North Dakota Medicaid
Drug Utilization Review Board Meeting
March 4, 2020
Brynhild Haugland Room

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North Dakota Medicaid
DUR Board Meeting Agenda
Brynhild Haugland Room
State Capitol
600 East Boulevard Avenue
Bismarck, ND
March 4, 2020
1:00 pm

1. Administrative items
    - DHS announcements
    - Update on North Dakota Medicaid Expansion population carve-in

2. Old business
    - Review and approval of December 2019 meeting minutes
    - Budget update
    - Review top 25 drugs for fourth quarter of 2019
    - Prior authorization/PDL update
        - Ubrelvy (ubrogepant) to Migraine Treatment
        - Dayvigo (lemborexant) to Sedative/Hypnotics
        - Talicia (omeprazole/amoxicillin/rifabutin) to Antibiotic Resistance - H. pylori
    - Second review of glucagon agents
    - Second review of Ofev for treatment of scleroderma with interstitial lung disease

3. New business
        - Review of Conjupri
        - Discussion on Spinraza and Zolgensma
        - Retrospective DUR criteria recommendations
        - Upcoming meeting date/agenda.
            - Next meeting is June 3, 2020 in the Brynhild Haugland Room

4. Adjourn

Please remember to silence all cellular phones during the meeting.

Drug Utilization Review (DUR) Meeting Minutes
December 4, 2019

Members Present: Andrea Honeyman, Katie Kram, Tanya Schmidt, Jennifer Iverson, Gabriela Balf, Laura Schield, Jennifer Iverson, Mary Aaland

Medicaid Pharmacy Department: Alexi Murphy

Announcements
The North Dakota Medicaid DUR Board held an election for the open DUR Board Chair position at the start of the meeting. A. Honeyman was nominated and K. Kram made a motion to close the nomination proceedings with no voiced opposition. A voice vote was called with A. Honeyman elected as the DUR Board Chair by unanimous vote of the present DUR Board members.

Old Business
Chair A. Honeyman called the meeting to order at 1:20 p.m. Chair A. Honeyman asked for a motion to approve the minutes of the September meeting. T. Schmidt moved that the minutes be approved, and L. Schield 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
T. DeRuiter and A. Murphy presented the quarterly review of the top 25 drugs based on total cost of claims, as well as the top 25 drugs based on the total number of claims for the 2nd quarter of 2019.

PDL/PA Criteria Updates
A. Murphy shared with the Board all of changes made to the Preferred Drug List since the most recent version of the Preferred Drug List was posted. Notable changes included removing PA requirements for asrmodafinil, and the pulmonary hypertension agents Orenitram ER, Treprostinil, Tyvaso, and Uptravi, as well as adding numerous agents to recently DUR Board approved PA class criteria. 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 Antifungal Agents for Aspergillus and Candidiasis Infections
A motion and second was made at the September meeting to place select antifungal agents for the treatment of aspergillus and candidiasis infections on prior authorization. The topic was brought up for a second review. K. Kram made a motion to amend the criteria to (a). allow approval in cases where documentation is provided showing preferred agents cannot be used; and (b). change the approval duration to “Per label recommendations”. A. Honeyman seconded the motion. There was no public comment. Chair A. Honeyman called for a voice vote on the motion to amend the criteria and the motion passed with no audible dissent. Chair A. Honeyman then called for a voice vote on approving the amended criteria, which passed with no audible dissent.

Second Review of Eosinophilic Asthma Agents
A motion and second was previously made to place agents for the treatment of eosinophilic asthma on prior authorization. The topic was brought up for a second review. During public comments, Kevin Duhrkopf of Sanofi Genzyme spoke regarding the use of Dupixent and it’s role in therapy. K. Kram made a motion to amend the criteria by removing requirements for baseline eosinophil levels and/or corticosteroid dependent asthma. L. Schield seconded the motion. Chair A. Honeyman called for a voice vote on the motion to amend the criteria and the motion passed with no audible dissent. Chair A. Honeyman then called for a voice vote on approving the amended criteria, which passed with no audible dissent.

Annual Review of Prior Authorization Forms and Criteria

The Board reviewed all forms and criteria utilized for all medications that are currently placed on prior authorization. A. Murphy explained how all prior authorization criteria will be moving to a single Preferred Drug List (PDL) document starting on 01/01/2020, which should simplify the process of locating criteria. A. Murphy specifically highlighted updates to the long-acting opioid analgesic criteria, that smoking cessation agents and preferred opioid dependence agents will no longer require prior authorization, and changes to criteria in some inhaler agents. She further discussed the continued consolidation of multiple request forms to the "General" prior authorization request form, as well as the consolidation of all opioid request forms to a single form. The Board recommended the following changes to the prior authorization forms: rearranging questions on the hepatitis C treatment agents form; removing the outdated language of a 30-day requirement language from the hyperkalemia form and adding language for chronic hyperkalemia; and correcting formatting/wording on the Orilissa and Insulin PA forms. A motion was made by K. Kram to approve the reviewed forms with the recommended changes, which was seconded by L. Schield. Chair A. Honeyman then called for a voice vote for approval of the reviewed forms and criteria, which passed with no audible dissent.

New Business

Review of Glucagon Agents

T. DeRuiter and A. Murphy presented a review of glucagon agents to the Board. A motion was made by T. Schmidt to manage these medications through prior authorization. The motion was seconded by L. Schield. This topic will be reviewed 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 usually consistent with new indications, new drugs added, and new warnings. These proposed criteria will be added to the current set of criteria and will be used in future DUR cycles. K. Kram moved to approve the new criteria and A. Honeyman seconded the motion. The motion passed with no audible dissent.

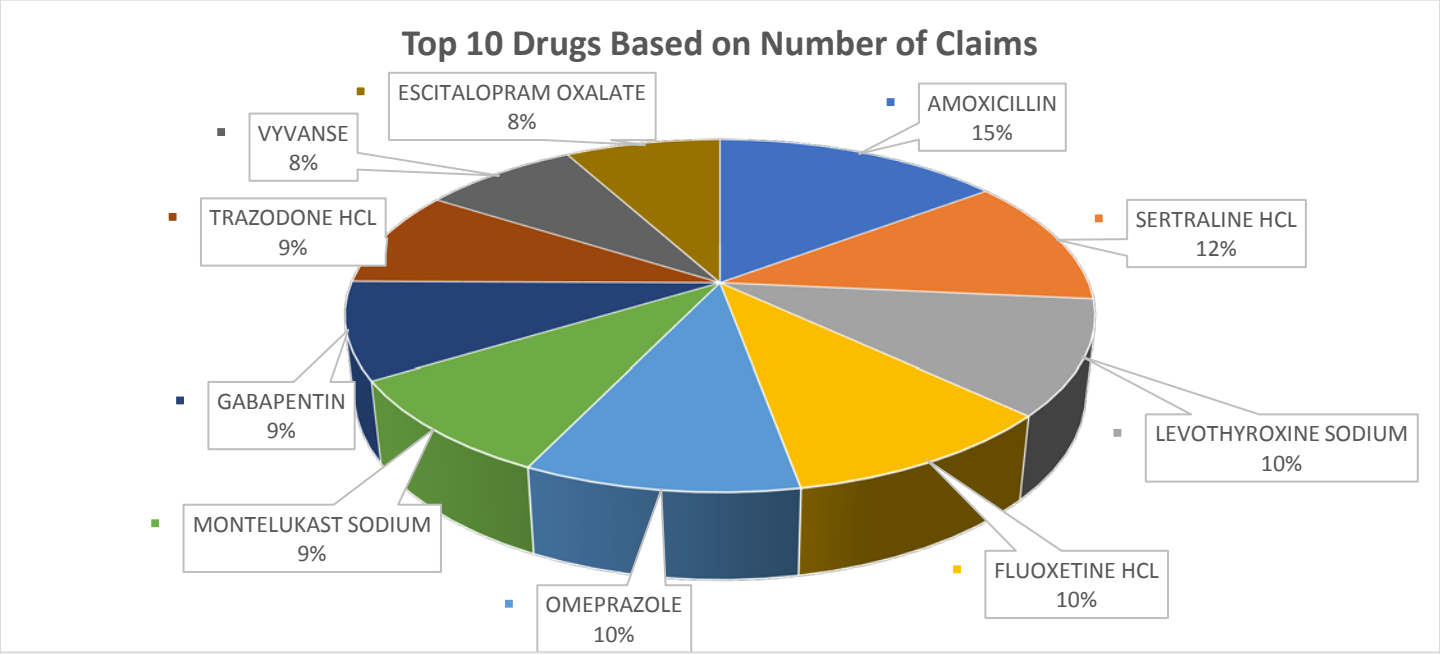
Adjournment and Upcoming Meeting Date

Chair A. Honeyman adjourned the meeting at 2:45 pm. The next DUR Board meeting will be held March 4, 2020 at 1:00 pm at the State Capitol building in the Brynhild -Haugland room.

TOP 25 DRUGS BASED ON NUMBER OF CLAIMS FROM 10/01/2019 – 12/31/2019

Drug	AHFS Class	Claims	Claims Cost	Patients	Cost Per Claim	% Total Claims
AMOXICILLIN	PENICILLIN ANTIBIOTICS	3,041	101,400.84	2,841	33.34	2.26%
SERTRALINE HCL	ANTIDEPRESSANTS	2,401	53,699.67	1,142	22.37	1.79%
LEVOTHYROXINE SODIUM	THYROID AGENTS	2,153	41,444.31	808	19.25	1.60%
FLUOXETINE HCL	ANTIDEPRESSANTS	2,089	45,262.36	1,002	21.67	1.55%
OMEPRAZOLE	PROTON-PUMP INHIBITORS	2,057	35,814.38	962	17.41	1.53%
MONTELUKAST SODIUM	LEUKOTRIENE MODIFIERS	1,877	36,892.97	938	19.66	1.40%
GABAPENTIN	ANTICONVULSANTS, MISCE	1,822	45,049.60	775	24.73	1.35%
TRAZODONE HCL	ANTIDEPRESSANTS	1,819	33,208.06	819	18.26	1.35%
VYVANSE	AMPHETAMINES	1,647	383,239.70	647	232.69	1.22%
ESCITALOPRAM OXALATE	ANTIDEPRESSANTS	1,643	33,921.60	801	20.65	1.22%
ATORVASTATIN CALCIUM	HMG-COA REDUCTASE INHI	1,616	37,102.15	705	22.96	1.20%
LISINOPRIL	ANGIOTENSIN-CONVERTING	1,467	39,386.94	686	26.85	1.09%
AZITHROMYCIN	MACROLIDE ANTIBIOTICS	1,460	31,497.02	1,361	21.57	1.09%
CLONIDINE HCL	CENTRAL ALPHA-AGONISTS	1,430	24,794.19	610	17.34	1.06%
HYDROCODONE-APAP	OPIATE AGONISTS	1,386	43,674.31	876	31.51	1.03%
CONCERTA	RESPIRATORY AND CNS ST	1,375	455,265.20	555	331.1	1.02%
ARIPIPRAZOLE	ANTIPSYCHOTIC AGENTS	1,351	31,408.41	544	23.25	1.00%
PROAIR HFA	BETA-ADRENERGIC AGONIS	1,336	99,039.46	1,320	74.13	0.99%
AMOXICILLIN-CLAVULANATE	PENICILLIN ANTIBIOTICS	1,312	47,605.31	1,244	36.28	0.98%
RISPERIDONE	ANTIPSYCHOTIC AGENTS	1,308	19,288.36	427	14.75	0.97%
ASPIRIN EC	NONSTEROIDAL ANTI-INFL	1,263	52,620.05	505	41.66	0.94%
METFORMIN HCL	BIGUANIDES	1,260	20,395.45	583	16.19	0.94%
LAMOTRIGINE	ANTICONVULSANTS, MISCE	1,258	19,378.51	430	15.4	0.94%
DULOXETINE HCL	ANTIDEPRESSANTS	1,254	27,245.71	523	21.73	0.93%
PREDNISONE	ADRENALS	1,201	19,705.93	892	16.41	0.89%

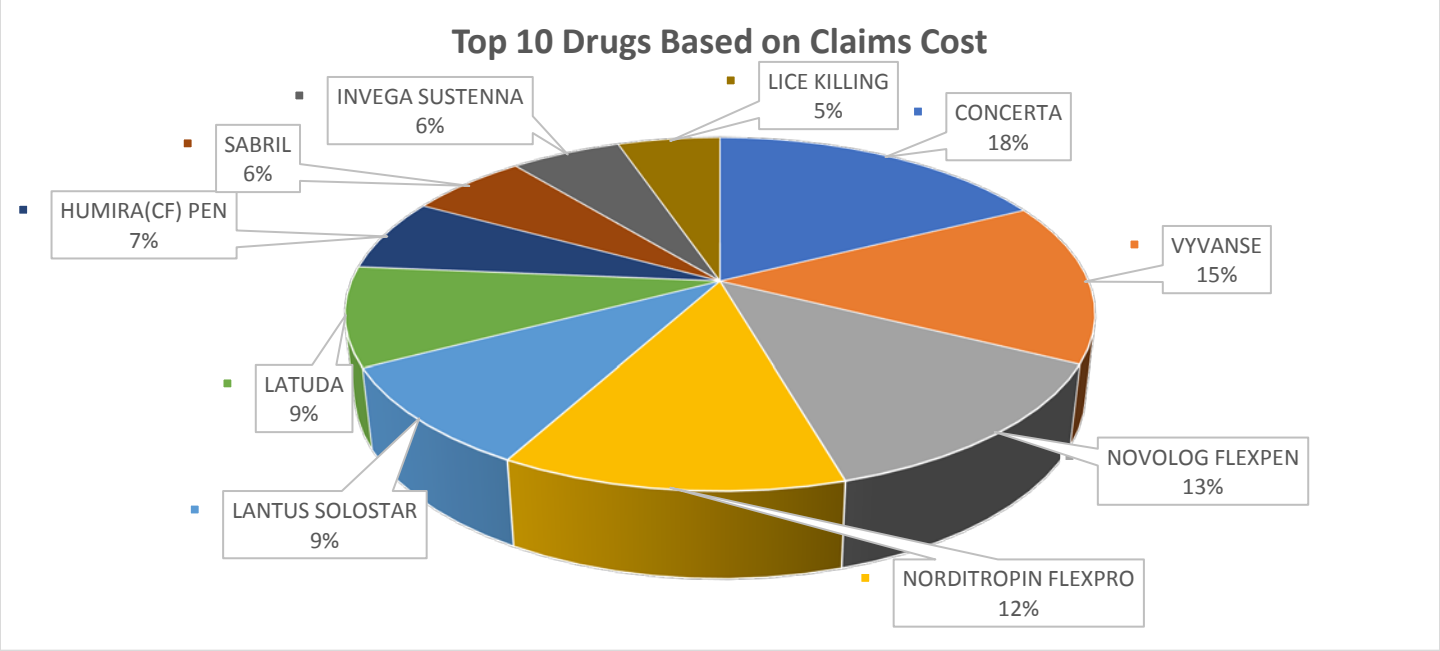
Total Claims From 10/01/2019 – 12/31/2019	**134,509**



TOP 25 DRUGS BASED ON TOTAL CLAIMS COST FROM 10/01/2019 – 12/31/2019

Drug	AHFS Class	Claims Cost	Claims	Patients	Cost Per Claim	% Total Cost
CONCERTA	CNS STIMULANTS	$455,265.20	1,375	555	$331.10	3.86%
VYVANSE	AMPHETAMINES	$383,239.70	1,647	647	$232.69	3.25%
NOVOLOG FLEXPEN	INSULINS	$339,724.78	569	300	$597.06	2.88%
NORDITROPIN FLEXPRO	PITUITARY	$324,427.58	89	39	$3,645.25	2.75%
LANTUS SOLOSTAR	INSULINS	$240,246.39	591	291	$406.51	2.04%
LATUDA	ANTIPSYCHOTIC AGENTS	$234,477.98	293	110	$800.27	1.99%
HUMIRA(CF) PEN	DMARDS	$171,806.95	27	10	$6,363.22	1.46%
SABRIL	ANTICONVULSANTS, MISC	$157,422.82	8	3	$19,677.85	1.33%
INVEGA SUSTENNA	ANTIPSYCHOTIC AGENTS	$146,894.06	75	27	$1,958.59	1.24%
LICE KILLING	SCABICIDES & PEDICULICIDES	$136,500.00	306	235	$446.08	1.16%
VIMPAT	ANTICONVULSANTS, MISC	$120,975.98	174	52	$695.26	1.03%
LEVEMIR FLEXTOUCH	INSULINS	$117,529.49	285	148	$412.38	1.00%
FOCALIN XR	CNS STIMULANTS	$112,934.85	339	134	$333.14	0.96%
GENVOYA	ANTIRETROVIRALS	$110,383.56	86	43	$1,283.53	0.94%
XIFAXAN	ANTIBACTERIALS, MISC	$107,929.52	63	28	$1,713.17	0.91%
FLOVENT HFA	INHALED CORTICOSTEROIDS	$107,831.17	496	326	$217.40	0.91%
NIX	SCABICIDES & PEDICULICIDES	$107,212.73	255	240	$420.44	0.91%
AMOXICILLIN	PENICILLIN ANTIBIOTICS	$101,400.84	3,041	2,841	$33.34	0.86%
LYRICA	ANTICONVULSANTS, MISC	$99,255.20	211	103	$470.40	0.84%
PROAIR HFA	BETA-ADRENERGIC AGONISTS	$99,039.46	1,336	1,320	$74.13	0.84%
SYMBICORT	INHALED CORTICOSTEROIDS	$92,547.33	290	165	$319.13	0.78%
NOVOLOG	INSULINS	$92,175.45	161	80	$572.52	0.78%
BIKTARVY	ANTIRETROVIRALS	$92,011.70	62	28	$1,484.06	0.78%
VICTOZA 3-PAK	INCRETIN MIMETICS	$91,321.72	108	49	$845.57	0.77%
ABILIFY MAINTENA	ANTIPSYCHOTIC AGENTS	$86,884.43	43	18	$2,020.57	0.74%

Total Claims Cost From 10/01/2019 – 12/31/2019	**$11,800,297.32**



PDL Update

Added to PA	
Medication	**Category**
Amzeeq	Acne - Tetracyclines
Asceniv	Immune Globulins
Bijuva	Estrogens
Gloperba	Gout
Humulin 70/30	Insulins
Humulin N	Insulins
Ilevro	Ophthalmic - Anti-Inflammatory
Jatenzo	Androgens
Nascobal	Preferred Dosage Forms
Neosporin Eye Drops	Ophthalmic - Anti-Infectives
ProAir Digihaler	Albuterol/Levalbuterol Rescue Inhalers
Relafen DS	NSAIDs
Rinvoq	Cytokine Modulators
Sunosi	Narcolepsy
Talicia	Antibiotics - Resistance Prevention
Tosymra	Headache/Migraine
Ubrelvy	Headache/Migraine
Vumerity	Multiple Sclerosis
Wakix	Narcolepsy

Removed from PA	
Medication	**Category**
Butorphanol	Opioid Analgesics - Long Acting
Butrans	Opioid Analgesics - Long Acting
Candesartan	Angiotension Receptor Blockers
Pentazocine-Naloxone	Opioid Analgesics - Long Acting
Farxiga	SGLT2 Inhibitors
Invokana	SGLT2 Inhibitors
Invokamet	SGLT2 Inhibitors
Invokamet XR	SGLT2 Inhibitors
Xigduo XR	SGLT2 Inhibitors
Nicotine Patch	Nicotine / Tobacco Dependence Treatment
Nicotine Lozenge	Nicotine / Tobacco Dependence Treatment
Nicotine Gum	Nicotine / Tobacco Dependence Treatment
Nicotrol Inhaler	Nicotine / Tobacco Dependence Treatment
Nicotrol Nasal Spray	Nicotine / Tobacco Dependence Treatment

Treatment of Migraine

Non-Preferred Agents Criteria:

- **Non-preferred step 1 agents:**
  - **Patients able to take oral medications:**
    A. Patients 18 years old or older: The patient must have had a 30-day trial of each preferred agent within the past 24 months, as evidenced by paid claims or pharmacy printouts.
    B. Patients 6 to 17 years of age: The patient must have had a 30-day trial of rizatriptan within the past 24 months, as evidenced by paid claims or pharmacy printouts.
  - **Patients not able to take oral medications (as evidenced by swallow study documentation):**
    A. The patient must have had a 30-day trial of rizatriptan within the past 24 months, as evidenced by paid claims or pharmacy printouts.
- **Non-preferred step 2 agents:**
  A. The patient must meet criteria for Step 1 agents
  B. Within the past 2 years, the patient must have had 30-day trials of at least two 'Non-Preferred Step 1 Agents', as evidenced by paid claims or pharmacy printouts

Product Specific Criteria:

- ***Sumatriptan/Tosymra Nasal Spray:**
  - The patient must have had a 30-day trial of each of the following agents within the past 24 months, as evidenced by paid claims or pharmacy printouts:
    - Zomig Nasal Spray 5mg
    - Onzetra Xsail 22mg
- ***Zolmitriptan tablet:**
  - The patient must have had a 30-day trial of naratriptan 2.5 mg within the past 24 months, as evidenced by paid claims or pharmacy printouts.
- ***Sumatriptan pen/syringe/cartridge, Frovatriptan, Almotriptan, Sumatriptan/Naproxen:**
  - The patient must have had a 30-day trial of each available triptan agent within the past 24 months, as evidenced by paid claims or pharmacy printouts.
  - Clinical justification must be provided explaining why the patient is unable to use all other products (subject to clinical review).

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED STEP 1 AGENTS (PA REQUIRED)	NON-PREFERRED STEP 2 AGENTS (PA REQUIRED)
RELPAX (eletriptan) – *Brand Preferred*	ONZETRA XSAIL (sumatriptan) NASAL SPRAY	Almotriptan Tablet***
Rizatriptan	ZOMIG (zolmitriptan) NASAL SPRAY	ALSUMA (sumatriptan) PEN INJCTR***
Rizatriptan ODT	zolmitriptan ODT	AMERGE (naratriptan) TABLET
Sumatriptan tablet		CAFERGOT (ergotamine/caffeine) TABLET
		D.H.E.45 (dihydroergotamine) INJECTION
		Dihydroergotamine Injection
		Dihydroergotamine Nasal Spray
		Eletriptan Tablet
		ERGOMAR (ergotamine) SL TABLET
		FROVA (frovatriptan) TABLET***
		Frovatriptan Tablet***
		IMITREX (sumatriptan) CARTRIDGE***
		IMITREX (sumatriptan) PEN INJCTR***
		IMITREX (sumatriptan) SPRAY***
		IMITREX (sumatriptan) TABLET
		IMITREX (sumatriptan) VIAL***

		MAXALT (rizatriptan) TABLET
		MAXALT MLT (rizatriptan)
		MIGERGOT (ergotamine/caffeine) RECTAL SUPPOSITORY
		MIGRANAL (dihydroergotamine) SPRAY
		Naratriptan Tablet
		Sumatriptan Cartridge***
		Sumatriptan Pen Injctr***
		Sumatriptan Spray***
		Sumatriptan Syringe***
		Sumatriptan Vial
		Sumatriptan/Naproxen Tablet***
		TOSYMRA (Sumatriptan) NASAL SPRAY***
		TREXIMET (Sumatriptan/Naproxen) TABLET
		UBRELVY (Ubrogepant)
		ZEMBRANCE SYMTOUCH (Sumatriptan)***
		Zolmitriptan Tablet***
		ZOMIG (zolmitriptan) TABLET***
		ZOMIG ODT (zolmitriptan)

Sedatives/Hypnotics

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

- **Zolpidem 10mg** (prior authorization required for females only):
  - The patient must have failed a 25-day trial of zolpidem 5 mg within the last 30 days, as evidenced by paid claims or pharmacy print outs
- **Zolpidem ER:**
  - The patient's insomnia must be characterized by difficulty with sleep maintenance
  - The patient must have failed a 25-day trial of eszopiclone within the last 30 days, as evidenced by paid claims or pharmacy printouts
- **Belsomra, Dayvigo:**
  - The patient's insomnia must be characterized by difficulty with sleep onset and maintenance
  - The patient must have had the following 25-day trials with the most recent failure within the last 30 days, as evidenced by paid claims or pharmacy printouts
    - Silenor (doxepin)
    - Eszopiclone
    - Zolpidem ER
- **Temazepam, zolpidem SL:**
  - The patient's insomnia must be characterized by difficulty with sleep onset and maintenance
  - The patient must have had the following 25-day trials with the most recent failure within the last 30 days, as evidenced by paid claims or pharmacy printouts
    - Zolpidem ER
    - Eszopiclone
    - Silenor (doxepin)
    - Belsomra
- **Edluar (Zolpidem):**
  - The patient's insomnia must be characterized by difficulty with sleep onset
  - The patient must have had the following 25-day trials with the most recent failure within the last 30 days, as evidenced by paid claims or pharmacy printouts
    - Zolpidem IR
    - Zaleplon
    - Eszopiclone
- **Triazolam, fluazepam, estazolam, Seconal sodium, Zolpimist:**
  - Clinical justification must be provided explaining why the patient 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 patient must be undergoing dose tapering

NON - DEA SCHEDULED (NON-ADDICTIVE) MEDICATION:	
PREFFERED AGENTS (NO PA REQUIRED)	NON-PREFFERED AGENTS (PA REQUIRED)
Mirtazapine	Doxepin
ROZEREM (ramelteon)	Ramelteon
SILENOR (doxepin)	
Trazodone	

DEA SCHEDULED MEDICATIONS	
PREFFERED AGENTS (NO PA REQUIRED)	**NON-PREFFERED AGENTS (PA REQUIRED)**
Eszopiclone	AMBIEN (Zolpidem)
Zaleplon	AMBIEN CR (Zolpidem)
Zolpidem 5mg	BELSOMRA (Suvorexant)
Zolpidem 10mg (for males)	DAYVIGO (Lemborexant)
	EDLUAR (Zolpidem)
	Estazolam
	Flurazepam
	LUNESTA (Eszopiclone)
	SECONAL SODIUM (Secobarbital)
	Temazepam
	Triazolam
	Zolpidem ER
	Zolpidem 10mg (for females)
	ZOLPIMIST (Zolpidem)
	Zolpidem SL tab

Antibiotics - Resistance Prevention

Non-Preferred Agents Criteria:

- **Initial Criteria:** *Approval Duration = 5 days*
  - Patient 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 a preferred antibiotic is not an option due to susceptibility, previous failed trials, or other contraindications (subject to clinical review)
    - B. The patient is continuing treatment upon discharge from an acute care facility
- **Renewal Criteria:** *Approval Duration = 5 days*
  - Prescriber must attest that the patient's condition is improving and that it is medically necessary to continue treatment course after re-evaluation of the patient'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

PREFFERED AGENTS (NO PA REQUIRED)	NON-PREFFERED 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):

PREFFERED AGENTS (NO PA REQUIRED)	NON-PREFFERED AGENTS (PA REQUIRED)
Clindamycin	BAXDELA (Delafloxacin)
Doxycycline	NUZYRA (Omadacycline)
Linezolid	SIVEXTRO (Tedizolid)
Minocycline	
Trimethoprim-Sulfamethoxazole	

Helicobacter pylori

PREFFERED AGENTS (NO PA REQUIRED)	NON-PREFFERED AGENTS (PA REQUIRED)
OMECLAMOX-PAK (Omeprazole/Clarithromycin/Amoxicillin)	TALICIA (Omeprazole/Amoxicillin/Rifabutin)
PYLERA (Bismuth Subcitrate Potassium/Metronidazole/Tetracycline)	
PREVPAC (Lansoprazole/Amoxicillin/Clarithromycin)	

Glucagon Agents

Group Criteria (Initial):

- Prescriptions for glucagon agents do require prior authorization for the initial dose

Group Criteria (Renewal):

- The provider must attest that it is known that the previous dose was taken by the patient (and not diverted or given to another patient)
- One of the following must be met (A or B):
    A. The provider must attest that adjustments to the patient's diabetes management regimen have been made to reduce incidence of hypoglycemia (basal and prandial insulin dose and timing, interacting drugs, meal and exercise timing).
    B. The provider has provided medical justification explaining why the patient does not need their diabetes management regimen adjusted.

Idiopathic Pulmonary Fibrosis & Interstitial Lung Disease

Category Criteria:

- The patient 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 patient must have forced vital capacity (FVC) ≥ 40% of predicted within prior 60 days.
- The patient must have carbon monoxide diffusing capacity (DLCO, corrected for hemoglobin) of 30% to 79% of predicted.

PREFFERED AGENTS (CLINICAL PA REQUIRED)	NON-PREFFERED AGENTS (PA REQUIRED)
ESBRIET (Pirfenidone)	
OFEV (Nintedanib)	

REVIEW OF CONJUPRI (levamlodipine)

CONJUPRI:

- **Indication**: treatment of hypertension
- **Mechanism of action**
  - A dihydropyridine (DHP) calcium channel blocker (CCB)
    - Inhibits the transmembrane influx of calcium ions into vascular smooth muscle and cardiac muscle, with a greater effect on vascular smooth muscle cells than on cardiac muscle cells.
      - Peripheral arterial vasodilation causing a reduction in peripheral vascular resistance
        - Lowered blood pressure
  - Levamlodipine is the active, anti-hypertensive isomer of amlodipine
- **Dosing:**
  - Adults and pediatric patients 6-17 years of age:
    - Initial: 1.25-2.5 mg once daily
    - Maximum recommended dose: 5 mg once daily
      - Doses >2.5 mg/day have not been studied in pediatric patients
    - Titration: Titrate every 1 to 2 weeks as needed based on patient response
  - Adjustments:
    - Renal Impairment: no dose adjustments
    - Hepatic impairment: start at 1.25 mg dose and titrate slowly in severe hepatic impairment
    -
- **Warnings and Precautions:**
  - Use with caution:
    - Patients with heart failure with reduced ejection fraction.
    - Patients with severe aortic stenosis; may cause hypotension or reduce coronary perfusion, resulting in ischemia.
    - Patients with hypertrophic cardiomyopathy and outflow tract obstruction since reduction in afterload may worsen symptoms associated with this condition.
  - ADR-Related:
    - Symptomatic hypotension
    - Peripheral edema
- **Pharmacokinetics**
    - Absorption
      - Peak concentration in 6-12 hours, with a bioavailability between 64-90%
    - Metabolism:
      - 90% metabolized to inactive metabolites via hepatic metabolism, with 10 parent compound excreted in urine.
- **Drug interactions**
  - CYP3A4 inhibitors and inducers
  - Increase in effects of other drugs
    - Simvastatin
    - Cyclosporin

COST

Drug	Strength	Package Size	AWP Pkg Price	AWP Unit Price
Amlodipine	10 mg tab	90	$14.40	$0.16
Conjupri	1.25 mf, 2.5 mg, and 5 mg	NA	NA	NA
felodipine	10 mg tab	100	$283.96	$2.83
Isradipine	5 mg cap	100	$136.49	$1.36
Nicardipine	30 mg cap	500	$414.97	$0.82
Nifedipine	90 mg tab	100	$302.81	$3.02

CURRENT UTILIZATION

ND Medicaid Utilization (02/2019 – 01/2020)		
Label Name	**Rx Num**	**Total Reimb Amt**
Amlodipine	10,423	$188,624.73
Conjupri	0	-
felodipine	15	$235.58
Isradipine	0	-
Nicardipine	0	-
Nifedipine	848	$207,783.09

REFERENCES:

1. Facts & Comparisons eAnswers. Available at http://online.factsandcomparisons.com. Accessed on January 21. 2020.
2. Conjupri (levamlodipine) [prescribing information]. CSPC Ouyi Pharmaceutical Co. Ltd; December 2019.

Spinraza

Criteria: *Approval Duration = 12 months*

- For a diagnosis of Spinal Muscular Atrophy (SMA) Type 1, 2, or 3:
    A. The patient must not have respiratory insufficiency (need for invasive or noninvasive ventilation for more than 6 hours per 24-hour period)
    B. The patient must not require gastric feeding tubes for the majority of feeds
    C. The patient must not have severe contractures or severe scoliosis
    D. The patient must not have wasting or cachexia
- For a diagnosis of Spinal Muscular Atrophy (SMA) Type 3:
    A. The patient must be less than 2 years of age
    B. The patient must be experiencing issues with ambulating (falls, trouble climbing stairs, unable to walk independently)

Zolgensma

Criteria: *Approval Duration = 1 month*

- Patient is less than 2 years of age AND less than 13.5 kg at time of infusion
- Patient has reached full gestational age
- Prescriber must be or in consultation with a pediatric neuromuscular specialist or neurologist specializing in spinal muscular atrophy (SMA)
- Patient must have diagnosis of SMA Type I with onset of symptoms prior to 6 months of age
- Genetic testing confirms one of the following:
    - Mutation or deletion of genes in chromosome 5q resulting in one of the following:
        - Homozygous gene deletion of SMN1 gene (absence of SMNI gene)
        - Homozygous mutation of SMN1 gene (biallelic mutations of the exon 7)
        - Compound heterozygote mutation of SMN1 gene (deletion of SNM1 exon 7 [allele 1] and mutation of SMN1 [allele 2])
    - ≤ 2 copies of the SMN2 gene
    - Absence of the c.859G>C modification in exon 7 o the SMN2 gene
- Baseline Documentation has been submitted confirming anti-adeno-associated virus serotype 9 (anti-AAV9) antibody titer is ≤ 1:50 measured by Enzyme-linked Immunosorbent Assay (ELISA) binding immunoassay
- Patient must not have advanced SMA type 1 evidenced by one of the following
    - Respiratory insufficiency (need for invasive or noninvasive ventilation for more than 6 hours per 24-hour period)
    - Gastric feeding tubes for the majority of feeds
    - Severe contractures or severe scoliosis
    - Wasting or cachexia
    - Established baseline motor ability score < 40 documented by submission of one of the following:
        - Hammersmith Infant Neurological Exam (HINE)
        - Children's Hospital of Philadelphia Test of Neuromuscular Disorders (CHOP INTEND)
- Patient will not be receiving SMN modifying therapy (e.g. Spinraza) after administration of Zolgensma

NORTH DAKOTA MEDICAID
RETROSPECTIVE DRUG UTILIZATION REVIEW
CRITERIA RECOMMENDATIONS
1ST QUARTER 2020

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

1. Pitolisant / Overuse _____ _____

Alert Message: The recommended dosage range for Wakix (pitolisant) is 17.8 mg to 35.6 mg administered orally once daily in the morning upon wakening. The recommended maximum dosage of 35.6 mg (two 17.8 mg tablets) once daily.

Drugs/Diseases

Util A	Util B	Util C **(Negating)**
Pitolisant		Hepatic Impairment

Max Dose: 35.6 mg/day

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Wakix Prescribing Information, August 2019, Harmony Biosciences.

2. Pitolisant / Overutilization – Hepatic Impairment _____ _____

Alert Message: In patients with moderate hepatic impairment, initiate Wakix (pitolisant) at 8.9 mg once daily and increase after 14 days to a maximum dosage of 17.8 mg once daily. Pitolisant is extensively metabolized by the liver, and there is a significant increase in pitolisant exposure in patients with moderate hepatic impairment. Pitolisant is contraindicated in patients with severe hepatic impairment.

Drugs/Diseases

Util A	Util B	Util C **(Include)**
Pitolisant		Hepatic Impairment

Max Dose: 17.8 mg/day

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Wakix Prescribing Information, August 2019, Harmony Biosciences.

3. Pitolisant / Therapeutic Appropriateness _____ _____

Alert Message: Wakix (pitolisant) is contraindicated in patients with severe hepatic impairment. Pitolisant is extensively metabolized by the liver and has not been studied in patients with severe hepatic impairment. There is a significant increase in pitolisant exposure in patients with moderate hepatic impairment, and a further increase in pitolisant exposure would be expected in severe hepatic impairment.

Drugs/Diseases

Util A	Util B	Util C
Pitolisant	Cirrhosis Hepatomegaly	

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Wakix Prescribing Information, August 2019, Harmony Biosciences.

4. Pitolisant / Overutilization – Mod. To Sev. Renal Impairment _____ _____

Alert Message: Dosage adjustment of Wakix (pitolisant) is recommended in patients with moderate and severe renal impairment. Pitolisant should be initiated at 8.9 mg once daily and increased after 7 days to a maximum dosage of 17.8 mg once daily. Pitolisant has been shown to prolong the QT interval, and the risks may be greater in patients with renal impairment due to higher concentrations of pitolisant. Pitolisant is not recommended in patients with end-stage renal disease (ESRD).

Drugs/Diseases

Util A	Util B	Util C **(Include)**
Pitolisant		CKD 3
		CKD 4
		CKD 5

Max Dose: 17.8 mg/day

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Wakix Prescribing Information, August 2019, Harmony Biosciences.

5. Pitolisant / Therapeutic Appropriateness – ESRD _____ _____

Alert Message: Wakix (pitolisant) use is not recommended in patients with end-stage renal disease (ESRD). Pitolisant has been shown to increase the QT interval, and the risk of QT prolongation may be greater in patients with renal impairment due to higher concentrations of pitolisant.

Drugs/Diseases

Util A	Util B	Util C **(Include)**
Pitolisant		End-Stage Renal Disease

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Wakix Prescribing Information, August 2019, Harmony Biosciences.

6. Pitolisant / Overutilization - CYP2D6 Inhibitors _____ _____

Alert Message: Concomitant administration of Wakix (pitolisant) with strong CYP2D6 inhibitors increases pitolisant exposure by 2.2-fold. For patients receiving strong CYP2D6 inhibitors, initiate pitolisant at 8.9 mg once daily, and increase after 7 days to a maximum dosage of 17.8 mg once daily. For patients on a stable dose of pitolisant, reduce the pitolisant dose by half upon initiating strong CYP2D6 inhibitors.

Util A	Util B	Util C
Pitolisant	Bupropion	
	Fluoxetine	
	Paroxetine	
	Quinidine	

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Wakix Prescribing Information, August 2019, Harmony Biosciences.

7. Pitolisant / Drugs that Prolong the QT Interval _____ _____

Alert Message: Wakix (pitolisant) prolongs the QT interval. The coadministration of pitolisant with other drugs that prolong the QT interval should be avoided. Concurrent use of these drugs may increase the risk of cardiac arrhythmia.

Drugs/Diseases

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

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Wakix Prescribing Information, August 2019, Harmony Biosciences.

8. Pitolisant / QT Prolongation _____ _____

Alert Message: Wakix (pitolisant) prolongs the QT interval. The use of pitolisant should be avoided in patients with known QT prolongation or in combination with other drugs known to prolong QT interval. Pitolisant should also be avoided in patients with a history of cardiac arrhythmias, as well as other circumstances that may increase the risk of the occurrence of torsade de pointes or sudden death, including symptomatic bradycardia, hypokalemia or hypomagnesemia, and the presence of congenital prolongation of the QT interval.

Drugs/Diseases

Util A	Util B	Util C
Pitolisant	Long QT Interval	
	Cardiac Arrhythmias	
	Bradycardia	
	Hypokalemia	
	Hypomagnesemia	

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Wakix Prescribing Information, August 2019, Harmony Biosciences.

9. Pitolisant / Overutilization – CYP3A4 Inducers _____ _____

Alert Message: Concomitant administration of Wakix (pitolisant) with strong CYP3A4 inducers decreases pitolisant exposure by 50%. Assess the patient for loss of efficacy after initiation of a strong CYP3A4 inducer. For patients stable on pitolisant 8.9 mg or 17.8 mg once daily, increase the dose of pitolisant to double the original daily dose (i.e., 17.8 mg or 35.6 mg, respectively) over 7 days. If concomitant dosing of a strong CYP3A4 inducer is discontinued, decrease pitolisant dosage by half.

Util A	Util B	Util C
Pitolisant	Carbamazepine	
	Phenytoin	
	Phenobarbital	
	Primidone	
	Rifampin	

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Wakix Prescribing Information, August 2019, Harmony Biosciences.

10. Pitolisant / H1 Receptor Antagonists _____ _____

Alert Message: The concurrent use of Wakix (pitolisant) with histamine-1 (H1) receptor antagonists should be avoided. Pitolisant increases the levels of histamine in the brain; therefore, H1 receptor antagonists that cross the blood-brain barrier may reduce the effectiveness of pitolisant.

Util A	Util B	Util C
Pitolisant	Clemastine	Hydroxyzine
	Chlorpheniramine	Pheniramine
	Cyproheptadine	Promethazine
	Dimenhydrinate	Tetracyclic Antidepressants
	Diphenhydramine	Tricyclic Antidepressants
	Doxylamine	Triprolidine

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Wakix Prescribing Information, August 2019, Harmony Biosciences.

