North Dakota Medicaid
Drug Utilization Review Board
Meeting
December 1st, 2021
Conference Room 210/212

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North Dakota Medicaid
DUR Board Meeting Agenda
Conference Room 210/212
North Dakota State Capitol

Click here to join the meeting

(Click on link)

Join by phone: 1 701-328-0950, Conference ID 262 340 82#

December 1, 2021

1:00 pm

1. Administrative items
    - DHS announcements

2. Old business
    - Review and approval of September 2021 meeting minutes
    - Budget update
    - Review top 25 drugs for third quarter of 2021
    - Prior authorization/PDL update
    - Update to eczema/atopic dermatitis (Opzelura)
    - Second review of non-stimulant agents for the treatment ADHD
    - Annual prior authorization review of prior authorization forms and criteria

3. New business
    - Review of chronic kidney disease
    - Review of lupus
    - Retrospective DUR profile review update
    - Retrospective DUR criteria recommendations
    - Upcoming meeting date/agenda.
        - Next meeting is March 2, 2022
4. Adjourn

Please remember to silence all cellular phones during the meeting.

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

Members Present: Joshua Askvig, Andrea Honeyman, Kathleen Traylor, Gabriela Balf, Mary Aaland, Amy Werremeyer, Laura Kroetsch, Tanya Schmidt

Medicaid Pharmacy Department: Alexi Murphy, Brendan Joyce

Old Business

Chair T. Schmidt called the meeting to order at 1:03 p.m. Chair T. Schmidt asked for a motion to approve the minutes of the June 2, 2021, meeting. J. Askvig moved that the minutes be approved, and A. Werremeyer seconded the motion. The chair called for a voice vote to approve the minutes. The motion passed with no audible dissent.

Review Top 25 Drugs

B. Joyce presented budget updates and the quarterly review of the top 25 drugs based on total cost of claims, the top 25 drugs based on the total number of claims, and the top drug classes based on claims and cost for the 3rd quarter of 2021. B. Joyce presented data to the Board that was reflective of the average number of patients enrolled in ND Medicaid expansion from 3Q 2017 to 2Q 2021 which showed a significant increase of patients beginning at 1Q 2020. The rise in number of patients is directly linked to the COVID-19 pandemic and the public health emergency that coincided with the pandemic. B. Joyce also presented utilization data of select medication classes to the Board to illustrate drug utilization trends during this time. Drug classes presented included steroids, immunomodulators, insulins, antidepressants, and antipsychotic agents. During public comment, J. Askvig asked if there was an uptick in antidepressants since the pandemic began in which B. Joyce stated antidepressants and narcotics have both increased. G. Balf noted that she has notice antidepressants being used more for anxiety than depression during the pandemic.

PDL/PA Criteria Updates

A. Murphy shared with the Board all of the changes made to the Preferred Drug List since the last version of the Preferred Drug List was posted. Notable changes include removing tetracycline, Peg 3350, and Clenpig from PA, as well as adding agents such as Ingrezza, Koselugo, Empaveli, Atelvia, and Varubi to already existing PA category criteria. All PDL updates are listed in the handouts for the September 2021 DUR Board meeting. When a new version of the PDL is published and posted to the website, all updates/changes made since the last version are called out at the top of the document itself.

Second Review of Agents Used in the Treatment of Heart Failure

A motion and second was made at the June 2021 DUR Board meeting to place some agents, Corlanor, Entresto, and Verquvo, for the management of heart failure on electronic diagnosis verification. The topic was brought up for a second review. Product specific heart failure criteria for Verquvo and Corlanor were presented to the Board by L. Morgan. Chair T. Schmidt called for a voice vote to approve the updated criteria, which passed with no audible dissent.

Proposed New Criteria for Nasal Polyps

L. Morgan presented the proposed prior authorization criteria for nasal polyps. The proposed updates included adding Xolair (omalizumab) and Dupixent (dupilumab) to preferred agents, requiring clinical prior authorization, and Nucala (mepolizumab) to non-preferred, requiring prior authorization. Xolair recently received the FDA indication for nasal polyps which supports the addition of nasal polyp criteria to the PDL. A. Werremeyer raised the question about requiring the patient to have bilateral nasal polyps for authorization. J. Ritter (guest) answered by

stating in the dupilumab trial, inclusion criteria required patients to have bilateral nasal polyps as they are more common than unilateral polyps.

Proposed New Criteria for Chronic Idiopathic Urticaria

L. Morgan presented criteria for the use of Xolair in chronic idiopathic urticaria. Xolair is a preferred agent and will require a clinical prior authorization. It is considered first-in-class therapy for patients with chronic idiopathic urticaria. There were no public comments or concerns about the criteria listed.

Update to the Prior Authorization Criteria for Uterine Fibroid Criteria

L. Morgan presented proposed updates to the prior authorization criteria for agents used to treat uterine fibroids. The proposed update included adding Myfembree (relugolix, estradiol, and norethindrone acetate) to the preferred agents list, requiring clinical prior authorization. During public comment, C. Lickert, with Myovant Sciences and representing Myfembree, brought to the Board's attention the recent update to The American Colleges of Obstetricians and Gynecologists guideline for management of symptomatic uterine fibroids. C. Lickert discussed the use of oral contraception for management of uterine fibroids to be less effective than other agents and the quality of evidence of oral contraception use to be low. C. Lickert added the suggestion to remove or edit the step therapy for oral contraception prior to Oriahnn and Myfembree approval. The Board discussed the requirement for a 3-menstual cycle trial of an oral contraceptive and decided to leave the criteria as is. H. Budlong, with Abbvie and representing Oriahnn, voiced agreement with C. Lickert's assessment of the criteria and thanked the Board for allowing coverage of additional products to treat uterine fibroids. No other public comments were made.

Review of Empaveli (pegcetacoplan)

L. Morgan presented a review of Empaveli (pegcetacoplan) for the treatment of paroxysmal nocturnal hemoglobinuria (PNH) to the Board. A prior authorization form was also presented for ease of prescriber submission, as well as ease of approval determination. Changes between the original handout and new handout were pointed out and discussed, as well. During public discussion, T. Schmidt discussed clarifying how much the Hb levels should increase prior to granting approval for renewal of Empaveli. J. Tobitt, with Apellis and representing Empaveli, clarified that patients eligible for Empaveli do not necessarily need to be transfusion dependent based on the patients included in Empaveli trials not requiring transfusions. G. Balf brought up the concern of documentation to support patient diagnosis for PNH if they are new to North Dakota Medicaid and have limited laboratory documentation. A. Murphy discussed now only requiring documentation of flow cytometry as it is the gold standard for diagnosis of PNH. A motion was made by A. Werremeyer to manage this medication through prior authorization. The motion was seconded by A. Honeyman. Chair T. Schmidt called for a voice vote to approve the updated criteria, which passed with no audible dissent.

Update to Non-24 Hour Sleep-Wake Disorder Criteria

L. Morgan presented an update to the criteria for agents used for non-24 hour sleep-wake disorder. Hetlioz (tasimelteon) is now indicated for sighted members diagnosed by self-reported sleep diaries or actigraphy for at least 14 days. A. Murphy discussed the drastic price difference between Rozerem (ramelteon) and Hetlioz (tasimelteon) – two agents that have the same mechanism-of-action and efficacy. The higher price and similar efficacy of Hetlioz were used to determine the non-preferred status. No public comment followed presentation.

New Business

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

L. Morgan presented a review of non-stimulant agents used in the treatment of attention-deficit hyperactivity disorder to the Board. During public comment, G. Balf commented on the confusion in the mechanism-of-action table which listed viloxazine and atomoxetine as SNRI agents, which is incorrect, as they are norepinephrine reuptake inhibitors. G. Balf also discussed the missing dosing information for atomoxetine which should include the utilization of higher doses, specifically up to 100mg per day. A motion was made by M. Aaland to manage these medications through prior authorization. The motion was seconded by A. Honeyman. Prior authorization criteria for these agents will be presented, reviewed, and voted on by the Board at the next meeting.

Utilization Review of Xifaxan and Potassium

A. Murphy presented utilization data to the board regarding the utilization of Xifaxan with and without lactulose, comparing utilization before and after new requirements were implemented that require a PA for Xifaxan for diagnoses other than hepatic encephalopathy, and required concomitant use of lactulose for a diagnosis of hepatic encephalopathy. A. Murphy then went on to discuss the requirement for liquid potassium to require prior authorization for swallow study and quantity limits, as patients were using liquid over tablets due to the inconvenience of swallowing a large tablet.

Retrospective Drug Utilization Review (RDUR) Criteria Recommendations

L. Morgan reviewed the RDUR criteria that were selected for review of each month of the last quarter. Presented data included number of profiles reviewed, number of cases identified for intervention, and the number of letters sent, as well as an overview of what RDUR interventions were identified as most prevalent for each monthly cycle. L. Morgan discussed the decrease in letters sent during the month of June and correlated the decrease to her taking over after T. DeRuiter. L. Morgan stated she will monitor letters sent in the future and will discuss changes in this process at the next meeting.

Retrospective Drug Utilization Review (RDUR) Criteria Recommendations

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. J. Askvig moved to approve the new criteria and M. Aaland 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.

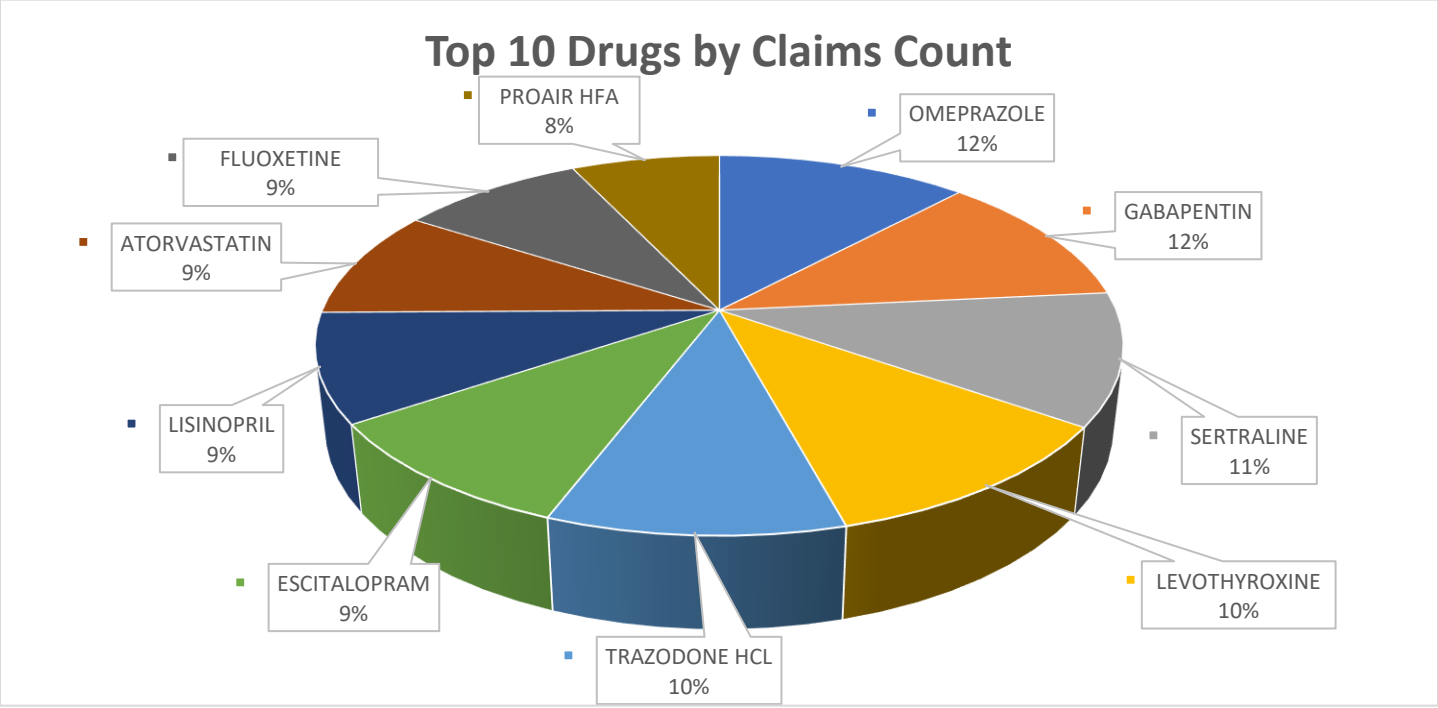
Adjournment and Upcoming Meeting Date

Chair T. Schmidt adjourned the meeting at 2:40 pm. The next DUR Board meeting will be held December 1, 2021, at 1:00 pm at the state capitol building.

Top 25 Drugs Based on Number of Claims from 07/01/2021 – 09/30/2021

Drug	Claims	Patients	Claims Cost	Cost / Claim	% Total Claims	Dif.
OMEPRAZOLE	4,668	2,301	60,593.72	$12.95	1.87%	NC
GABAPENTIN	4,626	1,943	69,007.69	$14.91	1.85%	NC
SERTRALINE HCL	4,226	2,276	58,143.37	$13.64	1.69%	NC
LEVOTHYROXINE SODIUM	3,938	1,777	76,660.94	$18.62	1.57%	NC
TRAZODONE HCL	3,775	1,844	51,893.80	$13.74	1.51%	NC
ESCITALOPRAM OXALATE	3,624	1,984	49,514.65	$12.79	1.45%	↑2
LISINOPRIL	3,573	1,990	46,323.98	$14.16	1.43%	↓2
ATORVASTATIN CALCIUM	3,556	1,885	50,135.83	$13.43	1.42%	↓1
FLUOXETINE HCL	3,378	1,814	46,566.10	$13.82	1.35%	NC
PROAIR HFA	2,874	2,831	224,139.29	$15.09	1.15%	↑10
HYDROCODONE-ACETAMINOPHEN	2,860	1,769	43,273.49	$17.58	1.14%	↓1
PANTOPRAZOLE SODIUM	2,811	1,357	37,769.76	$13.41	1.12%	NC
AMOXICILLIN	2,740	2,540	38,107.07	$13.03	1.10%	↑10
BUPROPION XL	2,675	1,376	47,076.39	$15.76	1.07%	↓3
METFORMIN HCL	2,568	1,353	33,707.98	$14.05	1.03%	↓2
MONTELUKAST SODIUM	2,547	1,413	35,591.09	$258.46	1.02%	↓1
PREDNISONE	2,515	1,976	31,298.92	$13.98	1.01%	↑7
DULOXETINE HCL	2,505	1,226	39,765.86	$11.57	1.00%	↓4
VYVANSE	2,455	1,007	626,592.35	$45.67	0.98%	↓3
BUPRENORPHINE-NALOXONE	2,397	555	104,851.66	$73.54	0.96%	↓1
CYCLOBENZAPRINE HCL	2,386	1,502	27,933.37	$12.63	0.95%	↓3
CLONIDINE HCL	2,298	1,105	28,811.37	$12.48	0.92%	↓1
CLONAZEPAM	2,260	957	30,984.85	$13.71	0.90%	↑2
LAMOTRIGINE	2,253	897	31,753.18	$12.54	0.90%	↓7
AMLODIPINE BESYLATE	2,122	1,197	26,577.41	$13.62	0.85%	↓3

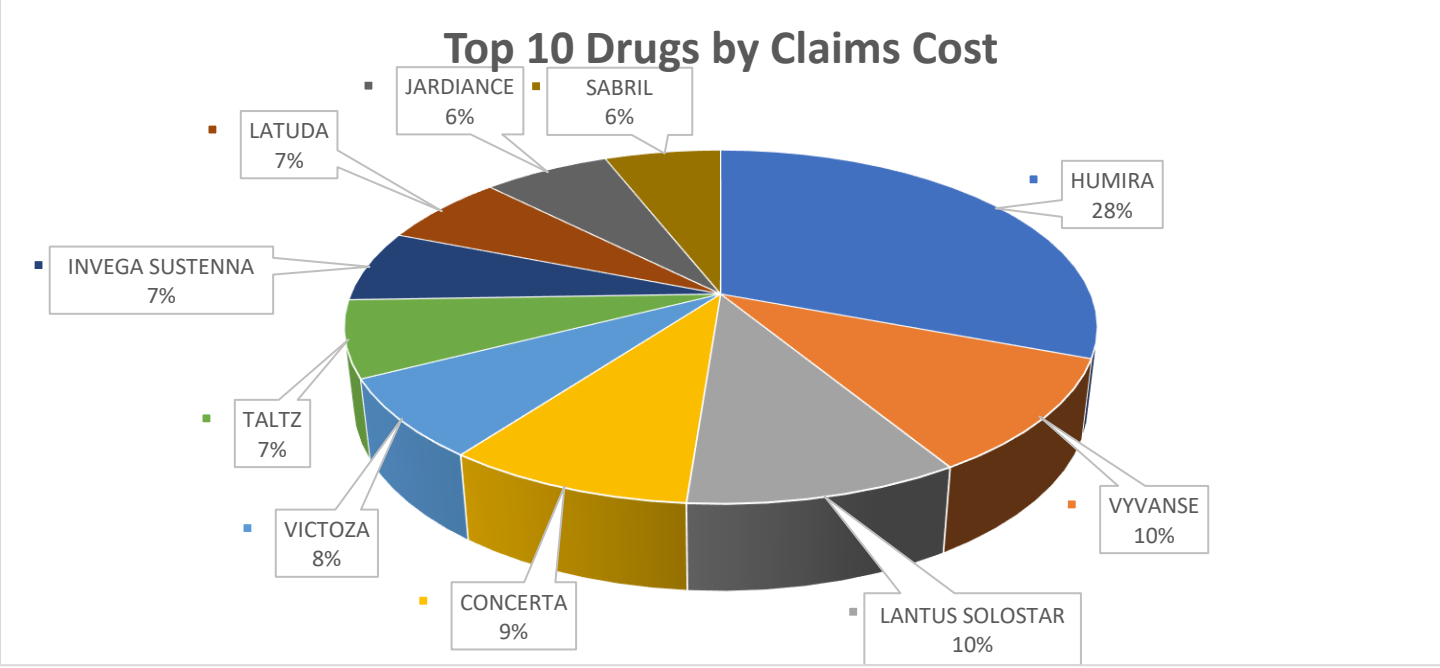
Total Claims	**250,036**



Top 25 Drugs Based on Total Claims Cost from 07/01/2021 – 09/30/2021

Drug	Claims Cost	Claims	Patients	Cost /Claim	% Total Cost	Dif.
HUMIRA PEN	1,747,399.22	259	108	$6,893.43	6.16%	NC
VYVANSE	626,592.35	2,455	1,007	$258.46	2.21%	NC
LANTUS SOLOSTAR	611,779.72	1,257	767	$344.48	2.16%	↑1
CONCERTA	574,551.57	1,695	727	$477.03	2.03%	↓1
VICTOZA 3-PAK	514,109.53	554	257	$2,371.89	1.81%	↑1
TALTZ AUTOINJECTOR	442,828.28	58	22	$908.95	1.56%	↑10
INVEGA SUSTENNA	438,876.71	186	77	$806.06	1.55%	↓2
LATUDA	422,797.49	503	194	$22,224.28	1.49%	↓1
JARDIANCE	399,778.16	827	371	$476.00	1.41%	NC
SABRIL	384,296.79	16	6	$709.72	1.36%	↓2
NOVOLOG FLEXPEN	377,592.58	524	330	$23,359.50	1.33%	↓1
STELARA	350,392.50	15	12	$4,102.31	1.24%	↓1
ADVAIR DISKUS	333,702.40	900	500	$334.58	1.18%	↓1
NORDITROPIN FLEXPRO	330,833.29	82	39	$23,880.01	1.17%	↓3
SYMBICORT	311,881.18	912	516	$7,444.03	1.10%	↓2
TRIKAFTA	310,419.47	13	5	$544.88	1.09%	↑1
BIKTARVY	307,448.16	160	74	$6,507.81	1.08%	↑6
ADDERALL XR	290,376.86	1,670	708	$173.51	1.02%	↑1
LEVEMIR FLEXTOUCH	284,724.86	520	298	$2,448.73	1.00%	↓2
COSENTYX PEN (2 PENS)	279,644.48	46	18	$8,310.49	0.99%	↓2
ELIQUIS	257,053.01	587	252	$433.59	0.91%	↑1
VICTOZA 2-PAK	255,079.81	421	220	$1,889.27	0.90%	↑4
XIFAXAN	251,855.54	108	49	$5,820.83	0.89%	↓4
STRATTERA	232,605.66	567	282	$401.66	0.82%	↑1
PROAIR HFA	224,139.29	2,874	2,831	$79.17	0.79%	↑9

Total Claims Cost	**$28,361,165.05**



Top 15 Therapeutic Classes Based on Number of Claims from 07/01/2021 – 09/30/2021

Therapeutic Class Description	Claims	Patients	Claims Cost	Cost/Claim	% Total Claims	Dif.
ANTIDEPRESSANTS	28,231	11,341	$607,837.52	$21.53	11.29%	NC
ANTICONVULSANTS	13,307	4,636	$1,119,956.77	$84.16	5.32%	NC
ANTIPSYCHOTIC AGENTS	8,549	3,217	$2,051,259.41	$239.94	3.42%	NC
PROTON-PUMP INHIBITORS	7,872	3,793	$142,138.19	$18.06	3.15%	NC
OPIATE AGONISTS	7,048	3,598	$126,365.63	$17.93	2.82%	NC
SEDATIVES/HYPNOTICS	6,456	3,191	$120,071.29	$18.60	2.58%	NC
NSAIDS	6,274	4,027	$91,424.01	$14.57	2.51%	NC
STATINS	6,020	3,159	$86,726.49	$14.41	2.41%	NC
BETA BLOCKERS	5,497	2,813	$100,698.17	$18.32	2.20%	NC
AMPHETAMINES	5,309	2,224	$955,304.00	$179.94	2.12%	NC
PENICILLIN ANTIBIOTICS	4,773	4,251	$75,048.16	$15.72	1.91%	↑4
ACE INHIBITORS	4,535	2,514	$65,676.87	$14.48	1.81%	↓1
NON-AMPHETAMINE STIMULANTS	4,506	1,730	$852,876.65	$189.28	1.80%	↓1
BETA AGONISTS	4,503	4,055	$332,174.31	$73.77	1.80%	↑4
THYROID AGENTS	4,235	1,855	$86,722.88	$20.48	1.69%	↓2

Top 15 Therapeutic Classes Based on Claims Cost from 07/01/2021 – 09/30/2021

Therapeutic Class Description	Claims Cost	Claims	Patients	Cost/Claim	% Total Cost	Dif.
DMARDS	2,658,149.54	484	189	$5,492.04	9.37%	NC
ANTIPSYCHOTIC AGENTS	2,051,259.41	8,549	2838	$239.94	7.23%	NC
SKIN AND MUCOUS MEMBRANE AGENTS	1,891,099.65	638	143	$2,964.11	6.67%	↑1
INSULINS	1,871,987.05	3,644	2055	$513.72	6.60%	↓1
ANTICONVULSANTS	1,119,956.77	13,307	4778	$84.16	3.95%	NC
INHALED CORTICOSTEROIDS	984,913.05	3,394	2183	$290.19	3.47%	↑1
AMPHETAMINES	955,304.00	5,309	1743	$179.94	3.37%	↓1
ANTIRETROVIRALS	917,856.47	706	524	$1,300.08	3.24%	↑2
ANTINEOPLASTIC AGENTS	873,426.31	549	251	$1,590.94	3.08%	↓1
INCRETIN MIMETICS	871,328.00	1,102	28	$790.68	3.07%	↑1
NON-AMPHETAMINE STIMULANTS	852,876.65	4,506	1598	$189.28	3.01%	↓2
IMMUNOMODULATORY AGENTS	677,728.42	89	36	$7,614.93	2.39%	↑1
ANTIDEPRESSANTS	607,837.52	28,231	500	$21.53	2.14%	↓1
SGLT-2 INHIBITORS	544,209.49	1,132	11931	$480.75	1.92%	NC
ANTIMUSCARINICS/ANTISPASMODICS	417,959.33	1,793	366	$233.11	1.47%	NC

PDL UPDATE

Drug Name	PA	Class
Betimol	PA	Glaucoma
Bevespi Aerosphere	PA	COPD - Anticholinergics/Beta Agonists Combination
Bronchitol	PA	Cystic Fibrosis
Bylvay	PA	Over 3000
desoximetasone 0.25% cream	PA	topical steroids
diflorasone diacetate	PA	topical steroids
Endari	PA	Sickle Cell Disease
Firdapse	PA	Over 3000
fluocinolone 0.1% cream	PA	topical steroids
Livmarli	PA	Over 3000
Mitagare	PA	Gout
Myfembree	PA	Uterine Fibroids
Nyvepria	PA	Hematopoietic, Colony Stimulating Factors
Rezurock	PA	Over 3000
Skytrofa	PA	Growth Hormone
Tudorza Pressair	PA	Long-Acting Anticholinergics
Varubi	PA	Nausea and Vomiting
voriconazole	PA	Antibiotic Resistance
Welireg	PA	Over 3000
Asmanex Twisthaler	remove PA	Corticosteroid - Inhaled
betamethasone dipropionate emollient 0.05% cream	remove PA	topical steroids
Brovana	remove PA	Long-Acting Beta Agonists
Cambia	remove PA	Migraine Treatment
clobetasol emollient 0.05% cream	remove PA	topical steroids
Delestrogen	remove PA	Estrogens
estradiol-norethindrone	remove PA	Estrogens
Femring	remove PA	Estrogens
fluocinonide 0.1% cream	remove PA	topical steroids
Frova	remove PA	Migraine Treatment
halobetasol 0.05% cream	remove PA	topical steroids
PANDEL (hydrocortisone probutate)	remove PA	topical steroids
Rebif	remove PA	Multiple Sclerosis
Spiriva Respimat	remove PA	Long-Acting Anticholinergics
Stiolto Respimat	remove PA	COPD - Anticholinergics/Beta Agonists Combination
triamcinolone acetonide 0.05% cream	remove PA	topical steroids
Zomig ODT	remove PA	Migraine Treatment
Zyptimag	remove PA	Hyperlipidemia

Eczema / Atopic Dermatitis

Electronic Age Verification

Product Specific: Protopic (tacrolimus) ointment 0.1%

- The member must be 16 years of age or older

Prior Authorization Criteria

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

Product Specific Criteria (Initial): *Approval Duration = 3 months*

- **Eucrisa, Dupixent, and Opzelura**
  - Member must meet FDA label recommendations for indication and age
  - Member must have had a 6-week trial of at least one of the following, as evidenced by paid claims or pharmacy printouts:
    - tacrolimus OR pimecrolimus
  - One of the following must be met (A or B):
    A. Member must have had two 2-week trials of topical corticosteroids of medium or higher potency, as evidenced by paid claims or pharmacy printouts.
    B. Member must meet both of the following (1 AND 2):
       1. Affected area is on face, groin, axilla, or under occlusion
       2. Member must have had two 2-week trials of topical corticosteroids of low or higher potency, as evidenced by paid claims or pharmacy printouts.
  - **Opzelura**: *Approval Duration = 3 months*
    - Indicated for short-term and non-continuous chronic treatment of mild to moderate atopic dermatitis.
    - The member must have a percentage BSA (excluding scalp) with AD involvement of 3% - 20%.
    - The member must not be immunocompromised.
    - The member must have had a 3-month trial of Eucrisa ointment, as evidenced by paid claims or pharmacy printouts.

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

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

Biologics

Prior Authorization Form - Dupixent

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

Oral

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
azathioprine	
Cyclosporine	
Methotrexate	
Systemic oral corticosteroids	

Topical

General Prior Authorization - Eucrisa

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ELIDEL (pimecrolimus) CREAM – *Brand Required*	EUCRISA (crisaborole) OINTMENT***
PROTOPIC (tacrolimus) OINTMENT 0.03% – *Brand Required*	OPZELURA (ruxolitinib)
PROTOPIC (tacrolimus) OINTMENT 0.1% – *Brand Required*	Tacrolimus 0.03%
Topical Corticosteroids	Tacrolimus 0.1%
	Pimecrolimus

SECOND REVIEW

Non-Stimulants

Prior Authorization Criteria

General Prior Authorization Form

Product Specific Criteria:

- **Qelbree:**
  - The member must have had a 30-day trial of a stimulant at the maximally tolerated dose, as evidenced by paid claims or pharmacy printouts

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
atomoxetine	INTUNIV (guanfacine ER)
clonidine	KAPVAY (clonidine ER) ***
clonidine ER***	STRATTERA (atomoxetine
guanfacine	
guanfacine ER	
QELBREE (viloxazine)	

ANNUAL REVIEW

Major Changes Since Last Version

Albuterol/Levalbuterol Rescue Inhalers
- electronic step added to Xopenex

Aplastic Anemia
- Renewal criteria added

Chronic hepatitis C infection-associated thrombocytopenia
- Initial criterion added
- Renewal criteria added

Cystic Fibrosis:
- Bronchitol added to prior authorization with Bronchitol Tolerance Test requirement

Diabetes
- Sulfonylureas and TZDs are covered together

Empaveli
- Hb level added for renewal criteria

Eosinophilic asthma
- Eosinophil and IgE levels added to criteria

Glucose Rescue Medications
- Added step therapy

Huntington's Disease
- Added step therapy

Narcolepsy
- Criteria added specific to Xywav

Insulins
- Regular insulin criteria added
- Humalog U-200 criteria added
- TZDs are allowed with insulin

Otezla
- Preferred for all indications

Parkinson's Disease
- Renewal therapy added

Plaque Psoriasis:
- Anti-interleukin (IL) 17 Antibodies - Taltz and Cosentyx: Require 3-month trial of a TNF Inhibitor
- Otezla covered for all indications without prior authorization

Steroid/Anticholinergic/Long-Acting Beta Agonist Combination:
- Step Therapy added with the entry of competitor

Taltz and Cosentyx:
- Require step therapy

Xeljanz
- Preferred for all indications

Preferred Drug Preferred Drug List (PDL)

General

Biosimilar Agents

General Prior Authorization Form

Group Criteria:

- The member must have an FDA-approved indication for use (meets label recommendations for diagnosis and age).
- Clinical justification must be provided explaining why the member is unable to use the preferred agents (subject to clinical review)

Combination Agents

General Prior Authorization Form

Group Criteria:

- Clinical justification must be provided for combination products that are comprised of components available and more cost effective when prescribed separately (subject to clinical review).

Dispense as Written (DAW1)

Prior Authorization Form - Dispense As Written (DAW1)
MedWatch Form

Criteria for ALL DAW requests (must meet one of the following (A or B):

A. Primary insurance requires a ND Medicaid non-preferred branded product
   - *Approval: until the end of the calendar year*

B. All of the following are met (1-4):
   1. The member must have an FDA-approved indication for use (meets label recommendations for diagnosis and age).
   2. The requested brand-name product must not have an authorized generic available
   3. The member must have failed a 30-day trial of each pharmaceutically equivalent generic product from each available manufacturer, as evidenced by paid claims or pharmacy print outs
      a. A failure is defined as product was not effective at maximum tolerated dose or caused adverse reaction where the branded product is expected to have a different result and other alternatives (e.g. medications in same class) are not an option for the member
      b. The member or prescriber preference is NOT criteria considered for approval
   4. A MedWatch form for each trial of each product from the available manufacturer(s) must be filled out and attached to request

Medications that cost over $3000/month

General Prior Authorization Form

Group Criteria:

- **Initial Criteria:** *Approval Duration = 6 months*
  - The member must meet criteria as outlined in prescribing information (PI) including recommendations for diagnosis and age.
  - The prescriber is a specialist, or the prescriber has consulted with a specialist in the area of the member's diagnosis
  - As applicable, documentation must be attached to confirm serum marker or pathogenic gene variants amenablTe to treatment
- **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).

PA REQUIRED
BYLVAY (odevixibat)
CERDELGA (eliglustat)
CYSTADROPS (cysteamine)
CYSTARAN (cysteamine)
DOJOVI (triheptanoin)
ENSPRYNG (satralizumab)
FIRDAPSE (amifampridine)
GATTEX (teduglutide)
ILARIS (canakinumab)
INCRELEX (mecasermin)
LUPKYNIS (voclosporin)
MYCAPSSA (octreotide)
NULIBRY (fosdenopterin)
OXERVATE (cenegermin-bkbj)
RAVICTI (glycerol phenylbutyrate)
REZUROCK (belumosudil)
SAMSCA (tolvaptan)
SYPRINE (trientine)
TAVNEOS (avacopan)
WELIREG (belzutifan)
ZOKINVY (lonafamib)

Non-solid dosage preparations

General Prior Authorization Form

Electronic Age Verification

A. Non-solid dosage preparations of preferred products are automatically covered for all members younger than 9 years old. For coverage of these products in members 9 years of age or older, one of the following criteria must be met (A or B): The member is unable to swallow solid dosage medications due to one of the following:
   - Swallow study documentation – *Approval 1 year*
   - Feeding tube placement and the medication is not available in a dosage form that can be crushed or poured into the tube – *Approval 1 year*
   - Permanent disability of swallowing solid dosage forms - A*pproval 2 years*
   - Short-term restriction (e.g. mouth surgery) - *Approval 1 month*

B. Clinical justification has been provided as to why a solid dosage medication cannot be used (subject to clinical review)

Preferred Dosage Forms List:

General Prior Authorization Form

See Preferred Dosage Forms List

Allergy/Immunology

Biologic Agents

Chronic Idiopathic Urticaria

General Prior Authorization Form

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

- The member must meet label recommendations for indication and age.
- Must be prescribed by, or in consult with, an allergist/immunologist.
- The member must have had a 30-day trial of a type 1 (H1) antihistamine at maximally tolerated dose either non-sedating (e.g. cetirizine, fexofenadine, loratadine, desloratadine, or levocetirizine) or sedating (e.g. diphenhydramine, chlorpheniramine, cyproheptadine) in addition to one of the following:
    - leukotriene receptor antagonist (e.g. montelukast, zafirlukast, zileuton)
    - histamine H2-receptor (e.g. ranitidine, famotidine, nizatidine, cimetidine)

Category Criteria (Renewal): *Approval Duration = 12 months*

- The prescriber must provide documentation showing that the member has achieved a clinical benefit since treatment initiation.

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
XOLAIR (omalizumab) SYRINGES	

Eosinophilic Asthma

General Prior Authorization Form

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

- The member must meet label recommendations for indication and age.
- Must be prescribed by, or in consult with, a pulmonologist or allergist/immunologist
- The member must have had at least one exacerbation 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

Product Specific Criteria (Initial):

- Anti-IL-5 and Anti-IL-4/13 biologics:
    - The member has eosinophilic phenotype with eosinophil count ≥ 150 cells/mcL within the past 90 days
- 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

Non-Preferred Agents Criteria:

- The member must have had a 3-month trial of 1 preferred Eosinophilic Asthma agent, as evidenced by paid claims or pharmacy printouts

Category Criteria (Renewal): *Approval Duration = 12 months*

- The prescriber must provide documentation showing that the member has achieved a significant reduction in asthma exacerbations and utilization of rescue medications since treatment initiation

Anti-IL-5 biologics

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
FASENRA (benralizumab) PEN	NUCALA (mepolizumab)

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	

Eosinophilic granulomatosis with polyangiitis (EGPA)

General Prior Authorization Form

Group Criteria:

- **Initial Criteria:** *Approval Duration = 6 months*
    - The member must be 18 years of age or older
    - The prescription must be written by, or in consultation with, a hematologist, pulmonolgist, or allergy/immunology specialist
    - The member must have a diagnosis of eosinophilic granulomatosis with polyangiitis (EGPA) characterized by
        - Member has asthma poorly controlled on moderate doses of inhaled glucocorticoids

        - Member has a greater than blood eosinophilia > 1000 cells/mcL or 10% eosinophils on the differential leukocyte count, as evidenced by laboratory documentation attached to the request
        - Two of more of the following:
            - Mononeuropathy (including multiplex) or polyneuropathy
            - Pulmonary infiltrates
            - Paranasal sinus abnormality
            - Eosinophilic vasculitis, perivascular eosinophilic infiltration, or eosinophil-rich granulomatous inflammation
            - Glomerulonephritis
            - Alveolar hemorrhage
            - Palpable purpura
            - Myocardial infarction due to coronaritis
            - Anti-neutrophil cytoplasmic antibody (ANCA) positivity
    - The member must have had relapsing or recurring disease requiring systemic corticosteroids in previous year despite a 3-month trial with good compliance of one of the following medication, as evidenced by paid claims or pharmacy printouts:
        - Cyclophosphamide
        - Azathioprine
        - Methotrexate
        - Leflunomide
- **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)

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

Hypereosinophilic Syndrome

General Prior Authorization Form

Group Criteria:

- **Initial Criteria:** *Approval Duration = 6 months*
    - The member must be 12 years of age or older
    - The prescription must be written by, or in consultation with, a hematologist, or allergy/immunology specialist
    - The member must have a diagnosis of hypereosinophilic syndrome (HES) characterized by the following:
        - The member must have experienced hypereosinophilic syndrome for ≥6 months
        - The provider must attest that there is no identifiable nonhematologic secondary cause
    - The member must have experienced at least 2 HES flares within the past 12 months despite continued compliant use of oral corticosteroids and/or steroid sparing therapy (e.g. hydroxyurea)
    - The member must have a blood eosinophil count of 1,000 cells/mcL or higher, as evidenced by laboratory documentation attached to the request
- **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)

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

Nasal polyps

General Prior Authorization Form

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

- The member must meet label recommendations for indication and age.
- Must be prescribed by, or in consult with, an ear/nose/throat specialist or allergist/immunologist.
- The member must have had a 12-week trial of intranasal or oral corticosteroid
- The member must have bilateral polyps confirmed by sinus CT, sinus MRI, or nasal endoscopy
- Member must have documentation of at least two of the following symptoms:

- Nasal blockade/obstruction/congestion or nasal discharge (anterior/posterior nasal drip)
- Facial pain/pressure
- Reduction or loss of smell

Non-Preferred Agent Criteria:

- The member must have had a 90-day trial with a preferred agent, as evidenced by paid claims or pharmacy printouts

Category Criteria (Renewal): *Approval Duration = 12 months*

- The prescriber must provide documentation showing that the member has achieved a significant reduction in nasal polyp size and symptoms since treatment initiation.
- The member must be receiving intranasal steroids

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
DUPIXENT (dupilumab)	NUCALA (mepolizumab)
XOLAIR (omalizumab) SYRINGES	

Medical Billing Drug Clinical Criteria Only

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
XOLAIR (omalizumab) VIAL	

Epinephrine

Electronic Duration Verification

- 3 packs (initial and replacement doses) are covered every 180 days without prior authorization.

General Prior Authorization Form

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
epinephrine – labeler 49502	epinephrine – labeler 00935
SYMJEPI (epinephrine)	epinephrine – labeler 11516
	EPIPEN (epinephrine)
	EPIPEN (epinephrine) JUNIOR

Gout

Krystexxa (pegloticase) – Medical Billing Drug Clinical Criteria

Prior Authorization

General Prior Authorization Form

Product Specific Criteria:

- **Colchicine capsules:**
  - See **Preferred Dosage Form List** Criteria
- **Uloric:**
  - The member must have had a 30-day trial of allopurinol, as evidenced by paid claims or pharmacy printouts

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
allopurinol tablet	colchicine capsules
COLCRYS (colchicine) TABLETS – *Brand Required*	colchicine tablets
probenecid-colchicine tablets	febuxostat
probenecid tablets	GLOPERBA (colchicine) ORAL SOLUTION
	MITIGARE (colchicine) CAPSULE
	ULORIC (febuxostat) TABLET
	ZYLOPRIM (allopurinol) TABLET

Hereditary Angioedema

General Prior Authorization Form

Group Criteria: *Approval Duration = 12 months*

- The member must have an FDA-approved indication for use (meets label recommendations for diagnosis and age)
- The medication must be prescribed by or in consultation with an allergist, immunologist, or rheumatologist

Non-Preferred Agents Criteria:

- The request must meet the group 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
    - Required trial durations
        - Agents for acute attacks: a single trial
        - Agents for attack prophylaxis: 3 months

Product Specific Criteria:

- Takhyzro
    - The number of attacks in the last 6 months must be included if the requested dose is 300mg every 2 weeks.

Acute Attack

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
BERINERT (C1 Esterase Inhibitor)	FIRAZYR (icatibant)
Icatibant	KALBITOR (ecallantide)
RUCONEST (C1 Esterase Inhibitor)	

Prophylaxis

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
HAEGARDA (C1 Esterase Inhibitor)	CINRYZE (C1 Esterase Inhibitor)
ORLADEYO (berotrlastat)	
TAKHZYRO (lanadelumab-flyo)	

Immune Globulins

General Prior Authorization Form

Category Criteria:

- If the member's BMI > 30, adjusted body weight must be provided along with the calculated dose
- The member must have a diagnosis of an FDA-approved indication for use

Non-Preferred Product Specific 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)

IVIG

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
BIVIGAM (human immunoglobulin gamma)	ASCENIV (human immune globulin G- slra)
FLEBOGAMMA DIF (human immunoglobulin gamma)	GAMMAPLEX (human immunoglobulin gamma)
GAMMAGARD S-D (human immunoglobulin gamma)	OCTAGAM (human immunoglobulin gamma)
PRIVIGEN (human immunoglobulin gamma)	PANZYGA (Immune Globulin- ifas)

IVIG/SCIG

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
GAMMAGARD LIQUID (human immunoglobulin gamma)	GAMMAKED (human immunoglobulin gamma)
GAMUNEX-C (human immunoglobulin gamma)	

SCIG

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
HIZENTRA (human immunoglobulin gamma)	CUTAQUIG (human immune globulin G - hipp)
	CUVITRU (human immunoglobulin gamma)
	HYQVIA (human immune globulin G and hyaluronidase)

Palforzia

Palforzia Prior Authorization Form

Group Criteria:

- **Initial Criteria:** *Approval Duration = 6 months*
    - The member must have an FDA-approved indication for use (meets label recommendations for diagnosis and age)
    - The member does not have any contraindications to treatment

- The prescriber must be or be in consultation with an allergy and/or immunology specialist
- 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 300mg dose*
  - The member must have been compliant with Palforzia, as evidenced by pharmacy records or pharmacy claims history showing on-time fills during the last 6 months
  - The member must not have any of the following:
    - Uncontrolled asthma
    - Severe or persistent GI symptoms
    - Eosinophilic esophagitis
  - The member must have experienced and maintained clinical benefit since starting treatment with Palforzia, as evidenced by the following:
    - The member continues to have a peanut allergy and has been/is being monitored for resolution of their allergy
    - The member has been able to tolerate the maintenance dose of Palforzia (300 mg daily)
      OR
    - The prescriber has submitted a plan to continue up-titration to a final dose of 300 mg daily and have not already requested a renewal PA for the up-titration period

PA REQUIRED
PALFORZIA (peanut allergen powder)

Steroids - Nasal

General Prior Authorization Form

Non-Preferred Agents Criteria:

- The member must have failed a 30-day trial (within the past 2 years) of 1 preferred agent, as evidenced by paid claims or pharmacy printouts

Product Specific Criteria:

- ***Xhance (fluticasone):**
  - Clinical justification must be provided explaining why the member is unable to use another product with the same active ingredient (subject to clinical review)

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
BECONASE AQ (beclomethasone)	flunisolide
Fluticasone	mometasone
OMNARIS (ciclesonide)	XHANCE (fluticasone)***
QNASL (beclomethasone)	
QNASL CHILDREN'S (beclomethasone)	
ZETONNA (ciclesonide)	

Cardiology

Therapeutic Duplication

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

- Medication classes not payable together:
  - Entresto, ACE Inhibitors, ARBs, and Renin Inhibitors are not allowed with each other
  - Sildenafil, Tadalafil, Adempas, nitrates are not allowed with each other
  - Carvedilol and Labetalol are not allowed with other alpha blockers (Alfuzosin ER, doxazosin, dutasteride-tamsulosin, prazosin, terazosin, and tamsulosin)
    - Carvedilol and Labetalol are nonselective beta blockers with alpha 1 blocking activity
  - Tizanidine is not allowed with other alpha 2 agonists (clonidine, clonidine/chlorthalidone, guanfacine, methyldopa)
    - Tizanidine is also an alpha 2 agonist
  - Clopidogrel is not covered with esomeprazole or omeprazole. Other PPIs such as pantoprazole are covered with clopidogrel.
    - Clopidogrel is a substrate for 2C19 and esomeprazole and omeprazole are strong 2C19 inhibitors and can decrease effectiveness of Clopidogrel.
  - Clopidogrel, Prasugrel, Ticagrelor, and Ticlopidine are not covered with morphine. Other opioid analgesics are covered with Clopidogrel, Prasugrel, Ticagrelor, and Ticlopidine.
    - Morphine may diminish the antiplatelet effect and serum concentrations of P2Y12 Inhibitor antiplatelet agents (clopidogrel, prasugrel, ticagrelor, and ticlopidine).

