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
XOLAIR (omalizumab) SYRINGE, AUTOINJECTOR	
XOLAIR (omalizumab) VIAL – *Medical Billing Only*	

Thymic Stromal Lymphopoietin (TSLP) blocker

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	TEZSPIRE (tezepelumab-ekko) PENS
	TEZSPIRE (tezepelumab-ekko) VIAL and SYRINGES – *Medical Billing Only*

Prior Authorization Criteria

Prior Authorization Form – Asthma

Initial Criteria – Approval Duration: 6 months

For Asthma Only

- The requested medication must be prescribed by, or in consult with, an allergist/immunologist or pulmonologist

- If the member is a current tobacco user, the member must have received tobacco cessation counseling in the past year
- The member must have had at least one exacerbation requiring use of oral corticosteroids in the past year despite continued compliant use of a high dose inhaled steroid in combination with a long-acting beta agonist (LABA) for at least 3 months prior to the exacerbation, as evidenced by paid claims or pharmacy printouts

Dupixent Only:

- The member must have an eosinophil count of ≥ 150 cells/mcL or FeNO ≥ 25 ppb within the past year

Xolair Only:

- The member has a serum total IgE level, measured before the start of treatment within the past year, of ≥ 30 IU/mL and ≤ 700 IU/mL in members age ≥ 12 years or ≥ 30 IU/mL and ≤ 1300 IU/mL in members ages 6 to < 12 years.
- The member has had a positive skin test or in vitro reactivity to a perennial aeroallergen

Anti-IL-5 biologics:

- The member has an eosinophil count ≥ 150 cells/mcL within the past year
- *Nucala and Cinqair Only*:
    - The member must have had at least one exacerbation requiring use of oral corticosteroids in the past year despite continued compliant use of a triple therapy regimen (high dose inhaled steroid + long-acting beta agonist (LABA) + long-acting muscarinic antagonist (LAMA)) in combination with each of the following for at least 4 months, as evidenced by paid claims or pharmacy printouts: Dupixent, Fasenra, and Tezspire

Tezspire Only:

- The member must have had at least one exacerbation requiring use of oral corticosteroids in the past year despite continued compliant use of a triple therapy regimen (high dose inhaled steroid + long-acting beta agonist (LABA) + long-acting muscarinic antagonist (LAMA)) in combination with each of the following for at least 4 months, as evidenced by paid claims or pharmacy printouts: Dupixent and Fasenra

For COPD Only

Dupixent Only:

- The requested medication must be prescribed by, or in consult with, an allergist/immunologist or pulmonologist
- If the member is a current tobacco user, the member must have received tobacco cessation counseling in the past year
- The member must have had at least one exacerbation requiring use of oral corticosteroids in the previous year despite continued compliant use of an inhaled steroid AND long-acting beta agonist (LABA) AND long-acting muscarinic antagonist (LAMA) as evidenced by paid claims or pharmacy printouts
- The member has an eosinophil count of ≥ 300 cells/mcL within the past year

Renewal Criteria – Approval Duration: 12 months

- The member must have achieved a significant reduction in exacerbations and utilization of systemic steroids and rescue medications since treatment initiation since starting treatment with the requested medication (subject to clinical review).

Corticosteroids – Inhaled

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ARNUITY ELLIPTA (fluticasone)	ALVESCO (ciclesonide)
ASMANEX (mometasone) TWISTHALER	ASMANEX HFA (mometasone)
budesonide suspension	fluticasone HFA
PULMICORT FLEXHALER (budesonide)	fluticasone diskus

	PULMICORT RESPULES (budesonide)
	QVAR REDIHALER (beclomethasone)

GINA and EPR-3 Guidelines – SMART:

- For steps 3-5, ICS-formoterol is preferred for use as an as needed and regular daily treatment
- Please consider SMART therapy instead of single agent inhaled corticosteroid.
  - Both Symbicort and Dulera are available as HFA products

Quantity Limits to accommodate SMART therapy:

- 2 Symbicort or Dulera inhalers per 30-day supply not to exceed a total of 9 inhalers per 182 days without prior approval.

References:

1. Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention, 2023. Updated July 2023. Available from: www.ginasthma.org
2. Cloutier, Michelle M., et al. "2020 focused updates to the asthma management guidelines: a report from the National Asthma Education and Prevention Program Coordinating Committee Expert Panel Working Group." *Journal of Allergy and Clinical Immunology* 146.6 (2020): 1217-1270. Available at: https://www.epa.gov/sites/default/files/2021-05/documents/_sites_default_files_publications_asthmamanagementguidelinesreport-2-4-21.pdf

Electronic Age Verification:

- Fluticasone HFA does not require PA for ages 4 and under

Electronic Duration Verification:

- Budesonide Suspension 1 mg/2 mL is payable for 30 days every 75 days. For diluted nasal rinses or oral use, please use 0.5 mg/2 mL instead of 1 mg/2 mL for doses 1 mg per day or higher.
  - Guidelines recommend that once control is achieved, dose should be titrated down to minimum dose required to maintain control. For doses 1.5 mg per day or lower, please use 0.5 mg/2 mL strength.

Prior Authorization

Initial Criteria – Approval Duration: 12 months

- The member must have failed a 30-day trial of each preferred inhaler of a unique active ingredient, as evidenced by paid claims or pharmacy printouts.
- *Asmanex HFA and QVAR Redihaler Only:*
  - Preferred agent trials may be bypassed if member meets one of the following criteria:
    - Member is unable to achieve inspiratory flow rate of 40 L/min.
    - Member is unable to achieve inspiratory flow rate of 60 L/min and has previously had adrenal insufficiency with fluticasone.
    - Permanent disability preventing use of a dry powder inhaler
- *fluticasone HFA only:*
  - Preferred agent trials may be bypassed if member meets one of the following criteria:
    - Member is unable to achieve inspiratory flow rate of 40 L/min.
    - Permanent disability preventing use of a dry powder inhaler

References:

1. Sannarangappa V, Jalleh R. Inhaled corticosteroids and secondary adrenal insufficiency. Open Respir Med J. 2014 Jan 31;8:93-100. doi: 10.2174/1874306401408010093. PMID: 25674179; PMCID: PMC4319207.
2. Saag KG, Furst DE, Barnes PJ . Major side effects of inhaled glucocorticoids In: *UpToDate*, Post TW (Ed), UpToDate, Waltham, MA, 2023

Corticosteroid/Long-Acting Beta Agonist (LABA) Combination Inhalers

Solid Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED STEP 1 AGENTS (PA REQUIRED)	NON-PREFERRED STEP 2 AGENTS (PA REQUIRED)
ADVAIR DISKUS (fluticasone/salmeterol) *– Brand Required*	BREO ELLIPTA (fluticasone/vilanterol) *– Brand Required*	BREYNA (budesonide/formoterol)
ADVAIR HFA (fluticasone/salmeterol) *– Brand Required*		budesonide/formoterol
AIRDUO RESPICLICK (fluticasone/salmeterol) *– Brand Required*		fluticasone/salmeterol
DULERA (mometasone/formoterol)		fluticasone/vilanterol
		SYMBICORT (budesonide/formoterol) *– Brand Required*
		WIXELA INHUB (fluticasone/salmeterol)

GINA Guidelines – SMART:

- For mild asthma, ICS-formoterol is the preferred reliever medication for as needed symptom relief
- For steps 3-5, ICS-formoterol is preferred for use as an as needed and regular daily treatment
  Quantity Limits to accommodate SMART therapy:
  - 2 Symbicort or Dulera inhalers per 30-day supply not to exceed a total of 9 inhalers per 182 days without prior approval.

Electronic Diagnosis Verification

- Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

Non-Preferred Step 1 Agents:

- The member must have failed a 30-day trial of each preferred agent of a unique ingredient, as evidenced by paid claims or pharmacy printouts.
- For COPD diagnosis only: The member must currently be taking a long acting antimuscarinic agent.

Non-Preferred Step 2 Agents:

- The member must have failed a 30-day trial of each preferred and non-preferred step 1 agent of a unique ingredient, as evidenced by paid claims or pharmacy printouts.
- If the member is a current tobacco user, the member must have received tobacco cessation counseling in the past year
- For COPD diagnosis only, the member must currently be taking a long acting antimuscarinic agent.

Corticosteroid/Short-Acting Beta Agonist (SABA) Combination Inhalers

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)

	AIRSUPRA (albuterol/budesonide)

GINA Guidelines – SMART:
- For mild asthma, ICS-formoterol is the preferred reliever medication for as needed symptom relief.
- For steps 3-5, ICS-formoterol is preferred for use as an as needed and regular daily treatment.
  Quantity Limits to accommodate SMART therapy:
  - 2 Symbicort or Dulera inhalers per 30-day supply not to exceed a total of 9 inhalers per 365 days without prior approval.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months
- The member must have failed a 30-day trial of Symbicort and Dulera, as evidenced by paid claims or pharmacy printouts.
- Clinical justification must be provided explaining why the member is unable to use the preferred Steroid/LABA or SABA agents (subject to clinical review).

Corticosteroid/Anticholinergics/Long-Acting Beta Agonists Combinations

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
TRELEGY ELLIPTA (fluticasone/umeclidinium/vilanterol)	BREZTRI AEROSPHERE (budesonide/glycopyrrolate/formoterol)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months
- The member must have blood eosinophil of ≥ 100 cells/mcL within the past 90 days
- If the member is a current tobacco user, the member must have received tobacco cessation counseling in the past year
- The member must have experienced an exacerbation while adherent to a 60-day trial of fluticasone inhaler + umeclidinium + vilanterol which have the same active ingredients as Trelegy Ellipta, as evidenced by paid claims or pharmacy printouts. Clinical justification must also be provided why Trelegy Ellipta is expected to improve outcomes versus using fluticasone inhaler + umeclidinium + vilanterol combination therapy (subject to clinical review).
  - available combination products to achieve this are fluticasone + Anoro Ellipta (umedclidium/vilanterol) and Breo Ellipta (fluticasone/vilanterol) + Incluse Ellipta (umeclidinium)
- The member must have experienced an exacerbation while adherent to a 60-day trial of triple therapy (Steroid/Long-Acting Beta Agonist/Long-Acting Anticholinergic) that has at least one ingredient different from fluticasone inhaler + umeclidinium + vilanterol combination therapy, as evidenced by paid claims or pharmacy printouts.

Non-Preferred Agents Criteria:
- The member must have failed a 30-day trial of the preferred product, as evidenced by paid claims or pharmacy printouts:

Phosphodiesterase-3 (PDE3) and Phosphodiesterase-4 (PDE4) Inhibitor

PREFERRED AGENTS (CLINICAL PA REQUIRED)
OHTUVAYRE (ensifentrine)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months
- The requested medication must be prescribed by, or in consult with, a pulmonologist

- If the member is a current tobacco user, the member must have received tobacco cessation counseling in the past year
- The member must meet one of the following criteria:
    - The member has a blood eosinophil of ≥ 100 cells/mcL and has experienced an exacerbation while adherent to a 60-day trial of a triple combination regimen consisting of an inhaled steroid, long-acting beta agonist, and long-acting anticholinergic.
    - The member has a blood eosinophil of < 100 cells/mcL and has experienced an exacerbation while adherent to a 60-day trial of a dual combination regimen consisting of a long-acting beta agonist and long-acting anticholinergic.

Cystic Fibrosis

Cystic Fibrosis – Inhaled Antibiotics

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
tobramycin (generic Tobi)	ARIKAYCE (amikacin/nebulizer)
PREFERRED AGENTS (PA REQUIRED)	BETHKIS (tobramycin)
TOBI PODHALER (tobramycin)	CAYSTON (aztreonam)
	KITABIS PAK (tobramycin/nebulizer)
	TOBI (tobramycin)
	tobramycin/nebulizer (generic Kitabis)
	tobramycin (generic Bethkis)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- Arikayce only:
    - The member must be colonized with *Mycobacterium avium* complex (MAC).
    - The member must have not achieved negative sputum cultures after a minimum duration of 6 consecutive months of background treatment with a macrolide, a rifamycin, and ethambutol.
- Cayston only:
    - The member must be colonized with *Pseudomonas aeruginosa.*
    - The member must have had a 28-day trial of tobramycin as evidenced by paid claims or pharmacy printouts.
- Tobi Podhaler only:
    - The member must have failed one 28-day trial of a tobramycin nebulized agent, as evidenced by paid claims or pharmacy printouts.
- All other agents: See Preferred Dosage Form Criteria

Cystic Fibrosis – CFTR Modulators

CLINICAL PA REQUIRED
KALYDECO (ivacaftor)
ORKAMBI (lumacaftor/ivacaftor)
SYMDEKO (tezacaftor/ivacaftor)
TRIKAFTA (elexacaftor/tezacaftor/ivacaftor) GRANULES
TRIKAFTA (elexacaftor/tezacaftor/ivacaftor) TABLETS

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months (Renewal Approval – 5 years)

- The member must have a CFTR mutation that the requested medication is FDA-approved to treat, as evidenced by medical documentation (e.g., chart notes, genetic testing) that is attached to the request.

Cystic Fibrosis – Osmotic Agent

CLINICAL PA REQUIRED
BRONCHITOL (mannitol) INHALER

Electronic Diagnosis Verification

- Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale.

Electronic Age Verification

- The member must be 18 years or older

Prior Authorization

Initial Criteria – Approval Duration: 12 months

- Documentation of the Bronchitol Tolerance Test must be submitted

Idiopathic Pulmonary Fibrosis

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
pirfenidone	ESBRIET (pirfenidone)
	OFEV (nintedanib)

Prior Authorization

Initial Criteria – Approval Duration: 12 months

- The requested medication must be prescribed by, or in consult with, a pulmonologist or rheumatologist.
- The prescriber must submit documentation of the following:
  - The member must have forced vital capacity (FVC) ≥ 40% of predicted within prior 60 days.
  - The member must have carbon monoxide diffusing capacity (DLCO, corrected for hemoglobin) of 30% to 79% of predicted.

Interstitial Lung Disease

First Line Therapy - Orals

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
azathioprine	
cyclophosphamide	
mycophenolate mofetil (MMF)	

First Line Therapy - Biologics

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
TYENNE (tocilizumab-aazg) AUTOINJECTOR, SYRINGE	ACTEMRA (tocilizumab) ACTPEN, SYRINGE
TYENNE (tocilizumab-aazg) VIAL – *Medical Billing Only*	ACTEMRA (tocilizumab) VIAL – *Medical Billing Only*
	TOFIDENCE (tocilizumab-aazg) VIAL – *Medical Billing Only*

Progressive Disease

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
RIABNI (rituximab-arrx) – *Medical Billing Only*	OFEV (nintedanib)
RUXIENCE (rituximab-pvvr) – *Medical Billing Only*	RITUXAN (rituximab) – *Medical Billing Only*
TRUXIMA (rituximab-abbs) – *Medical Billing Only*	

Prior Authorization

Initial Criteria – Approval Duration: 12 months

- The requested medication must be prescribed by, or in consult with, a pulmonologist or rheumatologist.
- The prescriber must submit documentation of the following:
  - The member must have forced vital capacity (FVC) ≥ 40% of predicted within prior 60 days
  - The member must have carbon monoxide diffusing capacity (DLCO, corrected for hemoglobin) of 30% to 79% of predicted.
- Rituxan, Actemra, and Non-Preferred Biosimilar Agents: See Biosimilar Agents criteria

Rheumatology

Axial Spondyloarthritis/Ankylosing Spondylitis

TNF Inhibitors

Adalimumab

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ABRILADA (adalimumab-afzb)	adalimumab-aacf
adalimumab-adbm – labeler 00597	adalimumab-aaty
adalimumab-fkjp	adalimumab-adaz
CYLTEZO (adalimumab-abdm)	adalimumab-adbm – labeler 82009
HADLIMA (adalimumab-bwwd)	adalimumab-ryvk
HULIO (adalimumab-fkjp)	AMJEVITA (adalimumab-atto)
HUMIRA (adalimumab)	HYRIMOZ (adalimumab-adaz)
SIMLANDI (adalimumab-ryvk)	IDACIO (adalimumab-aacf)
YUSIMRY (adalimumab-aqvh)	YUFLYMA (adalimumab-aaty)

Infliximab

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AVSOLA (infliximab-axxq) – *Medical Billing Only*	INFLECTRA (infliximab-dyyb) – *Medical Billing Only*
RENFLEXIS (infliximab-abda) – *Medical Billing Only*	infliximab – *Medical Billing Only*
	REMICADE (infliximab) – *Medical Billing Only*

Other TNF

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ENBREL (etanercept)	CIMZIA (certolizumab) SYRINGE
SIMPONI (golimumab)	CIMZIA (certolizumab) VIAL – *Medical Billing Only*
	SIMPONI ARIA (golimumab)– *Medical Billing Only*

Interleukin (IL) – 17 Inhibitors

PREFERRED AGENTS (ELECTRONIC STEP REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)

TALTZ (ixekizumab)***	COSENTYX (secukinumab)
	COSENTYX (secukinumab) – *Medical Billing Only*

Interleukin (IL)-17A and IL-17F inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	BIMZELX (bimekizumab-bkzx)

Janus Kinase (JAK) Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
XELJANZ IR (tofacitinib) 5 mg, oral solution	RINVOQ ER (upadacitinib)
	XELJANZ IR (tofacitinib) 10 mg
	XELJANZ XR (tofacitinib)

Electronic Step Therapy Required

- Taltz:
  - PA Not Required Criteria: A total of 84-day supply of a TNF Inhibitor has been paid within 120 days prior to Taltz's date of service.
  - PA Required Criteria: The member must have failed a 3-month trial of a TNF inhibitor, as evidenced by paid claims or pharmacy printouts.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- Cimzia Only: The member must have failed a 90-day trial of a TNF inhibitor, as evidenced by paid claims or pharmacy printouts.
- Rinvoq ER Only: The member must have failed a 30-day trial of Xeljanz and a 90-day trial of a TNF inhibitor, as evidenced by paid claims or pharmacy printouts.
- Bimzlex, Cosentyx and Simponi Aria Only: The member must have failed a 30-day trial of Xeljanz and Rinvoq ER, and a 90-day trial of a TNF inhibitor and Taltz, as evidenced by paid claims or pharmacy printouts.
- Inflectra, infliximab, Remicade, Rituxan: See Biosimilar Agents criteria
- Xeljanz IR 10 mg, Xeljanz XR Only: See Preferred Dosage Form Criteria
- Medical billing only agents: In addition to above criteria, clinical justification must be provided why a self-administered agent cannot be used (subject to clinical review).

Behçet syndrome

Phosphodiesterase 4 (PDE4) Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
OTEZLA (apremilast)	

TNF Inhibitors

Adalimumab

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ABRILADA (adalimumab-afzb)	adalimumab-aacf
adalimumab-adbm – labeler 00597	adalimumab-aaty
adalimumab-fkjp	adalimumab-adaz
CYLTEZO (adalimumab-abdm)	adalimumab-adbm – labeler 82009

HADLIMA (adalimumab-bwwd)	adalimumab-ryvk
HULIO (adalimumab-fkjp)	AMJEVITA (adalimumab-atto)
HUMIRA (adalimumab)	HYRIMOZ (adalimumab-adaz)
SIMLANDI (adalimumab-ryvk)	IDACIO (adalimumab-aacf)
YUSIMRY (adalimumab-aqvh)	YUFLYMA (adalimumab-aaty)

Infliximab

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AVSOLA (infliximab-axxq) – *Medical Billing Only*	INFLECTRA (infliximab-dyyb) – *Medical Billing Only*
RENFLEXIS (infliximab-abda) – *Medical Billing Only*	infliximab – *Medical Billing Only*
	REMICADE (infliximab) – *Medical Billing Only*

Other TNF

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ENBREL (etanercept)	

Prior Authorization Criteria

- See Biosimilar Agents criteria

Cryopyrin Associated Periodic Syndrome (CAPS)

Includes: Familiar Cold Autoinflammatory Syndrome, Muckle-Wells Syndrome, and Neonatal Onset Multisystem Inflammatory Disease (NOMID) or Chronic Infantile Neurological Cutaneous and Articular (CINCA) Syndrome

Interleukin (IL) -1 Receptor Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
KINERET (anakinra)	ARCALYST (rilonacept)
	ILARIS (canakinumab) – *Medical Billing Only*

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a specialist in the area of the member's diagnosis.
- The member has failed a 3-month trial of Kineret, as evidenced by paid claims or pharmacy print outs.
- The member has elevated pretreatment serum inflammatory markers (e.g., C-reactive protein (CRP), erythrocyte sedimentation rate (ESR) serum amyloid A(SAA))
- The member has at least two of the following symptoms (as evidenced by documentation):
  - Urticaria-like rash
  - Cold/stress triggered episodes
  - Sensorineural hearing loss
  - Musculoskeletal symptoms of arthralgia/arthritis/myalgia
  - Chronic aseptic meningitis
  - Skeletal abnormalities of epiphyseal overgrowth/frontal bossing

Familial Mediterranean Fever (FMF)

Colchicine

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
colchicine tablets	colchicine capsules
	GLOPERBA (colchicine) ORAL SOLUTION
	MITIGARE (colchicine) CAPSULE

Interleukin (IL) -1 Receptor Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
KINERET (anakinra)	ARCALYST (rilonacept)
	ILARIS (canakinumab) – *Medical Billing Only*

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a specialist in the area of the member's diagnosis.
- The member experiences one or more attacks each month despite receiving maximally tolerated dose of colchicine for at least 6 months, as evidenced by paid claims or pharmacy print outs and clinical documentation.
- The member has failed a 3-month trial of Kineret, as evidenced by paid claims or pharmacy print outs.

