

**North Dakota Medicaid  
Drug Utilization Review Board Meeting  
December 4, 2024  
Conference Room 210/212**

# Meeting Notice

## North Dakota Medicaid Drug Use Review Board

Wednesday, December 4<sup>th</sup>, 2024

1 to 4 p.m. Central Time

### In-Person Information

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

### Virtual Information

Join virtually: [Click here to join the meeting](#)

Join by phone: 701-328-0950, Conference ID: 394 833 97 #

### Agenda

1. Call to Order
2. Roll Call
3. Review and Approval of Minutes
4. Reports from Department
  - Administrative Report
  - Financial Report: Top Drugs
  - Retrospective DUR Report
  - Clinical Report:
    - Prior Authorization Update
    - Criteria updates: Amyloidosis, COPD / Asthma, and Secondary Hyperparathyroidism
    - Annual PDL Review
5. Unfinished Business: Alternative RDUR Communication
6. New business
  - Second Review of Attention-Deficit Hyperactivity Disorder Stimulants
  - First Review of Migraine Prophylaxis and Treatment
  - First Review of Nonsteroidal Anti-Inflammatory Drugs
  - First Review of Primary Biliary Cholangitis
  - Review of retrospective DUR criteria recommendations
7. Announcements: Next Meeting (March 5, 2025)
8. Adjourn

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

**Meeting Minutes**  
**North Dakota Medicaid Drug Use Review (DUR) Board**  
**Meeting Date:** September 4<sup>th</sup>, 2024  
**Time and Location:** 1:00 pm CST in Bismarck, North Dakota

**Call to Order:**

A regular quarterly meeting of the North Dakota Medicaid Drug Use Review (DUR) Board meeting was convened at 1:01 pm CST with T. Schmidt presiding as Presiding Officer. DUR Board Coordinator, C. Stauter recording minutes.

**Roll Call:**

*Board Members Voting:*

*Present:* Stephanie Antony, Amanda Dahl, Kurt Datz, Andrea Honeyman, Laura Kroetsch, Kevin Martian, Kristen Peterson, Tanya Schmidt, Amy Werremeyer

*Absent:* Gabriela Balf

*Quorum Present:* Yes

*Board Members Non-Voting:*

*Present:* Kathleen Traylor

*Medicaid Pharmacy Department:*

*Present:* Brendan Joyce, Alexi Murphy

*Absent:* Jeff Hostetter, LeNeika Roehrich

**Approval of Meeting Minutes:**

*Motion:* Moved by K. Datz to approve the minutes of the June 5<sup>th</sup>, 2024 meeting, motion was seconded by K. Martian. **Motion carried.**

The minutes of the June 5<sup>th</sup>, 2024 meeting were approved as distributed.

**Reports:**

*Administrative Report:* by A. Murphy

A. Murphy shared with the Board North Dakota Medicaid's biosimilar plan for 2024-2025 and data regarding hepatitis C treatment. This information can be found in the handout. Appreciation for Josh Askvig and Jennifer Iverson's service to the Board was expressed as their appointments have ended. Katie Steig will be starting as the new pharmacist on September 9<sup>th</sup>.

*Financial Report:* by B. Joyce

B. Joyce shared with the Board trends of pharmacy recipients and payments per prescription. B. Joyce also presented the quarterly review of the top 25 drugs based on total number and cost of claims and the top 15 therapeutic classes based on number and cost of claims. This report can be found in the handout.

*Retrospective Drug Utilization Review (RDUR) Report* by C. Stauter

C. Stauter reviewed the quarterly RDUR criteria that were selected for review of each month. This material can be found in the handout.

*Clinical Report: Prior Authorization and Criteria Updates* by C. Stauter

C. Stauter presented prior authorization and criteria updates with emphasis on the following sections in the PDL: asthma/COPD, chronic kidney disease, Duchenne muscular dystrophy, growth hormone, heart failure, hereditary angioedema, hypertrophic cardiomyopathy, lipid-lowering treatment, plaque psoriasis, medications over \$3000, and dry eye disease. The presented information can be found in the handout. Testimony was provided by Christine Dube from Astrazeneca on Fasenera, Giuseppe Miranda from BioCryst on Orladeyo, Sandy Kosmaczeski from Dermavent on Vtama, and Erin Nowak from Abbvie on Skyrizi.

*Unfinished business* by C. Stauter:

C. Stauter presented information regarding birth rates, alternative RDUR communication tools, dentist prescribed opioids, and biologics breakout cost. The presented material can be found in the handout.

*New business:*

*Second Reviews* presented by C. Stauter

C. Stauter presented group prior authorization criteria for molluscum contagiosum, epidermolysis bullosa, and metabolic dysfunction-associated steatohepatitis. The presented material can be found in the handout. Testimony was provided by Tara McKinley from Madrigal on Rezdifra.

*Motion:* Moved by K. Martin to place molluscum contagiosum on prior authorization, motion was seconded by K. Datz. **Motion carried.**

*Motion:* Moved by K. Datz to place epidermolysis bullosa on prior authorization, motion was seconded by A. Werremeyer. **Motion carried.**

*Motion:* Moved by K. Martin to place metabolic dysfunction-associated steatohepatitis on prior authorization, motion was seconded by K. Datz. **Motion carried.**

*First Reviews* presented by C. Stauter

C. Stauter presented an overview of attention-deficit hyperactivity disorder stimulants. The presented material can be found in the handout.

*Motion:* Moved by K. Datz to draft prior authorization for attention-deficit hyperactivity disorder stimulants, motion was seconded by A. Werremeyer. **Motion carried.**

*Retrospective Drug Utilization Review (RDUR) Criteria Recommendations:*

RDUR criteria recommendations were reviewed. The presented material can be found in the handout.

*Motion:* Moved by K. Martian to approve the RDUR criteria, motion was seconded by A. Honeyman. **Motion carried.**

**Announcements:**

Next meeting is December 4<sup>th</sup>, 2024.

**Adjournment:**

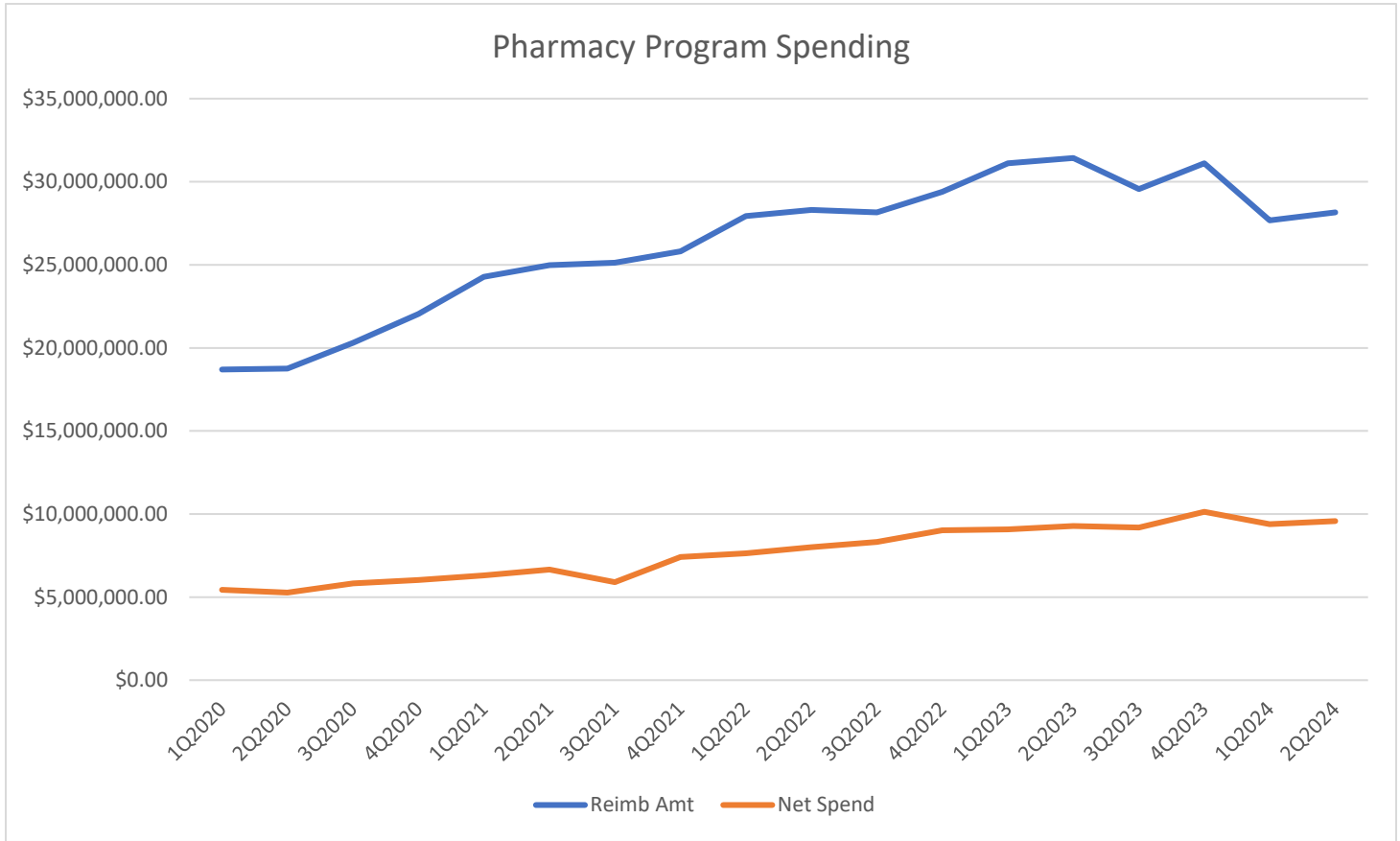
Meeting adjourned by T. Schmidt at 2:08 pm CST.

**Date of Minutes Approval:**

**Minutes submitted by:** Claire Stauter, Acentra Health

# Financial Report

The following graphs are pharmacy drug claims and do not include diabetic supplies, medical drugs (J-codes), or claims paid to Indian Health Services.

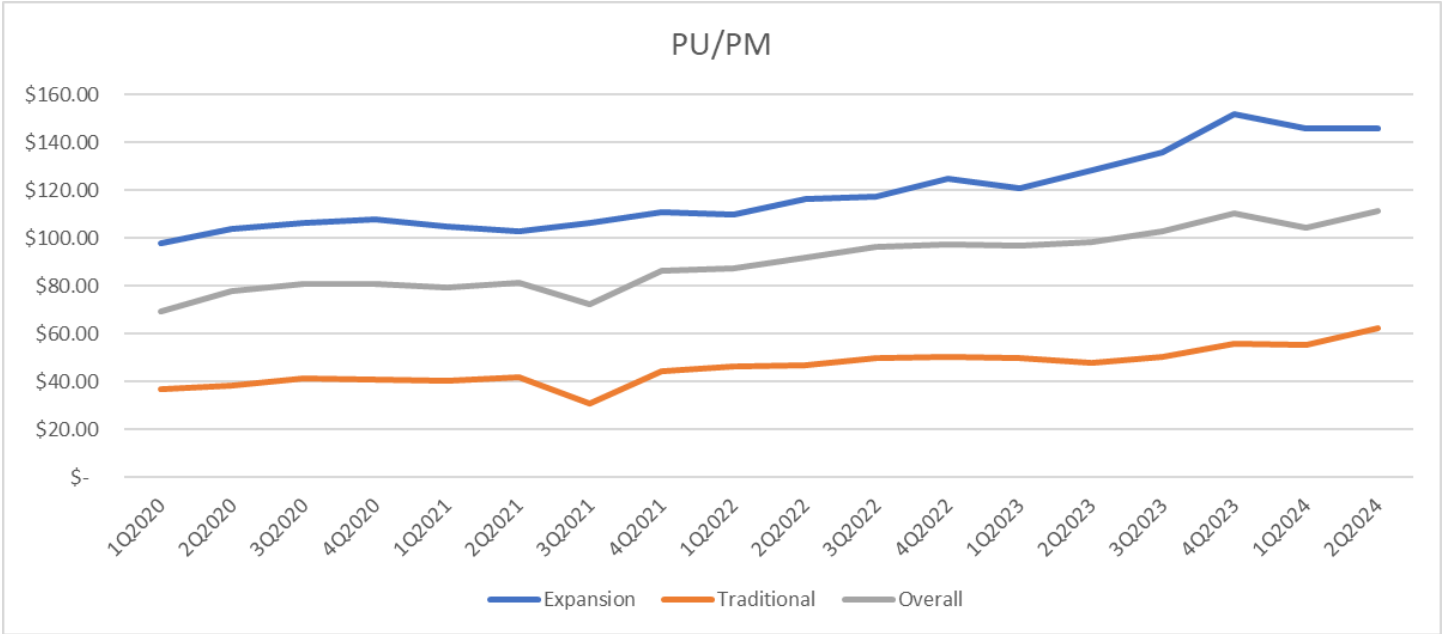
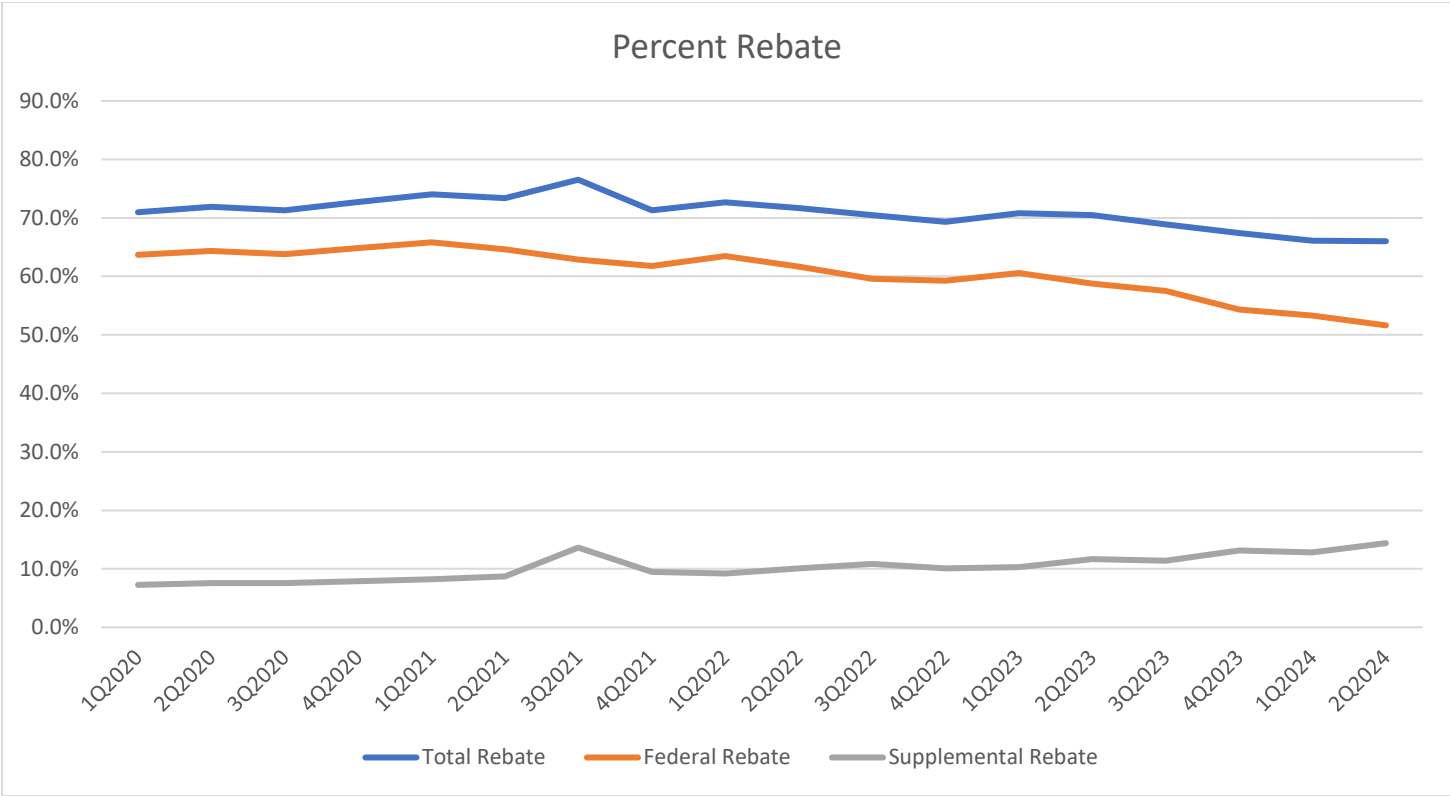


## **Decrease in reimbursement trend timeline:**

2Q23 - Insulin prices start to decrease

1Q24 – AMP cap is removed (some manufacturers choose to decrease price of their drugs to avoid the rebate increasing above AMP)

These changes in reimbursement do not reflect directly into net spend (which is increasing) as rebate % is decreasing during this same time period and net spend per utilizer is going up.



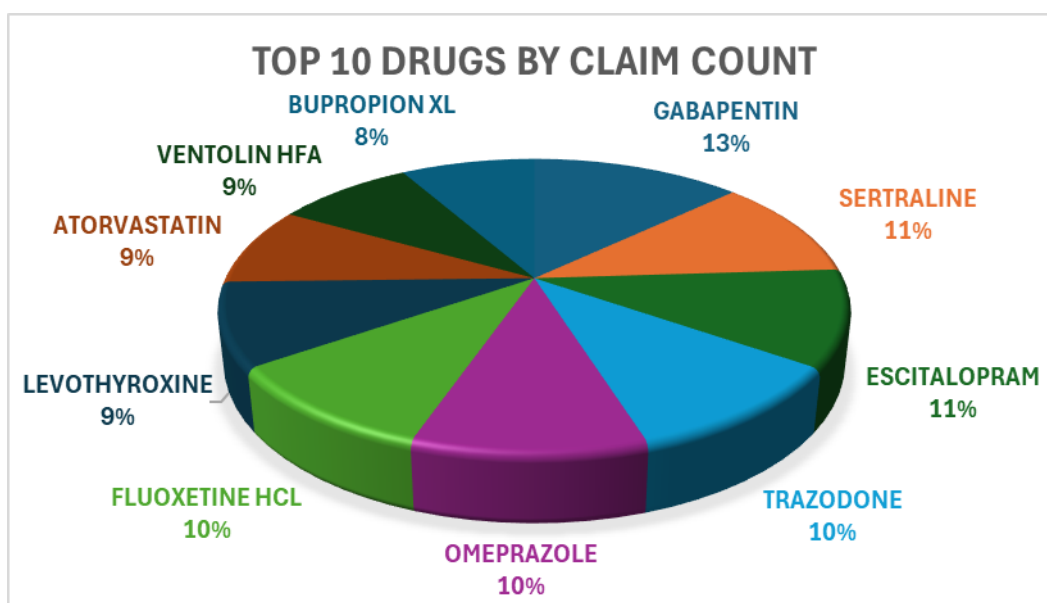
**Between 1Q19 and 1Q23: Primary Cost Drivers**

Antipsychotics (long acting injectables), cystic fibrosis (CFTR modulators), biologics (574.4% growth, Dupixent 1,714% growth), hepatitis C, HIV, migraine CGRPs and gepants, multiple sclerosis, narcotic treatment (long acting injectables), oncology, pulmonary hypertension, tardive dyskinesia, and hemophilia (loss of primary insurance payments on members).

These classes alone contribute to about 57% of our net spend and 200.7% of net spend growth, while all other drug classes account for 4.4% of net spend growth.

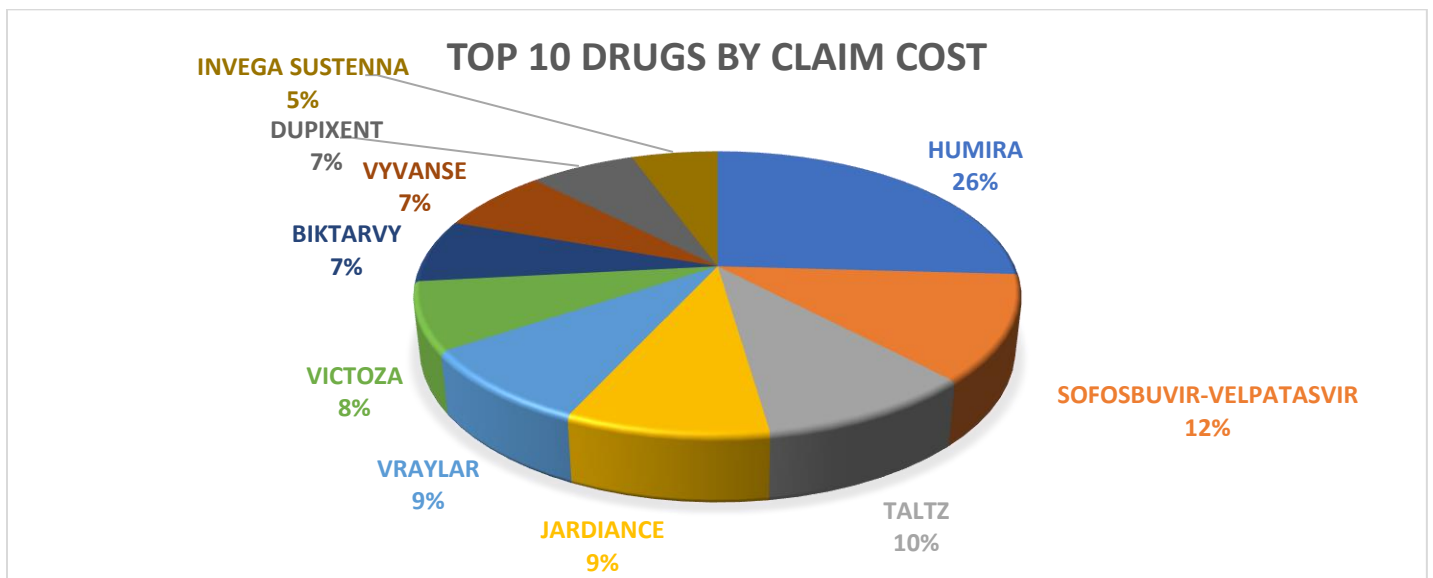
## Top 25 Drugs Based on Number of Claims from 07/01/2024 – 09/30/2024

Drug	Claims	Claims Cost	Patients	Cost / Claim	% Claims	Dif.
1. GABAPENTIN	4,001	\$59,134.68	1,755	\$14.78	1.8%	NC
2. SERTRALINE HCL	3,392	\$45,885.98	1,937	\$13.53	1.5%	NC
3. ESCITALOPRAM	3,274	\$43,957.21	1,920	\$13.43	1.5%	↑1
4. TRAZODONE HCL	3,226	\$43,436.63	1,750	\$13.46	1.5%	↑1
5. OMEPRAZOLE	3,152	\$41,762.80	1,812	\$13.25	1.4%	↓2
6. FLUOXETINE HCL	3,103	\$41,175.56	1,748	\$13.27	1.4%	NC
7. LEVOTHYROXINE	2,835	\$40,782.06	1,522	\$14.39	1.3%	↑1
8. ATORVASTATIN	2,646	\$36,989.06	1,564	\$13.98	1.2%	↑2
9. VENTOLIN HFA	2,623	\$170,091.54	2,598	\$64.85	1.2%	↑2
10. BUPROPION XL	2,551	\$41,710.02	1,423	\$16.35	1.1%	↑2
11. CLONIDINE HCL	2,542	\$31,200.49	1,294	\$12.27	1.1%	↑3
12. LISINAPRIL	2,523	\$32,586.27	1,546	\$12.92	1.1%	↑1
13. HYDROXYZINE HCL	2,352	\$34,906.37	1,505	\$14.84	1.1%	↑2
14. HYDROCODONE-APAP	2,280	\$33,812.88	1,438	\$14.83	1.0%	↑4
15. AMOXICILLIN	2,181	\$33,429.90	2,078	\$15.33	1.0%	↓8
16. VYVANSE	2,164	\$644,069.16	1,022	\$297.63	1.0%	↓7
17. ARIPIPRAZOLE	2,144	\$32,153.96	1,073	\$15.00	1.0%	↑5
18. PANTOPRAZOLE	2,134	\$30,195.23	1,247	\$14.15	1.0%	↑3
19. LAMOTRIGINE	2,126	\$30,060.97	882	\$14.14	1.0%	NC
20. PREDNISON	2,117	\$24,550.50	1,702	\$11.60	1.0%	↓4
21. DULOXETINE HCL	2,115	\$34,897.67	1,143	\$16.50	1.0%	↓1
22. CYCLOBENZAPRINE	2,054	\$24,345.34	1,328	\$11.85	0.9%	↑2
23. CLONAZEPAM	2,048	\$27,630.47	871	\$13.49	0.9%	↑2
24. BUSPIRONE HCL	1,914	\$28,413.57	1,090	\$14.85	0.9%	↓1
25. AMLODIPINE BESYLATE	1,890	\$23,977.36	1,174	\$12.69	0.8%	↑1
<b>Total Claims</b>					<b>222,444</b>	



### Top 25 Drugs Based on Total Claims Cost from 07/01/2024 – 09/30/2024

Drug	Claims	Claims Cost	Patients	Cost / Patient	% Cost	Dif.
1. HUMIRA	281	\$2,316,865.42	129	\$17,960.20	7.4%	NC
2. SOFOS-VELPATASVIR	48	\$1,077,627.16	48	\$22,450.57	3.4%	NC
3. TALTZ	110	\$873,207.22	50	\$17,464.14	2.8%	NC
4. JARDIANCE	1,088	\$820,597.45	605	\$ 1,356.36	2.6%	↑2
5. VRAYLAR	756	\$778,143.13	312	\$ 2,494.05	2.5%	↑2
6. VICTOZA	1040	\$690,750.44	619	\$ 1,115.91	2.2%	↓1
7. BIKTARVY	278	\$644,429.86	133	\$ 4,845.34	2.0%	↑3
8. VYVANSE	2,164	\$644,069.16	1,022	\$ 630.20	2.0%	↓4
9. DUPIXENT	171	\$607,688.37	76	\$ 7,995.90	1.9%	↑3
10. INVEGA SUSTENNA	178	\$493,788.64	77	\$ 6,412.84	1.6%	↑1
11. TRIKAFTA	22	\$469,369.32	11	\$42,669.94	1.5%	↓2
12. NORDITROPIN FLEXPOR	73	\$454,257.24	34	\$13,360.51	1.4%	↑1
13. STELARA	18	\$444,353.62	14	\$31,739.54	1.4%	↑2
14. ELIQUIS	628	\$387,498.38	327	\$ 1,185.01	1.2%	NC
15. INGREZZA	44	\$326,791.79	19	\$17,199.57	1.0%	↑3
16. SUBLOCADE	152	\$308,404.96	77	\$ 4,005.26	1.0%	↑3
17. JIVI	3	\$282,644.82	1	\$282,644.82	0.9%	↑9
18. ABILIFY MAINTENA	103	\$264,554.88	45	\$ 5,879.00	0.8%	↑2
19. COSENTYX	28	\$258,618.66	11	\$23,510.79	0.8%	↑10
20. ENBREL	38	\$257,061.03	19	\$13,529.53	0.8%	↓3
21. CONCERTA	627	\$221,995.27	464	\$478.44	0.7%	↓13
22. DULERA	654	\$210,447.62	395	\$532.78	0.7%	↑31
23. FARXIGA	324	\$205,149.70	176	\$1,165.62	0.7%	↑2
24. XIFAXAN	79	\$204,582.90	35	\$5,845.23	0.7%	↑9
25. ADDERALL XR	1,059	\$195,393.46	597	\$327.29	0.6%	↑8
<b>Total Claims Cost</b>					<b>\$31,455,890.38</b>	





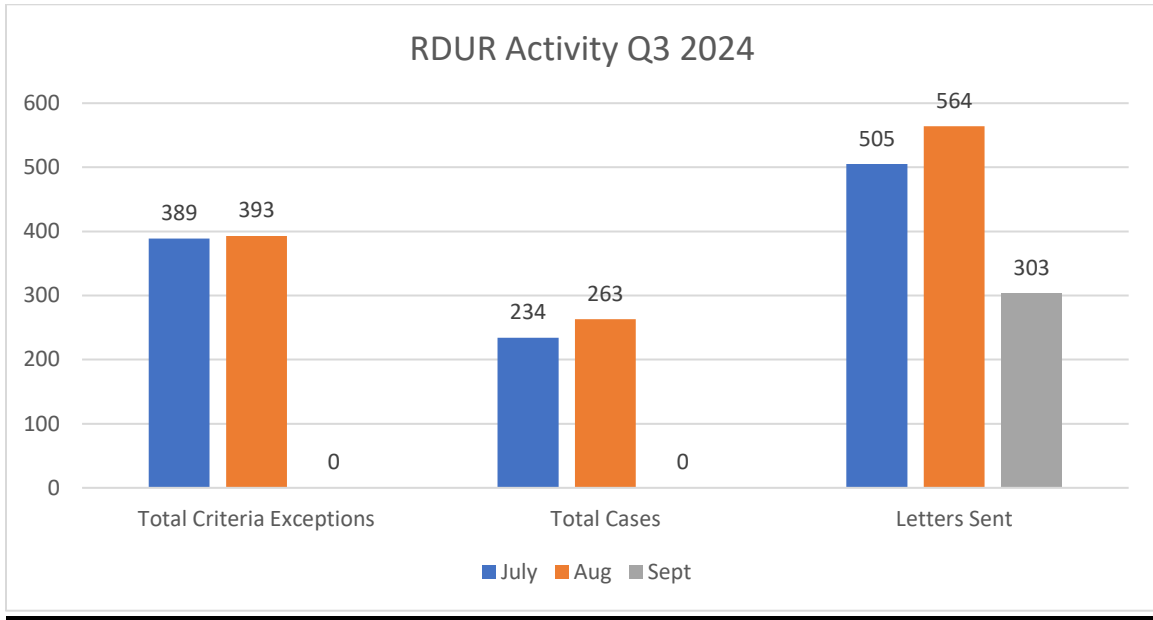
### Top 15 Therapeutic Classes Based on Number of Claims from 07/01/2024 – 09/30/2024

Therapeutic Class Description	Claims	Claims Cost	Patients	Cost/Claim	% Claims	Dif.
1. ANTIDEPRESSANTS	24,003	\$564,513.14	10,366	\$23.52	10.8%	NC
2. ANTIPSYCHOTIC AGENTS	8,949	\$2,395,961.66	3,706	\$267.74	4.0%	NC
3. AMPHETAMINES	6,444	\$989,228.11	2,719	\$153.51	2.9%	NC
4. GABA ANTICONVULSANTS	6,321	\$131,008.56	2,646	\$20.73	2.8%	↑1
5. RESP AND CNS STIMULANTS	5,883	\$536,916.93	2,408	\$91.27	2.6%	↓1
6. OPIOID AGONISTS	5,622	\$97,328.86	2,910	\$17.31	2.5%	↑3
7. PROTON-PUMP INHIBITORS	5,594	\$97,046.92	3,178	\$17.35	2.5%	↓1
8. BETA AGONISTS	5,313	\$708,637.71	3,654	\$133.38	2.4%	↑7
9. NSAIDS	5,214	\$74,067.87	3,552	\$14.21	2.3%	↑1
10. CENTRAL ALPHA-AGONISTS	4,771	\$69,558.18	2,205	\$14.58	2.1%	↑3
11. ANTICONVULSANTS	4,741	\$273,588.78	1,952	\$57.71	2.1%	NC
12. STATINS	4,741	\$68,552.25	2,795	\$14.46	2.1%	NC
13. BETA BLOCKING AGENTS	4,557	\$79,756.39	2,642	\$17.50	2.0%	↑1
14. PENICILLIN ANTIBIOTICS	4,146	\$68,604.93	3,735	\$16.55	1.9%	↓6
15. ADRENALS	4,102	\$199,060.73	2,996	\$48.53	1.8%	↓8

### Top 15 Therapeutic Classes Based on Claims Cost from 07/01/2024 – 09/30/2024

Therapeutic Class Description	Claims	Claims Cost	Patients	Cost/Patient	% Cost	Dif.
1. TNF INHIBITORS	342	\$2,724,267.33	148	\$18,407.21	8.7%	NC
2. ANTIPSYCHOTIC AGENTS	8,949	\$2,395,961.66	3,706	\$646.51	7.6%	NC
3. INTERLEUKIN AGENTS	162	\$1,599,842.84	72	\$22,220.04	5.1%	NC
4. ANTINEOPLASTIC AGENTS	513	\$1,268,314.77	214	\$5,926.70	4.0%	↑1
5. ANTIRETROVIRALS	699	\$1,205,276.19	275	\$4,382.82	3.8%	↑1
6. HCV ANTIVIRALS	48	\$1,077,627.16	48	\$22,450.57	3.4%	↑2
7. SGLT2 INHIBITORS	1,477	\$1,062,808.29	808	\$1,315.36	3.4%	NC
8. AMPHETAMINES	6,444	\$989,228.11	2,719	\$363.82	3.1%	↓4
9. INCRETIN MIMETICS	1,256	\$881,154.41	637	\$1,383.29	2.8%	NC
10. BETA AGONISTS	5,313	\$708,637.71	3,654	\$193.93	2.3%	↑15
11. SKIN AGENTS	203	\$610,126.49	101	\$6,040.86	1.9%	↑5
12. INSULINS	2,826	\$582,199.50	1,187	\$490.48	1.9%	↑1
13. ANTIDEPRESSANTS	24,003	\$564,513.14	10,366	\$54.46	1.8%	↓1
14. RESP AND CNS STIMULANTS	5,883	\$536,916.93	2,408	\$222.97	1.7%	↓4
15. CFTR MODULATORS	24	\$515,872.20	12	\$42,989.35	1.6%	↓4

## RDUR Report: Q3 2024



July Cases by Type of Criteria		
Criteria Description	# of Cases	% of Cases
Therapeutic Appropriateness	233	99.6%
Drug-Disease Interaction	1	0.4%

Aug Cases by Type of Criteria		
Criteria Description	# of Cases	% of Cases
Therapeutic Appropriateness	263	100%

### Introduction

At the bottom of this report, you will see patients receiving at least one attention-deficit-hyperactivity disorder (ADHD) stimulant medication above the maximum compendia recommended dose in the past 120 days per pharmacy claims data. If multiple prescribers are involved, each will receive this information.

### High-Dose Stimulants

Stimulant medications are oftentimes used in the management of ADHD and narcolepsy.<sup>1</sup> Stimulants are available in a variety of dosage formulations, allowing prescribers to meet patient-specific needs.<sup>2</sup> Prescribers should follow compendia or FDA label supported use (e.g., diagnosis, age, dosage, frequency, route) and routinely monitor treatment response to adjust the patient's regimen as needed.<sup>1</sup>

Stimulants can cause hypertension, gastrointestinal side effects, headache, insomnia, and a loss of appetite.<sup>2</sup> They also have warnings for cardiovascular events (e.g., acute myocardial infarction, stroke, sudden cardiac death), serotonin syndrome, growth suppression, and psychotic or manic symptoms. Risks of these side effects are increased when used at higher than recommended doses.<sup>3</sup>

Stimulant medications have a boxed warning for potential dependence and abuse, and overutilization of stimulants may increase the risk of misuse.<sup>2</sup> Misuse occurs when using a medication differently than instructed, without a prescription, or for recreational use; this has become a major health concern in the United States. Prescribers can help limit the risk of misuse by carefully choosing the medication (e.g., type, formulation), monitoring prescription drug monitoring programs (PDMP) when prescribing refills, requiring patient signed agreements, and educating patients on appropriate use and risks associated with dependence and abuse.<sup>3</sup>

### Key Takeaways:

- Reference compendia or FDA label for safe and supported prescribing (e.g., diagnosis, age, dosage, frequency, route)
- Routinely monitor treatment response to adjust the patient's regimen as needed<sup>1</sup>
- Prescribers can help limit the risk of misuse by carefully choosing the medication (e.g., type, formulation), monitoring prescription drug monitoring programs (PDMP) when prescribing refills, requiring patient signed agreements, and educating patients on appropriate use and risks associated with dependence and abuse.<sup>3</sup>

### References:

1. Agency for Healthcare Research and Quality. Evidence-based Practice Center Systematic Review Protocol Project Title: ADHD Diagnosis and Treatment in Children and Adolescents. Effective Healthcare Program. Available from: [https://effectivehealthcare.ahrq.gov/sites/default/files/product/pdf/deficit-hyperactivity-protocol.pdf?\\_gl=1\\*g41jnf\\*\\_ga\\*NDczODIwNzE3LjE3MjA3MjIwNTQ.\\*\\_ga\\_45NDDT15CJ\\*MTcyMDcyMjA2My4xLjAuMTcyMDcyMjA2My42MC4wLjA](https://effectivehealthcare.ahrq.gov/sites/default/files/product/pdf/deficit-hyperactivity-protocol.pdf?_gl=1*g41jnf*_ga*NDczODIwNzE3LjE3MjA3MjIwNTQ.*_ga_45NDDT15CJ*MTcyMDcyMjA2My4xLjAuMTcyMDcyMjA2My42MC4wLjA).
2. U.S. Department of Health and Human Services. Stimulant and Related Medications: Use in Adults. Centers for Medicare and Medicaid Services. October 2015. Available from: <https://www.cms.gov/medicare-medicare-coordination/fraud-prevention/medicaid-integrity-education/pharmacy-education-materials/downloads/stim-adult-factsheet11-14.pdf>
3. Substance Abuse and Mental Health Services Administration (SAMHSA). Prescription Stimulant Misuse and Prevention Among Youth and Young Adults. Publication No. PEP21-06-01-003. Rockville, MD: National Mental Health and Substance Use Policy Laboratory. Substance Abuse and Mental Health Services Administration, 2021. Available from: <https://store.samhsa.gov/sites/default/files/pep21-06-01-003.pdf>

## Clinical Report

### Prior Authorization Updates

Drug	PA Status	Class	
Bethkis	PA	Cystic Fibrosis	Starting with 2025 PDL
Nivestym	PA	Preferred Dosage Forms - figrastim	Starting with 2025 PDL
Nyvepria	PA	Preferred Dosage Forms - pegfilgrastim	Starting with 2025 PDL
Praluent	PA	cholesterol lowering drugs/PCSK9 inhibitors	Starting with 2025 PDL
Stimufend	PA	Preferred Dosage Forms - pegfilgrastim	Starting with 2025 PDL
Udenyca	PA	Preferred Dosage Forms - pegfilgrastim	Starting with 2025 PDL
Ziextenzo	PA	Preferred Dosage Forms - pegfilgrastim	Starting with 2025 PDL
Zimhi	PA	Preferred Dosage Forms - naloxone	Starting with 2025 PDL
Abrilada	Remove PA	Cytokine Modulators	Starting with 2025 PDL
Eysuvis	Remove PA	Dry Eye Syndrome	Starting with 2025 PDL
Hadlima	Remove PA	Cytokine Modulators	Starting with 2025 PDL
Rykindo ER	Remove PA	Preferred Dosage Forms - risperidone	Starting with 2025 PDL
Suflave	remove PA	Bowel Prep agents	Starting with 2025 PDL
Sutab	remove PA	Bowel Prep agents	Starting with 2025 PDL
Xaciato	Remove PA	Vaginal Infections	Starting with 2025 PDL
Akynzeo	PA	Nausea and Vomiting	
clobetasol 0.05% eye drops	PA	ophthalmic corticosteroids	
Crexont	PA	Parkinsons's Agents / Preferred Dosage Forms	
Ebglyss	PA	Atopic Dermatitis	
Elyxyb	PA	Migraine	
Iqirvo	PA	Medications > \$3000	
Neffy	PA	Epinephrine	
Nemludio	PA	Prurigo Nodularis	
Tyenne	PA	Cytokine Modulators	
Vyalev	PA	Parkinson's Disease	
Yorvipath	PA	Secondary Hypoparathyroidism	
Zituvimet XR	PA	DPP-4 inhibitors	
aprepitant	remove PA	Nausea and Vomiting	
Dificid	remove PA	Clostridioides difficile - associated diarrhea (CDAD)	

# Criteria Updates

## Summary of Changes

### RNA – targeted therapies

1. Guideline recommends genetic documentation as well as a positive amyloid biopsy for confirmation of diagnosis.
2. Added additional screening options as used in HELIO-A Trial (NCT03759379) and as indicated in the guidelines.
3. Updated signs and symptoms to correspond with initial symptoms as indicated in guidelines.

### TTR – stabilizers

1. Updated diagnostic confirmation and heart failure history criteria based on NCT01994889 inclusion criteria
2. Updated exclusion criteria based on exclusion criteria from NCT01994889 and results that were not statistically significant for class III HF.

### References:

1. Ando Y, Coelho T, Berk JL, Cruz MW, Ericzon BG, Ikeda S, Lewis WD, Obici L, Planté-Bordeneuve V, Rapezzi C, Said G, Salvi F. Guideline of transthyretin-related hereditary amyloidosis for clinicians. Orphanet J Rare Dis. 2013 Feb 20;8:31. doi: 10.1186/1750-1172-8-31. PMID: 23425518; PMCID: PMC3584981.

## Amyloidosis

### RNA – targeted therapies

#### *TTR-specific small interfering RNA (siRNA)*

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ONPATTRO (patisiran) – <i>Medical Billing Only</i>	

#### *Transthyretin-directed small interfering RNA (siRNA)*

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

#### *Antisense Oligonucleotide (ASO)*

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
TEGSEDI (inotersen)	
WAINUA (eplontersen)	

### *Prior Authorization Criteria*

#### Initial Criteria – Approval Duration: 6 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a neurologist, geneticist, or specialist in the treatment of amyloidosis.
- The diagnosis must be confirmed by both of the following:
  - Genetic testing confirming a pathogenic TTR mutation (e.g., V30M)
  - Amyloid deposits via tissue biopsy
- Documentation of one of the following must be provided:

- Baseline polyneuropathy disability (PND) score ≤ IIIb
- Baseline Coutinho staging system stage 1 or 2
- Baseline Neuropathy Impairment Score [NIS] of 5–130
- Karnofsky Performance Status score of ≥60%
- The member has not had a liver transplant.
- The member has clinical signs and symptoms of the disease (e.g., peripheral neuropathy, numbness, altered pain and temperature sensation, decreased pinprick sensation)
- The member is not receiving any other TTR reducing agent (i.e., vutrisiran, patisiran, tafamidis, inotersen, eplontersen).

**Renewal Criteria – Approval Duration: 12 months**

- Documentation of a therapeutic response as evidenced by stabilization or improvement (e.g., improved neurologic impairment, motor function, quality of life, slowing of disease progression, etc.) from baseline in one of the following:
  - PND score ≤ IIIb
  - Coutinho staging system stage 1 or 2
  - Baseline Neuropathy Impairment Score [NIS] of 5–130
  - Karnofsky Performance Status score of ≥60%

**TTR Stabilizers**

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
VYND AQEL (tafamidis)	
VYND AMAX (tafamidis)	

***Prior Authorization Criteria***

**Initial Criteria – Approval Duration: 12 months**

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a cardiologist, geneticist, or specialist in the treatment of amyloidosis.
- Documentation of confirmation of the diagnosis by both of the following must be provided:
  - genetic testing confirming a pathogenic TTR mutation (e.g., V30M)
  - amyloid deposits via tissue biopsy
- The member must have heart failure class I or II with at least 1 prior hospitalization for heart failure or with symptoms of volume overload or elevated intracardiac pressures (e.g., elevated jugular venous pressure, shortness of breath or signs of pulmonary congestion on x-ray or auscultation, peripheral edema) despite 6-months of adherent use of a diuretic.
- The member has an end-diastolic interventricular septal wall thickness of at least 12 mm.
- The member must not have any of the following:
  - NYHA class IV symptoms or severe aortic stenosis
  - Previous heart transplant or implanted cardiac mechanical assist device
  - Previous liver transplant
- Documentation of baseline 6MWT > 100 meters must be submitted.
- The member is not receiving any other TTR reducing agent (i.e., vutrisiran, patisiran, tafamidis, inotersen)

**Renewal Criteria – Approval Duration: 12 months**

- Documentation of a therapeutic response as evidenced by stabilization or improvement from baseline in both of the following:
  - 6MWT > 100 meters
  - NYHA class

## Summary of Changes

1. Ohtuvayre is a new to market drug.
  - a. Global Initiative for Chronic Obstructive Lung Disease (GOLD) 2024 report recommend LABA + LAMA + ICS for patients who develop exacerbations on LABA + LAMA and have a blood eosinophil count of  $\geq 100$ .
2. Dupixent received a new indication of COPD.
  - a. Biologics
3. Additional criteria added for Dupixent for asthma based on the QUEST trial, subjects with baseline blood eosinophil count  $<150$  cells/mcL and FeNO  $<25$  ppb, similar severe exacerbation rates were observed between Dupixent and placebo
4. Tobacco cessation counseling requirement was added for Asthma/COPD indicated drugs were treatment is being escalated as listed below.

## Asthma/COPD

### Biologics

#### Anti-IL-5 biologics

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
FASENRA (benralizumab)	CINQAIR (reslizumab) – <i>Medical Billing Only</i>
	NUCALA (mepolizumab) SYRINGE, AUTOINJECTOR
	NUCALA (mepolizumab) VIAL – <i>Medical Billing Only</i>

#### Anti-IL-4/13 biologics

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

#### Allergic Asthma-directed biologics

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
XOLAIR (omalizumab) SYRINGE, AUTOINJECTOR	
XOLAIR (omalizumab) VIAL – <i>Medical Billing Only</i>	

#### Thymic Stromal Lymphopoietin (TSLP) blocker

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	TEZSPIRE (tezepelumab-ekko) PENS
	TEZSPIRE (tezepelumab-ekko) VIAL and SYRINGES – <i>Medical Billing Only</i>

#### Prior Authorization Criteria

##### [Prior Authorization Form – Asthma](#)

Initial Criteria – Approval Duration: 6 months

## For Asthma Only

- The requested medication must be prescribed by, or in consult with, an allergist/immunologist or pulmonologist
- If the member is a current tobacco user, the member must have received tobacco cessation counseling in the past year
- The member must have had at least one exacerbation requiring use of oral corticosteroids in the past year despite continued compliant use of a high dose inhaled steroid in combination with a long-acting beta agonist (LABA) for at least 3 months prior to the exacerbation, as evidenced by paid claims or pharmacy printouts

### *Dupixent Only:*

- The member must have an eosinophil count of  $\geq 150$  cells/mcL or FeNO  $\geq 25$  ppb within the past year

### *Xolair Only:*

- The member has a serum total IgE level, measured before the start of treatment within the past year, of  $\geq 30$  IU/mL and  $\leq 700$  IU/mL in members age  $\geq 12$  years or  $\geq 30$  IU/mL and  $\leq 1300$  IU/mL in members ages 6 to  $< 12$  years.
- The member has had a positive skin test or in vitro reactivity to a perennial aeroallergen

### *Anti-IL-5 biologics:*

- The member has an eosinophil count  $\geq 150$  cells/mcL within the past year

### *Nucala and Cinqair Only:*

- The member must have had at least one exacerbation requiring use of oral corticosteroids in the past year despite continued compliant use of a triple therapy regimen (high dose inhaled steroid + long-acting beta agonist (LABA) + long-acting muscarinic antagonist (LAMA)) in combination with each of the following for at least 4 months, as evidenced by paid claims or pharmacy printouts: Dupixent, Fasenra, and Tezspire

### *Tezspire Only:*

- The member must have had at least one exacerbation requiring use of oral corticosteroids in the past year despite continued compliant use of a triple therapy regimen (high dose inhaled steroid + long-acting beta agonist (LABA) + long-acting muscarinic antagonist (LAMA)) in combination with each of the following for at least 4 months, as evidenced by paid claims or pharmacy printouts: Dupixent and Fasenra

## For COPD Only

### *Dupixent Only:*

- The requested medication must be prescribed by, or in consult with, an allergist/immunologist or pulmonologist
- If the member is a current tobacco user, the member must have received tobacco cessation counseling in the past year
- The member must have had at least one exacerbation requiring use of oral corticosteroids in the previous year despite continued compliant use of an inhaled steroid AND long-acting beta agonist (LABA) AND long-acting muscarinic antagonist (LAMA) as evidenced by paid claims or pharmacy printouts
- The member has an eosinophil count of  $\geq 300$  cells/mcL within the past year

### Renewal Criteria – Approval Duration: 12 months

- The member must have achieved a significant reduction in exacerbations and utilization of systemic steroids and rescue medications since treatment initiation since starting treatment with the requested medication (subject to clinical review).



## Phosphodiesterase-3 (PDE3) and Phosphodiesterase-4 (PDE4) Inhibitor

### PREFERRED AGENTS (CLINICAL PA REQUIRED)

OHTUVAYRE (ensifentrine)

#### Prior Authorization Criteria

##### Initial Criteria – Approval Duration: 12 months

- The requested medication must be prescribed by, or in consult with, a pulmonologist
- If the member is a current tobacco user, the member must have received tobacco cessation counseling in the past year
- The member must meet one of the following criteria:
  - The member has a blood eosinophil of  $\geq 100$  cells/mcL and has experienced an exacerbation while adherent to a 60-day trial of a triple combination regimen consisting of an inhaled steroid, long-acting beta agonist, and long-acting anticholinergic.
  - The member has a blood eosinophil of  $< 100$  cells/mcL and has experienced an exacerbation while adherent to a 60-day trial of a dual combination regimen consisting of a long-acting beta agonist and long-acting anticholinergic.

## Corticosteroid/Anticholinergics/Long-Acting Beta Agonists Combinations

### PREFERRED AGENTS (CLINICAL PA REQUIRED)

TRELEGY ELLIPTA  
(fluticasone/umeclidinium/vilanterol)

### NON-PREFERRED AGENTS (PA REQUIRED)

BREZTRI AEROSPHERE  
(budesonide/glycopyrrolate/formoterol)

#### Prior Authorization Criteria

##### Initial Criteria – Approval Duration: 12 months

- The member must have blood eosinophil of  $\geq 100$  cells/mcL within the past 90 days
- If the member is a current tobacco user, the member must have received tobacco cessation counseling in the past year
- The member must have experienced an exacerbation while adherent to a 60-day trial of fluticasone inhaler + umeclidinium + vilanterol which have the same active ingredients as Trelegy Ellipta, as evidenced by paid claims or pharmacy printouts. Clinical justification must also be provided why Trelegy Ellipta is expected to improve outcomes versus using fluticasone inhaler + umeclidinium + vilanterol combination therapy (subject to clinical review).
  - available combination products to achieve this are fluticasone + Anoro Ellipta (umeclidinium/vilanterol) and Breo Ellipta (fluticasone/vilanterol) + Include Ellipta (umeclidinium)
- The member must have experienced an exacerbation while adherent to a 60-day trial of triple therapy (Steroid/Long-Acting Beta Agonist/Long-Acting Anticholinergic) that has at least one ingredient different from fluticasone inhaler + umeclidinium + vilanterol combination therapy, as evidenced by paid claims or pharmacy printouts.

##### Non-Preferred Agents Criteria:

- The member must have failed a 30-day trial of the preferred product, as evidenced by paid claims or pharmacy printouts:

## Anticholinergics – Long-Acting

### PREFERRED AGENTS (NO PA REQUIRED)

### PREFERRED STEP 1 AGENTS (ELECTRONIC STEP REQUIRED)

### NON-PREFERRED STEP 2 AGENTS (PA REQUIRED)

INCRUSE ELLIPTA (umeclidinium)	SPIRIVA RESPIMAT 1.25 MCG (tiotropium)	tiotropium handihaler
SPIRIVA HANDIHALER (tiotropium)		TUDORZA PRESSAIR (aclidinium)
SPIRIVA RESPIMAT 2.5 MCG (tiotropium)		YUPELRI (revefenacin)

### Electronic Concurrent Medications Required

- Spiriva Respimat 1.25 mg: A total of 30 days of a long-acting beta agonist (ICS should be used with LABA as combination or single ingredient inhalers) must be paid within 40 days prior to the Spiriva Respimat 1.25 mg date of service.

### Electronic Diagnosis Verification

- Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale.
  - Spiriva Respimat 1.25 mg is indicated for asthma.
  - Spiriva Respimat 2.5 mg is indicated for COPD.

### Prior Authorization Criteria

#### Initial Criteria – Approval Duration: 12 months

- The member must have failed a 30-day trial of at least 2 preferred long-acting anticholinergic agents of unique ingredients (in combination or alone), as evidenced by paid claims or pharmacy printouts.
- If the member is a current tobacco user, the member must have received tobacco cessation counseling in the past year

## Corticosteroid/Long-Acting Beta Agonist (LABA) Combination Inhalers

### Solid Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED STEP 1 AGENTS (PA REQUIRED)	NON-PREFERRED STEP 2 AGENTS (PA REQUIRED)
ADVAIR DISKUS (fluticasone/salmeterol) – Brand Required	BREO ELLIPTA (fluticasone/vilanterol) – Brand Required	BREYNA (budesonide/formoterol)
ADVAIR HFA (fluticasone/salmeterol) – Brand Required		budesonide/formoterol
AIRDUO RESPICLICK (fluticasone/salmeterol) – Brand Required		fluticasone/salmeterol
DULERA (mometasone/formoterol)		fluticasone/vilanterol
		SYMBICORT (budesonide/formoterol) – Brand Required
		WIXELA INHUB (fluticasone/salmeterol)

GINA Guidelines – SMART:

- For mild asthma, ICS-formoterol is the preferred reliever medication for as needed symptom relief
  - For steps 3-5, ICS-formoterol is preferred for use as an as needed and regular daily treatment
- Quantity Limits to accommodate SMART therapy:*
- 2 Symbicort or Dulera inhalers per 30-day supply not to exceed a total of 9 inhalers per 182 days without prior approval.

### Electronic Diagnosis Verification

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

### Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

#### Non-Preferred Step 1 Agents:

- The member must have failed a 30-day trial of each preferred agent of a unique ingredient, as evidenced by paid claims or pharmacy printouts.
- For COPD diagnosis only: The member must currently be taking a long acting antimuscarinic agent.

#### Non-Preferred Step 2 Agents:

- The member must have failed a 30-day trial of each preferred and non-preferred step 1 agent of a unique ingredient, as evidenced by paid claims or pharmacy printouts.
- If the member is a current tobacco user, the member must have received tobacco cessation counseling in the past year
- For COPD diagnosis only, the member must currently be taking a long acting antimuscarinic agent.

## Summary of Changes

1. Yorvipath is a new to market drug. Calcium, magnesium, and vitamin D levels are based on the inclusion criteria for Study 1 (NCT04701203)

## Secondary Hyperparathyroidism

### Oral

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
calcitriol	cinacalcet
paricalcitol	doxercalciferol capsule
	HECTOROL (doxercalciferol) CAPSULE
	RAYALDEE ER (calcifediol)
	ROCALTROL (calcitriol)
	SENSIPAR (cinacalcet)
	ZEMPLAR (paricalcitol)

++ cinacalcet is associated with hypocalcemia, increased urinary calcium excretion, and increased serum phosphate levels

### Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

*Cinacalcet only:*

- If member is on renal dialysis, Medicare eligibility must be ruled out (6-month approval may be allowed to determine eligibility)

*All other agents:*

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The member must have failed a 30-day trial of paricalcitol
- Clinical justification must be provided explaining why the member is unable to use the preferred agents (subject to clinical review)

**References:**

1. Quarles LD. Management of secondary hyperparathyroidism in adult non-dialysis patients with chronic kidney disease. In: *UpToDate*, Post TW (Ed), UpToDate, Waltham, MA, 2023

*Subcutaneous*

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	YORVIPATH (palopegteriparatide)

*Prior Authorization Criteria*

Initial Criteria – Approval Duration: 12 months

- The requested medication must be prescribed by, or in consult with, an endocrinologist
- The member must have persistent hypoparathyroidism as evidenced by one of the following symptoms despite a 6-month trial of calcitriol or equivalent oral agent:
  - Symptomatic hypocalcemia
  - Hyperphosphatemia
  - Hypercalciuria
- The member must have an albumin-corrected serum calcium concentration must be  $\geq 7.8$  mg/dL
- The member must have a magnesium concentration  $\geq 1.3$  mg/dL
- The member must have a 25 (OH) vitamin D concentration between 20 and 80 ng/mL

Renewal Criteria – Approval Duration: 12 months

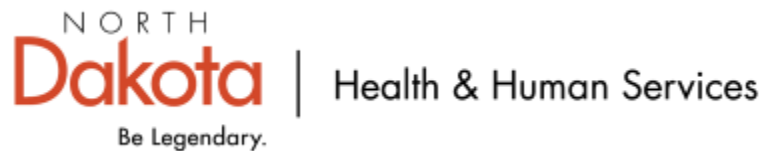
- The member no longer requires active vitamin D or has experienced a significant reduction in required dosage and is still titrating Yorvipath
- The member has an albumin-corrected serum calcium in the lower-half of the normal reference range or just below the reference range (~8-9 mg/dL)

# Pharmacy Coverage Policy Manual

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## Preferred Drug List (PDL)

This contains coverage rules for medications including prior authorization criteria for medications billed by pharmacy point of sale systems and for HCPCS codes billed by a physician/clinic through an 837P transactions.

## Preferred Diabetes Supply List (PDSL)

This is a list of diabetes supplies billed by pharmacy point of sale systems.

## Prior Authorization Review Dates

Please see DUR Board found at <https://ndmedicaid.acentra.com/>

# Preferred Drug List (PDL)

## Rules

1. Requests for non-preferred brand name agents with a generic formulation available must meet the Dispense as Written (DAW1) criteria for approval in addition to as any other applicable coverage criteria/rule (unless otherwise noted).
2. Non-solid dosage preparations must meet [Non-Solid Dosage Preparations](#) prior authorization criteria even if they are preferred in the clinical category.
3. [Renewal Request Criteria](#) must be met for all renewal requests.
4. The use of all preferred and non-preferred agents must meet recommendations found in the FDA label or compendia (e.g., diagnosis, age, dosage, frequency, route). Compendia supported use is defined as at least of level of IIa efficacy rating and IIb recommendation. ND Medicaid uses DrugDex ® compendia. Requests outside of FDA approved or compendia supported use are not reviewable by prior authorization and the request will be dismissed on PA review. Sec. 1927. [42 U.S.C. 1396r-8] (d).
5. Clinical justification may be provided when criteria does not encompass a standard of care or guideline supported therapy or a member's unique scenario, by faxing supporting chart notes and evidence using the [General Prior Authorization Form](#).
6. Grandfathering may be allowed in cases where the clinical condition has been verified by a specialist, member is currently receiving FDA or compendia approved medication, and there is clinical evidence for decompensation of member's condition if agent is switched (subject to clinical review).
7. A trial will be considered a failure if a product was not effective at the maximum therapeutic dose with good compliance with most recent trial within the past 6 months, as evidenced by paid claims or pharmacy print outs. If unable to titrate dose to maximum therapeutic dose due to contraindication, intolerance, or lack of effect; trial requirements must be met with alternative preferred product(s) when applicable. Mitigation efforts must be provided, as applicable, with a request to bypass a trial for a preferred product(s) due to intolerance (subject to clinical review).
8. The use of pharmaceutical samples will not be considered when evaluating the member's medical condition or prior prescription history for drugs that require prior authorization.
9. Unless otherwise specified, the listing of a brand or generic name includes all legend formulations of that drug. OTC drugs are not covered unless specified. All drugs are pharmacy billed medications unless otherwise specified.
10. Please use the following forms unless otherwise indicated:
  - Pharmacy Point of Sale: [General Prior Authorization Form](#)
  - Medical Office Billing: [Provider Administered Drug \(Medical Billing\) PA Form](#)
  - Requested product is same active ingredient as preferred product: [MedWatch Form](#)
11. For pharmacy billed medication: please use the prior authorization website <https://ndmedicaid.acentra.com/> to access PA forms, NDC Drug Lookup, quantity limits, and prior authorization information for all medications.
12. For medical billed medications: Please see the full list of medical drugs that require PA at <https://www.hhs.nd.gov/human-services/medicaid/provider> under the "Codes Requiring Service Authorization" tab at the bottom of the page.
13. All requirements outlined in the [Pharmacy Provider Manual](#) and any other federal or ND Medicaid manuals, policies, or guidance still apply. For example, when the PDL says a drug is covered without prior authorization, that does not imply that ND Medicaid will pay for that drug if someone has Medicare coverage.
14. If member is 65 years or older, on renal dialysis or has had a kidney transplant within the past 3 years, Medicare eligibility must be ruled out (6-month approval may be allowed to determine eligibility)

## Prior Authorization Updates

Drug name	PA Status	Class
Akynzeo	PA	Nausea and Vomiting
Bethkis	PA	Cystic Fibrosis

Nivestym	PA	Preferred Dosage Forms - figrastim
Nyvepria	PA	Preferred Dosage Forms - pegfilgrastim
Praluent	PA	cholesterol lowering drugs/PCSK9 inhibitors
Stimufend	PA	Preferred Dosage Forms - pegfilgrastim
Udenyca	PA	Preferred Dosage Forms - pegfilgrastim
Vyalev	PA	Parkinson's Disease
Ziextenzo	PA	Preferred Dosage Forms - pegfilgrastim
Zimhi	PA	Preferred Dosage Forms - naloxone
Zituvimet XR	PA	DPP-4 inhibitors
Abrilada	Remove PA	Cytokine Modulators
aprepitant	Remove PA	Nausea and Vomiting
Eysuvis	Remove PA	Dry Eye Syndrome
Hadlima	Remove PA	Cytokine Modulators
Rykindo ER	Remove PA	Preferred Dosage Forms - risperidone
Suflave	Remove PA	Bowel Prep agents
Sutab	Remove PA	Bowel Prep agents
Xaciato	Remove PA	Vaginal Infections

## Version Changes

Category	Change
Amyloidosis	Criteria updated
Antidepressants	Category added
Anti-infectives - Resistance Prevention	Criteria updated
Antipsychotics - Long Acting Injectables	Preferred products updated
Asthma / COPD	Criteria updated - Biologics
Biosimilars	Category added
Bowel Prep Agents	Preferred products updated
Chronic Rhinosinusitis with Nasal Polyps	Preferred products & criteria updated
Cystic Fibrosis	Preferred products updated
Diabetic Supplies - Continuous Glucose Monitors	Criteria & FAQ updated - Non-Preferred Guardian CGM added
Diabetic Supplies - Ketone Strips	Preferred products updated
Diabetic Supplies - Meters	Preferred products updated
Diabetic Supplies - Pen Needles	Preferred products updated
Diabetic Supplies - Syringes	Preferred products updated
Diabetic Supplies - Test Strips	Preferred products updated
Dry Eye Syndrome	Preferred products and criteria updated
Eczema / Atopic Dermatitis	Preferred products updated
Growth Hormone	Preferred products & criteria updated
Hematopoietic, Colony Stimulating Factors	Preferred products updated
Hemophilia	Criteria updated - gene therapy
Influenza	Criteria updated
Lipid Lowering Agents	PCSK9 inhibitors criteria updated - Praluent moved to non-preferred



Migraine - Prophylaxis	Preferred products and criteria updated
Omnipod	Criteria updated - Type 2 diabetes coverage added
Opioid Reveral Medications	Preferred products updated
Parkinson's Disease	Criteria updated and rearranged & Vyalev added
Plaque Psoriasis	Criteria updated for Otezla 20 mg and Tremfya
Psoriatic Arthritis	Criteria updated - Tremfya
Sickle Cell Disease	Criteria and preferred products updated
Stimulants	Preferred products & criteria updated
Vaginal Anti-infectives	Preferred products updated

## General Policies

### Dispense as Written (DAW1)

*Member or prescriber preference is NOT criteria considered for approval.*

#### *Prior Authorization Criteria*

##### Initial Criteria - Approval Duration: 12 months

- Request must meet one of the following (A or B):
  - A. Primary insurance requires a ND Medicaid non-preferred branded product.
  - B. All the following are met (1-4):
    1. The requested brand-name product must not have an authorized generic available.
    2. The member must have failed a 30-day trial of each pharmaceutically equivalent generic product at maximum tolerated dose from each available manufacturer, as evidenced by paid claims or pharmacy print outs.
    3. Clinical justification is provided for the different clinical outcome expected for the requested brand and other alternatives (e.g., medications in same class) are not an option for the member (subject to clinical review)
    4. A MedWatch form for each trial of each NDC from the available manufacturer(s) is filled out and attached to request.

### Generic Non-Preferred Requests

*Member or prescriber preference is NOT criteria considered for approval.*

#### *Prior Authorization Criteria*

##### Initial Criteria - Approval Duration: 12 months (1 month for short-term request)

- Request must meet one of the following (A, B, or C):
  - A. Primary insurance requires a ND Medicaid non-preferred generic product.
  - B. Pharmacy requests a short-term approval due to dose titration or supply issue.
  - C. All the following are met (1-3):
    1. The member must have failed a 30-day trial of preferred brand product, as evidenced by paid claims or pharmacy print outs.
    2. Clinical justification is provided for the different clinical outcome expected for the requested generic and other alternatives (e.g., medications in same class) are not an option for the member (subject to clinical review)



3. A MedWatch form for each trial of each product from the available manufacturer(s) is filled out and attached to request.

## Medications that cost over \$3000/month

### Prior Authorization Criteria

#### Initial Criteria - Approval Duration: 6 months

- Both of the following must be met:
  - The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational).
  - The medication must be used as recommended in available guidelines or expert consensus statements, including medication trials that are recommended prior to use of requested medication.
- The requested medication must be prescribed by, or in consult with, a specialist in the member's treated diagnosis.
- As applicable, documentation must be attached to confirm serum marker or pathogenic gene variants amenable to treatment.
- Documentation of the baseline labs, signs or symptoms that can be utilized for comparison to show member has experienced clinical benefit upon renewal has been submitted with request.

CLINICAL PA REQUIRED
ABECMA (idecabtagene vicleucel) – <i>Medical Billing Only</i>
ACTHAR (corticotropin) SELF-INJECTOR
BLINCYTO (blinatumomab) – <i>Medical Billing Only</i>
BREYANZI (lisocabtagene maraleucel) – <i>Medical Billing Only</i>
CARVYKTI (ciltacabtagene autoleucel) – <i>Medical Billing Only</i>
CYSTADROPS (cysteamine)
CYSTARAN (cysteamine)
DANYELZA (naxitamab-ggqk) – <i>Medical Billing Only</i>
DAYBUE (trofinetide)
DOJOVI (triheptanoin)
EPKINLY (epcoritamab-bysp) – <i>Medical Billing Only</i>
FIRDAPSE (amifampridine)
FUROSCIX (furosemide)
FUROSCIX (furosemide) – <i>Medical Billing Only</i>
FYARRO (sirolimus protein-bound particles) – <i>Medical Billing Only</i>
GATTEX (teduglutide)
INCRELEX (mecasermin)
IQIRVO (elafibranor)
JOENJA (leniolisib)
KIMMTRAK (tebentafusp-tebn) – <i>Medical Billing Only</i>
KYMRIAH (tisagenlecleucel) – <i>Medical Billing Only</i>
LIVDELZI (seldelpar lysine)
MYCAPSSA (octreotide)
NULIBRY (fosdenopterin)
OCALIVA (obeticholic acid)
OXERVATE (cenegermin-bkbj)
PYRUKYND (mitapivat)
REZUROCK (belumosudil)

SKYCLARYS (omaveloxolone)
SPEVIGO (spesolimab-sbzo)
SOHONOS (palovarotene)
TAVNEOS (avacopan)
TECARTUS (brexucabtagene autoleucel) – <i>Medical Billing Only</i>
TECVAYLI (Inj teclistamab cqyv 0.5 mg) – <i>Medical Billing Only</i>
TIVDAK (tisotumab vedotin-tftv) – <i>Medical Billing Only</i>
VIJOICE (apelisib)
VYJUVEK (beremagene geperpavec-svdt) – <i>Medical Billing Only</i>
WELIREG (belzutifan)
XENPOZYME (olipudase alfa) – <i>Medical Billing Only</i>
XOLREMDI (mavorixafor)
YESCARTA (axicabtagene ciloleucel) – <i>Medical Billing Only</i>
ZOKINVY (lonafamib)
ZYNLONTA (loncastuximab tesirine-lpyl) – <i>Medical Billing Only</i>

## Non-Solid Dosage Forms

### *Electronic Age Verification*

- Non-Solid Dosage Forms that do not require prior authorization for clinical criteria will reject at the point of sale for members 10 years and older to verify they meet Non-Solid Dosage Form prior authorization criteria.

### *Prior Authorization Criteria*

#### Initial Criteria - Approval Duration: 3 years (1 month for short-term restriction)

- One of the following criteria is met:
  - The member has a feeding tube placed and the medication is not available in a dosage form that can be crushed or poured into the tube.
  - The member does not have a feeding tube placement but one of the following apply:
    - Swallow study documentation has been submitted showing inability to swallow.
    - Permanent disability of swallowing solid dosage forms
    - Short-term restriction (e.g., mouth surgery)

## Renewal Requests

### *Prior Authorization Criteria*

#### Renewal Criteria

- The member must have experienced and maintained clinical benefit since starting treatment with the requested medication (subject to clinical review).
- The member must continue to meet applicable initial criteria. Additional renewal criteria may apply as indicated under specific category.
- One of the following must be met (1 or 2):
  1. Approval Duration: regular renewal approval duration or 1 year
    - The member was at least 80% adherent to medication, excluding any claim gaps due to hospitalization or eligibility.
  2. Approval Duration: 3 months
    - All the following must be met -
      - Clinical justification must be provided for the non-adherence.

- A method to improve adherence must be provided such as addressing adherence barriers, implementing a treatment plan, medication therapy management (MTM), etc.
- Clinical justification must be provided to continue treatment and how efficacy is assessed despite non-adherence.

## Allergy/Immunology

### Therapeutic Duplication

- One strength of one medication is allowed at a time.

## Chronic Idiopathic Urticaria

### Biologic Agents

#### CLINICAL PA REQUIRED

XOLAIR (omalizumab) SYRINGE, AUTOINJECTOR

XOLAIR (omalizumab) VIALS – *Medical Billing Only*

### Prior Authorization Criteria

#### Initial Criteria - Approval Duration: 3 months

- The requested medication must be prescribed by, or in consult with, an allergist/immunologist.
- The member must have failed a 30-day trial of a dose of fourfold normal dosing of second-generation H<sub>1</sub> antihistamine (e.g., cetirizine, desloratadine, fexofenadine, levocetirizine, loratadine) in addition to the following:
  - A. Leukotriene receptor antagonist (e.g., montelukast, zafirlukast, zileuton)
  - B. Histamine H<sub>2</sub>-receptor (e.g., ranitidine, famotidine, nizatidine, cimetidine)

#### References

1. Khan DA. Chronic spontaneous urticaria: Treatment of refractory symptoms. In: *UpToDate*, Post TW (Ed), UpToDate, Waltham, MA, 2023
2. Schaefer P. Acute and Chronic Urticaria: Evaluation and Treatment. *Am Fam Physician*. 2017 Jun 1;95(11):717-724. PMID: 28671445
3. Zuberbier, Torsten, et al. "The international EAACI/GA<sup>2</sup>LEN/EuroGuiDerm/APAAACI guideline for the definition, classification, diagnosis, and management of urticaria." *Allergy* 77.3 (2022): 734-766.

## Chronic Rhinosinusitis with Nasal Polyps

### Steroids – Nasal Spray

#### PREFERRED AGENTS (NO PA REQUIRED)

fluticasone

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

XHANCE (fluticasone)

#### Initial Criteria - Approval Duration: 12 months

- Xhance (fluticasone) Only: See [Preferred Dosage Form](#) criteria

## Biologics

### Anti-IL-4/13 biologics

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

### Anti-IL-5 biologics

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	NUCALA (mepolizumab) SYRINGE, AUTOINJECTOR
	NUCALA (mepolizumab) VIAL – <i>Medical Billing Only</i>

### Eosinophil-directed biologics

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
XOLAIR (omalizumab) SYRINGE, AUTOINJECTOR	
XOLAIR (omalizumab) VIAL – <i>Medical Billing Only</i>	

### Prior Authorization Criteria

#### [Prior Authorization Form - Nasal Polyps](#)

##### Initial Criteria - Approval Duration: 3 months

- The requested medication must be prescribed by, or in consult with, an ear/nose/throat specialist or allergist/immunologist.
- The member must have failed a 12-week trial of intranasal corticosteroids.
- The member must have trialed at least two courses of a 10-day trial of oral glucocorticoids in the past year.
- The member must have bilateral polyps confirmed by sinus CT, anterior rhinoscopy, or nasal endoscopy.

##### Non-Preferred Agent Criteria:

- The member must have failed a 90-day trial with each preferred agent, as evidenced by paid claims or pharmacy printouts. Dupixent trial may be bypassed if the member has eosinophilic granulomatosis with polyangiitis

##### Renewal Criteria - Approval Duration: 12 months

- Documentation must be provided including that the member has achieved a significant reduction in nasal polyp size and symptoms since treatment initiation.
- The member must be receiving intranasal steroids.

#### References:

1. Rank, Matthew A., et al. "The Joint Task Force on Practice Parameters GRADE guidelines for the medical management of chronic rhinosinusitis with nasal polyposis." *Journal of Allergy and Clinical Immunology* 151.2 (2023): 386-398.

## Cytokine Release Syndrome

### Biologic Agents

#### Tocilizumab

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
TYENNE (tocilizumab-aazg) AUTOINJECTOR, SYRINGE	ACTEMRA (tocilizumab) ACTPEN, SYRINGE

TYENNE (tocilizumab-aazg) VIAL – <i>Medical Billing Only</i>	ACTEMRA (tocilizumab) VIAL – <i>Medical Billing Only</i>
	TOFIDENCE (tocilizumab-aazg) VIAL – <i>Medical Billing Only</i>

### Prior Authorization Criteria

#### Initial Criteria - Approval Duration: 4 doses

- The member must have grade 3 or 4 Cytokine Release Syndrome resulting in hypotension and/or hypoxia.
- Non-preferred agents only: See [biosimilar agent](#) criteria

#### References

- Porter DL, Maloney DG. Cytokine Release Syndrome. In: *UpToDate*, Post TW (Ed), UpToDate, Waltham, MA, 2024

## Deficiency of IL-A Receptor Antagonists (DIRA)

### Biologic Agents

#### *Interleukin (IL) -1 Receptor Inhibitors*

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
KINERET (anakinra)	ARCALYST (rilonacept)

### Prior Authorization Criteria

#### Initial Criteria - Approval Duration: 6 months

- The member must have failed a 3-month trial of a preferred agent, as evidenced by paid claims or pharmacy printouts.