11. Pitolisant / Therapeutic Appropriateness – Pediatric Use _____ _____

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

Drugs/Diseases

Util A	Util B	Util C
Pitolisant		

Age Range: 0 – 17 yoa

References:

Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Wakix Prescribing Information, August 2019, Harmony Biosciences.

12. Pitolisant / Sensitive CYP3A4 Substrates _____ _____

Alert Message: Wakix (pitolisant) is a borderline/weak inducer of CYP3A4. Therefore, reduced effectiveness of sensitive CYP3A4 substrates may occur when used concomitantly with pitolisant.

Drugs/Diseases

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

References:

Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Wakix Prescribing Information, August 2019, Harmony Biosciences.
FDA U.S. Food & Drug Administration. Drug Development and Drug Interactions: Table of Substrates, Inhibitors and Inducers. Available at: https://www.fda.gov/drugs/drug-interactions-labeling/drug-development-and-drug-interactions-table-substrates-inhibitors-and-inducers

13. Pitolisant / Hormonal Contraceptives _____ _____

Alert Message: The effectiveness of hormonal contraceptives may be reduced when co-administered with Wakix (pitolisant). The effectiveness of the hormonal contraceptive may be reduced for 21 days after discontinuation of pitolisant therapy. Pitolisant is a borderline/weak inducer of CYP3A4, and co-administration with sensitive CYP3A4 substrates may decrease the substrate plasma concentrations, decreasing efficacy. Patients using hormonal contraception should be advised to use an alternative non-hormonal contraceptive method during treatment with pitolisant and for at least 21 days after discontinuing treatment.

Drugs/Diseases

Util A	Util B	Util C
Pitolisant	Hormonal Contraceptives	

Gender: Female
Age Range: 11 – 50 yoa

References:

Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Wakix Prescribing Information, August 2019, Harmony Biosciences.

14. Pitolisant / Lactation _____ _____

Alert Message: There are no data on the presence of Wakix (pitolisant) in human milk, the effects on the breastfed infant, or the effect of this drug on milk production. Pitolisant is present in the milk of lactating rats. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for pitolisant and any potential adverse effects on the breastfed child from pitolisant or the underlying maternal condition.

Drugs/Diseases

Util A	Util B	Util C
Pitolisant	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Wakix Prescribing Information, August 2019, Harmony Biosciences.

15. Pitolisant / Pregnancy / Pregnancy Negating _____ _____

Alert Message: Patients who become pregnant while on Wakix (pitolisant) should be encouraged to enroll in the WAKIX pregnancy registry. There are no adequate data on the developmental risk associated with pitolisant use during human pregnancy. In animal reproductive studies, administration of pitolisant during organogenesis caused maternal and embryofetal toxicity in rats and rabbits.

Drugs/Diseases

Util A	Util B	Util C **(Negating)**
Pitolisant	Pregnancy	Delivery
		Miscarriage
		Abortion

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Wakix Prescribing Information, August 2019, Harmony Biosciences.

16. Rizatriptan / Therapeutic Appropriateness _____ _____

Alert Message: The safety and effectiveness of rizatriptan in pediatric patients under 6 years of age have not been established.

Drugs/Diseases

Util A	Util B	Util C
Rizatriptan		

Age Range: 0 - 5 yoa

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Facts & Comparisons, 2019 Updates, Wolters Kluwer Health.

17. Baricitinib / Overutilization _____ _____

Alert Message: Olumiant (baricitinib) may be over-utilized. The recommended dose of baricitinib in patients with moderate renal impairment (estimated glomerular filtration rate (GFR) between 30 and 60 mL/min/1.73 m2) is 1 mg once daily. Baricitinib is not recommended for use in patients with severe renal impairment (estimated GFR of less than 30 mL/min/1.73 m2).

Drugs/Diseases

Util A	Util B	Util C
Baricitinib 2mg	CKD 3	

Max Dose: 1 mg/day

References:

Olumiant Prescribing Information, Oct. 2019, Eli Lilly and Company.

18. Dolutegravir/Lamivudine / Non-adherence _____ _____

Alert Message: Based on the refill history, your patient may be underutilizing Dovato (dolutegravir/lamivudine). Nonadherence to antiretroviral therapy may result in insufficient plasma levels and partial suppression of viral load leading to the development of resistance, HIV progression, and increased mortality.

Drugs/Diseases

Util A	Util B	Util C
Dolutegravir/Lamivudine		

References:

Osterberg L, Blaschke T. Adherence to Medication. N Engl J Med 2005;353:487-97.
Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the Use of Antiretroviral Agents in HIV-1 Infected Adults and Adolescents. Department of Health and Human Services. July 10, 2019.
Available at: http://www.aidsinfo.nih.gov/guidelines/ht,l/1/adult-and-adolescent-arv/0
Panel on Antiretroviral Therapy and Medical Management of HIV-Infected Children. Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection. September 12, 2019.
Available at: http://aidsinfo.nih.gov/contentfiles/lvguidelines/pediatricguidelines.pdf

19. Dolutegravir/Lamivudine / Overutilization _____ _____

Alert Message: Dovato (dolutegravir/lamivudine) may be over-utilized. The recommended dosage regimen of dolutegravir/lamivudine in adults is one tablet taken orally once daily with or without food.

Drugs/Diseases

Util A	Util B	Util C **(Negating)**
Dolutegravir/Lamivudine		Carbamazepine Rifampin

Max Dose: 1 tablet/day

References:

Dovato Prescribing Information, Oct. 2019, ViiV Healthcare.
Clinical Pharmacology, 2019 Elsevier/Gold Standard.

20. Dolutegravir/Lamivudine / Severe Renal Impairment _____ _____

Alert Message: Dovato (dolutegravir/lamivudine) is not recommended for patients with creatinine clearance < 50 mL/min because it is a fixed-dose combination product, and the dosage of the individual components cannot be adjusted. If a dose reduction of lamivudine, a component of dolutegravir/lamivudine, is required for patients with creatinine clearance < 50 mL/min, then the individual component should be used.

Drugs/Diseases

Util A	Util B	Util C **(Include)**
Dolutegravir/Lamivudine		CKD 4 & 5

References:
Dovato Prescribing Information, Oct. 2019, ViiV Healthcare.
Clinical Pharmacology, 2019 Elsevier/Gold Standard.

21. Dolutegravir/Lamivudine / Carbamazepine _____ _____

Alert Message: The dolutegravir dose (50 mg) in Dovato (dolutegravir/lamivudine) is insufficient when coadministered with the carbamazepine. Dolutegravir is a CYP3A4 substrate, and concurrent use with the strong CYP3A4 inducer carbamazepine may result in decreased dolutegravir concentrations. If these drugs are co-administered, an additional dolutegravir 50 mg tablet, separated by 12 hours from dolutegravir/lamivudine, should be taken.

Drugs/Diseases

Util A	Util B	Util C **(Negating)**
Dolutegravir/Lamivudine	Carbamazepine	Dolutegravir

References:
Dovato Prescribing Information, Oct. 2019, ViiV Healthcare.
Clinical Pharmacology, 2019 Elsevier/Gold Standard.

22. Dolutegravir/Lamivudine / Rifampin _____ _____

Alert Message: The dolutegravir dose (50 mg) in Dovato (dolutegravir/lamivudine) is insufficient when coadministered with the rifampin. Dolutegravir is a CYP3A4 substrate, and concurrent use with the strong CYP3A4 inducer rifampin may result in decreased dolutegravir concentrations. If these drugs are co-administered, an additional dolutegravir 50 mg tablet, separated by 12 hours from dolutegravir/lamivudine, should be taken.

Drugs/Diseases

Util A	Util B	Util C **(Negating)**
Dolutegravir/Lamivudine	Rifampin	Dolutegravir

References:
Dovato Prescribing Information, Oct. 2019, ViiV Healthcare.
Clinical Pharmacology, 2019 Elsevier/Gold Standard.

23. Dolutegravir/Lamivudine / Therapeutic Appropriateness _____ _____

Alert Message: The patient appears to be receiving other antiretroviral therapy in addition to Dovato (dolutegravir/lamivudine). Dolutegravir/lamivudine is a complete regimen for the treatment of HIV-1 infections and should not be administered with other antiretroviral medications.

Drugs/Diseases

Util A	Util B	Util C
Dolutegravir/Lamivudine	All Other HIV Antiretroviral Meds	

References:
Dovato Prescribing Information, Oct. 2019, ViiV Healthcare.
Clinical Pharmacology, 2019 Elsevier/Gold Standard.

24. Dolutegravir/Lamivudine / Therapeutic Appropriateness _____ _____

Alert Message: The safety and effectiveness of Dovato (dolutegravir/lamivudine) have not been established in pediatric patients.

Drugs/Diseases

Util A	Util B	Util C
Dolutegravir/Lamivudine		

Age Range: 0-17 yoa

References:
Dovato Prescribing Information, Oct. 2019, ViiV Healthcare.
Clinical Pharmacology, 2019 Elsevier/Gold Standard.

25. Dolutegravir/Lamivudine / Dofetilide _____ _____

Alert Message: Coadministration of Dovato (dolutegravir/lamivudine) with dofetilide is contraindicated due to the potential for increased dofetilide plasma concentrations and the risk of serious and/or life-threatening events (e.g., QT prolongation and torsades de pointes). The dolutegravir component of the combination antiretroviral product inhibits the renal organic transporter (OCT2) which is responsible for dofetilide elimination.

Drugs/Diseases

Util A	Util B	Util C
Dolutegravir/Lamivudine	Dofetilide	

References:
Dovato Prescribing Information, Oct. 2019, ViiV Healthcare.
Clinical Pharmacology, 2019 Elsevier/Gold Standard.

26. Dolutegravir/Lamivudine / Hepatitis B & C _____ _____

Alert Message: Hepatotoxicity has been reported in patients receiving dolutegravir-containing regimen. Patients with underlying hepatitis B or C may be at increased risk for worsening or development of transaminase elevations with the use of Dovato (dolutegravir/lamivudine). Monitoring for hepatotoxicity in this patient population is recommended.

Drugs/Diseases

Util A	Util B	Util C
Dolutegravir/Lamivudine	Hepatitis B Hepatitis C	

References:
Dovato Prescribing Information, Oct. 2019, ViiV Healthcare.
Clinical Pharmacology, 2019 Elsevier/Gold Standard.

27. Dolutegravir/Lamivudine / Iron and Calcium Supplements _____ _____

Alert Message: Concurrent use of supplements containing calcium and iron can bind to the dolutegravir component of Dovato (dolutegravir/lamivudine) in the GI tract and reduce dolutegravir bioavailability. Dolutegravir/lamivudine should be administered 2 hours before or 6 hours after taking oral calcium or iron supplements. When taken with food, dolutegravir/lamivudine and the supplement can be taken together.

Drugs/Diseases

Util A	Util B	Util C
Dolutegravir/Lamivudine	Oral Calcium Carbonate	
	Oral Iron Supplements	
	Multivitamins with Ca & Fe	

References:

Dovato Prescribing Information, Oct. 2019, ViiV Healthcare.
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Cottrel ML, Hadzic T, Kashuba AD. Clinical Pharmacokinetic, Pharmacodynamic and Drug-Interaction Profile of the Integrase Inhibitor Dolutegravir/Lamivudine. Clin Pharmacokinet. 04 July 2013 (Online).

28. Dolutegravir/Lamivudine / Lactic Acidosis & Hepatomegaly _____ _____

Alert Message: Lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, have been reported with the use of nucleoside analogs, including the lamivudine component of the combination antiretroviral Dovato (dolutegravir/lamivudine). Closely monitor patients with known risk factors for liver disease (e.g., female sex, obesity) receiving dolutegravir/lamivudine. Treatment with dolutegravir/lamivudine should be suspended in any patient who develops clinical or laboratory findings suggestive of lactic acidosis or pronounced hepatotoxicity.

Drugs/Diseases

Util A	Util B	Util C
Dolutegravir/Lamivudine	Lactic Acidosis	
	Hepatomegaly	
	Hepatic Steatosis	

References:

Dovato Prescribing Information, Oct. 2019, ViiV Healthcare.
Clinical Pharmacology, 2019 Elsevier/Gold Standard.

29. Dolutegravir/Lamivudine / Severe Hepatic Impairment _____ _____

Alert Message: Dovato (dolutegravir/lamivudine) is not recommended in patients with severe hepatic impairment (Child-Pugh Score C). Lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, have been reported with the use of nucleoside analogs, including the lamivudine component of the combination antiretroviral Dovato (dolutegravir/lamivudine).

Drugs/Diseases

Util A	Util B	Util C
Dolutegravir/Lamivudine	Cirrhosis	
	Hepatic Failure	
	Toxic Liver Disease	

References:

Dovato Prescribing Information, Oct. 2019, ViiV Healthcare.
Clinical Pharmacology, 2019 Elsevier/Gold Standard.

30. Dolutegravir/Lamivudine / Certain 3A4 Inducers _____ _____

Alert Message: The concurrent use of Dovato (dolutegravir/lamivudine) and the CYP3A4 inducers oxcarbazepine, phenytoin of phenobarbital should be avoided. The dolutegravir component of the combination antiretroviral is a CYP3A4 substrate and use with the CYP3A4 inducer may result in decreased dolutegravir concentrations. There is insufficient data to make dosing recommendations for this drug combination.

Drugs/Diseases

Util A	Util B	Util C
Dolutegravir/Lamivudine	Phenobarbital	
	Phenytoin	
	Oxcarbazepine	

References:

Dovato Prescribing Information, Oct. 2019, ViiV Healthcare.
Clinical Pharmacology, 2019 Elsevier/Gold Standard

31. Dolutegravir/Lamivudine / Metformin _____ _____

Alert Message: Concurrent use of Dovato (dolutegravir/lamivudine) and metformin may result in increased plasma concentrations of metformin, increasing the risk of metformin-related adverse effects (i.e., lactic acidosis). The dolutegravir component of the combination antiretroviral is an OCT2 and MATE1 inhibitor, and metformin is a substrate of both OCT2 and MATE1 substrate. If coadministration is required, limit the total daily dose of metformin to 1000 mg when starting metformin or dolutegravir. If treatment with dolutegravir is discontinued, dosage adjustment of metformin may be required.

Drugs/Diseases

Util A	Util B	Util C
Dolutegravir/Lamivudine	Metformin	

References:

Dovato Prescribing Information, Oct. 2019, ViiV Healthcare.
Clinical Pharmacology, 2013 Elsevier/Gold Standard.
Tivicay Prescribing Information, Oct. 2019, ViiV Healthcare.

32. Dolutegravir/Lamivudine / Medications Containing Polyvalent Cations _____ _____

Alert Message: Dovato (dolutegravir/lamivudine) should be administered 2 hours before or 6 hours after taking medications containing polyvalent cations. Medications containing polyvalent cations can bind to the dolutegravir component of the combination antiretroviral product in the GI tract and reduce dolutegravir bioavailability.

Drugs/Diseases

Util A	Util B	Util C
Dolutegravir/Lamivudine	Aluminum Hydroxide	
	Cation-containing Laxatives	
	Magnesium Hydroxide	
	Sucralfate	

References:

Dovato Prescribing Information, Oct. 2019, ViiV Healthcare.
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Cottrel ML, Hadzic T, Kashuba AD. Clinical Pharmacokinetic, Pharmacodynamic and Drug-Interaction Profile of the Integrase Inhibitor Dolutegravir/Lamivudine. Clin Pharmacokinet. 04 July 2013 (Online).

33. Dolutegravir / Pregnancy / Pregnancy Negating _____ _____

Alert Message: The use of dolutegravir has been associated with increased risk of neural tube defects when administered at the time of conception and in early pregnancy. Avoid the use of dolutegravir-containing agents at the time of conception through the first trimester of pregnancy. If there are plans to become pregnant or if pregnancy is confirmed within the first trimester while on a dolutegravir-containing agent, if possible, switch to an alternative regimen. Perform pregnancy testing before initiation of a dolutegravir-containing medication in individuals of childbearing potential.

Drugs/Diseases

Util A	Util B	Util C **(Negate)**
Dolutegravir	Pregnancy	Delivery
Dolutegravir/Rilpivirine		Miscarriage
Dolutegravir/Lamivudine		Abortion
Dolutegravir/Lamivudine/Abacavir		

Age Range: 11 – 50 yoa
Gender: Female

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Facts & Comparisons, 2019 Updates, Wolters Kluwer Health.

34. Semaglutide Tabs / Overuse _____ _____

Alert Message: Rybelsus (semaglutide) may be over-utilized. The recommended maximum daily dose of oral semaglutide is 14 mg once daily.

Drugs/Diseases

Util A	Util B	Util C
Semaglutide Tabs		

Max Dose: 14 mg/day

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Rybelsus Prescribing Information, Sept. 2019, Novo Nordisk, Inc.

35. Semaglutide Tabs / Non-adherence _____ _____

Alert Message: Based on refill history, your patient may be under-utilizing Rybelsus (semaglutide). 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
Semaglutide Tabs		

References:
Osterberg L, Blaschke T. Adherence to Medication. N Engl J Med 2005; 353:487- 497.
Ho PM, Rumsfeld JS, Masoudi FA, et al., Effect of Medication Nonadherence in Diabetes Mellitus. Cardiology Review, April 2007.
Currie CJ, Peyrot M, Morgan CL, et al. The Impact of Treatment Noncompliance on Mortality in People With Type 2 Diabetes. Diabetes Care 35:1279-1284, June 2012.

36. Semaglutide Tabs / Medullary Thyroid Carcinoma & MEN 2 (Black Box Warning) _____ _____

Alert Message: The use of Rybelsus (semaglutide), a glucagon-like peptide-1 (GLP-1) receptor agonist, is contraindicated in patients with a personal or family history of medullary thyroid carcinoma (MTC) or with Multiple Endocrine Neoplasia Syndrome type 2 (MEN 2). GLP-1 receptor agonists have been shown to increase the incidence of thyroid C-cell tumors in rodents. Patients should be counseled regarding the risk of MTC and the symptoms of thyroid tumors (e.g., a mass in the neck, dysphagia, dyspnea, or persistent hoarseness).

Drugs/Diseases

Util A	Util B	Util C **(Include)**
Semaglutide Tabs		Medullary Thyroid Carcinoma II
		Thyroid Carcinoma
		History of Thyroid Carcinoma

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Rybelsus Prescribing Information, Sept. 2019, Novo Nordisk, Inc.

37. Semaglutide Tabs / Therapeutic Appropriateness (Black Box Warning) _____ _____

Alert Message: Rybelsus (semaglutide) is a glucagon-like peptide-1 (GLP-1) receptor agonist and GLP-1 receptor agonists have been shown to cause thyroid C-cell tumors at clinically relevant exposure in rodents. It is unknown whether semaglutide causes thyroid C-cell tumors, including medullary thyroid carcinoma (MTC), in humans. Patients should be counseled regarding the risk of medullary thyroid carcinoma and the symptoms of thyroid tumors (e.g., a mass in the neck, dysphagia, dyspnea, or persistent hoarseness).

Drugs/Diseases

Util A	Util B	Util C
Semaglutide Tabs		

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Rybelsus Prescribing Information, Sept. 2019, Novo Nordisk, Inc.

38. Semaglutide / Pancreatitis _____ _____

Alert Message: In clinical trials, acute pancreatitis has been reported in association with Rybelsus (semaglutide) use. If pancreatitis is suspected, semaglutide should be discontinued promptly. If confirmed, semaglutide should not be restarted. Semaglutide has not been studied in patients with a history of pancreatitis to determine whether these patients are at increased risk for pancreatitis. Consider other antidiabetic therapies in patients with a history of pancreatitis.

Drugs/Diseases

Util A	Util B	Util C
Semaglutide	Pancreatitis	

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Rybelsus Prescribing Information, Sept. 2019, Novo Nordisk, Inc.

39. Semaglutide / Diabetic Retinopathy _____ _____

Alert Message: Patients with a history of diabetic retinopathy should be monitored for the progression of diabetic retinopathy when taking Rybelsus (semaglutide). In a pooled analysis of glycemic control trials with oral semaglutide, diabetic retinopathy complications occurred in 4.2% of patients receiving semaglutide and 3.8% with a comparator. Counsel patients to contact their physician if changes in vision are experienced during treatment with semaglutide.

Drugs/Diseases

Util A	Util B	Util C
Semaglutide	Diabetic Retinopathy	

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Rybelsus Prescribing Information, Sept. 2019, Novo Nordisk, Inc.

40. Semaglutide Tabs / Therapeutic Appropriateness _____ _____

Alert Message: The safety and effectiveness of Rybelsus (semaglutide) have not been established in pediatric patients (younger than 18 years).

Drugs/Diseases

Util A	Util B	Util C
Semaglutide Tabs		

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Rybelsus Prescribing Information, Sept. 2019, Novo Nordisk, Inc.

41. Semaglutide Tabs / Insulin and Insulin Secretagogues _____ _____

Alert Message: The risk of hypoglycemia is increased when Rybelsus (semaglutide) is used in combination with insulin secretagogues (e.g., sulfonylureas) or insulin. Therefore, patients may require a lower dose of sulfonylurea or insulin to reduce the risk of hypoglycemia in this setting.

Drugs/Diseases

Util A	Util B	Util C
Semaglutide Tabs	Insulins	
	Chlorpropamide	
	Glimepiride	
	Glipizide	
	Glyburide	
	Tolazamide	
	Tolbutamide	

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Rybelsus Prescribing Information, Sept. 2019, Novo Nordisk, Inc.

42. Semaglutide Tabs / Oral Drugs w/NTI _____ _____

Alert Message: Rybelsus (semaglutide) causes a delay of gastric emptying, and thereby has the potential to impact the absorption of other oral medications. When coadministering oral medications instruct patients to follow closely semaglutide administra-tion instructions. Consider increased clinical or laboratory monitoring for medications that have a narrow therapeutic index or that require clinical monitoring.

Drugs/Diseases

Util A	Util B		Util C
Semaglutide Tabs	Levothyroxine	Phenytoin	
	Carbamazepine	Procainamide	
	Ethosuximide	Tacrolimus	
	Cyclosporine	Theophylline	
	Digoxin	Warfarin	
	Lithium		

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Rybelsus Prescribing Information, Sept. 2019, Novo Nordisk, Inc.

43. Semaglutide Tabs / Renal Impairment _____ _____

Alert Message: There have been postmarketing reports of acute kidney injury and worsening of chronic renal failure, which may sometimes require hemodialysis, in patients treated with GLP-1 receptor agonists, including Rybelsus (semaglutide). Some of these events have been reported in patients without known underlying renal disease. A majority of the reported events occurred in patients who had experienced nausea, vomiting, diarrhea, or dehydration. Monitor renal function when initiating or escalating doses of semaglutide in patients reporting severe adverse gastrointestinal reactions.

Drugs/Diseases

Util A	Util B	Util C
Semaglutide Tabs	Renal Impairment	

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Rybelsus Prescribing Information, Sept. 2019, Novo Nordisk, Inc.

44. Semaglutide Tabs / Pregnancy / Delivery, Miscarriage & Abortion _____ _____

Alert Message: Available data with Rybelsus (semaglutide) use in pregnant women are insufficient to evaluate for a drug-associated risk of major birth defects, miscarriage, or other adverse maternal or fetal outcomes. There are clinical considerations regarding the risks of poorly controlled diabetes in pregnancy. Based on animal reproduction studies, there may be potential risks to the fetus from exposure to semaglutide during pregnancy. Semaglutide should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Drugs/Diseases

Util A	Util B	Util C **(Negating)**
Semaglutide Tabs	Pregnancy	Delivery
		Miscarriage
		Abortion

Age Range: 11 – 50 yoa
Gender: Female

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Rybelsus Prescribing Information, Sept. 2019, Novo Nordisk, Inc.

45. Semaglutide Tabs / Lactation _____ _____

Alert Message: Rybelsus (semaglutide) use is not recommended in patients who are breast-feeding. While there are no data on the presence of semaglutide in human milk, semaglutide and salcaprozate sodium (an absorption enhancer in the oral product) has been shown to be present in the milk of lactating rats. When a substance is present in animal milk, the substance will likely be present in human milk. Other hypoglycemics agents may be considered as possible alternatives for treatment.

Drugs/Diseases

Util A	Util B	Util C
Semaglutide Tabs	Lactation	

Age Range: 11 – 50 yoa
Gender: Female

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Rybelsus Prescribing Information, Sept. 2019, Novo Nordisk, Inc.

46. Exenatide ER / Severe Renal Impairment _____ _____

Alert Message: Exenatide extended-release (Bydureon & Bydureon BCise) is not recommended for use in patients with eGFR below 45 mL/min/1.73 m2 or end-stage renal disease. There have been postmarketing reports of altered renal function with exenatide, including increased serum creatinine, renal impairment, worsened chronic renal failure, and acute renal failure, sometimes requiring hemodialysis or kidney transplantation. If used in patients with renal transplantation, closely monitor for adverse reactions that may lead to hypovolemia.

Drugs/Diseases

Util A	Util B	Util C
Exenatide ER	CKD 4	
	CKD 5	
	ESRD	
	Kidney Transplant	

References:
Bydureon Prescribing Information, Feb. 2019, AstraZeneca Pharmaceuticals, Inc.
Bydureon BCise Prescribing Information, July 2019, AstraZeneca Pharmaceuticals, Inc.
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Facts & Comparisons, 2019 Updates, Wolters Kluwer Health.

47. Mepolizumab Prefilled / Overutilization _____ _____

Alert Message: The recommended dose of Nucala (mepolizumab) in children aged 6 to 11 years of age with severe asthma with an eosinophilic phenotype is 40 mg once every 4 weeks by subcutaneous injection in the upper arm, thigh, or abdomen. The mepolizumab prefilled autoinjector and prefilled syringe are only for use in adults and adolescents aged 12 years and older.

Drugs/Diseases

Util A	Util B	Util C **(Include)**
Mepolizumab prefilled syringe		Asthma
Mepolizumab prefilled autoinjector		

Age Range: 6 – 11 yoa

References:
Nucala Prescribing Information, Sept. 2019, GlaxoSmithKline.

48. Halobetasol/Tazarotene / Pregnancy / Pregnancy Negating _____ _____

Alert Message: Duobrii (halobetasol/tazarotene lotion) is contraindicated in pregnancy. Based on data from animal reproduction studies, retinoid pharmacology, and the potential for systemic absorption, halobetasol/tazarotene lotion may cause fetal harm when administered to a pregnant female. Tazarotene elicits teratogenic and developmental effects associated with retinoids after topical or systemic administration in rats and rabbits.

Drugs/Diseases

Util A	Util B	Util C **(Negating)**
Halobetasol/Tazarotene	Pregnancy	Miscarriage
		Delivery
		Abortion

Age Range: 11 – 50 yoa
Gender: Female

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Facts & Comparisons, 2019 Updates, Wolters Kluwer Health.
Duobrii Prescribing Information, April 2019, Bausch Health Companies Inc.

49. Halobetasol/Tazarotene / Therapeutic Appropriateness _____ _____

Alert Message: The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Duobrii (halobetasol/tazarotene lotion) and any potential adverse effects on the breastfed child from halobetasol/tazarotene lotion. There are no data on the presence of tazarotene, halobetasol propionate or its metabolites in human milk, the effects on the breastfed infant, or the effects on milk production after treatment with halobetasol/tazarotene lotion.

Drugs/Diseases

Util A	Util B	Util C
Halobetasol/Tazarotene	Lactation	

Age Range: 11 – 50 yoa
Gender: Female

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Facts & Comparisons, 2019 Updates, Wolters Kluwer Health.
Duobrii Prescribing Information, April 2019, Bausch Health Companies Inc.

50. Halobetasol/Tazarotene / Contraceptives _____ _____

Alert Message: Females of reproductive potential should be warned of the potential risk to a fetus if they were to become pregnant while on Duobrii (halobetasol/tazarotene lotion) therapy. The patient should be advised to use effective birth control measures during treatment with halobetasol/tazarotene lotion. A negative pregnancy test should be obtained within 2 weeks prior to halobetasol/tazarotene lotion therapy. Treatment should be initiated during a menstrual period.

Drugs/Diseases

Util A	Util B	Util C **(Negating)**
Halobetasol/Tazarotene		Contraceptives

Age Range: 11 – 50 yoa
Gender: Female

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Facts & Comparisons, 2019 Updates, Wolters Kluwer Health.
Duobrii Prescribing Information, April 2019, Bausch Health Companies Inc.

51. Halobetasol/Tazarotene / Therapeutic Appropriateness _____ _____

Alert Message: The safety and effectiveness of Duobrii (halobetasol/tazarotene lotion) in pediatric patients under the age of 18 years have not been evaluated. Because of higher skin surface area to body mass ratios, pediatric patients are at a greater risk than adults of HPA axis suppression and Cushing's syndrome when they are treated with topical corticosteroids. They are therefore also at greater risk of adrenal insufficiency during or after withdrawal of treatment. Adverse reactions, including striae, have been reported with the use of topical corticosteroids in infants and children.

Drugs/Diseases

Util A	Util B	Util C
Halobetasol/Tazarotene		

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Facts & Comparisons, 2019 Updates, Wolters Kluwer Health.
Duobrii Prescribing Information, April 2019, Bausch Health Companies Inc.

52. Ibuprofen/Famotidine / CKD 3, 4, & 5 _____ _____

Alert Message: Avoid the use of Duexis (ibuprofen/famotidine) in patients with advanced renal disease unless the benefits are expected to outweigh the risk of worsening renal failure. The ibuprofen component of the combination product can cause renal injury. Additionally, the famotidine component of the combination product has been associated with CNS adverse effects in patients with moderate to severe renal insufficiency.

Drugs/Diseases

Util A	Util B	Util C
Ibuprofen/Famotidine	CKD 3	
	CKD 4	
	CKD 5	

References:
Duexis Prescribing Information, June 2019, Horizon Pharma USA.
Clinical Pharmacology, 2019 Elsevier/gold Standard.

53. Ibuprofen/Famotidine / Geriatric _____ _____

Alert Message: Duexis (ibuprofen/famotidine) should be used with caution in the elderly. Elderly patients, compared to younger patients, are at greater risk for NSAID-associated adverse reactions. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection and dosing interval. Famotidine is substantially excreted by the kidney, and risk of famotidine-related adverse reactions may be greater in patients with impaired renal function.

Drugs/Diseases

Util A	Util B	Util C
Ibuprofen/Famotidine		

Age Range: ≥ 65 yoa

References:
Duexis Prescribing Information, June 2019, Horizon Pharma USA.
Clinical Pharmacology, 2019 Elsevier/gold Standard.

54. Ibuprofen/Famotidine / Overutilization _____ _____

Alert Message: The recommended daily dose of Duexis (ibuprofen/famotidine) is one tablet (ibuprofen 800 mg/famotidine 26.6 mg) 3 times daily.

Drugs/Diseases
Util A Util B Util C
Ibuprofen/Famotidine

Max Dose: 3 tablets/day

References:
Duexis Prescribing Information, June 2019, Horizon Pharma USA.
Clinical Pharmacology, 2019 Elsevier/gold Standard.

55. Riluzole Tablets & Film / Overutilization _____ _____

Alert Message: Riluzole may be over-utilized. The manufacturer's recommended dosage of riluzole is 50 mg twice daily.

Drugs/Diseases
Util A Util B Util C
Riluzole Tablets
Riluzole Oral Film

Max Dose: 100 mg/day

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Facts & Comparisons, 2019 Updates, Wolters Kluwer Health.

56. Riluzole Suspension / Overutilization _____ _____

Alert Message: Tiglutik (riluzole oral suspension) may be over-utilized. The manufacturer's recommended dosage of riluzole oral suspension is 50 mg (10 mL) twice daily, every 12 hours.

Drugs/Diseases
Util A Util B Util C
Riluzole Suspension

Max Dose: 100 mg/day

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Tiglutik Prescribing Information, September 2018, ITF Pharma.

57. Riluzole – All / Therapeutic Appropriateness _____ _____

Alert Message: Cases of drug-induced liver injury, some of which were fatal, have been reported in patients taking riluzole. Patients should be monitored for signs and symptoms of hepatic injury, every month for the first three months of treatment, and periodically thereafter. The use of riluzole is not recommended if patients develop hepatic transaminases levels greater than 5 times the ULN. Discontinue riluzole if there is evidence of liver dysfunction (e.g., elevated bilirubin).

Drugs/Diseases
Util A Util B Util C
Riluzole

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Facts & Comparisons, 2019 Updates, Wolters Kluwer Health.

58. Riluzole – All / Pulmonary Toxicity _____ _____

Alert Message: Interstitial lung disease, including hypersensitivity pneumonitis, has occurred in patients taking riluzole. Discontinue riluzole immediately if interstitial lung disease develops.

Drugs/Diseases

Util A	Util B	Util C
Riluzole	Acute Interstitial Pneumonia	
	Dyspnea	

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Facts & Comparisons, 2019 Updates, Wolters Kluwer Health.

59. Riluzole – All / Fever & Neutropenia _____ _____

Alert Message: Cases of severe neutropenia (absolute neutrophil count less than 500 per mm3) within the first 2 months of riluzole treatment have been reported. Advise patients to report febrile illnesses.

Drugs/Diseases

Util A	Util B	Util C
Riluzole	Fever	
	Neutropenia	

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Facts & Comparisons, 2019 Updates, Wolters Kluwer Health.

60. Riluzole – All / CYP1A2 Inhibitors _____ _____

Alert Message: The concomitant use of strong or moderate CYP1A2 inhibitors (e.g., ciprofloxacin, fluvoxamine, methoxsalen, mexiletine, oral contraceptive, vemurafenib, zileuton) with riluzole (a CYP1A2 substrate) may increase the risk of riluzole-associated adverse reactions.

Drugs/Diseases

Util A	Util B	Util C
Riluzole	Ciprofloxacin	
	Fluvoxamine	
	Methoxsalen	
	Mexiletine	
	Oral Contraceptives	
	Vemurafenib	
	Zileuton	

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Facts & Comparisons, 2019 Updates, Wolters Kluwer Health.

61. Riluzole – All / CYP1A2 Inducers _____ _____

Alert Message: Concurrent use of riluzole (a CYP1A substrate) with CYP1A2 inducers may decrease riluzole exposure, which may result in decreased riluzole efficacy.

Drugs/Diseases

Util A	Util B	Util C
Riluzole	Barbiturates	
	Carbamazepine	
	Cannabidiol	
	Leflunomide	
	Modafinil	
	Omeprazole	
	Rifampin	
	Ritonavir	
	Teriflunomide	
	Tipranavir	

References:

Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Facts & Comparisons, 2019 Updates, Wolters Kluwer Health.

62. Riluzole – All / Hepatotoxic Drugs _____ _____

Alert Message: Cases of drug-induced liver injury, some of which were fatal, have been reported in patients taking riluzole. Riluzole-treated patients who take other hepatotoxic drugs may be at an increased risk for hepatotoxicity.

Drugs/Diseases

Util A	Util B		Util C
Riluzole	Alectinib	Ixazomib	
	Allopurinol	Ketoconazole	
	Amiodarone	Larotrectinib	
	Amoxicillin-clavulanate	Maraviroc	
	Atorvastatin	Methotrexate	
	Azathioprine	Methyldopa	
	Busulfan	Minocycline	
	Carbamazepine	Nefazodone	
	Chlorpromazine	Nitrofurantoin	
	Dantrolene	Phenytoin	
	Diclofenac	Propylthiouracil	
	Didanosine	Pyrazinamide	
	Disulfiram	Quinidine	
	Efavirenz	Rifampin	
	Erythromycin	Simvastatin	
	Erlotinib	Sulfasalazine	
	Flutamide	Sulindac	
	Ibuprofen	Sunitinib	
	Idelalisib	Ticlopidine	
	Infliximab	TMP-SMZ	
	Interferon	Valproate	
	Isoniazid		
	Itraconazole		

References:

Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Facts & Comparisons, 2019 Updates, Wolters Kluwer Health.
Bjornsson ES. Hepatotoxicity by Drugs: The Most Common Implicated Agents. Int J Mol Sci. 2016;17(2):224. Published 2016 Feb 6. doi:10.3390/ijms17020224

63. Riluzole – All / Therapeutic Appropriateness _____ _____

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

Drugs/Diseases

Util A	Util B	Util C
Riluzole		

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Facts & Comparisons, 2019 Updates, Wolters Kluwer Health.

64. Riluzole – All / Nonadherence _____ _____

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

Drugs/Diseases

Util A	Util B	Util C
Riluzole		

References:
Osterberg L, Blaschke T. Adherence to Medication. N Engl J Med 2005; 353:487- 497.
Introna A, D'Errico E, Modugno B, et al., Adherence to Riluzole in Patients with Amyotrophic Lateral Sclerosis: An Observational Study. Neuropsych Dis Treat. 2018;14:193-203.
Viswanathan M, Golin CE, Jones CD, et al. Interventions to Improve Adherence to Self-administered Medications for Chronic Diseases in the United States: A Systematic Review. Ann Intern Med. 2012 Dec 4;157:785–795. doi: 10.7326/0003-4819-157-11-201212040-00538

65. Riluzole – All / Pregnancy / Pregnancy Negating _____ _____

Alert Message: There are no studies of riluzole in pregnant women, and case reports have been inadequate to inform the drug-associated risk. In studies in which riluzole was administered orally to pregnant animals, developmental toxicity (decreased embryofetal/offspring viability, growth, and functional development) was observed at clinically relevant doses. Based on these results, women should be advised of a possible risk to the fetus associated with the use of riluzole during pregnancy.

Drugs/Diseases

Util A	Util B	Util C **(Negating)**
Riluzole	Pregnancy	Delivery
		Miscarriage
		Abortion

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Facts & Comparisons, 2019 Updates, Wolters Kluwer Health.

66. Riluzole – All / Lactation _____ _____

Alert Message: It is not known if riluzole is excreted in human milk. Riluzole or its metabolites have been detected in the milk of lactating rats. Women should be advised that many drugs are excreted in human milk and that the potential for serious adverse reactions in nursing infants from riluzole is unknown.

Drugs/Diseases

Util A	Util B	Util C
Riluzole	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Facts & Comparisons, 2019 Updates, Wolters Kluwer Health.

67. Gilteritinib / Overutilization _____ _____

Alert Message: The recommended starting dose of Xospata (gilteritinib) is 120 mg orally once daily with or without food.

Drugs/Diseases

Util A	Util B	Util C
Gilteritinib		

Max Dose: 120 mg/day

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Xospata Prescribing Information, May 2019, Astellas Pharma US, Inc.

68. Gilteritinib / Pregnancy / Pregnancy Negating _____ _____

Alert Message: Based on findings in animals and its mechanism of action, Xospata (gilteritinib) can cause embryo-fetal harm when administered to a pregnant woman. In animal reproduction studies, administration of gilteritinib to pregnant rats during organogenesis caused embryo-fetal lethality, suppressed fetal growth and teratogenicity at maternal exposures approximately 0.4 times the AUC24 in patients receiving the recommended dose. Advise pregnant women of the potential risk to a fetus.

Drugs/Diseases

Util A	Util B	Util C **(Negating)**
Gilteritinib	Pregnancy	Delivery
		Miscarriage
		Abortion

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Xospata Prescribing Information, May 2019, Astellas Pharma US, Inc.

69. Gilteritinib / Therapeutic Appropriateness _____ _____

Alert Message: Advise males with female partners of reproductive potential to use effective contraception during treatment with gilteritinib and for at least 4 months after the last dose of Xospata (gilteritinib). Male patients with pregnant female partners should be apprised of the potential risk to the fetus.

Drugs/Diseases

Util A	Util B	Util C
Gilteritinib		

Gender: Male

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Xospata Prescribing Information, May 2019, Astellas Pharma US, Inc.

70. Gilteritinib / Therapeutic Appropriateness _____ _____

Alert Message: Females of reproductive potential should be advised to use effective contraception during treatment and for at least 6 months after the last dose of Xospata (gilteritinib). Based on findings in animals and its mechanism of action, gilteritinib can cause embryo-fetal harm when administered to a pregnant woman.

Drugs/Diseases

Util A	Util B	Util C **(Negating)**
Gilteritinib		Contraceptives

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Xospata Prescribing Information, May 2019, Astellas Pharma US, Inc.

71. Gilteritinib / Lactation _____ _____

Alert Message: There are no data on the presence of Xospata (gilteritinib) and/or its metabolites in human milk, the effects on the breastfed child, or the effects on milk production. In animal studies, gilteritinib and/or its metabolite(s) were distributed to the tissues in infant rats via the milk. Because of the potential for serious adverse reactions in a breastfed child, advise a lactating woman not to breastfeed during treatment with gilteritinib and for 2 months after the last dose.

Drugs/Diseases

Util A	Util B	Util C
Gilteritinib	Lactation	

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Xospata Prescribing Information, May 2019, Astellas Pharma US, Inc.