Giant Cell Arteritis (Temporal Arteritis)

Interleukin (IL) -6 Receptor Inhibitors

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
TYENNE (tocilizumab-aazg) AUTOINJECTOR, SYRINGE	ACTEMRA (tocilizumab) ACTPEN, SYRINGE
TYENNE (tocilizumab-aazg) VIAL – *Medical Billing Only*	ACTEMRA (tocilizumab) VIAL – *Medical Billing Only*
	TOFIDENCE (tocilizumab-aazg) VIAL – *Medical Billing Only*

Prior Authorization Criteria

- See Medications that cost over $3000/month criteria
- Non-Preferred Agents: See Biosimilar Agents criteria

Hyperimmunoglobulin D Syndrome/Mevalonate Kinase (MVK) Deficiency

Symptomatic Treatment

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
NSAIDs	
glucocorticoids	
KINERET (anakinra)	

Preventative Treatment

CLINICAL PA REQUIRED
ILARIS (canakinumab)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a specialist in the area of the member's diagnosis.
- The member has failed a 3-month trial of Kineret, as evidenced by paid claims or pharmacy print outs.
- The member is experiencing frequent and/or severe attacks that have significantly diminished quality of life

Juvenile Idiopathic Arthritis

Juvenile Idiopathic Arthritis – Enthesitis-Related Arthritis (ERA)

Interleukin (IL) – 17 Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	COSENTYX (secukinumab)
	COSENTYX (secukinumab) – *Medical Billing Only*

TNF Inhibitors

Adalimumab

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ABRILADA (adalimumab-afzb)	adalimumab-aacf
adalimumab-adbm – labeler 00597	adalimumab-aaty
adalimumab-fkjp	adalimumab-adaz
CYLTEZO (adalimumab-abdm)	adalimumab-adbm – labeler 82009
HADLIMA (adalimumab-bwwd)	adalimumab-ryvk
HULIO (adalimumab-fkjp)	AMJEVITA (adalimumab-atto)
HUMIRA (adalimumab)	HYRIMOZ (adalimumab-adaz)
SIMLANDI (adalimumab-ryvk)	IDACIO (adalimumab-aacf)
YUSIMRY (adalimumab-aqvh)	YUFLYMA (adalimumab-aaty)

Other TNF

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ENBREL (etanercept)	

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member has failed a 3-month trial of a TNF inhibitor, as evidenced by paid claims or pharmacy print outs.
- Biosimilars Only: See Preferred Dosage Form Criteria

Interleukin (IL) -6 Receptor Inhibitors

Tocilizumab

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
TYENNE (tocilizumab-aazg) AUTOINJECTOR, SYRINGE	ACTEMRA (tocilizumab) ACTPEN, SYRINGE
TYENNE (tocilizumab-aazg) VIAL – *Medical Billing Only*	ACTEMRA (tocilizumab) VIAL – *Medical Billing Only*
	TOFIDENCE (tocilizumab-aazg) VIAL – *Medical Billing Only*

Other

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	KEVZARA (sarilumab)

Janus Kinase (JAK) Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
XELJANZ IR (tofacitinib) 5 MG TABLET, SOLUTION	RINVOQ ER TABLET, SOLUTION
	XELJANZ IR (tofacitinib) 10 MG TABLET
	XELJANZ XR (tofacitinib)

T-cell Costimulation Blocker

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ORENCIA (abatacept) – 125 mg/mL syringe	ORENCIA (abatacept) - 50 mg/0.4 mL and 87.5 mg/0.7 ml syringes
	ORENCIA (abatacept) – *Medical Billing Only*

TNF Inhibitors

Adalimumab

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ABRILADA (adalimumab-afzb)	adalimumab-aacf
adalimumab-adbm – labeler 00597	adalimumab-aaty
adalimumab-fkjp	adalimumab-adaz
CYLTEZO (adalimumab-abdm)	adalimumab-adbm – labeler 82009
HADLIMA (adalimumab-bwwd)	adalimumab-ryvk
HULIO (adalimumab-fkjp)	AMJEVITA (adalimumab-atto)
HUMIRA (adalimumab)	HYRIMOZ (adalimumab-adaz)
SIMLANDI (adalimumab-ryvk)	IDACIO (adalimumab-aacf)
YUSIMRY (adalimumab-aqvh)	YUFLYMA (adalimumab-aaty)

Other TNF

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ENBREL (etanercept)	CIMZIA (certolizumab) SYRINGE
	CIMZIA (certolizumab) VIAL – *Medical Billing Only*
	SIMPONI ARIA (golimumab) – *Medical Billing Only*

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member has failed a 3-month trial of a TNF inhibitor, as evidenced by paid claims or pharmacy print outs.
- Xeljanz Oral Solution Only: The member has failed a 3-month trial of a TNF inhibitor, Orencia, as evidenced by paid claims or pharmacy print outs.
- Rinvoq ER Only: The member has failed a 3-month trial of a TNF inhibitor, Orencia, and Xeljanz, as evidenced by paid claims or pharmacy print outs.
- Actemra and Non-preferred Biosimilars Only: See Biosimilar Agents criteria
- Xeljanz IR 10mg, Xeljanz XR Only: See Preferred Dosage Form criteria
- Simponi Aria Only: The member must have failed a 30-day trial of Rinvoq ER, and Xeljanz and a 90-day trial of a TNF inhibitor and Orencia, as evidenced by paid claims or pharmacy printouts.
- Medical billing only agents: In addition to above criteria, clinical justification must be provided why a self-administered agent cannot be used (subject to clinical review)

Juvenile Chronic Arthritis – Systemic Onset

Interleukin (IL) -1 Receptor Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	ILARIS (canakinumab) – *Medical Billing Only*

Interleukin (IL) -6 Receptor Inhibitors

Tocilizumab

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
TYENNE (tocilizumab-aazg) AUTOINJECTOR, SYRINGE	ACTEMRA (tocilizumab) ACTPEN, SYRINGE
TYENNE (tocilizumab-aazg) VIAL – *Medical Billing Only*	ACTEMRA (tocilizumab) VIAL – *Medical Billing Only*
	TOFIDENCE (tocilizumab-aazg) VIAL – *Medical Billing Only*

TNF Inhibitors

Adalimumab

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ABRILADA (adalimumab-afzb)	adalimumab-aacf
adalimumab-adbm – labeler 00597	adalimumab-aaty
adalimumab-fkjp	adalimumab-adaz
CYLTEZO (adalimumab-abdm)	adalimumab-adbm – labeler 82009
HADLIMA (adalimumab-bwwd)	adalimumab-ryvk
HULIO (adalimumab-fkjp)	AMJEVITA (adalimumab-atto)
HUMIRA (adalimumab)	HYRIMOZ (adalimumab-adaz)
SIMLANDI (adalimumab-ryvk)	IDACIO (adalimumab-aacf)
YUSIMRY (adalimumab-aqvh)	YUFLYMA (adalimumab-aaty)

Other TNF

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ENBREL (etanercept)	

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member has failed a 3-month trial of a TNF inhibitor, as evidenced by paid claims or pharmacy print outs.
- Ilaris Only: The member has failed a 3-month trial of tocilizumab, as evidenced by paid claims or pharmacy print outs.
- Actemra and non-preferred biosimilars only: See Biosimilar Agents criteria

References:

1. Dewitt, E.M., Kimura, Y., Beukelman, T., Nigrovic, P.A., Onel, K., Prahalad, S., Schneider, R., Stoll, M.L., Angeles-Han, S., Milojevic, D., Schikler, K.N., Vehe, R.K., Weiss, J.E., Weiss, P., Ilowite, N.T., Wallace, C.A. and (2012), Consensus treatment plans for new-onset systemic juvenile idiopathic arthritis. Arthritis Care Res, 64: 1001-1010. https://doi.org/10.1002/acr.21625

Polymyalgia Rheumatica

Interleukin (IL) -6 Receptor Inhibitors

CLINICAL PA REQUIRED
KEVZARA (sarilumab)

Prior Authorization Criteria

- See Medications that cost over $3000/month criteria

Psoriatic Arthritis

TNF Inhibitors

Adalimumab

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ABRILADA (adalimumab-afzb)	adalimumab-aacf
adalimumab-adbm – labeler 00597	adalimumab-aaty
adalimumab-fkjp	adalimumab-adaz
CYLTEZO (adalimumab-abdm)	adalimumab-adbm – labeler 82009
HADLIMA (adalimumab-bwwd)	adalimumab-ryvk
HULIO (adalimumab-fkjp)	AMJEVITA (adalimumab-atto)
HUMIRA (adalimumab)	HYRIMOZ (adalimumab-adaz)
SIMLANDI (adalimumab-ryvk)	IDACIO (adalimumab-aacf)
YUSIMRY (adalimumab-aqvh)	YUFLYMA (adalimumab-aaty)

Infliximab

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AVSOLA (infliximab-axxq) – *Medical Billing Only*	INFLECTRA (infliximab-dyyb) – *Medical Billing Only*
RENFLEXIS (infliximab-abda) – *Medical Billing Only*	infliximab – *Medical Billing Only*
	REMICADE (infliximab) – *Medical Billing Only*

Other TNF

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ENBREL (etanercept)	CIMZIA (certolizumab) SYRINGE

SIMPONI (golimumab)	CIMZIA (certolizumab) VIAL – *Medical Billing Only*
	SIMPONI ARIA (golimumab)– *Medical Billing Only*

Phosphodiesterase 4 (PDE4) Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
OTEZLA (apremilast)	

Janus Kinase (JAK) Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
XELJANZ IR (tofacitinib) 5 mg, oral solution	RINVOQ ER (upadacitinib)
	XELJANZ IR (tofacitinib) 10 mg
	XELJANZ XR (tofacitinib)

T-cell Costimulation Blocker

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ORENCIA (abatacept) – 125 mg/mL syringe	ORENCIA (abatacept) – *Medical Billing Only*
	ORENCIA (abatacept) – 50 mg/0.4mL, 87.5 mg/0.7 mL syringe

Interleukin (IL) – 17 Inhibitors

PREFERRED AGENTS (ELECTRONIC STEP REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
TALTZ (ixekizumab)	COSENTYX (secukinumab)
	COSENTYX (secukinumab) – *Medical Billing Only*

Interleukin (IL)-17A and IL-17F inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	BIMZELX (bimekizumab-bkzx)

Interleukin (IL)-23p19 Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	SKYRIZI (risankizumab-rzaa)
	TREMFYA (guselkumab)

Interleukin (IL)-12/IL-23 Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	STELARA (ustekinumab)
	WEZLANA (ustekinumab-auub)

Electronic Step Therapy Required

- Taltz:
  - PA Not Required Criteria: A total of 84-day supply of a TNF Inhibitor has been paid within 120 days prior to Taltz's date of service.
  - PA Required Criteria: The member must have failed a 3-month trial of a TNF inhibitor, as evidenced by paid claims or pharmacy printouts.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months
Pediatric Members:
Cosentyx Only:
- The member must have failed a 90-day trial of etanercept, as evidenced by paid claims or pharmacy printouts:

All Other Agents:
- The member must have failed a 90-day trial of each of the following, as evidenced by paid claims or pharmacy printouts:
  - TNF inhibitor (etanercept)
  - Interleukin (IL) – 17 inhibitor (secukinumab)
- Xeljanz IR 10mg, Xeljanz XR Only: See Preferred Dosage Form criteria

Adult Members:
- Cimzia, Rinvoq ER, Cosentyx: The member must have failed a 90-day trial of each of the following, as evidenced by paid claims or pharmacy printouts:
  - TNF inhibitor
  - Interleukin (IL) – 17 inhibitor
- Skyrizi and Tremfya Only: The member must have failed a 90-day trial of each of the following, as evidenced by paid claims or pharmacy printouts:
  - TNF inhibitor
  - Interleukin (IL) – 17 inhibitor
  - Rinvoq ER
- Interleukin (IL)-12/IL-23 Inhibitor, Bimzelx, Simponi Aria Only: The member must have failed a 90-day trial of each of the following, as evidenced by paid claims or pharmacy printouts:
  - TNF inhibitor
  - Interleukin (IL) – 17 inhibitor
  - Interleukin (IL)-23p19 Inhibitor
  - Rinvoq ER
- Medical billing only agents: In addition to above criteria, clinical justification must be provided why self-administered agents cannot be used (subject to clinical review).
- Non-preferred biosimilars only: See Biosimilar Agents criteria
- All other Agents: See Preferred Dosage Form Criteria

Rheumatoid Arthritis

Anti-CD20 Monoclonal Antibodies

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
RIABNI (rituximab-arrx) – *Medical Billing Only*	RITUXAN (rituximab) – *Medical Billing Only*
RUXIENCE (rituximab-pvvr) – *Medical Billing Only*	
TRUXIMA (rituximab-abbs) – *Medical Billing Only*	

Interleukin (IL) -1 Receptor Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
KINERET (anakinra)	

Interleukin (IL) -6 Receptor Inhibitors

Tocilizumab

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)

TYENNE (tocilizumab-aazg) AUTOINJECTOR, SYRINGE	ACTEMRA (tocilizumab) ACTPEN, SYRINGE
TYENNE (tocilizumab-aazg) VIAL – *Medical Billing Only*	ACTEMRA (tocilizumab) VIAL – *Medical Billing Only*
	TOFIDENCE (tocilizumab-aazg) VIAL – *Medical Billing Only*

Other

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	KEVZARA (sarilumab)

Janus Kinase (JAK) Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
XELJANZ IR (tofacitinib) 5 mg, oral solution	OLUMIANT (baricitinib)
	RINVOQ ER (upadacitinib)
	XELJANZ IR (tofacitinib) 10 mg
	XELJANZ XR (tofacitinib)

T-cell Co-stimulation Blocker

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ORENCIA (abatacept) – 125 mg/mL syringe	ORENCIA (abatacept) – *Medical Billing Only*

TNF Inhibitors

Adalimumab

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ABRILADA (adalimumab-afzb)	adalimumab-aacf
adalimumab-adbm – labeler 00597	adalimumab-aaty
adalimumab-fkjp	adalimumab-adaz
CYLTEZO (adalimumab-abdm)	adalimumab-adbm – labeler 82009
HADLIMA (adalimumab-bwwd)	adalimumab-ryvk
HULIO (adalimumab-fkjp)	AMJEVITA (adalimumab-atto)
HUMIRA (adalimumab)	HYRIMOZ (adalimumab-adaz)
SIMLANDI (adalimumab-ryvk)	IDACIO (adalimumab-aacf)
YUSIMRY (adalimumab-aqvh)	YUFLYMA (adalimumab-aaty)

Infliximab

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AVSOLA (infliximab-axxq) – *Medical Billing Only*	INFLECTRA (infliximab-dyyb) – *Medical Billing Only*
RENFLEXIS (infliximab-abda) – *Medical Billing Only*	infliximab – *Medical Billing Only*
	REMICADE (infliximab) – *Medical Billing Only*

Other TNF

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ENBREL (etanercept)	CIMZIA (certolizumab) SYRINGE
SIMPONI (golimumab)	CIMZIA (certolizumab) VIAL – *Medical Billing Only*
	SIMPONI ARIA (golimumab)– *Medical Billing Only*

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must have had a 3-month trial of each of the following, as evidenced by paid claims and pharmacy printouts:
  - TNF Inhibitor
  - T-cell Co-stimulation Blocker
- Simponi Aria only: The member must have had a 3-month trial of each of the following, as evidenced by paid claims and pharmacy printouts:
  - TNF Inhibitor
  - T-cell Co-stimulation Blocker
  - Rinvoq ER
  - Interleukin – 6 inhibitors
- Xeljanz IR 10mg, Xeljanz XR only: See Preferred Dosage Form criteria
- Actemra and non-preferred biosimilar agents only: See Biosimilar Agents criteria
- Medical billing only agents: In addition to above criteria, clinical justification must be provided why a self-administered agent cannot be used (subject to clinical review).

Adult-Onset Still's Disease

Interleukin (IL) -1 Receptor Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
KINERET (anakinra)	ILARIS (canakinumab) – *Medical Billing Only*

TNF Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AVSOLA (infliximab-axxq) – *Medical Billing Only*	INFLECTRA (infliximab-dyyb) – *Medical Billing Only*
RENFLEXIS (infliximab-abda) – *Medical Billing Only*	infliximab – *Medical Billing Only*
	REMICADE (infliximab) – *Medical Billing Only*

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a specialist in the area of the member's diagnosis.
- The member must have had a 3-month trial of each of Kineret, as evidenced by paid claims and pharmacy printouts:
- Remicade, Rituxan, infliximab, and Inflectra Only: See Biosimilar Agents Criteria

Tumor Necrosis Factor Receptor Associated Periodic Syndrome

CLINICAL PA REQUIRED
ILARIS (canakinumab)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a specialist in the area of the member's diagnosis.

- Documentation must be attached to confirm one of the following:
  - Genetic testing confirming pathogenic variants in the tumor necrosis factor receptor 1 (TNFR1) gene (TNF receptor superfamily member 1A, TNFRSF1A).
  - Both of the following:
    - Elevated serum inflammatory markers (e.g., C-reactive protein (CRP), erythrocyte sedimentation rate (ESR) serum amyloid A(SAA))
    - History of recurrent fever, prominent myalgias, migratory rash, and periorbital edema

Osteoporosis

Antiresorptive Agents

Bisphosphonates

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
alendronate	ACTONEL (risedronate)
alendronate oral solution	ATELVIA (risedronate DR)
BONIVA (ibandronate) – *Medical Billing Only*	FOSAMAX (alendronate)
ibandronate – *Medical Billing Only*	FOSAMAX D (alendronate/vitamin D)
RECLAST (zolendronic acid) – *Medical Billing Only*	risedronate DR
risedronate IR	
zoledronic acid – *Medical Billing Only*	

Prior Authorization Criteria

- Risedronate DR Only: See Preferred Dosage Form criteria

Calcitonins

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
calcitonin, salmon nasal spray++	calcitonin, salmon vial
MIACALCIN (calcitonin, salmon) VIAL++ – *Medical Billing Only*	

++ Clinically Non-Preferred: An FDA advisory panel concluded that the benefits of calcitonin do not outweigh its potential risks as an osteoporosis drug due to increased risk of malignancy. Bisphosphonates are more effective agents.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- The member must be experiencing pain from an acute osteoporotic fracture

Estrogen Agonist/Antagonist

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
raloxifene	EVISTA (raloxifene)

Monoclonal Antibodies

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
PROLIA (denosumab) – *Medical Billing Only*	

Anabolic Agents

Parathyroid Hormone (PTH)

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
FORTEO (teriparatide) – *Brand Required*	teriparatide

PTH-related protein

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	TYMLOS (abaloparatide)

Monoclonal Anti-sclerostin Antibody

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
EVENITY (romosozumab-aqqg) – *Medical Billing Only*	

Prior Authorization Criteria

Initial Criteria – Approval Duration: 2 years (1 year for Evenity)

- The member must have a current BMD T-score ≤ -2.5 OR new fracture (as evidenced by submitted documentation) after a 6-month trial of each of the following, as evidenced by paid claims or pharmacy printouts:
  - teriparatide
- Member must be at high risk of fracture, confirmed by documentation of at least one of the following:
  - The member with a history of hip or vertebral fracture
  - The member with a T-score of −2.5 or lower at the femoral neck or spine
  - The member has a T-score of between −1.0 and −2.5 at the femoral neck or spine and a ten-year hip fracture risk of ≥3% as assessed with the FRAX
  - 10-year risk of a major osteoporosis-related fracture of ≥20% as assessed with the FRAX

Substance Use

Nicotine / Tobacco Dependence Treatment

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
bupropion SR	CHANTIX (varenicline)
nicotine lozenge	NICODERM CQ (nicotine) PATCH
nicotine patch	NICORETTE (nicotine polacrilex) GUM
nicotine polarcrilex gum	ZYBAN (bupropion SR)
NICOTROL (nicotine polacrilex) SPRAY	
varenicline	

Concurrent Medication Required

- Short-acting nicotine agents (nasal spray, lozenge, and gum) require concurrent nicotine patch, bupropion SR (generic Zyban), or varenicline since better outcomes are associated with concurrent use of short-acting and long-acting tobacco cessation products.
  - A total of 14 days of nicotine patch, bupropion SR (generic Zyban), or varenicline must be paid within 40 days prior to nicotine nasal spray, lozenge, or gum's date of service.

Clinically Important Information: Bupropion SR (generic Zyban) takes 5 to 7 days to reach steady state. It is recommended to start one week before target quit date. NRT products are allowed in addition to bupropion SR to bridge therapy until bupropion SR becomes effective and for concurrent use.

Electronic Duration Verification

- A total of 12 consecutive weeks will be covered for all other products, every 6 months.

  Varenicline or bupropion SR (generic Zyban): If the following conditions apply, please call for an override by calling provider relations at 1-800-755-2604:
  - Patient is abstinent from tobacco.
  - Treatment duration is requested to be extended to 24 consecutive weeks.

Therapeutic Duplication

- Nicotine gum, lozenge, and spray will not be paid concurrently.
- Bupropion SR (generic Zyban) will not be paid with other forms of bupropion.

Underutilization

- Nicotine Patch, varenicline, and bupropion SR (generic Zyban) must be used adherently and will reject on point of sale for late fill.

Opioid Use Disorder

Alpha-2 Adrenergic Agonists

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
clonidine	lofexidine
guanfacine	LUCEMYRA (lofexidine) – *Brand Required*

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must have had a 30-day trial of each preferred agent, as evidenced by paid claims or pharmacy printouts.
- Clinical justification must be provided explaining why the member is unable to use the preferred agents (subject to clinical review).

Opioid Antagonist

PREFERRED AGENTS (NO PA REQUIRED)
naltrexone tablets
VIVITROL (naltrexone microspheres) INJECTION

Opioid Reversal Medications

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
KLOXXADO (naloxone) NASAL SPRAY	ZIMHI (naloxone) SYRINGE
nalmefene injection	
naloxone nasal spray	
naloxone injection	
NARCAN (naloxone) NASAL SPRAY – *Brand Co-Preferred*	

OPVEE (nalmefene) NASAL SPRAY	
REXTOVY (naloxone) NASAL SPRAY – *Brand Co-Preferred*	

Electronic Duration Verification

- 4 doses are covered every 60 days without an override.

If one of the following criteria are met (A or B), please request an override by calling provider relations at 1-800-755-2604 or emailing medicaidpharmacy@nd.gov:

A. The previous dose has expired.
B. The dose was used by member for an opioid overdose. (In this case, it is recommended to follow up with prescriber to discuss frequency of use and potential regimen review/adjustments)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must have had a 30-day trial of each preferred agent, as evidenced by paid claims or pharmacy printouts.
- Clinical justification must be provided explaining why the member is unable to use the preferred agents (subject to clinical review)

Opioid Partial Agonist

Electronic Step Therapy Required

- A total of 28 days of Sublocade 300 mg must be paid within 60 days prior to Sublocade 100 mg date of service.

Per Sublocade package insert:

Established Transmucosal Buprenorphine Doses	Injection #1	Injection #2	Maintenance Dose
8 – 18 mg/day	300 mg	100 mg*	100 mg
20 – 24 mg/day	300 mg	300 mg	100 mg
*For patients still experiencing craving or withdrawal symptoms after the initial 300-mg dose, consider giving 300 mg as the second dose			

Sublocade is not indicated when established transmucosal buprenorphine dose is under 8 mg/day. Brixadi has dosing recommendations when established transmucosal buprenorphine dose is under 8 mg/day.

Therapeutic Duplication

- One strength of one medication is allowed at a time.
- Opioid partial agonists are not allowed with:
  - **A.** methadone
  - **B.** carisoprodol
  - **C.** opioids

- Opioid full agonist requested with member with history of opioid use disorder.
  - If 1 and 2 are met, please call for an override by calling provider relations at 1-800-755-2604 (chart notes will be required for requests beyond one fill)
    1. The request is for one of the following:
       - A one-time fill request where pain cannot be reasonably treated with non-opioid therapy (e.g., surgery)

- A request exceeding a one-time fill and a treatment plan has been provided with expected duration of use and why non-opioid therapy is not an option (subject to clinical review) or a taper plan is provided.

2. One of the following is met:
   - Prescribers of both opioid prescription and MOUD (medications for opioid use disorder) are aware of each other and agree to opioid therapy.
   - MOUD has been discontinued, and the prescriber of the opioid is aware of previous MOUD treatment and confirms opioid therapy is required.

- Opioid partial agonist injection + oral overlap

  Please call for an override by calling provider relations at 1-800-755-2604 to request a 4 month overlap period with oral buprenorphine/naloxone while initiating long-acting injectable buprenorphine (until the therapeutic levels are achieved).

Mono Product

Oral Agents

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	buprenorphine tablets++

++ Clinically Non-Preferred: Naloxone is added to buprenorphine to prevent misuse. When taken correctly, a baby will have little to no absorption of naloxone which a growing body of evidence show is safe. Taking combination product during pregnancy or breastfeeding means that products don't need to be switched to a different medication after the baby is born during this high anxiety time. Risk of withdrawal to a neonate is a labeled warning on each product. Pregnancy and breastfeeding are not listed as contraindications on either product.

References:

1. Opioid use and opioid use disorder in pregnancy. Committee Opinion No. 711. American College of Obstetricians and Gynecologists. Obstet Gynecol 2017;130:e81–94.
2. Perry, Briana N. MD; Vais, Simone BA; Miller, Melissa BA; Saia, Kelley A. MD. Buprenorphine-Naloxone Versus Buprenorphine for Treatment of Opioid Use Disorder in Pregnancy [07E]. Obstetrics & Gynecology 135():p 51S, May 2020. | DOI: 10.1097/01.AOG.0000663444.50960.74
3. Substance Abuse and Mental Health Services Administration. Clinical Guidance for Treating Pregnant and Parenting Women With Opioid Use Disorder and Their Infants. HHS Publication No. (SMA) 18-5054. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2018.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 1 year

- Clinical justification must be provided explaining why the member is unable to use the preferred agents (subject to clinical review)
  - Allergy to oral naloxone is extremely rare and must be well documented.
  - Any request for transmucosal buprenorphine should include justification why long-acting injectable buprenorphine can't be used
    - Pregnancy or breastfeeding will not be approved as clinical justification based on the clinically non-preferred information provided above.
    - Stability will not be approved as clinical justification, although limited approval may be granted to allow for recommended pre-treatment and titration prior to initiation of long-acting buprenorphine product – maximum of 7 days for Sublocade, and 1 dose for Brixadi

Non-Oral Agents

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)

BRIXADI (buprenorphine)	
SUBLOCADE (buprenorphine)	

Combination Product

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
buprenorphine-naloxone tablets	BUNAVAIL FILM (buprenorphine/naloxone)
	buprenorphine/naloxone film
	SUBOXONE FILM (buprenorphine/naloxone)
	ZUBSOLV (buprenorphine/naloxone)

Prior Authorization Criteria

- See DAW (Dispense As Written) Criteria

Biosimilar Agents:

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The member must have failed a 90-day trial of each preferred medication.
- Clinical justification must be provided explaining why the member is unable to use the preferred agents (subject to clinical review).

