North Dakota Medicaid
Drug Utilization Review Board Meeting
March 1, 2023
Conference Room 210/212

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Meeting Notice

North Dakota Medicaid Drug Use Review Board

Wednesday, March 1st, 2023
1 to 4 p.m. Central Time

In-Person Information

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

Virtual Information

Join virtually: Click here to join the meeting
Join by phone: 701-328-0950, Conference ID: 747 563 783#

Agenda

1. Administrative items
    - DHHS announcements

2. Old business
    - Review and approval of December 2022 meeting minutes
    - Budget update
    - Review top 25 drugs for the fourth quarter of 2022
    - Prior authorization/PDL update
    - Update to *C. difficile* associated diarrhea
    - Update to Vaginal Infections

3. New business
    - Review of Hyperparathyroidism
    - Review of Influenza
    - Review of Neuromyelitis Optica Spectrum Disorder
    - Review of Urea Cycle Agents
    - Discussion of RSV
    - Retrospective DUR profile review update
    - Retrospective DUR criteria recommendations
    - Upcoming meeting date/agenda.
        - Next meeting is June 7th, 2023

Adjourn

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

North Dakota Medicaid Drug Use Review (DUR) Board
Meeting Minutes
December 7, 2022

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

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

Old Business
Chair T. Schmidt called the meeting to order at 1:20 p.m.

DHHS Announcements
Chair T. Schmidt asked B. Joyce if there is a set date for the end of the public health emergency, in which he answered that there is no set date currently. Chair T. Schmidt followed up by asking if the end of the public health emergency would interfere with medication therapy management (MTM) services. B. Joyce answered that it would not affect MTM services, and they will continue to be covered.

Review and Approval of Meeting Minutes
Chair T. Schmidt asked for a motion to approve the minutes of the September 7, 2022, meeting. A. Werremeyer moved that the minutes be approved, and L. Kroetsch seconded the motion. The chair called for a voice vote to approve the minutes. The motion passed with no audible dissent.

Budget Update
B. Joyce presented budget updates and the overall increase due to the increase in Medicaid member numbers. B. Joyce shared that in 2020, the pre-rebate spend was 79 million dollars and post-rebate was 22.5 million dollars. In 2021, the pre-rebate spend was 100 million dollars and post-rebate was 27 million dollars. For the first 3 quarters of 2022, the pre-rebate spend was 84 million and is projected to be 112 to 114 million dollars pre-rebate total spend for 2022. It is projected, the post-rebate spend will be around 32 million dollars for 2022. Thus, in one year, the total spending rose 14%. B. Joyce assured that this amount of growth is congruent with other Medicaid programs. Chair T. Schmidt asked B. Joyce what the difference in members between 2020 and 2022 is in which he answered that in the beginning of 2020 there was a total of 88 thousand members and as of October of 2022, there was a total of 127 thousand members. B. Joyce went on to discuss that the increase of total spend is not necessarily a result of the amount of members, but rather, the increase in medication cost and utilization of those medications.

Review Top 25 Drugs
B. Joyce presented the quarterly review of the top 25 drugs based on total cost of claims, the top 25 drugs based on the total number of claims, and the top drug classes based on claims and cost for the 3rd quarter of 2022.

PDL/PA Criteria Updates
A. Murphy shared with the Board all the changes made to the Preferred Drug List (PDL) throughout the year 2022. Notable changes include removing Imitrex cartridge and nasal spray, Zomig nasal spray, Bromsite, Prolensa, and Rytary from PA.

Update to Prurigo Nodularis (Dupixent)
A. Murphy presented the criteria for Dupixent's new indication (prurigo nodularis). During public comment, Thu-Mai Duong, a representative of Dupixent, agreed with the criteria set forth for Dupixent therapy in prurigo nodularis; however, she expressed concern about the immunologic systemic therapy requirement for patients primarily since many patients with this disease state are elderly and it may pose a safety risk. There were no further comments from the Board members.

Update to Endometriosis Pain (Myfembree)
A. Murphy presented the criteria for Myfembree's new indication (endometriosis pain). Myfembree and Orilissa will now share the same criteria in the endometriosis pain category on the PDL. There were no further comments or questions.

Update to Hematopoietic Syndrome of Acute Raditaion Syndrome (NPlate)
A. Murphy presented the criteria for NPlate in the off-label use for Hematopoietic Syndrome of Acute Radiation Syndrome. There were no further comments or questions.

Second Review of Amyloidosis
A motion and second were made at the September 2022 DUR Board meeting to place agents for amyloidosis on prior authorization. Group criteria was presented to the Board by A. Murphy. Chair T. Schmidt called for a voice vote to approve the updated criteria, which passed with no audible dissent.

Second Review of Amyotrophic Lateral Sclerosis
A motion and second were made at the September 2022 DUR Board meeting to place agents for amyotrophic lateral sclerosis on prior authorization. Group criteria was presented to the Board by A. Murphy. Chair T. Schmidt called for a voice vote to approve the updated criteria, which passed with no audible dissent.

Second Review of Chelating Agents
A motion and second were made at the September 2022 DUR Board meeting to place agents for chelating agents on prior authorization. Group criteria was presented to the Board by A. Murphy. Chair T. Schmidt called for a voice vote to approve the updated criteria, which passed with no audible dissent.

Treatment follow-up Questions for Eosinophilic Esophagitis (EoE)
A. Murphy presented a document containing follow-up answers to questions asked at the September 2022 Board meeting that were not answered. During public comment, Thu-Mai Duong, a representative for Dupixent, had comments regarding the renewal criteria for Dupixent in EoE. Thu-Mai Duong expressed concerns for the requirement of an esophageal intraepithelial eosinophil count of ≤6 eos/hp in cases when a patient may have a count higher than 6 but has relief from Dupixent or vice versa. Thu-Mai Duong discussed that an esophageal intraepithelial eosinophil count is typically used for diagnosis but not for showing improvement in symptoms. A. Werremeyer followed up by asking if there were any quality-of-life assessments that were included in the trials regarding Dupixent use in EoE. Thu-Mai Duong answered that dysphagia and quality-of-life questionnaires were used in the study and stated she would follow-up with the questionnaires discussed.

Annual Review of Prior Authorization Forms and Criteria
The Board reviewed all forms and criteria utilized for all medications that are currently placed on prior authorization. A. Murphy discussed the major changes made in the preferred drug list (PDL) since the last update. Some of the most notable changes include adding criteria for medical billing only agents and preferring biosimilars of Remicade (Avsola and Renflexis). This list of changes is included in the handout, as well as, in the PDL. Chair T. Schmidt then called for any questions or concerns about the reviewed forms and criteria. G. Balf asked about the first-fill edit for ADHD medications and why these agents are limited initially. A. Murphy answered that the first-fill edit is utilized on few medications that one could notice soon after taking if it is therapeutic. The day supply of the first-fill is limited to ensure the member is on a therapeutic dose before paying for a full supply. Chair T. Schmidt asked for a motion to approve the updated PDL and PA forms. A. Werremeyer moved that the PDL and PA forms be approved, and K. Martian seconded the motion. The chair called for a voice vote to approve the PDL and PA forms. The motion passed with no audible dissent.

New Business

Discussion of RDUR Response Letter
S. Donald presented the RDUR response letters from the 3rd quarter of 2022. Most providers responded that the benefits of the drug outweigh the risks. Chair T. Schmidt discussed concerns of the low provider response rate and asked S. Donald how the rate of responses seen in North Dakota compared to other states. S. Donald stated that the rates are low across the board, but North Dakota is slightly lower than the average.

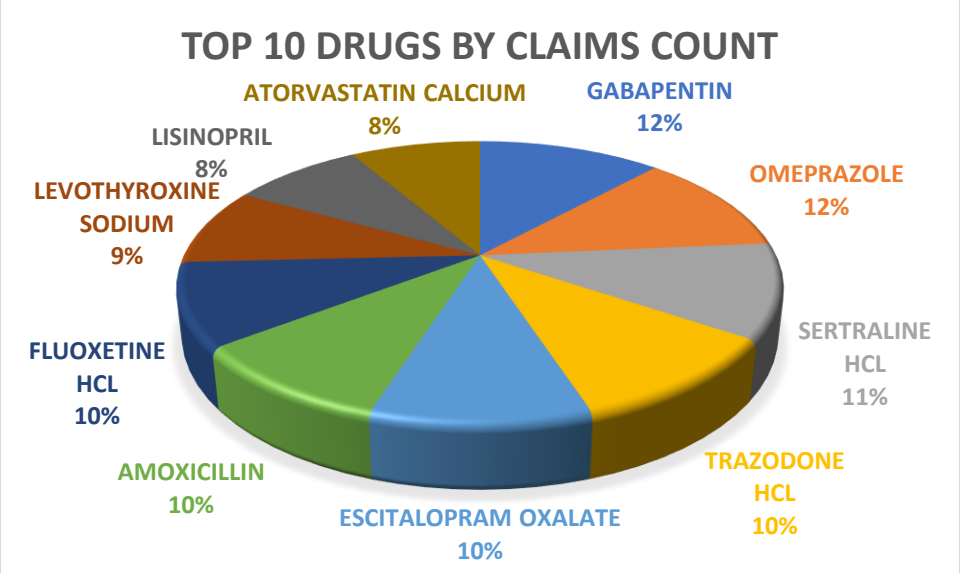
Retrospective Drug Utilization Review (RDUR) Criteria Recommendations
S. Donald reviewed the RDUR criteria that were selected for review of each month of the last quarter. Presented data included the number of profiles reviewed, number of cases identified for intervention, and the number of letters sent,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

Adjournment and Upcoming Meeting Date
Chair T. Schmidt adjourned the meeting at 2:37 pm. The next DUR Board meeting will be held March 1, 2023, at 1:00 pm at the state capitol building.

Top 25 Drugs Based on Number of Claims from 10/01/2022 – 12/31/2022

Drug	Claims	Patients	Claims Cost	Cost / Claim	% Total Claims	Dif.
1. GABAPENTIN	4,688	1,998	$69,585.74	$14.84	1.8%	↑1
2. OMEPRAZOLE	4,653	2,303	$60,379.00	$12.98	1.8%	↓1
3. SERTRALINE HCL	4,307	2,379	$58,913.12	$13.68	1.6%	NC
4. TRAZODONE HCL	4,167	2,052	$56,772.89	$13.62	1.6%	NC
5. ESCITALOPRAM OXALATE	3,972	2,227	$53,281.42	$13.41	1.5%	NC
6. AMOXICILLIN	3,832	3,591	$54,531.50	$14.23	1.4%	↑12
7. FLUOXETINE HCL	3,797	2,021	$52,227.52	$13.75	1.4%	↓1
8. LEVOTHYROXINE SODIUM	3,507	1,837	$57,164.86	$16.3	1.3%	↓1
9. LISINOPRIL	3,379	1,993	$43,587.30	$12.9	1.3%	↓1
10. ATORVASTATIN CALCIUM	3,329	1,884	$47,369.14	$14.23	1.3%	↓1
11. AMOXICILLIN-CLAV	3,189	3,006	$57,622.34	$18.07	1.2%	↑19
12. VYVANSE	3,097	1,263	$829,582.98	$267.87	1.2%	NC
13. BUPROPION XL	3,040	1,644	$51,321.65	$16.88	1.1%	↓3
14. PREDNISONE	2,970	2,440	$34,506.90	$11.62	1.1%	↑5
15. PANTOPRAZOLE SODIUM	2,912	1,432	$39,873.67	$13.69	1.1%	↓4
16. HYDROCODONE-ACET	2,777	1,759	$40,580.63	$14.61	1.0%	↓3
17. CYCLOBENZAPRINE HCL	2,599	1,610	$30,345.29	$11.68	1.0%	↓1
18. DULOXETINE HCL	2,597	1,339	$42,490.77	$16.36	1.0%	↓3
19. BUPRENORPHINE-NALOX	2,524	634	$109,902.84	$43.54	1.0%	↑2
20. CLONIDINE HCL	2,480	1,257	$30,899.72	$12.46	0.9%	↑3
21. LAMOTRIGINE	2,406	1,010	$35,751.61	$14.86	0.9%	↑2
22. METFORMIN HCL	2,340	1,299	$30,913.89	$13.21	0.9%	↓6
23. HYDROXYZINE HCL	2,319	1,397	$31,681.76	$13.66	0.9%	↑4
24. MONTELUKAST SODIUM	2,258	1,326	$31,363.31	$13.89	0.9%	↓3
25. CLONAZEPAM	2,248	954	$30,546.11	$13.59	0.8%	↑3

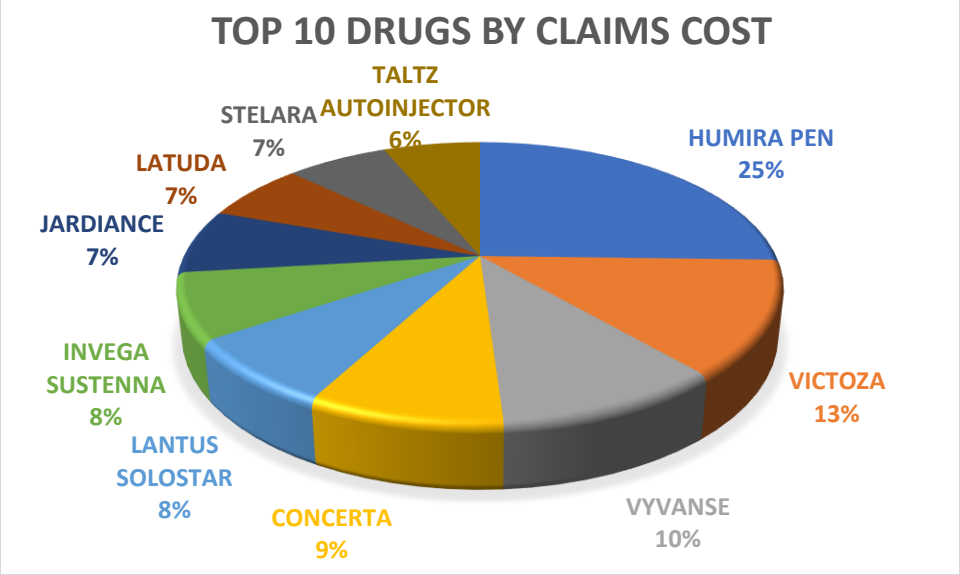
Total Claims	**265,138**



Top 25 Drugs Based on Total Claims Cost from 10/01/2022 – 12/31/2022

Drug	Claims Cost	Claims	Patients	Cost /Claim	% Total Cost	Dif.
1. HUMIRA PEN	$ 2,046,338.77	274	115	$ 7,468.39	6.3%	NC
2. VICTOZA	$ 1,063,839.77	1,271	615	$ 837.01	3.3%	NC
3. VYVANSE	$ 829,582.98	3,097	1,263	$ 656.84	2.5%	NC
4. CONCERTA	$ 715,354.85	2,079	856	$ 835.69	2.2%	NC
5. LANTUS SOLOSTAR	$ 618,928.91	1,202	757	$ 817.61	1.9%	NC
6. INVEGA SUSTENNA	$ 610,189.37	234	90	$ 6,779.88	1.9%	↑2
7. JARDIANCE	$ 592,325.04	924	477	$ 1,241.77	1.8%	NC
8. LATUDA	$ 537,502.33	632	243	$ 2,211.94	1.6%	↑2
9. STELARA	$ 530,513.46	23	18	$ 29,472.97	1.6%	↓3
10. TALTZ	$ 502,532.08	82	32	$ 15,704.13	1.5%	↓1
11. BIKTARVY	$ 460,878.83	216	98	$ 4,702.85	1.4%	↑1
12. TRIKAFTA	$ 401,272.00	16	6	$ 66,878.67	1.2%	↑8
13. VRAYLAR	$ 387,613.91	405	165	$ 2,349.18	1.2%	↑5
14. ADDERALL XR	$ 385,328.47	2,174	914	$ 421.58	1.2%	↑2
15. SYMBICORT	$ 368,306.37	1,057	601	$ 612.82	1.1%	↓1
16. ADVAIR DISKUS	$ 348,812.57	924	518	$ 673.38	1.1%	↑1
17. ELIQUIS	$ 348,007.86	651	316	$ 1,101.29	1.1%	↓2
18. NOVOLOG FLEXPEN	$ 347,498.37	459	281	$ 1,236.65	1.1%	NC
19. NORDITROPIN	$ 316,092.15	76	36	$ 8,780.34	1.0%	↓6
20. MAVYRET	$ 309,065.79	26	20	$ 15,453.29	0.9%	↓9
21. SOFOSBUVIR-VEL	$ 278,180.87	36	18	$ 15,454.49	0.9%	↑7
22. ABILIFY MAINTENA	$ 261,380.13	118	50	$ 5,227.60	0.8%	↓1
23. LEVEMIR FLEXTOUCH	$ 248,546.39	422	257	$ 967.11	0.8%	↓1
24. XIFAXAN	$ 247,554.16	90	48	$ 5,157.38	0.8%	↑1
25. ORKAMBI	$ 241,524.03	11	4	$ 60,381.01	0.7%	↑3

Total Claims Cost	**$32,709,611**



Top 15 Therapeutic Classes Based on Number of Claims from 10/01/2022 – 12/31/2022

Therapeutic Class Description	Claims	Patients	Claims Cost	Cost/Claim	% Total Claims	Dif.
1. ANTIDEPRESSANTS	29,683	12,245	$ 613,819.25	$ 20.68	11.2%	NC
2. ANTICONVULSANTS	13,434	4,800	$ 627,168.27	$ 46.69	5.1%	NC
3. ANTIPSYCHOTIC AGENTS	9,307	3,594	$ 2,547,210.95	$ 273.69	3.5%	NC
4. PROTON-PUMP INHIBITORS	7,926	3,857	$ 142,954.16	$ 18.04	3.0%	NC
5. PENICILLIN ANTIBIOTICS	7,379	6,570	$ 119,357.29	$ 16.18	2.8%	↑7
6. SEDATIVE / HYPNOTICS	7,099	3,545	$ 112,800.58	$ 15.89	2.7%	↓1
7. AMPHETAMINES	6,702	2,774	$ 1,260,324.68	$ 188.05	2.5%	NC
8. OPIATE AGONISTS	6,697	3,481	$ 108,422.84	$ 16.19	2.5%	↓2
9. NSAIDS	6,246	4,148	$ 91,159.98	$ 14.59	2.4%	↓1
10. STATINS	5,803	3,295	$ 84,883.47	$ 14.63	2.2%	↓1
11. RESPIRATORY / CNS STIMULANTS	5,449	2,073	$ 1,080,602.08	$ 198.31	2.1%	NC
12. BETA BLOCKERS	5,422	2,963	$ 100,159.36	$ 18.47	2.0%	↓2
13. ADRENALS	5,223	4,235	$ 70,907.47	$ 13.58	2.0%	↑2
14. BETA AGONISTS	5,017	4,593	$ 304,395.36	$ 60.67	1.9%	↓1
15. ACE - INHIBITORS	4,248	2,479	$ 65,401.37	$ 15.40	1.6%	↓1

Top 15 Therapeutic Classes Based on Claims Cost from 10/01/2022 – 12/31/2022

Therapeutic Class Description	Claims Cost	Claims	Patients	Cost/Claim	% Total Cost	Dif.
1. DMARDS	$ 3,301,747.78	592	250	$5,577.28	10.1%	NC
2. ANTIPSYCHOTIC AGENTS	$ 2,547,210.95	9,307	3,594	$273.69	7.8%	NC
3. INSULINS	$ 1,851,346.59	3,467	1,384	$533.99	5.7%	↑1
4. SKIN AND MUCOUS MEMBRANE AGENTS, MISC.	$ 1,804,942.79	622	373	$2,901.84	5.5%	↓1
5. AMPHETAMINES	$ 1,260,324.68	6,702	2,774	$188.05	3.9%	NC
6. ANTINEOPLASTIC AGENTS	$ 1,254,456.13	609	261	$2,059.86	3.8%	↑2
7. INCRETIN MIMETICS	$ 1,209,238.21	1,444	657	$837.42	3.7%	↓1
8. RESPIRATORY CORTICOSTEROIDS	$ 1,106,216.13	3,834	2,351	$288.53	3.4%	↑2
9. NON-AMPHETAMINE STIMULANTS	$ 1,080,602.08	5,449	2,073	$198.31	3.3%	↑1
10. ANTIRETROVIRALS	$ 1,031,313.43	727	267	$1,418.59	3.2%	↓1
11. SGLT2 INHIBITORS	$ 815,230.96	1,303	664	$625.66	2.5%	NC
12. ANTICONVULSANTS	$ 627,168.27	13,434	4,800	$46.69	1.9%	NC
13. ANTIDEPRESSANTS	$ 613,819.25	29,683	12,245	$20.68	1.9%	NC
14. HCV ANTIVIRALS	$ 591,991.43	63	38	$9,396.69	1.8%	↑1
15. IMMUNOMODULATORY AGENTS	$ 557,895.02	75	28	$7,438.60	1.7%	↓1

PDL Update

Drug	PA Status	Class
Amjevita	PA	Cytokine Modulators
betamethasone valerate foam 0.12%	remove PA	Topical Steroids
desoximetasone spray 0.25%	remove PA	Topical Steroids
hydrocortisone valerate cream 0.20%	remove PA	Topical Steroids
insulin NPH human/regular insulin human	PA	Insulin
NPH insulin	PA	Insulin
Rebyota	PA	C.difficle associated diarrhea (CDAD)
Tascenso ODT	PA	Multiple Sclerosis
Winlevi	PA	Acne Vulgaris

Clostridioides difficile-associated diarrhea (CDAD)

Prevention

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
REBYOTA (fecal microbiota, live – jslm) SUSPENSION	

Electronic Duration Verification:

- Rybyota is payable every 6 months.

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

- The member has had at least two episodes of diarrhea with a positive stool test for *C.difficile* toxin within the last year

Vaginal Infections

Fungal Infections

Oral

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
fluconazole tablet	BREXAFEMME (ibrexafungerp) TABLETS
SOLOSEC (secnidazole) GRANULE PACKET	VIVJOA (oteseconazole) CAPSULES
tinidazole tablet	

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)

REVIEW OF HYPERPARATHYROIDISM

Background

Overview

Calcitriol and other synthetic vitamin D derivatives have been proven to reduce parathyroid hormone (PTH), stabilize PTH, and improve bone histology. Unfortunately, these agents have not been shown to improve clinically important outcomes and can pose a risk of hypercalcemia. Secondary hyperparathyroidism is defined as adaptive parathyroid gland hyperplasia and increased production of parathyroid hormone (PTH). This includes biochemical abnormalities in calcium, phosphate, PTH, and vitamin D. High levels of PTH over time can cause high-turnover bone disease, fracture, hypercalcemia, and hyperphosphatemia.

Place-in-therapy/Guidelines

Treatment should not be initiated based on a single elevated PTH level. If PTH remains elevated after treating modifiable risk factors (hyperphosphatemia, high phosphate intake, and vitamin D deficiency), the vitamin D derivative calcitriol may be used. Most patients who have PTH >2.3 to 3 times the upper limit of normal of 65 pg/mL are treated with pharmacological interventions. If the member is on renal dialysis (i.e., end-stage renal disease), Medicare eligibility must be ruled out.

There are several treatment options for secondary hyperparathyroidism:

- Vitamin D supplements
- Cinacelcet
- Surgery – parathyroidectomy is reserved for very severe cases not responding to drug therapy
- Dietary measures in combination with phosphate binders – recommended for non-dialysis patients with a serum phosphorus >5.5 mg/dL

Recommended Agents:

- Vitamin D supplements
  - Should not be used in the absence of vitamin D deficiency
- Calcitriol and synthetic vitamin D analogs
  - Can reduce/stabilize PTH but pose a risk of hypercalcemia
  - Currently no recommendations for which agent to utilize over the other
  - Calcitriol is not used if the serum phosphate is above normal range or if the corrected serum total calcium concentration is ≥9.5 mg/dL (≥2.37 mmol/L)
  - The effects of calcitriol versus other synthetic vitamin D derivatives have not been evaluated in nondialysis CKD patients
- Calcimimetics
  - Generally, should only be used in dialysis patients

Advantages/Disadvantages

- Rayaldee (calcifediol)
  - Indication(s): Chronic renal failure, Stage 3 or 4 and with serum total 25-hydroxyvitamin D levels less than 30 nanograms/mL - Secondary hyperparathyroidism
  - Prohormone for calcitriol
  - Supplied as capsules
- Zemplar (paricalcitrol)
  - Indication(s): Chronic kidney disease - Secondary hyperparathyroidism; Treatment and Prophylaxis
  - Dosing available for pediatric patients
  - Supplied as a capsule and IV solution
- Rocaltrol (calcitriol)

- Indication(s): Hypocalcemia - Hypoparathyroidism, Postsurgical or idiopathic; Hypocalcemia – Pseudohypoparathyroidism; Hypocalcemia - Renal dialysis (Chronic); Plaque psoriasis (Mild to Moderate); Secondary hyperparathyroidism
- Dosing available for pediatric patients
- Supplied as a capsule, IV solution, and oral solution

- Hectorol (doxercalciferol)
  - Indication(s): Secondary hyperparathyroidism, In patients with stage 3 or 4 chronic kidney disease; Chronic kidney disease, On dialysis - Secondary hyperparathyroidism
  - Supplied as a capsule and IV solution

FDA Approval

Rayaldee: 505(b) New Drug Application (NDA) pathway, Type 5 - New Formulation or New Manufacturer; STANDARD
Zemplar: 505(b) New Drug Application (NDA) pathway, Type 3 - New Dosage Form; STANDARD
Rocaltrol capsule: 505(b) New Drug Application (NDA) pathway, Type 1 - New Molecular Entity; PRIORITY
Rocaltrol solution: 505(b) New Drug Application (NDA) pathway, Type 3 - New Dosage Form; STANDARD
Hectorol: 505(b) New Drug Application (NDA) pathway, Type 1 - New Molecular Entity; STANDARD

Cost

Drug	Strength	Package Size	WAC Pkg Price	Cost/ year*
Rayaldee capsule	30 mcg	30 each, 60 each	$1,181.40 for 30 mcg 30 each bottle	$28,747.40
calcitriol capsule	0.25 mcg, 0.5 mcg	30 each, 100 each	$8.10 for 0.25 mcg 30 each bottle	$98.55
calcitriol solution	1 mcg/mL	15 mL bottle	$75.00	$456.25
paricalcitol capsule	1 mcg, 2 mcg, 4 mcg	30 each	$30.00 for 1 mcg 30 each bottle	$365.00
doxercalciferol capsule	0.5 mcg, 1 mcg, 2.5 mcg	30 each, 50 each	$659.50 for 1 mcg 50 each bottle	$4,814.35

*Based on adult dosing at lowest per unit WAC cost

References:
1. Kidney Disease: Improving Global Outcomes (KDIGO) CKD-MBD Update Work Group. KDIGO 2017 Clinical Practice Guideline Update for the Diagnosis, Evaluation, Prevention, and Treatment of Chronic Kidney Disease–Mineral and Bone Disorder (CKD-MBD). Kidney Int Suppl. 2017;7:1–59.
2. Kidney Disease: Improving Global Outcomes (KDIGO) CKD-MBD Work Group. KDIGO clinical practice guideline for the diagnosis, evaluation, prevention, and treatment of Chronic Kidney Disease-Mineral and Bone Disorder (CKD-MBD). Kidney Int Suppl. 2009;(113):S1-130.[PubMed 19644521]
3. Hectorol (doxercalciferol capsules) [prescribing information]. Cambridge, MA: Genzyme; November 2018.
4. Doxercalciferol capsules [prescribing information]. East Brunswick, NJ: Avet Pharmaceuticals Inc; October 2019.
5. Rocaltrol (calcitriol) [prescribing information]. Parsippany, NJ: Validus Pharmaceuticals; May 2018.
6. Calcitriol (oral capsule) [prescribing information]. Sellersville, PA: Teva Pharmaceuticals; January 2014.
7. Rayaldee (calcifediol) [prescribing information]. Miami, FL: OPKO Pharmaceuticals; April 2021.
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REVIEW OF INFLUENZA

Background

Overview

There are six licensed prescription influenza antiviral medications approved in the United States. Only four antiviral agents are currently recommended by the U.S. Food and Drug Administration (FDA) for the 2022-2023 influenza season.

- Recommended for Use: Tamiflu (oseltamivir phosphate), Relenza (zanamivir), Rapivab (peramivir), and Xofluza (baloxavir marboxil) are active against influenza A and B
- Not Recommended for Use: Symmetrel (amantadine) and Flumadine (rimantadine) are active against influenza A virus, but are not recommended for antiviral treatment or chemoprophylaxis of currently circulating influenza A viruses

Studies have shown that treatment reduces the symptoms of influenza by approximately 30 hours versus placebo and chemoprophylaxis has been shown to prevent 70%-90% of influenza cases after exposure.

Place-in-therapy/Guidelines

Treatment:

Currently, the Centers for Disease Control and Prevention (CDC) recommends treatment within 48 hours of illness onset with antiviral medications for suspected or confirmed influenza regardless of vaccination status for any patient how is either:

- hospitalized
- has severe, complicated, or progressive illness; or
- at a higher risk for influenza complications

Providers can consider empiric antiviral therapy, however, of non-high-risk outpatients with suspected influenza based on clinical judgement if treatment can be initiated within 48 hours.

Recommended Agents –

- For outpatients with complications or progressive disease, oral oseltamivir is recommended as soon as possible.
- For outpatients with uncomplicated influenza, oral oseltamivir, inhaled zanamivir, intravenous peramivir, or oral baloxavir may be used for treatment.

Post-exposure chemoprophylaxis:

Currently, the Centers for Disease Control and Prevention (CDC) can be considered for post-exposure chemoprophylaxis for prevention of influenza in people at high risk of complications if vaccine has not been given or is not fully effective.

CDC does not recommend widespread or routine use of antiviral medications for chemoprophylaxis except as one of multiple interventions to control institutional influenza outbreaks. Routine use of post-exposure chemoprophylaxis is not recommended; one reason for this is to avoid sub-therapeutic treatment dosing if infection is already established, although the likelihood of emergence of antiviral resistant viruses is unknown.

Antiviral chemoprophylaxis is not recommended if more than 48 hours have elapsed since the first exposure to a person with influenza.

Recommended Agents -

- For post-exposure chemoprophylaxis, oral oseltamivir, inhaled zanamivir, or oral baloxavir may be used.

Pre-exposure chemoprophylaxis:
In general, the CDC does not recommend seasonal or pre-exposure antiviral chemoprophylaxis.

Advantages/Disadvantages

- Tamiflu (oseltamivir)
  - Can be used for treatment in any age group
  - Oral agent (capsules and suspension) - Multidose regimen
- Rapivab (peramivir)
  - IV agent
- Relenza (zanamivir)
  - Recommended for age 7 years and older
  - Not recommended for use in people with underlying respiratory disease
  - Inhaled agent
- Xofluza (baloxavir marboxil)
  - Recommended for age 5 years and older
  - Oral agent (tablet and suspension) - Single dose regimen

FDA Approval

Tamiflu: 505 (b) New Drug Application (NDA) pathway, Type 1 - New Molecular Entity, PRIORITY
Relenza: 505 (b) New Drug Application (NDA) pathway, Type 1 - New Molecular Entity, PRIORITY
Xofluza: 505 (b) New Drug Application (NDA) pathway, Type 1 - New Molecular Entity, PRIORITY

Cost

Drug	Strength	Package Size	WAC Pkg Price	Cost/ treatment course*
Oseltamivir phosphate	30mg, 45mg, 75mg	10 each	$18.50	$18.50
Oseltamivir susp	6 mg/mL	60mL	$30.00	$60.00
Relenza	5 mg/actuation	20 each Inhaler	$59.00	$59.00
Xofluza	40mg, 80mg	1 each	$154.50	$154.50

*Based on adult dosing at lowest per unit WAC cost

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2. Product Information: XOFLUZA(R) oral tablets, baloxavir marboxil oral tablets, oral suspension. Genentech USA Inc (per FDA), South San Francisco, CA, 2022.

3. Product Information: RELENZA(R) oral inhalation powder, zanamivir oral inhalation powder. GlaxoSmithKline (per manufacturer), Research Triangle Park, NC, 2018.
4. Product Information: RAPIVAB(R) intravenous injection, peramivir intravenous injection. BioCryst Pharmaceuticals, Inc (per FDA), Durham, NC, 2021.
5. Product Information: SYMMETREL(R) oral tablets, syrup, amantadine hydrochloride oral tablets, syrup. Endo Pharmaceuticals, Chadds Ford, PA, 2009.
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REVIEW OF NEUROMYELITIS OPTICA SPECTRUM DISORDER

Background

Overview

Enspryng is a human monoclonal antibody that targets interleukin-6 receptors. It is indicated for the treatment of neuromyelitis optica spectrum disorder in adults who are anti-aquaporin-4 (AQP4) antibody positive. Neuromyelitis optica spectrum disorder (NMOSD) is a rare autoimmune disease of the central nervous system. It attacks the optic nerves and spinal cord, and over-time, it can lead to blindness and/or paraplegia.

Place-in-therapy/Guidelines

Treatment for reversing recent symptoms:
Early treatment for a neuromyelitis optica (NMO) attack includes giving methylprednisolone IV for about five days then tapering slowly over several more days. Plasma exchange is also utilized as the first or second treatment in addition to steroids for severe symptoms or vision loss.

Preventing future attacks:
A lower dose of corticosteroids may be used over time to prevent future attacks and relapses.

Reducing relapses:
Monoclonal antibodies are effective in reducing the risk of NMO relapses. The only FDA approved monoclonal antibodies used for NMO are Soliris, Enspryng, and Uplizna.

The SAkuraSky and SAkuraStar studies demonstrated that treatment with Enspryng in anti-AQP4 antibody−positive patients reduced the risk of NMOSD relapse by 78% and 74%, respectively, compared with placebo. There was no evidence of a benefit in patients who were anti-AQP4 antibody−negative.

Rituximab, although not currently FDA approved for use in NMO, has been shown to be effective in clinical trials and is commonly used by providers for this disease. Other agents utilized for immune suppression include azathioprine, mycophenolate, methotrexate, cyclophosphamide, and Actemra. IV immunoglobulins may also decrease the relapse rate of NMO.

Advantages/Disadvantages

- Enspryng (satralizumab)
  - Self-administered subcutaneous agent
- Uplizna (inebilizumab), Soliris (eculizumab)
  - IV agents

FDA Approval

Enspryng: 351(a) Biologics License Agreement (BLA); Orphan

Cost

Drug	Strength	Package Size	WAC Pkg Price	Cost/ year*
Enspryng	120 mg/mL	1 mL syringe	$ 16,515.58	$198,186.96

*Based on adult maintenance dosing at lowest per unit WAC cost

References:

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REVIEW OF UREA CYCLE AGENTS

Background

Overview

The urea cycle is a metabolic pathway which converts nitrogen to urea to be excreted from the body. A deficiency of an enzyme within the pathway may cause a disorder in the conversion process. Urea cycle disorders (UCDs), except for arginase deficiency, cause hyperammonemia. The ammonia build-up can cause neurologic injury and life-threatening illnesses. Symptoms can include failure to feed, hypothermia, cerebral edema, and seizures. Mortality and morbidity are high in UCDs; however, survival rates are increased with earlier diagnosis and treatment. The different types of deficiencies are as follows:

- Carbamoyl phosphate synthetase I (CPSI) deficiency
- Ornithine transcarbamylase (OTC) deficiency
- Argininosuccinate synthetase (ASS) deficiency
- Argininosuccinate lyase (ASL) deficiency
- N-acetyl glutamate synthetase (NAGS) deficiency
- Arginase (ARG1) deficiency
- Ornithine translocase (ORNT1) deficiency
- Citrin deficiency

Place-in-therapy/Guidelines

Treatment depends on the deficient enzyme.

Initial Treatment:

- Rehydrate
- Remove nitrogen and ammonia using pharmacological interventions and/or hemodialysis
- Stop protein intake
- Stimulate anabolism and nitrogen uptake

Long-Term Management:

Maximizing neurodevelopment, preventing intercurrent hyperammonemia and comorbidities, and achieving normal fasting glutamine and low-normal fasting ammonia levels are goals in long-term management of UCDs.

- Protein intake adjustments
- Maintaining hydration
- Pharmacological interventions
- Liver transplant

Recommended Agents:

Oral phenylbutyrate is used as adjunctive therapy to standard care in most cases except for when NAGS deficiency is present. There are currently four oral phenylbutyrate agents available in the form of sodium phenylbutyrate (Buphenyl, Pheburane, Olpruva) or glycerol phenylbutyrate (Ravicti). NAGS deficiency may require treatment with carglumic acid (Carbaglu). ASL or ASS1 deficiency is treated with arginine.

Ravicti was found to be noninferior to Buphenyl.

Advantages/Disadvantages

- Buphenyl (sodium phenylbutyrate):
  - Generic available
  - Prodrug of phenylacetate
  - Strong salty taste and odor
  - Supplied as a tablet or powder

- Pheburane (sodium phenylbutyrate):
  - 505b2 to Buphenyl
  - Prodrug of phenylacetate
  - Supplied as oral granules that can be sprinkled onto food or liquid
- Olpruva (sodium phenylbutyrate):
  - 505b2 to Buphenyl
  - Prodrug of phenylacetate
  - Designed to enhance palatability compared to Buphenyl
  - Supplied as an oral suspension
- Ravicti (glycerol phenylbutyrate):
  - 505b2 to Buphenyl
  - Pre-prodrug of phenylacetate
  - Designed to enhance palatability compared to Buphenyl (tasteless and odorless)
  - Not a 1:1 conversion from sodium phenylbutyrate to glycerol phenylbutyrate
  - Supplied as a liquid
- Carbaglu (carglumic acid):
  - Generic available
  - Utilized in N-acetyl glutamate synthetase (NAGS) deficiency
  - Carbaglu is not available through pharmaceutical wholesalers or retail pharmacies, but only through direct shipping from the Accredo specialty pharmacy.
  - Supplied as a soluble tablet

FDA Approval

Buphenyl tablet: New Drug Application (NDA) pathway, Type 3 - New Dosage Form, PRIORITY; Orphan
Buphenyl powder: New Drug Application (NDA) pathway, Type 1 - New Molecular Entity, PRIORITY; Orphan
Pheburane: 505(b)(2) New Drug Application (NDA) pathway, Type 5 - New Formulation or New Manufacturer; STANDARD; Orphan
Olpruva: 505(b)(2) New Drug Application (NDA) pathway, Type 5 - New Formulation or New Manufacturer; STANDARD
Ravicti: 505(b)(2) New Drug Application (NDA) pathway, Type 2 - New Active Ingredient; STANDARD; Orphan
Carbaglu: 505(b) New Drug Application (NDA) pathway, Type 1 - New Molecular Entity; PRIORITY; Orphan

Cost

Drug	Strength	Package Size	WAC Pkg Price	Cost/ year*
sodium phenylbutyrate powder	3 gm/tsp	250 g Bottle	$4,499.50	$127,870.84
sodium phenylbutyrate tablet	500 mg	250 each	$3,000.00	$166,440.00
Pheburane pellet	483 mg/g	174 g Bottle	$4,374.99	$178,638.51
Olpruva suspension	Approved December 2022 – no pricing available			
Ravicti liquid	1.1 g/mL	25 mL Bottle	$5,478.25	$1,079,763.08
carglumic acid soluble tablet	200 mg	60 ea Bottle	$8,602.20	$1,203,591.15

*Based on adult dosing with an average body surface area of 1.7m(2) and average weight of 84.2 kg at lowest per unit WAC cost

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5. Pheburane (sodium phenylbutyrate) [prescribing information]. Bryn Mawr, PA: Medunik USA Inc; June 2022.[PubMed Pheburane.1]
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7. Ravicti (glycerol phenylbutyrate) [prescribing information]. Lake Forest, IL: Horizon Therapeutics USA Inc; September 2021.
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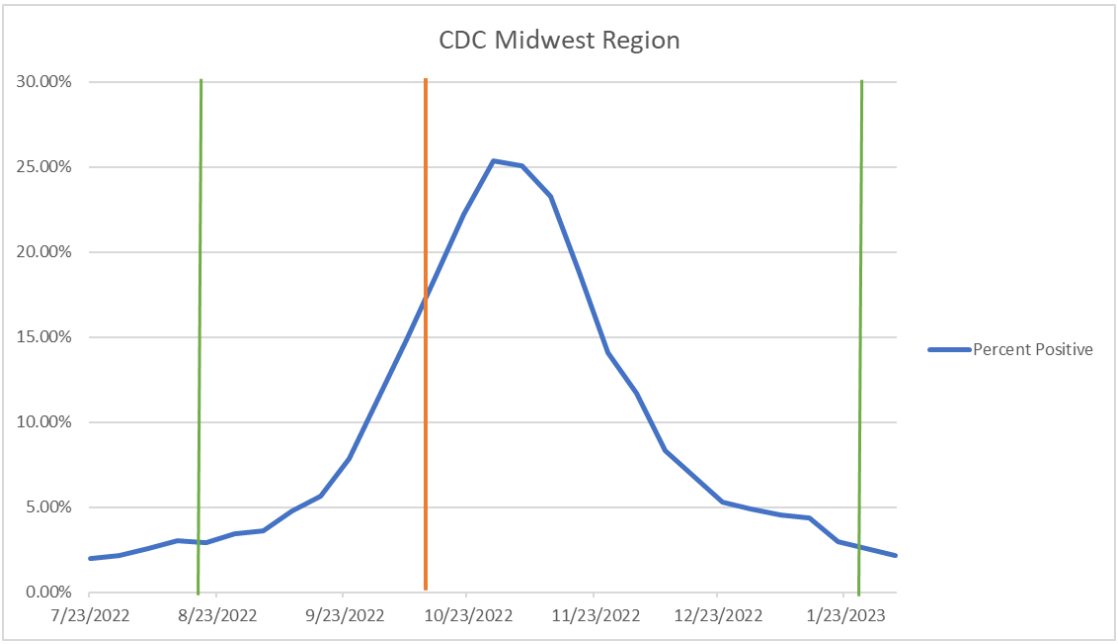
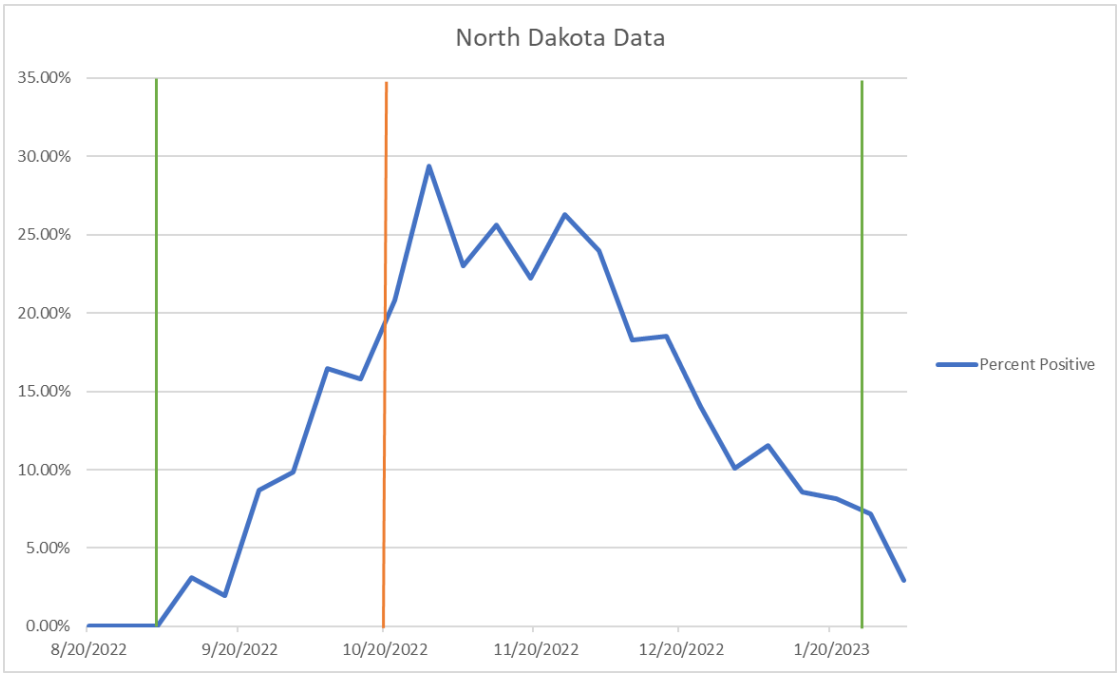
2022-2023 RSV season

Seasonal Data

Green markers indicate actual season (as determined by data), while the orange marker indicates previous date driven season onset. Using the date driven methodology, Synagis would have been fully effective after the peak of RSV season (given approx. 1 month to full efficacy). The season offset by date would occur in April.

Date driven season followed bell curve and actual PA request volume.





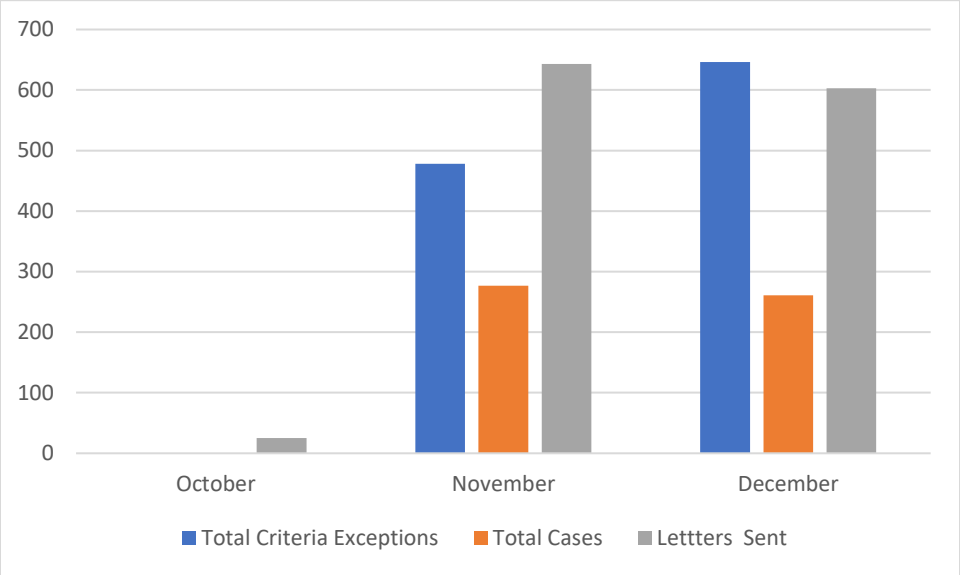
Season offset provider announcement

Effective January 28, the Respiratory Syncytial Virus (RSV) season offset criteria has been met. Season offset is defined as the last of two consecutive weeks when percentage of positive PCR tests for RSV is less than 3%, as reported to the Centers of Disease Control and Prevention. The RSV season is identified using data reported by the National Respiratory and Enteric Virus Surveillance System Midwest Region. No further prior authorization requests will be approved. Current Synagis authorization end dates are not impacted.

Proposed coverage for a season with a double peak:

Infants meeting clinical criteria would be eligible to receive doses until the age of 3 months old. Infants that have received 5 doses during the previous peak or have exceeded the age of 3 months old would not be eligible for additional doses.

RDUR Activity Overview: Q4 2022



October Special Mailing

Primary Therapeutic Consideration

Buprenorphine-naloxone is a combination product commonly used for patients who are diagnosed with opioid use disorder. Buprenorphine is a partial mu-opioid agonist, and naloxone is a pure mu-opioid antagonist. Currently available formulations include buccal film, sublingual film, and sublingual tablet

Naloxone, when taken orally, undergoes significant hepatic first-pass metabolism which, in turn, causes very low (<2%) systemic bioavailability. The combination product, when taken orally, does not cause withdrawal symptoms, but rather, deters patients from using the agent inappropriately. When misused by injecting or snorting, bioavailability increases greatly and can cause severe opioid withdrawal symptoms in patients who are physically dependent on full opioid agonists.

The buprenorphine monoproduct has historically been recommended during pregnancy to avoid severe withdrawal and prenatal exposure to naloxone in the case of misuse by snorting or injection. The buprenorphine monoproduct has a higher potential for misuse and diversion, and a higher street value in comparison to the combination product. If buprenorphine is prescribed as a monoproduct, the patient may need to be monitored more closely for misuse and diversion.

Switching a patient that is stable on the combination product to buprenorphine monoproduct due to pregnancy may not be necessary, as recent studies have found no adverse effects and similar outcomes when using the combination product versus buprenorphine monoproduct while pregnant. The use of combination therapy in pregnant patients will likely expand over time.

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November Cases by Type of Criteria		
Criteria Description	**# of Cases**	**% of Cases**
Drug-Disease Interactions	105	38%
Drug-Drug Conflicts	137	50%
Clinical Appropriateness	35	12%

DRUG-DISEASE INTERACTIONS: Renal Impairment / Hepatic Impairment
DRUG-DRUG CONFLICTS: CNS depressants / Opioids; Anticonvulsants / amphetamines
CLINICAL APPROPRIATENESS: Pregnancy / Impaired Contraceptives

December Cases by Type of Criteria		
Criteria Description	**# of Cases**	**% of Cases**
Clinical Appropriateness	17	7%
Drug-Drug Conflicts	106	41%
Overutilization	39	15%
Drug-Disease Interactions	99	38%

CLINICAL APPROPRIATENESS: Antidepressants/Suicidal Ideation
DRUG-DRUG CONFLICTS: CYP Inducers / Oxycodone-BZD/ Lithium - antidepressants
OVERUTILIZATION: PPI use
DRUG-DISEASE INTERACTIONS: Renal Impairment / Hepatic Impairment

December 13, 2022

Notice to Prescriber: Medical Drug PA Requirements Including Remicade and Biosimilars

You are receiving this notice because you have been identified as a provider that may be affected by these updates. Please review the following and should you have any further questions regarding claims processing, please direct them to mmisinfo@nd.gov or 877-328-7098. Please direct questions regarding prior authorizations to medicaidrx@nd.gov or 1-800-755-2604.

Remicade Biosimilar Requirements

Effective January 1, 2023 (date of service), ND Medicaid will prefer the biosimilars Avsola (Q5121) and Renflexis (Q5104) with no prior authorization. Remicade (J1745), Inflectra (Q5103), and infliximab (J1745) will require prior authorization.

Please see the current criteria by navigating to the most recent preferred drug list (PDL) found at http://www.hidesigns.com/ndmedicaid/pdl/

Grandfathering prior authorization will not be granted for Remicade, Inflectra, or inflximimab.

Additional Medical Drug Prior Authorization Requirements – Existing Patients

Effective January 1, 2023 (date of service), ND Medicaid will require prior authorization on Orencia (J0129), Simponi Aria (J1602), Entyvio (J3380), Sterlara (J3357), Tysabri (J2323), and Ilumya (J3245).

You may request a grandfathering prior authorization for any ND Medicaid patients you have currently receiving any of these products by providing the following information for each patient by fax to 701-328-1544 Attn: Pharmacy or secure email to medicaidrx@nd.gov:

- Medicaid ID, Name, DOB, J code, how many units are needed and frequency, billing and rendering NPIs

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.

New patient requests for medical drugs requiring prior authorization:

Medicare primary patients: Please use the SFN 511 form and indicate that the patient has Medicare. No further criteria need to be met.

Commercial insurance or Medicaid primary: Please use the SFN 511 form and the criteria found at http://www.hidesigns.com/ndmedicaid/pdl/ will need to be met for a prior authorization approval. The prior authorization number must be included on the billed claim.

The SFN 511 form can be found at: https://www.nd.gov/eforms/Doc/sfn00511.pdf

What are biosimilars?

A biosimilar is a biologic that is highly similar to and has no clinically meaningful differences from an existing FDA-approved biological medication, called a reference product.

Human pharmacokinetic and pharmacodynamic studies comparing a proposed product to the reference product are generally fundamental components to demonstrate similar exposure, efficacy, and safety.

Should I be concerned about using a biosimilar?

Biosimilars can be considered the equivalent of another lot of their reference product since even reference products vary from lot-to-lot. Switching between reference products and biosimilars and among biosimilars is no different than is switching from lot-to-lot of a reference product over time. Switching or substitution should not cause concern to patients or health care providers.

As part of the approval process, the FDA assesses the manufacturers' strategies to control for the pattern and degree of variations between different lots of the biological product to keep a consistent mix of variants between the lots to help ensure consistency in safety and effectiveness.

Biosimilar products can be used in patients who have previously been treated with the reference product or used in patients that have not previously been treated with a biologic. Biosimilars are expected to generally have the same type and amount of immunogenic response as the reference product, so if the patient does not respond to the biologic or develops anti-drug antibodies, then the same can be expected with the corresponding biosimilar or reference product.

What is the difference between a biosimilar and a generic?

In contrast to a chemical, which is synthesized and can be exactly copied, a biologic medication is made from living sources creating a natural variability that occurs in both biosimilars and the reference product and cannot be exactly copied. Because of this, the information needed to demonstrate that a biologic is biosimilar to another biologic can be much more extensive than what is needed for a generic.

How can I help my patients with the transition to a biosimilar?

Physicians, nurses, and pharmacists play essential roles in consistent education regarding biosimilars to patients, which is crucial in reducing the nocebo effect and improving acceptance of biosimilars.

Prevent the nocebo effect – provide reassurance that they can expect the same safety and effectiveness from the biosimilar over the course of treatment as they would with the reference product and discuss why the change is happening (i.e., reduced cost to the health system).

What references are available to help my staff and my patients understand biosimilars?

https://www.fda.gov/drugs/biosimilars/patient-materials

https://www.fda.gov/drugs/therapeutic-biologics-applications-bla/biosimilars

NORTH DAKOTA MEDICAID
RETROSPECTIVE DRUG UTILIZATION REVIEW
CRITERIA RECOMMENDATIONS
1ST QUARTER 2023

Criteria Recommendations ***Approved Rejected***

1. Deucravacitinib / Overuse _____ _____
Alert Message: Sotyktu (deucravacitinib) may be over-utilized. The recommended dosage of deucravacitinib is 6 mg, taken orally once daily, with or without food.

Drugs/Diseases
Util A Util B Util C
Deucravacitinib

Max Dose: 6 mg/day

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Sotyktu Prescribing Information, September 2022, Bristol-Myers Squibb.

2. Deucravacitinib / Therapeutic Appropriateness _____ _____
Alert Message: The safety and effectiveness of Sotyktu (deucravacitinib) in pediatric patients have not been established.

Drugs/Diseases
Util A Util B Util C
Deucravacitinib

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Sotyktu Prescribing Information, September 2022, Bristol-Myers Squibb.

3. Deucravacitinib / Therapeutic Appropriateness _____ _____
Alert Message: Sotyktu (deucravacitinib) is not recommended for use in patients with severe hepatic impairment (Child-Pugh C). No dose adjustment of deucravacitinib is recommended in patients with mild (Child-Pugh A) or moderate (Child-Pugh B) hepatic impairment.

Drugs/Diseases
Util A Util B Util C
Deucravacitinib Cirrhosis
Hepatic Failure
References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Sotyktu Prescribing Information, September 2022, Bristol-Myers Squibb.

4. Deucravacitinib / Serious Infections _____ _____

Alert Message: Avoid the use of Sotyktu (deucravacitinib) in patients with an active or serious infection. Serious infections have been reported in subjects with psoriasis who received deucravacitinib. Closely monitor patients for the development of signs and symptoms of infection during and after treatment with deucravacitinib. A patient who develops a new infection during treatment with deucravacitinib should undergo prompt and complete diagnostic testing; appropriate antimicrobial therapy should be initiated, and the patient should be closely monitored. Interrupt deucravacitinib if a patient develops a serious infection. Do not resume deucravacitinib until the infection resolves or is adequately treated.

Drugs/Diseases

Util A	Util B	Util C
Deucravacitinib	Serious Infections	

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Sotyktu Prescribing Information, September 2022, Bristol-Myers Squibb.

5. Deucravacitinib / Tuberculosis _____ _____

Alert Message: Sotyktu (deucravacitinib) is not recommended for use in patients with active tuberculosis. Evaluate patients for active and latent tuberculosis (TB) infection prior to initiating treatment with deucravacitinib. If positive, start treatment for TB prior to deucravacitinib use.

Drugs/Diseases

Util A	Util B	Util C
Deucravacitinib	Tuberculosis	
	History of Tuberculosis	

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Sotyktu Prescribing Information, September 2022, Bristol-Myers Squibb.

6. Deucravacitinib / Malignancies _____ _____

Alert Message: Malignancies, including lymphomas, were observed in clinical trials with Sotyktu (deucravacitinib). Consider the benefits and risks for the individual patient prior to initiating or continuing therapy with deucravacitinib, particularly in patients with a known malignancy (other than a successfully treated non-melanoma skin cancer) and patients who develop a malignancy when on treatment with deucravacitinib.

Drugs/Diseases

Util A	Util B	Util C
Deucravacitinib	Malignancies	

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Sotyktu Prescribing Information, September 2022, Bristol-Myers Squibb.

Recommendations ***Approved Rejected***

7. Deucravacitinib / Rhabdomyolysis & Symptoms _____ _____

Alert Message: In clinical trials, cases of rhabdomyolysis were reported in subjects treated with Sotyktu (deucravacitinib), resulting in interruption or discontinuation of deucravacitinib dosing. Treatment with deucravacitinib was associated with an increased incidence of asymptomatic creatine phosphokinase (CPK) elevation and rhabdomyolysis compared to treatment with placebo. Discontinue deucravacitinib if markedly elevated CPK levels occur, or myopathy is diagnosed or suspected. Instruct patients to promptly report any unexplained muscle pain, tenderness, or weakness, particularly if accompanied by malaise or fever.

Drugs/Diseases

Util A	Util B	Util C
Deucravacitinib	Muscle Cramps	
	Muscle Spasm	
	Fever	
	Malaise	
	Abnormal Findings in Urine	
	Elevation of levels of liver transaminase	
	Rhabdomyolysis	

References:

Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Sotyktu Prescribing Information, September 2022, Bristol-Myers Squibb.

8. Deucravacitinib / Potential Risks of JAK Inhibitors _____ _____

Alert Message: Sotyktu (deucravacitinib) is a tyrosine kinase 2 (TYK2) inhibitor indicated for the treatment of plaque psoriasis. It is not known whether TYK2 inhibition may be associated with the observed or potential adverse reactions of Janus Kinase (JAK) inhibition. In a large, randomized, postmarketing safety trial of a JAK inhibitor in rheumatoid arthritis (RA), patients 50 years of age and older with at least one cardiovascular risk factor, higher rates of all-cause mortality, including sudden cardiovascular death, major adverse cardiovascular events, overall thrombosis, deep venous thrombosis, pulmonary embolism, and malignancies (excluding non-melanoma skin cancer) were observed in patients treated with the JAK inhibitor compared to those treated with TNF blockers. Deucravacitinib is not approved for use in RA.

Drugs/Diseases

Util A	Util B	Util C
Deucravacitinib	Deep Vein Thrombosis	
	Thrombosis	
	Pulmonary Embolism	

References:

Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Sotyktu Prescribing Information, September 2022, Bristol-Myers Squibb.

9. Deucravacitinib / Pregnancy / Pregnancy Negating _____ _____

Alert Message: Available data from case reports on Sotyktu (deucravacitinib) use during pregnancy are insufficient to evaluate a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes. Report pregnancies to the Bristol-Myers Squibb Company's Adverse Event reporting line at 1- 800-721-5072.

Drugs/Diseases

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

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Sotyktu Prescribing Information, September 2022, Bristol-Myers Squibb.

10. Deucravacitinib / Potent Immunosuppressants _____ _____

Alert Message: Sotyktu (deucravacitinib) is not recommended for use in combination with other potent immunosuppressants. Concurrent use may result in enhanced immunosuppressive effects.

Drugs/Diseases

Util A	Util B	Util C
Deucravacitinib	Immunosuppressants	

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Sotyktu Prescribing Information, September 2022, Bristol-Myers Squibb.

11. Deucravacitinib / Lactation _____ _____

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

Drugs/Diseases

Util A	Util B	Util C
Deucravacitinib	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Sotyktu Prescribing Information, September 2022, Bristol-Myers Squibb.

Criteria Recommendations ***Approved Rejected***

12. Deucravacitinib / Non-adherence _____ _____
Alert Message: Based on refill history, your patient may be under-utilizing Sotyktu (deucravacitinib). 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
Deucravacitinib		

References:
Osterberg L, Blaschke T. Adherence to Medication. N Engl J Med 2005; 353:487- 497.
Brown MT, Bussell J, Supmarna D, et al. Medication Adherence: Truth and Consequences. Am J Med Sci. 2016 Apr;351(4):387-399.
Thorneloe RJ, Bundy C, Griffiths CE, Ashcroft DM, Cordingley L. Nonadherence to Psoriasis Medication as an Outcome of Limited Coping Resources and Conflicting Goals: Findings From a Qualitative Interview Study with People with Psoriasis. Br J Dermatol. 2017 Mar;176(3):667-676. doi: 10.1111/bjd.15086. Epub 2016 Dec 17. PMID: 27664406; PMCID: PMC5363250.
Belinchon I, Rivera R, Blanch C, Comellas M, Lizan L. Adherence, Satisfaction and Preferences for Treatment in Patients with Psoriasis in the European Union: A Systematic Review of the Literature. Patient Prefer Adherence. 2016 Nov 17;10:2357-2367. doi: 10.2147/PPA.S117006. PMID: 27895471; PMCID: PMC5118025.

13. Pemigatinib / Overuse _____ _____
Alert Message: Pemazyre (pemigatinib) may be over-utilized. The maximum recommended dosage (intermittent or continuous schedule) of pemigatinib is 13.5 mg per day.

Drugs/Diseases

Util A	Util B	Util C (Negating)
Pemigatinib		CKD Stage 4, 5, & ESRD
		Cirrhosis
		Liver Failure

Max Dose: 13.5 mg/day

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Pemazyre Prescribing Information, August 2022, Incyte Corporation.

14. Pemigatinib / Overuse _____ _____
Alert Message: Pemazyre (pemigatinib) may be over-utilized. The maximum recommended dosage (intermittent or continuous) of pemigatinib in patients with severe renal impairment is 9.0 mg per day.

Drugs/Diseases

Util A	Util B	Util C (Include)
Pemigatinib		CKD Stage 4, 5, & ESRD

Max Dose: 9.0 mg/day

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Pemazyre Prescribing Information, August 2022, Incyte Corporation.

Criteria Recommendations ***Approved Rejected***

15. Pemigatinib / Overuse _____ _____

Alert Message: Pemazyre (pemigatinib) may be over-utilized. The maximum recommended dosage (intermittent or continuous) of pemigatinib in patients with severe hepatic impairment (total bilirubin > 3 x ULN with any AST) is 9.0 mg per day.

Drugs/Diseases

Util A	Util B	Util C (Include)
Pemigatinib		Cirrhosis
		Liver Failure

Max Dose: 9.0 mg/day

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Pemazyre Prescribing Information, August 2022, Incyte Corporation.

16. Pemigatinib / Therapeutic Appropriateness _____ _____

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

Drugs/Diseases

Util A	Util B	Util C
Pemigatinib		

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Pemazyre Prescribing Information, August 2022, Incyte Corporation.

17. Pemigatinib / Ocular Toxicity _____ _____

Alert Message: Pemazyre (pemigatinib) can cause retinal pigment epithelial detachment (RPED), which may cause symptoms such as blurred vision, visual floaters, or photopsia. Perform a comprehensive ophthalmological examination, including OCT prior to initiation of pemigatinib and every 2 months for the first 6 months and every 3 months thereafter during treatment. For the onset of visual symptoms, refer patients for ophthalmologic evaluation urgently, with follow-up every 3 weeks until resolution or discontinuation of pemigatinib. Modify the dose or permanently discontinue pemigatinib as recommended.

Drugs/Diseases

Util A	Util B	Util C
Pemigatinib	Blurred Vision	
	Photopsia	
	Serous Detachment of retinal Pigment Epithelium	
	Vitreous Opacities	

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Pemazyre Prescribing Information, August 2022, Incyte Corporation.

Criteria Recommendations ***Approved Rejected***

18. Pemigatinib / Strong & Moderate CYP3A4 Inducers _____ _____

Alert Message: Concomitant use of Pemazyre (pemigatinib) with a strong or moderate CYP3A inducer decreases pemigatinib plasma concentrations, which may reduce the efficacy of pemigatinib. Avoid concomitant use of strong and moderate CYP3A inducers with pemigatinib.

Drugs/Diseases

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

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Pemazyre Prescribing Information, August 2022, Incyte Corporation.

19. Pemigatinib / Strong & Moderate CYP3A4 Inhibitors _____ _____

Alert Message: The concurrent use of Pemazyre (pemigatinib) with strong and moderate CYP3A4 inhibitors should be avoided. Coadministration of pemigatinib with strong or moderate CYP3A inhibitors increases pemigatinib plasma concentrations, which increases the incidence and severity of adverse reactions. If concomitant use with a strong or moderate CYP3A inhibitor cannot be avoided, reduce the pemigatinib dose from 13.5 mg to 9 mg or if taking 9 mg to 4.5 mg. If concomitant use of the CYP3A inhibitor is discontinued, increase the pemigatinib dosage (after 3 plasma half-lives of the CYP3A inhibitor) to the dosage that was used before starting the CYP3A4 inhibitor.

Drugs/Diseases

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

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Pemazyre Prescribing Information, August 2022, Incyte Corporation.

Criteria Recommendations ***Approved Rejected***

20. Pemigatinib / Pregnancy / Pregnancy Negating _____ _____

Alert Message: Based on findings in an animal study and its mechanism of action, Pemazyre (pemigatinib) can cause fetal harm when administered to a pregnant woman. Oral administration of pemigatinib to pregnant rats during the period of organogenesis caused fetal malformations, fetal growth retardation, and embryo-fetal death at maternal exposures lower than the human exposure based on area under the curve (AUC) at the clinical dose of 13.5 mg. Advise pregnant women of the potential risk to the fetus. Advise female patients of reproductive potential to use effective contraception during treatment with pemigatinib and for 1 week after the last dose.

Drugs/Diseases

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

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Pemazyre Prescribing Information, August 2022, Incyte Corporation.

21. Pemigatinib / Lactation _____ _____

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

Drugs/Diseases

Util A	Util B	Util C
Pemigatinib	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Pemazyre Prescribing Information, August 2022, Incyte Corporation.

22. Pemigatinib / Therapeutic Appropriateness _____ _____

Alert Message: Advise females of reproductive potential to use effective contraception during treatment with Pemazyre (pemigatinib) and for 1 week after the last pemigatinib dose.

Drugs/Diseases

Util A	Util B	Util C (Negating)
Pemigatinib		Contraceptives

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Pemazyre Prescribing Information, August 2022, Incyte Corporation.

Criteria Recommendations ***Approved Rejected***

23. Pemigatinib / Therapeutic Appropriateness _____ _____
Alert Message: Advise males with female partners of reproductive potential to use effective contraception during treatment with Pemazyre (pemigatinib) and for 1 week after the last dose.

Drugs/Diseases
Util A Util B Util C
Pemigatinib

Gender: Male

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Pemazyre Prescribing Information, August 2022, Incyte Corporation.

24. Pemigatinib / **Non-adherence** _____ _____
Alert Message: Based on refill history, your patient may be under-utilizing Pemazyre (pemigatinib). 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
Pemigatinib

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

25. Roflumilast / Therapeutic Appropriateness _____ _____
Alert Message: The safety and effectiveness of Zoryve (roflumilast cream) in pediatric patients below the age of 12 years have not been established.

Drugs/Diseases
Util A Util B Util C
Roflumilast Cream

Age Range: 0 – 11 yoa

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Zoryve Prescribing Information, August 2022, Arcutis Biotherapeutics, Inc.

Criteria Recommendations ***Approved Rejected***

26. Roflumilast / Moderate to Severe Hepatic Impairment _____ _____

Alert Message: Zoryve (roflumilast cream) is contraindicated in patients with moderate to severe liver impairment (Child-Pugh B or C). Topical roflumilast has not been studied in patients with hepatic impairment. In clinical studies with oral roflumilast, patients with mild to moderate hepatic impairment had significant increases in the AUC and Cmax of roflumilast as compared to healthy patients.

Drugs/Diseases

Util A	Util B	Util C
Roflumilast Cream	Hepatic Impairment	

References:

Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Zoryve Prescribing Information, August 2022, Arcutis Biotherapeutics, Inc.

27. Roflumilast / CYP3A4 Inhibitors & Dual 3A4 & 1A2 Inhibitors _____ _____

Alert Message: The coadministration of Zoryve (roflumilast cream) with systemic CYP3A4 inhibitors or dual inhibitors that inhibit both CYP3A4 and CYP1A2 simultaneously (e.g., erythromycin, ketoconazole, fluvoxamine, cimetidine) may increase roflumilast systemic exposure and may result in increased adverse reactions. The risk of such concurrent use should be weighed carefully against the benefit.

Drugs/Diseases

Util A	Util B		Util C
Roflumilast Cream	Ciprofloxacin	Itraconazole	
	Cimetidine	Ketoconazole	
	Clarithromycin	Nefazodone	
	Cobicistat	Nelfinavir	
	Delavirdine	Posaconazole	
	Erythromycin	Ritonavir	
	Fluvoxamine	Saquinavir	
	Indinavir	Voriconazole	

References:

Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Zoryve Prescribing Information, August 2022, Arcutis Biotherapeutics, Inc.

28. Roflumilast / Therapeutic Appropriateness _____ _____

Alert Message: There is no information regarding the presence of Zoryve (roflumilast cream) in human milk, the effects on the breastfed infant, or the effects on milk production. Roflumilast and its metabolites are excreted into the milk of lactating rats. The developmental and health benefits of breastfeeding should be considered, along with the mother's clinical need for roflumilast cream and any potential adverse effects on the breastfed infant from roflumilast cream or the underlying maternal condition. To minimize potential exposure to the breastfed infant via breast milk, use roflumilast cream on the smallest area of skin (avoiding the nipple and areola) and for the shortest duration possible while breastfeeding.

Drugs/Diseases

Util A	Util B	Util C
Roflumilast	Lactation	
Gender: Female		
Age Range: 11 – 50 yoa		

References:

Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Facts & Comparisons, 2022 Updates, Wolters Kluwer Health.

Criteria Recommendations ***Approved Rejected***

29. Alogliptin/Metformin / Therapeutic Appropriateness _____ _____

Alert Message: Kazano (alogliptin/metformin) is contraindicated in patients with severe renal impairment (eGFR < 30 mL/min/1.73m2). The metformin component of the combination product is substantially excreted by the kidney, and the risk of metformin accumulation and lactic acidosis increases with the degree of renal impairment.

Drugs/Diseases

Util A	Util B	Util C
Alogliptin/Metformin		CKD Stage 4
		CKD Stage 5
		ESRD

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Kazano Prescribing Information, March 2022, Takeda Pharmaceuticals America, Inc.

30. Dupilumab / Therapeutic Appropriateness _____ _____

Alert Message: The safety and efficacy of Dupixent (dupilumab) for the treatment of prurigo nodularis in pediatric patients have not been established.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Dupilumab	Prurigo Nodularis	Asthma
		Atopic Dermatitis
		Eosinophilic Esophagitis

Age Range: 0 – 17 yoa

References:

Clinical Pharmacology, 2022 Elsevier/Gold Standard.

Dupixent Prescribing Information, Sept. 2022, Regeneron Pharmaceuticals, Inc.

31. Vonoprazan/Amoxicillin/Clarithromycin / Therapeutic Appropriateness _____ _____

Alert Message: The safety and effectiveness of Voquezna Triple Pak (vonoprazan, amoxicillin, and clarithromycin) in pediatric patients have not been established.

Drugs/Diseases

Util A	Util B	Util C
Vonoprazan/Amoxicillin/Clarithromycin		

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Voquezna Triple Pak and Voquezna Dual Pak Prescribing Information, May 2022, Phantom Pharmaceuticals.

32. Vonoprazan/Amoxicillin/Clarithromycin / Rilpivirine-Containing Drugs _____ _____

Alert Message: Concurrent use of Voquezna Triple Pak (vonoprazan, amoxicillin, and clarithromycin) with rilpivirine-containing products is contraindicated. Vonoprazan reduces intragastric acidity, which may alter the absorption of rilpivirine, leading to changes in safety and/or effectiveness. The inhibitory effect of vonoprazan on acid secretion increases with repeated daily dosing.

Drugs/Diseases

Util A	Util B	Util C
Vonoprazan/Amoxicillin/Clarithromycin	Rilpivirine	
	Rilpivirine/Cabotegravir	
	Rilpivirine/Dolutegravir	
	Rilpivirine/Emtricitabine/Tenofovir ala	
	Rilpivirine/Emtricitabine/Tenofovir dis	

References:

Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Voquezna Triple Pak and Voquezna Dual Pak Prescribing Information, May 2022, Phantom Pharmaceuticals.

33. Vonoprazan/Amoxicillin/Clarithromycin / Atazanavir-Containing Drugs _____ _____

Alert Message: Concurrent use of Voquezna Triple Pak (vonoprazan, amoxicillin, and clarithromycin) with an atazanavir-containing product should be avoided. Vonoprazan reduces intragastric acidity, which may alter the absorption of atazanavir, leading to changes in safety and/or effectiveness. The inhibitory effect of vonoprazan on acid secretion increases with repeated daily dosing.

Drugs/Diseases

Util A	Util B	Util C
Vonoprazan/Amoxicillin/Clarithromycin	Atazanavir	
	Atazanavir/Cobicistat	

References:

Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Voquezna Triple Pak and Voquezna Dual Pak Prescribing Information, May 2022, Phantom Pharmaceuticals.

34. Vonoprazan/Amoxicillin/Clarithromycin / Nelfinavir _____ _____

Alert Message: Concurrent use of Voquezna Triple Pak (vonoprazan, amoxicillin, and clarithromycin) with nelfinavir should be avoided. Vonoprazan reduces intragastric acidity, which may alter the absorption of nelfinavir, leading to changes in safety and/or effectiveness. The inhibitory effect of vonoprazan on acid secretion increases with repeated daily dosing.

Drugs/Diseases

Util A	Util B	Util C
Vonoprazan/Amoxicillin/Clarithromycin	Nelfinavir	

References:

Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Voquezna Triple Pak and Voquezna Dual Pak Prescribing Information, May 2022, Phantom Pharmaceuticals.

35. Vonoprazan/Amoxicillin/Clarithromycin / Strong & Moderate 3A Inducers _____ _____

Alert Message: The vonoprazan and clarithromycin components of Voquezna Triple Pak (vonoprazan, amoxicillin, and clarithromycin) are CYP3A substrates. Strong or moderate CYP3A inducers may decrease the exposure of vonoprazan and clarithromycin, which may reduce the effectiveness of the CYP3A substrates.

Drugs/Diseases

Util A	Util B	Util C
Vonoprazan/Amoxicillin/Clarithromycin	Apalutamide	
	Bosentan	
	Carbamazepine	
	Efavirenz	
	Etravirine	
	Phenobarbital	
	Phenytoin	
	Primidone	
	Rifabutin	
	Rifampin	
	Rifapentine	

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Voquezna Triple Pak and Voquezna Dual Pak Prescribing Information, May 2022, Phantom Pharmaceuticals.

36. Vonoprazan/Amoxicillin/Clarithromycin / CYP3A4 Substrates w/ NTI _____ _____

Alert Message: The vonoprazan and clarithromycin components of Voquezna Triple Pak (vonoprazan, amoxicillin, and clarithromycin) are CYP3A inhibitors. Concurrent use of clarithromycin and vonoprazan with CYP3A substrates where minimal concentration changes may lead to serious toxicities should be done with caution. Frequent monitoring of substrate concentrations and/or adverse reactions related to the substrate drugs is recommended when used with vonoprazan and clarithromycin.

Drugs/Diseases

Util A	Util B	Util C
Vonoprazan/Amoxicillin/Clarithromycin	Cyclosporine	
	Sirolimus	
	Tacrolimus	

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Voquezna Triple Pak and Voquezna Dual Pak Prescribing Information, May 2022, Phantom Pharmaceuticals.

37. Vonoprazan/Amoxicillin/Clarithromycin / Clopidogrel _____ _____

Alert Message: The vonoprazan component of Voquezna Triple Pak (vonoprazan, amoxicillin, and clarithromycin) is a CYP2C19 inhibitor. Concurrent use of vonoprazan with clopidogrel, a CYP2C19 substrate, may result in reduced clopidogrel efficacy. Vonoprazan may reduce plasma concentrations of the active metabolite of clopidogrel and may cause a reduction in platelet inhibition. Carefully monitor the efficacy of clopidogrel and consider alternative anti-platelet therapy.

Drugs/Diseases

Util A	Util B	Util C
Vonoprazan/Amoxicillin/Clarithromycin	Clopidogrel	

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Voquezna Triple Pak and Voquezna Dual Pak Prescribing Information, May 2022, Phantom Pharmaceuticals.

Recommendations ***Approved Rejected***

38. Vonoprazan/Amoxicillin/Clarithromycin / Citalopram _____ _____

Alert Message: The vonoprazan component of Voquezna Triple Pak (vonoprazan, amoxicillin, and clarithromycin) is a CYP2C19 inhibitor. Concurrent use of vonoprazan with citalopram, a CYP2C19 substrate, may result in increased citalopram exposure, increasing the risk for citalopram adverse reactions. The dose of citalopram should be limited to 20 mg/day when co-administered with vonoprazan.

Drugs/Diseases

Util A	Util B	Util C
Vonoprazan/Amoxicillin/Clarithromycin	Citalopram	

References:

Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Voquezna Triple Pak and Voquezna Dual Pak Prescribing Information, May 2022, Phantom Pharmaceuticals.

39. Vonoprazan/Amoxicillin/Clarithromycin / Cilostazol _____ _____

Alert Message: The vonoprazan component of Voquezna Triple Pak (vonoprazan, amoxicillin, and clarithromycin) is a CYP2C19 inhibitor. Concurrent use of vonoprazan with cilostazol, a CYP2C19 substrate, may result in increased cilostazol exposure, increasing the risk of cilostazol-related adverse reactions. The dose of cilostazol should be limited to 50 mg twice daily when co-administered with vonoprazan.

Drugs/Diseases

Util A	Util B	Util C
Vonoprazan/Amoxicillin/Clarithromycin	Cilostazol	

References:

Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Voquezna Triple Pak and Voquezna Dual Pak Prescribing Information, May 2022, Phantom Pharmaceuticals.

40. Vonoprazan/Amoxicillin/Clarithromycin / Severe Renal Impairment _____ _____

Alert Message: Avoid the use of Voquezna Triple Pak (vonoprazan, amoxicillin, and clarithromycin) in patients with severe renal impairment (eGFR less than 30 mL/minute) or renal failure. The pack does not allow for appropriate dosage adjustments needed for these patients. In pharmacokinetic studies, patients with severe renal impairment exhibited increased systemic exposure to vonoprazan (2.4-times greater) compared to subjects with normal renal function.

Drugs/Diseases

Util A	Util B	Util C
Vonoprazan/Amoxicillin/Clarithromycin	CKD Stage 4 CKD Stage 5 ESRD	

References:

Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Voquezna Triple Pak and Voquezna Dual Pak Prescribing Information, May 2022, Phantom Pharmaceuticals.

Recommendations ***Approved Rejected***

41. Vonoprazan/Amoxicillin/Clarithromycin / Mod-Sev Hepatic Impairment _____ _____

Alert Message: Avoid the use of Voquezna Triple Pak (vonoprazan, amoxicillin, and clarithromycin) in patients with moderate to severe hepatic impairment (Child-Pugh Class B or C). The pack does not allow for appropriate dosage adjustments needed for these patients. In pharmacokinetic studies, patients with severe hepatic impairment exhibited increased systemic exposure to vonoprazan (2.6-times greater) compared to subjects with normal renal function.

Drugs/Diseases

Util A	Util B	Util C
Vonoprazan/Amoxicillin/Clarithromycin	Hepatic Impairment	

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Voquezna Triple Pak and Voquezna Dual Pak Prescribing Information, May 2022, Phantom Pharmaceuticals.

42. Vonoprazan/Amoxicillin/Clarithromycin / Pregnancy / Negating _____ _____

Alert Message: There are no adequate and well-controlled studies of Voquezna Triple Pak (vonoprazan, amoxicillin, clarithromycin) in pregnant women to evaluate for drug-associated risks of major birth defects, miscarriage, or other adverse maternal or fetal outcomes. The use of the triple pack is not recommended in pregnant women except in clinical circumstances where no alternative therapy is appropriate.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Vonoprazan/Amoxicillin/Clarithromycin	Pregnancy Delivery Miscarriage	Abortion

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Voquezna Triple Pak and Voquezna Dual Pak Prescribing Information, May 2022, Phantom Pharmaceuticals.

43. Vonoprazan/Amoxicillin/Clarithromycin / Lactation _____ _____

Alert Message: There are no data regarding the presence of the vonoprazan component of the Voquezna Triple Pak (vonoprazan, amoxicillin, and clarithromycin) in human milk, the effects on the breastfed infant, or the effects on milk production. Vonoprazan and its metabolites are present in rat milk. Liver injury occurred in offspring from pregnant and lactating rats administered oral vonoprazan. When a drug is present in animal milk, it is likely that the drug will be present in human milk. Because of the potential risk of adverse liver effects shown in animal studies with vonoprazan, a woman should pump and discard human milk for the duration of vonoprazan therapy, and for 2 days after therapy ends, and feed her infant stored human milk (collected prior to therapy) or formula.

Drugs/Diseases

Util A	Util B	Util C
Vonoprazan/Amoxicillin/Clarithromycin	Lactation	

Gender: Female
Age Range: 11 – 50 yoa
References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Voquezna Triple Pak and Voquezna Dual Pak Prescribing Information, May 2022, Phantom Pharmaceuticals.

Recommendations ***Approved Rejected***

44. Vonoprazan/Amoxicillin/Clarithromycin / Colchicine _____ _____
Alert Message: Life-threatening and fatal drug interactions have been reported in patients treated with clarithromycin, a component of Voquezna Triple Pak (vonoprazan, amoxicillin, and clarithromycin), and colchicine. If co-administration of Voquezna Triple Pak and colchicine is necessary for patients with normal renal and hepatic function, reduce the dose of colchicine. Monitor patients for clinical symptoms of colchicine toxicity. Concomitant administration of Voquezna Triple Pak and colchicine is contraindicated in patients with renal or hepatic impairment.

Drugs/Diseases

Util A	Util B	Util C (Negating)
Vonoprazan/Amoxicillin/Clarithromycin	Colchicine	Hepatic Impairment
		Renal Impairment

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Voquezna Triple Pak and Voquezna Dual Pak Prescribing Information, May 2022, Phantom Pharmaceuticals.

45. Vonoprazan/Amoxicillin/Clarithromycin / Omeprazole _____ _____
Alert Message: Avoid concomitant use of Voquezna Triple Pak (vonoprazan, amoxicillin, and clarithromycin) with omeprazole. In clinical studies, clarithromycin concentrations in the gastric tissue and mucus were increased by concomitant administration of omeprazole. Coadministration may result in clarithromycin-related adverse effects.

Drugs/Diseases

Util A	Util B	Util C
Vonoprazan/Amoxicillin/Clarithromycin	Omeprazole	

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Voquezna Triple Pak and Voquezna Dual Pak Prescribing Information, May 2022, Phantom Pharmaceuticals.

46. Vonoprazan/Amoxicillin/Clarithromycin / Itraconazole _____ _____
Alert Message: The concurrent use of Voquezna Triple Pak (vonoprazan, amoxicillin, and clarithromycin) with itraconazole may result in elevated clarithromycin and itraconazole exposure. Both clarithromycin and itraconazole are substrates and inhibitors of CYP3A, potentially leading to a bi-directional drug interaction when administered concomitantly. Patients taking itraconazole with Voquezna Triple Pak should be monitored closely for signs or symptoms of increased or prolonged adverse reactions associated with itraconazole and clarithromycin.