Beta Blockers – Override Request

Please have the following information when requesting an override by calling provider relations at 1-800-755-2604. Overrides may be available for beta blockers with slightly different mechanisms of action for use within the cardiac or nephrology specialty: non-selective or selective beta blocking activity; with or without alpha-1 blocker activity.

1. Are prescribers of each medication aware of the other?
2. Is a cardiologist and/or nephrologist involved in therapy who agrees to duplication?

Anticoagulants - Oral:

Underutilization

- Eliquis, Pradaxa, Xarelto, and Savaysa must be used compliantly and will reject on point of sale for late fill

Prior Authorization

General Prior Authorization Form

Product Specific Criteria:

***Xarelto 2.5mg** - Member must have an FDA approved indication.

Non-Preferred Agents Criteria:

- The member must have a diagnosis of an FDA-approved indication.
- The member must have had a 30-day trial of each preferred agent, as evidenced by paid claims or pharmacy printouts.

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ELIQUIS (Apixaban)	SAVAYSA (edoxaban)
PRADAXA (dabigatran)	
XARELTO (rivaroxaban) 10mg, 15mg, 20mg	
XARELTO (rivaroxaban) 2.5mg PA***	
XARELTO (rivaroxaban) STARTER PACK	

Anticoagulants - Injectable

Electronic Diagnosis Verification

- Fondaparinux is covered for a diagnosis of heparin-induced thrombocytopenia (HIT)

Prior Authorization Criteria

General Prior Authorization Form

Non-Preferred Agents Criteria:

- The member must have an FDA-approved indication for use (meets label recommendations for diagnosis and age).
- The member must have had a 30-day trial of enoxaparin, as evidenced by paid claims or pharmacy printouts.

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
enoxaparin	ARIXTRA (fondaparinux)
fondaparinux	FRAGMIN (dalteparin)

	LOVENOX (enoxaparin)

Heart Failure

Electronic Diagnosis Verification

- Corlanor, Entresto, and Verquvo require an FDA-approved indication for use.

Prior Authorization Criteria

General Prior Authorization Form

Product Specific Criteria:

- **Verquvo:**
  - The member must meet FDA-approved age for use.
  - The member must have left ventricular ejection fraction (LVEF) < 45%
  - Documentation of a recent hospitalization or need for IV diuretics (within the past 6 months) must be submitted with request
  - The member is receiving concurrent Entresto, a beta-blocker, a SGLT-2 Inhibitor, and a mineralocorticoid receptor antagonist.
- **Corlanor:**
  - The member must meet FDA-approved age for use.
  - The member must have a resting HR ≥ 70 beats per minute on maximally tolerated or target beta blocker dose in sinus rhythm

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

Loop Diuretics

General Prior Authorization Form

Product Specific Criteria:

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

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

Lipid-Lowering Agents

General Prior Authorization Form

Non-Preferred Agent Criteria (Initial): *Approval Duration = 3 months*

- The member must have an FDA-approved indication for use (meets label recommendations for diagnosis and age)
- The member must have LDL levels of >100 mg/dL after a 90-day trial of each of the following, as evidenced by paid claims or pharmacy printouts:
  - A PCSK9 inhibitor combined with Crestor (rosuvastatin) ≥20 mg or Lipitor (atorvastatin) ≥ 40 mg

Product Specific Criteria:

- Evkeeza: See Medical Billing Drug Clinical Criteria
- **Juxtapid:**
    - The member must have an FDA-approved indication for use (meets label recommendations for diagnosis and age)
    - The member must have LDL levels of >100 mg/dL after a 90-day trial of each of the following, as evidenced by paid claims or pharmacy printouts:
        - A PCSK9 inhibitor combined with Crestor (rosuvastatin) ≥20 mg or Lipitor (atorvastatin) ≥ 40 mg
        - Nexlizet combined with Crestor (rosuvastatin) ≥20 mg or Lipitor (atorvastatin) ≥ 40 mg
    - Clinical justification must be provided explaining why the member is unable to use all other products to lower their cholesterol (subject to clinical review)

Group Criteria (Renewal): *Approval Duration = 12 months*

- The member must currently be receiving a maximally tolerated statin (HMG-CoA reductase inhibitor) agent, as evidenced by paid claims or pharmacy printouts
- 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)

ACL (ATP Citrate Lyase) INHIBITORS	
PREFERRED AGENTS (NO PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**
	NEXLETOL (bempedioc acid)
	NEXLIZET (bempedoic acid and ezetimibe)
Cholesterol Absorption Inhibitor - 2-Azetidinone	
PREFERRED AGENTS (NO PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**
Ezetimibe	ZETIA (ezetimibe)
MTP (Microsomal Triglyceride Transfer Protein) INHIBITOR	
PREFERRED AGENTS (NO PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**
	JUXTAPID (lomitapide)
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	fenofibrate tablets 40mg, 120mg
fenofibrate tablets 48mg, 54mg, 145mg, 160mg	FENOGLIDE (fenofibrate)
	LIPOFEN (fenofibrate)
	TRICOR (fenofibrate)
	TRIGLIDE (fenofibrate)
PCSK9 (Proprotien Convertase Subtilisin/Kexin Type 9) INHIBITORS	
PREFERRED AGENTS (NO PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**
PRALUENT PEN (alirocumab)	REPATHA PUSHTRONEX (evolocumab)
	REPATHA SURECLICK (evolocumab)
	REPATHA SYRINGE (evolocumab)
STATINS (HMG-CoA (3-hydroxy-3-methylglutaryl-CoA Reductase Inhibitors)	
PREFERRED AGENTS (NO PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**
amlodipine/atorvastatin	ALTROPREV (lovastatin)
atorvastatin	CADUET (amlodipine/atorvastatin)
ezetimibe/simvastatin	CRESTOR (rosuvastatin)
fluvastatin	EZALLOR SPRINKLE (rosuvastatin)
LIVALO (pitavastatin)	Fluvastatin ER
lovastatin	LESCOL XL (fluvastatin)
pravastatin	LIPITOR (atorvastatin)
rosuvastatin	PRAVACHOL (pravastatin)
simvastatin	VYTORIN (ezetimibe/simvastatin)
ZYPITAMAG (pitavastatin)	ZOCOR (simvastatin)

Platelet Aggregation Inhibitors

General Prior Authorization Form

Non-Preferred Agents Criteria:

- The member must have an FDA-approved indication for use (meets label recommendations for diagnosis and age).

- The member must have had 30-day trials of at least 2 preferred platelet aggregation inhibitor agents, as evidenced by paid claims or pharmacy printouts.

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

Pulmonary Hypertension

PDE-5 Inhibitors

Electronic Age Verification

- Sildenafil/Tadalafil: Prior authorization is not required for ages less than 12 years old
- Revatio Suspension: Prior authorization is not required for ages less than 9 years old

Prior Authorization Criteria

General Prior Authorization Form

Group Criteria:

- The member must have an FDA-approved indication for use (meets label recommendations for diagnosis and age), with medical documentation (e.g. clinical notes) of their diagnosis attached to the request.

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
REVATIO (sildenafil) SUSPENSION – *Brand Required*	ADCIRCA (tadalafil) TABLET
sildenafil tablet	ALYQ (tadalafil)
tadalafil tablet	REVATIO (sildenafil) TABLET
	sildenafil suspension

Soluble Guanylate Cyclase Stimulators

Electronic Diagnosis Verification

- The member must have an FDA-approved diagnosis for use

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ADEMPAS (riociguat)	

Endothelin Receptor Antagonists

Electronic Diagnosis Verification

- The member must have an FDA-approved diagnosis for use

Prior Authorization Criteria

Group Criteria:

- The member must have an FDA-approved indication for use (meets label recommendations for diagnosis and age).
- The member must have had a 30-day trial of ambrisentan, as evidenced by paid claims or pharmacy printouts.

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ambrisentan	bosentan
TRACLEER (bosentan) SUSPENSION	LETAIRIS (ambrisentan)
TRACLEER (bosentan) TABLETS - *Brand Required*	OPSUMIT (macitentan)

Prostacyclins

Electronic Diagnosis Verification

- The member must have an FDA-approved diagnosis for use

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ORENITRAM ER (treprostinil) TABLET	REMODULIN (treprostinil) INJECTION

UPTRAVI (selexipag) TABLET	
treprostinil injection	
TYVASO (treprostinil) INHALATION	
UPTRAVI (selexipag) VIAL	
VENTAVIS (iloprost) INHALATION	

Vecamyl

General Prior Authorization Form

Group Criteria:

- 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

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

Electronic Age Verification

- The member must be between 12 and 35 years of age

Prior Authorization Criteria

General Prior Authorization Form

Non-Preferred Agents Criteria:

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

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%	
CLINDAMYCIN	
PREFERRED AGENTS (NO PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**
clindamycin capsule	CLEOCIN T (Clindamycin) GEL
clindamycin gel	CLEOCIN T (Clindamycin) LOTION
clindamycin lotion	CLEOCIN T (Clindamycin) MED SWAB
clindamycin solution	CLINDACIN P (Clindamycin) MED SWAB
clindamycin med. swab	CLINDACIN ETZ (Clindamycin) MED SWAB
EVOCLIN (Clindamycin) FOAM – *Brand Required*	CLINDAGEL (Clindamycin) GEL DAILY
ZIANA (Clindamycin-tretinoin 1.2%-0.025%) - *Brand Required*	clindamycin gel daily
	clindamycin foam
	clindamycin-tretinoin 1.2%-0.025%
RETINOID	
PREFERRED AGENTS (NO PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**
ALTRENO (tretinoin) LOTION	ATRALIN (tretinoin) 0.05% GEL
FABIOR (tazarotene) 0.1% FOAM - *Brand Required*	ARAZLO (tazarotene) 0.045% LOTION
RETIN-A MICRO PUMP (tretinoin microsphere) 0.04%, 0.1% - *Brand Required*	clindamycin-tretinoin 1.2%-0.025%

RETIN-A MICRO PUMP (tretinoin microsphere) 0.08%	RETIN-A (tretinoin) CREAM
tretinoin cream	RETIN-A (tretinoin) GEL
tretinoin gel	RETIN-A MICRO PUMP (tretinoin microsphere) 0.06%
tretinoin microsphere without pump	RETIN-A MICRO (tretinoin microsphere) GEL WITHOUT PUMP
ZIANA (clindamycin-tretinoin 1.2%-0.025%) - *Brand Required*	tazarotene 0.1% foam
	tretinoin microsphere with pump
ADAPALENE	
PREFERRED AGENTS (NO PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**
adapalene gel	adapalene cream
adapalene gel with pump	DIFFERIN (adapalene) GEL
adapalene/Benzoyl Peroxide 0.1%-2.5%	DIFFERIN (adapalene) GEL W/ PUMP
DIFFERIN (adapalene) CREAM - *Brand Required*	
DIFFERIN (adapalene) LOTION	
EPIDUO FORTE (adapalene/benzoyl peroxide) 0.3%-2.5%	
OTHER	
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%	AKLIEF (trifarotene) CREAM 0.005%
dapsone gel without pump 5%	BP 10-1 (sulfacetamide sodium/sulfur) CLEANSER
SSS 10-5 (sulfacetamide) FOAM	dapsone gel pump 7.5%
sulfacetamide 10% suspension	SSS 10-5 (sulfacetamide) CLEANSER
sodium sulfacetamide/sulfur cleanser 10%-5% (W/W)	sodium sulfacetamide/sulfur pads 10%-4%
sodium sulfacetamide/sulfur cleanser 9%-4%	sodium sulfacetamide/sulfur cream 10%-2%
sodium sulfacetamide/sulfur cleanser 9%-4.5%	SUMADAN (sodium sulfacetamide/sulfur) CLEANSER 9%-4.5%
sodium sulfacetamide/sulfur cleanser 9.8% -4.8%	SUMAXIN (sodium sulfacetamide/sulfur pads) PADS 10%-4%
sodium sulfacetamide/sulfur cleanser 10%-2%	SUMAXIN TS (sodium sulfacetamide/sulfur) SUSPENSION 8%-4%
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%	
TETRACYCLINES	
PREFERRED AGENTS (NO PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**
doxycycline hyclate capsule	AMZEEQ (minocycline) Foam
doxycycline hyclate tablet 20mg, 100mg	demeclocycline
doxycycline monohydrate 25 mg/5mL suspension	DORYX (doxycycline hyclate) TABLET DR
doxycycline monohydrate tablet 50 mg, 75mg, 100mg	DORYX MPC (doxycycline hyclate) TABLET DR
doxycycline monohydrate capsule 50 mg, 100mg	doxycycline monohydrate capsule 75mg, 150mg
minocycline capsule	doxycycline hyclate tablet 75mg, 150 mg
tetracycline	doxycycline monohydrate tablet 150 mg
VIBRAMYCIN (Doxycycline calcium) 50 mg/5mL SYRUP	doxycycline hyclate tablet DR
	MINOCIN (minocycline) CAPSULE
	minocycline tablet
	minocycline Tablet ER
	MINOLIRA ER (minocycline) TABLET
	MORGIDOX (doxycycline hyclate) CAPSULE
	SEYSARA (sarecycline)
	SOLODYN ER (minocycline) TABLET
	VIBRAMYCIN (doxycycline monohydrate) 25mg/5mL SUSPENSION
	XIMINO (minocycline) CAPSULE ER

Actinic Keratosis

General Prior Authorization Form

Product Specific Criteria:

- Diclofenac 3% sodium gel requires electronic diagnosis verification of FDA indication

Non-Preferred Agents Criteria:

- The member must have an FDA-approved indication for use (meets label recommendations for diagnosis and age).
- The member must have had a 6-month trial of each preferred agent of a unique active ingredient, as evidenced by paid claims or pharmacy printouts.

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
CARAC (fluorouracil) 0.5% CREAM – *Brand Required*	ALDARA (imiquimod) 0.5% CREAM
diclofenac 3% sodium gel	EFUDEX (fluorouracil) 5% CREAM
imiquimod 5% cream packet	fluorouracil 0.5% cream
fluorouracil 5% cream	imiquimod 3.75% cream pump
fluorouracil 2% solution	KLISYRI (tirbanibulin) OINTMENT
fluorouracil 5% solution	PICATO (ingenol mebutate)
ZYCLARA (imiquimod) 3.75% CREAM PUMP – *Brand Required*	TOLAK (fluorouracil) 4% CREAM
	ZYCLARA (imiquimod) 3.75% CREAM PACKET
	ZYCLARA (imiquimod) 2.5% CREAM PUMP

Antifungals – Topical

General Prior Authorization Form

Non-Preferred Agents Criteria:

- **Onychomycosis:** *Approval Duration = 12 months*
  - The member must have a diagnosis of an FDA approved indication for use
    - 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):
    A. Clinical justification must be provided explaining why the member is unable to use the preferred agents (subject to clinical review)
    B. The active ingredient of the requested product is not available in a preferred formulation
- **Other diagnoses:** *Approval Duration = 12 months*
  - The member must have had 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):
    A. Clinical justification must be provided explaining why the member is unable to use the preferred agents (subject to clinical review)
    B. The active ingredient of the requested product is not available in a preferred formulation

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ciclopirox cream	CICLODAN (ciclopirox) CREAM
ciclopirox gel	CICLODAN (ciclopirox) SOLUTION
ciclopirox shampoo	EXTINA (ketoconazole) FOAM
ciclopirox solution	JUBLIA (efinaconazole) SOLUTION
ciclopirox suspension	KERYDIN (tavaborole) SOLUTION
clotrimazole cream	ketoconazole foam
clotrimazole solution	LOPROX (ciclopirox) CREAM

econazole cream	LOPROX (ciclopirox) SHAMPOO
ERTACZO (sertraconazole) CREAM	LOPROX (ciclopirox) SUSPENSION
EXELDERM CREAM (sulconazole) – *Brand Required*	LUZU (luliconazole) Cream
EXELDERM SOLUTION (sulconazole) – *Brand Required*	miconazole/zinc oxide/white petrolatum ointment
ketoconazole cream	natfifine Cream
ketoconazole shampoo	natfifine Gel
luliconazole cream	NAFTIN (naftifine) CREAM
MENTAX (butenafine) CREAM	NAFTIN (naftifine) GEL
miconazole cream	oxiconazole cream
nystatin cream	OXISTAT (oxiconazole) CREAM
nystatin ointment	OXISTAT (oxiconazole) LOTION
nystatin powder	tavaborole solution
NYAMYC (nystatin) POWDER	VUSION (miconazole/zinc/white petrolatum) OINTMENT
nystatin – triamcinolone cream	
nystatin – triamcinolone ointment	
NYSTOP (nystatin) POWDER	

Eczema / Atopic Dermatitis

Electronic Age Verification

Product Specific: Protopic (tacrolimus) ointment 0.1%

- The member must be 16 years of age or older

Prior Authorization Criteria

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

Product Specific Criteria (Initial): *Approval Duration = 3 months*

- **Dupixent and Eucrisa**
  - Member must meet FDA label recommendations for indication and age
  - Member must have had a 6-week trial of at least one of the following, as evidenced by paid claims or pharmacy printouts:
    - tacrolimus OR pimecrolimus
  - One of the following must be met (A or B):
    A. Member must have had two 2-week trials of topical corticosteroids of medium or higher potency, as evidenced by paid claims or pharmacy printouts.
    B. Member must meet both of the following:
    - Affected area is on face, groin, axilla, or under occlusion
    - Member must have had two 2-week trials of topical corticosteroids of low or higher potency, as evidenced by paid claims or pharmacy printouts.

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

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

Biologics

Prior Authorization Form - Dupixent

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

Oral

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
azathioprine	
cyclosporine	
methotrexate	

systemic oral corticosteroids	

Topical

General Prior Authorization Form

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

Hidradenitis Suppurativa

Electronic Diagnosis Verification

- The member must have an FDA-approved indication for use

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
HUMIRA (adalimumab)	

Infantile Hemangioma

Electronic Age Verification

- The patient must be less than 1 years of age

Electronic Diagnosis Verification

- The patient must have an FDA approved diagnosis

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
HEMANGEOL (propranolol) ORAL SOLUTION	

Lice

General Prior Authorization Form

Category Criteria:

- The member must have had a 28-day/2-application trial of each preferred agent, as evidenced by paid claims or pharmacy printouts (not required *in the presence of a documented community breakout of a resistant strain that is only susceptible to a non-preferred agent).*

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
EURAX (crotamiton) CREAM	CROTAN (crotamiton)
LICE KILLING SHAMPOO (piperonyl butoxide/pyrethrins)	ELIMITE (permethrin) CREAM
NIX 1% (Permethrin) CRÈME RINSE LIQUID	EURAX (crotamiton) LOTION
Permethrin 5% cream	Lindane shampoo
SM LICE TREATMENT (permethrin) 1% CRÈME RINSE LIQUID	Malathion
Spinosad	NATROBA (spinosad)
VANALICE (piperonyl butoxide/pyrethrins)	OVIDE (malathion)

Plaque Psoriasis

Biologic Agents

Electronic Diagnosis Verification

- The member must have an FDA-approved indication for use

Prior Authorization

General Prior Authorization Form

Non-Preferred Agents Criteria:

- The member must have had a 3-month trial of a TNF inhibitor and an Anti-IL 17 agent, as evidenced by paid claims or pharmacy printouts.

Anti – TNF Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ENBREL (etanercept)	CIMZIA (certolizumab)
HUMIRA (adalimumab)	

Anti – Interleukin (IL) 12/IL-23

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

Anti – Interleukin (IL) 17 Antibodies

Product Specific Criteria:

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

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
TALTZ (ixekizumab)***	COSENTYX (secukinumab)

Anti – Interleukin (IL) 17 Receptor Antibody

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

Anti – Interleukin (IL) 23/ Interleukin (IL) 39

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	SKYRIZI (risankizumab-rzaa)
	TREMFYA (guselkumab)

Phosphodiesterase 4 (PDE4) Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
OTEZLA (apremilast)	

Topical

General Prior Authorization Form

Non-Preferred Agents Criteria:

- **For Foams and Sprays:**
  - Member must have failed 30-day trials of the preferred solution and shampoo formulations, as evidenced by paid claims or pharmacy print outs
- **For Lotions:**
  - Member must have failed a 30-day trial of a preferred agent, as evidenced by paid claims or pharmacy print outs
- **For Ointments:**
  - Member must have failed 30-day trials of the preferred ointment formulations, as evidenced by paid claims or pharmacy print outs

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
calcipotriene ointment	calcipotriene/betamethasone ointment
calcipotriene solution	calcipotriene/betamethasone suspension
calcipotriene cream	calcipotriene foam
ENSTILAR (calcipotriene/betamethasone) FOAM	calcitriol ointment
SORILUX (calcipotriene) FOAM – *Brand Required*	DOVONEX (calcipotriene) CREAM
TACLONEX (calcipotriene/betamethasone) SUSPENSION – *Brand Required*	DUOBRII (halobetasol/tazarotene) LOTION
TACLONEX (calcipotriene/betamethasone) OINTMENT – *Brand Required*	
tazarotene 0.1% cream	
VECTICAL (calcitriol) OINTMENT – *Brand Required*	

Steroids - Topical

Electronic Duration Verification

Class 1 topical steroids are covered for 30 days every 90 days. Joint AAD-NFP guidelines for management and treatment of psoriasis recommend limiting the use of Class 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. Class 1 steroids are covered with class 2 steroids to facilitate an alternating schedule.
- Please call for an override if the following conditions apply by calling provider relations at 1-800-755-2604:
  - Location of application: palms and soles
  - Indication: psoriasis
  - Close monitoring for side effects

Prior Authorization

General Prior Authorization Form

Non-Preferred Agents Criteria:

- **Non-preferred Step 1 agents (not labeled as "STEP 2"):**
  - 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
- **Non-preferred agents labeled as "STEP 2":**
  - The member must have failed a 2-week trial of all preferred and non-preferred drug entities within the same potency category and dosage form group within the last 3 months.

SUPER-HIGH POTENCY (GROUP 1)

Dosage Form	Preferred		Non-Preferred	
Cream	clobetasol emollient	0.05%		
	clobetasol propionate	0.05%		
	fluocinonide	0.10%		
	halobetasol propionate	0.05%		
Lotion	clobetasol propionate	0.05%	betamethasone dipropionate, augmented	0.05%
			STEP 2* IMPEKLO (clobetasol)	0.05%
			STEP 2* ULTRAVATE (halobetasol) MDP	0.05%
Ointment	betamethasone dipropionate, augmented	0.05%	halobetasol propionate	0.05%
	clobetasol propionate	0.05%		
Foam, Gel, Shampoo, Solution, Spray	clobetasol propionate shampoo	0.05%	betamethasone dipropionate, augmented gel	0.05%
	clobetasol propionate solution	0.05%	clobetasol propionate foam	0.05%
	clobetasol propionate spray	0.05%	clobetasol emulsion foam	0.05%
	clobetasol propionate gel	0.05%	STEP 2* halobetasol propionate foam	0.05%

HIGH POTENCY (GROUP 2)

Dosage Form	Preferred		Non-Preferred	
Cream	betamethasone dipropionate, augmented	0.05%	STEP 2* APEXICON E (diflorasone emollient)	0.05%
	fluocinonide	0.05%	desoximetasone	0.25%
	HALOG (halcinonide)– *Brand Required*	0.10%		
Lotion			BRYHALI (halobetasol) LOTION	0.01%
Ointment	betamethasone dipropionate	0.05%	STEP 2* diflorasone diacetate	0.05%
	desoximetasone	0.25%		

	fluocinonide	0.05%		
	fluticasone propionate	0.01%		
	HALOG (halcinonide)	0.10%		
Gel, Solution, Spray	fluocinonide gel	0.05%	desoximetasone gel	0.05%
	fluocinonide solution	0.05%	desoximetasone spray	0.25%
			STEP 2* HALOG (halcinonide) SOLUTION	0.10%

HIGH POTENCY (GROUP 3)

Dosage Form	Preferred		Non-Preferred	
Cream	betamethasone dipropionate emollient	0.05%	STEP2* amcinonide	0.10%
	triamcinolone acetonide	0.50%	desoximetasone	0.05%
			STEP2* diflorasone diacetate	0.05%
			fluocinonide-E	0.05%
Lotion			amcinonide	0.10%
Ointment	betamethasone valerate	0.10%	desoximetasone	0.05%
	fluticasone propionate	0.01%		
	mometasone furoate	0.10%		
	triamcinolone acetonide	0.50%		
Foam			betamethasone valerate foam	0.12%

MEDIUM POTENCY (GROUP 4)

Dosage Form	Preferred		Non-Preferred	
Cream	fluticasone propionate	0.05%	STEP2* clocortolone pivalate	0.10%
	mometasone furoate	0.10%		
	triamcinolone acetonide	0.10%		
Ointment	fluocinolone acetonide	0.025%	hydrocortisone valerate	0.20%
	triamcinolone acetonide	0.10%	STEP2* flurandrenolide	0.05%
	triamcinolone acetonide	0.05%		
Aerosol, Solution, Spray	mometasone furoate solution	0.10%	triamcinolone acetonide aerosol	0.147 MG/G
			STEP2* SERNIVO (betamethasone) SPRAY	0.05%

LOWER-MID POTENCY (GROUP 5)

Dosage Form	Preferred		Non-Preferred	
Cream	betamethasone valerate	0.10%	fluocinolone acetonide	0.03%
	PANDEL (hydrocortisone probutate)	0.10%	prednicarbate	0.10%
			STEP2* flurandrenolide	0.05%
			hydrocortisone butyrate	0.10%
			hydrocortisone butyrate emollient	0.10%
			hydrocortisone valerate	0.20%
Lotion	betamethasone dipropionate	0.05%	flurandrenolide	0.05%
	triamcinolone acetonide	0.10%	fluticasone propionate	0.05%
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		Non-Preferred	
Cream	alclometasone dipropionate	0.05%	fluocinolone acetonide	0.01%
	desonide	0.05%		
	triamcinolone acetonide	0.03%		
Lotion	betamethasone valerate lotion	0.10%		
	desonide lotion	0.05%		
	triamcinolone acetonide lotion	0.025%		
Ointment	alclometasone dipropionate	0.05%		
Oil, Shampoo, Solution	CAPEX (flucinolone) SHAMPOO	0.01%		
	fluocinolone acetonide oil	0.01%		
	fluocinolone acetonide solution	0.01%		

Least Potent (Group 7)

Dosage Form	Preferred		Non-Preferred	
Cream	hydrocortisone	2.50%		
Lotion	hydrocortisone	2.50%		
Ointment	hydrocortisone	2.50%		
Solution			TEXACORT (hydrocortisone) SOLUTION	2.50%

Endocrinology

Androgens

General Prior Authorization Form

Group Criteria:

- The member must have an FDA-approved indication for use (meets label recommendations for diagnosis and age).
- The member must have had 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).

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)	ANDROID (methyltestosterone)
	methyltestosterone
	METHITEST (methyltestosterone)
	TESTRED (methyltestosterone)

Topical

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ANDRODERM (testosterone) PATCH	ANDROGEL (testosterone)
testosterone 1% (50mg/5g) gel packet	FORTESTA (testosterone) 2% (10mg/0.5g) GEL MD PMP
testosterone 1% (25mg/2.5g) gel packet	TESTIM (testosterone) GEL TUBE
testosterone 1% (25mg/2.5g) gel tube	testosterone 2% (10mg/0.5g) gel MD PMP bottle
testosterone 1% (50mg/5g) gel tube	testosterone 1.62% (20.25mg/1.25g) gel packet
testosterone 1% (12.5mg/1.25g) gel MD PMP bottle	testosterone 1.62% (40.5mg/2.5g) gel packet
testosterone 1.62% (20.25mg/1.25g) gel MD PMP bottle	VOGELXO (testosterone)
testosterone 2% (30mg/1.5g) solution MD PMP	

Diabetes

References:

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

Underutilization

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

Therapeutic Duplication

- One Strength of one medication is allowed at a time
- Medication classes not payable together:
  - DPP4-Inhibitors and GLP-1 Agonists
    - GLP-1 and DPP4-Inhibitors should not be used concurrently due to similar mechanisms of action
  - DPP4-Inhibitors and Insulins
    - GLP-1 should be considered in most members prior to insulin
    - When initiating injectable therapy, sulfonylureas and DPP-4 inhibitors are typically discontinued
  - Sulfonylureas and Insulins
    - When initiating injectable therapy, sulfonylureas and DPP-4 inhibitors are typically discontinued
  - Humulin R U-500 is not allowed with any other insulin (basal or prandial)
    - Humulin R U-500 is indicated for monotherapy. It acts differently than regular insulin (U-100). It provides both basal and prandial coverage. Injections can be increased to 3 times per day for prandial coverage.

Covered options in combination with Insulin therapy:

GLP-1 Agonists, SGLT-2 inhibitors, TZDs, and metformin.

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

DPP4-Inhibitors

Electronic Age Verification

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

Electronic Step Care and Concurrent Medications

- DPP4-Inhibitors require concurrent metformin
  - A total of 84-day supply of metformin must be paid within 100 days prior to the DPP4-Inhibitor's date of service.
    - Metformin is recommended to be continued with escalation of therapy with DPP4-Inhibitors. If metformin is not tolerated, SGLT2 inhibitor and GLP-1 Agonists are recommended as part of the glucose-lowering regimen independent of A1C and are first line alternatives.
    - Members with GI intolerances to high dose IR metformin should trial at minimum a dose of 500mg ER.

Prior Authorization Criteria

General Prior Authorization Form

Non-Preferred Agents Criteria:

- The member must have an FDA-approved indication for use (meets label recommendations for diagnosis and age).
- The member must have had a 30-day trial with EACH of the following agents, as evidenced by paid claims or pharmacy printouts:
    - A preferred sitagliptin product (Janumet, Janumet XR, or Januvia)
    - A preferred linagliptin preferred product (Jentadueto or Tradjenta)
    - A preferred SGLT2 inhibitor

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

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)

DPP4-Inhibitors/SGLT2 Inhibitors Combination

General Prior Authorization Form

Non-Preferred Agent Criteria:

- The prescriber must provide medical justification explaining why the member cannot use individual preferred products separately

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

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

GLP-1 Agonists

General Prior Authorization Form

Non-Preferred Step 1 Agents Criteria:

- The member must have an FDA-approved indication for use (meets label recommendations for diagnosis and age).
- The member must have had 90-day trials of each of the following, as evidenced by paid claims or pharmacy printouts:
    - Victoza
    - An SGLT-2 Inhibitor: Jardiance, Farxiga, or Invokana

Non-Preferred Step 2 Agents Criteriae

- The member must have an FDA-approved indication for use (meets label recommendations for diagnosis and age).
- The member must have had 90-day trials of each of the following, as evidenced by paid claims or pharmacy printouts:
    - Victoza
    - An SGLT-2 Inhibitor: Jardiance, Farxiga, or Invokana
    - Trulicity titrated to max dose

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

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

		RYBELSUS (semaglutide)

Gastroparesis

General Prior Authorization Form

Non-Preferred Agents Criteria:

- **Initial Criteria:** *Approval Duration = 3 months*
  - The member must have an FDA-approved indication for use (meets label recommendations for diagnosis and age)
  - 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.
- **Renewal Criteria:** *Approval Duration = 3 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)

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

Glucose Rescue Medications

Electronic Duration Verification

- 2 doses (initial and replacement doses) are covered every 180 days without prior authorization.
  - The following information will need to be submitted as a follow up for the override by either emailing medicaidpharmacy@nd.gov or documenting on General Prior Authorization Form:
    - The provider must attest if it is known that the previous dose was taken by the member (and not diverted or given to another person)
    - One of the following criteria must be met (A, B, or C)
      A. The previous dose has expired
      B. The dose was used by member for a hypoglycemic episode
      C. The member is currently taking insulins or sulfonylureas and meets one of the following criteria:
        - The diabetes treatment has been adjusted to prevent future instances of hypoglycemia
        - The provider has provided medical justification why the diabetes treatment has not been adjusted at this time to prevent future instances of hypoglycemia.

Prior Authorization

General Prior Authorization Form:

Product Specific Criteria: Baqsimi and Zegalogue
One of the following criteria must be met:

- The member must have had a trial of glucagon kit, 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).

Non-Preferred Criteria:

- The member must have had a trial of Baqsimi, 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).

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
BAQSIMI (glucagon) SPRAY PA***	GVOKE (glucagon)
Glucagon Kit	GLUCOGEN (glucagon) HYPOKIT
ZEGALOGUE (dasiglucagon) AUTOINJECTOR PA***	

Insulin/GLP-1 Agonist Combination

General Prior Authorization Form

Group Criteria:

- The prescriber must provide medical justification explaining why the member cannot use the individual preferred products separately (subject to clinical review)

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	SOLIQUA (Insulin glargine/lixisenatide)

	XULTOPHY (insulin degludec/liraglutide)

Insulin

Electronic Duration Verification

- Products containing NPH insulin are limited to 210 days of coverage for every 365 days to allow for use in pregnancy and breastfeeding.
    - Lantus and Levemir have been demonstrated to reduce the risk of symptomatic and nocturnal hypoglycemia compared with NPH insulin.
    - For an override request: please submit clinical justification explaining why the member is unable to use Lantus or Levemir (subject to clinical review) and attach to Insulin Prior Authorization Form

Quantity Limit

- **Toujeo Max Solostar 300 unit/mL and Tresiba 200 unit/mL:**
    - Doses between 100 unit/day to 200 unit/day are covered automatically (do not require prior authorization approval for coverage).
        - Please request an override if day supply is less than 30 days and dose is between 100 units/day and 200 units/day by calling 1-800-755-2604 (e.g. short-cycle filling).
    - **For dose <100 unit/day**, member must meet prior authorization criteria
    - **For dose >200 units of insulin per 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 U500 insulin).

Prior Authorization

General Prior Authorization Form

Product Specific Criteria:

- **Fiasp:** *Approval 12 months*
    - The member must have had a 3-month trial of one of the following agents, as evidenced by paid claims or pharmacy printouts.
        - Novolog, Humalog, or Apidra
- **Humalog U-200:** *Approval 12 months*
    - 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
    - if insulin requirement is > 200 units/day: clinical justification must be provided why member is not a candidate for Humulin R U-500
    - Request must not be for use in an insulin pump: HUMALOG® (insulin lispro) 200 Units/mL: Do Not Use in a Pump (lillymedical.com)
- **Regular Insulin (Humulin R / Novolin R / Afrezza):** *Approval 12 months*
    - The member must have had a 3-month trial of two of the following agents, as evidenced by paid claims or pharmacy printouts.
        - Novolog, Humalog, or Apidra

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

- **Toujeo Solostar and Tresiba:**
    - **Initial Criteria:** *Approval 6 months*
        - The requested agent must be prescribed by or in consultation 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 (1 or 2):
            - 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
        - ~~Basal insulin requirement is less than 100 units per day~~
        - ~~**Toujeo Solostar 300 unit/mL**: Clinical justification must be provided explaining why the patient needs for a smaller volume of insulin (max is 80 units/injection for both Insulin glargine 300 units/mL and 100 units/mL. Patients using Insulin glargine 300 unit/mL may require more basal insulin than those receiving 100 units/mL).~~
    - **Renewal Criteria:** *Approval 12 months*

        - The member must have experienced at least one of the following, as evidenced by provided clinical notes or labs:
            - Reduction in frequency and/or severity of hypoglycemia
            - Improved glycemic control (A1C)
- **All other non-preferred insulins:**
    - 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	HUMALOG U-200 (insulin lispro) KWIKPEN
Insulin aspart syringe	++HUMULIN R (insulin regular, human) VIAL
Insulin aspart vial	LYUMJEV (Insulin lispro-aabc) KWIKPEN
Insulin lispro junior syringe	LYUMJEV (Insulin lispro-aabc) VIAL
Insulin lispro cartridge	++NOVOLIN R (insulin regular, human) FLEXPEN
Insulin lispro syringe	++NOVOLIN R (insulin regular, human) VIAL
Insulin lispro vial	
NOVOLOG (insulin aspart) CARTRIDGE – *Brand Co-Preferred*	
NOVOLOG (insulin aspart) FLEXPEN – *Brand Co-Preferred*	
NOVOLOG (insulin aspart) VIAL– *Brand Co-Preferred*	
Intermediate Acting Insulin	
PREFERRED AGENTS (NO PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**
NOVOLIN N (insulin NPH human isophane) FLEXPEN	HUMULIN N (insulin NPH human isophane) VIAL
HUMULIN R (Insulin regular, human) U-500 KWIKPEN	HUMULIN N (insulin NPH human isophane) KWIKPEN
HUMULIN R U-500 (insulin regular, human) VIAL	NOVOLIN N (insulin NPH human isophane) VIAL
Long Acting Insulin	
PREFERRED AGENTS (NO PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**
LANTUS (insulin glargine) SOLOSTAR	BASAGLAR KWIKPEN U-100 (insulin glargine)
LANTUS (insulin glargine) VIAL – *Brand Required*	SEMGLEE (insulin glargine)
LEVEMIR (insulin detemir) VIAL	TOUJEO SOLOSTAR (insulin glargine)***
LEVEMIR (insulin detemir) FLEXTOUCH	TRESIBA (insulin degludec) FLEXTOUCH U-100***
TOUJEO MAX SOLOSTAR (insulin glargine)[PA]***	TRESIBA (insulin degludec) VIAL***
TRESIBA (insulin degludec) FLEXTOUCH U-200 [PA]***	
Mixed Insulin	
PREFERRED AGENTS (NO PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**
HUMALOG MIX 50/50 (insulin NPL/insulin lispro) KWIKPEN	NOVOLIN 70-30 (insulin NPH human/regular insulin human) VIAL
HUMALOG MIX 75/25 (insulin NPL/insulin lispro) KWIKPEN – *Brand Required*	NOVOLIN 70-30 (insulin NPH human/regular insulin human) FLEXPEN
HUMALOG MIX 50/50 (insulin NPL/insulin lispro) VIAL	NOVOLOG MIX 70/30 (insulin aspart protamine/insulin aspart) FLEXPEN
HUMALOG MIX 75/25 (insulin NPL/insulin lispro) VIAL	NOVOLOG MIX 70/30 (insulin aspart protamine/insulin aspart) VIAL
HUMULIN 70/30 (insulin NPH human/regular insulin human) VIAL	
HUMULIN 70/30 (insulin NPH human/regular insulin human) KWIKPEN	
Insulin aspart protamine/insulin aspart insulin pen	

Insulin aspart protamine/insulin aspart vial	
Insulin lispro mix 75/25 kwikpen	

SGLT2 Inhibitors

General Prior Authorization Form

Non-Preferred Agents Criteria:

- The member must have an FDA-approved indication for use (meets label recommendations for diagnosis and age).
- The member must have had a 30-day trial of each preferred SGLT2 inhibitor of a unique active ingredient, as evidenced by paid claims or pharmacy printouts.

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
FARXIGA (dapagliflozin)	STEGLATRO (ertugliflozin
INVOKANA (canagliflozin)	STEGLATROMET (ertugliflozin/metformin)
INVOKAMET (canagliflozin)	
INVOKAMET XR (canagliflozin/metformin)	
JARDIANCE (empagliflozin)	
SYNJARDY (empagliflozin/metformin)	
SYNJARDY XR (empagliflozin/metformin)	
XIGDUO XR (dapagliflozin/metformin)	

Sulfonylureas

General Prior Authorization Form

Non-Preferred Agents Criteria:

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

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

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
glimepiride	++glyburide
glipizide	++glyburide/metformin
glipizide/metformin	++glyburide, micronized
glipizide ER	++GLYNASE (glyburide, micronized)

Growth Hormone

Prior Authorization Form - Growth Hormone

Category Criteria:

- Members new to GH therapy must meet the criteria below and be started on a preferred growth hormone.
    - Members continuing GH therapy and having met the criteria listed below must be switched to a preferred growth hormone.
- **For Initial or Renewal Requests:**
    - Member must have a diagnosis of a **covered indication** (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
    - For all covered indications:
        - Member must not have active malignancy
        - Prescriber must be an endocrinologist or nephrologist, or prescriber must have at least one annual consultation about the member with the pediatric specialty.

        - Member must not have epiphyseal closure and must still be growing, unless one of the below exceptions is present:
            - Exceptions:
                - Member has a diagnosis of Prader-Willi syndrome
                - Member has a diagnosis of endogenous growth hormone deficiency - and is experiencing hypoglycemic episodes without growth hormone and growth hormone is needed to maintain proper blood glucose.
                    - Skytrofa is contraindicated in patients with epiphyseal closure
    - Diagnosis of chronic renal insufficiency (additional criteria):
        - Member must not have received a renal transplant.
        - Member must consult with a dietitian to maintain a nutritious diet.
    - Diagnosis of Prader–Willi syndrome (additional criteria):
        - Sleep apnea must be ruled out by sleep study in obese members.
        - Member must consult with a dietitian to maintain a nutritious diet.
- **Additional Criteria for Initial Authorization Requests:**
    - Diagnosis of endogenous growth hormone deficiency:
        - Must meet ONE of below criteria (A OR B)
            A. Members with 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.
            B. Member must have had two GH stimulation tests by insulin, levodopa, L-arginine, propranolol, clonidine, or glucagon with a maximum peak of < 10ng/mL after stimulation no more than 6 months apart

- **Additional Criteria for Subsequent Authorization**
    - For all covered indications:
        - Member must have been compliant with growth hormone (last 6 fills must have been on time).
    - Diagnosis of Prader–Willi syndrome (additional criteria):
        - If member is obese, BMI must have decreased. If member is not obese, BMI must have maintained or decreased.

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
NORDITROPIN FLEXPRO (somatropin)	GENOTROPIN (somatropin)
	GENOTROPIN MINIQUICK (somatropin)
	NUTROPIN AQ (somatropin)
	OMNITROPE (somatropin)
	SAIZEN (somatropin)
	SKYTROFA (somatropin)
	ZOMACTON (somatropin)

Serostim

Prior Authorization Form - Growth Hormone

Product Specific Criteria (Initial):

- Member must have a diagnosis of treatment of HIV with wasting cachexia
- Member must not have an active malignancy
- Prescriber must be experienced in the diagnosis and management of HIV infection
- Member must be on concomitant antiretroviral therapy
- Member must have failed a 3-month trial with Megace, as evidenced by paid claims or pharmacy Printouts

Product Specific Criteria (Renewal):

- Lean body mass and body weight must have increased in the past 12 weeks
- Physical endurance must have increased in past 12 weeks
- Member must not have completed 48 weeks of continuous treatments

Zorbtive

Prior Authorization Form - Growth Hormone

Product Specific Criteria:

- Member must not have active malignancy
- Member must have diagnosis of short bowel syndrome
- Member must be receiving specialized nutritional support
- Treatment duration must not be longer than 4 weeks

Imcivree

General Prior Authorization Form

- **Initial Criteria:** *Approval Duration = 4 months*
  - The member must have a diagnosis of obesity (BMI > 30 kg/m2 for adults or > 95th percentile using growth chart assessments for pediatric members), as confirmed by genetic testing attached to the request
  - The member's obesity must be due to one of the following variants interpreted as pathogenic, likely pathogenic, or of unknown significance:
    - proopiomelanocortin (POMC)
    - proprotein convertase subtilisin/kexin type 1 (PCSK1)
    - leptin receptor (LEPR) deficiency
  - The member must be 6 years of age or older
  - The medication is prescribed by, or in consultation with, an endocrinologist or expert in rare genetic disorders of obesity
  - The member's weight and body mass index (BMI) must be provided within the last 60 days
  - The member must not have significant renal impairment (eGFR <60 mL/minute/1.73 m2)

- **Renewal Criteria:** *Approval Duration = 12 months*
  - The member must have achieved or maintained a 5% weight reduction or 5% of BMI for members < 18 years old, since starting treatment with Imcivree, as evidenced by medical documentation (e.g. chart notes) attached to the request.