#### References

- Nigrovic PA. Cryopyrin-associated periodic syndromes and related disorders. In: *UpToDate*, Post TW (Ed), UpToDate, Waltham, MA, 2023

## Eosinophilic Granulomatosis with Polyangiitis (EGPA)

### Biologic Agents

#### *Anti-B-cell Therapy*

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
RIABNI (rituximab-arrx) – <i>Medical Billing Only</i>	RITUXAN (rituximab) – <i>Medical Billing Only</i>
RUXIENCE (rituximab-pvvr) – <i>Medical Billing Only</i>	
TRUXIMA (rituximab-abbs) – <i>Medical Billing Only</i>	

#### *Anti-IL-5 Biologics*

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
FASENRA (benralizumab)	NUCALA (mepolizumab) SYRINGE, AUTOINJECTOR
	NUCALA (mepolizumab) VIAL – <i>Medical Billing Only</i>

### Prior Authorization Criteria

#### Initial Criteria - Approval Duration: 6 months

- The requested medication must be prescribed by, or in consult with, a pulmonologist, rheumatologist, or allergy/immunology specialist.
- The member must not have severe disease defined as vasculitis with life- or organ-threatening manifestations (e.g., alveolar hemorrhage, glomerulonephritis, central nervous system vasculitis, mononeuritis multiplex, cardiac involvement, mesenteric ischemia, limb/digit ischemia)
- The member must have received at least 4 weeks of an oral corticosteroid dose  $\geq 7.5$  mg/day to control relapsing or refractory disease.
- The member must have asthmatic manifestations on a combination of high doses of inhaled glucocorticoids and long acting  $\beta$ 2-agonist.
- The member must have blood eosinophil count of  $\geq 1000$  cells/mcL and/or  $\geq 10$  percent of leukocytes within the previous 6 weeks.

#### Non-Preferred Agents Criteria

- The member must have failed a 3-month trial of Fasena, as evidenced by paid claims or pharmacy printouts.
- Rituxan Only: See [Biosimilar Agents](#) criteria

#### Renewal Criteria - Approval Duration: 12 months (one time renewal except in history of multiple relapses)

- The member must have experienced a decrease in relapses\* and corticosteroid dose, and an increase of time of remission since starting treatment with the requested medication, as evidenced by medical documentation (e.g., chart notes) attached to the request (subject to clinical review).

\*Relapse is defined as active vasculitis, active asthma symptoms, active nasal or sinus disease requiring the use of glucocorticoids or immunosuppressants.

#### References

1. Chung SA, Langford CA, Maz M, Abril A, Gorelik M, Guyatt G, et al. 2021 American College of Rheumatology/Vasculitis Foundation guideline for the management of antineutrophil cytoplasmic antibody-associated vasculitis. *Arthritis Care Res (Hoboken)* 2021; 73: 1088– 1105.
2. Jennette, J.C., Falk, R.J., Bacon, P.A., Basu, N., Cid, M.C., Ferrario, F., Flores-Suarez, L.F., Gross, W.L., Guillevin, L., Hagen, E.C., Hoffman, G.S., Jayne, D.R., Kallenberg, C.G.M., Lamprecht, P., Langford, C.A., Luqmani, R.A., Mahr, A.D., Matteson, E.L., Merkel, P.A., Ozen, S., Pusey, C.D., Rasmussen, N., Rees, A.J., Scott, D.G.I., Specks, U., Stone, J.H., Takahashi, K. and Watts, R.A. (2013), 2012 Revised International Chapel Hill Consensus Conference Nomenclature of Vasculitides. *Arthritis & Rheumatism*, 65: 1-11. <https://doi.org/10.1002/art.37715>
3. King, Jr. TE. Eosinophilic granulomatosis with polyangiitis (Churg-Strauss): Treatment and prognosis. In: *UpToDate*, Post TW (Ed), UpToDate, Waltham, MA, 2023
4. Emmi, Giacomo, et al. "Evidence-Based Guideline for the diagnosis and management of eosinophilic granulomatosis with polyangiitis." *Nature reviews Rheumatology* 19.6 (2023): 378-393.

## Food Allergy

### Eosinophil-directed biologics

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
XOLAIR (omalizumab) SYRINGE, AUTOINJECTOR	
XOLAIR (omalizumab) VIAL – <i>Medical Billing Only</i>	

### Oral Immunotherapy

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

### Prior Authorization Criteria

#### Initial Criteria - Approval Duration: 6 months

- The requested medication must be prescribed by, or in consult with, an allergist/immunologist.

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

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

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

## Hypereosinophilic Syndrome (HES)

### Biologic Agents

#### CLINICAL PA REQUIRED

NUCALA (mepolizumab) SYRINGE, AUTOINJECTOR

NUCALA (mepolizumab) VIAL – *Medical Billing Only*

#### Prior Authorization Criteria

Initial Criteria - Approval Duration: 6 months

- The requested medication must be prescribed by, or in consult with, a hematologist, or allergy/immunology specialist.
- The member must be FIP1L1-PDGFR $\alpha$  kinase-negative.
- The member must have experienced at least 2 HES flares within the past 12 months despite a 3-month trial with oral corticosteroid  $\geq$  7.5 mg/day
- The member must have a blood eosinophil count of 1000 cells/mcL or higher.

Renewal Criteria - Approval Duration: 12 months

- The member must have experienced and maintained clinical benefit (e.g., reduction in flares, decreased blood eosinophilic count, reduction in corticosteroid dose or steroid sparing therapy) since starting treatment with the requested medication, as evidenced by medical documentation (e.g., chart notes) attached to the request (subject to clinical review)



# Gout

## Flare Treatment

### Oral agents

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
colchicine tablet	colchicine capsule
<a href="#">NSAIDs</a>	GLOPERBA (colchicine) ORAL SOLUTION
<a href="#">Oral Corticosteroids</a>	MITIGARE (colchicine) CAPSULE

#### Prior Authorization Criteria

- See applicable [Preferred Dosage Form](#) or [Non-Solid Oral Dosage Form](#) criteria.

### Biologic Agents

#### Interleukin (IL) -1 Receptor Inhibitors

PREFERRED AGENTS (CLINICAL PA REQUIRED)
ILARIS (canakinumab) – <i>Medical Billing Only</i>

#### Prior Authorization Criteria

##### Initial Criteria - Approval Duration: 6 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a rheumatologist or nephrologist.
- The member is concurrently taking a medication for prophylaxis of gout flares
- The member must have failed a 7-day trial of each of the following, as evidenced by paid claims or pharmacy printouts:
  - colchicine
  - NSAIDs
  - corticosteroids

## Urate Lowering Therapy

### Uricosuric Drugs

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
probenecid-colchicine tablets	
probenecid tablets	

### Xanthine Oxidase Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
6-mercaptopurine (6-MP)	AZASAN (azathioprine)
allopurinol 100 mg, 300 mg tablet	allopurinol 200 mg tablet
azathioprine 50 mg	azathioprine 75 mg, 100 mg tablet



	++febuxostat
	IMURAN (azathioprine)
	++ULORIC (febuxostat) TABLET
	ZYLOPRIM (allopurinol) TABLET

++Clinically Non-Preferred: In clinical trials, febuxostat had a higher incidence of thromboembolic cardiovascular events and hepatic abnormalities compared to allopurinol.

### Prior Authorization Criteria

#### Initial Criteria - Approval Duration: 12 months

The member must meet one of the following criteria:

- The member must have failed a 30-day trial of allopurinol, as evidenced by paid claims or pharmacy printouts.
- The member is HLA-B\*5801 positive

## Uricase

### PREFERRED AGENTS (CLINICAL PA REQUIRED)

KRYSTEXXA (pegloticase) – *Medical Billing Only*

### Prior Authorization Criteria

#### Initial Criteria - Approval Duration: 6 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a rheumatologist or nephrologist.
- The member must have failed a 3-month trial of two of the following, as evidenced by paid claims or pharmacy printouts:
  - allopurinol
  - febuxostat
  - allopurinol or febuxostat in combination with probenecid
- The failure of previous trials must be documented by both of the following (A and B):
  - A. Serum uric acid level  $\geq$  6 mg/dL within the past month
  - One of the following (i, ii, or iii):
    - At least 3 gout flares in the previous 18 months that were inadequately controlled.
    - At least 1 gouty tophus
    - Chronic gouty arthropathy/arthritis

#### Renewal Criteria - Approval Duration: 12 months

- The member is not experiencing infusion reactions.
- The member must have experienced and maintained clinical benefit since starting treatment with the requested medication, as evidenced by medical documentation (e.g., chart notes) attached to the request (subject to clinical review) including both of the following:
  - Serum uric acid level  $<$  6 mg/dL within the past month
  - Decrease in gout flares or nonrevolving tophaceous deposits

## Hereditary Angioedema (HAE)

### Acute Attack

#### PREFERRED AGENTS (CLINICAL PA REQUIRED)

icatibant

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

BERINERT (plasma derived C1 Esterase Inhibitor)

BERINERT (plasma derived C1 Esterase Inhibitor)

	– <i>Medical Billing Only</i>
	FIRAZYR (icatibant)
	KALBITOR (ecallantide) – <i>Medical Billing Only</i>
	RUCONEST (recombinant C1 Esterase Inhibitor)
	RUCONEST (recombinant C1 Esterase Inhibitor) – <i>Medical Billing Only</i>

### *Prior Authorization Criteria*

#### Initial Criteria - Approval Duration: 12 months

- The requested medication must be prescribed by, or in consult with, an allergist/immunologist or rheumatologist.

#### *Non-Preferred Agent Criteria:*

- The member must have a contraindication to or failed a trial of all preferred agents, as evidenced by paid claims or pharmacy printouts.
  - Berinert Only: The preferred agent trial may be bypassed for members who are pregnant, breastfeeding, or under 18 years old upon request.
  - Ruconest Only: The member must have a contraindication to or failed a trial of Berinert, as evidenced by paid claims or pharmacy printouts.

## Prophylaxis

<b>PREFERRED AGENTS (CLINICAL PA REQUIRED)</b>	<b>NON-PREFERRED AGENTS (PA REQUIRED)</b>
HAEGARDA (plasma derived C1 Esterase Inhibitor)	CINRYZE (plasma derived C1 Esterase Inhibitor)
TAKHZYRO (lanadelumab-flyo)	ORLADEYO (berotrlastat)

### *Prior Authorization Criteria*

#### Initial Criteria - Approval Duration: 12 months

- The requested medication must be prescribed by, or in consult with, an allergist/immunologist or rheumatologist.
- The member's weight and dose are provided.
- One of the following must be met (A, B, or C):
  - The member has had at least 1 moderate to severe acute attack in the past 3 months (e.g., airway swelling, facial swelling, severe abdominal pain)
  - The member is using short-term prophylaxis for one of the following:
    - a procedure related to pregnancy
    - oral cavity or invasive procedures
    - stressful life event at high risk for precipitating HAE attack (clinical justification subject to clinical review)
  - Estrogen treatment is required, and member is at high risk for estrogen-precipitated HAE attack (clinical justification subject to clinical review)

#### *Non-Preferred Agent Criteria:*

- The member must have a contraindication to or failed a 3-month trial of all preferred agents with the same indication for use (prophylaxis or acute treatment), as evidenced by paid claims or pharmacy printouts.

#### Renewal Criteria – Approval Duration: 12 months

- The member must have experienced meaningful clinical benefit since starting treatment with the requested medication, as evidenced by at least a 50% reduction in the number of HAE attacks.

## Quantity Override Request

- Takhyzro: The number of attacks in the last 6 months must be included if the requested dosing frequency is every 2 weeks (must be more than 0).

### References

1. Busse, Paula J., et al. "US HAEA medical advisory board 2020 guidelines for the management of hereditary angioedema." *The Journal of Allergy and Clinical Immunology: In Practice* 9.1 (2021): 132-150.

## Immune Globulins

### IM

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
GAMASTAN (immune globul G (IgG)/glycine)	
GAMASTAN (immune globul G (IgG)/glycine) – <i>Medical Billing Only</i>	

### IVIG

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
BIVIGAM (human immunoglobulin G)	ALYGLO (human immunoglobulin G - stwk)
BIVIGAM (human immunoglobulin G) – <i>Medical Billing Only</i>	ALYGLO (human immunoglobulin G - stwk) – <i>Medical Billing Only</i>
GAMMAGARD S-D (human immunoglobulin G)	ASCENIV (human immune globulin G- slra)
GAMMAPLEX (human immunoglobulin G)	ASCENIV (human immune globulin G- slra) – <i>Medical Billing Only</i>
GAMMAPLEX (human immunoglobulin G) – <i>Medical Billing Only</i>	PANZYGA (human immune globulin G- ifas)
OCTAGAM (human immunoglobulin G)	PANZYGA (human immune globulin G - ifas) – <i>Medical Billing Only</i>
OCTAGAM (human immunoglobulin G) – <i>Medical Billing Only</i>	
PRIVIGEN (human immunoglobulin G)	
PRIVIGEN (human immunoglobulin G) – <i>Medical Billing Only</i>	

### IVIG/SCIG

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
GAMMAGARD LIQUID (human immunoglobulin gamma)	
GAMMAKED (human immunoglobulin gamma)	
GAMMAKED (human immunoglobulin gamma) – <i>Medical Billing Only</i>	
GAMUNEX-C (human immunoglobulin gamma)	
GAMUNEX-C (human immunoglobulin gamma) – <i>Medical Billing Only</i>	

### SCIG

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
CUTAQUIG (human immune globulin G - hipp)	CUVITRU (human immunoglobulin gamma)

CUTAQUIG (human immune globulin G - hipp) – <i>Medical Billing Only</i>	CUVITRU (human immunoglobulin gamma) – <i>Medical Billing Only</i>
HIZENTRA (human immunoglobulin gamma)	HYQVIA (human immune globulin G and hyaluronidase)
HIZENTRA (human immunoglobulin gamma) – <i>Medical Billing Only</i>	HYQVIA (human immune globulin G and hyaluronidase) – <i>Medical Billing Only</i>
XEMBIFY (immune globulin,gamma(IgG)klhw)	
XEMBIFY (immune globulin,gamma(IgG)klhw) – <i>Medical Billing Only</i>	

### Electronic Diagnosis and Quantity Verification

- For medical billing only: the following Local Coverage Determination applies to applicable preferred and non-preferred agents: [Article - Billing and Coding: Immune Globulin Intravenous \(IVIg\) \(A57187\) \(cms.gov\)](#)

### Prior Authorization Criteria

#### Initial Criteria - Approval Duration: 12 months

- If the member's BMI > 30, adjusted body weight must be provided along with the calculated dose.
- The member must meet one of the following criteria:
  - The member must have failed a trial of each of the preferred products, as evidenced by paid claims or pharmacy printouts.
  - The member is stable on current therapy (have had a paid claim for requested therapy in the past 45 days)

## Steroids – Nasal Spray

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
DYMISTA (azelastine-fluticasone) – <i>Brand Required</i>	azelastine-fluticasone
fluticasone	BECONASE AQ (beclomethasone)
mometasone – labeler 60605	flunisolide
OMNARIS (ciclesonide)	mometasone – labeler 65152
QNASL (beclomethasone)	QNASL CHILDREN (beclomethasone)
ZETONNA (ciclesonide)	RYALTRIS (olopatadine/mometasone)
	XHANCE (fluticasone)

### Prior Authorization Criteria

#### Initial Criteria – Approval Duration: 12 months

- The member must have failed a 30-day trial of each preferred agent, as evidenced by paid claims or pharmacy printouts.
- Xhance (fluticasone) Only: See [Preferred Dosage Form Criteria](#)

## Cardiology

### Therapeutic Duplication

- One Strength of one medication is allowed at a time
  - Exceptions:
    - carvedilol IR 25 mg allowed with all other strengths
    - warfarin strengths are allowed together

- prazosin strengths are allowed together
- Medication classes not payable together:
  - Entresto, ACE Inhibitors, ARBs, and Renin Inhibitors are not allowed with each other.
  - sildenafil, tadalafil, Adempas, nitrates are not allowed with each other.
  - carvedilol and labetalol are not allowed with other non-selective alpha blockers (Alfuzosin ER, doxazosin, prazosin, and terazosin)
    - carvedilol and labetalol are non-selective beta blockers with alpha 1 blocking activity
  - tizanidine is not allowed with other alpha 2 agonists (clonidine, clonidine/chlorthalidone, guanfacine, methyl dopa)
    - tizanidine is also an alpha 2 agonist
  - clopidogrel is not covered with esomeprazole or omeprazole. Other PPIs such as pantoprazole are covered with clopidogrel.
    - clopidogrel is a substrate for 2C19 and esomeprazole and omeprazole are strong 2C19 inhibitors and can decrease effectiveness of clopidogrel.
  - clopidogrel, prasugrel, ticagrelor, and ticlopidine are not covered with morphine. Other opioid analgesics are covered with clopidogrel, prasugrel, ticagrelor, and ticlopidine.
    - Morphine may diminish the antiplatelet effect and serum concentrations of P2Y12 Inhibitor antiplatelet agents (clopidogrel, prasugrel, ticagrelor, and ticlopidine).

## Alpha and/or Beta Blockers Therapeutic Duplication – Override Request

Overrides may be available for alpha and/or beta blockers for use within the cardiac or nephrology specialties if they have a difference in mechanism of action (e.g., non-selective or selective beta blocking activity, with or without alpha-1 blocker activity). Please request an override by calling provider relations at 1-800-755-2604.

- The prescribers of each medication must be aware of each other.
- The requested medications must be prescribed by, or in consult with, a cardiologist or nephrologist.

## Anticoagulants

### Anticoagulants - Direct Oral Anticoagulants (DOACs)

#### Solid oral dosage forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ELIQUIS (apixaban)	dabigatran capsule
PRADAXA (dabigatran) capsule – <i>Brand Required</i>	SAVAYSA (edoxaban)
XARELTO (rivaroxaban)	

#### Non-solid oral dosage forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
XARELTO (rivaroxaban) SUSPENSION	PRADAXA (dabigatran) PELLETT

#### Prior Authorization Criteria

##### Initial Criteria – Approval Duration: 12 months

- The member must have failed a 30-day trial of each preferred agent and warfarin, as evidenced by paid claims or pharmacy printouts.

### Reduction of Risk of Major Cardiovascular Events in Chronic CAD or PAD

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
XARELTO (rivaroxaban) 2.5 mg	

## Prior Authorization Criteria

### Initial Criteria – Approval Duration: 12 months

- Xarelto 2.5 mg: The diagnosis must be provided with the request.

## Anticoagulants - Injectables

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
enoxaparin	ARIXTRA (fondaparinux)
	fondaparinux – <i>No PA required for HIT diagnosis*</i>
	FRAGMIN (dalteparin)
	LOVENOX (enoxaparin)

### Electronic Diagnosis Verification

- Fondaparinux: Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale\*

## Prior Authorization Criteria

### Initial Criteria – Approval Duration: 12 months

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

## Calcium Channel Blockers

### Non-solid oral dosage forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
NORLIQVA (amlodipine) SOLUTION	KATERZIA (amlodipine) SUSPENSION
NYMALIZE (nimodipine) SOLUTION	

### Electronic Diagnosis Verification

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

### Solid oral dosage forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
amlodipine	ADALAT CC (nifedipine)
CARTIA XR (diltiazem)	CALAN SR (verapamil)
diltiazem	CARDIZEM (diltiazem)
diltiazem ER	CARDIZEM CD (diltiazem)
DILT-XR (diltiazem)	levamlodipine
felodipine ER	nisoldipine ER 20 mg, 30 mg, 40 mg
isradipine	NORVASC (amlodipine)
MATZIM LA (diltiazem) ER	PROCARDIA XL (nifedipine)
nicardipine	SULAR ER (nisoldipine)
nifedipine	TIAZAC (diltiazem)
nifedipine ER	TIAZAC ER (diltiazem)
nimodipine	verapamil ER PM
nisoldipine ER 8.5 mg, 17 mg, 25.5 mg, 34 mg	VERELAN (verapamil)
TAZTIA XT (diltiazem)	VERELAN PM (verapamil)

TIADYLT ER (diltiazem)	
verapamil	
verapamil ER	

### Prior Authorization Criteria

- Katerzia, Verapamil ER PM, Nisoldipine ER 20 mg, 30 mg, 40 mg, levamlopidine:
  - See [Preferred Dosage Form](#) criteria

## Diuretics

### Diuretics – Loop

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
furosemide	ethacrynic acid
bumetanide	
toremide	

### Prior Authorization Criteria

#### Initial Criteria – Approval Duration: 12 months

- Ethacrynic acid: One of the following must be met:
  1. The member must have a documented sulfa allergy.
  2. The member must have failed a 30-day trial of each preferred agent, as evidenced by paid claims or pharmacy print outs.

### Diuretics – Potassium Sparing / Sodium channel blocker

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
amiloride	triamterene

### Prior Authorization Criteria

#### Initial Criteria – Approval Duration: 12 months

- The member must have failed a 30-day trial of each preferred agent of a unique ingredient, as evidenced by paid claims or pharmacy print outs.

### Diuretics – Potassium Sparing / Aldosterone Antagonist

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
amiloride	ALDACTONE (spironolactone) TABLET
eplerenone	CAROSPIR (spironolactone) SUSPENSION
spironolactone suspension	INSPRA (eplerenone)
spironolactone tablet	

## Heart Failure

### Solid Dosage Forms

#### First Line Agents

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
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ACE (angiotensin-converting enzyme) inhibitors – <i>all oral agents preferred</i>	dapagliflozin
ARBs (angiotensin receptor blockers) – <i>all oral agents preferred</i>	INPEFA (sotagliflozin)
Beta blockers – <i>all oral agents preferred</i>	SAMSCA (tolvaptan)
<a href="#">Diuretics</a>	tolvaptan
ENTRESTO (sacubitril/valsartan)	
FARXIGA (dapagliflozin) – <i>Brand Required</i>	
JARDIANCE (empagliflozin)	

### Second Line Agents

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

## Non-Solid Dosage Forms

### First Line Agents

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
enalapril oral solution	ENTRESTO (sacubitril/valsartan) SPRINKLE
	EPANED (enalapril) SOLUTION

### Electronic Diagnosis Verification

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

### Electronic Duration Verification:

- tolvaptan is payable for 30 days every year.

### Prior Authorization Criteria

#### Initial Criteria – Approval Duration: 12 months

- Corlanor Only:
  - The requested medication must be prescribed by, or in consult with, a cardiologist.
  - The member must have a resting HR  $\geq$  70 beats per minute on maximally tolerated or target beta blocker dose in sinus rhythm.
- Entresto Sprinkle
  - See [Non-Solid Dosage Form](#) criteria
  - The member has a diagnosis of heart failure with left ventricular ejection fraction of  $\leq$  45 %
  - The member has failed a 3-month trial of enalapril, as evidenced by paid claims or pharmacy printouts.
- Inpefa Only:
  - The requested medication must be prescribed by, or in consult with, a cardiologist or nephrologist.
  - The member is receiving concurrent Entresto, a beta-blocker, a SGLT-2 Inhibitor, and a mineralocorticoid receptor antagonist.
  - The member has been admitted to the hospital, a heart failure unit, infusion center, or emergency department for worsening heart failure within the past 3 months.



- Clinical justification must be provided explaining why the member is unable to use Farxiga and Jardiance (subject to clinical review)
- Tolvaptan Only:
  - The requested medication must be prescribed by, or in consult with, a cardiologist
  - The member is experiencing sodium levels less than 125 mEq/L despite a 30-day trial of an ACE inhibitor or ARB.
  - The member does not have liver disease.
- Verquvo Only:
  - The requested medication must be prescribed by, or in consult with, a cardiologist.
  - The member must have left ventricular ejection fraction (LVEF) < 45% at initiation.
  - The member must have had a hospitalization or need for IV diuretics within the past 3 months
  - The member is receiving concurrent Entresto, a beta-blocker, a SGLT-2 Inhibitor, and a mineralocorticoid receptor antagonist.

## Hypertrophic Cardiomyopathy

### CLINICAL PA REQUIRED

CAMZYOS (mavacamten)

#### *Prior Authorization Criteria*

##### Initial Criteria – Approval Duration: 12 months

- The requested medication must be prescribed by, or in consult with, a cardiologist.
- The member must have all the following:
  - left ventricular ejection fraction (LVEF) ≥ 55%
  - NYHA class II or III
  - Resting oxygen saturation of ≥ 90%
  - Valsava left ventricular outflow tract (LVOT) gradient ≥ 50 mmHg at rest or with provocation.
- The member must have persistent symptoms despite maximally tolerated therapy with each of the following:
  - Non-dihydropyridine calcium channel blocker
  - beta blocker

##### Renewal Criteria – Approval Duration: 12 months

- The member has one of the following:
  - an improved pVO<sub>2</sub> by ≥ 1.5 mL/kg/min plus improvement in NYHA class by at least 1
  - an improvement of pVO<sub>2</sub> by ≥ 3 mL/kg/min and no worsening in NYHA class.
  - NYHA class I or II without exertion-induced syncope
  - Valsalva LVOT gradient < 50 mmHg at rest or with provocation.

#### References

1. Olivotto, Iacopo, et al. "Mavacamten for treatment of symptomatic obstructive hypertrophic cardiomyopathy (EXPLORER-HCM): a randomised, double-blind, placebo-controlled, phase 3 trial." *The Lancet* 396.10253 (2020): 759-769.
2. Desai, Milind Y., et al. "Mavacamten in patients with hypertrophic cardiomyopathy referred for septal reduction: week 56 results From the VALOR-HCM randomized clinical trial." *JAMA cardiology* 8.10 (2023): 968-977.

## Inappropriate Sinus Tachycardia

### CLINICAL PA REQUIRED

CORLANOR (ivabradine)

## Electronic Diagnosis Verification

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

### Prior Authorization Criteria

#### Initial Criteria – Approval Duration: 12 months

- The diagnosis must be provided on the request.

## Lipid-Lowering Agents

### ACL (ATP Citrate Lyase) Inhibitors

PREFERRED AGENTS (ELECTRONIC STEP REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
NEXLETOL (bempedioc acid)	
NEXLIZET (bempedoic acid and ezetimibe)	

### Electronic Step Therapy Required

- Nexletol or Nexlizet:
  - PA Not Required Criteria: A total of 90-day supply of rosuvastatin or atorvastatin has been paid within 120 days prior to Nexletol or Nexlizet's date of service.
  - PA Required Criteria: The member must have failed a 90-day trial of rosuvastatin or atorvastatin, as evidenced by paid claims or pharmacy printouts.

### Cholesterol Absorption Inhibitor – 2-Azetidinone

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ezetimibe	ZETIA (ezetimibe)

### Eicosapentaenoic acid (ESA) Ethyl Ester

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
VASCEPA (icosapent ethyl) – <i>Brand Required</i>	icosapent ethyl

### Fenofibrate

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
fenofibrate, micronized 43 mg, 67 mg, 134 mg, 200mg	ANTARA (fenofibrate, micronized)
fenofibrate, nanocrystallized	fenofibrate capsules 50 mg, 150 mg
fenofibrate tablets 54 mg, 160 mg	fenofibrate, micronized 90 mg, 130 mg
fenofibric acid DR 45 mg, 135 mg	fenofibrate tablets 40 mg, 120 mg
	fenofibric acid 105 mg
	FENOGLIDE (fenofibrate)
	LIPOFEN (fenofibrate)
	TRICOR (fenofibrate, nanocrystalized)
	TRIGLIDE (fenofibrate)
	TRILIPIX (fenofibric acid)

### Prior Authorization Criteria

- See [Preferred Dosage Form](#) criteria

*MTP (Microsomal Triglyceride Transfer Protein) Inhibitor*

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	JUXTAPID (lomitapide)

*Prior Authorization Criteria*

Initial Criteria – Approval Duration: 3 months

- Clinical justification must be provided explaining why the member is unable to use all other products to lower their cholesterol (subject to clinical review)

*PCSK9 (Proprotein Convertase Subtilisin/Kexin Type 9) Inhibitors*

PREFERRED AGENTS (ELECTRONIC STEP REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
REPATHA PUSHTRONEX (evolocumab)	PRALUENT PEN (alirocumab)
REPATHA SURECLICK (evolocumab)	
REPATHA SYRINGE (evolocumab)	

*Underutilization*

- Praluent and Repatha must be used adherently and will reject on point of sale for late fill.

*Electronic Step Therapy Required*

- Repatha:
  - PA Not Required Criteria: A total of 90-day supply of rosuvastatin or atorvastatin has been paid within 120 days prior to Repatha’s date of service.
  - PA Required Criteria: The member must have failed a 90-day trial of rosuvastatin or atorvastatin, as evidenced by paid claims or pharmacy printouts.

*Prior Authorization Criteria*

Initial Criteria – Approval Duration: 6 months

- The member must have failed a 90-day trial of the preferred PCSK9 inhibitor agent, as evidenced by paid claims or pharmacy printouts

Renewal Criteria – Approval Duration: 12 months

- The member has an LDL-C level less than 100 mg/dL or has achieved a 40% reduction.

*Statins (HMG-CoA (3-hydroxy-3-methylglutaryl-CoA Reductase Inhibitors))*

Solid Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
atorvastatin	ALTROPREV (lovastatin)
CADUET (amlodipine/atorvastatin) – <i>Brand Required</i>	amlodipine/atorvastatin
ezetimibe/simvastatin	CRESTOR (rosuvastatin)
fluvastatin	fluvastatin ER
lovastatin	LESCOL XL (fluvastatin ER)
pravastatin	LIPITOR (atorvastatin)
rosuvastatin	LIVALO (pitavastatin)
simvastatin	pitavastatin
	PRAVACHOL (pravastatin)

	VYTORIN (ezetimibe/simvastatin)
	ZOCOR (simvastatin)
	ZYPITAMAG (pitavastatin)

### Prior Authorization Criteria

#### Initial Criteria – Approval Duration: 12 months

- Pitavastatin Only –
  - One of the following criteria must be met:
    - The member is receiving treatment with anti-retroviral therapy for HIV
    - The member is receiving treatment with a strong CYP3A4 inhibitor and is experiencing muscle toxicity despite 90-day trials with fluvastatin, rosuvastatin, and pravastatin.
- All other agents: See [Preferred Dosage Form](#) criteria

#### Non-Solid Dosage Forms

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
EZALLOR SPRINKLE (rosuvastatin)	ATORVALIQ (atorvastatin) SOLUTION

### Prior Authorization Criteria

#### Initial Criteria – Approval Duration: 12 months

- See [Non-Solid Dosage Form](#) criteria

#### Non-Preferred Agent Criteria

- The member has an LDL-C level greater than 100 mg/dL despite a 90-day trial with Ezallor Sprinkle.

#### Renewal Criteria – Approval Duration: 12 months

- The member has an LDL-C level less than 100 mg/dL or has achieved a 40% reduction.

#### Angiopoietin-like 3 (ANGPTL3) Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	EVKEEZA (evinacumab-dgnb) – <i>Medical Billing Only</i>

### Prior Authorization Criteria

#### Initial Criteria – Approval Duration: 6 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a cardiologist, endocrinologist, or lipid specialist.
- Documentation of one of the following must be provided:
  - Genetic testing confirming two mutant alleles at the low-density lipoprotein receptor (LDLR), apolipoprotein B (apo B), proprotein convertase subtilisin kexin type 9 (PCSK9) or low-density lipoprotein receptor adaptor protein 1 (LDLRAP1) gene locus
  - Untreated total cholesterol of > 500 mg/dL with one of the following:
    - Cutaneous or tendon xanthoma before age 10 years
    - Evidence of total cholesterol > 250 in both parents
  - Low-density lipoprotein cholesterol (LDL-C) level greater than 100 mg/dL after a 90-day trial of each of the following, as evidenced by paid claims or pharmacy printouts or clinical justification as to why a treatment is unable to be used (subject to clinical review):

- PCSK9 inhibitor and ezetimibe combined with rosuvastatin  $\geq 20$  mg or atorvastatin  $\geq 40$  mg
- Bempedoic acid and ezetimibe combined with rosuvastatin  $\geq 20$  mg or atorvastatin  $\geq 40$  mg

Renewal Criteria – Approval Duration: 12 months

- The member has an LDL-C level less than 100 mg/dL or has achieved a 40% reduction.

*siRNA (small interfering RNA) therapy*

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	LEQVIO (inclisiran) – <i>Medical Billing Only</i>

*Prior Authorization Criteria*

Initial Criteria – Approval Duration: 6 months

- The member must have failed a 90-day trial of both of the following, as evidenced by paid claims or pharmacy printouts:
  - PCSK9 inhibitor combined with rosuvastatin  $\geq 20$  mg or atorvastatin  $\geq 40$  mg
  - Bempedoic acid and ezetimibe combined with rosuvastatin  $\geq 20$  mg or atorvastatin  $\geq 40$  mg

Renewal Criteria – Approval Duration: 12 months

- The member has an LDL-C level less than 100 mg/dL or has achieved a 40% reduction.
- The member must currently be receiving a maximally tolerated statin (HMG-CoA reductase inhibitor) agent, as evidenced by paid claims or pharmacy printouts.

**Platelet Aggregation Inhibitors**

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
aspirin	clopidogrel 300 mg
aspirin/dipyridamole ER	EFFIENT (prasugrel)
BRILINTA (ticagrelor)	PLAVIX (clopidogrel)
clopidogrel 75 mg	ZONTIVITY (vorapaxar)
dipyridamole	
prasugrel	

*Prior Authorization Criteria*

Initial Criteria – Approval Duration: 12 months

- The member must have failed 30-day trials of at least 3 preferred platelet aggregation inhibitor agents, as evidenced by paid claims or pharmacy printouts.

**Pulmonary Hypertension**

**Activin Signaling Inhibitor**

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

*Electronic Diagnosis Verification*

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

*Prior Authorization Criteria*

Initial Criteria – Approval Duration: 6 months

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

**Renewal Criteria – Approval Duration: 12 months**

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

## Endothelin Receptor Antagonists

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

### Electronic Diagnosis Verification

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

### Prior Authorization Criteria

**Initial Criteria – Approval Duration: 12 months**

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

## PDE-5 Inhibitors

### Solid Dosage Forms

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

### Non-Solid Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
sildenafil suspension – all other labelers	LIQREV (sildenafil) SUSPENSION
	REVATIO (sildenafil) SUSPENSION
	sildenafil suspension – labeler 59762
	TADLIQ (tadalafil) SUSPENSION

### Electronic Age Verification

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

### Prior Authorization Criteria

**Initial Criteria – Approval Duration: 12 months**

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

### Non-Preferred Agents Criteria

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

## Prostacyclins

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
epoprostenol	
FLOLAN (epoprostenol)	
ORENITRAM ER (treprostinil) TABLET	
REMODULIN (treprostinil) INJECTION – <i>Brand Co-Preferred</i>	
treprostinil injection – <i>Generic Co-Preferred</i>	
TYVASO (treprostinil) DPI	
TYVASO (treprostinil) INHALATION	
UPTRAVI (selexipag) TABLET	
UPTRAVI (selexipag) VIAL	
VELETRI (epoprostenol)	
VENTAVIS (iloprost) INHALATION	

### Electronic Diagnosis Verification

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

## Soluble Guanylate Cyclase Stimulators

NO PA REQUIRED
ADEMPAS (riociguat)

### Electronic Diagnosis Verification

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

#### References:

1. Humbert, Marc, et al. "2022 ESC/ERS Guidelines for the diagnosis and treatment of pulmonary hypertension: Developed by the task force for the diagnosis and treatment of pulmonary hypertension of the European Society of Cardiology (ESC) and the European Respiratory Society (ERS). Endorsed by the International Society for Heart and Lung Transplantation (ISHLT) and the European Reference Network on rare respiratory diseases (ERN-LUNG)." *European heart journal* 43.38 (2022): 3618-3731.

## Reduction of Major Adverse Cardiovascular Events (MACE)

### Oral Agents

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
See <a href="#">Lipid-Lowering Agents</a>	
See <a href="#">Platelet Aggregation Inhibitors</a>	

### Injectable Agents

#### PCSK9 (Proprotein Convertase Subtilisin/Kexin Type 9) Inhibitors

PREFERRED AGENTS (ELECTRONIC STEP REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
PRALUENT PEN (alirocumab)	



REPATHA PUSHTRONEX (evolocumab)	
REPATHA SURECLICK (evolocumab)	
REPATHA SYRINGE (evolocumab)	

### Electronic Step Therapy Required

- Praluent and Repatha:
  - PA Not Required Criteria: A total of 90-day supply of rosuvastatin or atorvastatin has been paid within 120 days prior to Praluent and Repatha's date of service.
  - PA Required Criteria: The member must have failed a 90-day trial of rosuvastatin or atorvastatin, as evidenced by paid claims or pharmacy printouts.

### GLP-1 Agonists

<b>CLINICAL PA REQUIRED</b>
WEGOVY (semaglutide)

### Prior Authorization Criteria

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

#### Initial Criteria – Approval Duration: 12 months

- The member is ages of  $\geq 55$  and  $< 75$ .
- The member does not have diabetes, as evidenced by A1c within normal range without diabetes medication.
- The member has an initial BMI of  $\geq 27$  kg/m<sup>2</sup> and  $< 35$  kg/m<sup>2</sup>
- The member has one of the following:
  - Prior myocardial infarction (MI)
  - Prior stroke and peripheral arterial disease (PAD), as evidenced by intermittent claudication with ankle-brachial index  $< 0.85$ , peripheral arterial revascularization procure, or amputation due to atherosclerotic disease.
- The member is concurrently taking lipid-lowering and antiplatelet therapy
- If the member is a current tobacco user, the member must have received tobacco cessation counseling in the past year
- If the member qualifies for Wegovy, a dose escalation to 2mg of Ozempic (semaglutide) must be tolerated before Wegovy will be authorized (2.4mg is the only strength indicated for reduction of MACE)

## Dermatology

### Acne

#### Electronic Age Verification

- The member must be between 12 and 35 years of age for treatment of diagnosis of acne.

### Adapalene

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
adapalene cream	CABTREO (adapalene/benzoyl peroxide/clindamycin) 1.2%-0.15%-3.15% GEL
adapalene gel	



adapalene gel with pump	
adapalene/benzoyl peroxide 0.1%-2.5%	
adapalene/benzoyl peroxide 0.3%-2.5%	

### Therapeutic Duplication

- One strength of one benzoyl peroxide containing medication is allowed at a time.

### Prior Authorization Criteria

#### Initial Criteria – Approval Duration: 12 months

- See [Preferred Dosage Form](#) criteria

### Androgen Receptor Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	WINLEVI (clascoterone) CREAM

### Prior Authorization Criteria

#### Initial Criteria – Approval Duration: 12 months

- The member must have failed a 3-month trial of each of the following, as evidenced by paid claims or pharmacy printouts:
  - Topical antibiotics (erythromycin, clindamycin, minocycline, or dapsone) in combination with benzoyl peroxide
  - Topical retinoids in combination with benzoyl peroxide

### Clindamycin

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
clindamycin capsule	CLEOCIN T (clindamycin) GEL
clindamycin gel	CLEOCIN T (clindamycin) LOTION
clindamycin lotion	CLEOCIN T (clindamycin) PLEDGETS
	CLINDACIN (clindamycin) FOAM
clindamycin solution	CLINDACIN P (clindamycin) PLEDGETS
ZIANA (clindamycin-tretinoin 1.2%-0.025%) – <i>Brand Required</i>	CLINDACIN ETZ (clindamycin) PLEDGETS
	CLINDAGEL (clindamycin) GEL DAILY
	clindamycin gel daily
	clindamycin foam
	clindamycin pledgets
	clindamycin-tretinoin 1.2%-0.025%
	EVOCLIN (clindamycin) FOAM

### Clindamycin-Benzoyl Peroxide

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
clindamycin-benzoyl peroxide 1.2%-2.5%	ACANYA (clindamycin-benzoyl peroxide) 1.2%-2.5%
clindamycin-benzoyl peroxide 1%-5% with pump	BENZAACLIN (clindamycin/benzoyl peroxide without pump) 1%-5%
clindamycin-benzoyl peroxide 1.2%-5%	BENZAACLIN (clindamycin/benzoyl peroxide with pump) 1%-5%

clindamycin/benzoyl peroxide 1%-5% without pump	CABTREO (adapalene/benzoyl peroxide/clindamycin) 1.2%-0.15%-3.15% GEL
ONEXTON (clindamycin/benzoyl peroxide) 1.2%-3.75% - <i>Brand Required</i>	clindamycin/benzoyl peroxide 1.2%-3.75%
	NEUAC (clindamycin/benzoyl peroxide) 1.2%-5%

### Therapeutic Duplication

- One strength of one benzoyl peroxide containing medication is allowed at a time.

### Retinoid

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ALTRENO (tretinoin) LOTION	ATRALIN (tretinoin) 0.05% GEL
RENOVA WITHOUT PUMP (tretinoin/emollient base)	ARAZLO (tazarotene) 0.045% LOTION
RENOVA WITH PUMP (tretinoin/emollient base)	clindamycin-tretinoin 1.2%-0.025%
RETIN-A MICRO GEL PUMP (tretinoin microsphere) 0.04%, 0.1% - <i>Brand Required</i>	FABIOR (tazarotene) 0.1% FOAM
RETIN-A MICRO (tretinoin microsphere) GEL WITHOUT PUMP – <i>Brand Required</i>	RETIN-A (tretinoin) CREAM
tazarotene 0.1% cream	RETIN-A (tretinoin) GEL
tretinoin cream	RETIN-A MICRO GEL PUMP (tretinoin microsphere) 0.06%, 0.08%
tretinoin gel	tazarotene 0.05% cream
ZIANA (clindamycin-tretinoin 1.2%-0.025%) – <i>Brand Required</i>	tazarotene 0.1% foam
	tazarotene gel
	tretinoin microsphere gel with pump 0.04%, 0.1%
	tretinoin microsphere gel without pump

### Therapeutic Duplication

- One strength of one retinoid medication is allowed at a time.
- One strength of one benzoyl peroxide containing medication is allowed at a time.

### Prior Authorization Criteria

#### Initial Criteria – Approval Duration: 12 months

- See [Preferred Dosage Form](#) criteria

### Tetracyclines

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
doxycycline hyclate capsule	demeclocycline
doxycycline hyclate tablet 20 mg, 100 mg	DORYX (doxycycline hyclate) TABLET DR
doxycycline monohydrate 25 mg/5 mL suspension	DORYX MPC (doxycycline hyclate) TABLET DR
doxycycline monohydrate tablet 50 mg, 75 mg, 100 mg	doxycycline monohydrate capsule 75 mg, 150 mg
doxycycline monohydrate capsule 50 mg, 100 mg	doxycycline hyclate tablet 50 mg, 75 mg, 150 mg
minocycline capsule	doxycycline monohydrate tablet 150 mg
tetracycline	doxycycline hyclate tablet DR

	MINOCIN (minocycline) CAPSULE
	minocycline tablet
	minocycline tablet ER
	MINOLIRA ER (minocycline) TABLET
	MORGIDOX (doxycycline hyclate) CAPSULE

### Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- See [Preferred Dosage Form](#) criteria

## Sulfonamide

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
BP 10-1 (sodium sulfacetamide/sulfur cleanser) 10%-1%	ACZONE (dapson) GEL WITH PUMP 7.5%
BP CLEANSING WASH (sulfacetamide sodium/sulfur/urea) 10%-4%-10%	BP 10-1 (sulfacetamide sodium/sulfur) CLEANSER
dapsone gel pump 7.5%	KLARON (sulfacetamide sodium)
dapsone gel without pump 5%	SSS 10-5 (sulfacetamide) CLEANSER
sulfacetamide 10% cleansing gel	SSS 10-5 (sulfacetamide) FOAM
sulfacetamide 10% lotion	sodium sulfacetamide/sulfur pads 10%-4%
sulfacetamide 10% suspension	sodium sulfacetamide/sulfur cream 10%-2%
sulfacetamide 10% wash	SUMADAN (sodium sulfacetamide/sulfur) WASH 9%-4.5%
sodium sulfacetamide/sulfur cleanser 10%-5% (W/W)	SUMAXIN (sodium sulfacetamide/sulfur) WASH 9%-4%
sodium sulfacetamide/sulfur cleanser 9%-4%	SUMAXIN (sodium sulfacetamide/sulfur pads) PADS 10%-4%
sodium sulfacetamide/sulfur cleanser 9%-4.5%	SUMAXIN TS (sodium sulfacetamide/sulfur) SUSPENSION 8%-4%
sodium sulfacetamide/sulfur cleanser 9.8% -4.8%	ZMA CLEAR (sulfacetamide sodium/sulfur) SUSPENSION 9%-4.5%
sodium sulfacetamide/sulfur cleanser 10%-2%	
sodium sulfacetamide/sulfur cleanser 10%-5%-10%	
sodium sulfacetamide/sulfur cream 10%-5% (W/W)	
sodium sulfacetamide/sulfur suspension 8%-4%	
SUMAXIN (sodium sulfacetamide/sulfur) CLEANSER 9%-4%	

### Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- See [Preferred Dosage Form](#) criteria

## Actinic Keratosis

### Fluorouracil

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
CARAC (fluorouracil) 0.5% CREAM – <i>Brand Required</i>	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 – <i>Brand Required</i>	imiquimod 3.75% cream pump
	ZYCLARA (imiquimod) 3.75% CREAM PACKET
	ZYCLARA (imiquimod) 2.5% CREAM PUMP

## Diclofenac

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
diclofenac 3% sodium gel	

### Electronic Diagnosis Verification

- Diclofenac 3% sodium gel: Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale.

### Prior Authorization Criteria

#### Initial Criteria – Approval Duration: 12 months

- The member must have failed a 6-month trial of each preferred agent of a unique active ingredient, as evidenced by paid claims or pharmacy printouts.
- If requested product has preferred option with same active ingredient, see [Preferred Dosage Form](#) criteria

## Antifungals – Topical

### Cream

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
butenafine cream	CICLODAN (ciclopirox) CREAM
ciclopirox cream	ERTACZO (sertraconazole) CREAM
clotrimazole cream	EXELDERM (sulconazole) CREAM
econazole cream	LOPROX (ciclopirox) CREAM
ketoconazole cream	luliconazole cream
miconazole cream	LUZU (luliconazole) CREAM
NAFTIN (naftifine) CREAM	MENTAX (butenafine) CREAM
nystatin cream	naftifine cream
nystatin – triamcinolone cream	oxiconazole cream
	sulconazole cream

### Foam

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
EXTINA (ketoconazole) FOAM – <i>Brand Required</i>	KETODAN (ketoconazole) FOAM
	ketoconazole foam

## Gel

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ciclopirox gel	NAFTIN (naftifine) GEL

## Lotion

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	OXISTAT (oxiconazole) LOTION

## Ointment

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ALEVAZOL (clotrimazole) OINTMENT	miconazole/zinc oxide/white petrolatum ointment
nystatin ointment	
nystatin – triamcinolone ointment	
VUSION (miconazole/zinc/white petrolatum) OINTMENT – <i>Brand Required</i>	

## Powder

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
KLAYESTA (nystatin) POWDER	
nystatin powder	
NYAMYC (nystatin) POWDER	
NYSTOP (nystatin) POWDER	

## Shampoo

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ciclopirox shampoo	LOPROX (ciclopirox) SHAMPOO
ketoconazole shampoo	

## Solution

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ciclopirox solution	CICLODAN (ciclopirox) SOLUTION
clotrimazole solution	EXELDERM (sulconazole) SOLUTION
	JUBLIA (efinaconazole) SOLUTION
	KERYDIN (tavaborole) SOLUTION
	tavaborole solution

## Suspension

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ciclopirox suspension	LOPROX (ciclopirox) SUSPENSION

## Prior Authorization Criteria

### Initial Criteria – Approval Duration: 12 months

- Onychomycosis Only:
  - Diagnosis must be confirmed by potassium hydroxide (KOH) preparation.
  - The member must have had a trial of one oral agent (terbinafine, fluconazole, or itraconazole), for the length of recommended treatment time for member's particular infection, as evidenced by paid claims or pharmacy printouts.

- Adequate time must have passed since treatment cessation to accurately assess healthy toenail outgrow (at least 6 months)
- One of the following must be met (A or B):
  - [Preferred Dosage Form](#) Criteria
  - The active ingredient of the requested product is not available in a preferred formulation.
- Other Diagnoses:
  - The member must have failed a trial of 3 preferred agents, for the length of recommended treatment time for member's particular infection, as evidenced by paid claims or pharmacy printouts.
  - One of the following must be met (A or B):
    - [Preferred Dosage Form](#) Criteria
    - The active ingredient of the requested product is not available in a preferred formulation.

## Eczema / Atopic Dermatitis

### Oral

#### First Line Agents

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
azathioprine 50 mg	azathioprine 75 mg
cyclosporine	azathioprine 100 mg
methotrexate	
systemic oral corticosteroids	

#### Prior Authorization Criteria

- Azathioprine: See [Preferred Dosage Forms](#) Criteria – Use enough 50 mg to make correct dosage

### Topical

#### Calcineurin Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
tacrolimus 0.03%	ELIDEL (pimecrolimus) CREAM
tacrolimus 0.1%	pimecrolimus

#### Janus Kinase (JAK) inhibitor

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

#### Phosphodiesterase 4 (PDE-4) inhibitor

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
EUCRISA (crisaborole) OINTMENT	ZORYVE (roflumilast) 0.15% CREAM

#### Topical Corticosteroids

Please see the [Preferred Drug List of Topical Corticosteroids](#)

## Systemic

### *Interleukin (IL)-4/13 Inhibitor*

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

### *Interleukin (IL)-13 Inhibitor*

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

### *Janus Kinase (JAK) inhibitor*

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

### *Electronic Age Verification*

- Tacrolimus ointment 0.1%: The member must be 16 years of age or older.

### *Electronic Diagnosis Verification*

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

### *Prior Authorization Criteria*

#### [Prior Authorization Form – Atopic Dermatitis](#)

#### *Initial Criteria – Approval Duration: 3 months*

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

#### *Zoryve Only:*

- The member must have had a 28-day trial with Eucrisa, as evidenced by paid claims or pharmacy printouts

## **Epidermolysis Bullosa**

PREFERRED AGENTS (CLINICAL PA REQUIRED)
FILSUVEZ (birch triterpenes)
VYJUVEK (beremagene geperpavec-svdt) – <i>Medical Billing Only</i>

#### *Initial Criteria - Approval Duration: 12 months*

- The member has dystrophic epidermolysis bullosa.
- The requested medication must be prescribed by, or in consult with, a dermatologist or wound care specialist.
- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational).
- As applicable, documentation must be attached to confirm serum marker or pathogenic gene variants amenable to treatment.
- Documentation of the baseline symptoms (e.g., extensive skin blistering, number and size of wounds) that can be utilized for comparison to show member has experienced clinical benefit upon renewal has been submitted with request.

## Hidradenitis Suppurativa

### TNF Inhibitors

#### Adalimumab

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
adalimumab-adaz	ABRILADA (adalimumab-afzb)
adalimumab-adbm – labeler 00597	adalimumab-aacf
CYLTEZO (adalimumab-abdm)	adalimumab-aaty
HUMIRA (adalimumab)	adalimumab-adbm – labeler 82009
SIMLANDI (adalimumab-ryvk)	adalimumab-fkjp
YUSIMRY (adalimumab-aqvh)	adalimumab-ryvk
	AMJEVITA (adalimumab-atto)
	HADLIMA (adalimumab-bwwd)
	HULIO (adalimumab-fkjp)
	HYRIMOZ (adalimumab-adaz)
	IDACIO (adalimumab-aacf)
	YUFLYMA (adalimumab-aaty)

### Interleukin (IL) – 17 Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	COSENTYX (secukinumab)
	COSENTYX (secukinumab) – <i>Medical Billing Only</i>

#### Electronic Diagnosis Verification

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

#### Prior Authorization Criteria

##### Initial Criteria – Approval Duration: 12 months

- Cosentyx and Simponi Aria Only: The member must have failed a 90-day trial of a TNF inhibitor, as evidenced by paid claims or pharmacy printouts.
- Other agents: See [Preferred Dosage Form](#) criteria

## Infantile Hemangioma

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
propranolol oral solution	HEMANGEOL (propranolol) ORAL SOLUTION
	timolol gel forming solution (used topically)



### Electronic Age Verification

- Hemangeol: The patient must be less than 1 years of age.

### Electronic Diagnosis Verification

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

### Prior Authorization Criteria

#### Initial Criteria – Approval Duration: 12 months

- The member must have failed a 6-month trial of the preferred agent, as evidenced by paid claims or pharmacy printouts.
- Hemangeol Only:
  - The member must have failed a 6-month trial of timolol gel forming solution, as evidenced by paid claims or pharmacy printouts.

## Molluscum Contagiosum

### PREFERRED AGENTS (CLINICAL PA REQUIRED)

ZELSUVMI (berdazimer) GEL

YCANTH (cantharidin) SOLUTION – *Medical Billing Only*

#### Initial Criteria - Approval Duration: 12 months

- The requested medication must be prescribed by, or in consult with, a dermatologist or pediatrician.
- One of the following must be present (1 or 2):
  - The member is immunocompromised.
  - The member is immunocompetent but experiences severe bleeding, intense itching, recurring infection, or severe pain for greater than 6 months.

## Lice / Scabies

### PREFERRED AGENTS (NO PA REQUIRED)

LICE KILLING SHAMPOO (piperonyl butoxide/pyrethrins)

ivermectin

NATROBA (spinosad) – *Brand Required Only*

permethrin 5% cream

LICE TREATMENT (permethrin) 1% CRÈME RINSE LIQUID

VANALICE (piperonyl butoxide/pyrethrins) GEL

### NON-PREFERRED AGENTS (PA REQUIRED)

CROTAN (crotamiton)

malathion

SKLICE (ivermectin)

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 the preferred agents.

# Plaque Psoriasis

## Biologics

### Interleukin (IL)-12/IL-23 Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	STELARA (ustekinumab)
	WEZLANA (ustekinumab-auub)

### Interleukin (IL)-17A Inhibitor

PREFERRED AGENTS (ELECTRONIC STEP REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
TALTZ (ixekizumab)	COSENTYX (secukinumab)
	COSENTYX (secukinumab) – <i>Medical Billing Only</i>

### Interleukin (IL)-17A and IL-17F inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	BIMZELX (bimekizumab-bkzx)

### Interleukin (IL)-17 Receptor Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	SILIQ (brodalumab)

### Interleukin (IL)-23p19 Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	ILUMYA (tildrakizumab-asmn) – <i>Medical Billing Only</i>
	SKYRIZI (risankizumab-rzaa)
	TREMFYA (guselkumab)

### TNF Inhibitors

#### *Adalimumab*

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
adalimumab-adaz	ABRILADA (adalimumab-afzb)
adalimumab-adbm – labeler 00597	adalimumab-aacf
CYLTEZO (adalimumab-abdm)	adalimumab-aaty
HUMIRA (adalimumab)	adalimumab-adbm – labeler 82009
SIMLANDI (adalimumab-ryvk)	adalimumab-fkjp
YUSIMRY (adalimumab-aqvh)	adalimumab-ryvk
	AMJEVITA (adalimumab-atto)
	HADLIMA (adalimumab-bwwd)
	HULIO (adalimumab-fkjp)
	HYRIMOZ (adalimumab-adaz)
	IDACIO (adalimumab-aacf)
	YUFLYMA (adalimumab-aaty)

## Infliximab

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AVSOLA (infliximab-axxq) – <i>Medical Billing Only</i>	INFLECTRA (infliximab-dyyb) – <i>Medical Billing Only</i>
RENFLXIS (infliximab-abda) – <i>Medical Billing Only</i>	infliximab – <i>Medical Billing Only</i>
	REMICADE (infliximab) – <i>Medical Billing Only</i>

## Other TNF

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ENBREL (etanercept)	CIMZIA (certolizumab) SYRINGE
	CIMZIA (certolizumab) VIAL – <i>Medical Billing Only</i>

## Electronic Diagnosis Verification

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

## Electronic Step Therapy Required

- Taltz:
  - PA Not Required Criteria: A total of 84-day supply of a TNF Inhibitor has been paid within 120 days prior to Taltz's date of service.
  - PA Required Criteria: The member must have failed a 3-month trial of a TNF inhibitor, as evidenced by paid claims or pharmacy printouts.

## Prior Authorization

### Initial Criteria – Approval Duration: 12 months

- The member must have failed a 3-month trial of a TNF inhibitor (adalimumab, certolizumab pegol or infliximab) and an Interleukin (IL)-17A Inhibitor, as evidenced by paid claims or pharmacy printouts.
- Stelara, and Wezlana Only: The member must have failed a 3-month trial of a TNF inhibitor (adalimumab, certolizumab pegol or infliximab), an Interleukin (IL)-17A Inhibitor, and Siliq, as evidenced by paid claims or pharmacy printouts.
- Remicade, infliximab, and Inflectra Only: See [Biosimilar Agents](#) criteria
- Medical billing only agents: In addition to above criteria, clinical justification must be provided why a self-administered agent cannot be used (subject to clinical review).

## Oral

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
acitretin 10 mg, 25 mg	acitretin 17.5 mg
cyclosporine	OTEZLA (apremilast) 20 MG
methotrexate	SOTYKTU (deucravacitinib)
OTEZLA (apremilast) 30 MG	

## Prior Authorization Criteria

### Initial Criteria – Approval Duration: 12 months

- Acitretin 17.5 mg Only: See [Preferred Dosage Form](#) criteria
- Otezla 20 mg Only:
  - The member must weigh  $\geq 20$  kg and  $< 50$  kg

- The member must have failed a 3-month trial of adalimumab and an interleukin 17A inhibitor, as evidenced by paid claims or pharmacy printouts.
- Sotyktu Only: The member must have failed a trial of each of the following, as evidenced by paid claims or pharmacy printouts:
  - 30-day trial of Otezla
  - 3-month trial of an TNF inhibitor (adalimumab, certolizumab pegol or infliximab)

## Topical

### *Foams, Gel, Solution, Suspension*

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
calcipotriene solution	calcipotriene/betamethasone suspension
calcipotriene foam	SORILUX (calcipotriene) FOAM
ENSTILAR (calcipotriene/betamethasone) FOAM	tazarotene gel
TACLONEX (calcipotriene/betamethasone) SUSPENSION – <i>Brand Required</i>	

### *Cream, Lotion*

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
calcipotriene cream	DUOBRII (halobetasol/tazarotene) LOTION
	tazarotene cream
	VTAMA (tapinarof) 1% CREAM
	ZORYVE (roflumilast) 0.3% CREAM

### *Ointment*

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
calcipotriene ointment	calcitriol ointment
calcipotriene/betamethasone ointment	

### *Electronic Diagnosis Verification*

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

### *Prior Authorization Criteria*

#### *Initial Criteria – Approval Duration: 12 months*

- The member must have failed a 30-day trial of each preferred agent of a unique active ingredient(s) within same route/dosage form category, as evidenced by paid claims or pharmacy printouts.
- Zoryve Only:
  - The member has had a 30-day trial of each of the following, as evidenced by paid claims or pharmacy printouts.
    - calcipotriene/betamethasone
    - halobetasol/tazarotene combination
- Vtama Only:
  - The member has had a 30-day trial of each of the following, as evidenced by paid claims or pharmacy printouts.
    - calcipotriene/betamethasone
    - halobetasol/tazarotene combination
  - The member has had a 2-month trial of Zoryve, as evidenced by paid claims or pharmacy printouts.

## Prurigo Nodularis

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
DUPIXENT (dupilumab)	NEMLUVIO (nemolizumab-ilto)

### Prior Authorization Criteria

#### Initial Criteria – Approval Duration: 6 months

- The requested medication must be prescribed by, or in consult with, a dermatologist.
- The member is experiencing nodular lesions that produce itch for greater than 6 weeks that has significantly diminished quality of life, including sleep disturbances.
- The member has failed a 2-week trial of a topical corticosteroid of at least high potency, as evidenced by paid claims or pharmacy printouts.

#### Non-Preferred Agent Criteria

- The member must have failed a 3-month trial of Dupixent, as evidenced by paid claims or pharmacy printouts.

## Seborrheic Dermatitis

[See Antifungals – Topical](#)

[See Steroids – Topical](#)

### Topical Phosphodiesterase-4 (PDE-4) Inhibitors

CLINICAL PA REQUIRED
ZORYVE (roflumilast) FOAM

### Electronic Diagnosis Verification

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

### Prior Authorization Criteria

#### Initial Criteria – Approval Duration: 6 months

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

## Steroids – Topical

### Super-High Potency (Group 1)

Dosage Form	PREFERRED AGENTS (NO PA REQUIRED)		NON-PREFERRED AGENTS (PA REQUIRED)	
Cream	clobetasol emollient	0.05%		
	clobetasol propionate	0.05%		
	fluocinonide	0.10%		
	halobetasol propionate	0.05%		
Lotion	betamethasone dipropionate, augmented	0.05%	IMPEKLO (clobetasol)	0.05%
	clobetasol propionate	0.05%	ULTRAVATE (halobetasol) MDP	0.05%

Ointment	betamethasone dipropionate, augmented	0.05%		
	clobetasol propionate	0.05%		
	clobetasol propionate foam	0.05%		
	halobetasol propionate	0.05%		
Foam, Gel, Shampoo, Solution, Spray	clobetasol propionate shampoo	0.05%	betamethasone dipropionate, augmented gel	0.05%
	clobetasol propionate solution	0.05%	clobetasol emulsion foam	0.05%
	clobetasol propionate spray	0.05%	<sup>STEP 2*</sup> halobetasol propionate foam	0.05%
	clobetasol propionate gel	0.05%		

### Electronic Diagnosis Verification

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

### Electronic Duration Verification

Group 1 topical steroids are covered for 30 days every 90 days. Group 1 steroids are covered with group 2 steroids to facilitate an alternating schedule.

- If the following conditions apply, please call for an override by calling provider relations at 1-800-755-2604:  
*Approval: 1 year*
  - Location of application: palms, soles, or psoriatic crusts
  - Indication: psoriasis
  - Close monitoring for side effects

### Reference:

Joint AAD-NFP guidelines for management and treatment of psoriasis recommend limiting the use of Group 1 topical steroids to no more than twice daily up to 4 weeks. Transitions to lower potent agents, intermittent therapy, and combination treatment with non-steroids are recommended to minimize side effects.

### High Potency (Group 2)

Dosage Form	PREFERRED AGENTS (NO PA REQUIRED)		NON-PREFERRED AGENTS (PA REQUIRED)	
Cream	betamethasone dipropionate, augmented	0.05%	APEXICON E (diflorasone emollient)	0.05%
	desoximetasone	0.25%		
	fluocinonide	0.05%		
	HALOG (halcinonide)– <i>Brand Required</i>	0.10%		
Lotion			BRYHALI (halobetasol) LOTION	0.01%
Ointment	betamethasone dipropionate	0.05%	diflorasone diacetate	0.05%
	desoximetasone	0.25%		
	fluocinonide	0.05%		
	fluticasone propionate	0.01%		
	HALOG (halcinonide)	0.10%		
Gel, Solution, Spray	desoximetasone spray	0.25%	desoximetasone gel	0.05%
	fluocinonide gel	0.05%	HALOG (halcinonide) SOLUTION	0.10%
	fluocinonide solution	0.05%		

### High Potency (Group 3)

Dosage Form	PREFERRED AGENTS (NO PA REQUIRED)		NON-PREFERRED AGENTS (PA REQUIRED)	
Cream	betamethasone dipropionate	0.05%	STEP2* amcinonide	0.10%
	triamcinolone acetonide	0.50%	desoximetasone	0.05%
			STEP2* diflorasone diacetate	0.05%
			fluocinonide-E	0.05%
Lotion			amcinonide	0.10%
Ointment	betamethasone valerate	0.10%	desoximetasone	0.05%
	fluticasone propionate	0.01%		
	mometasone furoate	0.10%		
	triamcinolone acetonide	0.50%		
Foam	betamethasone valerate foam	0.12%		

### Medium Potency (Group 4)

Dosage Form	PREFERRED AGENTS (NO PA REQUIRED)		NON-PREFERRED AGENTS (PA REQUIRED)	
Cream	clo cortolone pivalate	0.10%	PANDEL (hydrocortisone probutate)	0.1%
	fluticasone propionate	0.05%		
	mometasone furoate	0.10%		
	triamcinolone acetonide	0.10%		
Ointment	fluocinolone acetonide	0.025%	hydrocortisone valerate	0.20%
	triamcinolone acetonide	0.10%	STEP2* flurandrenolide	0.05%
	triamcinolone acetonide	0.05%		
Aerosol, Paste Solution	mometasone furoate solution	0.10%	triamcinolone acetonide aerosol	0.147 MG/G
	triamcinolone acetonide paste	0.10%		

### Lower-Mid Potency (Group 5)

Dosage Form	PREFERRED AGENTS (NO PA REQUIRED)		NON-PREFERRED AGENTS (PA REQUIRED)	
Cream	betamethasone valerate	0.10%	fluocinolone acetonide	0.025%
	hydrocortisone valerate	0.20%	prednicarbate	0.10%
			STEP2* flurandrenolide	0.05%
			hydrocortisone butyrate	0.10%
			hydrocortisone butyrate emollient	0.10%
Lotion	betamethasone dipropionate	0.05%	STEP2* flurandrenolide	0.05%
	LOCOID (hydrocortisone butyrate) – Brand Required	0.10%	fluticasone propionate	0.05%
	triamcinolone acetonide	0.10%		
Ointment	desonide	0.05%	hydrocortisone butyrate	0.10%
	triamcinolone acetonide	0.025%	prednicarbate	0.10%

Gel, Solution	hydrocortisone butyrate solution	0.10%	desonide gel	0.05%
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### Low Potency (Group 6)

Dosage Form	PREFERRED AGENTS (NO PA REQUIRED)		NON-PREFERRED AGENTS (PA REQUIRED)	
Cream	alclometasone dipropionate	0.05%	fluocinolone acetonide	0.01%
	desonide	0.05%		
	triamcinolone acetonide	0.03%		
Lotion	betamethasone valerate lotion	0.10%		
	desonide lotion	0.05%		
	triamcinolone acetonide lotion	0.025%		
Ointment	alclometasone dipropionate	0.05%		
Oil, Solution	fluocinolone acetonide oil	0.01%		
	fluocinolone acetonide solution	0.01%		

### Least Potent (Group 7)

Dosage Form	PREFERRED AGENTS (NO PA REQUIRED)		NON-PREFERRED AGENTS (PA REQUIRED)	
Cream	hydrocortisone	1.00%		
	hydrocortisone	2.50%		
Lotion	hydrocortisone	2.50%		
Ointment	hydrocortisone	1.00%		
	hydrocortisone	2.50%		
Solution			TEXACORT (hydrocortisone) SOLUTION	2.50%

### Prior Authorization

#### Initial Criteria – Approval Duration: 12 months

- The member must have failed a 2-week trial of all preferred drug entities within the same potency category and dosage form group within the last 3 months, as evidenced by paid claims or pharmacy printouts.

#### Agents labeled as “STEP 2”

- The member must have failed a 2-week trial of all preferred and non-preferred drug entities not labeled “STEP 2” within the same potency category and dosage form group within the last 3 months.

## Endocrinology

### Androgens

#### Injectable

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
testosterone cypionate injection	AVEED (testosterone undecanoate)
testosterone enanthate injection	AVEED (testosterone undecanoate) – Medical Billing Only
	DEPO-TESTOSTERONE (testosterone cypionate)



	XYOSTED (testosterone enanthate)
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## Oral

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
JATENZO (testosterone undecanoate)	methyltestosterone
TLANDO (testosterone undecanoate)	METHITEST (methyltestosterone)

## Topical

### Gel Packet

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
testosterone 1% (50mg/5g) gel packet	ANDROGEL (testosterone) GEL PACKET
testosterone 1% (25mg/2.5g) gel packet	testosterone 1.62% (20.25mg/1.25g) gel packet
	testosterone 1.62% (40.5mg/2.5g) gel packet
	VOGELXO (testosterone) GEL PACKET

### Gel Pump

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ANDROGEL (testosterone) GEL MD PUMP – <i>Brand Co-Preferred</i>	testosterone 2% (10mg/0.5g) gel MD PMP bottle
FORTESTA (testosterone) 2% (10mg/0.5g) GEL MD PMP – <i>Brand Required</i>	VOGELXO (testosterone) GEL PMP
testosterone 1% (12.5mg/1.25g) gel MD PMP bottle	
testosterone 1.62% (20.25mg/1.25g) gel MD PMP bottle	
testosterone 2% (30mg/1.5g) solution MD PMP	

### Gel Tube

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
TESTIM (testosterone) GEL TUBE – <i>Brand Co-Preferred</i>	VOGELXO (testosterone) GEL TUBE
testosterone 1% (50mg/5g) gel tube	

### Nasal Gel

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	NATESTO (testosterone) GEL MD PMP

### Patch

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ANDRODERM (testosterone) PATCH	

### Solution MDP

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
testosterone (30mg/1.5mL)	

### Pellet

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
TESTOPEL (testosterone) PELLETT – <i>Medical Billing Only</i>	

### Electronic Diagnosis Verification

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

### Prior Authorization

#### Initial Criteria – Approval Duration: 12 months

- The member must have failed a 30-day trial of each preferred agent with a comparable route of administration, as evidenced by paid claims or pharmacy printouts.
- See [Preferred Dosage Form Criteria](#)

## Cushing Syndrome

### Adrenal Enzyme Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ketoconazole	ISTURISA (osilodrostat)
LYSODREN (mitotane)	RECORLEV (levoketoconazole)
METOPIRONE (metyrapone)	

### Electronic Diagnosis Verification

- Isturisa and Recorlev: Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale.

### Prior Authorization

#### Initial Criteria – Approval Duration: 6 months

- The requested medication must be prescribed by, or in consult with, an endocrinologist or specialist in the treatment of endogenous Cushing's syndrome.
- The member must have failed a 3-month trial of combination treatment with ketoconazole tablets and metyrapone.
- The member is not a candidate for surgery or surgery has not been curative; or is waiting for surgery or effect of pituitary radiation.
- The member must have a mean (at least two measurements) 24-hour urine free cortisol (UFC) level that is 3 x above the normal range per the reporting laboratory reference range.

#### Renewal Criteria – Approval Duration: 12 months

- The member has normalization of 24-hour urine free cortisol (UFC) level per the reporting laboratory reference range.

### Glucocorticoid Receptor Antagonist

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
mifepristone 200 mg	KORLYM (mifepristone) – <i>Brand Required</i>
	mifepristone 300 mg

### Electronic Diagnosis Verification

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

### Prior Authorization

#### Initial Criteria – Approval Duration: 6 months

- The requested medication must be prescribed by, or in consult with, an endocrinologist or specialist in the treatment of endogenous Cushing's syndrome.
- The member must have failed a 3-month trial of combination treatment with ketoconazole tablets and metyrapone, as evidenced by paid claims or pharmacy print outs.
- The member is not a candidate for surgery or surgery has not been curative; or is waiting for surgery or effect of pituitary radiation.
- The member has uncontrolled hyperglycemia (type 2 diabetes or glucose intolerance) as defined by a hemoglobin A1c > 7% or TIR < 70%, despite adherence to an anti-diabetes regimen.
- See [Preferred Dosage Form Criteria](#)

***Renewal Criteria – Approval Duration: 12 months***

- The member must have experienced and maintained an improvement in cushingoid appearance, acne, hirsutism, striae, psychiatric symptoms, or excess total body weight.
- The member has improved hyperglycemia as a hemoglobin A1c decrease of 1% or greater or increase in TIR of 10% not attributed to an increase in medications, dosages, or adherence to an anti-diabetes regimen.

**References:**

- Fleseriu, Maria, et al. "Consensus on diagnosis and management of Cushing's disease: a guideline update." *The lancet Diabetes & endocrinology* 9.12 (2021): 847-875.

## Diabetes

**References:**

1. American Diabetes Association Diabetes Care 2020 Jan; 43(Supplement 1): S98-S110.  
<https://doi.org/10.2337/dc20-S009>

**Covered options in combination with Insulin therapy:**

- GLP-1 agonists, DPP-4 inhibitors, SGLT-2 inhibitors, TZDs, and metformin
  - GLP-1 Agonist and SGLT-2 inhibitors are recommended first line treatments for every pathway indicated in the guidelines (ASCVD, HF, CKD, hypoglycemia risk, and to minimize weight gain)
  - TZDs increase insulin sensitivity and hypoglycemia risk should be monitored.
  - Metformin is recommended throughout treatment escalation.

*Therapeutic Duplication*

- One Strength of one medication is allowed at a time.
- Medication classes not payable together:
  - DPP-4 Inhibitors and GLP-1 Agonists
    - GLP-1 and DPP-4 Inhibitors should not be used concurrently due to similar mechanisms of action.
  - Sulfonylureas and Insulins
    - When initiating injectable therapy, sulfonylureas and DPP-4 inhibitors are typically discontinued.
  - Humulin R U-500 is not allowed with any other insulin (basal or prandial)
    - Humulin R U-500 is indicated for monotherapy. It acts differently than regular insulin (U-100). It provides both basal and prandial coverage. Injections can be increased to 3 times per day for prandial coverage.

*Underutilization*

- Toujeo, Tresiba, and Metformin 1000 mg must be used adherently and will reject on point of sale for late fill.

## Biologics

**CLINICAL PA REQUIRED**

**High-Cost Drug:**

This 14-day treatment course costs \$193,900.

- In study TN-10; 72 people were enrolled – 44 in active treatment group and 32 in placebo group. By month 36, 63.7% (28) in the active treatment group and 71.9% (23) in the placebo group had experienced Stage 3 Type 1 Diabetes onset.

*Prior Authorization Criteria*Initial Criteria – Approval Duration: 12 months

- The requested medication must be prescribed by, or in consult with, an endocrinologist.
- The member has a family history of Type 1 Diabetes
- The member has at least two of the following pancreatic islet cell autoantibodies:
  - A. Glutamic acid decarboxylase 65 (GAD) autoantibodies
  - B. Insulin autoantibody (IAA)
  - C. Insulinoma-associated antigen 2 autoantibody (IA-2A)
  - D. Zinc transporter 8 autoantibody (ZnT8A)
  - E. Islet cell autoantibody (ICA)
- The member has no symptoms of Type 1 Diabetes (e.g., polyuria, polydipsia, weight loss, fatigue, DKA)
- The member has abnormal blood sugar levels determined by an oral glucose tolerance test.

**DPP-4 Inhibitors**

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
JANUMET (sitagliptin/metformin)	alogliptan/pioglitazone
JANUMET XR (sitagliptin/metformin)	alogliptin
JANUVIA (sitagliptin)	alogliptin/metformin
JENTADUETO (linagliptin/metformin)	KAZANO (alogliptin/metformin)
JENTADUETO XR (linagliptin/metformin)	NESINA (alogliptin)
TRADJENTA (linagliptin)	ONGLYZA (saxagliptin)
	OSENI (alogliptin/pioglitazone)
	saxagliptin
	saxagliptin/metformin
	sitagliptin/metformin
	ZITUVAMET XR (sitagliptin/metformin)
	ZITUVIO (sitagliptin)

++Clinically Non-Preferred: Alogliptin and saxagliptin have a potentially higher risk for heart failure.

*Electronic Age Verification*

- The member must be 18 years or older for Januvia, Janumet, or Janumet XR

*Electronic Concurrent Medications Required*

- A total of 28-day supply of metformin must be paid within 100 days prior to the DPP-4 Inhibitor's date of service. Members with GI intolerances to high dose IR metformin must trial at minimum a dose of 500 mg ER.
  - Metformin is recommended to be continued with therapy with DPP-4 Inhibitors. If metformin is not tolerated, SGLT2 inhibitor and GLP-1 Agonists are recommended as part of the glucose-lowering regimen independent of A1C or TIR and are first line alternatives.

\* GI intolerances (typically will not be considered to bypass trial requirements):

- If on high dose IR metformin, member must trial at minimum a dose of 500 mg ER.
- Patient experiencing GI side effects should be counseled: reduction in meal size, eating slower, decreased intake of greasy, high-fat or spicy food, refrain from laying down after eating.

