

**North Dakota Medicaid
Drug Utilization Review Board Meeting
March 5, 2025
Conference Room 210/212**

Meeting Notice

North Dakota Medicaid Drug Use Review Board

Wednesday, March 5th, 2025

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: 431 451 256#

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:
 - o Prior Authorization Update
 - o Criteria updates: Amyloidosis, GLP-1 Receptor Agonist Combinations, Metabolic Dysfunction-Associated Steatohepatitis, Parkinson's Disease
5. Unfinished Business: Infantile Hemangioma, Rescue Inhalers
6. New business
 - First Review of Diabetes Mellitus
 - Second Review of Migraine Prophylaxis and Treatment
 - Second Review of Nonsteroidal Anti-Inflammatory Drugs
 - Second Review of Primary Biliary Cholangitis
 - Review of retrospective DUR criteria recommendations
7. Announcements: Next Meeting (June 4, 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: December 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 1:04 pm CST with K. Martian 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, Amy Werremeyer, Jessica Ziegler

Absent: Tanya Schmidt

Quorum Present: Yes

Board Members Non-Voting:

Absent: Kathleen Traylor

Medicaid Pharmacy Department:

Present: Jeff Hostetter, Brendan Joyce, Alexi Murphy, LeNeika Roehrich, Katie Steig

Approval of Meeting Minutes:

Motion: Moved by K. Datz to approve the minutes of the September 4th, 2024 meeting, motion was seconded by A. Werremeyer. **Motion carried.**

The minutes of the September 4th, 2024 meeting were approved as distributed.

Reports:

Administrative Report: provided by A. Murphy

A. Murphy introduced new pharmacist K. Steig and member J. Ziegler. A. Murphy discussed DUR board member vacant positions and updates regarding legislative session and new governor start dates.

Financial Report: Budget provided by B. Joyce

B. Joyce shared with the Board trends of reimbursement amount vs net spend for pharmacy drug claims. 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 and information from a targeted mailing. This material can be found in the handout.

Clinical Report and Annual PDL Review: 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: Amyloidosis, COPD/Asthma, Secondary Hyperparathyroidism, and Annual PDL Review. Testimony was provided by Arnele Mejia from Pierre Fabre Pharmaceuticals on Hemangeol, Jasmine Inman from Teva on Austedo, and Sunny Hirpara from Astrazeneca on Airsupra.

Unfinished business: provided by C. Stauter

C. Stauter provided updates on alternative RDUR communication tools. 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 attention-deficit hyperactivity disorder stimulants

Motion: Moved by K. Martian to place attention-deficit hyperactivity disorder stimulants on prior authorization, motion was seconded by K. Datz. **Motion carried.**

First Reviews presented by C. Stauter and J McKee

C. Stauter presented an overview of migraine prophylaxis and treatment and NSAIDs. J. McKee presented an overview of primary biliary cholangitis. The presented material can be found in the handout. Testimony was provided by Jasmine Inman from Teva on Ajovy, Craig Fjeldheim from Abbvie on Qulipta, and Porscha Showers from Gilead on Livdelzi.

Motion: Moved by A. Werremeyer to draft prior authorization for migraine prophylaxis and treatment, motion was seconded by A. Honeyman. **Motion carried.**

Motion: Moved by A. Werremeyer to draft prior authorization for NSAIDs, motion was seconded by A. Dahl. **Motion carried.**

Motion: Moved by K. Martian to draft prior authorization primary biliary cholangitis, 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. Peterson to approve the RDUR criteria, motion was seconded by S. Antony. **Motion carried.**

Announcements:

Next meeting is March 5th, 2025.

Adjournment:

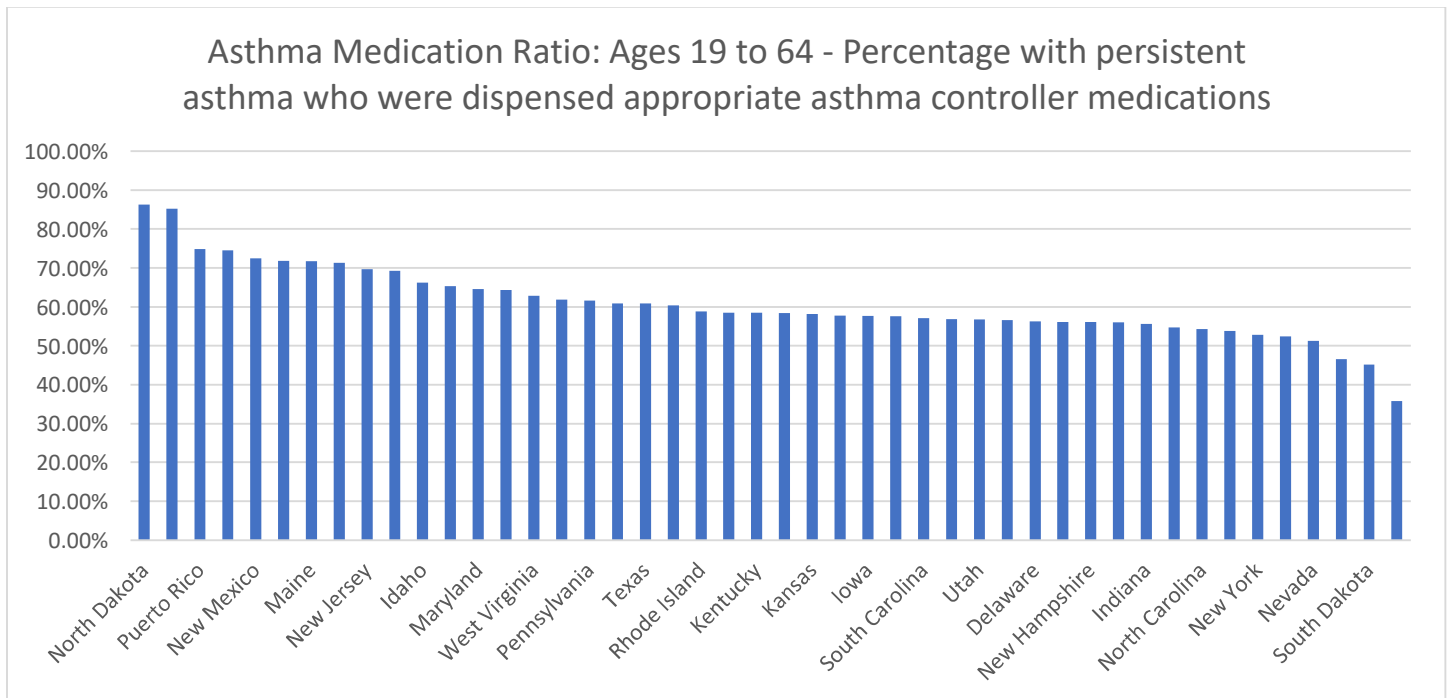
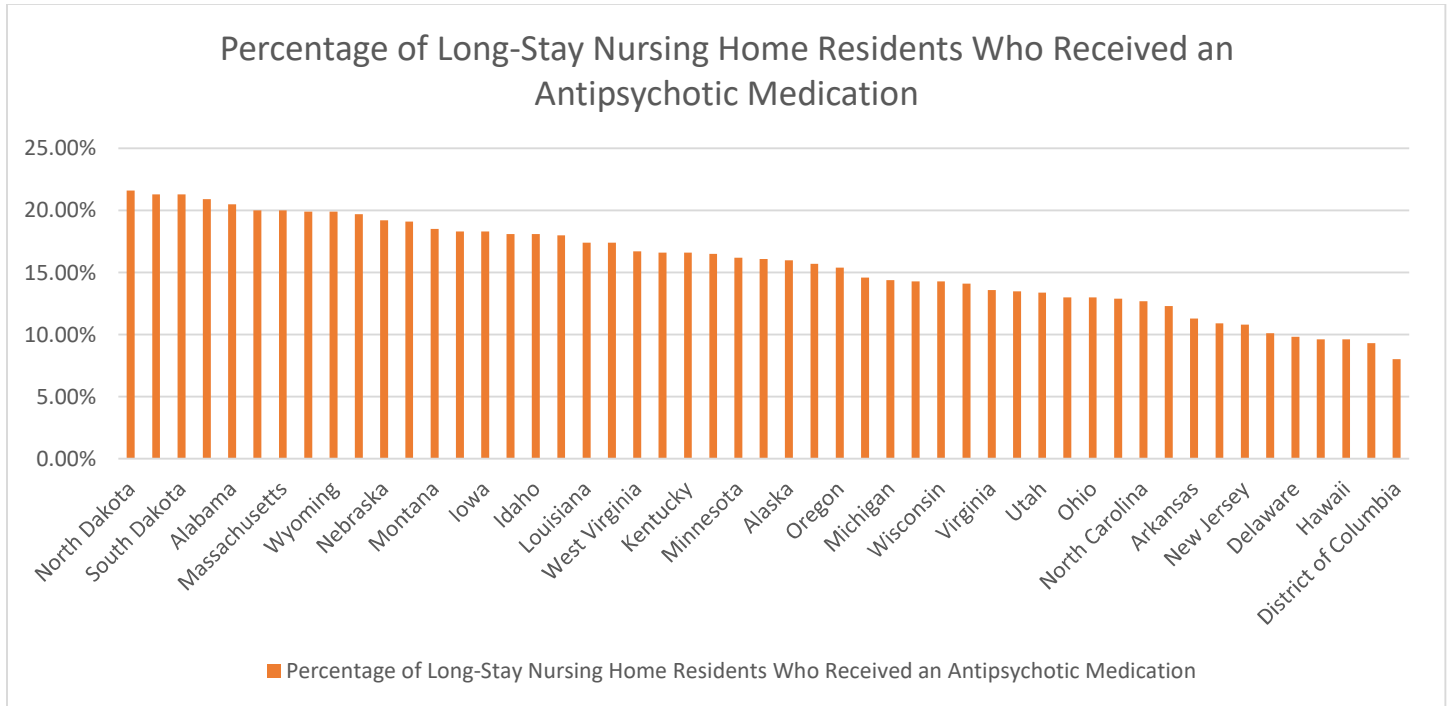
Meeting adjourned by K. Martian at 2:13 pm CST.

Date of Minutes Approval:

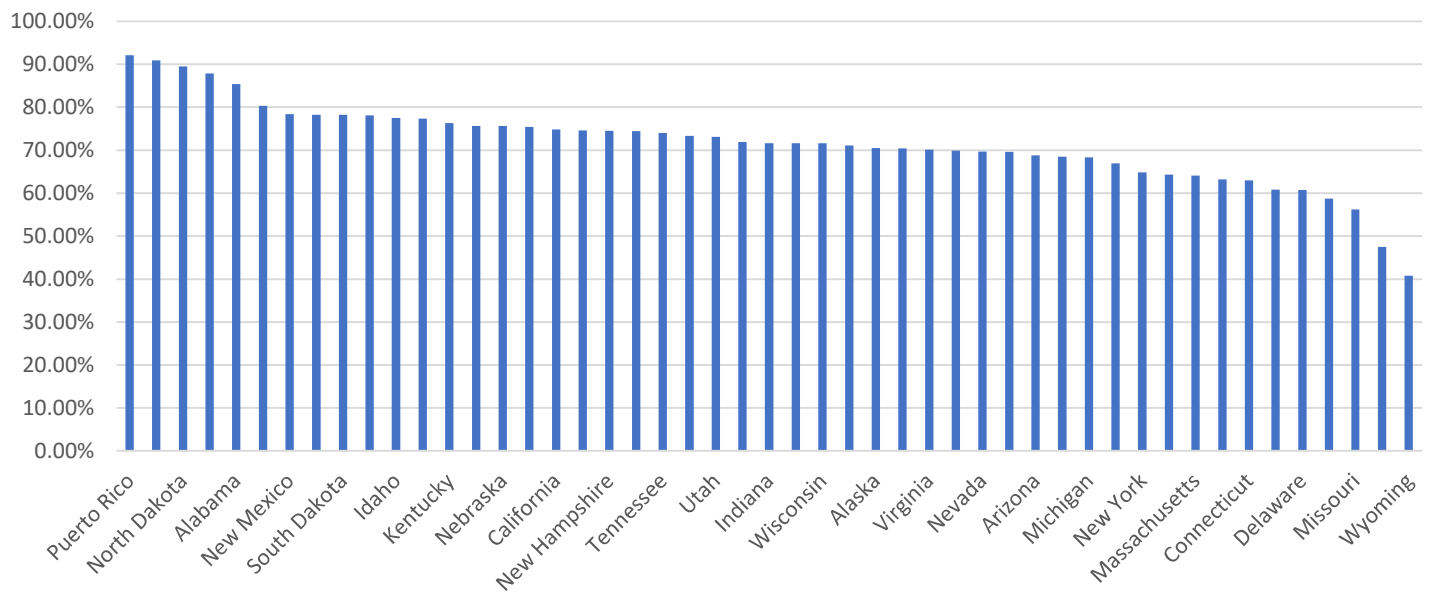
Minutes submitted by: Julie McKee, Acentra Health

Administrative Report

[Medicaid and CHIP Scorecard - Explore data](#)



Asthma Medication Ratio: Ages 5 to 18 - Percentage with persistent asthma who were dispensed appropriate asthma controller medications

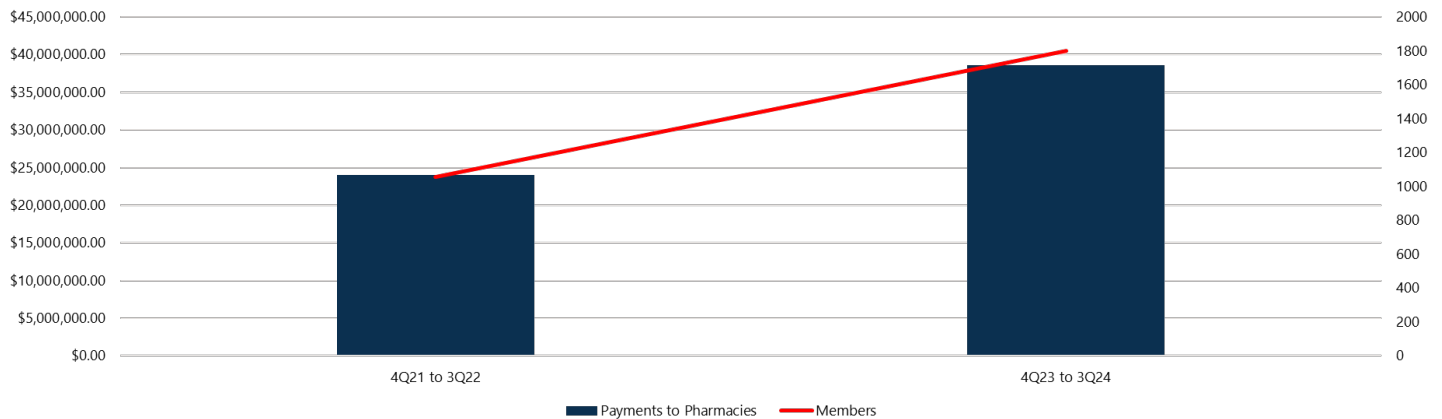


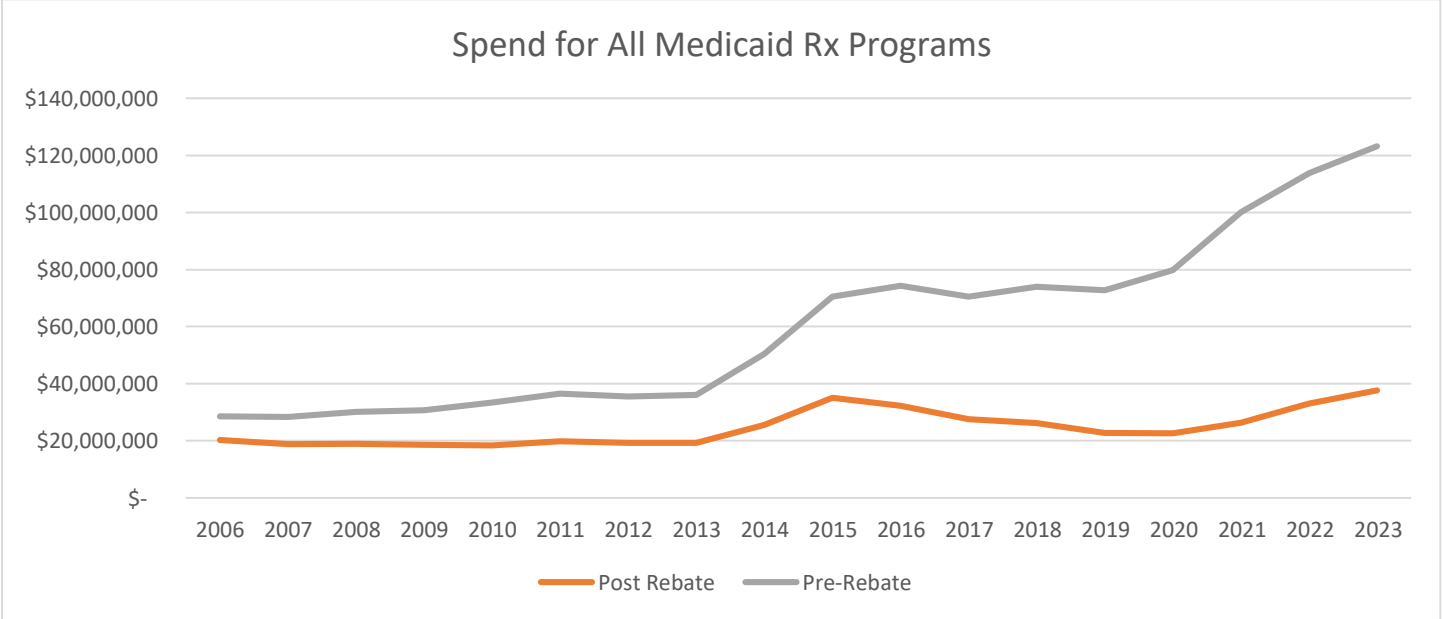
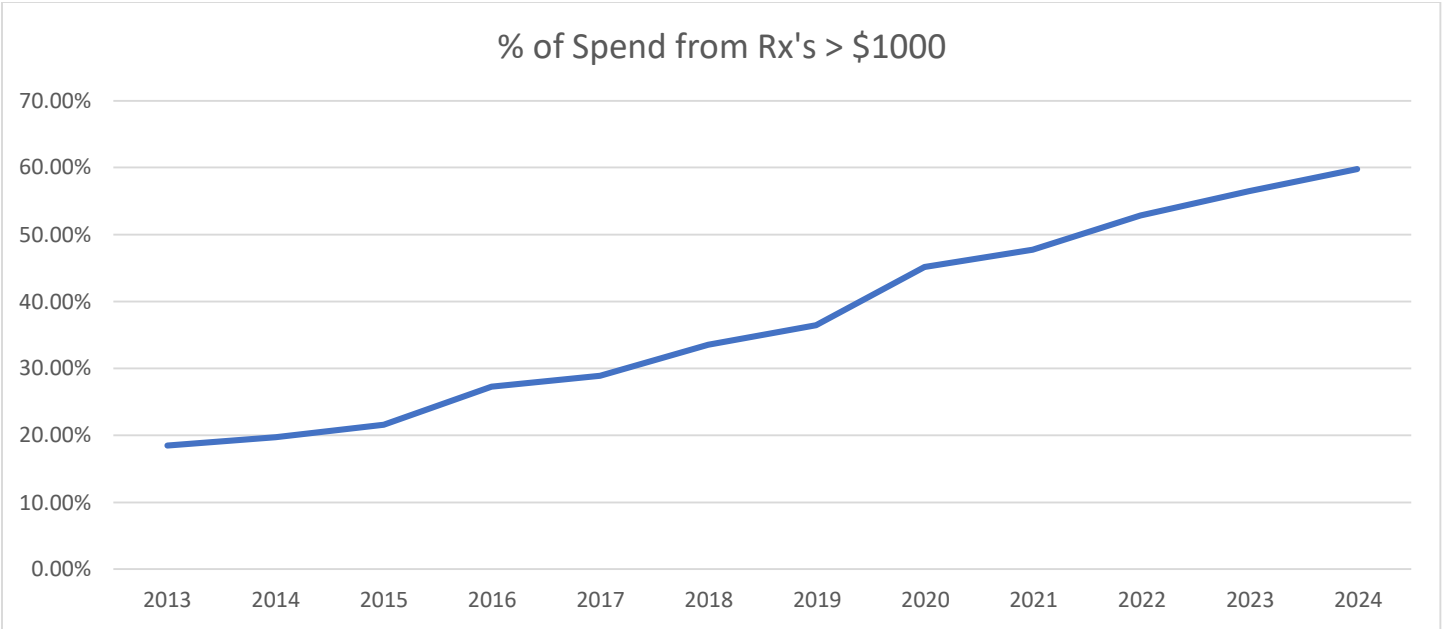
Financial Report

- **6 Drug Classes:** 6 drug classes make up 36.3% of the drug budget (4Q23 to 3Q24):
 - o Cystic Fibrosis, Immunomodulators, Migraine, Non-Insulin Diabetes, Pulmonary Hypertension, Tardive Dyskinesia
 - o Spend for these classes increased by 138% between 1Q2020 and 3Q2024 to \$10 million per quarter
 - o During the same period, claims volume for drugs in these classes only increased by 14%
- **50 Hyper-Cost Drugs:** 50 hyper-cost drugs make up 33.7% of the drug budget (4Q23 to 3Q24):
 - o Over \$950,000 spent on 22 claims from 4Q23 to 3Q24 on just 3 drugs: Daybue, Gattex, and Oxervate

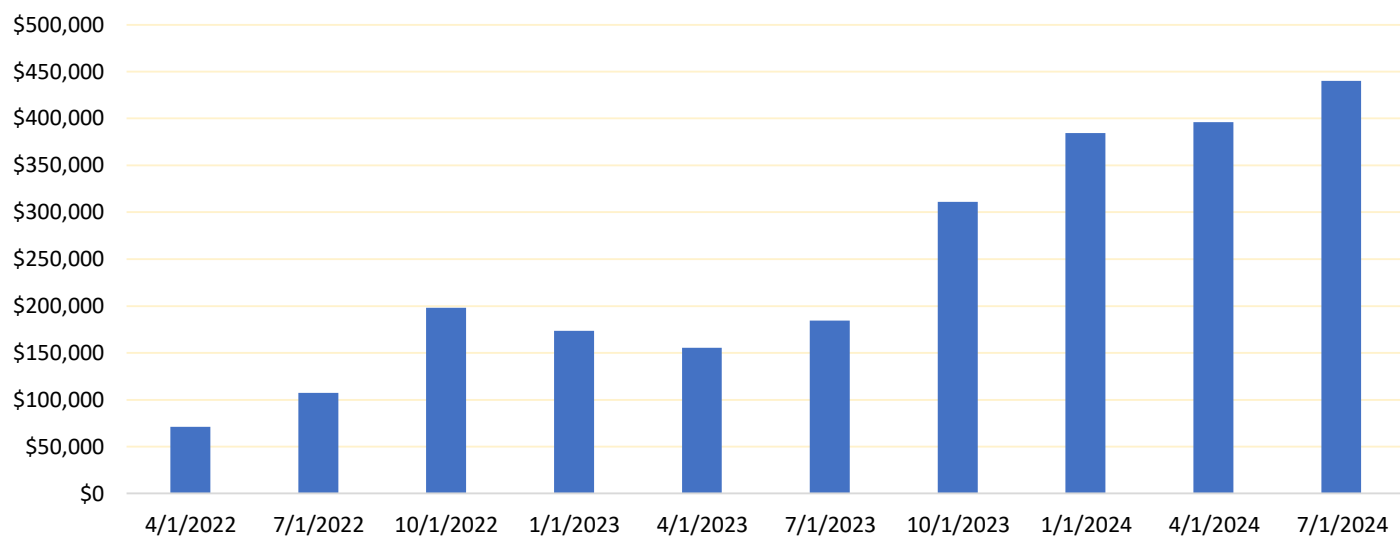
For the same 50 hyper-cost drugs:

- Over \$24.0 million spend for 1058 members in 4Q21 to 3Q22
- Over \$38.5 million spend for 1799 members in 4Q23 to 3Q24

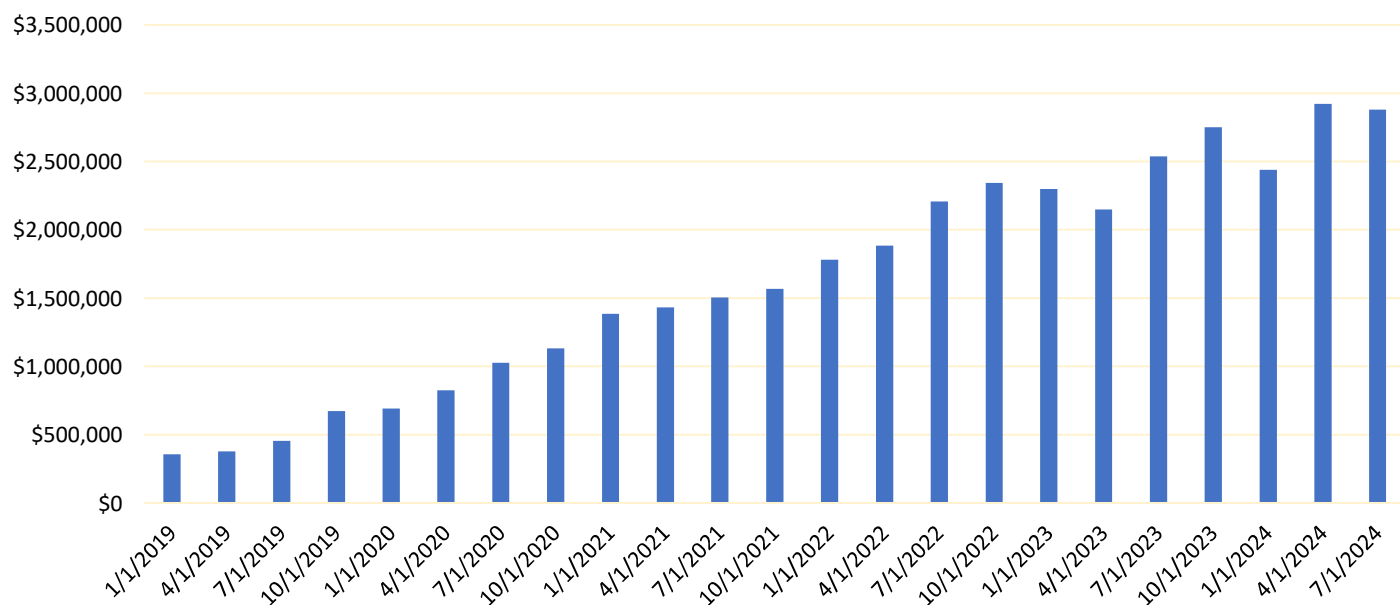




Post-Rebate Spend in Drug Classes Experiencing Shortages

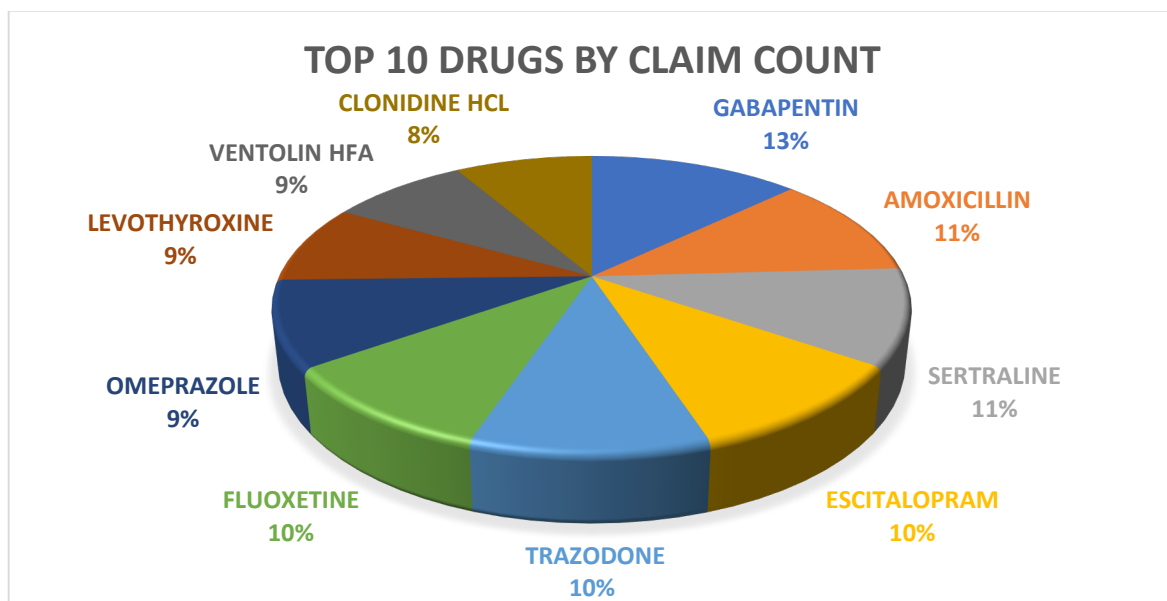


Post-Rebate Spend increased over 800% in 5+ Cost Driver Classes



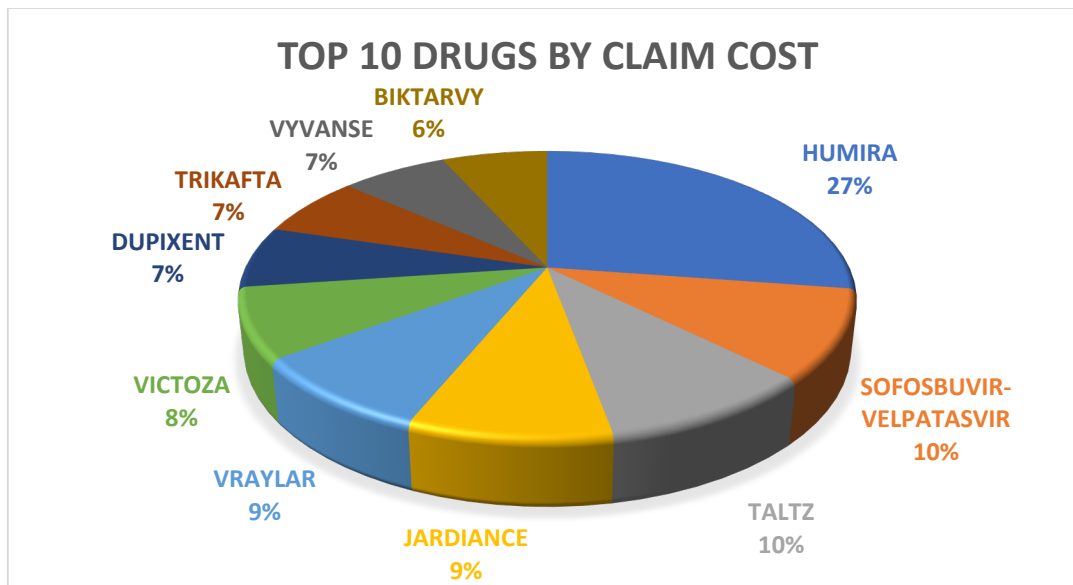
Top 25 Drugs Based on Number of Claims from 10/01/2024 – 12/31/2024

Drug	Claims	Claims Cost	Patients	Cost / Claim	% Claims	Dif.
1. GABAPENTIN	4,352	\$62,951.41	1,824	\$14.46	1.79%	NC
2. AMOXICILLIN	3,797	\$61,103.38	3,577	\$16.09	1.56%	↑13
3. SERTRALINE HCL	3,548	\$47,827.94	1,955	\$13.48	1.46%	↓1
4. ESCITALOPRAM	3,503	\$46,208.88	1,932	\$13.19	1.44%	↓1
5. TRAZODONE HCL	3,472	\$46,455.65	1,826	\$13.38	1.43%	↓1
6. FLUOXETINE HCL	3,377	\$44,558.45	1,838	\$13.19	1.39%	NC
7. OMEPRAZOLE	3,184	\$42,255.30	1,817	\$13.27	1.31%	↓2
8. LEVOTHYROXINE	2,899	\$43,117.47	1,511	\$14.87	1.19%	↓1
9. VENTOLIN HFA	2,850	\$184,573.35	2,820	\$64.76	1.17%	NC
10. CLONIDINE HCL	2,837	\$35,102.74	1,396	\$12.37	1.17%	↑1
11. ATORVASTATIN	2,791	\$40,454.96	1,629	\$14.49	1.15%	↓3
12. BUPROPION XL	2,647	\$43,846.67	1,450	\$16.56	1.09%	↓2
13. AMOXICILLIN-CLAV	2,636	\$46,528.76	2,445	\$17.65	1.08%	↑15
14. PREDNISONE	2,617	\$30,450.22	2,118	\$11.64	1.08%	↑6
15. LISINOPRIL	2,611	\$33,763.41	1,559	\$12.93	1.07%	↓3
16. HYDROXYZINE	2,581	\$35,748.26	1,537	\$13.85	1.06%	↓3
17. DEXTROAMP-AMP ER	2,418	\$70,648.78	1,007	\$29.22	0.99%	↑32
18. METHYLPHENIDATE ER	2,350	\$67,600.70	988	\$28.77	0.97%	↑18
19. ARIPIPRAZOLE	2,325	\$36,235.09	1,139	\$15.58	0.96%	↓2
20. PANTOPRAZOLE	2,284	\$32,024.86	1,317	\$14.02	0.94%	↓2
21. HYDROCODONE-APAP	2,251	\$33,281.55	1,434	\$14.79	0.93%	↓7
22. VYVANSE	2,211	\$641,849.77	1,005	\$290.30	0.91%	↑6
23. LAMOTRIGINE	2,208	\$31,020.27	893	\$14.05	0.91%	↓4
24. DULOXETINE	2,197	\$35,772.12	1,144	\$16.28	0.90%	↓3
25. CYCLOBENZAPRINE	2,170	\$25,423.64	1,340	\$11.72	0.89%	↓3
Total Claims					243, 280	



Top 25 Drugs Based on Total Claims Cost from 10/01/24 – 12/31/2024

Drug	Claims	Claims Cost	Patients	Cost / Patient	% Cost	Dif.
1. HUMIRA	308	\$2,599,026.69	130	\$109,784.11	7.87%	NC
2. SOFOSBUVIR-VELPATASVIR	42	\$953,734.53	42	\$22,707.97	2.89%	NC
3. TALTZ	118	\$920,514.69	52	\$74,512.32	2.79%	NC
4. JARDIANCE	1,122	\$861,770.10	602	\$1,431.51	2.61%	NC
5. VRAYLAR	795	\$827,547.36	313	\$2,643.92	2.51%	NC
6. VICTOZA	1092	\$749,074.37	630	\$2,220.53	2.27%	NC
7. DUPIXENT	182	\$655,198.07	79	\$16,182.44	1.98%	↑2
8. TRIKAFTA	29	\$649,356.47	10	\$64,935.65	1.97%	↑3
9. VYVANSE	2,211	\$641,849.77	1,005	\$638.66	1.94%	↑1
10. BIKTARVY	276	\$634,714.15	127	\$4,997.75	1.92%	↓3
11. INVEGA SUSTENNA	205	\$568,090.65	79	\$7,191.02	1.72%	↓1
12. NORDITROPIN FLEXPOR	84	\$516,651.36	36	\$14,351.43	1.56%	NC
13. ELIQUIS	699	\$431,803.69	348	\$1,240.82	1.31%	↑1
14. COSENTYX	36	\$365,179.37	16	\$50,846.69	1.11%	↑5
15. SUBLOCADE	172	\$348,101.30	87	\$4,001.16	1.05%	↑1
16. STELARA	13	\$309,996.50	10	\$30,999.65	0.94%	↓3
17. INGREZZA	37	\$288,789.46	17	\$16,987.62	0.87%	↓2
18. INVEGA TRINZA	30	\$263,309.21	26	\$10,127.28	0.80%	↑8
19. ENBREL	37	\$238,773.42	15	\$31,020.49	0.72%	↑1
20. DULERA	733	\$233,281.93	437	\$533.83	0.71%	↑2
21. ABILIFY MAINTENA	91	\$229,597.94	37	\$6,205.35	0.70%	↓3
22. XIFAXAN	84	\$226,490.74	41	\$5,524.16	0.69%	↑2
23. FARXIGA	339	\$209,360.96	166	\$1,261.21	0.63%	NC
24. VERZENIO	13	\$200,436.34	5	\$40,087.27	0.61%	↑3
25. ADVAIR DISKUS	932	\$188,040.21	538	\$349.52	0.57%	↑4
Total Claims Cost					\$33,035,140.79	



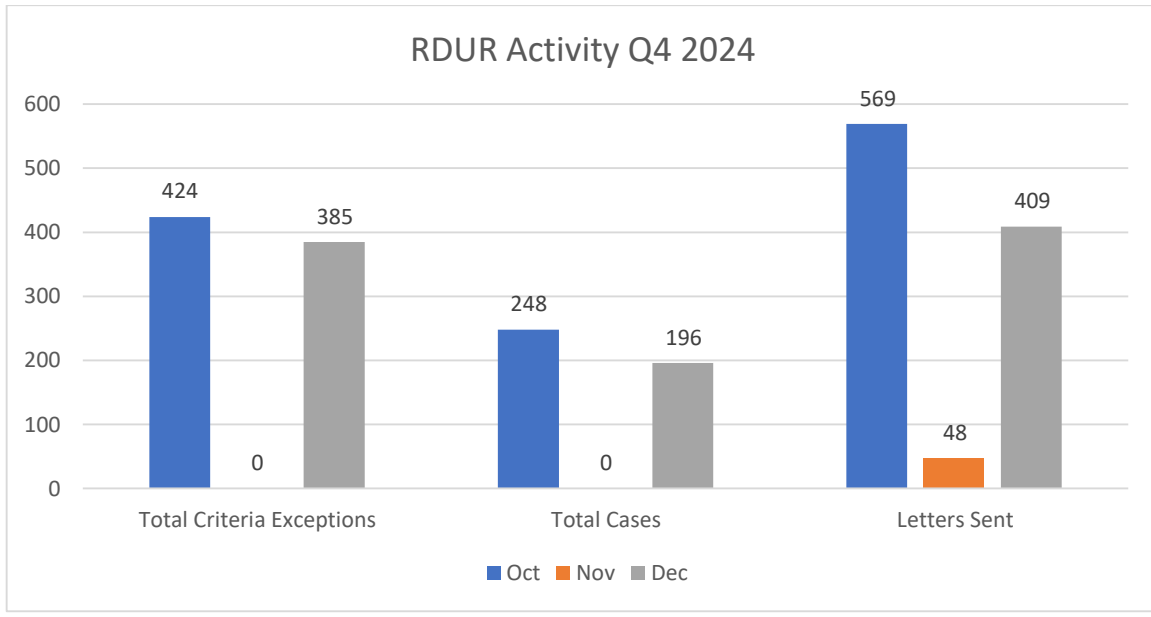
Top 15 Therapeutic Classes Based on Number of Claims from 10/01/2024 – 12/31/2024

Therapeutic Class Description	Claims	Claims Cost	Patients	Cost/Claim	% Claims	Dif.
1. ANTIDEPRESSANTS	25,484	\$597,439.41	10,577	\$23.44	10.48%	NC
2. ANTIPSYCHOTIC AGENTS	9,815	\$2,661,031.09	3,802	\$271.12	4.03%	NC
3. AMPHETAMINES	7,156	\$878,411.53	2,813	\$122.75	2.94%	NC
4. RESPIRATORY AND CNS STIMULANTS	6,903	\$474,960.75	2,606	\$68.80	2.84%	↑1
5. GABA-MEDIATED ANTICONVULSANTS	6,736	\$127,522.37	2,683	\$18.93	2.77%	↓1
6. PENICILLIN ANTIBIOTICS	6,651	\$110,956.25	5,925	\$16.68	2.73%	↑8
7. BETA-ADRENERGIC AGONISTS	6,053	\$756,707.56	4,210	\$125.01	2.49%	↑6
8. PROTON-PUMP INHIBITORS	5,798	\$102,479.26	3,263	\$17.67	2.38%	↓1
9. OPIOID AGONISTS	5,765	\$99,942.95	2,942	\$17.34	2.37%	↓9
10. CENTRAL ALPHA-AGONISTS	5,419	\$78,113.58	2,370	\$14.41	2.23%	NC
11. NONSTEROIDAL ANTI-INFLAMMATORY AGENTS	5,367	\$73,566.63	3,567	\$13.71	2.21%	↓2
12. ADRENALS	5,226	\$221,895.24	3,836	\$42.46	2.15%	↑3
13. HMG-COA REDUCTASE INHIBITORS	5,004	\$73,903.91	2,925	\$14.77	2.06%	↓1
14. ANTICONVULSANTS, MISCELLANEOUS	4,998	\$307,512.21	2,007	\$61.53	2.05%	↓3
15. BETA-ADRENERGIC BLOCKING AGENTS	4,873	\$81,744.74	2,717	\$16.78	2.00%	↓2

Top 15 Therapeutic Classes Based on Claims Cost from 10/01/024 – 12/31/2024

Therapeutic Class Description	Claims	Claims Cost	Patients	Cost/Patient	% Cost	Dif.
1. TNF INHIBITORS	377	\$3,043,366.15	148	\$20,563.28	9.21%	NC
2. ANTIPSYCHOTIC AGENTS	9,815	\$2,661,031.09	3,802	\$699.90	8.06%	NC
3. INTERLEUKIN AGENTS	171	\$1,608,302.50	75	\$21,444.03	4.87%	NC
4. ANTIRETROVIRALS	687	\$1,141,461.02	255	\$4,476.32	3.46%	↑1
5. SGLT2 INHIB	1,519	\$1,101,065.83	796	\$1,383.25	3.33%	↑2
6. ANTINEOPLASTIC AGENTS	517	\$1,099,997.16	202	\$5,445.53	3.33%	↓2
7. INCRETIN MIMETICS	1,323	\$956,042.70	633	\$1,510.34	2.89%	↑2
8. HCV ANTIVIRALS	42	\$953,734.53	42	\$22,707.97	2.89%	↓2
9. AMPHETAMINES	7,156	\$878,411.53	2,813	\$312.27	2.66%	↓1
10. BETAAGONISTS	6,053	\$756,707.56	4,210	\$179.74	2.29%	NC
11. CFTR CORRECTORS	32	\$719,110.79	11	\$65,373.71	2.18%	↑5
12. SKIN AGENTS	192	\$655,569.39	88	\$7,449.65	1.98%	↓1
13. INSULINS	3,005	\$629,926.20	1,220	\$516.33	1.91%	NC
14. ANTIDEPRESSANTS	25,484	\$597,439.41	10,577	\$56.48	1.81%	NC
15. ANTICOAGULANTS	1,270	\$563,145.69	588	\$957.73	1.70%	↑3

RDUR Report: Q4 2024



October Cases by Type of Criteria

Criteria Description	# of Cases	% of Cases
Drug-Drug Interactions	23	9.27%
Therapeutic Appropriateness	148	59.68%
Therapeutic Duplication	77	31.05%

December Cases by Type of Criteria

Criteria Description	# of Cases	% of Cases
Drug-Disease Precaution	52	26.53%
Drug-Drug and/or Diagnosis Interaction	12	6.12%
Drug-Drug Interaction	54	27.55%
Inferred Drug Disease Precaution	6	3.06%
Overuse Precaution	18	9.18%
Therapeutic Appropriateness	10	5.1%
Underuse Precaution	44	22.45%

Introduction

A recent analysis published by the American Dental Association (ADA) indicates overall opioid prescribing among dentists remains too high. Despite a national decrease in opioid utilization (i.e., quantity and strength) by dentists for Medicaid members from 2019 to 2023, the ADA analysis suggests opioid prescriptions are still being written unnecessarily since non-opioid alternatives are recommended first-line to manage pain and mitigate the risk of opioid use disorder.^{1, 2}

Claims data for North Dakota Medicaid show that the number of opioid prescriptions written by dentists decreased, but the quantity written per prescription increased from 2019 to 2023. Studies have shown that patients did not use half the opioids prescribed for recovery after a dental surgical extraction; unused medication may increase the risk of misuse.¹

At the bottom of this report, you will see a list of your patients who have received opioid medication(s) prescribed by a dentist or oral surgeon in the past 120 days per pharmacy claims data. If multiple prescribers are involved, each will receive this information.

Dentist Prescribed Opioids Guidance

Evidenced-based guidelines published by the ADA recommend:

- First-line use of nonsteroidal anti-inflammatory drugs (NSAIDs), alone or in combination with acetaminophen, for surgical tooth extraction and toothache associated with pulp and periapical disease.
- In the rare instance when pain control with an NSAID or acetaminophen is not adequate, use of an opioid at the lowest effective dose is recommended.
 - Use the fewest tablets for the shortest duration.
 - The duration should rarely exceed 3 days.^{2, 3}

When prescribing opioids, ADA guidelines recommend clinicians obtain informed consent and provide detailed information of potential risks, such as substance misuse, respiratory depression, and effects on driving. This is critical for adolescents and young adults who are at increased risk of subsequent misuse and substance use disorder after a single prescription. Clinicians can reduce risk of opioid misuse by assessing the appropriateness of opioids and potential drug interactions, checking prescription drug monitoring programs (PDMP), and educating patients on appropriate use and risks associated with overdose and misuse.^{2,3,4,5}

Opioid prescribing for children is common in dentistry. The American Academy of Pediatrics (AAP) has recently released guidelines for opioid prescribing in children. Nationally, dentists and surgeons are responsible for 61.4% of the opioid prescriptions written for children and adolescents under 21 years of age. However, expert consensus suggests that equally effective analgesia may be achieved using acetaminophen and NSAIDs alone for procedures such as third molar surgery and tooth extraction. The AAP guidelines further recommend prescribing naloxone alongside every opioid prescription for pediatric patients.^{2,3,5}

References:

1. Okunev I, Frantsve-Hawley J, Trandy E. 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. Available from: [https://jada.ada.org/article/S0002-8177\(21\)00244-0/fulltext](https://jada.ada.org/article/S0002-8177(21)00244-0/fulltext)
2. Carrasco-Labra A, Polk DE, Urquhart O, Aghaloo T, et al. Evidence-based clinical practice guideline for the pharmacologic management of acute dental pain in adolescents, adults, and older adults: A report from the American Dental Association Science and Research Institute, the University of Pittsburgh, and the University of Pennsylvania. *The Journal of the American Dental Association*, Volume 155, Issue 2, 2024, Pages 102-117.e9, ISSN 0002-8177. Available from: <https://doi.org/10.1016/j.adaj.2023.10.009>.
3. Dowell D, Ragan KR, Jones CM, Baldwin GT, Chou R. CDC Clinical Practice Guideline for Prescribing Opioids for Pain — United States, 2022. *MMWR Recomm Rep* 2022;71(No. RR-3):1–95. Available from: <http://dx.doi.org/10.15585/mmwr.rr7103a1>
4. Initiating Opioid Therapy. Centers for Disease Control and Prevention. May 7, 2024. Available from: <https://www.cdc.gov/overdose-prevention/hcp/clinical-care/initiating-opioid-therapy.html>
5. Hadland SE, Agarwal R, Raman SR, Smith MJ, et al. Opioid Prescribing for Acute Pain Management in Children and Adolescents in Outpatient Settings: Clinical Practice Guideline. *Pediatrics* 2024; e2024068752. 10.1542/peds.2024-068752. Available from: <https://doi.org/10.1542/peds.2024-068752>

Clinical Report

Prior Authorization Updates

Drug	PA Status	Class
Adzenys XR – ODT	PA	ADHD Stimulants
Alhemo	PA	Hemophilia
Alomide	PA	Ophthalmic Antihistamines
Alyftrek	PA	Cystic Fibrosis
Aptensio XR (and its generic)	PA	ADHD Stimulants
Aqneursa	PA	Medications that cost over \$3000
Attruby	PA	Amyloidosis
Azstarys	PA	ADHD Stimulants
Betimol	Remove PA	Glaucoma
Crenessity	PA	Medications that cost over \$3000
Durezol	Remove PA	Ophthalmic Corticosteroids
Dyanavel XR suspension	PA	ADHD Stimulants
Eohilia	PA	Non-preferred Dosage Forms
Hympavzi	PA	Hemophilia
Ilevro	PA	Non-preferred Dosage Forms
Jornay PM	PA	ADHD Stimulants
ketorolac 0.4%	PA	Non-preferred Dosage Forms
Miplyffa	PA	Medications that cost over \$3000
Mydayis (and its generic)	PA	ADHD Stimulants
Natacyn	PA	Ophthalmic Anti-infectives
OmvoH	PA	Crohn's Disease
Opipza	PA	Non-preferred dosage forms
Selarsdi	PA	Stelara Biosimilars
Steqeyma	PA	Stelara Biosimilars
Ustekinumab-ttwe	PA	Stelara Biosimilars
Vyvanse chew (and its generic)	PA	ADHD Stimulants
XelstryM	PA	ADHD Stimulants
Yesintek	PA	Stelara Biosimilars

Criteria Updates

Summary of Changes for Amyloidosis/TTR Stabilizers

Attruby was added to the section

Attruby-specific conditions were added from specific exclusion criteria from the ATTRIBUTE-CM clinical trial (NCT03860935):

- For Attruby only: The member must not have any of the following:
 - o ALT or AST > 2x ULN or Total Bilirubin >3x ULN
 - o NT-proBNP level > 8500 pg/mL

Significantly high NT-proBNP level is an indicator of more severe heart failure. These patients are much less likely to respond to treatment.

Attruby is metabolized by the liver, so impaired liver function could decrease the medication functionality or increase side effects.

References:

Gillmore JD, Judge DP, Cappelli F, Fontana M, Garcia-Pavia P, Gibbs S, Grogan M, Hanna M, Hoffman J, Masri A, Maurer MS, Nativi-Nicolau J, Obici L, Poulsen SH, Rockhold F, Shah KB, Soman P, Garg J, Chiswell K, Xu H, Cao X, Lystig T, Sinha U, Fox JC; ATTRIBUTE-CM Investigators. Efficacy and Safety of Acoramidis in Transthyretin Amyloid Cardiomyopathy. N Engl J Med. 2024 Jan 11;390(2):132-142. doi: 10.1056/NEJMoa2305434. PMID: 38197816.

Amyloidosis

TTR Stabilizers

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ATTRUBY (acoramidis)	
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.
- Confirmation of the diagnosis by both of the following must be provided:
 - o presence of grade 2 or 3 positive bone tracer cardiac scintigraphy
 - o absence of monoclonal protein confirmed by serum protein immunofixation, urine protein immunofixation, or serum free light chain ratio analysis
- 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.

- For Attruby only: The member must not have any of the following:
 - o ALT or AST > 2x ULN or Total Bilirubin >3x ULN
 - o NT-proBNP level > 8500 pg/mL
- The member must not have any of the following:
 - o eGFR < 25 mL/min/1.73m²
 - o NYHA class IV symptoms or severe aortic stenosis
 - o Previous heart transplant or implanted cardiac mechanical assist device
 - o Previous liver transplant
- Baseline 6MWT > 100 meters must be submitted.
- The member is not receiving any other TTR reducing agent (i.e., vutrisiran, patisiran, elplontersen, inotersen)

Renewal Criteria – Approval Duration: 12 months

- For Attruby only: The member has received a therapeutic response as evidenced by stabilization or improvement from baseline in both of the following:
 - o 6MWT
 - o NT-proBNP level
- For Vyndaqel/Vyndamax only: The member has received a therapeutic response as evidenced by stabilization or improvement from baseline in both of the following:
 - o 6MWT
 - o NYHA class

Summary of Changes for GLP-1 Agonist Combinations

GLP-1 / GIP Agonist combination molecule tirzepatide has a new indication – Obstructive Sleep Apnea.

Diabetes criteria for tirzepatide and semaglutide has been modified to account for the dual action in the indications of Obstructive Sleep Apnea and Major Adverse Cardiovascular Events respectively.

Diabetes

GLP-1 Agonists[^]

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (STEP 1 – PA REQUIRED)	NON-PREFERRED AGENTS (STEP 2 – PA REQUIRED)
VICTOZA (liraglutide) - <i>Brand Required</i>	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
 - o Victoza 1.2 mg = Trulicity 0.75 mg = Ozempic 0.25 mg = Rybelsus 7 mg
 - o Victoza 1.8 mg = Trulicity 1.5 mg = Ozempic 0.5 mg = Rybelsus 14 mg = Mounjaro 2.5 mg
 - o Trulicity 3 mg = Ozempic 0.5 mg or 1 mg
 - o Trulicity 4.5 mg = Ozempic 1 mg
 - o 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:
 - o One of the following apply (A or B):
 - The member has been unable to achieve goal A1C ($\leq 7\%$) 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).
 - o The request is for Ozempic and the member has had a 90-day trial of Victoza and is eligible for approval for semaglutide based on the MACE criteria or tirzepatide based on the Sleep Apnea criteria.
 - Step 2:
 - o The member has been unable to achieve goal A1C ($\leq 7\%$) 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).
 - o 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 lessening 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

- One of the following is met (A or B):
 - o The member meets both of the following (1 and 2):
 - The member has been unable to achieve goal A1C ($\leq 7\%$) 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.
 - o 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.
 - o 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 (a or b):
 - a. The requested medication must be prescribed by, or in consult with, an endocrinologist or diabetes specialist.
 - b. The member has received diabetes education from a diabetic specialist, diabetic educator, or pharmacist (may be accomplished through the MTM program).
 - o The request is for Mounjaro and the member is otherwise eligible for approval for tirzepatide based on the Sleep Apnea criteria.

*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 lessening 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.

Note: If the member qualifies for tirzepatide, the most cost effective tirzepatide product will be authorized.

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 (Proprotein 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:
 - o 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.
 - o 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/m² and < 35 kg/m²
- The member has one of the following:
 - o Prior myocardial infarction (MI)
 - o 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)

Obstructive Sleep Apnea (OSA)

CLINICAL PA REQUIRED
ZEPBOUND (tirzepatide)

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 neurologist, pulmonologist, otolaryngologist, or other sleep medicine specialist
- The member must have a diagnosis of moderate to severe OSA defined as apnea-hypopnea index (AHI) > 15 determined by in-lab attended sleep study or polysomnography (PSG)
- The member does not have diabetes type II
- The member must have a diagnosis of obesity (defined as BMI ≥ 30 kg/m²) AND at least one of the following weight-related comorbid conditions:
 - o Hypertension

- o Dyslipidemia
- o Cardiovascular Disease
- The member must have documentation of participation in a comprehensive weight management program that includes behavioral modification, a reduced-calorie diet, increased physical activity, and pharmacotherapy for at least 6 months, including phentermine (if phentermine is unable to be used, bupropion, naltrexone, topiramate may also be used to meet this requirement)
- The member must have failed a 6-month trial of continuous positive airway pressure (CPAP) along with the weight management program.
 - If the member qualifies for tirzepatide, the most cost effective tirzepatide product will be authorized

Renewal Criteria – Approval Duration: 12 months

- The member has a demonstrated clinical response evidenced by any of the following:
 - o Decrease in AHI determined by PSG $\geq 20\%$, or change in OSA severity status to Remission or Mild Non-Symptomatic OSA (defined as AHI < 5 or AHI 5-14 AND Epworth Sleepiness Scale (ESS) ≤ 10)
 - o Weight loss from base line $\geq 10\%$

Summary of Changes for MASH

Renewal criteria updated based on [FDA guidance for industry](#) for endpoints that are reasonably likely to predict clinical benefit.

Steps for Rezdiffra were added based on the following trial information:

Semaglutide: Phase 3 Essence trial (NCT04822181) achieved its primary endpoints by demonstrating a statistically significant and superior improvement in liver fibrosis with no worsening of steatohepatitis, as well as resolution of steatohepatitis with no worsening of liver fibrosis with semaglutide 2.4 mg compared to placebo. Resolution of MASH without worsening of fibrosis placebo-adjusted difference was 29%, while improvement of at least one fibrosis stage without worsening of MASH placebo-adjusted difference was 14%.

Rezdiffra: Phase 3 MAESTRO-NASH (NCT03900429) Resolution of MASH without worsening of fibrosis placebo-adjusted difference was 23%, while improvement of at least one fibrosis stage without worsening of MASH placebo-adjusted difference was 13%.

Pioglitazone: In a meta-analysis of thiazolidinedione studies, regardless of the presence of T2D, thiazolidinedione treatment was associated with resolution of MASH (odds ratio, 3.22; 95% CI, 2.17–4.79; $P < .001$) and reversal of advanced fibrosis (odds ratio, 3.15; 95% CI, 1.25–7.93; $P = .01$)

Updated guidance presented by AASLD (post Rezdiffra approval) indicated pioglitazone was more likely to be used with concurrent T2D.

Liraglutide, semaglutide and pioglitazone are not FDA approved but cost-effective compendia supported alternatives for treatment.

References

1. Halsey, Grace. "Semaglutide 2.4 mg: Shows Superior Improvement in Liver Fibrosis, MASH Resolution in Pivotal Phase 3 Trial."
2. Kanwal, Fasiha, et al. "Clinical care pathway for the risk stratification and management of patients with nonalcoholic fatty liver disease." *Gastroenterology* 161.5 (2021): 1657-1669.

Metabolic Dysfunction-Associated Steatohepatitis (MASH)

PREFERRED AGENTS (NO PA REQUIRED)

NON-PREFERRED AGENTS (PA REQUIRED)

pioglitazone	REZDIFFRA (resmetirom)
VICTOZA (liraglutide)	OZEMPIC (semaglutide)
	SAXENDA (liraglutide)
	WEGOVY (semaglutide)

Prior Authorization Criteria

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 within the past 5 years, one of the following must be met:
 1. The member has a phosphatidylethanol (PEth) level < 20 ng/mL.
 2. 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.
- Rezdiffra Only:
 - o If concurrent Type 2 DM diagnosis, the member has failed a 6-month trial of semaglutide combined with pioglitazone as evidenced by paid claims or pharmacy printouts
 - o If no concurrent Type 2 DM diagnosis, the member has failed a 6-month trial of semaglutide as evidenced by paid claims or pharmacy printouts.
- Saxenda Only:
 - o If the member qualifies for Saxenda, the most cost effective liraglutide product will be authorized.
- Wegovy Only:
 - o If the member qualifies for Wegovy, a dose escalation to 2mg weekly of Ozempic (semaglutide) must be tolerated before Wegovy will be authorized.

Renewal Criteria – Approval Duration: 12 months

- The member must have experienced one of the following (1-3):
 1. Resolution of steatohepatitis AND no worsening of liver fibrosis
 2. Improvement of liver fibrosis greater than or equal to one stage AND no worsening of steatohepatitis
 3. Both resolution of steatohepatitis AND improvement in fibrosis.
- Fibrosis and steatosis are measured 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)

Summary of Changes for Parkinson's disease

A section was created for Device-Assisted Refractory Therapies. Duopa and Vyalev were added to the section.

Parkinson's disease

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 has a minimum of 3 hours of “off” time per day despite a 3-month trial at least 1 g/day or frequency of 5x per day of levodopa/carbidopa in combination with at least one of the following: a dopamine agonist, a COMT inhibitor, a MOA-B inhibitor, and amantadine, as evidenced by paid claims or pharmacy printouts.
- 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.

Unfinished Business

Summary of Changes for Infantile Hemangioma

Removed trial for Hemangeol for timolol gel forming solution and added criteria to allow for low-risk hemangioma where propranolol may not be appropriate.

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

- For timolol gel forming solution only:
 - One of the following must be met:
 - The member is being tapered off of treatment with propranolol oral solution
 - The member has a low risk and uncomplicated hemangioma (e.g., < 2 cm, not ulcerated and not located in central face, periorbital area, lips, chin, neck, oral cavity, lumbosacral, perineal, or perianal area)
- For Hemangeol Only:
 - The member must have failed a 3-month trial of the propranolol oral solution, as evidenced by paid claims or pharmacy printouts.

Summary of Changes for Rescue Inhalers

Moved Airsupra into rescue inhalers category

Rescue Inhalers

Albuterol / Levalbuterol

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

Rescue Inhaler - Corticosteroid/Short-Acting Beta Agonist (SABA) Combination

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	AIRSUPRA (albuterol/budesonide)

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.

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:

- o 2 Symbicort or Dulera inhalers per 30-day supply not to exceed a total of 9 inhalers per 365 days without prior approval.

Electronic Step Therapy Required

- Levalbuterol HFA:
 - o 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.
 - o 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.
 - o 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).

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- Airsupra only:
 - o The member must have failed a 30-day trial of albuterol and an ICS/LABA, as evidenced by paid claims or pharmacy printouts.
- Non-preferred albuterol only: Xeljanz XR Only: See Preferred Dosage Form Criteria

Therapeutic Duplication

- Short acting beta agonist nebulizers and inhalers are not payable together.
 - o 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>

New Business:

First Reviews

FIRST REVIEW OF DIABETES MELLITUS

Patients with diabetes mellitus experience abnormal carbohydrate metabolism characterized by hyperglycemia. Type 2 diabetes is the most common type in adults affecting approximately 90% while type 1 diabetes affects approximately 5-10%.¹

Prevalence: Affects approximately 11.6% of the population.³

Goals of therapy:

- A1c < 7%
- Time in range (TIR) > 70%
- Cardiac risk reduction
 - o Smoking cessation
 - o Blood pressure control
 - o Reduction in serum lipids
 - o Diet and exercise
 - o Weight loss or maintenance

Choice of Pharmacological Therapy:

- Metformin for initial therapy for newly diagnosed T2DM
- Treatment algorithms are based on comorbid conditions such as metabolic syndrome, dyslipidemia, hypertension, ASCVD, heart failure, stroke/TIA, CKD, obesity, and hypoglycemia risk.
- The most commonly used medication classes are detailed below, less commonly used classes include alpha-glucosidase inhibitors, bile acid sequestrants, dopamine-2 agonists, and amylin mimetics.

Medication choice²:

		Oral					Subcutaneous		
		Metformin	SGLT2	DPP-4 inhibitors	Pioglitazone	Sulfonylureas	Insulin	GLP-1 agonists	GIP/GLP-1 agonists
Positive Effects	Effects on Weight Loss	X	X					X	X
	Effective for MACE	X	X					X	
	Effects on Heart Failure		X						
	Effects on Chronic Kidney Disease		X						
Negative Effects	Increased risk of hypoglycemia					X	X		
	Increased risk of weight gain				X				
	Increased risk of heart failure				X				
	Avoid in patients with CKD	X	X						
	Average Cost/month	\$6	\$445	\$243	\$6	\$25	\$65*	\$912	\$1,080

*Cost calculated per 1 vial

**Cost based on lowest WAC per unit, calculated using monthly quantity limits allowed when applicable or maximum recommended dose. Averaged by all medications in drug class.

Current Utilization:

	Quarter 1 2024			Quarter 2 2024		
Medication	Rx Count	% of Rx	Reimb Amount	Rx Count	% of Rx	Reimb Amount
acarbose	4	0.04%	\$ 86.08	18	0.17%	\$426.95
alogliptin benzoate	0	0.00%	\$ 0.00	0	0.00%	\$0.00
canagliflozin	24	0.22%	\$18,056.90	26	0.24%	\$ 19,346.95
canagliflozin/metformin HCl	8	0.07%	\$ 4,751.01	1	0.01%	\$ 583.59
dapaglifloz propaned/metformin	7	0.06%	\$ 1,807.06	5	0.05%	\$ 953.52
dapagliflozin propanediol	379	3.41%	\$ 238,664.08	330	3.11%	\$198,963.68
dulaglutide	142	1.28%	\$130,539.57	120	1.13%	\$113,023.92
empaglifloz/linagliptin/metformin	7	0.06%	\$ 3,291.90	13	0.12%	\$ 6,613.49
empagliflozin	1144	10.31%	\$841,689.36	1148	10.81%	\$ 845,153.13
empagliflozin/metformin HCl	30	0.27%	\$15,615.38	39	0.37%	\$19,866.02
exenatide microspheres	0	0.00%	\$ 0.00	1	0.01%	\$ 293.03
glimepiride	90	0.81%	\$1,269.71	79	0.74%	\$ 1,104.76
glipizide	259	2.33%	\$4,144.06	246	2.32%	\$3,776.52
glipizide/metformin HCl	1	0.01%	\$49.76	0	0.00%	\$0.00
insulin aspart	1292	11.64%	\$289,379.84	902	8.50%	\$184,508.88
insulin aspart (niacinamide)	8	0.07%	\$ 5,388.65	7	0.07%	\$5,113.77
insulin aspart prot/insulin asp	27	0.24%	\$ 4,848.57	21	0.20%	\$3,865.95
insulin aspart/B3/pump cart	0	0.00%	\$ 0.00	0	0.00%	\$0.00
insulin degludec	73	0.66%	\$ 64,709.36	59	0.56%	\$58,347.04
insulin detemir	313	13.02%	\$79,122.14	243	2.29%	\$49,178.93
insulin glargine hum.rec.analog	1445	0.31%	\$ 208,117.76	1474	13.89%	\$191,191.86
insulin glargine-yfgn	34	0.31%	\$ 6,860.75	5	0.05%	\$ 122.98
insulin glulisine	3	0.03%	\$ 910.02	3	0.03%	\$ 528.35
insulin lispro	300	2.70%	\$ 53,692.99	529	4.98%	\$102,757.11
insulin lispro protamin/lispro	0	0.00%	\$0.00	1	0.01%	\$ 94.52
insulin NPH human isophane	1	0.01%	\$ 99.76	0	0.00%	\$0.00
insulin regular	13	0.12%	\$29,211.81	19	0.18%	\$44,401.49
linagliptin	18	0.16%	\$ 8,784.91	11	0.10%	\$4,898.81
linagliptin/metformin HCl	3	0.03%	\$ 1,548.81	3	0.03%	\$1,544.56
liraglutide	1322	11.91%	\$952,824.71	1264	11.91%	\$ 849,527.86
metformin HCl	3764	33.91%	\$ 52,936.50	3669	34.56%	\$53,603.58
pioglitazone HCl	92	0.83%	\$ 1,509.87	86	0.81%	\$ 1,285.41
pramlintide acetate	0	0.00%	\$0.00	1	0.01%	\$ 1,242.62
semaglutide	47	0.42%	\$ 39,868.37	55	0.52%	\$ 47,884.87
sitagliptin phos/metformin HCl	111	1.00%	\$40,070.52	94	0.89%	\$42,203.32
sitagliptin phosphate	126	1.14%	\$ 84,982.99	129	1.22%	\$74,501.70
tirzepatide	12	0.11%	\$ 11,642.38	14	0.13%	\$ 14,603.34
TOTALS	11099		\$ 3,196,475.58	10615		\$ 2,941,085.56

	Quarter 3 2024			Quarter 4 2024		
Medication	Rx Count	% of Rx	Reimb Amount	Rx Count	% of Rx	Reimb Amount
acarbose	11	0.10%	\$259.81	19	0.19%	\$402.29
alogliptin benzoate	0	0.00%	\$0.00	0	0.00%	\$0.00
canagliflozin	17	0.15%	\$12,425.82	0	0.00%	\$0.00
canagliflozin/metformin HCl	0	0.00%	\$0.00	0	0.00%	\$0.00
dapaglifloz propaned/metformin	3	0.03%	\$1,101.49	8	0.08%	\$ 2,268.14
dapagliflozin propanediol	369	3.28%	\$233,592.02	339	3.35%	\$209,360.96
dulaglutide	66	0.59%	\$60,870.25	40	0.40%	\$35,283.37
empaglifloz/linagliptin/metformin	18	0.16%	\$ 9,432.85	20	0.20%	\$10,828.13
empagliflozin	1341	11.91%	\$928,945.07	1122	11.09%	\$861,770.10
empagliflozin/metformin HCl	39	0.35%	\$19,246.56	30	0.30%	\$16,838.50
exenatide microspheres	3	0.03%	\$1,393.39	3	0.03%	\$882.89
glimepiride	91	0.81%	\$1,935.91	88	0.87%	\$1,253.66
glipizide	250	2.22%	\$7,100.47	205	2.03%	\$3,190.98
glipizide/metformin HCl	0	0.00%	\$0.00	0	0.00%	\$0.00
insulin aspart	45	0.40%	\$5,044.61	39	0.39%	\$8,321.10
insulin aspart (niacinamide)	8	0.07%	\$4,607.88	14	0.14%	\$5,803.48
insulin aspart prot/insulin asp	20	0.18%	\$5,161.44	17	0.17%	\$2,906.61
insulin aspart/B3/pump cart	0	0.00%	\$0.00	1	0.01%	\$839.96
insulin degludec	83	0.74%	\$69,170.81	56	0.55%	\$60,495.26
insulin detemir	214	1.90%	\$40,466.28	72	0.71%	\$14,059.56
insulin glargine hum.rec.analog	1396	12.40%	\$182,063.55	1548	15.31%	\$231,885.29
insulin glargine-yfgn	53	0.47%	\$14,691.92	11	0.11%	\$173.05
insulin glulisine	0	0.00%	\$0.00	0	0.00%	\$0.00
insulin lispro	1347	11.96%	\$293,988.23	1373	13.58%	\$313,134.36
insulin lispro protamin/lispro	5	0.04%	\$ 511.46	2	0.02%	\$252.20
insulin NPH human isophane	0	0.00%	\$0.00	3	0.03%	\$395.35
insulin regular	20	0.18%	\$43,722.84	18	0.18%	\$31,923.98
linagliptin	13	0.12%	\$6,701.16	2	0.02%	\$1,031.57
linagliptin/metformin HCl	3	0.03%	\$1,545.47	3	0.03%	\$1,551.12
liraglutide	1200	10.66%	\$792,821.71	1093	10.81%	\$749,793.37
metformin HCl	3926	34.87%	\$109,069.88	3436	33.97%	\$49,171.75
pioglitazone HCl	130	1.15%	\$5,599.60	76	0.75%	\$1,151.97
pramlintide acetate	1	0.01%	\$1,242.62	3	0.03%	\$3,673.78
semaglutide	260	2.31%	\$166,751.03	173	1.71%	\$155,473.26
sitagliptin phos/metformin HCl	83	0.74%	\$ 50,684.12	80	0.79%	\$39,088.18
sitagliptin phosphate	232	2.06%	\$149,535.86	206	2.04%	\$142,654.74
tirzepatide	12	0.11%	\$12,521.10	14	0.14%	\$14,609.81
TOTALS	11259		\$3,232,205.21	10114		\$ 2,970,468.77

References:

1. Inzucchi, S, Lupsa, B. Clinical presentation, diagnosis, and initial evaluation of diabetes mellitus in adults. UpToDate, Hussain Z, Nathan DM (Ed) [Internet]. Waltham, MA: UpToDate; Dec 18, 2023. Available from: www.uptodate.com
2. Khan, SE. American Diabetes Association: Standards of Care in Diabetes – 2025. Jan 2025. Vol 48. Available from: www.professional.diabetes.org.
3. Statistics about Diabetes. Available from: diabetes.org.
4. Quick Answers and Red Book. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. January 31, 2025. <https://www.micromedexsolutions.com>

Second Review

Migraine

Prophylaxis of Episodic 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) – <i>Medical Billing Only</i>
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.

Prophylaxis of Chronic Migraine

Calcitonin Gene-Related Peptide (CGRP) Receptor Antagonist

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AIMOVIG (erenumab-aooe)	QULIPTA (atogepant) TABLETS
AJOVY (fremanezumab-vfrm)	VYEPTI (eptinezumab-jjmr) – <i>Medical Billing Only</i>
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

Non-Preferred Agents Criteria:

- Qulipta Only:
 - The member must have failed a 3-month trial of Ajovy, Emgality, and Aimovig, as evidenced by paid claims or pharmacy printouts.
- Vyepti Only:
 - The member must have failed a 3-month trial of Ajovy, Emgality, Aimovig, and Qulipta, 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

- 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

- 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/cafeine) 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

- 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) – <i>Brand Required</i>	FROVA (frovatriptan) TABLET – <i>Brand Required</i>	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

- 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

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

Therapeutic Duplication

- One strength of one medication for treatment of migraine is allowed at a time

Nasal Spray

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
sumatriptan spray	TOSYMRA (sumatriptan) NASAL SPRAY
	ZOMIG (zolmitriptan) NASAL SPRAY
	zolmitriptan spray

Injectable

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
sumatriptan injectable	IMITREX (sumatriptan) INJECTABLE
	ZEMBRACE SYMTOUCH (sumatriptan)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must be unable to take oral medications or experience nausea/emesis with oral triptans (subject to clinical review).
- Sumatriptan Nasal Spray Only:
 - The member must have failed a 30-day trial with zolmitriptan nasal spray, as evidenced by paid claims or pharmacy printouts.
- Sumatriptan 4mg Injectable Only:
 - The member must have failed a 30-day trial with each of the following: 6mg injectable and zolmitriptan nasal spray, as evidenced by paid claims or pharmacy printouts.

Non-Preferred Agent Criteria:

- See Preferred Dosage Form criteria

Therapeutic Duplication

- 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, as evidenced by paid claims or pharmacy printouts.

NSAIDS

Oral Solid Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
celecoxib	ARTHROTEC (diclofenac/misoprostol)
diclofenac potassium 50 mg tablet	CELEBREX (celecoxib)
diclofenac sodium DR 50 mg, 75 mg	DAYPRO (oxaprozin)
etodolac	diclofenac potassium 25 mg tablet
flurbiprofen	diclofenac potassium 25 mg capsule
ibuprofen	diclofenac sodium 25 mg DR
indomethacin	diclofenac sodium 100 mg ER tablet
indomethacin ER	diclofenac/misoprostol

ketoprofen IR	DUEXIS (famotidine/ibuprofen)
ketorolac	etodolac ER
meclofenamate	famotidine/ibuprofen
mefenamic acid	FELDENE (piroxicam)
meloxicam	fenoprofen
nabumetone	ketoprofen ER 200 mg
naproxen	LOFENA (diclofenac potassium)
piroxicam	meloxicam, submicronized
sulindac	NALFON (fenoprofen)
tolmetin	NAPRELAN (naproxen)
VIMOVO (naproxen/esomeprazole) – <i>Brand Required</i>	naproxen ER 500 mg
	naproxen/esomeprazole
	oxaprozin
	RELAFEN DS (nabumetone)
	SEGLENTIS (celecoxib/tramadol)

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
	diclofenac topical solution (labeler 59088)

Prior Authorization Criteria

- See Preferred Dosage Form Criteria

Primary Biliary Cholangitis

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ursodiol tablets	IQIRVO (elafibranor)
	LIVDELZI (seldelpar lysine)
	OCALIVA (obeticholic acid)

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 consultation with, a hepatologist or a gastroenterologist
- The diagnosis must be confirmed by liver biopsy
- The member must not have a concomitant terminal diagnosis where life expectancy is less than 1 year.
- The member must not have a history of decompensated cirrhosis
- The member must have failed at least a 6-month trial of ursodiol, as evidenced by paid claims or pharmacy printouts, as evidenced by one of the following
 - ALP > 1.67 x Upper Limits of Normal (ULN) as defined by reporting laboratory
 - Bilirubin > ULN
- If the member has a history of alcohol use within the past 5 years, 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.

Renewal Criteria – Approval Duration: 12 months

- The member has experienced a therapeutic response as evidenced by one of the following (A or B):
 - A. Both of the following (1 or 2):
 - 1. ALP < 1.67 x ULN OR > 15% decrease in ALP from baseline
 - 2. Total bilirubin is less than ULN
 - B. The member is currently on Livdelzi and is receiving itch benefit and has had previous trials of cholestyramine, rifampin, and naltrexone that did not provide itch relief.

NORTH DAKOTA MEDICAID
RETROSPECTIVE DRUG UTILIZATION REVIEW
CRITERIA RECOMMENDATIONS
1ST QUARTER 2025

Criteria Recommendations

Approved Rejected

1. Ensifentrine / Overuse

Alert Message: Ohtuvayre (ensifentrine) may be over-utilized. The recommended maintenance dose of ensifentrine is 3 mg (one unit-dose ampule) twice daily.

Drugs/Diseases

Util A

Util B

Util C

Ensifentrine

Max Dose: 6 mg/day

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.

Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.

Ohtuvayre Prescribing Information, June 2024, Verona Pharma.

2. Ensifentrine / Therapeutic Appropriateness

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

Drugs/Diseases

Util A

Util B

Util C

Ensifentrine

Age Range: 0 – 17 yoa

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.

Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.

Ohtuvayre Prescribing Information, June 2024, Verona Pharma.

3. Ensifentrine / Hepatic Impairment

Alert Message: Ohtuvayre (ensifentrine) should be used with caution in patients with hepatic impairment. In clinical trials, ensifentrine systemic exposure increased by 2.3-fold in subjects with moderate or severe hepatic impairment compared with healthy subjects.

Drugs/Diseases

Util A

Util B

Util C

Ensifentrine

Hepatic Impairment

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.

Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.

Ohtuvayre Prescribing Information, June 2024, Verona Pharma.

4. Ensifentrine / Psychiatric Adverse Reactions

Alert Message: Treatment with Ohtuvayre (ensifentrine) is associated with an increase in psychiatric adverse reactions. Psychiatric events, including suicide-related adverse reactions, were reported in clinical studies in patients who received ensifentrine. Carefully weigh the risks and benefits of treatment with ensifentrine in patients with a history of depression and/or suicidal thoughts or behavior.

Drugs/Diseases		
<u>Util A</u>	<u>Util B</u>	<u>Util C (Include)</u>
Ensifentrine		Attempted Suicide
Suicidal Ideation		
Psychiatric Disorders		

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Ohtuvayre Prescribing Information, June 2024, Verona Pharma.

5. Ensifentrine / Lactation

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

Drugs/Diseases		
<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Ensifentrine	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Ohtuvayre Prescribing Information, June 2024, Verona Pharma.

6. Ensifentrine / Non-adherence

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

Drugs/Diseases		
<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Ensifentrine		

References:
Osterberg L, Blaschke T. Adherence to Medication. N Engl J Med 2005; 353:487- 497.
Lareau SC, Yawn BP. Improving Adherence with Inhaler Therapy in COPD. International Journal of COPD. 2010 Nov 24;5:401-406.
Restrepo RD, Alvarez MT, Wittnebel LD, et al., Medication Adherence Issues in Patients Treated for COPD. International Journal of COPD. 2008;3(3):371-384.
Kim J, Combs K, Downs J, Tillman F., Medication Adherence: The Elephant in the Room. US Pharm. 2018;43(1)30-34.

7. Givinostat / Therapeutic Appropriateness

Alert Message: The safety and effectiveness of Duvyzat (givinostat) in pediatric patients younger than 6 years of age have not been established.

Drugs/Diseases		
<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Givinostat		

Age Range: 0 – 5 yoa

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Duvyzat Prescribing Information, March 2024, ITF Therapeutics, LLC.

8. Givinostat / Hematological Changes

Alert Message: Duvyzat (givinostat) can cause dose-related thrombocytopenia and other signs of myelosuppression, including decreased hemoglobin and neutropenia. Monitor blood counts every 2 weeks for the first 2 months of treatment, then monthly for the next 3 months, and every 3 months thereafter. Modify the dosage of givinostat per the official prescribing information for confirmed thrombocytopenia. Treatment should be permanently discontinued if the abnormalities worsen despite dose modification. If a patient develops signs or symptoms of thrombocytopenia, obtain a platelet count as soon as possible and hold dosing until the platelet count is confirmed.

Drugs/Diseases		
<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Givinostat	Anemia	
	Neutropenia	
	Thrombocytopenia	

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Duvyzat Prescribing Information, March 2024, ITF Therapeutics, LLC.

9. Givinostat / Elevated Triglycerides

Alert Message: Duvyzat (givinostat) can cause elevations in triglycerides. In clinical Study 1, hypertriglyceridemia occurred in 23% of patients treated with givinostat (one of whom had familial hypertriglyceridemia) compared to 7% of patients on placebo. Monitor triglycerides at 1 month, 3 months, 6 months, and then every 6 months thereafter. Modify the dosage if fasting triglycerides are verified > 300 mg/dL. Treatment with givinostat should be discontinued if triglycerides remain elevated despite adequate dietary intervention and dosage adjustment.

Drugs/Diseases		
<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Givinostat	Elevated Triglycerides	

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Duvyzat Prescribing Information, March 2024, ITF Therapeutics, LLC.

10. Givinostat / Gastrointestinal Adverse Effects

Alert Message: Gastrointestinal disturbances, including diarrhea, nausea/vomiting, and abdominal pain were common adverse reactions in Duvyzat (givinostat) clinical trials in DMD. Antiemetics or antidiarrheal medications may be considered during treatment with givinostat. Fluid and electrolytes should be replaced as needed to prevent dehydration. Modify the dosage of givinostat in patients with moderate or severe diarrhea, and treatment should be discontinued if significant gastrointestinal symptoms persist.

Drugs/Diseases		
<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Givinostat	Diarrhea	
	Nausea	
	Vomiting	

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Duvyzat Prescribing Information, March 2024, ITF Therapeutics, LLC.

11. Givinostat / Sensitive OCT2 Substrates

Alert Message: Duvyzat (givinostat) is a weak inhibitor of the renal uptake transporter OCT2. Closely monitor patients when givinostat is used in combination with drugs known as sensitive substrates of the OCT2 transporter, for which a small change in substrate plasma concentration may lead to serious toxicities.

Drugs/Diseases		
<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Givinostat	Dofetilide	
	Metformin	

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Duvyzat Prescribing Information, March 2024, ITF Therapeutics, LLC.

12. Givinostat / QT Prolongation

Alert Message: Duvyzat (givinostat) can cause prolongation of the QTc interval. Avoid the use of givinostat in patients who are at an increased risk for ventricular arrhythmias (including torsades de pointes), such as those with congenital long QT syndrome, coronary artery disease, and electrolyte disturbance, as well as patients concurrently taking other medications known to cause QT prolongation.

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Givinostat	Hypokalemia	
	Hypomagnesemia	
	QT Prolongation	
	Ventricular Arrhythmias	

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Duvyzat Prescribing Information, March 2024, ITF Therapeutics, LLC.

13. Givinostat / QT Prolongation

Alert Message: Duvyzat (givinostat) can cause prolongation of the QTc interval. Avoid the concomitant use of givinostat with other medicinal products known to cause QT prolongation. If concomitant use cannot be avoided, obtain ECGs when initiating givinostat, during concomitant use, and as clinically indicated. Withhold givinostat if the QTc interval is > 500 ms or the change from baseline is > 60 ms.

Drugs/Diseases

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

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.

Duvyzat Prescribing Information, March 2024, ITF Therapeutics, LLC.

14. Givinostat / Sensitive 3A4 Substrates

Alert Message: Duvyzat (givinostat) is a weak inhibitor of intestinal CYP3A4. Closely monitor patients when givinostat is used in combination with orally administered CYP3A4 sensitive substrates for which a small change in substrate plasma concentration may lead to serious toxicities.

Drugs/Diseases					
Util A	Util B				Util C
Givinostat	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.
Duvyzat Prescribing Information, March 2024, ITF Therapeutics, LLC.

15. Duvelisib / Moderate CYP3A4 Inducers

Alert Message: The concurrent use of Copiktra (duvelisib) with moderate CYP3A4 inducers should be avoided. Duvelisib is a CYP3A4 substrate, and co-administration with a moderate CYP3A4 inducer may result in decreased duvelisib exposure and loss of duvelisib efficacy. If co-administration with a moderate CYP3A4 inducer cannot be avoided, increase the duvelisib dose on Day 12 of co-administration with the moderate CYP3A4 inducer as recommended in the official prescribing information. After the inducer has been discontinued for at least 14 days, resume duvelisib at the dose taken prior to initiating the moderate CYP3A4 inducer.

Drugs/Diseases		
Util A	Util B	Util C
Duvelisib	Bosentan	Modafinil
	Cenobamate	Nafcillin
	Efavirenz	Rifapentine
	Etravirine	

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.

16. Clonidine XR Suspension / Overuse

Alert Message: Onyda XR (clonidine extended-release suspension) may be over-utilized. The maximum recommended dose of clonidine extended-release suspension is 0.4 mg once daily at bedtime.

Drugs/Diseases		
Util A	Util B	Util C
Clonidine XR Susp		

Max Dose: 0.4mg/day

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Onyda XR Prescribing Information, May 2024, Tris Pharma, Inc.

17. Clonidine XR Suspension / Therapeutic Appropriateness

Alert Message: The safety and efficacy of Onyda XR (clonidine extended-release suspension) in pediatric patients below the age of 6 years has not been established.

Drugs/Diseases

Util A Util B Util C

Clonidine XR Susp

Age Range: 0 – 5 yoa

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.

Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.

Onyda XR Prescribing Information, May 2024, Tris Pharma, Inc.

18. Clonidine XR Suspension / Drugs affecting Sinus Node or AV Node

Alert Message: Concomitant use of Onyda XR (clonidine extended-release suspension) with drugs that affect sinus node function or AV node conduction should be avoided. Concurrent use of clonidine with these agents potentiates bradycardia and the risk of AV block.

Drugs/Diseases

Util A Util B Util C

Clonidine XR Susp

Amiodarone

Beta-Blockers

Diltiazem

Digoxin

Verapamil

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.

Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.

Onyda XR Prescribing Information, May 2024, Tris Pharma, Inc.

19. Clonidine XR Suspension / Lactation

Alert Message: Exercise caution when Onyda XR (clonidine extended-release suspension) is administered to a nursing patient. Based on published lactation studies, clonidine is present in human milk. If an infant is exposed to clonidine through breastmilk, monitor for symptoms of hypotension and bradycardia, such as sedation, lethargy, tachypnea, and poor feeding. The developmental and health benefits of breastfeeding should be considered, along with the mother's clinical need for clonidine extended-release suspension and any potential adverse effects on the breastfed child from clonidine or the underlying maternal condition.

Drugs/Diseases

Util A Util B Util C

Clonidine XR Susp

Lactation

Gender: Female

Age Range: 11 – 50 yoa

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.

Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.

Onyda XR Prescribing Information, May 2024, Tris Pharma, Inc.

20. Capivasertib / Overuse

Alert Message: Truqap (capivasertib) may be over-utilized. The recommended dosage of capivasertib is 400 mg orally twice daily (approximately 12 hours apart) for 4 days followed by 3 days off.

Drugs/Diseases
Util A Util B Util C
Capivasertib

Max Dose: 800 mg/day

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Truqap Prescribing Information, Sept. 2024, AstraZeneca.

