North Dakota Medicaid

Drug Utilization Review Board Meeting

March 2nd, 2022

Conference Room 210/212

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Meeting Notice

North Dakota Medicaid Drug Use Review Board

Wednesday, March 2, 2022
1 to 4 p.m. Central Time

In-Person Information

Conference Room 210/212, 3rd 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: 830 134 184#

Agenda

1. Administrative items
    - DHS announcements

2. Old business
    - Review and approval of December 2021 meeting minutes
    - Budget update
    - Review top 25 drugs for fourth quarter of 2021
    - Prior authorization/PDL update
    - Update to Phenylketonuria
    - Update to Resistance Prevention
    - Update to Narcolepsy
    - Update to Eczema/Atopic Dermatitis
    - Second review of Chronic Kidney Disease
    - Second review of Lupus
    - Synagis discussion

3. New business
    - Review of Familial Cholestasis Pruritis
    - Review of drug utilization trends for select medication classes
    - Retrospective DUR profile review update
    - Retrospective DUR criteria recommendations
    - Upcoming meeting date/agenda.
        - Next meeting is June 1, 2022

Adjourn

Individuals with disabilities who need accommodations, including appropriate auxiliary aids to participate, can contact Stacey Koehly at 701-328-4807, toll-free 800-755-2604, 711 (TTY) or skoehly@nd.gov.

North Dakota Medicaid Drug Use Review (DUR) Board
Meeting Minutes
December 1, 2021

Members Present: Joshua Askvig, Andrea Honeyman, Kathleen Traylor, Gabriela Balf, Amy Werremeyer, Laura Kroetsch, Tanya Schmidt, Kevin Martian, Kristen Peterson, Jennifer Iverson

Medicaid Pharmacy Department: Alexi Murphy, Brendan Joyce

Old Business

Chair T. Schmidt called the meeting to order at 1:05 p.m. Chair T. Schmidt asked for a motion to approve the minutes of the September 1, 2021, meeting. J. Askvig moved that the minutes be approved, and L. Kroetsch seconded the motion. The chair called for a voice vote to approve the minutes. The motion passed with no audible dissent.

Review Top 25 Drugs

B. Joyce presented budget updates and the quarterly review of the top 25 drugs based on total cost of claims, the top 25 drugs based on the total number of claims, and the top drug classes based on claims and cost for the 4th quarter of 2021. B. Joyce presented data to the Board that was reflective of the net spend since merging traditional Medicaid and expansion. The rise in net spend over time, specifically after the first quarter in 2020, is directly linked to the COVID-19 pandemic and the public health emergency that coincided with the pandemic. B. Joyce also discussed the increase in total population covered by Medicaid after the first quarter in 2020. B. Joyce went on to discuss the per member per month and how some members may not be utilizing services for unknown reasons. During public comment, J. Askvig asked if the total number of claims has changed due to the pandemic, in which B. Joyce answered that the number of claims has remained about the same. G. Balf asked if there were claims for ivermectin to treat Covid-19, in which B. Joyce answered that there must be support in the compendia or FDA approved indication for the uses of medications. Thus, if there is no indication for use, then ND Medicaid does not cover the medication.

PDL/PA Criteria Updates

A. Murphy shared with the Board all the changes made to the Preferred Drug List since the last version of the Preferred Drug List was posted. Notable changes include removing certain estrogen products, certain topical steroids, and certain inhalers from PA, as well as adding hyper expensive agents to already existing PA category criteria. All PDL updates are listed in the handouts for the December 2021 DUR Board meeting. When a new version of the PDL is published and posted to the website, all updates/changes made since the last version are called out at the top of the document itself.

Proposed New Criteria for Eczema / Atopic Dermatitis

L. Morgan presented the proposed prior authorization criteria for Opzelura. The proposed updates included adding Opzelura to the list of non-preferred topical agents, requiring prior authorization. Since Opzelura is FDA indicated for short-term and non-continuous chronic treatment of mild to moderate atopic dermatitis, requiring prior authorization is essential to ensure proper use of the agent.

Second Review of Non-Stimulant Agents Used in the Treatment of ADHD

A motion and second was made at the September 2021 DUR Board meeting to place some agents, for the management of ADHD on the non-preferred list, requiring PA. The topic was brought up for a second review. Product specific ADHD criteria for Qelbree was presented to the Board by L. Morgan. Chair T. Schmidt called for a voice vote to approve the updated criteria, which passed with no audible dissent.

Annual Review of Prior Authorization Forms and Criteria

The Board reviewed all forms and criteria utilized for all medications that are currently placed on prior authorization. L. Morgan discussed the major changes made in the preferred drug list (PDL) since the last update. This list of changes is included in the handout, as well as, in the PDL. L. Morgan also discussed the changes made in the PA forms, most notably the Kepro logo replacing the Health Information Designs logo and the updated "General PA form." The updates in the "General PA form" include adding sections for member weight, primary insurance requirements, and reason for PA. By including more information in the general PA form, many drug specific PA forms were removed that were no longer necessary. Chair T. Schmidt then called for any questions or concerns about the reviewed forms and criteria, which had no audible questions or dissent.

New Business

Review of Agents Used in the Treatment of Chronic Kidney Disease

L. Morgan presented a review of agents used in the treatment of chronic kidney disease (CKD) to the Board. There was no public comment after review. A motion was made by A. Werremeyer to manage these medications through prior authorization. The motion was seconded by Chair T. Schmidt. Prior authorization criteria for these agents will be presented, reviewed, and voted on by the Board at the next meeting.

Review of Agents Used in the Treatment of Lupus

L. Morgan presented a review of agents used in the treatment systemic lupus erythematosus (SLE) and lupus nephritis (LN) to the Board. There was no public comment after review. A motion was made by K. Martian to manage these medications through prior authorization. The motion was seconded by A. Honeyman. Prior authorization criteria for these agents will be presented, reviewed, and voted on by the Board at the next meeting.

Retrospective Drug Utilization Review (RDUR) Criteria Recommendations

L. Morgan reviewed the RDUR criteria that were selected for review of each month of the last quarter. Presented data included number of profiles reviewed, number of cases identified for intervention, and the number of letters sent, as well as an overview of what RDUR interventions were identified as most prevalent for each monthly cycle. L. Morgan discussed the increase in letters sent during the months of July, August, and September and correlated the increase to the more relevant criteria. The recommended RDUR criteria enclosed in the packet were developed from product information provided by the manufacturers and are consistent with new indications, new drugs added, and new warnings. These proposed criteria will be added to the current set of criteria and will be used in future DUR cycles. Chair T. Schmidt moved to approve the new criteria and K. Peterson seconded the motion. Chair T. Schmidt called for a voice vote to approve the new criteria, which passed with all present members voting to approve.

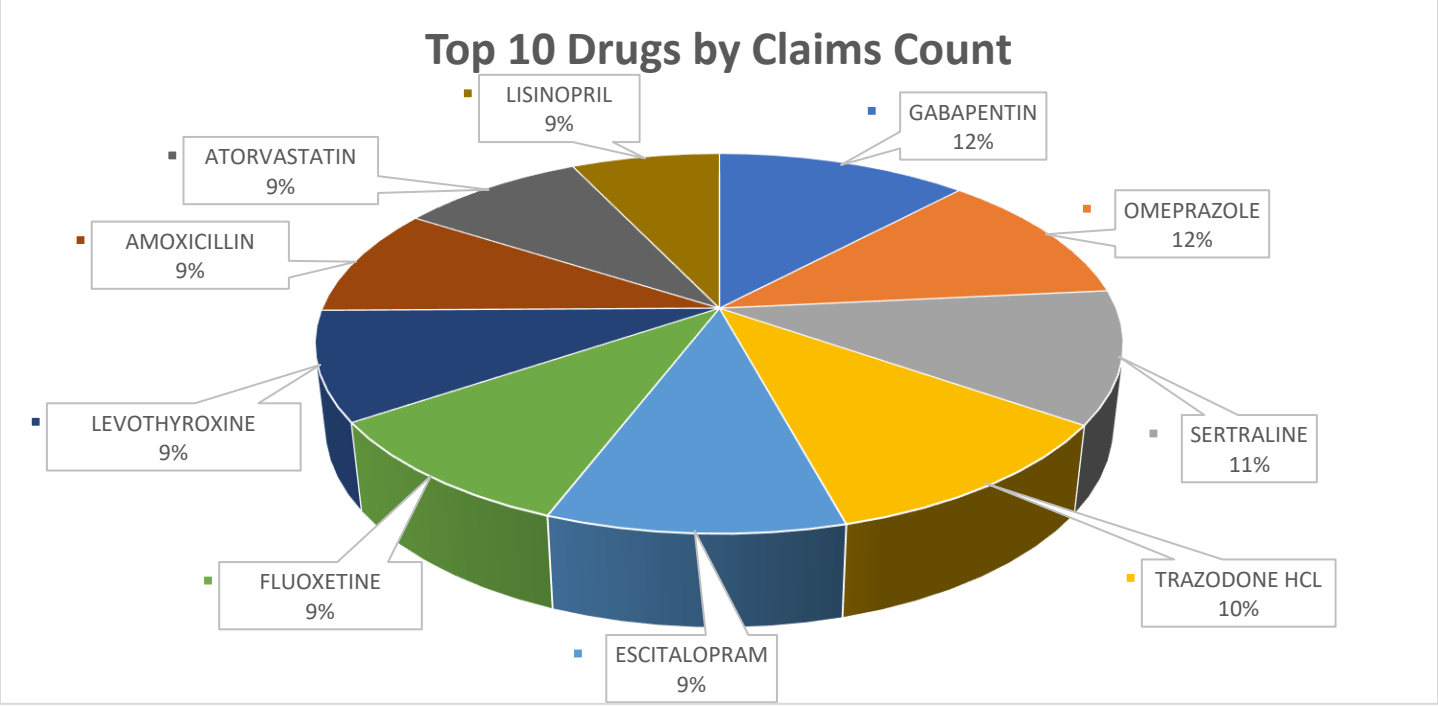
Adjournment and Upcoming Meeting Date

Chair T. Schmidt adjourned the meeting at 2:20 pm. The next DUR Board meeting will be held March 2, 2022, at 1:00 pm at the state capitol building.

Top 25 Drugs Based on Number of Claims from 10/01/2021 – 12/31/2021

Drug	Claims	Patients	Claims Cost	Cost / Claim	% Total Claims	Dif.
GABAPENTIN	4,636	1,943	$68,581.71	$14.79	2.84%	↑1
OMEPRAZOLE	4,625	2,287	$61,807.12	$13.36	2.83%	↓1
SERTRALINE HCL	4,185	2,255	$57,654.03	$13.78	2.56%	NC
TRAZODONE HCL	3,840	1,891	$53,032.03	$13.81	2.35%	↑1
ESCITALOPRAM OXALATE	3,676	2,058	$49,687.51	$13.52	2.25%	↑1
FLUOXETINE HCL	3,633	1,926	$49,361.83	$13.59	2.22%	↑3
LEVOTHYROXINE SODIUM	3,626	1,769	$71,196.27	$19.63	2.22%	↓3
AMOXICILLIN	3,576	3,357	$50,729.50	$14.19	2.19%	↑5
ATORVASTATIN CALCIUM	3,481	1,896	$48,905.57	$14.05	2.13%	↓1
LISINOPRIL	3,447	1,961	$45,744.28	$13.27	2.11%	↓3
PANTOPRAZOLE SODIUM	2,820	1,370	$37,947.48	$13.46	1.73%	↑1
PROAIR HFA	2,809	2,786	$218,698.73	$77.86	1.72%	↓2
VYVANSE	2,768	1,105	$689,452.27	$249.08	1.69%	↑6
BUPROPION XL	2,720	1,416	$47,633.61	$17.51	1.67%	NC
PREDNISONE	2,697	2,149	$33,152.78	$12.29	1.65%	↑2
HYDROCODONE-APAP	2,690	1,664	$40,537.40	$15.07	1.65%	↓5
BUPRENORPHINE-NALOXONE	2,495	553	$99,827.60	$40.01	1.53%	↑3
DULOXETINE HCL	2,448	1,245	$39,618.44	$16.18	1.50%	NC
METFORMIN HCL	2,432	1,331	$32,153.86	$13.22	1.49%	↓4
CYCLOBENZAPRINE HCL	2,420	1,496	$28,106.71	$11.61	1.48%	↑1
MONTELUKAST SODIUM	2,416	1,377	$34,150.13	$14.13	1.48%	↓5
AUGMENTIN	2,384	2,241	$43,668.45	$18.32	1.46%	↑11
CLONAZEPAM	2,259	935	$31,142.63	$13.79	1.38%	NC
LAMOTRIGINE	2,241	910	$31,987.99	$14.27	1.37%	NC
CLONIDINE HCL	2,210	1,067	$28,121.39	$12.72	1.35%	↓3

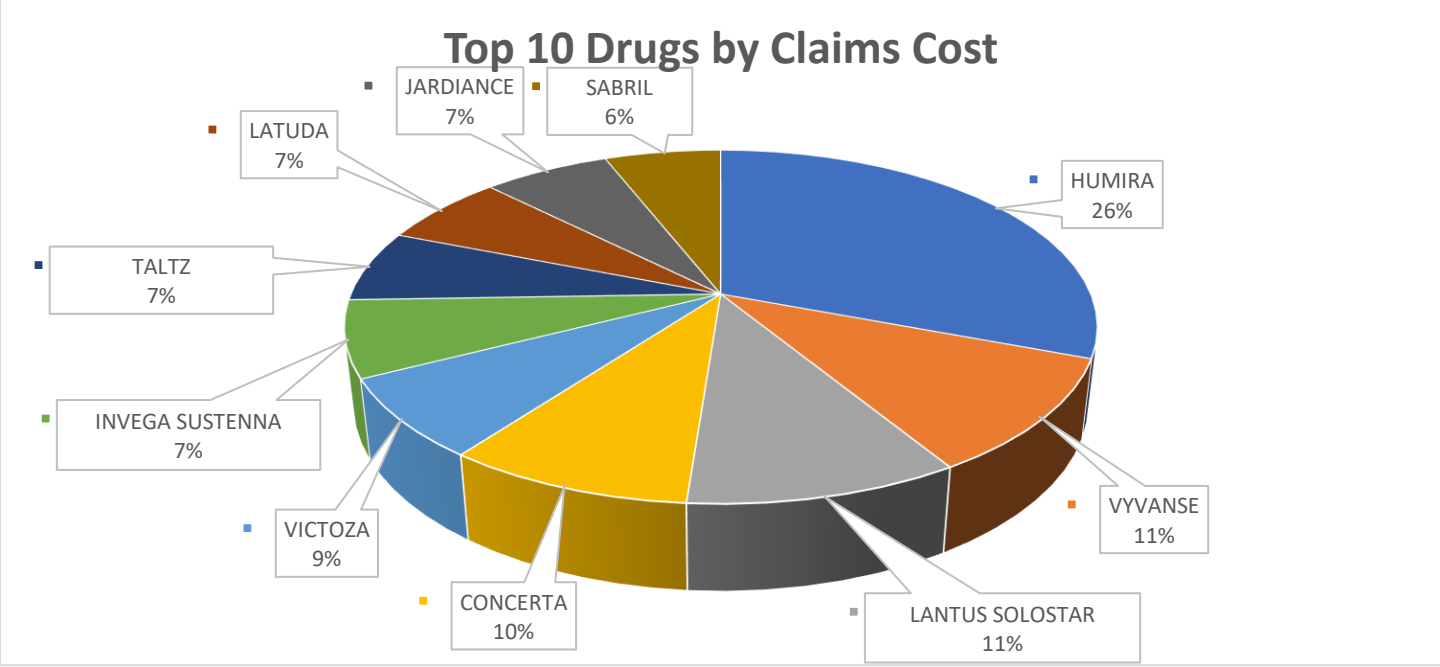
Total Claims	**163,356**



Top 25 Drugs Based on Total Claims Cost from 10/01/2021 – 12/31/2021

Drug	Claims Cost	Claims	Patients	Cost /Claim	% Total Cost	Dif.
HUMIRA PEN	$1,627,164.17	235	100	$6,924.10	5.62%	NC
VYVANSE	$689,452.27	2,768	1,105	$249.08	2.38%	NC
LANTUS SOLOSTAR	$655,854.77	1,292	787	$507.63	2.27%	NC
CONCERTA	$616,964.67	1,806	745	$341.62	2.13%	NC
VICTOZA 3-PAK	$545,708.04	583	260	$936.03	1.89%	NC
INVEGA SUSTENNA	$454,505.90	187	75	$2,430.51	1.57%	↑1
TALTZ AUTOINJECTOR	$448,964.66	71	31	$6,323.45	1.55%	↓1
LATUDA	$422,913.72	513	197	$824.39	1.46%	NC
JARDIANCE	$420,638.30	872	401	$482.38	1.45%	NC
SABRIL	$379,900.67	14	6	$27,135.76	1.31%	NC
STELARA	$373,752.00	16	11	$23,359.50	1.29%	↑1
NOVOLOG FLEXPEN	$372,971.22	527	335	$707.73	1.29%	↓1
TRIKAFTA	$333,543.66	14	5	$23,824.55	1.15%	↑3
SYMBICORT	$321,472.52	937	541	$343.09	1.11%	↑1
ADDERALL XR	$317,129.89	1,806	743	$175.60	1.10%	↑3
BIKTARVY	$315,455.17	174	83	$1,812.96	1.09%	↑1
ADVAIR DISKUS	$314,520.32	835	474	$376.67	1.09%	↓4
NORDITROPIN FLEXPRO	$313,898.74	76	32	$4,130.25	1.08%	↓4
LEVEMIR FLEXTOUCH	$273,422.46	502	281	$544.67	0.94%	NC
ELIQUIS	$264,740.43	601	265	$440.50	0.91%	↑1
COSENTYX PEN (2 PENS)	$251,799.21	45	18	$5,595.54	0.87%	↓1
XIFAXAN	$248,316.81	105	56	$2,364.92	0.86%	↑1
VICTOZA 2-PAK	$241,847.76	403	214	$600.12	0.84%	↓1
ABILIFY MAINTENA	$222,151.52	105	44	$2,115.73	0.77%	↑2
PROAIR HFA	$218,698.73	2,809	2,786	$84.02	0.76%	NC

Total Claims Cost	**$28,946,551.75**



Top 15 Therapeutic Classes Based on Number of Claims from 10/01/2021 – 12/31/2021

Therapeutic Class Description	Claims	Patients	Claims Cost	Cost/Claim	% Total Claims	Dif.
ANTIDEPRESSANTS	28,390	11,539	$606,335.85	$21.36	17.38%	NC
ANTICONVULSANTS	13,253	4,629	$1,135,213.38	$85.66	8.11%	NC
ANTIPSYCHOTIC AGENTS	8,660	3,335	$2,012,392.58	$232.38	5.30%	NC
PROTON-PUMP INHIBITORS	7,825	3,791	$147,683.55	$18.87	4.79%	NC
SEDATIVES/HYPNOTICS	6,692	3,354	$106,679.85	$15.94	4.10%	↑1
OPIATE AGONISTS	6,640	3,376	$118,193.13	$17.8	4.06%	↓1
PENICILLIN ANTIBIOTICS	6,233	5,552	$100,425.46	$16.11	3.82%	↑4
NSAIDS	6,179	4,015	$89,410.46	$14.47	3.78%	↓1
STATINS	5,881	3,186	$84,873.42	$14.43	3.60%	↓2
AMPHETAMINES	5,800	2,366	$1,048,355.30	$180.75	3.55%	NC
BETA BLOCKERS	5,329	2,753	$97,204.54	$18.24	3.26%	↓2
NON-AMPHETAMINE STIMULANTS	4,911	1,821	$920,467.60	$187.43	3.01%	↑1
BETA AGONISTS	4,754	4,303	$327,316.69	$68.85	2.91%	↑1
ADRENALS	4,667	3,684	$85,915.67	$18.41	2.86%	↑1
ACE-INHIBITORS	4,388	2,480	$71,429.04	$16.28	2.69%	↓3

Top 15 Therapeutic Classes Based on Claims Cost from 10/01/2021 – 12/31/2021

Therapeutic Class Description	Claims Cost	Claims	Patients	Cost/Claim	% Total Cost	Dif.
DMARDS	$2,540,918.46	445	190	$5,709.93	8.78%	NC
ANTIPSYCHOTIC AGENTS	$2,012,392.58	8,660	3,335	$232.38	6.95%	NC
INSULINS	$1,946,357.37	3,658	1,388	$532.08	6.72%	↑1
SKIN AND MUCOUS MEMBRANE AGENTS	$1,924,223.51	624	369	$3,083.69	6.65%	↓1
ANTICONVULSANTS	$1,135,213.38	13,253	4,629	$85.66	3.92%	NC
AMPHETAMINES	$1,048,355.30	5,800	2,366	$180.75	3.62%	↑1
ANTINEOPLASTIC AGENTS	$1,004,520.56	543	218	$1,849.95	3.47%	↑2
RESPIRATORY CORTICOSTEROIDS	$998,093.76	3,476	2,117	$287.14	3.45%	↓2
NON-AMPHETAMINE STIMULANTS	$920,467.60	4,911	1,821	$187.43	3.18%	↑2
INCRETIN MIMETICS	$891,975.69	1,116	502	$799.26	3.08%	NC
ANTIRETROVIRALS	$865,672.14	696	251	$1,243.78	2.99%	↓3
IMMUNOMODULATORY AGENTS	$702,904.40	87	34	$8,079.36	2.43%	NC
ANTIDEPRESSANTS	$606,335.85	28,390	11,539	$21.36	2.09%	NC
SGLT-2 INHIBITORS	$587,730.29	1,224	560	$480.17	2.03%	NC
ANTIMUSCARINICS/ANTISPASMODICS	$404,891.35	1,815	921	$223.08	1.40%	NC

PDL UPDATE

Drug Name	PA	Class
Adbry	PA	Atopic Dermatitis
Dartistla ODT	PA	Non-preferred dosage forms
Dupixent 100mg Syringe	PA	Asthma
Epclusa Pellets	PA	HIV
Leqvio	PA	Hyperlipidemia
Mavyret Pellets	PA	HIV
Opzelura	PA	Eczema/Atopic Dermatitis
Qelbree	PA	Non-stimulant ADHD
Qulipta	PA	Migraine Prophylaxis
Recorlev	PA	Over 3000
Tarpeyo	PA	Over 3000
Tyrvaya	PA	Dry Eyes

Phenylketonuria

Underutilization

- Kuvan and Palynziq must be used compliantly and will reject on point of sale for late fill

Prior Authorization Criteria

Prior Authorization Form - Phenylketonuria

Criteria for initial requests: *Approval Duration = 2 months (Kuvan); 12 months (Palynziq)*

- The member must have an FDA-approved indication for use (meets label recommendations for diagnosis and age).
- The member must have been compliant with a PHE restricted diet for the past 6 months (documentation must be attached).
- The prescriber must be, or in consult with, a geneticist or endocrinologist.
- Baseline PHE levels must be attached
    - For females of childbearing potential and children ≤ 12 years old: PHE levels must be above 360 μmol/liter (6mg/dL)
    - For males, females unable to bear children, or children >12 years old: PHE levels must be above 600 μmol/liter (10mg/dL)
- **Product specific criteria:**
    - Kuvan:
        - The member's weight must be provided. Requested initial dose must be 10 mg/kg.
    - Palynziq:
        - PHE levels must be attached documenting the member was unable to achieve a PHE level less than 600 micromoles/liter (10mg/dL) despite a 3-month trial of 20mg/kg dose of sapropterin with good compliance.

Criteria for renewal requests:

- If dose is the same or less than previous trial: ***Approval Duration = 12 months***
    - PHE level must be between 60 and 600 μmol/liter
- For a dose increase from previous trial ***Approval Duration = 4 months***
    - PHE levels must be attached that were taken after previous trial (at least 1 month for Kuvan; 4 months for Palynziq):
    - For females of childbearing potential and children ≤ 12 years old: PHE levels must be above 360 μmol/liter (6mg/dL)
    - For males or females unable to bear children > 12 years old: PHE levels must be above 600 μmol/liter (10mg/dL)
- **Product specific criteria:**
    - Kuvan:
        - The member's weight must be provided.

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

Anti-infectives - Resistance Prevention

General Prior Authorization Form

Non-Preferred Agents Criteria:

- **Initial Criteria:** *Approval Duration = 5 days*
  - Member must have an FDA-approved indication for use (meets label recommendations for diagnosis & age)
    - Diagnosis must be proven to be caused by a susceptible microorganism by culture and susceptibility testing
  - Medication must be prescribed by an infectious disease specialist, an antibiotic stewardship program, or protocol.
  - One of the following criteria must be met (A or B)
    - A. Prescriber must provide evidence-based medical justification for use, explaining why the preferred antibiotics are not an option due to susceptibility, previous failed trials, or other contraindications (subject to clinical review)
    - B. The member is continuing treatment upon discharge from an acute care facility
- **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).

Community-Acquired Pneumonia

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
amoxicillin	BAXDELA (delafloxacin)
amoxicillin-clavulanate	FACTIVE (gemifloxacin)
azithromycin	XENLETA (lefamulin)
cefpodoxime	
cefuroxime	
clarithromycin	
doxycycline	
levofloxacin	
linezolid	
moxifloxacin	

Cytomegalovirus infection

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
foscarnet	LIVTENCITY (maribavir)
valganciclovir	

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	HELIDAC (bismuth ssal/metronidazole/tetracycline)
PYLERA (bismuth subcitrate potassium/metronidazole/tetracycline)	OMECLAMOX-PAK (omeprazole/clarithromycin/amoxicillin)
	PREVPAC (lansoprazole/amoxicillin/clarithromycin)
	TALICIA (omeprazole/amoxicillin/rifabutin)

Tuberculosis

Product specific criteria:

***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.

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ethambutol	cycloserine
isoniazid[PA]	MYCOBUTIN (rifabutin)
PRIFTIN (rifapentine)	RIFADIN (rifampin)
pyrazinamide	SIRTURO (bedaquiline)
rifabutin	
rifampin	

Antifungals - Aspergillus and Candidiasis Infections

General Prior Authorization Form

Non-Preferred Agents Criteria: *Approval Duration = Per label recommendations*

- The request must be for use as prophylaxis of invasive Aspergillus and Candida infections or Oropharyngeal Candidiasis
- One of the following criteria must be met (A or B)
  A. Prescriber must provide evidence-based medical justification for use, explaining why the preferred antifungals are not an option due to susceptibility, previous failed trials, or other contraindications (subject to clinical review)
  B. The member is continuing treatment upon discharge from an acute care facility

Solid formulations

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
clotrimazole	CRESEMBA (isavuconazonium)
clotrimazole troche	DIFLUCAN (fluconazole)
fluconazole	posaconazole
itraconazole	SPORANOX (itraconazole)
NOXAFIL (posaconazole) – *Brand Required*	TOLSURA (itraconazole) CAPSULE
nystatin	VFEND (voriconazole)
ORAVIG (miconazole)	voriconazole
terbinafine	

Non-solid oral formulations

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
fluconazole suspension	DIFLUCAN (fluconazole) SUSPENSION
itraconazole solution	NOXAFIL (posaconazole) SUSPENSION
	SPORANOX (itraconazole) SOLUTION
	VFEND (voriconazole) SUSPENSION
	voriconazole suspension

Hypersomnolence (Narcolepsy and Idiopathic Hypersomnia)

Prior Authorization Criteria

General Prior Authorization Form

Non-Preferred Agents Criteria:

- The member must have an FDA-approved indication for use (meets label recommendations for diagnosis and age)
- 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
- Provider must submit documentation of prior treatment failure, as evidenced by documentation of one of the following, while on prior treatments:
  - Multiple Sleep Latency Test (MSLT) <8 minutes
  - EPWORTH sleepiness scale score ≥10

Product Specific Criteria:

- Xywav:
  - Clinical justification must be provided explaining why the member is unable to Xyrem due to sodium content (subject to clinical review).
  - The member must have had a 30-day trial with Wakix in addition to Non-Preferred Agents Criteria

Renewal Criteria:

- Provider must submit documentation of symptom improvement, as evidenced by documentation of one of the following, while on prior treatments:
  - Multiple Sleep Latency Test (MSLT) <8 minutes
  - EPWORTH sleepiness scale score ≥10

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
armodafinil	NUVIGIL (armodafinil)
modafinil	PROVIGIL (modafinil)
SUNOSI (solriamfetol)	WAKIX (pitolisant)
XYREM (sodium oxybate)	XYWAV (sodium, calcium, magnesium, potassium oxybate)

Eczema / Atopic Dermatitis

Electronic Age Verification

Product Specific: Protopic (tacrolimus) ointment 0.1%
The member must be 16 years of age or older

Prior Authorization Criteria

General Prior Authorization Form
Prior Authorization Form - Dupixent

Category criteria (Initial): *Approval Duration = 3 months*

- Member must meet FDA label recommendations for indication and age
- Member must have had a 6-week trial of at least one of the following, as evidenced by paid claims or pharmacy printouts:
    - tacrolimus OR pimecrolimus

1. One of the following must be met (A or B):
    A. Member must have had two 2-week trials of topical corticosteroids of medium or higher potency, as evidenced by paid claims or pharmacy printouts.
    B. Member must meet both of the following (1 AND 2):
        1. Affected area is on face, groin, axilla, or under occlusion
        2. Member must have had two 2-week trials of topical corticosteroids of low or higher potency, as evidenced by paid claims or pharmacy printouts.

Product Specific Criteria (Initial):
In addition to the category criteria:

- **Adbry**:
    - The member must have had a 3-month trial of Dupixent, as evidenced by paid claims or pharmacy printouts.
- **Opzelura**:
    - Indicated for short-term and non-continuous chronic treatment of mild to moderate atopic dermatitis.
    - The member must have a percentage BSA (excluding scalp) with AD involvement of 3% - 20%.
    - The member must not be immunocompromised.
- **Rinvoq ER**:
    - The member must have had a 3-month trial of Adbry and Dupixent, as evidenced by paid claims or pharmacy printouts.

Product Specific Criteria (Renewal): *Approval Duration = 12 months*

- The prescriber must submit documentation showing that the member has achieved a significant reduction in severity of atopic dermatitis since treatment initiation

First Line Agents

ORAL	
PREFERRED AGENTS (NO PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**
azathioprine	
cyclosporine	
methotrexate	
systemic oral corticosteroids	

TOPICAL	
PREFERRED AGENTS (NO PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**
ELIDEL (pimecrolimus) CREAM – *Brand Required*	pimecrolimus
PROTOPIC (tacrolimus) OINTMENT 0.03% – *Brand Required*	tacrolimus 0.03%
PROTOPIC (tacrolimus) OINTMENT 0.1% – *Brand Required*	tacrolimus 0.1%

Topical Corticosteroids: Please see the Preferred Drug List of Topical Corticosteroids

Interleukin (IL)-4/13 Inhibitor

Prior Authorization Form - Dupixent

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

Interleukin (IL)-13 Inhibitor

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

Phosphodiesterase 4 (PDE-4) inhibitor

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
EUCRISA (crisaborole) OINTMENT	

Janus Kinase (JAK) inhibitor

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	OPZELURA (ruxolitinib) 1.5% CREAM
	RINVOQ (upadacitinib) TABLET

Chronic Kidney Disease

Korsuva (difelikefalin) – Medical Billing Drug Clinical Criteria

Prior Authorization Criteria

General Prior Authorization Form

Criteria for initial requests: *Approval Duration = 12 months*

- Member must not be on kidney dialysis
- 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

Non-Preferred Product Criteria:

- **Tarpeyo:**
    - The member must have a diagnosis of Primary IgA nephropathy and be at risk of rapid disease progression.
    - The member must have eGFR ≥ 35.
    - The member must be experiencing proteinuria > 1 gram/day or UPCR ≥ 0.8 g/g (documentation must be attached) despite 6-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
        - Prednisone or methylprednisone
    - DAW (Dispense As Written) Criteria must be met.

SGLT-2 Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
FARXIGA (dapagliflozin)	
INVOKANA (canagliflozin)	

Renin-Angiotensin-Aldosterone System (RAAS) Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ACE (angiotensin-converting enzyme) inhibitors - *all oral agents preferred*	
ARBs (angiotensin receptor blockers) - *all oral agents preferred*	
TEKTURNA (aliskiren)	

Non-steroidal selective mineralcorticoid receptor antagonist (MRA)

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
KERENDIA (finerenone)[PA]	

Systemic Corticosteroids

See Non-Preferred Dosage Form Criteria

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
methylprednisolone	TARPEYO (budesonide EC)
prednisone	

Lupus

Prior Authorization Criteria

General Prior Authorization Form

Lupus Nephritis

Criteria for initial requests: *Approval Duration = 12 months*

- The member must have an FDA-approved indication for use (meets label recommendations for diagnosis and age)
- The medication is prescribed by, or in consultation with, a nephrologist or rheumatologist
- 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.
- The member has had clinical progression (e.g. worsening of proteinuria or serum creatinine) despite a 3-month trial with Benlysta (belimumab)

Criteria for renewal requests: *Approval Duration = 12 months*

The improvement in organ dysfunction, reduction in flares, reduction in corticosteroid dose, decrease of anti-dsDNA titer, and improvement in complement levels (i.e., C3, C4).

Calcineurin inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
cyclosporine	Lupkynis (voclosporin)
tacrolimus	

Medical Billing Only

B-lymphocyte stimulator (BLyS)-specific inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
Benlysta (belimumab)	

SYNAGIS WEB BASED FORM

Submit online or fax completed form to: 855-207-0250

For questions regarding this prior authorization, call

866-773-0695

Prior Authorization Vendor for ND Medicaid

Note:

- Synagis season will be October 19th through April 21st
- Providers will choose when to start dosing Synagis based on prevalence of RSV in the community
- Clinicians may administer up to a maximum of 5 monthly doses during the RSV season.
- Qualifying infants born during the RSV season may require fewer doses.

TO BE COMPLETED BY PRESCRIBER

Recipient Medicaid ID Number	Recipient Date of Birth	Recipient Weight (kg)	Prescriber NPI	Prescriber Fax Number

Billing Facility NPI	Billing Facility Name	ICD-10 code

Is this request for dose from the current RSV season, last RSV season, or both (please select one)?

☐ Previous Year's RSV season ☐ Current Year's RSV Season ☐ Both

Diagnosis (qualification for Synagis)

☐ **Prematurity** (max of 5 doses)
< 29 weeks, 0 days gestational age – Synagis allowed if younger than 12 months of age at the start of RSV season
Gestational Age (e.g., 28 weeks, 4 days)
Weeks _____ **Days** _____

☐ **Chronic Lung Disease of Prematurity (CLD)** – Child ≤12 months old with gestational age <32 weeks, 0 days and requires supplemental oxygen >21% for at least the first 28 days after birth.

☐ **Chronic Lung Disease of Prematurity (CLD)** – Child ≤24 months old with gestational age <32 weeks, 0 days ad requires supplemental oxygen >21% for at least the first 28 days after birth and continues to receive medical support within six months before the start of RSV season.

- ☐ Supplemental Oxygen
- ☐ Diuretic
- ☐ Chronic corticosteroid therapy

☐ **Congenital Heart Disease (CHD)** – Child ≤12 months old with hemodynamically significant cyanotic or acyanotic CHD
Medical Therapy Required _____

*Children less than 24 months who undergo cardiac transplant during RSV season may be considered for prophylaxis

☐ **Neuromuscular disease** (may be considered for prophylaxis during the first year of life)

☐ **Pulmonary abnormalities** (may be considered for prophylaxis during the first year of life)

☐ **Profoundly Immunocompromised children** (children <24 months of age may be considered for prophylaxis during the RSV season)

* **Accessed online at pediatrics.aappublications.org**

REVIEW OF FAMILIAL CHOLESTASIS PRURITIS

Cholestasis is an impairment of bile flow or formation in the liver. A few symptoms associated with this disease state include jaundice, yellowing skin, and itching. Currently, there is no explanation for why cholestasis causes pruritis; however, there are many hypotheses that point to the accumulation of acids in the skin that is associated with this disease state. Two specific conditions that can cause pruritis of cholestasis include Alagille Syndrome (ALGS) and progressive familial intrahepatic cholestasis (PFIC). ALGS is a rare generic condition in which multiple organs are affected, especially the liver. Most patients with ALGS experience a reduction in bile ducts found in the liver. In turn, this causes a reduction in bile flow. The estimated incidence of ALGS occurs in approximately 1 in 30,000 to 1 in 45,000. On the other hand, PFIC is a group of generic disorders that affect bile formation. It is an ultra-rare condition which most patients end up requiring biliary diversion surgery or liver transplant in adulthood. There are different types of PFIC, depending on the patient's genetic mutation. Types 1-3 are the most common, and types 1-2 are the most severe. The incidence of PFIC is estimated to be between 1 in 50,000 and 1 in 100,000 births.

Place in Therapy/Guidelines

Cholestasis Pruritis Treatment	
Conventional Treatment (Often ineffective)	
Antihistamines Rifampicin Cholestyramine Ursodiol Naltrexone Sertraline	
Progressive Familial Intrahepatic Cholestasis (PFIC)	**Alagille Syndrome (ALGS)**
Bylvay	Livmarli

General Dosing and FDA Indications

Bylvay (odevixibat)	
Mechanism of Action	Apical sodium-dependent bile acid transporter (ASBT) inhibitor
Dosing	40 mcg/kg PO QAM with a meal. The dose may be increased in 40 mcg/kg increments if there is no improvement of pruritis after 3 months. Max dose: 120 mcg/kg, not to exceed a daily dose of 6 mg.
Indications	Treatment of pruritus in patients 3 months of age and older with progressive familial intrahepatic cholestasis (PFIC)
Livmarli (maralixibat)	
Mechanism of Action	Apical sodium-dependent bile acid transporter (ASBT) inhibitor
Dosing	Starting dose: 190 mcg/kg PO Qday; after one week, increase to the target dose of 380 mcg/kg PO Qday 30 minutes before the first meal of the day
Indications	Treatment of cholestatic pruritus in patients with Alagille syndrome (ALGS) 1 year of age and older

Approval Status and Special Designations

Drugs@FDA: FDA-Approved Drugs
Fast Track, Breakthrough Therapy, Accelerated Approval, Priority Review | FDA
The Drug Development Process | FDA

Drug Name	Approval Letter Post Marketing Trial and Reporting Requirements
Bylvay	Approved on 07/20/2021 by NDA
Livmarli	Approved on 09/29/2021 by NDA

Therapeutically Important Adverse Effects/Advantages

Blyvay

- Liver test abnormalities, diarrhea, and fat-soluble vitamin deficiency
- First and only FDA-approved medication to treat PFIC
- May not be effective in PFIC subtype 2 patients with ABCB11 variants

Livmarli

- Liver test abnormalities, diarrhea, and fat-soluble vitamin deficiency
- First and only FDA-approved treatment for ALGS

Cost

Drug	Strength	Package Size	WAC Pkg Price	Cost/day*	Cost/month*	Cost/year*
Bylvay	200 mcg, 400 mcg, 600 mcg, 1200 mcg	30 each	$6,600 - $79,200	$220 - $2,640	$6,600 - $79,200	$79,200 - $950,400
Livmarli	9.5 mg/mL	30 mL	$46,500	$310 - $4,650	$9,300 - $139,500	$111,600 - $1,674,000

*Based on lowest per unit WAC cost

Current Utilization

ND Medicaid Utilization (10/01/2020 – 09/30/2021)

Label Name	Rx Number	Total Reimbursement Amt
Bylvay	0	0
Livmarli	0	0

Clinical Studies

- **ICONIC:** long-term, open-label Phase 2 study with a double-blind, placebo-controlled, randomized drug withdrawal period, as well as 5 years of data from supportive studies in children with ALGS. Livmarli was shown to reduce pruritus in these patients.

<table>
<tr><th colspan="4">Livmarli</th></tr>
<tr><th colspan="4">ICONIC</th></tr>
<tr><td>Study Design</td><td colspan="3">Long-term, open-label, double-blind, placebo-controlled, randomized drug withdrawal period</td></tr>
<tr><td rowspan="5">Study Population</td><td>Baseline Characteristics</td><td colspan="2">Livmarli (n = 13) Placebo (n = 16)</td></tr>
<tr><td>Age</td><td colspan="2">5 years (1 – 15)</td></tr>
<tr><td>Sex (% female)</td><td colspan="2">34</td></tr>
<tr><td>Mean (standard deviation) liver test</td><td colspan="2">• sBA levels: 280 (213) µmol/L
• AST: 158 (68) U/L
• ALT: 179 (112) U/L
• GGT: 498 (399) U/L
• TB: 5.6 (5.4) mg/dL</td></tr>
<tr><td>At least 1 medication to treat pruritis</td><td colspan="2">90.3%</td></tr>
<tr><td>Interventions</td><td colspan="2">Placebo: administered once daily on Week 19 to Week 22 (randomized withdrawal period)</td><td>Livmarli: administered once daily up to 400 mcg/kg of maralixibat chloride per day until Week 52, followed by an increase in dose twice daily during long-term follow-up period based on efficacy (measured by sBA level and pruritus) and safety</td></tr>
<tr><td>Endpoints and Results</td><td colspan="3">• Primary endpoints: Few patients met the prespecified sBA reduction criteria
○ Maralixibat (n = 5): LS mean (SE) sBA level µmol/L: -21.73 (43.125)
○ Placebo (n = 10): LS mean (SE) sBA level µmol/L: 95.55 (30.488)
• Secondary endpoints:
○ ItchRO assessed pruritus symptoms on a scale of 0 (none) to 4 (very severe)
○ Included in the trial were patients with an itch score >2.0 (moderate) in 2 weeks prior to baseline
○ For randomized patients, mean (SD) at baseline (pre-treatment) was 3.1 (0.5) and mean (SD) at Week 18 (pre-randomized withdrawal period) was 1.4 (0.9)</td></tr>
</table>

- **PEDFIC 1:** a phase 3, randomized, double-blind, placebo-controlled trial, which included 62 patients, and met both primary endpoints of improving pruritus and reducing serum bile acids. Information on key secondary outcomes, including transplant-free survival and additional liver function tests, will be forthcoming.
- **PEDFIC 2**: (NCT03659916) an ongoing single-arm, long-term extension study in patients with PFIC types 1, 2, or 3, aged 4 months to 25 years. This trial included 56 patients from PEDFIC 1 and 23 additional patients, totaling 79 patients. Preliminary results at Week 48 showed continued reductions in serum bile acid levels, improvements in pruritus and growth, and additional markers of liver function. Twelve patients discontinued Bylvay, two of which underwent surgery (one with liver transplant and the other with biliary diversion surgery) due to pruritus that was unresponsive to Bylvay.

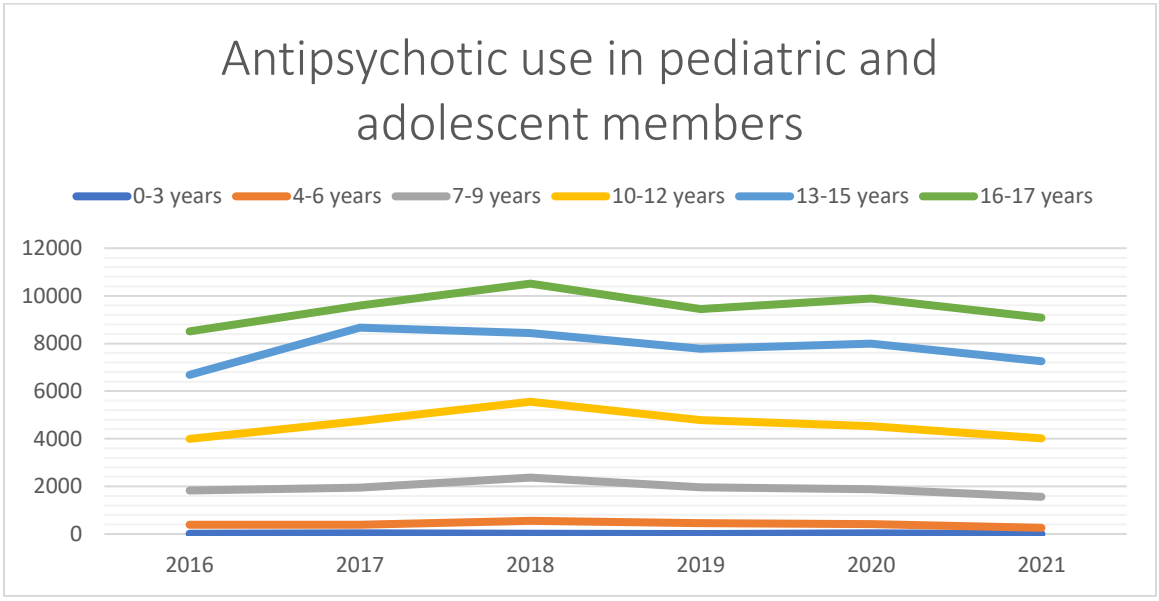
Bylvay				
Study Design	**PEDFIC 1**			**PEDFIC 2**
	Phase 3, randomized, double-blind, placebo-controlled trial			Ongoing single-arm, long-term extension study in patients with PFIC types 1, 2, or 3
Study Population	Baseline Characteristics	Placebo (n = 20)	Bylvay (n =42)	56 patients from the PEDFIC 1 trial plus 23 additional patients
	Age	3.75 years (0.5 – 15)	4.48 years (0.6 – 15.9)	4 months to 25 years
	Sex (% female)	40	54.8	Not available
	PFIC type	5 (25%) type 1 15 (75%) type 2	12 (28.6%) type 1 30 (71.4%) type 2	
	Bile acids, µmol/L (range)	247.53 (56.5 – 435)	252.1 (36 – 605)	
	Pruritus (0-4 scale)	3.02 (1.5 – 4)	3 (2 – 4)	
	Ursodiol	18 (90%)	32 (76.2%)	
	Rifampicin	17 (85%)	24 (57.1%)	
	ALT, U/L (range)	76.9 (19 – 236%)	110.2 (16 – 798)	
	Total bilirubin, mg/dL (range)	3.12 (0.3 – 11.4)	3.18 (0.2 – 18.6)	
24 – week Interventions	• Placebo once daily (n = 20) • Bylvay 40 mcg/kg once daily (n = 23) • Bylvay 120 mcg/kg once daily (n = 19)			Not available
Endpoints and Results	• Primary endpoints: Change in pruritus, bile acid reduction (defined as bile acid reduction ≥70% or reaching a bile acid level ≤70 µmol/L). Change in pruritus assessment (P = 0.004) and serum bile acid response (P = 0.003) were met. • Secondary endpoints: Patients also experienced improvements in growth, weight gain, and sleep.			• Primary endpoints: Change in pruritis and reduction in bile acid level • Secondary endpoints: All-cause mortality, number undergoing biliary diversion surgery, number undergoing liver transplant, change in growth, change in AST to platelet ratio index (APRI), change in Fib-4 score, change in pediatric end-stage liver disease, and change in use of antipruritic medication. Results currently not available

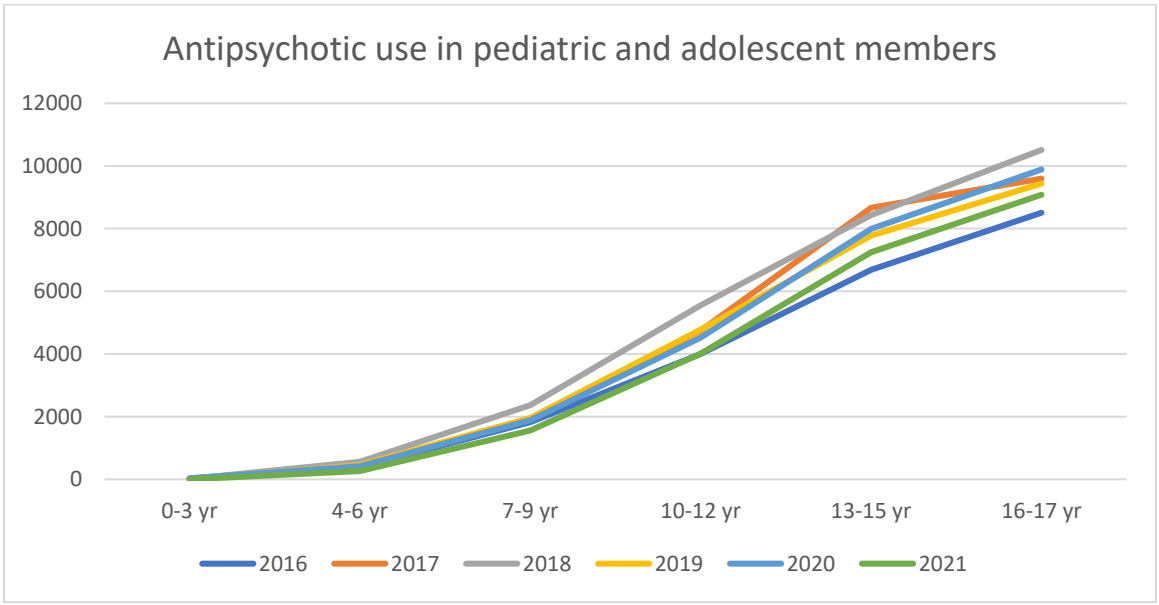
References:

1. Product Information: BYLVAY(TM) oral capsules, oral pellets, odevixibat oral capsules, oral pellets. Albireo Pharma Inc (per FDA), Boston, MA, 2021.
2. Product Information: LIVMARLI(TM) oral solution, maralixibat oral solution. Mirum Pharmaceuticals Inc (per FDA), Foster City, CA, 2021.
3. https://clinicaltrials.gov/ct2/show/study/NCT03659916

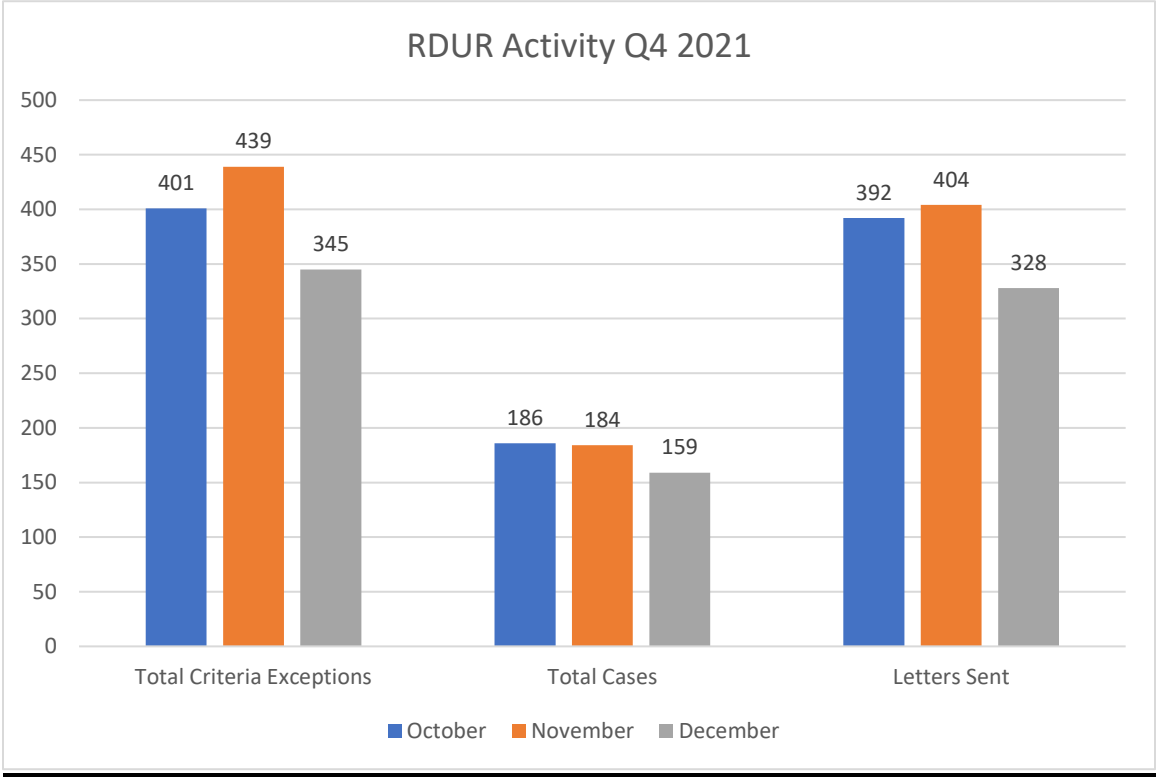
4. Gonzales E, Hardikar W, Stormon M, Baker A, Hierro L, Gliwicz D, Lacaille F, Lachaux A, Sturm E, Setchell KDR, Kennedy C, Dorenbaum A, Steinmetz J, Desai NK, Wardle AJ, Garner W, Vig P, Jaecklin T, Sokal EM, Jacquemin E. Efficacy and safety of maralixibat treatment in patients with Alagille syndrome and cholestatic pruritus (ICONIC): a randomised phase 2 study. Lancet. 2021 Oct 30;398(10311):1581-1592. doi: 10.1016/S0140-6736(21)01256-3. Epub 2021 Oct 28.
5. *Familial Cholestasis Pruritis*. IPD Analytics. Aventura, FL, 2021. https://www.ipdanalytics.com.

	0-3 years	4-6 years	7-9 years	10-12 years	13-15 years	16-17 years	Total
2016	19	389	1822	3996	6683	8508	21417
2017	31	392	1944	4749	8664	9597	25377
2018	14	555	2370	5554	8433	10512	27438
2019	5	456	1961	4777	7777	9441	24417
2020	31	415	1882	4521	7999	9890	24738





RDUR Activity Overview: Q4 2021



October Cases by Type of Criteria

Criteria Description	# of Cases	% of Cases
UNDERUTILIZATION*	80	43.0%
OVERUTILIZATION**	65	34.96%
MEDICATIONS WITH RENAL / HEPATIC IMPAIRMENT	17	9.14%
QDAY OMEPRAZOLE DOSING	9	4.84%
QDAY OLANZAPINE DOSING	3	1.61%
INAPPROPRIATE USE OF NORTRIPTYLINE IN ELDERLY	1	0.54%
CITALOPRAM AND QT PROLONGATION	11	5.91%

*UNDERUTILIZATION OF: BETA BLOCKERS, STATINS, ASTHMA CONTROLLERS, SULFONYLUREAS
**OVERUTILIZATION OF: ANXIOLYTICS / OPIOIDS, DEXMETHYLPHENIDATE IR, CYCLOBENZAPRINE, PREGABALIN, SSRIS / SNRIS, TRICYCLIC ANTIDEPRESSANTS, BEVESPI AEROSPHERE, DEXLANSOPRAZOLE, CETIRIZINE

November Cases by Type of Criteria

Criteria Description	# of Cases	% of Cases
NSAIDS AND PREGNANCY/HTN/ASTHMA/PUD	8	4.35%
UNDERUTILIZATION*	47	25.55%
MIRTAZAPINE AND CLONIDINE INTERACTION	3	1.63%
BENZODIAZIPINES AND COPD	15	8.15%
NON-ADHERENCE**	55	29.89%
NARCOTICS/OPIOIDS/HYPNOTICS AND H/O DRUG ABUSE	20	10.87%
SEDATIVE/HYPNOTICS AND DEPRESSION	9	4.89%
BETA BLOCKERS AND PULMONARY DISORDERS	2	1.09%
ATYPICAL ANTIPSYCHOTICS AND PREGNANCY	3	1.63%
ANTIPSYCHOTICS AND PARKINSON'S DISEASE	1	0.54%
INAPPROPRIATE QUETIAPINE DOSE	21	11.41%

*UNDERUTILIZATION: SSRIS/SNRIS, MIRTAZAPINE, VICTOZA, METFORMIN XR, BUPROPION
**NON-ADHERENCE: ANTIRETROVIRAL THERAPY, IMMUNOSUPPRESSANTS, LONG-TERM INHALERS, ANTICOAGULANTS/ANTIPLATELETS

December Cases by Type of Criteria

Criteria Description	# of Cases	% of Cases
OVERUTILIZATION OF TIZANIDINE	2	1.26%
THIAZIDES/LOOP DIURETICS AND HYPOKALEMIA/ HYPONATREMIA	13	8.17%
INAPPROPRATE THERAPY*	12	7.55%
TIZANIDINE ADVERSE EFFETCS	1	0.63%
FRACTURE RISK IN ELDERLY WITH CERTAIN AGENTS	5	3.14%
GASTRIC/URINARY RETENTION WITH ANTICHOLINERGICS	14	8.81%
MYOPATHY/RHABDOMYOLOSIS WITH STATINS	20	12.58%
CYCLIC ANTIDEPRESSANTS AND SUICIDE RISK	9	5.66%
DIABETES AND NEED FOR HYPERTENSION AGENTS	73	45.91%
PREGABALIN AND CONGESTIVE HEART FAILURE	2	1.26%
BRIVARACETAM AND ADVERSE PSYCHIATRIC REACTION	2	1.26%

METFORMIN AND LACTIC ACIDOSIS RISK	4	2.51%
SUVOREXANT AND RESPIRATORY DEPRESSION	1	0.63%
NALOXEGOL AND INTESTINAL OBSTRUCTION	1	0.63%

* INAPPROPRATE THERAPY: BENZODIAZEPINE USE IN ELDERLY POPULATION, RIVASTIGMINE IN ELDERLY POPULATION, MIGRAINE THERAPY, VICTOZA THERAPY

NORTH DAKOTA MEDICAID
RETROSPECTIVE DRUG UTILIZATION REVIEW
CRITERIA RECOMMENDATIONS
1ST QUARTER 2022

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

1. Fenfluramine / Overuse _____ _____

Alert Message: Fintepla (fenfluramine) may be over-utilized. The recommended maximum daily dose of fenfluramine is 26 mg per day.

Drugs/Disease

Util A	Util B	Util C (Negate)
Fenfluramine		Stiripentol
		Clobazam

Max Dose: 26 mg/day

Reference:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Fintepla Prescribing Information, June 2020, Zogenix Inc.

2. Fenfluramine / Overuse _____ _____

Alert Message: Fintepla (fenfluramine) may be over-utilized. Patients taking concomitant stiripentol and clobazam who are tolerating fenfluramine at 0.1 mg/kg twice daily and require further reduction of seizures may benefit from a dosage increase up to a maximum recommended maintenance dosage of 0.2 mg/kg twice daily (maximum daily dosage of 17 mg). The concurrent use of fenfluramine with stiripentol plus clobazam can result in increased fenfluramine plasma concentrations.

Drugs/Disease

Util A	Util B	Util C
Fenfluramine	Stiripentol	
	Clobazam	

Max Dose: 17 mg/day

Reference:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Fintepla Prescribing Information, June 2020, Zogenix Inc.

3. Fenfluramine / Therapeutic Appropriateness _____ _____

Alert Message: The safety and effectiveness of Fintepla (fenfluramine) for the treatment of seizures associated with Dravet syndrome have been established in patients 2 years of age and older.

Drugs/Disease

Util A	Util B	Util C
Fenfluramine		

Age Range: 0 – 1 yoa

Reference:

Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Fintepla Prescribing Information, June 2020, Zogenix Inc.

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

4. Fenfluramine / MAO Inhibitors _____ _____

Alert Message: Concomitant use of Fintepla (fenfluramine) with MAOIs is contraindicated. The use of fenfluramine within 14 days of an MAOI is also contraindicated. Fenfluramine can cause serotonin syndrome, particularly when co-administered with serotonergic drugs. If serotonin syndrome is suspected, treatment with fenfluramine should be stopped immediately, and symptomatic treatment should be started.

Drugs/Disease

Util A	Util B	Util C
Fenfluramine	Isocarboxazid	
	Linezolid	
	Phenelzine	
	Rasagiline	
	Safinamide	
	Selegiline	
	Tranylcypromine	

Reference:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Fintepla Prescribing Information, June 2020, Zogenix Inc.

IBM Micromedex DRUGDEX (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. 2021.

5. Fenfluramine / Hypertension _____ _____

Alert Message: Fintepla (fenfluramine) can cause an increase in blood pressure. Significant elevation in blood pressure, including hypertensive crisis, has been reported rarely in adult patients treated with fenfluramine, including patients without a history of hypertension. Monitor blood pressure in patients treated with fenfluramine.

Drugs/Disease

Util A	Util B	Util C
Fenfluramine	Hypertension	

Reference:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Fintepla Prescribing Information, June 2020, Zogenix Inc.

6. Fenfluramine / Valvular Heart Disorders _____ _____

Alert Message: Because of the association between serotonergic drugs with 5-HT2B receptor agonist activity, including Fintepla (fenfluramine), and valvular heart disease, cardiac monitoring is required prior to starting treatment during treatment, and after treatment with fenfluramine concludes. Cardiac monitoring via echocardiogram can identify evidence of valvular heart disease prior to a patient becoming symptomatic, aiding in early detection of this condition.

Drugs/Disease

Util A	Util B	Util C
Fenfluramine	Valvular Heart Disorders	

Reference:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Fintepla Prescribing Information, June 2020, Zogenix Inc.

Criteria Recommendations ***Approved Rejected***

7. Fenfluramine / Pulmonary Arterial Hypertension _____ _____

Alert Message: Because of the association between serotonergic drugs with 5-HT2B receptor agonist activity, including Fintepla (fenfluramine), and pulmonary arterial hypertension, cardiac monitoring is required prior to starting treatment, during treatment, and after treatment with fenfluramine concludes. Cardiac monitoring via echocardiogram can identify evidence of pulmonary arterial hypertension prior to a patient becoming symptomatic, aiding in early detection of this condition. In clinical trials of up to 3 years in duration, no patient receiving fenfluramine developed pulmonary arterial hypertension.

Drugs/Disease

Util A	Util B	Util C
Fenfluramine	Pulmonary Arterial Hypertension	

Reference:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Fintepla Prescribing Information, June 2020, Zogenix Inc.

8. Fenfluramine / Weight Loss _____ _____

Alert Message: Fintepla (fenfluramine) can cause decreases in appetite and weight. In clinical trials (Study 1 and Study 2 combined), approximately 37% of patients treated with fenfluramine reported, as an adverse reaction, decreased appetite and approximately 9% reported decreased weight, as compared to 8% and 1%, respectively, of patients on placebo. Given the frequency of these adverse reactions, the growth of pediatric patients treated with fenfluramine should be carefully monitored. Weight should be monitored regularly during treatment with fenfluramine, and dose modifications should be considered if a decrease in weight is observed.

Drugs/Disease

Util A	Util B	Util C
Fenfluramine	Weight Loss	
	Underweight	

Reference:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Fintepla Prescribing Information, June 2020, Zogenix Inc.

9. Fenfluramine / Ocular Issues _____ _____

Alert Message: Fintepla (fenfluramine) can cause mydriasis and can precipitate angle closure glaucoma. Consider discontinuing treatment with fenfluramine in patients with acute decreases in visual acuity or ocular pain.

Drugs/Disease

Util A	Util B	Util C
Fenfluramine	Glaucoma	
	Mydriasis	
	Ocular Pain	

Visual Disturbances

Reference:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Fintepla Prescribing Information, June 2020, Zogenix Inc.

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

10. Fenfluramine / Rifampin, CYP1A3 & CYP2B6 Inducers _____ _____

Alert Message: Coadministration with rifampin or strong CYP1A2 and CYP2B6 inducers will decrease Fintepla (fenfluramine) plasma concentrations, which may lower the efficacy of fenfluramine. Consider an increase in fenfluramine dosage when coadministered with rifampin or a strong CYP1A2 and CYP2B6 inducer; however, do not exceed the maximum daily dosage.

Drugs/Disease

Util A	Util B	Util C
Fenfluramine	Lansoprazole	
	Omeprazole	
	Phenobarbital	
	Rifampin	

Reference:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Fintepla Prescribing Information, June 2020, Zogenix Inc.

11. Fenfluramine / Serotonergic Drugs _____ _____

Alert Message: Concomitant administration of Fintepla (fenfluramine) and drugs (e.g., SSRIs, SNRIs, TCAs, MAO inhibitors, trazodone, etc.), over-the-counter medications (e.g., dextromethorphan) or herbal supplements (e.g., St. John's Wort) that increase serotonin may increase the risk of serotonin syndrome. Concomitant use of fenfluramine with or within 14 days of MAOIs is contraindicated. Use fenfluramine with caution in patients taking other medications that increase serotonin.

Drugs/Disease

Util A	Util B	Util C
Fenfluramine	SSRIs	
	SNRIs	
	TCAs	
	Dextromethorphan	

Reference:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Fintepla Prescribing Information, June 2020, Zogenix Inc.

12. Fenfluramine / Cyproheptadine _____ _____

Alert Message: Concurrent use of cyproheptadine with Fintepla (fenfluramine) may decrease the efficacy of fenfluramine. Fenfluramine and its active metabolite norfenfluramine increase extracellular levels of serotonin through interaction with serotonin transporter proteins and exhibit agonist activity at serotonin 5HT-2 receptors. Cyproheptadine is a serotonin receptor antagonist. Patients concurrently taking these medications should be monitored appropriately.

Drugs/Disease

Util A	Util B	Util C
Fenfluramine	Cyproheptadine	

Reference:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Fintepla Prescribing Information, June 2020, Zogenix Inc.

Criteria Recommendations ***Approved Rejected***

13. Fenfluramine / Pregnancy / Pregnancy Negating _____ _____

Alert Message: There are no adequate human or animal data on the developmental risks associated with the use of Fintepla (fenfluramine) in pregnant patients. There is a pregnancy exposure registry that monitors pregnancy outcomes in patients exposed to antiepileptic drugs (AEDs), such as fenfluramine, during pregnancy. Encourage patients taking fenfluramine during pregnancy to enroll in the North American Antiepileptic Drug (NAAED) Pregnancy Registry.

Drugs/Diseases

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

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Fintepla Prescribing Information, June 2020, Zogenix Inc.

14. Fenfluramine / Lactation _____ _____

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

Drugs/Diseases

Util A	Util B	Util C
Fenfluramine	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Fintepla Prescribing Information, June 2020, Zogenix Inc.

15. Fenfluramine / Non-adherence _____ _____

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

Drugs/Diseases

Util A	Util B	Util C
Fenfluramine		

References:
Osterberg L, Blaschke T. Adherence to Medication. N Engl J Med 2005; 353:487- 497.
Faught E, Duh MS, Weiner JR, et al. Nonadherence to Antiepileptic Drugs and Increased Mortality, Findings from the RANSOM Study. Neurology 2008;71(20): 1572-1578.

Hodges JC, Treadwell J, Malphrus AD, et al., Identification and Prevention of Antiepileptic Drug Noncompliance: The Collaborative Use of State-Supplied Pharmaceutical Data. ISRN Pediatr. 2014 Feb 19:1-8.

Viswanathan M, Golin CE, Jones DC, et al., Interventions to Improve Adherence to Self-administered Medications for Chronic Disease in the United States: A Systemic Review. Ann Intern Med. 2012:157:785-792.

Criteria Recommendations ***Approved Rejected***

16. Budesonide ER / Overuse _____ _____
Alert Message: The recommended dosage of Ortikos (budesonide extended-release) in adults with mild to moderately active Crohn's disease is 9 mg once daily for up to 8 weeks. Repeated 8-week courses of extended-release budesonide can be given for recurring episodes of active mild to moderate Crohn's disease.

Drugs/Diseases
Util A Util B Util C
Budesonide ER

Max Dose: 9 mg/day
Age Range: 18 – 999 yoa

References:
Facts & Comparisons, 2021 Updates, Wolters Kluwer Health.
Ortikos Prescribing Information, June 2021, Sun Pharmaceuticals Industries, Inc.

17. Budesonide ER / Overuse _____ _____
Alert Message: The recommended dosage of Ortikos (budesonide extended-release) in adults, following an 8-week course(s) of treatment for active disease and once the patient's symptoms are controlled (CDAI less than 150), is 6 mg orally once daily for maintenance of clinical remission up to 3 months. If symptom control is still maintained at 3 months, an attempt to taper to complete cessation is recommended. Continued treatment with extended-release budesonide 6 mg for more than 3 months has not been shown to provide substantial clinical benefit.

Drugs/Diseases
Util A Util B Util C
Budesonide ER

Max Dose: 6 mg/day
Day Supply: 90 day supply
Age Range: 18 – 999 yoa

References:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Ortikos Prescribing Information, June 2021, Sun Pharmaceuticals Industries, Inc.

18. Budesonide ER / Overuse _____ _____
Alert Message: Ortikos (budesonide extended-release) may be over-utilized. The recommended maintenance dose for pediatric patients 8 to 17 years of age who weigh more than 25 kg is 9 mg orally once daily for up to 8 weeks, followed by 6 mg once daily for 2 weeks.

Drugs/Diseases
Util A Util B Util C
Budesonide ER

Max Dose: 9 mg/day
Age Range: 8 – 17 yoa

References:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Ortikos Prescribing Information, June 2021, Sun Pharmaceuticals Industries, Inc.

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

19. Budesonide ER / Therapeutic Appropriateness _____ _____

Alert Message: The safety and effectiveness of Ortikos (budesonide extended-release) have not been established in pediatric patients less than 8 years of age for the treatment of mild to moderately active Crohn's disease involving the ileum and/or the ascending colon. Safety and effectiveness of budesonide extended-release have not been established in pediatric patients for the maintenance of clinical remission of mild to moderate Crohn's disease.

Drugs/Diseases

Util A	Util B	Util C
Budesonide ER		

Age Range: 0 – 7 yoa

References:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Ortikos Prescribing Information, June 2021, Sun Pharmaceuticals Industries, Inc.

20. Budesonide ER / Strong CYP3A4 Inhibitors _____ _____

Alert Message: The concurrent use of Ortikos (budesonide extended-release) with a strong CYP3A4 inhibitor should be avoided. Budesonide is a substrate for CYP3A4, and concomitant use with a strong CYP3A4 inhibitor can significantly increase budesonide concentrations. In drug studies, the coadministration of budesonide with ketoconazole, a strong CYP3A4 inhibitor, caused an eight-fold increase of the systemic exposure to oral budesonide compared to budesonide alone.

Drugs/Diseases

Util A	Util B		Util C
Budesonide ER	Clarithromycin	Nelfinavir	
	Cobicistat	Posaconazole	
	Indinavir	Ritonavir	
	Itraconazole	Saquinavir	
	Ketoconazole	Voriconazole	
	Nefazodone		

References:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Ortikos Prescribing Information, June 2021, Sun Pharmaceuticals Industries, Inc.

21. Budesonide ER / Pregnancy / Pregnancy Negating _____ _____

Alert Message: Based on animal data, Ortikos (budesonide extended-release) may cause fetal harm. In animal reproduction studies with pregnant rats and rabbits, administration of subcutaneous budesonide during organogenesis at doses approximately 0.5 times or 0.05 times, respectively, the maximum recommended human dose, resulted in increased fetal loss, decreased pup weights, and skeletal abnormalities. Maternal toxicity was observed in both rats and rabbits at these dose levels. Based on animal data, advise pregnant women of the potential risk to a fetus.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Budesonide ER	Pregnancy	Abortion
		Delivery
		Miscarriage

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Ortikos Prescribing Information, June 2021, Sun Pharmaceuticals Industries, Inc.

22. Budesonide ER / Lactation _____ _____

Alert Message: Lactation studies have not been conducted with oral budesonide, including Ortikos (budesonide extended-release), and no information is available on the effects of the drug on the breastfed infant or the effects of the drug on milk production. One published study reports that budesonide is present in human milk following maternal inhalation of budesonide. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for budesonide extended-release and any potential adverse effects on the breastfed infant from budesonide extended-release, or the underlying maternal condition.

Drugs/Diseases

Util A	Util B	Util C
Budesonide ER	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Facts & Comparisons, 2021 Updates, Wolters Kluwer Health.

23. Budesonide ER / Hepatic Impairment _____ _____

Alert Message: The use of Ortikos (budesonide extended-release) should be avoided in patients with moderate to severe hepatic impairment (Child-Pugh Class B and C, respectively). Budesonide is hepatically metabolized, and patients with moderate to severe hepatic impairment could be at an increased risk of hypercorticism and adrenal axis suppression due to an increased systemic exposure of oral budesonide. No dosage adjustment is needed in patients with mild hepatic impairment (Child-Pugh Class A).

Drugs/Diseases

Util A	Util B	Util C (Include)
Budesonide ER		Hepatic Impairment

References:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Ortikos Prescribing Information, June 2021, Sun Pharmaceuticals Industries, Inc.

24. Atogepant / Overuse _____ _____

Alert Message: Qulipta (atogepant) may be over-utilized. The maximum recommended dose of atogepant is 60 mg once daily.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Atogepant		Severe Renal Impairment
		ESRD

Max Dose: 60 mg/day

References:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Qulipta Prescribing Information, September 2021, AbbVie.

25. Atogepant / Overuse _____ _____

Alert Message: Qulipta (atogepant) may be over-utilized. The maximum recommended dose of atogepant in patients with severe renal impairment or end-stage renal disease (ESRD) is 10 mg once daily. For patients with ESRD undergoing intermittent dialysis, atogepant should preferably be taken after dialysis. No dose adjustment is recommended for patients with mild or moderate renal impairment.

Drugs/Diseases

Util A	Util B	Util C (Include)
Atogepant 30mg		Severe Renal Impairment
Atogepant 60 mg		ESRD

Max Dose: 10 mg/day

References:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Qulipta Prescribing Information, September 2021, AbbVie.

26. Atogepant / Therapeutic Appropriateness _____ _____

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

Drugs/Diseases

Util A	Util B	Util C
Atogepant		

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Qulipta Prescribing Information, September 2021, AbbVie.

27. Atogepant / Strong CYP3A4 Inhibitors _____ _____

Alert Message: Coadministration of Qulipta (atogepant) with a strong CYP3A4 inhibitor can result in a significant increase in atogepant exposure. The recommended dosage of atogepant with concomitant use of strong CYP3A4 inhibitors (e.g., ketoconazole, itraconazole, and clarithromycin) is 10 mg once daily. No dosage adjustment of atogepant is needed with concomitant use of moderate or weak CYP3A4 inhibitors.

Util A	Util B		Util C
Atogepant 30 mg	Clarithromycin	Nelfinavir	
Atogepant 60 mg	Cobicistat	Posaconazole	
	Indinavir	Ritonavir	
	Itraconazole	Saquinavir	
	Ketoconazole	Voriconazole	
	Nefazodone		

Max Dose: 10 mg/day

References:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Qulipta Prescribing Information, September 2021, AbbVie.

28. Atogepant / Moderate & Strong CYP3A4 Inducers _____ _____

Alert Message: Coadministration of Qulipta (atogepant) with a strong CYP3A4 inducer can result in a significant decrease in atogepant exposure. Concomitant administration of atogepant with moderate inducers of CYP3A4 can also result in decreased exposure of atogepant. The recommended dosage of atogepant with concomitant use of strong or moderate CYP3A4 inducers (e.g., rifampin, carbamazepine, phenytoin, efavirenz, and etravirine) is 30 mg or 60 mg once daily. No dosage adjustment of atogepant is needed with concomitant use of weak CYP3A4 inducers.

Drugs/Diseases

Util A	Util B	Util C
Atogepant 10 mg	Apalutamide	
	Bosentan	
	Carbamazepine	
	Efavirenz	
	Etravirine	
	Phenobarbital	
	Phenytoin	
	Primidone	
	Rifabutin	
	Rifampin	
	Rifapentine	

References:

Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Qulipta Prescribing Information, September 2021, AbbVie.

29. Atogepant / OATP Inhibitors _____ _____

Alert Message: Coadministration of Qulipta (atogepant) with an OATP inhibitor can result in a significant increase in atogepant exposure. The recommended dosage of atogepant, with concomitant use of an OATP inhibitor (e.g., cyclosporine, teriflunomide, and velpatasvir) is 10 mg once daily.

Drugs/Diseases

Util A	Util B	Util C
Atogepant 60 mg	Cyclosporine	
	Teriflunomide	
	Velpatasvir	

References:

Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Qulipta Prescribing Information, September 2021, AbbVie.

30. Atogepant / Pregnancy / Pregnancy Negating _____ _____

Alert Message: There are no adequate data on the developmental risk associated with the use of Qulipta (atogepant) in pregnant patients. Based on animal data, atogepant may cause fetal harm. In animal studies, oral administration of atogepant during the period of organogenesis (rats and rabbits) or throughout pregnancy and lactation (rats) resulted in adverse developmental effects (decreased fetal and offspring bodyweight in rats; increased incidence of fetal structural variations in rabbits) at exposures greater than those used clinically.

Drugs/Diseases

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

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Qulipta Prescribing Information, September 2021, AbbVie.

31. Atogepant / Lactation _____ _____

Alert Message: There are no data on the presence of Qulipta (atogepant) in human milk, the effects of atogepant on the breastfed infant, or the effects of atogepant on milk production. There are no data on the presence of atogepant in human milk, the effects of atogepant on the breastfed infant, or the effects of atogepant on milk production.

Drugs/Diseases

Util A	Util B	Util C
Atogepant	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Qulipta Prescribing Information, September 2021, AbbVie.

32. Atogepant / Non-adherence _____ _____

Alert Message: Based on refill history, your patient may be underutilizing Qulipta (atogepant). Nonadherence to the prescribed dosing regimen may result in sub-therapeutic effects, which may lead to decreased patient outcomes and additional healthcare costs.

Drugs/Diseases

Util A	Util B	Util C
Atogepant		

References:
Osterberg L, Blaschke T. Adherence to Medication. N Engl J Med 2005; 353:487- 497.
Qulipta Prescribing Information, September 2021, AbbVie.
Hepp Z, Bloudek, LM, Varon SF. Systemic Review of Migraine Prophylaxis Adherence and Persistence. J Manag Care Pharm. 2014;20(1):22-23.

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

33. Olanzapine/Samidorphan / Overuse _____ _____
Alert Message: Lybalvi (olanzapine/samidorphan) may be over-utilized. The maximum recommended dose of olanzapine/samidorphan is 20 mg/10 mg per day.

Drugs/Diseases

Util A	Util B	Util C
Olanzapine/Samidorphan		

Max Dose: 20mg/10mg per day

References:
Lybalvi Prescribing Information, June 2021, Alkermes.
Clinical Pharmacology, 2021 Elsevier/Gold Standard.

34. Olanzapine/Samidorphan / Therapeutic Appropriateness _____ _____
Alert Message: The safety and effectiveness of Lybalvi (olanzapine/samidorphan) have not been established in pediatric patients.

Drugs/Diseases

Util A	Util B	Util C
Olanzapine/Samidorphan		

Age Range: 0 – 17 yoa

References:
Lybalvi Prescribing Information, June 2021, Alkermes.
Clinical Pharmacology, 2021 Elsevier/Gold Standard.

35. Olanzapine/Samidorphan / Opioid Withdrawal _____ _____
Alert Message: The use of Lybalvi (olanzapine/samidorphan) is contraindicated in patients undergoing acute opioid withdrawal. The samidorphan component of the combination product is an opioid antagonist and can precipitate opioid withdrawal in patients who are dependent on opioids. If olanzapine/samidorphan use is being considered in a patient receiving opioids, the initiation of olanzapine/samidorphan must be delayed for a minimum of at least a 7-day opioid-free interval after the last use of short-acting opioids and a 14-day opioid-free interval after the last use of a long-acting opioid.

Drugs/Diseases

Util A	Util B	Util C
Olanzapine/Samidorphan	Opioid Dependence w/ Withdrawal	
	Opioid Use w/ Withdrawal	
	Opioid Related Disorders w/ Withdrawal	

References:
Lybalvi Prescribing Information, June 2021, Alkermes.
Clinical Pharmacology, 2021 Elsevier/Gold Standard.

36. Olanzapine/Samidorphan / Opioids _____ _____

Alert Message: The use of Lybalvi (olanzapine/samidorphan) is contraindicated in patients using opioids. Olanzapine/samidorphan can precipitate opioid withdrawal. If olanzapine/samidorphan use is being considered in a patient receiving opioids, the initiation of olanzapine/samidorphan must be delayed for a minimum of at least a 7-day opioid-free interval after the last use of a short-acting opioid and a 14-day opioid-free interval after the last use of a long-acting opioid.

Drugs/Diseases

Util A	Util B	Util C
Olanzapine/Samidorphan	Benzhydrocodone	
	Codeine	
	Fentanyl	
	Dihydrocodeine	
	Hydrocodone	
	Hydromorphone	
	Levorphanol	
	Meperidine	
	Morphine	
	Oxycodone	
	Oxymorphone	
	Tapentadol	
	Tramadol	
	Buprenorphine (pain)	

References:
Lybalvi Prescribing Information, June 2021, Alkermes.
Clinical Pharmacology, 2021 Elsevier/Gold Standard.

37. Olanzapine/Samidorphan / Tardive Dyskinesia _____ _____

Alert Message: Tardive dyskinesia, a syndrome consisting of potentially irreversible, involuntary, dyskinetic movements, may develop in patients treated with antipsychotic drugs. Therefore, Lybalvi (olanzapine/samidorphan) should be prescribed in a manner that is most likely to reduce the risk of tardive dyskinesia. The risk of developing tardive dyskinesia and the likelihood that it will become irreversible increases with the duration of treatment and the cumulative dose. If signs and symptoms of tardive dyskinesia appear in a patient on olanzapine/samidorphan, drug discontinuation should be considered.

Drugs/Diseases

Util A	Util B	Util C
Olanzapine/Samidorphan	Tardive Dyskinesia	

References:
Lybalvi Prescribing Information, June 2021, Alkermes.
Clinical Pharmacology, 2021 Elsevier/Gold Standard.

38. Olanzapine/Samidorphan / Anticholinergic (Antimuscarinic) Effects _____ _____

Alert Message: Olanzapine, a component of Lybalvi (olanzapine/samidorphan), exhibits in vitro muscarinic receptor affinity. In premarketing clinical trials with oral olanzapine, olanzapine was associated with constipation, dry mouth, and tachycardia, all adverse reactions possibly related to cholinergic antagonism. Such adverse reactions were not often the basis for discontinuations, but olanzapine/samidorphan should be used with caution in patients with a current diagnosis or prior history of urinary retention, clinically significant prostatic hypertrophy, constipation, or a history of paralytic ileus or related conditions. In post-marketing experience, the risk for severe adverse reactions (including fatalities) was increased with concomitant use of anticholinergic medications.

Drugs/Diseases

Util A	Util B	Util C
Olanzapine/Samidorphan	Urinary Retention	
	Prostatic Hypertrophy	
	Constipation	
	Paralytic Ileus	

References:
Lybalvi Prescribing Information, June 2021, Alkermes.
Clinical Pharmacology, 2021 Elsevier/Gold Standard.

39. Olanzapine/Samidorphan / Strong CYP3A4 Inducers _____ _____

Alert Message: Concomitant use of Lybalvi (olanzapine/samidorphan) with strong CYP3A4 inducers is not recommended. Concurrent use of strong 3A4 inducers with olanzapine/samidorphan may reduce olanzapine/samidorphan efficacy. The samidorphan component of the combination product is a CYP3A4 substrate and olanzapine is a CYP1A2 substrate. In drug interaction studies, coadministration of (olanzapine/samidorphan) with a strong CYP3A4 inducer significantly decreased AUCinf of the samidorphan component.

Drugs/Diseases

Util A	Util B	Util C
Olanzapine/Samidorphan	Apalutamide	
	Carbamazepine	
	Enzalutamide	
	Mitotane	
	Phenobarbital	
	Phenytoin	
	Primidone	
	Rifampin	

References:
Lybalvi Prescribing Information, June 2021, Alkermes.
Clinical Pharmacology, 2021 Elsevier/Gold Standard.

40. Olanzapine/Samidorphan / Strong CYP1A2 Inhibitors _____ _____

Alert Message: Concomitant use of Lybalvi (olanzapine/samidorphan) with a strong CYP1A2 inhibitor can increase olanzapine AUC and Cmax, which may increase the risk of olanzapine/samidorphan adverse reactions. Consider reducing the dosage of the olanzapine component olanzapine/samidorphan when used concomitantly with strong CYP1A2 inhibitors.

Drugs/Diseases

Util A	Util B	Util C
Olanzapine/Samidorphan	Ciprofloxacin	
	Fluvoxamine	

References:
Lybalvi Prescribing Information, June 2021, Alkermes.
Clinical Pharmacology, 2021 Elsevier/Gold Standard.

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

41. Olanzapine/Samidorphan / CYP1A2 Inducers _____ _____

Alert Message: Concomitant use of Lybalvi (olanzapine/samidorphan) with a CYP1A2 inducer decreases olanzapine exposure, which may reduce olanzapine/samidorphan efficacy. Consider increasing the dosage of the olanzapine component in olanzapine/samidorphan when used concomitantly with CYP1A2 inducers.

Drugs/Diseases

Util A	Util B	Util C
Olanzapine/Samidorphan	Ritonavir	

References:
Lybalvi Prescribing Information, June 2021, Alkermes.
Clinical Pharmacology, 2021 Elsevier/Gold Standard.

42. Olanzapine/Samidorphan / CNS Depressants _____ _____

Alert Message: Concomitant use of Lybalvi (olanzapine/samidorphan) with CNS depressants may potentiate the orthostatic hypotension observed with olanzapine. Olanzapine/samidorphan should be used with caution in patients receiving CNS depressants.

Drugs/Diseases

Util A	Util B	Util C
Olanzapine/Samidorphan	CNS Depressants	

References:
Lybalvi Prescribing Information, June 2021, Alkermes.
Clinical Pharmacology, 2021 Elsevier/Gold Standard.

43. Olanzapine/Samidorphan / Anticholinergic Agents _____ _____

Alert Message: Lybalvi (olanzapine/samidorphan) should be used with caution in patients receiving medications having anticholinergic (antimuscarinic) effects. Concomitant treatment with an olanzapine-containing medication and other drugs with anticholinergic activity can increase the risk for severe gastrointestinal adverse reactions related to hypomotility.

Drugs/Diseases

Util A	Util B	Util C
Olanzapine/Samidorphan	Anticholinergic Agents	

References:
Lybalvi Prescribing Information, June 2021, Alkermes.
Clinical Pharmacology, 2021 Elsevier/Gold Standard.

44. Olanzapine/Samidorphan / Levodopa and Dopamine Agonists _____ _____

Alert Message: Concomitant use of Lybalvi (olanzapine/samidorphan) is not recommended with levodopa and dopamine agonists. The olanzapine component in the combination agent is a dopamine antagonist, and concurrent use can antagonize the effects of levodopa and dopamine agonists.

Drugs/Diseases

Util A	Util B	Util C
Olanzapine/Samidorphan	Apomorphine	
	Bromocriptine	
	Cabergoline	
	Levodopa	
	Pramipexole	
	Ropinirole	
	Rotigotine	

References:
Lybalvi Prescribing Information, June 2021, Alkermes.
Clinical Pharmacology, 2021 Elsevier/Gold Standard.

45. Olanzapine/Samidorphan / Pregnancy / Pregnancy Negating _____ _____

Alert Message: Neonates exposed to antipsychotic drugs, including the olanzapine component of Lybalvi (olanzapine/samidorphan), during the third trimester, are at risk for extrapyramidal and/or withdrawal symptoms following delivery. There are no available data on the use of samidorphan or the combination of olanzapine and samidorphan in pregnant women to determine a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes. There are risks to the mother associated with untreated schizophrenia or bipolar I disorder and with exposure to antipsychotics, including olanzapine/samidorphan, during pregnancy.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Olanzapine/Samidorphan	Pregnancy	Abortion
		Delivery
		Miscarriage

Gender: Female
Age Range: 11 – 50 yoa

References:
Lybalvi Prescribing Information, June 2021, Alkermes.
Clinical Pharmacology, 2021 Elsevier/Gold Standard.

46. Olanzapine/Samidorphan / Lactation _____ _____

Alert Message: Olanzapine, a component of Lybalvi (olanzapine/samidorphan) is present in human milk. There are reports of excess sedation, irritability, poor feeding, and extrapyramidal symptoms (tremors and abnormal muscle movements) in infants exposed to olanzapine through breast milk. There are no data on the presence of samidorphan or the combination of olanzapine and samidorphan in human milk, the effects on the breastfed infant, or the effects on milk production. The development and health benefits of breastfeeding should be considered along with the mother's clinical need for olanzapine/samidorphan and any potential adverse effects on the breastfed infant from olanzapine/samidorphan or the underlying maternal condition.

Drugs/Diseases

Util A	Util B	Util C
Olanzapine/Samidorphan	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Lybalvi Prescribing Information, June 2021, Alkermes.
Clinical Pharmacology, 2021 Elsevier/Gold Standard.

47. Olanzapine/Samidorphan / Non-adherence _____ _____

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

Drugs/Diseases
Util A Util B Util C
Olanzapine/Samidorphan

References:
Theida P, et.al., An Economic Review of Compliance with Medication Therapy in the Treatment of Schizophrenia, Psychiatric Services, 2003;54:508-516.

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.

Berger A, Edelsbery J, Sanders KN, et al., Medication Adherence and Utilization in Patients with Schizophrenia or Bipolar Disorder Receiving Aripiprazole, Quetiapine, or Ziprasidone at Hospital Discharge: A Retrospective Cohort Study. BMC Psychiatry 2012,12:99.

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.

Morken G, Widen JH, Grawe RW. Non-adherence to Antipsychotic Medication, Relapse and Rehospitalization in Recent-Onset Schizophrenia. BMC Psychiatry. 2008, 8:32.

48. Amphetamine XR Tablets / Overuse _____ _____

Alert Message: Dyanavel XR tablets (amphetamine extended-release) may be over-utilized. The maximum recommended dosage of extended-release amphetamine is 20 mg once daily.

Drugs/Diseases
Util A Util B Util C
Amphetamine XR Tabs

Age Range: 6 – 12 yoa
Max Dose: 20 mg/day

References:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Dyanavel XR Prescribing Information, Nov. 2021, Tris Pharma Inc.

49. Amphetamine XR Tablets / Overuse _____ _____

Alert Message: The safety and efficacy of Dyanavel XR tablets (amphetamine extended-release tablets) in pediatric patients younger than 6 years old with ADHD have not been established.

Drugs/Diseases
Util A Util B Util C
Amphetamine XR Tabs

Age Range: 0 - 5 yoa

References:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Dyanavel XR Prescribing Information, Nov. 2021, Tris Pharma Inc.

50. Relugolix / Overuse _____ _____

Alert Message: Orgovyx (relugolix) may be over-utilized. Initiate treatment of relugolix with a loading dose of 360 mg on the first day and continue treatment with a 120 mg dose taken orally once daily at approximately the same time each day.

Drugs/Diseases

Util A	Util B	Util C (Negating)
Relugolix		Carbamazepine
		Phenytoin
		Rifampin

Max Dose: 120 mg/day

References:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Orgovyx Prescribing information, Dec. 2020, Myovant Sciences, Inc.

51. Relugolix / Therapeutic Appropriateness _____ _____

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

Drugs/Diseases

Util A	Util B	Util C
Relugolix		

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Orgovyx Prescribing information, Dec. 2020, Myovant Sciences, Inc.

52. Relugolix / Therapeutic Appropriateness _____ _____

Alert Message: Orgovyx (relugolix) may prolong the QT/QTc interval. Consider whether the benefits of androgen deprivation therapy outweigh the potential risks in patients with congenital long QT syndrome, congestive heart failure, or frequent electrolyte abnormalities and in patients taking drugs known to prolong the QT interval.

Drugs/Diseases

Util A	Util B	Util C
Relugolix	Long QT Syndrome	
	Congestive Heart Failure	

References:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Orgovyx Prescribing information, Dec. 2020, Myovant Sciences, Inc.

53. Relugolix / P-gp Inhibitors _____ _____

Alert Message: The concurrent use of Orgovyx (relugolix) with oral P-gp inhibitors should be avoided. If co-administration is unavoidable, take relugolix first and separate dosing of the oral P-gp inhibitor by at least 6 hours and monitor for relugolix adverse reactions. Relugolix is a P-gp substrate, and concomitant use with a P-gp inhibitor may increase the AUC and Cmax of relugolix increases in the risk of relugolix-related adverse events. Treatment with relugolix may be interrupted for up to two weeks if a course of treatment with a P-gp inhibitor is required.

Drugs/Diseases

Util A	Util B				Util C
Relugolix	Amiodarone	Flibanserin	Lomitapide	Ritonavir	
	Brigatinib	Fostamatinib	Mefloquine	Rolapitant	
	Cabozantinib	Glecaprevir	Mifepristone	Sapropterin	
	Carvedilol	Ibrutinib	Nelfinavir	Saquinavir	
	Clarithromycin	Isavuconazonium	Neratinib	Sarecycline	
	Cobicistat	Istradefylline	Osimertinib	Sorafenib	
	Cyclosporine	Itraconazole	Pibrentasvir	Ticagrelor	
	Daclatasvir	Ivacaftor	Ponatinib	Tolvaptan	
	Dronedarone	Ketoconazole	Posaconazole	Velpatasvir	
	Elagolix	Lapatinib	Propafenone	Vemurafenib	
	Erythromycin	Lasmiditan	Quinidine	Verapamil	
	Etravirine	Ledipasvir	Ranolazine	Voxilaprevir	

References:

Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Orgovyx Prescribing information, Dec. 2020, Myovant Sciences, Inc.

54. Relugolix / Combined P-gp & Strong CYP3A4 Inducers _____ _____

Alert Message: The concurrent use of Orgovyx (relugolix) with a combined P-gp and strong CYP3A4 inducers should be avoided. Relugolix is a P-gp and CYP3A4 substrate, and co-administration with a combined inducer of P-gp and CYP3A4 inducer can decrease the AUC and Cmax of relugolix. If concomitant use is unavoidable, increase the relugolix dose to 240 me once daily. After discontinuation of the combined P-gp and CYP3A4 inducer, resume the recommended relugolix dose of 120 mg once daily.

Drugs/Diseases

Util A	Util B	Util C
Relugolix	Carbamazepine	
	Phenytoin	
	Rifampin	

References:

Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Orgovyx Prescribing information, Dec. 2020, Myovant Sciences, Inc.

55. Relugolix / Drugs Causing Qt Prolongation _____ _____

Alert Message: Orgovyx (relugolix) may prolong the QT/QTc interval. Consider whether the benefits of androgen deprivation therapy outweigh the potential risks in patients with congenital long QT syndrome, congestive heart failure or frequent electrolyte abnormalities and in patients taking drugs known to prolong the QT interval.

Drugs/Diseases

Util A	Util B	Util C			
Relugolix	Abiraterone	Efavirenz	Levofloxacin	Rilpivirine	
	Alfuzosin	Eliglustat	Lithium	Risperidone	
	Amiodarone	Encorafenib	Lofexidine	Ritonavir	Amitriptyline
	Entrectinib	Loperamide	Romidepsin		
	Anagrelide	Eribulin	Maprotiline	Saquinavir	
	Aripiprazole	Erythromycin	Methadone	Sertraline	
	Arsenic Trioxide	Escitalopram	Metoclopramide	Siponimod	
	Asenapine	Ezogabine	Midostaurin	Solifenacin	
	Atazanavir	Famotidine	Mifepristone	Sotalol	
	Atomoxetine	Felbamate	Mirabegron	Sunitinib	
	Azithromycin	Fingolimod	Mirtazapine	Tacrolimus	
	Bedaquiline	Flecainide	Moexipril	Tamoxifen	
	Bortezomib	Fluconazole	Moxifloxacin	Telavancin	
	Bendamustine	Fluoxetine	Nelfinavir	Tetrabenazine	
	Bosutinib	Fluvoxamine	Nilotinib	Thioridazine	
	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	Pazopanib	Venlafaxine	
	Crizotinib	Ibutilide	Pentamidine	Voriconazole	
	Dabrafenib	Iloperidone	Pimavanserin		
	Dasatinib	Imipramine	Pimozide		
	Desipramine	Indapamide	Pitolisant		
	Deutetrabenazine	Indinavir	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, 2021 Elsevier/Gold Standard.
Orgovyx Prescribing information, Dec. 2020, Myovant Sciences, Inc.

56. Relugolix / Pregnancy / Pregnancy Negating _____ _____

Alert Message: Based on finding animal findings and mechanism of action, Orgovyx (relugolix) can cause fetal harm and loss of pregnancy when administered to a pregnant patient. There are no human data on the use of relugolix in pregnant patients to inform of drug-associated risk. In animal reproductive studies, administration of relugolix to pregnant rabbits during organogenesis caused embryo-lethality at maternal exposures that were 0.3 times the human exposure at the recommended relugolix dose.

Drugs/Diseases

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

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Orgovyx Prescribing information, Dec. 2020, Myovant Sciences, Inc.

57. Relugolix / Lactation _____ _____

Alert Message: The safety and efficacy of Orgovyx (relugolix) at the recommended dose of 120 mg per day have not been established in females. There are no data on the presence of relugolix in human milk, the effects on the breastfed child, or the effects on milk production. Relugolix and its metabolites were present in the milk of lactating rats.

Drugs/Diseases

Util A	Util B	Util C
Relugolix	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Orgovyx Prescribing information, Dec. 2020, Myovant Sciences, Inc.

58. Relugolix / Therapeutic Appropriateness _____ _____

Alert Message: Based on findings in animal studies and mechanism of action, advise male patients with partners of reproductive potential to use effective contraception during treatment and for 2 weeks after the last dose of Orgovyx (relugolix).

Drugs/Diseases

Util A	Util B	Util C
Relugolix		

Gender: Male

References:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Orgovyx Prescribing information, Dec. 2020, Myovant Sciences, Inc.

59. Relugolix / Non-adherence _____ _____

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

Drugs/Diseases

Util A	Util B	Util C
Relugolix		

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.

60. Decitabine/Cedazuridine / Overuse _____ _____

Alert Message: Inqovi (decitabine/cedazuridine) may be over-utilized. The recommended dosage of decitabine/cedazuridine is 1 tablet (containing 35 mg decitabine and 100 mg cedazuridine) orally once daily on Days 1 through 5 of each 28-day cycle for a minimum of 4 cycles until disease progression or unacceptable toxicity.

Drugs/Disease

Util A	Util B	Util C
Decitabine/Cedazuridine		

Max Dose: 1 tablet/day

Reference:

Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Inqovi Prescribing Information, July 2020, Taiho Oncology, Inc.

61. Decitabine/Cedazuridine / Therapeutic Appropriateness _____ _____

Alert Message: The safety and effectiveness of Inqovi (decitabine/cedazuridine) have not been established in pediatric patients.

Drugs/Disease

Util A	Util B	Util C
Decitabine/Cedazuridine		

Age Range: 0 – 17 yoa

Reference:

Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Inqovi Prescribing Information, July 2020, Taiho Oncology, Inc.

62. Decitabine/Cedazuridine / CDA Substrates _____ _____

Alert Message: The coadministration of Inqovi (decitabine/cedazuridine) with drugs that are metabolized by CDA should be avoided. The cedazuridine component of the combination product is an inhibitor of the cytidine deaminase (CDA) enzyme. Concurrent use of decitabine/cedazuridine with drugs that are metabolized by CDA may result in increased systemic exposure of the CDA substrate with the potential for increased substrate toxicity.

Drugs/Disease

Util A	Util B	Util C
Decitabine/Cedazuridine	Azacitidine	
	Cytarabine	
	Gemcitabine	

Reference:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Inqovi Prescribing Information, July 2020, Taiho Oncology, Inc.

63. Decitabine/Cedazuridine / Capecitabine _____ _____

Alert Message: The coadministration of Inqovi (decitabine/cedazuridine) with capecitabine should be avoided. The cedazuridine component of the combination product is an inhibitor of the cytidine deaminase (CDA) enzyme. Capecitabine is a prodrug that depends on CDA for conversion to the active metabolite 5-fluorouracil. Concurrent use of these agents may result in decreased effectiveness of capecitabine.

Drugs/Disease

Util A	Util B	Util C
Decitabine/Cedazuridine	Capecitabine	

Reference:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Inqovi Prescribing Information, July 2020, Taiho Oncology, Inc.

64. Decitabine/Cedazuridine / Pregnancy / Pregnancy Negating _____ _____

Alert Message: Based on findings from human data, animal studies, and its mechanism of action, Inqovi (decitabine/cedazuridine) can cause fetal harm when administered to a pregnant woman. In nonclinical studies with decitabine in mice and rats, decitabine was teratogenic, fetotoxic, and embryotoxic at doses less than the recommended human dose. Advise pregnant women of the potential risk to a fetus.

Drugs/Diseases

Util A	Util B	Util C **(Negating)**
Decitabine/Cedazuridine	Pregnancy	Abortion
		Delivery
		Miscarriage

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Inqovi Prescribing Information, July 2020, Taiho Oncology, Inc.

65. Decitabine/Cedazuridine / Lactation _____ _____

Alert Message: There are no data on the presence of cedazuridine, decitabine, or their metabolites in human milk or on their effects on the breastfed child or milk production. Because of the potential for serious adverse reactions in the breastfed child, advise women not to breastfeed during treatment with Inqovi (decitabine/cedazuridine) and for at least 2 weeks after the last dose.

Drugs/Diseases

Util A	Util B	Util C
Decitabine/Cedazuridine	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Inqovi Prescribing Information, July 2020, Taiho Oncology, Inc.

66. Decitabine/Cedazuridine / Therapeutic Appropriateness _____ _____

Alert Message: Advise females of reproductive potential to use effective contraception during treatment with Inqovi (decitabine/cedazuridine) and for 6 months after the last dose. Based on findings from human data, animal studies, and its mechanism of action, Inqovi (decitabine/cedazuridine) can cause fetal harm when administered to a pregnant woman.

Drugs/Disease

Util A	Util B	Util C
Decitabine/Cedazuridine		

Gender: Female
Age Range: 11 – 50 yoa

Reference:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Inqovi Prescribing Information, July 2020, Taiho Oncology, Inc.

67. Decitabine/Cedazuridine / Therapeutic Appropriateness _____ _____

Alert Message: Advise males with female partners of reproductive potential to use effective contraception during treatment with Inqovi (decitabine/cedazuridine) and for 3 months after the last dose.

Drugs/Disease

Util A	Util B	Util C
Decitabine/Cedazuridine		

Gender: Male

Reference:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Inqovi Prescribing Information, July 2020, Taiho Oncology, Inc.

68. Decitabine/Cedazuridine / Non-adherence _____ _____

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

Drugs/Diseases

Util A	Util B	Util C
Decitabine/Cedazuridine		

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.

69. Ibrexafungerp / Overuse _____ _____

Alert Message: Brexafemme (ibrexafungerp) may be over-utilized. The recommended dosage of ibrexafungerp in adult and post-menarchal pediatric females is 300 mg (two 150 mg tablets) administered approximately 12 hours apart (e.g., in the morning and in the evening) for one day, for a total daily dosage of 600 mg (four 150 mg tablets).