**References:**

1. American Diabetes Association Diabetes Care 2020 Jan; 43(Supplement 1): S98-S110.  
<https://doi.org/10.2337/dc20-S009>

*Prior Authorization Criteria*

Initial Criteria – Approval Duration: 12 months

- The member has been unable to achieve goal A1C ( $\leq 7\%$ ) or TIR ( $>70\%$ ) despite two 90-day trials of triple combination therapy, as evidenced by paid claims or pharmacy printouts.
- Zituvio and sitagliptin/metformin only: See [Preferred Dosage Form Criteria](#)

**DPP-4 Inhibitors / SGLT2 Inhibitors Combination**

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
TRIJARDY XR (empagliflozin/linagliptan/metformin)	GLYXAMBI (empagliflozin/linagliptin)
	STEGLUJAN (ertugliflozin/sitagliptin)
	++QTERN (dapagliflozin/saxagliptin)

++Clinically Non-Preferred: Saxagliptan has a potentially higher risk for heart failure.

*Prior Authorization Criteria*

Initial Criteria – Approval Duration: 12 months

- See [Preferred Dosage Form Criteria](#)
- Clinical justification must be provided explaining why the member cannot use individual preferred products separately or preferred agent.

**GLP-1 Agonists<sup>^</sup>**

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (STEP 1 – PA REQUIRED)	NON-PREFERRED AGENTS (STEP 2 – PA REQUIRED)
VICTOZA (liraglutide) - Brand Required	BYDUREON BCISE (exenatide microspheres)	++BYETTA (exenatide)
	OZEMPIC (semaglutide)	liraglutide
	RYBELSUS (semaglutide)	TRULICITY (dulaglutide)

++Clinically Non-Preferred: Byetta is less effective than other available agents.

<sup>^</sup> See GIP/GLP-1 Agonists section for Mounjaro (tirzepatide) criteria

Clinical information: dose comparison recommendations for switching between GLP-1 agonists

- For GI side effects (start titration at lowest available dose)
- For any other reason, may consider starting at equivalent dose to minimize disruption to glycemic control
  - Victoza 1.2 mg = Trulicity 0.75 mg = Ozempic 0.25 mg = Rybelsus 7 mg
  - Victoza 1.8 mg = Trulicity 1.5 mg = Ozempic 0.5 mg = Rybelsus 14 mg = Mounjaro 2.5 mg
  - Trulicity 3 mg = Ozempic 0.5 mg or 1 mg
  - Trulicity 4.5 mg = Ozempic 1 mg
  - Mounjaro 5 mg = Ozempic 2 mg

**References:**

- Almandoz JP, Lingvay I, Morales J, Campos C. Switching Between Glucagon-Like Peptide-1 Receptor Agonists: Rationale and Practical Guidance. Clin Diabetes. 2020 Oct;38(4):390-402. Doi: 10.2337/cd19-0100. PMID: 33132510; PMCID: PMC7566932.

### Prior Authorization Criteria

#### Initial Criteria – Approval Duration: 12 months

- Step 1: Ozempic, Rybelsus, Bydureon Bcise:
  - The member has been unable to achieve goal A1C ( $\leq 7\%$ ) or TIR ( $>70\%$ ) despite a 90-day trial of triple combination therapy with Victoza, metformin, SGLT-2 inhibitor or insulin, as evidenced by paid claims or pharmacy printouts.
    - If triple therapy cannot be met with Victoza, clinical justification must be provided (subject to clinical review\*), and triple therapy must be met with SGLT-2 inhibitor + DPP4 inhibitor + another agent (metformin must be used as tolerated).
    - If triple therapy cannot be met because of inability to use metformin, SGLT-2 inhibitor or insulin, clinical justification must be provided why product cannot be used (subject to clinical review\*), and triple therapy must be met with Victoza + two other agents (metformin, SGLT-2 inhibitor or insulin must be used as tolerated).
- Step 2:
  - The member has been unable to achieve goal A1C ( $\leq 7\%$ ) or TIR ( $>70\%$ ) despite two 90-day trials of triple combination therapy (one trial with Victoza and one with Ozempic, subject to clinical review\*) along with metformin, SGLT-2 inhibitor or insulin, as evidenced by paid claims or pharmacy printouts.
    - If triple therapy cannot be met with Victoza or Ozempic, clinical justification must be provided (subject to clinical review\*), and triple therapy must be met with SGLT-2 inhibitor + DPP4 inhibitor + another agent.
    - If triple therapy cannot be met because of inability to use metformin, SGLT-2 inhibitor or insulin, clinical justification must be provided why product cannot be used (subject to clinical review\*), and triple therapy must be met with Victoza or Ozempic + two other agents (metformin, SGLT-2 inhibitor, or insulin must be used as tolerated).
  - One of the following have been met:
    - The requested medication must be prescribed by, or in consult with, an endocrinologist or diabetes specialist.
    - The member has received diabetes education from a diabetic specialist, diabetic educator, or pharmacist (may be accomplished through the MTM program).

\*GI intolerances (typically will not be considered to bypass trial requirements):

- If on high dose IR metformin, member must trial at minimum a dose of 500 mg ER.
- If on Victoza or Ozempic, member should be evaluated on potential for GI side effects, with GI effects being common across all GLP-1 agonist agents and transient in nature, typically lessening with ongoing treatment.
- Patient experiencing GI side effects, mitigation efforts should be trialed for at least two months: reduction in meal size, eating slower, decreased intake of greasy, high-fat or spicy food, refrain from laying down after eating.

### GIP/GLP-1 Agonists

<b>CLINICAL PA REQUIRED</b>
MOUNJARO (tirzepatide)

### Prior Authorization Criteria

#### Initial Criteria – Approval Duration: 12 months

- The member has been unable to achieve goal A1C ( $\leq 7\%$ ) or TIR ( $>70\%$ ) despite two 90-day trials of triple combination therapy (one trial with Victoza and one with Ozempic, subject to clinical review\*) along with metformin, SGLT-2 inhibitor or insulin, as evidenced by paid claims or pharmacy printouts.

- If triple therapy cannot be met with Victoza or Ozempic, clinical justification must be provided (subject to clinical review\*), and triple therapy must be met with SGLT-2 inhibitor + DPP4 inhibitor + another agent.
- If triple therapy cannot be met because of inability to use metformin, SGLT-2 inhibitor or insulin, clinical justification must be provided why product cannot be used (subject to clinical review\*), and triple therapy must be met with Victoza or Ozempic + two other agents (metformin, SGLT-2 inhibitor, or insulin must be used as tolerated).
- One of the following have been met:
  - The requested medication must be prescribed by, or in consult with, an endocrinologist or diabetes specialist.
  - The member has received diabetes education from a diabetic specialist, diabetic educator, or pharmacist (may be accomplished through the MTM program).

\*GI intolerances (typically will not be considered to bypass trial requirements):

- If on high dose IR metformin, member must trial at minimum a dose of 500 mg ER.
- If on Victoza or Ozempic, member should be evaluated on potential for GI side effects, with GI effects being common across all GLP-1 agonist agents and transient in nature, typically lessening with ongoing treatment.
- Patient experiencing GI side effects, mitigation efforts should be trialed for at least two months: reduction in meal size, eating slower, decreased intake of greasy, high-fat or spicy food, refrain from laying down after eating.

## Gastroparesis

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
metoclopramide tablet	GIMOTI (metoclopramide nasal spray)

### Prior Authorization Criteria

#### Initial Criteria – Approval Duration: 3 months

- Clinical justification must be provided explaining why the member is unable to use an oral dosage formulation (including solution formulations) with relevant medical documentation attached to the request, subject to clinical review.

## Glucose Rescue Medications

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
BAQSIMI (glucagon) SPRAY – Labeler 00548	BAQSIMI (glucagon) SPRAY – Labeler 00002
GLUCAGEN (glucagon) HYPOKIT – <i>Brand Required</i>	glucagon kit
ZEGALOGUE (dasiglucagon) AUTOINJECTOR	GVOKE (glucagon) INJECTION

### Electronic Duration Verification

- 4 doses are covered every 60 days without an override.

If one of the following criteria are met (A or B), please request an override by calling provider relations at 1-800-755-2604 or emailing [medicaidpharmacy@nd.gov](mailto:medicaidpharmacy@nd.gov):

- The previous dose has expired.
- The dose was used by member for a hypoglycemic episode. (In this case, it is recommended to follow up with prescriber to discuss frequency of use and potential regimen review/adjustments)

## Insulin/GLP-1 Agonist Combination

### CLINICAL PA REQUIRED



SOLIQUA (insulin glargine/lixisenatide)
XULTOPHY (insulin degludec/liraglutide)

### Prior Authorization Criteria

#### Initial Criteria – Approval Duration: 12 months

- Clinical justification must be provided explaining why the member is unable to use the preferred products (subject to clinical review).

## Insulin

### Rapid Acting Insulin

#### Insulin Lispro

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
HUMALOG U-100 (insulin lispro) – <i>Kwikpen: Brand Co-Preferred</i>	ADMELOG (insulin lispro)
HUMALOG U-100 (insulin lispro) JUNIOR KWIKPEN – <i>Brand Co-Preferred</i>	HUMALOG U-200 (insulin lispro)
HUMALOG U-100 (insulin lispro) TEMPO PEN	insulin lispro vial
insulin lispro U-100 junior syringe	LYUMJEV U-100 (insulin lispro-aabc)
insulin lispro U-100 insulin pen	LYUMJEV U-200 (insulin lispro-aabc)
	LYUMJEV U-100 TEMPO PEN (insulin lispro-aabc)

#### Insulin Aspart

PREFERRED AGENTS (ELECTRONIC STEP REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
FIASP (insulin aspart)	insulin aspart
	NOVOLOG (insulin aspart)
	RELION NOVOLOG (insulin aspart)

#### Insulin Glulisine

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	APIDRA (insulin glulisine)

#### Insulin Regular, Human

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	++AFREZZA (insulin regular, human)
	++HUMULIN R (insulin regular, human) VIAL
	++NOVOLIN R (insulin regular, human)
	++ RELION NOVOLIN R (insulin regular, human)

++Clinically Non-Preferred: ACOG (American College of Obstetricians and Gynecologists) guidelines prefer insulin analogues (insulin aspart and lispro) over regular insulin due to better compliance, better glycemic control, and overall fewer hypoglycemic episodes.

### Electronic Step Therapy Required

- Fiasp



- PA Not Required Criteria: A 3-month supply of Humalog has been paid within 180 days prior to Fiasp's date of service.
- PA Required Criteria: The member must have failed a 3-month trial from Humalog, as evidenced by paid claims or pharmacy printouts.

### Prior Authorization Criteria

#### Initial Criteria – Approval Duration: 12 months

- Apidra: The member must have failed a 3-month trial of each of the following agents, as evidenced by paid claims or pharmacy printouts:
  - Humalog
  - Fiasp
- Humalog U-200: Request must not be for use in an insulin pump: [HUMALOG® \(insulin lispro\) 200 Units/mL: Do Not Use in a Pump \(lillymedical.com\)](#)
  - Doses ≤ 200 units/day: Clinical justification must be provided why member cannot tolerate the volume of insulin required to use Humalog U-100 or tolerate two injections per dose.
  - Doses > 200 units/day: Clinical justification must be provided why member is not a candidate for Humulin R U-500.
- Regular Insulin (Humulin R / Novolin R / Afrezza): The member must have failed a 3-month trial of each of the following agents, as evidenced by paid claims or pharmacy printouts:
  - Humalog and Fiasp
- Non-Preferred Agents: See [Preferred Dosage Form Criteria](#)

## Intermediate Acting Insulin

PREFERRED AGENTS (NO PA REQUIRED)	PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
HUMULIN R U-500 (insulin regular, human)	++ NOVOLIN N (insulin NPH human isophane)	++ HUMULIN N (insulin NPH human isophane)
	++ RELION NOVOLIN N (insulin NPH human isophane)	

++ Clinically non-preferred: Lantus and Levemir have been demonstrated to reduce the risk of symptomatic and nocturnal hypoglycemia compared with NPH insulin.

### Prior Authorization Criteria

#### Initial Criteria – Approval Duration: 12 months (6 months or until due date, if known, for gestational diabetes)

- One of the following must be met:
  - The member must be pregnant or breastfeeding.
  - The member must be tube feedings.
  - The member must be post-solid organ transplant.
    - For kidney transplant – Medicare eligibility must be ruled out (6-month approval may be allowed to determine eligibility)
  - Clinical justification explaining why the member is unable to use Lantus or Levemir (subject to clinical review)

#### Non-Preferred Agent Criteria

- See [Preferred Dosage Form Criteria](#)

## Long-Acting Insulin

### Insulin Glargine

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
LANTUS U-100 (insulin glargine)	BASAGLAR KWIKPEN U-100 (insulin glargine)

– Brand Required	
TOUJEO U-300 (insulin glargine) *No PA required for doses 100 unit/day to 200 unit/day – Brand Required	BASAGLAR TEMPO PEN U-100 (insulin glargine)
	insulin glargine U-100 (generic Toujeo)
	insulin glargine-yfgn U-100 (generic Semglee)
	REZVOGLAR U-100 (insulin glargine-aglr)
	SEMGLEE U-100 (insulin glargine) YFGN

## Insulin Degludec

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
TRESIBA (insulin degludec) FLEXTOUCH U-200 *No PA required for doses 100 unit/day to 200 unit/day - Brand Required	insulin degludec U-100 and U-200
	TRESIBA (insulin degludec) U-100 VIAL

### Quantity Override Request

- Toujeo Solostar 300 unit/mL, Toujeo Max Solostar 300 unit/mL and Tresiba 200 unit/mL:
  - Doses > 200 units/day:
    - Clinical justification must be provided explaining why the member is not a candidate for U-500R + Toujeo and Tresiba are not intended as replacements for U-500R insulin
  - Doses >100 units/day to ≤ 200 units/day: No prior authorization required.
    - Please call for an override by calling provider relations at 1-800-755-2604 if the day supply is less than 30 days and dose is between 100 units/day and 200 units/day (e.g., short-cycle filling).
  - Doses ≤ 100 units/day:
    - Must meet Prior Authorization Criteria below

### Prior Authorization Criteria

#### Initial Criteria – Approval Duration: 12 months

- The requested medication must be prescribed by, or in consult with, an endocrinologist or diabetes specialist.
- The member has had a 90-day trial of Lantus with good compliance, as evidenced by paid claims or pharmacy printouts.
- One of the following must be met, as evidenced by provided clinical notes or labs:
  - The member experiences recurrent episodes of hypoglycemia despite adjustments to current regimen (prandial insulin, interacting drugs, meal, and exercise timing).
  - The member must be experiencing inconsistent blood sugars.
- Biosimilar Agents: See [Preferred Dosage Form Criteria](#)

#### Renewal Criteria – Approval Duration: 12 months

- The member must have experienced at least one of the following, as evidenced by provided clinical notes or labs:
  - Reduction in frequency and/or severity of hypoglycemia
  - Improved glycemic control (evidenced by A1c or TIR)

## Mixed Insulin

### Insulin NPL/Insulin Lispro

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
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HUMALOG MIX 50/50 (insulin NPL/insulin lispro) VIAL	HUMALOG MIX 50/50 (insulin NPL/insulin lispro) KWIKPEN
insulin lispro mix 75/25 kwikpen	HUMALOG MIX 75/25 (insulin NPL/insulin lispro)

### Insulin Aspart Protamine/Insulin Aspart

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
insulin aspart protamine/insulin aspart 70/30	NOVOLOG MIX 70/30 (insulin aspart protamine/insulin aspart) – <i>Brand Required</i>
	RELION NOVOLOG MIX 70/30 (insulin aspart protamine/insulin aspart)

### Insulin NPH Human/Regular Insulin Human

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
HUMULIN MIX 70/30 (insulin NPH human/regular insulin human)	NOVOLIN MIX 70-30 (insulin NPH human/regular insulin human)
	RELION NOVOLIN MIX 70-30 (insulin NPH human/regular insulin human)

### Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months (6 months or until due date, if known, for gestational diabetes)

- Humulin 70/30 and Novolin 70/30 only:
  - One of the following must be met:
    - Member must be pregnant or breastfeeding.
    - Member must be on tube feedings.
    - Member must be post-solid organ transplant.
      - For kidney transplant – Medicare eligibility must be ruled out (6-month approval may be allowed to determine eligibility)

### Non-Preferred Agent Criteria

- See [Preferred Dosage Form Criteria](#)
- Clinical justification must be provided explaining why the member is unable to use the preferred products or a long acting plus short acting regimen (subject to clinical review).

### SGLT2 Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
FARXIGA (dapagliflozin) – <i>Brand Required</i>	dapagliflozin
JARDIANCE (empagliflozin)	dapagliflozin/metformin XR 5mg-1000mg, 10mg-1000mg
SYNJARDY (empagliflozin/metformin)	INVOKANA (canagliflozin)
XIGDUO XR (dapagliflozin/metformin) 5 MG-500 MG, 5 MG-1000 MG, 10 MG-500 MG, 10 MG-1000 MG – <i>Brand Required</i>	INVOKAMET (canagliflozin/metformin)
	INVOKAMET XR (canagliflozin/metformin)
	STEGLATRO (ertugliflozin)
	STEGLATROMET (ertugliflozin/metformin)
	SYNJARDY XR (empagliflozin/metformin)
	XIGDUO XR (dapagliflozin/metformin) 2.5 MG – 1000 MG

++ Canagliflozin has shown an increase in the risk of lower limb amputations and fractures in studies.

- ++ Dapagliflozin did not reduce atherosclerotic cardiovascular morbidity or mortality in a primary analysis, however it decreased cardiovascular in the sub analysis of prior myocardial infarction.
- ++ Ertugliflozin was not superior to placebo in reducing the primary composite cardiovascular endpoint.

*Prior Authorization Criteria*

Initial Criteria – Approval Duration: 12 months

- The member must have failed a 30-day trial of each preferred SGLT2 inhibitor of a unique active ingredient, as evidenced by paid claims or pharmacy printouts.
- Clinical justification must be provided explaining why the member is unable to use the preferred agents and other classes of medication (subject to clinical review).

**References:**

1. DeSantis A. Sodium-glucose cotransporter 2 inhibitors for the treatment of hyperglycemia in type 2 diabetes mellitus. In: *UpToDate*, Post TW (Ed), UpToDate, Waltham, MA, 2023

**Sulfonylureas**

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
glimepiride 1 mg, 2 mg, and 4 mg	glimepiride 3 mg
glipizide IR 5 mg, 10 mg	glipizide 2.5 mg
glipizide ER	++glyburide
glipizide/metformin	++glyburide/metformin
glipizide ER	++glyburide, micronized

++Clinically Non-preferred: Glyburide is not recommended due to hypoglycemia.

*Prior Authorization Criteria*

Initial Criteria – Approval Duration: 12 months

- The member must have failed a 30-day trial of glipizide and glimepiride, as evidenced by paid claims or pharmacy printouts.
- See [Preferred Dosage Form Criteria](#)

**Growth Hormone**

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
GENOTROPIN (somatropin)	HUMATROPE (somatropin)
GENOTROPIN MINIQUICK (somatropin)	NGENLA (somatrogon-ghla)
NORDITROPIN FLEXPRO (somatropin)	NUTROPIN AQ NUSPIN (somatropin)
PREFERRED AGENTS (PA REQUIRED)	OMNITROPE (somatropin)
SKYTROFA (lonapegsomatropin-tcgd)	SAIZEN (somatropin)
	SOGROYA (somapacitan-beco)
	ZOMACTON (somatropin)

*Prior Authorization Criteria*

Prior Authorization Form – Growth Hormone

Initial Criteria – Approval Duration: 12 months (except 6 months if criteria met in Prader-Willi Syndrome)

- Member must have one of the following covered diagnoses (listed below):
  - Panhypopituitarism OR multiple pituitary hormone deficiencies caused by a known hypothalamic-pituitary disease treatment (brain surgery and/or radiation)

- Turner's syndrome
- SHOX syndrome
- Noonan syndrome
- Chronic renal insufficiency
- Prader-Willi syndrome
- Endogenous growth hormone deficiency
- The requested medication must be prescribed by, or in consult annually with, an endocrinologist or nephrologist.
- The member must not have active malignancy.
- The member must not have epiphyseal closure and must still be growing, unless one of the below exceptions is present:
  - The member has a diagnosis of Prader-Willi syndrome.
  - The member has a diagnosis of endogenous growth hormone deficiency and is experiencing hypoglycemic episodes without growth hormone and growth hormone is needed to maintain proper blood glucose.

#### *Chronic Renal Insufficiency*

- The member must not have received a renal transplant.
- The member must consult with a dietitian annually to maintain a nutritious diet.

#### *Endogenous Growth Hormone Deficiency and Panhypopituitarism*

2. ONE of below criteria must be met:
  - The member has multiple pituitary hormone deficiencies caused by a known hypothalamic-pituitary disease or its treatment (brain surgery and/or radiation) and must have an IGF-1 or IGFBP-3 level of less than SDS -1.3.
  - The member has had GH stimulation testing by at least two different stimuli (e.g., insulin, levodopa, L-arginine, propranolol, clonidine, or glucagon) with a maximum peak of < 10 ng/mL after stimulation no more than 6 months apart.
  - For infants less than 18 months old, both of the following criteria are met:
    - The member has a plasma glucose level less than 70 mg/dL
    - The member has GH level < 5 mcg/L

#### *Prader-Willi Syndrome (PWS)*

See covered [medications for weight loss](#)

3. The member must not have severe obesity (class 2) defined as  $\geq 120\%$  of the 95<sup>th</sup> percentile for age and gender
4. If the member has obesity  $\geq 95^{\text{th}}$  percentile and < 120% of the 95<sup>th</sup> percentile for age and gender, all the following must be met (*6-month approval criteria*):
  - The prescriber must attest that member will meet with a dietician every 3 months
  - The member must have had a sleep study to rule out sleep apnea
  - The member must not have non-alcoholic fatty liver disease
  - The member must not have an A1c > 5.7%

#### *Non-Preferred Agent Criteria:*

- Skytrofa and Omnitrope Only: The member must have failed a 30-day trial of one preferred agent, as evidenced by paid claims or pharmacy printouts.
- All other agents: See [Preferred Dosage Form Criteria](#)

#### Renewal Criteria – Approval Duration: 12 months (6 months if criteria below for PWS is met )

- The member must have been compliant with growth hormone (last 6 fills must have been on time).

#### *Prader-Willi Syndrome*

- If the member has obesity  $\geq 95^{\text{th}}$  percentile and < 120% of the 95<sup>th</sup> percentile for age and gender, initial criteria must be met in addition to the following (*6-month approval criteria*):
  - The member must have met with a dietician at least 2 times in the past 6 months

## References:

1. Deal et al., Growth hormone research society workshop summary: consensus guidelines for recombinant human growth hormone therapy in Prader Will syndrome. J Clin Endocrin Metab. 2013. doi: 10.1210/jc.2012-3888

## Serostim

<b>CLINICAL PA REQUIRED</b>
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SEROSTIM (somatropin)
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### *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

<b>CLINICAL PA REQUIRED</b>
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IMCIVREE (setmelanotide)
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### *Prior Authorization Criteria*

##### Initial Criteria – Approval Duration: 4 months

- The member must have a diagnosis of obesity (BMI > 30 kg/m<sup>2</sup> for adults or > 95<sup>th</sup> percentile using growth chart assessments for pediatric members)
- The member's weight and body mass index (BMI) must be provided within the last 60 days.
- The requested medication must be prescribed by, or in consult with, endocrinologist or medical geneticist.
- The member's obesity must be due to one of the following:
  - Genetic testing confirms one of the following variants that is pathogenic, likely pathogenic, or of unknown significance:
    - Proopiomelanocortin (POMC)
    - Proprotein convertase subtilisin/kexin type 1 (PCSK1)
    - Leptin receptor (LEPR) deficiency
  - Bardet-Biedl syndrome as evidenced by three or more of the following:
    - Rod-cone dystrophy
    - Polydactyly
    - Genital anomalies

- Renal anomalies
- Intellectual impairment

Renewal Criteria – Approval Duration: 12 months

- One of the following must be met since starting treatment with Imcivree, as evidenced by medical documentation (e.g., chart notes) attached to the request:
  - Members ≥ 18 years old:
    - First renewal – a 5% weight reduction has been achieved or maintained.
    - Subsequent renewal – a 10% weight reduction has been achieved or maintained.
  - Members < 18 years old: a 5% reduction in BMI has been achieved or maintained.

## Hypothyroidism

### Solid Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
levothyroxine tablet	EUTHYROX (levothyroxine) TABLET
	levothyroxine capsule
	LEVO-T (levothyroxine) TABLET
	LEVOXYL (levothyroxine) TABLET
	SYNTHROID (levothyroxine) TABLET
	UNITHROID (levothyroxine) TABLET

### Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- Levothyroxine capsule only: The member must have documented celiac disease, yellow dye allergy, or lactose/milk protein allergy.
- All other agents: See [Preferred Dosage Form](#) criteria

### Non-Solid Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ERMEZA (levothyroxine) SOLUTION	THYQUIDITY (levothyroxine) ORAL SOLUTION

### Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- All other agents: See [Preferred Dosage Form](#) criteria

## Secondary Hyperparathyroidism

### Oral

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
calcitriol	cinacalcet
paricalcitol	doxercalciferol capsule
	HECTOROL (doxercalciferol) CAPSULE
	RAYALDEE ER (calcifediol)
	ROCALTROL (calcitriol)
	SENSIPAR (cinacalcet)



ZEMPLAR (paricalcitol)
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++ cinacalcet is associated with hypocalcemia, increased urinary calcium excretion, and increased serum phosphate levels

### Prior Authorization Criteria

#### Initial Criteria – Approval Duration: 12 months

*Cinacalcet only:*

- If member is on renal dialysis, Medicare eligibility must be ruled out (6-month approval may be allowed to determine eligibility)

*All other agents:*

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The member must have failed a 30-day trial of paricalcitol
- Clinical justification must be provided explaining why the member is unable to use the preferred agents (subject to clinical review)

#### **References:**

1. Quarles LD. Management of secondary hyperparathyroidism in adult non-dialysis patients with chronic kidney disease. In: *UpToDate*, Post TW (Ed), UpToDate, Waltham, MA, 2023

#### *Subcutaneous*

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	YORVIPATH (palopegteriparatide)

### Prior Authorization Criteria

#### Initial Criteria – Approval Duration: 12 months

- The requested medication must be prescribed by, or in consult with, an endocrinologist
- The member must have persistent hypoparathyroidism as evidenced by one of the following symptoms despite a 6-month trial of calcitriol or equivalent oral agent:
  - Symptomatic hypocalcemia
  - Hyperphosphatemia
  - Hypercalciuria
- The member must have an albumin-corrected serum calcium concentration must be  $\geq 7.8$  mg/dL
- The member must have a magnesium concentration  $\geq 1.3$  mg/dL
- The member must have a 25 (OH) vitamin D concentration between 20 and 80 ng/mL

#### Renewal Criteria – Approval Duration: 12 months

- The member no longer requires active vitamin D or has experienced a significant reduction in required dosage and is still titrating Yorvipath
- The member has an albumin-corrected serum calcium in the lower-half of the normal reference range or just below the reference range (~8-9 mg/dL)

## Precocious Puberty

NO PA REQUIRED	
FENSOLVI (leuprolide) – <i>Medical Billing Only</i>	SUPPRELIN LA (histrelin) – <i>Medical Billing Only</i>
LUPRON PED DEPOT (leuprolide) – <i>Medical Billing Only</i>	
SYNAREL (nafarelin) – <i>Medical Billing Only</i>	
TRIPTODUR (triptorelin) – <i>Medical Billing Only</i>	



## Prior Authorization Criteria

### Initial Criteria – Approval Duration: 1 month

- Clinical justification must be provided explaining why the member is unable to use the preferred agents (subject to clinical review).

## Thyroid Eye Disease

### CLINICAL PA REQUIRED

TEPEZZA (teprotumumab-trbw) – Medical Billing Only

## Prior Authorization Criteria

### Initial Criteria – Approval Duration: 6 months (8 infusions per lifetime)

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult annually with, an endocrinologist, ophthalmologist, or specialist in the treatment of Thyroid Eye Disease (TED)
- The provider must submit documentation of each of the following:
  - Thyroxine (FT4) and free triiodothyronine (FT3) levels less than 50% above or below normal limits
  - Must have a Clinical Activity Score of greater than or equal to 4
- The member has had a one-month trial of a maximally tolerated indicated dose of systemic glucocorticoids.
- The member has not required prior surgical ophthalmologic intervention.
- The member does not have any of the following:
  - A decrease in best corrected visual acuity (BVCA) due to optic neuropathy within the previous six months (i.e., decrease in vision of 2 lines on the Snellen chart, new visual field defect, or color defect secondary to optic nerve involvement)
  - Corneal decompensation that is unresponsive to medical management
  - Poorly controlled diabetes or diabetes must be maximally treated by, or in consult with, an endocrinologist with good adherence.

## X-linked Hypophosphatemia (XLH) or Tumor-Induced Osteomalacia

### CLINICAL PA REQUIRED

CRYSVITA (burosumab) – Medical Billing Only

## Prior Authorization Criteria

### Initial Criteria – Approval Duration: 12 months (one-time 6-month approval for adult with planned orthopedic surgical

- Documentation to confirm the diagnosis must be submitted, as evidenced by the following:
  - Genetic testing confirming phosphate regulating gene with homology to endopeptidases on the X chromosome (PHEX-gene) mutation
  - Increased (FGF23) level based on laboratory reference range with unresectable phosphaturic mesenchymal tumor
- The requested medication must be prescribed by, or in consult with, nephrologist, endocrinologist, geneticist, or specialist experienced in the treatment of metabolic bone disorders.
- Documentation must be submitted confirming the member is experiencing the following:
  - Phosphate manifestations (*must have one*)
    - Fasting serum phosphate is below provided age adjusted reference range.
    - Low tubular resorption of phosphate corrected for glomerular filtration rate (TmP/GFR) based on age
  - Bone manifestations (*must have one*)

- Epiphyseal plate has not fused
- Bone fractures
- Planned orthopedic surgical procedure

**Renewal Criteria – Approval Duration: 12 months**

- Documentation must be submitted demonstrating that the member has demonstrated a disease stability or beneficial response to therapy from baseline as shown by one or more of the following:
  - Normalization of phosphate levels as defined by laboratory
  - Decrease in serum alkaline phosphatase activity
  - Improvement of renal phosphate wasting
  - Normalization of growth velocity
  - Reduction or healing of fractures
  - Improvement of Thacher Rickets Severity Score (TRSS)

## Weight Loss

### Antipsychotic Induced Weight Gain

- Metformin is covered without prior authorization.
- Victoza is covered without prior authorization by submitting diagnosis code T43.505A

### Obesity

- The following drugs are covered without prior authorization by submitting a corresponding diagnosis code for the indication:
  - phentermine, bupropion, naltrexone, topiramate

## GI – Gastroenterology

### Acid Blockers

#### Proton Pump Inhibitor

#### Solid Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	PREFERRED STEP 1 AGENTS (ELECTRONIC STEP)	NON-PREFERRED STEP 2 AGENTS (PA REQUIRED)
lansoprazole	esomeprazole magnesium	ACIPHEX (rabeprazole)
omeprazole		DEXILANT (dexlansoprazole)
pantoprazole		dexlansoprazole
rabeprazole		NEXIUM (esomeprazole)
		omeprazole-sodium bicarbonate
		PREVACID (lansoprazole)
		PRILOSEC (omeprazole)
		PROTONIX (pantoprazole)
		ZEGERID (omeprazole/sodium bicarbonate)

### Electronic Step Therapy Required

- Preferred Step 1 Agents:
  - PA Not Required Criteria: A 14-day supply from at least 1 preferred agent at max dose has been paid within 365 days prior to preferred step 1 agent's date of service.
  - PA Required Criteria: The member must have failed a 14-day trial from at least 1 preferred agent at max dose, as evidenced by paid claims or pharmacy printouts.

### Prior Authorization Criteria

#### Initial Criteria – Approval Duration: 6 months

- Non-Preferred Agents Criteria – Step 2 Agents:
  - Member must have failed a 30-day trial with all preferred agents (including Step 1 Agents), as evidenced by paid claims or pharmacy printouts.

### Non-Solid Dosage Forms

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

### Prior Authorization Criteria

#### Initial Criteria – Approval Duration: 6 months

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

### Electronic Age Verification

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

### Therapeutic Duplication

- One strength of one medication is allowed at a time.
- Proton Pump Inhibitors is not allowed with:
  - Esomeprazole or omeprazole are not covered with clopidogrel.
    - Other PPIs such as pantoprazole are covered with clopidogrel. Clopidogrel is a substrate for 2C19 and esomeprazole and omeprazole are strong 2C19 inhibitors and can decrease effectiveness of clopidogrel.
  - Dextroamphetamine/Amphetamine ER:
    - Proton Pump Inhibitors increase blood levels and potentiate the action of amphetamine. Co-administration of Adderall XR and gastrointestinal or urinary alkalizing agents should be avoided.
  - H2 Blockers: If either of the following circumstances apply, please call for an override by calling provider relations at 1-800-755-2604:

- Member is experiencing nocturnal symptoms after compliance with nighttime dose of proton pump inhibitor. A two-month override may be approved for concurrent H2 blocker use.
- H2 blocker is being used concurrently with a H1 blocker for severe allergy prophylaxis, unrelated to PPI use for GI symptoms.

#### References

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

## Potassium Competitive Acid Blocker

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

### Prior Authorization Criteria

#### Initial Criteria – Approval Duration: 6 months

- The member must meet one of the following criteria (A, B, or C):
  - A. The member has a diagnosis of erosive esophagitis and have failed an 8-week trial of each of the following:
    - Omeprazole twice daily
    - Rabeprazole or esomeprazole daily.
  - B. The member has severe esophagitis (LA Grade C/D disease)
  - C. Member must have failed a 30-day trial with all preferred proton pump inhibitors (including Step 1 Agents), as evidenced by paid claims or pharmacy printouts.

## Acute Hepatic Porphyrria (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 coproporphyrria (HCP), delta-aminolevulinic acid dehydratase deficient porphyria (ADP)) with the following as defined by laboratory reference range (evidenced with submitted documentation):
  - Elevated urine porphobilinogen (PBG)
  - Increased aminolevulinic acid (ALA)
  - Genetic testing confirming a mutation
- The member has addressed identifiable lifestyle triggers (e.g., [certain drugs](#), smoking, stress)
- The member has had two documented porphyria attacks within the past 6 months requiring hospitalization, urgent healthcare visit, or intravenous hemin administration (number of attacks and days of hemin are documented)
- The member has not had a liver transplant.

#### Renewal Criteria – Approval Duration: 12 months

- The member has had a meaningful reduction (e.g., 30%) in each of the following:
  - Number of porphyria attacks
  - Days of Hemin Use
  - Reduction in urinary ALA

## Bowel Prep Agents

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
GAVILYTE-C	CLENPIQ
GAVILYTE-G	PEG 3350/SOD SUL/NAACL/KCL/ASB/C
GAVILYTE-N	PLENVU
GOLYTELY 236-22.74G – Brand Co-Preferred	
MOVIPREP – Brand Required	
PEG-3350 AND ELECTROLYTES 236-22.74G	
PEG 3350-ELECTROLYTE 420 G	
PEG 3350-ELECTROLYTE SOLUTION	
SOD SOL-POTASS SUL-MAG SUL	
SUFLAVE	
SUPREP – Brand Co-Preferred	
SUTAB	

### Prior Authorization Criteria

#### Initial Criteria – Approval Duration: 1 month

- Clinical justification must be provided explaining why the member is unable to use the preferred agents (subject to clinical review).

## Cholestatic Pruritis

### Alagille Syndrome (ALGS):

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

### Progressive Familial Intrahepatic Cholestasis (PFIC):

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

### Prior Authorization Criteria

#### Initial Criteria – Approval Duration: 6 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a hepatologist or gastroenterologist.
- The member is experiencing itch for greater than 6 weeks that has significantly diminished quality of life, including sleep disturbances.
- The member must have cholestasis, as evidenced by  $\geq 1$  of the following:
  - Serum bile acid > 3x upper limit of normal as defined by the reporting laboratory
  - Conjugated bilirubin > 1mg/dL
  - Fat soluble vitamin deficiency otherwise unexplainable
  - Gamma-glutamyl transferase > 3x the upper limit of normal
  - Intractable pruritus explainable only by liver disease

- The member must not have a history of liver transplant or decompensated cirrhosis.
- The member must not have history of biliary diversion surgery within the past 6 months.
- The member must have failed at least a 3-month trial of both of the following, as evidenced by paid claims or pharmacy printouts:
  - Ursodiol
  - agents to treat pruritis: cholestyramine, rifampin, antihistamines
- Bylvay Only:
  - ALGS:
    - Genetic testing confirms pathogenic variant (e.g., *JAG1* and *NOTCH2*).
    - The member has had a 6-month trial with Livmarli.
  - PFIC:
    - Genetic testing confirms pathogenic variant (e.g., *ATP8B1*, *ABCB11*, *ABCB4*, *TJP2*, *NR1H4*, and *MYO5B*).
    - Genetic testing does not indicate PFIC Type 2 with *ABCB11* variants that predict complete absence of BSEP-3 protein.
- Livmarli Only:
  - Genetic testing confirms pathogenic variant of *JAG1* or *NOTCH1*

Renewal Criteria – Approval Duration: 12 months

- The member has experienced an improvement in pruritis, as evidenced by clinical documentation.
- The member must have experienced a reduction in serum bilirubin < 6.5mg/dL and bile acids < 200 micromol/L

## Clostridioides difficile-associated diarrhea (CDAD)

### Prevention

#### Fecal Microbiota

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
REBYOTA (fecal microbiota, live–jslm) SUSPENSION – Medical Billing Only	
VOWST (fecal microbiota spores, live-brpk) CAPSULE	

#### Monoclonal Antibody

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ZINPLAVA (bezlotoxumab) – Medical Billing Only	

#### Electronic Duration Verification:

- Vowst is payable every 6 months.

#### Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member has one of the following (1 or 2):
  1. The member has had at least two episodes of diarrhea with a positive stool test for *C.difficile* toxin within the last year
  2. The member has had at least one previous episodes of diarrhea with a positive stool test for *C.difficile* toxin within the last year AND one of the following
    - *C. difficile* infection was severe (defined as ZAR score  $\geq 2$ )
    - Member is immunocompromised

## Treatment

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
DIFICID (fidaxomicin) 40 MG/ML SUSPENSION	FIRVANQ (vancomycin) SOLUTION
DIFICID (fidaxomicin) TABLET	VANCOCIN (vancomycin) CAPSULE
vancomycin capsule	
vancomycin solution	

### Prior Authorization Criteria

*Initial Criteria – Approval Duration: 1 month*

5. See [Preferred Dosage Form Criteria](#)

## Crohn's Disease

### Biologic Agents

#### α4 Integrin Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	TYSABRI (natalizumab) – <i>Medical Billing Only</i>

++ Clinically Non-Preferred: Tysabri is associated with a risk of developing progressive multifocal leukoencephalopathy (PML), a rare, potentially fatal neurologic disease caused by reactivation of JC virus (JCV) infection.

#### A4β7 Integrin Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	ENTYVIO (vedolizumab) – <i>Medical Billing Only</i>

#### Janus Kinase (JAK) Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	RINVOQ ER (upadacitinib)

#### Interleukin (IL) 12/IL-23 Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	STELARA (ustekinumab)
	STELARA (ustekinumab) – <i>IV Induction Medical Billing Only</i>
	WEZLANA (ustekinumab-auub)
	WEZLANA (ustekinumab-auub) – <i>IV Induction Medical Billing Only</i>

#### Interleukin (IL)-23p19 Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	SKYRIZI (risankizumab-rzaa)
	SKYRIZI (risankizumab-rzaa) – <i>IV Induction Medical Billing Only</i>



## TNF Inhibitors

### Adalimumab

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ABRILADA (adalimumab-afzb)	adalimumab-aacf
adalimumab-adbm – labeler 00597	adalimumab-aaty
adalimumab-fkjp	adalimumab-adaz
CYLTEZO (adalimumab-abdm)	adalimumab-adbm – labeler 82009
HADLIMA (adalimumab-bwwd)	adalimumab-ryvk
HULIO (adalimumab-fkjp)	AMJEVITA (adalimumab-atto)
HUMIRA (adalimumab)	HYRIMOZ (adalimumab-adaz)
SIMLANDI (adalimumab-ryvk)	IDACIO (adalimumab-aacf)
YUSIMRY (adalimumab-aqvh)	YUFLYMA (adalimumab-aaty)

### Infliximab

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AVSOLA (infliximab-axxq) – <i>Medical Billing Only</i>	INFLECTRA (infliximab-dyyb) – <i>Medical Billing Only</i>
RENFLXIS (infliximab-abda) – <i>Medical Billing Only</i>	infliximab – <i>Medical Billing Only</i>
	REMICADE (infliximab) – <i>Medical Billing Only</i>
	ZYMFENTRA (infliximab-dyyb)

### Other TNF

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	CIMZIA (certolizumab) SYRINGE
	CIMZIA (certolizumab) VIAL – <i>Medical Billing Only</i>

### Electronic Diagnosis Verification

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

### Prior Authorization Criteria

#### Initial Criteria – Approval Duration: 12 months

- The member must have failed a 3-month trial of a TNF inhibitor, as evidenced by paid claims or pharmacy printouts:

#### *Stelara and Wezlana Only:*

- The member has failed a 3-month trial of an TNF inhibitor, Rinvoq ER, Entyvio and Skyrizi, as evidenced by paid claims or printouts.

#### *Tysabri Only:*

- The requested medication must be prescribed by, or in consult with, an gastroenterologist

#### *Non-Preferred Biosimilars Only:*

- See [Biosimilar Agents](#) criteria

## Constipation

### Therapeutic Duplication

- One medication is allowed at a time.



## Chronic Idiopathic Constipation

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
LINZESS (linaclotide)	AMITIZA (lubiprostone)
lubiprostone	MOTEGRITY (prucalopride)
TRULANCE (plecanatide)	

### Prior Authorization Criteria

#### Initial Criteria – Approval Duration: 12 months

- Motegrity:
  1. The member must have had a 30-day trial with each of the following, as evidenced by paid claims or pharmacy printouts:
    - Linzess or Trulance
    - lubiprostone

## Functional Constipation

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
LINZESS (linaclotide) 72 mcg	

## Irritable Bowel Syndrome with Constipation (IBS-C)

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
LINZESS (linaclotide)	AMITIZA (lubiprostone)
lubiprostone	IBSRELA (tenapanor)
TRULANCE (plecanatide)	XPHOZAH (tenapanor)

### Prior Authorization Criteria

#### Initial Criteria – Approval Duration: 12 months

- Ibsrela Only:
  - a. The member must have had a 30-day trial with each of the following, as evidenced by paid claims or pharmacy printouts:
    - Linzess or Trulance
    - lubiprostone for members assigned female at birth
- Xphozah Only:
  - a. The member must have had a 30-day trial with each of the following, as evidenced by paid claims or pharmacy printouts:
    - Linzess or Trulance
    - lubiprostone for members assigned female at birth
    - Ibsrela

## Opioid-Induced Constipation

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
lubiprostone	AMITIZA (lubiprostone)
MOVANTIK (naloxegol)	RELISTOR (methylnaltrexone) TABLET
RELISTOR (methylnaltrexone) SYRINGE	
RELISTOR (methylnaltrexone) VIAL	
SYMPROIC (naldemedine)	

### Electronic Concurrent Medications Required

- A total of 28 days of opioid analgesics must be paid within 40 days prior to requested Movantik, Symproic, or Relistor's date of service.
  - Medications indicated for opioid-induced constipation should be discontinued when opioids are stopped.

### Prior Authorization Criteria

#### Initial Criteria – Approval Duration: 12 months

- a. The member must have had a 30-day trial with each of the following, as evidenced by paid claims or pharmacy printouts:
  - Movantik
  - Symproic

## Diarrhea

### Irritable Bowel Syndrome

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
antispasmodic (e.g., dicyclomine, hyoscyamine)	alosetron
loperamide	VIBERZI (eluxadoline)
LOTRONEX (alosetron) – <i>Brand Required</i>	XIFAXAN (rifaximin) 550 mg tablet
tricyclic antidepressants (e.g., amitriptyline)	

### Electronic Diagnosis Verification

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

### Electronic Concurrent Medications Required

- Xifaxan does not require prior authorization for hepatic encephalopathy if used concurrently with lactulose
  - A total of 30 days of lactulose must be paid within 65 days prior to Xifaxan's date of service
  - An override may be available after an adequate trial of lactulose where lactulose is not tolerated

### Prior Authorization Criteria

#### Initial Criteria – Approval Duration: 3 months

- Infectious and medication-induced etiologies of diarrhea must have been ruled out.
- The member must have failed a 30-day trial of a product in each preferred class, as evidenced by paid claims or pharmacy printouts.

## HIV / AIDS

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
antimotility agent (e.g., loperamide, diphenoxylate/atropine)	MYTESI (crofelemer)
octreotide	

### Prior Authorization Criteria

#### Initial Criteria – Approval Duration: 3 months

- Infectious and medication-induced etiologies of diarrhea must have been ruled out.

- The member must have failed a 30-day trial of an agent in each preferred class, as evidenced by paid claims or pharmacy printouts.

## Digestive Enzymes

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
CREON (lipase/protease/amylase)	PERTZYE (lipase/protease/amylase)
ZENPEP (lipase/protease/amylase)	VIOKACE (lipase/protease/amylase)

### Prior Authorization Criteria

#### Initial Criteria – Approval Duration: 12 months

- A 30-day trial of all preferred agents will be required before a non-preferred agent will be authorized unless member stable on a pancreatic enzyme written by a gastroenterologist or pancreas disease specialist.

## Eosinophilic Esophagitis

CLINICAL PA REQUIRED
DUPIXENT (dupilumab)

### Prior Authorization Criteria

#### Prior Authorization Form – Eosinophilic Esophagitis

#### Initial Criteria – Approval Duration: 6 months

- The requested medication must be prescribed by, or in consult with, a gastroenterologist.
- The member must have  $\geq 15$  intraepithelial eosinophils per high-power field (eos/hpf).
- The member must have failed a 3-month trial of a swallowed inhaled respiratory corticosteroid (budesonide or fluticasone).

#### Renewal Criteria – Approval Duration: 12 months

- The member has achieved a significant reduction in dysphagia symptoms since treatment initiation.
- The member must have achieved an esophageal intraepithelial eosinophil count of  $\leq 6$  eos/hp.

## Ulcerative Colitis

### Biologic Agents

#### $\alpha 4\beta 7$ Integrin Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	ENTYVIO (vedolizumab)
	ENTYVIO (vedolizumab) – <i>Medical Billing Only</i>

#### Interleukin (IL)-23p19 Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	OMVOH (mirikizumab)
	OMVOH (mirikizumab) – <i>IV Induction Medical Billing Only</i>
	SKYRIZI (risankizumab-rzaa)
	SKYRIZI (risankizumab-rzaa) – <i>IV Induction Medical Billing Only</i>

## Interleukin (IL) 12/IL-23 Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	STELARA (ustekinumab)
	STELARA (ustekinumab) – IV Induction Medical Billing Only
	WEZLANA (ustekinumab-auub)
	WEZLANA (ustekinumab-auub) – IV Induction Medical Billing Only

## Interleukin (IL)-23p19 Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	TREMFYA (guselkumab) – Medical Billing Only
	TREMFYA (guselkumab)

## TNF Inhibitors

### Adalimumab

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ABRILADA (adalimumab-afzb)	adalimumab-aacf
adalimumab-adbm – labeler 00597	adalimumab-aaty
adalimumab-fkjp	adalimumab-adaz
CYLTEZO (adalimumab-abdm)	adalimumab-adbm – labeler 82009
HADLIMA (adalimumab-bwwd)	adalimumab-ryvk
HULIO (adalimumab-fkjp)	AMJEVITA (adalimumab-atto)
HUMIRA (adalimumab)	HYRIMOZ (adalimumab-adaz)
SIMLANDI (adalimumab-ryvk)	IDACIO (adalimumab-aacf)
YUSIMRY (adalimumab-aqvh)	YUFLYMA (adalimumab-aaty)

### Infliximab

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AVSOLA (infliximab-axxq) – Medical Billing Only	INFLECTRA (infliximab-dyyb) – Medical Billing Only
RENFLIXIS (infliximab-abda) – Medical Billing Only	infliximab – Medical Billing Only
	REMICADE (infliximab) – Medical Billing Only

### Other TNF

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
SIMPONI (golimumab)	

## Electronic Diagnosis Verification

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

### Prior Authorization Criteria

#### Initial Criteria – Approval Duration: 12 months

- The requested medication must be prescribed by, or in consult with, a gastroenterologist.
- Non-Preferred Biosimilars Only: See [Biosimilar Agents](#) criteria
- Entyvio Only: The member must have failed a 3-month trial of a TNF inhibitor, as evidenced by paid claims or pharmacy printouts.

- Skyrizi and Tremfya Only: The member must have failed a 3-month trial of a TNF inhibitor and Entyvio, as evidenced by paid claims or pharmacy printouts.
- Omvoh, Stelara, and Wezlana Only: The member must have failed a 3-month trial of a TNF inhibitor, Entyvio, and Skyrizi, as evidenced by paid claims or pharmacy printouts.

## 5-Aminosalicylic Acid (5-ASA)

### Oral

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
APRISO ER (mesalamine) CAPSULE – <i>Brand Required</i>	AZULFIDINE (sulfasalazine)
balsalazide capsule	AZULFIDINE ENTAB (sulfasalazine)
DIPENTUM (olsalazine)	COLAZAL (balsalazide)
mesalamine 1.2 mg DR tablet	LIALDA (mesalamine) TABLET
PENTASA (mesalamine) – <i>Brand Required</i>	mesalamine ER 375 mg, 500 mg ER capsule
sulfasalazine DR tablet	mesalamine 400 mg DR capsule, 800 mg DR tablet
sulfasalazine tablet	

### Topical

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
hydrocortisone enema	budesonide rectal foam
mesalamine enema	CANASA (mesalamine) SUPPOSITORY
mesalamine rectal suppository	mesalamine enema kit
	ROWASA (mesalamine) ENEMA KIT
	SF ROWASA (mesalamine) ENEMA
	UCERIS (budesonide) RECTAL FOAM

#### Prior Authorization Criteria

##### Initial Criteria – Approval Duration: 12 months

- The member must have failed a 3-month trial of mesalamine, as evidenced by paid claims or pharmacy printouts.
- Mesalamine HD: See [Preferred Dosage Form](#) criteria

## Janus Kinase (JAK) Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
XELJANZ IR (tofacitinib) 5 mg, oral solution	RINVOQ ER (upadacitinib)
	XELJANZ IR (tofacitinib) 10 mg
	XELJANZ XR (tofacitinib)

#### Prior Authorization Criteria

##### Initial Criteria – Approval Duration: 12 months

- Xeljanz IR 10 mg, Xeljanz XR Only: See [Preferred Dosage Form](#) criteria
- Rinvoq ER Only:
  - The member must have failed a 3-month trial of a TNF inhibitor and a 30-day trial of Xeljanz, as evidenced by paid claims or pharmacy printouts.

## Sphingosine 1-Phosphate (S1P) Receptor Modulator

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	VELSIPITY (etrasimod)
	ZEPOSIA (ozanimod)

### Prior Authorization Criteria

#### Initial Criteria – Approval Duration: 12 months

- The member must have had a 3-month trial of a TNF inhibitor, and 30-day trials of Xeljanz and Rinvoq ER as evidenced by paid claims or pharmacy printouts.

## Wilson's Disease

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
CUPRIMINE (penicillamine) CAPSULE – Brand Required	CUVRIOR (trientine tetrahydrochloride)
DEPEN (penicillamine) TITRATAB – Brand Required	penicillamine capsule
trientine hydrochloride 250 mg	penicillamine tablet
	SYPRINE (trientine hydrochloride)
	trientine hydrochloride 500 mg

### Prior Authorization Criteria

#### Initial Criteria – Approval Duration: 12 months

- See [Preferred Dosage Form Criteria](#)

## Genetic and Rare Disease

### Amyloidosis

#### RNA – targeted therapies

##### TTR-specific small interfering RNA (siRNA)

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

##### Transhyretin-directed small interfering RNA (siRNA)

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

##### Antisense Oligonucleotide (ASO)

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
TEGSEDI (inotersen)	
WAINUA (eplontersen)	

### Prior Authorization Criteria

#### Initial Criteria – Approval Duration: 6 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a neurologist, geneticist, or specialist in the treatment of amyloidosis.
- The diagnosis must be confirmed by both of the following:
  - Genetic testing confirming a pathogenic TTR mutation (e.g., V30M)
  - Amyloid deposits via tissue biopsy
- Documentation of one of the following must be provided:
  - Baseline polyneuropathy disability (PND) score  $\leq$  IIIb
  - Baseline Coutinho staging system stage 1 or 2
  - Baseline Neuropathy Impairment Score [NIS] of 5–130
  - Karnofsky Performance Status score of  $\geq$ 60%
- The member has not had a liver transplant.
- The member has clinical signs and symptoms of the disease (e.g., peripheral neuropathy, numbness, altered pain and temperature sensation, decreased pinprick sensation)
- The member is not receiving any other TTR reducing agent (i.e., vutrisiran, patisiran, tafamidis, inotersen, eplontersen).

***Renewal Criteria – Approval Duration: 12 months***

- Documentation of a therapeutic response as evidenced by stabilization or improvement (e.g., improved neurologic impairment, motor function, quality of life, slowing of disease progression, etc.) from baseline in one of the following:
  - PND score  $\leq$  IIIb
  - Coutinho staging system stage 1 or 2
  - Baseline Neuropathy Impairment Score [NIS] of 5–130

Karnofsky Performance Status score of  $\geq$ 60% **TTR Stabilizers**

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
VYNDAQEL (tafamidis)	
VYNDAMAX (tafamidis)	

***Prior Authorization Criteria***

***Initial Criteria – Approval Duration: 12 months***

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a cardiologist, geneticist, or specialist in the treatment of amyloidosis.
- Documentation of confirmation of the diagnosis by both of the following must be provided:
  - genetic testing confirming a pathogenic TTR mutation (e.g., V30M)
  - amyloid deposits via tissue biopsy
- The member must have heart failure class I or II with at least 1 prior hospitalization for heart failure or with symptoms of volume overload or elevated intracardiac pressures (e.g., elevated jugular venous pressure, shortness of breath or signs of pulmonary congestion on x-ray or auscultation, peripheral edema) despite 6-months of adherent use of a diuretic.
- The member has an end-diastolic interventricular septal wall thickness of at least 12 mm.
- The member must not have any of the following:
  - NYHA class IV symptoms or severe aortic stenosis
  - Previous heart transplant or implanted cardiac mechanical assist device
  - Previous liver transplant
- Documentation of baseline 6MWT  $>$  100 meters must be submitted.
- The member is not receiving any other TTR reducing agent (i.e., vutrisiran, patisiran, tafamidis, inotersen)



Renewal Criteria – Approval Duration: 12 months

- Documentation of a therapeutic response as evidenced by stabilization or improvement from baseline in both of the following:
  - 6MWT > 100 meters
  - NYHA class

## Late Infantile Neuronal Ceroid Lipofuscinosis Type 2 (CLN2)

### CLINICAL PA REQUIRED

BRINEURA (cerliponase alfa) – *Medical Billing Only*

### Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- The member must be between 3 and 8 years of age.
- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a metabolic specialist, geneticist, or pediatric neurologist.
- Documentation of the diagnosis must be submitted, as evidenced by the following:
  - Molecular analysis that has detected two pathogenic variants/mutations in the TPP1/CLN2 gene.
  - An enzyme assay confirming deficiency of tripeptidyl peptidase 1 (TPP1)
- The member must not have ventriculoperitoneal shunts
- Baseline results of motor and language domains of the Hamburg CLN2 Clinical Rating Scale must be submitted and meet the following parameters:
  - Results must show a combined score of less than 6 in the motor and language domains.
  - Results must show a score of at least 1 in each of these domains.

Renewal Criteria – Approval Duration: 12 months

- The member must not have acute, unresolved localized infection on or around the device insertion site or suspected or confirmed CNS infection.
- The member maintains at a score of at least 1 in the motor domain on the Hamburg CLN2 Clinical Rating Scale
- The member has responded to therapy compared to pretreatment baseline with stability/lack of decline\* in motor function/milestones.

\* *Decline is defined as having an unreversed (sustained) 2-category decline or an unreversed score of 0 in the Motor domain of the CLN2 Clinical Rating Scale*

### References:

1. Ando Y, Coelho T, Berk JL, Cruz MW, Ericzon BG, Ikeda S, Lewis WD, Obici L, Planté-Bordeneuve V, Rapezzi C, Said G, Salvi F. Guideline of transthyretin-related hereditary amyloidosis for clinicians. Orphanet J Rare Dis. 2013 Feb 20;8:31. doi: 10.1186/1750-1172-8-31. PMID: 23425518; PMCID: PMC3584981.

## Fabry Disease

### Alpha-Galactosidase A Pharmacological Chaperone

### PREFERRED AGENTS (CLINICAL PA REQUIRED)

GALAFOLD (migalastat)



## Prior Authorization Criteria

### Initial Criteria – Approval Duration: 6 months

- The requested medication must be prescribed by, or in consult with, a metabolic specialist, geneticist, cardiologist, or specialist in Fabry disease.
- The member must be assigned male at birth.
- Baseline value for plasma or urinary globotriosylceramide (GL-3) levels  $\geq 5$  ng/mcL or GL-3 inclusions  $\geq 0.3$  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 m<sup>2</sup>)

### 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 arrhythmia of unknown etiology
  - Chronic kidney disease (CKD), multiple renal cysts, and/or proteinuria of unknown etiology

## Enzyme Replacement Therapy

<b>PREFERRED AGENTS (CLINICAL PA REQUIRED)</b>	<b>NON-PREFERRED AGENTS (PA REQUIRED)</b>
FABRAZYME (agalsidase beta) – Medical Billing Only	ELFABRIO (pegunigalsidase alfa) – Medical Billing Only

### Initial Criteria – Approval Duration: 6 months

- The requested medication must be prescribed by, or in consult with, a metabolic specialist, geneticist, cardiologist, or specialist in Fabry disease.
- The member will not be concurrently treated with Galafold (migalastat)
- The member must have a diagnosis of Fabry disease with the one of the following (as evidenced with submitted documentation):
  - In males assigned at birth:
    - Deficiency of less than 35% of mean normal alpha-galactosidase A ( $\alpha$ -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  $\alpha$ -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  $\geq 5$  ng/mcL or GL-3 inclusions  $\geq 0.3$  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 arrhythmia of unknown etiology
      - Chronic kidney disease (CKD), multiple renal cysts, and/or proteinuria of unknown etiology

#### *Non-Preferred Agent Criteria:*

- The member must have failed a trial of each of the preferred products, as evidenced by paid claims or pharmacy printouts
- Please provide explanation with the request why the preferred agent cannot be used (subject to clinical review)

#### Renewal Criteria – Approval Duration: 12 months

- The member must have a decreased Gb3 level or Cb3 inclusion per KIC level and experienced and maintained improvement in one of the following symptoms since starting treatment with requested product, as evidenced by medical documentation (e.g., chart notes) attached to the request (subject to clinical review):
  - Acroparesthesias (burning pain in the extremities)
  - Angiokeratomas (cutaneous vascular lesions)
  - Hypo- or anhidrosis (diminished perspiration)
  - Corneal and lenticular opacities
  - Left ventricular hypertrophy (LVH), hypertrophic cardiomyopathy, or arrhythmia of unknown etiology
  - Chronic kidney disease (CKD), multiple renal cysts, and/or proteinuria of unknown etiology

## Gaucher's Disease

### Enzyme Replacement Therapy

<b>PREFERRED AGENTS (CLINICAL PA REQUIRED)</b>	<b>NON-PREFERRED AGENTS (PA REQUIRED)</b>
ELELYSO (taliglucerase alfa) – <i>Medical Billing Only</i>	CEREZYME (imiglucerase) – <i>Medical Billing Only</i>
	VPRIV (velaglucerase alfa) – <i>Medical Billing Only</i>

#### *Prior Authorization Criteria*

#### Initial Criteria – Approval Duration: 6 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a geneticist, an endocrinologist, or a physician who specializes in the treatment of lysosomal storage disorders.
- The member must have a diagnosis of Gaucher disease Type I or Type III with the one of the following (as evidenced with submitted documentation):
  - Deficiency in beta-glucocerebrosidase enzyme activity in peripheral leukocytes
  - Genetic testing confirming biallelic pathogenic variants in the GBA1 gene
- The member must be experiencing one or more of the following (as evidenced with submitted documentation):
  - Anemia with hemoglobin less than or equal to the laboratory reported low for patient age and gender
  - Thrombocytopenia with platelet count less than 100,000/mm<sup>3</sup>
  - Bone disease (T-score below -1.0 [DXA], height SDS <-2.25 with decreased growth velocity, bone crisis)
  - Hepatomegaly (liver size 1.25 or more times normal)
  - Splenomegaly (spleen size five (5) or more times normal)

#### *Non-Preferred Agent Criteria:*

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

#### Renewal Criteria – Approval Duration: 12 months

- Documentation has been submitted that member has experienced a disease stability or beneficial response to therapy from baseline as shown by one or more of the following:
  - Reduction in liver volume to normal size or by 10%
  - Reduction in spleen volume by 15%
  - Increase in hemoglobin levels by 1 g/dL
  - Increase in platelet levels by 15%
  - Increased T-score [DXA] by 0.3, normalized growth velocity, or decrease in bone crisis

## Substrate Replacement Therapy

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ZAVESCA (miglustat) – <i>Brand Required</i>	miglustat
PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
CERDELGA (eliglustat)	

### Prior Authorization Criteria

#### Initial Criteria – Approval Duration: 12 months

- Cerdelga: See [Medications that cost over \\$3000/month](#) criteria

## Lysosomal Acid Lipase (LAL) deficiency

CLINICAL PA REQUIRED
KANUMA (sebelipase alfa) – <i>Medical Billing Only</i>

### Prior Authorization Criteria

#### Initial Criteria – Approval Duration: 6 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a specialist in the treatment of lysosomal acid lipase (LAL) such as a lipidologist, endocrinologist, cardiologist, or hepatologist.
- Documentation of the member’s diagnosis must be submitted, as evidenced by the following:
  - Genetic testing confirming 2 mutations in the LIPA gene
  - Deficiency of the LAL in peripheral blood leukocytes, fibroblasts, or dried blood spots

#### Renewal Criteria – Approval Duration: 12 months

- The member must have experienced and maintained clinical benefit since starting treatment with the requested medication, as evidenced by medical documentation (e.g., chart notes) attached to the request (subject to clinical review) including improvement in weight for age Z-scores for individuals with growth failure, improved LDL, HDL, AST, ALT and/or triglycerides.

## Alpha-Mannosidosis

CLINICAL PA REQUIRED
LAMZEDE (velmanase alfa-tycv) – <i>Medical Billing Only</i>

### Prior Authorization Criteria

#### Initial Criteria – Approval Duration: 12 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- Documentation of the member’s diagnosis must be submitted, as evidenced by one of the following:

- Deficiency of alpha-mannosidase activity in leukocytes or fibroblasts < 10% of normal activity
- Detection of biallelic pathogenic variants in the *MAN2B1* gene by molecular genetic testing
- The requested medication must be prescribed by, or in consult with, a specialist in lysosomal storage diseases
- Documentation of all of the following must be submitted:
  - Non-central nervous system manifestations (e.g., progressive motor function disturbances, physical disability, hearing and speech impairment, skeletal abnormalities, and immune deficiency)
  - Elevated level of serum oligosaccharide concentration, as defined by being above the upper limit of normal by the laboratory reference range
  - If 6 years of age or older, must be able to walk without support
  - Motor function as measured by one of the following:
    - 6-minute walk test (6-MWT) for 4 years of age and older
    - 2-minute walk test (2-MWT) for under 4 years of age
    - 3-minute stair climb test
    - Forced Vital Capacity (FVC) via Pulmonary Function Test

**Renewal Criteria – Approval Duration: 12 months**

- The member must have experienced meaningful clinical benefit since starting treatment with the requested medication, as evidenced in medical documentation (e.g., chart notes) attached to the request (subject to clinical review) by both of the following:
  - Reduction in serum oligosaccharide concentration
  - Stability or improvement in the one of the following scores and symptoms:
    - 6-MWT for 4 years of age and older
    - 2-MWT for under 4 years of age
    - 3-minute stair climb test
    - FVC via Pulmonary Function Test

## Mucopolysaccharidosis I (MPS I)

### CLINICAL PA REQUIRED

ALDURAZYME (Iaronidase) – *Medical Billing Only*

### *Prior Authorization Criteria*

**Initial Criteria – Approval Duration: 6 months**

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, an expert in lysosomal storage diseases.
- Documentation of the member’s diagnosis must be submitted, as evidenced by the following:
  - Genetic testing confirming biallelic pathogenic mutations in the IDUA gene
  - Deficiency in activity of the lysosomal enzyme α-L-iduronidase (IDUA) in fibroblast or leukocyte
- Documentation of the member’s current motor function must be submitted, as evidenced by scores from the following assessments:
  - 6-minute walk test (6MWT)
  - Forced Vital Capacity (FVC) via Pulmonary Function Test

**Renewal Criteria – Approval Duration: 12 months**

- The member must have experienced and maintained clinical benefit since starting treatment with the requested medication, as evidenced by medical documentation (e.g., chart notes) attached to the request (subject to clinical review) including improvement in the following scores and symptoms:
  - 6-minute walk test (6MWT)
  - Forced Vital Capacity (FVC) via Pulmonary Function Test

## Mucopolysaccharidosis II (MPS II) – Hunter Syndrome

### CLINICAL PA REQUIRED

ELAPRASE (idursulfase) – *Medical Billing Only*

#### *Prior Authorization Criteria*

##### Initial Criteria – Approval Duration: 6 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- Documentation of the member's diagnosis must be submitted, as evidenced by the following:
  - Deficiency in iduronate-2sulfatase (I2S) enzyme activity in white cells, fibroblasts, or plasma in the presence of normal activity of at least one other sulfatase
  - Genetic testing confirming pathogenic mutations in the IDS gene
- The requested medication must be prescribed by, or in consult with, an expert in lysosomal storage diseases.
- The member does not have severe cognitive or neurologic impairment (e.g., inability to swallow)
- Documentation of one of the following must be submitted:
  - The Forced Vital Capacity (FVC) via Pulmonary Function Test
  - Urinary glycosaminoglycan (uGAG) levels are elevated defined by laboratory reference range
  - 6-minute walk test (6MWT)
  - Hepatomegaly (liver size 1.25 or more times normal)
  - Splenomegaly (spleen size five (5) or more times normal)

##### Renewal Criteria – Approval Duration: 12 months

- Documentation must be submitted confirming improvement of one of the following:
  - The Forced Vital Capacity (FVC) via Pulmonary Function Test relative improvement of 10% over baseline
  - Urinary glycosaminoglycan (uGAG) levels normalization defined by laboratory reference range
  - 6-minute walk test (6MWT) increase
  - Reduction in liver volume to normal size or by 10%
  - Reduction in spleen volume by 15%

## Mucopolysaccharidosis IVA (MPS IVA) – Morquio A syndrome

### CLINICAL PA REQUIRED

VIMIZIM (elosulfase alfa) – *Medical Billing Only*

#### *Prior Authorization Criteria*

##### Initial Criteria – Approval Duration: 6 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- Documentation of the member's diagnosis must be submitted, as evidenced by the following:
  - Genetic testing confirming biallelic pathogenic mutations in the GALNS gene
  - Deficiency in activity of the n N-acetylgalactosamine 6-sulfatase (GALNS) enzyme
- The requested medication must be prescribed by, or in consult with, a geneticist, metabolic specialist, or specialist in mucopolysaccharidoses (MPS)
- The member is experiencing musculoskeletal signs and symptoms of MSP-IVA such as knee deformity, kyphosis, hip dysplasia, arthralgia, etc.
- Documentation of one of the following must be submitted:
  - Forced Vital Capacity (FVC) via Pulmonary Function Test
  - 6-minute walk test (6MWT)

- 3-minute stair climb test (3-MSCT)

Renewal Criteria – Approval Duration: 12 months

- The member must have experienced and maintained clinical benefit since starting treatment with the requested medication, as evidenced by medical documentation (e.g., chart notes) attached to the request (subject to clinical review) by one of the following scores:
  - Forced Vital Capacity (FVC) via Pulmonary Function Test
  - 6-minute walk test (6MWT)
  - 3-minute stair climb test (3-MSCT)
  - Reduced Urine Keratan Sulfate (KS) levels

## Mucopolysaccharidosis VI (MPS VI) – Maroteaux-Lamy syndrome

### CLINICAL PA REQUIRED

NAGLAZYME (galsulfase) – *Medical Billing Only*

### Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- Documentation of the member's diagnosis must be submitted, as evidenced by the following:
  - Deficiency of N-acetylgalactosamine 4-sulfatase (arylsulfatase B or ASB) enzyme activity of <10% of the lower limit of normal
  - Detection of pathogenic variants in the ARSB gene by molecular genetic testing
- The requested medication must be prescribed by, or in consult with, an expert in lysosomal storage diseases.
- Documentation of both of the following must be submitted:
  - Elevated level of urinary excretion of glycosaminoglycans (GAGs) such as chondroitin sulfate and dermatan sulfate, as defined by being above the upper limit of normal by the laboratory reference range
  - Motor function as measured by one of the following:
    - 6 or 12-minute walk test (6-MWT or 12-MWT)
    - 3-minute stair climb test
    - Forced Vital Capacity (FVC) via Pulmonary Function Test

Renewal Criteria – Approval Duration: 12 months

- The member must have experienced meaningful clinical benefit since starting treatment with the requested medication, as evidenced by medical documentation (e.g., chart notes) attached to the request (subject to clinical review) including improvement in the one of the following scores and symptoms:
  - Reduction in urinary excretion of glycosaminoglycans (GAGs)
  - Stability or improvement in 6 or 12-minute walk test (6-MWT or 12-MWT)
  - Stability or improvement in 3-minute stair climb test
  - Stability or improvement in Forced Vital Capacity (FVC) via Pulmonary Function Test

## Mucopolysaccharidosis VII (MPS VII) – Sly Syndrome

### CLINICAL PA REQUIRED

MEPSEVII (vestronidase alfa-vjbc) – *Medical Billing Only*

### Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)



- Documentation of the member’s diagnosis must be submitted, as evidenced by the following:
  - Deficiency of beta-glucuronidase enzyme
  - Detection of pathogenic variants in the GUSB gene by molecular genetic testing.
- The requested medication must be prescribed by, or in consult with, an expert in lysosomal storage diseases.
- One or more of the following documentations must be submitted:
  - Skeletal abnormalities
  - Elevated level of urinary excretion of glycosaminoglycans (GAGs) such as chondroitin sulfate and dermatan sulfate, as defined by being above the upper limit of normal by the laboratory reference range
  - Liver and/or spleen volume
  - 6-minute walk test (6MWT)
  - Motor function test (e.g., Bruininks-Oseretsky Test of Motor Proficiency (BOT-2))
  - Forced Vital Capacity (FVC) via Pulmonary Function Test

**Renewal Criteria – Approval Duration: 12 months**

- The member must have experienced meaningful clinical benefit since starting treatment with the requested medication, as evidenced by medical documentation (e.g., chart notes) attached to the request (subject to clinical review) including improvement in the one of the following scores and symptoms:
  - Stability or improvement in skeletal abnormalities shown on x-ray, short stature, macrocephaly
  - Reduction in urinary excretion of glycosaminoglycans (GAGs)
  - Reduction in liver and/or spleen volume
  - Stability or improvement in 6-minute walk test (6MWT)
  - Stability or improvement in Forced Vital Capacity (FVC) via Pulmonary Function Test

## Phenylketonuria

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

### *Underutilization*

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

### *Prior Authorization Criteria*

#### Prior Authorization Form – Phenylketonuria

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

- The member must have been compliant with a PHE restricted diet for past 6 months (documentation must be attached).
- The requested medication must be prescribed by, or in consult with, a geneticist or endocrinologist.
- Baseline PHE levels must meet one of the following:
  - For members of childbearing potential and children ≤ 12 years old: PHE levels must be above 360 µmoles/liter (6 mg/dL)
  - For members without childbearing potential, and children > 12 years old: PHE levels must be above 600 µmoles/liter 10 mg/dL)
- Sapropterin Only:
  - The member’s weight must be provided. Requested initial dose must be 10 mg/kg
  - The member must not have two null mutations in trans
- Palynziq Only: One of the following must be met:

- PHE levels must be attached documenting the member was unable to achieve a PHE level less than 600 µmoles/liter (10 mg/dL) despite a 3-month trial of 20 mg/kg dose of sapropterin with good compliance, as evidenced by paid claims or pharmacy printouts.
- The member is known to have two null mutations in trans

*Renewal Criteria:*

- For same or reduced dose from previous trial:  
*Approval Duration: 12 months* – if dose is the same or less than previous trial
  - PHE level must be between 60 and 600 µmoles per liter
  - Sapropterin Only: The member’s weight must be provided.
- For a dose increase from previous trial  
*Approval Duration: 4 months* – for a dose increase from previous trial
  - PHE level must be attached that were taken after previous trial (1 month for Kuvan, 4 months for Palynziq)
    - For members of childbearing potential and children ≤ 12 years old: PHE levels must be above 360 µmoles/liter (6mg/dL)
    - For members without childbearing potential, and children > 12 years old: PHE levels must be above 600 µmoles/liter 10mg/dL)
  - Sapropterin Only: The member’s weight must be provided.

## Pompe Disease

### CLINICAL PA REQUIRED

LUMIZYME (alglucosidase alpha) – *Medical Billing Only*

NEXVIAZYME (avalglucosidase alfa-ngpt) – *Medical Billing Only*

### *Prior Authorization Criteria*

#### Initial Criteria – Approval Duration: 6 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- Documentation of the member’s diagnosis must be submitted, as evidenced by the following:
  - Deficiency of acid alpha-glucosidase enzyme activity (2% to 40% partial deficiency of GAA non-classic infantile forms or late onset forms) of the lab specific normal mean value
  - Detection of pathogenic variants in the GAA gene by molecular genetic testing.
- The requested medication must be prescribed by, or in consult with, a cardiologist, neurologist or geneticist or specialist in Pompe disease.
- The member must not have permanent invasive ventilation.
- Documentation must be submitted of the member’s current motor function such as motor function, respiratory function, cardiac involvement (infantile onset) and scores from at least two of the following assessments:
  - 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

#### Renewal Criteria – Approval Duration: 12 months

- The member must have experienced and maintained clinical benefit since starting treatment with the requested medication, as evidenced by medical documentation (e.g., chart notes) attached to the request (subject to clinical review) including stabilization or improvement of the following:
  - Motor function, respiratory function, cardiac involvement (infantile onset)



- CHOP-INTEND, HINE, HFMSE, MFM-32, 6MWT, or RULM scores
- Forced Vital Capacity (FVC) via Pulmonary Function Test (ages 5 and older)

## Urea Cycle Agents

### Hyperammonemia

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
BUPHENYL (sodium phenylbutyrate) – <i>Brand Required</i>	sodium phenylbutyrate
PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
PHEBURANE (sodium phenylbutyrate)	OLPRUVA (sodium phenylbutyrate)
	RAVICTI (glycerol phenylbutyrate)

### N-acetylglutamate synthase (NAGS) deficiency

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
CARBAGLU (carglumic acid) – <i>Brand Required</i>	carglumic acid

#### Electronic Diagnosis Verification

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

#### Prior Authorization Criteria

##### Initial Criteria – Approval Duration: 12 months

- See [Medications that cost over \\$3000/month](#) criteria.