Drugs/Diseases

Util A	Util B	Util C
Vonoprazan/Amoxicillin/Clarithromycin	Itraconazole	

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Voquezna Triple Pak and Voquezna Dual Pak Prescribing Information, May 2022, Phantom Pharmaceuticals.

Recommendations ***Approved Rejected***

47. Tenofovir Alafenamide / Overutilization _____ _____

Alert Message: The safety and efficacy of Vemlidy (tenofovir alafenamide) have not been established in pediatric patients with chronic HBV infection who are less than 12 years of age.

Drugs/Diseases

Util A	Util B	Util C
Tenofovir Alafenamide		

Age Range 0 – 11 yoa

References:

Vemlidy Prescribing Information, Oct. 2022, Gilead Sciences, Inc.

48. Venlafaxine Besylate Tablets / Overuse _____ _____

Alert Message: Venlafaxine besylate extended-release may be over-utilized. The maximum recommended dose is 225 mg once daily.

Drugs/Diseases

Util A	Util B	Util C (Negating)
Venlafaxine besylate ER		CKD Stage 1, 2, 3, 4, & 5 ESRD Hemodialysis Hepatic Impairment

Max Dose: 225 mg/day

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Venlafaxine Besylate Tablets, Extended-Release, June 2022, Almatica Pharma, LLC.

49. Venlafaxine Besylate Tablets / Therapeutic Appropriateness _____ _____

Alert Message: The safety and effectiveness of venlafaxine besylate extended-release in pediatric patients have not been established.

Drugs/Diseases

Util A	Util B	Util C
Venlafaxine besylate ER		

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Venlafaxine Besylate Tablets, Extended-Release, June 2022, Almatica Pharma, LLC.

Recommendations ***Approved Rejected***

50. Venlafaxine Besylate Tablets / Renal Impairment _____ _____

Alert Message: Venlafaxine besylate extended-release should be used with caution in patients with renal impairment. Renal elimination of venlafaxine is the primary route of excretion. Reduce the total daily dose of venlafaxine by 25% to 50% in patients with mild (CLcr = 60-89 mL/min) or moderate (CLcr = 30-59 mL/min) renal impairment. In patients undergoing hemodialysis or with severe renal impairment (CLcr < 30 mL/min), the total daily dose should be reduced by 50% or more. Switch to another venlafaxine extended-release product if doses lower than 112.5 mg are needed.

Drugs/Diseases

Util A	Util B	Util C (Include)
Venlafaxine besylate ER		CKD Stage 1, 2, 3, 4, and 5 ESRD Hemodialysis

Max Dose: 112.5 mg/day

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Venlafaxine Besylate Tablets, Extended-Release, June 2022, Almatica Pharma, LLC.

51. Venlafaxine Besylate Tablets / Hepatic Impairment _____ _____

Alert Message: Venlafaxine besylate extended-release should be used with caution in patients with hepatic impairment. Reduce the total daily dose of venlafaxine by 50% in patients with mild (Child-Pugh Class A) to moderate (Child-Pugh Class B) hepatic impairment. In patients with severe hepatic impairment (Child-Pugh Class C) or hepatic cirrhosis, it may be necessary to reduce the dose by 50% or more. Switch to another venlafaxine extended-release product if doses lower than 112.5 mg are needed.

Drugs/Diseases

Util A	Util B	Util C (Include)
Venlafaxine besylate ER		Hepatic Impairment

Max Dose: 112.5 mg/day

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Venlafaxine Besylate Tablets, Extended-Release, June 2022, Almatica Pharma, LLC.

52. Venlafaxine Besylate Tablets / Nonadherence _____ _____

Alert Message: Based on the refill history, your patient may be underutilizing venlafaxine besylate extended-release. Non-adherence to the prescribed dosing regimen may result in sub-therapeutic effects, which may lead to decreased patient outcomes and additional healthcare costs.

Drugs/Diseases

Util A	Util B	Util C
Venlafaxine besylate ER		

References:

Iuga AO, McGuire MJ. Adherence and Health Care Costs. Risk Manag Healthc Policy. 2014 Feb 20;7:35-44.

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

Keene MS. Confusion and Complaints: The True Cost of Noncompliance in Antidepressant Therapy. Medscape Psychiatry & Mental Health. 2005;10(2). Available at: http://www.medscape.com/viewarticle/518273

Woldu H, Porta G, Goldstein T, et al. Pharmacokinetically and Clinician- Determined Adherence to an Antidepressant Regimen and Clinical Outcome in the TORDIA Trial. J Am Acad Child Adol Psy, 50;5:490-98. May 2011.
Chong WW, Aslani P, Chen TF. Effectiveness of Interventions to Improve Antidepressant Medication Adherence: A Systematic Review. Int J Clin Pract. 2011 Sep;65(9)954-975.

Recommendations ***Approved Rejected***

53. Upadacitinib 30 mg / Overutilization - Atopic Dermatitis _____ _____

Alert Message: Rinvoq (upadacitinib) may be over-utilized. The recommended dose of upadacitinib for maintenance treatment of atopic dermatitis in adults 65 years of age and older is 15 mg once daily. No differences in effectiveness were observed between these patients and younger patients; however, there was a higher rate of serious infections and malignancies in those patients 65 years of age or older in the 30 mg dosing group in the long-term trials.

Drugs/Diseases

Util A	Util B	Util C (Required)
Upadacitinib 30mg		Atopic Dermatitis

Age Range: ≥ 65 yoa
Max Dose: 30 mg
Day Supply: 90 days
References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Rinvoq Prescribing Information, Oct. 2022, AbbVie Inc.

54. SGLT2 Inhibitors / Lithium _____ _____

Alert Message: Concomitant use of an SGLT2 inhibitor with lithium may decrease serum lithium concentrations. Monitor serum lithium concentration more frequently during SGLT2 inhibitor initiation and dosage changes.

Drugs/Diseases

Util A	Util B	Util C
Canagliflozin	Lithium	
Dapagliflozin		
Empagliflozin		
Ertugliflozin		

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Facts & Comparison, 2022, Wolters Kluwer Health.

55. Triumeq PD / Non-adherence _____ _____

Alert Message: Based on the refill history, your patient may be underutilizing Triumeq PD (abacavir/dolutegravir/lamivudine). Nonadherence to antiretroviral therapy may result in

insufficient plasma levels and partial suppression of viral load leading to the development of

resistance, HIV progression, and increased mortality.

Drugs/Diseases

Util A	Util B	Util C
Abacavir/dolutegravir/lamivudine PD		

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. January 20, 2022. Available at https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/AdultandAdolescentGL.pdf. Accessed January 25, 2022.

Panel on Antiretroviral Therapy and Medical Management of Children Living with HIV. Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection. Updated December 30, 2021. Available at: http://aidsinfo.nih.gov/contentfiles/lvguidelines/pediatricguidelines.pdf. Accessed Jan. 5, 2022.

Panel on Treatment of Pregnant Women with HIV and Prevention of Perinatal Transmission. Recommendations for Use of Antiretroviral Drugs in Pregnant Women with HIV Infection and Intervention to Reduce Perinatal Transmission in the United States. Dec. 30, 2021. Available at: http://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/Perinatal_GL.pdf. Accessed Jan. 5, 2022.

Schaecher KL. The Importance of Treatment Adherence in HIV. Am J Manag Care. 2013 Sep;19(12 Suppl):231-7.

Recommendations ***Approved Rejected***

56. Triumeq PD / Overutilization _____ _____

Alert Message: Triumeq PD (abacavir/dolutegravir/lamivudine tablets for oral suspension) may be over-utilized. The manufacturer's maximum recommended dose of abacavir/dolutegravir/lamivudine tablets for oral suspension in children weighing, 20 to < 25 kg is 6 tablets once daily, 14 to < 20 kg is 5 tablets once daily, and 10 to < 14 kg is 4 tablets once daily. Triumeq PD is not recommended in pediatric patients weighing 25 kg or more.

Drugs/Diseases

Util A	Util B	Util C
Abacavir/dolutegravir/lamivudine PD		

Max Dose: 6 tablets per day

Age Range: 0 – 8 yoa

References:

Triumeq & Triumeq PD Prescribing Information, Oct. 2022, ViiV Healthcare.

Clinical Pharmacology, 2022 Elsevier/Gold Standard.

57. Triumeq PD / UGT1A1 & CYP3A4 Inducers / Dolutegravir (Negating) _____ _____

Alert Message: Concurrent use of Triumeq PD (abacavir/dolutegravir/lamivudine tablets for oral suspension) with an efavirenz-containing agent, fosamprenavir/rtv, tipranavir/rtv, carbamazepine, or rifampin may result in decreased plasma concentrations of the dolutegravir component of the antiretroviral and loss of efficacy. If co-administration is necessary for pediatric patients weighing 10 kg to < 25 kg, it is recommended that an additional weight-based dose of dolutegravir be given. Refer to the official prescribing information for the recommended dose for specific weight ranges.

Drugs/Diseases

Util A	Util B	Util C (Negating)
Abacavir/dolutegravir/lamivudine PD	Carbamazepine Efavirenz Fosamprenavir/ritonavir Tipranavir/ritonavir Rifampin	Dolutegravir

Age Range: 0 – 8 yoa

References:

Triumeq & Triumeq PD Prescribing Information, Oct. 2022, ViiV Healthcare.

Clinical Pharmacology, 2022 Elsevier/Gold Standard.

58. Triumeq PD / Therapeutic Appropriateness _____ _____

Alert Message: Triumeq PD (abacavir/dolutegravir/lamivudine oral tablets for oral suspension) is not recommended in patients weighing 25 kg or more. Triumeq PD (abacavir/dolutegravir/lamivudine) is a fixed-dose tablet, and the dosage of individual components cannot be adjusted and may lead to suboptimal dosing for patients weighing 25 kg or more.

Drugs/Diseases

Util A	Util B	Util C
Abacavir/dolutegravir/lamivudine PD		

Age Range: > 8 yoa

References:

Triumeq & Triumeq PD Prescribing Information, Oct. 2022, ViiV Healthcare.

Clinical Pharmacology, 2022 Elsevier/Gold Standard.

Recommendations ***Approved Rejected***

59. Asciminib / Overuse _____ _____

Alert Message: Scemblix (asciminib) may be over-utilized. The recommended dosage in patients with Ph+ CML in CP, previously treated with two or more TKIs, is 80 mg taken orally once daily at approximately the same time each day or 40 mg twice daily at approximately 12-hour intervals. The recommended dose of asciminib in patients with Ph+ CML-CP with T315I mutation is 200 mg taken orally twice daily at approximately 12-hour intervals.

Drugs/Diseases

Util A	Util B	Util C
Asciminib		

Max Dose: 400 mg/day

References:

IBM Micromedex DRUGDEX (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. 2022. Scemblix Prescribing Information, October 2022, Novartis Pharmaceuticals Corporation**.**

60. Asciminib / Therapeutic Appropriateness _____ _____

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

Drugs/Diseases

Util A	Util B	Util C
Asciminib		

Age Range: 0 – 17 yoa

References:

IBM Micromedex DRUGDEX (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. 2022. Scemblix Prescribing Information, October 2022, Novartis Pharmaceuticals Corporation**.**

61. Asciminib / Myelosuppression _____ _____

Alert Message: Thrombocytopenia, neutropenia, and anemia have occurred in patients receiving Scemblix (asciminib). Perform complete blood counts every two weeks for the first 3 months of treatment and monthly thereafter or as clinically indicated. Monitor patients for signs and symptoms of myelosuppression. Based on the severity of thrombocytopenia and/or neutropenia, reduce dose, temporarily withhold, or permanently discontinue asciminib per official prescribing information.

Drugs/Diseases

Util A	Util B	Util C
Asciminib	Anemia	
	Neutropenia	
	Thrombocytopenia	

References:

IBM Micromedex DRUGDEX (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. 2022. Scemblix Prescribing Information, October 2022, Novartis Pharmaceuticals Corporation**.**

Criteria Recommendations ***Approved Rejected***

62. Asciminib / Pancreatitis _____ _____

Alert Message: Pancreatitis occurred in 9 of 356 (2.5%) patients receiving Scemblix (asciminib). Assess serum lipase and amylase levels monthly during treatment with asciminib or as clinically indicated. Monitor the patient for signs and symptoms of pancreatic toxicity. Perform more frequent monitoring in patients with a history of pancreatitis. Based on the severity of lipase and amylase elevation, reduce the dose, temporarily withhold, or permanently discontinue asciminib.

Drugs/Diseases

Util A	Util B	Util C
Asciminib	Pancreatitis	

References:

IBM Micromedex DRUGDEX (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. 2022. Scemblix Prescribing Information, October 2022, Novartis Pharmaceuticals Corporation.

63. Asciminib / Antihypertensives (Negating) _____ _____

Alert Message: In clinical trials, hypertension occurred in 19% of patients receiving Scemblix (asciminib). Monitor and manage hypertension using standard antihypertensive therapy during treatment with asciminib as clinically indicated; for Grade 3 or higher hypertension, temporarily withhold, reduce dose, or permanently discontinue asciminib depending on the persistence of hypertension.

Drugs/Diseases

Util A	Util B	Util C (Negating)
Asciminib		Antihypertensives

References:

IBM Micromedex DRUGDEX (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. 2022. Scemblix Prescribing Information, October 2022, Novartis Pharmaceuticals Corporation.

64. Asciminib / Cardiovascular Toxicity _____ _____

Alert Message: In clinical trials, cardiovascular toxicity (including ischemic cardiac, arrhythmia, QT prolongation, arterial thrombotic and embolic conditions) and cardiac failure occurred in patients receiving Scemblix (asciminib). Monitor patients with a history of cardiovascular risk factors for cardiovascular signs and symptoms. Initiate appropriate treatment as clinically indicated; for Grade 3 or higher cardiovascular toxicity, temporarily withhold, reduce dose, or permanently discontinue asciminib depending on the persistence of cardiovascular toxicity.

Drugs/Diseases

Util A	Util B	Util C
Asciminib	Arrhythmias	
	Arterial Embolism & Thrombosis	
	Heart Failure	
	Ischemic heart Disease	

References:

IBM Micromedex DRUGDEX (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. 2022. Scemblix Prescribing Information, October 2022, Novartis Pharmaceuticals Corporation.

Criteria Recommendations ***Approved Rejected***

65. Asciminib / Strong CYP3A4 Inhibitors _____ _____

Alert Message: Concomitant use of Scemblix (asciminib) with a strong CYP3A4 inhibitor increases both the asciminib Cmax and AUC, which may increase the risk of adverse reactions. Asciminib is a CYP3A4 substrate. Closely monitor for adverse reactions in patients treated with asciminib at 200 mg twice daily with concomitant use of strong CYP3A4 inhibitors.

Drugs/Diseases

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

References:
IBM Micromedex DRUGDEX (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. 2022. Scemblix Prescribing Information, October 2022, Novartis Pharmaceuticals Corporation**.**

66. Asciminib / Itraconazole Oral Solution w/ HBC _____ _____

Alert Message: Concomitant use of Scemblix (asciminib) with itraconazole oral solution containing hydroxypropyl-B-cyclodextrin decreases asciminib Cmax and AUC, which may reduce asciminib efficacy. Avoid coadministration of asciminib at all recommended doses with itraconazole oral solution containing hydroxypropyl-B-cyclodextrin.

Drugs/Diseases

Util A	Util B	Util C
Asciminib	Itraconazole Oral Solution	

References:
IBM Micromedex DRUGDEX (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. 2022. Scemblix Prescribing Information, October 2022, Novartis Pharmaceuticals Corporation**.**

67. Asciminib / Sensitive CYP3A4 Substrates _____ _____

Alert Message: Scemblix (asciminib) is a CYP3A4 inhibitor. Concomitant use of asciminib can increase the Cmax and AUC of CYP3A4 substrates, which may increase the risk of adverse reactions of these substrates. Closely monitor for adverse reactions in patients treated with asciminib at 80 mg total daily dose with concomitant use of sensitive CYP3A4 substrates, where minimal concentration changes may lead to serious adverse reactions. Avoid coadministration of asciminib at 200 mg twice daily with sensitive CYP3A4 substrates.

Drugs/Diseases

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

References:
IBM Micromedex DRUGDEX (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. 2022. Scemblix Prescribing Information, October 2022, Novartis Pharmaceuticals Corporation**.**

Criteria Recommendations ***Approved Rejected***

68. Asciminib / Sensitive CYP2C9 Substrates _____ _____
Alert Message: Avoid concomitant use of CYP2C9 substrates with Scemblix (asciminib) at all asciminib recommended doses. Asciminib is a CYP2C9 inhibitor. Concurrent use of asciminib with a CYP2C9 substrate can increase the Cmax and AUC of the substrate, which may increase the risk of substrate-related serious adverse reactions.

Drugs/Diseases

Util A	Util B	Util C
Asciminib	Celecoxib	
	Glimepiride	
	Phenytoin	
	Warfarin	

References:
IBM Micromedex DRUGDEX (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. 2022. Scemblix Prescribing Information, October 2022, Novartis Pharmaceuticals Corporation**.**

69. Asciminib / Sensitive P-gp Substrates _____ _____
Alert Message: Scemblix (asciminib) is a P-gp inhibitor. Concomitant use of asciminib with a P-gp substrate can increase the plasma concentrations of the substrate, which may increase the risk of substrate-related adverse reactions. Closely monitor for adverse reactions in patients treated with asciminib at all recommended doses with concomitant use of P-gp substrates, where minimal concentration changes may lead to serious toxicities.

Drugs/Diseases

Util A	Util B		Util C
Asciminib	Cyclosporine	Sirolimus	
	Digoxin	Tacrolimus	
	Everolimus		

References:
IBM Micromedex DRUGDEX (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. 2022. Scemblix Prescribing Information, October 2022, Novartis Pharmaceuticals Corporation**.**

70. Asciminib / Pregnancy / Pregnancy Negating _____ _____
Alert Message: Based on findings from animal studies and its mechanism of action, Scemblix (asciminib) can cause fetal harm when administered to a pregnant woman. Animal reproduction studies in pregnant rats and rabbits demonstrated that oral administration of asciminib during organogenesis induced structural abnormalities, embryo-fetal mortality, and alterations to growth. Advise pregnant women and females of reproductive potential of the potential risk to a fetus. Verify the pregnancy status of females of reproductive potential prior to starting treatment with asciminib.

Drugs/Diseases

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

Gender: Female
Age Range: 11 – 50 yoa

References:
IBM Micromedex DRUGDEX (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. 2022. Scemblix Prescribing Information, October 2022, Novartis Pharmaceuticals Corporation**.**

Criteria Recommendations ***Approved Rejected***

71. Asciminib / Lactation _____ _____
Alert Message: There are no data on the presence of Scemblix (asciminib) or its metabolites in human milk, 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 asciminib and for 1 week after the last dose.

Drugs/Diseases

Util A	Util B	Util C
Asciminib	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
IBM Micromedex DRUGDEX (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. 2022. Scemblix Prescribing Information, October 2022, Novartis Pharmaceuticals Corporation**.**

72. Asciminib / Therapeutic Appropriateness _____ _____
Alert Message: Advise females of reproductive potential to use effective contraception during treatment with Scemblix (asciminib) and for at least 1 week after the last dose. Based on findings from animal studies and its mechanism of action, asciminib can cause fetal harm when administered to a pregnant woman. Verify the pregnancy status of females of reproductive potential prior to starting treatment with asciminib.

Drugs/Diseases

Util A	Util B	Util C (Negating)
Asciminib		Contraceptives

Gender: Female
Age Range: 11 – 50 yoa

References:
IBM Micromedex DRUGDEX (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. 2022. Scemblix Prescribing Information, October 2022, Novartis Pharmaceuticals Corporation**.**

73. Asciminib / Non-adherence _____ _____
Alert Message: Based on refill history, your patient may be under-utilizing Scemblix (asciminib). 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
Asciminib		

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

Criteria Recommendations ***Approved Rejected***

74. Futibatinib / Overuse _____ _____
Alert Message: Lytgobi (futibatinib) may be over-utilized. The recommended dosage of futibatinib is 20 mg (five 4 mg tablets) taken orally once daily until disease progression or unacceptable toxicity occurs.

Drugs/Diseases
Util A Util B Util C
Futibatinib

Max Dose: 20 mg/day

References:
Lytgobi Prescribing Information, September 2022, Taiho Oncology Inc.
Facts & Comparisons, 2022 Updates, Wolters Kluwer Health.

75. Futibatinib / Therapeutic Appropriateness _____ _____
Alert Message: The safety and effectiveness of Lytgobi (futibatinib) have not been established in pediatric patients.

Drugs/Diseases
Util A Util B Util C
Futibatinib

Age Range: 0 – 17 yoa

References:
Lytgobi Prescribing Information, September 2022, Taiho Oncology Inc.
Facts & Comparisons, 2022 Updates, Wolters Kluwer Health.

76. Futibatinib / Therapeutic Appropriateness _____ _____
Alert Message: Lytgobi (futibatinib) can cause retinal pigment epithelial detachment (RPED). Perform a comprehensive ophthalmological examination, including OCT of the macula, prior to initiation of therapy, every 2 months for the first 6 months, and every 3 months thereafter. For the onset of visual symptoms, refer patients for ophthalmologic evaluation urgently, with follow-up every 3 weeks until resolution or discontinuation of futibatinib. Withhold or reduce the dose of futibatinib as recommended in official prescribing information.

Drugs/Diseases
Util A Util B Util C
Futibatinib Retinal Detachment

References:
Lytgobi Prescribing Information, September 2022, Taiho Oncology Inc.
Facts & Comparisons, 2022 Updates, Wolters Kluwer Health.

77. Futibatinib / Hyperphosphatemia _____ _____

Alert Message: Lytgobi (futibatinib) can cause hyperphosphatemia leading to soft tissue mineralization, calcinosis, nonuremic calciphylaxis, and vascular calcification. Increases in phosphate levels are a pharmacodynamic effect of futibatinib. Monitor for hyperphosphatemia throughout treatment. Initiate a low phosphate diet and phosphate lowering therapy when serum phosphate level is >/= 5.5 mg/dL. For serum phosphate levels > 7 mg/dL, initiate or intensify phosphate lowering therapy and dose reduce, withhold, or permanently discontinue futibatinib based on the duration and severity of hyperphosphatemia.

Drugs/Diseases

Util A	Util B	Util C
Futibatinib	Hyperphosphatemia	

References:

Lytgobi Prescribing Information, September 2022, Taiho Oncology Inc.
Facts & Comparisons, 2022 Updates, Wolters Kluwer Health.

78. Futibatinib / Dual P-gp and CYP3A Inhibitors _____ _____

Alert Message: Avoid concomitant use of drugs that are dual P-gp and strong CYP3A inhibitors with Lytgobi (futibatinib). Concomitant use of drugs that are dual P-gp and strong CYP3A inhibitors with futibatinib may increase futibatinib exposure, which may increase the incidence and severity of adverse reactions.

Drugs/Diseases

Util A	Util B	Util C
Futibatinib	Cobicistat	
	Itraconazole	
	Ketoconazole	
	Ritonavir	

References:

Lytgobi Prescribing Information, September 2022, Taiho Oncology Inc.
Facts & Comparisons, 2022 Updates, Wolters Kluwer Health.

79. Futibatinib / Dual P-gp and CYP3A Inducers _____ _____

Alert Message: Avoid the concurrent use of dual P-gp and strong CYP3A inducers with Lytgobi (futibatinib). Concomitant use of drugs that are dual P-gp and strong CYP3A inducers may decrease futibatinib exposure, which may reduce the efficacy of futibatinib.

Drugs/Diseases

Util A	Util B	Util C
Futibatinib	Apalutamide	
	Carbamazepine	
	Phenobarbital	
	Phenytoin	
	Primidone	
	Rifampin	

References:

Lytgobi Prescribing Information, September 2022, Taiho Oncology Inc.
Facts & Comparisons, 2022 Updates, Wolters Kluwer Health.

Criteria Recommendations ***Approved Rejected***

80. Futibatinib / P-gp Substrates w/ NTI _____ _____

Alert Message: Lytgobi (futibatinib) is an inhibitor of P-gp. Consider more frequent monitoring for adverse reactions associated with concomitantly administered drugs that are sensitive substrates of P-gp and reduce the dose of these drugs per their prescribing Information. Futibatinib may increase exposure of drugs that are substrates of P-gp.

Conflict Code: DD - Drug/Drug Interaction
Drugs/Diseases

Util A	Util B	Util C
Futibatinib	Cyclosporine	
	Digoxin	
	Everolimus	
	Sirolimus	
	Tacrolimus	

References:

Lytgobi Prescribing Information, September 2022, Taiho Oncology Inc.
Facts & Comparisons, 2022 Updates, Wolters Kluwer Health.

81. Futibatinib / Pregnancy / Pregnancy Negating _____ _____

Alert Message: Based on findings in an animal study and its mechanism of action, Lytgobi (futibatinib) can cause fetal harm when administered to a pregnant woman. Oral administration of futibatinib to pregnant rats during the period of organogenesis caused fetal malformations, fetal growth retardation, and embryo-fetal death at maternal exposures lower than the human exposure at the clinical dose of 20 mg based on area under the curve (AUC). Advise pregnant women of the potential risk to the fetus.

Drugs/Diseases

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

Gender: Female
Age Range: 11 – 50 yoa

References:
Lytgobi Prescribing Information, September 2022, Taiho Oncology Inc.
Facts & Comparisons, 2022 Updates, Wolters Kluwer Health.

82. Futibatinib / Lactation _____ _____

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

Drugs/Diseases

Util A	Util B	Util C
Futibatinib	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Lytgobi Prescribing Information, September 2022, Taiho Oncology Inc.
Facts & Comparisons, 2022 Updates, Wolters Kluwer Health.

83. Futibatinib / Therapeutic Appropriateness _____ _____
Alert Message: Advise female patients of reproductive potential to use effective contraception during treatment with Lytgobi (futibatinib) and for 1 week after the last dose of futibatinib. Based on findings in an animal study and its mechanism of action, futibatinib can cause fetal harm when administered to a pregnant woman.

Drugs/Diseases
Util A Util B Util C
Futibatinib

Gender: Female
Age Range: 11 – 50 yoa

References:
Lytgobi Prescribing Information, September 2022, Taiho Oncology Inc.
Facts & Comparisons, 2022 Updates, Wolters Kluwer Health.

84. Futibatinib / Therapeutic Appropriateness _____ _____
Alert Message: Advise male patients with female partners of reproductive potential to use effective contraception during treatment with Lytgobi (futibatinib) and for 1 week after the last dose of futibatinib.

Drugs/Diseases
Util A Util B Util C
Futibatinib

Gender: Male

References:
Lytgobi Prescribing Information, September 2022, Taiho Oncology Inc.
Facts & Comparisons, 2022 Updates, Wolters Kluwer Health.

85. Futibatinib / Non-adherence _____ _____
Alert Message: Based on refill history, your patient may be under-utilizing Lytgobi (futibatinib). 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
Futibatinib

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.

Greer JA, Amoyal N, Nisotel L, et al. Systemic Review of Adherence to Oral Antineoplastic Therapies. The Oncologist. 2016;21:354-376.

Barillet M, Prevost V, Joly F, Clarisse B. Oral Antineoplastic Agents: How do We Care About Adherence? Br J Clin Pharmacol. 2015;80(6):1289-1302. doi:10.1111/bcp.1273

Recommendations ***Approved Rejected***

86. Olopatadine/Mometasone / Overuse _____ _____
Alert Message: Ryaltris (olopatadine/mometasone) may be over-utilized. The recommended dosage of olopatadine/mometasone is 2 sprays in each nostril twice daily. Hypercorticism and adrenal suppression may occur when nasal corticosteroids, including olopatadine/mometasone, are misused by taking higher-than-recommended dosages.

Drugs/Diseases

Util A	Util B	Util C
Olopatadine/Mometasone		

Max Dose: 8 sprays a day

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Ryaltris Prescribing Information, Oct. 2022, Hikma Specialty USA Inc.

87. Olopatadine/Mometasone / Therapeutic Appropriateness _____ _____
Alert Message: The safety and effectiveness of Ryaltris (olopatadine/mometasone) have not been established in pediatric patients less than 12 years of age, and olopatadine/mometasone is not indicated for use in this population. Nasal corticosteroids, including mometasone (a component in the combination product), may cause a reduction in growth velocity when administered to pediatric patients. Routinely monitor the growth of pediatric patients receiving olopatadine/mometasone nasal spray.

Drugs/Diseases

Util A	Util B	Util C
Olopatadine/Mometasone		

Age Range: 0 - 11 yoa

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Ryaltris Prescribing Information, Oct. 2022, Hikma Specialty USA Inc.

88. Olopatadine/Mometasone / Therapeutic Appropriateness _____ _____
Alert Message: The use of nasal and inhaled corticosteroids, including Ryaltris (olopatadine/mometasone), can result in the development of glaucoma and/or cataracts. Therefore, close monitoring is warranted in patients with a change in vision or with a history of increased intraocular pressure, glaucoma, and/or cataracts.

Drugs/Diseases

Util A	Util B	Util C
Olopatadine/Mometasone	Cataracts Glaucoma Visual Disturbances	

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Ryaltris Prescribing Information, Oct. 2022, Hikma Specialty USA Inc.

Criteria Recommendations ***Approved Rejected***

89. Olopatadine/Mometasone / CNS Depressants _____ _____

Alert Message: Concurrent use of Ryaltris (olopatadine/mometasone) with alcohol or other central nervous system depressants should be avoided because somnolence and impairment of central nervous system performance may occur. The olopatadine component of the combination product can cause CNS depression.

Drugs/Diseases

Util A	Util B	Util C
Olopatadine/Mometasone	CNS Depressants	

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Ryaltris Prescribing Information, Oct. 2022, Hikma Specialty USA Inc.

90. Olopatadine/Mometasone / Strong CYP3A4 Inhibitors _____ _____

Alert Message: Caution should be exercised when considering the coadministration of Ryaltris (olopatadine/mometasone) with strong CYP3A4 inhibitors. Mometasone furoate, a component of the combination product, is primarily and extensively metabolized by CYP3A4 to multiple metabolites. Concomitant administration with a CYP3A4 inhibitor may inhibit the metabolism of and increase the plasma concentration of mometasone furoate and potentially increase the risk for adverse reactions.

Drugs/Diseases

Util A	Util B	Util C
Olopatadine/Mometasone	Clarithromycin	Nelfinavir
	Cobicistat	Posaconazole
	Indinavir	Ritonavir
	Itraconazole	Saquinavir
	Ketoconazole	Voriconazole
	Nefazodone	

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Ryaltris Prescribing Information, Oct. 2022, Hikma Specialty USA Inc.
FDA: Drug Development and Drug Interactions: Tables of Substrates, Inhibitors and Inducers. Available at:
http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/DrugInteractionalLabeling/ucm093664.htm

91. Olopatadine/Mometasone / Therapeutic Appropriateness _____ _____

Alert Message: Nasal corticosteroids, including Ryaltris (olopatadine/mometasone), may cause a reduction in growth velocity when administered to pediatric patients. The growth of pediatric patients receiving nasal corticosteroids should be monitored routinely (e.g., via stadiometry). The safety and effectiveness of olopatadine/mometasone have not been established in pediatric patients less than 12 years of age, and olopatadine/mometasone is not indicated for use in this population. The potential growth effects of prolonged treatment should be weighed against the clinical benefits obtained and the risks/benefits of noncorticosteroid treatment alternatives.

Drugs/Diseases

Util A	Util B	Util C
Olopatadine/Mometasone		

Age Range: 12 - 17 yoa

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Ryaltris Prescribing Information, Oct. 2022, Hikma Specialty USA Inc.

92. Olopatadine/Mometasone / Pregnant / Pregnancy Negating _____ _____

Alert Message: Ryaltris (olopatadine/mometasone) should be used with caution during pregnancy. There are no available data on Ryaltris (olopatadine/mometasone) nasal spray in pregnant women to evaluate for a drug-associated risk of major birth defects, miscarriage, or other adverse maternal or fetal outcomes. In animal reproductive studies, fetal abnormalities have been reported with oral olopatadine hydrochloride and mometasone furoate.

Drugs/Diseases

Util A	Util B	Util C (Negating)
Olopatadine/Mometasone	Pregnancy	Abortion
		Delivery
		Miscarriage

Gender: Female
Age Range: 12 - 999 yoa

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Ryaltris Prescribing Information, Oct. 2022, Hikma Specialty USA Inc.

93. Olopatadine/Mometasone / Lactation _____ _____

Alert Message: There are no available data on the presence of Ryaltris (olopatadine/mometasone) in human milk, the effects on the breastfed child, or the effects on milk production. It is not known whether topical nasal administration could result in sufficient systemic absorption to produce detectable quantities in human breast milk. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for olopatadine/mometasone and any potential adverse effects on the breastfed infant from olopatadine/mometasone or from the underlying maternal condition.

Drugs/Diseases

Util A	Util B	Util C
Olopatadine/Mometasone	Lactation	

Gender: Female
Age Range: 12 - 999 yoa

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Ryaltris Prescribing Information, Oct. 2022, Hikma Specialty USA Inc.

94. Zonisamide / Overuse _____ _____

Alert Message: Zonisamide may be over-utilized. The recommended maximum dosage is 600 mg daily.

Drugs/Diseases

Util A	Util B	Util C
Zonisamide		

Max Dose: 600 mg/day

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Facts & Comparisons, 2022 Updates, Wolters Kluwer Health.

Criteria Recommendations ***Approved Rejected***

95. Zonisamide / Therapeutic Appropriateness _____ _____
Alert Message: The safety and effectiveness of zonisamide in pediatric patients below the age of 16 have not been established.

Drugs/Diseases

Util A	Util B	Util C
Zonisamide		

Age Range: 0 - 15 yoa

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Facts & Comparisons, 2022 Updates, Wolters Kluwer Health.

96. Zonisamide / Myopia & Secondary Glaucoma _____ _____
Alert Message: Acute myopia and secondary angle closure glaucoma have been reported in patients receiving zonisamide. Elevated intraocular pressure can lead to serious sequelae, including permanent vision loss if left untreated. The primary treatment to reverse symptoms is the discontinuation of zonisamide as rapidly as possible, according to the judgment of the treating physician. Other therapeutic measures, in conjunction with the discontinuation of zonisamide, may be helpful. Myopia and secondary angle closure glaucoma usually resolve or improve after discontinuation of zonisamide.

Drugs/Diseases

Util A	Util B	Util C
Zonisamide	Myopia	
	Ocular Pain	
	Secondary Glaucoma	

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Facts & Comparisons, 2022 Updates, Wolters Kluwer Health.

97. Zonisamide / Carbonic Anhydrase Inhibitors _____ _____
Alert Message: Concomitant use of zonisamide, a carbonic anhydrase inhibitor, with any other carbonic anhydrase inhibitor, may increase the severity of metabolic acidosis and may also increase the risk of kidney stone formation. Therefore, if zonisamide is given concomitantly with another carbonic anhydrase inhibitor, monitor the patient for the appearance or worsening of metabolic acidosis.

Drugs/Diseases

Util A	Util B	Util C
Zonisamide	Acetazolamide	
	Dichlorphenamide	
	Methazolamide	

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Facts & Comparisons, 2022 Updates, Wolters Kluwer Health.

Criteria Recommendations ***Approved Rejected***

98. Zonisamide / CYP3A4 Inducers _____ _____
Alert Message: Concomitant use of zonisamide with a potent CYP3A4 inducer can result in decreased systemic exposure and loss of zonisamide efficacy. Zonisamide is metabolized by hepatic cytochrome P450 enzyme CYP3A4, and concomitant use with a potent inducer can increase the metabolism of zonisamide.

Drugs/Diseases

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

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Facts & Comparisons, 2022 Updates, Wolters Kluwer Health.

99. Zonisamide Suspension / Pregnancy / Pregnancy Negating _____ _____
Alert Message: Based on animal data, zonisamide can cause fetal harm when administered to a pregnant woman. Zonisamide should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Drugs/Diseases

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

Gender: Female
Age Range: 11 - 50 yoa

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Facts & Comparisons, 2022 Updates, Wolters Kluwer Health.

100. Zonisamide / Lactation _____ _____
Alert Message: Zonisamide is readily transferred to human milk. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for zonisamide and any potential adverse effects on the breastfed infant zonisamide or the underlying maternal condition. Because zonisamide has been associated with metabolic acidosis in adult and pediatric patients and hyperthermia in pediatric patients, infants exposed to zonisamide during breastfeeding should be monitored for poor feeding, weight loss, excess sedation, decreased muscle tone, and elevated temperature.

Drugs/Diseases

Util A	Util B	Util C
Zonisamide	Lactation	

Gender: Female
Age Range: 16 - 50 yoa

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Facts & Comparisons, 2022 Updates, Wolters Kluwer Health.

Criteria Recommendations ***Approved Rejected***

101. Zonisamide / Contraceptives _____ _____

Alert Message: Advise females of reproductive potential to use effective contraception during treatment with zonisamide and for one month after discontinuation. Based on animal data, zonisamide can cause fetal harm when administered to a pregnant woman.

Drugs/Diseases

Util A	Util B	Util C (Negating)
Zonisamide		Contraceptives

Gender: Female
Age Range: 16 - 50 yoa

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Facts & Comparisons, 2022 Updates, Wolters Kluwer Health.

102. Dextroamphetamine Transdermal / Overuse _____ _____

Alert Message: Xelstrym (dextroamphetamine transdermal) may be over-utilized. The maximum recommended dose of transdermal dextroamphetamine is 18 mg/9 hours.

Drugs/Diseases

Util A	Util B	Util C (Negating)
Dextroamphetamine Transdermal		CKD 4
		CKD 5
		ESRD

Max Dose: 18.9 mg/9 hours

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Xelstrym Prescribing Information, March 2022, Noven Therapeutics, LLC.

103. Dextroamphetamine Transdermal / Overuse (CKD4 & CKD 5) _____ _____

Alert Message: Xelstrym (dextroamphetamine transdermal) may be over-utilized. The maximum recommended dose of transdermal dextroamphetamine in patients with severe renal impairment (GFR 15 to < 30 mL/min) is 13.5 mg/9 hours.

Drugs/Diseases

Util A	Util B	Util C (Include)
Dextroamphetamine Transdermal		CKD 4 and 5

Max Dose: 13.5 mg/9 hours

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Xelstrym Prescribing Information, March 2022, Noven Therapeutics, LLC.

104. Dextroamphetamine Transdermal / Overuse - ESRD _____ _____

Alert Message: Xelstrym (dextroamphetamine transdermal) may be over-utilized. The maximum recommended dose of transdermal dextroamphetamine in patients with end-stage renal disease (GFR < 15 mL/min/1.73 m2) is 9 mg/9 hours.

Drugs/Diseases

Util A	Util B	Util C (Include)
Dextroamphetamine Transdermal		ESRD

Max Dose: 9 mg/9 hours

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Xelstrym Prescribing Information, March 2022, Noven Therapeutics, LLC.

105. Dextroamphetamine Transdermal / Therapeutic Appropriateness _____ _____

Alert Message: The safety and effectiveness of Xelstrym (dextroamphetamine transdermal) have not been established in pediatric patients below the age of 6 years.

Drugs/Diseases

Util A	Util B	Util C
Dextroamphetamine Transdermal		

Age Range: 0 - 5 yoa

References:
Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Xelstrym Prescribing Information, March 2022, Noven Therapeutics, LLC.

106. Omalizumab / Therapeutic Appropriateness (Age) _____ _____

Alert Message: The safety and efficacy of Xolair (omalizumab) in pediatric patients below 18 years of age with nasal polys have not been established.

Drugs/Diseases

Util A	Util B	Util C (Negating)
Omalizumab	Nasal Polyps	Asthma
		Urticaria

Age Range: 0 - 18 yoa

References:

Clinical Pharmacology, 2022 Elsevier/Gold Standard.
Facts & Comparisons, 2022 Updates, Wolters Kluwer Health.

North Dakota Medicaid
Drug Utilization Review Board Meeting
June 7, 2023
Conference Room 210/212

NORTH Dakota
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| Health & Human Services

NORTH Dakota | Health & Human Services
Be Legendary.

Meeting Notice

North Dakota Medicaid Drug Use Review Board

Wednesday, June 7th, 2023
1 to 4 p.m. Central Time

In-Person Information

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

Virtual Information

Join virtually: Click here to join the meeting
Join by phone: 701-328-0950, Conference ID: 731 715 069#

Agenda

1. Call to Order
2. Roll Call
3. Review and Approval of Minutes
4. Reports from Department
    - Administrative Report: Member update, Legislative update, Robert's Rules of Order
    - Financial Report: Budget, Top drugs
    - Clinical Report: Prior authorization update, Criteria update
        - Update to Hepatitis C
        - Update to Chronic Kidney Disease (Filspari)
    - Retrospective DUR report
5. Special Orders
    - Presiding Officer and Vice-Presiding Officer Elections
6. New business
    - Second Review of Hyperparathyroidism
    - Second Review of Influenza
    - Second Review of Neuromyelitis Optica Spectrum Disorder
    - Second Review of Urea Cycle Agents
    - Review of retrospective DUR criteria recommendations
7. Announcements
    - Next Meeting (September 6th, 2023)
8. Adjourn

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

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

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

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

Meeting was called to order: A regular quarterly meeting of the North Dakota Medicaid Drug Use Review (DUR) Board meeting was convened at 1:09 pm CST with Presiding Officer T. Schmidt presiding, and DUR Board Coordinator, L. Morgan recording minutes.

Administrative Items: There were no DHHS announcements at this meeting.

Approval of Meeting Minutes: Motion was made by J. Askvig, and seconded to approve the minutes of the December 7, 2022, meeting as distributed. **Motion carried.**

Reports:
Budget Update provided by B. Joyce
B. Joyce reported on hyper-cost drugs (i.e., Stelara, Dupixent, Humira, Hepatitis C agents), 30 drugs making up 47% of the Medicaid drug budget, and 6 drug classes (i.e., immunomodulators, oncology, cystic fibrosis, HIV) which account for 93% of increase in spend. The increase in drug spend is not attributable to the increase in members, but rather, it is from the increased use of hyper-cost drugs.

Review Top 25 Drugs provided by B. Joyce
B. Joyce presented the quarterly review of the top 25 drugs based on total cost of claims, the top 25 drugs based on the total number of claims, and the top drug classes based on claims and cost for the 4th quarter of 2022. This report can be found in the handout.

PDL/PA Criteria Updates provided by L.Roehrich
L. Roehrich shared with the Board all changes made to the Preferred Drug List (PDL) since the last update. This report can be found in the handout.

Update to C. difficile Associated Diarrhea (CDAD) provided by L. Morgan
L. Morgan discussed the addition of a CDAD prevention section to the PDL which listed criteria for Rebyota. This report can be found in the handout.

Update to Vaginal Infections provided by L. Morgan
L. Morgan discussed the "Fungal Infections" category to the "Vaginal Infections" section of the PDL along with updated criteria. There are now two categories (Bacterial and Fungal) which separate treatment options for either infection. This report can be found in the handout.

First Reviews: L. Morgan presented an overview of hyperparathyroidism, influenza, neuromyelitis optica spectrum disorder, and urea cycle agents. The presented material can be found in the handout.

Hyperparathyroidism:
Motion: Moved by A. Werremeyer for the Department to develop criteria for hyperparathyroidism, motion was seconded.

Influenza:
Motion: Moved by J. Askvig for the Department to develop criteria for influenza, motion was seconded.

Neuromyelitis Optica Spectrum Disorder:
Motion: Moved by J. Askvig for the Department to develop criteria for neuromyelitis optica spectrum disorder, motion was seconded.

Urea Cycle Agents:
Motion: Moved by L. Kroetsch for the Department to develop criteria for urea cycle agents, motion was seconded.

Discussion of Respiratory Syncytial Virus (RSV): L. Roehrich presented data from the Midwest region and, more specifically, North Dakota for the 2022 – 2023 RSV season. The data set for North Dakota from start-to-finish matched the Midwest Region of the RSV season, which was presented in a bell-shaped curve. This presentation confirms that following the CDC RSV positivity data allows for better representation and coverage for members during the RSV season. The presented material can be found in the handout.

Retrospective Drug Utilization Review (RDUR) Criteria Recommendations: L. Morgan reviewed the RDUR criteria that were selected for review of each month of the last quarter. October consisted of a special mailing to prescribers of the buprenorphine monoproduct. The presented material can be found in the handout.
Motion: Moved by K. Martian to approve the RDUR criteria, motion was seconded. **Motion carried.**

Remicade Biosimilar Update: L. Roehrich presented a fax sent to providers discussing the preferred Remicade biosimilars effective January 1st, 2023. Biosimilars Avsola and Renflexis will not require prior authorization (PA). All other agents, Remicade, Inflectra, and infliximab will require PA. The presented material can be found in the handout.

Adjournment:
Motion: Moved by L. Kroetsch to adjourn the meeting, motion was seconded. **Motion carried.**

Meeting was adjourned at 2:15 pm CST.

Date of Minutes Approval:

Minutes submitted by: Lauren Morgan, Kepro

Legislative Update: Highlighted changes affecting DUR Board

Senate Bill 2156: Effective August 1, 2023

Quorum:

- Definition: One-half or more of nonvacant voting board member positions

Residency Requirements:

- Pharmacist and physician members do not have to be residents of the state of ND if they provide telehealth services to residents of ND. In-state members should continue to be recruited to fill positions and replace out-of-state members.
- Pharmaceutical representative members do not need to be in-state residents

Restricted Classes:

- Stimulant medications is no longer a restricted class; immunosuppressants for prophylaxis of organ transplant rejection has been added as a restricted class.
- Restricted classes may have prior authorization requirements if they are meet one of the following exceptions:
    - Multisource brands of the identical molecular structure
    - Extended-release products when the immediate-release product is available without prior authorization
    - Products that have the same active ingredient or moiety
    - Dosage forms that do not provide a unique route of administration

Terminology:

- Chairman has been changed to Presiding Officer

Procedure Changes to DUR Board

Elections:

- Elections for Presiding Officer and Vice-Presiding Officer will occur in June. Those elected will assume their positions in September.
    - The presiding officer runs the board meeting and ensures the rules of board are followed.
    - The vice-presiding officer acts as presiding offer when presiding officer is absent or steps down prior to the end of their term.
    - Any member is eligible for either position. The vice-presiding officer will not automatically assume the presiding officer's position at the end of their term. The election for each position will be open in June.

Debate:

- Each member is allowed two 10-minute speeches per day on a question. After the first 10 minutes, the member must wait until everyone has had the opportunity to speak before speaking a second 10 minutes.
- Debate should be germane to the agenda item being discussed
- A call for the orders of the day may occur to keep meeting on track

Minutes:

- Minutes are a record of what is done at the meeting, not what is said.
- Motions are recorded in minutes so please make a clearly worded motion. "I move that…"
- Approval of the minutes:
    - The presiding officer may assume the motion and obtain unanimous consent that the minutes be approved as distributed. If there are corrections to be made, this would require a motion/second/vote.

Old/Unfinished business:

- Reserved for resolving questions or agenda items that were not addressed from the previous meeting

Second Review:

- Purpose is to adopt criteria developed by the Department. Prior authorization becomes effective following this review.
- Needs a motion/second and vote to adopt criteria. Please state motions clearly and completely so they can be recorded in the minutes.
- The original motion can be to adopt the criteria with a change. An amendment motion/second/vote is not needed to change the criteria, only to change the original motion.

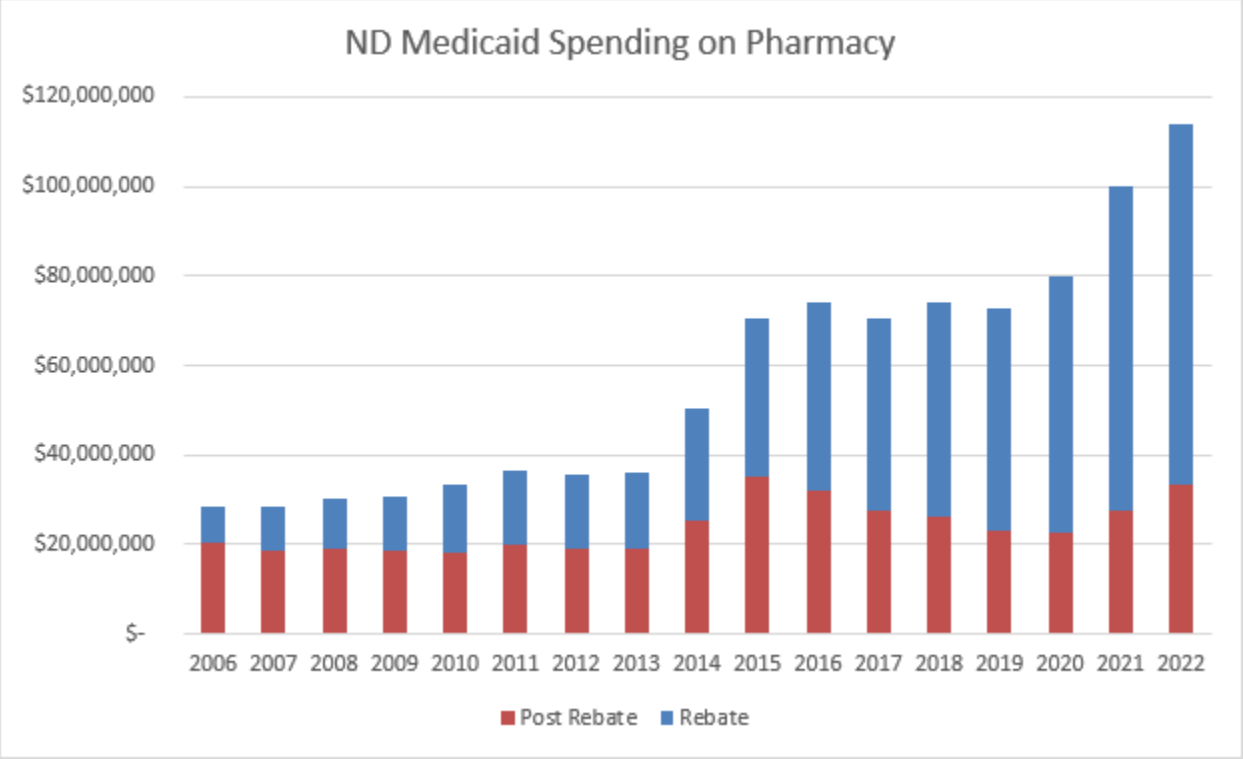
First Review:

- The purpose is to approve the Department to develop prior authorization criteria.
- Needs a motion/second and vote to develop criteria. Please state motions clearly and completely so they can be recorded in the minutes.

Adjournment:

- The presiding officer may adjourn the meeting without a motion/second/vote when it is time based on the agenda or allotted time for the meeting.
    - Adjournment outside of these parameters or an emergency would require a motion/second/vote.

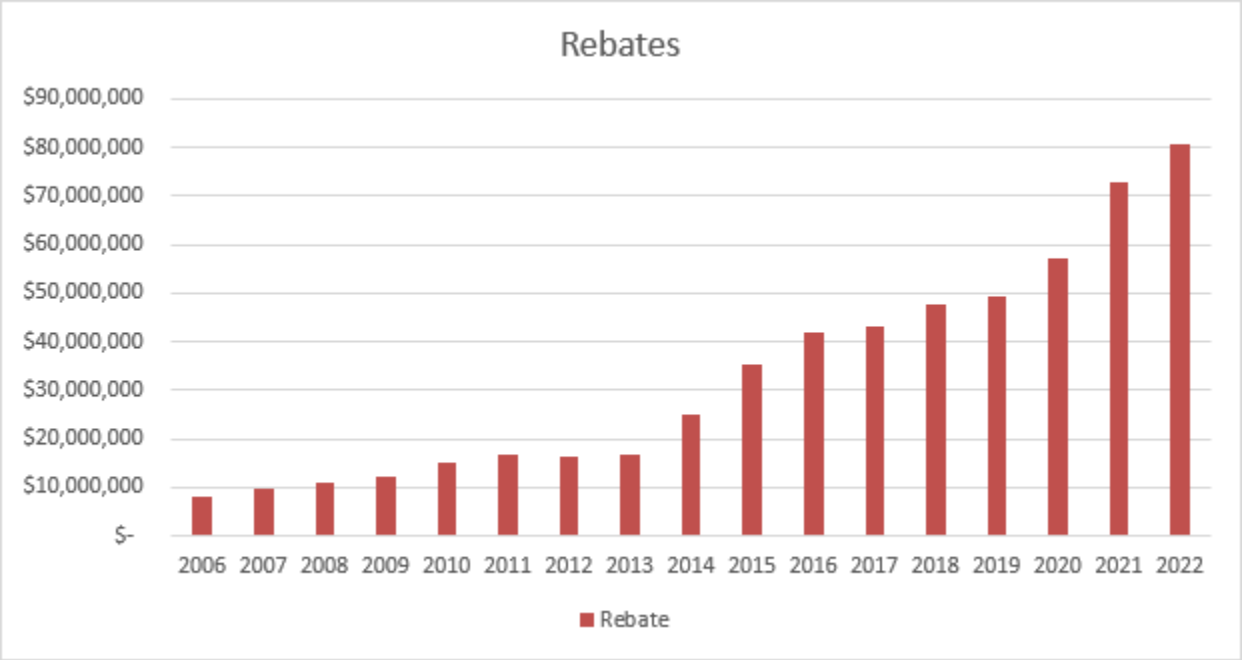
Timeline	
Pre - 2014	Brendan was only staff member
2014	Expansion (managed by Sanford MCO) started
2015	Alexi was hired
2016	Supplement rebates for only FFS
2017	January 1 - MCO supplementals start October 1 – MCO PBM complaint
2019	LeNeika was hired
2020	January 2020 - MCO carve-out March 2020 - COVID



Total payments to pharmacies in 2006 was $28.5 million.
Total payments to pharmacies in 2022 was $113.8 million.

Net pharmacy spend (i.e. post rebate) in 2006 was $20.26 million.
Net pharmacy spend (i.e. post rebate) in 2020 was $22.5 million.

Net pharmacy spend in 2022 was $33.2 million (still lower than $35.1 million in 2015).



MCO Carve Out Decrease in Net Spend

Class	% Decrease
ADHD Stimulants	36.68%
Antidepressants	22.23%
Beta Agonist	68.30%
Hypertension	16.82%
Muscle Relaxant	31.46%
Narcotics	21.79%
Narcotic Treatment	14.53%
NSAIDs/COX2	17.90%
Topical Steroid	29.89%
Total	**25.95%**

Spending Growth

Quarter	Reimb Amt	Net Spend	% Growth qtr/qtr
1Q2019	$ 17,874,850	$ 5,371,480	
2Q2019	$ 18,017,728	$ 5,667,672	5.5%
3Q2019	$ 17,468,060	$ 5,749,207	1.4%
4Q2019	$ 19,373,630	$ 6,458,292	12.3%
1Q2020	$ 18,696,018	$ 5,419,074	-16.1%
2Q2020	$ 18,758,703	$ 5,283,372	-2.5%
3Q2020	$ 20,307,648	$ 5,806,647	9.9%
4Q2020	$ 22,045,832	$ 5,990,144	3.2%
1Q2021	$ 24,272,343	$ 6,340,422	5.8%
2Q2021	$ 24,974,546	$ 6,683,444	5.4%
3Q2021	$ 25,124,024	$ 6,929,321	3.7%
4Q2021	$ 25,801,227	$ 7,431,914	7.3%
1Q2022	$ 27,927,425	$ 7,674,315	3.3%
2Q2022	$ 28,301,349	$ 8,071,019	5.2%
3Q2022	$ 28,153,701	$ 8,352,346	3.5%
4Q2022	$ 29,395,177	$ 9,081,519	8.7%
1Q2023	$ 31,430,413	$ 9,192,116	1.2%

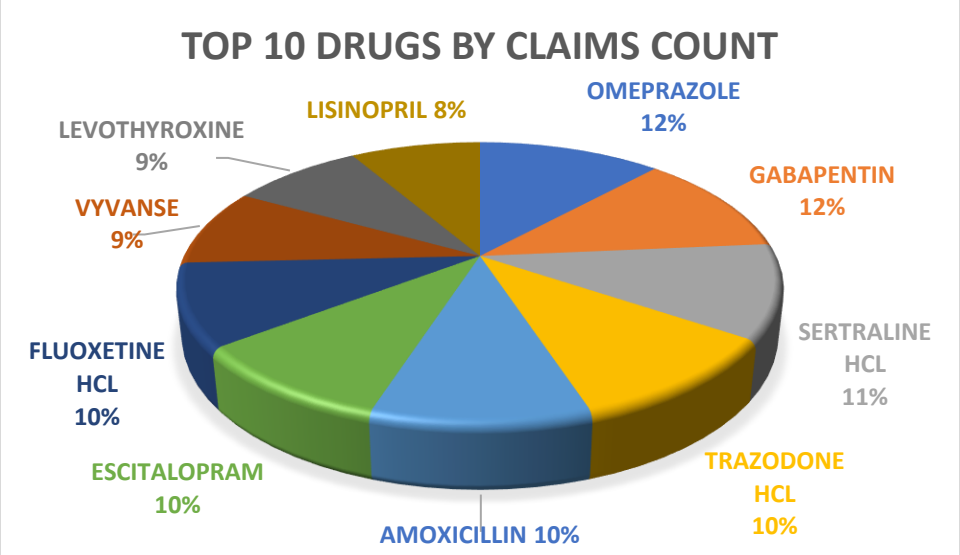
Yearly Average Net Spend Growth between 2018 to 2022

Class	% of total growth
Immunomodulators	35.8%
Oncology	15.5%
Cystic Fibrosis	15.5%
Antipsychotics	11.3%
Eczema	7.4%
HIV	4.8%
Total in these 6 classes	**93.0%**

Top 25 Drugs Based on Number of Claims from 01/01/2023 – 03/31/2023

Drug	Claims	Claims Cost	Patients	Cost / Claim	% Total Claims	Dif.
1. OMEPRAZOLE	5,168	$67,134.97	2,550	$12.99	1.8%	↑1
2. GABAPENTIN	5,144	$75,875.53	2,104	$14.75	1.8%	↓1
3. SERTRALINE HCL	4,829	$65,043.26	2,611	$13.47	1.6%	NC
4. TRAZODONE HCL	4,603	$62,207.79	2,229	$13.51	1.6%	NC
5. AMOXICILLIN	4,331	$61,990.27	4,049	$14.31	1.5%	↑1
6. ESCITALOPRAM OXALATE	4,326	$58,167.97	2,424	$13.45	1.5%	↓1
7. FLUOXETINE HCL	4,289	$57,231.53	2,254	$13.34	1.5%	NC
8. VYVANSE	4,025	$1,076,628.95	1,492	$267.49	1.4%	↑4
9. LEVOTHYROXINE SODIUM	3,940	$63,175.57	1,993	$16.03	1.3%	↓1
10. LISINOPRIL	3,704	$47,540.98	2,178	$12.84	1.3%	↓1
11. ATORVASTATIN CALCIUM	3,594	$52,187.07	2,036	$14.52	1.2%	↓1
12. BUPROPION XL	3,559	$59,034.04	1,844	$16.59	1.2%	↑1
13. PANTOPRAZOLE SODIUM	3,318	$45,639.82	1,597	$13.76	1.1%	↑2
14. HYDROCODONE-APAP	3,071	$44,533.85	1,919	$14.5	1.0%	↑2
15. CYCLOBENZAPRINE HCL	2,954	$34,015.15	1,830	$11.51	1.0%	↑2
16. DULOXETINE HCL	2,896	$46,760.92	1,485	$16.15	1.0%	↑2
17. AMOXICILLIN-CLAV	2,872	$51,727.21	2,690	$18.01	1.0%	↓6
18. CLONIDINE HCL	2,868	$35,256.33	1,403	$12.29	1.0%	↑2
19. ONDANSETRON ODT	2,852	$39,375.67	2,235	$13.81	1.0%	↑10
20. PREDNISONE	2,851	$32,716.26	2,296	$11.48	1.0%	↓6
21. HYDROXYZINE HCL	2,744	$37,909.69	1,676	$13.82	0.9%	↑2
22. BUPRENORPHINE-NALOX	2,741	$115,663.22	676	$42.2	0.9%	↓3
23. VENTOLIN HFA	2,740	$175,388.73	2,692	$64.01	0.9%	↑8
24. LAMOTRIGINE	2,740	$39,392.44	1,087	$14.38	0.9%	↓3
25. BUSPIRONE HCL	2,606	$39,980.16	1,351	$15.34	0.9%	↑1

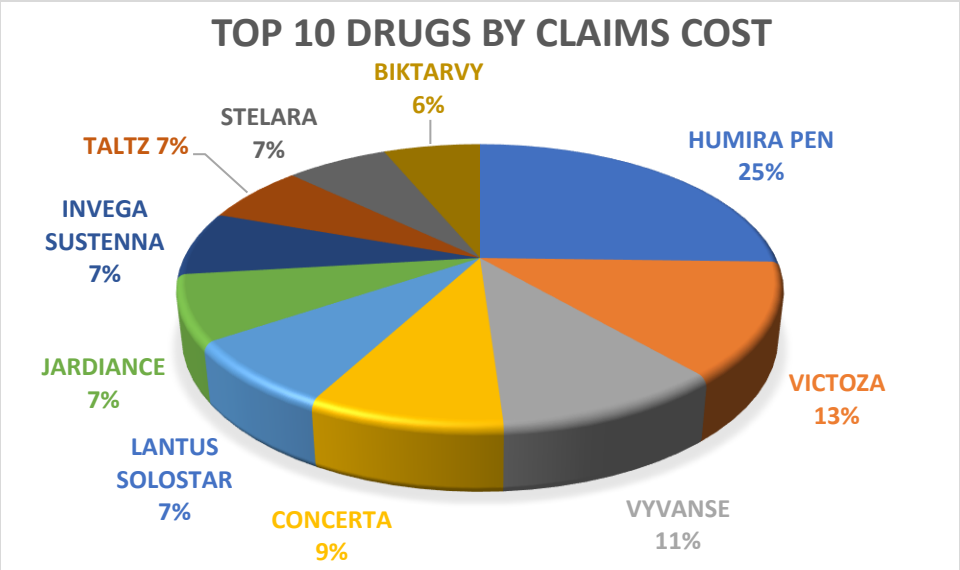
Total Claims	**292,740**



Top 25 Drugs Based on Total Claims Cost from 01/01/2023 – 03/31/2023

Drug	Claims	Claims Cost	Patients	Cost / Patient	% Total Cost	Dif.
1. HUMIRA PEN	295	$2,350,137.28	126	$36,582.22	6.2%	NC
2. VICTOZA	1448	$1,282,349.00	689	$3,624.68	3.4%	NC
3. VYVANSE	4,025	$1,076,628.95	1,492	$721.6	2.8%	NC
4. CONCERTA	2,301	$830,334.49	920	$902.54	2.2%	NC
5. LANTUS SOLOSTAR	1,360	$710,813.88	824	$862.64	1.9%	NC
6. JARDIANCE	1,067	$703,553.04	539	$1,305.29	1.9%	↑1
7. INVEGA SUSTENNA	271	$700,417.71	110	$6,367.43	1.9%	↓1
8. TALTZ AUTOINJECTOR	95	$667,695.10	34	$19,638.09	1.8%	↑2
9. STELARA	28	$655,455.02	18	$36,414.17	1.7%	NC
10. BIKTARVY	294	$610,112.83	129	$4,729.56	1.6%	↑1
11. MAVYRET	43	$522,443.63	28	$18,658.70	1.4%	↑9
12. VRAYLAR	520	$508,917.03	216	$2,356.10	1.3%	↑1
13. LATUDA	600	$482,987.32	244	$1,979.46	1.3%	↓5
14. ADDERALL XR	2,446	$436,081.56	990	$440.49	1.2%	NC
15. ELIQUIS	777	$419,051.56	354	$1,183.76	1.1%	↑2
16. SYMBICORT	1,159	$403,187.69	649	$621.24	1.1%	↓1
17. ADVAIR DISKUS	988	$361,302.25	538	$671.57	1.0%	↓1
18. NOVOLOG FLEXPEN	500	$358,449.53	299	$1,198.83	0.9%	NC
19. TRIKAFTA	16	$327,967.39	8	$40,995.92	0.9%	↓7
20. ABILIFY MAINTENA	137	$318,799.65	55	$5,796.36	0.8%	↑2
21. NORDITROPIN	83	$292,477.87	39	$7,499.43	0.8%	↓2
22. DUPIXENT	83	$285,163.36	34	$8,387.16	0.8%	↑7
23. XIFAXAN	96	$273,891.47	50	$5,477.83	0.7%	↑1
24. ORKAMBI	17	$237,449.07	6	$39,574.85	0.6%	↑1
25. INGREZZA	31	$236,023.46	11	$21,456.68	0.6%	↑13

Total Claims Cost	**$37,820,109.62**



Top 15 Therapeutic Classes Based on Number of Claims from 01/01/2023 – 03/31/2023

Therapeutic Class Description	Claims	Claims Cost	Patients	Cost/Claim	% Total Claims	Dif.
1. ANTIDEPRESSANTS	33,334	$705,163.73	13,454	$21.15	11.4%	NC
2. ANTICONVULSANTS	15,057	$631,660.79	5,140	$41.95	5.1%	NC
3. ANTIPSYCHOTIC AGENTS	10,460	$2,930,543.30	3,971	$280.17	3.6%	NC
4. PROTON-PUMP INHIBITORS	8,874	$158,311.36	4,276	$17.84	3.0%	NC
5. ANXIOLYTICS, SEDATIVES, HYPNOTICS	8,235	$120,581.28	4,112	$14.64	2.8%	↑1
6. AMPHETAMINES	8,181	$1,570,707.77	3,118	$191.99	2.8%	↑1
7. PENICILLIN ANTIBIOTICS	7,625	$122,940.30	6,743	$16.12	2.6%	↓2
8. OPIATE AGONISTS	7,590	$120,179.61	3,890	$15.83	2.6%	NC
9. NSAIDS	6,860	$99,441.64	4,472	$14.5	2.3%	NC
10. RESPIRATORY/CNS STIMULANTS	6,516	$1,112,383.00	2,335	$170.72	2.2%	↑1
11. STATINS	6,265	$92,382.41	3,522	$14.75	2.1%	↓1
12. BETA BLOCKING AGENTS	5,836	$105,231.85	3,155	$18.03	2.0%	NC
13. ADRENALS	4,735	$63,404.81	3,728	$13.39	1.6%	NC
14. BETA-ADRENERGIC AGONISTS	4,637	$274,032.69	4,218	$59.1	1.6%	NC
15. ACE INHIBITORS	4,618	$74,798.49	2,693	$16.2	1.6%	NC

Top 15 Therapeutic Classes Based on Claims Cost from 01/01/2023 – 03/31/2023

Therapeutic Class Description	Claims	Claims Cost	Patients	Cost/Patient	% Total Cost	Dif.
1. DMARDS	647	$3,812,849.15	261	$14,608.62	10.1%	NC
2. ANTIPSYCHOTIC AGENTS	10,460	$2,930,543.30	3,971	$737.99	7.7%	NC
3. SKIN/MUCOUS MEMBRANE AGENTS	799	$2,428,124.70	471	$5,155.25	6.4%	↑1
4. INSULINS	3,777	$1,986,331.84	1,456	$1,364.24	5.3%	↓1
5. ANTINEOPLASTIC AGENTS	703	$1,594,212.85	293	$5,441.00	4.2%	↑1
6. AMPHETAMINES	8,181	$1,570,707.77	3,118	$503.75	4.2%	↓1
7. INCRETIN MIMETICS	1,647	$1,454,711.44	718	$2,026.06	3.8%	NC
8. ANTIRETROVIRALS	934	$1,318,023.91	323	$4,080.57	3.5%	↑2
9. CORTICOSTEROIDS (RESPIRATORY)	3,949	$1,148,808.86	2,278	$504.31	3.0%	↑11
10. RESPIRATORY AND CNS STIMULANTS	6,516	$1,112,383.00	2,335	$476.4	2.9%	↓1
11. SGLT-2 INHIBITORS	1,528	$980,293.29	764	$1,283.11	2.6%	NC
12. ANTIDEPRESSANTS	33,334	$705,163.73	13,454	$52.41	1.9%	↑1
13. HCV ANTIVIRALS	66	$699,062.52	43	$16,257.27	1.8%	↑1
14. ANTICONVULSANTS	15,057	$631,660.79	5,140	$122.89	1.7%	↓2
15. ANTICOAGULANTS	1,668	$594,279.60	685	$867.56	1.6%	↑2

PDL Update

Drug Name	PA Status	Class
Altuviiio	PA	Extended half-life factor VIII products
Atorvaliq	PA	Non-Solid Dosage Forms
Austedo XR	PA	Tardive Dyskinesia
Cuvrior	PA	Wilson's Disease
Daybue	PA	Medications that cost greater than 3000
Joenja	PA	Medications that cost greater than 3000
Lumryz	PA	Narcolepsy
mesalamine HD	PA	Ulcerative Colitis
Nityr	PA	Preferred Dosage Forms
Pradaxa pellets	PA	Anticoagulants - oral
Rezvoglar	PA	Insulin
Skyclarys	PA	Medications that cost greater than 3000
Tezspire	PA	Eosinophilic Asthma
Vowst	PA	Clostridioides difficile-associated diarrhea (CDAD)

Update to Hepatitis C

Initial Criteria - Approval Duration: Based on label recommendations

- The member must have life expectancy greater than 12 months.
- The member and prescriber attestation forms must be attached to request
- The member must have established compliant behavior including attending scheduled provider visits (defined as 1 or less no-shows) and filling all maintenance medications on time for the past 90 days, as evidenced by pharmacy claims history.
- Chronic Hepatitis C must be documented by one of the following (within the last 12 months):
  - Liver fibrosis F1 and below or unknown: 2 positive HCV RNA levels at least 6 months apart
  - Liver fibrosis F2 and above: 1 positive HCV RNA test

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 treatments with Direct Acting Antivirals:

One of the following criteria must be met (1,2 or 3):

1. The member has completed 2 visits in the Harm Reduction MTM Program
2. The member does not have history of alcohol abuse or IV drug use within the past 5 years
3. The member has a history of alcohol use disorder or IV drug use within the past 5 years with one of the following criteria met:

Currently enrolled or has completed a substance use treatment program within the past 12 months	• 1 negative IV drug test (if history of IV drug use) or 1 negative alcohol test (if history of alcohol use disorder) within 30 days of the request date
Has not completed a substance use treatment program within the past 12 months	• 2 negative IV drug tests (if history of IV drug use) or 2 negative alcohol tests (if history of alcohol use disorder), dated at least 3 months apart, with the most current test completed within 30 days of the request date **OR** • Provider must submit chart notes documenting that the member has maintained sobriety for the past year or since last substance use treatment program completion

For <u>RE-TREATMENT</u> after Direct Acting Antivirals:

- Prescriber must be, or in consult with, a hepatology, gastroenterology, or infectious disease specialist (including via Project ECHO)
- The following criteria is met (as applicable due to reason for retreatment):

<table>
<tr><th colspan="3">Reason for retreatment:</th></tr>
<tr><td rowspan="4">Due to drugs of abuse by injection</td><td colspan="2">• The member is receiving treatment or must have received treatment for substance use disorder since initial Hepatitis C treatment with Direct Acting Antivirals, and the provider/facility name must be provided with the request.</td></tr>
<tr><td>Liver fibrosis F2 and below (or unknown)</td><td>Liver fibrosis F3 and above</td></tr>
<tr><td>• The provider must submit chart notes documenting that the member has abstained from drugs of abuse for the past year</td><td rowspan="2">• Two drug tests: 1 test completed 3 months prior to request and 1 test within 30 days of the request date</td></tr>
<tr><td>• Two drug tests: 1 test completed 6 months (+/- 1 months) prior to request and 1 test within 30 days of the request date</td></tr>
<tr><td rowspan="3">Due to non-compliance (defined as a medication possession ratio (MPR) of less than 80%)</td><td>Liver fibrosis F2 and below (or unknown)</td><td>Liver fibrosis F3 and above</td></tr>
<tr><td>• The member must have established compliant behavior including attending scheduled provider visits (defined as 1 or less no-shows) and filling all maintenance medications on time for the past 180 days, as evidenced by pharmacy claims history.</td><td>• The member must have established compliant behavior including attending scheduled provider visits (defined as 1 or less no-shows) and filling all maintenance medications on time for the past 90 days, as evidenced by pharmacy claims history.</td></tr>
<tr><td colspan="2">• The member has participated in 2 MTM sessions addressing adherence barriers within the past 180 days</td></tr>
<tr><td>Resistance</td><td colspan="2">• FIRST TIME treatment with Direct Acting Antivirals criteria must be met</td></tr>
</table>

Hepatitis C Treatments
Prior Authorization Form

Fax Completed Form to:
855-207-0250
For questions regarding this Prior authorization, call
866-773-0695

Prior Authorization Vendor for ND

ND Medicaid requires that members receiving a prescription for hepatitis C treatments must meet the criteria listed in the preferred drug list (PDL). Please see the PDL at www.hidesigns.com/assets/files/ndmedicaid/NDPDL.pdf

Part I: TO BE COMPLETED BY PRESCRIBER

Member Name		Member Date of Birth	Weight (kg)	Member Medicaid ID Number
Prescriber Name		Specialist involved in therapy		
Prescriber NPI		Telephone Number		Fax Number
Requested Drug and Dose:	**Duration requested:**	**Member's liver fibrosis score (RNA levels must be within the last 12 months):** □ Unknown – Attach 2 positive HCV RNA levels at least 6 months apart □ F0-F1 - Attach 2 positive HCV RNA levels at least 6 months apart □ F2 or above – Attach 1 positive RNA HCV level		
Diagnosis: □ HCV □ OTHER	**Genotype:**	**Member's Child–Pugh Class:** □ A □ B □ C □ N/A		

This request is for
- □ Initial treatment for Hepatitis C
- □ Re-treatment after Interferon and/or Ribavirin
- □ Re-treatment after Direct Acting Antiviral; Drug Name _____

Reason for re-treatment
- □ Re-infection due to IV Drug Use
- □ Non-compliance with previous regimen (MPR < 80%)
- □ Resistance
- □ Other _____

Does member have history of:
- □ HIV/HCV co-infection
- □ Liver or kidney transplant
- □ HCV-uninfected transplant recipient who received an organ from HCV-viremic donor
- □ Decompensated cirrhosis
  - Is member going to take Ribavirin alongside treatment? □ YES □ NO

Is the member's life expectancy greater than one year?	□ YES □ NO
Does the member attend scheduled visits with no more than 1 no-show and fill maintenance medications on time?	□ YES □ NO

Does member have history within the past 5 years of Alcohol Use Disorder or IV Drug Use?
- □ **Alcohol Use Disorder:**
  - □ Member is currently enrolled or has completed treatment program within past 12 months
    - □ 1 negative alcohol test completed within 30 days of the request date is attached
  - □ Member has not completed substance use treatment program within past 12 months
    - □ 2 negative alcohol tests dated at least 3 months apart, with most recent completed within 30 days of the request date
  - □ Chart notes attached documenting 2 completed visits in Harm Reduction MTM Program
- □ **IV Drug Use:**
  - □ Member is currently enrolled or has completed treatment program within past 12 months
    - □ 1 negative IV drug test completed within 30 days of the request date is attached
  - □ Member has not completed substance use treatment program within past 12 months
    - □ 2 negative IV drug tests dated at least 3 months apart, with most recent completed within 30 days of the request date
  - □ Chart notes attached documenting 2 completed visits in Harm Reduction MTM Program

Treatment Program Name: _____

Prescriber (or Staff) / Pharmacy Signature**	Date

**: *By completing this form, I hereby certify that the above request is true, accurate and complete. That the request is medically necessary, does not exceed the medical needs of the member, and is clinically supported in the member's medical records. I also understand that any misrepresentations or concealment of any information requested in the prior authorization request may subject me to audit and recoupment.*

Part II: TO BE COMPLETED BY PHARMACY

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #

Hepatitis C Member Consent Form

I am planning to live in North Dakota during the entire treatment period. I will complete the entire course of treatment, attend office visits, and have laboratory tests as ordered by my healthcare provider during the treatment period.

I will notify my chosen pharmacy of a need to refill one week prior to running out of medication. I understand I must take my medication each day as directed for the entire course of treatment. If the medication does not work due to missed doses, I may not be approved for re-treatment.

I understand to keep my liver healthy, I must not drink alcohol or use illicit injectable drugs prior to, during, or after my treatment. If indicated, I will participate in a treatment program to remain abstinent.

I understand that after treatment, I can be re-infected with Hepatitis C. My provider has educated me on routes of Hepatitis C transmission, and I will avoid or modify high risk activities to avoid re-infection.

I understand that medications that treat Hepatitis C may be harmful to unborn babies. I will use methods to avoid getting pregnant or another person pregnant during treatment and when advised by my provider or pharmacist, for at least 6 months after treatment is complete. If I become pregnant and stop treatment before it is completed, I may not be approved for re-treatment.

Member Signature _____Date __/__/____

Pharmacy or Prescriber Representative:

Signature _____Date __/__/____

By signature, the pharmacy or prescriber representative confirms the consent form has been reviewed with the member.

Hepatitis C Prescriber Agreement Form

I agree that I will counsel my patient on how, where, and when to obtain refills of their hepatitis C medications.

I agree that I will have intermittent telephone check-ins with my patient, at minimum at 2 weeks and 6 weeks of treatment. I will assess continued adherence with medication, labs, and office visits, treatment tolerability, as well as medication changes that may affect treatment.

I have reviewed my patient's medications for drug interactions that would make Hepatitis C medications less effective or cause other adverse effects.

I have reviewed the treatment plan with my patient including medications, lab, vaccinations, and follow-up visits.

I have assessed my patient's readiness for treatment and believe they are ready and willing to comply with the treatment plan. I have assessed social and psychological stability, substance use, compliance to follow up visits and medications, pregnancy status, and concurrent health risks.

I understand that ND Medicaid tracks refill history and may contact me to provide additional information in the event of a dropped or late refill.

I have a dedicated individual or team which may include pharmacy and nursing support to fulfill the elements of this form and have listed key members contact information below.

Name: _____ Location: _____

Phone #: _____

Name: _____ Location: _____

Phone #: _____

Pharmacy or Prescriber Representative:

Signature_____ **Date** __/__/____

Update to Chronic Kidney Disease (Filspari)

Chronic Kidney Disease

Dual endothelin angiotensin receptor antagonist

CLINICAL PA REQUIRED
FILSPARI (sparsentan)

Prior Authorization Criteria

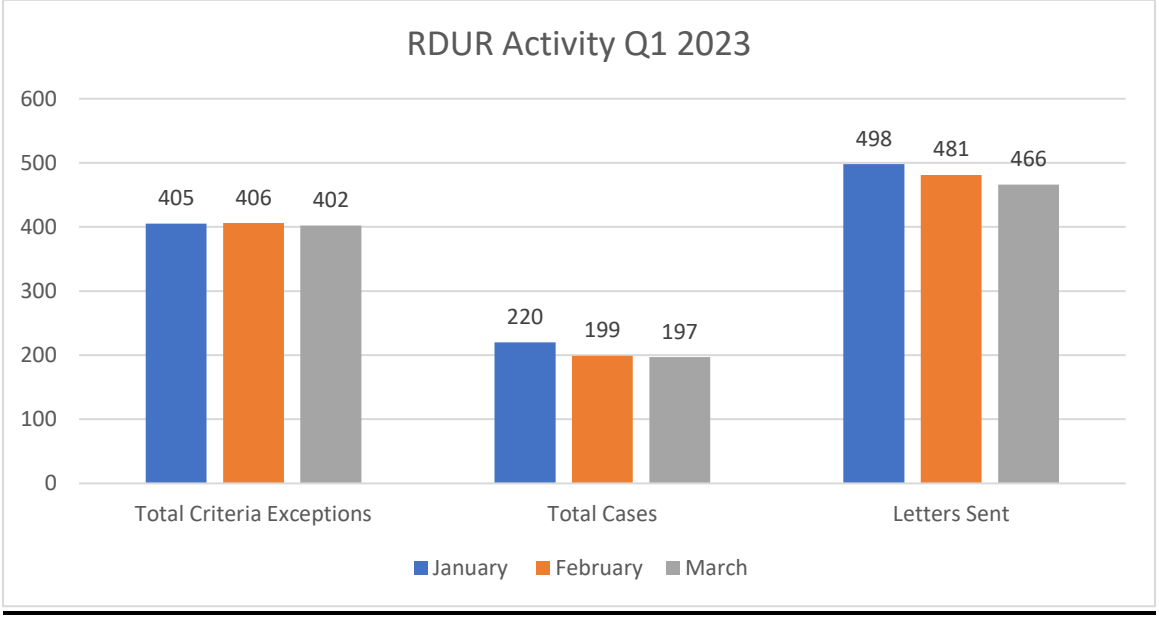
Initial Criteria - Approval Duration: 12 months

- If member is on renal dialysis, Medicare eligibility must be ruled out.
- The member must be on the following at the target or maximally tolerated dose, as evidenced by paid claims or pharmacy printouts:
  - An ACE-inhibitor or an ARB
  - A SGLT-2 inhibitor

Filspari Only

- The medication is prescribed by, or in consultation with, a nephrologist
- The diagnosis has been confirmed with kidney biopsy
- The member must have eGFR ≥ 30.
- The member must be experiencing proteinuria > 1 gram/day or UPCR ≥ 1.5 g/g (documentation must be attached) despite 3-month trials with good compliance of the following in combination at the target or maximally tolerated dose, as evidenced by paid claims or pharmacy printouts:
  - ACE inhibitor or an ARB
  - A SGLT-2 inhibitor

RDUR Activity Overview: Q1 2023



January Cases by Type of Criteria		
Criteria Description	**# of Cases**	**% of Cases**
Adverse Effects	3	1.4%
Clinical Appropriateness	23	10.5%
Drug-Disease Interactions	104	47.3%
Drug-Drug Conflicts	90	40.8%

February Cases by Type of Criteria		
Criteria Description	**# of Cases**	**% of Cases**
Clinical Appropriateness	133	66.8%
Drug-Disease Interactions	21	10.6%
Drug-Drug Conflicts	45	22.6%

March Cases by Type of Criteria		
Criteria Description	**# of Cases**	**% of Cases**
Adverse Effects	31	15.7%
Clinical Appropriateness	106	53.8%
Drug-Disease Interactions	1	0.6%
Drug-Drug Conflicts	59	29.9%

Second Reviews

Hyperparathyroidism

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
calcitrol capsule	doxercalciferol capsule
paricalcitrol capsule	HECTOROL (doxercalciferol) CAPSULE
	RAYALDEE ER (calcifediol)
	ROCALTROL (calcitriol)
	ZEMPLAR (paricalcitrol) CAPSULE

Prior Authorization Criteria

- See Preferred Dosage Form criteria

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

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

Neuromyelitis Optica Spectrum Disorder

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ENSPRING (satralizumab-mwge)	SOLIRIS (eculizumab) – *Medical Billing Only*
UPLIZNA (inebilizumab) – *Medical Billing Only*	

Prior Authorization Criteria

Initial Criteria - Approval Duration: 6 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational).
- The requested medication must be prescribed by, or in consult with, a neurologist
- The member has positive serologic test for anti-AQP4 antibodies.
- The member has a history of ≥ 1 relapses that required rescue therapy within the past 12 months
- The member has an Expanded Disability Status Score (EDSS) of ≤ 6.5

Non-Preferred Agents Criteria

- The member must have had a 3-month trial with each of the preferred agents

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 (e.g., pain, fatigue, motor function)

Urea Cycle Agents

Hyperammonemia

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
BUPHENYL (sodium phenylbutyrate)	RAVICTI (glycerol phenylbutyrate)
PHEBURANE (sodium phenylbutyrate)	
sodium phenylbutyrate	

NAS Deficiency

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
carglumic acid	CARBAGLU (carglumic acid)

Prior Authorization Criteria

See Medications that cost over $3000/month criteria

Non-Preferred Agents Criteria

- Carbaglu: See Preferred Dosage Form criteria
- Ravicti: The member is unable to tolerate sodium phenylbutyrate due to sodium content or GI distress

NORTH DAKOTA MEDICAID
RETROSPECTIVE DRUG UTILIZATION REVIEW
CRITERIA RECOMMENDATIONS
2ND QUARTER 2023

Criteria Recommendations ***Approved Rejected***

1. Odevixibat / Overuse _____ _____

Alert Message: Bylvay (odevixibat) may be over-utilized. The recommended dosage of odevixibat is 40 mcg/kg once daily in the morning with a meal. If there is no improvement in pruritus after 3 months, the dosage may be increased in 40 mcg/kg increments up to 120 mcg/kg once daily not to exceed a total daily dose of 6 mg.