72. Gilteritinib / Therapeutic Appropriateness _____ _____

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

Drugs/Diseases

Util A	Util B	Util C
Gilteritinib		

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Xospata Prescribing Information, May 2019, Astellas Pharma US, Inc.

73. Gilteritinib / Posterior Reversible Encephalopathy _____ _____

Alert Message: There have been rare reports of posterior reversible encephalopathy syndrome (PRES) with symptoms including seizure and altered mental status with Xospata (gilteritinib). Symptoms have resolved after discontinuation of gilteritinib. A diagnosis of PRES requires confirmation by brain imaging, preferably magnetic resonance imaging (MRI). Discontinue gilteritinib in patients who develop PRES.

Drugs/Diseases

Util A	Util B	Util C
Gilteritinib	Posterior Reversible Encephalopathy	

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Xospata Prescribing Information, May 2019, Astellas Pharma US, Inc.

74. Gilteritinib / QT Prolongation _____ _____

Alert Message: Xospata (gilteritinib) has been associated with prolonged cardiac ventricular repolarization (QT interval). Perform electrocardiogram (ECG) prior to initiation of treatment with gilteritinib, on days 8 and 15 of cycle 1, and prior to the start of the next two subsequent cycles. For patients who develop a QTcF > 500 msec, interrupt gilteritinib dosage. Resume gilteritinib at a reduced dosage of 80 mg when QTc interval returns to within 30 msec of baseline or less than or equal to 480 msec.

Drugs/Diseases

Util A	Util B	Util C
Gilteritinib	Prolonged QT Interval	

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Xospata Prescribing Information, May 2019, Astellas Pharma US, Inc.

75. Gilteritinib / Pancreatitis _____ _____

Alert Message: There have been rare reports of pancreatitis in patients receiving Xospata (gilteritinib) in clinical studies. Evaluate patients who develop signs and symptoms of pancreatitis. If pancreatitis confirmed interrupt gilteritinib therapy until pancreatitis is resolved. After pancreatitis is resolved resume gilteritinib at a reduced dose of 80 mg/day.

Drugs/Diseases

Util A	Util B	Util C
Gilteritinib	Pancreatitis	

References:

Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Xospata Prescribing Information, May 2019, Astellas Pharma US, Inc.

76. Gilteritinib / Combined P-gp and Strong CYP3A4 Inducers _____ _____

Alert Message: Avoid concurrent use of Xospata (gilteritinib) with combined P-gp and strong CYP3A inducers. Coadministration of gilteritinib with a combined P-gp and strong CYP3A inducer decreases gilteritinib exposure which may decrease gilteritinib efficacy.

Drugs/Diseases

Util A	Util B	Util C
Gilteritinib	Apalutamide	
	Carbamazepine	
	Fosphenytoin	
	Lumacaftor/Ivacaftor	
	Phenobarbital	
	Phenytoin	
	Primidone	
	Rifampin	

References:

Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Xospata Prescribing Information, May 2019, Astellas Pharma US, Inc.

77. Gilteritinib / Strong CYP3A Inhibitor _____ _____

Alert Message: Concurrent use of Xospata (gilteritinib) with a strong CYP3A inhibitor increases gilteritinib exposure. Consider alternative therapies that are not strong CYP3A inhibitors. If the concomitant use of these inhibitors is considered essential for the care of the patient, monitor the patient more frequently for gilteritinib adverse reactions. In patients who develop serious or life-threatening toxicity, interrupt gilteritinib therapy until toxicity improves to grade 1. Resume gilteritinib therapy at a reduced dose of 80 mg.

Drugs/Diseases

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

References:

Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Xospata Prescribing Information, May 2019, Astellas Pharma US, Inc.

78. Gilteritinib / 5HT2B & Sigma Nonspecific Receptor Drugs _____ _____

Alert Message: The concurrent use of Xospata (gilteritinib) with drugs that are a target of the 5HT2B receptor or sigma nonspecific receptor should be avoided unless their use is considered essential for the care of the patient. Coadministration of gilteritinib with these drugs may result in a decreased effect of the drugs that are targets of these receptors.

Drugs/Diseases

Util A	Util B	Util C
Gilteritinib	Citalopram	
	Escitalopram	
	Fluoxetine	
	Fluvoxamine	
	Paroxetine	
	Sertraline	

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Xospata Prescribing Information, May 2019, Astellas Pharma US, Inc.

79. Gilteritinib / Black Box Warning _____ _____

Alert Message: Patients treated with Xospata (gilteritinib) have experienced symptoms of differentiation syndrome, which can be fatal or life-threatening if not treated. Symptoms may include fever, dyspnea, hypoxia, pulmonary infiltrates, pleural or pericardial effusions, rapid weight gain or peripheral edema, hypotension, or renal dysfunction. If differentiation syndrome is suspected, initiate corticosteroid therapy and hemodynamic monitoring until symptom resolution.

Drugs/Diseases

Util A	Util B	Util C
Gilteritinib	Fever	
	Dyspnea	
	Hypoxia	
	Pericardial Effusion	
	Pleural Effusion	
	Edema	
	Hypotension	
	Renal Dysfunction	

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Xospata Prescribing Information, May 2019, Astellas Pharma US, Inc.

80. Glasdegib / Overutilization _____ _____

Alert Message: The recommended dose of Daurismo (glasdegib) is 100 mg orally once daily on days 1 to 28 in combination with cytarabine 20 mg subcutaneously twice daily on days 1 to 10 of each 28-day cycle in the absence of unacceptable toxicity or loss of disease control. For patients without unacceptable toxicity, treat for a minimum of 6 cycles to allow time for clinical response.

Drugs/Diseases

Util A	Util B	Util C
Glasdegib		

Max Dose: 100 mg/day

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Daurismo Prescribing Information, Nov. 2018, Pfizer U.S.

81. Glasdegib / Pregnancy / Pregnancy Negating _____ _____

Alert Message: Based on its mechanism of action and findings from animal embryo-fetal developmental toxicity studies, Daurismo (glasdegib) can cause embryo-fetal death or severe birth defects when administered to a pregnant woman.

Drugs/Diseases

Util A	Util B	Util C **(Negating)**
Glasdegib	Pregnancy	Delivery
		Miscarriage
		Abortion

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Daurismo Prescribing Information, Nov. 2018, Pfizer U.S.

82. Glasdegib / Males _____ _____

Alert Message: Advise males of the potential risk of exposure through semen and to use condoms with a pregnant partner or a female partner of reproductive potential during treatment with Daurismo (glasdegib) and for at least 30 days after the last dose to avoid potential drug exposure.

Drugs/Diseases

Util A	Util B	Util C
Glasdegib		

Gender: Male

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Daurismo Prescribing Information, Nov. 2018, Pfizer U.S.

83. Glasdegib / Females of Reproductive Potential _____ _____

Alert Message: Daurismo (glasdegib) is not recommended for use during pregnancy. Conduct pregnancy testing in female patients of reproductive potential prior to initiating glasdegib treatment. Advise females of reproductive potential to use effective contraception during treatment with glasdegib and for at least 30 days after the last dose. Advise women not to breastfeed during treatment with glasdegib and for at least 30 days after the last dose.

Drugs/Diseases

Util A	Util B	Util C **(Negating)**
Glasdegib		Contraceptives

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Daurismo Prescribing Information, Nov. 2018, Pfizer U.S.

84. Glasdegib / Lactation _____ _____

Alert Message: There are no data on the presence of Daurismo (glasdegib) or its active metabolites in human milk, the effects of the drug on the breastfed child, or its effect on milk production. Because of the potential for serious adverse reactions in a breastfed child from glasdegib, advise women who are taking glasdegib not to breastfeed or provide breast milk to infants or children during treatment with glasdegib and for at least 30 days after the last dose.

Drugs/Diseases

Util A	Util B	Util C
Glasdegib	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Daurismo Prescribing Information, Nov. 2018, Pfizer U.S.

85. Glasdegib / Strong CYP3A4 Inhibitors _____ _____

Alert Message: The concurrent use of Daurismo (glasdegib), a CYP3A4 substrate, with a strong CYP3A4 inhibitor may result in elevated glasdegib plasma concentrations, and increase the risk of adverse reactions including QTc interval prolongation. Consider alternative therapies that are not strong CYP3A4 inhibitors during treatment with glasdegib.

Drugs/Diseases

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

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Daurismo Prescribing Information, Nov. 2018, Pfizer U.S.

86. Glasdegib / Strong CYP3A4 Inducers _____ _____

Alert Message: The concurrent use of Daurismo (glasdegib) with a strong CYP3A4 inducer should be avoided. Glasdegib is a CYP3A4 substrate, and concomitant use with a CYP3A4 inducer may result in decreased glasdegib plasma concentrations and loss of therapeutic effects.

Drugs/Diseases

Util A	Util B	Util C
Glasdegib	Carbamazepine	
	Phenobarbital	
	Phenytoin	
	Primidone	
	Rifampin	

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Daurismo Prescribing Information, Nov. 2018, Pfizer U.S.

87. Glasdegib / Drugs That Cause QT Prolongation _____ _____

Alert Message: Daurismo (glasdegib) is associated with concentration-dependent QTc prolongation. The concurrent use of glasdegib with QTc prolonging drugs may increase the risk of QTc interval prolongation. Avoid co-administration of QTc prolonging drugs with glasdegib. If co-administration of a QTc prolonging drug is unavoidable, more frequent ECG monitoring is recommended. Interrupt glasdegib therapy if QTc increases to greater than 500 ms. Discontinue glasdegib permanently for patients who develop QTc interval prolongation with signs or symptoms of life-threatening arrhythmia.

Drugs/Diseases

Util A	Util B				Util C
Glasdegib	Abiraterone	Efavirenz	Levofloxacin	Rilpivirine	
	Adenosine	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	Voriconazole	Paliperidone	Trimipramine	
	Citalopram	Granisetron	Panobinostat	Valbenazine	
	Clarithromycin	Haloperidol	Paroxetine	Vandetanib	
	Clomipramine	Hydroxychloroquine	Pasireotide	Vemurafenib	
	Clozapine	Hydroxyzine	Pazopanib	Venlafaxine	
	Crizotinib	Ibutilide	Pentamidine		
	Dabrafenib	Indinavir	Pimavanserin		
	Dasatinib	Iloperidone	Pimozide		
	Desipramine	Ivabradine	Pitolisant		
	Deutetrabenazine	Imipramine	Posaconazole		
	Diphenhydramine	Indapamide	Procainamide		
	Disopyramide	Itraconazole	Promethazine		
	Dofetilide	Ivosidenib	Propafenone		
	Dolasetron	Ketoconazole	Quetiapine		
	Donepezil	Lapatinib	Quinidine		
	Dronedarone	Lefamulin	Quinine		
	Droperidol	Lenvatinib	Ranolazine		
	Doxepin	Leuprolide	Ribociclib		

References:

Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Daurismo Prescribing Information, Nov. 2018, Pfizer U.S.

88. Glasdegib / QT Prolongation _____ _____

Alert Message: Daurismo (glasdegib) is associated with concentration-dependent QTc prolongation. In patients with congenital long QT syndrome, congestive heart failure, electrolyte abnormalities, or those who are taking medications known to prolong the QTc interval, more frequent ECG monitoring is recommended. Interrupt glasdegib if QTc increases to greater than 500 ms. Discontinue glasdegib permanently for patients who develop QTc interval prolongation with signs or symptoms of life-threatening arrhythmia.

Drugs/Diseases

Util A	Util B	Util C
Glasdegib	Long QT Syndrome	
	Congestive Heart failure	
	Hypokalemia	
	Hypomagnesemia	
	Bradycardia	

References:

Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Daurismo Prescribing Information, Nov. 2018, Pfizer U.S.

89. Glasdegib / Nonadherence _____ _____

Alert Message: Based on the refill history, your patient may be under-utilizing Daurismo (glasdegib). 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
Glasdegib		

References:

Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Osterberg L, Blaschke T. Adherence to Medication. N Engl J Med 2005; 353:487- 497.
Daurismo Prescribing Information, Nov. 2018, Pfizer U.S.
Greer JA, Amoyal N, Nisotel L, et al. Systemic Review of Adherence to Oral Antineoplastic Therapies. The Oncologist. 2016;21:354-376.

90. Glasdegib / Therapeutic Appropriateness _____ _____

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

Drugs/Diseases

Util A	Util B	Util C
Glasdegib		

Age Range: 0 – 17 yoa

References:

Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Daurismo Prescribing Information, Nov. 2018, Pfizer U.S.

North Dakota Medicaid
Drug Utilization Review Board
Meeting
June 3, 2020
Via Teleconference

NORTH Dakota | Human Services
Be Legendary.™

North Dakota Medicaid
DUR Board Meeting Agenda
Join Microsoft Teams Meeting

(Click on link)
Join by phone: 1 701-328-0950, Conference ID: 312 304 233#
June 3, 2020
1:00 pm

1. Administrative items
    - DHS announcements

2. Old business
    - Review and approval of March 2020 meeting minutes
    - Budget update
    - Review top 25 drugs for first quarter of 2020
    - Prior authorization/PDL update
    - Update to criteria for medications costing >$3,000
    - Second review of Conjupri

3. New business
    - Review of cystic fibrosis agents
    - Review of ACL inhibitors (Nexletol and Nexlizet)
    - Review of antifibrinolytic agents
    - Review of Palforzia
    - Review of Mytesi
    - Retrospective DUR criteria recommendations
    - Upcoming meeting date/agenda.
        - Next meeting is September 2, 2020
4. Adjourn

Please remember to silence all cellular phones during the meeting.

North Dakota Medicaid
Drug Utilization Review (DUR) Meeting Minutes
March 4, 2020

Members Present: Peter Woodrow, Corey Miller, Mary Aaland, Tanya Schmidt, Andrea Honeyman, Gabriela Balf, Laura Schield, Amy Werremeyer

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

Old Business

Chair A. Honeyman called the meeting to order at 1:05 p.m. Chair A. Honeyman asked for a motion to approve the minutes of the December meeting. P. Woodrow moved that the minutes be approved, and L. Schield seconded the motion. The chair called for a voice vote to approve the minutes. The motion passed with no audible dissent.

DHS Announcements

B. Joyce announced a change made to first-fill requirements for agents used to treat attention deficit hyperactivity disorder (ADHD). The requirement has been changed to a maximum first fill of 14 days to a limit of 10 days.

Update On North Dakota Medicaid Expansion Population Carve-Out

B. Joyce updated the Board on the transition of the management of pharmacy benefits for the North Dakota Medicaid Expansion population. He described selected claims processing edits that had been in place for the fee-for-service population that had been turned off beginning January 1st in order to allow for continuation of care for expansion patients during the transition.

Review Top 15 Therapeutic Categories/Top 25 Drugs

B. Joyce presented the quarterly review of the top 15 therapeutic classes by total cost of claims, top 25 drugs based on number of claims, and top 25 drugs based on claims cost for the 4th quarter of 2019. M. Aaland inquired about reimbursement for IHS claims, and B. Joyce explained the process for how ND Medicaid pays for these claims.

PDL/PA Criteria Updates

A. Murphy shared with the Board the changes made to the Preferred Drug List since the most recent version of the Preferred Drug List was posted. Specifically, highlighted were changes made with the addition of Ubrelvy to the Migraine Treatment class, Davigo to the Sedative/Hypnotics class, and Talicia to the H. Pylori class. Tim Wardell of Allergan provided a brief presentation on Ubrelvy during public comment. M. Aaland inquired about the cost of Ubrelvy and T. DeRuiter gave pricing information based on average wholesale price. G. Balf asked whether a re-trial of prior sedative/hypnotic agents would be required if the most recent failure was not within the past 30-days, and A. Murphy explained that retrials are not required if the medication was discontinued due to lack of efficacy or intolerable adverse effects. 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 Glucagon Agents
A motion and second was made at the December meeting to place glucagon agents on prior authorization. The topic was brought up for a second review with prior authorization presented by T. DeRuiter. There was no public comment. M. Aaland inquired about current glucagon utilization in the North Dakota Medicaid population, which T. DeRuiter provided. Chair A. Honeyman called for a voice vote and the motion passed with no audible dissent.

Second Review of Ofev for Interstitial Lung Disease
A motion and second was previously made to place agents for the treatment of idiopathic pulmonary fibrosis/interstitial lung disease on prior authorization. The topic was brought up for a second review with prior authorization criteria including this indication presented by A. Murphy. M. Aaland inquired as to whether limiting coverage to those prescribed Ofev by or in consultation with a pulmonologist or rheumatologist would apply to just physicians with that specialty, and B. Joyce and A. Murphy explained that it would. Dan Joy of Boehringer Ingelheim presented during time for public comment. Chair A. Honeyman called for a voice vote and the motion passed with no audible dissent.

New Business
Review of Conjupri
T. DeRuiter presented a review of the newly approved drug, Conjupri to the Board. A motion was made by L. Schield for DHS to create PA criteria for the use of these agents and manage these medications through prior authorization. The motion was seconded by P. Woodrow. Criteria for Conjupri will be presented and voted on by the DUR Board at the next meeting.

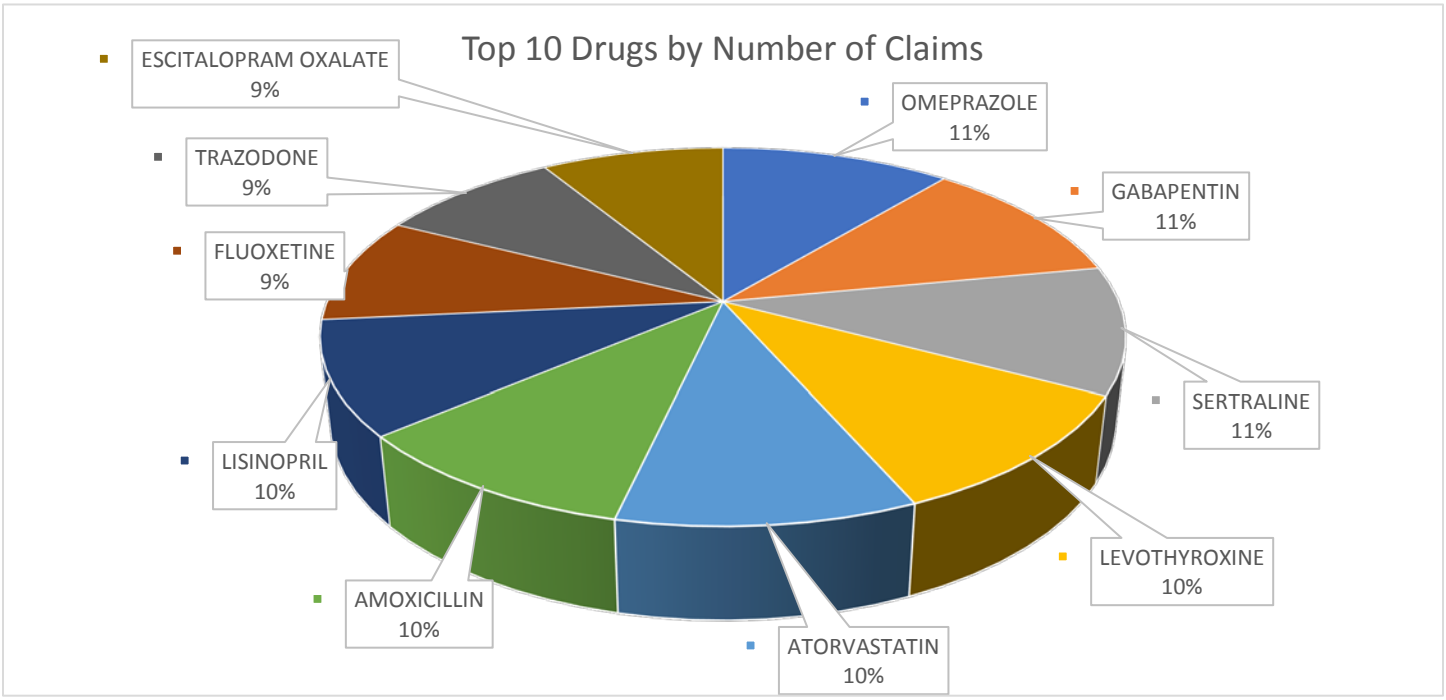
Discussion on Spinraza and Zolgensma
A. Murphy and B. Joyce presented on how DHS is currently managing utilization of Spinraza and Zolgensma, including presenting the criteria for coverage of these agents. Eric Cox and Beth Pegram of AveXis spoke about the role of Zolgensma in treatment of SMA. The Board inquired about cost of the medications, which B. Joyce provided based on public pricing data.

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 usually consistent with new indications, new drugs added, and new warnings. T. DeRuiter presented the new RDUR criteria and explained the RDUR profile review process. M. Aaland inquired as to whether the RDUR criteria is be overly burdensome to providers due to the high number of RDUR criteria ND Medicaid currently has approved. T. DeRuiter explained that the RDUR profile review process is targeted to a select few criteria each month to prevent alert fatigue. L. Schield moved to approve the new criteria and P. Woodrow seconded the motion. The motion passed with no audible dissent. These proposed criteria will be added to the current set of criteria and will be used in future DUR cycles.

Adjournment and Upcoming Meeting Date
Chair A. Honeyman adjourned the meeting at 3:15 pm. The next DUR Board meeting will be held June 3, 2020 at 1:00 pm at the State Capitol building in a meeting room to be announced at a later date.

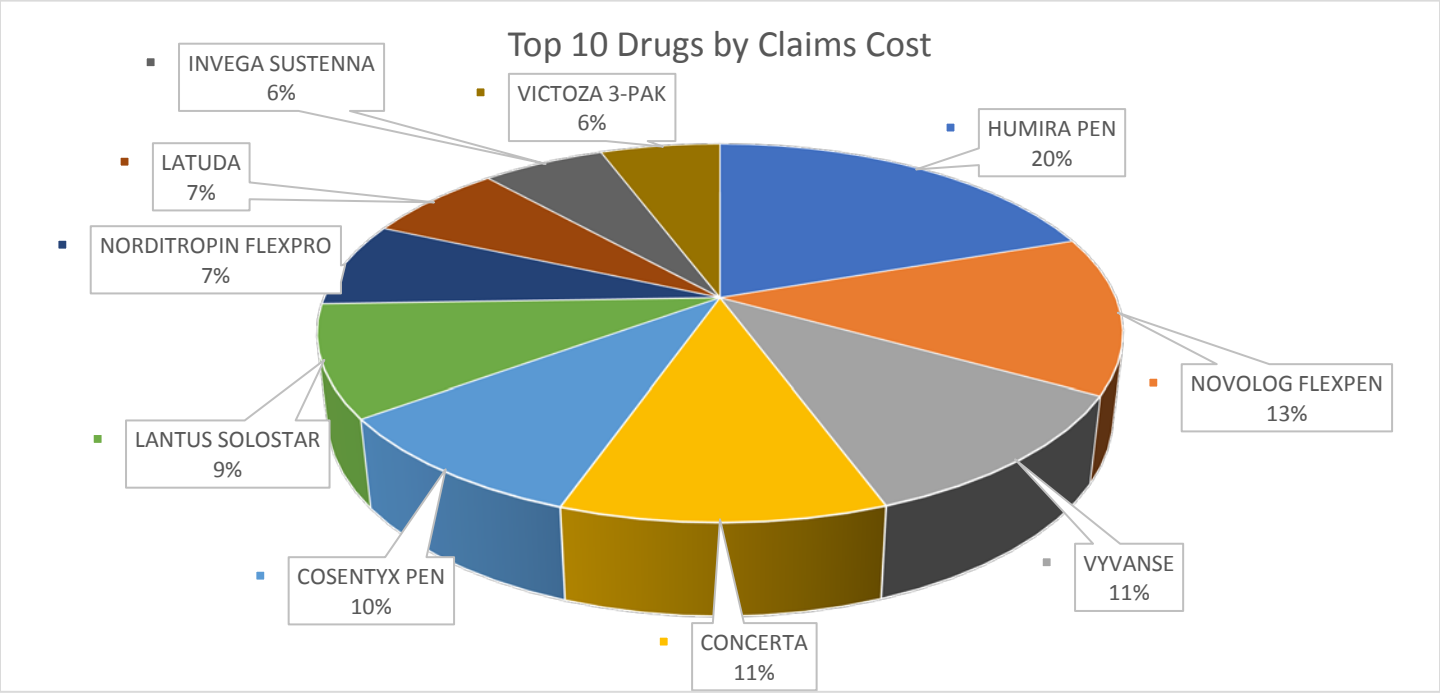
Top 25 Drugs Based on Number of Claims

Drug Name	AHFS Description	Claims	Claims Cost	Cost Per Claim	% Total Claims
OMEPRAZOLE	PPIs	4,227	$55,861.88	$13.22	1.73%
GABAPENTIN	ANTICONVULSANTS	4,203	$71,049.47	$16.90	1.72%
SERTRALINE	ANTIDEPRESSANTS	4,165	$56,340.86	$13.53	1.70%
LEVOTHYROXINE	THYROID AGENTS	4,072	$77,621.48	$19.06	1.66%
ATORVASTATIN	STATINS	3,906	$55,497.49	$14.21	1.59%
AMOXICILLIN	PENICILLIN ANTIBIOTICS	3,897	$54,588.53	$14.01	1.59%
LISINOPRIL	ACE INHIBITORS	3,724	$47,240.91	$12.69	1.52%
FLUOXETINE	ANTIDEPRESSANTS	3,477	$47,924.35	$13.78	1.42%
TRAZODONE	ANTIDEPRESSANTS	3,359	$46,489.23	$13.84	1.37%
ESCITALOPRAM	ANTIDEPRESSANTS	3,356	$43,891.28	$13.08	1.37%
METFORMIN	BIGUANIDES	2,662	$33,138.26	$12.45	1.09%
MONTELUKAST	LEUKOTRIENE MODIFIERS	2,655	$37,761.14	$14.22	1.08%
HYDROCODONE-APAP	OPIATE AGONISTS	2,608	$42,213.70	$16.19	1.06%
DULOXETINE	ANTIDEPRESSANTS	2,518	$42,971.83	$17.07	1.03%
OSELTAMIVIR	NEURAMINIDASE INHIB	2,422	$134,860.04	$55.68	0.99%
BUPROPION XL	ANTIDEPRESSANTS	2,422	$45,427.96	$18.76	0.99%
PROAIR HFA	BETA- AGONISTS	2,394	$160,923.49	$67.22	0.98%
VYVANSE	AMPHETAMINES	2,345	$576,734.21	$245.94	0.96%
PREDNISONE	ADRENALS	2,343	$28,814.36	$12.30	0.96%
PANTOPRAZOLE	PROTON-PUMP INHIBITORS	2,316	$31,423.96	$13.57	0.95%
AMLODIPINE BESYLATE	DIHYDROPYRIDINES	2,285	$28,658.56	$12.54	0.93%
CLONIDINE	ALPHA-AGONISTS	2,135	$26,711.25	$12.51	0.87%
AMOXICILLIN-CLAVULANATE	PENICILLIN ANTIBIOTICS	2,121	$38,980.24	$18.38	0.87%
AZITHROMYCIN	MACROLIDE ANTIBIOTICS	2,096	$35,253.69	$16.82	0.86%
ARIPIPRAZOLE	ANTIPSYCHOTIC AGENTS	2,094	$34,170.07	$16.32	0.85%
Total Claims for 01/01/2020-03/31/2020					244,948



Top 25 Drugs Based on Claims Cost

Drug Name	AHFS Description	Total Claims	Total Claims Cost	Cost/Claim	% Total Cost
HUMIRA PEN	CYTOKINE MODULATORS	171	$1,008,862.05	$5,899.78	4.50%
NOVOLOG FLEXPEN	INSULINS	1,120	$689,920.10	$616.00	3.08%
VYVANSE	AMPHETAMINES	2,345	$576,734.21	$245.94	2.57%
CONCERTA	CNS STIMULANTS	1,687	$565,320.84	$335.10	2.52%
COSENTYX PEN	CYTOKINE MODULATORS	70	$489,220.18	$6,988.86	2.18%
LANTUS SOLOSTAR	INSULINS	1,214	$489,036.08	$402.83	2.18%
NORDITROPIN FLEXPRO	PITUITARY	106	$370,288.63	$3,493.29	1.65%
LATUDA	ANTIPSYCHOTICS	415	$342,795.54	$826.01	1.53%
INVEGA SUSTENNA	ANTIPSYCHOTICS	145	$301,883.71	$2,081.96	1.35%
VICTOZA 3-PAK	INCRETIN MIMETICS	336	$294,245.24	$875.73	1.31%
XIFAXAN	ANTIBACTERIALS, MISC	131	$278,232.64	$2,123.91	1.24%
LEVEMIR FLEXTOUCH	INSULINS	576	$278,179.66	$482.95	1.24%
JARDIANCE	SGLT2 INHIB	630	$269,377.07	$427.58	1.20%
EPCLUSA	HCV ANTIVIRALS	11	$267,404.06	$24,309.46	1.19%
SYMBICORT	LABA/ICS	731	$236,172.33	$323.08	1.05%
SABRIL	ANTICONVULSANTS	10	$202,301.98	$20,230.20	0.90%
BIKTARVY	ANTIRETROVIRALS	131	$194,857.97	$1,487.47	0.87%
GENVOYA	ANTIRETROVIRALS	131	$191,670.21	$1,463.13	0.85%
CONTOUR TEST STRIP	DM TESTING	1,659	$187,970.02	$113.30	0.84%
NOVOLOG	INSULINS	311	$185,982.10	$598.01	0.83%
ABILIFY MAINTENA	ANTIPSYCHOTICS	90	$174,066.72	$1,934.07	0.78%
FLOVENT HFA	ICS	731	$166,766.52	$228.13	0.74%
PROAIR HFA	BETA AGONISTS	2,394	$160,923.49	$67.22	0.72%
SYMDEKO	CFTRS	7	$156,887.22	$22,412.46	0.70%
SPIRIVA	ANTIMUSCARINICS	374	$149,289.11	$399.17	0.67%
Total Claims Cost for 01/01/2020-03/31/2020					$22,425,799.14



Top 15 Therapeutic Classes Based on Number of Claims

Therapeutic Class Description	Claims	Claims Cost	Cost Per Claim	% Total Claims
ANTIDEPRESSANTS	27,262	$559,499.56	$20.52	11.13%
ANTICONVULSANTS, MISCELLANEOUS	12,775	$816,711.67	$63.93	5.22%
ANTIPSYCHOTIC AGENTS	8,781	$1,425,811.04	$162.37	3.58%
PROTON-PUMP INHIBITORS	7,010	$121,888.12	$17.39	2.86%
NONSTEROIDAL ANTI-INFLAMMATORY AGENTS	6,734	$95,411.10	$14.17	2.75%
OPIATE AGONISTS	6,584	$138,138.89	$20.98	2.69%
HMG-COA REDUCTASE INHIBITORS	6,366	$91,360.89	$14.35	2.60%
PENICILLIN ANTIBIOTICS	6,307	$98,590.94	$15.63	2.57%
BETA-ADRENERGIC BLOCKING AGENTS	5,599	$106,217.13	$18.97	2.29%
ANXIOLYTICS,SEDATIVES,AND HYPNOTICS,MISC	5,363	$88,029.08	$16.41	2.19%
BETA-ADRENERGIC AGONISTS	4,863	$285,524.37	$58.71	1.99%
ANGIOTENSIN-CONVERTING ENZYME INHIBITORS	4,826	$69,020.95	$14.30	1.97%
RESPIRATORY AND CNS STIMULANTS	4,696	$826,141.95	$175.92	1.92%
AMPHETAMINES	4,604	$674,367.77	$146.47	1.88%
THYROID AGENTS	4,335	$86,084.91	$19.86	1.77%

Top 15 Therapeutic Classes Based on Claims Cost

Therapeutic Class Description	Claims	Claims Cost	Cost/Claim	% Total Cost
INSULINS	3,596	$1,828,875.07	$508.59	8.16%
DISEASE-MODIFYING ANTIRHEUMATIC AGENTS	329	$1,612,559.50	$4,901.40	7.19%
ANTIPSYCHOTIC AGENTS	8,781	$1,425,811.04	$162.37	6.36%
ANTIRETROVIRALS	798	$876,082.65	$1,097.85	3.91%
SKIN AND MUCOUS MEMBRANE AGENTS, MISC.	503	$836,901.03	$1,663.82	3.73%
RESPIRATORY AND CNS STIMULANTS	4,696	$826,141.95	$175.92	3.68%
ANTICONVULSANTS, MISCELLANEOUS	12,775	$816,711.67	$63.93	3.64%
CORTICOSTEROIDS (RESPIRATORY TRACT)	3,192	$703,280.20	$220.33	3.14%
AMPHETAMINES	4,604	$674,367.77	$146.47	3.01%
ANTINEOPLASTIC AGENTS	506	$625,507.56	$1,236.18	2.79%
INCRETIN MIMETICS	806	$577,033.68	$715.92	2.57%
ANTIDEPRESSANTS	27,262	$559,499.56	$20.52	2.49%
HCV ANTIVIRALS	24	$435,197.57	$18,133.23	1.94%
IMMUNOMODULATORY AGENTS	56	$420,324.90	$7,505.80	1.87%
PITUITARY	380	$398,497.36	$1,048.68	1.78%

PDL Update

Added to PA

Drug	PA Form	Class
Azelex cream	General Form	Acne - other
Fenofibrate 40, 120 mg tablet	General Form	Non-Preferred Dosage Forms
Fluorouracil 2%, 5% solution	General Form	Actinic Keratosis
Harvoni	Hep C Form	Hepatitis C Treatments
Lindane shampoo	General Form	Lice
Minocycline 50, 75, 100 mg tablet	General Form	Acne - tetracyclines
Neomycin/bacitracin/polymyxin b/hydrocortisone ointment	General Form	Ophthalmic - Anti-infectives/Anti-inflammatories
Relistor tablet	General Form	Opioid-Induced Constipation:
Solaravix	Non-Preferred Dosage Formulation	Non-Preferred Dosage Forms
Sovaldi	Hep C Form	Hepatitis C Treatments
Sprix nasal spray	NSAIDs Form	NSAIDs - Nasal
Vibramycin 25 mg/ 5 mL suspension	General Form	Acne - tetracyclines
Vusion ointment	General Form	Antifungals – Topical
Xifaxan 550 mg	General Form	Traveler's Diarrhea
Zipsor	NSAIDs Form	NSAIDs - Oral

Removed from PA

Drug	Class
Aczone 5% gel	Acne - other
Akynzeo	Nausea/Vomiting
Alocril	Ophthalmic - Antihistamines
Apraclonidine 0.5%	Glaucoma - Alpha Adrenergics
Azelaic Acid 15% gel	Acne - other
Dicyclomine oral syrup	Diarrhea – Irritable Bowel Syndrome
Elmiron	Interstitial Cystitis
Epiduo 0.1-2.5% gel pump	Acne - Adapalene
Eprosartan Mesylate	Hypertension - ARBs
Eurax Cream	Lice
Humulin R U-500 Kwikpen	Diabetes - Insulin
Incruse Ellipta	Respiratory - Long Acting Anticholinergics
Lansoprazole	Proton Pump Inhibitors
Neomycin-Bacitracin-Polymyxin eye ointment	Ophthalmic - Anti-infectives
Neomycin-Polymyxin-Gramicidin eye drops	Ophthalmic - Anti-infectives
Praluent Pen	Lipid-Lowering Agents - PCSK9 Inhibitors
Proair Respiclick	Albuterol/Levalbuterol Rescue Inhalers
Repatha Pushtronex	Lipid-Lowering Agents - PCSK9 Inhibitors
Repatha Sureclick	Lipid-Lowering Agents - PCSK9 Inhibitors
Repatha Syringe	Lipid-Lowering Agents - PCSK9 Inhibitors
Taclonex ointment	Antipsoriatics – Topical
Tekturna Hct	Hypertension – Renin Inhibitors

Drug	Class
Tirosint tablets	Non-Preferred Dosage Forms
Tretinoin 0.05% gel	Acne - Retinoid
Vimovo	NSAIDs - Oral
Zetonna	Steroids - Nasal
Zolpidem 10 mg	Sedatives/Hypnotics
Zolpidem ER	Sedatives/Hypnotics

Hepatitis C Treatments

Prior Authorization Form – Hepatitis C

Category Criteria:

- The patient must have an FDA-approved indication for use (meets label recommendations for diagnosis and age).
- 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.
- The patient must be drug (illicit use of drugs by injection) and alcohol free as documented by 2 drug and alcohol tests dated at least 3 months apart and meet criteria as outlined below:
    - **If the patient has a history of alcohol use disorder**, the patient must have abstained from alcohol for at least 12 months OR patient must:
        - have abstained from alcohol for at least 3 months AND
        - be receiving treatment from an enrolled provider and agree to abstain from alcohol during treatment AND
        - be under the care of an addiction medicine/chemical dependency treatment provider and the provider attests the patient has abstained from alcohol use for at least 3 months
    - **If the patient has a history of illicit use of drugs by injection**, the patient must have abstained from drug use for at least 12 months OR patient must:
        - have abstained from drug use for at least 3 months AND
        - be receiving treatment from an enrolled provider and agree to abstain from said drug use during treatment AND
        - be under the care of an addiction medicine/chemical dependency treatment (or buprenorphine
        - waived provider) provider and the provider attests the patient agrees to abstain from drug use for at least 3 months
- The patient must not be receiving a known recreationally used high risk combination of drugs (e.g. “the holy trinity”) for the past 6 months.
- Patient must attest that they will continue treatment without interruption for the duration of therapy.
- Prescriber must be, or consult with, a hepatology, gastroenterology, or infectious disease specialist.
- Females using ribavirin must have a negative pregnancy test in the last 30 days and receive monthly pregnancy tests during treatment.
- Patient must have established compliant behavior including attending scheduled provider visits (defined as 1 or less no-shows) and filling maintenance medications on time as shown in the prescription medication history for the past 6 months.
- Patient must be tested for hepatitis B, and if the test is positive, hepatitis B must either be treated or closely monitored if patient does not need treatment.
- Patient must not have life expectancy of less than 12 months due to non-liver related comorbid conditions.
- PA approval duration will be based on label recommendation.

Non-Preferred Agents Criteria:

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

PREFFERED AGENTS (CLINICAL PA REQUIRED)	NON-PREFFERED AGENTS (PA REQUIRED)
EPCLUSA (sofosbuvir/velpatasvir) *Brand Preferred****	HARVONI (ledipasvir/sofosbuvir) 90mg/400mg tablet
HARVONI (ledipasvir/sofosbuvir) 45 mg/200mg tablet	Ledipasvir/sofosbuvir
MAVYRET (glecaprevir/pibrentasvir)***	Sofosbuvir/velpatasvir
SOVALDI (sofosbuvir) 200mg tablet	SOVALDI (sofosbuvir) 400mg tablet
	VIEKIRA PAK (dasabuvir/ombitasvir/paritaprevir/ritonavir)
	VOSEVI (sofosbuvir/velpatasvir/voxilaprevir)***
	ZEPATIER (elbasvir/grazoprevir)

Insulin

Insulin Prior Authorization Form

Group Criteria:

- **Non-preferred insulins:**
  - Clinical justification must be provided explaining why the patient is unable to use the preferred products (subject to clinical review).
- **Syringe/Pens:**
  - Clinical justification must be provided explaining why the patient is unable to use the preferred insulin vial/pen products (subject to clinical review).