21. Capivasertib / Therapeutic Appropriateness

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

Drugs/Diseases
Util A Util B Util C
Capivasertib

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Truqap Prescribing Information, Sept. 2024, AstraZeneca.

22. Capivasertib / Hyperglycemia

Alert Message: Severe hyperglycemia, associated with ketoacidosis, occurred in patients treated with Truqap (capivasertib). Hyperglycemia occurred in 18% of patients treated with capivasertib. If a patient experiences hyperglycemia after initiating treatment with capivasertib, monitor FG as clinically indicated, and at least twice weekly until FG decreases to normal levels. During treatment with antihyperglycemic medication, continue monitoring FG at least once a week for 8 weeks, followed by once every 2 weeks and as clinically indicated. Consider consultation with a healthcare practitioner with expertise in the treatment of hyperglycemia and counsel patients on lifestyle changes. Withhold, reduce dose, or permanently discontinue capivasertib based on severity.

Drugs/Diseases
Util A Util B Util C
Capivasertib Hyperglycemia

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Truqap Prescribing Information, Sept. 2024, AstraZeneca.

23. Capivasertib / Diabetes Requiring Insulin

Alert Message: The safety of Truqap (capivasertib) has not been established in patients with Type I diabetes or diabetes requiring insulin. Patients with insulin-dependent diabetes were excluded from the clinical trial CAPItello-291. Severe hyperglycemia, associated with ketoacidosis, occurred in patients treated with capivasertib.

Drugs/Diseases		
<u>Util A</u>	<u>Util B</u>	<u>Util C (Include)</u>
Capivasertib	Type 1 Diabetes	Insulin
	Type 2 Diabetes	

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Truqap Prescribing Information, Sept. 2024, AstraZeneca.

24. Capivasertib / Diarrhea

Alert Message: Severe diarrhea associated with dehydration occurred in patients who received Truqap (capivasertib). In clinical trials, diarrhea occurred in 72% of patients. Monitor patients for signs and symptoms of diarrhea. Advise patients to increase oral fluids and start antidiarrheal treatment at the first sign of diarrhea while taking capivasertib. Withhold, reduce dose, or permanently discontinue capivasertib based on severity.

Drugs/Diseases		
<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Capivasertib	Diarrhea	

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Truqap Prescribing Information, Sept. 2024, AstraZeneca.

25. Capivasertib / Cutaneous Adverse Reactions

Alert Message: Cutaneous adverse reactions, which can be severe, including erythema multiforme (EM), palmar-plantar erythrodysesthesia, and drug reaction with eosinophilia and systemic symptoms (DRESS), occurred in patients who received Truqap (capivasertib). Monitor patients for signs and symptoms of cutaneous adverse reactions. Early consultation with a dermatologist is recommended. Withhold, reduce dose, or permanently discontinue capivasertib based on severity.

Drugs/Diseases		
<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Capivasertib	Erythema Multiforme	
	Generalized Skin Eruptions due to Medications	
	Drug Rash with Eosinophilia and Systemic Symptoms Syndrome	

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Truqap Prescribing Information, Sept. 2024, AstraZeneca.

26. Capivasertib / Strong or Moderate CYP3A4 Inducers

Alert Message: Avoid concomitant use of Truqap (capivasertib) with strong or moderate CYP3A inducers. Capivasertib is a CYP3A substrate. Strong and moderate CYP3A inducers decrease capivasertib exposure, which may reduce the effectiveness of capivasertib.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Capivasertib	Apalutamide Bosentan Carbamazepine Efavirenz Etravirine Phenobarbital	Phenytoin Primidone Rifabutin Rifampin Rifapentine

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.

Truqap Prescribing Information, Sept. 2024, AstraZeneca.

27. Capivasertib / Strong CYP3A4 Inhibitors

Alert Message: Avoid concomitant use of Truqap (capivasertib) with a strong CYP3A inhibitor. Capivasertib is a CYP3A substrate. Strong CYP3A inhibitors increase capivasertib exposure, which may increase the risk of capivasertib adverse reactions. If concomitant use cannot be avoided, reduce the dose of capivasertib to 320 mg twice daily for 4 days followed by 3 days off, and monitor patients for adverse reactions. After discontinuation of a strong CYP3A inhibitor, resume the capivasertib dosage (after 3 to 5 half-lives of the inhibitor) that was taken prior to initiating the strong CYP3A inhibitor.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Capivasertib	Clarithromycin Cobicistat Itraconazole Ketoconazole Nefazodone	Nelfinavir Posaconazole Ritonavir Voriconazole

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.

Truqap Prescribing Information, Sept. 2024, AstraZeneca.

28. Capivasertib / Moderate CYP3A4 Inhibitors

Alert Message: Truqap (capivasertib) is a CYP3A substrate, and concurrent use with a moderate CYP3A inhibitor increases capivasertib exposure, which may increase the risk of capivasertib adverse reactions. When capivasertib is used with a moderate CYP3A inhibitor, reduce the dose of capivasertib to 320 mg twice daily for 4 days followed by 3 days off, and monitor patients for adverse reactions. After discontinuation of a moderate CYP3A inhibitor, resume the capivasertib dosage (after 3 to 5 half-lives of the inhibitor) that was taken prior to initiating the moderate CYP3A inhibitor.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Capivasertib	Aprepitant Cimetidine Ciprofloxacin Crizotinib	Cyclosporine Diltiazem Dronedarone Erythromycin Fluconazole Fluvoxamine Imatinib Verapamil

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.

Truqap Prescribing Information, Sept. 2024, AstraZeneca.

29. Capivasertib / Pregnancy / Pregnancy Negating

Alert Message: Based on findings in animals and the mechanism of action, Truqap (capivasertib) can cause fetal harm when administered during pregnancy. There are no available data on the use of capivasertib during pregnancy. In an animal reproduction study, oral administration of capivasertib to pregnant rats during the period of organogenesis caused adverse developmental outcomes, including embryo-fetal mortality and reduced fetal weights at maternal exposures 0.7 times the human exposure (AUC) at the recommended dose of 400 mg twice daily.

Drugs/Diseases
Util A Util B Util C (Negate)
Capivasertib Pregnancy Abortion
Delivery
Miscarriage
Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Truqap Prescribing Information, Sept. 2024, AstraZeneca.

30. Capivasertib / Lactation

Alert Message: There are no data on the presence of Truqap (capivasertib) or its metabolites in human milk or their effects on milk production or the breastfed child. Capivasertib was detected in the plasma of suckling rat pups. Because of the potential for serious adverse reactions in a breastfed child, advise against breastfeeding during treatment with capivasertib.

Drugs/Diseases
Util A Util B Util C
Capivasertib Lactation

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Truqap Prescribing Information, Sept. 2024, AstraZeneca.

31. Capivasertib / Therapeutic Appropriateness

Alert Message: Advise females of reproductive potential to use effective contraception during treatment with Truqap (capivasertib) and for 1 month after the last dose. Based on findings in animals and the mechanism of action, capivasertib can cause fetal harm when administered to a pregnant patient.

Drugs/Diseases
Util A Util B Util C
Capivasertib

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Truqap Prescribing Information, Sept. 2024, AstraZeneca.

Criteria Recommendations

Approved Rejected

32. Capivasertib / Therapeutic Appropriateness

Alert Message: Advise male patients with female partners of reproductive potential to use effective contraception during treatment with Truqap (capivasertib) and for 4 months after the last dose.

Alert Message:

Drugs/Diseases

Util A Util B Util C

Capivasertib

Gender: Male

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Truqap Prescribing Information, Sept. 2024, AstraZeneca.

33. Secukinumab / Overuse nr-axSpA & ERA

Alert Message: Cosentyx (secukinumab) may be over-utilized. The recommended maximum dose of subcutaneous secukinumab in adults with nr-axSpA or ERA is 150 mg every 4 weeks.

Drugs/Diseases

Util A Util B Util C (Include)

Secukinumab Non-Radiographic Axial Spondyloarthritis

Enthesitis-Related Arthritis

Max Dose: 150 mg q 4 weeks

Age Range: 18 – 999 yoa

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Cosentyx Prescribing Information, Oct. 2024, Novartis Pharmaceuticals Corp.

34. Secukinumab / Overuse Hidradenitis Suppurativa

Alert Message: Cosentyx (secukinumab) may be over-utilized. The recommended maximum dose of subcutaneous secukinumab in adults with hidradenitis suppurativa is 300 mg every 2 weeks.

Drugs/Diseases

Util A Util B Util C (Include)

Secukinumab Hidradenitis Suppurativa

Max Dose: 300 mg q 2 weeks
Age Range: 18 – 999 yoa

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Cosentyx Prescribing Information, Oct. 2024, Novartis Pharmaceuticals Corp.

35. Secukinumab / Therapeutic Appropriateness HD

Alert Message: The safety and effectiveness of Cosentyx (secukinumab) for the treatment of hidradenitis suppurativa in pediatric patients have not been established.

Drugs/Diseases		
<u>Util A</u>	<u>Util B</u>	<u>Util C (Include)</u>
Secukinumab		Hidradenitis Suppurativa

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Cosentyx Prescribing Information, Oct. 2024, Novartis Pharmaceuticals Corp.

36. Secukinumab / Therapeutic Appropriateness ERA

Alert Message: The safety and effectiveness of Cosentyx (secukinumab) for the treatment of enthesitis-related arthritis in pediatric patients below the age of 4 or with a body weight of less than 15 kg have not been established.

Drugs/Diseases		
<u>Util A</u>	<u>Util B</u>	<u>Util C(Include)</u>
Secukinumab		Enthesitis-Related Arthritis

Age Range: 0 – 3 yoa

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Cosentyx Prescribing Information, Oct. 2024, Novartis Pharmaceuticals Corp

37. Secukinumab / Therapeutic Appropriateness AS

Alert Message: The safety and effectiveness of Cosentyx (secukinumab) for the treatment of ankylosing spondylitis in pediatric patients have not been established.

Drugs/Diseases		
<u>Util A</u>	<u>Util B</u>	<u>Util C (Include)</u>
Secukinumab		Ankylosing Spondylitis

Age Range: 0 – 18 yoa

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Cosentyx Prescribing Information, Oct. 2024, Novartis Pharmaceuticals Corp.

38. Secukinumab / Therapeutic Appropriateness nr-axSpA

Alert Message: The safety and effectiveness of Cosentyx (secukinumab) for the treatment of non-radiographic axial spondyloarthritis in pediatric patients have not been established.

Drugs/Diseases		
<u>Util A</u>	<u>Util B</u>	<u>Util C (Include)</u>
Secukinumab		Non-Radiographic Axial Spondyloarthritis
Age Range: 0 – 18 yoa		

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Cosentyx Prescribing Information, Oct. 2024, Novartis Pharmaceuticals Corp.

39. Tofacitinib XR / Renal Impairment, Hepatic & Strong 3A4 Inhibitors / UC

Alert Message: Dosage modification of Xeljanz XR (tofacitinib extended-release) is recommended in patients with moderate or severe renal insufficiency or moderate hepatic impairment (Child-Pugh Class B). In patients with ulcerative colitis receiving tofacitinib extended-release 22 mg once daily, reduce the dose to 11 mg extended-release once daily. If the patient is taking 11 mg extended-release once daily, switch to 5 mg immediate-release tofacitinib once daily.

Drugs/Diseases		
<u>Util A</u>	<u>Util B</u>	<u>Util C (Include)</u>
Tofacitinib XR	Moderate & Severe Renal Insufficiency Moderate Hepatic Impairment	Ulcerative Colitis

References:
Xeljanz Prescribing Information, November 2024, Pfizer, Inc.
Clinical Pharmacology, 2024 Elsevier/Gold Standard.

40. Tofacitinib XR / Strong 3A4 Inhibitors & 3A4/2C19 Inhibitors / UC

Alert Message: Dosage modification of Xeljanz XR (tofacitinib extended-release) is recommended when it is co-administered with a strong CYP3A4 inhibitor or with one or more concomitant medications that cause both moderate CYP3A4 inhibition and potent CYP2C19 inhibition. In patients with ulcerative colitis receiving tofacitinib extended-release 22 mg once daily, reduce the dose to 11 mg extended-release once daily. If the patient is taking 11 mg extended-release once daily, reduce to 5 mg immediate-release tofacitinib once daily.

Drugs/Diseases		
<u>Util A</u>	<u>Util B</u>	<u>Util C (Include)</u>
Tofacitinib XR	Clarithromycin Cobicistat Fluconazole Fluvoxamine Itraconazole Ketoconazole Nefazodone Nelfinavir Posaconazole Ritonavir Voriconazole	Ulcerative Colitis

References:
Xeljanz Prescribing Information, November 2024, Pfizer, Inc.
Clinical Pharmacology, 2024 Elsevier/Gold Standard.

41. Erdafitinib / Overuse

Alert Message: Balversa (erdafitinib) may be over-utilized. The recommended starting dose of maximum erdafitinib is 8 mg (two 4 mg tablets) orally once daily, with a dose increase to a maximum of 9 mg (three 3 mg tablets) once daily based on tolerability, including hyperphosphatemia, at 14 to 21 days.

Drugs/Diseases

Util AUtil BUtil C

Erdafitinib

Max Dose: 9 mg/day

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Balversa Prescribing Information, Oct. 2024, Janssen Products, LP.

42. Erdafitinib / Therapeutic Appropriateness

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

Drugs/Diseases

Util AUtil BUtil C

Erdafitinib

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Balversa Prescribing Information, Oct. 2024, Janssen Products, LP.

43. Erdafitinib / Ocular Disorders

Alert Message: Balversa (erdafitinib) can cause ocular disorders, including central serous retinopathy/retinal pigment epithelial detachment (CSR/RPED) resulting in visual field defect. Perform monthly ophthalmological examinations during the first 4 months of treatment and every 3 months afterward and urgently at any time for visual symptoms. Withhold or permanently discontinue erdafitinib based on severity and/or ophthalmology exam findings.

Drugs/Diseases

Util AUtil BUtil C

ErdafitinibOcular Disorders

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Balversa Prescribing Information, Oct. 2024, Janssen Products, LP.

44. Erdafitinib / Hyperphosphatemia & Soft Tissue Mineralization

Alert Message: Balversa (erdafitinib) can cause hyperphosphatemia, leading to soft tissue mineralization, cutaneous calcinosis, non-uremic calciphylaxis, and vascular calcification. Increases in phosphate levels are a pharmacodynamic effect of erdafitinib. Monitor for hyperphosphatemia throughout treatment. Restrict dietary phosphate intake (600-800 mg daily) and avoid concomitant use of agents that may increase serum phosphate levels. If serum phosphate is above 7.0 mg/dL, consider adding an oral phosphate binder until serum phosphate levels returns < 7.0 mg/dL.

Drugs/Diseases		
<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Erdafitinib	Hyperphosphatemia	
Soft Tissue Mineralization		
Cutaneous Calcinosis		
Non-uremic Calciphylaxis		

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Balversa Prescribing Information, Oct. 2024, Janssen Products, LP.

45. Erdafitinib / Moderate CYP2C9 or Potent CYP3A4 Inhibitors

Alert Message: Co-administration of Balversa (erdafitinib) with moderate CYP2C9 or strong CYP3A4 inhibitors may result in increased erdafitinib plasma concentrations. Increased erdafitinib plasma concentrations may lead to increased drug-related toxicity. Consider alternative therapies that are not moderate CYP2C9 or strong CYP3A4 inhibitors during treatment with erdafitinib. If co-administration of a moderate CYP2C9 or strong CYP3A4 inhibitor is unavoidable, monitor closely for adverse reactions and consider modifications accordingly.

Drugs/Diseases			
<u>Util A</u>	<u>Util B</u>		<u>Util C</u>
Erdafitinib	Clarithromycin	Nefazodone	Voriconazole
	Cobicistat	Nelfinavir	Amiodarone
	Itraconazole	Posaconazole	Fluconazole
	Ketoconazole	Ritonavir	Miconazole

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Balversa Prescribing Information, Oct. 2024, Janssen Products, LP.

46. Erdafitinib / Strong CYP3A4 Inducers

Alert Message: Avoid co-administration of strong CYP3A4 inducers with Balversa (erdafitinib). Co-administration of erdafitinib (a CYP3A4 substrate) with strong CYP3A4 inducers may cause decreased erdafitinib plasma concentrations and decreased efficacy.

Drugs/Diseases		
<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Erdafitinib	Apalutamide	Phenobarbital
	Carbamazepine	Phenytoin
	Enzalutamide	Primidone
	Mitotane	Rifampin

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.

Criteria Recommendations

Approved Rejected

47. Erdafitinib / Moderate CYP3A4 Inducers

Alert Message: Co-administration of Balversa (erdafitinib) with moderate CYP3A4 inducers may result in decreased erdafitinib plasma concentrations and decreased efficacy. If a moderate CYP3A4 inducer must be co-administered at the start of erdafitinib treatment, administer erdafitinib at a dose of 9 mg daily. When a moderate CYP3A4 inducer is discontinued, continue erdafitinib at the same dose, in the absence of drug-related toxicity.

Drugs/Diseases		
<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Erdafitinib	Bosentan	Rifapentine
	Modafinil	Efavirenz
	Cenobamate	Etravirine
	Nafcillin	

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Balversa Prescribing Information, Oct. 2024, Janssen Products, LP.

48. Erdafitinib / P-gp Substrates

Alert Message: Co-administration of Balversa (erdafitinib) with P-gp substrates may result in increased plasma concentrations of P-gp substrates. Increased plasma concentrations of P-gp substrates may lead to increased toxicity of the P-gp substrates. If co-administration of erdafitinib with P-gp substrates is unavoidable, separate erdafitinib administration by at least 6 hours before or after administration of P-gp substrates with a narrow therapeutic index.

Drugs/Diseases		
<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Erdafitinib		

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Balversa Prescribing Information, Oct. 2024, Janssen Products, LP.

49. Erdafitinib / Pregnancy / Pregnancy Negating

Alert Message: Based on the mechanism of action and findings in animal reproduction studies, Balversa (erdafitinib) can cause fetal harm when administered to a pregnant patient. In an embryo-fetal toxicity study, oral administration of erdafitinib to pregnant rats during the period of organogenesis caused malformations and embryo-fetal death at maternal exposures that were less than the human exposures at the maximum human recommended dose based on the area under the curve (AUC). Advise pregnant women of the potential risk to the fetus. Advise female patients of reproductive potential to use effective contraception during treatment with erdafitinib and for one month after the last dose.

Drugs/Diseases		
<u>Util A</u>	<u>Util B</u>	<u>Util C (Negate)</u>
Erdafitinib	Pregnancy	Abortion
Delivery		
Miscarriage		
Gender: Female		
Age Range: 11 – 50 yoa		

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Balversa Prescribing Information, Oct. 2024, Janssen Products, LP.

Criteria Recommendations

Approved Rejected

50. Erdafitinib / Lactation

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

Drugs/Diseases		
<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Erdafitinib	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Balversa Prescribing Information, Oct. 2024, Janssen Products, LP.

51. Erdafitinib / Therapeutic Appropriateness

Alert Message: Advise females of reproductive potential to use effective contraception during treatment with Balversa (erdafitinib) and for one month after the last dose. Based on the mechanism of action and findings in animal reproduction studies, erdafitinib can cause fetal harm when administered to a pregnant woman.

Drugs/Diseases		
<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Erdafitinib		

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Balversa Prescribing Information, Oct. 2024, Janssen Products, LP.

52. Erdafitinib / Therapeutic Appropriateness

Alert Message: Advise male patients with female partners of reproductive potential to use effective contraception during treatment with Balversa (erdafitinib) and for one month after the last dose.

Drugs/Diseases		
<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Erdafitinib		

Gender: Male

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Balversa Prescribing Information, Oct. 2024, Janssen Products, LP.

53. Erdafitinib / Non-adherence

Alert Message: Based on refill history, your patient may be under-utilizing Balversa (erdafitinib).
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 AUtil BUtil C

Erdafitinib

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.

54. Sitagliptin/metformin / Overuse

Alert Message: Zituvimet (sitagliptin/metformin) may be over-utilized. The manufacturer's recommended maximum dose is 100 mg sitagliptin /2000 mg metformin daily.

Drugs/Diseases

Util AUtil BUtil C

Sitagliptin/Metformin

Max Dose: 100 mg/2000mg day

References:
Merative Micromedex DRUGDEX (electronic version). Merative, Ann Arbor, Michigan, USA. 2024.
UpToDate Inc. (2024). Sitagliptin and Metformin: Drug Information. Lexi-Drugs, UpToDate Lexidrug. Retrieved August 14, 2024.
Zituvimet Prescribing Information, Nov. 2023, Zydus Pharmaceuticals, Inc.

55. Sitagliptin/metformin / Therapeutic Appropriateness

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

Drugs/Diseases

Util AUtil BUtil C

Sitagliptin/Metformin

Age Range: 0 – 17 yoa

References:
Merative Micromedex DRUGDEX (electronic version). Merative, Ann Arbor, Michigan, USA. 2024.
UpToDate Inc. (2024). Sitagliptin and Metformin: Drug Information. Lexi-Drugs, UpToDate Lexidrug. Retrieved August 14, 2024.
Zituvimet Prescribing Information, Nov. 2023, Zydus Pharmaceuticals, Inc.

56. Sitagliptin/metformin / Severe Renal Impairment

Alert Message: Zituvimet (sitagliptin/metformin) use is contraindicated in patients with severe renal impairment (eGFR below 30 mL/min/1.73m2). In clinical studies, a 4-fold increase in the plasma AUC of sitagliptin was observed in patients with severe renal impairment including patients with end-stage renal disease (ESRD) on hemodialysis, compared to normal healthy control subjects.

Drugs/Diseases		
<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Sitagliptin/Metformin	CKD Stage 4	
	CKD Stage 5	
	ESRD	
	Hemodialysis	

References:
Merative Micromedex DRUGDEX (electronic version). Merative, Ann Arbor, Michigan, USA. 2024.
UpToDate Inc. (2024). Sitagliptin and Metformin: Drug Information. Lexi-Drugs, UpToDate Lexidrug. Retrieved August 14, 2024.
Zituvimet Prescribing Information, Nov. 2023, Zydus Pharmaceuticals, Inc.

57. Sitagliptin/metformin / Moderate Renal Impairment

Alert Message: Zituvimet (sitagliptin/metformin) use is not recommended in patients with an eGFR between 30 and less than 45 mL/min/1.73 m2 because these patients require a lower dosage of sitagliptin than what is available in the fixed combination sitagliptin/metformin product.

Drugs/Diseases		
<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Sitagliptin/Metformin	CKD Stage 3b	

References:
Merative Micromedex DRUGDEX (electronic version). Merative, Ann Arbor, Michigan, USA. 2024.
UpToDate Inc. (2024). Sitagliptin and Metformin: Drug Information. Lexi-Drugs, UpToDate Lexidrug. Retrieved August 14, 2024.
Zituvimet Prescribing Information, Nov. 2023, Zydus Pharmaceuticals, Inc.

58. Sitagliptin/metformin / Type 1 Diabetes

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

Drugs/Diseases		
<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Sitagliptin/Metformin	Type 1 Diabetes	

References:
Merative Micromedex DRUGDEX (electronic version). Merative, Ann Arbor, Michigan, USA. 2024.
UpToDate Inc. (2024). Sitagliptin and Metformin: Drug Information. Lexi-Drugs, UpToDate Lexidrug. Retrieved August 14, 2024.
Zituvimet Prescribing Information, Nov. 2023, Zydus Pharmaceuticals, Inc.

59. Sitagliptin/metformin / Insulin & Insulin Secretagogues

Alert Message: The concurrent use of Zituvimet (sitagliptin/metformin) 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 sitagliptin/metformin.

Drugs/Diseases		
<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Sitagliptin/Metformin	Insulin	Insulin Secretagogues

References:

Merative Micromedex DRUGDEX (electronic version). Merative, Ann Arbor, Michigan, USA. 2024.

UpToDate Inc. (2024). Sitagliptin and Metformin: Drug Information. Lexi-Drugs, UpToDate Lexidrug. Retrieved August 14, 2024.

Zituvimet Prescribing Information, Nov. 2023, Zydus Pharmaceuticals, Inc.

60. Sitagliptin/metformin / Pregnancy / Pregnancy Negating

Alert Message: Available data with Zituvimet (sitagliptin/metformin) and sitagliptin use in pregnant women are not sufficient to inform a sitagliptin/metformin-associated or sitagliptin-associated risk for major birth defects and miscarriage. Published studies with metformin use during pregnancy have not reported a clear association with metformin and major birth defect or miscarriage risk. During pregnancy, consider appropriate alternative therapies. Sitagliptin/metformin should be used during pregnancy only if clearly needed.

Drugs/Diseases		
<u>Util A</u>	<u>Util B</u>	<u>Util C (Negating)</u>
Sitagliptin/Metformin	Pregnancy	Abortion
Delivery		
Miscarriage		
Gender: Female		
Age Range: 11 – 50 yoa		

References:

Merative Micromedex DRUGDEX (electronic version). Merative, Ann Arbor, Michigan, USA. 2024.

UpToDate Inc. (2024). Sitagliptin and Metformin: Drug Information. Lexi-Drugs, UpToDate Lexidrug. Retrieved August 14, 2024.

Zituvimet Prescribing Information, Nov. 2023, Zydus Pharmaceuticals, Inc.

American Diabetes Association (ADA). 15. Management of Diabetes in Pregnancy. Standards of Care in Diabetes-2024. Diabetes Care 2024;47(Suppl. 1):S282-S294.

61. Sitagliptin/metformin / Lactation

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

Drugs/Diseases		
<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Sitagliptin/Metformin	Lactation	

Gender: Female

Age Range: 11 – 50 yoa

References:

Criteria Recommendations

Approved Rejected

62. Sitagliptin/metformin / Non-adherence

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

Drugs/Diseases			
<u>Util A</u>	<u>Util B</u>	<u>Util C</u>	
Sitagliptin/Metformin			

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.

63. Talicia / Overuse

Alert Message: Talicia (omeprazole/amoxicillin/rifabutin) may be over-utilized. The recommended maintenance dose is four (4) omeprazole/amoxicillin/rifabutin capsules 3 times daily (at least 4 hours apart) with food for 14 days.

Drugs/Diseases			
<u>Util A</u>	<u>Util B</u>	<u>Util C</u>	
Omeprazole/amoxicillin/rifabutin			

Max Dose: 4 capsules/day

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.

Talicia Prescribing Information, May 2024, RedHill Biopharma, Inc.

64. Talicia / Therapeutic Appropriateness

Alert Message: The safety and effectiveness of Talicia (omeprazole/amoxicillin/rifabutin) in pediatric patients below the age of 18 years with H. pylori infection have not been established.

Drugs/Diseases			
<u>Util A</u>	<u>Util B</u>	<u>Util C</u>	
Omeprazole/amoxicillin/rifabutin			

Age Range: 0 – 17 yoa

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.

Talicia Prescribing Information, May 2024, RedHill Biopharma, Inc.

65. Talicia / Overuse

Alert Message: Talicia (omeprazole/amoxicillin/rifabutin) may be over-utilized. The recommended duration of therapy with omeprazole/amoxicillin/rifabutin capsules is 14 days.

Drugs/Diseases

Util A

Util B

Util C

Omeprazole/amoxicillin/rifabutin

Max Duration: 14 days

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Talicia Prescribing Information, May 2024, RedHill Biopharma, Inc.

66. Talicia / Severe Renal Impairment

Alert Message: The use of Talicia (omeprazole/amoxicillin/rifabutin) should be avoided in patients with severe renal impairment (GFR < 30 mL/min). The amoxicillin-component of the combination product is primarily eliminated by the kidney.

Drugs/Diseases

Util A

Util B

Util C (Include)

Omeprazole/amoxicillin/rifabutin
Chronic Kidney Disease Stage 5
ESRD

Chronic Kidney Disease Stage 4

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Talicia Prescribing Information, May 2024, RedHill Biopharma, Inc.

67. Talicia / Hepatic Impairment

Alert Message: It is recommended to avoid the use of Talicia (omeprazole/amoxicillin/rifabutin) in patients with hepatic impairment. In patients with hepatic impairment (Child-Pugh Class A, B, or C) exposure to omeprazole substantially increased compared to healthy subjects.

Drugs/Diseases

Util A

Util B

Util C (Include)

Omeprazole/amoxicillin/rifabutin

Hepatic Impairment

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Talicia Prescribing Information, May 2024, RedHill Biopharma, Inc.

68. Talicia / Pregnancy / Pregnancy Negating

Alert Message: Talicia (omeprazole/amoxicillin/rifabutin) may cause fetal harm when administered to a pregnant patient. The use of omeprazole/amoxicillin/rifabutin is not recommended for use during pregnancy. If omeprazole/amoxicillin/rifabutin is used during pregnancy, advise pregnant women of the potential risk to a fetus.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C (Include)</u>
Omeprazole/amoxicillin/rifabutin	Pregnancy	Abortion
Delivery		
Miscarriage		
Gender: Female		
Age Range: 11 – 50 yoa		

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Talicia Prescribing Information, May 2024, RedHill Biopharma, Inc.

69. Talicia / Lactation

Alert Message: The developmental and health benefits of breastfeeding should be considered along with the mother’s clinical need for Talicia (omeprazole/amoxicillin/rifabutin) and any potential adverse effects on the breast-fed child from omeprazole/amoxicillin/rifabutin or the underlying condition.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Omeprazole/amoxicillin/rifabutin	Lactation	
Gender: Female		
Age Range: 11 – 50 yoa		

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Talicia Prescribing Information, May 2024, RedHill Biopharma, Inc.

**North Dakota Medicaid
Drug Utilization Review Board Meeting
June 4, 2025
Conference Room 210/212**



Meeting Notice

North Dakota Medicaid Drug Use Review Board

Wednesday, June 4th, 2025
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: 239 115 078 594

Agenda

1. Call to Order
2. Roll Call
3. Review and Approval of Minutes
4. Reports from Department
 - Administrative Report: Legislative Update, Member Updates
 - Financial Report: Top Drugs
 - Retrospective DUR Report
 - Clinical Report:
 - o Prior Authorization Update
 - o Criteria updates: Amyloidosis, Chronic Kidney Disease, Hemophilia
5. Special Orders: Presiding Officer and Vice-Presiding Officer Elections
6. New business
 - Second Review of Diabetes Mellitus
 - First Review of Non-Opioid Analgesia
 - Review of retrospective DUR criteria recommendations
 - Provider suggestions for clinical practice education or RDUR ICER criteria
7. Announcements: Next Meeting (September 3, 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: March 5th, 2025
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 with K. Martian presiding as Presiding Officer. DUR Board Coordinator, J. McKee recording minutes.

Roll Call:

Board Members Voting:

Present: Stephanie Antony, Gabriela Balf, Amanda Dahl, Kurt Datz, Andrea Honeyman, Laura Kroetsch, Kevin Martian, Kristen Peterson, Amy Werremeyer, Jessica Ziegler, Matthew Zimny

Absent: Tanya Schmidt

Quorum Present: Yes

Board Members Non-Voting: Kathleen Traylor

Absent:

Medicaid Pharmacy Department:

Present: Jeff Hostetter, Brendan Joyce, Alexi Murphy, Katie Steig

Absent: LeNeika Roehrich

Approval of Meeting Minutes:

Motion: Moved by K. Datz to approve the minutes of the December 4th, 2024, meeting, motion was seconded by K. Martian. **Motion carried.**

The minutes of the December 4th, 2024, meeting were approved as distributed.

Reports:

Financial Report: Budget provided by B. Joyce

B. Joyce shared with the Board trends of reimbursement amount vs net spend for pharmacy drug claims. 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 J. McKee

J. McKee reviewed the quarterly RDUR criteria that were selected for review of each month and information from a targeted mailing. This material can be found in the handout.

Clinical Report and Annual PDL Review: Prior Authorization and Criteria Updates by J. McKee

J. McKee presented prior authorization and criteria updates with emphasis on the following sections in the PDL: Amyloidosis, GLP-1 Receptor Agonist Combinations, Metabolic Dysfunction-Associated Steatohepatitis, Parkinson's Disease. Testimony was provided by Shawn Hanse from Novo Nordisk on Ozempic, Tara McKinely from Madrigal Pharmaceuticals on Rezdifra, and Christine Dube from Astrazeneca on Airsupra.

Unfinished business: provided by J. McKee

J. McKee provided updates on alternative RDUR communication tools. The presented material can be found in the handout.

New business:

First Reviews presented by J. McKee

J. McKee presented an overview of diabetes mellitus. The presented material can be found in the handout.

Motion: Moved by K. Martian to draft prior authorization for diabetes mellitus, motion was seconded by A. Werremeyer. **Motion carried.**

Second Reviews presented by J. McKee

J. McKee presented group prior authorization criteria for Migraine Prophylaxis and Treatment. Testimony was provided by Jasmine Inman from Teva on Ajovy.

Motion: Moved by K. Datz to place Migraine Prophylaxis and Treatment on prior authorization, motion was seconded by K. Martian. **Motion carried.**

J. McKee presented group prior authorization criteria for Nonsteroidal Anti-Inflammatory Drugs.

Motion: Moved by A. Werremeyer to place Nonsteroidal Anti-Inflammatory Drugs on prior authorization, motion was seconded by A. Dahl. **Motion carried.**

J. McKee presented group prior authorization criteria for Primary Biliary Cholangitis.

Motion: Moved by K. Martian to place Primary Biliary Cholangitis on prior authorization, 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 K. Datz. **Motion carried.**

Announcements:

Next meeting is June 4th, 2025.

Adjournment:

Meeting adjourned by K. Martian at 1:54 pm CST.

Date of Minutes Approval:

Minutes submitted by: Julie McKee, Acentra Health

Administrative Report

New Members

Dr. Matthew Zimney, MD – Welcome!

Expired Terms

Dr. Tanya Schmidt, PharmD - has served on the DUR Board since April 1, 2012

Legislative Report

[SB2076](#) Summary of Changes

Previous:

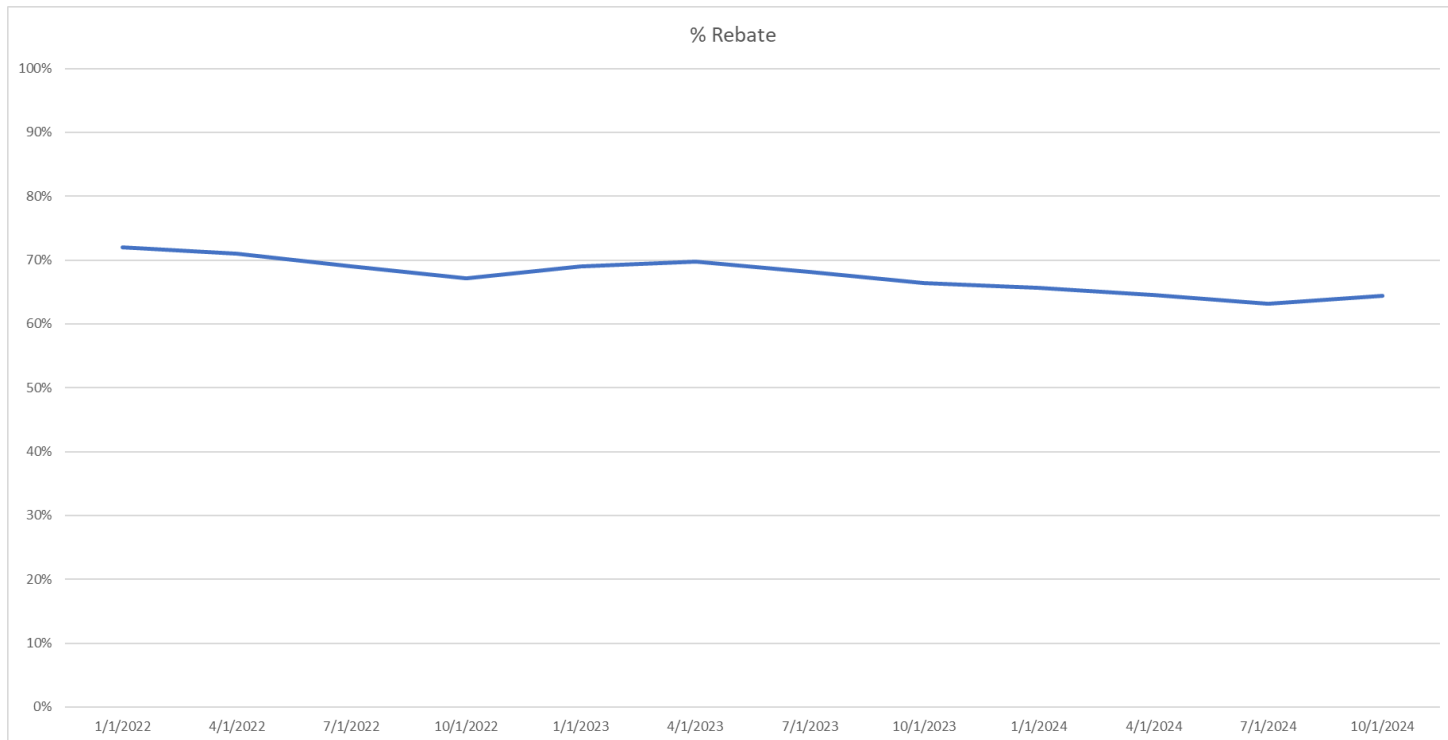
- Required prior authorization for members less than 18 years old that are on 5 or more psychotropic drugs for prescribers to have a peer-to-peer consult with a board-certified child and adolescent psychiatrist. Following the consultation, the department approves prior authorization.
- Department may not prior authorize substantially all drugs in the following restricted classes: antipsychotics, antidepressants, anticonvulsants, antiretrovirals for human immunodeficiency virus, antineoplastics, immunosuppressants for organ transplant.

Now:

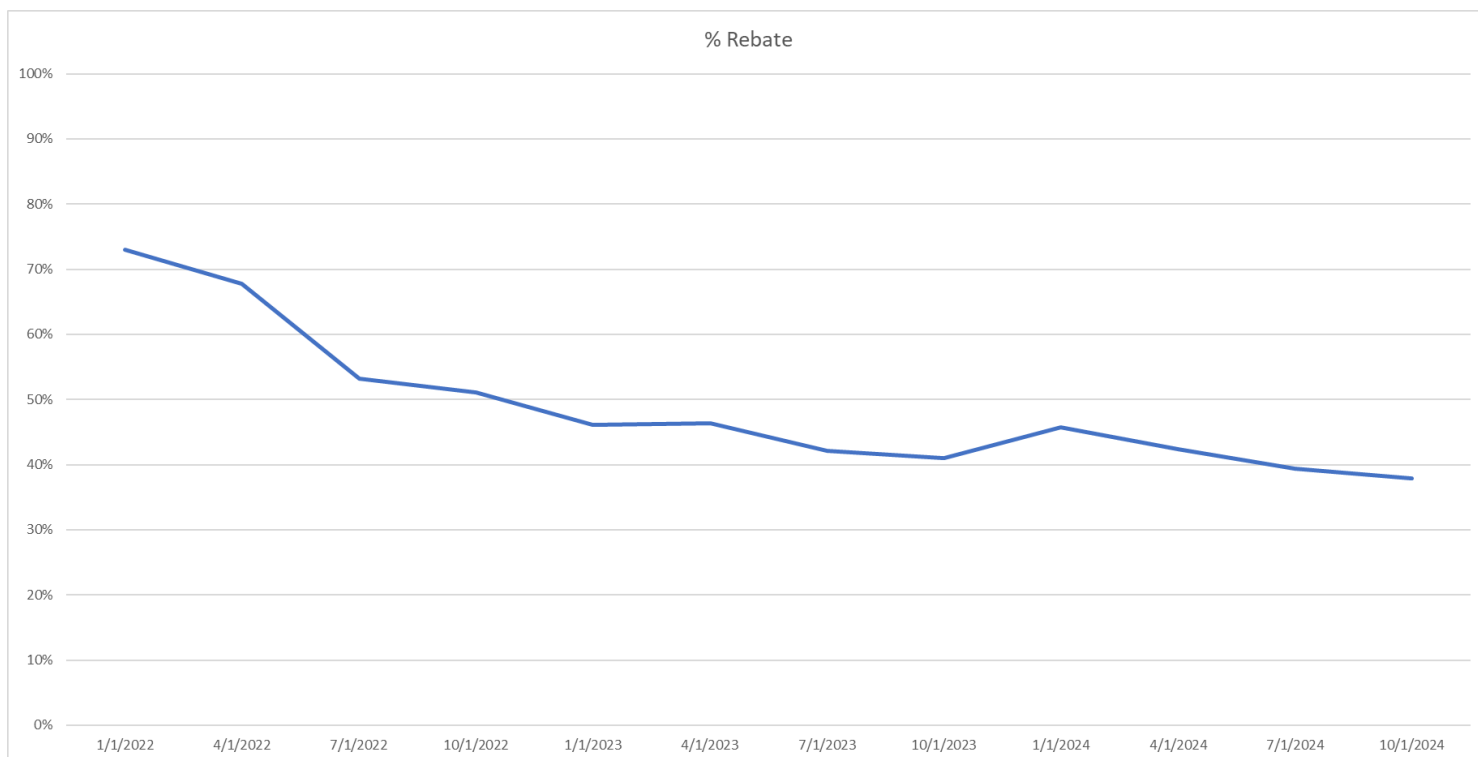
- Department will send letters to prescribers of members who are less than 22 years old that are on 5 or more psychotropic drugs to certify that the medication is medically necessary. If the prescriber does not certify, the department may deny payment until certification.
- Department may prior authorize drugs in the restricted classes if the department will not be able to access offers due to the restriction.

Financial Report

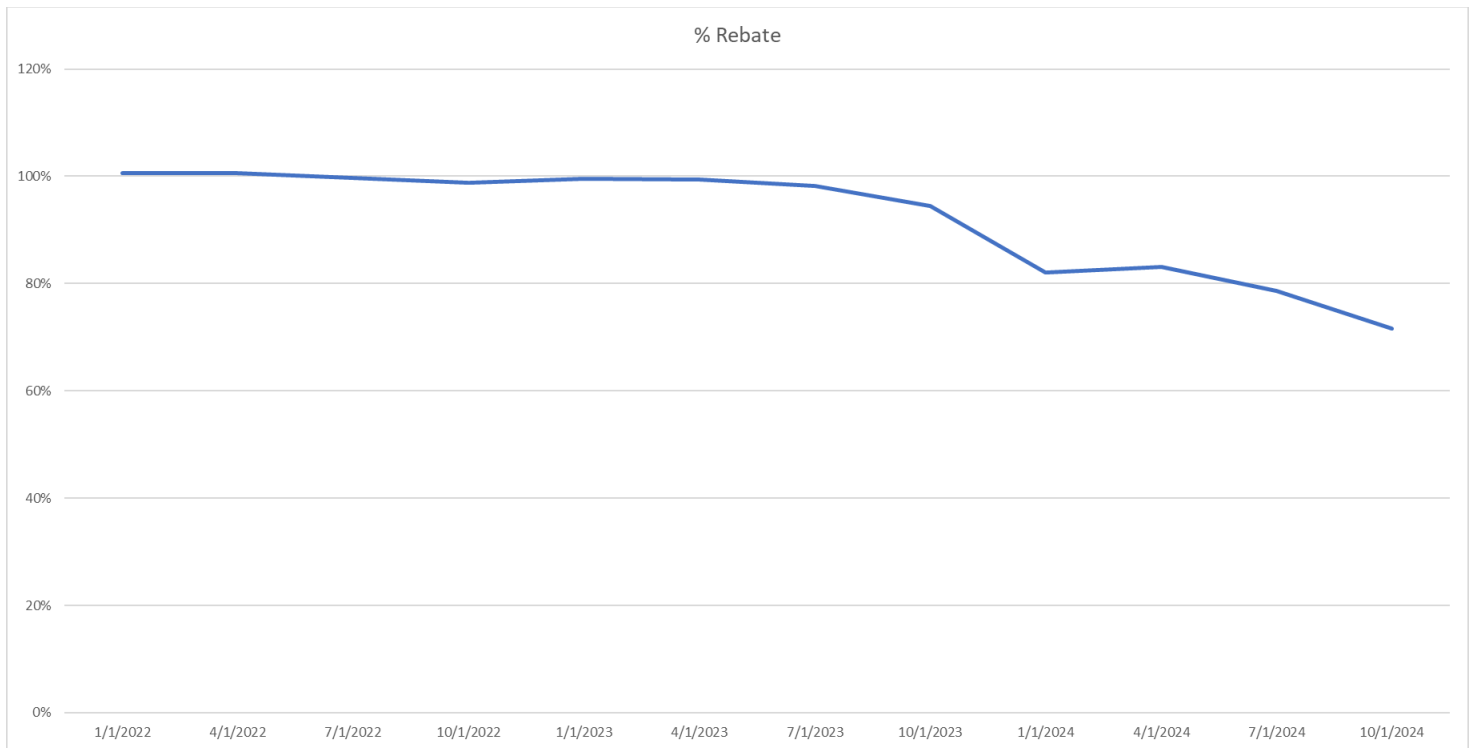
% Rebate is decreasing



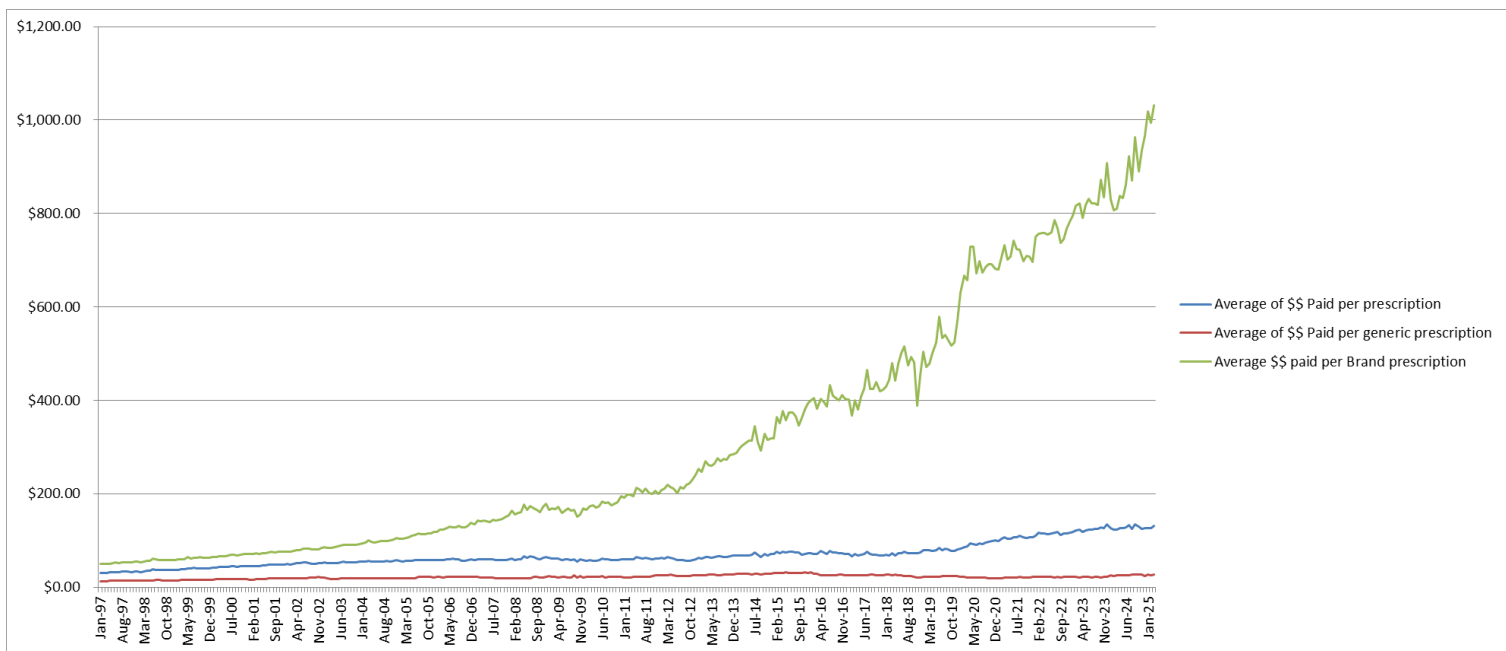
Drug classes dominated by generics driving rebate % decrease: Anticonvulsants, Cholesterol, Hypertension



AMP Cap price decreases and switches to generic preferences are a recent contributor particularly in the ADHD Stimulants, COPD, Insulins, and Steroid/LABA combinations classes.



Branded drugs now costing on average more than \$1000 per prescription

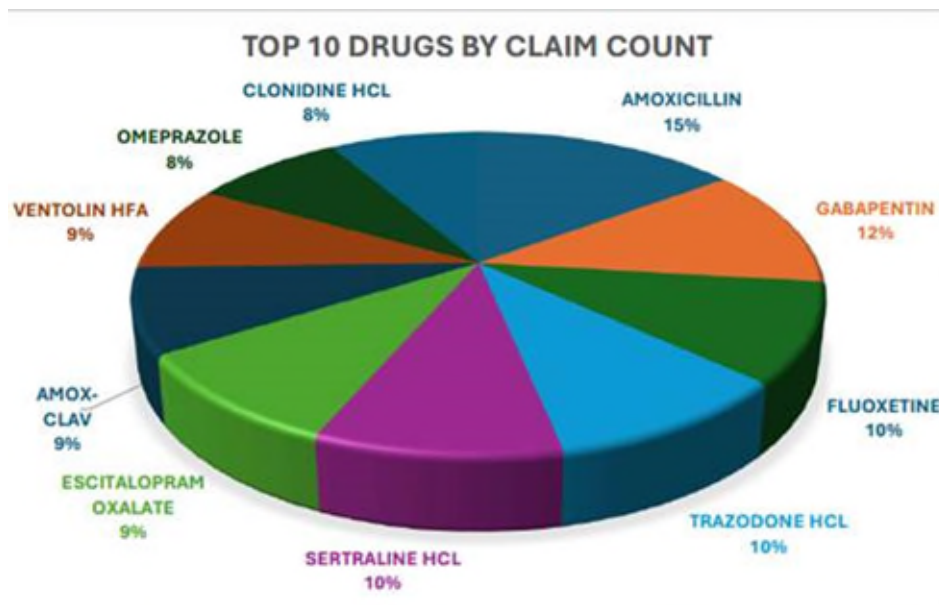


On the horizon:

- Linagliptin products will be sole preferred (e.g., Trajenta)
 - o Sitagliptin products (e.g., Januvia) will require prior authorization on 7/1/25
- Dulera will be sole preferred
 - o Advair Diskus and Advair HFA will require prior authorization on 10/1/25

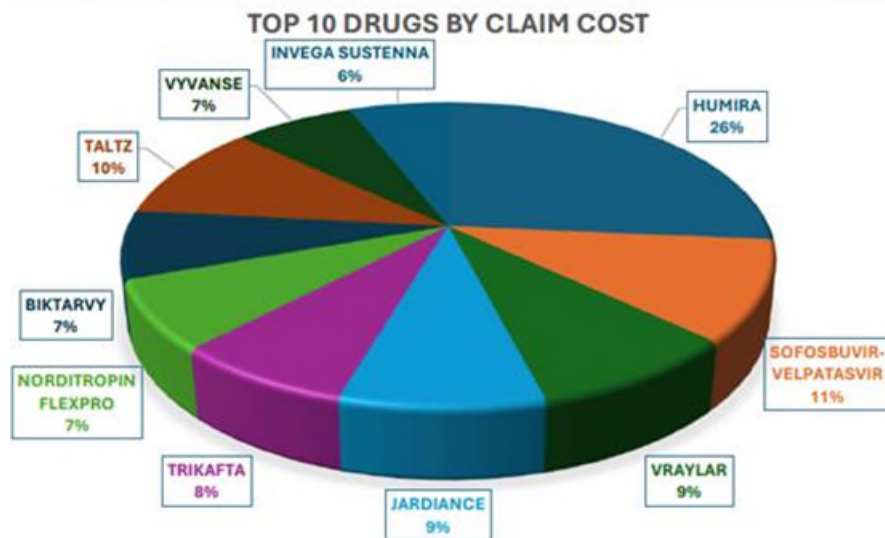
Top 25 Drugs Based on Number of Claims from 1/1/2025 to 3/31/2025

#	Drug Name	Claims	Claims Cost	Patients	Cost/Claim	% Claims	Dif.
1	AMOXICILLIN	5,532	\$87,859.33	5,151	\$15.88	2.10%	↑1
2	GABAPENTIN	4,479	\$64,377.67	1,861	\$14.37	1.70%	↓1
3	FLUOXETINE HCL	3,709	\$48,851.10	1,999	\$13.17	1.41%	↑3
4	TRAZODONE HCL	3,685	\$49,160.42	1,947	\$13.34	1.40%	↓1
5	SERTRALINE HCL	3,635	\$48,701.14	2,026	\$13.40	1.38%	↓2
6	ESCITALOPRAM OXALATE	3,551	\$47,248.60	1,974	\$13.31	1.35%	↓2
7	AMOXICILLIN-CLAVULANATE POTASS	3,185	\$56,759.20	2,988	\$17.82	1.21%	↑6
8	VENTOLIN HFA	3,183	\$204,529.06	3,143	\$64.26	1.21%	↑1
9	OMEPRAZOLE	3,145	\$41,836.28	1,887	\$13.30	1.19%	↓2
10	CLONIDINE HCL	3,136	\$38,549.24	1,538	\$12.29	1.19%	NC
11	PREDNISONE	3,030	\$35,804.87	2,425	\$11.82	1.15%	↑3
12	LEVOTHYROXINE SODIUM	2,988	\$42,960.97	1,580	\$14.38	1.13%	↓4
13	HYDROXYZINE HCL	2,813	\$38,081.84	1,729	\$13.54	1.07%	↑3
14	BUPROPION XL	2,791	\$46,624.08	1,503	\$16.71	1.06%	↓2
15	ATORVASTATIN CALCIUM	2,791	\$43,575.16	1,619	\$15.61	1.06%	↓4
16	DEXTROAMPHETAMINE-AMPHET ER	2,685	\$80,872.69	1,106	\$30.12	1.02%	↑1
17	LISINOPRIL	2,676	\$35,060.12	1,619	\$13.10	1.01%	↓2
18	ONDANSETRON ODT	2,639	\$37,714.34	2,109	\$14.29	1.00%	↑10
19	VYVANSE	2,605	\$747,501.09	1,212	\$286.95	0.99%	↑3
20	METHYLPHENIDATE ER	2,584	\$72,297.58	1,079	\$27.98	0.98%	↓2
21	ARIPIPRAZOLE	2,393	\$37,968.24	1,153	\$15.87	0.91%	↓2
22	LAMOTRIGINE	2,386	\$33,211.52	994	\$13.92	0.90%	↑1
23	PANTOPRAZOLE SODIUM	2,350	\$32,311.45	1,341	\$13.75	0.89%	↓3
24	HYDROCODONE-ACETAMINOPHEN	2,311	\$34,381.11	1,482	\$14.88	0.88%	↓3
25	DULOXETINE HCL	2,257	\$37,268.00	1,185	\$16.51	0.86%	↓1
Total Claims						263,703	



Top 25 Drugs Based on Total Claims Cost from 1/1/25 – 3/31/25

#	Drug Name	Claims	Claims Cost	Patients	Cost/Patient	% Cost	Dif.
1	HUMIRA	316	\$2,775,642.35	128	\$18,513.85	7.32%	NC
2	SOFOBUVIR-VELPATASVIR	49	\$1,115,439.45	49	\$22,764.07	2.94%	NC
3	TALTZ	130	\$1,079,290.08	59	\$71,097.34	2.85%	NC
4	VRAYLAR	875	\$938,432.87	347	\$ 2,704.42	2.48%	↑2
5	JARDIANCE	1,177	\$900,360.82	631	\$1,426.88	2.38%	NC
6	TRIKAFTA	35	\$796,751.15	14	\$56,910.80	2.10%	↑3
7	DUPIXENT	206	\$785,688.90	90	\$17,319.68	2.07%	NC
8	NORDITROPIN FLEXPOR	117	\$769,216.75	44	\$17,482.20	2.03%	↑4
9	BIKTARVY	353	\$756,722.07	154	\$4,913.78	2.00%	↑1
10	VYVANSE	2,605	\$747,501.09	1,212	\$ 616.75	1.97%	↑1
11	INVEGA SUSTENNA	221	\$623,742.07	86	\$7,252.81	1.65%	NC
12	VICTOZA	793	\$474,407.71	553	\$1,785.34	1.25%	↓6
13	ELIQUIS	734	\$450,768.72	356	\$1,266.20	1.19%	↑1
14	SUBLOCADE	178	\$370,786.60	78	\$4,753.67	0.98%	↑1
15	COSENTYX	36	\$356,217.91	15	\$72,283.97	0.94%	↓5
16	INGREZZA	42	\$336,111.86	18	\$18,672.88	0.89%	↑1
17	STELARA	12	\$297,522.21	9	\$33,058.02	0.79%	↓1
18	VERZENIO	19	\$277,585.95	7	\$39,655.14	0.73%	↑6
19	XIFAXAN	98	\$270,525.15	52	\$5,202.41	0.71%	↑3
20	DULERA	784	\$245,466.89	472	\$520.06	0.65%	NC
21	LISPRO	1156	\$ 242,774.38	743	\$537.48	0.64%	↑15
22	ABILIFY MAINTENA	91	\$ 237,419.19	36	\$6,594.98	0.63%	↓1
23	FARXIGA	357	\$221,670.04	186	\$1,191.77	0.58%	NC
24	SKYRIZI PEN	10	\$206,528.24	7	\$29,504.03	0.54%	↑26
25	VENTOLIN HFA	3,183	\$204,529.06	3,143	\$65.07	0.54%	↑1
Total Cost						\$37,895,615.57	



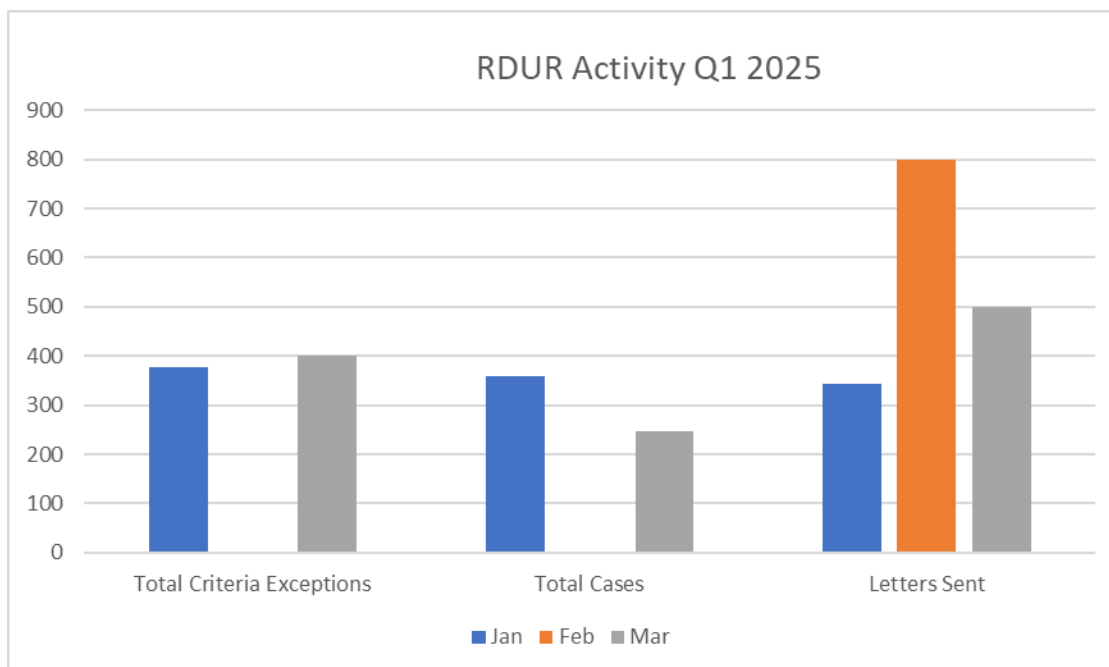
Top 15 Therapeutic Classes Based on Number of Claims from 1/1/25 – 3/31/25

#	Therapeutic Class Description	Claims	Claims Cost	Patients	Cost/Claim	% Claims	Dif.
1	ANTIDEPRESSANTS	26,651	585,037.61	11,036	21.95	10.11%	NC
2	ANTIPSYCHOTIC AGENTS	10,288	2,908,012.35	4,051	282.66	3.90%	NC
3	PENICILLIN ANTIBIOTICS	8,996	149,177.40	7,943	16.58	3.41%	↑3
4	AMPHETAMINES	7,476	960,498.93	2,976	128.48	2.84%	↓1
5	RESPIRATORY AND CNS STIMULANTS	7,289	425,894.57	2,765	58.43	2.76%	↓1
6	GABA-MEDIATED ANTICONVULSANTS	6,968	137,047.78	2,797	19.67	2.64%	↓1
7	BETA-ADRENERGIC AGONISTS	6,886	816,938.73	4,792	118.64	2.61%	NC
8	OPIOID AGONISTS (28:08)	6,008	106,877.56	3,113	17.79	2.28%	↑1
9	CENTRAL ALPHA-AGONISTS	5,938	83,044.96	2,605	13.99	2.25%	↑1
10	ADRENALS	5,919	212,706.65	4,326	35.94	2.24%	↑2
11	PROTON-PUMP INHIBITORS	5,835	102,346.14	3,364	17.54	2.21%	↓3
12	NONSTEROIDAL ANTI-INFLAMMATORY AGENTS	5,672	76,946.64	3,848	13.57	2.15%	↓1
13	ANTICONVULSANTS, MISCELLANEOUS	5,410	367,124.20	2,195	67.86	2.05%	↑1
14	HMG-COA REDUCTASE INHIBITORS	5,026	75,998.72	2,942	15.12	1.91%	↓1
15	BETA-ADRENERGIC BLOCKING AGENTS	4,960	81,948.07	2,816	16.52	1.88%	NC

Top 15 Therapeutic Classes Based on Claims Cost from 1/1/25 – 3/31/25

#	Therapeutic Class Description	Total Claims	Total Claims Cost	Total Patients	Cost Per Patient	% Cost	Dif.
1	TNF INHIBITORS	399	3,250,471.12	156	20,836.35	8.58%	NC
2	ANTIPSYCHOTIC AGENTS	10,288	2,908,012.35	4,051	717.85	7.67%	NC
3	INTERLEUKIN AGENTS	181	1,744,815.68	75	23,264.21	4.60%	NC
4	ANTINEOPLASTIC AGENTS	579	1,654,842.23	242	6,838.19	4.37%	↑3
5	ANTIRETROVIRALS	823	1,319,725.69	303	4,355.53	3.48%	↓1
6	HCV ANTIVIRALS	52	1,162,260.63	51	22,789.42	3.07%	↑2
7	SGLT2 INHIB	1,589	1,153,830.85	842	1,370.35	3.04%	↓2
8	AMPHETAMINES	7,476	960,498.93	2,976	322.75	2.53%	↓1
9	CFTR CORRECTORS	37	843,254.03	15	56,216.94	2.23%	↑2
10	PITUITARY	372	821,384.74	154	5,333.67	2.17%	↑6
11	BETA AGONISTS	6,886	816,938.73	4,792	170.48	2.16%	↓1
12	SKIN AGENTS	219	786,111.21	101	7,783.28	2.07%	NC
13	INCRETIN MIMETICS	1,200	767,560.71	600	1,279.27	2.03%	↓6
14	INSULINS	3,157	623,960.02	1,294	482.19	1.65%	↓1
15	ANTIDEPRESSANTS	26,651	585,037.61	11,036	53.01	1.54%	↓1

RDUR Report: Q1 2025



January Cases by Type of Criteria

Criteria Description	# of Cases	% of Cases
Underuse Precaution	96	58.53%
Drug-Drug/Diagnosis	35	21.34%
Therapeutic Appropriateness	16	9.76%
Drug-Drug Interaction	14	8.54%
Drug-Disease Precaution	2	1.22%
Overuse Precaution	1	0.61%

March Cases by Type of Criteria

Criteria Description	# of Cases	% of Cases
Underuse Precaution	122	49.39%
Overuse Precaution	37	14.98%
Drug-Disease Precaution	36	14.57%
Therapeutic Appropriateness	23	9.31%
Drug-Drug/Diagnosis	14	5.67%
High Dose Alert	10	4.05%
Drug-Drug Interaction	5	2.02%

February Special Mailing

800 Letters Sent

Dear Prescriber,

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, 2023 until September 30, 2024 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, 2023 through September 30, 2024 and fax it to 866-798-4904.**

Thank you for your professional consideration.

Sincerely,



Brendan K. Joyce, PharmD

Administrator, Pharmacy Services

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

Clinical Report

Prior Authorization Updates

Drug	PA Status	Class
Cortrophin	PA	>3000 criteria
diclofenac powder pack (generic Cambia)	PA	Migraine
Gomekli	PA	>3000 criteria
Hemiclor	PA	Antihypertensive
Inzirqo	PA	Diuretics
Onapgo	PA	Parkinson's Disease
Otulfi	PA	Cytokine Modulators
Qfitlia	PA	Hemophilia
Raldesy	PA	Non-Solid Dosage Forms
Symbravo	PA	Migraine treatment
Tezruly	PA	Benign Prostatic Hyperplasia
Vanrafia	PA	Chronic Kidney Disease
Xdemvy	PA	Ophthalmic Anti-infectives
Zunveyl	PA	Alzheimer's Disease

Criteria Updates

Summary of Changes

Amyloidosis

Amvuttra added indication for ATTR-CM

We have non-preferred Amvuttra for ATTR-CM, and added language allowing coverage if member meets criteria for both indications

Polyneuropathy of hereditary transthyretin-mediated amyloidosis (hATTR-PN)

TTR-specific small interfering RNA (siRNA)

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ONPATTRO (patisiran) – Medical Billing	

Transthyretin-directed small interfering RNA (siRNA)

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AMVUTTRA (vutrisiran) – Medical Billing	

Antisense Oligonucleotide (ASO)

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
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
- One of the following must be provided:
 - Baseline polyneuropathy disability (PND) score $\leq$ IIIb
 - Baseline Coutinho staging system stage 1 or 2
 - Baseline Neuropathy Impairment Score [NIS] of 5–130
 - Karnofsky Performance Status score of $\geq 60\%$
- 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., acoramidis, tafamidis)

Renewal Criteria – Approval Duration: 12 months

- The member has received 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 $\leq$ IIIb
 - Coutinho staging system stage 1 or 2
 - Baseline Neuropathy Impairment Score [NIS] of 5–130
 - Karnofsky Performance Status score of $\geq 60\%$

Cardiomyopathy of transthyretin-mediated amyloidosis (ATTR-CM)

Transthyretin-directed small interfering RNA (siRNA)

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	AMVUTTRA (vutrisiran) – <i>Medical Billing</i>

TTR Stabilizers

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ATTRUBY (acoramidis)	
VYNDALCEL (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.
- Confirmation of the diagnosis by both of the following must be provided:
 - o presence of grade 2 or 3 positive bone tracer cardiac scintigraphy
 - o absence of monoclonal protein confirmed by serum protein immunofixation, urine protein immunofixation, or serum free light chain ratio analysis
- 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.
- For Attruby only: The member must not have any of the following:
 - o ALT or AST > 2x ULN or Total Bilirubin >3x ULN
 - o NT-proBNP level > 8500 pg/mL
- The member must not have any of the following:
 - o eGFR < 25 mL/min/1.73m²
 - o NYHA class IV symptoms or severe aortic stenosis
 - o Previous heart transplant or implanted cardiac mechanical assist device
 - o Previous liver transplant
- Baseline 6MWT > 100 meters must be submitted.
- The member is not receiving any other TTR reducing agent (i.e., patisiran, elplontersen)

For Amvuttra Only:

- The member must have failed a 90-day trial of each Attruby and Vyndaqel/Vyndamax, as evidenced by paid claims or pharmacy printouts
- Coverage will be allowed without trial of preferred medications if the member also meets the criteria for hATTR-PN

Renewal Criteria – Approval Duration: 12 months

- For Attruby only: The member has received a therapeutic response as evidenced by stabilization or improvement from baseline in both of the following:
 - o 6MWT
 - o NT-proBNP level
- For Vyndaqel/Vyndamax and Amvuttra: The member has received a therapeutic response as evidenced by stabilization or improvement from baseline in both of the following:

- o 6MWT
- o NYHA class

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.

Chronic Kidney Disease

Vanrafia was added to the section

Fabhalta and Filspari criteria were split to differentiate the cause of proteinuria from Complement 3 Glomerulopathy (C3G) or IGA Nephropathy (IgAN).

Therapeutic Duplication

- Medication classes not payable together:
 - o Filspari, ACE Inhibitors, ARBs, and Renin Inhibitors are not allowed with each other.

Dual endothelin angiotensin receptor antagonist

CLINICAL PA REQUIRED

FILSPARI (sparsentan)

Endothelin receptor antagonist

CLINICAL PA REQUIRED

VANRAFIA (atrasentan)

Factor B Inhibitors

CLINICAL PA REQUIRED

FABHALTA (iptacopan)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

Fabhalta 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 ≥ 1.0 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:
 - o ACE inhibitor or an ARB
 - o systemic corticosteroid
 - o SGLT-2 inhibitor (IgAN diagnosis only)
 - o mycophenolate mofetil/sodium (C3G diagnosis only)

Filspari 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:
 - o ACE inhibitor or an ARB
 - o A SGLT-2 inhibitor
 - o systemic corticosteroid

Vanrafia 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:
 - o ACE inhibitor or an ARB
 - o A SGLT-2 inhibitor

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, Tarpeyo and Vanrafia Only*: proteinuria < 0.5 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:
 - o albuminuria < 1 gram/day or reduction of 30% from baseline
 - o UACR < 1.5 g/g or reduction of 30% from baseline

Hemophilia

Procoagulants Alhemo, Hympavzi, and Qfitlia were added to the section. These medications work to lower the amount of anticoagulants (such as antithrombin) to balance the clotting cascade from a different direction than from factor replacement.

Hemophilia A already has a subcutaneous prophylaxis option with a long half-life that is well-established as effective, so Hemlibra is preferred for these members.

Hemophilia B does not have any other SQ options for prophylaxis, so the member can use Alhemo or Hympavzi, depending on their inhibitor status, reserving Qfitlia for those who have failed previous trials.

Hemophilia A

Recombinant humanized bispecific monoclonal antibody

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
HEMLIBRA (emicizumab-kxwh)	

Procoagulant (TFPI inhibitors/Antithrombin inhibitors)

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

	ALHEMO (concizumab-mtci)
	HYMPAVZI (marstacimab-hncq)
	QFITLIA (fitusiran)

Hemophilia B

Procoagulant (TFPI inhibitors/Antithrombin inhibitors)

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ALHEMO (concizumab-mtci)	QFITLIA (fitusiran)
HYMPAVZI (marstacimab-hncq)	

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)
- *Alhemo only:*
 - o The member must have one of the following:
 - A diagnosis of Hemophilia A with inhibitors AND has failed a 6-month trial with Hemlibra
 - A diagnosis of Hemophilia B with inhibitors
- *Hympavzi only:*
 - o The member must have one of the following:
 - A diagnosis of Hemophilia A without inhibitors AND has failed a 6-month trial with Hemlibra
 - A diagnosis of Hemophilia B without inhibitors
- *Qfitlia only:*
 - o The member must have one of the following:
 - A diagnosis of Hemophilia A with or without inhibitors AND has failed a 6-month trial with Hemlibra
 - A diagnosis of Hemophilia B with or without inhibitors AND has failed a 6-month trial with Hympavzi OR Alhemo, depending on inhibitor status

New Business:

Second Review

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*

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:
 - o Glutamic acid decarboxylase 65 (GAD) autoantibodies
 - o Insulin autoantibody (IAA)
 - o Insulinoma-associated antigen 2 autoantibody (IA-2A)
 - o Zinc transporter 8 autoantibody (ZnT8A)
 - o 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
	ZITUVIMET XR (sitagliptin/metformin)
	ZITUVIO (sitagliptin)

++Clinically Non-Preferred: Alogliptin and saxagliptin 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, as evidenced by paid claims or pharmacy printouts.
 - o 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.
 - o Metformin is more effective than DPP-4 inhibitors and lowering A1c and weight when used as monotherapy.

* 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, as evidenced by paid claims or pharmacy printouts.
- The member 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 ($\leq 7\%$) 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/linagliptin/metformin)	GLYXAMBI (empagliflozin/linagliptin)
	STEGLUJAN (ertugliflozin/sitagliptin)
	++QTERN (dapagliflozin/saxagliptin)

++Clinically Non-Preferred: Saxagliptin 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)
liraglutide - <i>generic allowed due to shortage but brand preferred</i>	OZEMPIC (semaglutide)	TRULICITY (dulaglutide)
VICTOZA (liraglutide) - Brand Preferred	RYBELSUS (semaglutide)	

++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
 - o Victoza 1.2 mg = Trulicity 0.75 mg = Ozempic 0.25 mg
 - o Victoza 1.8 mg = Trulicity 1.5 mg = Ozempic 0.5 mg = Rybelsus 7 mg or 14 mg = Mounjaro 2.5 mg
 - o Trulicity 3 mg = Ozempic 0.5 mg or 1 mg
 - o Trulicity 4.5 mg = Ozempic 1 mg
 - o 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 and Rybelsus:
 - o One of the following apply (A or B):

- The member has been unable to achieve goal A1C ($\leq 7\%$) or TIR ($>70\%$) despite a 90-day trial of triple combination therapy with liraglutide, metformin, SGLT-2 inhibitor or insulin, as evidenced by paid claims or pharmacy printouts.
 - If triple therapy cannot be met with liraglutide, clinical justification must be provided (subject to clinical review*), and triple therapy must be met with SGLT-2 inhibitor + DPP4 inhibitor + metformin
 - If triple therapy cannot be met with SGLT-2 inhibitor + DPP4 inhibitor + metformin, clinical justification must be provided (subject to clinical review*)
- The request is for Ozempic, as evidenced by paid claims or pharmacy printouts, and is eligible for approval for semaglutide based on the MASH criteria or tirzepatide based on the Sleep Apnea criteria.
- Step 2:
 - o The member has been unable to achieve goal A1C ($\leq 7\%$) or TIR ($>70\%$) despite two 90-day trials of triple combination therapy (one trial with liraglutide 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 liraglutide or Ozempic, clinical justification must be provided (subject to clinical review*), and triple therapy must be met with SGLT-2 inhibitor + DPP4 inhibitor + metformin.
 - If triple therapy cannot be met with SGLT-2 inhibitor + DPP4 inhibitor + metformin, clinical justification must be provided (subject to clinical review*)
 - o 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, the member must trial at minimum a dose of 500 mg ER.
- If on liraglutide or Ozempic, the member should be evaluated on potential for GI side effects; GI effects are common across all GLP-1 agonist agents and transient in nature, typically lessening with ongoing treatment.
- If the member is 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.

Note: If the member qualifies for semaglutide, the most cost effective semaglutide product will be authorized.

GIP/GLP-1 Agonists

CLINICAL PA REQUIRED

MOUNJARO (tirzepatide)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- One of the following is met (A or B):
 - o The member meets both of the following (1 and 2):
 - The member has been unable to achieve goal A1C ($\leq 7\%$) or TIR ($>70\%$) despite two 90-day trials of triple combination therapy (one trial with liraglutide and one with Ozempic, subject to clinical review*) along with metformin, SGLT-2 inhibitor or insulin, as evidenced by paid claims or pharmacy printouts.
 - o If triple therapy cannot be met with liraglutide or Ozempic, clinical justification must be provided (subject to clinical review*), and triple therapy must be met with SGLT-2 inhibitor + DPP4 inhibitor + metformin.
 - o If triple therapy cannot be met with SGLT-2 inhibitor + DPP4 inhibitor + metformin, clinical justification must be provided (subject to clinical review*)

- One of the following have been met (a or b):
 - a. The requested medication must be prescribed by, or in consult with, an endocrinologist or diabetes specialist.
 - b. The member has received diabetes education from a diabetic specialist, diabetic educator, or pharmacist (may be accomplished through the MTM program).
- o The request is for Mounjaro and the member is otherwise eligible for approval for tirzepatide based on the Sleep Apnea criteria.

*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 liraglutide or Ozempic, the 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 lessening with ongoing treatment.
- If the member is 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.

Note: If the member qualifies for tirzepatide, the most cost effective tirzepatide product will be authorized.

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), 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
GVOKE (glucagon) INJECTION	glucagon kit
ZEGALOGUE (dasiglucagon) AUTOINJECTOR	

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) CARTRIDGE	insulin lispro vials – See Biosimilar Agents
insulin lispro U-100 pen, jr pen	

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 insulin lispro 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 insulin lispro, as evidenced by paid claims or pharmacy printouts.
- Insulin Vials
 - PA Not Required Criteria: A 28-day supply of Omnipod has been paid within 90 days prior to insulin lispro vial's date of service.
 - PA Required Criteria: The member has an insulin pump.

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:
 - o insulin lispro
 - o 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 \(lillymedical.com\)](#)
 - o 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.
 - o 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:
 - o insulin lispro
 - o 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 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:
 - o The member must be pregnant or breastfeeding.
 - o The member must be tube feedings.
 - o 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)
 - o Clinical justification explaining why the member is unable to use Lantus (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) – Brand Required	insulin glargine U-100 (generic Toujeo)
TOUJEO U-300 (insulin glargine) *No PA required for doses 100 unit/day to 200 unit/day – Brand Required	insulin glargine (Lantus) – See Biosimilar Agents

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 - <i>Brand Required</i>	insulin degludec U-100 and U-200
	TRESIBA (insulin degludec) U-100

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.

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) – <i>Brand Required</i>
	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) – <i>Brand Required</i>	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 – <i>Brand Required</i>	INVOKAMET (canagliflozin/metformin)
	INVOKAMET XR (canagliflozin/metformin)
	STEGLATRO (ertugliflozin)
	SEGLUROMET (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

First Review of Non-Opioid Analgesics

Nonopioid Analgesic Therapies ¹		
Medication	Type of Pain	Important Info
Acetaminophen	Acute pain (typically as part of a multimodal regimen)	• Max 4 g/day • Avoid in patients with hepatic impairment
Gabapentinoids	Neuropathic pain	• Use reduced dose in kidney impairment and older adults • Can cause respiratory depression when administered with opioids • Dose-dependent ataxia and somnolence (avoid in patients > 75 years of age) • Elevated abuse potential
NSAIDs	Acute pain (typically as part of a multimodal regimen)	• Risk of CV thrombotic events (higher with COX-2-selective) • Avoid use in patients with kidney dysfunction, CV disease, or peptic ulcer disease
Lidocaine	Localized pain	• May be less effective or convenient for some types of pain
Skeletal muscle relaxants	Muscle spasm contributing to pain	• Elevated abuse potential • Can cause sedation and dizziness • Use in caution with opioids

Treatment options for Moderate and Severe acute pain:

- Gabapentinoids
- Opioids on an as needed basis for both moderate and severe pain. Can be used scheduled for severe pain.

- Both NCT05558410 and NCT05553366 assessed Journavx vs placebo vs hydrocodone/APAP 5/325mg, along with ibuprofen 400mg prn, to treatment postsurgical pain after abdominoplasty and bunionectomy.
 - o Journavx showed a faster onset to pain relief if the abdominoplasty trial compared to hydrocodone/APAP.
 - o Journavx had a slower onset to pain relief in the bunionectomy trial
 - o Both trials showed similar efficacy between Journavx and hydrocodone/APAP 5/325mg in reduction of mean pain relief scale.

A NEW NONOPIOID ANALGESIC OPTION FOR ACUTE PAIN

Journavx is a sodium calcium channel blocker for the treatment of moderate to severe acute pain in adults.²

Mechanism of action: selective blocker of the Na(v)1.8 voltage-gated sodium channel which inhibits transmission of pain signals to the spinal cord and brain. ²

Journavx (suzetrigine) ²	
Indication	Moderate to severe acute pain
Market Landscape	
Clinical Studies ³	• NCT05558410 – studied 1,118 participants aged 18-69. The median time to meaningful pain relief (2-point reduction in NPRS) was 119 minutes. • NCT05553366 – studied 1,073 participants aged 18-75. The median time to meaningful pain relief (2-point reduction in NPRS) was 240 minutes.
Dosing	100mg once on an empty stomach, then 50mg every 12 hours
Important Considerations	• Duration beyond 14 days has not been studied and is only indicated for treatment of acute pain • Should not be used with strong CYP3A inhibitors • Half-life 23.6 hours (metabolite half-life 33 hours) • Avoid use in severe hepatic impairment • Avoid use in eGFR < 15 ml/min • Additional nonhormonal contraception should be used during and 28 days after discontinuation in patients taking progestins other than levonorgestrel and norethindrone
Cost	\$465 (30 count bottle) or \$18.60/unit ⁴

FDA Approval

Journavx (suzetrigine): May 30, 2024; 505(b) New Drug Application (NDA) pathway Type 1 – New Molecular Entity.⁵

Current Utilization

Quarter 2 2024 thru Quarter 1 2025

Medication	Rx Count	Claims Cost
Journavx	1	\$370.24

References:

1. Schwenk, ES, et al. Nonopioid pharmacotherapy for acute pain in adults. UpToDate. Feb 24, 2025. Nonopioid pharmacotherapy for acute pain in adults - UpToDate
2. Journavx (suzetrigine). Red Book. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. March 4, 2025. <https://www.Micromedexsolutions.com>
3. Journavx (suzetrigine). [prescribing information]. Vertex Pharmaceuticals, Inc. US Food and Drug Administration. Boston, MA. Jan 2025. https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/219209Orig1s000lbl.pdf
4. Journavx. Quick Answers and Red Book. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. April 15, 2025. <https://www.micromedexsolutions.com>
5. U.S. Food and Drug Administration, Center for Drug Evaluation and Research. Journavx NDA 219209 approval letter, May 30, 2024. www.accessdata.fda.gov/drugsatfda_docs/appletter/2025/219209Orig1s000ltr.pdf

NORTH DAKOTA MEDICAID

RETROSPECTIVE DRUG UTILIZATION REVIEW

CRITERIA RECOMMENDATIONS

2nd QUARTER 2025

Criteria Recommendations

Approved Rejected

1. Repotrectinib / Overuse

Alert Message: Augtyro (repotrectinib) may be over-utilized. The recommended dosage of repotrectinib for adult and pediatric patients 12 years of age and older is 160 mg taken orally once daily with or without food for 14 days, then increase to 160 mg twice daily and continue until disease progression or unacceptable toxicity.

Drugs/Diseases

Util A

Util B

Util C

Repotrectinib

Max Dose: 320 mg/day

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.

Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.

Augtyro Prescribing Information, June 2024, Bristol-Myers Squibb.

2. Repotrectinib / Therapeutic Appropriateness

Alert Message: The safety and effectiveness of Augtyro (repotrectinib) have not been established in pediatric patients younger than 12 years of age with solid tumors who have an NTRK gene fusion.

Drugs/Diseases

Util A

Util B

Util C

Repotrectinib

Age Range: 0 – 11 yoa

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.

Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.

Augtyro Prescribing Information, June 2024, Bristol-Myers Squibb.

3. Repotrectinib / Therapeutic Appropriateness

Alert Message: The safety and effectiveness of Augtyro (repotrectinib) in pediatric patients with ROS1-positive NSCLC have not been established.

Drugs/Diseases

Util A

Util B

Util C (Include)

Repotrectinib

Neoplasm of Lungs

Age Range: 0 – 17 yoa

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.

Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.

Augtyro Prescribing Information, June 2024, Bristol-Myers Squibb.

4. Repotrectinib / Hepatotoxicity

Alert Message: Augtyro (repotrectinib) can cause hepatotoxicity. Among the 426 patients treated with repotrectinib in clinical trials, increased alanine transaminase (ALT) occurred in 38%, and increased aspartate aminotransferase (AST) occurred in 41%. The median time to onset of increased ALT or AST was 15 days (range: 1 day to 1.9 years). Monitor liver function tests, including ALT, AST, and bilirubin, every 2 weeks during the first month of treatment, then monthly thereafter and as clinically indicated. Withhold and then resume at the same or reduced dose upon improvement or permanently discontinue repotrectinib based on the severity.

Drugs/Diseases		
<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Repotrectinib	Abnormal Liver Enzyme Test	

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Augtyro Prescribing Information, June 2024, Bristol-Myers Squibb.

5. Repotrectinib / Interstitial Lung Disease

Alert Message: Augtyro (repotrectinib) can cause interstitial lung disease (ILD)/pneumonitis. Monitor patients for new or worsening pulmonary symptoms indicative of ILD/pneumonitis. Immediately withhold repotrectinib in patients with suspected ILD/pneumonitis and permanently discontinue repotrectinib if ILD/pneumonitis is confirmed.

Drugs/Diseases		
<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Repotrectinib	Interstitial Lung Disease	

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Augtyro Prescribing Information, June 2024, Bristol-Myers Squibb.

6. Repotrectinib / Skeletal Fractures

Alert Message: Augtyro (repotrectinib) can cause skeletal fractures. Promptly evaluate patients with signs or symptoms (e.g., pain, changes in mobility, deformity) of fractures. There are no data on the effects of repotrectinib on the healing of known fractures and the risk of future fractures.

Drugs/Diseases		
<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Repotrectinib	Bone Fractures	

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Augtyro Prescribing Information, June 2024, Bristol-Myers Squibb.

7. Repotrectinib / P-gp Inhibitors

Alert Message: The concomitant use of Augtyro (repotrectinib), a P-gp substrate, with P-gp inhibitors should be avoided. Concomitant use of repotrectinib with a P-gp inhibitor may increase repotrectinib exposure, which may increase the incidence and severity of repotrectinib adverse reactions.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Repotrectinib	Abrocitinib	Lapatinib
	Amiodarone	Quinidine
	Cyclosporine	Ranolazine

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.

Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.

Augtyro Prescribing Information, June 2024, Bristol-Myers Squibb.

8. Repotrectinib / Strong & Moderate CYP3A4 Inhibitors

Alert Message: The concomitant use of Augtyro (repotrectinib) with strong or moderate CYP3A4 inhibitors should be avoided. Concurrent use of repotrectinib with a strong or moderate CYP3A4 inhibitor may increase repotrectinib exposure, which may increase the incidence and severity of adverse reactions of repotrectinib. Discontinue CYP3A4 inhibitors for 3 to 5 elimination half-lives of the CYP3A4 inhibitor prior to initiating repotrectinib.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Repotrectinib	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.