PREFERRED AGENTS (CLINICAL PA REQUIRED)
IMCIVREE (Setmelanotide)

GI - Gastroenterology

Bowel Prep Agents

General Prior Authorization Form

Non-Preferred Agents Criteria: *Approval Duration = 1 month*

- The member must have a diagnosis of an FDA-approved indication for use
- One of the following must be met (A or B):
  - A. The member must have failed a trial of each preferred agent within the past 2 years, as evidenced by paid claims or pharmacy printouts
  - B. 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).

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
CLENPIQ	GAVILYTE-N
GAVILYTE-C	GOLYTELY 236-22.74G
GAVILYTE-G	NULYTELY
GOLYTELY 227.1-21.5	PEG 3350/SOD SUL/NACL/KCL/ASB/C
MOVIPREP – *Brand Required*	PLENVU
OSMOPREP	SUPREP
PEG-3350 AND ELECTROLYTES 236-22.74G	SUTAB
PEG 3350-ELECTROLYTE 420 G	
TRILYTE	

Crohn's Disease

Electronic Diagnosis Verification

- The member must have an FDA-approved indication for use

Prior Authorization Criteria

General Prior Authorization Form

Non-Preferred Agents Criteria:

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

Anti – TNF inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
HUMIRA (adalimumab)	CIMZIA (certolizumab)

Anti – interleukin (IL) 12/IL-23

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

Clostridium difficile-associated diarrhea (CDAD)

General Prior Authorization Form

Non-Preferred Agents Criteria: *Approval Duration = 5 days*

- The member must have diagnosis of *Clostridium difficile*-associated diarrhea (CDAD)
- The member must have failed a 10-day trial with a preferred agent, as evidenced by paid claims or pharmacy printouts

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
FIRVANQ (vancomycin) SOLUTION 25mg/mL	DIFICID (fidaxomicin) 40 MG/ML SUSPENSION
Vancomycin capsule	DIFICID (fidaxomicin) TABLET
Vancomycin solution 50mg/mL	FIRVANQ (vancomycin) SOLUTION 50 MG/ML
	VANCOCIN (vancomycin) CAPSULE

Constipation – Irritable Bowel Syndrome/Opioid Induced

Therapeutic Duplication

- One medication is allowed at a time

Idiopathic Constipation

General Prior Authorization Form

Non-Preferred Agents Criteria:

- The member must have an FDA-approved indication for use (meets label recommendations for diagnosis and age).
- The member must have had a 30-day trial of Linzess, as evidenced by paid claims or pharmacy printouts

Product Specific Criteria

- ***Motegrity: The member must have had a 30-day trial with Trulance, as evidenced by paid claims or pharmacy printouts

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
	MOTEGRITY (prucalopride)***
	TRULANCE (plecanatide)

Opioid-Induced Constipation:

Electronic Step Care and Concurrent Medications

- Medications indicated for opioid-induced constipation should be discontinued when opioids are stopped.
    - 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

Prior Authorization Criteria

General Prior Authorization Form

Non-Preferred Agents Criteria:

- The member must have an FDA-approved indication for use (meets label recommendations for diagnosis and age).
- The member must have had 30-day trials of each of the oral preferred agents, as evidenced by paid claims or pharmacy printouts

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

Diarrhea

Electronic Step Care and Concurrent Medications

- Xifaxan: Xifaxan 550mg does not require prior authorization for hepatic encephalopathy if used concurrently with lactulose
  - A total of 30 days of Lactulose must be paid within 65 days prior to Xifaxan's date of service
  - An override may be available after an adequate trial of Lactulose where Lactulose is not tolerated

Non-Preferred Agents Criteria:

- **Initial Criteria**: *Approval Duration = 3 months*
  - The member must have an FDA-approved indication for use (meets label recommendations for diagnosis, age, and duration of treatment).
  - The provider must submit medication documentation confirming that infectious and medication-induced etiologies of diarrhea have been ruled out
  - The member must have had a 30-day trial of each preferred unique active ingredient, as evidenced by paid claims or pharmacy printouts.
- **Product Specific Criteria:**
  - ***__alosetron__: The member must be a female.
- **Renewal Criteria:** *Approval Duration = 12 months*
  - The member must have experienced and maintained clinical benefit since starting treatment with requested product, as evidenced by medical documentation (e.g. chart notes) attached to the request (subject to clinical review)

Irritable Bowel Syndrome

General Prior Authorization Form

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
dicyclomine capsule	alosetron***
dicyclomine tablet	dicyclomine oral syrup
diphenoxylate/atropine	LOMOTIL (diphenoxylate/atropine)
loperamide	VIBERZI (eluxadoline)
LOTRONEX (alosetron)*** - *Brand Required*	XIFAXAN (rifaximin) 550 mg tablet

HIV/AIDs

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
diphenoxylate/atropine	LOMOTIL (diphenoxylate/atropine)
loperamide	MYTESI (crofelemer)

Digestive Enzymes

General Prior Authorization Form

Non-Preferred Agents Criteria:

- 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

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)

Proton Pump Inhibitor

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.

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:
    - **Please call for an override** if any of the following circumstances apply 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

Electronic Age Verification

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

Electronic Step Care and Concurrent Medications

Non-Preferred Agents Criteria - Step 1 Agents:

- A total of 28 days of 2 preferred agents at max dose must be paid within 365 days prior to non-preferred step 1 agents date of service.

Prior Authorization Criteria

General Prior Authorization Form

Non-Preferred Agents Criteria - Step 2 Agents: *Approval Duration = 6 months*

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

Solid Dosage Forms

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

Non-Solid Dosage Forms

NON-SOLID DOSAGE FORMS		
PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED STEP 1 AGENTS (ELECTRONIC STEP)	NON-PREFERRED STEP 2 AGENTS (PA REQUIRED)
NEXIUM (esomeprazole) PACKET *– Brand Required*	PRILOSEC SUSPENSION (omeprazole)	ACIPHEX SPRINKLE (rabeprazole)
omeprazole ODT		esomeprazole solution packet
PREVACID (lansoprazole) SOLUTAB		lansoprazole ODT

– Brand Required		
PROTONIX (pantoprazole) PACKET *– Brand Required*		omeprazole-sodium bicarbonate packet
		pantoprazole packet

Ulcerative Colitis

Prior Authorization Criteria

General Prior Authorization Form

Non-Preferred Agents Criteria

- The member must have an FDA-approved indication for use (meets label recommendations for diagnosis and age).
- The member must have had a 30-day trial of each preferred biologic agent, as evidenced by paid claims or pharmacy printouts.

Biologic Agents

Electronic Diagnosis Verification

- The member must have an FDA-approved indication for use

Anti – TNF inhibitors

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

Anti – interleukin (IL) 12/IL-23

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

Janus Kinase (JAK) Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
XELJANZ (tofacitinib)	
XELJANZ XR (tofacitinib)	

Sphingosine 1-Phosphate (S1P) Receptor Modulator

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

Oral

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
APRISO (mesalamine) CAPSULE – *Brand Required*	AZULFIDINE (sulfasalazine)
ASACOL HD (mesalamine) – *Brand Required*	AZULFIDINE DR (sulfasalazine)
balsalazide capsule	COLAZAL (balsalazide)
DELZICOL (mesalamine) CAPSULE– *Brand Required*	mesalamine DR
DIPENTUM (olsalazine)	mesalamine ER
LIALDA (mesalamine) TABLET– *Brand Required*	mesalamine HD
PENTASA (mesalamine)	
sulfasalazine DR tablet	
sulfasalazine tablet	

Rectal

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

Genetic and Rare Disease

Biologics

General Prior Authorization Form

Category Criteria:

- The member must have an FDA-approved indication for use (meets label recommendations for diagnosis and age) as follows:

Chronic Infantile Neurological, Cutaneous and Articular Syndrome
Schnitzler Syndrome
Sterile Multifocal Osteomyelitis with Periostitis and Pustulosis

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
KINERET (anakinra)	

Deficiency of IL-A Receptor Antagonists (DIRA)

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ARCALYST (ritonacept)	
KINERET (anakinra)	

Cytokine release syndrome

PREFERRED AGENTS (PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ACTEMRA (tocilizumab)	

Phenylketonuria

Kuvan:

Underutilization

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

Prior Authorization Criteria

Prior Authorization Form - Phenylketonuria

Criteria for initial requests: *Approval Duration = 2 months*

- The member must have an FDA-approved indication for use (meets label recommendations for diagnosis and age).
- The member must have been compliant with a PHE restricted diet for past 6 months.
- The member must not have been known to have two null mutations in TRANS
- Baseline PHE levels must be attached
    - For females of childbearing potential: PHE levels must be above 360 micromoles/liter
    - For males or females unable to bear children: PHE levels must be above 600 micromoles/liter
- The member's weight must be provided. Requested initial dose must be 10 mg/kg or less.

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

- The member's weight must be provided
- If dose is the same or less than previous trial:
    - PHE level must be between 60 and 360 micromoles per liter
- For a dose increase from previous trial:
    - PHE levels must be attached that were taken after 1 month of previous trial
    - The member's PHE level must be greater than 360 micromoles per liter
    - For increase > 10 mg/kg - member must have failed a trial of 1 month of 10 mg/kg

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
KUVAN (sapropterin) – *Brand Required*	sapropterin

Palynziq (pegvaliase-pqpz):

Prior Authorization Form - Phenylketonuria

Criteria for initial requests: *Approval Duration = 6 months*

- The member must have an FDA-approved indication for use (meets label recommendations for diagnosis and age).
- PHE levels must be above 600 micromoles/liter
- The member must have been compliant with a PHE restricted diet and medication management for past 6 months.

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

- **If dose is the same or less than previous trial:**
  - PHE level must be between 60 and 360 micromoles per liter
- **For a dose increase to 40 mg:**
  - PHE levels must be attached that were taken after 24 weeks of 20 mg
  - The member's PHE level must be greater than 360 micromoles per liter

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

Hematology/Oncology

Antihemophilic Factor Products

General Prior Authorization Form

Category Criteria:

- The member must have an FDA-approved indication for use (meets label recommendations for diagnosis and age).
- The date of the member's last appointment with a Hemophilia Treatment Center must be within the past year.
- Contact information for treatment center must be provided

Non-Preferred Agents Criteria:

- Clinical justification must be provided explaining why the member is unable to use the PREFERRED AGENTS (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)

FACTOR VIIa	
PREFERRED AGENTS (CLINICAL PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**
NOVOSEVEN RT (coagulation Factor VIIa recombinant)	
SEVENFACT (coagulation Factor VIIa recombinant)	
FACTOR VIII – HEMOPHILIA A	
PREFERRED AGENTS (CLINICAL PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**
Non-Extended Half Life	
ADVATE (factor VIII recombinant)	KOVALTRY (factor VIII recombinant)
AFSTYLA (factor VIII recombinant, single chain)	NUWIQ (factor VIII recombinant)
HEMOFIL M (factor VIII plasma derived; mAb-purified)	
KOATE (factor VIII plasma derived, chromatography purified)	
KOGENATE FS (factor VIII recombinant)	
NOVOEIGHT (factor VIII recombinant)	
OBIZUR (recombinant, B domain-deleted porcine (pig) factor VIII)	
RECOMBINATE (factor VIII recombinant)	
XYNTHA (factor VIII recombinant)	
XYNTHA SOLOFUSE (factor VIII recombinant)	
Extended Half Life	
ESPEROCT (factor VIII recombinant, glycopegylated – exei)	ADYNOVATE (factor VIII recombinant, PEGylated)
	ELOCTATE (factor VIII recombinant, Fc fusion protein)
	JIVI (factor VIII recombinant, pegylated-aucl)
FACTOR VIII:C – HEMOPHILIA A	

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
MONOCLATE-P (Antihemophilic Factor VIII:C (human))	
FACTOR VIII – HEMOPHILIA A/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))	
FACTOR VIII – VON WILLEBRAND FACTOR - RECOMBINANT	
PREFERRED AGENTS (CLINICAL PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**
	VONVENDI (Recombinant human vWF)
FACTOR IX – HEMOPHILIA B	
PREFERRED AGENTS (CLINICAL PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**
Non-Extended Half Life	
ALPHANINE SD (factor IX, plasma-derived)	
BENEFIX (factor IX recombinant)	
IXINITY (factor IX recombinant)	
MONONINE (factor IX, plasma-derived mAb purified)	
PROFILNINE (factor IX complex)	
RIXUBIS (factor IX recombinant)	
Extended Half Life	
ALPROLIX (factor IX recombinant, Fc fusion)	IDELVION (factor IX recombinant, albumin fusion)
	REBINYN (factor IX recombinant, glycol-PEGylated)
FACTOR IXa/IX	
PREFERRED AGENTS (CLINICAL PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**
HEMLIBRA (Emicizumab-kxwh)	
FACTOR X	
PREFERRED AGENTS (CLINICAL PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**
COAGADEX (Coagulation Factor X (Human))	
FACTOR X	
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)	
ANTI-INHIBITOR COAGULANT COMPLEX	
PREFERRED AGENTS (CLINICAL PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**
FEIBA NF (Anti-Inhibitor Coagulant Complex)	

Paroxysmal Nocturnal Hemoglobinuria (PNH)

Soliris/Ultomiris: See Medical Billing Drug Clinical Criteria

Empaveli

Empavali - Prior Authorization Form

Initial Criteria: *Approval Duration = 6 months*

- The patient must be 18 years of age or older
- Must be prescribed by or in consultation with a hematologist, oncologist, or immunology specialist
- Must have a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) confirmed by flow cytometry (LDH level of 1.5 times the upper limit of normal)
- Must have documented have one of the following at least 2 weeks before starting treatment:
    a. A full course of meningococcal, pneumococcal, and Hib vaccines
    b. A test for antibodies against encapsulated bacteria
    c. 2 weeks of antibacterial drug prophylaxis against S. *pneumoniae*, N. *meningitis*, and H. *influenzae* type B if vaccines are administered less than 2 weeks prior to starting therapy

- One of the following criteria must be met (A or B):
    A. Member is transfusion-dependent
    B. 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)

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 (Hb) by ≥ 1 g/dL from baseline
    - Normalization in LDH levels ≤ 280 U/L

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

Medical Billing Drug Clinical Criteria Only

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
SOLIRIS (eculizumab)	
ULTOMIRIS (ravulizumab)	

Hematopoietic, Colony Stimulating Factors

General Prior Authorization Form

Non-Preferred Agents Criteria:

- The member must have an FDA-approved indication for use (meets label recommendations for diagnosis and age).
- Clinical justification must be provided explaining why the member is unable to use the preferred product (subject to clinical review).

Filgrastim

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
NEUPOGEN (filgrastim)	GRANIX (TBO-filgrastim)
	NIVESTYM (filgrastim-AAFI)
	ZARXIO (filgrastim-SNDZ)

Pegfilgrastim

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
NYVEPRIA (pegfilgrastrim – APGF)	FULPHILA (pegfilgrastrim-JMDB)
ZIEXTENZO (pegfilgrastim-BMEZ)	NEULASTA (pegfilgrastim)
	UDENYCA (pegfligrastim-CBQV)

Sargramostim

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
LEUKINE (sargramostim)	

Nausea/Vomiting

Chemo Induced

Electronic Diagnosis Verification

- **Dronabinol:** The member must have an FDA-approved indication for use

Prior Authorization Criteria

General Prior Authorization Form

Non-Preferred Agents Criteria: *Approval Duration = 6 months or until last day of chemotherapy*

- The member must have diagnosis of nausea and/or vomiting
- Prescriber must be 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

- Member must have failed a 3-day trial of each preferred product(s) in the same class within the last 6 months as evidenced by paid claims or pharmacy print outs
- Member must not have failed preferred chemical entity with same active ingredient as requested product due to side effects

NK1 RECEPTOR ANTAGONISTS	
PREFERRED AGENTS (NO PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**
AKYNZEO (netupitant/palonosetron)	aprepitant Capsule
	EMEND (aprepitant) CAPSULE
	EMEND (aprepitant) SUSPENSION
	VARUBI (rolapitant) TABLET
5-HT3 RECEPTOR ANTAGONISTS	
PREFERRED AGENTS (NO PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**
AKYNZEO (netupitant/palonosetron)	SANCUSO (granisetron) PATCH
granisetron tablet	ZOFRAN (ondansetron) TABLET
ondansetron ODT	SUSTOL (granisetron) SYRINGE
ondansetron solution	
ondansetron tablet	
CANNABINOIDS	
PREFERRED AGENTS (NO PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**
dronabinol capsule	MARINOL (dronabinol) CAPSULE

Sickle Cell Disease

General Prior Authorization Form

Non-Preferred Agents Criteria:

- **Initial Criteria**: *Approval Duration = 12 months*
  - The member must have an FDA-approved indication for use (meets label recommendations for diagnosis, age, and duration of treatment)
  - The member must have had a 30-day trial of a preferred agent at the maximum (35 mg/kg/day) or maximally tolerated dose, as evidenced by paid claims or pharmacy printouts
  - Prescribed by, or in consultation, with a hematologist, or other specialist with expertise in the diagnosis and management of sickle cell disease
  - Member has experienced at least one sickle cell-related vaso-occlusive crisis within past 12 months (documentation required)
- **Product Specific Criteria:**
  - **Oxbryta:**
    - Baseline hemoglobin (Hb) ≤ 10.5 g/dL
  - **Siklos:**
    - Baseline hemoglobin (Hb) ≤ 10.5 g/dL
    - Clinical justification must be provided explaining why the member is unable to use the preferred agents (subject to clinical review).

- **Renewal Criteria:** *Approval Duration = 12 months*
  - 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
    - Member has experienced a reduction in sickle cell-related vaso-occulusive crisis

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
DROXIA (hydroxyurea capsule)	ENDARI (glutamine)

hydroxyurea capsule	OXBRYTA (voxelotor)
	SIKLOS (hydroxyurea tablet)

Thrombocytopenia

General Prior Authorization Form

Non-Preferred Agents Criteria:

- The member must have had trials with each preferred agent (at the recommended dose and duration) with each preferred agent, as evidenced by paid claims or pharmacy Printouts.

Product Specific Criteria: Promacta Powder Pack: In addition to diagnosis specific criteria

- Patient must be 9 years old or younger OR unable to swallow a solid dosage form

Persistent or Chronic immune thrombocytopenia (ITP):

- **Initial Criteria:** *Approval Duration 4 months*
  - Member has diagnosis of immune thrombocytopenic purpura (ITP) lasting >6 months after diagnosis.
  - Documentation of platelet count of less than 30 x 10^9/L
  - The member must have experienced an inadequate response after one of the following (A, B or C):
    A. The member must have failed a trial of appropriate duration of a corticosteroid or immunoglobulins, as evidenced by paid claims or pharmacy print outs OR
    B. Rituximab OR
    C. The member must have undergone a splenectomy
- **Renewal Criteria:** *Approval Duration 12 months*
  -

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
PROMACTA (eltrombopag)	DOPTELET (avatrombopag)
PROMACTA (eltrombopag) POWDER PACK	NPLATE (romiplostim)
	TAVALISSE (fostamatinib)

Chronic liver disease-associated thrombocytopenia

- **Clinical Criteria:** *Approval Duration The 2 weeks prior to procedure*
  - The member must have a diagnosis of chronic liver disease
  - 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
    - The prescriber must include documentation of the name and scheduled date of the procedure
  - The provider must indicate the date therapy will be initiated and discontinued
    - Member must undergo procedure within 8 days after last dose*
      *Doptelet: Member must undergo procedure 5-8 days after last dose
      *Mulpleta: Member must undergo procedure 2-8 days after last dose

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
DOPTELET (Avatrombopag)	MULPLETA (Lusutrombopag)

Chronic hepatitis C infection-associated thrombocytopenia

- **Initial Criteria:** *Approval Duration 4 months*
  - Member has diagnosis of hepatitis C-associated thrombocytopenia
  - Prescriber must attest that the member's degree of thrombocytopenia prevents initiation or continuation of interferon-based therapy
  - Member is unable to receive direct acting antivirals for hepatitis C
- **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)
  - Member is currently receiving interferon-based therapy

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
PROMACTA (eltrombopag)	
PROMACTA (eltrombopag) POWDER PACK	

Aplastic Anemia

- **Initial Criteria:** *Approval Duration 4 months*
  - Member has diagnosis of aplastic anemia

- Member must have failed therapy or be receiving concurrent therapy with immunosuppressive therapy (e.g. corticosteroid, Atgam, cyclosporine, cyclosporine)
- Documentation of platelet count of less than 30 x 10^9/L

- **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)

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
PROMACTA (eltrombopag)	
PROMACTA (eltrombopag) POWDER PACK	

Infectious Disease

Antibiotics - Resistance Prevention

General Prior Authorization Form

Non-Preferred Agents Criteria:

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

Community-Acquired Pneumonia

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

Methicillin-Resistant *Staphylococcus aureus* (MRSA):

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
clindamycin	BAXDELA (delafloxacin)
doxycycline	NUZYRA (omadacycline)
linezolid	SIVEXTRO (tedizolid)
minocycline	
trimethoprim-sulfamethoxazole	

Helicobacter pylori

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
lansoprazole/amoxicillin/clarithromycin	HELIDAC (bismuth ssal/metronidazole/tetracycline)

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

Tuberculosis

Product specific criteria:

***isoniazid:

- ND Health Department provides for no cost. Please contact 701-328-2378 to obtain supply.

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

Antifungals - Aspergillus and Candidiasis Infections

General Prior Authorization Form

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

- The request must be for use as prophylaxis of invasive Aspergillus and Candida infections or Oropharyngeal Candidiasis
- The member must meet one of the following (A or B):
    - The member must have documented history of failure to all preferred agents as evidenced by paid claims or pharmacy printouts
    - Prescriber must provide evidence-based medical justification for use, explaining why preferred antifungals are not an option due to susceptibility, previous failed trials, or other contraindications (subject to clinical review)

Solid formulations

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

Non-solid oral formulations

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

Antimalarial Agents

Prior Authorization Criteria

General Prior Authorization Form

Group Criteria:

- The request must be for TREATMENT of malaria (*NOT covered for prophylaxis)*

Non-Preferred Agents Criteria:

- 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

Product specific criteria:

***atovaquone/proguanil 62.5-25 MG

- The member must be less than 18 years old

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)

Human Immunodeficiency Virus (HIV)

Antiretrovirals

References

Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV. Department of Health and Human Services. Available at https://clinicalinfo.hiv.gov/sites/default/files/inline-files/AdultandAdolescentGL.pdf. Accessed (October 9, 2020)

Category Criteria:

- **Branded non-preferred agents:** The member must have had a 30-day trial of each pharmaceutically equivalent preferred agent, as evidenced by paid claims or pharmacy printouts.
- **Generic non-preferred agents:** The member must have had a 30-day trial of a pharmaceutically equivalent preferred agent, as evidenced by paid claims or pharmacy printouts.

Integrase Strand Transfer Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
BIKTARVY (bictegravir/emtricitabine/tenofovir)	
CABENUVA (cabotegravir/rilprivirine)	
DOVATO (dolutegravir/Lamivudine)	
GENVOYA (elvitegravir/cobicistat/emtricitabine/tenofovir)	
ISENTRESS (raltegravir)	
JULUCA (dolutegravir/rilpivirine)	
STRIBILD (elvitegravir/cobicistat/emtricitabine/tenofovir)	
TIVICAY (dolutegravir)	
TRIUMEQ (abacavir/dolutegravir/lamivudine)	

Non-Nucleoside Reverse Transcriptase Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
COMPLERA (emtricitabine/rilpivirine/tenofovir)	ATRIPLA (efavirenz/emtricitabine/tenofovir)
EDURANT (rilpivirine)	efavirenz/lamivudine/tenofovir
efavirenz	SUSTIVA (efavirenz)
efavirenz/emtricitabine/tenofovir	
JULUCA (dolutegravir/rilpivirine)	
ODEFSEY (emtricitabine/rilpivirine/tenofovir)	
PIFELTRO (doravirine)	
rilpivirine	
SYMFI (efavirenz/lamivudine/tenofovir) – *Brand Required*	
SYMFI LO (efavirenz/lamivudine/tenofovir) – *Brand Required*	
NOT RECOMMENDED FOR FIRST LINE USE	
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.	
INTELENCE (etravirine) – *Brand Required*	etravirine

nevirapine	
nevirapine ER	

Nucleoside Reverse Transcriptase Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
abacavir	ATRIPLA (efavirenz/emtricitabine/tenofovir)
abacavir/lamivudine	efavirenz/lamivudine/tenofovir
BIKTARVY (bictegravir/Emtricitabine/Tenofovir)	emtricitabine capsule
CIMDUO (lamivudine/tenofovir)	EPIVIR (lamivudine)
COMPLERA (emtricitabine/rilpivirine/tenofovir)	EPZICOM (abacavir)
DELSTRIGO (doravirine/lamivudine/tenofovir)	TRIZIVIR (abacavir/lamivudine)
DESCOVY (emtricitabine/tenofovir)	TRUVADA (emtricitabine/tenofovir)
EMTRIVA (emtricitabine) CAPSULE – *Brand Required*	VIREAD (tenofovir)
efavirenz/emtricitabine/tenofovir	ZERIT (stavudine) CAPSULE
emtricitabine solution	ZIAGEN (abacavir)
emtricitabine/tenofovir	
GENVOYA (elvitegravir/cobicistat/emtricitabine/tenofovir)	
lamivudine	
ODEFSEY (emtricitabine/rilpivirine/tenofovir)	
SYMFI (efavirenz/lamivudine/tenofovir) – *Brand Required*	
SYMFI LO (efavirenz/lamivudine/tenofovir) – *Brand Required*	
STRIBILD (elvitegravir/cobicistat/emtricitabine/tenofovir)	
SYMTUZA (darumavir/cobicistat/emtricitabine/tenofovir)	
tenofovir	
TEMIXYS (Lamivudine/Tenofovir)	
TRIUMEQ (abacavir/dolutegravir/lamivudine)	
NOT RECOMMENDED FOR FIRST LINE USE	
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. **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). **didanosine –** Guidelines do not recommend ddl/3TC or ddl/FTC regimens due to inferior virologic efficacy, limited trial experience in ART-naïve members, and ddl toxicities (including pancreatitis and peripheral neuropathy). ddl/TDF regimens are not recommended due to high rate of early virologic failure, rapid selection of resistance mutations, potential for immunologic nonresponse/CD4 cell decline, and increased ddl drug exposure and toxicities. **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)	
abacavir/lamivudine/zidovudine	COMBIVIR (lamivudine/zidovudine)
didanosine	RETROVIR (zidovudine)
lamivudine/zidovudine	VIDEX EC (didanosine)
stavudine	ZERIT (stavudine) CAPSULE
VIDEX (didanosine)	
zidovudine	

Post-Attachment Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
TROGARZO (Ibalizumab-uiyk)	

Protease Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
atazanavir	NORVIR (ritonavir)
EVOTAZ (atazanavir/cobicistat)	REYATAZ (atazanavir) CAPSULE
PREZCOBIX (darunavir/cobicistat)	
PREZISTA (darunavir)	
REYATAZ (atazanavir) POWDER PACK	
ritonavir	
SYMTUZA (darumavir/cobicistat/emtricitabine/tenofovir)	
NOT RECOMMENDED FOR FIRST LINE USE	
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.	
APTIVUS (tipranavir)	KALETRA (lopinavir/ritonavir) SOLUTION
fosamprenavir	LEXIVA (fosamprenavir)
INVIRASE (saquinavir)	lopinavir/ritonavir tablet
KALETRA (lopinavir/ritonavir) TABLET – *Brand Required*	
lopinavir/ritonavir solution	
VIRACEPT (nelfinavir)	

Entry Inhibitor

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
NOT RECOMMENDED FOR FIRST LINE USE	
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.	
FUZEON (enfuvirtide)	
SELZENTRY (maraviroc)	

Diarrhea

Product Specific Criteria:

*** **Mytesi:** Jump to Criteria

Loss of Appetite

Product Specific Criteria:

*** **Dronabinol:** Jump to Criteria

Wasting Cachexia

Product Specific Criteria:

*** **Serostim:** Jump to Criteria

Hepatitis C Treatments

Electronic Step Care and Concurrent Medications

- A total of 28 days of ribavirin must be billed within the previous 14 days of an Epclusa (and its generic) claim if member has decompensated cirrhosis (Child Pugh B or C).
    - Epclusa (and its generic) requires prior authorization and after prior authorization is approved, Epclusa (and its generic) will continue to reject for prior authorization unless ribavirin is billed first when it is recommended to be used concurrently.

Prior Authorization Criteria

Prior Authorization Form – Hepatitis C

Antivirals

Category Criteria: *Approval duration – based on label recommendations*

- The member must have an FDA-approved indication for use (meets label recommendations for diagnosis and age).
- The member must not be receiving a known recreationally used high risk combination of drugs (e.g. “the holy trinity”) for the past 6 months.
- 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.
- Member must not have life expectancy of less than 12 months due to non-liver related comorbid conditions.
- Member and Prescriber attestation forms must be attached to request
- Chronic Hepatitis C must be documented by one of the following:
    - **Liver fibrosis F1 and below**: 2 positive HCV RNA levels at least 6 months apart.
    - **Liver fibrosis F2 and above**: 1 positive HCV RNA test within the last 12 months.

Prescriber may be primary care provider or family practice with the following exceptions:

Prescriber must be a hepatology, gastroenterology, or infectious disease specialist	• Decompensated cirrhosis (Child's Pugh B or C) • Status post solid organ transplantation • Known or suspected hepatocellular carcinoma • Evidence/suspicion of acute liver injury while on HCV treatment • HIV or HBsAg positive • Current pregnancy or breastfeeding
Prescriber must be, or in consult with, a hepatology, gastroenterology, or infectious disease specialist (including via Project ECHO)	• Compensated cirrhosis (Child's Pugh A) • For Hep C retreatment after Direct Acting Antivirals

For <u>FIRST TIME</u> treatments with Direct Acting Antivirals:

Must be drug (drugs of abuse by injection) and alcohol free as documented by:		
No history of alcohol use disorder or history of using drugs of abuse by injection		• 1 drug and alcohol test completed within 30 days of the request date
History of alcohol use disorder or history of drugs of abuse by injection	**Currently enrolled or has completed a substance use treatment program within the past 3 months**	• 1 drug and alcohol test completed within 30 days of the request date • Must be receiving treatment from an enrolled addiction medicine/chemical dependency treatment provider - provider/facility name must be provided with the request • Chart notes must be attached regarding assessment of member's readiness for treatment including readiness for abstinence from alcohol use during and after treatment
	<u>Has not</u> completed a substance use treatment program within the past 3 months	• 2 drug and alcohol tests, dated at least 3 months apart, with the most current test completed within 30 days of the request date • 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:

Reason for retreatment:		
Due to drugs of abuse by injection	• The member is receiving treatment or must have received from an enrolled addiction medicine/chemical dependency treatment (or buprenorphine waived) provider since initial Hepatitis C treatment with Direct Acting Antivirals, and the provider/facility name must be provided with the request. • The member must not be at high risk of relapse from illicit drug use by injection during and after treatment as evidenced by treatment provider notes or risk assessment	
	Liver fibrosis F2 and below	**Liver fibrosis F3 and above**
	• The provider must submit chart notes documenting that the member has abstained from drugs of abuse for the past year	• Two drug tests: 1 test completed 3 months prior to request and 1 test within 30 days of the request date

	• Two drug tests: 1 test completed 6 months (+/- 1 months) prior to request and 1 test within 30 days of the request date	
	Liver fibrosis F2 and below	**Liver fibrosis F3 and above**
Due to non-compliance (defined as a medication possession ratio (MPR) of less than 80%)	• 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.	• 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.
Resistance	• FIRST TIME treatment with Direct Acting Antivirals criteria must be met	

Non-Preferred Agents Criteria:

- The member must have had a trial of each preferred treatment options indicated for the member's genotype, as evidenced by paid claims or pharmacy printouts.

Product Specific Criteria:

- Epclusa:
  - 200mg-50mg: Member must be 6 years old or older and weigh between 17 to 30 kg
- Harvoni:
  - 45mg-200mg strength: Member must be 3 years old or older and weigh between 17 and 35 kg
  - 33.75mg/150mg strength: Member must be 3 years old or older and weigh less than 17 kg.
- Sovaldi:
  - 200mg strength: Member must be 3 years old or older and weigh between 17 to 35 kg

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
HARVONI (ledipasvir/sofosbuvir) 45 mg/200mg 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)

Ribavirin

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ribavirin capsule	
ribavirin tablet	

Influenza

Electronic Age Verification

- Xofluza: The member must be 12 years of age or older

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS:
oseltamivir	TAMIFLU (oseltamivir)
XOFLUZA (baloxavir marboxil)	

Nephrology/Urology

Benign Prostatic Hyperplasia

General Prior Authorization Form

Non-Preferred Agents Criteria:

- The member must have diagnosis of benign prostatic hyperplasia (BPH)
- The member must have had a 30-day trial of each preferred agent, as evidenced by paid claims or pharmacy printouts

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
alfuzosin ER	AVODART (dutasteride)
CARDURA XL (doxazosin)	CARDURA (doxazosin)
doxazosin	FLOMAX (tamsulosin)
dutasteride	MINIPRESS (prazosin)
finasteride	PROSCAR (finasteride)
prazosin	RAPAFLO (silodosin)
silodosin	sildenafil
tamsulosin	tadalafil
terazosin	

Chronic Kidney Disease

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
FARXIGA (dapagliflozin)	
KERENDIA (finerenone)	
TEKTURNA (aliskiren)	

Hematopoietic, Erythropoiesis Stimulating Agents

General Prior Authorization Form

Non-Preferred Agents Criteria:

- The member must have an FDA-approved indication for use (meets label recommendations for diagnosis and age).
- The member must have had a 4-week trial of each preferred agent, as evidenced by paid claims or pharmacy printouts.

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)

Hyperkalemia (Chronic)

General Prior Authorization Form

Non-Preferred Agents Criteria:

- **Initial criteria**: *Approval Duration = 3 months*
    - The member must be 18 years of age or older.
    - Medication must be prescribed by, or in consultation with, a nephrologist
    - The member's current serum potassium level must be exceeding the upper limit of normal, as evidenced by documentation from at least two separate lab values, submitted with the request
    - One of the following criteria must be met:
        - The member must have failed 30-day trials with at least two of the following products
            - Bumetanide, Chlorothiazide, Fludrocortisone, Furosemide, Hydrochlorothiazide, Indapamide, Metolazone, Torsemide
    - The member must not be receiving the medications known to cause hyperkalemia listed below, OR medical justification must be provided explaining why discontinuation of these agents would be clinically inappropriate in this member:
        - angiotensin-converting enzyme inhibitor

        - angiotensin II receptor blocker
        - aldosterone antagonist
        - nonsteroidal anti-inflammatory drugs (NSAIDs)
- **Renewal Criteria:** *Approval Duration = 6 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

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
LOKELMA (Sodium Zirconium Cyclosilicate)	VELTASSA (Patiromer)

Overactive Bladder

Step Care and Concurrent Medications

- Non-Preferred Step 1 Agents: Less expensive urinary antispasmodics must be trialed first
    - A total of 30 days of a preferred agent at max dose must be paid within 90 days prior to step 1 agents date of service.

Therapeutic Duplication

- One strength of one of the following medications is allowed at a time: dutasteride, Jalyn, or finasteride
- Alpha 1 blockers (alfuzosin ER, doxazosin, dutasteride-tamsulosin, prazosin, terazosin, tamsulosin) are not allowed with carvedilol or labetalol
    - carvedilol and labetalol are nonselective beta blockers with alpha 1 blocking activity
- Anticholinergic medications (tolterodine, oxybutynin, trospium, solifenacin) are not covered with Acetylcholinesterase Inhibitors. Click here for a full listing of medications included.
    - The effects of an anticholinergic (blocks the effect of acetylcholine) and acetylcholinesterase inhibitors (prevents breakdown of acetylcholine) oppose each other, and the therapeutic effect of both products is diminished

Prior Authorization Criteria

General Prior Authorization Form

Solid dosage forms

Non-Preferred Step 1 Agents Criteria:

- The member must have an FDA-approved indication for use (meets label recommendations for diagnosis and age).
- The member must have had a 30-day trial of a preferred agent, as evidenced by paid claims or pharmacy printouts.

Non-Preferred Step 2 Agents Criteria:

- The member must have an FDA-approved indication for use (meets label recommendations for diagnosis and age).
- The member must have had a 30-day trial of 2 preferred agents and 1 non-preferred step 1 agents, as evidenced by paid claims or pharmacy printouts.

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED STEP 1 AGENTS (PA REQUIRED)	NON-PREFERRED STEP 2 AGENTS (PA REQUIRED)
DETROL (tolterodine) – *Brand Required*	MYRBETRIQ (mirabegron)	darifenacin ER
DETROL LA (tolterodine) – *Brand Required*	flavoxate	DITROPAN XL (oxybutynin)
GELNIQUE (oxybutynin)		dutasteride/tamsulosin
oxybutynin ER		FLOMAX (tamsulosin)
oxybutynin tablet		GEMTESA (vibegron)
OXYTROL (oxybutynin) PATCH		JALYN (dutasteride/tamsulosin)
solifenacin		tolterodine
tamsulosin		tolterodine ER
TOVIAZ (fesoterodine)		trospium ER
trospium		VESICARE (solifenacin)

Non-solid dosage form

Non-Preferred Agents Criteria:

- The member must be 9 years old or younger or provide documentation of inability to swallow.
- The member must have an FDA-approved indication for use (meets label recommendations for diagnosis and age).
- The member must have had a 30-day trial of a preferred agent, as evidenced by paid claims or pharmacy printouts.

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
oxybutynin syrup	MYRBETRIQ (mirabegron) SUSPENSION
	VESICARE (solifenacin) LS SUSPENSION

Phosphate Binders

General Prior Authorization Form

Category Criteria:

- The member must have had 30-day trials of all preferred agents of a unique active ingredient, as evidenced by paid claims or pharmacy printouts.
- The member must have a diagnosis of end-stage renal disease or chronic kidney disease.
- If member is on renal dialysis, Medicare eligibility must be ruled out.

Solid dosage form

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
Calcium acetate	AURYXIA (ferric citrate) TABLET
FOSRENOL (lanthanum) CHEWABLE TABLET – *Brand Required*	Lanthanum chew tab
Sevelamer Carbonate Tablet	RENAGEL (Sevelamer HCl) TABLET
	RENVELA (sevelamer carbonate) TABLET
	Sevelamer HCl 400mg Tablet
	Sevelamer HCl 800mg Tablet
	VELPHORO (Sucroferric oxyhydroxide)

Non-solid dosage form

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
PHOSLYRA (calcium acetate) ORAL solution	FOSRENOL (lanthanum) POWDER PACK
RENVELA (sevelamer) POWDER PACK – *Brand Required*	Sevelamer Powder Pack

Neurology

Alzheimer's Disease

Therapeutic Duplication

- One memantine medication is allowed at a time
- Anticholinergic medications are not covered with acetylcholinesterase inhibitors **(**Aricept, Exelon, Razadyne, 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:** Members must have an FDA or compendia supported indication

Electronic Age Verification

- Members must be greater than 30 years old

Prior Authorization Criteria

General Prior Authorization Form

Non-Preferred Product Criteria:

- The member must have a diagnosis of an FDA-approved indication for use
- The member must have had 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 with skilled nursing care.

Product Specific Criteria:

- Donepezil 23mg:
  - Clinical justification must be provided explaining why the member is unable to use the preferred products (subject to clinical review).

Cholinesterase Inhibitors	
PREFERRED AGENTS (NO PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**
donepezil 5mg, 10mg Tablet	ARICEPT (donepezil)
EXELON (rivastigmine) PATCH – *Brand Required*	donepezil ODT

galantamine Tablet	donepezil 23mg tablet
galantamine ER	galantamine oral solution
rivastigmine capsule	RAZADYNE (galantamine)
	RAZADYNE ER (galantamine)
	rivastigmine patch
NMDA Receptor Antagonists	
PREFERRED AGENTS (NO PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**
memantine	memantine oral solution
	memantine ER
	NAMENDA (memantine)
	NAMENDA XR (memantine)
Cholinesterase Inhibitors / NMDA Receptor Antagonist Combinations	
PREFERRED AGENTS (NO PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**
NAMZARIC (memantine/donepezil)	

Anticonvulsants

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:
    - All of member's medications dispensed in solid formulations are being crushed or opened to administer because member is unable to swallow

Electronic Diagnosis Verification

- Diacomit, Epidiolex, Fentepla: The member must have an FDA approved diagnosis

Electronic Step Care and Concurrent Medications

- Diacomit is FDA approved to be used in combination with clobazam.
  - A total of 28 days of clobazam must be paid within 45 days prior to Diacomit (stiripentol)

Prior Authorization Criteria

Group Criteria:

- **Branded non-preferred agents:** The member must have had a 30-day trial of 2 pharmaceutically equivalent preferred agent, as evidenced by paid claims or pharmacy printouts.
- **Generic non-preferred agents:** The member must have had a 30-day trial of a pharmaceutically equivalent preferred agent, as evidenced by paid claims or pharmacy printouts.