Drugs/Diseases

Util A	Util B	Util C (Negating)	
Ibrexafungerp		Clarithromycin	Nelfinavir
		Cobicistat	Posaconazole
		Indinavir	Ritonavir
		Itraconazole	Saquinavir
		Ketoconazole	Voriconazole
		Nefazodone	

Max Dose: 600 mg/day

References:

Brexafemme Prescribing Information, June 2021, Scynexis, Inc.
Clinical Pharmacology, 2021 Elsevier/Gold Standard.

70. Ibrexafungerp / Therapeutic Appropriateness _____ _____

Alert Message: The safety and effectiveness of Brexafemme (ibrexafungerp) have not been established in pre-menarchal pediatric females.

Drugs/Diseases

Util A	Util B	Util C
Ibrexafungerp		

Gender: Female
Age Range: 0 – 8 yoa

References:

Brexafemme Prescribing Information, June 2021, Scynexis, Inc.
Clinical Pharmacology, 2021 Elsevier/Gold Standard.

71. Ibrexafungerp / Therapeutic Appropriateness _____ _____

Alert Message: Advise females of reproductive potential to use effective contraception during treatment with Brexafemme (ibrexafungerp) and for 4 days after the last dose. Based on findings from animal studies, ibrexafungerp use is contraindicated in pregnancy because it may cause fetal harm.

Drugs/Diseases

Util A	Util B	Util C (Negating)
Ibrexafungerp		Contraceptives

Gender: Female
Age Range: 11 – 50 yoa

References:
Brexafemme Prescribing Information, June 2021, Scynexis, Inc.
Clinical Pharmacology, 2021 Elsevier/Gold Standard.

72. Ibrexafungerp / Pregnancy / Pregnancy Negating _____ _____

Alert Message: Based on findings from animal studies, Brexafemme (ibrexafungerp) use is contraindicated in pregnancy because it may cause fetal harm. In animal reproduction studies, ibrexafungerp administered orally to pregnant rabbits during organogenesis was associated with fetal malformations at dose exposures greater or equal to approximately 5 times the human exposure at the recommended human dose (RHD). Prior to initiating treatment with ibrexafungerp, verify the pregnancy status in females of reproductive potential. Advise females of reproductive potential to use effective contraception during treatment with ibrexafungerp and for 4 days after the last dose.

Drugs/Diseases

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

Gender: Female
Age Range: 11 – 50 yoa

References:
Brexafemme Prescribing Information, June 2021, Scynexis, Inc.
Clinical Pharmacology, 2021 Elsevier/Gold Standard.

73. Ibrexafungerp / Lactation _____ _____

Alert Message: There are no data on the presence of Brexafemme (ibrexafungerp) 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 ibrexafungerp and any potential adverse effects on the breastfed child from ibrexafungerp or the underlying maternal condition.

Drugs/Diseases

Util A	Util B	Util C
Ibrexafungerp	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Brexafemme Prescribing Information, June 2021, Scynexis, Inc.
Clinical Pharmacology, 2021 Elsevier/Gold Standard.

74. Ibrexafungerp / Strong CYP3A4 Inhibitors _____ _____

Alert Message: Brexafemme (ibrexafungerp) is a substrate of CYP3A4. Drugs that inhibit or induce CYP3A may alter the plasma concentrations of ibrexafungerp and affect the safety and efficacy of ibrexafungerp. With concomitant use of a strong CYP3A inhibitor, administer ibrexafungerp 150 mg approximately 12 hours apart (e.g., in the morning and the evening) for one day. No dosage adjustment is warranted in patients with concomitant use of a weak or moderate CYP3A inhibitor.

Drugs/Diseases

Util A	Util B		Util C
Ibrexafungerp	Clarithromycin	Nelfinavir	
	Cobicistat	Posaconazole	
	Indinavir	Ritonavir	
	Itraconazole	Saquinavir	
	Ketoconazole	Voriconazole	
	Nefazodone		

References:
Brexafemme Prescribing Information, June 2021, Scynexis, Inc.
Clinical Pharmacology, 2021 Elsevier/Gold Standard.

75. Ibrexafungerp / Moderate & Strong CYP3A4 Inducers _____ _____

Alert Message: The concurrent use of Brexafemme (ibrexafungerp) with drugs that are moderate or strong CYP3A inducers should be avoided. Ibrexafungerp is a substrate of CYP3A4, and concomitant use with drugs that induce CYP3A metabolism may significantly reduce the plasma concentrations of ibrexafungerp and decrease ibrexafungerp efficacy.

Drugs/Diseases

Util A	Util B		Util C
Ibrexafungerp	Apalutamide	Mitotane	
	Bosentan	Phenobarbital	
	Butalbital	Phenytoin	
	Carbamazepine	Primidone	
	Efavirenz	Rifabutin	
	Enzalutamide	Rifampin	
	Etravirine	Rifapentine	
	Mitotane		

References:

Brexafemme Prescribing Information, June 2021, Scynexis, Inc.
Clinical Pharmacology, 2021 Elsevier/Gold Standard.

North Dakota Medicaid

Drug Utilization Review Board Meeting

June 1, 2022

Conference Room 210/212

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Meeting Notice

North Dakota Medicaid Drug Use Review Board

Wednesday, June 1, 2022
1 to 4 p.m. Central Time

In-Person Information

Conference Room 210/212, 2rd 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: 117 831 676 9#

Agenda

1. Administrative items
    - DHS announcements
    - Chair elections

2. Old business
    - Review and approval of March 2022 meeting minutes
    - Budget update
    - Review top 25 drugs for first quarter of 2022
    - Prior authorization/PDL update
        - Non-solid dosage form antifungals
        - Glucose rescue medications
    - Update to Sedative/Hypnotics
    - Update to Lupus Nephritis
    - Update to Chronic Kidney Disease
    - Update to Heart Failure
    - Update to Drug Utilization Review Policies
    - Synagis Discussion
    - Second review of Familial Cholestasis Pruritis

3. New business
    - Review of Wilson's Disease
    - Review of Cushing's Syndrome
    - Review of Presbyopia
    - Review of Vernal Keratoconjunctivitis
    - Retrospective DUR profile review update
    - Retrospective DUR criteria recommendations
    - Upcoming meeting date/agenda.
        - Next meeting is September 7th, 2022

Adjourn

Individuals with disabilities who need accommodations, including appropriate auxiliary aids to participate, can contact Stacey Koehly at 701-328-4807, toll-free 800-755-2604, 711 (TTY) or skoehly@nd.gov.

North Dakota Medicaid Drug Use Review (DUR) Board
Meeting Minutes
March 2, 2022

Members Present: Joshua Askvig, Andrea Honeyman, Kathleen Traylor, Amy Werremeyer, Laura Kroetsch, Tanya Schmidt, Kevin Martian, Kristen Peterson, Jennifer Iverson

Medicaid Pharmacy Department: Alexi Murphy, Brendan Joyce

Old Business

Chair T. Schmidt called the meeting to order at 1:03 p.m. Chair T. Schmidt asked for a motion to approve the minutes of the December 1, 2021, meeting. J. Askvig moved that the minutes be approved, and A. Honeyman seconded the motion. The chair called for a voice vote to approve the minutes. The motion passed with no audible dissent.

Review Top 25 Drugs

A. Murphy presented budget updates and the quarterly review of the top 25 drugs based on total claims cost, the top 25 drugs based on the total number of claims, and the top drug classes based on claims and cost for the 4th quarter of 2021. A. Murphy presented data to the Board that was reflective of the total number of Medicaid members in 4Q 2019 versus 4Q 2021 since merging traditional Medicaid and expansion. A. Murphy also discussed the net spend in 4Q 2019 versus 4Q 2021. The rise in members and net spend over time, specifically after the first quarter in 2020, is linked to the COVID-19 pandemic and the public health emergency that coincided with the pandemic. A. Murphy went on to discuss the pharmacy growth national health expenditure versus ND Medicaid, payment to pharmacies for several high-cost medication classes, utilization trends for several high-cost medication classes, and growth spend versus utilization of the same high-cost medication classes. Chair T. Schmidt asked if members must initiate the process of being removed from medical assistance due to changes made during the COVID-19 pandemic. A. Murphy answered that members do have to request to be taken off until the federal government says otherwise. J. Askvig followed up with a question about if the growth in membership from expansion members will potentially drop off, in which A. Murphy answered she was not sure.

PDL/PA Criteria Updates

A. Murphy shared with the Board all the changes made to the Preferred Drug List since the last version of the Preferred Drug List was posted. Notable changes include adding Adbry and Opzelura to PA for Eczema / Atopic Dermatitis, adding Epclusa and Mavyret Pellets to PA, and adding two agents, Recorlev and Tarpeyo, to PA for the Over 3000 criteria. All PDL updates are listed in the handouts for the March 2022 DUR Board meeting. When a new version of the PDL is published and posted to the website, all updates/changes made since the last version are called out at the top of the document itself.

Proposed New Criteria for Phenylketonuria

L. Morgan presented the proposed prior authorization criteria for Palynziq. The proposed criteria included member trial of sapropterin with good compliance prior to approval for Palynziq, and member weight must be included for Kuvan approval. Renewal criteria was added as well, which was dependent upon the requested dose and member response to prior treatment. Product specific criteria for renewal of Kuvan requires member weight be provided.

Update to Anti-infectives – Resistance Prevention

L. Morgan presented the proposed changes to the Anti-infectives – Resistance Prevention section, originally called the "Antibiotics – Resistance Prevention" section. In this section, cytomegalovirus agents were added, with one agent requiring PA. A. Murphy added comment about the Antifungal section, specifically for aspergillus and candidiasis infection. She states that this section will be lumped into the Anti-infectives section. A. Honeyman asked if the medication will only be covered during the 5-day approval date. A. Murphy explained that the approval date applies to the amount of time the pharmacy has to fill the medication – not the number of days in which the

medication is allowed to be filled. A. Honeyman also shared concern of the non-preferred agent Noxafil (posaconazole) being non-preferred in cases in which the member has an aspergillus infection and cannot swallow solid dosage forms. A. Murphy answered that in these cases, a PA can be submitted stating the type of infection and member need for non-solid dosage form.

Proposed New Criteria for Hypersomnolence
L. Morgan presented the only change made to this section in the second bullet. For non-preferred agent criteria, the member must have failed 30-day trials of each preferred agent (except Sunosi for idiopathic hypersomnia).

Proposed New Criteria for Eczema / Atopic Dermatitis
L. Morgan presented the new product specific criteria for Adbry, Opzelura, and Rinvoq ER. Adbry will require a trial of Dupixent, Opzelura will no longer require a trial of Eucrisa, and Rinvoq ER will require trial of Adbry and Dupixent prior to approval. All other criteria remained the same. During public comment, Mariola Vazquez gave testimony for Adbry. Thereafter, Nathan Blake gave testimony for Rinvoq ER. There were no questions or comments to follow.

Second Review of Chronic Kidney Disease
A motion and second were made at the December 2021 DUR Board meeting to place some agents for the management of chronic kidney disease (CKD) on the non-preferred list, requiring PA. The topic was brought up for a second review. Product specific CKD criteria for Korsuva was pointed out to the board by L. Morgan, as this agent will now be billed through medical billing. L. Morgan presented criteria for Kerendia and Tarpeyo, as well. During public comment, Bashir Kalayeh gave testimony for Kerendia. A. Werremeyer asked if there were methods of assessing patient blood glucose control during Kerendia clinical trials. Bashir then answered that glycemic control was not assessed in the trials. K. Martian then asked the UACR lab targets for the clinical trial inclusion criteria which was 30 – 5,000 mg/g per Bashir. Chair T. Schmidt called for a voice vote to approve the updated criteria, which passed with the caveat of adding EGFR criteria for approval of Kerendia.

Second Review of Lupus
L. Morgan presented initial and renewal criteria for non-preferred agent Lupkynis. Chair T. Schmidt asked for more clarification on what will be assessed for reduction in flares for the renewal criteria. A. Murphy answered that there are currently no specific criteria for reduction in flares, but this will be addressed at the next meeting. L. Morgan also added that Saphnelo will be added to the PDL for medical billing criteria only. Chair T. Schmidt called for a voice vote to approve the updated criteria, which passed with no audible dissent.

Synagis Discussion
L. Morgan discussed the Synagis PA form and the addition of the recipient weight in kilograms. The purpose of adding this section is to ensure that the correct number of units will be approved for 5 doses only for the RSV season. Additionally, A. Murphy asked the Board for input on how to assess appropriate start and end dates for RSV season.

<u>New Business</u>
Review of Agents Used in the Treatment of Familial Cholestasis Pruritis
L. Morgan presented a review of agents used in the treatment of familial cholestasis pruritis to the Board. During public comment, Stacy Sandate gave testimony for Bylvay. A motion was made by A. Werremeyer to manage these medications through prior authorization. The motion was seconded by L. Kroetsch. Prior authorization criteria for these agents will be presented, reviewed, and voted on by the Board at the next meeting.

Review of Drug Utilization Trends
A. Murphy presented the trends in antipsychotic use in the pediatric population. Drug edits for antipsychotics in the pediatric population were added at the end of 2018, which caused a decline in antipsychotic use in this

population. The purpose behind this is to ensure more appropriate use of antipsychotics in the pediatric population. The edits include age verification, diagnosis verification, and therapeutic duplication.

Retrospective Drug Utilization Review (RDUR) Criteria Recommendations

L. Morgan reviewed the RDUR criteria that were selected for review of each month of the last quarter. Presented data included number of profiles reviewed, number of cases identified for intervention, and the number of letters sent, as well as an overview of what RDUR interventions were identified as most prevalent for each monthly cycle. The recommended RDUR criteria enclosed in the packet were developed from product information provided by the manufacturers and are consistent with new indications, new drugs added, and new warnings. These proposed criteria will be added to the current set of criteria and will be used in future DUR cycles. Chair T. Schmidt requested for response rates to be presented. J. Askvig moved to approve the new criteria and Chair T. Schmidt seconded the motion. Chair T. Schmidt called for a voice vote to approve the new criteria, which passed with all present members voting to approve.

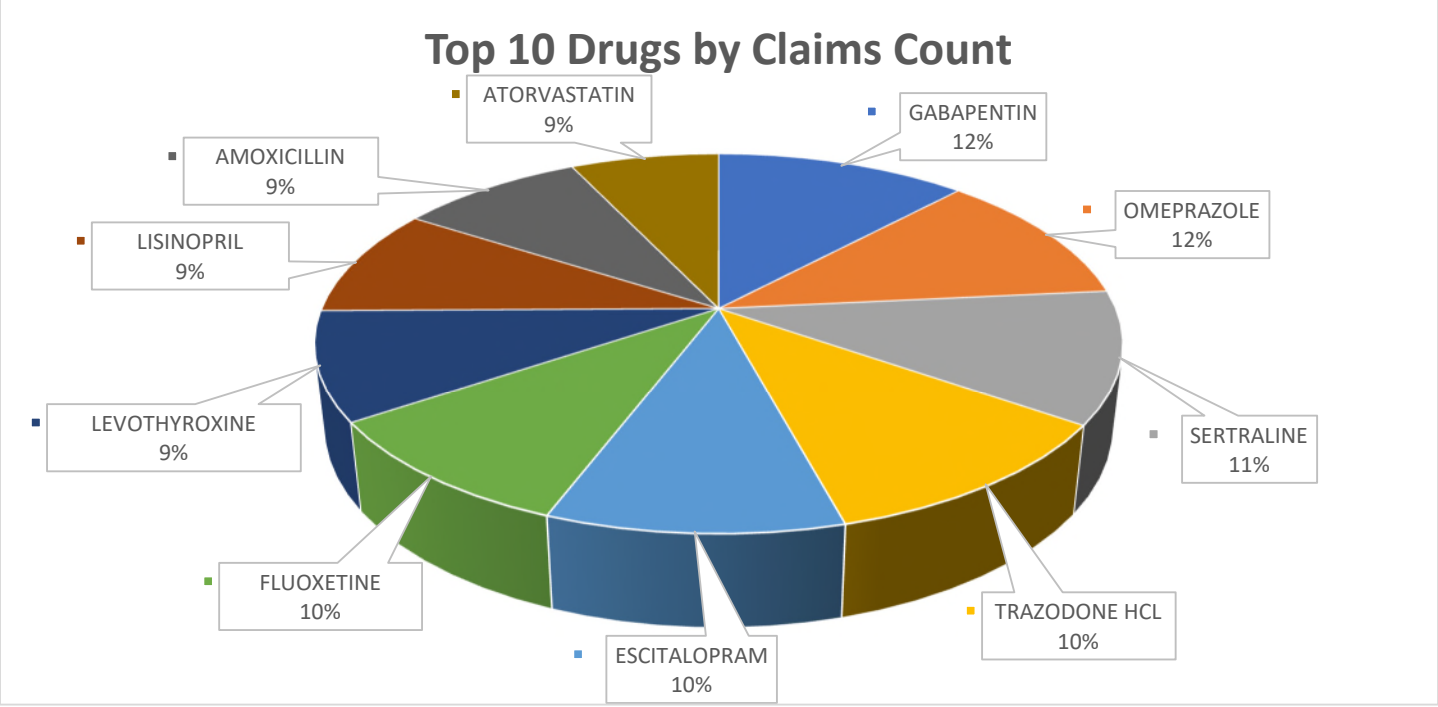
Adjournment and Upcoming Meeting Date

Chair T. Schmidt adjourned the meeting at 2:30 pm. The next DUR Board meeting will be held June 1st, 2022, at 1:00 pm at the state capitol building.

Top 25 Drugs Based on Number of Claims from 01/01/2022 – 03/31/2022

Drug	Claims	Patients	Claims Cost	Cost / Claim	% Total Claims	Dif.
GABAPENTIN	5,078	1,966	$74,450.38	$14.66	1.77%	NC
OMEPRAZOLE	4,992	2,395	$65,208.24	$13.06	1.74%	NC
SERTRALINE HCL	4,543	2,413	$62,660.40	$13.79	1.58%	NC
TRAZODONE HCL	4,382	2,047	$59,569.29	$13.59	1.53%	NC
ESCITALOPRAM OXALATE	4,222	2,266	$56,447.22	$13.37	1.47%	NC
FLUOXETINE HCL	4,193	2,088	$58,096.58	$13.86	1.46%	NC
LEVOTHYROXINE SODIUM	3,925	1,857	$70,467.40	$17.95	1.37%	NC
LISINOPRIL	3,651	1,997	$46,853.99	$12.83	1.27%	↑2
AMOXICILLIN	3,647	3,213	$50,990.32	$13.98	1.27%	↓1
ATORVASTATIN CALCIUM	3,618	1,926	$50,616.09	$13.99	1.26%	↓1
PROAIR HFA	3,183	2,847	$247,044.58	$77.61	1.11%	↑1
BUPROPION XL	3,178	1,570	$55,491.80	$17.46	1.11%	↑2
VYVANSE	3,174	1,206	$838,851.89	$264.29	1.11%	NC
HYDROCODONE-APAP	3,162	1,764	$46,790.27	$14.80	1.10%	↑2
PANTOPRAZOLE SODIUM	3,052	1,418	$40,752.53	$13.35	1.06%	↓4
PREDNISONE	3,046	2,300	$36,049.90	$11.84	1.06%	↓1
DULOXETINE HCL	2,791	1,330	$44,849.13	$16.07	0.97%	↑1
BUPRENORPHINE-NALOXONE	2,738	587	$110,815.38	$40.47	0.95%	↓1
METFORMIN HCL	2,637	1,371	$34,619.01	$13.13	0.92%	NC
CYCLOBENZAPRINE HCL	2,633	1,544	$30,184.95	$11.46	0.92%	NC
HYDROXYZINE HCL	2,609	1,482	$36,224.58	$13.88	0.91%	↑5
LAMOTRIGINE	2,595	989	$36,574.09	$14.09	0.90%	↑2
CLONIDINE HCL	2,589	1,198	$32,030.18	$12.37	0.90%	↑2
AUGMENTIN	2,580	2,272	$45,048.34	$17.46	0.90%	↓2
ONDANSETRON ODT	2,512	1,773	$35,787.48	$14.25	0.88%	↑12

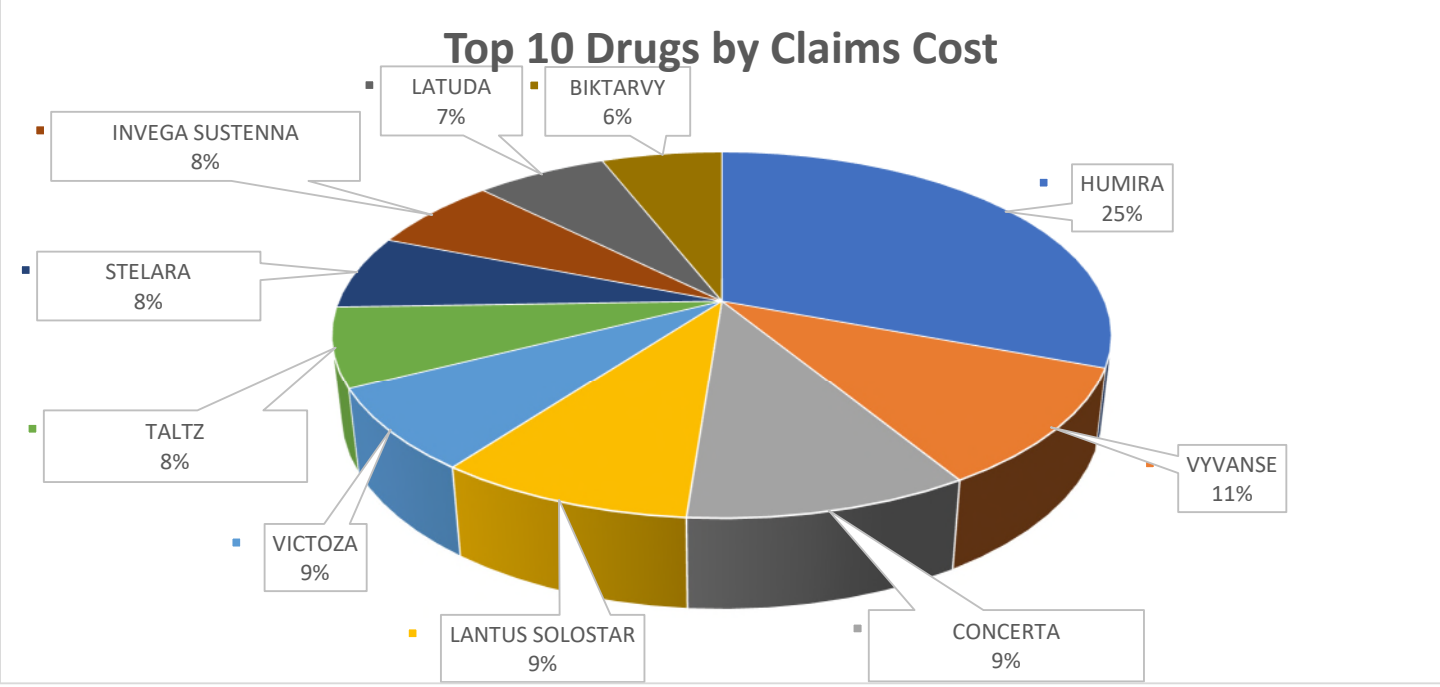
Total Claims	**286,960**



Top 25 Drugs Based on Total Claims Cost from 01/01/2022 – 03/31/2022

Drug	Claims Cost	Claims	Patients	Cost /Claim	% Total Cost	Dif.
HUMIRA PEN	$2,016,390.98	293	101	$6,881.88	$39,008.23	NC
VYVANSE	$838,851.89	3,174	1,206	$264.29	$695.57	NC
CONCERTA	$729,139.33	2,211	823	$329.78	$885.95	↑1
LANTUS SOLOSTAR	$725,483.19	1,443	791	$502.76	$917.17	↓1
VICTOZA 3-PAK	$724,444.11	754	319	$960.80	$2,270.98	NC
TALTZ AUTOINJECTOR	$676,371.04	104	33	$6,503.57	$20,496.09	↑1
STELARA	$633,128.81	27	17	$23,449.22	$37,242.87	↑4
INVEGA SUSTENNA	$604,846.32	246	83	$2,458.72	$7,287.31	↓2
LATUDA	$542,904.17	713	227	$761.44	$2,391.65	↓1
BIKTARVY	$498,401.18	268	109	$1,859.71	$4,572.49	↑6
JARDIANCE	$497,681.78	1,007	413	$494.22	$1,205.04	↓2
NORDITROPIN FLEXPRO	$467,349.11	115	40	$4,063.91	$11,683.73	↑6
SABRIL	$436,511.86	12	5	$36,375.99	$87,302.37	↓3
NOVOLOG FLEXPEN	$409,526.17	576	322	$710.98	$1,271.82	↓2
TRIKAFTA	$405,895.93	17	7	$23,876.23	$57,985.13	↓2
SYMBICORT	$395,684.42	1,167	593	$339.06	$667.26	↓2
ADDERALL XR	$367,591.09	2,201	835	$167.01	$440.23	↓2
MAVYRET	$349,815.78	31	17	$11,284.38	$20,577.40	↑12
ADVAIR DISKUS	$348,923.82	984	508	$354.60	$686.86	↓2
ELIQUIS	$322,528.48	730	307	$441.82	$1,050.58	NC
VICTOZA 2-PAK	$308,141.28	497	237	$620.00	$1,300.17	↑2
LEVEMIR FLEXTOUCH	$304,909.48	542	286	$562.56	$1,066.12	↓3
XIFAXAN	$293,687.46	116	49	$2,531.79	$5,993.62	↓1
ABILIFY MAINTENA	$279,842.51	126	45	$2,220.97	$6,218.72	NC
VRAYLAR	$274,924.78	304	104	$904.36	$2,643.51	↑2

Total Claims Cost	**$35,517,529.96**



Top 15 Therapeutic Classes Based on Number of Claims from 01/01/2022 – 03/31/2022

Therapeutic Class Description	Claims	Patients	Claims Cost	Cost/Claim	% Total Claims	Dif.
ANTIDEPRESSANTS	31,957	12,355	$679,117.48	$21.25	11.14%	NC
ANTICONVULSANTS	15,028	4,875	$1,418,902.68	$94.42	5.24%	NC
ANTIPSYCHOTIC AGENTS	10,274	3,576	$2,550,702.62	$248.27	3.58%	NC
PROTON-PUMP INHIBITORS	8,484	3,951	$160,700.26	$18.94	2.96%	NC
SEDATIVES/ HYPNOTICS	7,921	3,668	$123,169.10	$15.55	2.76%	NC
OPIATE AGONISTS	7,576	3,543	$132,937.68	$17.55	2.64%	NC
AMPHETAMINES	7,015	2,619	$1,258,143.76	$179.35	2.44%	↑3
NSAIDs	6,728	4,133	$98,358.61	$14.62	2.34%	NC
PENICILLIN ANTIBIOTICS	6,557	5,462	$103,475.52	$15.78	2.28%	↓2
STATINS	6,190	3,275	$89,145.16	$14.40	2.16%	↓1
NON-AMPHETAMINE STIMULANTS	6,111	2,032	$1,097,379.48	$179.57	2.13%	↑1
BETA BLOCKERS	5,899	2,946	$109,629.15	$18.58	2.06%	↓1
BETA AGONISTS	5,354	4,265	$374,153.70	$69.88	1.87%	NC
ADRENALS	4,953	3,637	$70,398.37	$14.21	1.73%	NC
ACE-INHIBITORS	4,669	2,546	$74,582.38	$15.97	1.63%	NC

Top 15 Therapeutic Classes Based on Claims Cost from 01/01/2022 – 03/31/2022

Therapeutic Class Description	Claims Cost	Claims	Patients	Cost/Claim	% Total Cost	Dif.
DMARDS	$3,576,360.49	663	247	$5,394.21	10.07%	NC
ANTIPSYCHOTIC AGENTS	$2,550,702.62	10,274	3,576	$248.27	7.18%	NC
SKIN AND MUCOUS MEMBRANE AGENTS	$2,221,256.33	756	399	$2,938.17	6.25%	↑1
INSULINS	$2,218,750.81	4,341	1,450	$511.12	6.25%	↓1
ANTINEOPLASTIC AGENTS	$1,562,341.06	665	242	$2,349.39	4.40%	↑2
ANTICONVULSANTS	$1,418,902.68	15,028	4,875	$94.42	3.99%	↓1
AMPHETAMINES	$1,258,143.76	7,015	2,619	$179.35	3.54%	↓1
ANTIRETROVIRALS	$1,241,020.08	1,008	309	$1,231.17	3.49%	↑3
INCRETIN MIMETICS	$1,175,188.70	1,423	581	$825.85	3.31%	↑1
RESPIRATORY CORTICOSTEROIDS	$1,164,203.84	4,144	2,242	$280.94	3.28%	↓2
NON-AMPHETAMINE STIMULANTS	$1,097,379.48	6,111	2,032	$179.57	3.09%	↓2
IMMUNOMODULATORY AGENTS	$714,737.74	89	33	$8,030.76	2.01%	NC
SGLT-2 INHIBITORS	$693,717.51	1,415	581	$490.26	1.95%	↑1
ANTIDEPRESSANTS	$679,117.48	31,957	12,355	$21.25	1.91%	↓1
HCV ANTIVIRALS	$619,326.99	61	29	$10,152.90	1.74%	↑5

PDL UPDATE

Drug Name	PA Status	Class
Luzu	PA	Antifungals - Topical
Releuko	PA	Biosimilars - CSF
Kerendia	PA	Chronic Kidney Disease
Cibinqo	PA	Eczema/Atopic Dermatitis
Pyrukynd	PA	Meds over 3000
Ferriprox	PA	Meds over 3000
Vijoice	PA	Meds over 3000
Soaanz	PA	Non-Preferred Dosage Forms/Loop Diuretics
Fleqsuvy (baclofen) ORAL SUSPENSION	PA	Non-Solid Dosage Forms
Quviviq	PA	Sedative-Hypnotics
Tlando	PA	Testosterone
Frova	PA	Triptans
Vusion	remove PA	Antifungals - Topical
Extina Foam	remove PA	Antifungals - Topical
Tobradex ST	remove PA	Anti-infectives/Anti-inflammatories
Climara	remove PA	Estrogens
Yuvafem	remove PA	Estrogens
Tasmar	remove PA	Parkinsons's Agents

Antifungals – Aspergillus and Candidiasis Infections

Non-Solid Dosage Forms	
PREFERRED AGENTS (NO PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**
fluconazole suspension	DIFLUCAN (fluconazole) SUSPENSION
itraconazole solution	SPORANOX (itraconazole) SOLUTION
NOXAFIL (posaconazole) SUSPENSION	voriconazole suspension
VFEND (voriconazole) SUSPENSION – *Brand Required*	

Glucose Rescue Medications

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
BAQSIMI (glucagon) SPRAY	glucagon kit – 00548, 63323
glucagon kit – Labeler 00002	GLUCOGEN (glucagon) HYPOKIT
GVOKE (glucagon) INJECTION	
ZEGALOGUE (dasiglucagon) AUTOINJECTOR	

Sedatives/Hypnotics

Smith-Magenis Syndrome

Group 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 prescriber is a specialist, or the prescriber has consulted with a specialist in sleep disorders
  - The diagnosis is Smith-Magenis Syndrome with genetic testing confirming deletion 17p11.2 (cytogenetic analysis or microarray) or RAI1 gene mutation
  - Documentation of self-reported sleep diaries or actigraphy for at least 14 days must be submitted.
- **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 self-reported sleep diary and medical documentation (e.g. chart notes) attached to the request (subject to clinical review).

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

Lupus

Lupus Nephritis

Product Specific: Lupkynis

- **Initial criteria**: *Approval Duration = 6 months*
  - The medication is prescribed by, or in consultation with, a nephrologist or rheumatologist
  - 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.
  - The member has had clinical progression (e.g., worsening of proteinuria or serum creatinine) despite a 3-month trial with Benlysta (belimumab)
- **Renewal Criteria:** *Approval Duration 12 months*
  - The provider must submit documentation showing that the member has experienced clinical benefit since starting treatment, as evidenced by documentation of one of the following:
    - Improvement of proteinuria (UPCR decreased by 50% and/or below 0.5 to 0.7 g/day)
    - Improvement of serum creatinine (SCr ≤ 1.4mg/dl)
    - Chronic steroid use to ≤ 7.5mg/day

Chronic Kidney Disease

Non-steroidal selective mineralocorticoid receptor antagonist (MRA)

Product Specific Criteria (Initial): *Approval Duration = 12 months*

1. **Kerendia**
   - Member must have history of diabetes
   - One of the following criteria must be met (1 or 2):
     1. Estimated glomerular filtration rate (eGFR) 25 to 60 mL/min/1.73 m2 AND urinary albumin-to-creatinine ratio (UACR) of 30 to under 300 mg/g
     2. Estimated glomerular filtration rate (eGFR) 25 to 75 mL/min/1.73 m2 AND urinary albumin-to-creatinine ratio (UACR) ≥ 300 mg/g

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

Heart Failure

Second Line Agents:

Product Specific Criteria:

- **Verquvo:**
  - The prescriber is, or is in consult with, a cardiologist
  - The member must have left ventricular ejection fraction (LVEF) < 45%
  - Documentation of a recent hospitalization or need for IV diuretics (within the past 6 months) must be submitted with request
  - The member is receiving concurrent Entresto, a beta-blocker, a SGLT-2 Inhibitor, and a mineralocorticoid receptor antagonist.
- **Corlanor:**
  - The prescriber is, or is 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

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
CORLANOR (ivabradine)	
VERQUVO (vericiguat)	

Drug Utilization Review policies:

- 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. Sec. 1927. [42 U.S.C. 1396r-8](d)

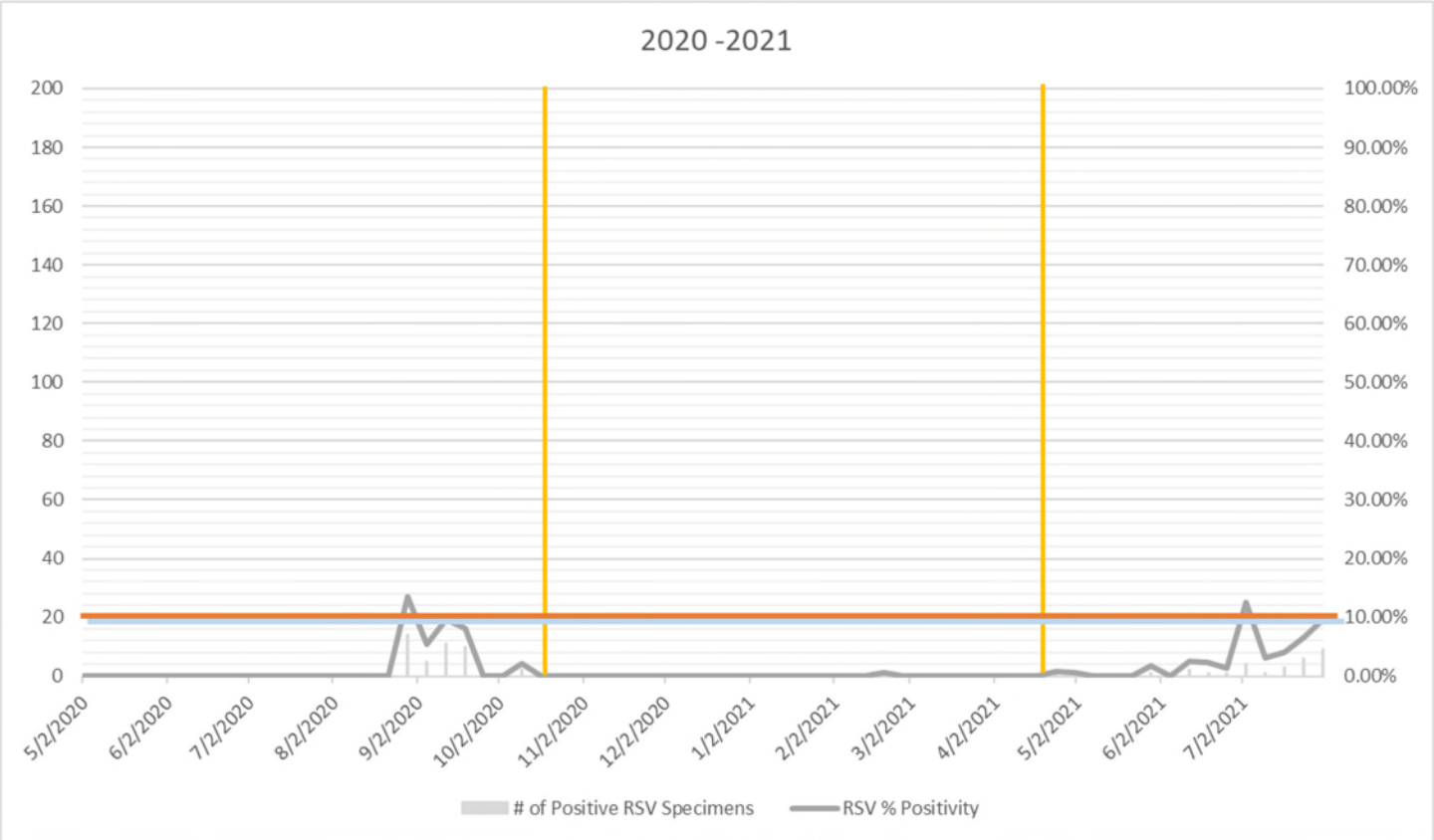
Synagis

Seasonal Cost

Season	Service Count	Payment	Third Party Amount	Total
2016 to 2017	245	$293,787.39	$38,751.74	$332,539.13
2017 to 2018	432	$579,049.67	$1,152.00	$580,201.67
2018 to 2019	300	$376,107.42	$33,002.02	$409,109.44
2019 to 2020	303	$362,647.55	$58,209.63	$420,857.18
2020 to 2021	267	$262,302.36	$50,834.40	$313,136.76

2020 to 2021

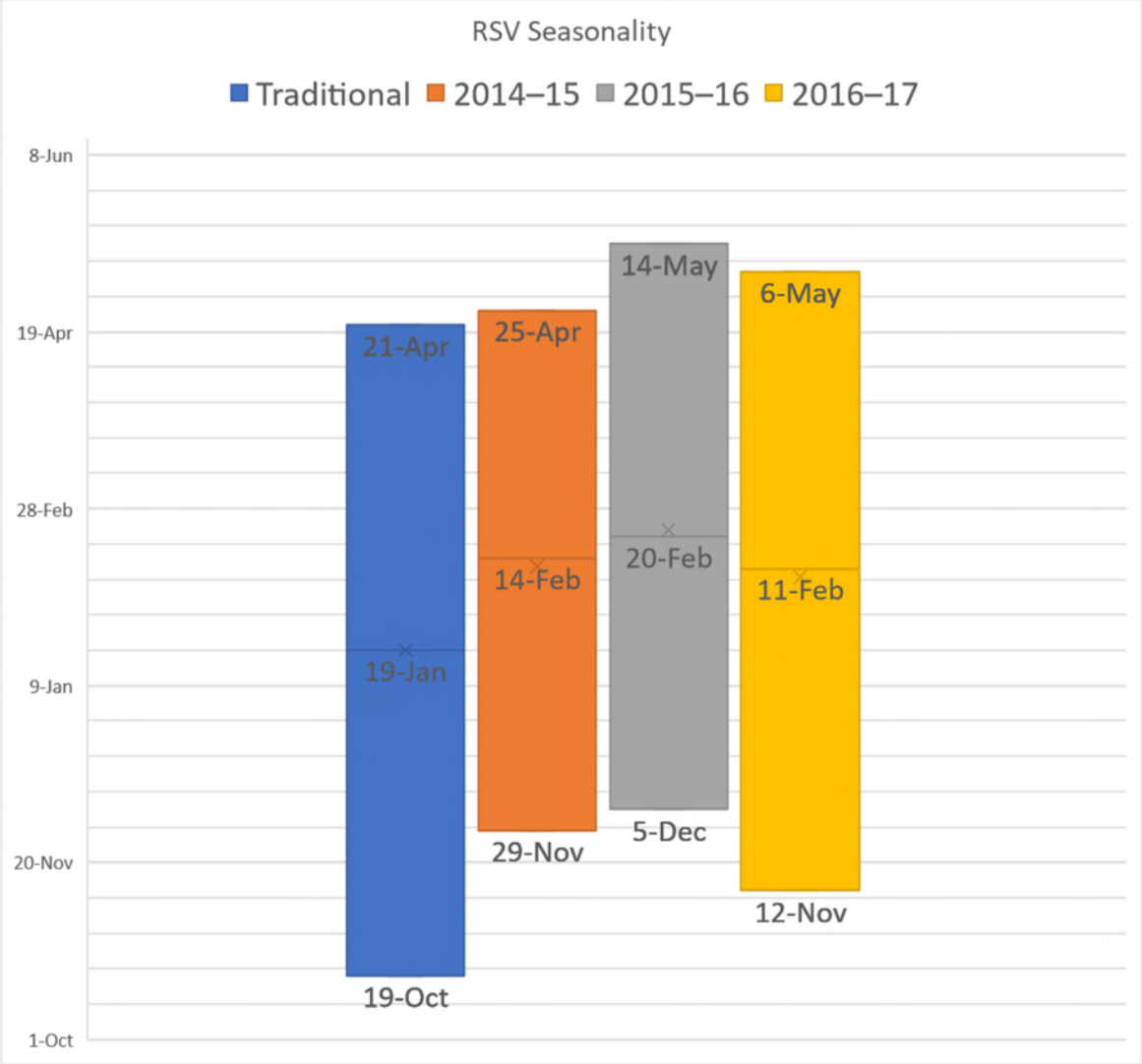
Method	Color	Start	Notice	End	Length	% annual detections
Date Based	Orange	19-Oct	21-Apr	N/A	26 weeks	2.74%
10%	N/A					
Tenfold	N/A					



CDC Reported Seasons

Region 8 (Denver): Colorado, Montana, North Dakota, South Dakota, Utah, and Wyoming

HHS region (headquarters) or state/RSV season	No. of laboratories reporting	Onset week ending	Peak week ending	Offset week ending	Season duration (weeks)
2014–15	7	11/29/2014	2/14/2015	4/25/2015	22
2015–16	10	12/5/2015	2/20/2016	5/14/2016	24
2016–17	11	11/12/2016	2/11/2017	5/6/2017	26
Traditional		10/19/2021	1/19/2022	4/21/2022	26



The CDC uses the RS10 (Retrospective Slope 10) method which is not applicable real-time and recommends the % positivity or tenfold baseline as alternatives for determining season real time.

References:

1. Claire M Midgley, Amber K Haynes, Jason L Baumgardner, Christina Chommanard, Sara W Demas, Mila M Prill, Glen R Abedi, Aaron T Curns, John T Watson, Susan I Gerber, Determining the Seasonality of Respiratory Syncytial Virus in the United States: The Impact of Increased Molecular Testing, *The Journal of Infectious Diseases*, Volume 216, Issue 3, 1 August 2017, Pages 345–355, https://doi.org/10.1093/infdis/jix275
2. Buescher, Paul, North Carolina Department of Health and Human Services Division of Public Health, State Center for Health Statistics, Problems with Rates Based on Small Numbers, *Statistical Primer*, No. 12, April 1997. https://schs.dph.ncdhhs.gov/schs/pdf/primer12_2.pdf
3. Rose EB, Wheatley A, Langley G, Gerber S, Haynes A. Respiratory Syncytial Virus Seasonality — United States, 2014–2017. MMWR Morb Mortal Wkly Rep 2018;67:71–76. DOI: http://dx.doi.org/10.15585/mmwr.mm6702a4external icon.

Ways to determine "seasonality" real time

Feature	10-Fold Baseline	3% Threshold	10% Threshold (Traditional)
Test Type	No denominator needed	Multi-target denominator	Single-target denominator
Data	Weekly no. of RSV detections	Weekly percentage of tests positive for RSV	Weekly percentage of tests positive for RSV
Data function	4-week moving average, using detections in 2 preceding weeks, current week, and following week	None	None
Onset	First of 2 consecutive weeks when 4-week moving average of RSV detections is >10 times the 4-week moving average at week 29	First of 2 consecutive weeks when percentage of tests positive for RSV is >3%	First of 2 consecutive weeks when percentage of tests positive for RSV is >10%
Offset	Last week that 4-week moving average of RSV detections is >10 times the 4-week moving average at week 29	Last week that percentage of tests positive for RSV is >3%	Last week that percentage of tests positive for RSV is >10%
Strengths	Applied in near real time	Applied in near real time	Applied in near real time
	Testing practices have less influence on season because testing denominator is excluded	Simple to use	Simple to use
	Region-specific approach because measure is relative to regional baseline	A possible approach in locales where RSV testing or reporting are not performed throughout the year.	A possible approach in locales where RSV testing or reporting are not performed throughout the year.
Limitations	Year-round RSV testing and reporting is required (including summer months) because (1) testing denominator has been excluded and (2) data are presented relative to other weeks	Use of denominator means that testing practices can influence season (e.g., panel vs target specific reporting)	Use of denominator means that testing practices can influence season (e.g., panel vs target specific reporting)
	Data are relative to a time of year when RSV detections are low and fewer laboratories are reporting	A single-value threshold might not be as precise for all seasons and regions, especially as testing practices vary	A single-value threshold might not be as precise for all seasons and regions, especially as testing practices vary

Measures of consistency:

The 10% approach with multi-target denominator capturing a 13–18-week season with 72%-82% of annual detections was deemed inappropriate for use. The 10% approach with single-target denominator capturing a 19 to 31 week with 82%-94% annual detections was acceptable.

Familial Cholestasis Pruritis

General Prior Authorization Form

Category Criteria (Initial): *Approval Duration = 6 months*

- Member must have presence of moderate to severe pruritis, as evidenced by clinical documentation.
- Prescriber must be, or in consult with, a hepatologist or gastroenterologist
- Member has 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
- Member must not have a history of liver transplant or decompensated cirrhosis.
- Member must not have history of biliary diversion surgery within the past 6 months.
- Member must have had at least a 3-month trial of ursodiol, as evidenced by paid claims or pharmacy printouts.
- Member must have had at least a 3-month trial of one of the following agents to treat pruritis: cholestyramine, rifampin, antihistamines, as evidenced by paid claims or pharmacy printouts.

Product Specific Criteria:

- **Bylvay:**
  - Genetic testing confirms pathogenic variant (e.g., *ATP8B1, ABCB11, ABCB4, TJP2, NR1H4, and MYO5B*) indicating the presence and type of PFIC Type 1 or 2.
  - Genetic testing does not indicate PFIC Type 2 with *ABCB11* variants that predict complete absence of BSEP-3 protein.
- **Livmarli:**
  - Genetic testing confirms pathogenic variant of *JAG1* or *NOTCH1*

Renewal Criteria: *Approval Duration = 12 months*

- Member has experienced an improvement in pruritis, as evidenced by clinical documentation.
- Member must have experienced a reduction in serum bile acid as defined as a bile acid reduction ≥70% or reaching a bile acid level ≤70 µmol/L
- Member must not have a history of liver transplant or decompensated cirrhosis.
- Member must not have history of biliary diversion surgery within the past 6 months.

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

REVIEW OF WILSON'S DISEASE

Wilson's disease is caused by genetic mutations in the intracellular copper-transporting *ATP7B* gene. This autosomal recessive mutation causes impaired copper metabolism. Symptoms associated with Wilson's disease include hepatic (abdominal pain, acute hepatitis, jaundice, etc.), neurologic (dysarthria, gait abnormalities, tremor, etc.), and psychiatric symptoms (depression, personality change, and irritability). The prevalence of Wilson's disease is 1:30,000 live births worldwide.

Place in Therapy/Guidelines

The American Association for the Study of Liver Diseases' (AASLD) guidelines

Pre-symptomatic	Initial treatment for symptomatic patients	Maintenance therapy
chelating agent (D-penicillamine or trientine) or zinc	chelating agent (D-penicillamine or trientine)	chelating agent (D-penicillamine or trientine) or zinc

- Chelators are used in two phases. Phase 1 is to remove existing copper, and Phase 2 is to prevent copper accumulation.
- D-penicillamine is recommended first-line since trientine hydrochloride has limited clinical use.
- The guidelines recognize however that trientine may be better tolerated than D-penicillamine.
- Patients should also eat a low-copper diet.
- Liver transplant is an option for patients with severe or resistant cases of Wilson's Disease.
- **D-penicillamine products available:** Depen and Cuprimine
- **Trientine products available:** Syprine and Cuvrior

General Dosing and FDA Indications

Depen (penicillamine) and Cuprimine (penicillamine)	
Mechanism of Action	Chelates mercury, lead, **copper**, iron, and possibly other heavy metals to form stable, soluble complexes to be excreted in the urine
Dosing	Adult • Initial: 750 mg to 1.5 g/day PO that results in an initial 24-h cupriuresis of over 2 mg/day, optimal dose based on urinary copper excretion and free copper in serum • Maintenance: up to 2 g/day; based on urinary copper excretion and free copper in serum
Indications	Cystinuria, Severe rheumatoid arthritis, Wilson's disease
Syprine (trientine hydrochloride)	
Mechanism of Action	Chelates copper to form stable, soluble complexes to be excreted in the urine
Dosing	Adult • 750 to 1250 mg/day PO in 2 to 4 divided doses • Max dose: 2,000 mg/day Pediatric • 500 to 750 mg/day PO in 2 to 4 divided doses for children aged 12 years & under • Max dose: 1,500 mg/day

Indications	Wilson's disease
Cuvrior (trientine tetrahydrochloride)	
Mechanism of Action	Chelates copper to form stable, soluble complexes to be excreted in the urine.
Dosing	Adult • 300 mg up to 3,000 mg PO in divided doses
Indications	Wilson's disease in those who are de-coppered and tolerant to penicillamine

Approval Status and Special Designations

Drugs@FDA: FDA-Approved Drugs
Fast Track, Breakthrough Therapy, Accelerated Approval, Priority Review | FDA
The Drug Development Process | FDA

Drug Name	Approval Letter Post Marketing Trial and Reporting Requirements
Depen Titratab (penicillamine)	Originally Approved on 11/08/1978 by NDA Type 5 - New Formulation or New Manufacturer, Standard
Cuprimine (penicillamine)	Originally Approved on 12/04/1970 by NDA Type 1 - New Molecular Entity, Standard
Syprine (trientine hydrochloride)	Approved on 11/08/1985 by NDA Type 1 - New Molecular Entity, PRIORITY; Orphan
Cuvrior (trientine tetrahydrochloride)	Approved on 04/28/2022 by 505(b)(2) NDA Type 2 - New Active Ingredient, Standard, Orphan 505(b)(2): an application that contains full reports of investigations of safety and effectiveness but where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference

Therapeutically Important Adverse Effects/Advantages

D-penicillamine

- Not as well-tolerated as trientine
- Lack of efficacy in treating neurological symptoms
- Adverse effects: rash, N/V/D, pancreatitis, thrombocytopenia, myasthenia gravis, Goodpasture's syndrome(rare)

Trientine hydrochloride

- Pediatric dosing
- Lower incidence of side effects than D-penicillamine agents
- Reserved for patients who develop serious side effects from D-penicillamine agents
- Adverse effects: contact dermatitis, myasthenia gravis, iron-deficiency anemia, and SLE

Trientine tetrahydrochloride

- Same active base ingredient and new salt form of trientine.

- Reserved for stable patients who are de-coppered and tolerant to penicillamine
- Adverse effects: abdominal pain, rash, alopecia, and mood swings.

Cost

Drug	Strength	Package Size	WAC Pkg Price	Cost/day*	Cost/month*	Cost/year*
Penicillamine tablet	250 mg	100 each	$4,652.90	$372.23	$11,166.96	$134,003.52
Penicillamine capsule	250 mg	100 each	$1,080	$86.40	$2,592.00	$31,104.00
Trientine hydrochloride capsule	250 mg	100 each	$750.00	$60.00	$1,800.00	$21,600.00
Cuvrior	Expected to launch in early 2023					

*Based on lowest per unit WAC cost

Current Utilization

ND Medicaid Utilization (04/01/2021 - 03/31/2022)

Label Name	Rx Number	Total Reimbursement Amt
Penicillamine tablet	0	0
Penicillamine capsule	0	0
Trientine hydrochloride capsule	18	$1,7944.6
Cuvrior	0	0

Clinical Studies

CHELATE (NCT03539952)	
Study design	Multicenter, randomized, phase 3, open-label study
Enrollees	53 participants
Inclusion Criteria	• 18 – 75 years of age • Patient's Wilson's disease is clinically stable and being treated with penicillamine for at least 1 year prior to screening/enrollment • Patient is on a stable dose and regimen of penicillamine for at least 4 months prior to screening/enrollment • Patient must be willing to maintain stable diet, avoiding foods high in copper content

Exclusion	• Patients with uncontrolled liver disease • Patients with severe anemia defined as hemoglobin of ≤ 9 g/dL • GI bleed within the past 6 months • Patient has renal impairment defined as creatinine clearance of ≤ 30 mL/min • Patient is currently receiving prescribed zinc therapy for management of Wilson's disease or has taken it within 4 months of screening/enrolment • Pregnant patients or patients not using a reliable form of contraception
Interventions	• Patients were randomized in a 1:1 ratio to receive either trientine tetrahydrochloride (TETA 4HCl) or to continue to receive penicillamine after a 12-week Penicillamine Baseline Period in which the patients take their current penicillamine under study conditions. • There is then a 24-week Post-randomization Phase comprising of a 1-month (4 weeks) run-in period for both treatment arms and a 5-month (20 weeks) evaluation period. • Patients who successfully complete the 24-week Post-randomization Phase of the study will have the opportunity to enter an 18-month (72 weeks) Extension Phase. • Initially they continue to receive their allocated TETA 4HCl or penicillamine for a further 24 weeks (i.e., up to Week 60 of the study). Thereafter, all patients will receive TETA 4HCl for 48 weeks (i.e., between Week 60 and Week 108).
Primary Outcome(s)	Serum nonceruloplasmin copper (NCC) concentration: Primary endpoint met. TETA 4HCl was noninferior to D-penicillamine
Secondary Outcome(s)	1. 24-hour urinary copper excretion 2. Clinical Global Impression of Change (CGIC) rating scale

References:

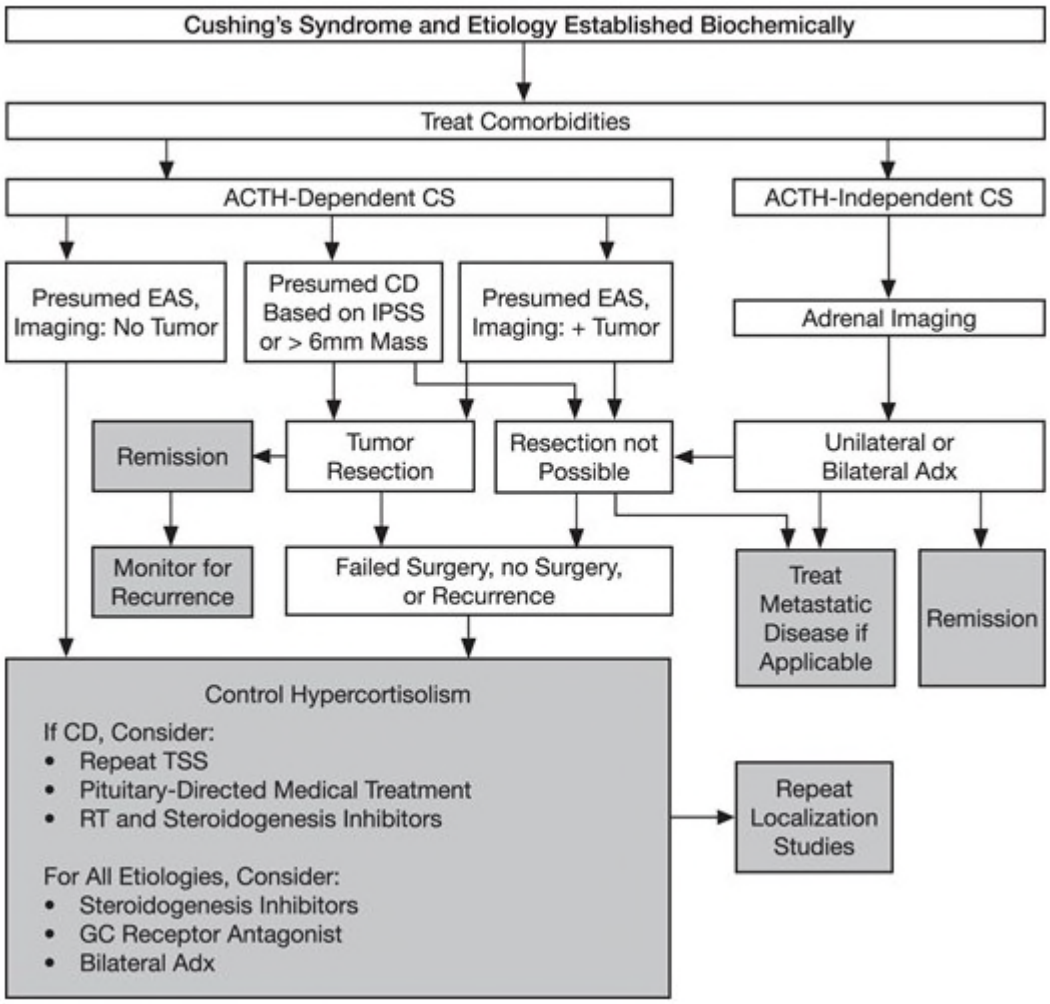
1. Product Information: CUPRIMINE(R) oral capsules, penicillamine oral capsules. Merck & Co,Inc, Whitehouse Station, NJ, 2004.
2. Product Information: DEPEN(R) titratable oral tablets, penicillamine titratable oral tablets. Meda Pharmaceuticals Inc, Somerset, NJ, 2009.
3. Product Information: Penicillamine. Merck & Co., US, 97.
4. Product Information: SYPRINE(R) oral capsules, trientine hcl oral capsules. Merck & Co,Inc, Whitehouse Station, NJ, 2001.
5. Roberts, E., Schilsky, M. AASLD Practice Guidelines: Diagnosis and Treatment of Wilson Disease: An Update. https://www.aasld.org/sites/default/files/2019-06/Wilson-Disease2009.pdf.
6. NCT03539952. Trientine Tetrahydrochloride (TETA 4HCL) for the Treatment of Wilson's Disease. Clinical Trials.gov. https://clinicaltrials.gov/ct2/show/study/NCT03539952.
7. *Wilsons Disease.* IPD Analytics. Aventura, FL, 2021. https://www.ipdanalytics.com.

REVIEW OF CUSHING'S SYNDROME

Cushing's syndrome (CS) is a condition caused by excess cortisol in the body, either by exogenous or endogenous means. Prolonged use of glucocorticoids can cause CS by exogenous means. Endogenous CS is a rare endocrine disorder caused by chronic, elevated cortisol exposure. Endogenous causes of CS include ACTH-dependent [Pituitary adenoma (Cushing's disease) and ectopic secretion by non-pituitary tumor] and ACTH-independent [Adrenocortical adenoma or carcinoma and nodular adrenal hyperplasia]. Approximately 1 per 26,000 people are affected each year by CS. Cushing's disease is a subset of CS and is the most common cause of CS. It is caused by a pituitary adenoma that produces excess adrenocorticotropic hormone (ACTH). Cushing's disease has the potential to cause other health concerns such as obesity, type 2 diabetes, clotting, hypertension, immunosuppression, etc. Signs and symptoms of CS include glucose intolerance, weight gain, striae over the abdomen, female balding, decreased fertility and/or libido, osteoporosis, hypertension, depression, and increased infections.

Place in Therapy/Guidelines

Cushing's Syndrome Treatment		
Class	**Drug**	**Indication/Comments**
Adrenal enzyme inhibitor	ketoconazole	Off-label use
	metyrapone	Off-label use; commonly used after irradiation or in mild disease due to insufficient cortisol lowering as monotherapy
	mitotane	Off-label use to achieve medical adrenalectomy; does not cure CD as monotherapy
	Isturisa	FDA approved for CS for whom pituitary surgery is not an option/has not been successful
	Recorlev	FDA approved for treatment of endogenous hypercortisolemia in adult patients with CS whom surgery is not an option/has not been successful
Pituitary-directed therapies	Signifor	FDA approved for CS for whom pituitary surgery is not an option/has not been successful
	Signifor LAR	FDA approved for CS for whom pituitary surgery is not an option/has not been successful
	cabergoline	Off-label use
Glucocorticoid receptor-directed therapy	Korlym	FDA approved to control hyperglycemia secondary to hypercortisolism in adult patients with endogenous CS who have type 2 diabetes mellitus for glucose intolerance and have failed surgery or are not candidates for surgery



Derived from Nieman LK, Biller BM, Finding, JW, et al. The diagnosis of Cushing's syndrome: an Endocrine Society Clinical Practice Guideline. *J Clin Endocrinol Metab*. 2008;93:1526–1540. (17)

- Cushing's syndrome treatment
  - FDA-approved agents for Cushing's disease: Korlym, Signifor/Signifor LAR, Isturisa, and Recorlev
  - First-line: Microsurgical resection of the ACTH-secreting pituitary adenoma (80-90% success rate)
  - Second-line: adrenal enzyme inhibitors (ketoconazole, metyrapone, Isturisa), adrenolytic agents (mitotane), pituitary tumor targeting drugs (cabergoline, Signifor), and glucocorticoid-receptor antagonists (mifepristone). The 2015 Endocrine Society Clinical Practice Guidelines on the Treatment of Cushing's Syndrome do not recommend any medical therapy over another.
    - Steroidogenesis inhibitors are recommended after transsphenoidal selective adenomectomy (TSS) in patients with CD, with or without radiation therapy (RT)/radiosurgery; as primary treatment of ectopic ACTH secretion (EAS) in patients with occult or metastatic EAS; and as adjunctive treatment to reduce cortisol levels in adrenocortical carcinoma.
    - Pituitary-directed medical treatments are recommended in patients with CD who are not surgical candidates or who have persistent disease after TSS.
    - Glucocorticoid antagonists are recommended in patients with diabetes or glucose intolerance who are not surgical candidates or who have persistent disease after TSS.

General Dosing and FDA Indications

Nizoral (ketoconazole)	
Mechanism of Action	Impairs adrenal and gonadal steroidogenesis by inhibiting side-chain cleavage, 17,20-lyase, and 11-beta hydroxylase enzymes
Dosing	Adult • 400-1,600 mg PO Qday; every 6 to 8 hours
Indications	Blastomycosis, candidiasis of skin, coccidioidomycosis, dandruff, histoplasmosis, paracoccidioidomycosis, pityriasis versicolor, seborrheic dermatitis, systemic chromomycosis, tinea corporis, tinea cruris, tinea pedis, atopic dermatitis, prostate cancer
Metopirone (metyrapone)	
Mechanism of Action	Inhibits 11-beta hydroxylase, which catalyzes the conversion of 11-deoxycortisol to cortisol
Dosing	Adult • Initial: (mild hypercortisolism) 500 mg/day PO in 2 divided dose; (moderate or severe hypercortisolism) 750 mg/day PO in 3 divided doses; (very severe hypercortisolism) 1,000 mg/day PO in 3 divided doses. • Dose titration: Increase by 250 mg if mean urinary free cortisol (mUFC) levels are less than ULN not achieved at month 1, 3, 6, or 12. • Max dose: 6g/day
Indications	Laboratory test of hypothalamic and pituitary hormones, Cushing's syndrome, Pituitary dependent hypercortisolism
Lysodren (mitotane)	
Mechanism of Action	Inhibits CYP11A1 (P450 side-chain cleavage) and has a direct cytotoxic action on the adrenal cortex
Dosing	Adult • Initial: 250 mg PO Qday • Maintenance: 500 mg PO Qday to 8 g PO Qday
Indications	Adrenal carcinoma, Inoperable and Adjuvant therapy
Isturisa (osilodrostat)	
Mechanism of Action	Cortisol synthesis inhibitor. Inhibits 11-beta hydroxylase (CYP11B1), the enzyme responsible for the final step of cortisol biosynthesis in the adrenal gland
Dosing	Adult • Initial: 2 mg PO twice daily with or without food • Dose titration: may increase by 1 to 2 mg twice daily, no more frequently than every 2 weeks, based on the rate of cortisol changes, individual tolerability, and improvement in signs and symptoms. If 10 mg twice daily is tolerated and 24-hour urine free cortisol levels continue to be above ULN, may increase by 5 mg twice daily every 2 weeks • Maintenance: 2 to 7 mg PO twice daily in clinical trials; dosage is individualized and determined by titration based on cortisol levels and signs and symptoms • Max dose: 30 mg twice daily
Indications	Pituitary dependent hypercortisolism
Recorlev (levoketoconazole)	

Mechanism of Action	Inhibits key steps in the synthesis of cortisol and testosterone, principally those mediated by CYP11B1 (11-beta hydroxylase), CYP11A1 (the cholesterol side-chain cleavage enzyme, the first step in the conversation of cholesterol to pregnenolone) and CYP17A1 (17-apha-hydroxylase)
Dosing	Adult • Initial: 150 mg PO BID • Titration: May increase the dosage by 150 mg daily, no more frequently than every 2 to 3 weeks based on 24-hour urine free cortisol levels and patient tolerability • Max dose: 1,200 mg/day in divided doses
Indications	Cushing's syndrome
Signifor (pasireotide diaspartate)	
Mechanism of Action	Somatostatin receptor (SST) agonist that binds to four or five SST subtypes with substantially higher affinity for SST1 and SST5 than octreotide or lanreotide.
Dosing	Adult • Initial: 0.6 mg or 0.9 mg subQ twice daily; range, 0.3 mg to 0.9 mg subQ twice daily • Titrate based on response and tolerability
Indications	Pituitary dependent hypercortisolism, Pancreatic fistula, Postoperative; Prophylaxis
Signifor LAR (pasireotide diaspartate)	
Mechanism of Action	Somatostatin receptor (SST) agonist that binds to four or five SST subtypes with substantially higher affinity for SST1 and SST5 than octreotide or lanreotide.
Dosing	Adult • Initial: 10 mg IM once every 4 weeks (28 days) • Titration: May increase after 4 months up to MAX dose once every 28 days based on normalization of 24-hour urinary free cortisol and tolerability • Max dose: 40 mg IM every 4 weeks
Indications	Acromegaly, Cushing's syndrome
Dostinex (cabergoline)	
Mechanism of Action	Dopamine agonist with high affinity for the dopamine receptor subtype 2, which is expressed by most corticotroph adenomas
Dosing	Adult • Initial: 0.5 mg administered once or twice weekly • Titration: May increase by 0.5 to 1 mg/week every 1 to 2 months until urinary free cortisol levels normalize • Maintenance dose: 1 to 7 mg/week
Indications	Hyperprolactinemia, Acromegaly, Erectile dysfunction, Lactation suppression, Puerperal, Restless legs syndrome, Idiopathic
Korlym (mifepristone)	
Mechanism of Action	A glucocorticoid receptor (GR-II) antagonist and blocks the effects of cortisol
Dosing	Adult • Initial: 300 mg PO Qday taken with a meal • Titration: based on tolerability and clinical response, may increase in 300 mg increments (dose increase once every 2 to 4 weeks), up to the MAX dose • Max dose: 1,200 mg PO Qday but not exceeding 20 mg/kg/day

Indications	Hyperglycemia - Idiopathic Cushing's syndrome, Termination of pregnancy, Dilation of cervical canal, Emergency contraception, Endometriosis, Induction of labor, Miscarriage, Ovarian cancer, Refractory

Approval Status and Special Designations

Drugs@FDA: FDA-Approved Drugs
Fast Track, Breakthrough Therapy, Accelerated Approval, Priority Review | FDA
The Drug Development Process | FDA

Drug Name	Approval Letter Post Marketing Trial and Reporting Requirements
Nizoral (ketoconazole)	Originally approved on 06/12/1981 by NDA, Type 1 - New Molecular Entity, Priority
Metopirone	Originally approved on 2/04/1961 by NDA. Type 1 - New Molecular Entity, Priority, Orphan drug designation.
Lysodren	Originally approved on 07/08/1970 by NDA, Type 1 - New Molecular Entity, Priority
Isturisa	Approved on 03/06/2020 by NDA. Type 1 - New Molecular Entity, Standard, Orphan drug designation.
Recorlev	Approved on 12/30/2021 by 505(b)(2) NDA, Type 2 - New Active Ingredient, Standard, Orphan drug designation. 505(b)(2): an application that contains full reports of investigations of safety and effectiveness but where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference
Signifor	Approved on 12/14/2012 by NDA Type 1 - New Molecular Entity, Standard, Orphan drug designation.
Signifor LAR	Approved on 12/15/2014 by NDA. Type 5 - New Formulation or New Manufacturer, Standard, Orphan drug designation
Dostinex (cabergoline)	Approved on 12/23/1996 by NDA Type 1 - New Molecular Entity, Standard
Korlym	Approved on 02/17/2012 by 505(b)(2) NDA. Type 5 - New Formulation or New Manufacturer, Standard, Orphan drug designation. 505(b)(2): an application that contains full reports of investigations of safety and effectiveness but where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference

Therapeutically Important Adverse Effects/Advantages

Nizoral (ketoconazole)

- Generic option
- Not FDA approved for use in CS
- Quick onset of action
- Adverse effects: GI, male hypogonadism, N/V, hepatic death
- Black box warning: hepatotoxicity

Metopirone (metyrapone)

- Quick onset of action
- Controls hypercortisolemia in 50-75% of patients with CS.
- Adverse effects: GI, hirsutism, hypokalemia
- Can be used in combination with ketoconazole to rapidly lower cortisol levels in severe hypercortisolism

Lysodren (mitotane)

- Adrenolytic approved for adrenal cancer
- Does not cure CD as monotherapy
- Slow onset of action
- Teratogenic
- Adverse effects: GI, gynecomastia, low WBC
- Black box warning: adrenal crisis in the setting of shock or severe trauma

Isturisa (osilodrostat)

- FDA approved for use in CD
- Adverse effects: Hypertension, adrenal insufficiency, nausea, headache fatigue, edema

Recorlev (levoketoconazole)

- FDA approved for use in CS
- The pure 2S,4R enantiomer of ketoconazole
- Xeris Biopharma announced that this agent is commercially available through PANTHERx Rare Specialty Pharmacy
- Adverse effects: cardiac dysrhythmia, hypertension, peripheral edema, erythema, N/V
- Black box warning: hepatotoxicity and QT prolongation

Signifor (pasireotide diaspartate)

- FDA approved for use in CD
- SubQ injection
- Providers should correct hyperglycemia and hypomagnesemia prior to initiating this drug.
- Adverse effects: hyperglycemia, abdominal pain, diarrhea, headache, prolonged QT interval, cholelithiasis

Signifor LAR (pasireotide diaspartate)

- FDA approved for use in CD
- IM dosing
- Providers should correct hyperglycemia and hypomagnesemia prior to initiating this drug.
- Adverse effects: hyperglycemia, abdominal pain, diarrhea, headache, prolonged QT interval, cholelithiasis

Dostinex (cabergoline)

- Generic option
- 30-40% of patients responded and continued to have normal UFC levels after 2-3 years of treatment in small studies
- Adverse effects: constipation, dizziness, fatigue, congestive heart failure, pulmonary fibrosis

Korlym (mifepristone)

- FDA approved for use in CD
- Rapid onset of action
- Adverse effects: fatigue, N/V, headache, hypertension, hypokalemia, edema
- Black box warning: termination of pregnancy

Cost

Drug	Strength	Package Size	WAC Pkg Price	Cost/day*	Cost/month*	Cost/year*
Ketoconazole	200 mg	30 and 100 tabs each	$31.50	$2.10 - $8.40	$63 - $252	$756 - $3,024
Metyrapone	250 mg	18 caps each	$724.64	$80.52 - $966.19	$2,415.60 - $28,985.70	$28,987.20 - $347,828.40
Mitotane	500 mg	100 tabs each	$1,165.40	$11.65 - $186.46	$349.50 - $5,593.80	$4,194 - $67,125.60
Isturisa	1 mg, 5 mg, and 10 mg	20 and 60 tabs each	$2,643.80	$528.76 - $1,057.88	$15,862.80 - $31,736.40	$190,353.60 - $380,836.80
Recorlev	150 mg	50 tabs each	$13,500	$540 – $2,160	$16,200 - $64,800	$194,400 - $777,600
Signifor	0.3 mg/mL, 0.6 mg/mL, and 0.9 mg/mL	1 mL ampule	$244.17	$488.34	$14,650.20	$175,802.40
Signifor LAR	10 mg, 20 mg, 30 mg, 40 mg, and 60 mg	1 vial	$14,602.56	$486.75	$14,602.56	$175,230.72
cabergoline	0.5 mg	8 tabs each	$25.04	$0.42 - $43.82	$12.52 - $1,314.60	$150.24 - $15,775.20

Korlym	300 mg	28 and 280 tabs each	$16,156	$577 - $2,308	$17,310 - $69,240	$207,720 - $830,880

*Based on lowest per unit WAC cost

Current Utilization

ND Medicaid Utilization (04/01/2021 - 03/31/2022)

Label Name	**Rx Number**	**Total Reimbursement Amt**
Ketoconazole	10	$202.10
Metyrapone	0	0
Mitotane	0	0
Isturisa	0	0
Recorlev	0	0
Signifor	0	0
Signifor LAR	0	0
Cabergoline	84	$2,680
Korlym	0	0

Clinical Studies

Recorlev		
Trial Name	**LOGICS (NCT03277690)**	**SONICS (NCT01838551)**
Study Design	Open-label dose titration and maintenance phase (up to 19 weeks) followed by an 8-week double-blind, placebo-controlled, randomized withdrawal phase	Open-label, single-arm, multicenter study consisting of dose titration, maintenance, and extended evaluation phases, which totaled an estimated treatment duration of 73 weeks
Study Population	• Patients with persistent or recurrent disease despite surgery, previously medically treated patients, and previously untreated patients. • CD: 83% • Adrenal CS: 10% • Ectopic ACTH secretion: 2% • Unknown: 5% • Mean age: 45 years • 76% female	• Patients with persistent or recurrent disease despite surgery, previously medically treated patients, and previously untreated patients. • CD: 85% • Adrenal CS: 9% • Ectopic ACTH secretion: 1% • Unknown: 5% • Mean age: 44 years • 82% female
Interventions	• All patients started on Recorlev in dose titration and maintenance phase (14-19 weeks).	There were three treatment phases:

	• 39 patients from initial phase entered randomized withdrawal phase, and were randomized 1:1 to continue Recorlev or receive placebo for 2 months or until early rescue was necessary	1. Dose titration (2-21 weeks); patients entered maintenance phase once a therapeutic dose was achieved (n = 94) 2. 6-month maintenance phase 3. Extended evaluation for another 6 months
Primary Endpoint	Number of patients with loss of therapeutic response to Recorlev upon withdrawing to placebo compared with those who continued treatment	Proportion of patients with normalization of mUFC at the end of the 6-month maintenance phase, without an increase in dose at any time during maintenance (in the intention-to-treat population)
Secondary Endpoint	Proportion of patients with a mUFC normalization at the end of the randomized withdrawal phase	Proportion of patients with a mUFC normalization
Results	52.4% patients in the Recorlev group versus 5.6% in the placebo group met the secondary endpoint	30.9% patients met the primary endpoint

References:

1. Nieman, Lynnette K et al. "Treatment of Cushing's Syndrome: An Endocrine Society Clinical Practice Guideline." *The Journal of clinical endocrinology and metabolism* vol. 100,8 (2015): 2807-31. doi:10.1210/jc.2015-1818.
2. Nieman LK, Biller BM, Finding, JW, et al. The diagnosis of Cushing's syndrome: an Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. 2008;93:1526–1540. (17).
3. Product Information: NIZORAL(R) oral tablets, ketoconazole oral tablets. Janssen Pharmaceuticals, Inc (per FDA), Titusville, NJ, 2014.
4. Product Information: Metopirone(R) oral capsules, metyrapone oral capsules. Direct Success, Inc. (per manufacturer), Farmingdale, NJ, 2018.
5. Product Information: LYSODREN(R) oral tablets, mitotane oral tablets. Bristol-Myers Squibb Company (per FDA), Princeton, NJ, 2017.
6. Product Information: ISTURISA(R) oral tablets, osilodrostat oral tablets. Recordati Rare Disease Inc (per FDA), Lebanon, NJ, 2020.
7. Product Information: RECORLEV(R) oral tablets, levoketoconazole oral tablets. Xeris Pharmaceuticals Inc (per manufacturer), Chicago, IL, 2021.
8. Product Information: SIGNIFOR(R) subcutaneous injection, pasireotide subcutaneous injection. Novartis Pharmaceuticals Corporation (per FDA), East Hanover, NJ, 2020.
9. Product Information: SIGNIFOR(R) LAR intramuscular injection suspension, pasireotide intramuscular injection suspension. Recordati Rare Diseases Inc (per FDA), Lebanon, NJ, 2020.
10. Product Information: DOSTINEX(R) oral tablets, cabergoline oral tablets. Pharmacia & Upjohn Company (per FDA), New York, NY, 2019.
11. Product Information: KORLYM oral tablets, mifepristone oral tablets. Corcept Therapeutics Inc (per FDA), Menlo Park, CA, 2017.
12. *Cushing's Syndrome.* IPD Analytics. Aventura, FL, 2021. https://www.ipdanalytics.com.
13. NCT03277690. A Study to Assess the Safety and Efficacy of Levoketoconazole in the Treatment of Endogenous Cushing's Syndrome. Clinical Trials.gov. https://clinicaltrials.gov/ct2/show/NCT03277690.
14. NCT01838551. Treatment for Endogenous Cushing's Syndrome (SONICS). Clinical Trials.gov. https://clinicaltrials.gov/ct2/show/NCT01838551.

REVIEW OF PRESBYOPIA

Presbyopia is the inability to see up close and is caused by the inability of the crystalline lens of the eye to round and shape normally to allow for near vision. Presbyopia can result from normal aging and can begin around the age of 40. There are about 1.8 billion people with this disease state worldwide.

Place in Therapy/Guidelines

- Corrective lenses (most common treatment)
- Elective surgical procedures (e.g., excimer laser ablation, multifocal or accommodating IOL implantation, corneal inlays, or femtosecond laser intrastromal correction)
- Vuity is the first and only treatment currently FDA approved for presbyopia

General Dosing and FDA Indications

Vuity (pilocarpine hydrochloride)	
Mechanism of Action	Vuity is a parasympathomimetic that stimulates cholinergic receptors. It contracts the iris sphincter muscle which constricts the pupil to improve near and intermediate visual acuity.
Dosing	Instill 1 drop in each eye once daily
Indications	Presbyopia

Approval Status and Special Designations

Drugs@FDA: FDA-Approved Drugs
Fast Track, Breakthrough Therapy, Accelerated Approval, Priority Review | FDA
The Drug Development Process | FDA

Drug Name	Approval Letter Post Marketing Trial and Reporting Requirements
Vuity	Approved on 10/28/2021 by 505(b)(2) NDA Type 5 - New Formulation or New Manufacturer, Standard 505(b)(2): an application that contains full reports of investigations of safety and effectiveness but where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference

Therapeutically Important Adverse Effects/Advantages

Vuity

- Cosmetic? – can avoid use of corrective lenses
- Adverse effects: sweating, headache, conjunctival hyperemia, pulmonary edema, retinal detachment
- Several agents currently in the pipeline in Phase III and Phase II trials

Cost

Drug	Strength	Package Size	WAC Pkg Price	Cost/day*	Cost/month*	Cost/year*
Vuity	1.25%	2.5 mL	$73.49	$2.94	$88.19	$1,058.26

*Based on lowest per unit WAC cost

Current Utilization

ND Medicaid Utilization (04/01/2021 - 03/31/2022)

Label Name	Rx Number	Total Reimbursement Amt
Vuity	0	0

Clinical Studies

Vuity Trials		
Trial name	**GEMINI 1 (NCT03804268)**	**GEMINI 2 (NCT03857542)**
Study design	Multicenter, phase 3, randomized, double-masked, vehicle-controlled study	Multicenter, phase 3, randomized, double-masked, vehicle-controlled study
Interventions	Randomized 750 patients (1:1) to vehicle (placebo) or Vuity (pilocarpine 1.25%), administered once daily for 30 days	Randomized 750 patients (1:1) to vehicle (placebo) or Vuity (pilocarpine 1.25%), administered once daily for 30 days
Primary endpoint	The proportion of participants gaining ≥ 3 lines from baseline in mesopic, high-contrast, binocular distance-corrected near visual acuity (DCNVA) at day 30, hour 3	The proportion of participants gaining ≥ 3 lines from baseline in mesopic, high-contrast, binocular DCNVA without losing >5 letters of mesopic, high-contrast, binocular corrected distance visual acuity (CDVA) with the same refractive correction at day 30, hour 3
Secondary endpoints	• Key secondary endpoint: The proportion of patients with ≥ 3-line improvement in mesopic DCNVA at hour 6, day 30 • Change from baseline in mesopic, high-contrast, binocular DCNVA letter at day 30, hours 0.25 and 0.5. • Proportion of participants achieving 20/40 or better in photopic DCNVA at day 30, hours 1 and 3 • Change from baseline in photopic, high-contrast, binocular distance corrected intermediate visual acuity (DCIVA) letters at day 30, hour 3	
Results	Statistically significant for the primary and key secondary endpoint	Statistically significant for all endpoints. No treatment-emergent serious adverse events were observed. The most common treatment-emergent non-serious adverse events occurring at a frequency of ≥3% in

		AGN-190584 treated participants were headache, conjunctival hyperemia, vision blurred, and eye pain.

References:

1. Vuity (pilocarpine hydrochloride) [prescribing information]. North Chicago, IL: AbbVie Inc; October 2021.[PubMed 8100087]
2. Waring, G., Price, F., et al. Safety and Efficacy of AGN-190584 in Individuals with Presbyopia: The GEMINI 1 Phase 3 Randomized Clinical Trial. JAMA Ophthalmol. doi:10.1001/jamaophthalmol.2022.0059. Published online March 3, 2022.
3. *Presbyopia*. IPD Analytics. Aventura, FL, 2021. https://www.ipdanalytics.com.

REVIEW OF VERNAL KERATOCONJUNCTIVITIS

Vernal keratoconjunctivitis (VKC) is a type of allergic response that takes place in the eyes. It appears to occur mostly in male adolescence who live in warm, dry climates, and it typically resolves during puberty. The cause of this response is unknown, but IgE hypersensitivity and T helper cell type-2 mediated responses are hypothesized to be involved. Symptoms that accompany vernal keratoconjunctivitis include photophobia, itching, stringy mucous discharge, Horner-Trantas dots, etc. This response has been found to occur in about 0.03% of the European population. Without treatment, symptoms can become severe enough to lead to corneal ulcers and vision loss.

Place in Therapy/Guidelines

- Treatment is similar to treatment for allergic conjunctivitis; may require ophthalmic corticosteroids or calcineurin inhibitor, however.

Treatment Guide	
Initial therapy	• Topical ophthalmic antihistamine with mast cell stabilizing properties (e.g., olopatadine, azelastine) (Considered off-label)
Add-on therapy	• Topical mast cell stabilizers (e.g., cromolyn, nedocromil) • Systemic antihistamines for more severe cases
Dx refractory to antihistamines/mast cell stabilizers	• Topical corticosteroids • Cyclosporine

- Verkazia is the first and only FDA-approved agent for VKC
- However, Restasis (cyclosporine 0.05% emulsion) is recognized in some compendia for treatment of VKC. The off-label use is a result of several clinical trials that evaluated Restasis in patients with VKC.
- Cequa (cyclosporine 0.09% ophthalmic solution), is not recognized as an off-label treatment due to lack of clinical studies to support its use for this indication.

General Dosing and FDA Indications

Verkazia	
Mechanism of Action	Inhibits T-cell activation and reduces the immune reaction that causes inflammation of the ocular surface VKC
Dosing	Adult, Pediatric ≥4 years of age, and adolescents Instill 1 drop into each affected eye 4 times per day, may discontinue after resolution of signs and symptoms
Indications	Vernal keratoconjunctivitis

Approval Status and Special Designations

Drugs@FDA: FDA-Approved Drugs
Fast Track, Breakthrough Therapy, Accelerated Approval, Priority Review | FDA
The Drug Development Process | FDA

Drug Name	Approval Letter Post Marketing Trial and Reporting Requirements
Verkazia	Approved on 06/23/2021 by 505(b)(2) NDA Type 5 - New Formulation or New Manufacturer, Standard, Orphan drug designation 505(b)(2): an application that contains full reports of investigations of safety and effectiveness but where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference

Therapeutically Important Adverse Effects/Advantages

Verkazia

- Only FDA approved agent for VKC
- Adverse effects: eye pain, eye pruritis, visual acuity reduced, cough, headache

Cost

Drug	Strength	Package Size	WAC Pkg Price	Cost/day*	Cost/month*	Cost/year*
Verkazia	0.1%	120 each	$1,464.96	$48.83	$1,464.96	$17,579.52

*Based on lowest per unit WAC cost

Current Utilization

ND Medicaid Utilization (04/01/2021 - 03/31/2022)

Label Name	Rx Number	Total Reimbursement Amt
Verkazia	0	0

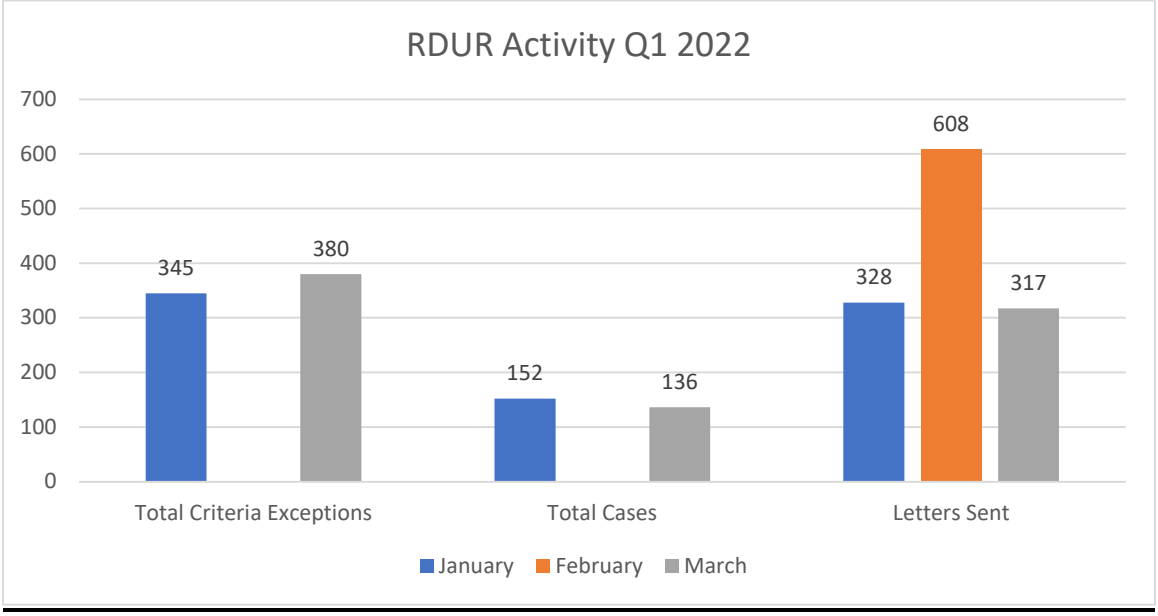
Clinical Studies

Verkazia Trials			
Trial Name		**VEKTIS (NCT01751126)**	**NOVATIVE (NCT00328653)**
Study Design		Randomized multicenter, double-blind, vehicle-controlled clinical trials	Randomized multicenter, double-blind, vehicle-controlled clinical trials
Demographics		Age: 4-17 years 79% male	Age: 4-21 years 81% male
Intervention	**Period 1**	168 patients with severe VKC were randomized to Verkazia QID, BID, or vehicle for 4 months	118 patients with moderate to severe VKC were randomized to Verkazia 1mg/mL QID, cyclosporin ophthalmic emulsion 0.5 mg/mL QID, or vehicle for the first 1 month
	Period 2	Patients were randomized to the vehicle group were switched to Verkazia (QID or BID) from month 4 to month 12	Patients randomized to the vehicle group were switched to cyclosporine ophthalmic emulsion 0.5 mg/mL or 1 mg/mL QID month 1 to month 4
Results		Statistically significant for both the high dose (P = 0.007) and the low dose (P = 0.010) groups. Treatment effect mainly driven by corneal fluorescein staining (CFS) score	Verkazia demonstrated improvements in inflammation or the cornea (keratitis score) and ocular itching
Adverse reactions		Eye pain (12%), eye pruritus (8%), which usually occurred during instillation	

References:

1. *Ophthalmology*. 2019 May;126(5):671-681. doi: 10.1016/j.ophtha.2018.12.027.
2. Verkazia (cyclosporine) [prescribing information]. Emeryville, CA: Santen Incorporated; June 2021.
3. *Vernal keratoconjunctivitis.* IPD Analytics. Aventura, FL, 2021. https://www.ipdanalytics.com.

RDUR Activity Overview: Q1 2022



January Cases by Type of Criteria

Criteria Description	# of Cases	% of Cases
ATOMOXETINE BLACK BOX WARNING	1	0.66%
NON-SELECTIVE BETA BLOCKERS IN DIABETES	5	3.29%
DPP-4 INHIBITOR AND ARTHRALGIA	1	0.66%
CLOBETASOL TOPICALS IN PEDIATRIC PATIENTS	1	0.66%
ADVERSE METABOLIC EFFECTS WITH ATYPICAL ANTIPSYCHOTICS	9	5.92%
ADVERSE METABOLIC EFFECTS WITH ATYPICAL NEUROLEPTICS	1	0.66%
*INAPPROPRIATE USE	47	30.92%
DRUG INTERACTIONS WITH LEVOMILNACIPRAN	1	0.66%
ASCVD INFERRING DRUGS	12	7.89%
CHOLESTEROL CONTROL IN MEMBERS WITH DM	42	27.63%
CHOLESTEROL CONTROL IN MEMBERS WITH DM AND FAMILY HISTORY OF ASCVD	28	18.42%
DEPRESSION/SUICIDALITY AND SUVOREXANT USE	1	0.66%
OPIOID-CONTAINING MEDICATION USE IN PEDIATRIC PATIENTS	3	1.97%

*INAPPROPRIATE USE: TENOFOVIR DISOPROXIL, TRUVADA, LIDODERM, PPI DURATION, LOVAZA, DOLUTEGRAVIR, PAROXETINE IN PEDIATRIC PATIENTS

February Special Mailing

Primary Therapeutic Consideration

According to the montelukast package insert, serious neuropsychiatric events have been reported in adult, adolescent, and pediatric patients. These events include agitation, aggressive behavior, depression, hallucinations, and suicidal thoughts and actions. These events have been highly variable in frequency and severity, and in some cases, they have taken place once the medication was discontinued. It is currently unknown what mechanisms are causing the neuropsychiatric events.

Although it is imperative to be more cautious in patients who already have a history of psychiatric disorder, reports have found that patients without a history of psychiatric disorder have experienced serious psychiatric events, as well.

Prescribing montelukast should be done on a case-by-case basis in which the risks and benefits are both assessed. In patients with mild symptoms, an alternative agent may be appropriate to adequately treat the patient. In more severe cases in which alternative therapies have been inadequate or the patient has intolerances/contraindications, montelukast may be the only option. Currently, it is suggested to reserve montelukast for patients with allergic rhinitis who have had an inadequate response/intolerance to other therapies.

For members who benefit from montelukast, consider advising members and their caregivers to look for behavioral changes while on therapy and when discontinuing therapy. If changes are observed, advise them to notify you immediately.

Product Information: SINGULAIR(R) oral tablets, oral chewable tablets, oral granules, montelukast sodium oral tablets, oral chewable tablets, oral granules. Merck Sharp & Dohme Corp (per manufacturer), Whitehouse Station, NJ, 2020.

PRESCRIBER RESPONSE: *Please fax it to 701-328-1544 when completed.*
NPI 1659582260 SEQ# 62

All information used to generate the enclosed letter, including Prescriber identification, was obtained from Pharmacy Claims Data. If there appears to be an error in the information provided, please note the discrepancy. Thank you for your cooperation.

1. This patient **is** under my care:

_____ I have reviewed the information and will continue without change.
_____ however, I did not prescribe the following medication(s)_____.
_____ and has an appointment to discuss drug therapy.
_____ however, has not seen me recently.
_____ however, I was not aware of other prescribers.
_____ I have reviewed the information and modified drug therapy.
_____ I have not modified drug therapy because benefits outweigh the risks.
_____ I have tried to modify therapy, however the patient refuses to change.
_____ I have tried to modify therapy, however symptoms reoccurred.

2. This patient **is not** under my care:
_____ however, I did prescribe medication while covering for other MD or in the ER.
_____ but has previously been a patient of mine.
_____ because the patient recently expired.
_____ and has never been under my care.

3. I have reviewed the enclosed information and found it:
_____ very useful_____ useful_____ neutral_____ somewhat useful_____ not useful.

4. Please check here if you wish to receive reference information on the identified problem___. (Please provide a fax number if available_____-_____-_____.)

Comments:
_____
_____
_____

March Cases by Type of Criteria

Criteria Description	# of Cases	% of Cases
LITHIUM USE IN RENAL IMPAIREMENT/FAILURE	11	8.09%
RESPIRATORY DEPRESSION WITH CNS DEPRESSANTS	30	22.1%
CHF AND NSAID USE	8	5.89%
INAPPROPRIATE BENZODIAZEPINE USE	8	5.89%
NSAID INTERACTIONS	11	8.09%
*OVERUTILIZATION	17	12.5%
CIRRHOSIS AND TRAMADOL IR USE	5	3.68%
TRICYCLIC ANTIDEPRESSANTS AND GLAUCOMA	1	0.74%
VALPROIC ACID AND HEPATIC IMPAIRMENT	1	0.74%
NON-SELECTIVE BETA BLOCKER AND PULMONARY DISORDER	1	0.74%
**THERAPEUTIC DUPLICATION	27	19.85%
ANTIDIABETIC MEDICATION WITH NO INSULIN	3	2.21%
CANAGLIFLOZIN AND RISK OF LOWER LIMB AMPUTATION	6	4.41%
BEERS CRITERIA - TRAMADOL	2	1.47%
VITAMIN B12 DEFICIENCY WITH METFORMIN USE	4	2.94%
INAPPROPRIATE STIRIPENTOL REGIMEN	1	0.74%

*OVERUTILIZATION: TIZANIDINE, SALMETEROL, ANTICONVULSANTS

**THERAPEUTIC DUPLICATION: ANTIHISTAMINES, THIAZIDE DIURETICS, ANTICHOLINERGIC BRONCHDILATORS, ANTIPSYCHOTICS, ANTICHOLINGERGICS, ANTICOAGULANTS

January RDUR Response Rate		
Prescriber	No response	162
	Benefits of the drug outweigh the risks	5
	Pt is no longer under this MD's care	2
	MD will reassess and modify drug therapy	3
	MD tried to modify therapy, pt non-cooperative	1
	Pt under my care but not seen recently	3
	Patient was never under MD care	1
	MD did not prescribe drug attributed to him/her	1
	MD saw patient only once in ER or as on-call MD	1
	Pharmacy can't provide MD information	1
Pharmacy	No response	129
	MD saw pt only once in the ER or as on-call MD	1
	Pharmacy can't provide MD information	1
	RPh will counsel pt on next visit	4
	Pt no longer uses pharmacy	1
	Spoke to MD, expect modification in therapy	7
	Benefit outweighs risk, no change recommended	11
	No change recommended, problem insignificant	3
	RPh disagrees, no further action taken	5
	RPh disagrees, but counselled pt	2
	RPh disagrees, but has conferred with MD	1

February Special Mailing Response Rate		
Prescriber	No response	534
	Pt is continuing drug without a problem	13
	Benefits outweigh the risk	5
	Pt is no longer under this MD's care	4
	MD feels problem is insignificant, no change	30
	MD tried to modify therapy, pt non-responsive	1
	Have not seen pt recently	5
	Pt deceased	1
	Pt never under this MD's care	3
	Pt has appt to discuss drug therapy	5
	Tried to modify therapy, symptoms recurred	1
	MD saw pt only once in ER or as on-call MD	6

March RDUR Response Rate		
Prescriber	No response	167
	Benefits of the drug outweigh the risks	8
	MD tried to modify therapy, pt non-cooperative	2
	Pt was never under MD care	1
	MD saw patient only once in ER or as on-call MD	1
	Tried to modify therapy, symptoms recurred	1
Pharmacy	No response	121
	RPh discussed under/overuse with pt	2
	Patient deceased	1
	Counselled pt, non-compliance continues	2
	RPh will counsel pt on next visit	7
	Pt no longer uses pharmacy	2
	Spoke to MD, expect modification in therapy	2
	Benefit outweighs risk, no change recommended	3
	No change recommended, problem insignificant	2
	RPh disagrees, no further action taken	4

NORTH DAKOTA MEDICAID
RETROSPECTIVE DRUG UTILIZATION REVIEW
CRITERIA RECOMMENDATIONS
2ND QUARTER 2022

Criteria Recommendations ***Approved Rejected***

1. Glycopyrrolate ODT / Overuse _____ _____
Alert Message: Dartisla ODT (glycopyrrolate orally disintegrating tablets) may be over-utilized. The maximum recommended daily dose of orally disintegrating glycopyrrolate is 6.8 mg.

Drugs/Diseases

Util A	Util B	Util C
Glycopyrrolate ODT		

Max Dose: 6.8 mg/day

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Dartisla ODT Prescribing Information, Dec. 2021, Edenbridge Pharmaceuticals, LLC.

2. Glycopyrrolate ODT / Therapeutic Appropriateness _____ _____
Alert Message: The safety and effectiveness of Dartisla ODT (glycopyrrolate orally disintegrating tablets) in pediatric patients have not been established.

Drugs/Diseases

Util A	Util B	Util C
Glycopyrrolate ODT		

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Dartisla ODT Prescribing Information, Dec. 2021, Edenbridge Pharmaceuticals, LLC.

3. Glycopyrrolate ODT / Therapeutic Appropriateness _____ _____
Alert Message: Dartisla ODT (glycopyrrolate orally disintegrating tablets) is indicated in adults to reduce symptoms of a peptic ulcer as an adjunct to treatment of peptic ulcer. Glycopyrrolate is not indicated as monotherapy for treatment of peptic ulcer because effectiveness in peptic ulcer healing has not been established.

Drugs/Diseases

Util A	Util B	Util C (Negating)
Glycopyrrolate ODT		H2 Antagonists
		Methscopolamine
		Misoprostol
		Propantheline
		Proton Pump Inhibitors

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Facts & Comparisons, 2022 Updates, Wolters Kluwer Health.
Dartisla ODT Prescribing Information, Dec. 2021, Edenbridge Pharmaceuticals, LLC.

Criteria Recommendations ***Approved Rejected***

4. Glycopyrrolate ODT / Contraindications _____ _____

Alert Message: Dartisla ODT (glycopyrrolate orally disintegrating tablets) is an anticholinergic agent and its use is contraindicated in patients at risk for anticholinergic toxicity due to an underlying medication condition, including; glaucoma obstructive uropathies, mechanical obstructive disease of gastrointestinal tract, gastrointestinal motility disorders, bleeding gastrointestinal ulcer, active inflammatory or infectious colitis which can lead to toxic megacolon, history of or current toxic megacolon, and myasthenia gravis.

Drugs/Diseases

Util A	Util B	Util C
Glycopyrrolate ODT	Glaucoma	
	Prostatic Hypertrophy	
	Pyloroduodenal Stenosis	
	Pyloroduodenal Strictures	
	Achalasia	
	Paralytic Ileus	
	Intestinal Atony	
	Bleeding Gastrointestinal Ulcer	
	Inflammatory/Infectious Colitis	
	Toxic Megacolon	
	Myasthenia Gravis	

References:

Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Dartisla ODT Prescribing Information, Dec. 2021, Edenbridge Pharmaceuticals, LLC.

5. Glycopyrrolate ODT / Anticholinergics _____ _____

Alert Message: There is potential for an additive interaction between Dartisla ODT (glycopyrrolate orally disintegrating tablets) and concomitantly used anticholinergic drugs (e.g., tricyclic antidepressants, anti-epileptics, class I antiarrhythmics, antispasmodics, and amantadine), resulting in increased anticholinergic adverse reactions. Coadministration of antipsychotics with glycopyrrolate may lead to worsening of tardive dyskinesia. Glycopyrrolate is not recommended in patients taking another anticholinergic drug.

Drugs/Diseases

Util A	Util B	Util C
Glycopyrrolate ODT	Anticholinergics	

References:

Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Dartisla ODT Prescribing Information, Dec. 2021, Edenbridge Pharmaceuticals, LLC.

6. Glycopyrrolate ODT / Potassium Chloride _____ _____

Alert Message: Dartisla ODT (glycopyrrolate orally disintegrating tablets) is not recommended in patients taking solid oral dosage forms of potassium chloride. Oral glycopyrrolate may worsen gastrointestinal mucosal injury reported with solid oral dosage forms of potassium chloride due to decreased gastric motility and increased transit time, leading to prolonged contact with the gastrointestinal mucosa.

Drugs/Diseases

Util A	Util B	Util C
Glycopyrrolate ODT	Potassium Chloride	

References:

Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Dartisla ODT Prescribing Information, Dec. 2021, Edenbridge Pharmaceuticals, LLC.

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

7. Glycopyrrolate ODT / Renal Impairment _____ _____

Alert Message: Dartisla ODT (glycopyrrolate orally disintegrating tablets) is substantially excreted by the kidney and should be used with caution in patients with renal impairment. Monitor patients with renal impairment for anticholinergic adverse reactions. If anticholinergic adverse reactions occur, discontinue glycopyrrolate.

Drugs/Diseases

Util A	Util B	Util C
Glycopyrrolate ODT	Renal Impairment	

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Facts & Comparisons, 2022 Updates, Wolters Kluwer Health.
Dartisla ODT Prescribing Information, Dec. 2021, Edenbridge Pharmaceuticals, LLC.

8. Glycopyrrolate ODT / Lactation _____ _____

Alert Message: There are no data on the presence of glycopyrrolate in either human or animal milk, the effects on the breastfed infant, or the effects on milk production. As with other anticholinergic drugs, glycopyrrolate may cause suppression of lactation. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Dartisla ODT (glycopyrrolate orally disintegrating tablets) and any potential adverse effects on the breastfed infant from glycopyrrolate.

Drugs/Diseases

Util A	Util B	Util C
Glycopyrrolate ODT	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Facts & Comparisons, 2022 Updates, Wolters Kluwer Health.
Dartisla ODT Prescribing Information, Dec. 2021, Edenbridge Pharmaceuticals, LLC.