Product Specific Criteria:

- ***Humulin N/Humulin 70/30:** One of the following must be met (A or B):
  - A. The patient must be pregnant or breastfeeding
  - B. Clinical justification must be provided explaining why the patient is unable to use the preferred products (subject to clinical review).
- ***Fiasp:** The patient 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
- ***Basaglar:** Clinical justification must be provided explaining why the patient is unable to use the preferred products (subject to clinical review).
- ***Toujeo/Tresiba:**
  - **Initial Criteria:** Approval 6 months
    - The requested agent must be prescribed by or in consultation with an endocrinologist or diabetes specialist.
    - One of the following must be met (medical documentation of reported events must be provided):
      - The patient experiences recurrent episodes of hypoglycemia on Insulin glargine U100, insulin detemir U100, or U-500R despite adjustments to current regimen (prandial insulin, interacting drugs, meal and exercise timing).
      - The patient currently experiences inconsistent blood sugars with a basal insulin requirement of a minimum of 100 units/day for a minimum of 3 months with good compliance, as evidenced by paid claims or pharmacy print outs.
      - 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).
    - **If dose is >200 units of insulin per day**, clinical justification must be provided explaining why the patient is not a candidate for U-500R (Toujeo and Tresiba are not intended as replacements for U500 insulin).
  - **Renewal Criteria:** Approval 12 months
    - The patient 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)

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

PREFFERED AGENTS (NO PA REQUIRED)	NON-PREFFERED AGENTS (PA REQUIRED)
APIDRA (insulin glulisine) VIAL	ADMELOG (insulin lispro) VIAL
APIDRA SOLOSTAR (insulin glulisine) INSULIN PEN	ADMELOG SOLOSTAR (insulin lispro) INSULIN PEN
HUMALOG JUNIOR KWIKPEN (insulin lispro)	AFREZZA (insulin regular, human)
**++HUMALOG MIX 50/50 (insulin NPL/insulin lispro) KWIKPEN	BASAGLAR KWIKPEN U-100 (insulin glargine)***
**++HUMALOG MIX 75/25 (insulin NPL/insulin lispro) KWIKPEN	FIASP (insulin aspart) CARTRIDGE***
HUMALOG MIX 50/50 (insulin NPL/insulin lispro) VIAL	FIASP (insulin aspart) VIAL***
HUMALOG MIX 75/25 (insulin NPL/insulin lispro) VIAL	HUMALOG U-100 (insulin lispro) KWIKPEN
***++HUMULIN 70/30 (insulin NPH human/regular insulin human) VIAL	HUMALOG (insulin lispro) VIAL
***++HUMULIN 70/30 (insulin NPH human/regular insulin human) KWIKPEN	HUMALOG (insulin lispro) CARTRIDGE
***++HUMULIN N (insulin NPH human isophane) VIAL	HUMALOG U-200 (insulin lispro) KWIKPEN
***++HUMULIN N (insulin NPH human isophane) KWIKPEN	Insulin aspart flexpan
HUMULIN R (insulin regular, human) VIAL	Insulin aspart vial
HUMULIN R (Insulin regular, human) U-500 KWIKPEN	Insulin aspart protamine/insulin aspart
HUMULIN R U-500 (insulin regular, human) VIAL	++NOVOLIN 70-30 (insulin NPH human/regular insulin human) VIAL
Insulin lispro vial	++NOVOLIN 70-30 (insulin NPH human/regular insulin human) FLEXPEN
Insulin lispro syringe	++NOVOLIN N (insulin NPH human isophane) FLEXPEN
LANTUS (insulin glargine) SOLOSTAR	++NOVOLIN N (insulin NPH human isophane) VIAL
LANTUS (insulin glargine) VIAL	TOUJEO MAX SOLOSTAR (insulin glargine)***
LEVEMIR (insulin detemir) VIAL	TOUJEO SOLOSTAR (insulin glargine)***
LEVEMIR (insulin detemir) FLEXTOUCH	TRESIBA (insulin degludec) FLEXTOUCH U-100***
NOVOLIN R (insulin regular, human) VIAL	TRESIBA (insulin degludec) FLEXTOUCH U-200***
NOVOLOG (insulin aspart) CARTRIDGE – *Brand Preferred*	TRESIBA (insulin degludec) VIAL***
NOVOLOG (insulin aspart) FLEXPEN – *Brand Preferred*	
NOVOLOG (insulin aspart) VIAL – *Brand Preferred*	
NOVOLOG MIX 70/30 (insulin aspart protamine/insulin aspart) FLEXPEN	
NOVOLOG MIX 70/30 (insulin aspart protamine/insulin aspart) VIAL	

Diarrhea – Irritable Bowel Syndrome

Electronic Step Care and Concurrent Medications

- Xifaxan: Xifaxan does not require prior authorization for hepatic encephalopathy if used concurrently with lactulose
  - A total of 30 days of Lactulose must be paid within 65 days prior to Xifaxan's date of service.

Prior Authorization Criteria

General Prior Authorization Form

Non-Preferred Agents Criteria:

- The patient must be 18 years of age or older.
- The patient must have an FDA-approved indication for use (meets label recommendations for diagnosis and age).
- The patient must have had a 30-day trial of each preferred agent, as evidenced by paid claims or pharmacy printouts.

Product Specific Criteria:

- ***Alosetron**: The patient must be a female.
- ***Xifaxan**: Must be used for an FDA-approved indication for use (meeting label recommendations for diagnosis, age, and duration of treatment)
- ***** **Dicylclomine Oral Syrup:** The patient must be unable to ingest solid dosage form as evidenced by swallow study documentation

PREFFERED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS:
Dicyclomine Capsule	Alosetron***
Dicyclomine Oral Syrup***	
Dicyclomine Tablet	
LOTRONEX (alosetron)***	
VIBERZI (eluxadoline)	
XIFAXAN (rifaximin) 550 mg tablet***	

Traveler's Diarrhea

Electronic Step Care and Concurrent Medications

- Xifaxan: Xifaxan does not require prior authorization for hepatic encephalopathy if used concurrently with lactulose
  - A total of 30 days of Lactulose must be paid within 65 days prior to Xifaxan's date of service.

Prior Authorization Criteria

Category Criteria:

- The patient must have an FDA-approved indication for use (meets label recommendations for diagnosis and age).
- The patient must have had a trial of appropriate duration with azithromycin and a fluoroquinolone

PREFFERED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS:
Azithromycin	XIFAXAN (Rifaximin) 550mg
Ciprofloxacin	
Levofloxacin	

Nasal

Non-Preferred Agents Criteria:

- The patient 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 patient is unable to use another dosage form (subject to clinical review).

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

Medications that cost over $3000/month

General Prior Authorization Form

Group Criteria:

- **Initial Criteria:** *Approval Duration = 6 months*
  - The patient must have an FDA-approved indication for use (meets label recommendations for diagnosis and age).
- **Renewal Criteria:** *Approval Duration = 12 months*
  - The provider 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
GATTEX (teduglutide)
INCRELEX (mecasermin)
OXERVATE (cenegermin-bkbj)
TRIENTINE

Hypertension

Calcium Channel Blockers

General Prior Authorization Form

Group Criteria:

- **Non-Preferred Agents Criteria:** *Approval Duration = 12 months*
  - The patient must have an FDA-approved indication for use (meets label recommendations for diagnosis and age).
  - The patient must have had a 30-day trial of each preferred agent of a unique active ingredient, as evidenced by paid claims or pharmacy printouts.
  - Clinical justification must be provided explaining why the patient is unable to use all other products to treat hypertension (subject to clinical review).

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
Amlodipine	CONJUPRI (levamlodipine)
Felodipine	
Isradipine	
Nicardipine	
Nifedipine	
Nisoldipine	

health information designs

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 that patients receiving a prescription for non-preferred medications to meet specific diagnosis and step-therapy requirements. Criteria for agents requiring prior authorization can be found at one of the following locations:

- The Preferred Drug List (PDL) available at www.hidesigns.com/assets/files/ndmedicaid/NDPDL.pdf
- Prior Authorization Criteria available at www.hidesigns.com/assets/files/ndmedicaid/2018/Criteria/PA_Criteria.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 PHYSICIAN

Recipient Name	Recipient Date of Birth	Recipient Medicaid ID Number	
Prescriber Name	Specialist involved in therapy (if not treating physician)		
Prescriber NPI	Telephone Number	Fax Number	
Address	City	State	Zip Code
Requested Drug and Dosage:	**Diagnosis for this request:**		
List all failed medications:		**Start Date:**	**End Date:**

Additional Qualifications for Coverage (e.g. medical justification explaining inability to meet required trials)

□ Patient is pregnant: Due Date _____
□ Patient has inability to take or tolerate solid oral dosage forms (please attach swallow study)
□ Patient has feeding tube in place: (please state specific type of feeding tube _____)
□ 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 patient's medical records. I also understand that any misrepresentations or concealment of any information requested in the prior authorization request may subject me to audit and recoupment.*

Part II: TO BE COMPLETED BY PHARMACY

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

REVIEW OF CFTR MODULATORS FOR CYSTIC FIBROSIS

Overview:

- Cystic fibrosis (CF) is a multisystem genetic disorder affecting the lungs, digestive system, sweat glands, and reproductive tract
- It is caused by pathogenic variants of the CF transmembrane conductance regulator (CFTR) gene, which leads to insufficient activity of CFTR proteins, resulting in abnormal transport of chloride and sodium across secretory epithelia, resulting in thickened, viscous secretions
    - The CFTR protein is present at the surface of epithelial cells in multiple organ systems that functions as a regulated chloride channel
        - Through its chloride regulation, CFTR protein can also regulate the activity of other chloride and sodium channels at the cell surface
- While there are multiple different mutations that can cause CF, all of these mutations result in inadequate CFTR activity in 1 of the following ways:
    - **Class I mutations:** Defective CFTR protein production
    - **Class II mutations**: Defective CFTR protein processing (vast majority of CF patients)
        - includes the F508del mutation
    - **Class III mutations:** Defective CFTR protein regulation
        - "gating mutations"
    - **Class IV mutations:** Defective CFTR conduction
    - **Class V mutations:** Reduced amounts of functional CFTR protein
        - Residual function mutations
- There is no cure for CF, and progressive lung disease continues to be the major cause of morbidity and mortality for most patients.

CFTR Modulators:

- Cystic fibrosis transmembrane conductance regulator (CFTR) modulators are a class of drugs that act by improving production, intracellular processing, and/or function of the defective CFTR protein
    - Advantageous over prior therapies as these target the production or function of the mutant CFTR protein rather than its downstream consequences
    - Have been shown to improve forced expiratory volume in one second (FEV_1) and symptom-related quality of life (QoL) and reduce acute pulmonary exacerbations in patients with CF
- All CFTR modulators are indicated for the treatment of cystic fibrosis but have different age and genetic testing requirements for use
- Their indications and efficacy depend upon the CFTR mutations in an individual patient

- **Products Available:**
    - Trikafta (elexacaftor/tezacaftor/ivacaftor)
        - **Tablet therapy pack:** Elexacaftor 100 mg / tezacaftor 50 mg / ivacaftor 75 mg tablets AND Ivacaftor 150 mg tablets
    - Kalydeco (ivacaftor)
        - **Oral Packet:** 25 mg, 50 mg, and 75 mg
        - **Tablet:** 150 mg
    - Orkambi (lumacaftor/ivacaftor)
        - **Oral Packet:** lumacaftor 100 mg / ivacaftor 125 mg
        - **Oral Packet:** lumacaftor 150 mg / ivacaftor 188 mg
        - **Tablet:** lumacaftor 100 mg / ivacaftor 125 mg
        - **Tablet:** lumacaftor 200 mg / ivacaftor 125 mg
    - Symdeko (tezacaftor/ivacaftor)
        - **Tablet therapy pack:** Tezacaftor 50 mg / Ivacaftor 75 mg tablets AND Ivacaftor 75 mg tablets
        - **Tablet therapy pack:** Tezacaftor 100 mg / Ivacaftor 150 mg tablets AND Ivacaftor 150 mg tablets

- **FDA-Approved Indications (specific mutations and age)**

	Kalydeco	Orkambi	Symdeko	Trikafta
Age Requirement	≥6 months	≥2 years	≥6 years	≥12 years
Homozygous F508del mutation	No	Yes	Yes	Yes
Heterozygous F508del mutation	No	No	No	Yes
Gating mutations*	Yes	No	No	No
Residual function mutations*	Yes	No	Yes	No
**= Genetic testing of specific residual function mutations and gating mutations is required.*				

- **Efficacy Comparison**
  - Based on the above chart, there are scenarios that would drive clinical decisions to one agent over another based on genetic testing and patient age
  - Specific Efficacy Comparison:
    - Homozygous F508del mutation
      - In a 4-week clinical trial, Trikafta achieved greater improvements in FEV1 and symptom-related QoL compared with Symdeko in treating patients that had a homozygous F508del mutation

- **Mechanism of Action/Pharmacology:**
  - **Elexacaftor & Tezacaftor**
    - Facilitates the cellular processing and trafficking of normal and select mutant forms of CFTR (including F508del-CFTR) to increase the amount of mature CFTR protein delivered to the cell surface
  - **Ivacaftor**
    - Increases chloride transport via potentiation of channel opening probability of CFTR proteins located at the cell surface
      - Improves the regulation of salt and water absorption and secretion in various tissues (eg, lung, GI tract)
  - **Lumacaftor:**
    - Lumacaftor improves the conformational stability of F508del-CFTR, resulting in increased processing and trafficking of mature protein to the cell surface

- **Contraindications:**

Kalydeco	Orkambi	Symdeko	Trikafta
There are no contraindications listed in the manufacturer's labeling	There are no contraindications listed in the manufacturer's labeling	There are no contraindications listed in the manufacturer's labeling	There are no contraindications listed in the manufacturer's labeling

- **Warnings/Precautions:**

<table>
<tr><th colspan="3">Ivacaftor</th></tr>
<tr><td colspan="3">Hepatic effects
• Increased LFTs may occur. Interrupt therapy for elevated LFTs. Consider the benefits and risks prior to resuming
Cataracts
• Non-congenital lens opacities and cataracts have been reported in pediatric patients treated with ivacaftor</td></tr>
<tr><th>Orkambi</th><th>Symdeko</th><th>Trikafta</th></tr>
<tr><td>Same as Kalydeco +…

Respiratory events
• Use was associated with an increased incidence of respiratory events; may result in drug discontinuation and may be serious
Hypertension
• Increased BP has been observed
Organ transplant recipients
• Not recommended in (has not been studied).</td><td>Same as Kalydeco +…

CNS effects
• May cause dizziness, which may impair physical or mental abilities; patients must be cautioned about performing tasks that require mental alertness (eg, operating machinery, driving).</td><td>Same as Kalydeco</td></tr>
</table>

- **Dosing:**

	Kalydeco	Orkambi	Symdeko	Trikafta
Adults*	150 mg q12h	400/250 mg q12h	100/150 mg qam, ivacaftor 150 mg qpm	2 tablets qam and 1 ivacaftor 150 mg qpm
Pediatric*	**≥6 years**: 150 mg every 12 hours **6 months-6 years:** • ≥14 kg: 75 mg q12h • 7-14 kg: 50 mg q12h • 5-7 kg: 25 q12h	**≥12 years**: 400/250 mg q12h **6-11 years:** 200/250 mg q12h **2-5 years:** • ≥14 kg: 150/188 mg q12h • <14 kg: 100/125 mg q12h	**≥12 years or ≥6 years + ≥30 kg**: same as adult **6-12 years, <30 kg:** 50/75 mg qam, ivacaftor 75 mg qpm	**≥12 years:** Same as adults
Renal Impairment	eGFR <30: Use with caution	eGFR <30: Use with caution	eGFR <30: Use with caution	eGFR <30: Use with caution
Hepatic Impairment	**Mild:** No adjustment necessary **Moderate:** Reduce dose to once daily **Severe:** has not been studied	**Mild:** No adjustment necessary **Moderate:** 1/2 evening dose **Severe:** dose adjustments required. Use with caution	**Mild:** No adjustment necessary **Moderate:** Omit ivacaftor dose **Severe:** Omit ivacaftor dose	**Mild:** No adjustment necessary **Moderate:** Omit ivacaftor dose **Severe:** Not recommended

**: Dosing recommendations for concomitant medication use are also in the label for each agent:*

- *All agents have specific dosage recommendations if taken with STRONG CYP3A4 inhibitors*
- *Symdeko, Kalydeco, and Trikafta have specific dosage recommendations if taken with MODERATE CYP3A4 inhibitors*
- *Kalydeco is not recommended to be used with strong CYP3A4 inducers*

- **Adverse Reactions**

Kalydeco	Orkambi	Symdeko	Trikafta
CNS: Headache (24%); Dizziness (9%) **Dermatologic:** Skin rash (13%); Acne vulgaris (4% to 7%) **Endocrine & metabolic:** ↑ BG (4-7%) **GI:** Abdominal pain (16%); diarrhea (13%), nausea (12%) **Hepatic:** ↑ liver enzymes (4-7%) **Infection:** Bacterial infection (4-7%) **Neuromuscular & skeletal:** Arthralgia (4-7%); musculoskeletal chest pain (4-7%), myalgia (4-7%) **Respiratory:** Oropharyngeal pain (22%); URTI (22%); nasal congestion (20%); nasopharyngitis (15%)	**CV:** Chest discomfort (≤22%, children: ≤11%); ↑ BP (≤4%) **CNS:** Headache (13%); Fatigue (9%) **Dermatologic:** Skin rash (7%) **Endocrine & metabolic:** Menstrual disease (10%) **GI:** Nausea (13%); upper abdominal pain (13%); diarrhea (12%); Flatulence (7%) **Hepatic:** ↑ LFTs >3x ULN: ≤15% **Infection:** Influenza (5%) **Neuromuscular & skeletal:** ↑ creatine phosphokinase (≤7%) **Respiratory:** Dyspnea (13-22%, children: ≤11%); changes in respiration (9-22%; children: ≤11%); cough (18%); congestion (17%); nasopharyngitis (13%); ↑ bronchial secretions (11%); URTI (10%); rhinorrhea (6%)	**CNS:** Headache (15%); Dizziness (4%) **GI:** Nausea (9%) **Respiratory:** Paranasal sinus congestion (4%)	**CV:** ↑ BP (4%) **CNS:** Headache (17%); Dizziness (2-5%) **Dermatologic:** Skin rash (10%), acne (2-5%), eczema (2-5%), pruritus (2-5%) **Endocrine & metabolic:** Hypoglycemia (2-5%) **Genitourinary**: Dysmenorrhea (2% to <5%), urinary tract infection (2% to <5%) **GI:** Abdominal pain (14%); diarrhea (13%); Abdominal distention (2-5%); flatulence (2-5%) **Hematologic & oncologic:** ↑ C-RP (2-5%) **Hepatic:** ↑ indirect serum bilirubin (11%) **Respiratory:** URTI (16%)

- **Drug Interactions**
  - Numerous drug interactions for all agents due to their active ingredients being metabolized primarily by CYP3A4, as well as some drug interaction potential for drugs affecting P-gp.

Ivacaftor	Lumacaftor	Tezacaftor	Elexacaftor
Substrate of CYP3A4 (major); **Inhibits** CYP3A4 (weak), P-glycoprotein/ABCB1 (weak), possibly inhibits CYP2C9	**Induces** CYP3A4 (strong)	**Substrate** of BCRP/ABCG2, CYP3A4 (major), OATP1B1/1B3, P-glycoprotein/ABCB1 **Inhibits** P-glycoprotein/ABCB1	**Substrate of** BCRP/ABCG2, CYP3A4 (major), OATP1B1/1B3, P-glycoprotein/ABCB1 **Inhibits** P-glycoprotein/ABCB1

COST

Drug	Strength	Package Size	AWP Pkg Price	AWP Unit Price
Trikafta	100 mg-75 mg-50 mg	84	$ 28,675.36	$ 341.37
Kalydeco	150 mg tab	60	$30,723.60	$512.06
Kalydeco	25 mg/1 packet 50 mg/1 packet 75 mg/1 packet	56	$ 28,675.36	$512.06
Orkambi	125 mg-100 mg tab 188 mg-150 mg tab	112	$25,103.08	$224.13
Orkambi	125 mg-100 mg granules 188 mg-150 mg granules	56	$25,103.08	$448.27
Symdeko	75 mg; 75 mg-50 mg 150 mg; 150 mg-100 mg	56	$26,880.00	$480.00

CURRENT UTILIZATION

ND Medicaid Utilization (03/2019 – 02/2020)			
Label Name	**Rx Num**	**Patients**	**Total Reimb Amt**
Trikafta	3	2	$47,827.81
Kalydeco	5	1	$119,542.95
Orkambi	8	2	$148,896.25
Symdeko	23	4	$409,324.48

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REVIEW OF ACL INHIBITORS

Overview of ACL:

- Adenosine triphosphate-citrate lyase (ACL) inhibitors lower low-density lipoprotein cholesterol (LDL-C) by inhibiting cholesterol synthesis in the liver
    - ACL is a cytoplasmic enzyme that is responsible for the generation of acetyl coenzyme A for the de novo synthesis of fatty acids and cholesterol
    - ACL's activity lies upstream of HMG-CoA reductase in the cholesterol biosynthesis pathway
        - HMG-CoA is formed from acetoacetyl-CoA, which is comprised of 2 acetyl coenzyme A molecules

ACL INHIBITORS:

- **Current products**
    - Currently, bempedoic acid is the only FDA-approved ACL inhibitor, with two products available:
        - Nexletol (bempedoic acid)
            - Oral tablet: bempedoic acid 180 mg
        - Nexlizet (bempedoic acid and ezetimibe)
            - Oral tablet: bempedoic acid 180 mg / ezetimibe 10 mg

- **Indications**
    - Treatment of established atherosclerotic cardiovascular disease, as an adjunct to diet and maximally tolerated statin therapy, in adult patients who require additional lowering of low-density lipoprotein cholesterol (LDL-C)
    - Treatment of heterozygous familial hypercholesterolemia, as an adjunct to diet and maximally tolerated statin therapy, in adult patients who require additional lowering of LDL-C
    - Limitations of use
        - The effect on cardiovascular morbidity and mortality has not been determined

- **Mechanism of Action/Pharmacology:**
    - Bempedoic acid and its active metabolite, ESP15228, require coenzyme A (CoA) activation by very long-chain acyl-CoA synthetase 1 (ACSVL1) to ETC-1002-CoA and ESP15228-CoA
        - Inhibition of ACL by ETC-1002-CoA causes ↓ cholesterol synthesis in the liver
            - Lowers LDL-C in blood via upregulation of LDL receptors
        - ESP15228 likely makes a minor contribution to overall clinical activity

- **Contraindications:**
    - Nexletol (bempedoic acid)
        - There are no contraindications listed in the manufacturer's labeling
    - Nexlizet (bempedoic acid and ezetimibe)
        - Hypersensitivity (eg, anaphylaxis, angioedema, rash, urticaria) to ezetimibe or any component of the formulation.

- **Warnings/Precautions:**
  - **Hyperuricemia**
    - Increases in serum uric acid have occurred (usually within the first 4 weeks of treatment) and persisted throughout treatment
      - Assess uric acid levels periodically as clinically indicated
      - Individuals who have a prior history of gout are at increased risk
      - Monitor for s/s and initiate treatment with urate-lowering drugs as needed
  - **Tendon rupture**
    - Tendon rupture or injury has occurred within weeks to months of treatment initiation
      - Risk factors:
        - Patients >60 years of age
        - Taking corticosteroid or fluoroquinolone drugs
        - Patients with renal failure.
      - Consider alternative therapy in patients with a history of tendon disorders or tendon rupture.
      - Consider discontinuing therapy if joint pain, swelling, or inflammation occurs; discontinue immediately if tendon rupture occurs
- **Dosing:**
  - For adults (safety and efficacy not established in pediatric patients)
    - Recommended dose for both FDA-approved indications:
      - Nexletol: 180 mg once daily
      - Nexlizet: 1 tablet (bempedoic acid 180 mg / ezetimibe 10 mg) once daily
  - **Renal Impairment:**
    - eGFR <30 mL/minute/1.73 m2
      - There are no dosage adjustments provided in labeling (limited experience)
    - End-stage renal disease receiving dialysis
      - Has not been studied
  - **Hepatic Impairment**
    - Mild to moderate impairment (Child-Pugh class A and B)
      - No dosage adjustment necessary
    - Severe impairment (Child-Pugh class C)
      - Has not been studied

- **Adverse Reactions**
  - **Commonly reported:**

Bempedoic acid	Ezetimibe
Endocrine o Hyperuricemia (4% to 26%) Cardiovascular o Atrial fibrillation (2%), increased serum creatine kinase (1%) Gastrointestinal o Abdominal distress (≤3%), abdominal pain (≤3%) Genitourinary o Benign prostatic hyperplasia (1%) Hematologic & oncologic o Anemia (3%), leukopenia (9%), thrombocythemia (10%) Hepatic o Increased liver enzymes (2%), increased serum aspartate aminotransferase (1%) Neuromuscular & skeletal o Back pain (3%), limb pain (3%), muscle spasm (4%) Renal o Increased blood urea nitrogen (4%), increased serum creatinine (2%) Respiratory o Upper respiratory tract infection (5%)	CNS o Fatigue (2.4%) Gastrointestinal o Diarrhea (4.1%) Neuromuscular & skeletal o Arthralgia (3%), pain in extremity (2.7%) Respiratory o Upper respiratory tract infection (4.3%) o Sinusitis (2%)

- **Drug Interactions**
  - Inhibits OATP1B1/1B3 (SLCO1B1/1B3)

Nexletol	Nexlizet
• Avoid o Asunaprevir o Elagolix o Grazoprevir o Revefenacin o Voxilaprevir • Dose modification o Eluxadoline (↓ dose to 75 mg BID) o Simvastatin (limit to 20 mg) o Pravastatin (limit to 40 mg)	• Same as Nexletol + interactions with ezetimibe • Avoid o Fibric Acid Derivatives (↑ ezetimibe) • Consider Modifications o Bile Acid Sequestrants (↓ ezetimibe) • Monitor o Cyclosporine (↑ ezetimibe)

COST

Drug	Strength	Package Size	WAC Pkg Price	WAC Unit Price
Nexletol	180 mg tab	30	$330.00	$11.00
Nexlizet	No pricing information available			
Atorvastatin	80 mg tab	90	$27.13	$0.30
Rosuvastatin	40 mg tab	90	$25.00	$0.28

CURRENT UTILIZATION

ND Medicaid Utilization (01/2020 **– 03/2020)**			
Label Name	**Rx Num**	**Patients**	**Total Reimb Amt**
Nexletol	0	0	$0.00
Atorvastatin	3,906	1,761	$55,497.49
Lovastatin	46	21	$660.45
Pitavastatin	3	1	$930.66
Pravastatin	308	135	$4,565.21
Rosuvatatin	1,189	2	$17,521.64
Simvastatin	909	386	$11,746.14

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3. Nexlizet (bempedoic acid and ezetimibe) [prescribing information]. Ann Arbor, MI: Esperion Therapeutics Inc; February 2020

REVIEW OF ANTIFIBRINOLYTIC AGENTS

ANTIFIBRINOLYTIC AGENTS

- **Current products**
  - **Tranexamic acid**
    - **Cyklokapron**: 1000 mg /10 mL solution for IV injection
    - **Lysteda**: 650 mg oral tablet
  - **Aminocaproic acid**
    - **Generic**: 250 mg/mL solution for IV injection
    - **Amicar**:
      - Oral solution: 25%
      - Oral tablet: 500 mg, 1,000 mg
- **Indications for Use**
  - **FDA-Approved Indications**
    - **Cyklokapron:**
      - Short-term use in hemophilia patients to reduce or prevent hemorrhage and reduce the need for replacement therapy during and following tooth extraction
    - **Lysteda:**
      - Treatment of cyclic heavy menstrual bleeding
    - **Aminocaproic acid for injection**
      - Excessive bleeding: Aminocaproic acid is useful in enhancing hemostasis when fibrinolysis contributes to bleeding.
    - **Amicar:**
      - To enhance hemostasis when fibrinolysis contributes to bleeding (causes may include cardiac surgery, hematologic disorders, neoplastic disorders, abruptio placentae, hepatic cirrhosis, and urinary fibrinolysis)

- **Mechanism of Action/Pharmacology:**
  - **Tranexamic acid**
    - Forms a reversible complex that displaces plasminogen from fibrin resulting in inhibition of fibrinolysis
    - Inhibits the proteolytic activity of plasmin
      - Reduces activation of complement and consumption of C1 esterase inhibitor thereby decreasing inflammation associated with hereditary angioedema
  - **Aminocaproic acid**
    - Binds competitively to plasminogen; blocking the binding of plasminogen to fibrin and the subsequent conversion to plasmin, resulting in inhibition of fibrin degradation (fibrinolysis).

- **Contraindications:**

Tranexamic acid	**Aminocaproic acid**
• Hypersensitivity to tranexamic acid or any component of the formulation • Acquired defective color vision • Active intravascular clotting Subarachnoid hemorrhage	• Evidence of an active intravascular clotting process • Disseminated intravascular coagulation without concomitant heparin

- **Warnings/Precautions:**

Tranexamic acid	Aminocaproic acid
Thrombotic events • Venous and arterial thrombosis or thromboembolism has been reported. Use with caution in patients with thromboembolic disease. Vascular disease • Use with caution in patients with uncorrected cardiovascular or cerebrovascular disease due to complications of thrombosis Ocular effects • Visual defects (eg, color vision change, visual loss) and retinal venous and arterial occlusions have been reported o D/c if ocular changes occur Seizures • Seizures have been reported with use o D/c if seizures occur Ureteral obstruction • Ureteral obstruction due to clot formation has been reported o Use with caution in patients with upper urinary tract bleeding, Disseminated intravascular coagulation • Use with extreme caution in patients with disseminated intravascular coagulation	Upper urinary tract bleeding • May cause intrarenal obstruction via thrombosis o Should not be used in hematuria of upper urinary tract unless the possible benefits outweigh the risk Skeletal muscle weakness • Rare muscle weakness with necrosis of muscle fibers has been reported following prolonged administration o D/c if a rise in CPK is noted Cardiac/Hepatic lesions • Have also been noted with muscle necrosis Hyperfibrinolysis • The drug should not be administered without a definite diagnosis and/or laboratory finding indicative of hyperfibrinolysis Neurological events • Incidence of hydrocephalus, cerebral ischemia, or cerebral vasospasm associated with the use of antifibrinolytic agents in the treatment of subarachnoid hemorrhage (SAH) o Drug relatedness remains unclear Thrombophlebitis • Thrombophlebitis should be guarded against by strict attention to the proper insertion of the needle and the fixing of its position.

- **Dosing:**

	Cyklokapron	Lysteda	aminocaproic acid	Amicar
Adults	10 mg/kg IV with replacement therapy immediately before tooth extraction, followed by 10 mg/kg 3 to 4 times daily for 2-8 days	1.3 g three times daily for up to 5 days during monthly menstruation	5 g, followed by 1-1.25 g hourly	5 g during the first hour 1 g or 1.25 g each hour after for 8 hours or until the bleeding situation has been controlled
Pediatric	Same as adult	**≥ 12 years old:** 1.3 g TID for up to 5 days per month	Not approved	Not approved
Renal Impairment	**SCr 1.36-2.83 mg/dl:** 10 mg/kg BID **SCr 2.83-5.66 mg/dl:** 10 mg/kg once daily **SCr >5.66 mg/dL:** 10 mg/kg q48h or 5 mg/kg daily	**SCr 1.4-2.8 mg/dL**: 1.3 g twice BID (up to 5 days) **SCr 2.9-5.7 mg/dL:** 1.3 g daily (up to 5 days) **SCr >5.7 mg/dL:** 650 g daily (up to 5 days)	Administer with caution.	Administer with caution. May accumulate in patients with decreased renal function
Hepatic Impairment	No dosage adjustment	No dosage adjustment	Administer with caution.	No dosage adjustment

- **Adverse Reactions**

Tranexamic acid	Aminocaproic acid
CNS • Headache (oral: 50%), Fatigue (oral: 5% **GI** • Abdominal pain (oral: 20%) **Neuromuscular & skeletal** • Back pain (oral: 21%), musculoskeletal pain (oral: 11%), Arthralgia (oral: 7%), muscle cramps (oral: ≤7%), muscle spasm (oral: ≤7%) **Respiratory** • Nasal signs and symptoms (oral: 25%; including sinus symptoms) **Hematologic & oncologic** • Anemia (oral: 6%)	**Cardiovascular** • Bradycardia; hypotension; peripheral ischemia; thrombosis. **CNS** • Confusion; convulsions; delirium; dizziness; hallucinations; intracranial hypertension; stroke; syncope. Two cases of convulsions following IV administration have been reported. **Dermatologic** • Pruritus; rash. **GI** • Abdominal pain; diarrhea; nausea; vomiting. **GU** • BUN increased; renal failure. **Hematologic** • Agranulocytosis; coagulation disorder; leukopenia; thrombocytopenia. **Hypersensitivity** • Allergic and anaphylactoid reactions; anaphylaxis. **Local** • Injection site reactions; pain and necrosis. **Musculoskeletal** • CPK increased; muscle weakness; myalgia; myopathy (see Warnings); myositis; rhabdomyolysis. **Respiratory** • Dyspnea; nasal congestion; pulmonary embolism. **Special Senses** • Tinnitus; vision decreased; watery eyes. **Miscellaneous** • Edema; headache; malaise.

- **Drug Interactions**

Tranexamic acid	Aminocaproic acid
Avoid (↑ thrombogenic effects) • Anti-inhibitor Coagulant Complex (Human) • Estrogen Derivatives (Contraceptive) • Progestins (Contraceptive) • Tretinoin (Systemic)	**Avoid (↑ thrombogenic effects)** • Anti-inhibitor Coagulant Complex (Human) • Factor IX Complex (human) • Tretinoin (Systemic)

COST

Drug	Strength	Package Size	AWP Pkg Price	AWP Price per dose
Amicar	0.25 g / 1 mL oral sln	236.5 mL	$3,018.57	$63.80
Amicar	500 mg tablet 1,000 mg tablet	30 tablets 30 tablets	$659.64 $1,319.27	$43.98 $43.98
Aminocaproic acid	250 mg/1 ml IV sln	20 ml	$10.80	$2.70
Lysteda	650 mg oral tab	30 tablets	$195.50	$19.56
Generic tranexamic acid	650 mg oral tab	30 tablets	$156.60	$15.66
Cyklokapron	100 mg/mL IV sln	10	$360.00	Cost per mL: $3.60

CURRENT UTILIZATION

ND Medicaid Utilization (03/2019 – 02/2020)			
Label Name	**Rx Num**	**Patients**	**Total Reimb Amt**
Amicar tabs	5	4	$13,767.37
Amicar sln	6	5	$17,299.84
Lysteda	0	0	$0.00
Tranexamic acid oral (generic)	42	25	$2,435.94

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3. Lysteda (tranexamic acid) [prescribing information]. Parsippany, NJ: Ferring Pharmaceuticals; March 2016.
4. Amicar (aminocaproic acid) [prescribing information]. Lake Forest, IL: Clover Pharmaceuticals; March 2017
5. Aminocaproic acid injection solution [prescribing information]. Shirley, NJ: American Regent, Inc; December 2018.

REVIEW OF PALFORZIA (peanut allergen powder)

Overview of Peanut Allergy:

- Food allergy causing a type 1 hypersensitivity reaction
    - Based on the severity of the reaction, can cause symptoms ranging from a runny nose, skin reactions, itching, digestive problems, and breathing issues, to anaphylaxis and death
- 1.2% of the overall US population and about 2.5% of the pediatric population have a peanut allergy (most common food allergy in children at ~25%)
    - U.S. peanut allergy prevalence has more than tripled 1997 and 2008, and increased another 21% since 2010
    - Only 20% of children will outgrow this allergy
- No cure. The principal treatment for anaphylaxis is the injection of epinephrine

PALFORZIA:

- **Product Indication:**
    - Oral immunotherapy for mitigation of allergic reactions, including anaphylaxis, that may occur with accidental exposure to peanut in patients with a confirmed diagnosis of peanut allergy.
        - Initial dose escalation may be administered to patients 4 to 17 years of age.
        - Up-dosing and maintenance may be continued in patients ≥4 years of age.
        - Peanut allergen powder is to be used in conjunction with a peanut-avoidant diet.
    - ****Limitation of Use****
        - Not indicated for the emergency treatment of allergic reactions, including anaphylaxis
- **Box Warning:**
    - Peanut allergen powder can cause anaphylaxis, which may be life-threatening and can occur at any time during therapy.
    - Prescribe injectable epinephrine, instruct and train patients on its appropriate use, and instruct patients to seek immediate medical care upon its use.
    - Do not administer peanut allergen powder to patients with uncontrolled asthma.
    - Dose modifications may be necessary following an anaphylactic reaction.
    - Observe patients during and after administration of the initial dose escalation and the first dose of each up-dosing level, for at least 60 minutes.
    - Because of the risk of anaphylaxis, peanut allergen powder is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the Palforzia REMS
        - Prescribers must be specially certified to prescribe Palforzia
            - Before treatment initiation, the prescriber must enroll each patient in the REMS Program
            - Provide patient counseling on anaphylaxis risks, s/s/, and management; monitoring requirements; peanut avoidance; and having epinephrine
            - Requires reporting of treatment discontinuation or transfer of care
        - Pharmacies must be specially certified to dispense Palforzia
            - Must verify prescriber certification, patient enrollment, and that initial escalation is only being dispensed to certified healthcare settings
            - Only one dose level is dispensed to the patient at a time during up-dosing
            - Must provide patient counseling
- **Contraindications:**
    - Uncontrolled asthma; history of eosinophilic esophagitis and other eosinophilic GI disease

- **Warnings/Precautions:**
  - **Anaphylaxis:**
    - Most commonly occurs within 2 hours after a dose but may be >10 hours
    - Do not initiate therapy in patients who have had severe or life-threatening anaphylaxis in the previous 60 days
    - Increased risk of anaphylaxis may occur with potential cofactors, including exercise, hot water exposure, illness, fasting, menstruation, sleep deprivation, NSAID use, or uncontrolled asthma
  - **Respiratory disease:**
    - Do not administer to patients with uncontrolled asthma
      - Risk factor for serious outcome in anaphylaxis, including death
    - Withhold treatment if patient is experiencing an acute asthma exacerbation
    - Reevaluate patients with recurrent asthma exacerbations and consider discontinuation
    - Use has not been studied in patients with severe asthma, persistently uncontrolled asthma, or in patients on long-term systemic corticosteroid therapy
  - **Esophagitis**
    - Eosinophilic esophagitis has been reported
    - Discontinue therapy in patients who experience severe or persistent GI symptoms (eg, dysphagia, vomiting, nausea, gastroesophageal reflux disease, chest pain, abdominal pain)
  - **GI effects**
    - GI adverse reactions (including abdominal pain, vomiting, nausea, oral pruritus, and oral paresthesia) have been reported
      - Dose adjustment may be necessary.
- **Dosing:**
  - Injectable epinephrine must be available during treatment
  - Do not initiate treatment if the patient has experienced severe or life-threatening anaphylaxis in the last 60 days
  - Do not swallow capsule or inhale powder
    - Open capsule or sachet and empty the entire dose of peanut allergen powder onto a few spoonfuls of refrigerated or room temperature semisolid food and mix well
    - Consume the entire volume of prepared mixture promptly
  - Treatment is administered in 3 phases: initial dose escalation phase, up-dosing phase, and maintenance phase
    - **<u>Initial dose escalation phase:</u>**
      - To be completed in a single day under the direct supervision of a certified health care provider
        - Observe patient for 20 to 30 minutes between each dose level and for 60 minutes after last dose of the initial phase
      - **Dose Modification:**
        - Doses should not be modified during this phase

Initial Dose Escalation Phase	
Dose Level	**Dose**
A	0.5 mg
B	1 mg
C	1.5 mg
D	3 mg
E	6 mg

- **Up-dosing phase:**
  - Should begin the day after initial dose escalation phase or within 4 days.
    - If not started within 4 days, the initial dose escalation phase must be repeated
  - The first dose at each level should be administered under the supervision of a health care provider and the patient should be observed for at least 60 minutes.
    - Subsequent doses at the dose level once daily (preferably in the pm).
  - **Dose Modification:**
    - Do not omit any dose levels
    - Do not progress dose more frequently than at 2-week intervals
    - May maintain dose level for longer than 2 weeks, reduce dose withhold dose, or discontinue therapy if needed due to severe reactions
    - Dose modifications may also be necessary for missed doses or patient convenience

Daily Dosing for Up-Dosing Phase	
Dose Level*	**Dose**
1	3 mg
2	6 mg
3	12 mg
4	20 mg
5	40 mg
6	80 mg
7	120 mg
8	160 mg
9	200 mg
10	240 mg
11	300 mg
*: The recommended duration of each dosing level is 2 weeks	

- **Maintenance phase:**
  - Dose is 300 mg once daily
  - **Dose Modification:**
    - May reduce dose withhold dose, or discontinue therapy if needed due to severe reactions
    - Dose modifications may also be necessary for missed doses or patient convenience.

- There are no dosage adjustments provided for renal or hepatic impairment

- **Adverse Reactions**
  - **Most common:**
    - Dermatologic
      - Pruritus (8% to 33%), urticaria (4% to 28%)
    - Gastrointestinal
    - Abdominal pain (26% to 67%), vomiting (3% to 37%), nausea (9% to 32%), oral paresthesia (2% to 14%)
    - Respiratory
      - Throat irritation (9% to 40%), cough (3% to 32%), rhinorrhea (1% to 21%), sneezing (3% to 20%), pharyngeal edema (3% to 14%), wheezing (≤12%)
  - **Less Common**
    - Gastrointestinal
      - Eosinophilic esophagitis (1%)
    - Hypersensitivity
      - Anaphylaxis (≤9%)
    - Respiratory
      - Dyspnea (≤8%)

- **Drug Interactions**
  - There are no known significant interactions.