Anticonvulsant Prevention

Carbamazepine Derivatives	
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*	oxcarbazepine oral solution
EQUETRO (carbamazepine)	TEGRETOL (carbamazepine)
oxcarbazepine tablet	TEGRETOL (carbamazepine oral suspension)
OXTELLAR XR (oxcarbazepine)	
TRILEPTAL (oxcarbazepine) – *Brand Co-Preferred*	
TRILEPTAL (oxcarbazepine) ORAL SUSPENSION – *Brand Required*	
TEGRETOL XR (carbamazepine) – *Brand Required*	
First Generation	
PREFERRED AGENTS (NO PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED):**
CELONTIN (methsuximide)	DEPAKENE (valproic acid) CAPSULE

clobazam	DEPAKENE (valproic acid) ORAL SOLUTION
clobazam oral solution	DEPAKOTE (divalproex sodium) TABLET
DEPAKOTE SPRINKLE (divalproex sodium) – *Brand Co-Preferred*	
divalproex ER	DEPAKOTE ER (divalproex sodium)
divalproex sprinkle	
divalproex tablet	DILANTIN (phenytoin) CHEWABLE TABLET
ethosuximide capsule	DILANTIN (phenytoin) ORAL SUSPENSION
ethosuximide oral solution	DILANTIN ER (phenytoin)
FELBATOL (felbamate) TABLET– *Brand Required*	felbamate oral suspension
FELBATOL (felbamate) ORAL SUSPENSION - *Brand Required*	felbamate tablet
PEGANONE (ethotoin)	MYSOLINE (primidone)
phenobarbital elixir	ONFI (clobazam)
phenobarbital tablet	ONFI (clobazam) ORAL SOLUTION
phenytoin chewable tablet	PHENYTEK (phenytoin)
phenytoin ER capsule	SYMPAZAN (clobazam)
phenytoin suspension	ZARONTIN (ethosuximide)
primidone	ZARONTIN (ethosuximide) ORAL SOLUTION
valproic acid capsule	
valproic acid oral solution	
Second Generation	
PREFERRED AGENTS (NO PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED):**
BANZEL (rufinamide) ORAL SUSPENSION – *Brand Required*	ELEPSIA XR (levetiracetam)
BANZEL (rufinamide) TABLET – *Brand Required*	KEPPRA (levetiracetam)
BRIVIACT (brivaracetam)	KEPPRA (levetiracetam) ORAL SOLUTION
DIACOMIT (stiripentol)	KEPPRA XR (levetiracetam)
EPIDIOLEX (cannabidiol)	LAMICTAL (lamotrigine)
FINTEPLA (fenfluramine) ORAL SOLUTION	LAMICTAL (lamotrigine) DOSE PACK
FYCOMPA (perampanel)	lamotrigine ODT
FYCOMPA (perampanel) ORAL SUSPENSION	lamotrigine ODT dose pack
gabapentin capsule	lamotrigine chewable tablet
gabapentin oral solution	lamotrigine ER
gabapentin tablet	LYRICA (pregabalin)
GABITRIL (tiagabine) - *Brand Required*	LYRICA (pregabalin) ORAL SOLUTION
LAMICTAL ODT (lamotrigine) DOSE PACK- *Brand Required*	NEURONTIN (gabapentin) CAPSULE
LAMICTAL ER (lamotrigine) DOSE PACK	NEURONTIN (gabapentin) ORAL SOLUTION
LAMICTAL XR (lamotrigine) - *Brand Required*	NEURONTIN (gabapentin) TABLET
LAMICTAL (lamotrigine) CHEWABLE TABLET- *Brand Required*	rufinamide tablet
LAMICTAL ODT (lamotrigine) - *Brand Required*	rufinamide suspension
lamotrigine dose pack	SPRITAM (levetiracetam)
lamotrigine tablet	SUBVENITE (lamotrigine)
levetiracetam ER	tiagabine
levetiracetam oral solution	TOPAMAX (topiramate)
levetiracetam tablet	TOPAMAX (topiramate) SPRINKLE CAPSULE
QUDEXY XR (topiramate) SPRINKLE CAPSULE – *Brand Co-Preferred*	topiramate ER sprinkle cap – Labeler 00245
pregabalin	VIGADRONE (vigabatrin)
pregabalin oral solution	vigabatrin
SABRIL (vigabatrin) - *Brand Required*	vigabatrin powder pack
SABRIL (vigabatrin) POWDER PACK - *Brand Required*	ZONEGRAN (zonisamide)
topiramate ER sprinkle cap – Labeler 00832	
topiramate ER	
topiramate sprinkle capsule	
topiramate tablet	
TROKENDI XR (topiramate)	
XCOPRI (cenobamate)	
zonisamide	
Third Generation	
PREFERRED AGENTS (NO PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED):**

APTIOM (Eslicarbazepine)	
VIMPAT (lacosamide)	
VIMPAT (lacosamide) ORAL SOLUTION	

Anticonvulsant treatment

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED):
DIASTAT PEDIATRIC (diazepam) RECTAL GEL – *Brand Required*	Diazepam pediatric rectal gel
DIASTAT ACUDIAL (diazepam) RECTAL GEL – *Brand Required*	Diazepam rectal gel
NAYZILAM (midazolam) SPRAY	
VALTOCO (diazepam) SPRAY	

Emflaza

Prior Authorization Form - Emflaza

Initial Criteria: *Approval Duration = 6 months*

- The member must be 2 years of age or older
- The member must have diagnosis of Duchenne Muscular Dystrophy (DMD) confirmed by the documented presence of abnormal dystrophin or a confirmed mutation of the dystrophin gene
- Onset of weakness must have occurred before 2 years of age
- The medication must be prescribed by or in consultation with a physician who specializes in the treatment of Duchenne Muscular Dystrophy (DMD) and/or neuromuscular disorders
- 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 due to inadequate treatment response, intolerance, or contraindication, 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 ONE of the following (A or B)
    - 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

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
Prednisone	EMFLAZA (deflazacort)

Fabry Disease

General Prior Authorization Form

Fabrazyme: See Medical Billing Drug Clinical Criteria

Initial Criteria: *Approval Duration = 6 months*

- The member must have a diagnosis of Fabry disease
- The member must be 18 years of age or older
- 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

PREFERRED AGENTS (CLINICAL PA REQUIRED)
GALAFOLD (migalastat)

Headache/Migraine

Vyepti – See Medical Billing Drug Clinical Criteria

Prophylaxis of Migraine – CGRP Inhibitors

Prior Authorization Form –Migraine/Cluster Headache Prophylaxis

Group Criteria:

Initial PA Criteria: *Approval Duration: 3 months*

- Member must experience 3 or more migraine days per month.
- The member must have had 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
- Prescriber must submit documentation, including clinical notes regarding failure of prior treatments to reduce migraine frequency after 2-month trial.

Non-Preferred Agents Criteria:

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

Renewal PA Criteria: *Approval Duration: 12 months*

- The member must have experienced at least a 50% reduction in migraines from baseline, since starting treatment with a CGRP inhibitor.

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AJOVY (fremanezumab-vfrm)	AIMOVIG (erenumab-aooe)
EMGALITY (galcanazumab-gnlm)	NURTEC ODT (rimegepant)
	QULIPTA (atogepant)

Treatment of Migraine

Therapeutic Duplication

- One strength of one medication is allowed at a time

Prior Authorization Criteria

General Prior Authorization Form

Group Criteria:

- Within the past 2 years, the member must have had 30-day trials of two triptans (5HT-1 agonists), as evidenced by paid claims or pharmacy printouts.

Non-Preferred Agents:

- Within the past 2 years, the member must have had a 30-day trial of the preferred agent, as evidenced by paid claims or pharmacy printouts.

Non-Triptan Agents

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
NURTEC ODT (rimegepant)	REYVOW (lasmiditan)
	UBRELVY (ubrogepant)
Ergot Alkaloids	
	D.H.E.45 (dihydroergotamine) INJECTION
	dihydroergotamine injection
	dihydroergotamine nasal spray
	ERGOMAR (ergotamine) SL TABLET
	MIGERGOT (ergotamine/caffeine) RECTAL SUPPOSITORY
	TRUDHESA (dihydroergotamine)

Triptans (5HT-1 agonists)

Approval Duration = 6 months

Solid Oral Dosage Forms

Non-Preferred Step 1 Agents Criteria:

- Members 18 years old or older: The member must have had a 30-day trial of rizatriptan and Relpax (eletriptan), as evidenced by paid claims or pharmacy printouts.
- Members 6 to 17 years of age: The member must have had a 30-day trial of rizatriptan, as evidenced by paid claims or pharmacy printouts.

Non-preferred step 2 agents:

- The member must have had either a 30-day trial of each available preferred triptan agent, as evidenced by paid claims or pharmacy printouts or provide clinical justification explaining why the member is unable to use all other products (subject to clinical review).

PREFERRED AGENTS (NO PA REQUIRED)	PREFERRED STEP 1 AGENTS (PA REQUIRED)	NON-PREFERRED STEP 2 AGENTS (PA REQUIRED)
FROVA (frovatriptan) TABLET– *Brand Required*	naratriptan tablet	almotriptan tablet
RELPAX (eletriptan) TABLET – *Brand Required*	zolmitriptan tablet	AMERGE (naratriptan) TABLET
rizatriptan tablet		eletriptan tablet
sumatriptan tablet		frovatriptan tablet
		IMITREX (sumatriptan) TABLET
		MAXALT (rizatriptan) TABLET
		sumatriptan/naproxen tablet
		TREXIMET (sumatriptan/naproxen) TABLET
		ZOMIG (zolmitriptan) TABLET

Non-Solid Oral Dosage Forms

Non-Preferred Agents Criteria:

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

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
Rizatriptan ODT	MAXALT MLT (rizatriptan)
ZOMIG ODT (zolmitriptan) – *Brand Required*	zolmitriptan ODT

Non-Oral Dosage Forms

All (Preferred and Non-Preferred) Non-Oral Dosage Form Agents:

- Members must not able to take oral medications (subject to clinical review).

Product Specific Criteria

- Onzetra Xsail: Member must have had a 30-day trial of zolmitriptan, as evidenced by paid claims or pharmacy printouts.

Non-Preferred Agents Criteria:

- Member must have had a 30-day trial of zolmitriptan and Imitrex (sumatriptan), as evidenced by paid claims or pharmacy printouts.

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
IMITREX (sumatriptan) CARTRIDGE – *Brand Required*	sumatriptan cartridge
IMITREX (sumatriptan) PEN INJCTR – *Brand Required*	sumatriptan pen injctr
IMITREX (sumatriptan) SPRAY – *Brand Required*	sumatriptan spray
IMITREX (sumatriptan) SYRINGE – *Brand Required*	sumatriptan syringe
zolmitriptan spray	sumatriptan vial
ONZETRA XSAIL (sumatriptan) NASAL SPRAY^{PA}***	TOSYMRA (sumatriptan) NASAL SPRAY
	ZEMBRACE SYMTOUCH (sumatriptan)
	ZOMIG (zolmitriptan) NASAL SPRAY

Cluster Headache

Initial PA Criteria: *Approval Duration: 3 months*

- Member must meet ICHD-3 criteria for diagnosis of cluster headache:
  - Severe or very severe unilateral orbital, supraorbital and/or temporal pain lasting 15-180 minutes (during active time course)
  - Either or both of the following:
    - At least one 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
    - A sense of restlessness or agitation
  - Occurring with a frequency between one every other day and 8 per day (during active time course)

Cluster Headache Prevention

Non-preferred agents:

- Member must use medication 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 medication is not indicated for chronic use
- Member must have had a 2-month trial with verapamil

Renewal PA Criteria: *Approval Duration: 12 months*

- Prescriber must submit documentation indicating that the members' cluster headaches have been reduced in frequency and/or severity as a result of therapy per member headache journal

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
topiramate	EMGALITY (galcanazumab-gnlm)
verapamil	

Cluster Headache Treatment

Non-preferred agents:

- The member must have had a 30-day trial of two unique pharmaceutical preferred agents within the past 24 months, as evidenced by paid claims or pharmacy printouts.

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ONZETRA XSAIL (sumatriptan) NASAL SPRAY	D.H.E.45 (dihydroergotamine) INJECTION
IMITREX (sumatriptan) CARTRIDGE – *Brand Required*	Dihydroergotamine (DHE) intranasal
IMITREX (sumatriptan) PEN INJCTR – *Brand Required*	Dihydroergotamine Injection
IMITREX (sumatriptan) SPRAY – *Brand Required*	Dihydroergotamine Nasal Spray
IMITREX (sumatriptan) SYRINGE – *Brand Required*	ERGOMAR (ergotamine) SL TABLET
zolmitriptan oral	IMITREX (sumatriptan) VIAL
zolmitriptan ODT	MIGRANAL (dihydroergotamine) SPRAY
zolmitriptan spray	Sumatriptan Cartridge
	Sumatriptan intranasal
	Sumatriptan Pen Injctr
	Sumatriptan Spray
	Sumatriptan subcutaneous
	Sumatriptan Syringe
	Sumatriptan Vial
	TOSYMRA (Sumatriptan) NASAL SPRAY
	ZEMBRANCE SYMTOUCH (Sumatriptan)
	ZOMIG (Zolmitriptan) NASAL SPRAY

Huntington's Disease

General Prior Authorization Form

- **Initial Criteria:** *Approval Duration = 12 months*
  - The member must have a diagnosis of an FDA-approved indication for use
  - The prescription must be written by/in consultation with a specialist (neurologist or psychiatrist).

  Non-Preferred Agents Criteria:
  - The member must have failed a 3-month trial of tetrabenazine, as evidenced by paid claims or pharmacy printouts
- **Renewal Criteria:** *Approval Duration = 12 months*
  - Documentation of disease stabilization or improvement in disease since initiation of treatment must be provided

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
tetrabenazine	AUSTEDO (deutetrabenazine)

Multiple Sclerosis

Injectable Agents

Interferons

General Prior Authorization Form

Non-Preferred Agents Criteria:

- The member must have an FDA-approved indication for use (meets label recommendations for diagnosis and age).
- The member must have had a 3-month trial of at least 1 preferred agent, as evidenced by paid claims or pharmacy printouts.

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AVONEX (interferon beta-1A) PEN	EXTAVIA (interferon beta-1B)
AVONEX (interferon beta-1A) SYRINGE	PLEGRIDY (peginterferon beta-1A) PEN
AVONEX (interferon beta-1A) VIAL	PLEGRIDY (peginterferon beta-1A) SYRINGE
BETASERON (interferon beta-1B)	
REBIF (interferon beta-1A)	
REBIF REBIDOSE (interferon beta-1A)	

Injectable Non-Interferons

General Prior Authorization Form

Non-Preferred Agents Criteria:

- The member must have an FDA-approved indication for use (meets label recommendations for diagnosis and age)
- The member must have had either a 30-day trial of each available preferred multiple sclerosis agent, as evidenced by paid claims or pharmacy printouts or provide clinical justification explaining why the member is unable to use all other products (subject to clinical review).

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
COPAXONE (glatiramer) 20 MG/ML – *Brand Required*	COPAXONE (glatiramer) 40 MG/ML
	glatiramer 20mg/ml
	glatiramer 40mg/ml
	GLATOPA (glatiramer)

Monoclonal Antibodies

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
KESIMPTA (ofatumumab)	

Oral Agents

Fumerates

General Prior Authorization Form

Non-Preferred Agents Criteria:

- The member must have an FDA-approved indication for use (meets label recommendations for diagnosis and age).
- The member must have had a 3-month trial of the preferred agent, as evidenced by paid claims or pharmacy printouts.

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
TECFIDERA (dimethyl fumarate) – *Brand Required*	BAFIERTAM (monomethyl fumarate)
	dimethyl fumarate
	VUMERITY (diroximel fumarate)

Sphingosine 1-Phosphate (S1P) Receptor Modulators

General Prior Authorization Form

Non-Preferred Agents Criteria:

- The member must have an FDA-approved indication for use (meets label recommendations for diagnosis and age).
- The member must have had a 3-month trial of the preferred agent, as evidenced by paid claims or pharmacy printouts.

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
GILENYA (fingolimod)	MAYZENT (siponimod)
	PONVORY (ponesimod)
	ZEPOSIA (ozanimod)

Pyrimidine Synthesis Inhibitor

General Prior Authorization Form

Non-Preferred Agents Criteria:

- The member must have an FDA-approved indication for use (meets label recommendations for diagnosis and age).
- The member must have had a 3-month trial of Kesimpta, as evidenced by paid claims or pharmacy printouts.

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AUBAGIO (teriflunomide)	MAVENCLAD (cladribine)

Narcolepsy

Therapeutic Duplication

- Sunosi and Wakix are not allowed together
- Provigil and Nuvigil are not allowed together
- Xyrem, Xywav is not allowed with sleeping medication or benzodiazepines

Electronic Step Care and Concurrent Medications

- Sunosi and Xyrem requires a 30-day trial of Nuvigil to be paid within 60 days of submitted claim
- Wakix requires titration to 17.8 mg dose with 4.45 mg tablets.

Underutilization

- Wakix, Sunosi, and Xywav must be used compliantly and will reject on point of sale for late fill

Prior Authorization Criteria

General Prior Authorization Form

Non-Preferred Agents Criteria- Narcolepsy**:**

- The member must have an FDA-approved indication for use (meets label recommendations for diagnosis and age)
- The member must have failed 30-day trials of each preferred agent and at least 1 additional CNS stimulant indicated for treatment of narcolepsy, as evidenced by paid claims or pharmacy printouts
- Provider must submit documentation of prior treatment failure, as evidenced by documentation of one of the following, while on prior treatments:
  - Multiple Sleep Latency Test (MSLT) <8 minutes
  - EPWORTH sleepiness scale score ≥10

Product Specific Criteria:

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

Renewal Criteria:

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

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

Nuedexta (dextromethorphan/quinidine)

Prior Authorization Form - Nuedexta

Group Criteria (Initial): *Approval Duration = 3 months*

- The member must be 18 years of age or older
- The member must not have a diagnosis of any of the following: prolonged QT interval, heart failure, or complete atrioventricular (AV) block
- The prescriber must provide the following information:
  - 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
- **Additional initial criteria for a diagnosis of PBA due to Alzheimer's disease or stroke:**
  - Neurologic condition must have been stable for at least 3 months
  - Member must have failed** a 3-month trial of at least one medication from each of the classes listed below (A and B), as evidenced by paid claims or pharmacy print outs:
    A. **SSRIs**: sertraline, fluoxetine, citalopram and paroxetine
    B. **Tricyclic Antidepressants**: nortriptyline and amitriptyline
  - A PBA episode count and CNS-LS score must be provided for before and after each trial

***A failure is defined as one of the following:*

- *PBA count decreased less than 75 percent, stayed the same, or increased from baseline in each trial*
- *CHS-LS score decreased less than 7 points, stayed the same, or increased from baseline in each trial*

Group Criteria (Renewal): *Approval Duration = 6 months*

- Benefit of continued therapy must be assessed
- Baseline and current PBA episode count must be included with request
- Current PBA episode must be reduced by at least 75% from baseline
- **Additional initial criteria for a diagnosis of PBA due to Alzheimer's disease or stroke:**
    - Baseline and current Center for Neurological Studies lability (CNS-LS) must be included with request
    - Current CNS-LS score must be reduced by at least 30% from baseline

Parkinson's disease

Electronic Step Care and Concurrent Medications

- Xadago and Nourianz is FDA approved for adjunctive treatment to levodopa/carbidopa.
    - A total of 28 days of levodopa/carbidopa treatment must be paid within 40 days prior to Xadago or Nourianz's date of service

Prior Authorization Criteria

General Prior Authorization Form

Parkinson's Agents – Adenosine Receptor Agonist

- **Non-Preferred Agents Criteria (Initial):**
    - The member must have a diagnosis of an FDA-approved indication for use
    - Medication must be prescribed by, or in consultation with, a neurologist
    - Documentation for deterioration in quality of response to levodopa/carbidopa therapy, including currently experiencing intermittent hypomobility, or "off" episodes (number and frequency) must be provided
    - The member must have had inadequate response to rasagiline and selegiline, as evidenced by paid claims or pharmacy printouts
- **Non-Preferred Agents Criteria (Renewal):**
    - Documentation of disease stabilization or improvement in disease since initiation of treatment must be provided

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

Parkinson's Agents –Dopaminergic Agents for Intermittent Treatment of Off Episode

- **Group Criteria**
    - The member must have a diagnosis of an FDA-approved indication for use
    - Medication must be prescribed by, or in consultation 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 of intermittent hypomobility or off episodes (number and frequency) must be provided
    - At least one of the following criteria must be met (A and/or B):
        A. Member is experiencing unpredictable off periods, morning off, delayed on, no on or failure of on response
        B. 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)

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
Subcutaneous	
APOKYN (apomorphine)	
Enteral Suspension	
DUOPA (levodopa/carbidopa)	
Inhalation	
INBRIJA (levodopa)	
Sublingual	
KYNMOBI (apomorphine)	

Parkinson's Agents –Non-ergot Dopamine Receptor Agonists Maintenance

Non-Preferred Agents Criteria:

- The member must have a diagnosis of an FDA-approved indication for use
- The member is must not currently be residing in a facility with skilled nursing care
- Clinical justification must be provided explaining why the member is unable to use the preferred agents (subject to clinical review).

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)
Maintenance - Topical	
PREFERRED AGENTS (NO PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**
NEUPRO (Rotigotine) PATCH	

Parkinson's Agents –Dopamine Precursor

Non-Preferred Agents Criteria:

- The member must have a diagnosis of an FDA-approved indication for use
- Clinical justification must be provided explaining why the member is unable to use a preferred agent (subject to clinical review).

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
carbidopa-levodopa-entacapone	carbidopa-levodopa ODT
carbidopa-levodopa	RYTARY (carbidopa-levodopa)
carbidopa-levodopa ER	SINEMET (carbidopa-levodopa)
	STALEVO (carbidopa-levodopa-entacapone)

Parkinson's Agents –MAO-B Inhibitors

Non-Preferred Agents Criteria

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

Product Specific Criteria:

- ***Xadago:**
  - The member must have a diagnosis of an FDA-approved indication for use
  - Medication must be prescribed by, or in consultation 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

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AZILECT (Rasagiline) – *Brand Required*	EMSAM (Selegiline) PATCH
Selegiline	Rasagiline
ZALAPAR ODT (selegiline)	XADAGO (Safinamide)***

Parkinson's Agents – COMT inhibitor

- **Non-Preferred Agents Criteria**
  - The member must have failed a 30-day trial of entacapone, as evidenced by paid claims or pharmacy printouts

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
entacapone	COMTAN (entacapone)
	ONGENTYS (opicapone)

	TASMAR (tolcapone)
	Tolcapone

Parkinson's Agents – Other

- **Non-Preferred Agents Criteria**
  - The member must have a diagnosis of an FDA-approved indication for use
  - The member is must not currently be residing in a facility with skilled nursing care
  - Clinical justification must be provided explaining why the member is unable to use the preferred agents (subject to clinical review).

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
amantadine IR capsule	amantadine IR tablet
	GOCOVRI (amantadine ER)
	OSMOLEX ER (amantadine ER)

Parkinson's Agents –Ergot Dopamine Receptor Agonists

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
bromocriptine	PARLODEL (bromocriptine)
cabergoline	

Parkinson's Agents – Anticholinergics

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
benztropine	COGENTIN (benztropine)
trihexyphenidyl	

Spinal Muscular Atrophy (SMA)

Zolgensma / Spinraza: See Medical Billing Drug Clinical Criteria

Evrysdi

Evrysdi Prior Authorization Form

- **Initial Criteria:** *Approval Duration = 12 months*
  - The member must have a diagnosis of spinal muscular atrophy (SMA) with 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 (A and/or B):
      - A. Member has number of SMN2 gene copies ≥ 1 but ≤ 4 as confirmed by genetic testing
      - B. Member is symptomatic (e.g. loss of reflexes, motor delay, motor weakness, abnormal EMG/neuromuscular ultrasound)
  - The medication must be prescribed by or in consultation 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 be 2 months of age or older
  - The member must not require continuous intubation > 3 weeks
  - The member must not be receiving/have received treatment with Zolgensma
  - The member's weight and prescribed dose must be provided and within dosing recommendations per the manufacturer label
  - The provider must submit documentation of the member's current motor function, as evidenced by 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'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 member must not require continuous intubation > 3 weeks
        A. The provider must submit documentation showing that the member has experienced clinical benefit since starting treatment with Evrysdi, as evidenced by documentation of current Forced Vital capacity (FVC and FEV1) via Pulmonary Function Test, CHOP-INTEND, HINE, HFMSE, MFM-32, 6MWT, or RULM scores showing maintenance of baseline motor function or significant slowed rate of decline (vs expected natural course of the disease).

PA REQUIRED
EVRYSDI (Risdiplam)

Tardive Dyskinesia

Electronic Step Care and Concurrent Medications

- Start Ingrezza with Initiation Pack before continuing therapy with 80mg capsules
    - The 30-count 40 mg bottle is not packaged for titration to 80 mg. If therapy is expected to be continued at 40 mg at time of drug initiation, please call for override.

Prior Authorization

Prior Authorization Form – Tardive Dyskinesia

- **Initial Criteria:** *Approval Duration = 12 months*
    - The member must have an FDA-approved indication for use (meets label recommendations for diagnosis and age)
    - The prescription must be written by/in consultation with a specialist (neurologist or psychiatrist).
    - The member must have a diagnosis of tardive dyskinesia, including the following:
        - Involuntary athetoid or choreiform movements
        - History of treatment with dopamine receptor blocking agent (DRBA)
        - Symptom duration lasting longer than 4-8 weeks
- **Renewal Criteria:** *Approval Duration = 12 months*
    - Documentation of disease stabilization or improvement in disease since initiation of treatment must be provided

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AUSTEDO (deutetrabenazine)	
INGREZZA (valbenazine)	
tetrabenazine	

Ophthalmology

Antihistamines

General Prior Authorization Form

Non-Preferred Agents Criteria:

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

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ALOCRIL (nedocromil)	bepotastine
ALOMIDE (lodoxamide)	epinastine
azelastine	olopatadine 0.2%
BEPREVE (bepotastine) – *Brand Required*	ZERVIATE (cetirizine)
cromolyn	
LASTACAFT (alcaftadine)	
olopatadine 0.1%	
PAZEO (olopatadine)	

Anti-infectives

General Prior Authorization Form

Non-Preferred Agents Criteria:

- The member must have had 3-day trials of at least 3 preferred agents, as evidenced by paid claims or pharmacy printouts.

Drops

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
BESIVANCE (besifloxacin) DROPS	AZASITE (azithromycin) DROPS
ciprofloxacin drops	BLEPH-10 (sulfacetamide) DROPS
gentamicin sulfate drops	CILOXAN (ciprofloxacin) DROPS
moxifloxacin drops	gatifloxacin drops
neomycin SU/polymyxin B/gramicidin drops	levofloxacin drops
ofloxacin drops	MOXEZA (moxifloxacin) DROPS
polymyxin B/trimethoprim drops	NEOSPORIN (neomycin SU/polymyxin B/gramicidin) DROPS
sulfacetamide drops	OCUFLOX (ofloxacin) DROPS
tobramycin drops	POLYTRIM (polymyxin B/trimethoprim) DROPS
	TOBREX (tobramycin) DROPS
	VIGAMOX (moxifloxacin) DROPS
	ZYMAXID (gatifloxacin) DROPS

Ointment

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
bacitracin/polymyxin B ointment	bacitracin ointment
CILOXAN (ciprofloxacin) OINTMENT	NEO-POLYCIN (neomycin SU/bacitracin/polymyxin B) OINTMENT
erythromycin ointment	POLYCIN (bacitracin/polymyxin) OINTMENT
GENTAK (gentamicin sulfate) OINTMENT	sulfacetamide ointment
gentamicin sulfate ointment	
neomycin SU/bacitracin/polymyxin B ointment	
TOBREX (tobramycin) OINTMENT	

Anti-infectives/Anti-inflammatories

General Prior Authorization Form

Non-Preferred Agents Criteria:

- The member must have had 7-day trials of at least 2 preferred agents, as evidenced by paid claims or pharmacy printouts.

Drops

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
BLEPHAMIDE (sulfacetamide/prednisolone) DROPS	MAXITROL (neomycin/polymyxin b/dexamethasone) DROPS
neomycin/polymyxin b/dexamethasone drops	neomycin/polymyxin b/hydrocortisone drops
PRED-G (gentamicin/prednisol ac) DROPS	TOBRADEX ST (tobramycin/dexamethasone) DROPS
sulfacetamide/prednisolone drops	tobramycin/dexamethasone drops
TOBRADEX (tobramycin/dexamethasone) DROPS – *Brand Required*	
ZYLET (tobramycin/lotepred etab) DROPS	

Ointment

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
neomycin/polymyxin b/dexamethasone ointment	BLEPHAMIDE S.O.P. (sulfacetamide/prednisolone) ointment
PRED-G (gentamicin/prednisol ac) 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

Anti-inflammatories

General Prior Authorization Form

Non-Preferred Agents Criteria:

- The member must have had 5-day trials of at least 2 preferred agents, as evidenced by paid claims or pharmacy printouts.

Drops

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ACUVAIL (ketorolac) DROPS	ACULAR (ketorolac) DROPS
ALREX (loteprednol) DROPS	ACULAR LS (ketorolac) DROPS
diclofenac sodium drops	bromfenac sodium drops
DUREZOL (difluprednate) DROPS – *Brand Required*	BROMSITE (bromfenac sodium) DROPS
FLAREX (fluorometholone) DROPS	dexamethasone sodium phosphate drops
fluorometholone drops	difluprednate drops
flurbiprofen sodium drops	EYSUVIS (loteprednol) DROPS
FML FORTE (fluorometholone) DROPS	INVELTYS (loteprednol) DROPS
ILEVRO (nepafenac) DROPS	FML (fluorometholone) DROPS
ketorolac tromethamine 0.4% drops	LOTEMAX SM (loteprednol) DROPS
ketorolac tromethamine 0.5% drops	loteprednol eye drops
LOTEMAX (loteprednol) DROPS – *Brand Required*	loteprednol gel eye drops
LOTEMAX (loteprednol) GEL DROPS – *Brand Required*	PRED FORTE 1% (prednisolone acetate) DROPS
MAXIDEX (dexamethasone) DROPS	PROLENSA (bromfenac) DROPS
NEVANAC (nepafenac) DROPS	
PRED MILD 0.12% (prednisolone acetate) DROPS	
prednisolone acetate 1% drops	
prednisolone sodium phosphate 1% drops	

Ointment

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
FML S.O.P. (fluorometholone) OINTMENT	
LOTEMAX (loteprednol) OINTMENT	

Dry Eye Syndrome

General Prior Authorization Form

Non-Preferred Agents Criteria:

- The member must have had a 14-day trial of the preferred agent, as evidenced by paid claims or pharmacy printouts.

Product Specific Criteria:

- **Cequa, Restasis Multidose**
  - The member must have had a 30-day trials of Xiidra, as evidenced by paid claims or pharmacy printouts.
  - Clinical justification must be provided explaining why the member is unable to use all other products (subject to clinical review).

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
RESTASIS (cyclosporine)	CEQUA (cyclosporine)***
	RESTASIS MULTIDOSE (cyclosporine)***
	XIIDRA (lifitegrast)

Glaucoma

Alpha Adrenergic

General Prior Authorization Form

Non-Preferred Agents Criteria:

- **Branded non-preferred agents:** The member must have had a 30-day trial of each pharmaceutically equivalent preferred agent, as evidenced by paid claims or pharmacy printouts.
- **Generic non-preferred agents:** The member must have had a 30-day trial of a pharmaceutically equivalent preferred agent, as evidenced by paid claims or pharmacy printouts.

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

ALPHAGAN P 0.1% (brimonidine) DROPS	brimonidine 0.15% drops
ALPHAGAN P 0.15% (brimonidine) DROPS – *Brand Required*	
apraclonidine 0.5% drops	
brimonidine 0.2% drops	
COMBIGAN (brimonidine/timolol) DROPS	
IOPIDINE (apraclonidine) 1% DROPS	
LUMIFY (brimonidine) 0.03% DROPS	
SIMBRINZA (brinzolamide/brimonidine) DROPS	

Beta Blockers

General Prior Authorization Form

Non-Preferred Agents Criteria:

- The member must have had a 30-day trial of at least 2 preferred ophthalmic beta blocker products of a unique active ingredient, as evidenced by paid claims or pharmacy printouts.

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	COSOPT (dorzolamide/timolol) PF DROPS
dorzolamide/timolol drops	ISTALOL (timolol maleate) DROPS ONCE DAILY
levobunolol drops	timolol drops once daily
timolol maleate drops	timolol gel forming solution
timolol maleate/PF drops	TIMOPTIC (timolol maleate) DROPS
TIMOPTIC OCUDOSE 0.25% (timolol) PF DROPS	TIMOPTIC OCUDOSE 0.5% (timolol) PF DROPS
	TIMOPTIC-XE (timolol gel forming solution)

Prostaglandins

General Prior Authorization Form

Non-Preferred Agents Criteria:

- The member must have had a 30-day trial of at least 2 preferred ophthalmic prostaglandin products of a unique active ingredient, as evidenced by paid claims or pharmacy printouts.

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
latanoprost	bimatoprost 0.03%
LUMIGAN (bimatoprost) 0.01%	travoprost
ROCKLATAN (netarsudil/Latanoprost)	VYZULTA (latanoprostene)
TRAVATAN Z (travoprost) - *Brand Required*	XALATAN (latanoprost)
ZIOPTAN (tafluprost)	XELPROS (latanoprost)

Other

Non-Preferred Agents Criteria:

- **Branded non-preferred agents:** The member must have had a 30-day trial of each pharmaceutically equivalent preferred agent, as evidenced by paid claims or pharmacy printouts.
- **Generic non-preferred agents:** The member must have had a 30-day trial of a pharmaceutically equivalent preferred agent, as evidenced by paid claims or pharmacy printouts.

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AZOPT (brinzolamide) – *Brand Required*	brinzolamide
dorzolamide	COSOPT (dorzolamide/timolol)
PHOSPHOLINE (Echothiophate Iodide)	ISOPTO CARPINE (pilocarbine)
pilocarpine	TRUSOPT (dorzolamide)
RHOPRESSA (netarsudil)	
ROCKLATAN (netarsudil/latanoprost)	
SIMBRINZA (brinzolamide/brimonidine)	

Uveitis

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
HUMIRA (adalimumab)	

Otic

Anti-infectives/Anti-inflammatories – Fluoroquinolones

General Prior Authorization Form

Non-Preferred Agents Criteria:

- The member must have had a 7-day trial of one preferred product in the past 3 months, as evidenced by paid claims or pharmacy printouts.

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
CIPRO HC (ciprofloxacin/hydrocortisone)	ciprofloxacin/dexamethasone otic drops
CIPRODEX (ciprofloxacin/dexamethasone) – *Brand Required*	ciprofloxacin/fluocinolone
	OTOVEL (ciprofloxacin/fluocinolone)

Pain

Lidocaine patch

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
lidocaine 4% patch	lidocaine 5% patch
LIDODERM (lidocaine) 5% PATCH – *Brand Required*	
ZTLIDO (lidocaine) 1.8% PATCH	

Lidocaine topical cream

General Prior Authorization Form

Group Criteria:

- The request must be for injection pain from a medically necessary procedure

NSAIDS

Therapeutic Duplication

- One strength of one medication is allowed at a time (topical and oral formulations are not allowed together)
  - **Please call for an override** if all the following circumstances apply by calling provider relations at 1-800-755-2604:
    - Member is prescribed ketorolac and will stop regular NSAID therapy during course of ketorolac

Electronic Diagnosis Verification

- **Mefenamic acid and Meclofenamate:** The member must have diagnosis of dysmenorrhea or endometriosis

Solid Oral Dosage Forms

General Prior Authorization Form

Non-Preferred Agents Criteria:

- The member must have failed a 30-day trial of 3 different oral generic NSAIDs including a COX-2 inhibitor with GI intolerances, as evidenced by paid claims or pharmacy print outs

Product Specific Criteria:

- **Branded NSAIDs and non-preferred strengths**:
  - Clinical justification must be provided explaining why the member is unable to use other NSAID agents (subject to clinical review)

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

celecoxib 50mg, 100mg, 200mg	ARTHROTEC (diclofenac/misoprostol)
diclofenac potassium	celecoxib 400mg
diclofenac sodium 50mg, 75mg	CELEBREX (celecoxib)
etodolac	CONSENSI (amlodipine/celecoxib)
flurbiprofen	DAYPRO (oxaprozin)
ibuprofen	diclofenac sodium ER 100mg
indomethacin	diclofenac sodium 35mg capsule, submicronized
indomethacin ER	diclofenac/misoprostol
ketorolac	DUEXIS (famotidine/ibuprofen)
meclofenamate	etodolac ER
mefenamic acid	FELDENE (piroxicam)
meloxicam	fenoprofen
nabumetone	INDOCIN (indomethacin)
naproxen	ketoprofen
piroxicam	ketoprofen ER 200mg
sulindac	meloxicam, submicronized
VIMOVO (naproxen/esomeprazole) – *Brand Required*	MOBIC (meloxicam)
ZIPSOR (diclofenac)	NALFON (fenoprofen)
	NAPRELAN (naproxen)
	naproxen ER 375 mg, 500mg
	naproxen/esomeprazole
	oxaprozin
	RELAFEN DS (nabumetone)
	tolmetin 200mg
	VIVLODEX (meloxicam, submicronized)
	ZORVOLEX (diclofenac, submicronized)

Non-Solid Oral Dosage Forms

General Prior Authorization Form

Non-Preferred Agents Criteria:

- The member must have had 30-day trials of each preferred agent, as evidenced by paid claims or pharmacy printouts.

PREFERRED AGENTS	NON-PREFERRED AGENTS
ibuprofen suspension	INDOCIN (Indomethacin) SOLUTION
naproxen suspension	

Nasal

General Prior Authorization Form

Non-Preferred Agents Criteria:

- The member must have had 30-day trials of 2 oral and 1 topical preferred agents, as evidenced by paid claims or pharmacy printouts.
- Clinical justification must be provided explaining why the member is unable to use another dosage form (subject to clinical review).

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	Ketorolac Nasal Spray
	SPRIX (Ketorolac) NASAL SPRAY

Topical:

General Prior Authorization Form

Non-Preferred Agents Criteria:

- The member must have had 30-day trials 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 products (subject to clinical review).

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
Diclofenac 1.5% Topical Solution	Diclofenac Patch
FLECTOR (diclofenac) PATCH - *Brand Required*	LICART (Diclofenac) PATCH 1.3%
PENNSAID (Diclofenac) 2% PUMP	

Opioid Analgesics – Long Acting

Therapeutic Duplication

- One extended-release product/strength is allowed at a time
- One immediate release product is allowed (single ingredient or combination)
- Nucynta and Nucynta ER are not allowed with other narcotic medications
- Opioid-acetaminophen combination products are not allowed with acetaminophen
- Tramadol immediate release with tramadol extended release
- Methadone is not allowed
- 3A4 Substrates (Fentanyl, methadone, and oxycodone) are not allowed with strong 3A4 inhibitors. Click here for a full listing of medications included.
- Methadone: Not allowed with opioids, benzodiazepines, or opioid use disorder medications
- Opioids are not allowed with:
    - Benzodiazepines: 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
        - **Opioids and Benzodiazepines Override Criteria:**
            - The prescriber must attest that they have reviewed the past 3 months of the member's North Dakota PDMP reports.
                - The member has access to Narcan and has been counseled on overdose risk
                - One of the following criteria must be met:
                    - Prescriber must be or be in consult with an oncologist, palliative care specialist, or pain management specialist including a pain management contract (with treatment plan including goals for pain and function, and urine and/or blood screens)
                    - Member must have taper plan of one or both agents
                - The following criteria is met:
                    - 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)
                    - Prescriber(s) from both the opioid and benzodiazepine attest to the following:
                        - The member must have not achieved therapeutic goal with non-narcotic medication (NSAIDs, TCAs, SNRIs, Corticosteroids, etc.) and non-medication alternatives (Weight Loss, Physical Therapy, Cognitive Behavioral Therapy, etc.
                        - Opioid dose does not exceed 90 MME/day
                        - The member has an acute condition that cannot be reasonably treated with non-opioid therapy (e.g. surgery)
    - 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.
    - **Opioid use disorder medications override criteria**:
        - Call provider relations at 1-800-755-2604 if all the following circumstances apply:
            - The member has an acute condition that cannot be reasonably treated with non-opioid therapy (e.g. surgery)
            - Prescribers of both opioid and opioid use disorder are aware of each other and agree to opioid therapy
            - Opioid duration is of a one-time occurrence or taper plan is provided

- Morphine is not covered with Clopidogrel, Prasugrel, Ticagrelor, and Ticlopidine. 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).

Underutilization

- Long-acting opioid analgesics must be used compliantly and will reject on point of sale for late fill

Morphine Milligram Equivalents (MME)

Prior Authorization Form – Opioid Analgesics

- A cumulative maximum of 90 MME will be allowed without authorization
- Member must meet Prior Authorization Criteria
- An MME calculator may be found at Opioid Dose Calculator

Prior Authorization Criteria

Prior Authorization Form – Opioid Analgesics

Category Criteria (initial):

- The prescriber must attest that they have reviewed the past 3 months of the member's North Dakota PDMP reports.
- The member must have not achieved therapeutic goal with non-narcotic medication (NSAIDs, TCAs, SNRIs, Corticosteroids, etc.) and non-medication alternatives (Weight Loss, Physical Therapy, Cognitive Behavioral Therapy, etc.).
- The member must have 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 must have access to Narcan and be counseled on overdose risk
- The prescription must be written by or in consultation 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 one of the following:
    - Cumulative daily dose of opioids exceeds 90 MED/day

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).

Category Criteria (renewal):

- Documentation noting progress toward therapeutic goal must be included with request (including pain level and function).

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 Agonist Opioids

Prior Authorization Form – Opioid Analgesics

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
NUCYNTA ER (tapentadol)	ARYMO ER (morphine)
OXYCONTIN (oxycodone) – *Brand Required*	CONZIP (tramadol ER) CAPSULES
tramadol ER Tablets	hydrocodone ER tablets
	HYSINGLA ER (hydrocodone)
	levorphanol
	methadone
	MORPHABOND ER (morphine)
	tramadol ER Capsules
	XTAMPZA ER (oxycodone)

Full Agonist Opioids Without Abuse Deterrent Formulations

Prior Authorization Form – Opioid Analgesics

Product Specific Criteria:

- **Fentanyl Patch:**

- Member must meet one of the following criteria:
  - The member has an indication of cancer pain or palliative care pain
  - The member requires a long-acting narcotic and cannot tolerate an oral dosage form
- Member must have a BMI ≥17
- **Fentanyl Patch 12 mcg/hr**:
  - Member must meet one of the following (A or B):

A. The member must be receiving a total daily opioid dose less than or equal to 60 Morphine Equivalent Dose (MED), as evidenced by paid claims or pharmacy printouts

B. The member must be continuously tapering off opioids from a higher strength Fentanyl patch

Full Agonist Opioids Without Abuse Deterrent Formulations	
PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
fentanyl 12 mcg/hr	EXALGO (hydromorphone)
fentanyl 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
	KADIAN (morphine)
	morphine ER capsules
	MS CONTIN (morphine)
	oxycodone ER
	oxymorphone ER tablets
	ZOHYDRO ER (hydrocodone)

Opioid Analgesic – Short Acting

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

Product Specific Criteria:

- **Subsys, Fentanyl Citrate Buccal Tablet, Lazanda, Actiq, and Abstral:**
  - The member's age must be within label recommendations
  - The member must have a diagnosis of cancer pain
  - The member must currently be on around-the-clock opioid therapy for at least a week, as evidenced by paid claims or pharmacy printouts
    - The around the clock opioid therapy must be equivalent to 60 mg oral morphine daily, 25 mcg transdermal fentanyl/hour, 30mg oxycodone daily, 8 mg of oral hydromorphone daily, or equianalgesic dose of another opioid daily
- **ALL Other Non-Preferred Short-Acting Opioid Analgesics (Initial):**
  - The member must have required around-the-clock pain relief for the past 90 days, as evidenced by paid claims or pharmacy printouts
  - The prescriber must attest that they have reviewed the past 3 months of the member's North Dakota PDMP reports
  - The member must have not achieved therapeutic goal with non-narcotic medication (NSAIDs, TCAs, SNRIs, Corticosteroids, etc.) and non-medication alternatives (Weight Loss, Physical Therapy, Cognitive Behavioral Therapy, etc.)
  - The prescription must be written by or in consultation 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)
- **Oxycodone IR**
  - The "ALL Other Non-Preferred Short-Acting Opioid Analgesics" above Initial Criteria must be met
  - The member must currently be on a long-acting opioid analgesic that provides a daily Morphine Equivalent Dose (MED) 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 MED for specific products):
    - **Oxycodone 15 mg tablet:** long-acting opioid must provide ≥150 mg MED per day
    - **Oxycodone 20 mg tablet:** long-acting opioid must provide ≥200 mg MED per day
    - **Oxycodone 30 mg tablet:** long-acting opioid must provide ≥300 mg MED per day
- **Meperidine, butalbital-codeine products:**

- The above Initial Criteria must be met
- Clinical justification must be provided explaining why the member is unable to use other opioid and non-opioid analgesic products (subject to clinical review).

- **ALL Other Non-Preferred Short-Acting Opioid Analgesics (Renewal):**
  - Documentation noting progress toward therapeutic goal must be included with request (including pain level and function).