Drugs/Diseases

Util A	Util B	Util C
Odevixibat		

Max Dose: 6 mg/day

References:
Bylvay Prescribing Information, Oct. 2022, Albireo Pharm, Inc.
Clinical Pharmacology, 2023 Elsevier/Gold Standard.

2. Odevixibat / Therapeutic Appropriateness _____ _____

Alert Message: The safety and effectiveness of Bylvay (odevixibat) for the treatment of pruritus in progressive familial intrahepatic cholestasis (PFIC) in adult patients, including those 65 years of age and older, have not been established.

Drugs/Diseases

Util A	Util B	Util C
Odevixibat		

Age Range: 18 - 999 yoa

References:
Bylvay Prescribing Information, Oct. 2022, Albireo Pharm, Inc.
Clinical Pharmacology, 2023 Elsevier/Gold Standard.

3. Odevixibat / Vitamin Deficiency _____ _____

Alert Message: Bylvay (odevixibat) may affect the absorption of fat-soluble vitamins (FSV). Obtain serum FSV levels at baseline and monitor during treatment, along with any clinical manifestations. If FSV deficiency is diagnosed, supplement with FSV. Discontinue odevixibat if FSV deficiency persists or worsens despite adequate FSV supplementation.

Drugs/Diseases

Util A	Util B	Util C
Odevixibat	Vitamin Deficiency A, D, E, & K	

References:
Bylvay Prescribing Information, Oct. 2022, Albireo Pharm, Inc.
Clinical Pharmacology, 2023 Elsevier/Gold Standard.

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

4. Odevixibat / Liver Test Abnormalities & Portal HTN _____ _____

Alert Message: Bylvay (odevixibat) can cause elevations of liver tests or worsening of liver tests relative to baseline values. Obtain baseline liver tests and monitor during treatment. Dose reduction or treatment interruption of odevixibat may be required if abnormalities occur. For persistent or recurrent liver test abnormalities, consider treatment discontinuation. Permanently discontinue treatment if a patient progresses to portal hypertension or experiences a hepatic decompensation event (e.g., variceal hemorrhage, ascites, hepatic encephalopathy).

Drugs/Diseases

Util A	Util B	Util C
Odevixibat	Abnormal Liver Function Studies	
	Ascites	
	Hepatic Encephalopathy	
	Portal Hypertension	
	Liver Failure	

References:

Bylvay Prescribing Information, Oct. 2022, Albireo Pharm, Inc.
Clinical Pharmacology, 2023 Elsevier/Gold Standard.

5. Odevixibat / Diarrhea _____ _____

Alert Message: Bylvay (odevixibat) treatment may cause diarrhea. If diarrhea occurs, monitor for dehydration and treat promptly. Interrupt odevixibat dosing if a patient experiences persistent diarrhea. Restart odevixibat at 40 mcg/kg/day when diarrhea resolves, and increase the dose as tolerated if appropriate. If diarrhea persists and no alternate etiology is identified, stop odevixibat treatment.

Drugs/Diseases

Util A	Util B	Util C
Odevixibat	Diarrhea	

References:

Bylvay Prescribing Information, Oct. 2022, Albireo Pharm, Inc.

6. Odevixibat / Bile Acid Resins _____ _____

Alert Message: Bile acid binding resins may bind Bylvay (odevixibat) in the gut, which may reduce odevixibat efficacy. Administer bile acid binding resins (e.g., cholestyramine, colesevelam, or colestipol) at least 4 hours before or 4 hours after administration of odevixibat.

Drugs/Diseases

Util A	Util B	Util C
Odevixibat	Cholestyramine	
	Colesevelam	
	Colestipol	

References:

Bylvay Prescribing Information, Oct. 2022, Albireo Pharm, Inc.
Clinical Pharmacology, 2023 Elsevier/Gold Standard.

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

7. Odevixibat / Pregnancy / Pregnancy Negating _____ _____

Alert Message: There are no human data on Bylvay (odevixibat) use in pregnant persons to establish a drug-associated risk of major birth defects, miscarriage, or adverse developmental outcomes. Based on findings from animal reproduction studies, odevixibat may cause cardiac malformations when a fetus is exposed during pregnancy.

Drugs/Diseases

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

Gender: Female
Age Range: 11 – 50 yoa

References:
Bylvay Prescribing Information, Oct. 2022, Albireo Pharm, Inc.
Clinical Pharmacology, 2023 Elsevier/Gold Standard.

8. Odevixibat / Lactation _____ _____

Alert Message: There are no data on the presence of Bylvay (odevixibat) in human milk, the effects on the breastfed infant, or the effects on milk production. Odevixibat has low absorption following oral administration, and breastfeeding is not expected to result in exposure of the infant to odevixibat at the recommended doses; however, odevixibat may reduce the absorption of fat-soluble vitamins (FSV). Monitor FSV levels and increase FSV intake, if FSV deficiency is observed during lactation. The developmental and health benefits of breastfeeding should be considered, along with the mother's clinical need for odevixibat and any potential adverse effects on the breastfed child from odevixibat or the underlying maternal condition.

Drugs/Diseases

Util A	Util B	Util C
Odevixibat	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Bylvay Prescribing Information, Oct. 2022, Albireo Pharm, Inc.
Clinical Pharmacology, 2023 Elsevier/Gold Standard.

9. Sotorasib / Overuse _____ _____

Alert Message: Lumakras (sotorasib) may be over-utilized. The recommended dosage of sotorasib is 960 mg (eight 120 mg tablets) orally once daily until disease progression or unacceptable toxicity.

Drugs/Diseases

Util A	Util B	Util C
Sotorasib		

Max Dose:

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Lumakras Prescribing Information, November 2022, Amgen Inc.

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

10. Sotorasib / Therapeutic Appropriateness _____ _____
Alert Message: The safety and effectiveness of Lumakras (sotorasib) have not been established in pediatric patients.

Drugs/Diseases

Util A	Util B	Util C
Sotorasib		

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Lumakras Prescribing Information, November 2022, Amgen Inc.

11. Sotorasib / Hepatotoxicity _____ _____
Alert Message: Lumakras (sotorasib) can cause hepatotoxicity, which may lead to drug-induced liver injury and hepatitis. Monitor liver function tests (ALT, AST, and total bilirubin) prior to the start of sotorasib, every 3 weeks for the first 3 months of treatment, then once a month or as clinically indicated, with more frequent testing in patients who develop transaminase and/or bilirubin elevations. Withhold, dose reduce or permanently discontinue sotorasib based on severity of adverse reaction.

Drugs/Diseases

Util A	Util B	Util C
Sotorasib		

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Lumakras Prescribing Information, November 2022, Amgen Inc.

12. Sotorasib / Interstitial Lung Disease & Pneumonitis _____ _____
Alert Message: Lumakras (sotorasib) can cause ILD/pneumonitis, which can be fatal. Monitor patients for new or worsening pulmonary symptoms indicative of ILD/pneumonitis (e.g., dyspnea, cough, fever). Immediately withhold sotorasib in patients with suspected ILD/pneumonitis and permanently discontinue sotorasib if no other potential causes of ILD/pneumonitis are identified.

Drugs/Diseases

Util A	Util B	Util C
Sotorasib	Cough	
	Dyspnea	
	Fever	
	Acute Interstitial Pneumonia	

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Lumakras Prescribing Information, November 2022, Amgen Inc.

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

13. Sotorasib / Proton Pump Inhibitors _____ _____

Alert Message: The solubility of Lumakras (sotorasib) is pH-dependent. Coadministration of sotorasib with gastric acid-reducing agents decreased sotorasib concentrations, which may reduce the efficacy of sotorasib. Avoid coadministration of sotorasib with proton pump inhibitors (PPIs), H2 receptor antagonists, and locally acting antacids. If coadministration with an acid-reducing agent cannot be avoided, administer sotorasib 4 hours before or 10 hours after administration of a locally acting antacid.

Drugs/Diseases

Util A	Util B	Util C
Sotorasib	Antacids	
	H-2 Blockers	
	PPIs	

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Lumakras Prescribing Information, November 2022, Amgen Inc.

14. Sotorasib / Strong CYP3A4 Inducers _____ _____

Alert Message: Avoid the coadministration of Lumakras (sotorasib) with strong CYP3A4 inducers. Sotorasib is a CYP3A4 substrate. Coadministration of sotorasib with a strong CYP3A4 inducer decreased sotorasib concentrations, which may reduce the efficacy of sotorasib.

Drugs/Diseases

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

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Lumakras Prescribing Information, November 2022, Amgen Inc.

15. Sotorasib / CYP3A4 Substrates w/ NTI _____ _____

Alert Message: Lumakras (sotorasib) is a CYP3A4 inducer. Coadministration of sotorasib with a CYP3A4 substrate has been shown in drug interaction studies to decrease the substrate plasma concentrations, which may reduce the efficacy of the substrate. Avoid coadministration of sotorasib with CYP3A4 sensitive substrates, for which minimal concentration changes may lead to therapeutic failures of the substrate. If concurrent use cannot be avoided, increase the sensitive CYP3A4 substrate dosage in accordance with the substrate's prescribing information.

Drugs/Diseases

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

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Lumakras Prescribing Information, November 2022, Amgen Inc.

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

16. Sotorasib / P-gp Substrates w/ NTI _____ _____

Alert Message: Lumakras (sotorasib) is a P-gp inhibitor. Coadministration of sotorasib with a P-gp substrate has been shown in drug interaction studies to increase the P-gp substrate plasma concentrations, which may increase the adverse reactions of the substrate. Avoid coadministration of sotorasib with P-gp substrates, for which minimal concentration changes may lead to serious toxicities. If coadministration cannot be avoided, decrease the P-gp substrate dosage in accordance with the substrate's official prescribing information.

Drugs/Diseases

Util A	Util B		Util C
Sotorasib	Cyclosporine	Sirolimus	
	Digoxin	Tacrolimus	
	Everolimus		

References:

Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Lumakras Prescribing Information, November 2022, Amgen Inc.

17. Sotorasib / BCRP Substrates _____ _____

Alert Message: Lumakras (sotorasib) is a BCRP inhibitor. Coadministration of sotorasib with a BCRP substrate has been shown in drug interaction studies to increase the substrate plasma concentrations, which may increase the risk of adverse reactions of the substrate. When coadministered with sotorasib, monitor for adverse reactions of the BCRP substrate and decrease the BCRP substrate dosage in accordance with the substrate's prescribing information.

Drugs/Diseases

Util A	Util B		Util C
Sotorasib	Alpelisib	Prazosin	
	Atorvastatin	Rosuvastatin	
	Dantrolene	Sulfasalazine	
	Dolutegravir	Talazoparib	
	Methotrexate	Tenofovir	
	Pazopanib	Topotecan	
	Pibrentasvir		

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Lumakras Prescribing Information, November 2022, Amgen Inc.

18. Sotorasib / Lactation _____ _____

Alert Message: There are no data on the presence of Lumakras (sotorasib) 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 sotorasib and for 1 week after the final dose.

Drugs/Diseases

Util A	Util B	Util C
Sotorasib	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Lumakras Prescribing Information, November 2022, Amgen Inc.

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

19. Sotorasib / Non-adherence _____ _____

Alert Message: Based on refill history, your patient may be under-utilizing Lumakras (sotorasib). 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

Sotorasib

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.
Greer JA, Amoyal N, Nisotel L, et al. Systemic Review of Adherence to Oral Antineoplastic Therapies. The Oncologist. 2016;21:354-376.
Barillet M, Prevost V, Joly F, Clarisse B. Oral Antineoplastic Agents: How do We Care About Adherence? Br J Clin Pharmacol. 2015;80(6):1289-1302. doi:10.1111/bcp.1273

20. Tasimelteon LQ / Overutilization _____ _____

Alert Message: The recommended dosage of Hetlioz LQ (tasimelteon oral suspension) in pediatric patients 3 to 15 years of age weighing more than 28 kg is 20 mg one hour before bedtime, at the same time every night. The recommended dosage in pediatric patients 3 to 15 years of age weighing 28 kg of less is 0.7 mg/kg one hour before bedtime, at the same time every night.

Drugs/Diseases

Util A Util B Util C

Tasimelteon LQ

Max Dose: 20 mg/day

Age Range 3 - 15 yoa

References:

Hetlioz & Hetlioz LQ Prescribing Information, Dec. 2020, Vanda Pharmaceuticals Inc.
Clinical Pharmacology, 2023, Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.

21. Tasimelteon LQ / Therapeutic Appropriateness _____ _____

Alert Message: The safety and effectiveness of Hetlioz LQ (tasimelteon oral suspension) for the treatment of nighttime sleep disturbances in SMS have not been established in patients younger than 3 years old.

Drugs/Diseases

Util A Util B Util C

Tasimelteon LQ

Age Range 0 – 2 yoa

References:

Hetlioz & Hetlioz LQ Prescribing Information, Dec. 2020, Vanda Pharmaceuticals Inc.
Clinical Pharmacology, 2023, Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.

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

22. Methylphenidate ER Tabs / Overutilization _____ _____

Alert Message: Relexxii (methylphenidate extended-release tablets) may be over-utilized. The manufacturer's recommended maximum daily dose of methylphenidate extended-release tablets for pediatric patients 6 to 12 years of age is 54 mg once daily.

Drugs/Diseases

Util A	Util B	Util C
Methylphenidate ER Tabs		

Max Dose: 54 mg/day

Age Range 6 - 12 yoa

References:

Relexxii Prescribing Information, June 2022, Vertical Pharmaceuticals, LLC.

Clinical Pharmacology, 2023, Elsevier/Gold Standard.

Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.

23. Opioids / CNS Depressants _____ _____

Alert Message: The concomitant use of opioids with CNS depressants, including alcohol, can increase the risk of hypotension, respiratory depression, profound sedation, coma, and death. Reserve concomitant prescribing of these drugs for use in patients for whom alternative treatment options are inadequate. Limit dosages and durations to the minimum required. Follow patients closely for signs of respiratory depression and sedation.

Drugs/Diseases

Util A	Util B	Util C
Benzhydrocodone	CNS Depressants	
Codeine		
Fentanyl		
Dihydrocodeine		
Hydrocodone		
Hydromorphone		
Levorphanol		
Meperidine		
Methadone		
Morphine		
Oxycodone		
Oxymorphone		
Tapentadol		
Tramadol		
Buprenorphine (pain)		

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

Criteria Recommendations ***Approved Rejected***

24. Dextromethorphan/Bupropion / Overuse _____ _____
Alert Message: Auvelity (dextromethorphan/bupropion) may be over-utilized. The maximum recommended dosage of dextromethorphan/bupropion is one tablet twice daily, given at least 8 hours apart. Do not exceed two doses within the same day.

Drugs/Diseases

Util A	Util B	Util C
Dextromethorphan/Bupropion		

Max Dose: 2 tablets/day

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Auvelity Prescribing Information, August 2022, Axsome Therapeutics.

25. Dextromethorphan/Bupropion / Therapeutic Appropriateness _____ _____
Alert Message: The safety and effectiveness of Auvelity (dextromethorphan/bupropion) have not been established in pediatric patients.

Drugs/Diseases

Util A	Util B	Util C
Dextromethorphan/Bupropion		

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Auvelity Prescribing Information, August 2022, Axsome Therapeutics.

26. Dextromethorphan/Bupropion / Contraindicated Disease States _____ _____
Alert Message: The use of Auvelity (dextromethorphan/bupropion) is contraindicated in patients with seizure disorders, a current or prior diagnosis of bulimia or anorexia nervosa, and those who are undergoing abrupt discontinuation of alcohol, benzodiazepines, barbiturates, and antiepileptic medications. The bupropion component of the combination product can cause seizures.

Drugs/Diseases

Util A	Util B	Util C (Include)
Dextromethorphan/Bupropion		Seizures Bulimia Anorexia

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Auvelity Prescribing Information, August 2022, Axsome Therapeutics.

Criteria Recommendations ***Approved Rejected***

27. Dextromethorphan/Bupropion / MAO Inhibitors _____ _____

Alert Message: The use of Auvelity (dextromethorphan/bupropion) is contraindicated in patients taking, or within 14 days of stopping, MAOIs due to the risk of serious and possibly fatal drug interactions, including hypertensive crisis and serotonin syndrome. Starting dextromethorphan/bupropion in a patient treated with reversible MAOIs such as linezolid or intravenous methylene blue is contraindicated.

Drugs/Diseases

Util A	Util B	Util C
Dextromethorphan/Bupropion	Isocarboxazid	
	Phenelzine	
	Tranylcypromine	
	Linezolid	
	Methylene Blue	

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Auvelity Prescribing Information, August 2022, Axsome Therapeutics.

28. Dextromethorphan/Bupropion / Severe Renal Impairment _____ _____

Alert Message: The pharmacokinetics of Auvelity (dextromethorphan/bupropion) have not been evaluated in patients with severe renal impairment. Dextromethorphan/bupropion is not recommended in patients with severe renal impairment (eGFR 15 to 29 mL/minute/1.73m2).

Drugs/Diseases

Util A	Util B	Util C (Include)
Dextromethorphan/Bupropion		CKD Stage 4

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Auvelity Prescribing Information, August 2022, Axsome Therapeutics.

29. Dextromethorphan/Bupropion / Severe Hepatic Impairment _____ _____

Alert Message: The pharmacokinetics of Auvelity (dextromethorphan/bupropion) have not been evaluated in patients with severe hepatic impairment. Dextromethorphan/bupropion is not recommended in patients with severe hepatic renal impairment (Child-Pugh C).

Drugs/Diseases

Util A	Util B	Util C (Include)
Dextromethorphan/Bupropion		Cirrhosis
		Liver Failure

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Auvelity Prescribing Information, August 2022, Axsome Therapeutics.

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

30. Dextromethorphan/Bupropion / Overuse – Mod Renal Imp. _____ _____
Alert Message: Auvelity (dextromethorphan/bupropion) may be over-utilized. The maximum recommended dosage of dextromethorphan/bupropion in patients with moderate renal impairment (eGFR 30 to 59 mL/min/1.73m2) is one tablet once daily in the morning.

Drugs/Diseases

Util A	Util B	Util C (Include)
Dextromethorphan/Bupropion		CKD Stage 3

Max Dose: 1 tablet/day

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Auvelity Prescribing Information, August 2022, Axsome Therapeutics.

31 Dextromethorphan/Bupropion / Strong CYP2D6 Inhibitors _____ _____
Alert Message: Concomitant use of Auvelity (dextromethorphan/bupropion) with strong CYP2D6 inhibitors increases plasma concentrations of the dextromethorphan component of the combination product. Dosage adjustment is necessary when dextromethorphan/bupropion is co-administered with strong inhibitors of CYP2D6. The recommended dosage of dextromethorphan/bupropion, when co-administered with strong CYP2D6 inhibitors, is one tablet once daily in the morning. Monitor patients for adverse reactions potentially attributable to dextromethorphan, such as somnolence and dizziness.

Drugs/Diseases

Util A	Util B	Util C (Include)
Dextromethorphan/Bupropion		Fluoxetine
		Dacomitinib
		Paroxetine
		Quinidine

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Auvelity Prescribing Information, August 2022, Axsome Therapeutics.

32. Dextromethorphan/Bupropion / Strong CYP2B6 Inducers _____ _____
Alert Message: Concomitant use of Auvelity (dextromethorphan/bupropion) with strong CYP2B6 inducers decreases plasma concentrations of both bupropion and dextromethorphan and may decrease efficacy. Avoid co-administration of dextromethorphan/bupropion with strong CYP2B6 inducers.

Drugs/Diseases

Util A	Util B	Util C
Dextromethorphan/Bupropion	Phenobarbital	

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Auvelity Prescribing Information, August 2022, Axsome Therapeutics.

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

33. Dextromethorphan/Bupropion / Drug That Decrease Seizure Threshold _____ _____

Alert Message: Coadministration of Auvelity (dextromethorphan/bupropion) and drugs that lower the seizure threshold should be approached with caution. Drugs such as antidepressants, antipsychotics, theophylline, and systemic steroids may have an additive effect with the bupropion component of the combination product, thereby increasing the risk of seizures.

Drugs/Diseases

Util A	Util B 1209	Util C
Dextromethorphan/Bupropion	Antidepressants	
	Antipsychotics	
	Baclofen	
	Metoclopramide	
	Theophylline	
	Tramadol	
	Steroids	

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Auvelity Prescribing Information, August 2022, Axsome Therapeutics.

34. Dextromethorphan/Bupropion / Pregnancy / Pregnancy Negating _____ _____

Alert Message: Based on animal studies, Auvelity (dextromethorphan/bupropion) may cause fetal harm when administered during pregnancy. Dextromethorphan/bupropion is not recommended during pregnancy. If a female becomes pregnant while being treated with dextromethorphan/bupropion, discontinue treatment and counsel the patient about the potential risk to a fetus.

Drugs/Diseases

Util A	Util B	Util C (Negating)
Dextromethorphan/Bupropion	Pregnancy	Abortion
		Delivery
		Miscarriage

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Auvelity Prescribing Information, August 2022, Axsome Therapeutics.

35. Dextromethorphan/Bupropion / Lactation _____ _____

Alert Message: Because of the potential for neurotoxicity, advise patients that breastfeeding is not recommended during treatment with Auvelity (dextromethorphan/bupropion) and for 5 days following the final dose.

Drugs/Diseases

Util A	Util B	Util C
Dextromethorphan/Bupropion	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Auvelity Prescribing Information, August 2022, Axsome Therapeutics.

Criteria Recommendations ***Approved Rejected***

36. Dextromethorphan/Bupropion / Non-adherence _____ _____
Alert Message: Based on refill history, your patient may be under-utilizing Auvelity (dextromethorphan/bupropion). 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
Dextromethorphan/Bupropion		

References:
Osterberg L, Blaschke T. Adherence to Medication. N Engl J Med 2005; 353:487- 497.
Iuga AO, McGuire MJ. Adherence and Health Care Costs. Risk Manag Healthc Policy. 2014 Feb 20;7:35-44.
Chong WW, Aslani P, Chen TF. Effectiveness of Interventions to Improve Antidepressant Medication Adherence: A Systematic Review. Int J Clin Pract. 2011 Sep;65(9)954-975.

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

37. Tivozanib / Overuse _____ _____
Alert Message: Fotivda (tivozanib) may be over-utilized. The recommended dosage of tivozanib is 1.34 mg taken orally once daily for 21 days on treatment, followed by 7 days off treatment for a 28-day cycle.

Drugs/Diseases

Util A	Util B	Util C (Negating)
Tivozanib		Moderate Hepatic Impairment Severe Hepatic Impairment

Max Dose: 1.34 mg/day

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Fotivda Prescribing Information, March 2021, Aveo Pharmaceuticals, Inc.

38. Tivozanib 1.34 mg / Overuse Hepatic Impairment _____ _____
Alert Message: Fotivda (tivozanib) may be over-utilized. The recommended dosage of tivozanib in patients with moderate hepatic impairment (total bilirubin > 1.5 to 3 times UKN with any AST) is 0.89 mg taken orally once daily for 21 days on treatment, followed by 7 days off treatment for a 28-day cycle. The recommended dosage of tivozanib in patients with severe hepatic impairment has not been established.

Drugs/Diseases

Util A	Util B	Util C
Tivozanib 1.34	Moderate Liver Impairment Severe Liver Impairment	

Max Dose: 0.89 mg/day

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Fotivda Prescribing Information, March 2021, Aveo Pharmaceuticals, Inc.

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

39. Tivozanib / Therapeutic Appropriateness _____ _____
Alert Message: The safety and effectiveness of Fotivda (tivozanib) in pediatric patients have not been established.

Drugs/Diseases

Util A	Util B	Util C
Tivozanib		

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Fotivda Prescribing Information, March 2021, Aveo Pharmaceuticals, Inc.

40. Tivozanib / Cardiac Failure _____ _____
Alert Message: Fotivda (tivozanib) can cause serious, sometimes fatal, cardiac failure. Tivozanib has not been studied in patients with symptomatic cardiac failure within the preceding 6 months before tivozanib treatment initiation. Periodically monitor patients for symptoms of cardiac failure throughout treatment with tivozanib. Management of cardiac failure events may require interruption, dose reduction, or permanent discontinuation of tivozanib therapy.

Drugs/Diseases

Util A	Util B	Util C
Tivozanib	Cardiac Failure	

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Fotivda Prescribing Information, March 2021, Aveo Pharmaceuticals, Inc.

41. Tivozanib / Hypertension _____ _____
Alert Message: Fotivda (tivozanib) can cause severe hypertension and hypertensive crisis. Control blood pressure prior to treatment with tivozanib. Monitor blood pressure after 2 weeks and at least monthly thereafter during treatment with tivozanib. Treat patients with antihypertensive therapy when hypertension occurs during treatment with tivozanib. Withhold tivozanib for severe hypertension despite optimal anti-hypertensive therapy. For persistent hypertension, despite the use of anti-hypertensive medications, reduce the tivozanib dose. Discontinue tivozanib if hypertension is severe and persistent despite anti-hypertensive therapy and dose reduction of tivozanib, or in patients who experience hypertensive crisis.

Drugs/Diseases

Util A	Util B	Util C (Negating)
Tivozanib	Hypertension	Antihypertensive Agents

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Fotivda Prescribing Information, March 2021, Aveo Pharmaceuticals, Inc.

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

42. Tivozanib / Cardiac Ischemia & Arterial Thromboembolic Events _____ _____

Alert Message: Fotivda (tivozanib) can cause serious, sometimes fatal, cardiac ischemia and arterial thromboembolic events. Tivozanib has not been studied in patients who had an arterial thrombotic event, myocardial infarction, or unstable angina within the preceding 6 months before tivozanib treatment initiation. Closely monitor patients who are at risk for or have a history of these events (such as myocardial infarction and stroke) during treatment with ‘ tivozanib. Discontinue tivozanib in patients who develop any severe or life-threatening arterial thromboembolic event.

Drugs/Diseases

Util A	Util B	Util C
Tivozanib	Arterial Embolism and Thrombosis	
	Myocardial Infarction	
	Unstable Angina	

References:

Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Fotivda Prescribing Information, March 2021, Aveo Pharmaceuticals, Inc.

43. Tivozanib / Venous Thromboembolic Events _____ _____

Alert Message: Fotivda (tivozanib) can cause serious, sometimes fatal, venous thromboembolic events. Closely monitor patients who are at risk for or have a history of these events during treatment with tivozanib. Discontinue tivozanib in patients who develop any severe or life-threatening venous thromboembolic event.

Drugs/Diseases

Util A	Util B	Util C
Tivozanib	Venous Embolism and Thrombosis	

References:

Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Fotivda Prescribing Information, March 2021, Aveo Pharmaceuticals, Inc.

44. Tivozanib / Hemorrhagic Events _____ _____

Alert Message: Fotivda (tivozanib) can cause serious, sometimes fatal, hemorrhagic events. Tivozanib has not been studied in patients with significant bleeding within the preceding 6 months before tivozanib treatment initiation. Closely monitor patients who are at risk for or who have a history of bleeding during treatment with tivozanib. Discontinue tivozanib in patients who develop severe or life-threatening hemorrhagic events.

Drugs/Diseases

Util A	Util B	Util C
Tivozanib	Hemorrhage	

References:

Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Fotivda Prescribing Information, March 2021, Aveo Pharmaceuticals, Inc.

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

45. Tivozanib / Proteinuria _____ _____

Alert Message: Fotivda (tivozanib) can cause proteinuria. In clinical trial experience, proteinuria occurred in 8% of tivozanib-treated patients, with 2% of events Grade 3. Of the patients who developed proteinuria, 3/81 (3.7%) had acute kidney injury either concurrently or later during treatment. Monitor patients for proteinuria before initiation of, and periodically throughout, treatment with tivozanib. For patients who develop moderate to severe proteinuria reduce the dose or interrupt tivozanib treatment. Discontinue tivozanib in patients who develop nephrotic syndrome.

Drugs/Diseases

Util A	Util B	Util C
Tivozanib	Proteinuria	

References:

Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Fotivda Prescribing Information, March 2021, Aveo Pharmaceuticals, Inc.

46. Tivozanib / Thyroid Dysfunction _____ _____

Alert Message: Fotivda (tivozanib) can cause thyroid dysfunction. In clinical trial experience, thyroid dysfunction events in tivozanib patients occurred in 11%, with 0.3% Grade 3 or 4 events. Hypothyroidism was reported in 8% of patients and hyperthyroidism was reported in 1% of patients. Monitor thyroid function before initiation of, and periodically throughout, treatment with tivozanib. Treat hypothyroidism and hyperthyroidism to maintain euthyroid state before and during treatment with tivozanib.

Drugs/Diseases

Util A	Util B	Util C
Tivozanib	Hyperthyroidism	
	Hypothyroidism	

References:

Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Fotivda Prescribing Information, March 2021, Aveo Pharmaceuticals, Inc.

47. Tivozanib / Reversible Posterior Leukoencephalopathy Syndrome _____ _____

Alert Message: Reversible posterior leukoencephalopathy syndrome (RPLS), a syndrome of subcortical vasogenic edema diagnosed by MRI, can occur with Fotivda (tivozanib). Evaluation for RPLS in any patient presenting with seizures, headaches, visual disturbances, confusion, or altered mental function. Discontinue tivozanib in patients who develop RPLS.

Drugs/Diseases

Util A	Util B	Util C
Tivozanib	Altered Mental Function	
	Headaches	
	Seizures	
	Visual Disturbances	

References:

Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Fotivda Prescribing Information, March 2021, Aveo Pharmaceuticals, Inc.

Criteria Recommendations	*Approved*	*Rejected*

48. Tivozanib / Strong CYP3A4 Inducers _____ _____

Alert Message: Avoid concomitant use of strong CYP3A inducers with Fotivda (tivozanib). Concomitant use of tivozanib with a strong CYP3A inducer decreases tivozanib exposure, which may reduce tivozanib anti-tumor activity.

Drugs/Diseases

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

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Fotivda Prescribing Information, March 2021, Aveo Pharmaceuticals, Inc.

49. Tivozanib / Pregnancy / Pregnancy Negating _____ _____

Alert Message: Based on findings from animal studies and its mechanism of action, Fotivda (tivozanib) can cause fetal harm when administered to a pregnant woman. In embryo-fetal developmental studies, oral administration of tivozanib to pregnant animals during the period of organogenesis caused maternal toxicity, fetal malformations, and embryo-fetal death at doses below the maximum recommended clinical dose on a mg/m2 basis. Advise the pregnant patient of the potential risk to the fetus.

Drugs/Diseases

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

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Fotivda Prescribing Information, March 2021, Aveo Pharmaceuticals, Inc.

50. Tivozanib / Lactation _____ _____

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

Drugs/Diseases

Util A	Util B	Util C
Tivozanib	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Fotivda Prescribing Information, March 2021, Aveo Pharmaceuticals, Inc.

51. Tivozanib / Therapeutic Appropriateness _____ _____
Alert Message: Advise females of reproductive potential to use effective contraception during treatment with Fotivda (tivozanib) and for one month after the last dose. Based on findings from animal studies and its mechanism of action, tivozanib can cause fetal harm when administered to a pregnant woman.

Drugs/Diseases

Util A	Util B	Util C (Negating)
Tivozanib		Contraceptives

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Fotivda Prescribing Information, March 2021, Aveo Pharmaceuticals, Inc.

52. Tivozanib / Therapeutic Appropriateness _____ _____
Alert Message: Advise males with female partners of reproductive potential to use effective contraception during treatment with Fotivda (tivozanib) and for one month after the last dose.

Drugs/Diseases

Util A	Util B	Util C
Tivozanib		

Gender: Male

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Fotivda Prescribing Information, March 2021, Aveo Pharmaceuticals, Inc.

53. Tivozanib / Non-adherence _____ _____
Alert Message: Based on refill history, your patient may be under-utilizing Fotivda (tivozanib). 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
Tivozanib		

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.

Greer JA, Amoyal N, Nisotel L, et al. Systemic Review of Adherence to Oral Antineoplastic Therapies. The Oncologist. 2016;21:354-376.

Barillet M, Prevost V, Joly F, Clarisse B. Oral Antineoplastic Agents: How do We Care About Adherence? Br J Clin Pharmacol. 2015;80(6):1289-1302. doi:10.1111/bcp.1273

Criteria Recommendations ***Approved Rejected***

54. Aripiprazole ER Injection 675mg / Therapeutic Appropriateness _____ _____
Alert Message: The safety and effectiveness of Aristada Initio (aripiprazole lauroxil extended-release injection) in patients less than 18 years of age have not been evaluated.

Drugs/Diseases

Util A	Util B	Util C
Aripiprazole 675mg Injection		

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Aristada Initio Prescribing Information, March 2021, Alkermes, Inc.

55. Aripiprazole ER Injection / Therapeutic Appropriateness _____ _____
Alert Message: The safety and effectiveness of Aristada (aripiprazole lauroxil extended-release injection) in patients less than 18 years of age have not been evaluated.

Drugs/Diseases

Util A	Util B	Util C
Aripiprazole ER Injection		

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Aristada Prescribing Information, March 2021, Alkermes, Inc.

56. Aripiprazole ER Injection 441mg / Strong CYP3A4 Inducers _____ _____
Alert Message: Aripiprazole is a CYP3A4 substrate, and concomitant use with a strong CYP3A4 inducer can result in decreased aripiprazole exposure. If Aristada 441 mg (aripiprazole extended-release injection) is used with a strong CYP3A4 inducer for more than 2 weeks, consider increasing the dose of aripiprazole to the next higher strength, 662 mg. No dosage adjustment is needed for the 662 mg, 882 mg, or 1064 mg dose.

Drugs/Diseases

Util A	Util B		Util C
Aripiprazole ER Inj 441mg	Apalutamide	Phenobarbital	
	Carbamazepine	Phenytoin	
	Enzalutamide	Primidone	
	Mitotane	Rifampin	

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Aristada Prescribing Information, March 2021, Alkermes, Inc.

57. Aripiprazole ER Injection / Strong 3A4 & 2D6 Inhibitors _____ _____

Alert Message: Aripiprazole is a CYP3A4 and CYP2D6 substrate, and concomitant use with a strong CYP3A4 or CYP2D6 inhibitor can result in increased aripiprazole exposure. If Aristada (aripiprazole lauroxil extended-release injection) is used with a strong CYP3A4 inhibitor or CYP2D6 inhibitor for more than 2 weeks, reduce the dose of aripiprazole to the next lower strength. No dosage adjustment is necessary for patients taking the 441 mg aripiprazole injection, if tolerated. Avoid the use of aripiprazole 662 mg, 882 mg, or 1064 mg with drugs that strongly inhibit both CYP3A4 and CPY2D6.

Drugs/Diseases

Util A	Util B	Util C
Aripiprazole ER Inj 662mg	Clarithromycin	Bupropion
Aripiprazole ER Inj 882mg	Cobicistat	Fluoxetine
Aripiprazole ER Inj 1064mg	Itraconazole	Paroxetine
	Ketoconazole	Quinidine
	Nefazodone	Terbinafine
	Nelfinavir	
	Posaconazole	
	Ritonavir	
	Voriconazole	

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Aristada Prescribing Information, March 2021, Alkermes, Inc

58. Aripiprazole ER 675 mg Injection / Aripiprazole ER Maintenance Injec _____ _____

Alert Message: Aristada Initio (aripiprazole lauroxil 675 mg extended-release injection) is only to be used as a single dose to initiate Aristada (aripiprazole lauroxil extended-release injection) treatment or as a single dose to re-initiate Aristada treatment following a missed dose of Aristada. Aristada Initio is not for repeated dosing.

Drugs/Diseases

Util A	Util B	Util C
Aristada Initio	Aristada	

Day Supply
Util A: Aristada Initio - 90 days
Util B: Aristada - 90 days

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Aristada Prescribing Information, March 2021, Alkermes, Inc

59. Paliperidone ER q 6 mo Injection / Therapeutic Appropriateness _____ _____

Alert Message: The safety and effectiveness of Invega Hafyera (6-month paliperidone extended-release injection) in patients less than 18 years of age have not been established. The use of extended-release injectable paliperidone is not recommended in pediatric patients because of the potential longer duration of an adverse event. In clinical trials of oral paliperidone, there were notably higher incidences of dystonia, hyperkinesia, tremor, and parkinsonism in the adolescent population as compared to the adult studies.

Drugs/Diseases

Util A	Util B	Util C
Paliperidone 6 mo Inject		

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Invega Hafyera Prescribing Information, August 2021, Janssen Pharmaceuticals, Inc.

60. Paliperidone ER q 6 mo Injection / Renal Impairment _____ _____

Alert Message: The use of Invega Hafyera (6-month paliperidone extended-release injection) is not recommended for use in patients with mild, moderate, or severe renal impairment (creatinine clearance < 90 mL/min) because necessary dosage adjustment is not possible with available strengths of the paliperidone injection. Paliperidone is substantially excreted by the kidney, and clearance is decreased in patients with renal impairment.

Drugs/Diseases

Util A	Util B	Util C
Paliperidone 6-Mo Inject	Renal Impairment	

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Invega Hafyera Prescribing Information, August 2021, Janssen Pharmaceuticals, Inc.

61. Paliperidone ER 3 mo Injection / Moderate to Severe Renal Impairment _____ _____

Alert Message: The use of Invega Trinza (3-month paliperidone extended-release injection) is not recommended in patients with moderate or severe renal impairment (creatinine clearance < 50 mL/min). Paliperidone is substantially excreted by the kidney, and clearance is decreased in patients with renal impairment.

Drugs/Diseases

Util A	Util B	Util C
Paliperidone 3 mo Inject	CKD Stage 3, 4 & 5 ESRD	

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Invega Trinza Prescribing Information, August 2021, Janssen Pharmaceuticals, Inc.

62. Paliperidone ER 3 mo Injection / Mild Renal Impairment _____ _____

Alert Message: Dose reduction of Invega Trinza (3-month paliperidone extended-release injection) is recommended for patients with mild renal impairment. Paliperidone is substantially excreted by the kidney, and clearance is decreased in patients with renal impairment. For patients with mild renal impairment (creatinine clearance >/= 50 mL/min to < 80 mL/min (Cockcroft-Gault Formula), adjust the dosage and stabilize the patient using the 1-month paliperidone palmitate extended-release injectable suspension, then transition to 3-month paliperidone extended-release injection.

Drugs/Diseases

Util A	Util B	Util C
Paliperidone 3 mo Inject	CKD Stage 2	

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Invega Trinza Prescribing Information, August 2021, Janssen Pharmaceuticals, Inc.

63. Paliperidone ER Monthly Injection / Mod to Severe Renal Impairment _____ _____

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

Drugs/Diseases

Util A	Util B	Util C
Paliperidone Monthly Inject	CKD Stage 3, 4 & 5 ESRD	

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Invega Sustenna Prescribing Information, July 2022, Janssen Pharmaceuticals, Inc.

64. Paliperidone ER 234 mg Monthly Injection / Mild Renal Impairment _____ _____

Alert Message: Dose reduction of Invega Sustenna (monthly paliperidone extended-release injection) is recommended for patients with mild renal impairment (creatinine clearance ≥ 50 mL/min to < 80 mL/min). Paliperidone is substantially excreted by the kidney and clearance is decreased in patients with renal impairment. The maximum monthly dose of the paliperidone injection is 156 mg for patients with mild renal impairment. Use of monthly paliperidone extended-release injection is not recommended in patients with moderate or severe renal impairment (creatinine clearance < 50 mL/min).

Drugs/Diseases

Util A	Util B	Util C
Paliperidone Monthly Inject 234mg	CKD Stage 2	

Max Dose: 156 mg/month

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Invega Sustenna Prescribing Information, July 2022, Janssen Pharmaceuticals, Inc.

Criteria Recommendations ***Approved Rejected***

65. Paliperidone ER Injections - All / Strong CYP3A4 & P-gp Inducers _____ _____

Alert Message: The concurrent use of paliperidone extended-release injection (e.g., Invega Sustenna, Invega Trinza, or Invega Hafyera) with a strong CYP3A4 or P-gp inducer may decrease the exposure to paliperidone. Paliperidone is a CYP3A4 and P-gp substrate. Avoid using strong CYP3A4 or P-gp inducers with a paliperidone injection during the dosing interval for the injection, if possible. If administering a strong inducer is necessary, consider managing the patient using paliperidone extended-release tablets.

Drugs/Diseases

Util A	Util B	Util C
Paliperidone Injections	Apalutamide	
	Carbamazepine	
	Phenobarbital	
	Phenytoin	
	Primidone	
	Rifampin	

References:

Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Invega Hafyera Prescribing Information, August 2021, Janssen Pharmaceuticals, Inc.
Invega Sustenna Prescribing Information, July 2022, Janssen Pharmaceuticals, Inc.
Invega Trinza Prescribing Information, August 2021, Janssen Pharmaceuticals, Inc.

66. Fingolimod / Overuse _____ _____

Alert Message: Tascenso ODT (fingolimod) may be over-utilized. The manufacturer's maximum recommended dose of fingolimod for adults and pediatric patients 10 years of age and older weighing more than 40 kg is 0.5 mg daily. In pediatric patients 10 years of age and older weighing less than or equal to 40 kg, the recommended dosage of fingolimod is 0.25 mg orally once daily.

Drugs/Diseases

Util A	Util B	Util C
Fingolimod		

Max Dose: 0.5 mg/day

Age Range: 10 – 999 yoa

References:

Tascenso ODT Prescribing Information, Dec. 2022, Cycle Pharmaceuticals Ltd.
Clinical Pharmacology, 2023 Elsevier/Gold Standard.

67. Fingolimod / Therapeutic Appropriateness _____ _____

Alert Message: The safety and effectiveness of Tascenso ODT (fingolimod) have not been established in patients less than 10 years of age.

Drugs/Diseases

Util A	Util B	Util C
Fingolimod		

Age Range: 0 – 9 yoa

References:

Tascenso ODT Prescribing Information, Dec. 2022, Cycle Pharmaceuticals Ltd.

Clinical Pharmacology, 2023 Elsevier/Gold Standard.

68. Fingolimod / Class Ia or Class III Antiarrhythmic Drugs _____ _____

Alert Message: Concurrent use of Tascenso ODT (fingolimod) with Class Ia or Class III antiarrhythmic drugs is contraindicated. Initiation of fingolimod results in decreased heart rate, and Class Ia/III antiarrhythmics have been associated with cases of torsades de pointes in patients with bradycardia.

Drugs/Diseases

Util A	Util B		Util C
Fingolimod	Quinidine (Ia)	Amiodarone (III)	
	Procainamide (Ia)	Sotalol (III)	
	Disopyramide (Ia)		

References:

Tascenso ODT Prescribing Information, Dec. 2022, Cycle Pharmaceuticals Ltd.

Clinical Pharmacology, 2023 Elsevier/Gold Standard.

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

69. Fingolimod / Cardiovascular Risk _____ _____

Alert Message: Tascenso ODT (fingolimod) is contraindicated in patients who have experienced myocardial infarction, unstable angina, stroke, TIA, decompensated heart failure requiring hospitalization, or Class III/IV heart failure in the last 6 months. Patients with these preexisting conditions may poorly tolerate fingolimod-induced bradycardia or experience serious rhythm disturbances after the first dose of fingolimod.

Drugs/Diseases

Util A	Util B	Util C (Include)
Fingolimod		Myocardial Infarction
		Unstable Angina
		Stroke/TIA
		Heart Failure

References:

Tascenso ODT Prescribing Information, Dec. 2022, Cycle Pharmaceuticals Ltd.

Clinical Pharmacology, 2023 Elsevier/Gold Standard.

70. Fingolimod / 2nd or 3rd Degree Heart Block & Sick Sinus Syndrome _____ _____

Alert Message: The use of Tascenso ODT (fingolimod) is contraindicated in patients with a history or presence of Mobitz Type II second- or third-degree atrioventricular (AV) block or sick sinus syndrome unless the patient has a functioning pacemaker.

Drugs/Diseases

Util A	Util B	Util C (Include)
Fingolimod		Mobitz Type II AV Block
		Sick Sinus Syndrome

References:

Tascenso ODT Prescribing Information, Dec. 2022, Cycle Pharmaceuticals Ltd.

Clinical Pharmacology, 2023 Elsevier/Gold Standard.

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

71. Fingolimod / QT Prolongation _____ _____

Alert Message: All patients should have an electrocardiogram (ECG) prior to initiation of Tascenso ODT (fingolimod) therapy. The use of fingolimod is contraindicated in patients with QT prolongation (defined as a baseline QTc interval >/= 500 msec).

Drugs/Diseases

Util A	Util B	Util C (Include)
Fingolimod		QT Prolongation

References:
Tascenso ODT Prescribing Information, Dec. 2022, Cycle Pharmaceuticals Ltd.
Clinical Pharmacology, 2023 Elsevier/Gold Standard.

72. Fingolimod / Macular Edema _____ _____

Alert Message: Patients with a history of uveitis and patients with diabetes mellitus are at increased risk of macular edema during Tascenso ODT (fingolimod) therapy. It is recommended that these patients undergo an adequate ophthalmologic evaluation and have regular follow-up evaluations while receiving fingolimod therapy.

Drugs/Diseases

Util A	Util B	Util C (Include)
Fingolimod		Diabetes Mellitus
		Uveitis

References:

Tascenso ODT Prescribing Information, Dec. 2022, Cycle Pharmaceuticals Ltd.

Clinical Pharmacology, 2023 Elsevier/Gold Standard.

73. Fingolimod / Increased Risk of Infection Meds _____ _____

Alert Message: Tascenso ODT (fingolimod) therapy leads to a dose-dependent reduction in peripheral lymphocyte count, and concomitant use with antineoplastic, immunosuppressive, or immune modulating therapies would be expected to increase the risk of immunosuppression.

Drugs/Diseases

Util A	Util B	Util C
Fingolimod	Antineoplastic Agents	
	Immunosuppressants	
	Immune Modulating therapies	

References:
Tascenso ODT Prescribing Information, Dec. 2022, Cycle Pharmaceuticals Ltd.
Clinical Pharmacology, 2023 Elsevier/Gold Standard.

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

74. Fingolimod / Ketoconazole _____ _____

Alert Message: Ketoconazole is a potent inhibitor of CYP3A and CYP4F. The blood levels of Tascenso ODT (fingolimod) and its active metabolite fingolimod-phosphate are increased by 1.7-fold when used concomitantly with ketoconazole. If ketoconazole and fingolimod must be co-administered, patients should be closely monitored, as the risk of adverse reactions is greater.

Drugs/Diseases

Util A	Util B	Util C
Fingolimod	Ketoconazole	

References:

Tascenso ODT Prescribing Information, Dec. 2022, Cycle Pharmaceuticals Ltd.
Clinical Pharmacology, 2023 Elsevier/Gold Standard.

75. Fingolimod / Cardiovascular Drugs _____ _____

Alert Message: Patients receiving concurrent therapy with Tascenso ODT (fingolimod) and drugs that slow heart rate or atrioventricular (AV) conduction (e.g., beta-blockers or digoxin) should be carefully evaluated prior to starting therapy. Concomitant treatment may be associated with severe bradycardia or heart block.

Drugs/Diseases

Util A	Util B	Util C
Fingolimod	Digoxin	
	Beta-blockers	
	Verapamil	
	Diltiazem	

References:

Tascenso ODT Prescribing Information, Dec. 2022, Cycle Pharmaceuticals Ltd.
Clinical Pharmacology, 2023 Elsevier/Gold Standard.

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

76. Fingolimod / Pregnancy / Pregnancy Negating _____ _____

Alert Message: Based on findings from animal studies, Tascenso ODT (fingolimod) may cause fetal harm when administered to a pregnant woman. In animal reproduction studies conducted in rats and rabbits, developmental toxicity was observed with administration of fingolimod at doses less than the recommended human dose. Advise pregnant women and females of reproductive potential of the potential risk to a fetus. Because it takes approximately 2 months to eliminate fingolimod from the body, advise females of reproductive potential to use effective contraception to avoid pregnancy during and for 2 months after stopping fingolimod treatment.

Drugs/Diseases

Util A	Util B	Util C (Negating)
Fingolimod	Pregnancy ICD-9s	Delivery
		Miscarriage
		Abortion

References:

Tascenso ODT Prescribing Information, Dec. 2022, Cycle Pharmaceuticals Ltd.

Clinical Pharmacology, 2023 Elsevier/Gold Standard.

77. Fingolimod / Lactation _____ _____

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

Drugs/Diseases

Util A	Util B	Util C
Fingolimod	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Tascenso ODT Prescribing Information, Dec. 2022, Cycle Pharmaceuticals Ltd.

Clinical Pharmacology, 2023 Elsevier/Gold Standard.

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

78. Fingolimod / Drugs that Prolong QT Interval _____ _____

Alert Message: Tascenso ODT (fingolimod) should be used with extreme caution with drugs that prolong the QT interval. Drugs that prolong the QT interval have been associated with cases of torsades de pointes in patients with bradycardia.

Drugs/Diseases

Util A	Util B				Util C
Fingolimod	Albuterol	Alfuzosin	Amantadine	Amitriptyline	
	Asenapine	Atazanavir	Atomoxetine	Azithromycin	
	Chloral Hydrate	Chloroquine	Chlorpromazine	Ciprofloxacin	
	Citalopram	Clarithromycin	Clomipramine	Clozapine	
	Crizotinib	Dasatinib	Desipramine	Diphenhydramine	
	Dofetilide	Dolasetron	Doxepin	Dronedarone	
	Droperidol	Erythromycin	Escitalopram	Famotidine	
	Felbamate	Fesoterodine	Flecainide	Fluconazole	
	Fluoxetine	Fluphenazine	Formoterol	Foscarnet	
	Fosphenytoin	Galantamine	Gemifloxacin	Granisetron	
	Haloperidol	Ibutilide	Iloperidone	Imipramine	
	Indapamide	Isradipine	Itraconazole	Lapatinib	
	Levalbuterol	Levofloxacin	Lithium	Maprotiline	
	Mefloquine	Methadone	Mexiletine	Moexipril	
	Moxifloxacin	Naratriptan	Nelfinavir	Nicardipine	
	Nilotinib	Norfloxacin	Nortriptyline	Octreotide	
	Ofloxacin	Ondansetron	Paliperidone	Paroxetine	
	Pazopanib	Pentamidine	Perphenazine	Pimozide	
	Posaconazole	Propafenone	Protriptyline	Quetiapine	
	Quinine	Ranolazine	Risperidone	Ritonavir	
	Salmeterol	Sertraline	Solifenacin	Tamoxifen	
	Sumatriptan	Sunitinib	Tacrolimus	Tocainide	
	Telithromycin	Thioridazine	Tizanidine	Tolterodine	
	Trazodone	Trifluoperazine	Trimipramine	Voriconazole	
	Vandetanib	Vardenafil	Venlafaxine	Ziprasidone	

*Amiodarone, disopyramide, ketoconazole, procainamide, quinidine and sotalol are not included. They are addressed in separate criteria.

References:
Tascenso ODT Prescribing Information, Dec. 2022, Cycle Pharmaceuticals Ltd.
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
AriCERT: Drugs that Prolong the QT Interval and/or Induce Torsades de Pointes.
Available at: www.azcer.org.

Criteria Recommendations	*Approved*	*Rejected*

79. Fingolimod / Severe Hepatic Impairment _____ _____

Alert Message: Because Tascenso ODT (fingolimod) exposure is doubled in patients with severe hepatic impairment, these patients should be closely monitored during treatment with fingolimod, as the risk of adverse reactions is greater.

Drugs/Diseases

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

References:

Tascenso ODT Prescribing Information, Dec. 2022, Cycle Pharmaceuticals Ltd.

Clinical Pharmacology, 2023 Elsevier/Gold Standard.

80. Fingolimod ODT / Nonadherence _____ _____

Alert Message: Based on refill history, your patient may be under-utilizing Tascenso ODT (fingolimod). 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 (Include)
Fingolimod ODT		

References:

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

McKay KA, Tremlett H, Patten SB, et al. Determinants of Non-Adherence to Disease-Modifying Therapies in Multiple Sclerosis: A Cross-Canada Prospective Study. Mult Scler. 2016;23(4):588-596.

Joplin S, van der Zwan R, Joshua F, Wong PK. Medication Adherence in Patients with Rheumatoid Arthritis: The Effect of Patient Education, Health Literacy, and Musculoskeletal Ultrasound. Biomed Res Int. 2015;2015:150658.

Criteria Recommendations ***Approved Rejected***

81. Ca/Mg/K/Na Oxybates / Overuse (Adults) _____ _____
Alert Message: Xywav (calcium/magnesium/potassium/sodium oxybates) may be over-utilized. The recommended dosage range for adults with narcolepsy and idiopathic hypersomnia is 6 to 9 mg per night. Doses higher than 9 g per night have not been studied and ordinarily should not be administered.

Drugs/Diseases

Util A	Util B	Util C
Ca/Mg/K/Na Oxybates		

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

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Xywav Prescribing Information, March 2022, Jazz Pharmaceuticals, Inc.

82. Ca/Mg/K/Na Oxybates / Overuse – Narcolepsy (Pediatric) _____ _____ Alert Message: For pediatric patients 7 years of age and older, Xywav (calcium/magnesium/potassium/sodium oxybates) is administered orally twice per night. The recommended starting pediatric dosage, titration regimen, and maximum total nightly dosage are based on patient weight. The dosage may be gradually titrated based on efficacy and tolerability. Refer to the official prescribing information for pediatric dosing. Doses higher than 9 g per night have not been studied and ordinarily should not be administered.

Drugs/Diseases

Util A	Util B	Util C (Include)
Ca/Mg/K/Na Oxybates		Narcolepsy w/ cataplexy

Max Dose: 9 g/day
Age Range: 7 - 17 yoa

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Xywav Prescribing Information, March 2022, Jazz Pharmaceuticals, Inc.

83. Ca/Mg/K/Na Oxybates / Therapeutic Appropriateness (Pediatric) _____ _____
Alert Message: The safety and effectiveness of Xywav (calcium/magnesium/potassium/sodium oxybates) for the treatment of cataplexy or excessive daytime sleepiness in pediatric patients below the age of 7 years have not been established.

Drugs/Diseases

Util A	Util B	Util C (Include)
Ca/Mg/K/Na Oxybates		Narcolepsy w/ Cataplexy

Age Range: 0 – 6 yoa

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Xywav Prescribing Information, March 2022, Jazz Pharmaceuticals, Inc.

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

84. Ca/Mg/K/Na Oxybates / Therapeutic Appropriateness _____ _____

Alert Message: The safety and effectiveness of Xywav (calcium/magnesium/potassium/sodium oxybates) for the treatment of idiopathic hypersomnia in pediatric patients have not been established.

Drugs/Diseases

Util A	Util B	Util C (Include)
Ca/Mg/K/Na Oxybates		Idiopathic hypersomnia

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Xywav Prescribing Information, March 2022, Jazz Pharmaceuticals, Inc.

85. Ca/Mg/K/Na Oxybates / Black Box Warning _____ _____

Alert Message: The active moiety of Xywav (calcium/magnesium/potassium/sodium oxybates) is oxybate or gamma-hydroxybutyrate (GHB). Abuse or misuse of illicit GHB, either alone or in combination with other CNS depressants, is associated with CNS adverse reactions, including seizure, respiratory depression, decreases in the level of consciousness, coma, and death. Because illicit use and abuse of GHB have been reported, healthcare providers should carefully evaluate patients for a history of drug abuse and follow them closely, particularly for signs of misuse or abuse of GHB. If abuse is suspected, treatment with Ca/Mg/K/Na oxybates should be discontinued.

Drugs/Diseases

Util A	Util B	Util C
Ca/Mg/K/Na Oxybates	History of Drug Abuse	

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Xywav Prescribing Information, March 2022, Jazz Pharmaceuticals, Inc.

86. Ca/Mg/K/Na Oxybates / Contraindication _____ _____

Alert Message: Xywav (calcium/magnesium/potassium/sodium oxybates) is contraindicated for use in patients with succinic semialdehyde dehydrogenase deficiency.

Drugs/Diseases

Util A	Util B	Util C (Include)
Ca/Mg/K/Na Oxybate		Succinic Semialdehyde Dehydrogenase Deficiency

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Xywav Prescribing Information, March 2022, Jazz Pharmaceuticals, Inc.

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

87. Ca/Mg/K/Na Oxybates / Sedative Hypnotics (Contraindication) _____ _____

7lert Message: Xywav (calcium/magnesium/potassium/sodium oxybates) is contraindicated in combination with alcohol and sedative-hypnotics. The calcium/magnesium/potassium/sodium oxybates product is a central nervous system (CNS) depressant. Clinically significant respiratory depression and obtundation have occurred in adult patients taking sodium oxybate (the same active moiety as Ca/Mg/K/Na oxybates) at recommended doses in clinical trials and may occur in patients treated with Ca/Mg/K/Na oxybates at recommended doses.

Drugs/Diseases

Util A	Util B		Util C
Ca/Mg/K/Na Oxybates	Estazolam	Temazepam	
	Eszopiclone	Triazolam	
	Flurazepam	Zaleplon	
	Lemborexant	Zolpidem	
	Quazepam		
	Phenobarbital		
	Ramelteon		
	Suvorexant		
	Tasimelteon		

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Xywav Prescribing Information, March 2022, Jazz Pharmaceuticals, Inc.

88. Ca/Mg/K/Na Oxybates / Divalproex Sodium _____ _____

Alert Message: The concurrent use of Xywav (calcium/magnesium/potassium/sodium oxybates) with divalproex sodium may result in an increased risk of CNS depression. In drug studies, coadministration of sodium oxybate and divalproex sodium resulted in 25% increase in the sodium oxybate AUC. When initiating divalproex sodium in patients taking a stable dosage of Ca/Mg/K/Na oxybates, a reduction of the Ca/Mg/K/Na oxybates dosage by at least 20% is recommended with initial concomitant use. When initiating Ca/Mg/K/Na oxybate in patients already taking divalproex sodium, a lower starting dosage of Ca/Mg/K/Na oxybate is recommended. Subsequently, the dosage of Ca/Mg/K/Na oxybates can be adjusted based on individual clinical response and tolerability.

Drugs/Diseases

Util A	Util B	Util C
Ca/Mg/K/Na Oxybates	Divalproex Sodium	

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Xywav Prescribing Information, March 2022, Jazz Pharmaceuticals, Inc.

89. Ca/Mg/K/Na Oxybates / CNS Depressants _____ _____

Alert Message: The concurrent use of Xywav (calcium/magnesium/potassium/sodium oxybates) with other CNS depressants may increase the risk of respiratory depression, hypotension, profound sedation, syncope, and death. The Ca/Mg/K/Na oxybates product is a central nervous system depressant. If the use of CNS depressants in combination with Ca/Mg/K/Na oxybates is required, dose reduction or discontinuation of one or more CNS depressants (including Ca/Mg/K/Na oxybates) should be considered.

Drugs/Diseases

Util A	Util B	Util C
Ca/Mg/K/Na Oxybates	CNS Depressants	

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Xywav Prescribing Information, March 2022, Jazz Pharmaceuticals, Inc.

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

90. Ca/Mg/K/Na Oxybates / Depression & Suicide _____ _____

Alert Message: Depression, and suicidal ideation and behavior can occur in patients treated with Xywav (calcium/magnesium/potassium/sodium oxybates). The emergence of depression in patients treated with Ca/Mg/K/Na oxybates requires careful and immediate evaluation. Patients with a previous history of a depressive illness and/or suicide attempt should be monitored carefully for the emergence of depressive symptoms while taking Ca/Mg/K/Na oxybates.

Drugs/Diseases

Util A	Util B	Util C
Ca/Mg/K/Na Oxybates	Depression	
	Suicidal Ideation	

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Xywav Prescribing Information, March 2022, Jazz Pharmaceuticals, Inc.

91. Ca/Mg/K/Na Oxybates / Pregnancy / Pregnancy Negating _____ _____

Alert Message: There are no adequate data on the developmental risks associated with the use of Xywav (calcium/magnesium/potassium/sodium oxybates) during human pregnancy. Animal studies produced no clear evidence of developmental toxicity; however, increased stillbirths and decreased postnatal viability and growth were seen at clinically relevant doses.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Ca/Mg/K/Na Oxybates	Pregnancy	Abortion
		Delivery
		Miscarriage

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Xywav Prescribing Information, March 2022, Jazz Pharmaceuticals, Inc.

92. Ca/Mg/K/Na Oxybates / Lactation _____ _____

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

Drugs/Diseases

Util A	Util B	Util C
Ca/Mg/K/Na Oxybates	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Facts & Comparisons, 2021 Updates, Wolters Kluwer Health.
Xywav Prescribing Information, March 2022, Jazz Pharmaceuticals, Inc.

North Dakota Medicaid
Drug Utilization Review Board Meeting
September 6, 2023
Conference Room 210/212

NORTH Dakota
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| Health & Human Services

NORTH Dakota | Health & Human Services
Be Legendary.

Meeting Notice

North Dakota Medicaid Drug Use Review Board

Wednesday, September 6th, 2023
1 to 4 p.m. Central Time

In-Person Information

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

Virtual Information

Join virtually: Click here to join the meeting
Join by phone: 701-328-0950, Conference ID: 617 220 993#

Agenda

1. Call to Order
2. Roll Call
3. Review and Approval of Minutes
4. Reports from Department
    - Administrative Report: Unwinding, Humira biosimilars, RSV
    - Financial Report: Budget, Top Drugs
    - Clinical Report:
        - Prior authorization update
        - Annual PDL Review Criteria Updates for Gout, Chronic Kidney Disease, Heart Failure, Long-Acting Opioid Analgesics, Opioid Use Disorder, Clostridioides difficile-associated diarrhea (CDAD), Medications over $3000
    - Retrospective DUR report
5. Unfinished Business
    - Update to Hyperparathyroidism (Sensipar)
6. New business
    - First Review of Diuretics (triamterene)
    - First Review of Menopause (Veozah)
    - Review of retrospective DUR criteria recommendations
7. Announcements
    - Next Meeting (December 6th, 2023)
8. Adjourn

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

Meeting Minutes
North Dakota Medicaid Drug Use Review (DUR) Board
Meeting Date: June 7th, 2023
Time and Location: 1:00 pm CST in Bismarck, North Dakota

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

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

Call to Order:
A regular quarterly meeting of the North Dakota Medicaid Drug Use Review (DUR) Board meeting was convened at 1:02 pm CST. with pro tem Presiding Officer K. Martian presiding, and DUR Board Coordinator, C. Stauter recording minutes. In Presiding Officer T. Schmidt's absence, K. Martian served as Presiding Officer pro tem.

Approval of Meeting Minutes:
The minutes of the March 1, 2023, meeting were approved as distributed.

Reports:
*Administrative Report***:** *Legislative Update* provided by A. Murphy
A. Murphy shared with the Board all changes made affecting the DUR Board from Senate Bill 2156, effective August 1, 2023. These changes can be found in the handout.

*Administrative Report***:** *Robert's Rules of Order* provided by A. Murphy
A. Murphy shared with the Board all changes made affecting the DUR Board elections, debate, minutes, old business, first and second reviews, and adjournment. These changes can be found in the handout.

*Administrative Report***:** *Member Update* provided by A. Murphy
A. Murphy introduced the new Board Member S. Antony. L. Morgan introduced the new DUR Board Coordinator C. Stauter.

Financial Report: Budget provided by A. Murphy
A. Murphy shared with the Board the history of ND Medicaid pharmacy spending and rebates. These specifics can be found in the handout.

Financial Report: Top Drugs provided by L. Morgan
L. Morgan 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.

Clinical Report: Prior Authorization Update provided by A. Murphy
A. Murphy shared with the Board new medications requiring prior authorizations. This list can be found in the handout.

Clinical Report: Criteria Update
Update to Hepatitis C provided by A. Murphy
A. Murphy discussed the changes to the hepatitis C section to the PDL. L. Morgan presented the updated prior authorization form and consent forms for discussion. These changes can be found in the handout.

Update to Chronic Kidney Disease (Filspari) provided by L. Morgan

L. Morgan discussed the changes to the chronic kidney disease section to the PDL for discussion. These changes can be found in the handout.

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

Special Orders:
Presiding Officer and Vice-Presiding Officer Elections
Nomination by J. Askvig for T. Schmidt as Presiding Officer, motion was seconded, **motion carried.**
Nomination by J. Askvig for A. Honeyman as Vice-Presiding Officer, motion was seconded, **motion carried.**

New Business:
L. Morgan presented an overview of hyperparathyroidism, influenza, neuromyelitis optica spectrum disorder, and urea cycle agents. The presented material can be found in the handout.

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

Second Review of Hyperparathyroidism:
Motion: Moved by K. Martian for the Department to adopt criteria as distributed for hyperparathyroidism, motion was seconded. **Motion carried.**

Second Review of Influenza:
Motion: Moved by K. Martian for the Department to adopt criteria as distributed for influenza, motion was seconded. **Motion carried.**

Second Review of Neuromyelitis Optica Spectrum Disorder:
Motion: Moved by J. Askvig for the Department to adopt criteria as distributed for neuromyelitis optica spectrum disorder, motion was seconded. **Motion carried.**

Second Review of Urea Cycle Agents:
Motion: Moved by K. Martian for the Department to adopt criteria as distributed for urea cycle agents, motion was seconded. **Motion carried.**

Retrospective Drug Utilization Review (RDUR) Criteria Recommendations:
Motion: Moved by J. Askvig to approve the RDUR criteria, motion was seconded. **Motion carried.**

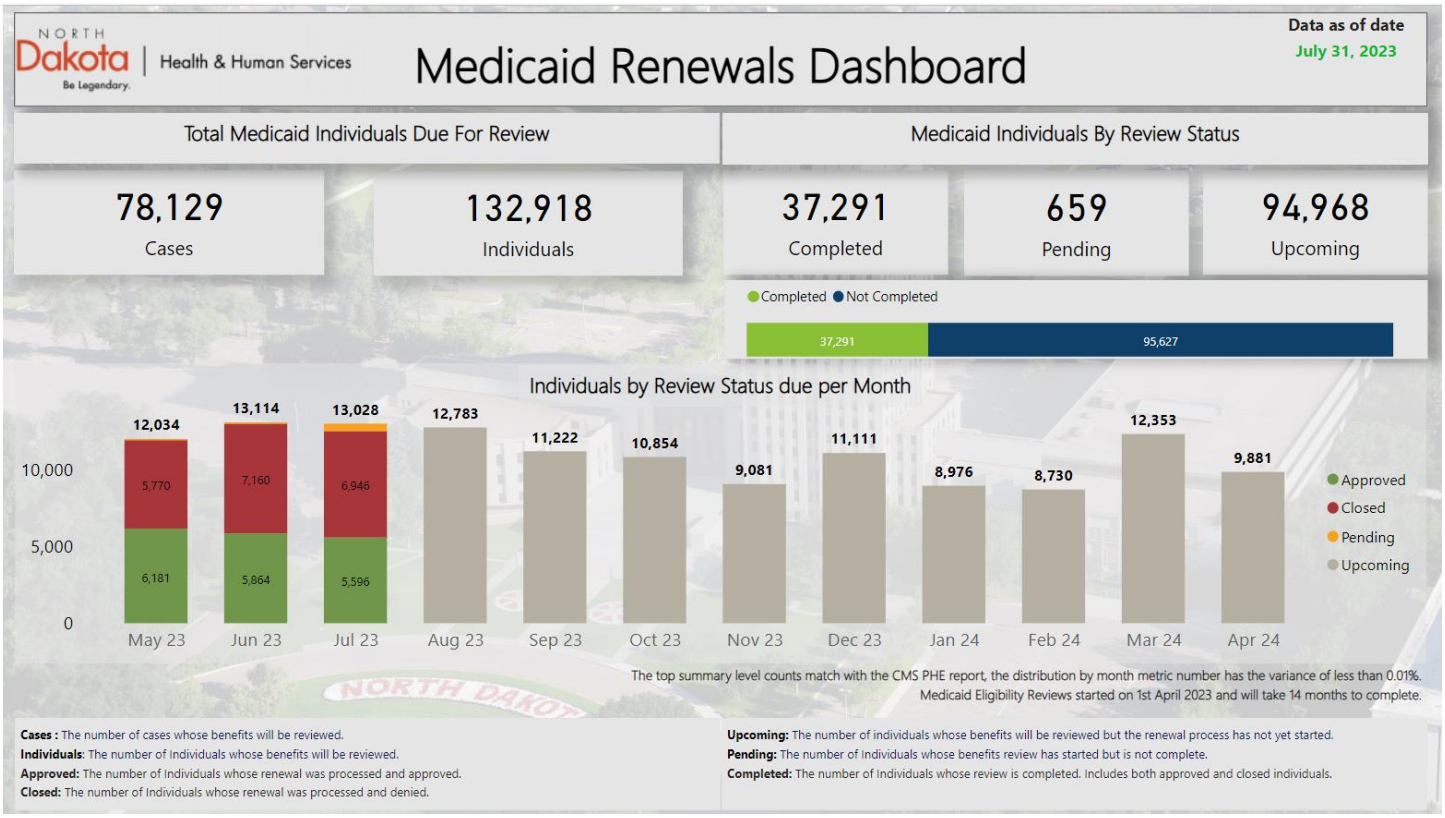
Announcements:
Next meeting is September 6th, 2023.

Adjournment:
Meeting adjourned by K. Martian at 2:25 pm CST.

Date of Minutes Approval:
Minutes submitted by: Claire Stauter, Kepro

Unwinding:

https://www.hhs.nd.gov/medicaid/data > Medicaid Renewals:



RSV:

ACIP and AAP Recommendations for Nirsevimab | Red Book Online | American Academy of Pediatrics

Advisory Committee on Immunization Practices (ACIP) Recommendations:

On August 3, 2023, the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention (CDC) recommended use of nirsevimab as indicated in its FDA package insert:

- Infants aged <8 months born during or entering their first Respiratory Syncytial Virus (RSV) season are recommended to receive one dose of nirsevimab (50 mg for infants <5 kg and 100 mg for infants ≥5 kg).
- Children aged 8–19 months who are at increased risk of severe RSV disease and entering their second RSV season are recommended to receive one dose of nirsevimab (200 mg).

The ACIP also voted for inclusion of nirsevimab in the Vaccines for Children (VFC) program.

American Academy of Pediatrics (AAP) Recommendations

American Academy of Pediatrics Recommendations for the 2023–2024 RSV season with regard to palivizumab versus nirsevimab administration for high-risk infants during the same RSV season:

- If nirsevimab is administered, palivizumab should not be administered later that season.
- If palivizumab was administered initially for the season and <5 doses were administered, the infant should receive 1 dose of nirsevimab. No further palivizumab should be administered.
- If palivizumab was administered in season 1 and the child is eligible for RSV prophylaxis in season 2, the child should receive nirsevimab in season 2, if available. If nirsevimab is not available, palivizumab should be administered as previously recommended.

No recommendations from AAP/ACIP for use with monoclonal antibody prophylaxis:

Vaccine for respiratory syncytial virus (RSV) : Abrysvo

- For protection of infants from the virus from birth to 6 months of age to be given between weeks 32 and 36 of pregnancy (Approved August 2023)
- For protection of people aged 60 years and older (Approved May 2023)

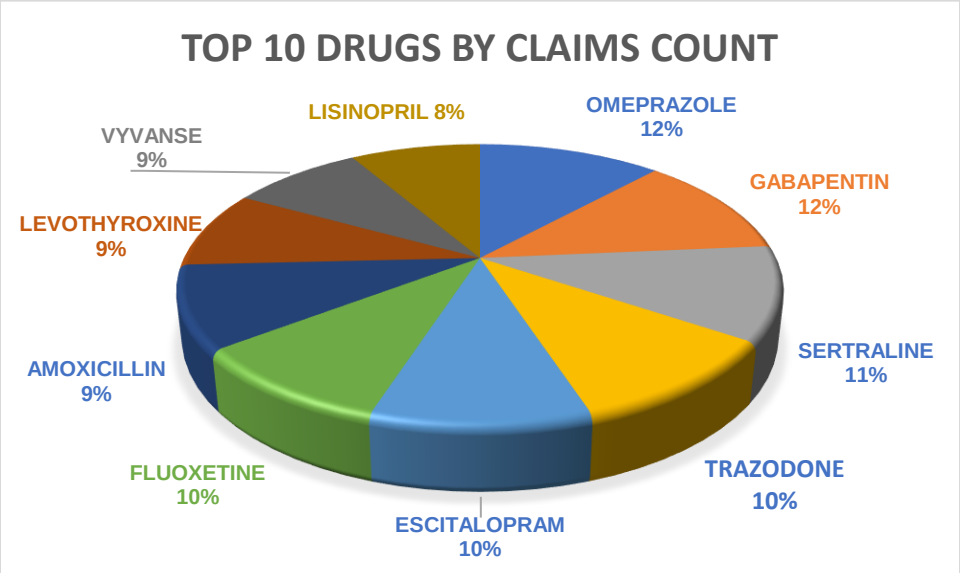
North Dakota Medicaid Plan

- Beyfortus (nirsevimab) is expected to be available in the U.S. ahead of the upcoming 2023-2024 RSV season.
- The North Dakota Department of Health and Human Services Immunization Unit supplies free vaccines for children who are eligible for the Vaccines for Children (VFC) program.
- ND Medicaid will not provide RSV prophylaxis (Synagis or Beyfortus) coverage for infants eligible to receive Beyfortus through the VFC program.
- Continue to monitor AAP/ACIP recommendations for updates regarding use of Abrysvo.

Top 25 Drugs Based on Number of Claims from 04/01/2023 – 06/30/2023

Drug	Claims	Claims Cost	Patients	Cost / Claim	% Total Claims	Dif.
1. OMEPRAZOLE	4,780	$61,334.67	2,452	$12.83	1.8%	NC
2. GABAPENTIN	4,756	$70,617.96	2,047	$14.85	1.8%	NC
3. SERTRALINE HCL	4,438	$60,082.07	2,548	$13.54	1.7%	NC
4. TRAZODONE HCL	4,034	$54,266.42	2,068	$13.45	1.5%	NC
5. ESCITALOPRAM	4,029	$54,166.97	2,369	$13.44	1.5%	↑1
6. FLUOXETINE HCL	3,967	$52,665.49	2,178	$13.28	1.5%	↑1
7. AMOXICILLIN	3,745	$53,781.88	3,529	$14.36	1.4%	↓2
8. LEVOTHYROXINE	3,558	$56,732.96	1,904	$15.95	1.3%	↑1
9. VYVANSE	3,445	$959,714.37	1,456	$278.58	1.3%	↓1
10. LISINOPRIL	3,408	$44,206.91	2,082	$12.97	1.3%	NC
11. ATORVASTATIN	3,311	$46,943.20	1,978	$14.18	1.2%	NC
12. BUPROPION XL	3,269	$55,023.40	1,806	$16.83	1.2%	NC
13. PANTOPRAZOLE	3,142	$43,799.50	1,565	$13.94	1.2%	NC
14. VENTOLIN HFA	3,049	$195,110.70	3,023	$63.99	1.1%	↑9
15. HYDROCODONE-APAP	2,812	$40,883.63	1,788	$14.54	1.0%	↓1
16. CYCLOBENZAPRINE	2,730	$31,639.66	1,737	$11.59	1.0%	↓1
17. DULOXETINE HCL	2,722	$44,150.27	1,448	$16.22	1.0%	↓1
18. CLONIDINE HCL	2,688	$32,921.20	1,355	$12.25	1.0%	NC
19. HYDROXYZINE HCL	2,653	$35,848.70	1,667	$13.51	1.0%	↑2
20. PREDNISONE	2,623	$31,457.70	2,148	$11.99	1.0%	NC
21. LAMOTRIGINE	2,597	$36,996.03	1,116	$14.25	1.0%	↑3
22. AMOXICILLIN-CLAV	2,487	$44,172.95	2,336	$17.76	0.9%	↓5
23. BUP-NALOXONE	2,472	$105,145.74	667	$42.53	0.9%	↓1
24. BUSPIRONE HCL	2,371	$36,045.20	1,329	$15.20	0.9%	↑1
25. AMLODIPINE	2,350	$30,116.93	1,363	$12.82	0.9%	↑4

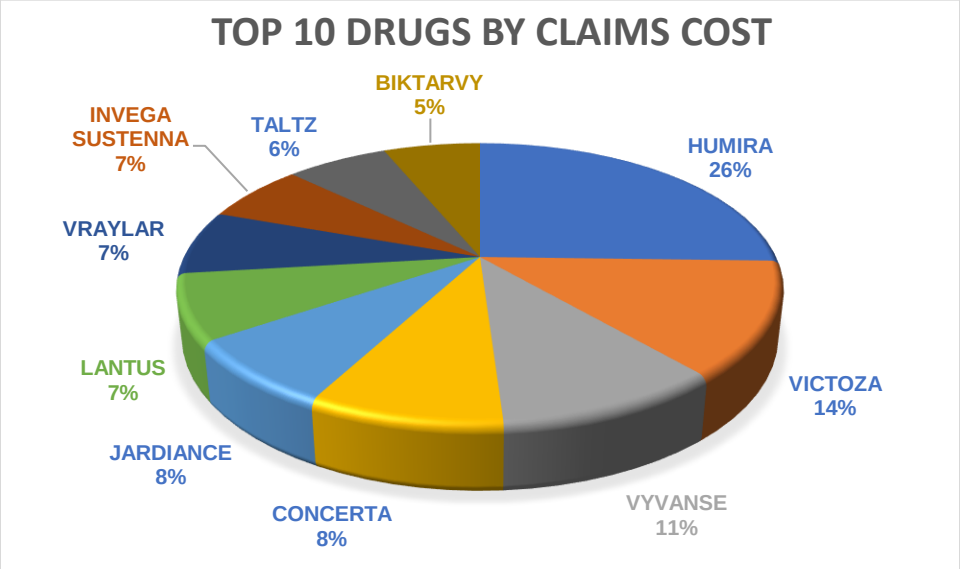
Total Claims	**268,762**



Top 25 Drugs Based on Total Claims Cost from 04/01/2023 – 06/30/2023

Drug	Claims	Claims Cost	Patients	Cost / Patient	% Total Cost	Dif.
1. HUMIRA	298	$2,369,800.15	129	$36,805.07	6.8%	NC
2. VICTOZA	1,440	$1,280,526.06	722	$3,437.17	3.7%	NC
3. VYVANSE	3,445	$959,714.37	1,456	$659.14	2.8%	NC
4. CONCERTA	2,021	$742,939.96	878	$846.17	2.1%	NC
5. JARDIANCE	1,054	$719,714.34	562	$1,280.63	2.1%	↑1
6. LANTUS SOLOSTAR	1,315	$674,274.62	815	$827.33	1.9%	↓1
7. VRAYLAR	627	$606,021.84	267	$2,269.74	1.7%	↑5
8. INVEGA SUSTENNA	234	$603,537.30	94	$6,420.61	1.7%	↓1
9. TALTZ	90	$563,834.38	37	$15,238.77	1.6%	↓1
10. BIKTARVY	246	$474,504.98	121	$3,921.53	1.4%	NC
11. STELARA	19	$449,263.66	16	$28,078.98	1.3%	↓2
12. ADDERALL XR	2,210	$407,926.75	972	$419.68	1.2%	↑2
13. MAVYRET	33	$404,248.01	21	$19,249.91	1.2%	↓3
14. ELIQUIS	706	$398,791.14	341	$1,169.48	1.1%	↓1
15. TRIKAFTA	19	$396,954.88	8	$49,619.36	1.1%	↑4
16. SYMBICORT	1,100	$386,516.13	640	$603.93	1.1%	NC
17. NORDITROPIN	85	$359,585.00	40	$8,989.63	1.0%	↑4
18. ADVAIR DISKUS	914	$342,726.20	506	$677.32	1.0%	↓1
19. NOVOLOG FLEXPEN	452	$340,017.54	287	$1,184.73	1.0%	↓1
20. ABILIFY MAINTENA	121	$288,510.77	49	$5,887.97	0.8%	NC
21. DUPIXENT PEN	88	$281,760.55	38	$7,414.75	0.8%	↑1
22. SOFO-VELPATASVIR	35	$273,263.30	15	$18,217.55	0.8%	↑17
23. XIFAXAN	93	$251,608.20	45	$5,591.29	0.7%	NC
24. SUBLOCADE	129	$249,351.84	60	$4,155.86	0.7%	↑10
25. LEVEMIR FLEXPEN	403	$248,682.67	251	$990.77	0.7%	↑2

Total Claims Cost	**$34,870,800.35**



Top 15 Therapeutic Classes Based on Number of Claims from 04/01/2023 – 06/30/2023

Therapeutic Class Description	Claims	Claims Cost	Patients	Cost/Claim	% Total Claims	Dif.
1. ANTIDEPRESSANTS	30,485	$660,732.16	13,096	$21.67	11.3%	NC
2. ANTICONVULSANTS	13,862	$551,732.40	5,065	$39.80	5.2%	NC
3. ANTIPSYCHOTICS	9,672	$2,433,160.77	3,922	$251.57	3.6%	NC
4. PPI'S	8,322	$157,833.32	4,160	$18.97	3.1%	NC
5. ANXIOLYTICS, SEDATIVES, HYPNOTICS	7,696	$111,802.75	4,041	$14.53	2.9%	NC
6. AMPHETAMINES	7,175	$1,423,056.31	3,065	$198.34	2.7%	NC
7. OPIATE AGONISTS	6,865	$108,986.71	3,680	$15.88	2.6%	↑1
8. PENICILLIN ANTIBIOTICS	6,564	$103,267.77	5,932	$15.73	2.4%	↓1
9. NSAIDS	6,416	$89,525.82	4,314	$13.95	2.4%	NC
10. STATINS	5,910	$85,875.84	3,491	$14.53	2.2%	↑1
11. RESP/CNS STIMULANTS	5,723	$957,880.83	2,250	$167.37	2.1%	↓1
12. BETA BLOCKING AGENTS	5,566	$99,228.03	3,125	$17.83	2.1%	NC
13. ADRENALS	4,374	$59,273.88	3,505	$13.55	1.6%	NC
14. BETA AGONISTS	4,333	$261,176.56	3,970	$60.28	1.6%	NC
15. ACE INHIBITORS	4,238	$67,143.00	2,567	$15.84	1.6%	NC

Top 15 Therapeutic Classes Based on Claims Cost from 04/01/2023 – 06/30/2023

Therapeutic Class Description	Claims	Claims Cost	Patients	Cost/Patient	% Total Cost	Dif.
1. DMARDS	652	$3,867,842.27	272	$14,220.01	11.1%	NC
2. ANTIPSYCHOTICS	9,672	$2,433,160.77	3,922	$620.39	7.0%	NC
3. SKIN AGENTS	702	$2,061,210.88	420	$4,907.64	5.9%	NC
4. INSULINS	3,609	$1,902,722.57	1,451	$1,311.32	5.5%	NC
5. INCRETIN MIMETICS	1,646	$1,461,430.59	756	$1,933.11	4.2%	↑2
6. ANTINEOPLASTICS	634	$1,436,618.88	267	$5,380.60	4.1%	↓1
7. AMPHETAMINES	7,175	$1,423,056.31	3,065	$464.29	4.1%	↓1
8. CORTICOSTEROID (RESP)	3,705	$1,102,822.73	2,242	$491.89	3.2%	↑1
9. SGLT-2 INHIBITORS	1,470	$978,569.30	782	$1,251.37	2.8%	↑2
10. RESP/CNS STIMULANTS	5,723	$957,880.83	2,250	$425.72	2.7%	NC
11. ANTIRETROVIRALS	736	$946,848.72	291	$3,253.78	2.7%	↓3
12. HCV ANTIVIRALS	68	$677,511.31	36	$18,819.76	1.9%	↑1
13. ANTIDEPRESSANTS	30,485	$660,732.16	13,096	$50.45	1.9%	↓1
14. IMMUNOMODULATORY	88	$586,616.81	36	$16,294.91	1.7%	↑2
15. ANTICOAGULANTS	1,508	$558,295.57	649	$860.24	1.6%	NC

PA / PDL Update	PA Status	Class
Fabior (tazarotene) foam	PA	Acne
Carac (fluorouracil) cream	PA	Actinic Keratosis
Suflave	PA	Bowel Prep Agents
Rinvoq	PA	Crohn's
alosetron	PA	Diarrhea - IBS
Miebo	PA	Dry Eye Disease
Olumiant	PA	Eczema/Atopic Dermatitis
Menest	PA	Estrogens
travoprost	PA	Glaucoma
apraclonidine	PA	Glaucoma
tafluprost	PA	Glaucoma
Sogroya	PA	Growth Hormone
Rayaldee ER	PA	Hyperparathyroidism
doxercalciferol	PA	Hyperparathyroidism
Xofluza	PA	Influenza
Zavzpret	PA	Migraine
Fosamax D	PA	Osteoporosis
Elepsia XR	PA	Preferred Dosage Forms
Spritam	PA	Preferred Dosage Forms
Sympazan	PA	Preferred Dosage Forms
olanzapine/fluoxetine	PA	Preferred Dosage Forms
Cotempla XR - ODT	PA	Preferred Dosage Forms
amphetamine ER Suspension	PA	Preferred Dosage Forms
Pexeva	PA	Preferred Dosage Forms
Liqrev	PA	Pulmonary Hypertension
Pandel	PA	Topical Steroids
Fluocinonide-E cream	PA	Topical Steroids
Olpruva	PA	Urea Cycle Disorders
Symproic	remove PA	Constipation (Opioid-Induced)
Simponi	remove PA	Cytokine Modulators
Nivestym	remove PA	Hematopoietic, Colony Stimulating Factor
Releuko	remove PA	Hematopoietic, Colony Stimulating Factor
Nexletol	remove PA	Lipid-Lowering Agents
Nexlizet	remove PA	Lipid-Lowering Agents
gatifloxacin eye drops	remove PA	Ophthalmic - Antiinfectives
Airduo Respiclick	remove PA	Steroid/LABA combination inhalers
Tlando	remove PA	Testosterone
clocortolone cream	remove PA	Topical Steroids
halobetasol ointment	remove PA	Topical Steroids
desoximetasone cream	remove PA	Topical Steroids

Chronic Kidney Disease

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months
- If member is on renal dialysis, Medicare eligibility must be ruled out.