##### Non-Preferred Agents Criteria:

- See [Preferred Dosage Form](#) criteria.
- *Ravicti Only:* The member is unable to tolerate sodium phenylbutyrate due to sodium content or GI distress.

#### Therapeutic Duplication

- One strength of one medication is allowed at a time.

## Hematology/Oncology

### Anemia

#### Disease-Modifying Agents

PREFERRED AGENTS (CLINICAL PA REQUIRED)
REBLOZYL (luspatercept) – <i>Medical Billing Only</i>

##### Initial Criteria – Approval Duration: 6 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a hematologist or oncologist, or prescriber specializing in the treatment of beta thalassemia or myelodysplastic syndrome/myeloproliferative neoplasm.
- The member must have a diagnosis of anemia due to beta thalassemia or myelodysplastic syndrome/myeloproliferative neoplasm with ring sideroblasts.

- Documentation must be submitted of a pretreatment hemoglobin of less than 11 g/dL.
- Other causes of anemia (e.g., hemolysis, bleeding, recent major surgery, vitamin deficiency, etc.) have been ruled out.
- Member must not have any of the following:
  - Deep vein thrombosis or stroke within the past 24 weeks
  - Platelet count greater than 1000 x 10<sup>9</sup> per liter

*For anemia due to myelodysplastic syndrome/myeloproliferative neoplasm:*

- Documentation must be submitted that the member requires 2 or more RBC units over an 8-week period as evidenced by the following:
  - One of the following:
    - Ring sideroblasts greater than or equal to 15%
    - Ring sideroblasts greater than or equal to 5% and less than 15% with an SF3B1 mutation
  - One of the following:
    - Serum erythropoietin greater than 500 mU/mL
    - Serum erythropoietin less than or equal to 500 mU/mL with inadequate response after a 3-month trial with a combination of an ESA (e.g., epoetin alfa) and granulocyte-colony stimulating factor (G-CSF)
  - Member has very low to intermediate risk disease defined as one of the following:
    - Revised International Prognostic Scoring System (IPSS-R); very low, low, or intermediate (Score of 0 to 4.5);
    - IPSS: low/intermediate-1 (Score 0 to 1)
    - WHO-Based Prognostic Scoring System (WPSS): WPSS: very low, low, or intermediate (Score 0 to 2)

*For anemia due to beta thalassemia:*

- No prior gene therapy
- No prior HSCT
- Documentation must be submitted confirming the following:
  - The member has required at least 6 red blood cell (RBC) transfusions in the previous 24 weeks.
  - The member has not had a transfusion-free period for ≥ 35 days during the most recent 24 weeks.

Renewal Criteria – Approval Duration: 12 months

- The member must have experienced stabilization, slowing of disease progression, or improvement of the condition since starting treatment with the requested medication, as evidenced by medical documentation (e.g., chart notes) attached to the request (subject to clinical review) including:
  - Reduction in transfusion requirements from pretreatment baseline achieving one of the following:
    - At least 2 units packed red blood cells
    - By one-half
    - Complete transfusions independence
- The member continues to have pretreatment hemoglobin of less than 11 g/dL.
- Dose will be increased to 1.25 mg/kg daily.

## Cell-based Gene Therapy

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
CASGEVY (exagamglogene autotemcel) – <i>Medical Billing Only</i>	ZYNTEGLO (betibeglogene autotemcel) – <i>Medical Billing Only</i>

Initial Criteria – Approval Duration: 12 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)

- The requested medication must be prescribed by, or in consult with, a hematologist or prescriber specializing in the treatment of beta thalassemia
- The member must have a transfusion-dependent beta thalassemia requiring one of the following:
  - At least 100 mL/kg/year of packed red blood cells (pRBCs) in the preceding 2 years
  - At least 8 transfusions of pRBCs per year in the preceding 2 years
- Other causes of anemia (e.g., hemolysis, bleeding, recent major surgery, vitamin deficiency, etc.) have been ruled out.
- Member must not have any of the following:
  - Prior receipt of gene therapy
  - Prior HSCT
  - Severely elevated iron in the heart as evidenced by any of the following:
    - Cardiac T2\* < 10 msec by MRI
    - LVEF < 45%
  - Advanced liver disease as evidenced by any of the following:
    - AST or ALT > 3 times the upper limit of normal
    - Direct bilirubin value > 2.5 times the upper limit of normal
    - Liver iron content ≥ 15 mg/g (per MRI) with liver biopsy, VCTE, ELF, or MRE demonstrating bridging fibrosis or cirrhosis

## Chelating Agents

### Iron Chelators

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
deferasirox tablet for suspension	EXJADE (deferasirox tablet for suspension)
deferasirox tablet	deferasirox sprinkle
deferoxamine mesylate vial – <i>Medical Billing Only</i>	DESFERAL (deferoxamine) MESYLATE VIAL – <i>Medical Billing Only</i>
	FERRIPROX (deferiprone)
	JADENU (deferasirox) SPRINKLE
	JADENU (deferasirox) TABLET

### Prior Authorization Criteria

#### Initial Criteria – Approval Duration: 12 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The member must have failed a trial duration of 30 days (or less if duration is FDA approved) of each preferred agent of a unique ingredient, as evidenced by paid claims or pharmacy printouts.
- Clinical justification must be provided explaining why the member is unable to use the preferred agents (subject to clinical review).

## Cold Agglutinin Disease (CAD)

### Anti-B-cell Therapy

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
RIABNI (rituximab-arrx) – <i>Medical Billing Only</i>	RITUXAN (rituximab) – <i>Medical Billing Only</i>
RUXIENCE (rituximab-pvvr) – <i>Medical Billing Only</i>	
TRUXIMA (rituximab-abbs) – <i>Medical Billing Only</i>	

## Anti-Complement Therapy

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	ENJAYMO (sutimlimab-jome) – <i>Medical Billing Only</i>

### Initial Criteria – Approval Duration: 6 months

- The requested medication must be prescribed by, or in consult with, a hematologist or specialist in cold agglutinin disease (CAD)
- The member must have all of the following:
  - Evidence of chronic hemolysis (e.g., high lactated dehydrogenase [LDH], low haptoglobin, high reticulocyte count)
  - Direct antiglobin (Coombs) test is positive for C3d
  - Cold agglutinin titer  $\geq 64$  at 4°C
- Cold agglutinin syndrome secondary to other factors has been ruled out (e.g., infection, rheumatologic disease, systemic lupus erythematosus, or overt hematologic malignancy)
- The member has a baseline hemoglobin level  $\leq 10$  g/dL
- The member has a baseline bilirubin level above normal reference range of the reporting laboratory
- The member has one or more of the following symptoms:
  - Symptomatic anemia
  - Acrocyanosis
  - Raynaud’s phenomenon
  - Hemoglobinuria
  - Disabling circulatory symptoms
  - Major adverse vascular event
- The member must have been unresponsive to previous rituximab-based therapy or one of the following must be documented:
  - Member has a medical reason why rituximab-based therapy is not appropriate or is contraindicated.
  - Member has severe anemia or acute exacerbations of hemolysis and needs a bridge therapy awaiting the effects of a rituximab-based therapy.
- Rituxan Only: See [Biosimilar Agents](#) Criteria

### Renewal Criteria – Approval Duration: 12 months

- Documentation must be submitted that the member has had a beneficial response to therapy from baseline as shown by one or more of the following:
  - Decrease in transfusions from baseline
  - Increase in hemoglobin (Hgb) by  $\geq 2$  g/dL from baseline or Hgb level  $\geq 12$  g/dL
  - Normalization of bilirubin levels to less than 1.2 mg/dL
- Therapy continues to be necessary due to ongoing cold agglutinin production and inability to use rituximab.

## Cytokine Release Syndrome

### Interleukin (IL) -6 Receptor Inhibitors

#### *Tocilizumab*

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
TYENNE (tocilizumab-aazg) AUTOINJECTOR, SYRINGE	ACTEMRA (tocilizumab) ACTPEN, SYRINGE
TYENNE (tocilizumab-aazg) VIAL – <i>Medical Billing Only</i>	ACTEMRA (tocilizumab) VIAL – <i>Medical Billing Only</i>
	TOFIDENCE (tocilizumab-aazg) VIAL – <i>Medical Billing Only</i>

## Prior Authorization Criteria

### Initial Criteria – Approval Duration: 12 months

- See [Medications that cost over \\$3000/month](#) criteria
- Non-preferred agents: See [biosimilar agents](#) criteria

## Hemophagocytic Lymphohistiocytosis (HLH)

### PREFERRED AGENTS (CLINICAL PA REQUIRED)

GAMIFANT (emapalumab-lzsg) – Medical Billing Only

### Initial Criteria – Approval Duration: 3 months or up to the hematopoietic stem cell transplantation (HSCT) date

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a hematologist, oncologist, immunologist, or transplant specialist.
- The member has refractory, recurrent or progressive disease or intolerance with conventional HLH therapy (i.e., etoposide + dexamethasone, cyclosporine A, or Anti-thymocyte globulin)
- The member must be a candidate for stem cell transplant.
- Documentation must be submitted confirming the diagnosis, as evidenced by the following:
  - Confirmation of a gene mutation known to cause primary HLH (e.g., PRF1, UNC13D, STX11 RAB27A, STXBP2)
  - Confirmation of 5 of the following clinical characteristics:
    - Fever  $\geq 101.3^{\circ}\text{F}$  for over 7 days
    - Splenomegaly
    - Two of the following cytopenias in the peripheral blood:
      - ❖ Hemoglobin  $< 9$  g/dL (or  $< 10$  g/dL in infants less than 4 weeks of age)
      - ❖ Platelet count  $< 100,000/\text{microL}$
      - ❖ ANC  $< 1000/\text{microL}$
    - One of the following:
      - ❖ Hypertriglyceridemia defined as fasting triglycerides  $\geq 265$  mg/dL (2 mmol/L)
      - ❖ Hypofibrinogenemia defined as fibrinogen  $\leq 1.5$  g/L
    - Hemophagocytosis in bone marrow or spleen or lymph nodes with no evidence of malignancy
    - Low or absent natural killer cell activity
    - Ferritin  $\geq 500$  mg/L
    - Soluble CD25 (i.e., soluble IL-2 receptor)  $\geq 2,400$  U/mL
- The requested medication must be administered with dexamethasone as part of the induction or maintenance phase of stem cell transplant, which is to be discontinued at the initiation of conditioning for stem cell transplant.

### Category Criteria (Renewal): Approval Duration: 3 months or up to the HSCT date

- At least 3 HLH abnormalities must be improved by at least 50% from baseline.

## Hemophilia

### Clotting Factor Products

## Hemophilia A Prophylaxis

### Factor VIII – Non-Extended Half Life

#### Plasma Derived

### PREFERRED AGENTS (CLINICAL PA REQUIRED)

### NON-PREFERRED AGENTS (PA REQUIRED)

HEMOFIL M (factor VIII plasma derived; mAb-purified)	
KOATE (factor VIII plasma derived, chromatography purified)	

*First Generation – Recombinant*

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	RECOMBINATE (factor VIII recombinant)

*Second Generation – Recombinant*

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
KOGENATE FS (factor VIII recombinant)	

*Third Generation – Recombinant*

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
NOVOEIGHT (factor VIII recombinant)	ADVATE (factor VIII recombinant)
KOVALTRY (factor VIII recombinant)	
XYNTHA (factor VIII recombinant)	
XYNTHA SOLOFUSE (factor VIII recombinant)	

*Fourth Generation – Recombinant*

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AFSTYLA (factor VIII recombinant, single chain)	
NUWIQ (factor VIII recombinant)	

**Factor VIII Extended Half Life**

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ADYNOVATE (factor VIII recombinant, PEGylated)	ELOCTATE (factor VIII recombinant, Fc fusion protein)
ALTUVIIIO (antihemophilic factor (recombinant), Fc-VWF-XTEN fusion protein-ehtl)	ESPEROCT (factor VIII recombinant, glycoPEGylated – exei)
JIVI (factor VIII recombinant, pegylated-aucl)	

**Recombinant humanized bispecific monoclonal antibody**

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

**Factor VII deficiency or Hemophilia A and B with Inhibitors**

*Factor VIIa*

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
NOVOSEVEN RT (coagulation Factor VIIa recombinant)	
SEVENFACT (coagulation Factor VIIa recombinant)	

*B domain-deleted porcine – Recombinant*

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
OBIZUR (recombinant, B domain-deleted porcine (pig) factor VIII)	

## Hemophilia B Prophylaxis

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### Factor IX – Non-Extended Half Life

#### *Plasma Derived*

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ALPHANINE SD (factor IX, plasma-derived)	
MONONINE (factor IX, plasma-derived mAb purified)	

#### *Recombinant*

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
BENEFIX (factor IX recombinant)	
IXINITY (factor IX recombinant)	
RIXUBIS (factor IX recombinant)	

### Factor IX – Extended Half Life

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ALPROLIX (factor IX recombinant, Fc fusion)	
IDELVION (factor IX recombinant, albumin fusion)	
REBINYN (factor IX recombinant, glycol-PEGylated)	

### Prothrombin Complex Concentrates

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
FEIBA NF (Anti-Inhibitor coagulant complex)	
KCENTRA (hum prothrombin cplx(PCC)4fact)	
PROFILNINE (factor IX cplx(pcc)no4,3factor)	

## Von Willebrand disease

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### Factor VIII/vWF

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ALPHANATE (antihemophilic factor/Von Willebrand Factor Complex (Human))	
HUMATE-P (factor VIII/von Willebrand Factor (human))	
WILATE (factor VIII/von Willebrand Factor (human))	

### Von Willebrand Factor

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
VONVENDI (recombinant human vWF)	

## Factor X Deficiency

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### Factor X – Plasma Derived

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
COAGADEX (coagulation factor X (human))	



## Factor XIII Deficiency

### Factor XIII – Plasma Derived

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
CORIFACT (factor XIII concentrate (human))	

### Factor XIII A – Subunit, Recombinant

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
TRETTEN (Factor XIII A-Subunit, recombinant)	

#### *Prior Authorization Criteria*

##### Initial Criteria – Approval Duration: 12 months

- The date of the member's last appointment with a Hemophilia Treatment Center must be within the past year.
- The contact information for Hemophilia Treatment Center must be provided.

##### *Non-Preferred Agents Criteria:*

- Clinical justification must be provided explaining why the member is unable to use a preferred agent (subject to clinical review).
- The member may qualify for non-preferred product if they are stable on current therapy (have had a paid claim for requested therapy in the past 45 days)

## Gene Therapy

PREFERRED AGENTS (CLINICAL PA REQUIRED)
BEQVEZ (fidanacogene elaparvovec-dzkt) – <i>Medical Benefit Only</i>
HEMGENIX (etranacogene dezaparvovec) – <i>Medical Benefit Only</i>

#### *Prior Authorization Criteria*

##### Initial Criteria – Approval Duration: 12 months

- The Medicaid Member must meet FDA-approved label for use
- The member has completed Factor IX inhibitor testing demonstrating the absence of a Factor IX inhibitor
- The member has completed liver health assessment including all of the following:
  - Enzyme testing [alanine aminotransferase (ALT), aspartate aminotransferase (AST), alkaline phosphatase (ALP) and total bilirubin
  - Hepatic ultrasound and elastography
  - In case of patients with either radiological liver abnormalities or sustained liver enzyme elevations, a consulting hepatologist has assessed that the member is eligible to receive the gene therapy
- Beqvez Only:
  - The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
  - The requested medication must be prescribed by, or in consult with, a hematologist at a dose of  $5 \times 10^{11}$  vector genomes per kg (vg/kg) of body weight.
  - The date of the member's last appointment with a Hemophilia Treatment Center must be within the past year.
  - The contact information for Hemophilia Treatment Center must be provided.
  - The member was assigned male at birth.



- The member must currently be treated with routine Factor IX prophylaxis therapy for at least 12 months.
- The member must have had a life-threatening hemorrhage, or have repeated, serious spontaneous bleeding episodes.
- The member has had HIV testing that confirms that member does not have a CD4+ cell count <200 mm<sup>3</sup> or viral load ≥20 copies/mL
- Clinical justification must be provided why Hemgenix cannot be used (subject to clinical review)

## Hematopoietic, Colony Stimulating Factors

### Filgrastim

#### Medical Billing

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
GRANIX (TBO-filgrastim) – <i>Medical Billing Only</i>	NEUPOGEN (filgrastim) – <i>Medical Billing Only</i>
NIVESTYM (filgrastim-aafi) – <i>Medical Billing Only</i>	RELEUKO (filgrastim-ayow) – <i>Medical Billing Only</i>
ZARXIO (filgrastim-sndz) – <i>Medical Billing Only</i>	

#### Pharmacy Billing

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
NEUPOGEN (filgrastim)	GRANIX (TBO-filgrastim)
RELEUKO (filgrastim-ayow)	NIVESTYM (filgrastim-aafi)
	ZARXIO (filgrastim-sndz)

### Pegfilgrastim

#### Medical Billing

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
NEULASTA (pegfilgrastim) – <i>Medical Billing Only</i>	FULPHILA (pegfilgrastim-jmdb) – <i>Medical Billing Only</i>
NEULASTA ONPRO (pegfilgrastim) – <i>Medical Billing Only</i>	FYLNETRA (pegfilgrastim -pbbk) – <i>Medical Billing Only</i>
NYVEPRIA (pegfilgrastim–apgf) – <i>Medical Billing Only</i>	STIMUFEND (pegfilgrastim-fpgk) – <i>Medical Billing Only</i>
UDENYCA ONBODY (pegfligrastim-cbqv) – <i>Medical Billing Only</i>	UDENYCA (pegfligrastim-cbqv) – <i>Medical Billing Only</i>
	ZIEXTENZO (pegfilgrastim-bmez) – <i>Medical Billing Only</i>
Pharmacy Billing PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
FULPHILA (pegfilgrastim-jmdb)	NEULASTA (pegfilgrastim)
FYLNETRA (pegfilgrastim -pbbk)	NYVEPRIA (pegfilgrastim–apgf)
NEULASTA ONPRO (pegfilgrastim)	STIMUFEND (pegfilgrastim-fpgk)
UDENYCA ONBODY (pegfligrastim-cbqv)	UDENYCA (pegfligrastim-cbqv)
	ZIEXTENZO (pegfilgrastim-bmez)

### Sargramostim

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
LEUKINE (sargramostim)	

LEUKINE (sargramostim) – <i>Medical Billing Only</i>	
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## Eflapegrastim-xnst

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	ROLVEDON (eflapegrastim-xnst)
	ROLVEDON (eflapegrastim-xnst) – <i>Medical Billing Only</i>

### Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- See [Preferred Dosage Form](#) criteria.

## Nausea/Vomiting

### Chemo-Induced

## NK1 Receptor Antagonists

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
aprepitant tripack	AKYNZEO (netupitant/palonosetron) CAPSULE
EMEND (aprepitant) SUSPENSION	aprepitant capsules
	EMEND (aprepitant) 125 MG-80 MG CAPSULE TRIPACK
	EMEND (aprepitant) CAPSULES

## 5-HT3 Receptor Antagonists

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
granisetron tablet	AKYNZEO (netupitant/palonosetron) CAPSULE
granisetron vial – <i>Medical Billing Only</i>	SANCUSO (granisetron) PATCH
SUSTOL (granisetron) SYRINGE – <i>Medical Billing Only</i>	ZOFRAN (ondansetron)

## Cannabinoids

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
dronabinol capsule	MARINOL (dronabinol) CAPSULE

### Electronic Diagnosis Verification

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

### Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months or until last day of chemotherapy

- The requested medication must be prescribed by, or in consult with, an oncologist.
- The member must be receiving a moderately or highly emetogenic chemotherapy.
- The final date of chemotherapy treatment must be provided with the request.

- The member must have failed a 3-day trial of each preferred product(s) in the same class within the last 6 months, as evidenced by paid claims or pharmacy printouts.
- The member must not have failed preferred chemical entity with same active ingredient as requested product due to side effects.

## Paroxysmal Nocturnal Hemoglobinuria (PNH)

### C5 inhibitors

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ULTOMIRIS (ravulizumab)	PIASKY (crovalimab-akkz) – <i>Medical Billing Only</i>
ULTOMIRIS (ravulizumab) – <i>Medical Billing Only</i>	SOLIRIS (eculizumab) – <i>Medical Billing Only</i>

### C3 Inhibitors

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

### Factor B Inhibitors

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

### Factor D Inhibitors

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

### *Prior Authorization Criteria*

#### [Prior Authorization Form – Paroxysmal Nocturnal Hemoglobinuria](#)

#### *Initial Criteria – Approval Duration: 6 months*

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

#### *Non-Preferred Agent Criteria:*

#### *Fabhalta Only:*

- The member must have failed a 6-month trial with Empaveli, as evidenced by paid claims or printouts, with one of the following criteria being met (A or B):
  - The member has had at least 1 transfusion in the past 6 months
  - The member has symptoms of PNH (e.g., abdominal pain, anemia, shortness of breath, hemolysis, organ dysfunction, debilitating fatigue) and one of the following:
    - granulocyte PNH clone size > 10%

- hemoglobin < 10 g/dL
- LDH level of 1.5 times the upper limit of normal (must include at least 2 different reagents tested on at least 2 cell lineages)

**Voydeya Only:**

- The member must have failed a 6-month trial with Ultomiris, with at least one transfusion, persistent anemia (Hb < 9.5 g/dL) and absolute reticulocyte count  $\geq 120 \times 10^9 /L$ , as evidenced by paid claims or printouts.

**Piasky and Soliris Only:**

- The member must have failed a 6-month trial with Ultomiris with Voydeya, as evidenced by paid claims or printouts, with at least one transfusion, persistent anemia (Hb < 9.5 g/dL) and absolute reticulocyte count  $\geq 120 \times 10^9 /L$ , as evidenced by paid claims or printouts.

**Renewal Criteria – Approval Duration: 12 months**

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

***Non-Preferred Agent Criteria:***

**Fabhalta Only:**

- The member must have experienced one of the clinical benefit metrics defined in the renewal criteria that was not met with Empaveli.

**Voydeya Only:**

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

**Piasky and Soliris Only:**

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

**References:**

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

**Plasminogen Deficiency Type 1 (Hypoplasminogenemia)**

**CLINICAL PA REQUIRED**

RYPLAZIM (plasminogen, human-tvmh) – *Medical Billing Only*

***Prior Authorization Criteria***

**Initial Criteria – Approval Duration: 3 months**

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a hematologist or specialist in treated condition

- Documentation of the diagnosis must be submitted, as evidenced by the following:
  - Baseline plasminogen activity level  $\leq 45\%$  (If the patient is receiving plasminogen supplementation with fresh frozen plasma, allow for a 7-day washout period before obtaining baseline plasminogen activity level.)
  - Documented history of lesions (e.g., ligneous conjunctivitis, ligneous gingivitis, occlusive hydrocephalus, abnormal wound healing)
  - Genetic testing to confirm biallelic pathogenic *PLG* mutation

**Renewal Criteria – Approval Duration: 12 months, a one-time 6-month approval for dose adjustment allowed for members not meeting renewal criteria upon request**

- The member must have experienced meaningful clinical benefit since starting treatment with the requested medication, as evidenced by medical documentation (e.g., chart notes) attached to the request (subject to clinical review) including the following:
  - The member has demonstrated a 50% resolution of lesions, with no active or recurrent lesions.
  - Trough plasminogen activity levels are  $>10\%$  above baseline.

## Sickle Cell Disease

### Disease-Modifying Agents

#### First Line Agents

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
DROXIA (hydroxyurea) capsule	HYDREA (hydroxyurea) CAPSULE
hydroxyurea capsule	SIKLOS (hydroxyurea) tablet

#### Second Line Agents

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ENDARI (glutamine) – <i>Brand Required</i>	+ADAKVEO (crizanlizumab-tmca) – <i>Medical Billing Only</i>
	L-glutamine

+ Based on results of the STAND clinical trial, the efficacy of Adakveo in the prevention of vaso-occlusive crisis (VOC) is unclear.

#### Prior Authorization Criteria

**Initial Criteria – Approval Duration: 12 months**

- The requested medication must be prescribed by, or in consult with, a hematologist, oncologist, or immunology specialist.
- The member has experienced at least one sickle cell-related VOC within past 12 months while adherent with hydroxyurea (documentation required) at the maximum (35 mg/kg/day) or maximally tolerated dose (mild myelosuppression is expected), as evidenced by paid claims or pharmacy printouts.
- Adakveo Only:
  - The member must have had a 30-day trial of a Endari, as evidenced by paid claims or pharmacy printouts.
- Siklos Only:
  - Baseline hemoglobin (Hb)  $\leq 10.5$  g/dL
  - See [Preferred Dosage Form Criteria](#)

**Renewal Criteria – Approval Duration: 12 months**

- Adakveo Only:

- The member must have experienced and/or maintained clinical benefit since starting treatment with the requested product, as evidenced by medical documentation (e.g., chart notes) attached to the request (subject to clinical review) by the reduction in sickle cell-related VOCs
- All Other Products:
  - The member must have experienced and/or maintained clinical benefit since starting treatment with the requested product, as evidenced by medical documentation (e.g., chart notes) attached to the request (subject to clinical review) by one of the following:
    - Increase in hemoglobin (Hb) by  $\geq 1$  g/dL from baseline
    - Decrease in indirect bilirubin from baseline
    - Decrease in percent reticulocyte count from baseline
    - Reduction in sickle cell-related vaso-occlusive crisis

## Cell-based Gene Therapy

### PREFERRED AGENTS (CLINICAL PA REQUIRED)

CASGEVY (exagamglogene autotemcel) – *Medical Billing Only*

LYFGENIA (lovotibeglogene autotemcel) – *Medical Billing Only*

#### Initial Criteria – Approval Duration: 12 months

- The member is  $\geq 12$  and  $\leq 50$  years of age
- The member has a diagnosis of sickle cell disease (SCD), with either  $\beta S/\beta S$  or  $\beta S/\beta 0$  or  $\beta S/\beta +$  genotype
- The member has experienced at least four (4) sickle cell-related VOCs or priapism within past 24 months that required pain medications or RBC transfusion at a medical facility while on hydroxyurea at the maximum (35 mg/kg/day) or maximally tolerated dose (mild myelosuppression is expected), as evidenced by paid claims or pharmacy printouts.
- The member does not have human immunodeficiency virus type 1 or 2 (HIV-1 and HIV-2), hepatitis B virus (HBV), or hepatitis C (HCV)
- The member does not have inadequate bone marrow function, as defined by an absolute neutrophil count of  $< 1000/\mu\text{L}$  ( $< 500/\mu\text{L}$  for members on hydroxyurea treatment) or a platelet count  $< 100,000/\mu\text{L}$
- The member must not be a recipient of a previous allogeneic transplant or gene therapy
- The member must not have a matched allogeneic transplant donor.

#### Lyfgenia Only:

- The member must not have more than two  $\alpha$ -globin gene deletions ( $-\alpha 3.7/-\alpha 3.7$ )

## Thrombocytopenia

### Immune Thrombocytopenic Purpura (ITP)

#### PREFERRED AGENTS (CLINICAL PA REQUIRED)

NPLATE (romiplostim)

PROMACTA (eltrombopag)

PROMACTA (eltrombopag) POWDER PACK

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

ALVAIZ (eltrombopag choline)

DOPTELET (avatrombopag)

TAVALISSE (fostamatinib)

#### Prior Authorization Criteria

#### Initial Criteria – Approval Duration: 4 months

- The member has diagnosis of immune thrombocytopenic purpura (ITP) lasting  $>3$  months.
- Documentation of platelet count of less than  $30 \times 10^9/\text{L}$
- The member must have experienced an inadequate response after one of the following (A, B or C):

- A. The member must have failed a trial of appropriate duration of a corticosteroid or immunoglobulins, as evidenced by paid claims or pharmacy printouts.
- B. Rituximab
- C. The member must have undergone a splenectomy.

*Non-Preferred Agents Criteria:*

- The member must have failed trials with eltrombopag (at the recommended dose and duration) with each preferred agent, as evidenced by paid claims or pharmacy printouts.

Renewal Criteria – Approval Duration: 12 months

- Platelet counts must have achieved greater than or equal to  $50 \times 10^9/L$  in response to therapy (supported by documentation)

**References:**

1. Neunert, Cindy, et al. “American Society of Hematology 2019 guidelines for immune thrombocytopenia.” *Blood advances* 3.23 (2019): 3829-3866.

## Chronic Liver Disease-Associated Thrombocytopenia

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
DOPTELET (avatrombopag)	MULPLETA (lusutrombopag)

*Prior Authorization Criteria*

Initial Criteria – Approval Duration: The 2 weeks prior to procedure

- The member must have platelet count of less than  $50 \times 10^9/L$
- The member must be scheduled to undergo a procedure that puts the member at risk of bleeding (documentation must include name and scheduled date of procedure)
- Documentation must include the date therapy will be initiated and discontinued:
  - Doptelet: Member must undergo procedure 5-8 days after last dose.
  - Mulpleta: Member must undergo procedure 2-8 days after last dose.

*Non-Preferred Agents Criteria:*

- The member must have failed trials with the preferred agent (at the recommended dose and duration) with each preferred agent, as evidenced by paid claims or pharmacy printouts.

## Chronic Hepatitis C Infection-Associated Thrombocytopenia

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
PROMACTA (eltrombopag)	ALVAIZ (eltrombopag choline)
PROMACTA (eltrombopag) POWDER PACK	

*Prior Authorization Criteria*

Initial Criteria – Approval Duration: 4 months

- The member is unable to receive direct acting antivirals for hepatitis C.
- The member’s degree of thrombocytopenia must prevent initiation or continuation of interferon-based therapy.

Renewal Criteria – Approval Duration: 12 months

- Platelet counts must have achieved greater than or equal to  $50 \times 10^9/L$  in response to therapy (supported by documentation)
- The member is currently receiving interferon-based therapy.



## Aplastic Anemia

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
PROMACTA (eltrombopag)	ALVAIZ (eltrombopag choline)
PROMACTA (eltrombopag) POWDER PACK	

### *Prior Authorization Criteria*

#### Initial Criteria – Approval Duration: 4 months

- The member must have platelet count of less than  $30 \times 10^9/L$
- The member must have failed therapy or be receiving concurrent therapy with immunosuppressive therapy (e.g., corticosteroid, Atgam, cyclosporine)

#### Renewal Criteria – Approval Duration: 12 months

- Platelet counts must have achieved greater than or equal to  $50 \times 10^9/L$  in response to therapy (supported by documentation)

## Hepatology

### Metabolic Dysfunction-Associated Steatohepatitis (MASH)

PREFERRED AGENTS (CLINICAL PA REQUIRED)
REZDIFFRA (resmetirom)

#### Initial Criteria - Approval Duration: 12 months

- The requested medication must be prescribed by, or in consult with, an endocrinologist, gastroenterologist or hepatologist.
- The member has moderate to severe fibrosis (F2 or F3) as determined by one of the following (1-5):
  1. Biopsy
  2. Vibration-controlled transient elastography (VCTE; e.g. Fibroscan)
  3. Enhanced Liver Fibrosis (ELF)
  4. Magnetic Resonance Imaging Proton Density Fat Fraction (MRI-PDFF).
  5. Magnetic resonance elastography (MRE)
- If the member has a history of alcohol use, one of the following must be met (1, 2 or 3):
  1. The member has a carbohydrate-deficient transferrin (CDT) level  $< 3\%$  within the past 3 months.
  2. The member has a phosphatidylethanol (PEth) level  $< 20$  ng/mL.
  3. The member has submitted two negative alcohol tests with the most recent alcohol test within the past 3 months.
- The member must not have a concomitant terminal diagnosis where life expectancy is less than 1 year.

#### Renewal Criteria – Approval Duration: 12 months

- A. The member must have experienced stabilization or improvement of fibrosis and steatohepatitis, as determined by one of the following (1-5):
1. Biopsy
  2. Vibration-controlled transient elastography (VCTE; e.g. Fibroscan)
  3. Enhanced Liver Fibrosis (ELF)
  4. Magnetic Resonance Imaging Proton Density Fat Fraction (MRI-PDFF)
  5. Magnetic resonance elastography (MRE)



# Infectious Disease

## Anti-infectives – Resistance Prevention

### Antifungals – Aspergillus and Candidiasis Infections

#### Solid Dosage Form

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

#### Non-Solid Dosage Forms

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

### Community-Acquired Pneumonia

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

### Cytomegalovirus infection

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

### Methicillin-Resistant *Staphylococcus aureus* (MRSA):

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
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clindamycin	BAXDELA (delafloxacin)
doxycycline	NUZYRA (omadacycline)
linezolid	SIVEXTRO (tedizolid)
minocycline	
trimethoprim-sulfamethoxazole	

### *Helicobacter pylori*

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
lansoprazole/amoxicillin/clarithromycin	bismuth subcitrate potassium/metronidazole/tetracycline
PYLERA (bismuth subcitrate potassium/metronidazole/tetracycline) – <i>Brand Required</i>	OMECLAMOX-PAK (omeprazole/clarithromycin/amoxicillin)
	TALICIA (omeprazole/amoxicillin/rifabutin)
	VOQUEZNA DUAL PAK (vonoprazan/amoxicillin)
	VOQUEZNA TRIPLE PAK (vonoprazan/amoxicillin/clarithromycin)

### *Tuberculosis*

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

### *Prior Authorization Criteria*

#### Initial Criteria – Approval Duration: 5 days or as supported in compendia for indication

- The requested medication must be prescribed by, or in consult with, an infection disease specialist, an antibiotic stewardship program, or protocol.
- Diagnosis must be proven to be caused by a susceptible microorganism by culture and susceptibility testing
  - For Voquezna Dual or Triple Pak – member must have a clarithromycin or amoxicillin resistant strain of *H. Pylori*)
- One of the following criteria must be met (A or B):
  - A. The member is continuing treatment upon discharge from an acute care facility.
  - B. Clinical justification must be provided explaining why the preferred antibiotics are not an option due to susceptibility, previous failed trials, or other contraindications (subject to clinical review)

#### *Tuberculosis Only:*

6. Isoniazid: The ND Division of Disease Control Tuberculosis Prevention and Control program provides isoniazid for no cost through the UND Center for Family Medicine Pharmacy. Please contact 701-328-2378 to obtain supply.

#### Renewal Criteria – Approval Duration: 5 days

- It is medically necessary to continue treatment course after re-evaluation of the member's condition.
- The total requested duration of use must not be greater than manufacturer labeling or treatment guideline recommendations (whichever is greater).

## Human Immunodeficiency Virus (HIV)

### Antiretrovirals – Pre-exposure Prophylaxis (PrEP)

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
APRETUDE (cabtegravir)	TRUVADA (emtricitabine/tenofovir disoproxil fumarate)
DESCOVY (emtricitabine/tenofovir alafenamide)	
emtricitabine/tenofovir disoproxil fumarate	

### Antiretrovirals – Treatment

#### References:

Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV. Department of Health and Human Services. Available at <https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/adult-adolescent-arv/guidelines-adult-adolescent-arv.pdf> Accessed (October 9, 2020)

### Integrase Strand Transfer Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
BIKTARVY (bictegravir/emtricitabine/tenofovir)	
CABENUVA (cabotegravir/rilpivirine) – <i>Medical Billing Only</i>	
DOVATO (dolutegravir/lamivudine)	
GENVOYA (elvitegravir/cobicistat/emtricitabine/tenofovir)	
ISENTRESS (raltegravir)	
JULUCA (dolutegravir/rilpivirine)	
STRIBILD (elvitegravir/cobicistat/emtricitabine/tenofovir)	
TIVICAY (dolutegravir)	
TRIUMEQ (abacavir/dolutegravir/lamivudine)	
TRIUMEQ PD (abacavir/dolutegravir/lamivudine)	

### Non-Nucleoside Reverse Transcriptase Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
COMPLERA (emtricitabine/rilpivirine/tenofovir)	ATRIPLA (efavirenz/emtricitabine/tenofovir)
efavirenz	EDURANT (rilpivirine)
efavirenz/emtricitabine/tenofovir	efavirenz/lamivudine/tenofovir
JULUCA (dolutegravir/rilpivirine)	rilpivirine
ODEFSEY (emtricitabine/rilpivirine/tenofovir)	
PIFELTRO (doravirine)	
SYMFI (efavirenz/lamivudine/tenofovir) – <i>Brand Required</i>	
SYMFI LO (efavirenz/lamivudine/tenofovir) – <i>Brand Required</i>	
<b>Not Recommended for First Line Use</b>	
etravirine	INTELENCE (etravirine)

nevirapine	nevirapine ER
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- Etravirine – Guidelines do not recommend for treatment-naïve members due to insufficient data. FDA indication is for treatment experienced members and so should be reserved for salvage therapy, pretreated members with NNRTI resistance and PI exposure or who have ongoing adverse effects with first line therapies.
- Nevirapine – Guidelines no longer recommend nevirapine for initial treatment of HIV infection in treatment-naïve members. In resource limited settings, it can be considered as a third agent. Nevirapine demonstrated inferiority relative to efavirenz and is associated with serious and fatal hepatic and rash events.

### Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- See [Preferred Dosage Form](#) criteria

## Nucleoside Reverse Transcriptase Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
abacavir	ATRIPLA (efavirenz/emtricitabine/tenofovir)
abacavir/lamivudine	efavirenz/lamivudine/tenofovir
BIKTARVY (bictegrovir/emtricitabine/tenofovir)	emtricitabine capsule
CIMDUO (lamivudine/tenofovir)	EMTRIVA (emtricitabine) CAPSULE
COMPLERA (emtricitabine/rilpivirine/tenofovir)	EPIVIR (lamivudine)
DELSTRIGO (doravirine/lamivudine/tenofovir)	lamivudine
DESCOVY (emtricitabine/tenofovir alafenamide)	TRIZIVIR (abacavir/lamivudine)
efavirenz/emtricitabine/tenofovir	TRUVADA (emtricitabine/tenofovir disoproxil fumarate)
emtricitabine solution	VIREAD (tenofovir)
emtricitabine/tenofovir disoproxil fumarate	ZIAGEN (abacavir)
GENVOYA (elvitegravir/cobicistat/emtricitabine/tenofovir)	
ODEFSEY (emtricitabine/rilpivirine/tenofovir)	
SYMFI (efavirenz/lamivudine/tenofovir) – <i>Brand Required</i>	
SYMFI LO (efavirenz/lamivudine/tenofovir) – <i>Brand Required</i>	
STRIBILD (elvitegravir/cobicistat/emtricitabine/tenofovir)	
SYMTUZA (darumavir/cobicistat/emtricitabine/tenofovir)	
tenofovir	
TEMIXYS (lamivudine/tenofovir)	
TRIUMEQ (abacavir/dolutegravir/lamivudine)	
TRIUMEQ PD (abacavir/dolutegravir/lamivudine)	
<b>Not Recommended for First Line Use</b>	
abacavir/lamivudine/zidovudine	RETROVIR (zidovudine)
didanosine	TRIZIVIR (abacavir/lamivudine/zidovudine)
lamivudine/zidovudine	ZERIT (stavudine) CAPSULE
stavudine	zidovudine capsule and tablet

zidovudine syrup	
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- abacavir/lamivudine/zidovudine – Guidelines do not recommend ABC/3TC/ZDU (as either a triple-NRTI combination regimen or in combination with tenofovir (TDF) as a quadruple-NRTI combination regimen) due to inferior virologic efficacy.
- didanosine – Guidelines do not recommend ddl/3TC or ddl/FTC regimens due to inferior virologic efficacy, limited trial experience in ART-naïve members, and ddl toxicities (including pancreatitis and peripheral neuropathy). Ddl/TDF regimens are not recommended due to high rate of early virologic failure, rapid selection of resistance mutations, potential for immunologic nonresponse/CD4 cell decline, and increased ddl drug exposure and toxicities.
- lamivudine/zidovudine – Guidelines do not recommend ZDV/3TC due to greater toxicities than recommended NRTIs (including bone marrow suppression, GI toxicities, skeletal muscle myopathy, cardiomyopathy, and mitochondrial toxicities such as lipoatrophy, lactic acidosis and hepatic steatosis).
- stavudine – Guidelines do not recommend d4T/3TC due to significant toxicities (including lipoatrophy, peripheral neuropathy) and hyperlactatemia (including symptomatic and life-threatening lactic acidosis, hepatic steatosis, and pancreatitis)

### Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- See [Preferred Dosage Form](#) criteria

### Post-Attachment Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
TROGARZO (Ibalizumab-uiyk)	

### Protease Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
atazanavir	darunavir
EVOTAZ (atazanavir/cobicistat)	NORVIR (ritonavir)
NORVIR (ritonavir) POWDER PACKET	REYATAZ (atazanavir)
PREZCOBIX (darunavir/cobicistat)	
PREZISTA (darunavir) – <i>Brand Required</i>	
REYATAZ (atazanavir) POWDER PACK	
ritonavir	
SYMTUZA (darunavir/cobicistat/emtricitabine/tenofovir)	
<b>Not Recommended for First Line Use</b>	
APTIVUS (tipranavir)	KALETRA (lopinavir/ritonavir)
fosamprenavir	
INVIRASE (saquinavir)	
lopinavir/ritonavir	
VIRACEPT (nelfinavir)	

- Fosamprenavir – Guidelines do not recommend use of unboosted FPV or FPV/r due to virologic failure with unboosted FPV-based regimens that may result in selection of mutations that confer resistance to FPV and DRV. There is also less clinical trial data for FPV/r than other RTV-boosted PIs.
- Lopinavir/ritonavir – Guidelines do not recommend LPV/r due to GI intolerance, higher pill burden and higher RTV dose than other PI-based regimens
- Nelfinavir – Guidelines do not recommend use of NFV due to inferior virologic efficacy and diarrhea.

- Saginavir – Guidelines do not recommend use of unboosted SQV due to inadequate bioavailability and inferior virologic efficacy or SQV/r due to high pill burden and QT and PR prolongation.
- Tipranavir – Guidelines do not recommend TPV/r due to inferior virologic efficacy, higher dose of RTV and higher rate of adverse events than other RTV-boosted PIs.

## Capsid Function Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
<b>Not Recommended for First Line Use</b>	
SUNLENCA (lenacapavir) INJECTION – <i>Medical Billing Only</i>	
SUNLENCA (lenacapavir) TABLET	

- lenacapavir – SUNLENCA, in combination with other antiretroviral(s), is indicated for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in heavily treatment-experienced adults with multidrug resistant HIV-1 infection failing their current antiretroviral regimen due to resistance, intolerance, or safety considerations.

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
<b>Not Recommended for First Line Use</b>	
FUZEON (enfuvirtide)	
SELZENTRY (maraviroc)	

- Enfuvirtide (Fusion Inhibitor)– Guidelines do not recommend T20 for initial therapy due to twice daily injections, high rate of injection site reactions, and it has only been studied in members with virologic failure
- Maraviroc (CCR5 Antagonist) – Guidelines do not recommend MVC for initial therapy due to twice daily dosing, no virologic benefit compared to recommended regimens, and required CCR5 tropism testing.

## Diarrhea

Mytesi: [Jump to Criteria](#)

## Loss of Appetite

Dronabinol: [Jump to Criteria](#)

## Wasting Cachexia

Serostim: [Jump to Criteria](#)

## Hepatitis C Antiviral Treatments

### Direct Acting Antivirals

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
HARVONI (ledipasvir/sofosbuvir) 45 mg/200 mg tablet	EPCLUSA (sofosbuvir/velpatasvir)
sofosbuvir/velpatasvir	HARVONI (ledipasvir/sofosbuvir) 90mg/400mg tablet
SOVALDI (sofosbuvir) 200 MG TABLET	HARVONI (ledipasvir/sofosbuvir) ORAL PALLET
	ledipasvir/sofosbuvir 90mg/400mg tablet
	MAVYRET (glecaprevir/pibrentasvir)
	SOVALDI (sofosbuvir) 400MG TABLET
	SOVALDI (sofosbuvir) ORAL PALLET
	VIEKIRA PAK (dasabuvir/ombitasvir/paritaprevir/ritonavir)

*Electronic Concurrent Medication Required*

- Epclusa (and its generic): A total of 84 days of ribavirin must be billed within the previous 14 days of a sofosbuvir/velpatasvir claim if member has decompensated cirrhosis (Child Pugh B or C).

*First Fill*

- Epclusa (and its generic) and Vosevi: The entire treatment course must be dispensed at the initial fill.
  - A. Please call pharmacy provider relations (1-701-328-4086) if a member has already partially completed their treatment course and needs less than a full course of therapy for their current fill.

*Prior Authorization Criteria*Prior Authorization Form – Hepatitis CInitial Criteria – Approval Duration: Based on label recommendations

- The member must have life expectancy greater than 12 months.
- One of the following must be met (1-4):
  1. The member has no history of alcohol use disorder or IV illicit drug use.
  2. The member has maintained sobriety for the past 12 months.
  3. The member has completed or be currently enrolled in a treatment program within the past 12 months.
  4. The Harm Reduction Program Participation Attestation Form is attached indicating one of the following (a or b):
    - a. The member participates in a [Syringe Service Program](#)
    - b. The member participates in at least 2 Harm Reduction Pathway appointments as defined in [Appendix D](#) (may be completed by any qualified healthcare provider)

*Non-Solid Dosage Form Agents Criteria:*

- Epclusa pellet packs: Members that weigh 30 kg or greater must meet [Non-Solid Dosage Preparations](#) criteria in addition to Hepatitis C criteria.
- Mavyret pellet packs: Members that weigh 45 kg or greater must meet [Non-Solid Dosage Preparations](#) criteria in addition to Hepatitis C criteria.

*Non-Preferred Agents Criteria:*

- Clinical justification must be provided explaining why the member is unable to use the preferred product (subject to clinical review).

**For FIRST TIME or RE-INFECTION Treatment with Direct Acting Antivirals or incomplete therapy after receiving < 28 days:**

- Chronic Hepatitis C must be documented by one of the following (most recent test within the last 24 months):
  - No liver fibrosis or unknown (one of the following):
    - 2 positive HCV RNA levels at least 3 months apart
    - 1 positive HCV RNA test with the last likely HCV exposure occurring at least 6 months before the most recent positive test
  - Liver fibrosis or cirrhosis: 1 positive HCV RNA test
- For incomplete therapy, the following criteria is met:

**Due to incomplete therapy (defined as a medication possession ratio (MPR) of less than 80%)**

The member has participated in 1 visit focused on addressing adherence barriers within the past 180 days.



	Adherence education may be provided by a pharmacist (may be billed through the MTM program) or clinic-based E&M billed service (provided by a nurse or independent practitioner).
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For **RE-TREATMENT** after **Direct Acting Antiviral failure or incomplete therapy after receiving ≥ 28 days**:

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ribavirin	MAVYRET (glecaprevir/pibrentasvir)
VOSEVI (sofosbuvir/velpatasvir/voxilaprevir)	SOVALDI (sofosbuvir) 400MG TABLET

- The requested medication must be prescribed by, or in consult with, a hepatology, gastroenterology, or infectious disease specialist (including via Project ECHO)
- Chronic Hepatitis C must be documented by 1 HCV RNA test since most recent DAA treatment (HCV RNA level must be within the last 24 months)
- The following criteria is met (as applicable due to reason for retreatment):

Reason for retreatment:	
<b>Due to incomplete therapy (defined as a medication possession ratio (MPR) of less than 80%)</b>	<p>The member has participated in 1 visit focused on addressing adherence barriers within the past 180 days.</p> <p>Adherence education may be provided by a pharmacist (may be billed through the MTM program) or clinic-based E&amp;M billed service (provided by a nurse or independent practitioner).</p>
<b>Resistance</b>	<ul style="list-style-type: none"> <li>• <b>FIRST TIME treatment with Direct Acting Antivirals</b> criteria must be met</li> </ul>

*Non-Preferred Agents Criteria:*

- The member has had a failed treatment course with Vosevi.

## Influenza

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
oseltamivir	TAMIFLU (oseltamivir)
	XOFLUZA (baloxavir marboxil)

### *Electronic Age Verification*

- Xofluza: The member must be 5 years of age or older

### *Prior Authorization Criteria*

#### Initial Criteria – Approval Duration: 5 days

- The member must have failed a 5-day trial of oseltamivir, as evidenced by paid claims or pharmacy printouts.
- Clinical justification must be provided explaining why the member is unable to use the preferred product (subject to clinical review).

## Malaria

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
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hydroxychloroquine	atovaquone/proguanil
quinine	chloroquine
	COARTEM (artemether/lumefantrine)
	KRINTAFEL (tafenoquine)
	MALARONE (atovaquone/proguanil)
	mefloquine
	primaquine
	QUALAQUIN (quinine)

### Prior Authorization Criteria

#### Initial Criteria – Approval Duration: 7 days

- The member must have had a trial of a generic quinine in the last 30 days, as evidenced by paid claims or pharmacy print outs
- The request must be for treatment of malaria (NOT covered for prophylaxis)

## Respiratory Syncytial Virus (RSV) Prophylaxis

### CLINICAL PA REQUIRED

SYNAGIS (palivizumab) – Medical Billing Only

### Prior Authorization Criteria

#### Prior Authorization Form – RSV Prophylaxis

Initial Criteria – Approval Duration: Up to 5 weight-based doses within 6 months of season onset. No further prior authorization requests will be approved following season offset. An SA will only be approved until age 2 or through the second season, whichever occurs first.

*Respiratory Syncytial Virus (RSV) Season defined as onset (1<sup>st</sup> of 2 consecutive weeks when percentage of PCR tests positive for RSV is > 3% and offset (Last of 2 consecutive weeks when percentage of PCR tests positive for RSV is < 3%) as reported by The National Respiratory and Enteric Virus Surveillance System (NREVSS) Region 8 [Interactive Dashboard | NREVSS | CDC](#) North Dakota data specific data is available at: [Respiratory Syncytial Virus \(RSV\) | Health and Human Services North Dakota](#)*

*If a post-season spike occurs (defined as season onset criteria met within 3 months of season offset), infants may be approved for doses until the age of 3 months old if they meet clinical criteria and have not already received 5 doses during the defined season.*

- Clinical justification must be provided addressing why nirsevimab could not be given from VFC (subject to clinical review)
- The member had not received another monoclonal antibody for RSV prophylaxis during the current RSV season.
- The member must not have received immunity through a maternal Respiratory Syncytial Virus Vaccine.
- The member must have one of the following diagnoses and the additional criteria outlined for diagnosis:
  - **Prematurity:**
    - < 29 weeks, 0 days gestational age
      - ≤ 12 months of age at start of RSV season
    - ≥ 29 weeks, 0 days gestational age to ≤ 35 weeks, 0 days gestational age

- ≤ 6 months of age at start of RSV season
- One of the following:
  - Neuromuscular disease or pulmonary abnormality that impairs ability to clear secretions from the upper airway because of ineffective cough
  - Profoundly immunocompromised receiving chemotherapy, solid organ transplantation, hematopoietic stem cell transplantation, or require colony stimulating factors
- **Chronic Lung Disease of Prematurity (CLD)**
  - < 32 weeks, 0 days gestational age
    - ≤12 months of age at start of RSV season
      - Requires supplemental oxygen > 21% for at least the first 28 days after birth
  - < 32 weeks, 0 days gestational age
    - 13-24 months of age at start of RSV season
    - Requires supplemental oxygen > 21% for at least the first 28 days after birth
    - Continues to receive medical support within six months before the start of RSV season with supplemental oxygen, diuretic, or chronic corticosteroid therapy
- **Congenital Heart Disease**
  - ≤12 months of age at start of RSV season
    - Hemodynamically significant cyanotic or acyanotic congenital heart disease with medical therapy required

**References:**

1. American Academy of Pediatrics. Updated Guidance: Use of Palivizumab Prophylaxis to Prevent Hospitalization From Severe Respiratory Syncytial Virus Infection During the 2022-2023 RSV Season. American Academy of Pediatrics; July 2022. Available at: <https://www.aap.org/en/pages/2019-novel-coronavirus-covid-19-infections/clinical-guidance/interim-guidance-for-use-of-palivizumab-prophylaxis-to-prevent-hospitalization/>
2. Midgley CM, Haynes AK, Baumgardner JL, et al. Determining the seasonality of respiratory syncytial virus in the United States: the impact of increased molecular testing. J Infect Dis 2017;216:345–55
3. Rose EB, Wheatley A, Langley G, Gerber S, Haynes A. Respiratory Syncytial Virus Seasonality — United States, 2014–2017. MMWR Morb Mortal Wkly Rep 2018;67:71–76. DOI: [http://dx.doi.org/10.15585/mmwr.mm6702a4external icon](http://dx.doi.org/10.15585/mmwr.mm6702a4external%20icon)

## Nephrology/Urology

### Complement-mediated Thrombotic Microangiopathy (TMA) / Complement-mediated Hemolytic Uremic Syndrome

**CLINICAL PA REQUIRED**

SOLIRIS (eculizumab) – *Medical Billing Only*

ULTOMIRIS (ravulizumab-cwvz)

ULTOMIRIS (ravulizumab-cwvz) – *Medical Billing Only*

*Prior Authorization Criteria*

Initial Criteria – Approval Duration: 6 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a hematologist or nephrologist.
- The member has all the following (as evidenced by submitted documentation):
  - Low platelet count, as defined by laboratory reference range or member requires dialysis.

- Evidence of hemolysis such as an elevation in serum lactate dehydrogenase (LDH), elevated indirect bilirubin, reduced haptoglobin, or increased reticulocyte, as defined by laboratory reference range or member requires dialysis.
- Serum creatinine above the upper limits of normal, as defined by laboratory reference range or member requires dialysis.
- The member does not have bloody diarrhea.

***Renewal Criteria – Approval Duration: 12 months***

- The member must have experienced meaningful clinical benefit since starting treatment with the requested medication, as evidenced by medical documentation (e.g., chart notes) attached to the request (subject to clinical review) including one of the following scores and symptoms:
  - Normalization of platelet count, as defined by laboratory reference range.
  - Normalization of lactate dehydrogenase (LDH), as defined by laboratory reference range.
  - ≥ 25% improvement in serum creatinine from baseline or ability to discontinue dialysis.

## Benign Prostatic Hyperplasia

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
alfuzosin ER	AVODART (dutasteride)
CARDURA XL (doxazosin)	CARDURA (doxazosin)
doxazosin	ENTADFI (finasteride/tadalafil)
dutasteride	FLOMAX (tamsulosin)
finasteride	MINIPRESS (prazosin)
prazosin	PROSCAR (finasteride)
silodosin	RAPAFLO (silodosin)
tamsulosin	sildenafil
terazosin	tadalafil

***Electronic Diagnosis Verification***

- Finasteride, sildenafil, and tadalafil: Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale

***Prior Authorization Criteria***

***Initial Criteria – Approval Duration: 12 months***

- The member must have failed a 30-day trial of each preferred agent, as evidenced by paid claims or pharmacy printouts.
- Sildenafil/tadalafil: Documentation (e.g., chart notes) must be provided confirming the diagnosis.

## Chronic Kidney Disease

***Therapeutic Duplication***

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

**Dual endothelin angiotensin receptor antagonist**

CLINICAL PA REQUIRED
FILSPARI (sparsentan)

## Factor B Inhibitors

### CLINICAL PA REQUIRED

FABHALTA (iptacopan)

## Kappa-opioid agonist

### CLINICAL PA REQUIRED

KORSUVA (difelikefalin) – *Medical Billing Only*

## Non-steroidal selective mineralocorticoid receptor antagonist (MRA)

### CLINICAL PA REQUIRED

KERENDIA (finerenone)

## Renin-Angiotensin-Aldosterone System (RAAS) Inhibitors

### NO PA REQUIRED

ACE (angiotensin-converting enzyme) inhibitors – *all oral agents preferred*

ARBs (angiotensin receptor blockers) – *all oral agents preferred*

TEKTURNA (aliskiren)

## SGLT-1/SGLT-2 Inhibitor

### CLINICAL PA REQUIRED

INPEFA (sotagliflozin)

## SGLT-2 Inhibitor

### PREFERRED AGENTS (NO PA REQUIRED)

FARXIGA (dapagliflozin) – *Brand Required*

INVOKANA (canagliflozin)

JARDIANCE (empagliflozin)

### NON-PREFERRED AGENTS (PA REQUIRED)

dapagliflozin

## Sodium/Hydrogen Exchanger 3 (NHE3)

### CLINICAL PA REQUIRED

XPHOZAH (tenapanor)

## Systemic Corticosteroids

### PREFERRED AGENTS (NO PA REQUIRED)

methylprednisolone

prednisone

### NON-PREFERRED AGENTS (PA REQUIRED)

TARPEYO (budesonide-targeted release)

## Vasopressin V2-receptor (V2R) Antagonist

### PREFERRED AGENTS (NO PA REQUIRED)

JYNARQUE (tolvaptan)

### NON-PREFERRED AGENTS (PA REQUIRED)

### Electronic Duration Verification:

- Tarpeyo is payable for 9 months every 3 years.

- tolvaptan is payable for 30 days every year.

### *Prior Authorization Criteria*

#### Initial Criteria – Approval Duration: 12 months

##### *Inpefa Only:*

- The requested medication must be prescribed by, or in consult with, a cardiologist or nephrologist.
- If member is on renal dialysis, Medicare eligibility must be ruled out. *(6-month approval allowed to determine eligibility)*
- The member has type 2 diabetes and chronic kidney disease.
- The member has a history of a cardiovascular event (e.g., heart failure, myocardial infarction, cerebrovascular event) or two or more risk factors (e.g., elevated cardiac and inflammatory biomarker, obesity, hyperlipidemia, hypertension)
- The member is receiving concurrent Entresto, a beta-blocker, a SGLT-2 Inhibitor, and a mineralocorticoid receptor antagonist.
- Clinical justification must be provided explaining why the member is unable to use a preferred SGLT-2 inhibitor (subject to clinical review)

##### *Kerendia Only*

- The member must have history of diabetes.
- The member must be on the following at the target or maximally tolerated dose, as evidenced by paid claims or pharmacy printouts:
  - An ACE-inhibitor or an ARB
  - A SGLT-2 inhibitor
- The member has an estimated glomerular filtration rate (eGFR)  $\geq 25$  mL/min/1.73 m<sup>2</sup>
- The member has one of the following (1 or 2) despite a 3-month trial with an ACE inhibitor or a 6-month trial with an ARB:
  1. urinary albumin-to-creatinine ratio (UACR)  $\geq 30$  mg/g ( $\geq 3$  mg/mmol)
  2. albuminuria  $\geq 300$  mg/day

##### *Korsuva Only*

- If member is on renal dialysis, Medicare eligibility must be ruled out *(6-month approval may be allowed to determine eligibility)*.
- The member must have failed a 90-day trial of pregabalin or gabapentin, as evidenced by paid claims or pharmacy printouts.

##### *Fabhalta, Filspari and Tarpeyo Only*

- The member must have eGFR  $\geq 30$ .
- If member is on renal dialysis, Medicare eligibility must be ruled out *(6-month approval may be allowed to determine eligibility)*.
- The member must be experiencing proteinuria  $> 1$  gram/day or UPCR  $\geq 1.5$  g/g despite 3-month trials with good compliance of the following at the target or maximally tolerated dose, as evidenced by paid claims or pharmacy printouts:
  - ACE inhibitor or an ARB
  - A SGLT-2 inhibitor
  - prednisone or methylprednisolone

##### *Tolvaptan Only*

- The requested medication must be prescribed by, or in consult with, a nephrologist.
- The member does not have liver disease.
- The member has eGFR  $\geq 25$

- The prescriber has provided clinical justification that the member is at high risk of kidney progression such as one of the following (subject to clinical review):
  - Autosomal dominant polycystic kidney disease mayo classes 1C, 1D, or 1E
  - Kidney length > 16.5 cm (by ultrasound, MRI, or CT scan)
  - An annual eGFR decline of at least 5 mL/min/1.73 m<sup>2</sup> in one year
  - An annual eGFR decline of at least 2.5 mL/min/1.73 m<sup>2</sup> per year over a period of five years
  - A greater than 5 % increase in total kidney volume per year on at least three repeated measurements (via MRI or CT (computed tomography), each at least 6 months apart

*Xphozah Only*

- If member is on renal dialysis, Medicare eligibility must be ruled out (*6-month approval may be allowed to determine eligibility*).
- The member must have failed 30-day trials of sevelamer carbonate and sucroferric oxyhydroxide, as evidenced by paid claims or pharmacy printouts.

Renewal Criteria – Approval Duration: 12 months

- If member is on renal dialysis, Medicare eligibility must be ruled out (*6-month approval may be allowed to determine eligibility*).
- The member must have experienced meaningful clinical benefit since starting treatment with the requested medication, as evidenced by the following scores and symptoms:
  - *Fabhalta, Filspari and Tarpeyo Only*: proteinuria <1 gram/day or UPCR < 1.5 g/g or reduction of 30% from baseline
  - *Kerendia Only*: The member has experienced a stabilization in eGFR or one of the following:
    - albuminuria <1 gram/day or reduction of 30% from baseline
    - UACR < 1.5 g/g or reduction of 30% from baseline

**References:**

1. Stevens, Paul E., et al. "KDIGO 2024 Clinical practice guideline for the evaluation and management of chronic kidney disease." *Kidney international* 105.4 (2024): S117-S314.
2. de Boer, Ian H., et al. "Diabetes management in chronic kidney disease: a consensus report by the American Diabetes Association (ADA) and Kidney Disease: Improving Global Outcomes (KDIGO)." *Diabetes care* 45.12 (2022): 3075-3090.

**Anemia**

**Hematopoietic, Erythropoiesis Stimulating Agents**

*Pharmacy Billing*

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ARANESP (darbepoetin alfa)	PROCRIT (epoetin alfa)
EPOGEN (epoetin alfa)	RETACRIT (epoetin alfa – epbx) – Labelers 59353
MIRCERA (methoxy polyethylene glycol-epoetin beta)	
RETACRIT (epoetin alfa – epbx) – Labeler 00069	

*Prior Authorization Criteria*

Initial Criteria – Approval Duration: 12 months

- The member must have had a 4-week trial of each preferred agent, as evidenced by paid claims or pharmacy printouts.
- If member is on renal dialysis, Medicare eligibility must be ruled out (*6-month approval may be allowed to determine eligibility*).



## HIF-PHIs (Hypoxia-Inducible Factor-Prolyl Hydroxylase Inhibitors)

### PREFERRED AGENTS (CLINICAL PA REQUIRED)

JESDUVROQ (daprodustat)

VAFSEO (vadadustat)

#### Prior Authorization Criteria

##### Initial Criteria – Approval Duration: 12 months

- If member is on renal dialysis, Medicare eligibility must be ruled out (6-month approval may be allowed to determine eligibility).

## Hematopoietic Syndrome of Acute Radiation Syndrome

### PREFERRED AGENTS (CLINICAL PA REQUIRED)

NPLATE (romiplostim)

#### Prior Authorization Criteria

##### Initial Criteria – Approval Duration: treatment plan must be documented in request

- The requested medication must be prescribed by, or in consult with, a hematologist or oncologist.
- The member meets one of the following:
  - The member has had a  $\geq 2$  gray exposure to radiation
  - The member has had exposure to radiation and experiencing one of the following:
    - Gross blood loss
    - $> 10\%$  decrease in hemoglobin
    - Platelet count  $< 50,000/\text{microL}$
    - Absolute neutrophil count  $< 1000$  cells/ $\text{microL}$
    - Absolute lymphocyte count  $< 1000$  cells/ $\text{microL}$

## Hyperkalemia (Chronic)

### PREFERRED AGENTS (CLINICAL PA REQUIRED)

LOKELMA (sodium zirconium cyclosilicate)

SPS (sodium polystyrene sulfonate) SUSPENSION+

### NON-PREFERRED AGENTS (PA REQUIRED)

VELTASSA (patiromer)

+ SPS can cause intestinal necrosis which may be fatal. Concomitant use of additional sorbitol is not recommended.

#### Prior Authorization Criteria

##### Initial Criteria – Approval Duration: 3 months

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

##### Non-Preferred Agent Criteria:

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

Renewal Criteria – Approval Duration: 12 months

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

**Reference:**

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

## Primary Hyperoxaluria Type 1 (PH1)

*RNA interference (RNAi)*

**CLINICAL PA REQUIRED**

OXLUMO (lumasiran) – *Medical Billing Only*

RIVFLOZA (nedosiran)

*Prior Authorization Criteria*

Initial Criteria – Approval Duration: 6 months

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

Renewal Criteria – Approval Duration: 12 months

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

## Lupus Nephritis

*First Line Agents*

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
cyclophosphamide	
mycophenolate	
systemic oral corticosteroids	

*Anti-CD20 Monoclonal Antibodies*

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
RIABNI (rituximab-arrx) – <i>Medical Billing Only</i>	RITUXAN (rituximab) – <i>Medical Billing Only</i>

RUXIENCE (rituximab-pvvr) – <i>Medical Billing Only</i>	
TRUXIMA (rituximab-abbs) – <i>Medical Billing Only</i>	

### *B-Lymphocyte Stimulator (BlyS) – Specific Inhibitor*

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
BENLYSTA (belimumab) – <i>Medical Billing Only</i>	

### *Calcineurin Inhibitors*

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

### *Prior Authorization Criteria*

#### Initial Criteria – Approval Duration: 6 months

- The requested medication must be prescribed by, or in consult with, a nephrologist or rheumatologist
- If member is on renal dialysis, Medicare eligibility must be ruled out (*6-month approval may be allowed to determine eligibility*).
- The member has an eGFR > 45
- The member must be using concurrently with mycophenolate and a systemic corticosteroid for 3 months, as evidenced by paid claims or pharmacy printouts.
- Rituxan Only: See [Biosimilar Agents](#) criteria

#### Renewal Criteria – Approval Duration: 12 months

- The provider must submit documentation showing that the member has experienced clinical benefit since starting treatment, as evidenced by documentation of one of the following:
  - Improvement of proteinuria (UPCR decreased by 50% and/or below 0.5 to 0.7 g/day)
  - Improvement of serum creatinine (SCr ≤ 1.4 mg/dl)
  - Chronic steroid use to ≤ 7.5 mg/day

## Overactive Bladder

### *Topical Formulations*

PREFERRED AGENTS (NO PA REQUIRED)
GELNIQUE (oxybutynin) GEL
OXYTROL (oxybutynin) PATCH

### *Oral Solid Dosage Formulations*

PREFERRED AGENTS (NO PA REQUIRED)	PREFERRED STEP 1 AGENTS (ELECTRONIC STEP)	NON-PREFERRED STEP 2 AGENTS (PA REQUIRED)
MYRBETRIQ (mirabegron) – <i>Brand Required</i>	fesoterodine ER	darifenacin ER
oxybutynin ER	tolterodine	DETROL (tolterodine)
oxybutynin tablet	tolterodine ER	DETROL LA (tolterodine)
solifenacin		DITROPAN XL (oxybutynin)
tamsulosin		dutasteride/tamsulosin
trospium		fesoterodine
		flavoxate
		FLOMAX (tamsulosin)
		GEMTESA (vibegron)

		JALYN (dutasteride/tamsulosin)
		mirabegron ER
		TOVIAZ ER (fesoterodine)
		trospium ER
		VESICARE (solifenacin)

### Therapeutic Duplication

- One strength of one of the following medications is allowed at a time: dutasteride, Jalyn, or finasteride
- Non-selective alpha 1 blockers (doxazosin, prazosin, and terazosin) are not allowed with carvedilol or labetalol
  - Carvedilol and labetalol are non-selective beta blockers with alpha 1 blocking activity

### Electronic Diagnosis Verification

- Oxybutynin 2.5 mg: Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale

### Electronic Step Therapy Required

- Preferred Step 1 Agents:
  - PA Not Required Criteria: A 30-day supply of a preferred agent at max dose has been paid within 100 days prior to step 1 agent's date of service.
  - PA Required Criteria: The member must have failed A 30-day trial of a preferred agent at max dose, as evidenced by paid claims or pharmacy printouts.

### Prior Authorization Criteria

#### Initial Criteria – Approval Duration: 12 months

- The member must have had a 30-day trial of solifenacin and Myrbetriq, as evidenced by paid claims or pharmacy printouts.

### Non-Solid Dosage Form

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
oxybutynin syrup	MYRBETRIQ (mirabegron) SUSPENSION
	VESICARE (solifenacin) LS SUSPENSION

### Prior Authorization Criteria

#### Initial Criteria – Approval Duration: 12 months

- The member must have had a 30-day trial of a preferred agent, as evidenced by paid claims or pharmacy printouts.
- Must meet [Non-Solid Dosage Forms](#) criteria

### Therapeutic Duplication

- Anticholinergic medications (tolterodine, oxybutynin, trospium, fesoterodine) are not covered with Acetylcholinesterase Inhibitors.
  - The effects of an anticholinergic (blocks the effect of acetylcholine) and acetylcholinesterase inhibitors (prevents breakdown of acetylcholine) oppose each other, and the therapeutic effect of both products is diminished.

## Phosphate Binders

### Solid Dosage Form

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
calcium acetate	AURYXIA (ferric citrate) TABLET
sevelamer carbonate tablet	RENAGEL (sevelamer HCl) TABLET
	RENVELA (sevelamer carbonate) TABLET
	sevelamer HCl

### Prior Authorization Criteria

#### Initial Criteria – Approval Duration: 12 months

- If member is on renal dialysis, Medicare eligibility must be ruled out (6-month approval may be allowed to determine eligibility).
- The member must have failed a 30-day trial of sevelamer carbonate, as evidenced by paid claims or pharmacy printouts.

### Non-Solid Dosage Form

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
FOSRENOL (lanthanum) CHEWABLE TABLET – <i>Brand Required</i>	FOSRENOL (lanthanum) POWDER PACK
RENVELA (sevelamer carbonate) POWDER PACK – <i>Brand Required</i>	lanthanum chew tab
	sevelamer carbonate powder pack
	VELPHORO (sucroferric oxyhydroxide)

### Prior Authorization Criteria

#### Initial Criteria – Approval Duration: 12 months

- If member is on renal dialysis, Medicare eligibility must be ruled out (6-month approval may be allowed to determine eligibility).
- The member must have failed a 30-day trial of sevelamer carbonate and lanthanum, as evidenced by paid claims or pharmacy printouts.
- Must meet [Preferred Dosage Forms](#) criteria
- Must meet [Non-Solid Dosage Forms](#) criteria

## Neurology

### Alzheimer's Disease

#### Cholinesterase Inhibitors

### Solid Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
donepezil 5 mg, 10 mg tablet	ARICEPT (donepezil)
galantamine tablet	donepezil 23 mg tablet
galantamine ER	donepezil ODT
rivastigmine capsule	RAZADYNE (galantamine)

	RAZADYNE ER (galantamine)
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### Non-Solid Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
EXELON (rivastigmine) PATCH – <i>Brand Required</i>	ADLARITY (donepezil) PATCH
	galantamine oral solution
	rivastigmine patch

## NMDA Receptor Antagonists

### Solid Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
memantine	NAMENDA (memantine)

### Non-Solid Dosage Forms

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
memantine ER capsule sprinkle	memantine oral solution
	NAMENDA XR (memantine) CAPSULE SPRINKLE

## Cholinesterase Inhibitors / NMDA Receptor Antagonist Combinations

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	NAMZARIC (memantine/donepezil)

### Therapeutic Duplication

- One memantine medication is allowed at a time
- Anticholinergic medications are not covered with acetylcholinesterase inhibitors (donepezil, rivastigmine, galantamine, pyridostigmine).
  - A. The effects of an anticholinergic (blocks the effect of acetylcholine) and acetylcholinesterase inhibitors (prevents breakdown of acetylcholine) oppose each other, and the therapeutic effect of both products is diminished.

### Electronic Diagnosis Verification

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

### Electronic Age Verification

- Submit chart notes to verify diagnosis for members less than 30 years old

### Prior Authorization Criteria

#### Initial Criteria – Approval Duration: 12 months

- The member must have failed a 30-day trial of a pharmaceutically equivalent preferred agent, as evidenced by paid claims or pharmacy printouts.
- The member must not reside in facility where medications are managed such as skilled nursing care.
- Donepezil 23 mg: Clinical justification must be provided explaining why the member is unable to use the preferred products (subject to clinical review).
- Memantine ER capsule sprinkle: Must meet [Non-Solid Dosage Forms](#) criteria

## Amyloid Beta-Directed Monoclonal Antibody

**CLINICAL PA REQUIRED**

*Prior Authorization Criteria*Initial Criteria – Approval Duration: 1 year*Leqembi Only:*

- The member must have been diagnosed with mild cognitive impairment or mild Alzheimer’s disease dementia, with documented evidence of beta-amyloid plaque on the brain.
- The member has a physician who participates in a qualifying registry with an appropriate clinical team and follow-up care.

**Amyotrophic Lateral Sclerosis (ALS)**

PREFERRED AGENTS (NO PA REQUIRED)	PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
riluzole tablet	EXSERVAN (riluzole) FILM	RILUTEK (riluzole) TABLET
	QALSODY (tofersen) + – <i>Medical Billing Only</i>	
	RADICAVA (edaravone) – <i>Medical Billing Only</i>	
	RADICAVA ORS (edaravone)	
	TIGLUTIK (riluzole) ORAL SUSPENSION	

+ Qalsody failed to demonstrate statistically significant benefit over placebo on the primary efficacy endpoint, the change from baseline to Week 28 in the Amyotrophic Lateral Sclerosis Functional Rating Scale – Revised (ALSFS-R) in the Phase 3 VALOR trial (NCT02623699) or clinical secondary endpoints. Continued approval of Qalsody for this indication may be contingent upon verification of clinical benefit in the ATLAS study (NCT04856982).

*Prior Authorization Criteria*Initial Criteria – Approval Duration: 6 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a neurologist or neuromuscular specialist.
- The member has had ALS symptoms present for less than 2 years.
- The member must have both of the following:
  - Forced vital capacity (FVC) > 80 percent of predicted.
  - ALS Function Rating Scale-Revised (ALSFRS-R) with a score of 2 or greater on each individual item of the scale
- The member must not have permanent invasive ventilation.

*Exservan and Tiglutik Only:* Must meet [Non-Solid Dosage Forms](#) criteria

Renewal Criteria – Approval Duration: 12 months

- The member must have both of the following:
  - Forced Vital Capacity (FVC) > 60 percent of predicted
  - Documentation of a therapeutic response (e.g., improved neurologic impairment, motor function, quality of life, slowing of disease progression, etc.) from baseline as evidenced by a score decline of less than 6 on the ALSFRS-R.