9. Budesonide ER Caps / Overuse _____ _____

Alert Message: Tarpeyo (budesonide delayed-release) may be over-utilized. The recommended maximum maintenance dose of delayed-release budesonide in adults is 16 mg once daily. The recommended duration of therapy is 9 months.

Drugs/Diseases

Util A	Util B	Util C
Budesonide ER		

Max Dose: 16 mg/day

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Tarpeyo Prescribing Information, Dec. 2021, Calliditas Therapeutics.

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

10. Budesonide ER / Therapeutic Appropriateness _____ _____

Alert Message: The safety and efficacy of Tarpeyo (budesonide delayed-release) in pediatric patients have not been established.

Drugs/Diseases

Util A	Util B	Util C
Budesonide ER		

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Tarpeyo Prescribing Information, Dec. 2021, Calliditas Therapeutics.

11. Budesonide ER / Therapeutic Appropriateness – Hepatic Impairment _____ _____

Alert Message: Tarpeyo (budesonide delayed-release) is a corticosteroid. When corticosteroids are used chronically, systemic effects such as hypercorticism and adrenal suppression may occur. The use of budesonide delayed-release should be avoided in patients with severe hepatic impairment (Child-Pugh Class C). Patients with moderate hepatic impairment (Child-Pugh Class B) could also be at an increased risk of hypercorticism and adrenal axis suppression due to increased systemic exposure of budesonide. Monitor for increased signs and/or symptoms of hypercorticism in patients with moderate hepatic impairment (Child-Pugh Class B).

Drugs/Diseases

Util A	Util B	Util C (Required)
Budesonide ER		Hepatic Impairment

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Tarpeyo Prescribing Information, Dec. 2021, Calliditas Therapeutics.

12. Budesonide ER / Strong CYP3A4 Inhibitors _____ _____

Alert Message: Tarpeyo (budesonide delayed-release) is a substrate for CYP3A4, and concurrent use with potent CYP3A4 inhibitors should be avoided. Concomitant use of strong 3A4 inhibitors and budesonide may result in elevated budesonide concentrations and an increased risk of budesonide-related adverse effects.

Drugs/Diseases

Util A	Util B		Util C
Budesonide ER	Clarithromycin	Nelfinavir	
	Cobicistat	Posaconazole	
	Indinavir	Ritonavir	
	Itraconazole	Saquinavir	
	Ketoconazole	Voriconazole	
	Nefazodone		

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Tarpeyo Prescribing Information, Dec. 2021, Calliditas Therapeutics.

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

13. Budesonide ER / Therapeutic Appropriateness _____ _____

Alert Message: Tarpeyo (budesonide delayed-release) is a systemically available corticosteroid and corticosteroid pharmacologic actions can exacerbate certain conditions. Monitor patients with hypertension, prediabetes, diabetes mellitus, osteoporosis, peptic ulcer, glaucoma or cataracts, or a family history of diabetes or glaucoma, or any other condition where corticosteroids may have unwanted effects.

Drugs/Diseases

Util A	Util B	Util C
Budesonide ER	Hypertension	
	Diabetes	
	Osteoporosis	
	Peptic Ulcer	
	Glaucoma	
	Cataracts	
	Family History of Diabetes	
	Family History of Glaucoma	

References:

Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Tarpeyo Prescribing Information, Dec. 2021, Calliditas Therapeutics.

14. Celecoxib/Tramadol / Overuse _____ _____

Alert Message: Seglentis (celecoxib/tramadol) may be over-utilized. The recommended dosage of celecoxib/tramadol is two tablets every 12 hours as needed for pain (total: 224 mg celecoxib/176 mg tramadol).

Drugs/Diseases

Util A	Util B	Util C
Celecoxib/Tramadol		

Max Dose: 224 mg/176 mg per day

References:

Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Seglentis Prescribing information, October 2021, Kowa Pharmaceuticals America, Inc.

15. Celecoxib/Tramadol / Other Celebrex or Tramadol Products _____ _____

Alert Message: Seglentis (celecoxib/tramadol) should not be co-administered with other tramadol or celecoxib-containing products. Duplication of therapy may increase the risk of adverse effects.

Drugs/Diseases

Util A	Util B	Util C
Celecoxib/Tramadol	Celebrex	
	Tramadol	

References:

Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Seglentis Prescribing information, October 2021, Kowa Pharmaceuticals America, Inc.

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

16. Upadacitinib / Therapeutic Appropriateness _____ _____

Alert Message: The safety and effectiveness of Rinvoq (upadacitinib) in pediatric patients less than 12 years of age with atopic dermatitis have not been established.

Drugs/Diseases

Util A	Util B	Util C (Required)
Upadacitinib		Atopic Dermatitis

Age Range: 0 – 11 yoa

References:

Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Rinvoq Prescribing Information, Jan. 2022, AbbVie Inc.

17. Upadacitinib 30 mg / Atopic Dermatitis / Severe Renal Impairment _____ _____

Alert Message: For patients with atopic dermatitis and severe renal impairment (CrCL < 30 mL/min), the maximum recommended dosage of Rinvoq (upadacitinib) is 15 mg once daily. No dosage adjustment is needed in patients with mild or moderate renal impairment. The use of upadacitinib has not been studied in patients with end-stage renal disease, and therefore, is not recommended for use in this population.

Drugs/Diseases

Util A	Util B	Util C (Required)
Upadacitinib 30mg	Atopic Dermatitis	CKD Stage 4 CKD Stage 5 ESRD

References:

Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Rinvoq Prescribing Information, Jan. 2022, AbbVie Inc.

18. Diazepam Nasal / Therapeutic Appropriateness _____ _____

Alert Message: The safety and effectiveness of Valtoco (diazepam nasal spray) in pediatric patients below the age of 6 have not been established.

Drugs/Diseases

Util A	Util B	Util C
Diazepam Nasal		

Age Range: 0 - 5 yoa

References:

Clinical Pharmacology, 2022 Elsevier/Gold Standard.

Valtoco Prescribing Information, Feb. 2022, Neurelis, Inc.

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

19. Diazepam Nasal Spray / Glaucoma _____ _____

Alert Message: Benzodiazepines, including Valtoco (diazepam nasal spray), can increase intraocular pressure in patients with glaucoma. Diazepam nasal spray is contraindicated in patients with narrow-angle glaucoma. Diazepam may be used in patients with open-angle glaucoma only if they are receiving appropriate therapy.

Drugs/Diseases

Util A	Util B	Util C
Diazepam Nasal	Narrow Angle Glaucoma	

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Valtoco Prescribing Information, Feb. 2022, Neurelis, Inc.

20. Diazepam Nasal Spray / Infants _____ _____

Alert Message: Valtoco (diazepam nasal spray) is not approved for use in neonates or infants. Serious and fatal adverse reactions, including "gasping syndrome", can occur in neonates and low birth weight infants treated with benzyl alcohol-preserved drugs, including diazepam nasal spray. The "gasping syndrome" is characterized by central nervous system depression, metabolic acidosis, and gasping respirations. The minimum amount of benzyl alcohol at which serious adverse reactions may occur is not known (diazepam nasal spray contains 10.5 mg of benzyl alcohol per 0.1 mL.

Drugs/Diseases

Util A	Util B	Util C
Diazepam Nasal		

Age Range: 0 - 1 yoa

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Valtoco Prescribing Information, Feb. 2022, Neurelis, Inc.

21. Diazepam Nasal Spray / Pregnancy / Pregnancy Negating _____ _____

Alert Message: There are no adequate data on the use of Valtoco (diazepam nasal spray) in pregnant patients. There are clinical considerations regarding exposure to benzodiazepines during the second and third trimesters of pregnancy or immediately prior to or during childbirth. These risks include decreased fetal movement and/or fetal heart rate variability, floppy infant syndrome, dependence, and withdrawal. Advise pregnant patients and patients of childbearing age of the potential risk to a fetus.

Drugs/Diseases

Util A	Util B	Util C (Negating)
Diazepam Nasal	Pregnancy	Abortion
		Delivery
		Miscarriage

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Valtoco Prescribing Information, Feb. 2022, Neurelis, Inc.

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

22. Diazepam Nasal Spray / Therapeutic Appropriateness _____ _____

Alert Message: Diazepam is excreted in human milk. There are no data to assess the effects of Valtoco (diazepam nasal spray) and/or its active metabolite(s) on the breastfed infant or milk production. Postmarketing experience suggests that breastfed infants of mothers taking benzodiazepines, such as diazepam nasal, may have effects of lethargy, somnolence, and poor sucking. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for diazepam nasal spray and any potential adverse effects on the breastfed infant from diazepam nasal spray or the underlying maternal condition.

Drugs/Diseases

Util A	Util B	Util C
Diazepam Nasal	Lactation	

Gender: Female

Age Range: 11 – 50 yoa

References:

Clinical Pharmacology, 2022 Elsevier/Gold Standard.

Valtoco Prescribing Information, Feb. 2022, Neurelis, Inc.

23. Tazemetostat / Overuse _____ _____ Alert Message:
Tazverik (tazemetostat) may be over-utilized. The dosage of tazemetostat is 800 mg orally twice daily with or without food until disease progression or unacceptable toxicity.

Drugs/Disease

Util A	Util B	Util C
Tazemetostat		

Max Dose: 1600 mg/day

Reference:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Tazverik Prescribing Information, July 2020, Epizyme, Inc.

24. Tazemetostat / Therapeutic Appropriateness _____ _____
Alert Message: The safety and effectiveness of Tazverik (tazemetostat) in pediatric patients less than 16 years of age have not been established.

Drugs/Disease

Util A	Util B	Util C
Tazemetostat		

Age Range: 0-15 yoa

Reference:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Tazverik Prescribing Information, July 2020, Epizyme, Inc.

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

25. Tazemetostat / Contraceptives _____ _____

Alert Message: The concurrent use of Tazverik (tazemetostat) with estrogen-containing contraceptives can result in decreased contraceptive plasma concentrations and reduced contraceptive efficacy. Tazemetostat is a weak CYP3 inducer, and estrogens are CYP3A substrates.

Drugs/Disease

Util A	Util B	Util C
Tazemetostat	Contraceptives	

Reference:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Tazverik Prescribing Information, July 2020, Epizyme, Inc.

26. Tazemetostat / Strong or Moderate CYP3A Inhibitors _____ _____

Alert Message: The coadministration of Tazverik (tazemetostat) with strong or moderate CYP3A inhibitors should be avoided. Tazemetostat is a CYP3A substrate, and concurrent use with a CYP3A4 inhibitor can result in elevated tazemetostat concentrations, which may increase the frequency or severity of tazemetostat-related adverse reactions. If coadministration with a moderate CYP3A inhibitor cannot be avoided, reduce the tazemetostat dose according to the official prescribing information. After discontinuation of the moderate CYP3A inhibitor for 3 elimination half-lives, resume the tazemetostat dose that was taken prior to initiating the inhibitor.

Drugs/Disease

Util A	Util B		Util C
Tazemetostat	Atazanavir	Fosamprenavir	
	Aprepitant	Idelalisib	
	Cimetidine	Indinavir	
	Ciprofloxacin	Itraconazole	
	Clarithromycin	Ketoconazole	
	Clotrimazole	Nefazodone	
	Cobicistat	Nelfinavir	
	Crizotinib	Posaconazole	
	Cyclosporine	Ritonavir	
	Diltiazem	Saquinavir	
	Dronedarone	Tipranavir	
	Erythromycin	Verapamil	
	Fluconazole	Voriconazole	
	Fluvoxamine		

Reference:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Tazverik Prescribing Information, July 2020, Epizyme, Inc.

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

27. Tazemetostat / Strong or Moderate CYP3A Inducers _____ _____

Alert Message: The coadministration of Tazverik (tazemetostat) with strong or moderate CYP3A inducers should be avoided. Tazemetostat is a CYP3A substrate, and concurrent use with a CYP3A4 inducer can result in decreased tazemetostat concentrations and potential loss of tazemetostat efficacy.

Drugs/Disease

Util A	Util B	Util C
Tazemetostat	Apalutamide	
	Bosentan	
	Butalbital	
	Carbamazepine	
	Efavirenz	
	Enzalutamide	
	Etravirine	
	Mitotane	
	Phenobarbital	
	Phenytoin	
	Primidone	
	Rifabutin	
	Rifampin	
	Rifapentine	

Reference:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Tazverik Prescribing Information, July 2020, Epizyme, Inc.

28. Tazemetostat / Pregnancy / Pregnancy Negating _____ _____

Alert Message: Based on findings from animal studies and its mechanism of action, Tazverik (tazemetostat) can cause fetal harm when administered to a pregnant patient. There are no available data on tazemetostat use in pregnant patients to inform the drug-associated risk. Administration of tazemetostat to pregnant rats and rabbits during organogenesis resulted in dose-dependent increases in skeletal developmental abnormalities in both species. Advise pregnant patients of the potential risk to a fetus.

Drugs/Diseases

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

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Tazverik Prescribing Information, July 2020, Epizyme, Inc.

Criteria Recommendations ***Approved Rejected***

29. Tazemetostat / Lactation _____ _____
Alert Message: There are no animal or human data on the presence of Tazverik (tazemetostat) in human milk or its effects on the breastfed child or milk production. Because of the potential risk for serious adverse reactions from tazemetostat in the breastfed child, advise patients not to breastfeed during treatment with tazemetostat and for one week after the final dose.

Drugs/Diseases

Util A	Util B	Util C
Tazemetostat	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Tazverik Prescribing Information, July 2020, Epizyme, Inc.

30. Tazemetostat / Therapeutic Appropriateness _____ _____ Alert Message:
Advise females of reproductive potential to use effective non-hormonal contraception during treatment with Tazverik (tazemetostat) and for 6 months after the final dose. Tazemetostat can cause fetal harm when administered to pregnant women.

Drugs/Disease

Util A	Util B	Util C (Negating)
Tazemetostat		Non-Hormonal Contraceptives

Gender: Female
Age Range: 11 – 50 yoa

Reference:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Tazverik Prescribing Information, July 2020, Epizyme, Inc.

31. Tazemetostat / Therapeutic Appropriateness _____ _____ Alert Message:
Advise males with female partners of reproductive potential to use effective contraception during treatment with Tazverik (tazemetostat) and for at least 3 months after the final dose.

Drugs/Disease

Util A	Util B	Util C
Tazemetostat		

Gender: Male

Reference:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Tazverik Prescribing Information, July 2020, Epizyme, Inc.

Criteria Recommendations ***Approved Rejected***

32. Tazemetostat / Non-adherence _____ _____
Alert Message: Based on refill history, your patient may be under-utilizing Tazverik (tazemetostat). Nonadherence to the prescribed dosing regimen may result in sub-therapeutic effects, which may lead to decreased outcomes and additional healthcare costs.

Drugs/Diseases
Util A Util B Util C
Tazemetostat

References:
Osterberg L, Blaschke T. Adherence to Medication. N Engl J Med. 2005;353:487-97.
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.

33. Finerenone / Overuse _____ _____
Alert Message: Kerendia (finerenone) may be over-utilized. The recommended maintenance finerenone dose is 202 mg once daily.

Drugs/Diseases
Util A Util B Util C
Finerenone

Max Dose: 20 mg/day

References:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Kerendia Prescribing Information, July 2021, Bayer HealthCare Pharmaceuticals.

34. Finerenone / Therapeutic Appropriateness _____ _____
Alert Message: The safety and efficacy of Kerendia (finerenone) have not been established in patients below 18 years of age.

Drugs/Diseases
Util A Util B Util C
Finerenone

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Kerendia Prescribing Information, July 2021, Bayer HealthCare Pharmaceuticals.

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

35. Finerenone / Strong CYP3A4 Inhibitors _____ _____

Alert Message: The concurrent use of Kerendia (finerenone) with strong CYP3A inhibitors is contraindicated. Finerenone is a CYP3A4 substrate, and concomitant use with a strong CYP3A4 inhibitor may increase the risk of finerenone-related adverse reactions.

Drugs/Diseases

Util A	Util B		Util C
Finerenone	Clarithromycin	Nelfinavir	
	Cobicistat	Posaconazole	
	Indinavir	Ritonavir	
	Itraconazole	Saquinavir	
	Ketoconazole	Voriconazole	
	Nefazodone		

References:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Kerendia Prescribing Information, July 2021, Bayer HealthCare Pharmaceuticals.

36. Finerenone / Adrenal Insufficiency _____ _____

Alert Message: Kerendia (finerenone) is contraindicated in patients with adrenal insufficiency. Finerenone is a nonsteroidal, selective antagonist of the mineralocorticoid receptor (MR), which is activated by aldosterone and cortisol and regulates gene transcription.

Drugs/Diseases

Util A	Util B	Util C
Finerenone	Adrenal Insufficiency	

References:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Kerendia Prescribing Information, July 2021, Bayer HealthCare Pharmaceuticals.

37. Finerenone / Hyperkalemia _____ _____

Alert Message: Kerendia (finerenone) can cause hyperkalemia. The risk for developing hyperkalemia increases with decreasing kidney function and is greater in patients with higher baseline potassium levels or other risk factors for hyperkalemia. Measure serum potassium and eGFR in all patients before initiation of treatment with finerenone and dose accordingly. Do not initiate finerenone if serum potassium is > 5.0 mEq/L. Measure serum potassium periodically during treatment with finerenone and adjust dose accordingly. More frequent monitoring may be necessary for patients at risk for hyperkalemia, including those on concomitant medications that impair potassium excretion or increase serum potassium.

Drugs/Diseases

Util A	Util B	Util C (Include)
Finerenone		Hyperkalemia

References:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Kerendia Prescribing Information, July 2021, Bayer HealthCare Pharmaceuticals.

Criteria Recommendations	*Approved*	*Rejected*

38. Finerenone / Moderate or Weak CYP3A4 Inhibitors _____ _____

Alert Message: Kerendia (finerenone) is a CYP3A4 substrate. Concomitant use of finerenone with a moderate or weak CYP3A4 inhibitor increases finerenone exposure, which may increase the risk of finerenone adverse reactions. Monitor serum potassium during drug initiation or dosage adjustment of either finerenone or the moderate or weak CYP3A4 inhibitor and adjust finerenone dosage as appropriate.

Drugs/Diseases

Util A	Util B				Util C
Finerenone	Atazanavir	Diltiazem	Verapamil	Istradefylline	
	Aprepitant	Dronedarone	Chlorzoxazone	Ivacaftor	
	Cimetidine	Erythromycin	Cilostazol	Lomitapide	
	Ciprofloxacin	Fluconazole	Cimetidine	Ranitidine	
	Crizotinib	Fluvoxamine	Clotrimazole	Ranolazine	
	Cyclosporine	Imatinib	Fosaprepitant	Ticagrelor	

References:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Kerendia Prescribing Information, July 2021, Bayer HealthCare Pharmaceuticals.

39. Finerenone / Strong and Moderate CYP3A4 Inducers _____ _____

Alert Message: Avoid concomitant use of Kerendia (finerenone) with strong or moderate CYP3A4 inducers. Finerenone is a CYP3A4 substrate. Concomitant use of finerenone with a strong or moderate CYP3A4 inducer decreases finerenone exposure, which may reduce the efficacy of finerenone.

Drugs/Diseases

Util A	Util B		Util C
Finerenone	Apalutamide	Mitotane	
	Bosentan	Phenobarbital	
	Butalbital	Phenytoin	
	Carbamazepine	Primidone	
	Efavirenz	Rifabutin	
	Enzalutamide	Rifampin	
	Etravirine	Rifapentine	

References:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Kerendia Prescribing Information, July 2021, Bayer HealthCare Pharmaceuticals.

40. Finerenone / Pregnancy / Pregnancy Negating _____ _____

Alert Message: There are no available data on Kerendia (finerenone) use in pregnancy to evaluate for a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes. Animal studies have shown developmental toxicity at exposures about 4 times those expected in humans. The clinical significance of these findings is unclear.

Drugs/Diseases

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

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Kerendia Prescribing Information, July 2021, Bayer HealthCare Pharmaceuticals.

Criteria Recommendations ***Approved Rejected***

41. Finerenone / Lactation _____ _____

Alert Message: There are no data on the presence of Kerendia (finerenone) or its metabolite in human milk, the effects on the breastfed infant, or the effects of the drug on milk production. In a pre- and postnatal developmental toxicity study in rats, increased pup mortality and lower pup weight were observed at about 4 times the AUCunbound expected in humans. These findings suggest that finerenone is present in rat milk. When a drug is present in animal milk, it is likely that the drug will be present in human milk. Because of the potential risk to breastfed infants from exposure to finerenone, avoid breastfeeding during treatment and for 1 day after treatment.

Drugs/Diseases

Util A	Util B	Util C
Finerenone	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Kerendia Prescribing Information, July 2021, Bayer HealthCare Pharmaceuticals.

42. Finerenone / Severe Hepatic Impairment _____ _____

Alert Message: Kerendia (finerenone) use should be avoided in patients with severe hepatic impairment. In clinical studies, finerenone mean AUC was increased by 38%, and the Cmax was unchanged in cirrhotic patients with moderate hepatic impairment (Child-Pugh B) compared to healthy control subjects. The effect of severe hepatic impairment (Child-Pugh C) on finerenone exposure was not studied.

Drugs/Diseases

Util A	Util B	Util C
Finerenone	Cirrhosis	
	Hepatic Failure	

References:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Kerendia Prescribing Information, July 2021, Bayer HealthCare Pharmaceuticals.

43. Finerenone / Medications Causing Increased Potassium _____ _____

Alert Message: Kerendia (finerenone) can cause hyperkalemia. More frequent monitoring may be necessary for patients at risk for hyperkalemia, including those on concomitant medications that impair potassium excretion or increase serum potassium.

Drugs/Diseases

Util A	Util B	Util C
Finerenone	ACE Inhibitors	
	Aliskiren	
	ARBs	
	Eplerenone	
	Potassium Sparing Diuretics	
	Potassium Supplements	

References:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Kerendia Prescribing Information, July 2021, Bayer HealthCare Pharmaceuticals.

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

44. Finerenone / Non-adherence _____ _____

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

Drugs/Diseases

Util A	Util B	Util C
Finerenone		

References:

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

Mechta Nielsen T, Frojk Juhl M, Feldt-Rasmussen B, Thomsen T. Adherence to Medication in Patients with Chronic Kidney Disease: A Systematic Review of Qualitative Research. Clin Kidney J. 2018. Aug;11(4):513-527.

Burnier M, Pruijm M, Wuerzner G. et al. Drug Adherence in Chronic Kidney Disease and Dialysis. Nephrol Dial Transplant 2015; 30: 39–44.

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

45. Selinexor / Therapeutic Appropriateness _____ _____

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

Drugs/Diseases

Util A	Util B	Util C
Selinexor		

Age Range: 0 – 17 yoa

References:

Clinical Pharmacology, 2021 Elsevier/Gold Standard.

Xpovio Prescribing Information, Aug. 2021, Karyopharm Therapeutics Inc.

46. Selinexor / Thrombocytopenia _____ _____

Alert Message: Xpovio (selinexor) can cause life-threatening thrombocytopenia, potentially leading to hemorrhage. Thrombocytopenia is the leading cause of selinexor dosage modification. Monitor platelet counts at baseline and throughout treatment. Monitor more frequently during the first three months of treatment. Institute platelet transfusion and/or other treatments as clinically indicated. Monitor patients for signs and symptoms of bleeding and evaluate promptly. Interrupt, reduce dose according to official prescribing information, or permanently discontinue selinexor based on the severity of the adverse reaction.

Drugs/Diseases

Util A	Util B	Util C
Selinexor	Thrombocytopenia	

References:

Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Xpovio Prescribing Information, Aug. 2021, Karyopharm Therapeutics Inc.

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

47. Selinexor / Neutropenia _____ _____

Alert Message: Xpovio (selinexor) can cause life-threatening neutropenia, potentially increasing the risk of infection. Obtain white blood cell counts with differential at baseline and throughout selinexor treatment. Monitor patients for signs and symptoms of concomitant infection and evaluate promptly. Consider supportive measures, including antimicrobials and growth factors (e.g., G-CSF). Interrupt, reduce the dose of selinexor per official prescribing information, or permanently discontinue based on the severity of the adverse reaction.

Drugs/Diseases

Util A	Util B	Util C
Selinexor	Neutropenia	

References:

Clinical Pharmacology, 2021 Elsevier/Gold Standard.

Xpovio Prescribing Information, Aug. 2021, Karyopharm Therapeutics Inc.

48. Selinexor / Gastrointestinal Toxicity _____ _____

Alert Message: Xpovio (selinexor) can cause severe gastrointestinal toxicities. Provide prophylactic antiemetics to patients receiving selinexor. Administer 5-HT3 receptor antagonists and other anti-nausea agents prior to and during treatment with selinexor. Interrupt, reduce dose according to the official prescribing information, or permanently discontinue based on the severity of the adverse reaction.

Drugs/Diseases

Util A	Util B	Util C (Negating)
Selinexor	Nausea	Antiemetics
	Vomiting	

References:

Clinical Pharmacology, 2021 Elsevier/Gold Standard.

Xpovio Prescribing Information, Aug. 2021, Karyopharm Therapeutics Inc.

49. Selinexor / Diarrhea _____ _____

Alert Message: Xpovio (selinexor) can cause diarrhea. Provide standard anti-diarrheal agents, administer intravenous fluids to prevent dehydration, and replace electrolytes as clinically indicated. Interrupt, reduce dose according to the official prescribing information, or permanently discontinue based on the severity of the adverse reaction.

Drugs/Diseases

Util A	Util B	Util C (Negate)

Selinexor	Diarrhea	Anti-diarrheal Agents

References:

Clinical Pharmacology, 2021 Elsevier/Gold Standard.

Xpovio Prescribing Information, Aug. 2021, Karyopharm Therapeutics Inc.

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

50. Selinexor / Hyponatremia _____ _____

Alert Message: Xpovio (selinexor) can cause severe or life-threatening hyponatremia. Monitor sodium level at baseline and throughout treatment. Monitor more frequently during the first two months of treatment. Correct sodium levels for concurrent hyperglycemia (serum glucose >150 mg/dL) and high serum paraprotein levels. Assess hydration status and manage hyponatremia per clinical guidelines, including intravenous saline and/or salt tablets as appropriate and dietary review. Interrupt, reduce the dose according to the official prescribing information, or permanently discontinue selinexor based on the severity of the adverse reaction.

Drugs/Diseases

Util A	Util B	Util C
Selinexor	Hyponatremia	

References:

Clinical Pharmacology, 2021 Elsevier/Gold Standard.

Xpovio Prescribing Information, Aug. 2021, Karyopharm Therapeutics Inc.

51. Selinexor / Serious Infections _____ _____

Alert Message: Xpovio (selinexor) can cause serious and fatal infections. Monitor for signs and symptoms of infection, evaluate and treat promptly.

Drugs/Diseases

Util A	Util B	Util C
Selinexor	Infections	

References:

Clinical Pharmacology, 2021 Elsevier/Gold Standard.

Xpovio Prescribing Information, Aug. 2021, Karyopharm Therapeutics Inc.

52. Selinexor / Neurological Toxicity _____ _____

Alert Message: Xpovio (selinexor) can cause life-threatening neurological toxicities. Coadministration of selinexor with other products that cause dizziness or mental status changes may increase the risk of neurological toxicity. Advise patients to refrain from driving and engaging in hazardous occupations or activities, such as operating heavy or potentially dangerous machinery, until the neurological toxicity fully resolves. Optimize hydration status, hemoglobin level, and concomitant medications to avoid exacerbating dizziness or mental status changes. Institute fall precautions as appropriate.

Drugs/Diseases

Util A	Util B	Util C
Selinexor		

References:

Clinical Pharmacology, 2021 Elsevier/Gold Standard.

Xpovio Prescribing Information, Aug. 2021, Karyopharm Therapeutics Inc.

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

53. Selinexor / Pregnancy / Pregnancy Negating _____ _____

Alert Message: Based on data from animal studies and its mechanism of action, Xpovio (selinexor) can cause fetal harm when administered to a pregnant patient. Selinexor administration to pregnant animals during organogenesis resulted in structural abnormalities and alterations to growth at exposures below those occurring clinically at the recommended dose. Advise pregnant patients of the potential risk to a fetus.

Drugs/Diseases

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

Gender: Female

Age Range: 11 – 50 yoa

References:

Clinical Pharmacology, 2021 Elsevier/Gold Standard.

Xpovio Prescribing Information, Aug. 2021, Karyopharm Therapeutics Inc.

54. Selinexor / Therapeutic Appropriateness _____ _____

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

Drugs/Diseases

Util A	Util B	Util C
Selinexor	Lactation	

Gender: Female

Age Range: 11 – 50 yoa

References:

Clinical Pharmacology, 2021 Elsevier/Gold Standard.

Xpovio Prescribing Information, Aug. 2021, Karyopharm Therapeutics Inc.

55. Selinexor / Therapeutic Appropriateness _____ _____

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

Drugs/Diseases

Util A	Util B	Util C (Negate)
Selinexor		Contraceptives

Gender: Female

Age Range: 11 – 50 yoa

References:

Clinical Pharmacology, 2021 Elsevier/Gold Standard.

Xpovio Prescribing Information, Aug. 2021, Karyopharm Therapeutics Inc.

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

56. Selinexor / Therapeutic Appropriateness _____ _____

Alert Message: Advise males with a partner of reproductive potential to use effective contraception during treatment with Xpovio (selinexor) and for 1 week after the last dose.

Drugs/Diseases

Util A Util B Util C

Selinexor

Gender: Male

References:

Clinical Pharmacology, 2021 Elsevier/Gold Standard.

Xpovio Prescribing Information, Aug. 2021, Karyopharm Therapeutics Inc.

57. Selinexor / Nonadherence _____ _____

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

Drugs/Diseases

Util A Util B Util C

Selinexor

References:

Osterberg L, Blaschke T. Adherence to Medication. N Engl J Med. 2005;353:487-97.

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.

58. Fostemsavir / Overuse _____ _____

Alert Message: Rukobia (fostemsavir) may be over-utilized. The recommended dosage fostemsavir is one 600 mg tablet taken orally twice daily with or without food.

Drugs/Diseases

Util A Util B Util C

Fostemsavir

Max Dose: 600 mg/day

References:

Clinical Pharmacology, 2022 Elsevier/Gold Standard.

Rukobia Prescribing Information, July 2020, ViiV Healthcare.

59. Fostemsavir / Therapeutic Appropriateness _____ _____

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

Drugs/Diseases

Util A	Util B	Util C
Fostemsavir		

Age Range: 0 – 17 yoa

References:

Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Rukobia Prescribing Information, July 2020, ViiV Healthcare.

Criteria Recommendations	*Approved*	*Rejected*

60. Fostemsavir / Strong C YP3A4 Inducers _____ _____

Alert Message: The coadministration of Rukobia (fostemsavir) with strong CYP3A4 inducers is contraindicated. Fostemsavir is a CYP3A4 substrate, and concurrent use with a strong CYP3A4 inducer can decrease the temsavir (active moiety of fostemsavir) plasma concentrations which may lead to loss of virologic response.

Drugs/Diseases

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

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Rukobia Prescribing Information, July 2020, ViiV Healthcare.

61. Fostemsavir / QT Prolongation _____ _____

Alert Message: Rukobia (fostemsavir) should be used with caution in patients with a history of QTc prolongation or with relevant pre-existing cardiac disease or who are taking drugs with a known risk of torsade de pointes. In drug studies, supratherapeutic doses of fostemsavir have been shown to significantly prolong the QTc interval.

Drugs/Diseases

Util A	Util B	Util C
Fostemsavir	Long QT Syndrome	
	Heart Failure	
	Bradycardia	
	Hypokalemia	
	Hypomagnesemia	

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Rukobia Prescribing Information, July 2020, ViiV Healthcare.

62. Fostemsavir / Hepatitis B _____ _____

Alert Message: Particular diligence should be applied in initiating or maintaining effective hepatitis B therapy (referring to treatment guidelines) when starting Rukobia (fostemsavir) in patients co-infected with hepatitis B. Monitoring of liver chemistries is recommended in patients with hepatitis B and/or C coinfection. In fostemsavir clinical studies, elevations in hepatic transaminases were observed in a greater proportion of subjects with HBV and/or HCV co-infection compared with those with HIV mono-infection. Some of these elevations in transaminases were consistent with hepatitis B reactivation, particularly in the setting where anti-hepatitis therapy was withdrawn.

Drugs/Diseases

Util A	Util B	Util C
Fostemsavir	Hepatitis B	

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Rukobia Prescribing Information, July 2020, ViiV Healthcare.

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

63. Fostemsavir / Grazoprevir _____ _____

Alert Message: Coadministration of Rukobia (fostemsavir) with a grazoprevir-containing agent may increase exposures of grazoprevir; however, the magnitude of increase in exposure is unknown. Increased exposures of grazoprevir may increase the risk of ALT elevations. Use an alternative HCV regimen if possible.

Drugs/Diseases

Util A	Util B	Util C
Fostemsavir	Elbasvir/Grazoprevir	

References:

Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Rukobia Prescribing Information, July 2020, ViiV Healthcare.
Rukobia (fostemsavir) Integrate Review, Center for Drug Evaluation and Research. NDA 212950, Reference ID: 4635241. Version 2019/10/16.

64. Fostemsavir / Voxilaprevir _____ _____

Alert Message: Coadministration of Rukobia (fostemsavir) with a voxilaprevir-containing agent may increase exposures of voxilaprevir; however, the magnitude of increase in exposure is unknown. Increased exposures of voxilaprevir may increase the risk of voxilaprevir-related side effects. Use an alternative HCV regimen if possible.

Drugs/Diseases

Util A	Util B	Util C
Fostemsavir	Sofosbuvir/Velpatasvir/Voxilaprevir	

References:

Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Rukobia Prescribing Information, July 2020, ViiV Healthcare.

65. Fostemsavir / OC > 30 mcg Ethinyl Estradiol _____ _____

Alert Message: Coadministration of Rukobia (fostemsavir) with an oral contraceptive containing ethinyl estradiol may result in increased ethinyl estradiol levels. The ethinyl estradiol daily dose should not exceed 30 mcg when coadministered with fostemsavir. Caution is advised particularly in patients with additional risk factors for thromboembolic events.

Drugs/Diseases

Util A	Util B	Util C
Fostemsavir	OC > 30 mcg ethinyl estradiol	

References:

Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Rukobia Prescribing Information, July 2020, ViiV Healthcare.

66. Fostemsavir / OAT1B1/3 Substrate Statins _____ _____

Alert Message: Coadministration of Rukobia (fostemsavir), an OATP1B1/3 inhibitor, with a statin that is an OATP1B1/3 substrate may result in increased statin exposure. Use the lowest possible starting dose for statins when administered with fostemsavir, and monitor for statin-associated adverse events.

Drugs/Diseases

Util A	Util B	Util C
Fostemsavir	Atorvastatin, Fluvastatin, Pitavastatin, Rosuvastatin, Simvastatin	

References:

Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Rukobia Prescribing Information, July 2020, ViiV Healthcare.

Criteria Recommendations ***Approved Rejected***

67. Fostemsavir / QT Prolongation Drugs _____ _____

Alert Message: Rukobia (fostemsavir) should be used with caution in patients who are coadministered drugs with a known risk of torsade de pointes. In drug studies, supratherapeutic doses of fostemsavir have been shown to significantly prolong the QTc interval. Coadministration of fostemsavir with a drug with a known risk of torsade de pointes may increase the risk of torsade de pointes.

Drugs/Diseases

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

References:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Facts & Comparisons, 2021 Updates, Wolters Kluwer Health.

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

68. Fostemsavir / Lactation _____ _____

Alert Message: It is not known whether Rukobia (fostemsavir) is present in human breast milk, affects human milk production or has effects on the breastfed infant. When administered to lactating rats, fostemsavir-related drug materials (temsavir and temsavir-derived metabolites) were present in rat milk. Because of the potential for (1) HIV-1 transmission (in HIV-negative infants), (2) developing viral resistance (in HIV-positive infants), and (3) adverse reactions in a breastfed infant similar to those seen in adults, instruct mothers not to breastfeed if they are receiving fostemsavir.

Drugs/Diseases

Util A	Util B	Util C
Fostemsavir	Lactation	

Gender: Female

Age Range: 11 – 50 yoa

References:

Clinical Pharmacology, 2021 Elsevier/Gold Standard.

Facts & Comparisons, 2021 Updates, Wolters Kluwer Health.

69. Trifluridine/Tipiracil / Therapeutic Appropriateness _____ _____

Alert Message: The safety and effectiveness of Lonsurf (trifluridine/tipiracil) in pediatric patients have not been established.

Drugs/Diseases

Util A	Util B	Util C

Age Range: 0 – 17 yoa

References:

Clinical Pharmacology, 2022 Elsevier/Gold Standard.

Facts & Comparisons, 2022 Updates, Wolters Kluwer Health.

70. Trifluridine/Tipiracil / Pregnancy / Pregnancy Negating _____ _____

Alert Message: Based on animal studies and its mechanism of action, Lonsurf (trifluridine/tipiracil) can cause fetal harm when administered to a pregnant patient. Trifluridine/tipiracil caused embryo-fetal lethality and embryo-fetal toxicity in pregnant rats when orally administered during gestation at dosage levels resulting in exposures lower than those achieved at the recommended dosage of 35 mg/m2 twice daily. Advise pregnant patients of the potential risk to the fetus. Advise females of reproductive potential to use an effective method of contraception during treatment with trifluridine/tipiracil and for at least 6 months after the final dose.

Drugs/Diseases

Util A	Util B	Util C (Negating)
Trifluridine/Tipiracil	Pregnancy	Abortion
		Delivery
		Miscarriage

Gender: Female

Age Range: 11 – 50 yoa

References:

Clinical Pharmacology, 2022 Elsevier/Gold Standard.

Facts & Comparisons, 2022 Updates, Wolters Kluwer Health.

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

71. Trifluridine/Tipiracil / Therapeutic Appropriateness _____ _____

Alert Message: There are no data on the presence of trifluridine, tipiracil or its metabolites in human milk or its effects on the breastfed child or milk production. In nursing rats, trifluridine and tipiracil or their metabolites were present in breast milk. Because of the potential for serious adverse reactions in breastfed children, advise women not to breastfeed during treatment with Lonsurf (trifluridine/tipiracil) and for 1 day following the final dose.

Drugs/Diseases

Util A	Util B	Util C
Trifluridine/Tipiracil	Lactation	

Gender: Female

Age Range: 11 – 50 yoa

References:

Clinical Pharmacology, 2022 Elsevier/Gold Standard.

Facts & Comparisons, 2022 Updates, Wolters Kluwer Health.

72. Zanubrutinib / Overuse _____ _____

Alert Message: Brukinsa (zanubrutinib) may be over-utilized. The recommended dose of zanubrutinib is 160 mg twice daily or 320 mg once daily until disease progression or unacceptable toxicity.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Zanubrutinib		Cirrhosis
		Hepatic Failure
		Strong CYP3A Inhibitors
		Moderate CYP3A Inhibitors

Max Dose: 320 mg/day

References:

Clinical Pharmacology, 2022 Elsevier/Gold Standard.

Brukinsa Prescribing Information, Sept. 2021, BeiGene.

73. Zanubrutinib / Overuse – Hepatic Impairment _____ _____

Alert Message: Brukinsa (zanubrutinib) may be over-utilized. The recommended dosage of zanubrutinib for patients with severe hepatic impairment is 80 mg orally twice daily.

Drugs/Diseases

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

Max Dose: 160 mg/day

References:

Clinical Pharmacology, 2022 Elsevier/Gold Standard.

Brukinsa Prescribing Information, Sept. 2021, BeiGene.

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

74. Zanubrutinib / Strong CYP3A Inhibitors _____ _____

Alert Message: Brukinsa (zanubrutinib) is a CYP3A substrate and co-administration of zanubrutinib with a strong CYP3A inhibitor can increase zanubrutinib Cmax and AUC, which may increase the risk of zanubrutinib toxicities. The zanubrutinib dosage should be reduced to 80 mg once daily when co-administered with a strong CYP3A inhibitor. After discontinuation of a CYP3A inhibitor, resume the previous dose of zanubrutinib.

Drugs/Diseases

Util A	Util B	Util C (Include)	
Zanubrutinib		Clarithromycin	Nelfinavir
		Cobicistat	Posaconazole
		Indinavir	Ritonavir
		Itraconazole	Saquinavir
		Ketoconazole	Voriconazole
		Nefazodone	

Max Dose: 80 mg/day

References:

Clinical Pharmacology, 2022 Elsevier/Gold Standard.

Brukinsa Prescribing Information, Sept. 2021, BeiGene.

75. Zanubrutinib / Moderate CYP3A Inhibitors _____ _____

Alert Message: Brukinsa (zanubrutinib) is a CYP3A substrate and co-administration of zanubrutinib with a moderate CYP3A inhibitor increases zanubrutinib Cmax and AUC, which may increase the risk of zanubrutinib toxicities. The zanubrutinib dosage should be reduced to 80 mg twice daily when co-administered with a moderate CYP3A inhibitor. After discontinuation of a CYP3A inhibitor, resume the previous dose of zanubrutinib.

Drugs/Diseases

Util A	Util B	Util C (Include)		
Zanubrutinib		Atazanavir	Diltiazem	Verapamil
		Aprepitant	Dronedarone	
		Cimetidine	Erythromycin	
		Ciprofloxacin	Fluconazole	
		Crizotinib	Fluvoxamine	
		Cyclosporine	Imatinib	

Max Dose: 160 mg/day

References:

Clinical Pharmacology, 2022 Elsevier/Gold Standard.

Brukinsa Prescribing Information, Sept. 2021, BeiGene.

76. Zanubrutinib / Moderate or Strong CYP3A Inducers _____ _____

Alert Message: The concurrent use of Brukinsa (zanubrutinib) with moderate or strong CYP3A inducers should be avoided. Zanubrutinib is a CYP3A substrate, and coadministration with a moderate or strong inducer can result in a decrease in the Cmax and AUC of zanubrutinib.

Drugs/Diseases

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

References:

Clinical Pharmacology, 2022 Elsevier/Gold Standard.

Brukinsa Prescribing Information, Sept. 2021, BeiGene.

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

77. Zanubrutinib / Therapeutic Appropriateness _____ _____

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

Drugs/Diseases

Util A	Util B	Util C
Zanubrutinib		

Age Range: 0 – 17 yoa

References:

Clinical Pharmacology, 2022 Elsevier/Gold Standard.

Brukinsa Prescribing Information, Sept. 2021, BeiGene.

78. Zanubrutinib / Hemorrhage _____ _____

Alert Message: Fatal and serious hemorrhagic events have occurred in patients with hematological malignancies treated with Brukinsa (zanubrutinib) monotherapy. In clinical trials, hemorrhage events of any grade occurred in 35% of patients treated with zanubrutinib monotherapy. Patients receiving zanubrutinib should be monitored for signs and symptoms of bleeding. Discontinue zanubrutinib intracranial hemorrhage of any grade occurs.

Drugs/Diseases

Util A	Util B	Util C
Zanubrutinib	Hemorrhage	

References:

Clinical Pharmacology, 2022 Elsevier/Gold Standard.

Brukinsa Prescribing Information, Sept. 2021, BeiGene.

79. Zanubrutinib / Infection _____ _____

Alert Message: Fatal and serious infections (including bacterial, viral, or fungal) and opportunistic infections have occurred in patients with hematological malignancies treated with Brukinsa (zanubrutinib) monotherapy. In clinical trials, grade 3 or higher infections occurred in 27% of patients, most commonly pneumonia. Monitor and evaluate patients for fever or other signs and symptoms of infection and treat appropriately.

Drugs/Diseases

Util A	Util B	Util C
Zanubrutinib	Infections	

References:

Clinical Pharmacology, 2022 Elsevier/Gold Standard.

Brukinsa Prescribing Information, Sept. 2021, BeiGene.

80. Zanubrutinib / Atrial Fib & Flutter _____ _____

Alert Message: In clinical trials, atrial fibrillation and atrial flutter were reported in 3.2% of patients treated with Brukinsa (zanubrutinib) monotherapy. Patients with cardiac risk factors, hypertension, and acute infections may be at increased risk. Grade 3 or higher events were reported in 1.1% of patients treated with zanubrutinib monotherapy. Monitor signs and symptoms for atrial fibrillation and atrial flutter and manage as appropriate.

Drugs/Diseases

Util A	Util B	Util C
Zanubrutinib	Atrial Flutter	
	Atrial Fibrillation	

References:

Clinical Pharmacology, 2022 Elsevier/Gold Standard.

Brukinsa Prescribing Information, Sept. 2021, BeiGene.

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

81. Zanubrutinib / Cytopenia _____ _____

Alert Message: In clinical trials, Grade 3 or 4 cytopenias, including neutropenia (26%), thrombocytopenia (11%), and anemia (8%) based on laboratory measurements developed in patients treated with Brukinsa (zanubrutinib) monotherapy. Grade 4 neutropenia occurred in 13% of patients, and Grade 4 thrombocytopenia occurred in 3.6% of Monitor complete blood counts regularly during treatment and interrupt treatment, reduce the dose, or discontinue treatment as warranted. Treat using growth factor or transfusions, as needed.

Drugs/Diseases

Util A	Util B	Util C
Zanubrutinib	Neutropenia	
	Thrombocytopenia	
	Anemia	

References:

Clinical Pharmacology, 2022 Elsevier/Gold Standard.

Brukinsa Prescribing Information, Sept. 2021, BeiGene.

82. Zanubrutinib / Pregnancy / Pregnancy Negating _____ _____

Alert Message: Based on findings in animals, Brukinsa (zanubrutinib) can cause fetal harm when administered to pregnant patients. There are no available data on zanubrutinib use in pregnant patients to evaluate for a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes. Women should be advised to avoid pregnancy while taking zanubrutinib. If zanubrutinib is used during pregnancy, or if the patient becomes pregnant while taking zanubrutinib, the patient should be apprised of the potential hazard to the fetus.

Drugs/Diseases

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

Gender: Female

Age Range: 11 – 50 yoa

References:

Clinical Pharmacology, 2022 Elsevier/Gold Standard.

Brukinsa Prescribing Information, Sept. 2021, BeiGene.

83. Zanubrutinib / Therapeutic Appropriateness _____ _____

Alert Message: There are no data on the presence of Brukinsa (zanubrutinib) or its metabolites in human milk, the effects on the breastfed child, or the effects on milk production. Because of the potential for serious adverse reactions from zanubrutinib in a breastfed child, advise lactating women not to breastfeed during treatment with zanubrutinib and for at least 2 weeks following the last dose.

Drugs/Diseases

Util A	Util B	Util C
Zanubrutinib	Lactation	

Gender: Female

Age Range: 11 – 50 yoa

References:

Clinical Pharmacology, 2022 Elsevier/Gold Standard.

Brukinsa Prescribing Information, Sept. 2021, BeiGene.

Criteria Recommendations ***Approved Rejected***

84. Zanubrutinib / Therapeutic Appropriateness _____ _____ Alert Message:

Advise females of reproductive potential to use effective contraception during

Brukinsa (zanubrutinib) treatment and for at least 1 week after the final zanubrutinib dose. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be informed of the potential hazard to a fetus.

Drugs/Disease

Util A	Util B	Util C (Negating)
Zanubrutinib		Contraceptives

Gender: Female
Age Range: 11 – 50 yoa

Reference:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Brukinsa Prescribing Information, Sept. 2021, BeiGene.

85. Zanubrutinib / Therapeutic Appropriateness _____ _____ Alert Message:

Advise men to avoid fathering a child while receiving Brukinsa (zanubrutinib) and for 1 week following the last dose of zanubrutinib.

Drugs/Disease

Util A	Util B	Util C
Zanubrutinib		

Gender: Male
Reference:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Brukinsa Prescribing Information, Sept. 2021, BeiGene.

86. Zanubrutinib / Non-adherence _____ _____

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

Drugs/Diseases		
Util A	Util B	Util C
Zanubrutinib		

References:
Osterberg L, Blaschke T. Adherence to Medication. N Engl J Med. 2005;353:487-97.
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***

87. Romosozumab-aqqg / Therapeutic Appropriateness _____ _____
Alert Message: The safety and effectiveness of Evenity (romosozumab-aqqg) have not been established in pediatric patients.

Drugs/Diseases

Util A	Util B	Util C
Romosozumab-aqqg		

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Evenity Prescribing Information, March 2020, Amgen, Inc.

88. Romosozumab-aqqg / Therapeutic Appropriateness _____ _____
Alert Message: Evenity (romosozumab-aqqg) should not be initiated in patients who have had a myocardial infarction or stroke within the preceding year. Consider whether the benefits outweigh the risks in patients with other cardiovascular risk factors. Monitor for signs and symptoms of myocardial infarction and stroke and instruct patients to seek prompt medical attention if symptoms occur. If a patient experiences a myocardial infarction or stroke during therapy, romosozumab-aqqg should be discontinued.

Drugs/Diseases

Util A	Util B	Util C (Include)
Romosozumab-aqqg		Myocardial Infarction
		Stroke

References:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Evenity Prescribing Information, March 2020, Amgen, Inc.

89. Romosozumab-aqqg / Hypocalcemia _____ _____
Alert Message: Evenity (romosozumab-aqqg) is contraindicated in patients with pre-existing hypocalcemia. Correct hypocalcemia prior to initiating romosozumab-aqqg. Monitor patients for signs and symptoms of hypocalcemia. Patients should be adequately supplemented with calcium and vitamin D while on romosozumab-aqqg.

Drugs/Diseases

Util A	Util B	Util C
Romosozumab-aqqg	Hypocalcemia	

References:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Facts & Comparisons, 2021 Updates, Wolters Kluwer Health.
Evenity Prescribing Information, March 2020, Amgen, Inc.

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

90. Romosozumab-aqqg / Osteonecrosis of the Jaw _____ _____

Alert Message: Osteonecrosis of the jaw (ONJ) has been reported in patients receiving Evenity (romosozumab-aqqg). A routine oral examination should be performed by the prescriber prior to initiation of romosozumab-aqqg treatment. Concomitant administration of drugs associated with ONJ (chemotherapy, bisphosphonates, denosumab, angiogenesis inhibitors, and corticosteroids) may increase the risk of developing ONJ. Patients who are suspected of having or who develop ONJ while on romosozumab-aqqg should receive care from a dentist or an oral surgeon. In these patients, dental surgery to treat ONJ may exacerbate the condition. Discontinuation of romosozumab-aqqg should be considered based on benefit-risk assessment.

Drugs/Diseases

Util A	Util B	Util C
Romosozumab-aqqg	Osteonecrosis of the Jaw	

References:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Evenity Prescribing Information, March 2020, Amgen, Inc.

91. Romosozumab-aqqg / Cardiovascular Risk Factors _____ _____

Alert Message: In a randomized controlled trial in postmenopausal women, there was a higher rate of major adverse cardiac events (MACE), a composite endpoint of cardiovascular death, nonfatal myocardial infarction, and nonfatal stroke, in patients treated with Evenity (romosozumab-aqqg) compared to those treated with alendronate. Consider whether the benefits outweigh the risks in patients with other cardiovascular risk factors. Monitor for signs and symptoms of myocardial infarction and stroke and instruct patients to seek prompt medical attention if symptoms occur. If a patient experiences a myocardial infarction or stroke during therapy, romosozumab-aqqg should be discontinued. Romosozumab-aqqg should not be initiated in patients who have had a myocardial infarction or stroke within the preceding year.

Drugs/Diseases

Util A	Util B	Util C
Romosozumab-aqqg	Family Hx of CVD Hypertension Hypercholesterolemia Obesity	

References:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Evenity Prescribing Information, March 2020, Amgen, Inc.

92. Romosozumab-aqqg / Pregnancy / Pregnancy Negating _____ _____

Alert Message: Evenity (romosozumab-aqqg) is not indicated for use in women of reproductive potential. In animal reproduction studies, weekly administration of romosozumab-aqqg to pregnant rats during the period of organogenesis at exposures greater than 31 times the clinical exposure produced skeletal abnormalities in the offspring.

Drugs/Diseases

Util A	Util B	Util C (Negating)
Romosozumab-aqqg	Pregnancy	Abortion Delivery Miscarriage

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Evenity Prescribing Information, March 2020, Amgen, Inc.

Criteria Recommendations	*Approved*	*Rejected*

93. Romosozumab-aqqg / Therapeutic Appropriateness _____ _____

Alert Message: Evenity (romosozumab-aqqg) is not indicated for use in women of reproductive potential. In animal studies where pregnant rats were given weekly doses of romosozumab-aqqg from 6 weeks before cohabitation through mating and lactation at 10, 60, or 300 mg/kg (equivalent to 1.4, 18, or 54 times the clinical exposure following a monthly subcutaneous dose of 210 mg, based on AUC comparison), romosozumab-aqqg was dose-dependently present in the serum of offspring on postnatal day 21 at 0.01 to 2.4 times maternal exposure due to gestational and/or lactational exposure.

Drugs/Diseases

Util A	Util B	Util C
Romosozumab-aqqg	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Evenity Prescribing Information, March 2020, Amgen, Inc.

North Dakota Medicaid

Drug Utilization Review Board Meeting

September 7th, 2022

Conference Room 210/212

NORTH Dakota
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| Health & Human Services

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Be Legendary.

Meeting Notice

North Dakota Medicaid Drug Use Review Board

Wednesday, September 7, 2022
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: 118 924 403 5 #

Agenda

1. Administrative items
    - DHS announcements

2. Old business
    - Review and approval of June 2022 meeting minutes
    - Budget update
    - Review top 25 drugs for the second quarter of 2022
    - Prior authorization/PDL update
    - Update to Eosinophilic Esophagitis (Dupixent)
    - Update to Bardet-Biedl Syndrome (Imcivree)
    - Update to Heart Failure (Camzyos)
    - Second review of Presbyopia
    - Second review of Cushing's Syndrome
    - Second review of Vernal Keratoconjunctivitis
    - Second review of Wilson's Disease

3. New business
    - Review of Amyloidosis (Vyndaqel, Vyndamax, Tegsedi)
    - Review of Amyotrophic Lateral Sclerosis (Radicava)
    - Review of Chelating Agents (Ferriprox)
    - Discussion of RSV
    - Discussion of RDUR response letter
    - Retrospective DUR profile review update
    - Retrospective DUR criteria recommendations
    - Upcoming meeting date/agenda.
        - Next meeting is December 7th, 2022

Adjourn

Individuals with disabilities who need accommodations, including appropriate auxiliary aids to participate, can contact Stacey Koehly at 701-328-4807, toll-free 800-755-2604, 711 (TTY) or skoehly@nd.gov.

North Dakota Medicaid Drug Use Review (DUR) Board
Meeting Minutes
June 1st, 2022

Members Present: Joshua Askvig, Andrea Honeyman, Kathleen Traylor, Amy Werremeyer, Laura Kroetsch, Tanya Schmidt, Kevin Martian, Kristen Peterson, Jennifer Iverson, Gabrielle Balf, Mary Aaland

Medicaid Pharmacy Department: Alexi Murphy, Brendan Joyce, LeNeika Roehrich

Old Business

Chair T. Schmidt called the meeting to order at 1:01 p.m. Vice Chair election was held during this meeting in which T. Schmidt was nominated and voted again to serve as the Board meeting Chair for the following year. Chair T. Schmidt asked for a motion to approve the minutes of the March 2nd, 2022, meeting. J. Askvig moved that the minutes be approved, and K. Martian seconded the motion. The chair called for a voice vote to approve the minutes. The motion passed with no audible dissent.

Review Top 25 Drugs

B. Joyce presented budget updates and the quarterly review of the top 25 drugs based on total claims cost, the top 25 drugs based on the total number of claims, and the top drug classes based on claims and cost for the 1st quarter of 2022. B. Joyce went on to discuss "per member per month" (PMPM) average cost which is the net of all rebates. Within the last eight quarters, the PMPM average has decreased since managed care is no longer involved in the process. However, the total expenses from 2020 to 2021 increased by 21%. B. Joyce presented the 5 drug classes which account for 75% of the cost increase. These classes include agents used for cystic fibrosis, oncology, immunomodulators, HIV, and eczema. The question was brought up about if there is a way to determine how many members will fall off once Medicaid enrollment redetermination begins again. B. Joyce answered that there is currently no way of knowing how many will fall off.

PDL/PA Criteria Updates

A. Murphy shared with the Board all the changes made to the Preferred Drug List since the last version of the Preferred Drug List was posted. Notable changes include adding Pyrukynd, Ferriprox, and Vijoice to PA for the Over 3000 criteria. A couple notable changes in the Antifungals section and Glucose Rescue Medications section include changing Noxafil and Vfend to preferred and Gvoke to preferred, respectively. All PDL updates are listed in the handout for the June 2022 DUR Board meeting. When a new version of the PDL is published and posted to the website, all updates/changes made since the last version are called out at the top of the document itself. During public comment, Vruti Patel from Xeris thanked the Board for allowing Gvoke to become a preferred agent.

Update to Sedatives/Hypnotics

L. Morgan presented the proposed changes to the Sedatives/Hypnotics section in which Smith-Magenis Syndrome was added with initial and renewal criteria. The preferred agent requiring a clinical PA is Hetlioz. M. Aaland asked how there will be confirmation of a specialist being involved in the member's treatment for this disease state. L. Morgan discussed that the provider submitting the PA must list the specialist involved in the treatment of the member. M. Aaland expressed concerns about the requirement for a sleep-disorder specialist to be involved, as it seemed vague about who is considered a specialist in the field. After discussion amongst the Board members, clarification was made about the requirement for a sleep-disorder specialist.

Update to Lupus Nephritis

L. Morgan presented changes made to the Lupus Nephritis section in the PDL. Initial approval duration for Lupkynis was adjusted from 12 months to 6 months. Additionally, more specific criteria about required documentation to support member clinical benefit and improvement since starting Lupkynis were added for renewal.

Update to Chronic Kidney Disease

L. Morgan presented updates to Kerendia in the Chronic Kidney Disease section. For this agent, the member must have a history of diabetes and meet the parameters listed for estimated glomerular filtration rate (eGFR) and urinary albumin-to-creatinine ratio (UACR). K. Martian asked if the requirement of the labs will be enforced for all facilities, including those that do not possess the ability to produce such labs. A. Murphy responded that if this does come up during review, then exceptions can be made depending on the situation. For now, that concern will be monitored. During public comment, Bashir Kalayah from Bayer Pharmaceuticals gave an overview of Kerendia. He made a request to the Board to allow Kerendia without concurrent use of an ACE-inhibitor, or ARB, and a SGLT-2 inhibitor. During discussion, A. Murphy stated that the requirement for concurrent use of those agents will be waved if the member has a contraindication, allergy, or other extenuating circumstance for why the member cannot take the agent.

Update to Heart Failure

L. Morgan presented updates to the Heart Failure second line agent's section. The prescriber must now be, or be in consult, with a cardiologist for approval of Verquvo and Corlanor. All other criteria remained the same.

Update to Drug Utilization Review Policies

L. Morgan presented an update to the Preferred Drug List (PDL) that discussed the Drug Utilization Review Policies. This policy was already in effect prior to the update; however, the policy was added to the PDL for provider clarity on the topic. A. Werremeyer discussed her concerns of this policy and how it may limit medical care for a member if his or her provider does not advocate for the member's need for the requested treatment. A.Werremeyer explained how many agents are used in practice based on literary support versus FDA-approval. A. Murphy answered that per federal law, clinical literature cannot be used as a basis for approval of agents not compendia supported. B. Joyce also added that Kepro, the contracted prior authorization reviewer, will not be utilized to review non-compendia supported use of agents. Rather, letters and emails may be submitted to ND Medicaid resources to discuss the use of non-compendia supported use of agents. G. Balf added her concerns also of the Drug Utilization Review policy and the restrictions it can pose on members. B. Joyce responded that this policy has always been in place, but it is just now being added to the PDL for reference. L. Kroetsch was also in favor of changing the language in this section to let practitioners know there is a route they can take to advocate for their patients to use non-compendia supported agents.

Synagis Discussion

A Murphy presented data on RSV and the use of Synagis in recent years. A. Murphy presented the seasonal cost of Synagis from 2016 to 2021 for ND Medicaid. She also presented Region 8 reported seasons and how North Dakota matched up to the start and end of those seasons. Overall, ND Medicaid started covering Synagis earlier than other states in Region 8. A. Murphy went on to discuss how to determine "seasonality" and how to measure consistency of RSV detection. This topic will be discussed more at the next meeting.

Second Review of Familial Cholestasis Pruritis

L. Morgan presented initial and renewal criteria for Bylvay and Livmarli. These agents will be approved for 6 months initially and 12 months for renewal. Bylvay and Livmarli both have product specific criteria listed which requires genetic testing to support appropriate diagnosis and medication use. Bylvay and Livmarli are listed as preferred agents that require clinical PA. Standing in for Chair T. Schmidt, A. Honeyman called for a voice vote to approve the updated criteria, which passed with no audible dissent.

<u>New Business</u>

Review of Wilson's Disease

L. Morgan presented a review of the disease state and agents used in the treatment of Wilson's Disease to the Board. A motion was made by A. Werremeyer to manage these medications through prior authorization. The motion was seconded by K. Martian. Prior authorization criteria for these agents will be presented, reviewed, and voted on by the Board at the next meeting.

Review of Cushing's Syndrome
L. Morgan presented a review of the disease state and agents used in the treatment of Cushing's Syndrome to the Board. During public comment, Vruti Patel from Xeris gave an overview of Recorlev and requested it be added to the PDL. K. Martian asked what, if any, clinical benefit would come from using the racemic mixture of ketoconazole (Recorlev) versus ketoconazole. Vruti Patel answered that there is currently no clinical benefit showing superiority of Recorlev over ketoconazole, but rather there is a broader indication and prescriber support for using Recorlev. A motion was made by K. Martian to manage these medications through prior authorization. The motion was seconded by A. Honeyman. Prior authorization criteria for these agents will be presented, reviewed, and voted on by the Board at the next meeting.

Review of Presbyopia
L. Morgan presented a review of the disease state and agents used in the treatment of presbyopia to the Board. During public comment, Nathan Blake from AbbVie made himself available for questions from the Board. A. Murphy then asked the Board if they want to consider this agent for cosmetic use or add it to the PDL for prior authorization. K. Martian and B. Joyce brought up the medical need for some members who may not be able to wear glasses. A motion was made by K. Martian to manage these medications through prior authorization. The motion was seconded by A. Werremeyer. Prior authorization criteria for these agents will be presented, reviewed, and voted on by the Board at the next meeting.

Review of Vernal Keratoconjunctivitis
L. Morgan presented a review of the disease state and agents used in the treatment of vernal keratoconjunctivitis to the Board. A motion was made by A. Werremeyer to manage these medications through prior authorization. The motion was seconded by J. Askvig. Prior authorization criteria for these agents will be presented, reviewed, and voted on by the Board at the next meeting.

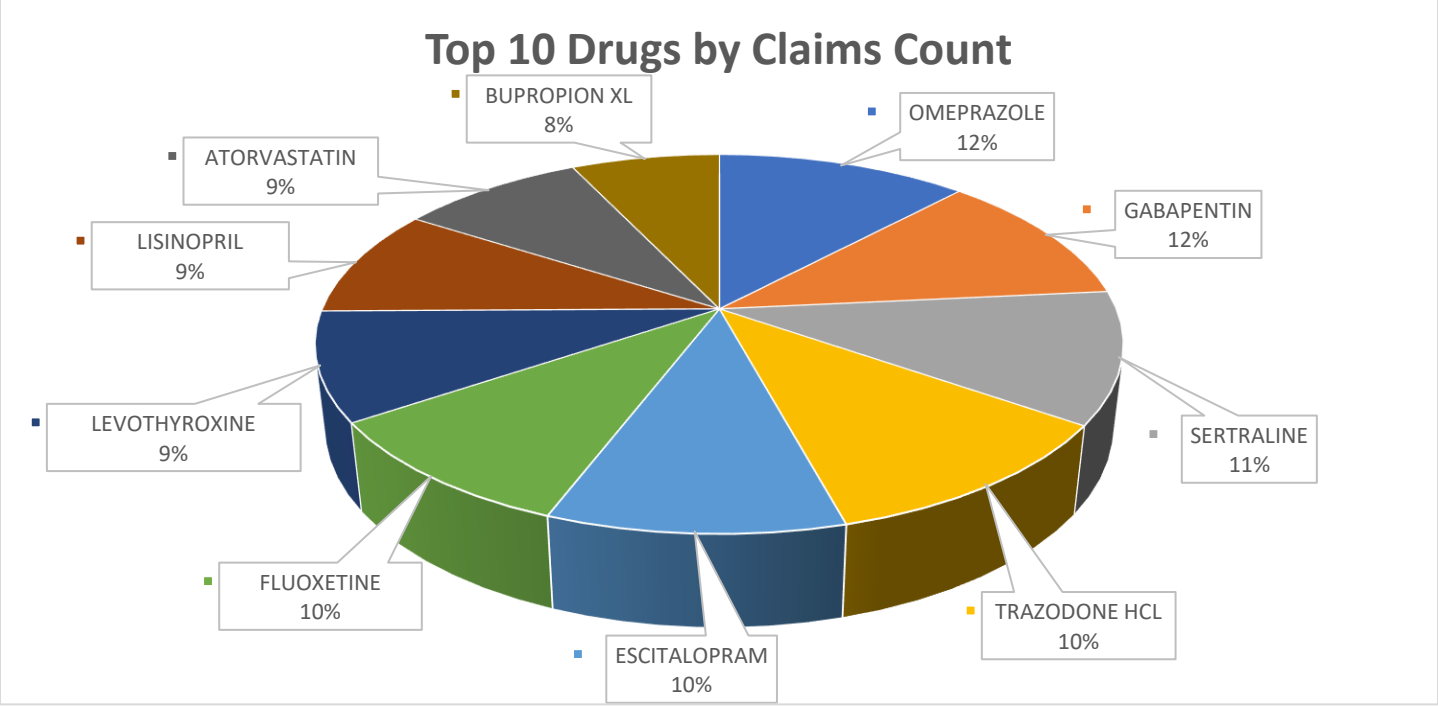
Retrospective Drug Utilization Review (RDUR) Criteria Recommendations
L. Morgan reviewed the RDUR criteria that were selected for review of January and March of Q1 2022. Presented data included number of profiles reviewed, number of cases identified for intervention, and the number of letters sent, as well as an overview of what RDUR interventions were identified as most prevalent for each monthly cycle. There was a special mailing sent in February to providers about neuropsychiatric events reported with the use of Singulair. Additionally, L. Morgan presented Q1 2022 RDUR response rate data from prescribers and pharmacies. M. Aaland discussed her concerns about the low response rate from prescribers and pharmacies, and from there, the Board discussed ways to increase the response rate. Some mentioned making the response form shorter and more direct, choosing more useful RDUR criteria, and narrowing down and communicating with the non-responders. The recommended RDUR criteria enclosed in the packet were developed from product information provided by the manufacturers and are consistent with new indications, new drugs added, and new warnings. These proposed criteria will be added to the current set of criteria and will be used in future DUR cycles. M. Aaland moved to approve the new criteria and K. Martian seconded the motion. Standing in for Chair T. Schmidt, A. Honeyman called for a voice vote to approve the new criteria, which passed with all present members voting to approve.

Adjournment and Upcoming Meeting Date
A. Honeyman adjourned the meeting at 3:25 pm. The next DUR Board meeting will be held September 7th, 2022, at 1:00 pm at the state capitol building.

Top 25 Drugs Based on Number of Claims from 04/01/2022 – 06/30/2022

Drug	Claims	Patients	Claims Cost	Cost / Claim	% Total Claims	Dif.
1. OMEPRAZOLE	4,846	2,403	$62,645.00	$12.93	1.86%	↑1
2. GABAPENTIN	4,688	1,958	$69,536.71	$14.83	1.80%	↓1
3. SERTRALINE HCL	4,368	2,393	$59,893.29	$13.71	1.68%	NC
4. TRAZODONE HCL	4,167	2,035	$56,455.50	$13.55	1.60%	NC
5. ESCITALOPRAM OXALATE	4,082	2,273	$55,106.37	$13.50	1.57%	NC
6. FLUOXETINE HCL	3,919	2,081	$53,495.61	$13.65	1.51%	NC
7. LEVOTHYROXINE SODIUM	3,648	1,860	$60,734.32	$16.65	1.40%	NC
8. LISINOPRIL	3,500	2,004	$44,850.90	$12.81	1.35%	NC
9. ATORVASTATIN CALCIUM	3,431	1,926	$48,339.61	$14.09	1.32%	↑1
10. BUPROPION XL	3,123	1,665	$55,332.02	$17.72	1.20%	↑2
11. VYVANSE	3,011	1,210	$797,616.43	$264.90	1.16%	↑2
12. PANTOPRAZOLE SODIUM	2,918	1,423	$39,148.04	$13.42	1.12%	↑3
13. HYDROCODONE-APAP	2,875	1,805	$41,794.54	$14.54	1.11%	↑1
14. AMOXICILLIN	2,862	2,688	$39,587.54	$13.83	1.10%	↓5
15. DULOXETINE HCL	2,550	1,328	$41,503.61	$16.28	0.98%	↑2
16. PROAIR HFA	2,529	2,496	$201,469.27	$79.66	0.97%	↓5
17. CYCLOBENZAPRINE HCL	2,499	1,582	$29,726.87	$11.90	0.96%	↑3
18. METFORMIN HCL	2,462	1,361	$32,389.07	$13.16	0.95%	↑1
19. HYDROXYZINE HCL	2,459	1,506	$34,088.56	$13.86	0.95%	↑3
20. CLONIDINE HCL	2,458	1,214	$31,087.60	$12.65	0.95%	↑3
21. BUPRENORPHINE-NALOXONE	2,446	594	$105,402.63	$43.09	0.94%	↓3
22. PREDNISONE	2,410	1,883	$28,906.80	$11.99	0.93%	↓6
23. MONTELUKAST SODIUM	2,403	1,405	$33,676.15	$14.01	0.92%	↑4
24. LAMOTRIGINE	2,397	973	$34,753.76	$14.50	0.92%	↓2
25. CLONAZEPAM	2,307	985	$31,363.57	$13.59	0.89%	↑1

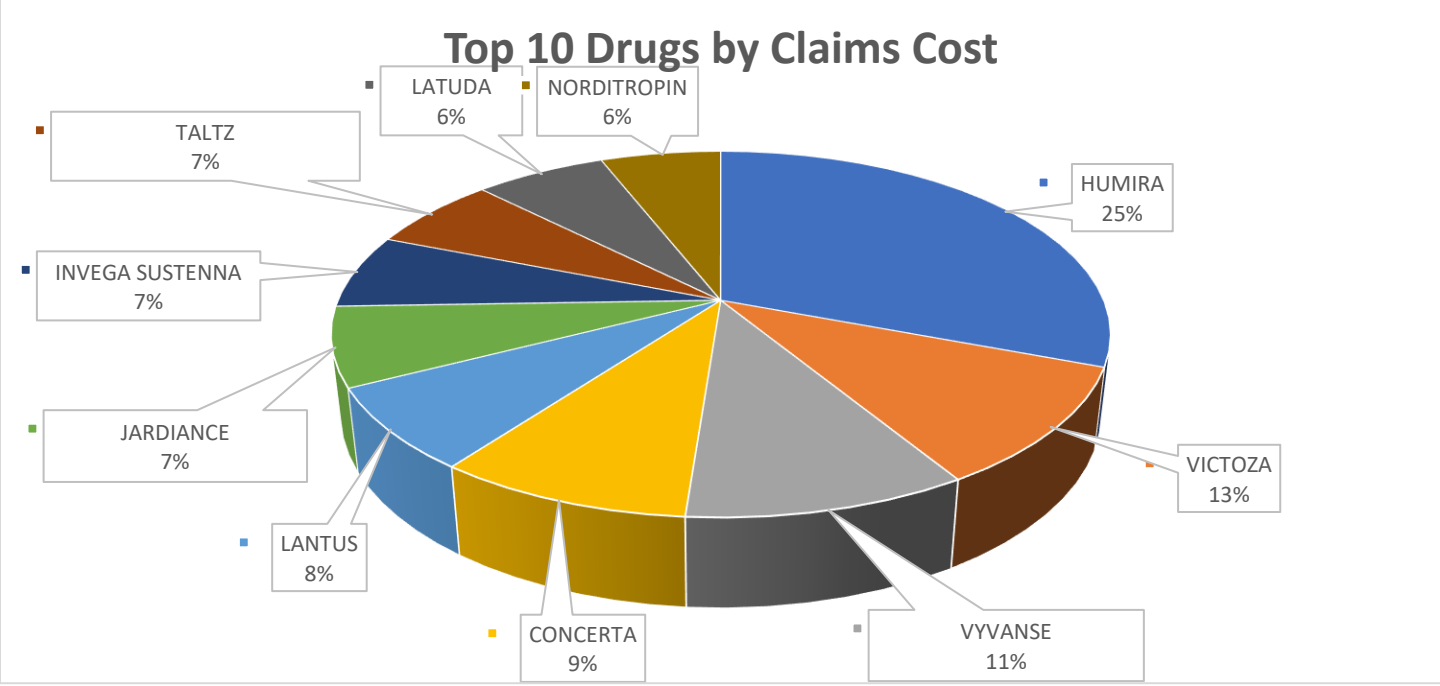
Total Claims	**259,935**



Top 25 Drugs Based on Total Claims Cost from 04/01/2022 – 06/30/2022

Drug	Claims Cost	Claims	Patients	Cost /Claim	% Total Cost	Dif.
1. HUMIRA PEN	$1,908,540.35	256	106	$7,455.24	5.97%	NC
2. VICTOZA	$966,894.90	1157	551	$835.69	3.02%	↑3
3. VYVANSE	$797,616.43	3,011	1,210	$264.90	2.49%	↓1
4. CONCERTA	$677,365.30	1,891	799	$358.20	2.12%	↓1
5. LANTUS SOLOSTAR	$626,924.46	1,246	771	$503.15	1.96%	↓1
6. JARDIANCE	$561,978.00	978	452	$574.62	1.76%	↑5
7. INVEGA SUSTENNA	$522,374.47	210	84	$2,487.50	1.63%	↑1
8. TALTZ AUTOINJECTOR	$521,676.58	83	33	$6,285.26	1.63%	↓2
9. LATUDA	$484,309.49	589	236	$822.26	1.51%	NC
10. NORDITROPIN FLEXPRO	$473,031.57	110	42	$4,300.29	1.48%	↑2
11. STELARA	$418,479.44	17	13	$24,616.44	1.31%	↓4
12. MAVYRET	$396,967.47	32	20	$12,405.23	1.24%	↑6
13. BIKTARVY	$386,920.19	216	98	$1,791.30	1.21%	↓3
14. SYMBICORT	$355,547.64	1,018	595	$349.26	1.11%	↑2
15. ADDERALL XR	$349,293.04	1,969	835	$177.40	1.09%	↑2
16. ADVAIR DISKUS	$340,032.40	922	505	$368.80	1.06%	↑3
17. NOVOLOG FLEXPEN	$335,844.83	486	287	$691.04	1.05%	↓3
18. ELIQUIS	$329,808.12	670	305	$492.25	1.03%	↑2
19. TRIKAFTA	$300,561.80	12	5	$25,046.82	0.94%	↓4
20. VRAYLAR	$292,956.38	317	133	$924.15	0.92%	↑5
21. ABILIFY MAINTENA	$269,404.80	116	47	$2,322.46	0.84%	↑3
22. LEVEMIR FLEXTOUCH	$268,986.86	479	274	$561.56	0.84%	NC
23. GILENYA	$238,174.31	27	10	$8,821.27	0.74%	↑9
24. COSENTYX PEN	$232,660.70	38	14	$6,122.65	0.73%	↑2
25. XIFAXAN	$224,935.00	90	45	$2,499.28	0.70%	↓2

Total Claims Cost	**$31,980,817.33**



Top 15 Therapeutic Classes Based on Number of Claims from 04/01/2022 – 06/30/2022

Therapeutic Class Description	Claims	Patients	Claims Cost	Cost/Claim	% Total Claims	Dif.
1. ANTIDEPRESSANTS	30,158	12,415	$636,897.32	$21.12	11.60%	NC
2. ANTICONVULSANTS	13,669	4,784	$794,503.36	$58.12	5.26%	NC
3. ANTIPSYCHOTIC AGENTS	9,336	3,593	$2,347,175.69	$251.41	3.59%	NC
4. PROTON-PUMP INHIBITORS	8,144	3,949	$145,481.30	$17.86	3.13%	NC
5. SEDATIVES/HYPNOTICS	7,318	3,688	$112,364.11	$15.35	2.82%	NC
6. OPIATE AGONISTS	7,032	3,600	$118,975.08	$16.92	2.71%	NC
7. AMPHETAMINES	6,433	2,656	$1,191,664.83	$185.24	2.47%	NC
8. NSAIDS	6,427	4,221	$96,528.18	$15.02	2.47%	NC
9. STATINS	5,933	3,294	$85,628.06	$14.43	2.28%	↑1
10. BETA BLOCKERS	5,496	2,902	$100,265.46	$18.24	2.11%	↑2
11. PENICILLIN ANTIBIOTICS	5,291	4,739	$82,457.07	$15.58	2.04%	↑2
12. NON-AMPHETAMINE STIMULANTS	5,150	1,982	$1,005,997.10	$195.34	1.98%	↓1
13. ACE-INHIBITORS	4,458	2,525	$70,224.93	$15.75	1.72%	↑2
14. BIGUANIDES	4,110	2,278	$57,055.48	$13.88	1.58%	↑2
15. BETA AGONISTS	4,078	3,662	$311,670.94	$76.43	1.57%	↑2

Top 15 Therapeutic Classes Based on Claims Cost from 04/01/2022 – 06/30/2022

Therapeutic Class Description	Claims Cost	Claims	Patients	Cost/Claim	% Total Cost	Dif.
1. DMARDS	$3,411,238.61	628	255	$5,431.91	10.67%	NC
2. ANTIPSYCHOTIC AGENTS	$2,347,175.69	9,336	3,593	$251.41	7.34%	NC
3. INSULINS	$1,877,264.60	3,635	1,403	$516.44	5.87%	↑1
4. SKIN AND MUCOUS MEMBRANE AGENTS	$1,656,560.21	627	384	$2,642.04	5.18%	↓1
5. AMPHETAMINES	$1,191,664.83	6,433	2,656	$185.24	3.73%	↑2
6. INCRETIN MIMETICS	$1,104,294.55	1,324	593	$834.06	3.45%	↑3
7. ANTINEOPLASTIC AGENTS	$1,079,500.57	573	241	$1,883.95	3.38%	↓2
8. RESPIRATORY CORTICOSTEROIDS	$1,064,547.91	3,643	2,182	$292.22	3.33%	↑2
9. NON-AMPHETAMINE STIMULANTS	$1,005,997.10	5,150	1,982	$195.34	3.15%	↑2
10. ANTIRETROVIRALS	$967,402.05	779	294	$1,241.85	3.02%	↓2
11. ANTICONVULSANTS	$794,503.36	13,669	4,784	$58.12	2.48%	↓5
12. SGLT-2 INHIBITORS	$768,726.22	1,358	627	$566.07	2.40%	↑1
13. IMMUNOMODULATORY AGENTS	$702,514.04	89	34	$7,893.42	2.20%	↓1
14. ANTIDEPRESSANTS	$636,897.32	30,158	12,415	$21.12	1.99%	NC
15. HCV ANTIVIRALS	$615,716.35	60	34	$10,261.94	1.93%	NC

PDL UPDATE

Drug Name	PA	Class
Adlarity	PA	Alzheimer's agents
Aspruzyo Sprinkle	PA	Non-Preferred Dosage Forms
Camzyos	PA	Heart Failure/3000
Lyvispah	PA	muscle relaxants
Mounjaro	PA	Diabetes
Radicava	PA	3000
Tegsedi	PA	3000
Voquenza	PA	anti-infectives resistance prevention
Vtama	PA	Topical plaque psoriasis
deferasirox (Jadenu) tablets	remove PA	Preferred Dosage Forms

Eosinophilic Esophagitis

Prior Authorization Form - Dupixent

Group Criteria:

- **Initial Criteria:** *Approval Duration = 6 months*
  - The prescriber must be, or be in consultation with, a gastroenterologist
  - The member must have ≥15 intraepithelial eosinophils per high-power field (eos/hpf).
  - Member must have failed a 3-month trial of a swallowed inhaled respiratory corticosteroid (budesonide or fluticasone).
- **Renewal Criteria:** *Approval Duration = 12 months*
  - The prescriber must provide documentation showing that 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/hpf.

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

Imcivree

General Prior Authorization Form

- **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 obesity must be due to one of the following (A or B):
    A. Variants interpreted as pathogenic, likely pathogenic, or of unknown significance:
      - proopiomelanocortin (POMC)
      - proprotein convertase subtilisin/kexin type 1 (PCSK1)
      - leptin receptor (LEPR) deficiency

    B. A diagnosis of Bardet-Biedl Syndrome (BBS) as evidenced by three or more of the following:
      - Rod-cone dystrophy
      - Polydactyly
      - Genital anomalies
      - Renal anomalies
      - Intellectual impairment
  - The medication is prescribed by, or in consultation with, an endocrinologist or expert in rare genetic disorders of obesity
  - The member's weight and body mass index (BMI) must be provided within the last 60 days
- **Renewal Criteria:** *Approval Duration = 12 months*
  - One of the following must be met since starting treatment with Imcivree, as evidenced by medical documentation (e.g., chart notes) attached to the request:
    - Members ≥ 18 years old:
      - First renewal - a 5% weight reduction has been achieved or maintained
      - Subsequent renewal - a 10% weight reduction has been achieved or maintained
    - Members < 18 years old: a 5% reduction in BMI has been achieved or maintained

PREFERRED AGENTS (CLINICAL PA REQUIRED)
IMCIVREE (setmelanotide)

Heart Failure

Electronic Diagnosis Verification

- Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale for Corlanor, Entresto, and Verquvo

Prior Authorization Criteria

General Prior Authorization Form

First Line Agents:

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ACE (angiotensin-converting enzyme) inhibitors - *all oral agents preferred*	
ARBs (angiotensin receptor blockers) - *all oral agents preferred*	
Beta blockers - *all oral agents preferred*	
ENTRESTO (sacubitril/valsartan)	
eplerenone	
FARXIGA (dapagliflozin)	
JARDIANCE (empagliflozin)	
spironolactone	

Second Line Agents:

Product Specific Criteria:

- **Verquvo:**
  - The prescriber is, or is in consult with, a cardiologist
  - The member must have left ventricular ejection fraction (LVEF) < 45%
  - Documentation of a recent hospitalization or need for IV diuretics (within the past 6 months) must be submitted with request
  - The member is receiving concurrent Entresto, a beta-blocker, a SGLT-2 Inhibitor, and a mineralocorticoid receptor antagonist.
- **Corlanor:**
  - The prescriber is, or is 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
- **Camzyos (Initial):** *Approval Duration = 6 months*
  - The prescriber is, or is in consult with, a cardiologist
  - Documentation of an echocardiogram assessment of LVEF ≥55% must be provided.
  - Documentation of a left ventricular outflow tract (LVOT) peak gradient ≥50 mmHg at rest or with provocation must be provided.
  - Documentation of oxygen saturation of ≥90% at rest must be provided.
  - The member is receiving concurrent Entresto, a beta-blocker, a SGLT-2 Inhibitor, and a mineralocorticoid receptor antagonist.

Product Specific Criteria (Renewal):

- **Camzyos:** *Approval Duration = 12 months*
  - Documentation of echocardiogram assessments of LVEF ≥50% must be provided
  - Documentation of mixed peak oxygen consumption (pVO_2) by ≥ 1.5 mL/kg/min plus improvement in NYHA class by at least 1 or improvement of pVO_2 by ≥3 mL/kg/min plus no worsening of NYHA class must be provided.

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
CAMZYOS (mavacamten)	
CORLANOR (ivabradine)	
VERQUVO (vericiguat)	

Presbyopia

General Prior Authorization Form

Group Criteria:

- **Initial Criteria:** *Approval Duration = 3 months*
  - The prescriber must be, or be in consultation with, an optometrist
  - Documentation of medical necessity must be provided, including contraindication to the use of corrective lenses and how activities of daily living are adversely impacted due to inability to correct vision with corrective lenses.
- **Renewal Criteria:** *Approval Duration = 12 months*
  - Documentation that activities of daily living are positively impacted by drug therapy.

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
VUITY (pilocarpine hydrochloride)	

Drug	Strength	Package Size	WAC Pkg Price	Cost/day*	Cost/month*	Cost/year*
Vuity	1.25%	2.5 mL	$73.49	$2.94	$88.19	$1,058.26

Cushing's Syndrome

General Prior Authorization Form

Group Criteria:

- The medication is prescribed by, or in consultation with, an endocrinologist or specialist in the treatment of endogenous Cushing's syndrome.
- Member must have failed a 3-month trial of combination treatment with ketoconazole tablets and metyrapone.
- Member is not a candidate for surgery or surgery has not been curative, or is waiting for surgery or effect of pituitary radiation.

Product Specific: Recorlev

- **Initial criteria**: *Approval Duration = 6 months*
  - Member must have a mean (at least two measurements) 24-hour urine free cortisol (UFC) level that is 3x above the normal range per the reporting laboratory reference range.
- **Renewal Criteria:** *Approval Duration 12 months*
  - Member must have experienced and maintained clinical benefit since starting treatment with the requested medication, as evidenced by medical documentation (e.g. chart notes) attached to the request (subject to clinical review).
  - Member has normalization of 24-hour urine free cortisol (UFC) level per the reporting laboratory reference range:

Product Specific: Korlym

- **Initial criteria**: *Approval Duration = 6 months*
  - Member has uncontrolled hyperglycemia (type 2 diabetes or glucose intolerance) as defined by a hemoglobin A1c > 7%, despite adherence to an anti-diabetes regimen.
- **Renewal Criteria:** *Approval Duration 12 months*
  - Member must have experienced and maintained clinical benefit since starting treatment with the requested medication, as evidenced by medical documentation (e.g. chart notes) attached to the request (subject to

clinical review) such as improvement in cushingoid appearance, acne, hirsutism, striae, psychiatric symptoms, and excess total body weight.
- Member has improved hyperglycemia as a hemoglobin A1c decrease of 1% or greater not attributed to an increase in medications, dosages, or adherence to an anti-diabetes regimen.

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
KORLYM (mifepristone)	
RECORLEV (levoketoconazole)	

Drug	Strength	Package Size	WAC Pkg Price	Cost/day*	Cost/month*	Cost/year*
Ketoconazole	200 mg	30 and 100 tabs each	$31.50	$2.10 - $8.40	$63 - $252	$756 - $3,024
Metyrapone	250 mg	18 caps each	$724.64	$80.52 - $966.19	$2,415.60 - $28,985.70	$28,987.20 - $347,828.40
Mitotane	500 mg	100 tabs each	$1,165.40	$11.65 - $186.46	$349.50 - $5,593.80	$4,194 - $67,125.60
Isturisa	1 mg, 5 mg, and 10 mg	20 and 60 tabs each	$2,643.80	$528.76 - $1,057.88	$15,862.80 - $31,736.40	$190,353.60 - $380,836.80
Recorlev	150 mg	50 tabs each	$13,500	$540 – $2,160	$16,200 - $64,800	$194,400 - $777,600
Signifor	0.3 mg/mL, 0.6 mg/mL, and 0.9 mg/mL	1 mL ampule	$244.17	$488.34	$14,650.20	$175,802.40
Signifor LAR	10 mg, 20 mg, 30 mg, 40 mg, and 60 mg	1 vial	$14,602.56	$486.75	$14,602.56	$175,230.72
cabergoline	0.5 mg	8 tabs each	$25.04	$0.42 - $43.82	$12.52 - $1,314.60	$150.24 - $15,775.20
Korlym	300 mg	28 and 280 tabs each	$16,156	$577 - $2,308	$17,310 - $69,240	$207,720 - $830,880

Vernal Keratoconjunctivitis

General Prior Authorization Form

Group Criteria:

- **Initial Criteria:** *Approval Duration = 6 months*
  - The prescriber must be or be in consultation with an allergist or ophthalmologist.
  - Member has failed* a 3-month trial of a combination of each of the following:
    - Topical dual-acting mast cell stabilizers/antihistamines such as olopatadine, azelastine hydrochloride, epinastine, pemirolast potassium, and ketotifen fumarate
    - Second- and third-generation oral antihistamines such as fexofenadine, loratadine, desloratadine, cetirizine, and 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
- **Renewal Criteria:** *Approval Duration = 12 months*

- Member must have experienced and maintained clinical benefit since starting treatment with the requested medication, as evidenced by medical documentation (e.g. chart notes) attached to the request (subject to clinical review).

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

Drug	Strength	Package Size	WAC Pkg Price	Cost/day*	Cost/month*	Cost/year*
Verkazia	0.1%	120 each	$1,464.96	$48.83	$1,464.96	$17,579.52

Wilson's Disease

General Prior Authorization Form

Product Specific: Trientine hydrochloride

- **Initial criteria**: *Approval Duration = 6 months*
  - Member must have had a 3-month therapeutic trial of a penicillamine agent.

Non-Preferred Agents Criteria:

- Clinical justification must be provided explaining why the member is unable to use the preferred agents (subject to clinical review).
- The member must have failed* a 30-day trial of each preferred agent (listed in boxes below) within the past 2 years, as evidenced by paid claims or pharmacy printouts.

*Failure is defined as product was not effective at maximum tolerated dose or member has a documented intolerance or adverse reaction to inactive ingredients where the non-preferred product is expected to have a different result and other alternatives (e.g. medications in same class) are not an option for the member

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
DEPEN (penicillamine) TITRATAB – *Brand Required*	CUPRIMINE (penicillamine) CAPSULE
trientine hydrochloride	penicillamine capsule
	penicillamine tablet
	SYPRINE (trientine hydrochloride)

Drug	Strength	Package Size	WAC Pkg Price	Cost/day*	Cost/month*	Cost/year*
Penicillamine tablet	250 mg	100 each	$4,652.90	$372.23	$11,166.96	$134,003.52
Penicillamine capsule	250 mg	100 each	$1,080	$86.40	$2,592.00	$31,104.00
Trientine hydrochloride capsule	250 mg	100 each	$750.00	$60.00	$1,800.00	$21,600.00
Cuvrior	Expected to launch in early 2023					

REVIEW OF AMYLOIDOSIS

Overview

Amyloidosis is caused by the deposition of insoluble protein fibrils in tissues and organs. There are several forms of amyloidosis but three main subtypes. These subtypes are AL Amyloidosis, AA Amyloidosis, and transthyretin-related amyloidosis (ATTR). ATTR can be broken down into two types: hereditary ATTR (hATTR) and wild-type ATTR (ATTRwt). The prevalence of hereditary ATTR is poorly characterized but is estimated to be 50,000 individuals worldwide. Most types of ATTR are associated with a 3-to-5-year life expectancy upon diagnosis. Most patients experience neurologic and cardiac symptoms due to the accumulation of these proteins.

Categories of amyloidosis:

- hATTR - PN
  - Val30Met is the most prevalent mutation found for this type
- hATTR-CM (variant ATTR)
  - Caused by a mutation in the transthyretin (TTR) gene
  - Diagnosed in patients as early as their 50s and 60s
  - One variant of hATTR is caused by the Val122Ile mutation (V122I). It is estimated that 4% of African Americans carry this variant.
- ATTRwt-CM (acquired ATTR)
  - Not associated with mutations
  - Associated with aging
  - Predominantly affects men older than 60
- Organ-specific categorization of ATTR
  - ATTR-CM: amyloid aggregates in the myocardium causing cardiomyopathy
  - ATTR-PN: amyloid deposits in the nervous system causing pain, muscle weakness, and autonomic dysfunction

Uncertainties still exist in screening, the assessment of progression, the management of asymptomatic carriers of ATTRv, the use of TTR silencing agents in ATTR-CM, and the financial impact of disease-modifying therapies.

Place in Therapy/Guidelines

Currently, there are three agents approved for treatment of polyneuropathy of hereditary transthyretin-mediated amyloidosis (hATTR - PN) in adults: Onpattro, Amvuttra**,** and Tegsedi. Additionally, there are two agents approved for treatment of cardiomyopathy caused by transthyretin-mediated amyloidosis (hATTR - CM and ATTRwt - CM) in adults: Vyndaqel and Vyndamax. Unfortunately, there are no agents approved for both polyneuropathy and cardiomyopathy.

FDA Approval
Tegsedi: 505(b) New Drug Application (NDA) pathway, Type 1 - New Molecular Entity, PRIORITY; Orphan
Vyndaqel: 505(b) New Drug Application (NDA) pathway, Type 1 - New Molecular Entity, PRIORITY; Orphan
Vyndamax: 505(b) New Drug Application (NDA) pathway, Type 2 - New Active Ingredient, STANDARD; Orphan

Tegsedi (inotersen)

- Mechanism of action: Antisense oligonucleotide
- ATTR-PN Treatment: Liver transplantation has been utilized for most patients. Onpattro, Tegsedi, and Amvuttra are the only treatment options currently**.**
- Patients with ATTRv and polyneuropathy should be considered for TTR silencing therapy with Onpattro or Tegsedi; currently, neither is indicated for ATTRv-CM without polyneuropathy or in ATTRwt-CM. In patients with ATTRv-CM with polyneuropathy, the choice between therapeutic agents is based on accessibility and side-effect profile.

Vyndaqel (tafamidis meglumine) and Vyndamax (tafamidis)

- Mechanism of action: Transthyretin (TTR) dissociation inhibitor
- ATTR-CM Treatment: Previously, treatment options included symptom management and heart transplant. Vyndaqel and Vyndamax are new medication therapies that stabilize the tetramer protein and slow the formation of amyloid that causes ATTR-CM.

- In patients with predominantly cardiac disease resulting from ATTRv or ATTRwt, tafamidis is indicated in those with NYHA class I to III symptoms, and early initiation appears to slow disease progression. The benefit of tafamidis has not been observed in patients with class IV symptoms, severe aortic stenosis, or impaired renal function (GFR < 25 mL/min)

Place in Therapy
The use of combination therapy with an antisense oligonucleotide and a transthyretin (TTR) dissociation inhibitor is appealing to synergistically target both TTR silencing and stabilization of the remaining synthesized protein, but this approach lacks data and may be cost-prohibitive.

Diflusinal (250 mg orally twice daily) may be considered with caution for off-label therapy for asymptomatic ATTR carriers, for patients with ATTR-CM who are not eligible for TTR silencers, or for patients with ATTR-CM who are intolerant of or cannot afford tafamidis.

Given the lack of consensus on defining disease onset in carriers of TTR mutations and what methods (imaging or biomarkers) should be used to monitor disease progression, the timing of initiation of therapy in ATTRv carriers remains an area of uncertainty.

In contrast, in patients with advanced disease, treatment aimed at TTR stabilization is unlikely to be of significant benefit. Although the package label for tafamidis does not provide restrictions on administration, patients with NYHA class IV symptoms, minimally ambulatory patients (walk <100m on a 6-minute walk test), and those with advanced renal dysfunction.

Therapeutically Important Advantages/Disadvantages

- **Tegsedi:**
  - Weekly subcutaneous injection - only self-injectable product of the three available treatment options.
  - Available only through a restricted distribution program called the Tegsedi REMS Program from Accredo Specialty Pharmacy.
- **Vyndaqel and Vyndamax:**
  - Daily oral administration
  - Available exclusively throughout the state pharmacies because of a limited distribution program.
  - Vyndamax 61 mg is bioequivalent to the Vyndaqel 80 mg dose
    - Vyndaqel is the meglumine salt form of tafamidis and available as a 20mg capsule and therefore takes 4 capsules to make a daily dose.
    - Vyndamax is available as a 61mg capsule and therefore has 1 capsule to make a daily dose.

Clinical Studies

- **Tegsedi (NCT01737398)**
  - Randomized, double-blind, placebo-controlled, multicenter clinical trial in adult patients with polyneuropathy caused by hATTR amyloidosis. Participants were randomized to receive either Tegsedi 284 mg (N=113) or placebo (N=60) as a weekly subcutaneous injection for 65 weeks, with 3 doses administered during the first week of treatment.
  - The co-primary efficacy endpoints were the change from baseline to Week 66 in the modified Neuropathy Impairment Scale+7 (mNIS+7) composite score and the Norfolk Quality of Life-Diabetic Neuropathy (QoL-DN) total score.
    - The mNIS+7 is an objective composite score and is a measure of neurologic impairment that evaluates muscle weakness, sensation, reflexes, nerve conduction, and autonomic function. The mNIS+7 Composite Score has a range of -22.32 to 346.32 and a higher mNIS+7 composite score indicates lower function.
      - The Norfolk QoL-DN patient- reported subjective score is a measure of physical function/large fiber neuropathy, symptoms, activities of daily living, small fiber neuropathy, and autonomic neuropathy. The Norfolk QoL-DN total score has a range of -4 to 136, and a higher Norfolk QoL-DN score indicates poorer quality of life. Both endpoints significantly favored Tegsedi.
  - The treatment arm of the pivotal trial had a higher proportion of serious adverse events and an adverse event that led to discontinuation, as well as death (1 drug-related) compared to placebo.
- **Vyndaqel (NCT01994889)**
  - The approval of Vyndaqel and Vyndamax was based on data from a 30-month multicenter, international, randomized, double-blind, placebo-controlled study of 441 patients with ATTR-CM caused by ATTRwt or hATTR-CM (Transthyretin

Amyloidosis Cardiomyopathy Clinical Trial (ATTR-ACT), NCT0199488). The phase 3 trial was done to determine efficacy, safety, and tolerability of Vyndaqel on clinical outcomes (i.e. all-cause mortality and frequency of cardiovascular-related hospitalizations) in subjects with either hATTR or ATTRwt resulting in ATTR-CM. Patients in the study received tafamidis 20 mg daily for 30 months, tafamidis 80 mg daily for 30 months or placebo for 30 months. In addition, patients had New York Heart Association (NYHA) classification I-III. Tafamidis was administered to 264 patients (pooled), and 177 patients received placebo.

- The primary outcome measure was the combination of all-cause mortality and frequency of cardiovascular-related hospitalizations.
  - Both of these endpoints significantly favored Vyndaqel
- Vyndaqel also showed significant improvement compared with placebo in patients' functional capacity and health status at six months and continuing through 30 months.
- Vyndaqel was well tolerated with an observed safety profile comparable to placebo.

Cost

Drug	Strength	Package Size	WAC Pkg Price	Cost/day*	Cost/month*	Cost/year*
Tegsedi	284 mg/1.5 mL	1.5 mL syringe	$6,117.86	$873.98	$26,219.40	$314,632.80
Vyndaqel	20 mg	120 capsules	$19,991.64	$666.39	$19,991.64	$239,899.68
Vyndamax	61 mg	1 blister pack, 30 capsules	$19,991.70	$666.39	$19,991.70	$239,900.40

*Based on lowest per unit WAC cost

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REVIEW OF AMYOTROPHIC LATERAL SCLEROSIS

Overview

Amyotrophic lateral sclerosis (ALS), also referred to as Lou Gehrig's disease, is a neurodegenerative disorder that affects upper and lower motor neurons. Initially, this begins with focal weakness then leads to muscle weakness over time. This disease is progressive and fatal, with most patients dying of respiratory failure within 2 to 5 years of onset. There are approximately 24,800 people with ALS in the United States. The average age of diagnosis is 55 to 65 years of age.

Place in Therapy/Guidelines

Currently, there are only two therapies approved for ALS.

- Rilutek – shown to slightly increase overall survival (2-3 months), but it has not been shown to have an effect on physical functioning
- Radicava – has not been shown to have an effect on overall survival, but it has shown to effect physical functioning. Early onset ALS patients (patients diagnosed with definite or probable ALS) were shown to have a greater magnitude of effect.

There are several agents in the pipeline with different mechanisms of action in late phase development for ALS. Two agents, however, Amylyx's AMXOO35 and Biogen/Ionis' Tofersen are under FDA review with decisions expected in September 2022 and January 2023, respectively.

FDA Approval

Rilutek: 505(b) New Drug Application (NDA) pathway, Type 1 - New Molecular Entity, PRIORITY; Orphan
Exservan: 505(b)(2) New Drug Application (NDA) pathway, Type 3 - New Dosage Form, STANDARD; Orphan
Tiglutik: 505(b)(2) New Drug Application (NDA) pathway, Type 3 - New Dosage Form, STANDARD; Orphan
Radicava: 505(b) New Drug Application (NDA) pathway, Type 1 - New Molecular Entity, STANDARD; Orphan
Radicava ORS: 505(b) New Drug Application (NDA) pathway, Type 3 - New Dosage Form, PRIORITY; Orphan

Place in Therapy

There are no treatments available that stop or significantly slow down the progression of ALS. Riluzole and Radicava are the only agents currently approved. These agents have been shown to only provide modest benefit. Riluzole is the only therapy found to impact survival, however.

Due to the limited agents available, treatment of ALS is focused on symptom management and palliative care.

Therapeutically Important Adverse Effects/Advantages

- **Rilutek, Exservan, and Tiglutik (riluzole):**
  - Mechanism of action: unknown for how it exerts its therapeutic effects in patients with ALS
  - Oral formulations (tablet, film, suspension) available only; tablets may be crushed and given via feeding tube, if necessary
  - Generic option available for tablet
  - Dosing: 50 mg PO BID
- **Radicava and Radicava ORS (edaravone):**
  - Mechanism of action: unknown for how it exerts its therapeutic effects in patients with ALS, but it is thought to work by eliminating oxygen-free radicals, which are responsible for nerve damage.
  - Available as an IV and oral formulation (suspension).
  - Initial dosing: 105 mg (5mL) PO daily for 14 days OR 60mg IV daily for 14 days, followed by 14 days dug free
  - Subsequent dosing: 105 mg (5mL) PO daily for 10 days of a 14-day period OR 60 mg IV daily for 10 days of a 14-day period, followed by 14 days drug free
  - Patients treated with 60 mg IV may be switched to 105 mg (5mL) oral suspension

Clinical Studies

- The global multi-center, open-label study MT-1186-A01, evaluated approximately 185 ALS patients across approximately 50 sites in the U.S., Canada, Europe and Japan over the course of 48 weeks of treatment. After a screening, study participants (18 to 75 years of age) received oral edaravone at a dose designed to deliver the therapeutic equivalent of the IV formulation of Radicava in 28-day cycles- once daily for 10 days in the first 14 days, followed by 14 days without treatment.
- The 24-week safety and tolerability results showed adverse events reported by ≥ 5% of subjects were muscular weakness, fatigue, back pain, constipation, headache, and dyspnea. 5.9% discontinued due to adverse events.
- Changes from baseline in participants' ALS functional rating scale-revised ALSFRS-R score to week 24 were evaluated. At the beginning of the study, patients had an average ALSFRS-R score of 40 (SD 4.5). At Week 24, the average change from baseline in ALSFRS-R score was -5.6 (95% CI -6.5 to -4.8).
- In addition to the current MT-1186-A01 Phase 3 study, an extension study, MT-1186-A03, is ongoing to explore patient safety after 96 weeks of edaravone administration. Changes in participants' ALSFRS-R scores and time until invasive breathing procedures or death also will be assessed.