Filspari Only
- The member must have eGFR ≥ 30.
- The member must be experiencing proteinuria ≥ 1 gram/day or UPCR ≥ 1.5 g/g (documentation must be attached) despite 3-month trials with good compliance of the following at the target or maximally tolerated dose, as evidenced by paid claims or pharmacy printouts:
  - ACE inhibitor or an ARB
  - A SGLT-2 inhibitor

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.
- 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 Farxiga and Jardiance (subject to clinical review)

Kerendia Only
- The member must have history of diabetes
- The member must be on the following at the target or maximally tolerated dose, as evidenced by paid claims or pharmacy printouts:
  - An ACE-inhibitor or an ARB
  - A SGLT-2 inhibitor
- The member has an estimated glomerular filtration rate (eGFR) ≥ 25 mL/min/1.73 m2 AND one of the following (1 or 2):
  1. Urinary albumin-to-creatinine ratio (UACR) ≥ 30 mg/g (≥3 mg/mmol)
  2. Albuminuria ≥ 300 mg/day

Korsuva Only
- The member must have failed a 90-day trial of pregabalin or gabapentin, as evidenced by paid claims or pharmacy printouts.

Tarpeyo Only
- The member must have eGFR ≥ 30.
- The member must be experiencing proteinuria > 1 gram/day or UPCR ≥ 1.5 g/g (documentation must be attached) despite 6-month trials with good compliance of the following at the target or maximally tolerated dose, as evidenced by paid claims or pharmacy printouts:
  - ACE inhibitor or an ARB
  - A SGLT-2 inhibitor
  - Prednisone or methylprednisolone

<u>Renewal Criteria - Approval Duration:</u> 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:
  - *Filspari and Tarpeyo Only*: proteinuria <1 gram/day or UPCR < 1.5 g/g
  - *Kerendia Only*: albuminuria <1 gram/day or UACR < 1.5 g/g

References:

1. *Rossing, Peter, et al. "KDIGO 2022 Clinical Practice Guideline for Diabetes Management in Chronic Kidney Disease." Kidney international 102.5 (2022): S1-S127.*
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.*

Heart Failure

First Line Agents

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

Second Line Agents

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

Electronic Diagnosis Verification

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

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

- Corlanor Only:
  - The requested medication must be prescribed by, or in consult with, a cardiologist.
  - The member must have a resting HR ≥ 70 beats per minute on maximally tolerated or target beta blocker dose in sinus rhythm.
- 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)
- Verquvo Only:
  - The requested medication must be prescribed by, or in consult with, a cardiologist.
  - The member must have left ventricular ejection fraction (LVEF) < 45% at initiation.
  - Documentation of a recent hospitalization or need for IV diuretics within the past 6 months must be provided with request.
  - The member is receiving concurrent Entresto, a beta-blocker, a SGLT-2 Inhibitor, and a mineralocorticoid receptor antagonist.

Opioid Analgesics

Opioid Analgesics – Long Acting

Partial Agonist/Antagonist Opioids

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
BELBUCA (buprenorphine)	buprenorphine patches
Butorphanol	
BUTRANS (buprenorphine) PATCHES - *Brand Required*	

Abuse Deterrent Formulations/Unique Mechanisms from Full Agonists Opioids

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
NUCYNTA ER (tapentadol)	CONZIP (tramadol ER) CAPSULES
OXYCONTIN (oxycodone) – *Brand Required*	hydrocodone ER tablets
tramadol ER Tablets	HYSINGLA ER (hydrocodone)
	levorphanol
	methadone
	MORPHABOND ER (morphine)
	tramadol ER capsules
	XTAMPZA ER (oxycodone)

Full Agonist Opioids Without Abuse Deterrent Formulations

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
fentanyl 12 mcg/hr, 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 Narcan and has been counseled on overdose risk
  - The member resides in a facility with skilled nursing care
- One of the following criteria must be met:
  - The member is currently on a long-acting opioid therapy
  - The member must have received opioid therapy during hospitalization requiring post discharge maintenance or tapering
  - 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 60 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 12.5 mcg/hr may be considered for approval for opioid naïve members (subject to clinical review).
    - Both of the following are met:
        - The member has established opioid tolerability by using short acting opioids daily for at least 90 days prior to request for long-acting opioid as evidenced by paid claims or pharmacy printouts
        - The member has not achieved therapeutic goal with non-narcotic medication (NSAIDs, TCAs, SNRIs, corticosteroids, etc.) and non-medication alternatives (weight loss, physical therapy, cognitive behavioral therapy, etc.).
- One of the following criteria must be met:
    - The member resides in a facility with skilled nursing care
    - The member must have taper plan of one or both agents
    - The opioid medication must be prescribed by, or in consult with, with an oncologist or pain management specialist with a pain management contract (with treatment plan including goals for pain and function, and urine and/or blood screens) if the cumulative daily dose of opioids exceeds 90 MME/day

Fentanyl Patch:

- The member must have a BMI ≥17

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).

<u>Renewal Criteria - Approval Duration:</u> 12 months

- One of the following must be met:
    - Documentation noting progress toward therapeutic goal must be included with request (e.g., improvement in pain level, quality in life, or function).
    - The member must be stable on long-acting opioid medication for 2 years or longer

Opioid Use Disorder

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

Prior Authorization Form – Opioid Dependence

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)
  - Pregnancy or breastfeeding will not be approved as clinical justification based on the clinically non-preferred information provided above.
  - 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 (while need for long-term transmucosal stability will not be considered, limited approval may be granted to allow for recommended pre-treatment and titration prior to initiation of long-acting buprenorphine product - maximum of 14 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

Clostridioides difficile-associated diarrhea (CDAD)

Prevention

Fecal Microbiota

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

Monoclonal Antibody

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

Electronic Duration Verification:

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

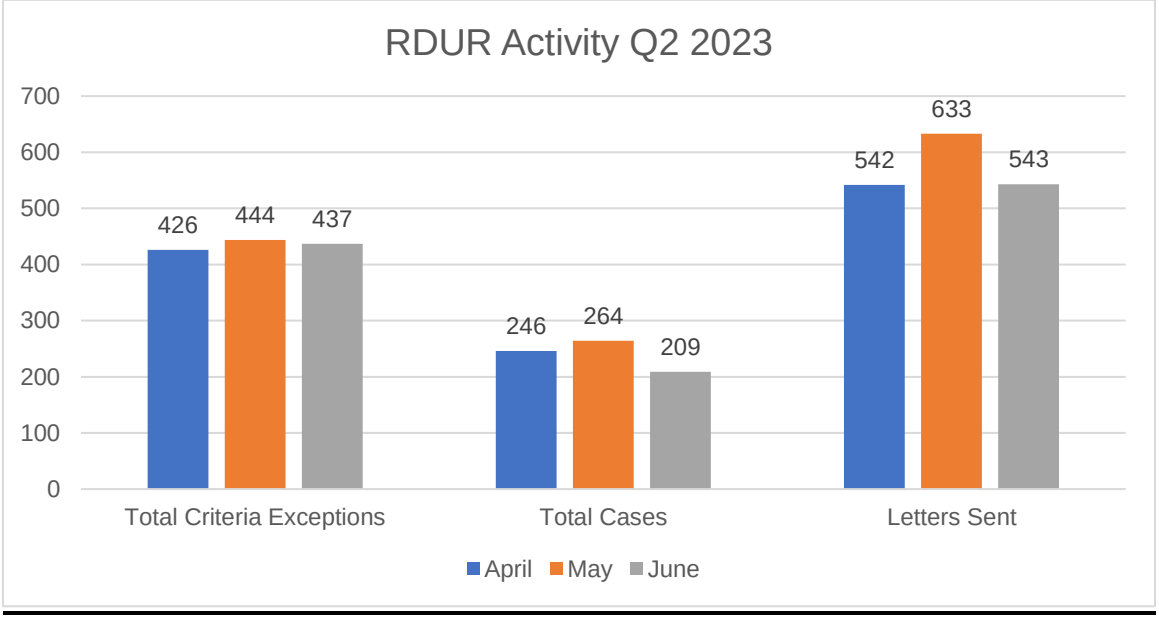
Medications that cost over $3000/month

Prior Authorization Criteria

Initial Criteria - Approval Duration: 6 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a specialist in the 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

RDUR Activity Overview: Q2 2023



April Cases by Type of Criteria		
Criteria Description	**# of Cases**	**% of Cases**
Clinical Appropriateness	45	18.3%
Drug-Disease Interactions	148	60.2%
Drug-Drug Conflicts	53	21.5%

May Cases by Type of Criteria		
Criteria Description	**# of Cases**	**% of Cases**
Adverse Effects	13	4.9%
Drug-Disease Interactions	251	95.1%

June Cases by Type of Criteria		
Criteria Description	**# of Cases**	**% of Cases**
Drug-Disease Interactions	38	18.2%
Drug-Drug Conflicts	169	80.9%
Therapeutic Duplication	2	1.0%

Hyperparathyroidism

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
calcitrol	doxercalciferol
paricalcitrol	HECTOROL (doxercalciferol)
	RAYALDEE ER (calcifediol)
	ROCALTROL (calcitriol)
	SENSIPAR (cinacalcet)
	ZEMPLAR (paricalcitrol)

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

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).

Cinacalet Only:

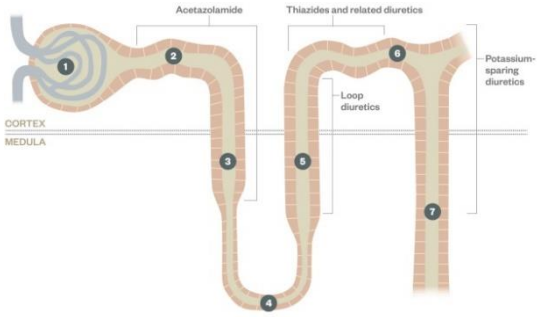
- If member is on renal dialysis, Medicare eligibility must be ruled out.

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*

REVIEW OF DIURETICS

Diuretics are oftentimes used in heart failure (HF) and hypertension (HTN) due to their ability to increase excretion of sodium and water. Diuretics consist of different classes based on their mechanism of action including loop, thiazide, potassium sparing, and carbonic anhydrase inhibitors. Carbonic anhydrase inhibitors are not included in the chart below due to their limited use as diuretics.



Per the Pharmaceutical Journal, Diuretic Therapy Explained

	Loop	Thiazides	Potassium (K)-Sparing	
Drugs	Bumetanide Ethacrynic acid Furosemide Torsemide	Chlorthalidone Hydrochlorothiazide Indapamide Metolazone	Amiloride Triamterene	Spironolactone Eplerenone
Mechanism	Inhibits sodium-chloride (Na-Cl) reabsorption in the ascending loop of Henle	Inhibits Na reabsorption in the distal tubule	Inhibits Na reabsorption in exchange for K at the distal tubule	Aldosterone antagonist
Primary use	**HF**: fluid retention	**HTN**	Added to limit **hypokalemia** caused by other diuretics	• Resistant **HTN** • **HF**: ascites
Key notes	• Sulfonamide derivatives (except ethacrynic acid) • Electrolyte imbalances (including hypokalemia)		• Risk of hyperkalemia, requires monitoring of K levels in patients at higher risk	

Triamterene

FDA Approval

Triamterene: 505(j) Abbreviated New Drug Application (ANDA) pathway, standard

Cost of Potassium-Sparing Diuretics Per Year	
Amiloride: $109.50 • Plus HCTZ ($10.95): $120.45 • Amiloride/HCTZ combination: $251	Spironolactone: $36.50 Plus HCTZ ($10.95): $47.45 • Spironolactone/HCTZ combination: $427.05
Triamterene: $4,872.75 • Plus HCTZ ($7.30): $4,880.05 • Triamterene/HCTZ combination: $73	Eplerenone: $474.50 • No combination products

Based on adult dosing at lowest per unit WAC cost.

Advantages	Disadvantages
• Limits hypokalemia when used alongside other diuretics	• Mono product increases pill burden and may decrease adherence • Cost is higher for mono product, and the most frequent use is in combination with HCTZ • Not a first line agent for HTN per guideline recommendations • Risk of hyperkalemia

References:

1. *Brater DC, Ellison DH. Mechanism of action of diuretics. UpToDate, November 30, 2022. https://www.uptodate.com/contents/mechanism-of-action-of-diuretics?search=diuretic&source=search_result&selectedTitle=1~150&usage_type=default&display_rank=1*
2. *Brater DC, Ellison DH. Loop diuretics: Dosing and major side effects. UpToDate, January 24, 2023. https://www.uptodate.com/contents/loop-diuretics-dosing-and-major-side-effects?search=diuretic&topicRef=2338&source=see_link*
3. *Loop Diuretics. Drug Facts And Comparisons, March 9, 2020. https://fco.factsandcomparisons.com/lco/action/doc/retrieve/docid/fc_dfc/5545873?cesid=3hUS8YbzYwE&searchUrl=%2Flco%2Faction%2Fsearch%3Fq%3Dloop%2Bdiuretics%26t%3Dname%26acs%3Dtrue%26acq%3Dloop%26nq%3Dtrue*
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REVIEW OF MENOPAUSE

Menopause is caused by decreased ovarian production of estrogen and other hormones with age. Patients may experience vasomotor symptoms (VMS) and genitourinary syndrome (GSM) which can decrease quality-of-life (QOL).

VMS: hot flashes	**GSM:** vulvovaginal atrophy (dryness, dyspareunia)
First line: systemic hormonal therapy * **Non-hormonal treatment** is recommended for women who are unable to take first line agents due to contraindications, comorbidities, or patient preference	First line: local therapies • Low-dose vaginal estrogens • Ospemifene • Lubricants

Hormonal Therapy • Most effective for VMS and GSM • Shown to prevent bone loss and fractures			
Drug class	**Estrogen**	**Estrogen-progestin**	**Estrogen-SERM: Duavee**
Patient population	Women who have had a hysterectomy	Women who have an intact uterus	Women who cannot tolerate progestin
Formulations	Multiple formulations for systemic and local use		Oral
Warnings	Risk of cardiovascular disease (CVD), hormonal cancer, lipid effects		
Cost per year	Ranges from approximately $21.92± to $3,660.95‡		$2,325.05
Contraindications	• History of hormone dependent cancer • History of venous thromboembolism (VTE), myocardial infarction (MI) or transient ischemic attack (TIA) • Liver disease • Unexplained vaginal bleeding, thrombophilia disorders • Pregnancy		
Non-Hormonal Therapy • Indicated for VMS • Recommended for patients who cannot take or are hesitant to take hormonal therapies			
Medication	**Paroxetine**	**Veozah**	
Mechanism	SSRI	Neurokinin-3 (NK3) receptor antagonist	
Key Points	Beneficial for patients also suffering from depression	• Liver function tests are needed every 3 months within the first year due to the risk of hepatic impairment • Contraindicated in liver and kidney impairment	
Cost per year	$1,671.70	$6,690.45	

Based on adult dosing at lowest per unit WAC cost. ± Oral estradiol ‡ Activella
**** Medications that do not have an FDA approved indication for menopause but are used off-label: selective serotonin reuptake inhibitors (SSRIs), selective norepinephrine reuptake inhibitors (SNRIs), gabapentin, clonidine, oxybutynin.*

Veozah

FDA Approval
Veozah: 505(b) New Drug Application (NDA) pathway, Type 1 – New Molecular Entity, PRIORITY

Advantages	**Disadvantages**
• Alternative for patients who are unable or hesitant to take hormonal therapy • No risk of VTE or cancer	• Cost • Liver dysfunction • Frequent liver function tests required • Minimal data and long-term effects are unknown • No head-to-head trials • Doesn't treat GSM symptoms

References:

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2. *New Drug Review: Veozah (fezolinetant). IPD Analytics. Aventura, FL, 2021. June 2023. https://www.ipdanalytics.com.*
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NORTH DAKOTA MEDICAID
RETROSPECTIVE DRUG UTILIZATION REVIEW
CRITERIA RECOMMENDATIONS
3RD QUARTER 2023

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

1. Elacestrant / Overuse _____ _____

Alert Message: Orserdu (elacestrant) may be over-utilized. The recommended dosage of elacestrant is 345 mg taken orally with food once daily until disease progression or unacceptable toxicity occurs.

Drugs/Diseases

Util A	Util B	Util C
Elacestrant		

Max Dose: 345 mg/day

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Orserdu Prescribing Information, Jan. 2023, Stemline Therapeutics, Inc.

2. Elacestrant / Therapeutic Appropriateness _____ _____

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

Drugs/Diseases

Util A	Util B	Util C
Elacestrant		

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Orserdu Prescribing Information, Jan. 2023, Stemline Therapeutics, Inc.

3. Elacestrant / Severe Hepatic Impairment _____ _____

Alert Message: Avoid the use of Orserdu (elacestrant) in patients with severe hepatic impairment (Child-Pugh C). Elacestrant has not been studied in patients with severe hepatic impairment.

Drugs/Diseases

Util A	Util B	Util C
Elacestrant	Cirrhosis	
	Liver Failure	

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Orserdu Prescribing Information, Jan. 2023, Stemline Therapeutics, Inc.

Criteria Recommendations	*Approved*	*Rejected*

4. Elacestrant 345 mg / Moderate Hepatic Impairment _____ _____

Alert Message: Patients who have moderate hepatic impairment (Child-Pugh B) taking Orserdu (elacestrant) should receive a reduced dose. The recommended dose of elacestrant in patients with moderate hepatic impairment is 258 mg once daily. In pharmacokinetic studies, the AUC of elacestrant increased in subjects with moderate hepatic impairment (Child-Pugh B) by 83%. There were no clinically significant differences in the Cmax and AUC of elacestrant in subjects with mild hepatic impairment (Child-Pugh A).

Drugs/Diseases

Util A	Util B	Util C
Elacestrant	Moderate Hepatic Impairment	

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Orserdu Prescribing Information, Jan. 2023, Stemline Therapeutics, Inc.

5. Elacestrant / Dyslipidemia _____ _____

Alert Message: In clinical trials, hypercholesterolemia and hypertriglyceridemia occurred in patients taking Orserdu (elacestrant) at an incidence of 30% and 27%, respectively. The incidence of Grade 3 and 4 hypercholesterolemia and hypertriglyceridemia were 0.9% and 2.2%, respectively. Monitor lipid profile prior to starting and periodically while taking elacestrant.

Drugs/Diseases

Util A	Util B	Util C
Elacestrant	Hypercholesterolemia	
	Hypertriglyceridemia	

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Orserdu Prescribing Information, Jan. 2023, Stemline Therapeutics, Inc.

6. Elacestrant / Strong and Moderate CYP3A4 Inducers _____ _____

Alert Message: The concurrent use of Orserdu (elacestrant) with a moderate or strong CYP3A4 inducer should be avoided. Elacestrant is a CYP3A4 substrate, and concomitant use with a strong or moderate CYP3A4 inducer may decrease elacestrant exposure, which may decrease the effectiveness of elacestrant.

Drugs/Diseases

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

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Orserdu Prescribing Information, Jan. 2023, Stemline Therapeutics, Inc.

Criteria Recommendations	*Approved*	*Rejected*

7. Elacestrant / Strong and Moderate CYP3A4 Inhibitors _____ _____

Alert Message: The concurrent use of Orserdu (elacestrant) with a moderate or strong CYP3A4 inhibitor should be avoided. Elacestrant is a CYP3A4 substrate, and concomitant use with a strong or moderate CYP3A4 inhibitor may increase elacestrant exposure, which may increase the risk of elacestrant-related adverse reactions.

Drugs/Diseases

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

References:

Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Orserdu Prescribing Information, Jan. 2023, Stemline Therapeutics, Inc.

8. Elacestrant / BCRP Substrates _____ _____

Alert Message: Orserdu (elacestrant) is a BCRP inhibitor. In drug interaction studies, the concomitant use of elacestrant with a BCRP substrate increased the plasma concentrations of a BCRP substrate. Concurrent use of elacestrant with a BCRP substrate may increase the risk for adverse reactions associated with a BCRP substrate. Reduce the dosage of BCRP substrates per the BCRP substrate prescribing information when minimal concentration changes may lead to serious or life-threatening adverse reactions.

Drugs/Diseases

Util A	Util B		Util C
Elacestrant	Alpelisib	Prazosin	
	Atorvastatin	Rosuvastatin	
	Dantrolene	Sulfasalazine	
	Dolutegravir	Talazoparib	
	Methotrexate	Tenofovir	
	Pazopanib	Topotecan	
	Pibrentasvir		

References:

Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Orserdu Prescribing Information, Jan. 2023, Stemline Therapeutics, Inc.

Criteria Recommendations	*Approved*	*Rejected*

9. Elacestrant / P-gp Substrates _____ _____

Alert Message: Orserdu (elacestrant) is a P-gp inhibitor. In drug interaction studies, concomitant use of elacestrant with a P-gp substrate increased the concentrations of P-gp substrate. Concurrent use of elacestrant with a P-gp substrate may increase the risk for adverse reactions associated with a P-gp substrate. Reduce the dosage of P-gp substrates per the P-gp substrate prescribing information when minimal concentration changes may lead to serious or life-threatening adverse reactions.

Drugs/Diseases

Util A	Util B	Util C
Elacestrant	Cyclosporine	
	Digoxin	
	Sirolimus	
	Tacrolimus	

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Orserdu Prescribing Information, Jan. 2023, Stemline Therapeutics, Inc.

10. Elacestrant / Pregnancy / Pregnancy Negating _____ _____

Alert Message: Based on findings in animals and its mechanism of action, Orserdu (elacestrant) can cause fetal harm when administered to a pregnant woman. Administration of elacestrant to pregnant rats resulted in adverse developmental outcomes, including embryo-fetal mortality and structural abnormalities, at maternal exposures below the recommended dose based on the area under the curve (AUC). Advise pregnant women and females of reproductive potential of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with elacestrant and for 1 week after the last dose.

Drugs/Diseases

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

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Orserdu Prescribing Information, Jan. 2023, Stemline Therapeutics, Inc.

11. Elacestrant / Lactation _____ _____

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

Drugs/Diseases

Util A	Util B	Util C
Elacestrant	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Orserdu Prescribing Information, Jan. 2023, Stemline Therapeutics, Inc.

Criteria Recommendations	*Approved*	*Rejected*

12. Elacestrant / Therapeutic Appropriateness _____ _____

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

Drugs/Diseases

Util A	Util B	Util C (Negating)
Elacestrant		Contraceptives

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Orserdu Prescribing Information, Jan. 2023, Stemline Therapeutics, Inc.

13. Elacestrant / Therapeutic Appropriateness _____ _____

Alert Message: Advise male patients with female partners of reproductive potential to use effective contraception during treatment with Orserdu (elacestrant) and for 1 week after the last dose.

Drugs/Diseases

Util A	Util B	Util C
Elacestrant		

Gender: Male

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Orserdu Prescribing Information, Jan. 2023, Stemline Therapeutics, Inc.

14. Elacestrant / Non-adherence _____ _____

Alert Message: Based on refill history, your patient may be under-utilizing Orserdu (elacestrant). 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
Elacestrant		

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

Criteria Recommendations	*Approved*	*Rejected*

15. Betamethasone Spray / Therapeutic Appropriateness - Pediatric _____ _____

Alert Message: The safety and effectiveness of Sernivo (betamethasone spray) in patients younger than 18 years of age have not been studied. Pediatric patients may be more susceptible to systemic toxicity due to their larger skin surface-to-body mass ratios. The use of betamethasone spray is not recommended in pediatric patients.

Drugs/Diseases

Util A	Util B	Util C
Betamethasone Spray		

Age Range: 0 – 17 yoa

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

16. Betamethasone Spray / Therapeutic Appropriateness - Duration _____ _____

Alert Message: The use of Sernivo (betamethasone spray) is recommended for up to 4 weeks of treatment. Treatment with betamethasone spray beyond 4 weeks is not recommended.

Drugs/Diseases

Util A	Util B	Util C
Betamethasone Spray		

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

17. Betamethasone Spray / Glaucoma, Cataracts & IOP _____ _____

Alert Message: The use of topical corticosteroids, including Sernivo (betamethasone spray), may increase the risk of posterior subcapsular cataracts and glaucoma. Cataracts, glaucoma, and intraocular pressure have been reported postmarketing with the use of topical corticosteroid products, including betamethasone dipropionate. Advise patients to avoid contact with betamethasone spray with the eyes and to report any visual symptoms.

Drugs/Diseases

Util A	Util B	Util C
Betamethasone Spray	Cataracts Glaucoma	

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

18. Betamethasone Spray / Therapeutic Appropriateness _____ _____

Alert Message: Sernivo (betamethasone spray) can produce reversible hypothalamic-pituitary-adrenal (HPA) axis suppression with the potential for glucocorticosteroid insufficiency. This may occur during or after the withdrawal of treatment. Factors that predispose to HPA axis suppression include the use of high-potency corticosteroids, large treatment surface areas, prolonged use, use of occlusive dressings, altered skin barrier, liver failure, and young age.

Drugs/Diseases

Util A	Util B	Util C
Betamethasone Spray		

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

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

19. Betamethasone Spray / Lactation _____ _____

Alert Message: There are no data regarding the presence of betamethasone dipropionate in human milk, the effects on the breastfed infant, or the effects on milk production after topical application of Sernivo (betamethasone spray) to women who are breastfeeding. It is possible that topical administration of betamethasone dipropionate could result in sufficient systemic absorption to produce detectable quantities in human milk. The developmental and health benefits of breastfeeding should be considered, along with the mother's clinical need for betamethasone spray and any potential adverse effects on the breastfed infant from betamethasone spray or the underlying maternal condition.

Drugs/Diseases

Util A	Util B	Util C
Betamethasone Spray	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

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

20. Atorvastatin Suspension / Overuse _____ _____

Alert Message: Atorvaliq (atorvastatin suspension) may be over-utilized. The maximum recommended dose of atorvastatin suspension in adults is 80 mg per day.

Drugs/Diseases

Util A	Util B	Util C
Atorvastatin Suspension		

Max Dose: 80 mg/day
Age Range: 18 – 999 yoa

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Atorvaliq Prescribing Information, Feb. 2023, CMP Pharma Inc.

21. Atorvastatin Suspension / Overuse _____ _____

Alert Message: Atorvaliq (atorvastatin suspension) may be over-utilized. The maximum recommended dose of atorvastatin suspension in pediatric patients 10 years of age and older with homozygous familial hypercholesterolemia (HoFH) is 80 mg per day. The maximum recommended dose of atorvastatin suspension in pediatric patients 10 years of age and older with heterozygous familial hypercholesterolemia (HeFH) is 20 mg per day.

Drugs/Diseases

Util A	Util B	Util C
Atorvastatin Suspension		

Max Dose: 80 mg/day
Age Range: 10 – 17 yoa

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Atorvaliq Prescribing Information, Feb. 2023, CMP Pharma Inc.

Criteria Recommendations	*Approved*	*Rejected*

22. Atorvastatin Suspension / Therapeutic Appropriateness _____ _____

Alert Message: The safety and effectiveness of Atorvaliq (atorvastatin suspension) have not been established in pediatric patients younger than 10 years of age with HeFH or HoFH, or in pediatric patients with other types of hyperlipidemia (other than HeFH or HoFH).

Drugs/Diseases

Util A	Util B	Util C
Atorvastatin Suspension		

Age Range: 0 - 9 yoa

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Atorvaliq Prescribing Information, Feb. 2023, CMP Pharma Inc.

23. Rosuvastatin / Darolutamide _____ _____

Alert Message: In patients taking Nubeqa (darolutamide), the dose of rosuvastatin should not exceed 5 mg once daily. Rosuvastatin is a BCRP substrate, and concurrent use with darolutamide, a BCRP inhibitor, has been shown to elevate rosuvastatin concentrations, increasing the risk of statin-associated adverse reactions.

Drugs/Diseases

Util A	Util B	Util C
Rosuvastatin	Darolutamide	

Max Dose: 5 mg/day

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

24. Rosuvastatin / Regorafenib _____ _____

Alert Message: In patients taking regorafenib, the dose of rosuvastatin should not exceed 10 mg once daily. Rosuvastatin is a BCRP substrate, and concurrent use with regorafenib, a BCRP inhibitor, has been shown to elevate rosuvastatin concentrations increasing the risk of statin-associated adverse reactions.

Drugs/Diseases

Util A	Util B	Util C
Rosuvastatin	Regorafenib	

Max dose: 10 mg/day

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

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

25. Atogepant / Severe Hepatic Impairment _____ _____
Alert Message: Due to the potential for liver injury in patients with severe hepatic impairment, avoid the use of Qulipta (atogepant) in this patient population. In pharmacokinetic studies, atogepant exposure was increased by 38% in patients with severe (Child-Pugh Class C) hepatic impairment compared to patients with normal hepatic function.

Drugs/Diseases

Util A	Util B	Util C
Atogepant	Cirrhosis	
	Hepatic Failure	

References:
Qulipta Prescribing Information, April 2023, AbbVie.
Clinical Pharmacology, 2023 Elsevier/Gold Standard.

26. Tucatinib / Overuse _____ _____ Alert Message:
Tukysa (tucatinib) may be over-utilized. The recommended daily dosage of tucatinib is 300 mg orally twice daily.

Drugs/Disease

Util A	Util B	Util C (Negate)
Tucatinib		Cirrhosis
		Hepatic Failure

Max Dose: 600 mg/day

Reference:
Clinical Pharmacology, 2023, Elsevier/Gold Standard.
Tukysa Prescribing Information, Jan. 2023, Seagen Inc.

27. Tucatinib / Overuse – Hepatic Impairment _____ _____
Alert Message: Tukysa (tucatinib) may be over-utilized. For patients with severe hepatic impairment (Child-Pugh C), the recommended dosage of tucatinib is 200 mg orally twice daily.

Drugs/Disease

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

Max Dose: 400 mg/day

Reference:
Clinical Pharmacology, 2023, Elsevier/Gold Standard.
Tukysa Prescribing Information, Jan. 2023, Seagen Inc.

28. Tucatinib / Therapeutic Appropriateness _____ _____
Alert Message: The safety and effectiveness of Tukysa (tucatinib) in pediatric patients have not been established.

Drugs/Diseases

Util A	Util B	Util C
Tucatinib		

Age Range: 0 – 17 yoa

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

Criteria Recommendations	*Approved*	*Rejected*

29. Tucatinib / Strong CYP3A4 Inducers or Moderate 2C8 Inducers _____ _____ Alert Message:
Concomitant use of Tukysa (tucatinib) with a strong CYP3A or moderate CYP2C8 inducer decreased tucatinib plasma concentrations, which may reduce tucatinib activity. Avoid the concomitant use of tucatinib with a strong CYP3A inducer or a moderate CYP2C8 inducer. If concomitant use with a strong CYP2C8 inhibitor cannot be avoided, reduce the recommended dosage to 100 mg orally twice daily.

Drugs/Disease

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

Reference:
Clinical Pharmacology, 2023, Elsevier/Gold Standard.
Tukysa Prescribing Information, Jan. 2023, Seagen Inc.

30. Tucatinib / Strong CYP2C8 Inhibitors _____ _____
Alert Message: The concurrent use of Tukysa (tucatinib) with strong CYP2C8 inhibitors should be avoided. If concomitant use with a strong CYP2C8 inhibitor cannot be avoided, reduce the recommended dosage to 100 mg orally twice daily. After discontinuation of the strong CYP2C8 inhibitor for 3 elimination half-lives, resume the tucatinib dose that was taken prior to initiating the inhibitor.

Drugs/Disease

Util A	Util B	Util C
Tucatinib	Gemfibrozil	

Reference:
Clinical Pharmacology, 2023, Elsevier/Gold Standard.
Tukysa Prescribing Information, Jan. 2023, Seagen Inc.

31. Tucatinib / CYP3A Substrates w/ NTI _____ _____
Alert Message: In drug interaction studies, concomitant use of Tukysa (tucatinib) with a CYP3A substrate increased the plasma concentrations of the CYP3A substrate, which may increase the toxicity associated with a CYP3A substrate. Avoid concomitant use of tucatinib with CYP3A substrates, where minimal concentration changes may lead to serious or life-threatening toxicities. If concomitant use is unavoidable, decrease the CYP3A substrate dosage in accordance with approved product labeling.

Drugs/Disease

Util A	Util B					Util C
Tucatinib	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		

Reference:
Clinical Pharmacology, 2023, Elsevier/Gold Standard.
Tukysa Prescribing Information, Jan. 2023, Seagen Inc.

Criteria Recommendations	*Approved*	*Rejected*	

32. Tucatinib / P-gp w/ NTI _____ _____ Alert Message:

In drug interaction studies, concomitant use of Tukysa (tucatinib) with a P-gp substrate increased the plasma concentrations of the P-gp substrate, which may increase the toxicity associated with a P-gp substrate. Consider reducing the dosage of P-gp substrates, where minimal concentration changes may lead to serious or life-threatening toxicities.

Drugs/Disease

Util A	Util B	Util C
Tucatinib	Cyclosporine	Sirolimus
	Digoxin	Tacrolimus
	Everolimus	

Reference:
Clinical Pharmacology, 2023, Elsevier/Gold Standard.
Tukysa Prescribing Information, Jan. 2023, Seagen Inc.

33. Tucatinib / Diarrhea _____ _____ Alert Message:

Tukysa (tucatinib) can cause severe diarrhea. If diarrhea occurs, administer antidiarrheal treatment as clinically indicated. Perform diagnostic tests as clinically indicated to exclude other causes of diarrhea. Based on the severity of the diarrhea, interrupt dose, then dose reduce or permanently discontinue tucatinib.

Drugs/Disease

Util A	Util B	Util C
Tucatinib	Diarrhea	

Reference:
Clinical Pharmacology, 2023, Elsevier/Gold Standard.
Tukysa Prescribing Information, Jan. 2023, Seagen Inc.

34. Tucatinib / Hepatotoxicity _____ _____

Alert Message: Tukysa (tucatinib) can cause severe hepatotoxicity. Monitor ALT, AST, and bilirubin prior to starting tucatinib, every 3 weeks during treatment, and as clinically indicated. Based on the severity of hepatotoxicity, interrupt dose, then dose reduce or permanently discontinue tucatinib.

Drugs/Disease

Util A	Util B	Util C
Tucatinib		

Reference:
Clinical Pharmacology, 2023, Elsevier/Gold Standard.
Tukysa Prescribing Information, Jan. 2023, Seagen Inc.

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

35. Tucatinib / Pregnancy / Pregnancy Negating _____ _____

Alert Message: Based on findings from animal studies and its mechanism of action, Tukysa (tucatinib) can cause fetal harm when administered to a pregnant woman. In animal reproduction studies, administration of tucatinib to pregnant rats and rabbits during organogenesis caused embryo-fetal mortality, reduced fetal weight and fetal abnormalities at maternal exposures >/= 3 times the human exposure (AUC) at the recommended dose. Advise pregnant women and females of reproductive potential of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with tucatinib and for at least 1 week after the last dose.

Drugs/Diseases

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

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2023, Elsevier/Gold Standard.
Tukysa Prescribing Information, Jan. 2023, Seagen Inc.

36. Tucatinib / Lactation _____ _____

Alert Message: There are no data on the presence of Tukysa (tucatinib) or its metabolites in human or animal milk or its effects on the breastfed child or on milk production. Because of the potential for serious adverse reactions in a breastfed child, advise women not to breastfeed during treatment with tucatinib. and for 1 week after the last dose. Tucatinib is used in combination with trastuzumab and capecitabine. Refer to the full prescribing information of trastuzumab and capecitabine for lactation information.

Drugs/Diseases

Util A	Util B	Util C
Tucatinib	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2023, Elsevier/Gold Standard.
Tukysa Prescribing Information, Jan. 2023, Seagen Inc.

37. Tucatinib / Therapeutic Appropriateness _____ _____ Alert Message:

Advise females of reproductive potential to use effective contraception during treatment with Tukysa (tucatinib) and for at least 1 week after the last dose. Based on findings from animal studies and its mechanism of action, Tukysa (tucatinib) can cause fetal harm when administered to a pregnant woman.

Drugs/Disease

Util A	Util B	Util C
Tucatinib		

Gender: Female
Age Range: 11 – 50 yoa

Reference:
Clinical Pharmacology, 2023, Elsevier/Gold Standard.
Tukysa Prescribing Information, Jan. 2023, Seagen Inc.

Criteria Recommendations	*Approved*	*Rejected*	
38. Tucatinib / Therapeutic Appropriateness Advise male patients with female partners of reproductive potential to use effective contraception during treatment with Tukysa (tucatinib) and for 1 week after the last dose.	_____	_____	Alert Message:

Drugs/Disease

Util A	Util B	Util C
Tucatinib		

Gender: Male

Reference:
Clinical Pharmacology, 2023, Elsevier/Gold Standard.
Tukysa Prescribing Information, Jan. 2023, Seagen Inc.

39. Tucatinib / Non-adherence _____ _____

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

Drugs/Diseases

Util A	Util B	Util C
Tucatinib		

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.

40. Mavacamten / Black Box Warning _____ _____

Alert Message: Camzyos (mavacamten) reduces systolic contraction and can cause heart failure or totally block ventricular function. Patients who experience a serious intercurrent illness (e.g., serious infection) or arrhythmia (e.g., atrial fibrillation or other uncontrolled tachyarrhythmia) are at greater risk of developing systolic dysfunction and heart failure. New or worsening arrhythmia, dyspnea, chest pain, fatigue, palpitations, leg edema, or elevations in N-terminal pro B-type natriuretic peptide (NT-proBNP) may be signs and symptoms of heart failure and should also prompt an evaluation of cardiac function.

Drugs/Diseases

Util A	Util B	Util C
Mavacamten	Heart Failure	
	Arrhythmias	
	Dyspnea	
	Angina	
	Palpitations	
	Localized Edema	

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Camzyos Prescribing Information, September 2022, Bristol-Myers Squibb.

Criteria Recommendations	*Approved*	*Rejected*

41. Mavacamten / Contraindication (Black Box) _____ _____

Alert Message: Concomitant use of Camzyos (mavacamten) with a moderate to strong CYP2C19 inhibitor or a strong CYP3A4 inhibitor is contraindicated. Concomitant use with a moderate to strong CYP2C19 or a strong CYP3A4 inhibitor increases mavacamten exposure, which may increase the risk of heart failure due to systolic dysfunction.

Drugs/Diseases

Util A	Util B		Util C
Mavacamten	Cobicistat	Ketoconazole	
	Clarithromycin	Nefazodone	
	Esomeprazole	Nelfinavir	
	Felbamate	Posaconazole	
	Fluconazole	Ritonavir	
	Fluvoxamine	Ticlopidine	
	Fluoxetine	Voriconazole	
	Itraconazole		

References:

Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Camzyos Prescribing Information, September 2022, Bristol-Myers Squibb.

42. Mavacamten / Contraindication (Black Box) _____ _____

Alert Message: Concomitant use of Camzyos (mavacamten) with a moderate to strong CYP2C19 inducer or a moderate to strong CYP3A4 inducer is contraindicated. Concomitant use with a moderate to strong CYP2C19 inducer or a moderate to strong CYP3A4 inducer decreases mavacamten exposure, which may reduce the efficacy of mavacamten. The risk of heart failure due to systolic dysfunction may increase with discontinuation of these inducers as the levels of induced enzyme normalize.

Drugs/Diseases

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

References:

Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Camzyos Prescribing Information, September 2022, Bristol-Myers Squibb.

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

43. Mavacamten / Weak CYP2C19 Inhibitors & Moderate 3A4 Inhibitors _____ _____

Alert Message: Concomitant use of Camzyos (mavacamten) with a weak CYP2C19 inhibitor or a moderate CYP3A4 inhibitor increases mavacamten exposure, which may increase the risk of adverse drug reactions. Initiate mavacamten at the recommended starting dosage of 5 mg orally once daily in patients who are on stable therapy with a weak CYP2C19 inhibitor or a moderate CYP3A4 inhibitor. Reduce dose of mavacamten by one level (i.e., 15 to 10 mg, 10 to 5 mg, or 5 to 2.5 mg) in patients who are on mavacamten treatment and intend to initiate a weak CYP2C19 inhibitor or a moderate CYP3A4 inhibitor. Avoid initiation of concomitant weak CYP2C19 and moderate CYP3A4 inhibitors in patients who are on stable treatment with 2.5 mg of mavacamten because a lower dose is not available.

Drugs/Diseases

Util A	Util B		Util C
Mavacamten	Aprepitant	Erythromycin	
	Ciprofloxacin	Esomeprazole	
	Cimetidine	Imatinib	
	Conivaptan	Omeprazole	
	Crizotinib	Verapamil	
	Cyclosporine		
	Diltiazem		

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Camzyos Prescribing Information, September 2022, Bristol-Myers Squibb.

44. Mavacamten / Therapeutic Appropriateness _____ _____

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

Drugs/Diseases

Util A	Util B	Util C
Mavacamten		

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Camzyos Prescribing Information, September 2022, Bristol-Myers Squibb.

45. Mavacamten / Disopyramide _____ _____

Alert Message: Avoid concomitant use of Camzyos (mavacamten) in patients on disopyramide or disopyramide in combination with verapamil or diltiazem. Concurrent use of mavacamten and disopyramide will have additive negative inotropic effects. Concomitant use of mavacamten with disopyramide in combination with verapamil or diltiazem has been associated with left ventricular systolic dysfunction and heart failure symptoms in patients with obstructive HCM.

Drugs/Diseases

Util A	Util B	Util C
Mavacamten	Disopyramide	

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Camzyos Prescribing Information, September 2022, Bristol-Myers Squibb.

Criteria Recommendations	*Approved*	*Rejected*

46. Mavacamten / Ranolazine _____ _____

Alert Message: Coadministration of ranolazine with Camzyos (mavacamten) is contraindicated due to decreased ranolazine exposure and efficacy. Ranolazine is a CYP3A substrate, and mavacamten is a moderate CYP3A inducer. Patients on therapy with ranolazine were excluded from the clinical trial of mavacamten in obstructive HCM (EXPLORER-HCM).

Drugs/Diseases

Util A	Util B	Util C
Mavacamten	Ranolazine	

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Ranexa Prescribing Information, Oct. 2019, Gilead Sciences, Inc.

47. Mavacamten / Combined Hormonal Contraceptives _____ _____

Alert Message: Concomitant use of Camzyos (mavacamten) with hormonal contraceptives that are CYP3A4 substrates may lead to contraceptive failure or an increase in breakthrough bleeding. Mavacamten is a CYP3A4 inducer and can induce the metabolism of progestin and ethinyl estradiol. Advise patients to use a contraceptive method that is not affected by CYP450 enzyme induction (e.g., intrauterine system) or add nonhormonal contraception (such as condoms) during concomitant use and for 4 months after the last dose of mavacamten.

Drugs/Diseases

Util A	Util B	Util C
Mavacamten	Contraceptives	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Camzyos Prescribing Information, September 2022, Bristol-Myers Squibb.

48. Mavacamten / Pregnancy / Pregnancy Negating _____ _____

Alert Message: Camzyos (mavacamten) may cause fetal toxicity when administered to a pregnant female, based on findings in animal studies. Confirm the absence of pregnancy in females of reproductive potential prior to treatment and advise patients to use effective contraception during treatment with mavacamten and for 4 months after the last dose. Mavacamten may reduce the effectiveness of combined hormonal contraceptives (CHCs). Advise patients using CHCs to use an alternative contraceptive method that is not affected by CYP450 enzyme induction or to add nonhormonal contraception.

Drugs/Diseases

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

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Camzyos Prescribing Information, September 2022, Bristol-Myers Squibb.

Criteria Recommendations ***Approved Rejected***

49. Mavacamten / Lactation _____ _____

Alert Message: The presence of Camzyos (mavacamten) in human or animal milk, the drug's effects on the breastfed infant, and the effects on milk production are unknown. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for mavacamten and any potential adverse effects on the breastfed child from mavacamten or from the underlying maternal condition.

Drugs/Diseases

Util A	Util B	Util C
Mavacamten	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Camzyos Prescribing Information, September 2022, Bristol-Myers Squibb.

50. Baclofen Granules / Overuse _____ _____

Alert Message: Lyvispah (baclofen granules) may be over-utilized. The maximum recommended dosage of baclofen granules is 80 mg daily (20 mg four times a day).

Drugs/Diseases

Util A	Util B	Util C
Baclofen granules		

Max Dose: 80 mg/day

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Lyvispah Prescribing Information, Nov. 2021, Saol Therapeutics.

51. Baclofen Granules / Therapeutic Appropriateness _____ _____

Alert Message: The safety and effectiveness of Lyvispah (baclofen granules) in pediatric patients below the age of 12 have not been established.

Drugs/Diseases

Util A	Util B	Util C
Baclofen granules		

Age Range: 0 – 11 yoa

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Lyvispah Prescribing Information, Nov. 2021, Saol Therapeutics.

Criteria Recommendations	*Approved*	*Rejected*

52. Baclofen Granules / Renal Impairment _____ _____

Alert Message: Because baclofen is primarily excreted unchanged through the kidneys, Lyvispah (baclofen granules) should be given with caution to patients with renal impairment, and it may be necessary to reduce the dosage.

Drugs/Diseases

Util A	Util B	Util C
Baclofen granules	Renal Impairment	

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Lyvispah Prescribing Information, Nov. 2021, Saol Therapeutics.

53. Baclofen Granules / Pregnancy / Pregnancy Negating _____ _____

Alert Message: There are no adequate data on the risk of major birth defects, miscarriages, or other maternal adverse outcomes associated with the use of Lyvispah (baclofen granules) in pregnant women. There are adverse effects on fetal outcomes associated with withdrawal from baclofen after delivery. Oral administration of baclofen to pregnant rats resulted in an increased incidence of fetal structural abnormalities at a dose which was also associated with maternal toxicity.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Baclofen granules	Pregnancy	Abortion
		Delivery
		Miscarriage

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Lyvispah Prescribing Information, Nov. 2021, Saol Therapeutics.

54. Baclofen Granules / Lactation _____ _____

Alert Message: At recommended oral doses, Lyvispah (baclofen) is present in human milk. Withdrawal symptoms can occur in breastfed infants when maternal administration of baclofen is stopped, or when breastfeeding is stopped. There are no adequate data on other effects of baclofen on the breastfed infant. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for baclofen and any potential adverse effects on the breastfed infant from baclofen or from the underlying maternal condition.

Drugs/Diseases

Util A	Util B	Util C
Baclofen granules	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Lyvispah Prescribing Information, Nov. 2021, Saol Therapeutics.

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

55. Perampanel /Therapeutic Appropriateness _____ _____
Alert Message: The safety and effectiveness of Fycompa (perampanel) in pediatric patients less than 4 years of age have not been established.

Drugs/Diseases
Util A Util B Util C
Perampanel

Age Range: 0 – 3 yoa

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

North Dakota Medicaid
Drug Utilization Review Board Meeting
December 6, 2023
Conference Room 210/212

NORTH Dakota | Health & Human Services
Be Legendary.

NORTH Dakota | Health & Human Services
Be Legendary.

Meeting Notice

North Dakota Medicaid Drug Use Review Board

Wednesday, December 6th, 2023
1 to 4 p.m. Central Time

In-Person Information

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

Virtual Information

Join virtually: Click here to join the meeting
Join by phone: 701-328-0950, Conference ID: 229 733 638 #

Agenda

1. Call to Order
2. Roll Call
3. Review and Approval of Minutes
4. Reports from Department
    - Administrative Report
    - Financial Report: Budget, Top Drugs
    - Retrospective DUR Report
    - Clinical Report:
        - Prior authorization update
        - Criteria updates: cholestasis pruritis, diabetes, hepatitis C
        - Annual PDL Review
5. New business
    - Second Review of Diuretics (triamterene)
    - Second Review of Menopause (Veozah)
    - Review of retrospective DUR criteria recommendations
6. Announcements
    - Next Meeting (March 6, 2024)
7. 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 6th, 2023
Time and Location: 1:00 pm CST in Bismarck, North Dakota

Call to Order:
A regular quarterly meeting of the North Dakota Medicaid Drug Use Review (DUR) Board meeting was convened at 1:03 pm CST. with pro tem Presiding Officer T. Schmidt presiding, and DUR Board Coordinator, C. Stauter recording minutes.

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

Board Members Non-Voting:
Present: Kathleen Traylor

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

Approval of Meeting Minutes:
Motion: Moved by A. Werremeyer to approve the minutes of the June 7th, 2023 meeting, motion was seconded by K. Martian. **Motion carried.**
The minutes of the June 7th, 2023, meeting were approved as distributed.

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

*Administrative Report***:** *Unwinding* by A. Murphy
A. Murphy shared with the Board trends regarding unwinding. This information can be found in the handout.

*Administrative Report***:** *RSV Prophylaxis* by A. Murphy
A. Murphy presented immunization recommendations and North Dakota's Medicaid plan for RSV Prophylaxis. This information can be found in the handout. Testimony was provided by Julie Gilpin from SOBI on Synagis.

*Administrative Report***:** *Humira Biosimilars* by A. Murphy
A. Murphy discussed biosimilars of Humira with the Board; North Dakota Medicaid will continue to prefer Humira brand name.

Financial Report: Budget provided by B. Joyce
B. Joyce shared with the Board the expected trends of unwinding and the impact on rebates of insulin price decreases.

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

Clinical Report: Annual PDL Review Criteria Update by C. Stauter
C. Stauter discussed updates to the following sections in the PDL: Gout, Chronic Kidney Disease, Heart Failure, Long-Acting Opioid Analgesics, Opioid Use Disorder, Clostridioides difficile-associated diarrhea (CDAD), and Medications over $3000. These changes can be found in the handout. Testimony was provided

by Christopher Ngai from Callidaitas Therapeutics on Tarpeyo, Jessica Jay from Indivior on Sublocade, and Jake Nichols from US World Meds on ZIMHI and Lucemyra.

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.

Unfinished business:
Update to Hyperparathyroidism (Sensipar) provided by A. Murphy
A. Murphy discussed the changes to the hyperparathyroidism section to the PDL. These changes can be found in the handout.

New business:
First Reviews provided by C. Stauter
C. Stauter presented an overview of diuretics (triamterene) and menopause (Veozah). The presented material can be found in the handout. Testimony was provided by Jeenal Choksi from Astellas on Veozah.
Motion: Moved by K. Martian to draft prior authorization for triamterene, motion was seconded by A. Werremeyer. **Motion carried.**
Motion: Moved by A. Werremeyer to draft prior authorization for menopause, motion was seconded by A. Honeyman. **Motion carried.**

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

Announcements:
Next meeting is December 6th, 2023.

Adjournment:
Meeting adjourned by T. Schmidt at 2:26 pm CST.

Date of Minutes Approval:
Minutes submitted by: Claire Stauter, Kepro

Administrative Report:

Changes to the Medicaid rebate calculation will occur on 1/1/2024 and be reflected on the 1Q24 rebate file available in May 2024.

- Prior to 1/1/2024 manufacturer statutory rebates to Medicaid could not exceed the AMP for the drug (ie the “AMP cap”).
- The “AMP cap” will be removed starting 1/1/2024, meaning that manufacturers can owe Medicaid Rebates greater than 100% of their AMP.

AMP = Average Manufacturer Price

To avoid losing money when their product is used, manufacturers may decide to:

1. Lower their list price
2. Reformulate (e.g., discontinue brand and release authorized generic)
3. Modify commercial contracts and increase best price
4. Discontinue their product
5. Do nothing

Options 1, 2, and 3 result in increased net price to Medicaid due to decreased inflation penalty and best price rebates. Option 4 will likely result in increased cost to Medicaid as the substituted product will likely not have rebate greater than 100% of AMP.

ND Medicaid consequences:

- Net cost to the program will increase as some affected products are very high volume
- Changes in preferred products will need to be quick in response to discontinued products, reformulations, and net price changes as more information becomes available.

Financial Report

Budget

Claims > $5000 make up 0.38% of claims, but 28.83% of cost.

Subset	# of Claims	Paid to Pharmacies
Claims > $5000	348	$3,502,249.93
Total Claims	91196	$12,148,042.77

Expansion

Subset	# of Claims	Paid to Pharmacies
Claims > $5000	189	$1,935,350.41
Total Claims	40412	$5,852,717.03
33.1% of spend is in > $5000 claims		

Traditional

Subset	# of Claims	Paid to Pharmacies
Claims > $5000	159	$1,566,899.52
Total Claims	50784	$6,295,325.74
24.9% of spend is in > $5000 claims		

Included are claims for August 2023 that paid to pharmacy amount > $5000

Brand Name	Paid to Pharmacy	Diagnosis Code	Plan
JIVI 2,000 UNIT VIAL	$91,031.50	D66	Expansion
OXERVATE 0.002 EYE DROP	$26,518.28	H16231	Expansion
OXERVATE 0.002 EYE DROP	$26,518.28	H16231	Expansion
STELARA 90 MG/ML SYRINGE	$25,595.48	K5000	Expansion
STELARA 90 MG/ML SYRINGE	$25,595.48	K51911	Expansion
STELARA 90 MG/ML SYRINGE	$25,595.48	K5000	Expansion
STELARA 90 MG/ML SYRINGE	$25,595.48	K5090	Expansion
STELARA 90 MG/ML SYRINGE	$25,595.48	K50819	Traditional
STELARA 90 MG/ML SYRINGE	$25,595.48	L4050	Traditional
KALYDECO 25 MG GRANULES PAC	$25,079.50	E849	Traditional
TRIKAFTA 100-50-75 MG/75MG	$25,079.50	E849	Traditional
TRIKAFTA 80-40-60MG/59.5MG	$25,079.50	E849	Traditional
TRIKAFTA 80-40-60MG/59.5MG	$25,079.50	E849	Traditional
TRIKAFTA 100-50-75 MG/75MG	$25,079.50	E849	Traditional
TRIKAFTA 100-50-75 MG/150 M	$24,703.49	E849	Traditional
TRIKAFTA 100-50-75 MG/150 M	$24,703.49	E849	Traditional

TRIKAFTA 100-50-75 MG/150 M	$24,703.49	E849	Traditional
TRIKAFTA 100-50-75 MG/150 M	$24,703.49	E849	Expansion
KALYDECO 150 MG TABLET	$24,703.49	E849	Traditional
TRIKAFTA 100-50-75 MG/150 M	$24,703.49	E849	Traditional
TRIKAFTA 100-50-75 MG/150 M	$24,703.49	E840	Expansion
UPTRAVI 1,000 MCG TABLET	$22,196.23	I2720	Expansion
UPTRAVI 1,000 MCG TABLET	$22,196.23	I2721	Traditional
ORKAMBI 150-188 MG GRANULE	$21,956.73	E849	Traditional
ORKAMBI 100 MG-125 MG TABLE	$21,956.73	E849	Traditional
KOSELUGO 10 MG CAPSULE	$21,036.50	Q8501	Traditional
HUMIRA(CF) PEN CRHN-UC-HS 8	$20,194.27	K5010	Traditional
HUMIRA(CF) PEN CRHN-UC-HS 8	$20,194.27	K50018	Expansion
SCEMBLIX 40 MG TABLET	$20,117.74	C9210	Expansion
INLYTA 1 MG TABLET	$19,959.71	C642	Expansion
LONSURF 15 MG-6.14 MG TABLE	$19,931.56	~	Expansion
LONSURF 15 MG-6.14 MG TABLE	$19,931.56	~	Expansion
INVEGA HAFYERA 1,560 MG/5 M	$19,928.87	F209	Expansion
BOSULIF 400 MG TABLET	$19,495.06	C91Z0	Traditional
SKYRIZI 150 MG/ML SYRINGE	$19,274.86	L400	Expansion
INLYTA 5 MG TABLET	$19,115.79	C649	Expansion
SKYRIZI 150 MG/ML PEN	$19,066.23	L400	Expansion
SKYRIZI 150 MG/ML PEN	$19,066.23	L400	Expansion
SKYRIZI 150 MG/ML PEN	$19,066.23	L400	Expansion
TALTZ 80 MG/ML AUTOINJECTOR	$18,902.26	L400	Expansion
REVLIMID 25 MG CAPSULE	$17,510.19	C9000	Expansion
REVLIMID 10 MG CAPSULE	$17,510.17	C9000	Expansion
TAGRISSO 80 MG TABLET	$16,147.12	C3491	Traditional
LUMAKRAS 120 MG TABLET	$15,095.36	C3431	Expansion
LUMAKRAS 120 MG TABLET	$15,095.36	C3431	Expansion
IBRANCE 75 MG TABLET	$15,090.19	C50912	Expansion
IBRANCE 75 MG TABLET	$15,090.19	C50919	Expansion
BRAFTOVI 75 MG CAPSULE	$15,019.90	C438	Expansion
CALQUENCE 100 MG TABLET	$14,687.05	C8300	Traditional
VERZENIO 150 MG TABLET	$14,546.14	C50211	Traditional
LYNPARZA 150 MG TABLET	$14,522.76	C252	Expansion
LYNPARZA 100 MG TABLET	$14,522.76	C562	Traditional
LYNPARZA 150 MG TABLET	$14,522.76	C50812	Traditional
LYNPARZA 150 MG TABLET	$14,522.76	C563	Expansion
ERLEADA 60 MG TABLET	$14,215.03	~	Expansion
NORDITROPIN FLEXPRO 30 MG/3	$13,833.76	R6252	Traditional
XTANDI 40 MG CAPSULE	$13,662.43	~	Expansion
HUMIRA(CF) PEN PS-UV-AHS 80	$13,549.19	L400	Expansion
HUMIRA(CF) 40 MG/0.4 ML SYR	$13,506.02	L400	Expansion
HUMIRA(CF) PEN 40 MG/0.4 ML	$13,498.42	L732	Expansion
HUMIRA(CF) PEN 40 MG/0.4 ML	$13,498.42	L732	Expansion
HUMIRA(CF) PEN 40 MG/0.4 ML	$13,498.42	K5090	Expansion
HUMIRA(CF) PEN 40 MG/0.4 ML	$13,498.42	G250	Expansion
HUMIRA(CF) PEN 40 MG/0.4 ML	$13,498.42	L732	Expansion
HUMIRA(CF) PEN 40 MG/0.4 ML	$13,498.42	L732	Expansion

HUMIRA(CF) PEN 40 MG/0.4 ML	$13,498.42	L732	Expansion
HUMIRA(CF) PEN 40 MG/0.4 ML	$13,498.42	L732	Expansion
HUMIRA(CF) PEN 40 MG/0.4 ML	$13,498.42	L732	Expansion
HUMIRA(CF) PEN 40 MG/0.4 ML	$13,498.42	L732	Traditional
HUMIRA(CF) PEN 40 MG/0.4 ML	$13,498.42	K50118	Traditional
HUMIRA(CF) PEN 40 MG/0.4 ML	$13,498.42	L732	Traditional
HUMIRA(CF) PEN 40 MG/0.4 ML	$13,498.42	K50818	Traditional
HUMIRA(CF) PEN 40 MG/0.4 ML	$13,498.42	K51019	Traditional
HUMIRA PEN 40 MG/0.8 ML	$13,488.59	M069	Expansion
HUMIRA PEN 40 MG/0.8 ML	$13,488.59	L732	Expansion
HUMIRA PEN 40 MG/0.8 ML	$13,488.59	L732	Traditional
HUMIRA PEN 40 MG/0.8 ML	$13,488.59	K5080	Traditional
HUMIRA(CF) PEN 80 MG/0.8 ML	$13,456.22	L732	Traditional
HUMIRA(CF) PEN 80 MG/0.8 ML	$13,456.22	L732	Traditional
HUMIRA(CF) PEN 80 MG/0.8 ML	$13,456.22	L732	Traditional
TREMFYA 100 MG/ML SYRINGE	$13,224.65	L400	Expansion
KOSELUGO 25 MG CAPSULE	$13,152.49	C7230	Traditional
ADEMPAS 2.5 MG TABLET	$13,063.36	I270	Traditional
ADEMPAS 2.5 MG TABLET	$13,063.36	I270	Traditional
ADEMPAS 2.5 MG TABLET	$13,063.36	I2721	Expansion
TREMFYA 100 MG/ML INJECTOR	$12,863.96	L4050	Expansion
TREMFYA 100 MG/ML INJECTOR	$12,863.96	L400	Expansion
TREMFYA 100 MG/ML INJECTOR	$12,863.96	L400	Expansion
MAVYRET 100-40 MG TABLET	$12,827.85	B182	Expansion
MAVYRET 100-40 MG TABLET	$12,827.85	B1920	Expansion
MAVYRET 100-40 MG TABLET	$12,827.85	B182	Traditional
MAVYRET 100-40 MG TABLET	$12,827.85	B182	Traditional
MAVYRET 100-40 MG TABLET	$12,827.85	~	Traditional
MAVYRET 100-40 MG TABLET	$12,827.85	~	Traditional
MAVYRET 100-40 MG TABLET	$12,827.85	B182	Expansion
MAVYRET 100-40 MG TABLET	$12,827.85	~	Expansion
MAVYRET 100-40 MG TABLET	$12,827.85	B182	Expansion
MAVYRET 100-40 MG TABLET	$12,827.85	B182	Traditional
MAVYRET 100-40 MG TABLET	$12,827.85	B182	Traditional
MAVYRET 100-40 MG TABLET	$12,827.85	~	Traditional
STELARA 45 MG/0.5 ML SYRING	$12,772.44	L400	Traditional
TALTZ 80 MG/ML AUTOINJ (2-P	$12,605.66	L400	Expansion
XELJANZ 5 MG TABLET	$10,726.63	K5190	Expansion
MAVYRET 50-20 MG PELLET PAC	$10,572.94	B182	Traditional
AUSTEDO 9 MG TABLET	$10,231.69	G2401	Expansion
REVATIO 10 MG/ML ORAL SUSP	$10,185.52	I270	Traditional
GILENYA 0.5 MG CAPSULE	$10,149.97	R51	Expansion
GILENYA 0.5 MG CAPSULE	$10,149.97	G35	Expansion
GILENYA 0.5 MG CAPSULE	$10,149.97	~	Traditional
GILENYA 0.5 MG CAPSULE	$10,149.97	~	Expansion
GILENYA 0.5 MG CAPSULE	$10,149.97	~	Traditional
REBIF 44 MCG/0.5 ML SYRINGE	$9,933.30	G35	Expansion
MEKTOVI 15 MG TABLET	$9,828.65	C438	Expansion
INVEGA TRINZA 819 MG/2.63 M	$9,660.00	F250	Expansion

INVEGA TRINZA 819 MG/2.63 M	$9,660.00	F250	Traditional
INVEGA TRINZA 819 MG/2.63 M	$9,660.00	F29	Traditional
INVEGA TRINZA 819 MG/2.63 M	$9,660.00	F201	Traditional
INVEGA TRINZA 819 MG/2.63 M	$9,660.00	F209	Traditional
SPRYCEL 20 MG TABLET	$9,563.17	~	Expansion
NORDITROPIN FLEXPRO 30 MG/3	$9,226.66	E230	Traditional
ZEPOSIA 0.92 MG CAPSULE	$8,399.12	~	Expansion
ZEPOSIA 0.92 MG CAPSULE	$8,399.12	~	Expansion
KESIMPTA 20 MG/0.4 ML PEN	$8,176.55	G35	Traditional
KESIMPTA 20 MG/0.4 ML PEN	$8,176.55	G35	Traditional
KESIMPTA 20 MG/0.4 ML PEN	$8,176.55	G35	Traditional
KESIMPTA 20 MG/0.4 ML PEN	$8,176.55	G35	Expansion
KESIMPTA 20 MG/0.4 ML PEN	$8,176.55	G35	Expansion
ZENPEP DR 20,000 UNIT CAPSU	$8,050.64	~	Expansion
SOFOSBUVIR-VELPATASVIR 400-	$7,806.06	~	Traditional
SOFOSBUVIR-VELPATASVIR 400-	$7,806.06	B182	Traditional
SOFOSBUVIR-VELPATASVIR 400-	$7,806.06	~	Traditional
SOFOSBUVIR-VELPATASVIR 400-	$7,806.06	D696	Traditional
SOFOSBUVIR-VELPATASVIR 400-	$7,806.06	B182	Traditional
INGREZZA 80 MG CAPSULE	$7,787.86	~	Traditional
INGREZZA 80 MG CAPSULE	$7,787.86	~	Expansion
INGREZZA 80 MG CAPSULE	$7,787.86	G2401	Expansion
INGREZZA 80 MG CAPSULE	$7,787.86	~	Expansion
INGREZZA 80 MG CAPSULE	$7,787.86	~	Expansion
INGREZZA 80 MG CAPSULE	$7,787.86	~	Traditional
AVONEX PREFILLED SYR 30 MCG	$7,761.72	~	Traditional
AVONEX PEN 30 MCG/0.5 ML KI	$7,728.61	G35	Traditional
AVONEX PEN 30 MCG/0.5 ML KI	$7,728.61	G35	Expansion
NUTROPIN AQ NUSPIN 20 INJEC	$7,544.04	E230	Traditional
NOVOLOG 100 UNIT/ML FLEXPEN	$7,529.16	~	Expansion
INGREZZA 40 MG CAPSULE	$7,314.46	G2401	Traditional
INGREZZA 40 MG CAPSULE	$7,314.46	T43505S	Expansion
INGREZZA 40 MG CAPSULE	$7,314.46	~	Expansion
INGREZZA 40 MG CAPSULE	$7,314.46	G2401	Expansion
INGREZZA 40 MG CAPSULE	$7,314.46	~	Traditional
COPAXONE 20 MG/ML SYRINGE	$7,126.46	G35	Traditional
COPAXONE 20 MG/ML SYRINGE	$7,126.46	G35	Expansion
COPAXONE 20 MG/ML SYRINGE	$7,126.46	M7910	Traditional
COPAXONE 20 MG/ML SYRINGE	$7,126.46	~	Expansion
COPAXONE 20 MG/ML SYRINGE	$7,126.46	G35	Expansion
COPAXONE 20 MG/ML SYRINGE	$7,126.46	~	Expansion
EPIDIOLEX 100 MG/ML SOLN PA	$7,077.46	G40814	Traditional
PREVYMIS 480 MG TABLET	$6,980.82	~	Traditional
PREVYMIS 480 MG TABLET	$6,980.82	~	Traditional
COSENTYX 300 MG DOSE-2 SYRI	$6,936.72	M458	Expansion
COSENTYX 300 MG DOSE-2 SYRI	$6,936.72	L400	Expansion
ENBREL 50 MG/ML SURECLICK	$6,884.47	M0579	Expansion
ENBREL 50 MG/ML SURECLICK	$6,884.47	M457	Expansion
ENBREL 50 MG/ML SURECLICK	$6,884.47	M069	Expansion

ENBREL 50 MG/ML SURECLICK	$6,884.47	M069	Expansion
ENBREL 50 MG/ML SURECLICK	$6,884.47	L400	Traditional
ENBREL 50 MG/ML SURECLICK	$6,884.47	L400	Traditional
ENBREL 50 MG/ML SURECLICK	$6,884.47	M0579	Expansion
ENBREL 50 MG/ML SURECLICK	$6,884.47	L400	Expansion
ENBREL 50 MG/ML SURECLICK	$6,884.47	M069	Traditional
ENBREL 50 MG/ML MINI CARTRI	$6,872.89	M0800	Expansion
ENBREL 50 MG/ML MINI CARTRI	$6,872.89	L400	Traditional
ENBREL 50 MG/ML SYRINGE	$6,872.74	M459	Traditional
ENBREL 50 MG/ML SYRINGE	$6,872.74	M069	Expansion
ENBREL 50 MG/ML SYRINGE	$6,872.74	M459	Traditional
ENBREL 50 MG/ML SYRINGE	$6,872.74	L4050	Traditional
HUMIRA(CF) 40 MG/0.4 ML SYR	$6,759.24	M0890	Traditional
HUMIRA(CF) 40 MG/0.4 ML SYR	$6,759.24	M450	Expansion
HUMIRA(CF) PEN 40 MG/0.4 ML	$6,755.44	M069	Traditional
HUMIRA(CF) PEN 40 MG/0.4 ML	$6,755.44	K5100	Traditional
HUMIRA(CF) PEN 40 MG/0.4 ML	$6,755.44	K50818	Traditional
HUMIRA(CF) PEN 40 MG/0.4 ML	$6,755.44	L400	Traditional
HUMIRA(CF) PEN 40 MG/0.4 ML	$6,755.44	L400	Traditional
HUMIRA(CF) PEN 40 MG/0.4 ML	$6,755.44	M069	Expansion
HUMIRA(CF) PEN 40 MG/0.4 ML	$6,755.44	L400	Expansion
HUMIRA(CF) PEN 40 MG/0.4 ML	$6,755.44	M0579	Expansion
HUMIRA(CF) PEN 40 MG/0.4 ML	$6,755.44	K5100	Expansion
HUMIRA(CF) PEN 40 MG/0.4 ML	$6,755.44	M0579	Expansion
HUMIRA(CF) PEN 40 MG/0.4 ML	$6,755.44	M0600	Expansion
HUMIRA(CF) PEN 40 MG/0.4 ML	$6,755.44	L4050	Expansion
HUMIRA(CF) PEN 40 MG/0.4 ML	$6,755.44	F411	Expansion
HUMIRA(CF) PEN 40 MG/0.4 ML	$6,755.44	M0600	Traditional
HUMIRA(CF) PEN 40 MG/0.4 ML	$6,755.44	K5090	Traditional
HUMIRA(CF) PEN 40 MG/0.4 ML	$6,755.44	L400	Traditional
HUMIRA(CF) PEN 40 MG/0.4 ML	$6,755.44	M0600	Expansion
HUMIRA(CF) PEN 40 MG/0.4 ML	$6,755.44	L409	Expansion
HUMIRA(CF) PEN 40 MG/0.4 ML	$6,755.44	M069	Expansion
HUMIRA(CF) PEN 40 MG/0.4 ML	$6,755.44	K5100	Expansion
HUMIRA(CF) PEN 40 MG/0.4 ML	$6,755.44	L400	Expansion
HUMIRA(CF) PEN 40 MG/0.4 ML	$6,755.44	L4050	Expansion
HUMIRA(CF) PEN 40 MG/0.4 ML	$6,755.44	M0600	Traditional
HUMIRA(CF) PEN 40 MG/0.4 ML	$6,755.44	L400	Traditional
HUMIRA(CF) PEN 40 MG/0.4 ML	$6,755.44	H2011	Traditional
HUMIRA(CF) PEN 40 MG/0.4 ML	$6,755.44	K50018	Expansion
HUMIRA(CF) PEN 40 MG/0.4 ML	$6,755.44	L400	Expansion
HUMIRA(CF) PEN 40 MG/0.4 ML	$6,755.44	M450	Expansion
HUMIRA(CF) PEN 40 MG/0.4 ML	$6,755.44	M458	Traditional
HUMIRA(CF) PEN 40 MG/0.4 ML	$6,755.44	K51018	Traditional
HUMIRA(CF) PEN 40 MG/0.4 ML	$6,755.44	K5000	Traditional
HUMIRA(CF) PEN 40 MG/0.4 ML	$6,755.44	L4050	Traditional
HUMIRA(CF) PEN 40 MG/0.4 ML	$6,755.44	H209	Traditional
HUMIRA(CF) PEN 40 MG/0.4 ML	$6,755.44	L400	Traditional
HUMIRA(CF) PEN 40 MG/0.4 ML	$6,755.44	L409	Expansion

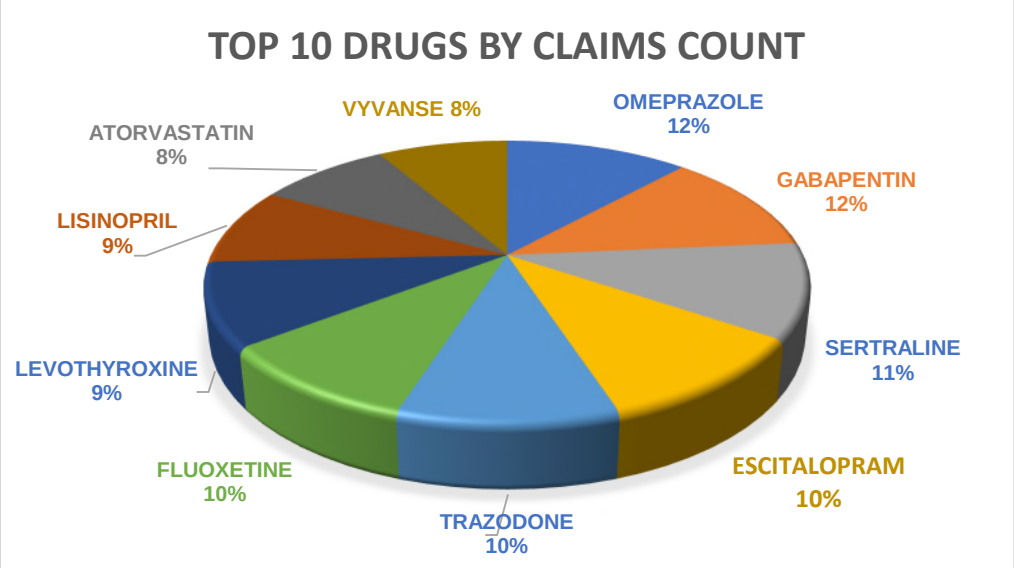
HUMIRA(CF) PEN 40 MG/0.4 ML	$6,755.44	K5000	Expansion
HUMIRA(CF) PEN 40 MG/0.4 ML	$6,755.44	M0600	Expansion
HUMIRA(CF) PEN 40 MG/0.4 ML	$6,755.44	L400	Expansion
HUMIRA(CF) PEN 40 MG/0.4 ML	$6,755.44	L400	Expansion
HUMIRA(CF) PEN 40 MG/0.4 ML	$6,755.44	L400	Expansion
HUMIRA(CF) PEN 40 MG/0.4 ML	$6,755.44	L400	Expansion
HUMIRA(CF) PEN 40 MG/0.4 ML	$6,755.44	L4050	Expansion
HUMIRA(CF) PEN 40 MG/0.4 ML	$6,755.44	K5010	Expansion
HUMIRA(CF) PEN 40 MG/0.4 ML	$6,755.44	M05741	Expansion
HUMIRA(CF) PEN 40 MG/0.4 ML	$6,755.44	Z79899	Expansion
HUMIRA(CF) PEN 40 MG/0.4 ML	$6,755.44	L409	Expansion
HUMIRA(CF) PEN 40 MG/0.4 ML	$6,755.44	L409	Traditional
HUMIRA(CF) PEN 40 MG/0.4 ML	$6,755.44	L400	Traditional
HUMIRA(CF) PEN 40 MG/0.4 ML	$6,755.44	M459	Expansion
HUMIRA(CF) PEN 40 MG/0.4 ML	$6,755.44	M459	Traditional
HUMIRA(CF) PEN 40 MG/0.4 ML	$6,755.44	M0890	Traditional
HUMIRA(CF) PEN 40 MG/0.4 ML	$6,755.44	K529	Traditional
HUMIRA 40 MG/0.8 ML SYRINGE	$6,754.39	L400	Expansion
HUMIRA PEN 40 MG/0.8 ML	$6,750.52	M059	Traditional
HUMIRA PEN 40 MG/0.8 ML	$6,750.52	M059	Traditional
HUMIRA PEN 40 MG/0.8 ML	$6,750.52	L4050	Traditional
HUMIRA PEN 40 MG/0.8 ML	$6,750.52	L4050	Traditional
HUMIRA PEN 40 MG/0.8 ML	$6,750.52	Z5181	Traditional
HUMIRA PEN 40 MG/0.8 ML	$6,750.52	L4050	Expansion
HUMIRA PEN 40 MG/0.8 ML	$6,750.52	K5000	Expansion
HUMIRA PEN 40 MG/0.8 ML	$6,750.52	M458	Expansion
HUMIRA PEN 40 MG/0.8 ML	$6,750.52	G43009	Traditional
HUMIRA PEN 40 MG/0.8 ML	$6,750.52	M069	Traditional
HUMIRA PEN 40 MG/0.8 ML	$6,750.52	L4050	Traditional
HUMIRA PEN 40 MG/0.8 ML	$6,750.52	M458	Expansion
HUMIRA PEN 40 MG/0.8 ML	$6,750.52	K5000	Expansion
HUMIRA PEN 40 MG/0.8 ML	$6,750.52	M0609	Expansion
HUMIRA PEN 40 MG/0.8 ML	$6,750.52	M459	Expansion
HUMIRA PEN 40 MG/0.8 ML	$6,750.52	M45A6	Expansion
HUMIRA PEN 40 MG/0.8 ML	$6,750.52	M458	Expansion
HUMIRA PEN 40 MG/0.8 ML	$6,750.52	M069	Expansion
HUMIRA PEN 40 MG/0.8 ML	$6,750.52	Z79899	Expansion
HUMIRA PEN 40 MG/0.8 ML	$6,750.52	L400	Expansion
HUMIRA PEN 40 MG/0.8 ML	$6,750.52	L4050	Expansion
HUMIRA PEN 40 MG/0.8 ML	$6,750.52	L4050	Traditional
HUMIRA PEN 40 MG/0.8 ML	$6,750.52	L400	Traditional
COSENTYX SNRDY 300MG DOSE-2	$6,718.60	L400	Expansion
COSENTYX SNRDY 300MG DOSE-2	$6,718.60	L400	Expansion
COSENTYX SNRDY 300MG DOSE-2	$6,718.60	L400	Traditional
COSENTYX SNRDY 300MG DOSE-2	$6,718.60	L400	Traditional
COSENTYX SNRDY 300MG DOSE-2	$6,718.60	L400	Expansion
COSENTYX SNRDY 300MG DOSE-2	$6,718.60	L400	Expansion
SOFOSBUVIR-VELPATASVIR 400-	$6,601.09	D696	Traditional
TALTZ 80 MG/ML SYRINGE	$6,598.86	L400	Expansion

TALTZ 80 MG/ML SYRINGE	$6,598.86	L400	Traditional
INVEGA TRINZA 546 MG/1.75 M	$6,414.78	F29	Expansion
INVEGA TRINZA 546 MG/1.75 M	$6,414.78	F319	Traditional
INVEGA TRINZA 546 MG/1.75 M	$6,414.78	F28	Expansion
TALTZ 80 MG/ML AUTOINJECTOR	$6,309.06	L400	Traditional
TALTZ 80 MG/ML AUTOINJECTOR	$6,309.06	L400	Traditional
TALTZ 80 MG/ML AUTOINJECTOR	$6,309.06	L400	Traditional
TALTZ 80 MG/ML AUTOINJECTOR	$6,309.06	L400	Expansion
TALTZ 80 MG/ML AUTOINJECTOR	$6,309.06	L4050	Expansion
TALTZ 80 MG/ML AUTOINJECTOR	$6,309.06	L400	Expansion
TALTZ 80 MG/ML AUTOINJECTOR	$6,309.06	L400	Expansion
TALTZ 80 MG/ML AUTOINJECTOR	$6,309.06	L400	Expansion
TALTZ 80 MG/ML AUTOINJECTOR	$6,309.06	M450	Expansion
TALTZ 80 MG/ML AUTOINJECTOR	$6,309.06	L400	Expansion
TALTZ 80 MG/ML AUTOINJECTOR	$6,309.06	L400	Expansion
TALTZ 80 MG/ML AUTOINJECTOR	$6,309.06	L400	Expansion
TALTZ 80 MG/ML AUTOINJECTOR	$6,309.06	L400	Traditional
TALTZ 80 MG/ML AUTOINJECTOR	$6,309.06	L400	Traditional
TALTZ 80 MG/ML AUTOINJECTOR	$6,309.06	L400	Expansion
TALTZ 80 MG/ML AUTOINJECTOR	$6,309.06	L400	Expansion
TALTZ 80 MG/ML AUTOINJECTOR	$6,309.06	L400	Expansion
TALTZ 80 MG/ML AUTOINJECTOR	$6,309.06	L400	Traditional
TALTZ 80 MG/ML AUTOINJECTOR	$6,309.06	L409	Traditional
TALTZ 80 MG/ML AUTOINJECTOR	$6,309.06	L400	Traditional
TALTZ 80 MG/ML AUTOINJECTOR	$6,309.06	L400	Traditional
TALTZ 80 MG/ML AUTOINJECTOR	$6,309.06	L400	Traditional
TALTZ 80 MG/ML AUTOINJECTOR	$6,309.06	L400	Traditional
TALTZ 80 MG/ML AUTOINJECTOR	$6,309.06	L400	Expansion
TALTZ 80 MG/ML AUTOINJECTOR	$6,309.06	L400	Expansion
TALTZ 80 MG/ML AUTOINJECTOR	$6,309.06	L400	Expansion
TALTZ 80 MG/ML AUTOINJECTOR	$6,309.06	L400	Expansion
TALTZ 80 MG/ML AUTOINJECTOR	$6,309.06	L400	Expansion
TALTZ 80 MG/ML AUTOINJECTOR	$6,309.06	L400	Expansion
NUTROPIN AQ NUSPIN 10 INJEC	$6,299.21	Q969	Traditional
EPIDIOLEX 100 MG/ML SOLN PA	$6,292.46	G40814	Traditional
BETHKIS 300 MG/4 ML AMPULE	$6,198.22	E849	Expansion
SOTYKTU 6 MG TABLET	$6,176.84	L400	Traditional
RINVOQ ER 30 MG TABLET	$6,137.42	K51311	Expansion
RINVOQ ER 30 MG TABLET	$6,137.42	K51311	Expansion
RINVOQ ER 30 MG TABLET	$6,137.42	L299	Traditional
RINVOQ ER 15 MG TABLET	$5,960.91	M0589	Expansion
RINVOQ ER 15 MG TABLET	$5,960.91	M0579	Expansion
RINVOQ ER 15 MG TABLET	$5,960.91	M0609	Expansion
NORDITROPIN FLEXPRO 10 MG/1	$5,958.06	Q969	Traditional
NORDITROPIN FLEXPRO 10 MG/1	$5,958.06	E230	Traditional
NORDITROPIN FLEXPRO 10 MG/1	$5,958.06	R6252	Traditional
NORDITROPIN FLEXPRO 10 MG/1	$5,958.06	E230	Traditional
SIMPONI 50 MG/0.5 ML SYRING	$5,879.90	M0609	Traditional
SIMPONI 50 MG/0.5 ML SYRING	$5,879.90	M0609	Traditional