Adalimumab

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ABRILADA (adalimumab-afzb)	adalimumab-aacf
adalimumab-adbm – labeler 00597	adalimumab-aaty
adalimumab-fkjp	adalimumab-adaz
CYLTEZO (adalimumab-abdm)	adalimumab-adbm – labeler 82009
HADLIMA (adalimumab-bwwd)	adalimumab-ryvk
HULIO (adalimumab-fkjp)	AMJEVITA (adalimumab-atto)
HUMIRA (adalimumab)	HYRIMOZ (adalimumab-adaz)
SIMLANDI (adalimumab-ryvk)	IDACIO (adalimumab-aacf)
YUSIMRY (adalimumab-aqvh)	YUFLYMA (adalimumab-aaty)

Bevacizumab

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
MVASI (bevacizumab – awwb) *– Medical Billing Only*	ALYMSYS (bevacizumab – maly) *– Medical Billing Only*
ZIRABEV (bevacizumab – bvzr) *– Medical Billing Only*	AVASTIN (bevacizumab) *– Medical Billing Only*
	VEGZELMA (bevacizumab – acdc) *– Medical Billing Only*

Filgrastim

Medical Billing

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
GRANIX (TBO-filgrastim) – *Medical Billing Only*	NEUPOGEN (filgrastim) – *Medical Billing Only*
NIVESTYM (filgrastim-aafi) – *Medical Billing Only*	RELEUKO (filgrastim-ayow) – *Medical Billing Only*
ZARXIO (filgrastim-sndz) – *Medical Billing Only*	

Pharmacy Billing

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
NEUPOGEN (filgrastim)	GRANIX (TBO-filgrastim)
RELEUKO (filgrastim-ayow)	NIVESTYM (filgrastim-aafi)
	ZARXIO (filgrastim-sndz)

Pegfilgrastim

Medical Billing

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
NEULASTA (pegfilgrastim) – *Medical Billing Only*	FULPHILA (pegfilgrastrim-jmdb) – *Medical Billing Only*
NEULASTA ONPRO (pegfilgrastim) – *Medical Billing Only*	FYLNETRA (pegfilgrastim -pbbk) – *Medical Billing Only*
NYVEPRIA (pegfilgrastrim–apgf) – *Medical Billing Only*	STIMUFEND (pegfilgrastim-fpgk) – *Medical Billing Only*
UDENYCA ONBODY (pegfligrastim-cbqv) – *Medical Billing Only*	UDENYCA (pegfligrastim-cbqv) – *Medical Billing Only*
	ZIEXTENZO (pegfilgrastim-bmez) – *Medical Billing Only*
Pharmacy Billing**PREFERRED AGENTS (NO PA REQUIRED)**	**NON-PREFERRED AGENTS (PA REQUIRED)**
FULPHILA (pegfilgrastrim-jmdb)	NEULASTA (pegfilgrastim)
FYLNETRA (pegfilgrastim -pbbk)	NYVEPRIA (pegfilgrastim–apgf)
NEULASTA ONPRO (pegfilgrastim)	STIMUFEND (pegfilgrastim-fpgk)
UDENYCA ONBODY (pegfligrastim-cbqv)	UDENYCA (pegfligrastim-cbqv)
	ZIEXTENZO (pegfilgrastim-bmez)

Infliximab

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AVSOLA (infliximab-axxq) – *Medical Billing Only*	infliximab – *Medical Billing Only*
INFLECTRA (infliximab-dyyb) – *Medical Billing Only*	RENFLEXIS (infliximab-abda) – *Medical Billing Only*
	REMICADE (infliximab) – *Medical Billing Only*

Rituximab

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
RIABNI (rituximab-arrx) – *Medical Billing Only*	RITUXAN (rituximab) – *Medical Billing Only*
RUXIENCE (rituximab-pvvr) – *Medical Billing Only*	
TRUXIMA (rituximab-abbs) – *Medical Billing Only*	

Tocilizumab

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
TYENNE (tocilizumab-aazg) AUTOINJECTOR, SYRINGE	ACTEMRA (tocilizumab) ACTPEN, SYRINGE
TYENNE (tocilizumab-aazg) VIAL – *Medical Billing Only*	ACTEMRA (tocilizumab) VIAL – *Medical Billing Only*
	TOFIDENCE (tocilizumab-aazg) VIAL – *Medical Billing Only*

Trastuzumab

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
KANJINTI (trastuzuamb – anns) – *Medical Billing Only*	OGIVRI (trastuzumab – dkst) – *Medical Billing Only*
TRAZIMERA (trastuzumab – qyyp) – *Medical Billing Only*	ONTRUZANT (trastuzumab – dttb) – *Medical Billing Only*
	HERZUMA (trastuzumab – pkrb) – *Medical Billing Only*
	HERCEPTIN (trastuzumab) – *Medical Billing Only*

Preferred Dosage Form Criteria List:

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The member must have failed a 30-day trial of each preferred medication.
- Clinical justification must be provided explaining why the member is unable to use the preferred agents (subject to clinical review).

Azathioprine

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
azathioprine 50 mg	azathioprine 75 mg
	azathioprine 100 mg

Brisdelle (paroxetine)

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
paroxetine tablets	paroxetine mesylate 7.5 mg capsules
	PEXEVA (paroxetine mesylate)

butalbital-acetaminophen-caffeine

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
butalbital-acetaminophen-caffeine tablets	butalbital-acetaminophen-caffeine capsules

VTOL LQ (butalbital-acetaminophen-caffeine) SOLUTION	ESGIC (butalbital-acetaminophen-caffeine) TABLET
	FIORICET (butalbital-acetaminophen-caffeine) CAPSULES
	ZEBUTAL (butalbital-acetaminophen-caffeine) CAPSULES

citalopram

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
citalopram tablets	citalopram capsules
citalopram solution	

colchicine

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
colchicine tablet	colchicine capsule
	GLOPERBA (colchicine) ORAL SOLUTION
	LODOCO (colchicine) TABLET
	MITIGARE (colchicine) CAPSULE

cyanocobalamin

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
cyanocobalamin injection	NASCOBAL (cyanocobalamin) NASAL SPRAY

epinephrine

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
epinephrine – labeler 49502	AUVI-Q (epinephrine)
EPIPEN (epinephrine) – *Brand Co-Preferred*	epinephrine – labeler 00093, 00115
EPIPEN (epinephrine) JUNIOR– *Brand Co-Preferred*	NEFFY (epinephrine)

Electronic Duration Verification

- 4 doses are covered every 60 days without an override

If one of the following criteria are met (A or B), please request an override by calling provider relations at 1-800-755-2604 or emailing medicaidpharmacy@nd.gov:

A. The previous dose has expired
B. The dose was used by member for an anaphylactic episode

gabapentin

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
gabapentin	gabapentin ER
	GRALISE (gabapentin)
	HORIZANT (gabapentin)

Jadenu (deferasirox)

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
deferasirox tablet for suspension	EXJADE (deferasirox tablet for suspension)
deferasirox tablets	deferasirox sprinkle
	JADENU (deferasirox) SPRINKLE
	JADENU (deferasirox) TABLETS

Kits

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
FDA approved products prescribed separately	CAMPHOTREX 4%-10% ROLL-ON G (menthol/camphor)
	CENTANY AT (mupirocin)
	CICLOPIROX (ciclopirox/urea/camphor/methol)
	CICLODAN (ciclopirox/urea/camphor/methol)
	CICLODAN (ciclopirox/skin cleanser 28)
	CLINDACIN ETZ (clindamycin phos/skin clnsr 19)
	CLINDACIN PAC (clindamycin phos/skin clnsr 19)
	CLINDAVIX (clindamycin/dimethacone/zinc oxide)
	CLOBETEX (clobetasol/desloratadine)
	CYCLOPAK (cyclobenzaprine/lidocaine/prilocaine/glycerine)
	DERMACINRX ARM PAK (lidocaine/dimethacone)
	DERMACINRX LEXITRAL PHARMAP (diclofenac/capsicum oleoresin)
	DERMACINRX PHN PAK (lidocaine/emollient cmb No. 102)
	DERMACINRX SILAPAK (triamcinolone/dimeth/silicone)
	DERMACINRX SILAZONE (triamcinolone/silicones)
	DERMACINRX SURGICAL PHARMAP (mupirocin/chlorhexidine/dimeth)
	DERMACINRX THERAZOLE PAK (clotrimazole/betameth dip/zinc)
	DERMACINRX ZRM PAK (lidocaine/dimethicone)
	DERMALID 5% PATCH (lidocaine/elastic bandage)
	ELLZIA PAK (triamcinolone/dimethicone)
	ESOMEP-EZS KIT (esomeprazole mag/glycerin)
	ECONASIL (econazole/gauze/silicone)
	FLUOPAR (fluocinonide/dimethacone)
	FLUOVIX PLUS (fluocinonide/silicone,adhesive)
	GABACAINE KIT (gabapentin/lidocaine)
	INAVIX (diclofenac/capsaicin)
	INFAMMACIN (diclofenac/capsicum)
	KETODAN (ketoconazole/skin cleanser 28)
	LIDOPURE PATCH 5% COMBO PAC (lidocaine/kinesiology tape)
	LIDOTIN (gabapentin/lidocaine/silicone)
	LIPRITIN (gabapentin/lidocaine/prilocaine/dressing)
	LOPROX (ciclopirox/skin cleanser No. 40)
	MIGRANOW KIT (sumatriptan/menthol/camphor)
	MORGIDOX (Doxycycline/skin cleanser No. 19)

	NAPROTIN (naproxen/capsicum)
	NOPIOID-TC KIT (cyclobenzaprine/lidocaine/menthaine)
	NUVAKAAN KIT (lidocaine/prilocaine/silicone)
	NUSURGEPAK (mupirocin/chlorhexidine/dimethacone)
	NUTRIARX (Triamcinolone/dimethacone/silicone)
	PRILO PATCH KIT (lidocaine/prilocaine)
	PRIZOTRAL II (lidocaine/prilocaine/lidocaine)
	PRO DNA MEDICATED COLLECTION (lidocaine/glycerin)
	REVIVASIL (gel pad/dmc/dime/dec/oct/vit E) KIT
	SALEX (salicylic acid/ceramide comb 1) CREAM KIT
	SALEX (salicylic acid/ceramide comb 1) LOTION KIT
	SILAZONE-II KIT (triamcinolone aceton/silicones)
	SOLARAVIX (Diclofenac/silicone, adhesive)
	SUMADAN KIT (sulfacetamide/sulfur/cleansr23)
	SUMAXIN CP KIT (sulfacetamide/sulfur/cleansr23)
	TICANASE KIT (fluticasone/sodium chloride/sodium bicarbonate)
	TRIVIX (Triamcinolone/dimethacone/silicone)
	TRIXYLITRAL (diclofenac/lidocaine/tape)
	XRYLIX 1.5% KIT (diclofenac/kinesiology tape)
	ZILACAINE PATCH 5% COMBO PA (lidocaine/silicone, adhesive)

lactulose

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
CONSTULOSE (lactulose) solution	KRISTALOSE (lactulose) PACKET
ENULOSE (lactulose) solution	lactulose packet
lactulose solution	

metformin

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
metformin ER	FORTAMET (metformin)
RIOMET (metformin) ORAL SOLUTION	GLUMETZA (metformin)
RIOMET ER (metformin) ORAL SOLUTION	metformin ER gastric retention 24 hr
	metformin ER osmotic

methotrexate

Required trial duration: 6 weeks

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
methotrexate	OTREXUP (methotrexate) AUTO-INJECTOR
JYLAMVO (methotrexate) SOLUTION	RASUVO (methotrexate) AUTO-INJECTOR
XATMEP (methotrexate) SOLUTION	REDITREX (methotrexate) SYRINGE
	TREXALL (methotrexate) TABLET

mycophenolate mofetil

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)

mycophenolate mofetil	CELLCEPT (mycophenolate mofetil)
	MYHIBBIN (mycophenolate mofetil)

montelukast

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
montelukast chewable tablets	montelukast granules
montelukast tablets	

Electronic Age Verification

- Montelukast granules are preferred for ages 1 and under

mupirocin

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
mupirocin ointment	mupirocin calcium cream

nitisinone

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ORFADIN (nitisinone) 2 MG, 5 MG, 10 MG CAPSULE	NITYR (nitisinone) TABLET
ORFADIN (nitisinone) SUSPENSION	ORFADIN (nitisinone) 20 MG CAPSULE

nitroglycerin

Required trial duration: 1 dose while on preventative medication

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
nitroglycerin sublingual tablets	GONITRO (nitroglycerin) SUBLINGUAL PACKET
	nitroglycerin spray
	NITROLINGUAL (nitroglycerin) SPRAY

Nocdurna (desmopressin)

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
desmopressin	NOCDURNA (desmopressin)

Pregabalin

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
pregabalin	LYRICA (pregabalin)
	LYRICA CR (pregabalin)
	pregabalin ER

Procysbi (cysteamine)

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
CYSTAGON (cysteamine)	PROCYSBI (cysteamine)
	PROCYSBI GRANULES (cysteamine)

Steroids – Oral

Agamree and Emflaza: See Duchenne Muscular Dystrophy Criteria on this document

Tarpeyo: See Tarpeyo Criteria on this document

Rayos required trial duration: 12 weeks with 2 AM dosing of prednisone

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
budesonide 3 mg EC capsules	AGAMREE (vamorolone)
cortisone	ALKINDI (hydrocortisone) SPRINKLE CAPSULE
dexamethasone	budesonide 9 mg ER tablet
EOHILIA (budesonide)	deflazacort
hydrocortisone	EMFLAZA (deflazacort) – *Brand Required*
methylprednisone	HEMADY (dexamethasone)
prednisolone sodium phosphate 5 mg/5 ml, 15 mg/5 ml, 25 mg/5 ml	MILLIPRED (prednisolone)
prednisone solution	ORTIKOS (budesonide)
prednisone tablets	prednisone intensol
	prednisolone sodium phosphate ODT
	prednisolone sodium phosphate 10 mg/5 ml, 20 mg/5 ml solution
	RAYOS (prednisone)
	TAPERDEX (dexamethasone)
	UCERIS (budesonide)

ursodiol

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ursodiol capsule	RELTONE (ursodiol) CAPSULE
ursodiol tablet	URSO 250 (ursodiol) TABLET
	URSO FORTE (ursodiol) TABLET

Preferred Diabetic Supply List (PDSL)

Electronic Concurrent Medications Required

- One of the following must apply:
  - A total of a 25-day supply of one of the following must be paid within 150 days prior to diabetic supplies' date of service:
    - agents that cause hypoglycemia (insulin or sulfonylureas)
    - agents that indicate pregnancy (folic acid or prenatal vitamins)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- For coverage of blood glucose monitoring devices for those not meeting electronic concurrent medication required criteria above, the member has one of the following (A or B):
  A. Recurrent hypoglycemia and the test strips are prescribed by or in consult with, a medical geneticist or an endocrinology specialist (subject to clinical review)
  B. A diagnosis of diabetes and meet **one of the following** criteria:
     1. Newly diagnosed within the last 6 months
     2. Acutely ill
     3. Significant change in health status causing blood sugar variability
     4. Currently pregnant

The ADA guidelines point out the lack of clinical utility and cost-effectiveness of routine Self-Monitoring of Blood Glucose (SMBG) in non-insulin treated members. Both the Society of General Internal Medicine and the Endocrine Society recommend against routine SMBG for type 2 diabetes members not on insulin or agents that cause hypoglycemia.

Test Strips

Quantity Limits

- 200 test strips are covered every 30 days

Manufacturer Name	NDC	Product Description
Roche Diabetes Care, Inc.	65702-0711-10	Accu-Chek Guide Test Strip
Roche Diabetes Care, Inc.	65702-0712-10	Accu-Chek Guide Test Strip

Meters

Quantity Limits

- 1 meter is covered every 365 days

Manufacturer Name	NDC	Product Description
Roche Diabetes Care, Inc.	65702-0731-10	Accu-Chek Guide Me Glucose Meter
Roche Diabetes Care, Inc.	65702-0729-10	Accu-Chek Guide Monitor System

InPen

Quantity Limits

- 1 InPen is covered every 365 days

Manufacturer Name	NDC	Product Description
Minimed Distribution Corporation	62088-0000-31	InPen Smart Insulin Pen (Humalog - Blue)
Minimed Distribution Corporation	62088-0000-32	InPen Smart Insulin Pen (Humalog - Grey)
Minimed Distribution Corporation	62088-0000-33	InPen Smart Insulin Pen (Humalog - Pink)
Minimed Distribution Corporation	62088-0000-34	InPen Smart Insulin Pen (Novolog or Fiasp – Blue)
Minimed Distribution Corporation	62088-0000-35	InPen Smart Insulin Pen (Novolog or Fiasp – Gray)
Minimed Distribution Corporation	62088-0000-36	InPen Smart Insulin Pen (Novolog or Fiasp – Pink)
Minimed Distribution Corporation	63000-0827-15	InPen Smart Insulin Pen (Humalog - Blue)
Minimed Distribution Corporation	63000-0827-16	InPen Smart Insulin Pen (Humalog - Grey)
Minimed Distribution Corporation	63000-0827-17	InPen Smart Insulin Pen (Humalog - Pink)
Minimed Distribution Corporation	63000-0827-18	InPen Smart Insulin Pen (Novolog or Fiasp – Blue)
Minimed Distribution Corporation	63000-0827-19	InPen Smart Insulin Pen (Novolog or Fiasp – Gray)
Minimed Distribution Corporation	63000-0827-20	InPen Smart Insulin Pen (Novolog or Fiasp – Pink)

Pen Needles

Manufacturer Name	NDC	Product Description
Becton Dickinson & Company	08290-3207-49	Ultra-Fine Micro Pen Needle
Becton Dickinson & Company	08290-3201-19	Ultra-Fine Mini Pen Needle
Becton Dickinson & Company	08290-3201-22	Ultra-Fine Nano Pen Needle
Becton Dickinson & Company	08290-3282-03	Ultra-Fine Original Pen Needle
Becton Dickinson & Company	08290-3201-09	Ultra-Fine Short Pen Needle
Owen Mumford USA, Inc.	08470-3429-01	Pentips
Owen Mumford USA, Inc.	08470-3430-01	Pentips
Owen Mumford USA, Inc.	08470-3440-01	Pentips
Owen Mumford USA, Inc.	08470-3450-01	Pentips
Owen Mumford USA, Inc.	08470-3490-01	Pentips
Owen Mumford USA, Inc.	08470-3495-01	Pentips
Owen Mumford USA, Inc.	08470-3529-01	Unifine Pentips
Owen Mumford USA, Inc.	08470-3530-01	Unifine Pentips
Owen Mumford USA, Inc.	08470-3540-01	Unifine Pentips
Owen Mumford USA, Inc.	08470-3550-01	Unifine Pentips
Owen Mumford USA, Inc.	08470-3560-01	Unifine Pentips
Owen Mumford USA, Inc.	08470-3590-01	Unifine Pentips
Owen Mumford USA, Inc.	08470-3595-01	Unifine Pentips
Owen Mumford USA, Inc.	08470-3829-01	Unifine Pentips Plus
Owen Mumford USA, Inc.	08470-3830-01	Unifine Pentips Plus
Owen Mumford USA, Inc.	08470-3840-01	Unifine Pentips Plus
Owen Mumford USA, Inc.	08470-3850-01	Unifine Pentips Plus
Owen Mumford USA, Inc.	08470-3860-01	Unifine Pentips Plus

Owen Mumford USA, Inc.	08470-3890-01	Unifine Pentips Plus
Owen Mumford USA, Inc.	08470-7935-01	Unifine Safecontrol
Owen Mumford USA, Inc.	08470-7930-01	Unifine Safecontrol
Owen Mumford USA, Inc.	08470-7940-01	Unifine Safecontrol
Owen Mumford USA, Inc.	08470-7950-01	Unifine Safecontrol
Owen Mumford USA, Inc.	08470-7955-01	Unifine Safecontrol
Owen Mumford USA, Inc.	08470-7990-01	Unifine Safecontrol

Syringes

Manufacturer Name	NDC	Product Description
Becton Dickinson & Company	08290-3284-11	BD syringe and needle,insulin,1mL
Becton Dickinson & Company	08290-3284-18	BD syringe and needle,insulin,1mL
Becton Dickinson & Company	08290-3284-31	BD syring-needl,disp,insul,0.3 mL
Becton Dickinson & Company	08290-3284-38	BD syring-needl,disp,insul,0.3 mL
Becton Dickinson & Company	08290-3284-40	BD syrge-ndl,ins 0.3 mL half mark
Becton Dickinson & Company	08290-3284-66	BD syringe-needle,insulin,0.5 mL
Becton Dickinson & Company	08290-3284-68	BD syringe-needle,insulin,0.5 mL
Becton Dickinson & Company	08290-3267-30	BD syringe,insul U-500,ndl,0.5mL
Becton Dickinson & Company	08290-3249-09	BD syring-needl,disp,insul,0.3 mL
Becton Dickinson & Company	08290-3249-10	BD syringe-ndl,ins 0.3 mL half mark
Becton Dickinson & Company	08290-3249-11	BD syringe-needle,insulin,0.5 mL
Becton Dickinson & Company	08290-3249-12	BD syringe and needle,insulin,1mL

Ketone Strips

Quantity Limits

- 120 strips per 30 days

Manufacturer Name	NDC	Product Description
Trivida Health, Inc.	56151-0601-01	Ketone Test Strip
Trivida Health, Inc.	56151-0601-50	Ketone Test Strip

Continuous Glucose Monitors (CGM)

Preferred CGM

Quantity Limits

- NDC 08627005303- Dexcom G6 Sensor: 3 ten-day sensors/box= up to qty 9/90-day supply
- NDC 08627001601- Dexcom G6 Transmitter: 1= 90-day supply (4 transmitters/365 days allowed)
- NDC 08627009011- Dexcom G6 Receiver: 1= 250-day supply (1 receiver/365 days allowed)
- NDC 08627007701- Dexcom G7 Sensor: 1 ten-day sensor/box= up to qty 9/90-day supply
- NDC 08627007801- Dexcom G7 Receiver: 1= 250-day supply (1 receiver/365 days allowed)

Manufacturer Name	NDC	Product Description
Dexcom, Inc.	08627-0016-01	Dexcom G6 Transmitter

Dexcom, Inc.	08627-0053-03	Dexcom G6 Sensor
Dexcom, Inc.	08627-0091-11	Dexcom G6 Receiver
Dexcom, Inc.	08627-0077-01	Dexcom G7 Sensor
Dexcom, Inc.	08627-0078-01	Dexcom G7 Receiver

Non-Preferred CGM

A coverage exception will be considered for members that has had a Medtronic Insulin pump for over a year or have had a Medtronic Insulin pump purchased by another payer prior to eligibility for ND Medicaid to allow for CGM integration with their insulin pumps. Please submit supporting information for the coverage of a Guardian CGM along with prior authorization information to meet the requirements as outlined in criteria below.

If the Medtronic Insulin pump is older than 4 years, the authorization period will be shortened to verify that the pump is still functioning for re-authorization. If the Medtronic Insulin pump fails, the expectation is to switch to an insulin pump that is compatible with a preferred CGM.

- Guardian Sensor 3: max of 15 sensors (3 boxes) per 90-day supply
- Guardian Link Transmitter 3: max of 1 per 365-day supply
- Guardian Sensor 4: max of 15 sensors (3 boxes) per 90-day supply
- Guardian Link Transmitter 4: max of 1 per 365-day supply

Guardian Sensor 4 is preferred since no calibration is required. Clinical justification for use of Guardian Sensor 3 must be submitted (subject to clinical review).
Calibrating your Sensor - MiniMed™ 780G System Support | Medtronic (medtronicdiabetes.com)

Please contact Medtronic for replacement sensor and transmitters:
Sensor and Transmitter Support - Product Support | Medtronic (medtronicdiabetes.com)

Concurrent Medication Required

- Please submit PA for sensor, if PA is approved, **please bill sensors first** followed by the transmitter or receiver. If the transmitter or receiver is billed first, a "prior authorization required" rejection will occur even if a sensor PA has already been approved.

Prior Authorization Criteria

Continuous Glucose Monitor (CGM) Prior Authorization Form

Initial Criteria – Approval Duration: 12 months (Until due date or 6 months, if unknown, for gestational diabetes)

- The member must meet **one of the following** criteria (1 or 2):
  1. The member has diabetes (e.g., type 1, type 2, gestational diabetes)
  2. The member has recurrent hypoglycemia and CGM is prescribed by or in consult with, a medical geneticist or an endocrinology specialist.
- The member must not have life expectancy of less than 12 months.
- The member must not reside in a skilled nursing facility.
- Member with Type 1 or Type 2 Diabetes (not applicable if pregnant) must meet **both of the following** (1 and 2):
  1. The most recent A1c must be provided.
  2. **Both the following** must be agreed to by attestation:
     - The member will maintain regular provider visits to review glycemic control every 3-6 months.
     - CGM data will be reviewed to adjust/modify medication regimen and improve outcomes and not solely for hypoglycemia alerts.
- Members with Type 2 Diabetes (not applicable if pregnant) must meet **one of the following** criteria (1, 2, or 3):

A. The member has been on short-acting and long-acting insulin for at least 6 months, as evidenced by refill history with paid claims or pharmacy printouts.
B. The member is currently Humulin R U-500 or an insulin pump.
C. The member was unable to achieve goal (A1c < 7% or TIR > 70%) despite triple combination therapy consisting of long-acting insulin dose of at least 10 units per day combined with two other non-insulin antihyperglycemic agents (oral or injectable), at the maximum tolerated dose with good adherence at least 3 months, as evidenced by refill history with paid claims or pharmacy printouts.

Renewal Criteria – Approval Duration: 12 months
For diagnosis of diabetes (not applicable when pregnant):

- The most recent A1c or TIR must be submitted.
- One of the following must be met:
  - *Approval 12 months*:
    A1c and/or TIR must progress toward or be within goal (A1c < 7% or TIR > 70%) from last approval:
  - *Approval 6 months:*
    A1c and/or TIR is outside of goal and has worsened (worsened is defined as > 0.5% increase of A1c or 5% decrease in TIR) from last approval.
    One of the following must be met:
    - A member has been referred to diabetic educator or diabetic specialist for treatment plan.
    - CGM data must have been reviewed to evaluate/adjust therapy and develop a treatment plan as provided in submitted documentation.