Augtyro Prescribing Information, June 2024, Bristol-Myers Squibb.

9. Repotrectinib / Strong or Moderate CYP3A4 Inducers

Alert Message: The concomitant use of Augtyro (repotrectinib) with strong or moderate CYP3A4 inducers should be avoided. Concomitant use of repotrectinib with a strong or moderate CYP3A4 inducer may decrease repotrectinib plasma concentrations, which may decrease the efficacy of repotrectinib.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Repotrectinib	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.
Augtyro Prescribing Information, June 2024, Bristol-Myers Squibb.

Criteria Recommendations

Approved Rejected

10. Repotrectinib / Certain 3A4 Substrates w/ NTI

Alert Message: The concurrent use of Augtyro (repotrectinib) with a CYP3A4 substrate with a narrow therapeutic index should be avoided unless the use is otherwise recommended in the Prescribing Information for CYP3A substrates. Repotrectinib is a CYP3A4 inducer. Concomitant use of repotrectinib with a sensitive CYP3A4 substrate decreases the concentration of the CYP3A4 substrate, which can reduce the efficacy of the substrate. If concomitant use is unavoidable, increase the CYP3A4 substrate dosage in accordance with approved product labeling.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Repotrectinib	Sirolimus	
	Tacrolimus	
	Warfarin	

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Augtyro Prescribing Information, June 2024, Bristol-Myers Squibb.

11. Repotrectinib / Hormonal Contraceptives

Alert Message: Augtyro (repotrectinib) is a CYP3A4 inducer, which can decrease progestin or estrogen exposure to an extent that could reduce the effectiveness of hormonal contraceptives. Avoid concomitant use of repotrectinib with hormonal contraceptives. Advise females of reproductive potential to use an effective nonhormonal contraceptive.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Repotrectinib	Progestin Estrogen Contraceptives	

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Augtyro Prescribing Information, June 2024, Bristol-Myers Squibb.

12. Repotrectinib / Pregnancy / Pregnancy Negating

Alert Message: Based on literature reports in humans with congenital mutations leading to

changes in tropomyosin receptor tyrosine kinase (TRK) signaling, findings from animal studies, and its mechanism of action, Augtyro (repotrectinib) can cause fetal harm when administered to a pregnant patient. Oral administration of repotrectinib to pregnant rats during the period of organogenesis resulted in fetal malformations at doses approximately 0.3 times the recommended 160 mg twice daily dose based on body surface area (BSA).

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C (Negate)</u>
Repotrectinib	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.

Augtyro Prescribing Information, June 2024, Bristol-Myers Squibb.

13. Repotrectinib / Lactation

Alert Message: There are no data on the presence of Augtyro (repotrectinib) in human milk or its effects on either the breastfed child or on milk production. Because of the potential for serious adverse reactions in breastfed children from repotrectinib, advise a lactating woman to discontinue breastfeeding during treatment with repotrectinib and for 10 days after the last dose.

Drugs/Diseases		
<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Repotrectinib	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Augtyro Prescribing Information, June 2024, Bristol-Myers Squibb.

14. Repotrectinib / Therapeutic Appropriateness

Alert Message: Advise females of reproductive potential to use effective non-hormonal contraception during treatment with Augtyro (repotrectinib) and for 2 months following the last dose, since repotrectinib can render some hormonal contraceptives ineffective. Repotrectinib can cause embryo-fetal harm when administered to a pregnant woman.

Drugs/Diseases		
<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Repotrectinib		

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Augtyro Prescribing Information, June 2024, Bristol-Myers Squibb.

15. Repotrectinib / Therapeutic Appropriateness

Alert Message: Based on genotoxicity findings, advise male patients with female partners of childbearing potential to use effective contraception during treatment with repotrectinib and for 4 months following the last dose.

Drugs/Diseases		
<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Repotrectinib		

Gender: Male

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Augtyro Prescribing Information, June 2024, Bristol-Myers Squibb.

16. Repotrectinib / Non-adherence

Alert Message: Based on refill history, your patient may be under-utilizing Augtyro (repotrectinib).
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
Repotrectinib

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.

17. Upadacitinib LQ / Therapeutic Appropriateness – Atopic Dermatitis

Alert Message: The safety and effectiveness of Rinvoq LQ (upadacitinib oral solution) in pediatric patients with atopic dermatitis, ankylosing spondylitis, non-radiographic axial spondyloarthritis, ulcerative colitis, or Crohn's disease have not been established.

Drugs/Diseases
Util A Util B Util C (Include)
Upadacitinib LQ Atopic Dermatitis
 Ankylosing Spondylitis
 Non-Radiographic Axial Spondyloarthritis,
 Ulcerative Colitis,
 Crohn's Disease

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Rinvoq/Rinvoq LQ Prescribing Information, April 2024, AbbVie Inc.

18. Upadacitinib LQ / Psoriatic Arthritis and pJIA

Alert Message: Rinvoq LQ (upadacitinib oral solution) may be overutilized. The recommended dosage of upadacitinib oral solution for the treatment of psoriatic arthritis or polyarticular juvenile idiopathic arthritis in pediatric patients is weight-based. For pediatric patients weighing 30 kg or more the recommended dose is 6 mg twice daily. Pediatric patients weighing 20 kg to less than 30 kg should receive 4 mg twice daily and patients weighing 10 kg to less than 20 kg should receive 3 mg twice daily.

Drugs/Diseases
Util A Util B Util C (Include)
Upadacitinib LQ Psoriatic Arthritis
 Polyarticular Juvenile Idiopathic Arthritis

Age Range: 2 – 17 yoa
Max Dose: 12 mg/day

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Rinvoq/Rinvoq LQ Prescribing Information, April 2024, AbbVie Inc.

19. Ketorolac / Probenecid

Alert Message: The concomitant use of ketorolac tromethamine and probenecid is contraindicated. In drug interaction studies, concomitant administration of ketorolac and probenecid resulted in decreased clearance and volume of distribution of ketorolac and significant increases in ketorolac plasma levels (total AUC increased approximately threefold from 5.4 mcg/h/mL to 17.8 mcg/h/mL), and terminal half-life increased approximately twofold from 6.6 hours to 15.1 hours.

Drugs/Diseases		
<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Ketorolac	Probenecid	

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Ketorolac Tromethamine Prescribing Information, August 2024, Chartwell RX, LLC.

20. Sitagliptin/metformin XR / Overuse

Alert Message: Zituvimet XR (sitagliptin/metformin extended-release) may be over-utilized. The manufacturer's recommended maximum dose is 100 mg sitagliptin/2000 mg metformin daily.

Drugs/Diseases		
<u>Util A</u>	<u>Util B</u>	<u>Util C (Negating)</u>
Sitagliptin/Metformin XR		CKD Stage 4 CKD Stage 5 ESRD Hemodialysis

Max Dose: 100 mg/2000mg day

References:
Merative Micromedex DRUGDEX (electronic version). Merative, Ann Arbor, Michigan, USA. 2024.
UpToDate Inc. (2024). Sitagliptin and Metformin: Drug Information. Lexi-Drugs, UpToDate Lexidrug. Retrieved August 14, 2024.
Zituvimet XR Prescribing Information, July 2024, Zydus Pharmaceuticals, Inc.

21. Sitagliptin/metformin XR / Therapeutic Appropriateness

Alert Message: The safety and effectiveness of Zituvimet XR (sitagliptin/metformin extended-release) have not been established in pediatric patients.

Drugs/Diseases		
<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Sitagliptin/Metformin XR		

Age Range: 0 – 17 yoa

References:
Merative Micromedex DRUGDEX (electronic version). Merative, Ann Arbor, Michigan, USA. 2024.
UpToDate Inc. (2024). Sitagliptin and Metformin: Drug Information. Lexi-Drugs, UpToDate Lexidrug. Retrieved August 14, 2024.
Zituvimet XR Prescribing Information, July 2024, Zydus Pharmaceuticals, Inc.

22. Sitagliptin/metformin XR / Severe Renal Impairment

Alert Message: Zituvimet XR (sitagliptin/metformin extended-release) use is contraindicated in patients with severe renal impairment (eGFR below 30 mL/min/1.73m2). In clinical studies, a 4-fold increase in the plasma AUC of sitagliptin was observed in patients with severe renal impairment including patients with end-stage renal disease (ESRD) on hemodialysis, compared to normal healthy control subjects.

Drugs/Diseases		
<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Sitagliptin/Metformin XR	CKD Stage 4	
	CKD Stage 5	
	ESRD	
	Hemodialysis	

References:
Merative Micromedex DRUGDEX (electronic version). Merative, Ann Arbor, Michigan, USA. 2024.
Zituvimet XR Prescribing Information, July 2024, Zydus Pharmaceuticals, Inc.

23. Sitagliptin/metformin XR / Moderate Renal Impairment

Alert Message: Zituvimet XR (sitagliptin/metformin extended-release) use is not recommended in patients with an eGFR between 30 and less than 45 mL/min/1.73 m2 because these patients require a lower dosage of sitagliptin than what is available in the fixed combination sitagliptin/metformin product.

Drugs/Diseases		
<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Sitagliptin/Metformin XR	CKD Stage 3b	

References:
Merative Micromedex DRUGDEX (electronic version). Merative, Ann Arbor, Michigan, USA. 2024.
UpToDate Inc. (2024). Sitagliptin and Metformin: Drug Information. Lexi-Drugs, UpToDate Lexidrug. Retrieved August 14, 2024.
Zituvimet XR Prescribing Information, July 2024, Zydus Pharmaceuticals, Inc.

24. Sitagliptin/metformin XR / Type 1 Diabetes

Alert Message: Zituvimet XR (sitagliptin/metformin extended-release) should not be used in patients with type 1 diabetes mellitus.

Drugs/Diseases		
<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Sitagliptin/Metformin XR	Type 1 Diabetes	

References:
Merative Micromedex DRUGDEX (electronic version). Merative, Ann Arbor, Michigan, USA. 2024.
UpToDate Inc. (2024). Sitagliptin and Metformin: Drug Information. Lexi-Drugs, UpToDate Lexidrug. Retrieved August 14, 2024.
Zituvimet XR Prescribing Information, July 2024, Zydus Pharmaceuticals, Inc.

25. Sitagliptin/metformin XR / Insulin & Insulin Secretagogues

Alert Message: The concurrent use of Zituviem XR (sitagliptin/metformin extended-release) 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 sitagliptin/metformin.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Sitagliptin/Metformin XR	Insulin	
	Insulin Secretagogues	

References:

Merative Micromedex DRUGDEX (electronic version). Merative, Ann Arbor, Michigan, USA. 2024.
UpToDate Inc. (2024). Sitagliptin and Metformin: Drug Information. Lexi-Drugs, UpToDate Lexidrug. Retrieved August 14, 2024.
Zituvimet XR Prescribing Information, July 2024, Zydus Pharmaceuticals, Inc.

26. Sitagliptin/metformin XR / Pregnancy / Pregnancy Negating

Alert Message: The limited available data with Zituviem XR (sitagliptin/metformin extended-release) in pregnant women are not sufficient to inform a drug associated risk for major birth defects and miscarriage. Published studies with methodologies use during pregnancy have not reported a clear association with metformin and major birth defect or miscarriage risk. During pregnancy, consider appropriate alternative therapies. Sitagliptin/metformin should be used during pregnancy only if clearly needed.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C (Negating)</u>
Sitagliptin/Metformin XR	Pregnancy	Abortion
		Delivery
		Miscarriage

Gender: Female

Age Range: 11 – 50 yoa

References:

Merative Micromedex DRUGDEX (electronic version). Merative, Ann Arbor, Michigan, USA. 2024.
UpToDate Inc. (2024). Sitagliptin and Metformin: Drug Information. Lexi-Drugs, UpToDate Lexidrug. Retrieved August 14, 2024.
Zituvimet XR Prescribing Information, July 2024, Zydus Pharmaceuticals, Inc.
American Diabetes Association (ADA). 15. Management of Diabetes in Pregnancy. Standards of Care in Diabetes-2024. Diabetes Care 2024;47(Suppl. 1):S282-S294.

27. Sitagliptin/metformin XR / Lactation

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

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Sitagliptin/Metformin XR	Lactation	

Gender: Female

Age Range: 11 – 50 yoa

References:

Merative Micromedex DRUGDEX (electronic version). Merative, Ann Arbor, Michigan, USA. 2024.
UpToDate Inc. (2024). Sitagliptin and Metformin: Drug Information. Lexi-Drugs, UpToDate Lexidrug. Retrieved August 14, 2024.
Zituvimet XR Prescribing Information, July 2024, Zydus Pharmaceuticals, Inc.

28. Sitagliptin/metformin XR / Non-adherence

Alert Message: Based on refill history, your patient may be under-utilizing Zituvimet XR (sitagliptin/metformin extended-release). 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/Metformin XR

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.

29. Ropinirole IR / Overuse – Parkinson's Disease

Alert Message: Ropinirole may be over-utilized. The maximum recommended dose of ropinirole for the treatment of Parkinson's disease is 24 mg per day (8 mg 3 times a day).

Drugs/Diseases

Util A

Util B

Util C (Include)

Ropinirole IR

Parkinson's Disease

Max Dose: 24 mg/day

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.

Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.

Ropinirole Hydrochloride Tablet Prescribing Information, Dec. 2024, Alembic Pharmaceuticals.

30. Ropinirole IR / Severe Renal Impairment

Alert Message: Ropinirole may be over-utilized. The maximum recommended dose of ropinirole for the treatment of Parkinson's disease in patients with end-stage renal disease on dialysis is 18 mg per day.

Drugs/Diseases

Util A

Util B

Util C (Include)

Ropinirole IR

Dialysis

Max Dose: 18 mg/day

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.

Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.

Ropinirole Hydrochloride Tablet Prescribing Information, Dec. 2024, Alembic Pharmaceuticals.

31. Ropinirole IR / Overuse – Restless Legs Syndrome

Alert Message: Ropinirole may be over-utilized. The maximum recommended dose of ropinirole for the treatment of Restless Legs Syndrome is 4 mg once daily.

Drugs/Diseases		
Util A	Util B	Util C (Include)
Ropinirole IR		Restless Legs Syndrome

Max Dose: 4 mg/day

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Ropinirole Hydrochloride Tablet Prescribing Information, Dec. 2024, Alembic Pharmaceuticals.

32. Ropinirole IR / Severe Renal Impairment in Restless Legs Syndrome

Alert Message: Ropinirole may be over-utilized. The maximum recommended dose of ropinirole for the treatment of Restless Legs Syndrome in patients with end-stage renal disease on dialysis is 3 mg per day.

Drugs/Diseases		
Util A	Util B	Util C (Include)
Ropinirole IR	Dialysis	Restless Legs Syndrome

Max Dose: 3 mg/day

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Ropinirole Hydrochloride Tablet Prescribing Information, Dec. 2024, Alembic Pharmaceuticals.

33. Ropinirole / Therapeutic Appropriateness

Alert Message: The safety and effectiveness of ropinirole in pediatric patients have not been established.

Drugs/Diseases		
Util A	Util B	Util C
Ropinirole IR		

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Ropinirole Hydrochloride Tablet Prescribing Information, Sept. 2024, Alembic Pharmaceuticals.

34. Ropinirole IR / Levodopa / Dyskinesia

Alert Message: Ropinirole tablets may cause or exacerbate pre-existing dyskinesia in patients treated with L-dopa for Parkinson's disease. Decreasing the dose of dopaminergic medications may ameliorate this adverse reaction.

<u>Util A</u>	<u>Util B</u>	<u>Util C (Include)</u>
Ropinirole IR	Levodopa	Dyskinesia

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Ropinirole Hydrochloride Tablet Prescribing Information, Sept. 2024, Alembic Pharmaceuticals.

35. Ropinirole IR / Impulse Control

Alert Message: Reports suggest that patients can experience intense urges to gamble, increased sexual urges, intense urges to spend money, binge or compulsive eating, and/or other intense urges, and the inability to control these urges while taking medications that increase central dopaminergic tones, including ropinirole tablets. Because patients may not recognize these behaviors as abnormal, it is important for prescribers to specifically ask patients or their caregivers about the development of new or increased gambling urges, sexual urges, uncontrolled spending, binge or compulsive eating, or other urges while being treated with ropinirole tablets for Parkinson's disease and RLS. Physicians should consider dose reduction or stopping the medication if a patient develops such urges while taking ropinirole tablets.

Drugs/Diseases		
<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Ropinirole IR	Pathological Gambling Other Impulse Disorders Binge Eating Disorder	

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Ropinirole Hydrochloride Tablet Prescribing Information, Dec. 2024, Alembic Pharmaceuticals.

36. Ropinirole IR / Hallucinations & Psychotic-Like Behavior

Alert Message: Postmarketing reports indicate that patients with Parkinson's disease or RLS may experience new or worsening mental status and behavioral changes, which may be severe, including psychotic-like behavior during treatment with ropinirole tablets or after starting or increasing the dose of ropinirole tablets. This abnormal thinking and behavior can consist of one or more of a variety of manifestations including paranoid ideation, delusions, hallucinations, confusion, psychotic-like behavior, mania, disorientation, aggressive behavior, agitation, and delirium. Patients with a major psychotic disorder should ordinarily not be treated with ropinirole tablets because of the risk of exacerbating psychosis.

Drugs/Diseases		
<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Ropinirole IR	Paranoid ideation Delusions Hallucinations Confusion Psychotic-like behavior Mania Schizophrenia Disorientation Aggressive behavior Agitation Delirium	

References:

37. Ropinirole IR / Dopamine Antagonists

Alert Message: Ropinirole is a dopamine agonist, and concurrent use with dopamine antagonists such as neuroleptics (e.g., phenothiazines, butyrophenones, thioxanthene) or metoclopramide may reduce the efficacy of ropinirole.

Drugs/Diseases

Util A	Util B	Util C
Ropinirole IR	Chlorpromazine	Aripiprazole
	Fluphenazine	Asenapine
	Haloperidol	Iloperidone
	Loxapine	Lumateperone
	Molindone	Lurasidone
	Perphenazine	Olanzapine
	Pimozide	Paliperidone
	Prochlorperazine	Risperidone
	Thioridazine	Ziprasidone
	Thiothixene	
	Trifluoperazine	
	Metoclopramide	

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Ropinirole Hydrochloride Tablet Prescribing Information, Dec. 2024, Alembic Pharmaceuticals.

38. Ropinirole IR / Higher Dose Estrogen

Alert Message: Concomitant use of ropinirole and higher doses of estrogens may increase the exposure of ropinirole. A dose adjustment of ropinirole may be needed when estrogen therapy is initiated or discontinued.

Drugs/Diseases

Util A	Util B	Util C
Ropinirole IR	Conjugated Estrogen	
	Esterified Estrogen	
	Estradiol	
	Ethinyl Estradiol	

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Ropinirole Hydrochloride Tablet Prescribing Information, Dec. 2024, Alembic Pharmaceuticals.

39. Ropinirole IR / CYP1A2 Inhibitors

Alert Message: Ropinirole is a CYP1A2 substrate, and concurrent use with a CYP1A2 inhibitor may result in increased ropinirole concentrations. Therefore, if therapy with a drug known to be a potent inhibitor of CYP1A2 is initiated or discontinued during treatment with ropinirole, adjustment of ropinirole dose may be required.

Drugs/Diseases

Util A	Util B	Util C
Ropinirole IR	Ciprofloxacin	
	Fluvoxamine	
	Viloxazine	

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Ropinirole Hydrochloride Tablet Prescribing Information, Dec. 2024, Alembic Pharmaceuticals.

40. Ropinirole IR / Pregnancy / Pregnancy Negating

Alert Message: There are no adequate data on the developmental risk associated with the use of ropinirole in pregnant women. In animal studies, ropinirole had adverse effects on development when administered to pregnant rats at doses similar to (neurobehavioral impairment) or greater than (teratogenicity and embryoletality at > 36 times) the MRHD for Parkinson's disease. Ropinirole should be used in pregnancy only if the potential benefit to the mother outweighs the potential risk to the fetus.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C (Negating)</u>
Ropinirole IR	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.

41. Ropinirole IR / Lactation

Alert Message: There are no data on the presence of ropinirole in human milk, the effects of ropinirole on the breastfed infant, or the effects of ropinirole on milk production. However, inhibition of lactation is expected because ropinirole inhibits the secretion of prolactin in humans. Ropinirole or metabolites, or both, are present in rat milk. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for ropinirole and any potential adverse effects on the breastfed infant from ropinirole or the underlying maternal condition.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Ropinirole IR	Lactation	

Gender: Female

Age Range: 11 – 50 yoa

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.

Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.

42. Ropinirole IR / Non-adherence

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

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Ropinirole IR		

References:

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

Richy FF, Guilhem P, Moran, et al., Compliance with Pharmacotherapy and Direct Healthcare Costs with Parkinson's Disease: A Retrospective Claims Database Analysis. Appl Health Econ Health Policy. 2013 Aug;11(4):395-406.

Daley DJ, Myint PK, Gray RJ, Deane KH. Interventions for Improving Medication Adherence in Patients with Idiopathic Parkinson's Disease. Cochrane Database Systematic Rev 2014. DOI:10.1002/14651858.CD011191

43. Sodium Oxybate ER Suspension / Overuse (Adults)

Alert Message: Lumryz (sodium oxybate extended-release oral suspension) may be overutilized. The recommended dosage range for the treatment of cataplexy or excessive daytime sleepiness in patients 7 years of age and older with narcolepsy is 6 g to 9 g once per night orally. Doses higher than 9 g per night have not been studied and should not ordinarily be administered.

Drugs/Diseases

Util A

Util B

Util C

Sodium Oxybate ER Susp

Max Dose: 9 g/day

Age Range: 18 – 999 yoa

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.

Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.

Lumryz Prescribing Information, Oct. 2024, Avadel CNS Pharmaceuticals, LLC.

44. Sodium Oxybate ER Suspension / Overuse (Pediatric)

Alert Message: Lumryz (sodium oxybate extended-release oral suspension) may be overutilized. The recommended starting dosage of sodium oxybate ER in pediatric patients 7 years and older weighing at least 45 kg is 4.5 g once per night administered orally. Increase the dosage by 1.5 g per night at weekly intervals to the maximum recommended dosage of 9 g once nightly. Because the recommended starting dosage in pediatric patients 7 years and older weighing less than 45 kg cannot be achieved with the available strengths of sodium oxybate ER, use another sodium oxybate product to initiate treatment. The maximum recommended dosage for patients 7 years and older weighing 20 kg to < 30 kg is 6 g once per night, and the maximum recommended dosage for patients 7 years and older weighing 30 kg to < 45 kg is 7.5 g once per night orally. There is insufficient information to provide specific dosing recommendations for patients 7 years and older who weigh less than 20 kg.

Drugs/Diseases

Util A

Util B

Util C

Sodium Oxybate ER Susp

Max Dose: 9 g/day

Age Range: 7 - 17 yoa

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.

Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.

Lumryz Prescribing Information, Oct. 2024, Avadel CNS Pharmaceuticals, LLC

45. Sodium Oxybate ER Suspension / Therapeutic Appropriateness

Alert Message: The safety and effectiveness of Lumryz (sodium oxybate extended-release oral suspension) have not been established in pediatric patients younger than 7.

Drugs/Diseases

Util A

Util B

Util C

Sodium Oxybate ER Susp

Age Range: 0 – 6 yoa

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.

Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.

Lumryz Prescribing Information, Oct. 2024, Avadel CNS Pharmaceuticals, LLC.

46. Sodium Oxybate ER Suspension / Box Warning

Alert Message: Lumryz (sodium oxybate extended-release oral suspension) is the sodium salt of gamma-hydroxybutyrate (GHB). Abuse or misuse of illicit GHB, either alone or in combination with other CNS depressants, is associated with CNS adverse reactions, including seizure, respiratory depression, decreases in the level of consciousness, coma, and death. Because illicit use and abuse of GHB have been reported, physicians should carefully evaluate patients for a history of drug abuse and follow such patients closely, observing them for signs of misuse or abuse of GHB.

Drugs/Diseases		
<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Sodium Oxybate ER Susp	History of Drug Abuse	

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Lumryz Prescribing Information, Oct. 2024, Avadel CNS Pharmaceuticals, LLC.

47. Sodium Oxybate ER Suspension / Contraindication

Alert Message: Lumryz (sodium oxybate extended-release oral suspension) is contraindicated for use in patients with succinic semialdehyde dehydrogenase deficiency.

Drugs/Diseases		
<u>Util A</u>	<u>Util B</u>	<u>Util C (Include)</u>
Sodium Oxybate ER Susp		Succinic Semialdehyde Dehydrogenase Deficiency

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Lumryz Prescribing Information, Oct. 2024, Avadel CNS Pharmaceuticals, LLC.

48. Sodium Oxybate ER Suspension / Sedative Hypnotics (Box Warning)

Alert Message: Lumryz (sodium oxybate extended-release oral suspension) is contraindicated in combination with alcohol and sedative-hypnotics. Sodium oxybate is a central nervous system (CNS) depressant. Clinically significant respiratory depression and obtundation have occurred in patients taking the immediate-release sodium oxybate. The concurrent use of sodium oxybate ER with other CNS depressants may increase the risk of respiratory depression, hypotension, profound sedation, syncope, and death.

Drugs/Diseases		
<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Sodium Oxybate ER Susp	Estazolam	Suvorexant
	Eszopiclone	Tasimelteon
	Flurazepam	Temazepam
	Lemborexant	Triazolam
	Quazepam	Zaleplon
	Phenobarbital	Zolpidem
	Ramelteon	

References:
Clinical Pharmacology, 2024 Elsevier/Gold Standard.
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
Lumryz Prescribing Information, Oct. 2024, Avadel CNS Pharmaceuticals, LLC.

49. Sodium Oxybate ER Suspension / Divalproex Sodium

Alert Message: The concurrent use of Lumryz (sodium oxybate extended-release oral suspension) with divalproex sodium may result in an increased risk of CNS depression. In a drug interaction study, co-administration of a single dose of sodium oxybate XR (6 g) with divalproex sodium ER at steady state resulted in an approximate 18% increase in AUC (90% CI ratio range of 112%-123%), which is not expected to be clinically meaningful, while Cmax was comparable. A single dose of sodium oxybate XR (6 g) did not appear to affect the pharmacokinetics of divalproex sodium. However, a pharmacodynamic interaction between sodium oxybate XR and divalproex sodium, a sedative antiepileptic drug, cannot be ruled out.

Drugs/Diseases

Util AUtil BUtil C

Sodium Oxybate ER Susp Divalproex Sodium

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.

Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.

Lumryz Prescribing Information, Oct. 2024, Avadel CNS Pharmaceuticals, LLC.

50. Sodium Oxybate ER Suspension / CNS Depressants

Alert Message: The concurrent use of Lumryz (sodium oxybate extended-release oral suspension) with other CNS depressants may increase the risk of respiratory depression, hypotension, profound sedation, syncope, and death. The sodium oxybate product is a central nervous system depressant. If the use of CNS depressants in combination with sodium oxybate is required, dose reduction or discontinuation of one or more CNS depressants (including sodium oxybate ER) should be considered.

Drugs/Diseases

Util AUtil BUtil C

Sodium Oxybate ER Susp CNS Depressants

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.

Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.

Lumryz Prescribing Information, Oct. 2024, Avadel CNS Pharmaceuticals, LLC.

51. Sodium Oxybate ER Suspension / Depression & Suicide

Alert Message: Depression and suicidal ideation and behavior can occur in patients treated with Lumryz (sodium oxybate extended-release oral suspension). The emergence of depression in patients treated with sodium oxybate requires careful and immediate evaluation. Patients with a previous history of a depressive illness and/or suicide attempt should be monitored carefully for the emergence of depressive symptoms while taking sodium oxybate.

Drugs/Diseases

Util AUtil BUtil CSodium Oxybate ER Susp Depression
Suicidal Ideation

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.

Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.

Lumryz Prescribing Information, Oct. 2024, Avadel CNS Pharmaceuticals, LLC.

52. Sodium Oxybate ER Suspension / Pregnancy / Pregnancy Negating

Alert Message: There are no adequate data on the developmental risks associated with the use of Lumryz (sodium oxybate extended-release oral suspension) during human pregnancy. Animal studies produced no clear evidence of developmental toxicity; however, increased stillbirths and decreased postnatal viability and growth were seen at clinically relevant doses.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C (Negate)</u>
Sodium Oxybate ER Susp	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.

Lumryz Prescribing Information, Oct. 2024, Avadel CNS Pharmaceuticals, LLC.

53. Sodium Oxybate ER Suspension / Lactation

Alert Message: The active moiety of Lumryz (sodium oxybate extended-release oral suspension) is oxybate or gamma-hydroxybutyrate (GHB). GHB is excreted in human milk after oral administration of sodium oxybate. There is insufficient information on the risk to a breastfed infant, and there is insufficient information on milk production in nursing mothers. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for sodium oxybate and any potential adverse effects on the breastfed infant from sodium oxybate or the underlying maternal condition.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Sodium Oxybate ER Susp	Lactation	

Gender: Female

Age Range: 11 – 50 yoa

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.

Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.

Lumryz Prescribing Information, Oct. 2024, Avadel CNS Pharmaceuticals, LLC.

54. Cabotegravir/Rilpivirine / Contraindication

Alert Message: The concurrent use of Cabenuva (cabotegravir/rilpivirine) is contraindicated with certain strong inducers of CYP3A4 or uridine diphosphate (UDP)-glucuronosyltransferase (UGT1A1/1A9). Coadministration of cabotegravir/rilpivirine with these agents may result in increased cabotegravir/rilpivirine clearance and loss of virologic response and development resistance.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Cabotegravir/Rilpivirine	Carbamazepine	Rifabutin
	Dexamethasone	Rifampin
	Oxcarbazepine	Rifapentine
	Phenobarbital	
	Phenytoin	

References:

Cabenuva Prescribing Information, Sept. 2024, ViiV Healthcare.

Clinical Pharmacology, 2025 Elsevier/Gold Standard.

55. Cabotegravir/Rilpivirine / Therapeutic Appropriateness

Alert Message: Cabenuva (cabotegravir/rilpivirine) is a complete regimen for the treatment of HIV-1 infection, and coadministration with other antiretroviral medications is not recommended.

Drugs/Diseases		
<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Cabotegravir/Rilpivirine	All Other Antiretrovirals	

References:
Cabenuva Prescribing Information, Sept. 2024, ViiV Healthcare.
Clinical Pharmacology, 2025 Elsevier/Gold Standard.

56. Cabotegravir/Rilpivirine / Therapeutic Appropriateness

Alert Message: The safety, efficacy, and pharmacokinetics of Cabenuva (cabotegravir/rilpivirine) have not been established in pediatric patients younger than 12 years of age or weighing less than 35 kg.

Drugs/Diseases		
<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Cabotegravir/Rilpivirine		

Age Range: 0 – 11 yoa

References:
Cabenuva Prescribing Information, Sept. 2024, ViiV Healthcare.
Clinical Pharmacology, 2025 Elsevier/Gold Standard.

57. Cabotegravir/Rilpivirine / Non-adherence

Alert Message: Based on the refill history, your patient may be under-utilizing Cabenuva (cabotegravir/rilpivirine). Nonadherence to antiretroviral therapy may result in insufficient plasma levels and partial suppression of viral load leading to the development of resistance, HIV progression, and increased mortality.

Drugs/Diseases		
<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Cabotegravir/Rilpivirine		

References:
Cabenuva Prescribing Information, Sept. 2024, ViiV Healthcare.
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/tables-adult-adolescent-arv.pdf> Accessed January 09, 2025.
Panel on Antiretroviral Therapy and Medical Management of Children Living with HIV. Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection. Available at: <https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/pediatric-arv/guidelines-pediatric-arv.pdf> Accessed Jan. 9, 2025.
Panel on Treatment of HIV During Pregnancy and Prevention of Perinatal Transmission. Recommendations for the Use of Antiretroviral Drugs During Pregnancy and Interventions to Reduce Perinatal HIV Transmission in the United States. Department of Health and Human Services. Available at <https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/perinatal-hiv/guidelines-perinatal.pdf> Accessed Jan. 09, 2025.

58. Xanomeline/Trospium / Overuse

Alert Message: Cobenfy (xanomeline/trospium) may be over-utilized. The maximum recommended dose of xanomeline/trospium is 125 mg/30 mg twice daily.

Drugs/Diseases

Util AUtil BUtil C

Xanomeline/Trospium

Max Dose: 250 mg/60 mg per day
Age Range: 18 – 64 yoa

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Cobenfy Prescribing Information, September 2024, Bristol Myers-Squibb.

59. Xanomeline/Trospium / Overuse

Alert Message: Cobenfy (xanomeline/trospium) may be over-utilized. The maximum recommended dose of xanomeline/trospium in geriatric patients is one 100 mg/20 mg capsule twice daily.

Drugs/Diseases

Util AUtil BUtil C

Xanomeline/Trospium

Max Dose: 200 mg/40 mg per day
Age Range: ≥ 65 yoa

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Cobenfy Prescribing Information, September 2024, Bristol Myers-Squibb.

60. Xanomeline/Trospium / Therapeutic Appropriateness

Alert Message: The safety and effectiveness of Cobenfy (xanomeline/trospium) in pediatric patients have not been established.

Drugs/Diseases

Util AUtil BUtil C

Xanomeline/Trospium

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Cobenfy Prescribing Information, September 2024, Bristol Myers-Squibb.

61. Xanomeline/Trospium / Urinary Retention

Alert Message: Cobenfy (xanomeline/trospium) use is contraindicated in patients with pre-existing urinary retention. Xanomeline/trospium can cause urinary retention. Monitor xanomeline/trospium recipients for symptoms of urinary retention, including urinary hesitancy, weak stream, incomplete bladder emptying, and dysuria. In patients with symptoms, consider reducing the dose of the medication, discontinuing treatment, or referring patients for urologic evaluation as clinically indicated.

Drugs/Diseases		
<u>Util A</u>	<u>Util B</u>	<u>Util C (Include)</u>
Xanomeline/Trospium		Urinary Retention

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Cobenfy Prescribing Information, September 2024, Bristol Myers-Squibb.

62. Xanomeline/Trospium / Hepatic Impairment

Alert Message: Cobenfy (xanomeline/trospium) use is contraindicated in patients with moderate to severe hepatic impairment (Child-Pugh Class B & C) and not recommended in patients with mild hepatic impairment. Patients with hepatic impairment have higher systemic exposures of xanomeline, a component of the combination product, compared to patients with normal hepatic function, which may result in an increased incidence of xanomeline-related adverse reactions.

Drugs/Diseases		
<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Xanomeline/Trospium	Hepatic Impairment	

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Cobenfy Prescribing Information, September 2024, Bristol Myers-Squibb.

63. Xanomeline/Trospium / Gastric Retention

Alert Message: Cobenfy (xanomeline/trospium) use is contraindicated in patients with gastric retention. The trospium component of the combination product is an antimuscarinic agent and may decrease gastrointestinal motility.

Drugs/Diseases		
<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Xanomeline/Trospium	Gastroparesis Pyloric Stenosis	

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Cobenfy Prescribing Information, September 2024, Bristol Myers-Squibb.

64. Xanomeline/Trospium / Narrow Angle Glaucoma

Alert Message: Cobenfy (xanomeline/trospium) use is contraindicated in patients with untreated narrow-angle glaucoma. Pupillary dilation may occur due to the anticholinergic effects of xanomeline/trospium and may trigger an acute angle closure attack in patients with anatomically narrow angles. In patients known to have anatomically narrow angles, xanomeline/trospium should only be used if the potential benefits outweigh the risks and with careful monitoring.

Drugs/Diseases		
<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Xanomeline/Trospium	Narrow Angle Glaucoma	

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Cobenfy Prescribing Information, September 2024, Bristol Myers-Squibb.

65. Xanomeline/Trospium / GI Obstruction

Alert Message: Cobenfy (xanomeline/trospium) should be administered with caution in patients with gastrointestinal obstructive disorders because of the risk of gastric retention. The trospium component of the combination product is an antimuscarinic agent and can decrease gastrointestinal motility. Xanomeline/trospium use is contraindicated in patients with gastric retention.

Drugs/Diseases		
<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Xanomeline/Trospium	GI Obstruction Ulcerative Colitis Intestinal Atony Myasthenia gravis	

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Cobenfy Prescribing Information, September 2024, Bristol Myers-Squibb.

66. Xanomeline/Trospium / Moderate to Severe Renal Impairment

Alert Message: The use of Cobenfy (xanomeline/trospium) is not recommended in patients with moderate to severe renal impairment. The trospium component of the combination product is an anticholinergic agent and is substantially excreted by the kidney. Systemic exposure to trospium is higher in patients with moderate and severe renal impairment, and anticholinergic adverse reactions are expected to be greater in this patient population.

Drugs/Diseases		
<u>Util A</u>	<u>Util B</u>	<u>Util C (Include)</u>
Xanomeline/Trospium		CKD Stage 3 CKD Stage 4 CKD Stage 5 ERD

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Cobenfy Prescribing Information, September 2024, Bristol Myers-Squibb.

67. Xanomeline/Trospium / Strong CYP2D6 Inhibitors

Alert Message: The xanomeline component of the combination product Cobenfy (xanomeline/trospium) is a CYP2D6 substrate. Concomitant use of xanomeline/trospium with strong CYP2D6 inhibitors may increase xanomeline plasma concentrations, increasing the frequency and/or severity of xanomeline-related adverse reactions. Monitor patients for increased frequency and/or severity of xanomeline-related adverse reactions.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Xanomeline/Trospium	Bupropion Fluoxetine Paroxetine	Quinidine Terbinafine

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Cobenfy Prescribing Information, September 2024, Bristol Myers-Squibb.

68. Xanomeline/Trospium / Drugs Eliminated by Tubular Secretion

Alert Message: Concomitant use of Cobenfy (xanomeline/trospium) with drugs that are eliminated by active tubular secretion may increase plasma concentrations of trospium, a component of the combination product, and/or the concomitantly used drug due to competition for this elimination pathway. Concurrent use may increase the frequency and/or severity of adverse reactions from xanomeline/trospium and/or the concurrent drug eliminated by active tubular secretion. Monitor patients for increased frequency and/or severity of adverse reactions.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Xanomeline/Trospium	Adefovir Amiloride Cimetidine Dofetilide	Entecavir Memantine Midodrine Procainamide Quinidine Ranitidine Tenofovir Trimethoprim

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Cobenfy Prescribing Information, September 2024, Bristol Myers-Squibb.

69. Xanomeline/Trospium / Sensitive CYP3A4 Substrates

Alert Message: The xanomeline component of the combination product Cobenfy (xanomeline/trospium) is a CYP3A4 inhibitor. Concomitant use of xanomeline/trospium with sensitive CYP3A4 substrates may result in increased plasma concentrations of the sensitive 3A4 substrate and frequency and/or severity of adverse reactions related to the sensitive 3A4 substrate. Monitor patients for increased frequency and/or severity of adverse reactions related to the sensitive 3A4 substrate.

Drugs/Diseases

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

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.

Cobenfy Prescribing Information, September 2024, Bristol Myers-Squibb.

70. Xanomeline/Trospium / P-gp Substrates w/ NTI

Alert Message: Concomitant use of Cobenfy (xanomeline/trospium) with drugs that are substrates of P-gp transport may increase plasma concentrations of the P-gp substrates, increasing the risk of P-gp substrate-related adverse reactions. The xanomeline component of the combination product transiently inhibits P-gp transport locally in the gut. Monitor patients for increased frequency and/or severity of adverse reactions related to oral drugs that are narrow therapeutic index substrates of P-gp transport.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Xanomeline/Trospium	Cyclosporine	Sirolimus
	Digoxin	Tacrolimus
	Everolimus	

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Cobenfy Prescribing Information, September 2024, Bristol Myers-Squibb.

71. Xanomeline/Trospium / Pregnancy / Pregnancy Negating

Alert Message: There are no available data on Cobenfy (xanomeline/trospium) use in pregnant women to evaluate for a drug-associated risk of major birth defects, miscarriage, or other adverse maternal or fetal outcomes. In animal reproduction studies, oral administration of xanomeline alone or in combination with trospium chloride during the period of organogenesis or pregnancy and lactation caused maternal toxicities of adverse clinical signs, decreased body weight, weight gain and food consumption, and/or maternal death. At these maternally toxic doses, embryofetal and developmental toxicities included decreased fetal and neonatal weight, stillborn pups, and/or neonatal deaths.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C (Negating)</u>
Xanomeline/Trospium	Pregnancy	Abortion
		Delivery
		Miscarriage

Gender: Female
Age Range: 11 – 50 yoa

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Cobenfy Prescribing Information, September 2024, Bristol Myers-Squibb.

72. Xanomeline/Trospium / Lactation

Alert Message: There are no data on the presence of either component of Cobenfy (xanomeline/trospium) in human milk, the effects on the breastfed infant, or the effects on milk production. Xanomeline and trospium are present in animal milk. When a drug is present in animal milk, it is likely that the drug will be present in human milk. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for xanomeline/trospium and any potential adverse effects on the breastfed infant from xanomeline/trospium or from the underlying maternal condition.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Xanomeline/Trospium	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.

Criteria Recommendations

Approved Rejected

73. Xanomeline/Trospium / Non-adherence

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

Drugs/Diseases		
<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Xanomeline/Trospium		

References:

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

Higashi k, Medic G, Littlewood K, et al., Medication Adherence in Schizophrenia: Factors Influencing Adherence and Consequences of Nonadherence, A Systemic Literature Review. Ther Adv Psychopharmacol. 2013 2(4):200-218.

Stephenson JJ, Tuncelli O, Gu T, et al. Adherence to Oral Second-Generation Antipsychotic Medications in Patients with Schizophrenia and Bipolar Disorder: Physicians' Perceptions of Adherence vs. Pharmacy Claims. Int J Clin Pract, June 2012, 66, 6, 565-573.

Acsher-Svanum H, Zhu B, Faries DE, et al., The Cost of Relapse and the Predictors of Relapse in the Treatment of Schizophrenia. BMC Psychiatry 2010, 10:2.

74. Suzetrigine / Overuse

Alert Message: Journavx (suzetrigine) may be over-utilized. The recommended maximum dose of suzetrigine is 50 mg orally every 12 hours. The use of suzetrigine for the treatment of moderate to severe acute pain has not been studied beyond 14 days.

Drugs/Diseases		
<u>Util A</u>	<u>Util B</u>	<u>Util C (Negating)</u>
Suzetrigine		Strong & Moderate CYP3A Inhibitors Moderate and Severe Hepatic Impairment
Max Dose: 100 mg/day		

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.

Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.

Journavx Prescribing Information, Jan. 2025, Vertex Pharmaceuticals Incorporated.

75. Suzetrigine / Therapeutic Appropriateness

Alert Message: The safety and effectiveness of Journavx (suzetrigine) has not been established in pediatric patients.

Drugs/Diseases		
<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Suzetrigine		

Age Range: 0 – 17 yoa

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.

Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.

76. Suzetrigine / Strong CYP3A Inhibitors

Alert Message: The concomitant use of Journavx (suzetrigine) with a strong CYP3A inhibitor is contraindicated. Suzetrigine and its active metabolite (M6-SUZ) are CYP3A substrates, and use with a strong CYP3A inhibitor will increase exposure to and adverse effects of suzetrigine. In clinical studies, concurrent use of suzetrigine with a strong CYP3A inhibitor increased the AUC of suzetrigine and M6-SUZ by 4.79-fold and 4.42-fold, respectively.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Suzetrigine	Clarithromycin	Nelfinavir
	Cobicistat	Posaconazole
	Itraconazole	Ritonavir
	Ketoconazole	Voriconazole
	Nefazodone	

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.

Journavx Prescribing Information, Jan. 2025, Vertex Pharmaceuticals Incorporated.

77. Suzetrigine / Moderate CYP3A Inhibitors

Alert Message: Exercise caution when Journavx (suzetrigine) is co-administered with a moderate CYP3A inhibitor. Suzetrigine and its active metabolite (M6-SUZ) are CYP3A substrates, and use with a moderate CYP3A inhibitor can increase exposure to and adverse effects of suzetrigine. Dosage adjustment of suzetrigine is recommended during concurrent use with a moderate CYP3A inhibitor. Dose 1 is 100 mg, then starting 12 hours after the initial dose, take 50 mg every 12 hours for Doses 2, 3, and 4. For Dose 5 (starting 12 hours after Dose 4) and subsequent doses, take 50 mg every 24 hours.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Suzetrigine	Aprepitant	Diltiazem
	Cimetidine	Dronedarone
	Ciprofloxacin	Erythromycin
	Crizotinib	Fluconazole
	Cyclosporine	Fluvoxamine
		Imatinib
		Verapamil

Max Dose: 50 mg every day starting after dose 4

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.

Journavx Prescribing Information, Jan. 2025, Vertex Pharmaceuticals Incorporated.

78. Suzetrigine / Severe Hepatic Impairment

Alert Message: The use of Journavx (suzetrigine) should be avoided in patients with severe hepatic impairment (Child-Pugh Class C). Suzetrigine has not been studied in this patient population. In pharmacokinetic studies, patients with moderate hepatic impairment (Child-Pugh Class B) receiving suzetrigine had higher systemic exposure to suzetrigine and its active metabolite, M6-SUX, at steady state than those with normal hepatic function. No significant

differences in pharmacokinetics were seen in patients with mild hepatic impairment.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Suzetrigine	Cirrhosis	
	Hepatic Failure	

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.

Journavx Prescribing Information, Jan. 2025, Vertex Pharmaceuticals Incorporated.

79. Suzetrigine / Strong or Moderate CYP3A Inducers

Alert Message: The concurrent use of Journavx (suzetrigine) with strong and moderate CYP3A inducers should be avoided. Suzetrigine and its active metabolite (M6-SUZ) are CYP3A substrates, and concurrent use with strong or moderate CYP3A inducers can decrease exposure to suzetrigine and M6-UZ, which may reduce suzetrigine efficacy.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Suzetrigine	Apalutamide	Phenytoin
	Bosentan	Primidone
	Carbamazepine	Rifabutin
	Efavirenz	Rifampin
	Etravirine	Rifapentine
	Phenobarbital	

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.

Journavx Prescribing Information, Jan. 2025, Vertex Pharmaceuticals Incorporated.

80. Suzetrigine / Moderate Hepatic Impairment

Alert Message: Caution should be exercised when Journavx (suzetrigine) is administered in patients with moderate hepatic impairment (Child-Pugh Class B). In pharmacokinetic studies, patients with moderate hepatic impairment receiving suzetrigine had higher systemic exposure to suzetrigine and its active metabolite, M6-SUX, at steady state than those with normal hepatic function. Dosage adjustment of suzetrigine is recommended in patients with moderate hepatic impairment. Dose 1 is 100 mg, then starting 12 hours after the initial dose, take 50 mg every 12 hours for Doses 2, 3, and 4. For Dose 5 (starting 12 hours after Dose 4) and subsequent doses, take 50 mg every 24 hours. No significant differences in pharmacokinetics were seen in patients with mild hepatic impairment.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Suzetrigine	Moderate Hepatic Impairment	

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.

Journavx Prescribing Information, Jan. 2025, Vertex Pharmaceuticals Incorporated.

81. Suzetrigine / Sensitive CYP3A Substrates

Alert Message: If Journavx (suzetrigine) is used concomitantly with sensitive CYP3A substrates or CYP3A substrates where minimal concentration changes may lead to loss of efficacy, refer to the prescribing information for the CYP3A substrates for dosing adjustment instructions. Suzetrigine is an inducer of CYP3A. Concomitant use with suzetrigine may reduce the exposure of sensitive CYP3A substrates, which may decrease the efficacy of these substrates. Discontinuation of suzetrigine may increase the exposure of sensitive CYP3A substrates. Dosage modification of the concomitant CYP3A substrates may be required when initiating or discontinuing suzetrigine.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Suzetrigine	Avanafil	Eletriptan
	Budesonide	Eplerenone
	Buspirone	Everolimus
		Lurasidone
		Maraviroc
		Midazolam
		Simvastatin
		Siroliimus
		Tacrolimus
		Vardenafil

Conivaptan	Felodipine	Naloxegol	Ticagrelor
Darifenacin	Ibrutinib	Nisoldipine	Tipranavir
Darunavir	Lomitapide	Quetiapine	Tolvaptan
Dronedarone	Lovastatin	Sildenafil	Triazolam

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.

Journavx Prescribing Information, Jan. 2025, Vertex Pharmaceuticals Incorporated.

82. Suzetrigine / Hormonal Contraceptives

Alert Message: Journavx (suzetrigine) treated patients using hormonal contraceptives containing progestins other than levonorgestrel and norethindrone should use additional nonhormonal contraceptives or alternative contraceptives during treatment with suzetrigine and for 28 days after discontinuation of suzetrigine. Suzetrigine is an inducer of CYP3A, and use with hormonal contraceptives that are CYP3A substrates may result in decreased efficacy of the contraceptive agent.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Suzetrigine	Desogestrel/Ethinyl Estradiol	Norgestrel
	Dienogest/Estradiol Valerate	Norgestrel/Ethinyl Estradiol
	Drospirenone/Ethinyl Estradiol	Segesterone/Ethinyl Estradiol
	Etonogestrel/Ethinyl Estradiol	

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Journavx Prescribing Information, Jan. 2025, Vertex Pharmaceuticals Incorporated.

83. Suzetrigine / Pregnancy / Pregnancy Negating

Alert Message: There are no available data with Journavx (suzetrigine) during pregnancy to evaluate for a drug-associated risk of major birth defects, miscarriage, or other adverse maternal or fetal outcomes. In animal studies, administration of suzetrigine to rats at exposures 2.2 times or more than the maximum recommended human dose (MRHD) during early embryonic development or throughout organogenesis resulted in adverse effects on implantation and maintenance of pregnancy. The clinical relevance of these findings to humans is unclear.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C (Negate)</u>
Suzetrigine	Pregnancy	Abortion Delivery Miscarriage

Gender: Female

Age Range: 11 – 50 yoa

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Journavx Prescribing Information, Jan. 2025, Vertex Pharmaceuticals Incorporated.

84. Suzetrigine / Lactation

Alert Message: There are no data on the presence of Journavx (suzetrigine) or its metabolites in human milk, the effects on the breastfed infant, or the effects on milk production. Suzetrigine is present in animal milk. When a drug is present in animal milk, the drug will likely be present in human milk. Development and health benefits of breastfeeding should be considered, along with the mother's clinical need for suzetrigine and any potential adverse effects on the breastfed child from suzetrigine or the underlying maternal condition.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Suzetrigine	Lactation	

Gender: Female

Age Range: 11 – 50 yoa

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.

Journavx Prescribing Information, Jan. 2025, Vertex Pharmaceuticals Incorporated.

Criteria Recommendations

Approved Rejected

85. Esketamine / Overuse

Alert Message: The recommended maximum maintenance dosage of Spravato (esketamine) for the treatment of depressive symptoms in adults with major depressive disorder with acute suicidal ideation or behavior is 84 mg twice weekly. Evidence of therapeutic benefit should be evaluated at the end of the induction phase to determine the need for continued treatment.

Util A

Esketamine

Util B

Util C (Include)

Attempted Suicide
Suicide Ideation

Max Dose: 84 mg twice a week

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.

Spravato Prescribing Information, Jan. 2025, Janssen Pharmaceuticals, Inc.

Board Suggestions for clinical practice education or RDUR ICER criteria

1. Is there anything in clinical practice that you've seen that you feel needs to be addressed?
 - a. New best practices?
 - b. Fraud, waste, or abuse?
2. Is there any new guideline information?
3. Requests for Utilization Review topics?

**North Dakota Medicaid
Drug Utilization Review Board Meeting
September 3, 2025
Conference Room 210/212**

Meeting Notice

North Dakota Medicaid Drug Use Review Board

Wednesday, September 3rd, 2025
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 227 173 260 751

Agenda

1. Call to Order
2. Roll Call
3. Review and Approval of Minutes
4. Reports from Department
 - Administrative Report: Member Updates, Core Measures, PDMP, Utilization Review
 - Financial Report: Top Drugs
 - Retrospective DUR Report
 - Clinical Report:
 - Prior Authorization Update
 - Criteria updates: Bullous Pemphigoid, Chronic Kidney Disease, Giant Cell Arteritis (Temporal Arteritis), Uveitis
5. Unfinished Business – 5th psychotropics RDUR letter discussion follow up
6. New business
 - Second Review of Non-Opioid Analgesia
 - First Review of ANCA-Associated Vasculitis
 - First Review of Niemann-Pick Type C
 - Review of retrospective DUR criteria recommendations
 - Provider suggestions for clinical practice education or RDUR ICER criteria
7. Announcements: Next Meeting (December 3, 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: June 4th, 2025

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 1:13 pm CST with T. Schmidt presiding as Presiding Officer. DUR Board Coordinator, J. McKee recording minutes.

Roll Call:

Board Members Voting:

Present: Stephanie Antony, Gabriela Balf, Amanda Dahl, Kurt Datz, Andrea Honeyman, Laura Kroetsch, Kevin Martian, Kristen Peterson, Tanya Schmidt, Amy Werremeyer, Jessica Ziegler, Matthew Zimny

Absent:

Quorum Present: Yes

Board Members Non-Voting: Kathleen Traylor

Absent:

Medicaid Pharmacy Department:

Present: Jeff Hostetter, Brendan Joyce, Alexi Murphy, LeNeika Roerich, Katie Steig

Absent:

Approval of Meeting Minutes:

Motion: Moved by M. Zimny to approve the minutes of the March 5, 2025 meeting, motion was seconded by K. Datz. **Motion carried.**

The minutes of the March 5, 2025, meeting were approved as distributed.

Reports:

Administrative Report: B. Joyce

B. Joyce introduced Dr. Matthew Zimny to the board and announced that this was the last board meeting for Tanya Schmidt as she is rolling off of the board.

Financial Report: Budget provided by B. Joyce

B. Joyce shared with the Board trends of reimbursement amount vs net spend for pharmacy drug claims. 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 J. McKee

J. McKee reviewed the quarterly RDUR criteria that were selected for review of each month and information from a targeted mailing. This material can be found in the handout.

Clinical Report and Annual PDL Review: Prior Authorization and Criteria Updates by J. McKee

J. McKee presented prior authorization and criteria updates with emphasis on the following sections in the PDL: Amyloidosis, Chronic Kidney Disease, Hemophilia

New business:

Special Orders: Presiding office and Vice-presiding Officer Elections.

*Kevin Martian was nominated for Presiding officer. Motion moved by M. Zimny and seconded by A. Werremeyer. **Motion carried***

*Kurt Datz nominated for Vice-Presiding Officer. Motion moved by K. Martian and seconded by M. Zimny. **Motion carried.***

Second Reviews presented by J. McKee

J. McKee presented group prior authorization criteria for Diabetes Mellitus

Motion: Moved by K. Datz to place Diabetes Mellitus on prior authorization, motion was seconded by K. Martian. **Motion carried.**

First Reviews presented by J. McKee

J. McKee presented an overview of Non-Opioid Analgesics. The presented material can be found in the handout.

Motion: Moved by K. Datz to draft prior authorization for Non-Opioid Analgesics, motion was seconded by L. Kroetsch. **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 M. Zimny. **Motion carried.**

Announcements:

Next meeting is September 3rd, 2025.

Adjournment:

Meeting adjourned by T. Schmidt at 2:34 pm CST.

Date of Minutes Approval:

Minutes submitted by: Julie McKee, Acentra Health

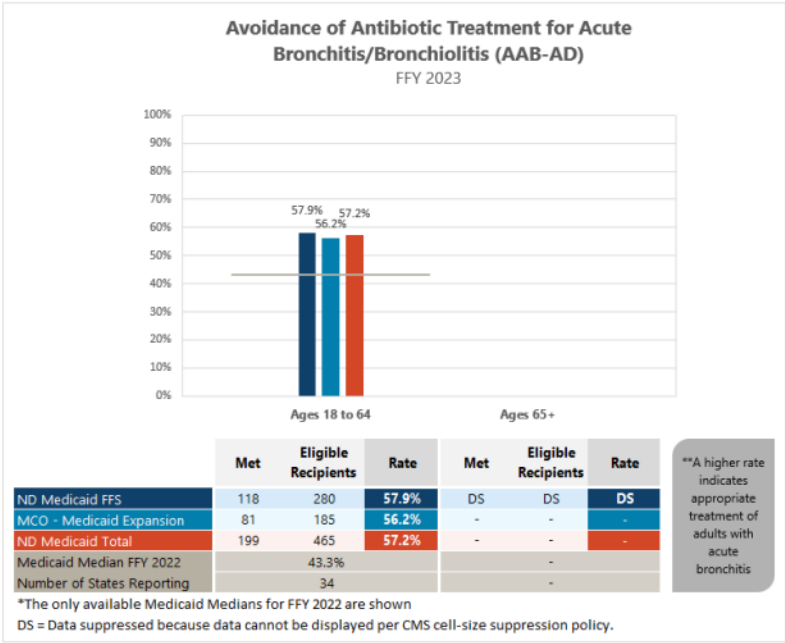
Administrative Report

New Members- Paige Adkins

Migraine Prophylaxis Utilization Review Since July 2024

Type of Prophylaxis	ER visits use due to Migraine	Average Qty of Rescue Doses
Non-CGRP	1 person in July 2024	34.0
CGRP		58.5

Core Measures / Quality Measures



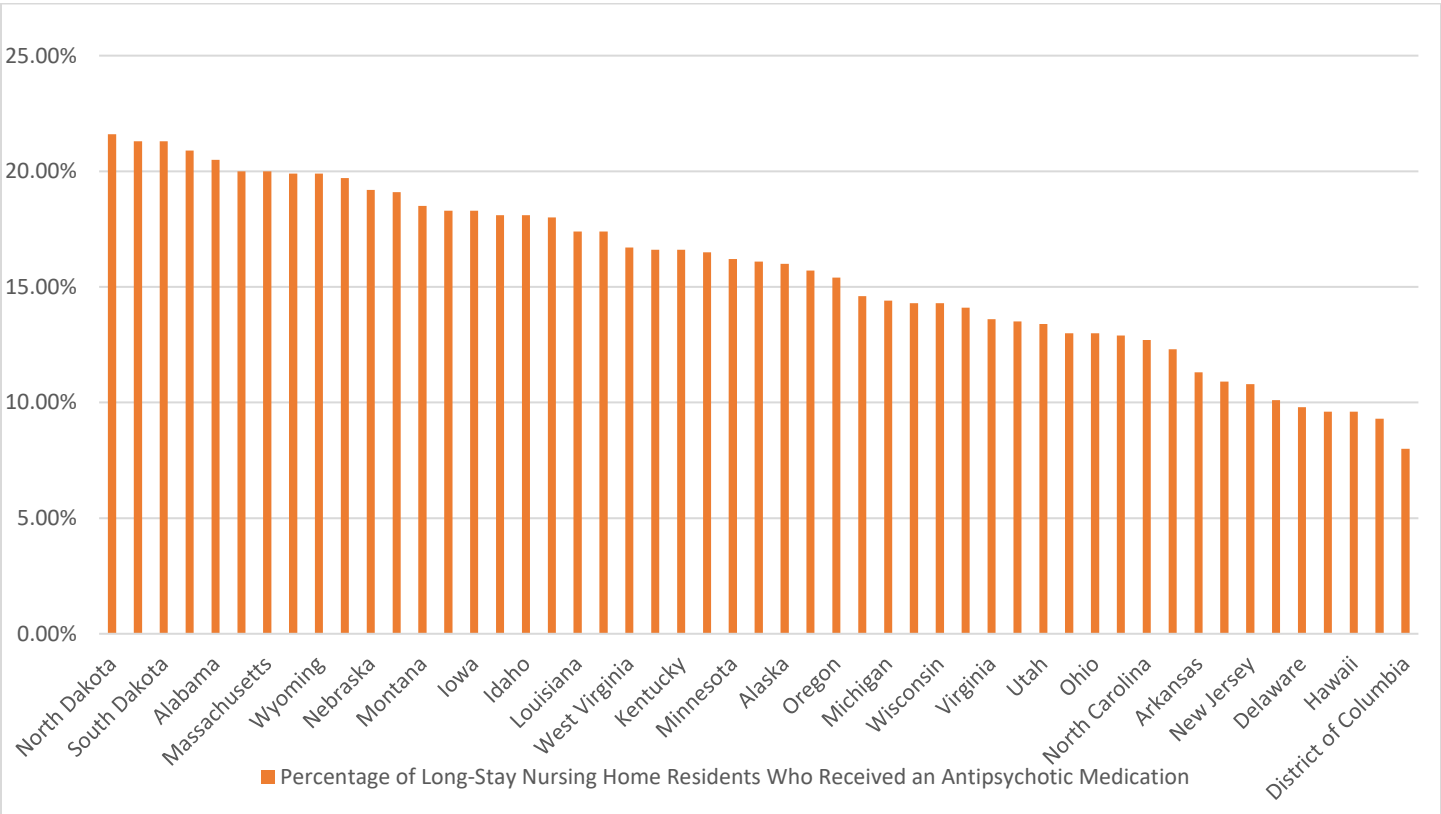
MEASURE DESCRIPTION

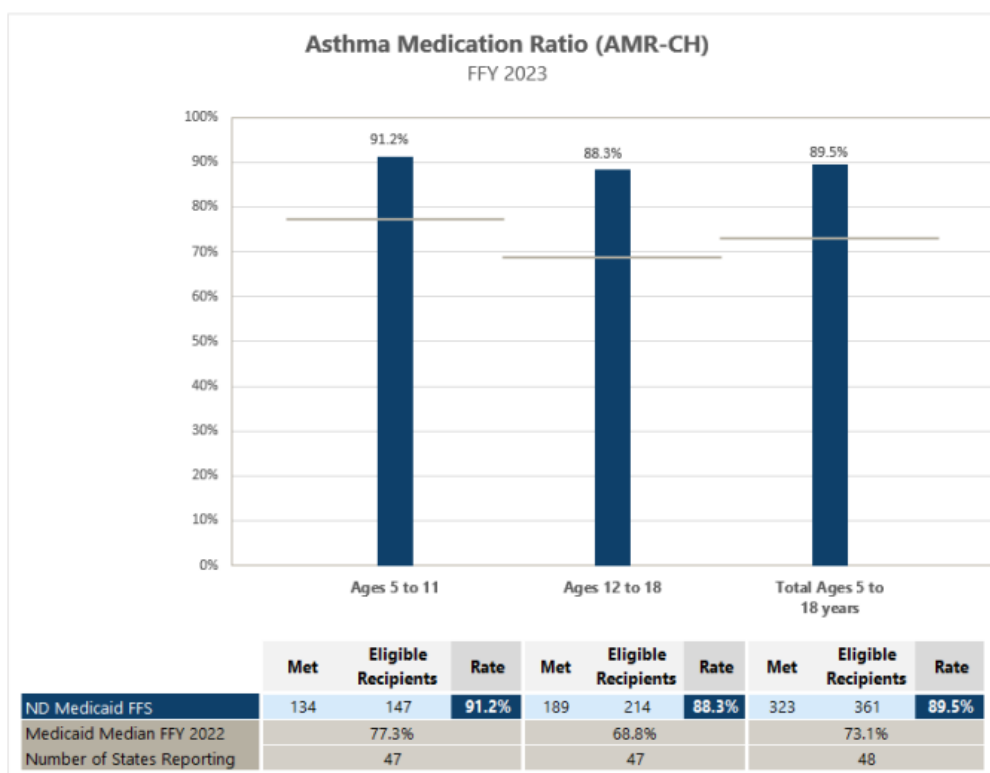
This measure shows a percentage of episodes for adults ages 18 and older with a diagnosis of acute bronchitis/bronchiolitis that did not result in an antibiotic dispensing event.

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Percentage of Long-Stay Nursing Home Residents Who Received an Antipsychotic Medication





MEASURE DESCRIPTION

This measure shows the percentage of children ages 5 to 18 with persistent asthma and were dispensed appropriate asthma controller medications during the measurement year.

ASTHMA MEDICATION RATIO: AGES 5 TO 18 (AMR-CH)

Percentage with Persistent Asthma who had a Ratio of Controller Medications to Total Asthma Medications of 0.50 or Greater: Ages 5 to 18

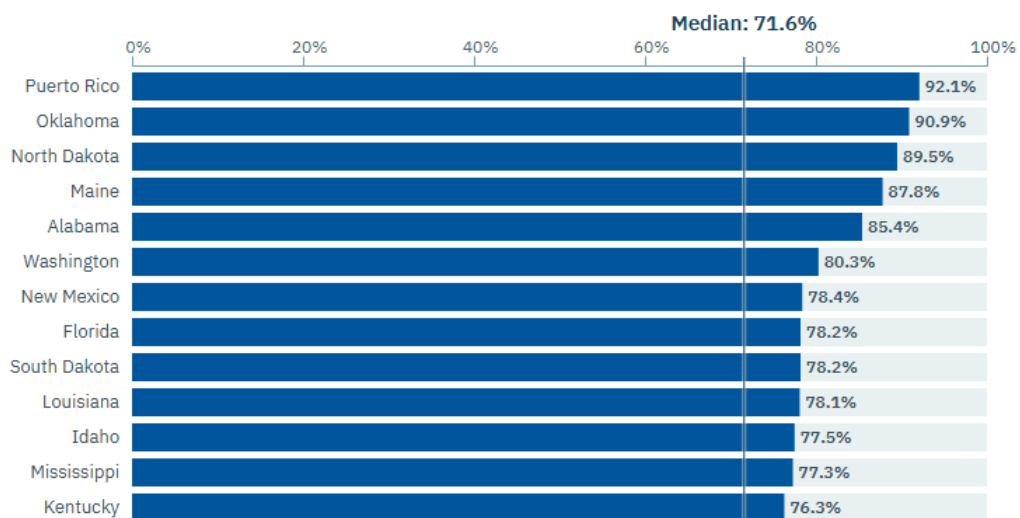
Age: Total (Ages 5-18)

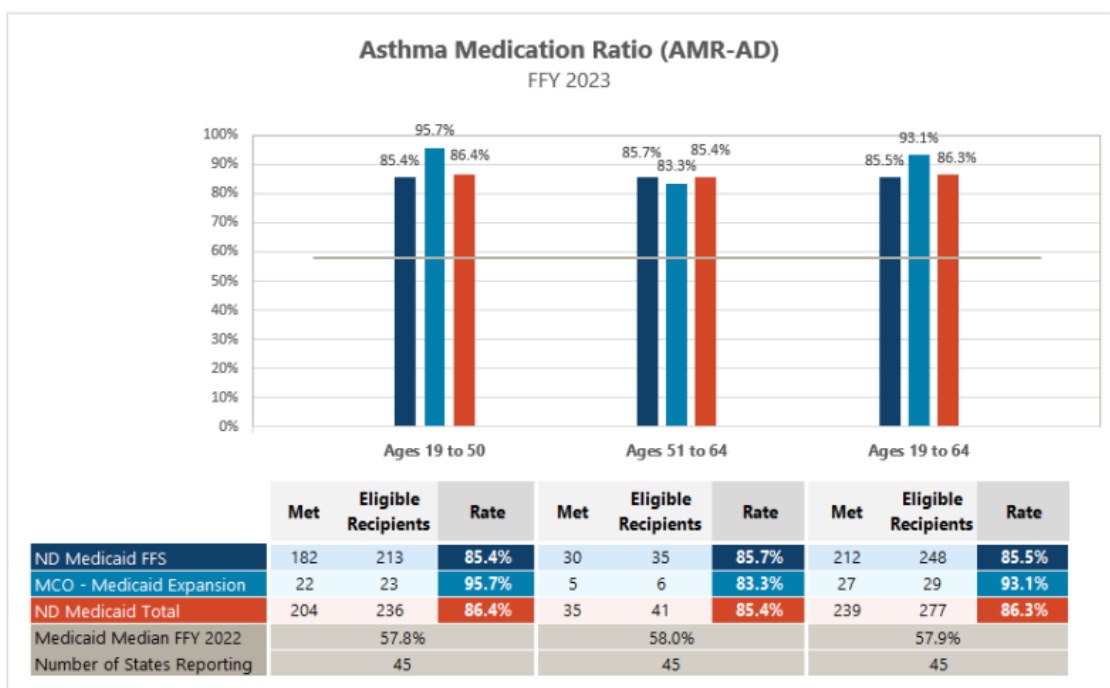
Population: All states view (mixed populations)

Methodology: Administrative

Core Set Year: 2023

Sort by: Alphabetical Values: High to Low Values: Low to High





MEASURE DESCRIPTION

This measure assesses the percentage of adults with persistent asthma who were dispensed appropriate asthma controller medications by the percentage of beneficiaries ages 19 to 64 who were identified as having persistent asthma and had a ratio of controller medications to total asthma medications of 0.50 or greater during the measurement year.

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ASTHMA MEDICATION RATIO: AGES 19 TO 64

Percentage with persistent asthma who were dispensed appropriate asthma controller medications

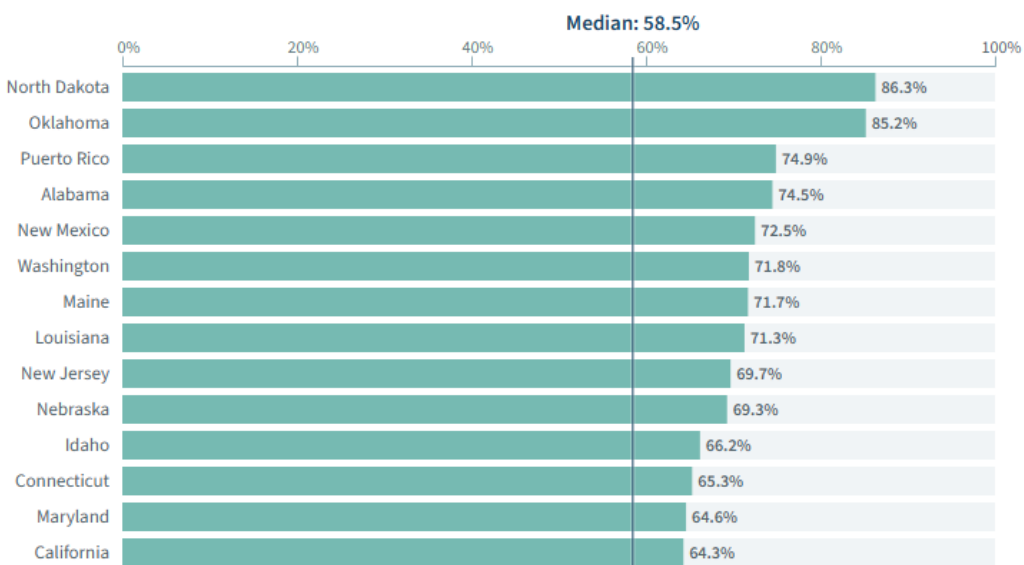
Age: Total (Ages 19 to 64)

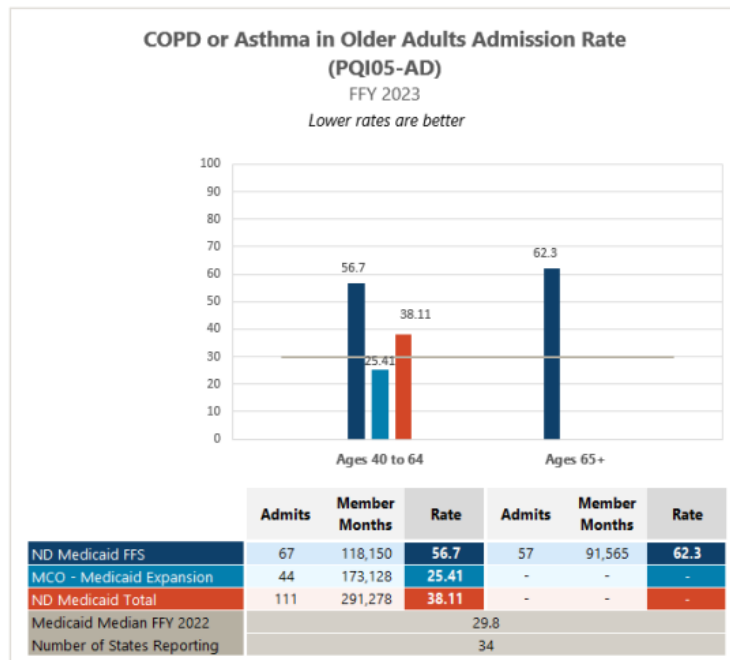
Population: All states view (mixed populations)

Methodology: Administrative

Core Set Year: 2023

Sort by: Alphabetical Values: High to Low Values: Low to High



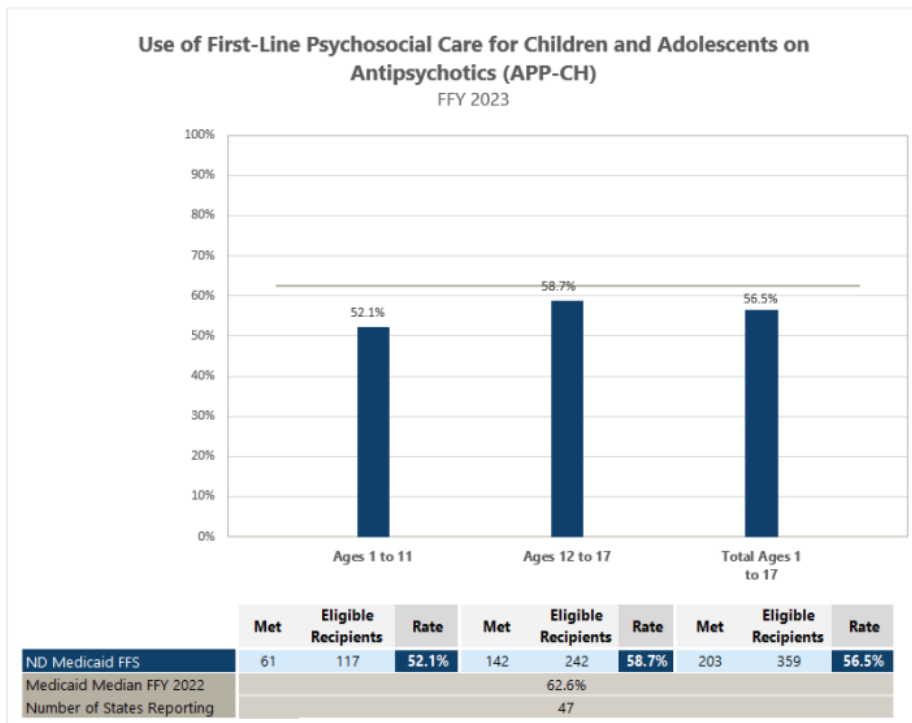


MEASURE DESCRIPTION

This measure assesses the frequency of hospital admissions to treat COPD or asthma among Medicaid adults ages 40 and older by the number of inpatient hospital admissions for chronic obstructive pulmonary disease (COPD) or asthma per 100,000 beneficiary months for beneficiaries ages 40 and older.

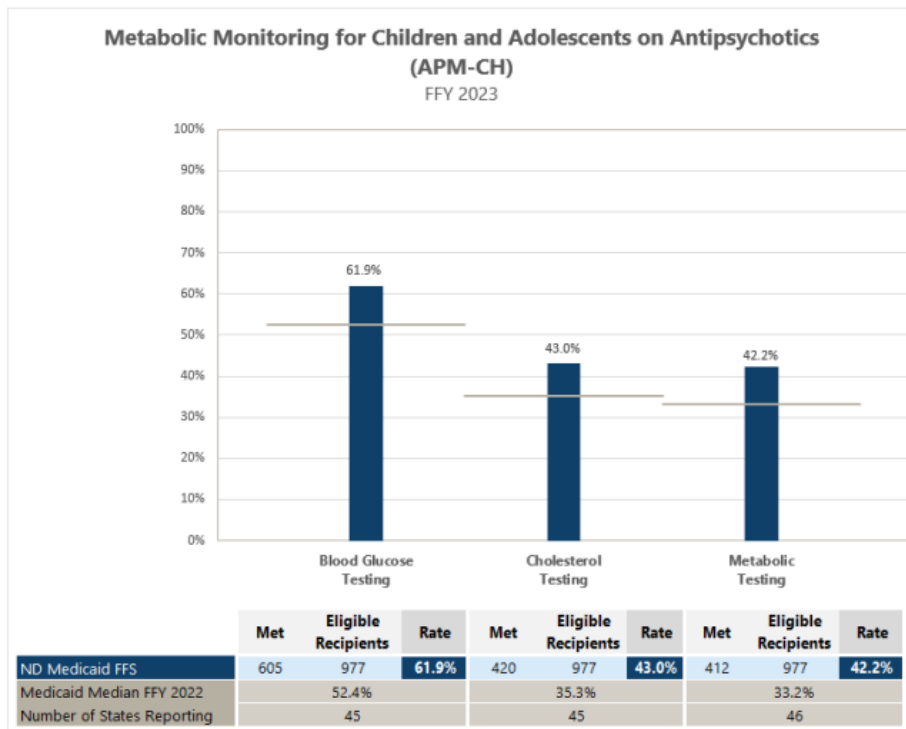
Note: A lower rate indicates better performance.

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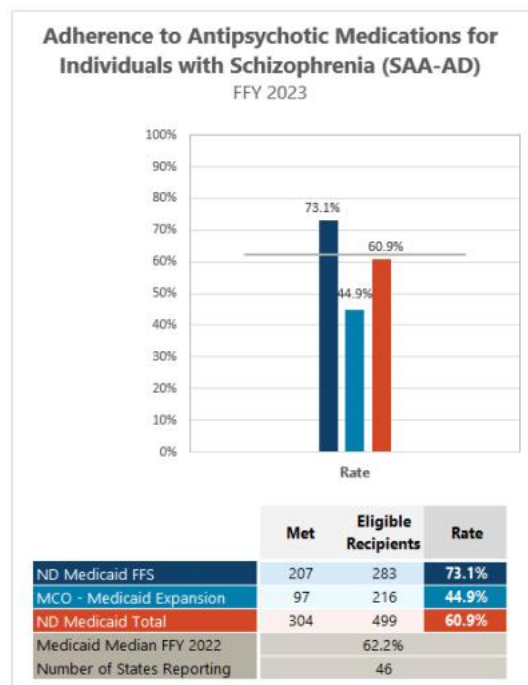
MEASURE DESCRIPTION

This measure assesses the percentage of children and adolescents ages 1 to 17 who had a new prescription for an antipsychotic medication *and had documentation* of psychosocial care as first-line treatment.



MEASURE DESCRIPTION

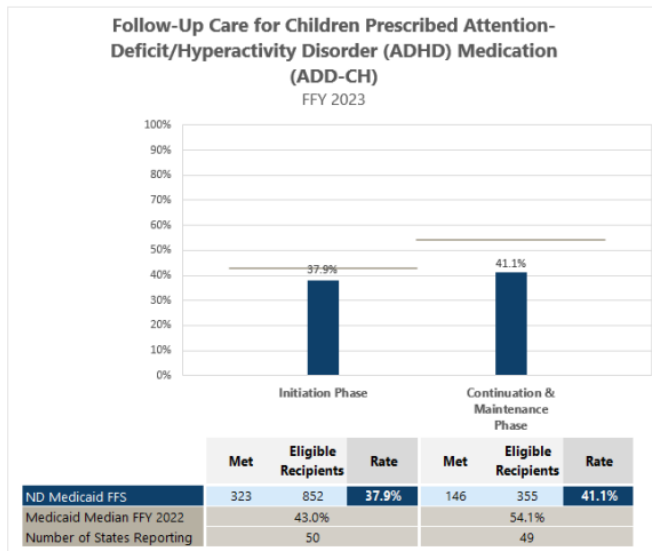
This measure assesses the percentage of children and adolescents ages 1 to 17 who had two or more antipsychotic prescriptions and had metabolic testing for blood glucose, cholesterol, and both blood glucose and cholesterol.



MEASURE DESCRIPTION

Adherence to antipsychotics for the treatment of schizophrenia can reduce the risk of relapse or hospitalization. This measure shows the percentage of adults ages 18 and older with schizophrenia or schizoaffective disorder who were dispensed and remained on an antipsychotic medication for at least 80 percent of their treatment period.

Behavioral Health Care

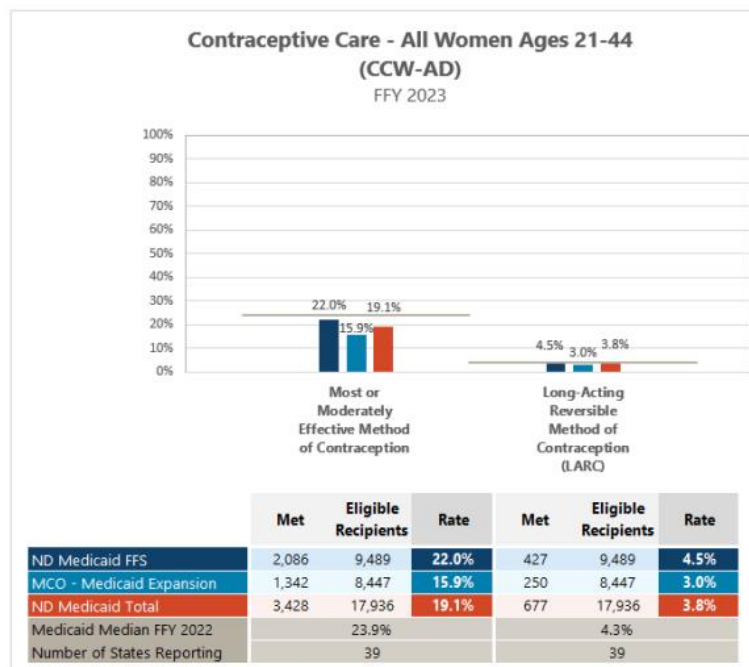


MEASURE DESCRIPTION

This measure shows the percentage of children ages 6 to 12 who were newly prescribed medication for ADHD and who had *at least one visit* during the 30-Day Initiation Phase and *at least two visits* During the 9-Month Continuation and Maintenance Phase.

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NORTH Dakota | Health & Human Services
Be Legendary.

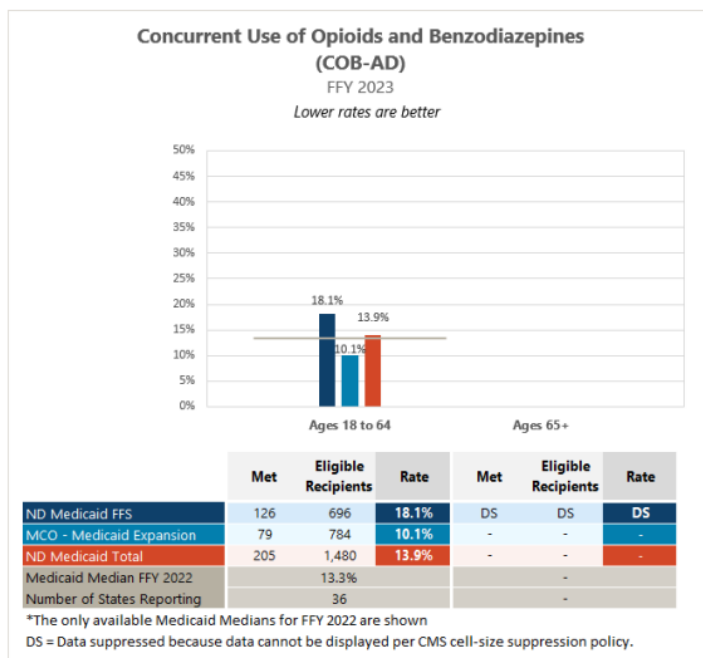


MEASURE DESCRIPTION

This measure assesses the percentage of women ages 21 to 44 at risk of unintended pregnancy who were provided a most or moderately effective method of contraception as well as the percentage who were provided a long-acting reversible method of contraception (LARC).

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NORTH Dakota | Health & Human Services
Be Legendary.

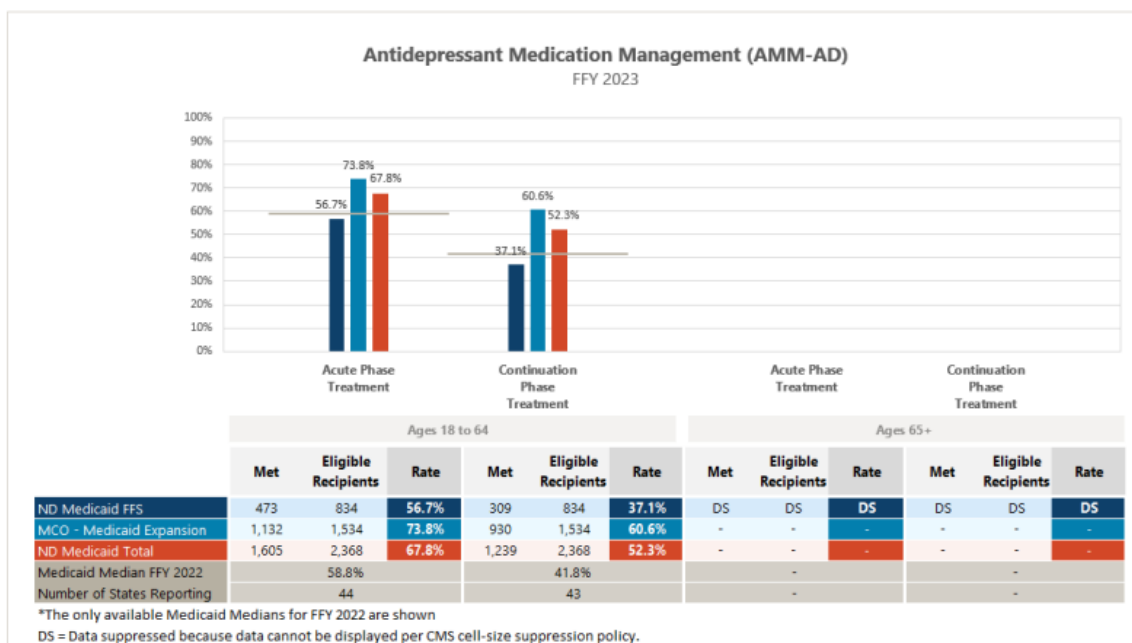


MEASURE DESCRIPTION

This measure assesses the percentage of adults age 18 and older that were prescribed both opioids and benzodiazepines for 30 or more cumulative days during the measurement year.

Note: A lower rate indicates better performance.