RINVOQ ER 15 MG TABLET	$5,787.02	M0609	Traditional
SIMPONI 50 MG/0.5 ML PEN IN	$5,721.47	M450	Traditional
SIMPONI 50 MG/0.5 ML PEN IN	$5,721.47	L4050	Expansion
CREON DR 12,000 UNIT CAPSUL	$5,703.76	E849	Traditional
FASENRA PEN 30 MG/ML	$5,523.87	J4550	Traditional
ABILIFY ASIMTUFII 960 MG/3.	$5,450.92	F28	Traditional
ABILIFY ASIMTUFII 960 MG/3.	$5,450.92	F250	Expansion
XELJANZ 5 MG TABLET	$5,369.55	M069	Traditional
XELJANZ 5 MG TABLET	$5,369.55	M0609	Expansion
XELJANZ 5 MG TABLET	$5,369.55	M069	Expansion
XELJANZ 5 MG TABLET	$5,369.55	M059	Expansion
XELJANZ 5 MG TABLET	$5,369.55	M0579	Expansion
XELJANZ 5 MG TABLET	$5,369.55	K51011	Expansion
XELJANZ 5 MG TABLET	$5,369.55	L4050	Expansion
CIMZIA 2X200 MG/ML SYRINGE	$5,248.30	K50118	Traditional
CIMZIA 2X200 MG/ML SYRINGE	$5,248.30	M450	Traditional
ORENCIA 125 MG/ML SYRINGE	$5,233.12	M0579	Expansion
ORENCIA 125 MG/ML SYRINGE	$5,233.12	M069	Expansion
ORENCIA CLICKJECT 125 MG/ML	$5,229.78	M0600	Expansion
ORENCIA CLICKJECT 125 MG/ML	$5,229.78	M0600	Expansion
ORENCIA CLICKJECT 125 MG/ML	$5,229.78	M0589	Expansion
ORENCIA CLICKJECT 125 MG/ML	$5,229.78	M0609	Traditional
ORENCIA CLICKJECT 125 MG/ML	$5,229.78	L4050	Traditional
ORENCIA CLICKJECT 125 MG/ML	$5,229.78	M069	Expansion
ORENCIA CLICKJECT 125 MG/ML	$5,229.78	M069	Expansion
ORENCIA CLICKJECT 125 MG/ML	$5,229.78	M0589	Expansion
KINERET 100 MG/0.67 ML SYRI	$5,165.02	M0820	Expansion
KINERET 100 MG/0.67 ML SYRI	$5,165.02	M0820	Expansion
KINERET 100 MG/0.67 ML SYRI	$5,165.02	M0609	Expansion
KINERET 100 MG/0.67 ML SYRI	$5,165.02	M0820	Traditional
LANTUS SOLOSTAR 100 UNIT/ML	$5,061.51	E119	Traditional
NUTROPIN AQ NUSPIN 10 INJEC	$5,041.86	E230	Traditional
NUTROPIN AQ NUSPIN 10 INJEC	$5,041.86	E230	Traditional
NUTROPIN AQ NUSPIN 10 INJEC	$5,041.86	E230	Traditional
NUTROPIN AQ NUSPIN 20 INJEC	$5,041.82	E230	Traditional
NUTROPIN AQ NUSPIN 20 INJEC	$5,041.82	E230	Traditional
NUTROPIN AQ NUSPIN 20 INJEC	$5,041.82	E230	Traditional
NUTROPIN AQ NUSPIN 10 INJEC	$5,029.40	E230	Traditional

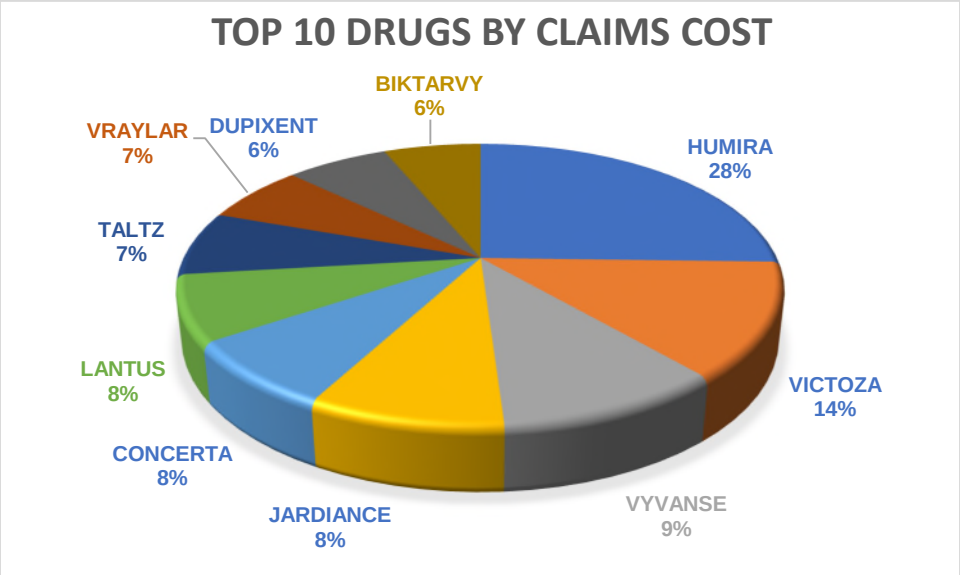
Top 25 Drugs Based on Number of Claims from 07/01/2023 – 09/30/2023

Drug	Claims	Claims Cost	Patients	Cost / Claim	% Total Claims	Dif.
1. OMEPRAZOLE	4,385	$55,909.86	2,244	$12.75	1.8%	NC
2. GABAPENTIN	4,323	$64,059.07	1,936	$14.82	1.8%	NC
3. SERTRALINE HCL	3,873	$52,788.93	2,231	$13.63	1.6%	NC
4. ESCITALOPRAM	3,698	$49,430.12	2,149	$13.37	1.5%	↑1
5. TRAZODONE HCL	3,634	$49,073.62	1,932	$13.50	1.5%	↓1
6. FLUOXETINE HCL	3,563	$47,224.70	1,991	$13.25	1.4%	NC
7. LEVOTHYROXINE	3,299	$51,665.24	1,794	$15.66	1.3%	↑1
8. LISINOPRIL	3,080	$39,342.04	1,924	$12.77	1.2%	↑2
9. ATORVASTATIN	3,042	$43,965.34	1,833	$14.45	1.2%	↑2
10. VYVANSE	2,995	$783,027.55	1,323	$261.44	1.2%	↓1
11. VENTOLIN HFA	2,975	$192,770.17	2,943	$64.80	1.2%	↑3
12. BUPROPION XL	2,929	$48,415.42	1,637	$16.53	1.2%	NC
13. PANTOPRAZOLE	2,909	$39,815.38	1,501	$13.69	1.2%	NC
14. NORCO	2,596	$38,347.06	1,633	$14.77	1.1%	↑1
15. CLONIDINE HCL	2,519	$30,947.96	1,272	$12.29	1.0%	↑3
16. DULOXETINE HCL	2,505	$40,987.48	1,375	$16.36	1.0%	↑1
17. LAMOTRIGINE	2,505	$35,544.77	1,051	$14.19	1.0%	↑4
18. CYCLOBENZAPRINE	2,465	$29,244.80	1,574	$11.86	1.0%	↓2
19. AMOXICILLIN	2,463	$34,118.04	2,334	$13.85	1.0%	↓12
20. PREDNISONE	2,446	$28,310.74	2,022	$11.57	1.0%	NC
21. HYDROXYZINE HCL	2,403	$32,043.07	1,526	$13.33	1.0%	↓2
22. AMLODIPINE	2,206	$28,233.94	1,353	$12.80	0.9%	↑3
23. BUSPIRONE HCL	2,165	$32,537.09	1,211	$15.03	0.9%	↑1
24. SUBOXONE	2,148	$90,859.89	630	$42.30	0.9%	↓1
25. CLONAZEPAM	2,122	$28,866.51	970	$13.60	0.9%	↑2
Total Claims						**246,914**



Top 25 Drugs Based on Total Claims Cost from 07/01/2023 – 09/30/2023

Drug	Claims	Claims Cost	Patients	Cost / Patient	% Total Cost	Dif.
1. HUMIRA	298	$2,487,213.40	141	$49,744.27	7.5%	NC
2. VICTOZA	3531	$1,245,842.62	706	$1,764.65	3.7%	NC
3. VYVANSE	2,995	$783,027.55	1,323	$591.86	2.4%	NC
4. JARDIANCE	1,070	$717,384.19	560	$1,281.04	2.2%	↑1
5. CONCERTA	1,985	$695,817.34	879	$791.60	2.1%	↓1
6. LANTUS	1323	$690,186.17	838	$823.61	2.1%	NC
7. TALTZ	92	$627,117.92	39	$16,079.95	1.9%	↑2
8. VRAYLAR	598	$586,772.85	251	$2,337.74	1.8%	↓1
9. DUPIXENT	167	$559,176.31	77	$7,262.03	1.7%	↑1
10. BIKTARVY	244	$525,221.00	114	$4,607.20	1.6%	NC
11. INVEGA SUSTENNA	204	$516,966.00	82	$6,304.46	1.6%	↓3
12. TRIKAFTA	28	$496,785.86	12	$41,398.82	1.5%	↑3
13. ELIQUIS	707	$399,889.86	342	$1,169.27	1.2%	↑1
14. NOVOLOG	550	$395,145.71	350	$1,128.99	1.2%	↓2
15. MAVYRET	31	$389,290.00	21	$18,537.62	1.2%	↓4
16. ADDERALL XR	2,021	$368,581.89	922	$399.76	1.1%	↓4
17. STELARA	15	$358,286.12	13	$27,560.47	1.1%	↓6
18. SYMBICORT	1,014	$356,644.03	591	$603.46	1.1%	↓2
19. ADVAIR DISKUS	853	$316,633.75	478	$662.41	1.0%	↓1
20. JIVI	3	$276,713.38	1	$276,713.38	0.8%	↑11
21. ABILIFY MAINTENA	117	$276,684.34	47	$5,886.90	0.8%	↓1
22. SUBLOCADE	140	$270,614.40	71	$3,811.47	0.8%	↑2
23. NORDITROPIN	51	$247,484.22	25	$9,899.37	0.7%	↓6
24. INGREZZA	32	$231,407.32	15	$15,427.15	0.7%	↑2
25. NUTROPIN AQ	53	$229,488.87	26	$8,826.50	0.7%	↑35
Total Claims Cost						**$33,236,654.11**



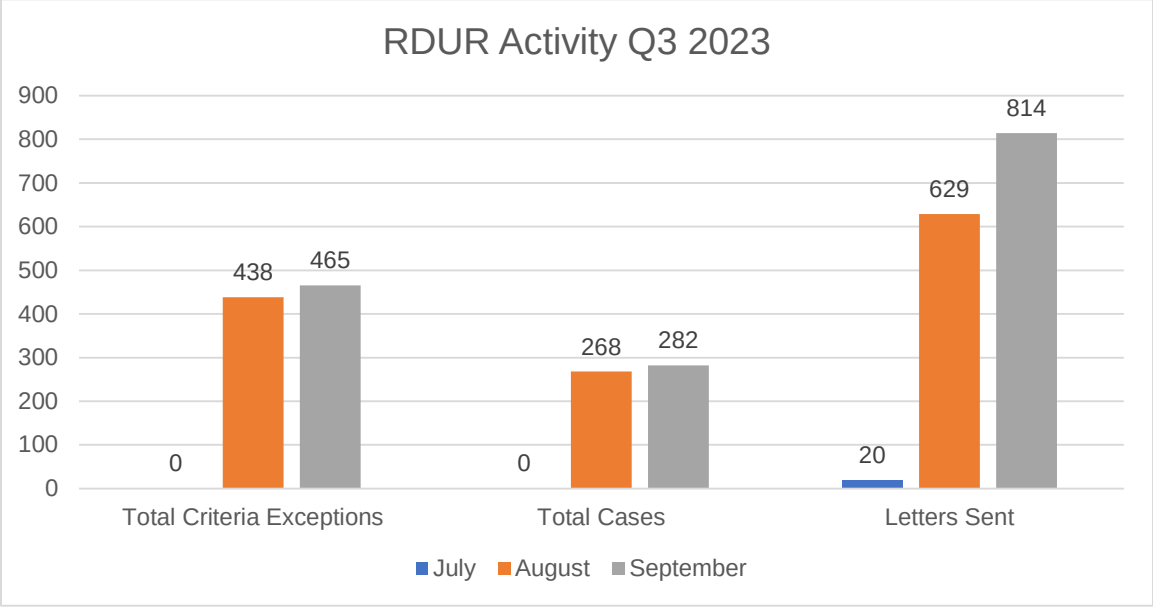
Top 15 Therapeutic Classes Based on Number of Claims from 07/01/2023 – 09/30/2023

Therapeutic Class Description	Claims	Claims Cost	Patients	Cost/Claim	% Total Claims	Dif.
1. ANTIDEPRESSANTS	27,538	$602,234.02	11,912	$21.87	11.2%	NC
2. ANTICONVULSANTS	12,978	$549,173.48	4,736	$42.32	5.3%	NC
3. ANTIPSYCHOTIC AGENTS	9,240	$2,256,244.56	3,727	$244.18	3.7%	NC
4. PROTON-PUMP INHIBITORS	7,680	$148,980.49	3,901	$19.40	3.1%	NC
5. ANXIOLYTICS, SEDATIVES, HYPNOTICS	7,139	$102,744.48	3,788	$14.39	2.9%	NC
6. AMPHETAMINES	6,660	$1,237,316.08	2,848	$185.78	2.7%	NC
7. OPIATE AGONISTS	6,357	$98,726.54	3,331	$15.53	2.6%	NC
8. NSAIDS	6,014	$85,348.57	4,082	$14.19	2.4%	↑1
9. STATINS	5,481	$80,389.41	3,267	$14.67	2.2%	↑1
10. RESP/CNS STIMULANTS	5,208	$905,271.68	2,083	$173.82	2.1%	↑1
11. BETA BLOCKING AGENTS	5,110	$89,461.94	2,907	$17.51	2.1%	↑1
12. PENICILLIN ANTIBIOTICS	4,728	$72,546.18	4,277	$15.34	1.9%	↓4
13. BETA AGONISTS	3,949	$245,276.63	3,651	$62.11	1.6%	↑1
14. ADRENALS	3,911	$52,725.94	3,145	$13.48	1.6%	↓1
15. ACE INHIBITORS	3,834	$61,323.45	2,370	$15.99	1.6%	NC

Top 15 Therapeutic Classes Based on Claims Cost from 07/01/2023 – 09/30/2023

Therapeutic Class Description	Claims	Claims Cost	Patients	Cost/Patient	% Total Cost	Dif.
1. DMARDS	601	$3,542,725.91	260	$13,625.87	10.7%	NC
2. ANTIPSYCHOTIC AGENTS	9,240	$2,256,244.56	3,727	$605.38	6.8%	NC
3. SKIN MEMBRANE AGENTS	654	$1,992,883.51	400	$4,982.21	6.0%	NC
4. INSULINS	3,372	$1,792,897.91	1,370	$1,308.68	5.4%	NC
5. INCRETIN MIMETICS	1,577	$1,411,845.11	735	$1,920.88	4.2%	NC
6. AMPHETAMINES	6,660	$1,237,316.08	2,848	$434.45	3.7%	↑1
7. ANTINEOPLASTIC AGENTS	594	$1,208,476.17	267	$4,526.13	3.6%	↓1
8. CORTICOSTEROIDS (RESP)	3,448	$1,040,011.50	2,086	$498.57	3.1%	NC
9. ANTIRETROVIRALS	740	$1,002,830.65	275	$3,646.66	3.0%	↑2
10. SGLT-2 INHIBITORS	1,480	$971,565.19	787	$1,234.52	2.9%	↓1
11. RESP/CNS STIMULANTS	5,208	$905,271.68	2,083	$434.60	2.7%	↓1
12. ANTIDEPRESSANTS	27,538	$602,234.02	11,912	$50.56	1.8%	↑1
13. ANTICOAGULANTS	1,472	$563,999.23	657	$858.45	1.7%	↑2
14. ANTICONVULSANTS	12,978	$549,173.48	4,736	$115.96	1.7%	↑2
15. HCV ANTIVIRALS	48	$520,788.05	31	$16,799.61	1.6%	↓3

RDUR Report: Q3 2023



July Special Mailing

20 letters sent to prescribers

Introduction

The top 20 buprenorphine prescribers by number of patients were selected for this report. At the bottom of this report, you will see claims data for prescriptions that have been attributed to you by the dispensing pharmacy since January 1, 2022. The data for the other 19 prescribers is provided for your awareness. These data points were chosen to indicate areas that may impact patient outcomes of adherence to the medication and maintaining treatment stability. Rationale for each data point is provided for your review.

- *Please be aware that ND Medicaid will no longer cover the oral buprenorphine monotherapy product for people who are pregnant or breastfeeding after August 1, 2023. Any prior authorizations that were in place before this date will not be affected by this change.*

Days' Supply Per Prescription

Requiring numerous trips to office visits and pharmacies to obtain treatment regimens may negatively impact outcomes due to access to transportation, childcare, and new job time off.
A high number of prescriptions per patient combined with a low average day supply of combination buprenorphine/ naloxone may impede adherence to the treatment plan.

Use of long-acting injectable buprenorphine

Consider long-acting injectable buprenorphine following induction or if unable to stabilize on transmucosal buprenorphine formulations, especially for those who have unsafe living environments or multiple opioid overdoses:

- Studies have shown superior results for long-acting injectable buprenorphine in achieving no illicit opioid use.
- Sublocade can be started following 7 days of an equivalent to 8-24 mg/day of transmucosal buprenorphine. Brixadi can be initiated following a single dose of transmucosal buprenorphine.
- Long-acting injectable buprenorphine at steady state offers less fluctuation and higher sustained plasma levels of buprenorphine than transmucosal buprenorphine. Sublocade (100 mg or 300 mg) and certain dosing schedules of Brixadi maintain trough levels above 2 ng/mL, which is the minimum level needed to achieve withdrawal suppression and blockade of opioid agonist subjective effects.

A high number of patients on a of long-acting injectable buprenorphine, such as Sublocade or Brixadi, may increase ability to achieve no illicit opioid use versus a daily tablet.

Pregnancy

Based on a growing body of evidence showing that maintenance on the combination buprenorphine/naloxone product does not negatively affect newborn outcomes, the American College of Obstetricians and Gynecologist (ACOG) and Substance Abuse and Mental Health Services Administration (SAMSHA) do not recommend that a person who is pregnant be transitioned to the transmucosal buprenorphine mono-product. SAMSHA also states that pregnancy alone is not an indication to change a member who is stable on one opioid agonist to another opioid agonist and any medication change represents a period of vulnerability to return to substance use. These are important counseling points for patients with concerns on continuing treatment with the buprenorphine/naloxone combination products:

- The buprenorphine mono-product has historically been used due to the risk of severe withdrawal to baby and mom and fetal distress to baby if the combination is injected. Naloxone has very low (<3%) systemic bioavailability when taken transmucosally, so withdrawal symptoms do not occur when used as directed.
- The buprenorphine mono-product has a higher potential for misuse by intravenous injection and diversion, including a higher street value.

- Neither product is specifically FDA approved for use in pregnancy and contain the same warning and precautions.

Maintaining buprenorphine/naloxone combination products throughout pregnancy may minimize treatment interruption and administrative burden without negatively impacting patient outcomes.

References:

1. *Lofwall MR, Walsh SL, Nunes EV, Bailey GL, Sigmon SC, Kampman KM, Frost M, Tiberg F, Linden M, Sheldon B, Oosman S, Peterson S, Chen M, Kim S. Weekly and Monthly Subcutaneous Buprenorphine Depot Formulations vs Daily Sublingual Buprenorphine With Naloxone for Treatment of Opioid Use Disorder: A Randomized Clinical Trial. JAMA Intern Med. 2018 Jun 1;178(6):764-773. doi: 10.1001/jamainternmed.2018.1052. PMID: 29799968; PMCID: PMC6145749.*
2. *Nasser AF, Heidbreder C, Gomeni R, et al. A population pharmacokinetic and pharmacodynamic modelling approach to support the clinical development of RBP-6000, a new, subcutaneously injectable, long-acting, sustained-release formulation of buprenorphine, for the treatment of opioid dependence. Clin Pharmacokinet. 2014;53:813-824.*
3. *Opioid use and opioid use disorder in pregnancy. Committee Opinion No. 711. American College of Obstetricians and Gynecologists. Obstet Gynecol 2017;130:e81–94.*
4. *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*
5. *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*

Adherence			**Sublocade**
% of Prescriber's prescriptions with day supply less than 5 days	% of Prescriber's prescriptions with day supply 21 or greater day supply	Average day supply of combination buprenorphine/ naloxone prescriptions	# Patients on Sublocade
6%	24%	14	5
2%	66%	22	0
7%	29%	14	0
12%	24%	12	0
1%	61%	21	20
2%	53%	19	11
4%	56%	19	1
15%	16%	11	1
11%	27%	14	1
8%	35%	16	0
1%	51%	19	20
1%	52%	20	13
14%	27%	13	0
3%	68%	22	8
6%	60%	11	0
4%	59%	20	7
11%	20%	12	1
12%	13%	10	7
3%	50%	19	11
0%	8%	10	0

August Cases by Type of Criteria		
Criteria Description	**# of Cases**	**% of Cases**
Clinical Appropriateness	6	2.2%
Drug-Drug Conflicts	260	97.0%
Therapeutic Duplication	2	0.7%

September Cases by Type of Criteria		
Criteria Description	**# of Cases**	**% of Cases**
Clinical Appropriateness	32	11.3%
Drug-Disease Interactions	248	87.9%
Drug-Drug Conflicts	2	0.7%

Clinical Report

Prior Authorization Update

Prior Authorization Update	PA Status	Class
Abrilada	PA	Immunomodulators
Airsupra	PA	Asthma/COPD - Steroid/Short-Acting Beta Agonist (SABA) Combination Inhalers
Arnuity Ellipta	remove PA	Asthma/COPD - Corticosteroids – Inhaled
Bimzelx	PA	Immunomodulators
Brenzavvy	PA	Diabetes - SGLT2 inhibitors
Dyanavel XR	PA	Preferred dosage form
emtricitabine	PA	Preferred dosage form
Entyvio	PA	Immunomodulators
Iyuzeh	PA	Ophthalmic - Prostaglandins
lamivudine	PA	Preferred dosage form
Motpoly XR	PA	Preferred dosage form
nevirapine ER	PA	Preferred dosage form
Ngenla	PA	Growth Hormone
Qalsody - *Medical Billing Only*	PA	Amyotropic Lateral Sclerosis (ALS)
rilpivirine	PA	Preferred dosage form
Sohonos	PA	Medications that cost > $3000
Supprelin LA - *Medical Billing Only*	PA	Precocious Puberty
Velsipity (etrasimod)	PA	Immunomodulators
Zidovudine	PA	Preferred dosage form

Cholestatis Pruritis Summary of Changes:

Bylvay (odevixibat) received a new indication for pruritis in Alagille Syndrome (ALGS). Livmarli (maralizibat) has this indication as well. Genetic testing criteria and step through Livmarli for the pruritis in Alagille Syndrome (ALGS) indication added. Bylvay remains sole preferred agent for pruritis in Progressive Familial Intrahepatic Cholestatis (PFIC) as Livmarli does not have this indication.

Cholestasis Pruritis

Alagille Syndrome (ALGS):

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

Progressive Familial Intrahepatic Cholestasis (PFIC):

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

Prior Authorization Criteria

Initial Criteria - Approval Duration: 6 months

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

Renewal Criteria - Approval Duration: 12 months

- The member has experienced an improvement in pruritis, as evidenced by clinical documentation.

- The member must have experienced a reduction in serum bile acid as defined as a bile acid reduction ≥70% or reaching a bile acid level ≤70 µmol/L

Diabetes Summary of Changes:

For GLP-1 Agonists and GIP/GLP-1 Agonists:

- Added requirement for inability to achieve goal after guideline supported triple therapy to criteria for non-preferred agents. Triple therapy is defined as Victoza, metformin, SGLT-2 inhibitor or insulin (may be met with other agents with clinical justification).
- Removed requirement to fail combination of SGLT-2 inhibitor and DPP4-inhibitor if Victoza trial is not possible due to contraindication or intolerance.
- Added verbiage about GI side effect mitigation for metformin and GLP-1 agonists, as well as class effect counseling.
- Added requirement that member receive diabetes education or see a diabetes specialist if unable to achieve goal with both Victoza and Trulicity as part of triple therapy prior to moving to GLP-1 Agonists Step 2 non-preferred agents and GIP/GLP-1 Agonists.

GLP-1 Agonists^

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

++Clinically Non-Preferred: Byetta is less effective than other available agents.
^ See GIP/GLP-1 Agonists section for Mounjaro (tirzepatide) criteria

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

- For GI side effects (start titration at lowest available dose)
- For any other reason, may consider starting at equivalent dose to minimize disruption to glycemic control
  - 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

References:

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

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

- Step 1: Trulicity:
  - The member has been unable to achieve goal A1C (≤ 7%) or TIR (>70%) despite a 90-day trial of triple combination therapy with Victoza, metformin, SGLT-2 inhibitor or insulin, as evidenced by paid claims or pharmacy printouts.
    - If triple therapy cannot be met with these agents, clinical justification must be provided (subject to clinical review*), and triple therapy must be met by other agents.
- Step 2:
  - The member has been unable to achieve goal A1C (≤ 7%) or TIR (>70%) despite two 90-day trials of triple combination therapy (one trial with Victoza and one with Trulicity, 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 these agents, clinical justification must be provided (subject to clinical review*), and triple therapy must be met by other agents.
    - 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, member should be counseled on potential for GI side effects, with GI effects being common across all GLP-1 agonist agents and transient in nature, typically lessoning with ongoing treatment.
- Patient experiencing GI side effects should be counseled: reduction in meal size, eating slower, decreased intake of greasy, high-fat or spicy food, refrain from laying down after eating.

GIP/GLP-1 Agonists

CLINICAL PA REQUIRED
MOUNJARO (tirzepatide)

Prior Authorization Criteria

<u>Initial Criteria - Approval Duration:</u> 12 months

- The member has been unable to achieve goal A1C (≤ 7%) or TIR (>70%) despite two 90-day trials of triple combination therapy (one trial with Victoza and one with Trulicity, 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 these agents, clinical justification must be provided (subject to clinical review*), and triple therapy must be met by other agents.
- 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, member should be counseled on potential for GI side effects, with GI effects being common across all GLP-1 agonist agents and transient in nature, typically lessoning with ongoing treatment.
- Patient experiencing GI side effects should be counseled: reduction in meal size, eating slower, decreased intake of greasy, high-fat or spicy food, refrain from laying down after eating.

Hepatitis C Antiviral Treatments Summary of Changes:

- Removed pre-adherence requirements
- Removed sobriety requirements
- Removed attestation form requirement
- Added requirement for participation in harm reduction pathway for active PWID and alcohol use disorder
- For F1, decreased the number of HCV RNA tests down to 1 test (instead of 2) to show chronic Hepatitis C
- First time and re-infection treatment are classified with the same criteria (re-treatment due to failure or incomplete therapy have additional criteria)
- Decreased Adherence MTM requirement to one visit for re-treatment

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)
MAVYRET (glecaprevir/pibrentasvir)	HARVONI (ledipasvir/sofosbuvir) 90mg/400mg tablet
sofosbuvir/velpatasvir	HARVONI (ledipasvir/sofosbuvir) ORAL PALLET
SOVALDI (sofosbuvir) 200 MG TABLET	ledipasvir/sofosbuvir 90mg/400mg tablet
VOSEVI (sofosbuvir/velpatasvir/voxilaprevir)	SOVALDI (sofosbuvir) 400MG TABLET
	SOVALDI (sofosbuvir) ORAL PALLET
	VIEKIRA PAK (dasabuvir/ombitasvir/paritaprevir/ritonavir)
	ZEPATIER (elbasvir/grazoprevir)

Electronic Step Care and Concurrent Medications

- Epclusa (and its generic): A total of 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), Mavyret, and Vosevi: The entire treatment course i must be dispensed at the initial fill.
    - Please call pharmacy provider relations (1-701-328-4086) if a member has already partially completed their treatment course and needs less than a full course of therapy for their current fill.

Prior Authorization Criteria

Prior Authorization Form – Hepatitis C

Initial Criteria - Approval Duration: Based on label recommendations

- The member must have life expectancy greater than 12 months.
- One of the following must be met (1-4):
    1. The member has no history of alcohol use disorder or IV illicit drug use.

2. The member has maintained sobriety for the past 12 months.
3. The member has completed or be currently enrolled in a treatment program within the past 12 months.
4. The Harm Reduction Program Participation Attestation Form is attached indicating one of the following (a or b):
    a. The member participates in a Syringe Service Program
    b. The member participates in at least 2 Harm Reduction Pathway appointments as defined in Appendix D (may be completed by any qualified healthcare provider)

Non-Solid Dosage Form Agents Criteria:

- Epclusa 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

- Chronic Hepatitis C must be documented by one of the following (most recent test within the last 24 months):
    - No liver fibrosis or unknown: 2 positive HCV RNA levels at least 3 months apart
    - Liver fibrosis or cirrhosis:1 positive HCV RNA test

For RE-TREATMENT after Direct Acting Antiviral failure or incomplete therapy:

- 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
- The following criteria is met (as applicable due to reason for retreatment):

Reason for retreatment:	
Due to non-compliance (defined as a medication possession ratio (MPR) of less than 80%)	The member has participated in 1 visit focused on addressing adherence barriers within the past 180 days. Adherence education may be provided by a pharmacist (may be billed through the MTM program) or clinic-based E&M billed service (provided by a nurse or independent practitioner).
Resistance	• **FIRST TIME treatment with Direct Acting Antivirals** criteria must be met

Pharmacy Coverage Policy Manual

Published By:

Medical Services Division
North Dakota Department of Health and Human Services
600 E Boulevard Ave Dept 325
Bismarck, ND 58505-0250

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NORTH Dakota | Health & Human Services
Be Legendary.

Preferred Drug List (PDL)

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

Preferred Diabetes Supply List (PDSL)

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

Prior Authorization Review Dates

Please see DUR Board found at www.hidesigns.com/ndmedicaid

Preferred Drug List (PDL)

Rules

1. Requests for non-preferred brand name agents with a generic formulation available must meet the Dispense as Written (DAW1) criteria for approval in addition to as any other applicable coverage criteria/rule (unless otherwise noted).
2. Non-solid dosage preparations must meet Non-Solid Dosage Preparations prior authorization criteria even if they are preferred in the clinical category.
3. Renewal Request Criteria must be met for all renewal requests.
4. The use of all preferred and non-preferred agents must meet recommendations found in the FDA label or compendia (e.g., diagnosis, age, dosage, frequency, route). Compendia supported use is defined as at least of level of IIa efficacy rating and IIb recommendation. ND Medicaid uses DrugDex ® compendia. Requests outside of FDA approved or compendia supported use are not reviewable by prior authorization and the request will be dismissed on PA review. Sec. 1927. [42 U.S.C. 1396r-8] (d).
5. Clinical justification may be provided when criteria does not encompass a standard of care or guideline supported therapy or a member's unique scenario, by faxing supporting chart notes and evidence to 701-328-1544.
6. Grandfathering may be allowed in cases where the clinical condition has been verified by a specialist, member is currently receiving FDA or compendia approved medication, and there is clinical evidence for decompensation of member's condition if agent is switched (subject to clinical review).
7. A trial will be considered a failure if a product was not effective at the maximum tolerated therapeutic dose with good compliance, 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 forms of that drug. OTC drugs are not covered unless specified.
10. Please use the following forms unless otherwise indicated:
    - Pharmacy Point of Sale: General Prior Authorization Form
    - Medical Office Billing: Medical Service Authorization Request
    - Requested product is same active ingredient as preferred product: MedWatch Form
11. For pharmacy billed medication: please use the prior authorization website http://www.hidesigns.com/ndmedicaid/ to access PA form, view coverage status, quantity limits, copay, 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.

Prior Authorization Updates

Drug name	PA Status	Class
Betaseron	PA	Multiple Sclerosis - Interferons
Perseris	PA	Antipsychotics – Long Acting Injectable (LAI)
Rykindo ER	PA	Antipsychotics – Long Acting Injectable (LAI)
Zimhi	Remove PA	Opioid Reversal Medications

Version Changes

Category	Change
Antipsychotics – Long Acting Injectable (LAI)	Preferred Products Updated
Diabetic Supplies	Covered Products Added Syringes, Inpen; test strip and Omnipod NDCs updated
Idiopathic Pulmonary Fibrosis	Preferred Products Updated
Multiple Sclerosis - Interferons	Preferred Products Updated
Opioid Reversal Medications	Preferred Products Updated
Uterine Fibroids	Preferred Products Updated

General Policies

Dispense as Written (DAW1)

The member or prescriber preference is NOT criteria considered for approval.

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

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

Generic Non-Preferred Requests

The member or prescriber preference is NOT criteria considered for approval.

Prior Authorization Criteria

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

- Request must meet one of the following (A, B, or C):
  - A. Primary insurance requires a ND Medicaid non-preferred generic product.

B. Pharmacy requests a short-term approval due to dose titration or supply issue.
C. All the following are met (1-3):
    1. The member must have failed a 30-day trial of preferred brand product, as evidenced by paid claims or pharmacy print outs.
    2. Clinical justification is provided for the different clinical outcome expected for the requested generic and other alternatives (e.g., medications in same class) are not an option for the member (subject to clinical review)
    3. A MedWatch form for each trial of each product from the available manufacturer(s) is filled out and attached to request.

Medications that cost over $3000/month

Prior Authorization Criteria

Initial Criteria - Approval Duration: 6 months

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

CLINICAL PA REQUIRED
ABECMA (idecabtagene vicleucel) – *Medical Billing Only*
BLINCYTO (blinatumomab) – *Medical Billing Only*
BREYANZI (lisocabtagene maraleucel) – *Medical Billing Only*
CARVYKTI (ciltacabtagene autoleucel) – *Medical Billing Only*
CYSTADROPS (cysteamine)
CYSTARAN (cysteamine)
DANYELZA (naxitamab-gqgk) – *Medical Billing Only*
DAYBUE (trofinetide)
DOJOVI (triheptanoin)
FIRDAPSE (amifampridine)
FUROSCIX (furosemide)
FUROSCIX (furosemide) – *Medical Billing Only*
FYARRO (sirolimus protein-bound particles) – *Medical Billing Only*
GATTEX (teduglutide)
INCRELEX (mecasermin)
JOENJA (leniolisib)
KIMMTRAK (tebentafusp-tebn) – *Medical Billing Only*
KYMRIAH (tisagenlecleucel) – *Medical Billing Only*
MYCAPSSA (octreotide)
NULIBRY (fosdenopterin)
OXERVATE (cenegermin-bkbj)
PYRUKYND (mitapivat)
REZUROCK (belumosudil)
SAMSCA (tolvaptan)

SKYCLARYS (omaveloxolone)
SOHONOS (palovarotene)
TAVNEOS (avacopan)
TECARTUS (brexucabtagene autoleucel) – *Medical Billing Only*
TECVAYLI (Inj teclistamab cqyv 0.5 mg) – *Medical Billing Only*
TIVDAK (tisotumab vedotin-tftv) – *Medical Billing Only*
VIJOICE (alpelisib)
WELIREG (belzutifan)
XENPOZYME (olipudase alfa) – *Medical Billing Only*
YESCARTA (axicabtagene ciloleucel) – *Medical Billing Only*
ZOKINVY (lonafamib)
ZYNLONTA (loncastuximab tesirine-lpyl) – *Medical Billing Only*

Non-Solid Dosage Forms

Electronic Age Verification

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

Prior Authorization Criteria

Initial Criteria - Approval Duration: 2 years (1 month for short-term restriction)

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

Renewal Requests

Prior Authorization Criteria

Renewal Criteria

- The member must have experienced and maintained clinical benefit since starting treatment with the requested medication, as evidenced by medical documentation (e.g., chart notes) attached to the request (subject to clinical review).
- The member must continue to meet applicable initial criteria. Additional renewal criteria may apply as indicated under specific category.
- One of the following must be met:
  1. *Approval Duration: regular renewal approval duration or 1 year*
     - The member was at least 80% adherent to medication.
     - The member had a claim gap due to hospitalization or eligibility.
  2. *Approval Duration: 3 months*
     - All the following must be met -
       - Clinical justification must be provided for the non-adherence.
       - A method to improve adherence must be provided such as addressing adherence barriers, implementing a treatment plan, medication therapy management (MTM), etc.

- 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) SYRINGES
XOLAIR (omalizumab) VIALS – *Medical Billing Only*

Prior Authorization Criteria

Initial Criteria - Approval Duration: 3 months

- The requested medication must be prescribed by, or in consult with, an allergist/immunologist.
- The member must have failed a 30-day trial of a dose of at least 100 mg of either hydroxyzine or doxepin in addition to one of the following:
  - Leukotriene receptor antagonist (e.g., montelukast, zafirlukast, zileuton)
  - Histamine H2-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

Chronic Rhinosinusitis with Nasal Polyps

Biologic Agents

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
DUPIXENT (dupilumab)	NUCALA (mepolizumab) SYRINGE, AUTOINJECTOR
XOLAIR (omalizumab) SYRINGES	NUCALA (mepolizumab) VIAL – *Medical Billing Only*

Prior Authorization Criteria

Prior Authorization Form - Nasal Polyps

Initial Criteria - Approval Duration: 3 months

- The requested medication must be prescribed by, or in consult with, an ear/nose/throat specialist or allergist/immunologist.
- The member must have failed a 12-week trial of each the following:
  - intranasal corticosteroids
  - oral corticosteroids
- 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 1 preferred agent, as evidenced by paid claims or pharmacy printouts.

Renewal Criteria - Approval Duration: 12 months

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

Cytokine Release Syndrome

Biologic Agents

CLINICAL PA REQUIRED
ACTEMRA (tocilizumab) VIAL – *Medical Billing Only*

Prior Authorization Criteria

Initial Criteria - Approval Duration: 4 doses

- The member must have hypotension and/or hypoxia.

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

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 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 a stable corticosteroid dose to control relapsing or refractory disease.
- The member must have asthma poorly controlled on moderate doses of inhaled glucocorticoids.
- The member must have blood eosinophil count of ≥ 1000 cells/mcL and/or ≥10 percent of leukocytes within the previous 6 weeks.

Renewal Criteria - Approval Duration: 12 months
- The member must have experienced a decrease in relapses* and corticosteroid dose, and an increase of time of remission since starting treatment with the requested medication, as evidenced by medical documentation (e.g., chart notes) attached to the request (subject to clinical review).

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

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

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 not be FIP1L1-PDGFRα kinase-positive.
- The member must have experienced at least 2 HES flares within the past 12 months despite a 3-month trial with each the following:
  - oral corticosteroids
  - steroid sparing therapy (e.g., hydroxyurea)
- 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

Colchicine

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
colchicine tablet	colchicine capsule
	COLCRYS (colchicine) TABLET
	GLOPERBA (colchicine) ORAL SOLUTION
	MITIGARE (colchicine) CAPSULE

Prior Authorization Criteria

- See applicable Preferred Dosage Form or Non-Solid Oral Dosage Form criteria.

Uricosuric Drugs

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

Xanthine Oxidase Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
6-mercaptopurine (6-MP)	allopurinol 200 mg tablet
allopurinol 100 mg, 300 mg tablet	azathioprine 75 mg, 100 mg tablet
azathioprine 50 mg	++febuxostat
	++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 have failed a 30-day trial of allopurinol, as evidenced by paid claims or pharmacy printouts.
- Azathioprine: See Preferred Dosage Form Criteria

Biologics

PREFERRED AGENTS (CLINICAL PA REQUIRED)
ILARIS (canakinumab) – *Medical Billing Only*
KRYSTEXXA (pegloticase) – *Medical Billing Only*

Prior Authorization Criteria

Initial Criteria - Approval Duration: 6 months

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

Acute Attack

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
BERINERT (plasma derived C1 Esterase Inhibitor)	FIRAZYR (icatibant)
icatibant	KALBITOR (ecallantide)
	RUCONEST (recombinant C1 Esterase Inhibitor)

Prophylaxis

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

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

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

Non-Preferred Agent Criteria:

- The member must have a contraindication to or failed a trial of all preferred agents with the same indication for use (prophylaxis or acute treatment), as evidenced by paid claims or pharmacy printouts with required trial durations as follows:
    - Agents for acute attacks: a single trial
    - Agents for attack prophylaxis: 3 months

Quantity Override Request

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

Immune Globulins

IM

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
GAMASTAN (immune globul G (IgG)/glycine)	

IVIG

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
BIVIGAM (human immunoglobulin gamma)	ASCENIV (human immune globulin G- slra)
FLEBOGAMMA DIF (human immunoglobulin gamma)	GAMMAPLEX (human immunoglobulin gamma)
GAMMAGARD S-D (human immunoglobulin gamma)	PANZYGA (immune globulin- ifas)
OCTAGAM (human immunoglobulin gamma)	
PRIVIGEN (human immunoglobulin gamma)	

IVIG/SCIG

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
GAMMAGARD LIQUID (human immunoglobulin gamma)	GAMMAKED (human immunoglobulin gamma)
GAMUNEX-C (human immunoglobulin gamma)	

SCIG

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
HIZENTRA (human immunoglobulin gamma)	CUTAQUIG (human immune globulin G - hipp)
HYQVIA (human immune globulin G and hyaluronidase)	CUVITRU (human immunoglobulin gamma)
	XEMBIFY (immune globulin,gamma(IgG)klhw)

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

- If the member's BMI > 30, adjusted body weight must be provided along with the calculated dose.

Non-Preferred Agent Criteria:

- The member must meet one of the following criteria:
  - The member must have failed a trial of each of the preferred products, as evidenced by paid claims or pharmacy printouts.
  - The member is stable on current therapy (have had a paid claim for requested therapy in the past 45 days)

Peanut Allergy

CLINICAL PA REQUIRED
PALFORZIA (peanut allergen powder)

Prior Authorization Form - Palforzia

Prior Authorization Criteria

Initial Criteria - Approval Duration: 6 months

- The requested medication must be prescribed by, or in consult with, an allergist/immunologist.
- The provider must attest that the member has access to injectable epinephrine, and that the member/caregiver has been instructed and trained on its appropriate use.
- The member must not have any of the following:
  - Uncontrolled asthma
  - A history of eosinophilic esophagitis or another eosinophilic GI disease
  - Severe or life-threatening anaphylaxis in the 60 days prior to the request
- The member must have a clinical history of allergy to peanuts or peanut-containing foods AND one of the following:
  - The member has had a serum immunoglobulin E (IgE) to peanut ≥0.35 kUA/L.
  - Skin prick test (SPT) to peanut ≥ 3mm compared to control
  - Allergic reaction produced during a provider observed intake of peanuts.

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

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

Steroids – Nasal Spray

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
fluticasone	BECONASE AQ (beclomethasone)
OMNARIS (ciclesonide)	flunisolide
QNASL (beclomethasone)	mometasone
ZETONNA (ciclesonide)	QNASL CHILDREN (beclomethasone)
	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: Clinical justification must be provided explaining why the member is unable to use another product with the same active ingredient (subject to clinical review).

Cardiology

Therapeutic Duplication

- One Strength of one medication is allowed at a time
  - Exceptions:

        - carvedilol IR 25 mg allowed with all other strengths
        - warfarin strengths are allowed together
        - prazosin strengths are allowed together
- Medication classes not payable together:
    - Entresto, ACE Inhibitors, ARBs, and Renin Inhibitors are not allowed with each other.
    - sildenafil, tadalafil, Adempas, nitrates are not allowed with each other.
    - carvedilol and labetalol are not allowed with other non-selective alpha blockers (Alfuzosin ER, doxazosin, prazosin, and terazosin)
        - carvedilol and labetalol are non-selective beta blockers with alpha 1 blocking activity
    - tizanidine is not allowed with other alpha 2 agonists (clonidine, clonidine/chlorthalidone, guanfacine, methyldopa)
        - tizanidine is also an alpha 2 agonist
    - clopidogrel is not covered with esomeprazole or omeprazole. Other PPIs such as pantoprazole are covered with clopidogrel.
        - clopidogrel is a substrate for 2C19 and esomeprazole and omeprazole are strong 2C19 inhibitors and can decrease effectiveness of clopidogrel.
    - clopidogrel, prasugrel, ticagrelor, and ticlopidine are not covered with morphine. Other opioid analgesics are covered with clopidogrel, prasugrel, ticagrelor, and ticlopidine.
        - Morphine may diminish the antiplatelet effect and serum concentrations of P2Y12 Inhibitor antiplatelet agents (clopidogrel, prasugrel, ticagrelor, and ticlopidine).

Alpha and/or Beta Blockers Therapeutic Duplication – Override Request

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

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

Anticoagulants - Oral:

Solid oral dosage forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ELIQUIS (apixaban)	dabigatran capsule
PRADAXA (dabigatran) capsule – *Brand Required*	SAVAYSA (edoxaban)
warfarin	
XARELTO (rivaroxaban)	

Non-solid oral dosage forms

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

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

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

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

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

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

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

Anticoagulants – Injectable

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

Electronic Diagnosis Verification

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

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

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

Calcium Channel Blockers

Non-solid oral dosage forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
diltiazem ER degradable	VERELAN (verapamil) ER PELLETS
KATERZIA (amlodipine) SUSPENSION	DILT-XR (diltiazem) ER DEGRADABLE
NORLIQVA (amlodipine) SOLUTION	
verapamil ER pellets	

Solid oral dosage forms

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

Prior Authorization Criteria

- Nisoldipine ER 20 mg, 30 mg, 40 mg: See Preferred Dosage Form criteria

Diuretics – Aldosterone Antagonist

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

Diuretics - Loop

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

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

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

Diuretics – Potassium Sparing

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

Heart Failure

First Line Agents

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

Second Line Agents

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

Electronic Diagnosis Verification

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

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

- Corlanor Only:
  - The requested medication must be prescribed by, or in consult with, a cardiologist.
  - The member must have a resting HR ≥ 70 beats per minute on maximally tolerated or target beta blocker dose in sinus rhythm.
- 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)
- Verquvo Only:
  - The requested medication must be prescribed by, or in consult with, a cardiologist.
  - The member must have left ventricular ejection fraction (LVEF) < 45% at initiation.
  - Documentation of a recent hospitalization or need for IV diuretics within the past 6 months must be provided with request.
  - The member is receiving concurrent Entresto, a beta-blocker, a SGLT-2 Inhibitor, and a mineralocorticoid receptor antagonist.

Hypertrophic Cardiomyopathy

CLINICAL PA REQUIRED
CAMZYOS (mavacamten)

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

- The requested medication must be prescribed by, or in consult with, a cardiologist.
- The member must have left ventricular ejection fraction (LVEF) ≥ 55% at initiation.
- The member has a peak Valsalva 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

- Member has an improved pVO_2 by ≥ 1.5 mL/kg/min plus improvement in NYHA class by at least 1 or improvement of pVO_2 by ≥ 3 mL/kg/min and no worsening in NYHA class.

Inappropriate Sinus Tachycardia

CLINICAL PA REQUIRED
CORLANOR (ivabradine)

Electronic Diagnosis Verification

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

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

3. 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

- A total of 90 days of rosuvastatin or atorvastatin must be paid within 120 days prior to Nexletol or Nexlizet's date of service or intolerance to statins justification must be provided (subject to clinical review)

Cholesterol Absorption Inhibitor - 2-Azetidinone

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

Eicosapentaenoic acid (ESA) Ethyl Ester

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
VASCEPA (icosapent ethyl) – *Brand Required*	icosapent ethyl

Fenofibrate

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
fenofibrate capsules 50mg, 150mg	ANTARA (fenofibrate, micronized)
fenofibrate, micronized 43mg, 67mg, 130mg, 134mg, 200mg	fenofibrate, micronized 30mg, 90mg
fenofibrate, nanocrystallized 48mg, 145mg	fenofibrate tablets 40mg, 120mg
fenofibrate tablets 54mg, 160mg	FENOGLIDE (fenofibrate)
fenofibric acid	LIPOFEN (fenofibrate)
	TRICOR (fenofibrate, nanocrystalized)
	TRIGLIDE (fenofibrate)
	TRILIPIX (fenofibric acid)

Prior Authorization Criteria

- See Preferred Dosage Form criteria

MTP (Microsomal Triglyceride Transfer Protein) Inhibitor

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

Prior Authorization Criteria

Initial Criteria - Approval Duration: 3 months

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

PCSK9 (Proprotien Convertase Subtilisin/Kexin Type 9) Inhibitors

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

Underutilization

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

Electronic Step Therapy Required

- Praluent: A total of 90 days of rosuvastatin or atorvastatin must be paid within 120 days prior to Praluent's date of service or intolerance to statins justification must be provided (subject to clinical review)

Prior Authorization Criteria

Initial Criteria - Approval Duration: 3 months

- One of the following (A or B) must be met:
  - A. Both of the following (i and ii):
    - i. The member is age 10 or greater and younger than 18 years old.
    - ii. The member must have LDL levels of >70 mg/dL after a 90-day trial of rosuvastatin ≥ 20 mg or atorvastatin ≥ 40 mg, as evidenced by paid claims or pharmacy printouts:
  - B. The member must have LDL levels of >70 mg/dL after a 90-day trial of both the following, as evidenced by paid claims or pharmacy printouts:
    - Praluent combined with rosuvastatin ≥ 20 mg or atorvastatin ≥ 40 mg
    - Nexlizet combined with rosuvastatin ≥ 20 mg or atorvastatin ≥ 40 mg

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

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
amlodipine/atorvastatin	ALTROPREV (lovastatin)
atorvastatin	ATORVALIQ (atorvastatin) SOLUTION
EZALLOR SPRINKLE (rosuvastatin)	CADUET (amlodipine/atorvastatin)
ezetimibe/simvastatin	CRESTOR (rosuvastatin)
fluvastatin	fluvastatin ER
LIVALO (pitavastatin)	LESCOL XL (fluvastatin)
lovastatin	LIPITOR (atorvastatin)
pravastatin	PRAVACHOL (pravastatin)
rosuvastatin	VYTORIN (ezetimibe/simvastatin)
simvastatin	ZOCOR (simvastatin)
	ZYPITAMAG (pitavastatin)

Prior Authorization Criteria

- See applicable Preferred Dosage Form or Non-Solid Dosage Form criteria.

Angiopoietin-like 3 (ANGPTL3) Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	EVKEEZA (evinacumab-dgnb) – *Medical Billing Only*

Prior Authorization Criteria

Initial Criteria - Approval Duration: 6 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a cardiologist, endocrinologist, or lipid specialist.
- Documentation of one of the following must be provided:
  - Genetic testing confirming two mutant alleles at the low-density lipoprotein receptor (LDLR), apolipoprotein B (apo B), proprotein convertase subtilisin kexin type 9 (PCSK9) or low-density lipoprotein receptor adaptor protein 1 (LDLRAP1) gene locus
  - Untreated total cholesterol of > 500 mg/dL with one of the following:
    - Cutaneous or tendon xanthoma before age 10 years
    - Evidence of total cholesterol > 250 in both parents
  - Low-density lipoprotein cholesterol (LDL-C) level greater than 100 mg/dL after a 90-day trial of each of the following, as evidenced by paid claims or pharmacy printouts or clinical justification as to why a treatment is unable to be used (subject to clinical review):
    - PCSK9 inhibitor and ezetimibe combined with rosuvastatin ≥20 mg or atorvastatin ≥ 40 mg
    - Nexlizet and ezetimibe combined with rosuvastatin ≥20 mg or atorvastatin ≥ 40 mg

Renewal Criteria – Approval Duration: 12 months

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

siRNA (small interfering RNA) therapy

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	LEQVIO (inclisiran) – *Medical Billing Only*

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- The member must have failed a 90-day trial of both of the following, as evidenced by paid claims or pharmacy printouts:
  - Praluent combined with rosuvastatin ≥20 mg or atorvastatin ≥ 40 mg
  - Nexlizet combined with rosuvastatin ≥20 mg or atorvastatin ≥ 40 mg

Renewal Criteria - Approval Duration: 12 months

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

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	
dipyridamole	
prasugrel	

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

- The member must have failed 30-day trials of at least 2 preferred platelet aggregation inhibitor agents, as evidenced by paid claims or pharmacy printouts.

Pulmonary Hypertension

Endothelin Receptor Antagonists

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

Electronic Diagnosis Verification

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

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

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

PDE-5 Inhibitors

Solid Dosage Forms

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

Non-Solid Dosage Forms

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

Electronic Age Verification

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

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

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

Non-Preferred Agents Criteria

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

Prostacyclins

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

Electronic Diagnosis Verification

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

Soluble Guanylate Cyclase Stimulators

NO PA REQUIRED
ADEMPAS (riociguat)

Electronic Diagnosis Verification

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

Vecamyl

CLINICAL PA REQUIRED
VECAMYL (mecamylamine)

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

- The member must have documented history of failure to achieve blood pressure goals (using maximum tolerated doses) of all first- and second-line agents as defined by the most recent JNC report.

Dermatology

Acne

Electronic Age Verification

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

Adapalene

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
adapalene cream	
adapalene 0.3% 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.

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 clindamycin or dapsone, as evidenced by paid claims or pharmacy printouts.

Clindamycin

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

Clindamycin-Benzoyl Peroxide

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
clindamycin-benzoyl peroxide 1.2%-2.5%	ACANYA (clindamycin-benzoyl peroxide) 1.2%-2.5%

clindamycin-benzoyl peroxide 1%-5% with pump	BENZACLIN (clindamycin/benzoyl peroxide without pump) 1%-5%
clindamycin-benzyl peroxide 1.2%-5%	BENZACLIN (clindamycin/benzoyl peroxide with pump) 1%-5%
clindamycin/benzoyl peroxide 1%-5% without pump	NEUAC (clindamycin/benzoyl peroxide) 1.2%-5%
ONEXTON (clindamycin/benzoyl peroxide) 1.2%-3.75%	

Therapeutic Duplication

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

Retinoid

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ALTRENO (tretinoin) LOTION	AKLIEF (trifarotene) CREAM 0.005%
RETIN-A MICRO GEL PUMP (tretinoin microsphere) 0.04%, 0.1% - *Brand Required*	ATRALIN (tretinoin) 0.05% GEL
RETIN-A MICRO (tretinoin microsphere) GEL WITHOUT PUMP – *Brand Required*	ARAZLO (tazarotene) 0.045% LOTION
tretinoin cream	clindamycin-tretinoin 1.2%-0.025%
tretinoin gel	FABIOR (tazarotene) 0.1% FOAM
ZIANA (clindamycin-tretinoin 1.2%-0.025%) - *Brand Required*	RETIN-A (tretinoin) CREAM
	RETIN-A (tretinoin) GEL
	RETIN-A MICRO GEL PUMP (tretinoin microsphere) 0.06%, 0.08%
	tazarotene 0.1% cream
	tazarotene 0.1% foam
	tazarotene gel
	tretinoin microsphere gel with pump 0.04%, 0.1%
	tretinoin microsphere gel without pump
	TWYNEO (tretinoin/benzoyl peroxide) 0.1%-0.3% CREAM

Therapeutic Duplication

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

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

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

Tetracyclines

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
doxycycline hyclate capsule	AMZEEQ (minocycline) foam
doxycycline hyclate tablet 20 mg, 100 mg	demeclocycline

doxycycline monohydrate 25 mg/5 mL suspension	DORYX (doxycycline hyclate) TABLET DR
doxycycline monohydrate tablet 50 mg, 75 mg, 100 mg	DORYX MPC (doxycycline hyclate) TABLET DR
doxycycline monohydrate capsule 50 mg, 100 mg	doxycycline monohydrate capsule 75 mg, 150 mg
minocycline capsule	doxycycline hyclate tablet 50 mg, 75 mg, 150 mg
tetracycline	doxycycline monohydrate tablet 150 mg
VIBRAMYCIN (doxycycline calcium) 50 mg/5 mL SYRUP	doxycycline hyclate tablet DR
	MINOCIN (minocycline) CAPSULE
	minocycline tablet
	minocycline tablet ER
	MINOLIRA ER (minocycline) TABLET
	MORGIDOX (doxycycline hyclate) CAPSULE
	SOLODYN ER (minocycline) TABLET
	VIBRAMYCIN (doxycycline monohydrate) 25 mg/5 mL SUSPENSION
	XIMINO (minocycline) CAPSULE ER

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

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

Sulfonamide

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
BP 10-1 (sodium sulfacetamide/sulfur cleanser) 10%-1%	ACZONE (dapsone) GEL WITH PUMP 7.5%
Cleansing Wash (sulfacetamide sodium/sulfur/urea) 10%-4%-10%	BP 10-1 (sulfacetamide sodium/sulfur) CLEANSER
dapsone gel without pump 5%	dapsone gel pump 7.5%
SSS 10-5 (sulfacetamide) FOAM	SSS 10-5 (sulfacetamide) CLEANSER
sulfacetamide 10% suspension	sodium sulfacetamide/sulfur pads 10%-4%
sodium sulfacetamide/sulfur cleanser 10%-5% (W/W)	sodium sulfacetamide/sulfur cream 10%-2%
sodium sulfacetamide/sulfur cleanser 9%-4%	SUMAXIN (sodium sulfacetamide/sulfur pads) PADS 10%-4%
sodium sulfacetamide/sulfur cleanser 9%-4.5%	SUMAXIN TS (sodium sulfacetamide/sulfur) SUSPENSION 8%-4%
sodium sulfacetamide/sulfur cleanser 9.8% -4.8%	
sodium sulfacetamide/sulfur cleanser 10%-2%	
sodium sulfacetamide/sulfur cleanser 10%-5%-10%	
sodium sulfacetamide/sulfur cream 10%-5% (W/W)	
sodium sulfacetamide/sulfur suspension 8%-4%	
SUMAXIN (sodium sulfacetamide/sulfur) CLEANSER 9%-4%	

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

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

Actinic Keratosis

Fluorouracil

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
fluorouracil 5% cream	CARAC (fluorouracil) 0.5% CREAM
fluorouracil 2% solution	EFUDEX (fluorouracil) 5% CREAM
fluorouracil 5% solution	fluorouracil 0.5% cream

Imiquimod

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
imiquimod 5% cream packet	imiquimod 3.75% cream packet
ZYCLARA (imiquimod) 3.75% CREAM PUMP – *Brand Required*	imiquimod 3.75% cream pump
	ZYCLARA (imiquimod) 3.75% CREAM PACKET
	ZYCLARA (imiquimod) CREAM PUMP

Diclofenac

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

Electronic Diagnosis Verification

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

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

- The member must have failed a 6-month trial of each preferred agent of a unique active ingredient, as evidenced by paid claims or pharmacy printouts.
- If requested product has preferred option with same active ingredient, clinical justification must be provided explaining why the member is unable to use preferred product (subject to clinical review).

Antifungals – Topical

Cream

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

	naftifine cream
	oxiconazole cream
	sulconazole cream

Foam

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
EXTINA (ketoconazole) FOAM – *Brand Required*	KETODAN (ketoconazole) FOAM
	ketoconazole foam

Gel

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

Lotion

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

Ointment

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

Powder

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

Electronic Age Verification

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

Janus Kinase (JAK) inhibitor

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

Phosphodiesterase 4 (PDE-4) inhibitor

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

Topical Corticosteroids

Please see the Preferred Drug List of Topical Corticosteroids

Systemic

Interleukin (IL)-4/13 Inhibitor

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

Interleukin (IL)-13 Inhibitor

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

Janus Kinase (JAK) inhibitor

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

Prior Authorization Criteria

Prior Authorization Form - Atopic Dermatitis

Initial Criteria - Approval Duration: 3 months

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

Janus Kinase (JAK) Inhibitors Only:

- The member must have had a 6-month trial with dupilumab.

Hidradenitis Suppurativa

Biologic Agents

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AVSOLA (infliximab-axxq) – *Medical Billing Only*	adalimumab-adaz
HUMIRA (adalimumab)	adalimumab-fkjp
RENFLEXIS (infliximab-abda) – *Medical Billing Only*	ABRILADA (adalimumab-afzb)
	AMJEVITA (adalimumab-atto)
	CYLTEZO (adalimumab-abdm)
	HADLIMA (adalimumab-bwwd)
	HULIO (adalimumab-fkjp)
	HYRIMOZ (adalimumab-adaz)
	IDACIO (adalimumab-aacf)
	INFLECTRA (infliximab-dyyb) – *Medical Billing Only*
	infliximab – *Medical Billing Only*
	REMICADE (infliximab) – *Medical Billing Only*
	SIMPONI (golimumab) ARIA – *Medical Billing Only*
	YUFLYMA (adalimumab-aaty)
	YUSIMRY (adalimumab-aqvh)

Electronic Diagnosis Verification

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

Infantile Hemangioma

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
propranolol oral solution	HEMANGEOL (propranolol) ORAL SOLUTION
	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.

See Preferred Dosage Form criteria Lice / Scabies

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
EURAX (crotamiton) CREAM	CROTAN (crotamiton)
LICE KILLING SHAMPOO (piperonyl butoxide/pyrethrins)	ELIMITE (permethrin) CREAM
NATROBA (spinosad) – *Brand Required Only*	EURAX (crotamiton) LOTION
NIX 1% (permethrin) CRÈME RINSE LIQUID	++ lindane shampoo
permethrin 5% cream	malathion
SM LICE TREATMENT (permethrin) 1% CRÈME RINSE LIQUID	OVIDE (malathion)
VANALICE (piperonyl butoxide/pyrethrins) GEL	spinosad

++ Clinically Non-Preferred: Lindane: Neurologic toxicity resulting in seizures and death has been reported in humans following topical lindane therapy.

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)

Interleukin (IL)-17A Inhibitor

PREFERRED AGENTS (ELECTRONIC STEP REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
TALTZ (ixekizumab)	COSENTYX (secukinumab)
	COSENTYX (secukinumab) – *Medical Billing Only*

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

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

Interleukin (IL)-17 Receptor Inhibitor

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

Interleukin (IL)-23p19 Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	ILUMYA (tildrakizumab-asmn) – *Medical Billing Only*

	SKYRIZI (risankizumab-rzaa)
	TREMFYA (guselkumab)

TNF Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AVSOLA (infliximab-axxq) – *Medical Billing Only*	adalimumab-adaz
CIMZIA (certolizumab pegol)	adalimumab-fkjp
ENBREL (etanercept)	AMJEVITA (adalimumab-atto)
HUMIRA (adalimumab)	CYLTEZO (adalimumab-abdm)
RENFLEXIS (infliximab-abda) – *Medical Billing Only*	HADLIMA (adalimumab-bwwd)
	HULIO (adalimumab-fkjp)
	HYRIMOZ (adalimumab-adaz)
	IDACIO (adalimumab-aacf)
	INFLECTRA (infliximab-dyyb) – *Medical Billing Only*
	infliximab – *Medical Billing Only*
	REMICADE (infliximab) – *Medical Billing Only*
	YUFLYMA (adalimumab-aaty)
	YUSIMRY (adalimumab-aqvh)

Electronic Diagnosis Verification

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

Electronic Step Care and Concurrent Medications

- Taltz: A total of 84 days of a TNF Inhibitor must be paid within 120 days prior to Taltz's date of service.

Prior Authorization

Initial Criteria - Approval Duration: 12 months

- The member must have failed a 3-month trial of a TNF inhibitor and an Interleukin (IL)-17A Inhibitor, as evidenced by paid claims or pharmacy printouts.
- Remicade, infliximab, and Inflectra Only: See Preferred Dosage Form criteria
- Stelara and Cosentyx Only: The member must have failed a 3-month trial of an Interleukin (IL)-23p19 Inhibitor, as evidenced by paid claims or pharmacy printouts.

Oral

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

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

- Acitretin 17.5 mg Only: See Preferred Dosage Form criteria

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

Topical

Foams, 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	
TACLONEX (calcipotriene/betamethasone) SUSPENSION – *Brand Required*	

Cream, Lotion

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
calcipotriene cream	DUOBRII (halobetasol/tazarotene) LOTION
	DOVONEX (calcipotriene) CREAM
	tazarotene 0.1% cream
	VTAMA (tapinarof) 1% CREAM
	ZORYVE (roflumilast) 0.3% CREAM

Ointment

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
calcipotriene ointment	calcipotriene/betamethasone ointment
TACLONEX (calcipotriene/betamethasone) OINTMENT – *Brand Required*	
calcitriol ointment	

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, as evidenced by paid claims or pharmacy printouts.

Prurigo Nodularis

PREFERRED AGENTS (CLINICAL PA REQUIRED)
DUPIXENT (dupilumab)

Prior Authorization Criteria

Initial Criteria - Approval Duration: 6 months

- The requested medication must be prescribed by, or in consult with, a dermatologist.
  - The member is experiencing nodular lesions that produce itch for greater than 6 weeks that has significantly diminished quality of life, including sleep disturbances.
  - The member has failed each of the following trials, as evidenced by paid claims or pharmacy printouts:
  - A 2-week trial of a topical corticosteroid of medium or higher potency
  - A 3-month trial of an immunologic systemic therapy (e.g., azathioprine, cyclosporine, methotrexate)

Steroids – Topical

Super-High Potency (Group 1)

Dosage Form	PREFERRED AGENTS (NO PA REQUIRED)		NON-PREFERRED AGENTS (PA REQUIRED)	
Cream	clobetasol emollient	0.05%		
	clobetasol propionate	0.05%		
	fluocinonide	0.10%		
	halobetasol propionate	0.05%		
Lotion	betamethasone dipropionate, augmented	0.05%	IMPEKLO (clobetasol)	0.05%
	clobetasol propionate	0.05%	ULTRAVATE (halobetasol) MDP	0.05%
Ointment	betamethasone dipropionate, augmented	0.05%		
	clobetasol propionate	0.05%		
	clobetasol propionate foam	0.05%		
	halobetasol propionate	0.05%		
Foam, Gel, Shampoo, Solution, Spray	clobetasol propionate shampoo	0.05%	betamethasone dipropionate, augmented gel	0.05%
	clobetasol propionate solution	0.05%	clobetasol emulsion foam	0.05%
	clobetasol propionate spray	0.05%	STEP 2* halobetasol propionate foam	0.05%
	clobetasol propionate gel	0.05%		

Electronic Diagnosis Verification

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

Electronic Duration Verification

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

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

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

High Potency (Group 2)

Dosage Form	PREFERRED AGENTS (NO PA REQUIRED)		NON-PREFERRED AGENTS (PA REQUIRED)	
Cream	betamethasone dipropionate, augmented	0.05%	APEXICON E (diflorasone emollient)	0.05%
	desoximetasone	0.25%		

	fluocinonide	0.05%		
	HALOG (halcinonide)– *Brand Required*	0.10%		
Lotion			BRYHALI (halobetasol) LOTION	0.01%
Ointment	betamethasone dipropionate	0.05%	diflorasone diacetate	0.05%
	desoximetasone	0.25%		
	fluocinonide	0.05%		
	fluticasone propionate	0.01%		
	HALOG (halcinonide)	0.10%		
Gel, Solution, Spray	desoximetasone spray	0.25%	desoximetasone gel	0.05%
	fluocinonide gel	0.05%	HALOG (halcinonide) SOLUTION	0.10%
	fluocinonide solution	0.05%		

High Potency (Group 3)

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

Medium Potency (Group 4)

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

Lower-Mid Potency (Group 5)

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

Low Potency (Group 6)

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

Least Potent (Group 7)

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

Prior Authorization

Initial Criteria - Approval Duration: 12 months

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

Agents labeled as "STEP 2"

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

Endocrinology

Androgens

Injectable

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
testosterone cypionate injection	AVEED (testosterone undecanoate)
testosterone enanthate injection	DEPO-TESTOSTERONE (testosterone cypionate)
	XYOSTED (testosterone enanthate)

Oral

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

Topical

Gel Packet

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

Gel Pump

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

Gel Tube

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

Nasal Gel

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

Patch

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

Solution MDP

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

Pellet

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
TESTOPEL (testosterone) PELLET *– Medical Billing Only*	

Electronic Diagnosis Verification

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

Prior Authorization

Initial Criteria - Approval Duration: 12 months

- The member must have failed a 30-day trial of each preferred agent with a comparable route of administration, as evidenced by paid claims or pharmacy printouts.
- Clinical justification must be provided explaining why the member is unable to use the preferred products (subject to clinical review).

Cushing Syndrome

Adrenal Enzyme Inhibitors

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

Electronic Diagnosis Verification

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

Prior Authorization

Initial Criteria - Approval Duration: 6 months

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

- The member must have a mean (at least two measurements) 24-hour urine free cortisol (UFC) level that is 3 x above the normal range per the reporting laboratory reference range.

Renewal Criteria - Approval Duration: 12 months
- The member has normalization of 24-hour urine free cortisol (UFC) level per the reporting laboratory reference range.

Glucocorticoid Receptor Antagonist

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
mifepristone	KORLYM (mifepristone)

Electronic Diagnosis Verification

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

Prior Authorization

Initial Criteria - Approval Duration: 6 months
- The requested medication must be prescribed by, or in consult with, an endocrinologist or specialist in the treatment of endogenous Cushing's syndrome.
- The member must have failed a 3-month trial of combination treatment with ketoconazole tablets and metyrapone.
- The member is not a candidate for surgery or surgery has not been curative; or is waiting for surgery or effect of pituitary radiation.
- The member has uncontrolled hyperglycemia (type 2 diabetes or glucose intolerance) as defined by a hemoglobin A1c > 7% 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.

Diabetes

References:

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

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

Therapeutic Duplication

- One Strength of one medication is allowed at a time.
- Medication classes not payable together:
  - DPP-4 Inhibitors and GLP-1 Agonists
    - GLP-1 and DPP-4 Inhibitors should not be used concurrently due to similar mechanisms of action.

- Sulfonylureas and Insulins
  - When initiating injectable therapy, sulfonylureas and DPP-4 inhibitors are typically discontinued.
- Humulin R U-500 is not allowed with any other insulin (basal or prandial)
  - Humulin R U-500 is indicated for monotherapy. It acts differently than regular insulin (U-100). It provides both basal and prandial coverage. Injections can be increased to 3 times per day for prandial coverage.

Underutilization

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

Biologics

CLINICAL PA REQUIRED
TZIELD (teplizumab-mzwv) – *Medical Billing Only*

High-Cost Drug:
This 14-day treatment course costs $193,900.

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

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

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

DPP-4 Inhibitors

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

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

Electronic Age Verification

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

Electronic Concurrent Medications Required

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

References:

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

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

- The member has been unable to achieve goal A1C (≤ 7%) or TIR (>70%) despite two 90-day trials of triple combination therapy, as evidenced by paid claims or pharmacy printouts.

* 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.

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

- Clinical justification must be provided explaining why the member cannot use individual preferred products separately or preferred agent.

GLP-1 Agonists^

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

++Clinically Non-Preferred: Byetta is less effective than other available agents.
^ See GIP/GLP-1 Agonists section for Mounjaro (tirzepatide) criteria

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

- For GI side effects (start titration at lowest available dose)

- For any other reason, may consider starting at equivalent dose to minimize disruption to glycemic control
    - 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

References:

2. 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: Trulicity:
    - The member has been unable to achieve goal A1C (≤ 7%) or TIR (>70%) despite a 90-day trial of triple combination therapy with Victoza, metformin, SGLT-2 inhibitor or insulin, as evidenced by paid claims or pharmacy printouts.
        - If triple therapy cannot be met with these agents, clinical justification must be provided (subject to clinical review*), and triple therapy must be met by other agents.
- Step 2:
    - The member has been unable to achieve goal A1C (≤ 7%) or TIR (>70%) despite two 90-day trials of triple combination therapy (one trial with Victoza and one with Trulicity, 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 these agents, clinical justification must be provided (subject to clinical review*), and triple therapy must be met by other agents.
    - 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, member should be counseled on potential for GI side effects, with GI effects being common across all GLP-1 agonist agents and transient in nature, typically lessoning with ongoing treatment.
- Patient experiencing GI side effects should be counseled: reduction in meal size, eating slower, decreased intake of greasy, high-fat or spicy food, refrain from laying down after eating.

GIP/GLP-1 Agonists

CLINICAL PA REQUIRED
MOUNJARO (tirzepatide)

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

- The member has been unable to achieve goal A1C (≤ 7%) or TIR (>70%) despite two 90-day trials of triple combination therapy (one trial with Victoza and one with Trulicity, 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 these agents, clinical justification must be provided (subject to clinical review*), and triple therapy must be met by other agents.
- 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, member should be counseled on potential for GI side effects, with GI effects being common across all GLP-1 agonist agents and transient in nature, typically lessoning with ongoing treatment.
- Patient experiencing GI side effects should be counseled: 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 ODT and solution formulations) with relevant medical documentation (e.g., swallow study) attached to the request, subject to clinical review.

Glucose Rescue Medications

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
BAQSIMI (glucagon) SPRAY	
glucagon kit	
GLUCAGEN (glucagon) HYPOKIT – *Brand Co-Preferred*	
GVOKE (glucagon) INJECTION	
ZEGALOGUE (dasiglucagon) AUTOINJECTOR	

Electronic Duration Verification

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

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

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

Insulin/GLP-1 Agonist Combination

CLINICAL PA REQUIRED
SOLIQUA (Insulin glargine/lixisenatide)
XULTOPHY (insulin degludec/liraglutide)

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

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

Rapid Acting Insulin

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
APIDRA (insulin glulisine) VIAL	ADMELOG (insulin lispro) VIAL
APIDRA SOLOSTAR (insulin glulisine) INSULIN PEN	ADMELOG SOLOSTAR (insulin lispro) INSULIN PEN
HUMALOG (insulin lispro) CARTRIDGE	++AFREZZA (insulin regular, human)
HUMALOG U-100 (insulin lispro) KWIKPEN – *Brand Co-Preferred*	FIASP (insulin aspart) CARTRIDGE***
HUMALOG (insulin lispro) VIAL– *Brand Co-Preferred*	FIASP (insulin aspart) SYRINGE***
HUMALOG JUNIOR KWIKPEN (insulin lispro) – *Brand Co-Preferred*	FIASP (insulin aspart) VIAL***
insulin aspart cartridge	FIASP (insulin aspart) – *Medical Billing Only*
insulin aspart syringe	HUMALOG U-200 (insulin lispro) KWIKPEN
insulin aspart vial	++HUMULIN R (insulin regular, human) VIAL
insulin lispro junior syringe	LYUMJEV (Insulin lispro-aabc) KWIKPEN
insulin lispro cartridge	LYUMJEV (Insulin lispro-aabc) VIAL
insulin lispro syringe	LYUMJEV TEMPO PEN (insulin lispro-aabc)
insulin lispro vial	++NOVOLIN R (insulin regular, human) FLEXPEN
NOVOLOG (insulin aspart) CARTRIDGE – *Brand Co-Preferred*	++NOVOLIN R (insulin regular, human) VIAL
NOVOLOG (insulin aspart) FLEXPEN – *Brand Co-Preferred*	
NOVOLOG (insulin aspart) VIAL– *Brand Co-Preferred*	

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

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

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

Intermediate Acting Insulin

PREFERRED AGENTS	PREFERRED AGENTS	NON-PREFERRED AGENTS

(NO PA REQUIRED)	(PA REQUIRED)	(PA REQUIRED)
HUMULIN R U-500 (insulin regular, human) KWIKPEN	++ HUMULIN N (insulin NPH human isophane) VIAL	++ HUMULIN N (insulin NPH human isophane) KWIKPEN
HUMULIN R U-500 (insulin regular, human) VIAL	++ NOVOLIN N (insulin NPH human isophane) FLEXPEN	++ NOVOLIN N (insulin NPH human isophane) VIAL
	++ RELION NOVOLIN N (insulin NPH human isophane) FLEXPEN	++ RELION NOVOLIN N (insulin NPH human isophane) VIAL

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

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

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
insulin glargine vial	BASAGLAR KWIKPEN U-100 (insulin glargine)
LANTUS (insulin glargine) SOLOSTAR – *Brand Required*	insulin degludec
LANTUS (insulin glargine) VIAL – *Brand Required*	insulin glargine solostar
LEVEMIR (insulin detemir) VIAL	insulin glargine-yfgn vial
LEVEMIR (insulin detemir) FLEXTOUCH	REZVOGLAR (insulin glargine-aglr)
TOUJEO SOLOSTAR (insulin glargine) *No PA required for doses 100 unit/day to 200 unit/day	SEMGLEE (insulin glargine) YFGN
TOUJEO MAX SOLOSTAR (insulin glargine) *No PA required for doses 100 unit/day to 200 unit/day	TRESIBA (insulin degludec) FLEXTOUCH U-100 - *Brand Required*
TRESIBA (insulin degludec) FLEXTOUCH U-200 *No PA required for doses 100 unit/day to 200 unit/day - *Brand Required*	TRESIBA (insulin degludec) VIAL - *Brand Required*

Quantity Override Request

- Toujeo Max Solostar 300 unit/mL and Tresiba 200 unit/mL:
  - Doses > 200 units/day:
    - Clinical justification must be provided explaining why the member is not a candidate for U-500R + Toujeo and Tresiba are not intended as replacements for U-500R insulin
  - Doses >100 units/day to ≤ 200 units/day: No prior authorization required.
    - Please call for an override by calling provider relations at 1-800-755-2604 if the day supply is less than 30 days and dose is between 100 units/day and 200 units/day (e.g., short-cycle filling).
  - Doses ≤ 100 units/day:
    - Must 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 with good compliance, as evidenced by paid claims or pharmacy printouts, of each of the following:
  - Lantus
  - Levemir
- One of the following must be met, as evidenced by provided clinical notes or labs:
  - The member experiences recurrent episodes of hypoglycemia despite adjustments to current regimen (prandial insulin, interacting drugs, meal, and exercise timing).
  - The member must be experiencing inconsistent blood sugars.
- Biosimilar Agents: Clinical justification must be provided explaining why the member is unable to use the preferred products (subject to clinical review).

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

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
HUMALOG MIX 50/50 (insulin NPL/insulin lispro) KWIKPEN	HUMULIN 70/30 (insulin NPH human/regular insulin human) VIAL
HUMALOG MIX 75/25 (insulin NPL/insulin lispro) KWIKPEN – *Brand required*	HUMULIN 70/30 (insulin NPH human/regular insulin human) KWIKPEN
HUMALOG MIX 50/50 (insulin NPL/insulin lispro) VIAL	insulin lispro mix 75/25 kwikpen
HUMALOG MIX 75/25 (insulin NPL/insulin lispro) VIAL	NOVOLIN 70-30 (insulin NPH human/regular insulin human) VIAL
insulin aspart protamine/insulin aspart 70/30 pen	NOVOLIN 70-30 (insulin NPH human/regular insulin human) FLEXPEN
Insulin aspart protamine/insulin aspart 70//30 vial	NOVOLOG MIX 70/30 (insulin aspart protamine/insulin aspart) FLEXPEN
	NOVOLOG MIX 70/30 (insulin aspart protamine/insulin aspart) VIAL
	RELION NOVOLIN 70-30 (insulin NPH human/regular insulin human) VIAL
	RELION NOVOLIN 70-30 (insulin NPH human/regular insulin human) FLEXPEN

Prior Authorization Criteria

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

- 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).
- 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)*

SGLT2 Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
FARXIGA (dapagliflozin)	BRENZAVVY (bexagliflozin)
INVOKANA (canagliflozin)	INVOKAMET XR (canagliflozin/metformin)
INVOKAMET (canagliflozin/metformin)	STEGLATRO (ertugliflozin)
JARDIANCE (empagliflozin)	STEGLATROMET (ertugliflozin/metformin)
SYNJARDY (empagliflozin/metformin)	SYNJARDY XR (empagliflozin/metformin)
XIGDUO XR (dapagliflozin/metformin) 5 MG-500 MG, 5 MG-1000 MG, 10 MG-500 MG, 10 MG – 1000 MG	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	glipizide 2.5mg
glipizide IR 5mg, 10mg	++glyburide
glipizide ER	++glyburide/metformin
glipizide/metformin	++glyburide, micronized
glipizide ER	++GLYNASE (glyburide, micronized)

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

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

- The member must have failed a 30-day trial of glipizide and glimepiride, 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).

Growth Hormone

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
NORDITROPIN FLEXPRO (somatropin)	GENOTROPIN (somatropin)
NUTROPIN AQ (somatropin)	GENOTROPIN MINIQUICK (somatropin)

	HUMATROPE (somatropin)
	NGENLA (somatrogon-ghla)
	OMNITROPE (somatropin)
	SAIZEN (somatropin)
	SKYTROFA (lonapegsomatropin-tcgd)
	SOGROYA (somapacitan-beco)
	ZOMACTON (somatropin)

Prior Authorization Criteria

Prior Authorization Form - Growth Hormone

Initial Criteria - Approval Duration: 12 months

- Member must have one of the following covered diagnoses (listed below):
  - Multiple pituitary hormone deficiencies caused by a known hypothalamic-pituitary disease or its treatment (brain surgery and/or radiation)
  - Turner's syndrome
  - SHOX syndrome
  - Noonan syndrome
  - Chronic renal insufficiency
  - Prader–Willi syndrome
  - Endogenous growth hormone deficiency
- The requested medication must be prescribed by, or in consult annually with, an endocrinologist or nephrologist.
- The member must not have active malignancy.
- The member must not have epiphyseal closure and must still be growing, unless one of the below exceptions is present:
  - The member has a diagnosis of Prader-Willi syndrome.
  - The member has a diagnosis of endogenous growth hormone deficiency and is experiencing hypoglycemic episodes without growth hormone and growth hormone is needed to maintain proper blood glucose.
  - The requested medication is not Skytrofa

Chronic Renal Insufficiency

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

Endogenous Growth Hormone Deficiency

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

Prader-Willi Syndrome

- If the member is obese, sleep apnea has been ruled out by sleep study.
- The member must consult with a dietitian annually to maintain a nutritious diet.

Non-Preferred Agent Criteria:

- Clinical justification must be provided why a preferred product cannot be used (subject to clinical review)

Renewal Criteria - Approval Duration: 12 months

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

Prader-Willi Syndrome

- If the member is obese, the BMI must have decreased.
- If member is not obese, BMI must have maintained or decreased.