Test Strip Requests after CGM approval

For replacement inquiries, sensor overpatches, and troubleshooting please contact Dexcom Global Technical Support at 1-844-607-8398 or visit https://www.dexcom.com/contact

- ND Medicaid will cover 200 test strips per year to facilitate instances where CGM is not displaying blood sugar readings that correspond with the symptoms member is experiencing or that are consistently outside of the 20 rule: Is my Dexcom sensor accurate?

Prior Authorization Criteria

- The following criteria will apply if CGM has previously been paid, but will no longer be used and regular test strip quantities are requested:
  - The member must be seen for education by a diabetic specialist or educator
  - Documentation must be submitted noting what caused the CGM failure and education / mitigation efforts that have been taken to prevent the failure, including the following as applicable:
    - Stickiness: Skin adhesive and / or overpatches have been trialed without success
    - Sensor not working: at least 2 sensor replacements have been trialed
    - Sensitive Skin: How can I avoid irritated or sensitive skin caused by the sensor adhesive?

CGM Supplies Coverage FAQ

Does ND Medicaid cover Dexcom daily calibration?

- No, the unique Dexcom sensor code must be entered that is printed on each sensor's adhesive label during the startup period, so finger sticks and calibration are not required.
- Does the Dexcom G6 Continuous Glucose Monitoring (CGM) System require calibrations?
- Can I calibrate Dexcom G7? | Dexcom

Will test strips be covered in addition to Dexcom?

- Yes, ND Medicaid will cover 200 test strips per year to facilitate instances where Dexcom is not displaying blood sugar readings that correspond with the symptoms member is experiencing or that are consistently outside of the 20 rule.
- Is my Dexcom sensor accurate?

Does ND Medicaid cover additional sensors, transmitters, or receivers if mine is faulty or broken?

- For replacement inquiries, sensor overpatches, and troubleshooting please contact Dexcom Global Technical Support at 1-844-607-8398 or visit https://www.dexcom.com/contact

If my patient is currently on a CGM that is not Dexcom, is there a grandfathering period?

- No, the member should be converted to Dexcom billed on the pharmacy side to obtain ND Medicaid coverage. Exceptions will be considered for members that already have a Medtronic insulin pump for over a year or has had a Medtronic Insulin pump purchased by another payer prior to eligibility for ND Medicaid to allow for CGM integration.

Does ND Medicaid cover Dexcom G6 for members in Long Term Care facilities?

- If a member has Medicare Part B, Medicare Part B will need to be billed primary and ND Medicaid may cover the remainder as a crossover claim with medical billing.
- If a member does not have Medicare Part B, an override will need to be obtained for coverage.
- In all cases, the member must meet prior authorization criteria for coverage.

How is CGM billed for Medicaid Expansion members?

- CGM will need to be billed to ND Medicaid for Medicaid Expansion members.

How is CGM billed for Special Health Services (SHS) members eligible for ND Medicaid?

- Members receiving CGM other than Dexcom will need to work with SHS for CGM coverage. Exceptions will be considered for members that already have a Medtronic insulin pump to allow for CGM integration.

Billing FAQ

If I bill Medtronics Guardian sensors under the code A9276 on the medical benefit, will this be covered?

- No, the code will only be covered for members with primary insurance plans that require CGM to be billed on the medical side. Members will need to be converted to Dexcom billed on the pharmacy side to obtain ND Medicaid coverage. Exceptions will be considered for members that have had a Medtronic insulin pump for over a year or has had a Medtronic Insulin pump purchased by another payer prior to eligibility for ND Medicaid or to allow for CGM integration. Medtronic CGM must be billed on the pharmacy side.

Will ND Medicaid cover Dexcom through medical billing?

- ND Medicaid requires Dexcom to be billed through pharmacy NCPDP D.0 billing.
- Exceptions may be made for cases where primary insurance requires Dexcom to be billed with medical billing.

Other Insurance FAQ

If primary insurance only covers CGM other than Dexcom, will ND Medicaid pay the copay?

- If primary insurance excludes coverage of a Dexcom, ND Medicaid may make an exception to cover a non-covered CGM if the copay is nominal. Documentation of the exclusion must be submitted with the prior authorization request.
- If primary insurance does cover Dexcom, the member will need to switch to Dexcom for ND Medicaid to pay the copay.

Does ND Medicaid cover Dexcom if member has primary insurance, but it does not cover CGM?

- ND Medicaid may cover Dexcom as a primary payer if CGM is wholly excluded from the primary insurance benefit. Documentation stating the exclusion from the primary insurance must be submitted with the prior authorization request.
- ND Medicaid will not cover CGM as a primary payer if a prior authorization is denied for medical necessity by the primary insurance.

Will ND Medicaid cover Dexcom if member meets primary insurance prior authorization criteria, but does not meet ND Medicaid prior authorization criteria?

- ND Medicaid will not cover Dexcom if ND Medicaid prior authorization criteria is not met, regardless of approval status with primary insurance. Under rare circumstances, exceptions may be made if the copay is nominal as long as the member maintains primary insurance coverage with a Dexcom benefit.

Tubeless Insulin Pumps

Quantity limits:

- NDC 08508200005 - Omnipod DASH Refill Pods – 10 pods per 30-day supply
- NDC 08508300001 - Omnipod 5 Intro Kit – 1 per 30-day supply (payable 1 per 365 days)
- NDC 08508300021 - Omnipod 5 Refill Pods – 10 pods per 30-day supply
- NDC 08508300053 - Omnipod 5 G6-G7 Pods (Gen 5) - 10 pods per 30-day supply
- NDC 08508300050 - Omnipod 5 G6-G7 Intro Kit - 1 per 30-day supply (payable 1 per 365 days)
- NDC 08508300088 - Omnipod 5 Intro G6 for Libre 2 – 1 per 30-day supply (payable 1 per 365 days)
- NDC 08508300042 - Omnipod 5 G6 Refill Pods for Libre 2 – 10 pods per 30-day supply

Requests for greater than 10 pods per 30 days must include clinical justification vs using a tubed pump. If requested quantity exceeds 15 pods per 30 days, request will be denied for Omnipod. Member may still be eligible for tubed pump (requires separate medical prior authorization).

Manufacturer Name	NDC	Product Description
Insulet, Inc.	08508-2000-05	Omnipod DASH Refill Pods
Insulet, Inc.	08508-3000-01	Omnipod 5 Intro Kit
Insulet, Inc.	08508-3000-21	Omnipod 5 Refill Pods
Insulet, Inc.	08508-3000-53	Omnipod 5 G7 Pack Pods
Insulet, Inc.	08508-3000-50	Omnipod 5 G7 Intro Kit
Insulet, Inc.	08508-3000-42	Omnipod 5 FSL2 Plus G6 Pods
Insulet, Inc.	08508-3000-88	Omnipod 5 FSL2 Plus G6 Intro Kits

Prior Authorization Criteria

Tubeless Insulin Pump (Omnipod) Prior Authorization Form

Initial Criteria – Approval Duration: 12 months

- The requested medication must be prescribed by, or in consult with, an endocrinologist, diabetic educator, or prescriber specializing in the treatment of diabetes or prescriber must attest to all of the following:
  A. The member will maintain regular provider visits to review glycemic control data every 3-6 months.
  B. The member will receive Omnipod training from Omnipod System Trainer or a healthcare provider.
- The member has not received a tubed insulin pump within the past 4 years or must be experiencing elevated glucose levels from disconnecting due to contact or swimming sports.
- The member must be using a compatible rapid-acting insulin.
- The member must have one of the following (A, B, or C):
  A. Diabetes type 1 or type 2
  B. Diabetes due to pancreatectomy
  C. Diabetes due to an auto-immune beta cell destruction requiring insulin therapy with a long-acting and short-acting insulin for the past 6 months, as evidenced by paid claims or pharmacy print outs.
- Members with Type 2 Diabetes must meet **one of the following** criteria (1 or 2):
  A. The member has been on short-acting and long-acting insulin for at least 6 months, as evidenced by refill history with paid claims or pharmacy printouts.
  B. The member is currently Humulin R U-500 or an insulin pump.
- Requests for greater than 10 pods per 30 days must include clinical justification vs using a tubed pump. If requested quantity exceeds 15 pods per 30 days, request will be denied for Omnipod. Member may still be eligible for tubed pump (requires separate medical prior authorization).

Omnipod Coverage FAQ

For replacement inquiries or troubleshooting please contact Insulet Customer Care team at 1-800-591-3455 or visit https://na.myomnipod.com/contact.

Does ND Medicaid cover insulin pens, syringes, or vials if Omnipod is discontinued?

- Transition should be coordinated with diabetic specialist or educator.
- Current vials of rapid acting insulin should be exhausted before switching to pens. See Insulin category for a list of preferred products.
- Current supply of pods should be exhausted prior to switching to injections.

Does ND Medicaid cover additional pods or Personal Diabetes Manager (PDM) if mine is faulty or broken?

- For replacement inquiries or troubleshooting please contact Insulet Customer Care team at 1-800-591-3455 or visit https://na.myomnipod.com/contact.

Does ND Medicaid cover additional pods, Personal Diabetes Manager (PDM), replacement USB cords or rechargeable batteries if mine is lost or stolen?

- For replacement inquiries or troubleshooting please contact Insulet Customer Care team at 1-800-591-3455 or visit https://na.myomnipod.com/contact.
- PDMs, USB cords, and rechargeable batteries may be replaced once every 365 days.
- Pods are not replaceable.

Will ND Medicaid cover Omnipod through medical billing?

- ND Medicaid requires Omnipod to be billed through pharmacy NCPDP D.0 billing.

How is Omnipod billed for Medicaid Expansion and Special Health Services (SHS) ND Medicaid eligible members?

- Omnipod will need to be billed to ND Medicaid for Medicaid Expansion members.
- Omnipod will need to be billed to ND Medicaid for SHS members who are eligible for ND Medicaid

Does ND Medicaid cover Omnipod for members in Long Term Care facilities?

- If a member is eligible for Medicare, Medicare Part D will need to be billed primary.
- If member is not eligible for Medicare, the member must meet prior authorization criteria for coverage.

Does ND Medicaid cover Omnipod if member has primary insurance, but it does not cover tubeless pumps?

- ND Medicaid may cover Omnipod as a primary payer if insulin pumps are wholly excluded from the primary insurance benefit. Documentation stating the exclusion from the primary insurance must be submitted with the prior authorization request.
- ND Medicaid will not cover Omnipod as a primary payer if a prior authorization is denied for medical necessity by the primary insurance or primary insurance only covers tubed pumps.

Will ND Medicaid cover Omnipod if member meets primary insurance prior authorization criteria, but does not meet ND Medicaid prior authorization criteria?

- ND Medicaid will not cover Omnipod if ND Medicaid prior authorization criteria is not met, regardless of approval status with primary insurance. Under rare circumstances, exceptions may be made if the copay is nominal as long as the member maintains primary insurance coverage with a Omnipod benefit.

Appendix A: Concurrent Antipsychotics

Concurrent Oral Antipsychotic

Please use the Concurrent Antipsychotics PA form and attach appropriate documentation as necessary.

Cross-Tapering Plans ARE covered

Antipsychotic cross-taper plans are covered upon request. An expected plan and timeline must be included with the request.

Use of Multiple Antipsychotics MAY be covered

The use of two or more antipsychotics should be limited to cases where three trials of adequate dose and duration monotherapy have been failed including a trial of clozapine. Documentation of previous adequate trials with response should be well documented.

The use of one antipsychotic to target one symptom and another antipsychotic to target an additional symptom is not covered. A single antipsychotic can target multiple symptoms.

Oral Combination Therapy Criteria

Please use the Concurrent Antipsychotics PA form and attach appropriate documentation as necessary.

Approval: An authorization of oral combination therapy for 3 months

- One of the following must be met (1-3):
  1. The member is stabilized on regimen and is establishing care with the prescriber.
  2. The member has been discharged from a psychiatric hospital within the past month.
  3. Cross tapering from one oral antipsychotic to another.
  4. The prescriber must provide clinical justification (subject to clinical review)

Approval: An authorization of oral combination therapy for 12 months

- For the treatment of schizophrenia, member must meet one of the following:
  - The member has tolerated 2 monotherapy antipsychotic trials at a therapeutic dose and duration.
- For other indications:
  - The prescriber must provide clinical justification that all alternative antipsychotic active ingredient options have been trialed or ruled out as monotherapy for member (subject to clinical review).

Approval: An authorization of oral combination therapy for 2 years

- The member is using aripiprazole for hyperprolactinemia.
- The member has been stabilized on oral combination for over a year and has not had any psychiatric hospitalizations or breakthrough symptoms.
- The prescriber must provide clinical justification (subject to clinical review)

Special considerations

Aripiprazole

- Aripiprazole is supported in the compendia for use for treatment of drug-induced hyperprolactinemia, caused by antipsychotics. Therefore, upon request, aripiprazole is allowed in combination with other antipsychotics for the treatment of hyperprolactemia.

Clozapine

- Clozapine should be reserved for treatment resistant cases where two or more monotherapy trials have already failed. In cases of clozapine treatment resistance and augmentation is considered, note that aripiprazole has been shown to be the most effective antipsychotic in combination with clozapine. Combination therapy is allowed without approval.

Haloperidol

- Haloperidol may be covered for PRN use for acute agitation / violence prevention. Requests should include clinical rationale of use to prevent harm to self or others. PRN use means 10 doses or less per 30 days. More frequent use will only be considered to allow for maintenance medication adjustments to decrease agitation.

Olanzapine

- Olanzapine may be covered for PRN use for acute agitation / violence prevention. Requests should include clinical rationale of use to prevent harm to self or others. PRN use means 10 doses or less per 30 days. More frequent use will only be considered to allow for maintenance medication adjustments to decrease agitation.

Quetiapine

- Nighttime akathisia (e.g., nighttime dosing with risperidone) or daytime sedation (e.g., quetiapine ER dosed at nighttime) must prevent ability to titrate to effective dose with monotherapy.
- Other sleeping medications must be trialed. Primary use for insomnia will not be approved.

Long-Acting Injectable and Oral Combination

Please use the Concurrent Antipsychotics PA form and attach appropriate documentation as necessary.

Shortened interval requests are ***not covered*** as they are not supported in the FDA dosing recommendations or compendia.

Experiencing wearing off symptoms during the titration period (first 3 months of treatment) or first-time experiencing breakthrough symptoms:

Approval: A 3-month authorization of oral supplemental of the same active ingredient

- The medication requires oral overlap at initiation.
- The member has received a proper loading dose at initiation or recommended oral supplementation and is experiencing breakthrough symptoms.

Ongoing request (> 1 incident of breakthrough symptoms after titration):

Approval: An authorization of oral supplemental for 12 months

- A MedWatch form for the long-acting antipsychotic must be filled out and attached to request
- The dose must be optimized to maximum FDA approved dose for the LAI antipsychotic
    - A 3-month override of the same active ingredient may be considered for breakthrough symptoms while optimizing dose
- The member must have breakthrough symptoms for 2 or more injection cycles
- One of the following (1, 2, or 3) must be met if breakthrough symptoms are occurring earlier than 75% of recommended interval:
    1. The member must have had greater than a 20% reduction in symptoms with continued improvement
    2. The member must have had greater than a 50% reduction in symptoms
    3. One of the following must be met:
        - The member has had 2 monotherapy antipsychotic trials for an adequate duration
        - The prescriber must provide justification that all alternative active ingredient options have been trialed or ruled out as monotherapy for member (subject to clinical review)

Appendix B: Antidepressant Cross Tapering:

Selective Serotonin Reuptake Inhibitors (SSRIs) switched to:

Selective Serotonin Reuptake Inhibitors (SSRIs)

Cross Taper is NOT covered

Direct switch between SSRIs is typically well-tolerated as SSRIs overlap in their mechanism of action.

Serotonin Norepinephrine Reuptake Inhibitors (SNRIs)

Cross Taper is generally NOT covered, case by case coverage may be provided

Direct switch between SNRI and SSRI is typically well-tolerated because both SNRIs and SSRIs have strong serotonergic properties, with the following exceptions:

- Patient switching from high dose SSRIs, cross tapering may be of benefit
- Patient switching from fluoxetine or paroxetine to duloxetine or venlafaxine should start SNRI at a low dose. Fluoxetine and paroxetine inhibit the metabolization of duloxetine and venlafaxine.

Tricyclic Antidepressants

Cross Taper is covered

Cross tapering is recommended. Tricyclic antidepressants should be started at a low dose especially when discontinuing fluoxetine, fluvoxamine, and paroxetine. These SSRIs can inhibit the metabolism of tricyclic antidepressants resulting in higher levels of tricyclic antidepressants. Tricyclic antidepressants can be fatal in overdose. Most SSRIs will clear the system within 5 days, but fluoxetine will persist for up to 5 weeks.

Monoamine oxidase inhibitor (MAOIs)

Cross Taper is NOT covered

Cross tapering is not recommended and can result in serotonin syndrome or severe hypertensive crisis. A washout period of two weeks is recommended between last dose of SSRI and MAOI except in the case of fluoxetine, where a 5-week washout period is recommended.

Other Antidepressants

Cross Taper is covered

All other Antidepressants:

Cross Taper is covered

Appendix C: Prior Authorization Review Dates

Date	Category
12/04/2024	Stimulants for ADHD
09/04/2024	Molluscum Contagiosum
09/04/2024	Epidermolysis Bullosa
09/04/2024	Metabolic Dysfunction–Associated Steatohepatitis
06/05/2024	Acid Blockers
06/05/2024	Seborrheic Dermatitis
06/05/2024	Primary Hyperoxaluria Type 1
06/05/2024	Myasthenia Gravis
06/05/2024	Duchenne Muscular Dystrophy
06/05/2024	Paroxysmal Nocturnal Hemoglobinuria
12/06/2023	Diuretics
12/06/2023	Menopause
06/07/2023	Hyperparathyroidism
06/07/2023	Influenza
06/07/2023	Neuromyelitis Optica Spectrum Disorder
06/07/2023	Urea Cycle Agents
12/07/2022	Prurigo Nodularis
12/07/2022	Endometriosis Pain
12/07/2022	Hematopoietic Syndrome of Acute Radiation Syndrome (Nplate)
12/07/2022	Amyloidosis
12/07/2022	Amyotrophic Lateral Sclerosis (ALS)
12/07/2022	Chelating Agents
09/07/2022	Presbyopia
09/07/2022	Hypertrophic Cardiomyopathy
09/07/2022	Cushing’s Syndrome
09/07/2022	Vernal Keratoconjunctivitis
09/07/2022	Wilson’s Disease
06/01/2022	Familial Cholestasis Pruritis
03/02/2022	Chronic Kidney Disease
03/02/2022	Lupus
12/01/2021	Atopic Dermatitis/Eczema
12/01/2021	Non-Stimulants for ADHD
09/01/2021	Heart Failure
09/01/2021	Nasal Polyps
09/01/2021	Chronic Idiopathic Urticaria
09/01/2021	Uterine Fibroids
09/01/2021	Sedative/Hypnotics – Hetlioz
06/02/2021	Sickle Cell Disease
06/02/2021	Fabry Disease
06/02/2021	Imcivree
06/02/2021	Bowel preparation agents
03/03/2021	Evrysdi

03/03/2021	Hereditary angioedema
03/03/2021	Irritable bowel syndrome
12/02/2020	Agents for the treatment of diabetic gastroparesis
12/02/2020	Oriahnn
12/02/2020	Dojolvi
09/02/2020	Palforzia
09/02/2020	Mytesi
09/02/2020	Antifibrinolytic agents
09/02/2020	ACL inhibitors (Nexletol, Nexlizet)
09/02/2020	Cystic fibrosis agents
06/03/2020	Conjupri
03/04/2020	Glucagon agents
03/04/2020	Ofev for treatment of scleroderma with interstitial lung disease
12/04/2019	antifungal agents for aspergillus and candidiasis infections
12/04/2019	eosinophilic asthma agents
09/04/2019	short-acting opioid analgesic agents
09/04/2019	agents for the treatment of thrombocytopenia
09/04/2019	agents for the treatment of interstitial cystitis
09/04/2019	agents for the treatment of narcolepsy
06/05/2019	Sivextro
06/05/2019	Nuzyra
06/05/2019	agents for treatment of osteoporosis
06/05/2019	agents for treatment of hyperkalemia
06/05/2019	agents for treatment of Parkinson’s disease
04/09/2019	Orilissa
04/09/2019	agents for treatment of vaginal anti-infectives
04/09/2019	agents for treatment of glaucoma
04/09/2019	agents for treatment of dry eye syndrome
12/05/2018	glyburide and Avandia
12/05/2018	Lucemyra
12/05/2018	Palynziq
12/05/2018	Roxybond
12/05/2018	Siklos
09/05/2018	Daxbia
09/05/2018	Dermatophytosis (Tinea infections) agents
09/05/2018	Migraine prophylaxis
09/05/2018	Millipred DP
09/05/2018	Rytary
06/06/2018	Anzemet and Zuplenz
06/06/2018	biosimilar agents
06/06/2018	topical corticosteroid agents
06/06/2018	Dupixent
06/06/2018	Gocovri
06/06/2018	Tussicaps

03/07/2018	Skelaxin
03/07/2018	Eucrisa
09/06/2017	Proglycem
09/06/2017	Biltricide
03/01/2017	prednisolone ODT, Millepred, Veripred
03/01/2017	metformin OSM
03/01/2017	testosterone oral
12/07/2016	Namenda XR
12/07/2016	Dihydroergotamine
12/07/2016	Tetracycline
12/07/2016	Spiriva Respimat 2.5 mcg
12/07/2016	ophthalmic corticosteroids
12/07/2016	erythropoiesis-stimulating agents
09/07/2016	Kits
09/07/2016	dipeptidyl peptidase-4 (DPP-4) inhibitors
09/07/2016	Immunoglobulins
09/07/2016	topical agents used to treat plaque psoriasis
09/07/2016	platelet aggregation inhibitors
09/07/2016	Antihyperuricemics
06/01/2016	Glumetza
06/01/2016	naloxone rescue medications
06/01/2016	Naltrexone
06/01/2016	Edecrin
06/01/2016	interleukin-5 antagonist monoclonal antibodies
06/01/2016	Acitretin
06/01/2016	lice medications
06/01/2016	NK1 receptor antagonists
06/01/2016	Tirosint
03/02/2016	insulins
03/02/2016	steroid inhalers
03/02/2016	digestive enzymes
03/02/2016	nasal steroids
03/02/2016	otic anti-infectives
03/02/2016	ulcer anti-infectives
12/02/2015	Marinol
12/02/2015	skin pigment products
12/02/2015	inhaled corticosteroid/LABA combination products
12/02/2015	Movantik
12/02/2015	medications used to treat irritable bowel syndrome/OIC
12/02/2015	medications used to treat ulcerative colitis
12/02/2015	SGLT2 products
12/02/2015	immediate release oxycodone
12/02/2015	inhaled anti-infectives for cystic fibrosis
12/02/2015	leukotriene modifiers

09/02/2015	cholesterol lowering drugs
09/02/2015	injectable anticoagulants
09/02/2015	Akynzeo
09/02/2015	Nuvessa
09/02/2015	Cholbam
06/03/2015	Otezla
06/03/2015	Xtoro
06/03/2015	Hemangeol
06/03/2015	Lemtrada
06/03/2015	agents used to treat idiopathic pulmonary fibrosis
06/03/2015	GLP-1 receptor agonists
06/03/2015	topical therapies for onychomycosis
12/03/2014	testosterone products
12/03/2014	phosphate binders
12/03/2014	Zontivity
12/03/2014	Evzio
09/03/2014	Northera
09/03/2014	Oral Allergen Extracts
06/02/2014	Cathflo
06/02/2014	Intranasal Cyanocobalamin Products
06/02/2014	Luzu
06/02/2014	Noxafil
06/02/2014	Bethkis
03/03/2014	Statins
03/03/2014	Vecamyl
12/03/2013	Brisdelle
12/03/2013	Nitroglycerin Lingual Spray/Sublingual Tablets
12/03/2013	Agents Used to Treat COPD
12/03/2013	Epinephrine Auto-Injection Devices
12/03/2013	Pulmozyme
09/09/2013	Rayos
09/09/2013	Diclegis
09/09/2013	Sitavig
09/09/2013	Onmel
09/09/2013	Giazo
06/03/2013	Fulyzaq
06/03/2013	Xeljanz
03/11/2013	Genitourinary Smooth Muscle Relaxants
03/11/2013	Agents Used to Treat Multiple Sclerosis
12/03/2012	Actinic Keratosis
12/03/2012	Moxeza
09/17/2012	Kalydeco
09/17/2012	Kuvan
09/17/2012	Elaprase

06/04/2012	Lorzone
06/04/2012	Provigil
06/04/2012	Kapvay
06/04/2012	Dexpak/Zemapak
06/04/2012	Xifaxan
06/04/2012	Vanos
03/05/2012	Pulmonary Arterial Hypertension Agents
03/05/2012	Topical Acne Agents
03/05/2012	Benign Prostatic Hyperplasia Agents
03/05/2012	Juvisync/Combination Products
03/05/2012	Gralise
12/05/2011	Dificid
12/05/2011	New Oral Anticoagulants
12/05/2011	agents used to treat Hereditary Angioedema
09/12/2011	Asacol HD
09/12/2011	Ophthalmic Antihistamines
09/12/2011	Horizant
09/12/2011	Daliresp
09/12/2011	narcotics with high dose APAP
06/06/2011	Nuedexta
06/06/2011	Nexiclon
06/06/2011	Topical ketoconazole products
03/07/2011	Statins
03/07/2011	Gilenya
03/07/2011	Xyrem
12/06/2010	agents used to treat Hepatitis C
12/06/2010	ODT preparations
12/06/2010	Oravig
12/06/2010	Zyclara
12/06/2010	Clorpres
12/06/2010	Livalo
12/07/2009	Hemophilia
12/07/2009	Sancuso
12/07/2009	Relistor
12/07/2009	Nuvigil
12/07/2009	Nucynta
09/14/2009	Uloric
09/14/2009	Moxatag
09/14/2009	Targeted Immune Modulators
06/01/2009	Aczone
12/01/2008	Triptans
12/01/2008	Vusion
09/08/2008	Chantix
09/08/2008	Carisoprodol

02/04/2008	Ophthalmic Anti-infectives
08/20/2007	High-Cost Medications
08/20/2007	Ketek
08/20/2007	Xopenex
08/20/2007	Tekturna
08/20/2007	Synagis
08/20/2007	Amrix
06/04/2007	Qualaquin
12/11/2006	Exubera
12/11/2006	Solodyn and Oracea
12/11/2006	Oxycontin
11/13/2006	Generic medications
11/13/2006	Vigamox and Zymar
11/13/2006	Boniva
05/01/2006	Growth Hormone
05/01/2006	Sedative/Hypnotics Agents
02/13/2006	Actoplus met
11/07/2005	Revatio
08/08/2005	Zanaflex capsule
12/13/2004	ACE inhibitors
12/13/2004	ARBs
12/13/2004	Proton Pump Inhibitors
01/26/2004	COX-II and brand name NSAIDS
11/03/2003	Antihistamines
04/29/2002	Out of State Drugs
09/01/1999	Xenical

Appendix D: Harm Reduction Pathway

Harm Reduction Pathway Criteria:

The following criteria may be provided by a pharmacist (billed through the MTM program), a Syringe Service Program, or clinic-based E&M billed service (provided by a nurse or independent practitioner)

- Two visits are required prior to drug approval, a third visit during treatment is strongly recommended.