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
acetaminophen-codeine solution	ABSTRAL (fentanyl) SUBLINGUAL TABLET
acetaminophen-codeine tablets	ACTIQ (fentanyl) LOZENGE
benzhydrocodone-acetaminophen	butalbital-codeine
codeine tablets	CONZIP (tramadol) CAPSULE
hydrocodone-acetaminophen 7.5-325/15ml Solution	DEMEROL (meperidine)
hydrocodone-acetaminophen 5-325 MG	DILAUDID (hydromorphone)
hydrocodone-acetaminophen 7.5-325 MG	ENDOCET (oxycodone-acetaminophen)
hydrocodone-acetaminophen 10-325 MG	FENTORA (fentanyl) EFFERVESCENT TABLET
hydrocodone-ibuprofen 7.5mg-200mg	fentanyl citrate buccal tablet
hydromorphone liquid	fentanyl lozenge
hydromorphone tablet	hydrocodone-acetaminophen 5-163mg/7.5mL solution
meperidine	hydrocodone-acetaminophen 2.5-325 MG
morphine tablets	hydrocodone-acetaminophen 10MG-300MG
morphine solution	hydrocodone-acetaminophen 5 MG-300MG
NUCYNTA (tapentadol) TABLETS	hydrocodone-acetaminophen 7.5-300 MG
oxycodone 5mg, 10mg tablets	hydrocodone-ibuprofen 5mg-200mg and 10mg-200mg
oxycodone solution	LAZANDA (fentanyl) SPRAY
oxycodone-acetaminophen 5-325 MG	LORCET (hydrocodone-acetaminophen)
oxycodone-acetaminophen 10 -325 MG	LORTAB (hydrocodone-acetaminophen) SOLUTION
oxymorphone tablets	NALOCET (oxycodone-acetaminophen)
tramadol 50mg tablets	NORCO (hydrocodone-acetaminophen)
tramadol-acetaminophen tablets	OPANA (oxymorphone)
	OXAYDO (oxycodone)
	oxycodone 15mg, 20mg, 30mg
	oxycodone-acetaminophen 2.5-325 MG
	oxycodone-acetaminophen 7.5-325 MG
	PERCOCET (oxycodone/acetaminophen)
	PRIMLEV (oxycodone/acetaminophen)
	PROLATE (oxycodone/acetaminophen)
	QDOLO (tramadol) ORAL SOLUTION
	ROXICODONE (oxycodone)
	ROXYBOND (oxycodone)
	SUBSYS (fentanyl) SPRAY
	tramadol 100mg tablets
	ULTRACET (tramadol/acetaminophen)
	ULTRAM (tramadol)
	VICODIN (hydrocodone/acetaminophen)

Skeletal Muscle Relaxants

Therapeutic Duplication

- One strength of one medication is allowed at a time
  - **Please call for an override** if all the following circumstances apply by calling provider relations at 1-800-755-2604:
    - Member has cerebral palsy or another chronic spastic disorder
    - Prescriber is a physiatrist
    - 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:
  - Antipsychotics: visual hallucinations being reported in 3% of members receiving tizanidine, psychosis has also been reported.
  - Other alpha 2 agonists (clonidine, clonidine/chlorthalidone, guanfacine, methyldopa) as tizanidine is also an alpha 2 agonist

Prior Authorization Criteria

General Prior Authorization Form

Non-Preferred Agents Criteria: *Approval Duration = 12 months*

- The member must have failed two 30-day trials of other skeletal muscle relaxants, as evidenced by paid claims or pharmacy printouts.

Product Specific Criteria

- **Metaxalone:** *Approval Duration = 12 months*
  - One of the required 30-day trials must be methocarbamol, as evidenced by paid claims or pharmacy printouts.
- **Carisoprodol:** *Approval Duration = 1 week*
  - The member must be undergoing dose tapering

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
baclofen	AMRIX (cyclobenzaprine) TAB 24HR
chlorzoxazone 500mg	chlorzoxazone 375mg and 750mg
cyclobenzaprine 5mg and 10mg	cyclobenzaprine 7.5mg
dantrolene	cyclobenzaprine ER
methocarbamol	carisoprodol
orphenadrine ER	carisoprodol-aspirin
tizanidine tablets	carisoprodol-aspirin-codeine
	DANTRIUM (dantrolene)
	FEXMID (cyclobenzaprine)
	LORZONE (chlorzoxazone)
	METAXALL (metaxalone)
	metaxalone
	NORGESIC FORTE (orphenadrine/aspirin/caffeine)
	OZOBAX (baclofen) SOLUTION
	ROBAXIN (methocarbamol)
	SKELAXIN (metaxalone)
	SOMA (carisoprodol)
	tizanidine capsules
	ZANAFLEX (tizanidine)

Psychiatry

ADHD Agents

Therapeutic Duplication

- **For all stimulants:**
  - The following are not payable:
    - Multiple strengths of a single medication
    - Amphetamine Agent + Methylphenidate Agent
    - Multiple Long-Acting Agents
    - Multiple Short Acting Agents
    - Non-Solid dosage + Solid dosage forms

- These long acting products are not allowed with short acting products:
  - Aptensio XR (Methylphenidate)
  - Adhansia XR (Methylphenidate)
  - Cotempla XR-ODT (Methylphenidate)
  - Daytrana (Methylphenidate)
  - Adderall XR (Mixed Salts of a Single-Entity Amphetamine Product)
  - Adzenys XR ODT (Amphetamine Suspension, Extended Release)
  - Adzenys ER (Amphetamine Suspension, Extended Release)
  - Dyanavel XR (amphetamine suspension, Extended Release)
  - 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 Adhansia XR with benzodiazepines or sedatives
    - Members reporting insomnia should use a shorter acting product that does not reach steady state.

- Methylphenidates: The following are not payable regimens
  - Concurrent use of dexmethylphenidate and methylphenidate

- **For all non-stimulants:**
  - One strength of one medication is allowed at a time except for Guanfacine 4mg IR and ER which may be combined Guanfacine IR and ER, respectively, to form dosages up to 7mg per day
  - Clonidine, guanfacine are not allowed with each other or other alpha 2 agonists (clonidine/chlorthalidone, methyldopa, or tizanidine)
    - Methyldopa and tizanidine are also alpha 2 agonists

First Fill

- Long-Acting ADHD medications (stimulants and guanfacine ER) must be filled with a 14-day supply (or less) if no previous fill within past 99 days

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

Prior Authorization Criteria

General Prior Authorization Form

Non-Preferred Agents Criteria:

- The member must have had a 10-day trial of a pharmaceutically equivalent preferred agent, as evidenced by paid claims or pharmacy printouts.

Non-Stimulants

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
atomoxetine	INTUNIV (guanfacine ER)
clonidine	KAPVAY (clonidine ER)***
clonidine ER***	STRATTERA (atomoxetine
guanfacine	
guanfacine ER	
QELBREE (viloxazine)	

Stimulants

Stimulants - Methylphenidates	
PREFERRED AGENTS (NO PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**
Solid Dosage Forms	
CONCERTA (methylphenidate) – *Brand Required*	dexmethylphenidate ER

Stimulants - Methylphenidates	
PREFERRED AGENTS (NO PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**
dexmethylphenidate	FOCALIN (dexmethylphenidate)
FOCALIN XR (dexmethylphenidate) – *Brand Required*	METADATE ER (methylphenidate)
methylphenidate CD 30-70	methylphenidate ER tablet (generic Concerta)
methylphenidate tablet	methylphenidate LA capsules - 50-50 (generic Ritalin LA)
methylphenidate ER tablet 10mg, 20mg	RITALIN (methylphenidate)
RITALIN LA (methylphenidate LA capsules - 50-50)– *Brand Required*	
High Cost Options	
ADHANSIA XR (methylphenidate)	methylphenidate ER 72 mg
AZSTARYS (serdexmethylphenidate/dexmethylphenidate)	methylphenidate ER capsule
JORNAY PM (methylphenidate)	
Non-Solid Dosage Forms	
DAYTRANA (methylphenidate)	METHYLIN (methylphenidate) chew tablets
methylphenidate chew tablet	METHYLIN (methylphenidate) solution
methylphenidate solution	
QUILLICHEW ER (methylphenidate)	
QUILLIVANT XR (methylphenidate)	
High Cost Options	
APTENSIO XR (methylphenidate) – *Brand Required*	
COTEMPLA XR - ODT (methylphenidate)	

Stimulants - Amphetamines	
PREFERRED AGENTS (NO PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**
Solid Dosage Forms	
ADDERALL XR (dextroamphetamine/amphetamine) – *Brand Required*	ADDERALL (dextroamphetamine/amphetamine)
amphetamine	DEXEDRINE ER (dextroamphetamine)
DESOXYN (methamphetamine) – *Brand Required*	dextroamphetamine/amphetamine ER
dextroamphetamine	EVEKEO (amphetamine)
dextroamphetamine ER	methamphetamine
dextroamphetamine/amphetamine	ZENZEDI (dextroamphetamine)
VYVANSE (lisdexamfetamine)	
High Cost Options	
MYDAYIS (dextroamphetamine/amphetamine)	
Non-Solid Dosage Forms	
DYANAVEL XR (amphetamine)	dextroamphetamine 5 mg/5 ml
EVEKEO ODT (amphetamine)	
PROCENTRA (dextroamphetamine) – *Brand Required*	
High Cost Options	
ADZENYS XR - ODT (amphetamine)	ADZENYS ER (amphetamine) SOLUTION
amphetamine ER solution	
VYVANSE (lisdexamfetamine) CHEW TABLET	

Atypical Antipsychotics

Electronic Age Verification

- FDA or compendia supported age is required

Electronic Diagnosis Verification

- FDA or compendia supported indications is required

Therapeutic Duplication

Multiple Antipsychotic Override Request Form

- **For all antipsychotics:** One strength of one medication is payable with the following exceptions:
  - risperidone 0.25mg, 0.5mg and 1mg are allowed with other strengths of risperidone.

    - quetiapine 25mg and 50mg are allowed with other strengths of quetiapine IR.
    - quetiapine 50mg ER is allowed with other strengths of quetiapine ER.
    - olanzapine 2.5mg is allowed with 10mg, 15mg, and 20mg
    - olanzapine 5mg is allowed with 7.5mg and 20mg
    - olanzapine 7.5mg is allowed with 5mg
    - olanzapine 10mg, 15mg, and 20mg are allowed with 2.5mg
- Tizanidine is not allowed with antipsychotics due to visual hallucinations being reported in 3% of members receiving tizanidine, psychosis has also been reported. Please use an alternate muscle relaxant.
- Lybalvi: Lybalvi is not allowed with any other antipsychotic or opioid analgesics. Please call for an override to allow olanzapine with Lybalvi for dose titrations.

Additional information on olanzapine:
- Quantity limit is 1 tablet per day due to the 30-hour half-life of the medication.
- Pharmacokinetic studies show that olanzapine tablets and olanzapine ODT are bioequivalent.

Additional information on quetiapine:
- Quetiapine is not covered for sleep. For sleep indications, please use a sleeping medication indicated for insomnia.
- **For an override** for therapeutic duplication with quetiapine: Please call provider relations at 1-800-755-2604 if all of the following circumstances apply:
    - Nighttime akathisia (e.g. nighttime dosing with risperidone) or daytime sedation (e.g. Seroquel XR 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.

Oral

Electronic Step Care and Concurrent Medication

- Start Vraylar with Initiation pack or 7 days of 1.5 mg tablets prior to continuing therapy with doses of 3 mg or more
    - Vraylar requires titration from 1.5 mg dose at initiation.

Underutilization

- Caplyta, Fanapt, Latuda, Paliperidone ER, Rexulti, Saphris, Sacuado, and Vraylar must be used compliantly and will reject on point of sale for late fill

First Fill

- Caplyta, Fanapt, Latuda, Paliperidone ER, Rexulti, Saphris, Sacuado, and Vraylar must be filled with a 10-day supply if no previous fill within past 99 days

Prior Authorization Criteria

Non-Preferred Agents Criteria:
- **Branded non-preferred agents:** The member must have had a 30-day trial of each pharmaceutically equivalent preferred agent, as evidenced by paid claims or pharmacy printouts.
- **Generic non-preferred agents:** The member must have had a 30-day trial of a pharmaceutically equivalent preferred agent, as evidenced by paid claims or pharmacy printouts.

Product Specific Criteria:
- ***olanzapine/fluoxetine**: Clinical justification must be provided explaining why the member is unable to use the preferred, individual products separately (subject to clinical review).

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
Solid Dosage Forms	
aripiprazole	ABILIFY (aripiprazole)
clozapine	asenapine
FANAPT (iloperidone)	CLOZARIL (clozapine)
INVEGA ER (paliperidone) – *Brand Required*	GEODON (ziprasidone)
LATUDA (lurasidone)	paliperidone ER
olanzapine	RISPERDAL (risperidone)
quetiapine	SEROQUEL (quetiapine)
quetiapine ER	SEROQUEL XR (quetiapine)
risperidone	ZYPREXA (olanzapine)

ziprasidone	
High Cost Options	
CAPLYTA (lumateperone)	olanzapine/fluoxetine***
LYBALVI (olanzapine/samidorphan)	
REXULTI (brexpiprazole)	
VRAYLAR (cariprazine)	
Non-Solid Dosage Forms	
clozapine ODT	RISPERDAL (risperidone) ORAL SOLUTION
olanzapine ODT	RISPERDAL M-TAB (risperidone)
risperidone ODT	ZYPREXA ZYDIS (olanzapine)
risperidone oral solution	
SAPHRIS (asenapine) – *Brand Required*	
High Cost Options	
aripiprazole solution	ABILIFY DISCMELT (aripiprazole)
aripiprazole ODT	
SECUADO (asenapine)	

Long Acting Injectable

Electronic Step Care and Concurrent Medication

- Oral formulations must be used prior to injectable formulations to establish tolerability and achieve steady state.
    - Please call for exception if there is a history of tolerability to active ingredient and no requirement for oral overlap for missed dose / initiation of long-acting injectable antipsychotic.

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ABILIFY MAINTENA (aripiprazole)	
ARISTADA (aripiprazole lauroxil)	
ARISTADA INITIO (aripiprazole lauroxil)	
INVEGA HAFYERA (paliperidone)	
INVEGA SUSTENNA (paliperidone)	
INVEGA TRINZA (paliperidone)	
PERSERIS (risperidone)	
RISPERDAL CONSTA (risperidone)	
ZYPREXA RELPREVV (olanzapine)	

Sedatives/Hypnotics

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 due to CNS depression
        - Belsomra and Dayvigo are not covered with short or long-acting benzodiazepines
- Ramelteon is a 1A2 Substrate and 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
- Benzodiazepines are not covered with Opioids: Override Criteria Available

Electronic Step Care and Concurrent Medications

- 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.
- Belsomra: The member must have had a 25- day trial of eszopiclone within the past 90 days

Prior Authorization Criteria

General Prior Authorization Form

Product Specific Criteria (Initial): *Approval Duration = 1 month*

- **temazepam, zolpidem SL, Dayvigo:**
  - The member's insomnia must be characterized by difficulty with sleep onset and maintenance
  - The member must have had the following 25-day trials with the most recent failure within the last 90 days, as evidenced by paid claims or pharmacy printouts
    - eszopiclone
    - zolpidem ER
    - Belsomra
- **Edluar (zolpidem):**
  - The member's insomnia must be characterized by difficulty with sleep onset
  - The member must have had the following 25-day trials with the most recent failure within the last 90 days, as evidenced by paid claims or pharmacy printouts
    - zolpidem IR
    - zaleplon
    - eszopiclone
- **triazolam, fluazepam, estazolam, seconal sodium**
  - Clinical justification must be provided explaining why the member is unable to use the preferred agents (subject to clinical review)

Product Specific Criteria (Renewal): *Approval Duration = 6 months (2 weeks for b*enzodiazepines)

- **ALL Agents:**
  - The prescriber has provided confirmation that other conditions causing sleep issues have been ruled out
- **benzodiazepines (temazepam, triazolam, flurazepam, estazolam):**
  - The member must be undergoing dose tapering

Insomnia

Non-DEA scheduled (non-addictive) medications:

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
doxepin – labeler 44183	doxepin – labeler 00228, 00378
hydroxyzine	ramelteon
mirtazapine	SILENOR (doxepin)
ROZEREM (ramelteon) – *Brand Required*	
trazodone	

DEA scheduled (addictive) medications:

PREFERRED AGENTS (NO PA REQUIRED)	ELECTRONIC STEP MEDICATIONS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
eszopiclone	BELSOMRA (suvorexant)	AMBIEN (zolpidem)
zaleplon	zolpidem 10mg	AMBIEN CR (zolpidem)
zolpidem 5mg		DAYVIGO (lemborexant)
zolpidem ER		EDLUAR (zolpidem)
		estazolam
		flurazepam
		LUNESTA (eszopiclone)
		SECONAL SODIUM (secobarbital)
		temazepam
		triazolam
		zolpidem SL tab

Non-24 Hour Sleep-Wake Disorder

Group Criteria:

- **Initial Criteria:** *Approval Duration = 6 months*
  - The member must meet criteria as outlined in prescribing information (PI) including recommendations for diagnosis and age.

- The prescriber is a specialist, or the prescriber has consulted with a specialist in sleep disorders
- The member must have had a 30-day trial of Rozerem (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.

- **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).

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ROZEREM (ramelteon) – *Brand Required*	HETLIOZ (tasimelteon)
	ramelteon

Pulmonology

Asthma/COPD

Therapeutic Duplication

- One medication from each class is allowed at time (nebulizers and inhalers are not payable together)
  - One inhaled steroid
  - Long-acting anticholinergic
  - Leukotriene pathway inhibitor
  - One long-acting beta agonist
  - One short acting beta agonist
    - 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.
    - **Please call for an override** if any of the following circumstances apply by calling provider relations at 1-800-755-2604:
      - Maximally treated members (compliance with inhaled steroid, long-acting beta agonist, long-acting muscarinic antagonist, and Daliresp) with end-stage COPD will be allowed an ongoing override
      - Acutely ill children will be allowed a one-time override
      - Members with cystic fibrosis will be allowed an ongoing override
- Anticholinergic medications are not covered with Acetylcholinesterase Inhibitors (Aricept, Exelon, Razadyne, 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.

Concurrent Medication and Step Care

- Daliresp
  - A total of 90 days of an inhaled short or long-acting anticholinergic must be paid within 110 days prior to Daliresp's date of service.
    - According to the Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines, Daliresp is a recommended add-on therapy to members experiencing exacerbations while on antimuscarinic therapy.

Albuterol/ Levalbuterol Rescue Inhalers

References:

2. Albuterol Overuse: A Marker of Psychological Distress? Joe K. Gerald, Tara F. Carr, Christine Y. Wei, Janet T. Holbrook, Lynn B. Gerald. J Allergy Clin Immunol Pract. 2015 Nov-Dec; 3(6): 957–962. Published online 2015 Sep 1. doi: 10.1016/j.jaip.2015.06.021. PMCID: PMC4641773
3. Global Initiative for Asthma. Global strategy for asthma management and prevention. 2019 GINA Main Report. Available from: www.ginasthma.org. (Accessed February 5, 2020)
4. 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 Healrth, Lung, and Blood Institute (US); 2007 Aug. Available from: https://www.ncbi.nlm.nih.gov/books/NBK7232

5. High-Dose Albuterol by Metered-Dose Inhaler Plus a Spacer Device Versus Nebulization in Preschool Children With Recurrent Wheezing: A Double-Blind, Randomized Equivalence Trial Dominique Ploin, François R. Chapuis, Didier Stamm, Jacques Robert, Louis David, Pierre G. Chatelain, Guy Dutau and Daniel Floret Pediatrics. August 2000, 106 (2) 311-317; DOI: https://doi.org/10.1542/peds.106.2.311

Concurrent Medication and Step Care

- Ventolin HFA
  - A total of 30 days of steroid inhaler must be paid within 40 days prior to Ventolin HFA or ProAir Respiclick's date of service. The quantity limit for ProAir HFA is set to 2 canisters per 6 months (2 puffs per day). If more is needed, member must switch to Ventolin HFA and be on a steroid inhaler to control asthma.
    - According to the GINA guidelines:
      - A low dose ICS should be taken whenever SABA taken for step 1 control of asthma.
      - Dispensing ≥ 3 canisters per year is associated with higher risk of emergency department presentations
      - Dispensing ≥ 12 canisters per year is associated with higher risk of death
  - **Please call for an override:** if the following circumstance applies by calling provider relations at 1-800-755-2604:
    - If primary insurance will only pay for Ventolin HFA or ProAir Respiclick and member is well-controlled without steroid inhaler (i.e., uses less than 2 canisters per 6 months).
- Xopenex HFA
  - A total of 30 days of albuterol HFA must be paid within 180 days prior to Xopenex HFA's date of service

Prior Authorization

General Prior Authorization Form
MedWatch Form

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
PROAIR (albuterol) HFA – *Brand Required*	albuterol HFA
PROAIR RESPICLICK (albuterol)	levalbuterol HFA
VENTOLIN (albuterol) HFA– *Brand Required*	PROAIR (albuterol) DIGIHALER
	PROVENTIL (albuterol) HFA
	XOPENEX (levalbuterol) HFA

Anticholinergics/Beta Agonists Combinations

General Prior Authorization Form

Non-Preferred Agents Criteria:

- The member must have an FDA-approved indication for use (meets label recommendations for diagnosis and age).
- The member must have had a 30-day trial of 2 preferred, combination anticholinergic/long-acting beta agonist products, as evidenced by paid claims or pharmacy printouts.

Product Specific Criteria:

- **Duaklir Pressair:**
  - The member must have had 30-day trials of Bevespi Aerosphere, 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).

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
albuterol/ipratropium	BEVESPI AEROSPHERE (glycopyrrolate/formoterol)
ANORO ELLIPTA (umeclidinium/vilanterol)	DUAKLIR PRESSAIR (aclidinium/formoterol)***
COMBIVENT RESPIMAT (albuterol/ipratropium)	DUONEB (albuterol/ipratropium)
STIOLTO RESPIMAT (tiotropium/olodaterol)	

Biologics

General Prior Authorization Form

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

- The member must meet label recommendations for indication and age.
- Must be prescribed by, or in consult with, a pulmonologist or allergist/immunologist

- The member must have had at least 1 asthma exacerbation requiring use of oral corticosteroids in previous year despite continued compliant use of a moderate to high dose inhaled steroid in combination with a long-acting beta agonist (LABA) and long-acting muscarinic antagonist (LAMA) as evidenced by paid claims or pharmacy printouts

Category Criteria (Renewal): *Approval Duration = 12 months*

- The prescriber must provide documentation showing that the member has achieved a significant reduction in asthma exacerbations and utilization of rescue medications since treatment initiation

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

Corticosteroids - Inhaled

Electronic Duration Verification:

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

Prior Authorization

General Prior Authorization Form

Non-Preferred Agents Criteria:

- The member must have had a 30-day trial of each preferred inhaler of a unique active ingredient, as evidenced by paid claims or pharmacy printouts.

Product Specific Criteria:

- **Alvesco, Armonair Digihaler**:
  - Member must have had 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).

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

Long-Acting Anticholinergics

Electronic Diagnosis Verification

- Spiriva Respimat 1.25mg: Member must have a diagnosis of asthma
- All other long-acting anticholinergics must have a diagnosis of COPD

Concurrent Medication and Step Care

- Spiriva Respimat 1.25mg
  - A total of 30 days of a long-acting beta agonist (in combination or alone) must be paid within 40 days prior to Spiriva Respimat 1.25mg's date

Prior Authorization Criteria

General Prior Authorization Form

Non-Preferred Agents Criteria:

- The member must have an FDA-approved indication for use (meets label recommendations for diagnosis and age).
- The member must have had a 30-day trial of at least 2 preferred long-acting anticholinergic agents, as evidenced by paid claims or pharmacy printouts.
  - Either single ingredient or combination products will count toward trials.

Product Specific Criteria:

- ***Lonhala Magnair**:
  - The member must have had a 30-day trial of Yupelri, as evidenced by paid claims or pharmacy printouts.
  - Clinical justification must be provided explaining why the member is unable to use the preferred products (subject to clinical review).

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

INCRUSE ELLIPTA (umeclidinium)	LONHALA MAGNAIR (glycopyrrolate)***
SPIRIVA HANDIHALER (tiotropium)	TUDORZA PRESSAIR (aclidinium)
SPIRIVA RESPIMAT 2.5 MCG (tiotropium)	YUPELRI (revefenacin)

Long-Acting Beta Agonists

General Prior Authorization Form

Group Criteria:

- **Generic non-preferred agents:** The member must have had a 10-day trial of a pharmaceutically equivalent preferred agent, as evidenced by paid claims or pharmacy printouts.

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
BROVANA (arformoterol) – *Brand Required*	arformoterol
PERFOROMIST (formoterol) – *Brand Required*	formoterol
SEREVENT DISKUS (salmeterol)	
STRIVERDI RESPIMAT (olodaterol)	

Steroid/Long-Acting Beta Agonist (LABA) Combination Inhalers

General Prior Authorization Form

Non-Preferred Agents Criteria:

- The member must have had 30-day trials of each preferred agent, as evidenced by paid claims or pharmacy printouts
- The member must have a diagnosis of an FDA-approved indication for use and meet the criteria for that diagnosis
    - **For COPD diagnosis:**
        A. The member must currently be taking a long acting antimuscarinic agent
    - **For asthma diagnosis:**
        - The member must have been reviewed for step down therapy for all renewal requests.

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

Steroid/Anticholinergics/Long-Acting Beta Agonists Combinations

General Prior Authorization Form

Group Criteria:

- The member must have an FDA-approved indication for use (meets label recommendations for diagnosis and age).
- **For COPD diagnosis:** the member must have had two 30-day trials of each of the following (either in combination or as single agents) as part of a maximized triple therapy, as evidenced by paid claims or pharmacy printouts:
    1. Long-Acting Anticholinergics
    2. Long-Acting Beta Agonist
    3. Inhaled Steroid
- **For asthma diagnosis:** the member must have had at least two 30-day trials of each of the following (either in combination or as single agents) in addition to Spiriva Respimat 1.25mg inhaler as part of a maximized triple therapy, as evidenced by paid claims or pharmacy printouts:
    1. Long-Acting Beta Agonist
    2. Inhaled Steroid

Non-Preferred Agents Criteria:

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

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
TRELEGY ELLIPTA (fluticasone/umeclidinium/vilanterol)	BREZTRI AEROSPHERE (budesonide/glycopyrrolate/formoterol)

Cystic Fibrosis

Cystic Fibrosis - Inhaled Antibiotics

General Prior Authorization Form

Product Specific Criteria:

- ***Tobi Podhaler:**
  - The member must have an FDA-approved indication for use (meets label recommendations for diagnosis and age).
  - The member must have had a 28-day trial of a preferred nebulized product, as evidenced by paid claims or pharmacy printouts.
- ***Cayston:**
  - The member must be colonized with *Pseudomonas aeruginosa.*
  - The member must have had a 28-day trial of TOBI Podhaler, as evidenced by paid claims or pharmacy printouts.
- ***Arikayce:**
  - 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.

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
BETHKIS (tobramycin)	ARIKAYCE (amikacin/nebulizer) ***
KITABIS PAK (tobramycin/nebulizer) - *Brand Required*	CAYSTON (aztreonam)***
TOBI PODHALER (tobramycin) PA***	TOBI (tobramycin) in 0.225% sodium chloride
tobramycin in 0.225% sodium chloride	tobramycin/nebulizer

Cystic Fibrosis – CFTR Modulators

General Prior Authorization Form

Group Criteria: *Approval Duration = 12 months*

- The member must have an FDA-approved indication for use (meets label recommendations for diagnosis and age).
- 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

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
KALYDECO (ivacaftor)	
ORKAMBI (lumacaftor/ivacaftor)	
SYMDEKO (tezacaftor/ivacaftor)	
TRIKAFTA (elexacaftor/tezacaftor/ivacaftor)	

Cystic Fibrosis – Osmotic Agent

Electronic Diagnosis Verification

- The member must have an FDA-approved indication for use

Electronic Age Verification

- The member must be 18 years or older

Prior Authorization

- Documentation of the Bronchitol Tolerance Test must be submitted

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
BRONCHITOL (Mannitol) INHALER	

Idiopathic Pulmonary Fibrosis / Interstitial Lung Disease

General Prior Authorization Form

Category Criteria:

- The member must have an FDA-approved indication for use (meets label recommendations for diagnosis and age).
- The prescriber must be, 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.

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ACTEMRA (tocilizumab)	
ESBRIET (pirfenidone)	
OFEV (nintedanib)	

Rheumatology

Biologics

Electronic Diagnosis Verification

- The member must have an FDA-approved indication for use

Prior Authorization

General Prior Authorization Form

Product Specific Criteria:

- Anti-interleukin (IL)17 antibodies:
  - The member must have a 3-month trial of an Anti-TNF inhibitor, as evidenced by paid claims or pharmacy printouts

Non-Preferred Agents Criteria:

- The member must have had a 3-month trial of a preferred agent from each class approved for patient's diagnosis, as evidenced by paid claims or pharmacy printouts.

ANKYLOSING SPONDYLITIS	
PREFERRED AGENTS (NO PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**
Anti-TNF Inhibitors	
ENBREL (etanercept)	CIMZIA (certolizumab)
HUMIRA (adalimumab)	SIMPONI (golimumab)
PREFERRED AGENTS (CLINICAL PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**
Anti–interleukin (IL) 17 Antibodies	
TALTZ (ixekizumab)***	COSENTYX (secukinumab)
BEHCET'S SYNDROME	
PREFERRED AGENTS (NO PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**
Anti-TNF Inhibitors	
HUMIRA (adalimumab)	
Phosphodiesterase 4 (PDE4) Inhibitor	
OTEZLA (apremilast)	
GIANT CELL ARTERITIS (TEMPORAL ARTERITIS)	
PREFERRED AGENTS (PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**
Anti-Interleukin-6 (IL-6) Receptor Inhibitors	
ACTEMRA (tocilizumab)	
JUVENILE IDIOPAHIC ARTHRITIS	
PREFERRED AGENTS (NO PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**
Anti-TNF Inhibitors	
ENBREL (etanercept)	
HUMIRA (adalimumab)	
NON-RADIOGRAPHIC AXIAL SPONDYLARTHRITIS	
PREFERRED AGENTS (NO PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**
Anti-TNF Inhibitors	
HUMIRA (adalimumab)	CIMZIA (certolizumab)
PREFERRED AGENTS (CLINICAL PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**
Anti–interleukin (IL) 17 Antibodies	
TALTZ (ixekizumab)***	COSENTYX (secukinumab)
POLYARTICULAR COURSE JUVENILE IDIOPATHIC ARTHRITIS	
PREFERRED AGENTS (NO PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**

Anti-Interleukin-6 (IL-6) Receptor Inhibitors	
	ACTEMRA (tocilizumab)
Cytotoxic T Lymphocyte Antigen Immunoglobulin (CTLA-4 Ig)	
	ORENCIA (abatacept)
Janus Kinase (JAK) Inhibitors	
XELJANZ (tofacitinib)	
XELJANZ (tofacitinib) ORAL SOLUTION	
XELJANZ XR (tofacitinib)	
PSORIATIC ARTHRITIS	
PREFERRED AGENTS (NO PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**
Anti-TNF Inhibitors	
ENBREL (etanercept)	CIMZIA (certolizumab)
HUMIRA (adalimumab)	SIMPONI (golimumab)
Phosphodiesterase 4 (PDE4) Inhibitor	
OTEZLA (apremilast)	
Janus Kinase (JAK) Inhibitors	
XELJANZ (tofacitinib)	XELJANZ XR (tofacitinib)
Cytotoxic T Lymphocyte Antigen Immunoglobulin (CTLA-4 Ig)	
	ORENCIA (abatacept)
Anti – Interleukin (IL) 23 Antibodies	
	STELARA (ustekinumab)
	TREMFYA (guselkumab)
PREFERRED AGENTS (CLINICAL PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**
Anti – Interleukin (IL) 17 Antibodies	
TALTZ (ixekizumab)***	COSENTYX (secukinumab)
RHEUMATOID ARTHRITIS	
PREFERRED AGENTS (NO PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**
Anti-TNF Inhibitors	
ENBREL (etanercept)	CIMZIA (certolizumab)
HUMIRA (adalimumab)	SIMPONI (golimumab)
Janus Kinase (JAK) Inhibitors	
XELJANZ (tofacitinib)	OLUMIANT (baricitinib)
	RINVOQ (upadacitinib)
	XELJANZ XR (tofacitinib)
Anti-Interleukin-1 (IL-1) Receptor Inhibitors	
KINERET (anakinra)	
Anti – Interleukin 17 (IL) 17 Antibodies	
	COSENTYX (secukinumab)
Anti-Interleukin-6 (IL-6) Receptor Inhibitors	
	ACTEMRA (tocilizumab)
	KEVZARA (sarilumab)
Cytotoxic T Lymphocyte Antigen Immunoglobulin (CTLA-4 Ig)	
	ORENCIA (abatacept)
SYSTEMIC ONSET JUVENILE CHRONIC ARTHRITIS	
PREFERRED AGENTS (NO PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**
Anti-Interleukin-6 (IL-6) Receptor Inhibitors	
ACTEMRA (tocilizumab)	

Osteoporosis

Electronic Diagnosis Verification

- Risedronate 30mg requires FDA indication of Paget's Disease of the bone and is not indicated for osteoporosis

Oral Bisphosphonates

Prior Authorization Form - Osteoporosis

- 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

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
alendronate	ACTONEL (risedronate)
alendronate oral solution	ATELVIA (risedronate DR)
ibandronate	FOSAMAX (alendronate)
risedronate IR	risedronate DR

Non-Oral Bisphosphonates

Prior Authorization Form - Osteoporosis

Non-Preferred Agents Criteria (Initial): *Approval Duration = 2 years*

- The member must have an FDA-approved indication for use (meets label recommendations for diagnosis and age).
- 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

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
calcitonin, salmon nasal spray	EVISTA (raloxifene)
MIACALCIN (calcitonin, salmon)	FORTEO (teriparatide)
raloxifene	TYMLOS (abaloparatide)
teriparatide	

Substance Use

Nicotine / Tobacco Dependence Treatment

Concurrent Medication and Step Care

- A total of 14 days of Nicotine patch, Chantix, or Zyban must be paid within 40 days prior to Nicotrol Nasal Spray, nicotine lozenge, nicotrol inhaler, or nicotine gum's date of service.
    - Better outcomes are associated with concurrent use of short acting and long-acting tobacco cessation products.
- A total of 14 days of Nicotine patch, gum, lozenge, inhaler, or spray must be paid within 40 days prior to Zyban's date of service.
    - Better outcomes are associated with concurrent use of short acting and long-acting tobacco cessation products. Nicotine products can help bridge treatment until Zyban becomes effective.

Electronic Duration Verification

- A total of 12 consecutive weeks will be covered for all other products, every 6 months
    - Chantix:
      Please call for an override if the following conditions apply by calling provider relations at 1-800-755-2604:
        - Patent is abstinent from tobacco
        - Treatment duration is requested to be extended to 24 consecutive weeks

Therapeutic Duplication

- nicotine gum, lozenge, inhaler, and spray will not be paid concurrently

- Zyban will not be paid with other forms of bupropion

Underutilization

- Nicotine Patch, Chantix, and Bupropion must be used compliantly and will reject on point of sale for late fill

Prior Authorization Criteria

General Prior Authorization Form

Non-Preferred Agents Criteria:

- **Branded non-preferred agents:** The member must have had a 30-day trial of each pharmaceutically equivalent preferred agent, as evidenced by paid claims or pharmacy printouts.

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
bupropion SR	NICODERM CQ (nicotine) PATCH
CHANTIX (varenicline)	NICORETTE (nicotine polacrilex) GUM
nicotine lozenge	ZYBAN (bupropion SR)
nicotine patch	
nicotine polarcrilex gum	
NICOTROL (nicotine polacrilex) INHALER	
NICOTROL (nicotine polacrilex) SPRAY	

Opioid Dependence Treatment

Lucemyra

General Prior Authorization Form

Group Criteria:

- The member must have a diagnosis of an FDA-approved indication for use
- 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)

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
clonidine	LUCEMYRA (lofexidine)
guanfacine	

Opioid Antagonist

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
VIVITROL (Naltrexone Microspheres)	

Naloxone Rescue Medications

Please call for an override by calling provider relations at 1-800-755-2604:
The following information will need to be submitted as a follow up for the override by either emailing medicaidpharmacy@nd.gov or documenting on General Prior Authorization Form:

- The provider must attest that it is known that the previous dose was taken by the member (and not diverted or given to another member)
- One of the following criteria must be met (A, B, or C)
    A. The previous dose has expired
    B. The dose was used by member for illicit drug use
    C. The member is currently taking opioids and meets one of the following criteria:
        - The opioid dose must have been decreased
        - The provider has provided medical justification why the opioid dose as not been Decreased

Non-Preferred Agents Criteria:

- The provider has provided medical justification explaining why the member cannot use Narcan Nasal Spray or injectable naloxone.

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
KLOXXADO (naloxone) NASAL SPRAY	
Naloxone injection	
NARCAN (naloxone) NASAL SPRAY	

Opioid Partial Agonist

Therapeutic Duplication

- One strength of one medication is allowed at a time
- Opioid Partial Agonists are not allowed with:
  - Methadone
  - Carisoprodol
  - Opioid Analgesics
    - **For an override,** please call provider relations at 1-800-755-2604 if all the following circumstances apply:
      - The member has an acute condition that cannot be reasonably treated with non-opioid therapy (e.g. surgery)
      - Prescribers of both opioid and opioid use disorder are aware of each other and agree to opioid therapy
      - Opioid duration is of a one-time occurrence or taper plan is provided

Underutilization

- Buprenorphine and buprenorphine/naloxone must be used compliantly and will reject on point of sale for late fill
- To request an override, submit a Opioid Dependence Underutilization Form. Both the 1st and 2nd pages must be filled out.

Prior Authorization Criteria

General Prior Authorization Form

Product Specific Criteria:

- *** **Buprenorphine tablets**: The member must be pregnant or breastfeeding, and estimated delivery date/duration of need for breastfeeding must be provided.

Non-Preferred Agents Criteria:

- The member must have had a 30-day trial of buprenorphine-naloxone SL tablets, 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).
- A MedWatch form for each trial of each product from the available manufacturer(s) must be filled out and attached to request
- DAW (Dispense As Written) Criteria must be met in addition to Opioid Partial Agonist Group PA Criteria.

Oral Agents

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
buprenorphine-naloxone tablets	BUNAVAIL FILM (buprenorphine/naloxone)
buprenorphine tablets[PA***]	buprenorphine/naloxone film
	SUBOXONE FILM (buprenorphine/naloxone)
	ZUBSOLV (buprenorphine/naloxone)

Non-Oral Agents

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
SUBLOCADE (buprenorphine)	

Obstetrics/Gynecology

Estrogens

General Prior Authorization Form

Non-Preferred Agents Criteria:

- The member must have an FDA approved or compendia supported indication
- The member must have failed 30-day trials of at least two preferred products, as evidenced by paid claims or pharmacy printouts.

Injectable

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
DELESTROGEN (estradiol valerate) INJECTION – *Brand Preferred*	DEPO-ESTRADIOL (estradiol cypionate) INJECTION
PREMARIN (estrogens, conjugated) INJECTION	estradiol valerate 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
FEMHRT (norethindrone-ethyl estradiol) TABLET	BIJUVA (estradiol-progesterone) CAPSULE
norethindrone-ethinyl estradiol tablet	ESTRACE (estradiol) TABLET
PREMARIN (estrogens, conjugated) TABLET	FYAVOLV (norethindrone-ethinyl estradiol) TABLET
PREMPHASE (estrogen, conj.,m-progest) TABLET	JINTELI (norethindrone-ethinyl estradiol) TABLET
PREMPRO (estrogen, conj.,m-progest) TABLET	LOPREEZA (estradiol-norgestimate) TABLET
	MENEST (estrogens, esterified) TABLET
	MIMVEY (estradiol-norgestimate) TABLET
	PREFEST (estradiol-norgestimate) TABLET

Topical Cream/Gel/Spray

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ELESTRIN (estradiol) GEL	DIVIGEL (estradiol) GEL
EVAMIST (estradiol) SPRAY	

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	DOTTI (estradiol) PATCH TWICE WEEKLY
COMBIPATCH (estradiol- norethindrone)	estradiol patch twice weekly
MENOSTAR (estradiol) PATCH	estradiol patch weekly
MINIVELLE (estradiol) PATCH TWICE WEEKLY - *Brand Required*	LYLLANA (estradiol) PATCH
VIVELLE-DOT (estradiol) PATCH TWICE WEEKLY - *Brand Required*	

Vaginal

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ESTRING (estradiol)	ESTRACE (estradiol) CREAM
FEMRING (estradiol)	estradiol vaginal cream
PREMARIN (estrogens, conjugated) VAGINAL CREAM	estradiol vaginal tablet
VAGIFEM (estradiol) VAGINAL TABLET – *Brand Required*	YUVAFEM (estradiol) VAGINAL TABLET

Mifepristone

Prior Authorization Form - Mifeprex

Criteria for coverage: *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. The provider has provided a signed written statement indicating that the rape or act of incest has been reported to the appropriate law enforcement agency, or in the case of a minor who is a victim of incest, to an agency authorized to receive child abuse and neglect reports. The statement must indicate to whom the report was made.
        - II. The provider has provided written statement signed by the recipient and the provider that the recipient's pregnancy resulted from rape or incest and by professional judgement, the provider agrees with the woman's statement.
    - B. **Both of the following must be met (I and II)**
        - I. The woman 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 woman in danger of death unless an abortion is performed
        - II. The provider must provide a signed written statement indicating why, in the provider's professional judgement, the life of a woman would be endangered if the fetus were carried to term

Nausea/Vomiting

Pregnancy

General Prior Authorization Form

Non-Preferred Agents Criteria: *Approval Duration = 3 months or until due date*

- Member must have diagnosis of nausea and vomiting of pregnancy
- 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)

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	

Uterine Fibroids

Electronic Diagnosis Verification

- The member must have an FDA approved indication

Electronic Age Verification

- The member must be 18 years of age or older

Prior Authorization Form

General Prior Authorization Form

Group Criteria:

- **Initial Criteria:** *Approval Duration = 12 months*
  - The member must have an FDA-approved indication for use (meets label recommendations for diagnosis and age)
  - The member must not be pregnant
  - The provider must attest that the member does not have any contraindications to treatment with Oriahnn
- The member must have failed the following trials (A and B), as evidenced by paid claims or pharmacy printouts (may be concurrent use):
  - A. A 3-menstual cycle trial of mefenamic acid or meclofenamate, celecoxib, ibuprofen 1800mg/day or equivalent high dose NSAID
  - B. A 3-menstual cycle trial of an oral estrogen-progestin or progestin contraceptives
- **Renewal Criteria:** *Approval Duration = 12 months*
  - The member must not have received ≥24 months of Oriahnn, as evidenced by paid claims or pharmacy printouts
  - The provider must attest that the member does not have any contraindications to treatment with Oriahnn
  - The member must have experienced and maintained clinical benefit since starting treatment with Oriahnn, as evidenced by medical documentation (e.g. chart notes) attached to the request (subject to clinical review)

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
MYFEMBREE (relugolix, estradiol, and norethindrone acetate)	
ORIAHNN (elagolix, estradiol, and norethindrone acetate)	

Orilissa

General Prior Authorization Form

Initial Criteria: *Approval Duration = 6 months*

- The member must have an FDA-approved indication for use (meets label recommendations for diagnosis and age)
- The member must have failed the following trials (A and B), as evidenced by paid claims or pharmacy printouts:
  - A. A 3-menstual cycle trial of mefenamic acid or meclofenamate, celecoxib, ibuprofen 1800mg/day or equivalent high dose NSAID
  - B. A 3-menstual cycle trial of an oral estrogen-progestin or progestin contraceptives

Renewal Criteria: *Approval Duration = 18 months*

- Prescriber must submit documentation of improvement in pain score from baseline

- Request must be for maintenance dosing (150 mg strength).

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

Progesterone

Prior Authorization Form - Makena

Category Criteria:

- The member must have an FDA-approved indication for use (meets label recommendations for diagnosis and age).
- The week of pregnancy and due date must be indicated on request (must be 20 weeks or greater).
- Clinical justification must be provided explaining why medication is medically necessary

Non-Preferred Agents Criteria:

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

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
MAKENA (hydroxyprogesterone caproate) – *Brand Required*	hydroxyprogesterone caproate

Vaginal Anti-Infectives

General Prior Authorization Form

Non-Preferred Agents Criteria:

- The member must have an FDA-approved indication for use (meets label recommendations for diagnosis and age).
- The member must have had 30-day trials of 3 preferred vaginal anti-infective agents, as evidenced by paid claims or pharmacy printouts.

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AVC (sulfanilamide)	clindamycin cream
CLEOCIN (clindamycin) SUPPOSITORY	CLEOCIN (clindamycin) CREAM
CLINDESSE (clindamycin) CREAM	GYNAZOLE 1 (butoconazole) CREAM
clotrimazole	METROGEL-VAGINAL (metronidazole)
metronidazole gel	MICONAZOLE 3 (miconazole) SUPPOSITORY
NUVESSA (metronidazole) GEL	terconazole suppository
SOLOSEC (secnidazole)	VANDAZOLE (metronidazole) GEL
terconazole cream	
tinidazole	

Preferred Dosage Forms List:

General Prior Authorization Form

Criteria for coverage:

- Clinical justification must be provided explaining why the member is unable to use the preferred agents (subject to clinical review).
- The member must have a diagnosis of an FDA-approved indication for use
- The member must not have any contraindication to the requested product
- The member must have failed* a therapeutic course** of each preferred agent (listed in boxes below) within the past 2 years, as evidenced by paid claims or pharmacy printouts.