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MEASURE DESCRIPTION

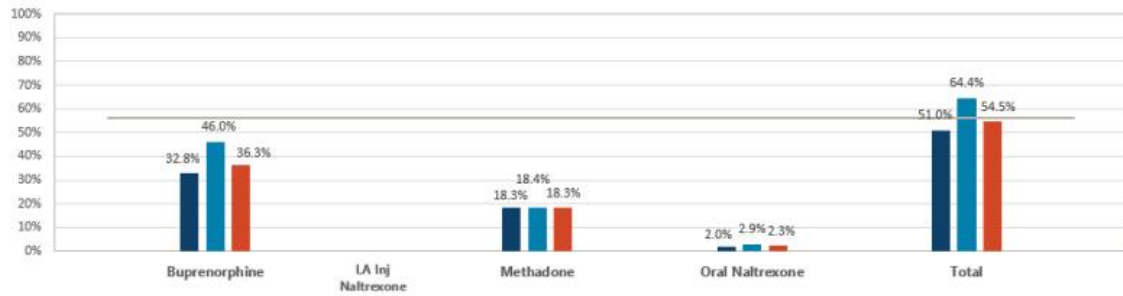
This measure shows the percentage of adults ages 18 and older diagnosed with major depression who were treated with antidepressant medication and who remained on antidepressant medication treatment. Two rates are reported: (1) the percentage who remained on antidepressant medication treatment for the 12-week *effective acute phase treatment*; and (2) the percentage who remained on antidepressant medication treatment for the 6-month *effective continuation phase treatment*.

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Use of Pharmacotherapy for Opioid Use Disorder (OUD-AD)

FFY 2023



	Met	Eligible Recipients	Rate	Met	Eligible Recipients	Rate	Met	Eligible Recipients	Rate	Met	Eligible Recipients	Rate	Met	Eligible Recipients	Rate
ND Medicaid FFS	289	881	32.8%	DS	DS	DS	161	881	18.3%	18	881	2.0%	449	881	51.0%
MCO - Medicaid Expansion	145	315	46.0%	DS	DS	DS	58	315	18.4%	9	315	2.9%	203	315	64.4%
ND Medicaid Total	434	1,196	36.3%	DS	DS	DS	219	1,196	18.3%	27	1,196	2.3%	652	1,196	54.5%
Medicaid Median FFY 2022	56.2%														
Number of States Reporting	33														

DS = Data suppressed because data cannot be displayed per CMS cell-size suppression policy.

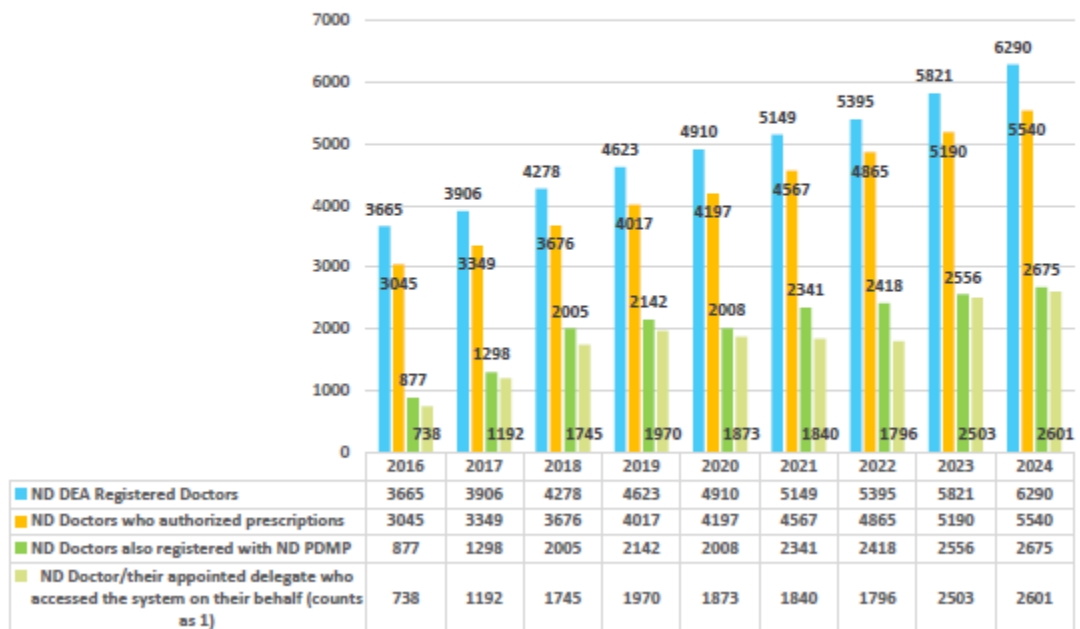
MEASURE DESCRIPTION

This measure shows the percentage of adults age 18 to 64 with an opioid use disorder (OUD) who filled a prescription for or were administered or dispensed an FDA-approved medication for the disorder during the measurement year. Five rates are reported:

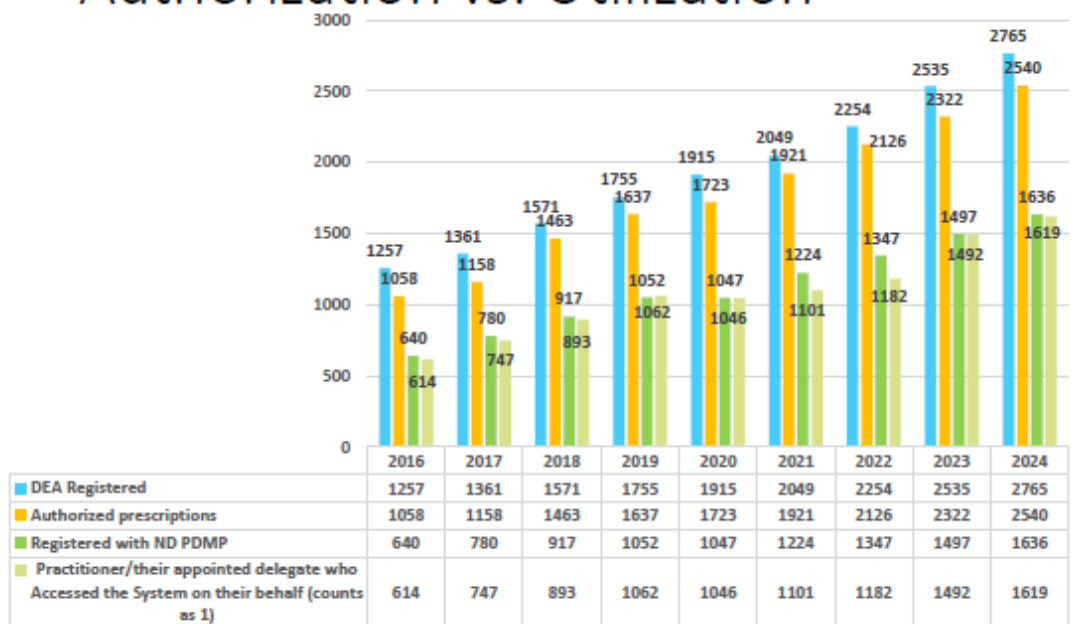
- A total (overall) rate capturing any medications used in medication assisted treatment of opioid dependence and addiction (Rate 1)
- Four separate rates representing the following types of FDA-approved drug products:
 - Buprenorphine (Rate 2)
 - Oral naltrexone (Rate 3)
 - Long-acting, injectable naltrexone (Rate 4)
 - Methadone (Rate 5)

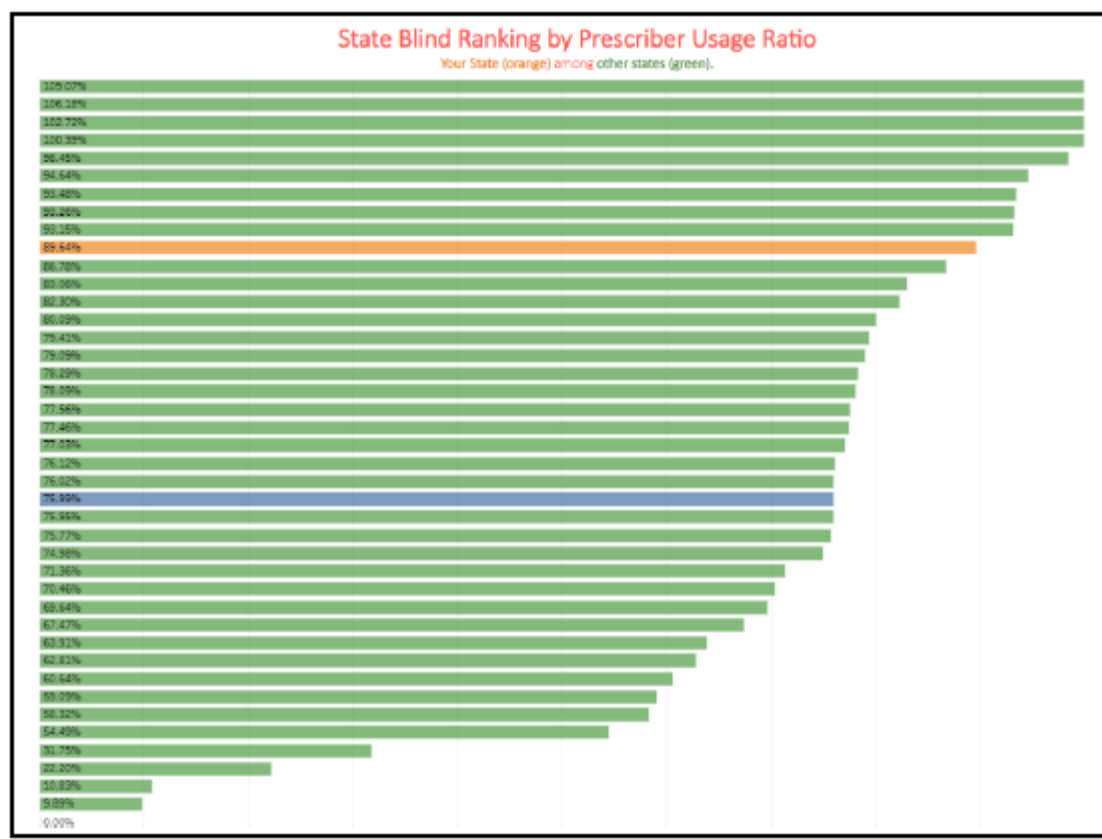
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Doctors – Authorization vs. Utilization



Advanced Practice Providers - Authorization vs. Utilization





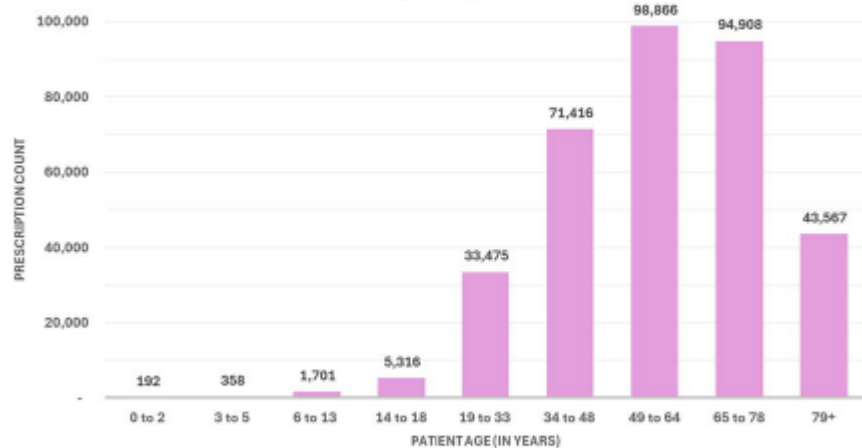
Avg. MME per Patient per County for the 2024 year

County	Average MME Per Patient Per Day	County	Average MME Per Patient Per Day	County	Average MME Per Patient Per Day
Adams	8.79	Grant	7.71	Ransom	4.65
Barnes	5.53	Griggs	4.09	Renville	3.91
Benson	5.93	Hettinger	7.13	Richland	4.35
Billings	2.57	Kidder	8.05	Rolette	5.52
Bottineau	5.49	LaMoure	3.62	Sargent	3.09
Bowman	6.12	Logan	4.71	Sheridan	9.79
Burke	8.95	McHenry	6.06	Sioux	5.70
Burleigh	6.08	McIntosh	6.68	Slope	9.25
Cass	4.08	McKenzie	4.31	Stark	6.68
Cavalier	5.56	McLean	6.76	Steele	4.88
Dickey	6.40	Mercer	7.62	Stutsman	5.29
Divide	12.38	Morton	7.15	Towner	8.98
Dunn	7.74	Mountrail	6.31	Traill	4.02
Eddy	7.59	Nelson	6.75	Walsh	6.95
Emmons	6.33	Oliver	7.91	Ward	4.91
Foster	7.78	Pembina	6.78	Wells	7.05
Golden Valley	5.52	Pierce	5.13	Williams	6.89
Grand Forks	6.34	Ramsey	6.76		

Avg. MME per Patient per County for the 2024 Year

County	Average MME Per Patient Per Day	County	Average MME Per Patient Per Day	County	Average MME Per Patient Per Day
Divide	12.38	Williams	6.89	Golden Valley	5.52
Sheridan	9.79	Pembina	6.78	Rolette	5.52
Slope	9.25	McLean	6.76	Bottineau	5.49
Towner	8.98	Ramsey	6.76	Stutsman	5.29
Burke	8.95	Nelson	6.75	Pierce	5.13
Adams	8.79	Stark	6.68	Ward	4.91
Kidder	8.05	McIntosh	6.68	Steele	4.88
Oliver	7.91	Dickey	6.40	Logan	4.71
Foster	7.78	Grand Forks	6.34	Ransom	4.65
Dunn	7.74	Emmons	6.33	Richland	4.35
Grant	7.71	Mountrail	6.31	McKenzie	4.31
Mercer	7.62	Bowman	6.12	Griggs	4.09
Eddy	7.59	Burleigh	6.08	Cass	4.08
Morton	7.15	McHenry	6.06	Traill	4.02
Hettinger	7.13	Benson	5.93	Renville	3.91
Wells	7.05	Sioux	5.70	LaMoure	3.62
Walsh	6.95	Cavalier	5.56	Sargent	3.09
		Barnes	5.53	Billings	2.57

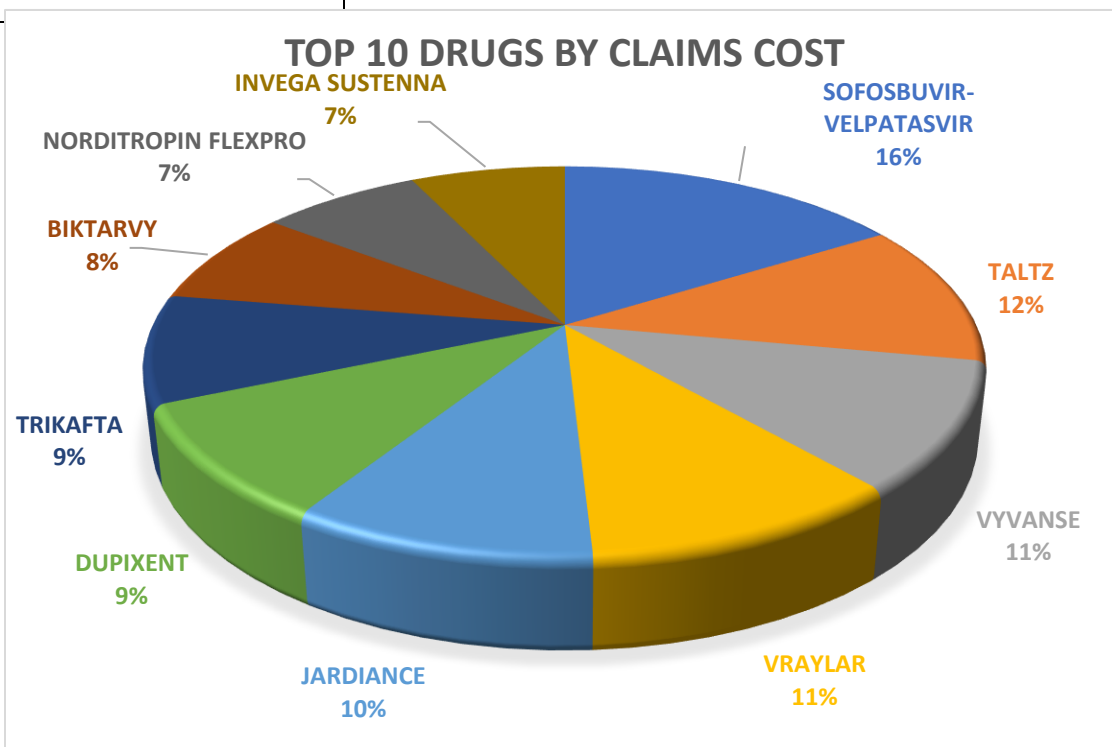
Opioid Prescription Count by Patient Age (2024)



Financial Report

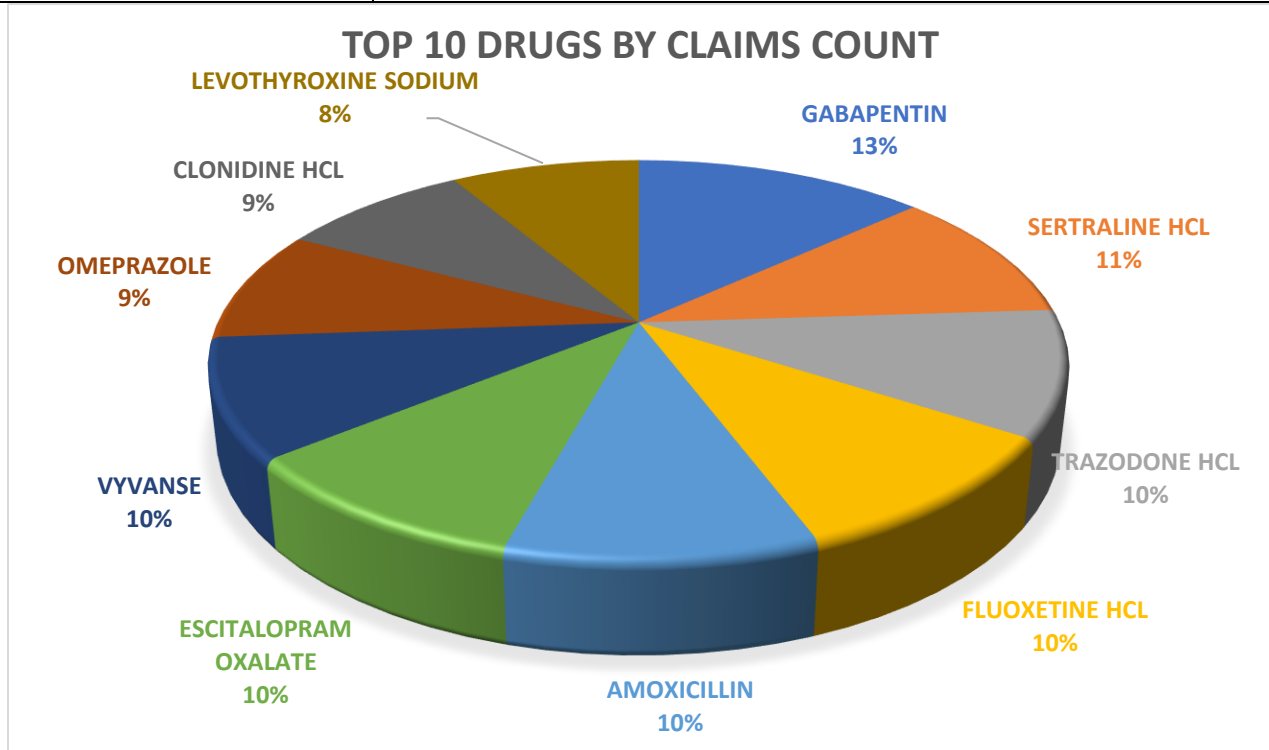
Top 25 Drugs Based on Total Claims Cost from 4/1/25 – 6/30/25

#	Drug Name	Claims	Claims Cost	Patients	Cost/Patient	% Cost	Dif
1	SOFOSBUVIR-VELPATASVIR	59	\$1,375,708.91	59	\$23,317.10	3.98%	↑1
2	TALTZ	129	\$1,002,855.20	54	\$75,744.96	2.90%	↑1
3	VYVANSE	3086	\$904,034.67	1275	\$709.05	2.61%	↑7
4	VRAYLAR	817	\$898,463.92	340	\$2,642.54	2.60%	NC
5	JARDIANCE	1085	\$846,170.83	615	\$1,375.89	2.45%	NC
6	DUPIXENT	209	\$811,192.58	107	\$14,590.61	2.34%	↑1
7	TRIKAFTA	31	\$763,170.00	12	\$63,597.50	2.21%	↓1
8	BIKTARVY	282	\$670,216.50	143	\$4,686.83	1.94%	↑1
9	NORDITROPIN FLEXP	85	\$631,765.30	37	\$17,074.74	1.83%	↓1
10	INVEGA SUSTENNA	222	\$610,835.38	93	\$6,568.12	1.77%	↑1
11	HUMIRA	282	\$609,243.56	127	\$101,648.79	1.76%	↓10
12	ELIQUIS	683	\$427,501.22	347	\$1,231.99	1.24%	↑1
13	SUBLOCADE	193	\$409,780.96	96	\$4,268.55	1.18%	↑1
14	COSENTYX	43	\$407,521.24	16	\$50,468.27	1.18%	↑1
15	INGREZZA	48	\$382,787.81	19	\$20,146.73	1.11%	↑1
16	LIRAGLUTIDE	894	\$326,117.44	498	\$654.85	0.94%	↑98
17	STELARA	13	\$325,057.42	10	\$32,505.74	0.94%	NC
18	VERZENIO	19	\$309,867.45	7	\$44,266.78	0.90%	NC
19	XIFAXAN	104	\$276,302.79	53	\$5,213.26	0.80%	NC
20	ENBREL	41	\$275,429.53	18	\$32,219.54	0.80%	↑10
21	INSULIN LISPRO	1223	\$266,231.29	756	\$579.84	0.77%	NC
22	DULERA	731	\$231,984.62	458	\$506.52	0.67%	↓2
23	ABILIFY MAINTENA	88	\$231,847.06	36	\$6,440.20	0.67%	↓1
24	FARXIGA	345	\$227,143.93	188	\$1,208.21	0.66%	↓1
25	OZEMPIC	239	\$220,362.05	101	\$2,181.80	0.64%	↑10
Total		\$13,441,591.66					



Top 25 Drugs Based on Number of Claims from 4/1/25 – 6/30/25

#	Drug Name	Claims	Claims Cost	Patients	Cost/Claim	% Claims	Dif
1	GABAPENTIN	4,226	\$ 61,819.49	1,873	\$14.63	1.82%	↑1
2	SERTRALINE HCL	3,435	\$ 46,277.13	1,948	\$13.47	1.48%	↑3
3	TRAZODONE HCL	3,266	\$ 43,869.68	1,813	\$13.43	1.41%	↑1
4	FLUOXETINE HCL	3,237	\$43,845.42	1,850	\$13.55	1.40%	↓1
5	AMOXICILLIN	3,194	\$ 49,440.88	3,015	\$ 15.48	1.38%	↓4
6	ESCITALOPRAM	3,166	\$ 42,029.53	1,842	\$13.28	1.36%	NC
7	VYVANSE	3,086	\$ 904,034.67	1,275	\$292.95	1.33%	↑12
8	OMEPRAZOLE	2,871	\$39,172.73	1,782	\$ 13.64	1.24%	↓1
9	CLONIDINE HCL	2,772	\$33,947.05	1,440	\$12.25	1.19%	↑1
10	LEVOTHYROXINE	2,737	\$ 39,318.57	1,492	\$14.37	1.18%	↑2
11	VENTOLIN HFA	2,701	\$ 74,454.66	2,688	\$64.59	1.16%	↓3
12	BUPROPION XL	2,601	\$ 42,948.48	1,488	\$16.51	1.12%	↑2
13	HYDROXYZINE HCL	2,511	\$35,050.68	1,549	\$ 13.96	1.08%	NC
14	ATORVASTATIN	2,480	\$35,406.72	1,498	\$ 14.28	1.07%	↑1
15	LISINOPRIL	2,385	\$ 30,635.25	1,517	\$ 12.84	1.03%	↑2
16	DEXTRO-AMPHET ER	2,358	\$ 72,199.22	1,071	\$30.62	1.02%	NC
17	PREDNISONE	2,351	\$ 28,590.48	1,905	\$12.16	1.01%	↓6
18	METHYLPHENIDATE ER	2,321	\$70,531.94	1,057	\$ 30.39	1.00%	↑2
19	AMOXICILLIN-CLAV	2,316	\$ 39,973.15	2,174	\$17.26	1.00%	↓12
20	LAMOTRIGINE	2,196	\$ 30,770.68	953	\$14.01	0.95%	↑2
21	PANTOPRAZOLE SODIUM	2,196	\$ 30,652.48	1,353	\$13.96	0.95%	↑2
22	ARIPIPIRAZOLE	2,177	\$33,450.88	1,107	\$15.37	0.94%	↓1
23	ONDANSETRON ODT	2,157	\$31,728.85	1,697	\$14.71	0.93%	↓5
24	HYDROCODONE-APAP	2,132	\$ 33,271.12	1,386	\$15.61	0.92%	↓1
25	DULOXETINE HCL	2,112	\$35,020.41	1,149	\$16.58	0.91%	NC
Total		66,984					

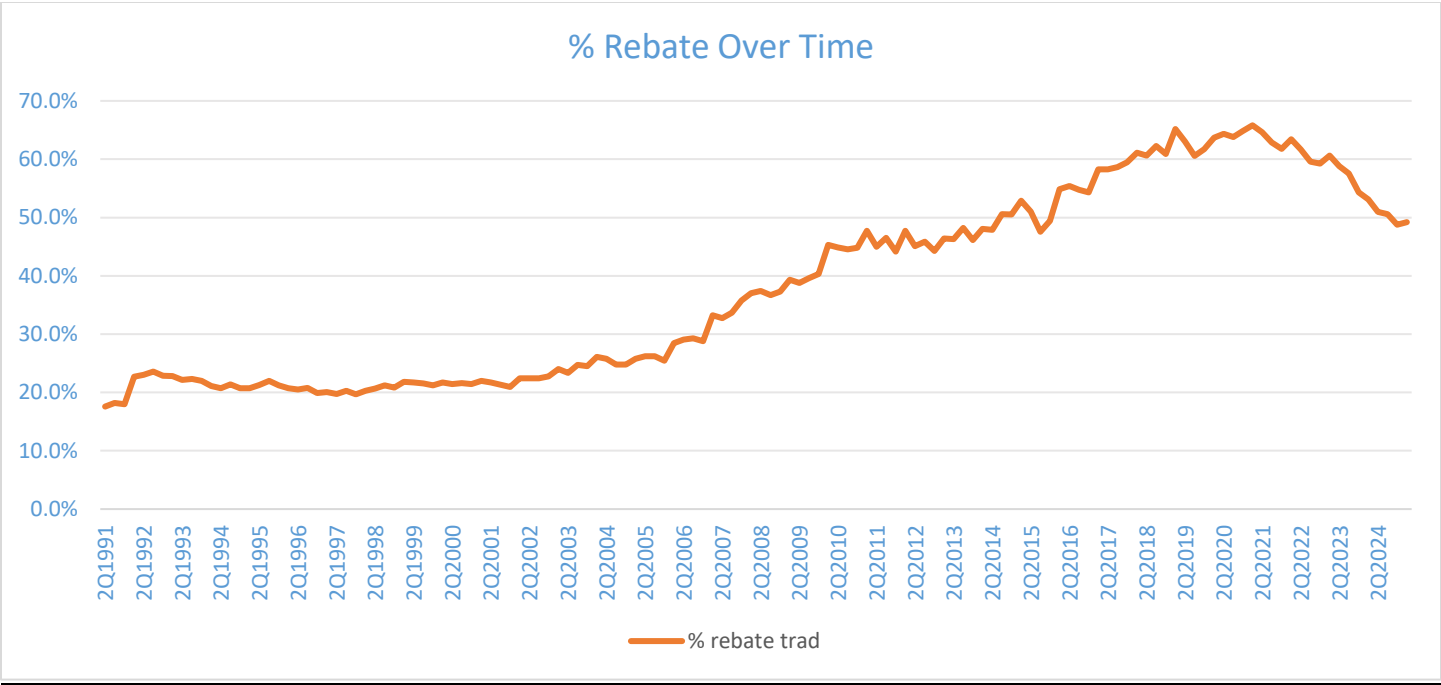


Top 15 Therapeutic Classes Based on Number of Claims from 4/1/25 – 6/30/25

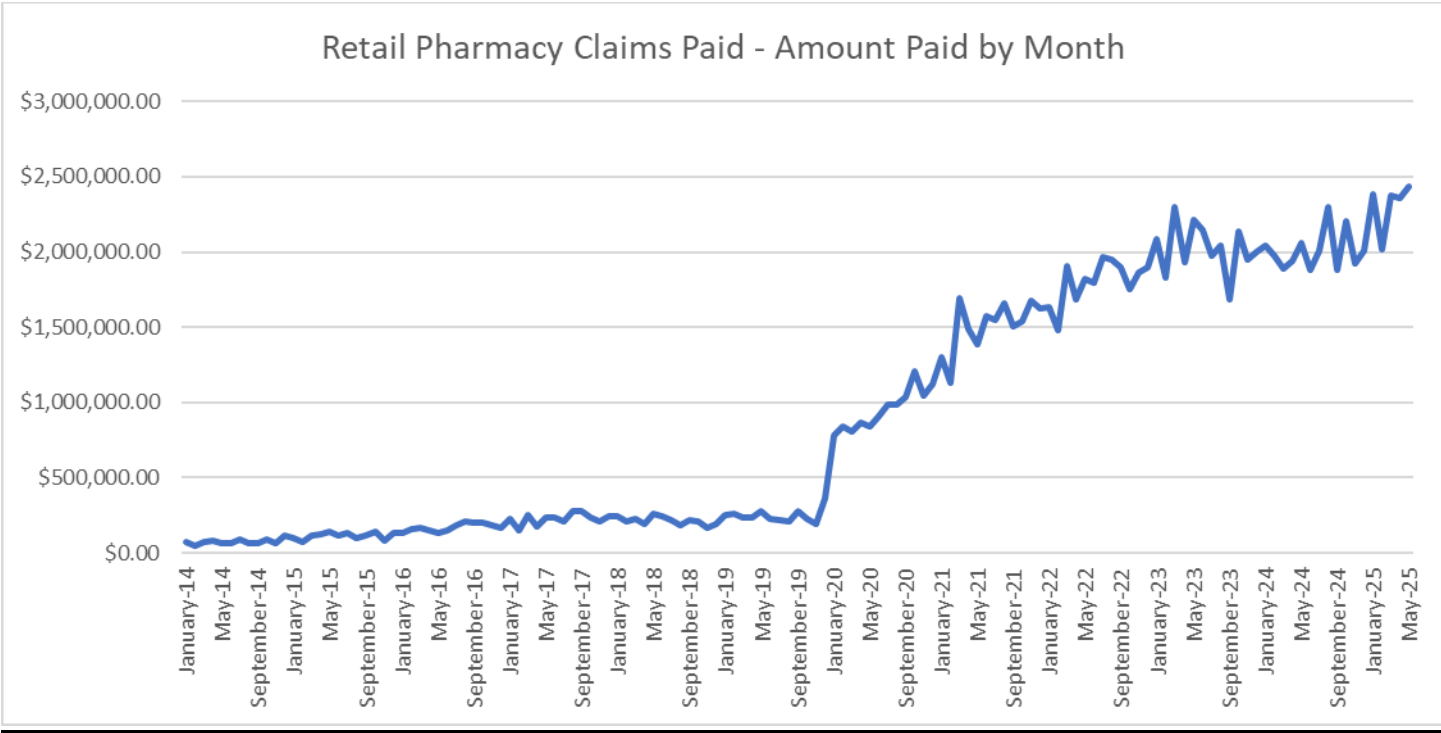
#	Therapeutic Class Description	Claims	Claims Cost	Patients	Cost/Claim	% Claims	Dif
1	ANTIDEPRESSANTS	24,203	564,534	10,526	\$23.32	10.43%	NC
2	ANTIPSYCHOTIC AGENTS	9,502	2,754,587	3,987	\$289.90	4.10%	NC
3	AMPHETAMINES	6,934	1,026,701	2,929	\$148.07	2.99%	↑1
4	GABA-MEDIATED ANTICONVULSANTS	6,511	140,234	2,792	\$21.54	2.81%	↑2
5	RESPIRATORY AND CNS STIMULANTS	6,374	347,575	2,662	\$54.53	2.75%	NC
6	PENICILLIN ANTIBIOTICS	5,773	95,072	5,188	\$16.47	2.49%	↓3
7	BETA-ADRENERGIC AGONISTS	5,694	733,129	3,962	\$128.75	2.45%	NC
8	OPIOID AGONISTS	5,541	104,160	2,928	\$18.80	2.39%	NC
9	PROTON-PUMP INHIBITORS	5,381	94,973	3,276	\$17.65	2.32%	↑2
10	CENTRAL ALPHA-AGONISTS	5,353	76,880	2,491	\$14.36	2.31%	↓1
11	NSAIDs	5,257	74,437	3,616	\$14.16	2.27%	↑1
12	ANTICONVULSANTS	4,866	302,925	2,086	\$62.25	2.10%	↑1
13	ADRENALS	4,707	180,272	3,472	\$38.30	2.03%	↓3
14	STATINS	4,587	66,281	2,833	\$14.45	1.98%	NC
15	BETA-BLOCKERS	4,509	77,491	2,636	\$17.19	1.94%	NC

Top 15 Therapeutic Classes Based on Claims Cost from 4/1/25 – 6/30/25

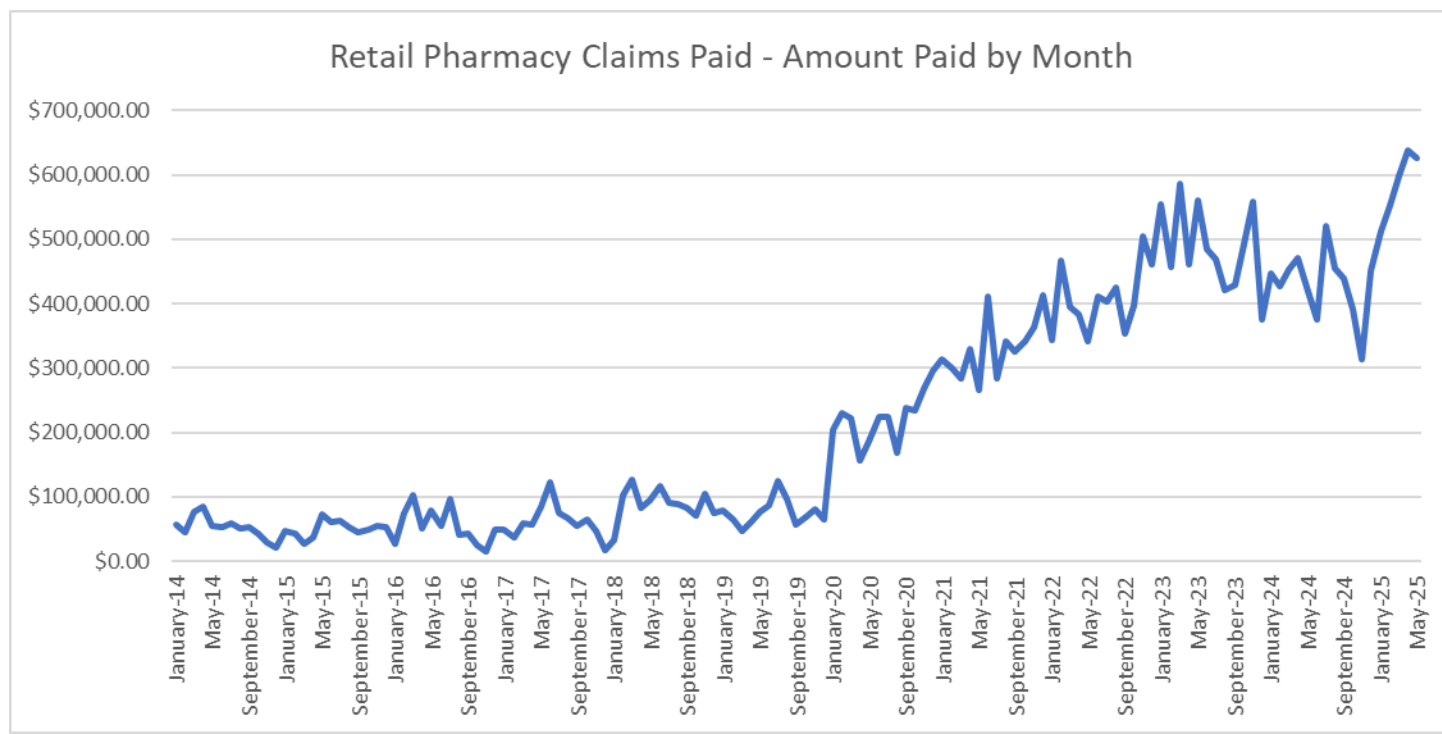
#	Therapeutic Class Description	Claims	Claims Cost	Patients	Cost/Patient	% Cost	Dif
1	TUMOR NECROSIS FACTOR INHIBITORS	370	\$ 2,976,706.38	162	\$ 18,374.73	8.60%	NC
2	ANTIPSYCHOTIC AGENTS	9502	\$ 2,754,586.63	3987	\$ 690.89	7.96%	NC
3	INTERLEUKIN-MEDIATED AGENTS	188	\$ 1,749,046.15	76	\$ 23,013.77	5.06%	NC
4	ANTINEOPLASTIC AGENTS	570	\$ 1,735,396.77	236	\$ 7,353.38	5.02%	NC
5	HCV ANTIVIRALS	60	\$ 1,386,281.85	60	\$ 23,104.70	4.01%	↑1
6	SGLT2 INHIBITORS	1472	\$ 1,100,669.32	825	\$ 1,334.14	3.18%	↑1
7	ANTIRETROVIRALS	644	\$ 1,059,413.84	268	\$ 3,953.04	3.06%	↓2
8	AMPHETAMINES	6934	\$ 1,026,700.71	2929	\$ 350.53	2.97%	NC
9	CFTR CORRECTORS	35	\$ 856,175.76	14	\$ 61,155.41	2.47%	NC
10	SKIN AGENTS	222	\$ 811,632.76	117	\$ 6,937.03	2.35%	↑2
11	BETA AGONISTS	5694	\$ 733,128.90	3962	\$ 185.04	2.12%	NC
12	INCRETIN MIMETICS	1320	\$ 685,123.94	666	\$ 1,028.71	1.98%	↑1
13	PITUITARY	302	\$ 675,505.41	139	\$ 4,859.75	1.95%	↓3
14	INSULINS	2842	\$ 574,417.83	1260	\$ 455.89	1.66%	NC
15	ANTIDEPRESSANTS	24203	\$ 564,533.84	10526	\$ 53.63	1.63%	NC



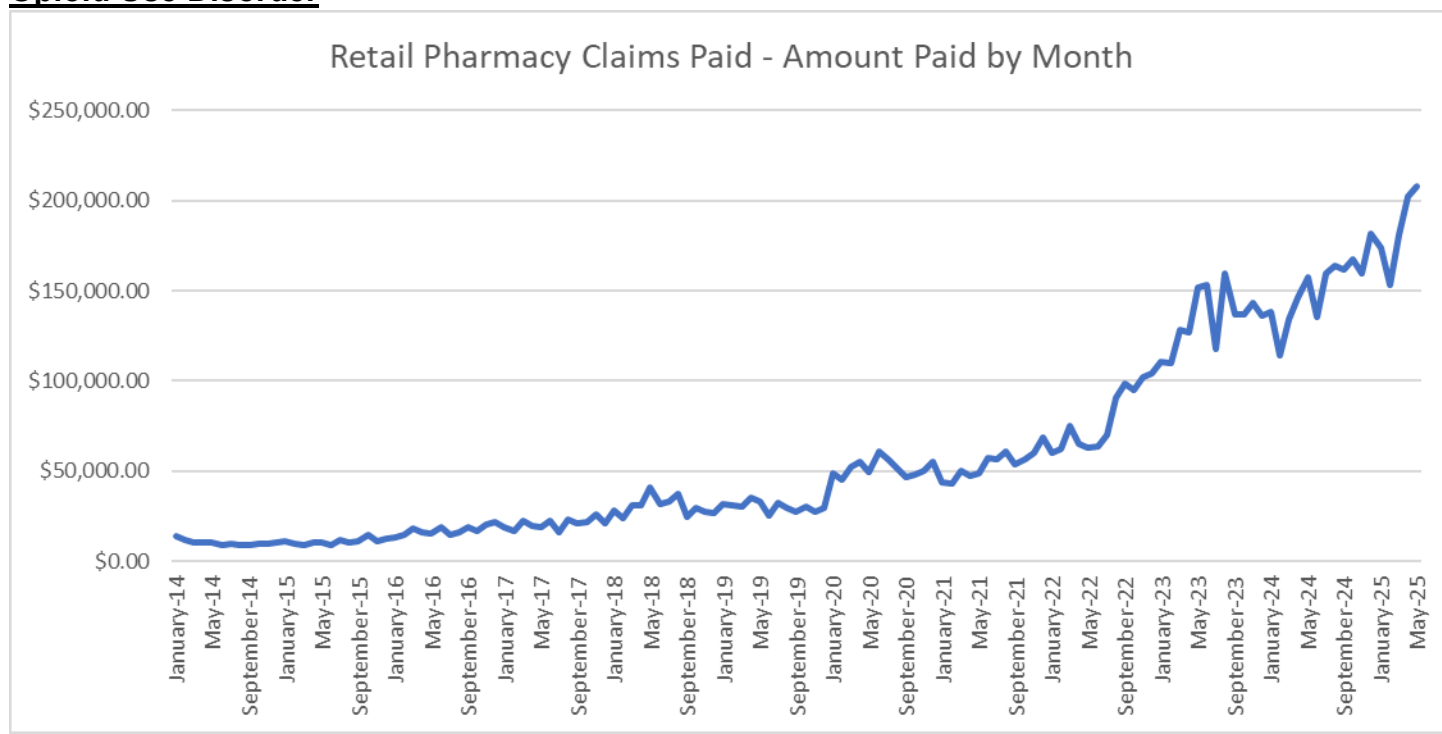
Immunomodulators



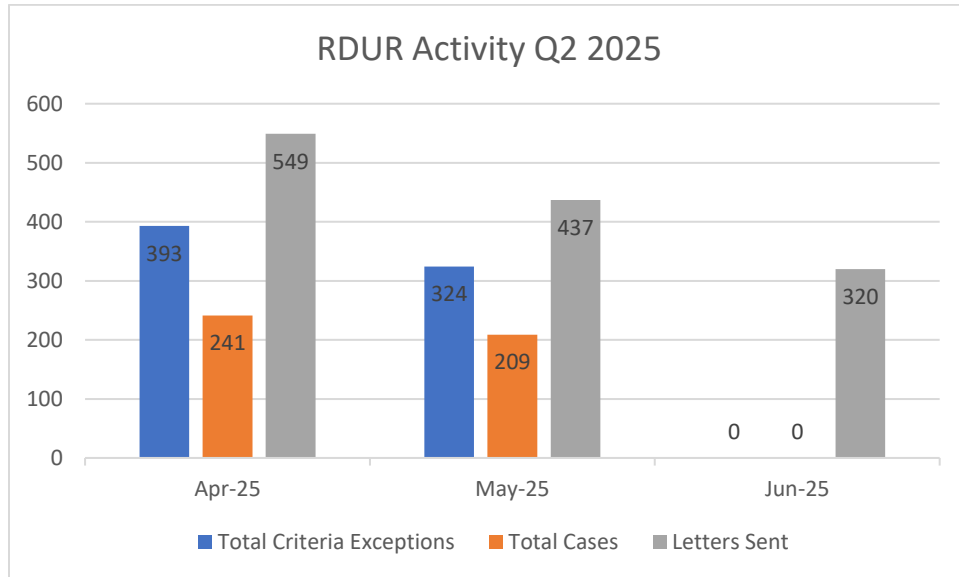
Oncology



Opioid Use Disorder



RDUR Report: Q2 2025 - Julie



April Cases by Type of Criteria		
Criteria Description	# of Cases	% of Cases
Drug-Drug Interactions	98	40.66%
Therapeutic Appropriateness	55	22.82%
Overutilization	37	15.35%
Drug-Disease Precaution	33	13.69%
Underutilization	15	6.22%
Drug-Drug Marker And/Or Diagnosis	3	1.24%

May Cases by Type of Criteria		
Criteria Description	# of Cases	% of Cases
Overutilization	71	33.97%
Underutilization	60	28.71%
Drug-Drug Interactions	39	18.66%
Therapeutic Appropriateness	39	18.66%

Dear Prescriber,

SUBJECT: ND MEDICAID UPCOMING COVERAGE CHANGES

ND Medicaid will be changing the preferred agents for the following drug classes:

1. Dipeptidyl peptidase-4 (DPP-4) inhibitors effective July 1, 2025
2. Inhaled corticosteroid/long-acting beta agonists (ICS/LABA) effective October 1, 2025

A summary of the Preferred Drug List (PDL) changes and a list of your patients who will potentially be affected are enclosed for your review. Please transition to a preferred agent or submit prior authorization (PA) before the changes are effective to minimize treatment disruption.

Thank you for your professional consideration.

Sincerely,

A handwritten signature in black ink that reads "Brendan K. Joyce PharmD". The signature is written in a cursive, flowing style.

Brendan K. Joyce, PharmD
Administrator, Pharmacy Services

Clinical Report

Prior Authorization Updates

Drug	PA Status	Class
Merilog	PA	Diabetes
Avmapki/Fakzyna	PA	> \$3000
Bomyntra	PA	Biosimilars
Brynovin	PA	DPP-4 inhibitors
Conexence	PA	Biosimilars
Edurant PED	PA	Preferred Dosage Forms
Emblaveo	PA	> \$3000
Enflonsia	PA	Medical Billing Only
Imuldosa	PA	Biosimilars
Khindivi	PA	Preferred Dosage Forms
Osenvelt	PA	Biosimilars
Perseris	PA	Preferred Dosage Forms
Soliqua	Remove PA	Insulin/GLP-1 Agonists
Stoboclo	PA	Biosimilars
Tryngolza	PA	> \$3000
Tryptyr	PA	Dry Eye Syndrome
Xultrophy	Remove PA	Insulin/GLP-1 Agonists

Criteria Updates

Summary of Changes

Bullous Pemphigoid

Dupixent received FDA approval for the treatment of Bullous Pemphigoid. Using Dupixent can reduce the need for corticosteroids, improving itch and overall disease severity. It will be considered for those who haven't responded to conventional therapy or for those unable to tolerate high doses of corticosteroids.

PREFERRED AGENTS (PA REQUIRED)

DUPIXENT (dupliumab)

Initial Criteria - Approval Duration: 4 months

- The member has a diagnosis of bullous pemphigoid
 - Drug-induced disease must be assessed/ruled out by prescriber attestation
- The requested medication must be prescribed by, or in consult with, a dermatologist
- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational).
- Current symptoms (e.g., extent or spread of the blisters/pruritus) have been submitted
- The member has experienced new development of nontransient lesions, extension of current lesions, failure of lesion healing, or continued pruritus despite at least 3 weeks of prednisone or prednisolone at 0.75 mg/kg/day within the past 2 months

Chronic Kidney Disease

Like SGLT2 inhibitors, GLP-1 receptor agonists have kidney and cardiovascular benefits in patients with diabetic kidney disease.

GLP-1 receptor agonist

PA REQUIRED

Ozempic (semaglutide)

Semaglutide Only

- The member has type 2 diabetes
- 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 in combination with a SGLT-2 inhibitor and liraglutide at the target or maximally tolerated dose, as evidenced by paid claims or pharmacy printouts:
 1. urinary albumin-to-creatinine ratio (UACR) ≥ 30 mg/g (≥ 3 mg/mmol)
 2. eGFR < 60 mL/min/1.73 m³

Giant Cell Arteritis (Temporal Arteritis)

Rinvoq received FDA approval to treat GCA. It is the only JAK-inhibitor to receive this indication so far, giving another option for treatment. It will be another option for those unable to tolerate high doses of corticosteroids.

Janus Kinase (JAK) inhibitor

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
RINVOQ ER (upadacitinib) TABLET	

Interleukin (IL) -6 Receptor Inhibitors

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
tocilizumab – See 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 requested medication must be prescribed by, or in consult with, a specialist in the area of the member's diagnosis.
- The member must meet one of the following conditions:
 - A minimum 7-day trial of high dose glucocorticoids
 - At high risk of glucocorticoid side effects or complications, including osteoporosis, diabetes, hypertension, or glaucoma

Uveitis

Adalimumab is the only agent currently FDA approved for the treatment of non-infective uveitis, however both infliximab and tocilizumab have compendia support, so they were added to this section.

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
adalimumab - See Biosimilar Agents	tocilizumab - See Biosimilar Agents
infliximab - See Biosimilar Agents	

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- The requested medication must be prescribed by, or in consult with, an ophthalmologist or rheumatologist.
- The member has failed a 6-month trial of a preferred agent, as evidenced by paid claims or pharmacy printouts.

Unfinished Business

Psychotropic Certification

Dear Prescriber,

SUBJECT: ND MEDICAID LEGISLATIVELY MANDATED PSYCHOTROPIC CERTIFICATION

ND Medicaid is required by state law N.D.C.C. § 50-24.6-04(7) to implement a certification program verifying medical necessity of each psychotropic drug when the regimen contains five or more concurrent prescriptions for the following drugs:

1. Antipsychotic	5. Mood stabilizer
2. Antidepressant	6. Sedative hypnotic
3. Anticonvulsant	7. Attention Deficit Hyperactivity Disorder (ADHD)
4. Benzodiazepine	

Coverage of the psychotropic drug may be denied if you fail to certify within 90 days of the date of this notification. A list of your patients and their psychotropic drugs are enclosed for your review. Please complete the certification response for each psychotropic drug you prescribed for each of the enclosed patients within 90 days to minimize treatment disruption.

Thank you for your professional consideration.

Sincerely,

ND Medicaid

State law requires ND Medicaid to implement a psychotropic certification program

Psychotropic certification of medical necessity is required annually for each drug within a regimen containing five or more concurrent prescriptions for the following drugs:

Antipsychotic

Anticonvulsant

Mood stabilizer

ADHD

Antidepressant

Benzodiazepine

Sedative hypnotic



Psychotropic certification **must be completed within 90 days** of the notice date to minimize treatment disruption.



Each prescriber of a medication in an impacted regimen must certify the medical necessity of each psychotropic drug they prescribed within the regimen.

Psychotropic Polypharmacy

Although psychotropic polypharmacy is common in clinical practice, there is limited data to assess the safety and efficacy of using multiple agents concurrently in certain populations (e.g., pediatric).^{1, 2}

Polypharmacy can contribute to negative consequences, including:

- Adverse effects
- Drug-drug interactions
- Nonadherence
- Therapeutic duplication
- Increased healthcare costs^{1, 2}

Safe & effective psychotropic treatment should include evaluation of:

- Guideline recommendations
- Appropriate indications for use
- Non-pharmacological interventions
- Patient education
- Continuous monitoring^{1, 2}

Prior to using multiple agents, implement non-pharmacological interventions and consider alternative monotherapy.

References

1. Medhekar R, Fujimoto K, Aparasu RR, Bhatara VS, Johnson ML, Alonzo JP, Schwarzwald HL, Chen H. Physician care coordination and the use of psychotropic polypharmacy in the management of pediatric mental disorders. *J Manag Care Spec Pharm*. 2019 Jan;25(1):29-39. doi: 10.18553/jmcp.2019.25.1.029.
2. Libowitz MR, Nurmi EL. The Burden of Antipsychotic-Induced Weight Gain and Metabolic Syndrome in Children. *Front Psychiatry*. 2021 Mar 12;12:623681. doi: 10.3389/fpsy.2021.623681. PMID: 33776816; PMCID: PMC7994286.

Psychotropic drugs where you have been identified as the prescriber through pharmacy claims data are highlighted within each member's psychotropic drug list (may not include medications paid out-of-pocket or fully covered by another payer). If there are multiple prescribers involved with the regimen, each will receive this information.

You must certify each psychotropic drug that you prescribed **within 90 days** to minimize treatment disruption.

TO CERTIFY MEDICAL NECESSITY:

1. Complete the Certification of Medical Necessity column
2. Initial in the Prescriber column for each drug you prescribed
3. Submit certification using one of the following options:
 - a. Fax this completed form to 866-798-4904
 - b. Mail this completed form in the envelope provided

Member: John Smith (DOB: 07/24/2010)		
Psychotropic Drug	Prescriber	Certification of Medical Necessity
Methylphenidate ER 36 mg		☐ Yes ☐ No, I am not the current prescriber ☐ No, the drug was/will be discontinued Time needed to taper: _____
Methylphenidate 10 mg		☐ Yes ☐ No, I am not the current prescriber ☐ No, the drug was/will be discontinued Time needed to taper: _____
Clonidine 0.1 mg	PCP name	
Aripiprazole 5 mg	Psychiatrist name	
Sertraline 50 mg	Psychiatrist name	

1. Were you aware of these other prescribers?
 - ☐ Yes, I was aware of ALL the other prescribers
 - ☐ Yes, I was aware of SOME of the other prescribers
 - ☐ No
2. Did you do anything additional with this information?
 - ☐ Yes. What action did you take? _____
 - ☐ No. Why not? _____

New Business

Second Review

Non-Opioid Pain Medications

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	CELEBREX (celecoxib)
diclofenac sodium DR 50 mg, 75 mg	DAYPRO (oxaprozin)
etodolac	diclofenac potassium 25 mg tablet
flurbiprofen	diclofenac potassium 25 mg capsule
ibuprofen	diclofenac sodium 25 mg DR
indomethacin	diclofenac sodium 100 mg ER tablet
indomethacin ER	diclofenac/misoprostol
ketoprofen IR	DUEXIS (famotidine/ibuprofen)
ketorolac	etodolac ER
meclofenamate	famotidine/ibuprofen
mefenamic acid	FELDENE (piroxicam)
meloxicam	fenoprofen
nabumetone	ketoprofen ER 200 mg
naproxen	LOFENA (diclofenac potassium)
piroxicam	meloxicam, submicronized
sulindac	NALFON (fenoprofen)
tolmetin	NAPRELAN (naproxen)
	naproxen ER 500 mg

	naproxen/esomeprazole
	oxaprozin
	RELAFEN DS (nabumetone)
	SEGLENTIS (celecoxib/tramadol)
	VIMOVO (naproxen/esomeprazole)

Electronic Diagnosis Verification

- Mefenamic acid and Meclofenamate: Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- *Non-preferred agents with no same active ingredient preferred:*
 - The member must have failed a 7-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

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
	diclofenac topical solution (labeler 59088)

Prior Authorization Criteria

- See [Preferred Dosage Form](#) Criteria

Sodium Channel Blockers

PREFERRED AGENTS (NO PA REQUIRED)
JOURNAVX (suzetrigine)

Electronic Duration Verification

- One 14-day fill allowed per 60 days

Therapeutic Duplication

- Concurrent use with opioid medication is not covered

First Review of Nieman-Pick Type C

Overview

Definition: an autosomal recessive disorder associated with splenomegaly, variable neurologic deficits, and the storage of lipids including sphingomyelin and cholesterol.¹

Niemann-Pick Type C (NPC) is caused by variants of the NPC1 and NPC2 genes that cause impaired processing and transport of LDL cholesterol and other macromolecules. It affects approximately 1:120,000 worldwide. It can present from the perinatal period until late adulthood. Greater than 85% of patients have liver, spleen, or lung involvement which precedes the development of neurologic symptoms. Acid sphingomyelinase deficiency (ASMD) types A and B were previously known as Niemann-Pick disease types A and B. ASMD is caused by pathogenic variants in the SMPD1 gene. ASMD-A is the more severe, early-onset form of the two types. Differential diagnosis should include Gaucher disease, lysosomal acid lipase deficiency, hepatosplenomegaly associated with infection, and hematologic malignancies.¹

Most Common Clinical Features:¹

- Vertical supranuclear gaze palsy: an eye movement disorder characterized by an inability to move the eyes up or down due to a problem in the brain
- Gelastic cataplexy: a sudden, brief loss of muscle tone triggered by strong emotions, especially laughter.
- Isolated unexplained splenomegaly with or without hepatomegaly
- Prolonged neonatal jaundice or cholestasis
- Premature cognitive decline or dementia

FDA Approval

Miplyffa (arimoclomol)²: September 20, 2024; 505(b) New Drug Application (NDA) pathway; Type 1 – New Molecular Entity; Priority; Orphan

Aqneursa (levacetylleucine)³: September 24, 2024; 505(b) New Drug Application (NDA) pathway Type 1 New Molecular Entity, Priority; Orphan

Current Utilization

Medication	Quarter 3 2024 – Quarter 2 2025		
	Rx Count	Rx Count	% of Rx
Miplyffa	0	0	0
Aqneursa	0	0	0

Medication Overview

Medication	Miplyffa (arimoclomol)	Aqneursa (levacetylleucine)
Dosing	Adults: 62-124mg three times daily based on actual body weight Pediatrics (2 years or older): 47-124mg three times daily based on actual body weight	Adults: 1-2g three times daily based on actual body weight Pediatrics: 1g twice daily to 2g three times daily based on actual body weight
Special Considerations	- Can cause an increase in creatinine without affecting GFR so other measures should be used to assess renal function - May cause embryo-fetal harm and impair fertility - Dosage adjustments required for eGFR < 50 ml/min - Should be used in combination with miglustat Common ADRs: weight decrease, upper respiratory infection, urticaria	- May cause fetal harm - No dosage adjustments required Common ADRs: rosacea, abdominal pain, dysphagia, vomiting, thrombocytopenia, upper respiratory infection
Clinical Trials	Evaluated safety only. Common adverse effects of each medication found in trials listed above.	
Cost (AWP)/month⁴	47mg – 124mg: \$40,185.00 to \$127,224.00	1gm: \$34,682.40 to 104,587.20
Place in Therapy¹	- Therapy should be initiated at the earliest evidence of neurologic manifestations - Choice between Aqneursa or Miplyffa plus miglustat should be individualized - Patients without neurologic manifestations do not require treatment	

References:

- Schiffmann, Raphael, et al. Niemann-Pick type C disease. UpToDate. May 15, 2025. Niemann-Pick type C disease - UpToDate
- Aqneursa (levacetylleucine). [prescribing information]. Zevra Therapeutics, Inc. US Food and Drug Administration. Celebration, FL Sept 2024. https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/219209Orig1s000lbl.pdf
- Miplyffa (arimoclomol). [prescribing information]. IntraBio Inc. US Food and Drug Administration. Austin, TX Sept 2024. https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/219209Orig1s000lbl.pdf
- Miplyffa (arimoclomol), Aqneursa (levacetylleucine) Red Book. IBM Micromedex Solutions. Tuven Health Analytics, Inc. Ann Arbor, MI. March 4, 2025. <https://www.micromedexsolutions.com>

First Review of ANCA-Associated vasculitis

Overview

Definition:

Antineutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis (AAV) includes granulomatosis with polyangiitis (GPA), microscopic polyangiitis (MPA), renal-limited vasculitis, and eosinophilic granulomatosis with polyangiitis (EGPA), previously called Churg-Strauss syndrome (CSS) or allergic granulomatosis and angiitis. All affect small-sized arteries and have similar effects on kidney histology. ¹

Prevalence^{1,2}:

GPA:

- 2.3 to 146 cases per million persons
- Mostly affects people of European ancestry

MPA:

- 9-94 cases per million persons
- Mostly affects people of Asian ancestry

EGPA:

- 12 to 15 cases per million persons

Clinical Features:

GPA and MPA¹:

- Can involve small blood vessels in almost any organ or tissue but mostly affects the respiratory tracts and kidneys
 - May develop interstitial lung disease complicated by pulmonary fibrosis and pulmonary arterial hypertension.
 - Kidney involvement includes rapidly progressive glomerulonephritis.
 - Asymptomatic hematuria with normal kidney function
 - Increase in serum creatinine over days or weeks with hematuria and cellular casts
- Initial presentation includes fever, malaise, anorexia, weight loss, myalgias, and arthralgias.
- May also see urinary abnormalities with or without kidney function impairment, purpuric skin lesions, and neurologic dysfunction (foot or wrist drop).
- Approximately one-fourth of patients present with migratory polyarthropathy, nasal crusting, or other findings that do not include organ-threatening manifestations.
 - Typically younger at disease onset and more likely to be women.
 - More likely to have chronic, recurring disease and destructive upper respiratory tract disease
- Ear, nose, and throat manifestations can occur in 90% of GPA patients and 35% in MPA patients.
- GPA patients typically have more bone and cartilage destruction.

EGPA²:

- Asthma
- Rhinitis
- Nasal polyps
- Prominent peripheral blood and tissue eosinophilia
- Commonly involved organs: lungs, skin, nervous system
- Vasculitis of small and medium sized arteries

Diagnosis¹: Patients who present with constitutional symptoms along with clinical evidence of glomerulonephritis, upper or lower respiratory tract involvement, or multiple mononeuropathy. Detection of antineutrophil cytoplasmic autoantibody (ANCA) should increase suspicion of GPA or MPA. Approximately 82 to 94% of patients have a positive ANCA. GPA is primarily associated with PR3-ANCA and MPA is associated with MPO-ANCA.

Asthma and eosinophilia may distinguish EGPA from GPA and MPA. Vasculitis is indistinguishable in all three.

FDA Approval

Tavneos (avacopan)³: October 7, 2021; 505(b) New Drug Application (NDA) pathway; Type 1 – New Molecular Entity; Standard; Orphan; Approved for GPA and MPA

Current Utilization

Medication	Quarter 3 2024 – Quarter 2 2025		
	Rx Count	Rx Count	% of Rx
Tavneos (avacopan)	0	0	0

Medication Overview ⁴

Treatment for organ or life-threatening disease⁴:

Organ- or life-threatening disease is characterized by active glomerulonephritis, pulmonary hemorrhage, cerebral vasculitis, progressive peripheral or cranial neuropathy, orbital pseudotumor, scleritis, GI bleeding due to vasculitis, or cardiac disease due to vasculitis (pericarditis, myocarditis). Induction therapy includes treatment with glucocorticoids combined with either rituximab or cyclophosphamide. If the patient achieves remission after 3 to 6 months, maintenance therapy with rituximab, azathioprine, methotrexate, or mycophenolate should be initiated. Rituximab is the preferred choice for maintenance therapy after remission of newly diagnosed disease.

Avacopan can be used as an adjunctive agent with standard induction therapy to limit the use of glucocorticoids. Glucocorticoids should be tapered over 4 to 6 weeks based on patient response. It is indicated for use in severe, active disease which is defined as vasculitis with organ- or life-threatening manifestations (e.g. alveolar hemorrhage, glomerulonephritis, CNS vasculitis, mononeuritis multiplex, cardiac involvement, mesenteric ischemia, limb/digit ischemia). Active disease is defined as new, persistent, or worsening clinical signs and symptoms attributed to GPA or MPA and not related to prior damage.⁵

Treatment for non-organ or non-life-threatening disease⁴:

Induction therapy includes glucocorticoids combined with weekly methotrexate. Rituximab is the suggested alternative for patients with an eGFR below 60 mL/min per 1.73m². Methotrexate, rituximab, or azathioprine can be used for maintenance therapy.

First-line treatment for non-severe EGPA is systemic glucocorticoids which typically results in remission within the first few weeks. If the patient does not experience remission with system glucocorticoids alone, mepolizumab or benralizumab should be added.⁶

Medication	Avacopan (Tanveos)
Mechanism of Action³	Complement 5a receptor antagonist that inhibits the interaction between C5aR and the anaphylatoxin C5a. It blocks C5a-mediated neutrophil activation and migration. Exact mechanism in AAV is not definitively established.
Dosing⁴	30mg twice daily
Special Considerations⁴	• Avoid in patients with chronic liver disease and those taking strong CYP3A4 inducers. • Liver function tests should be obtained at baseline and then monitored periodically.
Clinical Trials⁴	A trial of 331 patients with newly diagnosed or relapsing AAV found that at 52 weeks sustained remission was higher in the avacopan group than in the prednisone group (66 vs 55%).
Cost (AWP)/month⁷	\$21,457.37

References:

5. Falk, Ronald J, et al. *Granulomatosis with polyangiitis and microscopic polyangiitis: Clinical manifestations and diagnosis*. UpToDate. March 20, 2025. *Granulomatosis with polyangiitis and microscopic polyangiitis: Clinical manifestations and diagnosis – UpToDate*
6. Khoury, Paneez, et al. *Epidemiology, pathogenesis, and pathology of eosinophilic granulomatosis with polyangiitis*. UpToDate. Oct 30, 2024. *Epidemiology, pathogenesis, and pathology of eosinophilic granulomatosis with polyangiitis - UpToDate*
7. *Tavneos (avacopan)*. [prescribing information]. Thermo Fisher Scientific. US Food and Drug Administration. Cincinnati, OH Oct 2021. https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/214487s000lbl.pdf
8. Merkel, Peter A, et al. *Granulomatosis with polyangiitis and microscopic polyangiitis: Induction and maintenance therapy*. UpToDate. Jul 14, 2025. *Granulomatosis with polyangiitis and microscopic polyangiitis: Induction and maintenance therapy - UpToDate*
9. Chung, Sharon A, et al. *2021 American College of Rheumatology/Vasculitis Foundation Guideline for the Management of Antineutrophil Cytoplasmic Antibody-Associated Vasculitis*. Arthritis & Rheumatology. 2021. *2021-ACR-VF-Guideline-for-Management-of-ANCA-Associated-Vasculitis.pdf*
10. Khoury, Paneez, et al. *Eosinophilic granulomatosis with polyangiitis: Treatment and prognosis*. UpToDate. May 2, 2025. *Eosinophilic granulomatosis with polyangiitis: Treatment and prognosis - UpToDate*
11. *Tavneos (avacopan) Red Book*. IBM Micromedex Solutions. Tuven Health Analytics, Inc. Ann Arbor, MI. March 4, 2025. <https://www.Micromedexsolutions.com>

NORTH DAKOTA MEDICAID

RETROSPECTIVE DRUG UTILIZATION REVIEW

CRITERIA RECOMMENDATIONS

3RD QUARTER 2025

Criteria Recommendations

Approved Rejected

1. Nirogacestat / Overuse

Alert Message: Ogsiveo (nirogacestat) may be over-utilized. The recommended dosage nirogacestat is 150 mg administered orally twice daily until disease progression or unacceptable toxicity.

Drugs/Diseases

Util A

Util B

Util C

Nirogacesta

Max Dose: 300 mg/day

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.

Ogsiveo Prescribing Information, April 2024, SpringWorks Therapeutics Inc.

2. Nirogacestat / Therapeutic Appropriateness

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

Drugs/Diseases

Util A

Util B

Util C

Nirogacesta

Age Range: 0 – 17 yoa

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.

Ogsiveo Prescribing Information, April 2024, SpringWorks Therapeutics Inc.

3. Nirogacestat / Diarrhea

Alert Message: Diarrhea, sometimes severe, can occur in patients treated with Ogsiveo (nirogacestat). In the clinical trial for nirogacestat efficacy, diarrhea occurred in 84% of patients treated with nirogacestat, including Grade 3 events in 16% of patients. For diarrhea persisting for greater than 3 days despite maximal medical therapy, withhold nirogacestat until resolved to Grade 1 or baseline, then restart at a dose of 100 mg twice daily.

Drugs/Diseases

Util A

Util B

Util C

Nirogacesta

Diarrhea

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.

Ogsiveo Prescribing Information, April 2024, SpringWorks Therapeutics Inc.

4. Nirogacestat / Elevated Liver Enzymes - Dose

Alert Message: ALT or AST elevations occurred in 30% and 33% of patients who received Ogsiveo (nirogacestat) in the clinical trial, respectively. Grade 3 ALT or AST elevations (> 5 × ULN) occurred in 6% and 2.9% of patients, respectively. Monitor liver function tests regularly and modify dose as recommended for patients with Grade 2 (>= 3 to 5 x ULN) ALT or AST increased withhold nirogacestat until ALT, AST, or both are resolved to < 3 x ULN or baseline, then restart at a dose of 100 mg twice daily. Permanently discontinue nirogacestat if the patient has Garde 3 or 4 (> 5 x ULN).

Drugs/Diseases		
<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Nirogacesta	Abnormal Liver Function Studies	

Max Dose: 200 mg/day

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Ogsiveo Prescribing Information, April 2024, SpringWorks Therapeutics Inc.

5. Nirogacestat / Electrolyte Abnormalities

Alert Message: Electrolyte abnormalities can occur in patients treated with Ogsiveo (nirogacestat). In the clinical trial, electrolyte abnormalities included decreased phosphate (65%) and decreased potassium (22%). If Grade 3 or 4 hypophosphatemia persists for >= 3 days despite maximal replacement therapy, withhold nirogacestat until resolved to Grade 1 or lower or baseline, then restart at a dose of 100 mg twice daily. If Grade 3 or 4 hypokalemia occurs despite maximal replacement therapy, withhold nirogacestat until resolved to Grade 1 or lower, or baseline, then restart at a dose of 100 mg twice daily.

Drugs/Diseases		
<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Nirogacesta	Hypokalemia Hypophosphatemia	

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Ogsiveo Prescribing Information, April 2024, SpringWorks Therapeutics Inc.

6. Nirogacestat / Ovarian Toxicity

Alert Message: Female reproductive function and fertility may be impaired in patients being treated with Ogsiveo (nirogacestat). The long-term effects of nirogacestat on fertility have not been established. Advise patients on the potential risks for ovarian toxicity before initiating treatment with nirogacestat. Monitor patients for changes in menstrual cycle regularity or the development of symptoms of estrogen deficiency, including hot flashes, night sweats, and vaginal dryness.

Drugs/Diseases		
<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Nirogacesta		

Gender: Female
Age Range: 18 – 50 yoa

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Ogsiveo Prescribing Information, April 2024, SpringWorks Therapeutics Inc.

7. Nirogacestat / Strong or Moderate CYP3A4 Inhibitors

Alert Message: The concomitant use of Ogsiveo (nirogacestat) with a strong or moderate CYP3A inhibitor should be avoided. Nirogacestat is a CYP3A substrate, and concomitant use with a strong or moderate CYP3A inhibitor may increase nirogacestat exposure, which may increase the risk of nirogacestat adverse reactions.

Drugs/Diseases

Util A	Util B	Util C
Nirogacesta	Atazanavir	Idelalisib
	Aprepitant	Itraconazole
	Clarithromycin	Ketoconazole
	Cobicistat	Nefazodone
	Crizotinib	Nelfinavir
	Diltiazem	Posaconazole
	Dronedarone	Ritonavir
	Erythromycin	Tipranavir
	Fluconazole	Verapamil
	Fluvoxamine	Voriconazole
	Fosamprenavir	

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Ogsiveo Prescribing Information, April 2024, SpringWorks Therapeutics Inc.

8. Nirogacestat / Strong or Moderate CYP3A4 Inducers

Alert Message: The concomitant use of Ogsiveo (nirogacestat) with a strong or moderate CYP3A inducer should be avoided. Nirogacestat is a CYP3A substrate, and concomitant use with a strong or moderate CYP3A inducer may decrease nirogacestat exposure, which may reduce the effectiveness of nirogacestat.

Drugs/Diseases

Util A	Util B	Util C
Nirogacesta	Apalutamide	
	Bosentan	
	Carbamazepine	
	Efavirenz	
	Etravirine	
	Phenobarbital	
	Phenytoin	
	Primidone	
	Rifabutin	
	Rifampin	
	Rifapentine	

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Ogsiveo Prescribing Information, April 2024, SpringWorks Therapeutics Inc.

9. Nirogacestat / PPIs & H-s Antagonists

Alert Message: The concomitant use of Ogsiveo (nirogacestat) with proton pump inhibitors and H2 blockers should be avoided. Nirogacestat is poorly soluble at pH ≥ 6 . Gastric acid-reducing agents may decrease serum nirogacestat exposure, which may reduce the effectiveness of nirogacestat. If concomitant use cannot be avoided, nirogacestat can be staggered with antacids (e.g., administer nirogacestat 2 hours before or 2 hours after antacid use).

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Nirogacesta	Dexlansoprazole Esomeprazole Lansoprazole Omeprazole Rabeprazole	Cimetidine Famotidine Nizatidine

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.

Ogsiveo Prescribing Information, April 2024, SpringWorks Therapeutics Inc.

10. Nirogacestat / CYP3A4 Substrates w/NTI

Alert Message: Avoid the concomitant use of Ogsiveo (nirogacestat) with CYP3A4 substrates where minimal concentration changes may lead to serious adverse substrate-related reactions. Nirogacestat is a CYP3A4 inhibitor, and concurrent use with a CYP3A4 substrate with a narrow therapeutic index may increase CYP3A substrate exposure, which may increase the risk of substrate-related adverse reactions.

Drugs/Diseases

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

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.

Ogsiveo Prescribing Information, April 2024, SpringWorks Therapeutics Inc.

11. Nirogacestat / Pregnancy / Pregnancy Negating

Alert Message: Based on findings from animal studies and its mechanism of action, Ogsiveo (nirogacestat) can cause fetal harm or loss of pregnancy when administered to a pregnant woman. Oral administration of nirogacestat to pregnant rats during the period of organogenesis resulted in embryo-fetal toxicity and embryo-fetal death at maternal exposures below the human exposure at the recommended dose of 150 mg twice daily. Advise pregnant women of the potential risk to a fetus.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C (Negate)</u>
Nirogacesta	Pregnancy	Abortion Delivery Miscarriage

Gender: Female

Age Range: 11 – 50 yoa

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.

Ogsiveo Prescribing Information, April 2024, SpringWorks Therapeutics Inc.

12. Nirogacestat / Lactation

Alert Message: There are no data on the presence of Ogsiveo (nirogacestat) or its metabolites in human milk or the effects of nirogacestat on a breastfed child or milk production. Because of the potential for serious adverse reactions in breastfed children, advise women not to breastfeed during treatment with nirogacestat and for 1 week after the last dose.

Drugs/Diseases

Util A

Util B

Util C

Nirogacesta

Lactation

Gender: Female

Age Range: 11 – 50 yoa

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.

Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.

13. Nirogacestat /Therapeutic Appropriateness

Alert Message: Advise females of reproductive potential to use effective contraception during treatment with Ogsiveo (nirogacestat) and for 1 week after the last dose. Ogsiveo (nirogacestat) can cause fetal harm or loss of pregnancy when administered to a pregnant woman.

Drugs/Diseases

Util A

Util B

Util C

Nirogacesta

Gender: Female

Age Range: 11 – 50 yoa

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.

Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.

14. Nirogacestat /Therapeutic Appropriateness

Alert Message: Advise males with female partners of reproductive potential to use effective contraception during treatment with Ogsiveo (nirogacestat) and for 1 week after the last dose.

Drugs/Diseases

Util A

Util B

Util C

Nirogacesta

Gender: Male

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.

Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.

15. Nirogacesta / Non-adherence

Alert Message: Based on refill history, your patient may be under-utilizing Ogsiveo (nirogacestat).
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 AUtil BUtil C

Nirogacesta

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. Paliperidone ER Injection / Overuse

Alert Message: Erzofri (paliperidone extended-release injection) may be over-utilized. The maximum recommended dose of paliperidone extended-release injection is 234 mg monthly.

Drugs/Diseases

Util AUtil BUtil C (Exclude)

Paliperidone ER Injection

Renal Impairment

Max Dose: 234 mg/month

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.

Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.

Erzofri Prescribing Information, Jan. 2025, Luye Innomind Pharma Shijiazhuang Co., Ltd.

17. Paliperidone ER Injection / Therapeutic Appropriateness

Alert Message: The safety and effectiveness of Erzofri (paliperidone extended-release injection) in pediatric patients have not been established.

Drugs/Diseases

Util AUtil BUtil C

Paliperidone ER Injection

Age Range: 0 – 17 yoa

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.

Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.

Erzofri Prescribing Information, Jan. 2025, Luye Innomind Pharma Shijiazhuang Co., Ltd.

18. Paliperidone ER Injection / Therapeutic Appropriateness

Alert Message: The use of Erzofri (paliperidone extended-release injection) is not recommended in patients with moderate or severe renal impairment (creatinine clearance < 50 mL/min). Paliperidone is substantially excreted by the kidney, and clearance is decreased in patients with renal impairment.

Drugs/Diseases		
<u>Util A</u>	<u>Util B</u>	<u>Util C (Include)</u>
Paliperidone ER Injection		CKD Stage 3b CKD Stage 4 CKD Stage 5 ESRD

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Erzofri Prescribing Information, Jan. 2025, Luye Innomind Pharma Shijiazhuang Co., Ltd.

19. Paliperidone ER Injection / Mild Renal Impairment

Alert Message: Dose reduction of Erzofri (paliperidone extended-release injection) is recommended for patients with mild renal impairment. Paliperidone is substantially excreted by the kidney, and clearance is decreased in patients with renal impairment. For patients with mild renal impairment (creatinine clearance $\geq$ 50 mL/min to < 80 mL/min (Cockcroft-Gault Formula), initiate paliperidone extended-release injection with a dose of 234 mg on treatment Day 1 in the deltoid muscle. Follow with the recommended monthly dosage of 78 mg, administered in either the deltoid or gluteal muscle. Adjust monthly dosage based on tolerability and/or response within the strengths of 39 mg, 78 mg, 117 mg, or 156 mg. The maximum monthly dosage is 156 mg for patients with mild renal impairment.

Drugs/Diseases		
<u>Util A</u>	<u>Util B</u>	<u>Util C (Include)</u>
Paliperidone ER Injection		Mild Renal Impairment

Max Dose: 156 mg/day

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Erzofri Prescribing Information, Jan. 2025, Luye Innomind Pharma Shijiazhuang Co., Ltd.

20. Semaglutide Tabs / Overuse

Alert Message: Rybelsus (semaglutide formulation R2) may be over-utilized. The recommended maximum daily dose of oral semaglutide is 9 mg once daily.

Drugs/Diseases		
<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Semaglutide R2 Tabs		

Max Dose: 9 mg/day

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Rybelsus Prescribing Information, Dec. 2024, Novo Nordisk, Inc.

21. Topiramate Oral Solution / Overuse - Migraine

Alert Message: The recommended total daily dose of topiramate oral solution for the preventive treatment of migraine in patients 12 years of age and older is 100 mg per day in two divided doses.

Drugs/Diseases		
<u>Util A</u>	<u>Util B</u>	<u>Util C (Include)</u>
Topiramate Sol		Migraine

Max Dose: 100 mg/day

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.

22. Aripiprazole / Overuse

Alert Message: Opipza (aripiprazole) may be over-utilized. The manufacturer's recommended maximum dose of aripiprazole for the treatment of; schizophrenia is 30 mg/day, major depressive disorder or irritability associated with autistic disorder is 15 mg/day, and for Tourette's disorder it is 10 mg/day in patients < 50 kg or 15 mg/day for patients 50 kg or more.

Drugs/Diseases		
<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Aripiprazole Film		

Max Dose: 30 mg/day

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Opipza Prescribing Information, March 2025, Carwin Pharmaceutical Associates.

23. Benzgalantamine / Overuse

Alert Message: Zunveyl (benzgalantamine delayed-release) may be over-utilized. The maximum recommended dose of benzgalantamine is 15 mg twice a day (a total of 30 mg/day).

Drugs/Diseases		
<u>Util A</u>	<u>Util B</u>	<u>Util C (Negating)</u>
Benzgalantamine		Moderate to Severe Hepatic Impairment Moderate to Severe Renal Impairment

Max Dose: 30 mg/day

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Zunveyl Prescribing Information, July 2024, Alpha Cognition, Inc.

24. Benzgalantamine / Overuse – Moderate Hepatic Impairment

Zunveyl (benzgalantamine delayed-release) may be over-utilized. The maximum recommended dose of benzgalantamine in patients with moderate hepatic impairment is 10 mg twice a day (a total of 20 mg/day).

Alert Message:

Drugs/Diseases

Util AUtil BUtil C (Include)

Benzgalantamine

Moderate Hepatic Impairment

Max Dose: 20 mg/day

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.

Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.

Zunveyl Prescribing Information, July 2024, Alpha Cognition, Inc.

25. Benzgalantamine / Severe Hepatic Impairment

Alert Message: Zunveyl (benzgalantamine delayed-release) use is not recommended in patients with severe hepatic impairment.

Drugs/Diseases

Util AUtil BUtil C (Include)

Benzgalantamine

Severe Hepatic Impairment

Clinical Pharmacology, 2025 Elsevier/Gold Standard.

Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.

Zunveyl Prescribing Information, July 2024, Alpha Cognition, Inc.

26. Benzgalantamine / Overuse – Mod to Severe Renal Impairment

Alert Message: Zunveyl (benzgalantamine delayed-release) may be over-utilized. The maximum recommended dose of benzgalantamine in patients with creatinine clearance of 9 to 59 mL/min is 10 mg twice a day (total 20 mg/day). In patients with creatinine clearance of less than 9mL/min, the use of benzgalantamine is not recommended. In pharmacokinetic studies, the AUC increased by 37% and 67% in patients with moderate and severe renal impairment, respectively, compared with normal volunteers.

Drugs/Diseases

Util AUtil BUtil C (Include)

Benzgalantamine

CKD Stage 3
 CKD Stage 3a
 CKD Stage 3b
 CKD Stage 4
 CKD Stage 5
 ESRD

Max Dose: 20 mg/day

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.

Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.

Zunveyl Prescribing Information, July 2024, Alpha Cognition, Inc.

27. Benzgalantamine / Therapeutic Appropriateness

Alert Message: The safety and effectiveness of Zunveyl (benzgalantamine delayed-release) in pediatric patients have not been established.

Drugs/Diseases
Util A Util B Util C
Benzgalantamine

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Zunveyl Prescribing Information, July 2024, Alpha Cognition, Inc.

28. Benzgalantamine / Non-adherence

Alert Message: Based on refill history, your patient may be under-utilizing Zunveyl (benzgalantamine delayed-release). 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
Benzgalantamine

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.
Arlt S, Lindner R, Rosler A, et al., Adherence to Medication in Patients with Dementia, Predictors and Strategies for Improvement. Drugs Aging 2008;25(12):1033-1047.

29. Topiramate XR / Overuse - Migraine

Alert Message: The recommended total daily dose of topiramate extended-release for the preventive treatment of migraine in patients 12 years of age and older is 100 mg once daily.

Drugs/Diseases
Util A Util B Util C
Topiramate XR Migraine

Max Dose: 100 mg/day

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.

30. Seladelpar / Overuse

Alert Message: Livdelzi (seladelpar) may be over-utilized. The recommended dosage of seladelpar is 10 mg orally once daily.

Drugs/Diseases

Util A Util B Util C
Seladelpar

Max Dose: 10 mg/day

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Livdelzi Prescribing Information, August 2024, Gilead Sciences, Inc.

31. Seladelpar / Therapeutic Appropriateness

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

Drugs/Diseases

Util A Util B Util C
Seladelpar

Age Range: 0 – 17 yoa

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Livdelzi Prescribing Information, August 2024, Gilead Sciences, Inc.

32. Seladelpar / Therapeutic Appropriateness

Alert Message: The safety and efficacy of Livdelzi (seladelpar) in patients with decompensated cirrhosis have not been established. Use of seladelpar is not recommended in patients who have or develop decompensated cirrhosis (e.g., ascites, variceal bleeding, hepatic encephalopathy). Monitor patients with cirrhosis for evidence of decompensation. Consider discontinuing seladelpar if the patient progresses to moderate or severe hepatic impairment (Child-Pugh B or C).

Drugs/Diseases

Util A Util B Util C
Seladelpar
Ascites
Cirrhosis
Hepatic Encephalopathy
Variceal Bleeding

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Livdelzi Prescribing Information, August 2024, Gilead Sciences, Inc.

33. Seladelpar / Biliary Obstruction

Alert Message: Avoid the use of Livdelzi (seladelpar) in patients with complete biliary obstruction. If biliary obstruction is suspected, interrupt seladelpar and treat as clinically indicated.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Seladelpar	Biliary Obstruction	

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.

Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.

Livdelzi Prescribing Information, August 2024, Gilead Sciences, Inc.

34. Seladelpar / OAT3 Inhibitors

Alert Message: Concomitant administration of Livdelzi (seladelpar) with OAT3 inhibitors (e.g., probenecid) can increase seladelpar (an OAT3 substrate) exposure. Avoid concomitant administration of seladelpar with OAT3 inhibitors.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Seladelpar	Gemfibrozil Leflunomide Probenecid Pretomanid Teriflunomide Vadadustat	

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.

Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.

Livdelzi Prescribing Information, August 2024, Gilead Sciences, Inc.

35. Seladelpar / Rifampin

Alert Message: Co-administration of Livdelzi (seladelpar) with rifampin, an inducer of seladelpar metabolizing enzymes (CYP2D6, CYP2C8, and CYP3A4), may reduce systemic seladelpar exposure and result in delayed or suboptimal biochemical response. Monitor the biochemical response (e.g., ALP and bilirubin) when patients initiate rifampin during treatment with seladelpar.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Seladelpar	Rifampin	

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.

Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.

Livdelzi Prescribing Information, August 2024, Gilead Sciences, Inc.

36. Seladelpar / Dual Moderate CYP2C9 and Mod to Strong CYP3A4 Inh

Alert Message: Co-administration of Livdelzi (seladelpar) with a drug that is a dual moderate CYP2C9 and moderate or strong CYP3A4 inhibitor may result in increased seladelpar exposure. Seladelpar is a substrate of both CYP2C9 and CYP3A4. Patients receiving seladelpar with a dual inhibitor should be closely monitored for seladelpar adverse effects.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Seladelpar	Adagrasib	
	Mifepristone	

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Livdelzi Prescribing Information, August 2024, Gilead Sciences, Inc.

37. Seladelpar / BCRP Inhibitors

Alert Message: Concomitant administration of Livdelzi (seladelpar) with a BCRP inhibitor may increase seladelpar exposure. When seladelpar is concomitantly administered with drugs that inhibit BCRP, patients should be closely monitored for adverse effects.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Seladelpar	Acalabrutinib	Leflunomide
	Brigatinib	Vemurafenib
	Capmatinib	Osimertinib
	Cyclosporine	Pibrentasvir
	Darolutamide	Regorafenib
	Eltrombopag	Rolapitant
	Fostamatinib	Safinamide
	Grazoprevir	Sulfasalazine
	Ibrutinib	Tafamidis
	Itraconazole	Tedizolid
	Ledipasvir	Teriflunomide
		Velpatasvir

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Livdelzi Prescribing Information, August 2024, Gilead Sciences, Inc.