## Anticonvulsants

### Anticonvulsant Prevention

#### Narrow Spectrum:

##### Carbamazepine

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
carbamazepine 100 mg chewable tablet	carbamazepine 200 mg chewable tablet
carbamazepine oral suspension	carbamazepine ER capsule
carbamazepine tablet	carbamazepine XR tablet
CARBATROL (carbamazepine) – <i>Brand Required</i>	EPITOL (carbamazepine)
EQUETRO (carbamazepine)	TEGRETOL (carbamazepine oral suspension)
TEGRETOL XR (carbamazepine) – <i>Brand Required</i>	TEGRETOL (carbamazepine)

##### Ethosuximide

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ethosuximide capsule	ZARONTIN (ethosuximide)
ethosuximide oral solution	ZARONTIN (ethosuximide) ORAL SOLUTION

##### Gabapentin

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
gabapentin capsule	NEURONTIN (gabapentin) CAPSULE
gabapentin oral solution	NEURONTIN (gabapentin) ORAL SOLUTION
gabapentin tablet	NEURONTIN (gabapentin) TABLET

##### Lacosamine

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
lacosamide oral solution	MOTPOLY XR (lacosamide) CAPSULE
lacosamide tablet	VIMPAT (lacosamide) ORAL SOLUTION
	VIMPAT (lacosamide) TABLET

##### Oxcarbazepine

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
oxcarbazepine oral solution	oxcarbazepine ER
oxcarbazepine tablet	OXTELLAR XR (oxcarbazepine) – <i>Brand Required</i>
	TRILEPTAL (oxcarbazepine)
	TRILEPTAL (oxcarbazepine) ORAL SUSPENSION

##### Pregabalin

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
pregabalin	LYRICA (pregabalin)
pregabalin oral solution	LYRICA (pregabalin) ORAL SOLUTION
	LYRICA CR (pregabalin)
	pregabalin ER

## Phenytoin

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
phenytoin chewable tablet	DILANTIN (phenytoin) CHEWABLE TABLET
phenytoin sodium ER	DILANTIN (phenytoin) ORAL SUSPENSION
phenytoin suspension	DILANTIN ER (phenytoin)
	PHENYTEK (phenytoin)

## Primidone

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
primidone	MYSOLINE (primidone)

## Tiagabine

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
tiagabine	

## Vigabatrin

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
SABRIL (vigabatrin) TABLET – <i>Brand Required</i>	SABRIL (vigabatrin) POWDER PACK
vigabatrin powder pack	vigabatrin tablet
	VIGADRONE (vigabatrin)
	VIGAFYDE (vigabatrin)
	VIGPODER (vigabatrin)

## Other

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
APTIOM (eslicarbazepine)	methsuximide
CELONTIN (methsuximide) – <i>Brand Name Required</i>	
DIACOMIT (stiripentol)	
EPIDIOLEX (cannabidiol)	
FINTEPLA (fenfluramine) ORAL SOLUTION	
phenobarbital elixir	
phenobarbital tablet	
XCOPRI (cenobamate)	
ZTALMY (ganaxolone) SUSPENSION	

## Electronic Diagnosis Verification

- Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale for Diacomit, Epidiolex, and Fentepla

## Electronic Concurrent Medications Required

- A total of 28 days of clobazam must be paid within 45 days prior to Diacomit.
  - Diacomit is FDA approved to be used in combination with clobazam.

## Quantity Limit Override

- Gabapentin: 2400 mg max dose per day  
Please call for an override by calling provider relations at 1-800-755-2604 if dose exceeds 2400 mg per day and the indication is adjuvant seizure (if monotherapy, please send chart notes to verify indication)

### Prior Authorization Criteria:

- See [Preferred Dosage Form](#) Criteria

### Therapeutic Duplication

- One Vimpat strength is allowed at a time
- Lyrica and gabapentin are not allowed together.
- Lyrica and gabapentin oral solutions are not allowed with benzodiazepines, muscle relaxants (except baclofen), or narcotic solid dosage forms. If a member can swallow, they should be transitioned to a solid dosage form.

Please call for an override by calling provider relations at 1-800-755-2604 if the member's medications are dispensed in solid formulations are being crushed or opened to administer because member is unable to swallow

### Broad Spectrum:

#### Clobazam

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
clobazam	ONFI (clobazam)
clobazam oral solution	ONFI (clobazam) ORAL SOLUTION
	SYMPAZAN (clobazam) FILM

#### Divalproex/Valproic Acid

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
DEPAKOTE SPRINKLE (divalproex sodium) – <i>Brand Co-Preferred</i>	DEPAKENE (valproic acid) CAPSULE
divalproex sodium ER	DEPAKENE (valproic acid) ORAL SOLUTION
divalproex sodium sprinkle	DEPAKOTE (divalproex sodium) TABLET
divalproex sodium tablet	DEPAKOTE ER (divalproex sodium)
valproic acid capsule	
valproic acid oral solution	

#### Felbamate

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
felbamate oral suspension	felbamate tablet
FELBATOL (felbamate) TABLET – <i>Brand Required</i>	

#### Lamotrigine

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
lamotrigine chewable tablet	LAMICTAL (lamotrigine) CHEWABLE TABLET
lamotrigine ER	LAMICTAL (lamotrigine) DOSE PACK
lamotrigine ODT	LAMICTAL (lamotrigine) TABLET
lamotrigine ODT dose pack	lamotrigine dose pack
lamotrigine tablet	LAMICTAL ODT (lamotrigine)
SUBVENITE (lamotrigine)	LAMICTAL ODT (lamotrigine) DOSE PACK
	LAMICTAL XR (lamotrigine)
	LAMICTAL XR (lamotrigine) DOSE PACK
	SUBVENITE (lamotrigine) DOSE PACK

### Levetiracetam

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
levetiracetam ER	ELEPSIA XR (levetiracetam)
levetiracetam oral solution	KEPPRA (levetiracetam)
levetiracetam tablet	KEPPRA (levetiracetam) ORAL SOLUTION
	KEPPRA XR (levetiracetam)
	SPRITAM (levetiracetam) SUSPENSION

### Rufinamide

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
BANZEL (rufinamide) ORAL SUSPENSION – <i>Brand Co-Preferred</i>	
BANZEL (rufinamide) TABLET – <i>Brand Co-Preferred</i>	
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 – <i>Brand Required</i>	TOPAMAX (topiramate) SPRINKLE CAPSULE
topiramate sprinkle capsule	topiramate ER sprinkle cap
topiramate tablet	
TROKENDI XR (topiramate) – <i>Brand Required</i>	

### Other

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
BRIVIACT (brivaracetam)	
FYCOMPA (perampanel)	
FYCOMPA (perampanel) ORAL SUSPENSION	
zonisamide	

## Anticonvulsant Rescue Therapies

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
diazepam pediatric rectal gel	LIBERVANT (diazepam) FILM
diazepam rectal gel	
NAYZILAM (midazolam) NASAL SPRAY	
VALTOCO (diazepam) NASAL SPRAY	

### Electronic Duration Verification

- 4 doses are covered every 60 days without an override

If one of the following criteria are met (A or B), please request an override by calling provider relations at 1-800-755-2604 or emailing [medicaidpharmacy@nd.gov](mailto:medicaidpharmacy@nd.gov):

- The previous dose has expired
- The dose was used by member for a seizure (in this case, it is recommended to follow up with prescriber to discuss frequency of use and potential regimen review/adjustments)

*Prior Authorization Criteria:*

- See [Preferred Dosage Form](#) criteria

## Duchenne Muscular Dystrophy

### Corticosteroids

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AGAMREE (vamorolone)	deflazacort
EMFLAZA (deflazacort) – <i>Brand Required</i>	

*Prior Authorization Criteria*

[Prior Authorization Form – Duchenne Muscular Dystrophy](#)

Initial Criteria – Approval Duration: 6 months

*(approval may be granted for tapering if all initial criteria are not met)*

- Diagnosis must be confirmed by the presence of abnormal dystrophin or a confirmed mutation of the dystrophin gene
- The requested medication must be prescribed by, or in consult with, a physician who specializes in the treatment of Duchenne Muscular Dystrophy (DMD) and/or neuromuscular disorders
- Onset of weakness must have occurred before 2 years of age
- The member must have serum creatinine kinase activity of at least 10 times the upper limit of normal (ULN) prior to initiating treatment
- The member must have failed a 6-month trial of prednisone, as evidenced by paid claims or pharmacy printouts
- The provider must submit baseline assessment results from the following assessments (the member does not have to meet all of these parameters, but each assessment must be submitted, and provider must indicate which parameters are met and being preserved, must be at least one):
  - Stable cardiac function LVEF > 40% by echo
  - Scoliosis not requiring surgery
  - Stable respiratory function – FVC predicted > 50%, not requiring ventilatory assistance
  - The provider must submit baseline motor milestone score results from at least ONE the following assessments:
    - 6-minute walk test (6MWT)
    - North Star Ambulatory Assessment (NSAA)
    - Motor Function Measure (MFM)
    - Hammersmith Functional Motor Scale (HFMS)
    - Performance of Upper Limb (PUL)
    - 4 stair climb (4SC)
- The member must have ONE of the following significant intolerable adverse effects to prednisone supported by documentation:
  - i. Cushingoid appearance
  - ii. Central (truncal) obesity
  - iii. Severe behavioral adverse effect
  - iv. Undesirable weight gain (>10% of body weight gain increase over 6-month period)
  - v. Diabetes and/or hypertension that is difficult to manage

Renewal Criteria – Approval Duration: 12 months

- The member must have experienced stabilization, slowing of disease progression, or improvement of the condition since starting treatment with the requested medication, including the following assessments (the member does not have to meet all of these parameters, but each assessment must be submitted, and provider must indicate which parameters are met and being preserved, must be at least one):
  - Stable cardiac function LVEF > 40% by ECHO

- Scoliosis not requiring surgery
- Stable respiratory function – FVC predicted > 50%, not requiring ventilatory assistance
- Motor function assessment
  - 6MWT – improvement of 35 meters from baseline
  - NSAA – improvement of 2 points from baseline
  - MFM – improvement of 2 points from baseline
  - HFMS – improvement of 2 points from baseline
  - PUL – improvement of 4 points from baseline
  - 4SC – improvement of 1 second from baseline
- The member must have had improvement of adverse effects experienced on prednisone supported by documentation:
  - i. Cushingoid appearance
  - ii. Central (truncal) obesity
  - iii. Severe behavioral adverse effect
  - iv. Undesirable weight gain (>10% of body weight gain increase over 6-month period)
  - v. Diabetes and/or hypertension that is difficult to manage

**References:**

1. Muntoni, Francesco, et al. "Meaningful changes in motor function in Duchenne muscular dystrophy (DMD): A multi-center study." *PLoS one* 19.7 (2024): e0304984.

## Histone Deacetylase Inhibitor

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

### *Prior Authorization Criteria*

#### [Prior Authorization Form – Duchenne Muscular Dystrophy](#)

##### Initial Criteria – Approval Duration: 6 months

- The requested medication must be prescribed by, or in consult with, a physician who specializes in the treatment of Duchenne Muscular Dystrophy (DMD) and/or neuromuscular disorders.
- The member must be assigned male at birth.
- The diagnosis must be confirmed by the presence of abnormal dystrophin or a confirmed mutation of the dystrophin gene.
- The member must have a baseline 6-Minute Walk Time (6MWT) ≥ 300 meters while walking independently (e.g., without side-by-side assist, cane, walker, wheelchair, etc.)
- Weight and calculated dose must be provided consistent with approved FDA dose.
- The provider must submit baseline motor milestone score results from at least ONE the following assessments:
  - North Star Ambulatory Assessment (NSAA)
  - 4-stair claim (4SC)
- The member is on a stable dose of corticosteroids for the past 3 months, as evidenced by paid claims and pharmacy print outs.

##### Renewal Criteria – Approval Duration: 12 months

- The member must have maintained a 6MWT ≥ 300 meters while walking independently (e.g., without side-by-side assist, cane, walker, wheelchair, etc.)
- The member must have experienced stabilization, slowing of disease progression, or improvement of the condition since starting treatment with the requested medication, as evidenced by medical documentation (e.g., chart notes) attached to the request (subject to clinical review) including:
  - North Star Ambulatory Assessment (NSAA)
  - 4-stair claim (4SC)

## Genetic Therapies

### Exon 45 Skipping

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AMONDYS 45 (casimersen) – <i>Medical Billing Only</i>	

### Exon 51 Skipping

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
EXONDYS 51 (eteplirsen) – <i>Medical Billing Only</i>	

### Exon 53 Skipping

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
VILTEPSO (viltolarsen) – <i>Medical Billing Only</i>	VYONDYS 53 (golodirsen) – <i>Medical Billing Only</i>

### High-Cost Drug:

Amondys 45, Exondys 51, and Vyondys 53 cost \$758,000 per year for a 30 kg child.

Viltepsos cost \$733,200 per year for a 30 kg child.

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

### Prior Authorization Criteria

#### Initial Criteria – Approval Duration: 8 weeks

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

#### *Non-Preferred Agent Criteria (Initial)*



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

**Renewal Criteria – Approval Duration: 12 months**

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

## Huntington’s Disease

### CLINICAL PA REQUIRED

AUSTEDO (deutetrabenazine)

AUSTEDO XR (deutetrabenazine)

INGREZZA (valbenazine)

### Prior Authorization Criteria

**Initial Criteria – Approval Duration: 12 months**

- The requested medication must be prescribed by, or in consult with, a neurologist or psychiatrist.
- The member must have failed a 3-month trial of tetrabenazine, as evidenced by paid claims or pharmacy printouts.

## Hypersomnolence (Narcolepsy and Idiopathic Hypersomnia)

PREFERRED AGENTS (NO PA REQUIRED)	PREFERRED STEP 1 AGENTS (ELECTRONIC STEP)	NON-PREFERRED AGENTS (PA REQUIRED)
armodafinil	SUNOSI (solriamfetol)	NUVIGIL (armodafinil)
modafinil	XYREM (sodium oxybate) – Brand Required	PROVIGIL (modafinil)
		sodium oxybate
		WAKIX (pitolisant)
		XYWAV (sodium, calcium, magnesium, potassium oxybate)

### Electronic Step Therapy Required

- Sunosi and Xyrem:
  - PA Not Required Criteria: A 30-day supply of armodafinil or modafinil has been paid within 60 days prior to preferred step 1 agent’s date of service.
  - PA Required Criteria: The member must have failed a 30-day trial of armodafinil or modafinil, as evidenced by paid claims or pharmacy printouts.
- Wakix requires titration to 17.8 mg dose with 4.45 mg tablets.

### Prior Authorization Criteria

**Initial Criteria – Approval Duration: 12 months**

- The member must have failed 30-day trials of each preferred agent (except Sunosi for idiopathic hypersomnia) and at least 1 additional CNS stimulant indicated for treatment of narcolepsy, as evidenced by paid claims or pharmacy printouts
- Documentation of each treatment failure must be provided, as evidenced by one of the following:

- Multiple Sleep Latency Test (MSLT) <8 minutes
- EPWORTH sleepiness scale score ≥10
- **Xywav Only:**
  - The member must have failed a 30-day trial with Wakix
  - Clinical justification must be provided explaining why the member is unable to Xyrem due to sodium content (subject to clinical review).

***Renewal Criteria – Approval Duration: 12 months***

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

***Therapeutic Duplication***

- Sunosi and Wakix are not allowed together.
- Provigil and Nuvigil are not allowed together.
- Xyrem and, Xywav are not allowed with each other, sleeping medication or benzodiazepines.

***Underutilization***

- Wakix, Sunosi, and Xywav must be used adherently and will reject on point of sale for late fill.

**Migraine**

**Prophylaxis of Migraine**

**Calcitonin Gene-Related Peptide (CGRP) Receptor Antagonist**

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

***Prior Authorization Criteria***

**[Prior Authorization Form – Migraine Prophylaxis/Treatment](#)**

***Initial Criteria – Approval Duration: 6 months***

- The member must experience 3 or more migraine days per month.
- The member must have failed 2-month trials of at least two of the following agents from different therapeutic classes, as evidenced by paid claims or pharmacy printouts:
  - amitriptyline, atenolol, candesartan, divalproex sodium, metoprolol, nadolol, propranolol, topiramate, venlafaxine, zonisamide
- **Nurtec ODT Only:**
  - The member must have failed a 3-month trial of Ajovy and Emgality, as evidenced by paid claims or pharmacy printouts.

***Non-Preferred Agents Criteria:***

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

Renewal Criteria – Approval Duration: 12 months

- The member must have experienced at least a 50% reduction in migraine frequency, pain intensity, or duration from baseline.

## Treatment of Migraine

### Calcitonin Gene-Related Peptide (CGRP) Receptor Antagonist

*Therapeutic Duplication*

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

**Oral**

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
NURTEC ODT (rimegepant)	UBRELVY (ubrogepant)

*Prior Authorization Criteria*

[Prior Authorization Form – Migraine Prophylaxis/Treatment](#)

Initial Criteria – Approval Duration: 3 months

- The member must have failed a 30-day trial of two triptans (5HT-1 Agonists) of unique ingredients, as evidenced by paid claims or pharmacy printouts.

*Non-Preferred Agents Criteria:*

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

**Nasal**

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	ZAVZPRET NASAL SPRAY (zavegepant)

*Prior Authorization Criteria*

[Prior Authorization Form – Migraine Prophylaxis/Treatment](#)

Initial Criteria – Approval Duration: 3 months

*Non-Preferred Agents Criteria:*

- The member must have failed a 30-day trial of two triptans (5HT-1 Agonists), one of which must be nasal route, of unique ingredients, as evidenced by paid claims or pharmacy printouts.
- The member must have failed a 30-day trial of Nurtec ODT, Ubroelvy, and Reyvow, as evidenced by paid claims or pharmacy printouts.

### Non-Steroidal Anti-inflammatory Drugs (NSAIDS)

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

<a href="#">NSAIDs</a>	ELYXYB (celecoxib)
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*Prior Authorization Criteria:*

- See [Preferred Dosage Form](#) criteria

**Serotonin (5-HT) 1F Receptor Agonist**

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

*Prior Authorization Criteria*

[Prior Authorization Form – Migraine Prophylaxis/Treatment](#)

*Initial Criteria – Approval Duration: 3 months*

- The member must have failed a 30-day trial of two triptans (5HT-1 Agonists) of unique ingredients, as evidenced by paid claims or pharmacy printouts.
- The member must have failed a 30-day trial of Nurtec ODT and Ubrelvy, as evidenced by paid claims or pharmacy printouts.

*Therapeutic Duplication*

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

*Therapeutic Duplication*

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

**Ergot Alkaloids**

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	D.H.E.45 (dihydroergotamine) INJECTION
	dihydroergotamine injection
	dihydroergotamine nasal spray
	ERGOMAR (ergotamine) SL TABLET
	MIGERGOT (ergotamine/caffeine) RECTAL SUPPOSITORY
	TRUDHESA (dihydroergotamine)

*Prior Authorization Criteria*

[Prior Authorization Form – Migraine Prophylaxis/Treatment](#)

*Initial Criteria – Approval Duration: 3 months*

- The member must have failed a 30-day trial of two triptans (5HT-1 Agonists) of unique ingredients, as evidenced by paid claims or pharmacy printouts.
- The member must have failed a 30-day trial of a treatment CGRP receptor agonist, as evidenced by paid claims or pharmacy printouts.

*Therapeutic Duplication*

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

## Triptans (5HT-1 Agonists)

### Solid Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED STEP 1 AGENTS (PA REQUIRED)	NON-PREFERRED STEP 2 AGENTS (PA REQUIRED)
RELPAK (eletriptan) – <i>Brand Required</i>	FROVA (frovatriptan) TABLET – <i>Brand Required</i>	almotriptan tablet
rizatriptan tablet	naratriptan tablet	AMERGE (naratriptan) TABLET
sumatriptan tablet	zolmitriptan tablet	eletriptan tablet
		frovatriptan tablet
		IMITREX (sumatriptan) TABLET
		MAXALT (rizatriptan) TABLET
		sumatriptan/naproxen tablet
		TREXIMET (sumatriptan/naproxen) TABLET
		ZOMIG (zolmitriptan) TABLET

### Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

#### Non-Preferred Step 1 Agents:

- The member must have failed a 30-day trial of rizatriptan, as evidenced by paid claims or pharmacy printouts.
- Members over 18 years old: The member must also have failed a 30-day trial of sumatriptan and eletriptan, as evidenced by paid claims or pharmacy printouts.

#### Non-Preferred Step 2 Agents:

- The member must have failed a 30-day trial of each available preferred and non-preferred step 1 triptan agent, as evidenced by paid claims or pharmacy printouts

### Therapeutic Duplication

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

#### Non-Solid Oral Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
rizatriptan ODT	MAXALT MLT (rizatriptan)
	zolmitriptan ODT

### Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

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

### Therapeutic Duplication

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

## Nasal Spray

PREFERRED AGENTS (NO PA REQUIRED)	PREFERRED STEP 1 AGENTS (PA REQUIRED)	NON-PREFERRED STEP 2 AGENTS (PA REQUIRED)
ZOMIG (zolmitriptan) NASAL SPRAY – Brand Required	sumatriptan spray	TOSYMRA (sumatriptan) NASAL SPRAY
		zolmitriptan spray

## Injectable

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
IMITREX (sumatriptan) 6 MG/0.5 ML CARTRIDGE – Brand Required	IMITREX (sumatriptan) 4 MG/0.5 ML CARTRIDGE
IMITREX (sumatriptan) 6 MG/0.5 ML PEN INJECTOR – Brand Required	IMITREX (sumatriptan) 4 MG/0.5 ML PEN INJECTOR
	sumatriptan cartridge
	sumatriptan pen injector
	sumatriptan vial
	ZEMBRACE SYMTOUCH (sumatriptan)

## Prior Authorization Criteria

### Initial Criteria – Approval Duration: 12 months

14. The member must be unable to take oral medications (subject to clinical review).

### Non-Preferred Agent Criteria:

- See [Preferred Dosage Form](#) criteria

## Therapeutic Duplication

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

## Cluster Headache

### Cluster Headache Prevention

#### CLINICAL PA REQUIRED

EMGALITY (galcanazumab-gnlm)

- Emgality is to be used as preventative treatment during episodic cluster headache episodes (cluster periods usually last between 2 weeks and 3 months with pain-free periods lasting at least 3 months), as it is not indicated for chronic use

## Prior Authorization Criteria

### Prior Authorization Form – Migraine Prophylaxis/Treatment

#### Initial Criteria – Approval Duration: 3 months

- The member has had at least five attacks fulfilling criteria A-C
  - Severe or very severe unilateral orbital, supraorbital and/or temporal pain lasting at least 15 minutes
  - Occurring with a frequency of at least every other day
  - The member must have at least one of the following:
    - A sense of restlessness or agitation

- Any of the following symptoms or signs, ipsilateral to the headache:
  - Conjunctival injection and/or lacrimation
  - Nasal congestion and/or rhinorrhea
  - Eyelid edema
  - Forehead and facial swelling
  - Miosis and/or ptosis
- The member must have had a 2-month trial with verapamil.

## Myasthenia Gravis

### Glucocorticoid-Sparing Therapy

#### Oral Agents

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

#### Biologic Agents

##### Acetylcholine Receptor (AChR) Antibody Positive

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

##### Muscle Specific Kinase (MuSK) Positive

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

#### Prior Authorization Criteria

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

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational).
- The requested medication must be prescribed by, or in consult with, a neurologist or neuromuscular specialist.
- The member must have all of the following:
  - Myasthenia Gravis Foundation of America (MGFA) clinical classification class of II, III, or IV



- Positive serological lab test for one of the following (A or B):
  - A. Anti-AchR antibodies
  - B. Anti-MuSK antibodies
- The member must have Myasthenia Gravis-specific Activities of Daily Living (MG-ADL) total score of one of the following:
  - For Zilbrysq (zilucoplan), Soliris (eculizumab), or Ultomiris (ravulizumab-cwvz) requests: ≥ 6
  - For Vyvgart (efgartigimod alfa-fcab) or Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc) requests: ≥ 5
  - For Rystiggo (rozanolixizumab-noli) requests: ≥ 3 (with at least 3 points from non-ocular symptoms)
- Rituxan Only: See [Biosimilar Agents](#) Criteria

*Acetylcholine Receptor (AChR) Antibody Positive*

- One of the following (A or B):
  - A. The member is unable to complete glucocorticoid bridge therapy (e.g., diabetes) while waiting for efficacy of oral immunosuppressive therapies (e.g., azathioprine, cyclosporine, mycophenolate mofetil, tacrolimus)
  - B. The member required chronic intravenous immunoglobulin (IVIG) or chronic plasmapheresis/plasma exchange (i.e., at least every 3 months over 12 months without symptom control), despite a 12-month trial (total duration) of immunosuppressive therapies (e.g., azathioprine, cyclosporine, mycophenolate mofetil, tacrolimus)
- Soliris Only:
  - The member required chronic intravenous immunoglobulin (IVIG) or chronic plasmapheresis/plasma exchange (i.e., at least every 3 months over 12 months without symptom control), despite a 90-day trial or recommended cycle duration of each of the following:
    - A. Rituximab
    - B. Ultomiris
    - C. Vyvgart or Rystiggo

*Muscle Specific Kinase (MuSK) Positive*

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

*Renewal Criteria – Approval Duration: 12 months*

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

## Multiple Sclerosis

### Injectable Agents

*B-cell and T-cell Therapies*

PREFERRED AGENTS (NO PA REQUIRED)	PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
BRIUMVI (ublituximab-xiyy) – Medical Billing Only	TYSABRI (natalizumab) – Medical Billing Only	MAVENCLAD (cladribine)
KESIMPTA (ofatumumab)		LEMTRADA (alemtuzumab) – Medical Billing Only
OCREVUS (ocrelizumab) – Medical Billing Only		

### Prior Authorization Criteria

#### Initial Criteria – Approval Duration: 12 months

##### Tysabri Only:

- The requested medication must be prescribed by, or in consult with, a neurologist

##### Non-Preferred Agents:

- The member must have failed a 3-month trial of two agents in the class of the requested product, as evidenced by paid claims or pharmacy print outs.

##### Interferons

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AVONEX (interferon beta-1A) PEN	BETASERON (interferon beta-1B)
AVONEX (interferon beta-1A) SYRINGE	EXTAVIA (interferon beta-1B)
AVONEX (interferon beta-1A) VIAL	PLEGRIDY (peginterferon beta-1A) PEN
	PLEGRIDY (peginterferon beta-1A) SYRINGE
	REBIF (interferon beta-1A)
	REBIF REBIDOSE (interferon beta-1A)

### Prior Authorization Criteria

#### Initial Criteria – Approval Duration: 12 months

- The member must have failed a 3-month trial of the preferred agent in the class of the requested product, as evidenced by paid claims or pharmacy print outs.

##### Non-Interferons

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
COPAXONE (glatiramer) 20 MG/ML – Brand Required	COPAXONE (glatiramer) 40 MG/ML
	glatiramer 20 mg/ml
	glatiramer 40 mg/ml
	GLATOPA (glatiramer)

### Prior Authorization Criteria

#### Initial Criteria – Approval Duration: 12 months

- Copaxone: See [Preferred Dosage Form](#) criteria

## Oral Agents

##### Fumerates

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
dimethyl fumarate	BAFIERTAM (monomethyl fumarate)
	TECFIDERA (dimethyl fumarate)
	VUMERITY (diroximel fumarate)

##### Pyrimidine Synthesis Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
Teriflunomide	AUBAGIO (teriflunomide)

## Sphingosine 1-Phosphate (S1P) Receptor Modulators

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
fingolimod 0.5 mg	GILENYA (fingolimod) 0.5 MG
GILENYA (fingolimod) 0.25 MG	MAYZENT (siponimod)
TASCENSO ODT (fingolimod)	PONVORY (ponesimod)
	ZEPOSIA (ozanimod)

### Prior Authorization Criteria

#### Initial Criteria – Approval Duration: 12 months

- The member must have failed a 3-month trial of all oral preferred agents of an unique ingredient, as evidenced by paid claims or pharmacy print outs.

## Neuromyelitis Optica Spectrum Disorder

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ENSPRYNG (satralizumab-mwge)	SOLIRIS (eculizumab) – <i>Medical Billing Only</i>
ULTOMIRIS (ravulizumab-cwvz) – <i>Medical Billing Only</i>	
UPLIZNA (inebilizumab) – <i>Medical Billing Only</i>	

### Prior Authorization Criteria

#### Initial Criteria – Approval Duration: 6 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational).
- The requested medication must be prescribed by, or in consult with, a neurologist
- The member has positive serologic test for anti-AQP4 antibodies.
- The member has a history of  $\geq 1$  relapses that required rescue therapy within the past 12 months
- The member has an Expanded Disability Status Score (EDSS) of  $\leq 6.5$
- The member must have one of the core clinical characteristics from the following:
  - Optic neuritis
  - Acute myelitis
  - Area postrema syndrome: episode of otherwise unexplained hiccups or nausea and vomiting
  - Acute brainstem syndrome
  - Symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions
  - Symptomatic cerebral syndrome with NMOSD-typical brain lesions

#### Non-Preferred Agents Criteria

- The member must have had a 3-month trial with Enspryng, Ultomiris and Uplizna, as evidenced by paid claims or pharmacy print outs:

#### Renewal Criteria – Approval Duration: 12 months

- The member must have experienced stabilization, slowing of disease progression, or improvement of the condition since starting treatment with the requested medication, as evidenced by medical documentation (e.g., chart notes) attached to the request (subject to clinical review) including:
  - Reduction in relapse rate
  - Reduction in symptoms (such as pain, fatigue, motor function)

## Pseudobulbar Affect (PBA)

CLINICAL PA REQUIRED
NUDEXTA (dextromethorphan/quinidine)

## Prior Authorization Criteria

### [Prior Authorization Form – Nuedexta](#)

#### Initial Criteria – Approval Duration: 3 months

- The member must not have a diagnosis of any of the following: prolonged QT interval, heart failure, or complete atrioventricular (AV) block.
- The following must be provided:
  - Baseline Center for Neurological Studies lability (CNS-LS) score
  - Baseline weekly PBA episode count
- The member must have diagnosis of pseudobulbar affect (PBA) due to one of the following neurologic conditions and meet additional criteria for diagnosis:
  - Amyotrophic Lateral Sclerosis (ALS)
  - Multiple Sclerosis (MS)
  - Alzheimer’s Disease
  - Stroke
- For diagnosis of PBA due to Alzheimer’s disease or stroke only:
  - Neurologic condition must have been stable for at least 3 months
  - Member must have failed a 3-month trial of at least one medication from each of the following classes, as evidenced by paid claims or pharmacy print outs:
    - SSRIs: sertraline, fluoxetine, citalopram and paroxetine
    - Tricyclic Antidepressants: nortriptyline and amitriptyline
  - Documentation of each treatment failure of SSRI and tricyclic antidepressant must be provided, as evidenced by a PBA episode count and CNS-LS score before and after each trial showing one of the following:
    - PBA count has not decreased by more than 75 percent from baseline
    - CNS-LS score has not decreased by more than 7 points from baseline

#### Renewal Criteria – Approval Duration: 6 months

- Benefit of continued therapy must be assessed.
  - Spontaneous improvement of PBA occurs and should be ruled out periodically before continuing medication.
- For diagnosis of PBA due to Alzheimer’s disease or stroke only:
  - Current CNS-LS score must be reduced by at least 30% from baseline
- For all other indications:
  - Current PBA episode must be reduced by at least 75% from baseline

## Parkinson’s disease

### Parkinson’s Agents – First Line Therapy

#### Parkinson’s Agents – Levodopa

<b>PREFERRED AGENTS (NO PA REQUIRED)</b>	<b>NON-PREFERRED AGENTS (PA REQUIRED)</b>
carbidopa-levodopa-entacapone 25 mg/100 mg, 37.5 mg/150 mg, 50 mg/200 mg	carbidopa-levodopa-entacapone 12.5 mg/50 mg, 18.75 mg/75 mg, 31.25 mg/125 mg
carbidopa-levodopa	CREXONT (carbidopa-levodopa ER)
carbidopa-levodopa ER	DHIVY (carbidopa-levodopa)
carbidopa-levodopa ODT	SINEMET (carbidopa-levodopa) TABLET
RYTARY (carbidopa-levodopa) ER CAPSULE	STALEVO (carbidopa-levodopa-entacapone)

## Prior Authorization Criteria

- See [Preferred Dosage Form](#) criteria

## Parkinson's Agents – Adjunctive Therapy

### Parkinson's Agents – Adenosine Receptor Agonists

Oral

#### CLINICAL PA REQUIRED

NOURIANZ (Istradefylline)

## Prior Authorization Criteria

### Initial Criteria – Approval Duration: 3 months

- The requested medication must be prescribed by, or in consult with, a neurologist
- The member has a minimum of 3 hours of “off” time per day despite a 3-month trial of combination therapy with a carbidopa/levodopa, a dopamine agonist, a COMT inhibitor, a MOA-B inhibitor, and amantadine.
- The member has had a previous response to levodopa.

### Renewal Criteria – Approval Duration: 12 months

- The member has had either a 50% reduction or 3-hour reduction in hours per day of “off” time.

### Parkinson's Agents - Amantadine

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
amantadine IR capsule	amantadine IR tablet
amantadine solution	GOCOVRI (amantadine ER)
	OSMOLEX ER (amantadine ER)

## Electronic Age Verification:

- Amantadine: Member must be 18 years old or older

## Prior Authorization Criteria

### Initial Criteria – Approval Duration: 12 months

- The member must not reside in facility where medications are managed such as skilled nursing care.
- See [Preferred Dosage Form](#) Criteria

### Parkinson's Agents – Anticholinergics

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
benztropine	COGENTIN (benztropine)
trihexyphenidyl	

### Parkinson's Agents – COMT inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
entacapone	COMTAN (entacapone)

TASMAR (tolcapone) – <i>Brand Required</i>	ONGENTYS (opicapone)
	tolcapone

### Prior Authorization Criteria

#### Initial Criteria – Approval Duration: 12 months

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

### Parkinson’s Agents – Ergot Dopamine Receptor Agonists

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
bromocriptine	PARLODEL (bromocriptine)

### Parkinson’s Agents – MAO-B Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
rasagiline	AZILECT (rasagiline)
selegiline	EMSAM (selegiline) PATCH
ZALAPAR ODT (selegiline)	XADAGO (safinamide)

### Prior Authorization Criteria

#### Emsam Only:

- See [Preferred Dosage Form](#) and [Non-Solid Oral Dosage Form](#) criteria

#### Xadago Only:

- Initial Criteria – Approval Duration: 3 months
  - The requested medication must be prescribed by, or in consult with, a neurologist
  - The member has a minimum of 3 hours of “off” time per day despite a 3-month trial of combination therapy with a carbidopa/levodopa, a dopamine agonist, a COMT inhibitor, a MOA-B inhibitor, and amantadine.
  - The member has had a previous response to levodopa.
- Renewal Criteria – Approval Duration: 12 months
  - The member has had either a 50% reduction or 3-hour reduction in hours per day of “off” time.

### Parkinson’s Agents – Non-ergot Dopamine Receptor Agonists

#### Oral

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
pramipexole IR	MIRAPEX (pramipexole)
ropinirole IR	MIRAPEX ER (pramipexole)
ropinirole ER	pramipexole ER
	REQUIP (ropinirole)

#### Topical

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	NEUPRO (rotigotine) PATCH

### Prior Authorization Criteria

#### Initial Criteria – Approval Duration: 12 months

- The member must not reside in facility where medications are managed such as skilled nursing care.
- Clinical justification must be provided explaining why the member is unable to use the preferred agents (subject to clinical review).
- Pramipexole ER: See [Preferred Dosage Form](#) criteria

## Parkinson' Agents – Device-Assisted Refractory Therapies

### Enteral Suspension

#### CLINICAL PA REQUIRED

DUOPA (levodopa/carbidopa)

### Subcutaneous

#### CLINICAL PA REQUIRED

VYALEV (foscarbidopa/foslevodopa)

### Prior Authorization Criteria

#### Initial Criteria – Approval Duration: 3 months

- The requested medication must be prescribed by, or in consult with, a neurologist
- The member has a minimum of 3 hours of “off” time per day despite a 3-month trial of combination therapy with a carbidopa/levodopa, a dopamine agonist, a COMT inhibitor, a MOA-B inhibitor, and amantadine.
- The member has had a previous response to levodopa.

#### Renewal Criteria – Approval Duration: 12 months

- The member has had either a 50% reduction or 3-hour reduction in hours per day of “off” time.

## Parkinson's Agents – On-Demand Rescue for “Off” Episodes

### Subcutaneous

#### PREFERRED AGENTS (CLINICAL PA REQUIRED)

APOKYN (apomorphine) – *Brand Required*

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

apomorphine

### Inhalation

#### PREFERRED AGENTS (CLINICAL PA REQUIRED)

INBRIJA (levodopa)

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

### Prior Authorization Criteria

#### Initial Criteria – Approval Duration: 12 months

- The requested medication must be prescribed by, or in consult with, a neurologist
- The member must be currently taking carbidopa – levodopa, as evidenced by paid claims or pharmacy printouts, and will continue taking carbidopa – levodopa concurrently with requested agent
- Documentation must be provided of intermittent hypomobility or off episodes (number and frequency)
- At least one of the following criteria must be met:
  - The member is experiencing unpredictable off periods, morning off, delayed on, no on or failure of on response



- The member is experiencing wearing off episodes or other levodopa dose cycle related dystonias or akathisias, and a treatment adjustment plan is attached (e.g., levodopa dose and interval adjustments, bedtime dose of CR or ER levodopa/ carbidopa, addition of adjunctive therapy)

## Spinal Muscular Atrophy (SMA)

### SMN2 Gene Splicing Modifiers

#### CLINICAL PA REQUIRED

EVRYSDI (risdiplam)

SPINRAZA (nusinersen) – *Medical Billing Only*

#### *Prior Authorization Criteria*

#### [Prior Authorization Form – Evrysdi](#)

#### Initial Criteria – Approval Duration: 12 months

- The member must have a diagnosis of spinal muscular atrophy (SMA) with each of the following:
  - Bi-allelic deletions or mutations of SMN1 as confirmed by genetic testing, reported as one of the following:
    - Homozygous deletions of exon 7
    - Compound heterozygous mutations
  - One of the following:
    - The member has number of SMN2 gene copies  $\geq 1$  but  $\leq 4$  as confirmed by genetic testing
    - The member is symptomatic (e.g., loss of reflexes, motor delay, motor weakness, abnormal EMG/neuromuscular ultrasound)
- The requested medication must be prescribed by, or in consult with, a neuromuscular neurologist or neuromuscular physiatrist (medical geneticist may be allowed for initial request)
- The member must visit with a neuromuscular clinic - clinic name and contact information and date of last visit must be provided, and date of last visit must be within the last year (short term 6-month bypass of this criteria may be granted to allow time for appointment scheduling if genetic test showing 0 copies of SMN1 and SMN2 gene copies  $\geq 1$  but  $\leq 4$  is provided):
- The member must not require continuous intubation  $> 3$  weeks
- The member must not have received gene therapy (i.e., Zolgensma)
- The member's weight and prescribed dose must be provided and within dosing recommendations per the manufacturer label
- The member's baseline motor milestone score results must be provided from at least two of the following assessments (short term 6-month bypass of this criteria may be granted to allow time for appointment scheduling if genetic test showing 0 copies of SMN1 and SMN2 gene copies  $\geq 1$  but  $\leq 4$  is provided):
  - Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorder (CHOP-INTEND)
  - Hammersmith Infant Neurological Examination (HINE) Section 2 motor milestone score
  - Hammersmith Functional Motor Scale Expanded (HFMSE)
  - Motor Function Measure – 32 items (MFM-32)
  - Revised Upper Limb Module (RULM)
  - 6-minute walk test (6MWT)
  - Forced Vital Capacity (FVC and FEV1) via Pulmonary Function Test
- Spinraza Only: The member must not have severe contractures or severe scoliosis

#### Renewal Criteria – Approval Duration: 12 months

- The member's weight and prescribed dose must be provided and within dosing recommendations per the manufacturer label
- The member must visit with a neuromuscular clinic - clinic name, contact information, and date of last visit must be provided, and date of last visit must be within the last year

- The provider must submit motor milestone score results showing that the member has experienced clinical benefit (defined as maintenance of baseline motor function or significant slowed rate of decline vs expected natural course of the disease) since starting treatment, as evidenced by documentation of one of the following:
  - Current Forced Vital capacity (FVC and FEV1) via Pulmonary Function Test
  - CHOP-INTEND, HINE, HFMSE, MFM-32, 6MWT, or RULM scores

## Gene Therapy

### CLINICAL PA REQUIRED

ZOLGENSMA (onasemnogene abeparvovec) – *Medical Billing Only*

#### Prior Authorization Criteria

##### Initial Criteria – Approval Duration: 1 month (Approval is limited to a single intravenous infusion per lifetime)

- The member is less than 2 years of age
- The diagnosis is spinal muscular atrophy (SMA) with genetic testing confirming bi-allelic deletions or mutations in the *SMN1* gene
- The medication is prescribed per the dosing guidelines in the package insert (recommended dose is  $1.1 \times 10^{14}$  vector genomes per kilogram)
- Baseline Documentation has been provided confirming anti-adenovirus serotype 9 (anti-AAV9) antibody titer is  $\leq 1:50$  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 or more hours per day (including noninvasive ventilatory support) continuously for 14 or more days in the absence of an acute reversible illness, excluding perioperative ventilation.

## Tardive Dyskinesia

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

#### Electronic Step Therapy Required

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

#### Prior Authorization Criteria

##### [Prior Authorization Form – Tardive Dyskinesia](#)

##### Initial Criteria – Approval Duration: 12 months

- The requested medication must be prescribed by, or in consult with, a psychiatric or neurology specialist.
- The member must have a history of treatment with dopamine receptor blocking agent (DRBA).
- The member must have a total AIMS score (items 1-7) of  $\geq 6$  or AIMS score on item 8 or item 9  $\geq 3$

##### Renewal Criteria – Approval Duration: 12 months

- The member must have had improvement in AIMS score from baseline

# Obstetrics/Gynecology

## Endometriosis Pain

### CLINICAL PA REQUIRED

MYFEMBREE (relugolix, estradiol, and norethindrone acetate)

ORILISSA (elagolix)

### Prior Authorization Criteria

#### Initial Criteria – Approval Duration: 6 months

- The member must have failed the following trials (A and B), as evidenced by paid claims or pharmacy printouts:
  - A 3-menstrual cycle trial of mefenamic acid or meclofenamate, celecoxib, ibuprofen 1800 mg/day or equivalent high dose NSAID
  - A 3-menstrual cycle trial of an oral estrogen-progestin or progestin contraceptives

#### Renewal Criteria – Approval Duration: 18 months

- Documentation must be submitted of improvement in pain score from baseline

### Electronic Diagnosis Verification

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

## Estrogens

### Injectable

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
DELESTROGEN (estradiol valerate) INJECTION – Brand Required	estradiol valerate injection
DEPO-ESTRADIOL (estradiol cypionate) INJECTION	PREMARIN (estrogens, conjugated) INJECTION

### Oral

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
estradiol tablet	ACTIVELLA (estradiol-norethindrone) TABLET
estradiol-norethindrone tablet	AMABELZ (estradiol-norethindrone) TABLET
norethindrone-ethinyl estradiol tablet	BIJUVA (estradiol-progesterone) CAPSULE
PREMARIN (estrogens, conjugated) TABLET	ESTRACE (estradiol) TABLET
PREMPHASE (estrogen, conj. M-progest) TABLET	FEMHRT (norethindrone-ethyl estradiol) TABLET
PREMPRO (estrogen, conj. M-progest) TABLET	FYAVOLV (norethindrone-ethinyl estradiol) TABLET
	MENEST (estrogens, esterified) TABLET
	JINTELI (norethindrone-ethinyl estradiol) TABLET
	MIMVEY (estradiol-norgestimate) TABLET
	PREFEST (estradiol-norgestimate) TABLET

### Topical Gel/Spray

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ELESTRIN (estradiol) GEL MDP	DIVIGEL (estradiol) GEL PACKET
EVAMIST (estradiol) SPRAY	estradiol gel

### Topical Patch

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ALORA (estradiol) PATCH TWICE WEEKLY - Brand Required	CLIMARA (estradiol) PATCH WEEKLY
CLIMARA PRO (estradiol-levonorgestrel) PATCH - ONCE WEEKLY	DOTTI (estradiol) PATCH TWICE WEEKLY
COMBIPATCH (estradiol- norethindrone) PATCH - TWICE WEEKLY	estradiol patch twice weekly
estradiol patch weekly	LYLLANA (estradiol) PATCH TWICE WEEKLY
MENOSTAR (estradiol) PATCH ONCE WEEKLY	
MINIVELLE (estradiol) PATCH TWICE WEEKLY - Brand Required	
VIVELLE-DOT (estradiol) PATCH TWICE WEEKLY - Brand Required	

### Vaginal

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
estradiol vaginal cream	ESTRACE (estradiol) CREAM
ESTRING (estradiol)	estradiol vaginal tablet
FEMRING (estradiol)	YUVAFEM (estradiol) VAGINAL TABLET
PREMARIN (estrogens, conjugated) CREAM	
VAGIFEM (estradiol) VAGINAL TABLET – Brand Required	

### Electronic Diagnosis Verification

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

### Prior Authorization Criteria

#### Initial Criteria – Approval Duration: 12 months

- The member must have failed 30-day trials of at least two preferred products, as evidenced by paid claims or pharmacy printouts.

## Long-Acting Contraception

### Therapeutic Duplication

- One strength of one medication is allowed at a time

## Menopause – Vasomotor Symptoms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
citalopram	BRISDELLE (paroxetine mesylate)
clonidine	paroxetine mesylate 7.5mg capsules
desvenlafaxine	VEOZAH (fezolinetant)
escitalopram	
<a href="#">estrogen products</a>	
gabapentin	
oxybutynin	
paroxetine hydrochloride tablets	

*Prior Authorization Criteria*Initial Criteria - Approval Duration: 12 months

- BOTH of the following must be met (1 and 2):
  1. One of the following must be met (a or b):
    - a. The member must have failed a 90-day trial of estrogen therapy, as evidenced by paid claims or pharmacy printouts
    - b. The member has prior history of stroke, myocardial infarction, venous thromboembolism, coronary artery disease, or breast cancer.
  2. The member must have failed a 30-day trial of each of the following, as evidenced by paid claims or pharmacy printouts:
    - SNRI: Venlafaxine or desvenlafaxine
    - SSRI: citalopram, escitalopram, or paroxetine
- Paroxetine mesylate: See Preferred Dosage Form Criteria

**References:**

1. Khan SJ, Kapoor E, Faubion SS, Kling JM. Vasomotor Symptoms During Menopause: A Practical Guide on Current Treatments and Future Perspectives. *Int J Womens Health*. 2023 Feb 14;15:273-287. doi: 10.2147/IJWH.S365808. PMID: 36820056; PMCID: PMC9938702.

**Mifepristone***Electronic Diagnosis Verification*

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

[Prior Authorization Form – Mifepristone](#)Initial Criteria – Approval Duration: 1 month

- Gestational age must be less than or equal to 70 days
- One of the following criteria must be met (A or B):
  - A. Pregnancy must have resulted from an act of rape or incest, and one of the following (I or II)**
    - I. A written statement signed by the provider must be submitted stating that the rape or act of incest has been reported to the appropriate law enforcement agency, or in the case of a minor who is a victim of incest, to an agency authorized to receive child abuse and neglect reports and it must be indicated to whom the report was made.
    - II. A written statement signed by the member and the provider must be submitted stating that the member's pregnancy resulted from rape or incest and by professional judgement, the provider agrees with the statement.
  - B. Both of the following must be met (I and II)**
    - I. The member must suffer from a physical disorder, physical injury, or physical illness, including a life-endangering physical condition caused by or arising from the pregnancy itself, that would as certified by a provider, place the member in danger of death unless an abortion is performed
    - II. A written statement signed by the provider must be provided indicating why, in the provider's professional judgement, the life of the member would be endangered if the fetus were carried to term

**Nausea/Vomiting – Pregnancy****PREFERRED AGENTS (NO PA REQUIRED)****NON-PREFERRED AGENTS (PA REQUIRED)**

DICLEGIS (doxylamine/vitamin B6) – <i>Brand Required</i>	BONJESTA (doxylamine/vitamin B6)
meclizine	doxylamine/vitamin B6
metoclopramide	
ondansetron	

### Prior Authorization Criteria

#### Initial Criteria – Approval Duration: until due date

- Member's due date must be provided
- See [Preferred Dosage Form](#) criteria

## Progesterone

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
progesterone capsule	

### Electronic Diagnosis Verification

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

## Uterine Fibroids

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
MYFEMBREE (relugolix, estradiol, and norethindrone acetate)	ORIAHNN (elagolix, estradiol, and norethindrone acetate)

### Prior Authorization Criteria

#### Initial Criteria – Approval Duration: 6 months

- The member must have failed the following trials (A and B), as evidenced by paid claims or pharmacy printouts:
  - A 3-menstrual cycle trial of mefenamic acid or meclufenamate, celecoxib, ibuprofen 1800 mg/day or equivalent high dose NSAID
  - A 3-menstrual cycle trial of an oral estrogen-progestin or progestin contraceptives

#### Renewal Criteria – Approval Duration: 18 months

- Documentation must be submitted of improvement in pain score from baseline

### Electronic Diagnosis Verification

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

## Vaginal Infections

### Bacterial Infections

#### Oral

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
metronidazole tablet	

#### Vaginal

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
CLEOCIN (clindamycin) SUPPOSITORY	CLINDESSE (clindamycin) CREAM

clindamycin cream	VANDAZOLE (metronidazole) GEL
metronidazole gel	
NUVESSA (metronidazole) GEL	
XACIATO (clindamycin phosphate) GEL	

## Fungal Infections

### Oral

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
fluconazole tablet	BREXAFEMME (ibrexafungerp) TABLETS
tinidazole tablet	VIVJOA (oteseconazole) CAPSULES

### Vaginal

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
terconazole cream	GYNAZOLE 1 (butoconazole) CREAM
terconazole suppository – labeler 00713	terconazole suppository – labeler 45802

### Prior Authorization Criteria

#### Initial Criteria – Approval Duration: 12 months

- The member must have failed 30-day trials of all preferred agents of unique ingredients, as evidenced by paid claims or pharmacy printouts.
- Vivjoa Only:
  - The member must have failed a six-month trial of oral fluconazole maintenance prophylaxis treatment
  - The member must not be of reproductive potential defined as:
    - The member is postmenopausal
    - The member is known to not be of reproductive potential (e.g., history of tubal ligation, salpingo-oophorectomy, or hysterectomy)

## Ophthalmology

### Antihistamines

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
azelastine	ALOCRIIL (nedocromil)
BEPREVE (bepotastine) – <i>Brand Required</i>	ALOMIDE (Iodoxamide)
cromolyn	bepotastine
olopatadine 0.1%	epinastine
PAZEO (olopatadine)	olopatadine 0.2%
	ZERVIAATE (cetirizine)

### Prior Authorization Criteria

#### Initial Criteria – Approval Duration: 12 months

- The member must have failed 30-day trials of olopatadine and bepotastine, as evidenced by paid claims or pharmacy printouts.



## Anti-infectives

### Drops

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
BESIVANCE (besifloxacin) DROPS	AZASITE (azithromycin) DROPS
ciprofloxacin drops	CILOXAN (ciprofloxacin) DROPS
gentamicin sulfate drops	gatifloxacin drops
moxifloxacin drops (generic Vigamox)	moxifloxacin drops (generic Moxeza)
neomycin SU/polymyxin B/gramicidin drops	NATACYN (natamycin) DROPS
ofloxacin drops	OCUFLOX (ofloxacin) DROPS
polymyxin B/trimethoprim drops	POLYTRIM (polymyxin B/trimethoprim) DROPS
sulfacetamide drops	VIGAMOX (moxifloxacin) DROPS
tobramycin drops	
ZYMAXID (gatifloxacin) DROPS – <i>Brand Required</i>	

### Ointment

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
bacitracin/polymyxin B ointment	bacitracin ointment
CILOXAN (ciprofloxacin) OINTMENT	NEO-POLYCIN (neomycin SU/bacitracin/polymyxin B) OINTMENT
erythromycin ointment	POLYCIN (bacitracin/polymyxin B) OINTMENT
GENTAK (gentamicin sulfate) OINTMENT	sulfacetamide ointment
neomycin SU/bacitracin/polymyxin B ointment	
TOBREX (tobramycin) OINTMENT	

### Prior Authorization Criteria

#### Initial Criteria – Approval Duration: 12 months

- The member must have failed a 5-day trial of a preferred agent in each unique therapeutic class, as evidenced by paid claims or pharmacy printouts.

## Anti-infectives/Anti-inflammatories

### Drops

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
neomycin/polymyxin b/dexamethasone drops	MAXITROL (neomycin/polymyxin b/dexamethasone) DROPS
sulfacetamide/prednisolone drops	neomycin/polymyxin b/hydrocortisone drops
tobramycin/dexamethasone drops	
TOBRADEX ST (tobramycin/dexamethasone) DROPS	
ZYLET (tobramycin/lotepred etab) DROPS	

### Ointment

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
neomycin/polymyxin b/dexamethasone ointment	MAXITROL (neomycin/polymyxin b/dexamethasone) OINTMENT
TOBRADEX (tobramycin/dexamethasone) OINTMENT	neomycin/bacitracin/polymyxin b/hydrocortisone ointment
	NEO-POLYCIN HC (neomycin SU/bacitracin/

polymyxin B/hydrocortisone) OINTMENT
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### Prior Authorization Criteria

#### Initial Criteria – Approval Duration: 12 months

- The member must have failed a 5-day trial of a preferred agent in each unique therapeutic class, as evidenced by paid claims or pharmacy printouts.

## Anti-inflammatories

### Corticosteroids

#### Drops

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ALREX (loteprednol) DROPS – <i>Brand Required</i>	clobetasol 0.05% drops
FLAREX (fluorometholone) DROPS	dexamethasone sodium phosphate drops
fluorometholone drops	difluprednate drops
FML FORTE (fluorometholone) DROPS	DUREZOL (difluprednate) DROPS
LOTEMAX (loteprednol) DROPS – <i>Brand Required</i>	INVELTYS (loteprednol) DROPS
LOTEMAX (loteprednol) GEL DROPS – <i>Brand Required</i>	FML (fluorometholone) DROPS
MAXIDEX (dexamethasone) DROPS	LOTEMAX SM (loteprednol) DROPS
PRED MILD 0.12% (prednisolone acetate) DROPS	loteprednol eye drops
prednisolone acetate 1% drops	loteprednol gel eye drops
prednisolone sodium phosphate 1% drops	PRED FORTE 1% (prednisolone acetate) DROPS

#### Ointment

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
FML S.O.P. (fluorometholone) OINTMENT	
LOTEMAX (loteprednol) OINTMENT	

### Non-Steroidal Anti-inflammatory Drugs (NSAIDS)

#### Drops

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ACUVAIL (ketorolac) DROPS	ACULAR (ketorolac) DROPS
diclofenac sodium drops	ACULAR LS (ketorolac) DROPS
ILEVRO (nepafenac) DROPS	bromfenac sodium drops
ketorolac tromethaminedrops	BROMSITE (bromfenac sodium) DROPS
NEVANAC (nepafenac) DROPS	
PROLENSA (bromfenac) DROPS – <i>Brand Required</i>	

### Prior Authorization Criteria

#### Initial Criteria – Approval Duration: 12 months

- The member must have failed a 5-day trial of each preferred agent in the respective therapeutic class, as evidenced by paid claims or pharmacy printouts.

## Dry Eye Syndrome

### Initial Management - Lubricants

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ARTIFICIAL TEARS (dextran/hypromellose/glycerin)	FRESHKOTE (polyvinyl alcohol/povidone)
ARTIFICIAL TEARS (polyvinyl alcohol/povidone)	SENTIA (propylene glycol)
BION TEARS EYE DROPS (dextran 70/hypromellose)	VENTIVA (propylene glycol)
carboxymethylcellulose	VENTIVA (carboxymethylcellulose)
DRY EYE RELIEF (peg 400/Hypromellose/glycerin)	
GENTEAL TEARS (dextran/hypromellose/glycerin)	
GENTEAL TEARS (dextran 70/hypromellose)	
GENTEAL TEARS (hypromellose)	
LUBRICANT EYE DROPS (carboxymethylcellulose)	
LUBRICANT EYE DROPS (propylene glycol/peg 400)	
REFRESH (carboxymethylcellulose)	
REFRESH (polyvinyl alcohol/povidone)	
REFRESH (carboxymethylcellulose/glycerin)	
REFRESH (carboxymethylcellulose/glycerin/poly80)	
SYSTANE (hypromellose)	
SYSTANE (propylene glycol)	
SYSTANE (propylene glycol/peg 400)	

### Prior Authorization Criteria

#### Initial Criteria – Approval Duration: 12 months

- The member must have failed a 1-month trial of each preferred agent of a unique ingredient, as evidenced by paid claims or pharmacy printouts.
- See [Preferred Dosage Form](#) Criteria

#### Persistent Symptoms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED STEP 1 AGENTS (PA REQUIRED)	NON-PREFERRED STEP 2 AGENTS (PA REQUIRED)
EYSUVIS (loteprednol) DROPS	TYRVAYA (varenicline) NASAL SPRAY	CEQUA (cyclosporine)
RESTASIS (cyclosporine) DROPPERETTE – <i>Brand Required</i>		cyclosporine dropperette
XIIDRA (lifitegrast)		MIEBO (perfluorohexyloctane)
		RESTASIS MULTIDOSE (cyclosporine)
		VEVYE 0.1% EYE DROP (cyclosporine)

### Prior Authorization Criteria

#### Initial Criteria – Approval Duration: 12 months

#### Non-Preferred Step 1 Agents

- The requested medication must be prescribed by, or in consult with, an ophthalmologist.

- The member must have failed a 1-month trial of Eysuvis, a 6-month trial of Restasis and a 2-month trial of Xiidra, as evidenced by paid claims or pharmacy printouts.

*Non-Preferred Step 2 Agents:*

- The requested medication must be prescribed by, or in consult with, an ophthalmologist.
- The member must have failed a 6-month trial of Restasis and a 2-month trial of Xiidra, and a 1-month trial of Eysuvis and Tyrvaya as evidenced by paid claims or pharmacy printouts.
- Cyclosporine products: See [Preferred Dosage Form](#) criteria

## Glaucoma

### Alpha Adrenergic

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ALPHAGAN P 0.1% (brimonidine) DROPS – <i>Brand Required</i>	apraclonidine 0.5% drops
ALPHAGAN P 0.15% (brimonidine) DROPS – <i>Brand Required</i>	brimonidine 0.1% drops
brimonidine 0.2% drops	brimonidine 0.15% drops
COMBIGAN (brimonidine-timolol) DROPS – <i>Brand Required</i>	brimonidine-timolol 0.2%-0.5% drops
LUMIFY (brimonidine) 0.03% DROPS	IOPIDINE (apraclonidine) 1% DROPS
SIMBRINZA (brinzolamide/brimonidine) DROPS	

### Beta Blockers

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
BETOPTIC S (betaxolol) 0.25% DROPS	betaxolol 0.5% drops
carteolol drops	BETIMOL (timolol) DROPS
COMBIGAN (brimonidine/timolol) DROPS – <i>Brand Name Required</i>	brimonidine/timolol drops
dorzolamide/timolol drops	COSOPT (dorzolamide/timolol) PF DROPS
ISTALOL (timolol maleate) DROPS ONCE DAILY – <i>Brand Required</i>	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) – <i>Brand Required</i>	brinzolamide
dorzolamide	COSOPT (dorzolamide/timolol)
dorzolamide/timolol	TRUSOPT (dorzolamide)
SIMBRINZA (brinzolamide/brimonidine)	

## Prostaglandins

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
latanoprost	bimatoprost 0.03%
LUMIGAN (bimatoprost) 0.01%	IYUZEH (latanoprost/pf)
ROCKLATAN (netarsudil/latanoprost)	tafluprost/pf
	TRAVATAN Z (travoprost)
	travoprost
	VYZULTA (latanoprostene)
	XALATAN (latanoprost)
	XELPROS (latanoprost)
	ZIOPTAN (tafluprost/pf)

### Prior Authorization Criteria

- The member must have failed a 14-day trial of each of the preferred agents, as evidenced by paid claims or pharmacy printouts.

## Rho Kinase Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
RHOPRESSA (netarsudil)	
ROCKLATAN (netarsudil/latanoprost)	

## Presbyopia

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
pilocarpine	ISOPTO CARPINE (pilocarpine)
	VUITY (pilocarpine hydrochloride)

### Prior Authorization Criteria

#### Initial Criteria – Approval Duration: 12 months

- See [Preferred Dosage Form](#) criteria
- The requested medication must be prescribed by, or in consult with, an optometrist or ophthalmologist.
- Documentation of medical necessity must be provided, including contraindication to the use of corrective lenses and how activities of daily living are adversely impacted due to inability to correct vision with corrective lenses.

#### Renewal Criteria – Approval Duration: 12 months

- Documentation must be provided including activities of daily living are positively impacted by drug therapy.

## Inherited Retinal Dystrophy

CLINICAL PA REQUIRED
LUXTURNA (aglucosidase alfa) – <i>Medical Billing Only</i>

### Prior Authorization Criteria

#### Initial Criteria – Approval Duration: Approval Duration: 1 month (once per lifetime per eye)

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational).

- The requested medication must be prescribed by, or in consult with, an ophthalmologist or retinal surgeon with experience providing subretinal injections
- The member must have a diagnosis of inherited retinal dystrophy (i.e., Leber's congenital amaurosis [LCA], retinitis pigmentosa [RP]); confirmed by biallelic pathogenic variants in the RPE65 gene by molecular genetic testing (as evidenced with submitted documentation)
- The member has sufficient viable retinal cells as measured by OCT (optical coherence tomography) defined as one of the following:
  - retinal thickness greater than 100 microns within the posterior pole
  - ≥ 3-disc areas of the retina without atrophy or pigmentary degeneration within the posterior pole
  - remaining visual field within 30 degrees of fixation as measured by a III4e isopter or equivalent
- The member has remaining light perception in the eye(s) that will receive treatment.
- The member has not previously received RPE65 gene therapy in intended eye.

## Uveitis

### Adalimumab

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ABRILADA (adalimumab-afzb)	adalimumab-aacf
adalimumab-adbm – labeler 00597	adalimumab-aaty
adalimumab-fkjp	adalimumab-adaz
CYLTEZO (adalimumab-abdm)	adalimumab-adbm – labeler 82009
HADLIMA (adalimumab-bwwd)	adalimumab-ryvk
HULIO (adalimumab-fkjp)	AMJEVITA (adalimumab-atto)
HUMIRA (adalimumab)	HYRIMOZ (adalimumab-adaz)
SIMLANDI (adalimumab-ryvk)	IDACIO (adalimumab-aacf)
YUSIMRY (adalimumab-aqvh)	YUFLYMA (adalimumab-aaty)

### Vernal Keratoconjunctivitis

CLINICAL PA REQUIRED
VERKAZIA (cyclosporine) 0.1%

### Prior Authorization Criteria

#### Initial Criteria – Approval Duration: 6 months

- The requested medication must be prescribed by, or in consult with, an allergist or ophthalmologist.
- The member has failed\* a 3-month trial of combination of each of the following:
  - Topical dual-acting mast cell stabilizers/antihistamines (e.g., olopatadine, azelastine hydrochloride, epinastine, pemirolast potassium, or ketotifen fumarate)
  - Second- and third-generation oral antihistamines (e.g., fexofenadine, loratadine, desloratadine, cetirizine, or levocetirizine)
  - Cyclosporine ophthalmic emulsion 0.05%

\*Failure is defined as requiring frequent or prolonged courses of topical ophthalmic corticosteroids include prednisone acetate 1% and dexamethasone 0.1% for severe cases and prednisolone acetate 0.12%, fluorometholone, medrysone, loteprednol, etabonate 0.2 or 0.5%, and rimexolone 1% or compromised corneal epithelium

## Ophthalmology Injection- VEGF Inhibitor

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
BEOVU (brolucizumab-dbli) – Medical Billing Only	BYOOVIZ (ranibizumab -nuna) – Medical Billing Only

CIMERLI (ranibizumab-eqrn) – Medical Billing Only	LUCENTIS (ranibizumab) – Medical Billing Only
EYLEA (aflibercept) – Medical Billing Only	SUSVIMO (ranibizumab) – Medical Billing Only
PAVBLU (aflibercept-ayyh) – Medical Billing Only	
VABYSMO (faricimab-svoa) – Medical Billing Only	

**For the indication:**

1. Retinopathy of prematurity

*Prior Authorization Criteria*

- See [Medications that cost over \\$3000/month](#) Criteria

**For the indications:**

1. diabetic macular edema
2. macular edema following central retinal vein occlusion
3. macular edema following branch retinal vein occlusion
4. neovascular (wet) age-related macular degeneration

*Prior Authorization Criteria*

Initial Criteria – Approval Duration: 6 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational).
- The requested medication must be prescribed by, or in consult with, an ophthalmologist or retina specialist with experience providing intraocular injections and implants
- The member must have a mean visual acuity letter score (VALS) of 70 or Best Corrected Visual Acuity of 20/40 or worse at baseline
- The member must have failed a trial consisting of at least 2 doses of a bevacizumab agent

*Non-Preferred Agent Criteria:*

- Byooviz, Lucentis and Susvimo Only: See [Preferred Dosage Form Criteria](#)

Renewal Criteria – Approval Duration: 12 months

- The member must have experienced meaningful clinical benefit since starting treatment with the requested medication, as evidenced by medical documentation (e.g., chart notes) attached to the request (subject to clinical review) including improvement or stabilization in VALS, defined as a loss of not more than 5 letters compared to baseline.
- The member must have at least a mean VALS of 20 or BCVA of 20/400

## Otic

### Anti-infectives/Anti-inflammatories – Fluoroquinolones

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
CIPRO HC (ciprofloxacin/hydrocortisone)	ciprofloxacin/dexamethasone otic drops++
	ciprofloxacin/fluocinolone

++ Please note, for otitis externa with non-intact tympanic membrane, ciprofloxacin (eye drops) and ofloxacin (eye and ear drops) are required preferred agents.

If all the following conditions apply, please request an override for ciprofloxacin/dexamethasone by calling provider relations at 1-800-755-2604 or emailing [medicaidpharmacy@nd.gov](mailto:medicaidpharmacy@nd.gov):



- The member has tympanostomy tubes
- The member has otitis media
- There is granulation tissue present

### *Prior Authorization Criteria*

#### Initial Criteria – Approval Duration: 12 months

- The member must meet one of the following:
  - The member must have failed a 7-day trial of each of the preferred agent, as evidenced by paid claims or pharmacy printouts.

## Pain

### Lidocaine Patch

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
lidocaine 5% patch	LIDODERM (lidocaine) 5% PATCH
PREFERRED AGENTS (PA REQUIRED)	
ZTLIDO (lidocaine) 1.8% PATCH	

### *Prior Authorization Criteria*

#### Initial Criteria – Approval Duration: 12 months

- The member must have failed a 30-day trial of lidocaine 5% patch, as evidenced by paid claims or pharmacy printouts.

### Lidocaine Topical Cream

### *Prior Authorization Criteria*

#### Initial Criteria – Approval Duration: 12 months

- The request must be for injection pain from a medically necessary procedure

## NSAIDS

### Oral Solid Dosage Forms

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

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

### Electronic Diagnosis Verification

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

### Prior Authorization Criteria

#### Initial Criteria – Approval Duration: 12 months

- *Non-preferred agents with no same active ingredient preferred:*
  - The member must have failed a 30-day trial of 3 different oral generic NSAIDs including a COX-2 inhibitor if member has experienced GI intolerances, as evidenced by paid claims or pharmacy print outs
- *Non-preferred agents with same active ingredient preferred:*
  - See [Preferred Dosage Form](#) Criteria

### Therapeutic Duplication

- One strength of one medication is allowed at a time (topical and oral formulations are not allowed together)

If the following conditions apply, please call for an override by calling provider relations at 1-800-755-2604:

- The member is prescribed ketorolac and will stop regular NSAID therapy during course of ketorolac

### Oral Non-Solid Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ibuprofen suspension	indomethacin solution
naproxen suspension	

### Prior Authorization Criteria

#### Initial Criteria – Approval Duration: 12 months

- The member must have failed a 30-day trial of each preferred agent, as evidenced by paid claims or pharmacy print outs.

## Nasal Dosage Forms

### CLINICAL PA REQUIRED

ketorolac nasal spray

#### *Prior Authorization Criteria*

##### Initial Criteria – Approval Duration: 12 months

- The member must have failed a 30-day trial of 3 different oral generic NSAIDs including a COX-2 inhibitor if member has experienced GI intolerances, as evidenced by paid claims or pharmacy print outs
- Clinical justification must be provided explaining why the member is unable to use another dosage form (subject to clinical review).

## Topical Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
diclofenac gel	diclofenac 1.3% patch
diclofenac topical solution (all other labelers)	diclofenac 2% pump
FLECTOR (diclofenac) 1.3% PATCH – <i>Brand Required</i>	diclofenac topical solution (labeler 59088)
	LICART (diclofenac) PATCH 1.3%

#### *Prior Authorization Criteria*

- See [Preferred Dosage Form Criteria](#)

## Opioid Analgesics

The Centers for Disease Control (CDC) have [published guidelines](#) for the prescribing of opioids for pain.

#### *Therapeutic Duplication*

- One extended-release product/strength is allowed at a time
- One immediate release product is allowed (single ingredient or combination)
- Opioid-acetaminophen combination products are not allowed with acetaminophen
- Carisoprodol: The “Holy Trinity” consists of an opioid, a benzodiazepine, and carisoprodol and is a highly abused dangerous combination that can lead to additive CNS depression, overdose, and death. It is not covered.
- Methadone is not allowed with opioids, benzodiazepines, or opioid use disorder medications
- Morphine is not covered with clopidogrel, prasugrel, ticagrelor, and ticlopidine (does not include other opioid analgesics)
  - Morphine may diminish the antiplatelet effect and serum concentrations of P2Y12 Inhibitor antiplatelet agents (clopidogrel, prasugrel, ticagrelor, and ticlopidine).
- Tramadol immediate release with tramadol extended release

#### *Opioids and Benzodiazepine Concurrent Use*

##### [Opioid and Benzodiazepines Concurrent Use Form](#)

- Due to guidance in The SUPPORT for Members and Communities Act (H.R. 6) on CNS depression, this includes long-acting opioids over 90 MME/day or immediate release opioids over 15 MME/dose in combination with benzodiazepines.

##### Initial Criteria – Approval Duration: 12 months

- The member has access to an opioid reversal medication and has been counseled on overdose risk.
- The member has been counseled on the risks of utilizing opioids and benzodiazepines in combination with each other and other CNS depressing medications, including antipsychotics and sedatives.
- The member must currently be on long-acting opioid therapy or must not have achieved therapeutic goal with non-narcotic medication (NSAIDs, TCAs, SNRIs, corticosteroids, etc.) and non-medication alternatives (weight loss, physical therapy, cognitive behavioral therapy, etc.)
- One of the following criteria must be met:
  - The member resides in a facility with skilled nursing care.
  - The member must have taper plan of one or both agents.
  - The opioid medication must be prescribed by, or in consult with, with a palliative care, oncologist OR pain management specialist with a treatment plan including goals for pain and function, and urine and/or blood screens if the cumulative daily dose of opioids exceeds 90 MME/day (specialist requirement not applicable to skilled nursing facility residents or tapering requests).
- The prescriber(s) of both agents have provided reasons why opioid analgesics and benzodiazepines cannot be avoided, or lower doses be used (subject to clinical review).
- The past 3 months of the member's North Dakota PDMP reports must have been reviewed.

*Greater than 90 Morphine Milligram Equivalents (MME) per Day:*

Prior Authorization Form – Opioid Analgesics

- A cumulative maximum of 90 MME will be allowed without authorization: an MME calculator may be found at <https://www.mdcalc.com/calc/10170/morphine-milligram-equivalents-mme-calculator>

Initial Criteria – Approval Duration: 12 months

- One of the following criteria must be met:
  - The member resides in a facility with skilled nursing care.
  - The member must have taper plan of one or both agents.
  - The opioid medication must be prescribed by, or in consult with, with a palliative care, oncologist OR pain management specialist with a pain management contract with a treatment plan including goals for pain and function, and urine and/or blood screens

**Opioid Analgesics – Long Acting**

**Partial Agonist/Antagonist Opioids**

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
BELBUCA (buprenorphine)	buprenorphine patches
Butorphanol	
BUTRANS (buprenorphine) PATCHES - Brand Required	

**Abuse Deterrent Formulations/Unique Mechanisms from Full Agonists Opioids**

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
OXYCONTIN (oxycodone) – Brand Required	CONZIP (tramadol ER) CAPSULES
tramadol ER Tablets	hydrocodone ER tablets
	HYSINGLA ER (hydrocodone)
	levorphanol
	methadone
	MORPHABOND ER (morphine)
	tramadol ER capsules

## Full Agonist Opioids Without Abuse Deterrent Formulations

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
fentanyl 12 mcg/hr, 25 mcg/hr, 50 mcg/hr, 75 mcg/hr, 100 mcg/hr	fentanyl patch 37.5 mcg/hr, 62.5 mcg/hr, 87.5 mcg/hr
morphine ER tablets	hydrocodone ER capsules
	hydromorphone ER tablets
	morphine ER capsules
	MS CONTIN (morphine)
	oxycodone ER
	oxymorphone ER tablets

### Prior Authorization Criteria

#### [Prior Authorization Form – Opioid Analgesics](#)

##### Initial Criteria – Approval Duration: 12 months

- The past 3 months of the member's North Dakota PDMP reports must have been reviewed.
- One of the following criteria must be met:
  - The member has access to an opioid reversal medication and has been counseled on overdose risk.
  - The member resides in a facility with skilled nursing care.
- One of the following criteria must be met:
  - The member is currently on a long-acting opioid therapy.
  - The member must have been established on opioid therapy during hospitalization
  - Both of the following are met:
    - The member must have a diagnosis of cancer pain, palliative care, or sickle cell disease.
    - The member must currently be on around-the-clock opioid therapy of at least 30 Morphine Milligram equivalents (MME) for at least a week, as evidenced by paid claims or pharmacy printouts.
      - If member is unable to swallow (e.g., mucositis, head/neck radiation, head/neck cancers, uncontrollable vomiting) and has severe pain (>6/10), fentanyl patch 12 mcg/hr may be considered for approval for opioid naïve members (subject to clinical review).
  - Both of the following are met:
    - The member must currently be on around-the-clock opioid therapy of at least 30 Morphine Milligram equivalents (MME) for at least a week, as evidenced by paid claims or pharmacy printouts.
      - The member has not achieved therapeutic goal with non-narcotic medication (NSAIDs, TCAs, SNRIs, corticosteroids, etc.) and non-medication alternatives (weight loss, physical therapy, cognitive behavioral therapy, etc.).
- One of the following criteria must be met:
  - The member resides in a facility with skilled nursing care.
  - The member must have taper plan
  - The member must have with treatment plan including goals for pain and function, and urine and/or blood screens.

##### Fentanyl Patch:

- The member must have a BMI  $\geq 17$ .

##### Non-Preferred Agents Criteria:

- Clinical justification must be provided explaining why the member is unable to use other opioid and non-opioid analgesic agents (subject to clinical review).

##### Renewal Criteria – Approval Duration: 12 months

- One of the following must be met:
  - Progress toward therapeutic goal must be included with request (e.g., improvement in pain level, quality in life, or function).
  - The member must be stable on long-acting opioid medication for 2 years or longer.

### Underutilization

- Long-acting opioid analgesics must be used adherently and will reject on point of sale for late fill.