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

***: Trials must have been at least 30 days in duration unless otherwise indicated*

Amoxicillin ER

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
amoxicillin IR	amoxicillin ER

Antihistamines

Therapeutic Duplication

- One strength of one medication is allowed at a time

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
cetirizine chew tablet	desloratadine ODT
cetirizine Solution	levocetirizine solution
cetirizine tablet	
desloratadine tablet	
levocetirizine tablet	
loratadine solution	
loratadine tablet	

Bactroban

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
Bactroban ointment	Bactroban cream

Belladonna Alkaloids/Phenobarbital

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
belladonna alkaloids/phenobarbital tablets	belladonna alkaloids/phenobarbital elixir

Bowel Prep Agents

Required trial duration: 1 complete dose

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
GAVILYTE-G	CLENPIQ
GOLYTELY 227.1-21.5	COLYTE
MOVIPREP	GOLYTELY 236-22.74G
OSMOPREP	GAVILYTE-C
PEG-3350 AND ELECTROLYTES 236-22.74G	GAVILYTE-N
	NULYTELY
	PEG 3350-ELECTROLYTE 240-22.72G
	PEG 3350-ELECTROLYTE 420 G
	PEG 3350/SOD SUL/NACL/KCL/ASB/C
	PLENVU
	SUPREP
	SUTAB
	TRILYTE

Brisdelle (paroxetine)

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
paroxetine tablets	paroxetine mesylate 7.5mg capsules

butalbital-acetaminophen-caffeine

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
butalbital-acetaminophen-caffeine tablets	butalbital-acetaminophen-caffeine capsules
	ESGIC (butalbital-acetaminophen-caffeine) CAPSULES
	VANATOL LQ (butalbital-acetaminophen-caffeine) SOLUTION
	VANATOL S (butalbital-acetaminophen-caffeine) SOLUTION
	ZEBUTAL (butalbital-acetaminophen-caffeine) CAPSULES

cyanacobalamin

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
cyanocobalamin Injection	NASCOBAL (cyanocobalamin) NASAL SPRAY

Daxbia (cephalexin)

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
cephalexin	Daxbia (cephalexin)

gabapentin

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
gabapentin	GRALISE (gabapentin)
gabapentin	HORIZANT (gabapentin)
pramipexole	
ropinirole	

Jadenu (deferasirox)

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
deferasirox tablet for suspension	EXJADE (deferasirox tablet for suspension)
	deferasirox tablets
	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)
	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)
	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)
	QUTENZA (capsaicin/skin cleanser)
	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)

metformin

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
Metformin ER	FORTAMET (metformin)
	GLUMETZA (metformin)
	RIOMET (metformin) ORAL SOLUTION
	RIOMET ER (metformin) ORAL SOLUTION

methotrexate

Required trial duration: 6 weeks

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
methotrexate	OTREXUP (methotrexate)
	RASUVO (methotrexate)
	REDITREX (methotrexate)
	TREXALL (methotrexate)

montelukast

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
montelukast chewable tablets	montelukast granules
montelukast tablets	

mupirocin

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
mupirocin Ointment	mupirocin calcium cream

nitroglycerin spray

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)

Onmel (itraconazole)

Required trial duration: 12 weeks with 6 months outgrow following treatment for onychomycosis

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
Itraconazole capsule	ONMEL (itraconazole) TABLET
terbinafine	

penicillamine

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

DEPEN (penicillamine) TITRATAB – *Brand Required*	CUPRIMINE (penicillamine) CAPSULE
	penicillamine capsule
	penicillamine tablet

potassium

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
potassium tablets	potassium solution
	potassium powder for solution

Procysbi (cysteamine)

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
CYSTAGON (cysteamine)	PROCYSBI (cysteamine)
	PROCYSBI GRANULES (cysteamine)

Siklos (hydroxyurea)

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
DROXIA (hydroxyurea capsule)	SIKLOS (hydroxyurea tablet)
hydroxyurea capsule	

Steroids - Oral

Additional Criteria for coverage of Emflaza: See Emflaza Criteria on this document
Rayos required trial duration: 12 weeks with 2AM dosing of prednisone

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
budesonide 3mg EC capsules	ALKINDI (hydrocortisone) SPRINKLE CAPSULE
cortisone	budesonide 9 mg ER tablet
dexamethasone	DEXPAK (dexamethasone)
hydrocortisone	DXEVO (dexamethasone)
methylprednisone	EMFLAZA (deflazacort)
prednisolone sodium phosphate 5mg/5ml, 15mg/5ml, 25mg/5ml	HEMADY (dexamethasone)
prednisone solution	MILLIPRED (prednisolone)
prednisone tablets	ORTIKOS (budesonide)
	prednisone intensol
	prednisolone sodium phosphate ODT
	prednisolone sodium phosphate 10mg/5ml, 20mg/5ml solution
	RAYOS (prednisone)
	TAPERDEX (dexamethasone)
	UCERIS (budesonide)

tacrolimus

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
tacrolimus	ASTAGRAF XL (tacrolimus)
	ENVARSUS ER (tacrolimus)

Tiglutik (riluzole)

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
riluzole	RILUTEK (riluzole)
	TIGLUTIK (riluzole) ORAL SUSPENSION

Tirosint (levothyroxine)

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
levothyroxine tablet	levothyroxine capsules
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
	THYQUIDITY (levothyroxine) ORAL SOLUTION
	TIROSINT (levothyroxine) 175 mcg and 200 mcg capsule

	TIROSINT (levothyroxine) solution

Tussicaps

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
hydrocodone/chlorpheniramine ER suspension	TUSSICAPS (hydrocodone/chlorpheniramine)
promethazine/codeine	
ZODRYL AC (chlorpheniramine/codeine)	

ursodiol

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ursodiol capsule	RELTONE (ursodiol) CAPSULE
ursodiol tablet	URSO 250 (ursodiol) TABLET
	URSODIOL AVPAK (ursodiol) CAPSULE
	URSO FORTE (ursodiol) TABLET

General
Prior Authorization Form

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

Prior Authorization Vendor for ND

ND Medicaid requires members to meet specific diagnosis and step-therapy requirements for some medications. Criteria for agents requiring prior authorization can be found at the following location:

- The Preferred Drug List (PDL) is available at www.hidesigns.com/assets/files/ndmedicaid/NDPDL.pdf
- ***Completed Medwatch form(s) must be attached to this request for failed trial(s) in which the active ingredient of the failed product is the same as the requested product***

Part I: TO BE COMPLETED BY PRESCRIBER

Member Name		Member Date of Birth	Member Medicaid ID Number
Prescriber Name		Specialist involved in therapy (if not treating prescriber)	
Prescriber NPI		Telephone Number	Fax Number
Member Weight	Member Adjusted Weight	BMI	**Reason for PA request:**
Requested Drug and Dosage:		**Diagnosis for this request:**	
List all failed medications:		**Start Date:**	**End Date:**

Additional Qualifications for Coverage:

☐ Member is pregnant: Due Date

☐ Member has primary insurance requiring requested product

☐ Member is unable to use preferred dosage form (please provide medical justification below– e.g. contraindication, feeding tube, permanent disability, temporary restriction, swallow study, etc.)

☐ Other: (please fill out below)

☐ *I confirm that I have considered a generic or other alternative and that the requested drug is expected to result in the successful medical management of the recipient.*

Prescriber (or Staff) / Pharmacy Signature**	Date

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

Part II: TO BE COMPLETED BY PHARMACY

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

Benzodiazepine + Opioid Concurrent Use Prior Authorization Form

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

Prior Authorization Vendor for ND

ND Medicaid requires that members receiving both an opioid analgesic and a benzodiazepine must meet the following criteria:

-Member must have tried all treatment alternatives without achievement of therapeutic goal (please provide details on trial and outcome, or reason alternative cannot be attempted)

- Either a tapering plan must be included, or given the CDC guidelines and FDA black box warnings, clinical justification must be provided to explain:
  - Reason opioid analgesic cannot be avoided in this member currently receiving a benzodiazepine
  - Reason the member cannot use lower dose opioid treatment

Part I: TO BE COMPLETED BY PRESCRIBER OF THE OPIOID ANALGESIC

Recipient Name	Recipient Date of Birth	Recipient Medicaid ID Number
Prescriber Name	Pain, Palliative Care, or Oncology/Hematology Specialist involved in therapy (if not treating prescriber)	
Prescriber NPI	Telephone Number	Fax Number
Requested Opioid Analgesic:	**Diagnosis for use of opioid(s) in this member:**	
Plan to taper: (dose and length of treatment)	**Clinical justification for concurrent opioid and benzodiazepine treatment and/or reason opioid dose cannot be reduced:**	
Treatment Alternatives: ☐ NSAIDs ☐ TCAs ☐ SNRIs ☐ Corticosteroids ☐ Weight Loss ☐ Physical Therapy ☐ Cognitive Behavioral Therapy ☐ Other	**Start/End Date:**	**Reason for failure:**

Qualifications for coverage:

Does provider routinely check the PDMP?	☐ YES ☐NO
Has the provider established a realistic treatment plan with the member, addressing expected outcomes and limitations of therapy in totally eliminating pain?	☐ YES ☐NO
Will opioid therapy be routinely evaluated for effectiveness?	☐ YES ☐NO
Does the patient undergo routine drug screens?	☐ YES ☐NO
Has the provider discussed and counseled the patient on the known risks of utilizing opioid analgesics in combination with benzodiazepines and other CNS depressing medications/conditions?	☐ YES ☐NO

Please confirm that all the following is attached to the request, along with any other relevant documentation:

☐ Patient's treatment/tapering plan including an evaluation of effectiveness and plans for continuation/discontinuation
☐ Clinical documentation of previously tried and failed non-opioid therapies.

Prescriber (or Staff) / Pharmacy Signature**	Date

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

Benzodiazepine + Opioid Concurrent Use Prior Authorization Form

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

Prior Authorization Vendor for ND

ND Medicaid requires that members receiving both an opioid analgesic and a benzodiazepine must meet the following criteria:

- Member must have tried all treatment alternatives without achievement of therapeutic goal (please provide details on trial and outcome, or reason alternative cannot be attempted)
- Either a tapering plan must be included, or given the CDC guidelines and FDA black box warnings, clinical justification must be provided to explain:
  - Reason opioid analgesic cannot be avoided in this patient currently receiving a benzodiazepine
  - Reason the member cannot use lower dose opioid treatment

Part I: TO BE COMPLETED BY PRESCRIBER OF THE BENZODIAZEPINE

Recipient Name	Recipient Date of Birth	Recipient Medicaid ID Number
Prescriber Name	Specialist involved in therapy (if not treating prescriber)	
Prescriber NPI	Telephone Number	Fax Number
Requested Benzodiazepine:	**Diagnosis for use of a benzodiazepine in this member:**	
Plan to taper: (dose and length of treatment)	**Clinical justification for concurrent opioid and benzodiazepine treatment and/or reason opioid dose cannot be reduced:**	
List all failed treatments: ☐ **SSRIs** ☐ **SNRIs** ☐ **Buspirone** ☐ **Lyrica** ☐ **Mirtazapine** ☐ **Exercise Therapy** ☐ **Cognitive Behavioral Therapy** ☐ Relaxation and Breath Training ☐ **Other**	**Start/End Date:**	**Reason for failure:**

Qualifications for coverage:	
Does provider routinely check the PDMP?	☐ YES ☐NO
Has the provider established an appropriate treatment plan with the member, addressing the delayed onset of effectiveness of their maintenance therapy?	☐ YES ☐NO
Will the benzodiazepine therapy be routinely evaluated for continued necessity?	☐ YES ☐NO
Does the member undergo routine drug screens?	☐ YES ☐NO
Has the provider discussed and counseled the member on the known risks of utilizing benzodiazepines in combination with opioid analgesics and other CNS depressing medications/conditions?	☐ YES ☐NO

Please confirm that all of the following is attached to the request, along with any other relevant documentation:

☐ Member's treatment plan including an evaluation of effectiveness and plans for continuation/discontinuation
☐ Clinical documentation of previously tried and failed non-benzodiazepine therapies.

Prescriber (or Staff) / Pharmacy Signature**	Date

Multiple Antipsychotics Override Request
Prior Authorization Form

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

Prior Authorization Vendor for ND

ND Medicaid requires that members receiving a prescription for multiple antipsychotics to meet specific clinical criteria for coverage. Criteria for coverage for multiple antipsychotics can be found in the following location:

- The Preferred Drug List (PDL) available at www.hidesigns.com/assets/files/ndmedicaid/NDPDL.pdf

Part I: TO BE COMPLETED BY PRESCRIBER/PRESCRIBER'S OFFICE

Recipient Name	Recipient Date of Birth	Recipient Medicaid ID Number	
Prescriber Name	Specialist involved in therapy (if not treating prescriber)		
Prescriber NPI	Telephone Number	Fax Number	
Address	City	State	Zip Code

Requested Drug and Dosage:	**Diagnosis for this request:**

What non-antipsychotic mood stabilizers have been trialed or ruled out for treatment and justification for that decision?

Is clozapine an option for duplicate antipsychotic for unresolved symptoms? ☐ **Yes** ☐ **No**

Is hydroxyzine an option for sleep and/or anxiety? ☐ **Yes** ☐ **No**

☐ *I confirm that I have considered a generic or other alternative and that the requested drug is expected to result in the successful medical management of the recipient.*

Prescriber (or Staff) / Pharmacy Signature**	Date

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

Part II: TO BE COMPLETED BY PHARMACY

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

Multiple Antipsychotic Override Requests	
When are the breakthrough symptoms occurring (e.g. timeframe from injection)? Any other contributing factors (non-pharmacological) and how addressed, if so?	
At what point, would the first medication be considered a failure / other treatment would be considered?	
What is the anticipated benefit of another medication (vs. increasing dose or switching medication)?	
Why is one antipsychotic unable to be maximized to treat all targeted symptoms?	
What symptoms are being targeted with each antipsychotic?	
For injections:	What would be the tapering goal for oral antipsychotic if symptoms abate as long-term supplemental use of oral with injectable safety/efficacy data lacking?
	What is the site of administration?
For duplicate quetiapine requests:	If sedation/anxiety is part of a reason for the quetiapine treatment, which medications have been trialed? • A hydroxyzine trial is required for sedation/anxiety • Primary use for insomnia will not be approved

Dupixent
Prior Authorization Form

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

Prior Authorization Vendor for ND

ND Medicaid requires that members receiving a new prescription for Dupixent must meet criteria for coverage, as stated in the PA Criteria page of the North Dakota Medicaid Prior Authorization website http://www.hidesigns.com/ndmedicaid or directly at the following link: www.hidesigns.com/assets/files/ndmedicaid/NDPDL.pdf

Part I: TO BE COMPLETED BY PRESCRIBER/PRESCRIBER'S OFFICE

Recipient Name	Recipient Date of Birth	Recipient Medicaid ID Number
Prescriber Name	Specialist involved in therapy (if not treating prescriber)	
Prescriber NPI	Telephone Number	Fax Number
Requested Drug:	**Diagnosis for this request:**	

For atopic dermatitis:	**Is the affected area on the face, groin, axilla, or under occlusion?** ☐ YES ☐ NO
For asthma:	**Has the member had at least 1 asthma exacerbation requiring use of oral corticosteroids in previous year despite continued compliant use of a moderate to high dose inhaled steroid in combination with a long-acting beta agonist (LABA) and long-acting muscarinic antagonist (LAMA) as evidenced by paid claims or pharmacy printouts?** ☐ YES ☐ NO
For nasal polyps:	**Does the member have bilateral polyps confirmed by sinus CT, sinus MRI, or nasal endoscopy?** ☐ YES ☐ NO
	Has the member had a 12-week trial of intranasal or oral corticosteroid? ☐ YES ☐ NO

List all failed medications:	**Start Date:**	**End Date:**

☐ *I confirm that I have considered a generic or other alternative and that the requested drug is expected to result in the successful medical management of the recipient.*

Prescriber (or Staff) / Pharmacy Signature**	Date

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

Part II: TO BE COMPLETED BY PHARMACY

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

Emflaza
Prior Authorization Form

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

Prior Authorization Vendor for ND

ND Medicaid requires that members receiving a new prescription for Emflaza must meet the criteria for use available at www.hidesigns.com/assets/files/ndmedicaid/NDPDL.pdf

Part I: TO BE COMPLETED BY PRESCRIBER

Recipient Name	Recipient Date of Birth	Recipient Medicaid ID Number
Prescriber Name	Specialist involved in therapy (if not treating prescriber)	
Prescriber NPI	Telephone Number	Fax Number
Requested Drug and Dosage:	**Diagnosis for this request:**	
List all failed medications:	**Start Date:**	**End Date:**
• **Member's serum creatinine kinase activity prior to initiating treatment:**		
• **Member's current motor milestone score** (provide score and assessment used):		
• **Did the member experience onset of weakness before 5 years of age?**		☐ YES ☐ NO

INITIAL: **Member has experienced the following significant intolerable adverse effects*** (select all that apply)
- ☐ Cushingoid appearance
- ☐ Central (truncal) obesity
- ☐ Severe behavioral adverse effect
- ☐ Undesirable weight gain (>10% of body weight gain increase over 6-month period)
- ☐ Diabetes and/or hypertension that is difficult to manage

• *RENEWAL*: **Member has experienced an improvement from adverse effects experienced on prednisone***	☐ YES ☐ NO

Documentation of experienced adverse events or improvement on Emflaza must be provided with this request

☐ *I confirm that I have considered a generic or other alternative and that the requested drug is expected to result in the successful medical management of the recipient.*

Prescriber (or Staff) / Pharmacy Signature**	Date

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

Part II: TO BE COMPLETED BY PHARMACY

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

Empaveli

Prior Authorization Form

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

Prior Authorization Vendor for ND

ND Medicaid requires that members receiving a prescription for Empaveli (pegcetacoplan) to meet specific clinical criteria for coverage. Criteria for coverage for Empaveli can be found the following location:

- The Preferred Drug List (PDL) available at www.hidesigns.com/assets/files/ndmedicaid/NDPDL.pdf

Part I: TO BE COMPLETED BY PRESCRIBER/PRESCRIBER'S OFFICE

Recipient Name	Recipient Date of Birth	Recipient Medicaid ID Number	
Prescriber Name	Specialist involved in therapy (if not treating prescriber)		
Prescriber NPI	Telephone Number	Fax Number	
Address	City	State	Zip Code

Requested Drug and Dosage:	**Diagnosis for this request:** ☐ PAROXYSMAL NOCTURNAL HEMOGLOBINURIA (PNH) ☐ OTHER:

Qualifications for coverage:

Does the member have transfusion dependent anemia?	☐ YES ☐ NO
Does the member have symptoms of thromboembolic complications (abdominal pain, shortness of breath, chest pain, end-organ damage, fatigue)?	☐ YES ☐ NO
Has the member received one of the following? • A full course of meningococcal, pneumococcal, and Hib vaccines at least 2 weeks prior to starting treatment • A test for antibodies against encapsulated bacteria at least 2 weeks prior to starting treatment • Prophylactic antibiotics against encapsulated bacteria prior to starting treatment	☐ YES ☐ NO

Please confirm that all the following is attached to the request, along with any other relevant documentation:

☐ Documentation of lab results confirming a diagnosis of PNH
☐ (Renewal ONLY): Documentation supporting that the member has experienced and/or maintained a clinical benefit since starting treatment with Empaveli, as evidenced by medical documentation (e.g. reduced fatigue, decrease in transfusions, increase in Hb levels, or normalization of LDH).

☐ *I confirm that I have considered a generic or other alternative and that the requested drug is expected to result in the successful medical management of the recipient.*

Prescriber (or Staff) / Pharmacy Signature**	Date

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

Part II: TO BE COMPLETED BY PHARMACY

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

Evrysdi

Prior Authorization Form

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

Prior Authorization Vendor for ND

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

- Please complete this form in its entirety and provide all required documentation (if available)

Part I: TO BE COMPLETED BY PRESCRIBER/PRESCRIBER'S OFFICE

Recipient Name	Recipient Date of Birth	Recipient Medicaid ID Number	
Prescriber Name	Specialist involved in therapy (if not treating prescriber)		
Prescriber NPI	Telephone Number	Fax Number	
Address	City	State	Zip Code

Requested Drug:	**Diagnosis for this request:** ☐ SMA Type 1 ☐ SMA Type 2 ☐ SMA Type 3
Member Weight	**Requested Dose**
Neuromuscular Clinic Contact Information:	**Date of last Visit:**

Has the member required continuous intubation for greater than 3 weeks?	☐ YES	☐ NO
Is the member receiving/has the member received treatment with Zolgensma?	☐ YES	☐ NO
Is the member symptomatic (ex. loss of reflexes, motor delay/weakness, abnormal EMG/neuromuscular ultrasound)?	☐ YES	☐ NO

Please confirm that all of the following is attached to the request, if applicable, along with any other documentation required, as stated in the PDL:

☐ Documentation of the member's current motor function from at least 2 of the approved assessments
☐ Documentation of genetic testing confirming bi-allelic deletions or mutations of SMN1 gene
☐ Documentation of genetic testing confirming the number of the patient's SMN2 gene copies

Prescriber (or Staff) / Pharmacy Signature**	Date

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

Part II: TO BE COMPLETED BY PHARMACY

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

Growth Hormone
Prior Authorization Form

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

Prior Authorization Vendor for ND

ND Medicaid requires that members receiving preferred growth hormone meet one of the criteria below (member's receiving a non-preferred growth hormone product must be switched to a preferred agent):

- Multiple pituitary hormone deficiencies caused by a known hypothalamic-pituitary disease or its treatment (brain surgery and/or radiation)
- Turner's syndrome
- SHOX syndrome
- Noonan syndrome
- Chronic renal insufficiency
- Prader–Willi syndrome
- See growth hormone criteria for additional information – www.hidesigns.com/assets/files/ndmedicaid/NDPDL.pdf

Part I: TO BE COMPLETED BY PRESCRIBER

Recipient Name	Recipient Date of Birth	Recipient Medicaid ID Number
Prescriber Name	Specialist involved in therapy (if not treating prescriber)	
Prescriber NPI	Telephone Number	Fax Number
Requested Drug and Dosage:	**Diagnosis for this request:**	

Qualifications for coverage:

Does the member have any active malignancy?	☐ YES ☐NO
Has the member attained epiphyseal closure?	☐ YES ☐NO
Does the member consult with a dietician to maintain a nutritious diet?	☐ YES ☐NO
Is growth hormone needed to maintain proper blood glucose *(endogenous GH deficiency only)*?	☐ YES ☐NO
Does the member have multiple pituitary hormone deficiencies caused by a known hypothalamic-pituitary Disease *(endogenous GH deficiency only)*?	☐ YES ☐NO
Has the member received a renal transplant *(chronic renal insufficiency only)?*	☐ YES ☐NO
Has a diagnosis of sleep apnea been ruled out in this member *(Prader-Willi syndrome only)*?	☐ YES ☐NO
Are all lab values stated as required in the criteria attached to this request?	☐ YES ☐NO

Member's current BMI (Prader-Willi syndrome only):

Prescriber (or Staff) / Pharmacy Signature**	Date

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

Part II: TO BE COMPLETED BY PHARMACY

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

Hepatitis C Treatments
Prior Authorization Form

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

Prior Authorization Vendor for ND

ND Medicaid requires that members receiving a prescription for hepatitis C treatments must meet the criteria listed in the preferred drug list (PDL). Please see the PDL at www.hidesigns.com/assets/files/ndmedicaid/NDPDL.pdf
Please complete this form in its entirety and provide any and all required documentation (if available)

Part I: TO BE COMPLETED BY PRESCRIBER

Recipient Name	Recipient Date of Birth	Recipient Medicaid ID Number	
Prescriber Name	Specialist involved in therapy		
Prescriber NPI	Telephone Number	Fax Number	
Address	City	State	Zip Code

Requested Drug and Dose:	**Duration requested:**	**Member's liver fibrosis score:** ☐ F0-F1 ☐ F3-F4
Diagnosis: ☐ HCV ☐ OTHER:	**Genotype:**	**Member's Child–Pugh Class:** ☐ A ☐ B ☐ C ☐ N/A

Please list any previous treatments the member has failed for chronic HCV: ☐ N/A	Regimen:	Dates of treatment:	Response:

Has the member remained drug (illicit use by injection) and alcohol free for the past 3 months?	☐ YES ☐ NO
Does the member have a diagnosis of alcohol use disorder?	☐ YES ☐ NO
Does the member have a history of illicit use of drugs by injection?	☐ YES ☐ NO
Has the member completed or is currently in a treatment program from an enrolled addiction medicine/chemical dependency provider (or buprenorphine waived provider if history of IV drug use)? Approximate Dates of Treatment:	☐ YES ☐ NO Attested by: ☐ PROVIDER ☐ PATIENT
Please provide the name of the enrolled addiction medicine/chemical dependency treatment provider/facility name, if applicable:	
Does the member have Hepatitis B?	☐ YES ☐ NO
If the member has Hepatitis B, has it been treated or will it be closely monitored during treatment?	☐ YES ☐ NO
Is the member post-liver transplant?	☐ YES ☐ NO
Is the member's life expectancy greater than one year?	☐ YES ☐ NO
Does the member attend scheduled visits with no more than 1 no-show and fill maintenance medications on time?	☐ YES ☐ NO
Does the member have any contraindications to therapy with the requested agent?	☐ YES ☐ NO
Is the member going to take Ribavirin alongside treatment?	☐ YES ☐ NO

Please confirm that all of the following is attached to the request, along with any other documentation required, as stated in the PDL:

- o Baseline HCV RNA
- o ≥ 2 drug and alcohol tests dated at least 3 months apart
- o Patient & Prescriber attestation forms
- o Chart notes addressing member's alcohol and drug free status over the past year
- o Documentation of member's fibrosis score if available (e.g. APRI, Fibroscan, Fibrotest)

Prescriber (or Staff) / Pharmacy Signature**	Date

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

Part II: TO BE COMPLETED BY PHARMACY

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

Hepatitis C Patient Consent Form

I, ¸ have been counseled by my healthcare provider on the following:

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

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

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

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

I understand that medications that treat Hepatitis C may be harmful to unborn babies. I will use methods to avoid getting pregnant or another person pregnant during treatment and when advised by my provider or pharmacist, for at least 6 months after treatment is complete.

Patient Signature_____Date __/__/____

Pharmacy or Prescriber Representative:

Signature _____Date __/__/____

By signature, the pharmacy or prescriber representative confirms the contract has been reviewed with the patient

Hepatitis C Prescriber Agreement Form

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

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

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

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

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

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

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

Name: Location:

Phone #: _____ _____

Name: _____ Location:

Phone #: _____ _____

Pharmacy or Prescriber Representative:

Signature _____ **Date** __/__/____

Makena
Prior Authorization Form

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

Prior Authorization Vendor for ND

ND Medicaid requires that members receiving a prescription for Makena to meet criteria confirming the medication is being used according to its FDA-approved indication. Please fill out the following form in its entirety.

Part I: TO BE COMPLETED BY PRESCRIBER

Recipient Name	Recipient Date of Birth	Recipient Medicaid ID Number	
Prescriber Name	Specialist involved in therapy (if not treating prescriber)		
Prescriber NPI	Telephone Number	Fax Number	
Address	City	State	Zip Code
Requested Drug and Dosage:	**Diagnosis for this request:**		
Member's Estimated Date of Delivery or Gestational Age of Current Pregnancy (weeks and days):			
Does the member have a history of singleton spontaneous preterm birth? ☐ YES ☐ NO			
Is the member currently pregnant with singleton? ☐ YES ☐ NO			
Additional Qualifications for Coverage (*if applicable*)			
☐ *I confirm that I have considered a generic or other alternative and that the requested drug is expected to result in the successful medical management of the recipient.*			
Prescriber (or Staff) / Pharmacy Signature**		Date	
**: *By completing this form, I hereby certify that the above request is true, accurate and complete. That the request is medically necessary, does not exceed the medical needs of the member, and is clinically supported in the member's medical records. I also understand that any misrepresentations or concealment of any information requested in the prior authorization request may subject me to audit and recoupment.*			

Part II: TO BE COMPLETED BY PHARMACY

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

Mifeprex
Prior Authorization Form

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

Prior Authorization Vendor for ND

ND Medicaid requires that members receiving a new prescription for Mifeprex must meet the following criteria:

- **Member must have an FDA approved indication for the medication requested.**
- **Prescriber must provide signed written statement as listed in the Mifeprex Prior Authorization Criteria at** www.hidesigns.com/assets/files/ndmedicaid/NDPDL.pdf

Part I: TO BE COMPLETED BY PRESCRIBER

Recipient Name	Recipient Date of Birth	Recipient Medicaid ID Number	
Prescriber Name			
Prescriber Medicaid Provider Number	Telephone Number	Fax Number	
Address	City	State	Zip Code
Requested Drug and Dosage:	**FDA approved indication for this request:**		

- **Is the member terminating a pregnancy before 70 days of gestation? □ YES □ NO**
- **Is the member resulting from an act of rape or incest? □ YES □ NO** (If yes, please attach written statements as outlined in section 1 below)
- **Does the woman suffer from a physical disorder that would place the woman in danger of death unless abortion is performed? □ YES □ NO** (If yes, please attach a written statement as outlined in section 2 below)

Section 1:

- The provider has provided a signed written statement indicating that the rape or act of incest has been reported to the appropriate law enforcement agency, or in the case of a minor who is a victim of incest, to an agency authorized to receive child abuse and neglect reports. The statement must indicate to whom the report was made.
- The provider has provided written statement signed by the recipient and the provider that the recipient's pregnancy resulted from rape or incest and by professional judgement, the provider agrees with the woman's statement.

Section 2:

- The provider must provide a signed written statement indicating why, in the provider's professional judgement, the life of a woman would be endangered if the fetus were carried to term

Prescriber (or Staff) / Pharmacy Signature**	Date

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

Part II: TO BE COMPLETED BY PHARMACY

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

Migraine Prophylaxis/Treatment Prior Authorization Form

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

Prior Authorization Vendor for ND

ND Medicaid requires that members receiving a prescription for migraine prophylaxis/treatment must meet the following criteria:

Prophylaxis Initial Requests:

- Member must experience 3 or more migraine days per month.
- Member must submit documentation of treatment failure of a 2-month trial of two preferred agents from different therapeutic classes. Documentation must include clinical notes regarding failure to reduce migraine frequency.

Prophylaxis Renewal Requests: Member must experience a reduction in migraines of at least 50%

Treatment Initial Requests:

- Member must have had 30-day trials of two triptans (5HT-1 agonists) within the past 2 years

Part I: TO BE COMPLETED BY PRESCRIBER

Recipient Name	Recipient Date of Birth	Recipient Medicaid ID Number	
Prescriber Name	Specialist involved in therapy (if not treating prescriber)		
Prescriber NPI	Telephone Number	Fax Number	
Address	City	State	Zip Code
Requested Drug and Dosage:	**Diagnosis for this request:**		
Number of experienced migraine days per month:			
How will the requested product be used? ☐ Prophylaxis ☐ Treatment			
List all failed medications:	**Start Date:**	**End Date:**	
Additional Qualifications for Coverage (e.g. medical justification explaining inability to meet required trials)			
☐ *I confirm that I have considered a generic or other alternative and that the requested drug is expected to result in the successful medical management of the recipient.*			
Prescriber (or Staff) / Pharmacy Signature**	Date		
**: *By completing this form, I hereby certify that the above request is true, accurate and complete. That the request is medically necessary, does not exceed the medical needs of the member, and is clinically supported in the member's medical records. I also understand that any misrepresentations or concealment of any information requested in the prior authorization request may subject me to audit and recoupment.*			

Part II: TO BE COMPLETED BY PHARMACY

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

Nuedexta
Prior Authorization Form

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

Prior Authorization Vendor for ND

ND Medicaid requires that members receiving a new prescription for Nuedexta must meet the following criteria:

Initial Criteria

- Member must be 18 years of age or older
- Member must not have a prolonged QT interval, heart failure, or complete atrioventricular block
- Member's baseline CNS-LS and weekly PBA episode count must be provided
- Member must have a diagnosis of PBA due to one of the following conditions: ALS, MS, Alzheimer's disease, or stroke

For PBA due to Alzheimer's disease or stroke

- Neurologic condition must have been stable for at least 3 months
- Member must have failed a 3-month trial of one medication from BOTH classes listed: SSRIs (sertraline, fluoxetine, citalopram, and paroxetine) and Tricyclic Antidepressants (nortriptyline or amitriptyline)
  - A PBA episode count and CNS-LS score must be provided for before and after each trial

Renewal Criteria

- Benefit of renewal must be assessed
- Baseline and current PBA episode count must be included with request
- Current PBA episode count must be a 75 percent decrease from baseline

For PBA due to Alzheimer's disease or stroke

- Baseline and current Center for Neurological Studies lability (CNS-LS) must be included with request
- Current CNS-LS score must be a 30% decrease from baseline

Part I: TO BE COMPLETED BY PRESCRIBER

Recipient Name	Recipient Date of Birth	Recipient Medicaid ID Number
Prescriber Name	Specialist involved in therapy (if not treating prescriber)	
Prescriber NPI	Telephone Number	Fax Number
Requested Drug and Dosage:	**Diagnosis for this request (include cause of PBA):**	
List all failed medications:	**Start Date (PBA Count at Start):**	**End Date (PBA Count at End):**

Does the member have a prolonged QT interval, heart failure, or complete atrioventricular (AV) block?	☐ YES ☐ NO
Has the neurologic condition been stable for at least 3 months?	☐ YES ☐ NO

Baseline CNS-LS:	Baseline weekly PBA episode count:	Current CNS-LS:	Current weekly PBA episode count:

Prescriber (or Staff) / Pharmacy Signature**	Date

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

Part II: TO BE COMPLETED BY PHARMACY

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

Opioid Analgesics
Prior Authorization Form

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

Prior Authorization Vendor for ND

ND Medicaid requires that members receiving a long-acting opioid analgesic must meet the following criteria:

- Member must have required around-the-clock pain relief for the past 90 days
- The past 3 months of North Dakota PDMP reports must have been reviewed by the prescriber.
- Member must be in consult with oncologist or pain management specialist with a pain management contract (with treatment plan including goals for pain and function, and urine and/or blood screens) if:
  - Cumulative daily dose of narcotics exceed 90 MED/day
  - Member is using benzodiazepine concurrently with narcotic medication
- Member must have not achieved therapeutic goal with non-narcotic medication (NSAIDs, TCAs, SNRIs, Corticosteroids, etc.) and non-medication alternatives (Weight Loss, Physical Therapy, Cognitive Behavioral Therapy, etc.)

  *** For additional and agent-specific criteria, please see criteria for coverage in the Preferred Drug List at www.hidesigns.com/assets/files/ndmedicaid/NDPDL.pdf**

Part I: TO BE COMPLETED BY PRESCRIBER

Recipient Name	Recipient Date of Birth	Recipient Medicaid ID Number	
Prescriber Name	Pain, Palliative Care, or Oncology/Hematology Specialist involved in therapy (if not treating prescriber):		
Prescriber NPI	Telephone Number	Fax Number	
Requested Opioid Analgesic:	**Diagnosis for use of opioid(s) in this member:**		
List All Failed/Current Medications: ☐ NSAIDs ☐ TCAs ☐ SNRIs ☐ Corticosteroids ☐ Weight Loss ☐ Physical Therapy ☐ Cognitive Behavioral Therapy ☐ Other:	**Dose and Frequency:**	**Start/End Date:**	**Reason for failure:**

Qualifications for coverage:

Have the past 3 months of North Dakota PDMP reports been reviewed by the prescriber?	☐ YES ☐ NO
Has the provider established a realistic treatment plan with the member, addressing expected outcomes and limitations of therapy in eliminating pain?	☐ YES ☐ NO
Does the patient undergo routine drug screens?	☐ YES ☐ NO

Please confirm that all the following is attached to the request, along with any other relevant documentation:

☐ Member's treatment plan including an evaluation of effectiveness and plans for continuation/discontinuation
☐ Clinical documentation of previously tried and failed non-opioid therapies.

Prescriber (or Staff) / Pharmacy Signature**	Date

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

Palforzia
Prior Authorization Form

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

Prior Authorization Vendor for ND

ND Medicaid requires that members receiving a prescription for Palforzia to meet criteria confirming the medication is being used according to its FDA-approved indication. Please fill out the following form in its entirety.

Part I: TO BE COMPLETED BY PRESCRIBER

Recipient Name	Recipient Date of Birth	Recipient Medicaid ID Number
Prescriber Name	Specialist involved in therapy (if not treating prescriber)	
Prescriber NPI	Telephone Number	Fax Number
Requested Drug and Dosage:	**Diagnosis for this request:**	

Does the member have uncontrolled asthma?	☐ YES	☐ NO
Has the member experienced severe or life-threatening anaphylaxis in the 60 days?	☐ YES	☐ NO
Does the member have a history of eosinophilic esophagitis or another eosinophilic GI disease?	☐ YES	☐ NO
Has the member/caregiver been educated on appropriate use of epinephrine?	☐ YES	☐ NO
RENEWAL ONLY: Does the member continue to have a peanut allergy and has been/is being monitored for resolution of their allergy?	☐ YES	☐ NO
RENEWAL ONLY: Has the member been able to tolerate the maintenance dose of Palforzia (300	☐ YES	☐ NO

Additional Qualifications for Coverage (*if applicable*)

☐ *I confirm that I have considered a generic or other alternative and that the requested drug is expected to result in the successful medical management of the recipient.*

Prescriber (or Staff) / Pharmacy Signature**	Date

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

Part II: TO BE COMPLETED BY PHARMACY

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

Phenylketonuria Agents
Prior Authorization Form

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

Prior Authorization Vendor for ND

ND Medicaid requires that members receiving a new prescription for a phenylketonuria agent must meet the following criteria:

- **Member must have hyperphenalaninemia.**
- **Member must be following a PHE restricted diet.**

Part I: TO BE COMPLETED BY PRESCRIBER

Recipient Name		**Recipient Date of Birth**	Recipient Medicaid ID Number
Prescriber Name			
Prescriber NPI		Telephone Number	Fax Number
Address		City	State / Zip Code
Requested Drug and Dosage:	**PHE level:**	**Diagnosis for this Request:**	**Member's weight:**

Has the member been known to have two null mutations in TRANS?	☐ YES	☐ NO
Are baseline PHE levels attached?	☐ YES	☐ NO
Is the member of child-bearing potential?	☐ YES	☐ NO
Is this a renewal request?	☐ YES	☐ NO
Has the member been compliant with diet and medications for past 6 months?	☐ YES	☐ NO

☐ I confirm that I have considered a generic or other alternative and that the requested drug is expected to result in the successful medical management of the recipient.

Prescriber (or Staff) / Pharmacy Signature**	Date

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

Part II: TO BE COMPLETED BY PHARMACY

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

Sedative/Hypnotic
Prior Authorization Form

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

Prior Authorization Vendor for ND

ND Medicaid requires that members receiving a sedative/hypnotic must meet the agent criteria located on the Preferred Drug List (PDL), located on the North Dakota Department of Human Services Prior Authorization website at http://www.hidesigns.com/ndmedicaid.

Note:

- **Requires step therapy. See Sedative/Hypnotic PA criteria for more information.**
  - Zolpidem: Initiation with trial of 5 mg must be used for 7 days within 90 days prior to 10 mg tablets
  - Belsomra: The member must have had a 25- day trial of eszopiclone within the past 90 days

Part I: TO BE COMPLETED BY PRESCRIBER

Recipient Name	Recipient Date of Birth	Recipient Medicaid ID Number
Prescriber Name		
Prescriber NPI	Telephone Number	Fax Number
Requested Drug and Dosage:	**Diagnosis for this request:**	
Qualifications for coverage:		
List all failed medications:	**Start Date:**	**End Date:**

Have other conditions causing sleep issues been ruled out?	☐ YES ☐ NO
Does the member require dose tapering?	☐ YES ☐ NO
Is the member's insomnia characterized by difficulty with sleep maintenance?	☐ YES ☐ NO
Is the member's insomnia characterized by difficulty with sleep initiation?	☐ YES ☐ NO
Is the member's insomnia characterized by difficulty with middle of the night awakening with more than 4 hours left to sleep?	☐ YES ☐ NO
Is the member blind in both eyes? (For non-24 hour sleep-wake disorder)	☐ YES ☐ NO

☐ I *confirm that I have considered a generic or other alternative and that the requested drug is expected to result in the successful medical management of the recipient.*

Prescriber (or Staff) / Pharmacy Signature**	Date

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

Part II: TO BE COMPLETED BY PHARMACY

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

Tardive Dyskinesia Agents
Prior Authorization Form

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

Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that members receiving a new prescription for Austedo, Ingrezza, or tetrabenazine must meet the following criteria:

Category Criteria

- The member must be 18 years of age or older.
- The prescription must be written by/in consultation with a specialist (neurologist or psychiatrist).
- The member must have a diagnosis of tardive dyskinesia, including the following:
  - Involuntary athetoid or choreiform movements
  - History of treatment with dopamine receptor blocking agent (DRBA)
  - Symptom duration lasting longer than 4-8 weeks
- The member must not be taking monoamine oxidase inhibitor (MAOI)
- The member is not pregnant or breastfeeding

Product Specific Criteria: * Austedo/tetrabenazine:**

- The member must have a diagnosis of Huntington's disease or Tardive Dyskinesia.
- The member must not have hepatic impairment

Part I: TO BE COMPLETED BY PRESCRIBER/PRESCRIBER'S OFFICE

Recipient Name	Recipient Date of Birth	Recipient Medicaid ID Number
Prescriber Name		
Prescriber NPI	Telephone Number	Fax Number
Requested Drug and Dosage:	**FDA approved indication for this request:**	
List all failed medications (drug name, date of trial, reason for failure):		
Qualifications for coverage:		
Does the member's diagnosis include athetoid or choreiform movements?		☐ YES ☐ NO
Has the symptom duration lasted longer than 4-8 weeks?		☐ YES ☐ NO
Is the member pregnant or breastfeeding?		☐ YES ☐ NO
Prescriber (or Staff) / Pharmacy Signature**		Date

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

Part II: TO BE COMPLETED BY PHARMACY

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

REVIEW OF KIDNEY DISEASE

Kidney disease currently affects 37 million adults in the United States. Chronic kidney disease (CKD) is defined as kidney damage/decreased function for three months or greater. Any duration less would be considered acute kidney injury (AKI). Kidney damage is described as urinary albumin excretion ≥30 mg/day, and decreased kidney function is defined as estimated glomerular filtration rate (eGFR) <60 mL/min/1.73 m2. High blood pressure and diabetes are the main causes of CKD, and it is estimated that 50% of patients with CKD also have diabetes or cardiovascular disease.