38. Seladelpar / Bile Acid Sequestrants

Alert Message: Bile acid sequestrants may interfere with the action of Livdelzi (seladelpar) by reducing its absorption and systemic exposure, which may reduce seladelpar efficacy. Administer seladelpar at least 4 hours before or 4 hours after taking a bile acid sequestrant, or at as great an interval as possible.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Seladelpar	Cholestyramine	
	Colesevelam	
	Colestipol	

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Livdelzi Prescribing Information, August 2024, Gilead Sciences, Inc.

39. Seladelpar / Lactation

Alert Message: There are no data on the presence of Livdelzi (seladelpar) or its metabolite in either human or animal 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 seladelpar and any potential adverse effects on the breastfed infant from seladelpar or the underlying maternal condition.

Drugs/Diseases

Util A

Seladelpar

Util B

Lactation

Util C

Gender: Female

Age Range: 11 – 50 yoa

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.

Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.

Livdelzi Prescribing Information, August 2024, Gilead Sciences, Inc.

40. Seladelpar / Non-adherence

Alert Message: Based on refill history, your patient may be under-utilizing Livdelzi (seladelpar). 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

Seladelpar

Util BUtil C

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 F. The Unmet Challenge of Medication Nonadherence. Perm Jnl. 2018;22:18-033. doi:10.7812/TPP/18-033.

41. Metaxalone 640 mg / Overuse

Alert Message: Metaxalone may be over-utilized. The recommended dosage of metaxalone 640 mg tablets in adults and pediatric patients 13 years of age and older is 2,560 mg (640 mg four times a day).

Drugs/Diseases

Util A

Metaxalone 640

Util BUtil C

Max Dose: 2560 mg/day

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.

Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.

Metaxalone Tablet Prescribing Information, Feb. 2025, INA Pharmaceuticals Inc.

42. Metaxalone 640 mg/ Therapeutic Appropriateness

Alert Message: The safety and effectiveness of metaxalone 640 mg tablets in pediatric patients less than 13 years of age have not been established.

Drugs/Diseases

Util A

Util B

Util C

Metaxalone 640

Age Range: 0 – 12 yoa

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.

Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.

Metaxalone Tablet Prescribing Information, Feb. 2025, INA Pharmaceuticals Inc.

43. Metaxalone 640 mg / Severe Hepatic Impairment

Alert Message: Metaxalone 640 mg tablets use is contraindicated in patients with severe hepatic impairment. The effect of hepatic impairment on metaxalone pharmacokinetics is unknown; however, metaxalone undergoes extensive hepatic metabolism. Metaxalone 640 mg tablets should be used with caution and additional monitoring in patients with mild to moderate renal impairment.

Drugs/Diseases

Util A

Util B

Util C

Metaxalone 640 Cirrhosis
 Hepatic Failure

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.

Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.

Metaxalone Tablet Prescribing Information, Feb. 2025, INA Pharmaceuticals Inc.

44. Metaxalone 640 mg / Severe Renal Impairment

Alert Message: Metaxalone 640 mg tablets use is contraindicated in patients with severe renal impairment. The effect of renal impairment on metaxalone pharmacokinetics is unknown. Metaxalone undergoes renal excretion as unidentified metabolites. Metaxalone 640 mg tablets should be used with caution, and additional monitoring should be considered in patients with mild to moderate renal impairment.

Drugs/Diseases

Util A

Util B

Util C

Metaxalone 640 CKD Stage 4
 CKD Stage 5

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.

Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.

Metaxalone Tablet Prescribing Information, Feb. 2025, INA Pharmaceuticals Inc.

45. Meloxicam/Rizatriptan / Overuse

Alert Message: Symbravo (meloxicam/rizatriptan) may be over-utilized. The recommended maximum daily dose of meloxicam/rizatriptan is one tablet (20 mg meloxicam/10 mg rizatriptan).

Drugs/Diseases		
<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Meloxicam/Rizatriptan		

Max Dose: 1 Tablet per day

References:
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Symbravo Prescribing Information, Jan. 2025, Axsome Therapeutics.

46. Meloxicam/Rizatriptan / Therapeutic Appropriateness

Alert Message: The safety and effectiveness of Symbravo (meloxicam/rizatriptan) in pediatric patients have not been established.

Drugs/Diseases		
<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Meloxicam/Rizatriptan		

Age Range: 0 – 17 yoa

References:
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Symbravo Prescribing Information, Jan. 2025, Axsome Therapeutics.

47. Meloxicam/Rizatriptan / Therapeutic Appropriateness

Alert Message: The concurrent use of Symbravo (meloxicam/rizatriptan) with propranolol is contraindicated. Propranolol has been shown to increase the plasma AUC (area under the curve) of rizatriptan, a component of the combination medication. The combination formulation cannot be divided, and therefore, the recommended dose adjustment of rizatriptan is not possible.

Drugs/Diseases		
<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Meloxicam/Rizatriptan	Propranolol	

References:
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Symbravo Prescribing Information, Jan. 2025, Axsome Therapeutics.

48. Aripiprazole Film / Overuse

Alert Message: Mezofy (aripiprazole oral film) may be over-utilized. The maximum recommended dose of aripiprazole for the treatment of schizophrenia is 30 mg/day.

Drugs/Diseases

Util A

Util B

Util C

Aripiprazole Film

Max Dose: 30mg/day

References:

Mezofy Prescribing Information, April 2025, CMG Pharmaceutical Co., Ltd.

49. Aripiprazole Film / Therapeutic Appropriateness

Alert Message: The safety and effectiveness of Mezofy (aripiprazole oral film) have not been established in pediatric patients less than 13 years of age. This formulation of aripiprazole is only approved for the treatment of schizophrenia in adult and pediatric patients 13 years and older.

Drugs/Diseases

Util A

Util B

Util C

Aripiprazole Film

Age Range: 0 – 12 yoa

References:

Mezofy Prescribing Information, April 2025, CMG Pharmaceutical Co., Ltd.

50. Aripiprazole Film / Non-adherence

Alert Message: Based on refill history, your patient may be under-utilizing Mezofy (aripiprazole oral film). Non-adherence to the prescribed dosing regimen may result in sub-therapeutic effects, which may lead to decreased patient outcomes and additional medical cost.

Drugs/Diseases

Util A

Util B

Util C

Aripiprazole Film

References:

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

Higashi k, Medic G, Littlewood K, et al., Medication Adherence in Schizophrenia: Factors Influencing Adherence and Consequences of Nonadherence, A Systemic Literature Review. Ther Adv Psychopharmacol. 2013 2(4):200-218.

Acsher-Svanum H, Zhu B, Faries DE, et al., The Cost of Relapse and the Predictors of Relapse in the Treatment of Schizophrenia. BMC Psychiatry 2010, 10:2.

51. Vadadustat / Overuse

Alert Message: Vafseo (vadadustat) may be over-utilized. The maximum recommended dose of vadadustat is 600 mg per day.

Drugs/Diseases

Util AUtil BUtil C

Vadadustat

Max Dose: 600 mg/day

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Vafseo Prescribing Information, March 2024, Akebia Therapeutics, Inc.

52. Vadadustat / Therapeutic Appropriateness

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

Drugs/Diseases

Util AUtil BUtil C

Vadadustat

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Vafseo Prescribing Information, March 2024, Akebia Therapeutics, Inc.

53. Vadadustat / Therapeutic Appropriateness

Alert Message: Vafseo (vadadustat) is not recommended in patients with cirrhosis or active, acute liver disease. Vadadustat may cause hepatotoxicity. In clinical trials, hepatocellular injury attributed to vadadustat was reported in less than 1% of patients, including one case of severe hepatocellular injury with jaundice. All events were asymptomatic and resolved after discontinuation of vadadustat. The time to onset was generally within the first 3 months of treatment.

Drugs/Diseases

Util AUtil BUtil C

VadadustatAcute Liver DiseaseCirrhosis

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Vafseo Prescribing Information, March 2024, Akebia Therapeutics, Inc.

54. Vadadustat / Box Warning

Alert Message: Vafseo (vadadustat) increases the risk of arterial and venous thrombotic events, that may be fatal, including myocardial infarction, stroke, venous thromboembolism and vascular access thrombosis. Patients with cardiovascular or cerebrovascular disease are at increased risk of these events. Avoid use in patients with a history of myocardial infarction, cerebrovascular event, or acute coronary syndrome within the 3 months prior to starting vadadustat.

Drugs/Diseases		
Util A	Util B	Util C (Include)
Vadadustat		Cardiovascular Disease Cerebrovascular Disease

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Vafseo Prescribing Information, March 2024, Akebia Therapeutics, Inc.

55. Vadadustat / Gastrointestinal Erosion Risk

Alert Message: In clinical trials with Vafseo (vadadustat), gastric or esophageal erosions occurred in 6.4% and 5.3% of darbepoetin alfa-treated patients. Serious gastrointestinal erosions, including gastrointestinal bleeding and the need for red blood cell transfusions were reported in 3.4% and 3.3% of those receiving vadadustat and darbepoetin alfa, respectively. Consider this risk particularly in patients at increased risk for gastrointestinal erosions, such as those with a history of gastrointestinal erosion, peptic ulcer disease, use of concomitant medications that increase the risk of gastrointestinal erosion, and current tobacco smokers and alcohol drinkers.

Drugs/Diseases		
Util A	Util B	Util C
Vadadustat	Gastrointestinal Erosion Peptic Ulcer Disease Tobacco Use Alcohol Consumption NSAIDS	

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Vafseo Prescribing Information, March 2024, Akebia Therapeutics, Inc.

56. Vadadustat / Malignancy

Alert Message: Because increased hypoxia inducible factor (HIF)-1 levels may be associated with unfavorable effects on cancer growth, Vafseo (vadadustat) has not been studied and is not recommended in patients with active malignancies.

Drugs/Diseases		
Util A	Util B	Util C
Vadadustat	Malignancy	

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Vafseo Prescribing Information, March 2024, Akebia Therapeutics, Inc.

57. Vadadustat / Therapeutic Appropriateness

Alert Message: The safety of Vafseo (vadadustat) has not been established for the treatment of anemia due to CKD in adults not on dialysis and its use is not recommended in this setting.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C (Negate)</u>
Vadadustat		Dialysis

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.

Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.

Vafseo Prescribing Information, March 2024, Akebia Therapeutics, Inc.

58. Vadadustat / Iron Supplements & Phosphate Binders

Alert Message: Co-administration of Vafseo (vadadustat) with oral iron supplements, products containing iron, or phosphate binders decreases the exposure of vadadustat, which may reduce the effectiveness of vadadustat. Stagger administration when vadadustat is used with oral iron supplements, products containing iron, iron-containing phosphate binders, or non-iron containing phosphate binders.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Vadadustat	Iron Supplements Phosphate Binders	

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.

Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.

Vafseo Prescribing Information, March 2024, Akebia Therapeutics, Inc.

59. Vadadustat / OAT1/OAT3 Inhibitors

Alert Message: Co-administration with OAT1/OAT3 (Organic Anion Transporter) inhibitors may increase the area under the concentration curve (AUC) of Vafseo (vadadustat), which may increase the risk of vadadustat adverse reactions. Closely monitor for too large or too rapid an increase in Hb response and for adverse reactions.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Vadadustat	Clarithromycin Cobicistat Cyclosporine Gemfibrozil Probenecid Rifampin Teriflunomide Velpatasvir	

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.

Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.

Vafseo Prescribing Information, March 2024, Akebia Therapeutics, Inc.

60. Vadadustat / Sulfasalazine

Alert Message: The concurrent use of Vafseo (vadadustat) with sulfasalazine can result in increased exposure of sulfasalazine, which may increase the risk of sulfasalazine-related adverse reactions. Dosage reduction of sulfasalazine may be needed.

Drugs/Diseases		
<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Vadadustat	Sulfasalazine	

References:
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Vafseo Prescribing Information, March 2024, Akebia Therapeutics, Inc.

61. Vadadustat / Rosuvastatin 10, 20 & 40 mg

Alert Message: In pharmacokinetic studies, concurrent use of Vafseo (vadadustat) with rosuvastatin resulted in increases the maximal concentration (Cmax) and AUC of rosuvastatin. The maximum daily dose of rosuvastatin should not exceed 5 mg/day when used concurrently with vadadustat.

Drugs/Diseases		
<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Vadadustat	Rosuvastatin 10 mg	
	Rosuvastatin 20 mg	
	Rosuvastatin 40 mg	

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Vafseo Prescribing Information, March 2024, Akebia Therapeutics, Inc.

62. Vadadustat / Simvastatin 40 & 80 mg

Alert Message: In pharmacokinetic studies, concurrent use of Vafseo (vadadustat) with simvastatin resulted in increases the maximal concentration (Cmax) and AUC of simvastatin. The maximum daily dose of simvastatin should not exceed 20 mg/day when used concurrently with vadadustat.

Drugs/Diseases		
<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Vadadustat	Simvastatin 40 mg	
	Simvastatin 80 mg	

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.

63. Vadadustat / Pregnancy / Pregnancy Negating

Alert Message: Available data with Vafseo (vadadustat) use in pregnant women are insufficient to establish a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes. Vadadustat should only be used during pregnancy if the benefit justifies the potential risk to the fetus.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C (Negate)</u>
Vadadustat	Pregnancy	Abortion Delivery Miscarriage

Gender: Female

Age Range: 11 – 50 yoa

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.

Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.

Vafseo Prescribing Information, March 2024, Akebia Therapeutics, Inc.

64. Vadadustat / Lactation

Alert Message: There are no data on the presence of Vafseo (vadadustat) in human milk, the effects of vadadustat on the breastfed child, or the effects on milk production. Vadadustat is 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. Given the serious adverse reactions seen in adults treated with vadadustat, such as thrombotic vascular events, advise patients not to breastfeed during treatment with vadadustat, and for 2 days after the final dose.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Vadadustat	Lactation	

Gender: Female

Age Range: 11 – 50 yoa

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.

Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.

Vafseo Prescribing Information, March 2024, Akebia Therapeutics, Inc.

65. Ropinirole XR / Overuse – Parkinson's Disease

Alert Message: Ropinirole extended-release may be over-utilized. The maximum recommended dose of ropinirole ER for the treatment of Parkinson's disease is 24 mg per day.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C (Negating)</u>
Ropinirole XR		Dialysis

Max Dose: 24 mg/day

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.

Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.

Ropinirole Hydrochloride Tablet Extended-Release Prescribing Information, Sept. 2023, AvKARE.

66. Ropinirole XR / Severe Renal Impairment

Alert Message: Ropinirole extended-release may be over-utilized. The maximum recommended dose of ropinirole ER for the treatment of Parkinson's disease in patients with end-stage renal disease on dialysis is 18 mg per day.

Drugs/Diseases

Util A

Util B

Util C (Include)

Ropinirole XR

Dialysis

Max Dose: 18 mg/day

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.

Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.

Ropinirole Hydrochloride Tablet Extended-Release Prescribing Information, Sept. 2023, Solco Healthcare US, LLC.

67. Ropinirole XR / Therapeutic Appropriateness

Alert Message: Safety and effectiveness of ropinirole extended-release in pediatric patients have not been established.

Drugs/Diseases

Util A

Util B

Util C

Ropinirole XR

Age Range: 0 – 17 yoa

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.

Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.

Ropinirole Hydrochloride Tablet Extended-Release Prescribing Information, Sept. 2023, Solco Healthcare US, LLC.

68. Ropinirole XR / Dyskinesia

Alert Message: Ropinirole extended-release may cause or exacerbate pre-existing dyskinesia in patients treated with L-dopa for Parkinson's disease. Decreasing the dose of dopaminergic medications may ameliorate this adverse reaction.

Util A

Util B

Util C (Include)

Ropinirole XR

Levodopa

Dyskinesia

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.

Ropinirole Hydrochloride Tablet Extended-Release Prescribing Information, Sept. 2023, Solco Healthcare US, LLC.

69. Ropinirole XR / Impulse Control

Alert Message: Reports suggest that patients can experience intense urges to gamble, increased sexual urges, intense urges to spend money, binge or compulsive eating, and/or other intense urges, and the inability to control these urges while taking medications that increase central dopaminergic tones, including ropinirole extended-release. Because patients may not recognize these behaviors as abnormal, it is important for prescribers to specifically ask patients or their caregivers about the development of new or increased gambling urges, sexual urges, uncontrolled spending, binge or compulsive eating, or other urges while being treated with ropinirole tablets for Parkinson's disease. Physicians should consider dose reduction or stopping the medication if a patient develops such urges while taking ropinirole extended-release.

Drugs/Diseases		
Util A	Util B	Util C
Ropinirole XR	Pathological Gambling Other Impulse Disorders Binge Eating Disorder	

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Ropinirole Hydrochloride Tablet Extended-Release Prescribing Information, Sept. 2023, Solco Healthcare US, LLC.

70. Ropinirole XR / Hallucinations & Psychotic-Like Behavior

Alert Message: Postmarketing reports indicate that patients with Parkinson's disease may experience new or worsening mental status and behavioral changes, which may be severe, including psychotic-like behavior during treatment with ropinirole extended-release or after starting or increasing the dose of ropinirole. This abnormal thinking and behavior can consist of one or more of a variety of manifestations including paranoid ideation, delusions, hallucinations, confusion, psychotic-like behavior, mania, disorientation, aggressive behavior, agitation, and delirium. Patients with a major psychotic disorder should ordinarily not be treated with ropinirole ER because of the risk of exacerbating the psychosis.

Drugs/Diseases		
Util A	Util B	Util C
Ropinirole XR	Paranoid ideation Delusions Hallucinations Confusion Psychotic-like behavior Mania Disorientation Aggressive behavior Agitation Delirium	

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Ropinirole Hydrochloride Tablet Extended-Release Prescribing Information, Sept. 2023, Solco Healthcare US, LLC.

71. Ropinirole XR / Dopamine Antagonists

Alert Message: Ropinirole extended-release is a dopamine agonist, and concurrent use with a dopamine antagonist such as neuroleptics (e.g., phenothiazines, butyrophenones, thioxanthenes) or metoclopramide may reduce the efficacy of ropinirole.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Ropinirole XR	Chlorpromazine Fluphenazine Haloperidol Loxapine Molindone Perphenazine Pimozide Prochlorperazine Thioridazine Thiothixene Trifluoperazine Metoclopramide	Aripiprazole Asenapine Iloperidone Lumateperone Lurasidone Olanzapine Paliperidone Risperidone Ziprasidone

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.

Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.

Ropinirole Hydrochloride Tablet Extended-Release Prescribing Information, Sept. 2023, Solco Healthcare US, LLC.

72. Ropinirole XR / Higher Dose Estrogen

Alert Message: Concomitant use of ropinirole extended-release and higher doses of estrogens may increase the exposure of ropinirole. A dose adjustment of ropinirole ER may be needed when estrogen therapy is initiated or discontinued.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Ropinirole XR	Conjugated Estrogen Esterified Estrogen Estradiol Estropipate Ethinyl Estradiol	

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.

Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.

Ropinirole Hydrochloride Tablet Extended-Release Prescribing Information, Sept. 2023, Solco Healthcare US, LLC.

73. Ropinirole XR / CYP1A2 Inhibitors

Alert Message: Ropinirole is a CYP1A2 substrate, and concurrent use with a CYP1A2 inhibitor may result in increased ropinirole concentrations. Therefore, if therapy with a drug known to be a potent inhibitor of CYP1A2 is initiated or discontinued during treatment with ropinirole extended-release, adjustment of ropinirole ER dose may be required.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Ropinirole XR	Ciprofloxacin Fluvoxamine Viloxazine	

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.

Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.

Ropinirole Hydrochloride Tablet Extended-Release Prescribing Information, Sept. 2023, Solco Healthcare US, LLC.

74. Ropinirole XR / Pregnancy / Pregnancy Negating

Alert Message: There are no adequate data on the developmental risk associated with the use of ropinirole extended-release in pregnant patients. In animal studies, ropinirole had adverse effects on development when administered to pregnant rats at doses similar to (neurobehavioral impairment) or greater than (teratogenicity and embryolethality at >36 times) the MRHD for Parkinson's disease. Ropinirole should be used in pregnancy only if the potential benefit to the mother outweighs the potential risk to the fetus.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C (Negating)</u>
Ropinirole XR	Pregnancy	Abortion Delivery Miscarriage

Gender: Female

Age Range: 11 – 50 yoa

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.

Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.

Ropinirole Hydrochloride Tablet Extended-Release Prescribing Information, Sept. 2023, Solco Healthcare US, LLC.

75. Ropinirole XR / Lactation

Alert Message: There are no data on the presence of ropinirole in human milk, the effects of ropinirole on the breastfed infant, or the effects of ropinirole on milk production. However, inhibition of lactation is expected because ropinirole inhibits secretion of prolactin in humans. Ropinirole or metabolites, or both, are present in rat milk. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for ropinirole and any potential adverse effects on the breastfed infant from ropinirole or the underlying maternal condition.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Ropinirole XR	Lactation	

Gender: Female

Age Range: 11 – 50 yoa

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.

Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.

Ropinirole Hydrochloride Tablet Extended-Release Prescribing Information, Sept. 2023, Solco Healthcare US, LLC.

76. Ropinirole XR/ Non-adherence

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

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Ropinirole XR		

References:

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

Richy FF, Guilhem P, Moran, et al., Compliance with Pharmacotherapy and Direct Healthcare Costs with Parkinson's Disease: A Retrospective Claims Database Analysis. Appl Health Econ Health Policy. 2013 Aug;11(4):395-406.

Daley DJ, Myint PK, Gray RJ, Deane KH. Interventions for Improving Medication Adherence in Patients with Idiopathic Parkinson's Disease. Cochrane Database System Rev 2014. DOI:10.1002/14651858.CD011191

77. Mepolizumab / Therapeutic Appropriateness - COPD

Alert Message: The safety and effectiveness of Nucala (mepolizumab) in patients less than 18 years of age with chronic obstructive pulmonary disease (COPD) have not been established.

Drugs/Diseases		
<u>Util A</u>	<u>Util B</u>	<u>Util C (Include)</u>
Mepolizumab		COPD

Age Range: 0 – 17 yoa

References:
Nucala Prescribing Information, May 2025, GlaxoSmithKline

78. Mepolizumab / Overutilization - COPD

The manufacturer's recommended dosage of Nucala (mepolizumab) for the treatment of chronic obstructive pulmonary disease (COPD) in adults is 100 mg administered once every 4 weeks.

Drugs/Diseases		
<u>Util A</u>	<u>Util B</u>	<u>Util C (Include)</u>
Mepolizumab		COPD

Max Dose: 1 injection/4 weeks

References:
Nucala Prescribing Information, May 2025, GlaxoSmithKline

79. Hydroxyurea Oral Solution / Overuse - Renal

Alert Message: Xromi (hydroxyurea oral solution) may be over-utilized. Reduce the dose of hydroxyurea oral solution by 50% in patients with creatinine clearance of less than 60 mL/min or with end-stage renal disease (ESRD). The exposure to hydroxyurea is higher in patients with creatinine clearance of less than 60 mL/min. Closely monitor hematologic parameters when hydroxyurea is administered to this patient population.

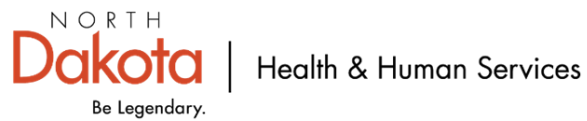
Drugs/Diseases		
<u>Util A</u>	<u>Util B</u>	<u>Util C (Include)</u>
Hydroxyurea Oral Solution		CKD Stage 3, 4 & 5 ESRD

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Xromi Prescribing Information, Dec. 2024, Rare Disease Therapeutics Inc.

Board Suggestions for clinical practice education or RDUR ICER criteria

1. Is there anything in clinical practice that you've seen that you feel needs to be addressed?
 - a. New best practices?
 - b. Fraud, waste, or abuse?
2. Is there any new guideline information?
3. Requests for Utilization Review topics?

**North Dakota Medicaid
Drug Utilization Review Board Meeting
December 3, 2025
Conference Room 210/212**



Meeting Notice

North Dakota Medicaid Drug Use Review Board

Wednesday, December 3rd, 2025

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 252 888 340 303

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: Heart Failure, Chronic Kidney Disease, Pulmonary Hypertension, Epidermolysis Bullosa, and Hemophilia
 - Annual Prior Authorization Review
5. Unfinished Business – RDUR Drug-Drug Interaction Follow-up
6. New business
 - Second Review of ANCA-Associated Vasculitis
 - Second Review of Niemann-Pick Type C
 - First Review of Non-Cystic Fibrosis Bronchiectasis
 - First Review of PKU
 - First Review of Alzheimer's
 - Review of retrospective DUR criteria recommendations
 - Provider suggestions for clinical practice education or RDUR ICER criteria
7. Announcements: Next Meeting (March 4, 2026)
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 3rd, 2025

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 1:00 pm CST with K. Martian presiding as Presiding Officer. DUR Board Coordinator, J. McKee recording minutes.

Roll Call:

Board Members Voting:

Present: Stephanie Antony, Gabriela Balf, Amanda Dahl, Kurt Datz, Andrea Honeyman, Laura Kroetsch, Kevin Martian, Paige Adkins, Amy Werremeyer, Jessica Ziegler

Absent: Kristen Peterson, Matthew Zimny

Quorum Present: Yes

Board Members Non-Voting:

Absent: Kathleen Traylor

Medicaid Pharmacy Department:

Present: Jeff Hostetter, Brendan Joyce, Alexi Murphy, LeNeika Roerich, Katie Steig

Absent:

Approval of Meeting Minutes:

Motion: Moved by K. Datz to approve the minutes of the June 4, 2025 meeting, motion was seconded by K.

Martian **Motion carried.**

The minutes of the June 4, 2025, meeting were approved as distributed.

Reports:

Administrative Report: A. Murphy

A. Murphy introduced Paige Adkins to the board.

A. Murphy shared Migraine Prophylaxis Utilization Review, Core Measures and PDMP.

Financial Report: Budget provided by A. Murphy

B. Joyce shared with the Board trends of reimbursement amount vs net spend for pharmacy drug claims. This information can be found in the handout.

Financial Report: Top Drugs provided by A. Murphy

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 J. McKee

J. McKee reviewed the quarterly RDUR criteria that were selected for review of each month and information from a targeted mailing. This material can be found in the handout.

Clinical Report and Annual PDL Review: Prior Authorization and Criteria Updates by J. McKee

J. McKee presented prior authorization and criteria updates with emphasis on the following sections in the PDL: Bullous Pemphigoid, Chronic Kidney Disease, Giant Cell Arteritis (Temporal Arteritis), Uveitis

Unfinished business:

Psychotropic Certification: Sample letter was presented to the board by A. Murphy. Board members made suggestions on some wording changes for the letter.

New business:

Second Reviews presented by J. McKee

J. McKee presented group prior authorization criteria for Non-Opioid Analgesics

Motion: Moved by A. Werremeyer to place Non-Opioid Analgesics on prior authorization, motion was seconded by K. Datz. **Motion carried.**

First Reviews presented by J. McKee

J. McKee presented an overview of Niemann-Pick Type C. The presented material can be found in the handout.

Motion: Moved by K. Martian to draft prior authorization for Niemann-Pick Type C, motion was seconded by K. Datz. **Motion carried.**

First Reviews presented by J. McKee

J. McKee presented an overview of ANCA-associated vasculitis. The presented material can be found in the handout.

Motion: Moved by K. Datz to draft prior authorization for ANCA-associated vasculitis, motion was seconded by K. Martian. **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 A. Werremeyer. **Motion carried.**

Announcements:

Next meeting is December 3rd, 2025.

Adjournment:

Meeting adjourned by K. Martian at 2:20 pm CST.

Date of Minutes Approval:

Minutes submitted by: Julie McKee, Acentra Health

Administrative Report

Medicaid pharmacists have been making visits to providers at the state hospital and Anne Carlson Center as part of the Psychotropic Monitoring Program to meet these requirements.

SUPPORT (Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment) for Patients and Communities Act, 2018

State Medicaid Programs are required to monitor and manage the appropriate use of antipsychotic medications for children under 18 years of age, especially children in foster care (42 U.S.C. §1396a(oo)(1)(B)).

Consolidated Appropriations Act, 2024:

State Medicaid programs are required to monitor antipsychotic medication utilization dispensed to individuals over the age of 18 who reside in institutional care settings (including nursing facilities, intermediate care facilities for individuals with intellectual disabilities, institutions for mental diseases, inpatient psychiatric hospitals, and other such institutional care settings).

Financial Report

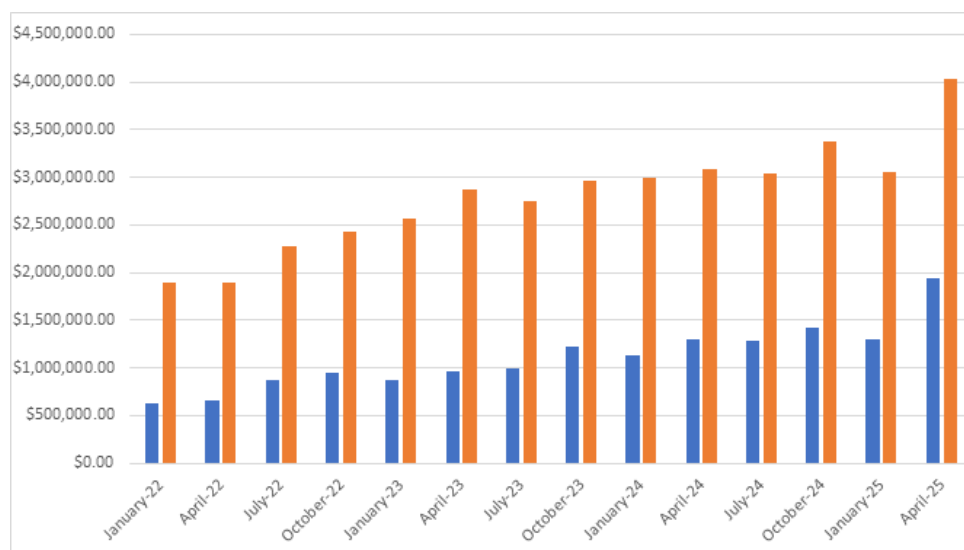
2Q25 vs 1Q25 Reimbursement and Rebate Differences

- Reimbursement increased by \$4.66 million (increased by \$2.82 million again 3Q)
- Net Spend increased by \$2.38 million
- % rebate decreased by 2.3%

Quarter	Reimb Amt	Net Spend	Change in Net Spend	% Rebate
1Q2024	\$ 27,705,351	\$ 9,438,920		65.9%
2Q2024	\$ 27,918,443	\$ 9,642,814	\$203,894	65.5%
3Q2024	\$ 27,489,587	\$ 9,591,450	(\$51,364)	65.1%
4Q2024	\$ 28,907,285	\$10,309,141	\$717,691	64.3%
1Q2025	\$ 26,904,240	\$ 9,696,087	(\$613,054)	64.0%
2Q2025	\$ 31,166,792	\$11,845,075	\$2,148,988	62.0%
3Q2025	\$ 33,987,358	\$13,080,004	\$1,234,929	61.5%

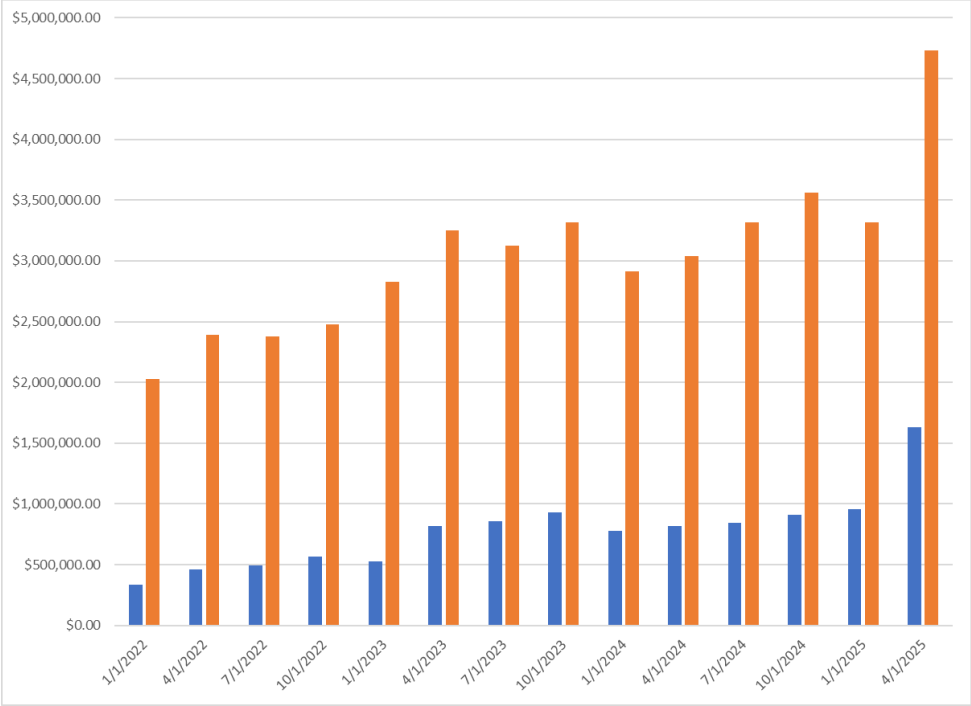
Traditional: Net Spend vs. Reimbursement

Vraylar, Trikafta, Fasenra, Benlysta, Bimzelx, Dupixent, Entyvio, Rinvoq, Stelara, Humira, Kesimpta, liraglutide, Januvia, Sublocade, Tyvaso DPI, Remodulin, Orenitram, Ingrezza, Vivitrol



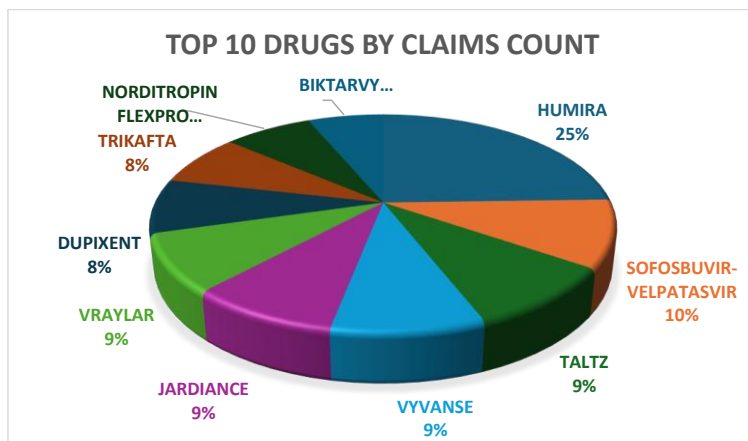
Expansion: Net Spend vs. Reimbursement

Vyvanse, Vraylar, Trikafta, Bikarvy, Humira, Nurtec ODT, Aimovig, Iiraglutide, Oncology (Revuforj, Verzenio, Klsqali, Xtandi, Braftovi, Lonsurf), Sublocade, lngrezza, Vivitrol



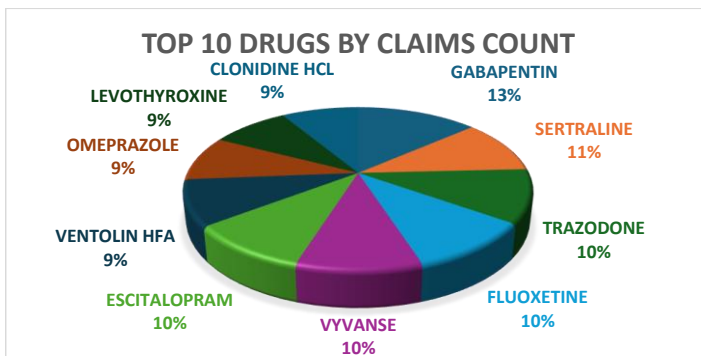
Top 25 Drugs Based on Total Claims Cost from 7/1/25 – 9/30/25

#	Drug Name	Claims	Claims Cost	Patients	Cost/Patient	% Cost	Dif
1	HUMIRA	304	\$2,688,555.19	129	\$20,841.51	6.97%	NC
2	SOFOSBUVIR-VELPATASVIR	47	\$1,097,873.96	47	\$23,359.02	2.84%	NC
3	TALTZ	134	\$1,039,371.39	56	\$18,560.20	2.69%	NC
4	VYVANSE	3,279	\$989,559.07	1,316	\$751.94	2.56%	NC
5	JARDIANCE	1,263	\$970,409.65	674	\$1,439.78	2.51%	↑1
6	VRAYLAR	857	\$942,011.23	346	\$2,722.58	2.44%	↓1
7	DUPIXENT	232	\$881,682.47	108	\$8,163.73	2.28%	NC
8	TRIKAFTA	34	\$848,139.64	13	\$65,241.51	2.20%	NC
9	NORDITROPIN FLEXP	102	\$808,310.08	41	\$19,714.88	2.09%	↑1
10	BIKTARVY	294	\$694,479.26	139	\$4,996.25	1.80%	↓1
11	INVEGA SUSTENNA	217	\$590,949.19	89	\$6,639.88	1.53%	NC
12	COSENTYX	50	\$549,708.21	22	\$24,986.74	1.42%	↑2
13	INGREZZA	59	\$471,282.36	23	\$20,490.54	1.22%	↑2
14	ELIQUIS	721	\$451,890.13	344	\$1,313.63	1.17%	↓2
15	LIRAGLUTIDE	1,117	\$417,046.05	577	\$722.78	1.08%	NC
16	SUBLOCADE	185	\$396,122.88	93	\$4,259.39	1.03%	↓3
17	BIMZELX	19	\$332,997.91	8	\$41,624.74	0.86%	↑39
18	ENBREL	44	\$327,105.63	21	\$15,576.46	0.85%	↑2
19	XIFAXAN	129	\$310,848.45	52	\$5,977.85	0.81%	NC
20	VERZENIO	19	\$309,580.88	6	\$51,596.81	0.80%	↓2
21	ABILIFY MAINTENA	114	\$302,233.44	53	\$5,702.52	0.78%	↑2
22	INSULIN LISPRO	1,311	\$284,369.00	770	\$369.31	0.74%	↓1
23	DULERA	848	\$270,513.28	520	\$520.22	0.70%	↓1
24	VIVITROL	152	\$248,396.07	75	\$3,311.95	0.64%	↑2
25	OZEMPIC	268	\$248,159.86	106	\$2,341.13	0.64%	NC
Total						\$16,471,595.28	



Top 25 Drugs Based on Number of Claims from 7/1/25 – 9/30/25

#	Drug Name	Claims	Claims Cost	Patients	Cost/Claim	% Claims	Dif
1	GABAPENTIN	4,511	\$65,848.32	1,877	\$14.60	1.82%	NC
2	SERTRALINE HCL	3,550	\$48,218.32	2,001	\$13.58	1.43%	NC
3	TRAZODONE HCL	3,532	\$47,478.32	1,871	\$13.44	1.43%	NC
4	FLUOXETINE HCL	3,389	\$45,598.24	1,840	\$13.45	1.37%	NC
5	VYVANSE	3,279	\$989,559.07	1,316	\$301.79	1.32%	↑3
6	ESCITALOPRAM OXALATE	3,248	\$43,407.64	1,860	\$13.36	1.31%	NC
7	VENTOLIN HFA	3,029	\$195,989.69	2,977	\$64.70	1.22%	↑4
8	OMEPRAZOLE	2,966	\$39,230.37	1,796	\$13.23	1.20%	NC
9	LEVOTHYROXINE SODIUM	2,914	\$41,488.10	1,537	\$14.24	1.18%	↑1
10	CLONIDINE HCL	2,867	\$35,185.17	1,442	\$12.27	1.16%	↓1
11	BUPROPION XL	2,844	\$46,842.62	1,570	\$16.47	1.15%	↑1
12	ATORVASTATIN CALCIUM	2,739	\$40,394.67	1,607	\$14.75	1.11%	↑2
13	HYDROXYZINE HCL	2,713	\$37,910.39	1,650	\$13.97	1.10%	NC
14	DEXTRO-AMPHET ER	2,542	\$76,471.64	1,075	\$30.08	1.03%	↑2
15	AMOXICILLIN	2,485	\$37,438.32	2,336	\$15.07	1.00%	↓10
16	LISINAPRIL	2,480	\$35,149.80	1,538	\$14.17	1.00%	↓1
17	PREDNISONE	2,441	\$28,309.71	1,956	\$11.60	0.99%	NC
18	PANTOPRAZOLE	2,408	\$34,915.12	1,405	\$14.50	0.97%	↑3
19	METHYLPHENIDATE ER	2,384	\$71,805.47	1,019	\$30.12	0.96%	↓1
20	LAMOTRIGINE	2,362	\$32,525.16	961	\$13.77	0.95%	NC
21	ARIPIRAZOLE	2,301	\$35,376.23	1,116	\$15.37	0.93%	↑1
22	BUSPIRONE HCL	2,296	\$34,384.78	1,185	\$14.98	0.93%	↑4
23	CYCLOBENZAPRINE HCL	2,244	\$26,350.14	1,410	\$11.74	0.91%	↑4
24	HYDROCODONE-APAP	2,242	\$34,753.33	1,438	\$15.50	0.91%	NC
25	DULOXETINE HCL	2,169	\$35,965.77	1,160	\$16.58	0.88%	NC
Total		69,935					



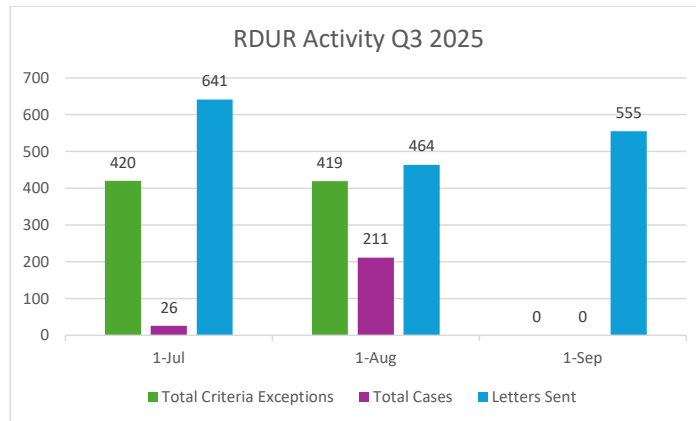
Top 15 Therapeutic Classes Based on Number of Claims from 7/1/25 – 9/30/25

#	Therapeutic Class Description	Claims	Claims Cost	Patients	Cost/Claim	% Claims	Dif
1	ANTIDEPRESSANTS	25,425	\$612,303.18	10,738	\$24.08	10.27%	NC
2	ANTIPSYCHOTIC AGENTS	9,998	\$2,939,831.85	3,980	\$294.04	4.04%	NC
3	AMPHETAMINES	7,340	\$1,108,664.96	2,991	\$151.04	2.96%	NC
4	GABA-MEDIATED ANTICONVULSANTS	6,971	\$158,650.17	2,812	\$22.76	2.82%	NC
5	RESPIRATORY & CNS STIMULANTS	6,488	\$343,261.89	2,580	\$52.91	2.62%	NC
6	BETA-ADRENERGIC AGONISTS	6,088	\$801,929.85	4,132	\$131.72	2.46%	↓1
7	OPIOID AGONISTS	5,963	\$110,228.55	3,067	\$18.49	2.41%	↑1
8	PROTON-PUMP INHIBITORS	5,716	\$99,549.01	3,329	\$17.42	2.31%	↑1
9	NSAIDs	5,595	\$75,953.84	3,809	\$13.58	2.26%	↑1
10	CENTRAL ALPHA-AGONISTS	5,515	\$77,775.31	2,480	\$14.10	2.23%	NC
11	ANTICONVULSANTS	5,090	\$362,114.01	2,104	\$71.14	2.06%	↑1
12	STATINS	5,047	\$73,481.67	3,005	\$14.56	2.04%	↑2
13	BETA-BLOCKERS	4,909	\$83,797.42	2,780	\$17.07	1.98%	↑2
14	PENICILLIN ANTIBIOTICS	4,840	\$77,926.81	4,322	\$16.10	1.95%	↓8
15	ADRENALS	4,792	\$176,440.51	3,496	\$36.82	1.94%	↓2
Total		109,777					

Top 15 Therapeutic Classes Based on Claims Cost from 7/1/25 to 9/30/25

#	Therapeutic Class Description	Claims	Claims Cost	Patients	Cost/Patient	% Cost	Dif
1	TUMOR NECROSIS FACTOR INHIBITORS	414	\$3,250,424.15	168	19,347.76	8.42%	NC
2	ANTIPSYCHOTIC AGENTS	9,998	\$2,939,831.85	3,980	738.65	7.62%	NC
3	ANTINEOPLASTIC AGENTS	615	\$1,972,377.00	252	7,826.89	5.11%	↑1
4	INTERLEUKIN-MEDIATED AGENTS	201	\$1,651,707.74	86	19,205.90	4.28%	↓1
5	SGLT2 INHIB	1,698	\$1,244,595.19	897	1,387.51	3.23%	↑1
6	AMPHETAMINES	7,340	\$1,108,664.96	2,991	370.67	2.87%	↑2
7	HCV ANTIVIRALS	48	\$1,099,098.96	48	22,897.90	2.85%	↓2
8	ANTIRETROVIRALS	680	\$1,077,033.01	261	4,126.56	2.79%	↓1
9	CFTR CORRECTORS	39	\$946,310.64	15	63,087.38	2.45%	NC
10	SKIN AGENTS	252	\$882,297.13	125	7,058.38	2.29%	NC
11	PITUITARY	345	\$839,264.91	138	6,081.63	2.17%	↑2
12	INCRETIN MIMETICS	1,615	\$818,600.92	762	1,074.28	2.12%	NC
13	BETA-ADRENERGIC AGONISTS	6,088	\$801,929.85	4,132	194.08	2.08%	↓2
14	IMMUNOMODULATORY AGENTS	214	\$798,556.01	164	4,869.24	2.07%	↑4
15	INSULINS	3,046	633,222.03	1,278	495.48	\$0.02	↓1
Total		\$20,063,914.35					

RDUR Report: Q3 2025



July 2025 Cases by Type of Criteria

Criteria Description	# of Cases	% of Cases
Drug-Disease Precaution	15	5.77%
Drug-Drug Interaction	150	57.69%
Overutilization	20	7.69%
Therapeutic Appropriateness	12	4.62%
Underutilization	63	24.23%

August 2025 Cases by Type of Criteria

Criteria Description	# of Cases	% of Cases
Drug-Disease Precaution	58	27.49%
Drug-Drug Interaction	71	33.65%
Drug-Drug Marker and/or Diagnosis	8	3.79%
Overutilization	14	6.64%
Therapeutic Appropriateness	15	7.11%
Underutilization	45	21.33%

September 2025 Special Mailing

555 Letters Sent

Dear Prescriber,

Subject: ND Medicaid Provider Alert – Potential Overuse of Short-Acting Beta₂ Agonists (SABA)
in Your Patients (Patient List Enclosed)

A list of your patients who have paid claims (through ND Medicaid) for at least 3 SABA inhalers over the past year is enclosed for your review. The 2025 Global Initiative for Asthma (GINA) Report indicates:

- SABA overuse is associated with increased risk of asthma exacerbations, emergency department visits, or hospitalization if three or more canisters are filled in a year
- Risk is increased for mortality if 12 or more are filled in a year

ND Medicaid is required by OBRA '90 federal law to implement a Retrospective Drug Utilization Review (RDUR) program that ensures Medicaid members receive optimal drug therapy at the lowest reasonable cost. This alert is informational in nature and should be incorporated into your ongoing assessment of your patients' drug therapy. In presenting this information to you, we recognize that the management of each patient's drug therapy depends upon an assessment of the patient's entire clinical situation, about which we are not fully aware.

The success of the RDUR program is enhanced by the two-way exchange of information. Therefore, at your convenience, we would appreciate learning of your assessment of this information and of any action taken in response to this notice. Although your participation in this program is voluntary, we find your feedback helpful in adjusting our program to address clinically important problems. Please complete the response form and fax it to 866-798-4904.

Thank you for your professional consideration.

Sincerely,

ND Medicaid

Clinical Report
Prior Authorization Updates

Drug	PA Status	Class
Anzupgo	PA	Atopic Dermatitis
Blujepa	PA	Anti-infectives Resistance Prevention
Brekiya	PA	Treatment of Migraine
Dawnzera	PA	Hereditary Angioedema
Doptelet Sprinkle Cap	PA	Thrombocytopenia
Ekterly	PA	Hereditary Angioedema
Eliquis tablet and capsule for susp	PA	Anticoagulants
Empaveli	PA	Chronic Kidney Disease
Kirsty	PA	Diabetes
Leqembi IQLIK	PA	Alzheimer's
Liraglutide	PA	GLP-1 Agonists
Lynkuet	PA	Menopause
Modeyso	PA	> \$3000
Orlynvah	PA	Anti-infectives Resistance Prevention
Otulfi	PA	Biosimilars
Ozempic	Remove PA	GLP-1 Agonists
Pyquvi	PA	DMD
Rhapsido	PA	Chronic Spontaneous Urticaria
Selarsdi	PA	Biosimilars
Starjemza	PA	Biosimilars
Steqeyma	Remove PA	Biosimilars
Vykat XR	PA	>\$3000
Wayrilz	PA	Thrombocytopenia
Yutrepia	PA	Pulmonary Hypertension
Zoryve	PA	Atopic Dermatitis/Eczema
Zurnai	PA	Opioid Reversal Medications

Criteria Updates

Summary of Changes

Chronic Kidney Disease

Empaveli recently was approved for new indications of C3 glomerulopathy (C3G) and C3 glomerulopathy (C3G) or primary immune-complex membranoproliferative glomerulonephritis (IC-MPGN) with proteinuria to help preserve kidney function. Empaveli was previously approved to treat paroxysmal nocturnal hemoglobinuria (PNH).

C3 Inhibitors

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

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

Empaveli Only:

- The member must have a diagnosis of native kidney or post-transplant recurrent C3G, or native kidney primary IC-MPGN
- The member must have eGFR ≥ 30 .
- The member must be experiencing proteinuria > 1 gram/day or UPCR ≥ 1.0 g/g despite 3-month trials with good compliance with at least one 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

Epidermolysis Bullosa

Vyjuvek was previously only available through medical billing, but the label was recently updated to allow for self-administration. This medication is now available through pharmacy billing.

PREFERRED AGENTS (PA REQUIRED)
FILSUVEZ (birch triterpenes)
VYJUVEK (beremagene geperpavec-svdt)

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).
- Genetic testing confirms pathogenic variant (e.g., KRT5 and KRT14).
- Baseline symptoms (e.g., extensive skin blistering, number and size of wounds) have been submitted.

Renewal Criteria – Approval Duration: 12 months

The member has received a therapeutic response (e.g., extensive skin blistering, number and size of wounds) from baseline.

Heart Failure

Kerendia had a label update to include the indication to reduce the risk of cardiovascular death hospitalization for heart failure, and urgent heart failure visits in adult patients with heart failure with left ventricular ejection fraction of 40% or greater. Kerendia has a prior indication for Chronic Kidney Disease associated with Type 2 Diabetes.

Solid Dosage Forms

Second Line Agents

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
CORLANOR (ivabradine)	
ivabradine	
KERENDIA (finerenone)	
VERQUVO (vericiguat)	

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- Kerendia Only:
 - The requested medication must be prescribed by, or in consult with, a cardiologist
 - The member has a diagnosis of heart failure with left ventricular ejection fraction of $\geq 40\%$
 - 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

Hemophilia

With the addition of Qfitlia and Alhemo both available to members with or without inhibitors, we made some adjustments and clarifications to preferred status of these meds as well as Hymfavzi. These three medications have a new mechanism of action for hemophilia that works on the anticoagulant side of the clotting cascade. If hemophilia is a scale that is off balance, there are not enough procoagulants on one side of the scale and/or too many anticoagulants on the other. Typical factor products, aPCC, and emicizumab work by adding more to the procoagulant side to restore balance. These newer medications work by taking more away from the anticoagulant side of the scale to restore balance in that way. They are all also given SQ, rather than by infusion, and the first SQ injections available to hemophilia B patients.

Clotting Factor Products

Hemophilia A

Procoagulant (TFPI inhibitors/Antithrombin inhibitors)

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
HYMPAVZI (marstacimab-hncq)	ALHEMO (concizumab-mtci)
	QFITLIA (fitusiran)

Hemophilia B

Procoagulant (TFPI inhibitors/Antithrombin inhibitors)

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
HYMPAVZI (marstacimab-hncq)	ALHEMO (concizumab-mtci)
	QFITLIA (fitusiran)

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)
- *Alhemo and Qfitlia only:*
 - The member must have one of the following:
 - A diagnosis of Hemophilia A with inhibitors AND has failed a 6-month trial with Hemlibra
 - A diagnosis of Hemophilia A without inhibitors AND has failed a 6-month trial with Hemlibra and Hympavzi
 - A diagnosis of Hemophilia B with inhibitors
 - A diagnosis of Hemophilia B without inhibitors AND has failed a 6-month trial with Hympavzi
 - *Hympavzi only:*
 - The member must have one of the following:
 - A diagnosis of Hemophilia A without inhibitors AND has failed a 6-month trial with Hemlibra
 - A diagnosis of Hemophilia B without inhibitors

Pulmonary Hypertension

Yutrepia is a new DPI inhaler formulation of treprostinil for pulmonary hypertension as well as pulmonary hypertension with interstitial lung disease.

Prostacyclins

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
epoprostenol	YUTREPIA (treprostinil)
FLOLAN (epoprostenol)	
ORENITRAM ER (treprostinil) TABLET	
REMODULIN (treprostinil) INJECTION	
– <i>Brand Co-Preferred</i>	
treprostinil injection – <i>Generic Co-Preferred</i>	
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.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 3 months

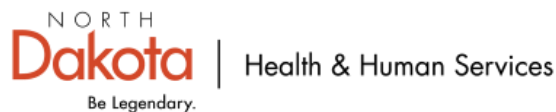
- Clinical justification must be provided explaining why the member is unable to use a preferred agent, subject to clinical review.

Pharmacy Coverage Policy Manual

Published By:

Medical Services Division
North Dakota Department of Health and Human Services
600 E Boulevard Ave Dept 325
Bismarck, ND 58505-0250

Version 2026.1
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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/>

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). A preferred product must be trialed prior to a non-preferred product approval.
 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 use the [Procedure Code Look-up Tool](#) to search for the HCPCS codes that require prior authorization.
 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
Avtozma	PA	Biosimilars
Doptelet Sprinkle Cap	PA	Thrombocytopenia
febuxostat	Remove PA	Uloric
Gazyva	PA	Lupus/Lupus Nephritis
Hulio	PA	Biosimilars
Jascayd	PA	Idiopathic Pulmonary Fibrosis
Juluca	PA	Non-Preferred Dosage Forms
Leqembi IQLIK	PA	Alzheimer's Disease
Liraglutide	PA	GLP-1 Agonists

Lynkuet	PA	Menopause
Otezla XR	PA	Otezla
Otulf	PA	Biosimilars
Pyzchiva	Remove PA	Biosimilars
Rhapsido	PA	Chronic Spontaneous Urticaria (Chronic Idiopathic Urticaria)
Starjemza	PA	Biosimilars
Striverdi Respirat	PA	COPD
Tyruko	PA	Biosimilars
Zoryve	PA	Atopic Dermatitis/Eczema

Version Changes

Category	Change
Adalimumab	Preferred biosimilars updated
Alopecia Areata	Category Added
Anemia	Criteria Updated - Zynteglo
Asthma / COPD	Criteria and Preferred Products Updated
Cholestatic Pruritis	Criteria Updated - Livmarli
Chronic Rhinosinusitis with Nasal Polyps	Criteria Updated for Xhance, preferred products updated
Chronic Spontaneous Urticaria (Chronic Idiopathic Urticaria)	Criteria Update - Rhapsido added
COVID - 19	Criteria Updated - Veklury added
Cystic Fibrosis	Criteria Preferred Products Updated - Tobi Podhaler
Cytokine Release Syndrome	Criteria Update
Deficiency of IL-A Receptor Antagonist (DIRA)	Criteria Update
Depression	Added Exxua
Eczema/Atopic Dermatitis	Criteria Updated - Systemic and Topical Agents
Epidermolysis Bullosa	Criteria Updated - Zevasyn added
Gaucher's Disease	Criteria Updated - Non-preferred agent criteria
General Rules	Trial definition updated
GIP/GLP-1 Agonists	Criteria Updated
GLP - 1 Agonists	Criteria Updated
Gout	Criteria Update - Ilaris, febuxostat, and Krystexxa
Growth Hormone	Criteria Updated - Ngenla and Sogrova
Hemophilia	Criteria and preferred products updated
Hereditary Angioedema	Criteria Update
Hypereosinophilic Syndrome	Criteria Update
Idiopathic Pulmonary Fibrosis	Criteira Updated - Non-Preferred Product Agents, Jascayd added
Interstitial Lung Disease	Criteria Updated
Menopause - Vasomotor Symptoms	Added Lynkuet
Migraine	Preferred Products Updated - Treatment
Molluscum Contagiosum	Criteria Updated - length of intiiial approval
Non-Solid Dosage Forms	Criteria Update
Obstructive Sleep Apnea	Criteria Updated
Plaque Psoriasis	Criteria Updated - Zoryve and Vtama

Pompe Disease	Criteria Update
Pseudobulbar Affect	Criteria Updated
Sickle Cell Disease	Criteria and preferred products updated - Lyfgenia
Uterine Fibroids	Preferred Products Updated
Vitiligo	Category Added
Weight Loss	Antipsychotic Induced Weight Gain approved products updated

General Policies

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, 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).

Adalimumab

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
adalimumab-adaz	ABRILADA (adalimumab-afzb)
adalimumab-fkjp	adalimumab-aacf
HADLIMA (adalimumab-bwwd)	adalimumab-aaty
HUMIRA (adalimumab)	adalimumab-adbm
SIMLANDI (adalimumab-ryvk)	adalimumab-ryvk
	AMJEVITA (adalimumab-atto)
	CYLTEZO (adalimumab-abdm)
	HYRIMOZ (adalimumab-adaz)
	HULIO (adalimumab-fkjp)
	IDACIO (adalimumab-aacf)
	YUFLYMA (adalimumab-aaty)
	YUSIMRY (adalimumab-aqvh)

Commented [AM1]: Hadlima, adalimumab-adaz, adalimumab-fkjp, Humira SRA -

Humira shall be 1 of Many preferred TIM's listed on Formulary for all Humira approved indications & not disadvantaged to any other Preferred TIM's agent No MCO utilization that doesn't follow FFS PDL

All available Simlandi Product NDCs are preferred for all FDA approved indications for Simlandi Simlandi is not disadvantaged in any way relative to competing products across all FDA approved indications for Simlandi

Hadlima High Concentration (CiF) Preferred Adalimumab Biosimilar Parity with Humira

Fkjp - Preferred not to be disadvantaged to any other product in the class

Aflibercept

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
PAVBLU (aflibercept-ayyh) – Medical Billing	EYLEA (aflibercept) – Medical Billing

Bevacizumab

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ALYMSYS (bevacizumab-maly) – Medical Billing	AVASTIN (bevacizumab) – Medical Billing *C9257 for ophthalmology injections does not require PA.
MVASI (bevacizumab-awwb) – Medical Billing	JOBEVNE (bevacizumab-nwgd) – Medical Billing
ZIRABEV (bevacizumab-bvzr) – Medical Billing	VEGZELMA (bevacizumab-acdc) – Medical Billing

Commented [KS2]: Watch for rebates 4Q 2026?

Denosumab

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
JUBBONTI (denosumab-bbdz) – Medical Billing	BILDYOS (denosumab-nxxp) – Medical Billing
WYOST (denosumab-bbdz) – Medical Billing	BILPREVDA (denosumab-nxxp) – Medical Billing
	BOMYNTRA (denosumab-bnht) – Medical Billing
	CONEXXENCE (denosumab-bnht) – Medical Billing
	OSPOMYV (denosumab-dssb) – Medical Billing
	OSENVELT (denosumab-bmwo) – Medical Billing
	PROLIA (denosumab) – Medical Billing
	STOBOCLO (denosumab-bmwo) – Medical Billing
	XGEVA (denosumab) – Medical Billing

Commented [AM3]: SRA - Jubbonti and Wyost

Eculizumab

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
EPYSQLI (eculizumab-aagh) – Medical Billing	BKEMV (eculizumab-aeab) – Medical Billing
	SOLIRIS (eculizumab) – Medical Billing

Filgrastim

Medical Billing

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
GRANIX (TBO-filgrastim) – Medical Billing	NEUPOGEN (filgrastim) – Medical Billing
NIVESTYM (filgrastim-aafi) – Medical Billing	RELEUKO (filgrastim-ayow) – Medical Billing
ZARXIO (filgrastim-sndz) – Medical Billing	

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)

Commented [AM4]: SRA Neupogen - Neupogen is not disadvantaged to all other G-CSFs in all approved indications

Pegfilgrastim

Medical Billing

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
NEULASTA (pegfilgrastim) – Medical Billing	FULPHILA (pegfilgrastim-jmdb) – Medical Billing
NEULASTA ONPRO (pegfilgrastim) – Medical Billing	FYLNTRA (pegfilgrastim -pbbk) – Medical Billing
ZIEXTENZO (pegfilgrastim-bmez) – Medical Billing	NYVEPRIA (pegfilgrastim-apgf) – Medical Billing
	STIMUFEND (pegfilgrastim-fpgk) – Medical Billing
	UDENYCA (pegfilgrastim-cbqv) – Medical Billing
	UDENYCA ONBODY (pegfilgrastim-cbqv) – Medical Billing

Pharmacy Billing

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
FULPHILA (pegfilgrastim-jmdb)	NEULASTA (pegfilgrastim)
FYLNTRA (pegfilgrastim -pbbk)	NYVEPRIA (pegfilgrastim-apgf)

Commented [AM5]: Fulphila SRA - Preferred not to be disadvantaged to any other product in the class

	STIMUFEND (pegfilgrastim-fpgk)
	UDENYCA (pegfilgrastim-cbqv)
	ZIEXTENZO (pegfilgrastim-bmez)

Infliximab

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AVSOLA (infliximab-axxq) – Medical Billing	RENFLEXIS (infliximab-abda) – Medical Billing
INFLECTRA (infliximab-dyyb) – Medical Billing	REMICADE (infliximab) – Medical Billing
infliximab – Medical Billing	ZYMFENTRA (infliximab-dyyb)

Insulin Aspart – Novolog/Fiasp

PREFERRED AGENTS (ELECTRONIC STEP REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
FIASP (insulin aspart)	insulin aspart
	KIRSTY (insulin aspart-xjhz)
	MERIOLOG (insulin aspart-szjj)
	NOVOLOG (insulin aspart)
	RELION NOVOLOG (insulin aspart)

Commented [KS6]: Watch for 4Q rebates

Insulin Glargine - Lantus

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
LANTUS U-100 (insulin glargine)	BASAGLAR (insulin glargine)
	insulin glargine-yfgn U-100 (generic Semglee)
	REZVOGLAR U-100 (insulin glargine-aglr)
	SEMGLEE U-100 (insulin glargine) YFGN

Commented [AM7]: Discontinued 12/31/25

Insulin Lispro - Humalog

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
HUMALOG U-100 (insulin lispro) CARTRIDGE	ADMELOG (insulin lispro)
insulin lispro U-100 pen, jr pen	HUMALOG (insulin lispro) VIAL, PEN, TEMPO
	insulin lispro vial
	LYUMJEV U-100 (insulin lispro-aabc)
	LYUMJEV U-200 (insulin lispro-aabc)
	LYUMJEV U-100 TEMPO PEN (insulin lispro-aabc)

Natalizumab

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
TYSABRI (natlizumab) – Medical Billing	TYRUKO (natlizumab-sztn) – Medical Billing

Ranibizumab

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
BYOOVIZ (ranibizumab-nuna) – Medical Billing	CIMERLI (ranibizumab-eqrn) – Medical Billing
LUCENTIS (ranibizumab) – Medical Billing	

Rituximab

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
RIABNI (rituximab-arxx) – Medical Billing	RITUXAN (rituximab) – Medical Billing

RUXIENCE (rituximab-pvvr) – <i>Medical Billing</i>	
TRUXIMA (rituximab-abbs) – <i>Medical Billing</i>	

Tocilizumab

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
TYENNE (tocilizumab-aazg) AUTOINJECTOR, SYRINGE	ACTEMRA (tocilizumab) ACTPEN, SYRINGE
TYENNE (tocilizumab-aazg) VIAL – <i>Medical Billing</i>	ACTEMRA (tocilizumab) VIAL – <i>Medical Billing</i>
	AVTOZMA (tocilizumab-anoh) VIAL – <i>Medical Billing</i>
	TOFIDENCE (tocilizumab-aazg) VIAL – <i>Medical Billing</i>

Commented [AM8]: Tyenne SRA - Rate is contingent on Tyenne being exclusive Tocilizumab on State PDL

Trastuzumab

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
TRAZIMERA (trastuzumab-qyyp) – <i>Medical Billing</i>	KANJINTI (trastuzumab-anns) – <i>Medical Billing</i>
	HERCESSI (trastuzumab-strf) – <i>Medical Billing</i>
	OGIVRI (trastuzumab-dkst) – <i>Medical Billing</i>
	ONTRUZANT (trastuzumab-dttb) – <i>Medical Billing</i>
	HERZUMA (trastuzumab-pkrb) – <i>Medical Billing</i>
	HERCEPTIN (trastuzumab) – <i>Medical Billing</i>

Ustekinumab

PREFERRED AGENTS (NO PA REQUIRED)	STEP 1 - NON-PREFERRED AGENTS (PA REQUIRED)	STEP 2 - NON-PREFERRED AGENTS (PA REQUIRED)
PYZCHIVA (ustekinumab-ttwe)	SELARSDI (ustekinumab-aekn)	IMULDOSA (ustekinumab-srlf)
STEQEYMA (ustekinumab-stba)	YESINTEK (ustekinumab-kfce)	IMULDOSA (ustekinumab-srlf) – <i>Medical Billing</i>
STEQEYMA (ustekinumab-stba) – <i>Medical Billing</i>	YESINTEK (ustekinumab-kfce) – <i>Medical Billing</i>	OTULFI (ustekinumab-aauz)
		OTULFI (ustekinumab-aauz) – <i>Medical Billing</i>
		PYZCHIVA (ustekinumab-ttwe) – <i>Medical Billing</i>
		STARJEMZA (ustekinumab-hmny)
		STARJEMZA (ustekinumab-hmny) – <i>Medical Billing</i>
		STELARA (ustekinumab) – <i>Medical Billing</i>
		SELARSDI (ustekinumab-aekn) – <i>Medical Billing</i>
		ustekinumab
		ustekinumab – <i>Medical Billing</i>
		ustekinumab-aekn
		ustekinumab-aekn – <i>Medical Billing</i>
		ustekinumab-ttwe
		ustekinumab-ttwe – <i>Medical Billing</i>
		WEZLANA (ustekinumab-auub)
		WEZLANA (ustekinumab-auub) – <i>Medical Billing</i>

Commented [AM9]: SRA Pyzchiva - SQ only, IV rejected

Dispense as Written (DAW1)

Member or prescriber preference is NOT criteria considered for approval.

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

- A. 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)

- B. 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 has been 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

- C. Both of the following must be met:
 - 1. The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational).
 - 2. 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.
- D. The requested medication must be prescribed by, or in consult with, a specialist in the member's treated diagnosis.

- E. As applicable, confirmation of diagnosis must be provided as evidenced by serum markers or pathogenic gene variants amenable to treatment.
- F. Baseline labs, signs or symptoms that can be utilized for comparison to show member has experienced clinical benefit upon renewal have been submitted with request.

PA REQUIRED
ABECMA (idecabtagene vicleucel) – <i>Medical Billing</i>
ACTHAR (corticotropin) SELF-INJECTOR
ADSTILADRIN (nadofaragene firadenovec-vncg) – <i>Medical Billing</i>
AQNEURSA (levacetyleucine)
AUCATZYL (obecabtagene autoleucel) – <i>Medical Billing</i>
AVMAPKI/FAKZYNJA (avutometinib/defacitinib)
BIZENGRI (zenocutuzumab-zbco) – <i>Medical Billing</i>
BLINCYTO (blinatumomab) – <i>Medical Billing</i>
BREYANZI (lisocabtagene maraleucel) – <i>Medical Billing</i>
BRINSUPRI (bresocatinib)
CARVYKTI (ciltacabtagene autoleucel) – <i>Medical Billing</i>
CORTROPHIN (corticotropin) GEL SYRINGE
CRENESSITY (crinercerfont)
CYSTADROPS (cysteamine)
CYSTARAN (cysteamine)
DANYELZA (naxitamab-ggqk) – <i>Medical Billing</i>
DAYBUE (trofinetide)
DATROWAY (datopotamab deruxtecan-dlnk) – <i>Medical Billing</i>
DOJOLVI (triheptanoin)
EMRELIS (telisotuzumab vedotin-tllv) – <i>Medical Billing</i>
ENCELTO (revakinagene taroretcel-lwey) – <i>Medical Billing</i>
EPKINLY (epcoritamab-bysp) – <i>Medical Billing</i>
FIRDAPSE (amifampridine)
FOLOTYN (pralatrexate) – <i>Medical Billing</i>
FUROSCIX (furosemide)
FUROSCIX (furosemide) – <i>Medical Billing</i>
FYARRO (sirolimus protein-bound particles) – <i>Medical Billing</i>
GATTEX (teduglutide)
IMAAVY (nipocalimab-aahu) – <i>Medical Billing</i>
INCRELEX (mecasermin)
JOENJA (leniolisib)
KIMMTRAK (tebentafusp-tebn) – <i>Medical Billing</i>
KYMRIAH (tisagenlecleucel) – <i>Medical Billing</i>
Lanreotide
MIPLYFFA (arimoclomol)
MODEYSO (dordaviprone)
MYCAPSSA (octreotide)
NIKTIMVO (axatilimab-csfr) – <i>Medical Billing</i>
NULIBRY (fosdenopterin)
OXERVATE (cenegermin-bkbj)
PYRUKYND (mitapivat)
REZUROCK (belumosudil)
RYONCIL (remestemcel-l-rknd) – <i>Medical Billing</i>

Commented [AM10]: December 2025 DUR

Commented [AM11]: March DUR

Commented [AM12R11]: criteria: 6+ Mo initial auth:PA to labelin consult w/Pulm;12 Mo re-auth:provider attest + clin benefit; for sPDL,MCO not more restrictive

Commented [AM13]: @Steig, Katie Review for criteria under Myasthenia Gravis.

Commented [AM14]: @Steig, Katie Should this be under growth hormone?

Commented [AM15]: @Steig, Katie Review for Acromegaly - December DUR?

Commented [KS16R15]: March 2026

Commented [AM17]: December 2025 DUR

Commented [AM18]: @Steig, Katie Review for Acromegaly - December DUR?

Commented [KS19R18]: March 2026

Commented [AM20]: @Steig, Katie Review for Graft vs. Host Disease - December DUR?

Commented [KS21R20]: March 2026

Commented [AM22]: @Steig, Katie Review for Graft vs. Host Disease - December DUR?

Commented [KS23R22]: March 2026

Commented [AM24]: @Steig, Katie Review for Graft vs. Host Disease - December DUR?

Commented [KS25R24]: March 2026

SKYCLARYS (omaveloxolone)
SPEVIGO (spesolimab-sbzo)
SOHONOS (palovarotene)
TAVNEOS (avacopan)
TECARTUS (brexucabtagene autoleucel) – <i>Medical Billing</i>
TECELRA (afamitresgene autoleucel) – <i>Medical Billing</i>
TECVAYLI (Inj teclistamab cqqv 0.5 mg) – <i>Medical Billing</i>
TIVDAK (tisotumab vedotin-tftv) – <i>Medical Billing</i>
TRYNGOLZA (olezarsen)
VEOPOZ (pozelimab) – <i>Medical Billing</i>
VIJOICE (alpelisib)
VYKAT XR (diazoxide)
WELIREG (belzutifan)
XENPOZYME (olipudase alfa) – <i>Medical Billing</i>
XOLREMDI (mavorixafor)
YESCARTA (axicabtagene ciloleucel) – <i>Medical Billing</i>
ZILHERA (zanidatamab-hrii) – <i>Medical Billing</i>
ZOKINVY (lonafamib)
ZYNLONTA (loncastuximab tesirine-lpyl) – <i>Medical Billing</i>

Commented [AM26]: December DUR Board

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.
- The member must not be on other solid dosage forms (this may reject for therapeutic duplication)

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):
 - Approval Duration: regular renewal approval duration or 1 year

1. The member was at least 80% adherent to medication, excluding any claim gaps due to hospitalization or eligibility.
2. Approval Duration: 3 months
 2. 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 Spontaneous Urticaria (Chronic Idiopathic Urticaria)

Biologic Agents

PA REQUIRED

DUPIXENT (dupilumab)

RHAPSIDO (remibrutinib)

XOLAIR (omalizumab) SYRINGE, AUTOINJECTOR

XOLAIR (omalizumab) VIALS – *Medical Billing*

Prior Authorization Criteria

Initial Criteria - Approval Duration: 3 months

- The member must have failed a 60-day trial of a dose of fourfold normal dosing of second-generation H₁ antihistamine (e.g., cetirizine, desloratadine, fexofenadine, levocetirizine) in addition to the following, as evidenced by paid claims or pharmacy printouts

References

1. Khan DA. Chronic spontaneous urticaria: Treatment of refractory symptoms. In: *UpToDate*, Post TW (Ed), UpToDate, Waltham, MA, 2025
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.
4. Zuberbier, T., Aberer, W., Asero, R., Bindslev-Jensen, C., Brzoza, Z., Canonica, G. W.,... & Maurer, M. (2014). The diagnosis and management of acute and chronic urticaria: 2014 update. *Journal of Allergy and Clinical Immunology*

Chronic Rhinosinusitis with Nasal Polyps

Steroids – Nasal Spray

PREFERRED AGENTS (NO PA REQUIRED)

[See Steroid – Nasal Spray](#)

NON-PREFERRED AGENTS (PA REQUIRED)

XHANCE (fluticasone)

Initial Criteria - Approval Duration: 12 months

- Xhance (fluticasone) Only: The member has failed two 30-day trials of steroid nasal sprays of different active ingredients, one must be fluticasone.

Commented [AM27]: Dupixent, Rhapsido, Xolair SRA -

Rhapsido - Preferred, PA to Label, not disadvantaged to any other agent with overlapping indications. Tied to enhanced rate for Kisempra

Dupixent - Preferred to label non-disadvantaged all indications
Allowing: AD:DSE;TCS&TCI min options (total use prior agents up to 90days max) ASTHMA:+1exacerbation max-tolerated ICS-LABA with 1)EOS>=150 or 2)OCS-dependency CRSwNP:INS and/or OCS EOE & PN:parity

Xolair - Market basket includes Dupixent NucalaCinqair Fasenra and Tezspire

Biologics

Anti-IL-4/13 biologics

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

Anti-IL-5 biologics

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
NUCALA (mepolizumab) SYRINGE, AUTOINJECTOR	
NUCALA (mepolizumab) VIAL – <i>Medical Billing</i>	

Eosinophil-directed biologics

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
XOLAIR (omalizumab) SYRINGE, AUTOINJECTOR	
XOLAIR (omalizumab) VIAL – <i>Medical Billing</i>	

Thymic Stromal Lymphopoietin (TSLP) blocker

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
TEZSPIRE (tezepelumab-ekko) PENS	
TEZSPIRE (tezepelumab-ekko) VIAL and SYRINGES – <i>Medical Billing</i>	

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, as evidenced by paid claims or pharmacy printouts.
- The member must have trialed at least two courses of a 10-day trial of oral glucocorticoids in the past year, as evidenced by paid claims or pharmacy printouts.
- 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.

Renewal Criteria - Approval Duration: 12 months

- The member must have received a therapeutic response as evidenced by 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.

Commented [AM28]: Dupixent, Tezspire, Nucala, Xolair SRA -

Dupixent - Preferred to label non-disadvantaged all indications
Allowing: AD:DSE;TCS&TCI min options (total use prior agents up to 90days max) ASTHMA:+1exacerbation max-tolerated ICS-LABA with 1)EOS>=150 or 2)OCS-dependency CRSwNP:INS and/or OCS EOE & PN:parity

Tezspire PA allowed if fully consistent with FDA-approved indication; simple PA form requiring physician attestation only comprising of yes/no questions with no requirement for additional documentation; no biomarker threshold or testing requirements

Nucala - Preferred Brand with PA to label

Xolair - Market basket includes Dupixent NucalaCinqair Fasenna and Tezspire

Cytokine Release Syndrome

Biologic Agents

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
tocilizumab – See Biosimilar Agents	

Prior Authorization Criteria

Initial Criteria - Approval Duration: 4 doses

- The member must have chimeric antigen receptor (CAR) T cell-induced Cytokine Release Syndrome
- The member must have grade 3 or 4 Cytokine Release Syndrome resulting in hypotension and/or hypoxia.
- The member must be on concurrent glucocorticoids.

References

- Porter DL, Maloney DG. Cytokine Release Syndrome. In: *UpToDate*, Post TW (Ed), UpToDate, Waltham, MA, 2025

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 15-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, 2025

Eosinophilic Granulomatosis with Polyangiitis (EGPA)

Biologic Agents

Anti-B-cell Therapy

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
rituximab – See Biosimilar Agents	

Anti-IL-5 Biologics

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
FASENRA (benralizumab)	
NUCALA (mepolizumab) SYRINGE, AUTOINJECTOR	
NUCALA (mepolizumab) VIAL – <i>Medical Billing</i>	

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 β 2-agonist.

Commented [AM29]: @Steig, Katie Remove this / combine when updating the PDL with the ANCA - Associated vasculitis criteria.

Commented [AM30]: Fasenna, Nucala SRA

Fasenna - If PA is required no competitive disadvantage to other preferred agents and aligned to product label for all FDA indications and w/EOS > or = 150

Nucala - Preferred Brand with PA to label

- 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 Fasenna, as evidenced by paid claims or pharmacy printouts.

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, 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 (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
XOLAIR (omalizumab) SYRINGE, AUTOINJECTOR	
XOLAIR (omalizumab) VIAL – Medical Billing	

Commented [AM31]: SRA Xolair - Market basket includes Dupixent NucalaCinqair Fasenna and Tezspire

Oral Immunotherapy

PREFERRED AGENTS (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, angioedema, 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 the first request for an up-titration renewal.

Hypereosinophilic Syndrome (HES)

Biologic Agents

PA REQUIRED

NUCALA (mepolizumab) SYRINGE, AUTOINJECTOR

NUCALA (mepolizumab) VIAL – *Medical Billing*

Commented [AM32]: Nucala SRA - Preferred Brand with PA to label

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 meet one of the following criteria:
 - The member has experienced at least 2 HES flares within the past 12 months despite a 3-month trial with oral corticosteroid ≥ 7.5 mg/day, as evidenced by paid claims or pharmacy printouts.
 - The member requires more than 10 mg/day of prednisone daily for control and has significant side effects from glucocorticoid therapy.
- 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, 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 (PA REQUIRED)

ILARIS (canakinumab) – Medical Billing

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 had at least three gout flares in the previous year that have been unmanaged despite at least a 7-day trial of each of the following, as evidenced by paid claims or pharmacy printouts:
 - colchicine
 - indomethacin or naproxen
 - glucocorticoids

Urate Lowering Therapy

Uricosuric Drugs

PREFERRED AGENTS (NO PA REQUIRED)

probenecid-colchicine tablets

probenecid tablets

NON-PREFERRED AGENTS (PA REQUIRED)

Xanthine Oxidase Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)

allopurinol 100 mg, 300 mg

azathioprine 50 mg

febuxostat

NON-PREFERRED AGENTS (PA REQUIRED)

allopurinol 200 mg

azathioprine 75 mg, 100 mg

AZASAN (azathioprine)

IMURAN (azathioprine)

ULORIC (febuxostat) TABLET

++ 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

- See applicable [Preferred Dosage Form](#) criteria

Uricase

PREFERRED AGENTS (PA REQUIRED)

KRYSTEXXA (pegloticase) – Medical Billing

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:
 - allopurinol
 - febuxostat
 - 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 must have experienced and maintained clinical benefit since starting treatment with the requested medication, 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 (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
icatibant	BERINERT (plasma derived C1 Esterase Inhibitor)
SAJAZIR (icatibant)	BERINERT (plasma derived C1 Esterase Inhibitor) – <i>Medical Billing</i>
	EKTERLY (sebetralstat)
	FIRAZYR (icatibant)
	KALBITOR (ecallantide) – <i>Medical Billing</i>
	RUCONEST (recombinant C1 Esterase Inhibitor)
	RUCONEST (recombinant C1 Esterase Inhibitor) – <i>Medical Billing</i>

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.
 - Berinert Only: The preferred agent trial may be bypassed for members who are pregnant, breastfeeding, or under 18 years old upon request.
 - Kalbitor Only: The member must have a contraindication to or failed a trial of Berinert or Ruconest, as evidenced by paid claims or pharmacy printouts.

Prophylaxis

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
HAEGARDA (plasma derived C1 Esterase Inhibitor)	ANDEMBRY (garadacimab-gxii)
ORLADEYO (berotralstat)	CINRYZE (plasma derived C1 Esterase Inhibitor)
TAKHZYRO (lanadelumab-flyo)	DAWNZERA (donidalorsen)

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):
 - 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)
 - 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)
 - 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

- Takhyzo: 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 PJ, Christiansen SC, Riedl MA, et al. US HAEA Medical Advisory Board 2020 Guidelines for the Management of Hereditary Angioedema. J Allergy Clin Immunol Pract. 2021;9(1):132–150. Published by Elsevier Inc. on behalf of the American Academy of Allergy, Asthma & Immunology. Available at: <https://www.haea.org/assets/img/TreatmentGuidelines040321.pdf>

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	

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	ALYGLO (human immunoglobulin G - stwk) – Medical Billing
GAMMAGARD S-D (human immunoglobulin G)	ASCENIV (human immune globulin G- slra)
GAMMAPLEX (human immunoglobulin G)	ASCENIV (human immune globulin G- slra) – Medical Billing
GAMMAPLEX (human immunoglobulin G) – Medical Billing	PANZYGA (human immune globulin G- ifas)

OCTAGAM (human immunoglobulin G)	PANZYGA (human immune globulin G - ifas) – <i>Medical Billing</i>
OCTAGAM (human immunoglobulin G) – <i>Medical Billing</i>	
PRIVIGEN (human immunoglobulin G)	
PRIVIGEN (human immunoglobulin G) – <i>Medical Billing</i>	

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) – <i>Medical Billing</i>	
GAMUNEX-C (human immunoglobulin gamma)	
GAMUNEX-C (human immunoglobulin gamma) – <i>Medical Billing</i>	

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) – <i>Medical Billing</i>	CUVITRU (human immunoglobulin gamma) – <i>Medical Billing</i>
HIZENTRA (human immunoglobulin gamma)	HYQVIA (human immune globulin G and hyaluronidase)
HIZENTRA (human immunoglobulin gamma) – <i>Medical Billing</i>	HYQVIA (human immune globulin G and hyaluronidase) – <i>Medical Billing</i>
XEMBIFY (immune globulin, gamma(IgG)klhw)	
XEMBIFY (immune globulin, gamma(IgG)klhw) – <i>Medical Billing</i>	

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) – <i>Brand Required</i>	azelastine-fluticasone
fluticasone	flunisolide
mometasone – labeler 60605	mometasone – labeler 65152, 59651
OMNARIS (ciclesonide)	QNASL CHILDREN (beclomethasone)

QNASL (beclomethasone)	RYALTRIS (olopatadine/mometasone)
	XHANCE (fluticasone)
	ZETONNA (ciclesonide)

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
 - 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, methylidopa)
 - 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)
dabigatran capsule	PRADAXA (dabigatran)

ELIQUIS (apixaban)	SAVAYSA (edoxaban)
XARELTO (rivaroxaban)	

Commented [AM33]: Eliquis SRA - Offer does not allow any step edits through a branded or generic agent.

Non-solid oral dosage forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
XARELTO (rivaroxaban) SUSPENSION – Brand Required	ELIQUIS (apixaban) SPRINKLE CAPSULE
	ELIQUIS (apixaban) TABLET FOR SUSPENSION
	PRADAXA (dabigatran) PELLET
	rivaroxaban suspension

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 (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
rivaroxaban 2.5 mg	XARELTO (rivaroxaban) 2.5 mg

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- rivaroxaban 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 (reamlodipine) SOLUTION	KATERZIA (amlodipine) SUSPENSION
nimodipine solution – PA required for non-solid dosage form	NYMALIZE (nimodipine) SOLUTION

Commented [AM34]: SRA Norliqva - If GNUP for Norliqva is better than Katerzia we request a step through Norliqva prior to Katerzia fulfillment A PA for Katerzia and No PA for Norliqva would qualify

Electronic Diagnosis Verification

- Nimodipine and 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

- See [Preferred Dosage Form](#) criteria

Diuretics

Diuretics – Solid Dosage Forms

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 a 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	INSPIRA (eplerenone)
spironolactone tablet	

Diuretics - Non-Solid Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
furosemide oral solution	CAROSPIR (spironolactone) SUSPENSION
spironolactone suspension	INZIRQO (hydrochlorothiazide) ORAL SUSP

Prior Authorization Criteria

- See [Preferred Dosage Form](#) Criteria

Heart Failure

Solid Dosage Forms

First Line Agents

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ACE (angiotensin-converting enzyme) inhibitors – <i>all oral agents preferred</i>	dapagliflozin
ARBs (angiotensin receptor blockers) – <i>all oral agents preferred</i>	INPEFA (sotagliflozin)
Beta blockers – <i>all oral agents preferred</i>	SAMSCA (tolvaptan)
Diuretics	sacubitril/valsartan
ENTRESTO (sacubitril/valsartan) – <i>Brand Required</i>	tolvaptan
FARXIGA (dapagliflozin) – <i>Brand Required</i>	
JARDIANCE (empagliflozin)	

Commented [AM35]: Jardiance SRA

Second Line Agents

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
CORLANOR (ivabradine)	
ivabradine	
KERENDIA (finerenone)	
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 $\leq 45\%$
 - 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)
- Kerendia Only:
 - The requested medication must be prescribed by, or in consult with, a cardiologist
 - The member has a diagnosis of heart failure with left ventricular ejection fraction of $\geq 40\%$
 - 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
- 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, as evidenced by paid claims or pharmacy printouts.
 - 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

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) $\geq 55\%$
 - NYHA class II or III
 - Resting oxygen saturation of $\geq 90\%$
 - 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 pVO₂ by ≥ 1.5 mL/kg/min plus improvement in NYHA class by at least 1
 - an improvement of pVO₂ 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. Olivetto, 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

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 (bempedioic acid)	
NEXLIZET (bempedioic 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,	ANTARA (fenofibrate, micronized)

200mg	
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, nanocrystallized)
	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 (Proprotein Convertase Subtilisin/Kexin Type 9) Inhibitors

PREFERRED AGENTS (ELECTRONIC STEP REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
REPATHA (evolocumab)	PRALUENT (alirocumab)

Commented [AM36]: SRA Repatha - Repatha is not disadvantaged to any product(s) that shares the same indication(s)

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)
amlodipine/atorvastatin	ALTROPREV (lovastatin)
atorvastatin	CADUET (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, as evidenced by paid claims or pharmacy printouts.
- All other agents: See [Preferred Dosage Form](#) criteria

Non-Solid Dosage Forms

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
EZALLOR SPRINKLE (rosuvastatin)	ATORVALIQ (atorvastatin) SOLUTION

Electronic Age Verification

- Ezallor Sprinkle: Prior authorization is not required for ages 7 and 8

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, 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.