Serostim

CLINICAL PA REQUIRED
SEROSTIM (somatropin)

Prior Authorization Criteria

Prior Authorization Form - Growth Hormone

Initial Criteria - Approval Duration: 3 months

- The member must not have an active malignancy.
- The requested medication must be prescribed by, or in consult with, and infectious disease specialist or a specialist in the diagnosis and management of HIV infection.
- The member must be on concomitant antiretroviral therapy.
- The member must have failed a 3-month trial with megestrol, as evidenced by paid claims or pharmacy printouts.
- Lean body mass and body weight must be provided.
- Documentation of physical endurance must be provided.

Renewal Criteria - Approval Duration: 8 months (one time)

- Lean body mass and body weight must have increased from baseline.
- Physical endurance must have increased from baseline.

Imcivree

CLINICAL PA REQUIRED
IMCIVREE (setmelanotide)

Prior Authorization Criteria

Initial Criteria - Approval Duration: 4 months

- The member must have a diagnosis of obesity (BMI > 30 kg/m2 for adults or > 95th percentile using growth chart assessments for pediatric members)
- The member's weight and body mass index (BMI) must be provided within the last 60 days.
- The requested medication must be prescribed by, or in consult with, endocrinologist or medical geneticist.
- The member's obesity must be due to one of the following:
    - Genetic testing confirms one of the following variants that is pathogenic, likely pathogenic, or of unknown significance:
        - Proopiomelanocortin (POMC)
        - Proprotein convertase subtilisin/kexin type 1 (PCSK1)
        - Leptin receptor (LEPR) deficiency
    - Bardet-Biedl syndrome as evidenced by three or more of the following:
        - Rod-cone dystrophy
        - Polydactyly

- Genital anomalies
- Renal anomalies
- Intellectual impairment

Renewal Criteria - Approval Duration: 12 months

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

Secondary Hyperparathyroidism

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 each preferred medication.
- 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

Precocious Puberty

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

Prior Authorization Criteria

Initial Criteria - Approval Duration: 1 month

- Clinical justification must be provided explaining why the member is unable to use the preferred agents, with medical documentation (e.g., chart notes) documenting the reason(s) preferred agents cannot be used (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, 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)

GI – Gastroenterology

Bowel Prep Agents

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

Prior Authorization Criteria

Initial Criteria - Approval Duration: 1 month

- Clinical justification must be provided explaining why the member is unable to use the preferred agents, with medical documentation (e.g., chart notes) documenting the reason(s) preferred agents cannot be used (subject to clinical review).

Clostridioides difficile-associated diarrhea (CDAD)

Prevention

Fecal Microbiota

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

Monoclonal Antibody

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

Electronic Duration Verification:

- Vowst is payable every 6 months.

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

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

Treatment

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

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

- The member must have failed a 10-day trial with a preferred agent, as evidenced by paid claims or pharmacy printouts.

Crohn's Disease

Biologic Agents

Interleukin (IL) 12/IL-23 Inhibitor

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

Interleukin (IL)-23p19 Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	SKYRIZI (risankizumab-rzaa)
	SKYRIZI (risankizumab-rzaa) *– IV Induction Medical Billing Only*

TNF inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AVSOLA (infliximab-axxq) – *Medical Billing Only*	adalimumab-adaz
CIMZIA (certolizumab pegol)	adalimumab-fkjp
HUMIRA (adalimumab)	AMJEVITA (adalimumab-atto)

RENFLEXIS (infliximab-abda) – *Medical Billing Only*	CYLTEZO (adalimumab-abdm)
	HADLIMA (adalimumab-bwwd)
	HULIO (adalimumab-fkjp)
	HYRIMOZ (adalimumab-adaz)
	IDACIO (adalimumab-aacf)
	INFLECTRA (infliximab-dyyb) – *Medical Billing Only*
	infliximab – *Medical Billing Only*
	REMICADE (infliximab) – *Medical Billing Only*
	YUFLYMA (adalimumab-aaty)
	YUSIMRY (adalimumab-aqvh)

α4 Integrin Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	TYSABRI (natalizumab) – *Medical Billing Only*

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

α4β7 Integrin Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	ENTYVIO (vedolizumab) – *Medical Billing Only*

Janus Kinase (JAK) Inhibitors

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

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:
  - Entyvio Only: TNF inhibitor trial not required if the member has a high risk of infection or malignancy (e.g., age > 55, history of malignancy, history of serious infection)

Remicade, Inflectra, infliximab only:

- See Preferred Dosage Form criteria

Stelara Only:

- The member has failed a 3-month trial of Entyvio or Skyrizi, as evidenced by paid claims or printouts.

Tysabri Only:

- The requested medication must be prescribed by, or in consult with, an gastroenterologist
- The member has failed a 3-month trial of Entyvio, as evidenced by paid claims or printouts.

Constipation

Therapeutic Duplication

- One medication is allowed at a time.

Chronic Idiopathic Constipation

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AMITIZA (lubiprostone) - *Brand Required*	LINZESS (linaclotide) 72 mcg
LINZESS (linaclotide) 145 mcg, 290 mcg	lubiprostone
TRULANCE (plecanatide)	MOTEGRITY (prucalopride)

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

- Linzess 72 mcg Only:
  - The member must be receiving good effect from the 145 mcg but experiencing adverse effects.
- Motegrity:
  - 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
    - Amitiza

Functional Constipation

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

Electronic Age Verification

- Linzess 72 mcg: Prior authorization is not required for members less than 18 years of age.

Irritable Bowel Syndrome with Constipation (IBS-C)

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AMITIZA (lubiprostone) - *Brand Required*	IBSRELA (tenapanor)
LINZESS (linaclotide) 145 mcg, 290 mcg	LINZESS (linaclotide) 72 mcg
TRULANCE (plecanatide)	lubiprostone

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

- Linzess 72 mcg Only:
  - The member must be receiving good effect from the 145 mcg but experiencing adverse effects.
- Ibsrela Only:
  - 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
    - Amitiza for members assigned female at birth

Opioid-Induced Constipation

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

AMITIZA (lubiprostone) - *Brand Required*	lubiprostone
MOVANTIK (naloxegol)	RELISTOR (methylnaltrexone) TABLET
RELISTOR (methylnaltrexone) SYRINGE	
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

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

Diarrhea

Irritable Bowel Syndrome

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
antispasmotic (e.g., dicyclomine, hyoscyamine)	alosetron
loperamide	LOTRONEX (alosetron)
tricyclic antidepressants (e.g., amitriptyline)	VIBERZI (eluxadoline)
	XIFAXAN (rifaximin) 550 mg tablet

Electronic Diagnosis Verification

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

Electronic Concurrent Medications Required

- Xifaxan: Xifaxan 550mg does not require prior authorization for hepatic encephalopathy if used concurrently with lactulose
  - A total of 30 days of lactulose must be paid within 65 days prior to Xifaxan's date of service
  - An override may be available after an adequate trial of lactulose where lactulose is not tolerated

Prior Authorization Criteria

Initial Criteria - Approval Duration: 3 months

- Documentation must be provided confirming that infectious and medication-induced etiologies of diarrhea have been ruled out
- The member must have failed a 30-day trial of 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

- Documentation must be provided confirming that infectious and medication-induced etiologies of diarrhea have been ruled out.
- The member must have failed a 30-day trial of 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)	PANCREAZE (lipase/protease/amylase)
ZENPEP (lipase/protease/amylase)	PERTZYE (lipase/protease/amylase)
	VIOKACE (lipase/protease/amylase)

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

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

Eosinophilic Esophagitis

CLINICAL PA REQUIRED
DUPIXENT (dupilumab)

Prior Authorization Criteria

Prior Authorization Form - Eosinophilic Esophagitis

Initial Criteria - Approval Duration: 6 months

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

Renewal Criteria - Approval Duration: 12 months

- Documentation must be submitted that the member has achieved a significant reduction in dysphagia symptoms since treatment initiation.
- The member must have achieved an esophageal intraepithelial eosinophil count of ≤6 eos/hp.

Cholestasis Pruritis

Alagille Syndrome (ALGS):

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

Progressive Familial Intrahepatic Cholestasis (PFIC):

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

Prior Authorization Criteria

Initial Criteria - Approval Duration: 6 months

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

Renewal Criteria - Approval Duration: 12 months

- The member has experienced an improvement in pruritis, as evidenced by clinical documentation.
- The member must have experienced a reduction in serum bile acid as defined as a bile acid reduction ≥70% or reaching a bile acid level ≤70 µmol/L

Acute Hepatic Porphyria (AHP)

CLINICAL PA REQUIRED
GIVLAARI (givosiran) – *Medical Billing Only*

Prior Authorization Criteria

Initial Criteria - Approval Duration: 6 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a geneticist, hepatologist, hematologist, gastroenterologist, or specialist in acute hepatic porphyria (AHP)
- The member must have a diagnosis of AHP (i.e., acute intermittent porphyria (AIP), variegate porphyria (VP), hereditary coproporphyria (HCP), delta-aminolevulinic acid dehydratase deficient porphyria (ADP)) with the following as defined by laboratory reference range (evidenced with submitted documentation):

- Elevated urine porphobilinogen (PBG)
- Increased aminolevulinic acid (ALA)
- Genetic testing confirming a mutation

- The member has addressed identifiable lifestyle triggers (e.g., certain drugs, smoking, stress)
- The member has had two documented porphyria attacks within the past 6 months requiring hospitalization, urgent healthcare visit, or intravenous hemin administration (number of attacks and days of hemin are documented)
- The member has not had a liver transplant.

Renewal Criteria - Approval Duration: 12 months

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

Proton Pump Inhibitor

Solid Dosage Forms

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

Electronic Step Therapy Required

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

Prior Authorization Criteria

Initial Criteria - Approval Duration: 6 months

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

Non-Solid Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED (PA REQUIRED)
ACIPHEX (rabeprazole) SPRINKLE	esomeprazole solution packet
lansoprazole ODT	omeprazole-sodium bicarbonate packet
KONVOMEP (omeprazole/sodium bicarbonate)	pantoprazole packet

NEXIUM (esomeprazole) PACKET- *Brand Required*	PREVACID (lansoprazole) SOLUTAB
PROTONIX (pantoprazole) PACKET – *Brand Required*	PRILOSEC SUSPENSION (omeprazole)
	rabeprazole sprinkle
	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.

Ulcerative Colitis

Biologic Agents

α4β7 Integrin Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	ENTYVIO (vedolizumab)
	ENTYVIO (vedolizumab) – *Medical Billing Only*

Interleukin (IL) 12/IL-23 Inhibitor

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

TNF inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AVSOLA (infliximab-axxq) – *Medical Billing Only*	adalimumab-adaz
HUMIRA (adalimumab)	adalimumab-fkjp
RENFLEXIS (infliximab-abda) – *Medical Billing Only*	AMJEVITA (adalimumab-atto)
SIMPONI (golimumab)	CYLTEZO (adalimumab-abdm)
	HADLIMA (adalimumab-bwwd)
	HULIO (adalimumab-fkjp)
	HYRIMOZ (adalimumab-adaz)
	IDACIO (adalimumab-aacf)
	INFLECTRA (infliximab-dyyb) – *Medical Billing Only*
	infliximab – *Medical Billing Only*
	REMICADE (infliximab) – *Medical Billing Only*
	YUFLYMA (adalimumab-aaty)
	YUSIMRY (adalimumab-aqvh)

Electronic Diagnosis Verification

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

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

- Entyvio Only: The member must meet one of the following (1 or 2):
  1. The member must have failed a 3-month trial of a TNF inhibitor, as evidenced by paid claims or pharmacy printouts.
  2. The member has a high risk of infection or malignancy (e.g., age > 55, history of malignancy, history of serious infection)
- Remicade, Inflectra, infliximab Only: See Preferred Dosage Form criteria
- Stelara Only: The member must have failed a 3-month trial of a TNF inhibitor and Entyvio, as evidenced by paid claims or pharmacy printouts.

5-Aminosalicylic Acid (5-ASA)

Oral

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
APRISO (mesalamine) CAPSULE – *Brand Required*	AZULFIDINE (sulfasalazine)
balsalazide capsule	AZULFIDINE DR (sulfasalazine)
DELZICOL (mesalamine) CAPSULE– *Brand Required*	COLAZAL (balsalazide)
DIPENTUM (olsalazine)	mesalamine DR
LIALDA (mesalamine) TABLET– *Brand Required*	mesalamine ER

PENTASA (mesalamine) – *Brand Required*	mesalamine HD
sulfasalazine DR tablet	
sulfasalazine tablet	

Topical

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

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

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

Wilson's Disease

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
CUPRIMINE (penicillamine) CAPSULE	CUVRIOR (trientine tetrahydrochloride)

– Brand Required	
DEPEN (penicillamine) TITRATAB – *Brand Required*	penicillamine capsule
trientine hydrochloride	penicillamine tablet
	SYPRINE (trientine hydrochloride)

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

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

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)	

Prior Authorization Criteria

Initial Criteria - Approval Duration: 6 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a neurologist, geneticist, or specialist in the treatment of amyloidosis.
- Documentation of genetic testing confirming a pathogenic TTR mutation (e.g., V30M) must be provided.
- Documentation of one of the following must be provided:
  - Baseline polyneuropathy disability (PND) score ≤ IIIb
  - Baseline Coutinho staging system stage 1 or 2
  -
- The member has not had a liver transplant.
- The member has clinical signs and symptoms of the disease (amyloid deposition in biopsy specimens, TTR protein variants in serum, weakness, sensory loss, decreased motor strength, decreased gait speed, etc.)
- The member is not receiving any other TTR reducing agent (i.e., vutrisiran, patisiran, tafamidis, inotersen).

Renewal Criteria - Approval Duration: 12 months

- Documentation of a therapeutic response as evidenced by stabilization or improvement (e.g., improved neurologic impairment, motor function, quality of life, slowing of disease progression, etc.) from baseline in one of the following:
  - PND score ≤ IIIb
  - Coutinho staging system stage 1 or 2
  -

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 member must have wild-type TTR mediated amyloidosis or documentation of genetic confirmation of hereditary TTR mediated amyloidosis as evidenced by a pathogenic TTR mutation (e.g., V30M)
- The requested medication must be prescribed by, or in consult with, a cardiologist, geneticist, or specialist in the treatment of amyloidosis.
- The member has clinical signs and symptoms of the disease (heart failure, dyspnea, edema, hepatomegaly, ascites, angina, etc.)
- The member must not have any of the following:
  - NYHA class IV symptoms or severe aortic stenosis
  - Impaired renal function (i.e., GFR < 25)
  - Previous heart or liver transplant
- Documentation of baseline 6MWT > 100 meters must be submitted.
- The member is not receiving any other TTR reducing agent (i.e., vutrisiran, patisiran, tafamidis, inotersen)

Renewal Criteria - Approval Duration: 12 months

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

Late Infantile Neuronal Ceroid Lipofuscinosis Type 2 (CLN2)

CLINICAL PA REQUIRED
BRINEURA (cerliponase alfa) – *Medical Billing Only*

Prior Authorization Criteria

Initial Criteria - Approval Duration: 6 months

- The member must be between 3 and 8 years of age.
- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a metabolic specialist, geneticist, or pediatric neurologist.
- Documentation of the diagnosis must be submitted, as evidenced by the following:
  - Molecular analysis that has detected two pathogenic variants/mutations in the TPP1/CLN2 gene.

- An enzyme assay confirming deficiency of tripeptidyl peptidase 1 (TPP1)
- The member must not have ventriculoperitoneal shunts
- Baseline results of motor and language domains of the Hamburg CLN2 Clinical Rating Scale must be submitted and meet the following parameters:
  - Results must show a combined score of less than 6 in the motor and language domains.
  - Results must show a score of at least 1 in each of these domains.

Renewal Criteria - Approval Duration: 12 months

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

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

Fabry Disease

Alpha-Galactosidase A Pharmacological Chaperone

PREFERRED AGENTS (CLINICAL PA REQUIRED)
GALAFOLD (migalastat)

Prior Authorization Criteria

Initial Criteria - Approval Duration: 6 months

- The requested medication must be prescribed by, or in consult with, a metabolic specialist, geneticist, cardiologist, or specialist in Fabry disease.
- The member must be assigned male at birth.
- Baseline value for plasma or urinary globotriosylceramide (GL-3) levels ≥ 5 ng/mcL or GL-3 inclusions ≥ 0.3 per kidney interstitial capillary (KIC) as measured in kidney biopsy.
- The member's diagnosis must be confirmed to be caused by a pathologic galactosidase alpha gene (GLA) variant that is amenable to treatment with Galafold interpreted from a clinical geneticist professional, as evidenced by medical documentation attached to the request.
- The medication must not be used in conjunction with enzyme replacement therapy.
- The member must not have significant renal impairment (eGFR <30 mL/minute/1.73 m2)

Renewal Criteria - Approval Duration: 12 months

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

Enzyme Replacement Therapy

PREFERRED AGENTS (CLINICAL PA REQUIRED)
Fabrazyme (agalsidase beta) – *Medical Billing Only*

Initial Criteria - Approval Duration: 6 months

- The member is 8 years of age or older.
- The requested medication must be prescribed by, or in consult with, a metabolic specialist, geneticist, cardiologist, or specialist in Fabry disease.
- The member will not be concurrently treated with Galafold (migalastat)
- The member must have a diagnosis of Fabry disease with the one of the following (as evidenced with submitted documentation):
  - In males assigned at birth:
    - Deficiency of less than 35% of mean normal alpha-galactosidase A (α-Gal A) enzyme activity
    - Diagnosis is confirmed to be caused by a pathologic galactosidase alpha gene (GLA)
  - In females assigned at birth and males assigned at birth with α-Gal A enzyme activity > 35 percent:
    - Diagnosis must be confirmed to be caused by a pathologic galactosidase alpha gene (GLA)
    - Baseline value for plasma or urinary globotriosylceramide (GL-3) levels ≥ 5 ng/mcL or GL-3 inclusions ≥ 0.3 per kidney interstitial capillary (KIC) as measured in kidney biopsy
    - The member is experiencing one of the following symptoms:
      - Acroparesthesias (burning pain in the extremities)
      - Angiokeratomas (cutaneous vascular lesions)
      - Hypo- or anhidrosis (diminished perspiration)
      - Corneal and lenticular opacities
      - Left ventricular hypertrophy (LVH), hypertrophic cardiomyopathy, or arrythmia of unknown etiology
      - Chronic kidney disease (CKD), multiple renal cysts, and/or proteinuria of unknown etiology

Renewal Criteria - Approval Duration: 12 months

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

Gaucher's Disease

Enzyme Replacement Therapy

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ELELYSO (taliglucerase alfa) – *Medical Billing Only*	CEREZYME (imiglucerase) – *Medical Billing Only*
	VPRIV (velaglucerase alfa) – *Medical Billing Only*

Prior Authorization Criteria

Initial Criteria - Approval Duration: 6 months

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

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

Non-Preferred Agent Criteria:
- Please provide explanation with the request why the preferred agent cannot be used (subject to clinical review)

Renewal Criteria - Approval Duration: 12 months
- Documentation has been submitted that member has experienced a disease stability or beneficial response to therapy from baseline as shown by one or more of the following:
  - Reduction in liver volume to normal size or by 10%
  - Reduction in spleen volume by 15%
  - Increase in hemoglobin levels by 1 g/dl
  - Increase in platelet levels by 15%
  - Increased T-score [DXA] by 0.3, normalized growth velocity, or decrease in bone crisis

Substrate Replacement Therapy

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ZAVESCA (miglustat) – *Brand Required*	miglustat
PREFERRED AGENTS (CLINICAL PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**
CERDELGA (eliglustat)	

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months
- Cerdelga: See Medications that cost over $3000/month criteria

Lysosomal Acid Lipase (LAL) deficiency

CLINICAL PA REQUIRED
KANUMA (sebelipase alfa) – *Medical Billing Only*

Prior Authorization Criteria

Initial Criteria - Approval Duration: 6 months
- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a specialist in the treatment of lysosomal acid lipase (LAL) such as a lipidologist, endocrinologist, cardiologist, or hepatologist.
- Documentation of the member's diagnosis must be submitted, as evidenced by the following:

- Genetic testing confirming 2 mutations in the LIPA gene
- Deficiency of the LAL in peripheral blood leukocytes, fibroblasts, or dried blood spots

Renewal Criteria - Approval Duration: 12 months

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

Mucopolysaccharidosis I (MPS I)

CLINICAL PA REQUIRED
ALDURAZYME (laronidase) – *Medical Billing Only*

Prior Authorization Criteria

Initial Criteria - Approval Duration: 6 months

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

Renewal Criteria - Approval Duration: 12 months

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

Mucopolysaccharidosis II (MPS II) – Hunter Syndrome

CLINICAL PA REQUIRED
ELAPRASE (idursulfase) – *Medical Billing Only*

Prior Authorization Criteria

Initial Criteria - Approval Duration: 6 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- Documentation of the member's diagnosis must be submitted, as evidenced by the following:
  - Deficiency in iduronate-2sulfatase (I2S) enzyme activity in white cells, fibroblasts, or plasma in the presence of normal activity of at least one other sulfatase
  - Genetic testing confirming pathogenic mutations in the IDS gene
- The member age must be 5 years of age or older.
- The requested medication must be prescribed by, or in consult with, an expert in lysosomal storage diseases.

- The member does not have severe cognitive or neurologic impairment (e.g., inability to swallow)
- Documentation of one of the following must be submitted:
  - The Forced Vital Capacity (FVC) via Pulmonary Function Test
  - Urinary glycosaminoglycan (uGAG) levels are elevated defined by laboratory reference range
  - 6-minute walk test (6MWT)
  - Hepatomegaly (liver size 1.25 or more times normal)
  - Splenomegaly (spleen size five (5) or more times normal)

Renewal Criteria - Approval Duration: 12 months

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

Mucopolysaccharidosis IVA (MPS IVA) - Morquio A syndrome

CLINICAL PA REQUIRED
VIMIZIM (elosulfase alfa) – *Medical Billing Only*

Prior Authorization Criteria

Initial Criteria - Approval Duration: 6 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- Documentation of the member's diagnosis must be submitted, as evidenced by the following:
  - Genetic testing confirming biallelic pathogenic mutations in the GALNS gene
  - Deficiency in activity of the n N-acetylgalactosamine 6-sulfatase (GALNS) enzyme
- The requested medication must be prescribed by, or in consult with, a geneticist, metabolic specialist, or specialist in mucopolysaccharidoses (MPS)
- The member is experiencing musculoskeletal signs and symptoms of MSP-IVA such as knee deformity, kyphosis, hip dysplasia, arthralgia, etc.
- Documentation of one of the following must be submitted:
  - Forced Vital Capacity (FVC) via Pulmonary Function Test
  - 6-minute walk test (6MWT)
  - 3-minute stair claim test (3-MSCT)

Renewal Criteria - Approval Duration: 12 months

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

Mucopolysaccharidosis VI (MPS VI) - Maroteaux-Lamy syndrome

CLINICAL PA REQUIRED
NAGLAZYME (galsulfase) – *Medical Billing Only*

Prior Authorization Criteria

Initial Criteria - Approval Duration: 6 months

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

Renewal Criteria - Approval Duration: 12 months

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

Mucopolysaccharidosis VII (MPS VII) - Sly Syndrome

CLINICAL PA REQUIRED
MEPSEVII (vestronidase alfa-vjbk) – *Medical Billing Only*

Prior Authorization Criteria

Initial Criteria - Approval Duration: 6 months

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

Renewal Criteria - Approval Duration: 12 months

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

Phenylketonuria

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

Underutilization

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

Prior Authorization Criteria

Prior Authorization Form - Phenylketonuria

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

- The member must have been compliant with a PHE restricted diet for past 6 months (documentation must be attached).
- The requested medication must be prescribed by, or in consult with, a geneticist or endocrinologist.
- Baseline PHE levels must be attached
  - For members of childbearing potential and children ≤ 12 years old: PHE levels must be above 360 µmoles/liter (6 mg/dL)
  - For members without childbearing potential, and children > 12 years old: PHE levels must be above 600 µmoles/liter 10 mg/dL)
- Sapropterin Only: The member's weight must be provided. Requested initial dose must be 10 mg/kg
- Palynziq Only: 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.

Renewal Criteria:

- For same or reduced dose from previous trial:

Approval Duration: 12 months - if dose is the same or less than previous trial

- PHE level must be between 60 and 600 µmoles per liter
- Sapropterin Only: The member's weight must be provided.

- For a dose increase from previous trial

Approval Duration: 4 months - for a dose increase from previous trial

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

Pompe Disease

CLINICAL PA REQUIRED
LUMIZYME (alglucosidase alpha) – *Medical Billing Only*
NEXVIAZYME (avalglucosidase alfa-ngpt) – *Medical Billing Only*

Prior Authorization Criteria

Initial Criteria - Approval Duration: 6 months

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

- Documentation must be submitted of the member's current motor function such as motor function, respiratory function, cardiac involvement (infantile onset) and scores from at least two of the following assessments:
  A. Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorder (CHOP-INTEND)
  B. Hammersmith Infant Neurological Examination (HINE) Section 2 motor milestone score
  C. Hammersmith Functional Motor Scale Expanded (HFMSE)
  D. Motor Function Measure – 32 items (MFM-32)
  E. Revised Upper Limb Module (RULM)
  F. 6-minute walk test (6MWT)
  G. Forced Vital Capacity (FVC) via Pulmonary Function Test

Renewal Criteria - Approval Duration: 12 months

- The member must have experienced and maintained clinical benefit since starting treatment with the requested medication, as evidenced by medical documentation (e.g., chart notes) attached to the request (subject to clinical review) including stabilization or improvement of the following:
  - Motor function, respiratory function, cardiac involvement (infantile onset)
  - CHOP-INTEND, HINE, HFMSE, MFM-32, 6MWT, or RULM scores
  - Forced Vital Capacity (FVC) via Pulmonary Function Test (ages 5 and older)

Urea Cycle Agents

Hyperammonemia

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

N-acetylglutamate synthase (NAGS) deficiency

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
carglumic acid	CARBAGLU (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

PREFERRED AGENTS (CLINICAL PA REQUIRED)
REBLOZYL (luspatercept) – *Medical Billing Only*

Initial Criteria - Approval Duration: 6 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a hematologist or oncologist, or prescriber specializing in the treatment of beta thalassemia or myelodysplastic syndrome/myeloproliferative neoplasm.
- The member must have a diagnosis of anemia due to beta thalassemia or myelodysplastic syndrome/myeloproliferative neoplasm with ring sideroblasts.
- Documentation must be submitted of a pretreatment hemoglobin of less than 11 g/dL.
- Other causes of anemia (e.g., hemolysis, bleeding, recent major surgery, vitamin deficiency, etc.) have been ruled out.
- Member must not have any of the following:
  - Diagnosis of hemoglobin S/β-thalassemia or alpha-thalassemia
  - Deep vein thrombosis or stroke within the past 24 weeks
  - Platelet count greater than 1000 x 109 per liter

For anemia due to myelodysplastic syndrome/myeloproliferative neoplasm:

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

- Revised International Prognostic Scoring System (IPSS-R); very low, low, or intermediate (Score of 0 to 4.5);
- IPSS: low/intermediate-1 (Score 0 to 1)
- WHO-Based Prognostic Scoring System (WPSS): WPSS: very low, low, or intermediate (Score 0 to 2)

For anemia due to beta thalassemia:

- Documentation must be submitted confirming the following:
  - The member has required at least 6 red blood cell (RBC) transfusions in the previous 24 weeks.
  - The member has not had a transfusion-free period for ≥ 35 days during the most recent 24 weeks.

Renewal Criteria - Approval Duration: 12 months

- The member must have experienced stabilization, slowing of disease progression, or improvement of the condition since starting treatment with the requested medication, as evidenced by medical documentation (e.g., chart notes) attached to the request (subject to clinical review) including:
  - Reduction in transfusion requirements from pretreatment baseline achieving one of the following:
    - At least 2 units packed red blood cells
    - By one-half
    - Complete transfusions independence
- The member continues to have pretreatment hemoglobin of less than 11 g/dL.
- Dose will be increased to 1.25 mg/kg daily.

Chelating Agents

Iron Chelators

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
deferasirox tablet for suspension	EXJADE (deferasirox tablet for suspension)
deferasirox tablet	deferasirox sprinkle
deferoxamine mesylate vial – *Medical Billing Only*	DESFERAL (deferoxamine) MESYLATE VIAL – *Medical Billing Only*
	FERRIPROX (deferiprone)
	JADENU (deferasirox) SPRINKLE
	JADENU (deferasirox) TABLET

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The member must have failed a trial duration of 30 days (or less if duration is FDA approved) of each preferred agent of a unique ingredient, as evidenced by paid claims or pharmacy printouts.
- Clinical justification must be provided explaining why the member is unable to use the preferred agents (subject to clinical review).

Cold Agglutin Disease (CAD)

Anti-B-cell Therapy

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

Anti-Complement Therapy

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	ENJAYMO (sutimlimab-jome) – *Medical Billing Only*

Initial Criteria - Approval Duration: 6 months

- The requested medication must be prescribed by, or in consult with, a hematologist or specialist in cold agglutinin disease (CAD)
- The member must have all of the following:
  - Evidence of chronic hemolysis (e.g., high lactated dehydrogenase [LDH], low haptoglobin, high reticulocyte count)
  - Direct antiglobin (Coombs) test is positive for C3d
  - Cold agglutinin titer ≥ 64 at 4°C
- Cold agglutinin syndrome secondary to other factors has been ruled out (e.g., infection, rheumatologic disease, systemic lupus erythematosus, or overt hematologic malignancy)
- The member has a baseline hemoglobin level ≤ 10 g/dL
- The member has a baseline bilirubin level above normal reference range of the reporting laboratory
- The member has one or more of the following symptoms:
  - Symptomatic anemia
  - Acrocyanosis
  - Raynaud's phenomenon
  - Hemoglobinuria
  - Disabling circulatory symptoms
  - Major adverse vascular event
- The member must have been unresponsive to previous rituximab-based therapy or one of the following must be documented:
  - Member has a medical reason why rituximab-based therapy is not appropriate or is contraindicated.
  - Member has severe anemia or acute exacerbations of hemolysis and needs a bridge therapy awaiting the effects of a rituximab-based therapy.

Renewal Criteria - Approval Duration: 12 months

- Documentation must be submitted that the member has had a beneficial response to therapy from baseline as shown by one or more of the following:
  - Decrease in transfusions from baseline
  - Increase in hemoglobin (Hgb) by ≥ 2 g/dL from baseline or Hgb level ≥ 12 g/dL
  - Normalization of bilirubin levels to less than 1.2 mg/dL
- Therapy continues to be necessary due to ongoing cold agglutinin production and inability to use rituximab.

Cytokine Release Syndrome

Interleukin (IL) -6 Receptor Inhibitors

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ACTEMRA (tocilizumab) VIAL – *Medical Billing Only*	

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

- Actemra: See Medications that cost over $3000/month criteria

Hemophagocytic Lymphohistiocytosis (HLH)

PREFERRED AGENTS (CLINICAL PA REQUIRED)
GAMIFANT (emapalumab-lzsg) – *Medical Billing Only*

Initial Criteria - Approval Duration: 3 months or up to the hematopoietic stem cell transplantation (HSCT) date

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a hematologist, oncologist, immunologist, or transplant specialist.
- The member has refractory, recurrent or progressive disease or intolerance with conventional HLH therapy (i.e., etoposide + dexamethasone, cyclosporine A, or Anti-thymocyte globulin)
- The member must be a candidate for stem cell transplant.
- Documentation must be submitted confirming the diagnosis, as evidenced by the following:
  - Confirmation of a gene mutation known to cause primary HLH (e.g., PRF1, UNC13D, STX11 RAB27A, STXBP2)
  - Confirmation of 5 of the following clinical characteristics:
    - Fever ≥ 101.3F for over 7 days
    - Splenomegaly
    - Two of the following cytopenias in the peripheral blood:
      - Hemoglobin < 9 g/dL (or < 10 g/dL in infants less than 4 weeks of age)
      - Platelet count < 100,000/microL
      - ANC <1000/microL
    - One of the following:
      - Hypertriglyceridemia defined as fasting triglycerides ≥ 265 mg/dL (2 mmol/L)
      - Hypofibrinogenemia defined as fibrinogen ≤ 1.5 g/L
    - Hemophagocytosis in bone marrow or spleen or lymph nodes with no evidence of malignancy
    - Low or absent natural killer cell activity
    - Ferritin ≥ 500 mg/L
    - Soluble CD25 (i.e., soluble IL-2 receptor) ≥ 2,400 U/mL
- The requested medication must be administered with dexamethasone as part of the induction or maintenance phase of stem cell transplant, which is to be discontinued at the initiation of conditioning for stem cell transplant.

Category Criteria (Renewal): *Approval Duration: 3 months or up to the HSCT date*

- At least 3 HLH abnormalities must be improved by at least 50% from baseline.

Hemophilia

Clotting Factor Products

Hemophilia A Prophylaxis

Factor VIII - Non-Extended Half Life

Plasma Derived

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
HEMOFIL M (factor VIII plasma derived; mAb-purified)	
KOATE (factor VIII plasma derived, chromatography purified)	

First Generation - Recombinant

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	RECOMBINATE (factor VIII recombinant)

Second Generation - Recombinant

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	KOGENATE FS (factor VIII recombinant)

Third Generation - Recombinant

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
NOVOEIGHT (factor VIII recombinant)	ADVATE (factor VIII recombinant)
KOVALTRY (factor VIII recombinant)	
XYNTHA (factor VIII recombinant)	
XYNTHA SOLOFUSE (factor VIII recombinant)	

Fourth Generation - Recombinant

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AFSTYLA (factor VIII recombinant, single chain)	NUWIQ (factor VIII recombinant)

Factor VIII Extended Half Life

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ADYNOVATE (factor VIII recombinant, PEGylated)	ELOCTATE (factor VIII recombinant, Fc fusion protein)
ALTUVIIIO (antihemophilic factor (recombinant), Fc-VWF-XTEN fusion protein-ehtl)	ESPEROCT (factor VIII recombinant, glycoPEGylated – exei)
JIVI (factor VIII recombinant, pegylated-aucl)	

Recombinant humanized bispecific monoclonal antibody

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

Factor VII deficiency or Hemophilia A and B with Inhibitors

Factor VIIa

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
NOVOSEVEN RT (coagulation Factor VIIa recombinant)	
SEVENFACT (coagulation Factor VIIa recombinant)	

B domain-deleted porcine - Recombinant

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
OBIZUR (recombinant, B domain-deleted porcine (pig) factor VIII)	

Hemophilia B Prophylaxis

Factor IX - Non-Extended Half Life

Plasma Derived

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ALPHANINE SD (factor IX, plasma-derived)	
MONONINE (factor IX, plasma-derived mAb purified)	

Recombinant

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

BENEFIX (factor IX recombinant)	
IXINITY (factor IX recombinant)	
RIXUBIS (factor IX recombinant)	

Factor IX - Extended Half Life

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ALPROLIX (factor IX recombinant, Fc fusion)	
IDELVION (factor IX recombinant, albumin fusion)	
REBINYN (factor IX recombinant, glycol-PEGylated)	

Prothrombin Complex Concentrates

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
FEIBA NF (Anti-Inhibitor coagulant complex)	
KCENTRA (hum prothrombin cplx(PCC)4fact)	
PROFILNINE (factor IX cplx(pcc)no4,3factor)	

Von Willebrand disease

Factor VIII/vWF

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ALPHANATE (antihemophilic factor/Von Willebrand Factor Complex (Human))	
HUMATE-P (factor VIII/von Willebrand Factor (human))	
WILATE (factor VIII/von Willebrand Factor (human))	

Von Willebrand Factor

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
VONVENDI (recombinant human vWF)	

Factor X Deficiency

Factor X - Plasma Derived

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
COAGADEX (coagulation factor X (human))	

Factor XIII Deficiency

Factor XIII - Plasma Derived

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
CORIFACT (factor XIII concentrate (human))	

Factor XIII A – Subunit, Recombinant

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
TRETTEN (Factor XIII A-Subunit, recombinant)	

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

- The date of the member's last appointment with a Hemophilia Treatment Center must be within the past year.
- The contact information for Hemophilia Treatment Center must be provided.

Non-Preferred Agents Criteria:

- Clinical justification must be provided explaining why the member is unable to use a preferred agent (subject to clinical review).
- The member may qualify for non-preferred product if they are stable on current therapy (have had a paid claim for requested therapy in the past 45 days)

Gene Therapy

PREFERRED AGENTS (CLINICAL PA REQUIRED)
HEMGENIX (etranacogene dezaparvovec) – *Medical Benefit Only*

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a hematologist at a dose of 2 x 10^13 genome copies (gc) per 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 6 months.
- The member must have had a life-threatening hemorrhage, or have repeated, serious spontaneous bleeding episodes.
- The member must be negative for Factor IX inhibitor titers within the previous 30 days.

Hematopoietic, Colony Stimulating Factors

Filgrastim

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
NEUPOGEN (filgrastim)	GRANIX (TBO-filgrastim)
NIVESTYM (filgrastim-aafi)	ZARXIO (filgrastim-sndz)
RELEUKO (filgrastim-ayow)	

Pegfilgrastim

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
FULPHILA (pegfilgrastrim-jmdb)	NEULASTA (pegfilgrastim)
NEULASTA ONPRO (pegfilgrastim)	
NYVEPRIA (pegfilgrastrim–apgf)	
STIMUFEND (pegfilgrastim-fpgk)	
UDENYCA (pegfligrastim-cbqv)	
ZIEXTENZO (pegfilgrastim-bmez)	

Sargramostim

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

LEUKINE (sargramostim)	

Eflapegrastim-xnst

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	ROLVEDON (eflapegrastim-xnst)

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

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

Nausea/Vomiting

Chemo-Induced

NK1 Receptor Antagonists

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AKYNZEO (netupitant/palonosetron) CAPSULE	aprepitant capsule
EMEND (aprepitant) 125 MG-80 MG CAPSULE TRIPACK – *Brand Required*	aprepitant tripack
	EMEND (aprepitant) 80 MG CAPSULES
	EMEND (aprepitant) SUSPENSION

5-HT3 Receptor Antagonists

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AKYNZEO (netupitant/palonosetron) CAPSULE	SANCUSO (granisetron) PATCH
granisetron tablet	ZOFRAN (ondansetron)
ondansetron	SUSTOL (granisetron) SYRINGE

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)

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

Prior Authorization Criteria

Prior Authorization Form - Empaveli

Initial Criteria - Approval Duration: 6 months
- The requested medication must be prescribed by, or in consult with, a hematologist, oncologist, or immunology specialist.
- Diagnosis must be confirmed by flow cytometry with LDL level of 1.5 times the upper limit of normal (must include at least 2 different reagents tested on at least 2 cell lineages) demonstrating that individual's peripheral blood cells are deficient in glycosylphosphatidylinositol (GPI) – linked proteins (as evidenced by submitted documentation)
- One of the following criteria must be met (A or B):
  - The member is transfusion-dependent.
  - The member has hemoglobin ≤ 7 g/dL or Hb ≤ 9 g/dL, and member has symptoms of thromboembolic complications (e.g., abdominal pain, shortness of breath, chest pain, end-organ damage, fatigue)

Non-Preferred Agent Criteria:
- The member must have failed a 3-month trial with Ultomiris and Empaveli, as evidenced by paid claims or printouts.

Renewal Criteria - Approval Duration: 12 months
- Documentation has been submitted that support one of the following positive responses to therapy:
  - Decrease in transfusions from baseline
  - Increase in hemoglobin by ≥ 1 g/dL from baseline
  - Normalization in LDH levels ≤ 280 U/L

Plasminogen Deficiency Type 1 (Hypoplasminogenemia)

CLINICAL PA REQUIRED
RYPLAZIM (plasminogen, human-tvmh) – *Medical Billing Only*

Prior Authorization Criteria

Initial Criteria - Approval Duration: 3 months
- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a hematologist or specialist in treated condition
- Documentation of the diagnosis must be submitted, as evidenced by the following:
  - Baseline plasminogen activity level ≤ 45% *(If the patient is receiving plasminogen supplementation with fresh frozen plasma, allow for a 7-day washout period before obtaining baseline plasminogen activity level.)*

- Documented history of lesions (e.g., ligneous conjunctivitis, ligneous gingivitis, occlusive hydrocephalus, abnormal wound healing)
- Genetic testing to confirm biallelic pathogenic *PLG* mutation

Renewal Criteria - Approval Duration: 12 months, a one-time 6-month approval for dose adjustment allowed for members not meeting renewal criteria upon request

- The member must have experienced meaningful clinical benefit since starting treatment with the requested medication, as evidenced by medical documentation (e.g., chart notes) attached to the request (subject to clinical review) including the following:
  - The member has demonstrated a 50% resolution of lesions, with no active or recurrent lesions.
  - Trough plasminogen activity levels are >10% above baseline.

Sickle Cell Disease

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)
ADAKVEO (crizanlizumab-tmca) – *Medical Billing Only*	
ENDARI (glutamine)	
OXBRYTA (voxelotor)	

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

- The requested medication must be prescribed by, or in consult with, a hematologist, oncologist, or immunology specialist.
- The member must have had a 30-day trial of a hydroxyurea at the maximum (35 mg/kg/day) or maximally tolerated dose (allowing mild myelosuppression), as evidenced by paid claims or pharmacy printouts.
- The member has experienced at least one sickle cell-related vaso-occlusive crisis within past 12 months while adherent with hydroxyurea (documentation required).
- Oxbryta Only:
  - Baseline hemoglobin (Hb) ≤ 10.5 g/dL
- Siklos Only:
  - Baseline hemoglobin (Hb) ≤ 10.5 g/dL
  - See Preferred Dosage Form criteria

Renewal Criteria - Approval Duration: 12 months

- The member must have experienced and/or maintained clinical benefit since starting treatment with the requested product, as evidenced by medical documentation (e.g., chart notes) attached to the request (subject to clinical review) by one of the following:
  - Increase in hemoglobin (Hb) by ≥ 1 g/dL from baseline
  - Decrease in indirect bilirubin from baseline
  - Decrease in percent reticulocyte count from baseline
  - Reduction in sickle cell-related vaso-occlusive crisis

Thrombocytopenia

Immune Thrombocytopenic Purpura (ITP)

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
NPLATE (romiplostim)	DOPTELET (avatrombopag)
PROMACTA (eltrombopag)	TAVALISSE (fostamatinib)
PROMACTA (eltrombopag) POWDER PACK	

Prior Authorization Criteria

Initial Criteria - Approval Duration: 4 months

- The member has diagnosis of immune thrombocytopenic purpura (ITP) lasting >3 months.
- Documentation of platelet count of less than 30 x 10^9/L
- The member must have experienced an inadequate response after one of the following (A, B or C):
  A. The member must have failed a trial of appropriate duration of a corticosteroid or immunoglobulins, as evidenced by paid claims or pharmacy printouts.
  B. Rituximab
  C. The member must have undergone a splenectomy.

Non-Preferred Agents Criteria:

- The member must have failed trials with eltrombopag (at the recommended dose and duration) with each preferred agent, as evidenced by paid claims or pharmacy printouts.

Renewal Criteria - Approval Duration: 12 months

- Platelet counts must have achieved greater than or equal to 50 x 10^9/L in response to therapy (supported by documentation)

References:

1. Neunert, Cindy, et al. "American Society of Hematology 2019 guidelines for immune thrombocytopenia." *Blood advances* 3.23 (2019): 3829-3866.

Chronic Liver Disease-Associated Thrombocytopenia

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
DOPTELET (avatrombopag)	MULPLETA (lusutrombopag)

Prior Authorization Criteria

Initial Criteria - Approval Duration: The 2 weeks prior to procedure

- The member must have platelet count of less than 50 x 10^9/L
- The member must be scheduled to undergo a procedure that puts the member at risk of bleeding (documentation must include name and scheduled date of procedure)
- Documentation must include the date therapy will be initiated and discontinued:
  - Doptelet: Member must undergo procedure 5-8 days after last dose.
  - Mulpleta: Member must undergo procedure 2-8 days after last dose.

Non-Preferred Agents Criteria:

- The member must have failed trials with the preferred agent (at the recommended dose and duration) with each preferred agent, as evidenced by paid claims or pharmacy printouts.

Chronic Hepatitis C Infection-Associated Thrombocytopenia

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

PROMACTA (eltrombopag)	
PROMACTA (eltrombopag) POWDER PACK	

Prior Authorization Criteria

Initial Criteria - Approval Duration: 4 months

- The member is unable to receive direct acting antivirals for hepatitis C.
- The member's degree of thrombocytopenia must prevent initiation or continuation of interferon-based therapy.

Renewal Criteria - Approval Duration: 12 months

- Platelet counts must have achieved greater than or equal to 50 x 10^9/L in response to therapy (supported by documentation)
- The member is currently receiving interferon-based therapy.

Aplastic Anemia

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
PROMACTA (eltrombopag)	
PROMACTA (eltrombopag) POWDER PACK	

Prior Authorization Criteria

Initial Criteria - Approval Duration: 4 months

- The member must have platelet count of less than 30 x 10^9/L
- The member must have failed therapy or be receiving concurrent therapy with immunosuppressive therapy (e.g., corticosteroid, Atgam, cyclosporine, cyclosporine)

Renewal Criteria - Approval Duration: 12 months

- Platelet counts must have achieved greater than or equal to 50 x 10^9/L in response to therapy (supported by documentation)

Infectious Disease

Anti-infectives - Resistance Prevention

Antifungals – Aspergillus and Candidiasis Infections

Solid Dosage Form

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

Non-Solid Dosage Forms

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

Community-Acquired Pneumonia

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

Cytomegalovirus infection

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

Methicillin-Resistant *Staphylococcus aureus* (MRSA):

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
clindamycin	BAXDELA (delafloxacin)
doxycycline	NUZYRA (omadacycline)
linezolid	SIVEXTRO (tedizolid)
minocycline	
trimethoprim-sulfamethoxazole	

Helicobacter pylori

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
lansoprazole/amoxicillin/clarithromycin	bismuth subcitrate potassium/metronidazole/tetracycline
PYLERA (bismuth subcitrate potassium/metronidazole/tetracycline) – *Brand Required*	OMECLAMOX-PAK (omeprazole/clarithromycin/amoxicillin)
	TALICIA (omeprazole/amoxicillin/rifabutin)

Tuberculosis

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

ethambutol	isoniazid	cycloserine
PRIFTIN (rifapentine)		MYCOBUTIN (rifabutin)
pyrazinamide		RIFADIN (rifampin)
rifabutin		SIRTURO (bedaquiline)

Prior Authorization Criteria

Initial Criteria - Approval Duration: 5 days

- Diagnosis must be proven to be caused by a susceptible microorganism by culture and susceptibility testing.
- The requested medication must be prescribed by, or in consult with, an infection disease specialist, an antibiotic stewardship program, or protocol.
- One of the following criteria must be met (A or B):
  A. The member is continuing treatment upon discharge from an acute care facility.
  B. Clinical justification must be provided explaining why the preferred antibiotics are not an option due to susceptibility, previous failed trials, or other contraindications (subject to clinical review)

Aspergillus and Candidiasis Infections Only:

- The request must be for use as prophylaxis of invasive Aspergillus and Candida infections or Oropharyngeal Candidiasis

Tuberculosis Only:

- Isoniazid: The ND Division of Disease Control Tuberculosis Prevention and Control program provides isoniazid for no cost through the UND Center for Family Medicine Pharmacy. Please contact 701-328-2378 to obtain supply.

Renewal Criteria - Approval Duration: 5 days

- It is medically necessary to continue treatment course after re-evaluation of the member's condition.
- The total requested duration of use must not be greater than manufacturer labeling or treatment guideline recommendations (whichever is greater).

Human Immunodeficiency Virus (HIV)

Antiretrovirals – Pre-exposure Prophylaxis (PrEP)

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
APRETUDE (cabtegravir)	TRUVADA (emtricitabine/tenofovir)
DESCOVY (emtricitabine/tenofovir)	
emtricitabine/tenofovir	

Antiretrovirals – Treatment

References:

2. Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV. Department of Health and Human Services. Available at https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/adult-adolescent-arv/guidelines-adult-adolescent-arv.pdf Accessed (October 9, 2020)

Integrase Strand Transfer Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
BIKTARVY (bictegravir/emtricitabine/tenofovir)	
CABENUVA (cabotegravir/rilprivirine)	

– Medical Billing Only	
DOVATO (dolutegravir/lamivudine)	
GENVOYA (elvitegravir/cobicistat/emtricitabine/tenofovir)	
ISENTRESS (raltegravir)	
JULUCA (dolutegravir/rilpivirine)	
STRIBILD (elvitegravir/cobicistat/emtricitabine/tenofovir)	
TIVICAY (dolutegravir)	
TRIUMEQ (abacavir/dolutegravir/lamivudine)	
TRIUMEQ PD (abacavir/dolutegravir/lamivudine)	

Non-Nucleoside Reverse Transcriptase Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
COMPLERA (emtricitabine/rilpivirine/tenofovir)	ATRIPLA (efavirenz/emtricitabine/tenofovir)
efavirenz	EDURANT (rilpivirine)
efavirenz/emtricitabine/tenofovir	efavirenz/lamivudine/tenofovir
JULUCA (dolutegravir/rilpivirine)	rilpivirine
ODEFSEY (emtricitabine/rilpivirine/tenofovir)	
PIFELTRO (doravirine)	
SYMFI (efavirenz/lamivudine/tenofovir) – *Brand Required*	
SYMFI LO (efavirenz/lamivudine/tenofovir) – *Brand Required*	
Not Recommended for First Line Use	
etravirine	INTELENCE (etravirine)
nevirapine	nevirapine ER

- Etravirine - Guidelines do not recommend for treatment-naïve members due to insufficient data. FDA indication is for treatment experienced members and so should be reserved for salvage therapy, pretreated members with NNRTI resistance and PI exposure or who have ongoing adverse effects with first line therapies.
- Nevirapine - Guidelines no longer recommend nevirapine for initial treatment of HIV infection in treatment-naïve members. In resource limited settings, it can be considered as a third agent. Nevirapine demonstrated inferiority relative to efavirenz and is associated with serious and fatal hepatic and rash events.

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

- See Preferred Dosage Form criteria

Nucleoside Reverse Transcriptase Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
abacavir	ATRIPLA (efavirenz/emtricitabine/tenofovir)
abacavir/lamivudine	efavirenz/lamivudine/tenofovir
BIKTARVY (bictegravir/emtricitabine/tenofovir)	emtricitabine capsule
CIMDUO (lamivudine/tenofovir)	EMTRIVA (emtricitabine) CAPSULE

COMPLERA (emtricitabine/rilpivirine/tenofovir)	EPIVIR (lamivudine)
DELSTRIGO (doravirine/lamivudine/tenofovir)	EPZICOM (abacavir)
DESCOVY (emtricitabine/tenofovir)	lamivudine
efavirenz/emtricitabine/tenofovir	TRIZIVIR (abacavir/lamivudine)
emtricitabine solution	TRUVADA (emtricitabine/tenofovir)
emtricitabine/tenofovir	VIREAD (tenofovir)
GENVOYA (elvitegravir/cobicistat/emtricitabine/tenofovir)	ZIAGEN (abacavir)
ODEFSEY (emtricitabine/rilpivirine/tenofovir)	
SYMFI (efavirenz/lamivudine/tenofovir) – *Brand Required*	
SYMFI LO (efavirenz/lamivudine/tenofovir) – *Brand Required*	
STRIBILD (elvitegravir/cobicistat/emtricitabine/tenofovir)	
SYMTUZA (darumavir/cobicistat/emtricitabine/tenofovir)	
tenofovir	
TEMIXYS (lamivudine/tenofovir)	
TRIUMEQ (abacavir/dolutegravir/lamivudine)	
TRIUMEQ PD (abacavir/dolutegravir/lamivudine)	
Not Recommended for First Line Use	
abacavir/lamivudine/zidovudine	COMBIVIR (lamivudine/zidovudine)
didanosine	RETROVIR (zidovudine)
lamivudine/zidovudine	TRIZIVIR (abacavir/lamivudine/zidovudine)
stavudine	ZERIT (stavudine) CAPSULE
zidovudine syrup	zidovudine capsule and tablet

- abacavir/lamivudine/zidovudine – Guidelines do not recommend ABC/3TC/ZDU (as either a triple-NRTI combination regimen or in combination with tenofovir (TDF) as a quadruple-NRTI combination regimen) due to inferior virologic efficacy.
- didanosine – Guidelines do not recommend ddI/3TC or ddI/FTC regimens due to inferior virologic efficacy, limited trial experience in ART-naïve members, and ddI toxicities (including pancreatitis and peripheral neuropathy). ddI/TDF regimens are not recommended due to high rate of early virologic failure, rapid selection of resistance mutations, potential for immunologic nonresponse/CD4 cell decline, and increased ddI drug exposure and toxicities.
- lamivudine/zidovudine – Guidelines do not recommend ZDV/3TC due to greater toxicities than recommended NRTIs (including bone marrow suppression, GI toxicities, skeletal muscle myopathy, cardiomyopathy, and mitochondrial toxicities such as lipoatrophy, lactic acidosis and hepatic steatosis).
- stavudine – Guidelines do not recommend d4T/3TC due to significant toxicities (including lipoatrophy, peripheral neuropathy) and hyperlactatemia (including symptomatic and life-threatening lactic acidosis, hepatic steatosis, and pancreatitis)

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

- See Preferred Dosage Form criteria

Post-Attachment Inhibitor

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

TROGARZO (Ibalizumab-uiyk)	

Protease Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
atazanavir	darunavir
EVOTAZ (atazanavir/cobicistat)	NORVIR (ritonavir) TABLET
NORVIR (ritonavir) POWDER PACKET	REYATAZ (atazanavir) CAPSULE
PREZCOBIX (darunavir/cobicistat)	
PREZISTA (darunavir) – *Brand Required*	
REYATAZ (atazanavir) POWDER PACK	
ritonavir	
SYMTUZA (darumavir/cobicistat/emtricitabine/tenofovir)	
Not Recommended for First Line Use	
APTIVUS (tipranavir)	KALETRA (lopinavir/ritonavir) SOLUTION
fosamprenavir	KALETRA (lopinavir/ritonavir) TABLET
INVIRASE (saquinavir)	LEXIVA (fosamprenavir)
lopinavir/ritonavir tablet	
lopinavir/ritonavir solution	
VIRACEPT (nelfinavir)	

- Fosamprenavir – Guidelines do not recommend use of unboosted FPV or FPV/r due to virologic failure with unboosted FPV-based regimens that may result in selection of mutations that confer resistance to FPV and DRV. There is also less clinical trial data for FPV/r than other RTV-boosted PIs.
- Lopinavir/ritonavir – Guidelines do not recommend LPV/r due to GI intolerance, higher pill burden and higher RTV dose than other PI-based regimens
- Nelfinavir – Guidelines do not recommend use of NFV due to inferior virologic efficacy and diarrhea.
- Saqinavir – Guidelines do not recommend use of unboosted SQV due to inadequate bioavailability and inferior virologic efficacy or SQV/r due to high bill burden and QT and PR prolongation.
- Tipranavir – Guidelines do not recommend TPV/r due to inferior virologic efficacy, higher dose of RTV and higher rate of adverse events than other RTV-boosted PIs.

Capsid Function Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
Not Recommended for First Line Use	
SUNLENCA (lenacapavir) INJECTION – *Medical Billing Only*	
SUNLENCA (lenacapavir) TABLET	

- lenacapavir - SUNLENCA, in combination with other antiretroviral(s), is indicated for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in heavily treatment-experienced adults with multidrug resistant HIV-1 infection failing their current antiretroviral regimen due to resistance, intolerance, or safety considerations.

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
Not Recommended for First Line Use	
FUZEON (enfuvirtide)	
SELZENTRY (maraviroc)	

- Enfuvirtide (Fusion Inhibitor)– Guidelines do not recommend T20 for initial therapy due to twice daily injections, high rate of injection site reactions, and it has only been studied in members with virologic failure

- Maraviroc (CCR5 Antagonist) – Guidelines do not recommend MVC for initial therapy due to twice daily dosing, no virologic benefit compared to recommended regimens, and required CCR5 tropism testing.

Diarrhea

Mytesi: Jump to Criteria

Loss of Appetite

Dronabinol: Jump to Criteria

Wasting Cachexia

Serostim: Jump to Criteria

Hepatitis C Antiviral Treatments

Direct Acting Antivirals

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
HARVONI (ledipasvir/sofosbuvir) 45 mg/200 mg tablet	EPCLUSA (sofosbuvir/velpatasvir)
MAVYRET (glecaprevir/pibrentasvir)	HARVONI (ledipasvir/sofosbuvir) 90mg/400mg tablet
sofosbuvir/velpatasvir	HARVONI (ledipasvir/sofosbuvir) ORAL PALLET
SOVALDI (sofosbuvir) 200 MG TABLET	ledipasvir/sofosbuvir 90mg/400mg tablet
VOSEVI (sofosbuvir/velpatasvir/voxilaprevir)	SOVALDI (sofosbuvir) 400MG TABLET
	SOVALDI (sofosbuvir) ORAL PALLET
	VIEKIRA PAK (dasabuvir/ombitasvir/paritaprevir/ritonavir)
	ZEPATIER (elbasvir/grazoprevir)

Electronic Step Care and Concurrent Medications

- Epclusa (and its generic): A total of 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), Mavyret, and Vosevi: The entire treatment course i must be dispensed at the initial fill.
    - Please call pharmacy provider relations (1-701-328-4086) if a member has already partially completed their treatment course and needs less than a full course of therapy for their current fill.

Prior Authorization Criteria

Prior Authorization Form – Hepatitis C

Initial Criteria - Approval Duration: Based on label recommendations

- The member must have life expectancy greater than 12 months.
- One of the following must be met (1-4):
    5. The member has no history of alcohol use disorder or IV illicit drug use.
    6. The member has maintained sobriety for the past 12 months.
    7. The member has completed or be currently enrolled in a treatment program within the past 12 months.

8. The Harm Reduction Program Participation Attestation Form is attached indicating one of the following (a or b):
    c. The member participates in a Syringe Service Program
    d. 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

- Chronic Hepatitis C must be documented by one of the following (most recent test within the last 24 months):
    - No liver fibrosis or unknown: 2 positive HCV RNA levels at least 3 months apart
    - Liver fibrosis or cirrhosis:1 positive HCV RNA test

For RE-TREATMENT after Direct Acting Antiviral failure or incomplete therapy:

- 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
- The following criteria is met (as applicable due to reason for retreatment):

Reason for retreatment:	
Due to non-compliance (defined as a medication possession ratio (MPR) of less than 80%)	The member has participated in 1 visit focused on addressing adherence barriers within the past 180 days. Adherence education may be provided by a pharmacist (may be billed through the MTM program) or clinic-based E&M billed service (provided by a nurse or independent practitioner).
Resistance	• **FIRST TIME treatment with Direct Acting Antivirals** criteria must be met

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

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

Malaria

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
hydroxychloroquine	atovaquone/proguanil
quinine	chloroquine
	COARTEM (artemether/lumefantrine)
	KRINTAFEL (tafenoquine)
	MALARONE (atovaquone/proguanil)
	mefloquine
	primaquine
	QUALAQUIN (quinine)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 7 days

- The member must have had a trial of a generic quinine in the last 30 days, as evidenced by paid claims or pharmacy print outs
- The request must be for treatment of malaria (*NOT covered for prophylaxis)*

Respiratory Syncytial Virus (RSV) Prophylaxis

CLINICAL PA REQUIRED
SYNAGIS (palivizumab) – *Medical Billing Only*

Prior Authorization Criteria

Prior Authorization Form – RSV Prophylaxis

Initial Criteria – Approval Duration: Up to 5 weight-based doses within 6 months of season onset. No further prior authorization requests will be approved following season offset.

Respiratory Syncytial Virus (RSV) Season defined as onset (1st of 2 consecutive weeks when percentage of PCR tests positive for RSV is > 3% and offset (Last of 2 consecutive weeks when percentage of PCR tests positive for RSV is < 3%) as reported by The National Respiratory and Enteric Virus Surveillance System (NREVSS) Midwest Region RSV Regional Trends – NREVSS | CDC

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)
  - In accordance with the Health Alert Network (HAN) Health Advisory, ND Medicaid will process prior authorization requests for palivizumab for infants 8 months to 19 months who otherwise meet criteria without further clinical justification.
- The member had not received another monoclonal antibody for RSV prophylaxis during the current RSV season.

- The member must not have received immunity through a maternal Respiratory Syncytial Virus Vaccine.
- The member must have one of the following diagnoses and the additional criteria outlined for diagnosis:
  - **Prematurity:**
    - < 29 weeks, 0 days gestational age
      - ≤ 12 months of age at start of RSV season
    - ≥ 29 weeks, 0 days gestational age to ≤ 35 weeks, 0 days gestational age
      - ≤ 6 months of age at start of RSV season
      - One of the following:
        - Neuromuscular disease or pulmonary abnormality that impairs ability to clear secretions from the upper airway because of ineffective cough
        - Profoundly immunocompromised receiving chemotherapy, solid organ transplantation, hematopoietic stem cell transplantation, or require colony stimulating factors
  - **Chronic Lung Disease of Prematurity (CLD)**
    - < 32 weeks, 0 days gestational age
      - ≤12 months of age at start of RSV season
      - Requires supplemental oxygen > 21% for at least the first 28 days after birth
    - < 32 weeks, 0 days gestational age
      - 13-24 months of age at start of RSV season
      - Requires supplemental oxygen > 21% for at least the first 28 days after birth
      - Continues to receive medical support within six months before the start of RSV season with supplemental oxygen, diuretic, or chronic corticosteroid therapy
  - **Congenital Heart Disease**
    - ≤12 months of age at start of RSV season
      - Hemodynamically significant cyanotic or acyanotic congenital heart disease with medical therapy required

References:

1. American Academy of Pediatrics. Updated Guidance: Use of Palivizumab Prophylaxis to Prevent Hospitalization From Severe Respiratory Syncytial Virus Infection During the 2022-2023 RSV Season. American Academy of Pediatrics; July 2022. Available at: https://www.aap.org/en/pages/2019-novel-coronavirus-covid-19-infections/clinical-guidance/interim-guidance-for-use-of-palivizumab-prophylaxis-to-prevent-hospitalization/
2. Midgley CM, Haynes AK, Baumgardner JL, et al. Determining the seasonality of respiratory syncytial virus in the United States: the impact of increased molecular testing. J Infect Dis 2017;216:345–55
3. Rose EB, Wheatley A, Langley G, Gerber S, Haynes A. Respiratory Syncytial Virus Seasonality — United States, 2014–2017. MMWR Morb Mortal Wkly Rep 2018;67:71–76. DOI: http://dx.doi.org/10.15585/mmwr.mm6702a4external icon

Nephrology/Urology

Complement-mediated Thrombotic Microangiopathy (TMA) / Complement-mediated Hemolytic Uremic Syndrome

CLINICAL PA REQUIRED
SOLIRIS (eculizumab) – *Medical Billing Only*
ULTOMIRIS (ravulizumab-cwvz)
ULTOMIRIS (ravulizumab-cwvz) – *Medical Billing Only*

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a hematologist or nephrologist.
- The member has all the following (as evidenced by submitted documentation):
  - Low platelet count, as defined by laboratory reference range or member requires dialysis.
  - Evidence of hemolysis such as an elevation in serum lactate dehydrogenase (LDH), elevated indirect bilirubin, reduced haptoglobin, or increased reticulocyte, as defined by laboratory reference range or member requires dialysis.
  - Serum creatinine above the upper limits of normal, as defined by laboratory reference range or member requires dialysis.
- The member does not have bloody diarrhea.

Renewal Criteria – Approval Duration: 12 months

- The member must have experienced meaningful clinical benefit since starting treatment with the requested medication, as evidenced by medical documentation (e.g., chart notes) attached to the request (subject to clinical review) including one of the following scores and symptoms:
  - Normalization of platelet count, as defined by laboratory reference range.
  - Normalization of lactate dehydrogenase (LDH), as defined by laboratory reference range.
  - ≥ 25% improvement in serum creatinine from baseline or ability to discontinue dialysis.

Benign Prostatic Hyperplasia

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
alfuzosin ER	AVODART (dutasteride)
CARDURA XL (doxazosin)	CARDURA (doxazosin)
doxazosin	ENTADFI (finasteride/tadalafil)
dutasteride	FLOMAX (tamsulosin)
finasteride	MINIPRESS (prazosin)
prazosin	PROSCAR (finasteride)
silodosin	RAPAFLO (silodosin)
tamsulosin	sildenafil
terazosin	tadalafil

Electronic Diagnosis Verification

- Finasteride, sildenafil, and tadalafil: Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

- The member must have failed a 30-day trial of each preferred agent, as evidenced by paid claims or pharmacy printouts.
- Sildenafil/tadalafil: Documentation (e.g., chart notes) must be provided confirming the diagnosis.

Chronic Kidney Disease

Therapeutic Duplication

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

Dual endothelin angiotensin receptor antagonist

CLINICAL PA REQUIRED
FILSPARI (sparsentan)

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

NO PA REQUIRED
FARXIGA (dapagliflozin)
INVOKANA (canagliflozin)
JARDIANCE (empagliflozin)

Systemic Corticosteroids

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

Electronic Duration Verification:

- Tarpeyo is payable for 9 months every 3 years.

Prior Authorization Criteria

<u>Initial Criteria – Approval Duration:</u> 12 months

Inpefa Only:

- The requested medication must be prescribed by, or in consult with, a cardiologist or nephrologist.
- If member is on renal dialysis, Medicare eligibility must be ruled out. *(6-month approval allowed to determine eligibility)*

- The member has type 2 diabetes and chronic kidney disease.
- The member has a history of a cardiovascular event (e.g., heart failure, myocardial infarction, cerebrovascular event) or two or more risk factors (e.g., elevated cardiac and inflammatory biomarker, obesity, hyperlipidemia, hypertension)
- The member is receiving concurrent Entresto, a beta-blocker, a SGLT-2 Inhibitor, and a mineralocorticoid receptor antagonist.
- Clinical justification must be provided explaining why the member is unable to use a preferred SGLT-2 inhibitor (subject to clinical review)

Kerendia Only

- The member must have history of diabetes.
- The member must be on the following at the target or maximally tolerated dose, as evidenced by paid claims or pharmacy printouts:
  - An ACE-inhibitor or an ARB
  - A SGLT-2 inhibitor
- The member has an estimated glomerular filtration rate (eGFR) ≥ 25 mL/min/1.73 m^2 AND one of the following (1 or 2):
  1. urinary albumin-to-creatinine ratio (UACR) ≥ 30 mg/g (≥3 mg/mmol)
  2. albuminuria ≥ 300 mg/day

Korsuva Only

- If member is on renal dialysis, Medicare eligibility must be ruled out *(6-month approval may be allowed to determine eligibility)*..
- The member must have failed a 90-day trial of pregabalin or gabapentin, as evidenced by paid claims or pharmacy printouts.

Filspari and Tarpeyo Only

- The member must have eGFR ≥ 30.
- If member is on renal dialysis, Medicare eligibility must be ruled out *(6-month approval may be allowed to determine eligibility)*..
- The member must be experiencing proteinuria > 1 gram/day or UPCR ≥ 1.5 g/g (documentation must be attached) despite 3-month trials with good compliance of the following at the target or maximally tolerated dose, as evidenced by paid claims or pharmacy printouts:
  - ACE inhibitor or an ARB
  - A SGLT-2 inhibitor
  - prednisone or methylprednisolone

<u>Renewal Criteria – Approval Duration:</u> 12 months

- If member is on renal dialysis, Medicare eligibility must be ruled out *(6-month approval may be allowed to determine eligibility)*..
- The member must have experienced meaningful clinical benefit since starting treatment with the requested medication, as evidenced by medical documentation (e.g., chart notes) attached to the request (subject to clinical review) including one of the following scores and symptoms:
  - *Filspari and Tarpeyo Only*: proteinuria <1 gram/day or UPCR < 1.5 g/g or reduction of 30% from baseline
  - *Kerendia Only*: albuminuria <1 gram/day or UACR < 1.5 g/g or reduction of 30% from baseline

References:

1. Rossing, Peter, et al. “KDIGO 2022 Clinical Practice Guideline for Diabetes Management in Chronic Kidney Disease.” *Kidney international* 102.5 (2022): S1-S127.
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.

Hematopoietic, Erythropoiesis Stimulating Agents

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ARANESP (darbepoetin alfa)	EPOGEN (epoetin alfa)
PROCRIT (epoetin alfa)	MIRCERA (methoxy polyethylene glycol-epoetin beta)
	RETACRIT (epoetin alfa – epbx)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must have had a 4-week trial of each preferred agent, as evidenced by paid claims or pharmacy printouts.
- If member is on renal dialysis, Medicare eligibility must be ruled out *(6-month approval may be allowed to determine eligibility)*..

Hematopoietic Syndrome of Acute Radiation Syndrome

PREFERRED AGENTS (CLINICAL PA REQUIRED)
NPLATE (romiplostim)

Prior Authorization Criteria

Initial Criteria – Approval Duration: treatment plan must be documented in request

- The requested medication must be prescribed by, or in consult with, a hematologist or oncologist.
- The member meets one of the following:
    - The member has had a ≥ 2 gray exposure to radiation
    - The member has had exposure to radiation and experiencing one of the following:
        - Gross blood loss
        - > 10% decrease in hemoglobin
        - Platelet count < 50,000/microL
        - Absolute neutrophil count < 1000 cells/microL
        - Absolute lymphocyte count < 1000 cells/microL

Hyperkalemia (Chronic)

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

Prior Authorization Criteria

Initial Criteria – Approval Duration: 3 months

- The requested medication must be prescribed by, or in consult with, a nephrologist.
- If member is on renal dialysis, Medicare eligibility must be ruled out *(6-month approval may be allowed to determine eligibility)*.
- The member's current serum potassium level must be exceeding the upper limit of normal, as evidenced by documentation from at least two separate lab values, submitted with the request.
- One of the following criteria must be met:
    - The member must have failed 30-day trials with at least two of the following products.
        - bumetanide, chlorothiazide, fludrocortisone, furosemide, hydrochlorothiazide, indapamide, metolazone, torsemide
    - The member must not be receiving the medications known to cause hyperkalemia listed below, OR medical justification must be provided explaining why discontinuation of these agents would be clinically inappropriate in this member:

o angiotensin-converting enzyme inhibitor
o angiotensin II receptor blocker
o aldosterone antagonist
o nonsteroidal anti-inflammatory drugs (NSAIDs)

Non-Preferred Agent Criteria:

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

Renewal Criteria – Approval Duration: 12 months

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

Primary Hyperoxaluria Type 1 (PH1)

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

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a nephrologist, urologist, geneticist or other provider experience in treating primary hyperoxaluria type 1 (PH1)
- Documentation of the member's diagnosis must be submitted, as evidenced by the following:
  - Mutation in the alanine: glyoxylate aminotransferase (AGXT) gene confirmed by genetic testing
  - Liver enzyme analysis confirming absent or significant deficiency in alanine: glyoxylate aminotransferase (AGT) activity
- The member does not have secondary causes of hyperoxaluria (e.g., diet with excessive intake of oxalate, gastric bypass surgery, IBD, other intestinal disorders, etc.)
- The member has had at least a 90-day trial of pyridoxine (vitamin B6) of maximally tolerated doses (maximum dose, 20 mg/kg per day) that failed to achieve at least a 30% reduction in urinary oxalate excretion
- The member has not received a liver transplant
- Documentation of the one of the following must be submitted:
  - Elevated urinary oxalate excretion (i.e., > 1 mmol/1.73 m^2 per day [90 mg/1.73 m^2 per day])
  - Elevated urinary oxalate: creatinine ratio as defined by age defined laboratory reference range
  - Elevated urinary excretion of glycolate (i.e., > 0.5 mmol/1.73 m^2 per day [45 mg/1.73 m^2 per day])

Renewal Criteria – Approval Duration: 12 months

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

Lupus Nephritis

First Line Agents

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

cyclophosphamide	
mycophenolate	
systemic oral corticosteroids	

Anti-CD20 Monoclonal Antibodies

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

B-Lymphocyte Stimulator (BlyS) – Specific Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
BENLYSTA (belimumab) – *Medical Billing Only*	

Calcineurin Inhibitors

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

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- The requested medication must be prescribed by, or in consult with, a nephrologist or rheumatologist
- If member is on renal dialysis, Medicare eligibility must be ruled out *(6-month approval may be allowed to determine eligibility)*.
- The member has an eGFR > 45
- The member must be using concurrently with mycophenolate and a systemic corticosteroid for 3 months, as evidenced by paid claims or pharmacy printouts.

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)
oxybutynin ER	MYRBETRIQ (mirabegron)	darifenacin ER
oxybutynin tablet	tolterodine	DETROL (tolterodine)
solifenacin	tolterodine ER	DETROL LA (tolterodine)

tamsulosin		DITROPAN XL (oxybutynin)
TOVIAZ (fesoterodine) – *Brand Required*		dutasteride/tamsulosin
trospium		fesoterodine
		flavoxate
		FLOMAX (tamsulosin)
		GEMTESA (vibegron)
		JALYN (dutasteride/tamsulosin)
		trospium ER
		VESICARE (solifenacin)

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: A total of 30 days of a preferred agent at max dose must be paid within 100 days prior to step 1 agents date of service.

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. Click here for a full listing of medications included.
  - The effects of an anticholinergic (blocks the effect of acetylcholine) and acetylcholinesterase inhibitors (prevents breakdown of acetylcholine) oppose each other, and the therapeutic effect of both products is diminished.

Phosphate Binders

Solid Dosage Form

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
calcium acetate	AURYXIA (ferric citrate) TABLET
sevelamer carbonate tablet	RENAGEL (sevelamer HCl) TABLET
	RENVELA (sevelamer carbonate) TABLET
	sevelamer HCl
	VELPHORO (sucroferric oxyhydroxide)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- If member is on renal dialysis, Medicare eligibility must be ruled out *(6-month approval may be allowed to determine eligibility)*.
- The member must have failed a 30-day trial of sevelamer carbonate, as evidenced by paid claims or pharmacy printouts.

Non-Solid Dosage Form

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
FOSRENOL (lanthanum) CHEWABLE TABLET – *Brand Required*	FOSRENOL (lanthanum) POWDER PACK
PHOSLYRA (calcium acetate) ORAL SOLUTION	lanthanum chew tab
RENVELA (sevelamer carbonate) POWDER PACK – *Brand Required*	sevelamer carbonate powder pack

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- If member is on renal dialysis, Medicare eligibility must be ruled out *(6-month approval may be allowed to determine eligibility).*
- Must meet Preferred Dosage Forms criteria
- Must meet Non-Solid Dosage Forms criteria

Neurology

Alzheimer's Disease

Cholinesterase Inhibitors

Solid Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
donepezil 5 mg, 10 mg tablet	ARICEPT (donepezil)
galantamine tablet	donepezil 23 mg tablet
galantamine ER	donepezil ODT
rivastigmine capsule	RAZADYNE (galantamine)
	RAZADYNE ER (galantamine)

Non-Solid Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
EXELON (rivastigmine) PATCH – *Brand Required*	ADLARITY (donepezil) PATCH
	galantamine oral solution
	rivastigmine patch

NMDA Receptor Antagonists

Solid Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
memantine	NAMENDA (memantine)

Non-Solid Dosage Forms

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
memantine ER capsule sprinkle	memantine oral solution
	NAMENDA XR (memantine) CAPSULE SPRINKLE

Cholinesterase Inhibitors / NMDA Receptor Antagonist Combinations

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	NAMZARIC (memantine/donepezil)

Therapeutic Duplication

- One memantine medication is allowed at a time
- Anticholinergic medications are not covered with acetylcholinesterase inhibitors (donepezil, rivastigmine, galantamine, pyridostigmine). Click here for a full listing of medications included.
  - The effects of an anticholinergic (blocks the effect of acetylcholine) and acetylcholinesterase inhibitors (prevents breakdown of acetylcholine) oppose each other, and the therapeutic effect of both products is diminished

Electronic Diagnosis Verification

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

Electronic Age Verification

- Submit chart notes to verify diagnosis for members less than 30 years old

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must have failed a 30-day trial of a pharmaceutically equivalent preferred agent, as evidenced by paid claims or pharmacy printouts.
- The member must not reside in facility where medications are managed such as skilled nursing care.
- Donepezil 23 mg: Clinical justification must be provided explaining why the member is unable to use the preferred products (subject to clinical review).
- Memantine ER capsule sprinkle: Must meet Non-Solid Dosage Forms criteria

Amyloid Beta-Directed Monoclonal Antibody

CLINICAL PA REQUIRED
ADUHELM (aducanumab-avwa) – *Medical Billing Only*

LEQEMBI (lecanemab-irmb) – *Medical Billing Only*

Prior Authorization Criteria

Initial Criteria – Approval Duration: Length of Clinical Trial (Aduhelm); 1 year (Leqembi)

Aduhelm Only:
- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The member must be participating in a National Institutes of Health (NIH) approved trial.

Leqembi Only:
- The member must have been diagnosed with mild cognitive impairment or mild Alzheimer's disease dementia, with documented evidence of beta-amyloid plaque on the brain.
- The member has a physician who participates in a qualifying registry with an appropriate clinical team and follow-up care.

Amyotrophic Lateral Sclerosis (ALS)

PREFERRED AGENTS (NO PA REQUIRED)	PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
riluzole tablet	EXSERVAN (riluzole) FILM	RILUTEK (riluzole) TABLET
	QALSODY (tofersen) – *Medical Billing Only*	
	RADICAVA (edaravone) – *Medical Billing Only*	
	RADICAVA ORS (edaravone)	
	RELYVRIO (sodium phenylbutyrate/taurursodiol) ORAL POWDER FOR SUSPENSION	
	TIGLUTIK (riluzole) ORAL SUSPENSION	

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months
Exservan and Tiglutik Only: Must meet Non-Solid Dosage Forms criteria

Qalsody and Relyvrio 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 neurologist.
- The member has had ALS symptoms present for less than 2 years.
- Documentation has been submitted that the member has a forced vital capacity (FVC) > 80 percent of predicted.
- Documentation of one of the following has been submitted:
  - ALS Function Rating Scale-Revised (ALSFRS-R) with a score of 2 or greater on each individual item of the scale
  - Japanese ALS Severity Scale with a grade of 1 or 2
- The member must not have permanent invasive ventilation.

Renewal Criteria – Approval Duration: 12 months
- Documentation of Forced Vital Capacity (FVC) > 60 percent of predicted

- Documentation of a therapeutic response as evidenced by stabilization or improvement (e.g., improved neurologic impairment, motor function, quality of life, slowing of disease progression, etc.) from baseline as evidenced by one of the following:
  - ALS Function Rating Scale-Revised (ALSFRS-R)
  - Japanese ALS Severity Scale

Anticonvulsants

Anticonvulsant Prevention

Narrow Spectrum:

Carbamazepine

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
carbamazepine chewable tablet	carbamazepine ER capsule
carbamazepine oral suspension	carbamazepine XR tablet
carbamazepine tablet	EPITOL (carbamazepine)
CARBATROL (carbamazepine) – *Brand Required*	TEGRETOL (carbamazepine oral suspension)
EQUETRO (carbamazepine)	TEGRETOL (carbamazepine)
TEGRETOL XR (carbamazepine) – *Brand Required*	

Ethosuximide

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ethosuximide capsule	ZARONTIN (ethosuximide)
ethosuximide oral solution	ZARONTIN (ethosuximide) ORAL SOLUTION

Gabapentin

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
gabapentin capsule	NEURONTIN (gabapentin) CAPSULE
gabapentin oral solution	NEURONTIN (gabapentin) ORAL SOLUTION
gabapentin tablet	NEURONTIN (gabapentin) TABLET

Lacosamine

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
lacosamide oral solution	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 tablet	oxcarbazepine oral solution
OXTELLAR XR (oxcarbazepine)	TRILEPTAL (oxcarbazepine)
TRILEPTAL (oxcarbazepine) ORAL SUSPENSION – Brand Required	

Pregabalin

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
pregabalin	LYRICA (pregabalin)
pregabalin oral solution	LYRICA (pregabalin) ORAL SOLUTION

	LYRICA CR (pregabalin)
	pregabalin ER

Phenytoin

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
phenytoin chewable tablet	DILANTIN (phenytoin) CHEWABLE TABLET
phenytoin 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)
GABITRIL (tiagabine) – *Brand Required*	tiagabine

Vigabatrin

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
SABRIL (vigabatrin) TABLET – *Brand Required*	SABRIL (vigabatrin) POWDER PACK
vigabatrin powder pack	vigabatrin tablet
	VIGADRONE (vigabatrin)

Other

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
APTIOM (eslicarbazepine)	methsuximide
CELONTIN (methsuximide) – *Brand Name Required*	
DIACOMIT (stiripentol)	
EPIDIOLEX (cannabidiol)	
FINTEPLA (fenfluramine) ORAL SOLUTION	
phenobarbital elixir	
phenobarbital tablet	
XCOPRI (cenobamate)	
ZTALMY (ganaxolone) SUSPENSION	

Electronic Diagnosis Verification

- Pharmacy must submit prescriber supplied diagnosis with the claim at point of sale for Diacomit, Epidiolex, and Fentepla

Electronic Concurrent Medications Required

- A total of 28 days of clobazam must be paid within 45 days prior to Diacomit.
  - Diacomit is FDA approved to be used in combination with clobazam.

Quantity Limit Override

- Gabapentin: 1800 mg max dose per day

Please call for an override by calling provider relations at 1-800-755-2604 if dose exceeds 1800 mg per day and the indication is adjuvant seizure (if monotherapy, please send chart notes to verify indication)

Prior Authorization Criteria:

- See Preferred Dosage Form Criteria

Therapeutic Duplication

- One Vimpat strength is allowed at a time
- Lyrica and gabapentin are not allowed together.
- Lyrica and gabapentin oral solutions are not allowed with benzodiazepines, muscle relaxants (except baclofen), or narcotic solid dosage forms. If a member can swallow, they should be transitioned to a solid dosage form.