Table 1. Classification of Chronic Kidney Disease (KDIGO 2012)

Stage	Description	Kidney Function (eGFR, mL/min/1.73 m²)	Albuminuria (mg/g)		
			<30	30–300	>300
Stage 1	Normal kidney function	>90	Low risk	Moderate risk	High risk
Stage 2	Mild loss of kidney function	60–89	Low risk	Moderate risk	High risk
Stage 3a	Mild to moderate loss of kidney function	45–59	Moderate risk	High risk	Very high risk
Stage 3b	Moderate to severe loss of kidney function	30–44	High risk	Very high risk	Very high risk
Stage 4	Severe loss of kidney function	15–29	Very high risk		
Stage 5 (ESRD)	Complete kidney failure	<15	Very high risk		

Source: KDIGO 2012 Clinical Practice Guideline for the Evaluation and Management of Chronic Kidney Disease. *Kidney Int Suppl.* 2013;3(1). https://kdigo.org/wp-content/uploads/2017/02/KDIGO_2012_CKD_GL.pdf

Abbreviations: eGFR, estimated glomerular filtration rate; ESRD, end-stage renal disease; KDIGO, Kidney Disease: Improving Global Outcomes

Place in Therapy/Guidelines

There is currently no cure for CKD; therefore, the goals of treatment include:

- Treating reversible causes of CKD
- Preventing or slowing the progression of disease
- Treating complications of kidney failure

CKD Treatment
All patients
• Treatment with an ACEi or ARB titrated to the highest approved, tolerated dose • Treating complications of kidney failure (e.g., volume overload, hyperkalemia, anemia) and ESRD (e.g., malnutrition, neuropathy).
Patients with Type 2 diabetes
• Treatment with metformin • Treatment with a SGLT-2 inhibitor (Farxiga or Invokana) OR with Kerendia Although not currently recommended or studied, triple therapy with an ACE inhibitor or ARB plus an SGLT2 inhibitor plus Kerendia could help target all possible mechanisms responsible for kidney damage in CKD: ▪ ACE inhibitors and ARBs generally target reduction in blood pressure control and glomerular hypertension ▪ SGLT2 inhibitors additionally target glycemic control and cardiovascular risk reduction ▪ Nonsteroidal MRAs (e.g. Kerendia) add an additional anti-inflammatory and antifibrotic effect
Patients with Type 2 diabetes who have not achieved glycemic targets despite use of metformin and SGLT2i, or who are unable to use those medications
• Treatment with a long-acting GLP-1 RA

General Dosing and FDA Indications

Farxiga (dapagliflozin propanediol)	
Mechanism of Action	Sodium-glucose linked transporter 2 (SGLT2) inhibitor
Dosing	• (eGFR 25 mL/min/1.73 m(2) or greater): 10 mg orally once daily. • (eGFR less than 25 mL/min/1.73 m(2)): Do not initiate therapy; may continue established dapagliflozin therapy at 10 mg orally once daily
Indications	• CKD, (At risk of progression) • Disorder of cardiovascular system; Prophylaxis – T2DM • HF, (NYHA class II to IV, reduced EF) to reduce risk of CV death and hospitalization
Invokana (canagliflozin)	
Mechanism of Action	Sodium-glucose linked transporter 2 (SGLT2) inhibitor
Dosing	<u>Diabetic nephropathy, With Albuminuria – T2DM:</u> • (eGFR 60 mL/min/1.73 m(2) or greater): 100 mg PO Qday, taken before the first meal of the day; may increase to 300 mg Qday for additional glycemic control. • (eGFR 30 to less than 60 mL/min/1.73 m(2)): 100 mg PO Qday, taken before the first meal of the day. • (eGFR less than 30 mL/min/1.73 m(2)): Do not initiate therapy in this population, however if albuminuria is greater than 300 mg/day may continue with 100 mg PO Qday, taken before the first meal of the day. <u>Disorder of cardiovascular system; Prophylaxis – T2DM:</u> • (eGFR 60 mL/min/1.73 m(2) or greater): 100 mg PO Qday, taken before the first meal of the day; may increase to 300 mg PO Qday for additional glycemic control. • (eGFR 30 to less than 60 mL/min/1.73 m(2)): 100 mg PO Qday, taken before the first meal of the day. • (eGFR less than 30 mL/min/1.73 m(2)): Do not initiate therapy in this population, however if albuminuria is greater than 300 mg/day may continue with 100 mg PO Qday, taken before the first meal of the day.
Indications	• Diabetic nephropathy, With Albuminuria – T2DM • Disorder of cardiovascular system; Prophylaxis – T2DM • T2DM
Kerendia (finerenone)	
Mechanism of Action	Selective mineralocorticoid receptor antagonist
Dosing	• (eGFR 60 mL/min/1.73 m(2) or greater) Initial, 20 mg PO Qday; titration, measure serum potassium 4 weeks after initiating treatment and maintain 20 mg daily for serum potassium up to 5.5 mEq/L; adjust dose as needed based on serum potassium obtained 4 weeks after a dose adjustment, and periodically. • (eGFR 25 to less than 60 mL/min/1.73 m(2)) Initial, 10 mg PO Qday; titration, measure serum potassium 4 weeks after initiating treatment and increase dose to 20 mg daily for serum potassium 4.8 mEq/L or less. Maintain 10 mg daily dose for serum potassium greater than 4.8 to 5.5 mEq/L. For serum potassium 4.8 mEq/L or less with eGFR decrease by more than 30% over previous measurement, maintain 10 mg/day dosage. Adjust dose as needed based on serum potassium obtained 4 weeks after a dose adjustment, and periodically. • Serum potassium 5.5 mEq/L or greater: Withhold finerenone. For patients who were receiving the 20 mg/day dose, restart at 10 mg Qday when serum potassium is 5 mEq/L or less. For patients who were receiving the 10 mg/day dose, consider restarting at 10 mg daily when serum potassium is 5 mEq/L or lower.
Indications	• CKD- T2DM

Approval Status and Special Designations

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

Drug Name	Approval Letter Post Marketing Trial and Reporting Requirements
Farxiga	Approved in 04/30/2021 – New Indication
Invokana	Approved in 09/27/2019- New Indication
Kerendia	Approved NDA in 07/09/2021

Therapeutically Important Adverse Effects/Advantages

Farxiga

- Approved for treatment of T2DM, heart failure, and kidney disease.
- ADEs: UTIs, nasopharyngitis, genital infection

Invokana

- Approved for treatment of T2DM and kidney disease in patients with T2DM.
- ADEs: Polyuria, UTIs, hypovolemia

Kerendia

- Currently only approved for kidney disease in patients with T2DM.
- ADEs: hypotension, hyponatremia, hyperkalemia

Cost

Drug	Strength	Package Size	WAC Pkg Price	Cost/day*	Cost/month*	Cost/year*
Farxiga	5mg, 10mg	7, 30 count	$532.84	$17.76	$532.84	$6,394.08
Invokana	100mg, 300mg	30, 90 count	$543.43	$18.11	$543.43	$6,521.16
Kerendia	10mg, 20mg	7, 30, 90 count	$569.10	$18.97	$569.10	$6,829.20

*Based on lowest per unit WAC cost

Current Utilization

ND Medicaid Utilization (9/01/2020 – 08/31/2021)		
Label Name	**Rx Number**	**Total Reimbursement Amt**
Farxiga	583	$277,535.82
Invokana	229	$112,467.50
Kerendia	0	0

Kerendia Clinical Trials:

- FIDELIO-DKD, a Phase 3, randomized, double-blind, placebo-controlled study, evaluated daily finerenone in patients with CKD and type-2 diabetes vs. placebo with all patients were receiving ACE or ARB. Patients with heart failure with reduced ejection fraction were excluded from the study.
    - Primary endpoint was time to first occurrence of the composite endpoint of onset of kidney failure, a sustained decrease of eGFR of at least 40% from baseline over at least 4 weeks or renal death after 2 years. This occurred in 17.8% of the finerenone group vs. 21.5% in the placebo group (HR 0.82, 95% CI; p=0.001) - showing an 18% risk reduction in finerenone vs. placebo. Patients treated with finerenone saw lower risk of CKD progression and cardiovascular events vs. placebo.

- FIGARO-DKD is an additional phase 3 study that investigated the drug's efficacy and safety versus placebo in addition to an ACE inhibitor or ARB in the reduction of cardiovascular morbidity and mortality in an additional 7437 patients with CKD and T2D. Compared with FIDELIO-DKD, FIGARO-DKD includes more patients at earlier stages of CKD (eGFR >60 mL/min).
    - Kerendia met its primary composite endpoint of time to first occurrence of CV death or nonfatal CV events with a 13% relative risk reduction over a median duration of 3.4 years when added to ACE/ARB therapy. This reduction was primarily driven by a decrease in hospitalization due to heart failure.
    - Safety and tolerability were similar to the FIDELIO-DKD study with hyperkalemia more common in the Kerendia group (10.8%) versus 5.3% in the placebo group.

- FINEARTS-HF (n=5500) is a phase 3 study in patients with heart failure with preserved ejection fraction. The study started in September 2020 and is expected to be completed in 2024 with a primary composite outcome of heart failure events (first and recurrent).

Comparison of Trials for SGLT-2 inhibitors and Kerendia					
	Invokana	**Farxiga**	**Jardiance**	**Kerendia**	
Manufacturer	Janssen/Vifor	AstraZeneca	Boehringer Ingelheim/ Eli Lilly	Bayer	
Renal Trial(s)	CREDENCE	DAPA-CKD	EMPA-KIDNEY (Phase 3)	FIDELIO-DKD	FIGARO-DKD
Patient population	T2DM with CKD (n = 4401)	CKD with or without DM (n = 4303)	CKD with or without DM (n = 6609)	T2DM with CKD (n = 5734)	T2DM with CKD (n = 7437)
eGFR Inclusion criteria (mL/min/1.73m^2)	30 to <90	≥25 to 75	≥20 to <90	≥25 to <75	≥25 to <90
CKD	Approved in T2DM	Approved	In Phase 3	Approved in T2DM	

References:

Product Information: JARDIANCE(R) oral tablets, empagliflozin oral tablets. Boehringer Ingelheim Pharmaceuticals Inc (per FDA), Ridgefield, CT, 2021.
Product Information: FARXIGA(R) oral tablets, dapagliflozin oral tablets. AstraZeneca Pharmaceuticals LP (per manufacturer), Wilmington, DE, 2021.
Product Information: INVOKANA(R) oral tablets, canagliflozin oral tablets. Janssen Pharmaceuticals Inc (per FDA), Titusville, NJ, 2020.
Product Information: KERENDIA(R) oral tablets, finerenone oral tablets. Bayer HealthCare Pharmaceuticals Inc (per manufacturer), Whippany, NJ, 2021.
Kidney Disease: Improving Global Outcomes (KDIGO) Diabetes Work Group. KDIGO 2020 Clinical Practice Guideline for Diabetes Management in Chronic Kidney Disease. Kidney Int. 2020;98(4S):S1–S115.

LUPUS

Lupus is an autoimmune disease that can affect many organ systems, most commonly, the heart and kidneys. There are four different types of lupus: Systemic lupus erythematosus (SLE), cutaneous lupus erythematosus, drug-induced lupus erythematosus, and neonatal lupus. SLE is the most common and most serious form of the disease. The cause of SLE is unknown, but it is thought to develop in response to many factors, including hormones, genetics, and external environmental factors. SLE can range in severity and can have phases of alternating symptoms. Lupus can cause severe inflammation in the kidneys which is called lupus nephritis. Additionally, lupus can affect the nervous system, brain, and arteries. The prevalence of SLE in the U.S. is believed to be close to 200,000 with women of childbearing age being more at risk for developing the disease. Lupus nephritis develops in approximately 40% of patients with SLE with 10% of those patients eventually developing end-stage renal disease (ESRD). The prevalence of lupus nephritis, however, is more common in men than in women.

Place in Therapy/Guidelines

There is currently no cure for lupus, but there are treatment options available to help minimize organ damage.

<table>
<tr><th>SLE Treatment</th><th>Lupus Nephritis Treatment</th></tr>
<tr><td>Mild (i.e. skin, joint, and mucosal involvement)</td><td>Induction therapy</td></tr>
<tr><td>• Hydroxychloroquine or chloroquine
• With or without NSAIDs
• With or without short term use of low-dose glucocorticoids</td><td>• Cyclophosphamide or mycophenolate mofetil (MMF) with steroids</td></tr>
<tr><td>Moderate (i.e. constitutional, cutaneous, musculoskeletal, or hematologic)</td><td>Maintenance therapy</td></tr>
<tr><td>• Hydroxychloroquine or chloroquine
• PLUS 5mg – 15mg of prednisone (or equivalent) per day. Prednisone is usually tapered once hydroxychloroquine or chloroquine has taken effect.
• A steroid-sparing immunosuppressive agent (e.g., azathioprine or methotrexate) is often required to control symptoms.</td><td rowspan="3">• Azathioprine, MMF, or calcineurin inhibitor (e.g., Lupkynis) and a low- dose steroid
• Most patients should receive maintenance therapy for at least 1 year before tapering
• The average length of immunosuppression in lupus nephritis can be ≥3 years, with up to 60% of patients with lupus nephritis never reaching full remission with current therapies</td></tr>
<tr><td>Severe (i.e. Renal and central nervous system)</td></tr>
<tr><td>• Intensive immunosuppressive therapy (induction therapy) to control the disease and halt tissue injury.
• High dose systemic glucocorticoids alone or in combination with immunosuppressant agents
• Immunosuppressant agents include Mycophenolate, Azathioprine, Cyclophosphamide, and Rituximab</td></tr>
<tr><td colspan="2">Biologics are recommended in patients with an inadequate response to standard therapies
• Benlysta (SLE and LN)
• Saphnelo (SLE only)</td></tr>
</table>

General Dosing and FDA Indications

Benlysta (belimumab)	
Mechanism of Action	B-lymphocyte stimulator inhibitor
Dosing	SLE IV: 10 mg/kg IV every 2 weeks for 3 doses, then every 4 weeks thereafter SubQ: 200mg every week Lupus Nephritis IV: 10 mg/kg IV every 2 weeks for 3 doses, then every 4 weeks thereafter SubQ: 400mg once weekly for first 4 doses, then 200mg once weekly thereafter
Indications	Active, autoantibody-positive SLE in patients ≥ 5 years of age receiving standard therapy Lupus nephritis in adult patients receiving standard therapy
Lupkynis (voclosporin)	
Mechanism of Action	Calcineurin inhibitor
Dosing	Oral: 23.7 mg twice daily with eGFR-based dosing modifications in combination with mycophenolate mofetil and corticosteroids
Indications	Lupus nephritis in adult patients receiving a background immunosuppressive therapy regimen
Saphnelo (anifrolumab)	
Mechanism of Action	Type I interferon (IFN) inhibitor
Dosing	IV: 300mg every 4 weeks
Indications	Adult patients with moderate to severe SLE who are receiving standard therapy

Approval Status and Special Designations

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

Drug Name	Approval Letter Post Marketing Trial and Reporting Requirements
Benlysta	Approved BLA on 03/09/2011 – SLE Approved on 12/16/2020 – Lupus Nephritis (New Indication)
Lupkynis	Approved NDA on 01/22/2021
Saphnelo	Approved BLA on 07/30/2021

Therapeutically Important Adverse Effects/Advantages

Benlysta

- Can be utilized in SLE and LN
- Can be given as an infusion or administered subcutaneously
- Weekly (SC) or monthly (IV) dosing
- Indicated in adults and pediatrics (5 years and older)

Lupkynis

- Only indicated for LN
- Taken orally
- Most expensive treatment

Saphnelo

- Only FDA indicated for SLE
- Once a month infusion

Cost

Drug	Strength	Package Size	WAC Pkg Price	Cost/day*	Cost/month*	Cost/year*
Benlysta	120mg/vial, 200mg/mL, 400mg/vial	4 single dose 1 mL autoinjectors, 1 vial	$995.78	$132.77	$3,983.12	$47,797.44
Lupkynis	7.9 mg	60-count	$3,949.99	$394.98	$11,849.40	$142,192.80
Saphnelo	300 mg/2 mL	2 mL vial	$4,600.54	$153.36	$4,600.54	$55,206.48

*Based on lowest per unit WAC cost

Current Utilization

ND Medicaid Utilization (9/01/2020 – 08/31/2021)

Label Name	Rx Number	Total Reimbursement Amt
Benlysta	5	$19,977.90
Lupkynis	0	0
Saphnelo	0	0

Clinical Trials:

Benlysta

- The Phase 3 BLISS-LN trial studied the efficacy and safety of intravenous (IV) belimumab versus placebo when added to standard therapy in adults with active lupus nephritis. In the primary endpoint analysis, significantly more patients who received belimumab had a renal response at Week 104 versus placebo (43% versus. 32%). In addition, more participants in the belimumab group reached a renal response earlier (Week 52) than the placebo group, which was sustained through Week 104. Other secondary endpoints found that the risk of a renal-related event or death was lower in the belimumab group versus placebo (hazard ratio [HR] 0.5). Adverse effects between the groups were similar; the most common adverse events were upper respiratory tract (12% treatment versus 11% placebo) and urinary tract infections (7% treatment versus 6% placebo).

Lupkynis

- The Phase 3 AURORA trial studied the efficacy and safety of oral voclosporin 23.7 mg twice daily vs. placebo, in addition to mycophenolate mofetil 2 g/day and tapered low dose corticosteroids. Voclosporin met its primary endpoint of renal response at week 52 (40.8% voclosporin vs. 22.5% placebo; OR 2.65, $p<0.001$). Voclosporin also achieved all secondary endpoints, including: renal response at week 24, partial renal response at week 24, and week 52, time to UPCR ≤0.5, time to 50% reduction in UPCR. Adverse effects were similar between groups with infection reported most commonly (10.1% voclosporin group vs. 11.2% placebo group).

Saphnelo

- Saphnelo's efficacy and safety data were evaluated in 3 trials: MUSE (Trial 1; NCT01438489), TULIP-1 (Trial 2; NCT02446912), and TULIP-2 (Trial 3; NCT02446899). All 3 studies were randomized, double-blind, placebo-controlled trials in patients ≥18 years of age diagnosed with SLE according to the American College of Rheumatology (ACR) classification criteria and who were receiving standard therapy (at least one of the following: oral corticosteroids (OCSs), antimalarials, and immunosuppressants [methotrexate, azathioprine, or mycophenolate mofetil]). Results from the trials were inconsistent: although MUSE and TULIP-2 met the primary endpoints, TULIP-1 failed to do so.

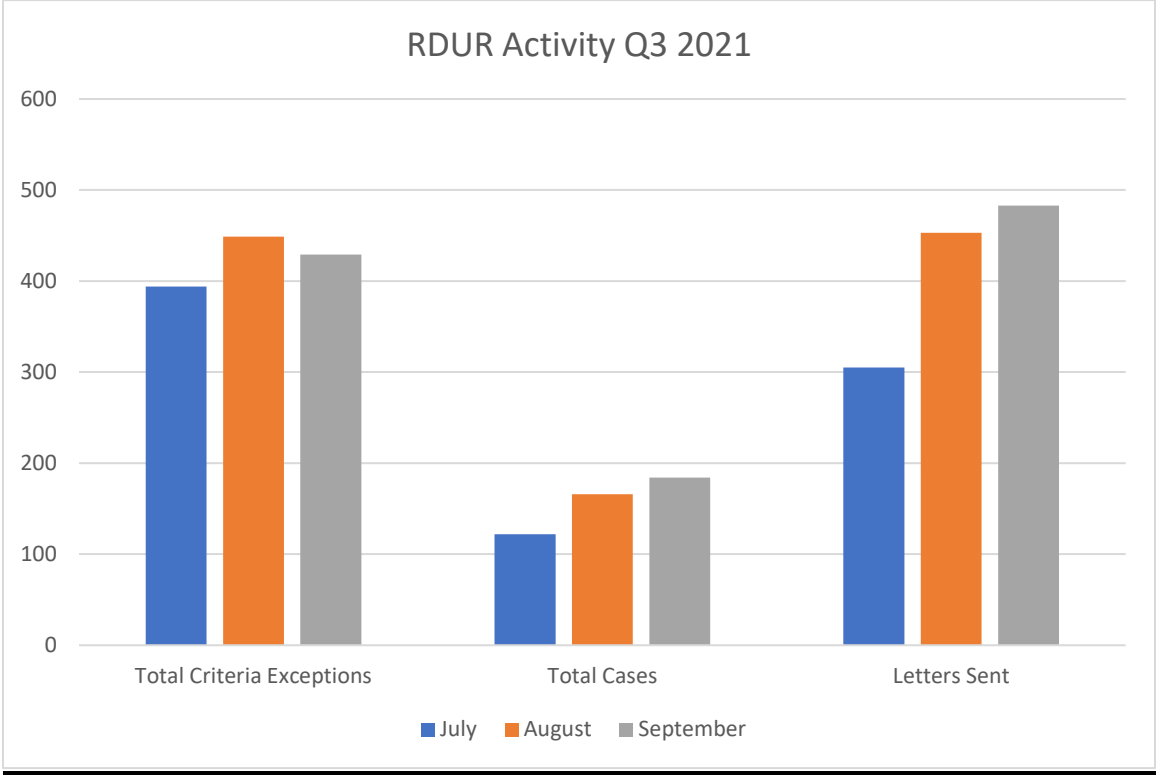
Benlysta vs. Lupkynis		
	Benlysta (belimumab)	**Lupkynis (voclosporin)**
Manufacturer	GlaxoSmithKline	Aurinia
Clinical Trial(s)	Phase 3 NCT01639339 (BLISS-LN) (N=448)	Phase 2 NCT02141672 (AURA-LV) (N=265), Phase 3 NCT03021499 (AURORA) (N=358)
Patient population	• Mean age: 33 years • 88% female • 50% Asian, 33% White, 14% Black	• Mean age: 33 years • 87% female • 38% Asian, 37% White, 8% Black
1-Year Outcome (vs. Placebo)	32.5% complete renal response vs. 25.5%	42.3% complete response (meta-analysis) vs. 23.3%
2-Year Outcome (vs. Placebo)	30% complete renal response vs. 19.7%	Not available

<table>
<tr><th colspan="4">Saphnelo Trials</th></tr>
<tr><th></th><th>Trial 1 (Phase 2) MUSE (NCT01438489)</th><th>Trial 2 (Phase 3) TULIP-1 (NCT02446912)</th><th>Trial 3 (Phase 3) TULIP-2 (NCT02446899)</th></tr>
<tr><td>Manufacturer</td><td colspan="3">MedImmune AstraZeneca</td></tr>
<tr><td>Patient population</td><td colspan="3">• Mean age of 41 years (range = 18-69 years)
• 93% female
• 42% - 70% White, 19%-42% Hispanic/Latino, 12%-14% Black/African American, 5%-17% Asian</td></tr>
<tr><td>Interventions</td><td colspan="3">N = 305
Randomized 1:1:1
Received one of the following in addition to standard therapy:
• Saphnelo IV 300mg
• Saphnelo IV 100mg
• Placebo</td></tr>
<tr><td>Interventions

Primary Endpoints</td><td rowspan="2">N = 305
Randomized 1:1:1
Received one of the following in addition to standard therapy:
• Saphnelo IV 300mg
• Saphnelo IV 100mg
• Placebo
• Combined assessment of SRI-4 and sustained reduction in OCS (10mg/day and ≤OCS dose at week 1, sustained for 12 weeks)</td><td>N = 457
Randomized 1:2:2
Received one of the following in addition to standard therapy:
• Saphnelo IV 150mg
• Saphnelo IV 300mg
• Placebo</td><td>N = 362
Randomized 1:1
Received one in addition to standard therapy:
• Saphnelo IV 300mg
• Placebo</td></tr>
<tr><td colspan="2">During weeks 8-40, patients with a baseline OCS ≥ 10mg/day were required to taper OCS dose to ≤ 7.5 mg/day, unless there was worsening of disease</td></tr>
<tr><td>BICLA Response (300mg)</td><td>54.6% Saphnelo (n=54) vs. 25.8% placebo (n=27)</td><td>Improvement in disease activity evaluated at 52 weeks, measured by SRI-4</td><td>Improvement in disease activity evaluated by 52 weeks, measured by BICLA</td></tr>
<tr><td>SRI-4 Response (300mg)</td><td>62.8% Saphnelo (n=62) vs. 38.8% placebo (n=41)</td><td>47.1% Saphnelo (n=85) vs. 30.2% placebo (n=55)</td><td>47.8% Saphnelo (n=86) vs. 31.5% placebo (n=57)</td></tr>
</table>

References:
Product Information: BENLYSTA(R) intravenous, subcutaneous injection, belimumab intravenous, subcutaneous injection. GlaxoSmithKline (per FDA), Research Triangle Park, NC, 2020.
Product Information: LUPKYNIS(TM) oral capsules, voclosporin oral capsules. Aurinia Pharma US Inc (per manufacturer), Rockville, MD, 2021.
Lupkynis Prescribing information, NCT02141672, NCT03021499
Saphnelo Prescribing Information; NCT01438489 (MUSE); NCT02446912 (TULIP-1); NCT02446899 (TULIP-2).
Product Information: SAPHNELO(TM) intravenous injection, anifrolumab-fnia intravenous injection. AstraZeneca Pharmaceuticals LP (per FDA), Wilmington, DE, 2021.
Fanouriakis A, Kostopoulou M, Alunno A, et al. Ann Rheum Dis 2019;78:736–745.

RDUR Activity Overview: Q3 2021



July Cases by Type of Criteria

Criteria Description	# of Cases	% of Cases
LAMOTRIGINE INTERACTIONS	7	5.74%
TIZANIDINE INTERACTIONS	19	15.6%
CONTRACEPTION AND HEPATIC ENZYME INDUCER INTERACTIONS	7	5.74%
TRAMADOL INTERACTIONS (TCAS, SSRIS, CARBAMAZEPINE)	12	9.84%
TOPIRAMATE INTERACTIONS	10	8.20%
STATIN INTERACTIONS	29	23.78%
CLOBAZAM INTERACTIONS	3	2.46%
CHOLESTYRAMINE INTERACTIONS	2	1.64%
CHOLESTYRAMINE & COLESTIPOL STAGGERING	5	4.10%
MIRABEGRON AND ANTIMUSCARINIC INTERACTION	1	0.82%
TACROLIMUS AND PPI INTERACTIONS	2	1.64%
CYCLOBENZAPRINE AND TCA INTERACTIONS	13	10.66%
DESMOPRESSIN AND DRUGS CAUSING WATER INTOXICATION	12	9.84%

August Cases by Type of Criteria

Criteria Description	# of Cases	% of Cases
ARIPIPRAZOLE INTERACTIONS	6	3.61%
DULPXETINE INTERACTIONS	2	1.20%
DESVENLAFAXINE INTERACTIONS	7	4.22%
CLOPIDOGREL AND PPI INTERACTION	1	0.60%
CONCURRENT OXYCODONE + BENZODIAZEPINE	29	17.47%
OTHER OXYCODONE INTERACTIONS	22	13.25%
CYP INTERACTIONS	36	21.69%
RANOLAZINE + P-GP INHIBITORS	1	0.60%
STIMULANTS + SEROTONERGIC AGENTS	20	12.05%
SGLT-2 INHIBITORS + INSULIN/SULFONYLUREA	10	6.02%
INHALERS + MAOIS/TCA'S/QT PROLONGING MEDS	5	3.01%
METFORMIN + CARBONIC ANHYDRASE INHIBITORS	2	1.20%
TRIPTANS + SSRIS/SNRIS	6	3.61%
DRONEDARONE + POTASSIUM WASTING DIURETICS	1	0.60%
PR AND QT PROLONING MEDICATIONS	4	2.41%
RIVAROXABAN AND NSAIDS	3	1.81%
LEVOMILNACIPRAN/ VORTIOXETINE + COAGULATION DRUGS	6	3.61%
ANTIPSYCHOTIC AND ANTIHYPERTENSIVE INTERACTIONS	5	3.01%

September Cases by Type of Criteria

Criteria Description	# of Cases	% of Cases
ANTI-ULCER AGENTS' LENGTH OF THERAPY	1	0.54%
HYPNOTICS LENGTH OF THERAPY	7	3.80%
SLEEP AGENTS AND ASSESSING FOR UNDERLYING CONDITIONS	6	3.26%
STIMULANTS AND PPIs	7	3.80%
PURE OPIOID AGONISTS/BUPRENORPHINE PAIN + BENZODIAZEPINES	96	52.17%
PURE OPIOID AGONISTS/BUPRENORPHINE PAIN + ANTIPSYCHOTICS	36	19.57%
QUINOLONES AND ANTIHYPERGLYCEMIC AGENTS	7	3.80%
CYP INTERACTIONS	8	4.34%
AGENTS + RENAL IMPAIRMENT	10	5.43%
DISULFURAM + BENZODIAZEPINES HEPATICALLY METABOLIZED	1	0.54%
ZIPRASIDONE + QT PROLONGATION AGENTS	4	2.17%
SOLRIAMFETOL + BP PRESSURE	1	0.54%

NORTH DAKOTA MEDICAID
RETROSPECTIVE DRUG UTILIZATION REVIEW
CRITERIA RECOMMENDATIONS
4TH QUARTER 2021

Criteria Recommendations ***Approved Rejected***

1. Selpercatinib / Overuse _____ _____
Alert Message: Retevmo (selpercatinib) may be over-utilized. The recommended daily dosage of selpercatinib is based on body weight. Patients weighing 50 kg or greater should receive 160 mg twice daily. Patients weighing less than 50 kg should receive 120 mg twice daily.

Drugs/Diseases

Util A	Util B	Util C (Negating)
Selpercatinib		Cirrhosis
		Hepatic Failure

Max Dose: 320 mg/day

References:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Retevmo Prescribing Information, Jan. 2021, Eli Lilly and Company.

2. Selpercatinib / Overuse – Severe Hepatic Impairment _____ _____
Alert Message: The dose of Retevmo (selpercatinib) should be reduced in patients with severe hepatic impairment [total bilirubin greater than 3 to 10 times the upper limit of normal (ULN) and any AST]. The daily dose of selpercatinib should not exceed 80 mg twice daily in patients with severe hepatic impairment.

Drugs/Diseases

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

Max Dose: 160 mg/day

References:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Retevmo Prescribing Information, Jan. 2021, Eli Lilly and Company.

3. Selpercatinib / Therapeutic Appropriateness _____ _____
Alert Message: The safety and effectiveness of Retevmo (selpercatinib) for the treatment of non-small cell lung cancer have not been established in pediatric patients.

Drugs/Diseases

Util A	Util B	Util C (Include)
Selpercatinib		Malignant Neoplasm of Bronchus and Lung

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Retevmo Prescribing Information, Jan. 2021, Eli Lilly and Company.

Criteria Recommendations ***Approved Rejected***

4. Selpercatinib / Therapeutic Appropriateness _____ _____
Alert Message: The safety and effectiveness of Retevmo (selpercatinib) have not been established in pediatric patients less than 12 years of age.

Drugs/Diseases

Util A	Util B	Util C
Selpercatinib		

Age Range: 0 – 11 yoa

References:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Retevmo Prescribing Information, Jan. 2021, Eli Lilly and Company.

5. Selpercatinib / Hypertension _____ _____
Alert Message: In clinical studies, hypertension occurred in 35% of patients receiving Retevmo (selpercatinib). Treatment-emergent hypertension was most commonly managed with anti-hypertension medications. Do not initiate selpercatinib in patients with uncontrolled hypertension. Optimize blood pressure prior to initiating selpercatinib. Monitor blood pressure after 1 week, at least monthly thereafter, and as clinically indicated. Initiate or adjust anti-hypertensive therapy as appropriate. Based on the severity of hypertension, withhold, reduce dose, or permanently discontinue selpercatinib.

Drugs/Diseases

Util A	Util B	Util C (Negating)
Selpercatinib	Hypertension	Antihypertensive Medications

References:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Retevmo Prescribing Information, Jan. 2021, Eli Lilly and Company.

6. Selpercatinib / Hemorrhage _____ _____
Alert Message: Serious including fatal hemorrhagic events can occur with Retevmo (selpercatinib). Grade ≥ 3 hemorrhagic events occurred in 2.3% of patients treated with selpercatinib, including 3 (0.4%) patients with fatal hemorrhagic events, including one case each of cerebral hemorrhage, tracheostomy site hemorrhage, and hemoptysis. Permanently discontinue selpercatinib in patients with severe or life-threatening hemorrhage.

Drugs/Diseases

Util A	Util B	Util C
Selpercatinib	Intracranial Hemorrhage	
	Gastrointestinal Bleeding	
	Hematuria	

References:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Retevmo Prescribing Information, Jan. 2021, Eli Lilly and Company.

7. Selpercatinib / Drugs That Prolong QT Interval _____ _____

Alert Message: Retevmo (selpercatinib) is associated with QTc interval prolongation. The concurrent use of selpercatinib with a drug that also increases the QT interval may have an additive effect. Monitor the QT interval with ECGs more frequently in patients who require treatment with concomitant medications known to prolong the QT interval.

Drugs/Diseases

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

References:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Retevmo Prescribing Information, Jan. 2021, Eli Lilly and Company.

8. Selpercatinib / QT Prolongation _____ _____

Alert Message: Retevmo (selpercatinib) can cause concentration-dependent QT interval prolongation. Monitor patients who are at significant risk of developing QTc prolongation, including patients with known long QT syndromes, clinically significant bradyarrhythmias, and severe or uncontrolled heart failure. Assess QT interval, electrolytes, and TSH at baseline and periodically during treatment, adjusting frequency based upon risk factors including diarrhea. Correct hypokalemia, hypomagnesemia, and hypocalcemia prior to initiating selpercatinib and during treatment. Based on the severity of QT prolongation, withhold and dose reduce or permanently discontinue selpercatinib.

Drugs/Diseases

Util A	Util B	Util C
Selpercatinib	Long QT Syndrome	
	Bradyarrhythmia	
	Heart Failure	

References:

Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Retevmo Prescribing Information, Jan. 2021, Eli Lilly and Company.

9. Selpercatinib / Proton Pump Inhibitors _____ _____

Alert Message: The coadministration of Retevmo (selpercatinib) with a proton pump inhibitor (PPI) should be avoided. Concomitant use of selpercatinib with acid-reducing agents decreases selpercatinib plasma concentrations, which may reduce selpercatinib anti-tumor activity. If] concurrent use of selpercatinib and a PPI cannot be avoided, take selpercatinib with food when coadministered with a PPI.

Drugs/Diseases

Util A	Util B	Util C
Selpercatinib	Dexlansoprazole	
	Esomeprazole	
	Lansoprazole	
	Omeprazole	
	Pantoprazole	
	Rabeprazole	

References:

Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Retevmo Prescribing Information, Jan. 2021, Eli Lilly and Company.

10. Selpercatinib / H2 Receptor Antagonists _____ _____

Alert Message: The coadministration of Retevmo (selpercatinib) with an H2 receptor antagonist should be avoided. Concomitant use of selpercatinib with acid-reducing agents decreases selpercatinib plasma concentrations, which may reduce selpercatinib anti-tumor activity. If concurrent use of selpercatinib and an H2 receptor antagonist cannot be avoided, take selpercatinib 2 hours before or 10 hours after administration of the H2 receptor antagonist.

Drugs/Diseases

Util A	Util B	Util C
Selpercatinib	Cimetidine	
	Famotidine	
	Nizatidine	
	Ranitidine	

References:

Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Retevmo Prescribing Information, Jan. 2021, Eli Lilly and Company.

11. Selpercatinib / Locally-Acting Antacids _____ _____

Alert Message: The coadministration of Retevmo (selpercatinib) with a locally-acting antacid should be avoided. Concomitant use of selpercatinib with acid-reducing agents decreases selpercatinib plasma concentrations, which may reduce selpercatinib anti-tumor activity. If concurrent use of selpercatinib and a locally-acting antacid cannot be avoided, take selpercatinib 2 hours before or 2 hours after administration of the locally-acting antacid.

Drugs/Diseases

Util A	Util B	Util C
Selpercatinib	Aluminum Carbonate	
	Calcium Carbonate	
	Magnesium Oxide	

References:

Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Retevmo Prescribing Information, Jan. 2021, Eli Lilly and Company.

12. Selpercatinib / Moderate & Strong CYP3A Inhibitors _____ _____

Alert Message: The coadministration of Retevmo (selpercatinib) with a moderate or strong CYP3A inhibitor should be avoided. Selpercatinib is a CYP3A substrate, and concomitant use with a moderate or strong CYP3A inhibitor increases selpercatinib plasma concentrations, which may increase the risk of selpercatinib adverse reactions, including QT interval prolongation. If concurrent use cannot be avoided, reduce the selpercatinib dose according to the approved product labeling, and monitor the QT interval.

Drugs/Diseases

Util A	Util B		Util C
Selpercatinib	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, 2021 Elsevier/Gold Standard.
Retevmo Prescribing Information, Jan. 2021, Eli Lilly and Company.

13. Selpercatinib / Moderate & Strong CYP3A Inducers _____ _____

Alert Message: The coadministration of Retevmo (selpercatinib) with a moderate or strong CYP3A inducer should be avoided. Selpercatinib is a CYP3A substrate, and concurrent use with a moderate or strong CYP3A inducer decreases selpercatinib plasma concentrations, which may reduce selpercatinib anti-tumor activity.

Drugs/Diseases

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

References:

Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Retevmo Prescribing Information, Jan. 2021, Eli Lilly and Company.

14. Selpercatinib / CYP2C8 & CYP3A Substrates _____ _____

Alert Message: Retevmo (selpercatinib) is a moderate CYP2C8 inhibitor and a weak CYP3A inhibitor. Concomitant use of selpercatinib with CYP2C8 and CYP3A substrates increases their plasma concentrations, which may increase the risk of adverse reactions related to these substrates. Avoid coadministration of selpercatinib with CYP2C8 and CYP3A substrates where minimal concentration changes may lead to increased adverse reactions. If coadministration cannot be avoided, follow recommendations for CYP2C8 and CYP3A substrates provided in their approved product labeling.

Drugs/Diseases

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

References:

Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Retevmo Prescribing Information, Jan. 2021, Eli Lilly and Company.

15. Selpercatinib / Pregnancy / Pregnancy Negating _____ _____

Alert Message: Based on findings from animal studies, and its mechanism of action, Retevmo (selpercatinib) can cause fetal harm when administered to a pregnant woman. There are no available data on selpercatinib use in pregnant women to inform of drug-associated risk. Administration of selpercatinib to pregnant rats during the period of organogenesis resulted in embryolethality and malformations at maternal exposures that were approximately equal to the human exposure at the clinical dose of 160 mg twice daily. Advise pregnant women of the potential risk to a fetus.

Drugs/Diseases

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

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Retevmo Prescribing Information, Jan. 2021, Eli Lilly and Company.

16. Selpercatinib / Therapeutic Appropriateness _____ _____

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

Drugs/Diseases

Util A	Util B	Util C
Selpercatinib	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Retevmo Prescribing Information, Jan. 2021, Eli Lilly and Company.

17. Selpercatinib / Therapeutic Appropriateness _____ _____ Alert Message:

Advise females of reproductive potential to use effective contraception during Retevmo (selpercatinib) treatment and for at least 1 week after the final dose. There are no available data on the use of selpercatinib in pregnant women to inform a drug-associated risk.

Drugs/Disease

Util A	Util B	Util C (Negating)
Selpercatinib		Contraceptives

Gender: Female
Age Rage: 11 – 50 yoa

Reference:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Retevmo Prescribing Information, Jan. 2021, Eli Lilly and Company.

18. Selpercatinib / Therapeutic Appropriateness _____ _____ Alert Message:
Advise males with female partners of reproductive potential to use effective contraception during treatment with Retevmo (selpercatinib) and for at least 1 week after the final selpercatinib dose.

Drugs/Disease
Util A Util B Util C
Selpercatinib

Gender: Male

Reference:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Retevmo Prescribing Information, Jan. 2021, Eli Lilly and Company.

19. Selpercatinib / Non-adherence _____ _____
Alert Message: Based on refill history, your patient may be under-utilizing Retevmo (selpercatinib). 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
Selpercatinib

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.

20. Ponesimod / Overuse _____ _____
Alert Message: Ponvory (ponesimod) may be over-utilized. The recommended maintenance dose of ponesimod is 20 mg orally once daily.

Drugs/Diseases
Util A Util B Util C
Ponesimod

Max Dose: 20 mg/day

References:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Ponvory Prescribing Information, March 2021, Janssen Pharmaceuticals, Inc.

21. Ponesimod / Therapeutic Appropriateness _____ _____
Alert Message: The safety and effectiveness of Ponvory (ponesimod) in pediatric patients have not been established.

Drugs/Diseases
Util A Util B Util C
Ponesimod

Age Range: 0 – 17 yoa
References:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Ponvory Prescribing Information, March 2021, Janssen Pharmaceuticals, Inc.

22. Ponesimod / Therapeutic Appropriateness _____ _____

Alert Message: Ponvory (ponesimod) is contraindicated in patients who: in the last 6 months, have experienced myocardial infarction, unstable angina, stroke, transient ischemic attack (TIA), decompensated heart failure requiring hospitalization, or Class III or IV heart failure. Ponesimod is also contraindicated in patients who have the presence of Mobitz type II second-degree, third-degree atrioventricular (AV) block, or sick sinus syndrome, or sino-atrial block, unless the patient has a functioning pacemaker.

Drugs/Diseases

Util A	Util B	Util C
Ponesimod		Heart Failure
		Heart Block
		Myocardial Infarction
		Stroke
		Transient Ischemic Attack
		Unstable Angina

References:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Ponvory Prescribing Information, March 2021, Janssen Pharmaceuticals, Inc.

23. Ponesimod / Infections _____ _____

Alert Message: Ponvory (ponesimod) may increase the susceptibility to infections. Initiation of treatment with ponesimod should be delayed in patients with an active infection until resolution. Effective diagnostic and therapeutic strategies should be employed in patients with symptoms of infection while on ponesimod. Consider interruption of treatment with ponesimod if a patient develops a serious infection.

Drugs/Diseases

Util A	Util B	Util C
Ponesimod	Infections	

References:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Ponvory Prescribing Information, March 2021, Janssen Pharmaceuticals, Inc.

24. Ponesimod / Respiratory Effects _____ _____

Alert Message: Ponvory (ponesimod) should be used with caution in patients with severe respiratory disease (i.e., pulmonary fibrosis, asthma, and chronic obstructive pulmonary disease). Ponesimod has been shown to cause dose-dependent reductions in forced expiratory volume over 1 second (FEV1) and reductions in diffusion lung capacity for carbon monoxide (DLco). There is insufficient information to determine the reversibility of the decrease in FEV1 or FVC after treatment.

Drugs/Diseases

Util A	Util B	Util C (Include)
Ponesimod		Asthma
		Chronic Obstructive Pulmonary
		Pulmonary Fibrosis

References:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Ponvory Prescribing Information, March 2021, Janssen Pharmaceuticals, Inc.

25. Ponesimod / Liver Injury _____ _____

Alert Message: Ponvory (ponesimod) is not recommended in patients with moderate or severe hepatic impairment (Child-Pugh class B and C, respectively). Patients who develop symptoms suggestive of hepatic dysfunction, such as unexplained nausea, vomiting, abdominal pain, fatigue, anorexia, a rash with eosinophilia, or jaundice and/or dark urine during treatment, should have hepatic enzymes checked. Ponesimod should be discontinued if significant liver injury is confirmed. Obtain transaminase and bilirubin levels, if not recently available (i.e., within the last 6 months) before initiation of ponesimod.

Drugs/Diseases

Util A	Util B	Util C
Ponesimod	Cirrhosis	
	Hepatic Failure	

References:

Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Ponvory Prescribing Information, March 2021, Janssen Pharmaceuticals, Inc.

26. Ponesimod / Hypertension / Antihypertensives (Negating) _____ _____

Alert Message: Ponvory (ponesimod) can cause hypertension. Blood pressure should be monitored during treatment with Ponvory (ponesimod) and managed appropriately.

Drugs/Diseases

Util A	Util B	Util C (Negating)
Ponesimod	Hypertension	Antihypertensives

References:

Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Ponvory Prescribing Information, March 2021, Janssen Pharmaceuticals, Inc.

27. Ponesimod /Skin Cancer _____ _____

Alert Message: Cases of basal cell carcinoma and other skin malignancies have been reported in patients treated with S1P receptor modulators, including Ponvory (ponesimod). Providers and patients are advised to monitor for suspicious skin lesions. If a suspicious skin lesion is observed, it should be promptly evaluated.

Drugs/Diseases

Util A	Util B	Util C (Require)
Ponesimod		Skin Cancer

References:

Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Ponvory Prescribing Information, March 2021, Janssen Pharmaceuticals, Inc.

28. Ponesimod / Strong CYP3A4 Inducers and UGT1A1 Inducers _____ _____

Alert Message: Coadministration of Ponvory (ponesimod) with strong CYP3A4 and UGT1A1 inducers is not recommended. In vitro assessments and limited clinical data indicated that concomitant use of strong CYP3A4 and UGT1A1 inducers (e.g., rifampin, phenytoin, carbamazepine) may decrease the systemic exposure of ponesimod. It is unclear whether this decrease in ponesimod systemic exposure would be considered of clinical relevance.

Drugs/Diseases

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

References:

Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Ponvory Prescribing Information, March 2021, Janssen Pharmaceuticals, Inc.

29. Ponesimod / Beta-Blockers _____ _____

Alert Message: Caution should be exercised when Ponvory (ponesimod) is initiated in patients receiving treatment with a beta-blocker because of the additive effects on lowering heart rate; temporary interruption of the beta-blocker treatment may be needed prior to initiation of ponesimod. Beta-blocker treatment can be initiated in patients receiving stable doses of ponesimod.