Persons who Inject Drugs (PWID):

ALL of the following must be provided/evaluated at the first, second, and third appointments:

- Referral to Syringe Service Program
- Access to and use of sterile syringes, needles, and injection equipment (may not be purchased using state funds including billing Medicaid per NDCC 23-01)
- Counseling on storage and disposal of injection equipment safe and legal manner
- Education and training on drug overdose response and treatment, including access and administration of overdose reversal medication.

- Education, referral, and linkage to human immunodeficiency virus, viral hepatitis, and sexually transmitted disease prevention, treatment, and care services
- Substance Use Disorder treatment information, and referrals to treatment programs as appropriate

Follow-up phone call (following first appointment) evaluating the implementation of the following:

- Use of sterile syringe, needle, and injection is implemented.
- Storage and disposal of injection equipment safe and legal manner

People with Alcohol Use Disorder:

ALL of the following must be provided/evaluated at the first, second, and third appointments:

- Education on the impact of alcohol to liver health (i.e., continued use can result in development of cirrhosis even in the absence of Hepatitis C)
- Counseling on how to reduce risk and severity of harmful consequences arising from severe alcohol intoxication (e.g., transportation services, condom use, avoiding fighting, drinking low alcohol beverages, padding furniture and stairs)
- Counseling on Safer-use Strategies: Alcohol
- Provide alcohol addiction treatment information and linkage to alcohol treatment programs as appropriate

Follow-up phone call (following first appointment) evaluating the implementation of the following:

- Safer-use and risk reduction strategies implemented.

References:

- Medical Pharmacy Billing Manual

Unfinished Business

Alternative RDUR Communication Tools:

- Provider and pharmacy online response form
- Faxing letters

New Business:

Second Review

Stimulants - Other State Criteria

MACPAC
Medicaid and CHIP Payment and Access Commission
Prior authorization can promote appropriate care when policies are based on clinical guidelines. For example, some FFS programs and MCOs apply prior authorization to pediatric attention-deficit/hyperactivity disorder (ADHD) medication prescribing (Center for Public Health Law Research (CPHLR) 2023a, 2023b). The American Academy of Pediatrics (AAP) clinical guidelines for medication treatment of ADHD vary by age. The AAP recommends behavioral interventions as the first-line treatment for most children age four to five, whereas medication can be included as a first-line treatment for children age 6 to 11 (Wolraich et al. 2019). As of April 2023, 34 Medicaid FFS programs applied prior authorization to ADHD medications prescribed to children under 18. Of these, 28 programs applied the prior authorization age restrictions to all medications (i.e., preferred and non-preferred medications). Of the 28 FFS programs with prior authorization requirements for some preferred ADHD medications, 15 programs applied the requirements only to children under age 6(CPHLR 2023a). A legal assessment found that some, but not all, state Medicaid prior authorization policies for ADHD medications analyzed were linked to AAP treatment guidelines (Hulkower et al. 2017)

Arizona
FFSPharmacyPAguidelineseffectiveNovember012024.pdf
1 - The requesting clinician has documented that the child has a diagnosis of attention deficit hyperactivity disorder (ADHD)
AND 2 - The requesting clinician has documented that psychosocial issues have been evaluated before request for ADHD medications
AND 3 - The requesting clinician has documented non-medication alternatives that have been attempted before request for ADHD medications
AND 4 - The requested dose does NOT exceed the Food and Drug Administration (FDA) recommended maximum daily dosage unless the provider has submitted clinical justification for the dose exceeding the FDA maximum

Florida
Long_Acting_Stimulant_Criteria.pdf
CLINICAL NOTES: According to the American Academy of Pediatrics Clinical Practice Guideline for the Evaluation and Treatment of Attention-Deficit/Hyperactivity Disorder (ADHD), evidence based parent and/or teacher administered behavior therapy is the first line of treatment for preschool age children who are 4 to 5 years of age. These guidelines go on to state that many young children with ADHD might still require medication to achieve maximum improvement, and medication is not contraindicated for children 4 through 5 years of age. There are limited clinical studies in this age group with most of the evidence based data surrounding the use of methylphenidate preparations.

INITIAL REVIEW CRITERIA:
1. Patient has had an adequate trial of parent training or teacher administered behavioral therapy and has persistent moderate to severe dysfunction as defined by:
    a. Symptoms that have persisted for at least 9 months
    b. Dysfunction that is manifested in both the home and other settings such as preschool or child care

Louisiana
Stimulants and Related agents
For non-preferred agents

• The child has a diagnosis approved for the medication requested (see POS Edits); AND
• ONE of the following (due to this diagnosis) is true and is stated on the request:
o Child has had a trial of behavioral therapy and has ongoing impairing and/or dangerous symptoms; OR
o Child has started behavioral therapy but has extremely impairing and/or potentially dangerous symptoms; OR
o Child has been referred to behavioral treatment but has extremely impairing and/or potentially dangerous symptoms that warrant treatment before therapy has had a chance to have an effect (with plan to follow up); OR
o There are no known behavioral therapy resources available to this child, who has extremely impairing and/or potentially dangerous symptoms; OR
o ALL of the following:
▪ The child is 6 years of age; AND
▪ The diagnosis for the requested medication is attention deficit hyperactivity disorder (ADHD); AND
▪ By submitting this request, the provider attests that behavioral treatment has been prescribed in addition to the requested medication; AND
• By submitting the authorization request, the prescriber attests to the following:
o Clinical monitoring parameters recommended in prescribing information are completed at baseline, every six months, and with dosage changes; AND
o The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; AND
o All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; AND
o The recipient has no concomitant drug therapies or disease states that limit the use of the requested medication and will not receive the requested medication with any other medication that is contraindicated or not recommended per FDA labeling;

Massachusetts
MassHealth PA Requirements for CNS Stimulants
Alpha2 Agonist or Cerebral Stimulant for members < three years of age:

- For all requests, individual drug PA criteria must be met first where applicable.
- Documentation of the following is required:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); or
    - member has a history of severe risk of harm to self or others; or
    - for an alpha2 agonist, member has a cardiovascular diagnosis only; or
  - all of the following:
    - appropriate diagnosis; and
    - prescriber is a specialist (e.g., psychiatrist, child adolescent psychiatrist [including psychiatric nurse practitioners], neurologist, pediatric neurologist, developmental and behavioral pediatrics) or consult is provided; and
    - treatment plan including names of current alpha2 agonist(s) and cerebral stimulant(s) and corresponding diagnoses; and
    - clinical rationale for use of alpha2 agonist or cerebral stimulant in member < three years of age; and
    - for requests for an amphetamine product, inadequate response (defined as > seven days of therapy), adverse reaction, or contraindication to a methylphenidate product.

Michigan
Michigan Medicaid Clinical and PDL Criteria
ADD / ADHD (PDL criteria apply):
• Under age 4: ADD / ADHD confirmed by a child and adolescent psychiatrist, developmental and behavioral

o MAPS has been reviewed and reconciled with prescribed drugs and any toxicology screening results
• Ages 4–5: ADD / ADHD confirmed by a comprehensive evaluation and/or standard assessment tool; AND
o MAPS has been reviewed and reconciled with prescribed drugs and any toxicology screening results
• Ages 6–17: No PA required

Missouri
ADHD Medication Prior Authorization Children Less than 6 Years Old | mydss.mo.gov
Pharmacy Clinical Edits and Preferred Drug Lists | mydss.mo.gov

- Documentation of the six signs and symptoms of ADHD elicited by the provider during assessment of the child
    - Per DSM 5, this should include six signs and symptoms of inattention OR six signs and symptoms of hyperactivity/impulsivity. If the child is diagnosed with the combined type of ADHD, then six signs and symptoms of inattention AND hyperactivity/impulsivity must be documented.•
    - An alternate form of documentation that is acceptable is acknowledgement in the provider's notes of agreement with the findings on the ADHD rating scales.
- The ADHD rating scales (e.g., Vanderbilt or Conners) completed by the child's parent/guardian and teacher. If there is no teacher, then a rating scale completed in another setting other than the home environment (such as daycare or pre-school) is required.

Nevada
Agents used for the treatment of ADHD

General Criteria (Children and Adults)
1. Only one agent at a time may be used for the treatment of ADHD (applies to the entire ADHD/Stimulant Class); a 30-day transitional overlap in therapy will allowed.
2. The following two criteria must be met and documented in the recipient's medical record for adult and pediatric recipients in order for Prior Approval of CNS Stimulants:
a. In the pediatric and adult population, the decision to medicate for Attention Deficit Disorder (ADD) or Attention Deficit Hyperactivity Disorder (ADHD) and any comorbidty based on problems that are persistent and sufficiently severe to cause functional impairment in one or more of the following social environments: at school, home, work or with peers, and
b. Before treatment with pharmacological methods is instituted, other treatable causes have been ruled out.

Children (up to age 18 years)
In addition to the general criteria, the following must be present and documented in the recipient's medical record for Prior Approval of CNS Stimulants:
1. An initial evaluation has been done by the treating physician, pediatrician, psychiatrist or neurologist documenting the developmental history, physical evaluation, medical history or neurological primary diagnosis (e.g. fetal alcohol syndrome, thyroid disease) and examination within the past twelve months, or more recently, if the clinical condition has changed, and
2. One of the following:
a. School information, Standardized Teachers Rating Scales testing reports such as TOVA (Test of Variables of Attention), achievement test, neuropsychological testing if indicated, Conner's scale, speech and language evaluation, or
b. DMS-IV (Diagnostic and Statistical Manual of Mental Disorders) symptoms of ADD or ADHD, presence or absence-child behavior checklist, development and context of symptoms and resulting impairment, including school, family and peers, DSM-IV symptoms of possible alternate or comorbid psychiatric diagnosis, history of psychiatric, psychological pediatric or neurological treatment for ADD or ADHD, or

c. Family history including diagnosis of ADD and ADHD, tic disorder, substance abuse disorder, conduct disorder, personality disorder and other anxiety disorder, past or present family stressors, crises, any abuse or neglect, interview with parents.

3. The following two criteria must be met and documented in the recipient's medical record for adult and pediatric recipients in order for Prior Approval of CNS Stimulants:

a. In the pediatric and adult population, the decision to medicate for Attention Deficit Disorder (ADD) or Attention Deficit Hyperactivity Disorder (ADHD) and any comorbidity is based on problems that are persistent and sufficiently severe to cause functional impairment in one or more of the following social environments: at school, home, work or with peers, and

b. Before treatment with pharmacological methods is instituted, other treatable causes have been ruled out.

Oklahoma

CNS/Behavioral Health: ADHD and Narcolepsy

- Prior Authorization is required for all tiers for members greater than 20 years of age and for members 0-4 years of age. All prior authorization requests for members under the age of 5 years must be reviewed by an OHCA contracted psychiatrist.

Utah

ADHD Stimulants.pdf

Less than 4 Years of Age or less than 6 years for Adzenys ER, Dyanavel XR, Desoxyn, Adhansia, Jornay PM, Cotempla XR)

- Diagnosis made by or in consultation with children psychiatrist or mental health specialist who is qualified in the diagnosis and treatment of neuropsychiatric disease (certified, licensed scope of practice, etc.) with prescribing authority.
- Appropriate clinical rationale for ADHD stimulant use under Medicaid age limit

Washington

ADHD-age-dose.pdf

https://www.hca.wa.gov/billers-providers-partners/program-information-providers/apple-health-second-opinion-program

Second opinion required for 0-4 years of age.

Virginia

Virginia Medicaid Service Authorization Form: Stimulants/ADHD Medications for Children Less Than FDA Indicated Age and Adults Over 18

*For patients ≤ 4 years old, prescriber must be a pediatric psychiatrist, pediatric neurologist, developmental/behavioral pediatrician, or in consultation with one of these specialists.

Stimulants – ND Proposed Criteria

Amphetamines

Solid Dosage Forms

Extended Release

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
dextroamphetamine/amphetamine ER (generic Adderall XR)	ADDERALL XR (dextroamphetamine/amphetamine)
dextroamphetamine ER	DEXEDRINE SPANSULE ER (dextroamphetamine)
lisdexamfetamine	dextroamphetamine/amphetamine ER

	(generic Mydayis ER
	DYANAVEL XR (amphetamine)
	MYDAYIS ER (dextroamphetamine/amphetamine)
	VYVANSE (lisdexamfetamine)

Immediate Release

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
amphetamine	ADDERALL (dextroamphetamine/amphetamine)
dextroamphetamine 2.5 mg, 5 mg, 10 mg	dextroamphetamine 7.5 mg, 15 mg, 20 mg, 30 mg
dextroamphetamine/amphetamine	EVEKEO (amphetamine)
	methamphetamine
	ZENZEDI (dextroamphetamine)

Non-Solid Dosage Forms

Extended Release

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
DYANAVEL XR (amphetamine) SUSPENSION	ADZENYS XR – ODT (amphetamine)
lisdexamfetamine chew	amphetamine ER suspension
	VYVANSE (lisdexamfetamine) CHEW TABLET
	XELSTRYM (dextroamphetamine) PATCH

Immediate Release

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
dextroamphetamine 5 mg/5 ml	PROCENTRA (dextroamphetamine) SOLUTION

Methylphenidate

Solid Dosage Forms

Extended Release

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
FOCALIN XR (dexmethylphenidate)	APTENSIO XR (methylphenidate)
methylphenidate CD 30-70	AZSTARYS (serdexmethylphenidate/dexmethylphenidate)
methylphenidate ER tablet (generic Concerta)	CONCERTA (methylphenidate)
methylphenidate ER tablet (generic Metadate CD)	dexmethylphenidate ER
RITALIN LA (methylphenidate LA capsules – 50-50) *Brand Name Required*	JORNAY PM (methylphenidate)
	methylphenidate ER 45 mg, 63 mg, 72 mg tablet (generic Relexxii ER)
	methylphenidate ER capsule (generic Aptensio XR)
	methylphenidate LA capsules – 50-50 (generic Ritalin LA) – 60 mg
	methylphenidate LA capsules – 50-50 (generic Ritalin LA) – 10 mg, 20 mg, 30 mg, 40 mg
	RELEXXII ER (methylphenidate)

Immediate Release

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
dexmethylphenidate	FOCALIN (dexmethylphenidate)
methylphenidate tablet	RITALIN (methylphenidate)

Non-Solid Dosage Forms

Extended Release

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
DAYTRANA (methylphenidate) PATCH – *Brand Required*	COTEMPLA XR – ODT (methylphenidate)
QUILLICHEW ER (methylphenidate)	methylphenidate patch
QUILLIVANT XR (methylphenidate)	

Immediate Release

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
methylphenidate chew tablet	METHYLIN (methylphenidate) SOLUTION
methylphenidate solution	

Electronic Age Verification

- The member must be age 6 or older or must meet prior authorization criteria for ages 5 and under listed below.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- For members ages 5 and under:
  - There is a moderate-severe continuing disturbance in the child's function in both home and other settings (e.g., preschool or daycare) despite a 9-month trial of parent and/or teacher-administered behavior therapy which helps parents learn age-appropriate developmental expectation, specific management skills for problem behaviors, and behaviors that strengthen the parent-child relationship (subject to clinical review).

Non-Preferred Agent Criteria:

- Amphetamine Non-Preferred Dosage Forms Only:
  - The member must have had a two 7-day trials of a methylphenidate non-solid dosage form.
- Aptensio XR Only:
  - The member must have a wearing off effect where late afternoon/evening functioning performance has been impacted despite a 7-day trial with a long-acting methylphenidate medication with an afternoon short acting booster.
  - The member must have a wearing off effect where late afternoon/evening functioning performance has been impacted despite a 7-day trial with Concerta or its generic alternative.
- Jornay PM Only:
  - The member must have had two 7-day trials of a fast onset to peak methylphenidate medication (i.e., Concerta, Focalin XR, Metadate CD, Methylin, Ritalin and their generic alternatives).
  - The member must have the inability to time the administration of medication where the peak is occurring at the start of work or school and early morning performance has been impacted at school or work due to the approximate 1-hour delay to peak after administration (subject to clinical review).
- All Other Agents: See Preferred Dosage Form criteria

References:

1. Wolraich, Mark L., et al. "Clinical practice guideline for the diagnosis, evaluation, and treatment of attention-deficit/hyperactivity disorder in children and adolescents." *Pediatrics* 144.4 (2019).
2. Hulkower RL, Kelley M, Cloud LK, Visser SN. Medicaid Prior Authorization Policies for Medication Treatment of Attention-Deficit/Hyperactivity Disorder in Young Children, United States, 2015. Public Health Rep. 2017 Nov/Dec;132(6):654-659. doi: 10.1177/0033354917735548. Epub 2017 Oct 26. PMID: 29072963; PMCID: PMC5692165.

FIRST REVIEWS

FIRST REVIEW OF MIGRAINE

Patients with migraines experience severe headaches that are oftentimes associated with nausea, visual disturbances, and sensitivity to light, sound, touch, and smell.

- **Episodic**: 0-14 migraine days per month
- **Chronic**: 15+ migraine days per month

Population:

- 37 million patients in US 12 years of age and older (28 million females, 9 million males)[1]

Treatment/Abortive Therapy:[1,2,3,7,10]

- **Goals:** pain relief, ability to function, limit the need for repeat dosing
- **Indication:** all patients with migraines
- **Considerations:**
  - May need to consider nonoral agents and/or antiemetics for those with severe nausea/vomiting
  - Medication overuse can worsen migraines; use should be limited to 2 days per week
  - All can cause medication overuse headaches except the CGRP antagonists
- **Medication choice** is dependent upon migraine severity:
  - Mild to moderate: nonsteroidal anti-inflammatory drugs (NSAIDs), acetaminophen (APAP), or caffeinated combination analgesics (APAP/aspirin/caffeine)
    - NSAIDs:
      - Established efficacy: aspirin, Elyxeb, diclofenac, ibuprofen, naproxen
      - Likely effective: flurbiprofen, ketoprofen, ketorolac
  - Moderate-severe or mild-moderate after poor response to non-specific agents: migraine specific agents (triptans, ergots, calcitonin gene-related peptide (CGRP) receptor antagonists, Reyvow)
  - A second triptan or different therapy may be trialed after treatment failure

Class	5-HT 1F receptor agonist (triptans)	CGRP antagonist (gepants)	5-HT 1F receptor agonist	Non-selective 5HT receptor agonist (ergots)
Medications	Almotriptan Eletriptan Frovatriptan Naratriptan Rizatriptan Sumatriptan Zolmitriptan	Nurtec Ubrelvy Zavzpret	Reyvow (lasmiditan)	Dihydroergotamine Ergotamine
Formulations	• Injectable • Nasal spray • Oral disintegrating tablet (ODT) • Oral film • Oral tablet	• Oral disintegrating tablet (ODT): Nurtec • Oral tablet: Ubrelv • Nasal spray: Zavzpret	Oral tablet	• Injectable • Nasal spray • Suppository
Key Notes	• Contraindications: Cerebrovascular disease, coronary artery disease, peripheral vascular disease, uncontrolled hypertension, and other vascular risk factors/disorders • Almotriptan can be used for adolescents	Generally well tolerated	• Schedule V controlled substance • Can impair driving and cause somnolence	• Similar contraindications to triptans • Minimal use due to increased risk of serious adverse effects

	• Rizatriptan and zolmitriptan can be used in pediatric patients depending on their age/formulation			
Cost/month	• Almotriptan: $396 • Eletriptan: $215.10 • Frovatriptan: $240 • Naratriptan: $20 • Rizatriptan: $14.82 (tablet) and $17.24 (ODT) • Sumatriptan: $72 (tablet), $125 (injection), $350 (spray) • Zolmitriptan: $7.90 (tablet), $47.14 (ODT), $518.23 (spray) • Sumatriptan/naloxone: $704	• Nurtec: $999.02 • Ubrelvy: $1,653.09 • Zavzpret: $1,100	Reyvow: $740.88	• Dihydroergotamine: $428.36 (spray), $1,326 (injection) • Ergotamine: $1,423.24

Cost based on lowest WAC per unit, calculated using monthly quantity limits allowed when applicable or maximum recommended dose

Prophylaxis:[1,3,4,5,6,7,8]

- **Goals:**
  - Decrease migraine frequency, severity, duration, and disability
  - Limit need for acute treatment
- **Indication:** ≥4 migraine days per month, significant disability or decreased quality of life, or uncontrolled with acute therapy
- **Considerations**: comorbid conditions that may be treated with the same agent or that may exacerbate side effects
- **Medication choice**:
  - Episodic and chronic migraine: topiramate, divalproex, beta blocker, candesartan, tricyclic antidepressant, SNRI, Aimovig, Ajovy, Emgality, Vyepti, Qulipta
    - Nurtec may also be used first line for episodic migraine
    - Botox (medical billing) has FDA approval for migraine prevention, administered quarterly, costs around $4,005.20 per year
- Non-pharmacological: relaxation training, electromyographic feedback, cognitive behavioral therapy

Class	Antihypertensives	Anticonvulsants	Antidepressants	CGRP Antagonist
Medications	Beta blockers: Atenolol Metoprolol* Propranolol* Timolol* ARB: Candesartan*	Divalproex* Topiramate* Zonisamide	Amitriptyline Venlafaxine	Oral: Nurtec ODT Qulipta Injectable: Aimovig* Ajovy* Emgality* Vyepti* *(IV, medical billing)*
Frequency	1-2 times daily depending on the agent	1-2 times daily depending on the agent	Once daily	• Every other day: Nurtec • Daily: Qulipta • Monthly: Aimovig, Emgality • Monthly or quarterly: Ajovy

				• Quarterly: Vyepti
Key Notes	Beta blockers: may be an issue for those with asthma/COPD or hypotension	Divalproex cannot be used in women of child-bearing age not on contraception (fetal harm)	• Amitriptyline: antimuscarinic effects (dry mouth, blurry vision, urinary retention, etc.) • Increase risk of serotonin syndrome	Shown to be as effective as other options but more tolerable
Cost/year	• Atenolol: $11.40 • Metoprolol: $21.60 • Propranolol: $22.39 • Timolol: $136.24 • Candesartan: $480	• Divalproex: $44.64 • Topiramate: $32.70 • Zonisamide: $49.64	• Amitriptyline: $18.72 • Venlafaxine: $42.84	• Nurtec: $23,976.48 • Qulipta: $13,110.96 • Aimovig: $9,031.44 • Ajovy: $8,797.92 • Emgality: $8,476.44 • Vyepti: $7,311.32