Angiopoietin-like 3 (ANGPTL3) Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	EVKEEZA (evinacumab-dgnb) – <i>Medical Billing</i>

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.
- One of the following must be met:

- 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) – <i>Medical Billing</i>

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.

Platelet Aggregation Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
aspirin	clopidogrel 300 mg
aspirin/dipyridamole ER	BRILINTA 90 MG (ticagrelor)
BRILINTA 60 MG (ticagrelor) – <i>Brand Required</i>	EFFIENT (prasugrel)
clopidogrel 75 mg	PLAVIX (clopidogrel)
dipyridamole	ticagrelor 60 mg
prasugrel	ZONTIVITY (vorapaxar)
ticagrelor 90 mg	

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 (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

- The member has received a therapeutic response as evidenced by stabilization or improvement from baseline in each of the following:
 - 6MWT ($\leq$ 15% decline)
 - WHO functional class

Endothelin Receptor Antagonists

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ambrisentan	LETAIRIS (ambrisentan)
bosentan	OPSUMIT (macitentan)
bosentan tablets for suspension	OPSYNVI (macitentan/tadalafil)
	TRACLEER (bosentan) SUSPENSION
	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	YUTREPIA (treprostinil)
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.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 3 months

- Clinical justification must be provided explaining why the member is unable to use a preferred agent, subject to clinical review.

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 (Proprotein Convertase Subtilisin/Kexin Type 9) Inhibitors

PREFERRED AGENTS (ELECTRONIC STEP REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
REPATHA (evolocumab)	PRALUENT (alirocumab)

Commented [AM37]: Repatha SRA - Repatha is not disadvantaged to any product(s) that shares the same indication(s)

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.

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

GLP-1 Agonists

PA REQUIRED
RYBELSUS (semaglutide)
WEGOVY (semaglutide)

Commented [AM38]: SRA Rybelsus - All presentations of Rybelsus® must be Preferred on the PDL and neither restricted nor disadvantaged to any product in the respective Therapeutic Class

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 between 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/m² and < 35 kg/m²
- 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	
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
clindamycin solution	CLINDACIN (clindamycin) FOAM
	CLINDACIN P (clindamycin) PLEDGETS
	CLINDACIN ETZ (clindamycin) PLEDGETS
	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%	BENZACLIN (clindamycin/benzoyl peroxide without pump) 1%-5%
clindamycin-benzoyl peroxide 1%-5% with pump	BENZACLIN (clindamycin/benzoyl peroxide with pump) 1%-5%

clindamycin-benzyl peroxide 1.2%-5%	CABTREO (adapalene/benzoyl peroxide/clindamycin) 1.2%-0.15%-3.15% GEL
clindamycin/benzoyl peroxide 1%-5% without pump	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)
tazarotene 0.1% cream	clindamycin-tretinoin 1.2%-0.025%
tretinoin cream	FABIOR (tazarotene) 0.1% FOAM
tretinoin gel	tazarotene 0.05% cream
	tazarotene 0.1% foam
	tazarotene gel
	tretinoin microsphere gel

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 (dapson) 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%	SSS 10-5 (sulfacetamide) CLEANSER
dapsone gel without pump	SSS 10-5 (sulfacetamide) FOAM
sulfacetamide 10% cleansing gel	sodium sulfacetamide/sulfur pads 10%-4%
sulfacetamide 10% lotion	sodium sulfacetamide/sulfur cream 10%-2%
sulfacetamide 10% suspension	SUMADAN (sodium sulfacetamide/sulfur) WASH 9%-4.5%
sulfacetamide 10% wash	SUMAXIN (sodium sulfacetamide/sulfur) WASH 9%-4%
sodium sulfacetamide/sulfur cleanser 10%-5% (W/W)	SUMAXIN (sodium sulfacetamide/sulfur pads) PADS 10%-4%
sodium sulfacetamide/sulfur cleanser 9%-4%	SUMAXIN TS (sodium sulfacetamide/sulfur) SUSPENSION 8%-4%
sodium sulfacetamide/sulfur cleanser 9%-4.5%	ZMA CLEAR (sulfacetamide sodium/sulfur) SUSPENSION 9%-4.5%
sodium sulfacetamide/sulfur cleanser 9.8% -4.8%	
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)
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
	imiquimod 3.75% 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

Alopecia Areata

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
LITFULO (ritlecitinib)	LEQSELVI (deuruxolitinib)
OLUMIANT (baricitinib)	

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- The member must be less than 21 years of age.
- The member must have one of the following:
 - The member must have at least 50% scalp hair loss for more than 6 months
 - The member has failed a 3-month trial of topical corticosteroids of high potency, as evidenced by paid claims or pharmacy printouts.

Non-Preferred Agent Criteria:

- *Leqselvi Only:* The member must have failed a 6-month trial each of Litfulo and Olumiant, as evidenced by paid claims or pharmacy printouts.

Renewal Criteria – Approval Duration: 12 months

- The member has achieved at least 80% of scalp hair coverage

Antifungals – Topical

Cream

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
butenafine cream	CICLODAN (ciclopirox) CREAM
ciclopirox cream	ERTACZO (sertracozazole) CREAM
clotrimazole cream	EXELDERM (sulconazole) CREAM
econazole cream	LOPROX (ciclopirox) CREAM
ketoconazole cream	Iuliconazole cream
miconazole cream	MENTAX (butenafine) CREAM
NAFTIN (naftifine) CREAM	naftifine cream
nystatin cream	oxiconazole cream
nystatin – triamcinolone cream	sulconazole cream

Foam

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ketoconazole foam	EXTINA (ketoconazole) FOAM
	KETODAN (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 – <i>Brand Required</i>	

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
	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.

Bullous Pemphigoid

PREFERRED AGENTS (PA REQUIRED)

DUPIXENT (duplimumab)

Initial Criteria - Approval Duration: 4 months

- The member has a diagnosis of bullous pemphigoid
 - Drug-induced disease must be assessed/ruled out by prescriber attestation
- The requested medication must be prescribed by, or in consult with, a dermatologist
- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational).
- Current symptoms (e.g., extent or spread of the blisters/pruritus) have been submitted
- The member has experienced new development of nontransient lesions, extension of current lesions, failure of lesion healing, or continued pruritus despite at least 3 weeks of prednisone or prednisolone at 0.75 mg/kg/day within the past 2 months

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

Aryl Hydrocarbon Receptor Agonist

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
VTAMA (tapinarof) CREAM	

Commented [AM39]: Vtama SRA

Calcineurin Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
tacrolimus	pimecrolimus

Janus Kinase (JAK) inhibitor

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
OPZELURA (ruxolitinib) CREAM	ANZUPGO (delgocitinib) CREAM

Commented [AM40]: Opzelura SRA - On PDL 1: Many or better Will allow a single topical step (TCS or TCI) Cannot step through a single source brand All indications and NDCs must be covered to the specific State's policy – which cannot negatively change within the term of the Agreement

Phosphodiesterase 4 (PDE-4) inhibitor

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
EUCRISA (crisaborole) OINTMENT	
ZORYVE (roflumilast) CREAM	

Topical Corticosteroids

Please see [Steroids – Topical](#)

Systemic

Interleukin (IL)-4/13 Inhibitor

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

Interleukin (IL)-13 Inhibitor

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ADBRY (tralokinumab-idrm) INJECTION	
EBGLYSS (lebrikizumab-lbkz) INJECTION	

Interleukin (IL)-31 Inhibitor

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
NEMLUVIO (nemolizumab) INJECTION	

Janus Kinase (JAK) inhibitor

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

Electronic Age Verification

- Tacrolimus ointment 0.1%: The member must be 16 years of age or older.
- Zoryve 0.05%: The member must be between the ages of 2 and 5 years old

Electronic Diagnosis Verification

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

Quantity Limits

- Nemluvio: Quantity of 1 every 56 days is allowed. Override must be requested for prurigo nodularis and the initial 16 weeks of treatment for atopic dermatitis.
 - For atopic dermatitis: After the initial 16 weeks of treatment, if skin is not clear or almost clear, only one additional 16 weeks of treatment of 30mg every 4 weeks will be authorized.

Prior Authorization Criteria

Prior Authorization Form – Atopic Dermatitis

Initial Criteria – Approval Duration: 3 months

Systemic Agents Only

- The member must have a body surface area involvement of 10% or greater
- 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.

Commented [AM41]: Adbry, Ebglyss, Nemluvio, Dupixent, Cibinqo SRAs

Nemluvio SRA - PA criteria is not more restrictive than label.
Nemluvio preferred (no steps through a biologic) in atopic dermatitis (AD)

Cibinqo SRA - Cibinqo may be subject to PA per label & ST failure of up to 1 branded biologic product for Mod-to-Severe AD is allowed Other JAKi products in this indication are not in better position Not subject to other JAKi failure

Adbry - Preferred Status- allows for a manual PA; Allows step-through one Topical CS AND/OR one Topical CNI; Not to be disadvantaged to any injectable immunomodulator for treatment of atopic dermatitis (ie Dupixent)

EBGLYSS is listed as preferred on the publicly available PDL and not disadvantaged to any other competitive branded product indicated for the treatment of moderate to severe atopic dermatitis

Dupixent - Preferred to label non-disadvantaged all indications
Allowing: AD:DSE;TCS&TCI min options (total use prior agents up to 90days max) ASTHMA:+1exacerbation max-tolerated ICS-LABA with 1)EOS>=150 or 2)OCS-dependency CRSwNP:INS and/or OCS EOE & PN:parity

Rinvoq ER Only

- The member must have failed a 30-day trial with Cibinqo and Olumiant, as evidenced by paid claims or pharmacy printouts.

Topical Agents Only

- The member must have failed a 6-week trial of tacrolimus or pimecrolimus, as evidenced by paid claims or pharmacy printouts

Anzupgo Only

- The member must have a diagnosis of moderate to severe chronic hand eczema
- The member must have failed an 8-week trial with Opzelura, as evidenced by paid claims or pharmacy printouts.

Renewal Criteria – Approval Duration: 12 months

- **Systemic Agents Only:**
 - The member meets one of the following as attested by treating provider:
 - Reduction in disease severity (e.g., improvement in IGA score or BSA affected)
 - Improvement in symptoms and quality of life (e.g., reduced itching, inflammation)

Epidermolysis Bullosa

PREFERRED AGENTS (PA REQUIRED)

FILSUVEZ (birch triterpenes)

VYJUVEK (beremagene geperpavec-svdt)

ZEVASKYN (prademagene zamikeracel, pz-cel) – *Medical Billing*

Initial Criteria - Approval Duration: 3 months (except Zevaskyn - Authorization will be valid for 1 year for each lifetime treatment per target wound)

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).
- Genetic testing confirms pathogenic variant (e.g., COL7A1)
- Baseline symptoms (e.g., extensive skin blistering, number and size of wounds) have been submitted.

Zevaskyn Only:

- The member has a diagnosis of Recessive Dystrophic Epidermolysis Bullosa (RDEB)
- Medication must be prescribed by a dermatologist at a Qualified Treatment Center (QTC)
- Vyjuvek or Filsuvez cannot be used on wounds treated or designated to be treated with Zevaskyn

Renewal Criteria – Approval Duration: 3 months (Except Zevaskyn – please call if PA needs an extension)

- The member has received a therapeutic response (e.g., extensive skin blistering, number and size of wounds) from baseline.

Commented [AM42]: SRA Zevaskyn - Prescribed by dermatologist at a QTC; No age, RDEB wound restrictions, step requirement or restrictions on prior or concomitant use of other therapies; Dx. of RDEB confirmed by genetic testing; (+) anti-C7 antibody test not required; 1yr service authorization

Hidradenitis Suppurativa

TNF Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)

adalimumab – See [Biosimilar Agents](#)

NON-PREFERRED AGENTS (PA REQUIRED)

Interleukin (IL) – 17 Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	COSENTYX (secukinumab)
	COSENTYX (secukinumab) – <i>Medical Billing</i>

Interleukin (IL)-17A and IL-17F inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	BIMZELX (bimekizumab-bkzx)

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 Only: The member must have failed a 90-day trial of adalimumab, as evidenced by paid claims or pharmacy printouts.
- Bimzelx Only: The member must have failed 90-day trials of adalimumab and Cosentyx as evidenced by paid claims or pharmacy printouts.

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

- For timolol gel forming solution only:
 - One of the following must be met:
 - The member is being tapered off of treatment with propranolol oral solution
 - The member has a low risk and uncomplicated hemangioma (e.g., < 2 cm, not ulcerated and not located in central face, periorbital area, lips, chin, neck, oral cavity, lumbosacral, perineal, or perianal area)
- For Hemangeol Only:
 - The member must have failed a 3-month trial of the propranolol oral solution, as evidenced by paid claims or pharmacy printouts.

Molluscum Contagiosum

PREFERRED AGENTS (PA REQUIRED)
ZELSUVMI (berdazimer) GEL
YCANTH (cantharidin) SOLUTION – <i>Medical Billing</i>

Initial Criteria - Approval Duration: 3 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 3 mg	ivermectin 6 mg tablet
NATROBA (spinosad) – <i>Brand Required</i>	malathion
permethrin 5% cream	SKLICE (ivermectin)
LICE TREATMENT (permethrin) 1% CRÈME RINSE LIQUID	spinosad
VANALICE (piperonyl butoxide/pyrethrins) GEL	

Commented [AM43]: SRA Natroba

Commented [AM44]: SRA Vanallice

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-23p40 Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ustekinumab - See Biosimilar Agents	

Interleukin (IL)-17A Inhibitor

PREFERRED AGENTS (ELECTRONIC STEP REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
TALTZ (ixekizumab)	COSENTYX (secukinumab)
	COSENTYX (secukinumab) – <i>Medical Billing</i>

Commented [AM45]: Taltz SRA - Taltz is the only IL-17 in preferred status; Taltz is not more restricted in its availability than any other competitor human interleukin antagonist; Taltz may be subject to 1 step behind no more than 1 anti-TNF product

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 (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
TREMFYA (guselkumab)	ILUMYA (tildrakizumab-asmn) – <i>Medical Billing</i>
	SKYRIZI (risankizumab-rzaa)

Commented [AM46]: Tremfya SRA - Preferred non-disadvantaged formulary coverage to all IL-23 inhibitor products

TNF Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
adalimumab – See Biosimilar Agents	CIMZIA (certolizumab) SYRINGE

ENBREL (etanercept) infliximab - See Biosimilar Agents	CIMZIA (certolizumab) VIAL – <i>Medical Billing</i>

Commented [AM47]: Enbrel SRA - Enbrel is not disadvantaged to any other BRMs in all approved indications

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 adalimumab or certolizumab pegol 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 adalimumab, certolizumab pegol, or infliximab, 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.
- Tremfya Only: The member must have failed a 3-month trial of a TNF inhibitor (adalimumab, certolizumab pegol or infliximab), an Interleukin (IL)-17A Inhibitor, and Bimzelx, as evidenced by paid claims or pharmacy printouts.
- Ilumya and Skyrizi Only: The member must have failed a 3-month trial of a TNF inhibitor (adalimumab, certolizumab pegol or infliximab), an Interleukin (IL)-17A Inhibitor, Bimzelx, and an interleukin (IL)-23p19 inhibitor, 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).
- The member must have failed all preferred agents in the same class as requested product

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	OTEZLA XR (apremilast)
OTEZLA (apremilast) 30 MG	SOTYKTU (deucravacitinib)

Commented [KS48]: Once daily WAC is the same as twice daily 30 mg. Watch 1Q/2Q for rebate

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 a 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 – <i>Brand Required</i>	ZORYVE (roflumilast) 0.3% FOAM

Cream, Lotion

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
calcipotriene cream *no PA required	ZORYVE (roflumilast) CREAM
tazarotene cream *no PA required for 0.1% strength	
VTAMA (tapinarof) CREAM	

Commented [AM49]: Vtama SRA

Ointment

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
calcipotriene ointment	calcitriol ointment
calcipotriene/betamethasone ointment	

Electronic Diagnosis Verification

- Vtama and 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 failed a 3 month trial of Vtama

Prurigo Nodularis

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
DUPIXENT (dupilumab)	NEMLUVIO (nemolizumab-ilto)

Commented [AM50]: Dupixent, Nemludio SRA -

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.

Dupixent Preferred to label non-disadvantaged all indications
Allowing: AD:DSE;TCS&TCI min options (total use prior agents up to 90days max) ASTHMA:+1exacerbation max-tolerated ICS-LABA with 1)EOS>=150 or 2)OCS-dependency CRSwNP:INS and/or OCS EOE & PN:parity

Nemludio - PA criteria is not more restrictive than label. Step through Dupixent in prurigo nodularis (PN) allowed.

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

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), as evidenced by paid claims or pharmacy printouts.

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

- Location of application: palms, soles, or psoriatic crusts
- Indication: psoriasis
- 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%	diflorasone emollient)	0.05%
	desoximetasone	0.25%	halcinonide	0.10%
	fluocinonide	0.05%		
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%	halcinonide solution	0.10%
	fluocinonide solution	0.05%	HALOG (halcinonide) SOLUTION	0.10%

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,	mometasone furoate solution	0.10%	triamcinolone acetonide aerosol	0.147
Paste				MG/G
Solution	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%	hydrocortisone butyrate	0.10%
Lotion	betamethasone dipropionate	0.05%	flurandrenolide	0.05%
	triamcinolone acetonide	0.10%	fluticasone propionate	0.05%
			STEP2 TM hydrocortisone butyrate	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			hydrocortisone solution	2.50%
			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, as evidenced by paid claims or pharmacy printouts.

Vitiligo

PREFERRED AGENTS (PA REQUIRED)

OPZELURA (ruxolitinib)

Commented [AM51]: Opzelura SRA - On PDL 1: Many or better Will allow a single topical step (TCS or TCI) Cannot step through a single source brand All indications and NDCs must be covered to the specific State's policy – which cannot negatively change within the term of the Agreement

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- The member must be less than 21 years of age.
- The member must have a body surface area involvement of 10% or less
- The member has vitiligo on face, neck, arms, or legs.
- The member must meet one of the following:
 - The member must have failed a 6-month trial of tacrolimus or pimecrolimus alternating with a high potency topical corticosteroid, as evidenced by paid claims or pharmacy printouts.
 - The member meets both of the following (1 AND 2):
 - Affected area is on face
 - The member must have failed a 6-month trial of tacrolimus or pimecrolimus, as evidenced by paid claims or pharmacy printouts.

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) – <i>Medical Billing</i>
	AZMIRO (testosterone cypionate) syringe – <i>Medical Billing</i>
	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)
testosterone 2% (10mg/0.5g) gel MD PMP bottle	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 – <i>Brand Co-Preferred</i>	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 – <i>Medical Billing</i>	

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)

METOPIRON (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, as evidenced by paid claims or pharmacy printouts.
- 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) – <i>Brand Required</i>
	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**PA REQUIRED**

TZIELD (teplizumab-mzwv) – Medical Billing

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:
 - Glutamic acid decarboxylase 65 (GAD) autoantibodies
 - Insulin autoantibody (IAA)
 - Insulinoma-associated antigen 2 autoantibody (IA-2A)
 - Zinc transporter 8 autoantibody (ZnT8A)
 - 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)
JENTADUETO (linagliptin/metformin)	alogliptan/pioglitazone
TRADJENTA (linagliptin)	alogliptin
	alogliptin/metformin
	BRYNOVIN (sitagliptin) ORAL SOLUTION
	JENTADUETO XR (linagliptin/metformin)
	KAZANO (alogliptin/metformin)
	NESINA (alogliptin)
	OSENI (alogliptin/pioglitazone)
	saxagliptin
	saxagliptin/metformin
	sitagliptin – See Preferred Dosage Forms
	sitagliptin/metformin – See Preferred Dosage Forms

++Clinically Non-Preferred: Alogliptin and saxagliptin have a potentially higher risk for heart failure.

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, as evidenced by paid claims or pharmacy printouts.
 - 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.
 - Metformin is more effective than DPP-4 inhibitors and lowering A1c and weight when used as monotherapy.
- * 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, as evidenced by paid claims or pharmacy printouts.
 - The member 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:

- 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 ($\leq 7\%$) or TIR ($>70\%$) despite two 90-day trials of triple combination therapy, as evidenced by paid claims or pharmacy printouts.
- Brynovin only:* Must also meet [Non-Solid Dosage Forms](#) criteria

DPP-4 Inhibitors / SGLT2 Inhibitors Combination

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
TRIJDY XR (empagliflozin/linagliptan/metformin)	GLYXAMBI (empagliflozin/linagliptin)
	STEGLUJAN (ertugliflozin/sitagliptin)

++Clinically Non-Preferred: Saxagliptin has a potentially higher risk for heart failure.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

Commented [AM52]: Trijardy XR SRA

- 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 (PA REQUIRED)
OZEMPIC (semaglutide)	liraglutide
RYBELSUS (semaglutide)	TRULICITY (dulaglutide)
VICTOZA (liraglutide) - <i>Brand Required</i>	

[^] 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
 - Victoza 1.8 mg = Trulicity 1.5 mg = Ozempic 0.5 mg = Rybelsus 7 mg or 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

- The member has been unable to achieve goal A1C ($\leq 7\%$) or TIR ($>70\%$) despite a 90-day trial of triple combination therapy consisting of Ozempic (For Trulicity, liraglutide must be trialed if semaglutide including Rybelsus is not tolerated), along with metformin, SGLT-2 inhibitor or insulin, as evidenced by paid claims or pharmacy printouts (subject to clinical review).
 1. If triple therapy cannot be met with liraglutide or Ozempic, clinical justification must be provided (subject to clinical review*), and triple therapy must be met with SGLT-2 inhibitor + DPP4 inhibitor + metformin.
 2. If triple therapy cannot be met with SGLT-2 inhibitor + DPP4 inhibitor + metformin, clinical justification must be provided (subject to clinical review*)
- One of the following have been met (1 or 2):
 1. The requested medication must be prescribed by, or in consult with, an endocrinologist or diabetes specialist.
 2. 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, the member must trial at minimum a dose of 500 mg ER.
- If on liraglutide or Ozempic, the member should be evaluated on potential for GI side effects; GI effects are common across all GLP-1 agonist agents and transient in nature, typically lessening with ongoing treatment.
- If the member is 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

PA REQUIRED

Commented [AM53]: SRA Ozempic - All presentations of Ozempic® must be Preferred on the PDL and neither restricted nor disadvantaged to any product in the respective Therapeutic Class. A clinical PA is permitted so long as it is consistent with label.

Commented [AM54]: SRA Rybelsus - All presentations of Rybelsus® must be Preferred on the PDL and neither restricted nor disadvantaged to any product in the respective Therapeutic Class.

MOUNJARO (tirzepatide)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- One of the following is met (A or B):
 - The member meets both of the following (1 and 2):
 - The member has been unable to achieve goal A1C ($\leq 7\%$) or TIR ($>70\%$) despite a 90-day trial of triple combination therapy consisting of Ozempic (liraglutide must be trialed if semaglutide including Rybelsus is not tolerated), along with metformin, SGLT-2 inhibitor or insulin, as evidenced by paid claims or pharmacy printouts (subject to clinical review).
 - If triple therapy cannot be met with liraglutide or Ozempic, clinical justification must be provided (subject to clinical review*), and triple therapy must be met with SGLT-2 inhibitor + DPP4 inhibitor + metformin.
 - If triple therapy cannot be met with SGLT-2 inhibitor + DPP4 inhibitor + metformin, clinical justification must be provided (subject to clinical review*)
 - One of the following have been met (a or b):
 - 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).
 - The request is for Mounjaro and the member is otherwise eligible for approval for tirzepatide based on the [Sleep Apnea](#) criteria.

*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 liraglutide or Ozempic, the 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 lessening with ongoing treatment.
- If the member is 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.

Note: If the member qualifies for tirzepatide, the most cost effective tirzepatide product will be authorized.

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), subject to clinical review.

Glucose Rescue Medications

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
BAQSIMI (glucagon) SPRAY	glucagon kit
GVOKE (glucagon) INJECTION	
ZEGALOGUE (dasiglucagon) AUTOINJECTOR	

Commented [AM55]: Baqsimi, Gvoke SRA

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

NO PA REQUIRED
SOLIQUA (insulin glargine/lixisenatide)
XULTOPHY (insulin degludec/liraglutide)

Commented [AM56]: Xultophy SRA - All presentations of Xultophy® 100/3.6 must be Preferred on the PDL and neither restricted nor disadvantaged to any product in the respective Therapeutic Class

Insulin

Rapid Acting Insulin

Insulin Lispro

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
HUMALOG U-100 (insulin lispro) CARTRIDGE	insulin lispro vials – See Biosimilar Agents
insulin lispro U-100 pen, jr pen	

Insulin Aspart

PREFERRED AGENTS (ELECTRONIC STEP REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
FIASP (insulin aspart)	insulin aspart - See Biosimilar Agents

Commented [AM57]: Check price decrease Jan 2026

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 insulin lispro 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 insulin lispro, as evidenced by paid claims or pharmacy printouts.
- Insulin Vials
 - PA Not Required Criteria: A 28-day supply of Omnipod has been paid within 90 days prior to insulin lispro vial's date of service.
 - PA Required Criteria: The member has an insulin pump.

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:
 - insulin lispro
 - 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:
 - insulin lispro
 - Fiasp
- Non-Preferred Agents: See [Preferred Dosage Form](#) Criteria

Intermediate Acting Insulin

PREFERRED AGENTS (NO PA REQUIRED)	PREFERRED AGENTS (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 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 (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) – Brand Required	insulin glargine U-100 (generic Toujeo)
TOUJEO U-300 (insulin glargine) *No PA required for doses 100 unit/day to 200 unit/day – Brand Required	insulin glargine (Lantus) – See Biosimilar Agents

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 - <i>Brand Required</i>	insulin degludec U-100 and U-200
	TRESIBA (insulin degludec) U-100

Commented [AM58]: Check price decrease Jan 2026

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.

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) – <i>Brand Required</i>
	RELION NOVOLOG MIX 70/30 (insulin aspart protamine/insulin aspart)

Insulin NPH Human/Regular Insulin Human

PREFERRED AGENTS (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) – <i>Brand Required</i>	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 – <i>Brand Required</i>	INVOKAMET (canagliflozin/metformin)
	INVOKAMET XR (canagliflozin/metformin)
	STEGLATRO (ertugliflozin)
	SEGLUROMET (ertugliflozin/metformin)
	SYNJARDY XR (empagliflozin/metformin)
	XIGDUO XR (dapagliflozin/metformin) 2.5 MG – 1000 MG

Commented [AM59]: Check price decrease 01/01/2026 for Farxiga Jardiance, and Synjardy

Commented [AM60]: SRA Jardiance

Commented [AM61]: SRA Synjardy

- ++ 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:

- 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

Short Acting

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
GENOTROPIN (somatropin)	HUMATROPE (somatropin)
NORDITROPIN FLEXPRO (somatropin)	OMNITROPE (somatropin)
	SAIZEN (somatropin)
	ZOMACTON (somatropin)

Long Acting

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
SKYTROFA (lonapegsomatropin-tcgd)	NGENLA (somatogon-ghla)
	SOGROYA (somapacitan-beco)

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 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.

Commented [AM62]: Genotropin, Norditropin, Skytrofa SRA

Genotropin SRA - Offer is for Genotropin preferred on Medicaid Preferred Drug List (PDL) Genotropin may be subject to prior authorization (PA) provided that the PA is equal to or less restrictive than that placed on any other product in the Growth Hormone Category

Norditropin SRA - All presentations of Norditropin® must be in a Preferred on the PDL and neither restricted nor disadvantaged to any product in the hGH class A clinical PA is allowed as long as it is applied to the entire human Growth Hormone class

Skytrofa SRA - 1) Product shall be listed with Pref Drug status 2) Step Therapy is permitted only in instances where it is limited to a single step through any Pref Short-Acting Growth Hormone 3) Product shall not be disadvantaged to any other Long-Acting Growth Hormone

- 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.
- Skytrofa and Omnitrope Only: The member must have failed a 30-day trial of Norditropin or Genotropin, as evidenced by paid claims or pharmacy printouts.
- Ngenla and Sogroya Only: The member must have failed a 30-day trial of Skytrofa and either Norditropin or Genotropin, as evidenced by paid claims or pharmacy printouts.
- All other agents: See [Preferred Dosage Form](#) Criteria

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, panhypopituitarism OR multiple pituitary hormone deficiencies caused by a known hypothalamic-pituitary disease or its treatment (brain surgery and/or radiation)

- 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)

- The member must not have severe obesity (class 2) defined as $\geq 120\%$ of the 95th percentile for age and gender
- If the member has obesity $\geq 95^{\text{th}}$ 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%
- Vykant XR: See [Medications that cost over \\$3000](#) criteria
- See [covered medications for weight loss](#)

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 $\geq 95^{\text{th}}$ 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

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, an 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.
- Baseline 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

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, an 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:
 - 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
	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

Commented [AM63]: Ermeza - Formulary Position: 1 of 1
Preferred / Non-Preferred Levothyroxine OS PA is permitted to confirm if a patient has the medical condition dysphagia All other Levothyroxine OS products step through Ermeza

Secondary Hyperparathyroidism

Oral

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
calcitriol	cinacalcet
paricalcitol	doxercalciferol capsule
	HECTOROL (doxercalciferol) CAPSULE
	RAYALDEE ER (calcifediol)
	ROCALTRON (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, 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)

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

Intravenous

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	PARSABIV (etelcalcetide) – <i>Medical Billing</i>

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 member must be on renal dialysis, so Medicare eligibility must be ruled out (*6-month approval may be allowed to determine eligibility*)
- The requested medication must be prescribed by, or in consult with, an endocrinologist or nephrologist
- The member has been unable to maintain iPTH (intact parathyroid hormone) between 2-7 times ULN with previous trials of a vitamin D analog AND cinacalcet as evidenced by paid claims or pharmacy printouts

Renewal Criteria – Approval Duration: 12 months

- The member has documented one of the following:
 - At least 30% reduction from baseline in mean iPTH
 - Decreased levels of corrected total serum calcium from baseline, while levels remain ≥ 8.4 mg/dL

Subcutaneous

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	YORVIPATH (palopecteriparatide)

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, as evidenced by paid claims or pharmacy printouts.:
 - 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 ($\sim 8-9$ mg/dL)

Precocious Puberty

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
FENSOLVI (leuprolide) – <i>Medical Billing</i>	SUPPRELIN LA (histrelin) – <i>Medical Billing</i>
LUPRON PED DEPOT (leuprolide) – <i>Medical Billing</i>	

Commented [AM64]: Triptodur, Fensolvi SRA

Triptodur: No step through any generic/brand GnRh agonist

SYNAREL (nafarelin)	
TRIPTODUR (triptorelin) – Medical Billing	

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

PA REQUIRED

TEPEZZA (teprotumumab-trbw) – Medical Billing

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)
- If the member is a current tobacco user, the member must have received tobacco cessation counseling in the past year
- The member has one of the following:
 - Inflamed eyes with increasing diplopia
 - Proptosis $\geq$ 3 mm above ULN
 - Lid retraction of $>$ 2 mm
 - Moderate to severe-soft tissue involvement
- The provider must submit each of the following:
 - Free thyroxine (FT4) and free triiodothyronine (FT3) levels are within normal limits
 - Must have a Clinical Activity Score $\geq$ 4
- The member has failed a one-month trial of a maximally tolerated indicated dose of IV systemic glucocorticoids.
- The member has not required prior surgical ophthalmologic intervention.

Tumor-Induced Osteomalacia

PA REQUIRED

CRYSVITA (burosumab) – Medical Billing

Initial Criteria – Approval Duration: 12 months

- The diagnosis has been confirmed by a serum fibroblast growth factor-23 (FGF23) level $>$ 30 pg/mL with unresectable phosphaturic mesenchymal tumor

Renewal Criteria – Approval Duration: 12 months

- The member has received a therapeutic response as evidenced by normalization of serum phosphate levels, improved ambulation, healing of bone fractures, or reduced pain.

X-linked Hypophosphatemia (XLH)

PA REQUIRED

CRYSVITA (burosumab) – Medical Billing

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The requested medication must be prescribed by, or in consult with, nephrologist, endocrinologist, geneticist, or specialist experienced in the treatment of metabolic bone disorders.
- The diagnosis has been confirmed by one of the following:
 - Family history of XLH, low serum phosphate, and increased alkaline phosphatase (ALP)
 - Genetic testing confirming a pathogenic mutation of the phosphate regulating gene with homology to endopeptidases on the X chromosome (PHEX gene)
 - Serum fibroblast growth factor-23 (FGF23) level > 30 pg/mL
- If the member is 18 years or older, one of the following must be met:
 - The member's epiphyseal plate has not fused
 - The member has bone fractures
 - The member has had a 3-month trial of conventional treatment with oral phosphate supplementation combined with active vitamin D (e.g., calcitriol), as evidenced by paid claims or pharmacy printouts, and continues to have significant musculoskeletal pain and limited mobility

Renewal Criteria – Approval Duration: 12 months

- For members 18 years and older: the member has received a therapeutic response as evidenced by improvement in bone pain, mobility, or healing of bone fractures) in addition to one of the following:
 - Normalization of phosphate levels
 - Normalization of bone-specific alkaline phosphatase activity
 - Normalization of tubular reabsorption of phosphate corrected for glomerular filtration rate (TmP/GFR)
- For members younger than 18 years old: One of the following must be met:
 - Increased serum phosphate levels
 - Increased tubular reabsorption of phosphate corrected for glomerular filtration rate (TmP/GFR)
 - Decreased of serum alkaline phosphatase activity

Weight Loss

Antipsychotic Induced Weight Gain

- Metformin is covered without prior authorization.
- Ozempic is covered without prior authorization by submitting diagnosis code T43.505A, T43.505D, or T43.505S if being used for antipsychotic-induced weight gain

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- <i>Brand Required</i>	KONVOMEK (omeprazole/sodium bicarbonate)
PROTONIX (pantoprazole) PACKET – <i>Brand Required</i>	omeprazole-sodium bicarbonate packet
	pantoprazole packet
	PREVACID (lansoprazole) SOLUTAB
	PRILOSEC SUSPENSION (omeprazole)
	ZEGERID (omeprazole-sodium bicarbonate) PACKET

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)
- Nexium 10 mg, 20 mg, and 40 mg Packet:
 - PA Not Required Criteria: The member is less than 5 years old.
 - PA Required Criteria: The member must meet [Non-Solid Dosage Preparations](#) criteria

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).

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

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months for erosive esophagitis, 4 weeks for GERD

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

PA REQUIRED
GIVLAARI (givosiran) – Medical Billing

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 (e.g., acute intermittent porphyria (AIP), porphyria cutanea tarda (PCT), erythropoietic protoporphyria (EPP)) with one of the following as defined by laboratory reference range:
 - Elevated urine porphobilinogen (PBG)
 - Genetic testing confirming a pathogenic mutation (e.g., *HMBS/PBGD*)

- The member has had two documented porphyria attacks within the past 6 months requiring hospitalization, urgent healthcare visit, or intravenous hemin administration
- The member has not had a liver transplant.
- The member has addressed identifiable lifestyle triggers (e.g., [certain drugs](#), stress) If the member is a current tobacco/marijuana user, the member must have received tobacco/marijuana cessation counseling in the past year
- If the member has a history of alcohol use within the past 5 years, 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.

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 *ALAS1* levels and urinary ALA and PBG

Bowel Prep Agents

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
GAVILYTE-C SOLUTION (peg3350/sod sulf,bicarb,Cl/KCl)	CLENPIQ (sod picosulf/mag ox/citric ac)
PEG 3350 – Electrolyte Solution (generic Gavilyte-N solution)	Sod Sul-Potass Sul-Mag Sul Sol (generic Suprep)
PEG-3350 and Electrolytes Soln (generic Golytely and Gavilyte-G solution)	
SUFLAVE (peg 3350/sod sulf,chl/pot/mag)	
SUTAB (sod sulf/pot chloride/mag sulf)	

Commented [AM65]: SRA Suflave - Preferred not disadvantaged

Commented [AM66]: SRA Sutab - Preferred not disadvantaged

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

Progressive Familial Intrahepatic Cholestasis (PFIC):

PREFERRED AGENTS (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 each of the following, as evidenced by paid claims or pharmacy printouts:
 - Ursodiol
 - agents to treat pruritis: cholestyramine, rifampin, naltrexone
- Bylvay Only:
 - ALGS:
 - Genetic testing confirms pathogenic variant (e.g., *JAG1* and *NOTCH2*).
 - The member has had a 6-month trial with Livmarli, as evidenced by paid claims or pharmacy printouts.
 - 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*
 - PFIC Only: The member must have failed at least a 3-month trial of Bylvay, as evidenced by paid claims or pharmacy printouts

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 (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
REBYOTA (fecal microbiota, live-jslm) SUSPENSION – Medical Billing	
VOWST (fecal microbiota spores, live-brpk) CAPSULE	

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	fidaxomicin tablet
DIFICID (fidaxomicin) TABLET – <i>Brand Required</i>	FIRVANQ (vancomycin) SOLUTION
vancomycin capsule	VANCOCIN (vancomycin) CAPSULE
vancomycin solution	

Prior Authorization Criteria

Initial Criteria – Approval Duration: 1 month

- See [Preferred Dosage Form Criteria](#)

Crohn's Disease

Biologic Agents

$\alpha 4$ Integrin Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	(natalizumab) – See Biosimilar Agents

++ 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.

A4 $\beta 7$ Integrin Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	ENTYVIO (vedolizumab)
	ENTYVIO (vedolizumab) – <i>Medical Billing</i>

Interleukin (IL) 12/IL-23p40 Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ustekinumab - See Biosimilar Agents	

Interleukin (IL)-23p19 Inhibitor

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
TREMFYA (guselkumab)	OMVOH (mirikizumab)
TREMFYA (guselkumab) – IV Induction Medical Billing	OMVOH (mirikizumab) – IV Induction Medical Billing
	SKYRIZI (risankizumab-rzaa)
	SKYRIZI (risankizumab-rzaa) – IV Induction Medical Billing

Commented [AM67]: Tremfya SRA - Preferred non-disadvantaged formulary coverage to all IL-23 inhibitor products

Commented [KS68]: Conditional Recommendation for risankizumab as compared with ustekinumab in patients with moderate-to-severe CD and prior exposure to anti-TNF therapy (2025 ACG Clinical Guideline)

Commented [AM69R68]: Done

TNF Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
adalimumab - See Biosimilar Agents	CIMZIA (certolizumab) SYRINGE
infliximab - See Biosimilar Agents	CIMZIA (certolizumab) VIAL – <i>Medical Billing</i>

Janus Kinase (JAK) Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	RINVOQ ER (upadacitinib)

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

- If the member is a current tobacco user, the member must have received tobacco cessation counseling in the past year
- The member must have failed all preferred agents in the same class as requested product

Cimzia and Rinvoq ER Only:

- The member must have failed a 3-month trial of ustekinumab, as evidenced by paid claims or pharmacy printouts
 - Ustekinumab trial may be bypassed if member has failed a 3-month trial of a TNF-inhibitor

Entyvio Only:

- The member must have failed a 30-day trial with Rinvoq ER and 3-month trial of the following, as evidenced by paid claims or printouts
 - TNF inhibitor
 - Ustekinumab

Tremfya Only:

- The member has failed a 30-day trial with Rinvoq ER and 3-month trial of ustekinumab, as evidenced by paid claims or printouts
 - Ustekinumab trial may be bypassed if member has failed a 3-month trial of a TNF-inhibitor

Tysabri Only:

- The requested medication must be prescribed by, or in consult with, a gastroenterologist
- The member has failed a 30-day trial with Rinvoq ER and 3-month trial of the following, as evidenced by paid claims or printouts:
 - TNF inhibitor
 - Ustekinumab

Omnivoh Only:

- The member has failed a 30-day trial with Rinvoq ER and 3-month trial of the following, as evidenced by paid claims or printouts:
 - TNF inhibitor
 - IL-23p19 Inhibitor
 - Ustekinumab

Skyrizi Only:

- The member has failed a 30-day trial with Rinvoq ER and 3-month trial of the following, as evidenced by paid claims or printouts:
 - TNF inhibitor
 - IL-23p19 Inhibitor

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)
prucalopride	

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:
 - The member must have had a 30-day trial with each of the following, as evidenced by paid claims or pharmacy printouts:
 - Linness or Trulance
 - lubiprostone for members assigned female at birth
- Xphozah Only:
 - The member must have had a 30-day trial with each of the following, as evidenced by paid claims or pharmacy printouts:
 - Linness 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)	
SYMPROIC (naldemedine)	

Electronic Concurrent Medications Required

- A total of 28 days of opioid analgesics must be paid within 40 days prior to requested Movantik or Symproic'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

- 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)
antispasmodic (e.g., dicyclomine, hyoscyamine)	alosetron
loperamide	VIBERZI (eluxadoline)
LOTIRONEX (alosetron) – <i>Brand Required</i>	
tricyclic antidepressants (e.g., amitriptyline)	

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)

Commented [AM70]: SRA Zenpep - Preferred Unrestricted

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- A 30-day trial of all preferred agents will be required, as evidenced by paid claims or pharmacy printouts, 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

PA REQUIRED
DUPIXENT (dupilumab)
EOHILIA (budesonide) STICK PACKETS

Commented [AM71]: SRA Dupixent - Preferred to label non-disadvantaged all indications Allowing: AD:DSE;TCS&TCI min options (total use prior agents up to 90days max)
ASTHMA:+1 exacerbation max-tolerated ICS-LABA with 1)EOS>=150 or 2)OCS-dependency CRSwNP:INS and/or OCS EOE & PN:parity

Prior Authorization Criteria

Prior Authorization Form – Eosinophilic Esophagitis

Initial Criteria – Approval Duration: 6 months (3 months for Eohilia)

- The requested medication must be prescribed by, or in consult with, an allergist or gastroenterologist.
- The member must have ≥15 intraepithelial eosinophils per high-power field (eos/hpf).
- The member must have failed an 8-week trial of twice daily proton pump inhibitors, as evidenced by paid claims or pharmacy printouts.
- Eohilia Only: The member must have failed a 12-week trial of swallowing oral viscous budesonide nebulizer twice daily, as evidenced by paid claims or pharmacy printouts.

Renewal Criteria – Approval Duration: 12 months (no renewal for Eohilia)

- 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

Commented [KS72]: •ACG Guideline recommendation: Recommend vedolizumab as compared with adalimumab for induction and maintenance of remission (strong rec, moderate evidence)f

Commented [AM73R72]: Done

Interleukin (IL)-23p19 Inhibitor

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
TREMFYA (guselkumab) – IV Induction Medical Billing	OMVOH (mirikizumab)
TREMFYA (guselkumab)	OMVOH (mirikizumab) – IV Induction Medical Billing
	SKYRIZI (risankizumab-rzaa)
	SKYRIZI (risankizumab-rzaa) – IV Induction Medical Billing

Commented [AM74]: Tremfya SRA - Preferred non-disadvantaged formulary coverage to all IL-23 inhibitor products

Interleukin (IL) 12/IL-23p40 Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ustekinumab - See Biosimilar Agents	

TNF Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
adalimumab - See Biosimilar Agents	
infliximab - See Biosimilar Agents	
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.
- The member must have failed all preferred agents in the same class as requested product

- The member must have failed a 3-month trial of infliximab and a 30-day trial with a JAK inhibitor, as evidenced by paid claims or pharmacy printouts.
- Tremfya Only: The member must have failed a 3-month trial of infliximab and Entyvio, and a 30-day trial with a JAK inhibitor as evidenced by paid claims or pharmacy printouts.
- Omvoh and Skyrizi Only: The member must have failed a 3-month trial of infliximab, Entyvio, an Interleukin (IL)-23p19 Inhibitor and a 30-day trial with a JAK inhibitor, as evidenced by paid claims or pharmacy printouts.

5-Aminosalicylic Acid (5-ASA)

Oral

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
balsalazide capsule	AZULFIDINE (sulfasalazine)
DIPENTUM (olsalazine)	AZULFIDINE ENTAB (sulfasalazine)
mesalamine 1.2 mg DR tablet	LIALDA (mesalamine) TABLET
mesalamine ER 375 mg	mesalamine ER 375 mg, 500 mg ER capsule
PENTASA (mesalamine) – <i>Brand Required</i>	mesalamine 400 mg DR capsule, 800 mg DR tablet
sulfasalazine 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

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)
DEPEN (penicillamine) TITRATAB – <i>Brand Required</i>	CUVRIOR (trientine tetrahydrochloride)
trientine hydrochloride 250 mg	penicillamine capsule
	penicillamine tablet
	trientine hydrochloride 500 mg

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- See [Preferred Dosage Form](#) Criteria

Genetic and Rare Disease

Amyloidosis

Polyneuropathy of hereditary transthyretin-mediated amyloidosis (hATTR-PN)

TTR-specific small interfering RNA (siRNA)

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ONPATTRO (patisiran) – <i>Medical Billing</i>	

Transthyretin-directed small interfering RNA (siRNA)

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AMVUTTRA (vutrisiran) – <i>Medical Billing</i>	

Antisense Oligonucleotide (ASO)

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

- One of the following must be provided:
 - Baseline polyneuropathy disability (PND) score $\leq$ IIIb
 - Baseline Coutinho staging system stage 1 or 2
 - Baseline Neuropathy Impairment Score [NIS] of 5–130
 - Karnofsky Performance Status score of $\geq$ 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., acoramidis, tafamidis)

Renewal Criteria – Approval Duration: 12 months

- The member has received 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 $\leq$ IIIb
 - Coutinho staging system stage 1 or 2
 - Baseline Neuropathy Impairment Score [NIS] of 5–130
 - Karnofsky Performance Status score of $\geq$ 60%

Cardiomyopathy of transthyretin-mediated amyloidosis (ATTR-CM)

Transthyretin-directed small interfering RNA (siRNA)

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	AMVUTTRA (vutrisiran) – Medical Billing

TTR Stabilizers

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ATTRUBY (acoramidis)	
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.
- Confirmation of the diagnosis by both of the following must be provided:
 - presence of grade 2 or 3 positive bone tracer cardiac scintigraphy
 - absence of monoclonal protein confirmed by serum protein immunofixation, urine protein immunofixation, or serum free light chain ratio analysis
- 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.
- For Attruby only: The member must not have any of the following:
 - ALT or AST $>$ 2x ULN or Total Bilirubin $>$ 3x ULN
 - NT-proBNP level $>$ 8500 pg/mL
- The member must not have any of the following:
 - eGFR $<$ 25 mL/min/1.73m²
 - NYHA class IV symptoms or severe aortic stenosis
 - Previous heart transplant or implanted cardiac mechanical assist device

- Previous liver transplant
- Baseline 6MWT > 100 meters must be submitted.
- The member is not receiving any other TTR reducing agent (i.e., patisiran, elplontersen)

For Amvuttra Only:

- The member must have failed a 90-day trial of each Attriby and Vyndaqel/Vyndamax, as evidenced by paid claims or pharmacy printouts
- Coverage will be allowed without trial of preferred medications if the member also meets the criteria for hATTR-PN

Renewal Criteria – Approval Duration: 12 months

- For Attriby only: The member has received a therapeutic response as evidenced by stabilization or improvement from baseline in both of the following:
 - 6MWT
 - NT-proBNP level
- For Vyndaqel/Vyndamax and Amvuttra: The member has received a therapeutic response as evidenced by stabilization or improvement from baseline in both of the following:
 - 6MWT
 - NYHA class

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.

Late Infantile Neuronal Ceroid Lipofuscinosis Type 2 (CLN2)

PA REQUIRED

BRINEURA (cerliponase alfa) – *Medical Billing*

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- The member must be less than 16 years old.
- 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.
- Confirmation of the diagnosis must be submitted, as evidenced by the following:
 1. Molecular analysis that has detected two pathogenic variants/mutations in the TPP1 gene.
 2. 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:
 1. Results must show a combined score of less than 6 in the motor and language domains.
 2. 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

Fabry Disease

Alpha-Galactosidase A Pharmacological Chaperone

PREFERRED AGENTS (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.
- 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
- The member must have a deficiency of less than 35% of mean normal alpha-galactosidase A (α -Gal A) enzyme activity
- 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) or have had a kidney transplant

Renewal Criteria – Approval Duration: 12 months

- The member must have a decreased Gb3 level or GL-3 inclusions per kidney interstitial capillary (KIC) and experienced improvement in one of the following symptoms since starting treatment with requested product, subject to clinical review:
 - Acroparesthesias (burning pain in the extremities)
 - Left ventricular hypertrophy (LVH)
 - Glomerular filtration rate (GFR) and/or proteinuria

Enzyme Replacement Therapy

PA REQUIRED

ELFABRIO (pegunigalsidase alfa) – Medical Billing

FABRAZYME (agalsidase beta) – Medical Billing

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 (A or B):
 - In males assigned at birth, must meet one of the following (1 or 2):
 - 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, all of the following must be met:
 - Diagnosis must be confirmed to be caused by a pathologic galactosidase alpha gene (GLA)
 - The member is experiencing one of the following symptoms:
 - Acroparesthesias (burning pain in the extremities)
 - Impaired glomerular filtration rate (GFR) or proteinuria

- Left ventricular hypertrophy (LVH)
- Gastrointestinal manifestations (e.g., diarrhea, abdominal pain)
- GL-3 deposits within the kidney

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

Renewal Criteria – Approval Duration: 12 months

- The member must have a decreased urine or plasma Gb3 level or GL-3 inclusions per kidney interstitial capillary (KIC) and experienced improvement in one of the following symptoms since starting treatment with requested product, subject to clinical review:
 - Acroparesthesias (burning pain in the extremities)
 - Left ventricular hypertrophy (LVH)
 - Glomerular filtration rate (GFR) and/or proteinuria
 - Gastrointestinal manifestations (e.g., diarrhea, abdominal pain)

Gaucher's Disease

Enzyme Replacement Therapy

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ELELYSO (taliglucerase alfa) – <i>Medical Billing</i>	CEREZYME (imiglucerase) – <i>Medical Billing</i>
	VPRIV (velaglucerase alfa) – <i>Medical Billing</i>

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 one of the following:
 - Deficiency in 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:
 - Low hemoglobin as reported by laboratory
 - Low platelet count (<120,000/mm³)
 - Bone disease (T-score below -1.0 [DXA], height ≤ 5th percentile for age and sex in children, bone pain or bone crisis, radiologic evidence of skeletal disease)
 - Hepatomegaly (liver size 1.25 or more times normal)
 - Splenomegaly (spleen size eight (8) or more times normal)

Non-Preferred Agent Criteria:

- The member must have failed a 9-month trial of Eleyso, as evidenced by paid claims or pharmacy printouts.

Renewal Criteria – Approval Duration: 12 months

- The member has experienced a beneficial response to therapy as evidenced by normalization or significant improvement in one of the following symptoms:
 - 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 pain or crisis

Substrate Replacement Therapy

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ZAVESCA (miglustat) – <i>Brand Required</i>	miglustat
PREFERRED AGENTS (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

PA REQUIRED

KANUMA (sebelipase alfa) – *Medical Billing*

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.
- Confirmation of the member's diagnosis must be submitted, as evidenced by the following:
 1. Genetic testing confirming 2 mutations in the LIPA gene
 2. Deficiency of the LAL in peripheral blood leukocytes, fibroblasts, or dried blood spots
- The member must have one of the following:
 1. The member is ≤ 8 months old and has growth failure, severe anemia, or hepatomegaly
 2. The member has an alanine aminotransferase (ALT) $\geq 1.5x$ upper limit of normal on 2 consecutive screenings at least one week apart.
- The member must not have had a hematopoietic stem cell or liver transplant.

Renewal Criteria – Approval Duration: 12 months

- The member must have experienced and maintained clinical benefit since starting treatment with the requested medication, 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.

Hereditary Thrombotic Thrombocytopenic Purpura (hTTP) / Congenital TTP (cTTP)

AKA Congenital TTP (cTTP)

PA REQUIRED

ADZYNMA (ADAMTS13, recombinant-krhn) – *Medical Billing*

Prior Authorization Criteria

Initial Criteria – Approval Duration: Prophylaxis: 6 months, On-Demand: 2 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
- The diagnosis must be confirmed by both of the following:
 - genetic test confirming biallelic ADAMTS13 mutation
 - Unless member has a positive response to Adzynma inpatient and is continuing outpatient treatment, then genetic tests should be provided upon renewal

- ADAMTS13 activity < 10% of normal with the absence of an inhibitor (i.e. ADAMTS13 autoantibodies)
- For members requesting prophylactic therapy:
 - Member must have a history of at least one of the following:
 - At least one documented TTP event
 - Member is pregnant (approval duration through 6 weeks post-partum)
 - The member must have a documented intolerance to plasma-based therapies
- For members requesting acute (On-Demand) treatment, must have an acute event defined by both of the following:
 - Platelet count < 150,000/uL or a drop in platelet count > 25% of baseline
 - Microangiopathic hemolytic anemia (LDH > 1.5 x baseline or > 1.5 x ULN)

Renewal Criteria – Approval Duration: 12 months

The member must have experienced a therapeutic response as evidenced by the following:

- For members receiving prophylaxis, any of the following:
 1. Decreased number of acute and subacute TTP events
 2. Increased platelet counts (within 25% of baseline or > 150,000/uL)
 3. Decreased microangiopathic hemolytic anemia episodes (defined as LDH < 1.5 x baseline or < 1.5 x ULN)
- For members receiving On-Demand treatment, both of the following:
 1. Increased platelet counts (within 25% of baseline or > 150,000/uL, whichever occurs first)
 2. Decreased microangiopathic hemolytic anemia (defined as LDH < 1.5 x baseline or < 1.5 x ULN)

Alpha-Mannosidosis

PA REQUIRED

LAMZEDE (velmanase alfa-tycv) – Medical Billing

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)
- Confirmation 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 neurologist, pulmonologist, geneticist or another prescriber specializing in lysosomal storage diseases.
- The member must not have had a hematopoietic stem cell transplant.
- 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 3 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)
 - 3-minute stair climb test
 - Forced Vital Capacity (FVC) via Pulmonary Function Test

Renewal Criteria – Approval Duration: 12 months

- The member must have experienced clinical benefit since starting treatment with the requested medication, 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
- 3-minute stair climb test
- FVC via Pulmonary Function Test

Metachromatic Leukodystrophy (MLD)

Cell-based Gene Therapy

PA REQUIRED

LENMELDY (atidarsagene autotemcel) – *Medical Billing*

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 has a diagnosis of Metachromatic Leukodystrophy (MLD), confirmed by all the following:
 - Genetic testing for biallelic ARSA pathogenic variants
 - Deficient ARSA enzyme activity in leukocytes
 - Elevated urinary excretion of sulfatides
- The member must be a child with one of the following:
 - Pre-symptomatic late infantile (PSLI) onset defined as the absence of neurological signs and symptoms of MLD
 - Pre-symptomatic early juvenile (PSEJ) onset defined as the absence of neurological signs and symptoms of MLD, or physical exam findings limited to abnormal reflexes and/or clonus
 - Early symptomatic early-juvenile (ESEJ) onset disease defined as walking independently (GMFC-MLD Level 0 with ataxia or GMFC-MLD Level 1) and IQ $\geq$ 85
- The member does not have human immunodeficiency virus type 1 or 2 (HIV-1 and HIV-2), human T-lymphotropic virus type 1 or 2 (HTLV-1 and HTLV-2), hepatitis B virus (HBV), or hepatitis C (HCV)
- The member must not be a recipient of a previous allogeneic transplant or gene therapy

Mucopolysaccharidosis I (MPS I)

PA REQUIRED

ALDURAZYME (laronidase) – *Medical Billing*

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, metabolic specialist, or specialist in mucopolysaccharidoses (MPS)
- Confirmation of the member's diagnosis must be submitted, as evidenced by the following:
 1. Genetic testing confirming biallelic pathogenic mutations in the IDUA gene
 2. Deficiency in activity of the lysosomal enzyme α -L-iduronidase (IDUA) in fibroblast or leukocyte $<$ 10% of normal activity
- The member must not have had a hematopoietic stem cell transplant.
- If 3 years of age or older, must be able to walk without support
- The member's current motor function must be submitted, as evidenced by scores from the following assessments:
 1. 6-minute walk test (6MWT)
 2. Forced Vital Capacity (FVC) via Pulmonary Function Test greater than 30%

Renewal Criteria – Approval Duration: 12 months

- The member must have experienced and maintained clinical benefit since starting treatment with the requested medication, subject to clinical review, including improvement in the following scores and symptoms:
 1. 6-minute walk test (6MWT)
 2. Forced Vital Capacity (FVC) via Pulmonary Function Test

Mucopolysaccharidosis II (MPS II) – Hunter Syndrome

PA REQUIRED

ELAPRASE (Idursulfase) – *Medical Billing*

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)
- Confirmation of the member's diagnosis must be submitted, as evidenced by the following:
 - Deficiency in iduronate-2sulfatase (I2S) enzyme activity of $\leq 10\%$ of the lower limit of normal 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 that leaves the Fragile X Messenger Ribonucleoprotein genes (*FMR1*, *FMR2*) intact
- The requested medication must be prescribed by, or in consult with, a geneticist, metabolic specialist, or specialist in mucopolysaccharidoses (MPS)
- One of the following must be submitted:
 - 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

- The member must have had a therapeutic response as evidenced by improvement of one of the following:
 - 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

PA REQUIRED

VIMIZIM (elosulfase alfa) – *Medical Billing*

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)
- Confirmation 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-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 must not have had a hematopoietic stem cell transplant.
- If 3 years of age or older, must be able to walk without support
- Baseline Urine Keratan Sulfate (KS) levels must be submitted
- 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, 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

PA REQUIRED

NAGLAZYME (galsulfase) – Medical Billing

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)
- Confirmation of the member's diagnosis must be submitted, as evidenced by the following:
 - Deficiency of N-acetylgalactosamine 4-sulfatase (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.
- 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 clinical benefit since starting treatment with the requested medication, 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

PA REQUIRED

MEPSEVII (vestronidase alfa-vjbk) – Medical Billing

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)
- Confirmation 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.
- The member must not have had a hematopoietic stem cell transplant.
- If 3 years of age or older, must be able to walk without support
- One or more 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 2 or more times normal
 - Hepatomegaly (liver size 1.25 or more times normal)
 - Splenomegaly (spleen size 5 or more times normal)
 - 6-minute walk test (6MWT)
 - Forced Vital Capacity (FVC) via Pulmonary Function Test

Renewal Criteria – Approval Duration: 12 months

- The member must have experienced clinical benefit since starting treatment with the requested medication, subject to clinical review, including improvement in the one of the following scores and symptoms:
 - Urinary glycosaminoglycan (uGAG) levels normalization defined by laboratory reference range
 - Reduction in liver volume to normal size or by 10%
 - Reduction in spleen volume by 15%
 - Improvement in 6-minute walk test (6MWT)
 - Improvement in Forced Vital Capacity (FVC) via Pulmonary Function Test

Phenylketonuria (PKU)

PREFERRED AGENTS (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
- 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

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
LUMIZYME (alglucosidase alpha) – <i>Medical Billing</i>	OPFOLDA (miglustat) *does not require PA
NEXVIAZYME (avalglucosidase alfa-ngpt) – <i>Medical Billing</i>	POMBILITI (cipaglucosidase alfa-atga) – <i>Medical Billing</i>

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)
- Confirmation of the member's diagnosis must be submitted, as evidenced by the following:
 - Deficiency of acid alpha-glucosidase enzyme activity in blood-based assay or fibroblasts
 - 2% to 40% of the lab specific normal mean value partial deficiency of GAA (associated with non-classic infantile forms or late onset forms)
 - ≤ 1 % of the lab specific normal mean value partial deficiency of GAA (associated with infantile forms)
 - Detection of two 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 ventilation support for > 6 hours/day while awake

Infantile Onset

- The member must be less than 12 months old
- The member must have cardiomyopathy

Late Onset

- The member has measurable signs of Pompe disease, such as impairment in pulmonary function or motor weakness
- Ages 5 years and older: The member's current motor function must be submitted, as evidenced by scores from at least two of the following assessments:
 - 6-minute walk test (6MWT) ≥ 40 meters
 - Forced Vital Capacity (FVC) via Pulmonary Function Test ≥ 30% of the predicted value for healthy adults
- Ages under 5 years The member's current motor function must be submitted, as evidenced by scores from at least two of the following assessments:
 - 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)

- F. 6-minute walk test (6MWT)
- Pombiliti Only:
 - The member must have failed a 6-month trial of Lumizyme and/or Nexvazyme, as evidenced by paid claims or pharmacy printouts.
 - Opfolda and Pombiliti must be taken concurrently

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 stabilization or improvement of the following (subject to clinical review):
 1. Ages 5 years and older:
 - 6MWT and/or FVC
 2. Ages under 5 years:
 - CHOP-INTEND, HINE, HFMSE, MFM-32, RULM or 6MWT scores

Urea Cycle Agents

Hyperammonemia

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
BUPHENYL (sodium phenylbutyrate) – <i>Brand Required</i>	sodium phenylbutyrate
PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
PHEBURANE (sodium phenylbutyrate)	OLPRUVA (sodium phenylbutyrate)
	RAVICTI (glycerol phenylbutyrate)

Commented [AM75]: Pheburane SRA - Preferred status Does not require prior use of any other UCD drug (Brand or Generic) Both Ravicti and Olpruva require a trial and failure of Pheburane for initial therapy and continuation of therapy

N-acetylglutamate synthase (NAGS) deficiency

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
CARBAGLU (carglumic acid) – <i>Brand Required</i>	carglumic acid

Commented [AM76]: Carbaglu SRA - coverage without being disadvantaged to generic Note we will accept if a generic is on formulary but will not accept eg step through generic No package exclusions

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:

- *Ravicti Only:* One of the following apply:
 - The member is unable to tolerate sodium phenylbutyrate due to sodium content or GI distress.
 - The member has failed a 30-day trial of Pheburane
- All other agents: See [Preferred Dosage Form](#) criteria.

Therapeutic Duplication

- One strength of one medication is allowed at a time.

Hematology/Oncology

Anemia

Disease-Modifying Agents

Telomerase Inhibitor

PA REQUIRED

RYTELO (imetelstat) – Medical Billing

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 not have deletion 5q cytogenetic abnormality
- The member meets the guidelines for low- to intermediate-1 risk myelodysplastic syndrome, defined as an IPSS-R score ≤ 3.5 points *without* TP53 mutation
- The member has transfusion-dependent anemia, defined as requiring transfusion of ≥ 4 red blood cell units over an 8-week period despite a 3-month trial with an erythropoiesis-stimulating agent (ESA), as evidenced by claims history or pharmacy printouts.

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:
 - Reduction in transfusion requirements from pretreatment baseline achieving one of the following:
 - At least 2 units packed red blood cells
 - By one-half from baseline
 - Complete transfusion independence

TGF-Beta Signaling Modulator

PREFERRED AGENTS (PA REQUIRED)

REBLOZYL (luspatercept) – Medical Billing

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 not have deletion 5q cytogenetic abnormality
- Other causes of anemia (e.g., hemolysis, bleeding, recent major surgery, vitamin deficiency, etc.) have been ruled out.

For anemia due to myelodysplastic syndrome/myeloproliferative neoplasm:

- The member must require 2 or more RBC units over an 8-week period in the past 3 months
- The member has ring sideroblasts $\geq 5\%$ or a mutated SF3B1 gene
- The member meets the guidelines for low- to intermediate-1 risk myelodysplastic syndrome, defined as an IPSS-R score ≤ 3.5 points *without* TP53 mutation
- The member must meet one of the following:
 - Serum erythropoietin greater than 200 mU/mL

- Serum erythropoietin less than or equal to 200 mU/mL with an inadequate response to ESA (defined as hemoglobin of less than 11 g/dL or continued need for transfusions) despite a 3-month trial with an erythropoiesis-stimulating agent (ESA), as evidenced by claims history or pharmacy printouts.

For anemia due to beta thalassemia:

- The member must not be a recipient of a previous allogeneic transplant or gene therapy
- 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 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
- Dose will be increased to 1.25 mg/kg daily if renewal criteria has not been met.

Cell-based Gene Therapy

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
CASGEVY (exagamglogene autotemcel) – <i>Medical Billing</i>	ZYNTEGLO (betibeglogene autotemcel) – <i>Medical Billing</i>

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
- For members older than 35 years old, clinical justification must be provided (including ability to provide minimum cells required for manufacturing), subject to clinical review.
- Diagnosis should be confirmed with a non- β^0/β^0 or β^0/β^+ genotype via genetic testing
- 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.
- 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.
- Member must not have any of the following:
 - 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

Zynteglo Only:

- The member must not have received and must not be a candidate for Casgevy (subject to clinical review)

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 – <i>Medical Billing</i>	DESFERAL (deferoxamine) MESYLATE VIAL – <i>Medical Billing</i>
	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 Agglutinin Disease (CAD)

Anti-B-cell Therapy

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
rituximab - See Biosimilar Agents	

Anti-Complement Therapy

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	ENJAYMO (sutimlimab-jome) – <i>Medical Billing</i>

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.

Renewal Criteria – Approval Duration: 12 months

- The member must have had a therapeutic 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.

Hemophagocytic Lymphohistiocytosis (HLH)

PREFERRED AGENTS (PA REQUIRED)

GAMIFANT (emapalumab-lzsg) – *Medical Billing*

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.
- Confirmation of the diagnosis must be submitted, 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 $\geq 101.3^{\circ}\text{F}$ 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 $< 100,000/\text{microL}$
 - ❖ ANC $< 1000/\text{microL}$
 - 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) $\geq 2,400$ 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

Factor VIII – Non-Extended Half Life

Plasma Derived

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ALPHANATE (antihemophilic factor/Von Willebrand Factor Complex (Human))	HEMOFIL M (factor VIII plasma derived; mAb-purified)
	HUMATE-P (factor VIII/von Willebrand Factor (human))
	KOATE (factor VIII plasma derived, chromatography purified)
	WILATE (factor VIII/von Willebrand Factor (human))

Commented [KS77]: Being globally discontinued, will be supplied until inventory is depleted: expectation mid-2026

First Generation – Recombinant

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	RECOMBIMATE (factor VIII recombinant)

Commented [KS78]: Being globally discontinued, will be supplied until inventory is depleted: expectation mid-2026

Second Generation – Recombinant

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	KOGENATE FS (factor VIII recombinant)

Third Generation – Recombinant

PREFERRED AGENTS (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)	

Commented [AM79]: SRA Novoeight, Kovaltry, Xyntha, Xyntha Solofuse

All presentations of Novoeight® must be Preferred on the PDL and all non-preferred products in the class must be subject to PA

Offer is for Xyntha to be preferred on Medicaid Preferred Drug List (PDL)

Fourth Generation – Recombinant

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AFSTYLA (factor VIII recombinant, single chain)	
NUWIQ (factor VIII recombinant)	

Factor VIII Extended Half Life

PREFERRED AGENTS (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 – exel)
JIVI (factor VIII recombinant, pegylated-aucl)	

Commented [AM80]: SRA Jivi, Altuviio

Altuviio must be Preferred on the State PDL Not disadvantaged against any treatment option for Hemophilia A

Recombinant humanized bispecific monoclonal antibody

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
HEMLIBRA (emicizumab-kxwh)	

Procoagulant (TFPI inhibitors/Antithrombin inhibitors)

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
HYMPAVZI (marstacimab-hncq)	ALHEMO (concizumab-mtci)

	QFITLIA (fitusiran)

Factor VII deficiency or Hemophilia A and B with Inhibitors

Factor VIIa

PREFERRED AGENTS (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 (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
OBIZUR (recombinant, B domain-deleted porcine (pig) factor VIII)	

Hemophilia B

Factor IX – Non-Extended Half Life

Plasma Derived

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ALPHANINE SD (factor IX, plasma-derived)	
MONONINE (factor IX, plasma-derived mAb purified)	

Recombinant

PREFERRED AGENTS (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 (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)	

Commented [AM81]: Benefix SRA - Offer is for BeneFIX to be preferred on Medicaid Preferred Drug List (PDL)

Procoagulant (TFPI inhibitors/Antithrombin inhibitors)

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
HYMPAVZI (marstacimab-hncq)	ALHEMO (concizumab-mtci)
	QFITLIA (fitusiran)

Commented [AM82]: Rebinyn SRA - All presentations of Rebinyn® must be Preferred on the PDL and all non-preferred products in the class must subject to PA

Prothrombin Complex Concentrates

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

VONVENDI (recombinant human vWF)	

Factor X Deficiency

Factor X – Plasma Derived

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
COAGADEX (coagulation factor X (human))	

Factor XIII Deficiency

Factor XIII – Plasma Derived

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
CORIFACT (factor XIII concentrate (human))	

Factor XIII A – Subunit, Recombinant

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
TRETEN (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)
- *Alhemo and Qfitlia only:*
 - The member must have one of the following:
 - A diagnosis of Hemophilia A with inhibitors AND has failed a 6-month trial with Hemlibra
 - A diagnosis of Hemophilia A without inhibitors AND has failed a 6-month trial with Hemlibra and Hymoviz
 - A diagnosis of Hemophilia B with inhibitors
 - A diagnosis of Hemophilia B without inhibitors AND has failed a 6-month trial with Hymoviz
 - *Hymoviz only:*
 - The member must have one of the following:
 - A diagnosis of Hemophilia A without inhibitors AND has failed a 6-month trial with Hemlibra
 - A diagnosis of Hemophilia B without inhibitors
 - *Obizur only:*
 - The member must have anti-porcine Factor VIII inhibitors noted by prescriber attestation

Gene Therapy

PA REQUIRED
HEMGENIX (etranacogene dezaparvovec) – <i>Medical Benefit Only</i>

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 that the member is eligible to receive the gene therapy

Hematopoietic, Colony Stimulating Factors

Filgrastim

Medical Billing

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
filgrastim – See Biosimilar Agents	

Pegfilgrastim

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
pegfilgrastim – See Biosimilar Agents	

Sargramostim

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
LEUKINE (sargramostim)	
LEUKINE (sargramostim) – <i>Medical Billing</i>	

Efbemalenograstim alfa-vuxw

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	RYZNEUTA (efbemalenograstim alfa-vuxw) – <i>Medical Billing</i>

Eflapegrastim-xnst

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	ROLVEDON (eflapegrastim-xnst)
	ROLVEDON (eflapegrastim-xnst) – <i>Medical Billing</i>

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 – <i>Medical Billing</i>	SANCUSO (granisetron) PATCH
ondansetron	ZOFRAN (ondansetron)
SUSTOL (granisetron) SYRINGE – <i>Medical Billing</i>	

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 (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ULTOMIRIS (ravulizumab)	eculizumab - See Biosimilar Agents
ULTOMIRIS (ravulizumab) – <i>Medical Billing</i>	PIASKY (crovalimab-akxz) – <i>Medical Billing</i>

C3 Inhibitors

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

Factor B Inhibitors

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

Factor D Inhibitors

PREFERRED AGENTS (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 $\geq 120 \times 10^9 /L$, as evidenced by paid claims or printouts.

Piasky and Eculizumab 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 $\geq 120 \times 10^9 /L$, 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 Eculizumab 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)

PA REQUIRED

RYPLAZIM (plasminogen, human-tvmh) – *Medical Billing*

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
- Confirmation of the diagnosis must be submitted, as evidenced by the following:
 - Baseline plasminogen activity level $\leq 45\%$ (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, 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)
hydroxyurea capsule	HYDREA (hydroxyurea) CAPSULE
	SIKLOS (hydroxyurea) tablet

Second Line Agents

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ENDARI (glutamine) – <i>Brand Required</i>	+ADAKVEO (crizanlizumab-tmca)
	– <i>Medical Billing</i>
	L-glutamine

+ Based on results of the STAND clinical trial, the efficacy of Adakveo in the prevention of vaso-occlusive crisis (VOC) is unclear.

Commented [AM83]: Endari SRA

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 Endari, as evidenced by paid claims or pharmacy printouts.
- Siklos Only:
 - Baseline hemoglobin (Hb) $\leq$ 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, 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, subject to clinical review, by one of the following:
 - Increase in hemoglobin (Hb) by $\geq$ 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

Non-Solid Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
XROMI (hydroxyurea)	

Cell-based Gene Therapy

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
CASGEVY (exagamglogene autotemcel) – Medical Billing	LYFGENIA (lovotibeglogene autotemcel) – Medical Billing

Initial Criteria – Approval Duration: 12 months

- The member is $\geq$ 12 and $\leq$ 50 years of age
- The member has a diagnosis of sickle cell disease (SCD), with either β S/ β S or β S/ β 0 or β S/ 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 $< 1000/\mu\text{L}$ ($< 500/\mu\text{L}$ for members on hydroxyurea treatment) or a platelet count $< 100,000/\mu\text{L}$
- 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 ($-\alpha 3.7/-\alpha 3.7$)

- The member must not have received and must not be a candidate for Casgevy (subject to clinical review)

Thrombocytopenia

Immune Thrombocytopenic Purpura (ITP)

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
eltrombopag powder pack	ALVAIZ (eltrombopag choline)
NPLATE (romiplostim)	DOPTELET (avatrombopag)
PROMACTA (eltrombopag) – <i>Brand Required</i>	DOPTELET (avatrombopag) SPRINKLE CAP
	eltrombopag
	PROMACTA (eltrombopag) POWDER PACK
	TAVALISSE (fostamatinib)
	WAYRILZ (rilzabrutinib)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 4 months

- The member has diagnosis of immune thrombocytopenic purpura (ITP) lasting >3 months.
- The member has a platelet count of less than $30 \times 10^9/L$
- 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

- The member has a platelet count greater than or equal to $50 \times 10^9/L$

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 (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
DOPTELET (avatrombopag)	MULPLETA (lusutrombopag)
	DOPTELET (avatrombopag) SPRINKLE CAP

Prior Authorization Criteria

Initial Criteria – Approval Duration: The 2 weeks prior to procedure

- The member must have platelet count of less than $50 \times 10^9/L$
- The member must be scheduled to undergo a procedure that puts the member at risk of bleeding
- The scheduled date of procedure, and date therapy will be initiated and discontinued has been submitted:
 - o Doptelet: Member must undergo procedure 5-8 days after last dose.
 - o 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 (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
eltrombopag powder pack	ALVAIZ (eltrombopag choline)
PROMACTA (eltrombopag) – <i>Brand Required</i>	eltrombopag
	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

- The member has a platelet count greater than or equal to $50 \times 10^9/L$
- The member is currently receiving interferon-based therapy.

Aplastic Anemia

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
eltrombopag powder pack	ALVAIZ (eltrombopag choline)
PROMACTA (eltrombopag) – <i>Brand Required</i>	eltrombopag
	PROMACTA (eltrombopag) POWDER PACK

Prior Authorization Criteria

Initial Criteria – Approval Duration: 4 months

- The member must have platelet count of less than $30 \times 10^9/L$
- 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

- The member has a platelet count greater than or equal to $50 \times 10^9/L$

Hepatology

Metabolic Dysfunction-Associated Steatohepatitis (MASH)

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
OZEMPIC (semaglutide)	liraglutide
pioglitazone	REZDIFFRA (resmetirom)
VICTOZA (liraglutide) – <i>Brand Preferred</i>	WEGOVY (semaglutide)

Commented [AM84]: SRA Ozempic

Prior Authorization Criteria

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):
 - Biopsy
 - Liver Stiffness Measurement (e.g. VCTE; Fibroscan)
 - Enhanced Liver Fibrosis (ELF)
 - Magnetic Resonance Imaging Proton Density Fat Fraction (MRI-PDFF).

- 5. Magnetic resonance elastography (MRE)
- If the member has a history of alcohol use within the past 5 years, one of the following must be met:
 1. The member has a phosphatidylethanol (PEth) level < 20 ng/mL.
 2. 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.
- Rezdiffra Only:
 - If concurrent Type 2 DM diagnosis, the member has failed a 6-month trial of semaglutide combined with pioglitazone as evidenced by paid claims or pharmacy printouts
 - If no concurrent Type 2 DM diagnosis, the member has failed a 6-month trial of semaglutide as evidenced by paid claims or pharmacy printouts.
- Wegovy Only:
 - If the member qualifies for Wegovy, a dose escalation to 2mg weekly of Ozempic (semaglutide) must be tolerated before Wegovy will be authorized.

Renewal Criteria – Approval Duration: 12 months

- The member must have experienced one of the following (1-3):
 1. Resolution of steatohepatitis AND no worsening of liver fibrosis
 2. Improvement of liver fibrosis greater than or equal to one stage AND no worsening of steatohepatitis
 3. Both resolution of steatohepatitis AND improvement in fibrosis.
- Fibrosis and steatosis are measured by one of the following (1-5):
 1. Biopsy
 2. Liver Stiffness Measurement (e.g. VCTE; Fibroscan)Enhanced Liver Fibrosis (ELF)
 3. Magnetic Resonance Imaging Proton Density Fat Fraction (MRI-PDFF)
 4. Magnetic resonance elastography (MRE)

Primary Biliary Cholangitis

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ursodiol tablets	IQIRVO (elaflibanor)
	LIVDELZI (seldelpar lysine)

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 consultation with, a hepatologist or a gastroenterologist
- The diagnosis must be confirmed by liver biopsy
- The member must not have a concomitant terminal diagnosis where life expectancy is less than 1 year.
- The member must not have a history of decompensated cirrhosis
- The member must have failed at least a 6-month trial of ursodiol, as evidenced by paid claims or pharmacy printouts, as evidenced by one of the following
 - ALP > 1.67 x Upper Limits of Normal (ULN) as defined by reporting laboratory
 - Bilirubin > ULN
- If the member has a history of alcohol use within the past 5 years, 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.

Renewal Criteria – Approval Duration: 12 months

- The member has experienced a therapeutic response as evidenced by one of the following (A or B):
 - A. Both of the following (1 or 2):
 1. ALP < 1.67 x ULN OR > 15% decrease in ALP from baseline
 2. Total bilirubin is less than ULN
- The member is currently on Livdelzi and is receiving itch benefit and has had previous trials of cholestyramine, rifampin, and naltrexone that did not provide itch relief.

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	

Complicated Intra-abdominal Infections (cIAI)

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	EMBLAVEO (aztreonam-avibactam) – <i>Medical Billing</i>

COVID-19

Antiviral

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
PAXLOVID (nirmatrelvir/ritonavir)	VEKLURY (remdesivir) – <i>Medical Billing</i>

Commented [AM85]: SRA Paxlovid - Offer is for Paxlovid Preferred on PDL UM not to exceed: PA to label with COVID diagnosis and testing requirements being no more restrictive than HCP attestation QL= 1 dose pack per 30 days

Electronic Diagnosis Verification

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

Prior Authorization Criteria

- The member must be at risk for hospitalization due to COVID-19 following a 5-day course of Paxlovid during the same infection.

IL-6 Receptor antagonist

PREFERRED AGENTS (PA REQUIRED)
tocilizumab - See Biosimilar Agents

Prior Authorization Criteria

- This medication is not covered for outpatient use since it is indicated for inpatient use only

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) – <i>Brand Required</i>	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)		RIFADIN (rifampin)
pyrazinamide		SIRTURO (bedaquiline)
rifabutin		

Urinary Tract Infection

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	ORLYNVAH (sulopenem etzadroxil and probenecid)
	BLUJEPa (gepotidacin)

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/antifungal 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):
 - The member is continuing treatment upon discharge from an acute care facility.
 - Clinical justification must be provided explaining why the preferred antibiotics/antifungals are not an option due to susceptibility, previous failed trials, or other contraindications (subject to clinical review)

Tuberculosis Only:

- 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 (cabotegravir) – Medical billing	TRUVADA (emtricitabine/tenofovir disoproxil fumarate)
DESCOVY (emtricitabine/tenofovir alafenamide)	
emtricitabine/tenofovir disoproxil fumarate	
YEZTUGO (lenacapavir)	
YEZTUGO (lenacapavir) – Medical billing	

Commented [AM86]: SRA Aprelude

Commented [AM87]: Descovy SRA - Descovy is preferred & not subject to product-specific PA & at least one non-Gilead Product within the Class is subject to PA Valid only for utilization subject to State's FFS PDL & where rebates are not knowingly collected by MCOs for same claims

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)	JULUCA (dolutegravir/rilpivirine)
CABENUVA (cabotegravir/rilpivirine) – Medical Billing	
DOVATO (dolutegravir/lamivudine)	
GENVOYA (elvitegravir/cobicistat/emtricitabine/tenofovir)	
ISENTRESS (raltegravir)	
STRIBILD (elvitegravir/cobicistat/emtricitabine/tenofovir)	
TIVICAY (dolutegravir)	
TRIUMEQ (abacavir/dolutegravir/lamivudine)	
TRIUMEQ PD (abacavir/dolutegravir/lamivudine)	

Commented [AM88]: SRA Biktary - Biktary is preferred & not subject to product-specific PA & at least one non- Gilead Product within the Class is subject to PA Valid only for utilization subject to State's FFS PDL & where rebates are not knowingly collected by MCOs for same claims

Commented [AM89]: SRA Cabenuva

Commented [AM90]: SRA Dovato

Commented [AM91]: Triumeq SRA

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	EDURANT PED (rilpivirine)
ODEFSEY (emtricitabine/rilpivirine/tenofovir)	efavirenz/lamivudine/tenofovir
PIFELTRO (doravirine)	JULUCA (dolutegravir/rilpivirine)
SYMFI (efavirenz/lamivudine/tenofovir) – Brand Required	rilpivirine
SYMFI LO (efavirenz/lamivudine/tenofovir) – Brand Required	
Not Recommended for First Line Use	
etravirine	INTELENCE (etravirine)
nevirapine	nevirapine ER

Commented [AM92]: Pifeltro SRA

Commented [AM93]: SRA Symfi - Formulary Position: 1 of many

- **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) – <i>Brand Required</i>	
SYMFI LO (efavirenz/lamivudine/tenofovir) – <i>Brand Required</i>	
STRIBILD (elvitegravir/cobicistat/emtricitabine/tenofovir)	
SYM TUZA (darunavir/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 ddl/3TC or ddl/FTC regimens due to inferior virologic efficacy, limited trial experience in ART-naïve members, and ddl toxicities (including pancreatitis and peripheral neuropathy). Ddl/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 ddl 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)

Commented [AM94]: SRA Biktary, Cinduo, Delstrigo, Descovy, Simfi, Symtuza

SRA Biktary - Biktary is preferred & not subject to product-specific PA & at least one non- Gilead Product within the Class is subject to PA Valid only for utilization subject to State's FFS PDL & where rebates are not knowingly collected by MCOs for same claims

SRA Cinduo - Formulary Position: 1 of many

SRA Descovy - Descovy is preferred & not subject to product-specific PA & at least one non-Gilead Product within the Class is subject to PA Valid only for utilization subject to State's FFS PDL & where rebates are not knowingly collected by MCOs for same claims

Symfi - Formulary Position: 1 of many

SRA Symtuza - Offer requires Symtuza to be placed on the PDL as a preferred HIV agent Symtuza may be subject to a quantity limit prior authorization and other utilization controls consistent with manufacturer drug label

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	NORVIR (ritonavir)
darunavir	PREZISTA (darunavir)
EVOTAZ (atazanavir/cobicistat)	REYATAZ (atazanavir)
NORVIR (ritonavir) POWDER PACKET	
PREZCOBIX (darunavir/cobicistat)	
REYATAZ (atazanavir) POWDER PACK	
ritonavir	
SYMTUZA (darunavir/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.
- Saquinavir – Guidelines do not recommend use of unboosted SQV due to inadequate bioavailability and inferior virologic efficacy or SQV/r due to high pill 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 – <i>Medical Billing</i>	
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)	

Commented [AM95]: SRA - Evotaz, Norvir, Prezcoibx, Symtuza

SRA Norvir - Norvir is rebate eligible without being posted to the Medicaid Preferred Drug List (PDL) No MCO utilization that doesn't follow FFS PDL

SRA Prezcoibx - Offer requires Prezcoibx to be placed on the PDL as a preferred HIV agent Prezcoibx may be subject to a quantity limit prior authorization and other utilization controls consistent with manufacturer drug label

SRA Symtuza - Offer requires Symtuza to be placed on the PDL as a preferred HIV agent Symtuza may be subject to a quantity limit prior authorization and other utilization controls consistent with manufacturer drug label

Commented [AM96]: 11/3/25: Evotaz is being discontinued beginning 04/2026

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 – See Diarrhea criteria

Loss of Appetite

Dronabinol: See Nausea/Vomiting criteria

Wasting Cachexia

Serostim: See Growth Hormone criteria

Hepatitis C Antiviral Treatments

Direct Acting Antivirals

Solid Dosage Forms

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
sofosbuvir/velpatasvir	EPCLUSA (sofosbuvir/velpatasvir)
	HARVONI (ledipasvir/sofosbuvir)
	ledipasvir/sofosbuvir 90mg/400mg tablet
	MAVYRET (glecaprevir/pibrentasvir)
	SOVALDI (sofosbuvir)
	VIEKIRA PAK (dasabuvir/ombitasvir/paritaprevir/ritonavir)

Commented [AM97]: Sofosbuvir/velpatasvir VBA 1 of 1 and to label required; SRA - Not disadvantaged including PDL status & PA criteria

Non-Solid Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
MAVYRET PELLET PACKET (glecaprevir/pibrentasvir)	EPCLUSA PALLET PACKET (sofosbuvir/velpatasvir)
	HARVONI PALLET PACKET (ledipasvir/sofosbuvir)
	SOVALDI PALLET PACKET (sofosbuvir)

Commented [AM98]: Mavyret SRA - Offer is contingent upon a 1 of 1 position Removal of Prescriber & Sobriety Restrictions and Prior Authorizations

Electronic Age Verification

- Mavyret Pellet Packet:
 - PA Not Required Criteria: The member is 9 years old or less.
 - PA Required Criteria: The member must meet [Non-Solid Dosage Preparations](#) criteria in addition to Hepatitis C criteria

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.