Cost

Drug	Strength	Package Size	WAC Pkg Price	Cost/day*	Cost/month*	Cost/year*
Rilutek	50 mg tab	60 each	$3,076.80	$102.56	$3,076.80	$36,921.60
Exservan	50mg film	60 each	$3,142.80	$104.76	$3,142.80	$37,713.60
Tiglutik	50 mg/10 mL suspension	600 mL bottle	$3,510.00	$117.00	$3,510.00	$42,120.00
Riluzole (generic)	50 mg tab	60 each	$40.20	$1.34	$40.20	$482.40
Radicava	30 mg/100 mL IV	100 mL bag	$612.00	$421.60	$12,648.00	$151,776.00
Radicava ORS	105 mg/5 mL suspension	50 mL bottle	$12,719.50	$438.12	$13,143.48	$157,721.80

*Based on lowest per unit WAC cost

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REVIEW OF CHELATING AGENTS

Overview

Chelating agents are utilized for reducing the amount of harmful heavy metals found in the blood and tissue. These agents are generally classified by which metal they target. The most common target metals include iron, copper, mercury, and lead. Some chelating agents have a high degree of specificity for a particular target metal, while others may target multiple metals.

Place in Therapy/Guidelines

Management of excessive heavy metal accumulation or poisoning is highly dependent on avoiding or eliminating the source of exposure. Chelating agents are used in conjunction with avoiding the source and have been found to be very effective.

- **Iron chelating agents:** deferoxamine (IV), deferasirox (PO), and deferiprone (PO)
- **Copper chelating agents:** penicillamine (PO), trientine (PO), and dimercaprol (IV)
    - These agents are used in the treatment of Wilson's disease
    - Dimercaprol is also effective in lowering arsenic and mercury levels
- **Lead and other heavy metals:** succimer (dimercaptonol) (PO), dimercaprol (BAL) (IV), and ethylenediaminetetraacetic acid (EDTA) (IV)
    - Succimer appears to be more effective and better tolerated than other agents
    - These agents can also be used for lowering arsenic, mercury, and cadmium levels

FDA Approval

Ferriprox tablet: 505(b) New Drug Application (NDA) pathway, Type 1 - New Molecular Entity, STANDARD; Orphan
Ferriprox solution: 505(b) New Drug Application (NDA) pathway, Type 3 – New Dosage Form, STANDARD; Orphan
Ferriprox BID tablet: 505(b) New Drug Application (NDA) pathway, Type 5 – New Formulation or New Manufacturer, STANDARD; Orphan

Therapeutically Important Adverse Effects/Advantages

- **Ferriprox (deferiprone):**
    - Mechanism of action: binds with ferric ions to form neutral 3:1 (deferiprone:iron) complexes that are stable over a large range of pH values. This binding affinity is lower for other metals (zinc and copper) than for iron.
    - Absolute neutrophil count, ALT, and zinc levels must be tested at baseline and monitored through treatment. Weekly white blood cell counts are recommended.
    - Black box warning: Agranulocytosis and Neutropenia
    - ADULT dosing for transfusion hemosiderosis, With thalassemia syndrome, sickle cell disease or other anemias:
        - (1000-mg tablet, 3-times-daily regimen) Initial, 75 mg/kg/day (actual body weight) orally in 3 divided doses
        - (500-mg tablet, 3-times-daily regimen) Initial, 75 mg/kg/day (actual body weight) orally in 3 divided doses
        - (100 mg/mL oral solution) Initial, 25 mg/kg (actual body weight) orally 3 times per day for a total of 75 mg/kg/day
        - (Ferriprox (R) Twice-a-Day, 1000-mg tablet) Initial, 75 mg/kg/day (actual body weight) orally in 2 divided doses per day, taken approximately 12 hours apart, with food
        - Maintenance, adjust dosage to individual patient response and therapeutic goals (maintenance or reduction of body iron burden); MAX 99 mg/kg/day in divided doses
    - PEDIATRIC dosing for transfusion hemosiderosis, With thalassemia syndrome, sickle cell disease or other anemias:
        - (1000-mg tablet, 3-times-daily regimen; 8 years or older) Initial, 75 mg/kg/day (actual body weight) orally in 3 divided doses
        - (500-mg tablet, 3-times-daily regimen; 8 years or older) Initial, 75 mg/kg/day (actual body weight) orally in 3 divided doses
        - (100 mg/mL oral solution; 3 years or older) Initial, 25 mg/kg (actual body weight) orally 3 times per day for a total of 75 mg/kg/day

- (Ferriprox (R) Twice-a-Day, 1000-mg tablet; 8 years or older) Initial, 75 mg/kg/day (actual body weight) orally in 2 divided doses, taken approximately 12 hours apart, with food
- Maintenance, adjust dosage to individual patient response and therapeutic goals (maintenance or reduction of body iron burden); MAX 99 mg/kg/day in divided doses

Clinical Studies

- Transfusional Iron Overload in Patients with Thalassemia Syndromes
  - A prospective, planned, pooled analysis of patients with thalassemia syndromes from several studies
  - Efficacy of deferiprone was assessed in transfusion-dependent iron overload patients in whom previous iron chelation therapy had failed or was considered inadequate due to poor tolerance
  - Deferiprone therapy (35-99 mg/kg/day) was considered successful in individual patients who experienced a ≥ 20% decline in serum ferritin within one year of starting therapy.
  - Data from a total of 236 patients were analyzed. Of the 224 patients with thalassemia who received deferiprone monotherapy and were eligible for serum ferritin analysis, 105 (47%) were male and 119 (53%) were female. The mean age of these patients was 18.2 years (range 2 to 62; 91 patients were <17).
  - For the patients in the analysis, the endpoint of at least a 20% reduction in serum ferritin was met in 50% (of 236 subjects), with a 95% confidence interval of 43% to 57%.
- Efficacy and Safety of Ferriprox® in Patients With Sickle Cell Disease or Other Anemias (FIRST) NCT02041299
  - An actively-controlled non-inferiority study compared the efficacy of FERRIPROX to that of deferoxamine in patients with sickle cell disease and other transfusion-dependent anemias by evaluating liver iron concentration (LIC)
  - The efficacy of FERRIPROX was established based upon the change in LIC from baseline after 12 months of FERRIPROX (75 or 99 mg/kg/day) compared to deferoxamine (20 or 40 mg/kg (pediatric patients); 40 or 50 mg/kg (adult patients)).
  - Among the 152 FERRIPROX treated patients, the mean age was 16.9; 54.6% were male; 78.9% were White, 15.1% were Black, and 5.9% were Multi-racial
  - Over 12 months, the Least Squares estimate of mean decrease from baseline in LIC was 4.13 ± 0.50 mg/g dw for FERRIPROX and 4.38 ± 0.59 mg/g dw for deferoxamine, and the non-inferiority criterion was met.

Cost

Drug	Strength	Package Size	WAC Pkg Price	Cost/day*	Cost/month*	Cost/year*
Ferriprox	100 mg/mL; 500 mg; 1,000 mg; 1,000 mg BID	500 mL solution; 100 tab; 50 tab	$7,650; $7,649; $7,648.50; $9,741	$1,071; $803.15; $803.10; $1,022.81	$32,130; $24,094.50; $24,093; $30,684.30	$385,560; $289,134; $289,116; $368,211.60
Deferiprone (generic)	500 mg; 1,000 mg	100 tab; 50 tab	$6,148.00; $6,975.50	$645.54; $732.43	$19,366.20; $21,972.90	$232,394.40; $263,674.80

*Based on lowest per unit WAC cost

References:
1. Ferriprox (deferiprone) 500 mg tablets [prescribing information]. Cary, NC: Chiesi USA Inc; November 2021.
2. Ferriprox (deferiprone) oral solution [prescribing information]. Cary, NC: Chiesi USA Inc; November 2021.
3. Ferriprox (deferiprone) 1,000 mg tablets [prescribing information]. Cary, NC: Chiesi USA Inc; November 2021.
4. LiverTox: Clinical and Research Information on Drug-Induced Liver Injury [Internet]. Bethesda (MD): National Institute of Diabetes and Digestive and Kidney Diseases; 2012-. Chelating Agents. [Updated 2017 Jan 23]. Available from: https://www.ncbi.nlm.nih.gov/books/NBK548531/

5. LiverTox: Clinical and Research Information on Drug-Induced Liver Injury [Internet]. Bethesda (MD): National Institute of Diabetes and Digestive and Kidney Diseases; 2012-. Deferiprone. [Updated 2017 Dec 27]. Available from: https://www.ncbi.nlm.nih.gov/books/NBK548086/
6. Kwiatkowski JL, Hamdy M, El-Beshlawy A, Ebeid FSE, Badr M, Alshehri A, Kanter J, Inusa B, Adly AAM, Williams S, Kilinc Y, Lee D, Tricta F, Elalfy MS. Deferiprone vs deferoxamine for transfusional iron overload in SCD and other anemias: a randomized, open-label noninferiority study. Blood Adv. 2022 Feb 22;6(4):1243-1254. doi: 10.1182/bloodadvances.2021004938. PMID: 34847228; PMCID: PMC8864642.

RSV Discussion

American Academy of Pediatrics Recommendations:

Following the institution of nonpharmacologic interventions (eg, masking, social distancing) for the prevention of COVID-19 in March of 2020, the number of RSV infections in the United States decreased rapidly and dramatically. Interactions between SARS-CoV-2 and other respiratory viruses also may have altered RSV epidemiology. RSV activity in the United States remained very low through the traditional 2020-2021 fall-winter season but increased in the spring of 2021, with numbers of cases rising to a level similar to a fall-winter season throughout the different regions of the United States and continuing over the spring, summer, and fall. This interseasonal activity was a marked deviation from the typical RSV seasonal epidemiology and was not generally followed by a second wave of increased RSV circulation in the winter.

Currently, RSV activity in the United States remains variable by region but is increasing in some parts of the country. The Centers for Disease Control and Prevention (CDC) monitors RSV activity in the United States in collaboration with state and county health departments and commercial and clinical laboratories. These data are available from the National Respiratory and Enteric Virus Surveillance System (NREVSS)

With the shift in seasonality noted in 2021 and the current regional rise in interseason RSV cases, the AAP continues to support the use of palivizumab in eligible infants in any region experiencing rates of RSV activity at any time in 2022 similar to a typical fall-winter season. The AAP recommends initiating the standard administration of palivizumab, which consists of 5 consecutive monthly doses. This regimen provides serum levels associated with protection for 6 months, the length of a typical RSV season.

Reference:

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/

Category Criteria: *Approval Duration = 5 weight-based doses within 6 months. No further prior authorization approvals will be given following season offset.*

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) Midwest Region
RSV Regional Trends - NREVSS | CDC

The Midwest region contains:
ND, MN, SD, NE, KS, IA, MO, WI, IL, MI, IN, OH

CDC Seasonal Data:
New methodology: Orange - Start Date (6/29/2021) and End Date (12/25/2021)
Old methodology: Green - Start Date (10/19/2021) and End date (04/21/2022)

Week	Date	PCR %	Week	Date	PCR %
38	05/01/21	0.528	72	12/25/21	2.446
39	05/08/21	0.772	73	01/01/22	2.250
40	05/15/21	1.027	74	01/08/22	2.040
41	05/22/21	1.570	75	01/15/22	1.568
42	05/29/21	1.957	76	01/22/22	1.482
43	06/05/21	3.008	77	01/29/22	1.215
44	06/12/21	2.851	78	02/05/22	1.139
45	06/19/21	3.644	79	02/12/22	1.291
46	06/26/21	5.911	80	02/19/22	1.143
47	07/03/21	5.670	81	02/26/22	1.052
48	07/10/21	8.358	82	03/05/22	1.037
49	07/17/21	9.324	83	03/12/22	1.095
50	07/24/21	13.525	84	03/19/22	1.130
51	07/31/21	15.945	85	03/26/22	0.941
52	08/07/21	16.661	86	04/02/22	1.059
53	08/14/21	16.226	87	04/09/22	0.854
54	08/21/21	21.921	88	04/16/22	1.192
55	08/28/21	20.783	89	04/23/22	0.936
56	09/04/21	20.548	90	04/30/22	1.119
57	09/11/21	19.446	91	05/07/22	0.873
58	09/18/21	18.233	92	05/14/22	1.214
59	09/25/21	18.413	93	05/21/22	1.223
60	10/02/21	18.213	94	05/28/22	1.350
61	10/09/21	17.660	95	06/04/22	1.797
62	10/16/21	16.468	96	06/11/22	1.827
63	10/23/21	15.765	97	06/18/22	1.950
64	10/30/21	14.583	98	06/25/22	2.224
65	11/06/21	11.779	99	07/02/22	2.230
66	11/13/21	10.022	100	07/09/22	2.034
67	11/20/21	7.224	101	07/16/22	2.182
68	11/27/21	5.229	102	07/23/22	1.984
69	12/04/21	5.625	103	07/30/22	2.151
70	12/11/21	3.822	104	08/06/22	2.740
71	12/18/21	2.669			

New Template:

PRESCRIBER RESPONSE: *Please fax it to 866-798-4904 when completed.*

All information used to generate the enclosed letter, including Prescriber identification, was obtained from Pharmacy Claims Data. If there appears to be an error in the information provided, please note the discrepancy. Thank you for your cooperation.

Is this patient under your care
_____Yes
_____ No, but has been in the past
_____ No, I provide ER / urgent care services or provided coverage for a colleague
_____ No, never

Did you do anything with this information?

_____Yes, what action did you take? _____

_____No, why not? _____

Did you find this information useful?
_____Yes
_____No

Please explain how this information was useful/not useful or other information that you would consider useful:

Previous Template:

PRESCRIBER RESPONSE: *Please fax it to 866-798-4904 when completed.*

All information used to generate the enclosed letter, including Prescriber identification, was obtained from Pharmacy Claims Data. If there appears to be an error in the information provided, please note the discrepancy. Thank you for your cooperation.

1. This patient **is** under my care:

_____ I have reviewed the information and will continue without change.
_____ however, I did not prescribe the following medication(s)_____.
_____ and has an appointment to discuss drug therapy.
_____ however, has not seen me recently.
_____ however, I was not aware of other prescribers.
_____ I have reviewed the information and modified drug therapy.
_____ I have not modified drug therapy because benefits outweigh the risks.
_____ I have tried to modify therapy, however the patient refuses to change.
_____ I have tried to modify therapy, however symptoms reoccurred.

2. This patient **is not** under my care:

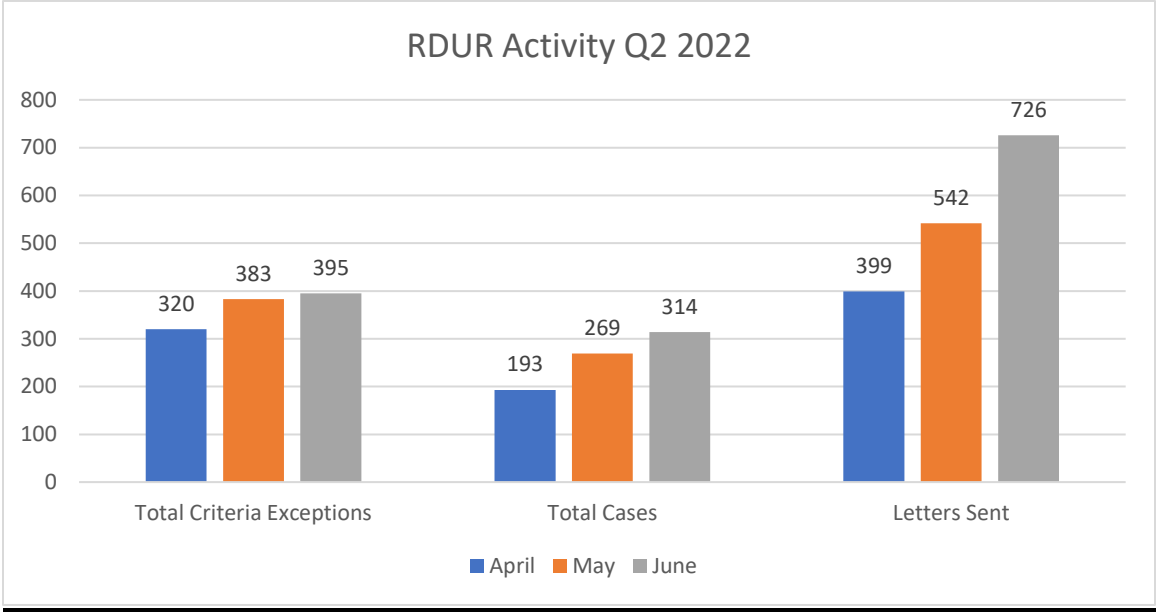
_____ however, I did prescribe medication while covering for other MD or in the ER.
_____ but has previously been a patient of mine.
_____ because the patient recently expired.
_____ and has never been under my care.

3. I have reviewed the enclosed information and found it:
_____ very useful_____ useful_____ neutral_____ somewhat useful_____ not useful.

4. Please check here if you wish to receive reference information on the identified problem___. (Please provide a fax number if available_____-_____-_____.)

Comments: _____
_____
_____
_____
If you would like to receive additional updates about the ND Medicaid pharmacy program by email, please provide your email address: _____

RDUR Activity Overview: Q2 2022



April Cases by Type of Criteria

Criteria Description	# of Cases	% of Cases
DRUG-DRUG INTERACTIONS	2	1.04%
DRUG-DISEASE INTERACTIONS	12	6.22%
INAPPROPRIATE PEDIATRIC THERAPY	27	13.99%
OVERUTILIZATION	40	20.73%
UNDERUTILIZATION	112	58.03%

DRUG-DRUG INTERATIONS: DUAL P-GP & 3A4 INHIBITION
DRUG-DISEASE INTERACTIONS: STATINS/NIACIN/FIBRIC ACID & HEPATIC IMPAIRMENT, NSAIDS & CV PROBLEMS
OVERUTILIZATION: SEDATIVE AGENTS
UNDERUTILIZATION: LONG-TERM ASTHMA CONTROLLERS, PIOGLITAZONE, METFORMIN IR/XR

May Cases by Type of Criteria

Criteria Description	# of Cases	% of Cases
DRUG-DISEASE INTERACTIONS	196	72.86%
DRUG-DRUG INTERACTION	58	21.56%
UNDERUTILIZATION	15	5.58%

DRUG-DISEASE INTERACTIONS: CYCLOBENZAPRINE & ARRHYTHMIAS, ZOPIDEM/SULFONYLUREA & HYPERKALEMIA, OLANZAPINE/MIRTAZAPINE & NARROW ANGLE GLAUCOMA
DRUG-DRUG INTERACTIONS: CETIRIZINE & CHLOROQUINE, ESCITALOPRAM/CITALOPRAM/FLUOXETINE/FLUVOXAMINE/PAROXETINE/SERTRALINE & PIMOZIDE
UNDERUTILIZATION: VENLAFAXINE IR/ER

June Cases by Type of Criteria

Criteria Description	# of Cases	% of Cases
ATYPICAL NEUROLEPTICS AND METABOLIC EFFECTS	10	3.18%
BISPHOSPHONATE ADE	11	3.50%
CONTRACEPTION & NICOTINE DEPENDENCE	4	1.27%
DRUG-DISEASE INTERACTION	4	1.27%
MODAFINIL AND NARCOTIC USE	1	0.32%
OVERUTILIZATION	13	4.14%
SUPPORT ACT CRITERIA	136	43.32%
TIZANIDINE TOXICITY	4	1.27%
UNDERUTILIZATION	131	41.72%

DRUG-DISEASE INTERACTIONS: ROSUVASTATIN & RENAL IMPAIRMENT, OXYBUTYNIN & URINARY RETENTION
OVERUTILIZATION: AFORMOTERAL, PREGABALIN, DESVENLAFAXINE
UNDERUTILIZATION: CLOZAPINE, OLANZAPINE, RISPERIDONE, ZIPRASIDONE, ARIPIPRAZOLE, QUETIAPINE, CHLORPROMAZINE, ARBS, DULOXETINE, DARUNAVIR, TRUVADA, ZIDOVUDINE, DESVENLAFAXINE, TIOTROPIUM/OLODATEROL, EMPAGLIFLOZIN/METFORMIN

NORTH DAKOTA MEDICAID
RETROSPECTIVE DRUG UTILIZATION REVIEW
CRITERIA RECOMMENDATIONS
3RD QUARTER 2022

Criteria Recommendations ***Approved Rejected***

1. Daridorexant / Overuse _____ _____

Alert Message: Quviviq (daridorexant) may be over-utilized. The recommended dosage range is 25 mg to 50 mg of daridorexant taken orally no more than once per night within 30 minutes of going to bed (with at least 7 hours remaining prior to planned awakening).

Drugs/Diseases

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

Max Dose: 50 mg/day

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Quviviq Prescribing Information, April 2022, Idorsia Pharmaceuticals Ltd.

2. Daridorexant / Overuse – Hepatic Impairment _____ _____

Alert Message: Quviviq (daridorexant) may be over-utilized. The maximum recommended dosage in patients with moderate hepatic impairment (Child-Pugh score 7–9) is 25 mg of daridorexant no more than once per night. Moderate hepatic impairment may increase daridorexant systemic exposure to a clinically relevant extent, which may increase the frequency or severity of adverse reactions.

Drugs/Diseases

Util A	Util B	Util C
Daridorexant	Hepatic Impairment	

Max Dose: 25 mg/day

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Quviviq Prescribing Information, April 2022, Idorsia Pharmaceuticals Ltd.

3. Daridorexant / Severe Hepatic Impairment _____ _____

Alert Message: Quviviq (daridorexant) is not recommended in patients with severe hepatic impairment (Child-Pugh score ≥ 10). Daridorexant has not been studied in this patient population.

Drugs/Diseases

Util A	Util B	Util C
Daridorexant	Cirrhosis Liver Failure	

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Quviviq Prescribing Information, April 2022, Idorsia Pharmaceuticals Ltd.

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

4. Daridorexant / Therapeutic Appropriateness _____ _____
Alert Message: The safety and effectiveness of Quviviq (daridorexant) have not been established in pediatric patients.

Drugs/Diseases
Util A Util B Util C
Daridorexant

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Quviviq Prescribing Information, April 2022, Idorsia Pharmaceuticals Ltd.

5. Daridorexant / Narcolepsy _____ _____
Alert Message: Quviviq (daridorexant) is contraindicated in patients with narcolepsy.

Drugs/Diseases
Util A Util B Util C
Daridorexant Narcolepsy

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Quviviq Prescribing Information, April 2022, Idorsia Pharmaceuticals Ltd.

6. Daridorexant / Therapeutic Appropriateness - Duration _____ _____
Alert Message: Because sleep disturbances may be the presenting manifestation of a medical and/or psychiatric disorder, treatment of insomnia should be initiated only after careful evaluation of the patient. The failure of insomnia to remit after 7 to 10 days of treatment may indicate the presence of a primary psychiatric and/or medical illness that should be evaluated. Worsening of insomnia or the emergence of new cognitive or behavioral abnormalities may be the result of an unrecognized underlying psychiatric or medical disorder and can emerge during the course of treatment with sleep-promoting drugs such as Quviviq (daridorexant).

Drugs/Diseases
Util A Util B Util C
Daridorexant

Day Supply: > 10 days

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Quviviq Prescribing Information, April 2022, Idorsia Pharmaceuticals Ltd.

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

7. Daridorexant / Complex Sleep Behavior _____ _____

Alert Message: Complex sleep behaviors, including sleepwalking, sleep-driving, and engaging in other activities while not fully awake (e.g., preparing and eating food, making phone calls, having sex), have been reported to occur with the use of hypnotics, including orexin receptor antagonists such as Quviviq (daridorexant). These events can occur in hypnotic-naïve as well as in hypnotic-experienced persons. Discontinue daridorexant immediately if a patient experiences a complex sleep behavior.

Drugs/Diseases

Util A	Util B	Util C
Daridorexant	Other Sleep Disorders	
	Sleepwalking	
	Parasomnia	

References:

Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Quviviq Prescribing Information, April 2022, Idorsia Pharmaceuticals Ltd.

8. Daridorexant / Depression & Suicidality _____ _____

Alert Message: As with other hypnotics, Quviviq (daridorexant) should be administered with caution in patients exhibiting symptoms of depression. Worsening of depression or suicidal ideation may occur. Patients with psychiatric disorders, including insomnia, are at increased risk of suicide. In primarily depressed patients treated with hypnotics, worsening of depression and suicidal thoughts and actions (including completed suicides) have been reported.

Drugs/Diseases

Util A	Util B	Util C
Daridorexant	Depression	
	Suicidal Ideation	

References:

Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Quviviq Prescribing Information, April 2022, Idorsia Pharmaceuticals Ltd.

9. Daridorexant / Compromised Respiratory Function _____ _____

Alert Message: The effects of Quviviq (daridorexant) on respiratory function should be considered if prescribed to patients with compromised respiratory function. Daridorexant has not been studied in patients with moderate OSA requiring CPAP or severe OSA. Daridorexant has not been studied in patients with severe COPD.

Drugs/Diseases

Util A	Util B	Util C
Daridorexant	COPD	
	Obstructive Sleep Apnea	

References:

Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Quviviq Prescribing Information, April 2022, Idorsia Pharmaceuticals Ltd.

10. Daridorexant / Strong CYP3A4 Inhibitors _____ _____

Alert Message: The concurrent use of Quviviq (daridorexant) with a strong CYP3A4 inhibitor is not recommended. Daridorexant is a CYP3A4 substrate, and concomitant use with a strong 3A4 inhibitor has been shown to significantly increase exposure to daridorexant, increasing the risk of daridorexant-related adverse reactions.

Drugs/Diseases

Util A	Util B		Util C
Daridorexant	Clarithromycin	Nelfinavir	
	Cobicistat	Posaconazole	
	Indinavir	Ritonavir	
	Itraconazole	Saquinavir	
	Ketoconazole	Voriconazole	
	Nefazodone		

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Quviviq Prescribing Information, April 2022, Idorsia Pharmaceuticals Ltd.

11. Daridorexant / Moderate CYP3A4 Inhibitors _____ _____

Alert Message: Concomitant use with Quviviq (daridorexant) with a moderate CYP3A4 inhibitor increases exposure to daridorexant, which may increase the risk of daridorexant-related adverse reactions. The recommended dose of daridorexant is 25 mg when used with a moderate CYP3A4 inhibitor.

Drugs/Diseases

Util A	Util B			Util C
Daridorexant	Atazanavir	Diltiazem	Verapamil	
	Aprepitant	Dronedarone		
	Cimetidine	Erythromycin		
	Ciprofloxacin	Fluconazole		
	Crizotinib	Fluvoxamine		
	Cyclosporine	Imatinib		

Max Dose: 25 mg/day

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Quviviq Prescribing Information, April 2022, Idorsia Pharmaceuticals Ltd.

12. Daridorexant / Strong to Moderate CYP3A4 Inducers _____ _____

Alert Message: Concomitant use of Quviviq (daridorexant) with a strong or moderate CYP3A4 inducer decreases exposure to daridorexant, which may reduce the efficacy of daridorexant. Concomitant use of daridorexant with a strong or moderate inducer of CYP3A4 is not recommended.

Drugs/Diseases

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

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Quviviq Prescribing Information, April 2022, Idorsia Pharmaceuticals Ltd.

13. Daridorexant / CNS Depressants _____ _____

Alert Message: Concomitant use of alcohol or other CNS depressants with Quviviq (daridorexant) may lead to additive impairment of psychomotor performance and risk of CNS depression. Use daridorexant with caution in patients receiving CNS depressants. Consider dose adjustment of daridorexant and/or the CNS depressant(s) if used concomitantly. Avoid alcohol consumption with daridorexant.

Drugs/Diseases

Util A	Util B	Util C
Daridorexant	CNS Depressants	

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Quviviq Prescribing Information, April 2022, Idorsia Pharmaceuticals Ltd.

14. Daridorexant / Pregnancy / Pregnancy Negating _____ _____

Alert Message: There are no available data on Quviviq (daridorexant) use in pregnant women to evaluate for drug-associated risks of major birth defects, miscarriage, or other adverse maternal or fetal outcomes. There will be a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to daridorexant during pregnancy. Pregnant women exposed to daridorexant and their healthcare providers are encouraged to call and register with Idorsia Pharmaceuticals Ltd.

Drugs/Diseases

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

Gender: Female
Age Range: 11 – 50 yoa

References:
References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Quviviq Prescribing Information, April 2022, Idorsia Pharmaceuticals Ltd.

15. Daridorexant / Therapeutic Appropriateness _____ _____

Alert Message: There are no data on the presence of Quviviq (daridorexant) in human milk, the effects on the breastfed infant, or the effects on milk production. Daridorexant and its metabolites were 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. Infants exposed to daridorexant through breastmilk should be monitored for excessive sedation. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for daridorexant and any potential adverse effects on the breastfed infant from daridorexant or the underlying maternal condition.

Drugs/Diseases

Util A	Util B	Util C
Daridorexant	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Quviviq Prescribing Information, April 2022, Idorsia Pharmaceuticals Ltd.

16. Tezepelumab-ekko / Overuse _____ _____
Alert Message: Tezspire (tezepelumab-ekko) may be over-utilized. The recommended dosage of tezepelumab-ekko is 210 mg administered subcutaneously, once every 4 weeks.

Drugs/Diseases

Util A	Util B	Util C
Tezepelumab-ekko		

Max Dose: 210 mg q 4 weeks

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Tezspire Prescribing Information, Dec. 2021, AstraZeneca.

17. Tezepelumab-ekko / Therapeutic Appropriateness _____ _____
Alert Message: The safety and effectiveness of Tezspire (tezepelumab-ekko) in patients younger than 12 years of age have not been established.

Drugs/Diseases

Util A	Util B	Util C
Tezepelumab-ekko		

Age Range: 0 – 11 yoa

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Tezspire Prescribing Information, Dec. 2021, AstraZeneca.

18. Tezepelumab-ekko / Corticosteroids _____ _____
Alert Message: Do not discontinue systemic or inhaled corticosteroids abruptly upon initiation of therapy with Tezspire (tezepelumab-ekko). Reductions in corticosteroid dose, if appropriate, should be gradual and performed under the direct supervision of a physician. Reduction in corticosteroid dose may be associated with systemic withdrawal symptoms and/or unmask conditions previously suppressed by systemic corticosteroid therapy.

Drugs/Diseases

Util A	Util B	Util C
Tezepelumab-ekko	Corticosteroids	

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Tezspire Prescribing Information, Dec. 2021, AstraZeneca.

19. Tezepelumab-ekko / Helminth Infections _____ _____

Alert Message: Treat patients with pre-existing helminth infections before initiating therapy with Tezspire (tezepelumab-ekko). If patients become infected while receiving treatment with tezepelumab-ekko and do not respond to anti-helminth treatment, discontinue treatment with tezepelumab-ekko until the infection resolves.

Drugs/Diseases

Util A	Util B	Util C
Tezepelumab-ekko	Helminth Infection	

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Tezspire Prescribing Information, Dec. 2021, AstraZeneca.

20. Tezepelumab-ekko / Pregnancy / Pregnancy Negating _____ _____

Alert Message: There are no available data on Tezspire (tezepelumab-ekko) use in pregnant women to evaluate for any drug-associated risk of major birth defects, miscarriage, or other adverse maternal or fetal outcomes. Placental transfer of monoclonal antibodies such as tezepelumab-ekko is greater during the third trimester of pregnancy; therefore, potential effects on a fetus are likely to be greater during the third trimester of pregnancy.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Tezepelumab-ekko	Pregnancy	Abortion
		Delivery
		Miscarriage

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Tezspire Prescribing Information, Dec. 2021, AstraZeneca.

21. Tezepelumab-ekko / Lactation _____ _____

Alert Message: There is no information regarding the presence of Tezspire (tezepelumab-ekko) in human milk, its effects on the breastfed infant, or its effects on milk production. However, tezepelumab-ekko is a human monoclonal antibody immunoglobulin (IgG2 lambda), and immunoglobulin G (IgG) is present in human milk in small amounts. The developmental and health benefits of breastfeeding should be considered, along with the mother's clinical need for tezepelumab-ekko and any potential adverse effects on the breastfed infant from tezepelumab-ekko or the underlying maternal condition.

Drugs/Diseases

Util A	Util B	Util C
Tezepelumab-ekko	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Tezspire Prescribing Information, Dec. 2021, AstraZeneca.

22. Tezepelumab-ekko / Non-adherence _____ _____

Alert Message: Based on refill history, your patient may be underutilizing Tezspire (tezepelumab-ekko). 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
Tezepelumab-ekko		

References:

Osterberg L, Blaschke T. Adherence to Medication. N Enel J Med 2005; 353:487- 497.
Murphy AC, Proeschal A, Brightling CE, et al. The Relationship Between Clinical Outcomes and Medication Adherence in difficult-to-control Asthma. Thorax. 2012;67:751-753.
Lindsay JT, Heaney LG. Nonadherence in Difficult Asthma - Facts, Myths, and a Time to Act. Patient Prefer Adherence. 2013;7:329-336. Published 2013 Apr 19. doi:10.2147/PPA.S38208

23. Baclofen Oral Solution / Overuse _____ _____

Alert Message: Ozobax (baclofen oral solution) may be over-utilized. The maximum recommended dose of baclofen oral solution is 80 mg daily (20 mg four times a day).

Drugs/Diseases

Util A	Util B	Util C
Baclofen Oral Solution		

Max Dose: 80 mg/day

References:

Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Ozobax Prescribing Information, Sept. 2019, Metacel Pharmaceuticals, LLC.

24. Baclofen Oral Solution / Therapeutic Appropriateness _____ _____

Alert Message: The safety and effectiveness of Ozobax (baclofen oral solution) in pediatric patients below the age of 12 years have not been established.

Drugs/Diseases

Util A	Util B	Util C
Baclofen Oral Solution		

Age Range: 0 – 11 yoa

References:

Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Ozobax Prescribing Information, Sept. 2019, Metacel Pharmaceuticals, LLC.

25. Baclofen Oral Solution / Renal Impairment _____ _____

Alert Message: Because baclofen is primarily excreted unchanged by the kidneys, Ozobax (baclofen oral solution) should be used with caution in patients with renal impairment. Dosage reduction may be necessary for patients with renal impairment.

Drugs/Diseases

Util A	Util B	Util C
Baclofen Oral Solution	Renal Impairment	

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Ozobax Prescribing Information, Sept. 2019, Metacel Pharmaceuticals, LLC.

26. Baclofen Oral Solution / Pregnancy / Pregnancy Negating _____ _____

Alert Message: There are no adequate data on the risk of major birth defects, miscarriages, or other maternal adverse outcomes associated with the use of Ozobax (baclofen oral solution) in pregnant women. There are adverse effects on fetal outcomes associated with withdrawal from baclofen after delivery.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Baclofen Oral Solution	Pregnancy	Abortion
		Delivery
		Miscarriage

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Ozobax Prescribing Information, Sept. 2019, Metacel Pharmaceuticals, LLC.

27. Baclofen Oral Solution / Lactation _____ _____

Alert Message: At recommended oral doses, baclofen is present in human milk. There are no human data on the effects of baclofen on milk production. Withdrawal symptoms can occur in breastfed infants when maternal administration of Ozobax (baclofen oral solution) is stopped, or when breastfeeding is stopped. There are no adequate data on other effects of baclofen on the breastfed infant. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for baclofen oral solution and any potential adverse effects on the breastfed infant from baclofen oral solution or the underlying maternal condition.

Drugs/Diseases

Util A	Util B	Util C
Baclofen Oral Solution	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Ozobax Prescribing Information, Sept. 2019, Metacel Pharmaceuticals, LLC.

Criteria Recommendations	*Approved*	*Rejected*

28. Baricitinib / Overutilization _____ _____

Alert Message: The maximum recommended dose of Olumiant (baricitinib) for the treatment of alopecia areata is 4 mg per day.

Drugs/Diseases

Util A	Util B	Util C (Negating)
Baricitinib		Strong OAT3 Inhibitors CKD Stage 3, 4, 5 ESRD Dialysis Rheumatoid Arthritis

Max Dose: 4 mg/day

References:

Olumiant Prescribing Information, June 2022, Eli Lilly and Company.

29. Baricitinib / OAT3 Inhibitors / Alopecia Areata _____ _____

Alert Message: The recommended dose of Olumiant (baricitinib) in patients with alopecia areata taking strong organic anion transporter 3 (OAT3) inhibitors is 2 mg once daily (half the maximum recommended dose of 4 mg). Baricitinib is an OAT3 substrate, and concurrent use with a strong inhibitor of OAT3 inhibitor may result in increased baricitinib exposure.

Drugs/Diseases

Util A	Util B	Util C (Include)
Baricitinib	Probenecid Teriflunomide Leflunomide	Alopecia Areata

Max Dose: 2 mg/day

References:

Olumiant Prescribing Information, June 2022, Eli Lilly and Company.

30. Baricitinib / Renal Impairment / Alopecia Areata _____ _____

Alert Message: Olumiant (baricitinib) may be over-utilized. The recommended maximum dose of baricitinib in patients with alopecia areata with moderate renal impairment (estimated glomerular filtration rate (GFR) between 30 and 60 mL/min/1.73 m2) is 2 mg once daily. Baricitinib is not recommended for use in patients with alopecia areata and severe renal impairment (estimated GFR of less than 30 mL/min/1.73 m2).

Drugs/Diseases

Util A	Util B	Util C (Included)
Baricitinib	CKD 3	Alopecia areata

References:

Olumiant Prescribing Information, June 2022, Eli Lilly and Company.

31. Baricitinib / Myocardial Infarction & Stoke _____ _____

Alert Message: Olumiant (baricitinib), a Janus kinase inhibitor (JAK), should be discontinued in patients that have experienced a myocardial infarction or stroke. In a postmarketing safety study, RA patients ≥50 years of age with ≥1 cardiovascular risk factor treated with another JAK inhibitor, a higher rate of major adverse cardiovascular events (defined as cardiovascular death, myocardial infarction, and stroke) was observed when compared with TNF blockers. Patients who are current or past smokers are at additional increased risk.

Drugs/Diseases

Util A	Util B	Util C
Baricitinib	Myocardial Infarction	
	Stroke	

References:

Olumiant Prescribing Information, June 2022, Eli Lilly and Company.

32. GLP-1 Receptor Agonists / Gallbladder Disease _____ _____

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

Drugs/Diseases

Util A	Util B	Util C
Albiglutide	Cholelithiasis	
Dulaglutide	Biliary Colic	
Exenatide	Cholecystitis	
Liraglutide		
Lixisenatide		
Semaglutide		

References:

Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Facts & Comparison, 2022, Wolters Kluwer Health.

33. Metoclopramide Nasal Spray / Therapeutic Appropriateness _____ _____

Alert Message: The safety and effectiveness of Gimoti (metoclopramide) in pediatric patients have not been established. Metoclopramide is not recommended for use in pediatric patients due to the risk of tardive dyskinesia (TD) and other extrapyramidal symptoms, as well as the risk of methemoglobinemia in neonates. Dystonias and other extrapyramidal symptoms associated with metoclopramide are more common in pediatric patients than in adults.

Drugs/Diseases

Util A	Util B	Util C
Metoclopramide Nasal		

Age Range: 0 – 17 yoa

References:

Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Gimoti Prescribing Information, Jan. 2021, Evoke Pharma, Inc.

34. Metoclopramide Nasal Spray / Tardive Dyskinesia (Black Box) _____ _____

Alert Message: Gimoti (metoclopramide) is contraindicated in patients with a history of tardive dyskinesia (TS) or a dystonic reaction to metoclopramide. Metoclopramide can cause tardive dyskinesia (TD), a syndrome of potentially irreversible and disfiguring involuntary movements. The risk of developing TD and the likelihood that TD will become irreversible increases with duration of treatment and total cumulative dosage. Additionally, the risk of developing TD is increased among the elderly, especially elderly women, and in patients with diabetes mellitus. Due to the risk of developing TD, avoid treatment with metoclopramide for longer than 12 weeks. Metoclopramide is not recommended in geriatric patients as initial therapy.

Drugs/Diseases

Util A	Util B	Util C (Include)
Metoclopramide Nasal		Tardive Dyskinesia

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Gimoti Prescribing Information, Jan. 2021, Evoke Pharma, Inc.

35. Metoclopramide Nasal Spray / Gastrointestinal Motility Issues _____ _____

Alert Message: Gimoti (metoclopramide) is contraindicated in patients with conditions where stimulation of gastrointestinal motility might be dangerous (e.g., in the presence of gastrointestinal hemorrhage, mechanical obstruction, or perforation).

Drugs/Diseases

Util A	Util B	Util C (Include)
Metoclopramide Nasal		GI Hemorrhage
		GI Obstruction
		GI Perforation

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Gimoti Prescribing Information, Jan. 2021, Evoke Pharma, Inc.

36. Metoclopramide Nasal Spray / Pheochromocytoma _____ _____

Alert Message: Gimoti (metoclopramide) is contraindicated In patients with pheochromocytoma or other catecholamine-releasing paragangliomas. Metoclopramide may cause a hypertensive/pheochromocytoma crisis, probably due to the release of catecholamines from the tumor.

Drugs/Diseases

Util A	Util B	Util C (Include)
Metoclopramide Nasal		Pheochromocytoma

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Gimoti Prescribing Information, Jan. 2021, Evoke Pharma, Inc.

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

37. Metoclopramide Nasal Spray / Epilepsy _____ _____
Alert Message: Gimoti (metoclopramide) is contraindicated in patients with epilepsy. Metoclopramide may increase the frequency and severity of seizures.

Drugs/Diseases

Util A	Util B	Util C (Include)
Metoclopramide Nasal		Epilepsy

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Gimoti Prescribing Information, Jan. 2021, Evoke Pharma, Inc.

38. Metoclopramide Nasal Spray / Depression _____ _____
Alert Message: Avoid Gimoti (metoclopramide) use in patients with a history of depression. Depression has occurred in metoclopramide-treated patients with and without a history of depression. Symptoms have included suicidal ideation and suicide.

Drugs/Diseases.

Util A	Util B	Util C (Include)
Metoclopramide Nasal		Depression

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Gimoti Prescribing Information, Jan. 2021, Evoke Pharma, Inc.

39. Metoclopramide Nasal Spray / Hypertension _____ _____
Alert Message: The use of Gimoti (metoclopramide) should be avoided in patients with hypertension. Metoclopramide may elevate blood pressure.

Drugs/Diseases

Util A	Util B	Util C
Metoclopramide Nasal	Hypertension	

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Gimoti Prescribing Information, Jan. 2021, Evoke Pharma, Inc.

40. Metoclopramide Nasal Spray / Fluid Retention & Volume Overload _____ _____
Alert Message: Because metoclopramide produces a transient increase in plasma aldosterone, patients with cirrhosis or congestive heart failure may be at risk of developing fluid retention and volume overload. Discontinue Gimoti (metoclopramide) if any of these adverse reactions occur.

Drugs/Diseases

Util A	Util B	Util C (Include)
Metoclopramide Nasal	Fluid Retention	Cirrhosis
	Volume Overload	Congestive Heart Failure

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Gimoti Prescribing Information, Jan. 2021, Evoke Pharma, Inc.

41. Metoclopramide Nasal Spray / Moderate to Severe Renal Impairment _____ _____

Alert Message: Gimoti (metoclopramide) is not recommended in patients with moderate and severe renal impairment (creatinine clearance less than 60 mL/minute), including those receiving hemodialysis and continuous ambulatory peritoneal dialysis. The clearance of metoclopramide is decreased, and the systemic exposure is increased in patients with moderate to severe renal impairment compared to patients with normal renal function, which may increase the risk of adverse reactions.

Drugs/Diseases

Util A	Util B	Util C (Include)
Metoclopramide Nasal		CKD Stage 3, 4, and 5
		ESRD
		Hemodialysis

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Gimoti Prescribing Information, Jan. 2021, Evoke Pharma, Inc.

42. Metoclopramide Nasal Spray / Antipsychotics _____ _____

Alert Message: The concurrent use of Gimoti (metoclopramide) with antipsychotics should be avoided. Both metoclopramide and antipsychotics can cause tardive dyskinesia (TD), other extrapyramidal symptoms (EPS), and neuroleptic malignant syndrome (NMS). Concomitant use of metoclopramide with these drugs may have an additive effect.

Drugs/Diseases

Util A	Util B	Util C
Metoclopramide Nasal	Antipsychotics	

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Gimoti Prescribing Information, Jan. 2021, Evoke Pharma, Inc.

43. Metoclopramide Nasal Spray / Strong CY2D6 Inhibitors _____ _____

Alert Message: The concurrent use of Gimoti (metoclopramide) with strong CYP2D6 inhibitors (e.g., bupropion, fluoxetine, paroxetine, and quinidine) is not recommended. Metoclopramide is a CYP2D6 substrate, and inhibition of CYP2D6-mediated metabolism may result in increased metoclopramide plasma concentrations and increased risk of adverse effects, including extrapyramidal symptoms.

Drugs/Diseases

Util A	Util B	Util C
Metoclopramide Nasal	Bupropion	
	Fluoxetine	
	Paroxetine	
	Quinidine	

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Gimoti Prescribing Information, Jan. 2021, Evoke Pharma, Inc.

Recommendations ***Approved Rejected***

44. Metoclopramide Nasal Spray / MAOIs _____ _____

Alert Message: The concurrent use of Gimoti (metoclopramide) with monoamine oxidase inhibitors (MAOIs) should be avoided. Both metoclopramide and MAOIs can elevate blood pressure, and concurrent use of these drugs increase the risk of hypertension.

Drugs/Diseases

Util A	Util B	Util C
Metoclopramide Nasal	Isocarboxazid	
	Phenelzine	
	Tranylcypromine	

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Gimoti Prescribing Information, Jan. 2021, Evoke Pharma, Inc.

45. Metoclopramide Nasal Spray / Drugs Decreasing Gastric Motility _____ _____

Alert Message: Caution should be exercised when Gimoti (metoclopramide) is coadministered with a drug that impairs gastrointestinal motility. Metoclopramide stimulates gastric motility, and concurrent use with drugs that decrease gastric motility may cause a decrease in metoclopramide efficacy.

Drugs/Diseases

Util A	Util B	Util C
Metoclopramide Nasal	Anticholinergics	
	Opioids	

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Gimoti Prescribing Information, Jan. 2021, Evoke Pharma, Inc.

46. Metoclopramide Nasal Spray / Dopamine Agonists _____ _____

Alert Message: Gimoti (metoclopramide) is a dopamine antagonist, and concurrent use with a dopamine agonist (e.g., bromocriptine, levodopa, and rotigotine) may decrease the effectiveness of either drug. Avoid concomitant use of these agents if possible.

Drugs/Diseases

Util A	Util B	Util C
Metoclopramide Nasal	Apomorphine	
	Bromocriptine	
	Cabergoline	
	Levodopa	
	Pramipexole	
	Ropinirole	
	Rotigotine	

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Gimoti Prescribing Information, Jan. 2021, Evoke Pharma, Inc.

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

47. Metoclopramide Nasal Spray / Hepatic Impairment _____ _____

Alert Message: Gimoti (metoclopramide) use is not recommended in patients with moderate or severe (Child-Pugh B or C) hepatic impairment. Patients with severe hepatic impairment (Child-Pugh C) have reduced systemic metoclopramide clearance (by approximately 50%) compared to patients with normal hepatic function. The resulting increase in metoclopramide blood concentrations increases the risk of adverse reactions. There are no pharmacokinetic data evaluating the safety of metoclopramide in patients with moderate hepatic impairment (Child-Pugh B).

Drugs/Diseases

Util A	Util B	Util C
Metoclopramide Nasal	Hepatic Impairment	

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Gimoti Prescribing Information, Jan. 2021, Evoke Pharma, Inc.

48. Abaloparatide / Overuse _____ _____

Alert Message: Tymlos (abaloparatide) may be over-utilized. The recommended dose is 80 mcg subcutaneously once daily. The cumulative use of abaloparatide for more than 2 years during a patient's lifetime is not recommended.

Drugs/Diseases

Util A	Util B	Util C
Abaloparatide		

Max Dose: 80 mcg/day

References:

Clinical Pharmacology, 2022 Elsevier/Gold Standard.

Tymlos Prescribing Information, Dec. 2021, Radius Health, Inc.

49. Abaloparatide / Therapeutic Appropriateness _____ _____

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

Drugs/Diseases

Util A	Util B	Util C
Abaloparatide		

Age Range: 0 – 17 yoa

References:

Clinical Pharmacology, 2022 Elsevier/Gold Standard.

Tymlos Prescribing Information, Dec. 2021, Radius Health, Inc.

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

50. Abaloparatide / Risk of Osteosarcoma _____ _____

Alert Message: In animal studies, Tymlos (abaloparatide) caused a dose-dependent increase in the incidence of osteosarcoma in male and female rats. It is not known if abaloparatide will cause osteosarcoma in humans. The use of abaloparatide is not recommended in patients at increased risk for osteosarcoma, including those with Paget's disease of the bone or unexplained elevations of alkaline phosphatase, open epiphyses, bone metastases or skeletal malignancies, hereditary disorders predisposing to osteosarcoma, or prior external beam or implant radiation therapy involving the skeleton. The cumulative use of abaloparatide and parathyroid hormone analogs (e.g., teriparatide) for more than 2 years during a patient's lifetime is not recommended.

Drugs/Diseases

Util A	Util B	Util C (Include)
Abaloparatide		Paget's Disease
		Malignant Neoplasm of the Bone

References:

Clinical Pharmacology, 2022 Elsevier/Gold Standard.

Tymlos Prescribing Information, Dec. 2021, Radius Health, Inc.

51. Abaloparatide / Hypercalcemia _____ _____

Alert Message: Tymlos (abaloparatide) may cause hypercalcemia. Abaloparatide use is not recommended in patients with pre-existing hypercalcemia or in patients who have an underlying hypercalcemia disorder, such as primary hyperparathyroidism, because of the possibility of exacerbating hypercalcemia.

Drugs/Diseases

Util A	Util B	Util C (Include)
Abaloparatide		Hypercalcemia
		Primary Hyperparathyroidism

References:

Clinical Pharmacology, 2022 Elsevier/Gold Standard.

Tymlos Prescribing Information, Dec. 2021, Radius Health, Inc.

52. Abaloparatide / Hypercalciuria & Urolithiasis _____ _____

Alert Message: Tymlos (abaloparatide) may cause hypercalciuria. It is unknown whether abaloparatide may exacerbate urolithiasis in patients with a history of urolithiasis. If active urolithiasis or pre-existing hypercalciuria is suspected, measurement of urinary calcium excretion should be considered.

Drugs/Diseases

Util A	Util B	Util C
Abaloparatide	Hypercalciuria	
	Urolithiasis	

References:

Clinical Pharmacology, 2022 Elsevier/Gold Standard.

Tymlos Prescribing Information, Dec. 2021, Radius Health, Inc.

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

53. Abaloparatide / Pregnancy / Pregnancy Negating _____ _____

Alert Message: Tymlos (abaloparatide) is not intended for use in females of reproductive potential. There are no human data with abaloparatide use in pregnant women to inform any drug-associated risks. Animal reproduction studies with abaloparatide have not been conducted.

Drugs/Diseases

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

Gender: Female

Age Range: 11 – 50 yoa

References:

Clinical Pharmacology, 2022 Elsevier/Gold Standard.

Tymlos Prescribing Information, Dec. 2021, Radius Health, Inc.

54. Abaloparatide / Therapeutic Appropriateness _____ _____ Alert Message:
Tymlos (abaloparatide) is not intended for use in females of reproductive potential.
There is no information on the presence of abaloparatide in human milk, the effects on the breastfed infant, or the effects on milk production.

Drugs/Diseases

Util A	Util B	Util C
Abaloparatide	Lactation	

Gender: Female

Age Range: 11 – 50 yoa

References:

Clinical Pharmacology, 2022 Elsevier/Gold Standard.

Tymlos Prescribing Information, Dec. 2021, Radius Health, Inc.

55. Abrocitinib / Overuse _____ _____
Alert Message: Cibinqo (abrocitinib) may be over-utilized. The recommended dosage of abrocitinib is 100 mg once daily. If an adequate response is not achieved with abrocitinib 100 mg daily after 12 weeks, consider increasing the dosage to 200 mg once daily. Discontinue abrocitinib therapy if an inadequate response is seen after the dosage increase to 200 mg once daily.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Abrocitinib		Cirrhosis
		Hepatic Failure
		CKD 2, 3, 4, 5, & ESRD

Max Dose: 200 mg/day

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Cibinqo Prescribing Information, Jan. 2022, Pfizer, Inc.

56. Abrocitinib / Overuse Mild Renal Impairment _____ _____

Alert Message: Cibinqo (abrocitinib) may be over-utilized. The recommended dosage of abrocitinib in patients with mild renal impairment (eGFR 60 – 89 mL/min) is 100 mg once daily. If an adequate response is not achieved after 12 weeks, the dose of abrocitinib can be doubled to 200 mg once daily.

Drugs/Diseases

Util A	Util B	Util C (Include)
Abrocitinib		CKD Stage 2

Max Dose: 200 mg/day

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Cibinqo Prescribing Information, Jan. 2022, Pfizer, Inc.

57. Abrocitinib / Overuse Moderate Renal Impairment _____ _____

Alert Message: Cibinqo (abrocitinib) may be over-utilized. The recommended dosage of abrocitinib in patients with moderate renal impairment (eGFR 30 – 59 mL/min) is 50 mg once daily. If an adequate response is not achieved after 12 weeks, the dose of abrocitinib can be doubled to a maximum of 100 mg once daily.

Drugs/Diseases

Util A	Util B	Util C (Include)
Abrocitinib		CKD Stage 3

Max Dose: 100 mg/day

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Cibinqo Prescribing Information, Jan. 2022, Pfizer, Inc.

58. Abrocitinib / Severe Renal Impairment & ESRD _____ _____

Alert Message: Cibinqo (abrocitinib) is not recommended for use in patients with severe renal impairment (eGFR 15 - 29 mL/min) or end-stage renal disease (eGFR < 15 mL/min) hepatic impairment. Abrocitinib has not been studied in this patient population.

Drugs/Diseases

Util A	Util B	Util C (Include)
Abrocitinib		CKD Stage 4
		CKD Stage 5
		ESRD

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Cibinqo Prescribing Information, Jan. 2022, Pfizer, Inc.

59. Abrocitinib / Severe Hepatic Impairment _____ _____

Alert Message: Cibinqo (abrocitinib) is not recommended for use in patients with severe hepatic impairment. Abrocitinib has not been studied in this patient population.

Drugs/Diseases

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

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Cibinqo Prescribing Information, Jan. 2022, Pfizer, Inc.

60. Abrocitinib / Therapeutic Appropriateness _____ _____

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

Drugs/Diseases

Util A	Util B	Util C
Abrocitinib		

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Cibinqo Prescribing Information, Jan. 2022, Pfizer, Inc.

61. Abrocitinib / Antiplatelets (minus 81 mg Aspirin) _____ _____

Alert Message: Cibinqo (abrocitinib) is contraindicated in patients taking antiplatelet therapies, except for low-dose aspirin (≤81 mg daily), during the first 3 months of treatment. Coadministration of abrocitinib with antiplatelet therapy drugs may increase the risk of bleeding with thrombocytopenia. Treatment with abrocitinib was associated with an increased incidence of thrombocytopenia and lymphopenia.

Drugs/Diseases

Util A	Util B	Util C
Abrocitinib	Aspirin > 81 mg	
	Anagrelide	
	Cilostazol	
	Clopidogrel	
	Dipyridamole	
	Prasugrel	
	Pentoxifylline	
	Ticagrelor	
	Ticlopidine	
	Vorapaxar	

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Cibinqo Prescribing Information, Jan. 2022, Pfizer, Inc.

62. Abrocitinib / Serious Infections (Black Box) _____ _____

Alert Message: Patients treated with Cibinqo (abrocitinib) may be at increased risk for developing serious infections that may lead to hospitalization or death. The most frequent serious infections reported with abrocitinib were herpes simplex, herpes zoster, and pneumonia. Avoid the use of abrocitinib in patients with an active, serious infection, including localized infections. The risks and benefits of treatment with abrocitinib should be carefully considered prior to initiating therapy in patients with chronic or recurrent infections. If a serious or opportunistic infection develops, discontinue abrocitinib and control the infection.

Drugs/Diseases

Util A	Util B	Util C
Abrocitinib	Serious Infections	

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Cibinqo Prescribing Information, Jan. 2022, Pfizer, Inc.

63. Abrocitinib / Tuberculosis (Black Box) _____ _____

Alert Message: Cibinqo (abrocitinib) is not recommended for use in patients with active tuberculosis (TB). Evaluate and test patients for TB before starting. Abrocitinib therapy and consider yearly screening for patients in highly endemic areas for TB. For patients with a new diagnosis of latent TB or prior untreated latent TB, or patients with a negative test for latent TB but who are at high risk for TB infection, start preventive therapy for latent TB prior to initiation of abrocitinib. Monitor patients for the development of signs and symptoms of TB, including patients who were tested negative for latent TB infection prior to initiating therapy.

Drugs/Diseases

Util A	Util B	Util C
Abrocitinib	Tuberculosis	

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Cibinqo Prescribing Information, Jan. 2022, Pfizer, Inc.

64. Abrocitinib / Rheumatoid Arthritis (Black Box) _____ _____

Alert Message: Cibinqo (abrocitinib) is not approved for use in rheumatoid arthritis (RA). In a large, randomized, postmarketing safety study of another JAK inhibitor in RA patients 50 years of age and older with at least one cardiovascular risk factor, a higher rate of all-cause mortality, including sudden cardiovascular death, was observed in patients treated with the JAK inhibitor compared with TNF blockers. Consider the benefits and risks for the individual patient prior to initiating or continuing therapy with abrocitinib.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Abrocitinib	Rheumatoid Arthritis	Atopic Dermatitis

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Cibinqo Prescribing Information, Jan. 2022, Pfizer, Inc.

Criteria Recommendations ***Approved Rejected***

65. Abrocitinib / Malignancies (Black Box) _____ _____
Alert Message: Malignancies, including non-melanoma skin cancer (NMSC), were observed in clinical studies with Cibinqo (abrocitinib) for atopic dermatitis. Perform periodic skin examinations for patients who are at increased risk for skin cancer. Exposure to sunlight and UV light should be limited by wearing protective clothing and using a broad-spectrum sunscreen. Consider the benefits and risks for the individual patient prior to initiating or continuing therapy with abrocitinib, particularly in patients with a known malignancy (other than a successfully treated NMSC), patients who develop a malignancy when on treatment, and patients who are current or past smokers.

Drugs/Diseases

Util A	Util B	Util C
Abrocitinib	Malignant Neoplasms	

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Cibinqo Prescribing Information, Jan. 2022, Pfizer, Inc.

66. Abrocitinib / Myocardial Infarction & Stoke (Black Box) _____ _____
Alert Message: Major adverse cardiovascular events were reported in clinical studies of Cibinqo (abrocitinib) for atopic dermatitis. Consider the benefits and risks for the individual patient prior to initiating or continuing therapy with abrocitinib, particularly in patients who are current or past smokers and patients with other cardiovascular risk factors. Patients should be informed about the symptoms of serious cardiovascular events and the steps to take if they occur. Discontinue abrocitinib in patients that have experienced a myocardial infarction or stroke.

Drugs/Diseases

Util A	Util B	Util C
Abrocitinib	Myocardial Infarction Stroke	

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Cibinqo Prescribing Information, Jan. 2022, Pfizer, Inc.

67. Abrocitinib / Thrombosis (Black Box) _____ _____ Alert Message:
Deep venous thrombosis (DVT) and pulmonary embolism (PE) have been reported in patients treated with Cibinqo (abrocitinib). Thrombosis, including PE, DVT, and arterial thrombosis, have been reported in patients receiving JAK inhibitors used to treat inflammatory conditions. Many of these adverse reactions were serious and some resulted in death. In RA patients 50 years of age and older with at least one cardiovascular risk factor treated with another JAK inhibitor, a higher rate of thrombosis was observed when compared with TNF blockers. Avoid abrocitinib in patients at risk. If symptoms of thrombosis occur, discontinue abrocitinib and treat appropriately.

Drugs/Diseases

Util A	Util B	Util C
Abrocitinib	Pulmonary Embolism Deep Vein Thrombosis Arterial Thrombosis	

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Cibinqo Prescribing Information, Jan. 2022, Pfizer, Inc.

68. Abrocitinib / Strong 2C19 Inhibitors _____ _____

Alert Message: Coadministration of Cibinqo (abrocitinib) with strong CYP2C19 inhibitors increases the combined exposure of abrocitinib and its two active metabolites, M1 and M2, which may increase the adverse reactions of abrocitinib. In patients taking strong inhibitors of CYP2C19, reduce the dosage to 50 mg once daily. If an adequate response is not achieved with abrocitinib 50 mg daily after 12 weeks, consider increasing the dosage to 100 mg once daily. Discontinue therapy if an inadequate response is seen after dosage increase to 100 mg once daily.

Drugs/Diseases

Util A	Util B	Util C
Abrocitinib	Fluconazole	
	Fluoxetine	
	Fluvoxamine	
	Ticlopidine	

Max Dose: 100 mg/day

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Cibinqo Prescribing Information, Jan. 2022, Pfizer, Inc.

69. Abrocitinib / Moderate to Strong Inhibitors of Both 2C19 & 2C9 _____ _____

Alert Message: Coadministration of Cibinqo (abrocitinib) with drugs that are moderate to strong inhibitors of both CYP2C19 and CYP2C9 increases the exposure of abrocitinib and its two active metabolites, M1 and M2, which may increase the adverse reactions of abrocitinib. Avoid concomitant use of abrocitinib with drugs that are moderate to strong inhibitors of both CYP2C19 and CYP2C9.

Drugs/Diseases

Util A	Util B	Util C
Abrocitinib	Efavirenz	
	Etravirine	

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Cibinqo Prescribing Information, Jan. 2022, Pfizer, Inc.

70. Abrocitinib / Strong Inducers of Both 2C19 & 2C9 _____ _____

Alert Message: Coadministration of Cibinqo (abrocitinib) with strong CYP2C19 or CYP2C9 inducers decreases the combined exposure of abrocitinib and its two active metabolites, M1 and M2, which may result in loss of or reduced clinical response. Avoid concomitant use of abrocitinib with strong CYP2C19 or CYP2C9 inducers.

Drugs/Diseases

Util A	Util B	Util C
Abrocitinib	Apalutamide	
	Rifampin	

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Cibinqo Prescribing Information, Jan. 2022, Pfizer, Inc.

71. Abrocitinib / P-gp Substrates _____ _____

Alert Message: Coadministration of Cibinqo (abrocitinib) with P-gp substrate increases plasma concentrations of P-gp substrates and may result in potential adverse reactions of the P-gp substrate where small concentration changes may lead to serious or life-threatening toxicities (e.g., digoxin). Monitor appropriately or dose titrate P-gp substrate where small concentration changes may lead to toxicities when coadministered with abrocitinib.

Drugs/Diseases

Util A	Util B	Util C
Abrocitinib	Atorvastatin	
	Cobimetinib	
	Cyclosporine	
	Dabigatran	
	Digoxin	
	Dolutegravir	
	Everolimus	
	Glecaprevir/Pibrentasvir	
	Lapatinib	
	Lefamulin	
	Loperamide	
	Lovastatin	
	Maraviroc	
	Morphine	
	Naldemedine	
	Ranolazine	
	Simvastatin	
	Sirolimus	
	Tenofovir	

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Cibinqo Prescribing Information, Jan. 2022, Pfizer, Inc.

72. Abrocitinib / Pregnancy / Pregnancy Negating _____ _____

Alert Message: Available data from pregnancies reported in clinical trials with Cibinqo (abrocitinib) are not sufficient to establish a drug associated risk for major birth defects, miscarriage, or other adverse maternal or fetal outcomes. In animal reproduction studies, oral administration of abrocitinib to pregnant rats and rabbits during organogenesis at exposure 14 or 5 times the maximum recommended human dose (MRHD) based on AUC comparison, respectively, resulted in maternal dystocia and skeletal variations in rats and no adverse effects in rabbits.

Drugs/Diseases

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

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Cibinqo Prescribing Information, Jan. 2022, Pfizer, Inc.

73. Abrocitinib / Lactation _____ _____

Alert Message: There are no data on the presence of Cibinqo (abrocitinib) in human milk, the effects on the breastfed infant, or the effects on milk production. In animal studies, abrocitinib was secreted in the milk of lactating rats. When a drug is present in animal milk, the drug will likely be present in human milk. Because of the serious adverse findings in adults, including risks of serious infections, malignancy, and thrombosis, advise women not to breastfeed during treatment with abrocitinib and for one day after the last dose (approximately 5-6 elimination half-lives).

Drugs/Diseases

Util A	Util B	Util C
Abrocitinib	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Cibinqo Prescribing Information, Jan. 2022, Pfizer, Inc.

74. Abrocitinib / Non-adherence _____ _____

Alert Message: Based on refill history, your patient may be under-utilizing Cibinqo (abrocitinib). 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
Abrocitinib		

References:
Osterberg L, Blaschke T. Adherence to Medication. N Engl J Med 2005; 353:487- 497.
Feldman SR, Cox LS, Strowd LC, Gerber RA, Faulkner S, Sierka D, Smith TW, Cappelleri JC, Levenberg ME. The Challenge of Managing Atopic Dermatitis in the United States. Am Health Drug Benefits. 2019. Apr;12(2):83-93. PMID: 31057694; PMCID: PMC6485648.
Eicher L. Knop M, Aszodi N, et al. A Systemic Review of Factors Influencing Treatment Adherence in Chronic Inflammatory Skin Disease – Strategies for Optimizing Treatment Outcome. JEADV. 2019. (33):2253-2263.

75. Dupilumab / Overutilization _____ _____

Alert Message: The recommended maximum maintenance dose of Dupixent (dupilumab) for the treatment of eosinophilic esophagitis in adults and pediatric patients 12 years of age and older weighing at least 40 kg is 300 mg given every week.

Drugs/Diseases

Util A	Util B	Util C (Include)
Dupilumab		Eosinophilic Esophagitis

Maintenance Max Dose: 300mg every week.

Age Range: 12 - yoa

References:

Clinical Pharmacology, 2017 Elsevier/Gold Standard.

Dupixent Prescribing Information, May 2022, Regeneron Pharmaceuticals, Inc.

76. Dupilumab / Therapeutic Appropriateness _____ _____

Alert Message: The safety and efficacy of Dupixent (dupilumab) for the treatment of eosinophilic esophagitis in pediatric patients less than 12 years of age and weighing less than 40 kg have not been established.

Drugs/Diseases`1 week

Util A	Util B	Util C (Negate**)**
Dupilumab	Eosinophilic Esophagitis	Asthma
		Atopic Dermatitis

Age Range: 0 – 11 yoa

References:

Clinical Pharmacology, 2017 Elsevier/Gold Standard.

Dupixent Prescribing Information, May 2022, Regeneron Pharmaceuticals, Inc.

77. Lurasidone / Therapeutic Appropriateness _____ _____

Alert Message: The safety and effectiveness of Latuda (lurasidone) for the treatment of bipolar depression in pediatric patients less than 10 years of age have not been established.

Drugs/Diseases

Util A	Util B	Util C (Include)
Lurasidone		Bipolar Depression

Age Range: 0 – 9 yoa

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Facts & Comparisons, 2022 Updates, Wolters Kluwer Health.

78. Mirtazapine / Therapeutic Appropriateness _____ _____

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

Drugs/Diseases

Util A	Util B	Util C
Mirtazapine		

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Facts & Comparisons, 2022 Updates, Wolters Kluwer Health.

79. Selumetinib / Therapeutic Appropriateness _____ _____

Alert Message: The safety and effectiveness of Koselugo (selumetinib) have not been established in pediatric patients younger than 2 years of age.

Drugs/Diseases

Util A	Util B	Util C
Selumetinib		

Age Range: 0 – 1 yoa

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Koselugo Prescribing Information, May 2021, AstraZeneca.

80 Selumetinib / Cardiomyopathy _____ _____

Alert Message: The safety of Koselugo (selumetinib) has not been established in patients with a history of impaired left ventricular ejection fraction (LVEF) or a baseline ejection fraction that is below the institutional lower limit of normal (LLN). Cardiomyopathy, defined as a decrease in LVEF ≥ 10% below baseline, occurred in 23% of 74 pediatric patients who received selumetinib in a clinical trial (SPRINT). Assess ejection fraction by echocardiogram prior to initiating treatment, every 3 months during the first year of treatment, every 6 months thereafter, and as clinically indicated. Withhold, reduce dose, or permanently discontinue selumetinib based on the severity of the adverse reaction.

Drugs/Diseases

Util A	Util B	Util C (Include)
Selumetinib		Heart Failure

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Koselugo Prescribing Information, May 2021, AstraZeneca.

81. Selumetinib / Skin Toxicity _____ _____

Alert Message: Skin toxicities, including severe palmar-plantar erythrodysesthesia syndrome, have occurred in adult patients with multiple tumor types who received Koselugo (selumetinib) as a single agent or in combination with other anti-cancer agents. Monitor patients for severe skin rashes. Withhold, reduce dose, or permanently discontinue selumetinib based on the severity of the adverse reaction.

Drugs/Diseases

Util A	Util B	Util C
Selumetinib	Rash	
	Pruritus	
	Dermatitis	

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Koselugo Prescribing Information, May 2021, AstraZeneca.

82. Selumetinib / Ocular Toxicity _____ _____

Alert Message: Koselugo (selumetinib) can cause ocular toxicity (e.g., blurred vision, photophobia, retinal vein occlusion (RVO), and retinal pigment epithelial detachment (RPED)). Conduct comprehensive ophthalmic assessments prior to initiating selumetinib, at regular intervals during treatment, and for new or worsening visual changes. Permanently discontinue selumetinib in patients with RVO. Withhold selumetinib in patients with RPED, follow up with optical coherence tomography assessments every 3 weeks until resolution, and resume selumetinib at a reduced dose. For other ocular toxicities, withhold, reduce dose, or permanently discontinue selumetinib based on the severity of the adverse reaction.

Drugs/Diseases

Util A	Util B	Util C
Selumetinib	Blurred Vision	
	Photophobia	
	Retinal Vein Occlusion	
	Retinal Pigment Epithelia Detachment	

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Koselugo Prescribing Information, May 2021, AstraZeneca.

83. Selumetinib / Gastrointestinal Toxicity _____ _____

Alert Message: Serious gastrointestinal toxicities, including perforation, colitis, ileus, and intestinal obstruction, occurred in an unapproved population of adult patients with multiple tumor types who received Koselugo (selumetinib) as a single agent or in combination with other anti-cancer agents. Advise patients to start an anti-diarrheal agent (e.g., loperamide) immediately after the first episode of unformed, loose stool and increase fluid intake during diarrhea episodes. Withhold, reduce dose, or permanently discontinue selumetinib based on the severity of the adverse reaction.

Drugs/Diseases

Util A	Util B	Util C
Selumetinib	Colitis	
	Diarrhea	
	Intestinal Perforation	
	Intestinal Obstruction	
	Ileus	

References:

Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Koselugo Prescribing Information, May 2021, AstraZeneca.

84. Selumetinib / Moderate or Strong CYP3A4 Inhibitors _____ _____

Alert Message: The co-administration of Koselugo (selumetinib) with moderate or strong CYP3A4 inhibitors should be avoided. Selumetinib is a CYP3A4 substrate, and concomitant use of selumetinib with a moderate or strong CYP3A4 inhibitor increases selumetinib plasma concentrations, which may increase the risk of adverse reactions. If coadministration with strong or moderate CYP3A4 inhibitors cannot be avoided, reduce the selumetinib dosage as recommended in the official prescribing information. After discontinuation of a strong or moderate CYP3A4 inhibitor for 3 elimination half-lives, resume the selumetinib dose that was taken prior to initiating the inhibitor or fluconazole.

Drugs/Diseases

Util A	Util B		Util C
Selumetinib	Atazanavir	Fosamprenavir	
	Aprepitant	Idelalisib	
	Cimetidine	Indinavir	
	Ciprofloxacin	Itraconazole	
	Clarithromycin	Ketoconazole	
	Clotrimazole	Nefazodone	
	Cobicistat	Nelfinavir	
	Crizotinib	Posaconazole	
	Cyclosporine	Ritonavir	
	Diltiazem	Saquinavir	
	Dronedarone	Tipranavir	
	Erythromycin	Verapamil	
	Fluconazole	Voriconazole	
	Fluvoxamine		

References:

Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Koselugo Prescribing Information, May 2021, AstraZeneca.

85. Selumetinib / Moderate or Strong CYP3A4 Inducers _____ _____

Alert Message: The co-administration of Koselugo (selumetinib) with moderate or strong CYP3A4 inducers should be avoided. Selumetinib is a CYP3A4 substrate, and concomitant use of selumetinib with a moderate or strong CYP3A4 inducer decreases selumetinib plasma concentrations, which may reduce selumetinib efficacy.

Drugs/Diseases

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

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Koselugo Prescribing Information, May 2021, AstraZeneca.

86. Selumetinib / Vitamin E Supplements _____ _____

Alert Message: Koselugo (selumetinib) capsules contain vitamin E, and daily intake of vitamin E that exceeds the recommended or safe limits may increase the risk of bleeding. Supplemental vitamin E is not recommended if daily vitamin E intake exceeds the recommended or safe limits. An increased risk of bleeding may occur in patients who are co-administered selumetinib with vitamin K antagonists or anti-platelet agents.

Drugs/Diseases

Util A	Util B	Util C
Selumetinib	Vitamin E	

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Koselugo Prescribing Information, May 2021, AstraZeneca.

87. Selumetinib / Vitamin K Antagonist & Antiplatelet agents _____ _____

Alert Message: Koselugo (selumetinib) capsules contain vitamin E, and coadministration with vitamin K antagonist or antiplatelet agents may increase the risk of bleeding. Monitor for bleeding in these patients. Increase international normalized ratio (INR) monitoring, as appropriate, in patients taking a vitamin-K antagonist. Perform anticoagulant assessments, including INR or prothrombin time, more frequently and adjust the dose of vitamin K antagonists or anti-platelet agents as appropriate.

Drugs/Diseases

Util A	Util B		Util C
Selumetinib	Anagrelide	Ticagrelor	
	Cilostazol	Ticlopidine	
	Clopidogrel	Vorapaxar	
	Dipyridamole	Warfarin	
	Prasugrel		

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Koselugo Prescribing Information, May 2021, AstraZeneca.

88. Selumetinib / Pregnancy / Pregnancy Negating _____ _____

Alert Message: Based on findings from animal studies and its mechanism of action, Koselugo (selumetinib) can cause fetal harm when administered to a pregnant patient. There are no available data on the use of selumetinib in pregnant patients to evaluate drug-associated risk. In animal reproduction studies, administration of selumetinib to mice during organogenesis caused reduced fetal weight, adverse structural defects, and effects on embryo-fetal survival at approximate exposures > 5-times the human exposure at the clinical dose of 25 mg/m2 twice daily. Advise pregnant patients of the potential risk to the fetus.

Drugs/Diseases

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

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Koselugo Prescribing Information, May 2021, AstraZeneca.

89. Selumetinib / Lactation _____ _____

Alert Message: There are no data on the presence of Koselugo (selumetinib) and its active metabolite in human milk or their effects on the breastfed child or milk production. Selumetinib and its active metabolite were present in the milk of lactating mice. Due to the potential for adverse reactions in a breastfed child, advise patients not to breastfeed during treatment with selumetinib and for 1 week after the last dose.

Drugs/Diseases

Util A	Util B	Util C
Selumetinib	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Koselugo Prescribing Information, May 2021, AstraZeneca.

90. Selumetinib / Therapeutic Appropriateness _____ _____

Alert Message: Advise patients of reproductive potential to use effective contraception during treatment and for 1 week after the last dose of Koselugo (selumetinib). Selumetinib can cause fetal harm when administered to a pregnant patient.

Drugs/Diseases

Util A	Util B	Util C (Negating)
Selumetinib		Contraceptives

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Koselugo Prescribing Information, May 2021, AstraZeneca.

Criteria Recommendations ***Approved Rejected***

91. Selumetinib / Therapeutic Appropriateness _____ _____
Alert Message: Advise male patients with partners of reproductive potential to use effective contraception during treatment with Koselugo (selumetinib) and for 1 week after the last dose.

Drugs/Diseases
Util A Util B Util C
Selumetinib

Gender: Male

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Koselugo Prescribing Information, May 2021, AstraZeneca.

92. Selumetinib / Non-adherence _____ _____
Alert Message: Based on refill history, your patient may be under-utilizing Koselugo (selumetinib). Nonadherence to the prescribed dosing regimen may result in sub-therapeutic effects, which may lead to decreased outcomes and additional healthcare costs.

Drugs/Diseases
Util A Util B Util C
Selumetinib

References:
Osterberg L, Blaschke T. Adherence to Medication. N Engl J Med. 2005;353:487-97.
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.

North Dakota Medicaid
Drug Utilization Review Board Meeting
December 7th, 2022
Conference Room 210/212

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NORTH Dakota | Health & Human Services
Be Legendary.

Meeting Notice

North Dakota Medicaid Drug Use Review Board

Wednesday, December 7, 2022
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: 278 214 277#

Agenda

1. Administrative items
   - DHS announcements
2. Old business
   - Review and approval of September 2022 meeting minutes
   - Budget update
   - Review top 25 drugs for the third quarter of 2022
   - Prior authorization/PDL update
   - Update to Prurigo Nodularis (Dupixent)
   - Update to Endometriosis Pain (Myfembree)
   - Update to Hematopoietic Syndrome of Acute Radiation Syndrome (NPlate)
   - Second Review of Amyloidosis (Vyndaqel, Vyndamax, Tegsedi)
   - Second Review of Amyotrophic Lateral Sclerosis (Radicava)
   - Second Review of Chelating Agents (Ferriprox)
   - Treatment follow up questions for Eosinophilic Esophagitis
   - Annual prior authorization review of prior authorization forms and criteria
3. New business
   - Discussion of RDUR response letter
   - Retrospective DUR profile review update
   - Retrospective DUR criteria recommendations
   - Upcoming meeting date/agenda.
     - Next meeting is March 1st, 2023
4. Adjourn

Individuals with disabilities who need accommodations, including appropriate auxiliary aids to participate, can contact Stacey Koehly at 701-328-4807, toll-free 800-755-2604, 711 (TTY) or skoehly@nd.gov.

North Dakota Medicaid Drug Use Review (DUR) Board
Meeting Minutes
September 7th, 2022

Members Present: Joshua Askvig, Andrea Honeyman, Kathleen Traylor, Amy Werremeyer, Laura Kroetsch, Kevin Martian, Kristen Peterson, Gabrielle Balf

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

Old Business

A. Honeyman called the meeting to order at 1:18 p.m.; however, there were technical issues that arose in the Board meeting room. The microphones were not working, thus the members in the Board room were not heard by virtual attendees. L. Morgan relayed the conversations that took place in the Board meeting room to those who joined virtually. A. Honeyman stood for T. Schmidt as Chair. L. Morgan discussed the meeting minutes from the June meeting with the Board members. There were several moments during the June Board meeting in which the microphones in the Board meeting room did not pick up voices. With this in mind, L. Morgan asked the Board members to state their name and speak up during discussion and voting from now on. The Board members agreed to this request. L. Morgan asked for a motion to approve the minutes of the June 1st, 2022, meeting. J. Askvig moved that the minutes be approved, and A. Honeyman seconded the motion. A. Honeyman called for a voice vote to approve the minutes with revisions, and the motion passed with no audible dissent. Lastly, Dr. Hostetter was introduced as a new Ex-officio Board member.

Review Top 25 Drugs

L. Morgan presented the quarterly review of the top 25 drugs based on total claims cost, the top 25 drugs based on the total number of claims, and the top drug classes based on claims and cost for the 2nd quarter of 2022. There were no budget updates presented during this meeting.

PDL/PA Criteria Updates

L. Morgan shared with the Board all the changes made to the Preferred Drug List since the last version of the Preferred Drug List was posted. Notable changes include adding Camzyos, Radicava, and Tegsedi to PA for the Over 3000 criteria. All PDL updates are listed in the handout for the September 2022 DUR Board meeting. When a new version of the PDL is published and posted to the website, all updates/changes made since the last version are called out at the top of the document itself.

Update to Eosinophilic Esophagitis (Dupixent)

L. Morgan presented the proposed criteria for the Eosinophilic Esophagitis section. The preferred agent requiring a clinical PA is Dupixent. Initial approval will be granted for 6 months, and renewal will be for 12 months. There was no public comment made during this section. Within the Board room, a member asked if the esophageal intraepithelial eosinophil count needed to be a requirement, considering it would require the member to receive an upper endoscopy. After further discussion, it was agreed upon that the criteria should remain. A. Werremeyer followed up asking why it was felt this information was pertinent for renewal, considering the requirement for documentation showing that the member achieved a significant reduction in dysphagia symptoms. A. Murphy responded that even if the member no longer has symptoms of the disease, he or she may still have the disease itself. Therefore, an endoscopy is utilized to determine if the member still has eosinophilic esophagitis regardless of symptom presentation. A. Murphy stated that this topic will be investigated further and will be addressed at the next meeting whether an endoscopy is essential for renewal criteria.

Update to Bardet-Biedl Syndrome (Imcivree)

L. Morgan presented changes made to the Imcivree section in the PDL. The main addition to this section is the criteria added for Bardet-Biedl Syndrome which is a new indication for Imcivree. Additionally, the renewal criteria were updated. L. Kroetsch asked for clarification about the subsequent renewal criteria requirement for a 10% weight reduction to be achieved or maintained and whether that applies to baseline weight or weight from the prior approval. A. Murphy answered that the 10% weight reduction will be assessed from baseline weight.

Update to Heart Failure (Camzyos)

L. Morgan presented updates to the Heart Failure section regarding Camzyos. The initial approval duration was reduced from 12 months to 6 months. Initial and renewal criteria was updated, as well. During public comment, Dr. Sara Hovland from Bristol Myers Squibb gave testimony for Camzyos. Dr. Hovland presented two requests for changes to the criteria which included: 1) To remove the ≥90% oxygen saturation at rest requirement and 2) To change the concurrent medication requirement from Entresto, a beta-blocker, a SGLT-2 inhibitor, and a mineralocorticoid receptor antagonist to just a beta-blocker and a calcium-channel blocker. L. Kroetsch agreed with the requested changes, as they corresponded with the research she did. Members in the room questioned Dr. Hovland about North Dakota Medicaid's proposed criteria and how it relates to criteria seen in other states. Dr. Hovland responded that she has not seen the ≥90% oxygen saturation at rest requirement and concurrent medication requirement in other states at this time. Another question from the members in the room was if the diagnostic criteria for cardiomyopathy and heart failure were similar, in which Dr. Hovland stated that the diagnosis for HCM is typically a diagnosis of exclusion. Dr. Hovland added that there is a genetic test that can be done which can determine HCM in about 20-40% of patients and there are also subjective NYHA class symptoms that can be assessed for exclusion of any other disease state to determine a diagnosis of HCM. Lastly, the members in the Board meeting room asked Dr. Hovland about the ≥90% oxygen saturation at rest requirement being listed as an inclusion criterion for the EXPLORER-HCM trial and why it was not considered relevant for the proposed criteria. Dr. Hovland said she would look into it and get back to the Board with information.

Second Review of Presbyopia

L. Morgan presented initial and renewal criteria for Vuity. This agent will be approved for 3 months initially and 12 months for renewal. Vuity is listed as a preferred agent requiring clinical PA. During discussion, the Board members questioned if an optometrist and ophthalmologist can be listed as the prescriber or consulted prescriber instead of just an optometrist. A. Murphy responded that since this medication relates to vision, then an optometrist may be more appropriate for prescribing. G. Balf responded that since ophthalmologists can prescribe corrective lenses, then perhaps they should be included for prescribing Vuity. The Board members agreed with G. Balf; therefore, an ophthalmologist will be included in prescriber requirement criteria. Standing In for Standing in for Chair T. Schmidt, A. Honeyman called for a voice vote to approve the updated criteria, which passed with no audible dissent.

Second Review of Cushing's Syndrome

L. Morgan presented group criteria for all agents requiring prior authorization for Cushing's Syndrome. This criteria included that the member must have failed a 3-month trial of combination treatment with ketoconazole tablets and metyrapone. There were also product specific criteria listed for Recorlev and Korlym. During public comment, Dr. Patel from Xeris Pharmaceuticals gave testimony for Recorlev. Dr. Patel respectfully requested for Recorlev to be added to the preferred drug list (PDL) without the requirement of stepping through ketoconazole and metyrapone prior to approval. The Board members within the meeting room asked Dr. Patel if it would cause the patient any harm to trial step-therapy with ketoconazole and metyrapone first, considering the cost differences between the generic products and brand name Recorlev. Dr. Patel answered that allowing patients to try a compendia-supported agent with a broad indication gives patients with adrenal issues or outside tumors more options. G. Balf asked about the enantiomers (ketoconazole and levoketoconazole) and how they may affect patients differently, specifically when it comes to liver toxicities, QT-prolongation, etc. G. Balf also address concern about Korlym not being a viable solution to some patients in regard to recent abortion laws. Dr. Patel answered that studies have found that Recorlev is more potent than ketoconazole, and in vitro, Recorlev could have less effect on liver toxicity. Additionally, Dr. Patel stated that Recorlev was found to have all of the inhibition of cortisol levels, in vitro; whereas, ketoconazole had no activity towards inhibition of cortisol levels. Standing In for Chair T. Schmidt, A. Honeyman called for a voice vote to approve the updated criteria, which passed with no audible dissent.

Second Review of Vernal Keratoconjunctivitis

L. Morgan presented initial and renewal criteria for Verkazia. For initial approval, Verkazia will be allowed for 6 months and 12 months for renewal. Verkazia was listed as a preferred agent with clinical PA required. L. Kroetsch asked about the list of agents the member can trial prior to Verkazia and if the member must trial all listed agents prior to approval. L. Morgan responded that the member could trial any agent listed rather than all agents listed under each medication class. L. Morgan stated that the wording can be adjusted to reflect the intent of the trial requirement more accurately. G. Balf also clarified that cyclosporin ophthalmic emulsion does not come as a 0.5% concentration, but rather, it comes

as a 0.05% concentration. This concentration was updated to 0.05% on the handout and will be reflected in the criteria. Standing in for Chair T. Schmidt, A. Honeyman called for a voice vote to approve the updated criteria, which passed with no audible dissent.

Second Review of Wilson's Disease

L. Morgan presented product specific criteria for trientine hydrochloride and non-preferred agent criteria for Cuprimine, penicillamine capsules and tablets, and Syprine. Once Cuvrior launches in 2023, it will be added to the proposed criteria. There was no public comment. Standing In for Chair T. Schmidt, A. Honeyman called for a voice vote to approve the updated criteria, which passed with no audible dissent.

New Business

Review of Amyloidosis (Vyndaqel, Vyndamax, Tegsedi)

L. Morgan presented a review of the disease state and agents used in the treatment of amyloidosis to the Board. G. Balf asked if the member can still be on a transplant list while taking one of these agents. L. Morgan and A. Murphy both answered they did not find any information which stated the member could not be on a transplant list while taking such agents. A motion was made by A. Werremeyer to manage these medications through prior authorization. The motion was seconded by J. Askvig. Prior authorization criteria for these agents will be presented, reviewed, and voted on by the Board at the next meeting.

Review of Amyotrophic Lateral Sclerosis (Radicava)

L. Morgan presented a review of the disease state and agents used in the treatment of amyotrophic lateral sclerosis (ALS) to the Board. A motion was made by J. Askvig to manage these medications through prior authorization. The motion was seconded by K. Martian. Prior authorization criteria for these agents will be presented, reviewed, and voted on by the Board at the next meeting.

Review of Chelating Agents (Ferriprox)

L. Morgan presented a review of chelating agents and their indications to the Board. A motion was made by J. Askvig to manage these medications through prior authorization. The motion was seconded by A. Werremeyer. Prior authorization criteria for these agents will be presented, reviewed, and voted on by the Board at the next meeting.

Synagis Discussion

A. Murphy presented data on respiratory syncytial virus (RSV) seasonal data which was provided by the CDC. A. Murphy went on to discuss the rationale for why ND Medicaid chose the Midwest region to determine seasonality. Since North Dakota has a large population concentration on the Minnesota border, the data will be more applicable to the members within North Dakota. The other option to choose from included Montana and South Dakota, but not Minnesota, which would not be a good representation of the population within North Dakota. Additionally, A. Murphy explained how ND Medicaid will define the start and end of the RSV season. The season will be 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) Midwest Region. Additionally, the decision was made to only allow 5 weight-based doses within a 6-month period. This way, members will be limited to an appropriate number of doses, and ND Medicaid will have a more cost-effective way of monitoring Synagis distribution.

RDUR Response Letter Discussion

L. Morgan presented the updates made to the RDUR response letter to allow for a more straight-forward and less time-consuming response from providers. The reason for making this response form more user-friendly is to hopefully improve response rates amongst providers. K. Martian asked for "Optional" to be added to the comments section of the new response form to let the providers know they do not have to fill-out that section. The update will be made accordingly.

Retrospective Drug Utilization Review (RDUR) Criteria Recommendations

L. Morgan reviewed the RDUR criteria that were selected for review for April, May, and June (Q2 2022). Presented data included number of profiles reviewed, number of cases identified for intervention, and the number of letters sent. An overview of what RDUR interventions were identified as most prevalent for each monthly cycle was given, as well. The recommended RDUR criteria enclosed in the packet were developed from product information provided by the manufacturers and are consistent with new indications, new drugs added, and new warnings. These proposed criteria will be added to the current set of criteria and will be used in future DUR cycles. A. Honeyman moved to approve the new criteria and J. Askvig seconded the motion. Standing in for Chair T. Schmidt, A. Honeyman called for a voice vote to approve the new criteria, which passed with all present members voting to approve.

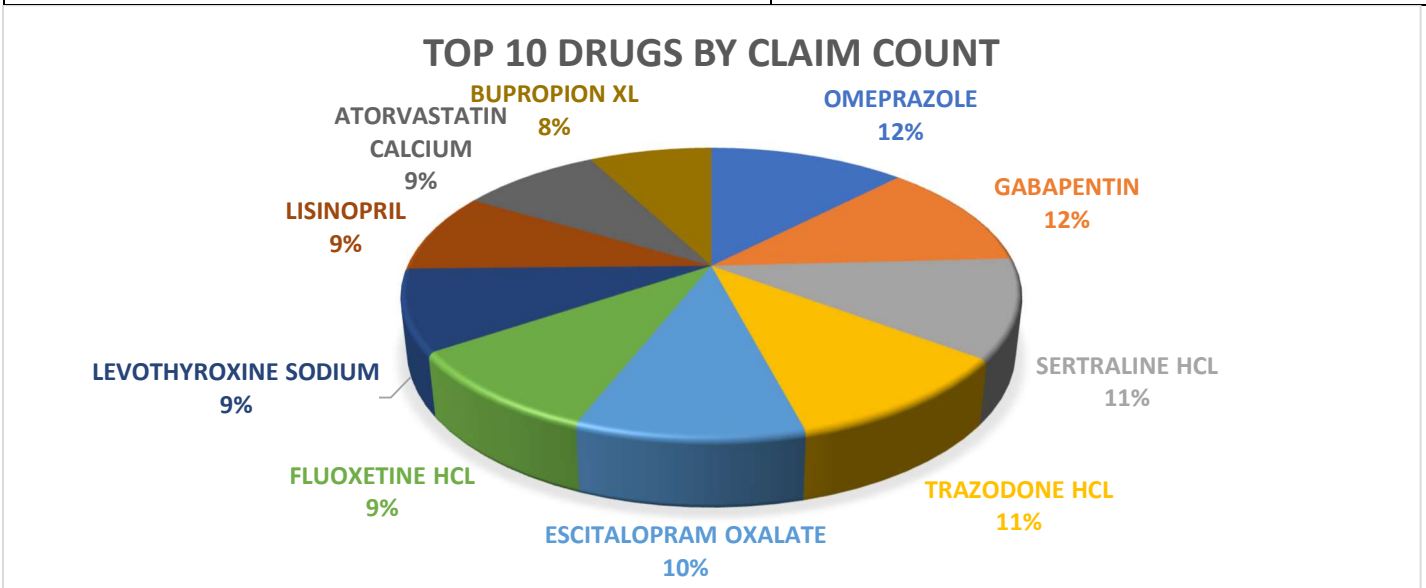
Adjournment and Upcoming Meeting Date

A. Honeyman adjourned the meeting at 3:42 pm. The next DUR Board meeting will be held December 7th, 2022, at 1:00 pm at the state capitol building.

Top 25 Drugs Based on Number of Claims from 07/01/2022 – 09/30/2022

Drug	Claims	Patients	Claims Cost	Cost / Claim	% Total Claims	Dif.
1. OMEPRAZOLE	4775	2401	$ 61,831.16	$ 12.95	1.86%	NC
2. GABAPENTIN	4592	1998	$ 68,667.15	$ 14.95	1.78%	NC
3. SERTRALINE HCL	4285	2366	$ 58,944.50	$ 13.76	1.66%	NC
4. TRAZODONE HCL	4149	2041	$ 56,719.55	$ 13.67	1.61%	NC
5. ESCITALOPRAM OXALATE	3919	2200	$ 52,939.06	$ 13.51	1.52%	NC
6. FLUOXETINE HCL	3722	2010	$ 52,020.24	$ 13.98	1.45%	NC
7. LEVOTHYROXINE SODIUM	3527	1815	$ 58,237.75	$ 16.51	1.37%	NC
8. LISINOPRIL	3431	1997	$ 44,811.27	$ 13.06	1.33%	NC
9. ATORVASTATIN CALCIUM	3397	1920	$ 48,280.25	$ 14.21	1.32%	NC
10. BUPROPION XL	2987	1619	$ 51,624.45	$ 17.28	1.16%	NC
11. PANTOPRAZOLE SODIUM	2914	1441	$ 39,991.06	$ 13.72	1.13%	↑1
12. VYVANSE	2879	1213	$ 752,598.19	$ 261.41	1.12%	↓1
13. HYDROCODONE-ACETAMINOPHEN	2835	1780	$ 41,070.34	$ 14.49	1.10%	NC
14. PROAIR HFA	2734	2705	$ 220,021.10	$ 80.48	1.06%	↑2
15. DULOXETINE HCL	2593	1349	$ 42,094.25	$ 16.23	1.01%	NC
16. CYCLOBENZAPRINE HCL	2569	1639	$ 30,626.49	$ 11.92	1.00%	↑1
17. BUPRENORPHINE-NALOXONE	2486	628	$ 104,854.10	$ 42.18	0.97%	↑4
18. AMOXICILLIN	2471	2325	$ 33,860.04	$ 13.70	0.96%	↓4
19. PREDNISONE	2455	1978	$ 29,030.35	$ 11.82	0.95%	↑3
20. CLONIDINE HCL	2449	1212	$ 30,968.92	$ 12.65	0.95%	NC
21. MONTELUKAST SODIUM	2376	1395	$ 33,192.65	$ 13.97	0.92%	↑2
22. METFORMIN HCL	2366	1325	$ 31,310.80	$ 13.23	0.92%	↓4
23. LAMOTRIGINE	2365	981	$ 34,634.14	$ 14.64	0.92%	↑1
24. HYDROXYZINE HCL	2342	1481	$ 32,338.94	$ 13.81	0.91%	↓6
25. BUSPIRONE HCL	2284	1231	$ 34,743.27	$ 15.21	0.89%	↑3

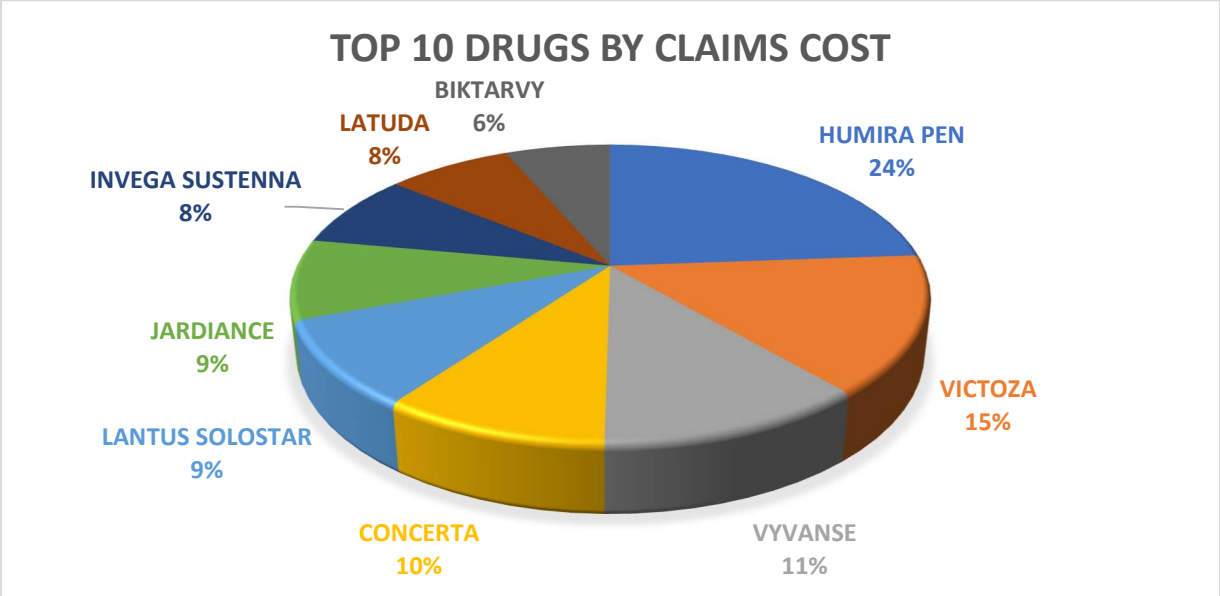
Total Claims	257404



Top 25 Drugs Based on Total Claims Cost from 07/01/2022 – 09/30/2022

Drug	Claims Cost	Claims	Patients	Cost /Claim	% Total Cost	Dif.
1. HUMIRA PEN	$ 2,223,980.48	304	84	$ 7,315.73	6.97%	NC
2. VYVANSE	$ 813,503.44	3112	1240	$261.41	2.55%	↑1
3. VICTOZA	$1,044,416.35	1240	318	$ 842.27	3.27%	↓1
4. CONCERTA	$686,121.39	1942	807	$353.31	2.15%	NC
5. LANTUS SOLOSTAR	$661,470.44	1297	787	$510.00	2.07%	NC
6. STELARA	$641,720.56	28	19	$22,918.59	2.01%	↑5
7. JARDIANCE	$607,030.96	987	457	$615.03	1.90%	↓1
8. INVEGA SUSTENNA	$572,522.07	225	88	$ 2,544.54	1.79%	↓1
9. TALTZ	$569,437.08	90	33	$6,327.08	1.78%	↓1
10. LATUDA	$539,465.15	636	232	$848.22	1.69%	↓1
11. MAVYRET	$506,110.48	43	28	$11,770.01	1.59%	↑1
12. BIKTARVY	$464,638.78	235	104	$1,977.19	1.46%	↑1
13. NORDITROPIN	$451,562.09	100	40	$4,515.62	1.42%	↓3
14. SYMBICORT	$394,885.44	1127	631	$350.39	1.24%	NC
15. ELIQUIS	$392,657.58	771	334	$509.28	1.23%	↑3
16. ADDERALL XR	$381,054.52	2201	878	$173.13	1.19%	↓1
17. ADVAIR DISKUS	$375,093.03	1013	550	$370.28	1.18%	↓1
18. VRAYLAR	$374,070.63	423	158	$884.33	1.17%	↑2
19. NOVOLOG FLEXPEN	$369,321.52	488	292	$756.81	1.16%	↓2
20. TRIKAFTA	$326,033.50	13	5	$25,079.50	1.02%	↓1
21. ABILIFY MAINTENA	$293,089.65	131	51	$2,237.33	0.92%	NC
22. LEVEMIR FLEXTOUCH	$274,247.22	486	270	$564.29	0.86%	NC
23. COSENTYX PEN	$236,508.94	36	13	$6,569.69	0.74%	↑1
24. PROAIR HFA	$ 234,143.14	2904	2852	$80.63	0.73%	↑3
25. XIFAXAN	$230,250.24	86	43	$2,677.33	0.72%	NC

Total Claims Cost	$31,910,470.96



Top 15 Therapeutic Classes Based on Number of Claims from 07/01/2022 – 09/30/2022

Therapeutic Class Description	Claims	Patients	Claims Cost	Cost/Claim	% Total Claims	Dif.
1. ANTIDEPRESSANTS	29480	12229	$613,471.66	$20.81	11.5%	NC
2. ANTICONVULSANTS, MISC	13241	4766	$ 629,245.05	$47.52	5.1%	NC
3. ANTIPSYCHOTIC AGENTS	9023	3539	$2,357,399.03	$261.27	3.5%	NC
4. PROTON-PUMP INHIBITORS	8075	3978	$142,254.99	$17.62	3.1%	NC
5. SEDATIVES/HYPNOTICS	7155	3677	$111,633.01	$15.60	2.8%	NC
6. OPIATE AGONISTS	6959	3589	$115,364.66	$16.58	2.7%	NC
7. AMPHETAMINES	6330	2660	$1,149,210.95	$181.55	2.5%	NC
8. NSAIDS	6316	4190	$92,434.11	$14.63	2.5%	NC
9. STATINS	5936	3339	$86,875.18	$14.64	2.3%	NC
10. BETA BLOCKERS	5462	2949	$100,249.15	$18.35	2.1%	NC
11. RESPIRATORY / CNS STIMULANTS	4859	1918	$958,653.73	$197.29	1.9%	↑2
12. PENICILLIN ANTIBIOTICS	4765	4267	$74,776.46	$15.69	1.9%	↓1
13. BETA AGONISTS	4383	4015	$323,884.86	$73.90	1.7%	↑2
14. ACE INHIBITORS	4335	2487	$68,283.17	$15.75	1.7%	↓1
15. ADRENALS	4120	3266	$57,809.26	$14.03	1.6%	↑2

Top 15 Therapeutic Classes Based on Claims Cost from 07/01/2022 – 09/30/2022

Therapeutic Class Description	Claims Cost	Claims	Patients	Cost/Claim	% Total Cost	Dif.
1. DMARDS	$3,355,066.56	616	245	$5,446.54	10.5%	NC
2. ANTIPSYCHOTIC AGENTS	$2,357,399.03	9023	3539	$ 261.27	7.4%	NC
3. SKIN AND MUCOUS MEMBRANE AGENTS	$2,020,009.08	622	387	$3,247.60	6.3%	↑1
4. INSULINS	$1,839,116.52	3486	1397	$527.57	5.8%	↓1
5. AMPHETAMINES	$1,149,210.95	6330	2660	$181.55	3.6%	NC
6. INCRETIN MIMETICS	$1,122,760.79	1338	610	$839.13	3.5%	NC
7. RESPIRATORY CORTICOSTEROIDS	$1,073,567.14	3660	2222	$293.32	3.4%	↑1
8. ANTINEOPLASTIC AGENTS	$1,059,311.53	561	249	$1,888.26	3.3%	↓1
9. ANTIRETROVIRALS	$973,189.18	699	274	$1,392.26	3.0%	↑1
10. RESPIRATORY CORTICOSTEROIDS	$ 958,653.73	4859	1918	$197.29	3.0%	↓2
11. SGLT-2 INHIBITORS	$785,292.02	1298	632	$605.00	2.5%	↑1
12. ANTICONVULSANTS	$629,245.05	13241	4766	$47.52	2.0%	↓1
13. ANTIDEPRESSANTS	$613,471.66	29480	12229	$20.81	1.9%	↑1
14. IMMUNOMODULATORY AGENTS	$602,151.18	74	31	$8,137.18	1.9%	↓1
15. HCV ANTIVIRALS	$541,317.70	50	30	$10,826.35	1.7%	NC

Drug Name	PA Status	Class
tazarotene gel	PA	Acne
Namzarac	PA	Alzheimer's Disease
Ertaczo cream	PA	Antifungal - Topical
Exelderm cream	PA	Antifungal - Topical
Exelderm solution	PA	Antifungal - Topical
Entadfi	PA	Benign Prostatic Hyperplasia
Ibsrela	PA	Constipation – Irritable Bowel Syndrome (IBS) / Opioid Induced
Korlym	PA	Cushing syndrome
Isturisa	PA	Cushing Syndrome
Tobi Podhaler	PA	Cystic Fibrosis - Inhaled Antibiotics
Premarin Injection	PA	Estrogens
Fylnetra	PA	Hematopoietic, Colony Stimulating Factors
Lokelma	PA	Hyperkalemia
Hemangeol	PA	Infantile Hemangioma
Naprotin Kit	PA	Kits
Zypitamag	PA	Lipid-Lowering Agents
Pheburane	PA	Medications that cost greater than 3000
Relyvrio	PA	Medications that cost greater than 3000
Lyrica CR	PA	Non-preferred Dosage Form
Alocril	PA	Ophthalmology Antihistamines
Alomide	PA	Ophthalmology Antihistamines
Natacyn	PA	Ophthalmology Anti-infectives
Durezol	PA	Ophthalmology Anti-inflammatories
calcitonin, salmon nasal spray	PA	Osteoporosis
calcitonin, salmon nasal vial	PA	Osteoporosis
Javygtor	PA	Phenylketonuria
Zoryve	PA	Plaque Psoriasis
Sotyktu	PA	Plaque Psoriasis
Vuity	PA	Presbyopia
Tadliq	PA	Pulmonary Hypertension
Ryaltris	PA	Steroid - Nasal Spray
Qnasl Children	PA	Steroids - Nasal Spray
Vivjoa	PA	Vaginal Infections
Verkazia	PA	Vernal Keratoconjunctivitis
butenafine cream	Remove PA	Antifungal - Topical
Suprep	Remove PA	Bowel Prep Agents
Depo-estradiol	Remove PA	Estrogens
Menest	Remove PA	Estrogens
Estradiol vaginal cream	Remove PA	Estrogens
Imitrex cartridge	Remove PA	Migraine
Imitrex nasal spray	Remove PA	Migraine

Zomig nasal spray	Remove PA	Migraine
Tobradex ST	Remove PA	Ophthalmology Anti-infectives/Anti-inflammatories
Bromsite	Remove PA	Ophthalmology Anti-inflammatories
Prolensa	Remove PA	Ophthalmology Anti-inflammatories
Rytary	Remove PA	Parkinson's Disease

Prurigo Nodularis

PREFERRED AGENTS (CLINICAL PA REQUIRED)
DUPIXENT (dupilumab)

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 greater than 20 nodular lesions that produce itch that has significantly diminished quality of life, including sleep disturbances.
- The member has failed each of the following trials, as evidenced by paid claims or pharmacy printouts:
  - A 2-week trial of a topical corticosteroid of medium or higher potency
  - A 3-month trial of an immunologic systemic therapy (e.g., azathioprine, cyclosporine, methotrexate)

Endometriosis Pain

CLINICAL PA REQUIRED
MYFEMBREE (relugolix, estradiol, and norethindrone acetate)
ORILISSA (elagolix)

Prior Authorization Criteria

Initial Criteria - Approval Duration: 6 months

- The member must have failed the following trials (A and B), as evidenced by paid claims or pharmacy printouts:
  A. A 3-menstrual cycle trial of mefenamic acid or meclofenamate, celecoxib, ibuprofen 1800 mg/day or equivalent high dose NSAID
  B. A 3-menstrual cycle trial of an oral estrogen-progestin or progestin contraceptives

Renewal Criteria - Approval Duration: 18 months

- Documentation must be submitted of improvement in pain score from baseline

Hematopoietic Syndrome of Acute Radiation Syndrome (NPlate)

PREFERRED AGENTS (CLINICAL PA REQUIRED)
NPLATE (romiplostim)

Prior Authorization Criteria

Initial Criteria - Approval Duration: treatment plan must be documented in request

- The requested medication must be prescribed by, or in consult with, a hematologist or oncologist.
- The member meets one of the following:
  - The member has had a ≥ 2 gray exposure to radiation
  - The member has had exposure to radiation and experiencing one of the following:
    - Gross blood loss

- > 10% decrease in hemoglobin
- Platelet count < 50,000/microL
- Absolute neutrophil count < 1000 cells/microL
- Absolute lymphocyte count < 1000 cells/microL

Amyloidosis

TTR (transthyretin) silencers

TTR-Specific small interfering RNA (siRNA)

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

Transhyretin-directed small interfering RNA (siRNA)

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

Antisense Oligonucleotide (ASO)

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

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
- Documentation of genetic testing confirming a pathogenic TTR mutation (e.g., V30M) must be provided
- Documentation of one of the following must be provided:
  - Baseline polyneuropathy disability (PND) score ≤ IIIb
  - Baseline FAB Stage 1 or 2
  - Baseline neuropathy impairment (NIS) score ≥ 10 and ≤ 130
- The member has not had a liver transplant
- The member has clinical signs and symptoms of the disease (amyloid deposition in biopsy specimens, TTR protein variants in serum, weakness, sensory loss, decreased motor strength, decreased gait speed, etc.)
- The member is not receiving any other TTR reducing agent (i.e., vutrisiran, patisiran, tafamidis, inotersen).