COST

Drug	Strength	Package Size	AWP Pkg Price	AWP Unit Price
Palforzia	Dose escalation (0.5, 1 mg)	13 each	$36.00	$2.77
Palforzia	Level 1 (1 mg)	45	$534.00	$11.87
Palforzia	Level 2 (1 mg)	90	$534.00	$5.93
Palforzia	Level 3 (1, 10 mg)	45 each	$534.00	$11.87
Palforzia	Level 4 (20 mg)	15	$534.00	$35.60
Palforzia	Level 5 (20 mg)	30	$534.00	$17.80
Palforzia	Level 6 (20 mg)	60	$534.00	$8.90
Palforzia	Level 7 (20 mg, 100 mg)	30 each	$534.00	$17.80
Palforzia	Level 8 (20 mg, 100 mg)	60 each	$534.00	$8.90
Palforzia	Level 9 (100 mg)	30	$534.00	$17.80
Palforzia	Level 10 (20 mg, 100 mg)	60 each	$534.00	$8.90
Palforzia	Level 11 (300 mg)	15	$534.00	$35.60
Palforzia	Level 11 (300 mg)	30	$1,068.00	$35.60

CURRENT UTILIZATION

ND Medicaid Utilization (03/2019 – 02/2020)			
Label Name	**Rx Num**	**Patients**	**Total Reimb Amt**
Palforzia	0	0	$0.00

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NORTH DAKOTA MEDICAID
RETROSPECTIVE DRUG UTILIZATION REVIEW
CRITERIA RECOMMENDATIONS
2ND QUARTER 2020

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

1. Binimetinib / Overuse _____ _____

Alert Message: Mektovi (binimetinib) may be over-utilized. The recommended dosage of binimetinib is 45 mg orally taken twice daily, approximately 12 hours apart, in combination with encorafenib until disease progression or unacceptable toxicity.

Drugs/Diseases

Util A	Util B	Util C **(Negating)**
Binimetinib		Cirrhosis
		Hepatic Failure

Max Dose: 90 mg/day

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Mektovi Prescribing Information, Jan. 2019, Array BioPharma Inc.

2. Binimetinib / Overuse Hepatic Impairment _____ _____

Alert Message: For patients with moderate (total bilirubin greater than 1.5 and less than or equal to 3 × ULN and any AST) or severe (total bilirubin levels greater than 3 × ULN and any AST) hepatic impairment, the recommended dosage of Mektovi (binimetinib) is 30 mg orally taken twice daily. Dose adjustment of binimetinib is not recommended in patients with mild hepatic impairment.

Drugs/Diseases

Util A	Util B	Util C **(Include)**
Binimetinib		Cirrhosis
		Hepatic Failure

Max Dose: 60 mg/day

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Mektovi Prescribing Information, Jan. 2019, Array BioPharma Inc.

3. Binimetinib / Therapeutic Appropriateness _____ _____

Alert Message: A review of the patient's drug profile does not reveal a prescription for an encorafenib. Mektovi (binimetinib) is approved to be used in combination with encorafenib. If encorafenib is permanently discontinued, discontinue binimetinib.

Drugs/Diseases

Util A	Util B	Util C **(Negating)**
Binimetinib		Encorafenib

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Mektovi Prescribing Information, Jan. 2019, Array BioPharma Inc.

4. Binimetinib / Pregnancy / Pregnancy Negating _____ _____

Alert Message: Based on findings from animal reproduction studies and its mechanism of action, Mektovi (binimetinib) can cause fetal harm when administered to a pregnant woman. In animal reproduction studies, oral administration of binimetinib during the period of organogenesis was embryotoxic and an abortifacient in rabbits at doses greater than or equal to those resulting in exposures approximately 5 times the human exposure at the clinical dose of 45 mg twice daily. Advise pregnant women of the potential risk to a fetus.

Drugs/Diseases

Util A	Util B	Util C **(Negating)**
Binimetinib	Pregnancy	Abortion
		Delivery
		Miscarriage

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Mektovi Prescribing Information, Jan. 2019, Array BioPharma Inc.

5. Binimetinib / Lactation _____ _____

Alert Message: There are no data on the presence of Mektovi (binimetinib) or its active metabolite in human milk, or the effects of binimetinib on the breastfed infant, or milk production. Because of the potential for serious adverse reactions from binimetinib in breastfed infants, advise women not to breastfeed during treatment with binimetinib and for 3 days after the final dose.

Drugs/Diseases

Util A	Util B	Util C
Binimetinib	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Mektovi Prescribing Information, Jan. 2019, Array BioPharma Inc.

6. Binimetinib / Therapeutic Appropriateness _____ _____

Alert Message: Advise females of reproductive potential to use effective contraception during treatment with Mektovi (binimetinib) and for at least 30 days after the final dose. Binimetinib can cause fetal harm when administered to a pregnant woman.

Drugs/Diseases

Util A	Util B	Util C **(Negating)**
Binimetinib		Contraceptives

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Mektovi Prescribing Information, Jan. 2019, Array BioPharma Inc.

7. Binimetinib / Therapeutic Appropriateness _____ _____

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

Drugs/Diseases

Util A	Util B	Util C
Binimetinib		

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Mektovi Prescribing Information, Jan. 2019, Array BioPharma Inc.

8. Binimetinib / Cardiomyopathy _____ _____

Alert Message: Cardiomyopathy, manifesting as left ventricular dysfunction associated with symptomatic or asymptomatic decreases in ejection fraction, has been reported in patients treated with Mektovi (binimetinib) in combination with encorafenib. Patients with cardiovascular risk factors should be monitored closely when treated with binimetinib. Withhold, reduce dose per official prescribing information, or permanently discontinue based on the severity of the adverse reaction.

Drugs/Diseases

Util A	Util B	Util C
Binimetinib	Cardiomyopathy	

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Mektovi Prescribing Information, Jan. 2019, Array BioPharma Inc.

9. Binimetinib / Venous Thromboembolism _____ _____

Alert Message: In a clinical trial, venous thromboembolism (VTE) occurred in 6% of patients receiving Mektovi (binimetinib) in combination with encorafenib, including 3.1% of patients who developed pulmonary embolism (PE). For patients who develop uncomplicated DVT or PE, withhold binimetinib until improvement to Grade 0-1, and resume at a reduced dose. If no improvement, permanently discontinue binimetinib. Permanently discontinue binimetinib in cases of life-threatening PE.

Drugs/Diseases

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

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Mektovi Prescribing Information, Jan. 2019, Array BioPharma Inc.

10. Binimetinib / Retinopathy _____ _____

Alert Message: In a clinical trial, serous retinopathy occurred in approximately 20% of patients treated with Mektovi (binimetinib) in combination with encorafenib. Assess visual symptoms at each patient visit. Perform an ophthalmologic examination at regular intervals, for new or worsening visual disturbances, and to follow new or persistent ophthalmologic findings. If symptomatic serous retinopathy or retinal pigment epithelial detachments occur, withhold binimetinib for up to 10 days. If condition improves or becomes asymptomatic, resume binimetinib at the same dose. If no improvement occurs, resume binimetinib at a lower dose or permanently discontinue.

Drugs/Diseases

Util A	Util B	Util C
Binimetinib	Retinal Detachment	
	Macular Edema	
	Retinopathy	

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Mektovi Prescribing Information, Jan. 2019, Array BioPharma Inc.

11. Binimetinib / Retinal Vein Occlusion _____ _____

Alert Message: Retinal vein occlusion (RVO) is a known class-related adverse reaction of MEK inhibitors and may occur in patients treated with Mektovi (binimetinib) in combination with encorafenib. The safety of binimetinib has not been established in patients with a history of RVO or current risk factors for RVO, including uncontrolled glaucoma or a history of hyperviscosity or hypercoagulability syndromes. Perform an ophthalmologic evaluation for patient-reported acute vision loss or other visual disturbance within 24 hours. Permanently discontinue binimetinib in patients with documented RVO.

Drugs/Diseases

Util A	Util B	Util C
Binimetinib	Retinal Vein Occlusion	
	Glaucoma	

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Mektovi Prescribing Information, Jan. 2019, Array BioPharma Inc.

12. Binimetinib / Uveitis _____ _____

Alert Message: Uveitis has been reported in patients treated with Mektovi (binimetinib) in combination with encorafenib. Assess visual symptoms at each patient visit. Perform an ophthalmologic evaluation at regular intervals, and for new or worsening visual disturbances. For patients who develop Grade 3 uveitis or Grade 1 or 2 that does not respond to specific ocular therapy, withhold binimetinib for up to 6 weeks. If condition improves, resume binimetinib at the same or a reduced dose or if no improvement permanently discontinue therapy. For Grade 4 uveitis, permanently discontinue.

Drugs/Diseases

Util A	Util B	Util C
Binimetinib	Uveitis	
	Iridocyclitis	

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Mektovi Prescribing Information, Jan. 2019, Array BioPharma Inc.

13. Binimetinib / Interstitial Lung Disease _____ _____

Alert Message: Mektovi (binimetinib) can cause interstitial lung disease (ILD), including pneumonitis. Assess new or progressive unexplained pulmonary symptoms or findings for possible ILD. For patients who develop Grade 2 ILD, withhold binimetinib for up to 4 weeks. If toxicity improves to Grade 0-1, resume at a reduced dose. If toxicity does not resolve within 4 weeks, permanently discontinue binimetinib. For patients with Grade 3 or 4 ILD, permanently discontinue binimetinib.

Drugs/Diseases

Util A	Util B	Util C
Binimetinib	Dyspnea	
	Cough	
	Fever	
	Interstitial Pneumonia	

References:

Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Mektovi Prescribing Information, Jan. 2019, Array BioPharma Inc.

14. Binimetinib / Hepatotoxicity _____ _____

Alert Message: Hepatotoxicity can occur when Mektovi (binimetinib) is administered in combination with encorafenib. Monitor liver laboratory tests before initiation of binimetinib, monthly during treatment, and as clinically indicated. For patients who develop toxicities, withhold, reduce dose, or permanently discontinue binimetinib therapy based on the severity of the adverse reaction.

Drugs/Diseases

Util A	Util B	Util C
Binimetinib	Encorafenib	

References:

Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Mektovi Prescribing Information, Jan. 2019, Array BioPharma Inc.

15. Binimetinib / Rhabdomyolysis _____ _____

Alert Message: Rhabdomyolysis can occur when Mektovi (binimetinib) is administered in combination with encorafenib. Monitor CPK and creatinine levels prior to initiating binimetinib, periodically during treatment, and as clinically indicated. For patients who develop Grade 4 asymptomatic elevated CPK level or any grade elevated CPK level with symptoms or renal impairment, hold binimetinib for up to 4 weeks. If the toxicity improves to grade 1 or less, resume binimetinib at a reduced dose. If the toxicity does not resolve within 4 weeks, permanently discontinue binimetinib.

Drugs/Diseases

Util A	Util B	Util C
Binimetinib	Myopathy	
	Rhabdomyolysis	

References:

Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Mektovi Prescribing Information, Jan. 2019, Array BioPharma Inc.

16. Binimetinib / Hemorrhage _____ _____

Alert Message: Hemorrhage can occur when Mektovi (binimetinib) is administered in combination with encorafenib. In a clinical trial, hemorrhage occurred in 19% of patients receiving binimetinib in combination with encorafenib. The most frequent hemorrhagic events were gastrointestinal. Fatal intracranial hemorrhage in the setting of new or progressive brain metastases occurred in 1.6% of patients. Withhold, reduce dose, or permanently discontinue binimetinib based on the severity of the adverse reaction.

Drugs/Diseases

Util A	Util B	Util C
Binimetinib	Gastrointestinal Hemorrhage	
	Intracranial Hemorrhage	
	Subarachnoid Hemorrhage	

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Mektovi Prescribing Information, Jan. 2019, Array BioPharma Inc.

17. Amlodipine/Celecoxib / Overutilization _____ _____

Alert Message: The recommended dose of Consensi (amlodipine/celecoxib) is 10 mg amlodipine/200 mg celecoxib per day. Use the lowest effective dosage of the celecoxib-containing product for the shortest duration consistent with individual treatment goals. If analgesic therapy is no longer indicated, discontinue amlodipine/celecoxib and initiate patient on alternative antihypertensive therapy, such as amlodipine monotherapy.

Drugs/Diseases

Util A	Util B	Util C
Amlodipine/Celecoxib		

Max Dose: 10 mg amlodipine/200 mg celecoxib

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Facts & Comparisons, 2020 Updates, Wolters Kluwer Health.

18. Amlodipine/Celecoxib / Advanced Renal Disease _____ _____

Alert Message: The use of Consensi (amlodipine/celecoxib) should be avoided in patients with advanced renal disease unless the benefits are expected to outweigh the risk of worsening renal function. The celecoxib component of the combination product may hasten the progression of renal dysfunction in patients with preexisting renal disease. If use of the celecoxib-containing product cannot be avoided in patients with advanced renal disease, monitor patients for signs of worsening renal function.

Drugs/Diseases

Util A	Util B	Util C **(Include)**
Amlodipine/Celecoxib		CKD Stage 3, 4, & 5

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Facts & Comparisons, 2020 Updates, Wolters Kluwer Health.

19. Amlodipine/Celecoxib / Heart Failure _____ _____

Alert Message: Avoid the use of Consensi (amlodipine/celecoxib) in patients with severe heart failure unless the benefits are expected to outweigh the risk of worsening heart failure. If a celecoxib-containing product is used in patients with severe heart failure, monitor the patients for signs of worsening heart failure.

Drugs/Diseases

Util A	Util B	Util C **(Include)**
Amlodipine/Celecoxib	Hear Failure	Edema

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Facts & Comparisons, 2020 Updates, Wolters Kluwer Health.

20. Amlodipine/Celecoxib / Recent Myocardial Infarction _____ _____

Alert Message: Avoid the use of Consensi (amlodipine/celecoxib) in patients with a recent myocardial infarction unless the benefits are expected to outweigh the risk of recurrent CV thrombotic events. If use of a celecoxib-containing product cannot be avoided in patients with a recent myocardial infarction, monitor the patients for signs of cardiac ischemia.

Drugs/Diseases

Util A	Util B	Util C
Amlodipine/Celecoxib	Myocardial Infarction	

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Facts & Comparisons, 2020 Updates, Wolters Kluwer Health.

21. Amlodipine/Celecoxib / Therapeutic Appropriateness _____ _____

Alert Message: The safety and efficacy of Consensi (amlodipine/celecoxib) in pediatric patients have not been established.

Drugs/Diseases

Util A	Util B	Util C
Amlodipine/Celecoxib		

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Facts & Comparisons, 2020 Updates, Wolters Kluwer Health.

22. Triclabendazole / Therapeutic Appropriateness _____ _____

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

Drugs/Diseases

Util A	Util B	Util C
Triclabendazole		

Age Range: 0 – 5 yoa

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Egaten Prescribing Information, Sept. 2019, Novartis Pharmaceuticals Corp.

23. Triclabendazole / QT prolongation _____ _____

Alert Message: Egaten (triclabendazole) should be used with caution in patients with a known history of QT prolongation or other conditions that may increase the risk of QT prolongation. Transient prolongation of the mean QTc interval was noted on the electrocardiographic recordings in dogs. Monitor ECG in patients with a history of prolongation of the QTc interval or a history of symptoms compatible with a long QT interval or when triclabendazole is used in patients who receive drugs that prolong the QT interval.

Drugs/Diseases

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

References:

Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Egaten Prescribing Information, Sept. 2019, Novartis Pharmaceuticals Corp.

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

24. Triclabendazole / QT prolongation _____ _____

Alert Message: Egaten (triclabendazole) should be used with caution in patients with a known history of QT prolongation or other conditions that may increase the risk of QT prolongation. Transient prolongation of the mean QTc interval was noted on the electrocardiographic recordings in dogs. Monitor ECG in patients with a history of prolongation of the QTc interval or a history of symptoms compatible with a long QT interval or when triclabendazole is used in patients who receive drugs that prolong the QT interval.

Drugs/Diseases

Util A	Util B	Util C
Triclabendazole	Long QT Syndrome	
	Arrhythmias	
	Bradycardia	
	Hypokalemia	
	Hypomagnesemia	

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Egaten Prescribing Information, Sept. 2019, Novartis Pharmaceuticals Corp.

25. Triclabendazole / Lactation _____ _____

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

Drugs/Diseases

Util A	Util B	Util C
Triclabendazole	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Egaten Prescribing Information, Sept. 2019, Novartis Pharmaceuticals Corp.

26. Venetoclax / Posaconazole _____ _____

Alert Message: In patients with AML, the steady daily dose of Venclexta (venetoclax), after completion of the initiation and ramp-up phase for venetoclax, should not exceed 70 mg per day when also receiving posaconazole. Posaconazole is a strong CYP3A4 and P-gp inhibitor, and venetoclax is a substrate for both CYP3A4 and P-gp. In drug studies, concurrent use of these agents resulted in significant increases in venetoclax AUC and Cmax. Coadministration of posaconazole with venetoclax is contraindicated during the initiation and ramp-up phase in patients with CLL or SLL.

Drugs/Diseases

Util A	Util B	Util C **(Include)**
Venetoclax 100mg	Posaconazole	AML

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Facts & Comparisons, 2020 Updates, Wolters Kluwer Health.

27. Lumateperone / Overuse _____ _____

Alert Message: Caplyta (lumateperone) may be over-utilized. The recommended daily dose of lumateperone for adult patients with schizophrenia is 42 mg orally once daily with food.

Drugs/Diseases

Util A	Util B	Util C
Lumateperone		

Max Dose: 42 mg/day

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Facts & Comparisons, 2020 Updates, Wolters Kluwer Health.
Caplyta Prescribing Information, Dec. 2019, Intra-Cellular Therapies, Inc.

28. Lumateperone / Therapeutic Appropriateness _____ _____

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

Drugs/Diseases

Util A	Util B	Util C
Lumateperone		

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Facts & Comparisons, 2020 Updates, Wolters Kluwer Health.
Caplyta Prescribing Information, Dec. 2019, Intra-Cellular Therapies, Inc.

29. Lumateperone / Cirrhosis _____ _____

Alert Message: The use of Caplyta (lumateperone) should be avoided in patients with moderate to severe hepatic impairment (Child-Pugh B or C). Patients with moderate to severe hepatic impairment experience higher exposure to lumateperone and are at increased risk for lumateperone-related adverse reactions. No dosage adjustment is recommended for patients with mild hepatic impairment (Child-Pugh A).

Drugs/Diseases

Util A	Util B	Util C
Lumateperone	Cirrhosis	

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Facts & Comparisons, 2020 Updates, Wolters Kluwer Health.
Caplyta Prescribing Information, Dec. 2019, Intra-Cellular Therapies, Inc.

30. Lumateperone / Tardive Dyskinesia _____ _____

Alert Message: Like other antipsychotics, Caplyta (lumateperone) may cause tardive dyskinesia. Lumateperone should be prescribed in a manner to most likely reduce the risk of tardive dyskinesia, i.e., using the lowest dose and for the shortest duration of treatment producing a satisfactory clinical response. If signs and symptoms of tardive dyskinesia appear, drug discontinuation should be considered.

Drugs/Diseases

Util A	Util B	Util C
Lumateperone	Tardive Dyskinesia	

References:

Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Facts & Comparisons, 2020 Updates, Wolters Kluwer Health.
Caplyta Prescribing Information, Dec. 2019, Intra-Cellular Therapies, Inc.

31. Lumateperone / Seizures _____ _____

Alert Message: Caplyta (lumateperone) should be used with caution in patients with a history of seizures or with conditions that lower the seizure threshold. Like other antipsychotics, lumateperone may cause seizures. Conditions that lower the seizure threshold may be more prevalent in older patients.

Drugs/Diseases

Util A	Util B	Util C
Lumateperone	Seizures	
	Epilepsy	
	Stroke	
	Head Trauma	
	Intracranial infection	
	Anorexia Nervosa	
	Meningitis	

References:

Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Caplyta Prescribing Information, Dec. 2019, Intra-Cellular Therapies, Inc.
Oh CY and Bainbridge J. Lowering the Seizure Threshold Associated with Antidepressants, Stimulants, Antipsychotics, and Others. Mental Health Clinician: Nov. 2012, Vol 2, No. 5, pp.127 – 128.

32. Lumateperone / CYP3A4 Inducers _____ _____

Alert Message: The concurrent use of Caplyta (lumateperone) with CYP3A4 inducers should be avoided. Lumateperone is a CYP3A4 substrate, and coadministration with a CYP3A4 inducer may result in decreased lumateperone exposure and loss of efficacy.

Drugs/Diseases

Util A	Util B		Util C
Lumateperone	Apalutamide	Mitotane	
	Bosentan	Modafinil	
	Carbamazepine	Phenobarbital	
	Dexamethasone	Phenytoin	
	Efavirenz	Primidone	
	Enzalutamide	Rifabutin	
	Etravirine	Rifampin	
	Lumacaftor	Rifapentine	

References:

Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Facts & Comparisons, 2020 Updates, Wolters Kluwer Health.

33. Lumateperone / Moderate to Strong CYP3A4 Inhibitors _____ _____

Alert Message: The concurrent use of Caplyta (lumateperone) with CYP3A4 inhibitors should be avoided. Lumateperone is a CYP3A4 substrate, and coadministration with a CYP3A4 inhibitor may result in increased lumateperone exposure and risk of lumateperone-related adverse reactions.

Drugs/Diseases

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

References:

Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Facts & Comparisons, 2020 Updates, Wolters Kluwer Health.
Caplyta Prescribing Information, Dec. 2019, Intra-Cellular Therapies, Inc.
FDA: Drug Development and Drug Interactions: Tables of Substrates, Inhibitors and Inducers. Available at: http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/DrugInteractionaLabeling/ucm093664.htm

34. Lumateperone / UGT Inhibitors _____ _____

Alert Message: The concurrent use of Caplyta (lumateperone) with UGT inhibitors should be avoided. Lumateperone is a UGT substrate, and coadministration with a UGT inhibitor may result in increased lumateperone exposure and risk of lumateperone-related adverse reactions.

Drugs/Diseases

Util A	Util B	Util C
Lumateperone	Probenecid	
	Valproic Acid	

References:

Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Facts & Comparisons, 2020 Updates, Wolters Kluwer Health.
Caplyta Prescribing Information, Dec. 2019, Intra-Cellular Therapies, Inc.
FDA: Drug Development and Drug Interactions: Tables of Substrates, Inhibitors and Inducers. Available at: http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/DrugInteractionaLabeling/ucm093664.htm

35. Lumateperone / Lactation _____ _____

Alert Message: Based on findings of toxicity in animal studies and the potential for serious adverse reactions in the breastfed infant, breastfeeding is not recommended during treatment with Caplyta (lumateperone). There are no available data on the presence of lumateperone or its metabolites in human milk, the effects on the breastfed infant, or the effects on milk production.

Drugs/Diseases

Util A	Util B	Util C
Lumateperone	Lactation	

References:

Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Facts & Comparisons, 2020 Updates, Wolters Kluwer Health.
Caplyta Prescribing Information, Dec. 2019, Intra-Cellular Therapies, Inc.

36. Lumateperone / Non-adherence _____ _____

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

Drugs/Diseases

Util A	Util B	Util C
Lumateperone		

References:

Theida P, et.al., An Economic Review of Compliance with Medication Therapy in the Treatment of Schizophrenia, Psychiatric Services, 2003;54:508-516.
Acsher-Svanum H, Zhu B, Faries DE, et al., The Cost of Relapse and the Predictors of Relapse in the Treatment of Schizophrenia. BMC Psychiatry 2010, 10:2.
Berger A, Edelsbery J, Sanders KN, et al., Medication Adherence and Utilization in Patients with Schizophrenia or Bipolar Disorder Receiving Aripiprazole, Quetiapine, or Ziprasidone at Hospital Discharge: A Retrospective Cohort Study. BMC Psychiatry 2012,12:99.
Stephenson JJ, Tuncelli O, Gu T, et al., Adherence to Oral Second-Generation Antipsychotic Medications in Patients with Schizophrenia and Bipolar Disorder: Physicians' Perceptions of Adherence vs. Pharmacy Claims. Int J Clin Pract, June 2012, 66, 6, 565-573.

37. Lasmiditan / Overuse _____ _____

Alert Message: Reyvow (lasmiditan) may be over-utilized. The maximum dose of lasmiditan is 200 mg. The recommended dose of lasmiditan is 50 mg, 100 mg, or 200 mg taken orally, as needed. No more than one dose should be taken in a 24 hour period. A second dose of lasmiditan has not been shown to be effective for the same migraine attack. The safety of treating more than 4 migraine attacks in a 30-day period has not been established.

Drugs/Diseases

Util A	Util B	Util C
Lasmiditan		

Max Dose: 200 mg/day

References:

Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Reyvow Prescribing Information, Oct. 2019, Eli Lilly and Company.

38. Lasmiditan / Therapeutic Appropriateness _____ _____

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

Drugs/Diseases

Util A	Util B	Util C
Lasmiditan		

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Reyvow Prescribing Information, Oct. 2019, Eli Lilly and Company.

39. Lasmiditan / Therapeutic Appropriateness _____ _____

Alert Message: Reyvow (lasmiditan) has not been studied in patients with severe hepatic impairment (Child-Pugh C), and its use in these patients is not recommended.

Drugs/Diseases

Util A	Util B	Util C
Lasmiditan	Cirrhosis	

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Reyvow Prescribing Information, Oct. 2019, Eli Lilly and Company.

40. Lasmiditan / CNS Depressants _____ _____

Alert Message: Reyvow (lasmiditan) can cause central nervous system (CNS) depression, including dizziness and sedation. Because of the potential for lasmiditan to cause sedation, other cognitive and/or neuropsychiatric adverse reactions, and driving impairment, lasmiditan should be used with caution if used in combination with alcohol or other CNS depressants.

Drugs/Diseases

Util A	Util B	Util C
Lasmiditan	Anticonvulsants	
	Antidepressants	
	Antihistamines	
	Antipsychotics	
	Barbiturates	
	Benzodiazepines	
	Cannabidiol	
	Muscle Relaxants	
	Narcotics	
	Sedative/Hypnotics	

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Reyvow Prescribing Information, Oct. 2019, Eli Lilly and Company.

41. Lasmiditan / Serotonergic Agents _____ _____

Alert Message: Caution should be exercised when Reyvow (lasmiditan) is co-administered with drugs that increase serotonin (i.e., SSRIs, SNRIs, TCAs, and MAOIs) due to the increased risk for serotonin syndrome. In clinical trials, the use of lasmiditan (a 5-HT1F receptor agonist) has been associated with reactions consistent with serotonin syndrome. Lasmiditan should be discontinued if serotonin syndrome is suspected.

Drugs/Diseases

Util A	Util B		Util C
Lasmiditan	Buspirone	Trazodone	
	Bupropion	Tramadol	
	Fentanyl	Triptans	
	Linezolid		
	MAOIs		
	Meperidine		
	SNRIs		
	SSRIs		
	TCA's		

References:

Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Reyvow Prescribing Information, Oct. 2019, Eli Lilly and Company.

42. Lasmiditan / P-gp and BCRP Substrates _____ _____

Alert Message: Concomitant use of Reyvow (lasmiditan) and drugs that are P-gp or BCRP substrates should be avoided. Lasmiditan has been shown to inhibit P-gp and BCRP transport in vitro. Concurrent use of lasmiditan with these substrates would be expected to decrease substrate exposure and efficacy.

Drugs/Diseases

Util A	Util B		Util C
Lasmiditan	Afatinib	Methotrexate	
	Apixaban	Morphine	
	Aliskiren	Nilotinib	
	Alpelisib	Quinidine	
	Ambrisentan	Paliperidone	
	Canagliflozin	Pazopanib	
	Colchicine	Pibrentasvir	
	Dabigatran	Prazosin	
	Digoxin	Ranolazine	
	Dolutegravir	Rivaroxaban	
	Edoxaban	Rosuvastatin	
	Empagliflozin	Saxagliptin	
	Erythromycin	Sirolimus	
	Everolimus	Sitagliptin	
	Fexofenadine	Sulfasalazine	
	Fluvastatin	Talazoparib	
	Gefitinib	Tenofovir	
	Glyburide	Topotecan	
	Imatinib	Verapamil	
	Indinavir		
	Lapatinib		
	Loperamide		
	Maraviroc		

References:

Reyvow Prescribing Information, Oct. 2019, Eli Lilly and Company.
Lee CA, O'Connor MA, Ritchie TK, et al., Breast Cancer Resistance Protein (ABCG2) in Clinical Pharmacokinetics and Drug Interactions: Practical Recommendations for Clinical Victim and Perpetrator Drug-Drug Interaction Study Design. Drug Metab Dispos. 2015 Apr;43(4):490-509. doi:10.1124/dmd.114.062174.

43. Lasmiditan / Heart Rate Lowering Drugs _____ _____

Alert Message: Caution should be exercised when Reyvow (lasmiditan) is co-administered with drugs that lowering heart rate, due to the risk of decreased heart rate. In clinical trials, lasmiditan use was associated with a mean decrease in heart rate of 5 to 10 beats per minute (bpm).

Drugs/Diseases

Util A	Util B		Util C
Lasmiditan	Amiodarone	Flecainide	
	Beta Blockers	Galantamine	
	Brigatinib	Ivabradine	
	Carbamazepine	Lacosamide	
	CCBs	Lanreotide	
	Ceritinib	Lithium	
	Clonidine	Mexiletine	
	Crizotinib	Pasireotide	
	Digoxin	Procainamide	
	Disopyramide	Propafenone	
	Donepezil	Quinidine	
	Dronedarone	Rivastigmine	
	Fingolimod	Siponimod	
		Thalidomide	

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Reyvow Prescribing Information, Oct. 2019, Eli Lilly and Company.

44. Dimethyl Fumarate / Overuse _____ _____

Alert Message: Tecfidera (dimethyl fumarate) may be over-utilized. The recommended maintenance dose after 7 days of initial treatment is 240 mg twice a day orally.

Drugs/Diseases

Util A	Util B	Util C
Dimethyl Fumarate		

Max Dose: 480 mg/day

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Tecfidera Prescribing Information, Feb. 2020, Biogen.

45. Dimethyl Fumarate / Therapeutic Appropriateness _____ _____

Alert Message: The safety and effectiveness of Tecfidera (dimethyl fumarate) in pediatric patients have not been established.

Drugs/Diseases

Util A	Util B	Util C
Dimethyl Fumarate		

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Tecfidera Prescribing Information, Feb. 2020, Biogen.

46. Dimethyl Fumarate / Pregnancy / Pregnancy Negating _____ _____

Alert Message: There are no adequate data on the developmental risk associated with the use of Tecfidera (dimethyl fumarate) in pregnant women. Dimethyl fumarate may cause fetal harm. In animals, 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 **(Negating)**
Dimethyl Fumarate	Pregnancy	Abortion
		Delivery
		Miscarriage

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Tecfidera Prescribing Information, Feb. 2020, Biogen.

47. Dimethyl Fumarate / Lactation _____ _____

Alert Message: There are no data on the presence of Tecfidera (dimethyl fumarate) or its active metabolite monomethyl fumarate (MMF) in human milk. The effects on the breastfed infant and on milk production are unknown. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for dimethyl fumarate and any potential adverse effects on the breastfed infant from the drug or from the underlying maternal condition.

Drugs/Diseases

Util A	Util B	Util C
Dimethyl Fumarate	Lactation	

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Tecfidera Prescribing Information, Feb. 2020, Biogen.

48. Dimethyl Fumarate / Progressive Multifocal Leukoencephalopathy _____ _____

Alert Message: Progressive multifocal leukoencephalopathy (PML) has occurred in patients with MS treated with Tecfidera (dimethyl fumarate). At the first sign or symptom suggestive of PML, withhold dimethyl fumarate and perform an appropriate diagnostic evaluation.

Drugs/Diseases

Util A	Util B	Util C
Dimethyl Fumarate	Visual Disturbances	
	Muscle Weakness	
	Disorientation	
	Altered Mental Status	

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Tecfidera Prescribing Information, Feb. 2020, Biogen.

49. Dimethyl Fumarate / Flushing / Aspirin _____ _____

Alert Message: Tecfidera (dimethyl fumarate) may cause flushing (e.g., warmth, redness, itching, and/or burning sensation). Administration of dimethyl fumarate with food may reduce the incidence of flushing. Alternatively, 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 **(Negating)**
Dimethyl Fumarate	Flushing	Aspirin

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Tecfidera Prescribing Information, Feb. 2020, Biogen.

50. Dimethyl Fumarate / Serious Opportunistic Infections _____ _____

Alert Message: Serious opportunistic infections have occurred with Tecfidera (dimethyl 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
Dimethyl Fumarate	Herpes	
	West Nile Virus	
	Cytomegalovirus	
	Candida	
	Aspergillus	
	Nocardia	
	Listeria monocytogenes	
	Mycobacterium Tuberculosis	

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Tecfidera Prescribing Information, Feb. 2020, Biogen.

51. Tenapanor / Overuse _____ _____

Alert Message: The recommended maximum daily dose of Ibsrela (tenapanor) is 50 mg twice daily.

Drugs/Diseases

Util A	Util B	Util C
Tenapanor		

Max Dose: 100 mg/day

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Ibsrela Prescribing Information, Sept. 2019, Ardelyx, Inc.

52. Tenapanor / Gastrointestinal Obstruction _____ _____

Alert Message: Ibsrela (tenapanor) is contraindicated in patients with known or suspected mechanical gastrointestinal obstruction.

Drugs/Diseases

Util A	Util B	Util C
Tenapanor	Gastrointestinal Obstruction	
	Impaction of Intestine	
	Paralytic Ileus	

References:

Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Ibsrela Prescribing Information, Sept. 2019, Ardelyx, Inc.

53. Tenapanor / Therapeutic Appropriateness (Black Box) _____ _____

Alert Message: Ibsrela (tenapanor) is contraindicated in patients less than 6 years of age. The use of tenapanor should be avoided in patients 6 years to less than 12 years of age. In young juvenile rats (less than 1 week old; approximate human age equivalent to less than 2 years of age), decreased body weight and deaths occurred, presumed to be due to dehydration, following oral administration of tenapanor. There are no data available in older juvenile rats (human age equivalent 2 years to less than 12 years). The safety and effectiveness of tenapanor in patients less than 18 years of age have not been established.

Drugs/Diseases

Util A	Util B	Util C
Tenapanor		

Age Range: 0 – 5 yoa

References:

Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Ibsrela Prescribing Information, Sept. 2019, Ardelyx, Inc.

54. Tenapanor / Therapeutic Appropriateness (Black Box) _____ _____

Alert Message: The safety and effectiveness of Ibsrela (tenapanor) in patients less than 18 years of age have not been established. In young juvenile rats (less than 1 week old; approximate human age equivalent of less than 2 years of age), decreased body weight and deaths occurred, presumed to be due to dehydration, following oral administration of tenapanor. There are no data available in older juvenile rats (human age equivalent 2 years to less than 12 years). The use of tenapanor should be avoided in patients 6 years to less than 12 years of age. Tenapanor is contraindicated in patients less than 6 years of age.

Drugs/Diseases

Util A	Util B	Util C
Tenapanor		

Age Range: 6 – 17 yoa

References:

Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Ibsrela Prescribing Information, Sept. 2019, Ardelyx, Inc.

55. Tenapanor / Diarrhea _____ _____

Alert Message: Ibsrela (tenapanor) has been shown to cause severe diarrhea. Diarrhea was the most common adverse reaction in two randomized, double-blind, placebo-controlled trials of IBS-C. Severe diarrhea was reported in 2.5% of tenapanor-treated patients. If severe diarrhea occurs, suspend tenapanor dosing and rehydrate the patient.

Drugs/Diseases

Util A	Util B	Util C
Tenapanor	Diarrhea	

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Ibsrela Prescribing Information, Sept. 2019, Ardelyx, Inc.

56. Odactra / Overutilization _____ _____

Alert Message: The recommended daily dose of Odactra (dust mite allergen extract) in adults, 18 through 65 years of age, is one tablet sublingually once daily.

Drugs/Diseases

Util A	Util B	Util C
Odactra		

Max Dose: 1 tablet daily

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Odactra Prescribing Information, April 2017, Merck Sharp & Dohme Corp.

57. Odactra / Contraindications _____ _____

Alert Message: Odactra (dust mite allergen extract) is contraindicated in patients with severe, unstable or uncontrolled asthma, a history of severe allergic reactions, a history of any severe local reaction after taking any sublingual allergen immunotherapy, and a history of eosinophilic esophagitis.

Drugs/Diseases

Util A	Util B	Util C
Odactra	Severe Persistent Asthma	
	Eosinophilic Esophagitis	

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Odactra Prescribing Information, April 2017, Merck Sharp & Dohme Corp.

58. Odactra / Therapeutic Appropriateness _____ _____

Alert Message: The safety and effectiveness of Odactra (dust mite allergen extract) have not been established in patients younger than 18 years of age.

Drugs/Diseases

Util A	Util B	Util C
Odactra		

Age Range: ≤ 18 yoa

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Odactra Prescribing Information, April 2017, Merck Sharp & Dohme Corp.

59. Odactra / Therapeutic Appropriateness _____ _____

Alert Message: The safety and effectiveness of Odactra (dust mite allergen extract) have not been established in patients older than 65 years of age.

Drugs/Diseases

Util A	Util B	Util C
Odactra		

Age Range: > 65 yoa

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Odactra Prescribing Information, April 2017, Merck Sharp & Dohme Corp.

60. Odactra / Oral Wounds or Oral Inflammation _____ _____

Alert Message: Discontinue treatment with Odactra (dust mite allergen extract) to allow for complete healing of the oral cavity in patients with oral inflammation (e.g., oral lichen planus, mouth ulcers, or thrush) or oral wounds, such as those following oral surgery or dental extraction.

Drugs/Diseases

Util A	Util B	Util C
Odactra	Lesions of oral mucosa	
	Candidal Stomatitis	
	Oral Mucositis	
	Encounter for surgical aftercare following surgery on teeth or oral cavity	

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Odactra Prescribing Information, April 2017, Merck Sharp & Dohme Corp.

61. Odactra / Therapeutic Appropriateness _____ _____

Alert Message: A review of the patient's prescription history does not reveal a current prescription for auto-injectable epinephrine. Odactra (dust mite allergen extract) can cause systemic allergic reactions, including anaphylaxis, which may be life-threatening. Patients should be informed of the signs and symptoms of anaphylaxis and prescribed an epinephrine auto-injector along with training on how and when to use it.

Drugs/Diseases

Util A	Util B	Util C **(Negating)**
Odactra		Epinephrine Injection

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Odactra Prescribing Information, April 2017, Merck Sharp & Dohme Corp.

62. Nuedexta / Pregnancy / Pregnancy Negating _____ _____

Alert Message: Based on animal data, Nuedexta (dextromethorphan/quinidine) may cause fetal harm. There are no adequate data on the developmental risk associated with the use of dextromethorphan/quinidine in pregnant women. In oral studies conducted in rats and rabbits, a combination of dextromethorphan/quinidine demonstrated developmental toxicity, including teratogenicity (rabbits) and embryolethality, when given to pregnant animals.

Drugs/Diseases

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

Age Range: 11 – 50 yoa
Gender: Female

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Nuedexta Prescribing Information, June 2019, Avanir Pharmaceuticals, Inc.

63. Nuedexta / Lactation _____ _____

Alert Message: The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Nuedexta (dextromethorphan/quinidine) and any potential adverse effects on the breastfed infant from dextromethorphan/quinidine or from the underlying maternal condition. Quinidine is excreted in human milk. It is not known whether dextromethorphan is excreted in human milk. There are no data on the effects of quinidine or dextromethorphan on the breastfed infant or the effects on milk production.

Drugs/Diseases

Util A	Util B	Util C
Dextromethorphan/quinidine	Lactation	

Age Range: 11 – 50 yoa
Gender: Female

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Nuedexta Prescribing Information, June 2019, Avanir Pharmaceuticals, Inc.

64. Sonidegib / Pregnancy / Pregnancy Negating _____ _____

Alert Message: Based on its mechanism of action and data from animal reproduction studies, Odomzo (sonidegib) can cause fetal harm when administered to a pregnant woman. There are no available data on the use of sonidegib in pregnant women. In animal reproduction studies, sonidegib was embryotoxic, fetotoxic, and teratogenic at maternal exposures below the recommended dose of 200 mg. Teratogenic effects observed included severe midline defects, missing digits, and other irreversible malformations. Advise pregnant women of the potential risk to a fetus.

Drugs/Diseases

Util A	Util B	Util C **(Negating)**
Sonidegib	Pregnancy	Abortion
		Delivery
		Miscarriage

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Odomzo Prescribing Information, May 2019, Sun Pharmaceutical Industries, Inc.