  Please call for an override by calling provider relations at 1-800-755-2604 if the member's medications are dispensed in solid formulations are being crushed or opened to administer because member is unable to swallow

Broad Spectrum:

Clobazam

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
clobazam	ONFI (clobazam)
clobazam oral solution	ONFI (clobazam) ORAL SOLUTION
	SYMPAZAN (clobazam) FILM

Divalproex/Valproic Acid

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
DEPAKOTE SPRINKLE (divalproex sodium) – *Brand Co-Preferred*	DEPAKENE (valproic acid) CAPSULE
divalproex sodium ER	DEPAKENE (valproic acid) ORAL SOLUTION
divalproex sodium sprinkle	DEPAKOTE (divalproex sodium) TABLET
divalproex sodium tablet	DEPAKOTE ER (divalproex sodium)
valproic acid capsule	
valproic acid oral solution	

Felbamate

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
FELBATOL (felbamate) ORAL SUSPENSION – *Brand Required*	felbamate oral suspension
FELBATOL (felbamate) TABLET– *Brand Required*	felbamate tablet

Lamotrigine

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
lamotrigine chewable tablet	LAMICTAL (lamotrigine) CHEWABLE TABLET
lamotrigine ER	LAMICTAL (lamotrigine) DOSE PACK
lamotrigine ODT	LAMICTAL (lamotrigine) TABLET
lamotrigine ODT dose pack	lamotrigine dose pack
lamotrigine tablet	LAMICTAL ODT (lamotrigine)
SUBVENITE (lamotrigine)	LAMICTAL ODT (lamotrigine) DOSE PACK

	LAMICTAL XR (lamotrigine)
	LAMICTAL XR (lamotrigine) DOSE PACK
	SUBVENITE (lamotrigine) DOSE PACK

Levetiracetam

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
levetiracetam ER	ELEPSIA XR (levetiracetam)
levetiracetam oral solution	KEPPRA (levetiracetam)
levetiracetam tablet	KEPPRA (levetiracetam) ORAL SOLUTION
	KEPPRA XR (levetiracetam)
	SPRITAM (levetiracetam) SUSPENSION

Rufinamide

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
BANZEL (rufinamide) ORAL SUSPENSION – *Brand Co-Preferred*	
BANZEL (rufinamide) TABLET – *Brand Co-Preferred*	
rufinamide suspension	
rufinamide tablet	

Topiramate

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
EPRONTIA (topiramate) SOLUTION	TOPAMAX (topiramate)
QUDEXY XR (topiramate) SPRINKLE CAPSULE – *Brand Required*	TOPAMAX (topiramate) SPRINKLE CAPSULE
topiramate sprinkle capsule	topiramate ER sprinkle cap
topiramate tablet	
TROKENDI XR (topiramate) – *Brand Required*	

Other

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
BRIVIACT (brivaracetam)	
FYCOMPA (perampanel)	
FYCOMPA (perampanel) ORAL SUSPENSION	
zonisamide	

Anticonvulsant Rescue Therapies

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
diazepam pediatric rectal gel	
diazepam rectal gel	
NAYZILAM (midazolam) NASAL SPRAY	
VALTOCO (diazepam) NASAL SPRAY	

Electronic Duration Verification

- 4 doses are covered every 60 days without an override

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

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

Prior Authorization Criteria:

- See Preferred Dosage Form Criteria

Duchenne Muscular Dystrophy

Corticosteroids

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
prednisone	EMFLAZA (deflazacort)

High-Cost Drug:
Emflaza costs $92,000 per year for a 30 kg child.
In the FOR-DMD trial:

- Slowing of growth was greater with daily deflazacort compared with daily prednisone. The difference in height at three years for daily prednisone compared with daily deflazacort was 2.3 cm (98.3% CI 0.7-3.9 cm)
- Weight gain was greater with daily prednisone compared with daily deflazacort. The difference in weight gain for daily prednisone compared with daily deflazacort was 2.6 kg (98.3% CI 0.2-5.0 kg)

Prior Authorization Criteria

Prior Authorization Form – Emflaza

Initial Criteria – Approval Duration: 6 months

- Diagnosis must be confirmed by the documented presence of abnormal dystrophin or a confirmed mutation of the dystrophin gene
- The requested medication must be prescribed by, or in consult with, a physician who specializes in the treatment of Duchenne Muscular Dystrophy (DMD) and/or neuromuscular disorders
- Onset of weakness must have occurred before 2 years of age
- The member must have serum creatinine kinase activity of at least 10 times the upper limit of normal (ULN) prior to initiating treatment
- The member must have failed a 6-month trial of prednisone, as evidenced by paid claims or pharmacy printouts
- The provider must submit baseline motor milestone score results from at least ONE the following assessments:
  i. 6-minute walk test (6MWT)
  ii. North Star Ambulatory Assessment (NSAA)
  iii. Motor Function Measure (MFM)
  iv. Hammersmith Functional Motor Scale (HFMS)
- The member must have ONE of the following significant intolerable adverse effects supported by documentation:
  i. Cushingoid appearance
  ii. Central (truncal) obesity
  iii. Undesirable weight gain (>10% of body weight gain increase over 6-month period)
  iv. Diabetes and/or hypertension that is difficult to manage
  v. Severe behavioral adverse effect

Renewal Criteria – Approval Duration: 12 months

- The member must have improvement in motor milestone score from baseline from ONE the following assessments:
    i. 6MWT – improvement of 20 meters from baseline
    ii. NSAA – improvement of 2 points from baseline
    iii. MFM – improvement of 2 points from baseline
    iv. HFMS – improvement of 2 points from baseline
- The member must have had improvement of adverse effects experienced on prednisone supported by documentation:
    i. Cushingoid appearance
    ii. Central (truncal) obesity
    iii. Undesirable weight gain (>10% of body weight gain increase over 6-month period)
    iv. Diabetes and/or hypertension that is difficult to manage
    v. Severe behavioral adverse effect

Genetic Therapies

Exon 45 Skipping

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AMONDYS 45 (casimersen) – *Medical Billing Only*	

Exon 51 Skipping

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

Exon 53 Skipping

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

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

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

Prior Authorization Criteria

Initial Criteria – Approval Duration: 8 weeks

- The member must be assigned male at birth between ages of 4 and 19 years old

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

Non-Preferred Agent Criteria (Initial)
- Please provide explanation with the request why the preferred agent cannot be used (subject to clinical review)

Renewal Criteria – Approval Duration: 12 months
- Medical records must be provided confirming the member has maintained:
  - A 6MWT ≥ 300 meters while walking independently (e.g., without side-by-side assist, cane, walker, wheelchair, etc.)
  - Stable respiratory function – FVC predicted > 50%, not requiring ventilatory assistance
  - Stable cardiac function – LVEF > 40 % by ECHO

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)	LUMRYZ (sodium oxybate)
modafinil	XYREM (sodium oxybate) *– Brand Required*	NUVIGIL (armodafinil)
		PROVIGIL (modafinil)
		sodium oxybate
		WAKIX (pitolisant)
		XYWAV (sodium, calcium, magnesium, potassium oxybate)

Electronic Step Therapy Required

- Sunosi and Xyrem requires a 30-day trial of armodafinil to be paid within 60 days of submitted claim.
- Wakix requires titration to 17.8 mg dose with 4.45 mg tablets.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must have failed 30-day trials of each preferred agent (except Sunosi for idiopathic hypersomnia) and at least 1 additional CNS stimulant indicated for treatment of narcolepsy, as evidenced by paid claims or pharmacy printouts
- Documentation of each treatment failure must be provided, as evidenced by one of the following:
  - Multiple Sleep Latency Test (MSLT) <8 minutes
  - EPWORTH sleepiness scale score ≥10
- Lumryz Only:
  - The member must have failed a 30-day trial with Wakix
  - See Preferred Dosage Form criteria
- 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.
- Lumryz, Xyrem, Xywav are not allowed with each other, sleeping medication or benzodiazepines.

Underutilization

- Lumryz, Wakix, Sunosi, and Xywav must be used adherently and will reject on point of sale for late fill.

Migraine

Prophylaxis of Migraine

Calcitonin Gene-Related Peptide (CGRP) Receptor Antagonist

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

Prior Authorization Criteria

Prior Authorization Form – Migraine Prophylaxis/Treatment

Initial Criteria – Approval Duration: 6 months

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

Non-Preferred Agents Criteria:

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

Renewal Criteria – Approval Duration: 12 months

- The member must have experienced at least a 50% reduction in migraine frequency, pain intensity, or duration from baseline.

Treatment of Migraine

Calcitonin Gene-Related Peptide (CGRP) Receptor Antagonist

Therapeutic Duplication

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

Oral

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
NURTEC ODT (rimegepant)	UBRELVY (ubrogepant)

Prior Authorization Criteria

Prior Authorization Form – Migraine Prophylaxis/Treatment

Initial Criteria – Approval Duration: 3 months

- The member must have failed a 30-day trial of two triptans (5HT-1 Agonists) of unique ingredients, as evidenced by paid claims or pharmacy printouts.

Non-Preferred Agents Criteria:

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

Nasal

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	ZAVZPRET NASAL SPRAY (zavegepant)

Prior Authorization Criteria

Prior Authorization Form – Migraine Prophylaxis/Treatment

Initial Criteria – Approval Duration: 3 months

Non-Preferred Agents Criteria:

- The member must have failed a 30-day trial of two triptans (5HT-1 Agonists) of unique ingredients, as evidenced by paid claims or pharmacy printouts.
- The member must have failed a 30-day trial of the oral CGRP agents, as evidenced by paid claims or pharmacy printouts.
- Clinical justification must be provided explaining why the member is unable to use the preferred agents (subject to clinical review).

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 a treatment CGRP receptor agonist, as evidenced by paid claims or pharmacy printouts.

Therapeutic Duplication

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

Therapeutic Duplication

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

Ergot Alkaloids

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	D.H.E.45 (dihydroergotamine) INJECTION
	dihydroergotamine injection
	dihydroergotamine nasal spray
	ERGOMAR (ergotamine) SL TABLET
	MIGERGOT (ergotamine/caffeine) RECTAL SUPPOSITORY
	TRUDHESA (dihydroergotamine)

Prior Authorization Criteria

Prior Authorization Form – Migraine Prophylaxis/Treatment

Initial Criteria – Approval Duration: 3 months
- The member must have failed a 30-day trial of two triptans (5HT-1 Agonists) of unique ingredients, as evidenced by paid claims or pharmacy printouts.
- The member must have failed a 30-day trial of a treatment CGRP receptor agonist, as evidenced by paid claims or pharmacy printouts.

Therapeutic Duplication

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

Triptans (5HT-1 Agonists)

Solid Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED STEP 1 AGENTS (PA REQUIRED)	NON-PREFERRED STEP 2 AGENTS (PA REQUIRED)
RELPAX (eletriptan) – *Brand Required*	FROVA (frovatriptan) TABLET – *Brand Required*	almotriptan tablet
rizatriptan tablet	naratriptan tablet	AMERGE (naratriptan) TABLET
sumatriptan tablet	zolmitriptan tablet	eletriptan tablet
		frovatriptan tablet
		IMITREX (sumatriptan) TABLET
		MAXALT (rizatriptan) TABLET
		sumatriptan/naproxen tablet
		TREXIMET (sumatriptan/naproxen) TABLET
		ZOMIG (zolmitriptan) TABLET

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

Non-Preferred Step 1 Agents:

- The member must have failed a 30-day trial of rizatriptan, as evidenced by paid claims or pharmacy printouts.
- Members over 18 years old: The member must also have failed a 30-day trial of eletriptan, as evidenced by paid claims or pharmacy printouts.

Non-Preferred Step 2 Agents:

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

Therapeutic Duplication

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

Non-Solid Oral Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
rizatriptan ODT	MAXALT MLT (rizatriptan)
	zolmitriptan ODT

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

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

Therapeutic Duplication

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

Nasal Spray

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
IMITREX (sumatriptan) NASAL SPRAY – *Brand Required*	ONZETRA XSAIL (sumatriptan) NASAL SPRAY
ZOMIG (zolmitriptan) NASAL SPRAY – *Brand Required*	sumatriptan spray
	TOSYMRA (sumatriptan) NASAL SPRAY
	zolmitriptan spray

Injectable

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
IMITREX (sumatriptan) 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

- The member must be unable to take oral medications (subject to clinical review).
- The member must have had a 30-day trial of a preferred injectable and preferred nasal spray, as evidenced by paid claims and pharmacy printouts.

Therapeutic Duplication

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

Cluster Headache

Cluster Headache Prevention

CLINICAL PA REQUIRED
EMGALITY (galcanazumab-gnlm)

- Emgality is to be used as preventative treatment during episodic cluster headache episodes (cluster periods usually last between 2 weeks and 3 months with pain-free periods lasting at least 3 months), as it is not indicated for chronic use

Prior Authorization Criteria

Prior Authorization Form – Migraine Prophylaxis/Treatment

Initial Criteria – Approval Duration: 3 months

- The member has had at least five attacks fulfilling criteria A-C
  - *A.* Severe or very severe unilateral orbital, supraorbital and/or temporal pain lasting at least 15 minutes
  - *B.* Occurring with a frequency of at least every other day
  - *C.* The member must have at least one of the following:
    - A sense of restlessness or agitation
    - Any of the following symptoms or signs, ipsilateral to the headache:

- Conjunctival injection and/or lacrimation
- Nasal congestion and/or rhinorrhea
- Eyelid edema
- Forehead and facial swelling
- Miosis and/or ptosis

- The member must have had a 2-month trial with verapamil.

Myasthenia Gravis

Glucocorticoid-Sparing Therapy

Oral Agents

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

Biologic Agents

Acetylcholine Receptor (AChR) Antibody Positive

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

Muscle Specific Kinase (MuSK) Positive

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

Prior Authorization Criteria

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

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational).
- The requested medication must be prescribed by, or in consult with, a neurologist or neuromuscular specialist.
- The following documentation must be submitted:
  - The member has a 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

- One of the following (A or B):
  A. The member has a Myasthenia Gravis-specific Activities of Daily Living (MG-ADL) total score ≥ 3 from non-ocular symptoms.
  B. Documented baseline Quantitative Myasthenia Gravis (QMG) score ≥ 12

Acetylcholine Receptor (AChR) Antibody Positive

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

Muscle Specific Kinase (MuSK) Positive

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

Soliris Only:

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

Renewal Criteria – Approval Duration: 12 months

- The member must have experienced meaningful clinical benefit since starting treatment with the requested medication, as evidenced by medical documentation (e.g., chart notes) attached to the request (subject to clinical review) including one of the following scores and symptoms:
  - Decreased rate of Myasthenia Gravis exacerbations
  - A 2-point improvement in the member's total MG-ADL score
  - A 3-point improvement in QMG total score

Multiple Sclerosis

Injectable Agents

B-cell and T-cell Therapies

PREFERRED AGENTS (NO PA REQUIRED)	PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
BRIUMVI (ublituximab-xiiy) *– Medical Billing Only*	TYSABRI (natalizumab) *– Medical Billing Only*	MAVENCLAD (cladribine)
KESIMPTA (ofatumumab)		LEMTRADA (alemtuzumab) *– Medical Billing Only*
OCREVUS (ocrelizumab) *– Medical Billing Only*		

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months
Tysabri Only:
- The requested medication must be prescribed by, or in consult with, a neurologist

Non-Preferred Agents:
- The member must have failed a 3-month trial of two agents in the class of the requested product, as evidenced by paid claims or pharmacy print outs.

Interferons

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AVONEX (interferon beta-1A) PEN	BETASERON (interferon beta-1B)
AVONEX (interferon beta-1A) SYRINGE	EXTAVIA (interferon beta-1B)
AVONEX (interferon beta-1A) VIAL	PLEGRIDY (peginterferon beta-1A) PEN
	PLEGRIDY (peginterferon beta-1A) SYRINGE
	REBIF (interferon beta-1A)
	REBIF REBIDOSE (interferon beta-1A)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months
- The member must have failed a 3-month trial of the preferred agent in the class of the requested product, as evidenced by paid claims or pharmacy print outs.

Non-Interferons

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
COPAXONE (glatiramer) 20 MG/ML – *Brand Required*	COPAXONE (glatiramer) 40 MG/ML
	glatiramer 20 mg/ml
	glatiramer 40 mg/ml
	GLATOPA (glatiramer)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months
- Copaxone: See Preferred Dosage Form criteria

Oral Agents

Fumerates

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
dimethyl fumarate	BAFIERTAM (monomethyl fumarate)
	TECFIDERA (dimethyl fumarate)
	VUMERITY (diroximel fumarate)

Pyrimidine Synthesis Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
teriflunomide	AUBAGIO (teriflunomide)

Sphingosine 1-Phosphate (S1P) Receptor Modulators

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
GILENYA (fingolimod) – *Brand Required*	fingolimod
TASCENSO ODT (fingolimod)	MAYZENT (siponimod)
	PONVORY (ponesimod)
	ZEPOSIA (ozanimod)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must have failed a 3-month trial of 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)
ENSPRING (satralizumab-mwge)	SOLIRIS (eculizumab) – *Medical Billing Only*
UPLIZNA (inebilizumab) – *Medical Billing Only*	

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational).
- The requested medication must be prescribed by, or in consult with, a neurologist
- The member has positive serologic test for anti-AQP4 antibodies.
- The member has a history of ≥ 1 relapses that required rescue therapy within the past 12 months
- The member has an Expanded Disability Status Score (EDSS) of ≤ 6.5
- The member must have one of the core clinical characteristics from the following:
  - Optic neuritis
  - Acute myelitis
  - Area postrema syndrome: episode of otherwise unexplained hiccups or nausea and vomiting
  - Acute brainstem syndrome
  - Symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions
  - Symptomatic cerebral syndrome with NMOSD-typical brain lesions

Non-Preferred Agents Criteria

- The member must have had a 3-month trial with Enspryng and Uplizna, as evidenced by paid claims or pharmacy print outs:

Renewal Criteria – Approval Duration: 12 months

- The member must have experienced stabilization, slowing of disease progression, or improvement of the condition since starting treatment with the requested medication, as evidenced by medical documentation (e.g., chart notes) attached to the request (subject to clinical review) including:
  - Reduction in relapse rate
  - Reduction in symptoms (such as pain, fatigue, motor function)

Pseudobulbar Affect (PBA)

CLINICAL PA REQUIRED
NUEDEXTA (dextromethorphan/quinidine)

Prior Authorization Criteria

Prior Authorization Form – Nuedexta

Initial Criteria – Approval Duration: 3 months

- The member must not have a diagnosis of any of the following: prolonged QT interval, heart failure, or complete atrioventricular (AV) block.
- Documentation of the following must be provided:
    - Baseline Center for Neurological Studies lability (CNS-LS) score
    - Baseline weekly PBA episode count
- The member must have diagnosis of pseudobulbar affect (PBA) due to one of the following neurologic conditions and meet additional criteria for diagnosis:
    - Amytrophic Lateral Sclerosis (ALS)
    - Multiple Sclerosis (MS)
    - Alzheimer's Disease
    - Stroke
    - For diagnosis of PBA due to Alzheimer's disease or stroke only:
        - Neurologic condition must have been stable for at least 3 months
        - Member must have failed a 3-month trial of at least one medication from each of the following classes, as evidenced by paid claims or pharmacy print outs:
            - SSRIs: sertraline, fluoxetine, citalopram and paroxetine
            - Tricyclic Antidepressants: nortriptyline and amitriptyline
        - Documentation of each treatment failure of SSRI and tricyclic antidepressant must be provided, as evidenced by a PBA episode count and CNS-LS score before and after each trial showing one of the following:
            - PBA count has not decreased by more than 75 percent from baseline
            - CHS-LS score has not decreased by more than 7 points from baseline

Renewal Criteria – Approval Duration: 6 months

- Benefit of continued therapy must be assessed.
    - Spontaneous improvement of PBA occurs and should be ruled out periodically before continuing medication.
- Baseline and current PBA episode count must be included with request
    - Current PBA episode must be reduced by at least 75% from baseline
- For diagnosis of PBA due to Alzheimer's disease or stroke only:
    - Baseline and current Center for Neurological Studies lability (CNS-LS) must be included with request
    - Current CNS-LS score must be reduced by at least 30% from baseline

Parkinson's disease

Parkinson's Agents – Adenosine Receptor Agonist

CLINICAL PA REQUIRED
NOURIANZ (Istradefylline)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The requested medication must be prescribed by, or in consult with, a neurologist
- Documentation must be provided describing deterioration in quality of response to levodopa/carbidopa therapy, including currently experiencing intermittent hypomobility, or "off" episodes (number and frequency)
- The member must have had inadequate response to rasagiline and selegiline, as evidenced by paid claims or pharmacy printouts

Parkinson's Agents – Anticholinergics

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
benztropine	COGENTIN (benztropine)
trihexyphenidyl	

Parkinson's Agents – COMT inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
entacapone	COMTAN (entacapone)
TASMAR (tolcapone) – *Brand Required*	ONGENTYS (opicapone)
	tolcapone

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

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

Parkinson's Agents – Dopamine Precursor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
carbidopa-levodopa-entacapone 25 mg/100 mg, 37.5 mg/150 mg, 50 mg/200 mg	carbidopa-levodopa-entacapone 12.5 mg/50 mg, 18.75 mg/75 mg, 31.25 mg/125 mg
carbidopa-levodopa	DHIVY (carbidopa/levodopa)
carbidopa-levodopa ER	SINEMET (carbidopa-levodopa) TABLET
carbidopa-levodopa ODT	STALEVO (carbidopa-levodopa-entacapone)
RYTARY (carbidopa-levodopa) ER CAPSULE	

Prior Authorization Criteria

- See Preferred Dosage Form criteria

Parkinson's Agents – Dopaminergic Agents for Intermittent Treatment of Off Episode

Subcutaneous

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
APOKYN (apomorphine) – *Brand Required*	apomorphine

Enteral Suspension

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
DUOPA (levodopa/carbidopa)	

Inhalation

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

Sublingual

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

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The requested medication must be prescribed by, or in consult with, a neurologist
- The member must be currently taking carbidopa – levodopa, as evidenced by paid claims or pharmacy printouts, and will continue taking carbidopa – levodopa concurrently with requested agent
- Documentation must be provided of intermittent hypomobility or off episodes (number and frequency)
- At least one of the following criteria must be met:
  - The member is experiencing unpredictable off periods, morning off, delayed on, no on or failure of on response
  - The member is experiencing wearing off episodes or other levodopa dose cycle related dystonias or akathisias, and a treatment adjustment plan is attached (e.g., levodopa dose and interval adjustments, bedtime dose of CR or ER levodopa/ carbidopa, addition of adjunctive therapy)

Parkinson's Agents – Ergot Dopamine Receptor Agonists

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
bromocriptine	PARLODEL (bromocriptine)
cabergoline	

Parkinson's Agents – MAO-B Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
rasagiline	AZILECT (rasagiline)
selegiline	EMSAM (selegiline) PATCH
ZALAPAR ODT (selegiline)	XADAGO (safinamide)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must have failed a 30-day trial of selegiline, as evidenced by paid claims or pharmacy printouts
- Xadago Only:
  - The requested medication must be prescribed by, or in consult with, a psychiatrist or neurologist
  - The member must be currently experiencing intermittent hypomobility or "off" episodes
  - The member must be currently taking an extended-release formulation of carbidopa – levodopa, as evidenced by paid claims or pharmacy printouts, and will continue taking carbidopa – levodopa concurrently with requested agent
  - The member must be exhibiting deterioration in quality of response to during levodopa/carbidopa therapy for intermittent hypomobility, or "off" episodes
  - The member must have failed a 30-day trial of rasagiline and selegiline, as evidenced by paid claims or pharmacy printouts

Parkinson's Agents – Non-ergot Dopamine Receptor Agonists Maintenance

Oral

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
pramipexole IR	MIRAPEX (pramipexole)
ropinirole IR	MIRAPEX ER (pramipexole)
ropinirole ER	pramipexole ER
	REQUIP (ropinirole)

Topical

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	NEUPRO (rotigotine) PATCH

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must not reside in facility where medications are managed such as skilled nursing care.
- Clinical justification must be provided explaining why the member is unable to use the preferred agents (subject to clinical review).
- Pramipexole ER: See Preferred Dosage Form Criteria

Parkinson's Agents – Other

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
amantadine IR capsule	amantadine IR tablet
amantadine solution	GOCOVRI (amantadine ER)
	OSMOLEX ER (amantadine ER)

Electronic Age Verification:

- Amantadine: Member must be 18 years old or older

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must not reside in facility where medications are managed such as skilled nursing care.
- See Preferred Dosage Form Criteria

Spinal Muscular Atrophy (SMA)

SMN2 Gene Splicing Modifiers

CLINICAL PA REQUIRED
EVRYSDI (risdiplam)
SPINRAZA (nusinersen) – *Medical Billing Only*

Prior Authorization Criteria

Prior Authorization Form – Evrysdi

Initial Criteria – Approval Duration: 12 months

- The member must have a diagnosis of spinal muscular atrophy (SMA) with each of the following (as evidenced with submitted documentation):
  - Bi-allelic deletions or mutations of SMN1 as confirmed by genetic testing, reported as one of the following:
    - Homozygous deletions of exon 7
    - Compound heterozygous mutations
  - One of the following:
    - The member has number of SMN2 gene copies ≥ 1 but ≤ 4 as confirmed by genetic testing
    - The member is symptomatic (e.g., loss of reflexes, motor delay, motor weakness, abnormal EMG/neuromuscular ultrasound)

- The requested medication must be prescribed by, or in consult with, a neuromuscular neurologist or neuromuscular physiatrist
- The member must visit with a neuromuscular clinic once per year and clinic name, contact information, and date of last visit must be provided
- The member must not require continuous intubation > 3 weeks
- The member must not have received gene therapy (i.e., Zolgensma)
- The member's weight and prescribed dose must be provided and within dosing recommendations per the manufacturer label
- Documentation must be provided of the member's current motor function, as evidenced by scores from at least two of the following assessments
  - Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorder (CHOP-INTEND)
  - Hammersmith Infant Neurological Examination (HINE) Section 2 motor milestone score
  - Hammersmith Functional Motor Scale Expanded (HFMSE)
  - Motor Function Measure – 32 items (MFM-32)
  - Revised Upper Limb Module (RULM)
  - 6-minute walk test (6MWT)
  - Forced Vital Capacity (FVC) via Pulmonary Function Test
- Spinraza Only: The member must not have severe contractures or severe scoliosis

Renewal Criteria – Approval Duration: 12 months

- The member's weight and prescribed dose must be provided and within dosing recommendations per the manufacturer label
- The member must visit with a neuromuscular clinic once per year and clinic name, contact information, and date of last visit must be provided
- The provider must submit documentation showing that the member has experienced clinical benefit (defined as maintenance of baseline motor function or significant slowed rate of decline vs expected natural course of the disease) since starting treatment, as evidenced by documentation of one of the following:
  - Current Forced Vital capacity (FVC and FEV1) via Pulmonary Function Test
  - CHOP-INTEND, HINE, HFMSE, MFM-32, 6MWT, or RULM scores

Gene Therapy

CLINICAL PA REQUIRED
ZOLGENSMA (onasemnogene abeparvovec) – *Medical Billing Only*

Prior Authorization Criteria

Initial Criteria – Approval Duration: 1 month (Approval is limited to a single intravenous infusion per lifetime)

- The member is less than 2 years of age
- The diagnosis is spinal muscular atrophy (SMA) with genetic testing confirming bi-allelic deletions or mutations in the *SMN1 gene*
- The medication is prescribed per the dosing guidelines in the package insert (recommended dose is 1.1 x 10^{14} vector genomes per kilogram)
- Baseline Documentation has been provided confirming anti-adeno-associated virus serotype 9 (anti-AAV9) antibody titer is ≤ 1:50 measured by Enzyme-linked Immunosorbent Assay (ELISA) binding immunoassay
- Member must not have advanced SMA evidenced by one of the following
  - Complete paralysis of limbs
  - Permanent ventilator dependence (defined as requiring invasive ventilation (tracheostomy) or respiratory assistance for 16 of more hours per day (including noninvasive ventilatory support) continuously for 14 or more days in the absence of an acute reversible illness, excluding perioperative ventilation.

Tardive Dyskinesia

PREFERRED AGENTS (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 neurologist or psychiatrist.
- The member must have a history of treatment with dopamine receptor blocking agent (DRBA).
- The member must have symptom duration lasting longer than 4-8 weeks.

Ophthalmology

Antihistamines

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
azelastine	ALOCRIL (nedocromil)
BEPREVE (bepotastine) – *Brand Required*	ALOMIDE (lodoxamide)
cromolyn	bepotastine
olopatadine 0.1%	epinastine
PAZEO (olopatadine)	olopatadine 0.2%
	ZERVIATE (cetirizine)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months
- The member must have failed 30-day trials of olopatadine and bepotastine, as evidenced by paid claims or pharmacy printouts.

Anti-infectives

Drops

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
BESIVANCE (besifloxacin) DROPS	AZASITE (azithromycin) DROPS
ciprofloxacin drops	CILOXAN (ciprofloxacin) DROPS
gentamicin sulfate drops	gatifloxacin drops
moxifloxacin drops (generic Vigamox)	moxifloxacin drops (generic Moxeza)
neomycin SU/polymyxin B/gramicidin drops	NATACYN (natamycin) DROPS
ofloxacin drops	OCUFLOX (ofloxacin) DROPS
polymyxin B/trimethoprim drops	POLYTRIM (polymyxin B/trimethoprim) DROPS

sulfacetamide drops	VIGAMOX (moxifloxacin) DROPS
tobramycin drops	
ZYMAXID (gatifloxacin) DROPS – *Brand Required*	

Ointment

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
bacitracin/polymyxin B ointment	bacitracin ointment
CILOXAN (ciprofloxacin) OINTMENT	NEO-POLYCIN (neomycin SU/bacitracin/polymyxin B) OINTMENT
erythromycin ointment	POLYCIN (bacitracin/polymyxin B) OINTMENT
GENTAK (gentamicin sulfate) OINTMENT	sulfacetamide ointment
neomycin SU/bacitracin/polymyxin B ointment	
TOBREX (tobramycin) OINTMENT	

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must have failed a 5-day trial of a preferred agent in each unique therapeutic class, as evidenced by paid claims or pharmacy printouts.

Anti-infectives/Anti-inflammatories

Drops

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
neomycin/polymyxin b/dexamethasone drops	MAXITROL (neomycin/polymyxin b/dexamethasone) DROPS
sulfacetamide/prednisolone drops	neomycin/polymyxin b/hydrocortisone drops
tobramycin/dexamethasone drops	
TOBRADEX ST (tobramycin/dexamethasone) DROPS	
ZYLET (tobramycin/lotepred etab) DROPS	

Ointment

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
neomycin/polymyxin b/dexamethasone ointment	MAXITROL (neomycin/polymyxin b/dexamethasone) OINTMENT
TOBRADEX (tobramycin/dexamethasone) OINTMENT	neomycin/bacitracin/polymyxin b/hydrocortisone ointment
	NEO-POLYCIN HC (neomycin SU/bacitracin/ polymyxin B/hydrocortisone) OINTMENT

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must have failed a 5-day trial of a preferred agent in each unique therapeutic class, as evidenced by paid claims or pharmacy printouts.

Anti-inflammatories

Corticosteroids

Drops

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ALREX (loteprednol) DROPS	dexamethasone sodium phosphate drops
FLAREX (fluorometholone) DROPS	difluprednate drops
fluorometholone drops	DUREZOL (difluprednate) DROPS
FML FORTE (fluorometholone) DROPS	EYSUVIS (loteprednol) DROPS
LOTEMAX (loteprednol) DROPS – *Brand Required*	INVELTYS (loteprednol) DROPS
LOTEMAX (loteprednol) GEL DROPS – *Brand Required*	FML (fluorometholone) DROPS
MAXIDEX (dexamethasone) DROPS	LOTEMAX SM (loteprednol) DROPS
PRED MILD 0.12% (prednisolone acetate) DROPS	loteprednol eye drops
prednisolone acetate 1% drops	loteprednol gel eye drops
prednisolone sodium phosphate 1% drops	PRED FORTE 1% (prednisolone acetate) DROPS

Ointment

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
FML S.O.P. (fluorometholone) OINTMENT	
LOTEMAX (loteprednol) OINTMENT	

Non-Steroidal Anti-inflammatory Drugs (NSAIDS)

Drops

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ACUVAIL (ketorolac) DROPS	ACULAR (ketorolac) DROPS
diclofenac sodium drops	ACULAR LS (ketorolac) DROPS
ILEVRO (nepafenac) DROPS	bromfenac sodium drops
ketorolac tromethamine 0.4% drops	BROMSITE (bromfenac sodium) DROPS
ketorolac tromethamine 0.5% drops	
NEVANAC (nepafenac) DROPS	
PROLENSA (bromfenac) DROPS	

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must have failed a 5-day trial of each preferred agent in the respective therapeutic class, as evidenced by paid claims or pharmacy printouts.

Dry Eye Syndrome

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED STEP 2 AGENTS (PA REQUIRED)
RESTASIS (cyclosporine) DROPPERETTE – *Brand Required*	CEQUA (cyclosporine)
XIIDRA (lifitegrast)	cyclosporine dropperette

	MIEBO (perfluorohexyloctane)
	RESTASIS MULTIDOSE (cyclosporine)
	TYRVAYA (varenicline) NASAL SPRAY

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must have failed a 6-month trial of each of the preferred agents, as evidenced by paid claims or pharmacy printouts.
- Cyclosporine products: See Preferred Dosage Form criteria

Glaucoma

Alpha Adrenergic

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ALPHAGAN P 0.1% (brimonidine) DROPS – *Brand Required*	apraclonidine 0.5% drops
ALPHAGAN P 0.15% (brimonidine) DROPS – *Brand Required*	brimonidine 0.1% drops
brimonidine 0.2% drops	brimonidine 0.15% drops
COMBIGAN (brimonidine-timolol) DROPS – *Brand Required*	brimonidine-timolol 0.2%-0.5% drops
LUMIFY (brimonidine) 0.03% DROPS	IOPIDINE (apraclonidine) 1% DROPS
SIMBRINZA (brinzolamide/brimonidine) DROPS	

Beta Blockers

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
BETOPTIC S (betaxolol) 0.25% DROPS	betaxolol 0.5% drops
carteolol drops	BETIMOL (timolol) DROPS
COMBIGAN (brimonidine/timolol) DROPS – *Brand Name Required*	brimonidine/timolol drops
dorzolamide/timolol drops	COSOPT (dorzolamide/timolol) PF DROPS
ISTALOL (timolol maleate) DROPS ONCE DAILY – *Brand Required*	timolol drops once daily
levobunolol drops	timolol gel forming solution
timolol maleate drops	TIMOPTIC (timolol maleate) DROPS
timolol maleate/PF drops 0.5%	TIMOPTIC OCUDOSE 0.5% (timolol) PF DROPS
TIMOPTIC OCUDOSE 0.25% (timolol) PF DROPS	TIMOPTIC-XE (timolol gel forming solution)

Prior Authorization Criteria

- See Preferred Dosage Form criteria

Carbonic Anhydrase Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AZOPT (brinzolamide) – *Brand Required*	brinzolamide
dorzolamide	COSOPT (dorzolamide/timolol)
dorzolamide/timolol	TRUSOPT (dorzolamide)

SIMBRINZA (brinzolamide/brimonidine)	

Prostaglandins

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
latanoprost	bimatoprost 0.03%
LUMIGAN (bimatoprost) 0.01%	IYUZEH (latanoprost/pf)
ROCKLATAN (netarsudil/latanoprost)	tafluprost/pf
	TRAVATAN Z (travoprost)
	travoprost
	VYZULTA (latanoprostene)
	XALATAN (latanoprost)
	XELPROS (latanoprost)
	ZIOPTAN (tafluprost/pf)

Prior Authorization Criteria

- The member must have failed a 14-day trial of each of the preferred agents, as evidenced by paid claims or pharmacy printouts.

Rho Kinase Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
RHOPRESSA (netarsudil)	
ROCKLATAN (netarsudil/latanoprost)	

Presbyopia

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
pilocarpine	ISOPTO CARPINE (pilocarpine)
	VUITY (pilocarpine hydrochloride)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- See Preferred Dosage Form criteria
- The requested medication must be prescribed by, or in consult with, an optometrist or ophthalmologist.
- Documentation of medical necessity must be provided, including contraindication to the use of corrective lenses and how activities of daily living are adversely impacted due to inability to correct vision with corrective lenses.

Renewal Criteria – Approval Duration: 12 months

- Documentation must be provided including activities of daily living are positively impacted by drug therapy.

Inherited Retinal Dystrophy

CLINICAL PA REQUIRED
LUXTURNA (alglucosidase alfa) – *Medical Billing Only*

Prior Authorization Criteria

Initial Criteria – Approval Duration: Approval Duration: 1 month (once per lifetime per eye)

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational).
- The requested medication must be prescribed by, or in consult with, an ophthalmologist or retinal surgeon with experience providing subretinal injections
- The member must have a diagnosis of inherited retinal dystrophy (i.e., Leber's congenital amaurosis [LCA], retinitis pigmentosa [RP]); confirmed by biallelic pathogenic variants in the RPE65 gene by molecular genetic testing (as evidenced with submitted documentation)
- The member has sufficient viable retinal cells as measured by OCT (optical coherence tomography) defined as one of the following:
  - retinal thickness greater than 100 microns within the posterior pole
  - ≥ 3-disc areas of the retina without atrophy or pigmentary degeneration within the posterior pole
  - remaining visual field within 30 degrees of fixation as measured by a III4e isopter or equivalent
- The member has remaining light perception in the eye(s) that will receive treatment.
- The member has not previously received RPE65 gene therapy in intended eye.

Uveitis

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
HUMIRA (adalimumab)	adalimumab-adaz
	adalimumab-adbm
	adalimumab-fkjp
	AMJEVITA (adalimumab-atto)
	CYLTEZO (adalimumab-abdm)
	HADLIMA (adalimumab-bwwd)
	HULIO (adalimumab-fkjp)
	HYRIMOZ (adalimumab-adaz)
	IDACIO (adalimumab-aacf)
	YUFLYMA (adalimumab-aaty)
	YUSIMRY (adalimumab-aqvh)

Vernal Keratoconjunctivitis

CLINICAL PA REQUIRED
VERKAZIA (cyclosporine) 0.1%

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- The requested medication must be prescribed by, or in consult with, an allergist or ophthalmologist.
- The member has failed* a 3-month trial of combination of each of the following:
  - Topical dual-acting mast cell stabilizers/antihistamines (e.g., olopatadine, azelastine hydrochloride, epinastine, pemirolast potassium, or ketotifen fumarate)
  - Second- and third-generation oral antihistamines (e.g., fexofenadine, loratadine, desloratadine, cetirizine, or levocetirizine)
  - Cyclosporine ophthalmic emulsion 0.05%

*Failure is defined as requiring frequent or prolonged courses of topical ophthalmic corticosteroids include prednisone acetate 1% and dexamethasone 0.1% for severe cases and prednisolone acetate 0.12%, fluorometholone, medrysone, loteprednol, etabonate 0.2 or 0.5%, and rimexolone 1% or compromised corneal epithelium

Ophthalmology Injection- VEGF Inhibitor

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
BEOVU (brolucizumab-dbll) – *Medical Billing Only*	BYOOVIZ (ranibizumab -nuna) – *Medical Billing Only*
CIMERLI (ranibizumab-eqrn) – *Medical Billing Only*	LUCENTIS (ranibizumab) – *Medical Billing Only*
EYLEA (aflibercept) – *Medical Billing Only*	SUSVIMO (ranibizumab) – *Medical Billing Only*
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 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/fluocinolone
ciprofloxacin/dexamethasone otic drops	OTOVEL (ciprofloxacin/fluocinolone)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must have failed a 7-day trial of each of the preferred agent, as evidenced by paid claims or pharmacy printouts.

Pain

Lidocaine Patch

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
lidocaine 5% patch	LIDODERM (lidocaine) 5% PATCH
ZTLIDO (lidocaine) 1.8% PATCH	

Lidocaine Topical Cream

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The request must be for injection pain from a medically necessary procedure

NSAIDS

Oral Solid Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
celecoxib	ARTHROTEC (diclofenac/misoprostol)
diclofenac potassium 50 mg tablet	CELEBREX (celecoxib)
diclofenac sodium DR 50 mg, 75 mg	DAYPRO (oxaprozin)
etodolac	diclofenac potassium 25 mg tablet
flurbiprofen	diclofenac potassium 25 mg capsule
ibuprofen	diclofenac sodium 25 mg DR
indomethacin	diclofenac sodium 100 mg ER tablet
indomethacin ER	diclofenac/misoprostol
ketoprofen IR	DUEXIS (famotidine/ibuprofen)
ketorolac	etodolac ER
meclofenamate	famotidine/ibuprofen
mefenamic acid	FELDENE (piroxicam)
meloxicam	fenoprofen
nabumetone	INDOCIN (indomethacin)
naproxen	ketoprofen ER 200 mg
piroxicam	LOFENA (diclofenac potassium)
sulindac	meloxicam, submicronized
tolmetin	MOBIC (meloxicam)
VIMOVO (naproxen/esomeprazole) – *Brand Required*	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	INDOCIN (indomethacin) SOLUTION
naproxen suspension	

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

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

Nasal Dosage Forms

CLINICAL PA REQUIRED
ketorolac nasal spray

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)
FLECTOR (diclofenac) 1.3% PATCH – *Brand Required*	diclofenac 1.3% patch
PENNSAID (diclofenac) 2% PUMP – *Brand Required*	diclofenac 2% pump
	LICART (diclofenac) PATCH 1.3%

Prior Authorization Criteria

- See Preferred Dosage Form Criteria

Opioid Analgesics

Therapeutic Duplication

- One extended-release product/strength is allowed at a time
- One immediate release product is allowed (single ingredient or combination)
- Opioid-acetaminophen combination products are not allowed with acetaminophen
- Carisoprodol: The "Holy Trinity" consists of an opioid, a benzodiazepine, and carisoprodol and is a highly abused dangerous combination that can lead to additive CNS depression, overdose, and death. It is not covered.
- Methadone is not allowed with opioids, benzodiazepines, or opioid use disorder medications
- Morphine is not covered with clopidogrel, prasugrel, ticagrelor, and ticlopidine (does not include other opioid analgesics)
  - Morphine may diminish the antiplatelet effect and serum concentrations of P2Y12 Inhibitor antiplatelet agents (clopidogrel, prasugrel, ticagrelor, and ticlopidine).
- Nucynta and Nucynta ER are not allowed with other narcotic medications
- Tramadol immediate release with tramadol extended release

Opioids and Benzodiazepine Concurrent Use

Opioid and Benzodiazepines Concurrent Use Form

- Due to guidance in The SUPPORT for Members and Communities Act (H.R. 6) on CNS depression, this includes long-acting opioids over 90 MME/day or immediate release opioids over 15 MME/dose in combination with benzodiazepines.

Initial Criteria – Approval Duration: 12 months

- The member has access to an opioid reversal medication and has been counseled on overdose risk.
- The member undergoes routine drug screens (blood and/or urine).
- The member has been counseled on the risks of utilizing opioids and benzodiazepines in combination with each other and other CNS depressing medications, including antipsychotics and sedatives.
- The member must currently be on long-acting opioid therapy or must not have achieved therapeutic goal with non-narcotic medication (NSAIDs, TCAs, SNRIs, corticosteroids, etc.) and non-medication alternatives (weight loss, physical therapy, cognitive behavioral therapy, etc.)
- One of the following criteria must be met:
  - The member resides in a facility with skilled nursing care.
  - The member must have taper plan of one or both agents.
  - The opioid medication must be prescribed by, or in consult with, with an palliative care, oncologist or pain management specialist with a pain management contract (with treatment plan including goals for pain and function, and urine and/or blood screens) if the cumulative daily dose of opioids

exceeds 90 MME/day (specialist requirement not applicable to skilled nursing facility residents or tapering requests).

- The prescriber(s) of both agents have provided reasons why opioid analgesics and benzodiazepines cannot be avoided, or lower doses be used (subject to clinical review).
- The prescriber(s) of both agents routinely check the PDMP.
- The prescriber(s) of both agents routinely evaluate for medical necessity.

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
- 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 (specialist requirement not applicable to skilled nursing facility residents or tapering requests).

Opioid Analgesics – Long Acting

Partial Agonist/Antagonist Opioids

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
BELBUCA (buprenorphine)	buprenorphine patches
Butorphanol	
BUTRANS (buprenorphine) PATCHES - *Brand Required*	

Abuse Deterrent Formulations/Unique Mechanisms from Full Agonists Opioids

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
NUCYNTA ER (tapentadol)	CONZIP (tramadol ER) CAPSULES
OXYCONTIN (oxycodone) – *Brand Required*	hydrocodone ER tablets
tramadol ER Tablets	HYSINGLA ER (hydrocodone)
	levorphanol
	methadone
	MORPHABOND ER (morphine)
	tramadol ER capsules
	XTAMPZA ER (oxycodone)

Full Agonist Opioids Without Abuse Deterrent Formulations

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
fentanyl 12 mcg/hr, 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 has been established on opioid therapy during hospitalization
  - Both of the following are met:
    - The member must have a diagnosis of cancer pain, palliative care, or sickle cell disease.
    - The member must currently be on around-the-clock opioid therapy of at least 30 Morphine Milligram equivalents (MME) for at least a week, as evidenced by paid claims or pharmacy printouts.
      - If member is unable to swallow (e.g., mucositis, head/neck radiation, head/neck cancers, uncontrollable vomiting) and has severe pain (>6/10), fentanyl patch 12 mcg/hr may be considered for approval for opioid naïve members (subject to clinical review).
  - Both of the following are met:
    - The member must currently be on around-the-clock opioid therapy of at least 30 Morphine Milligram equivalents (MME) for at least a week, as evidenced by paid claims or pharmacy printouts.
    - The member has not achieved therapeutic goal with non-narcotic medication (NSAIDs, TCAs, SNRIs, corticosteroids, etc.) and non-medication alternatives (weight loss, physical therapy, cognitive behavioral therapy, etc.).
- One of the following criteria must be met:
  - The member resides in a facility with skilled nursing care.
  - The member must have taper plan
  - The member must have with treatment plan including goals for pain and function, and urine and/or blood screens.

Fentanyl Patch:

- The member must have a BMI ≥17.

Non-Preferred Agents Criteria:

- Clinical justification must be provided explaining why the member is unable to use other opioid and non-opioid analgesic agents (subject to clinical review).

Renewal Criteria – Approval Duration: 12 months

- One of the following must be met:
  - Documentation noting progress toward therapeutic goal must be included with request (e.g., improvement in pain level, quality in life, or function).
  - The member must be stable on long-acting opioid medication for 2 years or longer.

Underutilization

- Long-acting opioid analgesics must be used adherently and will reject on point of sale for late fill.

Opioid Analgesic – Short Acting

Fentanyl Products

PREFERRED AGENTS (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 Solid Oral Products

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
acetaminophen-codeine solution	hydrocodone-acetaminophen 5-163 mg/7.5 mL solution
hydrocodone-acetaminophen 7.5-325/15 ml solution	LORTAB (hydrocodone-acetaminophen) SOLUTION

Opioid Single Agent Solid Oral Products

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
codeine tablets	butalbital-codeine tablet
hydromorphone tablet	DEMEROL (meperidine) TABLET
meperidine tablet	DILAUDID (hydromorphone) TABLET
morphine tablet	OXAYDO (oxycodone) TABLET
NUCYNTA (tapentadol) TABLET	oxycodone 15 mg, 20 mg, 30 mg tablet
oxycodone 5 mg, 10 mg tablet	ROXICODONE (oxycodone) TABLET
oxymorphone tablet	ROXYBOND (oxycodone) TABLET
tramadol 50 mg tablet	tramadol 100 mg tablet
	ULTRAM (tramadol) TABLET

Opioid Single Agent Non-Solid Oral Products

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
hydromorphone liquid	
morphine solution	

oxycodone solution	

First Fill

- Short acting opioid analgesics must be filled with a 7-day supply if no previous fill within past 34 days
  - If member is filling prescription less than every 34 days due to decreased utilization, please get a new prescription for a lower quantity that reflects actual utilization within a 34-day window.

Prior Authorization Criteria

Prior Authorization Form – Opioid Analgesics

Initial Criteria – Approval Duration: 12 months
Fentanyl Only:
- The member must currently be on around-the-clock opioid therapy of at least 60 Morphine Milligram equivalents (MME) for at least a week, as evidenced by paid claims or pharmacy printouts

Meperidine and Butalbital-Codeine Only:
- Clinical justification must be provided explaining why the member is unable to use other opioid and non-opioid analgesic products (subject to clinical review).

Oxycodone IR Only
- The past 3 months of the member's North Dakota PDMP reports must have been reviewed.
- The member must currently be on a long-acting opioid analgesic that provides a daily Morphine Milligram Equivalent (MME) which meets requirements below (based on requested strength), as evidenced by paid claims or pharmacy printouts (Please use an Opioid Dose Calculator to find the MME for specific products):
  - Oxycodone 15 mg tablet: long-acting opioid must provide ≥150 mg MME per day
  - Oxycodone 20 mg tablet: long-acting opioid must provide ≥200 mg MME per day
  - Oxycodone 30 mg tablet: long-acting opioid must provide ≥300 mg MME per day

Non-preferred agents with same active ingredient preferred:
- See Preferred Dosage Form Criteria

Member with a History of Opioid Use Disorder
If 1 and 2 are met, please call for an override by calling provider relations at 1-800-755-2604 (chart notes will be required for requests beyond one fill):
1. The request is for one of the following:
   - A one-time fill request where pain cannot be reasonably treated with non-opioid therapy (e.g., surgery)
   - A request exceeding a one-time fill and a treatment plan has been provided with expected duration of use and why non-opioid therapy is not an option (subject to clinical review) or a taper plan is provided
2. One of the following is met:
   - Prescribers of both opioid prescription and MOUD (medication for opioid use disorder) are aware of each other and agree to opioid therapy
   - MOUD has been discontinued, and the prescriber of the opioid is aware of previous MOUD treatment and confirms opioid therapy is required

Renewal Criteria – Approval Duration: 12 months
- Documentation noting progress toward therapeutic goal must be provided including pain level and function

Qutenza (capsaicin patch)

CLINICAL PA REQUIRED
QUTENZA (capsaicin patch) – *Medical Billing Only*

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a pain specialist
- The member must have failed a 3-month treatment of topical lidocaine patch

Skeletal Muscle Relaxants

Solid Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
baclofen	AMRIX (cyclobenzaprine) TAB 24 HR
chlorzoxazone 500 mg	chlorzoxazone 375 mg and 750 mg
cyclobenzaprine 5 mg and 10 mg	cyclobenzaprine 7.5 mg
dantrolene	cyclobenzaprine ER
methocarbamol	carisoprodol
orphenadrine ER	carisoprodol-aspirin
tizanidine tablets	carisoprodol-aspirin-codeine
	DANTRIUM (dantrolene)
	LORZONE (chlorzoxazone)
	METAXALL (metaxalone)
	metaxalone
	NORGESIC FORTE (orphenadrine/aspirin/caffeine)
	ROBAXIN (methocarbamol)
	SKELAXIN (metaxalone)
	SOMA (carisoprodol)
	tizanidine capsules
	ZANAFLEX (tizanidine)

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months (carisoprodol = 1 week)

- Carisoprodol products only:
  - The member must be undergoing dose tapering
- Metaxalone
  - The member must have failed two 30-day trials of other skeletal muscle relaxants, including methocarbamol, as evidenced by paid claims or pharmacy printouts.
- All other products:
  - See Preferred Dosage Form Criteria

Therapeutic Duplication

- One strength of one medication is allowed at a time
  - If the following conditions apply, please call for an override by calling provider relations at 1-800-755-2604:
    - The member has cerebral palsy or another chronic spastic disorder
    - The prescriber is a physiatrist
    - The requested combination is baclofen and tizanidine
- Carisoprodol is not allowed with opioids, benzodiazepines, or opioid use disorder medications

- The “Holy Trinity” consists of an opioid, a benzodiazepine, and carisoprodol and is a highly abused dangerous combination that can lead to additive CNS depression, overdose, and death. It is not covered.

- Tizanidine is not allowed with other alpha 2 agonists (clonidine, clonidine/chlorthalidone, guanfacine, methyldopa)
  - tizanidine is also an alpha 2 agonist

Non-Solid Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
baclofen solution 5 mg/5 mL	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
guanfacine		INTUNIV (guanfacine ER)
guanfacine ER		KAPVAY (clonidine ER)

First Fill

- Clonidine ER and guanfacine ER must be filled with a 14-day supply (or less) if no previous fill within past 99 days

Therapeutic Duplication

Please see the **Psychotropic Monitoring Program** document for detailed information regarding clinical criteria for Therapeutic Duplication Requests.

- One strength of one medication is allowed at a time. Guanfacine 4 mg IR or ER can be combined with other strengths to form dosages up to 7 mg per day. Guanfacine IR and ER cannot be combined.
- Clonidine and guanfacine are not allowed with each other or other alpha 2 agonists (clonidine/chlorthalidone, methyldopa, or tizanidine)

Electronic Step Care and Concurrent Medication

- Clonidine ER: A total of 30 days of clonidine IR must be paid within 40 days prior to clonidine ER

Norepinephrine Reuptake Inhibitors

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

atomoxetine	STRATTERA (atomoxetine)
PREFERRED AGENTS (CLINICAL PA REQUIRED)	
QELBREE (viloxazine)	

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must meet one of the following:
  - The member has failed a 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)
ADDERALL XR (dextroamphetamine/amphetamine) – *Brand Required*	DEXEDRINE SPANSULE ER (dextroamphetamine)
dextroamphetamine ER	dextroamphetamine/amphetamine ER (generic Adderall XR)
VYVANSE (lisdexamfetamine) – *Brand Required*	lisdexamfetamine
High-Cost Options	
MYDAYIS ER (dextroamphetamine/amphetamine) – *Brand Required*	DYANAVEL XR (amphetamine)
	dextroamphetamine/amphetamine ER (generic Mydayis ER)

Immediate Release

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
amphetamine	ADDERALL (dextroamphetamine/amphetamine)
dextroamphetamine 5 mg, 10 mg	dextroamphetamine – 2.5 mg, 7.5 mg, 15 mg, 20 mg, 30 mg
dextroamphetamine/amphetamine	EVEKEO (amphetamine)
	methamphetamine
	ZENZEDI (dextroamphetamine)

Non-Solid Dosage Forms

Extended Release

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ADZENYS XR – ODT (amphetamine)	

DYANAVEL XR (amphetamine) SUSPENSION	
High-Cost Options	
VYVANSE (lisdexamfetamine) CHEW TABLET – *Brand Required*	amphetamine ER suspension
XELSTRYM (dextroamphetamine) PATCH	lisdexamfetamine chew

Immediate Release

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
EVEKEO ODT (amphetamine)	dextroamphetamine 5 mg/5 ml
PROCENTRA (dextroamphetamine) SOLUTION – *Brand Required*	

Methylphenidate

Solid Dosage Forms

Extended Release

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
CONCERTA (methylphenidate) – *Brand Required*	FOCALIN XR (dexmethylphenidate)
dexmethylphenidate ER	methylphenidate ER tablet (generic Concerta)
methylphenidate CD 30-70	methylphenidate LA capsules – 50-50 (generic Ritalin LA) – 60 mg
methylphenidate ER tablet 10 mg and 20 mg	RITALIN LA (methylphenidate LA capsules – 50-50)
methylphenidate LA capsules – 50-50 (generic Ritalin LA) – 10 mg, 20 mg, 30 mg, 40 mg	
High-Cost Options	
APTENSIO XR (methylphenidate) – *Brand Required*	methylphenidate ER 45 mg
AZSTARYS (serdexmethylphenidate/dexmethylphenidate)	methylphenidate ER capsule
JORNAY PM (methylphenidate)	methylphenidate ER 63 mg
	methylphenidate ER 72 mg
	methylphenidate ER capsule
	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*	methylphenidate patch
QUILLICHEW ER (methylphenidate)	
QUILLIVANT XR (methylphenidate)	
High-Cost Options	
	COTEMPLA XR – ODT (methylphenidate)

Immediate Release

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
methylphenidate chew tablet	METHYLIN (methylphenidate) chew tablets
methylphenidate solution	METHYLIN (methylphenidate) solution

Prior Authorization Criteria

Initial Criteria – Approval Duration: 3 months

- The member must have failed a 30-day trial of each preferred medication under the same release and form group.

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)
- 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

Electronic Step Care and Concurrent Medications

- Trintellix Only: Initiation with 10 mg must be used for 10 days prior to continuing therapy with 20 mg.
  - Trintellix recommended starting dose is 10 mg once daily.
- Desvenlafaxine ER Only: 30 days of 50 mg must be paid within 40 days of 25 mg date of service.
  - 25 mg is intended only for gradual titration before discontinuation. It is not a therapeutic dose.

First Fill

- Viibryd and Trintellix must be filled with a 10-day supply if no previous fill within past 99 days

Therapeutic Duplication

Please see the **Appendix B** for clinical criteria for multiple oral antipsychotics and oral and injectable antipsychotic requests

- 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 antidepressant medications (exceptions: trazodone and mirtazapine)
- Fluvoxamine, a strong 1A2 inhibitor, is not covered with Ramelteon, a 1A2 Substrate.

Atypical Antipsychotics

Oral

Solid Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
aripiprazole	ABILIFY (aripiprazole)
clozapine	CLOZARIL (clozapine)
FANAPT (iloperidone)	GEODON (ziprasidone)
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

LYBALVI (olanzapine/samidorphan)	SYMBYAX (olanzapine/fluoxetine)
REXULTI (brexpiprazole)	
VRAYLAR (cariprazine)	

Non-Solid Dosage Forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
asenapine	RISPERDAL (risperidone) ORAL SOLUTION
clozapine ODT	RISPERDAL M-TAB (risperidone)
olanzapine ODT	SAPHRIS (asenapine) 2.5 MG
risperidone ODT	ZYPREXA ZYDIS (olanzapine)
risperidone oral solution	
SAPHRIS (asenapine) 5 MG, 10 MG *– Brand Co-Preferred*	
High-Cost Options	
aripiprazole ODT	ABILIFY DISCMELT (aripiprazole)
aripiprazole solution	
SECUADO (asenapine) PATCH	

Electronic Step Care and Concurrent Medication

Vraylar requires initiation titration:
- For 3 mg dose: Initiation pack or 1 day of the 1.5 mg tablet is required
- For 4.5 mg dose: Initiation pack or 1 day of the 1.5 mg tablet plus 6 days of 3 mg tablets is required

Therapeutic Duplication

Prior Authorization Form - Concurrent Antipsychotics

Please see the **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, 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, 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)	PERSERIS (risperidone)
ABILIFY MAINTENA (aripiprazole)	RYKINDO ER (risperidone)
ARISTADA (aripiprazole lauroxil)	
ARISTADA INITIO (aripiprazole lauroxil)N	
INVEGA HAFYERA (paliperidone)	
INVEGA SUSTENNA (paliperidone)	
INVEGA TRINZA (paliperidone)	
RISPERDAL CONSTA (risperidone)	
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 the **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: The member must have had a 7-day trial of eszopiclone within the past 90 days
- Zolpidem: Initiation with trial of 5 mg must be used for 7 days within 90 days prior to 10 mg tablets
  - Zolpidem is recommended to be used at lowest dose possible.

Prior Authorization Criteria

Prior Authorization Form – Sedative/Hypnotic

Initial Criteria – Approval Duration: 3 months

- Doxepin only
  - The member must have failed a 25-day trial with ramelteon with the most recent failure within the last 90 days, as evidenced by paid claims or pharmacy printouts.
  - Clinical justification must be provided explaining why the member is unable to use mirtazapine, hydroxyzine, or trazodone (subject to clinical review)
- Edluar (zolpidem) only
  - The member's insomnia must be characterized by difficulty with sleep onset.
  - The member must have failed a 25-day trial of each of the following with the most recent failure within the last 90 days, as evidenced by paid claims or pharmacy printouts.
    - eszopiclone
    - zolpidem IR
    - zaleplon

- temazepam, zolpidem SL, Dayvigo, Quviviq only
  - The member's insomnia must be characterized by difficulty with sleep onset and maintenance.
  - The member must have failed a 25-day trial of each of the following with the most recent failure within the last 90 days, as evidenced by paid claims or pharmacy printouts.
    - eszopiclone
    - zolpidem ER
    - Belsomra
- triazolam, fluazepam, estazolam, seconal sodium, zolpidem 7.5mg only
  - Clinical justification must be provided explaining why the member is unable to use the preferred agents (subject to clinical review)

*Renewal Criteria – Approval Duration: 6 months (2 weeks for b*enzodiazepines)

- Other conditions causing sleep issues have been ruled out
- benzodiazepines (temazepam, triazolam, flurazepam, estazolam) only:
  - The member must be undergoing dose tapering

Therapeutic Duplication

- One strength of one medication is allowed at a time
  - Benzodiazepines indicated only for insomnia are not covered with other non-barbiturate insomnia medications or other benzodiazepines
- Sedative/hypnotics are not covered with:
  - Xyrem
  - Mydayis
    - Insomnia has been reported in 25-56% of members receiving Mydayis. Members reporting insomnia should use a shorter acting product that does not reach steady state.
  - Long-acting benzodiazepines. Belsomra and Dayvigo are not covered with short or long-acting benzodiazepines.
    - Concomitant use can lead to CNS depression.
- Ramelteon, a 1A2 Substrate, is not covered with fluvoxamine, a strong 1A2 inhibitor
- Mirtazapine is not allowed with other alpha 2 agonists (clonidine, clonidine/chlorthalidone, guanfacine, methyldopa)
  - Mirtazapine is also an alpha 2 agonist
- Sedating benzodiazepines are not covered with opioids

Non-24-hour Sleep-Wake Disorder

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ramelteon	HETLIOZ (tasimelteon) – *Brand Required*
	ROZEREM (ramelteon)
	tasimelteon

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a specialist in sleep disorders.
- The member must have had a 30-day trial of ramelteon, as evidenced by paid claims or pharmacy printouts.
- One of the following must be met:
  - Member must be unable to perceive light in either eye.

- Sighted members must confirm diagnosis by documentation submitted of self-reported sleep diaries or actigraphy for at least 14 days demonstrating a gradual daily drift (typically later) in rest-activity patterns not better explained by sleep hygiene, substance, or medication use, or other neurological or mental disorders.

Underutilization

- Hetlioz/tasimelteon must be used compliantly and will reject on point of sale for late fill.

Smith-Magenis Syndrome

CLINICAL PA REQUIRED
HETLIOZ (tasimelteon) – *Brand Required*
Tasimelteon

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a specialist in sleep disorders.
- Documentation is submitted of genetic testing confirming deletion 17p11.2 (cytogenetic analysis or microarray) or RAI1 gene mutation.
- Documentation of self-reported sleep diaries or actigraphy must be submitted for at least 14 days must be submitted.

Underutilization

- Hetlioz/tasimelteon must be used compliantly and will reject on point of sale for late fill.

Pulmonary

Asthma/COPD

Therapeutic Duplication

- One medication from each class is allowed at time.
  - One inhaled steroid
  - Long-acting anticholinergic
  - Leukotriene pathway inhibitor
  - One short-acting beta agonist
  - One long-acting beta agonist

Electronic Step Care and Concurrent Medications

- Daliresp: A total of 90 days of an inhaled short or long-acting anticholinergic must be paid within 115 days prior to daliresp's date of service.
  - According to the Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines, Daliresp is a recommended add-on therapy to members experiencing exacerbations while on antimuscarinic therapy.

Albuterol / Levalbuterol Rescue Inhalers

PREFERRED AGENTS	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)	PROAIR (albuterol) DIGIHALER
		PROVENTIL (albuterol) HFA
		XOPENEX (levalbuterol) HFA

According to the GINA guidelines:

- A low dose ICS should be taken whenever SABA taken for step 1 control of asthma.
- Dispensing ≥ 3 SABA canisters/year is associated with higher risk of emergency department presentations.
- Dispensing ≥ 12 SABA canisters/year is associated with higher risk of death.

Electronic Step Therapy Required

- Levalbuterol HFA: A total of 30 days of albuterol HFA must be paid within 180 days prior to levalbuterol HFA's date of service.

Electronic Concurrent Medications Required

- ProAir Respiclick: A total of 30 days of steroid inhaler must be paid within 40 days prior to ProAir Respiclick's date of service.
  - The quantity limit for Ventolin HFA is set to 2 canisters per 6 months (2 puffs per day). If more is needed, member must switch to ProAir Respiclick HFA and be on a steroid inhaler to control asthma.

  If the following conditions apply, please call for an override by calling provider relations at 1-800-755-2604:
  - If primary insurance will only pay for ProAir Respiclick and member is well-controlled without steroid inhaler (i.e., uses less than 2 canisters per 6 months).

Therapeutic Duplication

- Short acting beta agonist nebulizers and inhalers are not payable together.
  - Inhalers and Nebulizers work equally well whether used at home, in school, or otherwise outside of the home. If member receives multiple forms of rescue medication, the risk of unidentified uncontrolled asthma and rescue inhaler dependence is increased.

  If the following conditions apply, please call for an override by calling provider relations at 1-800-755-2604:
  - Maximally treated members with end-stage COPD will be allowed an ongoing override (compliance with inhaled steroid, long-acting beta agonist, long-acting muscarinic antagonist, and Daliresp)
  - Members with cystic fibrosis will be allowed an ongoing override.
  - Acutely ill children will be allowed a one-time override.

References:

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2. Global Initiative for Asthma. Global strategy for asthma management and prevention. 2019 GINA Main Report. Available from: www.ginasthma.org. (Accessed February 5, 2020)
3. National Asthma Education and Prevention Program, Third Expert Panel on the Diagnosis and Management of Asthma. Expert Panel Report 3: Guidelines for the Diagnosis and Management of Asthma. Bethesda (MD): National Health, Lung, and Blood Institute (US); 2007 Aug. Available from: https://www.ncbi.nlm.nih.gov/books/NBK7232
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François R. Chapuis, Didier Stamm, Jacques Robert, Louis David, Pierre G. Chatelain, Guy Dutau and Daniel Floret Pediatrics. August 2000, 106 (2) 311-317; DOI: https://doi.org/10.1542/peds.106.2.311

Anticholinergics/Beta Agonists Combinations – Short Acting

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
albuterol/ipratropium	DUONEB (albuterol/ipratropium)
COMBIVENT RESPIMAT (albuterol/ipratropium)	

Anticholinergics/Beta Agonists Combinations – Long Acting

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED STEP 1 AGENTS (PA REQUIRED)	NON-PREFERRED STEP 2 AGENTS (PA REQUIRED)
ANORO ELLIPTA (umeclidinium/vilanterol)	BEVESPI AEROSPHERE (glycopyrrolate/formoterol)	DUAKLIR PRESSAIR (aclidinium/formoterol)
STIOLTO RESPIMAT (tiotropium/olodaterol)		

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

Non-Preferred Step 1 Agents

- The member must have failed a 30-day trial of 2 preferred agents, as evidenced by paid claims or pharmacy printouts

Non-Preferred Step 2 Agents:

- The member must have failed a 30-day trial of Bevespi Aerosphere and 2 preferred agents, as evidenced by paid claims or pharmacy printouts
- Clinical justification must be provided explaining why the member is unable to use the preferred products (subject to clinical review).

Anticholinergics – Long-Acting

PREFERRED AGENTS (NO PA REQUIRED)	PREFERRED STEP 1 AGENTS (ELECTRONIC STEP REQUIRED)	NON-PREFERRED STEP 2 AGENTS (PA REQUIRED)
INCRUSE ELLIPTA (umeclidinium)	SPIRIVA RESPIMAT 1.25 MCG (tiotropium)	LONHALA MAGNAIR (glycopyrrolate)
SPIRIVA HANDIHALER (tiotropium)		tiotropium handihaler
SPIRIVA RESPIMAT 2.5 MCG (tiotropium)		TUDORZA PRESSAIR (aclidinium)
		YUPELRI (revefenacin)

Electronic Concurrent Medications Required

- Spiriva Respimat 1.25 mg: A total of 30 days of a long-acting beta agonist (in combination or alone) must be paid within 40 days prior to the Spiriva Respimat 1.25 mg date of service.

Electronic Diagnosis Verification

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

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must have failed a 30-day trial of at least 2 preferred long-acting anticholinergic agents of unique ingredients (in combination or alone), as evidenced by paid claims or pharmacy printouts.
- Lonhala Magnair (glycopyrrolate) only:
  - The member must have failed a 30-day trial of Yupelri, as evidenced by paid claims or pharmacy printouts.

Therapeutic Duplication

- Anticholinergic medications are not covered with acetylcholinesterase inhibitors.
  - The effects of an anticholinergic (blocks the effect of acetylcholine) and acetylcholinesterase inhibitors (prevents breakdown of acetylcholine) oppose each other, and the therapeutic effect of both products is diminished.

Beta Agonists – Long-Acting

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
arformoterol	BROVANA (arformoterol)
formoterol	PERFOROMIST (formoterol)
SEREVENT DISKUS (salmeterol)	
STRIVERDI RESPIMAT (olodaterol)	

Biologics

Anti-IL-5 biologics

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

Anti-IL-4/13 biologics

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

Eosinophil-directed biologics

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

Thymic Stromal Lymphopoietin (TSLP) blocker

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

Prior Authorization Criteria

Prior Authorization Form – Asthma

Initial Criteria – Approval Duration: 3 months

- The requested medication must be prescribed by, or in consult with, an allergist/immunologist or pulmonologist
- The member must have had at least one exacerbation requiring use of oral corticosteroids in the previous year despite continued compliant use of a high dose inhaled steroid in combination with a long-acting beta agonist (LABA) and long-acting muscarinic antagonist (LAMA) as evidenced by paid claims or pharmacy printouts

Anti-IL-5 biologics:

- The member has eosinophilic phenotype with eosinophil count ≥ 150 cells/mcL within the past 90 days
- Nucala: The member must have failed a 3-month trial of a preferred Anti-IL-5 biologic, as evidenced by paid claims or pharmacy printouts

Eosinophil-directed biologics:

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

Renewal Criteria – Approval Duration: 12 months

- The member must have achieved a significant reduction in asthma exacerbations and utilization of rescue medications since treatment initiation since starting treatment with the requested medication, as evidenced by medical documentation (e.g., chart notes) attached to the request (subject to clinical review).

Corticosteroids – Inhaled

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

Electronic Duration Verification:

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

Prior Authorization

Initial Criteria – Approval Duration: 12 months

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

Steroid/Long-Acting Beta Agonist (LABA) Combination Inhalers

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ADVAIR DISKUS (fluticasone/salmeterol) – *Brand Required*	AIRDUO DIGIHALER (fluticasone/salmeterol)

ADVAIR HFA (fluticasone/salmeterol) – *Brand Required*	BREO ELLIPTA (fluticasone/vilanterol) – *Brand Required*
AIRDUO RESPICLICK (fluticasone/salmeterol) – *Brand Required*	budesonide/formoterol
DULERA (mometasone/formoterol)	fluticasone/salmeterol
SYMBICORT (budesonide/formoterol) – *Brand Required*	fluticasone/vilanterol
	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 365 days without prior approval.

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 printouts.
- For COPD diagnosis only: The member must currently be taking a long acting antimuscarinic agent.

Electronic Diagnosis Verification

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

Steroid/Short-Acting Beta Agonist (SABA) Combination Inhalers

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

GINA Guidelines – SMART:

- For mild asthma, ICS-formoterol is the preferred reliever medication for as needed symptom relief.
- For steps 3-5, ICS-formoterol is preferred for use as an as needed and regular daily treatment.
  Quantity Limits to accommodate SMART therapy:
  - 2 Symbicort or Dulera inhalers per 30-day supply not to exceed a total of 9 inhalers per 365 days without prior approval.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must have failed a 30-day trial of Symbicort and Dulera, as evidenced by paid claims or pharmacy printouts.
- Clinical justification must be provided explaining why the member is unable to use the preferred Steroid/LABA or SABA agents (subject to clinical review).

Steroid/Anticholinergics/Long-Acting Beta Agonists Combinations

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
TRELEGY ELLIPTA (fluticasone/umeclidinium/vilanterol)	BREZTRI AEROSPHERE (budesonide/glycopyrrolate/formoterol)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must have failed a 60-day trial of Flovent HFA + Anoro Ellipta 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 Flovent HFA + Anoro Ellipta combination therapy (subject to clinical review).
- The member must have failed a 60-day trial of triple therapy (Steroid/Long-Acting Beta Agonist/Long-Acting Anticholinergic) that has at least one ingredient different from Flovent HFA + Anoro Ellipta 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:

Cystic Fibrosis

Cystic Fibrosis – Inhaled Antibiotics

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
BETHKIS (tobramycin) – *Brand Required*	ARIKAYCE (amikacin/nebulizer)
KITABIS PAK (tobramycin/nebulizer) – *Brand Required*	CAYSTON (aztreonam)
tobramycin in 0.225% sodium chloride	TOBI (tobramycin) in 0.225% sodium chloride
	TOBI PODHALER (tobramycin)
	tobramycin/nebulizer 300 mg/5 mL
	tobramycin 300 mg/4 mL

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- 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.
- Cayston only:
  - The member must be colonized with *Pseudomonas aeruginosa.*
  - The member must have had a 28-day trial of tobramycin as evidenced by paid claims or pharmacy printouts.
- Arikayce only:
  - The member must be colonized with *Mycobacterium avium* complex (MAC).
  - The member must have not achieved negative sputum cultures after a minimum duration of 6 consecutive months of background treatment with a macrolide, a rifamycin, and ethambutol

Cystic Fibrosis – CFTR Modulators

CLINICAL PA REQUIRED
KALYDECO (ivacaftor)
ORKAMBI (lumacaftor/ivacaftor)
SYMDEKO (tezacaftor/ivacaftor)
TRIKAFTA (elexacaftor/tezacaftor/ivacaftor) GRANULES
TRIKAFTA (elexacaftor/tezacaftor/ivacaftor) TABLETS

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months (Renewal Approval – 5 years)

- The member must have a CFTR mutation that the requested medication is FDA-approved to treat, as evidenced by medical documentation (e.g., chart notes, genetic testing) that is attached to the request.

Cystic Fibrosis – Osmotic Agent

CLINICAL PA REQUIRED
BRONCHITOL (mannitol) INHALER

Electronic Diagnosis Verification

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

Electronic Age Verification

- The member must be 18 years or older

Prior Authorization

Initial Criteria – Approval Duration: 12 months

- Documentation of the Bronchitol Tolerance Test must be submitted

Idiopathic Pulmonary Fibrosis

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
pirfenidone	ESBRIET (pirfenidone)
	OFEV (nintedanib)

Prior Authorization

Initial Criteria – Approval Duration: 12 months

- The requested medication must be prescribed by, or in consult with, a pulmonologist or rheumatologist.
- The prescriber must submit documentation of the following:
  - The member must have forced vital capacity (FVC) ≥ 40% of predicted within prior 60 days.
  - The member must have carbon monoxide diffusing capacity (DLCO, corrected for hemoglobin) of 30% to 79% of predicted.

Interstitial Lung Disease

First Line Therapy

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
azathioprine	ACTEMRA (tocilizumab) ACTPEN, SYRINGE
cyclophosphamide	ACTEMRA (tocilizumab) VIAL – *Medical Billing Only*
mycophenolate mofetil (MMF)	

Progressive Disease

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
RIABNI (rituximab-arrx) – *Medical Billing Only*	OFEV (nintedanib)
RITUXAN (rituximab) – *Medical Billing Only*	
RUXIENCE (rituximab-pvvr) – *Medical Billing Only*	

TRUXIMA (rituximab-abbs) – *Medical Billing Only*	

Prior Authorization

Initial Criteria – Approval Duration: 12 months

- The requested medication must be prescribed by, or in consult with, a pulmonologist or rheumatologist.
- The prescriber must submit documentation of the following:
  - The member must have forced vital capacity (FVC) ≥ 40% of predicted within prior 60 days
  - The member must have carbon monoxide diffusing capacity (DLCO, corrected for hemoglobin) of 30% to 79% of predicted.

Rheumatology

Axial Spondyloarthritis/Ankylosing Spondylitis

TNF Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AVSOLA (infliximab-axxq) – *Medical Billing Only*	adalimumab-adaz
CIMZIA (certolizumab)	adalimumab-fkjp
ENBREL (etanercept)	AMJEVITA (adalimumab-atto)
HUMIRA (adalimumab)	CYLTEZO (adalimumab-abdm)
RENFLEXIS (infliximab-abda) – *Medical Billing Only*	HADLIMA (adalimumab-bwwd)
SIMPONI (golimumab)	HULIO (adalimumab-fkjp)
	HYRIMOZ (adalimumab-adaz)
	IDACIO (adalimumab-aacf)
	INFLECTRA (infliximab-dyyb) – *Medical Billing Only*
	infliximab – *Medical Billing Only*
	REMICADE (infliximab) – *Medical Billing Only*
	SIMPONI (golimumab) ARIA – *Medical Billing Only*
	YUFLYMA (adalimumab-aaty)
	YUSIMRY (adalimumab-aqvh)

Interleukin (IL) – 17 Inhibitors

PREFERRED AGENTS (ELECTRONIC STEP REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
TALTZ (ixekizumab)***	COSENTYX (secukinumab)
	COSENTYX (secukinumab) – *Medical Billing Only*

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: A total of 84 days of a TNF Inhibitor must be paid within 120 days prior to Taltz's date of service

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- Cosentyx Only: The member must have failed a 90-day trial of a TNF inhibitor and Taltz, as evidenced by paid claims or pharmacy printouts.
- Rinvoq ER Only: The member must have failed 90-day trials of Xeljanz and another preferred product, as evidenced by paid claims or pharmacy printouts.
- Inflectra, infliximab, Remicade, Xeljanz IR 10 mg, Xeljanz XR Only: See Preferred Dosage Form Criteria

Behçet syndrome

Phosphodiesterase 4 (PDE4) Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
OTEZLA (apremilast)	

TNF Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AVSOLA (infliximab-axxq) – *Medical Billing Only*	adalimumab-adaz
ENBREL (etanercept)	adalimumab-fkjp
HUMIRA (adalimumab)	AMJEVITA (adalimumab-atto)
RENFLEXIS (infliximab-abda) – *Medical Billing Only*	CYLTEZO (adalimumab-abdm)
	HADLIMA (adalimumab-bwwd)
	HULIO (adalimumab-fkjp)
	HYRIMOZ (adalimumab-adaz)
	IDACIO (adalimumab-aacf)
	INFLECTRA (infliximab-dyyb) – *Medical Billing Only*
	infliximab – *Medical Billing Only*
	REMICADE (infliximab) – *Medical Billing Only*
	SIMPONI (golimumab) ARIA – *Medical Billing Only*
	YUFLYMA (adalimumab-aaty)
	YUSIMRY (adalimumab-aqvh)

Prior Authorization Criteria

- See Preferred Dosage Form Criteria

Cryopyrin Associated Periodic Syndrome (CAPS)

Includes: Familiar Cold Autoinflammatory Syndrome, Muckle-Wells Syndrome, and Neonatal Onset Multisystem Inflammatory Disease (NOMID) or Chronic Infantile Neurological Cutaneous and Articular (CINCA) Syndrome

Interleukin (IL) -1 Receptor Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
KINERET (anakinra)	ARCALYST (rilonacept)
	ILARIS (canakinumab) – *Medical Billing Only*

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a specialist in the area of the member's diagnosis.
- The member has failed a 3-month trial of Kineret, as evidenced by paid claims or pharmacy print outs.
- The member has elevated pretreatment serum inflammatory markers (e.g., C-reactive protein (CRP), erythrocyte sedimentation rate (ESR) serum amyloid A(SAA))
- The member has at least two of the following symptoms (as evidenced by documentation):
  - Urticaria-like rash
  - Cold/stress triggered episodes
  - Sensorineural hearing loss
  - Musculoskeletal symptoms of arthralgia/arthritis/myalgia
  - Chronic aseptic meningitis
  - Skeletal abnormalities of epiphyseal overgrowth/frontal bossing

Familial Mediterranean Fever (FMF)

Colchicine

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
colchicine tablets	colchicine capsules
	COLCRYS (colchicine) TABLETS
	GLOPERBA (colchicine) ORAL SOLUTION
	MITIGARE (colchicine) CAPSULE

Interleukin (IL) -1 Receptor Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
KINERET (anakinra)	ARCALYST (rilonacept)
	ILARIS (canakinumab) – *Medical Billing Only*

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a specialist in the area of the member's diagnosis.
- The member experiences one or more attacks each month despite receiving maximally tolerated dose of colchicine for at least 6 months, as evidenced by paid claims or pharmacy print outs and clinical documentation.
- The member has failed a 3-month trial of Kineret, as evidenced by paid claims or pharmacy print outs.

Giant Cell Arteritis (Temporal Arteritis)

Interleukin (IL) -6 Receptor Inhibitors

CLINICAL PA REQUIRED
ACTEMRA (tocilizumab) ACTPEN, SYRINGE
ACTEMRA (tocilizumab) VIAL – *Medical Billing Only*

Prior Authorization Criteria

- See Medications that cost over $3000/month criteria

Hyperimmunoglobulin D Syndrome/Mevalonate Kinase (MVK) Deficiency

Symptomatic Treatment

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
NSAIDs	
glucocorticoids	
KINERET (anakinra)	

Preventative Treatment

CLINICAL PA REQUIRED
ILARIS (canakinumab)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a specialist in the area of the member's diagnosis.
- The member has failed a 3-month trial of Kineret, as evidenced by paid claims or pharmacy print outs.
- The member is experiencing frequent and/or severe attacks that have significantly diminished quality of life

Juvenile Idiopathic Arthritis

Juvenile Idiopathic Arthritis – Enthesitis-Related Arthritis (ERA)

TNF Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ENBREL (etanercept)	adalimumab-adaz
HUMIRA (adalimumab)	adalimumab-fkjp
	AMJEVITA (adalimumab-atto)
	CYLTEZO (adalimumab-abdm)
	HADLIMA (adalimumab-bwwd)
	HULIO (adalimumab-fkjp)
	HYRIMOZ (adalimumab-adaz)
	IDACIO (adalimumab-aacf)
	YUFLYMA (adalimumab-aaty)
	YUSIMRY (adalimumab-aqvh)

Interleukin (IL) – 17 Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	COSENTYX (secukinumab)
	COSENTYX (secukinumab) – *Medical Billing Only*

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member has failed a 3-month trial of a TNF inhibitor, as evidenced by paid claims or pharmacy print outs.
- Amjevita Only: See Preferred Dosage Form Criteria

Juvenile Idiopathic Arthritis – Polyarticular Course

TNF Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ENBREL (etanercept)	adalimumab-adaz
HUMIRA (adalimumab)	adalimumab-fkjp
	AMJEVITA (adalimumab-atto)
	CYLTEZO (adalimumab-abdm)
	HADLIMA (adalimumab-bwwd)
	HULIO (adalimumab-fkjp)
	HYRIMOZ (adalimumab-adaz)
	IDACIO (adalimumab-aacf)
	SIMPONI (golimumab) ARIA – *Medical Billing Only*
	YUFLYMA (adalimumab-aaty)
	YUSIMRY (adalimumab-aqvh)

Interleukin (IL) -6 Receptor Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	ACTEMRA (tocilizumab) ACTPEN, SYRINGE
	ACTEMRA (tocilizumab) VIAL – *Medical Billing Only*

T-cell Costimulation Blocker

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ORENCIA (abatacept) – 125 mg/mL syringe	ORENCIA (abatacept) - 50 mg/0.4 mL and 87.5 mg/0.7 ml syringes
	ORENCIA (abatacept) – *Medical Billing Only*

Janus Kinase (JAK) Inhibitors

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

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member has failed a 3-month trial of a TNF inhibitor, as evidenced by paid claims or pharmacy print outs.
- Orencia IV: See Preferred Dosage Form Criteria
- Xeljanz IR 10mg, Xeljanz XR Only: See Preferred Dosage Form Criteria

Juvenile Chronic Arthritis – Systemic Onset

Interleukin (IL) -1 Receptor Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	ILARIS (canakinumab) – *Medical Billing Only*

Interleukin (IL) -6 Receptor Inhibitors

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ACTEMRA (tocilizumab) ACTPEN, SYRINGE	
ACTEMRA (tocilizumab) VIAL – *Medical Billing Only*	

TNF Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ENBREL (etanercept)	adalimumab-adaz
HUMIRA (adalimumab)	adalimumab-fkjp
	AMJEVITA (adalimumab-atto)
	CYLTEZO (adalimumab-abdm)
	HADLIMA (adalimumab-bwwd)
	HULIO (adalimumab-fkjp)
	HYRIMOZ (adalimumab-adaz)
	IDACIO (adalimumab-aacf)
	YUFLYMA (adalimumab-aaty)
	YUSIMRY (adalimumab-aqvh)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- Actemra: See Medications that cost over $3000/month criteria
  - Ilaris: The member has failed a 3-month trial of Actemra, as evidenced by paid claims or pharmacy print outs.