- 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, Harvoni, and Sovaldi pellets: All of the following are met (A or B)
 - A. The member must meet [Non-Solid Dosage Preparations](#) criteria in addition to Hepatitis C criteria
 - B. The member is unable to use Mavyret pellets

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 (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ribavirin	MAVYRET (glecaprevir/pibrentasvir)
VOSEVI (sofosbuvir/velpatasvir/voxilaprevir)	SOVALDI (sofosbuvir) 400MG TABLET

Commented [AM99]: VBA for Vosevi - must prefer generic
Epclusa 1 of 1

- 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

PA REQUIRED

SYNAGIS (palivizumab) – Medical Billing

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:

Commented [KS100]: Sobi is voluntarily discontinuing the availability of SYNAGIS for RSV prophylaxis as of December 31, 2025. Effective that date, the product will no longer be manufactured, distributed, or available for purchase

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.mm6702a4>external icon

Nephrology/Urology

Complement-mediated Thrombotic Microangiopathy (TMA) /

Complement-mediated Hemolytic Uremic Syndrome

PA REQUIRED

eculizumab - See [Biosimilar Agents](#)

ULTOMIRIS (ravulizumab-cwvz)

ULTOMIRIS (ravulizumab-cwvz) – *Medical Billing*

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:
 1. Low platelet count, as defined by laboratory reference range or member requires dialysis.
 2. 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.
 3. 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 clinical benefit since starting treatment with the requested medication, 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)

alfuzosin ER

CARDURA XL (doxazosin)

doxazosin

dutasteride

finasteride

prazosin

NON-PREFERRED AGENTS (PA REQUIRED)

AVODART (dutasteride)

CARDURA (doxazosin)

ENTADFI (finasteride/tadalafil)

FLOMAX (tamsulosin)

MINIPRESS (prazosin)

PROSCAR (finasteride)

silodosin	RAPAFLO (silodosin)
tamsulosin	sildenafil
terazosin	tadalafil
	TEZRULY (terazosin) ORAL SOLUTION

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.
- Tezruly only*: Must meet Non-Solid Dosage Forms criteria

Chronic Kidney Disease

Therapeutic Duplication

- Medication classes not payable together:
 - Filspari, ACE Inhibitors, ARBs, and Renin Inhibitors are not allowed with each other.

C3 Inhibitors

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

Dual endothelin angiotensin receptor antagonist

PA REQUIRED
FILSPARI (sparsentan)

Endothelin receptor antagonist

PA REQUIRED
VANRAFIA (atrasentan)

Factor B Inhibitors

PA REQUIRED
FABHALTA (iptacopan)

GLP-1 receptor agonist

NO PA REQUIRED
OZEMPIC (semaglutide)

Kappa-opioid agonist

PA REQUIRED
KORSUVA (difelikefalin) – Medical Billing

Non-steroidal selective mineralocorticoid receptor antagonist (MRA)

PA REQUIRED

Commented [AM101]: SRA - Ozempic All presentations of Ozempic® must be Preferred on the PDL and neither restricted nor disadvantaged to any product in the respective Therapeutic Class. A clinical PA is permitted so long as it is consistent with label

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*

TEKTURN (aliskiren)

SGLT-1/SGLT-2 Inhibitor

PA REQUIRED

INPEFA (sotagliflozin)

SGLT-2 Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)

FARXIGA (dapagliflozin) – *Brand Required*

JARDIANCE (empagliflozin)

NON-PREFERRED AGENTS (PA REQUIRED)

dapagliflozin

INVOKANA (canagliflozin)

INVOKAMET (canagliflozin/metformin)

INVOKAMET XR (canagliflozin/metformin)

Commented [AM102]: SRA Jardiance

Sodium/Hydrogen Exchanger 3 (NHE3)

PA REQUIRED

XPHOZAH (tenapanor)

Systemic Corticosteroids

PREFERRED AGENTS (NO PA REQUIRED)

methylprednisolone

prednisone

NON-PREFERRED AGENTS (PA REQUIRED)

TARPEYO (budesonide-targeted release)

Vasopressin V2-receptor (V2R) Antagonist

PREFERRED AGENTS (NO PA REQUIRED)

JYNARQUE (tolvaptan) – *Brand Required*

NON-PREFERRED AGENTS (PA REQUIRED)

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

Empaveli Only:

- The member must have a diagnosis of native kidney or post-transplant recurrent C3G, or native kidney primary IC-MPGN
- The member must have eGFR ≥ 30 .
- The member must be experiencing proteinuria > 1 gram/day or UPCR ≥ 1.0 g/g despite 3-month trials with good compliance with at least one 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

Fabhalta 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 ≥ 1.0 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
 - systemic corticosteroid
 - SGLT-2 inhibitor (IgAN diagnosis only)
 - mycophenolate mofetil/sodium (C3G diagnosis only)

Filspari 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
 - systemic corticosteroid

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 m²
- 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, as evidenced by paid claims or pharmacy printouts:
 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.

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 concurrently on the following agents at the target or maximally tolerated dose, as evidenced by paid claims or pharmacy printouts:
 - ACE inhibitor or an ARB or Filspari
 - A SGLT-2 inhibitor

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

Vanrafia 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

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, Tarpeyo and Vanrafia Only*: proteinuria < 0.5 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	

Commented [AM103]: SRA Aranesp - Aranesp is not disadvantaged to all other ESAs in all approved indications

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*).

Medical Billing

PREFERRED AGENTS (PA REQUIRED)
J0604 - Cinacalcet, oral, 1 mg, (for ESRD on dialysis)
J0882 - Injection, darbepoetin alfa, 1 microgram (for ESRD on dialysis)
Q4081 - Injection, epoetin alfa, 100 units (for ESRD on dialysis) (for renal dialysis facilities and hospital use)
J0887 - Injection, epoetin beta, 1 microgram, (for ESRD on dialysis)
Q0139 - Injection, ferumoxytol, for treatment of iron deficiency anemia, 1 mg (for ESRD on dialysis)
J0879 - Injection, difelikefalin, 0.1 microgram, (for ESRD on dialysis)
Q5105 - Injection, epoetin alfa-epbx, biosimilar, (retacrit) (for ESRD on dialysis), 100 units
J3591 - Unclassified drug or biological used for ESRD on dialysis

Prior Authorization Criteria

Initial Criteria – Approval Duration: 3-month approval if member has diagnosis of End Stage Renal Disease

- If member is on renal dialysis, Medicare eligibility must be ruled out
- If member does not have End Stage Renal Disease diagnosis, non-ESRD HCPCS code should be used or ESRD should be added as a diagnosis (as appropriate).

HIF-PHIs (Hypoxia-Inducible Factor-Prolyl Hydroxylase Inhibitors)

PREFERRED AGENTS (PA REQUIRED)
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 (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 $< 50,000/\text{microL}$
 - Absolute neutrophil count $< 1000 \text{ cells}/\text{microL}$
 - Absolute lymphocyte count $< 1000 \text{ cells}/\text{microL}$

Hyperkalemia (Chronic)

PREFERRED AGENTS (CLINCIAL PA REQUIRED)

LOKELMA (sodium zirconium cyclosilicate)

SPS (sodium polystyrene sulfonate) SUSPENSION+

NON-PREFERRED AGENTS (PA REQUIRED)

VELTASSA (patiromer)

+ SPS can cause intestinal necrosis which may be fatal. Concomitant use of additional sorbitol is not recommended.

Commented [AM104]: Lokelma SRA - 1 of 2 or better Branded K-Binders Preferred PDL access with no restrictions or disadvantage to any other K-Binder

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 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, as evidenced by paid claims or pharmacy printouts:
 - 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 printouts.

Renewal Criteria – Approval Duration: 12 months

- The member's current serum potassium level is within normal limits or has been significantly reduced from baseline

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)

PA REQUIRED

OXLUMO (lumasiran) – *Medical Billing*

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), as evidenced by paid claims or pharmacy printouts.
- The member has not received a liver transplant
- One of the following must be submitted:
 - Elevated urinary oxalate excretion > 1 mmol/1.73 m² per day or 90 mg/1.73 m² 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)

cyclophosphamide

mycophenolate

systemic oral corticosteroids

NON-PREFERRED AGENTS (PA REQUIRED)

Anti-CD20 Monoclonal Antibodies

PREFERRED AGENTS (NO PA REQUIRED)

rituximab - See [Biosimilar Agents](#)

NON-PREFERRED AGENTS (PA REQUIRED)

GAZYVA (obinutuzumab) – *Medical Billing*

B-Lymphocyte Stimulator (BlyS) – Specific Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)

BENLYSTA (belimumab) – *Medical Billing*

NON-PREFERRED AGENTS (PA REQUIRED)

Calcineurin Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)

cyclosporine

tacrolimus

NON-PREFERRED AGENTS (PA REQUIRED)

LUPKYNIS (voclosporin)

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.

Renewal Criteria – Approval Duration: 12 months

- The member has experienced a therapeutic response since starting treatment, as evidenced by 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) – <i>Brand Required</i>	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	ferric citrate 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)
lanthanum chew tab	FOSRENOL (lanthanum) CHEWABLE TABLET
sevelamer carbonate powder pack	FOSRENOL (lanthanum) POWDER PACK
	RENVELA (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)
	ZUNVEYL (benzgalantamine)

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 (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)
	memantine/donepezil
	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).

- 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/Zunveyl: 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

PA REQUIRED

KISUNLA (donanemab-azbt) – *Medical Billing*

LEQEMBI (lecanemab-irmb) – *Medical Billing*

LEQEMBI IQLIK (lecanemab-irmb)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- The requested medication must be prescribed by, or in consult with, a neurologist, geriatric psychiatrist, or geriatrician specializing in dementia.
- 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.

Leqembi Iqlik only

- The member must have completed 18 months of maintenance treatment with Leqembi IV infusions

Renewal Criteria – Approval Duration: 1 year

- The member continues to show positive clinical response, such as stable or improved cognitive function

Amyotrophic Lateral Sclerosis (ALS)

PREFERRED AGENTS (NO PA REQUIRED)	PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
riluzole tablet	edaravone – <i>Medical Billing</i>	RILUTEK (riluzole) TABLET
	EXSERVAN (riluzole) FILM	
	QALSODY (tofersen) + – <i>Medical Billing</i>	
	RADICAVA (edaravone) – <i>Medical Billing</i>	
	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
 - The member has received 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.

Anticonvulsants

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 100 mg ER capsule	CARBATROL 100 MG (carbamazepine) CAPSULE
carbamazepine oral suspension	carbamazepine ER 200 mg, 300 mg capsule
carbamazepine tablet	carbamazepine XR tablet
CARBATROL 200 MG, 300 MG (carbamazepine) CAPSULE – <i>Brand Required</i>	EPITOL (carbamazepine)
EQUETRO (carbamazepine)	TEGRETOL (carbamazepine oral suspension)
TEGRETOL XR (carbamazepine) – <i>Brand Required</i>	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

Lacosamide

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) – <i>Brand Required</i>
	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	

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 – <i>Brand Required</i>	SABRIL (vigabatrin) POWDER PACK
vigabatrin powder pack	vigabatrin tablet
	VIGADRONE (vigabatrin)
	VIGAFYDE (vigabatrin)

Other

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
CELONTIN (methsuximide) – <i>Brand Required</i>	APTOM (eslicarbazepine)
DIACOMIT (stiripentol)	methsuximide
EPIDIOLEX (cannabidiol)	
eslicarbazepine	
FINTEPLA (fenfluramine) ORAL SOLUTION	
phenobarbital elixir	
phenobarbital tablet	
XCOPRI (cenobamate)	
ZTALMY (ganaxolone) SUSPENSION	

Commented [AM105]: Epidiolex SRA - Epidiolex not subject to a manual PA allows a 12-mo electronic lookback of ICD-10 codes for seizures assoc with LGS Dravet Syndrome and TSC (including G40811,G40812,G40813,G40814,G4083,G40833,G40834,Q85.1,G40.411,G40.419,G40.803,G40.804)

Commented [AM106]: Xcopri SRA

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.
 - 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 suspension	ONFI (clobazam) ORAL SUSPENSION
	SYMPAZAN (clobazam) FILM

Divalproex/Valproic Acid

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
divalproex sodium ER	DEPAKOTE SPRINKLE (divalproex sodium)
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 tablet	lamotrigine dose pack
SUBVENITE (lamotrigine)	lamotrigine ODT dose pack
	LAMICTAL ODT (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)
	levetiracetam tablet for suspension
	SPRITAM (levetiracetam) TAB FOR SUSPENSION

Rufinamide

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
rufinamide suspension	BANZEL (rufinamide) TABLET
rufinamide tablet	BANZEL (rufinamide) ORAL SUSPENSION

Topiramate

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
EPRONTIA (topiramate) SOLUTION – <i>Brand Required</i>	TOPAMAX (topiramate)
topiramate ER sprinkle cap	TOPAMAX (topiramate) SPRINKLE CAPSULE
topiramate sprinkle capsule	topiramate solution
topiramate tablet	topiramate ER capsule
TROKENDI XR (topiramate) – <i>Brand Required</i>	

Other

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
BRIVIACT (brivaracetam)	perampanel tablet
BRIVIACT (brivaracetam) ORAL SOLUTION	
FYCOMPA (perampanel) – <i>Brand Required</i>	
FYCOMPA (perampanel) ORAL SUSPENSION	
zonisamide	
zonisamide oral suspension	

Commented [AM107]: Briviact and oral solution SRA - Preferred; with PA to label allowed; First right of refusal to negotiate at generic entry

Anticonvulsant Rescue Therapies

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
diazepam rectal gel	
NAYZILAM (midazolam) NASAL SPRAY	
VALTOCO (diazepam) NASAL SPRAY	

Commented [AM108]: Nayzilam SRA

Commented [AM109]: Valtoco SRA - No restrictions, preferred

Electronic Duration Verification

- 5 doses are covered every 75 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:

- 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 (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
EMFLAZA (deflazacort) – <i>Brand Required</i>	AGAMREE (vamorolone)
	deflazacort
	PYQUVI (deflazacort)

Commented [AM110]: SRA Emflaza listed on the PDL; Not to be disadvantaged to any generic equivalents; First right of refusal to negotiate at generic entry

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:
 - Cushingoid appearance
 - Central (truncal) obesity
 - Severe behavioral adverse effect
 - Undesirable weight gain (>10% of body weight gain increase over 6-month period)
 - Diabetes and/or hypertension that is difficult to manage

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

- 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 (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, subject to clinical review, including:
 - North Star Ambulatory Assessment (NSAA)
 - 4-stair claim (4SC)

Genetic Therapies

Adeno-Associate Virus Vector

PA REQUIRED

ELEVIDYS (delandistrogene moxeparvovec-rokl) – *Medical Billing*

Exon 45 Skipping

PREFERRED AGENTS (PA REQUIRED)

AMONDYS 45 (casimersen) – *Medical Billing*

NON-PREFERRED AGENTS (PA REQUIRED)

Exon 51 Skipping

PREFERRED AGENTS (PA REQUIRED)

EXONDYS 51 (eteplirsen) – *Medical Billing*

NON-PREFERRED AGENTS (PA REQUIRED)

Exon 53 Skipping

PREFERRED AGENTS (PA REQUIRED)

VILTEPSO (viltolarsen) – *Medical Billing*

NON-PREFERRED AGENTS (PA REQUIRED)

VYONDYS 53 (golodirsen) – *Medical Billing*

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.

Elevidys is a once-per-lifetime treatment that costs > \$3 million.

- 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 dystrophin of 0.92% of normal levels.
- Elevidys is awaiting verification of clinical benefit in confirmatory trials. This gene therapy received traditional approval for ambulatory patients aged 4 years and older, and accelerated approval for non-ambulatory patients in the same age group. However, this decision was made despite the drug failing to meet its primary endpoint in a pivotal Phase III clinical trial. Consider also: administering adeno-associated virus (AAV) vector therapy to patients may prevent them from accessing future, potentially more effective gene therapies, as it can lead to the development of neutralizing antibodies against the viral vector.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 8 weeks

- The member must be assigned male at birth and be 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) $\geq$ 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, including Elevidys

Initial Criteria (Elevidys only)

- The member must be assigned male at birth and be between the ages of 4 and 7
- 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
- Diagnosis must be confirmed by the presence of abnormal dystrophin or a confirmed mutation of the dystrophin gene
- The member cannot have any deletion in exon 8 and/or exon 9 in the DMD gene
- The member does not have an elevated anti-AAVrh74 total binding antibody titer $\geq$ 1:400
- The member must be ambulatory as confirmed by the North Star Ambulatory Assessment (NSAA) scale (score of $\geq$ 1)
- The member is not on concomitant therapy with DMD-directed antisense oligonucleotides (e.g., golodirsen, casimersen, viltolarsen, eteplirsen)

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 (Elevidys is for one-time use only and will not be renewed)

- The member must meet the following parameters:
 - A 6MWT $\geq$ 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
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	PREFERRED STEP 1 AGENTS	NON-PREFERRED AGENTS

Commented [AM111]: Ingrezza, Austedo SRA

Allow step through tetrabenazine when claim is for chorea associated with Huntington's Disease Only

Preferred;QL $\geq$ 4tabs/day;TD:No req for DC or modification of offending agent if specialist required must include neuro&psychno specific AIMS score reduction for reauth&no step allowed;HD:Xenazine/Gx step allowed

(NO PA REQUIRED)	(ELECTRONIC STEP)	(PA REQUIRED)
armodafinil	SUNOSI (solriamfetol)	NUVIGIL (armodafinil)
modafinil	XYREM (sodium oxybate) – <i>Brand Required</i>	PROVIGIL (modafinil)
		sodium oxybate
		WAKIX (pitolisant)
		XYWAV (sodium, calcium, magnesium, potassium oxybate)

Electronic Step Therapy Required

- Sunosi and Xyrem:
 - 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.
 - 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, as evidenced by paid claims or pharmacy printouts.
 - 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

- The member must have received a therapeutic response, as evidenced by 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 Episodic Migraine

Calcitonin Gene-Related Peptide (CGRP) Receptor Antagonist

PREFERRED AGENTS (PA REQUIRED)	PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AIMOVIG (erenumab-aoee)	NURTEC ODT (rimegepant) TABLETS	QULIPTA (atogepant) TABLETS
AJOVY (fremanezumab-vfrm)		VYEPTI (eptinezumab-jjmr) – <i>Medical Billing</i>
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.

Prophylaxis of Chronic Migraine

Calcitonin Gene-Related Peptide (CGRP) Receptor Antagonist

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AIMOVIG (erenumab-aoee)	QULIPTA (atogepant) TABLETS
AJOVY (fremanezumab-vfrm)	VYEPTI (eptinezumab-jjmr) – <i>Medical Billing</i>
EMGALITY (galcanazumab-gnlm)	

Prior Authorization Criteria

[Prior Authorization Form – Migraine Prophylaxis/Treatment](#)

Initial Criteria – Approval Duration: 6 months

Commented [AM112]: Ajovy, Nurtec, Emgality SRA

Ajovy SRA - Not disadvantaged to any branded oral or injectable therapies indicated for migraine prevention. A step-edit may exist if limited to no more than 2 generically available oral therapies utilized for migraine prevention.

Nurtec SRA - 1 of 2 Preferred-Ubrelvy & Qulipta, option step for acute treatment up to 2 triptans with monthly QL8. Prevention of episodic, option step up to 2 preferred injectable CGRPs with monthly QL16. No disadvantage to Qulipta.

Emgality SRA - Emg & =2 self-administered injectable formulation CGRP antagonists listed as preferred; Emg may be subject to step behind =2 generic competitor products; Emg is not disadvantaged to any injectable or oral CGRP antagonist.

- The member must experience 3 or more migraine days per month.
- The member must have failed a 2-month trial 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

Non-Preferred Agents Criteria:

- **Qulipta Only:**
 - The member must have failed a 3-month trial of Ajovy, Emgality, and Aimovig, as evidenced by paid claims or pharmacy printouts.
- **Vyepti Only:**
 - The member must have failed a 3-month trial of Ajovy, Emgality, Aimovig, and Qulipta, 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

- One strength of one medication for treatment of migraine is allowed at a time.

Oral

PREFERRED AGENTS (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 (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.

Commented [AM113]: Ubrelvy, Nurtec SRA

Ubrelvy SRA - 1 of Many Preferred access with option to include PA criteria permitting use of up to two triptans prior to dispensing Ubrelvy Not disadvantaged to Nurtec No MCO utilization that doesn't follow FFS PDL

Offer is for Nurtec Preferred-Ubrelvy & Qulipta, option step for acute treatment up to 2 triptans with monthly QL8. Prevention of episodic, option step up to 2 preferred injectable CGRPs with monthly QL16.

- 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 (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
NSAIDS	diclofenac potassium powder packet (generic Cambia)
	ELYXYB (celecoxib)

Prior Authorization Criteria:

- See [Preferred Dosage Form](#) criteria

Serotonin (5-HT) 1F Receptor Agonist

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	REYVOW (lasmiditan)

Commented [KS114]: Being discontinued, distribution and production will end by 12/31/25

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

- One strength of one medication for treatment of migraine is allowed at a time

Ergot Alkaloids

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
dihydroergotamine nasal spray	BREKIYA (dihydroergotamine) INJECTION
ERGOMAR (ergotamine) SL TABLET	dihydroergotamine injection
	MIGERGOT (ergotamine/cafeine) RECTAL SUPPOSITORY

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.

Migergot rectal suppository and dihydroergotamine injection only:

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

Bekiya injection only:

- The member must have failed a 30-day trial of each of the following, as evidenced by paid claims or pharmacy printouts:
 - Dihydroergotamine nasal spray

- Ergomar SL tablet
- dihydroergotamine injection
- Migergot rectal suppository

Therapeutic Duplication

- 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)
RELPAK (eletriptan) – <i>Brand Required</i>	FROVA (frovatriptan) TABLET – <i>Brand Required</i>	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
		SYMBRAVO (rizatriptan/meloxicam) 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
- For Symbravo/Treximet: clinical justification must be provided explaining why the member cannot use individual preferred products separately or preferred agent.

Therapeutic Duplication

- 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

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

Therapeutic Duplication

- One strength of one medication for treatment of migraine is allowed at a time

Nasal Spray

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
sumatriptan spray	TOSYMRA (sumatriptan) NASAL SPRAY
	ZOMIG (zolmitriptan) NASAL SPRAY
	zolmitriptan spray

Injectable

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
sumatriptan injectable	IMITREX (sumatriptan) INJECTABLE
	ZEMBRACE SYMTOUCH (sumatriptan)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must be unable to take oral medications or experience nausea/emesis with oral triptans (subject to clinical review).
- Zolmitriptan Nasal Spray Only:
 - The member must have failed a 30-day trial with sumatriptan nasal spray, as evidenced by paid claims or pharmacy printouts.
- Sumatriptan 4mg Injectable Only:
 - The member must have failed a 30-day trial with each of the following: sumatriptan 6mg injectable and nasal spray, as evidenced by paid claims or pharmacy printouts.

Non-Preferred Agent Criteria:

- See [Preferred Dosage Form](#) criteria

Therapeutic Duplication

- One strength of one medication for treatment of migraine is allowed at a time

Cluster Headache

Cluster Headache Prevention

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, as evidenced by paid claims or pharmacy printouts.

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)
rituximab - See Biosimilar Agents	eculizumab - See Biosimilar Agents
PREFERRED AGENTS (PA REQUIRED)	
ULTOMIRIS (ravulizumab-cwvz) – <i>Medical Billing</i>	
RYSTIGGO (rozanolixizumab-noli) – <i>Medical Billing</i>	
VYVGART (ergartigimod alfa) – <i>Medical Billing</i>	
VYVGART HYTRULO (efgartigimod alfa/hyaluronidase) syringes	
VYVGART HYTRULO (efgartigimod alfa/hyaluronidase) – <i>Medical Billing</i>	
ZILBRYSQ (zilucoplan)	

Muscle Specific Kinase (MuSK) Positive

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
rituximab - See Biosimilar Agents	RYSTIGGO (rozanolixizumab-noli) – <i>Medical Billing</i>

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), 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), as evidenced by paid claims or pharmacy printouts.
- 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, as evidenced by paid claims or pharmacy printouts:
 - 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, 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 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-xiyy) – Medical Billing	(natalizumab) – See Biosimilar Agents	MAVENCLAD (cladribine)
KESIMPTA (ofatumumab)		LEMTRADA (alemtuzumab) – Medical Billing
OCREVUS (ocrelizumab) – Medical Billing		

Commented [AM115]: Kesimpta SRA - Preferred, not disadvantaged to any product in the therapeutic class. Enhanced Kesimpta rebate offer becomes effective on date in which State satisfies Rhapsido rebate offer requirements. Rhapsido requirements must be met by 7/1/2026.

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)	PLEGRIDY (peginterferon beta-1A)
BETASERON (interferon beta-1B)	
REBIF (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 – <i>Brand Required</i>	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

Fumarates

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 (NO PA REQUIRED)	PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
rituximab - See Biosimilar Agents	ENSPRYNG (satralizumab-mwge)	eculizumab - See Biosimilar Agents
	ULTOMIRIS (ravulizumab-cwvz) – <i>Medical Billing</i>	
	UPLIZNA (inebilizumab) – <i>Medical Billing</i>	

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 a positive serologic test for aquaporin-4 (AQP4)-Immunoglobulin G (IgG) antibodies
- 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 failed 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, subject to clinical review, including:
 - Reduction in relapse rate
 - Reduction in symptoms (such as pain, fatigue, motor function)

Pseudobulbar Affect (PBA)

PA REQUIRED

NUDEXTA (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:
 - Amyotrophic Lateral Sclerosis (ALS)
 - Multiple Sclerosis (MS)
 - Alzheimer's Disease

- Parkinson's Disease
 - Stroke
 - Traumatic Brain Injury (TBI)
- For diagnosis of PBA secondary to a neurological condition *other than* Amyotrophic Lateral Sclerosis or Multiple Sclerosis:
 - 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 secondary to a neurological condition other than Amyotrophic Lateral Sclerosis or Multiple Sclerosis:
 - 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

<i>Oral</i>
PA REQUIRED
NOURIANZ (lisdexamfetamine)

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 at least 1 g/day or frequency of 5x per day of levodopa/carbidopa in combination with at least one of the following: a dopamine agonist, a COMT inhibitor, a MOA-B inhibitor, and amantadine, as evidenced by paid claims or pharmacy printouts.
- 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)
	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 at least 1 g/day or frequency of 5x per day of levodopa/carbidopa in combination with at least one of the following: a dopamine agonist, a COMT inhibitor, a MOA-B inhibitor, and amantadine, as evidenced by paid claims or pharmacy printouts.
 - 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's Agents – Device-Assisted Refractory Therapies

Enteral Suspension

PA REQUIRED
DUOPA (levodopa/carbidopa)

Subcutaneous

PA REQUIRED
ONAPGO (apomorphine)
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 has a minimum of 3 hours of “off” time per day despite a 3-month trial at least 1 g/day or frequency of 5x per day of levodopa/carbidopa in combination with at least one of the following: a

dopamine agonist, a COMT inhibitor, a MOA-B inhibitor, and amantadine, as evidenced by paid claims or pharmacy printouts.

- 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 (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
APOKYN (apomorphine) – <i>Brand Required</i>	apomorphine

Inhalation

PREFERRED AGENTS (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
- The number and frequency of intermittent hypomobility or off episodes must be provided.
- 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

PA REQUIRED
EVRYSDI (risdiplam)
SPINRAZA (nusinersen) – <i>Medical Billing</i>

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 (HFME)
 - 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

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 one of the following:
 - Current Forced Vital capacity (FVC and FEV1) via Pulmonary Function Test
 - CHOP-INTEND, HINE, HFME, MFM-32, 6MWT, or RULM scores

Gene Therapy

PA REQUIRED

ZOLGENSMA (onasemnogene abeparvovec) – Medical Billing

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 1.1×10^{14} vector genomes per kilogram)
- Baseline confirmation must be submitted of anti-adenovirus serotype 9 (anti-AAV9) antibody titer is $\leq 1:50$ measured by Enzyme-linked Immunosorbent Assay (ELISA) binding immunoassay
- The 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 or 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 (PA REQUIRED)

NON-PREFERRED AGENTS (PA REQUIRED)

Commented [AM116]: Zolgensma SRA - Medicaid FFS lives only Requires policy to FDA-approved label For purposes of clarity policies for Zolgensma must have language that includes treatment of patients with ≥ 4 SMN2 copies No other restrictions allowed

Commented [AM117]: Ingrezza, Austedo SRA

Allow step through tetrabenazine when claim is for chorea associated with Huntington's Disease Only

Preferred;QL: ≥ 4 tabs/day;TD:No req for DC or modification of offending agent if specialist required must include neuro&psychno specific AIMS score reduction for reauth&no step allowed;HD:Xenazine/Gx step allowed

AUSTEDO (deutetrabenazine)	
AUSTEDO XR (deutetrabenazine)	
INGREZZA (valbenazine)	

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 a dopamine receptor blocking agent (DRBA) or dopamine receptor modifier that reduces dopaminergic tone (i.e., a partial agonist).
- 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

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 3-menstrual cycle trial of mefenamic acid or meclizolamine, celecoxib, ibuprofen 1800 mg/day or equivalent high dose NSAID
 - A 3-menstrual cycle trial of an oral estrogen-progestin or progestin contraceptives

Renewal Criteria – Approval Duration: 18 months

- The member must have received therapeutic response, as evidenced by 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

Commented [AM118]: Orilissa, Myfembree SRA

Myfembree SRA - The offer is for Preferred Coverage and not disadvantaged to other brands in the Uterine Disorder Treatments Therapeutic Class

Orilissa SRA - Preferred brand 1 of Many

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	estrogens, conjugated tablet
PREMPRO (estrogen, conj. M-progest) TABLET	FEMHRT (norethindrone-ethyl estradiol) 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)
CLIMARA PRO (estradiol-levonorgestrel) PATCH - ONCE WEEKLY	CLIMARA (estradiol) PATCH WEEKLY
COMBIPATCH (estradiol- norethindrone) PATCH - TWICE WEEKLY	DOTTI (estradiol) PATCH TWICE WEEKLY
estradiol patch weekly	estradiol patch twice weekly
MENOSTAR (estradiol) PATCH ONCE WEEKLY	LYLLANA (estradiol) PATCH TWICE 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	LYNKUET (elinzanetant)
desvenlafaxine	paroxetine mesylate 7.5mg capsules
escitalopram	VEOZAH (fezolinetant)
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):
 - One of the following must be met (a or b):
 - The member must have failed a 90-day trial of estrogen therapy, as evidenced by paid claims or pharmacy printouts
 - The member has prior history of stroke, myocardial infarction, venous thromboembolism, coronary artery disease, or breast cancer.
 - 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:

- 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):
 - Pregnancy must have resulted from an act of rape or incest, and one of the following (I or II)**
 - 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.
 - 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.
 - 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) – <i>Brand Required</i>	BONJESTA (doxylamine/vitamin B6)
meclizine	doxylamine/vitamin B6
metoclopramide	
ondansetron	

Commented [AM119]: Diclegis SRA - Preferred No PA

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 (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
MYFEMBREE (relugolix, estradiol, and norethindrone acetate)	
ORIAHNN (elagolix, estradiol, and norethindrone acetate)	

Commented [AM120]: Myfembree and Oriahnn SRA

Myfembree SRA - The offer is for Preferred Coverage and not disadvantaged to other brands in the Uterine Disorder Treatments Therapeutic Class

Oriahnn SRA - Preferred brand 1 of Many

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 meclufenamate, 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

- The member has received therapeutic response as evidenced by 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	metronidazole 125 mg tablet
tinidazole tablet	SOLOSEC (secnidazole)

Vaginal

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
CLEOCIN (clindamycin) SUPPOSITORY	CLINDESSE (clindamycin) CREAM
clindamycin cream	VANAZOLE (metronidazole) GEL
metronidazole gel	
NUVESSA (metronidazole) GEL	
XACIATO (clindamycin phosphate) GEL	

Commented [AM121]: Nuversa and Xaciato SRAs

Fungal Infections

Oral

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
fluconazole tablet	BREXAFEMME (ibrexafungerp) TABLETS
	VIVJOA (oteseconazole) CAPSULES

Vaginal

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
terconazole cream	miconazole 3 suppository
terconazole suppository – labeler 00713	GYNAZOLE 1 (butoconazole) CREAM
	terconazole suppository – labeler 45802

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must have failed trials of all preferred agents of unique ingredients (oral and vaginal), 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, as evidenced by paid claims or pharmacy printouts.
 - 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	ALOMIDE (loodoxamide)
BEPREVE (bepotastine) – Brand Required	bepotastine
cromolyn	epinastine
olopatadine 0.1%	olopatadine 0.2%

	ZERVIAE (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	gatifloxacin drops
gentamicin sulfate drops	OCUFLOX (ofloxacin) DROPS
moxifloxacin drops (generic Vigamox)	VIGAMOX (moxifloxacin) DROPS
NATACYN (natamycin) DROPS	XDEMVIY (lotilaner)
neomycin SU/polymyxin B/gramicidin drops	
ofloxacin drops	
polymyxin B/trimethoprim drops	
sulfacetamide drops	
tobramycin drops	

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
neomycin SU/bacitracin/polymyxin B ointment	sulfacetamide ointment
TOBREX (tobramycin) OINTMENT	

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- Xdemvy Only:* The member must have failed a 2-dose regimen of oral ivermectin, as evidenced by paid claims or pharmacy printouts.
- All other agents:* 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	BLEPHAMIDE (sulfacetamide/prednisone)
TOBRADEX (tobramycin/dexamethasone) OINTMENT	MAXITROL (neomycin/polymyxin b/dexamethasone) OINTMENT
	neomycin/bacitracin/polymyxin b/hydrocortisone ointment
	NEO-POLYCIN HC (neomycin SU/bacitracin/polymyxin B/hydrocortisone) OINTMENT
	PRED G S.O.P. (gentamicin/prednisone) 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 – <i>Brand Required</i>	clobetasol 0.05% drops
DUREZOL (difluprednate) DROPS – <i>Brand Required</i>	dexamethasone sodium phosphate drops
FLAREX (fluorometholone) DROPS	difluprednate drops
fluorometholone drops	INVELTYS (loteprednol) DROPS
FML FORTE (fluorometholone) DROPS	fluorometholone drops (labeler 60219)
LOTEMAX (loteprednol) GEL DROPS – <i>Brand Required</i>	FML LIQUIFILM (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)
LOTEMAX (loteprednol) OINTMENT	

Non-Steroidal Anti-inflammatory Drugs (NSAIDS)

Drops

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
diclofenac sodium drops	ACULAR (ketorolac) DROPS
ketorolac 0.5% drops	ACULAR LS (ketorolac) DROPS
NEVANAC (nepafenac) DROPS	ACUVAIL (ketorolac) DROPS
PROLENSA (bromfenac) DROPS – <i>Brand Required</i>	bromfenac sodium drops
	BROMSITE (bromfenac sodium) DROPS
	ILEVRO (nepafenac) DROPS
	ketorolac 0.4% drops

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 – <i>Brand Required</i>		cyclosporine dropperette
XIIDRA (lifitegrast)		MIEBO (perfluorohexyloctane)
		RESTASIS MULTIDOSE (cyclosporine)
		TRYPTYA (acoltremon)
		VEVYE 0.1% EYE DROP (cyclosporine)

Commented [AM122]: Eysuvis SRA - Eysuvis shall not be subject to a step edit through a brand or generic prescription product

Commented [KS123]: Watch for pricing, maybe 4Q2025?

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 – <i>Brand Required</i>	apraclonidine 0.5% drops
ALPHAGAN P 0.15% (brimonidine) DROPS – <i>Brand Required</i>	brimonidine 0.1% drops
brimonidine 0.2% drops	brimonidine 0.15% drops
COMBIGAN (brimonidine-timolol) DROPS – <i>Brand Required</i>	brimonidine-timolol 0.2%-0.5% drops
SIMBRINZA (brinzolamide/brimonidine) DROPS	IOPIDINE (apraclonidine) 1% DROPS

Beta Blockers

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
BETIMOL (timolol) DROPS	betaxolol 0.5% drops
BETOPTIC S (betaxolol) 0.25% DROPS	brimonidine/timolol drops
carteolol drops	COSOPT (dorzolamide/timolol) DROPS
COMBIGAN (brimonidine/timolol) DROPS – <i>Brand Name Required</i>	timolol drops once daily
dorzolamide/timolol drops	timolol drops (Betimol generic)
ISTALOL (timolol maleate) DROPS ONCE DAILY – <i>Brand Required</i>	timolol gel forming solution
levobunolol drops	TIMOPTIC (timolol maleate) DROPS
timolol maleate drops (Timoptic generic)	TIMOPTIC OCUDOSE (timolol) PF DROPS
timolol maleate/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) – <i>Brand Required</i>	brinzolamide
dorzolamide	COSOPT (dorzolamide/timolol)
dorzolamide/timolol	
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)	

Commented [AM124]: Rhopressa, Rocklatan SRA

For both - Bid for unrestricted access only PA or step is not allowed

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.
- Clinical justification must be provided (subject to clinical review), 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

- Clinical justification must be provided (subject to clinical review), including activities of daily living are positively impacted by drug therapy.

Inherited Retinal Dystrophy

PA REQUIRED
LUXTURN A (alglucosidase alfa) – Medical Billing

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
- 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

- 3. 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

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
adalimumab - See Biosimilar Agents	tocilizumab - See Biosimilar Agents
infliximab - See Biosimilar Agents	

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- The requested medication must be prescribed by, or in consult with, an ophthalmologist or rheumatologist.
- The member has failed a 6-month trial of a preferred agent, as evidenced by paid claims or pharmacy printouts.

Vernal Keratoconjunctivitis

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, as evidenced by paid claims or pharmacy printouts:
 - 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- Complement Inhibitors

PA REQUIRED
IZERVAY (avacincaptad pegol) – <i>Medical Billing</i>
SYFOVRE (pegcetacoplan) – <i>Medical Billing</i>

Izervay was tested in two key studies (GATHER1 NCT02686658 and GATHER2 NCT04435366) and showed significant reduction in autofluorescence loss at 12 months. However, patients in the treatment groups did not show any improvement in best-corrected visual acuity or low luminance visual acuity compared to placebo.

In two Phase 3 clinical studies of Syfovre (OAKS NCT03525613 and DERBY NCT03525600), at 24 months both studies showed a significant reduction in autofluorescence-detected atrophy compared to placebo. However, there were no functional improvements in visual acuity, reading speed, reading independence, or mean microperimetry sensitivity between the treatment and placebo groups.

Prior Authorization Criteria

For Izervay:

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, an ophthalmologist or retina specialist with experience providing intraocular injections and implants
- The member must be ≥50 years of age
- The member must have a diagnosis of GA not affecting the foveal center point, secondary to AMD
- The member must meet the following requirements:
 - Best-Corrected Visual Acuity (BCVA) between 20/25 and 20/320 in study eye
 - GA lesion size ≥2.5 and ≤17.5 mm² with at least 1 lesion ≥1.25 mm²
 - Absence of Choroidal neovascularization (CNV) in both eyes

For Syfovre:

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, an ophthalmologist or retina specialist with experience providing intraocular injections and implants
- The member must be ≥60 years of age
- The member must meet the following requirements:
 - Best-Corrected Visual Acuity (BCVA) ≥ 24 Early Treatment of Diabetic Retinopathy Study (ETDRS) letters
 - GA lesion size ≥2.5 and ≤17.5 mm² with at least 1 lesion ≥1.25 mm²
 - Presence of extrafoveal lesions
 - Absence of Choroidal neovascularization (CNV) in both eyes

Renewal Criteria – Approval Duration: 12 months

- The member must have experienced clinical benefit since starting treatment with the requested medication, subject to clinical review

Ophthalmology Injection- VEGF Inhibitor

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
aflibercept – See Biosimilar Agents	SUSVIMO (ranibizumab) – <i>Medical Billing</i>
BEOVU (brolocizumab-dbl) – <i>Medical Billing</i>	
EYLEA HD (aflibercept) – <i>Medical Billing</i>	
ranibizumab – See Biosimilar Agents	
VABYSMO (faricimab-svoa) – <i>Medical Billing</i>	

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
5. diabetic retinopathy (ranibizumab 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 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, as evidenced by paid claims or pharmacy printouts.
- For Susvimo only: the member must have previously responded to at least two intravitreal injections of a VEGF inhibitor medication

Renewal Criteria – Approval Duration: 12 months

- The member must have experienced clinical benefit since starting treatment with the requested medication, 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

Non-Opioid Pain Medications

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	

Commented [AM125]: Ztlido SRA - 1 of Many - Preferred PDL access with an optional Step Edit or PA after a 30 day or less trial of a preferred lidocaine 5% 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	CELEBREX (celecoxib)
diclofenac sodium DR 50 mg, 75 mg	DAYPRO (oxaprozin)
etodolac	diclofenac potassium 25 mg tablet
flurbiprofen	diclofenac potassium 25 mg capsule
ibuprofen	diclofenac sodium 25 mg DR
indomethacin	diclofenac sodium 100 mg ER tablet
indomethacin ER	diclofenac/misoprostol
ketoprofen IR	etodolac ER
ketorolac	famotidine/ibuprofen
meclofenamate	FELDENE (piroxicam)
mefenamic acid	fenoprofen
meloxicam	ketoprofen ER 200 mg
nabumetone	LOFENA (diclofenac potassium)
naproxen	meloxicam, submicronized
piroxicam	NALFON (fenoprofen)
sulindac	NAPRELAN (naproxen)
tolmetin	naproxen ER 500 mg
	naproxen/esomeprazole
	oxaprozin
	RELAFEN DS (nabumetone)

Electronic Diagnosis Verification

- Mefenamic acid and Meclofenamate: Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- Non-preferred agents with no same active ingredient preferred:
 - The member must have failed a 7-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

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
	diclofenac topical solution (labeler 59088)

Prior Authorization Criteria

- See [Preferred Dosage Form](#) Criteria

Sodium Channel Blockers

PREFERRED AGENTS (NO PA REQUIRED)

JOURNAVX (suzetrigine)

Electronic Age Verification

- The member must be 18 years of age or older.

Electronic Duration Verification

- 14-days allowed per 60 days

First Fill

- Journavx must be filled with a 7-day supply if no previous fill within past 40 days

Therapeutic Duplication

- Concurrent use with opioid medication is not covered

Opioid Pain Medications

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

[Abuse-Deterrent Opioid Analgesics | FDA](#)

PREFERRED AGENTS (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 (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 (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 25 mg, 75 mg, 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)

PA REQUIRED

QUTENZA (capsaicin patch) – Medical Billing

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, methylidopa)
 - 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
LYVISPAAH (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	INTUNIV (guanfacine ER)
ONYDA XR (clonidine)		
guanfacine		
guanfacine ER		

Commented [AM126]: Onyda SRA

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, methylodopa, or tizanidine)

Electronic Step Therapy Required

- Clonidine ER:
 - 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.
 - 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 (PA REQUIRED)	
QELBREE (viloxazine)	

Commented [AM127]: Qelbree SRA - Trial and failure of any 2 preferred ADHD Agents or Atomoxetine Both pathways to approval must be available

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 60-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	dextroamphetamine/amphetamine ER (generic Mydayis ER)
DEXEDRINE SPANSULE (dextroamphetamine ER) - Brand Co-Preferred	DYANAVEL XR (amphetamine)
lisdexamfetamine 10 mg capsules	lisdexamfetamine capsules
VYVANSE (lisdexamfetamine) – Brand Required except for 10 mg	MYDAYIS ER (dextroamphetamine/amphetamine)
	VYVANSE (lisdexamfetamine) 10 mg

Commented [AM128]: SRA - okay to co-prefer with generic

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 (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
lisdexamfetamine chew	ADZENYS XR – ODT (amphetamine) – Brand Required
	amphetamine ER ODT
	DYANAVEL XR (amphetamine) SUSPENSION
	VYVANSE (lisdexamfetamine) CHEW TABLET
	XELSTRYM (dextroamphetamine) PATCH

Immediate Release

PREFERRED AGENTS (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)
dexmethylphenidate ER	APTENSIO XR (methylphenidate) – <i>Brand Preferred</i>
methylphenidate CD 30-70 (generic Metadate CD)	AZSTARYS (serdexmethylphenidate/dexmethylphenidate)
methylphenidate ER tablet (generic Concerta)	CONCERTA (methylphenidate)
methylphenidate ER tablet (generic Metadate CD)	FOCALIN XR (dexmethylphenidate)
methylphenidate LA capsules – 50-50 (generic Ritalin LA) – 10 mg, 20 mg, 30 mg, 40 mg	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
	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 – <i>Brand Required</i>	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 solution	METHYLIN (methylphenidate) SOLUTION
	methylphenidate chew tablet

Electronic Age Verification

- The member must be age 6 or older or must meet prior authorization criteria for ages 5 and under listed below.
- Non-solid dosage forms:
 - The member must meet both of the following criteria or meet [Non-Solid Dosage Form](#) criteria
 - The member must be age 9 or younger
 - The member must not be on other solid dosage forms (this will reject for therapeutic duplication)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- For members ages 5 and under:

Commented [AM129]: SRA Quillichew and Quilivant

- 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-teacher behavior management and/or behavior classroom interventions to help 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-Solid Dosage Forms Only:
 - The member must have had two 7-day trials of a methylphenidate non-solid dosage form, as evidenced by paid claims or pharmacy printouts.
- Aptensio XR and Azstarys Only – Both of the following must be met:
 - 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, as evidenced by paid claims or pharmacy printouts.
 - 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, as evidenced by paid claims or pharmacy printouts.
- Jornay PM Only - Both of the following must be met:
 - 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), as evidenced by paid claims or pharmacy printouts.
 - 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).
- Mydayis Only:
 - The member must have a wearing off effect where late afternoon/evening functioning performance has been impacted despite a 7-day trial with Vyvanse or its generic alternative, as evidenced by paid claims or pharmacy printouts.
- 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. Hultkower 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 stimulants are not allowed with short-acting stimulants:

- 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 (lisdexamfetamine)
- Vyvanse Chewable (lisdexamfetamine)

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 alkalinizing 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 dexamethylphenidate 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	CELEXA (citalopram)
amoxapine	citalopram capsule 30 mg
AUVELITY (dextromethorphan/bupropion)	CYMBALTA (duloxetine)
bupropion	EFFEXOR XR (venlafaxine)
bupropion ER	LEXAPRO (escitalopram)
bupropion SR	PAXIL (paroxetine)
citalopram tablet	PAXIL CR (paroxetine)
clomipramine	PRISTIQ ER (desvenlafaxine)
desipramine	PROZAC (fluoxetine)
desvenlafaxine ER	REMERON (mirtazapine)
doxepin	sertraline capsule
duloxetine	VIIBRYD (vilazodone)
escitalopram	WELLBUTRIN (bupropion)
fluoxetine	WELLBUTRIN SR (bupropion)
fluvoxamine	WELLBUTRIN XL (bupropion)
mirtazapine	ZOLOFT (sertraline)

Commented [AM130]: SRA Auvelity - 1)Non-Preferred Tier Status
 2) May be subject to up to two generic steps Step therapy criteria must not mandate trial/failure of any specific agent or class of agents
 3)May be subject to PA to confirm age and diagnosis with minimum authorization of 12 months

nefazodone	
nortriptyline	
paroxetine	
paroxetine ER	
protriptyline	
sertraline tablet	
trazodone	
venlafaxine	
venlafaxine ER	
vilazodone	
High-Cost Options	
EXXUA (gepirone)	
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 oral solution	RALDESY (trazodone) ORAL SOLUTION
mirtazapine ODT	REMERON (mirtazapine) SOLTAB
sertraline oral concentrate	ZOLOFT (sertraline) ORAL CONCENTRATE
High-Cost Options	
paroxetine oral suspension	

Electronic Age Verification

- Auvelity, Exxua, Fezima: The member must be 18 years of age or older.

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.
- Exxua Only: Titration required, at least 3 days of 18.2 mg before increasing to 36.3 mg; at least 4 days of 36.3 mg before increasing to 54.5 mg; after an additional 7 days the dose can be increased to the maximum dosage of 72.6 mg.
- 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

- Exxua, 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
- Exxua, 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)	

Commented [AM131]: Caplyta SRA - Offer excludes states with mental health prohibition language or provider-specific or dispense as written policies or requirements Preferred one of many PDL unrestricted

Commented [AM132]: SRA Vraylar - Preferred brand Unrestricted for all indications with exception for AMDD: allows for insufficient response to no more than 1 antidepressant

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 – <i>Brand Co-Preferred</i>	
High-Cost Options	
aripiprazole ODT	ABILIFY DISCMELT (aripiprazole)
aripiprazole solution	OPIZA FILM (aripiprazole)
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)	
ERZOFRI (paliperidone)	
INVEGA HAFYERA (paliperidone)	
INVEGA SUSTENNA (paliperidone)	
INVEGA TRINZA (paliperidone)	
RISPERDAL CONSTA (risperidone microspheres) – <i>Brand Required</i>	
UZEDY (risperidone)	
ZYPREXA RELPREVV (olanzapine)	

Commented [AM133]: SRA - Invega Hafyera, Invega Sustenna, Invega Trinza, Aristada, Aristada Initio, Erzofri, Abilify Asimtufii, Abilify Maintena, Uzedy

SRA - not to be disadvantaged among any other long-acting antipsychotics ("aLAI") product

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: chlorthalidopoxide, clonazepam, diazepam, alprazolam ER
- Benzodiazepines are not covered with:
 - Opioids: Override Criteria Available – See Opioid or Benzodiazepine criteria
 - 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 criteria

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:
 - PA Not Required Criteria: A 7-day supply of eszopiclone has been paid within 90 days prior to Belsomra's date of service.
 - PA Required Criteria: The member must have failed 7-day trial of eszopiclone, as evidenced by paid claims or pharmacy printouts.
- Zolpidem:
 - PA Not Required Criteria: A 7-day supply of zolpidem 5mg or zolpidem ER has been paid within 90 days prior to zolpidem 10mg's date of service.
 - PA Required Criteria: The member must have failed 7-day trial of zolpidem 5mg or zolpidem ER, 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.
 1. eszopiclone
 2. zolpidem IR
 3. 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, flurazepam, 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 benzodiazepines)

- 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.

- o 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, methylidopa)
 - 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)
	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:
 - o The member must be unable to perceive light in either eye.
 - o 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

PA REQUIRED
HETLIOZ (tasimelteon) – <i>Brand Required</i>
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.
- Genetic testing confirms 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.

Pulmonology

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.

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)	

Commented [AM134]: Combivent SRA

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) – <i>Brand Required</i>	BEVESPI AEROSPHERE (glycopyrrolate/formoterol)	DUAKLIR PRESSAIR (aclidinium/formoterol)
STIOLTO RESPIMAT (tiotropium/olodaterol)		umeclidinium/vilanterol

Commented [AM135]: Stiolto SRA

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) – <i>Brand Required</i>	TUDORZA PRESSAIR (aclidinium)
SPIRIVA RESPIMAT 2.5 MCG (tiotropium)	YUPELRI (revefenacin)

Commented [AM136]: SRA Spiriva Respimat 2.5mcg and 1.25mcg

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	PERFORMIST (formoterol)
SEREVENT DISKUS (salmeterol)	STRIVERDI RESPIMAT (olodaterol)

Biologics

Anti-IL-5 biologics

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
FASENRA (benralizumab)	CINQAIR (reslizumab) – <i>Medical Billing</i>
NUCALA (mepolizumab) SYRINGE, AUTOINJECTOR	
NUCALA (mepolizumab) VIAL – <i>Medical Billing</i>	

Anti-IL-4/13 biologics

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

Allergic Asthma-directed biologics

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
XOLAIR (omalizumab) SYRINGE, AUTOINJECTOR	
XOLAIR (omalizumab) VIAL – <i>Medical Billing</i>	

Thymic Stromal Lymphopoietin (TSLP) blocker

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
TEZSPIRE (tezepelumab-ekko) PENS	
TEZSPIRE (tezepelumab-ekko) VIAL and SYRINGES – <i>Medical Billing</i>	

Prior Authorization Criteria

Prior Authorization Form – Asthma

Commented [AM137]: Fasenra, Tezspire, Dupixent, Nucala, Xolair SRA

Fasenra - If PA is required no competitive disadvantage to other preferred agents and aligned to product label for all FDA indications and w/EOS > or = 150

Tezspire - SRA PA allowed if fully consistent with FDA-approved indication; simple PA form requiring physician attestation only comprising of yes/no questions with no requirement for additional documentation; no biomarker threshold or testing requirements

Dupixent - Preferred to label non-disadvantaged all indications
Allowing: AD:DSE;TCS&TCI min options (total use prior agents up to 90days max) ASTHMA:+1exacerbation max-tolerated ICS-LABA with 1)EOS>=150 or 2)OCS-dependency CRSwNP:INS and/or OCS EOE & PN:parity

Xolair - Market basket includes Dupixent NucalaCinqair Fasenra and Tezspire

Nucala - Preferred Brand with PA to label

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

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, Nucala 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

Nucala 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 months despite continued compliant use of an inhaled steroid AND long-acting beta agonist (LABA) AND long-acting muscarinic antagonist (LAMA) AND Dupixent for at least 4 months, 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 (Steroid Inhalers)

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ARNUITY ELLIPTA (fluticasone) – <i>Brand Required</i>	ALVESCO (ciclesonide)
ASMANEX HFA (mometasone)	fluticasone ellipta
ASMANEX (mometasone) TWISTHALER	fluticasone HFA
budesonide suspension	fluticasone diskus
PULMICORT FLEXHALER (budesonide)	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_asthmanagementguidelinesreport-2-4-21.pdf

Electronic Age Verification:

- Fluticasone HFA does not require PA for ages 4 and under
- Asmanex Twisthaler/Arnuity Ellipta 50 mcg – The member must be 5 years old or greater and less than 12 years old.
- Arnuity Ellipta 100 mcg and 200 mcg – The member must be 12 years of age or older

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.
- *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

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED STEP 1 AGENTS (PA REQUIRED)	NON-PREFERRED STEP 2 AGENTS (PA REQUIRED)
DULERA (mometasone/formoterol)	ADVAIR DISKUS (fluticasone/salmeterol) – <i>Brand Required</i>	*BREYNA (budesonide/formoterol)
	ADVAIR HFA (fluticasone/salmeterol) – <i>Brand Required</i>	BREO ELLIPTA (fluticasone/vilanterol) – <i>Brand Required</i>
		*budesonide/formoterol
		*fluticasone/salmeterol
		*fluticasone/vilanterol
		SYMBICORT (budesonide/formoterol) – <i>Brand Required</i>
		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.
- *Generic Non-Preferred Agents: See [Generic Non-Preferred Agents](#) Criteria

Corticosteroid/Anticholinergics/Long-Acting Beta Agonists Combinations

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
BREZTRI AEROSPHERE (budesonide/glycopyrrolate/formoterol)	
TRELEGY ELLIPTA (fluticasone/umeclidinium/vilanterol)	

Commented [AM138]: Breztri, Trelegy SRA

BREZTRI to be Preferred on PDL. If PA is required, no competitive disadvantage to other triple combination inhaler preferred agents and aligned to product label for all FDA indications.

Trelegy SRA - Preferred and not disadvantaged to any other triple combination product

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 90-day trial of triple therapy (Steroid/Long-Acting Beta Agonist/Long-Acting Anticholinergic), as evidenced by paid claims or pharmacy printouts.

Phosphodiesterase-3 (PDE3) and Phosphodiesterase-4 (PDE4) Inhibitor

PREFERRED AGENTS (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, as evidenced by paid claims or pharmacy printouts.
 - 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, as evidenced by paid claims or pharmacy printouts.

Rescue Inhalers

Albuterol / Levalbuterol		
PREFERRED AGENTS	PREFERRED STEP 1 AGENTS	NON-PREFERRED STEP 2 AGENTS

(NO PA REQUIRED)	(ELECTRONIC STEP REQUIRED)	(PA REQUIRED)
VENTOLIN (albuterol) HFA – <i>Brand Required</i>	levalbuterol HFA	albuterol HFA
	PROAIR RESPICLICK (albuterol)	PROVENTIL (albuterol) HFA
		XOPENEX (levalbuterol) HFA

Rescue Inhaler - Corticosteroid/Short-Acting Beta Agonist (SABA) Combination

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	AIRSUPRA (albuterol/budesonide)

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.

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.

Electronic Step Therapy Required

- Levalbuterol HFA:
 - 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.
 - 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.
 - 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.
 - 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.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- Airsupra only:
 - One of the following must be met (1 or 2):
 1. The member must have failed a 30-day trial of each albuterol and an ICS/formoterol, as evidenced by paid claims or pharmacy printouts.
 2. The member is not on any other asthma medications and ages ≥ 6 or ≤ 11
- Non-preferred albuterol only: See [Preferred Dosage Form](#) Criteria

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. PMID: PMC4641773
2. Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention, 2025. Updated May 2025. Available from: www.ginasthma.org 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
3. [Ploin, D., Chapuis, F. R., Stamm, D., Robert, J., David, L., Chatelain, P. G., Dutau, G., & Floret, D. \(2000\). 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. Pediatrics, 106\(2\), 311–317. <https://doi.org/10.1542/peds.106.2.311>](#)

Fibrosis

Cystic Fibrosis – Inhaled Antibiotics

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
tobramycin (generic Tobl)	BETHKIS (tobramycin)
PREFERRED AGENTS (PA REQUIRED)	CAYSTON (aztreonam)
ARIKAYCE (amikacin/nebulizer)	KITABIS PAK (tobramycin/nebulizer)
	TOBI (tobramycin)
	TOBI PODHALER (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.
- Tobl Podhaler only:
 - The member must have failed one 28-day trial of each: Kitabis Pak and a generic tobramycin nebulized agent, as evidenced by paid claims or pharmacy printouts.

- All other agents: See [Preferred Dosage Form Criteria](#)

Cystic Fibrosis – CFTR Modulators

PA REQUIRED
ALYFTREK (vanzacaftor/tezacaftor/deutivacaft)
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

Cystic Fibrosis – Osmotic Agent

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 (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
pirfenidone	ESBRIET (pirfenidone)
	JASCAYD (nerandomilast)
	OFEV (nintedanib)

Commented [KS139]: WAC is twice (SSDC x 2) for Esbriet and Ofev. Step? Watch 1Q/2Q Rebate

Prior Authorization

Initial Criteria – Approval Duration: 12 months

- The requested medication must be prescribed by, or in consult with, a pulmonologist or rheumatologist.
- The member must have forced vital capacity (FVC) $\geq$ 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.

Non-Preferred Agent Criteria:

- The member must have failed a 6-month trial with the preferred agent, as evidenced by paid claims or pharmacy printouts.

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 (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
tocilizumab – See Biosimilar Agents	

Progressive Disease

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
rituximab - See Biosimilar Agents	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 member must have forced vital capacity (FVC) $\geq$ 45% of predicted within prior 60 days
- The member must have carbon monoxide diffusing capacity (DLCO, corrected for hemoglobin) of 30% to 79% of predicted.
- The member must have one of the following within the past 24 months:
 - a FVC decline of $\geq$ 10%
 - a FVC decline of $\geq$ 5% and worsening respiratory symptoms or fibrotic changes
 - worsening respiratory symptoms and fibrotic changes

Obstructive Sleep Apnea (OSA)

PA REQUIRED

ZEPBOUND (tirzepatide)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The requested medication must be prescribed by, or in consult with, a neurologist, pulmonologist, otolaryngologist, or other sleep medicine specialist
- The member must have a diagnosis of moderate to severe OSA defined as apnea-hypopnea index (AHI) $>$ 15 determined by in-lab attended sleep study or polysomnography (PSG)
- The member does not have diabetes type II
- The member must have a diagnosis of obesity (defined as BMI $\geq$ 30 kg/m²)
- The member must have failed a 6-month trial of continuous positive airway pressure (CPAP) along with the weight management program.
- If the member qualifies for tirzepatide, the most cost effective tirzepatide product will be authorized
- **Zepbound Only:**
 - The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
 - The member must have documentation of participation in a comprehensive weight management program that includes behavioral modification, a reduced-calorie diet, increased physical activity, and pharmacotherapy for at least 6 months with semaglutide.
If semaglutide is not tolerated, the pharmacotherapy requirement must be met with phentermine (if phentermine is unable to be used, bupropion, naltrexone, or topiramate may also be used to meet this requirement)

Renewal Criteria – Approval Duration: 12 months

- The member has a demonstrated clinical response evidenced by any of the following:
 - Decrease in AHI determined by PSG $\geq$ 20%, or change in OSA severity status to Remission or Mild Non-Symptomatic OSA (defined as AHI $<$ 5 or AHI 5-14 AND Epworth Sleepiness Scale (ESS) $\leq$ 10)
 - Weight loss from base line $\geq$ 10%

Rheumatology

Axial Spondyloarthritis/Ankylosing Spondylitis

TNF Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
adalimumab - See Biosimilar Agents	CIMZIA (certolizumab) SYRINGE
infliximab - See Biosimilar Agents	CIMZIA (certolizumab) VIAL – <i>Medical Billing</i>
ENBREL (etanercept)	SIMPONI ARIA (golimumab) – <i>Medical Billing</i>
SIMPONI (golimumab)	

Commented [AM140]: Enbrel SRA - Enbrel is not disadvantaged to any other BRMs in all approved indications

Interleukin (IL) – 17 Inhibitors

PREFERRED AGENTS (ELECTRONIC STEP REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
TALTZ (ixekizumab)	COSENTYX (secukinumab)
	COSENTYX (secukinumab) – <i>Medical Billing</i>

Commented [AM141]: Taltz SRA - Taltz is the only IL-17 in preferred status; Taltz is not more restricted in its availability than any other competitor human interleukin antagonist; Taltz may be subject to 1 step behind no more than 1 anti-TNF product

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 adalimumab or certolizumab 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 (adalimumab, certolizumab, infliximab, or golimumab), as evidenced by paid claims or pharmacy printouts.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must have failed all preferred agents in the same class as requested product
- Cimzia Only: The member must have failed a 90-day trial of TNF inhibitor (adalimumab, certolizumab, infliximab, or golimumab), 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 (adalimumab, certolizumab, infliximab, or golimumab), 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 (adalimumab, certolizumab, infliximab, or golimumab) and Taltz, as evidenced by paid claims or pharmacy printouts.
- 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)	OTEZLA XR (apremilast)

TNF Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
adalimumab - See Biosimilar Agents	
infliximab - See Biosimilar Agents	

Prior Authorization Criteria

- See [Medications that cost over \\$3000/month](#) criteria

Cryopyrin Associated Periodic Syndrome (CAPS)

Includes: Familial 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) – <i>Medical Billing</i>

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:
 - 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

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)

Janus Kinase (JAK) inhibitor

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
RINVOQ ER (upadacitinib) TABLET	

Interleukin (IL) -6 Receptor Inhibitors

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
tocilizumab – See 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 requested medication must be prescribed by, or in consult with, a specialist in the area of the member's diagnosis.
- The member must meet one of the following conditions:
 - A minimum 7-day trial of high dose glucocorticoids
 - At high risk of glucocorticoid side effects or complications, including osteoporosis, diabetes, hypertension, or glaucoma

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

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) – <i>Medical Billing</i>

TNF Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
adalimumab - See Biosimilar Agents	
ENBREL (etanercept)	

Commented [AM142]: Enbrel SRA - Enbrel is not disadvantaged to any other BRMs in all approved indications

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.

Juvenile Idiopathic Arthritis – Polyarticular Course

Interleukin (IL) -6 Receptor Inhibitors

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
tocilizumab – See Biosimilar Agents	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) – <i>Medical Billing</i>

TNF Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
adalimumab - See Biosimilar Agents	CIMZIA (certolizumab) SYRINGE
ENBREL (etanercept)	CIMZIA (certolizumab) VIAL – <i>Medical Billing</i>
	SIMPONI ARIA (golimumab) – <i>Medical Billing</i>

Commented [AM143]: Enbrel SRA - Enbrel is not disadvantaged to any other BRMs in all approved indications

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member has failed all preferred agents in the same class as requested product
- The member has failed a 3-month trial of a TNF inhibitor, as evidenced by paid claims or pharmacy print outs.
- Cimzia, Orenzia, and Tocilizumab Only: The member has failed a 3-month trial of a TNF inhibitor and a 30-day trial of Xeljanz, as evidenced by paid claims or pharmacy print outs.

- Kevzara, Rinvoq, and Simponi Aria Only: The member has failed a 3-month trial of a TNF inhibitor, tocilizumab, and Orencia, and a 30-day trial of Xeljanz, as evidenced by paid claims or pharmacy print outs.
- Xeljanz IR 10mg, 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)

Juvenile Chronic Arthritis – Systemic Onset

Interleukin (IL) -1 Receptor Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	ILARIS (canakinumab) – <i>Medical Billing</i>

Interleukin (IL) -6 Receptor Inhibitors

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
tocilizumab – See Biosimilar Agents	

TNF Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
adalimumab - See Biosimilar Agents	
ENBREL (etanercept)	

Commented [AM144]: Enbrel SRA - Enbrel is not disadvantaged to any other BRMs in all approved indications

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- Ilaris Only: The member has failed a 3-month trial of a TNF inhibitor tocilizumab, as evidenced by paid claims or pharmacy print outs.
- Tocilizumab Only: The member has failed a 3-month trial of a TNF inhibitor, as evidenced by paid claims or pharmacy print outs.

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>

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) – <i>Medical Billing</i>	FOSAMAX (alendronate)
ibandronate – <i>Medical Billing</i>	FOSAMAX D (alendronate/vitamin D)
RECLAST (zoledronic acid) – <i>Medical Billing</i>	risedronate DR
risedronate IR	
zoledronic acid – <i>Medical Billing</i>	

Prior Authorization Criteria

- Risedronate DR Only: See Preferred Dosage Form criteria

Calcitonins

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

calcitonin, salmon nasal spray++	calcitonin, salmon vial
MIACALCIN (calcitonin, salmon) VIAL++ – Medical Billing	

++ 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)
denosumab- See Biosimilar Agents	

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)
EVENTY (romosozumab-aqqg) – Medical Billing	

Prior Authorization Criteria

Initial Criteria – Approval Duration: 2 years

- The member must have a current BMD T-score ≤ -2.5 OR new fracture 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 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 $\geq 3\%$ as assessed with the FRAX
 - 10-year risk of a major osteoporosis-related fracture of $\geq 20\%$ as assessed with the FRAX

Polymyalgia Rheumatica

Interleukin (IL) -6 Receptor Inhibitors

PA REQUIRED
KEVZARA (sarilumab)

Prior Authorization Criteria

- See Medications that cost over \$3000/month criteria

Psoriatic Arthritis

TNF Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
adalimumab - See Biosimilar Agents	CIMZIA (certolizumab) SYRINGE
infliximab - See Biosimilar Agents	CIMZIA (certolizumab) VIAL – <i>Medical Billing</i>
ENBREL (etanercept)	SIMPONI ARIA (golimumab) – <i>Medical Billing</i>
SIMPONI (golimumab)	

Commented [AM145]: Enbrel SRA - Enbrel is not disadvantaged to any other BRMs in all approved indications

Phosphodiesterase 4 (PDE4) Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
OTEZLA (apremilast)	OTEZLA XR (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) – <i>Medical Billing</i>
	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) – <i>Medical Billing</i>

Commented [AM146]: Taltz SRA - Taltz is the only IL-17 in preferred status; Taltz is not more restricted in its availability than any other competitor human interleukin antagonist; Taltz may be subject to 1 step behind no more than 1 anti-TNF product

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 (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
TREMFYA (guselkumab)	SKYRIZI (risankizumab-rzaa)

Interleukin (IL)-12/IL-23 Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ustekinumab - See Biosimilar Agents	

Electronic Step Therapy Required

- Taltz:
 - PA Not Required Criteria: A total of 84-day supply of adalimumab or certolizumab 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:

- The member must have failed a 90-day trial of etanercept, as evidenced by paid claims or pharmacy printouts:

Adult Members:

- The member must have failed all preferred agents in the same class as requested product
- Bimzelx, Cimzia, Cosentyx, Rinvoq ER, and Simponi Aria Only:
 - The member must have failed a 30-day trial of a JAK inhibitor and a 90-day trial of each of the following, as evidenced by paid claims or pharmacy printouts:
 - Interleukin (IL) – 17 inhibitor
 - TNF inhibitor
- Tremfya Only:
 - The member must have failed a 30-day trial of a JAK inhibitor and a 90-day trial of each of the following, as evidenced by paid claims or pharmacy printouts:
 - Bimzelx
 - Interleukin (IL) – 17 inhibitor
 - TNF inhibitor
- Skyrizi Only:
 - The member must have failed a 30-day trial of a JAK inhibitor and a 90-day trial of each of the following, as evidenced by paid claims or pharmacy printouts:
 - Bimzelx
 - Interleukin (IL) – 17 inhibitor
 - TNF inhibitor
 - Tremfya
- 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).
- All other Agents: See [Preferred Dosage Form Criteria](#)

Rheumatoid Arthritis

Anti-CD20 Monoclonal Antibodies

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
rituximab - See Biosimilar Agents	

Interleukin (IL) -1 Receptor Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
KINERET (anakinra)	

Interleukin (IL) -6 Receptor Inhibitors

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
tocilizumab – See Biosimilar Agents	KEVZARA (sarilumab)

Interleukin (IL) – 17 Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	COSENTYX (secukinumab)
	COSENTYX (secukinumab) – <i>Medical Billing</i>

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) – <i>Medical Billing</i>

TNF Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
adalimumab - See Biosimilar Agents	CIMZIA (certolizumab) SYRINGE
infliximab - See Biosimilar Agents	CIMZIA (certolizumab) VIAL – <i>Medical Billing</i>
ENBREL (etanercept)	SIMPONI ARIA (golimumab) – <i>Medical Billing</i>
SIMPONI (golimumab)	

Commented [AM147]: Enbrel SRA - Enbrel is not disadvantaged to any other BRMs in all approved indications

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must have failed all preferred agents in the same class as requested product
- The member must have had a 3-month trial of each of the following, as evidenced by paid claims and pharmacy printouts:
 - TNF Inhibitor
 - Orencia
 - Xeljanz
- Cosentyx, Kevzara, Rinvoq ER and 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
 - Orencia
 - Xeljanz
 - Tocilizumab
- Xeljanz IR 10mg, 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).

Adult-Onset Still's Disease

Interleukin (IL) -1 Receptor Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
KINERET (anakinra)	ILARIS (canakinumab) – <i>Medical Billing</i>

Infliximab

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
infliximab – See 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 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:

Tumor Necrosis Factor Receptor Associated Periodic Syndrome

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.
- One of the following must be met (A or B):
 - A. Genetic testing confirming pathogenic variants in the tumor necrosis factor receptor 1 (TNFR1) gene (TNF receptor superfamily member 1A, TNFRSF1A).
 - B. 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

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 polacrilex 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) – <i>Brand Required</i>

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

Commented [AM148]: Vivitrol SRA - Preferred on the state Medicaid PDL with no restrictions; covered via both pharmacy and medical benefit

Opioid Reversal Medications

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
KLOXXADO (naloxone) NASAL SPRAY	ZIMHI (naloxone) SYRINGE
nalmefene injection	ZURNAL (nalmefene) INJECTOR
naloxone nasal spray	
naloxone injection	
NARCAN (naloxone) NASAL SPRAY – <i>Brand Co-Preferred</i>	
OPVEE (nalmefene) NASAL SPRAY	
REXTOVY (naloxone) NASAL SPRAY – <i>Brand Co-Preferred</i>	

Commented [AM149]: Kloxxado SRA

Commented [AM150]: Opvee SRA

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:

- The previous dose has expired.
- 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	Initial Dose of TM Buprenorphine	Injection #1	Injection #2 ^a	Maintenance Dose ^b
N/A, none	4 mg ^c	300 mg	100 mg	100 mg
8 – 24 mg/day	N/A	300 mg	300 mg ^d	100 mg

^aThe second injection may be administered as early as 1 week and up to 1 month after the initial injection based on patient need.

^bA monthly maintenance dosage of 300 mg may be considered in patients who tolerate SUBLOCADE, but do not demonstrate a satisfactory clinical response

^cOn induction day, additional transmucosal buprenorphine may be administered as needed to manage withdrawal symptoms. Monitor patients for 1 hour to confirm tolerability before administering the first injection of Sublocade

^dPatients established on long-term treatment and whose symptoms are controlled with 8 mg to 18 mg daily of transmucosal buprenorphine may receive 100 mg of SUBLOCADE as their second dose if symptoms remain controlled following the initial dose of 300 mg

Therapeutic Duplication

- One strength of one medication is allowed at a time.
- Opioid partial agonists are not allowed with:
 - methadone
 - carisoprodol
 - 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(5):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)	
BRIXADI (buprenorphine – <i>Medical Billing</i>)	
SUBLOCADE (buprenorphine)	
SUBLOCADE (buprenorphine) – <i>Medical Billing</i>	

Commented [AM151]: Brixadi, Sublocade SRA

Brixadi - contingent on no prior authorization and no clinical criteria requirements (no step edits; no other restrictions); preferred unrestricted and covered under both pharmacy and medical benefits

Sublocade - Preferred clinical PA to label Where open access acceptance of this contract will not add to the current criteria Not be disadvantaged to any other opioid dependence product

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 "Preferred Dosage Form Criteria"

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):
 - Recurrent hypoglycemia and the test strips are prescribed by or in consult with, a medical geneticist or an endocrinology specialist (subject to clinical review)
 - A diagnosis of diabetes and meet **one of the following** criteria:
 - Newly diagnosed within the last 6 months
 - Acutely ill
 - Significant change in health status causing blood sugar variability
 - 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

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

Commented [AM152]: SRA Accu-check test strips 1:1

Electronic Quantity Per Duration Verification

- Override not required: 200 test strips are covered every 365 days without an override.

If BOTH of the following criteria are met (A and B), please request an override for up to 6 test strips per day by calling provider relations at 1-800-755-2604 or emailing medicaidpharmacy@nd.gov:

- The member is not currently using a continuous glucose monitor
- The member meets [prior authorization criteria](#) or [electronic concurrent medications required](#) criteria for diabetic supplies above (under Preferred Diabetic Supply List header).

Test Strip Electronic Duration Verification Override 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 over 400 test strips per year 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?](#)

Meters

Commented [AM153]: SRA Accu-check meters - 1 of 1

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

Commented [AM154]: Inpen - SRA

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

Commented [AM155]: SRA 1 of 2 BD/embecta

Manufacturer Name	NDC	Product Description	Gauge/Size
Becton Dickinson & Company	08290-3207-49	Ultra-Fine Micro Pen Needle	32 G X 1/4"
Becton Dickinson & Company	08290-3201-19	Ultra-Fine Mini Pen Needle	31 G X 3/16"
Becton Dickinson & Company	08290-3201-22	Ultra-Fine Nano Pen Needle	32 G X 5/32"
Becton Dickinson & Company	08290-3282-03	Ultra-Fine Original Pen Needle	29 G X 1/2"
Becton Dickinson & Company	08290-3201-09	Ultra-Fine Short Pen Needle	31 G X 5/16"
Becton Dickinson & Company	08290-3205-50	Nano 2 Gen Pen Needle	32 G X 5/32"
Embecta	83017-0109-03	Ultra-Fine Pen Needle	31 G x 5/16"
Embecta	83017-0119-03	Ultra-Fine Pen Needle	31 G X 3/16"
Embecta	83017-0122-03	Nano Pen Needle	32 G X 5/32"
Embecta	83017-0550-03	Nano 2 Pen Needle	32 G X 5/32"
Embecta	83017-0749-03	Ultra-Fine Pen Needle	32 G X 1/4"

Embecta	83017-8203-03	Ultra-Fine Pen Needle	29 G X 1/2"
Owen Mumford USA, Inc.	08470-0540-01	Unifine Pentips	32GX 5/32"
Owen Mumford USA, Inc.	08470-0540-41	Unifine Pentips	32GX 5/32"
Owen Mumford USA, Inc.	08470-3429-01	Pentips	29 G X 1/2"
Owen Mumford USA, Inc.	08470-3430-01	Pentips	31 G X 5/16"
Owen Mumford USA, Inc.	08470-3440-01	Pentips	32 G X 5/32"
Owen Mumford USA, Inc.	08470-3450-01	Pentips	31 G X 3/16"
Owen Mumford USA, Inc.	08470-3490-01	Pentips	31 G X 1/4"
Owen Mumford USA, Inc.	08470-3495-01	Pentips	32 G X 1/4"
Owen Mumford USA, Inc.	08470-3529-01	Unifine Pentips	29 G X 1/2"
Owen Mumford USA, Inc.	08470-3530-01	Unifine Pentips	31 G X 5/16"
Owen Mumford USA, Inc.	08470-3540-01	Unifine Pentips	32 G X 5/32"
Owen Mumford USA, Inc.	08470-3550-01	Unifine Pentips	31 G X 3/16"
Owen Mumford USA, Inc.	08470-3560-01	Unifine Pentips	33 G X 5/32"
Owen Mumford USA, Inc.	08470-3590-01	Unifine Pentips	31 G X 1/4"
Owen Mumford USA, Inc.	08470-3595-01	Unifine Pentips	32 G X 1/4"
Owen Mumford USA, Inc.	08470-3829-01	Unifine Pentips Plus	29 G X 1/2"
Owen Mumford USA, Inc.	08470-3830-01	Unifine Pentips Plus	31 G X 5/16"
Owen Mumford USA, Inc.	08470-3840-01	Unifine Pentips Plus	32 G X 5/32"
Owen Mumford USA, Inc.	08470-3850-01	Unifine Pentips Plus	31 G X 3/16"
Owen Mumford USA, Inc.	08470-3860-01	Unifine Pentips Plus	33 G X 5/32"
Owen Mumford USA, Inc.	08470-3890-01	Unifine Pentips Plus	31 G X 1/4"
Owen Mumford USA, Inc.	08470-7935-01	Unifine Safecontrol	30 G X 5/16"
Owen Mumford USA, Inc.	08470-7930-01	Unifine Safecontrol	31 G X 5/16"
Owen Mumford USA, Inc.	08470-7940-01	Unifine Safecontrol	32 G X 5/32"
Owen Mumford USA, Inc.	08470-7950-01	Unifine Safecontrol	31 G X 3/16"
Owen Mumford USA, Inc.	08470-7955-01	Unifine Safecontrol	30 G X 3/16"
Owen Mumford USA, Inc.	08470-7990-01	Unifine Safecontrol	31 G X 1/4"

Insulin Syringes

Manufacturer Name	NDC	Product Description	Gauge/Size
Becton Dickinson & Company	08290-3284-11	BD syringe and needle,insulin,1mL	30 G X 1/2"
Becton Dickinson & Company	08290-3284-18	BD syringe and needle,insulin,1mL	31 G X 5/16"
Becton Dickinson & Company	08290-3284-31	BD syringe-needl,disp,insul,0.3 mL	30 G X 1/2"
Becton Dickinson & Company	08290-3284-38	BD syringe-needl,disp,insul,0.3 mL	31 G X 5/16"
Becton Dickinson & Company	08290-3284-40	BD syringe-ndl,ins 0.3 mL half mark	31 G X 5/16"
Becton Dickinson & Company	08290-3284-66	BD syringe-needle,insulin,0.5 mL	30 G X 1/2"
Becton Dickinson & Company	08290-3284-68	BD syringe-needle,insulin,0.5 mL	31 G X 5/16"
Becton Dickinson & Company	08290-3267-30	BD syringe,insul U-500,ndI,0.5mL	31 G X 15/64"
Becton Dickinson & Company	08290-3249-09	BD syringe-needl,disp,insul,0.3 mL	31 G X 15/64"
Becton Dickinson & Company	08290-3249-10	BD syringe-ndl,ins 0.3 mL half mark	31 G X 15/64"
Becton Dickinson & Company	08290-3249-11	BD syringe-needle,insulin,0.5 mL	31 G X 15/64"
Becton Dickinson & Company	08290-3249-12	BD syringe and needle,insulin,1mL	31 G X 15/64"
Embecta	83017-4909-03	syringe-needl,disp,insul,0.3 mL	31 G X 15/64"

Commented [AM156]: SRA 2 of 2 BD/embecta

Commented [KS157]: I think all of these NDCs are manuf. Discontinued. They all come up that way in Cardinal.

Commented [KS158R157]: @Murphy, Alexi J.

Embecta	83017-4910-03	syrge-ndl,ins 0.3 mL half mark	31 G X 15/64"
Embecta	83017-4911-03	syringe-needle,insulin,0.5 mL	31 G X 15/64"
Embecta	83017-4912-03	syringe and needle,insulin,1mL	31 G X 15/64"
Embecta	83017-6730-03	syringe,insul U-500,ndl,0.5mL	31 G X 15/64"
Embecta	83017-8411-03	syringe and needle,insulin,1mL	30 G X 1/2"
Embecta	83017-8418-03	syringe and needle,insulin,1mL	31 G X 5/16"
Embecta	83017-8431-03	syring-needl,disp,insul,0.3 mL	30 G X 1/2"
Embecta	83017-8438-03	syring-needl,disp,insul,0.3 mL	31 G X 5/16"
Embecta	83017-8440-03	syrge-ndl,ins 0.3 mL half mark	31 G X 5/16"
Embecta	83017-8466-03	syringe-needle,insulin,0.5 mL	30 G X 1/2"
Embecta	83017-8468-03	syringe-needle,insulin,0.5 mL	31 GX5/16"
Ultimed Inc.	08222-0933-56	Ulticare Ins 0.3 MI	30 G X 1/2"
Ultimed Inc.	08222-9100-66	Ulticare Ins 0.3 MI	31 G X 1/4"
Ultimed Inc.	08222-9100-80	Ulticare Ins 0.5 MI	31 G X 1/4"
Ultimed Inc.	08222-9100-97	Ulticare Ins 1 MI	31 G X 1/4"
Ultimed Inc.	08222-0933-94	Ulticare Syr 0.3 MI	30 G X 5/16"
Ultimed Inc.	08222-0935-92	Ulticare Syr 0.5 MI	30 G X 5/16"
Ultimed Inc.	08222-0931-96	Ulticare Syr 1 MI	30 G X 5/16"
Ultimed Inc.	08222-0943-91	Ulticare Syr 0.3 MI	31 G X 5/16"
Ultimed Inc.	08222-0945-99	Ulticare Syr 0.5 MI	31 G X 5/16"
Ultimed Inc.	08222-0941-93	Ulticare Ins Syr 1 MI	31 G X 5/16"
Ultimed Inc.	08222-0931-58	Ulticare Ins Syr 1 MI	30 G X 1/2"
Ultimed Inc.	08222-0935-54	Ulticare Ins 0.5 MI	30 G X 1/2"
Ultimed Inc.	08222-0933-56	Ulticare Ins 0.3 MI	30 G X 1/2"
Ultimed Inc.	08222-0821-83	Ulticare Ins Syr 1 MI	28 G X 1/2"
Ultimed Inc.	08222-0923-97	Ulticare Syrin 0.3 MI	29 G X 1/2"
Ultimed Inc.	08222-0925-95	Ulticare Syr 0.5 MI	29 G X 1/2"
Ultimed Inc.	08222-0921-99	Ulticare Ins Syr 1 MI	29 G X 1/2"

Ketone Strips

Quantity Limits

- 120 strips per 30 days

Manufacturer Name	NDC	Product Description
Trividia Health, Inc.	56151-0601-50	Ketone Test Strip

Commented [AM160]: SRA Ketone Strip

Continuous Glucose Monitors (CGM)

Preferred CGM

Quantity Limits

- NDC 08627005303- Dexcom G6 Sensor: up to 9 sensors/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: up to 9 sensors/90-day supply

- NDC 08627007801- Dexcom G7 Receiver: 1= 250-day supply (1 receiver/365 days allowed)
- NDC 08627007901- Dexcom G7 Sensor: up to 6 sensors/90-day supply

Manufacturer Name	NDC	Product Description
Dexcom, Inc.	08627-0016-01	Dexcom G6 Transmitter
Dexcom, Inc.	08627-0053-03	Dexcom G6 10-day Sensor
Dexcom, Inc.	08627-0091-11	Dexcom G6 Receiver
Dexcom, Inc.	08627-0077-01	Dexcom G7 10-day Sensor
Dexcom, Inc.	08627-0078-01	Dexcom G7 Receiver
Dexcom, Inc.	08627-0079-01	Dexcom G7 15-day Sensor

Commented [AM161]: SRA Dexcom 1 of 1- Medicaid as secondary payor claims to Medicare are ineligible for rebates

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 5 sensors (1 box) per 35-day supply
- Guardian Link Transmitter 3: max of 1 per 365-day supply
- Guardian Sensor 4: max of 5 sensors (1 box) per 35-day supply
- Guardian Link Transmitter 4: max of 1 per 365-day supply
- Instinct Sensor: max of 2 sensors per 30-day supply
- Simpler Sensor: max of 5 sensors per 35-day supply
- Simpler Sync Sensor: max of 5 sensors per 30-day supply

Commented [AM162]: SRA Guardian - May be allowed only for members already coming onto plan with Medtronic pump

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

- Dexcom Sensors:
 - PA Not Required Criteria: A total of 50-day supply of insulin has been paid within 90 days prior to Dexcom sensor's date of service.
 - PA Required Criteria: The member must meet the prior authorization requirements below.
- Dexcom Transmitters and Receivers: **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 does not require PA or has already been approved.