65. Sonidegib / Lactation _____ _____

Alert Message: No information is available on the presence of Odomzo (sonidegib) in human milk, the effects of the drug on the breastfed infant, or the effects of the drug on milk production. Because of the potential for serious adverse reactions in breastfed infants from sonidegib, advise a nursing woman not to breastfeed during treatment with sonidegib and for 20 months after the last dose.

Drugs/Diseases

Util A	Util B	Util C
Sonidegib	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Odomzo Prescribing Information, May 2019, Sun Pharmaceutical Industries, Inc.

66. Sonidegib / Females of Reproductive Potential _____ _____

Alert Message: Verify pregnancy status of females of reproductive potential prior to initiating Odomzo (sonidegib) treatment. Advise pregnant women of the potential risk to a fetus. Advise females to use effective contraception during treatment with sonidegib and for at least 20 months after the last dose.

Drugs/Diseases

Util A	Util B	Util C **(Negating)**
Sonidegib		Contraceptives

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Odomzo Prescribing Information, May 2019, Sun Pharmaceutical Industries, Inc.

67. Sonidegib / Males _____ _____

Alert Message: Advise male patients with female partners with reproductive potential to use condoms, even after a vasectomy, during treatment with Odomzo (sonidegib) and for at least 8 months after the last dose to avoid potential drug exposure in pregnant females or females of reproductive potential.

Drugs/Diseases

Util A	Util B	Util C
Sonidegib		

Gender: Male

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Odomzo Prescribing Information, May 2019, Sun Pharmaceutical Industries, Inc.

68. Sonidegib / Therapeutic Appropriateness _____ _____

Alert Message: The safety and effectiveness of Odomzo (sonidegib) have not been established in pediatric patients. Epiphyseal disorders, including premature fusion of the epiphyses, have been reported in pediatric patients exposed to sonidegib in a clinical trial. In some cases, pediatric patients treated with other Hh pathway inhibitors have experienced progression of epiphyseal fusion despite discontinuation of the Hh pathway inhibitor.

Drugs/Diseases
Util A Util B Util C
Sonidegib

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Odomzo Prescribing Information, May 2019, Sun Pharmaceutical Industries, Inc.

69. Sonidegib / Therapeutic Appropriateness _____ _____ _____

Alert Message: The recommended dosage of Odomzo (sonidegib) is 200 mg taken orally once daily on an empty stomach, at least 1 hour before or 2 hours after a meal, administered until disease progression or unacceptable toxicity.

Drugs/Diseases
Util A Util B Util C
Sonidegib

Max Dose: 200 mg/day

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Odomzo Prescribing Information, May 2019, Sun Pharmaceutical Industries, Inc.

70. Sonidegib / Nonadherence _____ _____

Alert Message: Based on the refill history, your patient may be under-utilizing Odomzo (sonidegib). 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
Sonidegib

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Odomzo Prescribing Information, May 2019, Sun Pharmaceutical Industries, Inc.
Greer JA, Amoyal N, Nisotel L, et al. Systemic Review of Adherence to Oral Antineoplastic Therapies. The Oncologist. 2016;21:354-376.
Osterberg L, Blaschke T. Adherence to Medication. N Engl J Med 2005; 353:487- 497.

71. Darolutamide / Overutilization _____ _____

Alert Message: Nubeqa (darolutamide) may be over-utilized. The recommended dose of darolutamide is 600 mg (two 300 mg film-coated tablets) taken orally, twice daily, equivalent to a total daily dose of 1200 mg. Patients receiving darolutamide should also receive a gonadotropin-releasing hormone (GnRH) analog concurrently or should have had a bilateral orchiectomy.

Drugs/Diseases

Util A	Util B	Util C **(Negating)**
Darolutamide		CKD 4, 5, & ESRD
		Hepatic Impairment

Max Dose: 1200 mg/day

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Nubeqa Prescribing Information, August 2019, Bayer Healthcare Pharma.

72. Darolutamide / Overutilization – Renal Impairment _____ _____

Alert Message: For patients with severe renal impairment (eGFR 15–29 mL/min/1.73 m2) not receiving hemodialysis, the recommended dose of Nubeqa (darolutamide) is 300 mg twice daily. No dose reduction is needed for patients with mild or moderate renal impairment (eGFR 30-89 mL/min/1.73 m2). The effect of end-stage renal disease (eGFR ≤15 mL/min/1.73 m2) on darolutamide pharmacokinetics is unknown.

Drugs/Diseases

Util A	Util B	Util C **(Include)**
Darolutamide		CKD 4, 5, & ESRD

Max Dose: 600 mg/day

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Nubeqa Prescribing Information, August 2019, Bayer Healthcare Pharma.

73. Darolutamide / Overutilization – Hepatic Impairment _____ _____

Alert Message: For patients with moderate hepatic impairment (Child-Pugh Class B), the recommended dose of Nubeqa (darolutamide) is 300 mg twice daily. Darolutamide undergoes hepatic metabolism, and moderate hepatic impairment will result in higher exposure to darolutamide. No dose reduction is needed for patients with mild hepatic impairment. The effect of severe hepatic impairment (Child-Pugh C) on darolutamide pharmacokinetics is unknown.

Drugs/Diseases

Util A	Util B	Util C **(Include)**
Darolutamide		Hepatic Impairment

Max Dose: 600 mg/day

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Nubeqa Prescribing Information, August 2019, Bayer Healthcare Pharma.

74. Darolutamide / Embryo-Fetal Toxicity _____ _____

Alert Message: Based on the mechanism of action, advise male patients with female partners of reproductive potential to use effective contraception during treatment and for 1 week after the last dose of Nubeqa (darolutamide).

Drugs/Diseases

Util A	Util B	Util C
Darolutamide		

Gender: Male

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Nubeqa Prescribing Information, August 2019, Bayer Healthcare Pharma.

75. Darolutamide / Therapeutic Appropriateness (0 - 17 yoa) _____ _____

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

Drugs/Diseases

Util A	Util B	Util C
Darolutamide		

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Nubeqa Prescribing Information, August 2019, Bayer Healthcare Pharma.

76. Darolutamide / Combined P-gp and Strong or Moderate 3A4 Inducers _____ _____

Alert Message: Concomitant use of Nubeqa (darolutamide), a P-gp and CYP3A4 substrate, with a combined P-gp and strong or moderate CYP3A4 inducer decreases darolutamide exposure, which may decrease darolutamide activity. Avoid concomitant use of darolutamide with combined P-gp and strong or moderate CYP3A4 inducers.

Drugs/Diseases

Util A	Util B	Util C
Darolutamide	Apalutamide	
	Carbamazepine	
	Lumacaftor	
	Phenobarbital	
	Phenytoin	
	Primidone	
	Rifampin	

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Nubeqa Prescribing Information, August 2019, Bayer Healthcare Pharma.

77. Darolutamide / Combined P-gp and Strong or Moderate 3A4 Inhibitors _____ _____

Alert Message: Concomitant use of Nubeqa (darolutamide), a P-gp and CYP3A4 substrate, with a combined P-gp and strong or moderate CYP3A4 inhibitor increases darolutamide exposure, which may increase the risk of darolutamide-related adverse reactions. Monitor patients more frequently for darolutamide adverse reactions and modify darolutamide dosage as needed.

Drugs/Diseases

Util A	Util B	Util C
Darolutamide	Clarithromycin	
	Cobicistat	
	Ritonavir	
	Nelfinavir	
	Saquinavir	
	Itraconazole	
	Ketoconazole	
	Posaconazole	
	Mifepristone	

References:

Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Nubeqa Prescribing Information, August 2019, Bayer Healthcare Pharma.

78. Darolutamide / BCRP Substrates _____ _____

Alert Message: Nubeqa (darolutamide) is an inhibitor of BCRP transporter. Concomitant use of darolutamide increases the AUC and Cmax of BCRP substrates, which may increase the risk of BCRP substrate-related toxicities. Avoid concomitant use of a darolutamide with drugs that are BCRP substrates where possible. If used together, monitor patients more frequently for adverse reactions, and consider a dose reduction of the BCRP substrate drug. Consult the approved product labeling of the BCRP substrate when used concomitantly with darolutamide.

Drugs/Diseases

Util A	Util B	Util C
Darolutamide	Alpelisib	
	Dasabuvir/Ombitasvir/Paritaprevir/Ritonavir	
	Dolutegravir	
	Dantrolene	
	Methotrexate	
	Pazopanib	
	Pibrentasvir	
	Prazosin	
	Rosuvastatin	
	Talazoparib	
	Tenofovir	
	Sulfasalazine	

References:

Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Nubeqa Prescribing Information, August 2019, Bayer Healthcare Pharma.
FDA: Drug Development and Drug Interactions: Tables of Substrates, Inhibitors and Inducers. Available at: http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/Drug\InteractionaLabeling/ucm093664.htm

79. Darolutamide / Nonadherence _____ _____

Alert Message: Based on refill history, your patient may be under-utilizing Nubeqa (darolutamide). Non-adherence 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
Darolutamide		

References:

Osterberg L, Blaschke T. Adherence to Medication. N Engl J Med 2005; 353:487- 497.
Paolella GA, Boyd AD, Wirth SM, Cuellar S, Venepalli NK, Crawford SY. Adherence to Oral Anticancer Medications: Evolving Interprofessional Roles and Pharmacist Workforce Considerations. *Pharmacy (Basel)*. 2018;6(1):23. Published 2018 Mar 8. doi:10.3390/pharmacy6010023.
Greer JA, Amoyal N, Nisotel L, Fishbein JN, et al., A Systematic Review of Adherence to Oral Antineoplastic Therapies. The Oncologist. 2016;21:354–376.

80. Amifampridine / Overutilization _____ _____

Alert Message: Ruzurgi (amifampridine) may be over-utilized. The recommended maximum total daily dosage of amifampridine in pediatric patients 6 to less than 17 years of age weighing 45 kg or more is 100 mg. The recommended maximum total daily dosage of amifampridine in pediatric patients 6 to less than 17 years of age weighing less than 45 kg is 50 mg.

Drugs/Diseases

Util A	Util B	Util C
Amifampridine		

Max Dose: 100 mg/day
Age Range: 6 – 16 yoa

References:

Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Ruzurgi Prescribing Information, May 2019, Jacobus Pharmaceutical Company, Inc.

81. Amifampridine / History of Seizures _____ _____

Alert Message: Ruzurgi (amifampridine) is contraindicated in patients with a history of seizures. Seizures have been observed in patients with and without a history of seizures taking amifampridine at the recommended doses, and at various times after initiation of treatment. Many of the patients were taking medications or had comorbid medical conditions that may have lowered the seizure threshold. Seizures may be dose-dependent. Consider discontinuation or dose-reduction of amifampridine in patients who have a seizure while on treatment.

Drugs/Diseases

Util A	Util B	Util C **(Include)**
Amifampridine		Seizures
		Convulsions

References:

Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Ruzurgi Prescribing Information, May 2019, Jacobus Pharmaceutical Company, Inc.

82. Amifampridine / Cholinergic Drugs _____ _____

Alert Message: The concomitant use of Ruzurgi (amifampridine) and drugs with cholinergic effects (e.g., direct or indirect cholinesterase inhibitors) may increase the risk of adverse reactions due to additive cholinergic effects.

Drugs/Diseases

Util A	Util B	Util C
Amifampridine	Donepezil	
	Galantamine	
	Pyridostigmine	
	Rivastigmine	

References:

Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Ruzurgi Prescribing Information, May 2019, Jacobus Pharmaceutical Company, Inc.

83. Amifampridine / Drugs that Lower Seizure Threshold _____ _____

Alert Message: The concomitant use of Ruzurgi (amifampridine) with drugs that lower seizure threshold may lead to an increased risk of seizures. The decision to administer amifampridine concomitantly with drugs that lower the seizure threshold should be carefully considered in light of the severity of the associated risks.

Drugs/Diseases

Util A	Util B	Util C
Amifampridine	1st Generation Antipsychotics	
	Aripiprazole	
	Asenapine	
	Baclofen	
	Bupropion	
	Clozapine	
	Diphenhydramine	
	Olanzapine	
	Paliperidone	
	Quetiapine	
	Quinolones	
	SNRIs	
	SSRIs	
	Steroids	
	Stimulants	
	Tacrolimus	
	TCAs	
	Tramadol	
	Ziprasidone	

References:

Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Ruzurgi Prescribing Information, May 2019, Jacobus Pharmaceutical Company, Inc.

84. Amifampridine / Pregnancy / Pregnancy Negating _____ _____

Alert Message: There are no data on the developmental risk associated with the use of Ruzurgi (amifampridine) in pregnant women. In animal studies, administration of amifampridine phosphate to rats during pregnancy and lactation resulted in developmental toxicity (increase in stillbirths and pup deaths, reduced pup weight, and delayed sexual development) at doses associated with maternal plasma drug levels lower than therapeutic drug levels.

Drugs/Diseases

Util A	Util B	Util C **(Negating)**
Amifampridine	Pregnancy	Abortion
		Delivery
		Miscarriage

Age Range: 11 – 50 yoa
Gender: Female

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Ruzurgi Prescribing Information, May 2019, Jacobus Pharmaceutical Company, Inc.

85. Amifampridine / Lactation _____ _____

Alert Message: There are no data on the presence of Ruzurgi (amifampridine) in human milk, the effects on the breastfed infant, or the effects on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for amifampridine and any potential adverse effects on the breastfed infant from amifampridine or the underlying maternal condition. In lactating rats, amifampridine was excreted in milk and reached levels similar to those in maternal plasma.

Drugs/Diseases

Util A	Util B	Util C
Amifampridine	Lactation	

Age Range: 11 – 50 yoa
Gender: Female

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Ruzurgi Prescribing Information, May 2019, Jacobus Pharmaceutical Company, Inc.

86. Amifampridine / Therapeutic Appropriateness _____ _____

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

Drugs/Diseases

Util A	Util B	Util C
Amifampridine		

Age Range: 0 – 5 yoa

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Ruzurgi Prescribing Information, May 2019, Jacobus Pharmaceutical Company, Inc.

87. Amifampridine / Nonadherence _____ _____

Alert Message: Based on the refill history, your patient may be underutilizing Ruzurgi (amifampridine). 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
Amifampridine		

References:

Osterberg L, Blaschke T. Adherence to Medication. N Engl J Med 2005; 353:487- 497.
Marcum ZA, Sevick MA, Handler SM. Medication Nonadherence: A Diagnosable and Treatable Medical Condition. *JAMA*. 2013;309(20):2105–2106. doi:10.1001/jama.2013.4638.
Kleinsinger F. The Unmet Challenge of Medication Nonadherence. Perm J. 2018;22:18–033. doi:10.7812/TPP/18-033.

88. Venlafaxine ER / Renal Impairment _____ _____ _____

Alert Message: The total daily dose of venlafaxine extended release (ER) should be reduced by 25% to 50% in patients with mild (CLcr = 60–89 mL/min) or moderate (CLcr = 30–59 mL/min) renal impairment. In patients undergoing hemodialysis or with severe renal impairment (CLcr < 30 mL/min), the total daily dose of venlafaxine ER should be reduced by 50% or more. Because there was much individual variability in clearance between patients with renal impairment, individualization of dosage may be desirable in some patients.

Drugs/Diseases

Util A	Util B	Util C **(Include)**
Venlafaxine ER		Renal Impairment

References:

Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Facts & Comparisons, 2019, Wolters Kluwer Health.

89. Nintedanib / Overutilization _____ _____

Alert Message: The manufacturer's recommended daily dose of Ofev (nintedanib) 150 mg twice daily, approximately 12 hours apart taken with food.

Drugs/Diseases

Util A	Util B	Util C **(Negating)**
Nintedanib		Hepatic Impairment

Max Dose: 300 mg/day

References:

Ofev Prescribing Information, Sept. 2019, Boehringer Ingelheim Pharmaceuticals, Inc.
Clinical Pharmacology, 2020 Elsevier/Gold Standard.

90. Nintedanib / Overutilization – Hepatic Impairment _____ _____

Alert Message: The manufacturer's recommended daily dose of Ofev (nintedanib) in patients with mild hepatic impairment (Child-Pugh A) is 100 mg twice daily, approximately 12 hours apart taken with food. Monitor the patient for adverse reactions and consider treatment interruption or discontinuation for the management of adverse reactions. Treatment of patients with moderate (Child-Pugh B) and severe (Child-Pugh C) hepatic impairment with nintedanib is not recommended.

Drugs/Diseases

Util A	Util B	Util C **(Include)**
Nintedanib		Hepatic Impairment

Max Dose: 200 mg/day

References:
Ofev Prescribing Information, Sept. 2019, Boehringer Ingelheim Pharmaceuticals, Inc.
Clinical Pharmacology, 2020 Elsevier/Gold Standard.

91. Nintedanib / Gastrointestinal Disorders _____ _____

Alert Message: Ofev (nintedanib) therapy can result in gastrointestinal disorders (i.e., diarrhea, nausea, and vomiting), which may become severe. Treat patients at first signs with adequate hydration and antidiarrheal medicine or antiemetics. Discontinue nintedanib if severe diarrhea, nausea or vomiting persists despite symptomatic treatment.

Drugs/Diseases

Util A	Util B	Util C
Nintedanib		

References:
Ofev Prescribing Information, Sept. 2019, Boehringer Ingelheim Pharmaceuticals, Inc.
Clinical Pharmacology, 2020 Elsevier/Gold Standard.

92. Nintedanib / Pregnancy / Pregnancy Negating _____ _____

Alert Message: Ofev (nintedanib) can cause fetal harm when administered to a pregnant woman. Women of childbearing potential should be advised to avoid becoming pregnant while receiving nintedanib treatment. These patients should use highly effective contraception during treatment and for at least 3 months after the last dose of nintedanib.

Drugs/Diseases

Util A	Util B	Util C **(Negating)**
Nintedanib	Pregnancy	Abortion
		Delivery
		Miscarriage

Age Rage: 11 – 50 yoa
Gender: Female

References:
Ofev Prescribing Information, Sept. 2019, Boehringer Ingelheim Pharmaceuticals, Inc.
Clinical Pharmacology, 2020 Elsevier/Gold Standard.

93. Nintedanib / Lactation _____ _____

Alert Message: There is no information on the presence of Ofev (nintedanib) in human milk, the effects on the breast-fed infant, or the effects on milk production. Nintedanib and its metabolites are present in the milk of lactating rats. Because of the potential for serious nintedanib-related adverse reactions in nursing infants, advise women that breastfeeding is not recommended during treatment with nintedanib.

Drugs/Diseases

Util A	Util B	Util C
Nintedanib	Lactation	

Age Rage: 11 – 50 yoa
Gender: Female

References:
Ofev Prescribing Information, Sept. 2019, Boehringer Ingelheim Pharmaceuticals, Inc.
Clinical Pharmacology, 2020 Elsevier/Gold Standard.

94. Nintedanib / Arterial Thromboembolic Events _____ _____

Alert Message: Arterial thromboembolic events, including myocardial infarction, have been reported in patients treated with Ofev (nintedanib). Use caution when treating patients with a higher cardiovascular risk, including coronary artery disease.

Drugs/Diseases

Util A	Util B	Util C **(Include)**
Nintedanib		Coronary Atherosclerosis
		Ischemic Heart Disease

References:
Ofev Prescribing Information, Sept. 2019, Boehringer Ingelheim Pharmaceuticals, Inc.
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Kamba T and McDonald DM. Mechanism of Adverse Effects of Anti-VEGF Therapy for Cancer. Br Jrnl Can. 2017(96);1788-1795.

95. Nintedanib / Anticoagulants - Increased Risk of Bleeding _____ _____

Alert Message: Concurrent use of Ofev (nintedanib) with an anticoagulant agent may increase the risk of bleeding. Carefully monitor patients who are receiving nintedanib with anticoagulant therapy and adjust anticoagulation treatment as necessary.

Drugs/Diseases

Util A	Util B	Util C
Nintedanib	Apixaban	
	Dabigatran	
	Dalteparin	
	Enoxaparin	
	Fondaparinux	
	Heparin	
	Rivaroxaban	
	Warfarin	

References:
Ofev Prescribing Information, Sept. 2019, Boehringer Ingelheim Pharmaceuticals, Inc.
Clinical Pharmacology, 2020 Elsevier/Gold Standard.

96. Nintedanib / Gastrointestinal Perforation _____ _____

Alert Message: Serious gastrointestinal (GI) perforation events have been reported with Ofev (nintedanib), some of which were fatal. Nintedanib therapy should be discontinued if GI perforation develops. Advise patients to report signs and symptoms of gastrointestinal perforation. Only use nintedanib in patients with a known risk of gastrointestinal perforation if the anticipated benefit outweighs the potential risk.

Drugs/Diseases

Util A	Util B	Util C
Nintedanib	Gastrointestinal Perforation	

References:
Ofev Prescribing Information, Sept. 2019, Boehringer Ingelheim Pharmaceuticals, Inc.
Clinical Pharmacology, 2020 Elsevier/Gold Standard.

97. Nintedanib / Diverticular Disease _____ _____

Alert Message: Serious gastrointestinal (GI) perforation events have been reported with Ofev (nintedanib), some of which were fatal. Use caution when treating patients who have had recent abdominal surgery, previous history of diverticular disease or receiving concomitant corticosteroids or NSAIDs. Nintedanib therapy should be discontinued if GI perforation develops. Only use nintedanib in patients with a known risk of gastrointestinal perforation if the anticipated benefit outweighs the potential risk.

Drugs/Diseases

Util A	Util B	Util C **(Include)**
Nintedanib		Diverticular Disease

References:
Ofev Prescribing Information, Sept. 2019, Boehringer Ingelheim Pharmaceuticals, Inc.
Clinical Pharmacology, 2020 Elsevier/Gold Standard.

98. Nintedanib / NSAIDS & Corticosteroids _____ _____

Alert Message: Serious gastrointestinal (GI) perforation events have been reported with Ofev (nintedanib), some of which were fatal. Use caution when treating patients who have had recent abdominal surgery, previous history of diverticular disease or receiving concomitant corticosteroids or NSAIDs. Nintedanib therapy should be discontinued if GI perforation develops. Only use nintedanib in patients with a known risk of gastrointestinal perforation if the anticipated benefit outweighs the potential risk.

Drugs/Diseases

Util A	Util B	Util C
Nintedanib	NSAIDS Corticosteroids	

References:
Ofev Prescribing Information, Sept. 2019, Boehringer Ingelheim Pharmaceuticals, Inc.
Clinical Pharmacology, 2020 Elsevier/Gold Standard.

99. Nintedanib / P-gp & CYP3A4 Inhibitors _____ _____

Alert Message: Concurrent use of Ofev (nintedanib) with a P-gp and CYP3A4 inhibitor may result in increased exposure to nintedanib and risk of adverse effects. If co-administration is necessary, patients should be monitored closely for tolerability of nintedanib. Management of adverse reactions may require interruption, dose reduction, or discontinuation of nintedanib therapy.

Drugs/Diseases

Util A	Util B		Util C
Nintedanib	Amiodarone	Itraconazole	Ritonavir
	Ciprofloxacin	Ivacaftor	Saquinavir
	Clarithromycin	Ketoconazole	Ticagrelor
	Cobicistat	Lapatinib	Tipranavir
	Cyclosporine	Mifepristone	Verapamil
	Dronedarone	Nelfinavir	
	Erythromycin	Posaconazole	
	Fostamatinib	Ranolazine	

References:
Ofev Prescribing Information, Sept. 2019, Boehringer Ingelheim Pharmaceuticals, Inc.
Clinical Pharmacology, 2020 Elsevier/Gold Standard.

100. Nintedanib / P-gp & CYP3A4 Inducers _____ _____

Alert Message: Concurrent use of Ofev (nintedanib) with a P-gp and CYP3A4 inducer should be avoided. Coadministration of these agents may result in decreased exposure to nintedanib and loss of efficacy.

Drugs/Diseases

Util A	Util B	Util C
Nintedanib	Apalutamide	
	Carbamazepine	
	Fosphenytoin	
	Phenobarbital	
	Phenytoin	
	Primidone	
	Rifampin	

References:
Ofev Prescribing Information, Sept. 2019, Boehringer Ingelheim Pharmaceuticals, Inc.
Clinical Pharmacology, 2020 Elsevier/Gold Standard.

101. Nintedanib / Nicotine Dependence, Cigarettes _____ _____

Alert Message: A review of the diagnostic history reveals that the patient may smoke. Smoking has been shown to decrease the exposure to Ofev (nintedanib), which may alter the efficacy profile of nintedanib. Encourage patients to stop smoking prior to treatment with nintedanib and to avoid smoking when using nintedanib. Smoking has been associated with decreased exposure to nintedanib.

Drugs/Diseases

Util A	Util B	Util C
Nintedanib	Nicotine Dependence, Cigarettes	

References:
Ofev Prescribing Information, Sept. 2019, Boehringer Ingelheim Pharmaceuticals, Inc.
Clinical Pharmacology, 2020 Elsevier/Gold Standard.

102. Nintedanib / Therapeutic Appropriateness < 18 yoa _____ _____

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

Drugs/Diseases

Util A	Util B	Util C
Nintedanib		

Age Range: 0 - 17 yoa

References:

Ofev Prescribing Information, Sept. 2019, Boehringer Ingelheim Pharmaceuticals, Inc.
Clinical Pharmacology, 2020 Elsevier/Gold Standard.

North Dakota Medicaid
Drug Utilization Review Board
Meeting
September 2, 2020
Via Teleconference

North Dakota Medicaid
DUR Board Meeting Agenda
Join Microsoft Teams Meeting

(Click on link)
Join by phone: 1 701-328-0950, Conference ID: 312 304 233#
September 2, 2020
1:00 pm

1. Administrative items
    - DHS announcements

2. Old business
    - Review and approval of June 2020 meeting minutes
    - Budget update
    - Review top 25 drugs for second quarter of 2020
    - Prior authorization/PDL update
    - Second review of Palforzia
    - Second review of Mytesti
    - Second review of antifibrinolytic agents
    - Second review of ACL inhibitors
    - Second review of cystic fibrosis agents

3. New business
    - Retrospective DUR criteria recommendations
    - Review of agents for the treatment of diabetic gastroparesis
    - Review of Ohriahnn (elagolix/estradiol/norethindrone)
    - Review of Dojolvi (triheptanoin)
    - Review of utilization data for select medication classes
    - Upcoming meeting date/agenda.
        - Next meeting is December 2, 2020
4. Adjourn

Please remember to silence all cellular phones during the meeting.

Drug Utilization Review (DUR) Meeting Minutes
June 3, 2020

Members Present: Andrea Honeyman, Tanya Schmidt, Jennifer Iverson, Gabriela Balf, Laura Schield, Jennifer Iverson, Mary Aaland, Peter Woodrow, Amy Werremeyer, Cory Miller

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

Old Business

Chair A. Honeyman called the meeting to order at 1:05 p.m. Chair A. Honeyman asked for a motion to approve the minutes of the March meeting. L. Schield moved that the minutes be approved, and T. Schmidt 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

T. DeRuiter and A. Murphy presented the quarterly review of the top 25 drugs based on total cost od claims, as well as the top 25 drugs based on the total number of claims for the 1st quarter of 2020.

PDL/PA Criteria Updates

A. Murphy shared with the Board all of changes made to the Preferred Drug List since the most recent version of the Preferred Drug List was posted. Notable changes included updates to the criteria for Hepatitis C Treatments and Insulin, as well as changes to coverage requirements for Xifaxan in the Diarrhea – Irritable Bowel Syndrome and Traveler's Diarrhea criteria. All PDL updates are listed in the handouts for the June 2020 DUR Board meeting. When a new version of the PDL is published and posted to the website, all updates/changes made since the last version are called out at the top of the document itself.

Update to Criteria for Medications Costing >$3,000

A. Murphy presented a proposed update to the prior authorization criteria for medications that cost >$3,000. The update included new renewal criteria which requires documentation indicating that the patient has experienced and maintained a clinical benefit since starting the requested medication. There was no public comment. Chair A. Honeyman called for a voice vote to approve the updated criteria, which passed with no audible dissent.

Second Review of Conjupri

A motion and second was made at the March 2020 DUR Board meeting to place Conjupri on prior authorization. The topic was brought up for a second review. Prior authorization criteria were presented to the Board by T. DeRuiter. There were no public comments. Chair A. Honeyman called for a voice vote to approve the updated criteria, which passed with no audible dissent.

New Business

Review of Cystic Fibrosis Agents

T. DeRuiter and A. Murphy presented a review of CFTR modulators for the treatment of cystic fibrosis to the Board. During public comment, J. Rusinak from Vertex Pharmaceuticals presented an overview of clinical information on the available CFTR modulators to the Board. A motion was made by L. Schield to manage these medications through prior authorization. The motion was seconded by P. Woodrow. Prior authorization criteria for these agents will be presented, reviewed, and voted on by the Board at the next meeting.

Review of ACL Inhibitors

T. DeRuiter and A. Murphy presented a review of ACL inhibitors to the Board. A motion was made by A. Werremeyer to manage these medications through prior authorization. The motion was seconded by P. Woodrow. Prior authorization criteria for these agents will be presented, reviewed, and voted on by the Board at the next meeting.

Review of Antifibrinolytic Agents

T. DeRuiter and A. Murphy presented a review of antifibrinolytic agents to the Board. A motion was made by T. Schmidt to manage these medications through prior authorization. The motion was seconded by P. Woodrow. Prior authorization criteria for these agents will be presented, reviewed, and voted on by the Board at the next meeting.

Review of Palforzia

T. DeRuiter and A. Murphy presented a review of Palforzia for use in patients with a peanut allergy. to the Board. A. Honeyman and M. Aaland inquired as to the recommended duration of use. S. Payne from Aimmune explained the recommendations on treatment duration to the Board. A motion was made by P. Woodrow to manage this medication through prior authorization. The motion was seconded by J. Iverson. Prior authorization criteria will be presented, reviewed, and voted on by the Board 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. L. Schield moved to approve the new criteria and P. Woodrow seconded the motion. The motion passed with no audible dissent.

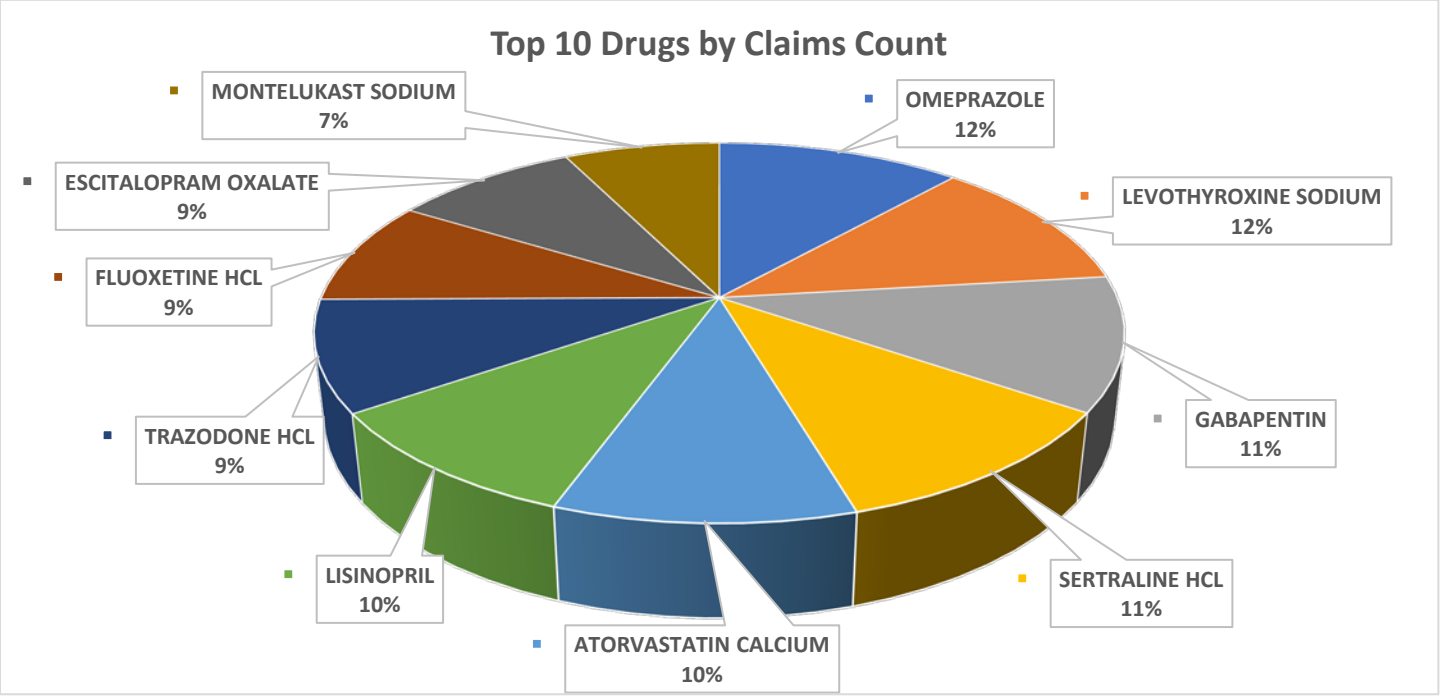
Adjournment and Upcoming Meeting Date

Chair A. Honeyman adjourned the meeting at 2:45 pm. The next DUR Board meeting will be held September 2, 2020 at 1:00 pm with location to be determined.

Top 25 Drugs Based on Number of Claims from 04/01/2020 – 06/30/2020

Drug	AHFS Class	Claims	Claims Cost	Cost Per Claim	% Total Claims
OMEPRAZOLE	PROTON-PUMP INHIBITORS	4,421	$57,716.90	$13.06	1.92%
LEVOTHYROXINE SODIUM	THYROID AGENTS	4,369	$81,280.27	$18.60	1.90%
GABAPENTIN	ANTICONVULSANTS, MISC	4,316	$70,284.45	$16.28	1.87%
SERTRALINE HCL	ANTIDEPRESSANTS	4,141	$55,929.71	$13.51	1.80%
ATORVASTATIN CALCIUM	STATINS	3,856	$54,671.99	$14.18	1.67%
LISINOPRIL	ACE INHIBITORS	3,733	$47,482.79	$12.72	1.62%
TRAZODONE HCL	ANTIDEPRESSANTS	3,587	$49,919.95	$13.92	1.56%
FLUOXETINE HCL	ANTIDEPRESSANTS	3,369	$46,725.57	$13.87	1.46%
ESCITALOPRAM OXALATE	ANTIDEPRESSANTS	3,365	$44,832.14	$13.32	1.46%
MONTELUKAST SODIUM	LEUKOTRIENE MODIFIERS	2,815	$40,149.52	$14.26	1.22%
METFORMIN HCL	BIGUANIDES	2,725	$34,036.58	$12.49	1.18%
BUPROPION XL	ANTIDEPRESSANTS	2,536	$46,535.48	$18.35	1.10%
DULOXETINE HCL	ANTIDEPRESSANTS	2,518	$43,984.52	$17.47	1.09%
HYDROCODONE-APAP	OPIATE AGONISTS	2,500	$40,685.84	$16.27	1.08%
PANTOPRAZOLE SODIUM	PROTON-PUMP INHIBITORS	2,490	$33,985.61	$13.65	1.08%
AMLODIPINE BESYLATE	DIHYDROPYRIDINES	2,285	$28,810.56	$12.61	0.99%
ARIPIPRAZOLE	ANTIPSYCHOTIC AGENTS	2,201	$34,545.56	$15.70	0.96%
CLONIDINE HCL	CENTRAL ALPHA-AGONISTS	2,180	$27,460.74	$12.60	0.95%
BUPRENORPHINE-NALOXONE	OPIATE PARTIAL AGONISTS	2,162	$124,696.96	$57.68	0.94%
VYVANSE	AMPHETAMINES	2,107	$537,697.83	$255.20	0.91%
LAMOTRIGINE	ANTICONVULSANTS, MISC	2,076	$28,404.11	$13.68	0.90%
VENLAFAXINE HCL ER	ANTIDEPRESSANTS	2,010	$33,804.42	$16.82	0.87%
CLONAZEPAM	BENZODIAZEPINES	1,994	$26,756.14	$13.42	0.87%
QUETIAPINE FUMARATE	ANTIPSYCHOTIC AGENTS	1,988	$28,299.07	$14.23	0.86%
CYCLOBENZAPRINE HCL	SKELETAL MUSCLE RELAXNT	1,925	$22,883.22	$11.89	0.84%

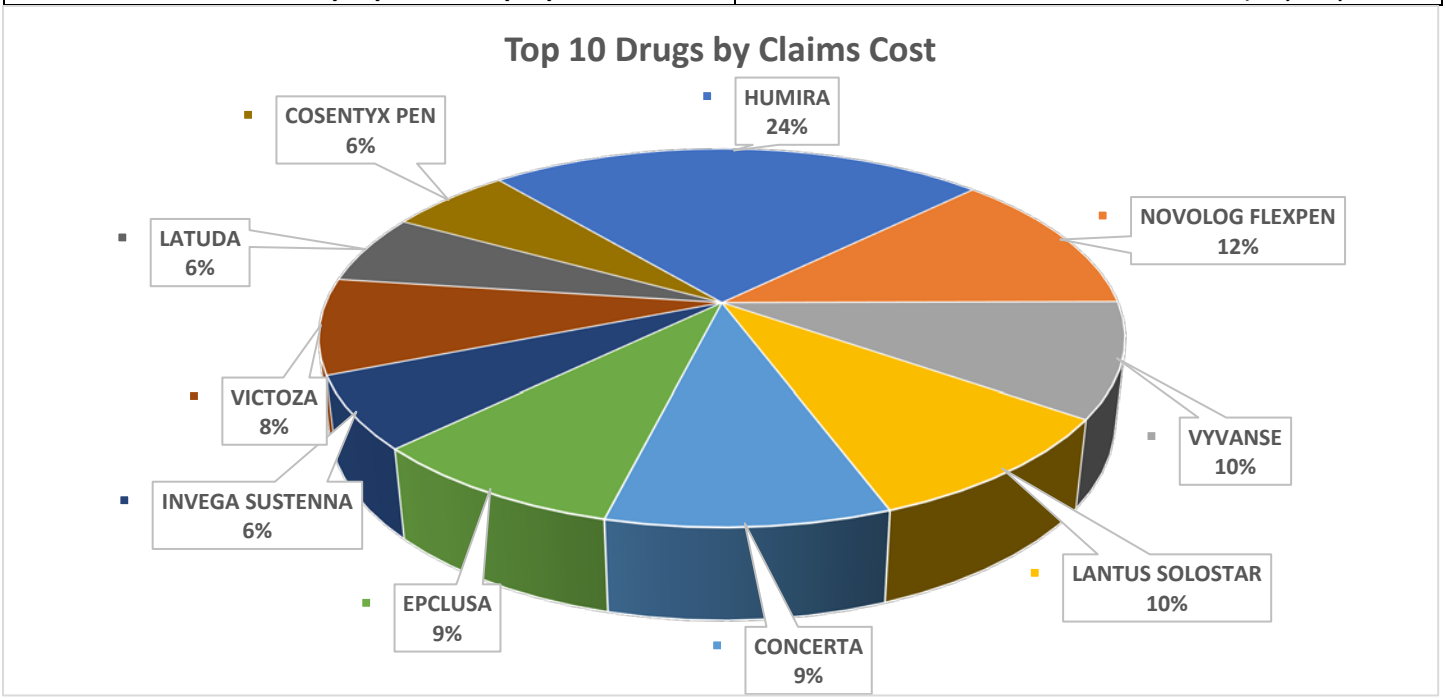
Total Claims From 04/01/2020 – 06/30/2020	**230,447**