## Opioid Analgesic – Short Acting

### Fentanyl Products

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
fentanyl citrate effervescent tablet	ACTIQ (fentanyl) LOZENGE
fentanyl lozenge	FENTORA (fentanyl) EFFERVESCENT TABLET

### Opioid Combination Solid Oral Products

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
acetaminophen-codeine tablets	ENDOCET (oxycodone-acetaminophen)
benzhydrocodone-acetaminophen	hydrocodone-acetaminophen 2.5-325 MG
hydrocodone-acetaminophen 5-325 MG	hydrocodone-acetaminophen 10-300 MG
hydrocodone-acetaminophen 7.5-325 MG	hydrocodone-acetaminophen 5-300 MG
hydrocodone-acetaminophen 10-325 MG	hydrocodone-acetaminophen 7.5-300 MG
oxycodone-acetaminophen 5-325 MG, 7.5-325 MG, 10-325 MG	hydrocodone-ibuprofen 5-200 MG and 10-200 MG
tramadol-acetaminophen tablets	LORCET (hydrocodone-acetaminophen)
hydrocodone-ibuprofen 7.5-200 MG	NALOCET (oxycodone-acetaminophen)
	NORCO (hydrocodone-acetaminophen)
	oxycodone-acetaminophen 2.5-325 MG
	PERCOCET (oxycodone/acetaminophen)
	PRIMLEV (oxycodone/acetaminophen)
	PROLATE (oxycodone/acetaminophen)
	SEGLENTIS (celecoxib/tramadol)
	ULTRACET (tramadol/acetaminophen)
	VICODIN (hydrocodone/acetaminophen)

### Opioid – Acetaminophen Combination Non-Solid Oral Products

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
acetaminophen-codeine solution	hydrocodone-acetaminophen 5-163 mg/7.5 mL solution
hydrocodone-acetaminophen 7.5-325/15 ml solution	hydrocodone-acetaminophen 10-325/15 ml solution
	LORTAB (hydrocodone-acetaminophen) SOLUTION

### Opioid Single Agent Solid Oral Products

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
codeine tablets	butalbital-codeine tablet
hydromorphone tablet	DEMEROL (meperidine) TABLET
meperidine tablet	DILAUDID (hydromorphone) TABLET
morphine tablet	OXAYDO (oxycodone) TABLET

oxycodone 5 mg, 10 mg tablet	oxycodone tablet (Roxybond generic)
oxymorphone tablet	oxycodone 15 mg, 20 mg, 30 mg tablet
tramadol 50 mg tablet	ROXICODONE (oxycodone) TABLET
	ROXYBOND (oxycodone) TABLET
	tramadol 25mg tablet
	tramadol 100 mg tablet
	ULTRAM (tramadol) TABLET

### *Opioid Single Agent Non-Solid Oral Products*

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
hydromorphone liquid	
morphine solution	
oxycodone solution	

### *First Fill*

- Short acting opioid analgesics must be filled with a 7-day supply if no previous fill within past 34 days
  - If member is filling prescription less than every 34 days due to decreased utilization, please get a new prescription for a lower quantity that reflects actual utilization within a 34-day window.

### *Prior Authorization Criteria*

#### [Prior Authorization Form – Opioid Analgesics](#)

#### *Initial Criteria – Approval Duration: 12 months*

##### *Fentanyl Only:*

- The member must currently be on around-the-clock opioid therapy of at least 60 Morphine Milligram equivalents (MME) for at least a week, as evidenced by paid claims or pharmacy printouts

##### *Meperidine and Butalbital-Codeine Only:*

- Clinical justification must be provided explaining why the member is unable to use other opioid and non-opioid analgesic products (subject to clinical review).

##### *Oxycodone IR Only*

- The past 3 months of the member’s North Dakota PDMP reports must have been reviewed.
- The member must currently be on a long-acting opioid analgesic that provides a daily Morphine Milligram Equivalent (MME) which meets requirements below (based on requested strength), as evidenced by paid claims or pharmacy printouts (Please use an [Opioid Dose Calculator](#) to find the MME for specific products):
  - Oxycodone 15 mg tablet: long-acting opioid must provide  $\geq 150$  mg MME per day
  - Oxycodone 20 mg tablet: long-acting opioid must provide  $\geq 200$  mg MME per day
  - Oxycodone 30 mg tablet: long-acting opioid must provide  $\geq 300$  mg MME per day

#### *Non-preferred agents with same active ingredient preferred:*

- See [Preferred Dosage Form](#) Criteria

#### *Member with a History of Opioid Use Disorder*

If 1 and 2 are met, please call for an override by calling provider relations at 1-800-755-2604 (chart notes will be required for requests beyond one fill):

1. The request is for one of the following:
  - A one-time fill request where pain cannot be reasonably treated with non-opioid therapy (e.g., surgery)
  - A request exceeding a one-time fill and a treatment plan has been provided with expected duration of use and why non-opioid therapy is not an option (subject to clinical review) or a taper plan is provided



2. One of the following is met:
  - Prescribers of both opioid prescription and MOUD (medication for opioid use disorder) are aware of each other and agree to opioid therapy
  - MOUD has been discontinued, and the prescriber of the opioid is aware of previous MOUD treatment and confirms opioid therapy is required

Renewal Criteria – Approval Duration: 12 months

- Progress toward therapeutic goal must be included with request (e.g., improvement in pain level, quality in life, or function).

## Qutenza (capsaicin patch)

### CLINICAL PA REQUIRED

QUTENZA (capsaicin patch) – Medical Billing Only

### Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a pain specialist
- The member must have failed a 3-month treatment of topical lidocaine patch

## Skeletal Muscle Relaxants

### Solid Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
baclofen	AMRIX (cyclobenzaprine) TAB 24 HR
chlorzoxazone 500 mg	chlorzoxazone 375 mg and 750 mg
cyclobenzaprine 5 mg and 10 mg	cyclobenzaprine 7.5 mg
dantrolene	cyclobenzaprine ER
methocarbamol	carisoprodol
orphenadrine ER	carisoprodol-aspirin
tizanidine tablets	carisoprodol-aspirin-codeine
	DANTRIUM (dantrolene)
	LORZONE (chlorzoxazone)
	METAXALL (metaxalone)
	metaxalone
	NORGESIC FORTE (orphenadrine/aspirin/caffeine)
	ROBAXIN (methocarbamol)
	SKELAXIN (metaxalone)
	SOMA (carisoprodol)
	tizanidine capsules
	ZANAFLEX (tizanidine)

### Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months (carisoprodol = 1 week)

- Carisoprodol products only:
  - The member must be undergoing dose tapering
- Metaxalone

- The member must have failed two 30-day trials of other skeletal muscle relaxants, including methocarbamol, as evidenced by paid claims or pharmacy printouts.
- All other products:
  - See [Preferred Dosage Form](#) Criteria

### Therapeutic Duplication

- One strength of one medication is allowed at a time
  - If the following conditions apply, please call for an override by calling provider relations at 1-800-755-2604:
    - The member has cerebral palsy or another chronic spastic disorder
    - The prescriber is a physiatrist
    - The requested combination is baclofen and tizanidine
- Carisoprodol is not allowed with opioids, benzodiazepines, or opioid use disorder medications
  - The “Holy Trinity” consists of an opioid, a benzodiazepine, and carisoprodol and is a highly abused dangerous combination that can lead to additive CNS depression, overdose, and death. It is not covered.
- Tizanidine is not allowed with other alpha 2 agonists (clonidine, clonidine/chlorthalidone, guanfacine, methyl dopa)
  - tizanidine is also an alpha 2 agonist

### Non-Solid Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
baclofen solution 5 mg/5 mL	baclofen 25mg/5mL suspension
LYVISPAH (baclofen) GRANULE PACKET	FLEQSUVY (baclofen) 25mg/5mL SUSPENSION

### Prior Authorization Criteria

- See [Preferred Dosage Form](#) Criteria

## Psychiatry

### ADHD

#### Non-Stimulants

#### Alpha 2 Agonists

PREFERRED AGENTS (NO PA REQUIRED)	PREFERRED STEP 1 AGENTS (ELECTRONIC STEP)	NON-PREFERRED STEP 2 AGENTS (PA REQUIRED)
clonidine	clonidine ER 0.1 mg	clonidine ER 0.17 mg
ONYDA XR (clonidine)		INTUNIV (guanfacine ER)
guanfacine		
guanfacine ER		

### First Fill

- Clonidine ER and guanfacine ER must be filled with a 14-day supply (or less) if no previous fill within past 99 days

## Therapeutic Duplication

Please see the [Psychotropic Monitoring Program](#) document for detailed information regarding clinical criteria for Therapeutic Duplication Requests.

- One strength of one medication is allowed at a time. Guanfacine 4 mg IR or ER can be combined with other strengths to form dosages up to 7 mg per day. Guanfacine IR and ER cannot be combined.
- Clonidine and guanfacine are not allowed with each other or other alpha 2 agonists (clonidine/chlorthalidone, methyl dopa, or tizanidine)

## Electronic Step Therapy Required

- Clonidine ER:
  - A. PA Not Required Criteria: A 30-day supply of clonidine IR has been paid within 90 days prior to clonidine ER's date of service.
  - B. PA Required Criteria: The member must have failed a 30-day trial of clonidine IR, as evidenced by paid claims or pharmacy printouts.

## Norepinephrine Reuptake Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
atomoxetine	STRATTERA (atomoxetine)
PREFERRED AGENTS (CLINICAL PA REQUIRED)	
QELBREE (viloxazine)	

## Prior Authorization Criteria

### Initial Criteria – Approval Duration: 12 months

- The member must meet one of the following:
  - The member has failed a 14-day trial of two stimulants, as evidenced by paid claims or pharmacy printouts.
  - The member has failed a 30-day trial of atomoxetine, as evidenced by paid claims or pharmacy printouts.

## Therapeutic Duplication

- One strength of one medication is allowed at a time.

## Stimulants

## Amphetamines

### Solid Dosage Forms

#### Extended Release

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
dextroamphetamine/amphetamine ER (generic Adderall XR)	ADDERALL XR (dextroamphetamine/amphetamine)
dextroamphetamine ER	DEXEDRINE SPANSULE ER (dextroamphetamine)
lisdexamfetamine	dextroamphetamine/amphetamine ER (generic Mydayis ER)
	DYANAVAL XR (amphetamine)

	MYDAYIS ER (dextroamphetamine/amphetamine)
	VYVANSE (lisdexamfetamine)

*Immediate Release*

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
amphetamine	ADDERALL (dextroamphetamine/amphetamine)
dextroamphetamine 2.5 mg, 5 mg, 10 mg	dextroamphetamine 7.5 mg, 15 mg, 20 mg, 30 mg
dextroamphetamine/amphetamine	EVEKEO (amphetamine)
	methamphetamine
	ZENZEDI (dextroamphetamine)

## Non-Solid Dosage Forms

*Extended Release*

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
DYANAVEL XR (amphetamine) SUSPENSION	ADZENYS XR – ODT (amphetamine)
lisdexamfetamine chew	amphetamine ER suspension
	VYVANSE (lisdexamfetamine) CHEW TABLET
	XELSTRYM (dextroamphetamine) PATCH

*Immediate Release*

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
dextroamphetamine 5 mg/5 ml	PROCENTRA (dextroamphetamine) SOLUTION

## Methylphenidate

### Solid Dosage Forms

*Extended Release*

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
FOCALIN XR (dexmethylphenidate)	APTENSIO XR (methylphenidate)
methylphenidate CD 30-70	AZSTARYS (serdexmethylphenidate/dexmethylphenidate)
methylphenidate ER tablet (generic Concerta)	CONCERTA (methylphenidate)
methylphenidate ER tablet (generic Metadate CD)	dexmethylphenidate ER
RITALIN LA (methylphenidate LA capsules – 50-50) <i>Brand Name Required</i>	JORNAY PM (methylphenidate)
	methylphenidate ER 45 mg, 63 mg, 72 mg tablet (generic Relexxii ER)
	methylphenidate ER capsule (generic Aptensio XR)
	methylphenidate LA capsules – 50-50 (generic Ritalin LA) – 60 mg
	methylphenidate LA capsules – 50-50 (generic Ritalin LA) – 10 mg, 20 mg, 30 mg, 40 mg
	RELEXXII ER (methylphenidate)

*Immediate Release*

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
dexmethylphenidate	FOCALIN (dexmethylphenidate)
methylphenidate tablet	RITALIN (methylphenidate)

## Non-Solid Dosage Forms

### Extended Release

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
DAYTRANA (methylphenidate) PATCH – Brand Required	COTEMPLA XR – ODT (methylphenidate)
QUILLICHEW ER (methylphenidate)	methylphenidate patch
QUILLIVANT XR (methylphenidate)	

### Immediate Release

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
methylphenidate chew tablet	METHYLIN (methylphenidate) SOLUTION
methylphenidate solution	

### Electronic Age Verification

- The member must be age 6 or older or must meet prior authorization criteria for ages 5 and under listed below.

### Prior Authorization Criteria

#### Initial Criteria – Approval Duration: 6 months

- For members ages 5 and under:
  - There is a moderate-severe continuing disturbance in the child's function in both home and other settings (e.g., preschool or daycare) despite a 9-month trial of parent and/or teacher-administered behavior therapy which helps parents learn age-appropriate developmental expectation, specific management skills for problem behaviors, and behaviors that strengthen the parent-child relationship (subject to clinical review).

#### *Non-Preferred Agent Criteria:*

- Amphetamine Non-Preferred Dosage Forms Only:
  - The member must have had a two 7-day trials of a methylphenidate non-solid dosage form.
- Aptensio XR Only:
  - The member must have a wearing off effect where late afternoon/evening functioning performance has been impacted despite a 7-day trial with a long-acting methylphenidate medication with an afternoon short acting booster.
  - The member must have a wearing off effect where late afternoon/evening functioning performance has been impacted despite a 7-day trial with Concerta or its generic alternative.
- Jornay PM Only:
  - The member must have had two 7-day trials of a fast onset to peak methylphenidate medication (i.e., Concerta, Focalin XR, Metadate CD, Methylin, Ritalin and their generic alternatives).
  - The member must have the inability to time the administration of medication where the peak is occurring at the start of work or school and early morning performance has been impacted at school or work due to the approximate 1-hour delay to peak after administration (subject to clinical review).

16. All Other Agents: See [Preferred Dosage Form Criteria](#)

### References:

2. Wolraich, Mark L., et al. "Clinical practice guideline for the diagnosis, evaluation, and treatment of attention-deficit/hyperactivity disorder in children and adolescents." *Pediatrics* 144.4 (2019).
3. Hulkower RL, Kelley M, Cloud LK, Visser SN. Medicaid Prior Authorization Policies for Medication Treatment of Attention-Deficit/Hyperactivity Disorder in Young Children, United States, 2015. Public Health Rep. 2017 Nov/Dec;132(6):654-659. doi: 10.1177/0033354917735548. Epub 2017 Oct 26. PMID: 29072963; PMCID: PMC5692165.

## Therapeutic Duplication

Please see the [Psychotropic Monitoring Program](#) document for detailed information regarding clinical criteria for therapeutic duplication requests.

For all stimulants, the following are not payable:

- multiple strengths of a single medication
- amphetamine agent + methylphenidate agent
- multiple long-acting agents
- multiple short acting agents
- non-solid dosage + solid dosage forms

These long-acting products are not allowed with short-acting products:

- Aptensio XR (methylphenidate)
- Adhansia XR (methylphenidate)
- Azstarys (serdexmethylphenidate/dexmethylphenidate)
- Cotempla XR-ODT (methylphenidate)
- Daytrana (methylphenidate)
- Jornay PM (methylphenidate)
- Adderall XR (mixed salts of a single-entity amphetamine product)
- Adzenys XR ODT (amphetamine suspension, extended release)
- Adzenys ER (amphetamine suspension, extended release)
- Dyanavel XR (amphetamine)
- Mydayis (mixed salts of a single-entity amphetamine product)
- Quillivant XR (methylphenidate)
- Vyvanse (lisexamfetamine)
- Vyvanse Chewable (lisexamfetamine)

Amphetamines: One product will be allowed at a time. The following are not payable regimens:

- Dextroamphetamine/Amphetamine ER with Proton Pump Inhibitors
  - Proton pump inhibitors increase blood levels and potentiate the action of amphetamine. Co-administration of Adderall XR and gastrointestinal or urinary alkalizing agents should be avoided.
- Concurrent use of Mydayis and Dyanavel XR with sedatives
  - Members reporting insomnia can use a shorter acting product that does not reach steady state.

Methylphenidates: The following are not payable regimens:

- Concurrent use of dexmethylphenidate and methylphenidate
- Concurrent use of Adhansia XR and Azstarys with sedatives
  - Members reporting insomnia can use a shorter acting product that does not reach steady state.

## Electronic Diagnosis Verification

- Adderall, Azstarys, Jornay PM, Mydayis: Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale.

## First Fill

- Long-acting stimulants must be filled with a 14-day supply (or less) if no previous fill within past 99 days

## Antidepressants

### Oral

#### Solid Dosage Forms

**PREFERRED AGENTS (NO PA REQUIRED)**

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

amitriptyline	APLENZIN ER (bupropion)
amoxapine	CELEXA (citalopram)
AUVELITY (dextromethorphan/bupropion)	citalopram capsule 30 mg
bupropion	CYMBALTA (duloxetine)
bupropion ER	EFFEXOR XR (venlafaxine)
bupropion SR	LEXAPRO (escitalopram)
citalopram tablet	PAXIL (paroxetine)
clomipramine	PAXIL CR (paroxetine)
desipramine	PRISTIQ ER (desvenlafaxine)
desvenlafaxine ER	PROZAC (fluoxetine)
doxepin	REMERON (mirtazapine)
duloxetine	sertraline capsule
escitalopram	VIIBRYD (vilazodone)
fluoxetine	WELLBUTRIN (bupropion)
fluvoxamine	WELLBUTRIN SR (bupropion)
mirtazapine	WELLBUTRIN XL (bupropion)
nefazodone	ZOLOFT (sertraline)
nortriptyline	
paroxetine	
paroxetine ER	
protriptyline	
sertraline tablet	
trazodone	
venlafaxine	
venlafaxine ER	
vilazodone	
<b>High-Cost Options</b>	
FETZIMA (levomilnacipran)	
fluoxetine weekly	
fluvoxamine ER	
imipramine	
trimipramine	
TRINTELLIX (vortioxetine)	

### *Non-Solid Dosage Forms*

<b>PREFERRED AGENTS (NO PA REQUIRED)</b>	<b>NON-PREFERRED AGENTS (PA REQUIRED)</b>
citalopram oral solution	DRIZALMA (duloxetine) SPRINKLE CAPSULE
duloxetine sprinkle capsule	LEXAPRO (escitalopram) ORAL SOLUTION
escitalopram oral solution	PAXIL (paroxetine) ORAL SUSPENSION
fluoxetine solution	REMERON (mirtazapine) SOLTAB
mirtazapine ODT	ZOLOFT (sertraline) ORAL CONCENTRATE
sertraline oral concentrate	
<b>High-Cost Options</b>	
paroxetine oral suspension	

### *Electronic Step Therapy Required*

- Trintellix Only: Initiation with 10 mg must be used for 10 days prior to continuing therapy with 20 mg.
  - Trintellix recommended starting dose is 10 mg once daily.



- Desvenlafaxine ER Only: 30 days of 50 mg must be paid within 40 days of 25 mg date of service.
  - 25 mg is intended only for gradual titration before discontinuation. It is not a therapeutic dose.

### First Fill

- Viibryd and Trintellix must be filled with a 10-day supply if no previous fill within past 99 days

### Therapeutic Duplication

Please see [Appendix B](#) for antidepressant cross tapering coverage guidance.

- One strength of one medication per therapeutic class is allowed at a time
  - Therapeutic classes:
    - SSRIs
    - SNRIs
    - Tricyclic Antidepressants
    - Bupropion
    - Mirtazapine
    - Selegiline
- Fetzima, Viibryd, or Trintellix are not allowed with other SSRIs or SNRIs (exceptions: trazodone)
- Fluvoxamine, a strong 1A2 inhibitor, is not covered with Ramelteon, a 1A2 Substrate.

## Antipsychotics

### Oral

#### Solid Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
aripiprazole	ABILIFY (aripiprazole)
clozapine	CLOZARIL (clozapine)
FANAPT (iloperidone)	GEODON (ziprasidone)
lurasidone	INVEGA ER (paliperidone)
olanzapine	LATUDA (lurasidone)
quetiapine	RISPERDAL (risperidone)
quetiapine ER	SEROQUEL (quetiapine)
paliperidone ER	SEROQUEL XR (quetiapine)
risperidone	ZYPREXA (olanzapine)
ziprasidone	
High-Cost Options	
CAPLYTA (lumateperone)	olanzapine/fluoxetine
COBENFY (xanomeline/trospium)	SYMBYAX (olanzapine/fluoxetine)
LYBALVI (olanzapine/samidorphan)	
REXULTI (brexpiprazole)	
VRAYLAR (cariprazine)	

#### Non-Solid Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
asenapine	RISPERDAL (risperidone) ORAL SOLUTION
clozapine ODT	RISPERDAL M-TAB (risperidone)
olanzapine ODT	SAPHRIS (asenapine) 2.5 MG
risperidone ODT	ZYPREXA ZYDIS (olanzapine)

risperidone oral solution	
SAPHRIS (asenapine) 5 MG, 10 MG – Brand Co-Preferred	
<b>High-Cost Options</b>	
aripiprazole ODT	ABILIFY DISCMELT (aripiprazole)
aripiprazole solution	
SECUADO (asenapine) PATCH	

### Electronic Step Therapy Required

Vraylar requires initiation titration:

- For 3 mg dose: Initiation pack or 1 day of the 1.5 mg tablet is required
- For 4.5 mg dose: Initiation pack or 1 day of the 1.5 mg tablet plus 6 days of 3 mg tablets is required

Cobenfy requires initiation titration:

- For 100 mg/20 mg dose: Initiation pack or 2 days of the 50 mg/20 mg capsules is required
- For 125 mg/30 mg dose: Initiation pack or 5 days of the 100 mg/20 mg capsules is required

### Therapeutic Duplication

#### Prior Authorization Form - Concurrent Antipsychotics

Please see [Appendix A](#) for clinical criteria for multiple oral antipsychotics and oral and injectable antipsychotic requests

- One strength of one medication is allowed at a time with the following exceptions:
  - risperidone 0.25 mg, 0.5 mg and 1 mg are allowed with other strengths of risperidone
  - quetiapine 25 mg and 50 mg are allowed with other strengths of quetiapine IR
  - quetiapine 50 mg ER is allowed with other strengths of quetiapine ER
  - olanzapine 2.5 mg is allowed with 10 mg, 15 mg, and 20 mg
  - olanzapine 5 mg is allowed with 7.5 mg and 20 mg

### Underutilization

- Caplyta, Cobenfy, Fanapt, Latuda, Paliperidone ER, Rexulti, Saphris, Sacuado, and Vraylar must be used adherently and will reject on point of sale for late fill

### First Fill

- Caplyta, Cobenfy, Fanapt, Paliperidone ER, Rexulti, Saphris, Sacuado, and Vraylar must be filled with a 10-day supply if no previous fill within past 99 days

## Long Acting Injectable (LAI)

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ABILIFY ASIMTUFII (aripiprazole)	risperidone ER (risperidone microspheres)
ABILIFY MAINTENA (aripiprazole)	
ARISTADA (aripiprazole lauroxil)	
ARISTADA INITIO (aripiprazole lauroxil)	
INVEGA HAFYERA (paliperidone)	
INVEGA SUSTENNA (paliperidone)	

INVEGA TRINZA (paliperidone)	
PERSERIS (risperidone)	
RISPERDAL CONSTA (risperidone microspheres) – Brand Required	
RYKINDO ER (risperidone microspheres)	
UZEDY (risperidone)	
ZYPREXA RELPREVV (olanzapine)	

### Electronic Step Therapy Required

- Oral formulations must be used prior to injectable formulations to establish tolerability and achieve steady state.

If the following conditions apply, please call for an override by calling provider relations at 1-800-755-2604:

- There is a history of tolerability to active ingredient and no requirement for oral overlap for missed dose / initiation of long-acting injectable antipsychotic.
- Invega Sustenna is being initiated (234 mg x 7 days requires an override for correct billing)

- Aristada Initio: Requires Aristada claim to be billed first.

### Therapeutic Duplication

#### [Prior Authorization Form - Concurrent Antipsychotics](#)

Please see [Appendix A](#) for clinical criteria for multiple oral antipsychotics and oral and injectable antipsychotic requests

- One strength of one medication is allowed at a time.

### Prior Authorization Criteria

- See [Preferred Dosage Form Criteria](#)

## Benzodiazepines

### Therapeutic Duplication

- One short acting medication is allowed at a time: alprazolam, lorazepam, oxazepam.
- One long-acting medication is allowed at a time: chlordiazepoxide, clonazepam, diazepam, alprazolam ER
- Benzodiazepines are not covered with:
  - Opioids: [Override Criteria Available](#)
  - Xyrem, Xywav
  - Mydayis
    - Insomnia has been reported in 25-56% of members receiving Mydayis. Members reporting insomnia should use a shorter acting product that does not reach steady state.
- For benzodiazepines only indicated for insomnia: see [Insomnia](#)

## Insomnia

### Non-addictive (Non-DEA scheduled) medications

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
Hydroxyzine	doxepin

Mirtazapine	ROZEREM (ramelteon)
Ramelteon	SILENOR (doxepin)
Trazodone	

## Addictive (DEA scheduled) Medications

PREFERRED AGENTS (NO PA REQUIRED)	PREFERRED STEP 1 AGENTS (ELECTRONIC STEP)	NON-PREFERRED STEP 2 AGENTS (PA REQUIRED)
eszopiclone	BELSOMRA (suvorexant)	AMBIEN (zolpidem)
zaleplon	zolpidem 10 mg	AMBIEN CR (zolpidem)
zolpidem 5 mg		DAYVIGO (lemborexant)
zolpidem ER		EDLUAR (zolpidem)
		estazolam
		flurazepam
		LUNESTA (eszopiclone)
		QUVIVIQ (daridorexant)
		SECONAL SODIUM (secobarbital)
		temazepam
		triazolam
		zolpidem 7.5 mg
		zolpidem SL tab

### Electronic Step Therapy Required

- Belsomra:
  - A. PA Not Required Criteria: A 7-day supply of eszopiclone has been paid within 90 days prior to Belsomra's date of service.
  - B. PA Required Criteria: The member must have failed 7-day trial of eszopiclone, as evidenced by paid claims or pharmacy printouts.
- Zolpidem:
  - A. PA Not Required Criteria: A 7-day supply of zolpidem 5mg has been paid within 90 days prior to zolpidem 10mg's date of service.
  - B. PA Required Criteria: The member must have failed 7-day trial of zolpidem 5mg, as evidenced by paid claims or pharmacy printouts.

### Prior Authorization Criteria

#### [Prior Authorization Form – Sedative/Hypnotic](#)

#### Initial Criteria – Approval Duration: 3 months

- Doxepin only
  - The member must have failed a 25-day trial with ramelteon with the most recent failure within the last 90 days, as evidenced by paid claims or pharmacy printouts.
  - Clinical justification must be provided explaining why the member is unable to use mirtazapine, hydroxyzine, or trazodone (subject to clinical review)
- Edluar (zolpidem) only
  - The member's insomnia must be characterized by difficulty with sleep onset.
  - The member must have failed a 25-day trial of each of the following with the most recent failure within the last 90 days, as evidenced by paid claims or pharmacy printouts.
    - eszopiclone
    - zolpidem IR
    - zaleplon

- temazepam, zolpidem SL, Dayvigo, Quviviq only
  - The member's insomnia must be characterized by difficulty with sleep onset and maintenance.
  - The member must have failed a 25-day trial of each of the following with the most recent failure within the last 90 days, as evidenced by paid claims or pharmacy printouts.
    - eszopiclone
    - zolpidem ER
    - Belsomra
- triazolam, fluazepam, estazolam, seconal sodium, zolpidem 7.5mg only
  - Clinical justification must be provided explaining why the member is unable to use the preferred agents (subject to clinical review)

Renewal Criteria – Approval Duration: 6 months (2 weeks for 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, methyl dopa)
  - 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) – <i>Brand Required</i>
	ROZEREM (ramelteon)
	tasimelteon

*Prior Authorization Criteria*

Initial Criteria – Approval Duration: 6 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a specialist in sleep disorders.
- The member must have had a 30-day trial of ramelteon, as evidenced by paid claims or pharmacy printouts.
- One of the following must be met:
  - Member must be unable to perceive light in either eye.

- Sighted members must confirm diagnosis by documentation submitted of self-reported sleep diaries or actigraphy for at least 14 days demonstrating a gradual daily drift (typically later) in rest-activity patterns not better explained by sleep hygiene, substance, or medication use, or other neurological or mental disorders.

### Underutilization

- Hetlioz/tasimelteon must be used compliantly and will reject on point of sale for late fill.

## Smith-Magenis Syndrome

### CLINICAL PA REQUIRED

HETLIOZ (tasimelteon) – *Brand Required*

Tasimelteon

### Prior Authorization Criteria

#### Initial Criteria – Approval Duration: 6 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a specialist in sleep disorders.
- Documentation is submitted of genetic testing confirming deletion 17p11.2 (cytogenetic analysis or microarray) or RAI1 gene mutation.
- Documentation of self-reported sleep diaries or actigraphy must be submitted for at least 14 days must be submitted.

### Underutilization

- Hetlioz/tasimelteon must be used compliantly and will reject on point of sale for late fill.

## Pulmonary

### Asthma/COPD

#### Therapeutic Duplication

- One medication from each class is allowed at time.
  - One inhaled steroid
  - Long-acting anticholinergic
  - Leukotriene pathway inhibitor
  - One short-acting beta agonist
  - One long-acting beta agonist

#### Electronic Concurrent Medication Required

- Roflumilast: A total of 90 days of an inhaled short or long-acting anticholinergic must be paid within 115 days prior to roflumilast's date of service.
  - According to the Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines, roflumilast is a recommended add-on therapy to members experiencing exacerbations while on antimuscarinic therapy.

### Albuterol / Levalbuterol Rescue Inhalers

PREFERRED AGENTS

PREFERRED STEP 1 AGENTS

NON-PREFERRED STEP 2 AGENTS

(NO PA REQUIRED)	(ELECTRONIC STEP REQUIRED)	(PA REQUIRED)
VENTOLIN (albuterol) HFA – Brand Required	levalbuterol HFA	albuterol HFA
	PROAIR RESPICLICK (albuterol)	PROVENTIL (albuterol) HFA
		XOPENEX (levalbuterol) HFA

According to the GINA guidelines:

- A low dose ICS should be taken whenever SABA taken for step 1 control of asthma.
- Dispensing  $\geq 3$  SABA canisters/year is associated with higher risk of emergency department presentations.
- Dispensing  $\geq 12$  SABA canisters/year is associated with higher risk of death.

### *Electronic Step Therapy Required*

- Levalbuterol HFA:
  - A. PA Not Required Criteria: A 30-day supply of albuterol HFA has been paid within 180 days prior to levalbuterol HFA's date of service.
  - B. PA Required Criteria: The member must have failed a 30-day trial of albuterol HFA, as evidenced by paid claims or pharmacy printouts.

### *Electronic Concurrent Medications Required*

- ProAir Respiclick: A total of 30 days of steroid inhaler must be paid within 40 days prior to ProAir Respiclick's date of service.
  - A. The quantity limit for Ventolin HFA is set to 2 canisters per 6 months (2 puffs per day). If more is needed, member must switch to ProAir Respiclick HFA and be on a steroid inhaler to control asthma. If the following conditions apply, please call for an override by calling provider relations at 1-800-755-2604:
    - If primary insurance will only pay for ProAir Respiclick and member is well-controlled without steroid inhaler (i.e., uses less than 2 canisters per 6 months).

### *Therapeutic Duplication*

- Short acting beta agonist nebulizers and inhalers are not payable together.
  - A. Inhalers and Nebulizers work equally well whether used at home, in school, or otherwise outside of the home. If member receives multiple forms of rescue medication, the risk of unidentified uncontrolled asthma and rescue inhaler dependence is increased.

If the following conditions apply, please call for an override by calling provider relations at 1-800-755-2604:

- Maximally treated members with end-stage COPD will be allowed an ongoing override (compliance with inhaled steroid, long-acting beta agonist, long-acting muscarinic antagonist, and Daliresp)
- Members with cystic fibrosis will be allowed an ongoing override.
- Acutely ill children will be allowed a one-time override.

### **References:**

1. [Albuterol Overuse: A Marker of Psychological Distress?](#) Joe K. Gerald, Tara F. Carr, Christine Y. Wei, Janet T. Holbrook, Lynn B. Gerald. J Allergy Clin Immunol Pract. 2015 Nov-Dec; 3(6): 957–962. Published online 2015 Sep 1. Doi: 10.1016/j.jaip.2015.06.021. PMID: 2641773
2. Global Initiative for Asthma. Global strategy for asthma management and prevention. 2019 GINA Main Report. Available from: [www.ginasthma.org](http://www.ginasthma.org). (Accessed February 5, 2020)
3. National Asthma Education and Prevention Program, Third Expert Panel on the Diagnosis and Management of Asthma. Expert Panel Report 3: Guidelines for the Diagnosis and Management of Asthma. Bethesda (MD): National Health, Lung, and Blood Institute (US); 2007 Aug. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK7232>



4. [High-Dose Albuterol by Metered-Dose Inhaler Plus a Spacer Device Versus Nebulization in Preschool Children With Recurrent Wheezing: A Double-Blind, Randomized Equivalence Trial](#) Dominique Ploin, François R. Chapis, Didier Stamm, Jacques Robert, Louis David, Pierre G. Chatelain, Guy Dutau and Daniel Floret Pediatrics. August 2000, 106 (2) 311-317; DOI: <https://doi.org/10.1542/peds.106.2.311>

### Anticholinergics/Beta Agonists Combinations – Short Acting

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
albuterol/ipratropium	DUONEB (albuterol/ipratropium)
COMBIVENT RESPIMAT (albuterol/ipratropium)	

### Anticholinergics/Beta Agonists Combinations – Long Acting

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED STEP 1 AGENTS (PA REQUIRED)	NON-PREFERRED STEP 2 AGENTS (PA REQUIRED)
ANORO ELLIPTA (umeclidinium/vilanterol)	BEVESPI AEROSPHERE (glycopyrrolate/formoterol)	DUAKLIR PRESSAIR (aclidinium/formoterol)
STIOLTO RESPIMAT (tiotropium/olodaterol)		

#### Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

#### Non-Preferred Step 1 Agents

- The member must have failed a 30-day trial of 2 preferred agents, as evidenced by paid claims or pharmacy printouts

#### Non-Preferred Step 2 Agents:

- The member must have failed a 30-day trial of Bevespi Aerosphere and 2 preferred agents, as evidenced by paid claims or pharmacy printouts
- Clinical justification must be provided explaining why the member is unable to use the preferred products (subject to clinical review).

### Anticholinergics – Long-Acting

PREFERRED AGENTS (NO PA REQUIRED)	PREFERRED STEP 1 AGENTS (ELECTRONIC STEP REQUIRED)	NON-PREFERRED STEP 2 AGENTS (PA REQUIRED)
INCRUSE ELLIPTA (umeclidinium)	SPIRIVA RESPIMAT 1.25 MCG (tiotropium)	tiotropium handihaler
SPIRIVA HANDIHALER (tiotropium)		TUDORZA PRESSAIR (aclidinium)
SPIRIVA RESPIMAT 2.5 MCG (tiotropium)		YUPELRI (revefenacin)

#### Electronic Concurrent Medications Required

- Spiriva Respimat 1.25 mg: A total of 30 days of a long-acting beta agonist (ICS should be used with LABA as combination or single ingredient inhalers) must be paid within 40 days prior to the Spiriva Respimat 1.25 mg date of service.

#### Electronic Diagnosis Verification

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

- Spiriva Respimat 1.25 mg is indicated for asthma.
- Spiriva Respimat 2.5 mg is indicated for COPD.

### Prior Authorization Criteria

#### Initial Criteria – Approval Duration: 12 months

- The member must have failed a 30-day trial of at least 2 preferred long-acting anticholinergic agents of unique ingredients (in combination or alone), as evidenced by paid claims or pharmacy printouts.
- If the member is a current tobacco user, the member must have received tobacco cessation counseling in the past year

### Beta Agonists – Long-Acting

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
arformoterol	BROVANA (arformoterol)
formoterol	PERFOROMIST (formoterol)
SEREVENT DISKUS (salmeterol)	
STRIVERDI RESPIMAT (olodaterol)	

### Biologics

#### Anti-IL-5 biologics

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
FASENRA (benralizumab)	CINQAIR (reslizumab) – <i>Medical Billing Only</i>
	NUCALA (mepolizumab) SYRINGE, AUTOINJECTOR
	NUCALA (mepolizumab) VIAL – <i>Medical Billing Only</i>

#### Anti-IL-4/13 biologics

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

#### Allergic Asthma-directed biologics

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
XOLAIR (omalizumab) SYRINGE, AUTOINJECTOR	
XOLAIR (omalizumab) VIAL – <i>Medical Billing Only</i>	

#### Thymic Stromal Lymphopoietin (TSLP) blocker

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	TEZSPIRE (tezepelumab-ekko) PENS
	TEZSPIRE (tezepelumab-ekko) VIAL and SYRINGES – <i>Medical Billing Only</i>

### Prior Authorization Criteria

#### Prior Authorization Form – Asthma

#### Initial Criteria – Approval Duration: 6 months

### For Asthma Only

- The requested medication must be prescribed by, or in consult with, an allergist/immunologist or pulmonologist

- If the member is a current tobacco user, the member must have received tobacco cessation counseling in the past year
- The member must have had at least one exacerbation requiring use of oral corticosteroids in the past year despite continued compliant use of a high dose inhaled steroid in combination with a long-acting beta agonist (LABA) for at least 3 months prior to the exacerbation, as evidenced by paid claims or pharmacy printouts

*Dupixent Only:*

- The member must have an eosinophil count of  $\geq 150$  cells/mcL or FeNO  $\geq 25$  ppb within the past year

*Xolair Only:*

- The member has a serum total IgE level, measured before the start of treatment within the past year, of  $\geq 30$  IU/mL and  $\leq 700$  IU/mL in members age  $\geq 12$  years or  $\geq 30$  IU/mL and  $\leq 1300$  IU/mL in members ages 6 to  $< 12$  years.
- The member has had a positive skin test or in vitro reactivity to a perennial aeroallergen

*Anti-IL-5 biologics:*

- The member has an eosinophil count  $\geq 150$  cells/mcL within the past year

*Nucala and Cinqair Only:*

- The member must have had at least one exacerbation requiring use of oral corticosteroids in the past year despite continued compliant use of a triple therapy regimen (high dose inhaled steroid + long-acting beta agonist (LABA) + long-acting muscarinic antagonist (LAMA)) in combination with each of the following for at least 4 months, as evidenced by paid claims or pharmacy printouts: Dupixent, Fasenera, and Tezspire

*Tezspire Only:*

- The member must have had at least one exacerbation requiring use of oral corticosteroids in the past year despite continued compliant use of a triple therapy regimen (high dose inhaled steroid + long-acting beta agonist (LABA) + long-acting muscarinic antagonist (LAMA)) in combination with each of the following for at least 4 months, as evidenced by paid claims or pharmacy printouts: Dupixent and Fasenera

**For COPD Only**

*Dupixent Only:*

- The requested medication must be prescribed by, or in consult with, an allergist/immunologist or pulmonologist
- If the member is a current tobacco user, the member must have received tobacco cessation counseling in the past year
- The member must have had at least one exacerbation requiring use of oral corticosteroids in the previous year despite continued compliant use of an inhaled steroid AND long-acting beta agonist (LABA) AND long-acting muscarinic antagonist (LAMA) as evidenced by paid claims or pharmacy printouts
- The member has an eosinophil count of  $\geq 300$  cells/mcL within the past year

Renewal Criteria – Approval Duration: 12 months

- The member must have achieved a significant reduction in exacerbations and utilization of systemic steroids and rescue medications since treatment initiation since starting treatment with the requested medication (subject to clinical review).

**Corticosteroids – Inhaled**

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ARNUITY ELLIPTA (fluticasone)	ALVESCO (ciclesonide)
ASMANEX (mometasone) TWISTHALER	ASMANEX HFA (mometasone)
budesonide suspension	fluticasone HFA
PULMICORT FLEXHALER (budesonide)	fluticasone diskus

	PULMICORT RESPULES (budesonide)
	QVAR REDIHALER (beclomethasone)

**GINA and EPR-3 Guidelines – SMART:**

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

*Quantity Limits to accommodate SMART therapy:*

- 2 Symbicort or Dulera inhalers per 30-day supply not to exceed a total of 9 inhalers per 182 days without prior approval.

**References:**

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

*Electronic Age Verification:*

- Fluticasone HFA does not require PA for ages 4 and under

*Electronic Duration Verification:*

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

*Prior Authorization*

Initial Criteria – Approval Duration: 12 months

- The member must have failed a 30-day trial of each preferred inhaler of a unique active ingredient, as evidenced by paid claims or pharmacy printouts.
- *Asmanex HFA and QVAR Redihaler Only:*
  - Preferred agent trials may be bypassed if member meets one of the following criteria:
    - Member is unable to achieve inspiratory flow rate of 40 L/min.
    - Member is unable to achieve inspiratory flow rate of 60 L/min and has previously had adrenal insufficiency with fluticasone.
    - Permanent disability preventing use of a dry powder inhaler
- *fluticasone HFA only:*
  - Preferred agent trials may be bypassed if member meets one of the following criteria:
    - Member is unable to achieve inspiratory flow rate of 40 L/min.
    - Permanent disability preventing use of a dry powder inhaler

**References:**

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

## Corticosteroid/Long-Acting Beta Agonist (LABA) Combination Inhalers

### Solid Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED STEP 1 AGENTS (PA REQUIRED)	NON-PREFERRED STEP 2 AGENTS (PA REQUIRED)
ADVAIR DISKUS (fluticasone/salmeterol) – Brand Required	BREO ELLIPTA (fluticasone/vilanterol) – Brand Required	BREYNA (budesonide/formoterol)
ADVAIR HFA (fluticasone/salmeterol) – Brand Required		budesonide/formoterol
AIRDUO RESPICLICK (fluticasone/salmeterol) – Brand Required		fluticasone/salmeterol
DULERA (mometasone/formoterol)		fluticasone/vilanterol
		SYMBICORT (budesonide/formoterol) – Brand Required
		WIXELA INHUB (fluticasone/salmeterol)

#### GINA Guidelines – SMART:

- For mild asthma, ICS-formoterol is the preferred reliever medication for as needed symptom relief
- For steps 3-5, ICS-formoterol is preferred for use as an as needed and regular daily treatment  
*Quantity Limits to accommodate SMART therapy:*
  - 2 Symbicort or Dulera inhalers per 30-day supply not to exceed a total of 9 inhalers per 182 days without prior approval.

#### Electronic Diagnosis Verification

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

#### Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

#### Non-Preferred Step 1 Agents:

- The member must have failed a 30-day trial of each preferred agent of a unique ingredient, as evidenced by paid claims or pharmacy printouts.
- For COPD diagnosis only: The member must currently be taking a long acting antimuscarinic agent.

#### Non-Preferred Step 2 Agents:

- The member must have failed a 30-day trial of each preferred and non-preferred step 1 agent of a unique ingredient, as evidenced by paid claims or pharmacy printouts.
- If the member is a current tobacco user, the member must have received tobacco cessation counseling in the past year
- For COPD diagnosis only, the member must currently be taking a long acting antimuscarinic agent.

## Corticosteroid/Short-Acting Beta Agonist (SABA) Combination Inhalers

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
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## GINA Guidelines – SMART:

- For mild asthma, ICS-formoterol is the preferred reliever medication for as needed symptom relief.
- For steps 3-5, ICS-formoterol is preferred for use as an as needed and regular daily treatment.  
*Quantity Limits to accommodate SMART therapy:*
  - 2 Symbicort or Dulera inhalers per 30-day supply not to exceed a total of 9 inhalers per 365 days without prior approval.

*Prior Authorization Criteria*Initial Criteria – Approval Duration: 12 months

- The member must have failed a 30-day trial of Symbicort and Dulera, as evidenced by paid claims or pharmacy printouts.
- Clinical justification must be provided explaining why the member is unable to use the preferred Steroid/LABA or SABA agents (subject to clinical review).

**Corticosteroid/Anticholinergics/Long-Acting Beta Agonists Combinations**

<b>PREFERRED AGENTS (CLINICAL PA REQUIRED)</b>	<b>NON-PREFERRED AGENTS (PA REQUIRED)</b>
TRELEGY ELLIPTA (fluticasone/umeclidinium/vilanterol)	BREZTRI AEROSPHERE (budesonide/glycopyrrolate/formoterol)

*Prior Authorization Criteria*Initial Criteria – Approval Duration: 12 months

- The member must have blood eosinophil of  $\geq 100$  cells/mcL within the past 90 days
- If the member is a current tobacco user, the member must have received tobacco cessation counseling in the past year
- The member must have experienced an exacerbation while adherent to a 60-day trial of fluticasone inhaler + umeclidinium + vilanterol which have the same active ingredients as Trelegy Ellipta, as evidenced by paid claims or pharmacy printouts. Clinical justification must also be provided why Trelegy Ellipta is expected to improve outcomes versus using fluticasone inhaler + umeclidinium + vilanterol combination therapy (subject to clinical review).
  - available combination products to achieve this are fluticasone + Anoro Ellipta (umeclidinium/vilanterol) and Breo Ellipta (fluticasone/vilanterol) + Incline Ellipta (umeclidinium)
- The member must have experienced an exacerbation while adherent to a 60-day trial of triple therapy (Steroid/Long-Acting Beta Agonist/Long-Acting Anticholinergic) that has at least one ingredient different from fluticasone inhaler + umeclidinium + vilanterol combination therapy, as evidenced by paid claims or pharmacy printouts.

*Non-Preferred Agents Criteria:*

- The member must have failed a 30-day trial of the preferred product, as evidenced by paid claims or pharmacy printouts:

**Phosphodiesterase-3 (PDE3) and Phosphodiesterase-4 (PDE4) Inhibitor**

<b>PREFERRED AGENTS (CLINICAL PA REQUIRED)</b>
OHTUVAYRE (ensifentrine)

*Prior Authorization Criteria*Initial Criteria – Approval Duration: 12 months

- The requested medication must be prescribed by, or in consult with, a pulmonologist

- If the member is a current tobacco user, the member must have received tobacco cessation counseling in the past year
- The member must meet one of the following criteria:
  - The member has a blood eosinophil of  $\geq 100$  cells/mcL and has experienced an exacerbation while adherent to a 60-day trial of a triple combination regimen consisting of an inhaled steroid, long-acting beta agonist, and long-acting anticholinergic.
  - The member has a blood eosinophil of  $< 100$  cells/mcL and has experienced an exacerbation while adherent to a 60-day trial of a dual combination regimen consisting of a long-acting beta agonist and long-acting anticholinergic.

## Cystic Fibrosis

### Cystic Fibrosis – Inhaled Antibiotics

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
tobramycin (generic Tobi)	ARIKAYCE (amikacin/nebulizer)
PREFERRED AGENTS (PA REQUIRED)	BETHKIS (tobramycin)
TOBI PODHALER (tobramycin)	CAYSTON (aztreonam)
	KITABIS PAK (tobramycin/nebulizer)
	TOBI (tobramycin)
	tobramycin/nebulizer (generic Kitabis)
	tobramycin (generic Bethkis)

#### Prior Authorization Criteria

##### Initial Criteria – Approval Duration: 12 months

- Arikayce only:
  - The member must be colonized with *Mycobacterium avium* complex (MAC).
  - The member must have not achieved negative sputum cultures after a minimum duration of 6 consecutive months of background treatment with a macrolide, a rifamycin, and ethambutol.
- Cayston only:
  - The member must be colonized with *Pseudomonas aeruginosa*.
  - The member must have had a 28-day trial of tobramycin as evidenced by paid claims or pharmacy printouts.
- Tobi Podhaler only:
  - The member must have failed one 28-day trial of a tobramycin nebulized agent, as evidenced by paid claims or pharmacy printouts.
- All other agents: See [Preferred Dosage Form Criteria](#)

### Cystic Fibrosis – CFTR Modulators

CLINICAL PA REQUIRED
KALYDECO (ivacaftor)
ORKAMBI (lumacaftor/ivacaftor)
SYMDEKO (tezacaftor/ivacaftor)
TRIKAFTA (elexacaftor/tezacaftor/ivacaftor) GRANULES
TRIKAFTA (elexacaftor/tezacaftor/ivacaftor) TABLETS

#### Prior Authorization Criteria

##### Initial Criteria – Approval Duration: 12 months (Renewal Approval – 5 years)



- The member must have a CFTR mutation that the requested medication is FDA-approved to treat, as evidenced by medical documentation (e.g., chart notes, genetic testing) that is attached to the request.

## Cystic Fibrosis – Osmotic Agent

### CLINICAL PA REQUIRED

BRONCHITOL (mannitol) INHALER

#### Electronic Diagnosis Verification

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

#### Electronic Age Verification

- The member must be 18 years or older

#### Prior Authorization

##### Initial Criteria – Approval Duration: 12 months

- Documentation of the Bronchitol Tolerance Test must be submitted

## Idiopathic Pulmonary Fibrosis

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
pirfenidone	ESBRIET (pirfenidone)
	OFEV (nintedanib)

#### Prior Authorization

##### Initial Criteria – Approval Duration: 12 months

- The requested medication must be prescribed by, or in consult with, a pulmonologist or rheumatologist.
- The prescriber must submit documentation of the following:
  - The member must have forced vital capacity (FVC)  $\geq$  40% of predicted within prior 60 days.
  - The member must have carbon monoxide diffusing capacity (DLCO, corrected for hemoglobin) of 30% to 79% of predicted.

## Interstitial Lung Disease

#### First Line Therapy - Orals

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

#### First Line Therapy - Biologics

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
TYENNE (tocilizumab-aazg) AUTOINJECTOR, SYRINGE	ACTEMRA (tocilizumab) ACTPEN, SYRINGE
TYENNE (tocilizumab-aazg) VIAL – <i>Medical Billing Only</i>	ACTEMRA (tocilizumab) VIAL – <i>Medical Billing Only</i>
	TOFIDENCE (tocilizumab-aazg) VIAL – <i>Medical Billing Only</i>

## Progressive Disease

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
RIABNI (rituximab-arrx) – <i>Medical Billing Only</i>	OFEV (nintedanib)
RUXIENCE (rituximab-pvvr) – <i>Medical Billing Only</i>	RITUXAN (rituximab) – <i>Medical Billing Only</i>
TRUXIMA (rituximab-abbs) – <i>Medical Billing Only</i>	

## Prior Authorization

### Initial Criteria – Approval Duration: 12 months

- The requested medication must be prescribed by, or in consult with, a pulmonologist or rheumatologist.
- The prescriber must submit documentation of the following:
  - The member must have forced vital capacity (FVC) ≥ 40% of predicted within prior 60 days
  - The member must have carbon monoxide diffusing capacity (DLCO, corrected for hemoglobin) of 30% to 79% of predicted.
- Rituxan, Actemra, and Non-Preferred Biosimilar Agents: See [Biosimilar Agents](#) criteria

## Rheumatology

### Axial Spondyloarthritis/Ankylosing Spondylitis

#### TNF Inhibitors

##### Adalimumab

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ABRILADA (adalimumab-afzb)	adalimumab-aacf
adalimumab-adbm – labeler 00597	adalimumab-aaty
adalimumab-fkjp	adalimumab-adaz
CYLTEZO (adalimumab-abdm)	adalimumab-adbm – labeler 82009
HADLIMA (adalimumab-bwwd)	adalimumab-ryvk
HULIO (adalimumab-fkjp)	AMJEVITA (adalimumab-atto)
HUMIRA (adalimumab)	HYRIMOZ (adalimumab-adaz)
SIMLANDI (adalimumab-ryvk)	IDACIO (adalimumab-aacf)
YUSIMRY (adalimumab-aqvh)	YUFLYMA (adalimumab-aaty)

##### Infliximab

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AVSOLA (infliximab-axxq) – <i>Medical Billing Only</i>	INFLECTRA (infliximab-dyyb) – <i>Medical Billing Only</i>
RENFLIXIS (infliximab-abda) – <i>Medical Billing Only</i>	infliximab – <i>Medical Billing Only</i>
	REMICADE (infliximab) – <i>Medical Billing Only</i>

##### Other TNF

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ENBREL (etanercept)	CIMZIA (certolizumab) SYRINGE
SIMPONI (golimumab)	CIMZIA (certolizumab) VIAL – <i>Medical Billing Only</i>
	SIMPONI ARIA (golimumab) – <i>Medical Billing Only</i>

#### Interleukin (IL) – 17 Inhibitors

PREFERRED AGENTS (ELECTRONIC STEP REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
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TALTZ (ixekizumab)***	COSENTYX (secukinumab)
	COSENTYX (secukinumab) – <i>Medical Billing Only</i>

### Interleukin (IL)-17A and IL-17F inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	BIMZELX (bimekizumab-bkzx)

### Janus Kinase (JAK) Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
XELJANZ IR (tofacitinib) 5 mg, oral solution	RINVOQ ER (upadacitinib)
	XELJANZ IR (tofacitinib) 10 mg
	XELJANZ XR (tofacitinib)

### Electronic Step Therapy Required

- Taltz:
  - PA Not Required Criteria: A total of 84-day supply of a TNF Inhibitor has been paid within 120 days prior to Taltz's date of service.
  - PA Required Criteria: The member must have failed a 3-month trial of a TNF inhibitor, as evidenced by paid claims or pharmacy printouts.

### Prior Authorization Criteria

#### Initial Criteria – Approval Duration: 12 months

- Cimzia Only: The member must have failed a 90-day trial of a TNF inhibitor, as evidenced by paid claims or pharmacy printouts.
- Rinvoq ER Only: The member must have failed a 30-day trial of Xeljanz and a 90-day trial of a TNF inhibitor, as evidenced by paid claims or pharmacy printouts.
- Bimzlex, Cosentyx and Simponi Aria Only: The member must have failed a 30-day trial of Xeljanz and Rinvoq ER, and a 90-day trial of a TNF inhibitor and Taltz, as evidenced by paid claims or pharmacy printouts.
- Inflectra, infliximab, Remicade, Rituxan: See [Biosimilar Agents](#) criteria
- Xeljanz IR 10 mg, Xeljanz XR Only: See [Preferred Dosage Form Criteria](#)
- Medical billing only agents: In addition to above criteria, clinical justification must be provided why a self-administered agent cannot be used (subject to clinical review).

## Behçet syndrome

### Phosphodiesterase 4 (PDE4) Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
OTEZLA (apremilast)	

### TNF Inhibitors

#### Adalimumab

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ABRILADA (adalimumab-afzb)	adalimumab-aacf
adalimumab-adbm – labeler 00597	adalimumab-aaty
adalimumab-fkjp	adalimumab-adaz
CYLTEZO (adalimumab-abdm)	adalimumab-adbm – labeler 82009

HADLIMA (adalimumab-bwwd)	adalimumab-ryvk
HULIO (adalimumab-fkjp)	AMJEVITA (adalimumab-atto)
HUMIRA (adalimumab)	HYRIMOZ (adalimumab-adaz)
SIMLANDI (adalimumab-ryvk)	IDACIO (adalimumab-aacf)
YUSIMRY (adalimumab-aqvh)	YUFLYMA (adalimumab-aaty)

### *Infliximab*

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AVSOLA (infliximab-axxq) – <i>Medical Billing Only</i>	INFLECTRA (infliximab-dyyb) – <i>Medical Billing Only</i>
RENFLEXIS (infliximab-abda) – <i>Medical Billing Only</i>	infliximab – <i>Medical Billing Only</i>
	REMICADE (infliximab) – <i>Medical Billing Only</i>

### *Other TNF*

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ENBREL (etanercept)	

### *Prior Authorization Criteria*

- See [Biosimilar Agents](#) criteria

## **Cryopyrin Associated Periodic Syndrome (CAPS)**

*Includes: Familiar Cold Autoinflammatory Syndrome, Muckle-Wells Syndrome, and Neonatal Onset Multisystem Inflammatory Disease (NOMID) or Chronic Infantile Neurological Cutaneous and Articular (CINCA) Syndrome*

### *Interleukin (IL) -1 Receptor Inhibitors*

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
KINERET (anakinra)	ARCALYST (riloncept)
	ILARIS (canakinumab) – <i>Medical Billing Only</i>

### *Prior Authorization Criteria*

#### *Initial Criteria – Approval Duration: 12 months*

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a specialist in the area of the member's diagnosis.
- The member has failed a 3-month trial of Kineret, as evidenced by paid claims or pharmacy print outs.
- The member has elevated pretreatment serum inflammatory markers (e.g., C-reactive protein (CRP), erythrocyte sedimentation rate (ESR) serum amyloid A(SAA))
- The member has at least two of the following symptoms (as evidenced by documentation):
  - Urticaria-like rash
  - Cold/stress triggered episodes
  - Sensorineural hearing loss
  - Musculoskeletal symptoms of arthralgia/arthritis/myalgia
  - Chronic aseptic meningitis
  - Skeletal abnormalities of epiphyseal overgrowth/frontal bossing

## Familial Mediterranean Fever (FMF)

### Colchicine

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
colchicine tablets	colchicine capsules
	GLOPERBA (colchicine) ORAL SOLUTION
	MITIGARE (colchicine) CAPSULE

### Interleukin (IL) -1 Receptor Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
KINERET (anakinra)	ARCALYST (rilonacept)
	ILARIS (canakinumab) – <i>Medical Billing Only</i>

#### *Prior Authorization Criteria*

##### *Initial Criteria – Approval Duration: 12 months*

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a specialist in the area of the member's diagnosis.
- The member experiences one or more attacks each month despite receiving maximally tolerated dose of colchicine for at least 6 months, as evidenced by paid claims or pharmacy print outs and clinical documentation.
- The member has failed a 3-month trial of Kineret, as evidenced by paid claims or pharmacy print outs.

## Giant Cell Arteritis (Temporal Arteritis)

### Interleukin (IL) -6 Receptor Inhibitors

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
TYENNE (tocilizumab-aazg) AUTOINJECTOR, SYRINGE	ACTEMRA (tocilizumab) ACTPEN, SYRINGE
TYENNE (tocilizumab-aazg) VIAL – <i>Medical Billing Only</i>	ACTEMRA (tocilizumab) VIAL – <i>Medical Billing Only</i>
	TOFIDENCE (tocilizumab-aazg) VIAL – <i>Medical Billing Only</i>

#### *Prior Authorization Criteria*

- See [Medications that cost over \\$3000/month](#) criteria
- Non-Preferred Agents: See [Biosimilar Agents](#) criteria

## Hyperimmunoglobulin D Syndrome/Mevalonate Kinase (MVK) Deficiency

#### *Symptomatic Treatment*

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
NSAIDs	
glucocorticoids	
KINERET (anakinra)	

## Preventative Treatment

### CLINICAL PA REQUIRED

ILARIS (canakinumab)

### Prior Authorization Criteria

#### Initial Criteria – Approval Duration: 12 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a specialist in the area of the member's diagnosis.
- The member has failed a 3-month trial of Kineret, as evidenced by paid claims or pharmacy print outs.
- The member is experiencing frequent and/or severe attacks that have significantly diminished quality of life

## Juvenile Idiopathic Arthritis

### Juvenile Idiopathic Arthritis – Enthesitis-Related Arthritis (ERA)

#### Interleukin (IL) – 17 Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	COSENTYX (secukinumab)
	COSENTYX (secukinumab) – <i>Medical Billing Only</i>

#### TNF Inhibitors

##### Adalimumab

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ABRILADA (adalimumab-afzb)	adalimumab-aacf
adalimumab-adbm – labeler 00597	adalimumab-aaty
adalimumab-fkjp	adalimumab-adaz
CYLTEZO (adalimumab-abdm)	adalimumab-adbm – labeler 82009
HADLIMA (adalimumab-bwwd)	adalimumab-ryvk
HULIO (adalimumab-fkjp)	AMJEVITA (adalimumab-atto)
HUMIRA (adalimumab)	HYRIMOZ (adalimumab-adaz)
SIMLANDI (adalimumab-ryvk)	IDACIO (adalimumab-aacf)
YUSIMRY (adalimumab-aqvh)	YUFLYMA (adalimumab-aaty)

##### Other TNF

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ENBREL (etanercept)	

### Prior Authorization Criteria

#### Initial Criteria – Approval Duration: 12 months

- The member has failed a 3-month trial of a TNF inhibitor, as evidenced by paid claims or pharmacy print outs.
- Biosimilars Only: See [Preferred Dosage Form Criteria](#)

## Juvenile Idiopathic Arthritis – Polyarticular Course

### Interleukin (IL) -6 Receptor Inhibitors

#### *Tocilizumab*

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
TYENNE (tocilizumab-aazg) AUTOINJECTOR, SYRINGE	ACTEMRA (tocilizumab) ACTPEN, SYRINGE
TYENNE (tocilizumab-aazg) VIAL – <i>Medical Billing Only</i>	ACTEMRA (tocilizumab) VIAL – <i>Medical Billing Only</i>
	TOFIDENCE (tocilizumab-aazg) VIAL – <i>Medical Billing Only</i>

#### *Other*

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	KEVZARA (sarilumab)

### Janus Kinase (JAK) Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
XELJANZ IR (tofacitinib) 5 MG TABLET, SOLUTION	RINVOQ ER TABLET, SOLUTION
	XELJANZ IR (tofacitinib) 10 MG TABLET
	XELJANZ XR (tofacitinib)

### T-cell Costimulation Blocker

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ORENCIA (abatacept) – 125 mg/mL syringe	ORENCIA (abatacept) - 50 mg/0.4 mL and 87.5 mg/0.7 ml syringes
	ORENCIA (abatacept) – <i>Medical Billing Only</i>

### TNF Inhibitors

#### *Adalimumab*

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ABRILADA (adalimumab-afzb)	adalimumab-aacf
adalimumab-adbm – labeler 00597	adalimumab-aaty
adalimumab-fkjp	adalimumab-adaz
CYLTEZO (adalimumab-abdm)	adalimumab-adbm – labeler 82009
HADLIMA (adalimumab-bwwd)	adalimumab-ryvk
HULIO (adalimumab-fkjp)	AMJEVITA (adalimumab-atto)
HUMIRA (adalimumab)	HYRIMOZ (adalimumab-adaz)
SIMLANDI (adalimumab-ryvk)	IDACIO (adalimumab-aacf)
YUSIMRY (adalimumab-aqvh)	YUFLYMA (adalimumab-aaty)

#### *Other TNF*

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ENBREL (etanercept)	CIMZIA (certolizumab) SYRINGE
	CIMZIA (certolizumab) VIAL – <i>Medical Billing Only</i>
	SIMPONI ARIA (golimumab) – <i>Medical Billing Only</i>



## Prior Authorization Criteria

### Initial Criteria – Approval Duration: 12 months

- The member has failed a 3-month trial of a TNF inhibitor, as evidenced by paid claims or pharmacy print outs.
- Xeljanz Oral Solution Only: The member has failed a 3-month trial of a TNF inhibitor, Orencia, as evidenced by paid claims or pharmacy print outs.
- Rinvoq ER Only: The member has failed a 3-month trial of a TNF inhibitor, Orencia, and Xeljanz, as evidenced by paid claims or pharmacy print outs.
- Actemra and Non-preferred Biosimilars Only: See [Biosimilar Agents](#) criteria
- Xeljanz IR 10mg, Xeljanz XR Only: See [Preferred Dosage Form](#) criteria
- Simponi Aria Only: The member must have failed a 30-day trial of Rinvoq ER, and Xeljanz and a 90-day trial of a TNF inhibitor and Orencia, as evidenced by paid claims or pharmacy printouts.
- Medical billing only agents: In addition to above criteria, clinical justification must be provided why a self-administered agent cannot be used (subject to clinical review)

## Juvenile Chronic Arthritis – Systemic Onset

### Interleukin (IL) -1 Receptor Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	ILARIS (canakinumab) – <i>Medical Billing Only</i>

### Interleukin (IL) -6 Receptor Inhibitors

#### Tocilizumab

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
TYENNE (tocilizumab-aazg) AUTOINJECTOR, SYRINGE	ACTEMRA (tocilizumab) ACTPEN, SYRINGE
TYENNE (tocilizumab-aazg) VIAL – <i>Medical Billing Only</i>	ACTEMRA (tocilizumab) VIAL – <i>Medical Billing Only</i>
	TOFIDENCE (tocilizumab-aazg) VIAL – <i>Medical Billing Only</i>

### TNF Inhibitors

#### Adalimumab

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ABRILADA (adalimumab-afzb)	adalimumab-aacf
adalimumab-adbm – labeler 00597	adalimumab-aaty
adalimumab-fkjp	adalimumab-adaz
CYLTEZO (adalimumab-abdm)	adalimumab-adbm – labeler 82009
HADLIMA (adalimumab-bwwd)	adalimumab-ryvk
HULIO (adalimumab-fkjp)	AMJEVITA (adalimumab-atto)
HUMIRA (adalimumab)	HYRIMOZ (adalimumab-adaz)
SIMLANDI (adalimumab-ryvk)	IDACIO (adalimumab-aacf)
YUSIMRY (adalimumab-aqvh)	YUFLYMA (adalimumab-aaty)

#### Other TNF

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ENBREL (etanercept)	

## Prior Authorization Criteria

### Initial Criteria – Approval Duration: 12 months

- The member has failed a 3-month trial of a TNF inhibitor, as evidenced by paid claims or pharmacy print outs.
- Ilaris Only: The member has failed a 3-month trial of tocilizumab, as evidenced by paid claims or pharmacy print outs.
- Actemra and non-preferred biosimilars only: See [Biosimilar Agents](#) criteria

### References:

1. Dewitt, E.M., Kimura, Y., Beukelman, T., Nigrovic, P.A., Onel, K., Prahalad, S., Schneider, R., Stoll, M.L., Angeles-Han, S., Milojevic, D., Schikler, K.N., Vehe, R.K., Weiss, J.E., Weiss, P., Ilowite, N.T., Wallace, C.A. and (2012), Consensus treatment plans for new-onset systemic juvenile idiopathic arthritis. Arthritis Care Res, 64: 1001-1010. <https://doi.org/10.1002/acr.21625>

## Polymyalgia Rheumatica

### Interleukin (IL) -6 Receptor Inhibitors

#### CLINICAL PA REQUIRED

KEVZARA (sarilumab)

## Prior Authorization Criteria

- See [Medications that cost over \\$3000/month](#) criteria

## Psoriatic Arthritis

### TNF Inhibitors

#### Adalimumab

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ABRILADA (adalimumab-afzb)	adalimumab-aacf
adalimumab-adbm – labeler 00597	adalimumab-aaty
adalimumab-fkjp	adalimumab-adaz
CYLTEZO (adalimumab-abdm)	adalimumab-adbm – labeler 82009
HADLIMA (adalimumab-bwwd)	adalimumab-ryvk
HULIO (adalimumab-fkjp)	AMJEVITA (adalimumab-atto)
HUMIRA (adalimumab)	HYRIMOZ (adalimumab-adaz)
SIMLANDI (adalimumab-ryvk)	IDACIO (adalimumab-aacf)
YUSIMRY (adalimumab-aqvh)	YUFLYMA (adalimumab-aaty)

#### Infliximab

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AVSOLA (infliximab-axxq) – Medical Billing Only	INFLECTRA (infliximab-dyyb) – Medical Billing Only
RENFLIXIS (infliximab-abda) – Medical Billing Only	infliximab – Medical Billing Only
	REMICADE (infliximab) – Medical Billing Only

#### Other TNF

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ENBREL (etanercept)	CIMZIA (certolizumab) SYRINGE

SIMPONI (golimumab)	CIMZIA (certolizumab) VIAL – <i>Medical Billing Only</i>
	SIMPONI ARIA (golimumab)– <i>Medical Billing Only</i>

### 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) – <i>Medical Billing Only</i>
	ORENCIA (abatacept) – 50 mg/0.4mL, 87.5 mg/0.7 mL syringe

### Interleukin (IL) – 17 Inhibitors

PREFERRED AGENTS (ELECTRONIC STEP REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
TALTZ (ixekizumab)	COSENTYX (secukinumab)
	COSENTYX (secukinumab) – <i>Medical Billing Only</i>

### Interleukin (IL)-17A and IL-17F inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	BIMZELX (bimekizumab-bkzx)

### Interleukin (IL)-23p19 Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	SKYRIZI (risankizumab-rzaa)
	TREMFYA (guselkumab)

### Interleukin (IL)-12/IL-23 Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	STELARA (ustekinumab)
	WEZLANA (ustekinumab-auub)

### *Electronic Step Therapy Required*

- Taltz:
  - PA Not Required Criteria: A total of 84-day supply of a TNF Inhibitor has been paid within 120 days prior to Taltz's date of service.
  - PA Required Criteria: The member must have failed a 3-month trial of a TNF inhibitor, as evidenced by paid claims or pharmacy printouts.

## Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

### Pediatric Members:

*Cosentyx Only:*

- The member must have failed a 90-day trial of etanercept, as evidenced by paid claims or pharmacy printouts:

*All Other Agents:*

- The member must have failed a 90-day trial of each of the following, as evidenced by paid claims or pharmacy printouts:
  - TNF inhibitor (etanercept)
  - Interleukin (IL) – 17 inhibitor (secukinumab)
- Xeljanz IR 10mg, Xeljanz XR Only: See [Preferred Dosage Form](#) criteria

### Adult Members:

- Cimzia, Rinvoq ER, Cosentyx: The member must have failed a 90-day trial of each of the following, as evidenced by paid claims or pharmacy printouts:
  - TNF inhibitor
  - Interleukin (IL) – 17 inhibitor
- Skyrizi and Tremfya Only: The member must have failed a 90-day trial of each of the following, as evidenced by paid claims or pharmacy printouts:
  - TNF inhibitor
  - Interleukin (IL) – 17 inhibitor
  - Rinvoq ER
- Interleukin (IL)-12/IL-23 Inhibitor, Bimzelx, Simponi Aria Only: The member must have failed a 90-day trial of each of the following, as evidenced by paid claims or pharmacy printouts:
  - TNF inhibitor
  - Interleukin (IL) – 17 inhibitor
  - Interleukin (IL)-23p19 Inhibitor
  - Rinvoq ER
- Medical billing only agents: In addition to above criteria, clinical justification must be provided why self-administered agents cannot be used (subject to clinical review).
- Non-preferred biosimilars only: See [Biosimilar Agents](#) criteria
- All other Agents: See [Preferred Dosage Form Criteria](#)

## Rheumatoid Arthritis

### Anti-CD20 Monoclonal Antibodies

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
RIABNI (rituximab-arrx) – <i>Medical Billing Only</i>	RITUXAN (rituximab) – <i>Medical Billing Only</i>
RUXIENCE (rituximab-pvvr) – <i>Medical Billing Only</i>	
TRUXIMA (rituximab-abbs) – <i>Medical Billing Only</i>	

### Interleukin (IL) -1 Receptor Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
KINERET (anakinra)	

### Interleukin (IL) -6 Receptor Inhibitors

*Tocilizumab*

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
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TYENNE (tocilizumab-aazg) AUTOINJECTOR, SYRINGE	ACTEMRA (tocilizumab) ACTPEN, SYRINGE
TYENNE (tocilizumab-aazg) VIAL – <i>Medical Billing Only</i>	ACTEMRA (tocilizumab) VIAL – <i>Medical Billing Only</i>
	TOFIDENCE (tocilizumab-aazg) VIAL – <i>Medical Billing Only</i>

*Other*

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	KEVZARA (sarilumab)

**Janus Kinase (JAK) Inhibitor**

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
XELJANZ IR (tofacitinib) 5 mg, oral solution	OLUMIANT (baricitinib)
	RINVOQ ER (upadacitinib)
	XELJANZ IR (tofacitinib) 10 mg
	XELJANZ XR (tofacitinib)

**T-cell Co-stimulation Blocker**

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ORENCIA (abatacept) – 125 mg/mL syringe	ORENCIA (abatacept) – <i>Medical Billing Only</i>

**TNF Inhibitors**

*Adalimumab*

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ABRILADA (adalimumab-afzb)	adalimumab-aacf
adalimumab-adbm – labeler 00597	adalimumab-aaty
adalimumab-fkjp	adalimumab-adaz
CYLTEZO (adalimumab-abdm)	adalimumab-adbm – labeler 82009
HADLIMA (adalimumab-bwwd)	adalimumab-ryvk
HULIO (adalimumab-fkjp)	AMJEVITA (adalimumab-atto)
HUMIRA (adalimumab)	HYRIMOZ (adalimumab-adaz)
SIMLANDI (adalimumab-ryvk)	IDACIO (adalimumab-aacf)
YUSIMRY (adalimumab-aqvh)	YUFLYMA (adalimumab-aaty)

*Infliximab*

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AVSOLA (infliximab-axxq) – <i>Medical Billing Only</i>	INFLECTRA (infliximab-dyyb) – <i>Medical Billing Only</i>
RENFLEXIS (infliximab-abda) – <i>Medical Billing Only</i>	infliximab – <i>Medical Billing Only</i>
	REMICADE (infliximab) – <i>Medical Billing Only</i>

*Other TNF*

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ENBREL (etanercept)	CIMZIA (certolizumab) SYRINGE
SIMPONI (golimumab)	CIMZIA (certolizumab) VIAL – <i>Medical Billing Only</i>
	SIMPONI ARIA (golimumab) – <i>Medical Billing Only</i>

## Prior Authorization Criteria

### Initial Criteria – Approval Duration: 12 months

- The member must have had a 3-month trial of each of the following, as evidenced by paid claims and pharmacy printouts:
  - TNF Inhibitor
  - T-cell Co-stimulation Blocker
- Simponi Aria only: The member must have had a 3-month trial of each of the following, as evidenced by paid claims and pharmacy printouts:
  - TNF Inhibitor
  - T-cell Co-stimulation Blocker
  - Rinvoq ER
  - Interleukin – 6 inhibitors
- Xeljanz IR 10mg, Xeljanz XR only: See [Preferred Dosage Form](#) criteria
- Actemra and non-preferred biosimilar agents only: See [Biosimilar Agents](#) criteria
- Medical billing only agents: In addition to above criteria, clinical justification must be provided why a self-administered agent cannot be used (subject to clinical review).

## Adult-Onset Still's Disease

### *Interleukin (IL) -1 Receptor Inhibitors*

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
KINERET (anakinra)	ILARIS (canakinumab) – <i>Medical Billing Only</i>

### *TNF Inhibitors*

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AVSOLA (infliximab-axxq) – <i>Medical Billing Only</i>	INFLECTRA (infliximab-dyyb) – <i>Medical Billing Only</i>
RENFLIXIS (infliximab-abda) – <i>Medical Billing Only</i>	infliximab – <i>Medical Billing Only</i>
	REMICADE (infliximab) – <i>Medical Billing Only</i>

## Prior Authorization Criteria

### Initial Criteria – Approval Duration: 12 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a specialist in the area of the member's diagnosis.
- The member must have had a 3-month trial of each of Kineret, as evidenced by paid claims and pharmacy printouts:
- Remicade, Rituxan, infliximab, and Inflectra Only: See [Biosimilar Agents](#) Criteria

## Tumor Necrosis Factor Receptor Associated Periodic Syndrome

CLINICAL PA REQUIRED
ILARIS (canakinumab)

## Prior Authorization Criteria

### Initial Criteria – Approval Duration: 12 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a specialist in the area of the member's diagnosis.