Renewal Criteria - Approval Duration: 12 months

- Documentation of a therapeutic response as evidenced by stabilization or improvement (e.g., improved neurologic impairment, motor function, quality of life, slowing of disease progression, etc.) from baseline in one of the following:
  - Baseline polyneuropathy disability (PND) score ≤ IIIb
  - Baseline FAB Stage 1 or 2
  - Baseline neuropathy impairment (NIS) score ≥ 10 and ≤ 130

TTR Stabilizers

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
VYNDAQEL (tafamidis)	
VYNDAMAX (tafamidis)	

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The member must have wild-type TTR mediated amyloidosis or documentation of genetic confirmation of hereditary TTR mediated amyloidosis as evidenced by a pathogenic TTR mutation (e.g., V30M)
- The requested medication must be prescribed by, or in consult with, a cardiologist, geneticist, or specialist in the treatment of amyloidosis
- The member has clinical signs and symptoms of the disease (heart failure, dyspnea, edema, hepatomegaly, ascites, angina, etc.)
- The member must not have any of the following:
  - NYHA class IV symptoms or severe aortic stenosis
  - Impaired renal function (i.e., GFR < 25)
  - Previous heart or liver transplant
- Documentation of baseline 6MWT > 100 meters must be submitted
- The member is not receiving any other TTR reducing agent (i.e., vutrisiran, patisiran, tafamidis, inotersen)

Renewal Criteria - Approval Duration: 12 months

- Documentation of a therapeutic response as evidenced by stabilization or improvement from baseline in both of the following:
  - 6MWT > 100 meters
  - NYHA class

Amyotrophic Lateral Sclerosis (ALS)

PREFERRED AGENTS (NO PA REQUIRED)	PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
EXSERVAN (riluzole) FILM	RADICAVA (edaravone) – *Medical Billing Only*	RILUTEK (riluzole) TABLET
riluzole tablet	RADICAVA ORS (edaravone)	TIGLUTIK (riluzole) ORAL SUSPENSION
	RELYVRIO (sodium phenylbutyrate/taurursodiol) ORAL POWDER FOR SUSPENSION	

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 had ALS symptoms present for less than 2 years
- Documentation has been submitted that the member has a forced vital capacity (FVC) > 80 percent of predicted
- Documentation of one of the following has been submitted:
  - ALS Function Rating Scale-Revised (ALSFRS-R) with a score of 2 or greater on each individual item of the scale
  - Japanese ALS Severity Scale with a grade of 1 or 2
- The member must not have permanent invasive ventilation

Renewal Criteria - Approval Duration: 12 months

- Documentation of Forced Vital Capacity (FVC) > 60 percent of predicted

- Documentation of a therapeutic response as evidenced by stabilization or improvement (e.g., improved neurologic impairment, motor function, quality of life, slowing of disease progression, etc.) from baseline as evidenced by one of the following:
  - ALS Function Rating Scale-Revised (ALSFRS-R)
  - Japanese ALS Severity Scale

Chelating Agents

Iron Chelators

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
deferasirox tablet for suspension	EXJADE (deferasirox tablet for suspension)
deferasirox tablets	deferasirox sprinkle
deferoxamine mesylate vial – *Medical Billing Only*	DESFERAL MESYLATE VIAL – *Medical Billing Only*
	FERRIPROX (deferiprone)
	JADENU (deferasirox) SPRINKLE
	JADENU (deferasirox) TABLETS

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)
- Clinical justification must be provided explaining why the member is unable to use the preferred agents (subject to clinical review).
- The member must have failed a trial duration of 30 days (or less if duration is FDA approved) of each preferred agent (listed in boxes below) within the past 2 years, as evidenced by paid claims or pharmacy printouts.

Treatment follow up questions for Eosinophilic Esophagitis

1. **Is endoscopy required to determine treatment effectiveness?**

   The efficacy of any therapy should be checked by a follow-up endoscopy after a 6- to 12-week initial course. Symptoms do not correlate accurately with histologic disease activity, so histology currently continues to be necessary to monitor the disease.

   Endoscopy and biopsy sampling, and not symptoms alone, are needed to assess EoE activity before and after any change in dietary elimination therapy or pharmacologic treatment. Endoscopy with biopsy sampling should be considered in several circumstances: to evaluate a treatment regimen chosen to control symptoms and ideally resolve esophageal eosinophilia, after the institution of new treatments if the previous treatment failed, changes in symptoms or compliance with therapy, and to identify specific food triggers that cause EoE in children and adults. Endoscopy with biopsy sampling should be repeated no earlier than 4 weeks after a change in diet therapy or 8 to 12 weeks for pharmacologic treatment to allow adequate time for a significant histologic change to occur. The principle supporting the absolute need for endoscopy and biopsy sampling to assess medical therapy is guided by the poor correlation between histology and symptoms.

2. **Can treatment be discontinued/de-escalated after histological remission is achieved or will need to be a chronic/lifelong medication?**

   When pharmacological treatment for EoE is stopped, symptoms and/or esophageal eosinophilia typically recur over a 3–6 month period. However, the long-term therapeutic strategy and best maintenance doses for pharmacologic therapies are yet to be defined. An approach where the dose is progressively decreased to the lowest dose that keeps the disease in remission seems reasonable until more data are available. Long-term treatment with an effective anti-inflammatory drug or diet is recommended in the guidelines.

   It is well accepted that active esophageal eosinophilic infiltration in EoE can lead to esophageal fibrosis and stenosis and that 50% of EoE patients will have recurrent dysphagia at 15 months after dilation if not treated with maintenance anti-inflammatory therapy. Because EoE is a chronic and progressive disease that cannot be cured, monitoring patients after initial diagnosis is necessary. Several studies clearly demonstrated that symptoms and inflammation recur consistently after cessation of successful medical or dietary therapy. Further, it is well known that inflammatory activity and symptom severity have only a modest correlation. Once diagnosed, EoE requires a long-term management strategy. Anti-inflammatory maintenance treatment must be continued after achieving a state of remission.

3. **How often should the endoscopy/biopsy be repeated if histological reemission was achieved on treatment?**

   Because absence of symptoms is not a guarantee of endoscopic or histologic remission, a periodic assessment of inflammatory activity using endoscopy with structured biopsy sampling or with less-invasive methods such as the string or sponge test can be considered in symptom-free patients. There are little data to guide the frequency of clinical and endoscopic assessments, although expert opinion dictates that at least an annual clinical evaluation in well-controlled patients is reasonable.

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Annual Review of Online Forms and Criteria

Pharmacy Drug Coverage Policy Manual

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NORTH Dakota | Health & Human Services
Be Legendary.

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 www.hidesigns.com/ndmedicaid

Preferred Drug List (PDL)

Rules

1. Requests for non-preferred brand name agents with a generic formulation available must meet the Dispense as Written (DAW1) criteria for approval in addition to as any other applicable coverage criteria/rule (unless otherwise noted).
2. Non-solid dosage preparations must meet Non-Solid Dosage Preparations prior authorization criteria even if they are preferred in the clinical category.
3. Renewal Request Criteria must be met for all renewal requests.
4. The use of all preferred and non-preferred agents must meet recommendations found in the FDA label or compendia (e.g., diagnosis, age, dosage, frequency, route). Compendia supported use is defined as at least of level of IIa efficacy rating and IIb recommendation. ND Medicaid uses DrugDex ® compendia. Requests outside of FDA approved or compendia supported use are not reviewable by prior authorization and the request will be dismissed on PA review. Sec. 1927. [42 U.S.C. 1396r-8] (d).
5. Clinical justification may be provided when criteria does not encompass a standard of care or guideline supported therapy or a member's unique scenario, by faxing supporting chart notes and evidence to 701-328-1544.
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 maximum tolerated dose with good compliance, as evidenced by paid claims or pharmacy print outs. If alternative preferred product(s) are available that the member does not have a documented contraindication, intolerance, or adverse reaction to the same active ingredient, trial requirements must be met with alternative preferred product(s). A trial for preferred product(s) will not be required for which a documented contraindication exists. Intolerance and adverse reaction mitigation efforts must be provided with a request to bypass a trial for a preferred product(s), subject to clinical review.
8. The use of pharmaceutical samples will not be considered when evaluating the member's medical condition or prior prescription history for drugs that require prior authorization.
9. Unless otherwise specified, the listing of a brand or generic name includes all legend forms of that drug. OTC drugs are not covered unless specified.
10. Please use the following forms unless otherwise indicated:
    - Pharmacy Point of Sale: General Prior Authorization Form
    - Medical Office Billing: Medical Service Authorization Request
    - Requested product is same active ingredient as preferred product: MedWatch Form
11. Please use the NDC Drug Lookup tool to access PA form, view coverage status, quantity limits, copay, and prior authorization information for all medications.

Version Changes

Category	Change
Adult-Onset Still's Disease	Preferred Products/Criteria updated
Albuterol/Levalbuterol Rescue Inhalers	Preferred Products Updated
Axial Spondyloarthritis	Ankylosing spondylitis and Nonradiographic axial spondyloarthritis categories combined
Antifungal - Topical	Preferred Products Updated
Bowel Prep Agents	Preferred Products/Criteria updated
Crohn's Disease	Criteria Updated
Constipation - IBS / Idiopathic	Criteria Updated
Cryopyrin Associated Periodic Syndrome (CAPS)	Criteria Updated
Cystic Fibrosis - Inhaled Aibiotics	Preferred Products Updated
Cytokine Release Syndrome	Criteria Added
Endometriosis Pain	Category Updated to include Myfembree
Eosinophilic Asthma	Moved under Pulmonary, Biologics
Eosinophilic granulomatosis with polyangiitis (EGPA)	Criteria Updated
Estrogens	Preferred Products Updated
Familial Mediterranean Fever	Criteria Updated
Generic Non-Preferred Requests	Criteria Added
Hemophilia	Preferred Products Updated
Hyperimmunoglobulin D Syndrome/Mevalonate Kinase (MVK) Deficiency	Criteria Updated
Infantile Hemangioma	Preferred Products/Criteria updated
Medical Billing Drug Clinical Criteria	Integrated into PDL
Migraine	Preferred Products Updated
Ophthalmology Anti-infectives/Anti-inflammatories	Preferred Products Updated
Ophthalmology Anti-inflammatories	Preferred Products Updated
Osteoporosis	Preferred Products/Criteria updated
Overactive Bladder	Preferred Products Updated
Parkinson's Agents - Dopamine Precursors	Preferred Products Updated
Plaque Psoriasis	Criteria Updated
Proton Pump Inhibitors	Preferred Products Updated
Renewal Requests	Criteria Added
Rheumatoid Arthritis	Preferred Products/Criteria updated
Serostim	Criteria Updated
Statins	Preferred Products Updated
Steroids - Nasal Spray	Preferred Products Updated
Thrombocytopenia	Preferred Products Updated
Tumor Necrosis Factor Receptor Associated Periodic Syndrome	Criteria Updated
Ulcerative Colitis	Criteria Updated

General Policies

Biosimilar Agents

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

- Clinical justification must be provided explaining why the member is unable to use the preferred agents (subject to clinical review)

Combination Agents

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

- Clinical justification must be provided for combination products that are comprised of components available and more cost effective when prescribed separately (subject to clinical review).

Dispense as Written (DAW1)

The member or prescriber preference is NOT criteria considered for approval

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

- Request must meet one of the following (A or B):
  - A. Primary insurance requires a ND Medicaid non-preferred branded product
  - B. All the following are met (1-4):
    1. The requested brand-name product must not have an authorized generic available
    2. The member must have failed a 30-day trial of each pharmaceutically equivalent generic product at maximum tolerated dose from each available manufacturer, as evidenced by paid claims or pharmacy print outs
    3. Clinical justification is provided for the different clinical outcome expected for the requested brand and other alternatives (e.g., medications in same class) are not an option for the member (subject to clinical review)
    4. A MedWatch form for each trial of each product from the available manufacturer(s) is filled out and attached to request

Generic Non-Preferred Requests

The member or prescriber preference is NOT criteria considered for approval

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months (1 month for short-term request)

- Request must meet one of the following (A, B, or C):
  - A. Primary insurance requires a ND Medicaid non-preferred generic product
  - B. Pharmacy requests a short-term approval due to dose titration or supply issue
  - C. All the following are met (1-3):
    1. The member must have failed a 30-day trial of preferred brand product, as evidenced by paid claims or pharmacy print outs

2. Clinical justification is provided for the different clinical outcome expected for the requested generic and other alternatives (e.g., medications in same class) are not an option for the member (subject to clinical review)
3. A MedWatch form for each trial of each product from the available manufacturer(s) is filled out and attached to request

Medications that cost over $3000/month

Prior Authorization Criteria

Initial Criteria - Approval Duration: 6 months

- 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 treated diagnosis
- As applicable, documentation must be attached to confirm serum marker or pathogenic gene variants amenable to treatment

CLINICAL PA REQUIRED
ABECMA (idecabtagene vicleucel) – *Medical Billing Only*
BLINCYTO (blinatumomab) – *Medical Billing Only*
BREYANZI (lisocabtagene maraleucel) – *Medical Billing Only*
CERDELGA (eliglustat)
CYSTADROPS (cysteamine)
CYSTARAN (cysteamine)
DANYELZA (naxitamab-gqgk) – *Medical Billing Only*
DOJOVI (triheptanoin)
ENSPRYNG (satralizumab)
FERRIPROX (deferiprone)
FIRDAPSE (amifampridine)
GATTEX (teduglutide)
INCRELEX (mecasermin)
MYCAPSSA (octreotide)
NULIBRY (fosdenopterin)
OXERVATE (cenegermin-bkbj)
PHEBURANE (sodium phenylbutyrate)
PYRUKYND (mitapivat)
RADICAVA ORS (edaravone)
RAVICTI (glycerol phenylbutyrate)
RELYVRIO (sodium pheylbutyrate/taurursodiol)
REZUROCK (belumosudil)
SAMSCA (tolvaptan)
TAVNEOS (avacopan)
TECARTUS (brexucabtagene autoleucel) – *Medical Billing Only*
TEGSEDI (inotersen)
TIVDAK (tisotumab vedotin-tftv)
VIJOICE (alpelisib)
VYNDAMAX (tafamidis)
WELIREG (belzutifan)
YESCARTA (axicabtagene ciloleucel) – *Medical Billing Only*
ZOKINVY (lonafamib)

ZYNLONTA (loncastuximab tesirine-lpyl) – *Medical Billing Only*

Non-Solid Dosage Forms

Electronic Age Verification

- Non-Solid Dosage Forms that do not require prior authorization for clinical criteria will reject at the point of sale for members 10 years and older to verify they meet Non-Solid Dosage Form prior authorization criteria

Prior Authorization Criteria

Initial Criteria - Approval Duration: 2 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)
    - The member is 9 years old or younger

Renewal Requests

Prior Authorization Criteria

Renewal Criteria

- The member must have experienced and maintained clinical benefit since starting treatment with the requested medication, as evidenced by medical documentation (e.g., chart notes) attached to the request (subject to clinical review).
- The member must continue to meet applicable initial criteria. Additional criteria may apply as indicated under specific category
- One of the following must be met:
  1. *Approval Duration: regular renewal approval duration*
     - The member was at least 80% adherent to medication
     - The member had a claim gap due to hospitalization or eligibility
  2. *Approval Duration: 3 months*
     - All the following must be met -
       - Clinical justification must be provided for the non-adherence.
       - A method to improve adherence must be provided such as addressing adherence barriers, implementing a treatment plan, medication therapy management (MTM), etc.
       - Medical justification must be provided to continue treatment and how efficacy is assessed despite non-adherence

Allergy/Immunology

Therapeutic Duplication

- One strength of one medication is allowed at a time

Chronic Idiopathic Urticaria

CLINICAL PA REQUIRED
XOLAIR (omalizumab) SYRINGES

XOLAIR (omalizumab) VIALS – *Medical Billing Only*

Prior Authorization Criteria

Initial Criteria - Approval Duration: 3 months

- The requested medication must be prescribed by, or in consult with, an allergist/immunologist.
- The member must have failed a 30-day trial of a type 1 (H1) antihistamine at maximally tolerated dose either non-sedating (e.g., cetirizine, fexofenadine, loratadine, desloratadine, or levocetirizine) or sedating (e.g., diphenhydramine, chlorpheniramine, cyproheptadine) in addition to one of the following:
  - Leukotriene receptor antagonist (e.g., montelukast, zafirlukast, zileuton)
  - Histamine H2-receptor (e.g., ranitidine, famotidine, nizatidine, cimetidine)

Deficiency of IL-A Receptor Antagonists (DIRA)

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 30-day trial of a preferred agent, as evidenced by paid claims or pharmacy printouts.

Eosinophilic Granulomatosis with Polyangiitis (EGPA)

CLINICAL PA REQUIRED
NUCALA (mepolizumab)

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 have active, non-severe disease defined as vasculitis without life- or organ-threatening manifestations (e.g., rhinosinusitis, asthma, mild systemic symptoms, uncomplicated cutaneous disease, mild inflammatory arthritis)
- The member must have received at least 4 weeks of a stable corticosteroid dose to control relapsing or refractory disease.
- The member must have asthma poorly controlled on moderate doses of inhaled glucocorticoids
- The member must have blood eosinophil level ≥ 1500 cells per microliter and/or ≥10 percent of leukocytes within the previous 6 weeks, as evidenced by laboratory documentation attached to the request
- The member must have at least 2 of the following:
  - Paranasal sinusitis
  - Pulmonary infiltrates, sometimes transient
  - Histologic evidence of vasculitis with extravascular eosinophils
  - Multiple mononeuropathy or polyneuropathy

Renewal Criteria - Approval Duration: 12 months

- The member must have experienced a decrease in relapses* and corticosteroid dose, and an increase of time of remission since starting treatment with the requested medication, as evidenced by medical documentation (e.g., chart notes) attached to the request (subject to clinical review).

*Relapse is defined as active vasculitis, active asthma symptoms, active nasal or sinus disease requiring the use of glucocorticoids or immunosuppressants.

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Hypereosinophilic Syndrome (HES)

CLINICAL PA REQUIRED
NUCALA (mepolizumab)

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 have experienced at least 2 HES flares within the past 12 months despite a 3-month trial with the following:
  - oral corticosteroids
  - steroid sparing therapy (e.g., hydroxyurea)
- The member must have a blood eosinophil count of 1000 cells/mcL or higher, as evidenced by laboratory documentation attached to the request

Renewal Criteria - Approval Duration: 12 months

- The member must have experienced a decrease in HES flares* and a blood eosinophil count < 1000 cells/mcL since starting treatment with the requested medication, as evidenced by medical documentation (e.g., chart notes) attached to the request (subject to clinical review).

  *HES flares are defined as worsening of clinical signs and symptoms of HES or increasing eosinophils, resulting in the need to increase OCS or increase/add cytotoxic or immunosuppressive HES therapy.

Nasal Polyps

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
DUPIXENT (dupilumab)	NUCALA (mepolizumab)
XOLAIR (omalizumab) SYRINGES	

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 the following:
  - intranasal corticosteroids
  - oral corticosteroids
- The member must have bilateral polyps confirmed by sinus CT, sinus MRI, or nasal endoscopy

- Member must have documentation of at least two of the following symptoms:
  - nasal obstruction or nasal discharge (anterior/posterior nasal drip)
  - facial pain or pressure
  - reduction in or loss of smell

Non-Preferred Agent Criteria:

- The member must have failed a 90-day trial with 1 preferred agent, as evidenced by paid claims or pharmacy printouts

Renewal Criteria - Approval Duration: 12 months

- Documentation must be provided including that the member has achieved a significant reduction in nasal polyp size and symptoms since treatment initiation.
- The member must be receiving intranasal steroids

Gout

Colchicine

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
COLCRYS (colchicine) TABLETS – *Brand Required*	colchicine capsules
	colchicine tablets
	GLOPERBA (colchicine) ORAL SOLUTION
	MITIGARE (colchicine) CAPSULE

Prior Authorization Criteria

- See applicable Preferred Dosage Form or Non-Solid Oral Dosage Form criteria

Uricosuric Drugs

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
probenecid-colchicine tablets	
probenecid tablets	

Xanthine Oxidase Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
6-mercaptopurine (6-MP)	allopurinol 200 mg tablet
allopurinol 100 mg tablet	azathioprine 75 mg
allopurinol 300 mg tablet	azathioprine 100 mg
azathioprine 50mg	febuxostat
	ULORIC (febuxostat) TABLET
	ZYLOPRIM (allopurinol) TABLET

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

- The member must have failed a 30-day trial of allopurinol, as evidenced by paid claims or pharmacy printouts
- Azathioprine: See Preferred Dosage Form Criteria

Uricase Drugs

PREFERRED AGENTS (CLINICAL PA REQUIRED)

KRYSTEXXA (pegloticase) – *Medical Billing Only*

Prior Authorization Criteria

Initial Criteria - Approval Duration: 6 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a rheumatologist
- The member must have failed a 30-day trial of each of the following, as evidenced by paid claims or pharmacy printouts:
  - allopurinol at 300 mg/day (or maximally tolerated dose) in combination with probenecid
  - febuxostat in combination with probenecid
- The failure of previous trials must be documented by each of the following:
  - Serum uric acid level ≥ 6 mg/dL within the past month
  - At least two gout flares within the past year or at least one nonrevolving tophaceous deposit

Renewal Criteria - Approval Duration: 12 months

- The member must have experienced and maintained clinical benefit since starting treatment with the requested medication, as evidenced by medical documentation (e.g., chart notes) attached to the request (subject to clinical review) including 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

Acute Attack

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
BERINERT (C1 Esterase Inhibitor)	FIRAZYR (icatibant)
Icatibant	KALBITOR (ecallantide)
RUCONEST (C1 Esterase Inhibitor)	

Prophylaxis

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
HAEGARDA (C1 Esterase Inhibitor)	CINRYZE (C1 Esterase Inhibitor)
ORLADEYO (berotrlastat)	
TAKHZYRO (lanadelumab-flyo)	

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 with the same indication for use (prophylaxis or acute treatment), as evidenced by paid claims or pharmacy printouts with required trial durations as follows:
  - Agents for acute attacks: a single trial
  - Agents for attack prophylaxis: 3 months

Quantity Override Request

- Takhyzro: The number of attacks in the last 6 months must be included if the requested dose is 300 mg every 2 weeks

Immune Globulins

IM

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
GAMASTAN (immune globul G (IgG)/glycine)	
GAMASTAN S-D (immune globul G (IgG)/glycine)	

IVIG

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
BIVIGAM (human immunoglobulin gamma)	ASCENIV (human immune globulin G- slra)
FLEBOGAMMA DIF (human immunoglobulin gamma)	GAMMAPLEX (human immunoglobulin gamma)
GAMMAGARD S-D (human immunoglobulin gamma)	OCTAGAM (human immunoglobulin gamma)
PRIVIGEN (human immunoglobulin gamma)	PANZYGA (Immune Globulin- ifas)

IVIG/SCIG

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
GAMMAGARD LIQUID (human immunoglobulin gamma)	GAMMAKED (human immunoglobulin gamma)
GAMUNEX-C (human immunoglobulin gamma)	

SCIG

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
HIZENTRA (human immunoglobulin gamma)	CUTAQUIG (human immune globulin G - hipp)
	CUVITRU (human immunoglobulin gamma)
	HYQVIA (human immune globulin G and hyaluronidase)
	XEMBIFY (immune globulin,gamma(IgG)klhw)

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

Non-Preferred Agent Criteria:

- 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)

Peanut Allergy

CLINICAL PA REQUIRED
PALFORZIA (peanut allergen powder)

Prior Authorization Form - Palforzia

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 must not have any of the following:
  - Uncontrolled asthma
  - A history of eosinophilic esophagitis or another eosinophilic GI disease
  - Severe or life-threatening anaphylaxis in the 60 days prior to the request
- The member must have a clinical history of allergy to peanuts or peanut-containing foods AND one of the following:
  - The member has had a serum immunoglobulin E (IgE) to peanut ≥0.35 kUA/L
  - Skin prick test (SPT) to peanut ≥ 3mm compared to control
  - Allergic reaction produced during a provider observed intake of peanuts

Renewal Criteria - 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:
  - The member has been able to tolerate the maintenance dose of Palforzia (300 mg daily)
    OR
  - An up-titration plan to a final dose of 300 mg daily has been submitted and this is a first request for an up-titration renewal

Steroids – Nasal Spray

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
BECONASE AQ (beclomethasone)	flunisolide
fluticasone	mometasone
OMNARIS (ciclesonide)	QNASL CHILDREN (beclomethasone)
QNASL (beclomethasone)	RYALTRIS (olopatadine/mometasone)
ZETONNA (ciclesonide)	XHANCE (fluticasone)

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

- The member must have failed a 30-day trial of each preferred agent, as evidenced by paid claims or pharmacy printouts
- Xhance (fluticasone) Only: Clinical justification must be provided explaining why the member is unable to use another product with the same active ingredient (subject to clinical review)

Cardiology

Therapeutic Duplication

- One Strength of one medication is allowed at a time
  - Exceptions:
    - carvedilol IR 25mg 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 alpha blockers (Alfuzosin ER, doxazosin, dutasteride-tamsulosin, prazosin, terazosin, and tamsulosin)
  - carvedilol and labetalol are nonselective beta blockers with alpha 1 blocking activity
- tizanidine is not allowed with other alpha 2 agonists (clonidine, clonidine/chlorthalidone, guanfacine, methyldopa)
  - tizanidine is also an alpha 2 agonist
- clopidogrel is not covered with esomeprazole or omeprazole. Other PPIs such as pantoprazole are covered with clopidogrel.
  - clopidogrel is a substrate for 2C19 and esomeprazole and omeprazole are strong 2C19 inhibitors and can decrease effectiveness of clopidogrel.
- clopidogrel, prasugrel, ticagrelor, and ticlopidine are not covered with morphine. Other opioid analgesics are covered with clopidogrel, prasugrel, ticagrelor, and ticlopidine.
  - Morphine may diminish the antiplatelet effect and serum concentrations of P2Y12 Inhibitor antiplatelet agents (clopidogrel, prasugrel, ticagrelor, and ticlopidine).

Beta Blockers – Override Request

Overrides may be available for beta blockers with slightly different mechanisms of action for use within the cardiac or nephrology specialty: 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 - Oral:

Underutilization

- Eliquis, Pradaxa, Xarelto, and Savaysa must be used adherently and will reject on point of sale for late fill

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ELIQUIS (Apixaban)	dabigatran
PRADAXA (dabigatran) – *Brand Required*	SAVAYSA (edoxaban)
warfarin	
XARELTO (rivaroxaban) 10 mg, 15 mg, 20 mg, 1 mg/mL suspension	
XARELTO (rivaroxaban) STARTER PACK	

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.

Reduction of Risk of Major Cardiovascular Events in Chronic CAD or PAD

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
XARELTO (rivaroxaban) 2.5 mg	

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

- Xarelto 2.5 mg: The request must include medical documentation (e.g., clinical notes) to verify diagnosis.

Anticoagulants – Injectable

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
enoxaparin	ARIXTRA (fondaparinux)
fondaparinux	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)
diltiazem ER degradable	VERELAN (verapamil) ER PELLETS
KATERZIA (amlodipine) SUSPENSION	DILT-XR (diltiazem) ER DEGRADABLE
NORLIQVA (amlodipine) SOLUTION	
verapamil ER pellets	

Solid oral dosage forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
amlodipine	CALAN SR (verapamil)
CARTIA XR (diltiazem)	CARDIZEM (diltiazem)
diltiazem	nisoldipine ER 20 mg, 30 mg, 40 mg
DILT-XR (diltiazem)	NORVASC (amlodipine)
felodipine ER	PROCARDIA XL (nifedipine)
isradipine	SULAR (nisoldipine)
MATZIM LA (diltiazem) ER	TIAZAC (diltiazem)
nicardipine	VERELAN (verapamil)
nifedipine	
nimodipine	
nisoldipine ER 8.5 mg, 17 mg, 25.5 mg, 34 mg	
TAZTIA XT (diltiazem)	
TIADYLT ER (diltiazem)	
verapamil	

Prior Authorization Criteria

- Nisoldipine ER 20 mg, 30 mg, 40 mg: See Preferred Dosage Form Criteria

Diuretics - Loop

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
furosemide	ethacrynic acid
bumetanide	SOAANZ (torsemide)

torsemide	

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

- Ethacrynic acid: One of the following must be met:
  - The member must have a documented sulfa allergy
  - The member must have failed a 30-day trial of each preferred agent, as evidenced by paid claims or pharmacy print outs.
- Soaanz: See Preferred Dosage Form Criteria

Diuretics – Aldosterone Antagonist

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
amiloride	ALDACTONE (spironolactone)
CAROSPIR (spironolactone) SUSPENSION	INSPRA (eplerone)
eplerenone	
spironolactone	
triamterene	

Heart Failure

First Line Agents

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ACE (angiotensin-converting enzyme) inhibitors - *all oral agents preferred*	
ARBs (angiotensin receptor blockers) - *all oral agents preferred*	
Beta blockers - *all oral agents preferred*	
ENTRESTO (sacubitril/valsartan)	
FARXIGA (dapagliflozin)	
JARDIANCE (empagliflozin)	

Second Line Agents

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
CORLANOR (ivabradine)	
VERQUVO (vericiguat)	

Electronic Diagnosis Verification

- Corlanor, Entresto, and Verquvo: Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale

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
- 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
- Documentation of a recent hospitalization or need for IV diuretics within the past 6 months must be provided with request
- The member is receiving concurrent Entresto, a beta-blocker, a SGLT-2 Inhibitor, and a mineralocorticoid receptor antagonist.

Hypertrophic Cardiomyopathy

CLINICAL PA REQUIRED
CAMZYOS (mavacamten)

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

- The requested medication must be prescribed by, or in consult with, a cardiologist
- The member must have left ventricular ejection fraction (LVEF) < 55% at initiation and < 50% at renewal
- The member has a peak left ventricular outflow tract (LVOT) gradient ≥ 50 mmHg at rest or with provocation
- The member is receiving concurrent a beta-blocker and a nondihydropyridine calcium channel blocker.

Renewal Criteria - Approval Duration: 12 months

- Member has an improved pVO_2 by ≥ 1.5 mL/kg/min plus improvement in NYHA class by at least 1 or improvement of pVO_2 by ≥ 3 mL/kg/min and no worsening in NYHA class.

Inappropriate Sinus Tachycardia

CLINICAL PA REQUIRED
CORLANOR (ivabradine)

Electronic Diagnosis Verification

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

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

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

Lipid-Lowering Agents

ACL(ATP Citrate Lyase) Inhibitors

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
NEXLETOL (bempedioc acid)	
NEXLIZET (bempedoic acid and ezetimibe)	

Prior Authorization Criteria

Initial Criteria - Approval Duration: 3 months

- The member must have LDL levels of >70 mg/dL after a 120-day trial of one of the following, as evidenced by paid claims or pharmacy printouts:
  - Crestor (rosuvastatin) ≥20 mg
  - Lipitor (atorvastatin) ≥ 40 mg

Electronic Step Care and Concurrent Medications

- A total of 90 days of Crestor (rosuvastatin) or Lipitor (atorvastatin) must be paid within 120 days prior to Nexletol or Nexlizet's date of service or intolerance to statins justification must be provided (subject to clinical review)

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 capsules 50mg, 150mg	ANTARA (fenofibrate, micronized)
fenofibrate, micronized 43mg, 67mg, 130mg, 134mg, 200mg	fenofibrate, micronized 30mg, 90mg
fenofibrate, nanocrystallized 48mg, 145mg	fenofibrate tablets 40mg, 120mg
fenofibrate tablets 54mg, 160mg	FENOGLIDE (fenofibrate)
fenofibric acid	LIPOFEN (fenofibrate)
	TRICOR (fenofibrate, nanocrystalized)
	TRIGLIDE (fenofibrate)
	TRILIPIX (fenofibric acid)

Prior Authorization Criteria

- See Preferred Dosage Form Criteria

MTP (Microsomal Triglyceride Transfer Protein) Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	JUXTAPID (lomitapide)

Prior Authorization Criteria

Initial Criteria - Approval Duration: 3 months

- Clinical justification must be provided explaining why the member is unable to use all other products to lower their cholesterol (subject to clinical review)

PCSK9 (Proprotien Convertase Subtilisin/Kexin Type 9) Inhibitors

PREFERRED AGENTS (ELECTRONIC STEP REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
PRALUENT PEN (alirocumab)	REPATHA PUSHTRONEX (evolocumab)
	REPATHA SURECLICK (evolocumab)
	REPATHA SYRINGE (evolocumab)

Underutilization

- Praluent and Repatha must be used adherently and will reject on point of sale for late fill

Electronic Step Care and Concurrent Medications

- Praluent: A total of 90 days of Crestor (rosuvastatin) or Lipitor (atorvastatin) must be paid within 120 days prior to Praluent's date of service or intolerance to statins justification must be provided (subject to clinical review)

Prior Authorization Criteria

Initial Criteria - Approval Duration: 3 months

- One of the following must be met:
  - The member is age 10 or greater and younger than 18 years old and is concurrently on a statin, as evidenced by paid claims or pharmacy printouts.
  - The member must have LDL levels of >70 mg/dL after a 90-day trial of the following, as evidenced by paid claims or pharmacy printouts:
    - Praluent combined with Crestor (rosuvastatin) ≥20 mg or Lipitor (atorvastatin) ≥ 40 mg
    - Nexlizet combined with Crestor (rosuvastatin) ≥20 mg or Lipitor (atorvastatin) ≥ 40 mg

Statins (HMG-CoA (3-hydroxy-3-methylglutaryl-CoA Reductase Inhibitors)

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
amlodipine/atorvastatin	ALTROPREV (lovastatin)
atorvastatin	CADUET (amlodipine/atorvastatin)
ezetimibe/simvastatin	CRESTOR (rosuvastatin)
fluvastatin	EZALLOR SPRINKLE (rosuvastatin)
LIVALO (pitavastatin)	fluvastatin ER
lovastatin	LESCOL XL (fluvastatin)
pravastatin	LIPITOR (atorvastatin)
rosuvastatin	PRAVACHOL (pravastatin)
simvastatin	VYTORIN (ezetimibe/simvastatin)
	ZOCOR (simvastatin)
	ZYPITAMAG (pitavastatin)

Prior Authorization Criteria

- See applicable Preferred Dosage Form or Non-Solid Dosage Form criteria

Angiopoietin-like 3 (ANGPTL3) Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	EVKEEZA (evinacumab-dgnb) – *Medical Billing Only*

Prior Authorization Criteria

Initial Criteria - Approval Duration: 6 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a cardiologist, endocrinologist, or lipid specialist
- Documentation of one of the following must be provided:
  - Genetic testing confirming two mutant alleles at the low-density lipoprotein receptor (LDLR), apolipoprotein B (apo B), proprotein convertase subtilisin kexin type 9 (PCSK9) or low-density lipoprotein receptor adaptor protein 1 (LDLRAP1) gene locus
  - Untreated total cholesterol of > 500mg/dL with one of the following:
    - Cutaneous or tendon xanthoma before age 10 years
    - Evidence of heterozygous familial hypercholesterolemia in both parents

- Low-density lipoprotein cholesterol (LDL-C) level greater than 100 mg/dL after a 90-day trial of each of the following, as evidenced by paid claims or pharmacy printouts or clinical justification as to why a treatment is unable to be used (subject to clinical review):
  - PCSK9 inhibitor and ezetimibe combined with rosuvastatin ≥20 mg or atorvastatin ≥ 40 mg
  - Nexlizet and ezetimibe combined with rosuvastatin ≥20 mg or atorvastatin ≥ 40 mg

Renewal Criteria - Approval Duration: 12 months

- The member has an LDL-C level less than 100 mg/dL or has achieved a 40% reduction

siRNA (small interfering RNA) therapy

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	LEQVIO (inclisiran) – *Medical Billing Only*

Prior Authorization Criteria

Initial Criteria - Approval Duration: 6 months

- The member must have LDL levels of >70 mg/dL after a 90-day trial of the following, as evidenced by paid claims or pharmacy printouts:
  - Praluent combined with Crestor (rosuvastatin) ≥20 mg or Lipitor (atorvastatin) ≥ 40 mg
  - Nexlizet combined with Crestor (rosuvastatin) ≥20 mg or Lipitor (atorvastatin) ≥ 40 mg

Renewal Criteria - Approval Duration: 12 months

- The member has an LDL-C level less than 100 mg/dL or has achieved a 40% reduction
- The member must currently be receiving a maximally tolerated statin (HMG-CoA reductase inhibitor) agent, as evidenced by paid claims or pharmacy printouts

Platelet Aggregation Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
aspirin	clopidogrel 300mg
aspirin/dipyridamole ER	EFFIENT (prasugrel)
BRILINTA (ticagrelor)	PLAVIX (clopidogrel)
clopidogrel 75 mg	ZONTIVITY (vorapaxar)
dipyridamole	
prasugrel	

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

- The member must have failed 30-day trials of at least 2 preferred platelet aggregation inhibitor agents, as evidenced by paid claims or pharmacy printouts.

Pulmonary Hypertension

PDE-5 Inhibitors

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
REVATIO (sildenafil) SUSPENSION – *Brand Required*	ADCIRCA (tadalafil) TABLET
sildenafil tablet	ALYQ (tadalafil)
tadalafil tablet	REVATIO (sildenafil) TABLET
	sildenafil suspension
	TADLIQ (tadalafil) SUSPENSION

Electronic Age Verification

- Sildenafil/tadalafil: Prior authorization is not required for ages less than 12 years old
- Revatio suspension: Prior authorization is not required for ages less than 9 years old

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

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

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

Endothelin Receptor Antagonists

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ambrisentan	bosentan
TRACLEER (bosentan) SUSPENSION	LETAIRIS (ambrisentan)
TRACLEER (bosentan) TABLETS - *Brand Required*	OPSUMIT (macitentan)

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.

Prostacyclins

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

Electronic Diagnosis Verification

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

Vecamyl

CLINICAL PA REQUIRED
VECAMYL (mecamylamine)

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

- The member must have documented history of failure to achieve blood pressure goals (using maximum tolerated doses) of all first- and second-line agents as defined by the most recent JNC report.

Dermatology

Acne

Electronic Age Verification

- The member must be between 12 and 35 years of age

Adapalene

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
adapalene gel	adapalene cream
adapalene gel with pump	adapalene/benzoyl peroxide 0.3%-2.5%
adapalene/benzoyl peroxide 0.1%-2.5%	DIFFERIN (adapalene) GEL
DIFFERIN (adapalene) CREAM - *Brand Required*	DIFFERIN (adapalene) GEL W/ PUMP
DIFFERIN (adapalene) LOTION	
EPIDUO FORTE (adapalene/benzoyl peroxide) 0.3%-2.5% - *Brand Required*	

Therapeutic Duplication

- One strength of one benzoyl peroxide containing medication is allowed at a time

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) MED SWAB
clindamycin solution	CLINDACIN P (clindamycin) MED SWAB
clindamycin med. swab	CLINDACIN ETZ (clindamycin) MED SWAB
EVOCLIN (clindamycin) FOAM – *Brand Required*	CLINDAGEL (clindamycin) GEL DAILY
ZIANA (clindamycin-tretinoin 1.2%-0.025%) - *Brand Required*	clindamycin gel daily
	clindamycin foam
	clindamycin-tretinoin 1.2%-0.025%

Clindamycin-Benzoyl Peroxide

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
clindamycin-benzoyl peroxide 1.2%-2.5%	ACANYA (clindamycin-benzoyl peroxide) 1.2%-2.5%
clindamycin-benzoyl peroxide 1%-5% with pump	BENZACLIN (clindamycin/benzoyl peroxide without pump) 1%-5%
clindamycin-benzyl peroxide 1.2%-5%	BENZACLIN (clindamycin/benzoyl peroxide with pump) 1%-5%
clindamycin/benzoyl peroxide 1%-5% without pump	NEUAC (clindamycin/benzoyl peroxide) 1.2%-5%

ONEXTON (clindamycin/benzoyl peroxide) 1.2%-3.75%	

Therapeutic Duplication

- One strength of one benzoyl peroxide containing medication is allowed at a time

Retinoid

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ALTRENO (tretinoin) LOTION	AKLIEF (trifarotene) CREAM 0.005%
FABIOR (tazarotene) 0.1% FOAM - *Brand Required*	ATRALIN (tretinoin) 0.05% GEL
RETIN-A MICRO PUMP (tretinoin microsphere) 0.04%, 0.1% - *Brand Required*	ARAZLO (tazarotene) 0.045% LOTION
tretinoin cream	clindamycin-tretinoin 1.2%-0.025%
tretinoin gel	RETIN-A (tretinoin) CREAM
tretinoin microsphere without pump	RETIN-A (tretinoin) GEL
ZIANA (clindamycin-tretinoin 1.2%-0.025%) - *Brand Required*	RETIN-A MICRO PUMP (tretinoin microsphere) 0.06%, 0.08%
	RETIN-A MICRO (tretinoin microsphere) GEL WITHOUT PUMP
	tazarotene 0.1% foam
	tazarotene gel
	tretinoin microsphere with pump
	TWYNEO (tretinoin/benzoyl peroxide) 0.1%-0.3% CREAM

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

- Clinical justification must be provided explaining why the member is unable to use the preferred agents (subject to clinical review)

Tetracyclines

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
doxycycline hyclate capsule	AMZEEQ (minocycline) Foam
doxycycline hyclate tablet 20 mg, 100 mg	demeclocycline
doxycycline monohydrate 25 mg/5 mL suspension	DORYX (doxycycline hyclate) TABLET DR
doxycycline monohydrate tablet 50 mg, 75 mg, 100 mg	DORYX MPC (doxycycline hyclate) TABLET DR
doxycycline monohydrate capsule 50 mg, 100 mg	doxycycline monohydrate capsule 75 mg, 150 mg
minocycline capsule	doxycycline hyclate tablet 50 mg, 75 mg, 150 mg
tetracycline	doxycycline monohydrate tablet 150 mg
VIBRAMYCIN (doxycycline calcium) 50 mg/5 mL SYRUP	doxycycline hyclate tablet DR
	MINOCIN (minocycline) CAPSULE
	minocycline tablet

	minocycline tablet ER
	MINOLIRA ER (minocycline) TABLET
	MORGIDOX (doxycycline hyclate) CAPSULE
	SOLODYN ER (minocycline) TABLET
	VIBRAMYCIN (doxycycline monohydrate) 25 mg/5 mL SUSPENSION
	XIMINO (minocycline) CAPSULE ER

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

- Clinical justification must be provided explaining why the member is unable to use the preferred agents (subject to clinical review)

Sulfonamide

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
BP 10-1 (sodium sulfacetamide/sulfur cleanser) 10%-1%	ACZONE (dapsone) GEL WITH PUMP 7.5%
Cleansing Wash (sulfacetamide sodium/sulfur/urea) 10%-4%-10%	BP 10-1 (sulfacetamide sodium/sulfur) CLEANSER
dapsone gel without pump 5%	dapsone gel pump 7.5%
SSS 10-5 (sulfacetamide) FOAM	SSS 10-5 (sulfacetamide) CLEANSER
sulfacetamide 10% suspension	sodium sulfacetamide/sulfur pads 10%-4%
sodium sulfacetamide/sulfur cleanser 10%-5% (W/W)	sodium sulfacetamide/sulfur cream 10%-2%
sodium sulfacetamide/sulfur cleanser 9%-4%	SUMAXIN (sodium sulfacetamide/sulfur pads) PADS 10%-4%
sodium sulfacetamide/sulfur cleanser 9%-4.5%	SUMAXIN TS (sodium sulfacetamide/sulfur) SUSPENSION 8%-4%
sodium sulfacetamide/sulfur cleanser 9.8% -4.8%	
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

- Clinical justification must be provided explaining why the member is unable to use the preferred agents (subject to clinical review)

Actinic Keratosis

Fluorouracil

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
CARAC (fluorouracil) 0.5% CREAM – *Brand Required*	EFUDEX (fluorouracil) 5% CREAM
fluorouracil 5% cream	fluorouracil 0.5% cream
fluorouracil 2% solution	
fluorouracil 5% solution	

Imiquimod

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
imiquimod 5% cream packet	imiquimod 3.75% cream packet
ZYCLARA (imiquimod) 3.75% CREAM PUMP – *Brand Required*	imiquimod 3.75% cream pump
	ZYCLARA (imiquimod) 3.75% CREAM PACKET
	ZYCLARA (imiquimod) 2.5% CREAM PUMP

Diclofenac

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
diclofenac 3% sodium gel	

Electronic Diagnosis Verification

- Diclofenac 3% sodium gel: Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

- The member must have failed a 6-month trial of each preferred agent of a unique active ingredient, as evidenced by paid claims or pharmacy printouts.
- If requested product has preferred option with same active ingredient, clinical justification must be provided explaining why the member is unable to use preferred product (subject to clinical review)

Antifungals – Topical

Cream

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
butenafine cream	CICLODAN (ciclopirox) CREAM
ciclopirox cream	ERTACZO (sertraconazole) CREAM
clotrimazole cream	EXELDERM (sulconazole) CREAM
econazole cream	LOPROX (ciclopirox) CREAM
ketoconazole cream	luliconazole cream
miconazole cream	LUZU (luliconazole) CREAM
nystatin cream	MENTAX (butenafine) CREAM
nystatin – triamcinolone cream	natfifine cream
	NAFTIN (naftifine) CREAM
	oxiconazole cream
	OXISTAT (oxiconazole) CREAM
	sulconazole cream

Foam

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
EXTINA (ketoconazole) FOAM – *Brand Required*	KETODAN (ketoconazole) FOAM
	ketoconazole foam

Gel

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ciclopirox gel	NAFTIN (naftifine) GEL

Lotion

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	OXISTAT (oxiconazole) LOTION

Ointment

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ALEVAZOL (clotrimazole) OINTMENT	miconazole/zinc oxide/white petrolatum ointment
nystatin ointment	VUSION (miconazole/zinc/white petrolatum) OINTMENT
nystatin – triamcinolone ointment	

Powder

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
nystatin powder	
NYAMYC (nystatin) POWDER	
NYSTOP (nystatin) POWDER	

Shampoo

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ciclopirox shampoo	LOPROX (ciclopirox) SHAMPOO
ketoconazole shampoo	

Solution

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ciclopirox solution	CICLODAN (ciclopirox) SOLUTION
clotrimazole solution	EXELDERM (sulconazole) SOLUTION
	JUBLIA (efinaconazole) SOLUTION
	KERYDIN (tavaborole) SOLUTION
	tavaborole solution

Suspension

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ciclopirox suspension	LOPROX (ciclopirox) SUSPENSION

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

- Onychomycosis Only:
  - Diagnosis must be confirmed by potassium hydroxide (KOH) preparation
  - The member must have had a trial of one oral agent (terbinafine, fluconazole, or itraconazole), for the length of recommended treatment time for member's particular infection, as evidenced by paid claims or pharmacy printouts
  - Adequate time must have passed since treatment cessation to accurately assess healthy toenail outgrow (at least 6 months)
  - One of the following must be met (A or B):
    - Preferred Dosage Form Criteria
    - The active ingredient of the requested product is not available in a preferred formulation
- Other Diagnosis:
  - The member must have failed a trial of 3 preferred agents, for the length of recommended treatment time for member's particular infection, as evidenced by paid claims or pharmacy printouts
  - One of the following must be met (A or B):

- Preferred Dosage Form Criteria
- The active ingredient of the requested product is not available in a preferred formulation

Eczema / Atopic Dermatitis

Oral

First Line Agents

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
azathioprine 50mg	azathioprine 75mg
cyclosporine	azathioprine 100mg
methotrexate	
systemic oral corticosteroids	

Prior Authorization Criteria

- Azathioprine: See Preferred Dosage Forms Criteria

Topical

Calcineurin Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ELIDEL (pimecrolimus) CREAM – *Brand Required*	pimecrolimus
tacrolimus 0.03%	
tacrolimus 0.1%	

Electronic Age Verification

- Tacrolimus ointment 0.1%: The member must be 16 years of age or older

Janus Kinase (JAK) inhibitor

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
OPZELURA (ruxolitinib) 1.5% CREAM	

Phosphodiesterase 4 (PDE-4) inhibitor

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
EUCRISA (crisaborole) OINTMENT	

Topical Corticosteroids

Please see the Preferred Drug List of Topical Corticosteroids

Systemic

Interleukin (IL)-4/13 Inhibitor

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

Interleukin (IL)-13 Inhibitor

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

Janus Kinase (JAK) inhibitor

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

Prior Authorization Criteria

Prior Authorization Form - Atopic Dermatitis

Initial Criteria - Approval Duration: 3 months

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

Systemic Janus Kinase (JAK) Inhibitors Only

- The member must have failed a 3-month trial of Adbry and Dupixent, as evidenced by paid claims or pharmacy printouts.

Hidradenitis Suppurativa

NO PA REQUIRED
HUMIRA (adalimumab)

Electronic Diagnosis Verification

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

Infantile Hemangioma

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
propranolol oral solution	HEMANGEOL (propranolol) ORAL SOLUTION

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

- See Preferred Dosage Form Criteria

Lice

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
EURAX (crotamiton) CREAM	CROTAN (crotamiton)
NATROBA (spinosad) – *Brand Required*	ELIMITE (permethrin) CREAM
LICE KILLING SHAMPOO (piperonyl butoxide/pyrethrins)	EURAX (crotamiton) LOTION
NIX 1% (permethrin) CRÈME RINSE LIQUID	lindane shampoo
permethrin 5% cream	malathion
SM LICE TREATMENT (permethrin) 1% CRÈME RINSE LIQUID	OVIDE (malathion)
	spinosad

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 a preferred agent

Plaque Psoriasis

Biologics

Interleukin (IL)-12/IL-23 Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	STELARA (ustekinumab)

Interleukin (IL)-17 Inhibitor

PREFERRED AGENTS (ELECTRONIC STEP REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
TALTZ (ixekizumab)	COSENTYX (secukinumab)

Interleukin (IL)-17 Receptor Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	SILIQ (brodalumab)

Interleukin (IL)-23/IL-39 Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	SKYRIZI (risankizumab-rzaa)
	TREMFYA (guselkumab)

TNF Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AVSOLA (infliximab-axxq) – *Medical Billing Only*	INFLECTRA (infliximab-dyyb) – *Medical Billing Only*
CIMZIA (certolizumab pegol)	infliximab – *Medical Billing Only*
ENBREL (etanercept)	REMICADE (infliximab) – *Medical Billing Only*
HUMIRA (adalimumab)	
RENFLEXIS (infliximab-abda) – *Medical Billing Only*	

Interleukin (IL)-23/IL-39 inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	ILUMYA (tildrakizumab-asmn) – *Medical Billing Only*

Electronic Diagnosis Verification

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

Electronic Step Care and Concurrent Medications

- Taltz: A total of 90 days of a TNF Inhibitor must be paid within 120 days prior to Taltz's date of service.

Prior Authorization

Initial Criteria - Approval Duration: 12 months

- The member must have failed a 3-month trial of a TNF inhibitor and an Interleukin (IL)-17 Inhibitor, as evidenced by paid claims or pharmacy printouts.
- Remicade, infliximab, and Inflectra Only: See Preferred Dosage Form Criteria
- Stelara and Cosentyx Only: The member must have failed a 3-month trial of an Interleukin (IL)-23/IL-39 Inhibitor, as evidenced by paid claims or pharmacy printouts

Oral

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
acitretin 10 mg, 25 mg	acitretin 17.5 mg
cyclosporine	SOTYKTU (deucravacitinib)
methotrexate	
OTEZLA (apremilast)	

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

- Acitretin 17.5 mg Only: See Preferred Dosage Form Criteria
- Sotyktu Only: The member must have failed a 30-day trial of Otezla, as evidenced by paid claims or pharmacy print outs

Topical

Foams, Solution, Suspension

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
calcipotriene solution	calcipotriene foam
ENSTILAR (calcipotriene/betamethasone) FOAM	calcipotriene/betamethasone suspension
SORILUX (calcipotriene) FOAM – *Brand Required*	
TACLONEX (calcipotriene/betamethasone) SUSPENSION – *Brand Required*	

Cream, Lotion

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
calcipotriene cream	DUOBRII (halobetasol/tazarotene) LOTION
tazarotene 0.1% cream	DOVONEX (calcipotriene) CREAM
	VTAMA (tapinarof) 1% CREAM

	ZORYVE (roflumilast) 0.3% CREAM

Ointment

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
calcipotriene ointment	calcipotriene/betamethasone ointment
TACLONEX (calcipotriene/betamethasone) OINTMENT – *Brand Required*	calcitriol ointment
VECTICAL (calcitriol) OINTMENT – *Brand Required*	

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

- The member must have failed a 30-day trial of each preferred agent of an unique active ingredient, as evidenced by paid claims or pharmacy print outs

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	clobetasol propionate	0.05%	betamethasone dipropionate, augmented	0.05%
			STEP 2* IMPEKLO (clobetasol)	0.05%
			STEP 2* ULTRAVATE (halobetasol) MDP	0.05%
Ointment	betamethasone dipropionate, augmented	0.05%	halobetasol propionate	0.05%
	clobetasol 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 propionate foam	0.05%
	clobetasol propionate spray	0.05%	clobetasol emulsion foam	0.05%
	clobetasol propionate gel	0.05%	STEP 2* halobetasol propionate foam	0.05%

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:
  - Location of application: palms and soles
  - 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%	STEP 2* APEXICON E (diflorasone emollient)	0.05%
	fluocinonide	0.05%	desoximetasone	0.25%
	HALOG (halcinonide)– *Brand Required*	0.10%		
Lotion			BRYHALI (halobetasol) LOTION	0.01%
Ointment	betamethasone dipropionate	0.05%	STEP 2* diflorasone diacetate	0.05%
	desoximetasone	0.25%		
	fluocinonide	0.05%		
	fluticasone propionate	0.01%		
	HALOG (halcinonide)	0.10%		
Gel, Solution, Spray	fluocinonide gel	0.05%	desoximetasone gel	0.05%
	fluocinonide solution	0.05%	desoximetasone spray	0.25%
			STEP 2* HALOG (halcinonide) SOLUTION	0.10%

High Potency (Group 3)

Dosage Form	PREFERRED AGENTS (NO PA REQUIRED)		NON-PREFERRED AGENTS (PA REQUIRED)	
Cream	betamethasone dipropionate emollient	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	fluticasone propionate	0.05%	STEP2* clocortolone pivalate	0.10%
	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%		
	mometasone furoate solution	0.10%	triamcinolone acetonide aerosol	0.147 MG/G

Aerosol, Solution, Spray			STEP2*SERNIVO (betamethasone) SPRAY	0.05%

Lower-Mid Potency (Group 5)

Dosage Form	PREFERRED AGENTS (NO PA REQUIRED)		NON-PREFERRED AGENTS (PA REQUIRED)	
Cream	betamethasone valerate	0.10%	fluocinolone acetonide	0.03%
	PANDEL (hydrocortisone probutate)	0.10%	prednicarbate	0.10%
			STEP2*flurandrenolide	0.05%
			hydrocortisone butyrate	0.10%
			hydrocortisone butyrate emollient	0.10%
			hydrocortisone valerate	0.20%
Lotion	betamethasone dipropionate	0.05%	flurandrenolide	0.05%
	LOCOID (hydrocortisone butyrate) – *Brand Required*	0.10%	fluticasone propionate	0.05%
	triamcinolone acetonide	0.10%		
Ointment	desonide	0.05%	hydrocortisone butyrate	0.10%
	triamcinolone acetonide	0.025%	prednicarbate	0.10%
Gel, Solution	hydrocortisone butyrate solution	0.10%	desonide gel	0.05%

Low Potency (Group 6)

Dosage Form	PREFERRED AGENTS (NO PA REQUIRED)		NON-PREFERRED AGENTS (PA REQUIRED)	
Cream	alclometasone dipropionate	0.05%	fluocinolone acetonide	0.01%
	desonide	0.05%		
	triamcinolone acetonide	0.03%		
Lotion	betamethasone valerate lotion	0.10%		
	desonide lotion	0.05%		
	triamcinolone acetonide lotion	0.025%		
Ointment	alclometasone dipropionate	0.05%		
Oil, Shampoo, Solution	CAPEX (flucinolone) SHAMPOO	0.01%		
	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	2.50%		
Lotion	hydrocortisone	2.50%		
Ointment	hydrocortisone	2.50%		
Solution			TEXACORT (hydrocortisone) SOLUTION	2.50%

Prior Authorization

Initial Criteria - Approval Duration: 12 months

- The member must have failed a 2-week trial of all preferred drug entities within the same potency category and dosage form group within the last 3 months, as evidenced by paid claims or pharmacy printouts

Agents labeled as "STEP 2"

- The member must have failed a 2-week trial of all preferred and non-preferred drug entities not labeled "STEP 2" within the same potency category and dosage form group within the last 3 months.

Endocrinology

Androgens

Injectable

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
testosterone cypionate injection	AVEED (testosterone undecanoate)
testosterone enanthate injection	DEPO-TESTOSTERONE (testosterone cypionate)
	XYOSTED (testosterone enanthate)

Oral

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
JATENZO (testosterone undecanoate)	methyltestosterone
	METHITEST (methyltestosterone)
	TLANDO (testosterone undecanoate)

Topical

Gel Packet

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ANDROGEL (testosterone) GEL PACKET– *Brand Co-Preferred*	testosterone 1.62% (20.25mg/1.25g) gel packet
testosterone 1% (50mg/5g) gel packet	testosterone 1.62% (40.5mg/2.5g) gel packet
testosterone 1% (25mg/2.5g) gel packet	

Gel Pump

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ANDROGEL (testosterone) GEL MD PUMP – *Brand Co-Preferred*	testosterone 2% (10mg/0.5g) gel MD PMP bottle
FORTESTA (testosterone) 2% (10mg/0.5g) GEL MD PMP – *Brand Required*	
testosterone 1% (12.5mg/1.25g) gel MD PMP bottle	
testosterone 1.62% (20.25mg/1.25g) gel MD PMP bottle	
testosterone 2% (30mg/1.5g) solution MD PMP	

Gel Tube

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)

TESTIM (testosterone) GEL TUBE – *Brand Co-Preferred*	
testosterone 1% (50mg/5g) gel tube	

Nasal Gel

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	NATESTO (testosterone) GEL MD PMP

Patch

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ANDRODERM (testosterone) PATCH	

Solution MDP

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	testosterone (30mg/1.5mL)

Pellet

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
TESTOPEL (testosterone) PELLET – *Medical Billing Only*	

Electronic Diagnosis Verification

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

Prior Authorization

Initial Criteria - Approval Duration: 12 months

- The member must have failed a 30-day trial of each preferred agent with a comparable route of administration, as evidenced by paid claims or pharmacy printouts.
- Clinical justification must be provided explaining why the member is unable to use the preferred products (subject to clinical review).

Cushing Syndrome

Adrenal Enzyme Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ketoconazole	ISTURISA (osilodrostat)
LYSODREN (mitotane)	RECORLEV (levoketoconazole)
METOPIRONE (metyrapone)	

Electronic Diagnosis Verification

- Isturisa and Recorlev: Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale

Prior Authorization

Initial Criteria - Approval Duration: 6 months

- The requested medication must be prescribed by, or in consult with, an endocrinologist or specialist in the treatment of endogenous Cushing's syndrome.
- The member must have failed a 3-month trial of combination treatment with ketoconazole tablets and metyrapone.
- The member is not a candidate for surgery or surgery has not been curative; or is waiting for surgery or effect of pituitary radiation.

- The member must have a mean (at least two measurements) 24-hour urine free cortisol (UFC) level that is 3 x above the normal range per the reporting laboratory reference range.

Renewal Criteria - Approval Duration: 12 months
- The member has normalization of 24-hour urine free cortisol (UFC) level per the reporting laboratory reference range.

Glucocorticoid Receptor Antagonist

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
mifepristone	KORLYM (mifepristone)

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.
- 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%, 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 not attributed to an increase in medications, dosages, or adherence to an anti-diabetes regimen.

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, 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:
  - DPP4-Inhibitors and GLP-1 Agonists
    - GLP-1 and DPP4-Inhibitors should not be used concurrently due to similar mechanisms of action
  - DPP4-Inhibitors and Insulins
    - GLP-1 should be considered in most members prior to insulin
    - When initiating injectable therapy, sulfonylureas and DPP-4 inhibitors are typically discontinued

- 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 1000mg must be used adherently and will reject on point of sale for late fill

DPP4-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)	++KOMBIGLYZE XR (saxagliptin/metformin)
TRADJENTA (linagliptin)	++NESINA (alogliptin)
	++ONGLYZA (saxagliptin)
	++OSENI (alogliptin/pioglitazone)

++Clinically Non-Preferred: Alogliptin and Saxagliptan have a potentially higher risk for heart failure

Electronic Age Verification

- The member must be 18 years or older for Januvia, Janumet, or Janumet XR

Electronic Step Care and Concurrent Medications

- A total of 28-day supply of metformin must be paid within 100 days prior to the DPP4-Inhibitor's date of service. Members with GI intolerances to high dose IR metformin must trial at minimum a dose of 500mg ER.
  - Metformin is recommended to be continued with therapy with DPP4-Inhibitors**.** If metformin is not tolerated, SGLT2 inhibitor and GLP-1 Agonists are recommended as part of the glucose-lowering regimen independent of A1C and are first line alternatives.

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 must have failed a 30-day trial with EACH of the following agents, as evidenced by paid claims or pharmacy printouts:
  - A preferred sitagliptin product (Janumet, Janumet XR, or Januvia)
  - A preferred linagliptin preferred product (Jentadueto or Tradjenta)
  - A preferred SGLT2 inhibitor

DPP4-Inhibitors / SGLT2 Inhibitors Combination

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
TRIJARDY XR (empagliflozin/linagliptan/metformin)	GLYXAMBI (empagliflozin/linagliptin)
	STEGLUJAN (ertugliflozin/sitagliptin)

	++QTERN (dapagliflozin/saxagliptin)

++Clinically Non-Preferred: Saxagliptan has a potentially higher risk for heart failure

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

- Clinical justification must be provided explaining why the member cannot use individual preferred products separately or preferred agent

GLP-1 Agonists

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (STEP 1 – PA REQUIRED)	NON-PREFERRED AGENTS (STEP 2 – PA REQUIRED)
VICTOZA (liraglutide)	TRULICITY (dulaglutide)	ADLYXIN (lixisenatide)
		BYDUREON BCISE (exenatide microspheres)
		++BYETTA (exenatide)
		OZEMPIC (semaglutide)
		RYBELSUS (semaglutide)

++Clinically Non-Preferred: Byetta is less effective than other available agents

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

- Step 1: Trulicity: One of the following apply:
  - The member must have failed a 90-day trial of a combination of a SGLT-2 Inhibitor and Victoza, as evidenced by paid claims or pharmacy printouts.
    - If failure is due to inability to meet A1c goal with good adherence, documentation of A1c level and goal must be provided.
  - The member must have failed a 90-day trial of a combination of a SGLT-2 inhibitor and a DPP-4 inhibitor, as evidenced by paid claims or pharmacy printouts, if the following apply:
    - Member has previously failed a trial of Victoza due to intolerance
    - A GLP-1 has not been previously used in combination therapy with an SGLT-2 inhibitor or insulin
- Step 2: The member must have failed 90-day trial of a combination of a SGLT-2 Inhibitor and each of the following, titrated to max tolerated dose, as evidenced by paid claims or pharmacy printouts:
  - Victoza
  - Trulicity

GIP/GLP-1 Agonists

CLINICAL PA REQUIRED
MOUNJARO (tirzepatide)

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

- The member must have failed 90-day trial of a combination of a SGLT-2 Inhibitor and each of the following, titrated to max tolerated dose, as evidenced by paid claims or pharmacy printouts:
  - Victoza
  - Trulicity

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 ODT and solution formulations) with relevant medical documentation (e.g., swallow study) attached to the request, subject to clinical review.

Glucose Rescue Medications

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
BAQSIMI (glucagon) SPRAY	glucagon kit – 00548, 63323
glucagon kit – Labeler 00002	
GLUCOGEN (glucagon) HYPOKIT – *Brand Co-Preferred*	
GVOKE (glucagon) INJECTION	
ZEGALOGUE (dasiglucagon) AUTOINJECTOR	

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).

Electronic Duration Verification

- 2 doses (initial and replacement doses) are covered every 180 days without prior authorization.
  - The following information will need to be submitted as a follow up for the override by either emailing medicaidpharmacy@nd.gov or documenting on General Prior Authorization Form:
    - The provider must attest if it is known that the previous dose was taken by the member (and not diverted or given to another person)
    - One of the following criteria must be met (A, B, or C)
      A. The previous dose has expired
      B. The dose was used by member for a hypoglycemic episode
      C. The member is currently taking insulins or sulfonylureas and meets one of the following criteria:
        - The diabetes treatment has been adjusted to prevent future instances of hypoglycemia
        - The provider has provided medical justification why the diabetes treatment has not been adjusted at this time to prevent future instances of hypoglycemia.

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

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
APIDRA (insulin glulisine) VIAL	ADMELOG (insulin lispro) VIAL
APIDRA SOLOSTAR (insulin glulisine) INSULIN PEN	ADMELOG SOLOSTAR (insulin lispro) INSULIN PEN
HUMALOG (insulin lispro) CARTRIDGE	++AFREZZA (insulin regular, human)
HUMALOG U-100 (insulin lispro) KWIKPEN – *Brand Co-Preferred*	FIASP (insulin aspart) CARTRIDGE***
HUMALOG (insulin lispro) VIAL– *Brand Co-Preferred*	FIASP (insulin aspart) SYRINGE***
HUMALOG JUNIOR KWIKPEN (insulin lispro) – *Brand Co-Preferred*	FIASP (insulin aspart) VIAL***
Insulin aspart cartridge	HUMALOG U-200 (insulin lispro) KWIKPEN
Insulin aspart syringe	++HUMULIN R (insulin regular, human) VIAL
Insulin aspart vial	LYUMJEV (Insulin lispro-aabc) KWIKPEN
Insulin lispro junior syringe	LYUMJEV (Insulin lispro-aabc) VIAL
Insulin lispro cartridge	++NOVOLIN R (insulin regular, human) FLEXPEN
Insulin lispro syringe	++NOVOLIN R (insulin regular, human) VIAL
Insulin lispro vial	
NOVOLOG (insulin aspart) CARTRIDGE – *Brand Co-Preferred*	
NOVOLOG (insulin aspart) FLEXPEN – *Brand Co-Preferred*	
NOVOLOG (insulin aspart) VIAL– *Brand Co-Preferred*	

++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

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

- Fiasp: The member must have failed a one 3-month trial of Novolog, Humalog, or Apidra, as evidenced by paid claims or pharmacy printouts.
- 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.
- Lyumjev: The member must have failed a one 3-month trial of Fiasp, as evidenced by paid claims or pharmacy printouts.
- Regular Insulin (Humulin R / Novolin R / Afrezza): The member must have failed a 3-month trial of two of the following agents, as evidenced by paid claims or pharmacy printouts:
    - Novolog, Humalog, or Apidra

Intermediate Acting Insulin

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
++ NOVOLIN N (insulin NPH human isophane) FLEXPEN	++ HUMULIN N (insulin NPH human isophane) VIAL

HUMULIN R U-500 (insulin regular, human) KWIKPEN	++ HUMULIN N (insulin NPH human isophane) KWIKPEN
HUMULIN R U-500 (insulin regular, human) VIAL	++ NOVOLIN N (insulin NPH human isophane) VIAL

++ Clinically non-preferred: Lantus and Levemir have been demonstrated to reduce the risk of symptomatic and nocturnal hypoglycemia compared with NPH insulin.

Electronic Duration Verification

- Products containing NPH insulin are limited to 210 days of coverage for every 365 days to allow for use in pregnancy and breastfeeding. For an override request: please submit clinical justification explaining why the member is unable to use Lantus or Levemir (subject to clinical review)

Long-Acting Insulin

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
LANTUS (insulin glargine) SOLOSTAR – *Brand Required*	BASAGLAR KWIKPEN U-100 (insulin glargine)
LANTUS (insulin glargine) VIAL – *Brand Required*	insulin degludec
LEVEMIR (insulin detemir) VIAL	insulin glargine solostar
LEVEMIR (insulin detemir) FLEXTOUCH	insulin glargine-yfgn vial
TOUJEO MAX SOLOSTAR (insulin glargine) *No PA required for doses 100 unit/day to 200 unit/day	SEMGLEE (insulin glargine)
TRESIBA (insulin degludec) FLEXTOUCH U-200 *No PA required for doses 100 unit/day to 200 unit/day *- Brand Required*	TOUJEO SOLOSTAR (insulin glargine)
	TRESIBA (insulin degludec) FLEXTOUCH U-100 *- Brand Required*
	TRESIBA (insulin degludec) VIAL *- Brand Required*

Quantity Override Request

- 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 meeting 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 with good compliance, as evidenced by paid claims or pharmacy printouts, of each of the following:
  - Lantus
  - Levemir
- 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 (A1C)

Mixed Insulin

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
HUMALOG MIX 50/50 (insulin NPL/insulin lispro) KWIKPEN	insulin lispro mix 75/25 kwikpen
HUMALOG MIX 75/25 (insulin NPL/insulin lispro) KWIKPEN – *Brand required*	NOVOLIN 70-30 (insulin NPH human/regular insulin human) VIAL
HUMALOG MIX 50/50 (insulin NPL/insulin lispro) VIAL	NOVOLIN 70-30 (insulin NPH human/regular insulin human) FLEXPEN
HUMALOG MIX 75/25 (insulin NPL/insulin lispro) VIAL	NOVOLOG MIX 70/30 (insulin aspart protamine/insulin aspart) FLEXPEN
HUMULIN 70/30 (insulin NPH human/regular insulin human) VIAL	NOVOLOG MIX 70/30 (insulin aspart protamine/insulin aspart) VIAL
HUMULIN 70/30 (insulin NPH human/regular insulin human) KWIKPEN	
insulin aspart protamine/insulin aspart 70/30 pen	
Insulin aspart protamine/insulin aspart 70//30 vial	

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 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)	INVOKAMET XR (canagliflozin/metformin)
INVOKANA (canagliflozin)	STEGLATRO (ertugliflozin)
INVOKAMET (canagliflozin)	STEGLATROMET (ertugliflozin/metformin)
JARDIANCE (empagliflozin)	SYNJARDY XR (empagliflozin/metformin)
SYNJARDY (empagliflozin/metformin)	XIGDUO XR (dapagliflozin/metformin) 2.5 MG – 1000 MG
XIGDUO XR (dapagliflozin/metformin) 5 MG-500 MG, 5 MG-1000 MG, 10 MG-500 MG, 10 MG – 1000 MG	

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).

Sulfonylureas

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
glimepiride	++glyburide
glipizide	++glyburide/metformin
glipizide/metformin	++glyburide, micronized
glipizide ER	++GLYNASE (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, 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).

Graves' Disease

CLINICAL PA REQUIRED
TEPEZZA (teprotumumab-trbw) - *Medical Billing Only*

Prior Authorization Criteria

Initial Criteria - Approval Duration: 6 months (8 infusions per lifetime)

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult annually with, endocrinologist, ophthalmologist, or specialist in the treatment of Graves' disease associated with Thyroid Eye Disease (TED)
- The member must have a diagnosis of moderate to severe Graves' disease associated with Thyroid Eye Disease
- The onset of Thyroid Eye Disease symptoms is within 9 months of request for treatment
- The provider must submit documentation of each of the following:
  - Thyroxine (FT4) and free triiodothyronine (FT3) levels less than 50% above or below normal limits
  - Must have a Clinical Activity Score of greater than or equal to 4
- The member has had a one-month trial of a maximally tolerated indicated dose of systemic glucocorticoids.
- The member has not required prior surgical ophthalmologic intervention
- The member does not have any of the following:
  - A decrease in best corrected visual acuity (BVCA) due to optic neuropathy within the previous six months (i.e., decrease in vision of 2 lines on the Snellen chart, new visual field defect, or color defect secondary to optic nerve involvement)
  - Corneal decompensation that is unresponsive to medical management
  - Poorly controlled diabetes or diabetes must be maximally treated by, or in consult with, an endocrinologist with good adherence.

Growth Hormone

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
NORDITROPIN FLEXPRO (somatropin)	GENOTROPIN (somatropin)
	GENOTROPIN MINIQUICK (somatropin)
	NUTROPIN AQ (somatropin)
	OMNITROPE (somatropin)

	SAIZEN (somatropin)
	SKYTROFA (somatropin)
	ZOMACTON (somatropin)

Prior Authorization Criteria

Prior Authorization Form - Growth Hormone

Initial Criteria - Approval Duration: 12 months

- Member must have one of the following covered diagnoses (listed below):
  - Multiple pituitary hormone deficiencies caused by a known hypothalamic-pituitary disease or its treatment (brain surgery and/or radiation)
  - Turner's syndrome
  - SHOX syndrome
  - Noonan syndrome
  - Chronic renal insufficiency
  - Prader–Willi syndrome
  - Endogenous growth hormone deficiency
- The requested medication must be prescribed by, or in consult annually with, an endocrinologist or nephrologist.
- The member must not have active malignancy
- The member must not have epiphyseal closure and must still be growing, unless one of the below exceptions is present:
  - The member has a diagnosis of Prader-Willi syndrome
  - The member has a diagnosis of endogenous growth hormone deficiency and is experiencing hypoglycemic episodes without growth hormone and growth hormone is needed to maintain proper blood glucose.
  - The requested medication is not Skytrofa

Chronic Renal Insufficiency

- The member must not have received a renal transplant.
- The member must consult with a dietitian annually to maintain a nutritious diet.

Endogenous Growth Hormone Deficiency

- ONE of below criteria must be met:
  - The member has multiple pituitary hormone deficiencies caused by a known hypothalamic-pituitary disease or its treatment (brain surgery and/or radiation) 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 < 10ng/mL after stimulation no more than 6 months apart

Prader-Willi Syndrome

- If the member is obese, sleep apnea has been ruled out by sleep study
- The member must consult with a dietitian annually to maintain a nutritious diet.

Renewal Criteria - Approval Duration: 12 months

- The member must have been compliant with growth hormone (last 6 fills must have been on time).

Prader-Willi Syndrome

- If the member is obese, the BMI must have decreased
- If member is not obese, BMI must have maintained or decreased

Serostim

CLINICAL PA REQUIRED

SEROSTIM (somatropin)

Prior Authorization Criteria

Prior Authorization Form - Growth Hormone

Initial Criteria - Approval Duration: 3 months

- The member must not have an active malignancy
- The requested medication must be prescribed by, or in consult with, and infectious disease specialist or a specialist in the diagnosis and management of HIV infection
- The member must be on concomitant antiretroviral therapy
- The member must have failed a 3-month trial with megestrol, as evidenced by paid claims or pharmacy printouts
- Lean body mass and body weight must be provided
- Documentation of physical endurance must be provided.

Renewal Criteria - Approval Duration: 8 months (one time)

- Lean body mass and body weight must have increased from baseline
- Physical endurance must have increased from baseline

Imcivree

CLINICAL PA REQUIRED
IMCIVREE (setmelanotide)

Prior Authorization Criteria

Initial Criteria - Approval Duration: 4 months

- The member must have a diagnosis of obesity (BMI > 30 kg/m2 for adults or > 95th percentile using growth chart assessments for pediatric members)
- The member's weight and body mass index (BMI) must be provided within the last 60 days
- The requested medication must be prescribed by, or in consult with, endocrinologist or medical geneticist
- The member's obesity must be due to one of the following:
  - Genetic testing confirms one of the following variants that is pathogenic, likely pathogenic, or of unknown significance:
    - Proopiomelanocortin (POMC)
    - Proprotein convertase subtilisin/kexin type 1 (PCSK1)
    - Leptin receptor (LEPR) deficiency
  - Bardet-Biedl syndrome as evidenced by three or more of the following:
    - Rod-cone dystrophy
    - Polydactyly
    - Genital anomalies
    - Renal anomalies
    - Intellectual impairment

Renewal Criteria - Approval Duration: 12 months

- One of the following must be met since starting treatment with Imcivree, as evidenced by medical documentation (e.g., chart notes) attached to the request:
  - Members ≥ 18 years old:
    - First renewal - a 5% weight reduction has been achieved or maintained
    - Subsequent renewal - a 10% weight reduction has been achieved or maintained

- Members < 18 years old: a 5% reduction in BMI has been achieved or maintained

Precocious Puberty

NO PA REQUIRED
FENSOLVI (leuprolide) – *Medical Billing Only*
LUPRON DEPOT (leuprolide) – *Medical Billing Only*
SUPPRELIN LA (histrelin) – *Medical Billing Only*
SYNAREL (nafarelin) – *Medical Billing Only*
TRIPTODUR (triptorelin) – *Medical Billing Only*

X-linked Hypophosphatemia (XLH) or Tumor-Induced Osteomalacia

CLINICAL PA REQUIRED
CRYSVITA (burosumab) – *Medical Billing Only*

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months (one-time 6-month approval for adult with planned orthopedic surgical

- Documentation to confirm the diagnosis must be submitted, as evidenced by the following:
  - Genetic testing confirming phosphate regulating gene with homology to endopeptidases on the X chromosome (PHEX-gene) mutation
  - Increased (FGF23) level based on laboratory reference range with unresectable phosphaturic mesenchymal tumor
- The requested medication must be prescribed by, or in consult with, nephrologist, endocrinologist, geneticist, or specialist experienced in the treatment of metabolic bone disorders
- Documentation must be submitted confirming the member is experiencing the following:
  - Phosphate manifestations *(must have one)*
    - Fasting serum phosphate is below provided age adjusted reference range
    - Low tubular resorption of phosphate corrected for glomerular filtration rate (TmP/GFR) based on age
  - Bone manifestations *(must have one)*
    - Epiphyseal plate has not fused
    - Bone fractures
    - Planned orthopedic surgical procedure

Renewal Criteria - Approval Duration: 12 months

- Documentation must be submitted demonstrating that the member has demonstrated a disease stability or beneficial response to therapy from baseline as shown by one or more of the following:
  - Normalization of phosphate levels as defined by laboratory
  - Decrease in serum alkaline phosphatase activity
  - Improvement of renal phosphate wasting
  - Normalization of growth velocity
  - Reduction or healing of fractures
  - Improvement of Thacher Rickets Severity Score (TRSS)

GI – Gastroenterology

Bowel Prep Agents

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
CLENPIQ	PEG 3350/SOD SUL/NACL/KCL/ASB/C
GAVILYTE-C	PLENVU
GAVILYTE-G	SUTAB

GAVILYTE-N	
GOLYTELY 236-22.74G – *Brand Co-Preferred*	
MOVIPREP – *Brand Required*	
OSMOPREP	
PEG-3350 AND ELECTROLYTES 236-22.74G	
PEG 3350-ELECTROLYTE 420 G	
PEG 3350-ELECTROLYTE SOLUTION	
SOD SOL-POTASS SUL-MAG SUL	
SUPREP – *Brand Co-Preferred*	

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, with medical documentation (e.g., chart notes) documenting the reason(s) preferred agents cannot be used (subject to clinical review).

Crohn's Disease

Interleukin (IL) 12/IL-23 Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	STELARA (ustekinumab)
	STELARA (ustekinumab) – *IV Induction Medical Billing Only*

Interleukin (IL) - 23 Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	SKYRIZI (risankizumab-rzaa)
	SKYRIZI (risankizumab-rzaa) – *IV Induction Medical Billing Only*

TNF inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AVSOLA (infliximab-axxq) – *Medical Billing Only*	INFLECTRA (infliximab-dyyb) – *Medical Billing Only*
CIMZIA (certolizumab pegol)	infliximab – *Medical Billing Only*
HUMIRA (adalimumab)	REMICADE (infliximab) – *Medical Billing Only*
RENFLEXIS (infliximab-abda) – *Medical Billing Only*	

α4 Integrin Inhibitors

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	TYSABRI (natalizumab) – *Medical Billing Only*

α4β7 Integrin Inhibitors

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	ENTYVIO (vedolizumab) – *Medical Billing Only*

Electronic Diagnosis Verification

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

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

- Entyvio Only:
  - The member must meet one of the following:
    - The member must have failed a 3-month trial of a TNF Inhibitor, as evidenced by paid claims or pharmacy printouts.
    - The member has a high risk of infection or malignancy (e.g., age > 55, history of malignancy, history of serious infection)
- Remicade, Inflectra, infliximab Only:
  - See Preferred Dosage Form Criteria
- Skyrizi Only:
  - The member must have failed a 3-month trial of a TNF Inhibitor, as evidenced by paid claims or pharmacy printouts.
- Stelara Only:
  - The member has failed a 3-month trial of Entyvio or Skyrizi, as evidenced by paid claims or printouts
- Tysabri Only
  - The member has failed a 3-month trial of Entyvio, as evidenced by paid claims or printouts

Clostridium difficile-associated diarrhea (CDAD)

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
FIRVANQ (vancomycin) SOLUTION 25 mg/mL	DIFICID (fidaxomicin) 40 MG/ML SUSPENSION
vancomycin capsule	DIFICID (fidaxomicin) TABLET
vancomycin solution 50 mg/mL	FIRVANQ (vancomycin) SOLUTION 50 MG/ML
	VANCOCIN (vancomycin) CAPSULE

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

- The member must have failed a 10-day trial with a preferred agent, as evidenced by paid claims or pharmacy printouts

Constipation – Irritable Bowel Syndrome (IBS) / Opioid Induced

Irritable Bowel Syndrome (IBS) / Idiopathic Constipation

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AMITIZA (lubiprostone) - *Brand Required*	IBSRELA (tenapanor)
LINZESS (linaclotide) 145 mcg, 290 mcg	LINZESS (linaclotide) 72 mcg
TRULANCE (plecanatide)	lubiprostone
	MOTEGRITY (prucalopride)

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

- Linzess Only:
  - The member must be receiving good effect from the 145 mcg but experiencing adverse effects
- Motegrity and Ibsrela Only:
  - The member must also have had a 30-day trial with Trulance, as evidenced by paid claims or pharmacy printouts

Therapeutic Duplication

- One medication is allowed at a time

Opioid-Induced Constipation

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AMITIZA (lubiprostone) - *Brand Required*	lubiprostone
MOVANTIK (naloxegol)	RELISTOR (methylnaltrexone) TABLET
RELISTOR (methylnaltrexone) SYRINGE	SYMPROIC (naldemedine)
RELISTOR (methylnaltrexone) VIAL	

Electronic Step Care and Concurrent Medications

- A total of 28 days of opioid analgesics must be paid within 40 days prior to requested Movantik, Symproic, or Relistor's date of service
  - Medications indicated for opioid-induced constipation should be discontinued when opioids are stopped.

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

- The member must have failed 30-day trials of each of the oral preferred agents, as evidenced by paid claims or pharmacy printouts. Lubiprostone is required for females assigned at birth only.

Diarrhea

Irritable Bowel Syndrome

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
dicyclomine capsule	alosetron
dicyclomine tablet	dicyclomine oral syrup
diphenoxylate/atropine	LOMOTIL (diphenoxylate/atropine)
loperamide	VIBERZI (eluxadoline)
LOTRONEX (alosetron) - *Brand Required*	XIFAXAN (rifaximin) 550 mg tablet

Electronic Diagnosis Verification

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

Electronic Step Care and Concurrent Medications

- Xifaxan: Xifaxan 550mg does not require prior authorization for hepatic encephalopathy if used concurrently with lactulose
  - A total of 30 days of lactulose must be paid within 65 days prior to Xifaxan's date of service
  - An override may be available after an adequate trial of lactulose where lactulose is not tolerated

Prior Authorization Criteria

Initial Criteria - Approval Duration: 3 months

- Documentation must be provided confirming that infectious and medication-induced etiologies of diarrhea have been ruled out
- The member must have failed a 30-day trial of each preferred unique active ingredient, as evidenced by paid claims or pharmacy printouts. Alestron is required for females assigned at birth only.

HIV / AIDs

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
diphenoxylate/atropine	LOMOTIL (diphenoxylate/atropine)
loperamide	MYTESI (crofelemer)

Prior Authorization Criteria

Initial Criteria - Approval Duration: 3 months

- Documentation must be provided confirming that infectious and medication-induced etiologies of diarrhea have been ruled out
- The member must have failed a 30-day trial of each preferred unique active ingredient, as evidenced by paid claims or pharmacy printouts.

Digestive Enzymes

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
CREON (lipase/protease/amylase)	PANCREAZE (lipase/protease/amylase)
ZENPEP (lipase/protease/amylase)	PERTZYE (lipase/protease/amylase)
	VIOKACE (lipase/protease/amylase)

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

- A 30-day trial of all preferred agents will be required before a non-preferred agent will be authorized unless member stable on a pancreatic enzyme written by a gastroenterologist or pancreas disease specialist

Eosinophilic Esophagitis

CLINICAL PA REQUIRED
DUPIXENT (dupilumab)

Prior Authorization Criteria

Prior Authorization Form - Eosinophilic Esophagitis

Initial Criteria - Approval Duration: 6 months

- The requested medication must be prescribed by, or in consult with, a gastroenterologist
- The member must have ≥15 intraepithelial eosinophils per high-power field (eos/hpf).
- The member must have failed a 3-month trial of a swallowed inhaled respiratory corticosteroid (budesonide or fluticasone).

Renewal Criteria - Approval Duration: 12 months

- Documentation must be submitted that 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.

Familial Cholestasis Pruritis

CLINICAL PA REQUIRED
BYLVAY (odevixibat)
LIVMARLI (maralixibat)

Prior Authorization Criteria

Initial Criteria - Approval Duration: 6 months

- Documentation must be provided to support the presence of moderate to severe pruritis
- The requested medication must be prescribed by, or in consult with, a hepatologist or gastroenterologist
- 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 ursodiol, as evidenced by paid claims or pharmacy printouts.
    - The member must have failed at least a 3-month trial of one of the following agents to treat pruritis: cholestyramine, rifampin, antihistamines, as evidenced by paid claims or pharmacy printouts.
    - Bylvay Only:
- Genetic testing confirms pathogenic variant (e.g., *ATP8B1, ABCB11, ABCB4, TJP2, NR1H4, and MYO5B*) indicating the presence and type of PFIC Type 1 or 2.
- Genetic testing does not indicate PFIC Type 2 with *ABCB11* variants that predict complete absence of BSEP-3 protein.
    - Livmarli Only:
- Genetic testing confirms pathogenic variant of *JAG1* or *NOTCH1*

Renewal Criteria - Approval Duration: 12 months
- The member has experienced an improvement in pruritis, as evidenced by clinical documentation.
- The member must have experienced a reduction in serum bile acid as defined as a bile acid reduction ≥70% or reaching a bile acid level ≤70 µmol/L

Acute Hepatic Porphyria (AHP)

CLINICAL PA REQUIRED
GIVLAARI (givosiran) – *Medical Billing Only*

Prior Authorization Criteria

Initial Criteria - Approval Duration: 6 months
- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a geneticist, hepatologist, hematologist, gastroenterologist, or specialist in acute hepatic porphyria (AHP)
- The member must have a diagnosis of AHP (i.e., acute intermittent porphyria (AIP), variegate porphyria (VP), hereditary coproporphyria (HCP), delta-aminolevulinic acid dehydratase deficient porphyria (ADP)) with the following as defined by laboratory reference range (evidenced with submitted documentation):
    - Elevated urine porphobilinogen (PBG)
    - Increased aminolevulinic acid (ALA)
    - Genetic testing confirming a mutation
- The member has addressed identifiable lifestyle triggers (e.g., certain drugs, smoking, stress)
- The member has had two documented porphyria attacks within the past 6 months requiring hospitalization, urgent healthcare visit, or intravenous hemin administration (number of attacks and days of hemin are documented)
- The member has not had a liver transplant

Renewal Criteria - Approval Duration: 12 months
- The member has had a meaningful reduction (e.g., 30%) in each of the following:
    - Number of porphyria attacks
    - Days of Hemin Use
    - Reduction in urinary ALA

Proton Pump Inhibitor

Solid Dosage Forms

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

Electronic Step Care and Concurrent Medications

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

Prior Authorization Criteria

Initial Criteria - Approval Duration: 6 months

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

Non-Solid Dosage Forms

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

Prior Authorization Criteria

Initial Criteria - Approval Duration: 6 months

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

Electronic Age Verification

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

Therapeutic Duplication

- One strength of one medication is allowed at a time
- Proton Pump Inhibitors is not allowed with:
  - Esomeprazole or omeprazole are not covered with clopidogrel.
    - Other PPIs such as pantoprazole are covered with clopidogrel. Clopidogrel is a substrate for 2C19 and esomeprazole and omeprazole are strong 2C19 inhibitors and can decrease effectiveness of Clopidogrel.
  - Dextroamphetamine/Amphetamine ER:
    - Proton Pump Inhibitors increase blood levels and potentiate the action of amphetamine. Co-administration of Adderall XR and gastrointestinal or urinary alkalizing agents should be avoided
  - H2 Blockers: If 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.

Ulcerative Colitis

Biologic Agents

α4β7 Integrin Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	ENTYVIO (vedolizumab) – *Medical Billing Only*

Interleukin (IL) 12/IL-23 Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	STELARA (ustekinumab) – *IV Induction Medical Billing Only*

TNF inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AVSOLA (infliximab-axxq) – *Medical Billing Only*	INFLECTRA (infliximab-dyyb) – *Medical Billing Only*
HUMIRA (adalimumab)	infliximab – *Medical Billing Only*
RENFLEXIS (infliximab-abda) – *Medical Billing Only*	REMICADE (infliximab) – *Medical Billing Only*
	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

- Entyvio Only: The member must meet one of the following:

- The member must have failed a 3-month trial of a TNF inhibitor, as evidenced by paid claims or pharmacy printouts.
- The member has a high risk of infection or malignancy (e.g., age > 55, history of malignancy, history of serious infection)

- Remicade, Inflectra, infliximab Only: See Preferred Dosage Form Criteria
- Simponi Only: The member must have failed a 3-month trial of a TNF inhibitor, as evidenced by paid claims or pharmacy printouts.
- Stelara Only: The member must have failed a 3-month trial of Entyvio, as evidenced by paid claims or pharmacy printouts.

5-Aminosalicylic Acid (5-ASA)

Oral

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
APRISO (mesalamine) CAPSULE – *Brand Required*	AZULFIDINE (sulfasalazine)
ASACOL HD (mesalamine) – *Brand Required*	AZULFIDINE DR (sulfasalazine)
balsalazide capsule	COLAZAL (balsalazide)
DELZICOL (mesalamine) CAPSULE– *Brand Required*	mesalamine DR
DIPENTUM (olsalazine)	mesalamine ER
LIALDA (mesalamine) TABLET– *Brand Required*	mesalamine HD
PENTASA (mesalamine) – *Brand Required*	
sulfasalazine DR tablet	
sulfasalazine tablet	

Topical

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
hydrocortisone enema	CANASA (mesalamine) SUPPOSITORY
mesalamine enema	mesalamine enema kit
mesalamine rectal suppository	ROWASA (mesalamine) ENEMA KIT
	SF ROWASA (mesalamine) ENEMA
	UCERIS (budesonide) RECTAL FOAM

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

- The member must have failed a 3-month trial of mesalamine, as evidenced by paid claims or pharmacy printouts.

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 Only:

- The member must have failed a 3-month trial of Humira and Xeljanz IR, as evidenced by paid claims or pharmacy printouts.

Sphingosine 1-Phosphate (S1P) Receptor Modulator

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	ZEPOSIA (ozanimod)

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

- The member must have had a 30-day trial of a preferred agent, or a TNF inhibitor as evidenced by paid claims or pharmacy printouts.

Wilson's Disease

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

- Clinical justification must be provided explaining why the member is unable to use the preferred agents (subject to clinical review)
- The member must have failed a 30-day trial of each preferred agent (listed in boxes below) within the past 2 years, as evidenced by paid claims or pharmacy printouts

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
DEPEN (penicillamine) TITRATAB – *Brand Required*	CUPRIMINE (penicillamine) CAPSULE
trientine hydrochloride	penicillamine capsule
	penicillamine tablet
	SYPRINE (trientine hydrochloride)

Genetic and Rare Disease

Transthyretin-Mediated Amyloidosis (hATTR)

CLINICAL PA REQUIRED
NAGLAZYME (galsulfase) – *Medical Billing Only*

Prior Authorization Criteria

Initial Criteria - Approval Duration: 6 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- Documentation of the member's diagnosis must be submitted, as evidenced by the following:
  - Any transthyretin (TTR) mutation confirmed by genetic testing
  - Clinical signs and symptoms of the disease (e.g., peripheral/autonomic neuropathy, motor disability)
- The requested medication must be prescribed by, or in consult with, a neurologist, geneticist, or specialist in the treatment of amyloidosis
- Documentation of one of the following must be submitted:
  - Polyneuropathy disability (PND) score of ≤ IIIb
  - Familial amyloid polyneuropathy (FAP) of stage 1 or 2

Renewal Criteria - Approval Duration: 12 months

- The member must have experienced meaningful clinical benefit since starting treatment with the requested medication, as evidenced by medical documentation (e.g., chart notes) attached to the request (subject to clinical review) including maintenance or improvement in the one of the following scores and symptoms:
  - PND score
  - FAP stage

Late Infantile Neuronal Ceroid Lipofuscinosis Type 2 (CLN2)

CLINICAL PA REQUIRED
BRINEURA (cerliponase alfa) – *Medical Billing Only*

Prior Authorization Criteria

Initial Criteria - Approval Duration: 6 months

- The member must be between 3 and 8 years of age.
- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a metabolic specialist, geneticist, or pediatric neurologist
- Documentation of the diagnosis must be submitted, as evidenced by the following:
  - Molecular analysis that has detected two pathogenic variants/mutations in the TPP1/CLN2 gene
  - An enzyme assay confirming deficiency of tripeptidyl peptidase 1 (TPP1)
- The member must not have ventriculoperitoneal shunts
- Baseline results of motor and language domains of the Hamburg CLN2 Clinical Rating Scale must be submitted and meet the following parameters:
  - Results must show a combined score of less than 6 in the motor and language domains
  - Results must show a score of at least 1 in each of these domains

Renewal Criteria - Approval Duration: 12 months

- The member must not have acute, unresolved localized infection on or around the device insertion site or suspected or confirmed CNS infection
- The member maintains at a score of at least 1 in the motor domain on the Hamburg CLN2 Clinical Rating Scale
- The member has responded to therapy compared to pretreatment baseline with stability/lack of decline* in motor function/milestones.

  ** Decline is defined as having an unreversed (sustained) 2-category decline or an unreversed score of 0 in the Motor domain of the CLN2 Clinical Rating Scale*

Fabry Disease

Alpha-Galactosidase A Pharmacological Chaperone

PREFERRED AGENTS (CLINICAL PA REQUIRED)
GALAFOLD (migalastat)

Prior Authorization Criteria

Initial Criteria - Approval Duration: 6 months

- The requested medication must be prescribed by, or in consult with, a metabolic specialist, geneticist, cardiologist, or specialist in Fabry disease
- The member must be assigned male at birth.