**Established efficacy; others are likely effective*
Cost based on lowest WAC per unit, calculated using initial compendia recommended dose

Current Utilization

	Quarter 4 2023			Quarter 1 2024		
Medication	**Rx Count**	**% of Rx**	**Reimb Amount**	**Rx Count**	**% of Rx**	**Reimb Amount**
Aimovig	74	4.0%	$51,023.45	56	2.9%	$40,880.25
Ajovy	45	2.4%	$41,625.72	55	2.9%	$50,061.05
Botox	281	15.2%	$7,502.01	336	17.7%	$10,297.80
eletriptan	105	5.7%	$68,173.55	105	5.5%	$68,836.53
Emgality	135	7.3%	$91,789.82	122	6.4%	$86,536.19
frovatriptan	2	0.1%	$161.26	3	0.2%	$222.50
naratriptan	10	0.5%	$134.37	6	0.3%	$79.94
Nurtec	72	3.9%	$66,310.71	97	5.1%	$93,678.80
Qulipta	14	0.8%	$14,152.09	12	0.6%	$11,966.56
Reyvow	0	0.0%	$-	1	0.1%	$722.36
rizatriptan	402	21.8%	$6,504.27	410	21.6%	$6,630.60
sumatriptan	686	37.2%	$20,750.16	675	35.5%	$14,359.26
Ubrelvy	14	0.8%	$13,405.84	16	0.8%	$15,882.59
Vyepti	4	0.2%	$341.13	4	0.2%	$608.17
Zavzpret	0	0.0%	$-	1	0.1%	$1,068.12
zolmitriptan	1	0.1%	$15.44	0	0.0%	$-
TOTALS	**1,845**		**$381,889.82**	**1,899**		**$401,830.72**
	Quarter 2 2024			**Quarter 4 2024**		
Medication	**Rx Count**	**% of Rx**	**Reimb Amount**	**Rx Count**	**% of Rx**	**Reimb Amount**
Aimovig	43	2.5%	$31,742.05	43	2.7%	$31,743.64
Ajovy	58	3.4%	$46,814.11	72	4.5%	$60,975.47
Botox	303	17.8%	$11,479.74	175	10.9%	$7,502.01
eletriptan	81	4.8%	$57,514.45	87	5.4%	$58,697.94
Emgality	95	5.6%	$65,858.76	103	6.4%	$74,215.30
frovatriptan	2	0.1%	$84.63	0	0.0%	$-
naratriptan	7	0.4%	$121.01	10	0.6%	$183.38
Nurtec	104	6.1%	$100,253.47	119	7.4%	$117,373.49
Qulipta	15	0.9%	$15,916.34	14	0.9%	$14,868.53
Reyvow	0	0.0%	$-	0	0.0%	$-

rizatriptan	360	21.1%	$5,866.34	343	21.3%	$5,682.02
sumatriptan	613	36.0%	$13,654.28	616	38.3%	$12,570.66
Ubrelvy	20	1.2%	$19,371.12	22	1.4%	$19,893.11
Vyepti	0	0.0%	$-	0	0.0%	$-
Zavzpret	1	0.1%	$1,068.12	0	0.0%	$-
zolmitriptan	3	0.2%	$915.05	5	0.3%	$707.67
TOTALS	**1,705**		**$370,659.47**	**1,609**		**$404,413.22**

References:

1. *Pain management: migraine. IPD Analytics. Aventura, FL. https://www.ipdanalytics.com*
2. *Garza I, Schwedt TJ. Acute treatment of migraine in adults. UpToDate, Goddeau RP, Swanson JW (Ed) [Internet]. Waltham, MA: UptoDate; Oct 7, 2024. Available from: www.uptodate.com*
3. *Ailani J, Burch RC, Robbins MS; the Board of Directors of the American Headache Society. The American Headache Society Consensus Statement: Update on integrating new migraine treatments into clinical practice. Headache. 2021;61:1021–1039. https://doi.org/10.1111/head.14153*
4. *Charles AC, Digre KB, Goadsby PJ, Robbins MS, Hershey A. Calcitonin gene-related peptide-targeting therapies are a first-line option for the prevention of migraine: An American Headache Society position statement update. Headache. 2024;64:333-341. doi:10.1111/head.14692*
5. *Garza I, Schwedt TJ. Chronic migraine. UpToDate, Goddeau RP, Robertson CE (Ed) [Internet]. Waltham, MA: UptoDate; Oct 3, 2023. Available from: www.uptodate.com*
6. *Garza I, Schwedt TJ. Preventive treatment of episodic migraine in adults. UpToDate, Goddeau RP, Swanson JW (Ed) [Internet]. Waltham, MA: UptoDate; Oct 7, 2024. Available from: www.uptodate.com*
7. *Migraine Prophylaxis and Treatment in Adults – Clinical Practice Guidelines. Drug Consults. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. July 16, 2024. https://www.micromedexsolutions.com*
8. *Lew C, Punnapuzha S. Migraine Medications. [Updated 2023 May 1]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2024 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK553159/*
9. *Almotriptan. eletriptan frovatriptan, naratriptan, rizatriptan, sumatriptan, zolmitriptan, Nurtec, Ubrelvy, Zavzpret, Reyvow, dihydroergotamine, ergotamine, atenolol, metoprolol, propranolol, timolol, candesartan, divalproex, topiramate, zonisamide, amitriptyline, venlafaxine, Qulipta, Aimovig, Ajovy, Emgality, Vyepti, Botox. Red Book. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. https://www.micromedexsolutions.com*
10. *Serotonin 5-HT1 Receptor Agonists (Triptans). Drug Facts and Comparisons. Wolters Kluwer Health, Inc. Riverwoods, IL. August 22, 2024. http://online.factsandcomparisons.com*

FIRST REVIEW OF NON-STEROIDAL ANTI-INFLAMMATORY DRUGS (NSAIDS)

Cyclooxygenase (COX) enzymes convert arachidonic acid to prostaglandins, prostacyclins, and thromboxanes. NSAIDs work by blocking COX1 and/or COX2 enzymes which lead to a decrease in prostaglandin formation, inflammation, pain, and fever. COX2 enzymes are more concentrated at inflammatory sites; COX1 enzymes are more concentrated in the stomach, platelets, and blood vessels.

Use: analgesic, antipyretic, and anti-inflammatory; symptomatic relief

Adverse Effects:

- Cardiovascular (CV): cardiovascular events, thromboembolic events, atrial fibrillation, hypertension (HTN)
- Gastrointestinal (GI): dyspepsia, peptic ulcer disease, bleeding
- Hepatic and renal toxicity
- Tinnitus

Contraindications and precautions for use:

- People with known coronary artery disease or at a higher risk for these conditions; heart failure
- History of GI bleed
- Cirrhosis
- Kidney disease

- Pregnancy (third trimester): can cause premature closure of ductus arteriosus

Drug interactions:

- Anticoagulant and antiplatelet agents: increase bleeding risk
- Antihypertensive agents: can block their effects
- Phenytoin: can increase phenytoin levels, monitoring requires

Non-Selective NSAIDS			
Medication	**Key Notes**	**Duration**	**Cost/month**
Diclofenac	• Available as a topical gel, over the counter (OTC) • Increase rate of hepatotoxic effects	<6 hours	$13.20
Etodolac		<6 hours	$31.77
Ketorolac	Can be used for a total of 5 days due to bleeding risk	<6 hours	$11.29
Indomethacin	More central nervous system adverse effects	<6 hours	$11.46
Sulindac	More hepatic inflammation	>6 hours	$12.00
Tolmetin		<6 hours	$61.20
Fenamates: meclofenamate, mefenamic acid	• Used for dysmenorrhea • More GI effects	<6 hours	$400.15
Nabumetone		>6 hours	$13.80
Meloxicam		>6 hours	$1.20
Piroxicam		>6 hours	$22.48
Fenoprofen		>6 hours	$1,758.00
Flurbiprofen		<6 hours	$42.07
Ibuprofen	Available OTC	<6 hours	$7.54
Ketoprofen		<6 hours	$80.12
Naproxen	Available OTC	>6 hours	$3.38
Oxaprozin		>6 hours	$67.50
Salicylate: aspirin	• Irreversibly blocks platelet function • Used for primary and secondary prevention of CVE • Available OTC	<6 hours	$0.22
COX-2 Selective NSAIDs • Decreases GI risk but increases CV risk			
Celecoxib	Cannot be used for those with sulfa allergy	>6 hours	$2.00

Cost based on lowest WAC per unit, calculated using monthly quantity limits allowed when applicable or maximum recommended dose

Current Utilization

	Quarter 4 2023			Quarter 1 2024		
Medication	**Rx Count**	**% of Rx**	**Reimb Amount**	**Rx Count**	**% of Rx**	**Reimb Amount**
aspirin	1446	23.8%	$13,432.99	1369	22.7%	$12,503.99
celecoxib	620	10.2%	$10,296.64	586	9.7%	$9,779.85
diclofenac epolamine	0	0.0%	$-	1	0.0%	$324.73
diclofenac potassium	91	1.5%	$1,626.86	93	1.5%	$1,680.85
diclofenac sodium	657	10.8%	$11,070.87	591	9.8%	$10,188.11
etodolac	10	0.2%	$231.88	11	0.2%	$208.90
ibuprofen	1397	23.0%	$19,603.35	1508	25.0%	$21,865.93
indomethacin	62	1.0%	$813.49	67	1.1%	$922.76
ketorolac tromethamine	356	5.8%	$7,157.90	337	5.6%	$6,774.92
meclofenamate sodium	0	0.0%	$-	1	0.0%	$198.17
mefenamic acid	2	0.0%	$97.81	2	0.0%	$97.81

meloxicam	860	14.1%	$11,241.54	866	14.3%	$10,628.80
nabumetone	47	0.8%	$950.27	36	0.6%	$735.42
naproxen	523	8.6%	$7,113.82	561	9.3%	$7,544.65
naproxen sodium	7	0.1%	$69.53	9	0.1%	$115.67
oxaprozin	0	0.0%	$-	0	0.0%	$-
piroxicam	3	0.0%	$65.54	4	0.1%	$85.61
salsalate	1	0.0%	$48.46	0	0.0%	$-
sulindac	4	0.1%	$82.08	2	0.0%	$32.98
TOTALS	**6086**		**$83,903.03**	**6044**		**$83,689.15**
	Quarter 2 2024			**Quarter 4 2024**		
Medication	**Rx Count**	**% of Rx**	**Reimb Amount**	**Rx Count**	**% of Rx**	**Reimb Amount**
aspirin	1324	23.2%	$12,955.10	1360	23.7%	$14,409.28
celecoxib	592	10.4%	$9,720.63	555	9.7%	$9,176.50
diclofenac epolamine	2	0.0%	$639.87	0	0.0%	$-
diclofenac potassium	81	1.4%	$1,401.98	103	1.8%	$1,681.49
diclofenac sodium	593	10.4%	$10,502.25	580	10.1%	$10,078.83
etodolac	13	0.2%	$288.13	22	0.4%	$516.84
ibuprofen	1432	25.1%	$22,054.35	1404	24.5%	$20,062.91
indomethacin	50	0.9%	$724.43	63	1.1%	$831.00
ketorolac tromethamine	324	5.7%	$5,927.01	330	5.8%	$6,565.03
meclofenamate sodium	0	0.0%	$-	0	0.0%	$-
mefenamic acid	2	0.0%	$79.51	1	0.0%	$41.26
meloxicam	759	13.3%	$11,465.30	792	13.8%	$10,548.97
nabumetone	38	0.7%	$734.03	45	0.8%	$891.45
naproxen	480	8.4%	$6,685.73	473	8.2%	$6,458.28
naproxen sodium	8	0.1%	$135.99	9	0.2%	$161.54
oxaprozin	1	0.0%	$27.33	0	0.0%	$-
piroxicam	0	0.0%	$-	1	0.0%	$16.94
salsalate	2	0.0%	$44.20	0	0.0%	$-
sulindac	1	0.0%	$16.49	0	0.0%	$-
TOTALS	**5702**		**$83,402.33**	**5738**		**$81,440.32**

References:

1. *Nonsteroidal Anti-Inflammatory Agents. Drug Facts and Comparisons. Wolters Kluwer Health, Inc. Riverwoods, IL. August 22, 2024. http://online.factsandcomparisons.com*
2. *Solomon DH. Patient education: Nonsteroidal anti-inflammatory drugs (NSAIDs) (Beyond the Basics). UpToDate, Case SM, Furst DE, Ridby WF (Ed) [Internet]. Waltham, MA: UptoDate; Sept 10, 2024. Available from: www.uptodate.com*
3. *Solomon DH. NSAIDs (including aspirin): Pharmacology and mechanism of action. UpToDate, Case SM, Furst DE, Ridby WF (Ed) [Internet]. Waltham, MA: UptoDate; June 11, 2024. Available from: www.uptodate.com*
4. *Solomon DH. NSAIDs: Therapeutic use and variability of response in adults. UpToDate, Case SM, Furst DE, Ridby WF (Ed) [Internet]. Waltham, MA: UptoDate; Oct 10, 2024. Available from: www.uptodate.com*
5. *Ghlichloo I, Gerriets V. Nonsteroidal Anti-Inflammatory Drugs (NSAIDs) [Updated 2023 May 1]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2024 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK547742/*
6. *Diclofenac, etodolac, ketorolac, indomethacin, sulindac, tolmetin, meclofenamate, mefenamic acid, nabumetone, meloxicam, piroxicam, fenoprofen, flurbiprofen, ibuprofen, ketoprofen, naproxen, oxaprozin, aspirin, celecoxib. Red Book. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. https://www.micromedexsolutions.com*

FIRST REVIEW OF PRIMARY BILIARY CHOLANGITIS

Primary biliary cholangitis (PBC) is a rare liver disease characterized by destruction and inflammation of the small bile ducts. If left untreated, PBC can progress to liver cirrhosis end-stage liver disease, the need for liver transplant, and death. Patients often have pruritus and fatigue. [1]

Population[1]:

- 131,000 patients in the US, primarily women between ages of 45 to 65 years
- Patients 18 years and older US prevalence is 39.2 per 100,000 people

Treatment Recommendations[1]:

- First-line treatment:
  - Ursodiol (UDCA)
- Second-line treatment (to be used in combination with UDCA unless unable to tolerate UDCA):
  - Ocaliva (obeticholic acid)
  - Iqirvo (elafibranor)
  - Livdelvi (seladelpar)
- Off-label treatments:
  - Benzafibrate
  - Fenofibrate

Ursodiol[10]	
Indication	Treatment of PBC for patients 18 years and older
Clinical Studies	Meta-analysis of 1447 patients showed improvement in liver biochemistries and lower risk of histologic disease progression[11]
Dosing	13 to 15 mg/kg BID, oral
Important Considerations	• MOA: increased hydrophilic index of the circulating bile acid pool, stimulation of hepatocellular and ductular secretions, cytoprotection against hydrophobic bile acid- and cytokine-induced injury, and immunomodulation and anti-inflammatory effects • Approximately 40% suboptimal response or cannot tolerate
Cost/month	$129.60[11]
Ocaliva (obeticholic acid)[1]	
Indication	Treatment of PBC in combination with ursodeoxycholic acid (UDCA) in adults who fail UDCA or as monotherapy in patients unable to tolerate UDCA for patients 18 years and older
Dosing	5 mg/day, oral
Important Considerations	• MOA: Farnesoid X receptor agonist suppresses synthesis of bile acids from cholesterol and increases transport of bile acids out of the hepatocytes • Boxed warning: hepatic decompensation/failure, severe pruritus (limits use), reduction in HDL • Contraindications: decompensated cirrhosis, a prior decompensation event, or compensated cirrhosis who have evidence of portal hypertension; patients with cirrhosis require monitoring
Cost/month	$9,554.05[5]
Livdelzi (seladelpar)[1]	
Indication	Treatment of PBC in combination with ursodeoxycholic acid (UDCA) in adults who have failed UDCA or as monotherapy in patients unable to tolerate UDCA for patients 18 years and older
Dosing	10 mg/day, oral
Important Considerations	• MOA: PPAR-delta agonist which inhibits bile acid synthesis through activation of PPAR-delta. • Administer 4 hours before or after bile acid sequestrants • Warnings: fractures, liver test abnormalities, biliary obstruction • Cannot be used for those with decompensated cirrhosis • Reduction in pruritus is main differentiation from Ocaliva and Iqirvo
Cost/month	$12,606[4]

Iqirvo (elafibranor)[7]	
Indication	Treatment of PBC in combination with ursodeoxycholic acid (UDCA) in adults who have failed UDCA or as monotherapy in patients unable to tolerate UDCA for patients 18 years and older
Dosing	80 mg/day, oral
Important Considerations	• MOA: PPAR-agonist (alpha, gamma, and delta) • Not recommended for patients with decompensated cirrhosis • Not shown to worsen pruritus or dyslipidemia • Warnings: myalgia, myopathy, rhabdomyolysis, fractures, drug-induced liver injury, biliary obstruction, fetal development
Cost/month	$ 11,460.00[6]

**Cost based on lowest per unit WAC cost for initial adult dosing (weight 100 kg if applicable)*

FDA Approval

Livdelzi (seladelpar): August 8, 2024; 505(b) New Drug Application (NDA) pathway Type 1 Molecular Entity, PRIORITY; Orphan, Accelerated Approval

Iqirvo (elafibranor): June 10, 2024; 505(b) New Drug Application (NDA) pathway Type 1 Molecular Entity, PRIORITY; Orphan, Accelerated Approval

Ocaliva (obeticholic acid): May 27, 2016; 505(b) New Drug Application (NDA) pathway Type 1 Molecular Entity, PRIORITY; Orphan, Accelerated Approval

Clinical Trials

Ocaliva (obeticholic acid)[1, 12, 13, 14, 15, 16]	
Accelerated Approval Study	• 217 adult patients who had an inadequate response or intolerance to UDCA, followed for 12 months **Outcomes:** • **Primary:** Biochemical response (*defined as ALP <1.67 times upper limit of normal (ULN), ≥ 15% decrease ALP, normal total bilirubin)* achieved by more patients on Ocaliva (47% vs 10%, p<0.0001) • **Pruritus:** 70% (10 mg), 56% (titration arm), and 38% (placebo) reported pruritus
Confirmatory Study	• Post marketing studies terminated due to enrollment difficulties and safety issues due to cirrhosis
News Updates	• FDA denied traditional approval in September 2024; still on market under accelerated approval • Has been removed from the market in Europe due to inability to confirm benefits ○ Study 747-302 failed to show differences between Ocaliva and placebo for primary composite endpoint of death, liver transplant, or hepatic decompensation (HR 1.01, p=0.954)
Livdelzi (seladelpar)[1, 17]	
Accelerated Approval Study	• 193 patients who had an inadequate response or intolerance to UDCA aged 28-75 years, followed over 12 months **Outcomes:** • **Primary:** Biochemical response (*defined as ALP <1.67 times upper limit of normal (ULN), ≥ 15% decrease ALP, normal total bilirubin)* achieved by more patients on Livdelzi (62% vs 20%, p<0.001)

	○ *Biochemical response defined as ALP <1.67 times upper limit of normal (ULN), ≥ 15% decrease ALP, normal total bilirubin for all trials* • **Secondary:** ○ Normal ALP levels: achieved by more patients on Livdelzi (25% vs 0%, p<0.001) ○ Pruritus: Livdelzi group also experienced greater reduction in pruritus score (change from baseline -3.2 vs -1.7, p=0.005)
Confirmatory Study	Ongoing, estimated completion July 2029
Iqirvo (elafibranor)[7, 18]	
Accelerated Approval Study	• 161 patients who had an inadequate response or intolerance to UDCA aged 36 to 76 years, 96% female **Outcomes:** • **Primary:** Biochemical response (*defined as ALP <1.67 times upper limit of normal (ULN), ≥ 15% decrease ALP, normal total bilirubin)* achieved by more patients on Iqirvo (51% vs 4%, p<0.001) • **Secondary:** ○ Normal ALP levels: achieved by more patients on Iqirvo (15% vs 0%, p=0.002) ○ Pruritus: change in pruritus score was not statistically significant (change from baseline -1/93 vs -1.15, p=0.20)
Confirmatory Study	Ongoing, estimated completion 2030

Current Utilization

	Quarter 4 2023			Quarter 1 2024		
Medication	**Rx Count**	**% of Rx**	**Reimb Amount**	**Rx Count**	**% of Rx**	**Reimb Amount**
Ocaliva	0	0%	$ -	0	0%	$-
ursodiol	83	100%	$3,252.73	79	100%	$2,907.77
TOTALS	**83**		**$3,252.73**	**79**		**$2,907.77**
	Quarter 2 2024			**Quarter 3 2024**		
Medication	**Rx Count**	**% of Rx**	**Reimb Amount**	**Rx Count**	**% of Rx**	**Reimb Amount**
Ocaliva	1	1.45%	$9,566.51	2	3.57%	$19,133.02
ursodiol	68	98.55%	$2,290.31	54	96.43%	$1,883.51
TOTALS	**69**		**$11,856.82**	**56**		**$21,016.53**

***No utilization of Livdelzi or Iqirvo from Q4 2023-Q3 2024*

References:

1. *Livdelzi (seladelpar): New Drug Review. IPD Analytics. Aventura, FL. September 2024.*
2. *U.S. Food and Drug Administration, Center for Drug Evaluation and Research. Livdelzi NDA 217899 approval letter, August 8, 2024. https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2024/217899Orig1s000ltr.pdf*
3. *U.S. Food and Drug Administration, Center for Drug Evaluation and Research. Ocaliva NDA 207999 approval letter, May 27, 2016. https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2016/207999Orig1s000ltr.pdf*
4. *Livdelvi. Quick Answers and Red Book. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. November 6, 2024. https://www.micromedexsolutions.com*
5. *Ocaliva. Quick Answers and Red Book. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. November 6, 2024. https://www.micromedexsolutions.com*
6. *Iqirvo. Quick Answers and Red Book. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. November 6, 2024. https://www.micromedexsolutions.com*
7. *Igirvo (elafibranor): New Drug Review. IPD Analytics. Aventura, FL. July 2024.*

8. *U.S. Food and Drug Administration, Center for Drug Evaluation and Research. Iqirvo NDA 218860 approval letter, June 10, 2016 https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2024/218860Orig1s000ltr.pdf*
9. *Ocaliva. November 6, 2020. Obeticholic Acid Oral (Drug Facts And Comparisons) - Facts and Comparisons®.*
10. *Overview of the management of primary biliary cholangitis. November 6, 2024. Clinical manifestations, diagnosis, and prognosis of primary biliary cholangitis – UpToDate.*
11. *Ursodiol. Quick Answers and Red Book. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. November 6, 2024. https://www.micromedexsolutions.com*
12. *Phase 3 Study of Obeticholic Acid in Patients with Primary Biliary Cirrhosis (POISE). ClinicalTrials.gov identifier: NCT01473524. May 6, 2016. https://clinicaltrials.gov/study/NCT01473524*
13. *Satija B, Singh P. US FDA declines full approval for Intercept's liver disease drug. Reuters. November 13, 2024. https://www.reuters.com/business/healthcare-pharmaceuticals/us-fda-declines-full-approval-intercepts-liver-disease-drug-2024-11-12/*
14. *Kansteiner F. FDA rejects Intercept's ask for Ocaliva full nod in rare liver disease, but accelerated approval remains. Fierce Pharma. November 12, 2024. Available from: https://www.fiercepharma.com/pharma/fda-declines-grant-intercepts-ocaliva-full-approval-rare-liver-disease*
15. *U.S. Food and Drug Administration, Center for Drug Evaluation and Research. Application number: 207999Orig1s000 Summary Review. May 26, 2016. https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/207999Orig1s000SumR.pdf*
16. *EMA recommends revoking conditional marketing authorisation for Ocaliva. European Medicines Agency. June 28, 2024. Available from: https://www.ema.europa.eu/en/news/ema-recommends-revoking-conditional-marketing-authorisation-ocaliva*
17. *Hirschfield GM, Bowlus CL, Mayo MJ, et al. RESPONSE Study Group. A Phase 3 Trial of Seladelpar in Primary Biliary Cholangitis. N Engl J Med. 2024 Feb 29;390(9):783-794. doi: 10.1056/NEJMoa2312100. Epub 2024 Feb 21. PMID: 38381664.*
18. *Kowdley KV, Bowlus CL, Levy C, et al. ELATIVE Study Investigators' Group; ELATIVE Study Investigators' Group. Efficacy and Safety of Elafibranor in Primary Biliary Cholangitis. N Engl J Med. 2024 Feb 29;390(9):795-805. doi: 10.1056/NEJMoa2306185. Epub 2023 Nov 13. PMID: 37962077.*

NORTH DAKOTA MEDICAID
RETROSPECTIVE DRUG UTILIZATION REVIEW
CRITERIA RECOMMENDATIONS
DUR BOARD MEETING SEPTEMBER 2024

1. Methylphenidate & Dexmethylphenidate / Drug Abuse & Dependence
Alert Message:Methylphenidate and dexmethylphenidate-containing products should be prescribed cautiously in patients with a history of drug abuse or alcoholism.Chronic, abusive use can lead to marked tolerance and psychological dependence with varying degrees of abnormal behavior.