Prior Authorization Criteria

[Continuous Glucose Monitor \(CGM\) Prior Authorization Form](#)

Initial Criteria – Approval Duration: 1 year (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 a life expectancy of less than 12 months.
 - The member must not reside in a skilled nursing facility, intermediate care facility, or swing bed.
 - Members with type 2 diabetes must be on insulin
 - Members with gestational diabetes using insulin, type 1 diabetes, or type 2 diabetes, must meet one of the following (1, 2, 3 or 4):
 1. The member is newly diagnosed with diabetes using insulin and only has had one fill of insulin
 2. The member was at least 80% adherent to insulin, excluding any claim gaps due to hospitalization or eligibility.
 3. Clinical justification must be provided for non-adherence to insulin (subject to clinical review).
 4. A method to improve adherence to insulin must be provided such as addressing adherence barriers, implementing a treatment plan, medication therapy management (MTM), etc.

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 for members with Medicare?

- 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 but has Medicare part A, an override will need to be obtained for coverage and Dexcom must be billed on the pharmacy benefit.
- If the member has a Medicare Advantage plan, any remaining amount will need to be billed to ND Medicaid through the MMIS portal as a medical claim.
- 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 Medtronic 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 or Medicare 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 different 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

Commented [AM163]: SRA Omnipod 1 of 3 - PA in place

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 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.	08508-3000-42	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?

- 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. 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 metabolism 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
09/03/2025	Non-Opioid Analgesics
06/04/2025	Diabetes Mellitus
03/05/2025	Migraine Prophylaxis and Treatment
03/05/2025	Nonsteroidal Anti-Inflammatory Drugs (NSAIDs)
03/05/2025	Primary Biliary Cholangitis
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	Anti-infectives Resistance Prevention
03/02/2022	Chronic Kidney Disease
03/02/2022	Lupus/Lupus Nephritis
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 Spontaneous Urticaria (Chronic Idiopathic Urticaria)

09/01/2021	Uterine Fibroids
09/01/2021	Sedative/Hypnotics – Hettioz
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	Direct Acting Oral Anticoagulants (DOACs)
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:

- [Pharmacy Provider Manual](#)

Appendix E: 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, 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).

Azathioprine

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
azathioprine 50 mg	azathioprine 75 mg
	azathioprine 100 mg

Bendamustine

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
bendamustine 25 mg and 100 mg vials – Medical Billing	BELRAPZO (bendamustine) 100 MG/4 ML VIALS – Medical Billing
BENDEKA (bendamustine) 100 MG/4 ML VIALS – Medical Billing	bendamustine 100 mg/4 mL vials – Medical Billing
	VIVIMUSTA (bendamustine) 100 MG/4 ML VIALS – Medical Billing

paroxetine

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
paroxetine tablets	paroxetine mesylate 7.5 mg capsules

butalbital-acetaminophen-caffeine

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
butalbital-acetaminophen-caffeine tablets	butalbital-acetaminophen-caffeine capsules
	FIORICET (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) – <i>Brand Co-Preferred</i>	epinephrine – labeler 00093, 00115
EPIPEN (epinephrine) JUNIOR – <i>Brand Co-Preferred</i>	NEFFY (epinephrine)

Commented [AM164]: 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:

- The previous dose has expired
- The dose was used by member for an anaphylactic episode

gabapentin

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
gabapentin	gabapentin ER
	GABARONE (gabapentin)
	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)
	ESOMEPR-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 acetone/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	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

desmopressin

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
desmopressin tablets	desmopressin nasal spray
	NOC DURNA (desmopressin) SUBLINGUAL TABS

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)

sitagliptan

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
JANUVIA (sitagliptin)	JANUMET (sitagliptin/metformin)
ZITUVIMET (sitagliptin/metformin) – <i>Brand Required</i>	JANUMET XR (sitagliptin/metformin)
ZITUVIMET XR (sitagliptin/metformin)	sitagliptin
	sitagliptin/metformin
	sitagliptin/metformin ER
	ZITUVIO (sitagliptin)

Steroids – Oral

Agamree and Emflaza (deflazacort): See [Duchenne Muscular Dystrophy](#) Criteria on this document

Eohilia: See [Eosinophilic Esophagitis](#) on this document

Tarpeyo: See [Tarpeyo Criteria](#) on this document

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
budesonide 3 mg EC capsules	ALKINDI (hydrocortisone) SPRINKLE CAPSULE
cortisone	budesonide 9 mg ER tablet
dexamethasone	HEMADY (dexamethasone)
hydrocortisone	KHINDIVI (hydrocortisone) ORAL SOLUTION
methylprednisone	prednisone intensol
prednisolone sodium phosphate 5 mg/5 ml, 15 mg/5 ml, 25 mg/5 ml	prednisolone sodium phosphate ODT
prednisone solution	prednisolone sodium phosphate 10 mg/5 ml, 20 mg/5 ml solution
prednisone tablets	*RAYOS (prednisone)
	TAPERDEX (dexamethasone)

* Rayos required trial duration: 12 weeks with 2 AM dosing of prednisone

ursodiol

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)

ursodiol capsule	RELTONE (ursodiol) CAPSULE
ursodiol tablet	URSO FORTE (ursodiol) TABLET

Unfinished Business

Criteria	Response	Provider's Response	Interaction	Severity Level
2683	No response		Coadministration of triptans and SSRIs or SNRIs should be done with caution. Concomitant use may increase the risk of serotonin syndrome. Prescribers are advised to weigh the potential risk of serotonin syndrome with the expected benefit of using the drugs in combination.	1 - major
3000	no response		Brovana (arformoterol), as well as other beta-2 agonists, should be administered with extreme caution to patients being treated with monoamine oxidase inhibitors, tricyclic antidepressants, or drugs known to prolong the QTc interval. Concurrent use of these agents may potentiate the adrenergic agonist action of arformoterol on the cardiovascular system.	1 - major
3776	1 no response 1 yes (CA)	HIV under control on current regimen	Concurrent use of Descovy (emtricitabine/tenofovir alafenamide) with an anticonvulsant that is a p-glycoprotein inducer (carbamazepine, phenytoin, and oxcarbazepine) is not recommended. The tenofovir component of the fixed dose combo antiretroviral agent is a p-glycoprotein substrate, and concomitant use with a CYP3A4 inducer may result in significant decreases in the tenofovir plasma concentrations, leading to loss of virologic response and possible viral resistance. Consider alternative anticonvulsants in patients receiving Descovy.	1 - major
3824	1 no response Yes (CA) Yes (CA) Yes (CA)	Omeprazole was d/c for Hep C tx duration Pt advised to stop omeprazole during Hep C tx Addressed at time of med education	The concurrent use of Eplusa (sofosbuvir/velpatasvir) with proton pump inhibitors is not recommended. The solubility of the velpatasvir component of the antiviral combo product is pH dependent, and drugs that increase the gastric pH are expected to decrease velpatasvir solubility. If concomitant use is considered medically necessary, sofosbuvir/velpatasvir should be administered with food and taken 4 hours before omeprazole 20 mg. Use with other PPIs has not been studied.	1 - major
4062	no response		Concomitant use of clopidogrel with omeprazole or esomeprazole should be avoided. In clinical studies omeprazole and esomeprazole, CYP2C19 inhibitors, have been shown to reduce the antiplatelet activity of the CYP2C19 substrate clopidogrel when given concomitantly or 12 hours apart. Consider using another acid-reducing agent with minimal or no CYP2C19 effect on the formation of clopidogrel active metabolite.	1 - major
4232	no response		The use of disulfiram with or within 2 weeks of metronidazole-containing agent is contraindicated due to the risk of CNS toxicity (e.g., acute psychosis and confusion).	1 - major
13921	no response		The concurrent use of tamoxifen and a moderate or strong CYP2D6 inhibitor may result in decreased tamoxifen efficacy. Tamoxifen is a CYP2D6 substrate, and coadministration with a moderate or strong CYP2D6 inhibitor may result in decreased serum concentrations of the potent active metabolites of tamoxifen (endoxifen and 4-hydroxytamoxifen). If appropriate for this patient, consider alternate therapy with an agent that does not inhibit the CYP2D6 enzyme.	1 - major
4616	No response		The concurrent use of an ACEI (angiotensin-converting enzyme inhibitor) with an ARB (angiotensin II receptor blocker) may result in significant adverse effects (e.g., hyperkalemia, hypotension, and renal impairment) without improving patient outcomes. Consider switching the patient to a safer recommended combination therapy.	1 - major
7523	No response/pt never under MD care		The dose of a simvastatin-containing agent should not exceed 20 mg/per day in patients also receiving an amiodipine-containing product due to the increased risk of simvastatin-related myopathy and/or rhabdomyolysis. If the dose of simvastatin needs to be increased beyond 20 mg per day consider switching to an alternative statin with less potential for interaction.	1 - major
7637	no response		The concurrent use of the simvastatin-containing agent with gemfibrozil, cyclosporine, danazol, or a potent CYP3A4 inhibitor is contraindicated due to the risk of simvastatin-related myopathy and rhabdomyolysis.	1 - major
7767	no response		Onfi (clobazam) is a weak CYP3A4 inducer and concurrent use with CYP3A4-mediated hormonal contraceptives may diminish the effectiveness of the contraceptive agent. The manufacturer recommends the use of additional non-hormonal form of contraception when using clobazam.	1 - major
8031	no response		The daily dose of atorvastatin should not exceed 20 mg in patients receiving the ritonavir-boosted HIV protease inhibitors darunavir and fosamprenavir or unboosted fosamprenavir. Protease inhibitors are CYP3A4 inhibitors, and concurrent use with atorvastatin, a 3A4 substrate, may elevate atorvastatin levels and increase the risk of statin-related myopathy and rhabdomyolysis.	1 - major
8994	no response		The manufacturer recommends that the daily dose of Trintellix (vortioxetine) be reduced by half when patients are receiving a strong CYP2D6 inhibitor (i.e., bupropion, fluoxetine, and quinidine) concomitantly. The dose should be increased to the original level when the CYP2D6 inhibitor is discontinued.	1 - major
9209	no response		Noxafil (posaconazole) is contraindicated with CYP3A4 substrates that prolong the QT interval. Posaconazole is a strong CYP3A4 inhibitor and concurrent use with a CYP3A4 substrate may result in increased substrate plasma concentrations, leading to QT prolongation and torsades de pointes. In addition, posaconazole has been associated with prolongation of the QT interval.	1 - major
9754	No response		Concomitant use of Xarelto (rivaroxaban) with drugs affecting hemostasis (e.g., aspirin, platelet aggregation inhibitors, and NSAIDs) may increase the risk of bleeding. Promptly evaluate any signs or symptoms of blood loss if the patient is treated concurrently with these agents.	1 - major
9966	no response		The concurrent use of sacubitril/valsartan with an ACE inhibitor is contraindicated due to the increased risk of angioedema. If switching from an ACE inhibitor to sacubitril/valsartan, or vice versa, allow a washout period of 36 hours between administration of the two drugs.	1 - major
10220	no response		Juluca (dolutegravir/rilpivirine) is a complete regimen, and co-administration with other antiretroviral medications for the treatment of HIV-1 infection is not recommended.	1 - major

New Business

Second Review

ANCA-Associated Vasculitis

Eosinophilic Granulomatosis with Polyangiitis (EGPA)

Biologic Agents

Anti-B-cell Therapy

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
rituximab – See Biosimilar Agents	

Anti-IL-5 Biologics

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
FASENRA (benralizumab)	NUCALA (mepolizumab) SYRINGE, AUTOINJECTOR
	NUCALA (mepolizumab) VIAL – <i>Medical Billing</i>

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., active glomerulonephritis, pulmonary hemorrhage, cerebral vasculitis, progressive peripheral or cranial neuropathy, gastrointestinal bleeding due to vasculitis, cardiac involvement (coronary vasculitis, pericarditis, or myocarditis), 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 β_2 -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.

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, 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

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7. King, Jr. TE. Eosinophilic granulomatosis with polyangiitis (Churg-Strauss): Treatment and prognosis. In: *UpToDate*, Post TW (Ed), UpToDate, Waltham, MA, 2023
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Granulomatosis with Polyangiitis (GPA)/Microscopic Polyangiitis (MPA)

Biologic Agents

Anti-B-cell Therapy

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
cyclophosphamide	
rituximab – See Biosimilar Agents	

Complement C5a Receptor Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	TAVNEOS (avacopan)

Prior Authorization Criteria

Initial Criteria - Approval Duration: 6 months

- The requested medication must be prescribed by, or in consult with, a nephrologist, rheumatologist, pulmonologist, or other specialist.
- The member must have severe disease defined as vasculitis with life- or organ-threatening manifestations (e.g., active glomerulonephritis, pulmonary hemorrhage, progressive peripheral or cranial neuropathy, orbital pseudotumor, scleritis, gastrointestinal bleeding due to vasculitis, cardiac disease due to vasculitis such as pericarditis or myocarditis)
- The member must be receiving adjunctive standard induction therapy with rituximab or cyclophosphamide
- Clinical justification must be provided explaining why the member needs to limit use of glucocorticoids (subject to clinical review)

Renewal Criteria - Approval Duration: 6 months (the safety and efficacy of avacopan beyond 52 weeks have not yet been addressed)

- 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, subject to clinical review.

*Relapse is defined as active vasculitis in any organ system after remission is achieved

Niemann-Pick Type C

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AQNEURSA (levacetyleucine)	MIPLYFFA (arimoclomol)

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, neurologist or other specialist with treatment of NPC
- The member is symptomatic with neurological manifestations associated with NPC such as gait problems, ataxia, cognitive deterioration, or vertical gaze palsy (chart notes must be submitted)
- Confirmation of the diagnosis must be submitted, as evidenced by one of the following:
 - Confirmation by genetic testing identifying disease-causing mutations in both alleles of NPC1 or NPC2
 - Confirmation by genetic testing identifying disease-causing mutation in one allele of NPC1 or NPC2 AND either a positive filipin-staining or elevated cholestane triol/oxysterols (> 2x the upper limit of normal)
- For Aqneursa only: The member must weigh ≥ 15 kg
- For Miplyffa only:
 1. The member must weigh ≥ 8 kg
 2. The member must be ≥ 2 years of age
 3. The member must not have significant renal impairment (eGFR < 15 mL/min)

Non-Preferred Agents Criteria:

- The member must have failed a 3-month trial of the preferred agent, as evidenced by paid claims or pharmacy printouts

Renewal Criteria – Approval Duration: 12 months

- The member demonstrates a positive response with a slowed progression or decrease in neurological symptoms compared to baseline

First Review of Non-Cystic Fibrosis Bronchiectasis

Overview¹

Definition: Pathologic airway dilation and wall thickening caused by chronic airway inflammation. The acute exacerbations stimulate neutrophilic airway inflammation which eventually leads to progressive lung damage, lung function decline, and worsened quality of life. Bronchiectasis can be caused by cystic fibrosis, certain immunodeficiencies, nontuberculous mycobacterial infection (NTM), alpha-1 antitrypsin deficiency, and allergic bronchopulmonary aspergillosis. Management is aimed at treating exacerbations, controlling infection, reducing inflammation, and improving bronchial hygiene.

Prevalence²:

- 350,000 to 500,000 adults in the U.S.
- Prevalence increases with age
- More common in women

Clinical Features:

- Chronic cough
- Viscid daily sputum production
- Recurrent upper airway infections

Diagnosis: An exacerbation is defined as presence of at least 3 of the below symptoms for 48 hours or longer and requires a change in therapy. Other causes such as pneumonia, anemia, pulmonary embolism, and heart failure should be ruled out. Gram stain and sputum culture should be obtained prior to antibiotic therapy. Patients typically do not have fever or chills.

Symptoms:

- Cough
- Sputum volume and/or consistency
- Sputum purulence
- Breathlessness and/or exercise intolerance
- Fatigue and/or malaise
- Hemoptysis

Common Pathogens:

- *Haemophilus influenzae*
- *Moraxella catarrhalis*
- *Staphylococcus aureus*
- *Pseudomonas aeruginosa*
- *Stenotrophomonas maltophilia*
- *Streptococcus pneumoniae* (less common)

FDA Approval

Brinsupri (brensocatib)³: August 12, 2025; 505(b) New Drug Application (NDA) pathway; Type 1 – New Molecular Entity; Standard; Priority

Current Utilization

Medication	Quarter 4 2024 – Quarter 3 2025		
	Rx Count	Rx Count	% of Rx
Brinsupri (brensocatib)	0	0	0

Treatment Overview^{1,4}

Pharmacotherapy:

- **Antibiotic therapy:**
 - No sputum culture – broad spectrum coverage with a fluoroquinolone is preferred
 - Positive for beta-lactamases – amoxicillin or doxycycline
 - Positive for non-pseudomonal beta-lactamase – amoxicillin/clavulanate, second or third generation cephalosporin, doxycycline, or fluoroquinolone
 - Pseudomonas positive - ciprofloxacin (if no quinolone resistance)
 - If quinolone resistant - piperacillin/tazobactam, fourth generation cephalosporin (cefepime or ceftazidime), aminoglycoside (tobramycin – not as monotherapy), carbapenem (meropenem or imipenem), or aztreonam
 - MRSA positive – vancomycin or linezolid
 - Prophylactic antibiotics⁴:
 - Macrolides for patients with recurrent exacerbations and no *Pseudomonas aeruginosa* infection
 - Inhaled tobramycin for patients with 3 or more exacerbations per year, significant morbidity from fewer exacerbations, and *P. aeruginosa* infection.
- **Antiviral therapy** – for exacerbations caused by influenza or COVID-19
- **Asthma and COPD** – oral or inhaled glucocorticoids
 - Glucocorticoids should not be used in patients without asthma or COPD because they depress host immunity, promote bacterial and fungal colonization, and may perpetuate infection.
- **Surgical resection and lung transplant** may also be required for patients continuing to have debilitating exacerbations or worsening lung function.
- **Elastase inhibitors (brensocatib)** reduce activity of neutrophil serine proteases (NSPs) which reduces inflammation and lung destruction.
 - Addition of brensocatib is recommended for patients with 2 or more exacerbations in a year despite antibiotic therapy or those who cannot tolerate ongoing antibiotic therapies⁴
 - Second-line therapy due to modest efficacy, high cost, and lack of clinical experience⁴
- **Bronchodilators** – may be recommended for patients who show bronchodilator reversibility by assessing airflow obstruction on spirometry before and after bronchodilator administration.

Medication	Brinsupri (brensocatib)⁵
Mechanism of Action	A competitive, reversible inhibitor of dipeptidyl peptidase 1 (DPP1) which reduces activity of neutrophil serine proteases (NSPs) and decreases inflammation.
Dosing	Ages 12 years of age and older: 10 to 25 mg daily

Special Considerations	• Avoid use of live attenuated vaccines during therapy • Routine dental exams required to monitor for gingival and periodontal adverse reactions • Monitor for rash, dry skin, and hyperkeratosis
Clinical Trials⁴	The ASPEN trial • Showed a reduction in annual exacerbations of 1.02/year (10mg group), 1.04/year (25mg group), and 1.29/year (placebo group). • Improvements in pulmonary function (FEV1) were seen in the higher-dose group. • Quality of life assessments increased by 6.8 points (10mg group), 8.6 points (25 mg group), and 4.8 points (placebo group). **An 8-point increase is considered significant. • Sputum cultures from the brensocatib groups showed a reduction in inflammatory chemokines, reduced MUC5AC, and increases in antimicrobial peptides serum leukoproteinase and alpha defensin-3.
Cost (AWP)/30 days (both strengths)⁶	\$8800.00

References:

1. Barker, Alan, et al. *Bronchiectasis in adults: Treatment of acute and recurrent exacerbations*. UpToDate. September 8, 2025. *Bronchiectasis in adults: Treatment of acute and recurrent exacerbations* - UpToDate
2. Barker, Alan, et al. *Clinical manifestations and diagnosis of bronchiectasis in adults*. UpToDate. September 30, 2025. *Clinical manifestations and diagnosis of bronchiectasis in adults* - UpToDate
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First Review of Phenylketonuria (PKU)

Overview¹

Definition: A disorder that results from a deficiency in phenylalanine hydroxylase (PAH). This can lead to irreversible intellectual disability and other clinical symptoms. Excessive phenylalanine can interfere with brain growth, myelination, and neurotransmitter synthesis. PKU inheritance is autosomal recessive and is caused by mutations in the gene PAH located on chromosome c.

Degree of enzyme activity	Phenylalanine concentrations (micromol/L)
Classic PKU	1200
Moderate PKU	900-1200
Mild PKU	600-900
Mild hyperphenylalaninemia (HPA)	360-600
Benign mild HPA**	120-360

**Typically does not require treatment

Prevalence:

- Affects 1 in 10,000 to 15,000 live births.
- Highest prevalence in European and East Asian populations

Clinical Features: Clinical manifestations are rare due to widespread neonatal screening. However, if left untreated, patients may experience irreversible intellectual disability, seizures, behavioral abnormalities, microcephaly, and skin disease (eczematous rash, light pigmentation). Some other manifestations include abnormal gait, sitting posture, and stance, and a "mousy" odor to urine.

Diagnosis: Elevated serum concentration of phenylalanine, followed by molecular testing.

FDA Approval

Sephience (sepiapterin)²: July 28, 2025; 505(b) New Drug Application (NDA) pathway; Type 1 – New Molecular Entity; Standard; Orphan

Zelvysia (sapropterin)³: April 29, 2025; Abbreviated NDA; Standard

Kuvan (sapropterin)⁴: December 13, 2007; 505(b) New Drug Application (NDA) pathway; Type 1 – New Molecular Entity; Standard; Orphan

Palyziq (pegvaliase-pqpz)⁵: May 24, 2018; Biologics License Application; Orphan

Sapropterin⁶: May 10, 2019; 505(j) Abbreviated New Drug Application (NDA) pathway; Standard

Current Utilization

Medication	Quarter 4 2024 – Quarter 3 2025		
	Rx Count	Total Claim Cost	% of Rx
Sepience (sepiapterin)	0	0	0
Sapropterin (includes all brand and generic products)	22	\$91,751.37	0.002%
Palynziq (pegvaliase-pqpz)	0	0	0

Treatment Overview¹

The primary treatment is **dietary** restriction of phenylalanine. Medical foods and phenylalanine-free protein substitutes are used. Treatment should be initiated immediately, usually before one week of age. Treatment is recommended for newborns with persistent phenylalanine levels of 360 micromol/L or greater. Dietary treatment should continue throughout the patient's life.

Pharmacotherapy:

Medication	Sepience (Sepiapterin)	Sapropterin	Palynziq (Pegvaliase)
Mechanism of Action	A novel synthetic BH4 precursor that increases BH4 levels and binds to misfolded PAH to retain its tertiary structure and improve enzyme activity	A biologically active synthetic form of BH4.	Enzyme that converts phenylalanine to ammonia and trans-cinnamic acid which reduces blood concentrations of blood phenylalanine
Dosing	7.5 to 60 mg/kg daily ⁵	5 to 20mg/kg daily	20 to 60 mg/day
Special Considerations	• Approved for treatment in PKU patients 1 month and older.⁷ • Should be used in conjunction with a phenylalanine-restricted diet.⁷ • May be superior to sapropterin due to its dual MOA which explains why some patients respond to sepiapterin that don't respond to sapropterin. • A natural precursor to BH4 and is more stable and efficiently transported into the	• Ineffective in patients with 2 null mutations in trans • Baseline phenylalanine levels should be obtained prior to initiation and at regular intervals • Phenylalanine levels should be drawn at 24 hours and then in 1-4 weeks to assess appropriateness of treatment	• Approved for use in adults only

	cells than sapropterin. ⁸		
Clinical Trials	APHENITY trial showed a $\geq 15\%$ reduction in blood phenylalanine from baseline after 14 days. Levels were reduced by 63% at 6 weeks. Patients were also able to liberalize their diet and increase mean protein intake by 126%.	44% of patients treated with sapropterin had a reduction in blood phenylalanine of 30% from baseline after 6 weeks.	PRISM-1 and PRISM-2 trials which evaluated safety and efficacy showed that 70% of patients achieved phenylalanine levels < 600 micromol/L at 24 months and 60% achieved levels < 360 micromol/L.
Cost (AWP)/30 packets^{9, 10, 11}	250mg packet - \$4687.50 1000mg packet – \$18,750.00 **Cost will vary based on patient weight	100mg - \$1360.80 500mg - \$6804.00 **Cost will vary based on patient weight	\$24,192.00 to \$72,576.00 per month (20mg to 60mg/day for 30 days)

Other therapies:

- **Phenylalanine ammonia-lyase** degrades phenylalanine and is approved for use in adults with PKU.
- **Long-chain polyunsaturated fatty acids** are used for supplementation to improve neurodevelopment.
- **Large neutral amino acids** supplementation reduces the influx of phenylalanine into the brain by competing with phenylalanine for the amino transport at the blood-brain barrier.

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- Zelvsia (sapropterin) Red Book. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. <https://www.Micromedexsolutions.com>
- Palynziq (pegvaliase-pqpz) Red Book. IBM Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. <https://www.Micromedexsolutions.com>

First Review of Alzheimer's Disease

Overview¹

Definition: A neurodegenerative disease that affects primarily older adults and is the most common cause of dementia. It is categorized as preclinical phase, mild cognitive impairment, and dementia. Early onset begins before age 65. Age of onset > 80 years may be associated with a slower rate of decline.

Prevalence²:

- 47 million people globally
- 4.5 million people over the age of 65 years in the U.S. in 2011

Clinical Features:

- Memory impairment
- Executive function and judgement/problem solving impairment
- Visuospatial impairments and word-finding difficulty
- Neuropsychiatric symptoms like apathy, social disengagement, and irritability
- Other: difficulty performing learned motor tasks, olfactory dysfunction, sleep disturbances, and seizures.

Assessment Tools:

- Functional Activities Questionnaire
- Quick Dementia Rating System
- Mini-Mental State Examination
 - Studies have shown that patients decline 3 to 3.5 points on average each year
 - < 10% decline by 5 to 6 points per year
- Montreal Cognitive Assessment
- Clinical dementia rating scale

Diagnosis: criteria for diagnosis is established by the National Institute on Aging and the Alzheimer's Association (NIA-AA). Diagnostic and Statistical Manual of Mental Disorders (DSM) criteria is also used for diagnosis.

Differential Diagnosis: Vascular dementia and other neurodegenerative dementias (e.g. dementia with Lewy bodies (DLB) and frontotemporal dementia (FTD)).

FDA Approval

Leqembi (lecanemab)³: January 6, 2023; Biologics license application (BLA)

Leqembi Iqlik (levanemab-irmb)⁴: August 29, 2025; Biologics license application (BLA)

Kisunla (donanemab-azbt)⁵: July 2, 2024; Biologics license application (BLA)

Zunveyl (benzgalantamine)⁶: July 26, 2024; 505(b) New Drug Application (NDA) pathway; Type 2 – New Active Ingredient and Type 3 New Dosage Form; Standard

Current Utilization

Quarter 4 2024				
Medication	Rx Count	% of Rx	Reimb Amount	Total Claim Cost
Donepezil	43	46.74%	\$583.63	\$13369.37
Rivastigmine	17	18.48%	\$327.22	\$3856.46
Galantamine	2	2.17%	\$98.53	\$532.80
Zunveyl	0	0.00%	\$0.00	\$0.00
Memantine	30	32.61%	\$397.77	\$11583.76
Memantine/donepezil	0	0.00%	\$0.00	\$0.00
Leqembi	0	0.00%	\$0.00	\$0.00
Kisunla	0	0.00%	\$0.00	\$0.00
Totals	92		\$1407.15	\$29,342.39
Quarter 1 2025				
Medication	Rx Count	% of Rx	Reimb Amount	Total Claim Cost
Donepezil	38	45.78%	\$503.83	\$14208.49
Rivastigmine	11	13.25%	\$186.23	\$1583.96
Galantamine	5	6.02%	\$234.65	\$1378.98
Zunveyl	0	0.00%	\$0.00	\$0.00
Memantine	29	34.94%	\$390.99	\$10073.62
Memantine/donepezil	0	0.00%	\$0.00	\$0.00
Leqembi	0	0.00%	\$0.00	\$0.00
Kisunla	0	0.00%	\$0.00	\$0.00
Totals	83		\$1,315.70	\$27,245.05
Quarter 2 2025				
Medication	Rx Count	% of Rx	Reimb Amount	Total Claim Cost
Donepezil	39	45.88%	\$535.97	\$14196.08
Rivastigmine	6	7.06%	\$110.70	\$1028.34
Galantamine	3	3.53%	\$130.62	\$846.18
Zunveyl	0	0.00%	\$0.00	\$0.00
Memantine	37	43.53%	\$484.99	\$11304.57
Memantine/donepezil	0	0.00%	\$0.00	\$0.00
Leqembi	0	0.00%	\$0.00	\$0.00
Kisunla	0	0.00%	\$0.00	\$0.00
Totals	85		\$1,262.28	\$27,375.17
Quarter 3 2025				
Medication	Rx Count	% of Rx	Reimb Amount	Total Claim Cost
Donepezil	36	48.00%	\$501.95	\$13883.60
Rivastigmine	7	9.33%	\$122.02	\$1199.73
Galantamine	2	2.67%	\$77.79	\$579.78
Zunveyl	0	0.00%	\$0.00	\$0.00
Memantine	30	40.00%	\$425.97	\$11834.96
Memantine/donepezil	0	0.00%	\$0.00	\$0.00
Leqembi	0	0.00%	\$0.00	\$0.00
Kisunla	0	0.00%	\$0.00	\$0.00
Totals	75		\$1,127.73	\$27,498.07

Treatment Overview

Pharmacotherapy⁷:

- **Cholinesterase inhibitors:**
 - Donepezil, rivastigmine, and galantamine
 - Cause a decrease in acetylcholine synthesis and impair cortical cholinergic function
 - Expected benefit is modest.
 - Trial of cholinesterase inhibitors recommended for mild to moderate cognitive impairment
- **Memantine**
 - NMDA receptor antagonist
 - Neuroprotective
 - It is recommended to use memantine in combination with a cholinesterase inhibitor in patients with moderate to severe AD
- **Amyloid-Targeted therapies**
 - Lecanemab and donanemab
 - Recombinant monoclonal antibodies directed against amyloid beta which reduces the amyloid plaque burden
 - These are considered disease-modifying therapies unlike cholinesterase inhibitors and memantine which are symptomatic therapies.
 - Should be initiated in patients with mild cognitive impairment or mild dementia
 - Use should be limited to patients who are proven to be amyloid positive by amyloid PET scan or presence of AD biomarkers in the cerebrospinal fluid

Medication	Leqembi (lecanemab-irmb) and Leqembi Iqlik ⁸	Kisunla (donanemab-azbt) ⁹	Zunveyl (benzgalantamine) ¹⁰
Mechanism of Action	Directed against aggregated soluble and insoluble forms of amyloid beta, thereby reducing amyloid beta plaques	IgG1 monoclonal antibody directed against insoluble N-truncated pyroglutamate amyloid beta which reduces amyloid beta plaques.	Exact MOA unknown. Improves cholinergic function by increasing acetylcholine levels by reversibly inhibiting hydrolysis by cholinesterase. Does not alter clinical course of the dementing process.
Dosing	10mg/kg every 2 weeks x 18 months, then 10mg/kg every 4 weeks or 360mg weekly	1400mg every 4 weeks (after induction infusions)	5mg twice daily for 4 weeks then titrate to 10mg twice daily. May increase to a max dose of 15mg twice daily.
Special Considerations	• Use caution with coadministration of antithrombotic or thrombolytic agents • Use with caution in patients at risk for intracerebral hemorrhage • Monitor for Amyloid-related imaging abnormalities (ARIA), including ARIA with edema and ARIA with hemosiderin deposition.		• If therapy is interrupted for more than 3 days, then restart at the lowest dosage. • Prodrug of galantamine is used for mild to moderate disease.
Clinical Trials	• Clarity AD trial showed slower decline on the Clinical Dementia Rating-Sum of Boxes	• TRAILBLAZER-ALZ 2 trial showed that clinical decline	• Safety profile is similar to that of galantamine IR. • Mean change in the Alzheimer's Disease

	compared to placebo which translated into approximately 5 fewer months of decline over 1 month or 30% slowing of decline. Efficacy was sustained through 24 months. ¹¹	slowed by 25-40%.	Assessment Scale (ADAS-cog) scores at 21 weeks ranged from 1.7 to 3.6 units based on the dose of galantamine. ¹²
Cost (AWP)/30 days (both strengths)	• Leqembi: \$2638.44 (based on 100kg) • Leqembi Iqlik: \$450.00	\$3380.88	\$984.18

References:

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**NORTH DAKOTA MEDICAID
RETROSPECTIVE DRUG UTILIZATION REVIEW
CRITERIA RECOMMENDATIONS
4TH QUARTER 2025**

Criteria Recommendations

Approved Rejected

1. Pazopanib / Overuse

Alert Message: Votrient (pazopanib) may be over-utilized. The recommended dosage of pazopanib is 800 mg (four 200 mg tablets) orally once daily without food (at least 1 hour before or 2 hours after a meal) until disease progression or unacceptable toxicity.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C (Negating)</u>
Pazopanib		Hepatic Impairment

Max Dose: 800 mg/day

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Votrient Prescribing Information, Jan. 2024, Novartis Pharmaceuticals Corporation.

2. Pazopanib / Therapeutic Appropriateness

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

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Pazopanib		

Age Range: 0 – 17 yoa

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Votrient Prescribing Information, Jan. 2024, Novartis Pharmaceuticals Corporation.

3. Pazopanib / Hepatotoxicity – Box Warning

Alert Message: Hepatotoxicity, manifested as increases in ALT, AST, and bilirubin, has occurred in patients who received Votrient (pazopanib). Severe and fatal hepatotoxicity has been observed in clinical trials. Monitor liver function test according to prescribing information. If hepatotoxicity occurs, withhold pazopanib until improvement and resume at a reduced dose with continued monitoring for 8 weeks or permanently discontinue with weekly monitoring until resolution based on severity of hepatotoxicity.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C (Include)</u>
Pazopanib		Hepatic Impairment

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Votrient Prescribing Information, Jan. 2024, Novartis Pharmaceuticals Corporation.

4. Pazopanib / Overuse – Hepatic Impairment

Alert Message: Votrient (pazopanib) may be over-utilized. The recommended dosage of pazopanib in patients with moderate hepatic impairment (total bilirubin > 11.5 to 3 x ULN and any ALT value) is 200 mg orally once daily. Pazopanib use is not recommended in patients with severe hepatic impairment. No dosage adjustment is recommended in patients with mild hepatic impairment.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C (Include)</u>
Pazopanib		Hepatic Impairment

Max Dose: 200 mg/day

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Votrient Prescribing Information, Jan. 2024, Novartis Pharmaceuticals Corporation.

5. Pazopanib / Severe Hepatic Impairment

Alert Message: Votrient (pazopanib) use is not recommended in patients with severe hepatic impairment. In a pharmacokinetic study in patients with severe hepatic impairment receiving 200 mg once daily, the median steady-state Cmax and the median AUC0-24h were approximately 18% and 15%, respectively, of the corresponding median values after administration of 800 mg once daily in patients with no hepatic impairment.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Pazopanib	Cirrhosis	
	Liver Failure	

Max Dose: 200 mg/day

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Votrient Prescribing Information, Jan. 2024, Novartis Pharmaceuticals Corporation.

6. Pazopanib / QT Prolongation

Alert Message: Votrient (pazopanib) use can cause QT prolongation. Monitor patients who are at significant risk of developing QTc prolongation, including patients with a history of QT interval prolongation, taking antiarrhythmics or other medications that may prolong the QT interval, and those with relevant preexisting cardiac disease. Monitor ECGs and electrolytes at baseline and as clinically indicated.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Pazopanib	QT Prolongation	
	Arrhythmias	
	Heart Failure	
	Myocardial Infarction	

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Votrient Prescribing Information, Jan. 2024, Novartis Pharmaceuticals Corporation.

7. Pazopanib / Heart failure

Alert Message: Votrient (pazopanib) use can cause cardiac dysfunction, including decreased ventricular ejection fraction and congestive heart failure. Monitor blood pressure and manage as appropriate. Monitor patients for signs and symptoms of congestive heart failure. Withhold or permanently discontinue pazopanib based on the severity of cardiac dysfunction.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Pazopanib	Heart Failure	

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Votrient Prescribing Information, Jan. 2024, Novartis Pharmaceuticals Corporation.

8. Pazopanib / Arterial Thromboembolic Events

Alert Message: Votrient (pazopanib) should be used with caution in patients at risk for arterial thromboembolic events. In clinical trials, arterial thromboembolic events, some fatal, occurred in patients treated with pazopanib. Pazopanib has not been studied in patients who have had an arterial thromboembolic event within the previous 6 months. Permanently discontinue pazopanib in case of an arterial thromboembolic event.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Pazopanib	Arterial Thromboembolism	

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Votrient Prescribing Information, Jan. 2024, Novartis Pharmaceuticals Corporation.

9. Pazopanib / Venous Thromboembolic Events

Alert Message: Venous thromboembolic events (VTEs) have been reported with the use of Votrient (pazopanib). In the renal cell carcinoma (RCC) clinical trial, VETs occurred in 1% of 290 patients treated with pazopanib. In the soft tissue sarcoma trial (STS), VTEs were reported in 5% of 240 patients, and fatal pulmonary embolism (PE) was reported in 1% of 240 patients. Monitor patients for signs and symptoms of VTE and PE. For Grade 3 VET, withhold pazopanib and resume at the same dose if managed with appropriate therapy for at least one week. Permanently discontinue pazopanib in case of Grade 4 VTE.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Pazopanib	Pulmonary Embolism	
	Venous Thromboembolism	

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Votrient Prescribing Information, Jan. 2024, Novartis Pharmaceuticals Corporation.

10. Pazopanib / Thrombotic Microangiopathy

Alert Message: Thrombotic Microangiopathy (TMA), including thrombotic thrombocytopenic purpura (TTP) and hemolytic uremic syndrome (HUS), have been reported in clinical trials with Votrient (pazopanib). Monitor patients for signs and symptoms of TMA. Permanently discontinue pazopanib in patients developing TMA.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Pazopanib	Hemolytic Uremic Syndrome	
	Thrombotic Microangiopathy	
	Thrombotic Thrombocytopenic Purpura	

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Votrient Prescribing Information, Jan. 2024, Novartis Pharmaceuticals Corporation.

11. Pazopanib / Interstitial Lung Disease/Pneumonitis

Alert Message: Interstitial Lung Disease/Pneumonitis (ILD)/pneumonitis, which can be fatal, has been reported with Votrient (pazopanib) across clinical trials. Monitor patients for signs and symptoms of ILD/ pneumonitis. Permanently discontinue pazopanib in patients who develop ILD or pneumonitis.

Drugs/Diseases

Util A	Util B	Util C
Pazopanib	Interstitial Lung Disease Pneumonitis Cough Dyspnea Fever	

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Votrient Prescribing Information, Jan. 2024, Novartis Pharmaceuticals Corporation.

12. Pazopanib / Posterior Reversible Encephalopathy Syndrome

Alert Message: Posterior Reversible Encephalopathy Syndrome (PRES) has been reported in patients who received Votrient (pazopanib). PRES is a neurologic disorder that can present with headache, seizures, lethargy, confusion, visual, and neurologic disturbances. PRES can be fatal. Permanently discontinue pazopanib in patients who develop PRES.

Drugs/Diseases

Util A	Util B	Util C
Pazopanib	Confusion Headache Lethargy PRES	

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Votrient Prescribing Information, Jan. 2024, Novartis Pharmaceuticals Corporation.

13. Pazopanib / Gastrointestinal Perforation & Fistula

Alert Message: Votrient (pazopanib) can cause gastrointestinal perforation and fistula, some fatal. Monitor the patient for signs and symptoms of gastrointestinal perforation and fistula. Withhold pazopanib in case of Grade 2 or 3 gastrointestinal fistula and resume based on medical judgment. Permanently discontinue pazopanib in case of gastrointestinal perforation or Grade 4 gastrointestinal fistula.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Pazopanib	Perforation of Intestine	
	Fistula of Intestine	

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Votrient Prescribing Information, Jan. 2024, Novartis Pharmaceuticals Corporation.

14. Pazopanib / Strong CYP3A4 Inhibitors

Alert Message: Avoid the concurrent use of Votrient (pazopanib) with strong CYP3A4 inhibitors. Pazopanib is a CYP3A4 substrate, and coadministration with strong CYP3A4 inhibitors can cause increased pazopanib concentrations and risk of pazopanib-related adverse effects. Consider an alternate concomitant medication with no or minimal enzyme-inhibiting potential. If coadministration cannot be avoided, reduce the dose of pazopanib to 400 mg once daily.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Pazopanib	Clarithromycin	Nelfinavir
	Cobicistat	Posaconazole
	Itraconazole	Ritonavir
	Ketoconazole	Voriconazole
	Nefazodone	

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Votrient Prescribing Information, Jan. 2024, Novartis Pharmaceuticals Corporation.

Criteria Recommendations

Approved Rejected

15. Pazopanib / Strong CYP3A4 Inducers

Alert Message: Avoid the concurrent use of Votrient (pazopanib) with strong CYP3A4 inducers. Pazopanib is a CYP3A4 substrate, and coadministration with strong CYP3A4 inducers results in decreased pazopanib plasma concentrations. Consider an alternate concomitant medication with no or minimal enzyme induction potential.

Drugs/Diseases

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

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Votrient Prescribing Information, Jan. 2024, Novartis Pharmaceuticals Corporation.

16. Pazopanib / CYP3A4, 2D6, & 2C8 Substrates with NTI

Alert Message: The concomitant use of Votrient (pazopanib) with medications with narrow therapeutic windows that are metabolized by CYP3A4, CYP2D6, or CYP2C8 is not recommended. Pazopanib is an inhibitor of CYP3A4-, CYP2D6-, and CYP2C8-mediated metabolism. Concurrent use of pazopanib with agents that are CYP3A4, CYP2D6, or CYP2C8 substrates with narrow therapeutic windows may result in the inhibition of the metabolism of these agents, increased plasma concentrations, and potential for serious adverse reactions.

Drugs/Diseases

Util A	Util B			Util C
Pazopanib	Avanafil	Eletriptan	Naloxegol	Ticagrelor
	Atomoxetine	Eliglustat	Nisoldipine	Tipranavir
	Budesonide	Eplerenone	Pioglitazone	Tolvaptan
	Buspirone	Felodipine	Quetiapine	Tolterodine
	Conivaptan	Ibrutinib	Quinidine	Triazolam
	Cyclosporine	Lomitapide	Selexipag	Vardenafil
	Ceritinib	Lovastatin	Sildenafil	Venlafaxine
	Darifenacin	Lurasidone	Simvastatin	
	Darunavir	Maraviroc	Sirolimus	
	Dronedarone	Midazolam	Tacrolimus	
	Dextromethorphan			

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Merative Micromedex RED BOOK (electronic version). Merative, Ann Arbor, Michigan, USA. 2025.
Votrient Prescribing Information, Jan. 2024, Novartis Pharmaceuticals Corporation.
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

17. Pazopanib / Simvastatin

Alert Message: The concurrent use of Votrient (pazopanib) with simvastatin increases the incidence of ALT elevations. If a patient receiving concomitant simvastatin develops ALT elevations, increase to weekly monitoring of liver function as recommended. Withhold pazopanib and resume at reduced dose per prescribing information or permanently discontinue based on the severity of hepatotoxicity.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Pazopanib	Simvastatin	

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Votrient Prescribing Information, Jan. 2024, Novartis Pharmaceuticals Corporation.

18. Pazopanib / QT Prolongation Drugs

Alert Message: Votrient (pazopanib) use can cause QT prolongation. Monitor patients who are at significant risk of developing QTc prolongation, including patients with a history of QT interval prolongation, taking antiarrhythmics or other medications that may prolong the QT interval, and those with relevant preexisting cardiac disease. Monitor ECGs and electrolytes at baseline and as clinically indicated.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>			<u>Util C</u>
Pazopanib	Alfuzosin	Eliglustat	Lithium	Risperidone
	Amiodarone	Encorafenib	Lofexidine	Ritonavir
	Amitriptyline	Entrectinib	Loperamide	Romidepsin
	Anagrelide	Eribulin	Maprotiline	Sertraline
	Aripiprazole	Erythromycin	Methadone	Siponimod
	Arsenic Trioxide	Escitalopram	Metoclopramide	Solifenacin
	Asenapine	Ezogabine	Midostaurin	Sotalol
	Atazanavir	Famotidine	Mifepristone	Sunitinib
	Atomoxetine	Felbamate	Mirabegron	Tacrolimus
	Azithromycin	Fingolimod	Mirtazapine	Tamoxifen
	Bortezomib	Flecainide	Moexipril	Telavancin
	Venlafaxine	Fluconazole	Moxifloxacin	Tetrabenazine
	Bendamustine	Fluoxetine	Nelfinavir	Thioridazine
	Bosutinib	Fluvoxamine	Nilotinib	Voriconazole
	Buprenorphine	Foscarnet	Nortriptyline	Tizanidine
	Ceritinib	Galantamine	Ofloxacin	Tolterodine
	Chloroquine	Ganciclovir	Ondansetron	Toremifene
	Chlorpromazine	Gemifloxacin	Osimertinib	Tramadol
	Cilostazol	Gilteritinib	Oxaliplatin	Trazodone
	Ciprofloxacin	Glasdegib	Paliperidone	Trimipramine
	Citalopram	Granisetron	Panobinostat	Valbenazine
	Clarithromycin	Haloperidol	Paroxetine	Vandetanib
	Clomipramine	Hydroxychloroquine	Pasireotide	Vemurafenib
	Clozapine	Hydroxyzine	Vemurafenib	
	Crizotinib	Ibutilide	Pentamidine	
	Dabrafenib	Iloperidone	Pimavanserin	

Dasatinib	Imipramine	Pimozide
Desipramine	Indapamide	Pitolisant
Deutetrabenazine	Vemurafenib	Posaconazole
Diphenhydramine	Ivabradine	Procainamide
Disopyramide	Itraconazole	Promethazine
Dofetilide	Ivosidenib	Propafenone
Dolasetron	Ketoconazole	Quetiapine
Donepezil	Lapatinib	Quinidine
Doxepin	Lefamulin	Quinine
Dronedarone	Lenvatinib	Ranolazine
Droperidol	Leuprolide	Ribociclib

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
 Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
 Votrient Prescribing Information, Jan. 2024, Novartis Pharmaceuticals Corporation.

19. Pazopanib / H2 Blockers & PPIs

Alert Message: The concurrent use of Votrient (pazopanib) with gastric acid-reducing agents should be avoided. Pazopanib displays pH-dependent solubility with decreased solubility at higher pH. If concomitant administration with a gastric acid-reducing agent cannot be avoided, consider short-acting antacids in place of PPIs and H2-receptor antagonists. Separate short-acting antacid and pazopanib dosing by several hours to avoid a reduction in pazopanib exposure.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Pazopanib	Dexlansoprazole	Rabeprazole
	Esomeprazole	Cimetidine
	Lansoprazole	Famotidine
	Omeprazole	Nizatidine
	Pantoprazole	

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
 Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
 Votrient Prescribing Information, Jan. 2024, Novartis Pharmaceuticals Corporation.

20. Pazopanib / Pregnancy / Pregnancy Negating

Alert Message: Based on animal reproductive studies and its mechanism of action, Votrient (pazopanib) can cause fetal harm when administered to a pregnant woman. In animal developmental and reproductive toxicology studies, oral administration of pazopanib to pregnant rats and rabbits throughout organogenesis resulted in teratogenicity, and abortion at system exposures lower than that observed at the MRHD. Advise pregnant women of the potential risk to a fetus.

Drugs/Diseases		
<u>Util A</u>	<u>Util B</u>	<u>Util C (Negating)</u>
Pazopanib	Pregnancy	Abortion Delivery Miscarriage

Gender: Female

Age Range: 11 – 50 yoa

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Votrient Prescribing Information, Jan. 2024, Novartis Pharmaceuticals Corporation.

21. Pazopanib / Lactation

Alert Message: There are no data on the presence of Votrient (pazopanib) or its metabolites in human milk or their effects on the breastfed infant or milk production. Because of the potential for serious adverse reactions in breastfed infants, advise women not to breastfeed during treatment with pazopanib and for 2 weeks after the final dose.

Drugs/Diseases		
<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Pazopanib	Lactation	

Gender: Female

Age Range: 11 – 50 yoa

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Votrient Prescribing Information, Jan. 2024, Novartis Pharmaceuticals Corporation.

22. Pazopanib / Therapeutic Appropriateness

Alert Message: Advise females of reproductive potential to use effective contraception during treatment with Votrient (pazopanib) and for at least 2 weeks after the final dose. Pazopanib can cause fetal harm when administered to a pregnant woman.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C (Negating)</u>
Pazopanib		Contraceptives

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Votrient Prescribing Information, Jan. 2024, Novartis Pharmaceuticals Corporation.

23. Pazopanib / Therapeutic Appropriateness

Alert Message: Advise males (including those who have had vasectomies) with female partners of reproductive potential to use condoms during treatment with Votrient (pazopanib) and for at least 2 weeks after the final dose. Pazopanib can cause fetal harm when administered to a pregnant woman.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Pazopanib	Lactation	

Gender: Male

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Votrient Prescribing Information, Jan. 2024, Novartis Pharmaceuticals Corporation.

24. Pazopanib / Non-adherence

Alert Message: Based on refill history, your patient may be under-utilizing Votrient (pazopanib). 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 AUtil BUtil C

Pazopanib

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.

25. Lazertinib / Overuse

Alert Message: Lazcluze (lazertinib) may be over-utilized. The recommended dosage of lazertinib in adults is 240 mg orally once daily.

Drugs/Diseases

Util AUtil BUtil C

Lazertinib

Max Dose: 240 mg/day

References:
Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Lazcluze Prescribing Information, August 2024, Janssen Biotech, Inc.

Criteria Recommendations

Approved Rejected

26. Lazertinib / Therapeutic Appropriateness

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

Drugs/Diseases

Util A

Util B

Util C

Lazertinib

Age Range: 0 – 17 yoa

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Lazcluze Prescribing Information, August 2024, Janssen Biotech, Inc.

27. Lazertinib / Venous Thromboembolic Events

Alert Message: Lazcluze (lazertinib) in combination with amivantamab can cause serious and fatal venous thromboembolism events (VTE), including deep vein thrombosis and pulmonary embolism. Monitor for signs and symptoms of VTE. If a Grade 2 or 3 VTE occurs, withhold lazertinib and amivantamab and initiate anticoagulant therapy. Once anticoagulant therapy has been initiated, resume the combination therapy at the prior dose level. For Grade 4 VTE or recurrent Grade 2 or 3 VTE, withhold lazertinib, permanently discontinue amivantamab, and initiate anticoagulant therapy. Once anticoagulant therapy has been initiated, resume the lazertinib therapy at the same dose level.

Drugs/Diseases

Util A

Util B

Util C (Negate)

Lazertinib

Deep Vein Thrombosis
Pulmonary Embolism
Venous Thromboembolic Events

Anticoagulant

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Lazcluze Prescribing Information, August 2024, Janssen Biotech, Inc.

Criteria Recommendations

Approved Rejected

28. Lazertinib / Interstitial Lung Disease/Pneumonitis

Alert Message: Lazcluze (lazertinib) in combination with amivantamab can cause interstitial lung disease/pneumonitis (ILD)/pneumonitis. Monitor patients for signs and symptoms indicative of ILD/ pneumonitis (e.g., dyspnea, cough, fever). Immediately withhold both lazertinib and amivantamab in patients with suspected (ILD)/pneumonitis and permanently discontinue if ILD/pneumonitis is confirmed.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Lazertinib	Interstitial Lung Disease Pneumonitis Cough Dyspnea Fever	

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Lazcluze Prescribing Information, August 2024, Janssen Biotech, Inc.

29. Lazertinib / Dermatologic Adverse Reactions

Alert Message: Lazcluze (lazertinib) in combination with amivantamab can cause severe rash, including dermatitis acneiform, pruritus, and dry skin. If skin reactions develop, initiate supportive care management (e.g., corticosteroids and topical or oral antibiotics). Withhold, reduce the dose, or permanently discontinue lazertinib and amivantamab based on severity.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Lazertinib	Dermatitis Acneiform Pruritus Rash	

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Lazcluze Prescribing Information, August 2024, Janssen Biotech, Inc.

Criteria Recommendations

Approved Rejected

30. Lazertinib / Ocular Toxicity

Alert Message: Lazcluze (lazertinib) in combination with amivantamab can cause ocular toxicity, including keratitis. Promptly refer patients presenting with new or worsening eye symptoms to an ophthalmologist. Withhold, reduce the dose, or permanently discontinue amivantamab and continue lazertinib based on severity.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Lazertinib	Keratitis	
	Dry Eye	
	Eye Pain	
	Photophobia	
	Visual Discomfort/Disturbances	

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Lazcluze Prescribing Information, August 2024, Janssen Biotech, Inc.

31. Lazertinib / Strong CYP3A4 Inducers

Alert Message: Lazcluze (lazertinib) is a CYP3A4 substrate, and concurrent use with a strong or moderate CYP3A4 inducer can decrease lazertinib concentrations, which may reduce the efficacy of lazertinib. Avoid the concomitant use of lazertinib with strong and moderate CYP3A4 inducers.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Lazertinib	Apalutamide	
	Carbamazepine	
	Enzalutamide	
	Mitotane	
	Phenobarbital	
	Phenytoin	
	Primidone	
	Rifampin	

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Lazcluze Prescribing Information, August 2024, Janssen Biotech, Inc.

32. Lazertinib / BCRP Substrates with NTI

Alert Message: Lazcluze (lazertinib) is a BCRP inhibitor. The concurrent use of lazertinib with a BCRP substrate with a narrow therapeutic index can result in increased BCRP substrate concentrations and increased risk of substrate-related adverse reactions.

Drugs/Diseases

Util A	Util B	Util C
Lazertinib	Atorvastatin Methotrexate Rosuvastatin Sulfasalazine Topotecan	

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Lazcluze Prescribing Information, August 2024, Janssen Biotech, Inc.

33. Lazertinib / CYP3A4 Substrates with NTI

Alert Message: Lazcluze (lazertinib) is a CYP3A4 inhibitor. The concurrent use of lazertinib with a CYP3A4 substrate with a narrow therapeutic index can result in increased CYP3A4 substrate concentrations and increased risk of substrate-related adverse reactions.

Drugs/Diseases

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

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Lazcluze Prescribing Information, August 2024, Janssen Biotech, Inc.

34. Lazertinib / Pregnancy / Pregnancy Negating

Alert Message: Based on findings from animal studies and the mechanism of action, Lazcluze (lazertinib) can cause fetal harm when administered to a pregnant woman. Advise pregnant women and females of reproductive potential of the potential risk to a fetus. In animal reproduction studies, oral administration of lazertinib to pregnant animals during the period of organogenesis resulted in reduced embryo-fetal survival and fetal body weight in rats, and fetal malformations in rabbits.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C (Negate)</u>
Lazertinib	Pregnancy	Abortion Delivery Miscarriage

Gender: Female
Age Range: 11 – 50 yoa

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Lazcluze Prescribing Information, August 2024, Janssen Biotech, Inc.

35. Lazertinib / Lactation

Alert Message: There are no data on the presence of Lazcluze (lazertinib) or its metabolites in human milk or their effects on the breastfed infant or milk production. Because of the potential for serious adverse effects in breastfed children, advise women not to breastfeed during treatment with lazertinib and for 3 weeks after the last dose.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Lazertinib	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Lazcluze Prescribing Information, August 2024, Janssen Biotech, Inc.

Criteria Recommendations

Approved Rejected

36. Lazertinib / Therapeutic Appropriateness

Alert Message: Advise females of reproductive potential to use effective contraception during treatment with Lazcluze (lazertinib) and for 3 weeks after the last dose. Lazertinib can cause fetal harm when administered to a pregnant woman.

Drugs/Diseases

Util A
Lazertinib

Util B

Util C (Negating)
Contraceptives

Gender: Female
Age Range: 11 – 50 yoa

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Lazcluze Prescribing Information, August 2024, Janssen Biotech, Inc.

37. Lazertinib /Therapeutic Appropriateness

Alert Message: Advise males with female partners of reproductive potential to use effective contraception during treatment with Lazcluze (lazertinib) and for 3 weeks after the last dose.

Drugs/Diseases

Util A
Lazertinib

Util B

Util C

Gender: Male

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Lazcluze Prescribing Information, August 2024, Janssen Biotech, Inc.

38. Lazertinib / Non-adherence

Alert Message: Based on refill history, your patient may be under-utilizing Lazcluze (lazertinib). 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
Lazertinib

Util B

Util C

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

39. Vanzacaftor/Tezacaftor/Deutivacaftor / Overuse

Alert Message: Alyftrek (vanzacaftor/tezacaftor/deutivacaftor) may be over-utilized. The maximum recommended dose of vanzacaftor/tezacaftor/deutivacaftor in patients 12 years of age and older is two vanzacaftor 10 mg/tezacaftor 50 mg/deutivacaftor 125 mg tablets per day.

Drugs/Diseases

Util AUtil BUtil C

Vanzacaftor/tezacaftor/deutivacaftor

Max Dose: 2 tablets/day (total dose vanzacaftor 20 mg/tezacaftor 100 mg/deutivacaftor 250 mg)
Age Range: 12 – 999 yoa

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Alyftrek Prescribing Information, Dec. 2024, Vertex Pharmaceuticals, Inc.

40. Vanzacaftor/Tezacaftor/Deutivacaftor / Overuse

Alert Message: Alyftrek (vanzacaftor/tezacaftor/deutivacaftor) may be over-utilized. The maximum recommended dose of vanzacaftor/tezacaftor/deutivacaftor in patients 6 to less than 12 years old weighing 40 kg or more is two tablets of vanzacaftor 10 mg/tezacaftor 50 mg/deutivacaftor 125 mg per day. The maximum recommended dose of vanzacaftor/tezacaftor/deutivacaftor in patients 6 to less than 12 years of age weighing less than 40 kg is three tablets of vanzacaftor 4mg/tezacaftor 20 mg/deutivacaftor 50 mg per day.

Drugs/Diseases

Util AUtil BUtil C

Vanzacaftor/tezacaftor/deutivacaftor

Max Dose: 2 tablets/day
Age Range: 6 – 11 yoa

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Alyftrek Prescribing Information, Dec. 2024, Vertex Pharmaceuticals, Inc.

Criteria Recommendations

Approved Rejected

41. Vanzacaftor/Tezacaftor/Deutivacaftor / Therapeutic Appropriateness

Alert Message: The safety and effectiveness of Alyftrek (vanzacaftor/tezacaftor/deutivacaftor) in patients with CF younger than 6 years of age have not been established.

Drugs/Diseases

Util A
Vanzacaftor/tezacaftor/deutivacaftor

Util B

Util C

Age Range: 0 – 5 yoa

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Alyftrek Prescribing Information, Dec. 2024, Vertex Pharmaceuticals, Inc.

42. Vanzacaftor/Tezacaftor/Deutivacaftor / Severe Renal Impairment

Alert Message: Alyftrek (vanzacaftor/tezacaftor/deutivacaftor) use is not recommended in patients with severe renal impairment (eGFR < 30 mL/min/1.73m2) or end-stage renal disease. Use is recommended only if the benefits are expected to outweigh the risks. The effects of severe renal impairment on vanzacaftor/tezacaftor/deutivacaftor are unknown.

Drugs/Diseases

Util A
Vanzacaftor/tezacaftor/deutivacaftor

Util B
CKD Stage 4 & 5
ESRD

Util C

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Alyftrek Prescribing Information, Dec. 2024, Vertex Pharmaceuticals, Inc.

43. Vanzacaftor/Tezacaftor/Deutivacaftor / Severe Hepatic Impairment

Alert Message: Alyftrek (vanzacaftor/tezacaftor/deutivacaftor) has not been studied in patients with severe hepatic impairment (Child-Pugh Class C) and should not be used in this patient population.

Drugs/Diseases

Util A
Vanzacaftor/tezacaftor/deutivacaftor

Util B
Cirrhosis
Liver Failure

Util C

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Alyftrek Prescribing Information, Dec. 2024, Vertex Pharmaceuticals, Inc.

44. Vanzacaftor/Tezacaftor/Deutivacaftor / Moderate Hepatic Impairment

Alert Message: Alyftrek (vanzacaftor/tezacaftor/deutivacaftor) use is not recommended in patients with moderate hepatic impairment (Child-Pugh Class B) and should only be considered when there is a clear medical need, and the benefit outweighs the risk. Monitor liver function tests closely. Cases of serious and potentially fatal drug-induced liver injury and liver failure have been reported in patients taking a fixed-dose of vanzacaftor/tezacaftor/deutivacaftor.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Vanzacaftor/tezacaftor/deutivacaftor	Hepatic Impairment	

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Alyftrek Prescribing Information, Dec. 2024, Vertex Pharmaceuticals, Inc.

45. Vanzacaftor/Tezacaftor/Deutivacaftor / Strong 3A Inhibitors ≥ 12 yoa

Alert Message: Concomitant use of Alyftrek (vanzacaftor/tezacaftor/deutivacaftor) with strong CYP3A inhibitors may require dosage reduction of the fixed-dose combination medication. The dose of vanzacaftor/tezacaftor/deutivacaftor when used concurrently with a strong CYP3A inhibitor in patients 12 years of age and older is one vanzacaftor 10 mg/tezacaftor 50 mg/deutivacaftor 125 mg tablet once a week. All three components of the combination product are substrates of CYP3A, and concomitant use with a strong CYP3A inhibitor may result in increased exposure to all components and risk of vanzacaftor/tezacaftor/deutivacaftor-related adverse effects.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Vanzacaftor/tezacaftor/deutivacaftor	Clarithromycin	Nelfinavir
	Cobicistat	Posaconazole
	Itraconazole	Ritonavir
	Ketoconazole	Voriconazole
	Nefazodone	

Max Dose: 1 tablet per week
Age Range: 12 – 999 yoa

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Alyftrek Prescribing Information, Dec. 2024, Vertex Pharmaceuticals, Inc.

Criteria Recommendations

Approved Rejected

46. Vanzacافتor/Tezacافتor/Deutivacافتor / Moderate 3A Inhibitor ≥ 12 yoa

Alert Message: Concomitant use of Alyftrek (vanzacافتor/tezacافتor/deutivacافتor) with moderate CYP3A inhibitors may require dosage reduction of the fixed-dose combination medication. The dose of vanzacافتor/tezacافتor/deutivacافتor when used concurrently with a moderate CYP3A inhibitor in patients 12 years of age and older is one vanzacافتor 10 mg/tezacافتor 50 mg/deutivacافتor 125 mg tablet every other day. All three components of the combination product are substrates of CYP3A, and concomitant use with a moderate CYP3A inhibitor may result in increased exposure to all components and risk of vanzacافتor/tezacافتor/deutivacافتor-related adverse effects.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>		<u>Util C</u>
Vanzacافتor/tezacافتor/deutivacافتor	Aprepitant Cimetidine Ciprofloxacin Crizotinib Cyclosporine	Diltiazem Dronedarone Erythromycin Fluconazole Fluvoxamine	Imatinib Verapamil

Max Dose: 1 tablet every other day
Age Range: 12 – 999 yoa

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Alyftrek Prescribing Information, Dec. 2024, Vertex Pharmaceuticals, Inc.

47. Vanzacافتor/Tezacافتor/Deutivacافتor / Strong 3A Inhibitors 6 – 11 yoa

Alert Message: Concomitant use of Alyftrek (vanzacافتor/tezacافتor/deutivacافتor) with strong CYP3A inhibitors may require a dosage reduction of the fixed-dose combination medication. The dose of vanzacافتor/tezacافتor/deutivacافتor when used concurrently with a strong CYP3A inhibitor in patients 6 to less than 12 years of age weighing 40 kg or more is one vanzacافتor 10 mg/tezacافتor 50 mg/deutivacافتor 125 mg tablet once a week. For patients 6 to less than 12 years of age weighing less than 40 kg, the dose should be reduced to two vanzacافتor 4 mg/tezacافتor 20 mg/deutivacافتor 50 mg tablets once a week.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Vanzacافتor/tezacافتor/deutivacافتor	Clarithromycin Cobicistat Itraconazole Ketoconazole Nefazodone	Nelfinavir Posaconazole Ritonavir Voriconazole

Max Dose: 1 tablet per week
Age Range: 6 - 11 yoa

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Alyftrek Prescribing Information, Dec. 2024, Vertex Pharmaceuticals, Inc.

48. Vanzacافتor/Tezacافتor/Deutivacافتor / Moderate 3A Inhibitor 6-11 yoa

Alert Message: Concomitant use of Alyftrek (vanzacافتor/tezacافتor/deutivacافتor) with moderate CYP3A inhibitors may require dosage reduction of the fixed dose combination medication. The dose of vanzacافتor/tezacافتor/deutivacافتor when used concurrently with a moderate CYP3A inhibitor in patients 6 to less than 12 years of age weighing 40 kg or more is one vanzacافتor 10 mg/tezacافتor 50 mg/deutivacافتor 125 mg tablet every other day. For patients 6 to less than 12 years of age weighing less than 40 kg the dose should be reduced to two vanzacافتor 40 mg/tezacافتor 20 mg/deutivacافتor 50 mg tablets every other day.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>		<u>Util C</u>
Vanzacافتor/tezacافتor/deutivacافتor	Aprepitant	Diltiazem	Imatinib
	Cimetidine	Dronedaron	Verapamil
	Ciprofloxacin	Erythromycin	
	Crizotinib	Fluconazole	
	Cyclosporine	Fluvoxamine	

Max Dose: 1 tablet every other day
Age Range: 6 -11 yoa

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Alyftrek Prescribing Information, Dec. 2024, Vertex Pharmaceuticals, Inc.

49. Vanzacافتor/Tezacافتor/Deutivacافتor / Strong or Moderate 3A Inducers

Alert Message: Concomitant use of Alyftrek (vanzacافتor/tezacافتor/deutivacافتor) with strong or moderate CYP3A inducers is not recommended. Vanzacافتor, tezacافتor, and deutivacافتor are substrates of CYP3A, and concurrent use with strong or moderate CYP3A inducers decreases substrate exposure, which may reduce the substrate efficacy.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Vanzacافتor/tezacافتor/deutivacافتor	Apalutamide	
	Bosentan	
	Carbamazepine	
	Efavirenz	
	Etravirine	
	Phenobarbital	
	Phenytoin	
	Primidone	
	Rifabutin	
	Rifampin	
	Rifapentine	

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Alyftrek Prescribing Information, Dec. 2024, Vertex Pharmaceuticals, Inc.

50. Vanzacافتor/Tezacافتor/Deutivacافتor / Pregnancy / Pregnancy Negating

Alert Message: There are no available data on Alyftrek (vanzacافتor/tezacافتor/deutivacافتor) use in pregnant women to evaluate for a drug-associated risk of major birth defects, miscarriage, or other adverse maternal or fetal outcomes. There are animal studies that have been conducted separately with vanzacافتor, tezacافتor, and ivacافتor (deutivacافتor is the deuterated isotopologue of ivacافتor). No adverse developmental effects were observed after oral administration of vanzacافتor, tezacافتor, or ivacافتor to pregnant rats from the period of organogenesis through lactation at doses that produced maternal exposures approximately 18 times, 1 time, and 8 times the exposures at the MRHD, respectively. Placental transfer of vanzacافتor, tezacافتor, and ivacافتor was observed in pregnant rats.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C (Negate)</u>
Vanzacافتor/tezacافتor/deutivacافتor	Pregnancy	Abortion Delivery Miscarriage

Gender: Female
Age Range: 11 – 50 yoa

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Alyftrek Prescribing Information, Dec. 2024, Vertex Pharmaceuticals, Inc.

51. Vanzacافتor/Tezacافتor/Deutivacافتor / Lactation

Alert Message: There are no data on the presence of Alyftrek (vanzacافتor/tezacافتor/deutivacافتor) in human milk, the effects on the breastfed infant, or the effects on milk production. Vanzacافتor, tezacافتor, and ivacافتor (deutivacافتor is the deuterated isotopologue of ivacافتor) are excreted into the milk of female rats. When a drug is present in animal milk, it is likely that the drug will be present in human milk. The developmental and health benefits of breastfeeding should be considered along with the mother’s clinical need for vanzacافتor/tezacافتor/deutivacافتor and any potential adverse effects on the breastfed child from vanzacافتor/tezacافتor/deutivacافتor or the underlying maternal condition.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Vanzacافتor/tezacافتor/deutivacافتor	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Alyftrek Prescribing Information, Dec. 2024, Vertex Pharmaceuticals, Inc.

Criteria Recommendations

Approved Rejected

52. Vanzacaftor/Tezacaftor/Deutivacaftor / Non-adherence

Alert Message: Based on refill history, your patient may be under-utilizing Alyftrek (vanzacaftor/tezacaftor/deutivacaftor). 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

Vanzacaftor/tezacaftor/deutivacaftor

References:

Osterberg L, Blaschke T. Adherence to Medication. N Engl J Med 2005;353:487-97.
Eakin MN, Bilderback A, Boyle MP, et al., Longitudinal Association Between Medication Adherence and Lung Health in People with Cystic Fibrosis. Jmnl Cyst Fib. 2011;10(4):258-264.
Bishay LC, Sawicki GS., Strategies to Optimize Adherence in Adolescent Patients with Cystic Fibrosis. Adolesc Health, Med & Ther. 2016 Oct 21;7:117-124.

53. Inavolisib / Overuse

Alert Message: Itovebi (inavolisib) may be over-utilized. The recommended dosage of inavolisib is 9 mg once daily until disease progression or unacceptable toxicity.

Drugs/Diseases

Util A

Util B

Util C (Negating)

Inavolisib

CKD Stage 3, 3a, & 3b

Max Dose: 9 mg/day

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Itovebi Prescribing Information, Oct 2024, Genentech, Inc.

54. Inavolisib / Overuse

Alert Message: Itovebi (inavolisib) may be over-utilized. The recommended dosage of inavolisib for patients with moderate renal impairment (eGFR 30 to < 60 mL/min based on CKD-EPI) is 6 mg once daily. In pharmacokinetic studies, the AUC was 73% higher in patients with moderate renal impairment compared to patients with normal renal function. Inavolisib has not been evaluated in patients with severe renal impairment. No dosage adjustment is recommended in patients with mild renal impairment.

Drugs/Diseases

Util A

Util B

Util C (Include)

Inavolisib

CKD Stage 3, 3a, & 3b

Max Dose: 6 mg/day

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Itovebi Prescribing Information, Oct 2024, Genentech, Inc.

Criteria Recommendations

Approved Rejected

55. Inavolisib / Therapeutic Appropriateness

Alert Message: The safety and efficacy of Itovebi (inavolisib) in pediatric patients has not been established.

Drugs/Diseases

Util A
Inavolisib

Util B

Util C

Age Range: 0 – 17 yoa

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Itovebi Prescribing Information, Oct 2024, Genentech, Inc.

56. Inavolisib / Hyperglycemia

Alert Message: Itovebi (inavolisib) can cause severe hyperglycemia. After initiating inavolisib, monitor or have the patient self-monitor fasting glucose levels once every 3 days for the first week, then once every week for the next 3 weeks, then once every 2 weeks for the next 8 weeks, and then once every 4 weeks thereafter. Manage hyperglycemia with anti-hyperglycemic medications as clinically indicated. Based on the severity of hyperglycemia, inavolisib may require interruption, dose reduction, or discontinuation.

Drugs/Diseases

Util A
Inavolisib

Util B
Hyperglycemia

Util C (Negate)
Antidiabetic Medication

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Itovebi Prescribing Information, Oct 2024, Genentech, Inc.

57. Inavolisib / Stomatitis

Alert Message: Itovebi (inavolisib) can cause severe stomatitis. Monitor patients for signs and symptoms of stomatitis. Initiate or intensify appropriate medical therapy (e.g., corticosteroid-containing mouthwash) if stomatitis occurs. Withhold, reduce dose, or permanently discontinue inavolisib, based on severity.

Drugs/Diseases

Util A
Inavolisib

Util B
Stomatitis
Recurrent Oral Aphthae
Oral Mucositis

Util C

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Itovebi Prescribing Information, Oct 2024, Genentech, Inc.

58. Inavolisib / Diarrhea

Alert Message: Severe diarrhea, including dehydration and acute kidney injury, can occur in patients treated with Itovebi (inavolisib). In clinical trials, diarrhea occurred in 48% of patients receiving inavolisib with palbociclib and fulvestrant. Monitor patients for signs and symptoms of diarrhea. Advise the patient to increase oral fluids and start antidiarrheal treatment at the first sign of diarrhea while taking inavolisib. Withhold, reduce the dose, or permanently discontinue inavolisib based on the severity of diarrhea.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Inavolisib	Diarrhea	

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Itovebi Prescribing Information, Oct 2024, Genentech, Inc.

59. Inavolisib / Pregnancy / Pregnancy Negating

Alert Message: Based on animal data and its mechanism of action, Itovebi (inavolisib) can cause fetal harm when administered to a pregnant woman. In an animal reproductive study, oral administration of inavolisib to pregnant rats during organogenesis caused adverse developmental outcomes, including structural abnormalities and embryo-fetal mortality. Advise pregnant women and females of reproductive potential of the potential risk to a fetus.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C (Negate)</u>
Inavolisib	Pregnancy	Abortion Delivery Miscarriage

Gender: Female
Age Range: 11 – 50 yoa

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.

60. Inavolisib / Lactation

Alert Message: There are data on the presence of Itovebi (inavolisib) or its metabolites in human milk, its effects on milk production, or the breastfed child. Because of the potential for serious reactions in a breastfed child, advise lactating women not to breastfeed during treatment with inavolisib and for 1 week after the last dose.

Drugs/Diseases

Util A
Inavolisib

Util B
Lactation

Util C

Gender: Female
Age Range: 11 – 50 yoa

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.

61. Inavolisib / Therapeutic Appropriateness

Alert Message: Advise females of reproductive potential to use effective contraception during treatment with Itovebi (inavolisib) and for 1 week after the last dose. Inavolisib can cause fetal harm when administered to a pregnant woman.

Drugs/Diseases

Util A
Inavolisib

Util B

Util C

Gender: Female
Age Range: 11 – 50 yoa

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.

62. Inavolisib /Therapeutic Appropriateness

Alert Message: Advise males with female partners of reproductive potential to use effective contraception during treatment with Itovebi (inavolisib) and for 1 week after the last dose.

Drugs/Diseases

Util A
Inavolisib

Util B

Util C

Gender: Male

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.

Criteria Recommendations

Approved Rejected

63. Inavolisib / Non-adherence

Alert Message: Based on refill history, your patient may be under-utilizing Itovebi (inavolisib). 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
Inavolisib

Util B

Util C

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.

64. Sparsentan / Overuse

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

Drugs/Diseases

Util A
Sparsentan

Util B

Util C

Max Dose: 400 mg/day

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Filspari Prescribing Information, August 2025, Traverre Therapeutics, Inc.

65. Sparsentan / Therapeutic Appropriateness

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

Drugs/Diseases

Util A
Sparsentan

Util B

Util C

Age Range: 0 – 17 yoa

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Filspari Prescribing Information, August 2025, Traverre Therapeutics, Inc.

66. Sparsentan / Pregnancy – Contraindication Box Warning

Alert Message: Based on animal reproductive toxicity studies, Filspari (sparsentan) may cause fetal harm, including birth defects and fetal death, when administered to a pregnant patient and is contraindicated during pregnancy.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C (Negating)</u>
Sparsentan	Pregnancy	Abortion Delivery Miscarriage

Gender: Female
Age Range: 11 – 50 yoa

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Filspari Prescribing Information, August 2025, Traverre Therapeutics, Inc.

67 Sparsentan / ARBs, ERAs, or Aliskiren

Alert Message: Prior to initiating Filspari (sparsentan), discontinue the use of renin-angiotensin-aldosterone system (RAAS) inhibitors and endothelin receptor antagonists (ERAs). The coadministration of sparsentan with ARBs, ERAs, or aliskiren is contraindicated.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Sparsentan	Azilsartan Candesartan Irbesartan Losartan Olmesartan Telmisartan Valsartan	Ambrisentan Aprocitentan Bosentan Macitentan Aliskiren Eplerenone

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Filspari Prescribing Information, August 2025, Traverre Therapeutics, Inc.

68. Sparsentan / Hepatic Impairment – Box Warning

Alert Message: Filspari (sparsentan) may cause hepatotoxicity. Advise patients with symptoms suggesting hepatotoxicity to immediately stop treatment with sparsentan and seek medical attention. If aminotransferase levels are abnormal at any time during treatment, interrupt sparsentan and monitor as recommended. Avoid initiation of sparsentan in patients with elevated aminotransferases, as these patients may be at increased risk for serious hepatotoxicity.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Sparsentan	Abnormal result of liver function studies	
	Elevated transaminase levels	
	Nausea	
	Vomiting	
	Right upper quadrant pain	
	Fatigue	
	Anorexia	

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Filspari Prescribing Information, August 2025, Traverre Therapeutics, Inc.

69. Sparsentan / Acute Kidney Injury

Alert Message: Filspari (sparsentan) may cause acute kidney failure, and periodic kidney function monitoring is recommended during treatment with sparsentan. Sparsentan is an endothelin and angiotensin II receptor antagonist, and drugs that inhibit the renin-angiotensin-aldosterone system (RAAS) can adversely affect the kidneys. Patients whose kidney function may depend in part on the activity of the renin-angiotensin system (e.g., patients with renal artery stenosis, chronic kidney disease, severe congestive heart failure or volume depletion) may be at particular risk of developing acute kidney injury.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Sparsentan	Acute Renal Failure	
	Chronic Kidney Disease	
	Heart Failure	
	Hypovolemia	

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Filspari Prescribing Information, August 2025, Traverre Therapeutics, Inc.

70. Sparsentan / Hyperkalemia

Alert Message: Filspari (sparsentan) may cause hyperkalemia. Patients with advanced kidney disease or taking concomitant potassium-increasing drugs (e.g., potassium supplement, potassium-sparing diuretics, or potassium-containing salt substitutes are at increased risk for developing hyperkalemia. Dosage reduction of discontinuation of sparsentan may be required.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Sparsentan	Hyperkalemia	
	Potassium-Sparing Diuretics	
	Potassium Supplements	

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Filspari Prescribing Information, August 2025, Traverre Therapeutics, Inc.

71. Sparsentan / Fluid Retention

Alert Message: Fluid retention may occur with the use of Filspari (sparsentan). If clinically significant fluid retention develops, evaluate the patient to determine the cause and the potential need to initiate or modify the dose of diuretic treatment, then consider modifying the dose of sparsentan.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Sparsentan	Fluid Retention	

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Filspari Prescribing Information, August 2025, Traverre Therapeutics, Inc.

72. Sparsentan / Strong CYP3A Inhibitors

Alert Message: The use of Filspari (sparsentan) with strong CYP3A inhibitors should be avoided. Sparsentan is a CYP3A substrate, and concomitant use with strong CYP3A inhibitors may increase sparsentan Cmax and AUC, which may increase the risk of sparsentan-related adverse reactions. If the use of a strong CYP3A inhibitor cannot be avoided, interrupt treatment with sparsentan. When resuming treatment with sparsentan, consider dose titration (initial treatment with sparsentan at 200 mg once daily, after 14 days, increase to the recommended dose of 400 mg once daily, as tolerated).

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>		<u>Util C</u>
Sparsentan	Clarithromycin	Nelfinavir	
	Cobicistat	Posaconazole	
	Itraconazole	Ritonavir	
	Ketoconazole	Voriconazole	
	Nefazodone		

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Filspari Prescribing Information, August 2025, Travere Therapeutics, Inc.

73. Sparsentan / Moderate CYP3 Inhibitors

Alert Message: The concomitant use of Filspari (sparsentan), a CYP3A substrate, with a moderate CYP3A inhibitor may result in increased sparsentan exposure and risk of sparsentan-related adverse effects. If sparsentan is co-administered with a moderate CYP3A inhibitor, monitor the patient's blood pressure, serum potassium, and kidney function regularly. No sparsentan dose adjustment is needed.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>		<u>Util C</u>
Sparsentan	Aprepitant	Diltiazem	Imatinib
	Cimetidine	Dronedarone	Verapamil
	Ciprofloxacin	Erythromycin	
	Crizotinib	Fluconazole	
	Cyclosporine	Fluvoxamine	

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Filspari Prescribing Information, August 2025, Travere Therapeutics, Inc.

74. Sparsentan / Strong CYP3A Inducers

Alert Message: The use of Filspari (sparsentan) with strong CYP3A inducers should be avoided. Sparsentan is a CYP3A substrate, and concomitant use with a strong CYP3A inducer may decrease sparsentan Cmax and AUC, which may reduce sparsentan efficacy.

Drugs/Diseases

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

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Filspari Prescribing Information, August 2025, Travele Therapeutics, Inc.

75. Sparsentan / H2-Blockers & PPIs

Alert Message: Avoid the concomitant use of Filspari (sparsentan) with H2-blockers or PPIs. Sparsentan exhibits pH-dependent solubility, and concurrent use with an acid-reducing agent may decrease sparsentan exposure, which may reduce sparsentan efficacy.

Drugs/Diseases

Util A	Util B	Util C
Sparsentan	Cimetidine Famotidine Nizatidine Dexlansoprazole Esomeprazole	Lansoprazole Omeprazole Pantoprazole Rabeprazole

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Filspari Prescribing Information, August 2025, Travele Therapeutics, Inc.

Criteria Recommendations

Approved Rejected

76. Sparsentan / Antacids

Alert Message: The concurrent use of Filspari (sparsentan) with an antacid may result in decreased sparsentan efficacy. Sparsentan exhibits pH-dependent solubility, and concurrent use with an antacid may decrease sparsentan exposure, which may reduce sparsentan efficacy. If concurrent use cannot be avoided, administer sparsentan 2 hours before or after the antacids.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Sparsentan	Al, Mg, & Ca Antacids	

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Filspari Prescribing Information, August 2025, Traverre Therapeutics, Inc.

77. Sparsentan / NSAIDS

Alert Message: The concurrent use of Filspari (sparsentan) with an NSAID may result in worsening renal function. The concomitant use of NSAIDs with drugs that antagonize the angiotensin II receptor may result in deterioration of kidney function. Monitor the patient for signs of worsening renal function when sparsentan is co-administered with an NSAID.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Sparsentan	NSAIDS	

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Filspari Prescribing Information, August 2025, Traverre Therapeutics, Inc.

78. Sparsentan / P-gp and BCRP Substrates w/ NTI

Alert Message: Avoid the use of Filspari (sparsentan) with sensitive substrates of P-gp and BCRP transport. Sparsentan is an inhibitor of P-gp and BCRP transport, and concomitant use with a sensitive P-gp or BCRP substrate may increase substrate exposure and the risk of substrate-related adverse reactions.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Sparsentan	Cyclosporine	Sirolimus
	Digoxin	Tacrolimus
	Everolimus	Methotrexate

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Filspari Prescribing Information, August 2025, Traverre Therapeutics, Inc.

79. Sparsentan / Lactation

Alert Message: There are no data on the presence of Filspari (sparsentan) in human milk, the effects on the breastfed infant, or the effect on milk production. Because of the potential for adverse reactions, such as hypotension in breastfed infants, advise patients not to breastfeed during treatment with sparsentan.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Sparsentan	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Filspari Prescribing Information, August 2025, Traverre Therapeutics, Inc.

80. Sparsentan / Therapeutic Appropriateness

Alert Message: Advise females of reproductive potential to use effective contraception before initiation of treatment, during treatment, and for 2 weeks after discontinuation of sparsentan. Sparsentan can cause fetal harm if used by pregnant patients.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C (Negating)</u>
Sparsentan		Contraceptives

Gender: Female
Age Range: 11 – 50 yoa

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.
Filspari Prescribing Information, August 2025, Traverre Therapeutics, Inc.

81. Sparsentan / Non-adherence

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

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Sparsentan		

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 F. The Unmet Challenge of Medication Nonadherence. Perm Jnl. 2018;22:18-033. doi:10.7812/TPP/18-033.

Criteria Recommendations

Approved Rejected

82. Fremanezumab-vfrm / Overuse

Alert Message: Ajovy (fremanezumab-vfrm) may be over-utilized. The recommended dosage of fremanezumab-vfrm for the preventive treatment of episodic migraine in pediatric patients who are 6 to 17 years of age and who weigh 45 kg or more is 225 mg monthly.

Drugs/Diseases

Util A

Util B

Util C

Fremanezumab-vfrm

Max Dose: 225 mg/month
Age Range: 6 – 17 yoa

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Ajovy Prescribing Information, August 2025, Teva Pharmaceuticals USA, Inc.

83. Dihydroergotamine 0.725 Nasal / Overuse

Alert Message: Trudhesa (dihydroergotamine nasal spray) may be over-utilized. The recommended dose of nasal dihydroergotamine is 1.45 mg administered as two metered sprays (one 0.725 mg spray in each nostril). The dose may be repeated, if needed, a minimum of 1 hour after the first dose. Do not use more than 2 doses of dihydroergotamine nasal spray within 24 hours or 3 doses within a 7-day period.

Drugs/Diseases

Util A

Util B

Util C

Dihydroergotamine Nasal

Max Dose: 2.9 mg/day

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.

84. Dihydroergotamine 0.75 Nasal / Therapeutic Appropriateness

Alert Message: The safety and efficacy of Trudhesa (dihydroergotamine nasal spray) in pediatric patients have not been established.

Drugs/Diseases

Util A

Util B

Util C

Dihydroergotamine Nasal

Age Range: 0 – 17 yoa

References:

Clinical Pharmacology, 2025 Elsevier/Gold Standard.
Facts & Comparisons, 2025 Updates, Wolters Kluwer Health.

Criteria Recommendations

Approved Rejected

85. Eplerenone / Non-adherence

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

Drugs/Diseases

Util AUtil BUtil C

Eplerenone

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.
Chobanian AV. Impact of Nonadherence to Antihypertensive Therapy. Circulation. 2009;120:1558-1560.
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.

86. Aliskiren / Non-adherence

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

Drugs/Diseases

Util AUtil BUtil C

Aliskiren

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.
Chobanian AV. Impact of Nonadherence to Antihypertensive Therapy. Circulation. 2009;120:1558-1560.
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.

Board Suggestions for clinical practice education or RDUR ICER criteria

1. Is there anything in clinical practice that you've seen that you feel needs to be addressed?
 - a. New best practices?
 - b. Fraud, waste, or abuse?
2. Is there any new guideline information?
3. Requests for Utilization Review topics?