Drugs/Diseases

Util A	Util B	Util C
Ponesimod	Acebutolol	
	Atenolol	
	Betaxolol	
	Bisoprolol	
	Carvedilol	
	Labetalol	
	Metoprolol	
	Nadolol	
	Nebivolol	
	Pindolol	
	Propranolol	
	Sotalol	
	Timolol	

References:

Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Ponvory Prescribing Information, March 2021, Janssen Pharmaceuticals, Inc.

30. Ponesimod / QT Prolonging Drugs w/ Arrhythmogenic Properties _____ _____

Alert Message: Because of the potential additive effects on heart rate, treatment with Ponvory (ponesimod) should generally not be initiated in patients who are concurrently treated with QT-prolonging drugs with known arrhythmogenic properties, heart rate lowering calcium channel blockers (e.g., verapamil, diltiazem), or other drugs that may decrease heart rate (e.g., digoxin). If treatment with ponesimod is considered, advice from a cardiologist should be sought.

Drugs/Diseases

Util A	Util B	Util C
Ponesimod	Amiodarone	
	Digoxin	
	Diltiazem	
	Procainamide	
	Quinidine	
	Verapamil	

References:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Ponvory Prescribing Information, March 2021, Janssen Pharmaceuticals, Inc.

31. Ponesimod / Pregnancy / Pregnancy Negating _____ _____

Alert Message: Based on animal studies, Ponvory (ponesimod) may cause fetal harm. There are no adequate and well-controlled studies of ponesimod in pregnant women. In animal studies, administration of ponesimod during pregnancy produced adverse effects on development, including embryo lethality and fetal malformations, in the absence of maternal toxicity.

Drugs/Diseases

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

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Ponvory Prescribing Information, March 2021, Janssen Pharmaceuticals, Inc.

32. Ponesimod / Therapeutic Appropriateness _____ _____

Alert Message: Because it takes approximately 1 week to eliminate Ponvory (ponesimod) from the body, women of childbearing potential should use effective contraception to avoid pregnancy during and for 1 week after stopping ponesimod treatment. Based on animal studies, ponesimod may cause fetal harm.

Drugs/Diseases

Util A	Util B	Util C (Negating)
Ponesimod		Contraceptives

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Ponvory Prescribing Information, March 2021, Janssen Pharmaceuticals, Inc.

33. Ponesimod / Therapeutic Appropriateness _____ _____

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

Drugs/Diseases

Util A	Util B	Util C
Ponesimod	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Ponvory Prescribing Information, March 2021, Janssen Pharmaceuticals, Inc.

34. Ponesimod / Non-adherence _____ _____

Alert Message: Based on refill history, your patient may be under-utilizing Ponvory (ponesimod). 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
Ponesimod		

References:
Ponvory Prescribing Information, March 2021, Janssen Pharmaceuticals, Inc.
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.
Higuera L, Carlin CS, Anderson S. Adherence to Disease-Modifying Therapies for Multiple Sclerosis. J Manag Care Spec Pharm. 2016;22(12):1394-1401.

35. Ozanimod / Overuse _____ _____

Alert Message: Zeposia (ozanimod) may be overutilized. The recommended maximum maintenance dose, after the initial 7-day titration, is 0.92 mg once daily.

Drugs/Diseases

Util A	Util B	Util C
Ozanimod		

Max Dose: 0.92 mg/day

References:
Zeposia Prescribing Information, May 2021, Celgene Corporation.
Clinical Pharmacology, 2021 Elsevier/Gold Standard.

Criteria Recommendations ***Approved Rejected***

36. Ozanimod / Therapeutic Appropriateness _____ _____
Alert Message: The safety and effectiveness of Zeposia (ozanimod) in pediatric patients have not been established.

Drugs/Diseases

Util A	Util B	Util C
Ozanimod		

Age Range: 0 – 17 yoa

References:
Zeposia Prescribing Information, May 2021, Celgene Corporation.
Clinical Pharmacology, 2021 Elsevier/Gold Standard.

37. Ozanimod / Ozanimod Contraindications _____ _____
Alert Message: Zeposia (ozanimod) is contraindicated in patients who, in the last 6 months, have experienced a myocardial infarction, unstable angina, stroke, transient ischemic attack (TIA), decompensated heart failure requiring hospitalization, or Class III or IV heart failure. Ozanimod is also contraindicated in patients who have the presence of Mobitz type II second-degree, third-degree atrioventricular (AV) block, or sick sinus syndrome, or sino-atrial block, unless the patient has a functioning pacemaker.

Drugs/Diseases

Util A	Util B	Util C (Include)
Ozanimod		Heart Failure
		Heart Block
		Myocardial Infarction
		Stroke
		Transient Ischemic Attack
		Unstable Angina

References:
Zeposia Prescribing Information, May 2021, Celgene Corporation.
Clinical Pharmacology, 2021 Elsevier/Gold Standard.

38. Ozanimod / Sleep Apnea _____ _____
Alert Message: Zeposia (ozanimod) is contraindicated in patients who have severe untreated sleep apnea.

Drugs/Diseases

Util A	Util B	Util C
Ozanimod	Sleep Apnea	

References:
Zeposia Prescribing Information, May 2021, Celgene Corporation.
Clinical Pharmacology, 2021 Elsevier/Gold Standard.

39. Ozanimod / Monoamine Oxidase Inhibitors _____ _____

Alert Message: Zeposia (ozanimod) is contraindicated in patients who taking MAO inhibitors (e.g., selegiline, phenelzine, linezolid). At least 14 days should elapse between discontinuation of ozanimod and initiation of treatment with MAO inhibitors. Metabolites of ozanimod inhibit MAO. The potential for a clinical interaction with MAO inhibitors has not been studied; however, the increased risk of nonselective MAO inhibition may lead to a hypertensive crisis.

Drugs/Diseases

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

References:
Zeposia Prescribing Information, May 2021, Celgene Corporation.
Clinical Pharmacology, 2021 Elsevier/Gold Standard.

40. Ozanimod / Hepatic Impairment _____ _____

Alert Message: The use of Zeposia (ozanimod) in patients with hepatic impairment is not recommended. Elevations of aminotransferases may occur in patients receiving ozanimod. Patients who develop symptoms suggestive of hepatic dysfunction, such as unexplained nausea, vomiting, abdominal pain, fatigue, anorexia, or jaundice and/or dark urine, should have hepatic enzymes checked, and ozanimod should be discontinued if significant liver injury is confirmed.

Drugs/Diseases

Util A	Util B	Util C
Ozanimod	Hepatic Impairment	

References:
Zeposia Prescribing Information, May 2021, Celgene Corporation.
Clinical Pharmacology, 2021 Elsevier/Gold Standard.

41. Ozanimod / Infections _____ _____

Alert Message: Zeposia (ozanimod) may increase the susceptibility to infections, some serious in nature. Life-threatening and rare fatal infections have occurred in patients receiving ozanimod. Consider interruption of treatment with ozanimod if a patient develops a serious infection. Because the elimination of ozanimod after discontinuation may take up to 3 months, continue monitoring for infections throughout this period.

Drugs/Diseases

Util A	Util B	Util C
Ozanimod	Infections	

References:
Zeposia Prescribing Information, May 2021, Celgene Corporation.
Clinical Pharmacology, 2021 Elsevier/Gold Standard.

42. Ozanimod / Hypertension / Antihypertensives (Negating) _____ _____

Alert Message: In a clinical study, hypertension was reported as an adverse reaction in patients treated with Zeposia (ozanimod). Blood pressure should be monitored during treatment with ozanimod and managed appropriately.

Drugs/Diseases

Util A	Util B	Util C (Negating)
Ozanimod	Hypertension	Antihypertensives

References:
Zeposia Prescribing Information, May 2021, Celgene Corporation.
Clinical Pharmacology, 2021 Elsevier/Gold Standard.

43. Ozanimod / Macula Edema _____ _____

Alert Message: Sphingosine 1-phosphate (S1P) receptor modulators, including Zeposia (ozanimod), have been associated with an increased risk of macular edema. An ophthalmic evaluation of the fundus, including the macula, is recommended in all patients at any time if there is any change in vision while taking ozanimod. Continuation of ozanimod therapy in patients with macular edema has not been evaluated. A decision on whether or not ozanimod should be discontinued needs to take into account the potential benefits and risks for the individual patient.

Drugs/Diseases

Util A	Util B	Util C
Ozanimod	Macula Edema	

References:
Zeposia Prescribing Information, May 2021, Celgene Corporation.
Clinical Pharmacology, 2021 Elsevier/Gold Standard.

44. Ozanimod / CYP2C8 Inhibitors _____ _____

Alert Message: The co-administration of Zeposia (ozanimod), a CYP2C8 substrate, with a strong CYP2C8 inhibitor may increase the exposure of the active metabolites of ozanimod, which may increase the risk of ozanimod-related adverse reactions. Co-administration of ozanimod with strong CYP2C8 inhibitors (e.g., gemfibrozil) is not recommended.

Drugs/Diseases

Util A	Util B	Util C
Ozanimod	Gemfibrozil	

References:
Zeposia Prescribing Information, May 2021, Celgene Corporation.
Clinical Pharmacology, 2021 Elsevier/Gold Standard.

45. Ozanimod / CYP2C8 Inducers _____ _____

Alert Message: The co-administration of Zeposia (ozanimod), a CYP2C8 substrate, with a strong CYP2C8 inducer may decrease the exposure of the active metabolites of ozanimod, which may decrease the ozanimod efficacy. Co-administration of ozanimod with strong CYP2C8 inhibitors (e.g., gemfibrozil) is not recommended.

Drugs/Diseases

Util A	Util B	Util C
Ozanimod	Rifampin	

References:
Zeposia Prescribing Information, May 2021, Celgene Corporation.
Clinical Pharmacology, 2021 Elsevier/Gold Standard.

46. Ozanimod / Drugs that Increase Serotonin or Norepinephrine _____ _____

Alert Message: The co-administration of Zeposia (ozanimod) with medications that can increase norepinephrine or serotonin (e.g., opioid drugs, SSRIs, SNRIs, and tricyclics) is not recommended. Ozanimod has an active metabolite that is an MOA-B inhibitor and there is a potential for serious adverse reactions, including hypertensive crisis with coadministration of ozanimod with these medications.

Drugs/Diseases

Util A	Util B	Util C
Ozanimod	Amphetamines	
	Opioids	
	SNRI's	
	SSRIs	
	Tricyclic Antidepressants	

References:
Zeposia Prescribing Information, May 2021, Celgene Corporation.
Clinical Pharmacology, 2021 Elsevier/Gold Standard.

47. Ozanimod / Calcium Channel Blockers / Beta Blockers _____ _____

Alert Message: The co-administration of Zeposia (ozanimod) with both a beta-blocker and a calcium channel blocker has not been studied. The triple-drug combination of ozanimod, a beta-blocker, and a calcium channel blocker could potentially have an additive effect on the heart rate. Initiation of ozanimod may result in a transient decrease in heart rate and atrioventricular conduction delays. Treatment with ozanimod should generally not be initiated in patients who are concurrently treated with both a heart rate lowering calcium channel blocker (e.g., verapamil, diltiazem) and beta-blocker. If treatment initiation with ozanimod is considered in patients on both a heart rate lowering calcium channel blocker and beta-blocker, advice from a cardiologist should be sought.

Drugs/Diseases

Util A	Util B	Util C (Include)	
Ozanimod	Diltiazem	Acebutolol	Nadolol
	Verapamil	Atenolol	Nebivolol
		Betaxolol	Pindolol
		Bisoprolol	Propranolol
		Carvedilol	Sotalol
		Labetalol	Timolol
		Metoprolol	

References:
Zeposia Prescribing Information, May 2021, Celgene Corporation.
Clinical Pharmacology, 2021 Elsevier/Gold Standard.

48. Ozanimod / QT prolongation Drugs _____ _____

Alert Message: Zeposia (ozanimod) has not been studied in patients taking QT prolonging drugs. Because of the potential additive effects on heart rate, treatment with ozanimod should generally not be initiated in patients who are concurrently treated with QT-prolonging drugs with known arrhythmogenic properties. If treatment initiation with ozanimod is considered in patients on QT-prolonging drugs, advice from a cardiologist should be sought.

Drugs/Diseases

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

References:
Zeposia Prescribing Information, May 2021, Celgene Corporation.
Clinical Pharmacology, 2021 Elsevier/Gold Standard.

49. Ozanimod / Pregnancy / Pregnancy Negating _____ _____

Alert Message: There are no adequate data on the developmental risk associated with the use of Zeposia (ozanimod) in pregnant women. In animal studies, administration of ozanimod during pregnancy produced adverse effects on development, including embryolethality, an increase in fetal malformations, and neurobehavioral changes, in the absence of maternal toxicity. In rabbits, fetal blood vessel malformations occurred at clinically relevant maternal ozanimod and metabolite exposures. The receptor affected by ozanimod (sphingosine1-phosphate) has been demonstrated to have an important role in embryogenesis, including vascular and neural development.

Drugs/Diseases

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

Gender: Female
Age Range: 11 – 50 yoa

References:
Zeposia Prescribing Information, May 2021, Celgene Corporation.
Clinical Pharmacology, 2021 Elsevier/Gold Standard.

50. Ozanimod / Lactation _____ _____

Alert Message: There are no data on the presence of Zeposia (ozanimod) in human milk, the effects on the breastfed infant, or the effects of the drug on milk production. In animal studies, following oral administration of ozanimod, ozanimod and/or metabolites were detected in the milk of lactating rats at levels higher than those in maternal plasma. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for ozanimod and any potential adverse effects on the breastfed infant from ozanimod or the underlying maternal condition.

Drugs/Diseases

Util A	Util B	Util C
Ozanimod	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

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

51. Ozanimod / Therapeutic Appropriateness _____ _____

Alert Message: Before initiation of Zeposia (ozanimod) treatment, women of childbearing potential should be counseled on the potential for serious risk to the fetus and the need for contraception during treatment with ozanimod. Because of the time it takes to eliminate the drug from the body after stopping treatment, the potential risk to the fetus may persist and women of childbearing age should also use effective contraception for 3 months after stopping ozanimod.

Drugs/Diseases

Util A	Util B	Util C (Negating)
Ozanimod		Contraceptives

Gender: Female
Age Range: 11 – 50 yoa

References:
Zeposia Prescribing Information, May 2021, Celgene Corporation.

52. Ozanimod / Non-adherence _____ _____

Alert Message: Based on refill history, your patient may be under-utilizing Zeposia (ozanimod). 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
Ozanimod		

References:

Osterberg L, Blaschke T. Adherence to Medication. N Engl J Med 2005; 353:487- 497.
McKay KA, Tremlett H, Patten SB, et al. Determinants of Non-Adherence to Disease-Modifying Therapies in Multiple Sclerosis: A Cross-Canada Prospective Study. Mult Scler. 2016;23(4):588-596.
Higuera L, Carlin CS, Anderson S. Adherence to Disease-Modifying Therapies for Multiple Sclerosis. J Manag Care Spec Pharm. 2016;22(12):1394–1401.

53. Serdexmethylphenidate/Dexmethylphenidate / Overuse _____ _____

Alert Message: Azstarys (serdexmethylphenidate/dexmethylphenidate) may be over-utilized. The maximum recommended dosage of serdexmethylphenidate/dexmethylphenidate, in patients 6 to 12 years of age is 52.3 mg serdexmethylphenidate /10.4mg dexmethylphenidate once daily.

Drugs/Diseases

Util A	Util B	Util C
Serdexmethylphenidate/dexmethylphenidate		

Age Range: 6 – 12 yoa
Max Dose: 52.3 mg/10.4mg once daily

References:

Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Azstarys Prescribing Information, March 2021, Corium, Inc.

54. Serdexmethylphenidate/Dexmethylphenidate / Overuse _____ _____

Alert Message: Azstarys (serdexmethylphenidate/dexmethylphenidate) may be over-utilized. The maximum recommended dosage of serdexmethylphenidate/dexmethylphenidate, in patients 13 years of age and older is 52.3 mg serdexmethylphenidate /10.4mg dexmethylphenidate once daily.

Drugs/Diseases

Util A	Util B	Util C
Serdexmethylphenidate/dexmethylphenidate		

Age Range: ≥13 yoa
Max Dose: 52.3 mg/10.4mg once daily

References:

Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Azstarys Prescribing Information, March 2021, Corium, Inc.

55. Serdexmethylphenidate/Dexmethylphenidate / Risperidone _____ _____

Alert Message: When Azstarys (serdexmethylphenidate/dexmethylphenidate) is co-administered with risperidone, and there is a change in dosage of either or both medications, whether an increase or decrease, this may increase the risk of extrapyramidal symptoms (EPS). Monitor patients for signs of EPS.

Drugs/Diseases

Util A	Util B	Util C
Serdexmethylphenidate/dexmethylphenidate	Risperidone	

References:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Azstarys Prescribing Information, March 2021, Corium, Inc.

56. Serdexmethylphenidate/Dexmethylphenidate / Pregnancy _____ _____

Alert Message: There are no available data on Azstarys (serdexmethylphenidate/dexmethylphenidate) use in pregnant women to evaluate for a drug-associated risk of major birth defects, miscarriage, or other adverse maternal or fetal outcomes. Serdexmethylphenidate is a prodrug of dexmethylphenidate and dexmethylphenidate is the d-threo enantiomer of racemic methylphenidate. There may be risks to the fetus associated with the use of CNS stimulants use during pregnancy. CNS stimulants, such as serdexmethylphenidate/dexmethylphenidate, can cause vasoconstriction and thereby decrease placental perfusion.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Serdexmethylphenidate/dexmethylphenidate	Pregnancy	Abortion Delivery Miscarriage

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Azstarys Prescribing Information, March 2021, Corium, Inc.

57. Serdexmethylphenidate/Dexmethylphenidate / Lactation _____ _____

Alert Message: The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Azstarys (serdexmethylphenidate/dexmethylphenidate) and any potential adverse effects on the breastfed infant from serdexmethylphenidate/dexmethylphenidate or the underlying maternal condition. There are no available data on the presence of serdexmethylphenidate in human milk, effects on the breastfed infant, or effects on milk production. Dexmethylphenidate is the d-threo enantiomer of racemic methylphenidate, and methylphenidate has been shown to be present in human breast milk.

Drugs/Diseases

Util A	Util B	Util C
Serdexmethylphenidate/dexmethylphenidate	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Azstarys Prescribing Information, March 2021, Corium, Inc.

58. Serdexmethylphenidate/Dexmethylphenidate / MAOIs _____ _____
Alert Message: The safety and effectiveness of Azstarys (serdexmethylphenidate/dexmethylphenidate) in pediatric patients less than 6 years have not been established.

Drugs/Diseases

Util A	Util B	Util C
Serdexmethylphenidate/dexmethylphenidate		

Age Range: 0 - 5 yoa

References:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Azstarys Prescribing Information, March 2021, Corium, Inc.

59. Exenatide ER / Therapeutic Appropriateness _____ _____
Alert Message: The safety and effectiveness of Bydureon Bcise (exenatide extended-release) have not been established in pediatric patients less than 10 years of age.

Drugs/Diseases

Util A	Util B	Util C
Exenatide ER		

Age Range: 0 – 9 yoa

References:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Bydureon Bcise Prescribing Information. July 2021, AstraZeneca.

60. Risperidone SubQ / Overuse _____ _____
Alert Message: Perseris (risperidone extended-release subcutaneous injection) may be over-utilized. Initiate subcutaneous risperidone at a dose of 90 mg or 120 mg once monthly. Do not administer more than one dose (90 mg or 120 mg total) per month.

Drugs/Diseases

Util A	Util B	Util C
Risperidone SubQ		

Max Dose: 1 injection/month

References:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Facts & Comparisons, 2021 Updates, Wolters Kluwer Health.
Perseris Prescribing Information, December 2019, Indivior, Inc.

61. Risperidone SubQ / Oral Risperidone / Strong 3A4 Inducers (Negating) _____ _____
Alert Message: Neither a loading dose nor any supplemental oral risperidone is recommended with Perseris (risperidone extended-release subcutaneous injection).

Drugs/Diseases

Util A	Util B	Util C (Negating)	
Risperidone SubQ	Oral Risperidone	Apalutamide	Phenobarbital
		Carbamazepine	Phenytoin
		Enzalutamide	Primidone
		Mitotane	Rifampin

References:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.

Facts & Comparisons, 2021 Updates, Wolters Kluwer Health.
Perseris Prescribing Information, December 2019, Indivior, Inc.

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

62. Risperidone SubQ / Therapeutic Appropriateness _____ _____
Alert Message: The safety and effectiveness of Perseris (risperidone extended-release subcutaneous injection) have not been established in pediatric patients.

Drugs/Diseases

Util A	Util B	Util C
Risperidone SubQ		

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Facts & Comparisons, 2021 Updates, Wolters Kluwer Health.
Perseris Prescribing Information, December 2019, Indivior, Inc.

63. Risperidone SubQ / Strong CYP34A4 Inducers _____ _____
Alert Message: Concomitant use of Perseris (risperidone extended-release subcutaneous injection) with a strong CYP3A4 inducer may result in decreased risperidone plasma concentrations, which could lead to decreased risperidone efficacy. A risperidone dosage increase may be considered. Refer to the official prescribing information for risperidone dosage modifications.

Drugs/Diseases

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

References:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Facts & Comparisons, 2021 Updates, Wolters Kluwer Health.
Perseris Prescribing Information, December 2019, Indivior, Inc.

64. Risperidone SubQ / Strong CYP2D6 Inhibitors _____ _____
Alert Message: Concomitant use of Perseris (risperidone extended-release subcutaneous injection) with a strong CYP2D6 inhibitor may increase risperidone plasma concentrations, increasing the risk of risperidone-related adverse effects. A risperidone dosage adjustment may be considered when a strong CYP2D6 inhibitor is initiated or discontinued. Refer to the official prescribing information for risperidone dosage modifications.

Drugs/Diseases

Util A	Util B	Util C
Risperidone SubQ	Bupropion	
	Dacomitinib	
	Fluoxetine	
	Paroxetine	
	Quinidine	

References:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Facts & Comparisons, 2021 Updates, Wolters Kluwer Health.
Perseris Prescribing Information, December 2019, Indivior, Inc.

65. Risperidone SubQ / Non-adherence _____ _____

Alert Message: Based on refill history, your patient may be under-utilizing Perseris (risperidone extended-release subcutaneous injection). 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
Risperidone SubQ		

References:

Higashi k, Medic G, Littlewood K, et al., Medication Adherence in Schizophrenia: Factors Influencing Adherence and Consequences of Nonadherence, A Systemic Literature Review. There Adv Psychopharmacol. 2013 2(4):200-218.
Acsher-Svanum H, Zhu B, Faries DE, et al., The Cost of Relapse and the Predictors of Relapse in the Treatment of Schizophrenia. BMC Psychiatry 2010, 10:2.
Berger A, Edelsbery J, Sanders KN, et al., Medication Adherence and Utilization in Patients with Schizophrenia or Bipolar Disorder Receiving Aripiprazole, Quetiapine, or Ziprasidone at Hospital Discharge: A Retrospective Cohort Study. BMC Psychiatry 2012;12:99.
Stephenson JJ, Tuncelli O, Gu T, et al. Adherence to Oral Second-Generation Antipsychotic Medications in Patients with Schizophrenia and Bipolar Disorder: Physicians' Perceptions of Adherence vs. Pharmacy Claims. Int J Clin Pract. June 2012, 66, 6, 565-573.

66. Elexacaftor/Tezacaftor/Ivacaftor / Hepatic Impairment _____ _____

Alert Message: In clinical studies, the use of Trikafta (elexacaftor/tezacaftor/ivacaftor) in patients with moderate hepatic impairment (Child-Pugh Class B) resulted in a higher AUC and Cmax for each individual. Treatment is not recommended for patients with moderate hepatic impairment. If use is clinically warranted in patients with moderate hepatic impairment, elexacaftor/tezacaftor/ivacaftor should be used with caution at a reduced dose, according to official prescribing information. Liver function tests should be closely monitored in patients with mild and moderate hepatic impairment. No dose modification is recommended for patients with mild hepatic impairment (Child-Pugh Class A).

Drugs/Diseases

Util A	Util B	Util C
Elexacaftor/Tezacaftor/Ivacaftor	Hepatic Impairment	

References:

Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Trikafta Prescribing Information, June 2021, Vertex Pharmaceuticals Inc.

67. Elexacaftor/Tezacaftor/Ivacaftor / Severe Hepatic Impairment _____ _____

Alert Message: Trikafta (elexacaftor/tezacaftor/ivacaftor) should not be used in patients with severe hepatic impairment (Child-Pugh Class C). Elexacaftor/tezacaftor/ivacaftor has not been studied in this patient population. In clinical studies, patients with moderate hepatic impairment (Child-Pugh Class B) had increased exposure to all three components of the co-packaged product. Drug exposure is expected to be even higher in patients with severe hepatic impairment.

Drugs/Diseases

Util A	Util B	Util C
Elexacaftor/Tezacaftor/Ivacaftor	Cirrhosis Hepatic Failure	

References:

Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Trikafta Prescribing Information, June 2021, Vertex Pharmaceuticals Inc.

68. Elexacaftor/Tezacaftor/Ivacaftor / Therapeutic Appropriateness _____ _____
Alert Message: The safety and effectiveness of Trikafta (elexacaftor/tezacaftor/ivacaftor) in patients with CF younger than 6 years of age have not been established.

Drugs/Diseases

Util A	Util B	Util C
Elexacaftor/Tezacaftor/Ivacaftor		

Age Range: 0 – 5 yoa

References:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Trikafta Prescribing Information, June 2021, Vertex Pharmaceuticals Inc.

69. Elexacaftor/Tezacaftor/Ivacaftor / CYP3A Inducers _____ _____
Alert Message: Exposure to ivacaftor is significantly decreased and exposure to elexacaftor and tezacaftor are expected to decrease by the concomitant use of strong CYP3A inducers, which may reduce the therapeutic effectiveness of Trikafta (elexacaftor/tezacaftor/ivacaftor). Therefore, co-administration with strong CYP3A inducers is not recommended.

Drugs/Diseases

Util A	Util B	Util C
Elexacaftor/Tezacaftor/Ivacaftor	Apalutamide	
	Carbamazepine	
	Enzalutamide	
	Mitotane	
	Phenobarbital	
	Phenytoin	
	Primidone	
	Rifampin	

References:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Trikafta Prescribing Information, June 2021, Vertex Pharmaceuticals Inc.

70. Elexacaftor/Tezacaftor/Ivacaftor / Moderate & Strong CYP3A4 Inhibitors _____ _____
Alert Message: Exposure to elexacaftor, tezacaftor, and ivacaftor is increased when co-administered with strong or moderate CYP3A inhibitors. The dose of Trikafta (elexacaftor/tezacaftor/ivacaftor) should be reduced, according to the official prescribing information, when used concomitantly with moderate or strong CYP3A inhibitors.

Drugs/Diseases

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

References:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Trikafta Prescribing Information, June 2021, Vertex Pharmaceuticals Inc.

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

71. Elexacaftor/Tezacaftor/Ivacaftor / Sensitive P-gp Substrates _____ _____
Alert Message: Caution and appropriate monitoring should be used when Trikafta (elexacaftor/tezacaftor/ivacaftor) is co-administered with a P-gp substrate with a narrow therapeutic index. The ivacaftor component of the co-packaged combination product is a P-gp inhibitor, and concurrent use with a sensitive P-gp substrate may result in increased substrate exposure. Appropriate monitoring should be used when these agents are co-administered.

Drugs/Diseases

Util A	Util B	Util C
Elexacaftor/Tezacaftor/Ivacaftor	Digoxin	
	Cyclosporine	
	Tacrolimus	
	Sirolimus	
	Everolimus	

References:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Trikafta Prescribing Information, June 2021, Vertex Pharmaceuticals Inc.

72. Elexacaftor/Tezacaftor/Ivacaftor / Pregnancy / Pregnancy Negating _____ _____
Alert Message: There are limited and incomplete human data from clinical trials on the use of Trikafta (elexacaftor/tezacaftor/ivacaftor) or its individual components in pregnant women to inform a drug-associated risk. Although there are no animal reproduction studies with the concomitant administration of elexacaftor, tezacaftor, and ivacaftor, separate reproductive and developmental studies were conducted with each component in pregnant rats and rabbits. Placental transfer in pregnant rats was observed for each component. No component was found to affect fetal survival or to be teratogenic.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Elexacaftor/Tezacaftor/Ivacaftor	Pregnancy	Abortion
		Delivery
		Miscarriage

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Trikafta Prescribing Information, June 2021, Vertex Pharmaceuticals Inc.

73. Elexacaftor/Tezacaftor/Ivacaftor / Lactation _____ _____
Alert Message: There is no information regarding the presence of elexacaftor, tezacaftor, or ivacaftor in human milk, the effects on the breastfed infant, or the effects on milk production. In animal studies, elexacaftor, tezacaftor, and ivacaftor 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 Trikafta (elexacaftor/tezacaftor/ivacaftor) and any potential adverse effects on the breastfed child from (elexacaftor/tezacaftor/ivacaftor) or the underlying maternal condition.

Drugs/Diseases

Util A	Util B	Util C
Elexacaftor/Tezacaftor/Ivacaftor	Lactation	

Gender: Female

Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Trikafta Prescribing Information, June 2021, Vertex Pharmaceuticals Inc.

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

74. Elexacaftor/Tezacaftor/Ivacaftor / Non-adherence _____ _____
Alert Message: Based on refill history, your patient may be under-utilizing Trikafta (elexacaftor/tezacaftor/ivacaftor). 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
Elexacaftor/Tezacaftor/Ivacaftor

References:
Osterberg L, Blaschke T. Adherence to Medication. N Engl J Med 2005;353:487-97.
Eakin MN, Bilderback A, Boyle MP, et al., Longitudinal Association Between Medication Adherence and Lung Health in People with Cystic Fibrosis. Jrnl Cyst Fib. 2011:10(4):258-264.
Bishay LC, Sawicki GS., Strategies to Optimize Adherence in Adolescent Patients with Cystic Fibrosis. Adolesc Health, Med & Ther. 2016 Oct21;7:117-124.

75. Monomethyl Fumarate / Overuse _____ _____
Alert Message: Bafiertam (monomethyl fumarate) may be over-utilized. The recommended maintenance dose after 7 days is 190 mg twice a day.

Drugs/Diseases
Util A Util B Util C
Monomethyl Fumarate

Max Dose: 380 mg/day

References:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Bafiertam Prescribing Information, May 2021, Banner Life Sciences.

76. Monomethyl Fumarate / Therapeutic Appropriateness _____ _____
Alert Message: The safety and effectiveness of Bafiertam (monomethyl fumarate) in pediatric patients have not been established.

Drugs/Diseases
Util A Util B Util C
Monomethyl Fumarate

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Bafiertam Prescribing Information, May 2021, Banner Life Sciences.

77. Monomethyl Fumarate / Dimethyl Fumarate & Diroximel Fumarate _____ _____

Alert Message: Coadministration of Bafiertam (monomethyl fumarate) with dimethyl fumarate or diroximel fumarate is contraindicated. Both dimethyl fumarate and diroximel fumarate are metabolized to monomethyl fumarate. Concurrent use of monomethyl fumarate with these drugs may lead to toxic adverse effects. Monomethyl fumarate may be initiated the day following discontinuation of either drug.

Drugs/Diseases

Util A	Util B	Util C
Monomethyl Fumarate	Dimethyl Fumarate	
	Diroximel Fumarate	

References:

Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Bafiertam Prescribing Information, May 2021, Banner Life Sciences.

78. Monomethyl Fumarate / Progressive Multifocal Leukoencephalopathy _____ _____

Alert Message: Progressive multifocal leukoencephalopathy (PML) has occurred in patients with MS treated with dimethyl fumarate, the prodrug of Bafiertam (monomethyl fumarate). At the first sign or symptom suggestive of PML, withhold monomethyl fumarate and perform an appropriate diagnostic evaluation. Typical symptoms associated with PML are diverse, progress over days to weeks, and include progressive weakness on one side of the body or clumsiness of limbs, disturbance of vision, and changes in thinking, memory, and orientation leading to confusion and personality changes.

Drugs/Diseases

Util A	Util B	Util C
Monomethyl Fumarate	Visual Disturbances	
	Muscle Weakness	
	Disorientation	
	Altered Mental Status	

References:

Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Bafiertam Prescribing Information, May 2021, Banner Life Sciences.

79. Monomethyl Fumarate / Serious Opportunistic Infections _____ _____

Alert Message: Serious opportunistic infections have occurred with dimethyl fumarate, the product of Bafiertam (monomethyl fumarate), including cases of serious viral (herpes simplex virus, West Nile virus, cytomegalovirus), fungal (Candida and Aspergillus), and bacterial (Nocardia, Listeria monocytogenes, Mycobacterium tuberculosis) infections. Patients with symptoms and signs consistent with any of these infections should undergo prompt diagnostic evaluation and receive appropriate treatment. Consider withholding dimethyl fumarate treatment in patients with herpes zoster or other serious infections until the infection has resolved.

Drugs/Diseases

Util A	Util B	Util C
Monomethyl Fumarate	Infections	

References:

Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Bafiertam Prescribing Information, May 2021, Banner Life Sciences.

80. Monomethyl Fumarate / Flushing / Aspirin _____ _____

Alert Message: Bafiertam (monomethyl fumarate) may cause flushing (e.g., warmth, redness, itching, and/or burning sensation). Studies with dimethyl fumarate, the prodrug of monomethyl fumarate, show that administration of non-enteric coated aspirin (up to a dose of 325 mg) 30 minutes prior to dosing may reduce the incidence or severity of flushing.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Dimethyl Fumarate	Flushing	Aspirin

References:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Bafiertam Prescribing Information, May 2021, Banner Life Sciences.

81. Monomethyl Fumarate / Pregnancy / Pregnancy Negating _____ _____

Alert Message: There are no adequate data on the developmental risk associated with the use of Bafiertam (monomethyl fumarate) or dimethyl fumarate (the prodrug of monomethyl fumarate) in pregnant women. Monomethyl fumarate may cause fetal harm. In animal studies, adverse effects on offspring survival, growth, sexual maturation, and neurobehavioral function were observed when dimethyl fumarate was administered during pregnancy and lactation at clinically relevant doses.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Monomethyl Fumarate	Pregnancy	Abortion
		Delivery
		Miscarriage

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Bafiertam Prescribing Information, May 2021, Banner Life Sciences.

82. Monomethyl Fumarate / Therapeutic Appropriateness _____ _____

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

Drugs/Diseases

Util A	Util B	Util C
Monomethyl Fumarate	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Bafiertam Prescribing Information, May 2021, Banner Life Sciences.

83. Monomethyl Fumarate / Abnormal Liver Function Studies _____ _____

Alert Message: Clinically significant cases of liver injury have been reported in patients treated with dimethyl fumarate, the prodrug of Bafiertam (monomethyl fumarate, in the postmarketing setting. Obtain serum aminotransferase, alkaline phosphatase (ALP), and total bilirubin levels prior to treatment with monomethyl fumarate and during treatment, as clinically indicated. Discontinue monomethyl fumarate if clinically significant liver injury induced by monomethyl fumarate is suspected.

Drugs/Diseases

Util A	Util B	Util C
Monomethyl Fumarate	Abnormal Results in Liver Function Studies	

References:

Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Bafiertam Prescribing Information, May 2021, Banner Life Sciences.

84. Monomethyl Fumarate / Non-adherence _____ _____

Alert Message: Based on refill history, your patient may be under-utilizing Bafiertam (monomethyl fumarate). 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
Monomethyl Fumarate		

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

85. **Cyclobenzaprine ER / Therapeutic Appropriateness** _____ _____

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

Drugs/Diseases

Util A	Util B	Util C
Cyclobenzaprine ER		

Age Range: 0 – 17 yoa

References:

Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Retevmo Prescribing Information, Jan.2021, Eli Lilly and Company.

86. Ripretinib / Overuse _____ _____ Alert Message:
Qinlock (ripretinib) may be over-utilized. The manufacturer's recommended maximum daily dosage of ripretinib is 150 mg orally once daily.

Drugs/Disease
Util A Util B Util C
Ripretinib

Max Dose: 150 mg/day

Reference:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Qinlock Prescribing Information, June 2021, Deciphera Pharmaceuticals, LLC.

87. Ripretinib / Therapeutic Appropriateness _____ _____ Alert Message:
The safety and effectiveness of Qinlock (ripretinib) in pediatric patients have not been established.

Drugs/Disease
Util A Util B Util C
Ripretinib

Age Range: 0 – 17 yoa

Reference:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Qinlock Prescribing Information, June 2021, Deciphera Pharmaceuticals, LLC.

88. Ripretinib / Therapeutic Appropriateness _____ _____ Alert Message:
Palmar-plantar erythrodysesthesia syndrome (PPES) has occurred in patients who received Qinlock (ripretinib). In clinical trials, PPES led to dose discontinuation in 1.2% of patients, dose interruption in 2.4% of patients, and dose reduction in 1.2% of patients. Based on severity, withhold ripretinib and then resume at the same or reduced dose.

Drugs/Disease
Util A Util B Util C
Ripretinib Localized skin eruption due to drugs and medications taken internally

Reference:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Qinlock Prescribing Information, June 2021, Deciphera Pharmaceuticals, LLC.

89. Ripretinib / Other Malignancies _____ _____

Alert Message: New primary malignancy (e.g., cutaneous squamous-cell carcinoma, keratoacanthoma, and melanoma) has been reported with Qinlock (ripretinib) therapy. Dermatologic evaluations should be performed prior to starting ripretinib therapy and routinely during treatment. Manage suspicious skin lesions with excision and dermatopathologic evaluation. Continue ripretinib at the same dose.

Drugs/Disease

Util A	Util B	Util C
Ripretinib	Squamous Cell Carcinoma	
	Keratoacanthoma	
	Melanoma	

Reference:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Qinlock Prescribing Information, June 2021, Deciphera Pharmaceuticals, LLC.

90. Ripretinib / Hypertension _____ _____

Alert Message: Hypertension has been reported with Qinlock (ripretinib) therapy. Do not initiate ripretinib in patients with uncontrolled hypertension. Adequately control blood pressure prior to initiating ripretinib. Monitor blood pressure as clinically indicated during treatment with ripretinib and initiate or adjust antihypertensive therapy as appropriate. Based on severity, withhold ripretinib and then resume at the same or reduced dose or permanently discontinue.

Drugs/Disease

Util A	Util B	Util C (Negating)
Ripretinib	Hypertension	Antihypertensives

Reference:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Qinlock Prescribing Information, June 2021, Deciphera Pharmaceuticals, LLC.

91. Ripretinib / Cardiovascular Issues _____ _____

Alert Message: Qinlock (ripretinib) should be used with caution in patients with cardiovascular disease. Cardiac dysfunction (including cardiac failure, acute left ventricular failure, diastolic dysfunction, and ventricular hypertrophy) has occurred during ripretinib therapy. Assess ejection fraction by echocardiogram or MUGA scan prior to initiating ripretinib and during treatment, as clinically indicated. Permanently discontinue ripretinib for Grade 3 or 4 left ventricular systolic dysfunction.

Drugs/Disease

Util A	Util B	Util C
Ripretinib	Acute Coronary Syndrome	
	Myocardial Infarction	
	Cardiac Failure	
	Ventricular Hypertrophy	

Reference:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Qinlock Prescribing Information, June 2021, Deciphera Pharmaceuticals, LLC.

92. Ripretinib / Therapeutic Appropriateness _____ _____

Alert Message: Qinlock (ripretinib) inhibits the vascular endothelial growth factor (VEGF) signaling pathway and may impaired wound healing. Therefore, ripretinib has the potential to adversely affect wound healing. Withhold ripretinib for at least one week prior to elective surgery. Do not administer ripretinib for at least two weeks following major surgery and until adequate wound healing. The safety of resumption of ripretinib after the resolution of wound healing complications has not been established.

Drugs/Disease

Util A	Util B	Util C
Ripretinib		

Reference:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Qinlock Prescribing Information, June 2021, Deciphera Pharmaceuticals, LLC.

93. Ripretinib / Strong CYP3A Inhibitors _____ _____

Alert Message: The concurrent use of Qinlock (ripretinib), a CYP3A substrate, with a strong CYP3A inhibitor can increase the exposure of ripretinib and its active metabolite (DP-5439), which may increase the risk of adverse reactions. If ripretinib is used concomitantly with a strong CYP3A inhibitor, monitor the patient more frequently for ripretinib-related adverse reactions.

Drugs/Disease

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

Reference:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Qinlock Prescribing Information, June 2021, Deciphera Pharmaceuticals, LLC.

94. Ripretinib / Strong CYP3A Inducers _____ _____

Alert Message: The concurrent use of Qinlock (ripretinib) with a strong CYP3A inducer should be avoided. Ripretinib is a CYP3A substrate, and the use of ripretinib with strong CYP3A inducers may decrease the exposure of ripretinib and its active metabolite (DP-5439), which may decrease ripretinib anti-tumor activity.

Drugs/Disease

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

Reference:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Qinlock Prescribing Information, June 2021, Deciphera Pharmaceuticals, LLC.

95. Ripretinib / Moderate CYP3A Inducers _____ _____

Alert Message: The concurrent use of Qinlock (ripretinib) with a moderate CYP3A inducer should be avoided. Ripretinib is a CYP3A substrate, and the use of ripretinib with moderate CYP3A inducers may decrease the exposure of ripretinib and its active metabolite (DP-5439), which may decrease ripretinib anti-tumor activity. If a moderate CYP3A inducer cannot be avoided, increase ripretinib dosing frequency from the recommended dose of 150 mg once daily to 150 mg twice daily during the co-administration period. Monitor the patient for clinical response and tolerability.

Drugs/Disease

Util A	Util B		Util C
Ripretinib	Bosentan	Etravirine	
	Butalbital	Modafinil	
	Efavirenz		

Reference:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Qinlock Prescribing Information, June 2021, Deciphera Pharmaceuticals, LLC.

96. Ripretinib / Pregnancy / Pregnancy Negating _____ _____

Alert Message: Based on findings from animal studies and its mechanism of action, Qinlock (ripretinib) can cause fetal harm when administered to a pregnant patient. There are no available data on the use of ripretinib in pregnant patients to inform a drug-associated risk. Administration of ripretinib to pregnant rats and rabbits during the period of organogenesis resulted in malformations primarily associated with the cardiovascular and skeletal systems, anatomic variations, reduced fetal body weight, and increased post-implantation loss at maternal exposures that were approximately equal to the human exposure at the recommended dose of 150 mg. Advise pregnant patients of the potential risk to a fetus.

Drugs/Diseases

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

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Qinlock Prescribing Information, June 2021, Deciphera Pharmaceuticals, LLC.

97. Ripretinib / Lactation _____ _____

Alert Message: There are no data regarding the presence of Qinlock (ripretinib) or its metabolites in either human milk or its effects on a breastfed child or milk production. Because of the potential for serious adverse reactions in the breastfed child, advise patients not to breastfeed during treatment with ripretinib and for at least 1 week after the final dose.

Drugs/Diseases

Util A	Util B	Util C
Ripretinib	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Qinlock Prescribing Information, June 2021, Deciphera Pharmaceuticals, LLC.

98. Ripretinib / Therapeutic Appropriateness _____ _____ Alert Message:
Advise females of reproductive potential to use effective contraception during Qinlock (ripretinib) treatment and for at least 1 week after the final dose. There are no available data on the use of ripretinib in pregnant women to inform a drug-associated risk.

Drugs/Disease

Util A	Util B	Util C (Negating)
Ripretinib		Contraceptives

Gender: Female
Age Rage: 11 – 50 yoa

Reference:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Qinlock Prescribing Information, June 2021, Deciphera Pharmaceuticals, LLC.

99. Ripretinib / Therapeutic Appropriateness _____ _____ Alert Message:
Advise males with female partners of reproductive potential to use effective contraception during treatment with Qinlock (ripretinib) and for at least 1 week after the final ripretinib dose.

Drugs/Disease

Util A	Util B	Util C
Ripretinib		

Gender: Male

Reference:
Clinical Pharmacology, 2021 Elsevier/Gold Standard.
Qinlock Prescribing Information, June 2021, Deciphera Pharmaceuticals, LLC.

100. Ripretinib / Non-adherence _____ _____
Alert Message: Based on refill history, your patient may be under-utilizing Qinlock (ripretinib). 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
Ripretinib		

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.