Top 25 Drugs Based on Total Claims Cost from 04/01/2020 – 06/30/2020

Drug	AHFS Class	Claims Cost	Claims	Cost Per Claim	% Total Cost
HUMIRA	DMARDS	$1,309,696.32	212	$6,177.81	5.84%
NOVOLOG FLEXPEN	INSULINS	$672,750.01	1,142	$589.10	3.00%
VYVANSE	AMPHETAMINES	$537,697.83	2,107	$255.20	2.40%
LANTUS SOLOSTAR	INSULINS	$529,917.69	1,196	$443.07	2.36%
CONCERTA	AMPHETAMINES	$528,520.86	1,491	$354.47	2.36%
EPCLUSA	HCV ANTIVIRALS	$486,516.26	20	$24,325.81	2.17%
INVEGA SUSTENNA	ANTIPSYCHOTIC AGENTS	$341,027.25	155	$2,200.18	1.52%
VICTOZA	INCRETIN MIMETICS	$447,832.12	582	$769.47	2.00%
LATUDA	ANTIPSYCHOTIC AGENTS	$326,972.27	408	$801.40	1.46%
COSENTYX PEN	SKIN/MUCOUS MEMBRANE	$322,897.19	56	$5,766.02	1.44%
NORDITROPIN FLEXPRO	PITUITARY	$318,597.15	94	$3,389.33	1.42%
JARDIANCE	SGLT2 INHIB	$302,636.13	681	$444.40	1.35%
LEVEMIR FLEXTOUCH	INSULINS	$292,073.03	574	$508.84	1.30%
SYMBICORT	INHALED CORTICOSTEROIDS	$237,036.22	755	$313.96	1.06%
SABRIL	ANTICONVULSANTS, MISC	$230,220.79	12	$19,185.07	1.03%
XIFAXAN	ANTIBACTERIALS, MISC	$228,838.91	108	$2,118.88	1.02%
TRIKAFTA	CFTR CORRECTORS	$215,177.31	9	$23,908.59	0.96%
BIKTARVY	ANTIRETROVIRALS	$193,652.45	121	$1,600.43	0.86%
GENVOYA	ANTIRETROVIRALS	$193,495.86	130	$1,488.43	0.86%
ABILIFY MAINTENA	ANTIPSYCHOTIC AGENTS	$192,822.28	98	$1,967.57	0.86%
CONTOUR NEXT TEST STRIP	DIABETES MELLITUS	$189,195.98	1,649	$114.73	0.84%
NOVOLOG	INSULINS	$180,676.45	310	$582.83	0.81%
ELIQUIS	ANTICOAGULANTS	$157,740.03	385	$409.71	0.70%
BYDUREON PEN	INCRETIN MIMETICS	$155,519.00	248	$627.09	0.69%
FLOVENT HFA	INHALED CORTICOSTEROIDS	$155,257.85	668	$232.42	0.69%

Total Claims Cost From 04/01/2020 – 06/30/2020	$22,407,994.13



Top 15 Therapeutic Classes Based on Number of Claims from 04/01/2020 – 06/30/2020

Therapeutic Class Description	Claims	Claims Cost	Cost per Claim	% Total Claims
ANTIDEPRESSANTS	27,567	$570,724.84	$20.70	11.96%
ANTICONVULSANTS, MISC	13,019	$853,288.73	$65.54	5.65%
ANTIPSYCHOTIC AGENTS	8,986	$1,494,611.38	$166.33	3.90%
PROTON-PUMP INHIBITORS	7,387	$126,311.82	$17.10	3.21%
OPIATE AGONISTS	6,511	$131,054.36	$20.13	2.83%
NSAIDS	6,390	$90,885.56	$14.22	2.77%
HMG-COA REDUCTASE INHIBITORS	6,357	$91,192.10	$14.35	2.76%
BETA-ADRENERGIC BLOCKING AGENTS	5,631	$105,371.79	$18.71	2.44%
ANXIOLYTICS, SEDATIVES, AND HYPNOTICS	5,561	$90,345.20	$16.25	2.41%
ACE INHIBITORS	4,794	$68,150.76	$14.22	2.08%
THYROID AGENTS	4,648	$90,533.43	$19.48	2.02%
AMPHETAMINES	4,342	$689,297.87	$158.75	1.88%
NON-AMPHETAMINE STIMULANTS	3,982	$749,548.50	$188.23	1.73%
BIGUANIDES	3,960	$54,699.52	$13.81	1.72%
INSULINS	3,615	$1,845,924.41	$510.63	1.57%

Top 15 Therapeutic Classes Based on Claims Cost from 04/01/2020 – 06/30/2020

Therapeutic Class Description	Claims Cost	Claims	Cost/Claim	% Total Cost
INSULINS	$1,845,924.41	3,615	$510.63	8.24%
DMARDS	$1,767,487.97	373	$4,738.57	7.89%
ANTIPSYCHOTICS	$1,494,611.38	8,986	$166.33	6.67%
SKIN AND MUCOUS MEMBRANE AGENTS, MISC.	$932,354.99	437	$2,133.54	4.16%
ANTICONVULSANTS, MISC	$853,288.73	13,019	$65.54	3.81%
ANTIRETROVIRALS	$835,623.66	750	$1,114.16	3.73%
NON-AMPHETAMINE STIMULANTS	$749,548.50	3,982	$188.23	3.35%
INHALED CORTICOSTEROIDS	$704,831.50	3,069	$229.66	3.15%
AMPHETAMINES	$689,297.87	4,342	$158.75	3.08%
INCRETIN MIMETICS	$632,450.02	880	$718.69	2.82%
HCV ANTIVIRALS	$627,486.89	32	$19,608.97	2.80%
ANTIDEPRESSANTS	$570,724.84	27,567	$20.70	2.55%
ANTINEOPLASTIC AGENTS	$563,475.85	518	$1,087.79	2.51%
IMMUNOMODULATORY AGENTS	$443,496.65	61	$7,270.44	1.98%
URINARY ANTISPASMODICS	$368,465.70	1,614	$228.29	1.64%

PDL Update

ADDED TO PA	
Drug	**Class**
Ajovy Autoinjector	Prophylaxis of Migraine – CGRP Inhibitors
Arazlo	Acne - Retinoid
Asmanex HFA	Corticosteroids – Inhaled
Consensi	NSAIDs
Crinone	Progesterone
Cuvitru	Immune Globulins
Dexabliss	Steroids - Oral
Esperoct	Antihemophilic Factor Products
Gvoke Syringe	Glucose Rescue Medications
Halog Solution	Steroids - Topical
Harvoni Pallet	Hepatitis C Treatments
Helidac	Antibiotics - Resistance Prevention - H. pylori
Hizentra Syringe	Immune Globulins
Ingrezza Initiation Pack	Tardive Dyskinesia
Kynmobi	Parkinson's disease
Licart	NSAIDs
Lumify	Glaucoma - Alpha Adrenergics
Molindone	Antipsychotics
Nalocet	Opioid Analgesic – Short Acting
Nurtec ODT	Migraine Treatment - Non-Triptan Agents
Nuzyra	Antibiotics - Resistance Prevention - MRSA
Osmolex Er 332 Mg/Day Pack	Parkinson's disease
Oxervate	Medications >$3,000
Promacta Suspension	Thrombocytopenia
Reyvow	Migraine Treatment - Non-Triptan Agents
Riomet ER	Non-Preferred Dosage Form
Skyrizi	Cytokine Modulators
Sovaldi Pallets	Hepatitis C Treatments
Teriparatide	Osteoporosis
Tiglutik	Medications >$3,000
Trijardy XR	DPP4-Inhibitors/SGLT2 Inhibitors Combination
Udenyca	Hematopoietic, Colony Stimulating Factors
Xeljanz XR 22Mg	Cytokine Modulators
Xenleta	Antibiotics - Resistance Prevention - CAP
Zelnorm	Idiopathic Constipation
Zeposia	Multiple Sclerosis - Injectable Non-Interferons

Palforzia

Palforzia Prior Authorization Form

Group Criteria:

- **Initial Criteria:** *Approval Duration = 6 months*
  - The patient must have an FDA-approved indication for use (meets label recommendations for diagnosis and age)
  - The patient 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 patient has access to injectable epinephrine, and that the patient/caregiver has been instructed and trained on its appropriate use
  - The patient 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 patient must have a clinical history of allergy to peanuts or peanut-containing foods AND one of the following:
    - The patient 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 patient 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 patient must not have any of the following:
    - Uncontrolled asthma
    - Severe or persistent GI symptoms
    - Eosinophilic esophagitis
  - The patient must have experienced and maintained clinical benefit since starting treatment with Palforzia, as evidenced by the following:
    - The patient continues to have a peanut allergy and has been/is being monitored for resolution of their allergy
    - The patient 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)

health information designs

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 patients 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 PHYSICIAN

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

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

Does the patient have uncontrolled asthma?	□ YES	□ NO
Has the patient experienced severe or life-threatening anaphylaxis in the 60 days?	□ YES	□ NO
Does the patient have a history of eosinophilic esophagitis or another eosinophilic GI disease?	□ YES	□ NO
Has the patient/caregiver been educated on appropriate use of epinephrine?	□ YES	□ NO
RENEWAL ONLY: Does the patient continue to have a peanut allergy and has been/is being monitored for resolution of their allergy?	□ YES	□ NO
RENEWAL ONLY: Has the patient been able to tolerate the maintenance dose of Palforzia (300 mg daily)?	□ 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 patient's medical records. I also understand that any misrepresentations or concealment of any information requested in the prior authorization request may subject me to audit and recoupment.*

Part II: TO BE COMPLETED BY PHARMACY

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

Mytesi

General Prior Authorization Form

Group Criteria:

- **Initial Criteria:** *Approval Duration = 3 months*
  - The patient must have an FDA-approved indication for use (meets label recommendations for diagnosis and age)
  - The provider must submit medical documentation confirming that infectious and medication-induced etiologies of diarrhea have been ruled out
  - The patient must have had a 30-day trial of each preferred agent of a unique active ingredient, as evidenced by paid claims or pharmacy printouts
- **Renewal Criteria:** *Approval Duration = 12 months*
  - The patient must have experienced and maintained clinical benefit since starting treatment with Mytesi, 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)
Loperamide	LOMOTIL (diphenoxylate HCl/atropine)
Diphenoxylate HCl / atropine	MYTESTI (crofelemer)

Antifibrinolytic Agents

General Prior Authorization Form

Group Criteria:

- **Non-Preferred Agents Criteria:** *Approval Duration = 12 months*
  - The patient must have an FDA-approved indication for use (meets label recommendations for diagnosis and age)
  - The patient 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 patient is unable to use all other products (subject to clinical review)

Product Specific Criteria:

- **Non-Solid Dosage Formulations:** The patient must be unable to ingest solid dosage form as evidenced by swallow study documentation

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	LYSTEDA (tranexamic acid)
	AMICAR (aminocaproic acid) oral solution
	AMICAR (aminocaproic acid) tablet
	aminocaproic acid oral solution
	aminocaproic acid tablet
	tranexamic acid tablet

Lipid-Lowering Agents

General Prior Authorization Form

Additional Criteria for HMG-CoA (3-hydroxy-3-methylglutaryl-CoA) REDUCTASE INHIBITORS

Group Criteria:

- **Initial Criteria:** *Approval Duration = 3 months*
  - The patient must have an FDA-approved indication for use (meets label recommendations for diagnosis and age)
  - The patient must have LDL levels of >130 mg/dL after a 90-day trial of each of the following, as evidenced by paid claims or pharmacy printouts:
    - A lipid lowering agent other than a statin combined with either Crestor (rosuvastatin) ≥20 mg or Lipitor (atorvastatin) ≥ 40 mg
    - A PCSK9 Inhibitor combined with either Crestor (rosuvastatin) ≥20 mg or Lipitor (atorvastatin) ≥ 40 mg
  - The patient must currently be receiving a maximally tolerated statin (HMG-CoA reductase inhibitor) agent, as evidenced by paid claims or pharmacy printouts
  - Clinical justification must be provided explaining why the patient is unable to use all other products to lower their cholesterol (subject to clinical review)
- **Renewal Criteria:** *Approval Duration = 12 months*
  - The patient must currently be receiving a maximally tolerated statin (HMG-CoA reductase inhibitor) agent, as evidenced by paid claims or pharmacy printouts
  - The patient 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 (bempedoic acid)
	NEXLIZET (bempedoic acid and ezetimibe)
MTP (Microsomal Triglyceride Transfer Protein) INHIBITOR	
PREFERRED AGENTS (NO PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**
	JUXTAPID (lomitapide)
PCSK9 (Proprotien Convertase Subtilisin/Kexin Type 9) INHIBITORS	
PREFERRED AGENTS (NO PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**
PRALUENT PEN (alirocumab) – Labeler 72733	PRALUENT PEN (alirocumab) – Labeler 00024
REPATHA PUSHTRONEX (evolocumab)	
REPATHA SURECLICK (evolocumab)	
REPATHA SYRINGE (evolocumab)	

CFTR Modulators

General Prior Authorization Form

Group Criteria: *Approval Duration = 12 months*

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

health information designs

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 that patients receiving a prescription for non-preferred medications to meet specific diagnosis and step-therapy requirements. Criteria for agents requiring prior authorization can be found at one of the following locations:

- The Preferred Drug List (PDL) available at www.hidesigns.com/assets/files/ndmedicaid/NDPDL.pdf
- Prior Authorization Criteria available at www.hidesigns.com/assets/files/ndmedicaid/2018/Criteria/PA_Criteria.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 PHYSICIAN

Recipient Name	Recipient Date of Birth	Recipient Medicaid ID Number	
Prescriber Name	Specialist involved in therapy (if not treating physician)		
Prescriber NPI	Telephone Number	Fax Number	
Address	City	State	Zip Code
Requested Drug and Dosage:	**Diagnosis for this request:**		
List all failed medications:		**Start Date:**	**End Date:**

Additional Qualifications for Coverage (e.g. medical justification explaining inability to meet required trials)

□ Patient is pregnant: Due Date _____
□ Patient has inability to take or tolerate solid oral dosage forms (please attach swallow study)
□ Patient has feeding tube in place: (please state specific type of feeding tube _____)
□ 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 patient's medical records. I also understand that any misrepresentations or concealment of any information requested in the prior authorization request may subject me to audit and recoupment.*

Part II: TO BE COMPLETED BY PHARMACY

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

REVIEW OF PHARMACOLOGIC TREATMENT OF DIABETIC GASTROPARESIS

Diabetic Gastroparesis:

- Diabetic gastroparesis is thought to result from impaired neural control of gastric function in patients with diabetes mellitus
    - It is not progressive, and treatment is directed toward alleviating symptoms
        - Primary treatment of gastroparesis:
            - Improved glycemic control
            - Dietary modification
            - Administration of prokinetic agents
            - Avoidance of medications that can delay gastric emptying (e.g. incretin mimetics)

Pharmacological Treatment

- Prokinetics: increase the rate of gastric emptying and should be administered 10 to 15 minutes before meals with an additional dose before bedtime in patients with persistent symptoms
    - **Metoclopramide (only Rx-only medication with FDA-approved indication for use)**
        - Oral tablet
        - ODT
        - Injection
        - Nasal (Gimoti)
    - Macrolide antibiotics (off-label)
        - Erythromycin
        - Azithromycin
    - *Investigational drugs*
        - *Domperidone*
        - *Cisapride*

Metoclopramide:

- **Indication**:
    - Relief of symptoms associated with acute and recurrent diabetic gastric stasis
- **Mechanism of action:**
    - Dopamine 2 receptor antagonist, 5-HT4 agonist, & a weak 5-HT3 receptor antagonist
        - Enhances the response to acetylcholine of tissue in upper GI tract
            - Causes enhanced motility and accelerated gastric emptying; increases lower esophageal sphincter tone
- **Boxed Warning:**
    - Treatment with metoclopramide can cause tardive dyskinesia (TD). The risk of developing TD increases with duration of treatment and total cumulative dose. Discontinue metoclopramide therapy in patients who develop signs or symptoms of TD. There is no known treatment for tardive dyskinesia. In some patients, symptoms lessen or resolve after metoclopramide treatment is stopped.

- **Contraindications:**
    - Hypersensitivity to metoclopramide or any component of the formulation
    - Situations where stimulation of GI motility may be dangerous (GI obstruction, perforation, or hemorrhage)
    - Pheochromocytoma or other catecholamine-releasing paragangliomas
    - Seizure disorders (eg, epilepsy)
    - History of tardive dyskinesia or dystonic reaction to metoclopramide
    - Concomitant use with other agents likely to increase extrapyramidal reactions

- **Warnings/Precautions**
  - Tardive dyskinesia
  - May cause extrapyramidal symptoms, generally manifested as acute dystonic reactions within the initial 24 to 48 hours of use
    - Avoid with Parkinson's disease
  - Use may be associated with neuroleptic malignant syndrome (NMS)
  - May cause QT prolongation and torsades de pointes in certain individuals (eg, heart failure patients with renal impairment)
  - Depression has occurred
  - May elevate blood pressure; avoid use in patients with hypertension
  - Elevates prolactin levels
  - Use with caution in patients who are at risk of fluid overload (heart failure, cirrhosis)

- **Dosing:**

	Solution	**Oral Tablet**	**ODT**	**Injection**	**Nasal**
Adult	5-10 mg 2-3 times daily (max of 40 mg/day)				One spray (15 mg) in 1 nostril
Pediatric	Off-label only				N/A
Renal Impairment	Use with caution in patients with moderate to severe renal impairment; dosage adjustment recommended				
Hepatic Impairment	Use caution in patients with moderate to severe hepatic impairment; dosage adjustment recommended				
In chronic therapy, limit course to ≤12 weeks. Consider a "drug holiday" or dose reduction (eg, 5 mg twice daily before the 2 main meals of the day) for ~2 weeks whenever clinically feasible or at least every 12 weeks (whichever is shorter) to evaluate efficacy and necessity of continued treatment					

- **Drug interactions:**
  - **Antipsychotics**
    - Potential for increased frequency and severity of TD, EPS, & NMS
  - **Strong CYP2D6 Inhibitors**
    - Increased plasma concentrations of metoclopramide
  - **MAOIs**
    - Increased risk of hypertension
  - **CNS Depressants**
    - Increased risk of CNS depression
  - **Drugs that Impair Gastrointestinal Motility**
    - Reduced efficacy
  - **Dopamine Agonists**
    - Decreased therapeutic effect of metoclopramide due to opposing effects on dopamine

COST

Drug	**Strength**	**Package Size**	**AWP Pkg Price**	**AWP Unit Price**
Metoclopramide	5 mg/ 5 mL	473 mL	$35.40	$0.07
Metoclopramide	5 mg tablet	100	$32.00	$0.32
Metoclopramide	10 mg tablet	1,000	$215.00	$0.21
Metoclopramide	5 mg/mL solution	2 mL (25 syr)	$33.30	$0.67
Metoclopramide	5 mg ODT	100	$949.30	$9.49
Metoclopramide	10 mg ODT	100	$949.30	$9.49
Gimoti	10 mL nasal spray	NA	NA	NA

CURRENT UTILIZATION

ND Medicaid Utilization (06/2019 – 06/2020)		
Label Name	**Rx Num**	**Total Reimb Amt**
Metoclopramide tablet	1,121	$14,949.91
Metoclopramide oral sln	75	$1,264.59
Metoclopramide ODT	0	-
Metoclopramide injection	1	$15.96
Gimoti	0	-

REFERENCES:

1. Facts & Comparisons eAnswers. Available at http://online.factsandcomparisons.com. Accessed on August 14. 2020.
2. UpToDate. Available at https://www.uptodate.com/contents/search. Accessed on August 14. 2020.
3. Reglan (metoclopramide) [prescribing information]. Baudette, MN: ANI Pharmaceuticals; August 2017.

REVIEW OF OHRIAHNN (elagolix/estradiol/norethindrone)

Indication:

- Management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal women
    - Use should be limited to 24 months due to the risk of continued bone loss, which may not be reversible
- **Other agents used for this indication:**
    - Estrogen/progestin contraceptives
        - Oral contraceptive pills, vaginal ring, or transdermal patch
            - Little high-quality evidence supporting this practice, but many guidelines still recommend as first-line therapy
    - Progestin IUDs
        - Primarily levonorgestrel -releasing IUDs
            - Supporting data are mainly observational, but most guidelines support the use of LNG IUDs as a first-line agent
    - Progestin-only contraceptives
        - Little evidence for efficacy, but some guidelines support use
    - Tranexamic acid
        - Small studies have shown benefit

Mechanism of action

- Elagolix is a short-acting, gonadotropin-releasing hormone antagonist that suppresses pituitary and ovarian hormone function in a dose-dependent manner
    - Concentrations of luteinizing hormone, follicle stimulating hormone, estradiol, and progesterone are decreased during therapy, reducing bleeding associated with uterine fibroids
- Estradiol may reduce the bone loss associated with elagolix
- Norethindrone may protect the uterus from adverse endometrial effects of unopposed estrogen

Boxed Warning:

- Thromboembolic disorders and vascular events
    - Estrogen and progestin combinations increase the risk of thrombotic or thromboembolic disorders including pulmonary embolism, deep vein thrombosis, stroke, and myocardial infarction, especially in women at increased risk for these events. Elagolix, estradiol, and norethindrone is contraindicated in women with current or a history of thrombotic or thromboembolic disorders and in women at increased risk for these events, including women >35 years of age who smoke and women with uncontrolled hypertension

Contraindications:

- Hypersensitivity to any ingredient of the formulation
- Osteoporosis
- Current or history of breast cancer or other hormone-sensitive malignancies, and with increased risk for hormone-sensitive malignancies
- Hepatic impairment or disease
- Undiagnosed abnormal uterine bleeding
- Concurrent use of organic anion transporting polypeptide (OATP)1B1 inhibitors that are known or expected to significantly increase elagolix plasma concentrations
- Pregnancy
- Females at high risk of arterial, venous thrombotic, or thromboembolic disorders
    - Women >35 years of age who smoke
    - Current diagnosis of or history of deep vein thrombosis or pulmonary embolism, vascular disease, inherited or acquired hypercoagulopathies, uncontrolled hypertension, or headaches with focal neurological symptoms or have migraine headaches with aura if >35 years of age

Warnings/Precautions:

- Increased risk of thromboembolic disorders and vascular events
  - Discontinue use if an arterial or venous thrombotic event occurs or is suspected
- Retinal vascular thrombosis
  - Discontinue if unexplained loss of vision, proptosis, diplopia, papilledema, or retinal vascular lesions occur and immediately evaluate for retinal vein thrombosis
- May increase the risk for breast cancer and other hormone-sensitive malignancies
  - Discontinue if a hormone-sensitive malignancy is diagnosed
- Menstrual bleeding patterns may change
  - May alter the ability to detect pregnancy. Pregnancy testing should be conducted if pregnancy is suspected; discontinue use if pregnancy is confirmed
- Depression
  - May increase the risk of depression and mood changes. Consider risks and benefits of therapy if mood disturbances occur
- Bone mineral density loss
  - Associated with bone mineral density (BMD) loss; risk is increased with duration of use and may not be completely reversible following discontinuation. Evaluate BMD at baseline with dual-energy x-ray absorptiometry. Consider supplementation with calcium and vitamin D. Limit duration of treatment to 24 months to reduce the extent of BMD loss. Use caution in patients with risk factors for osteoporosis, including medications which may decrease BMD. Use is contraindicated in women with known osteoporosis.
- Gallbladder disease
  - May increase risk of gallbladder disease, especially in women with a history of cholestatic jaundice associated with past estrogen use or with pregnancy. Discontinue if jaundice occurs.
- Hypertension
  - Discontinue if BP rises significantly with use.
- Lipid effects
  - May adversely affect lipid levels, including serum triglycerides leading to pancreatitis.
- Diabetes
  - May impair glucose tolerance; closely monitor women with diabetes or prediabetes
- Alopecia
  - May cause alopecia. Reversibility is unknown; hair loss continued after discontinuation of therapy in most affected women. Consider discontinuation if alopecia occurs
- Drug-drug interactions
  - Potentially significant interactions may exist, requiring dose or frequency adjustment, additional monitoring, and/or selection of alternative therapy. Consult drug interactions database for more detailed information.
- Surgical patients
  - Whenever possible, discontinue 4 to 6 weeks prior to surgeries known to have an increased risk of thromboembolism or during periods of prolonged immobilization
- Tartrazine
  - Contains tartrazine (ie, FD&C Yellow No. 5), which may cause hypersensitivity reactions, especially in patients with aspirin hypersensitivity
- Laboratory changes
  - May change the results of some laboratory tests (eg, coagulation factors, lipids, glucose tolerance, binding proteins). Estrogens may raise serum concentrations of thyroxine-binding globulin, sex hormone-binding globulin, and cortisol-binding globulin. Females on thyroid replacement therapy may require higher doses of thyroid hormone while receiving estrogens

Dosing:

- **Adults:**
  - Elagolix 300 mg/estradiol 1 mg/norethindrone 0.5 mg every morning and elagolix 300 mg every evening
    - Maximum of 24 months of treatment
    - Not indicated for use in postmenopausal females****
- **Pediatric:**
  - Safety and efficacy have not been established
- **Renal Impairment**
  - No dosage adjustment necessary
- **Hepatic Impairment**
  - Contraindicated for use in mild, moderate or severe hepatic impairment

Drug interactions

- Strong CYP3A4 Inhibitors
- OATP1B1/1B3 inhibitors
- P-glycoprotein/ABCB1 substrates
- Related to mechanism:
  - Anticoagulants: diminished therapeutic effect of anticoagulants
  - Anastrozole diminished therapeutic effect
  - Increase in effects of other drugs
  - Simvastatin
  - Cyclosporin

COST

Drug	Strength	Package Size	AWP Pkg Price	AWP Unit Price
Oriahnn	300 mg – 300 mg – 1 mg	56 capsules	$1,088.97	$19.44
Tranexamic acid	650 mg oral tab	30 tablets	$156.60	$15.66
Mirena	52 mg	1 IUD	$1,144.21	$1,144.21
Ethinyl Estradiol and Levonorgestrel	0.02 mg – 0.1 mg	28 tablets	$105.48	$1.26

CURRENT UTILIZATION

ND Medicaid Utilization (06/2019 – 06/2020)		
Label Name	**Rx Num**	**Total Reimb Amt**
Oriahnn	0	-

REFERENCES:

1. Facts & Comparisons eAnswers. Available at http://online.factsandcomparisons.com. Accessed on August 14. 2020.
2. UpToDate. Available at https://www.uptodate.com/contents/search. Accessed on August 14. 2020.
3. Oriahnn (elagolix/estradiol/norethindrone) [prescribing information]. North Chicago, IL: AbbVie Inc; May 2020.
4. American College of Obstetricians and Gynecologists. ACOG practice bulletin. Alternatives to hysterectomy in the management of leiomyomas. Obstetrics and gynecology. 2008 Aug;112(2 Pt 1):387.

REVIEW OF DOJOLVI (triheptanoin)

Indication:

- As a source of calories and fatty acids for the treatment of molecularly confirmed long-chain fatty acid oxidation disorders (LC-FAOD) in adults and pediatric patients

Long-Chain Fatty Acid Oxidation Disorders (LC-FAOD)

- Fatty acid oxidation disorders (FAODs) are autosomal recessive disorders of metabolism resulting in failure of mitochondrial beta-oxidation or the carnitine-based transport of fatty acids into mitochondria
    - Leads to deficient energy production and produce widely variable clinical presentations ranging from mild hypotonia in adults to sudden death in infants
- Treatment of LC-FAOD:
    - Treatment involves avoidance of prolonged fasting, dietary fat restriction, and medium chain triglyceride supplementation
        - High cab diet, low in long-chain fats

Mechanism of action:

- It is a medium-chain triglyceride that provide a source of calories and fatty acids to bypass the long-chain fatty acid oxidation disorder enzyme deficiencies for energy production and replacement

Contraindications:

- There are no contraindications listed in the manufacturer's labeling

Warnings and Precautions:

- Avoid use in patients with pancreatic insufficiency; reduced absorption leading to insufficient supplementation of medium-chain fatty acids may occur
- Do not use PVC feeding tubes; the performance and functionality of feeding tubes may degrade over time depending on usage and environmental conditions

Dosing:

- **Adults:**
    - Patients not currently receiving a medium-chain triglyceride product
        - ~10% of the patient's total prescribed daily caloric intake (DCI) divided into at least 4 times daily orally initially
        - Increase dosage by ~5% of the patient's total prescribed DCI every 2 to 3 days until target dose of up to 35% of the patient's prescribed DCI is achieved
    - Patients switching from another medium-chain triglyceride product
        - Prior to initiation, discontinue any other medium-chain triglyceride products
        - Initiate at the last tolerated daily dosage of medium-chain triglyceride divided into at least 4 times daily orally
        - Increase dosage by ~5% of the patient's total prescribed DCI every 2 to 3 days until target dose of up to 35% of the patient's prescribed DCI is achieved
    - Formula for triheptanoin dose
        - Total daily dose (mL) = (Patient's DCI [kcal] x desired % of DCI) divided by 8.3 kcal/mL.
- **Pediatric:**
    - Same as adult
        - In neonates, may need increased dosage due to higher fat intake
- **Renal Impairment**
    - No dosage adjustment provided per labeling
- **Hepatic Impairment**
    - No dosage adjustment provided per labeling

Drug interactions

- Orlistat: may decrease active metabolite of Dojolvi

COST

Drug	Strength	Package Size	AWP Pkg Price	AWP Unit Price
Dojolvi	100 %	500 mL	$5,850.00	$11.70

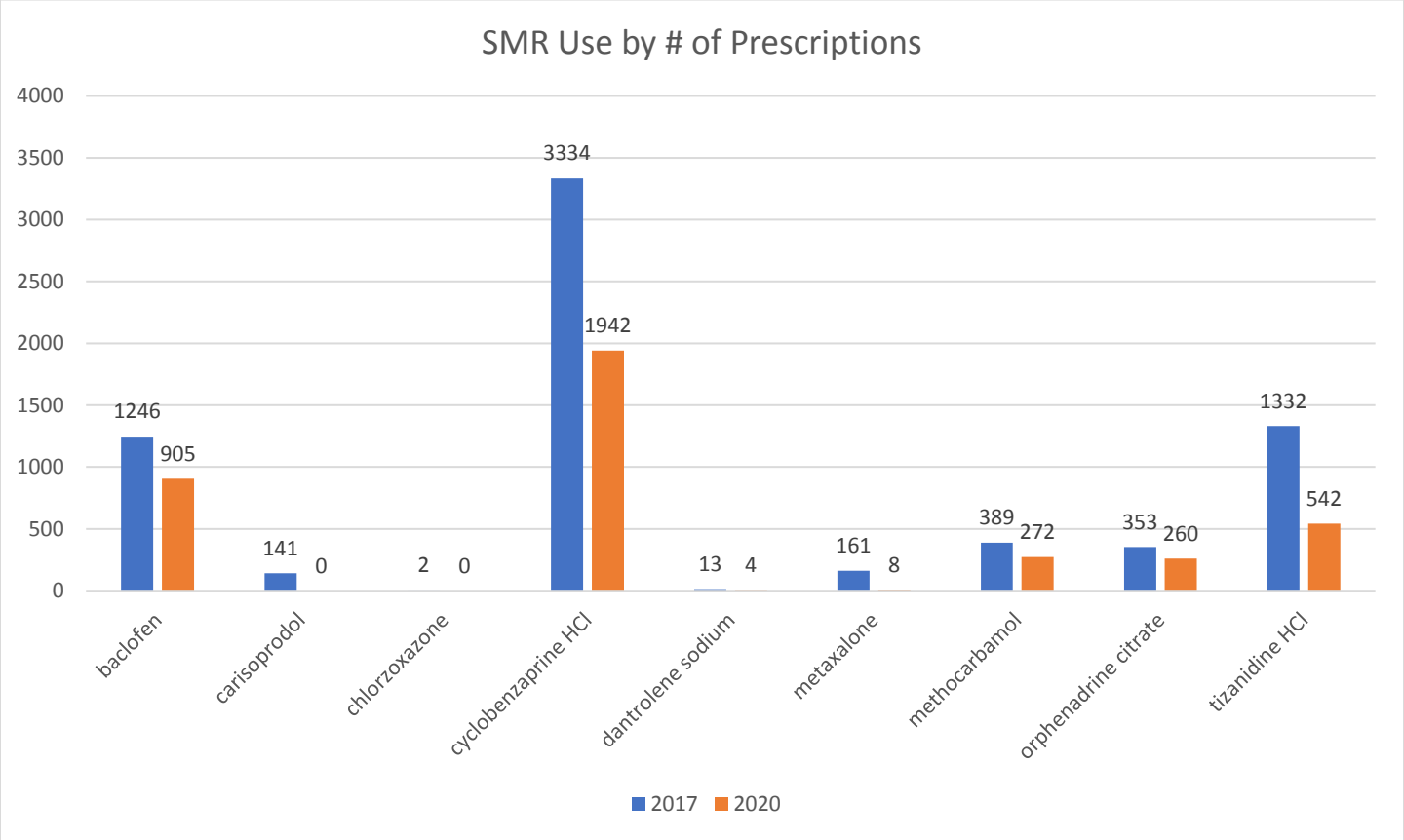
CURRENT UTILIZATION

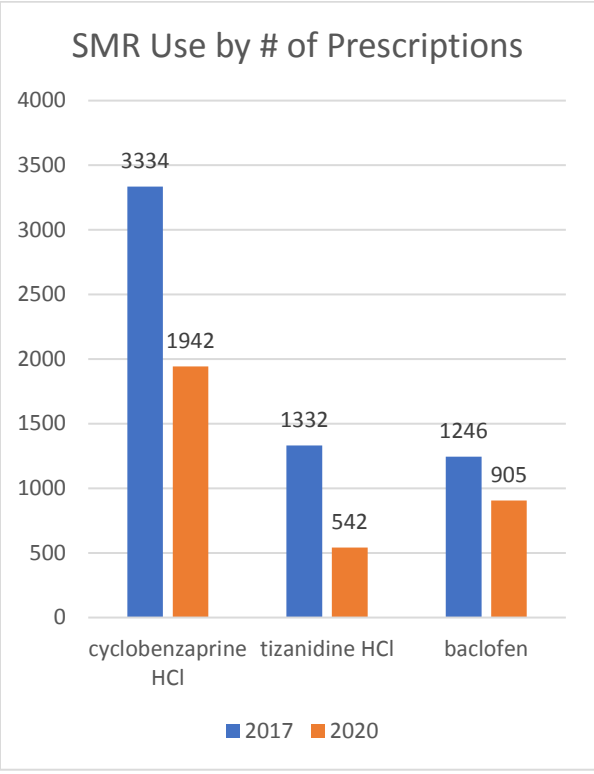
ND Medicaid Utilization (06/2019 – 06/2020)		
Label Name	**Rx Num**	**Total Reimb Amt**
Dojolvi	0	-

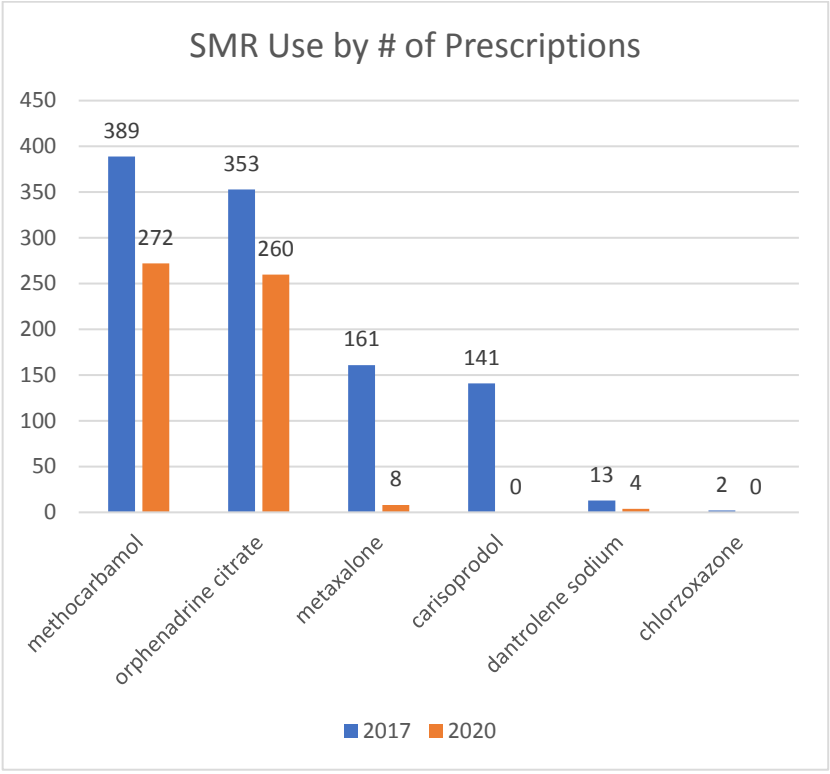
REFERENCES:

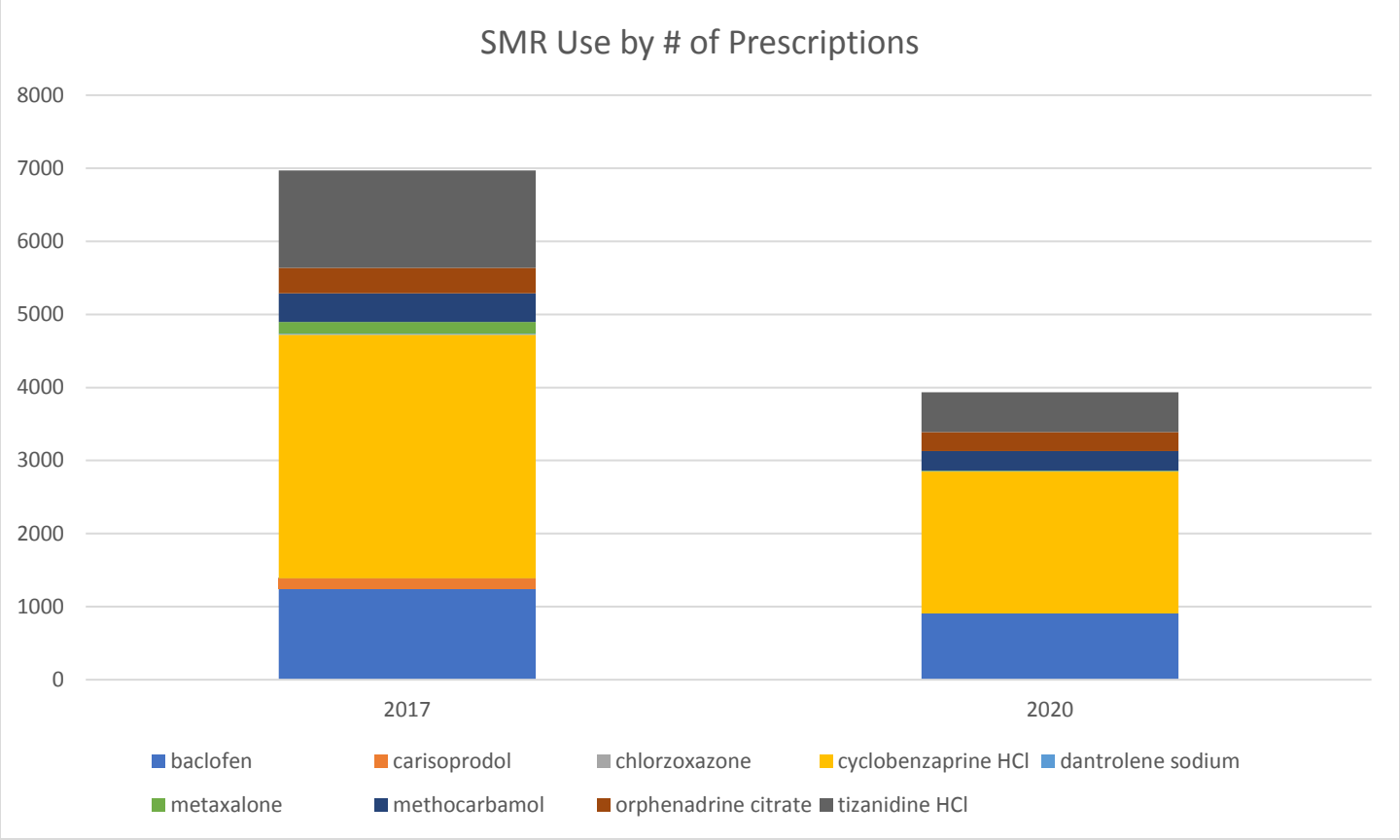
1. Facts & Comparisons eAnswers. Available at http://online.factsandcomparisons.com. Accessed on August 21. 2020.
2. UpToDate. Available at https://www.uptodate.com/contents/search. Accessed on August 21. 2020.
3. Dojolvi (triheptanoin) [prescribing information]. Novato, CA: Ultragenyx Pharmaceutical Inc; June 2020.