- Documentation must be attached to confirm one of the following:
  - Genetic testing confirming pathogenic variants in the tumor necrosis factor receptor 1 (TNFR1) gene (TNF receptor superfamily member 1A, TNFRSF1A).
  - Both of the following:
    - Elevated serum inflammatory markers (e.g., C-reactive protein (CRP), erythrocyte sedimentation rate (ESR) serum amyloid A(SAA))
    - History of recurrent fever, prominent myalgias, migratory rash, and periorbital edema

## Osteoporosis

### Antiresorptive Agents

#### Bisphosphonates

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
alendronate	ACTONEL (risedronate)
alendronate oral solution	ADELVIA (risedronate DR)
BONIVA (ibandronate) – <i>Medical Billing Only</i>	FOSAMAX (alendronate)
ibandronate – <i>Medical Billing Only</i>	FOSAMAX D (alendronate/vitamin D)
RECLAST (zoledronic acid) – <i>Medical Billing Only</i>	risedronate DR
risedronate IR	
zoledronic acid – <i>Medical Billing Only</i>	

#### 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++ – <i>Medical Billing Only</i>	

++ Clinically Non-Preferred: An FDA advisory panel concluded that the benefits of calcitonin do not outweigh its potential risks as an osteoporosis drug due to increased risk of malignancy. Bisphosphonates are more effective agents.

#### Prior Authorization Criteria

##### Initial Criteria – Approval Duration: 6 months

- The member must be experiencing pain from an acute osteoporotic fracture

#### Estrogen Agonist/Antagonist

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
raloxifene	EVISTA (raloxifene)

#### Monoclonal Antibodies

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
PROLIA (denosumab) – <i>Medical Billing Only</i>	



## Anabolic Agents

### Parathyroid Hormone (PTH)

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
FORTEO (teriparatide) – <i>Brand Required</i>	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) – <i>Medical Billing Only</i>	

### Prior Authorization Criteria

#### Initial Criteria – Approval Duration: 2 years (1 year for Evenity)

- The member must have a current BMD T-score  $\leq -2.5$  OR new fracture (as evidenced by submitted documentation) after a 6-month trial of each of the following, as evidenced by paid claims or pharmacy printouts:
  - teriparatide
- Member must be at high risk of fracture, confirmed by documentation of at least one of the following:
  - The member with a history of hip or vertebral fracture
  - The member with a T-score of  $-2.5$  or lower at the femoral neck or spine
  - The member has a T-score of between  $-1.0$  and  $-2.5$  at the femoral neck or spine and a ten-year hip fracture risk of  $\geq 3\%$  as assessed with the FRAX
  - 10-year risk of a major osteoporosis-related fracture of  $\geq 20\%$  as assessed with the FRAX

## Substance Use

### Nicotine / Tobacco Dependence Treatment

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
bupropion SR	CHANTIX (varenicline)
nicotine lozenge	NICODERM CQ (nicotine) PATCH
nicotine patch	NICORETTE (nicotine polacrilex) GUM
nicotine polacrilex gum	ZYBAN (bupropion SR)
NICOTROL (nicotine polacrilex) SPRAY	
varenicline	

### Concurrent Medication Required

- Short-acting nicotine agents (nasal spray, lozenge, and gum) require concurrent nicotine patch, bupropion SR (generic Zyban), or varenicline since better outcomes are associated with concurrent use of short-acting and long-acting tobacco cessation products.
  - A total of 14 days of nicotine patch, bupropion SR (generic Zyban), or varenicline must be paid within 40 days prior to nicotine nasal spray, lozenge, or gum's date of service.

Clinically Important Information: Bupropion SR (generic Zyban) takes 5 to 7 days to reach steady state. It is recommended to start one week before target quit date. NRT products are allowed in addition to bupropion SR to bridge therapy until bupropion SR becomes effective and for concurrent use.

### Electronic Duration Verification

- A total of 12 consecutive weeks will be covered for all other products, every 6 months.

Varenicline or bupropion SR (generic Zyban): If the following conditions apply, please call for an override by calling provider relations at 1-800-755-2604:

- Patient is abstinent from tobacco.
- Treatment duration is requested to be extended to 24 consecutive weeks.

### Therapeutic Duplication

- Nicotine gum, lozenge, and spray will not be paid concurrently.
- Bupropion SR (generic Zyban) will not be paid with other forms of bupropion.

### Underutilization

- Nicotine Patch, varenicline, and bupropion SR (generic Zyban) must be used adherently and will reject on point of sale for late fill.

## Opioid Use Disorder

### Alpha-2 Adrenergic Agonists

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
clonidine	lofexidine
guanfacine	LUCEMYRA (lofexidine) – <i>Brand Required</i>

### Prior Authorization Criteria

#### Initial Criteria – Approval Duration: 12 months

- The member must have had a 30-day trial of each preferred agent, as evidenced by paid claims or pharmacy printouts.
- Clinical justification must be provided explaining why the member is unable to use the preferred agents (subject to clinical review).

### Opioid Antagonist

PREFERRED AGENTS (NO PA REQUIRED)
naltrexone tablets
VIVITROL (naltrexone microspheres) INJECTION

### Opioid Reversal Medications

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
KLOXXADO (naloxone) NASAL SPRAY	ZIMHI (naloxone) SYRINGE
nalmefene injection	
naloxone nasal spray	
naloxone injection	
NARCAN (naloxone) NASAL SPRAY – <i>Brand Co-Preferred</i>	

OPVEE (nalmeferene) NASAL SPRAY	
REXTOVY (naloxone) NASAL SPRAY – <i>Brand Co-Preferred</i>	

### Electronic Duration Verification

- 4 doses are covered every 60 days without an override.

If one of the following criteria are met (A or B), please request an override by calling provider relations at 1-800-755-2604 or emailing [medicaidpharmacy@nd.gov](mailto:medicaidpharmacy@nd.gov):

- The previous dose has expired.
- The dose was used by member for an opioid overdose. (In this case, it is recommended to follow up with prescriber to discuss frequency of use and potential regimen review/adjustments)

### Prior Authorization Criteria

#### Initial Criteria – Approval Duration: 12 months

- The member must have had a 30-day trial of each preferred agent, as evidenced by paid claims or pharmacy printouts.
- Clinical justification must be provided explaining why the member is unable to use the preferred agents (subject to clinical review)

## Opioid Partial Agonist

### Electronic Step Therapy Required

- A total of 28 days of Sublocade 300 mg must be paid within 60 days prior to Sublocade 100 mg date of service.

Per Sublocade package insert:

Established Transmucosal Buprenorphine Doses	Injection #1	Injection #2	Maintenance Dose
8 – 18 mg/day	300 mg	100 mg*	100 mg
20 – 24 mg/day	300 mg	300 mg	100 mg

\*For patients still experiencing craving or withdrawal symptoms after the initial 300-mg dose, consider giving 300 mg as the second dose

Sublocade is not indicated when established transmucosal buprenorphine dose is under 8 mg/day. Brixadi has dosing recommendations when established transmucosal buprenorphine dose is under 8 mg/day.

### Therapeutic Duplication

- One strength of one medication is allowed at a time.
- Opioid partial agonists are not allowed with:
  - methadone
  - carisoprodol
  - opioids
- Opioid full agonist requested with member with history of opioid use disorder.
  - If 1 and 2 are met, please call for an override by calling provider relations at 1-800-755-2604 (chart notes will be required for requests beyond one fill)
    - The request is for one of the following:
      - A one-time fill request where pain cannot be reasonably treated with non-opioid therapy (e.g., surgery)

- A request exceeding a one-time fill and a treatment plan has been provided with expected duration of use and why non-opioid therapy is not an option (subject to clinical review) or a taper plan is provided.
- 2. One of the following is met:
  - Prescribers of both opioid prescription and MOUD (medications for opioid use disorder) are aware of each other and agree to opioid therapy.
  - MOUD has been discontinued, and the prescriber of the opioid is aware of previous MOUD treatment and confirms opioid therapy is required.
- Opioid partial agonist injection + oral overlap  
 Please call for an override by calling provider relations at 1-800-755-2604 to request a 4 month overlap period with oral buprenorphine/naloxone while initiating long-acting injectable buprenorphine (until the therapeutic levels are achieved).

## Mono Product

### Oral Agents

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	buprenorphine tablets++

++ Clinically Non-Preferred: Naloxone is added to buprenorphine to prevent misuse. When taken correctly, a baby will have little to no absorption of naloxone which a growing body of evidence show is safe. Taking combination product during pregnancy or breastfeeding means that products don't need to be switched to a different medication after the baby is born during this high anxiety time. Risk of withdrawal to a neonate is a labeled warning on each product. Pregnancy and breastfeeding are not listed as contraindications on either product.

### References:

1. Opioid use and opioid use disorder in pregnancy. Committee Opinion No. 711. American College of Obstetricians and Gynecologists. *Obstet Gynecol* 2017;130:e81–94.
2. Perry, Briana N. MD; Vais, Simone BA; Miller, Melissa BA; Saia, Kelley A. MD. Buprenorphine-Naloxone Versus Buprenorphine for Treatment of Opioid Use Disorder in Pregnancy [07E]. *Obstetrics & Gynecology* 135():p 51S, May 2020. | DOI: 10.1097/01.AOG.0000663444.50960.74
3. Substance Abuse and Mental Health Services Administration. Clinical Guidance for Treating Pregnant and Parenting Women With Opioid Use Disorder and Their Infants. HHS Publication No. (SMA) 18-5054. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2018.

### Prior Authorization Criteria

#### Initial Criteria – Approval Duration: 1 year

- Clinical justification must be provided explaining why the member is unable to use the preferred agents (subject to clinical review)
  - Allergy to oral naloxone is extremely rare and must be well documented.
  - Any request for transmucosal buprenorphine should include justification why long-acting injectable buprenorphine can't be used
    - Pregnancy or breastfeeding will not be approved as clinical justification based on the clinically non-preferred information provided above.
    - Stability will not be approved as clinical justification, although limited approval may be granted to allow for recommended pre-treatment and titration prior to initiation of long-acting buprenorphine product – maximum of 7 days for Sublocade, and 1 dose for Brixadi

### Non-Oral Agents

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

BRIXADI (buprenorphine)	
SUBLOCADE (buprenorphine)	

## Combination Product

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
buprenorphine-naloxone tablets	BUNAVAIL FILM (buprenorphine/naloxone)
	buprenorphine/naloxone film
	SUBOXONE FILM (buprenorphine/naloxone)
	ZUBSOLV (buprenorphine/naloxone)

### Prior Authorization Criteria

- See [DAW \(Dispense As Written\) Criteria](#)

## Biosimilar Agents:

### Prior Authorization Criteria

#### Initial Criteria – Approval Duration: 12 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The member must have failed a 90-day trial of each preferred medication.
- Clinical justification must be provided explaining why the member is unable to use the preferred agents (subject to clinical review).

## Adalimumab

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ABRILADA (adalimumab-afzb)	adalimumab-aacf
adalimumab-adbm – labeler 00597	adalimumab-aaty
adalimumab-fkjp	adalimumab-adaz
CYLTEZO (adalimumab-abdm)	adalimumab-adbm – labeler 82009
HADLIMA (adalimumab-bwwd)	adalimumab-ryvk
HULIO (adalimumab-fkjp)	AMJEVITA (adalimumab-atto)
HUMIRA (adalimumab)	HYRIMOZ (adalimumab-adaz)
SIMLANDI (adalimumab-ryvk)	IDACIO (adalimumab-aacf)
YUSIMRY (adalimumab-aqvh)	YUFLYMA (adalimumab-aaty)

## Bevacizumab

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
MVASI (bevacizumab – awwb) – Medical Billing Only	ALYMSYS (bevacizumab – maly) – Medical Billing Only
ZIRABEV (bevacizumab – bvzr) – Medical Billing Only	AVASTIN (bevacizumab) – Medical Billing Only
	VEGZELMA (bevacizumab – acdc) – Medical Billing Only

## Filgrastim

### Medical Billing

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
GRANIX (TBO-filgrastim) – Medical Billing Only	NEUPOGEN (filgrastim) – Medical Billing Only
NIVESTYM (filgrastim-aafi) – Medical Billing Only	RELEUKO (filgrastim-ayow) – Medical Billing Only
ZARXIO (filgrastim-sndz) – Medical Billing Only	

### Pharmacy Billing

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
NEUPOGEN (filgrastim)	GRANIX (TBO-filgrastim)
RELEUKO (filgrastim-ayow)	NIVESTYM (filgrastim-aafi)
	ZARXIO (filgrastim-sndz)

## Pegfilgrastim

### Medical Billing

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
NEULASTA (pegfilgrastim) – Medical Billing Only	FULPHILA (pegfilgrastim-jmdb) – Medical Billing Only
NEULASTA ONPRO (pegfilgrastim) – Medical Billing Only	FYLNETRA (pegfilgrastim -pbbk) – Medical Billing Only
NYVEPRIA (pegfilgrastim-apgf) – Medical Billing Only	STIMUFEND (pegfilgrastim-fpgk) – Medical Billing Only
UDENYCA ONBODY (pegfilgrastim-cbqv) – Medical Billing Only	UDENYCA (pegfilgrastim-cbqv) – Medical Billing Only
	ZIEXTENZO (pegfilgrastim-bmez) – Medical Billing Only

Pharmacy Billing PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
FULPHILA (pegfilgrastim-jmdb)	NEULASTA (pegfilgrastim)
FYLNETRA (pegfilgrastim -pbbk)	NYVEPRIA (pegfilgrastim-apgf)
NEULASTA ONPRO (pegfilgrastim)	STIMUFEND (pegfilgrastim-fpgk)
UDENYCA ONBODY (pegfilgrastim-cbqv)	UDENYCA (pegfilgrastim-cbqv)
	ZIEXTENZO (pegfilgrastim-bmez)

## Infliximab

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AVSOLA (infliximab-axxq) – Medical Billing Only	infliximab – Medical Billing Only
INFLECTRA (infliximab-dyyb) – Medical Billing Only	RENFLIXIS (infliximab-abda) – Medical Billing Only
	REMICADE (infliximab) – Medical Billing Only

## Rituximab

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

## Tocilizumab

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
TYENNE (tocilizumab-aazg) AUTOINJECTOR, SYRINGE	ACTEMRA (tocilizumab) ACTPEN, SYRINGE
TYENNE (tocilizumab-aazg) VIAL – <i>Medical Billing Only</i>	ACTEMRA (tocilizumab) VIAL – <i>Medical Billing Only</i>
	TOFIDENCE (tocilizumab-aazg) VIAL – <i>Medical Billing Only</i>

## Trastuzumab

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
KANJINTI (trastuzuamb – anns) – <i>Medical Billing Only</i>	OGIVRI (trastuzumab – dkst) – <i>Medical Billing Only</i>
TRAZIMERA (trastuzumab – qyyp) – <i>Medical Billing Only</i>	ONTRUZANT (trastuzumab – dttb) – <i>Medical Billing Only</i>
	HERZUMA (trastuzumab – pkrb) – <i>Medical Billing Only</i>
	HERCEPTIN (trastuzumab) – <i>Medical Billing Only</i>

## Preferred Dosage Form Criteria List:

### *Prior Authorization Criteria*

#### Initial Criteria – Approval Duration: 12 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The member must have failed a 30-day trial of each preferred medication.
- Clinical justification must be provided explaining why the member is unable to use the preferred agents (subject to clinical review).

## Azathioprine

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
azathioprine 50 mg	azathioprine 75 mg
	azathioprine 100 mg

## Brisdelle (paroxetine)

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
paroxetine tablets	paroxetine mesylate 7.5 mg capsules
	PEXEVA (paroxetine mesylate)

## butalbital-acetaminophen-caffeine

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
butalbital-acetaminophen-caffeine tablets	butalbital-acetaminophen-caffeine capsules



VTOL LQ (butalbital-acetaminophen-caffeine) SOLUTION	ESGIC (butalbital-acetaminophen-caffeine) TABLET
	FIORICET (butalbital-acetaminophen-caffeine) CAPSULES
	ZEBUTAL (butalbital-acetaminophen-caffeine) CAPSULES

## citalopram

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
citalopram tablets	citalopram capsules
citalopram solution	

## colchicine

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
colchicine tablet	colchicine capsule
	GLOPERBA (colchicine) ORAL SOLUTION
	LODOCO (colchicine) TABLET
	MITIGARE (colchicine) CAPSULE

## cyanocobalamin

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
cyanocobalamin injection	NASCOBAL (cyanocobalamin) NASAL SPRAY

## epinephrine

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
epinephrine – labeler 49502	AUVI-Q (epinephrine)
EPIPEN (epinephrine) – <i>Brand Co-Preferred</i>	epinephrine – labeler 00093, 00115
EPIPEN (epinephrine) JUNIOR – <i>Brand Co-Preferred</i>	NEFFY (epinephrine)

### Electronic Duration Verification

- 4 doses are covered every 60 days without an override

If one of the following criteria are met (A or B), please request an override by calling provider relations at 1-800-755-2604 or emailing [medicaidpharmacy@nd.gov](mailto:medicaidpharmacy@nd.gov):

- The previous dose has expired
- The dose was used by member for an anaphylactic episode

## gabapentin

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
gabapentin	gabapentin ER
	GRALISE (gabapentin)
	HORIZANT (gabapentin)

## Jadenu (deferasirox)

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
deferasirox tablet for suspension	EXJADE (deferasirox tablet for suspension)
deferasirox tablets	deferasirox sprinkle
	JADENU (deferasirox) SPRINKLE
	JADENU (deferasirox) TABLETS

## Kits

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
FDA approved products prescribed separately	CAMPHOTREX 4%-10% ROLL-ON G (menthol/camphor)
	CENTANY AT (mupirocin)
	CICLOPIROX (ciclopirox/urea/camphor/methol)
	CICLODAN (ciclopirox/urea/camphor/methol)
	CICLODAN (ciclopirox/skin cleanser 28)
	CLINDACIN ETZ (clindamycin phos/skin clnsr 19)
	CLINDACIN PAC (clindamycin phos/skin clnsr 19)
	CLINDAVIX (clindamycin/dimethacone/zinc oxide)
	CLOBETEX (clobetasol/desloratadine)
	CYCLOPAK (cyclobenzaprine/lidocaine/prilocaine/glycerine)
	DERMACINRX ARM PAK (lidocaine/dimethacone)
	DERMACINRX LEXITRAL PHARMAP (diclofenac/capsicum oleoresin)
	DERMACINRX PHN PAK (lidocaine/emollient cmb No. 102)
	DERMACINRX SILAPAK (triamcinolone/dimeth/silicone)
	DERMACINRX SILAZONE (triamcinolone/silicones)
	DERMACINRX SURGICAL PHARMAP (mupirocin/chlorhexidine/dimeth)
	DERMACINRX THERAZOLE PAK (clotrimazole/betameth dip/zinc)
	DERMACINRX ZRM PAK (lidocaine/dimethicone)
	DERMALID 5% PATCH (lidocaine/elastic bandage)
	ELLZIA PAK (triamcinolone/dimethicone)
	ESOMEPE-EZS KIT (esomeprazole mag/glycerin)
	ECONASIL (econazole/gauze/silicone)
	FLUOPAR (fluocinonide/dimethacone)
	FLUOVIX PLUS (fluocinonide/silicone, adhesive)
	GABACAINE KIT (gabapentin/lidocaine)
	INAVIX (diclofenac/capsaicin)
	INFAMMACIN (diclofenac/capsicum)
	KETODAN (ketoconazole/skin cleanser 28)
	LIDOPURE PATCH 5% COMBO PAC (lidocaine/kinesiology tape)
	LIDOTIN (gabapentin/lidocaine/silicone)
	LIPRITIN (gabapentin/lidocaine/prilocaine/dressing)
	LOPROX (ciclopirox/skin cleanser No. 40)
	MIGRANOW KIT (sumatriptan/menthol/camphor)
	MORGIDOX (Doxycycline/skin cleanser No. 19)

	NAPROTIN (naproxen/capsicum)
	NOPIOID-TC KIT (cyclobenzaprine/lidocaine/menthaine)
	NUVAKAAN KIT (lidocaine/prilocaine/silicone)
	NUSURGEPAK (mupirocin/chlorhexidine/dimethacone)
	NUTRIARX (Triamcinolone/dimethacone/silicone)
	PRILO PATCH KIT (lidocaine/prilocaine)
	PRIZOTRAL II (lidocaine/prilocaine/lidocaine)
	PRO DNA MEDICATED COLLECTION (lidocaine/glycerin)
	REVIVASIL (gel pad/dmc/dime/dec/oct/vit E) KIT
	SALEX (salicylic acid/ceramide comb 1) CREAM KIT
	SALEX (salicylic acid/ceramide comb 1) LOTION KIT
	SILAZONE-II KIT (triamcinolone acetone/silicones)
	SOLARAVIX (Diclofenac/silicone, adhesive)
	SUMADAN KIT (sulfacetamide/sulfur/cleansr23)
	SUMAXIN CP KIT (sulfacetamide/sulfur/cleansr23)
	TICANASE KIT (fluticasone/sodium chloride/sodium bicarbonate)
	TRIVIX (Triamcinolone/dimethacone/silicone)
	TRIXYLITRAL (diclofenac/lidocaine/tape)
	XRYLIX 1.5% KIT (diclofenac/kinesiology tape)
	ZILACAINE PATCH 5% COMBO PA (lidocaine/silicone, adhesive)

## lactulose

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
CONSTULOSE (lactulose) solution	KRISTALOSE (lactulose) PACKET
ENULOSE (lactulose) solution	lactulose packet
lactulose solution	

## metformin

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
metformin ER	FORTAMET (metformin)
RIOMET (metformin) ORAL SOLUTION	GLUMETZA (metformin)
RIOMET ER (metformin) ORAL SOLUTION	metformin ER gastric retention 24 hr
	metformin ER osmotic

## methotrexate

Required trial duration: 6 weeks

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
methotrexate	OTREXUP (methotrexate) AUTO-INJECTOR
JYLAMVO (methotrexate) SOLUTION	RASUVO (methotrexate) AUTO-INJECTOR
XATMEP (methotrexate) SOLUTION	REDITREX (methotrexate) SYRINGE
	TREXALL (methotrexate) TABLET

## mycophenolate mofetil

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
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mycophenolate mofetil	CELLCEPT (mycophenolate mofetil)
	MYHIBBIN (mycophenolate mofetil)

## montelukast

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
montelukast chewable tablets	montelukast granules
montelukast tablets	

### *Electronic Age Verification*

- Montelukast granules are preferred for ages 1 and under

## mupirocin

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
mupirocin ointment	mupirocin calcium cream

## nitisinone

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ORFADIN (nitisinone) 2 MG, 5 MG, 10 MG CAPSULE	NITYR (nitisinone) TABLET
ORFADIN (nitisinone) SUSPENSION	ORFADIN (nitisinone) 20 MG CAPSULE

## nitroglycerin

**Required trial duration:** 1 dose while on preventative medication

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
nitroglycerin sublingual tablets	GONITRO (nitroglycerin) SUBLINGUAL PACKET
	nitroglycerin spray
	NITROLINGUAL (nitroglycerin) SPRAY

## Nocdurna (desmopressin)

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
desmopressin	NOCDURNA (desmopressin)

## Pregabalin

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
pregabalin	LYRICA (pregabalin)
	LYRICA CR (pregabalin)
	pregabalin ER

## Procysbi (cysteamine)

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
CYSTAGON (cysteamine)	PROCYSBI (cysteamine)
	PROCYSBI GRANULES (cysteamine)

## Steroids – Oral

Agamree and Emflaza: See [Duchenne Muscular Dystrophy](#) Criteria on this document

Tarpeyo: See [Tarpeyo](#) Criteria on this document

Rayos required trial duration: 12 weeks with 2 AM dosing of prednisone

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
budesonide 3 mg EC capsules	AGAMREE (vamorolone)
cortisone	ALKINDI (hydrocortisone) SPRINKLE CAPSULE
dexamethasone	budesonide 9 mg ER tablet
EOHILIA (budesonide)	deflazacort
hydrocortisone	EMFLAZA (deflazacort) – <i>Brand Required</i>
methylprednisone	HEMADY (dexamethasone)
prednisolone sodium phosphate 5 mg/5 ml, 15 mg/5 ml, 25 mg/5 ml	MILLIPRED (prednisolone)
prednisone solution	ORTIKOS (budesonide)
prednisone tablets	prednisone intensol
	prednisolone sodium phosphate ODT
	prednisolone sodium phosphate 10 mg/5 ml, 20 mg/5 ml solution
	RAYOS (prednisone)
	TAPERDEX (dexamethasone)
	UCERIS (budesonide)

## ursodiol

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ursodiol capsule	RELTONE (ursodiol) CAPSULE
ursodiol tablet	URSO 250 (ursodiol) TABLET
	URSO FORTE (ursodiol) TABLET

# Preferred Diabetic Supply List (PDSL)

## Electronic Concurrent Medications Required

- One of the following must apply:
  - A total of a 25-day supply of one of the following must be paid within 150 days prior to diabetic supplies' date of service:
    - agents that cause hypoglycemia (insulin or sulfonylureas)
    - agents that indicate pregnancy (folic acid or prenatal vitamins)

## Prior Authorization Criteria

### Initial Criteria – Approval Duration: 6 months

- For coverage of blood glucose monitoring devices for those not meeting electronic concurrent medication required criteria above, the member has one of the following (A or B):
  - A. Recurrent hypoglycemia and the test strips are prescribed by or in consult with, a medical geneticist or an endocrinology specialist (subject to clinical review)
  - B. A diagnosis of diabetes and meet **one of the following** criteria:
    1. Newly diagnosed within the last 6 months
    2. Acutely ill
    3. Significant change in health status causing blood sugar variability
    4. Currently pregnant

The ADA guidelines point out the lack of clinical utility and cost-effectiveness of routine Self-Monitoring of Blood Glucose (SMBG) in non-insulin treated members. Both the Society of General Internal Medicine and the Endocrine Society recommend against routine SMBG for type 2 diabetes members not on insulin or agents that cause hypoglycemia.

## Test Strips

### Quantity Limits

- 200 test strips are covered every 30 days

Manufacturer Name	NDC	Product Description
Roche Diabetes Care, Inc.	65702-0711-10	Accu-Chek Guide Test Strip
Roche Diabetes Care, Inc.	65702-0712-10	Accu-Chek Guide Test Strip

## Meters

### Quantity Limits

- 1 meter is covered every 365 days

Manufacturer Name	NDC	Product Description
Roche Diabetes Care, Inc.	65702-0731-10	Accu-Chek Guide Me Glucose Meter
Roche Diabetes Care, Inc.	65702-0729-10	Accu-Chek Guide Monitor System

## InPen

### Quantity Limits

- 1 InPen is covered every 365 days

Manufacturer Name	NDC	Product Description
Minimed Distribution Corporation	62088-0000-31	InPen Smart Insulin Pen (Humalog - Blue)
Minimed Distribution Corporation	62088-0000-32	InPen Smart Insulin Pen (Humalog - Grey)
Minimed Distribution Corporation	62088-0000-33	InPen Smart Insulin Pen (Humalog - Pink)
Minimed Distribution Corporation	62088-0000-34	InPen Smart Insulin Pen (Novolog or Fiasp – Blue)
Minimed Distribution Corporation	62088-0000-35	InPen Smart Insulin Pen (Novolog or Fiasp – Gray)
Minimed Distribution Corporation	62088-0000-36	InPen Smart Insulin Pen (Novolog or Fiasp – Pink)
Minimed Distribution Corporation	63000-0827-15	InPen Smart Insulin Pen (Humalog - Blue)
Minimed Distribution Corporation	63000-0827-16	InPen Smart Insulin Pen (Humalog - Grey)
Minimed Distribution Corporation	63000-0827-17	InPen Smart Insulin Pen (Humalog - Pink)
Minimed Distribution Corporation	63000-0827-18	InPen Smart Insulin Pen (Novolog or Fiasp – Blue)
Minimed Distribution Corporation	63000-0827-19	InPen Smart Insulin Pen (Novolog or Fiasp – Gray)
Minimed Distribution Corporation	63000-0827-20	InPen Smart Insulin Pen (Novolog or Fiasp – Pink)

## Pen Needles

Manufacturer Name	NDC	Product Description
Becton Dickinson & Company	08290-3207-49	Ultra-Fine Micro Pen Needle
Becton Dickinson & Company	08290-3201-19	Ultra-Fine Mini Pen Needle
Becton Dickinson & Company	08290-3201-22	Ultra-Fine Nano Pen Needle
Becton Dickinson & Company	08290-3282-03	Ultra-Fine Original Pen Needle
Becton Dickinson & Company	08290-3201-09	Ultra-Fine Short Pen Needle
Owen Mumford USA, Inc.	08470-3429-01	Pentips
Owen Mumford USA, Inc.	08470-3430-01	Pentips
Owen Mumford USA, Inc.	08470-3440-01	Pentips
Owen Mumford USA, Inc.	08470-3450-01	Pentips
Owen Mumford USA, Inc.	08470-3490-01	Pentips
Owen Mumford USA, Inc.	08470-3495-01	Pentips
Owen Mumford USA, Inc.	08470-3529-01	Unifine Pentips
Owen Mumford USA, Inc.	08470-3530-01	Unifine Pentips
Owen Mumford USA, Inc.	08470-3540-01	Unifine Pentips
Owen Mumford USA, Inc.	08470-3550-01	Unifine Pentips
Owen Mumford USA, Inc.	08470-3560-01	Unifine Pentips
Owen Mumford USA, Inc.	08470-3590-01	Unifine Pentips
Owen Mumford USA, Inc.	08470-3595-01	Unifine Pentips
Owen Mumford USA, Inc.	08470-3829-01	Unifine Pentips Plus
Owen Mumford USA, Inc.	08470-3830-01	Unifine Pentips Plus
Owen Mumford USA, Inc.	08470-3840-01	Unifine Pentips Plus
Owen Mumford USA, Inc.	08470-3850-01	Unifine Pentips Plus
Owen Mumford USA, Inc.	08470-3860-01	Unifine Pentips Plus



Owen Mumford USA, Inc.	08470-3890-01	Unifine Pentips Plus
Owen Mumford USA, Inc.	08470-7935-01	Unifine Safecontrol
Owen Mumford USA, Inc.	08470-7930-01	Unifine Safecontrol
Owen Mumford USA, Inc.	08470-7940-01	Unifine Safecontrol
Owen Mumford USA, Inc.	08470-7950-01	Unifine Safecontrol
Owen Mumford USA, Inc.	08470-7955-01	Unifine Safecontrol
Owen Mumford USA, Inc.	08470-7990-01	Unifine Safecontrol

## Syringes

Manufacturer Name	NDC	Product Description
Becton Dickinson & Company	08290-3284-11	BD syringe and needle,insulin,1 mL
Becton Dickinson & Company	08290-3284-18	BD syringe and needle,insulin,1 mL
Becton Dickinson & Company	08290-3284-31	BD syring-needl,disp,insul,0.3 mL
Becton Dickinson & Company	08290-3284-38	BD syring-needl,disp,insul,0.3 mL
Becton Dickinson & Company	08290-3284-40	BD syрге-ndl,ins 0.3 mL half mark
Becton Dickinson & Company	08290-3284-66	BD syringe-needle,insulin,0.5 mL
Becton Dickinson & Company	08290-3284-68	BD syringe-needle,insulin,0.5 mL
Becton Dickinson & Company	08290-3267-30	BD syringe,insul U-500,ndl,0.5mL
Becton Dickinson & Company	08290-3249-09	BD syring-needl,disp,insul,0.3 mL
Becton Dickinson & Company	08290-3249-10	BD syringe-ndl,ins 0.3 mL half mark
Becton Dickinson & Company	08290-3249-11	BD syringe-needle,insulin,0.5 mL
Becton Dickinson & Company	08290-3249-12	BD syringe and needle,insulin,1 mL

## Ketone Strips

### Quantity Limits

- 120 strips per 30 days

Manufacturer Name	NDC	Product Description
Trivida Health, Inc.	56151-0601-01	Ketone Test Strip
Trivida Health, Inc.	56151-0601-50	Ketone Test Strip

## Continuous Glucose Monitors (CGM)

### Preferred CGM

### Quantity Limits

- NDC 08627005303- Dexcom G6 Sensor: 3 ten-day sensors/box= up to qty 9/90-day supply
- NDC 08627001601- Dexcom G6 Transmitter: 1= 90-day supply (4 transmitters/365 days allowed)
- NDC 08627009011- Dexcom G6 Receiver: 1= 250-day supply (1 receiver/365 days allowed)
- NDC 08627007701- Dexcom G7 Sensor: 1 ten-day sensor/box= up to qty 9/90-day supply
- NDC 08627007801- Dexcom G7 Receiver: 1= 250-day supply (1 receiver/365 days allowed)

Manufacturer Name	NDC	Product Description
Dexcom, Inc.	08627-0016-01	Dexcom G6 Transmitter

Dexcom, Inc.	08627-0053-03	Dexcom G6 Sensor
Dexcom, Inc.	08627-0091-11	Dexcom G6 Receiver
Dexcom, Inc.	08627-0077-01	Dexcom G7 Sensor
Dexcom, Inc.	08627-0078-01	Dexcom G7 Receiver

## Non-Preferred CGM

A coverage exception will be considered for members that has had a Medtronic Insulin pump for over a year or have had a Medtronic Insulin pump purchased by another payer prior to eligibility for ND Medicaid to allow for CGM integration with their insulin pumps. Please submit supporting information for the coverage of a Guardian CGM along with prior authorization information to meet the requirements as outlined in criteria below.

If the Medtronic Insulin pump is older than 4 years, the authorization period will be shortened to verify that the pump is still functioning for re-authorization. If the Medtronic Insulin pump fails, the expectation is to switch to an insulin pump that is compatible with a preferred CGM.

- Guardian Sensor 3: max of 15 sensors (3 boxes) per 90-day supply
- Guardian Link Transmitter 3: max of 1 per 365-day supply
- Guardian Sensor 4: max of 15 sensors (3 boxes) per 90-day supply
- Guardian Link Transmitter 4: max of 1 per 365-day supply

Guardian Sensor 4 is preferred since no calibration is required. Clinical justification for use of Guardian Sensor 3 must be submitted (subject to clinical review).

[Calibrating your Sensor - MiniMed™ 780G System Support | Medtronic \(medtronicdiabetes.com\)](#)

Please contact Medtronic for replacement sensor and transmitters:

[Sensor and Transmitter Support - Product Support | Medtronic \(medtronicdiabetes.com\)](#)

### Concurrent Medication Required

- Please submit PA for sensor, if PA is approved, **please bill sensors first** followed by the transmitter or receiver. If the transmitter or receiver is billed first, a "prior authorization required" rejection will occur even if a sensor PA has already been approved.

### Prior Authorization Criteria

#### [Continuous Glucose Monitor \(CGM\) Prior Authorization Form](#)

**Initial Criteria – Approval Duration:** 12 months (Until due date or 6 months, if unknown, for gestational diabetes)

- The member must meet **one of the following** criteria (1 or 2):
  1. The member has diabetes (e.g., type 1, type 2, gestational diabetes)
  2. The member has recurrent hypoglycemia and CGM is prescribed by or in consult with, a medical geneticist or an endocrinology specialist.
- The member must not have life expectancy of less than 12 months.
- The member must not reside in a skilled nursing facility.
- Member with Type 1 or Type 2 Diabetes (not applicable if pregnant) must meet **both of the following** (1 and 2):
  1. The most recent A1c must be provided.
  2. **Both the following** must be agreed to by attestation:
    - The member will maintain regular provider visits to review glycemic control every 3-6 months.
    - CGM data will be reviewed to adjust/modify medication regimen and improve outcomes and not solely for hypoglycemia alerts.
- Members with Type 2 Diabetes (not applicable if pregnant) must meet **one of the following** criteria (1, 2, or 3):

- A. The member has been on short-acting and long-acting insulin for at least 6 months, as evidenced by refill history with paid claims or pharmacy printouts.
- B. The member is currently Humulin R U-500 or an insulin pump.
- C. The member was unable to achieve goal (A1c < 7% or TIR > 70%) despite triple combination therapy consisting of long-acting insulin dose of at least 10 units per day combined with two other non-insulin antihyperglycemic agents (oral or injectable), at the maximum tolerated dose with good adherence at least 3 months, as evidenced by refill history with paid claims or pharmacy printouts.

***Renewal Criteria – Approval Duration: 12 months***

*For diagnosis of diabetes (not applicable when pregnant):*

- The most recent A1c or TIR must be submitted.
- One of the following must be met:
  - *Approval 12 months:*  
A1c and/or TIR must progress toward or be within goal (A1c < 7% or TIR > 70%) from last approval:
  - *Approval 6 months:*  
A1c and/or TIR is outside of goal and has worsened (worsened is defined as > 0.5% increase of A1c or 5% decrease in TIR) from last approval.  
One of the following must be met:
    - A member has been referred to diabetic educator or diabetic specialist for treatment plan.
    - CGM data must have been reviewed to evaluate/adjust therapy and develop a treatment plan as provided in submitted documentation.

**Test Strip Requests after CGM approval**

For replacement inquiries, sensor overpatches, and troubleshooting please contact Dexcom Global Technical Support at 1-844-607-8398 or visit <https://www.dexcom.com/contact>

- ND Medicaid will cover 200 test strips per year to facilitate instances where CGM is not displaying blood sugar readings that correspond with the symptoms member is experiencing or that are consistently outside of the 20 rule: [Is my Dexcom sensor accurate?](#)

***Prior Authorization Criteria***

- The following criteria will apply if CGM has previously been paid, but will no longer be used and regular test strip quantities are requested:
  - The member must be seen for education by a diabetic specialist or educator
  - Documentation must be submitted noting what caused the CGM failure and education / mitigation efforts that have been taken to prevent the failure, including the following as applicable:
    - Stickiness: Skin adhesive and / or overpatches have been trialed without success
    - Sensor not working: at least 2 sensor replacements have been trialed
    - Sensitive Skin: [How can I avoid irritated or sensitive skin caused by the sensor adhesive?](#)

**CGM Supplies Coverage FAQ**

**Does ND Medicaid cover Dexcom daily calibration?**

- No, the unique Dexcom sensor code must be entered that is printed on each sensor’s adhesive label during the startup period, so finger sticks and calibration are not required.
- [Does the Dexcom G6 Continuous Glucose Monitoring \(CGM\) System require calibrations?](#)
- [Can I calibrate Dexcom G7? | Dexcom](#)

**Will test strips be covered in addition to Dexcom?**

- Yes, ND Medicaid will cover 200 test strips per year to facilitate instances where Dexcom is not displaying blood sugar readings that correspond with the symptoms member is experiencing or that are consistently outside of the 20 rule.
- [Is my Dexcom sensor accurate?](#)

**Does ND Medicaid cover additional sensors, transmitters, or receivers if mine is faulty or broken?**

- For replacement inquiries, sensor overpatches, and troubleshooting please contact Dexcom Global Technical Support at 1-844-607-8398 or visit <https://www.dexcom.com/contact>

**If my patient is currently on a CGM that is not Dexcom, is there a grandfathering period?**

- No, the member should be converted to Dexcom billed on the pharmacy side to obtain ND Medicaid coverage. Exceptions will be considered for members that already have a Medtronic insulin pump for over a year or has had a Medtronic Insulin pump purchased by another payer prior to eligibility for ND Medicaid to allow for CGM integration.

**Does ND Medicaid cover Dexcom G6 for members in Long Term Care facilities?**

- If a member has Medicare Part B, Medicare Part B will need to be billed primary and ND Medicaid may cover the remainder as a crossover claim with medical billing.
- If a member does not have Medicare Part B, an override will need to be obtained for coverage.
- In all cases, the member must meet prior authorization criteria for coverage.

**How is CGM billed for Medicaid Expansion members?**

- CGM will need to be billed to ND Medicaid for Medicaid Expansion members.

**How is CGM billed for Special Health Services (SHS) members eligible for ND Medicaid?**

- Members receiving CGM other than Dexcom will need to work with SHS for CGM coverage. Exceptions will be considered for members that already have a Medtronic insulin pump to allow for CGM integration.

*Billing FAQ*

**If I bill Medtronics Guardian sensors under the code A9276 on the medical benefit, will this be covered?**

- No, the code will only be covered for members with primary insurance plans that require CGM to be billed on the medical side. Members will need to be converted to Dexcom billed on the pharmacy side to obtain ND Medicaid coverage. Exceptions will be considered for members that have had a Medtronic insulin pump for over a year or has had a Medtronic Insulin pump purchased by another payer prior to eligibility for ND Medicaid or to allow for CGM integration. Medtronic CGM must be billed on the pharmacy side.

**Will ND Medicaid cover Dexcom through medical billing?**

- ND Medicaid requires Dexcom to be billed through pharmacy NCPDP D.0 billing.
- Exceptions may be made for cases where primary insurance requires Dexcom to be billed with medical billing.

*Other Insurance FAQ*

**If primary insurance only covers CGM other than Dexcom, will ND Medicaid pay the copay?**

- If primary insurance excludes coverage of a Dexcom, ND Medicaid may make an exception to cover a non-covered CGM if the copay is nominal. Documentation of the exclusion must be submitted with the prior authorization request.
- If primary insurance does cover Dexcom, the member will need to switch to Dexcom for ND Medicaid to pay the copay.

**Does ND Medicaid cover Dexcom if member has primary insurance, but it does not cover CGM?**

- ND Medicaid may cover Dexcom as a primary payer if CGM is wholly excluded from the primary insurance benefit. Documentation stating the exclusion from the primary insurance must be submitted with the prior authorization request.
- ND Medicaid will not cover CGM as a primary payer if a prior authorization is denied for medical necessity by the primary insurance.

**Will ND Medicaid cover Dexcom if member meets primary insurance prior authorization criteria, but does not meet ND Medicaid prior authorization criteria?**

- ND Medicaid will not cover Dexcom if ND Medicaid prior authorization criteria is not met, regardless of approval status with primary insurance. Under rare circumstances, exceptions may be made if the copay is nominal as long as the member maintains primary insurance coverage with a Dexcom benefit.

## Tubeless Insulin Pumps

### Quantity limits:

- NDC 08508200005 - Omnipod DASH Refill Pods – 10 pods per 30-day supply
- NDC 08508300001 - Omnipod 5 Intro Kit – 1 per 30-day supply (payable 1 per 365 days)
- NDC 08508300021 - Omnipod 5 Refill Pods – 10 pods per 30-day supply
- NDC 08508300053 - Omnipod 5 G6-G7 Pods (Gen 5) - 10 pods per 30-day supply
- NDC 08508300050 - Omnipod 5 G6-G7 Intro Kit - 1 per 30-day supply (payable 1 per 365 days)
- NDC 08508300088 - Omnipod 5 Intro G6 for Libre 2 – 1 per 30-day supply (payable 1 per 365 days)
- NDC 08508300042 - Omnipod 5 G6 Refill Pods for Libre 2 – 10 pods per 30-day supply

Requests for greater than 10 pods per 30 days must include clinical justification vs using a tubed pump. If requested quantity exceeds 15 pods per 30 days, request will be denied for Omnipod. Member may still be eligible for tubed pump (requires separate medical prior authorization).

Manufacturer Name	NDC	Product Description
Insulet, Inc.	08508-2000-05	Omnipod DASH Refill Pods
Insulet, Inc.	08508-3000-01	Omnipod 5 Intro Kit
Insulet, Inc.	08508-3000-21	Omnipod 5 Refill Pods
Insulet, Inc.	08508-3000-53	Omnipod 5 G7 Pack Pods
Insulet, Inc.	08508-3000-50	Omnipod 5 G7 Intro Kit
Insulet, Inc.	08508-3000-42	Omnipod 5 FSL2 Plus G6 Pods
Insulet, Inc.	08508-3000-88	Omnipod 5 FSL2 Plus G6 Intro Kits

### Prior Authorization Criteria

#### [Tubeless Insulin Pump \(Omnipod\) Prior Authorization Form](#)

##### Initial Criteria – Approval Duration: 12 months

- The requested medication must be prescribed by, or in consult with, an endocrinologist, diabetic educator, or prescriber specializing in the treatment of diabetes or prescriber must attest to all of the following:
  - A. The member will maintain regular provider visits to review glycemic control data every 3-6 months.
  - B. The member will receive Omnipod training from Omnipod System Trainer or a healthcare provider.
- The member has not received a tubed insulin pump within the past 4 years or must be experiencing elevated glucose levels from disconnecting due to contact or swimming sports.
- The member must be using a compatible rapid-acting insulin.
- The member must have one of the following (A, B, or C):
  - A. Diabetes type 1 or type 2
  - B. Diabetes due to pancreatectomy
  - C. Diabetes due to an auto-immune beta cell destruction requiring insulin therapy with a long-acting and short-acting insulin for the past 6 months, as evidenced by paid claims or pharmacy print outs.
- Members with Type 2 Diabetes must meet **one of the following** criteria (1 or 2):
  - A. The member has been on short-acting and long-acting insulin for at least 6 months, as evidenced by refill history with paid claims or pharmacy printouts.
  - B. The member is currently Humulin R U-500 or an insulin pump.
- Requests for greater than 10 pods per 30 days must include clinical justification vs using a tubed pump. If requested quantity exceeds 15 pods per 30 days, request will be denied for Omnipod. Member may still be eligible for tubed pump (requires separate medical prior authorization).



## Omnipod Coverage FAQ

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For replacement inquiries or troubleshooting please contact Insulet Customer Care team at 1-800-591-3455 or visit <https://na.myomnipod.com/contact>.

### **Does ND Medicaid cover insulin pens, syringes, or vials if Omnipod is discontinued?**

- Transition should be coordinated with diabetic specialist or educator.
- Current vials of rapid acting insulin should be exhausted before switching to pens. See Insulin category for a list of preferred products.
- Current supply of pods should be exhausted prior to switching to injections.

### **Does ND Medicaid cover additional pods or Personal Diabetes Manager (PDM) if mine is faulty or broken?**

- For replacement inquiries or troubleshooting please contact Insulet Customer Care team at 1-800-591-3455 or visit <https://na.myomnipod.com/contact>.

### **Does ND Medicaid cover additional pods, Personal Diabetes Manager (PDM), replacement USB cords or rechargeable batteries if mine is lost or stolen?**

- For replacement inquiries or troubleshooting please contact Insulet Customer Care team at 1-800-591-3455 or visit <https://na.myomnipod.com/contact>.
- PDMs, USB cords, and rechargeable batteries may be replaced once every 365 days.
- Pods are not replaceable.

### **Will ND Medicaid cover Omnipod through medical billing?**

- ND Medicaid requires Omnipod to be billed through pharmacy NCPDP D.0 billing.

### **How is Omnipod billed for Medicaid Expansion and Special Health Services (SHS) ND Medicaid eligible members?**

- Omnipod will need to be billed to ND Medicaid for Medicaid Expansion members.
- Omnipod will need to be billed to ND Medicaid for SHS members who are eligible for ND Medicaid

### **Does ND Medicaid cover Omnipod for members in Long Term Care facilities?**

- If a member is eligible for Medicare, Medicare Part D will need to be billed primary.
- If member is not eligible for Medicare, the member must meet prior authorization criteria for coverage.

### **Does ND Medicaid cover Omnipod if member has primary insurance, but it does not cover tubeless pumps?**

- ND Medicaid may cover Omnipod as a primary payer if insulin pumps are wholly excluded from the primary insurance benefit. Documentation stating the exclusion from the primary insurance must be submitted with the prior authorization request.
- ND Medicaid will not cover Omnipod as a primary payer if a prior authorization is denied for medical necessity by the primary insurance or primary insurance only covers tubed pumps.

### **Will ND Medicaid cover Omnipod if member meets primary insurance prior authorization criteria, but does not meet ND Medicaid prior authorization criteria?**

- ND Medicaid will not cover Omnipod if ND Medicaid prior authorization criteria is not met, regardless of approval status with primary insurance. Under rare circumstances, exceptions may be made if the copay is nominal as long as the member maintains primary insurance coverage with a Omnipod benefit.

## Appendix A: Concurrent Antipsychotics

### Concurrent Oral Antipsychotic

Please use the [Concurrent Antipsychotics PA form](#) and attach appropriate documentation as necessary.

***Cross-Tapering Plans ARE covered***

Antipsychotic cross-taper plans are covered upon request. An expected plan and timeline must be included with the request.

### ***Use of Multiple Antipsychotics MAY be covered***

The use of two or more antipsychotics should be limited to cases where three trials of adequate dose and duration monotherapy have been failed including a trial of clozapine. Documentation of previous adequate trials with response should be well documented.

The use of one antipsychotic to target one symptom and another antipsychotic to target an additional symptom is not covered. A single antipsychotic can target multiple symptoms.

## **Oral Combination Therapy Criteria**

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Please use the [Concurrent Antipsychotics PA form](#) and attach appropriate documentation as necessary.

*Approval:* An authorization of oral combination therapy for 3 months

- One of the following must be met (1-3):
  1. The member is stabilized on regimen and is establishing care with the prescriber.
  2. The member has been discharged from a psychiatric hospital within the past month.
  3. Cross tapering from one oral antipsychotic to another.
  4. The prescriber must provide clinical justification (subject to clinical review)

*Approval:* An authorization of oral combination therapy for 12 months

- For the treatment of schizophrenia, member must meet one of the following:
  - The member has tolerated 2 monotherapy antipsychotic trials at a therapeutic dose and duration.
- For other indications:
  - The prescriber must provide clinical justification that all alternative antipsychotic active ingredient options have been trialed or ruled out as monotherapy for member (subject to clinical review).

*Approval:* An authorization of oral combination therapy for 2 years

- The member is using aripiprazole for hyperprolactinemia.
- The member has been stabilized on oral combination for over a year and has not had any psychiatric hospitalizations or breakthrough symptoms.
- The prescriber must provide clinical justification (subject to clinical review)

### ***Special considerations***

#### Aripiprazole

- Aripiprazole is supported in the compendia for use for treatment of drug-induced hyperprolactinemia, caused by antipsychotics. Therefore, upon request, aripiprazole is allowed in combination with other antipsychotics for the treatment of hyperprolactemia.

#### Clozapine

- Clozapine should be reserved for treatment resistant cases where two or more monotherapy trials have already failed. In cases of clozapine treatment resistance and augmentation is considered, note that aripiprazole has been shown to be the most effective antipsychotic in combination with clozapine. Combination therapy is allowed without approval.

#### Haloperidol



- Haloperidol may be covered for PRN use for acute agitation / violence prevention. Requests should include clinical rationale of use to prevent harm to self or others. PRN use means 10 doses or less per 30 days. More frequent use will only be considered to allow for maintenance medication adjustments to decrease agitation.

### Olanzapine

- Olanzapine may be covered for PRN use for acute agitation / violence prevention. Requests should include clinical rationale of use to prevent harm to self or others. PRN use means 10 doses or less per 30 days. More frequent use will only be considered to allow for maintenance medication adjustments to decrease agitation.

### Quetiapine

- Nighttime akathisia (e.g., nighttime dosing with risperidone) or daytime sedation (e.g., quetiapine ER dosed at nighttime) must prevent ability to titrate to effective dose with monotherapy.
- Other sleeping medications must be trialed. Primary use for insomnia will not be approved.

## Long-Acting Injectable and Oral Combination

Please use the [Concurrent Antipsychotics PA form](#) and attach appropriate documentation as necessary.

Shortened interval requests are **not covered** as they are not supported in the FDA dosing recommendations or compendia.

Experiencing wearing off symptoms during the titration period (first 3 months of treatment) or first-time experiencing breakthrough symptoms:

---

*Approval:* A 3-month authorization of oral supplemental of the same active ingredient

- The medication requires oral overlap at initiation.
- The member has received a proper loading dose at initiation or recommended oral supplementation and is experiencing breakthrough symptoms.

Ongoing request (> 1 incident of breakthrough symptoms after titration):

---

*Approval:* An authorization of oral supplemental for 12 months

- A MedWatch form for the long-acting antipsychotic must be filled out and attached to request
- The dose must be optimized to maximum FDA approved dose for the LAI antipsychotic
  - A 3-month override of the same active ingredient may be considered for breakthrough symptoms while optimizing dose
- The member must have breakthrough symptoms for 2 or more injection cycles
- One of the following (1, 2, or 3) must be met if breakthrough symptoms are occurring earlier than 75% of recommended interval:
  1. The member must have had greater than a 20% reduction in symptoms with continued improvement
  2. The member must have had greater than a 50% reduction in symptoms
  3. One of the following must be met:
    - The member has had 2 monotherapy antipsychotic trials for an adequate duration
    - The prescriber must provide justification that all alternative active ingredient options have been trialed or ruled out as monotherapy for member (subject to clinical review)

## Appendix B: Antidepressant Cross Tapering:

### Selective Serotonin Reuptake Inhibitors (SSRIs) switched to:

#### Selective Serotonin Reuptake Inhibitors (SSRIs)

**Cross Taper is NOT covered**

Direct switch between SSRIs is typically well-tolerated as SSRIs overlap in their mechanism of action.

#### Serotonin Norepinephrine Reuptake Inhibitors (SNRIs)

**Cross Taper is generally NOT covered, case by case coverage may be provided**

Direct switch between SNRI and SSRI is typically well-tolerated because both SNRIs and SSRIs have strong serotonergic properties, with the following exceptions:

- Patient switching from high dose SSRIs, cross tapering may be of benefit
- Patient switching from fluoxetine or paroxetine to duloxetine or venlafaxine should start SNRI at a low dose. Fluoxetine and paroxetine inhibit the metabolism of duloxetine and venlafaxine.

#### Tricyclic Antidepressants

**Cross Taper is covered**

Cross tapering is recommended. Tricyclic antidepressants should be started at a low dose especially when discontinuing fluoxetine, fluvoxamine, and paroxetine. These SSRIs can inhibit the metabolism of tricyclic antidepressants resulting in higher levels of tricyclic antidepressants. Tricyclic antidepressants can be fatal in overdose. Most SSRIs will clear the system within 5 days, but fluoxetine will persist for up to 5 weeks.

#### Monoamine oxidase inhibitor (MAOIs)

**Cross Taper is NOT covered**

Cross tapering is not recommended and can result in serotonin syndrome or severe hypertensive crisis. A washout period of two weeks is recommended between last dose of SSRI and MAOI except in the case of fluoxetine, where a 5-week washout period is recommended.

#### Other Antidepressants

**Cross Taper is covered**

### All other Antidepressants:

**Cross Taper is covered**

## Appendix C: Prior Authorization Review Dates

Date	Category
12/04/2024	Stimulants for ADHD
09/04/2024	Molluscum Contagiosum
09/04/2024	Epidermolysis Bullosa
09/04/2024	Metabolic Dysfunction–Associated Steatohepatitis
06/05/2024	Acid Blockers
06/05/2024	Seborrheic Dermatitis
06/05/2024	Primary Hyperoxaluria Type 1
06/05/2024	Myasthenia Gravis
06/05/2024	Duchenne Muscular Dystrophy
06/05/2024	Paroxysmal Nocturnal Hemoglobinuria
12/06/2023	Diuretics
12/06/2023	Menopause
06/07/2023	Hyperparathyroidism
06/07/2023	Influenza
06/07/2023	Neuromyelitis Optica Spectrum Disorder
06/07/2023	Urea Cycle Agents
12/07/2022	Prurigo Nodularis
12/07/2022	Endometriosis Pain
12/07/2022	Hematopoietic Syndrome of Acute Radiation Syndrome (Nplate)
12/07/2022	Amyloidosis
12/07/2022	Amyotrophic Lateral Sclerosis (ALS)
12/07/2022	Chelating Agents
09/07/2022	Presbyopia
09/07/2022	Hypertrophic Cardiomyopathy
09/07/2022	Cushing's Syndrome
09/07/2022	Vernal Keratoconjunctivitis
09/07/2022	Wilson's Disease
06/01/2022	Familial Cholestasis Pruritis
03/02/2022	Chronic Kidney Disease
03/02/2022	Lupus
12/01/2021	Atopic Dermatitis/Eczema
12/01/2021	Non-Stimulants for ADHD
09/01/2021	Heart Failure
09/01/2021	Nasal Polyps
09/01/2021	Chronic Idiopathic Urticaria
09/01/2021	Uterine Fibroids
09/01/2021	Sedative/Hypnotics – Hetlioz
06/02/2021	Sickle Cell Disease
06/02/2021	Fabry Disease
06/02/2021	Imcivree
06/02/2021	Bowel preparation agents
03/03/2021	Evrysdi

03/03/2021	Hereditary angioedema
03/03/2021	Irritable bowel syndrome
12/02/2020	Agents for the treatment of diabetic gastroparesis
12/02/2020	Oriahnn
12/02/2020	Dojolvi
09/02/2020	Palforzia
09/02/2020	Mytesi
09/02/2020	Antifibrinolytic agents
09/02/2020	ACL inhibitors (Nexletol, Nexlizet)
09/02/2020	Cystic fibrosis agents
06/03/2020	Conjupri
03/04/2020	Glucagon agents
03/04/2020	Ofev for treatment of scleroderma with interstitial lung disease
12/04/2019	antifungal agents for aspergillus and candidiasis infections
12/04/2019	eosinophilic asthma agents
09/04/2019	short-acting opioid analgesic agents
09/04/2019	agents for the treatment of thrombocytopenia
09/04/2019	agents for the treatment of interstitial cystitis
09/04/2019	agents for the treatment of narcolepsy
06/05/2019	Sivextro
06/05/2019	Nuzyra
06/05/2019	agents for treatment of osteoporosis
06/05/2019	agents for treatment of hyperkalemia
06/05/2019	agents for treatment of Parkinson's disease
04/09/2019	Orilissa
04/09/2019	agents for treatment of vaginal anti-infectives
04/09/2019	agents for treatment of glaucoma
04/09/2019	agents for treatment of dry eye syndrome
12/05/2018	glyburide and Avandia
12/05/2018	Lucemyra
12/05/2018	Palynziq
12/05/2018	Roxybond
12/05/2018	Siklos
09/05/2018	Daxbia
09/05/2018	Dermatophytosis (Tinea infections) agents
09/05/2018	Migraine prophylaxis
09/05/2018	Millipred DP
09/05/2018	Rytary
06/06/2018	Anzemet and Zuplenz
06/06/2018	biosimilar agents
06/06/2018	topical corticosteroid agents
06/06/2018	Dupixent
06/06/2018	Gocovri
06/06/2018	Tussicaps

03/07/2018	Skelaxin
03/07/2018	Eucrisa
09/06/2017	Proglycem
09/06/2017	Biltricide
03/01/2017	prednisolone ODT, Millepred, Veripred
03/01/2017	metformin OSM
03/01/2017	testosterone oral
12/07/2016	Namenda XR
12/07/2016	Dihydroergotamine
12/07/2016	Tetracycline
12/07/2016	Spiriva Respimat 2.5 mcg
12/07/2016	ophthalmic corticosteroids
12/07/2016	erythropoiesis-stimulating agents
09/07/2016	Kits
09/07/2016	dipeptidyl peptidase-4 (DPP-4) inhibitors
09/07/2016	Immunoglobulins
09/07/2016	topical agents used to treat plaque psoriasis
09/07/2016	platelet aggregation inhibitors
09/07/2016	Antihyperuricemics
06/01/2016	Glumetza
06/01/2016	naloxone rescue medications
06/01/2016	Naltrexone
06/01/2016	Edecrin
06/01/2016	interleukin-5 antagonist monoclonal antibodies
06/01/2016	Acitretin
06/01/2016	lice medications
06/01/2016	NK1 receptor antagonists
06/01/2016	Tirosint
03/02/2016	insulins
03/02/2016	steroid inhalers
03/02/2016	digestive enzymes
03/02/2016	nasal steroids
03/02/2016	otic anti-infectives
03/02/2016	ulcer anti-infectives
12/02/2015	Marinol
12/02/2015	skin pigment products
12/02/2015	inhaled corticosteroid/LABA combination products
12/02/2015	Movantik
12/02/2015	medications used to treat irritable bowel syndrome/OIC
12/02/2015	medications used to treat ulcerative colitis
12/02/2015	SGLT2 products
12/02/2015	immediate release oxycodone
12/02/2015	inhaled anti-infectives for cystic fibrosis
12/02/2015	leukotriene modifiers

09/02/2015	cholesterol lowering drugs
09/02/2015	injectable anticoagulants
09/02/2015	Akynzeo
09/02/2015	Nuessa
09/02/2015	Cholbam
06/03/2015	Otezla
06/03/2015	Xtoro
06/03/2015	Hemangeol
06/03/2015	Lemtrada
06/03/2015	agents used to treat idiopathic pulmonary fibrosis
06/03/2015	GLP-1 receptor agonists
06/03/2015	topical therapies for onychomycosis
12/03/2014	testosterone products
12/03/2014	phosphate binders
12/03/2014	Zontivity
12/03/2014	Evzio
09/03/2014	Northera
09/03/2014	Oral Allergen Extracts
06/02/2014	Cathflo
06/02/2014	Intranasal Cyanocobalamin Products
06/02/2014	Luzu
06/02/2014	Noxafil
06/02/2014	Bethkis
03/03/2014	Statins
03/03/2014	Vecamyl
12/03/2013	Brisdelle
12/03/2013	Nitroglycerin Lingual Spray/Sublingual Tablets
12/03/2013	Agents Used to Treat COPD
12/03/2013	Epinephrine Auto-Injection Devices
12/03/2013	Pulmozyme
09/09/2013	Rayos
09/09/2013	Diclegis
09/09/2013	Sitavig
09/09/2013	Onmel
09/09/2013	Giazo
06/03/2013	Fulyzaq
06/03/2013	Xeljanz
03/11/2013	Genitourinary Smooth Muscle Relaxants
03/11/2013	Agents Used to Treat Multiple Sclerosis
12/03/2012	Actinic Keratosis
12/03/2012	Moxeza
09/17/2012	Kalydeco
09/17/2012	Kuvan
09/17/2012	Elaprase



06/04/2012	Lorzone
06/04/2012	Provigil
06/04/2012	Kapvay
06/04/2012	Dexpak/Zemapak
06/04/2012	Xifaxan
06/04/2012	Vanos
03/05/2012	Pulmonary Arterial Hypertension Agents
03/05/2012	Topical Acne Agents
03/05/2012	Benign Prostatic Hyperplasia Agents
03/05/2012	Juvisync/Combination Products
03/05/2012	Gralise
12/05/2011	Dificid
12/05/2011	New Oral Anticoagulants
12/05/2011	agents used to treat Hereditary Angioedema
09/12/2011	Asacol HD
09/12/2011	Ophthalmic Antihistamines
09/12/2011	Horizant
09/12/2011	Daliresp
09/12/2011	narcotics with high dose APAP
06/06/2011	Nuedexta
06/06/2011	Nexiclon
06/06/2011	Topical ketoconazole products
03/07/2011	Statins
03/07/2011	Gilenya
03/07/2011	Xyrem
12/06/2010	agents used to treat Hepatitis C
12/06/2010	ODT preparations
12/06/2010	Oravig
12/06/2010	Zyclara
12/06/2010	Clorpres
12/06/2010	Livalo
12/07/2009	Hemophilia
12/07/2009	Sancuso
12/07/2009	Relistor
12/07/2009	Nuvigil
12/07/2009	Nucynta
09/14/2009	Uloric
09/14/2009	Moxatag
09/14/2009	Targeted Immune Modulators
06/01/2009	Aczone
12/01/2008	Triptans
12/01/2008	Vusion
09/08/2008	Chantix
09/08/2008	Carisoprodol

02/04/2008	Ophthalmic Anti-infectives
08/20/2007	High-Cost Medications
08/20/2007	Ketek
08/20/2007	Xopenex
08/20/2007	Tekturna
08/20/2007	Synagis
08/20/2007	Amrix
06/04/2007	Qualaquin
12/11/2006	Exubera
12/11/2006	Solodyn and Oracea
12/11/2006	Oxycontin
11/13/2006	Generic medications
11/13/2006	Vigamox and Zymar
11/13/2006	Boniva
05/01/2006	Growth Hormone
05/01/2006	Sedative/Hypnotics Agents
02/13/2006	Actoplus met
11/07/2005	Revatio
08/08/2005	Zanaflex capsule
12/13/2004	ACE inhibitors
12/13/2004	ARBs
12/13/2004	Proton Pump Inhibitors
01/26/2004	COX-II and brand name NSAIDS
11/03/2003	Antihistamines
04/29/2002	Out of State Drugs
09/01/1999	Xenical

## Appendix D: Harm Reduction Pathway

### Harm Reduction Pathway Criteria:

The following criteria may be provided by a pharmacist (billed through the MTM program), a Syringe Service Program, or clinic-based E&M billed service (provided by a nurse or independent practitioner)

- Two visits are required prior to drug approval, a third visit during treatment is strongly recommended.

### **Persons who Inject Drugs (PWID):**

ALL of the following must be provided/evaluated at the first, second, and third appointments:

- Referral to Syringe Service Program
- Access to and use of sterile syringes, needles, and injection equipment (may not be purchased using state funds including billing Medicaid per NDCC 23-01)
- Counseling on storage and disposal of injection equipment safe and legal manner
- Education and training on drug overdose response and treatment, including access and administration of overdose reversal medication.

- Education, referral, and linkage to human immunodeficiency virus, viral hepatitis, and sexually transmitted disease prevention, treatment, and care services
  - Substance Use Disorder treatment information, and referrals to treatment programs as appropriate
- Follow-up phone call (following first appointment) evaluating the implementation of the following:
- Use of sterile syringe, needle, and injection is implemented.
  - Storage and disposal of injection equipment safe and legal manner

***People with Alcohol Use Disorder:***

ALL of the following must be provided/evaluated at the first, second, and third appointments:

- Education on the impact of alcohol to liver health (i.e., continued use can result in development of cirrhosis even in the absence of Hepatitis C)
- Counseling on how to reduce risk and severity of harmful consequences arising from severe alcohol intoxication (e.g., transportation services, condom use, avoiding fighting, drinking low alcohol beverages, padding furniture and stairs)
- Counseling on [Safer-use Strategies: Alcohol](#)
- Provide alcohol addiction treatment information and linkage to alcohol treatment programs as appropriate

Follow-up phone call (following first appointment) evaluating the implementation of the following:

- Safer-use and risk reduction strategies implemented.

**References:**

- [Medical Pharmacy Billing Manual](#)

## **Unfinished Business**

### **Alternative RDUR Communication Tools:**

- Provider and pharmacy online response form
- Faxing letters

## **New Business:**

### Second Review

#### Stimulants - Other State Criteria

##### **MACPAC**

###### [Medicaid and CHIP Payment and Access Commission](#)

Prior authorization can promote appropriate care when policies are based on clinical guidelines. For example, some FFS programs and MCOs apply prior authorization to pediatric attention-deficit/hyperactivity disorder (ADHD) medication prescribing (Center for Public Health Law Research (CPHLR) 2023a, 2023b). The American Academy of Pediatrics (AAP) clinical guidelines for medication treatment of ADHD vary by age. The AAP recommends behavioral interventions as the first-line treatment for most children age four to five, whereas medication can be included as a first-line treatment for children age 6 to 11 (Wolraich et al. 2019). As of April 2023, 34 Medicaid FFS programs applied prior authorization to ADHD medications prescribed to children under 18. Of these, 28 programs applied the prior authorization age restrictions to all medications (i.e., preferred and non-preferred medications). Of the 28 FFS programs with prior authorization requirements for some preferred ADHD medications, 15 programs applied the requirements only to children under age 6 (CPHLR 2023a). A legal assessment found that some, but not all, state Medicaid prior authorization policies for ADHD medications analyzed were linked to AAP treatment guidelines (Hulkower et al. 2017)

##### **Arizona**

###### [FFS Pharmacy PA Guidelines effective November 01 2024.pdf](#)

1 - The requesting clinician has documented that the child has a diagnosis of attention deficit hyperactivity disorder (ADHD)

AND 2 - The requesting clinician has documented that psychosocial issues have been evaluated before request for ADHD medications

AND 3 - The requesting clinician has documented non-medication alternatives that have been attempted before request for ADHD medications

AND 4 - The requested dose does NOT exceed the Food and Drug Administration (FDA) recommended maximum daily dosage unless the provider has submitted clinical justification for the dose exceeding the FDA maximum

##### **Florida**

###### [Long Acting Stimulant Criteria.pdf](#)

CLINICAL NOTES: According to the American Academy of Pediatrics Clinical Practice Guideline for the Evaluation and Treatment of Attention-Deficit/Hyperactivity Disorder (ADHD), evidence based parent and/or teacher administered behavior therapy is the first line of treatment for preschool age children who are 4 to 5 years of age. These guidelines go on to state that many young children with ADHD might still require medication to achieve maximum improvement, and medication is not contraindicated for children 4 through 5 years of age. There are limited clinical studies in this age group with most of the evidence based data surrounding the use of methylphenidate preparations.

##### INITIAL REVIEW CRITERIA:

1. Patient has had an adequate trial of parent training or teacher administered behavioral therapy and has persistent moderate to severe dysfunction as defined by:

a. Symptoms that have persisted for at least 9 months

b. Dysfunction that is manifested in both the home and other settings such as preschool or child care

##### **Louisiana**

###### [Stimulants and Related agents](#)

*For non-preferred agents*

- The child has a diagnosis approved for the medication requested (see POS Edits); AND
  - ONE of the following (due to this diagnosis) is true and is stated on the request:
    - Child has had a trial of behavioral therapy and has ongoing impairing and/or dangerous symptoms;
- OR
- Child has started behavioral therapy but has extremely impairing and/or potentially dangerous symptoms; OR
  - Child has been referred to behavioral treatment but has extremely impairing and/or potentially dangerous symptoms that warrant treatment before therapy has had a chance to have an effect (with plan to follow up); OR
  - There are no known behavioral therapy resources available to this child, who has extremely impairing and/or potentially dangerous symptoms; OR
- o ALL of the following:
- The child is 6 years of age; AND
  - The diagnosis for the requested medication is attention deficit hyperactivity disorder (ADHD); AND
  - By submitting this request, the provider attests that behavioral treatment has been prescribed in addition to the requested medication; AND
- By submitting the authorization request, the prescriber attests to the following:
- o Clinical monitoring parameters recommended in prescribing information are completed at baseline, every six months, and with dosage changes; AND
  - o The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; AND
  - o All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; AND
  - o The recipient has no concomitant drug therapies or disease states that limit the use of the requested medication and will not receive the requested medication with any other medication that is contraindicated or not recommended per FDA labeling;

## Massachusetts

### [MassHealth PA Requirements for CNS Stimulants](#)

#### *Alpha2 Agonist or Cerebral Stimulant for members < three years of age:*

- For all requests, individual drug PA criteria must be met first where applicable.
- Documentation of the following is required:
  - one of the following:
    - member had a recent psychiatric hospitalization (within the last three months); or
    - member has a history of severe risk of harm to self or others; or
    - for an alpha2 agonist, member has a cardiovascular diagnosis only; or
  - all of the following:
    - appropriate diagnosis; and
    - prescriber is a specialist (e.g., psychiatrist, child adolescent psychiatrist [including psychiatric nurse practitioners], neurologist, pediatric neurologist, developmental and behavioral pediatrics) or consult is provided; and
    - treatment plan including names of current alpha2 agonist(s) and cerebral stimulant(s) and corresponding diagnoses; and
    - clinical rationale for use of alpha2 agonist or cerebral stimulant in member < three years of age; and
    - for requests for an amphetamine product, inadequate response (defined as > seven days of therapy), adverse reaction, or contraindication to a methylphenidate product.

## Michigan

### [Michigan Medicaid Clinical and PDL Criteria](#)

#### ADD / ADHD (PDL criteria apply):

- Under age 4: ADD / ADHD confirmed by a child and adolescent psychiatrist, developmental and behavioral

- o MAPS has been reviewed and reconciled with prescribed drugs and any toxicology screening results
- Ages 4–5: ADD / ADHD confirmed by a comprehensive evaluation and/or standard assessment tool; AND
  - o MAPS has been reviewed and reconciled with prescribed drugs and any toxicology screening results
- Ages 6–17: No PA required

## Missouri

[ADHD Medication Prior Authorization Children Less than 6 Years Old | mydss.mo.gov](#)

[Pharmacy Clinical Edits and Preferred Drug Lists | mydss.mo.gov](#)

- Documentation of the six signs and symptoms of ADHD elicited by the provider during assessment of the child
  - o Per DSM 5, this should include six signs and symptoms of inattention OR six signs and symptoms of hyperactivity/impulsivity. If the child is diagnosed with the combined type of ADHD, then six signs and symptoms of inattention AND hyperactivity/impulsivity must be documented.
  - o An alternate form of documentation that is acceptable is acknowledgement in the provider's notes of agreement with the findings on the ADHD rating scales.
- The ADHD rating scales (e.g., Vanderbilt or Conners) completed by the child's parent/guardian and teacher. If there is no teacher, then a rating scale completed in another setting other than the home environment (such as daycare or pre-school) is required.

## Nevada

[Agents used for the treatment of ADHD](#)

### General Criteria (Children and Adults)

1. Only one agent at a time may be used for the treatment of ADHD (applies to the entire ADHD/Stimulant Class); a 30-day transitional overlap in therapy will allowed.
2. The following two criteria must be met and documented in the recipient's medical record for adult and pediatric recipients in order for Prior Approval of CNS Stimulants:
  - a. In the pediatric and adult population, the decision to medicate for Attention Deficit Disorder (ADD) or Attention Deficit Hyperactivity Disorder (ADHD) and any comorbidity based on problems that are persistent and sufficiently severe to cause functional impairment in one or more of the following social environments: at school, home, work or with peers, and
  - b. Before treatment with pharmacological methods is instituted, other treatable causes have been ruled out.

### Children (up to age 18 years)

In addition to the general criteria, the following must be present and documented in the recipient's medical record for Prior Approval of CNS Stimulants:

1. An initial evaluation has been done by the treating physician, pediatrician, psychiatrist or neurologist documenting the developmental history, physical evaluation, medical history or neurological primary diagnosis (e.g. fetal alcohol syndrome, thyroid disease) and examination within the past twelve months, or more recently, if the clinical condition has changed, and
2. One of the following:
  - a. School information, Standardized Teachers Rating Scales testing reports such as TOVA (Test of Variables of Attention), achievement test, neuropsychological testing if indicated, Conner's scale, speech and language evaluation, or
  - b. DMS-IV (Diagnostic and Statistical Manual of Mental Disorders) symptoms of ADD or ADHD, presence or absence-child behavior checklist, development and context of symptoms and resulting impairment, including school, family and peers, DSM-IV symptoms of possible alternate or comorbid psychiatric diagnosis, history of psychiatric, psychological pediatric or neurological treatment for ADD or ADHD, or



c. Family history including diagnosis of ADD and ADHD, tic disorder, substance abuse disorder, conduct disorder, personality disorder and other anxiety disorder, past or present family stressors, crises, any abuse or neglect, interview with parents.