- Baseline value for plasma or urinary globotriosylceramide (GL-3) levels ≥ 5 ng/mcL or GL-3 inclusions ≥ 0.3 per kidney interstitial capillary (KIC) as measured in kidney biopsy
- The member's diagnosis must be confirmed to be caused by a pathologic galactosidase alpha gene (GLA) variant that is amenable to treatment with Galafold interpreted from a clinical geneticist professional, as evidenced by medical documentation attached to the request.
- The medication must not be used in conjunction with enzyme replacement therapy.
- The member must not have significant renal impairment (eGFR <30 mL/minute/1.73 m2)

Renewal Criteria - Approval Duration: 12 months

- The member must have a decreased Gb3 level or Cb3 inclusion per KIC level and experienced and maintained improvement in one of the following symptoms since starting treatment with requested product, as evidenced by medical documentation (e.g., chart notes) attached to the request (subject to clinical review):
  - Acroparesthesias (burning pain in the extremities)
  - Angiokeratomas (cutaneous vascular lesions)
  - Hypo- or anhidrosis (diminished perspiration)
  - Corneal and lenticular opacities
  - Left ventricular hypertrophy (LVH), hypertrophic cardiomyopathy, or arrythmia of unknown etiology
  - Chronic kidney disease (CKD), multiple renal cysts, and/or proteinuria of unknown etiology

Enzyme Replacement Therapy

PREFERRED AGENTS (CLINICAL PA REQUIRED)
Fabrazyme (agalsidase beta) – *Medical Billing Only*

Initial Criteria - Approval Duration: 6 months

- The member is 8 years of age or older
- The requested medication must be prescribed by, or in consult with, a metabolic specialist, geneticist, cardiologist, or specialist in Fabry disease
- The member will not be concurrently treated with Galafold (migalastat)
- The member must have a diagnosis of Fabry disease with the one of the following (as evidenced with submitted documentation):
  - In males assigned at birth:
    - Deficiency of less than 35% of mean normal alpha-galactosidase A (α-Gal A) enzyme activity
    - Diagnosis is confirmed to be caused by a pathologic galactosidase alpha gene (GLA)
  - In females assigned at birth and males assigned at birth with α-Gal A enzyme activity > 35 percent:
    - Diagnosis must be confirmed to be caused by a pathologic galactosidase alpha gene (GLA)
    - Baseline value for plasma or urinary globotriosylceramide (GL-3) levels ≥ 5 ng/mcL or GL-3 inclusions ≥ 0.3 per kidney interstitial capillary (KIC) as measured in kidney biopsy
    - The member is experiencing one of the following symptoms:
      - Acroparesthesias (burning pain in the extremities)
      - Angiokeratomas (cutaneous vascular lesions)
      - Hypo- or anhidrosis (diminished perspiration)
      - Corneal and lenticular opacities
      - Left ventricular hypertrophy (LVH), hypertrophic cardiomyopathy, or arrythmia of unknown etiology
      - Chronic kidney disease (CKD), multiple renal cysts, and/or proteinuria of unknown etiology

Renewal Criteria - Approval Duration: 12 months

- The member must have a decreased Gb3 level or Cb3 inclusion per KIC level and experienced and maintained improvement in one of the following symptoms since starting treatment with requested product, as evidenced by medical documentation (e.g., chart notes) attached to the request (subject to clinical review):
  - Acroparesthesias (burning pain in the extremities)
  - Angiokeratomas (cutaneous vascular lesions)
  - Hypo- or anhidrosis (diminished perspiration)

- Corneal and lenticular opacities
- Left ventricular hypertrophy (LVH), hypertrophic cardiomyopathy, or arrythmia of unknown etiology
- Chronic kidney disease (CKD), multiple renal cysts, and/or proteinuria of unknown etiology

Gaucher's Disease

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ELELYSO (taliglucerase alfa) – *Medical Billing Only*	CEREZYME (imiglucerase) – *Medical Billing Only*
	VPRIV (velaglucerase alfa) – *Medical Billing Only*

Prior Authorization Criteria

Initial Criteria - Approval Duration: 6 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a geneticist, an endocrinologist, or a physician who specializes in the treatment of lysosomal storage disorders
- The member must have a diagnosis of Gaucher disease Type I or Type III with the one of the following (as evidenced with submitted documentation):
  - Deficiency in beta-glucocerebrosidase enzyme activity in peripheral leukocytes
  - Genetic testing confirming biallelic pathogenic variants in the GBA1 gene
- The member must be experiencing one or more of the following (as evidenced with submitted documentation):
  - Anemia with hemoglobin less than or equal to the laboratory reported low for patient age and gender
  - Thrombocytopenia with platelet count less than 100,000/mm³
  - Bone disease (T-score below -1.0 [DXA], height SDS <-2.25 with decreased growth velocity, bone crisis)
  - Hepatomegaly (liver size 1.25 or more times normal)
  - Splenomegaly (spleen size five (5) or more times normal)

Non-Preferred Agent Criteria:

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

Initial Criteria - Approval Duration: 12 months

- Documentation has been submitted that member has experienced a disease stability or beneficial response to therapy from baseline as shown by one or more of the following:
  - Reduction in liver volume to normal size or by 10%
  - Reduction in spleen volume by 15%
  - Increase in hemoglobin levels by 1 g/dl
  - Increase in platelet levels by 15%
  - Increased T-score [DXA] by 0.3, normalized growth velocity, or decrease in bone crisis

Lysosomal Acid Lipase (LAL) deficiency

CLINICAL PA REQUIRED
KANUMA (sebelipase alfa) – *Medical Billing Only*

Prior Authorization Criteria

Initial Criteria - Approval Duration: 6 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a specialist in the treatment of lysosomal acid lipase (LAL) such as a lipidologist, endocrinologist, cardiologist, or hepatologist

- Documentation of the member's diagnosis must be submitted, as evidenced by the following:
  - Genetic testing confirming 2 mutations in the LIPA gene
  - Deficiency of the LAL in peripheral blood leukocytes, fibroblasts, or dried blood spots

Renewal Criteria - Approval Duration: 12 months

- The member must have experienced and maintained clinical benefit since starting treatment with the requested medication, as evidenced by medical documentation (e.g., chart notes) attached to the request (subject to clinical review) including improvement in weight for age Z-scores for individuals with growth failure, improved LDL, HDL, AST, ALT and/or triglycerides

Mucopolysaccharidosis I (MPS I)

CLINICAL PA REQUIRED
ALDURAZYME (laronidase) – *Medical Billing Only*

Prior Authorization Criteria

Initial Criteria - Approval Duration: 6 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, an expert in lysosomal storage diseases
- Documentation of the member's diagnosis must be submitted, as evidenced by the following:
  - Genetic testing confirming biallelic pathogenic mutations in the IDUA gene
  - Deficiency in activity of the lysosomal enzyme α-L-iduronidase (IDUA) in fibroblast or leukocyte
- Documentation of the member's current motor function must be submitted, as evidenced by scores from the following assessments:
  - 6-minute walk test (6MWT)
  - Forced Vital Capacity (FVC) via Pulmonary Function Test

Renewal Criteria - Approval Duration: 12 months

- The member must have experienced and maintained clinical benefit since starting treatment with the requested medication, as evidenced by medical documentation (e.g., chart notes) attached to the request (subject to clinical review) including improvement in the following scores and symptoms:
  - 6-minute walk test (6MWT)
  - Forced Vital Capacity (FVC) via Pulmonary Function Test

Mucopolysaccharidosis II (MPS II) – Hunter Syndrome

CLINICAL PA REQUIRED
ELAPRASE (idursulfase) – *Medical Billing Only*

Prior Authorization Criteria

Initial Criteria - Approval Duration: 6 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- Documentation of the member's diagnosis must be submitted, as evidenced by the following:
  - Deficiency in iduronate-2sulfatase (I2S) enzyme activity in white cells, fibroblasts, or plasma in the presence of normal activity of at least one other sulfatase
  - Genetic testing confirming pathogenic mutations in the IDS gene
- The member age must be 5 years of age or older
- The requested medication must be prescribed by, or in consult with, an expert in lysosomal storage diseases
- The member does not have severe cognitive or neurologic impairment (e.g., inability to swallow)

- Documentation of one of the following must be submitted:
  - The Forced Vital Capacity (FVC) via Pulmonary Function Test
  - Urinary glycosaminoglycan (uGAG) levels are elevated defined by laboratory reference range
  - 6-minute walk test (6MWT)
  - Hepatomegaly (liver size 1.25 or more times normal)
  - Splenomegaly (spleen size five (5) or more times normal)

Renewal Criteria - Approval Duration: 12 months
- Documentation must be submitted confirming improvement of one of the following:
  - The Forced Vital Capacity (FVC) via Pulmonary Function Test relative improvement of 10% over baseline
  - Urinary glycosaminoglycan (uGAG) levels normalization defined by laboratory reference range
  - 6-minute walk test (6MWT) increase
  - Reduction in liver volume to normal size or by 10%
  - Reduction in spleen volume by 15%

Mucopolysaccharidosis IVA (MPS IVA) - Morquio A syndrome

CLINICAL PA REQUIRED
VIMIZIM (elosulfase alfa) – *Medical Billing Only*

Prior Authorization Criteria

Initial Criteria - Approval Duration: 6 months
- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- Documentation of the member's diagnosis must be submitted, as evidenced by the following:
  - Genetic testing confirming biallelic pathogenic mutations in the GALNS gene
  - Deficiency in activity of the n N-acetylgalactosamine 6-sulfatase (GALNS) enzyme
- The requested medication must be prescribed by, or in consult with, a geneticist, metabolic specialist, or specialist in mucopolysaccharidoses (MPS)
- The member is experiencing musculoskeletal signs and symptoms of MSP-IVA such as knee deformity, kyphosis, hip dysplasia, arthralgia, etc.
- Documentation of one of the following must be submitted:
  - Forced Vital Capacity (FVC) via Pulmonary Function Test
  - 6-minute walk test (6MWT)
  - 3-minute stair claim test (3-MSCT)

Renewal Criteria - Approval Duration: 12 months
- The member must have experienced and maintained clinical benefit since starting treatment with the requested medication, as evidenced by medical documentation (e.g., chart notes) attached to the request (subject to clinical review) by one of the following scores:
  - Forced Vital Capacity (FVC) via Pulmonary Function Test
  - 6-minute walk test (6MWT)
  - 3-minute stair claim test (3-MSCT)
  - Reduced Urine Keratan Sulfate (KS) levels

Mucopolysaccharidosis VI (MPS VI) - Maroteaux-Lamy syndrome

CLINICAL PA REQUIRED
NAGLAZYME (galsulfase) – *Medical Billing Only*

Prior Authorization Criteria

Initial Criteria - Approval Duration: 6 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- Documentation of the member's diagnosis must be submitted, as evidenced by the following:
  - Deficiency of N-acetylgalactosamine 4-sufatase (arylsulfatase B or ASB) enzyme activity of <10% of the lower limit of normal
  - Detection of pathogenic variants in the ARSB gene by molecular genetic testing
- The requested medication must be prescribed by, or in consult with, an expert in lysosomal storage diseases
- Documentation of both of the following must be submitted:
  - Elevated level of urinary excretion of glycosaminoglycans (GAGs) such as chondroitin sulfate and dermatan sulfate, as defined by being above the upper limit of normal by the laboratory reference range
  - Motor function as measured by one of the following:
    - 6 or 12-minute walk test (6-MWT or 12-MWT)
    - 3-minute stair claim test
    - Forced Vital Capacity (FVC) via Pulmonary Function Test

Renewal Criteria - Approval Duration: 12 months
- The member must have experienced meaningful clinical benefit since starting treatment with the requested medication, as evidenced by medical documentation (e.g., chart notes) attached to the request (subject to clinical review) including improvement in the one of the following scores and symptoms:
  - Reduction in urinary excretion of glycosaminoglycans (GAGs)
  - Stability or improvement in 6 or 12-minute walk test (6-MWT or 12-MWT)
  - Stability or improvement in 3-minute stair claim test
  - Stability or improvement in Forced Vital Capacity (FVC) via Pulmonary Function Test

Mucopolysaccharidosis VII (MPS VII) - Sly Syndrome

CLINICAL PA REQUIRED
MEPSEVII (vestronidase alfa-vjbk) – *Medical Billing Only*

Prior Authorization Criteria

Initial Criteria - Approval Duration: 6 months
- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- Documentation of the member's diagnosis must be submitted, as evidenced by the following:
  - Deficiency of beta-glucuronidase enzyme
  - Detection of pathogenic variants in the GUSB gene by molecular genetic testing.
- The requested medication must be prescribed by, or in consult with, an expert in lysosomal storage diseases
- One or more of the following documentations must be submitted:
  - Skeletal abnormalities
  - Elevated level of urinary excretion of glycosaminoglycans (GAGs) such as chondroitin sulfate and dermatan sulfate, as defined by being above the upper limit of normal by the laboratory reference range
  - Liver and/or spleen volume
  - 6-minute walk test (6MWT)
  - Motor function test (e.g., Bruininks-Oseretsky Test of Motor Proficiency (BOT-2))
  - Forced Vital Capacity (FVC) via Pulmonary Function Test

Renewal Criteria - Approval Duration: 12 months
- The member must have experienced meaningful clinical benefit since starting treatment with the requested medication, as evidenced by medical documentation (e.g., chart notes) attached to the request (subject to clinical review) including improvement in the one of the following scores and symptoms:
  - Stability or improvement in skeletal abnormalities shown on x-ray, short stature, macrocephaly
  - Reduction in urinary excretion of glycosaminoglycans (GAGs)

- Reduction in liver and/or spleen volume
- Stability or improvement in 6-minute walk test (6MWT)
- Stability or improvement in Forced Vital Capacity (FVC) via Pulmonary Function Test

Phenylketonuria

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
sapropterin	JAVYGTOR (sapropterin)
	KUVAN (sapropterin)
	PALYNZIQ (pegvaliase-pqpz)

Underutilization

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

Prior Authorization Criteria

Prior Authorization Form - Phenylketonuria

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

- The member must have been compliant with a PHE restricted diet for past 6 months (documentation must be attached).
- The requested medication must be prescribed by, or in consult with, a geneticist or endocrinologist
- Baseline PHE levels must be attached
  - For members of childbearing potential and children ≤ 12 years old: PHE levels must be above 360 µmoles/liter (6 mg/dL)
  - For members without childbearing potential, and children > 12 years old: PHE levels must be above 600 µmoles/liter 10 mg/dL)
- Sapropterin Only: The member's weight must be provided. Requested initial dose must be 10 mg/kg
- Palynziq Only: PHE levels must be attached documenting the member was unable to achieve a PHE level less than 600 µmoles/liter (10mg/dL) despite a 3-month trial of 20mg/kg dose of sapropterin with good compliance.

Renewal Criteria:

- *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

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

Pompe Disease

CLINICAL PA REQUIRED
LUMIZYME (alglucosidase alpha) – *Medical Billing Only*
NEXVIAZYME (avalglucosidase alfa-ngpt) – *Medical Billing Only*

Prior Authorization Criteria

Initial Criteria - Approval Duration: 6 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- Documentation of the member's diagnosis must be submitted, as evidenced by the following:
  - Deficiency of acid alpha-glucosidase enzyme activity (2% to 40% partial deficiency of GAA non-classic infantile forms or late onset forms) of the lab specific normal mean value
  - Detection of pathogenic variants in the GAA gene by molecular genetic testing.
- The requested medication must be prescribed by, or in consult with, a cardiologist, neurologist or geneticist or specialist in the area of Pompe disease
- The member must not have permanent invasive ventilation
- Documentation must be submitted of the member's current motor function such as motor function, respiratory function, cardiac involvement (infantile onset) and scores from at least two of the following assessments:
  A. Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorder (CHOP-INTEND)
  B. Hammersmith Infant Neurological Examination (HINE) Section 2 motor milestone score
  C. Hammersmith Functional Motor Scale Expanded (HFMSE)
  D. Motor Function Measure – 32 items (MFM-32)
  E. Revised Upper Limb Module (RULM)
  F. 6-minute walk test (6MWT)
  G. Forced Vital Capacity (FVC) via Pulmonary Function Test

Category Criteria (Renewal): *Approval Duration: 12 months*

- The member must have experienced and maintained clinical benefit since starting treatment with the requested medication, as evidenced by medical documentation (e.g., chart notes) attached to the request (subject to clinical review) including stabilization or improvement of the following:
  - Motor function, respiratory function, cardiac involvement (infantile onset)
  - CHOP-INTEND, HINE, HFMSE, MFM-32, 6MWT, or RULM scores
  - Forced Vital Capacity (FVC) via Pulmonary Function Test (ages 5 and older)

N-acetylglutamate synthase (NAGS) deficiency

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
carglumic acid	CARBAGLU (carglumic acid)

Hematology/Oncology

Anemia

PREFERRED AGENTS (CLINICAL PA REQUIRED)
REBLOZYL (luspatercept) – *Medical Billing Only*

Initial Criteria - Approval Duration: 6 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a hematologist or oncologist, or prescriber specializing in the treatment of beta thalassemia or myelodysplastic syndrome/myeloproliferative neoplasm
- The member must have a diagnosis of anemia due to beta thalassemia or myelodysplastic syndrome/myeloproliferative neoplasm with ring sideroblasts
- Documentation must be submitted of a pretreatment hemoglobin of less than 11 g/dL
- Other causes of anemia (e.g., hemolysis, bleeding, recent major surgery, vitamin deficiency, etc.) have been ruled out
- Member must not have any of the following:
  - Diagnosis of hemoglobin S/β-thalassemia or alpha-thalassemia
  - Deep vein thrombosis or stroke within the past 24 weeks
  - Platelet count greater than 1000 x 109 per liter

For anemia due to myelodysplastic syndrome/myeloproliferative neoplasm:

- Documentation must be submitted that the member requires 2 or more RBC units over an 8-week period as evidenced by the following:
  - One of the following:
    - Ring sideroblasts greater than or equal to 15%
    - Ring sideroblasts greater than or equal to 5% and less than 15% with an SF3B1 mutation
  - One of the following:
    - Serum erythropoietin greater than 500 mU/mL
    - Serum erythropoietin less than or equal to 500 mU/mL with inadequate response after a 3-month trial with a combination of an ESA (e.g., epoetin alfa) and granulocyte-colony stimulating factor (G-CSF)
  - Member has very low to intermediate risk disease defined as one of the following:
    - Revised International Prognostic Scoring System (IPSS-R); very low, low, or intermediate (Score of 0 to 4.5);
    - IPSS: low/intermediate-1 (Score 0 to 1)
    - WHO-Based Prognostic Scoring System (WPSS): WPSS: very low, low, or intermediate (Score 0 to 2)

For anemia due to beta thalassemia:

- Documentation must be submitted confirming the following:
  - The member has required at least 6 red blood cell (RBC) transfusions in the previous 24 weeks
  - The member has not had a transfusion-free period for ≥ 35 days during the most recent 24 weeks

Renewal Criteria - Approval Duration: 12 months

- The member must have experienced stabilization, slowing of disease progression, or improvement of the condition since starting treatment with the requested medication, as evidenced by medical documentation (e.g., chart notes) attached to the request (subject to clinical review) including:
  - Reduction in transfusion requirements from pretreatment baseline achieving one of the following:
    - At least 2 units packed red blood cells
    - By one-half
    - Complete transfusions independence
- The member continues to have pretreatment hemoglobin of less than 11 g/dL
- Dose will be increased to 1.25 mg/kg daily

Cold Agglutin Disease (CAD)

Anti-B-cell Therapy

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
RITUXAN (rituximab)	

Anti-Complement Therapy

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	ENJAYMO (sutimlimab-jome) – *Medical Billing Only*

Initial Criteria - Approval Duration: 6 months

- The requested medication must be prescribed by, or in consult with, a hematologist or specialist in cold agglutinin disease (CAD)
- The member must have all of the following:
  - Evidence of chronic hemolysis (e.g., high lactated dehydrogenase [LDH], low haptoglobin, high reticulocyte count)
  - Direct antiglobin (Coombs) test is positive for C3d
  - Cold agglutinin titer ≥ 64 at 4°C

- The member must have had at least one blood transfusion in the previous six months
- 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

- Documentation must be submitted that the member has had a beneficial response to therapy from baseline as shown by one or more of the following:
  - Decrease in transfusions from baseline
  - Increase in hemoglobin (Hgb) by ≥ 2 g/dL from baseline or Hgb level ≥ 12 g/dL
  - Normalization of bilirubin levels to less than 1.2mg/dL
- Therapy continues to be necessary due to ongoing cold agglutinin production and inability to use rituximab

Cytokine Release Syndrome

Interleukin (IL) -6 Receptor Inhibitors

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ACTEMRA (tocilizumab)	
ACTEMRA (tocilizumab) – *Medical Billing Only*	

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

- Actemra: See Medications that cost over $3000/month Criteria

Hemophagocytic Lymphohistiocytosis (HLH)

PREFERRED AGENTS (CLINICAL PA REQUIRED)
GAMIFANT (emapalumab-lzsg) – *Medical Billing Only*

Initial Criteria - Approval Duration: 3 months or up to the hematopoietic stem cell transplantation (HSCT) date

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a hematologist, oncologist, immunologist, or transplant specialist
- The member has refractory, recurrent or progressive disease or intolerance with conventional HLH therapy (i.e., etoposide + dexamethasone, cyclosporine A, or Anti-thymocyte globulin)
- The member must be a candidate for stem cell transplant
- Documentation must be submitted confirming the diagnosis, as evidenced by the following:
  - Confirmation of a gene mutation known to cause primary HLH (e.g., PRF1, UNC13D, STX11 RAB27A, STXBP2)

- Confirmation of 5 of the following clinical characteristics:
  - Fever ≥ 101.3F for over 7 days
  - Splenomegaly
  - Two of the following cytopenias in the peripheral blood:
    - Hemoglobin < 9 g/dL (or < 10 g/dL in infants less than 4 weeks of age)
    - Platelet count < 100,000/microL
    - ANC <1000/microL
  - One of the following:
    - Hypertriglyceridemia defined as fasting triglycerides ≥ 265 mg/dL (2 mmol/L)
    - Hypofibrinogenemia defined as fibrinogen ≤ 1.5 g/L
  - Hemophagocytosis in bone marrow or spleen or lymph nodes with no evidence of malignancy
  - Low or absent natural killer cell activity
  - Ferritin ≥ 500 mg/L
  - Soluble CD25 (i.e., soluble IL-2 receptor) ≥ 2,400 U/mL
- The requested medication must be administered with dexamethasone as part of the induction or maintenance phase of stem cell transplant, which is to be discontinued at the initiation of conditioning for stem cell transplant

Category Criteria (Renewal): *Approval Duration: 3 months or up to the HSCT date*

- At least 3 HLH abnormalities must be improved by at least 50% from baseline.

Hemophilia

Factor VIIa

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
NOVOSEVEN RT (coagulation Factor VIIa recombinant)	
SEVENFACT (coagulation Factor VIIa recombinant)	

Factor VIII – Hemophilia A

Non-Extended Half Life

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AFSTYLA (factor VIII recombinant, single chain)	ADVATE (factor VIII recombinant)
HEMOFIL M (factor VIII plasma derived; mAb-purified)	KOGENATE FS (factor VIII recombinant)
KOATE (factor VIII plasma derived, chromatography purified)	KOVALTRY (factor VIII recombinant)
NOVOEIGHT (factor VIII Rrecombinant)	NUWIQ (factor VIII recombinant)
OBIZUR (recombinant, B domain-deleted porcine (pig) factor VIII)	RECOMBINATE (factor VIII recombinant)
XYNTHA (factor VIII recombinant)	
XYNTHA SOLOFUSE (factor VIII recombinant)	

Extended Half Life

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ADYNOVATE (factor VIII recombinant, PEGylated)	ELOCTATE (factor VIII recombinant, Fc fusion protein)
JIVI (factor VIII recombinant, pegylated-aucl)	ESPEROCT (factor VIII recombinant, glycopegylated – exei)

Factor VIII; C-Hemophilia A

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
MONOCLATE-P (Antihemophilic Factor VIII:C (human))	

Factor VIII – Hemophilia A/vWF

PREFERRED AGENTS (NO 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))	

Factor VIII – Von Willebrand Factor – Recombinant

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	VONVENDI (Recombinant human vWF)

Factor IX – Hemophilia B

Non-Extended Half Life

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ALPHANINE SD (factor IX, plasma-derived)	
BENEFIX (factor IX recombinant)	
IXINITY (factor IX recombinant)	
MONONINE (factor IX, plasma-derived mAb purified)	
PROFILNINE (factor IX complex)	
RIXUBIS (factor IX recombinant)	

Extended Half Life

PREFERRED AGENTS (NO 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)	

Factor IXa/IX

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
HEMLIBRA (Emicizumab-kxwh)	

Factor X

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
COAGADEX (Coagulation Factor X (Human))	

Factor XIII

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
CORIFACT (Factor XIII Concentrate (Human))	

Factor XIII A – Subunit, Recombinant

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
TRETTEN (Factor XIII A-Subunit, recombinant)	

Anti-inhibitor Coagulant Complex

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
FEIBA NF (Anti-Inhibitor Coagulant Complex)	

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.
- Contact information for 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)

Hematopoietic, Colony Stimulating Factors

Filgrastim

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
NEUPOGEN (filgrastim)	GRANIX (TBO-filgrastim)
	NIVESTYM (filgrastim-AAFI)
	RELEUKO (filgrastim-AYOW)
	ZARXIO (filgrastim-SNDZ)

Pegfilgrastim

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
NYVEPRIA (pegfilgrastrim – APGF)	FULPHILA (pegfilgrastrim-JMDB)
ZIEXTENZO (pegfilgrastim-BMEZ)	FYLNETRA (pegfilgrastim-PBBK)
	NEULASTA (pegfilgrastim)
	UDENYCA (pegfligrastim-CBQV)

Sargramostim

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
LEUKINE (sargramostim)	

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

- Clinical justification must be provided explaining why the member is unable to use the preferred product (subject to clinical review).

Nausea/Vomiting

Chemo-Induced

NK1 Receptor Antagonists

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AKYNZEO (netupitant/palonosetron) CAPSULE	aprepitant capsule
EMEND (aprepitant) CAPSULE 125 MG-80 MG TRIPACK – *Brand Required*	EMEND (aprepitant) CAPSULES 80 MG and 125 MG
	EMEND (aprepitant) SUSPENSION

5-HT3 Receptor Antagonists

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AKYNZEO (netupitant/palonosetron)	SANCUSO (granisetron) PATCH
granisetron tablet	ZOFRAN (ondansetron) TABLET
ondansetron ODT	SUSTOL (granisetron) SYRINGE
ondansetron solution	
ondansetron tablet	

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 print outs
- The member must not have failed preferred chemical entity with same active ingredient as requested product due to side effects

Paroxysmal Nocturnal Hemoglobinuria (PNH)

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

Prior Authorization Criteria

Prior Authorization Form - Empaveli

Initial Criteria - Approval Duration: 6 months

- The requested medication must be prescribed by, or in consult with, a hematologist, oncologist, or immunology specialist
- Diagnosis must be confirmed by flow cytometry with LDL level of 1.5 times the upper limit of normal (must include at least 2 different reagents tested on at least 2 cell lineages) demonstrating that individual's peripheral blood cells are deficient in glycosylphosphatidylinositol (GPI) – linked proteins (as evidenced by submitted documentation)
- One of the following criteria must be met (A or B):
  - The member is transfusion-dependent
  - The member has hemoglobin ≤ 7 g/dL or Hb ≤ 9 g/dL, and member has symptoms of thromboembolic complications (e.g., abdominal pain, shortness of breath, chest pain, end-organ damage, fatigue)

Non-Preferred Agent Criteria:

- The member must have failed a 3-month trial with Ultomiris, as evidenced by paid claims or printouts.

Renewal Criteria - Approval Duration: 12 months

- Documentation has been submitted that support one of the following positive responses to therapy:
  - Decrease in transfusions from baseline
  - Increase in hemoglobin by ≥ 1 g/dL from baseline
  - Normalization in LDH levels ≤ 280 U/L

Paroxysmal Nocturnal Hemoglobinuria (PNH)

CLINICAL PA REQUIRED
RYPLAZIM (plasminogen, human-tvmh) – *Medical Billing Only*

Prior Authorization Criteria

Initial Criteria - Approval Duration: 3 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a hematologist or specialist in treated condition
- Documentation of the diagnosis must be submitted, as evidenced by the following:
  - Baseline plasminogen activity level ≤ 45% *(If the patient is receiving plasminogen supplementation with fresh frozen plasma, allow for a 7-day washout period before obtaining baseline plasminogen activity level.)*
  - Documented history of lesions (e.g., ligneous conjunctivitis, ligneous gingivitis, occlusive hydrocephalus, abnormal wound healing)
  - Genetic testing to confirm biallelic pathogenic *PLG* mutation

Renewal Criteria - Approval Duration: 12 months, a one-time 6-month approval for dose adjustment allowed for members not meeting renewal criteria upon request

- The member must have experienced meaningful clinical benefit since starting treatment with the requested medication, as evidenced by medical documentation (e.g., chart notes) attached to the request (subject to clinical review) including the following:
  - 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

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
DROXIA (hydroxyurea capsule)	ENDARI (glutamine)
hydroxyurea capsule	OXBRYTA (voxelotor)
	SIKLOS (hydroxyurea tablet)

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 must have had a 30-day trial of a preferred agent at the maximum (35 mg/kg/day) or maximally tolerated dose, as evidenced by paid claims or pharmacy printouts
- The member has experienced at least one sickle cell-related vaso-occlusive crisis within past 12 months (documentation required)
- Oxbryta Only:
  - Baseline hemoglobin (Hb) ≤ 10.5 g/dL
- Siklos Only:
  - Baseline hemoglobin (Hb) ≤ 10.5 g/dL
  - See Preferred Dosage Form Criteria

Renewal Criteria - Approval Duration: 12 months

- The member must have experienced and/or maintained clinical benefit since starting treatment with the requested product, as evidenced by medical documentation (e.g., chart notes) attached to the request (subject to clinical review) by one of the following:
  - Increase in hemoglobin (Hb) by ≥ 1 g/dL from baseline
  - Decrease in indirect bilirubin from baseline
  - Decrease in percent reticulocyte count from baseline
  - Reduction in sickle cell-related vaso-occlusive crisis

Thrombocytopenia

Immune Thrombocytopenic Purpura (ITP)

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
NPLATE (romiplostim)	DOPTELET (avatrombopag)
PROMACTA (eltrombopag)	TAVALISSE (fostamatinib)
PROMACTA (eltrombopag) POWDER PACK	

Prior Authorization Criteria

Initial Criteria - Approval Duration: 4 months

- The member has diagnosis of immune thrombocytopenic purpura (ITP) lasting >6 months
- Documentation of platelet count of less than 30 x 10^9/L
- The member must have experienced an inadequate response after one of the following (A, B or C):

A. The member must have failed a trial of appropriate duration of a corticosteroid or immunoglobulins, as evidenced by paid claims or pharmacy print outs
B. Rituximab
C. The member must have undergone a splenectomy

Non-Preferred Agents Criteria:

- The member must have failed trials with each preferred agent (at the recommended dose and duration) with each preferred agent, as evidenced by paid claims or pharmacy printouts.

Renewal Criteria - Approval Duration: 12 months

- Platelet counts must have achieved greater than or equal to 50 x 10^9/L in response to therapy (supported by documentation)

Chronic Liver Disease-Associated Thrombocytopenia

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

DOPTELET (Avatrombopag)	MULPLETA (Lusutrombopag)

Prior Authorization Criteria

Initial Criteria - Approval Duration: The 2 weeks prior to procedure

- The member must have platelet count of less than 50 x 10^9/L
- The member must be scheduled to undergo a procedure that puts the member at risk of bleeding (documentation must include name and scheduled date of procedure)
- Documentation must include the date therapy will be initiated and discontinued:
  - Doptelet: Member must undergo procedure 5-8 days after last dose
  - Mulpleta: Member must undergo procedure 2-8 days after last dose

Chronic Hepatitis C Infection-Associated Thrombocytopenia

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

- Platelet counts must have achieved greater than or equal to 50 x 10^9/L in response to therapy (supported by documentation)
- The member is currently receiving interferon-based therapy

Aplastic Anemia

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
PROMACTA (eltrombopag)	
PROMACTA (eltrombopag) POWDER PACK	

Prior Authorization Criteria

Initial Criteria - Approval Duration: 4 months

- The member must have platelet count of less than 30 x 10^9/L
- The member must have failed therapy or be receiving concurrent therapy with immunosuppressive therapy (e.g., corticosteroid, Atgam, cyclosporine, cyclosporine)

Renewal Criteria - Approval Duration: 12 months

- Platelet counts must have achieved greater than or equal to 50 x 10^9/L in response to therapy (supported by documentation)

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	posaconazole
itraconazole	SPORANOX (itraconazole)
NOXAFIL (posaconazole) – *Brand Required*	VFEND (voriconazole)
nystatin	
ORAVIG (miconazole)	
terbinafine	
voriconazole	

Non-Solid Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
fluconazole suspension	DIFLUCAN (fluconazole) SUSPENSION
itraconazole solution	SPORANOX (itraconazole) SOLUTION
NOXAFIL (posaconazole) SUSPENSION	TOLSURA (itraconazole) DISPERSE CAPSULE
VFEND (voriconazole) SUSPENSION – *Brand Required*	voriconazole suspension

Community-Acquired Pneumonia

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
amoxicillin	BAXDELA (delafloxacin)
amoxicillin-clavulanate	FACTIVE (gemifloxacin)
azithromycin	XENLETA (lefamulin)
cefpodoxime	
cefuroxime	
clarithromycin	
doxycycline	
levofloxacin	
linezolid	
moxifloxacin	

Cytomegalovirus infection

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
valganciclovir	LIVTENCITY (maribavir)

Methicillin-Resistant *Staphylococcus aureus* (MRSA):

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
clindamycin	BAXDELA (delafloxacin)
doxycycline	NUZYRA (omadacycline)
linezolid	SIVEXTRO (tedizolid)

minocycline	
trimethoprim-sulfamethoxazole	

Helicobacter pylori

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
lansoprazole/amoxicillin/clarithromycin	OMECLAMOX-PAK (omeprazole/clarithromycin/amoxicillin)
PYLERA (bismuth subcitrate potassium/metronidazole/tetracycline)	TALICIA (omeprazole/amoxicillin/rifabutin)
	VOQENZA DUAL PAK (vonoprazan/amoxicillin)
	VOQENZA TRIPLE PAK (vonoprazan/amoxicillin/clarithromycin)

Tuberculosis

PREFERRED AGENTS (NO PA REQUIRED)	PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ethambutol	isoniazid	cycloserine
PRIFTIN (rifapentine)		MYCOBUTIN (rifabutin)
pyrazinamide		RIFADIN (rifampin)
rifabutin		SIRTURO (bedaquiline)

Prior Authorization Criteria

Initial Criteria - Approval Duration: 5 days

- Diagnosis must be proven to be caused by a susceptible microorganism by culture and susceptibility testing
- The requested medication must be prescribed by, or in consult with, an infection disease specialist, an antibiotic stewardship program, or protocol.
- One of the following criteria must be met (A or B):

A. The member is continuing treatment upon discharge from an acute care facility
B. Clinical justification must be provided explaining why the preferred antibiotics are not an option due to susceptibility, previous failed trials, or other contraindications (subject to clinical review)

Aspergillus and Candidiasis Infections Only:

- The request must be for use as prophylaxis of invasive Aspergillus and Candida infections or Oropharyngeal Candidiasis

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 (cabtegravir)	TRUVADA (emtricitabine/tenofovir)

DESCOVY (emtricitabine/tenofovir)	
emtricitabine/tenofovir	

Antiretrovirals – Treatment

References:

1. 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/inline-files/AdultandAdolescentGL.pdf. Accessed (October 9, 2020)

Integrase Strand Transfer Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
BIKTARVY (bictegravir/emtricitabine/tenofovir)	
CABENUVA (cabotegravir/rilprivirine)	
DOVATO (dolutegravir/lamivudine)	
GENVOYA (elvitegravir/cobicistat/emtricitabine/tenofovir)	
ISENTRESS (raltegravir)	
JULUCA (dolutegravir/rilpivirine)	
STRIBILD (elvitegravir/cobicistat/emtricitabine/tenofovir)	
TIVICAY (dolutegravir)	
TRIUMEQ (abacavir/dolutegravir/lamivudine)	
TRIUMEQ PD (abacavir/dolutegravir/lamivudine)	

Non-Nucleoside Reverse Transcriptase Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
COMPLERA (emtricitabine/rilpivirine/tenofovir)	ATRIPLA (efavirenz/emtricitabine/tenofovir)
EDURANT (rilpivirine)	efavirenz/lamivudine/tenofovir
efavirenz	SUSTIVA (efavirenz)
efavirenz/emtricitabine/tenofovir	
JULUCA (dolutegravir/rilpivirine)	
ODEFSEY (emtricitabine/rilpivirine/tenofovir)	
PIFELTRO (doravirine)	
rilpivirine	
SYMFI (efavirenz/lamivudine/tenofovir) – *Brand Required*	
SYMFI LO (efavirenz/lamivudine/tenofovir) – *Brand Required*	
Not Recommended for First Line Use	
INTELENCE (etravirine) – *Brand Required*	etravirine
nevirapine	
nevirapine ER	

- Etravirine - Guidelines do not recommend for treatment-naïve members due to insufficient data. FDA indication is for treatment experienced members and so should be reserved for salvage therapy, pretreated members with NNRTI resistance and PI exposure or who have ongoing adverse effects with first line therapies.

- Nevirapine - Guidelines no longer recommend nevirapine for initial treatment of HIV infection in treatment-naïve members. In resource limited settings, it can be considered as a third agent. Nevirapine demonstrated inferiority relative to efavirenz and is associated with serious and fatal hepatic and rash events.

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)	EPIVIR (lamivudine)
COMPLERA (emtricitabine/rilpivirine/tenofovir)	EPZICOM (abacavir)
DELSTRIGO (doravirine/lamivudine/tenofovir)	TRIZIVIR (abacavir/lamivudine)
DESCOVY (emtricitabine/tenofovir)	TRUVADA (emtricitabine/tenofovir)
EMTRIVA (emtricitabine) CAPSULE – *Brand Required*	VIREAD (tenofovir)
efavirenz/emtricitabine/tenofovir	ZERIT (stavudine) CAPSULE
emtricitabine solution	ZIAGEN (abacavir)
emtricitabine/tenofovir	
GENVOYA (elvitegravir/cobicistat/emtricitabine/tenofovir)	
lamivudine	
ODEFSEY (emtricitabine/rilpivirine/tenofovir)	
SYMFI (efavirenz/lamivudine/tenofovir) – *Brand Required*	
SYMFI LO (efavirenz/lamivudine/tenofovir) – *Brand Required*	
STRIBILD (elvitegravir/cobicistat/emtricitabine/tenofovir)	
SYMTUZA (darumavir/cobicistat/emtricitabine/tenofovir)	
tenofovir	
TEMIXYS (lamivudine/tenofovir)	
TRIUMEQ (abacavir/dolutegravir/lamivudine)	
TRIUMEQ PD (abacavir/dolutegravir/lamivudine)	
Not Recommended for First Line Use	
abacavir/lamivudine/zidovudine	COMBIVIR (lamivudine/zidovudine)
didanosine	RETROVIR (zidovudine)
lamivudine/zidovudine	VIDEX EC (didanosine)
stavudine	ZERIT (stavudine) CAPSULE
VIDEX (didanosine)	
zidovudine	

- abacavir/lamivudine/zidovudine – Guidelines do not recommend ABC/3TC/ZDU (as either a triple-NRTI combination regimen or in combination with tenofovir (TDF) as a quadruple-NRTI combination regimen) due to inferior virologic efficacy.
- didanosine – Guidelines do not recommend ddI/3TC or ddI/FTC regimens due to inferior virologic efficacy, limited trial experience in ART-naïve members, and ddI toxicities (including pancreatitis and peripheral neuropathy). ddI/TDF regimens are not recommended due to high rate of early virologic failure, rapid selection of resistance mutations, potential for immunologic nonresponse/CD4 cell decline, and increased ddI drug exposure and toxicities.

- lamivudine/zidovudine – Guidelines do not recommend ZDV/3TC due to greater toxicities than recommended NRTIs (including bone marrow suppression, GI toxicities, skeletal muscle myopathy, cardiomyopathy, and mitochondrial toxicities such as lipoatrophy, lactic acidosis and hepatic steatosis).
- stavudine – Guidelines do not recommend d4T/3TC due to significant toxicities (including lipoatrophy, peripheral neuropathy) and hyperlactatemia (including symptomatic and life-threatening lactic acidosis, hepatic steatosis, and pancreatitis)

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) TABLET
EVOTAZ (atazanavir/cobicistat)	REYATAZ (atazanavir) CAPSULE
NORVIR (ritonavir) POWDER	
NORVIR (ritonavir) SOLUTION	
PREZCOBIX (darunavir/cobicistat)	
PREZISTA (darunavir)	
REYATAZ (atazanavir) POWDER PACK	
ritonavir	
SYMTUZA (darumavir/cobicistat/emtricitabine/tenofovir)	
Not Recommended for First Line Use	
APTIVUS (tipranavir)	KALETRA (lopinavir/ritonavir) SOLUTION
fosamprenavir	KALETRA (lopinavir/ritonavir) TABLET
INVIRASE (saquinavir)	LEXIVA (fosamprenavir)
lopinavir/ritonavir tablet	
lopinavir/ritonavir solution	
VIRACEPT (nelfinavir)	

- Fosamprenavir – Guidelines do not recommend use of unboosted FPV or FPV/r due to virologic failure with unboosted FPV-based regimens that may result in selection of mutations that confer resistance to FPV and DRV. There is also less clinical trial data for FPV/r than other RTV-boosted PIs.
- Lopinavir/ritonavir – Guidelines do not recommend LPV/r due to GI intolerance, higher pill burden and higher RTV dose than other PI-based regimens
- Nelfinavir – Guidelines do not recommend use of NFV due to inferior virologic efficacy and diarrhea.
- Saqinavir – Guidelines do not recommend use of unboosted SQV due to inadequate bioavailability and inferior virologic efficacy or SQV/r due to high bill burden and QT and PR prolongation.
- Tipranavir – Guidelines do not recommend TPV/r due to inferior virologic efficacy, higher dose of RTV and higher rate of adverse events than other RTV-boosted PIs.

Entry Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
Not Recommended for First Line Use	
FUZEON (enfuvirtide)	
SELZENTRY (maraviroc)	

- Enfuvirtide (Fusion Inhibitor)– Guidelines do not recommend T20 for initial therapy due to twice daily injections, high rate of injection site reactions, and it has only been studied in members with virologic failure

- Maraviroc (CCR5 Antagonist) – Guidelines do not recommend MVC for initial therapy due to twice daily dosing, no virologic benefit compared to recommended regimens, and required CCR5 tropism testing.

Diarrhea

Mytesi: Jump to Criteria

Loss of Appetite

Dronabinol: Jump to Criteria

Wasting Cachexia

Serostim: Jump to Criteria

Hepatitis C Antiviral Treatments

Direct Acting Antivirals

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
HARVONI (ledipasvir/sofosbuvir) 45 mg/200 mg tablet	EPCLUSA (sofosbuvir/velpatasvir)
MAVYRET (glecaprevir/pibrentasvir)***	HARVONI (ledipasvir/sofosbuvir) 90mg/400mg tablet
sofosbuvir/velpatasvir	HARVONI (ledipasvir/sofosbuvir) ORAL PALLET
SOVALDI (sofosbuvir) 200 MG TABLET	ledipasvir/sofosbuvir 90mg/400mg tablet
VOSEVI (sofosbuvir/velpatasvir/voxilaprevir)	SOVALDI (sofosbuvir) 400MG TABLET
	SOVALDI (sofosbuvir) ORAL PALLET
	VIEKIRA PAK (dasabuvir/ombitasvir/paritaprevir/ritonavir)
	ZEPATIER (elbasvir/grazoprevir)

Electronic Step Care and Concurrent Medications

- Epclusa (and its generic): A total of 28 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).

Prior Authorization Criteria

Prior Authorization Form – Hepatitis C

Initial Criteria - Approval Duration: Based on label recommendations

- The member must not be receiving a known recreationally used high risk combination of drugs (e.g., “the holy trinity”) for the past 6 months.
- The member must have established compliant behavior including attending scheduled provider visits (defined as 1 or less no-shows) and filling all maintenance medications on time for the past 90 days, as evidenced by pharmacy claims history.
- The member must not have life expectancy of less than 12 months.
- The member and prescriber attestation forms must be attached to request
- Chronic Hepatitis C must be documented by one of the following:
  - Liver fibrosis F1 and below: 2 positive HCV RNA levels at least 6 months apart
  - Liver fibrosis F2 and above: 1 positive HCV RNA test within the last 12 months
- Epclusa pellet packs: Members that weigh 30 kg or greater must meet Non-Solid Dosage Preparations criteria in addition to Hepatitis C criteria

- Mavyret pellet packs: Members that weigh 45 kg or greater must meet Non-Solid Dosage Preparations criteria in addition to Hepatitis C criteria

Non-Preferred Agents Criteria:

- Clinical justification must be provided explaining why the member is unable to use the preferred product (subject to clinical review).

Prescriber may be primary care provider or family practice with the following exceptions:	
Prescriber must be a hepatology, gastroenterology, or infectious disease specialist	• Decompensated cirrhosis (Child's Pugh B or C) • Status post solid organ transplantation • Known or suspected hepatocellular carcinoma • Evidence/suspicion of acute liver injury while on HCV treatment • HIV or HBsAg positive • Current pregnancy or breastfeeding
Prescriber must be, or in consult with, a hepatology, gastroenterology, or infectious disease specialist (including via Project ECHO)	• Compensated cirrhosis (Child's Pugh A) • For Hep C retreatment after Direct Acting Antivirals

For FIRST TIME treatments with Direct Acting Antivirals:

Must be drug (drugs of abuse by injection) and alcohol free as documented by:		
No history of alcohol use disorder or history of using drugs of abuse by injection		• 1 drug and alcohol test completed within 30 days of the request date
History of alcohol use disorder or history of drugs of abuse by injection	Currently enrolled or has completed a substance use treatment program within the past 12 months	• 1 negative IV drug and/or alcohol test within 30 days of the request date (if history of use within past 5 years) • Must be receiving treatment from an enrolled addiction medicine/chemical dependency treatment provider - provider/facility name must be provided with the request • Chart notes must be attached regarding assessment of member's readiness for treatment including readiness for abstinence from alcohol and IV drug use during and after treatment
	Has not completed a substance use treatment program within the past 12 months	• 2 negative IV drug and/or alcohol tests, dated at least 3 months apart, with the most current test completed within 30 days of the request date (if history of use within past 5 years) • Provider must submit chart notes documenting that the member has maintained sobriety for the past year or since last substance use treatment program completion

For RE-TREATMENT after Direct Acting Antivirals:

Reason for retreatment:

<table>
<tr><td rowspan="4">Due to drugs of abuse by injection</td><td colspan="2">• The member is receiving treatment or must have received from an enrolled addiction medicine/chemical dependency treatment (or buprenorphine waived) provider since initial Hepatitis C treatment with Direct Acting Antivirals, and the provider/facility name must be provided with the request.</td></tr>
<tr><td colspan="2">• The member must not be at high risk of relapse from illicit drug use by injection during and after treatment as evidenced by treatment provider notes or risk assessment</td></tr>
<tr><td>Liver fibrosis F2 and below</td><td>Liver fibrosis F3 and above</td></tr>
<tr><td>• The provider must submit chart notes documenting that the member has abstained from drugs of abuse for the past year

• Two drug tests: 1 test completed 6 months (+/- 1 months) prior to request and 1 test within 30 days of the request date</td><td>• Two drug tests: 1 test completed 3 months prior to request and 1 test within 30 days of the request date</td></tr>
<tr><td rowspan="2">Due to non-compliance (defined as a medication possession ratio (MPR) of less than 80%)</td><td>Liver fibrosis F2 and below</td><td>Liver fibrosis F3 and above</td></tr>
<tr><td>• The member must have established compliant behavior including attending scheduled provider visits (defined as 1 or less no-shows) and filling all maintenance medications on time for the past 180 days, as evidenced by pharmacy claims history.</td><td>• The member must have established compliant behavior including attending scheduled provider visits (defined as 1 or less no-shows) and filling all maintenance medications on time for the past 90 days, as evidenced by pharmacy claims history.</td></tr>
<tr><td>Resistance</td><td colspan="2">• FIRST TIME treatment with Direct Acting Antivirals criteria must be met</td></tr>
</table>

Malaria

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
hydroxychloroquine	atovaquone/proguanil
quinine	chloroquine
	COARTEM (artemether/lumefantrine)
	KRINTAFEL (tafenoquine)
	MALARONE (atovaquone/proguanil)
	mefloquine
	primaquine
	QUALAQUIN (quinine)

Prior Authorization Criteria

Initial Criteria - Approval Duration: 7 days

- The member must have had a trial of a generic quinine in the last 30 days, as evidenced by paid claims or pharmacy print outs
- The request must be for treatment of malaria (*NOT covered for prophylaxis)*

Respiratory Syncytial Virus (RSV) Prophylaxis

CLINICAL PA REQUIRED
SYNAGIS (palivizumab) – *Medical Billing Only*

Prior Authorization Criteria

Prior Authorization Form - Synagis

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

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) Midwest Region RSV Regional Trends - NREVSS | CDC

- The member must have one of the following diagnoses and the additional criteria outlined for diagnosis:
  - **Prematurity:**
    - < 29 weeks, 0 days gestational age
      - ≤ 12 months of age at start of RSV season
    - ≥ 29 weeks, 0 days gestational age to ≤ 35 weeks, 0 days gestational age
      - ≤ 6 months of age at start of RSV season
      - One of the following:
        - Neuromuscular disease or pulmonary abnormality that impairs ability to clear secretions from the upper airway because of ineffective cough
        - Profoundly immunocompromised receiving chemotherapy, solid organ transplantation, hematopoietic stem cell transplantation, or require colony stimulating factors
  - **Chronic Lung Disease of Prematurity (CLD)**
    - < 32 weeks, 0 days gestational age
      - ≤12 months of age at start of RSV season
      - Requires supplemental oxygen > 21% for at least the first 28 days after birth
    - < 32 weeks, 0 days gestational age
      - 13-24 months of age at start of RSV season
      - Requires supplemental oxygen > 21% for at least the first 28 days after birth
      - Continues to receive medical support within six months before the start of RSV season with supplemental oxygen, diuretic, or chronic corticosteroid therapy
  - **Congenital Heart Disease**
    - ≤12 months of age at start of RSV season
      - Hemodynamically significant cyanotic or acyanotic congenital heart disease with medical therapy required

References:

1. American Academy of Pediatrics. Updated Guidance: Use of Palivizumab Prophylaxis to Prevent Hospitalization From Severe Respiratory Syncytial Virus Infection During the 2022-2023 RSV Season. American Academy of Pediatrics; July 2022. Available at: https://www.aap.org/en/pages/2019-novel-coronavirus-covid-19-infections/clinical-guidance/interim-guidance-for-use-of-palivizumab-prophylaxis-to-prevent-hospitalization/
2. Midgley CM, Haynes AK, Baumgardner JL, et al. Determining the seasonality of respiratory syncytial virus in the United States: the impact of increased molecular testing. J Infect Dis 2017;216:345–55
3. Rose EB, Wheatley A, Langley G, Gerber S, Haynes A. Respiratory Syncytial Virus Seasonality — United States, 2014–2017. MMWR Morb Mortal Wkly Rep 2018;67:71–76. DOI: http://dx.doi.org/10.15585/mmwr.mm6702a4external icon

Nephrology/Urology

Complement-mediated Thrombotic Microangiopathy (TMA) / Complement-mediated Hemolytic Uremic Syndrome

CLINICAL PA REQUIRED
SOLIRIS (eculizumab) – *Medical Billing Only*
ULTOMIRIS (ravulizumab-cwvz)
ULTOMIRIS (ravulizumab-cwvz) – *Medical Billing Only*

Prior Authorization Criteria

Initial Criteria - Approval Duration: 6 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a hematologist or nephrologist
- The member has all the following (as evidenced by submitted documentation):
  - Low platelet count, as defined by laboratory reference range or member requires dialysis
  - Evidence of hemolysis such as an elevation in serum lactate dehydrogenase (LDH), elevated indirect bilirubin, reduced haptoglobin, or increased reticulocyte, as defined by laboratory reference range or member requires dialysis
  - Serum creatinine above the upper limits of normal, as defined by laboratory reference range or member requires dialysis
- The member does not have bloody diarrhea

Renewal Criteria - Approval Duration: 12 months

- The member must have experienced meaningful clinical benefit since starting treatment with the requested medication, as evidenced by medical documentation (e.g., chart notes) attached to the request (subject to clinical review) including one of the following scores and symptoms:
  - Normalization of platelet count, as defined by laboratory reference range
  - Normalization of lactate dehydrogenase (LDH), as defined by laboratory reference range
  - ≥ 25% improvement in serum creatinine from baseline or ability to discontinue dialysis

Benign Prostatic Hyperplasia

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
alfuzosin ER	AVODART (dutasteride)
CARDURA XL (doxazosin)	CARDURA (doxazosin)
doxazosin	ENTADFI (finasteride/tadalafil)
dutasteride	FLOMAX (tamsulosin)
finasteride	MINIPRESS (prazosin)
prazosin	PROSCAR (finasteride)
silodosin	RAPAFLO (silodosin)
tamsulosin	sildenafil
terazosin	tadalafil

Electronic Diagnosis Verification

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

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

- The member must have failed a 30-day trial of each preferred agent, as evidenced by paid claims or pharmacy printouts
- Sildenafil/tadalafil: Documentation (e.g., chart notes) must be provided confirming the diagnosis

Chronic Kidney Disease

Non-steroidal selective mineralocorticoid receptor antagonist (MRA)

CLINICAL PA REQUIRED
KERENDIA (finerenone)

Renin-Angiotensin-Aldosterone System (RAAS) Inhibitors

NO PA REQUIRED
ACE (angiotensin-converting enzyme) inhibitors - *all oral agents preferred*
ARBs (angiotensin receptor blockers) - *all oral agents preferred*
TEKTURNA (aliskiren)

SGLT-2 Inhibitor

NO PA REQUIRED
FARXIGA (dapagliflozin)
INVOKANA (canagliflozin)

Systemic Corticosteroids

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
methylprednisolone	TARPEYO (budesonide EC)
prednisone	

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

- If member is on renal dialysis, Medicare eligibility must be ruled out.
- 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

Kerendia Only

- The member must have history of diabetes
- One of the following criteria must be met (1 or 2):
  1. Estimated glomerular filtration rate (eGFR) 25 to 60 mL/min/1.73 m^2 AND urinary albumin-to-creatinine ratio (UACR) of 30 mg/g to under 300 mg/g
  2. Estimated glomerular filtration rate (eGFR) 25 to 75 mL/min/1.73 m^2 AND urinary albumin-to-creatinine ratio (UACR) ≥ 300 mg/g

Tarpeyo Only

- The member must have eGFR ≥ 30.
- The member must be experiencing proteinuria > 1 gram/day or UPCR ≥ 0.8 g/g (documentation must be attached) despite 6-month trials with good compliance of the following at the target or maximally tolerated dose, as evidenced by paid claims or pharmacy printouts:
  - ACE inhibitor or an ARB

- A SGLT-2 inhibitor
- Prednisone or methylprednisolone

Hematopoietic, Erythropoiesis Stimulating Agents

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ARANESP (darbepoetin alfa)	EPOGEN (epoetin alfa)
PROCRIT (epoetin alfa)	MIRCERA (methoxy polyethylene glycol-epoetin beta)
	RETACRIT (epoetin alfa - epbx)

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.

Hyperkalemia (Chronic)

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

Prior Authorization Criteria

Initial Criteria - Approval Duration: 3 months

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

Non-Preferred Agent Criteria:

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

Renewal Criteria - Approval Duration: 12 months

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

Primary Hyperoxaluria Type 1 (PH1)

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

Prior Authorization Criteria

Initial Criteria - Approval Duration: 6 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a nephrologist, urologist, geneticist or other provider experience in treating primary hyperoxaluria type 1 (PH1)
- Documentation of the member's diagnosis must be submitted, as evidenced by 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 does not have secondary causes of hyperoxaluria (e.g., diet with excessive intake of oxalate, gastric bypass surgery, IBD, other intestinal disorders, etc.)
- The member has had at least a 90-day trial of pyridoxine (vitamin B6) of maximally tolerated doses (maximum dose, 20 mg/kg per day) that failed to achieve at least a 30% reduction in urinary oxalate excretion
- The member has not received a liver transplant
- Documentation of the one of the following must be submitted:
  - Elevated urinary oxalate excretion (i.e., > 1 mmol/1.73 m^2 per day [90 mg/1.73 m^2 per day])
  - Elevated urinary oxalate: creatinine ratio as defined by age defined laboratory reference range
  - Elevated urinary excretion of glycolate (i.e., > 0.5 mmol/1.73 m^2 per day [45 mg/1.73 m^2 per day])

Initial Criteria - Approval Duration: 12 months

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

Lupus Nephritis

First Line Agents

NO PA REQUIRED
cyclophosphamide
mycophenolate
systemic oral corticosteroids

Anti-CD20 Monoclonal Antibodies

NO PA REQUIRED
RITUXAN (rituximab) – *Medical Billing Only*

B-Lymphocyte Stimulator (BLyS) – Specific Inhibitor

NO PA REQUIRED
BENLYSTA (belimumab) – *Medical Billing Only*

Calcineurin Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
cyclosporine	LUPKYNIS (voclosporin)
tacrolimus	

Prior Authorization Criteria

Initial Criteria - Approval Duration: 6 months

- The requested medication must be prescribed by, or in consult with, a nephrologist or rheumatologist
- If member is on renal dialysis, Medicare eligibility must be ruled out.
- 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.
- The member has had clinical progression (e.g., worsening of proteinuria or serum creatinine) despite a 3-month trial with Benlysta (belimumab)

Renewal Criteria - Approval Duration: 12 months

- The provider must submit documentation showing that the member has experienced clinical benefit since starting treatment, as evidenced by documentation of one of the following:
  - Improvement of proteinuria (UPCR decreased by 50% and/or below 0.5 to 0.7 g/day)
  - Improvement of serum creatinine (SCr ≤ 1.4 mg/dl)
  - Chronic steroid use to ≤ 7.5 mg/day

Overactive Bladder

Topical Formulations

PREFERRED AGENTS (NO PA REQUIRED)
GELNIQUE (oxybutynin)
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)
oxybutynin ER	MYRBETRIQ (mirabegron)	darifenacin ER
oxybutynin tablet	tolterodine	DETROL (tolterodine)
solifenacin	tolterodine ER	DETROL LA (tolterodine)
tamsulosin		DITROPAN XL (oxybutynin)
TOVIAZ (fesoterodine) – *Brand Required*		dutasteride/tamsulosin
trospium		fesoterodine
		flavoxate
		FLOMAX (tamsulosin)
		GEMTESA (vibegron)
		JALYN (dutasteride/tamsulosin)
		trospium ER
		VESICARE (solifenacin)

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

- The member must have had a 30-day trial of three preferred agents including Myrbetriq, as evidenced by paid claims or pharmacy printouts.

Step Care and Concurrent Medications

- Preferred Step 1 Agents: A total of 30 days of a preferred agent at max dose must be paid within 100 days prior to step 1 agents date of service.

Therapeutic Duplication

- One strength of one of the following medications is allowed at a time: dutasteride, Jalyn, or finasteride
- Alpha 1 blockers (alfuzosin ER, doxazosin, dutasteride-tamsulosin, prazosin, terazosin, tamsulosin) are not allowed with carvedilol or labetalol
  - Carvedilol and labetalol are nonselective beta blockers with alpha 1 blocking activity
- Anticholinergic medications (tolterodine, oxybutynin, trospium, solifenacin) are not covered with Acetylcholinesterase Inhibitors. Click here for a full listing of medications included.
  - 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

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, solifenacin) are not covered with Acetylcholinesterase Inhibitors. Click here for a full listing of medications included.
  - The effects of an anticholinergic (blocks the effect of acetylcholine) and acetylcholinesterase inhibitors (prevents breakdown of acetylcholine) oppose each other, and the therapeutic effect of both products is diminished

Phosphate Binders

Solid Dosage Form

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
calcium acetate	AURYXIA (ferric citrate) TABLET
sevelamer carbonate tablet	RENAGEL (sevelamer HCl) TABLET
	RENVELA (sevelamer carbonate) TABLET
	sevelamer HCl
	VELPHORO (sucroferric oxyhydroxide)

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

- If member is on renal dialysis, Medicare eligibility must be ruled out.
- The member must have failed a 30-day trial of sevelamer carbonate, as evidenced by paid claims or pharmacy printouts.

Non-Solid Dosage Form

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
FOSRENOL (lanthanum) CHEWABLE TABLET – *Brand Required*	FOSRENOL (lanthanum) POWDER PACK

PHOSLYRA (calcium acetate) ORAL SOLUTION	lanthanum chew tab
RENVELA (sevelamer carbonate) POWDER PACK – *Brand Required*	sevelamer carbonate powder pack

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

- If member is on renal dialysis, Medicare eligibility must be ruled out.

Neurology

Alzheimer's Disease

Cholinesterase Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
donepezil 5 mg, 10 mg tablet	ADLARITY (donepezil) PATCH
EXELON (rivastigmine) PATCH – *Brand Required*	ARICEPT (donepezil)
galantamine tablet	donepezil 23 mg tablet
galantamine ER	donepezil ODT
rivastigmine capsule	galantamine oral solution
	RAZADYNE (galantamine)
	RAZADYNE ER (galantamine)
	rivastigmine patch

NMDA Receptor Antagonists

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
memantine	memantine oral solution
	memantine ER capsule sprinkle
	NAMENDA (memantine)
	NAMENDA XR (memantine) CAPSULE SPRINKLE

Cholinesterase Inhibitors / NMDA Receptor Antagonist Combinations

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	NAMZARIC (memantine/donepezil)

Therapeutic Duplication

- One memantine medication is allowed at a time
- Anticholinergic medications are not covered with acetylcholinesterase inhibitors (donepezil, rivastigmine, galantamine, pyridostigmine). Click here for a full listing of medications included.
  - The effects of an anticholinergic (blocks the effect of acetylcholine) and acetylcholinesterase inhibitors (prevents breakdown of acetylcholine) oppose each other, and the therapeutic effect of both products is diminished

Electronic Diagnosis Verification

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

Electronic Age Verification

- Submit chart notes to verify diagnosis for members less than 30 years old

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

- The member must have failed a 30-day trial of a pharmaceutically equivalent preferred agent, as evidenced by paid claims or pharmacy printouts.
- The member must not reside in facility where medications are managed such as skilled nursing care.
- Donepezil 23 mg: Clinical justification must be provided explaining why the member is unable to use the preferred products (subject to clinical review).

Amyloid Beta-Directed Monoclonal Antibody

CLINICAL PA REQUIRED
ADUHELM (aducanumab-avwa) – *Medical Billing Only*

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a specialist in neurology or gerontology
- The member has mild cognitive impairment (MCI) or mild Alzheimer's dementia due to Alzheimer's disease (Stage 3 or 4) as evidenced by all the following with the past 6 months:
  - objective evidence of cognitive impairment at screening
  - Positron Emission Tomography (PET) scan or Cerebral Spinal Fluid (CSF) is positive for amyloid beta plaques
- Other conditions of non-Alzheimer's dementia etiology have been ruled out (e.g., vascular dementia, dementia with Lewy bodies [DLB], frontotemporal dementia [FTD], Parkinson's Disease dementia)
- The member has received a baseline brain magnetic resonance imaging (MRI) within past year prior to initiating treatment verifying the member does not have the following:
  - acute or subacute hemorrhage
  - macrohemorrhage
  - > 4 brain microhemorrhages
  - any areas of superficial siderosis
- Documentation must be submitted including baseline disease severity utilizing one of the following scores (within the past 6 months):
  - Mini-Mental Status Exam (MMSE) score ≥ 21
  - Clinical Dementia Rating - Global Score (CDR-GS) ≤ 1.0
  - Montreal Cognitive Assessment (MoCA) ≥ 17

Renewal Criteria - Approval Duration: 12 months

- The member must have experienced meaningful clinical benefit since starting treatment with the requested medication, as evidenced by medical documentation (e.g., chart notes) attached to the request (subject to clinical review) including one of the following scores and symptoms (within the past 6 months):
  - CDR-GS of ≤ 1.0
  - MMSE score ≥ 21
  - MoCA ≥ 17
- Prior to the 5th, 7th, 12th infusion, documentation of recent (within the previous month) brain MRI showing one of the following:
  - ≤ 4 new incident microhemorrhages and 1 focal area of superficial siderosis
  - radiographic stabilization since baseline (i.e., no increase in size or number of amyloid-related imaging abnormalities – hemosiderin deposition (ARIA-H))

Amyotropic Lateral Sclerosis (ALS) – Lou Gehrig's Disease

CLINICAL PA REQUIRED

RADICAVA (edaravone) – *Medical Billing Only*

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a neurologist or other healthcare provider experience in treating ALS
- The member must be able to perform activities of daily living (ADLs) such as eating and moving around independently as documented by one of the following provided from the past 6 months:
  - ALS Functional Rating Scale-Revised (ALSFRS-R) score of greater than or equal to 2 in all items of the ALSFRS-R criteria at the initiation of treatment
  - Japanese ALS Severity Scale with a grade of 1 or 2
  - Documentation of both of the following must be provided:
  - "Definite" or "probable" amyotrophic lateral sclerosis (ALS), by the revised EL Escorial and Airlie House diagnostic criteria
  - Forced Vital Capacity (FVC) via Pulmonary Function Test ≥ 80%
- The member must not have permanent invasive ventilation
- Disease duration from onset of symptoms must be less than 2 years

Renewal Criteria - Approval Duration: 12 months

- The member must have experienced stabilization, slowing of disease progression, or improvement of the condition since starting treatment with the requested medication, as evidenced by medical documentation (e.g., chart notes) attached to the request (subject to clinical review) including one of the following scores provided from the past 12 months:
  - ALS Functional Rating Scale-Revised (ALSFRS-R) score of greater than or equal to 2 in all items of the ALSFRS-R criteria at the initiation of treatment
  - Japanese ALS Severity Scale with a grade of 1 or 2

Anticonvulsants

Anticonvulsant Prevention

Narrow Spectrum:

Carbamazepine

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
carbamazepine chewable tablet	carbamazepine ER capsule
carbamazepine oral suspension	carbamazepine XR tablet
carbamazepine tablet	EPITOL (carbamazepine)
CARBATROL (carbamazepine) – *Brand Required*	TEGRETOL (carbamazepine oral suspension)
EQUETRO (carbamazepine)	TEGRETOL (carbamazepine)
TEGRETOL XR (carbamazepine) – *Brand Required*	

Ethosuximide

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ethosuximide capsule	ZARONTIN (ethosuximide)
ethosuximide oral solution	ZARONTIN (ethosuximide) ORAL SOLUTION

Gabapentin

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)

gabapentin capsule	NEURONTIN (gabapentin) CAPSULE
gabapentin oral solution	NEURONTIN (gabapentin) ORAL SOLUTION
gabapentin tablet	NEURONTIN (gabapentin) TABLET

Lacosamine

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
lacosamide oral solution	VIMPAT (lacosamide) ORAL SOLUTION
lacosamide tablet	VIMPAT (lacosamide) TABLET

Oxcarbazepine

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
oxcarbazepine tablet	oxcarbazepine oral solution
OXTELLAR XR (oxcarbazepine)	TRILEPTAL (oxcarbazepine)
TRILEPTAL (oxcarbazepine) ORAL SUSPENSION – Brand Required	

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 ER capsule	DILANTIN (phenytoin) ORAL SUSPENSION
phenytoin suspension	DILANTIN ER (phenytoin)
phenytoin sodium ER	PHENYTEK (phenytoin)

Primidone

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
primidone	MYSOLINE (primidone)

Tiagabine

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
GABITRIL (tiagabine) – *Brand Required*	tiagabine

Vigabatrin

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
SABRIL (vigabatrin) TABLET – *Brand Required*	SABRIL (vigabatrin) POWDER PACK
vigabatrin powder pack	vigabatrin tablet
	VIGADRONE (vigabatrin)

Other

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
APTIOM (eslicarbazepine)	
CELONTIN (methsuximide)	
DIACOMIT (stiripentol)	
EPIDIOLEX (cannabidiol)	

FINTEPLA (fenfluramine) ORAL SOLUTION	
phenobarbital elixir	
phenobarbital tablet	
XCOPRI (cenobamate)	
ZTALMY (ganaxolone) SUSPENSION	

Electronic Diagnosis Verification

- Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale for Diacomit, Epidiolex, and Fentepla

Electronic Step Care and Concurrent Medications

- 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.

Prior Authorization Criteria:

- Pregabalin CR: See Preferred Dosage Form Criteria

Therapeutic Duplication

- One Vimpat strength is allowed at a time
- Lyrica and gabapentin are not allowed together.
- Lyrica and gabapentin oral solutions are not allowed with benzodiazepines, muscle relaxants (except baclofen), or narcotic solid dosage forms. If a member can swallow, they should be transitioned to a solid dosage form.

  Please call for an override by calling provider relations at 1-800-755-2604 if the member's medications are dispensed in solid formulations are being crushed or opened to administer because member is unable to swallow

Broad Spectrum:

Clobazam

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
clobazam	ONFI (clobazam)
clobazam oral solution	ONFI (clobazam) ORAL SOLUTION
	SYMPAZAN (clobazam)

Divalproex/Valproic Acid

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
DEPAKOTE SPRINKLE (divalproex sodium) – *Brand Co-Preferred*	DEPAKENE (valproic acid) CAPSULE
divalproex sodium ER	DEPAKENE (valproic acid) ORAL SOLUTION
divalproex sodium sprinkle	DEPAKOTE (divalproex sodium) TABLET
divalproex sodium tablet	DEPAKOTE ER (divalproex sodium)
valproic acid capsule	
valproic acid oral solution	

Felbamate

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)

FELBATOL (felbamate) ORAL SUSPENSION - *Brand Required*	felbamate oral suspension
FELBATOL (felbamate) TABLET– *Brand Required*	felbamate tablet

Lamotrigine

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
lamotrigine chewable tablet	LAMICTAL (lamotrigine) CHEWABLE TABLET
lamotrigine ER	LAMICTAL (lamotrigine) DOSE PACK
lamotrigine ODT	LAMICTAL (lamotrigine) TABLET
lamotrigine ODT dose pack	lamotrigine dose pack
lamotrigine tablet	LAMICTAL ODT (lamotrigine)
SUBVENITE (lamotrigine)	LAMICTAL ODT (lamotrigine) DOSE PACK
	LAMICTAL XR (lamotrigine)
	LAMICTAL XR (lamotrigine) DOSE PACK
	SUBVENITE (lamotrigine) DOSE PACK

Levetiracetam

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
levetiracetam ER	ELEPSIA XR (levetiracetam)
levetiracetam oral solution	KEPPRA (levetiracetam)
levetiracetam tablet	KEPPRA (levetiracetam) ORAL SOLUTION
	KEPPRA XR (levetiracetam)
	SPRITAM (levetiracetam)

Rufinamide

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
BANZEL (rufinamide) ORAL SUSPENSION – *Brand Co-Preferred*	
BANZEL (rufinamide) TABLET – *Brand Co-Preferred*	
rufinamide suspension	
rufinamide tablet	

Topiramate

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
EPRONTIA (topiramate) SOLUTION	TOPAMAX (topiramate)
QUDEXY XR (topiramate) SPRINKLE CAPSULE – *Brand Required*	TOPAMAX (topiramate) SPRINKLE CAPSULE
topiramate sprinkle capsule	topiramate ER sprinkle cap
topiramate tablet	
TROKENDI XR (topiramate)	

Other

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
BRIVIACT (brivaracetam)	
FYCOMPA (perampanel)	
FYCOMPA (perampanel) ORAL SUSPENSION	
zonisamide	

Anticonvulsant Rescue Therapies

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
DIASTAT PEDIATRIC (diazepam) RECTAL GEL – *Brand Required*	diazepam pediatric rectal gel
DIASTAT ACUDIAL (diazepam) RECTAL GEL – *Brand Required*	diazepam rectal gel
NAYZILAM (midazolam) NASAL SPRAY	
VALTOCO (diazepam) NASAL SPRAY	

Duchenne Muscular Dystrophy

Corticosteroids

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
prednisone	EMFLAZA (deflazacort)

Prior Authorization Criteria

Prior Authorization Form - Emflaza

- In the FOR-DMD trial:
  - Slowing of growth was greater with daily deflazacort compared with daily prednisone. The difference in height at three years for daily prednisone compared with daily deflazacort was 2.3 cm (98.3% CI 0.7-3.9 cm)
  - Weight gain was greater with daily prednisone compared with daily deflazacort. The difference in weight gain for daily prednisone compared with daily deflazacort was 2.6 kg (98.3% CI 0.2-5.0 kg)

Initial Criteria - Approval Duration: 6 months

- Diagnosis must be confirmed by the documented presence of abnormal dystrophin or a confirmed mutation of the dystrophin gene
- The requested medication must be prescribed by, or in consult with, a 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 motor milestone score results from at least ONE the following assessments:
  i. 6-minute walk test (6MWT)
  ii. North Star Ambulatory Assessment (NSAA)
  iii. Motor Function Measure (MFM)
  iv. Hammersmith Functional Motor Scale (HFMS)
- The member must have ONE of the following significant intolerable adverse effects supported by documentation:

i. Cushingoid appearance
ii. Central (truncal) obesity
iii. Undesirable weight gain (>10% of body weight gain increase over 6-month period)
iv. Diabetes and/or hypertension that is difficult to manage
v. Severe behavioral adverse effect

Renewal Criteria - Approval Duration: 12 months

- The member must have improvement in motor milestone score from baseline from ONE the following assessments:

i. 6MWT – improvement of 20 meters from baseline
ii. NSAA – improvement of 2 points from baseline
iii. MFM – improvement of 2 points from baseline
iv. HFMS – improvement of 2 points from baseline

- The member must have had improvement of adverse effects experienced on prednisone supported by documentation:
  i. Cushingoid appearance
  ii. Central (truncal) obesity
  iii. Undesirable weight gain (>10% of body weight gain increase over 6-month period)
  iv. Diabetes and/or hypertension that is difficult to manage
  v. Severe behavioral adverse effect

Genetic Therapies

Exon 45 Skipping

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AMONDYS 45 (casimersen) – *Medical Billing Only*	

Exon 51 Skipping

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

Exon 53 Skipping

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

Prior Authorization Criteria

Initial Criteria - Approval Duration: 8 weeks

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

Non-Preferred Agent Criteria (Initial)

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

Renewal Criteria - Approval Duration: 12 months

- Medical records must be provided confirming the member has maintained:
  - A 6MWT ≥ 300 meters while walking independently (e.g., without side-by-side assist, cane, walker, wheelchair, etc.)
  - Stable respiratory function – FVC predicted > 50%, not requiring ventilatory assistance
  - Stable cardiac function – LVEF > 40 % by ECHO

Huntington's Disease

CLINICAL PA REQUIRED
AUSTEDO (deutetrabenazine)

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

- The requested medication must be prescribed by, or in consult with, a neurologist or psychiatrist
- The member must have failed a 3-month trial of tetrabenazine, as evidenced by paid claims or pharmacy printouts

Hypersomnolence (Narcolepsy and Idiopathic Hypersomnia)

PREFERRED AGENTS (NO PA REQUIRED)	PREFERRED STEP 1 AGENTS (ELECTRONIC STEP)	NON-PREFERRED AGENTS (PA REQUIRED)
armodafinil	SUNOSI (solriamfetol)	NUVIGIL (armodafinil)
modafinil	XYREM (sodium oxybate)	PROVIGIL (modafinil)
		WAKIX (pitolisant)
		XYWAV (sodium, calcium, magnesium, potassium oxybate)

Electronic Step Care and Concurrent Medications

- Sunosi and Xyrem requires a 30-day trial of armodafinil to be paid within 60 days of submitted claim
- Wakix requires titration to 17.8 mg dose with 4.45 mg tablets.

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

- The member must have failed 30-day trials of each preferred agent (except Sunosi for idiopathic hypersomnia) and at least 1 additional CNS stimulant indicated for treatment of narcolepsy, as evidenced by paid claims or pharmacy printouts
- Documentation of each treatment failure must be provided, as evidenced by one of the following:
  - Multiple Sleep Latency Test (MSLT) <8 minutes
  - EPWORTH sleepiness scale score ≥10
- Xywav Only:
  - The member must have failed a 30-day trial with Wakix
  - Clinical justification must be provided explaining why the member is unable to Xyrem due to sodium content (subject to clinical review).

Renewal Criteria - Approval Duration: 12 months

- Provider must submit documentation of symptom improvement, as evidenced by documentation of one of the following, while on prior treatments:
  - Multiple Sleep Latency Test (MSLT) <8 minutes
  - EPWORTH sleepiness scale score ≥10

Therapeutic Duplication

- Sunosi and Wakix are not allowed together
- Provigil and Nuvigil are not allowed together
- Xyrem, Xywav is not allowed with sleeping medication or benzodiazepines

Underutilization

- Wakix, Sunosi, and Xywav must be used adherently and will reject on point of sale for late fill

Migraine

Prophylaxis of Migraine

Calcitonin Gene-Related Peptide (CGRP) Receptor Antagonist

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

Prior Authorization Criteria

Prior Authorization Form – Migraine Prophylaxis/Treatment

Initial Criteria - Approval Duration: 6 months

- The member must experience 3 or more migraine days per month
- The member must have failed 2-month trials of at least two of the following agents from different therapeutic classes, as evidenced by paid claims or pharmacy printouts:
  - amitriptyline, atenolol, divalproex sodium, metoprolol, nadolol, propranolol, timolol, topiramate, venlafaxine
- Documentation must include clinical notes regarding failure of prior treatments to reduce migraine frequency after each 2-month trial.

Non-Preferred Agents Criteria:

- The member must have failed a 3-month trial of each preferred agent, as evidenced by paid claims or pharmacy printouts.
- Vyepti Only:
  - The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
  - The prescriber is, or is in consult with a neurologist, or specialist in migraine treatment and prevention
  - The member must have failed a 3-month trial of each self-administered CGRP (Ajovy, Emgality, and Aimovig), 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 migraines from baseline

Treatment of Migraine

Calcitonin Gene-Related Peptide (CGRP) Receptor Antagonist

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.

Therapeutic Duplication

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

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, as evidenced by paid claims or pharmacy printouts.

Therapeutic Duplication

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

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/caffeine) RECTAL SUPPOSITORY
	TRUDHESA (dihydroergotamine)

Prior Authorization Criteria

Prior Authorization Form – Migraine Prophylaxis/Treatment

Initial Criteria - Approval Duration: 3 months
- The member must have failed a 30-day trial of two triptans (5HT-1 Agonists) of unique ingredients, as evidenced by paid claims or pharmacy printouts.
- The member must have failed a 30-day trial of Nurtec 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

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) TABLET – *Brand Required*	FROVA (frovatriptan) TABLET – *Brand Required*	almotriptan tablet
rizatriptan tablet	naratriptan tablet	AMERGE (naratriptan) TABLET
sumatriptan tablet	zolmitriptan tablet	eletriptan tablet
		frovatriptan tablet
		IMITREX (sumatriptan) TABLET
		MAXALT (rizatriptan) TABLET
		sumatriptan/naproxen tablet
		TREXIMET (sumatriptan/naproxen) TABLET
		ZOMIG (zolmitriptan) TABLET

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

Non-Preferred Step 1 Agents:

- The member must have failed a 30-day trial of rizatriptan, as evidenced by paid claims or pharmacy printouts.
- Members over 18 years old: The member must also have failed a 30-day trial of Relpax (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 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 (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
IMITREX (sumatriptan) NASAL SPRAY – *Brand Required*	ONZETRA XSAIL (sumatriptan) NASAL SPRAY
ZOMIG (zolmitriptan) NASAL SPRAY – *Brand Required*	sumatriptan spray
	TOSYMRA (sumatriptan) NASAL SPRAY
	zolmitriptan spray

Injectable

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
IMITREX (sumatriptan) 0.6 MG/0.5 ML CARTRIDGE – *Brand Required*	IMITREX (sumatriptan) 0.4 MG/0.5 ML CARTRIDGE
	IMITREX (sumatriptan) 0.4 MG/0.5 ML SYRINGE
	IMITREX (sumatriptan) PEN INJECTOR
	sumatriptan cartridge
	sumatriptan pen injector
	sumatriptan vial
	ZEMBRACE SYMTOUCH (sumatriptan)

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

- The member must be unable to take oral medications (subject to clinical review).
- The member must have had a 30-day trial of a preferred injectable and preferred nasal spray, as evidenced by paid claims and pharmacy printouts.

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

Myasthenia Gravis

Acetylcholinesterase inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
neostigmine	
pyridostigmine	

Immunotherapy

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
RITUXAN (rituximab) – *Medical Billing Only*	SOLIRIS (eculizumab) – *Medical Billing Only*
ULTOMIRIS (ravulizumab) – *Medical Billing Only*	
VYVGART (ergartigimod alfa) – *Medical Billing Only*	

Prior Authorization Criteria

Initial Criteria - Approval Duration: 6 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational).
- The requested medication must be prescribed by, or in consult with, a neurologist
- The following documentation must be submitted:
  - The member has a Myasthenia Gravis Foundation of America (MGFA) clinical classification class of II, III, or IV
  - The member has a Myasthenia Gravis-specific Activities of Daily Living (MG-ADL) total score ≥ 6
  - Documented baseline Quantitative Myasthenia Gravis (QMG) score ≥ 12
  - The member has a positive serological test for anti-AChR antibodies (lab test must be submitted)
  - The member has failed a 90-day trial of an acetylcholinesterase inhibitor

Non-Preferred Agent Criteria:

- The member has failed both of the following:
  - A 12-month trial (total duration) of at least two (2) immunosuppressive therapies (e.g., azathioprine, cyclosporine, mycophenolate mofetil, tacrolimus, methotrexate, cyclophosphamide)
  - 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)

Renewal Criteria - Approval Duration: 12 months

- The member must have experienced meaningful clinical benefit since starting treatment with the requested medication, as evidenced by medical documentation (e.g., chart notes) attached to the request (subject to clinical review) including one of the following scores and symptoms:
  - Decreased rate of Myasthenia Gravis exacerbations
  - A 2-point improvement in the member's total MG-ADL score
  - A 3-point improvement in QMG total score

Multiple Sclerosis

Injectable Agents

B-cell and T-cell Therapies

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
KESIMPTA (ofatumumab)	MAVENCLAD (cladribine)
LEMTRADA (alemtuzumab) – *Medical Billing Only*	TYSABRI (natalizumab) – *Medical Billing Only*

OCREVUS (ocrelizumab) – *Medical Billing Only*	

Interferons

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AVONEX (interferon beta-1A) PEN	EXTAVIA (interferon beta-1B)
AVONEX (interferon beta-1A) SYRINGE	PLEGRIDY (peginterferon beta-1A) PEN
AVONEX (interferon beta-1A) VIAL	PLEGRIDY (peginterferon beta-1A) SYRINGE
BETASERON (interferon beta-1B)	
REBIF (interferon beta-1A)	
REBIF REBIDOSE (interferon beta-1A)	

Non-Interferons

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
COPAXONE (glatiramer) 20 MG/ML – *Brand Required*	COPAXONE (glatiramer) 40 MG/ML
	glatiramer 20mg/ml
	glatiramer 40mg/ml
	GLATOPA (glatiramer)

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

- The member must have failed a 3-month trial of an agent from each available preferred multiple sclerosis class, as evidenced by paid claims
- Copaxone: See Preferred Dosage Form Criteria

Oral Agents

Fumerates

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
dimethyl fumarate	BAFIERTAM (monomethyl fumarate)
	TECFIDERA (dimethyl fumarate)
	VUMERITY (diroximel fumarate)

Pyrimidine Synthesis Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AUBAGIO (teriflunomide)	

Sphingosine 1-Phosphate (S1P) Receptor Modulators

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
GILENYA (fingolimod) – *Brand Required*	fingolimod
	MAYZENT (siponimod)
	PONVORY (ponesimod)
	ZEPOSIA (ozanimod)

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

- The member must have failed a 3-month trial of an agent from each available preferred multiple sclerosis class, as evidenced by paid claims

Neuromyelitis Optica Spectrum Disorder

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
UPLIZNA (inebilizumab) – *Medical Billing Only*	SOLIRIS (eculizumab) – *Medical Billing Only*

Prior Authorization Criteria

Initial Criteria - Approval Duration: 6 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational).
- The requested medication must be prescribed by, or in consult with, a neurologist
- The member has positive serologic test for anti-AQP4 antibodies.
  - The member has a history of ≥ 1 relapses that required rescue therapy within the past 12 months
  - The member has an Expanded Disability Status Score (EDSS) of ≤ 6.5
  - The member must have one of the core clinical characteristics from the following:
    - Optic neuritis
    - Acute myelitis
    - Area postrema syndrome: episode of otherwise unexplained hiccups or nausea and vomiting
    - Acute brainstem syndrome
    - Symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions
    - Symptomatic cerebral syndrome with NMOSD-typical brain lesions

Non-Preferred Agents Criteria

- The member must have had a 3-month trial with Enspryng and/or Uplizna

Renewal Criteria - Approval Duration: 12 months

- The member must have experienced stabilization, slowing of disease progression, or improvement of the condition since starting treatment with the requested medication, as evidenced by medical documentation (e.g., chart notes) attached to the request (subject to clinical review) including:
  - Reduction in relapse rate
  - Reduction in symptoms (such as pain, fatigue, motor function)

Pseudobulbar Affect (PBA)

CLINICAL PA REQUIRED
NUEDEXTA (dextromethorphan/quinidine)

Prior Authorization Criteria

Prior Authorization Form - Nuedexta

Initial Criteria - Approval Duration: 3 months

- The member must not have a diagnosis of any of the following: prolonged QT interval, heart failure, or complete atrioventricular (AV) block
- Documentation of the following must be provided:
  - Baseline Center for Neurological Studies lability (CNS-LS) score
  - Baseline weekly PBA episode count
- The member must have diagnosis of pseudobulbar affect (PBA) due to one of the following neurologic conditions and meet additional criteria for diagnosis:
  - Amytrophic Lateral Sclerosis (ALS)
  - Multiple Sclerosis (MS)
  - Alzheimer's Disease
  - Stroke
  - For diagnosis of PBA due to Alzheimer's disease or stroke only:
    - Neurologic condition must have been stable for at least 3 months

- Member must have failed a 3-month trial of at least one medication from each of the following classes, as evidenced by paid claims or pharmacy print outs:
  - **SSRIs**: sertraline, fluoxetine, citalopram and paroxetine
  - **Tricyclic Antidepressants**: nortriptyline and amitriptyline
- Documentation of each treatment failure of SSRI and tricyclic antidepressant must be provided, as evidenced by a PBA episode count and CNS-LS score before and after each trial showing one of the following:
  - PBA count has not decreased by more than 75 percent from baseline
  - CHS-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.
- Baseline and current PBA episode count must be included with request
  - Current PBA episode must be reduced by at least 75% from baseline
- For diagnosis of PBA due to Alzheimer's disease or stroke only:
  - Baseline and current Center for Neurological Studies lability (CNS-LS) must be included with request
  - Current CNS-LS score must be reduced by at least 30% from baseline

Parkinson's disease

Parkinson's Agents - Adenosine Receptor Agonist

CLINICAL PA REQUIRED
NOURIANZ (Istradefylline)

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

- The requested medication must be prescribed by, or in consult with, a neurologist
- Documentation must be provided describing deterioration in quality of response to levodopa/carbidopa therapy, including currently experiencing intermittent hypomobility, or "off" episodes (number and frequency)
- The member must have had inadequate response to rasagiline and selegiline, as evidenced by paid claims or pharmacy printouts

Parkinson's Agents – Anticholinergics

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
benztropine	COGENTIN (benztropine)
trihexyphenidyl	

Parkinson's Agents – COMT inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
entacapone	COMTAN (entacapone)
TASMAR (tolcapone) – *Brand Required*	ONGENTYS (opicapone)
	tolcapone

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

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

Parkinson's Agents - Dopamine Precursor

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	SINEMET (carbidopa-levodopa) TABLET
carbidopa-levodopa ER	STALEVO (carbidopa-levodopa-entacapone)
carbidopa-levodopa ODT	
RYTARY (carbidopa-levodopa) ER CAPSULE	

Prior Authorization Criteria

- See Preferred Dosage Form Criteria

Parkinson's Agents - Dopaminergic Agents for Intermittent Treatment of Off Episode

Subcutaneous

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
APOKYN (apomorphine) – *Brand Required*	apomorphine

Enteral Suspension

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
DUOPA (levodopa/carbidopa)	

Inhalation

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

Sublingual

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

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

- The requested medication must be prescribed by, or in consult with, a neurologist
- The member must be currently taking carbidopa – levodopa, as evidenced by paid claims or pharmacy printouts, and will continue taking carbidopa – levodopa concurrently with requested agent
- Documentation must be provided of intermittent hypomobility or off episodes (number and frequency)
- At least one of the following criteria must be met:
  - The member is experiencing unpredictable off periods, morning off, delayed on, no on or failure of on response
  - The member is experiencing wearing off episodes or other levodopa dose cycle related dystonias or akathisias, and a treatment adjustment plan is attached (e.g., levodopa dose and interval adjustments, bedtime dose of CR or ER levodopa/ carbidopa, addition of adjunctive therapy)

Parkinson's Agents – Ergot Dopamine Receptor Agonists

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
bromocriptine	PARLODEL (bromocriptine)
cabergoline	

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

Initial Criteria - Approval Duration: 12 months

- The member must have failed a 30-day trial of selegiline, as evidenced by paid claims or pharmacy printouts
- Xadago Only:
  - The requested medication must be prescribed by, or in consult with, a psychiatrist or neurologist
  - The member must be currently experiencing intermittent hypomobility or "off" episodes
  - The member must be currently taking an extended-release formulation of carbidopa – levodopa, as evidenced by paid claims or pharmacy printouts, and will continue taking carbidopa – levodopa concurrently with requested agent
  - The member must be exhibiting deterioration in quality of response to during levodopa/carbidopa therapy for intermittent hypomobility, or "off" episodes
  - The member must have failed a 30-day trial of rasagiline and selegiline, as evidenced by paid claims or pharmacy printouts

Parkinson's Agents - Non-ergot Dopamine Receptor Agonists Maintenance

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 – Other

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

Spinal Muscular Atrophy (SMA)

SMN2 Gene Splicing Modifiers

CLINICAL PA REQUIRED
EVRYSDI (risdiplam)
SPINRAZA (nusinersen) – *Medical Billing Only*

Prior Authorization Criteria

Prior Authorization Form - Evrysdi

Initial Criteria - Approval Duration: 12 months
- The member must have a diagnosis of spinal muscular atrophy (SMA) with each of the following (as evidenced with submitted documentation):
  - 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
- The member must visit with a neuromuscular clinic once per year and clinic name, contact information, and date of last visit must be 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
- Documentation must be provided of the member's current motor function, 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)
  - 6-minute walk test (6MWT)
  - Forced Vital Capacity (FVC) via Pulmonary Function Test
- Spinraza Only: The member must not have severe contractures or severe scoliosis

Renewal Criteria - Approval Duration: 12 months
- The member's weight and prescribed dose must be provided and within dosing recommendations per the manufacturer label

- The member must visit with a neuromuscular clinic once per year and clinic name, contact information, and date of last visit must be provided
- The provider must submit documentation showing that the member has experienced clinical benefit (defined as maintenance of baseline motor function or significant slowed rate of decline vs expected natural course of the disease) since starting treatment, as evidenced by documentation of one of the following:
  - Current Forced Vital capacity (FVC and FEV1) via Pulmonary Function Test
  - CHOP-INTEND, HINE, HFMSE, MFM-32, 6MWT, or RULM scores

Gene Therapy

CLINICAL PA REQUIRED
ZOLGENSMA (onasemnogene abeparvovec) – *Medical Billing Only*

Prior Authorization Criteria

Initial Criteria - Approval Duration: 1 month (Approval is limited to a single intravenous infusion per lifetime)

- The member is less than 2 years of age
- The diagnosis is spinal muscular atrophy (SMA) with genetic testing confirming bi-allelic deletions or mutations in the *SMN1 gene*
- The medication is prescribed per the dosing guidelines in the package insert (recommended dose is 1.1 x 10^{14} vector genomes per kilogram)
- Baseline Documentation has been provided confirming anti-adeno-associated virus serotype 9 (anti-AAV9) antibody titer is ≤ 1:50 measured by Enzyme-linked Immunosorbent Assay (ELISA) binding immunoassay
- Member must not have advanced SMA evidenced by one of the following
  - Complete paralysis of limbs
  - Permanent ventilator dependence (defined as requiring invasive ventilation (tracheostomy) or respiratory assistance for 16 of more hours per day (including noninvasive ventilatory support) continuously for 14 or more days in the absence of an acute reversible illness, excluding perioperative ventilation.

Tardive Dyskinesia

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AUSTEDO (deutetrabenazine)	
INGREZZA (valbenazine)	
tetrabenazine	

Electronic Step Care and Concurrent Medications

- If titrating Ingrezza, please use Initiation Pack before continuing therapy with 80 mg capsules
  - The 30-count 40 mg bottle is not packaged for titration to 80 mg. If therapy is expected to be continued at 40 mg at time of drug initiation, please call for override.

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 neurologist or psychiatrist
- The member must have a diagnosis of tardive dyskinesia, including the following:
  - Involuntary athetoid or choreiform movements
  - History of treatment with dopamine receptor blocking agent (DRBA)
  - Symptom duration lasting longer than 4-8 weeks

Ophthalmology

Antihistamines

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
azelastine	ALOCRIL (nedocromil)
BEPREVE (bepotastine) – *Brand Required*	ALOMIDE (lodoxamide)
cromolyn	bepotastine
olopatadine 0.1%	epinastine
PAZEO (olopatadine)	olopatadine 0.2%
	ZERVIATE (cetirizine)

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

- The member must have failed 30-day trials of at least 3 preferred agents, as evidenced by paid claims or pharmacy printouts.

Anti-infectives

Drops

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
BESIVANCE (besifloxacin) DROPS	AZASITE (azithromycin) DROPS
ciprofloxacin drops	CILOXAN (ciprofloxacin) DROPS
gentamicin sulfate drops	gatifloxacin drops
moxifloxacin drops	levofloxacin drops
neomycin SU/polymyxin B/gramicidin drops	NATACYN (natamycin) DROPS
ofloxacin drops	OCUFLOX (ofloxacin) DROPS
polymyxin B/trimethoprim drops	POLYTRIM (polymyxin B/trimethoprim) DROPS
sulfacetamide drops	VIGAMOX (moxifloxacin) DROPS
tobramycin drops	ZYMAXID (gatifloxacin) DROPS

Ointment

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
bacitracin/polymyxin B ointment	bacitracin ointment
CILOXAN (ciprofloxacin) OINTMENT	NEO-POLYCIN (neomycin SU/bacitracin/polymyxin B) OINTMENT
erythromycin ointment	POLYCIN (bacitracin/polymyxin B) OINTMENT
GENTAK (gentamicin sulfate) OINTMENT	sulfacetamide ointment
neomycin SU/bacitracin/polymyxin B ointment	
TOBREX (tobramycin) OINTMENT	

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

- The member must have failed a 5-day trial of a preferred agent in each unique therapeutic class, as evidenced by paid claims or pharmacy printouts.

Anti-infectives/Anti-inflammatories

Drops

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
neomycin/polymyxin b/dexamethasone drops	MAXITROL (neomycin/polymyxin b/dexamethasone) DROPS
PRED-G (gentamicin/prednisol ac) DROPS	neomycin/polymyxin b/hydrocortisone drops
sulfacetamide/prednisolone drops	tobramycin/dexamethasone drops
TOBRADEX (tobramycin/dexamethasone) DROPS *– Brand Required*	
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 S.O.P. (sulfacetamide/prednisolone) ointment
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 (gentamicin/prednisol ac) 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	dexamethasone sodium phosphate drops
FLAREX (fluorometholone) DROPS	difluprednate drops
fluorometholone drops	DUREZOL (difluprednate) DROPS
FML FORTE (fluorometholone) DROPS	EYSUVIS (loteprednol) DROPS
LOTEMAX (loteprednol) DROPS – *Brand Required*	INVELTYS (loteprednol) DROPS
LOTEMAX (loteprednol) GEL DROPS *– Brand Required*	FML (fluorometholone) DROPS
MAXIDEX (dexamethasone) DROPS	LOTEMAX SM (loteprednol) DROPS
PRED MILD 0.12% (prednisolone acetate) DROPS	loteprednol eye drops
prednisolone acetate 1% drops	loteprednol gel eye drops
prednisolone sodium phosphate 1% drops	PRED FORTE 1% (prednisolone acetate) DROPS

Ointment

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
FML S.O.P. (fluorometholone) OINTMENT	
LOTEMAX (loteprednol) OINTMENT	

Non-Steroidal Anti-inflammatory Drugs (NSAIDS)

Drops

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ACUVAIL (ketorolac) DROPS	ACULAR (ketorolac) DROPS
BROMSITE (bromfenac sodium) DROPS	ACULAR LS (ketorolac) DROPS
diclofenac sodium drops	bromfenac sodium drops
ILEVRO (nepafenac) DROPS	
ketorolac tromethamine 0.4% drops	
ketorolac tromethamine 0.5% drops	
NEVANAC (nepafenac) DROPS	
PROLENSA (bromfenac) 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

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED STEP 1 AGENTS (PA REQUIRED)	NON-PREFERRED STEP 2 AGENTS (PA REQUIRED)
RESTASIS (cyclosporine) DROPPERETTE	XIIDRA (lifitegrast)	CEQUA (cyclosporine)
		cyclosporine dropperette
		RESTASIS MULTIDOSE (cyclosporine)
		TYRVAYA (varenicline) NASAL SPRAY

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

Non-Preferred Step 1 Agents:

- The member must have failed a 14-day trial of the preferred agent, as evidenced by paid claims or pharmacy printouts.

Non-Preferred Step 2 Agents:

- The member must have failed a 14-day trial of the preferred agent, as evidenced by paid claims or pharmacy printouts.
- The member must have failed a 30-day trial of Xiidra, as evidenced by paid claims or pharmacy printouts.
- Clinical justification must be provided explaining why the member is unable to use all other products (subject to clinical review).

Glaucoma

Alpha Adrenergic

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ALPHAGAN P 0.1% (brimonidine) DROPS	brimonidine 0.15% drops
ALPHAGAN P 0.15% (brimonidine) DROPS – *Brand Required*	brimonidine-timolol 0.2%-0.5% drops
apraclonidine 0.5% drops	
brimonidine 0.2% drops	
COMBIGAN (brimonidine-timolol) DROPS – *Brand Required*	
IOPIDINE (apraclonidine) 1% DROPS	
LUMIFY (brimonidine) 0.03% DROPS	
SIMBRINZA (brinzolamide/brimonidine) DROPS	

Beta Blockers

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
BETOPTIC S (betaxolol) 0.25% DROPS	betaxolol 0.5% drops
carteolol drops	BETIMOL (timolol) DROPS
COMBIGAN (brimonidine/timolol) DROPS – *Brand Name Required*	brimonidine/timolol drops
dorzolamide/timolol drops	COSOPT (dorzolamide/timolol) PF DROPS
ISTALOL (timolol maleate) DROPS ONCE DAILY – *Brand Required*	timolol drops once daily
levobunolol drops	timolol gel forming solution
timolol maleate drops	TIMOPTIC (timolol maleate) DROPS
timolol maleate/PF drops 0.5%	TIMOPTIC OCUDOSE 0.5% (timolol) PF DROPS
TIMOPTIC OCUDOSE 0.25% (timolol) PF DROPS	TIMOPTIC-XE (timolol gel forming solution)

Prior Authorization Criteria

- See Preferred Dosage Form Criteria

Carbonic Anhydrase Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AZOPT (brinzolamide) – *Brand Required*	brinzolamide
dorzolamide	COSOPT (dorzolamide/timolol)
dorzolamide/timolol	TRUSOPT (dorzolamide)
SIMBRINZA (brinzolamide/brimonidine)	

Prostaglandins

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
latanoprost	bimatoprost 0.03%
LUMIGAN (bimatoprost) 0.01%	travoprost
ROCKLATAN (netarsudil/latanoprost)	VYZULTA (latanoprostene)
TRAVATAN Z (travoprost) - *Brand Required*	XALATAN (latanoprost)
	XELPROS (latanoprost)

Prior Authorization Criteria

- See Preferred Dosage Form Criteria

Rho Kinase Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
RHOPRESSA (netarsudil)	
ROCKLATAN (netarsudil/latanoprost)	

Presbyopia

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
pilocarpine	ISOPTO CARPINE (pilocarpine)
	VUITY (pilocarpine hydrochloride)

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

- See Preferred Dosage Form Criteria
- The requested medication must be prescribed by, or in consult with, an optometrist or ophthalmologist.
- Documentation of medical necessity must be provided, including contraindication to the use of corrective lenses and how activities of daily living are adversely impacted due to inability to correct vision with corrective lenses.

Renewal Criteria - Approval Duration: 12 months

- Documentation must be provided including activities of daily living are positively impacted by drug therapy.

Inherited Retinal Dystrophy

CLINICAL PA REQUIRED
LUXTURNA (alglucosidase alfa) – *Medical Billing Only*

Prior Authorization Criteria

Initial Criteria - Approval Duration: Approval Duration: 1 month (once per lifetime per eye)

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational).
- The requested medication must be prescribed by, or in consult with, an ophthalmologist or retinal surgeon with experience providing subretinal injections
- The member must have a diagnosis of inherited retinal dystrophy (i.e., Leber's congenital amaurosis [LCA], retinitis pigmentosa [RP]); confirmed by biallelic pathogenic variants in the RPE65 gene by molecular genetic testing (as evidenced with submitted documentation)
- The member has sufficient viable retinal cells as measured by OCT (optical coherence tomography) defined as one of the following:
  - retinal thickness greater than 100 microns within the posterior pole
  - ≥ 3-disc areas of the retina without atrophy or pigmentary degeneration within the posterior pole
  - remaining visual field within 30 degrees of fixation as measured by a III4e isopter or equivalent
- The member has remaining light perception in the eye(s) that will receive treatment.
- The member has not previously received RPE65 gene therapy in intended eye.