Drugs/Diseases

Util A	Util B	Util C (Include)
Methylphenidate		History of Drug Abuse & Dependence
Dexmethylphenidate		
Serdexmethylphenidate/Dexmethylphenidate		

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.

2. Amphetamines / Drug Abuse & Dependence
Alert Message:Amphetamines have a high potential for abuse.Administration of amphetamines for prolonged periods of time may lead to the development of substance abuse disorder, including addiction. Assess the risk of abuse prior to prescribing and monitor for signs of abuse and dependence while on therapy.

Drugs/Diseases

Util A	Util B	Util C (Include)
Amphetamine		History of Drug Abuse & Dependence
Dextroamphetamine		
Methamphetamine		
Lisdexamfetamine		

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.

NORTH DAKOTA MEDICAID
RETROSPECTIVE DRUG UTILIZATION REVIEW
CRITERIA RECOMMENDATIONS
DUR BOARD MEETING DECEMBER 2024

NORTH DAKOTA MEDICAID
RETROSPECTIVE DRUG UTILIZATION REVIEW
CRITERIA RECOMMENDATIONS
4TH QUARTER 2024

Criteria Recommendations ***Approved Rejected***

1. Adagrasib / Overuse _____

Alert Message:Krazati (adagrasib) may be over-utilized.The recommended dosage of adagrasib is 600 mg orally twice daily until disease progression or unacceptable toxicity.

Drugs/Diseases

Util A	Util B	Util C
Adagrasib		

Max Dose: 1200 mg/day

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Krazati Prescribing information, June 2024, Mirati Therapeutics, Inc.

2. Adagrasib / Therapeutic Appropriateness _____

Alert Message:The safety and effectiveness of Krazati (adagrasib) has not been established in pediatric patients.

Drugs/Diseases

Util A	Util B	Util C
Adagrasib		

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Krazati Prescribing information, June 2024, Mirati Therapeutics, Inc.

3. Adagrasib / Adverse Gastrointestinal Adverse Effects _____

Alert Message:Krazati (adagrasib) can cause severe gastrointestinal adverse reactions (gastrointestinal bleeding, obstruction, colitis, and ileus).Monitor and manage patients using supportive care, including antidiarrheals, antiemetics, or fluid replacement, as indicated. Withhold, reduce the dose, or permanently discontinue adagrasib based on severity.Reduce the dose in accordance with the official prescribing information, withhold, or permanently discontinue adagrasib based on severity.

Drugs/Diseases

Util A	Util B	Util C
Adagrasib	Gastrointestinal Bleeding	
	Gastrointestinal Obstruction	
	Colitis	
	Diarrhea	
	Ileus	

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Krazati Prescribing information, June 2024, Mirati Therapeutics, Inc.

4. Adagrasib / QT Prolongation _____

Alert Message:Krazati (adagrasib) can cause QTc interval prolongation, which can increase the risk for ventricular tachyarrhythmias (e.g., torsades de pointes) or sudden death.Avoid the use of adagrasib in patients with congenital long QT syndrome and patients with concurrent QTc prolongation.Withhold, reduce the dose in accordance with the official prescribing information, or permanently discontinue adagrasib depending on severity.

Drugs/Diseases

Util A	Util B	Util C
Adagrasib	QT Prolongation	

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Krazati Prescribing information, June 2024, Mirati Therapeutics, Inc.

5. Adagrasib / Hepatotoxicity _____

Alert Message:Krazati (adagrasib) can cause hepatotoxicity, which may lead to drug-induced liver injury and hepatitis.In clinical trials, overall hepatotoxicity occurred in 37%, and 7% were Grade 3 or 4.Hepatotoxicity leading to dose interruption or reduction occurred in 12% of patients. Adagrasib was discontinued due to hepatotoxicity in 0.5% of patients.Reduce the dose in accordance with the official prescribing information, withhold, or permanently discontinue adagrasib based on severity.

Drugs/Diseases

Util A	Util B	Util C
Adagrasib	Transaminase Elevations	
	Toxic Liver Disease	

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Krazati Prescribing information, June 2024, Mirati Therapeutics, Inc.

6. Adagrasib / Interstitial Lung Disease/Pneumonitis _____

Alert Message:Krazati (adagrasib) can cause interstitial lung disease (ILD)/pneumonitis, which can be fatal.In the pooled safety population study, ILD/pneumonitis occurred in 4.1% of patients, 1.4% were Grade 3 or 4, and one case was fatal.Monitor patients for new or worsening respiratory symptoms indicative of ILD/pneumonitis (e.g., dyspnea, cough, fever) during treatment with adagrasib.Withhold adagrasib in patients with suspected ILD/pneumonitis and permanently discontinue adagrasib if no other potential causes of ILD/pneumonitis are identified.

Drugs/Diseases

Util A	Util B	Util C
Adagrasib	Interstitial Lung Disease	
	Pneumonitis	
	Cough	
	Dyspnea	
	Fever	

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Krazati Prescribing information, June 2024, Mirati Therapeutics, Inc.

7. Adagrasib / Strong CYP3A4 Inducers _____

Alert Message:Avoid concomitant use of Krazati (adagrasib) with strong CYP3A4 inducers. Adagrasib is a CYP3A4 substrate. Concomitant use of adagrasib with a strong CYP3A4 inducer reduces adagrasib exposure, which may reduce the effectiveness of adagrasib.

Drugs/Diseases

Util A	Util B	Util C
Adagrasib	Apalutamide	
	Carbamazepine	
	Enzalutamide	
	Mitotane	
	Phenobarbital	
	Phenytoin	
	Primidone	
	Rifampin	

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Krazati Prescribing information, June 2024, Mirati Therapeutics, Inc.

8. Adagrasib / Strong CYP3A4 Inhibitors _____

Alert Message:Avoid concomitant use of Krazati (adagrasib) with strong CYP3A4 inhibitors until adagrasib concentrations have reached steady state (after approximately 8 days). Adagrasib is a CYP3A4 substrate.If adagrasib concentrations have not reached steady state, concomitant use of a strong CYP3A4 inhibitor will increase adagrasib concentrations, which may increase the risk of adagrasib adverse reactions.

Drugs/Diseases

Util A	Util B	Util C
Adagrasib	Clarithromycin	
	Cobicistat	
	Nefazodone	
	Nelfinavir	
	Ritonavir	

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Krazati Prescribing information, June 2024, Mirati Therapeutics, Inc.

9. Adagrasib / Sensitive CYP3A4 Substrates _____

Alert Message:Avoid concomitant use of Krazati (adagrasib) with sensitive CYP3A substrates unless otherwise recommended in the official prescribing information for these substrates. Adagrasib is a CYP3A inhibitor. Concomitant use with adagrasib increases exposure of CYP3A substrates, which may increase the risk of adverse reactions related to these substrates.

Drugs/Diseases

Util A	Util B				Util C
Adagrasib	Avanafil	Everolimus	Quetiapine	Vardenafil	
	Budesonide	Felodipine	Sildenafil		
	Buspirone	Ibrutinib	Sirolimus		
	Cyclosporine	Maraviroc	Tacrolimus		
	Darifenacin	Midazolam	Ticagrelor		
	Darunavir	Nisoldipine	Tipranavir		

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Krazati Prescribing information, June 2024, Mirati Therapeutics, Inc.

10. Adagrasib / Sensitive CYP2C9 Substrates _____

Alert Message:Avoid concomitant use of Krazati (adagrasib) with sensitive CYP2C9 substrates where minimal concentration changes may lead to serious adverse reactions unless otherwise recommended in the official prescribing information for these substrates.Adagrasib is a CYP2C9 inhibitor.Concomitant use with adagrasib increases exposure of CYP2C9 substrates, which may increase the risk of adverse reactions related to these substrates.

Drugs/Diseases

Util A	Util B	Util C
Adagrasib	Celecoxib	
	Glimepiride	
	Phenytoin	
	Warfarin	

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Krazati Prescribing information, June 2024, Mirati Therapeutics, Inc.

11. Adagrasib / Sensitive CYP2D6 Substrates _____

Alert Message:Avoid concomitant use of Krazati (adagrasib) with sensitive CYP2D6 substrates where minimal concentration changes may lead to serious adverse reactions unless otherwise recommended in the official prescribing information for these substrates.Adagrasib is a CYP2D6 inhibitor.Concomitant use with adagrasib increases exposure of CYP2D6 substrates, which may increase the risk of adverse reactions related to these substrates.

Drugs/Diseases

Util A	Util B	Util C
Adagrasib	Atomoxetine	
	Desipramine	
	Dextromethorphan	
	Nebivolol	
	Perphenazine	
	Tolterodine	
	Venlafaxine	

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Krazati Prescribing information, June 2024, Mirati Therapeutics, Inc.

12. Adagrasib / Sensitive P-gp Substrates _____

Alert Message:Avoid concomitant use of Krazati (adagrasib) with P-gp substrates where minimal concentration changes may lead to serious adverse reactions unless otherwise recommended in the official prescribing information for these substrates.Adagrasib is a P-gp inhibitor.Concomitant use with adagrasib increases exposure of P-gp substrates, which may increase the risk of adverse reactions related to these substrates.

Drugs/Diseases

Util A	Util B	Util C
Adagrasib	Dabigatran	
	Digoxin	
	Edoxaban	

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Krazati Prescribing information, June 2024, Mirati Therapeutics, Inc.

Criteria Recommendations ***Approved Rejected***

13. Adagrasib / Drug that Prolong QT Interval _____

Alert Message:Krazati (adagrasib) can cause QTc interval prolongation, which can increase the risk for ventricular tachyarrhythmias (e.g., torsades de pointes) or sudden death.Avoid concomitant use of adagrasib with other products with a known potential to prolong the QTc interval.Monitor ECGs and electrolytes prior to starting adagrasib, during concomitant use, and as clinically indicated in patients who are unable to avoid concomitant medications that are known to prolong the QT interval.Withhold, reduce the dose, or permanently discontinue adagrasib depending on severity.

Drugs/Diseases

Util A	Util B				Util C	
Adagrasib	Abiraterone	Efavirenz	Levofloxacin	Ribociclib		
Doxepin	Droperidol	Lithium	Risperidone			
	Amiodarone	Encorafenib	Lofexidine	Rilpivirine		Amitriptyline
Entrectinib	Loperamide		Ritonavir			
	Anagrelide	Eribulin	Maprotiline	Romidepsin		
	Apomorphine	Erythromycin	Mavorixafor	Sertraline		
	Aripiprazole	Escitalopram	Methadone	Siponimod		
	Arsenic Trioxide	Ezogabine	Midostaurin	Solifenacin		
	Asenapine	Famotidine	Mifepristone	Sotalol		
	Atomoxetine	Felbamate	Mirabegron	Sunitinib		
	Azithromycin	Fingolimod	Mirtazapine	Tacrolimus		
	Bedaquiline	Flecainide	Moexipril	Tamoxifen		
	Bortezomib	Moxifloxacin	Tetrabenazine	Telavancin		
	Bendamustine	Fluoxetine	Nelfinavir	Vemurafenib		
	Bosutinib	Fluvoxamine	Nilotinib	Tizanidine		
	Buprenorphine	Foscarnet	Nortriptyline	Tolterodine		
	Ceritinib	Galantamine	Ofloxacin	Toremifene		
	Chloroquine	Ganciclovir	Ondansetron	Tramadol		
	Chlorpromazine	Gemifloxacin	Osimertinib	Trazodone		
	Cilostazol	Gilteritinib	Oxaliplatin	Triclabendazole		
	Ciprofloxacin	Glasdegib	Paliperidone	Trimipramine		
	Citalopram	Granisetron	Panobinostat	Vardenafil		
	Clarithromycin	Haloperidol	Paroxetine	Venlafaxine		
	Clomipramine	HydroxychloroquinePasireotide				
	Clozapine	Hydroxyzine	Pazopanib			
	Crizotinib	Ibutilide	Pentamidine			
	Dabrafenib	Iloperidone	Pimavanserin			
	Dasatinib	Imipramine	Pitolisant			
	Desipramine	Indapamide	Vandetanib			
	Deutetrabenazine	Valbenazine	Procainamide			
	Diphenhydramine	Ivosidenib	Promethazine			
	Disopyramide	Lapatinib	Propafenone			
	Dofetilide	Lefamulin	Quetiapine			Dolasetron
Lenvatinib	Quinidine					
	Donepezil	Leuprolide	Quinine			

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Krazati Prescribing information, June 2024, Mirati Therapeutics, Inc.

Criteria Recommendations ***Approved Rejected***

14. Adagrasib / Lactation _____

Alert Message:There are no data on the presence of Krazati (adagrasib) or its metabolites in human milk, the effects on the breastfed child, or milk production.Because of the potential for serious adverse reactions in breastfed children, advise women not to breastfeed during treatment with adagrasib and for 1 week after the last dose.

Drugs/Diseases

Util A	Util B	Util C
Adagrasib	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Krazati Prescribing information, June 2024, Mirati Therapeutics, Inc.

15. Adagrasib / Non-adherence _____

Alert Message:Based on refill history, your patient may be under-utilizing Krazati (adagrasib). Nonadherence to the prescribed dosing regimen may result in subtherapeutic effects, which may lead to decreased patient outcomes and additional healthcare costs.

Drugs/Diseases

Util A	Util B	Util C
Adagrasib		

References:
Osterberg L, Blaschke T. Adherence to Medication. N Engl J Med 2005; 353:487- 497.
Ruddy K, Mayer E, Partridge A. Patient Adherence and Persistence With Oral Anticancer Treatment. CA Cancer J Clin 2009;59:56-66.
Barillet M, Prevost V, Joly F, Clarisse B. Oral Antineoplastic Agents: How do We Care About Adherence?. Br J Clin Pharmacol. 2015;80(6):1289–1302. doi:10.1111/bcp.12734
Greer JA, Amoyal N, Nisotel L, et al. Systemic Review of Adherence to Oral Antineoplastic Therapies. The Oncologist. 2016;21:354-376.

16. Diazepam Buccal / Overuse _____

Alert Message:Libervant (diazepam) may be over-utilized.Buccal diazepam should not be used to treat more than 1 episode every 5 days and no more than 5 episodes per month. Do not use more than 2 doses of buccal diazepam to treat a single episode.

Drugs/Diseases

Util A	Util B	Util C
Diazepam Buccal		

Quantity: 10 tablets per month

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Libervant Prescribing Information, April 2024, Aquestive Therapeutics, Inc.

17. Diazepam Buccal / Therapeutic Appropriateness _____

Alert Message:Libervant (diazepam) is approved for use in pediatric patients 2 to 5 years of age. The unapproved use of buccal diazepam exposes users to risks of abuse, misuse, and addiction, which can lead to overdose or death. Abuse and misuse of benzodiazepines commonly involve concomitant use of other medications, alcohol, and/or illicit substances, which is associated with an increased frequency of serious adverse outcomes.

Drugs/Diseases

Util A	Util B	Util C
Diazepam Buccal		

Age Range: 6 - 999 yoa

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Libervant Prescribing Information, April 2024, Aquestive Therapeutics, Inc.

18. Diazepam Buccal / Therapeutic Appropriateness _____

Alert Message:Benzodiazepines, including Libervant (diazepam), can increase intraocular pressure in patients with glaucoma.Diazepam nasal spray is contraindicated in patients with narrow-angle glaucoma.Diazepam may be used in patients with open-angle glaucoma only if they are receiving appropriate therapy.

Drugs/Diseases

Util A	Util B	Util C
Diazepam Buccal	Narrow Angle Glaucoma	

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Libervant Prescribing Information, April 2024, Aquestive Therapeutics, Inc.

19. Diazepam Buccal / Therapeutic Appropriateness _____

Alert Message:Libervant (diazepam) is not approved for use in neonates or infants.Serious and fatal adverse reactions including “gasping syndrome” can occur in neonates and low birth weight infants treated with benzyl alcohol-preserved drugs, including buccal diazepam.The “gasping syndrome” is characterized by central nervous system depression, metabolic acidosis, and gasping respiration.The minimum amount of benzyl alcohol at which serious adverse reactions may occur is not known (buccal diazepam contains 3.96 to 11.87 mg of benzyl alcohol per buccal film).

Drugs/Diseases

Util A	Util B	Util C
Diazepam Buccal		

Age Range: 0 - 1 yoa

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Libervant Prescribing Information, April 2024, Aquestive Therapeutics, Inc.

20. Diazepam Buccal / CYP2C19 and CYP3A4 Inhibitors _____

Alert Message:Libervant (diazepam) is a substrate for CYP2C19 and CYP3A4.The concurrent use of diazepam with a CYP2C19 or CYP3A4 inhibitor may decrease the rate of diazepam elimination and increase the risk of diazepam-related adverse effects.

Drugs/Diseases

Util A	Util B		Util C
Diazepam Buccal	Cimetidine	Modafinil	
	Clarithromycin	Nefazodone	
	Cobicistat	Nelfinavir	
	Fluconazole	Omeprazole	
	Esomeprazole	Posaconazole	
	Fluoxetine	Ritonavir	
	Fluvoxamine	Ticlopidine	
	Itraconazole	Tranylcypromine	
	Ketoconazole	Voriconazole	
	Lonafarnib		

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Libervant Prescribing Information, April 2024, Aquestive Therapeutics, Inc.

21. Diazepam Buccal / CYP2C19 and CYP3A4 Inducers _____

Alert Message:Libervant (diazepam) is a substrate for CYP2C19 and CYP3A4.The concurrent use of diazepam with a CYP2C19 or CYP3A4 inducer may increase the rate of diazepam elimination and decrease diazepam efficacy.

Drugs/Diseases

Util A	Util B		Util C
Diazepam Buccal	Apalutamide	Phenytoin	
	Carbamazepine	Primidone	
	Enzalutamide	Rifampin	
	Mitotane		
	Phenobarbital		

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Libervant Prescribing Information, April 2024, Aquestive Therapeutics, Inc.

22. Pirtobrutinib / Overuse _____

Alert Message:Jaypirca (pirtobrutinib) may be over-utilized.The recommended dosage of pirtobrutinib is 200 mg orally once daily until disease progression or unacceptable toxicity.

Drugs/Diseases

Util A	Util B	Util C (Negating)
Pirtobrutinib		CKD Stage 4

Max Dose: 200 mg/day

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Jaypirca Prescribing Information, June 2024, Eli Lilly and Company.

23. Pirtobrutinib / CKD Stage 4 _____

Alert Message:For patients with severe renal impairment (eGFR 15-29 mL/min), reduce the Jaypirca (pirtobrutinib) dose to 100 mg once daily if the current dose is 200 mg once daily; otherwise, reduce the dose by 50 mg.If the current dosage is 50 mg once daily, discontinue pirtobrutinib.No dosage adjustment of pirtobrutinib is recommended in patients with mild to moderate renal impairment (eGFR 30-89 mL/min).

Drugs/Diseases

Util A	Util B	Util C (Include)
Pirtobrutinib		CKD Stage 4

Max Dose: 100 mg/day

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Jaypirca Prescribing Information, June 2024, Eli Lilly and Company.

24. Pirtobrutinib / Therapeutic Appropriateness _____

Alert Message:The safety and effectiveness of Jaypirca (pirtobrutinib) have not been established in pediatric patients.

Drugs/Diseases

Util A	Util B	Util C
Pirtobrutinib		

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Jaypirca Prescribing Information, June 2024, Eli Lilly and Company.

25. Pirtobrutinib / Infections _____

Alert Message:Fatal and serious infections (including bacterial, viral, or fungal infections) and opportunistic infections have occurred in patients treated with Jaypirca (pirtobrutinib). In the clinical trial, Grade 3 or higher infections occurred in 24% of 593 patients, most commonly pneumonia (14%), with fatal infections occurring in 4.4% of patients.Monitor patients for signs and symptoms of infection, evaluate promptly and treat appropriately. Based on severity, reduce the dose, temporarily withhold or permanently discontinue pirtobrutinib.

Drugs/Diseases

Util A	Util B	Util C
Pirtobrutinib	Infections	

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Jaypirca Prescribing Information, June 2024, Eli Lilly and Company.

26. Pirtobrutinib / Hemorrhage _____

Alert Message:Fatal and serious hemorrhage has occurred with Jaypirca (pirtobrutinib). Major hemorrhage occurred in 3% of 593 patients treated with pirtobrutinib.Bleeding of any grade, excluding bruising and petechiae, occurred in 17% of patients.Major hemorrhage occurred in 2.3% of patients taking pirtobrutinib without antithrombotic agents and 0.7% of patients taking pirtobrutinib with antithrombotic agents.Consider the risks and benefits of antithrombotic agents when co-administered with pirtobrutinib.Monitor patients for signs of bleeding.Based on the severity of bleeding, reduce the dose, temporarily withhold, or permanently discontinue pirtobrutinib.

Drugs/Diseases

Util A	Util B	Util C
Pirtobrutinib	Gastrointestinal hemorrhage	
	Hematemesis	
	Hematochezia	
	Intracerebral hemorrhage	
	Intracranial hemorrhage	
	Melena	

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Jaypirca Prescribing Information, June 2024, Eli Lilly and Company.

27. Pirtobrutinib / Cytopenias _____

Alert Message:Jaypirca (pirtobrutinib) can cause cytopenias, including neutropenia, thrombocytopenia, and anemia.In the clinical trial, Grade 3 or 4 cytopenias, including decreased neutrophils (26%), decreased platelets (12%), and decreased hemoglobin (12%) developed in patients treated with pirtobrutinib.Grade 4 decreased neutrophils developed in 14% of patients, and Grade 4 decreased platelets developed in 6% of patients.Monitor complete blood counts regularly during pirtobrutinib treatment.Based on severity, reduce the dose, temporarily withhold or permanently discontinue pirtobrutinib.

Drugs/Diseases

Util A	Util B	Util C
Pirtobrutinib	Neutropenia	
	Thrombocytopenia	
	Anemia	

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Jaypirca Prescribing Information, June 2024, Eli Lilly and Company.

28. Pirtobrutinib / Arrhythmias _____

Alert Message:Cardiac arrhythmias, including atrial fibrillation and atrial flutter, were reported in recipients receiving Jaypirca (pirtobrutinib).Atrial fibrillation or flutter were reported in 3.2% of patients, with Grade 3 or 4 atrial fibrillation or flutter reported in 1.5% of 593 patients in the clinical trial.Patients with cardiac risk factors, such as hypertension or previous arrhythmias, may be at increased risk.Monitor for signs and symptoms of arrhythmias (e.g., palpitations, dizziness, syncope, dyspnea) and manage appropriately.Based on severity, reduce the dose, temporarily withhold or permanently discontinue pirtobrutinib.

Drugs/Diseases

Util A	Util B	Util C
Pirtobrutinib	Arrhythmias	

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Jaypirca Prescribing Information, June 2024, Eli Lilly and Company.

29. Pirtobrutinib / Hepatotoxicity _____

Alert Message:Hepatotoxicity, including severe, life-threatening, and potentially fatal cases of drug-induced liver injury (DILI), has occurred in patients treated with Bruton tyrosine kinase inhibitors, including Jaypirca (pirtobrutinib).Evaluate bilirubin and transaminases at baseline and throughout treatment with pirtobrutinib.For patients who develop abnormal liver tests after pirtobrutinib, monitor more frequently for liver test abnormalities and clinical signs and symptoms of hepatic toxicity.If DILI is suspected, withhold pirtobrutinib.Upon confirmation of DILI, discontinue pirtobrutinib.

Drugs/Diseases

Util A	Util B	Util C
Pirtobrutinib	Abnormal Results of Liver Function Studies	
	Anorexia	
	Chronic Fatigue	
	Jaundice	
	Nausea	

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Jaypirca Prescribing Information, June 2024, Eli Lilly and Company.

30. Pirtobrutinib / Strong CYP3A4 Inhibitors _____

Alert Message:Avoid concomitant use of strong CYP3A inhibitors with Jaypirca (pirtobrutinib). If concomitant use of a strong CYP3A inhibitor is unavoidable, reduce the pirtobrutinib dose by 50 mg.If the current dosage is 50 mg once daily, interrupt pirtobrutinib treatment for the duration of strong CYP3A inhibitor use.After discontinuation of a strong CYP3A inhibitor for 5 half-lives, resume the pirtobrutinib dose that was taken prior to initiating the strong CYP3A inhibitor.

Drugs/Diseases

Util A	Util B		Util C
Pirtobrutinib	Clarithromycin	Nelfinavir	
	Cobicistat	Posaconazole	
	Itraconazole	Ritonavir	
	Ketoconazole	Voriconazole	
	Nefazodone		

Max Dose: 150 mg/day

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Jaypirca Prescribing Information, June 2024, Eli Lilly and Company.