3. The following two criteria must be met and documented in the recipient’s medical record for adult and pediatric recipients in order for Prior Approval of CNS Stimulants:

a. In the pediatric and adult population, the decision to medicate for Attention Deficit Disorder (ADD) or Attention Deficit Hyperactivity Disorder (ADHD) and any comorbidity is based on problems that are persistent and sufficiently severe to cause functional impairment in one or more of the following social environments: at school, home, work or with peers, and

b. Before treatment with pharmacological methods is instituted, other treatable causes have been ruled out.

**Oklahoma**

[CNS/Behavioral Health: ADHD and Narcolepsy](#)

- Prior Authorization is required for all tiers for members greater than 20 years of age and for members 0-4 years of age. All prior authorization requests for members under the age of 5 years must be reviewed by an OHCA contracted psychiatrist.

**Utah**

[ADHD Stimulants.pdf](#)

Less than 4 Years of Age or less than 6 years for Adzenys ER, Dyanavel XR, Desoxyn, Adhansia, Jornay PM, Cotempla XR)

- Diagnosis made by or in consultation with children psychiatrist or mental health specialist who is qualified in the diagnosis and treatment of neuropsychiatric disease (certified, licensed scope of practice, etc.) with prescribing authority.
- Appropriate clinical rationale for ADHD stimulant use under Medicaid age limit

**Washington**

[ADHD-age-dose.pdf](#)

<https://www.hca.wa.gov/billers-providers-partners/program-information-providers/apple-health-second-opinion-program>

Second opinion required for 0-4 years of age.

**Virginia**

[Virginia Medicaid Service Authorization Form: Stimulants/ADHD Medications for Children Less Than FDA Indicated Age and Adults Over 18](#)

\*For patients ≤ 4 years old, prescriber must be a pediatric psychiatrist, pediatric neurologist, developmental/behavioral pediatrician, or in consultation with one of these specialists.

**Stimulants – ND Proposed Criteria**

**Amphetamines**

**Solid Dosage Forms**

*Extended Release*

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
dextroamphetamine/amphetamine ER (generic Adderall XR)	ADDERALL XR (dextroamphetamine/amphetamine)
dextroamphetamine ER	DEXEDRINE SPANSULE ER (dextroamphetamine)
lisdexamfetamine	dextroamphetamine/amphetamine ER

	(generic Mydayis ER
	DYANAVEL XR (amphetamine)
	MYDAYIS ER (dextroamphetamine/amphetamine)
	VYVANSE (lisdexamfetamine)

*Immediate Release*

<b>PREFERRED AGENTS (NO PA REQUIRED)</b>	<b>NON-PREFERRED AGENTS (PA REQUIRED)</b>
amphetamine	ADDERALL (dextroamphetamine/amphetamine)
dextroamphetamine 2.5 mg, 5 mg, 10 mg	dextroamphetamine 7.5 mg, 15 mg, 20 mg, 30 mg
dextroamphetamine/amphetamine	EVEKEO (amphetamine)
	methamphetamine
	ZENZEDI (dextroamphetamine)

**Non-Solid Dosage Forms**

*Extended Release*

<b>PREFERRED AGENTS (CLINICAL PA REQUIRED)</b>	<b>NON-PREFERRED AGENTS (PA REQUIRED)</b>
DYANAVEL XR (amphetamine) SUSPENSION	ADZENYS XR – ODT (amphetamine)
lisdexamfetamine chew	amphetamine ER suspension
	VYVANSE (lisdexamfetamine) CHEW TABLET
	XELSTRYM (dextroamphetamine) PATCH

*Immediate Release*

<b>PREFERRED AGENTS (NO PA REQUIRED)</b>	<b>NON-PREFERRED AGENTS (PA REQUIRED)</b>
dextroamphetamine 5 mg/5 ml	PROCENTRA (dextroamphetamine) SOLUTION

**Methylphenidate**

**Solid Dosage Forms**

*Extended Release*

<b>PREFERRED AGENTS (NO PA REQUIRED)</b>	<b>NON-PREFERRED AGENTS (PA REQUIRED)</b>
FOCALIN XR (dexmethylphenidate)	APTENSIO XR (methylphenidate)
methylphenidate CD 30-70	AZSTARYS (serdexmethylphenidate/dexmethylphenidate)
methylphenidate ER tablet (generic Concerta)	CONCERTA (methylphenidate)
methylphenidate ER tablet (generic Metadate CD)	dexmethylphenidate ER
RITALIN LA (methylphenidate LA capsules – 50-50) <i>Brand Name Required</i>	JORNAY PM (methylphenidate)
	methylphenidate ER 45 mg, 63 mg, 72 mg tablet (generic Relexxii ER)
	methylphenidate ER capsule (generic Aptensio XR)
	methylphenidate LA capsules – 50-50 (generic Ritalin LA) – 60 mg
	methylphenidate LA capsules – 50-50 (generic Ritalin LA) – 10 mg, 20 mg, 30 mg, 40 mg
	RELEXXII ER (methylphenidate)

*Immediate Release*

<b>PREFERRED AGENTS (NO PA REQUIRED)</b>	<b>NON-PREFERRED AGENTS (PA REQUIRED)</b>
dexmethylphenidate	FOCALIN (dexmethylphenidate)
methylphenidate tablet	RITALIN (methylphenidate)

## Non-Solid Dosage Forms

### Extended Release

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
DAYTRANA (methylphenidate) PATCH – Brand Required	COTEMPLA XR – ODT (methylphenidate)
QUILLICHEW ER (methylphenidate)	methylphenidate patch
QUILLIVANT XR (methylphenidate)	

### Immediate Release

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
methylphenidate chew tablet	METHYLIN (methylphenidate) SOLUTION
methylphenidate solution	

### Electronic Age Verification

- The member must be age 6 or older or must meet prior authorization criteria for ages 5 and under listed below.

### Prior Authorization Criteria

#### Initial Criteria – Approval Duration: 6 months

- For members ages 5 and under:
  - There is a moderate-severe continuing disturbance in the child's function in both home and other settings (e.g., preschool or daycare) despite a 9-month trial of parent and/or teacher-administered behavior therapy which helps parents learn age-appropriate developmental expectation, specific management skills for problem behaviors, and behaviors that strengthen the parent-child relationship (subject to clinical review).

#### *Non-Preferred Agent Criteria:*

- Amphetamine Non-Preferred Dosage Forms Only:
  - The member must have had a two 7-day trials of a methylphenidate non-solid dosage form.
- Aptensio XR Only:
  - The member must have a wearing off effect where late afternoon/evening functioning performance has been impacted despite a 7-day trial with a long-acting methylphenidate medication with an afternoon short acting booster.
  - The member must have a wearing off effect where late afternoon/evening functioning performance has been impacted despite a 7-day trial with Concerta or its generic alternative.
- Jornay PM Only:
  - The member must have had two 7-day trials of a fast onset to peak methylphenidate medication (i.e., Concerta, Focalin XR, Metadate CD, Methylin, Ritalin and their generic alternatives).
  - The member must have the inability to time the administration of medication where the peak is occurring at the start of work or school and early morning performance has been impacted at school or work due to the approximate 1-hour delay to peak after administration (subject to clinical review).
- All Other Agents: See [Preferred Dosage Form](#) criteria

#### References:

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# FIRST REVIEWS

## FIRST REVIEW OF MIGRAINE

Patients with migraines experience severe headaches that are oftentimes associated with nausea, visual disturbances, and sensitivity to light, sound, touch, and smell.

- **Episodic:** 0-14 migraine days per month
- **Chronic:** 15+ migraine days per month

### Population:

- 37 million patients in US 12 years of age and older (28 million females, 9 million males)<sup>1</sup>

### Treatment/Abortive Therapy:<sup>1,2,3,7,10</sup>

- **Goals:** pain relief, ability to function, limit the need for repeat dosing
- **Indication:** all patients with migraines
- **Considerations:**
  - May need to consider nonoral agents and/or antiemetics for those with severe nausea/vomiting
  - Medication overuse can worsen migraines; use should be limited to 2 days per week
  - All can cause medication overuse headaches except the CGRP antagonists
- **Medication choice** is dependent upon migraine severity:
  - Mild to moderate: nonsteroidal anti-inflammatory drugs (NSAIDs), acetaminophen (APAP), or caffeinated combination analgesics (APAP/aspirin/caffeine)
    - NSAIDs:
      - Established efficacy: aspirin, Elyxeb, diclofenac, ibuprofen, naproxen
      - Likely effective: flurbiprofen, ketoprofen, ketorolac
  - Moderate-severe or mild-moderate after poor response to non-specific agents: migraine specific agents (triptans, ergots, calcitonin gene-related peptide (CGRP) receptor antagonists, Reyvow)
  - A second triptan or different therapy may be trialed after treatment failure

Class	5-HT 1F receptor agonist (triptans)	CGRP antagonist (gepants)	5-HT 1F receptor agonist	Non-selective 5HT receptor agonist (ergots)
<b>Medications</b>	Almotriptan Eletriptan Frovatriptan Naratriptan Rizatriptan Sumatriptan Zolmitriptan	Nurtec Ubrelvy Zavzpret	Reyvow (lasmiditan)	Dihydroergotamine Ergotamine
<b>Formulations</b>	<ul style="list-style-type: none"> <li>• Injectable</li> <li>• Nasal spray</li> <li>• Oral disintegrating tablet (ODT)</li> <li>• Oral film</li> <li>• Oral tablet</li> </ul>	<ul style="list-style-type: none"> <li>• Oral disintegrating tablet (ODT): Nurtec</li> <li>• Oral tablet: Ubrelvy</li> <li>• Nasal spray: Zavzpret</li> </ul>	Oral tablet	<ul style="list-style-type: none"> <li>• Injectable</li> <li>• Nasal spray</li> <li>• Suppository</li> </ul>
<b>Key Notes</b>	<ul style="list-style-type: none"> <li>• Contraindications: Cerebrovascular disease, coronary artery disease, peripheral vascular disease, uncontrolled hypertension, and other vascular risk factors/disorders</li> <li>• Almotriptan can be used for adolescents</li> </ul>	Generally well tolerated	<ul style="list-style-type: none"> <li>• Schedule V controlled substance</li> <li>• Can impair driving and cause somnolence</li> </ul>	<ul style="list-style-type: none"> <li>• Similar contraindications to triptans</li> <li>• Minimal use due to increased risk of serious adverse effects</li> </ul>

	<ul style="list-style-type: none"> <li>Rizatriptan and zolmitriptan can be used in pediatric patients depending on their age/formulation</li> </ul>			
<b>Cost/month</b>	<ul style="list-style-type: none"> <li>Almotriptan: \$396</li> <li>Eletriptan: \$215.10</li> <li>Frovatriptan: \$240</li> <li>Naratriptan: \$20</li> <li>Rizatriptan: \$14.82 (tablet) and \$17.24 (ODT)</li> <li>Sumatriptan: \$72 (tablet), \$125 (injection), \$350 (spray)</li> <li>Zolmitriptan: \$7.90 (tablet), \$47.14 (ODT), \$518.23 (spray)</li> <li>Sumatriptan/naloxone: \$704</li> </ul>	<ul style="list-style-type: none"> <li>Nurtec: \$999.02</li> <li>Ubrelvy: \$1,653.09</li> <li>Zavzpret: \$1,100</li> </ul>	Reyvow: \$740.88	<ul style="list-style-type: none"> <li>Dihydroergotamine: \$428.36 (spray), \$1,326 (injection)</li> <li>Ergotamine: \$1,423.24</li> </ul>

Cost based on lowest WAC per unit, calculated using monthly quantity limits allowed when applicable or maximum recommended dose

**Prophylaxis:** 1,3,4,5,6,7,8

• **Goals:**

- Decrease migraine frequency, severity, duration, and disability
- Limit need for acute treatment

• **Indication:** ≥4 migraine days per month, significant disability or decreased quality of life, or uncontrolled with acute therapy

• **Considerations:** comorbid conditions that may be treated with the same agent or that may exacerbate side effects

• **Medication choice:**

- Episodic and chronic migraine: topiramate, divalproex, beta blocker, candesartan, tricyclic antidepressant, SNRI, Aimovig, Ajovy, Emgality, Vyepti, Qulipta
  - Nurtec may also be used first line for episodic migraine
  - Botox (medical billing) has FDA approval for migraine prevention, administered quarterly, costs around \$4,005.20 per year

• Non-pharmacological: relaxation training, electromyographic feedback, cognitive behavioral therapy

Class	Antihypertensives	Anticonvulsants	Antidepressants	CGRP Antagonist
<b>Medications</b>	<u>Beta blockers:</u> Atenolol Metoprolol* Propranolol* Timolol*  <u>ARB:</u> Candesartan*	Divalproex* Topiramate* Zonisamide	Amitriptyline Venlafaxine	<u>Oral:</u> Nurtec ODT Qulipta  <u>Injectable:</u> Aimovig* Ajovy* Emgality* Vyepti* (IV, medical billing)
<b>Frequency</b>	1-2 times daily depending on the agent	1-2 times daily depending on the agent	Once daily	<ul style="list-style-type: none"> <li>• Every other day: Nurtec</li> <li>• Daily: Qulipta</li> <li>• Monthly: Aimovig, Emgality</li> <li>• Monthly or quarterly: Ajovy</li> </ul>

<b>Key Notes</b>	Beta blockers: may be an issue for those with asthma/COPD or hypotension	Divalproex cannot be used in women of child-bearing age not on contraception (fetal harm)	<ul style="list-style-type: none"> <li>• Amitriptyline: antimuscarinic effects (dry mouth, blurry vision, urinary retention, etc.)</li> <li>• Increase risk of serotonin syndrome</li> </ul>	<ul style="list-style-type: none"> <li>• Quarterly: Vyepti</li> </ul> Shown to be as effective as other options but more tolerable
<b>Cost/year</b>	<ul style="list-style-type: none"> <li>• Atenolol: \$11.40</li> <li>• Metoprolol: \$21.60</li> <li>• Propranolol: \$22.39</li> <li>• Timolol: \$136.24</li> <li>• Candesartan: \$480</li> </ul>	<ul style="list-style-type: none"> <li>• Divalproex: \$44.64</li> <li>• Topiramate: \$32.70</li> <li>• Zonisamide: \$49.64</li> </ul>	<ul style="list-style-type: none"> <li>• Amitriptyline: \$18.72</li> <li>• Venlafaxine: \$42.84</li> </ul>	<ul style="list-style-type: none"> <li>• Nurtec: \$12,976.48</li> <li>• Qulipta: \$13,110.96</li> <li>• Aimovig: \$9,031.44</li> <li>• Ajovy: \$8,797.92</li> <li>• Emgality: \$8,476.44</li> <li>• Vyepti: \$7,311.32</li> </ul>

\*Established efficacy; others are likely effective

Cost based on lowest WAC per unit, calculated using initial compendia recommended dose

### Current Utilization

Medication	Quarter 4 2023			Quarter 1 2024		
	Rx Count	% of Rx	Reimb Amount	Rx Count	% of Rx	Reimb Amount
Aimovig	74	4.0%	\$51,023.45	56	2.9%	\$40,880.25
Ajovy	45	2.4%	\$41,625.72	55	2.9%	\$50,061.05
Botox	281	15.2%	\$7,502.01	336	17.7%	\$10,297.80
eletriptan	105	5.7%	\$68,173.55	105	5.5%	\$68,836.53
Emgality	135	7.3%	\$91,789.82	122	6.4%	\$86,536.19
frovatriptan	2	0.1%	\$161.26	3	0.2%	\$222.50
naratriptan	10	0.5%	\$134.37	6	0.3%	\$79.94
Nurtec	72	3.9%	\$66,310.71	97	5.1%	\$93,678.80
Qulipta	14	0.8%	\$14,152.09	12	0.6%	\$11,966.56
Reyvow	0	0.0%	\$-	1	0.1%	\$722.36
rizatriptan	402	21.8%	\$6,504.27	410	21.6%	\$6,630.60
sumatriptan	686	37.2%	\$20,750.16	675	35.5%	\$14,359.26
Ubrelvy	14	0.8%	\$13,405.84	16	0.8%	\$15,882.59
Vyepti	4	0.2%	\$341.13	4	0.2%	\$608.17
Zavzpret	0	0.0%	\$-	1	0.1%	\$1,068.12
zolmitriptan	1	0.1%	\$15.44	0	0.0%	\$-
<b>TOTALS</b>	<b>1,845</b>		<b>\$381,889.82</b>	<b>1,899</b>		<b>\$401,830.72</b>
Medication	Quarter 2 2024			Quarter 4 2024		
	Rx Count	% of Rx	Reimb Amount	Rx Count	% of Rx	Reimb Amount
Aimovig	43	2.5%	\$31,742.05	43	2.7%	\$31,743.64
Ajovy	58	3.4%	\$46,814.11	72	4.5%	\$60,975.47
Botox	303	17.8%	\$11,479.74	175	10.9%	\$7,502.01
eletriptan	81	4.8%	\$57,514.45	87	5.4%	\$58,697.94
Emgality	95	5.6%	\$65,858.76	103	6.4%	\$74,215.30
frovatriptan	2	0.1%	\$84.63	0	0.0%	\$-
naratriptan	7	0.4%	\$121.01	10	0.6%	\$183.38
Nurtec	104	6.1%	\$100,253.47	119	7.4%	\$117,373.49
Qulipta	15	0.9%	\$15,916.34	14	0.9%	\$14,868.53
Reyvow	0	0.0%	\$-	0	0.0%	\$-



rizatriptan	360	21.1%	\$5,866.34	343	21.3%	\$5,682.02
sumatriptan	613	36.0%	\$13,654.28	616	38.3%	\$12,570.66
Ubrelyvy	20	1.2%	\$19,371.12	22	1.4%	\$19,893.11
Vyepti	0	0.0%	\$-	0	0.0%	\$-
Zavzpret	1	0.1%	\$1,068.12	0	0.0%	\$-
zolmitriptan	3	0.2%	\$915.05	5	0.3%	\$707.67
<b>TOTALS</b>	<b>1,705</b>		<b>\$370,659.47</b>	<b>1,609</b>		<b>\$404,413.22</b>

#### References:

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10. Serotonin 5-HT1 Receptor Agonists (Triptans). Drug Facts and Comparisons. Wolters Kluwer Health, Inc. Riverwoods, IL. August 22, 2024. <http://online.factsandcomparisons.com>

## FIRST REVIEW OF NON-STEROIDAL ANTI-INFLAMMATORY DRUGS (NSAIDS)

Cyclooxygenase (COX) enzymes convert arachidonic acid to prostaglandins, prostacyclins, and thromboxanes. NSAIDs work by blocking COX1 and/or COX2 enzymes which lead to a decrease in prostaglandin formation, inflammation, pain, and fever. COX2 enzymes are more concentrated at inflammatory sites; COX1 enzymes are more concentrated in the stomach, platelets, and blood vessels.

**Use:** analgesic, antipyretic, and anti-inflammatory; symptomatic relief

#### Adverse Effects:

- Cardiovascular (CV): cardiovascular events, thromboembolic events, atrial fibrillation, hypertension (HTN)
- Gastrointestinal (GI): dyspepsia, peptic ulcer disease, bleeding
- Hepatic and renal toxicity
- Tinnitus

#### Contraindications and precautions for use:

- People with known coronary artery disease or at a higher risk for these conditions; heart failure
- History of GI bleed
- Cirrhosis
- Kidney disease



- Pregnancy (third trimester): can cause premature closure of ductus arteriosus

#### Drug interactions:

- Anticoagulant and antiplatelet agents: increase bleeding risk
- Antihypertensive agents: can block their effects
- Phenytoin: can increase phenytoin levels, monitoring requires

Non-Selective NSAIDs			
Medication	Key Notes	Duration	Cost/month
Diclofenac	<ul style="list-style-type: none"> <li>• Available as a topical gel, over the counter (OTC)</li> <li>• Increase rate of hepatotoxic effects</li> </ul>	<6 hours	\$13.20
Etodolac		<6 hours	\$31.77
Ketorolac	Can be used for a total of 5 days due to bleeding risk	<6 hours	\$11.29
Indomethacin	More central nervous system adverse effects	<6 hours	\$11.46
Sulindac	More hepatic inflammation	>6 hours	\$12.00
Tolmetin		<6 hours	\$61.20
Fenamates: meclofenamate, mefenamic acid	<ul style="list-style-type: none"> <li>• Used for dysmenorrhea</li> <li>• More GI effects</li> </ul>	<6 hours	\$400.15
Nabumetone		>6 hours	\$13.80
Meloxicam		>6 hours	\$1.20
Piroxicam		>6 hours	\$22.48
Fenoprofen		>6 hours	\$1,758.00
Flurbiprofen		<6 hours	\$42.07
Ibuprofen	Available OTC	<6 hours	\$7.54
Ketoprofen		<6 hours	\$80.12
Naproxen	Available OTC	>6 hours	\$3.38
Oxaprozin		>6 hours	\$67.50
Salicylate: aspirin	<ul style="list-style-type: none"> <li>• Irreversibly blocks platelet function</li> <li>• Used for primary and secondary prevention of CVE</li> <li>• Available OTC</li> </ul>	<6 hours	\$0.22
COX-2 Selective NSAIDs			
• Decreases GI risk but increases CV risk			
Celecoxib	Cannot be used for those with sulfa allergy	>6 hours	\$2.00

Cost based on lowest WAC per unit, calculated using monthly quantity limits allowed when applicable or maximum recommended dose

#### Current Utilization

Medication	Quarter 4 2023			Quarter 1 2024		
	Rx Count	% of Rx	Reimb Amount	Rx Count	% of Rx	Reimb Amount
aspirin	1446	23.8%	\$13,432.99	1369	22.7%	\$12,503.99
celecoxib	620	10.2%	\$10,296.64	586	9.7%	\$9,779.85
diclofenac epolamine	0	0.0%	\$-	1	0.0%	\$324.73
diclofenac potassium	91	1.5%	\$1,626.86	93	1.5%	\$1,680.85
diclofenac sodium	657	10.8%	\$11,070.87	591	9.8%	\$10,188.11
etodolac	10	0.2%	\$231.88	11	0.2%	\$208.90
ibuprofen	1397	23.0%	\$19,603.35	1508	25.0%	\$21,865.93
indomethacin	62	1.0%	\$813.49	67	1.1%	\$922.76
ketorolac tromethamine	356	5.8%	\$7,157.90	337	5.6%	\$6,774.92
meclofenamate sodium	0	0.0%	\$-	1	0.0%	\$198.17
mefenamic acid	2	0.0%	\$97.81	2	0.0%	\$97.81

meloxicam	860	14.1%	\$11,241.54	866	14.3%	\$10,628.80
nabumetone	47	0.8%	\$950.27	36	0.6%	\$735.42
naproxen	523	8.6%	\$7,113.82	561	9.3%	\$7,544.65
naproxen sodium	7	0.1%	\$69.53	9	0.1%	\$115.67
oxaprozin	0	0.0%	\$-	0	0.0%	\$-
piroxicam	3	0.0%	\$65.54	4	0.1%	\$85.61
salsalate	1	0.0%	\$48.46	0	0.0%	\$-
sulindac	4	0.1%	\$82.08	2	0.0%	\$32.98
<b>TOTALS</b>	<b>6086</b>		<b>\$83,903.03</b>	<b>6044</b>		<b>\$83,689.15</b>
	<b>Quarter 2 2024</b>			<b>Quarter 4 2024</b>		
<b>Medication</b>	<b>Rx Count</b>	<b>% of Rx</b>	<b>Reimb Amount</b>	<b>Rx Count</b>	<b>% of Rx</b>	<b>Reimb Amount</b>
aspirin	1324	23.2%	\$12,955.10	1360	23.7%	\$14,409.28
celecoxib	592	10.4%	\$9,720.63	555	9.7%	\$9,176.50
diclofenac epolamine	2	0.0%	\$639.87	0	0.0%	\$-
diclofenac potassium	81	1.4%	\$1,401.98	103	1.8%	\$1,681.49
diclofenac sodium	593	10.4%	\$10,502.25	580	10.1%	\$10,078.83
etodolac	13	0.2%	\$288.13	22	0.4%	\$516.84
ibuprofen	1432	25.1%	\$22,054.35	1404	24.5%	\$20,062.91
indomethacin	50	0.9%	\$724.43	63	1.1%	\$831.00
ketorolac tromethamine	324	5.7%	\$5,927.01	330	5.8%	\$6,565.03
meclofenamate sodium	0	0.0%	\$-	0	0.0%	\$-
mefenamic acid	2	0.0%	\$79.51	1	0.0%	\$41.26
meloxicam	759	13.3%	\$11,465.30	792	13.8%	\$10,548.97
nabumetone	38	0.7%	\$734.03	45	0.8%	\$891.45
naproxen	480	8.4%	\$6,685.73	473	8.2%	\$6,458.28
naproxen sodium	8	0.1%	\$135.99	9	0.2%	\$161.54
oxaprozin	1	0.0%	\$27.33	0	0.0%	\$-
piroxicam	0	0.0%	\$-	1	0.0%	\$16.94
salsalate	2	0.0%	\$44.20	0	0.0%	\$-
sulindac	1	0.0%	\$16.49	0	0.0%	\$-
<b>TOTALS</b>	<b>5702</b>		<b>\$83,402.33</b>	<b>5738</b>		<b>\$81,440.32</b>

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# FIRST REVIEW OF PRIMARY BILIARY CHOLANGITIS

Primary biliary cholangitis (PBC) is a rare liver disease characterized by destruction and inflammation of the small bile ducts. If left untreated, PBC can progress to liver cirrhosis end-stage liver disease, the need for liver transplant, and death. Patients often have pruritus and fatigue. <sup>1</sup>

## Population<sup>1</sup>:

- 131,000 patients in the US, primarily women between ages of 45 to 65 years
- Patients 18 years and older US prevalence is 39.2 per 100,000 people

## Treatment Recommendations<sup>1</sup>:

- First-line treatment:
  - Ursodiol (UDCA)
- Second-line treatment (to be used in combination with UDCA unless unable to tolerate UDCA):
  - Ocaliva (obeticholic acid)
  - Iqirvo (elafibranor)
  - Livdelvi (seladelpar)
- Off-label treatments:
  - Bezafibrate
  - Fenofibrate

<b>Ursodiol<sup>10</sup></b>	
<b>Indication</b>	Treatment of PBC for patients 18 years and older
<b>Clinical Studies</b>	Meta-analysis of 1447 patients showed improvement in liver biochemistries and lower risk of histologic disease progression <sup>11</sup>
<b>Dosing</b>	13 to 15 mg/kg BID, oral
<b>Important Considerations</b>	<ul style="list-style-type: none"> <li>• MOA: increased hydrophilic index of the circulating bile acid pool, stimulation of hepatocellular and ductular secretions, cytoprotection against hydrophobic bile acid- and cytokine-induced injury, and immunomodulation and anti-inflammatory effects</li> <li>• Approximately 40% suboptimal response or cannot tolerate</li> </ul>
<b>Cost/month</b>	\$129.60 <sup>11</sup>
<b>Ocaliva (obeticholic acid)<sup>1</sup></b>	
<b>Indication</b>	Treatment of PBC in combination with ursodeoxycholic acid (UDCA) in adults who fail UDCA or as monotherapy in patients unable to tolerate UDCA for patients 18 years and older
<b>Dosing</b>	5 mg/day, oral
<b>Important Considerations</b>	<ul style="list-style-type: none"> <li>• MOA: Farnesoid X receptor agonist suppresses synthesis of bile acids from cholesterol and increases transport of bile acids out of the hepatocytes</li> <li>• Boxed warning: hepatic decompensation/failure, severe pruritus (limits use), reduction in HDL</li> <li>• Contraindications: decompensated cirrhosis, a prior decompensation event, or compensated cirrhosis who have evidence of portal hypertension; patients with cirrhosis require monitoring</li> </ul>
<b>Cost/month</b>	\$9,554.05 <sup>5</sup>
<b>Livdelzi (seladelpar)<sup>1</sup></b>	
<b>Indication</b>	Treatment of PBC in combination with ursodeoxycholic acid (UDCA) in adults who have failed UDCA or as monotherapy in patients unable to tolerate UDCA for patients 18 years and older
<b>Dosing</b>	10 mg/day, oral
<b>Important Considerations</b>	<ul style="list-style-type: none"> <li>• MOA: PPAR-delta agonist which inhibits bile acid synthesis through activation of PPAR-delta.</li> <li>• Administer 4 hours before or after bile acid sequestrants</li> <li>• Warnings: fractures, liver test abnormalities, biliary obstruction</li> <li>• Cannot be used for those with decompensated cirrhosis</li> <li>• Reduction in pruritus is main differentiation from Ocaliva and Iqirvo</li> </ul>
<b>Cost/month</b>	\$12,606 <sup>4</sup>

<b>Iqirvo (elafibranor)<sup>7</sup></b>	
<b>Indication</b>	Treatment of PBC in combination with ursodeoxycholic acid (UDCA) in adults who have failed UDCA or as monotherapy in patients unable to tolerate UDCA for patients 18 years and older
<b>Dosing</b>	80 mg/day, oral
<b>Important Considerations</b>	<ul style="list-style-type: none"> <li>• MOA: PPAR-agonist (alpha, gamma, and delta)</li> <li>• Not recommended for patients with decompensated cirrhosis</li> <li>• Not shown to worsen pruritus or dyslipidemia</li> <li>• Warnings: myalgia, myopathy, rhabdomyolysis, fractures, drug-induced liver injury, biliary obstruction, fetal development</li> </ul>
<b>Cost/month</b>	\$ 11,460.00 <sup>6</sup>

\*Cost based on lowest per unit WAC cost for initial adult dosing (weight 100 kg if applicable)

## FDA Approval

**Livdelzi (seladelpar):** August 8, 2024; 505(b) New Drug Application (NDA) pathway Type 1 Molecular Entity, PRIORITY; Orphan, Accelerated Approval

**Iqirvo (elafibranor):** June 10, 2024; 505(b) New Drug Application (NDA) pathway Type 1 Molecular Entity, PRIORITY; Orphan, Accelerated Approval

**Ocaliva (obeticholic acid):** May 27, 2016; 505(b) New Drug Application (NDA) pathway Type 1 Molecular Entity, PRIORITY; Orphan, Accelerated Approval

## Clinical Trials

<b>Ocaliva (obeticholic acid)<sup>1, 12, 13, 14, 15, 16</sup></b>	
<b>Accelerated Approval Study</b>	<ul style="list-style-type: none"> <li>• 217 adult patients who had an inadequate response or intolerance to UDCA, followed for 12 months</li> </ul> <p><b>Outcomes:</b></p> <ul style="list-style-type: none"> <li>• <b>Primary:</b> Biochemical response (<i>defined as ALP &lt;1.67 times upper limit of normal (ULN), ≥ 15% decrease ALP, normal total bilirubin</i>) achieved by more patients on Ocaliva (47% vs 10%, p&lt;0.0001)</li> <li>• <b>Pruritus:</b> 70% (10 mg), 56% (titration arm), and 38% (placebo) reported pruritus</li> </ul>
<b>Confirmatory Study</b>	<ul style="list-style-type: none"> <li>• Post marketing studies terminated due to enrollment difficulties and safety issues due to cirrhosis</li> </ul>
<b>News Updates</b>	<ul style="list-style-type: none"> <li>• FDA denied traditional approval in September 2024; still on market under accelerated approval</li> <li>• Has been removed from the market in Europe due to inability to confirm benefits <ul style="list-style-type: none"> <li>◦ Study 747-302 failed to show differences between Ocaliva and placebo for primary composite endpoint of death, liver transplant, or hepatic decompensation (HR 1.01, p=0.954)</li> </ul> </li> </ul>
<b>Livdelzi (seladelpar)<sup>1, 17</sup></b>	
<b>Accelerated Approval Study</b>	<ul style="list-style-type: none"> <li>• 193 patients who had an inadequate response or intolerance to UDCA aged 28-75 years, followed over 12 months</li> </ul> <p><b>Outcomes:</b></p> <ul style="list-style-type: none"> <li>• <b>Primary:</b> Biochemical response (<i>defined as ALP &lt;1.67 times upper limit of normal (ULN), ≥ 15% decrease ALP, normal total bilirubin</i>) achieved by more patients on Livdelzi (62% vs 20%, p&lt;0.001)</li> </ul>

	<ul style="list-style-type: none"> <li>○ Biochemical response defined as ALP &lt;1.67 times upper limit of normal (ULN), ≥ 15% decrease ALP, normal total bilirubin for all trials</li> <li>● <b>Secondary:</b> <ul style="list-style-type: none"> <li>○ <u>Normal ALP levels:</u> achieved by more patients on Livdelzi (25% vs 0%, p&lt;0.001)</li> <li>○ <u>Pruritus:</u> Livdelzi group also experienced greater reduction in pruritus score (change from baseline -3.2 vs -1.7, p=0.005)</li> </ul> </li> </ul>
<b>Confirmatory Study</b>	Ongoing, estimated completion July 2029
<b>Iqirvo (elafibrator)<sup>7, 18</sup></b>	
<b>Accelerated Approval Study</b>	<ul style="list-style-type: none"> <li>● 161 patients who had an inadequate response or intolerance to UDCA aged 36 to 76 years, 96% female</li> <li><b>Outcomes:</b> <ul style="list-style-type: none"> <li>● <b>Primary:</b> Biochemical response (defined as ALP &lt;1.67 times upper limit of normal (ULN), ≥ 15% decrease ALP, normal total bilirubin) achieved by more patients on Iqirvo (51% vs 4%, p&lt;0.001)</li> <li>● <b>Secondary:</b> <ul style="list-style-type: none"> <li>○ <u>Normal ALP levels:</u> achieved by more patients on Iqirvo (15% vs 0%, p=0.002)</li> <li>○ <u>Pruritus:</u> change in pruritus score was <u>not statistically significant</u> (change from baseline -1/93 vs -1.15, p=0.20)</li> </ul> </li> </ul> </li> </ul>
<b>Confirmatory Study</b>	Ongoing, estimated completion 2030

### Current Utilization

Medication	Quarter 4 2023			Quarter 1 2024		
	Rx Count	% of Rx	Reimb Amount	Rx Count	% of Rx	Reimb Amount
Ocaliva	0	0%	\$ -	0	0%	\$-
ursodiol	83	100%	\$3,252.73	79	100%	\$2,907.77
<b>TOTALS</b>	<b>83</b>		<b>\$3,252.73</b>	<b>79</b>		<b>\$2,907.77</b>
Medication	Quarter 2 2024			Quarter 3 2024		
	Rx Count	% of Rx	Reimb Amount	Rx Count	% of Rx	Reimb Amount
Ocaliva	1	1.45%	\$9,566.51	2	3.57%	\$19,133.02
ursodiol	68	98.55%	\$2,290.31	54	96.43%	\$1,883.51
<b>TOTALS</b>	<b>69</b>		<b>\$11,856.82</b>	<b>56</b>		<b>\$21,016.53</b>

\*\*No utilization of Livdelzi or Iqirvo from Q4 2023-Q3 2024

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

**1. Methylphenidate & Dexmethylphenidate / Drug Abuse & Dependence**

Alert Message: Methylphenidate and dexmethylphenidate-containing products should be prescribed cautiously in patients with a history of drug abuse or alcoholism. Chronic, abusive use can lead to marked tolerance and psychological dependence with varying degrees of abnormal behavior.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C (Include)</u>
Methylphenidate		History of Drug Abuse & Dependence
Dexmethylphenidate		
Serdexmethylphenidate/Dexmethylphenidate		

References:

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

**2. Amphetamines / Drug Abuse & Dependence**

Alert Message: Amphetamines have a high potential for abuse. Administration of amphetamines for prolonged periods of time may lead to the development of substance abuse disorder, including addiction. Assess the risk of abuse prior to prescribing and monitor for signs of abuse and dependence while on therapy.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C (Include)</u>
Amphetamine		History of Drug Abuse & Dependence
Dextroamphetamine		
Methamphetamine		
Lisdexamfetamine		

References:

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

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



**NORTH DAKOTA MEDICAID  
RETROSPECTIVE DRUG UTILIZATION REVIEW  
CRITERIA RECOMMENDATIONS  
4TH QUARTER 2024**

**Criteria Recommendations**

**Approved Rejected**

**1. Adagrasib / Overuse**

Alert Message:Krazati (adagrasib) may be over-utilized.The recommended dosage of adagrasib is 600 mg orally twice daily until disease progression or unacceptable toxicity.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Adagrasib		

Max Dose: 1200 mg/day

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.  
Krazati Prescribing information, June 2024, Mirati Therapeutics, Inc.

**2. Adagrasib / Therapeutic Appropriateness**

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

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Adagrasib		

Age Range: 0 – 17 yoa

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.  
Krazati Prescribing information, June 2024, Mirati Therapeutics, Inc.

**3. Adagrasib / Adverse Gastrointestinal Adverse Effects**

Alert Message:Krazati (adagrasib) can cause severe gastrointestinal adverse reactions (gastrointestinal bleeding, obstruction, colitis, and ileus).Monitor and manage patients using supportive care, including antidiarrheals, antiemetics, or fluid replacement, as indicated. Withhold, reduce the dose, or permanently discontinue adagrasib based on severity.Reduce the dose in accordance with the official prescribing information, withhold, or permanently discontinue adagrasib based on severity.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Adagrasib	Gastrointestinal Bleeding	
	Gastrointestinal Obstruction	
	Colitis	
	Diarrhea	
	Ileus	

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.  
Krazati Prescribing information, June 2024, Mirati Therapeutics, Inc.

**4. Adagrasib / QT Prolongation**

Alert Message:Krazati (adagrasib) can cause QTc interval prolongation, which can increase the risk for ventricular tachyarrhythmias (e.g., torsades de pointes) or sudden death.Avoid the use of adagrasib in patients with congenital long QT syndrome and patients with concurrent QTc prolongation.Withhold, reduce the dose in accordance with the official prescribing information, or permanently discontinue adagrasib depending on severity.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Adagrasib	QT Prolongation	

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.  
Krazati Prescribing information, June 2024, Mirati Therapeutics, Inc.

**5. Adagrasib / Hepatotoxicity**

Alert Message:Krazati (adagrasib) can cause hepatotoxicity, which may lead to drug-induced liver injury and hepatitis.In clinical trials, overall hepatotoxicity occurred in 37%, and 7% were Grade 3 or 4.Hepatotoxicity leading to dose interruption or reduction occurred in 12% of patients. Adagrasib was discontinued due to hepatotoxicity in 0.5% of patients.Reduce the dose in accordance with the official prescribing information, withhold, or permanently discontinue adagrasib based on severity.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Adagrasib	Transaminase Elevations Toxic Liver Disease	

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.  
Krazati Prescribing information, June 2024, Mirati Therapeutics, Inc.

**6. Adagrasib / Interstitial Lung Disease/Pneumonitis**

Alert Message:Krazati (adagrasib) can cause interstitial lung disease (ILD)/pneumonitis, which can be fatal.In the pooled safety population study, ILD/pneumonitis occurred in 4.1% of patients, 1.4% were Grade 3 or 4, and one case was fatal.Monitor patients for new or worsening respiratory symptoms indicative of ILD/pneumonitis (e.g., dyspnea, cough, fever) during treatment with adagrasib.Withhold adagrasib in patients with suspected ILD/pneumonitis and permanently discontinue adagrasib if no other potential causes of ILD/pneumonitis are identified.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Adagrasib	Interstitial Lung Disease Pneumonitis Cough Dyspnea Fever	

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.  
Krazati Prescribing information, June 2024, Mirati Therapeutics, Inc.

**7. Adagrasib / Strong CYP3A4 Inducers**

Alert Message: Avoid concomitant use of Krazati (adagrasib) with strong CYP3A4 inducers. Adagrasib is a CYP3A4 substrate. Concomitant use of adagrasib with a strong CYP3A4 inducer reduces adagrasib exposure, which may reduce the effectiveness of adagrasib.

Drugs/Diseases

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

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.  
Krazati Prescribing information, June 2024, Mirati Therapeutics, Inc.

**8. Adagrasib / Strong CYP3A4 Inhibitors**

Alert Message: Avoid concomitant use of Krazati (adagrasib) with strong CYP3A4 inhibitors until adagrasib concentrations have reached steady state (after approximately 8 days). Adagrasib is a CYP3A4 substrate. If adagrasib concentrations have not reached steady state, concomitant use of a strong CYP3A4 inhibitor will increase adagrasib concentrations, which may increase the risk of adagrasib adverse reactions.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Adagrasib	Clarithromycin	
	Cobicistat	
	Nefazodone	
	Nelfinavir	
	Ritonavir	

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.  
Krazati Prescribing information, June 2024, Mirati Therapeutics, Inc.

**9. Adagrasib / Sensitive CYP3A4 Substrates**

Alert Message: Avoid concomitant use of Krazati (adagrasib) with sensitive CYP3A substrates unless otherwise recommended in the official prescribing information for these substrates. Adagrasib is a CYP3A inhibitor. Concomitant use with adagrasib increases exposure of CYP3A substrates, which may increase the risk of adverse reactions related to these substrates.

## Drugs/Diseases

<u>Util A</u>	<u>Util B</u>			<u>Util C</u>
Adagrasib	Avanafil	Everolimus	Quetiapine	Vardenafil
	Budesonide	Felodipine	Sildenafil	
	Buspirone	Ibrutinib	Sirolimus	
	Cyclosporine	Maraviroc	Tacrolimus	
	Darifenacin	Midazolam	Ticagrelor	
	Darunavir	Nisoldipine	Tipranavir	

## References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.  
Krazati Prescribing information, June 2024, Mirati Therapeutics, Inc.

**10. Adagrasib / Sensitive CYP2C9 Substrates**

Alert Message: Avoid concomitant use of Krazati (adagrasib) with sensitive CYP2C9 substrates where minimal concentration changes may lead to serious adverse reactions unless otherwise recommended in the official prescribing information for these substrates. Adagrasib is a CYP2C9 inhibitor. Concomitant use with adagrasib increases exposure of CYP2C9 substrates, which may increase the risk of adverse reactions related to these substrates.

## Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Adagrasib	Celecoxib	
	Glimepiride	
	Phenytoin	
	Warfarin	

## References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.  
Krazati Prescribing information, June 2024, Mirati Therapeutics, Inc.

**11. Adagrasib / Sensitive CYP2D6 Substrates**

Alert Message: Avoid concomitant use of Krazati (adagrasib) with sensitive CYP2D6 substrates where minimal concentration changes may lead to serious adverse reactions unless otherwise recommended in the official prescribing information for these substrates. Adagrasib is a CYP2D6 inhibitor. Concomitant use with adagrasib increases exposure of CYP2D6 substrates, which may increase the risk of adverse reactions related to these substrates.

## Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Adagrasib	Atomoxetine	
	Desipramine	
	Dextromethorphan	
	Nebivolol	
	Perphenazine	
	Tolterodine	
	Venlafaxine	

## References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.  
Krazati Prescribing information, June 2024, Mirati Therapeutics, Inc.

**12. Adagrasib / Sensitive P-gp Substrates**

Alert Message: Avoid concomitant use of Krazati (adagrasib) with P-gp substrates where minimal concentration changes may lead to serious adverse reactions unless otherwise recommended in the official prescribing information for these substrates. Adagrasib is a P-gp inhibitor. Concomitant use with adagrasib increases exposure of P-gp substrates, which may increase the risk of adverse reactions related to these substrates.

## Drugs/Diseases

Util A

Adagrasib

Util B

Dabigatran

Digoxin

Edoxaban

Util C

## References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.

Krazati Prescribing information, June 2024, Mirati Therapeutics, Inc.

**Criteria Recommendations**

**Approved Rejected**

**13. Adagrasib / Drug that Prolong QT Interval**

Alert Message:Krazati (adagrasib) can cause QTc interval prolongation, which can increase the risk for ventricular tachyarrhythmias (e.g., torsades de pointes) or sudden death.Avoid concomitant use of adagrasib with other products with a known potential to prolong the QTc interval.Monitor ECGs and electrolytes prior to starting adagrasib, during concomitant use, and as clinically indicated in patients who are unable to avoid concomitant medications that are known to prolong the QT interval.Withhold, reduce the dose, or permanently discontinue adagrasib depending on severity.

Drugs/Diseases

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

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.  
 Krazati Prescribing information, June 2024, Mirati Therapeutics, Inc.

**14. Adagrasib / Lactation**

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

Drugs/Diseases

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

Gender: Female

Age Range: 11 – 50 yoa

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.

Krazati Prescribing information, June 2024, Mirati Therapeutics, Inc.

**15. Adagrasib / Non-adherence**

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

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Adagrasib		

References:

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

Ruddy K, Mayer E, Partridge A. Patient Adherence and Persistence With Oral Anticancer Treatment. CA Cancer J Clin 2009;59:56-66.

Barillet M, Prevost V, Joly F, Clarisse B. Oral Antineoplastic Agents: How do We Care About Adherence?. Br J Clin Pharmacol. 2015;80(6):1289–1302. doi:10.1111/bcp.12734

Greer JA, Amoyal N, Nisotel L, et al. Systemic Review of Adherence to Oral Antineoplastic Therapies. The Oncologist. 2016;21:354-376.

**16. Diazepam Buccal / Overuse**

Alert Message: Libervant (diazepam) may be over-utilized. Buccal diazepam should not be used to treat more than 1 episode every 5 days and no more than 5 episodes per month. Do not use more than 2 doses of buccal diazepam to treat a single episode.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Diazepam Buccal		

Quantity: 10 tablets per month

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.

Libervant Prescribing Information, April 2024, Aquestive Therapeutics, Inc.



**17. Diazepam Buccal / Therapeutic Appropriateness**

Alert Message: Libervant (diazepam) is approved for use in pediatric patients 2 to 5 years of age. The unapproved use of buccal diazepam exposes users to risks of abuse, misuse, and addiction, which can lead to overdose or death. Abuse and misuse of benzodiazepines commonly involve concomitant use of other medications, alcohol, and/or illicit substances, which is associated with an increased frequency of serious adverse outcomes.

Drugs/Diseases

Util AUtil BUtil C

Diazepam Buccal

Age Range: 6 - 999 yoa

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.

Libervant Prescribing Information, April 2024, Aquestive Therapeutics, Inc.

**18. Diazepam Buccal / Therapeutic Appropriateness**

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

Drugs/Diseases

Util AUtil BUtil C

Diazepam Buccal

Narrow Angle Glaucoma

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.

Libervant Prescribing Information, April 2024, Aquestive Therapeutics, Inc.

**19. Diazepam Buccal / Therapeutic Appropriateness**

Alert Message: Libervant (diazepam) is not approved for use in neonates or infants. Serious and fatal adverse reactions including "gaspings syndrome" can occur in neonates and low birth weight infants treated with benzyl alcohol-preserved drugs, including buccal diazepam. The "gaspings syndrome" is characterized by central nervous system depression, metabolic acidosis, and gasping respiration. The minimum amount of benzyl alcohol at which serious adverse reactions may occur is not known (buccal diazepam contains 3.96 to 11.87 mg of benzyl alcohol per buccal film).

Drugs/Diseases

Util AUtil BUtil C

Diazepam Buccal

Age Range: 0 - 1 yoa

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.

Libervant Prescribing Information, April 2024, Aquestive Therapeutics, Inc.

**20. Diazepam Buccal / CYP2C19 and CYP3A4 Inhibitors**

Alert Message: Libervant (diazepam) is a substrate for CYP2C19 and CYP3A4. The concurrent use of diazepam with a CYP2C19 or CYP3A4 inhibitor may decrease the rate of diazepam elimination and increase the risk of diazepam-related adverse effects.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Diazepam Buccal	Cimetidine	Modafinil
	Clarithromycin	Nefazodone
	Cobicistat	Nelfinavir
	Fluconazole	Omeprazole
	Esomeprazole	Posaconazole
	Fluoxetine	Ritonavir
	Fluvoxamine	Ticlopidine
	Itraconazole	Tranylcypromine
	Ketoconazole	Voriconazole
	Lonafarnib	

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.

Libervant Prescribing Information, April 2024, Aquestive Therapeutics, Inc.

**21. Diazepam Buccal / CYP2C19 and CYP3A4 Inducers**

Alert Message: Libervant (diazepam) is a substrate for CYP2C19 and CYP3A4. The concurrent use of diazepam with a CYP2C19 or CYP3A4 inducer may increase the rate of diazepam elimination and decrease diazepam efficacy.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Diazepam Buccal	Apalutamide	Phenytoin
	Carbamazepine	Primidone
	Enzalutamide	Rifampin
	Mitotane	
	Phenobarbital	

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.

Libervant Prescribing Information, April 2024, Aquestive Therapeutics, Inc.

## Criteria Recommendations

Approved Rejected

### 22. Pirtobrutinib / Overuse

Alert Message: Jaypirca (pirtobrutinib) may be over-utilized. The recommended dosage of pirtobrutinib is 200 mg orally once daily until disease progression or unacceptable toxicity.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C (Negating)</u>
Pirtobrutinib		CKD Stage 4

Max Dose: 200 mg/day

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.

Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.

Jaypirca Prescribing Information, June 2024, Eli Lilly and Company.

### 23. Pirtobrutinib / CKD Stage 4

Alert Message: For patients with severe renal impairment (eGFR 15-29 mL/min), reduce the Jaypirca (pirtobrutinib) dose to 100 mg once daily if the current dose is 200 mg once daily; otherwise, reduce the dose by 50 mg. If the current dosage is 50 mg once daily, discontinue pirtobrutinib. No dosage adjustment of pirtobrutinib is recommended in patients with mild to moderate renal impairment (eGFR 30-89 mL/min).

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C (Include)</u>
Pirtobrutinib		CKD Stage 4

Max Dose: 100 mg/day

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.

Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.

Jaypirca Prescribing Information, June 2024, Eli Lilly and Company.

### 24. Pirtobrutinib / Therapeutic Appropriateness

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

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Pirtobrutinib		

Age Range: 0 – 17 yoa

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.

Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.

Jaypirca Prescribing Information, June 2024, Eli Lilly and Company.

**25. Pirtobrutinib / Infections**

Alert Message: Fatal and serious infections (including bacterial, viral, or fungal infections) and opportunistic infections have occurred in patients treated with Jaypirca (pirtobrutinib). In the clinical trial, Grade 3 or higher infections occurred in 24% of 593 patients, most commonly pneumonia (14%), with fatal infections occurring in 4.4% of patients. Monitor patients for signs and symptoms of infection, evaluate promptly and treat appropriately. Based on severity, reduce the dose, temporarily withhold or permanently discontinue pirtobrutinib.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Pirtobrutinib	Infections	

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.  
 Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.  
 Jaypirca Prescribing Information, June 2024, Eli Lilly and Company.

**26. Pirtobrutinib / Hemorrhage**

Alert Message: Fatal and serious hemorrhage has occurred with Jaypirca (pirtobrutinib). Major hemorrhage occurred in 3% of 593 patients treated with pirtobrutinib. Bleeding of any grade, excluding bruising and petechiae, occurred in 17% of patients. Major hemorrhage occurred in 2.3% of patients taking pirtobrutinib without antithrombotic agents and 0.7% of patients taking pirtobrutinib with antithrombotic agents. Consider the risks and benefits of antithrombotic agents when co-administered with pirtobrutinib. Monitor patients for signs of bleeding. Based on the severity of bleeding, reduce the dose, temporarily withhold, or permanently discontinue pirtobrutinib.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Pirtobrutinib	Gastrointestinal hemorrhage Hematemesis Hematochezia Intracerebral hemorrhage Intracranial hemorrhage Melena	

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.  
 Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.  
 Jaypirca Prescribing Information, June 2024, Eli Lilly and Company.

**27. Pirtobrutinib / Cytopenias**

Alert Message: Jaypirca (pirtobrutinib) can cause cytopenias, including neutropenia, thrombocytopenia, and anemia. In the clinical trial, Grade 3 or 4 cytopenias, including decreased neutrophils (26%), decreased platelets (12%), and decreased hemoglobin (12%) developed in patients treated with pirtobrutinib. Grade 4 decreased neutrophils developed in 14% of patients, and Grade 4 decreased platelets developed in 6% of patients. Monitor complete blood counts regularly during pirtobrutinib treatment. Based on severity, reduce the dose, temporarily withhold or permanently discontinue pirtobrutinib.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Pirtobrutinib	Neutropenia Thrombocytopenia Anemia	

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.  
 Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.  
 Jaypirca Prescribing Information, June 2024, Eli Lilly and Company.

**28. Pirtobrutinib / Arrhythmias**

Alert Message: Cardiac arrhythmias, including atrial fibrillation and atrial flutter, were reported in recipients receiving Jaypirca (pirtobrutinib). Atrial fibrillation or flutter were reported in 3.2% of patients, with Grade 3 or 4 atrial fibrillation or flutter reported in 1.5% of 593 patients in the clinical trial. Patients with cardiac risk factors, such as hypertension or previous arrhythmias, may be at increased risk. Monitor for signs and symptoms of arrhythmias (e.g., palpitations, dizziness, syncope, dyspnea) and manage appropriately. Based on severity, reduce the dose, temporarily withhold or permanently discontinue pirtobrutinib.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Pirtobrutinib	Arrhythmias	

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.  
Jaypirca Prescribing Information, June 2024, Eli Lilly and Company.

**29. Pirtobrutinib / Hepatotoxicity**

Alert Message: Hepatotoxicity, including severe, life-threatening, and potentially fatal cases of drug-induced liver injury (DILI), has occurred in patients treated with Bruton tyrosine kinase inhibitors, including Jaypirca (pirtobrutinib). Evaluate bilirubin and transaminases at baseline and throughout treatment with pirtobrutinib. For patients who develop abnormal liver tests after pirtobrutinib, monitor more frequently for liver test abnormalities and clinical signs and symptoms of hepatic toxicity. If DILI is suspected, withhold pirtobrutinib. Upon confirmation of DILI, discontinue pirtobrutinib.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Pirtobrutinib	Abnormal Results of Liver Function Studies Anorexia Chronic Fatigue Jaundice Nausea	

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.  
Jaypirca Prescribing Information, June 2024, Eli Lilly and Company.

**30. Pirtobrutinib / Strong CYP3A4 Inhibitors**

Alert Message: Avoid concomitant use of strong CYP3A inhibitors with Jaypirca (pirtobrutinib). If concomitant use of a strong CYP3A inhibitor is unavoidable, reduce the pirtobrutinib dose by 50 mg. If the current dosage is 50 mg once daily, interrupt pirtobrutinib treatment for the duration of strong CYP3A inhibitor use. After discontinuation of a strong CYP3A inhibitor for 5 half-lives, resume the pirtobrutinib dose that was taken prior to initiating the strong CYP3A inhibitor.

Drugs/Diseases

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

Max Dose: 150 mg/day

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.  
Jaypirca Prescribing Information, June 2024, Eli Lilly and Company.

**31. Pirtobrutinib / Strong or Moderate CYP3A4 Inducers**

Alert Message: Avoid concomitant use of strong or moderate CYP3A inducers with Jaypirca (pirtobrutinib). If concomitant use with moderate CYP3A inducers is unavoidable and the current dosage of pirtobrutinib is 200 mg once daily, increase the dose to 300 mg. If the current dosage is 50 mg or 100 mg once daily, increase the dose by 50 mg.

Drugs/Diseases

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

References:

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

**32. Pirtobrutinib / Sensitive CYP2C8, 2C19, 3A, P-gp, & BCRP Substrates**

Alert Message: Jaypirca (pirtobrutinib) is a P-gp inhibitor, a moderate CYP2C8 and BCRP inhibitor, and a weak CYP2C19 and CYP3A inhibitor. Concomitant use of pirtobrutinib with sensitive P-gp, CYP2C8, BCRP, CYP2C19, or CYP3A substrates increases the substrate plasma concentrations, which may increase the risk of substrate-related adverse reactions. Follow the recommendations for sensitive CYP2C8, CYP2C19, CYP3A, P-gp, or BCRP substrates provided in their approved product labeling.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Pirtobrutinib	Buspirone	
	Citalopram	
	Cyclosporine	
	Edoxaban	
	Everolimus	
	Felodipine	
	Dabigatran	
	Digoxin	
	Lonafarnib	
	Sirolimus	
	Tacrolimus	
	Triazolam	
	Warfarin	

References:

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

**33. Pirtobrutinib / Antithrombotic Agents**

Alert Message: Consider the risks and benefits of antithrombotic agents when co-administered with Jaypirca (pirtobrutinib). In a clinical trial, major hemorrhage occurred in 3% of 593 patients treated with pirtobrutinib. Monitor patients for signs of bleeding. Based on the severity of bleeding, reduce the dose, temporarily withhold, or permanently discontinue pirtobrutinib.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Pirtobrutinib	Apixaban Fondaparinux  Dabigatran Heparin  Dalteparin Rivaroxaban  Edoxaban Warfarin  Enoxaparin	

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.  
Jaypirca Prescribing Information, June 2024, Eli Lilly and Company.

**34. Pirtobrutinib / Pregnancy / Pregnancy Negating**

Alert Message: Based on findings from animal studies, Jaypirca (pirtobrutinib) can cause fetal harm when administered to a pregnant woman. There are no available data on pirtobrutinib use in pregnant women to evaluate for a drug-associated risk. In an animal reproduction study, administration of pirtobrutinib to pregnant rats during organogenesis resulted in adverse developmental outcomes at maternal exposures approximately 3-times those in patients at the recommended daily dose of 200 mg. Advise pregnant women of the potential risk to a fetus.

Drugs/Diseases

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

Gender: Female

Age Range: 11 – 50 yoa

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.  
Jaypirca Prescribing Information, June 2024, Eli Lilly and Company.

**35. Pirtobrutinib / Lactation**

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

Drugs/Diseases

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

Gender: Female

Age Range: 11 – 50 yoa

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.  
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.  
Jaypirca Prescribing Information, June 2024, Eli Lilly and Company.

**36. Pirtobrutinib / Non-adherence**

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

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Pirtobrutinib		

References:

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

**37. Tovorafenib / Hemorrhage**

Alert Message:Major hemorrhagic events can occur during treatment with Ojemda (tovorafenib). Monitor for signs and symptoms of hemorrhage and evaluate as clinically indicated.Withhold, resume at reduced dose, or permanently discontinue tovorafenib based on severity.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Tovorafenib	Gastrointestinal hemorrhage Hematemesis Hematochezia Intracerebral hemorrhage Intracranial hemorrhage Melena	

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.  
Ojemda Prescribing Information, June 2024, Day One Biopharmaceuticals.

**38. Tovorafenib / Hepatotoxicity**

Alert Message:Ojemda (tovorafenib) can cause hepatotoxicity.Monitor liver function tests, including ALT, AST, and bilirubin, before initiation of tovorafenib, one month after initiation, and then every three months thereafter, and as clinically indicated.Withhold and resume at the same or reduced dose upon improvement, or permanently discontinue tovorafenib based on the severity.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Tovorafenib	Abnormal Results of Liver Function Studies Anorexia Chronic Fatigue Jaundice Nausea	

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.  
Ojemda Prescribing Information, June 2024, Day One Biopharmaceuticals.



**39. Tovorafenib / Moderate & Strong CYP2C8 Inhibitors**

Alert Message: Avoid coadministration of Ojemda (tovorafenib) with strong or moderate CYP2C8 inhibitors. Tovorafenib is a CYP2C8 substrate. Strong or moderate CYP2C8 inhibitors are predicted to increase tovorafenib exposure based on a mechanistic understanding of its elimination, which may increase the risk of adverse reactions with tovorafenib.

## Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Tovorafenib	Gemfibrozil	
	Clopidogrel	
	Deferasirox	
	Teriflunomide	

## References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.  
Ojemda Prescribing Information, June 2024, Day One Biopharmaceuticals.

**40. Tovorafenib / Moderate & Strong CYP2C8 Inducers**

Alert Message: Avoid coadministration of Ojemda (tovorafenib) with strong or moderate CYP2C8 inducers. Tovorafenib is a CYP2C8 substrate. Strong or moderate CYP2C8 inducers are predicted to decrease tovorafenib exposure based on a mechanistic understanding of its elimination, which may reduce the effectiveness of tovorafenib.

## Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Tovorafenib	Rifampin	

## References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.  
Ojemda Prescribing Information, June 2024, Day One Biopharmaceuticals.

**41. Tovorafenib / Sensitive CYP3A Substrates**

Alert Message: Avoid coadministration of Ojemda (tovorafenib) with certain CYP3A substrates where minimal concentration changes may lead to serious therapeutic failures. Tovorafenib is a CYP3A inducer. If coadministration is unavoidable, monitor patients for loss of efficacy of the substrate drug unless otherwise recommended in the Prescribing Information for CYP3A substrates.

## Drugs/Diseases

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

## References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.  
Ojemda Prescribing Information, June 2024, Day One Biopharmaceuticals.

**42. Tovorafenib / Hormonal Contraceptives**

Alert Message: Avoid coadministration of hormonal contraceptives with Ojemda (tovorafenib). Tovorafenib is a CYP3A inducer, and hormonal contraceptives are CYP3A substrates. Concurrent use of these agents may lead to therapeutic failure of the CYP3A hormonal contraceptives. If coadministration is unavoidable, use an additional effective nonhormonal contraceptive method during coadministration and for 28 days after discontinuation of tovorafenib.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Tovorafenib	Hormonal Contraceptives	

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.  
Ojemda Prescribing Information, June 2024, Day One Biopharmaceuticals.

**43. Tovorafenib / Pregnancy / Pregnancy Negating**

Alert Message: Based on findings from animal studies and its mechanism of action, Ojemda (tovorafenib) can cause fetal harm when administered to a pregnant woman. There are no available data on the use of tovorafenib in pregnant women. Advise pregnant women of the potential risk to a fetus.

Drugs/Diseases

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

Gender: Female

Age Range: 11 – 50 yoa

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.  
Ojemda Prescribing Information, June 2024, Day One Biopharmaceuticals.

**44. Tovorafenib / Lactation**

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

Drugs/Diseases

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

Gender: Female

Age Range: 11 – 50 yoa

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.  
Ojemda Prescribing Information, June 2024, Day One Biopharmaceuticals.

**45. Tovorafenib / Reproductive Potential**

Alert Message: Advise females of reproductive potential to use effective nonhormonal contraception during treatment with Ojemda (tovorafenib) and for 28 days after the last dose. Tovorafenib can render hormonal contraceptives ineffective. Tovorafenib can cause fetal harm when administered to a pregnant woman.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C (Negating)</u>
Tovorafenib		Non-Hormonal Contraception

Gender: Female

Age Range: 11 – 50 yoa

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.

Ojemda Prescribing Information, June 2024, Day One Biopharmaceuticals.

**46. Tovorafenib / Reproductive Potential**

Alert Message: Advise male patients with female partners of reproductive potential to use effective nonhormonal contraception during treatment with Ojemda (tovorafenib) and for 2 weeks after the last dose.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Tovorafenib		

Gender: Male

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.

Ojemda Prescribing Information, June 2024, Day One Biopharmaceuticals.

**47. Tovorafenib / Non-adherence**

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

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Tovorafenib		

References:

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

Ruddy K, Mayer E, Partridge A. Patient Adherence and Persistence With Oral Anticancer Treatment. CA Cancer J Clin 2009;59:56-66.

Barillet M, Prevost V, Joly F, Clarisse B. Oral Antineoplastic Agents: How do We Care About Adherence?. Br J Clin Pharmacol. 2015;80(6):1289–1302. doi:10.1111/bcp.12734

Greer JA, Amoyal N, Nisotel L, et al. Systemic Review of Adherence to Oral Antineoplastic Therapies. The Oncologist. 2016;21:354-376.

**48. Pitolisant / Overuse - Pediatric**

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Alert Message: The recommended maximum dose of Wakix (pitolisant) for the treatment of excessive daytime sleepiness in pediatric patients 6 years of age and older weighing 40 kg or more with narcolepsy is 35.6 mg orally once daily in the morning upon waking. For pediatric patients under 40 kg, the maximum dose is 17.8 mg once daily.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C (Negating)</u>
Pitolisant		Hepatic Impairment CKD Stage 3, 4, & 5

Max Dose: 35.6 mg/day

Age Range: 6 – 17 yoa

References:

Wakix Prescribing Information, June 2024, Harmony Biosciences.

**49. Pitolisant / Overutilization – Hepatic Impairment**

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Alert Message: Wakix (pitolisant) may be overutilized. Pitolisant is extensively metabolized by the liver, and there is a significant increase in pitolisant exposure in patients with moderate hepatic impairment. For pediatric patients 6 years and older, weighing 40 kg or more with moderate hepatic impairment, pitolisant should be initiated at 4.45 mg once daily and increased after 14 days to 8.9 mg once daily. The dose may increase after another 14 days to a maximum of 17.8 mg daily. For pediatric patients 6 and older, weighing less than 40 kg, pitolisant should be initiated at 4.45 mg once daily, then increased after 14 days to a maximum of 8.9 mg once daily.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C (Include)</u>
Pitolisant		Hepatic Impairment

Max Dose: 17.8 mg/day

Age Range: 6 – 17 yoa

References:

Wakix Prescribing Information, June 2024, Harmony Biosciences.

**50. Pitolisant / Overutilization – Mod. To Sev. Renal Impairment**

Alert Message:Wakix (pitolisant) may be over-utilized.Dosage adjustment for pitolisant is recommended in pediatric patients with moderate to severe renal impairment.For pediatric patients 6 years of age and older, weighing 40 kg or more with an eGFR < 60 ml/min/1.73m<sup>2</sup>, pitolisant should be initiated at 4.45 mg once daily and increased after 7 days to 8.9 mg once daily.The dose may be increased after another 7 days to a maximum of 17.8 mg once daily. For those patients weighing less than 40 kg with an eGFR < 60 ml/min/1.73m<sup>2</sup>, pitolisant should be initiated at 4.45 mg once daily and increased after 7 days to a maximum dosage of 8.9 mg once daily.

## Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C (Include)</u>
Pitolisant		CKD Stage 3, 4 & 5

Max Dose: 8.9 mg/day

Age Range: 6 – 17 yoa

## References:

Wakix Prescribing Information, June 2024, Harmony Biosciences.

**51. Aprocitentan / Overuse**

Alert Message:Tryvio (aprocitentan) may be over-utilized.The recommended dosage of aprocitentan is 12.5 mg once daily.

## Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Aprocitentan		

Max Dose: 12.5 mg/day

## References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.  
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.  
Tryvio Prescribing Information, March 2024, Idorsia Pharmaceuticals Ltd.

**52. Aprocitentan / Therapeutic Appropriateness**

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

## Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Aprocitentan		

Age Range: 0 – 17 yoa

## References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.  
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.  
Tryvio Prescribing Information, March 2024, Idorsia Pharmaceuticals Ltd.

**53. Aprocitentan / Therapeutic Appropriateness**

Alert Message:Tryvio (aprocitentan) is not recommended in patients with kidney failure (eGFR < 15 ml/min) or on dialysis.The effect of kidney failure (eGFR < 15 mL/min) or dialysis on aprocitentan pharmacokinetics is unknown.Patients with renal impairment are at increased risk of edema/fluid retention.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Aprocitentan	CKD Stage 5 ESRD Dialysis	

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.  
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.  
Tryvio Prescribing Information, March 2024, Idorsia Pharmaceuticals Ltd.

**54. Aprocitentan / Moderate to Severe Hepatic Impairment**

Alert Message:Tryvio (aprocitentan) is not recommended in patients with moderate and severe hepatic impairment (Child-Pugh Class B and C) because these patients may be at increased risk for poor outcomes from hepatotoxicity.Elevations of aminotransferases and hepatotoxicity are known effects of endothelin receptor antagonists (ERAs).

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Aprocitentan	Cirrhosis Liver Failure	

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.  
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.  
Tryvio Prescribing Information, March 2024, Idorsia Pharmaceuticals Ltd.

**55. Aprocitentan / Fluid Retention**

Alert Message:Fluid retention and peripheral edema are known effects of endothelin receptor antagonists (ERAs), including Tryvio (aprocitentan).Monitor the patient for signs and symptoms of fluid retention, weight gain, and worsening heart failure.If clinically significant fluid retention develops, treat appropriately, and consider discontinuation of aprocitentan.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Aprocitentan	Fluid Retention Peripheral Edema	

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.  
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.  
Tryvio Prescribing Information, March 2024, Idorsia Pharmaceuticals Ltd.

**56. Aprocitantan / Heart Failure**

Alert Message:Tryvio (aprocitantan) has not been studied in patients with heart failure New York Heart Association stage III-IV, unstable cardiac function, or with NTproBNP >= 500 pg/mL.The use of aprocitantan is not recommended in these patients because aprocitantan can cause fluid retention and peripheral edema.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Aprocitantan	Heart failure	

References:

- Clinical Pharmacology, 2024 Elsevier/Gold Standard.
- Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
- Tryvio Prescribing Information, March 2024, Idorsia Pharmaceuticals Ltd.

**57. Aprocitantan / Pregnancy / Pregnancy Negating (Box Warning)**

Alert Message:The use of Tryvio (aprocitantan) is contraindicated in pregnancy.Aprocitantan can cause fetal harm, including birth defects and fetal death, when administered during pregnancy.To prevent pregnancy, patients who can become pregnant should use acceptable contraception prior to initiation of treatment, during treatment, and for one month after discontinuation of treatment with aprocitantan.

Drugs/Diseases

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

Gender: Female

Age Range: 11 – 50 yoa

References:

- Clinical Pharmacology, 2024 Elsevier/Gold Standard.
- Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
- Tryvio Prescribing Information, March 2024, Idorsia Pharmaceuticals Ltd.

**58. Aprocitantan / Lactation**

Alert Message:There are no data on the presence of Tryvio (aprocitantan) in human milk, the effects on the breastfed infant, or the effect on milk production.In rats, aprocitantan was excreted into milk during lactation.When a drug is present in animal milk, the drug will likely be present in human milk.Because of the potential for serious adverse reactions in breastfed infants, advise women not to breastfeed during treatment with aprocitantan.

Drugs/Diseases

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

Gender: Female

Age Range: 11 – 50 yoa

References:

- Clinical Pharmacology, 2024 Elsevier/Gold Standard.
- Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.
- Tryvio Prescribing Information, March 2024, Idorsia Pharmaceuticals Ltd.

**59. Aprocitentan / Therapeutic Appropriateness (Box Warning)**

Alert Message: Patients using Tryvio (aprocitentan) who can become pregnant should use acceptable contraception prior to initiation of treatment, during treatment, and for one month after discontinuation of treatment with aprocitentan. Aprocitentan can cause fetal harm, including birth defects and fetal death.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C (Negate)</u>
Aprocitentan		Contraceptives

Gender: Female

Age Range: 11 – 50 yoa

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.

Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.

Tryvio Prescribing Information, March 2024, Idorsia Pharmaceuticals Ltd.

**60. Aprocitentan / Non-adherence**

Alert Message: Based on refill history, your patient may be under-utilizing Tryvio (aprocitentan).

Nonadherence to the prescribed dosing regimen may result in subtherapeutic effects, which may lead to decreased patient outcomes and additional healthcare costs.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Aprocitentan		

References:

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

Munger MA, Van Tassel BW, La Fleur J, Medication Nonadherence: An Unrecognized Cardiovascular Risk Factor. MedGenMed. Sep. 2007;19;9(3):58.

Bitton A, Choudhry NK, Matlin OS, et al., The Impact of Medication Adherence on Coronary Artery Disease Costs and Outcomes: A Systematic Review. Am J Med. 2013 Apr;126(4):357.e7-357.e27.

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

**61. Zilucoplan / Overuse**

Alert Message: Zilbrysq (zilucoplan) may be over-utilized. The recommended dosage of zilucoplan is given once daily as a subcutaneous injection and is dependent on actual body weight. Patients weighing less than 56 kg should receive one 16.6 mg subq injection per day. Those patients weighing 56 to 77 kg should receive one 23 mg subq injection daily, and patients weighing 77kg or more should receive one 32.4 mg subq injection.

Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Zilucoplan		

Max Dose: 32.4 mg/ml per day

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.

Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.

Zilbrysq Prescribing Information, April 2024, UCB, Inc.



**62. Zilucoplan / Therapeutic Appropriateness**

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

Drugs/Diseases

Util A                      Util B                      Util C  
Zilucoplan

Age Range: 0 – 17 yoa

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.  
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.  
Zilbrysq Prescribing Information, April 2024, UCB, Inc.

**63. Zilucoplan / Therapeutic Appropriateness**

Alert Message: Zilbrysq (zilucoplan) is contraindicated in patients with unresolved Neisseria meningitidis infection. The use of zilucoplan, a complement inhibitor, increases a patient’s susceptibility to serious and life-threatening meningococcal infections (septicemia and/or meningitis) caused by any serogroup, including non-groupable strains.

Drugs/Diseases

Util A                      Util B                      Util C  
Zilucoplan                      Meningococcal Infection

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.  
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.  
Zilbrysq Prescribing Information, April 2024, UCB, Inc.

**64. Zilucoplan / Infections**

Alert Message: Patients receiving Zilbrysq (zilucoplan) are at increased risk for infections due to these bacteria, even after vaccination. Zilucoplan blocks terminal complement activation; therefore, patients may have increased susceptibility to infections, especially with encapsulated bacteria.

Drugs/Diseases

Util A                      Util B                      Util C  
Zilucoplan                      Infections

References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.  
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.  
Zilbrysq Prescribing Information, April 2024, UCB, Inc.

**65. Zilucoplan / Pancreatitis & Pancreatic Cysts**

Alert Message: Pancreatitis and pancreatic cysts have been reported in patients treated with Zilbrysq (zilucoplan). During the open-label extension studies, seven (3.3%) patients experienced pancreatic events, including 4 (1.9%) patients with pancreatitis and 3 (1.4%) with pancreatic cysts. Discontinue zilucoplan in patients with suspected pancreatitis and initiate appropriate management until pancreatitis is ruled out or has resolved.

## Drugs/Diseases

<u>Util A</u>	<u>Util B</u>	<u>Util C</u>
Zilucoplan	Cysts of the Pancreas Pancreatitis	

## References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.  
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.  
Zilbrysq Prescribing Information, April 2024, UCB, Inc.

**66. Zilucoplan / Pregnancy / Pregnancy Negating**

Alert Message: There are no available data on Zilbrysq (zilucoplan) use in pregnant women to evaluate for a drug-associated risk of major birth defects, miscarriage, or other adverse maternal or fetal outcomes. Based on animal data, zilucoplan may cause fetal harm. Administration of zilucoplan to pregnant monkeys resulted in increases in embryofetal death at maternal exposures similar to those in humans at therapeutic doses.

## Drugs/Diseases

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

Gender: Female

Age Range: 11 – 50 yoa

## References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.  
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.  
Zilbrysq Prescribing Information, April 2024, UCB, Inc.

**67. Zilucoplan / Lactation**

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

## Drugs/Diseases

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

Gender: Female

Age Range: 11 – 50 yoa

## References:

Clinical Pharmacology, 2024 Elsevier/Gold Standard.  
Facts & Comparisons, 2024 Updates, Wolters Kluwer Health.  
Zilbrysq Prescribing Information, April 2024, UCB, Inc.

**Criteria Recommendations**

**Approved Rejected**

**68. Zilucoplan / Non-adherence**

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

Drugs/Diseases

Util A

Util B

Util C

Zilucoplan

References:

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

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

Su Y, Wang X, Xing Y, et al. The Analysis of Factors Affecting Medication Adherence in Patients with Myasthenia Gravis: A Cross-Sectional Study. Therapeutic Advances in Neurological Disorders. 2024;17. doi:[10.1177/17562864231206877](https://doi.org/10.1177/17562864231206877)