Uveitis

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)

HUMIRA (adalimumab)	

Vernal Keratoconjunctivitis

CLINICAL PA REQUIRED
VERKAZIA (cyclosporine)

Prior Authorization Criteria

Initial Criteria - Approval Duration: 6 months

- The requested medication must be prescribed by, or in consult with, an allergist or ophthalmologist.
- The member has failed* a 3-month trial of combination of each of the following:
  - Topical dual-acting mast cell stabilizers/antihistamines (e.g., olopatadine, azelastine hydrochloride, epinastine, pemirolast potassium, or ketotifen fumarate)
  - Second- and third-generation oral antihistamines (e.g., fexofenadine, loratadine, desloratadine, cetirizine, or levocetirizine)
  - Cyclosporine ophthalmic emulsion 0.05%

*Failure is defined as requiring frequent or prolonged courses of topical ophthalmic corticosteroids include prednisone acetate 1% and dexamethasone 0.1% for severe cases and prednisolone acetate 0.12%, fluorometholone, medrysone, loteprednol, etabonate 0.2 or 0.5%, and rimexolone 1% or compromised corneal epithelium

VEGF Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ALYMSYS (bevacizumab-maly) – *Medical Billing Only*	BEOVU (brolucizumab-dbll) – *Medical Billing Only*
AVASTIN (bevacizumab) – *Medical Billing Only*	EYLEA (aflibercept) – *Medical Billing Only*
MVASI (bevacizumab-awwb) – *Medical Billing Only*	LUCENTIS (ranibizumab) – *Medical Billing Only*
ZIRABEV (bevacizumab-bvzr) – *Medical Billing Only*	SUSVIMO (ranibizumab) – *Medical Billing Only*
	VABYSMO (faricimab-svoa) – *Medical Billing Only*

Prior Authorization Criteria

Initial Criteria - Approval Duration: 6 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational).
- The requested medication must be prescribed by, or in consult with, an 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 Avastin (bevacizumab)

Renewal Criteria - Approval Duration: 12 months

- The member must have experienced meaningful clinical benefit since starting treatment with the requested medication, as evidenced by medical documentation (e.g., chart notes) attached to the request (subject to clinical review) including improvement or stabilization in VALS, defined as a loss of not more than 5 letters compared to baseline.
- The member must have at least a mean VALS of 20 or BCVA of 20/400

Otic

Anti-infectives/Anti-inflammatories – Fluoroquinolones

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
CIPRO HC (ciprofloxacin/hydrocortisone)	ciprofloxacin/dexamethasone otic drops
CIPRODEX (ciprofloxacin/dexamethasone) *– Brand Required*	ciprofloxacin/fluocinolone
	OTOVEL (ciprofloxacin/fluocinolone)

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

- The member must have failed a 7-day trial of each of the preferred agent, as evidenced by paid claims or pharmacy printouts.

Pain

Lidocaine Patch

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
lidocaine 5% patch	LIDODERM (lidocaine) 5% PATCH
ZTLIDO (lidocaine) 1.8% PATCH	

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 50 mg, 100 mg, 200 mg	ARTHROTEC (diclofenac/misoprostol)
diclofenac potassium 50 mg tablet	celecoxib 400 mg
diclofenac sodium DR 50 mg, 75 mg	CELEBREX (celecoxib)
etodolac tablet	DAYPRO (oxaprozin)
flurbiprofen	diclofenac potassium 25 mg capsule
ibuprofen	diclofenac sodium 25 mg DR
indomethacin	diclofenac sodium 100 mg ER tablet
indomethacin ER	diclofenac/misoprostol
ketoprofen	DUEXIS (famotidine/ibuprofen)
ketorolac	etodolac capsule
meclofenamate	etodolac ER
mefenamic acid	famotidine/ibuprofen
meloxicam	FELDENE (piroxicam)
nabumetone	fenoprofen
naproxen	INDOCIN (indomethacin)

piroxicam	ketoprofen ER 200 mg
sulindac	meloxicam, submicronized
tolmetin	MOBIC (meloxicam)
VIMOVO (naproxen/esomeprazole) – *Brand Required*	NALFON (fenoprofen)
ZIPSOR (diclofenac) – *Brand Required*	NAPRELAN (naproxen)
	naproxen ER 375 mg, 500 mg
	naproxen/esomeprazole
	oxaprozin
	RELAFEN DS (nabumetone)
	SEGLENTIS (celecoxib/tramadol)
	VIVLODEX (meloxicam, submicronized)
	ZORVOLEX (diclofenac, submicronized)

Electronic Diagnosis Verification

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

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

- *Non-preferred agents with no same active ingredient preferred:*
  - The member must have failed a 30-day trial of 3 different oral generic NSAIDs including a COX-2 inhibitor with 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	INDOCIN (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
SPRIX (ketorolac) NASAL SPRAY

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

- The member must have failed 30-day trials of 2 oral and 1 topical preferred agent, as evidenced by paid claims or pharmacy printouts.
- 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)
FLECTOR (diclofenac) PATCH - *Brand Required*	diclofenac patch
PENNSAID (diclofenac) 2% PUMP – *Brand Required*	diclofenac 2% pump
	LICART (diclofenac) PATCH 1.3%

Prior Authorization Criteria

- See Preferred Dosage Form Criteria

Opioid Analgesics

Therapeutic Duplication

- One extended-release product/strength is allowed at a time
- One immediate release product is allowed (single ingredient or combination)
- 3A4 substrates (fentanyl, methadone, and oxycodone) are not allowed with strong 3A4 inhibitors.
- 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).
- Nucynta and Nucynta ER are not allowed with other narcotic medications
- 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 Narcan and has been counseled on overdose risk
  - The member undergoes routine drug screens (blood and/or urine).
  - 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 an oncologist or pain management specialist with a pain management contract (with 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 prescriber(s) of both agents routinely check the PDMP.
- The prescriber(s) of both agents routinely evaluated for medical necessity

Greater than 90 Morphine Milligram Equivalents (MME) per Day

Prior Authorization Form – Opioid Analgesics

Initial Criteria - Approval Duration: 12 months

- See Opioid Analgesics – Long-Acting Prior Authorization Criteria
- A cumulative maximum of 90 MME will be allowed without authorization.
  - An MME calculator may be found at Opioid Dose Calculator

Opioid Analgesics – Long Acting

Partial Agonist/Antagonist Opioids

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
BELBUCA (buprenorphine)	buprenorphine patches
Butorphanol	
BUTRANS (buprenorphine) PATCHES - *Brand Required*	

Abuse Deterrent Formulations/Unique Mechanisms from Full Agonists Opioids

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
NUCYNTA ER (tapentadol)	CONZIP (tramadol ER) CAPSULES
OXYCONTIN (oxycodone) – *Brand Required*	hydrocodone ER tablets
tramadol ER Tablets	HYSINGLA ER (hydrocodone)
	levorphanol
	methadone
	MORPHABOND ER (morphine)
	tramadol ER Capsules
	XTAMPZA ER (oxycodone)

Full Agonist Opioids Without Abuse Deterrent Formulations

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
fentanyl 12 mcg/hr	fentanyl patch 37.5 mcg/hr, 62.5 mcg/hr, 87.5 mcg/hr
fentanyl 25 mcg/hr, 50 mcg/hr, 75 mcg/hr, 100 mcg/hr	hydrocodone ER capsules
morphine ER tablets	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 Narcan 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 exceeded 90 MME during hospitalization requiring post discharge maintenance or tapering
  - Both of the following are met:
    - The member has established opioid tolerability by using short acting opioids daily for at least 90 days prior to request for long-acting opioid 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 of one or both agents
  - The opioid medication must be prescribed by, or in consult with, with an oncologist or pain management specialist with a pain management contract (with 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

Fentanyl Patch:

- The member must have a BMI ≥17
- The member must meet one of the following criteria:
  - The member has an indication of cancer pain or palliative care pain
  - The member requires a long-acting narcotic and cannot tolerate an oral dosage form
- Fentanyl Patch 12 mcg/hr Only:
  - Member must meet one of the following:
    - The member must be receiving a total daily opioid dose less than or equal to 60 Morphine Milligram equivalents (MME), as evidenced by paid claims or pharmacy printouts
    - The member must be continuously tapering off opioids from a higher strength fentanyl patch

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:
  - Documentation noting 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 (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	ACTIQ (fentanyl) LOZENGE
	FENTORA (fentanyl) EFFERVESCENT TABLET
	fentanyl citrate effervescent tablet
	fentanyl lozenge

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 MG-300 MG
hydrocodone-acetaminophen 7.5-325 MG	hydrocodone-acetaminophen 5 MG-300 MG
hydrocodone-acetaminophen 10-325 MG	hydrocodone-acetaminophen 7.5-300 MG
oxycodone-acetaminophen 5-325 MG	hydrocodone-ibuprofen 5 mg-200 mg and 10 mg-200 mg
oxycodone-acetaminophen 10 -325 MG	LORCET (hydrocodone-acetaminophen)
tramadol-acetaminophen tablets	NALOCET (oxycodone-acetaminophen)
hydrocodone-ibuprofen 7.5 mg-200 mg	NORCO (hydrocodone-acetaminophen)
	oxycodone-acetaminophen 2.5-325 MG
	oxycodone-acetaminophen 7.5-325 MG
	PERCOCET (oxycodone/acetaminophen)
	PRIMLEV (oxycodone/acetaminophen)
	PROLATE (oxycodone/acetaminophen)
	SEGLENTIS (celecoxib/tramadol)
	ULTRACET (tramadol/acetaminophen)
	VICODIN (hydrocodone/acetaminophen)

Opioid - Acetaminophen Combination 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	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
NUCYNTA (tapentadol) TABLET	oxycodone 15 mg, 20 mg, 30 mg tablet
oxycodone 5 mg, 10 mg tablet	ROXICODONE (oxycodone) TABLET
oxymorphone tablet	ROXYBOND (oxycodone) TABLET
tramadol 50 mg tablet	tramadol 100 mg tablet
	ULTRAM (tramadol) TABLET

Opioid Single Agent Non-Solid Oral Products

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
hydromorphone liquid	

morphine solution	
oxycodone solution	

First Fill

- Short acting opioid analgesics must be filled with a 7-day supply if no previous fill within past 34 days
  - If member is filling prescription less than every 34 days due to decreased utilization, please get a new prescription for a lower quantity that reflects actual utilization within a 34-day window.

Prior Authorization Criteria

Prior Authorization Form – Opioid Analgesics

Initial Criteria - Approval Duration: 12 months

- 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.).
- The past 3 months of the member's North Dakota PDMP reports must have been reviewed.
- The opioid medication must be prescribed by, or in consult with, with an oncologist or pain management specialist with a pain management contract (with 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

Fentanyl Only:

- The member's age must be within label recommendations
- The member must have a diagnosis of cancer pain
- The member must currently be on around-the-clock opioid therapy for at least a week, as evidenced by paid claims or pharmacy printouts
  - The around the clock opioid therapy must be equivalent to 60 mg oral morphine daily, 25 mcg transdermal fentanyl/hour, 30 mg oxycodone daily, 8 mg of oral hydromorphone daily, or equianalgesic dose of another opioid daily

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 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

Member with a History of Opioid Use Disorder

- If all of the following conditions apply, please call for an override by calling provider relations at 1-800-755-2604:
  - The member has an acute condition that cannot be reasonably treated with non-opioid therapy (e.g., surgery)
  - Prescribers of both opioid and opioid use disorder are aware of each other and agree to opioid therapy
  - Opioid duration is of a one-time occurrence or taper plan is provided

Renewal Criteria - Approval Duration: 12 months

- Documentation noting progress toward therapeutic goal must be provided including pain level and function

Qutenza (capsaicin patch)

CLINICAL PA REQUIRED

QUTENZA (capsaicin patch) – *Medical Billing Only*

Prior Authorization Criteria

Initial Criteria - Approval Duration: 6 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a pain specialist
- The member must have failed a 3-month treatment of topical lidocaine patch

Skeletal Muscle Relaxants

Solid Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
baclofen	AMRIX (cyclobenzaprine) TAB 24 HR
chlorzoxazone 500 mg	chlorzoxazone 375 mg and 750 mg
cyclobenzaprine 5 mg and 10 mg	cyclobenzaprine 7.5 mg
dantrolene	cyclobenzaprine ER
methocarbamol	carisoprodol
orphenadrine ER	carisoprodol-aspirin
tizanidine tablets	carisoprodol-aspirin-codeine
	DANTRIUM (dantrolene)
	LORZONE (chlorzoxazone)
	METAXALL (metaxalone)
	metaxalone
	NORGESIC FORTE (orphenadrine/aspirin/caffeine)
	ROBAXIN (methocarbamol)
	SKELAXIN (metaxalone)
	SOMA (carisoprodol)
	tizanidine capsules
	ZANAFLEX (tizanidine)

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months (carisoprodol = 1 week)

- Carisoprodol products only:
  - The member must be undergoing dose tapering
- Metaxalone
  - The member must have failed two 30-day trials of other skeletal muscle relaxants, including methocarbamol, as evidenced by paid claims or pharmacy printouts.
- All other products:
  - See Preferred Dosage Form Criteria

Therapeutic Duplication

- One strength of one medication is allowed at a time
  - If the following conditions apply, please call for an override by calling provider relations at 1-800-755-2604:
    - The member has cerebral palsy or another chronic spastic disorder
    - The prescriber is a physiatrist
    - The requested combination is baclofen and tizanidine
- Carisoprodol is not allowed with opioids, benzodiazepines, or opioid use disorder medications

- The “Holy Trinity” consists of an opioid, a benzodiazepine, and carisoprodol and is a highly abused dangerous combination that can lead to additive CNS depression, overdose, and death. It is not covered.

- Tizanidine is not allowed with other alpha 2 agonists (clonidine, clonidine/chlorthalidone, guanfacine, methyldopa)
  - tizanidine is also an alpha 2 agonist

Non-Solid Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
baclofen solution 5 mg/5 mL	FLEQSUVY (baclofen) SUSPENSION
	LYVISPAH (baclofen) GRANULE PACKET

Prior Authorization Criteria

- See Preferred Dosage Form Criteria

Psychiatry

ADHD

Non-Stimulants

Alpha 2 Agonists

PREFERRED AGENTS (NO PA REQUIRED)	PREFERRED STEP 1 AGENTS (ELECTRONIC STEP)	NON-PREFERRED STEP 2 AGENTS (PA REQUIRED)
clonidine	clonidine ER 0.1 mg	clonidine ER 0.17 mg
guanfacine		INTUNIV (guanfacine ER)
guanfacine ER		KAPVAY (clonidine ER)

First Fill

- Clonidine ER and guanfacine ER must be filled with a 14-day supply (or less) if no previous fill within past 99 days

Therapeutic Duplication

Please see the **Psychotropic Monitoring Program** document for detailed information regarding clinical criteria for Therapeutic Duplication Requests.

- One strength of one medication is allowed at a time except guanfacine 4 mg IR and ER which may be combined guanfacine IR and ER, respectively, to form dosages up to 7 mg per day
- Clonidine and guanfacine are not allowed with each other or other alpha 2 agonists (clonidine/chlorthalidone, methyldopa, or tizanidine)

Electronic Step Care and Concurrent Medication

- Clonidine ER: A total of 30 days of clonidine IR must be paid within 40 days prior to clonidine ER

Norepinephrine Reuptake Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
atomoxetine	STRATTERA (atomoxetine)
PREFERRED AGENTS (CLINICAL PA REQUIRED)	

QELBREE (viloxazine)	

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

- The member must meet one of the following:
  - The member has failed a 30-day trial of two stimulants at the maximally tolerated dose, as evidenced by paid claims or pharmacy printouts
  - The member has failed a 30-day trial of atomoxetine

Therapeutic Duplication

- One strength of one medication is allowed at a time.

Stimulants

Amphetamines

Solid Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ADDERALL XR (dextroamphetamine/amphetamine) – *Brand Required*	ADDERALL (dextroamphetamine/amphetamine)
amphetamine	DEXEDRINE ER (dextroamphetamine)
DESOXYN (methamphetamine) – *Brand Required*	dextroamphetamine/amphetamine ER
dextroamphetamine	EVEKEO (amphetamine)
dextroamphetamine ER	methamphetamine
dextroamphetamine/amphetamine	ZENZEDI (dextroamphetamine)
VYVANSE (lisdexamfetamine)	
High-Cost Options	
DYANAVEL XR (amphetamine)	
MYDAYIS (dextroamphetamine/amphetamine)	

Non-Solid Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
DYANAVEL XR (amphetamine)	dextroamphetamine 5 mg/5 ml
EVEKEO ODT (amphetamine)	
PROCENTRA (dextroamphetamine) – *Brand Required*	
High-Cost Options	
ADZENYS XR - ODT (amphetamine)	
amphetamine ER suspension	
VYVANSE (lisdexamfetamine) CHEW TABLET	
XELSTRYM (dextroamphetamine) PATCH	

Methylphenidate

Solid Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
CONCERTA (methylphenidate) – *Brand Required*	FOCALIN (dexmethylphenidate)
dexmethylphenidate	FOCALIN XR (dexmethylphenidate)
dexmethylphenidate ER	METADATE ER (methylphenidate)

methylphenidate CD 30-70	methylphenidate ER tablet (generic Concerta)
methylphenidate tablet	RITALIN (methylphenidate)
methylphenidate ER tablet 10mg, 20mg	RITALIN LA (methylphenidate LA capsules - 50-50)
methylphenidate LA capsules - 50-50 (generic Ritalin LA)	
High-Cost Options	
ADHANSIA XR (methylphenidate)	methylphenidate ER 72 mg
AZSTARYS (serdexmethylphenidate/dexmethylphenidate)	methylphenidate ER capsule
JORNAY PM (methylphenidate)	

Non-Solid Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
DAYTRANA (methylphenidate) PATCH – *Brand Required*	Methylphenidate patch
methylphenidate chew tablet	METHYLIN (methylphenidate) chew tablets
methylphenidate solution	METHYLIN (methylphenidate) solution
QUILLICHEW ER (methylphenidate)	
QUILLIVANT XR (methylphenidate)	
High-Cost Options	
APTENSIO XR (methylphenidate) – *Brand Required*	
COTEMPLA XR - ODT (methylphenidate)	

Therapeutic Duplication

Please see the **Psychotropic Monitoring Program** document for detailed information regarding clinical criteria for Therapeutic Duplication Requests.

For all stimulants, the following are not payable:
- multiple strengths of a single medication
- amphetamine agent + methylphenidate agent
- multiple long-acting agents
- multiple short acting agents
- non-solid dosage + solid dosage forms

These long-acting products are not allowed with short-acting products:
- Aptensio XR (methylphenidate)
- Adhansia XR (methylphenidate)
- Cotempla XR-ODT (methylphenidate)
- Daytrana (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)
- Vyvanse (lisexamfetamine)
- Vyvanse Chewable (lisexamfetamine)

Amphetamines: One product will be allowed at a time. The following are not payable regimens:
- Dextroamphetamine/Amphetamine ER with Proton Pump Inhibitors
  - Proton pump inhibitors increase blood levels and potentiate the action of amphetamine. Co-administration of Adderall XR and gastrointestinal or urinary alkalizing agents should be avoided
- Concurrent use of Mydayis and Dyanavel XR with benzodiazepines or sedatives
  - Members reporting insomnia should use a shorter acting product that does not reach steady state

Methylphenidates: The following are not payable regimens:

- Concurrent use of dexmethylphenidate and methylphenidate
- Concurrent use of Adhansia XR and Azstarys with benzodiazepines or sedatives
  - Members reporting insomnia should use a shorter acting product that does not reach steady state

First Fill

- Long-acting stimulants must be filled with a 14-day supply (or less) if no previous fill within past 99 days

Antidepressants

Electronic Step Care and Concurrent Medications

- Trintellix Only: Initiation with 10 mg must be used for 10 days prior to continuing therapy with 20 mg
  - Trintellix recommended starting dose is 10 mg once daily.
- Desvenlafaxine ER Only: 30 days of 50 mg must be paid within 40 days of 25 mg date of service
  - 25 mg is intended only for gradual titration before discontinuation. It is not a therapeutic dose.

First Fill

- Viibryd and Trintellix must be filled with a 10-day supply if no previous fill within past 99 days

Therapeutic Duplication

- One strength of one medication per therapeutic class is allowed at a time
  - Therapeutic classes:
    - SSRIs
    - SNRIs
    - Tricyclic Antidepressants
    - Bupropion
    - Mirtazapine
    - Selegiline
- Mirtazapine is not allowed with other alpha 2 agonists (clonidine, clonidine/chlorthalidone, guanfacine, methyldopa)
  - Mirtazapine is also an alpha 2 agonist
- Fetzima, Viibryd, or Trintellix are not allowed with other antidepressant medications (exceptions: trazodone and mirtazapine)
- Fluvoxamine, a strong 1A2 inhibitor, is not covered with Ramelteon, a 1A2 Substrate.

Atypical 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)
INVEGA ER (paliperidone) – *Brand Required*	paliperidone ER
LATUDA (lurasidone)	RISPERDAL (risperidone)
olanzapine	SEROQUEL (quetiapine)
quetiapine	SEROQUEL XR (quetiapine)
quetiapine ER	ZYPREXA (olanzapine)
risperidone	
ziprasidone	

High-Cost Options	
CAPLYTA (lumateperone)	SYMBYAX (olanzapine/fluoxetine)
LYBALVI (olanzapine/samidorphan)	
olanzapine/fluoxetine	
REXULTI (brexpiprazole)	
VRAYLAR (cariprazine)	

Non-Solid Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
clozapine ODT	asenapine
olanzapine ODT	RISPERDAL (risperidone) ORAL SOLUTION
risperidone ODT	RISPERDAL M-TAB (risperidone)
risperidone oral solution	ZYPREXA ZYDIS (olanzapine)
SAPHRIS (asenapine) – *Brand Required*	
High-Cost Options	
aripiprazole solution	ABILIFY DISCMELT (aripiprazole)
aripiprazole ODT	
SECUADO (asenapine)	

Electronic Step Care and Concurrent Medication

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

Therapeutic Duplication

Prior Authorization Form - Concurrent Antipsychotics

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

Underutilization

- Caplyta, Fanapt, Latuda, Paliperidone ER, Rexulti, Saphris, Sacuado, and Vraylar must be used adherantly and will reject on point of sale for late fill

First Fill

- Caplyta, Fanapt, Latuda, 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 MAINTENA (aripiprazole)	
ARISTADA (aripiprazole lauroxil)	
ARISTADA INITIO (aripiprazole lauroxil)	
INVEGA HAFYERA (paliperidone)	
INVEGA SUSTENNA (paliperidone)	
INVEGA TRINZA (paliperidone)	

PERSERIS (risperidone)	
RISPERDAL CONSTA (risperidone)	
ZYPREXA RELPREVV (olanzapine)	

Electronic Step Care and Concurrent Medication

- 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.

Therapeutic Duplication

Prior Authorization Form - Concurrent Antipsychotics

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

Benzodiazepines

Therapeutic Duplication

- One short acting medication is allowed at a time: alprazolam, lorazepam, oxazepam
- One long-acting medication is allowed at a time: chlordiazepoxide, clonazepam, diazepam, alprazolam ER
- Benzodiazepines are not covered with
  - Opioids: Override Criteria Available
  - Xyrem, Xywav
  - Mydayis
    - Insomnia has been reported in 25-56% of members receiving Mydayis. Members reporting insomnia should use a shorter acting product that does not reach steady state.
- 3A4 Substrates (alprazolam, clonazepam, midazolam,) are not allowed with strong 3A4 inhibitors
- For benzodiazepines only indicated for insomnia: see Insomnia

Insomnia

Non-addictive (Non-DEA scheduled) medications

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
hydroxyzine	doxepin
mirtazapine	ROZEREM (ramelteon)
ramelteon	SILENOR (doxepin)
trazodone	

Addictive (DEA scheduled) medications

PREFERRED AGENTS (NO PA REQUIRED)	PREFERRED STEP 1 AGENTS (ELECTRONIC STEP)	NON-PREFERRED STEP 2 AGENTS (PA REQUIRED)
eszopiclone	BELSOMRA (suvorexant)	AMBIEN (zolpidem)
zaleplon	zolpidem 10 mg	AMBIEN CR (zolpidem)
zolpidem 5 mg		DAYVIGO (lemborexant)
zolpidem ER		EDLUAR (zolpidem)

		estazolam
		flurazepam
		LUNESTA (eszopiclone)
		QUVIVIQ (daridorexant)
		SECONAL SODIUM (secobarbital)
		temazepam
		triazolam
		zolpidem SL tab

Electronic Step Care and Concurrent Medications

- Belsomra: The member must have had a 25-day trial of eszopiclone within the past 90 days
- Zolpidem: Initiation with trial of 5 mg must be used for 7 days within 90 days prior to 10 mg tablets
    - Zolpidem is recommended to be used at lowest dose possible.

Prior Authorization Criteria

Prior Authorization Form – Sedative/Hypnotic

Initial Criteria - Approval Duration: 3 months

- Doxepin only
    - The member must have failed a 25-day trial with ramelteon with the most recent failure within the last 90 days, as evidenced by paid claims or pharmacy printouts
    - Clinical justification must be provided explaining why the member is unable to use mirtazapine, hydroxyzine, or trazodone (subject to clinical review)
- Edluar (zolpidem) only
    - The member's insomnia must be characterized by difficulty with sleep onset
    - The member must have failed a 25-day trial of each of the following with the most recent failure within the last 90 days, as evidenced by paid claims or pharmacy printouts
        - eszopiclone
        - zolpidem IR
        - zaleplon
- temazepam, zolpidem SL, Dayvigo, Quviviq only
    - The member's insomnia must be characterized by difficulty with sleep onset and maintenance
    - The member must have failed a 25-day trial of each of the following with the most recent failure within the last 90 days, as evidenced by paid claims or pharmacy printouts
        - eszopiclone
        - zolpidem ER
        - Belsomra
- triazolam, fluazepam, estazolam, seconal sodium 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.
- Long-acting benzodiazepines. Belsomra and Dayvigo are not covered with short or long-acting benzodiazepines.
  - Concomitant use can lead to CNS depression.

- Ramelteon, a 1A2 Substrate, is not covered with fluvoxamine, a strong 1A2 inhibitor
- Mirtazapine is not allowed with other alpha 2 agonists (clonidine, clonidine/chlorthalidone, guanfacine, methyldopa)
  - Mirtazapine is also an alpha 2 agonist
- Sedating benzodiazepines are not covered with opioids

Non-24-hour Sleep-Wake Disorder

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ramelteon	HETLIOZ (tasimelteon)
	ROZEREM (ramelteon)

Prior Authorization Criteria

Initial Criteria - Approval Duration: 6 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a specialist in sleep disorders
- The member must have had a 30-day trial of ramelteon, as evidenced by paid claims or pharmacy printouts.
- One of the following must be met:
- Member must be unable to perceive light in either eye
- Sighted members must confirm diagnosis by documentation submitted of self-reported sleep diaries or actigraphy for at least 14 days demonstrating a gradual daily drift (typically later) in rest-activity patterns not better explained by sleep hygiene, substance or medication use, or other neurological or mental disorders.

Underutilization

- Hetlioz must be used compliantly and will reject on point of sale for late fill

Smith-Magenis Syndrome

CLINICAL PA REQUIRED
HETLIOZ (tasimelteon)

Prior Authorization Criteria

Initial Criteria - Approval Duration: 6 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a specialist in sleep disorders
- Documentation is submitted of genetic testing confirming deletion 17p11.2 (cytogenetic analysis or microarray) or RAI1 gene mutation
- Documentation of self-reported sleep diaries or actigraphy must be submitted for at least 14 days must be submitted.

Underutilization

- Hetlioz must be used compliantly and will reject on point of sale for late fill

Pulmonary

Asthma/COPD

Therapeutic Duplication

- One medication from each class is allowed at time
  - One inhaled steroid
  - Long-acting anticholinergic
  - Leukotriene pathway inhibitor
  - One short-acting beta agonist
  - One long-acting beta agonist

Electronic Step Care and Concurrent Medications

- Daliresp: A total of 90 days of an inhaled short or long-acting anticholinergic must be paid within 110 days prior to daliresp's date of service.
  - According to the Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines, daliresp is a recommended add-on therapy to members experiencing exacerbations while on antimuscarinic therapy.

Albuterol/ Levalbuterol Rescue Inhalers

PREFERRED AGENTS (NO PA REQUIRED)	PREFERRED STEP 1 AGENTS (ELECTRONIC STEP REQUIRED)	NON-PREFERRED STEP 2 AGENTS (PA REQUIRED)
VENTOLIN (albuterol) HFA *– Brand Required*	levalbuterol HFA	albuterol HFA
	PROAIR RESPICLICK (albuterol)	PROAIR (albuterol) DIGIHALER
		PROVENTIL (albuterol) HFA
		XOPENEX (levalbuterol) HFA

Electronic Step Care and Concurrent Medications

- Levalbuterol HFA: A total of 30 days of albuterol HFA must be paid within 180 days prior to levalbuterol HFA's date of service
- 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.
  - According to the GINA guidelines:
    - A low dose ICS should be taken whenever SABA taken for step 1 control of asthma.
    - Dispensing ≥ 3 canisters per year is associated with higher risk of emergency department presentations
    - Dispensing ≥ 12 canisters per year is associated with higher risk of death

  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

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3. National Asthma Education and Prevention Program, Third Expert Panel on the Diagnosis and Management of Asthma. Expert Panel Report 3: Guidelines for the Diagnosis and Management of Asthma. Bethesda (MD): National Health, Lung, and Blood Institute (US); 2007 Aug. Available from: https://www.ncbi.nlm.nih.gov/books/NBK7232
4. High-Dose Albuterol by Metered-Dose Inhaler Plus a Spacer Device Versus Nebulization in Preschool Children With Recurrent Wheezing: A Double-Blind, Randomized Equivalence Trial Dominique Ploin, François R. Chapuis, Didier Stamm, Jacques Robert, Louis David, Pierre G. Chatelain, Guy Dutau and Daniel Floret Pediatrics. August 2000, 106 (2) 311-317; DOI: https://doi.org/10.1542/peds.106.2.311

Anticholinergics/Beta Agonists Combinations – Short Acting

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
albuterol/ipratropium	DUONEB (albuterol/ipratropium)
COMBIVENT RESPIMAT (albuterol/ipratropium)	

Anticholinergics/Beta Agonists Combinations – Long Acting

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED STEP 1 AGENTS (PA REQUIRED)	NON-PREFERRED STEP 2 AGENTS (PA REQUIRED)
ANORO ELLIPTA (umeclidinium/vilanterol)	BEVESPI AEROSPHERE (glycopyrrolate/formoterol)	DUAKLIR PRESSAIR (aclidinium/formoterol)
STIOLTO RESPIMAT (tiotropium/olodaterol)		

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

Non-Preferred Step 1 Agents

- The member must have failed a 30-day trial of 2 preferred agents, as evidenced by paid claims or pharmacy printouts

Non-Preferred Step 2 Agents:

- The member must have failed a 30-day trial of Bevespi Aerosphere and 2 preferred agents, as evidenced by paid claims or pharmacy printouts
- Clinical justification must be provided explaining why the member is unable to use the preferred products (subject to clinical review).

Therapeutic Duplication

- Anticholinergic medications 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.

Anticholinergics - Long-Acting

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
INCRUSE ELLIPTA (umeclidinium)	LONHALA MAGNAIR (glycopyrrolate)
SPIRIVA HANDIHALER (tiotropium)	TUDORZA PRESSAIR (aclidinium)
SPIRIVA RESPIMAT 1.25 MCG (tiotropium)	YUPELRI (revefenacin)
SPIRIVA RESPIMAT 2.5 MCG (tiotropium)	

Electronic Step Care and Concurrent Medications

- Spiriva Respimat 1.25 mg: A total of 30 days of a long-acting beta agonist (in combination or alone) 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 (in combination or alone), as evidenced by paid claims or pharmacy printouts.
- Lonhala Magnair (glycopyrrolate) only:
  - The member must have failed a 30-day trial of Yupelri, as evidenced by paid claims or pharmacy printouts.
  - Clinical justification must be provided explaining why the member is unable to use the preferred products (subject to clinical review).

Therapeutic Duplication

- Anticholinergic medications 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.

Beta Agonists – Long-Acting

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
BROVANA (arformoterol) – *Brand Required*	arformoterol
PERFOROMIST (formoterol) – *Brand Required*	formoterol
SEREVENT DISKUS (salmeterol)	
STRIVERDI RESPIMAT (olodaterol)	

Biologics

Anti-IL-5 biologics

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
CINQAIR (reslizumab) – *Medical Billing Only*	NUCALA (mepolizumab)
FASENRA (benralizumab)	

Anti-IL-4/13 biologics

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

Eosinophil-directed biologics

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

Thymic Stromal Lymphopoietin (TSLP) blocker

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
TEZSPIRE (tezepelumab-ekko) VIALS – *Medical Billing Only*	

Prior Authorization Criteria

Prior Authorization Form - Asthma

Initial Criteria - Approval Duration: 3 months

- The requested medication must be prescribed by, or in consult with, an allergist/immunologist or pulmonologist
- The member must have failed at least one exacerbation requiring use of oral corticosteroids in the previous year despite continued compliant use of a high dose inhaled steroid in combination with a long-acting beta agonist (LABA) and long-acting muscarinic antagonist (LAMA) as evidenced by paid claims or pharmacy printouts

Anti-IL-5 biologics:

- The member has eosinophilic phenotype with eosinophil count ≥ 150 cells/mcL within the past 90 days
- Nucala: The member must have failed a 3-month trial of a preferred Anti-IL-5 biologic, as evidenced by paid claims or pharmacy printouts

Eosinophil-directed biologics:

- The member has a serum total IgE level, measured before the start of treatment, of ≥ 30 IU/mL and ≤ 700 IU/mL in members age ≥ 12 years or ≥ 30 IU/mL and ≤ 1300 IU/mL in members ages 6 to < 12 years.
- The member has had a positive skin test or in vitro reactivity to a perennial aeroallergen

Renewal Criteria - Approval Duration: 12 months

- The member must have achieved a significant reduction in asthma exacerbations and utilization of rescue medications since treatment initiation since starting treatment with the requested medication, as evidenced by medical documentation (e.g., chart notes) attached to the request (subject to clinical review).

Corticosteroids – Inhaled

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ASMANEX (mometasone) TWISTHALER	ALVESCO (ciclesonide)
budesonide suspension	ARMONAIR DIGIHALER (fluticasone)***
FLOVENT DISKUS (fluticasone)	ARNUITY ELLIPTA (fluticasone)
FLOVENT HFA (fluticasone) – *Brand Required*	ASMANEX HFA (mometasone)

PULMICORT FLEXHALER (budesonide)	fluticasone HFA
	PULMICORT RESPULES (budesonide)
	QVAR REDIHALER (beclomethasone)

Electronic Duration Verification:

- Budesonide Suspension 1mg/2mL is payable for 30 days every 75 days. For diluted nasal rinses, please use 0.5mg/2mL instead of 1mg/2mL for doses 1mg 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 1.5mg per day or lower, please use 0.5mg/2mL strength.

Prior Authorization

Initial Criteria - Approval Duration: 12 months

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

Steroid/Long-Acting Beta Agonist (LABA) Combination Inhalers

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ADVAIR DISKUS (fluticasone/salmeterol) – *Brand Required*	AIRDUO DIGIHALER (fluticasone/salmeterol)
ADVAIR HFA (fluticasone/salmeterol)	AIRDUO RESPICLICK (fluticasone/salmeterol)
DULERA (mometasone/formoterol)	BREO ELLIPTA (fluticasone/vilanterol) – *Brand Required*
SYMBICORT (budesonide/formoterol) – *Brand Required*	budesonide/formoterol
	fluticasone/salmeterol
	fluticasone/vilanterol
	WIXELA INHUB (fluticasone/salmeterol)

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
- For COPD diagnosis only: The member must currently be taking a long acting antimuscarinic agent

Steroid/Anticholinergics/Long-Acting Beta Agonists Combinations

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
TRELEGY ELLIPTA (fluticasone/umeclidinium/vilanterol)	BREZTRI AEROSPHERE (budesonide/glycopyrrolate/formoterol)

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

- The member must have failed two 30-day trials of the following in unique combinations as part of a maximized triple therapy, as evidenced by paid claims or pharmacy printouts:

- Long-Acting Anticholinergics
- Long-Acting Beta Agonist
- Inhaled Steroid

Non-Preferred Agents Criteria:

- The member must have failed a 30-day trial of the preferred product, as evidenced by paid claims or pharmacy printouts:

Cystic Fibrosis

Cystic Fibrosis – Inhaled Antibiotics

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
BETHKIS (tobramycin)	ARIKAYCE (amikacin/nebulizer)
KITABIS PAK (tobramycin/nebulizer) - *Brand Required*	CAYSTON (aztreonam)
tobramycin in 0.225% sodium chloride	TOBI (tobramycin) in 0.225% sodium chloride
	TOBI PODHALER (tobramycin)
	tobramycin/nebulizer

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

- Tobi Podhaler only:
  - The member must have failed two 28-day trials of tobramycin nebulized agents, as evidenced by paid claims or pharmacy printouts.
- 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.
- 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

Cystic Fibrosis – CFTR Modulators

CLINICAL PA REQUIRED
KALYDECO (ivacaftor)
ORKAMBI (lumacaftor/ivacaftor)
SYMDEKO (tezacaftor/ivacaftor)
TRIKAFTA (elexacaftor/tezacaftor/ivacaftor)

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

- The member must have a CFTR mutation that the requested medication is FDA-approved to treat, as evidenced by medical documentation (e.g., chart notes, genetic testing) that is attached to the request

Cystic Fibrosis – Osmotic Agent

CLINICAL PA REQUIRED
BRONCHITOL (mannitol) INHALER

Electronic Diagnosis Verification

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

Electronic Age Verification

- The member must be 18 years or older

Prior Authorization

Initial Criteria - Approval Duration: 12 months
- Documentation of the Bronchitol Tolerance Test must be submitted

Idiopathic Pulmonary Fibrosis

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
OFEV (nintedanib)	ESBRIET (pirfenidone)
pirfenidone	

Prior Authorization

Initial Criteria - Approval Duration: 12 months
- The requested medication must be prescribed by, or in consult with, a pulmonologist or rheumatologist.
- The prescriber must submit documentation of the following:
  - The member must have forced vital capacity (FVC) ≥ 40% of predicted within prior 60 days
  - The member must have carbon monoxide diffusing capacity (DLCO, corrected for hemoglobin) of 30% to 79% of predicted

Interstitial Lung Disease

First Line Therapy

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
azathioprine	ACTEMRA (tocilizumab)
cyclophosphamide	
mycophenolate mofetil (MMF)	

Progressive Disease

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	OFEV (nintedanib)
	RITUXAN (rituximab) – *Medical Billing Only*

Prior Authorization

Initial Criteria - Approval Duration: 12 months
- The requested medication must be prescribed by, or in consult with, a pulmonologist or rheumatologist.
- The prescriber must submit documentation of the following:
  - The member must have forced vital capacity (FVC) ≥ 40% of predicted within prior 60 days
  - The member must have carbon monoxide diffusing capacity (DLCO, corrected for hemoglobin) of 30% to 79% of predicted.

Rheumatology

Axial Spondyloarthritis/Ankylosing spondylitis

TNF Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AVSOLA (infliximab-axxq) – *Medical Billing Only*	INFLECTRA (infliximab-dyyb) – *Medical Billing Only*
CIMZIA (certolizumab)	infliximab – *Medical Billing Only*
ENBREL (etanercept)	REMICADE (infliximab) – *Medical Billing Only*
HUMIRA (adalimumab)	SIMPONI (golimumab)
RENFLEXIS (infliximab-abda) – *Medical Billing Only*	SIMPONI (golimumab) ARIA – *Medical Billing Only*

Interleukin (IL) – 17 Inhibitors

PREFERRED AGENTS (ELECTRONIC STEP REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
TALTZ (ixekizumab)***	COSENTYX (secukinumab)

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 Care and Concurrent Medications

- Taltz: A total of 90 days of a TNF Inhibitor must be paid within 120 days prior to Taltz's date of service

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

- Cosentyx Only: The member must have failed a 90-day trial of Taltz, as evidenced by paid claims or pharmacy printouts.
- Rinvoq ER Only: The member must have failed 90-day trials of Xeljanz and another preferred product, as evidenced by paid claims or pharmacy printouts.
- Simponi Only: The member must have failed a 3-month trial of a TNF inhibitor, as evidenced by paid claims or pharmacy printouts.
- Inflectra, infliximab, Remicade, Xeljanz IR 10 mg, Xeljanz XR Only: See Preferred Dosage Form Criteria

Behçet syndrome

Phosphodiesterase 4 (PDE4) Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
OTEZLA (apremilast)	

TNF Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AVSOLA (infliximab-axxq) – *Medical Billing Only*	INFLECTRA (infliximab-dyyb) – *Medical Billing Only*
ENBREL (etanercept)	infliximab – *Medical Billing Only*
HUMIRA (adalimumab)	REMICADE (infliximab) – *Medical Billing Only*

RENFLEXIS (infliximab-abda) – *Medical Billing Only*	

Prior Authorization Criteria

- See Preferred Dosage Form Criteria

Cryopyrin Associated Periodic Syndrome (CAPS)

Includes: Familiar Cold Autoinflammatory Syndrome, Muckle-Wells Syndrome, and Neonatal Onset Multisystem Inflammatory Disease (NOMID) or Chronic Infantile Neurological Cutaneous and Articular (CINCA) Syndrome

Interleukin (IL) -1 Receptor Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
KINERET (anakinra)	ARCALYST (rilonacept)
	ILARIS (canakinumab) – *Medical Billing Only*

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a specialist in the area of the member's diagnosis.
- The member has failed a 3-month trial of Kineret, as evidenced by paid claims or pharmacy print outs.
- The member has elevated pretreatment serum inflammatory markers (e.g., C-reactive protein (CRP), erythrocyte sedimentation rate (ESR) serum amyloid A(SAA))
- The member has at least two of the following symptoms (as evidenced by documentation):
  - Urticaria-like rash
  - Cold/stress triggered episodes
  - Sensorineural hearing loss
  - Musculoskeletal symptoms of arthralgia/arthritis/myalgia
  - Chronic aseptic meningitis
  - Skeletal abnormalities of epiphyseal overgrowth/frontal bossing

Familial Mediterranean Fever (FMF)

Colchicine

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
COLCRYS (colchicine) TABLETS – *Brand Required*	colchicine capsules
	colchicine tablets
	GLOPERBA (colchicine) ORAL SOLUTION
	MITIGARE (colchicine) CAPSULE

Interleukin (IL) -1 Receptor Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
KINERET (anakinra)	ARCALYST (rilonacept)
	ILARIS (canakinumab) – *Medical Billing Only*

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a specialist in the area of the member's diagnosis.
- The member experiences one or more attacks each month despite receiving maximally tolerated dose of colchicine for at least 6 months, as evidenced by paid claims or pharmacy print outs and clinical documentation.
- The member has failed a 3-month trial of Kineret, as evidenced by paid claims or pharmacy print outs.

Giant Cell Arteritis (Temporal Arteritis)

Interleukin (IL) -6 Receptor Inhibitors

CLINICAL PA REQUIRED
ACTEMRA (tocilizumab)
ACTEMRA (tocilizumab) – *Medical Billing Only*

Prior Authorization Criteria

See Medications that cost over $3000/month Criteria

Hyperimmunoglobulin D Syndrome/Mevalonate Kinase (MVK) Deficiency

Symptomatic Treatment

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
NSAIDs	
glucocorticoids	
KINERET (anakinra)	

Preventative Treatment

CLINICAL PA REQUIRED
ILARIS (canakinumab)

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a specialist in the area of the member's diagnosis.
- The member has failed a 3-month trial of Kineret, as evidenced by paid claims or pharmacy print outs.
- The member is experiencing frequent and/or severe attacks that have significantly diminished quality of life

Juvenile Idiopathic Arthritis

Juvenile Idiopathic Arthritis – Enthesitis-Related Arthritis (ERA)

TNF Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ENBREL (etanercept)	
HUMIRA (adalimumab)	

Interleukin (IL) – 17 Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	COSENTYX (secukinumab)

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

TNF Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ENBREL (etanercept)	SIMPONI ARIA (golimumab) – *Medical Billing Only*
HUMIRA (adalimumab)	

Interleukin (IL) -6 Receptor Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	ACTEMRA (tocilizumab)
	ACTEMRA (tocilizumab) – *Medical Billing Only*

T-cell Costimulation Blocker

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ORENCIA (abatacept) – 125 mg/mL syringe	ORENCIA (abatacept) - 50 mg/0.4 mL and 87.5 mg/0.7 ml syringes
	ORENCIA (abatacept) – *Medical Billing Only*

Janus Kinase (JAK) Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
XELJANZ IR (tofacitinib) 5 mg, oral solution	XELJANZ IR (tofacitinib) 10 mg
	XELJANZ XR (tofacitinib)

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

- The member has failed a 3-month trial of a TNF inhibitor, as evidenced by paid claims or pharmacy print outs.
- Xeljanz IR 10mg, Xeljanz XR Only: See Preferred Dosage Form Criteria

Juvenile Chronic Arthritis – Systemic Onset

Interleukin (IL) -1 Receptor Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	ILARIS (canakinumab) – *Medical Billing Only*

Interleukin (IL) -6 Receptor Inhibitors

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ACTEMRA (tocilizumab)	
ACTEMRA (tocilizumab) – *Medical Billing Only*	

TNF Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ENBREL (etanercept)	
HUMIRA (adalimumab)	

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

- Actemra: See Medications that cost over $3000/month Criteria
- Ilaris: The member has failed a 3-month trial of Actemra, 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

Psoriatic Arthritis

TNF Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
CIMZIA (certolizumab)	SIMPONI (golimumab)
ENBREL (etanercept)	SIMPONI (golimumab) ARIA – *Medical Billing Only*
HUMIRA (adalimumab)	

Phosphodiesterase 4 (PDE4) Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
OTEZLA (apremilast)	

Janus Kinase (JAK) Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
XELJANZ IR (tofacitinib) 5 mg, oral solution	RINVOQ ER (upadacitinib)
	XELJANZ IR (tofacitinib) 10 mg
	XELJANZ XR (tofacitinib)

T-cell Costimulation Blocker

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ORENCIA (abatacept) – 125 mg/mL syringe	ORENCIA (abatacept) – *Medical Billing Only*

Interleukin (IL)-23 Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	SKYRIZI (risankizumab)
	TREMFYA (guselkumab)

Interleukin (IL)-12/IL-23 Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	STELARA (ustekinumab)

Interleukin (IL) – 17 Inhibitors

PREFERRED AGENTS (ELECTRONIC STEP REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
TALTZ (ixekizumab)***	COSENTYX (secukinumab)

Electronic Step Care and Concurrent Medications

- Taltz: A total of 90 days of a TNF Inhibitor must be paid within 120 days prior to Taltz's date of service.

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

- The member must have failed a 90-day trial of each of the following, as evidenced by paid claims or pharmacy printouts:
  - TNF inhibitor
  - Interleukin (IL) – 17 inhibitor
- Xeljanz IR 10mg, Xeljanz XR Only: See Preferred Dosage Form Criteria

Rheumatoid Arthritis

Anti-CD20 Monoclonal Antibodies

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
RITUXAN (rituximab) – *Medical Billing Only*	

T-cell Costimulation Blocker

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ORENCIA (abatacept) – 125 mg/mL syringe	ORENCIA (abatacept) – *Medical Billing Only*

Interleukin (IL) -1 Receptor Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
KINERET (anakinra)	

Interleukin (IL) -6 Receptor Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	ACTEMRA (tocilizumab)
	ACTEMRA (tocilizumab) – *Medical Billing Only*
	KEVZARA (sarilumab)

Janus Kinase (JAK) Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
XELJANZ IR (tofacitinib) 5 mg, oral solution	OLUMIANT (baricitinib)
	RINVOQ ER (upadacitinib)
	XELJANZ IR (tofacitinib) 10 mg
	XELJANZ XR (tofacitinib)

TNF Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
CIMZIA (certolizumab)	SIMPONI (golimumab)
ENBREL (etanercept)	SIMPONI (golimumab) ARIA – *Medical Billing Only*
HUMIRA (adalimumab)	

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

- Xeljanz IR 10mg, Xeljanz XR Only: See Preferred Dosage Form Criteria
- The member must have had a 3-month trial of each of the following, as evidenced by paid claims and pharmacy printouts:
  - TNF Inhibitor
  - JAK inhibitor
  - T-cell Costimulation Blocker

Adult-Onset Still's Disease

Interleukin (IL) -1 Receptor Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
KINERET (anakinra)	ARCALYST (rilonacept)
	ILARIS (canakinumab) – *Medical Billing Only*

TNF Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AVSOLA (infliximab-axxq) – *Medical Billing Only*	INFLECTRA (infliximab-dyyb) – *Medical Billing Only*
RENFLEXIS (infliximab-abda) – *Medical Billing Only*	infliximab – *Medical Billing Only*
	REMICADE (infliximab) – *Medical Billing Only*

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a specialist in the area of the member's diagnosis.
- The member must have had a 3-month trial of each of Kineret, as evidenced by paid claims and pharmacy printouts:
- Remicade, infliximab, and Inflectra Only: See Preferred Dosage Form Criteria

Tumor Necrosis Factor Receptor Associated Periodic Syndrome

CLINICAL PA REQUIRED
ILARIS (canakinumab)

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a specialist in the area of the member's diagnosis.
- Documentation must be attached to confirm one of the following:
  - Genetic testing confirming pathogenic variants in the tumor necrosis factor receptor 1 (TNFR1) gene (TNF receptor superfamily member 1A, TNFRSF1A).
  - Both of the following:
    - Elevated serum inflammatory markers (e.g., C-reactive protein (CRP), erythrocyte sedimentation rate (ESR) serum amyloid A(SAA))
    - History of recurrent fever, prominent myalgias, migratory rash, and periorbital edema

Osteoporosis

Antiresorptive Agents

Bisphosphonates

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
alendronate	ACTONEL (risedronate)
alendronate oral solution	ATELVIA (risedronate DR)
ibandronate	FOSAMAX (alendronate)
risedronate IR	risedronate DR

Prior Authorization Criteria

- Risedronate DR Only: See Preferred Dosage Form Criteria

Calcitonins

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
calcitonin, salmon nasal spray	calcitonin, salmon vial
MIACALCIN (calcitonin, salmon) VIAL – *Medical Billing Only*	

Prior Authorization Criteria

Initial Criteria - Approval Duration: 6 months

- The member must be experiencing pain from an acute osteoporotic fracture
  - 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.

Estrogen Agonist/Antagonist

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
raloxifene	EVISTA (raloxifene)

Monoclonal Antibodies

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
PROLIA (denosumab) – *Medical Billing Only*	

Anabolic Agents

Parathyroid Hormone (PTH)

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
FORTEO (teriparatide)	teriparatide

PTH-related protein

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	TYMLOS (abaloparatide)

Monoclonal Anti-sclerostin Antibody

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	EVENITY (romosozumab-aqqg) – *Medical Billing Only*

Prior Authorization Criteria

Initial Criteria - Approval Duration: 2 years (1 year for Evenity)

- The member must have a current BMD T-score ≤ -2.5 OR new fracture (as evidenced by submitted documentation) after a 6-month trial of each of the following, as evidenced by paid claims or pharmacy printouts:
  - alendronate or risedronate
  - teriparatide
- Member must be at high risk of fracture, confirmed by documentation of at least one of the following:
  - The member with a history of hip or vertebral fracture
  - The member with a T-score of −2.5 or lower at the femoral neck or spine
  - The member has a T-score of between −1.0 and −2.5 at the femoral neck or spine and a ten-year hip fracture risk of ≥3% as assessed with the FRAX
  - 10-year risk of a major osteoporosis-related fracture of ≥20% as assessed with the FRAX

Substance Use

Nicotine / Tobacco Dependence Treatment

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
bupropion SR	NICODERM CQ (nicotine) PATCH
CHANTIX (varenicline)	NICORETTE (nicotine polacrilex) GUM
nicotine lozenge	ZYBAN (bupropion SR)
nicotine patch	
nicotine polarcrilex gum	
NICOTROL (nicotine polacrilex) INHALER	
NICOTROL (nicotine polacrilex) SPRAY	

Concurrent Medication and Step Care

- A total of 14 days of nicotine patch, Chantix, or Zyban must be paid within 40 days prior to Nicotrol Nasal Spray, nicotine lozenge, Nicotrol inhaler, or nicotine gum's date of service.
  - Better outcomes are associated with concurrent use of short acting and long-acting tobacco cessation products.
- A total of 14 days of nicotine patch, gum, lozenge, inhaler, or spray must be paid within 40 days prior to Zyban's date of service.
  - Better outcomes are associated with concurrent use of short acting and long-acting tobacco cessation products. Nicotine products can help bridge treatment until Zyban becomes effective.

Electronic Duration Verification

- A total of 12 consecutive weeks will be covered for all other products, every 6 months

  Chantix: If the following conditions apply, please call for an override by calling provider relations at 1-800-755-2604:
  - Patent is abstinent from tobacco
  - Treatment duration is requested to be extended to 24 consecutive weeks

Therapeutic Duplication

- nicotine gum, lozenge, inhaler, and spray will not be paid concurrently
- Zyban will not be paid with other forms of bupropion

Underutilization

- Nicotine Patch, Chantix, and Bupropion must be used adherantly 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	LUCEMYRA (lofexidine)
guanfacine	

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

Naloxone Rescue Medications

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
KLOXXADO (naloxone) NASAL SPRAY	naloxone nasal spray – labeler 00093
nalmefene injection	ZIMHI (naloxone) SYRINGE
naloxone injection	
naloxone nasal spray – labeler 00781	
NARCAN (naloxone) NASAL SPRAY – *Brand Preferred*	

Electronic Duration Verification

- One dose per 365 days is covered without prior authorization

  The following information will need to be submitted as a follow up for the override by either emailing medicaidpharmacy@nd.gov or documenting on General Prior Authorization Form:

  - The provider must attest that it is known that the previous dose was taken by the member (and not diverted or given to another member)
  - One of the following criteria must be met (A, B, or C)
    A. The previous dose has expired
    B. The dose was used by member for illicit drug use
    C. The member is currently taking opioids and meets one of the following criteria:
       - The opioid dose must have been decreased
       - The provider has provided medical justification why the opioid dose as not been Decreased

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

Therapeutic Duplication

- One strength of one medication is allowed at a time
- Opioid partial agonists are not allowed with:
  - Methadone
  - Carisoprodol
  - Opioids

  If all of the following conditions apply, please call for an override by calling provider relations at 1-800-755-2604:
  - The member has an acute condition that cannot be reasonably treated with non-opioid therapy (e.g., surgery)
  - Prescribers of both opioid and opioid use disorder are aware of each other and agree to opioid therapy
  - Opioid duration is of a one-time occurrence or taper plan is provided

Underutilization

- Buprenorphine and buprenorphine/naloxone must be used compliantly and will reject on point of sale for late fill
- To request an override, submit a Opioid Use Disorder Underutilization Form. Both the 1st and 2nd pages must be filled out.

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.

Prior Authorization Criteria

Prior Authorization Form – Opioid Dependence

Initial Criteria - Approval Duration: Until end of pregnancy / breastfeeding

- The member must be pregnant or breastfeeding, and estimated delivery date/duration of need for breastfeeding must be provided.

Non-Oral Agents

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
SUBLOCADE (buprenorphine)	

Combination Product

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
buprenorphine-naloxone tablets	BUNAVAIL FILM (buprenorphine/naloxone)
	buprenorphine/naloxone film
	SUBOXONE FILM (buprenorphine/naloxone)
	ZUBSOLV (buprenorphine/naloxone)

Prior Authorization Criteria

- See DAW (Dispense As Written) Criteria

Obstetrics/Gynecology

Endometriosis Pain

CLINICAL PA REQUIRED
MYFEMBREE (relugolix, estradiol, and norethindrone acetate)
ORILISSA (elagolix)

Prior Authorization Criteria

Initial Criteria - Approval Duration: 6 months

- The member must have failed the following trials (A and B), as evidenced by paid claims or pharmacy printouts:
  C. A 3-menstrual cycle trial of mefenamic acid or meclofenamate, celecoxib, ibuprofen 1800 mg/day or equivalent high dose NSAID
  D. A 3-menstrual cycle trial of an oral estrogen-progestin or progestin contraceptives

Renewal Criteria - Approval Duration: 18 months

- Documentation must be submitted of improvement in pain score from baseline

Electronic Diagnosis Verification

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

Estrogens

Injectable

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
DELESTROGEN (estradiol valerate) INJECTION *– Brand Required*	estradiol valerate injection
DEPO-ESTRADIOL (estradiol cypionate) INJECTION	PREMARIN (estrogens, conjugated) INJECTION

Oral

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
estradiol tablet	ACTIVELLA (estradiol-norethindrone) TABLET
estradiol-norethindrone tablet	AMABELZ (estradiol-norethindrone) TABLET
MENEST (estrogens, esterified) TABLET	BIJUVA (estradiol-progesterone) CAPSULE
norethindrone-ethinyl estradiol tablet	ESTRACE (estradiol) TABLET
PREMARIN (estrogens, conjugated) TABLET	FEMHRT (norethindrone-ethyl estradiol) TABLET
PREMPHASE (estrogen, conj. m-progest) TABLET	FYAVOLV (norethindrone-ethinyl estradiol) TABLET
PREMPRO (estrogen, conj. m-progest) TABLET	JINTELI (norethindrone-ethinyl estradiol) TABLET

	LOPREEZA (estradiol-norgestimate) TABLET
	MIMVEY (estradiol-norgestimate) TABLET
	PREFEST (estradiol-norgestimate) TABLET

Topical Cream/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 packet

Topical Patch

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ALORA (estradiol) PATCH TWICE WEEKLY *- Brand Required*	CLIMARA (estradiol) PATCH WEEKLY
CLIMARA PRO (estradiol-levonorgestrel) PATCH - ONCE WEEKLY	DOTTI (estradiol) PATCH TWICE WEEKLY
COMBIPATCH (estradiol- norethindrone) PATCH - TWICE WEEKLY	estradiol patch twice weekly
estradiol patch weekly	LYLLANA (estradiol) PATCH TWICE WEEKLY
MENOSTAR (estradiol) PATCH ONCE WEEKLY	
MINIVELLE (estradiol) PATCH TWICE WEEKLY *- Brand Required*	
VIVELLE-DOT (estradiol) PATCH TWICE WEEKLY *- Brand Required*	

Vaginal

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
estradiol vaginal cream	ESTRACE (estradiol) CREAM
ESTRING (estradiol)	estradiol vaginal tablet
PREMARIN (estrogens, conjugated) CREAM	FEMRING (estradiol)
VAGIFEM (estradiol) VAGINAL TABLET *– Brand Required*	YUVAFEM (estradiol) VAGINAL TABLET

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

Mifepristone

Electronic Diagnosis Verification

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

Prior Authorization Form - Mifepristone

Initial Criteria - Approval Duration: 1 month

- Gestational age must be less than or equal to 70 days
- One of the following criteria must be met (A or B):
  - **A. Pregnancy must have resulted from an act of rape or incest, and one of the following (I or II)**
    - I. A written statement signed by the provider must be submitted stating that the rape or act of incest has been reported to the appropriate law enforcement agency, or in the case of a minor who is a victim of incest, to an agency authorized to receive child abuse and neglect reports and it must be indicated to whom the report was made.
    - II. A written statement signed by the member and the provider must be submitted stating that the member's pregnancy resulted from rape or incest and by professional judgement, the provider agrees with the statement.
  - **B. Both of the following must be met (I and II)**
    - I. The member must suffer from a physical disorder, physical injury, or physical illness, including a life-endangering physical condition caused by or arising from the pregnancy itself, that would as certified by a provider, place the member in danger of death unless an abortion is performed
    - II. A written statement signed by the provider must be provided indicating why, in the provider's professional judgement, the life of the member would be endangered if the fetus were carried to term

Nausea/Vomiting – Pregnancy

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
DICLEGIS (doxylamine/vitamin B6) – *Brand Required*	BONJESTA (doxylamine/vitamin B6)
meclizine	doxylamine/vitamin B6
metoclopramide	
ondansetron	

Prior Authorization Criteria

Initial Criteria - Approval Duration: until due date

- Member's due date must be provided
- The prescriber must submit medical justification explaining why the member cannot use a preferred product (subject to clinical review)

Progesterone

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
MAKENA (hydroxyprogesterone caproate) – *Brand Required*	hydroxyprogesterone caproate
progesterone	

Prior Authorization Criteria

Prior Authorization Form - Makena

Initial Criteria - Approval Duration: Week 20 to Week 37 of pregnancy

- The week of pregnancy and due date must be indicated on request (must be 20 weeks or greater).
- Clinical justification must be provided explaining why medication is medically necessary

Uterine Fibroids

CLINICAL PA REQUIRED
MYFEMBREE (relugolix, estradiol, and norethindrone acetate)
ORIAHNN (elagolix, estradiol, and norethindrone acetate)

Prior Authorization Criteria

Initial Criteria - Approval Duration: 6 months

- The member must have failed the following trials (A and B), as evidenced by paid claims or pharmacy printouts:
  A. A 3-menstrual cycle trial of mefenamic acid or meclofenamate, celecoxib, ibuprofen 1800 mg/day or equivalent high dose NSAID
  B. A 3-menstrual cycle trial of an oral estrogen-progestin or progestin contraceptives

Renewal Criteria - Approval Duration: 18 months

- Documentation must be submitted of improvement in pain score from baseline

Electronic Diagnosis Verification

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

Vaginal Infections

Oral

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
fluconazole tablet	BREXAFEMME (ibrexafungerp) TABLETS
metronidazole tablet	VIVJOA (oteseconazole) CAPSULES
SOLOSEC (secnidazole) GRANULE PACKET	
tinidazole tablet	

Vaginal

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
CLEOCIN (clindamycin) SUPPOSITORY	CLEOCIN (clindamycin) CREAM
clindamycin cream	GYNAZOLE 1 (butoconazole) CREAM
CLINDESSE (clindamycin) CREAM	METROGEL-VAGINAL (metronidazole)
metronidazole gel	terconazole suppository – labeler 45802
NUVESSA (metronidazole) GEL	VANDAZOLE (metronidazole) GEL
terconazole cream	XACIATO (clindamycin phosphate) GEL
terconazole suppository – labeler 00713	

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

- The member must have failed 30-day trials of 3 preferred agents, as evidenced by paid claims or pharmacy printouts.
- Vivjoa Only:
  - The member must have failed a six-month trial of oral fluconazole maintenance prophylaxis treatment
  - The member must not be of reproductive potential defined as:
    - The member is postmenopausal

- The member is known to not be of reproductive potential (e.g., history of tubal ligation, salpingo-oophorectomy, or hysterectomy)

Preferred Dosage Forms 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)
- Clinical justification must be provided explaining why the member is unable to use the preferred agents (subject to clinical review).
- The member must have failed a trial duration of 30 days (or less if duration is FDA approved) of each preferred agent (listed in boxes below) within the past 2 years, as evidenced by paid claims or pharmacy printouts.

Azathioprine

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
azathioprine 50 mg	azathioprine 75 mg
	azathioprine 100 mg

Brisdelle (paroxetine)

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
paroxetine tablets	paroxetine mesylate 7.5 mg capsules

butalbital-acetaminophen-caffeine

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
butalbital-acetaminophen-caffeine tablets	butalbital-acetaminophen-caffeine capsules
VTOL LQ (butalbital-acetaminophen-caffeine) SOLUTION	ESGIC (butalbital-acetaminophen-caffeine) TABLET
	FIORICET (butalbital-acetaminophen-caffeine) CAPSULES
	ZEBUTAL (butalbital-acetaminophen-caffeine) CAPSULES

citalopram

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
citalopram tablets	citalopram capsules
citalopram solution	

cyanacobalamin

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 00093, 49502	epinephrine – labeler 11516
	EPIPEN (epinephrine)

	EPIPEN (epinephrine) JUNIOR
	SYMJEPI (epinephrine)

Electronic Duration Verification

- 3 packs (initial and replacement doses) are covered every 180 days without prior authorization.

gabapentin

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
gabapentin	GRALISE (gabapentin)
gabapentin	HORIZANT (gabapentin)
pramipexole	
ropinirole	

glycopyrrolate

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
CUVPOSA (glycopyrrolate) SOLUTION	DARTISLA ODT (glycopyrrolate)
glycopyrrolate	

Jadenu (deferasirox)

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
deferasirox tablet for suspension	EXJADE (deferasirox tablet for suspension)
deferasirox tablets	deferasirox sprinkle
	JADENU (deferasirox) SPRINKLE
	JADENU (deferasirox) TABLETS

Kits

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
FDA approved products prescribed separately	CAMPHOTREX 4%-10% ROLL-ON G (menthol/camphor)
	CENTANY AT (mupirocin)
	CICLOPIROX (ciclopirox/urea/camphor/methol)
	CICLODAN (ciclopirox/urea/camphor/methol)
	CICLODAN (ciclopirox/skin cleanser 28)
	CLINDACIN ETZ (clindamycin phos/skin clnsr 19)
	CLINDACIN PAC (clindamycin phos/skin clnsr 19)
	CLINDAVIX (clindamycin/dimethacone/zinc oxide)
	CLOBETEX (clobetasol/desloratadine)
	CYCLOPAK (cyclobenzaprine/lidocaine/prilocaine/glycerine)
	DERMACINRX ARM PAK (lidocaine/dimethacone)
	DERMACINRX LEXITRAL PHARMAP (diclofenac/capsicum oleoresin)
	DERMACINRX PHN PAK (lidocaine/emollient cmb No. 102)
	DERMACINRX SILAPAK (triamcinolone/dimeth/silicone)
	DERMACINRX SILAZONE (triamcinolone/silicones)
	DERMACINRX SURGICAL PHARMAP (mupirocin/chlorhexidine/dimeth)
	DERMACINRX THERAZOLE PAK (clotrimazole/betameth dip/zinc)

	DERMACINRX ZRM PAK (lidocaine/dimethicone)
	DERMALID 5% PATCH (lidocaine/elastic bandage)
	ELLZIA PAK (triamcinolone/dimethicone)
	ESOMEP-EZS KIT (esomeprazole mag/glycerin)
	ECONASIL (econazole/gauze/silicone)
	FLUOPAR (fluocinonide/dimethacone)
	FLUOVIX PLUS (fluocinonide/silicone,adhesive)
	GABACAINE KIT (gabapentin/lidocaine)
	INAVIX (diclofenac/capsaicin)
	INFAMMACIN (diclofenac/capsicum)
	KETODAN (ketoconazole/skin cleanser 28)
	LIDOPURE PATCH 5% COMBO PAC (lidocaine/kinesiology tape)
	LIDOTIN (gabapentin/lidocaine/silicone)
	LIPRITIN (gabapentin/lidocaine/prilocaine/dressing)
	LOPROX (ciclopirox/skin cleanser No. 40)
	MIGRANOW KIT (sumatriptan/menthol/camphor)
	MORGIDOX (Doxycycline/skin cleanser No. 19)
	NAPROTIN (naproxen/capsicum)
	NOPIOID-TC KIT (cyclobenzaprine/lidocaine/menthaine)
	NUVAKAAN KIT (lidocaine/prilocaine/silicone)
	NUSURGEPAK (mupirocin/chlorhexidine/dimethacone)
	NUTRIARX (Triamcinolone/dimethacone/silicone)
	PRILO PATCH KIT (lidocaine/prilocaine)
	PRIZOTRAL II (lidocaine/prilocaine/lidocaine)
	PRO DNA MEDICATED COLLECTION (lidocaine/glycerin)
	SALEX (salicylic acid/ceramide comb 1) CREAM KIT
	SALEX (salicylic acid/ceramide comb 1) LOTION KIT
	SILAZONE-II KIT (triamcinolone aceton/silicones)
	SOLARAVIX (Diclofenac/silicone, adhesive)
	SUMADAN KIT (sulfacetamide/sulfur/cleansr23)
	SUMAXIN CP KIT (sulfacetamide/sulfur/cleansr23)
	TICANASE KIT (fluticasone/sodium chloride/sodium bicarbonate)
	TRIVIX (Triamcinolone/dimethacone/silicone)
	TRIXYLITRAL (diclofenac/lidocaine/tape)
	XRYLIX 1.5% KIT (diclofenac/kinesiology tape)
	ZILACAINE PATCH 5% COMBO PA (lidocaine/silicone, adhesive)

levothyroxine

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
levothyroxine tablet	levothyroxine capsules
THYQUIDITY (levothyroxine) ORAL SOLUTION	SYNTHROID (levothyroxine) TABLET
TIROSINT (levothyroxine) 13 mcg, 25 mcg, 50 mcg, 75 mcg, 88 mcg 100 mcg 112 mcg, 125 mcg, 137 mcg, and 150 mcg capsule – *Brand Required*	TIROSINT (levothyroxine) 175 mcg and 200 mcg capsule
	TIROSINT (levothyroxine) solution

metformin

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
metformin ER	FORTAMET (metformin)
RIOMET (metformin) ORAL SOLUTION	GLUMETZA (metformin)
RIOMET ER (metformin) ORAL SOLUTION	metformin ER gastric retention 24 hr
	metformin ER osmotic

methotrexate

Required trial duration: 6 weeks

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
methotrexate	OTREXUP (methotrexate) AUTO-INJECTOR
XATMEP (methotrexate) SOLUTION	RASUVO (methotrexate) AUTO-INJECTOR
	REDITREX (methotrexate) SYRINGE
	TREXALL (methotrexate) TABLET

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

nitroglycerin

Required trial duration: 1 dose while on preventative medication

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
nitroglycerin sublingual tablets	GONITRO (nitroglycerin) SUBLINGUAL PACKET
	nitroglycerin spray
	NITROLINGUAL (nitroglycerin) SPRAY

Nocdurna (desmopressin)

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
desmopressin	NOCDURNA (desmopressin)

Pregabalin

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
pregabalin	LYRICA (pregabalin)
	LYRICA CR (pregabalin)
	pregabalin ER

Procysbi (cysteamine)

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
CYSTAGON (cysteamine)	PROCYSBI (cysteamine)
	PROCYSBI GRANULES (cysteamine)

Steroids – Oral

Emflaza: See Emflaza Criteria on this document

Tarpeyo: See Tarpeyo Criteria on this document

Rayos required trial duration: 12 weeks with 2 AM dosing of prednisone

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
budesonide 3 mg EC capsules	ALKINDI (hydrocortisone) SPRINKLE CAPSULE
cortisone	budesonide 9 mg ER tablet
dexamethasone	EMFLAZA (deflazacort)
hydrocortisone	HEMADY (dexamethasone)
methylprednisone	MILLIPRED (prednisolone)
prednisolone sodium phosphate 5 mg/5 ml, 15 mg/5 ml, 25 mg/5 ml	ORTIKOS (budesonide)
prednisone solution	prednisone intensol
prednisone tablets	prednisolone sodium phosphate ODT
	prednisolone sodium phosphate 10 mg/5 ml, 20 mg/5 ml solution
	RAYOS (prednisone)
	TAPERDEX (dexamethasone)
	TARPEYO (budesonide EC)
	UCERIS (budesonide)

tacrolimus

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
tacrolimus	ASTAGRAF XL (tacrolimus)
	ENVARSUS ER (tacrolimus)

ursodiol

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ursodiol capsule	RELTONE (ursodiol) CAPSULE
ursodiol tablet	URSO 250 (ursodiol) TABLET
	URSO FORTE (ursodiol) TABLET

Preferred Diabetic Supply List (PDSL)

Electronic Step Care and Concurrent Medications

- 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)

  If the following condition applies, please call for a 6-month override by calling provider relations at 1-800-755-2604:
    - The member has diabetes and is newly diagnosed, acutely ill, or has a significant change in health status causing blood sugar variability despite not being on a agent causing hypoglycemia or having a gestational diabetes diagnosis

- The ADA guidelines point out the lack of clinical utility and cost-effectiveness of routine Self-Monitoring of Blood Glucose (SMBG) in non-insulin treated members. Both the Society of General Internal Medicine and the Endocrine Society recommend against routine SMBG for type 2 diabetes members not on insulin or agents that cause hypoglycemia.

Test Strips

Quantity Limits

- 200 test strips are covered every 30 days

Manufacturer Name	NDC	Product Description
LifeScan Inc.	53885-0244-50	OneTouch Ultra Blue
LifeScan Inc.	53885-0245-10	OneTouch Ultra Blue
LifeScan Inc.	53885-0270-25	One Touch Verio Test Strip
LifeScan Inc.	53885-0271-50	One Touch Verio Test Strip
LifeScan Inc.	53885-0272-10	One Touch Verio Test Strip
LifeScan Inc.	53885-0994-25	OneTouch Ultra Blue
Ascensia Diabetes Care	00193-7080-50	Contour Blood Glucose Test Strips
Ascensia Diabetes Care	00193-7090-21	Contour Blood Glucose Test Strips
Ascensia Diabetes Care	00193-7311-50	Contour Next Blood Glucose Test Strips
Ascensia Diabetes Care	00193-7312-21	Contour Next Blood Glucose Test Strips

Meters

Quantity Limits

- 1 meter is covered every 365 days

Manufacturer Name	NDC	Product Description
LifeScan Inc.	53885-0044-01	OneTouch Verio Flex Blood Glucose Meter
LifeScan Inc.	53885-0046-01	OneTouch Ultra 2 Blood Glucose Meter
LifeScan Inc.	53885-0194-01	OneTouch Verio Flex Blood Glucose Meter
LifeScan Inc.	53885-0208-01	OneTouch Ultra Mini Blood Glucose Meter
LifeScan Inc.	53885-0267-01	OneTouch Verio IQ Blood Glucose Meter

LifeScan Inc.	53885-0448-01	OneTouch Ultra 2 Blood Glucose Meter
LifeScan Inc.	53885-0657-01	OneTouch Verio Blood Glucose Meter
LifeScan Inc.	53885-0927-01	OneTouch Verio Reflect System
Ascensia Diabetes Care	00193-7377-01	Contour Next Blood Glucose Meter
Ascensia Diabetes Care	00193-7252-01	Contour Next EZ Blood Glucose Meter
Ascensia Diabetes Care	00193-7189-01	Contour Blood Glucose Meter
Ascensia Diabetes Care	00193-9545-01	Contour Blood Glucose Meter
Ascensia Diabetes Care	00193-9628-01	Contour Next EZ Blood Glucose Meter
Ascensia Diabetes Care	00193-7553-01	Contour Next EZ Blood Glucose Meter
Ascensia Diabetes Care	00193-7818-01	Contour Next One Blood Glucose Meter
LifeScan Inc.	53885-0044-01	OneTouch Verio Flex Blood Glucose Meter
LifeScan Inc.	53885-0046-01	OneTouch Ultra 2 Blood Glucose Meter

Continuous Glucose Monitors (CGM)

Quantity Limits:

- NDC 08627005303- Dexcom G6 Sensors 3 ten-day sensors/box= up to qty 9/90-day supply
- NDC 08627001601- Dexcom G6 Transmitter- 1= 90-day supply (4 Transmitters/year)
- NDC 08627009011- Dexcom G6 Receiver- 1= 250-day supply (warranty is 1 year)

Manufacturer Name	NDC	Product Description
Dexcom, Inc.	08627-0016-01	Dexcom G6 Transmitter
Dexcom, Inc.	08627-0053-03	Dexcom G6 Sensor
Dexcom, Inc.	08627-0091-11	Dexcom G6 Receiver

Prior Authorization Criteria

Continuous Glucose Monitor (CGM) Prior Authorization Form

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

- The member must meet **one of the following** criteria (1, 2, or 3):
  1. The member uses **one of the following** insulin regimens, as evidenced by paid claims or pharmacy print outs:
     - Intensive insulin regimen - 3 or more insulin injections per day consisting of short acting and long-acting insulin doses
     - Humulin R U-500
     - Short acting insulin using an insulin pump
  2. The member is pregnant with pre-existing or gestational diabetes
  3. The member has recurrent hypoglycemia due to one of the following diagnoses and CGM is recommended by a medical geneticist, or an endocrinology specialist as evidenced by chart notes:
     - Inborn errors of metabolism/metabolic syndrome with risk of hypoglycemia (e.g., glycogen storage disease (GSD), hereditary fructose intolerance (HFI), fatty acid oxidation disorders, gluconeogenesis disorders, ketogenesis disorders)
     - Hyperinsulinemia syndromes (e.g., Insulinoma, Persistent Hyperinsulinemia Hypoglycemia of Infancy (PHHI), Non-insulinoma Pancreatogenesis Hypoglycemia Syndrome (NIPHS), Nesideoblastosis)
- In addition, members with Type 2 Diabetes (not on Humulin R U-500 or insulin pump) must meet **one of the following** criteria:

- 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 print outs and is adjusting dose based on glucose levels, as evidenced by submitted chart notes.
- The member was unable to achieve goal (A1c < 7%) despite triple combination therapy consisting of long-acting insulin dose of at least 10 units per day combined with two other non-insulin antihyperglycemic agents (oral or injectable), at the maximum tolerated dose with good adherence at least 3 months, as evidenced by refill history with paid claims or pharmacy printouts.

- The prescriber must attest to **all the following**:
  - The member will maintain regular provider visits to review glycemic control every 3-6 months.
    - CGM data will be reviewed at provider office visits
    - CGM data will be used in the clinical decision-making process and documented in chart notes
- The prescriber must provide most recent A1c for members with diabetes.
- The member must not have life expectancy of less than 12 months.

Renewal Criteria - Approval Duration: 12 months
For diagnosis of diabetes:
- Time-in-Range (TIR) percentage must be submitted
- The most recent A1c must be submitted for members with diabetes.
- One of the following must be met:
  - *Approval 12 months*:
    A1c and/or TIR must progress toward or be within goal (A1c < 7% or TIR > 70%) from last approval:
    - Progress note must be submitted for 1 visit within the past year indicating CGM data was reviewed by provider to evaluate/adjust therapy
  - *Approval 6 months:*
    A1c and/or TIR is outside of goal and has worsened (for A1c, worsened is defined as > 0.1% increase) from last approval.
    - A treatment plan to improve control has been submitted
    - Progress notes must be submitted for 2 visits within the past year indicating CGM data was reviewed by provider to evaluate/adjust therapy and member is following treatment plan for adjusting insulin doses based on CGM glucose readings

Test Strip Requests after CGM approval

For replacement inquiries, sensor overpatches, and troubleshooting please contact Dexcom Global Technical Support at 1-844-607-8398 or visit https://www.dexcom.com/contact

- ND Medicaid will cover 200 test strips per year to facilitate instances where Dexcom G6 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?
- The following criteria will apply if Dexcom G6 has previously been paid, but will no longer be used and regular test strip quantities are requested:
  - The member must be seen for education by a diabetic specialist or educator
  - Documentation must be submitted noting what caused the CGM failure and education / mitigation efforts that have been taken to prevent the failure, including the following as applicable:
    - Stickiness: Skin adhesive and / or overpatches have been trialed without success
    - Sensor not working: at least 2 sensor replacements have been trialed

CGM Supplies Coverage FAQ

Does ND Medicaid cover Dexcom G6 daily calibration?
- No, the unique Dexcom G6 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?

Will test strips be covered in addition to Dexcom G6?
- Yes, ND Medicaid will cover 200 test strips per year to facilitate instances where Dexcom G6 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 G6, is there a grandfathering period?

- No, the member should be converted to Dexcom G6 billed on the pharmacy side to obtain ND Medicaid coverage.

Does ND Medicaid cover Dexcom G6 for members in Long Term Care facilities?

- If a member has Medicare Part B, Medicare Part B will need to be billed primary and ND Medicaid may cover the remainder as a crossover claim with medical billing.
- If a member does not have Medicare Part B, an override will need to be obtained for coverage.
- In all cases, the member must meet prior authorization criteria for coverage.

How is CGM billed for Medicaid Expansion members?

- Dexcom will need to be billed to ND Medicaid for Dexcom G6 for Medicaid Expansion members.
- Grandfathered Medicaid Expansion members: ND Medicaid renewal prior authorization criteria will need to be met for coverage continuation beyond the 1 year grandfathering period.

How is CGM billed for Special Health Services (SHS) members eligible for ND Medicaid?

- Dexcom will need to be billed to ND Medicaid for Dexcom G6 for SHS members. The group will need to be changed from the SHS group to the ND Medicaid group.
- Grandfathered Special Health Services members: ND Medicaid renewal prior authorization criteria will need to be met for coverage continuation beyond the 1 year grandfathering period.
- Members receiving CGM other than Dexcom G6 will need to continue to work with SHS for CGM coverage.

Billing FAQ

If I bill Medtronics Guardian sensors under the code A9276 on the medical benefit, will this still 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 G6 billed on the pharmacy side to obtain ND Medicaid coverage.

Will ND Medicaid cover Dexcom G6 through medical billing?

- ND Medicaid requires Dexcom to be billed through pharmacy NCPDP D.0 billing.
- Exceptions may be made for cases where primary insurance requires Dexcom to be billed with medical billing.

Other Insurance FAQ

If primary insurance only covers CGM other than Dexcom G6, will ND Medicaid pay the copay?

- If primary insurance excludes coverage of a Dexcom G6, ND Medicaid may make an exception to cover a non-preferred CGM if the copay is nominal. Documentation of the exclusion must be submitted with the prior authorization request.
- If primary insurance does cover Dexcom G6, the member will need to switch to Dexcom G6 for ND Medicaid to pay the copay.

Does ND Medicaid cover Dexcom G6 if member has primary insurance, but it does not cover CGM?

- ND Medicaid may cover Dexcom G6 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 G6 if member meets primary insurance prior authorization criteria, but does not meet ND Medicaid prior authorization criteria?

- ND Medicaid will not cover Dexcom G6 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 G6 benefit.

Tubeless Insulin Pumps

Quantity limits:

- NDC 08508200032- Omnipod DASH Intro Kit – 1 per 30-day supply (payable 1 per 365 days)
- 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

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.	08508-2000-32	Omnipod DASH Intro Kit
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

Prior Authorization Criteria

Tubeless Insulin Pump (Omnipod) Prior Authorization Form

Initial Criteria - Approval Duration: 12 months

- The member must have Diabetes Type 1
- The member must be less than 21 years old
- The member must be receiving multiple daily injections of insulin (at least 3 injections per day)
- The member has documented frequency of blood glucose-testing an average of 4 times per day or use of CGM during the 2 months prior to request
- The prescriber must attest to all the following:
  - The prescriber is trained in the data management platform used with the Omnipod System.
  - The member will maintain regular provider visits to review Omnipod data every 3-6 months.
  - The member has been adherent to provider appointments for past 6 months
  - The member or caregiver has the mental, physical, auditory, visual, and motivational ability to manage the pump.
  - The member will receive Omnipod training from Omnipod System Trainer or a healthcare provider.
  - The member must have received diabetic education within past year
- The prescriber must provide most recent A1C and/or Time-in-Range percentage
- The member had 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

Renewal Criteria - Approval Duration: 12 months

- The member must be less than 21 years old unless request is for continuation of coverage where ND Medicaid has previously paid for Omnipod
- The most recent A1C and/or Time-in-Range percentage must be submitted
- The member has documented frequency of blood glucose-testing an average of 4 times per day or use of CGM during the 2 months prior to request
- Omnipod data has been reviewed with member as evidenced by submitted progress note within the past 6 months
- The member must be using a compatible rapid acting insulin

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. The group will need to be changed from the SHS group to the ND Medicaid group.
- ND Medicaid has pre-emptively entered initial prior authorizations for SHS members utilizing Omnipod for 1 year. ND Medicaid renewal prior authorization criteria will need to be met for coverage continuation beyond the grandfathering period.

Does ND Medicaid cover Omnipod for members in Long Term Care facilities?

- If a member is eligible for Medicare, Medicare Part D will need to be billed primary.
- If member is not eligible for Medicare, the member must meet prior authorization criteria for coverage.

Does ND Medicaid cover Omnipod if member has primary insurance, but it does not cover tubeless pumps?

- ND Medicaid may cover Omnipod as a primary payer if insulin pumps are wholly excluded from the primary insurance benefit. Documentation stating the exclusion from the primary insurance must be submitted with the prior authorization request.
- ND Medicaid will not cover Omnipod as a primary payer if a prior authorization is denied for medical necessity by the primary insurance or primary insurance only covers tubed pumps.

Will ND Medicaid cover Omnipod if member meets primary insurance prior authorization criteria, but does not meet ND Medicaid prior authorization criteria?

- ND Medicaid will not cover Omnipod if ND Medicaid prior authorization criteria is not met, regardless of approval status with primary insurance. Under rare circumstances, exceptions may be made if the copay is nominal as long as the member maintains primary insurance coverage with a Omnipod benefit.

Kepro

General
Prior Authorization Form

Fax Completed Form to:
855-207-0250
For questions regarding this Prior authorization, call
866-773-0695

Prior Authorization Vendor for ND

ND Medicaid requires members to meet specific diagnosis and step-therapy requirements for some medications. Criteria for agents requiring prior authorization can be found at the following location:

- The Preferred Drug List (PDL) is available at www.hidesigns.com/assets/files/ndmedicaid/NDPDL.pdf
- ***Completed Medwatch form(s) must be attached to this request for failed trial(s) in which the active ingredient of the failed product is the same as the requested product***

Part I: TO BE COMPLETED BY PRESCRIBER

Member Name	Member Date of Birth	Member Medicaid ID Number
Prescriber Name	Specialist involved in therapy (if not treating prescriber)	
Prescriber NPI	Telephone Number	Fax Number

Member Weight	Member Adjusted Weight	BMI	**Reason for PA request:**

Requested Drug and Dosage:	**Diagnosis for this request:**

List all failed medications:	**Start Date:**	**End Date:**

Additional Qualifications for Coverage:

☐ Member is pregnant: Due Date

☐ Member has primary insurance requiring requested product

☐ Member is unable to use preferred dosage form (please provide medical justification below– e.g. contraindication, feeding tube, permanent disability, temporary restriction, swallow study, etc.)

☐ Other: (please fill out below)

☐ *I confirm that I have considered a generic or other alternative and that the requested drug is expected to result in the successful medical management of the recipient.*

Prescriber (or Staff) / Pharmacy Signature**	Date

**: *By completing this form, I hereby certify that the above request is true, accurate and complete. That the request is medically necessary, does not exceed the medical needs of the member, and is clinically supported in the member's medical records. I also understand that any misrepresentations or concealment of any information requested in the prior authorization request may subject me to audit and recoupment.*

Part II: TO BE COMPLETED BY PHARMACY

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #

Kepro

Benzodiazepine + Opioid Concurrent Use Prior Authorization Form

Fax Completed Form to: 855-207-0250
For questions regarding this Prior authorization, call 866-773-0695

Prior Authorization Vendor for ND

ND Medicaid requires that members receiving both an opioid analgesic and a benzodiazepine must meet the following criteria:

-Member must have tried all treatment alternatives without achievement of therapeutic goal (please provide details on trial and outcome, or reason alternative cannot be attempted)

- Either a tapering plan must be included, or given the CDC guidelines and FDA black box warnings, clinical justification must be provided to explain:
  - Reason opioid analgesic cannot be avoided in this member currently receiving a benzodiazepine
  - Reason the member cannot use lower dose opioid treatment

Part I: TO BE COMPLETED BY PRESCRIBER OF THE OPIOID ANALGESIC

Recipient Name	Recipient Date of Birth	Recipient Medicaid ID Number

Prescriber Name	Pain, Palliative Care, or Oncology/Hematology Specialist involved in therapy (if not treating prescriber

Prescriber NPI	Telephone Number	Fax Number

Requested Opioid Analgesic:	**Diagnosis for use of opioid(s) in this member:**

Plan to taper: (dose and length of treatment)	**Clinical justification for concurrent opioid and benzodiazepine treatment and/or reason opioid dose cannot be reduced:**

Treatment Alternatives:	**Start/End Date:**	**Reason for failure:**
☐ NSAIDs ☐ TCAs ☐ SNRIs ☐ Corticosteroids ☐ Weight Loss ☐ Physical Therapy ☐ Cognitive Behavioral Therapy ☐ Other		

Qualifications for coverage:	
Does provider routinely check the PDMP?	☐ YES ☐NO
Has the provider established a realistic treatment plan with the member, addressing expected outcomes and limitations of therapy in totally eliminating pain?	☐ YES ☐NO
Will opioid therapy be routinely evaluated for effectiveness?	☐ YES ☐NO
Does the patient undergo routine drug screens?	☐ YES ☐NO
Has the provider discussed and counseled the patient on the known risks of utilizing opioid analgesics in combination with benzodiazepines and other CNS depressing medications/conditions?	☐ YES ☐NO

Please confirm that all the following is attached to the request, along with any other relevant documentation:

☐ Patient's treatment/tapering plan including an evaluation of effectiveness and plans for continuation/discontinuation
☐ Clinical documentation of previously tried and failed non-opioid therapies.

Prescriber (or Staff) / Pharmacy Signature**	Date

***: By completing this form, I hereby certify that the above request is true, accurate and complete. That the request is medically necessary, does not exceed the medical needs of the member, and is clinically supported in the member's medical records. I also understand that any misrepresentations or concealment of any information requested in the prior authorization request may subject me to audit and recoupment.*

Benzodiazepine + Opioid Concurrent Use Prior Authorization Form

Fax Completed Form to: 855-207-0250
For questions regarding this Prior authorization, call 866-773-0695

Prior Authorization Vendor for ND

ND Medicaid requires that members receiving both an opioid analgesic and a benzodiazepine must meet the following criteria:

-Member must have tried all treatment alternatives without achievement of therapeutic goal (please provide details on trial and outcome, or reason alternative cannot be attempted)

- Either a tapering plan must be included, or given the CDC guidelines and FDA black box warnings, clinical justification must be provided to explain:
  - Reason opioid analgesic cannot be avoided in this member currently receiving a benzodiazepine
  - Reason the member cannot use lower dose opioid treatment

Part I: TO BE COMPLETED BY PRESCRIBER OF THE OPIOID ANALGESIC

Recipient Name	Recipient Date of Birth	Recipient Medicaid ID Number

Prescriber Name	Pain, Palliative Care, or Oncology/Hematology Specialist involved in therapy (if not treating prescriber)

Prescriber NPI	Telephone Number	Fax Number

Requested Opioid Analgesic:	**Diagnosis for use of opioid(s) in this member:**

Plan to taper: (dose and length of treatment)	**Clinical justification for concurrent opioid and benzodiazepine treatment and/or reason opioid dose cannot be reduced:**

Treatment Alternatives:	**Start/End Date:**	**Reason for failure:**
☐ NSAIDs ☐ TCAs ☐ SNRIs ☐ Corticosteroids ☐ Weight Loss ☐ Physical Therapy ☐ Cognitive Behavioral Therapy ☐ Other		

Qualifications for coverage:

Does provider routinely check the PDMP?	☐ YES ☐NO
Has the provider established a realistic treatment plan with the member, addressing expected outcomes and limitations of therapy in totally eliminating pain?	☐ YES ☐NO
Will opioid therapy be routinely evaluated for effectiveness?	☐ YES ☐NO
Does the patient undergo routine drug screens?	☐ YES ☐NO
Has the provider discussed and counseled the patient on the known risks of utilizing opioid analgesics in combination with benzodiazepines and other CNS depressing medications/conditions?	☐ YES ☐NO

Please confirm that all the following is attached to the request, along with any other relevant documentation:

☐ Patient's treatment/tapering plan including an evaluation of effectiveness and plans for continuation/discontinuation
☐ Clinical documentation of previously tried and failed non-opioid therapies.

Prescriber (or Staff) / Pharmacy Signature**	Date

**: *By completing this form, I hereby certify that the above request is true, accurate and complete. That the request is medically necessary, does not exceed the medical needs of the member, and is clinically supported in the member's medical records. I also understand that any misrepresentations or concealment of any information requested in the prior authorization request may subject me to audit and recoupment.*

Multiple Antipsychotics Override Request
Prior Authorization Form

Fax Completed Form to:
855-207-0250
For questions regarding this Prior authorization, call
866-773-0695

Prior Authorization Vendor for ND

ND Medicaid requires that members receiving a prescription for multiple antipsychotics to meet specific clinical criteria for coverage. Criteria for coverage for multiple antipsychotics can be found in the following location:

- The Preferred Drug List (PDL) available at www.hidesigns.com/assets/files/ndmedicaid/NDPDL.pdf

Part I: TO BE COMPLETED BY PRESCRIBER/PRESCRIBER'S OFFICE

Recipient Name	Recipient Date of Birth	Recipient Medicaid ID Number	
Prescriber Name	Specialist involved in therapy (if not treating prescriber)		
Prescriber NPI	Telephone Number	Fax Number	
Address	City	State	Zip Code
Requested Drug and Dosage:	**Diagnosis for this request:**		
What non-antipsychotic mood stabilizers have been trialed or ruled out for treatment and justification for that decision?			
Is clozapine an option for duplicate antipsychotic for unresolved symptoms? ☐ **Yes** ☐ **No**			
Is hydroxyzine an option for sleep and/or anxiety? ☐ **Yes** ☐ **No**			
☐ *I confirm that I have considered a generic or other alternative and that the requested drug is expected to result in the successful medical management of the recipient.*			
Prescriber (or Staff) / Pharmacy Signature**		Date	
**: *By completing this form, I hereby certify that the above request is true, accurate and complete. That the request is medically necessary, does not exceed the medical needs of the member, and is clinically supported in the member's medical records. I also understand that any misrepresentations or concealment of any information requested in the prior authorization request may subject me to audit and recoupment.*			

Part II: TO BE COMPLETED BY PHARMACY

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #

Multiple Antipsychotic Override Requests

When are the breakthrough symptoms occurring (e.g. timeframe from injection)? Any other contributing factors (non-pharmacological) and how addressed, if so?	
At what point, would the first medication be considered a failure / other treatment would be considered?	
What is the anticipated benefit of another medication (vs. increasing dose or switching medication)?	
Why is one antipsychotic unable to be maximized to treat all targeted symptoms?	
What symptoms are being targeted with each antipsychotic?	
For injections:	What would be the tapering goal for oral antipsychotic if symptoms abate as long-term supplemental use of oral with injectable safety/efficacy data lacking?
	What is the site of administration?
For duplicate quetiapine requests:	If sedation/anxiety is part of a reason for the quetiapine treatment, which medications have been trialed? • A hydroxyzine trial is required for sedation/anxiety • Primary use for insomnia will not be approved

Kepro

Continuous Glucose Monitoring Prior Authorization Form

Fax Completed Form to: 855-207-0250
For questions regarding this Prior authorization, call 866-773-0695

Prior Authorization Vendor for ND

ND Medicaid requires that patients receiving a prescription for continuous glucose monitoring to meet specific diagnosis and clinical criteria requirements. Criteria for CGM can be found the following location:

- The Preferred Diabetic Supplies List (PDSL) available at www.hidesigns.com/assets/files/ndmedicaid/NDPDL.pdf

Part I: TO BE COMPLETED BY PRESCRIBER/PRESCRIBER'S OFFICE

Recipient Name	Recipient Date of Birth	Recipient Medicaid ID Number	
Prescriber Name	Specialist involved in therapy (if not treating prescriber)		
Prescriber NPI	Telephone Number	Fax Number	
Address	City	State	Zip Code
Requested Product:	**Diagnosis for this request:**		

List all current medications used for control of patient's blood glucose:

Qualifications for Coverage (please answer all of the questions below)	
Will the patient maintain regular provider visits to review glycemic control every 3-6 months?	☐ YES ☐ NO
Is CGM data reviewed at provider's office visits?	☐ YES ☐ NO
Will the provider use CGM data in the clinical decision-making process and document it in chart notes?	☐ YES ☐ NO
Have chart notes been attached (from within the past 6 months) showing CGM data and documentation of clinical decision-making based on CGM data? (renewal requests only)	☐ YES ☐ NO
Have chart notes been attached showing that the use of CGM has been recommended by a medical geneticist or an endocrinology specialist? (requests for off-label use only)	☐ YES ☐ NO

Most recent Time in Range %: (renewal requests only)	**Patient's current A1c** (for patients with diabetes mellitus):

O *I confirm that I have considered a generic or other alternative and that the requested drug is expected to result in the successful medical management of the recipient.*

Prescriber (or Staff) / Pharmacy Signature**	Date

**: *By completing this form, I hereby certify that the above request is true, accurate and complete. That the request is medically necessary, does not exceed the medical needs of the member, and is clinically supported in the patient's medical records. I also understand that any misrepresentations or concealment of any information requested in the prior authorization request may subject me to audit and recoupment.*

Part II: TO BE COMPLETED BY PHARMACY

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #

Kepro

Dupixent
Prior Authorization Form

Fax Completed Form to:
855-207-0250
For questions regarding this Prior authorization, call
866-773-0695

Prior Authorization Vendor for ND

ND Medicaid requires that members receiving a new prescription for Dupixent must meet criteria for coverage, as stated in the PA Criteria page of the North Dakota Medicaid Prior Authorization website http://www.hidesigns.com/ndmedicaid or directly at the following link: www.hidesigns.com/assets/files/ndmedicaid/NDPDL.pdf

Part I: TO BE COMPLETED BY PRESCRIBER/PRESCRIBER'S OFFICE

Recipient Name	Recipient Date of Birth	Recipient Medicaid ID Number
Prescriber Name	Specialist involved in therapy (if not treating prescriber)	
Prescriber NPI	Telephone Number	Fax Number
Requested Drug:	**Diagnosis for this request:**	

For atopic dermatitis:	**Is the affected area on the face, groin, axilla, or under occlusion?** ☐ YES ☐ NO
For asthma:	**Has the member had at least 1 asthma exacerbation requiring use of oral corticosteroids in previous year despite continued compliant use of a moderate to high dose inhaled steroid in combination with a long-acting beta agonist (LABA) and long-acting muscarinic antagonist (LAMA) as evidenced by paid claims or pharmacy printouts?** ☐ YES ☐ NO
For nasal polyps:	**Does the member have bilateral polyps confirmed by sinus CT, sinus MRI, or nasal endoscopy?** ☐ YES ☐ NO
	Has the member had a 12-week trial of intranasal or oral corticosteroid? ☐ YES ☐ NO

List all failed medications:	**Start Date:**	**End Date:**

☐ *I confirm that I have considered a generic or other alternative and that the requested drug is expected to result in the successful medical management of the recipient.*

Prescriber (or Staff) / Pharmacy Signature**	Date

**: *By completing this form, I hereby certify that the above request is true, accurate and complete. That the request is medically necessary, does not exceed the medical needs of the member, and is clinically supported in the member's medical records. I also understand that any misrepresentations or concealment of any information requested in the prior authorization request may subject me to audit and recoupment.*

Part II: TO BE COMPLETED BY PHARMACY

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #

Kepro

Emflaza
Prior Authorization Form

Fax Completed Form to:
855-207-0250
For questions regarding this Prior authorization, call
866-773-0695

Prior Authorization Vendor for ND

ND Medicaid requires that members receiving a new prescription for Emflaza must meet the criteria for use available at www.hidesigns.com/assets/files/ndmedicaid/NDPDL.pdf

Part I: TO BE COMPLETED BY PRESCRIBER

Recipient Name	Recipient Date of Birth	Recipient Medicaid ID Number

Prescriber Name	Specialist involved in therapy (if not treating prescriber)

Prescriber NPI	Telephone Number	Fax Number

Requested Drug and Dosage:	**Diagnosis for this request:**

List all failed medications:	**Start Date:**	**End Date:**

• **Member's serum creatinine kinase activity prior to initiating treatment:**	
• **Member's current motor milestone score** (provide score and assessment used):	
• **Did the member experience onset of weakness before 5 years of age?**	☐ YES ☐ NO

INITIAL: **Member has experienced the following significant intolerable adverse effects*** (select all that apply)
- ☐ 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

• *RENEWAL*: **Member has experienced an improvement from adverse effects experienced on prednisone***	☐ YES ☐ NO

Documentation of experienced adverse events or improvement on Emflaza must be provided with this request

☐ *I confirm that I have considered a generic or other alternative and that the requested drug is expected to result in the successful medical management of the recipient.*

Prescriber (or Staff) / Pharmacy Signature**	Date

**: *By completing this form, I hereby certify that the above request is true, accurate and complete. That the request is medically necessary, does not exceed the medical needs of the member, and is clinically supported in the member's medical records. I also understand that any misrepresentations or concealment of any information requested in the prior authorization request may subject me to audit and recoupment.*

Part II: TO BE COMPLETED BY PHARMACY

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:

TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #

Empaveli

Prior Authorization Form

Fax Completed Form to:
855-207-0250
For questions regarding this Prior authorization, call
866-773-0695

Prior Authorization Vendor for ND

ND Medicaid requires that members receiving a prescription for Empaveli (pegcetacoplan) to meet specific clinical criteria for coverage. Criteria for coverage for Empaveli can be found the following location:

- The Preferred Drug List (PDL) available at www.hidesigns.com/assets/files/ndmedicaid/NDPDL.pdf

Part I: TO BE COMPLETED BY PRESCRIBER/PRESCRIBER'S OFFICE

Recipient Name	Recipient Date of Birth	Recipient Medicaid ID Number	
Prescriber Name	Specialist involved in therapy (if not treating prescriber)		
Prescriber NPI	Telephone Number	Fax Number	
Address	City	State	Zip Code

Requested Drug and Dosage:	**Diagnosis for this request:** ☐ PAROXYSMAL NOCTURNAL HEMOGLOBINURIA (PNH) ☐ OTHER:

Qualifications for coverage:

Does the member have transfusion dependent anemia?	☐ YES ☐ NO
Does the member have symptoms of thromboembolic complications (abdominal pain, shortness of breath, chest pain, end-organ damage, fatigue)?	☐ YES ☐ NO
Has the member received one of the following? • A full course of meningococcal, pneumococcal, and Hib vaccines at least 2 weeks prior to starting treatment • A test for antibodies against encapsulated bacteria at least 2 weeks prior to starting treatment • Prophylactic antibiotics against encapsulated bacteria prior to starting treatment	☐ YES ☐ NO

Please confirm that all the following is attached to the request, along with any other relevant documentation:

☐ Documentation of lab results confirming a diagnosis of PNH
☐ (Renewal ONLY): Documentation supporting that the member has experienced and/or maintained a clinical benefit since starting treatment with Empaveli, as evidenced by medical documentation (e.g. reduced fatigue, decrease in transfusions, increase in Hb levels, or normalization of LDH).