References:

1. Dewitt, E.M., Kimura, Y., Beukelman, T., Nigrovic, P.A., Onel, K., Prahalad, S., Schneider, R., Stoll, M.L., Angeles-Han, S., Milojevic, D., Schikler, K.N., Vehe, R.K., Weiss, J.E., Weiss, P., Ilowite, N.T., Wallace, C.A. and (2012), Consensus treatment plans for new-onset systemic juvenile idiopathic arthritis. Arthritis Care Res, 64: 1001-1010. https://doi.org/10.1002/acr.21625

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

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
CIMZIA (certolizumab)	adalimumab-adaz
ENBREL (etanercept)	adalimumab-fkjp
HUMIRA (adalimumab)	AMJEVITA (adalimumab-atto)
SIMPONI (golimumab)	CYLTEZO (adalimumab-abdm)
	HADLIMA (adalimumab-bwwd)
	HULIO (adalimumab-fkjp)
	HYRIMOZ (adalimumab-adaz)
	IDACIO (adalimumab-aacf)
	SIMPONI (golimumab) ARIA – *Medical Billing Only*
	YUFLYMA (adalimumab-aaty)
	YUSIMRY (adalimumab-aqvh)

Phosphodiesterase 4 (PDE4) Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
OTEZLA (apremilast)	

Janus Kinase (JAK) Inhibitor

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

T-cell Costimulation Blocker

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ORENCIA (abatacept) – 125 mg/mL syringe	ORENCIA (abatacept) – *Medical Billing Only*

Interleukin (IL)-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)

Interleukin (IL) – 17 Inhibitors

PREFERRED AGENTS (ELECTRONIC STEP REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
TALTZ (ixekizumab)	COSENTYX (secukinumab)
	COSENTYX (secukinumab) – *Medical Billing Only*

Electronic Step Therapy Required

- Taltz: A total of 84 days of a TNF Inhibitor must be paid within 120 days prior to Taltz's date of service.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must have failed a 90-day trial of each of the following, as evidenced by paid claims or pharmacy printouts:
  - TNF inhibitor
  - Interleukin (IL) – 17 inhibitor
- Xeljanz IR 10mg, Xeljanz XR Only: See Preferred Dosage Form Criteria

Rheumatoid Arthritis

Anti-CD20 Monoclonal Antibodies

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

T-cell Co-stimulation Blocker

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ORENCIA (abatacept) – 125 mg/mL syringe	ORENCIA (abatacept) – *Medical Billing Only*

Interleukin (IL) -1 Receptor Inhibitors

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

Interleukin (IL) -6 Receptor Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	ACTEMRA (tocilizumab) ACTPEN, SYRINGE
	ACTEMRA (tocilizumab) VIAL – *Medical Billing Only*
	KEVZARA (sarilumab)

Janus Kinase (JAK) Inhibitor

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

TNF Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
CIMZIA (certolizumab)	adalimumab-adaz
ENBREL (etanercept)	adalimumab-fkjp
HUMIRA (adalimumab)	AMJEVITA (adalimumab-atto)
SIMPONI (golimumab)	CYLTEZO (adalimumab-abdm)
	HADLIMA (adalimumab-bwwd)
	HULIO (adalimumab-fkjp)
	HYRIMOZ (adalimumab-adaz)
	IDACIO (adalimumab-aacf)

	SIMPONI (golimumab) ARIA – *Medical Billing Only*
	YUFLYMA (adalimumab-aaty)
	YUSIMRY (adalimumab-aqvh)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- Xeljanz IR 10mg, Xeljanz XR, Orencia IV Only: See Preferred Dosage Form Criteria
- The member must have had a 3-month trial of each of the following, as evidenced by paid claims and pharmacy printouts:
  - TNF Inhibitor
  - JAK inhibitor
  - T-cell Costimulation Blocker

Adult-Onset Still's Disease

Interleukin (IL) -1 Receptor Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
KINERET (anakinra)	ARCALYST (rilonacept)
	ILARIS (canakinumab) – *Medical Billing Only*

TNF Inhibitors

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

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a specialist in the area of the member's diagnosis.
- The member must have had a 3-month trial of each of Kineret, as evidenced by paid claims and pharmacy printouts:
- Remicade, infliximab, and Inflectra Only: See Preferred Dosage Form Criteria

Tumor Necrosis Factor Receptor Associated Periodic Syndrome

CLINICAL PA REQUIRED
ILARIS (canakinumab)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- The requested medication must be prescribed by, or in consult with, a specialist in the area of the member's diagnosis.
- Documentation must be attached to confirm one of the following:

- Genetic testing confirming pathogenic variants in the tumor necrosis factor receptor 1 (TNFR1) gene (TNF receptor superfamily member 1A, TNFRSF1A).
- Both of the following:
  - Elevated serum inflammatory markers (e.g., C-reactive protein (CRP), erythrocyte sedimentation rate (ESR) serum amyloid A(SAA))
  - History of recurrent fever, prominent myalgias, migratory rash, and periorbital edema

Osteoporosis

Antiresorptive Agents

Bisphosphonates

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
alendronate	ACTONEL (risedronate)
alendronate oral solution	ATELVIA (risedronate DR)
BONIVA (ibandronate) – *Medical Billing Only*	FOSAMAX (alendronate)
ibandronate – *Medical Billing Only*	FOSAMAX D (alendronate/vitamin D)
RECLAST (zolendronic acid) – *Medical Billing Only*	risedronate DR
risedronate IR	
zoledronic acid – *Medical Billing Only*	

Prior Authorization Criteria

- Risedronate DR Only: See Preferred Dosage Form Criteria

Calcitonins

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
calcitonin, salmon nasal spray++	calcitonin, salmon vial
MIACALCIN (calcitonin, salmon) VIAL++ – *Medical Billing Only*	

++ Clinically Non-Preferred: An FDA advisory panel concluded that the benefits of calcitonin do not outweigh its potential risks as an osteoporosis drug due to increased risk of malignancy. Bisphosphonates are more effective agents.

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- The member must be experiencing pain from an acute osteoporotic fracture

Estrogen Agonist/Antagonist

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
raloxifene	EVISTA (raloxifene)

Monoclonal Antibodies

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
PROLIA (denosumab) – *Medical Billing Only*	

Anabolic Agents

Parathyroid Hormone (PTH)

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

FORTEO (teriparatide) – *Brand Required*	teriparatide

PTH-related protein

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	TYMLOS (abaloparatide)

Monoclonal Anti-sclerostin Antibody

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
EVENITY (romosozumab-aqqg) – *Medical Billing Only*	

Prior Authorization Criteria

Initial Criteria – Approval Duration: 2 years (1 year for Evenity)

- The member must have a current BMD T-score ≤ -2.5 OR new fracture (as evidenced by submitted documentation) after a 6-month trial of each of the following, as evidenced by paid claims or pharmacy printouts:
  - alendronate or risedronate
  - teriparatide
- Member must be at high risk of fracture, confirmed by documentation of at least one of the following:
  - The member with a history of hip or vertebral fracture
  - The member with a T-score of −2.5 or lower at the femoral neck or spine
  - The member has a T-score of between −1.0 and −2.5 at the femoral neck or spine and a ten-year hip fracture risk of ≥3% as assessed with the FRAX
  - 10-year risk of a major osteoporosis-related fracture of ≥20% as assessed with the FRAX

Substance Use

Nicotine / Tobacco Dependence Treatment

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
bupropion SR	CHANTIX (varenicline)
nicotine lozenge	NICODERM CQ (nicotine) PATCH
nicotine patch	NICORETTE (nicotine polacrilex) GUM
nicotine polarcrilex gum	ZYBAN (bupropion SR)
NICOTROL (nicotine polacrilex) INHALER	
NICOTROL (nicotine polacrilex) SPRAY	
varenicline	

Concurrent Medication Required

- Short-acting nicotine agents (nasal spray, lozenge, inhaler, 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, inhaler, 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:
  - o Patient is abstinent from tobacco.
  - o Treatment duration is requested to be extended to 24 consecutive weeks.

Therapeutic Duplication

- Nicotine gum, lozenge, inhaler, 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	LUCEMYRA (lofexidine)
guanfacine	

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must have had a 30-day trial of each preferred agent, as evidenced by paid claims or pharmacy printouts.
- Clinical justification must be provided explaining why the member is unable to use the preferred agents (subject to clinical review).

Opioid Antagonist

PREFERRED AGENTS (NO PA REQUIRED)
naltrexone tablets
VIVITROL (naltrexone microspheres) INJECTION

Opioid Reversal Medications

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
KLOXXADO (naloxone) NASAL SPRAY	
nalmefene injection	
naloxone injection	
naloxone nasal spray	
NARCAN (naloxone) NASAL SPRAY *– Brand Co-Preferred*	
OPVEE (nalmefene) NASAL SPRAY	
ZIMHI (naloxone) SYRINGE	

Electronic Duration Verification

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

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

A. The previous dose has expired.
B. The dose was used by member for an opioid overdose. (In this case, it is recommended to follow up with prescriber to discuss frequency of use and potential regimen review/adjustments)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must have had a 30-day trial of each preferred agent, as evidenced by paid claims or pharmacy printouts.
- Clinical justification must be provided explaining why the member is unable to use the preferred agents (subject to clinical review)

Opioid Partial Agonist

Electronic Step Therapy Required

- A total of 56 days of Sublocade 300 mg must be paid within 75 days prior to Sublocade 100 mg date of service.

Therapeutic Duplication

- One strength of one medication is allowed at a time.
- Opioid partial agonists are not allowed with:
  - methadone
  - carisoprodol
  - opioids

- Opioid full agonist requested with member with history of opioid use disorder.
  - If 1 and 2 are met, please call for an override by calling provider relations at 1-800-755-2604 (chart notes will be required for requests beyond one fill)
    1. The request is for one of the following:
       - A one-time fill request where pain cannot be reasonably treated with non-opioid therapy (e.g., surgery)
       - A request exceeding a one-time fill and a treatment plan has been provided with expected duration of use and why non-opioid therapy is not an option (subject to clinical review) or a taper plan is provided.
    2. One of the following is met:
       - Prescribers of both opioid prescription and MOUD (medications for opioid use disorder) are aware of each other and agree to opioid therapy.
       - MOUD has been discontinued, and the prescriber of the opioid is aware of previous MOUD treatment and confirms opioid therapy is required.

- Opioid partial agonist injection + oral overlap

  Please call for an override by calling provider relations at 1-800-755-2604 to request a 2 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:

6. Opioid use and opioid use disorder in pregnancy. Committee Opinion No. 711. American College of Obstetricians and Gynecologists. Obstet Gynecol 2017;130:e81–94.
7. 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
8. 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 (while need for long-term transmucosal
    - 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 14 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

Obstetrics/Gynecology

Endometriosis Pain

CLINICAL PA REQUIRED
MYFEMBREE (relugolix, estradiol, and norethindrone acetate)
ORILISSA (elagolix)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- The member must have failed the following trials (A and B), as evidenced by paid claims or pharmacy printouts:

A. A 3-menstrual cycle trial of mefenamic acid or meclofenamate, celecoxib, ibuprofen 1800 mg/day or equivalent high dose NSAID
B. A 3-menstrual cycle trial of an oral estrogen-progestin or progestin contraceptives

Renewal Criteria – Approval Duration: 18 months

- Documentation must be submitted of improvement in pain score from baseline

Electronic Diagnosis Verification

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

Estrogens

Injectable

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
DELESTROGEN (estradiol valerate) INJECTION *– Brand Required*	estradiol valerate injection
DEPO-ESTRADIOL (estradiol cypionate) INJECTION	PREMARIN (estrogens, conjugated) INJECTION

Oral

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
estradiol tablet	ACTIVELLA (estradiol-norethindrone) TABLET
estradiol-norethindrone tablet	AMABELZ (estradiol-norethindrone) TABLET
norethindrone-ethinyl estradiol tablet	BIJUVA (estradiol-progesterone) CAPSULE
PREMARIN (estrogens, conjugated) TABLET	ESTRACE (estradiol) TABLET
PREMPHASE (estrogen, conj. M-progest) TABLET	FEMHRT (norethindrone-ethyl estradiol) TABLET
PREMPRO (estrogen, conj. M-progest) TABLET	FYAVOLV (norethindrone-ethinyl estradiol) TABLET
	MENEST (estrogens, esterified) TABLET
	JINTELI (norethindrone-ethinyl estradiol) TABLET
	MIMVEY (estradiol-norgestimate) TABLET
	PREFEST (estradiol-norgestimate) TABLET

Topical Gel/Spray

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

ELESTRIN (estradiol) GEL MDP	DIVIGEL (estradiol) GEL PACKET
EVAMIST (estradiol) SPRAY	estradiol gel packet

Topical Patch

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ALORA (estradiol) PATCH TWICE WEEKLY *- Brand Required*	CLIMARA (estradiol) PATCH WEEKLY
CLIMARA PRO (estradiol-levonorgestrel) PATCH - ONCE WEEKLY	DOTTI (estradiol) PATCH TWICE WEEKLY
COMBIPATCH (estradiol- norethindrone) PATCH - TWICE WEEKLY	estradiol patch twice weekly
estradiol patch weekly	LYLLANA (estradiol) PATCH TWICE WEEKLY
MENOSTAR (estradiol) PATCH ONCE WEEKLY	
MINIVELLE (estradiol) PATCH TWICE WEEKLY *- Brand Required*	
VIVELLE-DOT (estradiol) PATCH TWICE WEEKLY *- Brand Required*	

Vaginal

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
estradiol vaginal cream	ESTRACE (estradiol) CREAM
ESTRING (estradiol)	estradiol vaginal tablet
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

Mifepristone

Electronic Diagnosis Verification

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

Prior Authorization Form – Mifepristone

Initial Criteria – Approval Duration: 1 month

- Gestational age must be less than or equal to 70 days
- One of the following criteria must be met (A or B):

A. Pregnancy must have resulted from an act of rape or incest, and one of the following (I or II)

I. A written statement signed by the provider must be submitted stating that the rape or act of incest has been reported to the appropriate law enforcement agency, or in the case of a minor who is a victim of incest, to an agency authorized to receive child abuse and neglect reports and it must be indicated to whom the report was made.

II. A written statement signed by the member and the provider must be submitted stating that the member's pregnancy resulted from rape or incest and by professional judgement, the provider agrees with the statement.

B. Both of the following must be met (I and II)

I. The member must suffer from a physical disorder, physical injury, or physical illness, including a life-endangering physical condition caused by or arising from the pregnancy itself, that would as certified by a provider, place the member in danger of death unless an abortion is performed

II. A written statement signed by the provider must be provided indicating why, in the provider's professional judgement, the life of the member would be endangered if the fetus were carried to term

Nausea/Vomiting – Pregnancy

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
DICLEGIS (doxylamine/vitamin B6) – *Brand Required*	BONJESTA (doxylamine/vitamin B6)
Meclizine	doxylamine/vitamin B6
metoclopramide	
ondansetron	

Prior Authorization Criteria

Initial Criteria – Approval Duration: until due date

- Member's due date must be provided
- The prescriber must submit medical justification explaining why the member cannot use a preferred product (subject to clinical review)

Progesterone

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
progesterone capsule	

Electronic Diagnosis Verification

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

Uterine Fibroids

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
MYFEMBREE (relugolix, estradiol, and norethindrone acetate)	ORIAHNN (elagolix, estradiol, and norethindrone acetate)

Prior Authorization Criteria

Initial Criteria – Approval Duration: 6 months

- The member must have failed the following trials (A and B), as evidenced by paid claims or pharmacy printouts:

A. A 3-menstrual cycle trial of mefenamic acid or meclofenamate, celecoxib, ibuprofen 1800 mg/day or equivalent high dose NSAID
B. A 3-menstrual cycle trial of an oral estrogen-progestin or progestin contraceptives

Renewal Criteria – Approval Duration: 18 months

- Documentation must be submitted of improvement in pain score from baseline

Electronic Diagnosis Verification

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

Vaginal Infections

Bacterial Infections

Oral

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
metronidazole tablet	

Vaginal

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
CLEOCIN (clindamycin) SUPPOSITORY	CLEOCIN (clindamycin) CREAM
clindamycin cream	METROGEL-VAGINAL (metronidazole)
CLINDESSE (clindamycin) CREAM	VANDAZOLE (metronidazole) GEL
metronidazole gel	XACIATO (clindamycin phosphate) GEL
NUVESSA (metronidazole) GEL	

Fungal Infections

Oral

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
fluconazole tablet	BREXAFEMME (ibrexafungerp) TABLETS
SOLOSEC (secnidazole) GRANULE PACKET	VIVJOA (oteseconazole) CAPSULES
tinidazole tablet	

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)

Preferred Dosage Forms List:

Prior Authorization Criteria

Initial Criteria – Approval Duration: 12 months

- The member must meet FDA-approved label for use (e.g., use outside of studied population will be considered investigational)
- 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
	COLCRYS (colchicine) TABLET
	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 11516, 49502	AUVI-Q (epinephrine)
EPIPEN (epinephrine) – *Brand Co-Preferred*	epinephrine – labeler 00093
EPIPEN (epinephrine) JUNIOR– *Brand Co-Preferred*	SYMJEPI (epinephrine)

Electronic Duration Verification

- 4 doses are covered every 60 days without an override

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

A. The previous dose has expired
B. The dose was used by member for an anaphylactic episode

gabapentin

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
gabapentin	GRALISE (gabapentin)
	HORIZANT (gabapentin)

Jadenu (deferasirox)

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
deferasirox tablet for suspension	EXJADE (deferasirox tablet for suspension)
deferasirox tablets	deferasirox sprinkle
	JADENU (deferasirox) SPRINKLE
	JADENU (deferasirox) TABLETS

Kits

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
FDA approved products prescribed separately	CAMPHOTREX 4%-10% ROLL-ON G (menthol/camphor)
	CENTANY AT (mupirocin)
	CICLOPIROX (ciclopirox/urea/camphor/methol)
	CICLODAN (ciclopirox/urea/camphor/methol)
	CICLODAN (ciclopirox/skin cleanser 28)
	CLINDACIN ETZ (clindamycin phos/skin clnsr 19)
	CLINDACIN PAC (clindamycin phos/skin clnsr 19)
	CLINDAVIX (clindamycin/dimethacone/zinc oxide)
	CLOBETEX (clobetasol/desloratadine)
	CYCLOPAK (cyclobenzaprine/lidocaine/prilocaine/glycerine)
	DERMACINRX ARM PAK (lidocaine/dimethacone)
	DERMACINRX LEXITRAL PHARMAP (diclofenac/capsicum oleoresin)

	DERMACINRX PHN PAK (lidocaine/emollient cmb No. 102)
	DERMACINRX SILAPAK (triamcinolone/dimeth/silicone)
	DERMACINRX SILAZONE (triamcinolone/silicones)
	DERMACINRX SURGICAL PHARMAP (mupirocin/chlorhexidine/dimeth)
	DERMACINRX THERAZOLE PAK (clotrimazole/betameth dip/zinc)
	DERMACINRX ZRM PAK (lidocaine/dimethicone)
	DERMALID 5% PATCH (lidocaine/elastic bandage)
	ELLZIA PAK (triamcinolone/dimethicone)
	ESOMEP-EZS KIT (esomeprazole mag/glycerin)
	ECONASIL (econazole/gauze/silicone)
	FLUOPAR (fluocinonide/dimethacone)
	FLUOVIX PLUS (fluocinonide/silicone,adhesive)
	GABACAINE KIT (gabapentin/lidocaine)
	INAVIX (diclofenac/capsaicin)
	INFAMMACIN (diclofenac/capsicum)
	KETODAN (ketoconazole/skin cleanser 28)
	LIDOPURE PATCH 5% COMBO PAC (lidocaine/kinesiology tape)
	LIDOTIN (gabapentin/lidocaine/silicone)
	LIPRITIN (gabapentin/lidocaine/prilocaine/dressing)
	LOPROX (ciclopirox/skin cleanser No. 40)
	MIGRANOW KIT (sumatriptan/menthol/camphor)
	MORGIDOX (Doxycycline/skin cleanser No. 19)
	NAPROTIN (naproxen/capsicum)
	NOPIOID-TC KIT (cyclobenzaprine/lidocaine/menthaine)
	NUVAKAAN KIT (lidocaine/prilocaine/silicone)
	NUSURGEPAK (mupirocin/chlorhexidine/dimethacone)
	NUTRIARX (Triamcinolone/dimethacone/silicone)
	PRILO PATCH KIT (lidocaine/prilocaine)
	PRIZOTRAL II (lidocaine/prilocaine/lidocaine)
	PRO DNA MEDICATED COLLECTION (lidocaine/glycerin)
	SALEX (salicylic acid/ceramide comb 1) CREAM KIT
	SALEX (salicylic acid/ceramide comb 1) LOTION KIT
	SILAZONE-II KIT (triamcinolone aceton/silicones)
	SOLARAVIX (Diclofenac/silicone, adhesive)
	SUMADAN KIT (sulfacetamide/sulfur/cleansr23)
	SUMAXIN CP KIT (sulfacetamide/sulfur/cleansr23)
	TICANASE KIT (fluticasone/sodium chloride/sodium bicarbonate)
	TRIVIX (Triamcinolone/dimethacone/silicone)
	TRIXYLITRAL (diclofenac/lidocaine/tape)
	XRYLIX 1.5% KIT (diclofenac/kinesiology tape)
	ZILACAINE PATCH 5% COMBO PA (lidocaine/silicone, adhesive)

lactulose

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
CONSTULOSE (lactulose) solution	KRISTALOSE (lactulose) PACKET
ENULOSE (lactulose) solution	lactulose packet
lactulose solution	

levothyroxine

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
levothyroxine tablet	THYQUIDITY (levothyroxine) ORAL SOLUTION
ERMEZA (levothyroxine) SOLUTION	levothyroxine capsule
TIROSINT (levothyroxine) 13 mcg, 25 mcg, 50 mcg, 75 mcg, 88 mcg, 100 mcg, 112 mcg, 125 mcg, 137 mcg, and 150 mcg CAPSULE – *Brand Required*	SYNTHROID (levothyroxine) TABLET
	TIROSINT (levothyroxine) 175 mcg, and 200 mcg CAPSULE
	TIROSINT (levothyroxine) SOLUTION

metformin

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
metformin ER	FORTAMET (metformin)
RIOMET (metformin) ORAL SOLUTION	GLUMETZA (metformin)
RIOMET ER (metformin) ORAL SOLUTION	metformin ER gastric retention 24 hr
	metformin ER osmotic

methotrexate

Required trial duration: 6 weeks

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
methotrexate	OTREXUP (methotrexate) AUTO-INJECTOR
XATMEP (methotrexate) SOLUTION	RASUVO (methotrexate) AUTO-INJECTOR
	REDITREX (methotrexate) SYRINGE
	TREXALL (methotrexate) TABLET

montelukast

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
montelukast chewable tablets	montelukast granules
montelukast tablets	

Electronic Age Verification

- Montelukast granules are preferred for ages 1 and under

mupirocin

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
mupirocin ointment	mupirocin calcium cream

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

Emflaza: See Emflaza Criteria on this document

Tarpeyo: See Tarpeyo Criteria on this document

Rayos required trial duration: 12 weeks with 2 AM dosing of prednisone

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
budesonide 3 mg EC capsules	ALKINDI (hydrocortisone) SPRINKLE CAPSULE
cortisone	budesonide 9 mg ER tablet
dexamethasone	EMFLAZA (deflazacort)
hydrocortisone	HEMADY (dexamethasone)
methylprednisone	MILLIPRED (prednisolone)
prednisolone sodium phosphate 5 mg/5 ml, 15 mg/5 ml, 25 mg/5 ml	ORTIKOS (budesonide)
prednisone solution	prednisone intensol
prednisone tablets	prednisolone sodium phosphate ODT

	prednisolone sodium phosphate 10 mg/5 ml, 20 mg/5 ml solution
	RAYOS (prednisone)
	TAPERDEX (dexamethasone)
	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

1. For coverage of blood glucose monitoring devices for those not meeting electronic concurrent medication required criteria above, the member must have one of the following (A or 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
      5. The member has recurrent hypoglycemia due and CGM is prescribed by or in consult with, a medical geneticist or an endocrinology specialist (subject to clinical review)

The ADA guidelines point out the lack of clinical utility and cost-effectiveness of routine Self-Monitoring of Blood Glucose (SMBG) in non-insulin treated members. Both the Society of General Internal Medicine and the Endocrine Society recommend against routine SMBG for type 2 diabetes members not on insulin or agents that cause hypoglycemia.

Test Strips

Quantity Limits

- 200 test strips are covered every 30 days

Manufacturer Name	NDC	Product Description
LifeScan Inc.	53885-0244-50	OneTouch Ultra Blue
LifeScan Inc.	53885-0245-10	OneTouch Ultra Blue
LifeScan Inc.	53885-0270-25	One Touch Verio Test Strip
LifeScan Inc.	53885-0271-50	One Touch Verio Test Strip
LifeScan Inc.	53885-0272-10	One Touch Verio Test Strip
LifeScan Inc.	53885-0994-25	OneTouch Ultra Blue
Ascensia Diabetes Care	00193-7080-50	Contour Blood Glucose Test Strips
Ascensia Diabetes Care	00193-7090-21	Contour Blood Glucose Test Strips
Ascensia Diabetes Care	00193-7311-50	Contour Next Blood Glucose Test Strips
Ascensia Diabetes Care	00193-7312-21	Contour Next Blood Glucose Test Strips

Meters

Quantity Limits

- 1 meter is covered every 365 days

Manufacturer Name	NDC	Product Description
LifeScan Inc.	53885-0044-01	OneTouch Verio Flex Blood Glucose Meter
LifeScan Inc.	53885-0046-01	OneTouch Ultra 2 Blood Glucose Meter
Ascensia Diabetes Care	00193-7553-01	Contour Next EZ Blood Glucose Meter
Ascensia Diabetes Care	00193-7825-01	Contour Next One Blood Glucose Monitor
Ascensia Diabetes Care	00193-7917-01	Contour Next Gen Blood Glucose Monitor
Ascensia Diabetes Care	00193-9545-01	Contour Blood Glucose Meter
Ascensia Diabetes Care	00193-9628-01	Contour Next EZ Blood Glucose Meter

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)

Syringes

Manufacturer Name	NDC	Product Description
Becton Dickinson & Company	08290-3284-11	BD syringe and needle,insulin,1mL
Becton Dickinson & Company	08290-3284-18	BD syringe and needle,insulin,1mL
Becton Dickinson & Company	08290-3284-31	BD syring-needl,disp,insul,0.3 mL
Becton Dickinson & Company	08290-3284-38	BD syring-needl,disp,insul,0.3 mL
Becton Dickinson & Company	08290-3284-40	BD syrge-ndl,ins 0.3 mL half mark
Becton Dickinson & Company	08290-3284-66	BD syringe-needle,insulin,0.5 mL
Becton Dickinson & Company	08290-3284-68	BD syringe-needle,insulin,0.5 mL
Becton Dickinson & Company	08290-3267-30	BD syringe,insul U-500,ndl,0.5mL
Becton Dickinson & Company	08290-3249-06	BD syring-needl,disp,insul,0.3 mL
Becton Dickinson & Company	08290-3249-07	BD syringe-needle,insulin,0.5 mL
Becton Dickinson & Company	08290-3249-08	BD syringe and needle,insulin,1mL
Becton Dickinson & Company	08290-3249-09	BD syring-needl,disp,insul,0.3 mL
Becton Dickinson & Company	08290-3249-10	BD syringe-ndl,ins 0.3 mL half mark
Becton Dickinson & Company	08290-3249-11	BD syringe-needle,insulin,0.5 mL
Becton Dickinson & Company	08290-3249-12	BD syringe and needle,insulin,1mL

Ultimed Inc.	08222-0941-93	Ulticare syringe and needle,insulin,1mL
Ultimed Inc.	08222-0741-95	Ulticare syringe and needle,insulin,1mL
Ultimed Inc.	08222-0931-58	Ulticare syringe and needle,insulin,1mL
Ultimed Inc.	57515-0093-15	Ulticare syringe and needle,insulin,1mL
Ultimed Inc.	08222-0921-99	Ulticare syringe and needle,insulin,1mL
Ultimed Inc.	57515-0092-19	Ulticare syringe and needle,insulin,1mL
Ultimed Inc.	08222-0945-99	Ulticare syringe-needle,insulin,0.5 mL
Ultimed Inc.	08222-0745-91	Ulticare syringe-needle,insulin,0.5 mL
Ultimed Inc.	08222-0943-91	Ulticare syring-needl,disp,insul,0.3 mL
Ultimed Inc.	57515-0094-39	Ulticare syring-needl,disp,insul,0.3 mL

Continuous Glucose Monitors (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

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 (subject to clinical review)
- 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 at provider office visits, be used to adjust/modify medication regimen to 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):
  1. 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.

2. The member is currently Humulin R U-500 or an insulin pump.
3. 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:
    - CGM data must have been reviewed to evaluate/adjust therapy.
  - *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.

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.

Does ND Medicaid cover Dexcom G6 for members in Long Term Care facilities?

- If a member has Medicare Part B, Medicare Part B will need to be billed primary and ND Medicaid may cover the remainder as a crossover claim with medical billing.
- If a member does not have Medicare Part B, an override will need to be obtained for coverage.
- In all cases, the member must meet prior authorization criteria for coverage.

How is CGM billed for Medicaid Expansion members?

- Dexcom will need to be billed to ND Medicaid for Dexcom 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.

Billing FAQ

If I bill Medtronics Guardian sensors under the code A9276 on the medical benefit, will this still be covered?

- No, the code will only be covered for members with primary insurance plans that require CGM to be billed on the medical side. Members will need to be converted to Dexcom billed on the pharmacy side to obtain ND Medicaid coverage.

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-preferred CGM if the copay is nominal. Documentation of the exclusion must be submitted with the prior authorization request.
- If primary insurance does cover Dexcom, 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

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

Prior Authorization Criteria

Tubeless Insulin Pump (Omnipod) Prior Authorization Form

Initial Criteria – Approval Duration: 12 months

- The member must have Diabetes Type 1
- The member must be less than 21 years old.
- The member must be receiving multiple daily injections of insulin (at least 3 injections per day)
- The member has documented frequency of blood glucose-testing an average of 4 times per day or use of CGM during the 2 months prior to request.
- The prescriber must attest to all the following:
  1. The member will maintain regular provider visits to review glycemic control data every 3-6 months.
  2. The member has been adherent to provider appointments for past 6 months.
  3. The member will receive Omnipod training from Omnipod System Trainer or a healthcare provider.
  4. The member must have received diabetic education within past year.
- The prescriber must provide most recent A1C and/or Time-in-Range percentage.
- The member had not received a tubed insulin pump within the past 4 years or must be experiencing elevated glucose levels from disconnecting due to contact or swimming sports.

Renewal Criteria – Approval Duration: 12 months

- The member must be less than 21 years old unless request is for continuation of coverage where ND Medicaid has previously paid for Omnipod
- The most recent A1C and/or Time-in-Range percentage must be submitted.
- The member has documented frequency of blood glucose-testing an average of 4 times per day or use of CGM during the 2 months prior to request.
- Omnipod data has been reviewed with member as evidenced by submitted progress note within the past 6 months.
- The member must be using a compatible rapid acting insulin.

Omnipod Coverage FAQ

For replacement inquiries or troubleshooting please contact Insulet Customer Care team at 1-800-591-3455 or visit https://na.myomnipod.com/contact.

Does ND Medicaid cover insulin pens, syringes, or vials if Omnipod is discontinued?

- Transition should be coordinated with diabetic specialist or educator.
- Current vials of rapid acting insulin should be exhausted before switching to pens. See Insulin category for a list of preferred products.
- Current supply of pods should be exhausted prior to switching to injections.

Does ND Medicaid cover additional pods or Personal Diabetes Manager (PDM) if mine is faulty or broken?

- For replacement inquiries or troubleshooting please contact Insulet Customer Care team at 1-800-591-3455 or visit https://na.myomnipod.com/contact.

Does ND Medicaid cover additional pods, Personal Diabetes Manager (PDM), replacement USB cords or rechargeable batteries if mine is lost or stolen?

- For replacement inquiries or troubleshooting please contact Insulet Customer Care team at 1-800-591-3455 or visit https://na.myomnipod.com/contact.
- PDMs, USB cords, and rechargeable batteries may be replaced once every 365 days.
- Pods are not replaceable.

Will ND Medicaid cover Omnipod through medical billing?

- ND Medicaid requires Omnipod to be billed through pharmacy NCPDP D.0 billing.

How is Omnipod billed for Medicaid Expansion and Special Health Services (SHS) ND Medicaid eligible members?

- Omnipod will need to be billed to ND Medicaid for Medicaid Expansion members.
- Omnipod will need to be billed to ND Medicaid for SHS members who are eligible for ND Medicaid. The group will need to be changed from the SHS group to the ND Medicaid group.
- ND Medicaid has pre-emptively entered initial prior authorizations for SHS members utilizing Omnipod for 1 year. ND Medicaid renewal prior authorization criteria will need to be met for coverage continuation beyond the grandfathering period.

Does ND Medicaid cover Omnipod for members in Long Term Care facilities?

- If a member is eligible for Medicare, Medicare Part D will need to be billed primary.
- If member is not eligible for Medicare, the member must meet prior authorization criteria for coverage.

Does ND Medicaid cover Omnipod if member has primary insurance, but it does not cover tubeless pumps?

- ND Medicaid may cover Omnipod as a primary payer if insulin pumps are wholly excluded from the primary insurance benefit. Documentation stating the exclusion from the primary insurance must be submitted with the prior authorization request.
- ND Medicaid will not cover Omnipod as a primary payer if a prior authorization is denied for medical necessity by the primary insurance or primary insurance only covers tubed pumps.

Will ND Medicaid cover Omnipod if member meets primary insurance prior authorization criteria, but does not meet ND Medicaid prior authorization criteria?

- ND Medicaid will not cover Omnipod if ND Medicaid prior authorization criteria is not met, regardless of approval status with primary insurance. Under rare circumstances, exceptions may be made if the copay is nominal as long as the member maintains primary insurance coverage with a Omnipod benefit.

Appendix A: Concurrent Antipsychotics

Concurrent Oral Antipsychotics

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.

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.

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.

Concurrent Long-Acting Injectable and Oral Antipsychotics

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.

During the titration period (first 3 months of treatment) or first request:

Approval: A one-time 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 of the same active ingredient for 6 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 one-time override may be considered for breakthrough symptoms while optimizing dose
- The prescriber must submit documentation of consistent breakthrough symptoms
- If breakthrough symptoms are occurring earlier than 75% of recommended interval, the prescriber must provide justification that all alternative active ingredient options have been trialed or ruled out as monotherapy for member
- The prescriber must indicate a follow up period for a trial taper of the oral supplementation
- The prescriber must indicate when the long-acting medication would be considered a failure
- The following patient considerations must be assessed:
    - New starts and stops of interacting medications
    - Proper injection technique
        - Insufficient mixing prior to injection
        - Lack of deep intramuscular injection
        - Syringe malfunction/defect
    - Site of administration
    - Issues related to injection appointment adherence (e.g., transportation)
        - Non-emergent transportation to pharmacy and medical appointments can be coordinated through the Human Service Zone.
    - Non-pharmacological reasons for exacerbations
        - Substance use
        - Psychosocial stressors

Renewal: An authorization of oral supplemental of the same active ingredient for 12 months

- The prescriber must submit documentation of benefit and controlled symptoms with oral supplementation
- The patient must have a trial taper of oral supplementation with recurrence of symptoms

Appendix B: Antidepressant Cross Tapering:

Selective Serotonin Reuptake Inhibitors (SSRIs) switched to:

Selective Serotonin Reuptake Inhibitors (SSRIs)

Cross Taper is NOT covered

Direct switch between SSRIs is typically well-tolerated as SSRIs overlap in their mechanism of action.

Serotonin Norepinephrine Reuptake Inhibitors (SNRIs)

Cross Taper is generally NOT covered, case by case coverage may be provided

Direct switch between SNRI and SSRI is typically well-tolerated because both SNRIs and SSRIs have strong serotonergic properties, with the following exceptions:

- Patient switching from high dose SSRIs, cross tapering may be of benefit
- Patient switching from fluoxetine or paroxetine to duloxetine or venlafaxine should start SNRI at a low dose. Fluoxetine and paroxetine inhibit the metabolization of duloxetine and venlafaxine.

Tricyclic Antidepressants

Cross Taper is covered

Cross tapering is recommended. Tricyclic antidepressants should be started at a low dose especially when discontinuing fluoxetine, fluvoxamine, and paroxetine. These SSRIs can inhibit the metabolism of tricyclic antidepressants resulting in higher levels of tricyclic antidepressants. Tricyclic antidepressants can be fatal in overdose. Most SSRIs will clear the system within 5 days, but fluoxetine will persist for up to 5 weeks.

Monoamine oxidase inhibitor (MAOIs)

Cross Taper is NOT covered

Cross tapering is not recommended and can result in serotonin syndrome or severe hypertensive crisis. A washout period of two weeks is recommended between last dose of SSRI and MAOI except in the case of fluoxetine, where a 5-week washout period is recommended.

Other Antidepressants

Cross Taper is covered

All other Antidepressants:

Cross Taper is covered

Appendix C: Prior Authorization Review Dates

Date	Category
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
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/PCSK9 inhibitors
09/02/2015	injectable anticoagulants
09/02/2015	Akynzeo
09/02/2015	Nuvessa
09/02/2015	Cholbam
06/03/2015	Otezla
06/03/2015	Xtoro
06/03/2015	Hemangeol
06/03/2015	Lemtrada
06/03/2015	agents used to treat idiopathic pulmonary fibrosis
06/03/2015	GLP-1 receptor agonists
06/03/2015	topical therapies for onychomycosis
12/03/2014	testosterone products
12/03/2014	phosphate binders
12/03/2014	Zontivity
12/03/2014	Evzio
09/03/2014	Northera

09/03/2014	Oral Allergen Extracts
06/02/2014	Cathflo
06/02/2014	Intranasal Cyanocobalamin Products
06/02/2014	Luzu
06/02/2014	Noxafil
06/02/2014	Bethkis
03/03/2014	Statins
03/03/2014	Vecamyl
12/03/2013	Brisdelle
12/03/2013	Nitroglycerin Lingual Spray/Sublingual Tablets
12/03/2013	Agents Used to Treat COPD
12/03/2013	Epinephrine Auto-Injection Devices
12/03/2013	Pulmozyme
09/09/2013	Rayos
09/09/2013	Diclegis
09/09/2013	Sitavig
09/09/2013	Onmel
09/09/2013	Giazo
06/03/2013	Fulyzaq
06/03/2013	Xeljanz
03/11/2013	Genitourinary Smooth Muscle Relaxants
03/11/2013	Agents Used to Treat Multiple Sclerosis
12/03/2012	Actinic Keratosis
12/03/2012	Moxeza
09/17/2012	Kalydeco
09/17/2012	Kuvan
09/17/2012	Elaprase
06/04/2012	Lorzone
06/04/2012	Provigil
06/04/2012	Kapvay
06/04/2012	Dexpak/Zemapak
06/04/2012	Xifaxan
06/04/2012	Vanos
03/05/2012	Pulmonary Arterial Hypertension Agents
03/05/2012	Topical Acne Agents
03/05/2012	Benign Prostatic Hyperplasia Agents Brendan
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

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

Diuretics

Diuretics - Loop

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

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

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

Diuretics – Potassium Sparing

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

Diuretics - Aldosterone Antagonist

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

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

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

Menopause – Vasomotor Symptoms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
citalopram	BRISDELLE (paroxetine mesylate)
clonidine	paroxetine mesylate 7.5mg capsules
desvenlafaxine	VEOZAH (fezolinetant)
escitalopram	
estrogen products	
gabapentin	
oxybutynin	
paroxetine hydrochloride tablets	
venlafaxine	

Prior Authorization Criteria

Initial Criteria - Approval Duration: 12 months

- BOTH of the following must be met (1 and 2):
  1. One of the following must be met (a or b):
     a. The member must have failed a 90-day trial of estrogen therapy, as evidenced by paid claims or pharmacy printouts
     b. The member has prior history of stroke, myocardial infarction, venous thromboembolism, coronary artery disease, or breast cancer.
  2. The member must have failed a 90-day trial of venlafaxine, as evidenced by paid claims or pharmacy printouts
- 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.

NORTH DAKOTA MEDICAID
RETROSPECTIVE DRUG UTILIZATION REVIEW
CRITERIA RECOMMENDATIONS
4TH QUARTER 2023

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

1. Fedratinib / Overuse _____ _____

Alert Message: Inrebic (fedratinib)may be over-utilized. The recommended dosage of fedratinib is 400 mg taken orally once daily.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Fedratinib		CKD Stage 4

Max Dose: 400mg/day

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Inrebic Prescribing Information, May 2023, Bristol-Myers Squibb.

2. Fedratinib / Therapeutic Appropriateness _____ _____

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

Drugs/Diseases

Util A	Util B	Util C
Fedratinib		

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Inrebic Prescribing Information, May 2023, Bristol-Myers Squibb.

3. Fedratinib / Thiamine Deficiency Box Warning _____ _____

Alert Message: Serious and fatal encephalopathy, including Wernicke's, has occurred in patients treated with Inrebic (fedratinib). Wernicke's encephalopathy is a neurologic emergency. Assess thiamine levels in all patients prior to starting fedratinib, periodically during treatment, and as clinically indicated. Do not start fedratinib in patients with thiamine deficiency; replete thiamine prior to treatment initiation. If encephalopathy is suspected, immediately discontinue fedratinib and initiate parenteral thiamine. Monitor until symptoms resolve or improve and thiamine levels normalize.

Drugs/Diseases

Util A	Util B	Util C
Fedratinib	Thiamine Deficiency	

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Inrebic Prescribing Information, May 2023, Bristol-Myers Squibb.

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

4. Fedratinib / Severe Hepatic Impairment _____ _____

Alert Message: Avoid use of Inrebic (fedratinib) in patients with severe hepatic impairment. Fedratinib pharmacokinetics has not been evaluated in patients with severe hepatic impairment (total bilirubin > 3 times ULN and any AST).

Drugs/Diseases

Util A	Util B	Util C
Fedratinib	Cirrhosis	
	Hepatic Failure	

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Inrebic Prescribing Information, May 2023, Bristol-Myers Squibb.

5. Fedratinib / Severe Renal Impairment _____ _____

Alert Message: In pharmacokinetic drug studies, patients with severe renal impairment receiving Inrebic (fedratinib) experienced a 1.9-fold increase in the AUCinf of fedratinib compared to that in subjects with normal renal function. Reduce Inrebic (fedratinib) dose to 200 mg once daily in patients with severe renal impairment (creatinine clearance (CLcr 15 mL/min to 29 mL/min as estimated by Cockcroft-Gault equation).

Drugs/Diseases

Util A	Util B	Util C (Include)
Fedratinib		CKD Stage 4

Max Dose: 200 mg/day

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Inrebic Prescribing Information, May 2023, Bristol-Myers Squibb.

6. Fedratinib / Strong CYP3A4 Inhibitors _____ _____

Alert Message: Coadministration of Inrebic (fedratinib) with a strong CYP3A4 inhibitor increases fedratinib exposure. The dose of fedratinib when administering with strong CYP3A4 inhibitors should be reduced to 200 mg once daily. Increased exposure may increase the risk of fedratinib-related adverse reactions. Consider alternative therapies that do not strongly inhibit CYP3A4 activity.

Drugs/Diseases

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

Max Dose: 200 mg/day

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Inrebic Prescribing Information, May 2023, Bristol-Myers Squibb.

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

7. Fedratinib / Strong & Moderate CYP3A4 Inducers _____ _____

Alert Message: Coadministration of Inrebic (fedratinib) with a strong or moderate CYP3A4 inducer can decrease fedratinib exposure. Decreased exposure may reduce the effectiveness of fedratinib. Avoid fedratinib with strong and moderate CYP3A4 inducers.

Drugs/Diseases

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

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Inrebic Prescribing Information, May 2023, Bristol-Myers Squibb.

8. Fedratinib / Dual CYP3A4 and CYP2C19 inhibitor _____ _____

Alert Message: In clinical drug studies, the coadministration of Inrebic (fedratinib) with a dual CYP3A4 and CYP2C19 inhibitor resulted in increased fedratinib exposure. Increased fedratinib exposure may increase the risk of fedratinib-related adverse reactions. Due to the potential for increased exposure, patients taking concomitant dual CYP3A4 and CYP2C19 inhibitors require more intensive safety monitoring and, if necessary, dose modifications of fedratinib based on adverse reactions.

Drugs/Diseases

Util A	Util B	Util C
Fedratinib	Fluconazole	
	Fluvoxamine	

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Inrebic Prescribing Information, May 2023, Bristol-Myers Squibb.

9. Fedratinib / Pregnancy / Pregnancy Negating _____ _____

Alert Message: There are no available data on Inrebic (fedratinib) use in pregnant women to evaluate for a drug-associated risk of major birth defects, miscarriage or adverse maternal or fetal outcomes. In animal reproduction studies, oral administration of fedratinib to pregnant rats during organogenesis at doses considerably lower than the recommended human daily dose of 400 mg/day resulted in adverse developmental outcomes. Consider the benefits and risks of fedratinib for the mother and possible risks to the fetus when prescribing fedratinib to a pregnant woman.

Drugs/Diseases

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

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Inrebic Prescribing Information, May 2023, Bristol-Myers Squibb.

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

10. Fedratinib / Lactation _____ _____

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

Drugs/Diseases

Util A	Util B	Util C
Fedratinib	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Inrebic Prescribing Information, May 2023, Bristol-Myers Squibb.

11. Fedratinib / Non-adherence _____ _____

Alert Message: Based on refill history, your patient may be under-utilizing Inrebic (fedratinib). 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
Fedratinib		

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.
Greer JA, Amoyal N, Nisotel L, et al. Systemic Review of Adherence to Oral Antineoplastic Therapies. The Oncologist. 2016;21:354-376.
Barillet M, Prevost V, Joly F, Clarisse B. Oral Antineoplastic Agents: How do We Care About Adherence? Br J Clin Pharmacol. 2015;80(6):1289-1302. doi:10.1111/bcp.1273

12. Talazoparib / Overutilization (Prostate Cancer) _____ _____

Alert Message: Talzenna (talazoparib) may be over-utilized. The recommended dosage of talazoparib for the treatment of HRR gene-mutated mCRPC is 0.5 mg taken orally once daily in combination with enzalutamide until disease progression or unacceptable toxicity.

Drugs/Diseases

Util A	Util B	Util C (Include)
Talazoparib		Prostate Cancer

Max Dose: 0.5 mg/day
Gender: Male

References:
Talzenna Prescribing Information, June 2023, Pfizer, Inc.

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

13. Talazoparib / Prostate Cancer / Severe Renal Impairment _____ _____

Alert Message: Talzenna (talazoparib) may be over-utilized. For patients with prostate cancer with severe renal impairment (CLcr 15 - 29 mL/min), the recommended dose of talazoparib is 0.25 mg once daily in combination with enzalutamide. Patients with moderate or severe renal impairment have a higher exposure to talazoparib than patients with normal renal function. Talazoparib has not been studied in patients requiring hemodialysis.

Drugs/Diseases

Util A	Util B	Util C (Include)
Talazoparib	Prostate Cancer	CKD Stage 4

Max Dose: 0.25 mg/day
Gender: Male

References:
Talzenna Prescribing Information, June 2023, Pfizer, Inc.

14. Talazoparib / Prostate Cancer – Moderate Renal Impairment _____ _____

Alert Message: Talzenna (talazoparib) may be over-utilized. For patients with prostate cancer with moderate renal impairment (CLcr 30 - 59 mL/min), the recommended dose of talazoparib is 0.35 mg once daily in combination with enzalutamide. Patients with moderate or severe renal impairment have a higher exposure to talazoparib than patients with normal renal function. Talazoparib has not been studied in patients requiring hemodialysis.

Drugs/Diseases

Util A	Util B	Util C (Include)
Talazoparib	Prostate	CKD Stage 3

Max Dose: 0.35 mg/day
Gender: Male

References:
Talzenna Prescribing Information, June 2023, Pfizer, Inc.

15. Talazoparib / Breast Cancer - Severe Renal Impairment _____ _____

Alert Message: Talzenna (talazoparib) may be over-utilized. For patients with breast cancer and severe renal impairment (CLcr 15 - 29 mL/min), the recommended dose of talazoparib is 0.5 mg once daily. Patients with moderate or severe renal impairment have a higher exposure to talazoparib than patients with normal renal function. Talazoparib has not been studied in patients requiring hemodialysis.

Drugs/Diseases

Util A	Util B	Util C (Include)
Talazoparib	Breast Cancer	CKD Stage 4

Max Dose: 0.5 mg/day

References:
Talzenna Prescribing Information, June 2023, Pfizer, Inc.

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

16. Brexpiprazole 4 mg / Overutilization – Alzheimer's w/ Agitation _____ _____

Alert Message: Rexulti (brexpiprazole) may be over-utilized. The maximum recommended daily dose of brexpiprazole in patients with agitation associated with dementia due to Alzheimer's disease is 3 mg once daily.

Drugs/Diseases

Util A	Util B	Util C (Include)
Brexpiprazole 4 mg		Alzheimer's Disease

Max Dose: 3 mg/day

References:
Rexulti Prescribing Information, May 2023, Otsuka American Pharmaceutical, Inc.
Clinical Pharmacology, 2023 Elsevier/Gold Standard.

17. Brexpiprazole 3 mg & 4 mg / Hepatic Impairment / Alzheimer's _____ _____

Alert Message: Rexulti (brexpiprazole) may be over-utilized. The maximum recommended dosage of brexpiprazole in patients with agitation associated with dementia due to Alzheimer's disease with moderate to severe hepatic impairment is 2 mg once daily.

Drugs/Diseases

Util A	Util B	Util C (Include)
Brexpiprazole 3 mg & 4 mg	Hepatic Impairment	Alzheimer's Disease

Max Dose: 2 mg/day

References:
Rexulti Prescribing Information, May 2023, Otsuka American Pharmaceutical, Inc.
Clinical Pharmacology, 2023 Elsevier/Gold Standard.

18. Brexpiprazole 3 mg & 4 mg / Renal Impairment / Alzheimer's _____ _____

Alert Message: Rexulti (brexpiprazole) may be over-utilized. The maximum recommended dosage of brexpiprazole in patients with agitation associated with dementia due to Alzheimer's disease with creatinine clearance CrCl < 60 ml/minute is 2 mg once daily.

Drugs/Diseases

Util A	Util B	Util C (Include)
Brexpiprazole 3 mg & 4 mg	CKD Stage 3, 4, & 5 ESRD	Alzheimer's Disease

Max Dose: 2 mg/day

References:
Rexulti Prescribing Information, May 2023, Otsuka American Pharmaceutical, Inc.
Clinical Pharmacology, 2023 Elsevier/Gold Standard.

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

19. Linaclotide / Overuse - Functional Constipation _____ _____

Alert Message: Linzess (linaclotide) may be over-utilized. The recommended dosage of linaclotide for the treatment of functional constipation in pediatric patients 6 to 17 years of age is 72 mcg orally once daily.

Drugs/Diseases

Util A	Util B	Util C (Include)
Linaclotide		Functional Constipation

Max Dose: 72 mcg/day
Age Range: 6 – 17 yoa

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Linzess Prescribing Information, June 2023, AbbVie Inc.

20. Odevixibat / Overuse – Alagille Syndrome _____ _____

Alert Message: Bylvay (odevixibat) may be over-utilized. The recommended dosage of odevixibat for the treatment of cholestatic pruritis in patients 12 months of age and older with Alagille syndrome is 120 mcg/kg once daily in the morning with a meal, not to exceed a maximum dose of 7200 mcg/day.

Drugs/Diseases

Util A	Util B	Util C (Include)
Odevixibat		Alagille Syndrome

Max Dose: 7200 mcg/day

References:
Bylvay Prescribing Information, June 2023, Albireo Pharm, Inc.
Clinical Pharmacology, 2023 Elsevier/Gold Standard.

21. Zavegepant / Overuse _____ _____

Alert Message: Zavzpret (zavegepant) may be over-utilized. The recommended dose of zavegepant is 10 mg given as a single spray in one nostril, as needed. The maximum dose that may be given in a 24-hour period is 10 mg (one spray). The safety of treating more than 8 migraines in a 30-day period has not been established.

Drugs/Diseases

Util A	Util B	Util C
Zavegepant		

Max Dose: 1 spray/day

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

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

22. Zavegepant / Therapeutic Appropriateness _____ _____

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

Drugs/Diseases

Util A	Util B	Util C
Zavegepant		

Age Range: 0 – 17 yoa

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

23. Zavegepant / Severe Hepatic Impairment _____ _____

Alert Message: Avoid the use of Zavzpret (zavegepant) in patients with severe hepatic impairment. Zavegepant has not been studied in patients with severe hepatic impairment (Child-Pugh Class C). In a dedicated clinical study comparing the pharmacokinetics of zavegepant in subjects with moderate hepatic impairment (Child-Pugh B) to that of normal subjects, zavegepant Cmax was 16% higher, and AUC was 1.9-fold higher in patients with moderate hepatic impairment. No dosage adjustment of zavegepant is necessary in patients with mild hepatic impairment (Child-Pugh Class A) or moderate hepatic impairment (Child-Pugh Class B).

Drugs/Diseases

Util A	Util B	Util C
Zavegepant	Cirrhosis	
	Hepatic Failure	

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

24. Zavegepant / Severe Renal Impairment _____ _____

Alert Message: The use of Zavzpret (zavegepant) should be avoided in patients with severe renal impairment (CLcr less than 30 mL/min). In a pharmacokinetic study, patients with CLcr 15 to 29 mL/min had accumulation of uremic solutes, which can cause an increase in zavegepant exposures by inhibiting OATP transporters. Zavegepant has not been studied in patients with CLcr less than 15 mL/min.

Drugs/Diseases

Util A	Util B	Util C (Include)
Zavegepant		CKD Stage 4
		CKD Stage 5
		ESRD

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

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

25. Zavegepant / OATP1B3 or NTCP Inhibitors _____ _____

Alert Message: Concomitant administration of Zavzpret (zavegepant) with inhibitors of the organic anion transporting polypeptide 1B3 (OATP1B3) or sodium taurocholate co-transporting polypeptide (NTCP) transporters may result in a significant increase in zavegepant exposure. Avoid concomitant administration of zavegepant with drugs that inhibit OATP1B3 or NTCP transporters.

Drugs/Diseases

Util A	Util B		Util C
Zavegepant	Clarithromycin	Leniolisib	
	Cobicistat	Letermovir	
	Daclatasvir	Pibrentasvir	
	Enasidenib	Rifampin	
	Encorafenib	Teriflunomide	
	Erythromycin	Velpatasvir	
	Fostemsavir	Voxilaprevir	
	Leflunomide		

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

26. Zavegepant / Intranasal Decongestants _____ _____

Alert Message: Concomitant administration of Zavzpret (zavegepant) with intranasal decongestants may decrease the absorption of zavegepant. Avoid concomitant administration of intranasal decongestants with zavegepant. When concomitant use is unavoidable, intranasal decongestants should be administered at least 1 hour after zavegepant administration.

Drugs/Diseases

Util A	Util B	Util C
Zavegepant	Intranasal Decongestants	

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

27. Zavegepant / Lactation _____ _____

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

Drugs/Diseases

Util A	Util B	Util C
Zavegepant	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

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

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

28. Zavegepant / OATP1B3 or NTCP Inducers _____ _____

Alert Message: Concomitant administration of Zavzpret (zavegepant) with inducers of OATP1B3 or NTCP transporters may result in a decrease in zavegepant exposure. Avoid concomitant administration of zavegepant with drugs that induce OATP1B3 or NTCP transporters.

Drugs/Diseases

Util A	Util B	Util C
Zavegepant	Clotrimazole	

References:

Zavzpret Prescribing Information, March 2023, Pfizer Inc.
Karlgren M, Vildhede A, Norinder U, et al. Classification of Inhibitors of Hepatic Organic Anion Transporting Polypeptides (OATPs): Influence of Protein Expression on Drug-Drug Interactions. J Med Chem. 2012 May 24;55(10):4740-63. doi: 10.1021/jm300212s. Epub 2012 May 15. PMID: 22541068; PMCID: PMC3361267.

29. Risperidone ER Subq Injection Susp / Therapeutic Appropriateness _____ _____

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

Drugs/Diseases

Util A	Util B	Util C
Risperidone ER Injection Susp.		

Age Range: 0 – 17 yoa

References:

Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Uzedy Prescribing Information, April 2023, Teva Pharmaceuticals.

30. Risperidone ER Subq Injection Susp / Therapeutic Appropriateness _____ _____

Alert Message: Uzedy (risperidone extended-release subcutaneous injection) may be over-utilized. Following oral titration with risperidone to at least 2 mg once daily and based on clinical response and tolerability, the recommended dosage of risperidone ER suspension injection in patients with renal or hepatic impairment is 50 mg once monthly.

Drugs/Diseases

Util A	Util B	Util C
Risperidone ER Injection Susp. 75mg/0.21ml	Hepatic Impairment	
Risperidone ER Injection Susp. 100mg/0.28ml	Renal impairment	
Risperidone ER Injection Susp. 125mg/0.35ml		
Risperidone ER Injection Susp. 150mg/0.42ml		
Risperidone ER Injection Susp. 200mg/0.56ml		
Risperidone ER Injection Susp. 250mg/0.70ml		

References:

Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Uzedy Prescribing Information, April 2023, Teva Pharmaceuticals.

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

31. Risperidone ER Subq Injection Susp / Strong CYP3A4 Inducers _____ _____

Alert Message: Concomitant use of Uzedy (risperidone extended-release subcutaneous injection) and a strong CYP3A4 inducer may cause decreases in the combined plasma concentrations of risperidone and 9-hydroxyrisperidone which could lead to decreased efficacy of risperidone ER suspension injection. Changes in efficacy and safety should be carefully monitored with any dose adjustment of risperidone ER suspension injection. Refer to the official prescribing information for recommended dosage adjustments.

Drugs/Diseases

Util A	Util B		Util C
Risperidone ER Injection Susp.	Apalutamide	Phenobarbital	
Carbamazepine	Phenytoin		
Enzalutamide	Primidone		
Mitotane	Rifampin		

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Uzedy Prescribing Information, April 2023, Teva Pharmaceuticals.

32. Risperidone ER Subq Injection Susp / Strong 2D6 Inhibitors _____ _____

Alert Message: Concomitant use of Uzedy (risperidone extended-release subcutaneous injection) with strong CYP2D6 inhibitors (e.g., fluoxetine or paroxetine) may increase the plasma exposure of risperidone and lower the plasma exposure of a major active metabolite, 9-hydroxyrisperidone. When initiation of a strong CYP2D6 inhibitor is considered, place patients on a lower dose of risperidone extended-release injection prior to the planned start of strong CYP2D6 inhibitor therapy to adjust for the expected increase in plasma concentrations of risperidone. When a strong CYP2D6 inhibitor is initiated in patients receiving the recommended dose of 50 mg once monthly or 100 mg once every 2 months of risperidone, continue treatment with these doses unless clinical judgment necessitates interruption of risperidone ER injection.

Drugs/Diseases

Util A	Util B	Util C
Risperidone ER Injection Susp	Bupropion	
	Fluoxetine	
	Paroxetine	
	Quinidine	

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Uzedy Prescribing Information, April 2023, Teva Pharmaceuticals.

33. Tapentadol IR / Therapeutic Appropriateness _____ _____

Alert Message: The safety and effectiveness of Nucynta (tapentadol) tablets in pediatric patients less than 6 years of age have not been established.

Drugs/Diseases

Util A	Util B	Util C
Tapentadol IR		

Age Range: 0 – 5 yoa

References:
Nucynta Prescribing Information, July 2023, Collegium Pharmaceutical, Inc.

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

34. Tapentadol IR / Overutilization 6 – 17 yoa _____ _____

Alert Message: Nucynta (tapentadol) may be over-utilized. For pediatric patients 6 years and older weighing 40 to 59 kg, administer 50 mg every 4 hours. Do not exceed a maximum single dose of 50 mg. If adequate analgesia is not achieved with a 50 mg tapentadol tablet every 4 hours, do not increase to a 75 mg tapentadol tablet. The maximum daily dose is 7.5 mg/kg/day (i.e., six 1.25 mg/kg doses over 24 hours).

Util A Util B Util C
Tapentadol IR

Max Dose: 300 mg/day
Age Range: 6 – 17 yoa

References:
Nucynta Prescribing Information, July 2023, Collegium Pharmaceutical, Inc.

35. Tapentadol IR / Overutilization 6 – 17 yoa _____ _____

Alert Message: Nucynta (tapentadol) may be over-utilized. For pediatric patients 6 years and older weighing 60 to 79 kg, initiate treatment with 50 mg every 4 hours. Increase the dose, if needed, to 75 mg every 4 hours to maintain adequate analgesia with acceptable tolerability. Do not exceed a maximum single dose of 75 mg. If adequate analgesia is not achieved with a 75 mg tapentadol tablet every 4 hours, do not increase to a 100 mg tapentadol tablet. The maximum daily dose is 7.5 mg/kg/day (i.e., six 1.25 mg/kg doses over 24 hours).

Drugs/Diseases
Util A Util B Util C
Tapentadol IR

Max Dose: 450 mg/day
Age Range: 6 – 17 yoa

References:
Nucynta Prescribing Information, July 2023, Collegium Pharmaceutical, Inc.

36. Tapentadol IR / Overutilization 6 – 17 yoa _____ _____

Alert Message: Nucynta (tapentadol) may be over-utilized. For pediatric patients 6 years and older weighing greater than or equal to 80 kg, initiate treatment with 50 mg every 4 hours. Increase the dose if needed to 75 mg every 4 hours to maintain adequate analgesia with acceptable tolerability. If adequate pain relief is not attained with a 75 mg tapentadol tablet every 4 hours, increase the dose to 100 mg every 4 hours to maintain adequate analgesia with acceptable tolerability. Do not exceed a maximum single dose of 100 mg. The maximum daily dose is 7.5 mg/kg/day (i.e., six 1.25 mg/kg doses over 24 hours).

Drugs/Diseases
Util A Util B Util C
Tapentadol 100 mg

Max Dose: 600 mg/day
Age Range: 6 – 17 yoa

References:
Nucynta Prescribing Information, July 2023, Collegium Pharmaceutical, Inc.

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

37. Tapentadol IR / Therapeutic Appropriateness - Duration _____ _____

Alert Message: In pediatric patients, the duration of treatment with Nucynta (tapentadol) should not exceed 3 days as the safety and effectiveness of longer treatment have not been established. Tapentadol tablets are intended for the management of acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate. As with all symptomatic treatments, the continued use of tapentadol must be evaluated on an ongoing basis.

Drugs/Diseases

Util A	Util B	Util C
Tapentadol IR		

Age Range: 0 – 17 yoa
Duration: > 3 days

References:
Nucynta Prescribing Information, July 2023, Collegium Pharmaceutical, Inc.

38. Tapentadol IR / Severe Hepatic Impairment _____ _____

Alert Message: Nucynta (tapentadol) tablets have not been studied in pediatric patients with hepatic or renal impairment; therefore, use in these populations is not recommended.

Drugs/Diseases

Util A	Util B	Util C
Tapentadol IR	Hepatic Impairment	
	Renal Impairment	

References:
Nucynta Prescribing Information, July 2023, Ortho-McNeil-Janssen Pharmaceuticals, Inc.

39. Viloxazine / Overuse _____ _____

Alert Message: Qelbree (viloxazine) may be over-utilized. The maximum recommended dosage of viloxazine in adults is 600 mg once daily.

Drugs/Diseases

Util A	Util B	Util C
Viloxazine		

Max Dose: 600 mg/day
Age Range: ≥18 yoa

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

40. Valbenazine / Black Box Warning _____ _____

Alert Message: Patients with Huntington's disease are at increased risk for depression, and suicidal ideation or behaviors. VMAT2 inhibitors, including Ingrezza (valbenazine), can increase the risk for suicidal ideation and behaviors in patients with Huntington's disease. When considering the use of valbenazine, the risk of suicidal ideation and behaviors must be balanced against the need for treatment of chorea. All patients treated with valbenazine should be observed for new or worsening depression, suicidal ideation or behaviors. If any of these reactions occur and do not resolve, consider discontinuing treatment with valbenazine.

Drugs/Diseases

Util A	Util B	Util C (Include)
Valbenazine	Huntington's Disease	Suicidal Ideation
		Depression

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Ingrezza Prescribing Information, August 2023. Neurocrine Bioscience, Inc.

41. Bexagliflozin / Overuse _____ _____

Alert Message: Brenzavvy (bexagliflozin) may be over-utilized. The recommended dosage of bexagliflozin is 20 mg orally, taken once daily in the morning.

Drugs/Diseases

Util A	Util B	Util C
Bexagliflozin		

Max Dose: 20 mg/day

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Brenzavvy Prescribing Information, Sept. 2023, TheracosBio, LLC.

42. Bexagliflozin / Therapeutic Appropriateness _____ _____

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

Drugs/Diseases

Util A	Util B	Util C
Bexagliflozin		

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Brenzavvy Prescribing Information, Sept. 2023, TheracosBio, LLC.

43. Bexagliflozin / Dialysis _____ _____

Alert Message: Brenzavvy (bexagliflozin) use is contraindicated in patients receiving dialysis. The glucose-lowering pharmacodynamic response to bexagliflozin declines with increasing severity of renal impairment.

Drugs/Diseases

Util A	Util B	Util C
Bexagliflozin	Dialysis	

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Brenzavvy Prescribing Information, Sept. 2023, TheracosBio, LLC.

44. Bexagliflozin / CKD Stage 4 and 5 _____ _____

Alert Message: Brenzavvy (bexagliflozin) use is not recommended in patients with an eGFR less than 30 mL/min/1.73 m2. The glucose-lowering pharmacodynamic response to bexagliflozin declines with increasing severity of renal impairment. In a clinical pharmacology study, consistent with the mechanism of action of bexagliflozin, the 24-hour UGE in patients with type 2 diabetes mellitus and mild, moderate, and severe renal impairment was 17%, 60%, and 83% lower than in patients with type 2 diabetes mellitus with normal renal function, respectively.

Drugs/Diseases

Util A	Util B	Util C
Bexagliflozin	CKD Stage 4	
	CKD Stage 5	

References:

Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Brenzavvy Prescribing Information, Sept. 2023, TheracosBio, LLC.

45. Bexagliflozin / Amputation _____ _____

Alert Message: An increased incidence of lower limb amputations occurred in Brenzavvy (bexagliflozin)-treated patients compared to placebo-treated patients (8.3 versus 5.1 events per 1,000 patient-years) in a clinical trial evaluating patients with type 2 diabetes who had either established cardiovascular disease (CVD) or were at risk for CVD. Before initiating bexagliflozin, consider factors in the patient history that may predispose to the need for amputations (i.e., a history of prior amputation, peripheral vascular disease, neuropathy and diabetic foot ulcers). Counsel patients about the importance of routine preventative foot care. Monitor patients receiving bexagliflozin for signs and symptoms of infection (including osteomyelitis), new pain or tenderness, sores or ulcers involving the lower limbs, and discontinue bexagliflozin if these complications occur.

Drugs/Diseases

Util A	Util B	Util C
Bexagliflozin	Acquired Absence of Lower Limb	
	Diabetes with Foot Ulcer	
	Neuropathy	
	Non-pressure Ulcer of Lower Limb	
	Osteomyelitis	
	Pain in Legs, Thighs, Legs, Feet, and Toes	
	Peripheral Vascular Disease	

References:

Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Brenzavvy Prescribing Information, Sept. 2023, TheracosBio, LLC.

46. Bexagliflozin / Cirrhosis & Hepatic Failure _____ _____

Alert Message: Brenzavvy (bexagliflozin) has not been studied in patients with severe hepatic impairment and is not recommended for use in this patient population. The recommended dosage for patients with mild to moderate hepatic impairment is the same as the recommended dosage for patients with normal hepatic function.

Drugs/Diseases

Util A	Util B	Util C
Bexagliflozin	Cirrhosis	
	Hepatic Failure	

References:

Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Brenzavvy Prescribing Information, Sept. 2023, TheracosBio, LLC.

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

47. Bexagliflozin / Insulin and Insulin Secretagogues _____ _____

Alert Message: The concurrent use of Brenzavvy (bexagliflozin) with insulin or an insulin secretagogue can increase the risk of hypoglycemia. A lower dose of insulin or insulin secretagogue may be required to minimize the risk of hypoglycemia when used in combination with bexagliflozin.

Drugs/Diseases

Util A	Util B	Util C
Bexagliflozin	Insulin	
	Insulin Secretagogues	

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Brenzavvy Prescribing Information, Sept. 2023, TheracosBio, LLC.

48. Bexagliflozin / UGT Inducers _____ _____

Alert Message: The concurrent use of Brenzavvy (bexagliflozin) with a UGT inducer (e.g., rifampin, phenytoin, phenobarbital) may result in decreased bexagliflozin exposure. Consider adding another antihyperglycemic agent in patients who require additional glycemic control.

Drugs/Diseases

Util A	Util B	Util C
Bexagliflozin	Phenobarbital	
	Phenytoin	
	Rifampin	
	Ritonavir	

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Brenzavvy Prescribing Information, Sept. 2023, TheracosBio, LLC.

49. Bexagliflozin / Pregnancy / Pregnancy Negating _____ _____

Alert Message: Based on animal data showing adverse renal effects, Brenzavvy (bexagliflozin) is not recommended during the second and third trimesters of human pregnancy.

Drugs/Diseases

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

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Brenzavvy Prescribing Information, Sept. 2023, TheracosBio, LLC.

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

50. Bexagliflozin / Lactation _____ _____

Alert Message: There is no information regarding the presence of Brenzavvy (bexagliflozin)

in human milk, the effects on the breastfed infant, or the effects on milk production. Bexagliflozin is excreted in the milk of lactating rats. When a drug is present in animal milk, it is likely that the drug will be present in human milk. Because of the potential for serious adverse reactions in a breastfed infant, including the potential for bexagliflozin to affect postnatal renal development, advise patients that the use of bexagliflozin is not recommended while breastfeeding.

Drugs/Diseases

Util A	Util B	Util C
Bexagliflozin	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Brenzavvy Prescribing Information, Sept. 2023, TheracosBio, LLC.

51. Bexagliflozin / Hypotension, Hypovolemia, Dehydration, & CKD 3 _____ _____

Alert Message: Brenzavvy (bexagliflozin) can cause intravascular volume contraction which may sometimes manifest as symptomatic hypotension or acute transient changes in creatinine. There have been postmarketing reports of acute kidney injury in patients with type 2 diabetes mellitus receiving SGLT2 inhibitors. Patients with impaired renal function (eGFR less than 60 mL/min/1.73 m2), elderly patients, patients with low systolic blood pressure, or patients on loop diuretics may be at increased risk for volume depletion or hypotension. Monitor for signs and symptoms of volume depletion, and renal function after initiating therapy.

Drugs/Diseases

Util A	Util B	Util C
Bexagliflozin	Dehydration	
	CKD Stage 3	
	Hypotension	
	Hypovolemia	

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Brenzavvy Prescribing Information, Sept. 2023, TheracosBio, LLC.

52. Bexagliflozin / Genital Mycotic Infections _____ _____

Alert Message: Brenzavvy (bexagliflozin) increases the risk of genital mycotic infections. Patients who have a history of genital mycotic infections or who are uncircumcised are more likely to develop genital mycotic infections. Monitor and treat appropriately.

Drugs/Diseases

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

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Brenzavvy Prescribing Information, Sept. 2023, TheracosBio, LLC.

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

53. Bexagliflozin / Non-adherence _____ _____

Alert Message: Based on refill history, your patient may be under-utilizing Brenzavvy (bexagliflozin). 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
Bexagliflozin

References:
Osterberg L, Blaschke T. Adherence to Medication. N Engl J Med 2005; 353:487- 497.
Ho PM, Rumsfeld JS, Masoudi FA, et al., Effect of Medication Nonadherence in Diabetes Mellitus. Cardiology Review, April 2007, Vol. 24 No. 4. p.18-22.
Currie CJ, Peyrot M, Morgan CL, et al. The Impact of Treatment Noncompliance on Mortality in People With Type 2 Diabetes. Diabetes Care 35:1279-1284, June 2012.
Butler RJ, Davis TK, Johnson WL, et al. Effects of Nonadherence with Prescription Drugs Among Older Adults. Am J Manag Care. 2011 Feb; 17(2):153-60.
Polonsky WH, Henry RR. Poor Medication Adherence in Type 2 Diabetes: Recognizing the Scope of the Problem and its Key Contributors. Patient Prefer Adherence. 2016 Jul 22;10:1299-1307.

54. Liraglutide / Overutilization _____ _____
Alert Message: The recommended maximum dose of Saxenda (liraglutide) is 3.0 mg by subcutaneous injection once daily.

Drugs/Diseases
Util A Util B Util C
Liraglutide

Max Dose: 3.0 mg injection/day

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Facts & Comparisons, 2023 Updates, Wolters Kluwer Health.
Saxenda Prescribing Information, April 2023, Novo Nordisk Inc.

55. Liraglutide / Therapeutic Appropriateness _____ _____
Alert Message: The safety and effectiveness of Saxenda (liraglutide) have not been established in pediatric patients less than 12 years of age.

Drugs/Diseases
Util A Util B Util C

Age Range: 0 – 11 yoa

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Saxenda Prescribing Information, April 2023, Novo Nordisk Inc.

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

56. Liraglutide / Therapeutic Appropriateness _____ _____

Alert Message: Saxenda (liraglutide) is contraindicated in patients with a personal or family history of MTC or in patients with MEN 2. Counsel patients regarding the potential risk for MTC with the use of liraglutide and inform them of symptoms of thyroid tumors (e.g., a mass in the neck, dysphagia, dyspnea, persistent hoarseness).

Drugs/Diseases

Util A	Util B	Util C (Include)
Liraglutide		Medullary Thyroid Carcinoma II
		Thyroid Carcinoma
		History of Thyroid Carcinoma

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Saxenda Prescribing Information, April 2023, Novo Nordisk Inc.

57. Liraglutide / Pregnancy / Pregnancy Negating _____ _____

Alert Message: Saxenda (liraglutide) is contraindicated during pregnancy because weight loss offers no potential benefit to a pregnant woman and may result in fetal harm. There are no available data with liraglutide in pregnant women to inform a drug associated risk for major birth defects and miscarriage. Liraglutide should not be used during pregnancy. If a patient wishes to become pregnant or pregnancy occurs, treatment with liraglutide should be discontinued.

Drugs/Diseases

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

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Saxenda Prescribing Information, April 2023, Novo Nordisk Inc.

58. Liraglutide / Therapeutic Appropriateness (Black Box Warning) _____ _____

Alert Message: Saxenda (liraglutide) causes dose-dependent and treatment-duration-dependent thyroid C-cell tumors (adenomas and/or carcinomas) at clinically relevant exposures in both genders of rats and mice. Malignant thyroid C-cell carcinomas were detected in rats and mice. It is unknown whether liraglutide will cause thyroid C-cell tumors, including medullary thyroid carcinoma (MTC), in humans, as the human relevance of liraglutide-induced rodent thyroid C-cell tumors has not been determined.

Drugs/Diseases

Util A	Util B	Util C
Liraglutide		

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

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

59. Liraglutide / Pancreatitis _____ _____

Alert Message: Based on spontaneous postmarketing reports, acute pancreatitis, including fatal and non-fatal hemorrhagic or necrotizing pancreatitis, has been observed in patients treated with liraglutide. After initiation of Saxenda (liraglutide), observe patients carefully for signs and symptoms of pancreatitis (including persistent severe abdominal pain, sometimes radiating to the back and which may or may not be accompanied by vomiting). If pancreatitis is suspected, liraglutide should promptly be discontinued, and appropriate management should be initiated. If pancreatitis is confirmed, liraglutide should not be restarted.

Drugs/Diseases

Util A	Util B	Util C
Liraglutide	Pancreatitis	

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Saxenda Prescribing Information, April 2023, Novo Nordisk Inc.

60. Liraglutide / Insulin & Sulfonylureas _____ _____

Alert Message: Adult patients with type 2 diabetes mellitus on an insulin secretagogue (e.g., sulfonylurea) or insulin may have an increased risk of hypoglycemia with the use of Saxenda (liraglutide), including severe hypoglycemia. In patients with type 2 diabetes, monitor blood glucose prior to starting liraglutide and during liraglutide treatment. The risk of hypoglycemia may be lowered by a reduction in the dose of sulfonylurea (or other concomitantly administered insulin secretagogues) or insulin. Inform patients using these concomitant medications of the risk of hypoglycemia and educate them on the signs and symptoms of hypoglycemia.

Drugs/Diseases

Util A	Util B	Util C
Liraglutide	Insulin	
	Sulfonylureas	

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Saxenda Prescribing Information, April 2023, Novo Nordisk Inc.

61. Liraglutide / Depression & Suicidality _____ _____

Alert Message: Patients treated with Saxenda (liraglutide) should be monitored for the emergence or worsening of depression, suicidal thoughts or behavior, and/or any unusual changes in mood or behavior. Discontinue liraglutide in patients who experience suicidal thoughts or behaviors. Avoid liraglutide in patients with a history of suicidal attempts or active suicidal ideation.

Drugs/Diseases

Util A	Util B	Util C
Liraglutide	Depression	
	Suicidality	

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Saxenda Prescribing Information, April 2023, Novo Nordisk Inc.

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

62. Liraglutide / Palpitations & Tachycardia _____ _____

Alert Message: Mean increases in resting heart rate of 2 to 3 beats per minute (bpm) were observed with routine clinical monitoring in Saxenda (liraglutide) treated adult patients compared to placebo in clinical trials. Heart rate should be monitored at regular intervals consistent with usual clinical practice. Patients should inform health care providers of palpitations or feelings of a racing heartbeat while at rest during liraglutide treatment. For patients who experience a sustained increase in resting heart rate while taking liraglutide, liraglutide should be discontinued.

Drugs/Diseases

Util A	Util B	Util C
Liraglutide	Palpitations	
	Tachycardia	

Age Range: 18 -999 yoa

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Saxenda Prescribing Information, April 2023, Novo Nordisk Inc.

63. Liraglutide / Palpitations & Tachycardia _____ _____

Alert Message: In a pediatric clinical trial, mean increases from baseline in resting heart rate of 3 to 7 bpm were observed with Saxenda (liraglutide) treatment. Heart rate should be monitored at regular intervals consistent with usual clinical practice. Patients should inform health care providers of palpitations or feelings of a racing heartbeat while at rest during liraglutide treatment. For patients who experience a sustained increase in resting heart rate while taking liraglutide, liraglutide should be discontinued.

Drugs/Diseases

Util A	Util B	Util C
Liraglutide	Palpitations	
	Tachycardia	

Age Range: 12 -17 yoa

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Saxenda Prescribing Information, April 2023, Novo Nordisk Inc.

64. Liraglutide / Renal Impairment _____ _____

Alert Message: In patients treated with GLP-1 receptor agonists, including Saxenda (liraglutide), there have been reports of acute renal failure and worsening of chronic renal failure, sometimes requiring hemodialysis. Use caution when initiating or escalating doses of liraglutide in patients with renal impairment.

Drugs/Diseases

Util A	Util B	Util C
Liraglutide	Renal Impairment	

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Saxenda Prescribing Information, April 2023, Novo Nordisk Inc.

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

65. Liraglutide / Gallbladder & Biliary Disease _____ _____

Alert Message: In clinical trials in adults, 2.2% of Saxenda (liraglutide)-treated patients reported adverse events of cholelithiasis versus 0.8% of placebo-treated patients. The incidence of cholecystitis was 0.8% in liraglutide-treated patients versus 0.4% in placebo-treated patients. The majority of liraglutide-treated patients with adverse events of cholelithiasis and cholecystitis required cholecystectomy. If cholelithiasis is suspected, gallbladder studies and appropriate clinical follow-up are indicated.

Drugs/Diseases

Util A	Util B	Util C
Liraglutide	Cholelithiasis	
	Biliary Colic	
	Cholecystitis	

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Saxenda Prescribing Information, April 2023, Novo Nordisk Inc.

66. Liraglutide / Gastroparesis _____ _____

Alert Message: Saxenda (liraglutide) slows gastric emptying. Liraglutide has not been studied in patients with pre-existing gastroparesis.

Drugs/Diseases

Util A	Util B	Util C
Liraglutide	Gastroparesis	

References:
Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Saxenda Prescribing Information, April 2023, Novo Nordisk Inc.

67. Liraglutide / Lactation _____ _____

Alert Message: There are no data on the presence of Saxenda (liraglutide) in human milk, the effects on the breastfed infant, or the effects on milk production. Liraglutide has been shown to be present in the milk of lactating rats. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for liraglutide and any potential adverse effects on the breastfed infant from liraglutide or the underlying maternal condition.

Drugs/Diseases

Util A	Util B	Util C
Liraglutide	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

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

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

68. Carbamazepine / Dantrolene, Ibuprofen, & Olanzapine _____ _____

Alert Message: Concomitant use of carbamazepine with olanzapine, dantrolene, or ibuprofen may increase plasma carbamazepine levels. Monitor carbamazepine concentrations closely during coadministration with one of these medications.

Drugs/Diseases

Util A	Util B	Util C
Carbamazepine	Dantrolene	
	Ibuprofen	
	Olanzapine	

References:

Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Tegretol Prescribing Information, Sept. 2023, Novartis Pharmaceutical Corporation.

69. Pralsetinib / CYP3A4 Inducers _____ _____

Alert Message: Avoid coadministration of Gavreto (pralsetinib) with moderate CYP3A inducers. Coadministration of pralsetinib with a moderate CYP3A inducer decreases pralsetinib exposure, which may decrease the efficacy of pralsetinib. If coadministration cannot be avoided, increase the current dose of pralsetinib starting on Day 7 of coadministration of pralsetinib with the moderate CYP3A inducer as follows; current dose 400 mg qd increase to 600 mg qd, 300 mg qd increase to 500 mg qd, and 200 mg qd increase to 300 mg qd. After the inducer has been discontinued for at least 14 days, resume pralsetinib at the dose taken prior to initiating the moderate CYP3A inducer.

Drugs/Diseases

Util A	Util B		Util C
Pralsetinib	Bosentan	Modafinil	
	Cenobamate	Nevirapine	
	Efavirenz	Rifapentine	
	Etravirine		

References:

Clinical Pharmacology, 2023 Elsevier/Gold Standard.
Gavreto Prescribing Information, August 2023, Genentech, Inc.

70. Drugs for HF / Heart Failure / SGLT2 Inhibitors _____ _____

Alert Message: A review of the patient's history reveals that the patient has heart failure but is not receiving a sodium-glucose co-transporter 2 (SGLT-2) inhibitor. In clinical trials, SGLT2 inhibitors have demonstrated significant improvement in heart failure outcomes in patients with or without type 2 diabetes. Consider the addition of a SGLT2 inhibitor in patients with heart failure unless a contraindication is present.

Drugs/Diseases

Util A	Util B	Util C (Negating)
Digoxin	Heart Failure	Bexagliflozin
Ivabradine		Canagliflozin
Sacubitril/Valsartan		Dapagliflozin
Vericiguat		Empagliflozin
		Ertugliflozin

References:

Anker SD, Usman MS, Butler J. SGLT2 Inhibitors: From Antihyperglycemic Agents to All-Around Heart Failure Therapy. Circulation. 2022 Jul 26;146(4):299-302. doi: 10.1161/CIRCULATIONAHA.122.060348. Epub 2022 Jul 25. PMID: 35877834.
Kittleson M, Panjrath G, Amancherla K, et al. 2023 ACC Expert Consensus Decision Pathway on Management of Heart Failure With Preserved Ejection Fraction. J Am Coll Cardiol. 2023 May, 81 (18) 1835-1878. https://doi.org/10.1016/j.jacc.2023.03.393
Talha KM, Anker SD, Butler J. SGLT-2 Inhibitors in Heart Failure: A Review of Current Evidence. Int J Heart Fail. 2023 Mar 13;5(2):82-90. doi: 10.36628/ijhf.2022.0030. PMID: 37180562; PMCID: PMC10172076.