31. Pirtobrutinib / Strong or Moderate CYP3A4 Inducers _____

Alert Message:Avoid concomitant use of strong or moderate CYP3A inducers with Jaypirca (pirtobrutinib).If concomitant use with moderate CYP3A inducers is unavoidable and the current dosage of pirtobrutinib is 200 mg once daily, increase the dose to 300 mg.If the current dosage is 50 mg or 100 mg once daily, increase the dose by 50 mg.

Drugs/Diseases

Util A	Util B		Util C
Pirtobrutinib	Apalutamide	Phenytoin	
	Bosentan	Primidone	
	Carbamazepine	Rifabutin	
	Efavirenz	Rifampin	
	Etravirine	Rifapentine	
	Phenobarbital		

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.

32. Pirtobrutinib / Sensitive CYP2C8, 2C19, 3A, P-gp, & BCRP Substrates _____

Alert Message:Jaypirca (pirtobrutinib) is a P-gp inhibitor, a moderate CYP2C8 and BCRP inhibitor, and a weak CYP2C19 and CYP3A inhibitor.Concomitant use of pirtobrutinib with sensitive P-gp, CYP2C8, BCRP, CYP2C19, or CYP3A substrates increases the substrate plasma concentrations, which may increase the risk of substrate-related adverse reactions. Follow the recommendations for sensitive CYP2C8, CYP2C19, CYP3A, P-gp, or BCRP substrates provided in their approved product labeling.

Drugs/Diseases

Util A	Util B	Util C
Pirtobrutinib	Buspirone	
	Citalopram	
	Cyclosporine	
	Edoxaban	
	Everolimus	
	Felodipine	
	Dabigatran	
	Digoxin	
	Lonafarnib	
	Sirolimus	
	Tacrolimus	
	Triazolam	
	Warfarin	

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.

33. Pirtobrutinib / Antithrombotic Agents _____

Alert Message:Consider the risks and benefits of antithrombotic agents when co-administered with Jaypirca (pirtobrutinib).In a clinical trial, major hemorrhage occurred in 3% of 593 patients treated with pirtobrutinib.Monitor patients for signs of bleeding.Based on the severity of bleeding, reduce the dose, temporarily withhold, or permanently discontinue pirtobrutinib.

Drugs/Diseases

Util A	Util B	Util C
Pirtobrutinib	ApixabanFondaparinux	
	DabigatranHeparin	
	DalteparinRivaroxaban	
	EdoxabanWarfarin	
	Enoxaparin	

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Jaypirca Prescribing Information, June 2024, Eli Lilly and Company.

34. Pirtobrutinib / Pregnancy / Pregnancy Negating _____

Alert Message:Based on findings from animal studies, Jaypirca (pirtobrutinib) can cause fetal harm when administered to a pregnant woman.There are no available data on pirtobrutinib use in pregnant women to evaluate for a drug-associated risk.In an animal reproduction study, administration of pirtobrutinib to pregnant rats during organogenesis resulted in adverse developmental outcomes at maternal exposures approximately 3-times those in patients at the recommended daily dose of 200 mg.Advise pregnant women of the potential risk to a fetus.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Pirtobrutinib	Pregnancy	Abortion
		Delivery
		Miscarriage

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Jaypirca Prescribing Information, June 2024, Eli Lilly and Company.

35.Pirtobrutinib / Lactation _____

Alert Message:There are no data on the presence of Jaypirca (pirtobrutinib) in human milk or the effects on the breastfed child or milk production.Because of the potential for serious adverse reactions in the breastfed child, advise women not to breastfeed during treatment with pirtobrutinib and for one week after the last dose.

Drugs/Diseases

Util A	Util B	Util C
Pirtobrutinib	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Jaypirca Prescribing Information, June 2024, Eli Lilly and Company.

36. Pirtobrutinib / Non-adherence _____

Alert Message:Based on refill history, your patient may be under-utilizing Jaypirca (pirtobrutinib). Nonadherence to the prescribed dosing regimen may result in subtherapeutic effects, which may lead to decreased patient outcomes and additional healthcare costs.

Drugs/Diseases

Util A	Util B	Util C
Pirtobrutinib		

References:

Osterberg L, Blaschke T. Adherence to Medication. N Engl J Med 2005; 353:487- 497.
Ruddy K, Mayer E, Partridge A. Patient Adherence and Persistence With Oral Anticancer Treatment. CA Cancer J Clin 2009;59:56-66.
Barillet M, Prevost V, Joly F, Clarisse B. Oral Antineoplastic Agents: How do We Care About Adherence?. Br J Clin Pharmacol. 2015;80(6):1289–1302. doi:10.1111/bcp.12734
Greer JA, Amoyal N, Nisotel L, et al. Systemic Review of Adherence to Oral Antineoplastic Therapies. The Oncologist. 2016;21:354-376.

37. Tovorafenib / Hemorrhage _____

Alert Message:Major hemorrhagic events can occur during treatment with Ojemda (tovorafenib). Monitor for signs and symptoms of hemorrhage and evaluate as clinically indicated.Withhold, resume at reduced dose, or permanently discontinue tovorafenib based on severity.

Drugs/Diseases

Util A	Util B	Util C
Tovorafenib	Gastrointestinal hemorrhage	
	Hematemesis	
	Hematochezia	
	Intracerebral hemorrhage	
	Intracranial hemorrhage	
	Melena	

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Ojemda Prescribing Information, June 2024, Day One Biopharmaceuticals.

38. Tovorafenib / Hepatotoxicity _____

Alert Message:Ojemda (tovorafenib) can cause hepatotoxicity.Monitor liver function tests, including ALT, AST, and bilirubin, before initiation of tovorafenib, one month after initiation, and then every three months thereafter, and as clinically indicated.Withhold and resume at the same or reduced dose upon improvement, or permanently discontinue tovorafenib based on the severity.

Drugs/Diseases

Util A	Util B	Util C
Tovorafenib	Abnormal Results of Liver Function Studies	
	Anorexia	
	Chronic Fatigue	
	Jaundice	
	Nausea	

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Ojemda Prescribing Information, June 2024, Day One Biopharmaceuticals.

39. Tovorafenib / Moderate & Strong CYP2C8 Inhibitors _____

Alert Message:Avoid coadministration of Ojemda (tovorafenib) with strong or moderate CYP2C8 inhibitors.Tovorafenib is a CYP2C8 substrate.Strong or moderate CYP2C8 inhibitors are predicted to increase tovorafenib exposure based on a mechanistic understanding of its elimination, which may increase the risk of adverse reactions with tovorafenib.

Drugs/Diseases

Util A	Util B	Util C
Tovorafenib	Gemfibrozil	
	Clopidogrel	
	Deferasirox	
	Teriflunomide	

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Ojemda Prescribing Information, June 2024, Day One Biopharmaceuticals.

40. Tovorafenib / Moderate & Strong CYP2C8 Inducers _____

Alert Message:Avoid coadministration of Ojemda (tovorafenib) with strong or moderate CYP2C8 inducers.Tovorafenib is a CYP2C8 substrate.Strong or moderate CYP2C8 inducers are predicted to decrease tovorafenib exposure based on a mechanistic understanding of its elimination, which may reduce the effectiveness of tovorafenib.

Drugs/Diseases

Util A	Util B	Util C
Tovorafenib	Rifampin	

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Ojemda Prescribing Information, June 2024, Day One Biopharmaceuticals.

41. Tovorafenib / Sensitive CYP3A Substrates _____

Alert Message:Avoid coadministration of Ojemda (tovorafenib) with certain CYP3A substrates where minimal concentration changes may lead to serious therapeutic failures.Tovorafenib is a CYP3A inducer.If coadministration is unavoidable, monitor patients for loss of efficacy of the substrate drug unless otherwise recommended in the Prescribing Information for CYP3A substrates.

Drugs/Diseases

Util A	Util B					Util C
Tovorafenib	Avanafil	Eletriptan	Lurasidone	Simvastatin	Vardenafil	
	Budesonide	Eplerenone	Maraviroc	Sirolimus		
	Buspirone	Everolimus	Midazolam	Tacrolimus		
	Conivaptan	Felodipine	Naloxegol	Ticagrelor		
	Darifenacin	Ibrutinib	Nisoldipine	Tipranavir		
	Darunavir	Lomitapide	Quetiapine	Tolvaptan		
	Dronedarone	Lovastatin	Sildenafil	Triazolam		

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Ojemda Prescribing Information, June 2024, Day One Biopharmaceuticals.

42. Tovorafenib / Hormonal Contraceptives _____

Alert Message:Avoid coadministration of hormonal contraceptives with Ojemda (tovorafenib). Tovorafenib is a CYP3A inducer, and hormonal contraceptives are CYP3A substrates. Concurrent use of these agents may lead to therapeutic failure of the CYP3A hormonal contraceptives.If coadministration is unavoidable, use an additional effective nonhormonal contraceptive method during coadministration and for 28 days after discontinuation of tovorafenib.

Drugs/Diseases

Util A	Util B	Util C
Tovorafenib	Hormonal Contraceptives	

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Ojemda Prescribing Information, June 2024, Day One Biopharmaceuticals.

43. Tovorafenib / Pregnancy / Pregnancy Negating _____

Alert Message:Based on findings from animal studies and its mechanism of action, Ojemda (tovorafenib) can cause fetal harm when administered to a pregnant woman.There are no available data on the use of tovorafenib in pregnant women.Advise pregnant women of the potential risk to a fetus.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Tovorafenib	Pregnancy	Abortion
		Delivery
		Miscarriage

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Ojemda Prescribing Information, June 2024, Day One Biopharmaceuticals.

44. Tovorafenib / Lactation _____

Alert Message:There are no data on the presence of Ojemda (tovorafenib) or its metabolites in human milk, their effects on the breastfed child, or milk production.Due to the potential for serious adverse reactions in breastfed children from tovorafenib, advise lactating women not to breastfeed during treatment with tovorafenib and for 2 weeks following the last dose.

Drugs/Diseases

Util A	Util B	Util C
Tovorafenib	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Ojemda Prescribing Information, June 2024, Day One Biopharmaceuticals.

Criteria Recommendations ***Approved Rejected***

45. Tovorafenib / Reproductive Potential _____
Alert Message:Advise females of reproductive potential to use effective nonhormonal contraception during treatment with Ojemda (tovorafenib) and for 28 days after the last dose. Tovorafenib can render hormonal contraceptives ineffective.Tovorafenib can cause fetal harm when administered to a pregnant woman.

Drugs/Diseases

Util A	Util B	Util C (Negating)
Tovorafenib		Non-Hormonal Contraception

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Ojemda Prescribing Information, June 2024, Day One Biopharmaceuticals.

46. Tovorafenib / Reproductive Potential _____
Alert Message:Advise male patients with female partners of reproductive potential to use effective nonhormonal contraception during treatment with Ojemda (tovorafenib) and for 2 weeks after the last dose.

Drugs/Diseases

Util A	Util B	Util C
Tovorafenib		

Gender: Male

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Ojemda Prescribing Information, June 2024, Day One Biopharmaceuticals.

47. Tovorafenib / Non-adherence _____
Alert Message:Based on refill history, your patient may be under-utilizing Ojemda (tovorafenib). Nonadherence to the prescribed dosing regimen may result in subtherapeutic effects, which may lead to decreased patient outcomes and additional healthcare costs.

Drugs/Diseases

Util A	Util B	Util C
Tovorafenib		

References:
Osterberg L, Blaschke T. Adherence to Medication. N Engl J Med 2005; 353:487- 497.
Ruddy K, Mayer E, Partridge A. Patient Adherence and Persistence With Oral Anticancer Treatment. CA Cancer J Clin 2009;59:56-66.
Barillet M, Prevost V, Joly F, Clarisse B. Oral Antineoplastic Agents: How do We Care About Adherence?. Br J Clin Pharmacol. 2015;80(6):1289–1302. doi:10.1111/bcp.12734
Greer JA, Amoyal N, Nisotel L, et al. Systemic Review of Adherence to Oral Antineoplastic Therapies. The Oncologist. 2016;21:354-376.

Criteria Recommendations ***Approved Rejected***

48. Pitolisant / Overuse - Pediatric _____

Alert Message:The recommended maximum dose of Wakix (pitolisant) for the treatment of excessive daytime sleepiness in pediatric patients 6 years of age and older weighing 40 kg or more with narcolepsy is 35.6 mg orally once daily in the morning upon wakening.For pediatric patients under 40 kg, the maximum dose is 17.8 mg once daily.

Drugs/Diseases

Util A	Util B	Util C (Negating)
Pitolisant		Hepatic Impairment
		CKD Stage 3, 4, & 5

Max Dose:35.6 mg/day

Age Range: 6 – 17 yoa

References:

Wakix Prescribing Information, June 2024, Harmony Biosciences.

49. Pitolisant / Overutilization – Hepatic Impairment _____

Alert Message:Wakix (pitolisant) may be overutilized.Pitolisant is extensively metabolized by the liver, and there is a significant increase in pitolisant exposure in patients with moderate hepatic impairment. For pediatric patients 6 years and older, weighing 40 kg or more with moderate hepatic impairment, pitolisant should be initiated at 4.45 mg once daily and increased after 14 days to 8.9 mg once daily.The dose may increase after another 14 days to a maximum of 17.8 mg daily.For pediatric patients 6 and older, weighing less than 40 kg, pitolisant should be initiated at 4.45 mg once daily, then increased after 14 days to a maximum of 8.9 mg once daily.

Drugs/Diseases

Util A	Util B	Util C (Include)
Pitolisant		Hepatic Impairment

Max Dose:17.8 mg/day

Age Range: 6 – 17 yoa

References:

Wakix Prescribing Information, June 2024, Harmony Biosciences.

50. Pitolisant / Overutilization – Mod. To Sev. Renal Impairment _____

Alert Message:Wakix (pitolisant) may be over-utilized.Dosage adjustment for pitolisant is recommended in pediatric patients with moderate to severe renal impairment.For pediatric patients 6 years of age and older, weighing 40 kg or more with an eGFR < 60 ml/min/1.73m2, pitolisant should be initiated at 4.45 mg once daily and increased after 7 days to 8.9 mg once daily.The dose may be increased after another 7 days to a maximum of 17.8 mg once daily. For those patients weighing less than 40 kg with an eGFR < 60 ml/min/1.73m2, pitolisant should be initiated at 4.45 mg once daily and increased after 7 days to a maximum dosage of 8.9 mg once daily.

Drugs/Diseases

Util A	Util B	Util C (Include)
Pitolisant		CKD Stage 3, 4 & 5

Max Dose: 8.9 mg/day

Age Range: 6 – 17 yoa

References:

Wakix Prescribing Information, June 2024, Harmony Biosciences.

51. Aprocitentan / Overuse _____

Alert Message:Tryvio (aprocitentan) may be over-utilized.The recommended dosage of aprocitentan is 12.5 mg once daily.

Drugs/Diseases

Util A	Util B	Util C
Aprocitentan		

Max Dose: 12.5 mg/day

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Tryvio Prescribing Information, March 2024, Idorsia Pharmaceuticals Ltd.

52. Aprocitentan / Therapeutic Appropriateness _____

Alert Message:The safety and efficacy of Tryvio (aprocitentan) in pediatric patients have not been established.

Drugs/Diseases

Util A	Util B	Util C
Aprocitentan		

Age Range: 0 – 17 yoa

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Tryvio Prescribing Information, March 2024, Idorsia Pharmaceuticals Ltd.

53. Aprocitentan / Therapeutic Appropriateness _____

Alert Message:Tryvio (aprocitentan) is not recommended in patients with kidney failure (eGFR < 15 ml/min) or on dialysis.The effect of kidney failure (eGFR < 15 mL/min) or dialysis on aprocitentan pharmacokinetics is unknown.Patients with renal impairment are at increased risk of edema/fluid retention.

Drugs/Diseases

Util A	Util B	Util C
Aprocitentan	CKD Stage 5	
	ESRD	
	Dialysis	

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Tryvio Prescribing Information, March 2024, Idorsia Pharmaceuticals Ltd.

54. Aprocitentan / Moderate to Severe Hepatic Impairment _____

Alert Message:Tryvio (aprocitentan) is not recommended in patients with moderate and severe hepatic impairment (Child-Pugh Class B and C) because these patients may be at increased risk for poor outcomes from hepatotoxicity.Elevations of aminotransferases and hepatotoxicity are known effects of endothelin receptor antagonists (ERAs).

Drugs/Diseases

Util A	Util B	Util C
Aprocitentan	Cirrhosis	
	Liver Failure	

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Tryvio Prescribing Information, March 2024, Idorsia Pharmaceuticals Ltd.

55. Aprocitentan / Fluid Retention _____

Alert Message:Fluid retention and peripheral edema are known effects of endothelin receptor antagonists (ERAs), including Tryvio (aprocitentan).Monitor the patient for signs and symptoms of fluid retention, weight gain, and worsening heart failure.If clinically significant fluid retention develops, treat appropriately, and consider discontinuation of aprocitentan.

Drugs/Diseases

Util A	Util B	Util C
Aprocitentan	Fluid Retention	
	Peripheral Edema	

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Tryvio Prescribing Information, March 2024, Idorsia Pharmaceuticals Ltd.

56. Aprocitentan / Heart Failure _____

Alert Message:Tryvio (aprocitentan) has not been studied in patients with heart failure New York Heart Association stage III-IV, unstable cardiac function, or with NTproBNP >/= 500 pg/mL.The use of aprocitentan is not recommended in these patients because aprocitentan can cause fluid retention and peripheral edema.

Drugs/Diseases

Util A	Util B	Util C
Aprocitentan	Heart failure	

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Tryvio Prescribing Information, March 2024, Idorsia Pharmaceuticals Ltd.

57. Aprocitentan / Pregnancy / Pregnancy Negating (Box Warning) _____

Alert Message:The use of Tryvio (aprocitentan) is contraindicated in pregnancy.Aprocitentan can cause fetal harm, including birth defects and fetal death, when administered during pregnancy.To prevent pregnancy, patients who can become pregnant should use acceptable contraception prior to initiation of treatment, during treatment, and for one month after discontinuation of treatment with aprocitentan.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Aprocitentan	Pregnancy	Abortion
		Delivery
		Miscarriage

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Tryvio Prescribing Information, March 2024, Idorsia Pharmaceuticals Ltd.

58. Aprocitentan / Lactation _____

Alert Message:There are no data on the presence of Tryvio (aprocitentan) in human milk, the effects on the breastfed infant, or the effect on milk production.In rats, aprocitentan was excreted into milk during lactation.When a drug is present in animal milk, the drug will likely be present in human milk.Because of the potential for serious adverse reactions in breastfed infants, advise women not to breastfeed during treatment with aprocitentan.

Drugs/Diseases

Util A	Util B	Util C
Aprocitentan	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Tryvio Prescribing Information, March 2024, Idorsia Pharmaceuticals Ltd.

59. Aprocitentan / Therapeutic Appropriateness (Box Warning) _____

Alert Message:Patients using Tryvio (aprocitentan) who can become pregnant should use acceptable contraception prior to initiation of treatment, during treatment, and for one month after discontinuation of treatment with aprocitentan.Aprocitentan can cause fetal harm, including birth defects and fetal death.

Drugs/Diseases

Util A	Util B	Util C(Negate)
Aprocitentan		Contraceptives

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Tryvio Prescribing Information, March 2024, Idorsia Pharmaceuticals Ltd.

60. Aprocitentan / Non-adherence _____

Alert Message:Based on refill history, your patient may be under-utilizing Tryvio (aprocitentan). Nonadherence to the prescribed dosing regimen may result in subtherapeutic effects, which may lead to decreased patient outcomes and additional healthcare costs.

Drugs/Diseases

Util A	Util B	Util C
Aprocitentan		

References:
Osterberg L, Blaschke T. Adherence to Medication. N Engl J Med 2005; 353:487- 497.
Munger MA, Van Tassell BW, La Fleur J, Medication Nonadherence: An Unrecognized Cardiovascular Risk Factor. MedGenMed. Sep. 2007;19;9(3):58.

Bitton A, Choudhry NK, Matlin OS, et al., The Impact of Medication Adherence on Coronary Artery Disease Costs and Outcomes: A Systematic Review. Am J Med. 2013 Apr;126(4):357.e7-357.e27.

Kim J, Combs K, Downs J, Tillman F., Medication Adherence: The Elephant in the Room. US Pharm. 2018;43(1)30-34.

61. Zilucoplan / Overuse _____

Alert Message:Zilbrysq (zilucoplan) may be over-utilized.The recommended dosage of zilucoplan is given once daily as a subcutaneous injection and is dependent on actual body weight.Patients weighing less than 56 kg should receive one 16.6 mg subq injection per day. Those patients weighing 56 to 77 kg should receive one 23 mg subq injection daily, and patients weighing 77kg or more should receive one 32.4 mg subq injection.

Drugs/Diseases

Util A	Util B	Util C
Zilucoplan		

Max Dose: 32.4 mg/ml per day

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Zilbrysq Prescribing Information, April 2024, UCB, Inc.

62. Zilucoplan / Therapeutic Appropriateness _____

Alert Message:The safety and effectiveness of Zilbrysq (zilucoplan) in pediatric patients have not been established.

Drugs/Diseases

Util A	Util B	Util C
Zilucoplan		

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Zilbrysq Prescribing Information, April 2024, UCB, Inc.

63. Zilucoplan / Therapeutic Appropriateness _____

Alert Message:Zilbrysq (zilucoplan) is contraindicated in patients with unresolved Neisseria meningitidis infection.The use of zilucoplan, a complement inhibitor, increases a patient's susceptibility to serious and life-threatening meningococcal infections (septicemia and/or meningitis) caused by any serogroup, including non-groupable strains.

Drugs/Diseases

Util A	Util B	Util C
Zilucoplan	Meningococcal Infection	

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Zilbrysq Prescribing Information, April 2024, UCB, Inc.

64. Zilucoplan / Infections _____

Alert Message:Patients receiving Zilbrysq (zilucoplan) are at increased risk for infections due to these bacteria, even after vaccination.Zilucoplan blocks terminal complement activation; therefore, patients may have increased susceptibility to infections, especially with encapsulated bacteria.

Drugs/Diseases

Util A	Util B	Util C
Zilucoplan	Infections	

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Zilbrysq Prescribing Information, April 2024, UCB, Inc.

65. Zilucoplan / Pancreatitis & Pancreatic Cysts _____

Alert Message:Pancreatitis and pancreatic cysts have been reported in patients treated with Zilbrysq (zilucoplan).During the open-label extension studies, seven (3.3%) patients experienced pancreatic events, including 4 (1.9%) patients with pancreatitis and 3 (1.4%) with pancreatic cysts.Discontinue zilucoplan in patients with suspected pancreatitis and initiate appropriate management until pancreatitis is ruled out or has resolved.

Drugs/Diseases

Util A	Util B	Util C
Zilucoplan	Cysts of the Pancreas	
	Pancreatitis	

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Zilbrysq Prescribing Information, April 2024, UCB, Inc.

66. Zilucoplan / Pregnancy / Pregnancy Negating _____

Alert Message:There are no available data on Zilbrysq (zilucoplan) use in pregnant women to evaluate for a drug-associated risk of major birth defects, miscarriage, or other adverse maternal or fetal outcomes.Based on animal data, zilucoplan may cause fetal harm. Administration of zilucoplan to pregnant monkeys resulted in increases in embryofetal death at maternal exposures similar to those in humans at therapeutic doses.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Zilucoplan	Pregnancy	Abortion
		Delivery
		Miscarriage

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Zilbrysq Prescribing Information, April 2024, UCB, Inc.

67. Zilucoplan / Lactation _____

Alert Message:There are no data on the presence of Zilbrysq (zilucoplan) in human milk, the effects on the breastfed infant, or the effects on milk production.The developmental and health benefits of breastfeeding should be considered, along with the mother's clinical need for zilucoplan and any potential adverse effects on the breastfed infant from zilucoplan or the underlying maternal condition.

Drugs/Diseases

Util A	Util B	Util C
Zilucoplan	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Zilbrysq Prescribing Information, April 2024, UCB, Inc.

Criteria Recommendations	*Approved Rejected*

68. Zilucoplan / Non-adherence _____

Alert Message:Based on refill history, your patient may be under-utilizing Zilbrysq (zilucoplan). Nonadherence to the prescribed dosing regimen may result in subtherapeutic effects, which may lead to decreased patient outcomes and additional healthcare costs.

Drugs/Diseases

Util A	Util B	Util C
Zilucoplan		

References:
Osterberg L, Blaschke T. Adherence to Medication. N Engl J Med 2005; 353:487- 497.
Kim J, Combs K, Downs J, Tillman F., Medication Adherence: The Elephant in the Room. US Pharm. 2018;43(1)30-34.

Su Y, Wang X, Xing Y, et al. The Analysis of Factors Affecting Medication Adherence in Patients with Myasthenia Gravis: A Cross-Sectional Study. Therapeutic Advances in Neurological Disorders. 2024;17. doi:10.1177/17562864231206877