☐ *I confirm that I have considered a generic or other alternative and that the requested drug is expected to result in the successful medical management of the recipient.*

Prescriber (or Staff) / Pharmacy Signature**	Date

**: *By completing this form, I hereby certify that the above request is true, accurate and complete. That the request is medically necessary, does not exceed the medical needs of the member, and is clinically supported in the member's medical records. I also understand that any misrepresentations or concealment of any information requested in the prior authorization request may subject me to audit and recoupment.*

Part II: TO BE COMPLETED BY PHARMACY

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #

Kepro

Evrysdi

Prior Authorization Form

Fax Completed Form to: 855-207-0250
For questions regarding this Prior authorization, call 866-773-0695

Prior Authorization Vendor for ND

ND Medicaid requires that members receiving a prescription for Evrysdi must meet the criteria listed in the preferred drug list (PDL). Please see the PDL at www.hidesigns.com/assets/files/ndmedicaid/NDPDL.pdf

- Please complete this form in its entirety and provide all required documentation (if available)

Part I: TO BE COMPLETED BY PRESCRIBER/PRESCRIBER'S OFFICE

Recipient Name	Recipient Date of Birth	Recipient Medicaid ID Number	
Prescriber Name	Specialist involved in therapy (if not treating prescriber)		
Prescriber NPI	Telephone Number	Fax Number	
Address	City	State	Zip Code

Requested Drug:	**Diagnosis for this request:** ☐ SMA Type 1 ☐ SMA Type 2 ☐ SMA Type 3
Member Weight	**Requested Dose**

Neuromuscular Clinic Contact Information:	**Date of last Visit:**

Has the member required continuous intubation for greater than 3 weeks?	☐ YES	☐ NO
Is the member receiving/has the member received treatment with Zolgensma?	☐ YES	☐ NO
Is the member symptomatic (ex. loss of reflexes, motor delay/weakness, abnormal EMG/neuromuscular ultrasound)?	☐ YES	☐ NO

Please confirm that all of the following is attached to the request, if applicable, along with any other documentation required, as stated in the PDL:

☐ Documentation of the member's current motor function from at least 2 of the approved assessments
☐ Documentation of genetic testing confirming bi-allelic deletions or mutations of SMN1 gene
☐ Documentation of genetic testing confirming the number of the patient's SMN2 gene copies

Prescriber (or Staff) / Pharmacy Signature**	Date

***: By completing this form, I hereby certify that the above request is true, accurate and complete. That the request is medically necessary, does not exceed the medical needs of the member, and is clinically supported in the member's medical records. I also understand that any misrepresentations or concealment of any information requested in the prior authorization request may subject me to audit and recoupment.*

Part II: TO BE COMPLETED BY PHARMACY

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #

Kepro

Growth Hormone
Prior Authorization Form

Fax Completed Form to:
855-207-0250
For questions regarding this Prior authorization, call
866-773-0695

Prior Authorization Vendor for ND

ND Medicaid requires that members receiving preferred growth hormone meet one of the criteria below (member's receiving a non-preferred growth hormone product must be switched to a preferred agent):

- 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
- See growth hormone criteria for additional information – www.hidesigns.com/assets/files/ndmedicaid/NDPDL.pdf

Part I: TO BE COMPLETED BY PRESCRIBER

Recipient Name	Recipient Date of Birth	Recipient Medicaid ID Number
Prescriber Name	Specialist involved in therapy (if not treating prescriber)	
Prescriber NPI	Telephone Number	Fax Number
Requested Drug and Dosage:	**Diagnosis for this request:**	

Qualifications for coverage:

Does the member have any active malignancy?	☐ YES ☐NO
Has the member attained epiphyseal closure?	☐ YES ☐NO
Does the member consult with a dietician to maintain a nutritious diet?	☐ YES ☐NO
Is growth hormone needed to maintain proper blood glucose *(endogenous GH deficiency only)*?	☐ YES ☐NO
Does the member have multiple pituitary hormone deficiencies caused by a known hypothalamic-pituitary Disease *(endogenous GH deficiency only)*?	☐ YES ☐NO
Has the member received a renal transplant *(chronic renal insufficiency only)?*	☐ YES ☐NO
Has a diagnosis of sleep apnea been ruled out in this member *(Prader-Willi syndrome only)*?	☐ YES ☐NO
Are all lab values stated as required in the criteria attached to this request?	☐ YES ☐NO

Member's current BMI (Prader-Willi syndrome only):

Prescriber (or Staff) / Pharmacy Signature**	Date

**: *By completing this form, I hereby certify that the above request is true, accurate and complete. That the request is medically necessary, does not exceed the medical needs of the member, and is clinically supported in the member's medical records. I also understand that any misrepresentations or concealment of any information requested in the prior authorization request may subject me to audit and recoupment.*

Part II: TO BE COMPLETED BY PHARMACY

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #

Kepro

Hepatitis C Treatments
Prior Authorization Form

Fax Completed Form to:
855-207-0250
For questions regarding this Prior authorization, call
866-773-0695

Prior Authorization Vendor for ND

ND Medicaid requires that members receiving a prescription for hepatitis C treatments must meet the criteria listed in the preferred drug list (PDL). Please see the PDL at www.hidesigns.com/assets/files/ndmedicaid/NDPDL.pdf
Please complete this form in its entirety and provide all required documentation (if available)

Part I: TO BE COMPLETED BY PRESCRIBER

Recipient Name	Recipient Date of Birth	Recipient Medicaid ID Number	
Prescriber Name	Specialist involved in therapy		
Prescriber NPI	Telephone Number	Fax Number	
Address	City	State	Zip Code

Requested Drug and Dose:	**Duration requested:**	**Member's liver fibrosis score:** □ F0-F1 □ F2-F4
Diagnosis: □ HCV □ OTHER:	**Genotype:**	**Member's Child–Pugh Class:** □ A □ B □ C □ N/A

Please list any previous treatments the member has failed for chronic HCV: □ N/A	Regimen:	Dates of treatment:	Response:

Has the member remained drug (illicit use by injection) and alcohol free for the past 3 months?	□ YES □ NO
Does the member have a diagnosis of alcohol use disorder?	□ YES □ NO
Does the member have a history of illicit use of drugs by injection?	□ YES □ NO
Has the member completed or is currently in a treatment program from an enrolled addiction medicine/chemical dependency provider (or buprenorphine waived provider if history of IV drug use)? Approximate Dates of Treatment (REQUIRED, if applicable):	□ YES □ NO Attested by: □ PROVIDER □ PATIENT
Please provide the name of the enrolled addiction medicine/chemical dependency treatment provider/facility name, if applicable:	
Does the member have Hepatitis B?	□ YES □ NO
If the member has Hepatitis B, has it been treated or will it be closely monitored during treatment?	□ YES □ NO
Is the member post-liver transplant?	□ YES □ NO
Is the member's life expectancy greater than one year?	□ YES □ NO
Does the member attend scheduled visits with no more than 1 no-show and fill maintenance medications on time?	□ YES □ NO
Does the member have any contraindications to therapy with the requested agent?	□ YES □ NO
Is the member going to take Ribavirin alongside treatment?	□ YES □ NO

Please confirm that all of the following is attached to the request, along with any other documentation required, as stated in the PDL:

- o Baseline HCV RNA
- o ≥ 2 drug and alcohol tests dated at least 3 months apart
- o Patient & Prescriber attestation forms
- o Chart notes addressing member's alcohol and drug free status over the past year
- o Documentation of member's fibrosis score if available (e.g. APRI, Fibroscan, Fibrotest)

Prescriber (or Staff) / Pharmacy Signature**	Date

***: By completing this form, I hereby certify that the above request is true, accurate and complete. That the request is medically necessary, does not exceed the medical needs of the member, and is clinically supported in the member's medical records. I also understand that any misrepresentations or concealment of any information requested in the prior authorization request may subject me to audit and recoupment.*

Part II: TO BE COMPLETED BY PHARMACY

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #

Hepatitis C Patient Consent Form

I,_____, have been counseled by my healthcare provider on the following:

I am planning to live in North Dakota during the entire treatment period. I will complete the entire course of treatment, attend office visits, and have laboratory tests as ordered by my healthcare provider during the treatment period.

I will notify my chosen pharmacy of a need to refill one week prior to running out of medication. I understand I must take my medication each day as directed for the entire course of treatment. If the medication does not work due to missed doses, I may not be approved for re-treatment.

I understand to keep my liver healthy, I must not drink alcohol or use illicit injectable drugs prior to, during, or after my treatment. If indicated, I will participate in a treatment program to remain abstinent.

I understand that after treatment, I can be re-infected with Hepatitis C. My provider has educated me on routes of Hepatitis C transmission, and I will avoid or modify high risk activities to avoid re-infection.

I understand that medications that treat Hepatitis C may be harmful to unborn babies. I will use methods to avoid getting pregnant or another person pregnant during treatment and when advised by my provider or pharmacist, for at least 6 months after treatment is complete.

Patient Signature_____**Date** __/__/____

Pharmacy or Prescriber Representative:

Signature _____**Date** __/__/____

By signature, the pharmacy or prescriber representative confirms the contract has been reviewed with the patient

Hepatitis C Prescriber Agreement Form

I agree that I will counsel my patient on how, where, and when to obtain refills on their hepatitis C medications.

I agree that I will have intermittent telephone check-ins with my patient, at minimum at 2 weeks and 6 weeks of treatment. I will assess continued adherence with medication, labs, and office visits, treatment tolerability, as well as medication changes that may affect treatment.

I have reviewed my patient's medications for drug interactions that would make Hepatitis C medications less effective or cause other adverse effects.

I have reviewed the treatment plan with my patient including medications, lab, vaccinations, and follow-up visits.

I have assessed my patient's readiness for treatment and believe they are ready and willing to comply with the treatment plan. I have assessed social and psychological stability, substance use abstinence, compliance to follow up visits and medications, pregnancy status, and concurrent health risks.

I understand that ND Medicaid tracks refill history and may contact me to provide additional information in the event of a dropped or late refill.

I have a dedicated individual or team which may include pharmacy and nursing support to fulfill the elements of this form and have listed key members contact information below.

Name: _____ Location: _____

Phone #: _____

Name: _____ Location: _____

Phone #: _____

Pharmacy or Prescriber Representative:

Signature_____ **Date** __/__/____

Makena
Prior Authorization Form

Fax Completed Form to:
855-207-0250
For questions regarding this Prior authorization, call
866-773-0695

Prior Authorization Vendor for ND

ND Medicaid requires that members receiving a prescription for Makena to meet criteria confirming the medication is being used according to its FDA-approved indication. Please fill out the following form in its entirety.

Part I: TO BE COMPLETED BY PRESCRIBER

Recipient Name	Recipient Date of Birth	Recipient Medicaid ID Number
Prescriber Name	Specialist involved in therapy (if not treating prescriber)	
Prescriber NPI	Telephone Number	Fax Number
Requested Drug and Dosage:	**Diagnosis for this request:**	
Member's Estimated Date of Delivery or Gestational Age of Current Pregnancy (weeks and days):		
Does the member have a history of singleton spontaneous preterm birth? ☐ YES ☐ NO		
Is the member currently pregnant with singleton? ☐ YES ☐ NO		
The U.S. FDA Center for Drug Evaluation and Research proposed that Makena be withdrawn from market after a required post-market study failed to show clinical benefit or efficacy for its approved use. Considering the U.S. FDA proposal for withdrawal of this agent, does the prescriber acknowledge the FDA request to remove Makena from market and deem it medically necessary to use anyway? ☐ YES ☐ NO		
Clinical rationale for using this agent is <u>required</u> for coverage:		
☐ *I confirm that I have considered a generic or other alternative and that the requested drug is expected to result in the successful medical management of the recipient.*		
Prescriber (or Staff) / Pharmacy Signature**		Date
***: By completing this form, I hereby certify that the above request is true, accurate and complete. That the request is medically necessary, does not exceed the medical needs of the member, and is clinically supported in the member's medical records. I also understand that any misrepresentations or concealment of any information requested in the prior authorization request may subject me to audit and recoupment.*		

Part II: TO BE COMPLETED BY PHARMACY

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #

Mifeprex
Prior Authorization Form

Fax Completed Form to:
855-207-0250
For questions regarding this Prior authorization, call
866-773-0695

Prior Authorization Vendor for ND

ND Medicaid requires that members receiving a new prescription for Mifeprex must meet the following criteria:

- **Member must have an FDA approved indication for the medication requested.**
- **Prescriber must provide signed written statement as listed in the Mifeprex Prior Authorization Criteria at** www.hidesigns.com/assets/files/ndmedicaid/NDPDL.pdf

Part I: TO BE COMPLETED BY PRESCRIBER

Recipient Name	Recipient Date of Birth	Recipient Medicaid ID Number	
Prescriber Name			
Prescriber Medicaid Provider Number	Telephone Number	Fax Number	
Address	City	State	Zip Code
Requested Drug and Dosage:	**FDA approved indication for this request:**		

- **Is the member terminating a pregnancy before 70 days of gestation? □ YES □ NO**
- **Is the member resulting from an act of rape or incest? □ YES □ NO** (If yes, please attach written statements as outlined in section 1 below)
- **Does the woman suffer from a physical disorder that would place the woman in danger of death unless abortion is performed? □ YES □ NO** (If yes, please attach a written statement as outlined in section 2 below)

Section 1:

- The provider has provided a signed written statement indicating 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. The statement must indicate to whom the report was made.
- The provider has provided written statement signed by the recipient and the provider that the recipient's pregnancy resulted from rape or incest and by professional judgement, the provider agrees with the woman's statement.

Section 2:

- The provider must provide a signed written statement indicating why, in the provider's professional judgement, the life of a woman would be endangered if the fetus were carried to term

Prescriber (or Staff) / Pharmacy Signature**	Date

***: By completing this form, I hereby certify that the above request is true, accurate and complete. That the request is medically necessary, does not exceed the medical needs of the member, and is clinically supported in the member's medical records. I also understand that any misrepresentations or concealment of any information requested in the prior authorization request may subject me to audit and recoupment.*

Part II: TO BE COMPLETED BY PHARMACY

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #

Kepro

Migraine Prophylaxis/Treatment Prior Authorization Form

Fax Completed Form to: 855-207-0250 For questions regarding this Prior authorization, call 866-773-0695

Prior Authorization Vendor for ND

ND Medicaid requires that members receiving a prescription for migraine prophylaxis/treatment must meet the following criteria:

Prophylaxis Initial Requests:

- Member must experience 3 or more migraine days per month.
- Member must submit documentation of treatment failure of a 2-month trial of two preferred agents from different therapeutic classes. Documentation must include clinical notes regarding failure to reduce migraine frequency.

Prophylaxis Renewal Requests: Member must experience a reduction in migraines of at least 50%

Treatment Initial Requests:

- Member must have had 30-day trials of two triptans (5HT-1 agonists) within the past 2 years

Part I: TO BE COMPLETED BY PRESCRIBER

Recipient Name	Recipient Date of Birth	Recipient Medicaid ID Number	
Prescriber Name	Specialist involved in therapy (if not treating prescriber)		
Prescriber NPI	Telephone Number	Fax Number	
Address	City	State	Zip Code
Requested Drug and Dosage:	**Diagnosis for this request:**		
Number of experienced migraine days per month:			
How will the requested product be used? ☐ Prophylaxis ☐ Treatment			
List all failed medications:		**Start Date:**	**End Date:**
Additional Qualifications for Coverage (e.g. medical justification explaining inability to meet required trials)			
☐ *I confirm that I have considered a generic or other alternative and that the requested drug is expected to result in the successful medical management of the recipient.*			
Prescriber (or Staff) / Pharmacy Signature**		Date	
**: *By completing this form, I hereby certify that the above request is true, accurate and complete. That the request is medically necessary, does not exceed the medical needs of the member, and is clinically supported in the member's medical records. I also understand that any misrepresentations or concealment of any information requested in the prior authorization request may subject me to audit and recoupment.*			

Part II: TO BE COMPLETED BY PHARMACY

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #

Nuedexta
Prior Authorization Form

Fax Completed Form to:
855-207-0250
For questions regarding this Prior authorization, call
866-773-0695

Prior Authorization Vendor for ND

ND Medicaid requires that members receiving a new prescription for Nuedexta must meet the following criteria:

Initial Criteria

- Member must be 18 years of age or older
- Member must not have a prolonged QT interval, heart failure, or complete atrioventricular block
- Member's baseline CNS-LS and weekly PBA episode count must be provided
- Member must have a diagnosis of PBA due to one of the following conditions: ALS, MS, Alzheimer's disease, or stroke

For PBA due to Alzheimer's disease or stroke

- Neurologic condition must have been stable for at least 3 months
- Member must have failed a 3-month trial of one medication from BOTH classes listed: SSRIs (sertraline, fluoxetine, citalopram, and paroxetine) and Tricyclic Antidepressants (nortriptyline or amitriptyline)
  - A PBA episode count and CNS-LS score must be provided for before and after each trial

Renewal Criteria

- Benefit of renewal must be assessed
- Baseline and current PBA episode count must be included with request
- Current PBA episode count must be a 75 percent decrease from baseline

For PBA due to Alzheimer's disease or stroke

- Baseline and current Center for Neurological Studies lability (CNS-LS) must be included with request
- Current CNS-LS score must be a 30% decrease from baseline

Part I: TO BE COMPLETED BY PRESCRIBER

Recipient Name	Recipient Date of Birth	Recipient Medicaid ID Number
Prescriber Name	Specialist involved in therapy (if not treating prescriber)	
Prescriber NPI	Telephone Number	Fax Number
Requested Drug and Dosage:	**Diagnosis for this request (include cause of PBA):**	
List all failed medications:	**Start Date (PBA Count at Start):**	**End Date (PBA Count at End):**
Does the member have a prolonged QT interval, heart failure, or complete atrioventricular (AV) block? ☐ YES ☐ NO Has the neurologic condition been stable for at least 3 months? ☐ YES ☐ NO		
Baseline CNS-LS:	Baseline weekly PBA episode count:	Current CNS-LS: / Current weekly PBA episode count:
Prescriber (or Staff) / Pharmacy Signature**	Date	
**: *By completing this form, I hereby certify that the above request is true, accurate and complete. That the request is medically necessary, does not exceed the medical needs of the member, and is clinically supported in the member's medical records. I also understand that any misrepresentations or concealment of any information requested in the prior authorization request may subject me to audit and recoupment.*		

Part II: TO BE COMPLETED BY PHARMACY

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #

Kepro

Opioid Analgesics
Prior Authorization Form

Fax Completed Form to:
855-207-0250
For questions regarding this Prior authorization, call
866-773-0695

Prior Authorization Vendor for ND

ND Medicaid requires that members receiving a long-acting opioid analgesic must meet the following criteria:

- Member must have required around-the-clock pain relief for the past 90 days
- The past 3 months of North Dakota PDMP reports must have been reviewed by the prescriber.
- Member must be in consult with oncologist or pain management specialist with a pain management contract (with treatment plan including goals for pain and function, and urine and/or blood screens) if:
  - Cumulative daily dose of narcotics exceed 90 MED/day
  - Member is using benzodiazepine concurrently with narcotic medication
- Member must have 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.)

  *** For additional and agent-specific criteria, please see criteria for coverage in the Preferred Drug List at www.hidesigns.com/assets/files/ndmedicaid/NDPDL.pdf**

Part I: TO BE COMPLETED BY PRESCRIBER

Recipient Name	Recipient Date of Birth	Recipient Medicaid ID Number
Prescriber Name	Pain, Palliative Care, or Oncology/Hematology Specialist involved in therapy (if not treating prescriber):	
Prescriber NPI	Telephone Number	Fax Number
Requested Opioid Analgesic:	**Diagnosis for use of opioid(s) in this member:**	

List All Failed/Current Medications:	**Dose and Frequency:**	**Start/End Date:**	**Reason for failure:**
☐ NSAIDs ☐ TCAs ☐ SNRIs ☐ Corticosteroids ☐ Weight Loss ☐ Physical Therapy ☐ Cognitive Behavioral Therapy ☐ Other:			

Qualifications for coverage:	
Have the past 3 months of North Dakota PDMP reports been reviewed by the prescriber?	☐ YES ☐ NO
Has the provider established a realistic treatment plan with the member, addressing expected outcomes and limitations of therapy in eliminating pain?	☐ YES ☐ NO
Does the patient undergo routine drug screens?	☐ YES ☐ NO

Please confirm that all the following is attached to the request, along with any other relevant documentation:

☐ Member's treatment plan including an evaluation of effectiveness and plans for continuation/discontinuation
☐ Clinical documentation of previously tried and failed non-opioid therapies.

Prescriber (or Staff) / Pharmacy Signature**	Date

**: *By completing this form, I hereby certify that the above request is true, accurate and complete. That the request is medically necessary, does not exceed the medical needs of the member, and is clinically supported in the member's medical records. I also understand that any misrepresentations or concealment of any information requested in the prior authorization request may subject me to audit and recoupment.*

Kepro

Underutilization
Prior Authorization Form

Fax Completed Form to:
855-207-0250
For questions regarding this Prior authorization, call
866-773-0695

Part I: TO BE COMPLETED BY PRESCRIBER

Recipient Name	**Recipient Date of Birth**	Recipient Medicaid ID Number	
Prescriber Name	**(SAMHSA ID-X DEA Number)**		
Prescriber NPI	Telephone Number	Fax Number	
Address	City	State	Zip Code
Requested Drug and Dosage:	**FDA Approved Indication for this request:**		

Has a contract between the prescriber and member been signed?
□ YES □ NO
Does the prescriber perform routine drug screens?
□ YES □ NO
Does the prescriber routinely check the PDMP system?
□ YES □ NO
Does the patient have access to naloxone rescue therapy?
□ YES □ NO
Is the patient pregnant or breastfeeding? Due date, if pregnant: _____
□ YES □ NO
Has the patient experienced a gap in therapy? Please, fill out page 2 to request override for underuse rejection. ***
□ YES □ NO

☐ *I confirm that I have considered a generic or other alternative and that the requested drug is expected to result in the successful medical management of the recipient.*

Prescriber (or Staff) / Pharmacy Signature**	Date

**: *By completing this form, I hereby certify that the above request is true, accurate and complete. That the request is medically necessary, does not exceed the medical needs of the member, and is clinically supported in the member's medical records. I also understand that any misrepresentations or concealment of any information requested in the prior authorization request may subject me to audit and recoupment.*

Part II: TO BE COMPLETED BY PHARMACY

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #

Opioid Use Disorder Medications Gap in therapy***	
What is the reason for the gap in therapy?	
☐ **Non-adherence**	Identified adherence barriers:
	Treatment plan adjustments to improve adherence:
☐ **Other (please explain – e.g., hospitalization, eligibility, etc.):**	
Has the patient been re-assessed for readiness of treatment?	
Why isn't the patient a candidate for a long-acting injectable buprenorphine product?	
Has the patient been counseled regarding the increased risk of overdose during relapse (due to decreased tolerance during periods of treatment) if they go back to the same dose of the drug of abuse?	

Palforzia
Prior Authorization Form

Fax Completed Form to:
855-207-0250
For questions regarding this Prior authorization, call
866-773-0695

Prior Authorization Vendor for ND

ND Medicaid requires that members receiving a prescription for Palforzia to meet criteria confirming the medication is being used according to its FDA-approved indication. Please fill out the following form in its entirety.

Part I: TO BE COMPLETED BY PRESCRIBER

Recipient Name	Recipient Date of Birth	Recipient Medicaid ID Number
Prescriber Name	Specialist involved in therapy (if not treating prescriber)	
Prescriber NPI	Telephone Number	Fax Number
Requested Drug and Dosage:	**Diagnosis for this request:**	

Does the member have uncontrolled asthma?	☐ YES	☐ NO
Has the member experienced severe or life-threatening anaphylaxis in the 60 days?	☐ YES	☐ NO
Does the member have a history of eosinophilic esophagitis or another eosinophilic GI disease?	☐ YES	☐ NO
Has the member/caregiver been educated on appropriate use of epinephrine?	☐ YES	☐ NO
RENEWAL ONLY: Does the member continue to have a peanut allergy and has been/is being monitored for resolution of their allergy?	☐ YES	☐ NO
RENEWAL ONLY: Has the member been able to tolerate the maintenance dose of Palforzia (300	☐ YES	☐ NO

Additional Qualifications for Coverage (*if applicable*)

☐ *I confirm that I have considered a generic or other alternative and that the requested drug is expected to result in the successful medical management of the recipient.*

Prescriber (or Staff) / Pharmacy Signature**	Date

**: *By completing this form, I hereby certify that the above request is true, accurate and complete. That the request is medically necessary, does not exceed the medical needs of the member, and is clinically supported in the member's medical records. I also understand that any misrepresentations or concealment of any information requested in the prior authorization request may subject me to audit and recoupment.*

Part II: TO BE COMPLETED BY PHARMACY

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #

Phenylketonuria Agents
Prior Authorization Form

Fax Completed Form to:
855-207-0250
For questions regarding this Prior authorization, call
866-773-0695

Prior Authorization Vendor for ND

ND Medicaid requires that members receiving a new prescription for a phenylketonuria agent must meet the following criteria:

- **Member must have hyperphenalaninemia.**
- **Member must be following a PHE restricted diet.**

Part I: TO BE COMPLETED BY PRESCRIBER

Recipient Name	**Recipient Date of Birth**	Recipient Medicaid ID Number	
Prescriber Name			
Prescriber NPI	Telephone Number	Fax Number	
Address	City	State	Zip Code

Requested Drug and Dosage:	**PHE level:**	**Diagnosis for this Request:**	**Member's weight:**

Has the member been known to have two null mutations in TRANS?	☐ YES	☐ NO
Are baseline PHE levels attached?	☐ YES	☐ NO
Is the member of child-bearing potential?	☐ YES	☐ NO
Is this a renewal request?	☐ YES	☐ NO
Has the member been compliant with diet and medications for past 6 months?	☐ YES	☐ NO

☐ I confirm that I have considered a generic or other alternative and that the requested drug is expected to result in the successful medical management of the recipient.

Prescriber (or Staff) / Pharmacy Signature**	Date

**: *By completing this form, I hereby certify that the above request is true, accurate and complete. That the request is medically necessary, does not exceed the medical needs of the member, and is clinically supported in the member's medical records. I also understand that any misrepresentations or concealment of any information requested in the prior authorization request may subject me to audit and recoupment.*

Part II: TO BE COMPLETED BY PHARMACY

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #

Sedative/Hypnotic
Prior Authorization Form

Fax Completed Form to:
855-207-0250
For questions regarding this Prior authorization, call
866-773-0695

Prior Authorization Vendor for ND

ND Medicaid requires that members receiving a sedative/hypnotic must meet the agent criteria located on the Preferred Drug List (PDL), located on the North Dakota Department of Human Services Prior Authorization website at http://www.hidesigns.com/ndmedicaid.

Note:

- **Requires step therapy. See Sedative/Hypnotic PA criteria for more information.**
  - Zolpidem: Initiation with trial of 5 mg must be used for 7 days within 90 days prior to 10 mg tablets
  - Belsomra: The member must have had a 25- day trial of eszopiclone within the past 90 days

Part I: TO BE COMPLETED BY PRESCRIBER

Recipient Name	Recipient Date of Birth	Recipient Medicaid ID Number
Prescriber Name		
Prescriber NPI	Telephone Number	Fax Number
Requested Drug and Dosage:	**Diagnosis for this request:**	
Qualifications for coverage:		
List all failed medications:	**Start Date:**	**End Date:**

Have other conditions causing sleep issues been ruled out?	☐ YES ☐ NO
Does the member require dose tapering?	☐ YES ☐ NO
Is the member's insomnia characterized by difficulty with sleep maintenance?	☐ YES ☐ NO
Is the member's insomnia characterized by difficulty with sleep initiation?	☐ YES ☐ NO
Is the member's insomnia characterized by difficulty with middle of the night awakening with more than 4 hours left to sleep?	☐ YES ☐ NO
Is the member blind in both eyes? (For non-24 hour sleep-wake disorder)	☐ YES ☐ NO

☐ *I confirm that I have considered a generic or other alternative and that the requested drug is expected to result in the successful medical management of the recipient.*

Prescriber (or Staff) / Pharmacy Signature**	Date

***: By completing this form, I hereby certify that the above request is true, accurate and complete. That the request is medically necessary, does not exceed the medical needs of the member, and is clinically supported in the member's medical records. I also understand that any misrepresentations or concealment of any information requested in the prior authorization request may subject me to audit and recoupment.*

Part II: TO BE COMPLETED BY PHARMACY

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #

Kepro

SYNAGIS WEB BASED FORM

Submit online or fax completed form to: 855-207-0250

For questions regarding this prior authorization, call 866-773-0695

Prior Authorization Vendor for ND Medicaid

Note:

- RSV season will be determined based on RSV prevalence in the CDC NREVSS Midwest Region
- Clinicians may administer up to a maximum of 5 monthly weight-based doses during the RSV season
- Qualifying infants born during the RSV season may require fewer doses.

TO BE COMPLETED BY PRESCRIBER

Recipient Medicaid ID Number	Recipient Date of Birth	Recipient Weight (kg)	Prescriber NPI	Prescriber Fax Number

Billing Facility NPI	Billing Facility Name	ICD-10 code

Is this request for dose from the current RSV season, last RSV season, or both (please select one)?

☐ Previous Year's RSV season ☐ Current Year's RSV Season ☐ Both

Diagnosis (qualification for Synagis)

☐ **Prematurity** (max of 5 doses)
< 29 weeks, 0 days gestational age – Synagis allowed if younger than 12 months of age at the start of RSV season
Gestational Age (e.g., 28 weeks, 4 days)
Weeks _____ **Days** _____

☐ **Chronic Lung Disease of Prematurity (CLD)** – Child ≤12 months old with gestational age <32 weeks, 0 days and requires supplemental oxygen >21% for at least the first 28 days after birth.

☐ **Chronic Lung Disease of Prematurity (CLD)** – Child ≤24 months old with gestational age <32 weeks, 0 days ad requires supplemental oxygen >21% for at least the first 28 days after birth and continues to receive medical support within six months before the start of RSV season.

- ☐ Supplemental Oxygen
- ☐ Diuretic
- ☐ Chronic corticosteroid therapy

☐ **Congenital Heart Disease (CHD)** – Child ≤12 months old with hemodynamically significant cyanotic or acyanotic CHD
Medical Therapy Required _____

*Children less than 24 months who undergo cardiac transplant during RSV season may be considered for prophylaxis

☐ **Neuromuscular disease** (may be considered for prophylaxis during the first year of life)

☐ **Pulmonary abnormalities** (may be considered for prophylaxis during the first year of life)

☐ **Profoundly Immunocompromised children** (children <24 months of age may be considered for prophylaxis during the RSV season)

Tardive Dyskinesia Agents
Prior Authorization Form

Fax Completed Form to:
855-207-0250
For questions regarding this Prior authorization, call
866-773-0695

Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that members receiving a new prescription for Austedo, Ingrezza, or tetrabenazine must meet the following criteria:

Category Criteria

- The member must be 18 years of age or older.
- The prescription must be written by/in consultation with a specialist (neurologist or psychiatrist).
- The member must have a diagnosis of tardive dyskinesia, including the following:
  - Involuntary athetoid or choreiform movements
  - History of treatment with dopamine receptor blocking agent (DRBA)
  - Symptom duration lasting longer than 4-8 weeks
- The member must not be taking monoamine oxidase inhibitor (MAOI)
- The member is not pregnant or breastfeeding

Product Specific Criteria: * Austedo/tetrabenazine:**

- The member must have a diagnosis of Huntington's disease or Tardive Dyskinesia.
- The member must not have hepatic impairment

Part I: TO BE COMPLETED BY PRESCRIBER/PRESCRIBER'S OFFICE

Recipient Name	Recipient Date of Birth	Recipient Medicaid ID Number
Prescriber Name		
Prescriber NPI	Telephone Number	Fax Number
Requested Drug and Dosage:	**FDA approved indication for this request:**	
List all failed medications (drug name, date of trial, reason for failure):		
Qualifications for coverage:		
Does the member's diagnosis include athetoid or choreiform movements?		☐ YES ☐ NO
Has the symptom duration lasted longer than 4-8 weeks?		☐ YES ☐ NO
Is the member pregnant or breastfeeding?		☐ YES ☐ NO
Prescriber (or Staff) / Pharmacy Signature**		Date
**: *By completing this form, I hereby certify that the above request is true, accurate and complete. That the request is medically necessary, does not exceed the medical needs of the member, and is clinically supported in the member's medical records. I also understand that any misrepresentations or concealment of any information requested in the prior authorization request may subject me to audit and recoupment.*		

Part II: TO BE COMPLETED BY PHARMACY

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #

Kepro

Tubeless Insulin Pump (Omnipod)
Prior Authorization Form

Fax Completed Form to:
855-207-0250
For questions regarding this Prior authorization, call
866-773-0695

Prior Authorization Vendor for ND

ND Medicaid requires that patients receiving a prescription for Omnipod meet specific diagnosis and clinical criteria requirements. Criteria for the tubeless insulin pump can be found in the Preferred Diabetic Supplies List (PDSL) available at: www.hidesigns.com/assets/files/ndmedicaid/NDPDL.pdf

Part I: TO BE COMPLETED BY PRESCRIBER/PRESCRIBER'S OFFICE

Recipient Name	Recipient Date of Birth	Recipient Medicaid ID Number	
Prescriber Name	Specialist involved in therapy (if not treating prescriber)		
Prescriber NPI	Telephone Number	Fax Number	
Address	City	State	Zip Code
Requested Product:	**Diagnosis for this request:**		
List all current medications used for control of patient's blood glucose:			

Qualifications for Coverage (please answer all of the questions below)	
Is the prescriber trained in the data management platform used with the Omnipod system?	☐ YES ☐ NO
Will the member maintain regular provider visits to review Omnipod data every 3-6 months?	☐ YES ☐ NO
Has the member been adherent to provider appointments for the past 6 months?	☐ YES ☐ NO
Does the member or caregiver have the mental, physical, auditory, visual, and motivational ability to manage the pump?	☐ YES ☐ NO
Will the member receive Omnipod training from Omnipod System Trainer or a healthcare provider?	☐ YES ☐ NO
Has the member received diabetic education within the past year?	☐ YES ☐ NO
Has the member received a tubed insulin pump within the past 4 years?	☐ YES ☐ NO
Is the member experiencing elevated glucose levels from disconnecting due to contact or swimming sports? *If answered "yes", please provide documentation/clinical notes to support this.	☐ YES ☐ NO

Most recent Time in Range % (if available):	**Patient's current A1c:**

☐ *I confirm that I have considered a generic or other alternative and that the requested DME is expected to result in the successful medical management of the recipient.*

Prescriber (or Staff) / Pharmacy Signature**	Date

***: By completing this form, I hereby certify that the above request is true, accurate and complete. That the request is medically necessary, does not exceed the medical needs of the member, and is clinically supported in the patient's medical records. I also understand that any misrepresentations or concealment of any information requested in the prior authorization request may subject me to audit and recoupment.*

Part II: TO BE COMPLETED BY PHARMACY

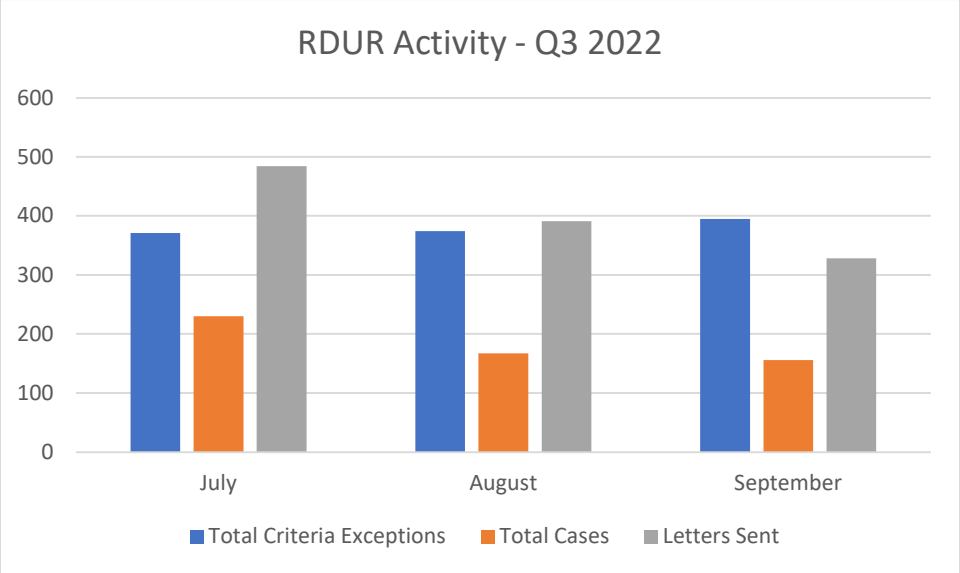
PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #

RDUR Activity Overview: Q3 2022

Jul-22		
Responses	35	
Total Cases	259	
Response Rate	14%	
BENEFITS OF THE DRUG OUTWEIGH THE RISKS	15	43%
PHARMACY CAN'T PROVIDE MD INFORMATION	9	26%
MD WILL REASSESS AND MODIFY DRUG THERAPY	3	9%
PT UNDER MY CARE BUT NOT SEEN RECENTLY	2	6%
TRIED TO MODIFY THERAPY,SX RECURRED	2	6%
PT IS NO LONGER UNDER THIS MD's CARE	1	3%
MD DID NOT RX DRUG ATTRIBUTED TO HIM.	1	3%
MD SAW PATIENT ONLY ONCE IN ER OR AS ON-CALL MD	1	3%
RPH WILL COUNSEL PT ON NEXT VISIT	1	3%

Aug-22		
Responses	41	
Total Cases	226	
Response Rate	18%	
BENEFITS OF THE DRUG OUTWEIGH THE RISKS	13	32%
PHARMACY CAN'T PROVIDE MD INFORMATION	11	31%
MD WILL REASSESS AND MODIFY DRUG THERAPY	4	11%
MD SAW PATIENT ONLY ONCE IN ER OR AS ON-CALL MD	4	11%
PT UNDER MY CARE BUT NOT SEEN RECENTLY	2	6%
PT IS NO LONGER UNDER THIS MD's CARE	2	6%
MD DID NOT RX DRUG ATTRIBUTED TO HIM.	2	6%
MD UNAWARE OF WHAT OTHER MD PRESCRIBING	1	3%
TRIED TO MODIFY THERAPY, PT NON-COOP	1	3%
RPH WILL COUNSEL PT ON NEXT VISIT	1	3%

Sep-22		
Responses	15	
Total Cases	169	
Response Rate	9%	
BENEFITS OF THE DRUG OUTWEIGH THE RISKS	8	53%
PT UNDER MY CARE BUT NOT SEEN RECENTLY	2	6%
TRIED TO MODIFY THERAPY,SX RECURRED	2	6%
MD SAW PATIENT ONLY ONCE IN ER OR AS ON-CALL MD	2	6%
PHARMACY CAN'T PROVIDE MD INFORMATION	1	3%
PT IS NO LONGER UNDER THIS MD's CARE	1	3%



July Cases by Type of Criteria		
Criteria Description	**# of Cases**	**% of Cases**
Clinical Appropriateness	13	5.7%
Drug-Drug Conflicts	37	16.1%
Drug-Disease Interactions	30	13.0%
Overutilization	50	21.7%
Underutilization	100	43.5%

DRUG-DRUG INTERACTIONS: CLOPIDOGREL/OMEPRAZOLE OR ESOMEPRAZOLE
DRUG-DISEASE INTERACTIONS: METFORMIN / HEPATIC IMPAIRMENT
OVERUTILIZATION: SEDATIVE AGENTS
UNDERUTILIZATION: LONG-TERM ASTHMA CONTROLLERS, PIOGLITAZONE, METFORMIN IR/XR

August Cases by Type of Criteria		
Criteria Description	**# of Cases**	**% of Cases**
Drug-disease interaction	6	3.6%
Drug-drug conflicts	60	35.9%
Over-utilization	9	5.4%
Therapeutic duplication	1	0.6%
Non-compliance	91	54.5%

DRUG-DISEASE INTERACTIONS: NSAIDS / HYPERTENSION
DRUG-DRUG INTERACTIONS: ANTIPSYCHOTICS / NARCOTICS
OVERUTILIZATION: SEDATIVE AGENTS
NON-COMPLIANCE: POTASSIUM-SPARING DIURETICS, ADAIR DISKUS

September Cases by Type of Criteria		
Criteria Description	**# of Cases**	**% of Cases**
Drug-disease interactions	112	65.9%
Clinical appropriateness	4	2.4%
Over-utilization	4	2.4%
Non-compliance	50	29.4%

DRUG-DISEASE INTERACTIONS: NSAIDS / ASTHMA, BENZODIAZEPINES / HEPTACTIC IMPAIRMENT
OVERUTILIZATION: BETA AGONISTS
NON-COMPLIANCE: LIPID LOWERING AGENTS, PRENATAL VITAMINS

NORTH DAKOTA MEDICAID

RETROSPECTIVE DRUG UTILIZATION REVIEW

CRITERIA RECOMMENDATIONS

4TH QUARTER 2022

Criteria Recommendations ***Approved Rejected***

1. Tirzepatide / Overuse _____ _____

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

Drugs/Diseases

Util A	Util B	Util C
Tirzepatide		

Max Dose: 15 mg q weekly

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Mounjaro Prescribing Information, May 2022, Eli Lilly and Company.

2. Tirzepatide / Therapeutic Appropriateness _____ _____

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

Drugs/Diseases

Util A	Util B	Util C
Tirzepatide		

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Mounjaro Prescribing Information, May 2022, Eli Lilly and Company.

3. Tirzepatide / Therapeutic Appropriateness _____ _____

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

Drugs/Diseases

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

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Mounjaro Prescribing Information, May 2022, Eli Lilly and Company.

Criteria Recommendations	*Approved*	*Rejected*

4. Tirzepatide / Therapeutic Appropriateness (Black Box Warning) _____ _____

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

Drugs/Diseases

Util A	Util B	Util C
Tirzepatide		

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Mounjaro Prescribing Information, May 2022, Eli Lilly and Company.

5. Tirzepatide / Pancreatitis _____ _____

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

Drugs/Diseases

Util A	Util B	Util C
Tirzepatide	Pancreatitis	

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Mounjaro Prescribing Information, May 2022, Eli Lilly and Company.

6. Tirzepatide / Kidney Injury _____ _____

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

Drugs/Diseases

Util A	Util B	Util C
Tirzepatide	Renal Impairment	

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Mounjaro Prescribing Information, May 2022, Eli Lilly and Company.

7. Tirzepatide / Gastroparesis _____ _____

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

Drugs/Diseases

Util A	Util B	Util C
Tirzepatide	Gastroparesis	

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Mounjaro Prescribing Information, May 2022, Eli Lilly and Company.

8. Tirzepatide / Diabetic Retinopathy _____ _____

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

Drugs/Diseases

Util A	Util B	Util C
Tirzepatide	Diabetic Retinopathy	

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Mounjaro Prescribing Information, May 2022, Eli Lilly and Company.

9. Tirzepatide / Gallbladder Disease _____ _____

Alert Message: Acute events of gallbladder disease such as cholelithiasis or cholecystitis have been reported in GLP-1 receptor agonist (including tirzepatide) trials and postmarketing. In Mounjaro (tirzepatide) placebo-controlled clinical trials, acute gallbladder disease (cholelithiasis, biliary colic, and cholecystectomy) was reported by 0.6% of tirzepatide-treated patients and 0% of placebo-treated patients. If cholelithiasis is suspected, gallbladder diagnostic studies and appropriate clinical follow-up are indicated.

Drugs/Diseases

Util A	Util B	Util C
Tirzepatide	Cholelithiasis	
	Biliary Colic	
	Cholecystitis	

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Mounjaro Prescribing Information, May 2022, Eli Lilly and Company.

Criteria Recommendations ***Approved Rejected***

10. Tirzepatide / Insulin & Insulin Secretagogues _____ _____

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

Drugs/Diseases

Util A	Util B	Util C
Tirzepatide	Insulin	
	Insulin Secretagogues	

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Mounjaro Prescribing Information, May 2022, Eli Lilly and Company.

11. Tirzepatide / Oral Drugs with NTI _____ _____

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

Drugs/Diseases

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

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Mounjaro Prescribing Information, May 2022, Eli Lilly and Company.

12. Tirzepatide / Pregnancy / Pregnancy Negating _____ _____

Alert Message: Available data with Mounjaro (tirzepatide) use in pregnant women are insufficient to evaluate a drug-related risk of major birth defects, miscarriage, or other adverse maternal or fetal outcomes. Based on animal reproduction studies, there may be risks to the fetus from exposure to tirzepatide during pregnancy. Tirzepatide should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Drugs/Diseases

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

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Mounjaro Prescribing Information, May 2022, Eli Lilly and Company.

Criteria Recommendations ***Approved Rejected***

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

Drugs/Diseases

Util A	Util B	Util C
Tirzepatide	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Mounjaro Prescribing Information, May 2022, Eli Lilly and Company.

14. Tirzepatide / Non-adherence _____ _____
Alert Message: Based on refill history, your patient may be under-utilizing Mounjaro (tirzepatide). Nonadherence to the prescribed dosing regimen may result in sub-therapeutic effects, which may lead to decreased outcomes and additional healthcare costs.

Drugs/Diseases

Util A	Util B	Util C
Tirzepatide		

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 on Hospitalization and Mortality Among Patients with Diabetes Mellitus. Arch Intern Med. 2006;166:1836-1841.
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 Non-adherence with Prescription Drugs Among Older Adults. Am J Manag Care. 2011 Feb; 17(2):153-60.
Polonsky WH, Henry RR. Poor Medication Adherence in Type 2 Diabetes: Recognizing the Scope of the Problem and its Key Contributors. Patient Prefer Adherence. 2016 Jul 22;10:1299-1307.

15. Belumosudil / Overuse _____ _____
Alert Message: Rezurock (belumosudil) may be over-utilized. The recommended dose of belumosudil is 200 mg given orally once daily until the progression of chronic GVHD requires new systemic therapy.

Drugs/Diseases

Util A	Util B	Util C (Negating)
Belumosudil		Strong CYP3A4 Inducers
		Proton Pump Inhibitors

Max Dose: 200 mg/day

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Rezurock Prescribing Information, Kadmon Pharmaceuticals, LLC.

Criteria Recommendations ***Approved Rejected***

16. Belumosudil / Therapeutic Appropriateness _____ _____
Alert Message: The safety and effectiveness of Rezurock (belumosudil) in pediatric patients less than 12 years old have not been established.

Drugs/Diseases

Util A	Util B	Util C
Belumosudil		

Age Range: 0 – 11 yoa

References:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Rezurock Prescribing Information, Kadmon Pharmaceuticals, LLC.

17. Belumosudil / Strong CYP3A4 Inducers _____ _____
Alert Message: Coadministration of Rezurock (belumosudil) with strong CYP3A inducers decreases belumosudil exposure, which may reduce the efficacy of belumosudil. If concurrent therapy is warranted, increase the dosage of belumosudil, a CYP3A4 substrate, to 200 mg twice daily when coadministered with strong CYP3A inducers.

Drugs/Diseases

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

References:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Rezurock Prescribing Information, Kadmon Pharmaceuticals, LLC.

18. Belumosudil / Proton Pump Inhibitors _____ _____
Alert Message: Coadministration of Rezurock (belumosudil) with a proton pump inhibitor decreases belumosudil exposure, which may reduce the efficacy of belumosudil. If concurrent therapy is warranted, increase the dosage of belumosudil to 200 mg twice daily when coadministered with a proton pump inhibitor.

Drugs/Diseases

Util A	Util B	Util C
Belumosudil	Dexlansoprazole	
	Esomeprazole	
	Lansoprazole	
	Omeprazole	
	Pantoprazole	
	Rabeprazole	

Minimum Dose: 400 mg/day

References:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Rezurock Prescribing Information, Kadmon Pharmaceuticals, LLC.

19. Belumosudil / Pregnancy / Pregnancy Negating _____ _____

Alert Message: Based on findings in animals and its mechanism of action, Rezurock (belumosudil) can cause fetal harm when administered to a pregnant woman. In animal reproduction studies, administration of belumosudil to pregnant rats and rabbits during the period of organogenesis caused adverse developmental outcomes including embryofetal mortality and malformations at maternal exposures (AUC) less than those in patients at the recommended dose. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential and males with female partners of reproductive potential to use effective contraception during treatment with belumosudil and for at least one week after the last dose.

Drugs/Diseases

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

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Rezurock Prescribing Information, Kadmon Pharmaceuticals, LLC.

20. Belumosudil / Therapeutic Appropriateness _____ _____

Alert Message: There are no data available on the presence of Rezurock (belumosudil) or its metabolites in human milk, or the effects on the breastfed child, or milk production. Because of the potential for serious, adverse reactions from belumosudil in the breastfed child, advise lactating women not to breastfeed during treatment with belumosudil and for at least one week after the last dose.

Drugs/Diseases

Util A	Util B	Util C
Belumosudil	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Rezurock Prescribing Information, Kadmon Pharmaceuticals, LLC.

21. Belumosudil / Therapeutic Appropriateness _____ _____

Alert Message: Advise females of reproductive potential to use effective contraception during treatment with Rezurock (belumosudil) and for at least one week after the last dose of belumosudil. If this drug is used during pregnancy or if the patient becomes pregnant while taking this drug, the patient should be informed of the potential hazard to a fetus.

Drugs/Diseases

Util A	Util B	Util C
Belumosudil		

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Rezurock Prescribing Information, Kadmon Pharmaceuticals, LLC.

Criteria Recommendations ***Approved Rejected***

22. Belumosudil / Therapeutic Appropriateness _____ _____

Alert Message: Advise males with partners of reproductive potential to use effective contraception during treatment with Rezurock (belumosudil) and for at least one week after the last dose of belumosudil.

Drugs/Diseases

Util A	Util B	Util C
Belumosudil		

Gender: Male

References:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Rezurock Prescribing Information, Kadmon Pharmaceuticals, LLC.

23. Belumosudil / Non-adherence _____ _____

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

Drugs/Diseases

Util A	Util B	Util C
Belumosudil		

References:
Osterberg L, Blaschke T. Adherence to Medication. N Engl J Med. 2005;353:487-97.

Ruddy K, Mayer E, Partridge A. Patient Adherence and Persistence With Oral Anticancer Treatment. CA Cancer J Clin 2009;59:56-66.

Greer JA, Amoyal N, Nisotel L, et al. Systemic Review of Adherence to Oral Antineoplastic Therapies. The Oncologist. 2016;21:354-376.

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.1273

24. Benralizumab / Therapeutic Appropriateness _____ _____

Alert Message: The safety and efficacy of Fasenra (benralizumab) in pediatric patients less than 12 years of age have not been established.

Drugs/Diseases

Util A	Util B	Util C
Benralizumab		

Age Range: 0 – 11 yoa

References:

Clinical Pharmacology, 2022 Elsevier/Gold Standard.

Fasenra Prescribing Information, June 2022, AstraZeneca.

25. Benralizumab / Helminth Infections _____ _____

Alert Message: Treat patients with pre-existing helminth infections before initiating therapy with Fasenra (benralizumab). If patients become infected while receiving treatment with benralizumab and do not respond to anti-helminth treatment, discontinue treatment with benralizumab until the infection resolves.

Drugs/Diseases

Util A	Util B	Util C
Tezepelumab-ekko	Helminth Infection	

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Fasenra Prescribing Information, June 2022, AstraZeneca.

26. Benralizumab / Pregnancy / Pregnancy Negating _____ _____

Alert Message: The data on pregnancy exposure from the clinical trials for Fasenra (benralizumab) are insufficient to inform on drug-associated risk. Monoclonal antibodies such as benralizumab are transported across the placenta during the third trimester of pregnancy; therefore, potential effects on a fetus are likely to be greater during the third trimester of pregnancy.

Drugs/Diseases

Util A	Util B	Util C (Negating)
Tezepelumab-ekko	Pregnancy	Abortion
		Delivery
		Miscarriage

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Fasenra Prescribing Information, June 2022, AstraZeneca.

27. Benralizumab / Lactation _____ _____

Alert Message: There is no information regarding the presence of Fasenra (benralizumab) in human or animal milk, and the effects of benralizumab on the breastfed infant and milk production are not known. However, benralizumab is a humanized monoclonal antibody (IgG1/κ-class), and immunoglobulin G (IgG) is present in human milk in small amounts. If benralizumab is transferred into human milk, the effects of local exposure in the gastrointestinal tract and potential limited systemic exposure in the infant to benralizumab are unknown. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for benralizumab and any potential adverse effects on the breast-fed child from benralizumab or the underlying maternal condition.

Drugs/Diseases

Util A	Util B	Util C
Tezepelumab-ekko	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Fasenra Prescribing Information, June 2022, AstraZeneca.

Criteria Recommendations ***Approved Rejected***

28. Afatinib / Overuse _____ _____
Alert Message: Gilotrif (afatinib) may be over-utilized. The recommended dosage of afatinib is 40 mg orally once daily until disease progression or no longer tolerated by the patient.

Drugs/Diseases

Util A	Util B	Util C (Negating)
Afatinib		CKD Stage 4, 5, & ESRD

Max Dose: 40 mg/day

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Gilotrif Prescribing Information, April 2022, Boehringer Ingelheim Pharmaceuticals, Inc.

29. Afatinib / Therapeutic Appropriateness _____ _____
Alert Message: The safety and effectiveness of Gilotrif (afatinib) in pediatric patients have not been established.

Drugs/Diseases

Util A	Util B	Util C
Afatinib		

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Gilotrif Prescribing Information, April 2022, Boehringer Ingelheim Pharmaceuticals, Inc.

30. Afatinib / Overuse – Severe Renal Impairment _____ _____
Alert Message: Gilotrif (afatinib) may be over-utilized. The recommended dosage of afatinib in patients with pre-existing severe renal impairment (estimated glomerular filtration rate [eGFR] 15 to 29 mL/min /1.73 m2) is 30 mg orally once daily. The eGFR should be determined by Modification of Diet in Renal Disease formula.

Drugs/Diseases

Util A	Util B	Util C (Include)
Afatinib		CKD Stage 4

Max Dose: 30 mg/day

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Gilotrif Prescribing Information, April 2022, Boehringer Ingelheim Pharmaceuticals, Inc.

31. Afatinib / Therapeutic Appropriateness _____ _____

Alert Message: Gilotrif (afatinib) has not been studied in patients with eGFR < 15 mL/min/1.73m2 or on dialysis. Patients with severe renal impairment have a higher exposure to afatinib than patients with normal renal function.

Drugs/Diseases

Util A	Util B	Util C
Afatinib	CKD Stage 5	
	ESRD	
	Dialysis	

References:

Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Gilotrif Prescribing Information, April 2022, Boehringer Ingelheim Pharmaceuticals, Inc.

32. Afatinib / Hepatic Impairment _____ _____

Alert Message: Hepatotoxicity has occurred in patients treated with Gilotrif (afatinib). Obtain periodic liver testing in patients during treatment with afatinib. Withhold afatinib in patients who develop worsening of liver function. In patients who develop severe hepatic impairment while taking afatinib, discontinue treatment.

Drugs/Diseases

Util A	Util B	Util C
Afatinib	Hepatic Impairment	

References:

Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Gilotrif Prescribing Information, April 2022, Boehringer Ingelheim Pharmaceuticals, Inc.

33. Afatinib / Interstitial Lung Disease _____ _____

Alert Message: Gilotrif (afatinib) can cause interstitial lung disease (ILD) or ILD-like adverse reactions. Monitor the patient for new or worsening pulmonary symptoms indicative of ILD/pneumonitis (e.g., dyspnea, cough, fever). Withhold afatinib during evaluation of patients with suspected ILD and discontinue afatinib in patients with confirmed ILD and discontinue afatinib in patients with confirmed ILD.

Drugs/Diseases

Util A	Util B	Util C
Afatinib	Cough	
	Dyspnea	
	Fever	
	Acute Interstitial Pneumonia	

References:

Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Gilotrif Prescribing Information, April 2022, Boehringer Ingelheim Pharmaceuticals, Inc.

34. Afatinib / Gastrointestinal Perforation _____ _____

Alert Message: Gastrointestinal perforation, including fatal cases, has occurred with Gilotrif (afatinib). Patients receiving concomitant corticosteroids, nonsteroidal anti-inflammatory drugs (NSAIDs) or anti-angiogenic agents, or patients with increasing age or who have an underlying history of gastrointestinal ulceration, underlying diverticular disease or bowel metastases may be at increased risk of perforation. Permanently discontinue afatinib in patients who develop gastrointestinal perforation.

Drugs/Diseases

Util A	Util B	Util C
Afatinib	Diverticulitis	
	GI Perforation	
	Anti-Angiogenic Agents	
	NSAIDS	

References:

Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Gilotrif Prescribing Information, April 2022, Boehringer Ingelheim Pharmaceuticals, Inc.

35. Afatinib / Keratitis _____ _____

Alert Message: Keratitis has occurred in patients treated with Gilotrif (afatinib). Advise patients to immediately report eye problems (e.g., eye pain, swelling, redness, blurred vision, or other vision changes). Withhold afatinib during evaluation of patients with suspected keratitis, and if diagnosis of ulcerative keratitis is confirmed, interrupt or discontinue afatinib. If keratitis is diagnosed, the benefits and risks of continuing treatment should be carefully considered. Afatinib should be used with caution in patients with a history of keratitis, ulcerative keratitis, or severe dry eye. Contact lens use is also a risk factor for keratitis and ulceration.

Drugs/Diseases

Util A	Util B	Util C
Afatinib	Keratitis	
	Visual Disturbances	

References:

Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Gilotrif Prescribing Information, April 2022, Boehringer Ingelheim Pharmaceuticals, Inc.

36. Afatinib / P-gp Inhibitors _____ _____

Alert Message: The concurrent use of Gilotrif (afatinib), a P-gp substrate, with a P-gp inhibitor can result in increased afatinib exposure. Reduce the afatinib daily dose by 10 mg if not tolerated for patients who require therapy with a P-gp inhibitor. Resume the previous afatinib dose after discontinuation of the P-gp inhibitor as tolerated.

Drugs/Diseases

Util A	Util B	Util C
Afatinib	Amiodarone	
	Cyclosporine	
	Erythromycin	
	Itraconazole	
	Ketoconazole	
	Nelfinavir	
	Quinidine	
	Ritonavir	
	Saquinavir	
	Tacrolimus	
	Verapamil	

References:

Clinical Pharmacology, 2022 Elsevier/Gold Standard.

Gilotrif Prescribing Information, April 2022, Boehringer Ingelheim Pharmaceuticals, Inc.

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

37. Afatinib / P-gp Inducers _____ _____

Alert Message: The concurrent use of Gilotrif (afatinib), a P-gp substrate, with a P-gp inducer can result in decreased afatinib exposure. Increase the afatinib daily dose by 10 mg as tolerated for patients who require chronic therapy with a P-gp inducer. Resume the previous afatinib dose 2 to 3 days after discontinuation of the P-gp inducer.

Drugs/Diseases

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

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Gilotrif Prescribing Information, April 2022, Boehringer Ingelheim Pharmaceuticals, Inc.

38. Afatinib / Pregnancy / Pregnancy Negating _____ _____

Alert Message: There are no available data on the use of Gilotrif (afatinib) in pregnant women. Based on findings from animal studies and its mechanism of action, afatinib 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.

Drugs/Diseases

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

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Gilotrif Prescribing Information, April 2022, Boehringer Ingelheim Pharmaceuticals, Inc.

39. Afatinib / Therapeutic Appropriateness _____ _____

Alert Message: There are no data on the presence of Gilotrif (afatinib) in human milk or its effects on the breastfed infant or milk production. Afatinib was present in the milk of lactating rats. Because of the potential for serious adverse reactions in breastfed infants from afatinib, advise women not to breastfeed during treatment with afatinib and for 2 weeks after the final dose.

Drugs/Diseases

Util A	Util B	Util C
Afatinib	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Facts & Comparisons, 2022 Updates, Wolters Kluwer Health.

Criteria Recommendations ***Approved Rejected***

40. Afatinib / Therapeutic Appropriateness _____ _____
Alert Message: Advise females of reproductive potential to use effective contraception during treatment and for at least 2 weeks after the last dose of Gilotrif (afatinib). Based on findings from animal studies and its mechanism of action, afatinib can cause fetal harm when administered to a pregnant woman.

Drugs/Diseases

Util A	Util B	Util C (Include)
Afatinib		Contraceptives

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Gilotrif Prescribing Information, April 2022, Boehringer Ingelheim Pharmaceuticals, Inc.

41. Afatinib / Non-adherence _____ _____
Alert Message: Based on refill history, your patient may be under-utilizing Gilotrif (afatinib). Non-adherence to the prescribed dosing regimen may result in sub-therapeutic effects, which may lead to decreased patient outcomes and additional healthcare costs.

Drugs/Diseases

Util A	Util B	Util C
Afatinib		

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.1273
Greer JA, Amoyal N, Nisotel L, et al. Systemic Review of Adherence to Oral Antineoplastic Therapies. The Oncologist. 2016;21:354-376.

42. Mobocertinib / Overuse _____ _____
Alert Message: Exkivity (mobocertinib) may be over-utilized. The recommended dosage of mobocertinib is 160 mg orally once daily until disease progression or unacceptable toxicity.

Drugs/Diseases

Util A	Util B	Util C
Mobocertinib		

Max Dose: 160 mg/day

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Exkivity Prescribing Information, September 2021, Takeda Pharmaceuticals America.

Recommendations ***Approved Rejected***

43. Mobocertinib / Therapeutic Appropriateness _____ _____
Alert Message: The safety and effectiveness of Exkivity (mobocertinib) in pediatric patients have not been established.

Drugs/Diseases

Util A	Util B	Util C
Mobocertinib		

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Exkivity Prescribing Information, September 2021, Takeda Pharmaceuticals America.

44. Mobocertinib / Therapeutic Appropriateness (Black Box) _____ _____
Alert Message: Exkivity (mobocertinib) can cause life-threatening heart rate-corrected QT (QTc) prolongation, including Torsades de Pointes, which can be fatal, and requires monitoring of QTc and electrolytes at baseline and periodically during treatment. Assess QTc and electrolytes at baseline and correct abnormalities in sodium, potassium, calcium, and magnesium before initiating mobocertinib. Monitor QTc and electrolytes periodically during treatment. Increase monitoring frequency in patients with risk factors for QTc prolongation, such as patients with congenital long QT syndrome, heart disease, or electrolyte abnormalities. Withhold, reduce the dose, or permanently discontinue mobocertinib based on the severity of QTc prolongation.

Drugs/Diseases

Util A	Util B	Util C
Mobocertinib	QT Prolongation	

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Exkivity Prescribing Information, September 2021, Takeda Pharmaceuticals America.

Recommendations ***Approved Rejected***

45. Mobocertinib / QT Prolonging Drugs (Black Box) _____ _____

Alert Message: Exkivity (mobocertinib) can cause life-threatening heart rate-corrected QT (QTc) prolongation, including Torsades de Pointes, which can be fatal and requires monitoring of QTc and electrolytes at baseline and periodically during treatment. Avoid the use of concomitant drugs, which are known to prolong the QTc interval.

Drugs/Diseases

Util A	Util B				Util C
Mobocertinib	Abiraterone	Efavirenz	Levofloxacin	Rilpivirine	
	Alfuzosin	Eliglustat	Lithium	Risperidone	
	Amiodarone	Encorafenib	Lofexidine	Ritonavir	Amitriptyline
	Entrectinib	Loperamide	Romidepsin		
	Anagrelide	Eribulin	Maprotiline	Saquinavir	
	Aripiprazole	Erythromycin	Methadone	Sertraline	
	Arsenic Trioxide	Escitalopram	Metoclopramide	Siponimod	
	Asenapine	Ezogabine	Midostaurin	Solifenacin	
	Atazanavir	Famotidine	Mifepristone	Sotalol	
	Atomoxetine	Felbamate	Mirabegron	Sunitinib	
	Azithromycin	Fingolimod	Mirtazapine	Tacrolimus	
	Bedaquiline	Flecainide	Moexipril	Tamoxifen	
	Bortezomib	Fluconazole	Moxifloxacin	Telavancin	
	Bendamustine	Fluoxetine	Nelfinavir	Tetrabenazine	
	Bosutinib	Fluvoxamine	Nilotinib	Thioridazine	
	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	Pazopanib	Venlafaxine	
	Crizotinib	Ibutilide	Pentamidine	Voriconazole	
	Dabrafenib	Iloperidone	Pimavanserin		
	Dasatinib	Imipramine	Pimozide		
	Desipramine	Indapamide	Pitolisant		
	Deutetrabenazine	Indinavir	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, 2022 Elsevier/Gold Standard.
Exkivity Prescribing Information, September 2021, Takeda Pharmaceuticals America.

Recommendations	*Approved*	*Rejected*

46. Mobocertinib / Strong CYP3A4 Inhibitors (Black Box) _____ _____

Alert Message: Coadministration of Exkivity (mobocertinib) with a strong CYP3A4 inhibitor should be avoided. Mobocertinib is a CYP3A4 substrate, and concurrent use with a strong CYP3A4 inhibitor may significantly increase mobocertinib exposure and the risk of mobocertinib-related QT (QTc) prolongation.

Drugs/Diseases

Util A	Util B		Util C
Mobocertinib	Clarithromycin	Nelfinavir	
	Cobicistat	Posaconazole	
	Indinavir	Ritonavir	
	Itraconazole	Saquinavir	
	Ketoconazole	Voriconazole	
	Nefazodone		

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Exkivity Prescribing Information, September 2021, Takeda Pharmaceuticals America.

47. Mobocertinib / Moderate CYP3A4 Inhibitors (Black Box) _____ _____

Alert Message: Coadministration of Exkivity (mobocertinib) with a moderate CYP3A4 inhibitor should be avoided. Mobocertinib is a CYP3A4 substrate, and concurrent use with a CYP3A4 inhibitor may increase mobocertinib exposure and the risk of mobocertinib-related QT (QTc) prolongation. If concomitant use with a moderate CYP3A inhibitor cannot be avoided, reduce the mobocertinib dose by approximately 50% and monitor the QTc interval more frequently with ECGs. After the moderate CYP3A inhibitor has been discontinued for 3 to 5 elimination half-lives, resume mobocertinib at the dose taken before initiating the moderate CYP3A inhibitor.

Drugs/Diseases

Util A	Util B			Util C
Mobocertinib	Atazanavir	Diltiazem	Verapamil	
	Aprepitant	Dronedarone		
	Cimetidine	Erythromycin		
	Ciprofloxacin	Fluconazole		
	Crizotinib	Fluvoxamine		
	Cyclosporine	Imatinib		

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Exkivity Prescribing Information, September 2021, Takeda Pharmaceuticals America.

48. Mobocertinib / Interstitial Lung Disease _____ _____

Alert Message: Exkivity (mobocertinib) can cause ILD/pneumonitis, which can be fatal. Monitor patients for new or worsening pulmonary symptoms indicative of ILD/pneumonitis. Immediately withhold mobocertinib in patients with suspected ILD/pneumonitis (any grade) and permanently discontinue mobocertinib if ILD/pneumonitis is confirmed.

Drugs/Diseases

Util A	Util B	Util C
Mobocertinib	Cough	
	Dyspnea	
	Fever	
	Acute Interstitial Pneumonia	

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Exkivity Prescribing Information, September 2021, Takeda Pharmaceuticals America.

Recommendations ***Approved Rejected***

49. Mobocertinib / Cardiac Toxicity _____ _____

Alert Message: Exkivity (mobocertinib) can cause cardiac toxicity (including decreased ejection fraction, cardiomyopathy, and congestive heart failure) resulting in heart failure, which can be fatal. Monitor cardiac function, including assessment of left ventricular ejection fraction at baseline and during treatment. Withhold, reduce the dose, or permanently discontinue mobocertinib based on the severity.

Drugs/Diseases

Util A	Util B	Util C
Mobocertinib	Cardiomyopathy	
	Heart Failure	

References:

Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Exkivity Prescribing Information, September 2021, Takeda Pharmaceuticals America.

50. Mobocertinib / Diarrhea _____ _____

Alert Message: Exkivity (mobocertinib) can cause diarrhea, which can be severe. In the pooled mobocertinib safety population, diarrhea occurred in 93% of patients. Diarrhea may lead to dehydration or electrolyte imbalance, with or without renal impairment. Treat diarrhea promptly. Advise patients to start an antidiarrheal agent (e.g., loperamide) at the first sign of diarrhea or increased bowel movement frequency and to increase fluid and electrolyte intake. Monitor electrolytes and withhold mobocertinib, reduce the dose or permanently discontinue mobocertinib based on the severity.

Drugs/Diseases

Util A	Util B	Util C (Negating)
Mobocertinib	Diarrhea	Loperamide

References:

Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Exkivity Prescribing Information, September 2021, Takeda Pharmaceuticals America.

51. Mobocertinib / Pregnancy / Pregnancy Negating _____ _____

Alert Message: Based on findings from animal studies and its mechanism of action, Exkivity (mobocertinib) can cause fetal harm when administered to a pregnant woman. There are no available data on mobocertinib use in pregnant women. Oral administration of mobocertinib to pregnant rodents during the period of organogenesis resulted in embryolethality (embryo-fetal death) and maternal toxicity at plasma exposures approximately 1.7 times the human exposure based on AUC at the 160 mg once daily clinical dose. Advise pregnant women of the potential risk to a fetus.

Drugs/Diseases

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

Gender: Female
Age Range: 11 – 50 yoa

References:

Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Exkivity Prescribing Information, September 2021, Takeda Pharmaceuticals America.

Recommendations ***Approved Rejected***

52. Mobocertinib / Lactation _____ _____

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

Drugs/Diseases

Util A	Util B	Util C
Mobocertinib	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Exkivity Prescribing Information, September 2021, Takeda Pharmaceuticals America.

53. Mobocertinib / Hormonal Contraceptives _____ _____

Alert Message: Advise females of reproductive potential to use effective non-hormonal contraception during treatment with Exkivity (mobocertinib) and for 1 month after the last dose. Mobocertinib may render hormonal contraceptives ineffective.

Drugs/Diseases

Util A	Util B	Util C
Mobocertinib	Hormonal Contraceptives	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Exkivity Prescribing Information, September 2021, Takeda Pharmaceuticals America.

54. Mobocertinib / Sensitive CYP3A4 Substrates _____ _____

Alert Message: Coadministration of Exkivity (mobocertinib) with a CYP3A4 substrate may result in decreased plasma concentrations of the CYP3A4 substrate. Avoid concomitant use of mobocertinib with other CYP3A substrates where minimal concentration changes may lead to serious therapeutic failures. If concomitant use is unavoidable, increase the CYP3A substrate dosage in accordance with the approved product prescribing information.

Drugs/Diseases

Util A	Util B					Util C
Mobocertinib	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, 2022 Elsevier/Gold Standard.
Exkivity Prescribing Information, September 2021, Takeda Pharmaceuticals America.

Recommendations ***Approved Rejected***

55. Mobocertinib / Strong & Moderate CYP3A4 Inducers _____ _____
Alert Message: Coadministration of Exkivity (mobocertinib) with a strong or moderate CYP3A4 inducer should be avoided. Mobocertinib is a CYP3A4 substrate, and concurrent use with a strong or moderate CYP3A4 inducer may decrease mobocertinib exposure and reduce mobocertinib anti-tumor activity.

Drugs/Diseases

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

References:

Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Exkivity Prescribing Information, September 2021, Takeda Pharmaceuticals America.

56. Mobocertinib / Non-adherence _____ _____
Alert Message: Based on refill history, your patient may be under-utilizing Exkivity (mobocertinib). Non-adherence to the prescribed dosing regimen may result in sub-therapeutic effects, which may lead to decreased patient outcomes and additional healthcare costs.

Drugs/Diseases

Util A	Util B	Util C
Mobocertinib		

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.1273
Greer JA, Amoyal N, Nisotel L, et al. Systemic Review of Adherence to Oral Antineoplastic Therapies. The Oncologist. 2016;21:354-376.

57. Myfembree / Overuse _____ _____
Alert Message: Myfembree (relugolix/estradiol/norethindrone) may be over-utilized. The recommended dosage is one relugolix/estradiol/norethindrone tablet orally once daily.

Drugs/Diseases

Util A	Util B	Util C
Relugolix/Estradiol/Norethindrone		

Max Dose: 1 tablet per day

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Myfembree Prescribing Information, June 2022, Myovant Sciences, Inc.

Recommendations ***Approved Rejected***

58. Myfembree / Therapeutic Appropriateness _____ _____
Alert Message: The safety and effectiveness of Myfembree (relugolix/estradiol/norethindrone) in pediatric patients have not been established.

Drugs/Diseases

Util A	Util B	Util C
Relugolix/Estradiol/Norethindrone		

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Myfembree Prescribing Information, June 2022, Myovant Sciences, Inc.

59. Myfembree / Thrombosis/Embolism & Risk Factors _____ _____
Alert Message: Myfembree (relugolix/estradiol/norethindrone) use is contraindicated in women with a current or history of thrombotic or thromboembolic disorders and women at increased risk for these events. Estrogen and progestin combinations, including the estradiol/norethindrone acetate component of the combination product, increase the risk of thrombotic or thromboembolic disorders, including pulmonary embolism, deep vein thrombosis, stroke, and myocardial infarction, especially in women at high-risk for these events. In general, the risk is greatest among women over 35 years of age who smoke and women with uncontrolled hypertension, dyslipidemia, vascular disease, or obesity.

Drugs/Diseases

Util A	Util B	Util C (Include)
Relugolix/Estradiol/Norethindrone		Personal History of Thrombosis/Embolism Thrombosis Embolism Vascular Disease Migraine with Aura Factor V Leiden Prothrombin Gene Mutation

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Myfembree Prescribing Information, June 2022, Myovant Sciences, Inc.

60. Myfembree / Osteoporosis _____ _____
Alert Message: Myfembree (relugolix/estradiol/norethindrone) is contraindicated in women with known osteoporosis because of the risk of further bone loss. Relugolix/estradiol/norethindrone may cause a decrease in bone mineral density (BMD) in patients. BMD loss may be greater with increasing duration of use and may not be completely reversible after stopping treatment.

Drugs/Diseases

Util A	Util B	Util C (Include)
Relugolix/Estradiol/Norethindrone		Osteoporosis

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Myfembree Prescribing Information, June 2022, Myovant Sciences, Inc.

Recommendations ***Approved Rejected***

61. Myfembree / Breast Cancer _____ _____

Alert Message: Myfembree (relugolix/estradiol/norethindrone) is contraindicated in women with a current or a history of hormone-sensitive malignancies (e.g., breast cancer) and women at increased risk for hormone-sensitive malignancies. Discontinue relugolix/estradiol/norethindrone if a hormone-sensitive malignancy is diagnosed.

Drugs/Diseases

Util A	Util B	Util C (Include)
Relugolix/Estradiol/Norethindrone		Malignant Neoplasm of Breast
		History of Neoplasm of Breast
		Malignant Neoplasm of Ovary
		History of Neoplasm of Ovary
		Malignant Neoplasm of Uterus
		History of Neoplasm of Uterus

References:

Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Myfembree Prescribing Information, June 2022, Myovant Sciences, Inc.

62. Myfembree / Hepatic Impairment or Disease _____ _____

Alert Message: Myfembree (relugolix/estradiol/norethindrone) is contraindicated in patients with known hepatic impairment or disease. The estradiol component of the combination product is a steroid hormone and may be poorly metabolized in patients with impaired liver function. Use of the estradiol agent in patients with hepatic impairment or liver disease can result in increased estradiol exposure and increased risk of estradiol-associated adverse reactions.

Drugs/Diseases

Util A	Util B	Util C (Include)
Relugolix/Estradiol/Norethindrone		Hepatic Impairment
		Hepatic Disease

References:

Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Myfembree Prescribing Information, June 2022, Myovant Sciences, Inc.

63. Myfembree / Abnormal Uterine Bleeding _____ _____

Alert Message: Myfembree (relugolix/estradiol/norethindrone) is contraindicated in women with abnormal uterine bleeding.

Drugs/Diseases

Util A	Util B	Util C
Relugolix/Estradiol/Norethindrone	Abnormal Uterine Bleeding	

References:

Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Myfembree Prescribing Information, June 2022, Myovant Sciences, Inc.

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

64. Myfembree / Depression or Suicidal Ideation _____ _____

Alert Message: The relugolix component of Myfembree (relugolix/estradiol/norethindrone) is a gonadotropin-releasing hormone (GnRH) receptor antagonist. GnRH receptor antagonists have been associated with mood disorders (including depression) and suicidal ideation. Advise patients to seek immediate medical attention for suicidal ideation and behavior. Re-evaluate the benefits and risks of continuing relugolix/estradiol/norethindrone if such events occur.

Drugs/Diseases

Util A	Util B	Util C
Relugolix/Estradiol/Norethindrone	Depression	
	Bipolar Disorder	
	Suicidal Ideation	

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Myfembree Prescribing Information, June 2022, Myovant Sciences, Inc.

65. Myfembree / P-gp Inhibitors _____ _____

Alert Message: Co-administration of Myfembree (relugolix/estradiol/norethindrone) with P-gp inhibitors increases the AUC and maximum concentration (Cmax) of the relugolix component (a P-gp substrate) of the combination product and may increase the risk of relugolix-related adverse reactions. Avoid the use of relugolix/estradiol/norethindrone with oral P-gp inhibitors. If use is unavoidable, take relugolix/estradiol/norethindrone first, separate dosing of the P-gp inhibitor by at least 6 hours and monitor patients for adverse reactions.

Drugs/Diseases

Util A	Util B				Util C
Relugolix/Estradiol/Norethindrone	Amiodarone	Flibanserin	Lomitapide	Ritonavir	
	Brigatinib	Fostamatinib	Mefloquine	Rolapitant	
	Cabozantinib	Glecaprevir	Mifepristone	Saquinavir	
	Carvedilol	Ibrutinib	Nelfinavir	Sarecycline	
	Clarithromycin	Isavuconazonium	Neratinib	Sorafenib	
	Cobicistat	Istradefylline	Osimertinib	Ticagrelor	
	Cyclosporine	Itraconazole	Pibrentasvir	Tolvaptan	
	Daclatasvir	Ivacaftor	Ponatinib	Velpatasvir	
	Dronedarone	Ketoconazole	Posaconazole	Vemurafenib	
	Elagolix	Lapatinib	Propafenone	Verapamil	
	Erythromycin	Lasmiditan	Quinidine	Voxilaprevir	
	Etravirine	Ledipasvir	Ranolazine		

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Myfembree Prescribing Information, June 2022, Myovant Sciences, Inc.

66. Myfembree / Combined P-gp & Strong CYP3A4 Inducers _____ _____

Alert Message: The use of Myfembree (relugolix/estradiol/norethindrone) with combined P-gp and strong CYP3A inducers decreases the AUC and Cmax of relugolix, estradiol, and/or norethindrone and may decrease the therapeutic effects of relugolix/estradiol/norethindrone. Avoid the use of relugolix/estradiol/norethindrone with combined P-gp and strong CYP3A inducers.

Drugs/Diseases

Util A	Util B		Util C
Relugolix/Estradiol/Norethindrone	Apalutamide	Phenytoin	
	Carbamazepine	Rifampin	
	Fosphenytoin		
	Phenobarbital		

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Myfembree Prescribing Information, June 2022, Myovant Sciences, Inc.

Recommendations ***Approved Rejected***

67. Myfembree / Hormonal Contraceptives _____ _____

Alert Message: Advise women of reproductive potential to use effective non-hormonal contraception during treatment with Myfembree (relugolix/estradiol/norethindrone) and for one week after the final dose. Avoid concomitant use of hormonal contraceptives with relugolix/estradiol/norethindrone. The use of estrogen-containing hormonal contraceptives can increase estrogen levels which may increase the risk of estrogen-associated adverse events and decrease the efficacy of relugolix/estradiol/norethindrone.

Drugs/Diseases

Util A	Util B	Util C
Relugolix/Estradiol/Norethindrone	Hormonal Contraceptives	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Myfembree Prescribing Information, June 2022, Myovant Sciences, Inc.

68. Myfembree / Therapeutic Appropriateness _____ _____

Alert Message: Advise women not to breastfeed while taking Myfembree (relugolix/estradiol/norethindrone). There are no data on the presence of relugolix or its metabolites in human milk, the effects on the breastfed child, or the effects on milk production. Relugolix was detected in milk in lactating rats. When a drug is present in animal milk, the drug will likely be present in human milk.

Drugs/Diseases

Util A	Util B	Util C
Relugolix/Estradiol/Norethindrone	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Facts & Comparisons, 2022 Updates, Wolters Kluwer Health.

69. Myfembree / Pregnancy / Pregnancy Negating _____ _____

Alert Message: Myfembree (relugolix/estradiol/norethindrone) is contraindicated for use in pregnancy. Based on findings from animal studies and its mechanism of action, relugolix/estradiol/norethindrone can cause early pregnancy loss. Discontinue relugolix/estradiol/norethindrone if pregnancy occurs during treatment.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Relugolix/Estradiol/Norethindrone	Pregnancy	Abortion Delivery Miscarriage

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Myfembree Prescribing Information, June 2022, Myovant Sciences, Inc.

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

70. Upadacitinib / Overutilization – Ulcerative Colitis _____ _____

Alert Message: Rinvoq (upadacitinib) may be over-utilized. The recommended dose of upadacitinib for maintenance treatment of ulcerative colitis is 15 mg once daily. A maximum dosage of 30 mg once daily may be considered for patients with refractory, severe, or extensive disease. Discontinue upadacitinib if an adequate therapeutic response is not achieved with the 30 mg dosage. Use the lowest effective dosage needed to maintain response.

Drugs/Diseases

Util A	Util B	Util C (Required)
Upadacitinib		Ulcerative Colitis

Max Dose: 30 mg

Day Supply: 90 days

Age Range: 18 - 999 yoa

References:

Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Rinvoq Prescribing Information, April 2022, AbbVie Inc.

71. Upadacitinib / Ulcerative Colitis / Severe Renal Impairment _____ _____

Alert Message: Rinvoq (upadacitinib) may be over-utilized. The recommended dose of upadacitinib for maintenance treatment of ulcerative colitis in patients with severe renal impairment (eGFR 15 < 30 mL/min/1.73m2) is 15 mg once daily. No dosage adjustment is needed for patients with mild or moderate renal impairment (eGFR =/> 30 mL/min/1.73m2). Upadacitinib use is not recommended in patients with end-stage renal disease (eGFR < 15 mL/min/1.73m2).

Drugs/Diseases

Util A	Util B	Util C (Required)
Upadacitinib	Ulcerative colitis	CKD Stage 4 CKD Stage 5

Max Dose: 15 mg

Day Supply: 90 days

Age Range: 18 - 999 yoa

References:

Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Rinvoq Prescribing Information, April 2022, AbbVie Inc.

72. Upadacitinib 30 mg / Ulcerative Colitis / Hepatic Impairment _____ _____

Alert Message: Rinvoq (upadacitinib) may be over-utilized. The recommended dose of upadacitinib for maintenance treatment of ulcerative colitis in patients with mild to moderate hepatic impairment is 15 mg once daily.

Drugs/Diseases

Util A	Util B	Util C (Required)
Upadacitinib	Ulcerative colitis	Hepatic Impairment

Max Dose: 15 mg

Day Supply: 90 days

Age Range: 18 - 999 yoa

References:

Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Rinvoq Prescribing Information, April 2022, AbbVie Inc.

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

73. Upadacitinib / Overutilization - Atopic Dermatitis _____ _____

Alert Message: Rinvoq (upadacitinib) may be over-utilized. The recommended dose of upadacitinib for maintenance treatment of atopic dermatitis in adults and patients 12 years of age and older weighing at least 40 kg is 15 mg once daily. If an adequate response is not achieved, consider increasing the dosage to a maximum of 30 mg once daily. Discontinue upadacitinib if an adequate response is not achieved with the 30 mg dose. Use the lowest effective dose needed to maintain response.

Drugs/Diseases

Util A	Util B	Util C (Required)
Upadacitinib		Atopic Dermatitis

Max Dose: 30 mg

Day Supply: 90 days

Age Range: 12 - 999 yoa

References:

Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Rinvoq Prescribing Information, April 2022, AbbVie Inc.

74. Upadacitinib / Atopic Dermatitis / Severe Renal Impairment _____ _____

5lert Message: Rinvoq (upadacitinib) may be over-utilized. The recommended dose of upadacitinib for maintenance treatment of atopic dermatitis in patients with severe renal impairment (eGFR 15 < 30 mL/min/1.73m2) is 15 mg once daily. No dosage adjustment is needed for patients with mild or moderate renal impairment (eGFR =/> 30 mL/min/1.73m2). Upadacitinib use is not recommended in patients with end-stage renal disease (eGFR < 15 mL/min/1.73m2).

Drugs/Diseases

Util A	Util B	Util C (Required)
Upadacitinib	Atopic Dermatitis	CKD Stage 4 CKD Stage 5

Max Dose: 15 mg

Day Supply: 90 days

Age Range: 12 - 999 yoa

References:

Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Rinvoq Prescribing Information, April 2022, AbbVie In

75. Vonoprazan/Amoxicillin / Therapeutic Appropriateness _____ _____

Alert Message: The safety and effectiveness of Voquezna Dual Pak (vonoprazan and amoxicillin) in pediatric patients have not been established.

Drugs/Diseases

Util A	Util B	Util C
Vonoprazan/Amoxicillin		

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Voquezna Triple Pak and Voquezna Dual Pak Prescribing Information, May 2022, Phantom Pharmaceuticals.

Recommendations ***Approved Rejected***

76. Vonoprazan/Amoxicillin / Rilpivirine-Containing Drugs _____ _____

Alert Message: Concurrent use of Voquezna Dual Pak (vonoprazan and amoxicillin) with rilpivirine-containing products is contraindicated. Vonoprazan reduces intragastric acidity, which may alter the absorption of rilpivirine, leading to changes in safety and/or effectiveness. The inhibitory effect of vonoprazan on acid secretion increases with repeated daily dosing.

Drugs/Diseases

Util A	Util B	Util C
Vonoprazan/Amoxicillin	Rilpivirine	
	Rilpivirine/Cabotegravir	
	Rilpivirine/Dolutegravir	
	Rilpivirine/Emtricitabine/Tenofovir ala	
	Rilpivirine/Emtricitabine/Tenofovir dis	

References:

Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Voquezna Triple Pak and Voquezna Dual Pak Prescribing Information, May 2022, Phantom Pharmaceuticals.

77. Vonoprazan/Amoxicillin / Atazanavir-Containing Drugs _____ _____

Alert Message: Concurrent use of Voquezna Dual Pak (vonoprazan and amoxicillin) with an atazanavir-containing product should be avoided. Vonoprazan reduces intragastric acidity, which may alter the absorption of atazanavir, leading to changes in safety and/or effectiveness. The inhibitory effect of vonoprazan on acid secretion increases with repeated daily dosing.

Drugs/Diseases

Util A	Util B	Util C
Vonoprazan/Amoxicillin	Atazanavir	
	Atazanavir Cobicistat	

References:

Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Voquezna Triple Pak and Voquezna Dual Pak Prescribing Information, May 2022, Phantom Pharmaceuticals.

78. Vonoprazan/Amoxicillin / Nelfinavir _____ _____

Alert Message: Concurrent use of Voquezna Dual Pak (vonoprazan and amoxicillin) with nelfinavir should be avoided. Vonoprazan reduces intragastric acidity, which may alter the absorption of nelfinavir, leading to changes in safety and/or effectiveness. The inhibitory effect of vonoprazan on acid secretion increases with repeated daily dosing.

Drugs/Diseases

Util A	Util B	Util C
Vonoprazan/Amoxicillin	Nelfinavir	

References:

Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Voquezna Triple Pak and Voquezna Dual Pak Prescribing Information, May 2022, Phantom Pharmaceuticals.

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

79. Vonoprazan/Amoxicillin / Strong or Moderate CYP3A4 Inducers _____ _____

Alert Message: The vonoprazan component of Voquezna Dual Pak (vonoprazan and amoxicillin) is a CYP3A substrate. Strong or moderate CYP3A inducers may decrease vonoprazan exposure, which may reduce the effectiveness of the vonoprazan and amoxicillin dual pack.

Drugs/Diseases

Util A	Util B	Util C
Vonoprazan/Amoxicillin	Apalutamide	
	Bosentan	
	Carbamazepine	
	Efavirenz	
	Etravirine	
	Phenobarbital	
	Phenytoin	
	Primidone	
	Rifabutin	
	Rifampin	
	Rifapentine	

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Voquezna Triple Pak and Voquezna Dual Pak Prescribing Information, May 2022, Phantom Pharmaceuticals.

80. Vonoprazan/Amoxicillin / CYP3A4 Substrates w/ NTI _____ _____

Alert Message: The vonoprazan component of Voquezna Dual Pak (vonoprazan and amoxicillin) is a weak CYP3A inhibitor. Concurrent use of vonoprazan with CYP3A substrates where minimal concentration changes may lead to serious toxicities should be done with caution. Frequent monitoring of substrate concentrations and/or adverse reactions related to the substrate drugs is recommended when used with vonoprazan.

Drugs/Diseases

Util A	Util B	Util C
Vonoprazan/Amoxicillin	Cyclosporine	
	Sirolimus	
	Tacrolimus	

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Voquezna Triple Pak and Voquezna Dual Pak Prescribing Information, May 2022, Phantom Pharmaceuticals.

81. Vonoprazan/Amoxicillin / Clopidogrel _____ _____

Alert Message: The vonoprazan component of Voquezna Dual Pak (vonoprazan and amoxicillin) is a CYP2C19 inhibitor. Concurrent use of vonoprazan with clopidogrel, a CYP2C19 substrate, may result in reduced clopidogrel efficacy. Vonoprazan may reduce plasma concentrations of the active metabolite of clopidogrel and may cause a reduction in platelet inhibition. Carefully monitor the efficacy of clopidogrel and consider alternative anti-platelet therapy.

Drugs/Diseases

Util A	Util B	Util C
Vonoprazan/Amoxicillin	Clopidogrel	

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Voquezna Triple Pak and Voquezna Dual Pak Prescribing Information, May 2022, Phantom Pharmaceuticals.

Recommendations ***Approved Rejected***

82. Vonoprazan/Amoxicillin / Citalopram _____ _____
Alert Message: The vonoprazan component of Voquezna Dual Pak (vonoprazan and amoxicillin) is a CYP2C19 inhibitor. Concurrent use of vonoprazan with citalopram, a CYP2C19 substrate, may result in increased citalopram exposure, increasing the risk for citalopram adverse reactions. The dose of citalopram should be limited to 20 mg/day when co-administered with vonoprazan.

Drugs/Diseases

Util A	Util B	Util C
Vonoprazan/Amoxicillin	Citalopram	

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Voquezna Triple Pak and Voquezna Dual Pak Prescribing Information, May 2022, Phantom Pharmaceuticals.

83. Vonoprazan/Amoxicillin / Cilostazol _____ _____
Alert Message: The vonoprazan component of Voquezna Dual Pak (vonoprazan and amoxicillin) is a CYP2C19 inhibitor. Concurrent use of vonoprazan with cilostazol, a CYP2C19 substrate, may result in increased cilostazol exposure, increasing the risk for cilostazol-related adverse reactions. The dose of cilostazol should be limited to 50 mg twice daily when co-administered with vonoprazan.

Drugs/Diseases

Util A	Util B	Util C
Vonoprazan/Amoxicillin	Cilostazol	

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Voquezna Triple Pak and Voquezna Dual Pak Prescribing Information, May 2022, Phantom Pharmaceuticals.

84. Vonoprazan/Amoxicillin / Severe Renal Impairment _____ _____
Alert Message: The use of Voquezna Dual Pak (vonoprazan and amoxicillin) should be avoided in patients with severe renal impairment (eGFR less than 30 mL/minute) or renal failure. The pack does not allow for appropriate dosage adjustments needed in these patients. In pharmacokinetic studies, patients with severe renal impairment had increased systemic exposure (2.4-times greater) to vonoprazan compared to subjects with normal renal function.

Drugs/Diseases

Util A	Util B	Util C
Vonoprazan/Amoxicillin	CKD Stage 4 CKD Stage 5 ESRD	

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Voquezna Triple Pak and Voquezna Dual Pak Prescribing Information, May 2022, Phantom Pharmaceuticals.

Recommendations ***Approved Rejected***

85. Vonoprazan/Amoxicillin / Moderate to Severe Hepatic Impairment _____ _____

Alert Message: Avoid the use of Voquezna Dual Pak (vonoprazan and amoxicillin) in patients with moderate to severe hepatic impairment (Child-Pugh Class B or C). The pack does not allow for appropriate dosage adjustments needed for these patients. In pharmacokinetic studies, patients with severe hepatic impairment exhibited increased systemic exposure of vonoprazan (2.6-times greater) as compared to subjects with normal renal function.

Drugs/Diseases

Util A	Util B	Util C
Vonoprazan/Amoxicillin	Cirrhosis	
	Hepatic Failure	

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Voquezna Triple Pak and Voquezna Dual Pak Prescribing Information, May 2022, Phantom Pharmaceuticals.

86. Vonoprazan/Amoxicillin / Pregnancy / Pregnancy Negating _____ _____

Alert Message: There are no adequate and well-controlled studies of Voquezna Dual Pak (vonoprazan and amoxicillin) in pregnant women to evaluate for drug-associated risks of major birth defects, miscarriage, or other adverse maternal or fetal outcomes. Avoid the use of vonoprazan and amoxicillin dual pack during pregnancy unless other treatments are not clinically appropriate.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Vonoprazan/Amoxicillin	Pregnancy	Abortion
		Delivery
		Miscarriage

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Voquezna Triple Pak and Voquezna Dual Pak Prescribing Information, May 2022, Phantom Pharmaceuticals.

87. Vonoprazan/Amoxicillin / Lactation _____ _____

Alert Message: There are no data regarding the presence of the vonoprazan component of the Voquezna Dual Pak (vonoprazan and amoxicillin) in human milk, the effects on the breastfed infant or the effects on milk production. Vonoprazan and its metabolites are present in rat milk. Liver injury occurred in offspring from pregnant and lactating rats administered oral vonoprazan. When a drug is present in animal milk, it is likely that the drug will be present in human milk. Because of the potential risk of adverse liver effects shown in animal studies with vonoprazan, a woman should pump and discard human milk for the duration of vonoprazan therapy, and for 2 days after therapy ends, and feed her infant stored human milk (collected prior to therapy) or formula.

Drugs/Diseases

Util A	Util B	Util C
Vonoprazan/Amoxicillin	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Voquezna Triple Pak and Voquezna Dual Pak Prescribing Information, May 2022, Phantom Pharmaceuticals.

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

88. Finasteride/Tadalafil / Overuse _____ _____
Alert Message: Entadfi (finasteride/tadalafil) may be over-utilized. The maximum recommended dose is one capsule (5mg finasteride/ 5 mg tadalafil) once daily for up to 26 weeks.

Drugs/Diseases

Util A	Util B	Util C
Finasteride/Tadalafil		

Max Dose: 1 capsule/day

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Facts & Comparisons, 2022 Updates, Wolters Kluwer Health.
Entadfi Prescribing Information, Dec. 2021, Veru Inc.

87. Finasteride/Tadalafil / Therapeutic Appropriateness _____ _____
Alert Message: The safety and effectiveness of Entadfi (finasteride/tadalafil) have not been established in patients less than 18 years of age.

Drugs/Diseases

Util A	Util B	Util C
Finasteride/Tadalafil		

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Facts & Comparisons, 2022 Updates, Wolters Kluwer Health.
Entadfi Prescribing Information, Dec. 2021, Veru Inc.

90. Finasteride/Tadalafil / Severe Hepatic Impairment _____ _____
Alert Message: Entadfi (finasteride/tadalafil) use is not recommended in patients with severe hepatic impairment (Child-Pugh Class C). The finasteride component of the combination product is extensively metabolized in the liver. Finasteride has not been studied in patients with hepatic impairment.

Drugs/Diseases

Util A	Util B	Util C
Finasteride/Tadalafil	Cirrhosis Hepatic Failure	

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Facts & Comparisons, 2022 Updates, Wolters Kluwer Health.
Entadfi Prescribing Information, Dec. 2021, Veru Inc.

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

91. Finasteride/Tadalafil / Hepatic Impairment _____ _____

Alert Message: Entadfi (finasteride/tadalafil) should be used with caution in patients with mild to moderate hepatic impairment (Child-Pugh Class A or B). The finasteride component of the combination product is extensively metabolized in the liver. Finasteride has not been studied in patients with hepatic impairment.

Drugs/Diseases

Util A	Util B	Util C
Finasteride/Tadalafil	Hepatic Impairment	

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Facts & Comparisons, 2022 Updates, Wolters Kluwer Health.
Entadfi Prescribing Information, Dec. 2021, Veru Inc.

92. Finasteride/Tadalafil / Renal Impairment _____ _____

Alert Message: Entadfi (finasteride/tadalafil) use is not recommended in patients with creatinine clearance less than 50 mL/min or on hemodialysis. Due to increased tadalafil exposure (AUC), limited clinical experience, and the lack of ability to influence clearance by dialysis, finasteride/tadalafil use is not recommended in patients with creatinine clearance less than 50 mL/min or on hemodialysis.

Drugs/Diseases

Util A	Util B	Util C
Finasteride/Tadalafil	CKD Stage 3	
	CKD Stage 4	
	CKD Stage 5	
	Hemodialysis	

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Facts & Comparisons, 2022 Updates, Wolters Kluwer Health.
Entadfi Prescribing Information, Dec. 2021, Veru Inc.

93. Finasteride/Tadalafil / Pregnancy / Pregnancy Negating _____ _____

Alert Message: Entadfi (finasteride/tadalafil) is contraindicated in pregnancy and not indicated for use in females. Based on animal studies and its mechanism of action, finasteride, a component of finasteride/tadalafil, may cause abnormal development of external genitalia in a male fetus if administered to a pregnant female. Females of reproductive potential, including pregnant females, should not handle crushed or open finasteride/tadalafil capsules because of possible exposure of a male fetus.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Finasteride/Tadalafil	Pregnancy	Abortion
	Delivery	
	Miscarriage	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Facts & Comparisons, 2022 Updates, Wolters Kluwer Health.
Entadfi Prescribing Information, Dec. 2021, Veru Inc.

Recommendations	*Approved*	*Rejected*

94. Vericiguat / Overuse _____ _____

Alert Message: Verquvo (vericiguat) may be over-utilized. The recommended target maintenance dose of vericiguat is 10 mg once daily, as tolerated by patients

Drugs/Diseases

Util A	Util B	Util C
Vericiguat		

Max Dose: 10 mg/day

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Facts & Comparisons, 2022 Updates, Wolters Kluwer Health.
Verquvo Prescribing Information, Jan. 2021, Merck Sharp & Dohme Corp.

95. Vericiguat / Therapeutic Appropriateness _____ _____

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

Drugs/Diseases

Util A	Util B	Util C
Vericiguat		

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Facts & Comparisons, 2022 Updates, Wolters Kluwer Health.
Verquvo Prescribing Information, Jan. 2021, Merck Sharp & Dohme Corp.

96. Vericiguat / Guanylate Cyclase Stimulators _____ _____

Alert Message: The concurrent use of Verquvo (vericiguat) with another soluble guanylate cyclase (sGC) stimulator is contraindicated.

Drugs/Diseases

Util A	Util B	Util C
Vericiguat	Riociguat	

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Facts & Comparisons, 2022 Updates, Wolters Kluwer Health.
Verquvo Prescribing Information, Jan. 2021, Merck Sharp & Dohme Corp.

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

97. Vericiguat / PDE-5 Inhibitors _____ _____

Alert Message: Coadministration of Verquvo (vericiguat) with phosphodiesterase type 5 (PDE-5) inhibitors is not recommended due to the potential for hypotension.

Drugs/Diseases

Util A	Util B	Util C
Vericiguat	Avanafil	
	Sildenafil	
	Tadalafil	
	Vardenafil	

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Facts & Comparisons, 2022 Updates, Wolters Kluwer Health.
Verquvo Prescribing Information, Jan. 2021, Merck Sharp & Dohme Corp.

98. Vericiguat / Pregnancy / Pregnancy Negating (Black Box) _____ _____

Alert Message: Based on data from animal reproduction studies, Verquvo (vericiguat) may cause fetal harm when administered to a pregnant woman and is contraindicated during pregnancy.

Drugs/Diseases

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

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Facts & Comparisons, 2022 Updates, Wolters Kluwer Health.
Verquvo Prescribing Information, Jan. 2021, Merck Sharp & Dohme Corp.

99. Vericiguat / Lactation _____ _____

Alert Message: There are no data on the presence of Verquvo (vericiguat) in human milk, the effects on the breastfed infant, or the effects on milk production. Vericiguat is present in the milk of lactating rats, and it is likely that vericiguat or its metabolites are present in human milk. Because of the potential for serious adverse reactions in breastfed infants from vericiguat, advise women not to breastfeed during treatment with vericiguat.

Drugs/Diseases

Util A	Util B	Util C
Vericiguat	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Facts & Comparisons, 2022 Updates, Wolters Kluwer Health.
Verquvo Prescribing Information, Jan. 2021, Merck Sharp & Dohme Corp.

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

100. Vericiguat / Therapeutic Appropriateness (Black Box) _____ _____
Alert Message: Advise females of reproductive potential to use effective contraception during treatment with Verquvo (vericiguat) and for one month after the final dose. Verify the pregnancy status in females of reproductive potential prior to initiating vericiguat. Vericiguat may cause fetal harm when administered to a pregnant woman.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Vericiguat		Contraceptives

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Facts & Comparisons, 2022 Updates, Wolters Kluwer Health.
Verquvo Prescribing Information, Jan. 2021, Merck Sharp & Dohme Corp.

101. Vericiguat / Non-adherence _____ _____
Alert Message: Based on refill history, your patient may be under-utilizing Verquvo (vericiguat). Non-adherence to the prescribed dosing regimen may result in sub-therapeutic effects, which may lead to decreased patient outcomes and additional healthcare costs.

Drugs/Diseases

Util A	Util B	Util C

References:
Osterberg L, Blaschke T. Adherence to Medication. N Engl J Med 2005; 353:487- 497.
Waxman A, Chen SY, Boulanger L, Golden G. Adherence to Phosphodiesterase Type 5 Inhibitors for the Treatment of Pulmonary Arterial Hypertension - A Real-World Analysis. *Chest*. 2011;140:736A.
Roebuck MC, Liberman JN, Gemmill-Toyama M, Brennan TA. Medication Adherence Leads to Lower Health Care Use and Costs Despite Increased Drug Spending. Health Affairs. No.1 (2011):91-99.
Ho PM, Bryson CL, Rumsfeld JS. Medication Adherence: Its Importance in Cardiovascular Outcomes. Circulation. 2009;119:3028-3035.

102. Cannabidiol / Sensitive P-gp Substrates _____ _____
Alert Message: Coadministration of Epidiolex (cannabidiol), a P-gp inhibitor, with a sensitive P-gp substrate (i.e., cyclosporine digoxin, everolimus, sirolimus, and tacrolimus) may result in increased P-gp substrate exposure and risk of P-gp substrate-related toxicity. Increase monitoring of serum P-gp substrate concentrations and watch for potential signs and symptoms of clinical toxicity when starting, adjusting, or discontinuing cannabidiol. Dosage reduction of the P-gp substrate may be necessary.

Drugs/Diseases

Util A	Util B	Util C
Cannabidiol	Cyclosporine	
	Digoxin	
	Everolimus	
	Sirolimus	
	Tacrolimus	

References:

Clinical Pharmacology, 2022 Elsevier/Gold Standard.

Facts & Comparisons, 2022 Updates, Wolters Kluwer Health.