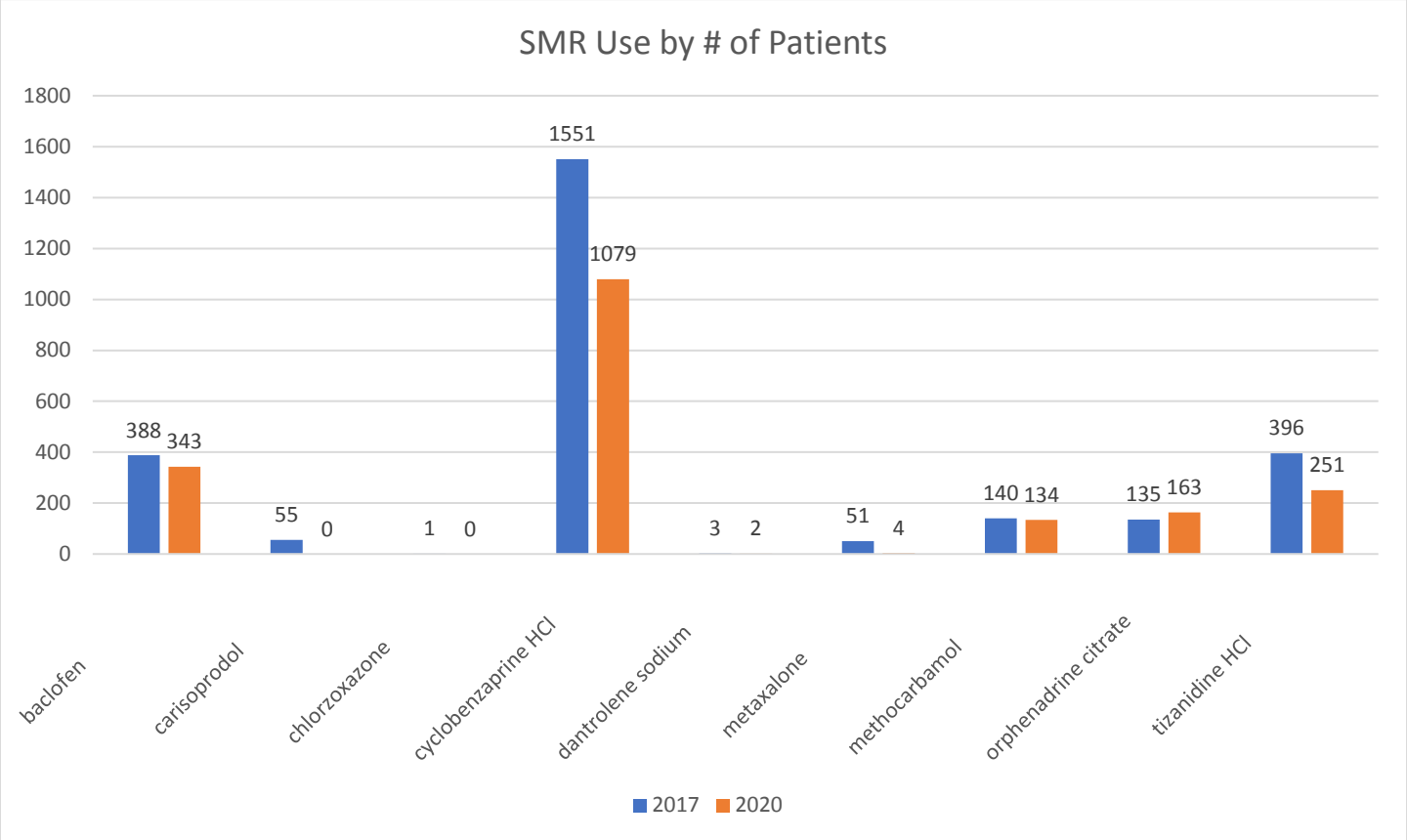
Skeletal Muscle Relaxant (SMR) Utilization

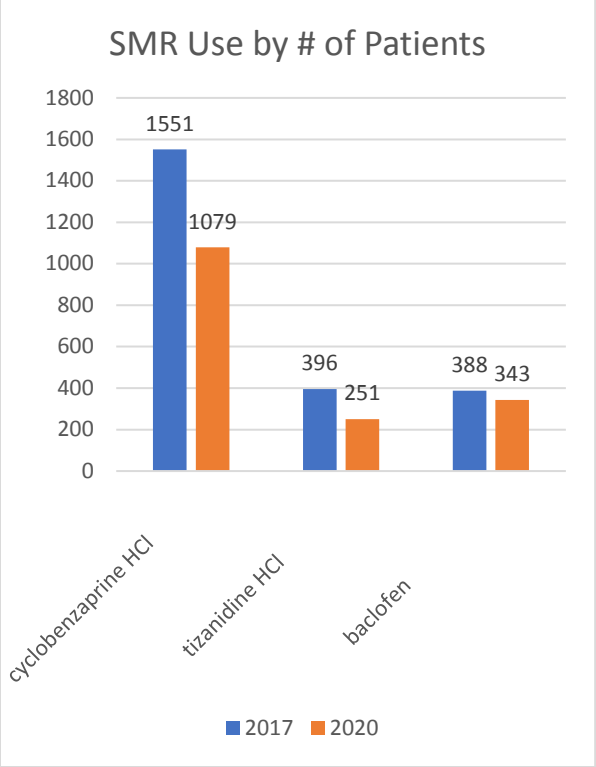


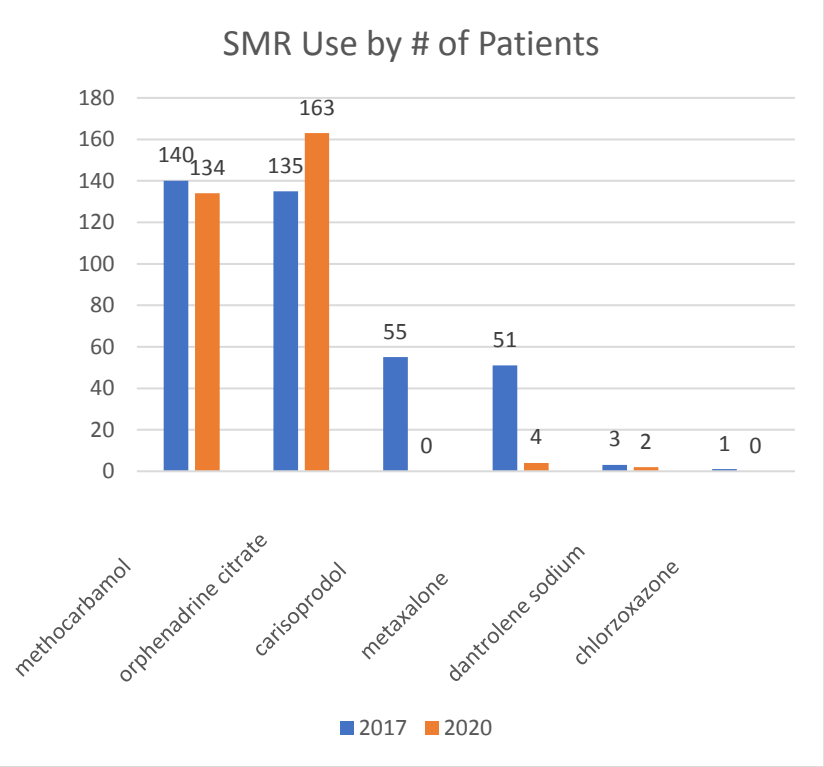


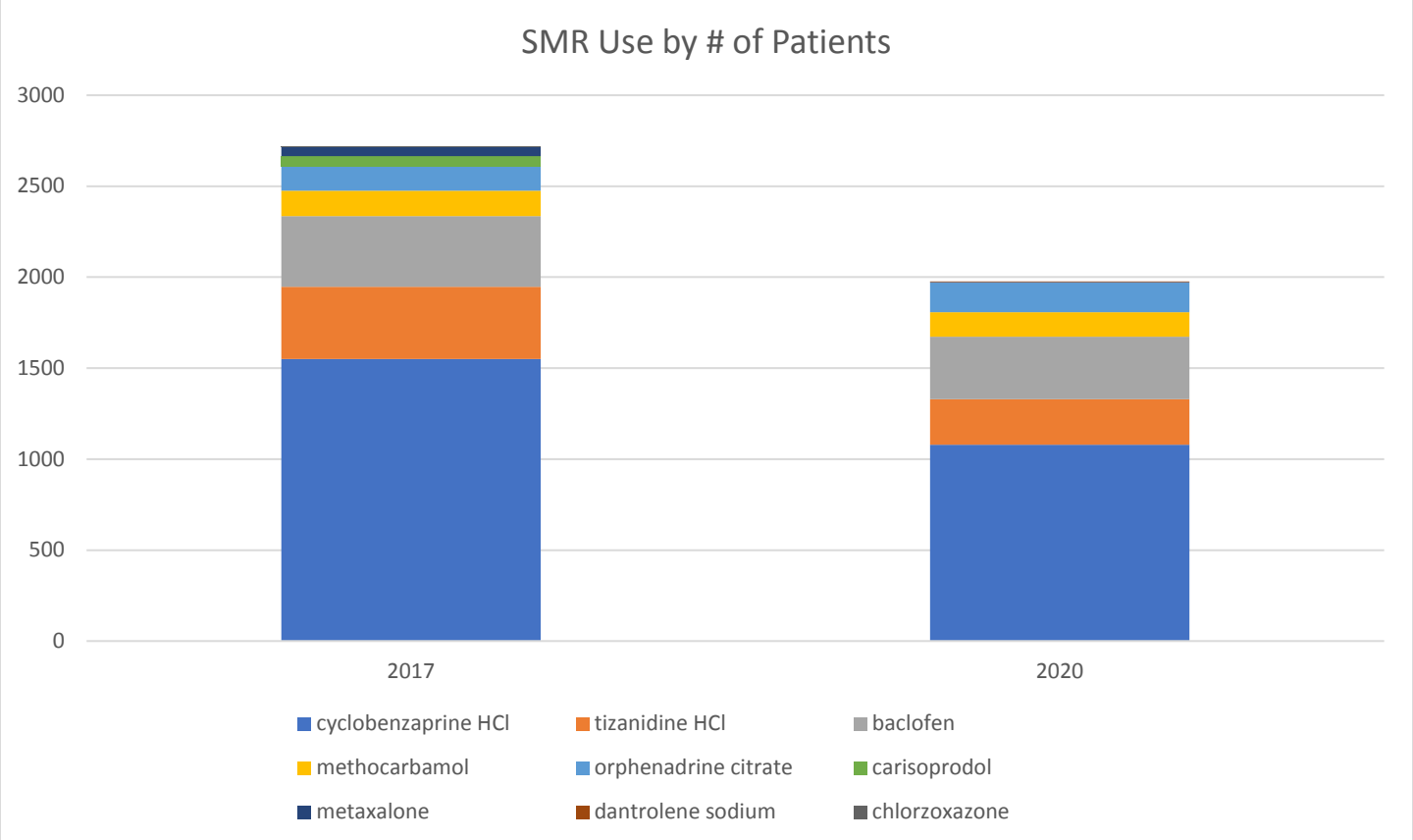


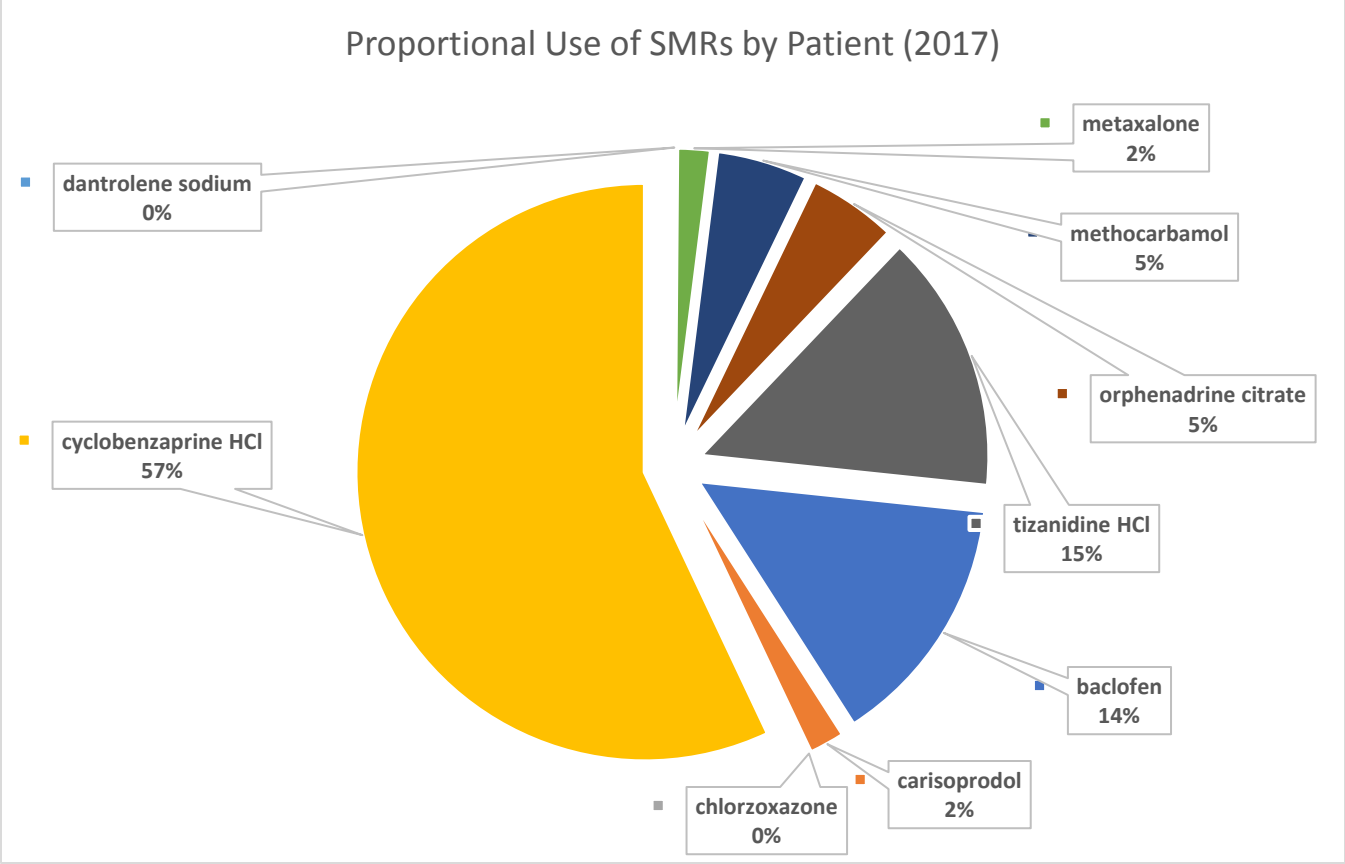

SMR Use by # of Prescriptions
8000
7000
6000
5000
4000
3000
2000
1000
0
2017
2020
baclofen
carisoprodol
chlorzoxazone
cyclobenzaprine HCl
dantrolene sodium
metaxalone
methocarbamol
orphenadrine citrate
tizanidine HCl

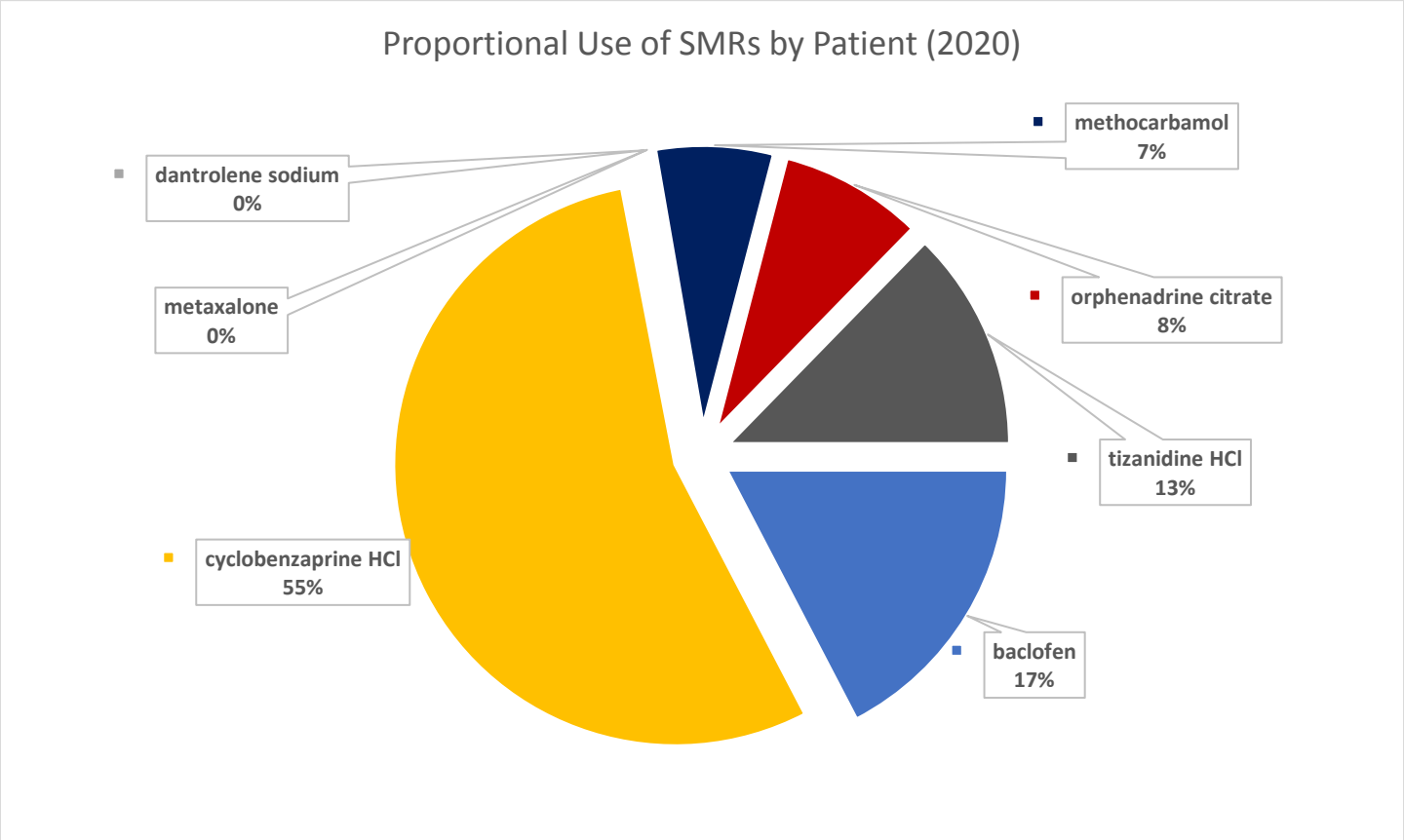

SMR Use by # of Patients
1800
1600
1400
1200
1000
800
600
400
200
0
388
343
55
0
1
0
1551
1079
3
2
51
4
140
134
135
163
396
251
baclofen
carisoprodol
chlorzoxazone
cyclobenzaprine HCl
dantrolene sodium
metaxalone
methocarbamol
orphenadrine citrate
tizanidine HCl
2017
2020


SMR Use by # of Patients
1800
1600
1400
1200
1000
800
600
400
200
0
1551
1079
396
251
388
343
cyclobenzaprine HCl
tizanidine HCl
baclofen
2017
2020

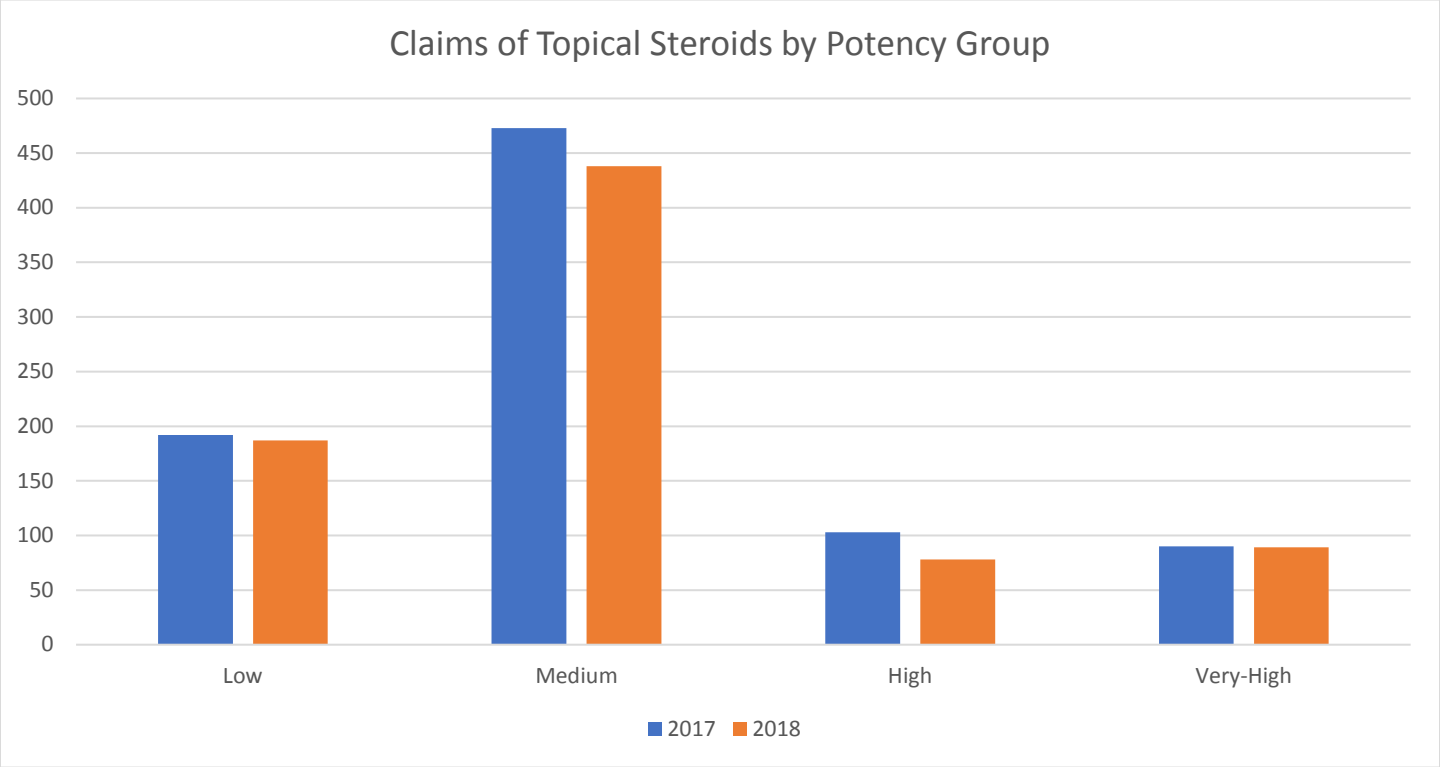

SMR Use by # of Patients
180
160
140
120
100
80
60
40
20
0
140
134
135
163
55
0
51
4
3
2
1
0
methocarbamol
orphenadrine citrate
carisoprodol
metaxalone
dantrolene sodium
chlorzoxazone
2017
2020

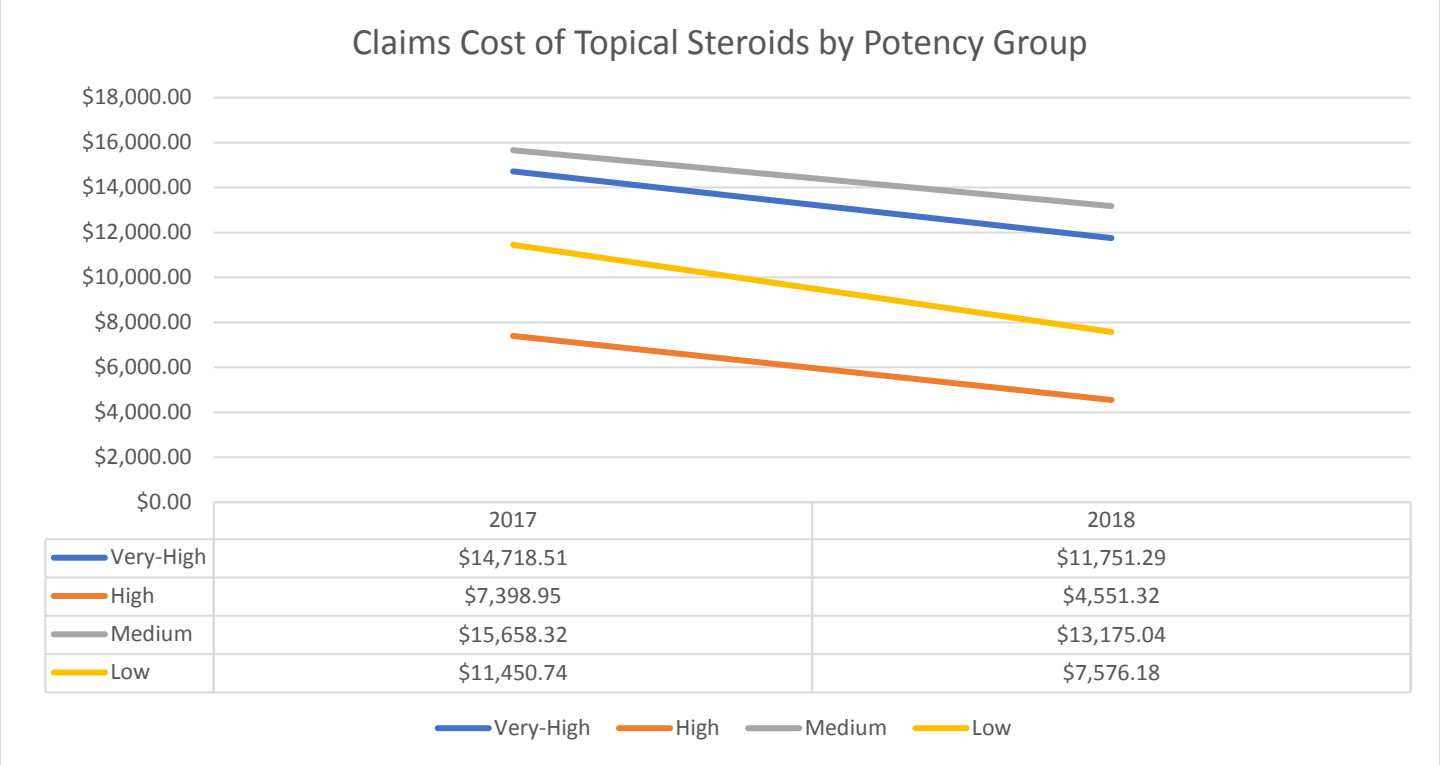

SMR Use by # of Patients
3000
2500
2000
1500
1000
500
0
2017
2020
cyclobenzaprine HCl
tizanidine HCl
baclofen
methocarbamol
orphenadrine citrate
carisoprodol
metaxalone
dantrolene sodium
chlorzoxazone


Proportional Use of SMRs by Patient (2017)
metaxalone 2%
dantrolene sodium 0%
methocarbamol 5%
orphenadrine citrate 5%
cyclobenzaprine HCl 57%
tizanidine HCl 15%
baclofen 14%
carisoprodol 2%
chlorzoxazone 0%

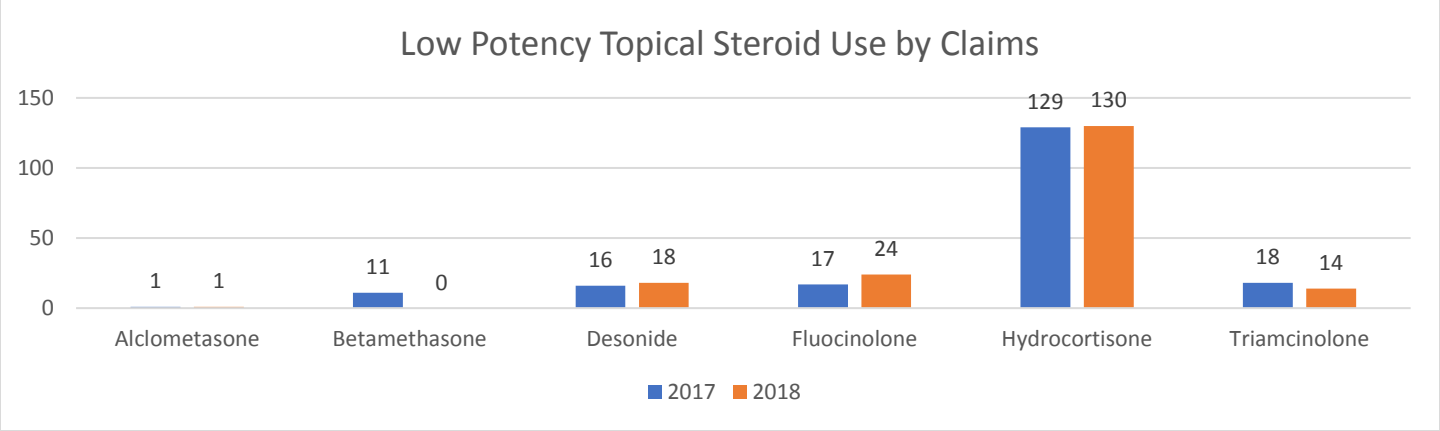

Proportional Use of SMRs by Patient (2020)
methocarbamol 7%
dantrolene sodium 0%
metaxalone 0%
orphenadrine citrate 8%
tizanidine HCl 13%
cyclobenzaprine HCl 55%
baclofen 17%

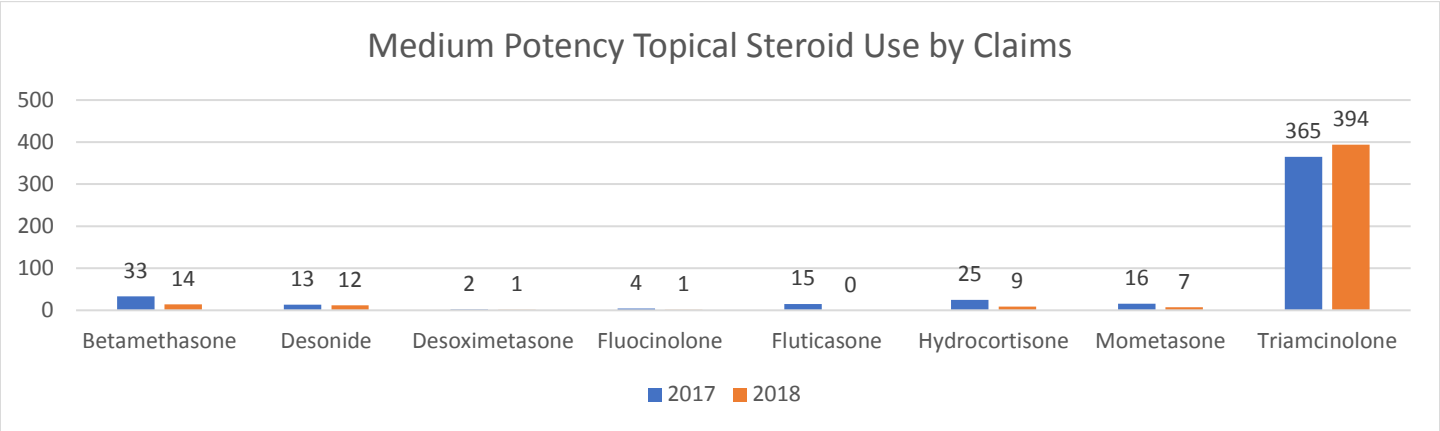
Topical Corticosteroid Utilization

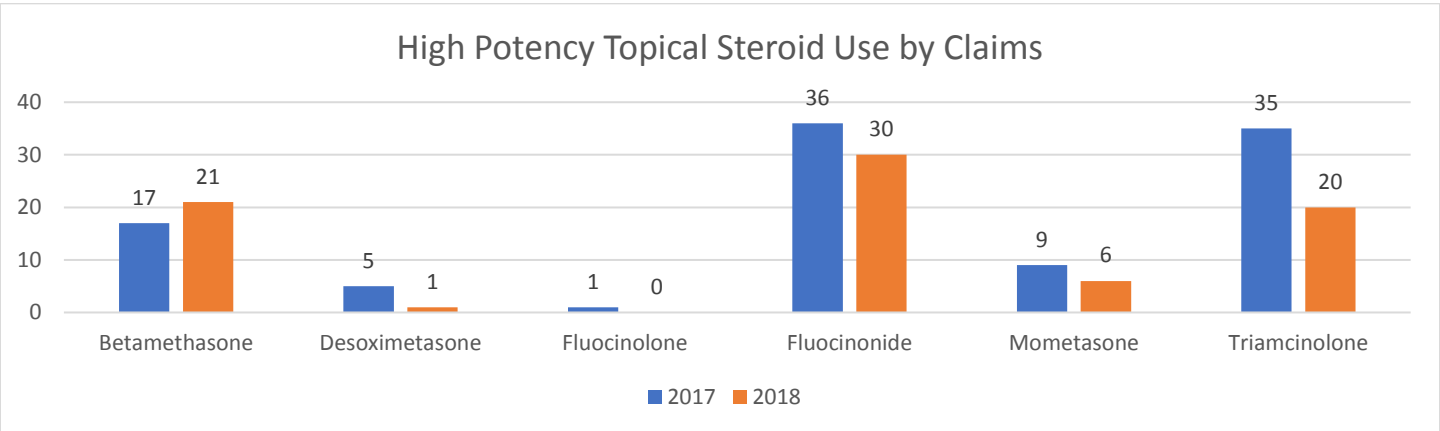


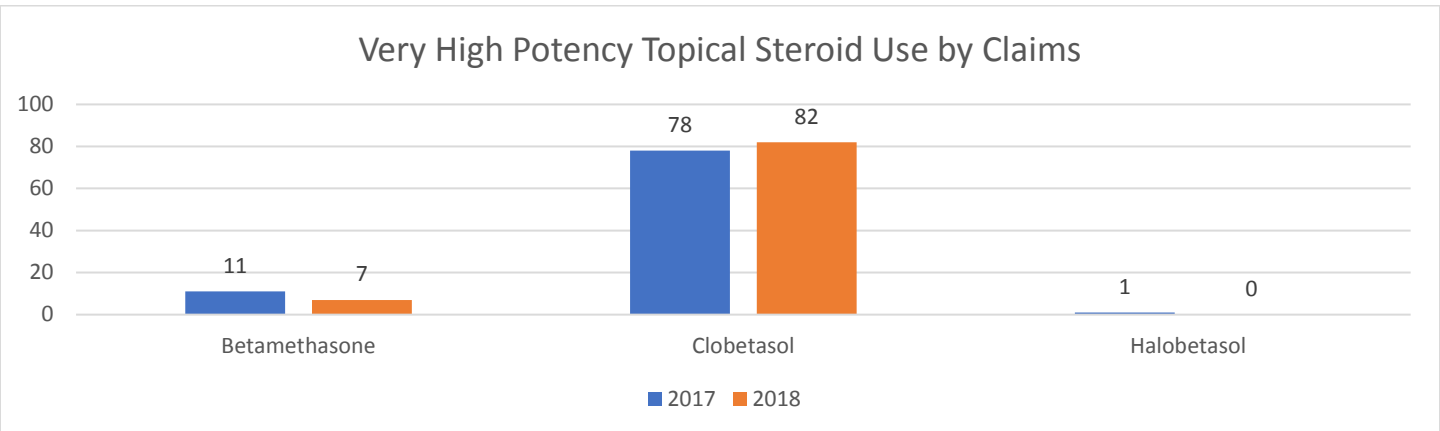


	2017	2018
Very-High	$14,718.51	$11,751.29
High	$7,398.95	$4,551.32
Medium	$15,658.32	$13,175.04
Low	$11,450.74	$7,576.18


Low Potency Topical Steroid Use by Claims
150
100
50
0
1 1
11 0
16 18
17 24
129 130
18 14
Alclometasone
Betamethasone
Desonide
Fluocinolone
Hydrocortisone
Triamcinolone
2017 2018


Medium Potency Topical Steroid Use by Claims
500
400
300
200
100
0
33 14
13 12
2 1
4 1
15 0
25 9
16 7
365 394
Betamethasone
Desonide
Desoximetasone
Fluocinolone
Fluticasone
Hydrocortisone
Mometasone
Triamcinolone
2017 2018


High Potency Topical Steroid Use by Claims
40
30
20
10
0
17 21
5 1
1 0
36 30
9 6
35 20
Betamethasone
Desoximetasone
Fluocinolone
Fluocinonide
Mometasone
Triamcinolone
2017 2018


Very High Potency Topical Steroid Use by Claims
100
80
60
40
20
0
11 7
78 82
1 0
Betamethasone
Clobetasol
Halobetasol
2017 2018

NORTH DAKOTA MEDICAID
RETROSPECTIVE DRUG UTILIZATION REVIEW
CRITERIA RECOMMENDATIONS
3RD QUARTER 2020

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

1. Lemborexant / Overuse _____ _____

Alert Message: The recommended dosage of Dayvigo (lemborexant) is 5 mg taken no more than once per night, immediately before going to bed, with at least 7 hours remaining before the planned time of awakening. The dose may be increased to the maximum recommended dose of 10 mg based on clinical response and tolerability.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Lemborexant		Hepatic Impairment
		Weak CYP3A4 Inhibitors

Max Dose: 10 mg/day

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Dayvigo Prescribing Information, Dec. 2019, Eisai Inc.

2. Lemborexant 10 mg / Overuse – Hepatic Impairment _____ _____

Alert Message: The maximum recommended dose of Dayvigo (lemborexant) is 5 mg no more than once per night in patients with moderate hepatic impairment. In drug studies, lemborexant exposure (AUC and Cmax) and terminal half-life were increased in patients with moderate hepatic impairment (Child-Pugh B). Dosage adjustment is recommended in patients with moderate hepatic impairment. No dosage adjustment is recommended in patients with mild hepatic impairment (Child-Pugh A), but they may experience an increased risk of somnolence.

Drugs/Diseases

Util A	Util B	Util C (Include)
Lemborexant 10 mg		Hepatic Impairment

Max Dose: 5 mg/day

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Dayvigo Prescribing Information, Dec. 2019, Eisai Inc.

3. Lemborexant / Cirrhosis _____ _____

Alert Message: Dayvigo (lemborexant) is not recommended in patients with severe hepatic impairment. In drug studies, lemborexant exposure (AUC and Cmax) and terminal half-life were increased in patients with moderate hepatic impairment (Child-Pugh B). Lemborexant has not been studied in patients with severe hepatic impairment.

Drugs/Diseases

Util A	Util B	Util C
Lemborexant	Cirrhosis	

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Dayvigo Prescribing Information, Dec. 2019, Eisai Inc.

4. Lemborexant / Therapeutic Appropriateness _____ _____

Alert Message: Dayvigo (lemborexant) use is contraindicated in patients with narcolepsy. Lemborexant is a central nervous system (CNS) depressant that can impair daytime wakefulness even when used as prescribed.

Drugs/Diseases

Util A	Util B	Util C (Include)
Lemborexant		Narcolepsy

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Dayvigo Prescribing Information, Dec. 2019, Eisai Inc.

5. Lemborexant / Sleep Paralysis & Hallucinations _____ _____

Alert Message: Sleep paralysis (an inability to move or speak for up to several minutes during sleep-wake transitions) and hypnagogic/hypnopompic hallucinations (including vivid and disturbing perceptions) can occur with the use of Dayvigo (lemborexant). Symptoms similar to mild cataplexy also can occur with lemborexant. Such symptoms can include periods of leg weakness lasting from seconds to a few minutes, can occur either at night or during the day, and may not be associated with an identified triggering event (e.g., laughter or surprise). Prescribers should explain the nature of these events to patients when prescribing lemborexant.

Drugs/Diseases

Util A	Util B	Util C
Lemborexant	Recurrent Sleep Paralysis	
	Hallucinations	

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Dayvigo Prescribing Information, Dec. 2019, Eisai Inc.

6. Lemborexant / Complex Sleep Behaviors _____ _____

Alert Message: Complex sleep behaviors, including sleep-walking, sleep-driving, and engaging in other activities while not fully awake (e.g., preparing and eating food, making phone calls, having sex), have been reported to occur with the use of hypnotics such as Dayvigo (lemborexant). Discontinue lemborexant immediately if a patient experiences a complex sleep behavior.

Drugs/Diseases

Util A	Util B	Util C
Lemborexant	Sleep Walking	
	Other Parasomnia	

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Dayvigo Prescribing Information, Dec. 2019, Eisai Inc.

7. Lemborexant / Suicidal Ideation & Depression _____ _____

Alert Message: Worsening of depression or suicidal thinking may occur in patients receiving Dayvigo (lemborexant). Prescribe the lowest number of tablets feasible to avoid intentional overdose. The emergence of any new behavioral sign or symptom of concern requires careful and immediate evaluation.

Drugs/Diseases

Util A	Util B	Util C
Lemborexant	Depression	
	Suicide Attempt	
	Suicidal Ideation	

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Dayvigo Prescribing Information, Dec. 2019, Eisai Inc.

8. Lemborexant / Compromised Respiratory Function _____ _____

Alert Message: The effect of Dayvigo (lemborexant) on respiratory function should be considered if prescribed to patients with compromised respiratory function. Lemborexant has not been studied in patients with moderate to severe obstructive sleep apnea (OSA) or in patients with chronic obstructive pulmonary disease (COPD).

Drugs/Diseases

Util A	Util B	Util C
Lemborexant	COPD	
	OSA	

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Dayvigo Prescribing Information, Dec. 2019, Eisai Inc.

9. Lemborexant / Moderate & Strong CYP3A4 Inhibitors _____ _____

Alert Message: The concurrent use of Dayvigo (lemborexant) with a moderate or strong CYP3A4 inhibitor should be avoided. Lemborexant is a CYP3A4 substrate, and concomitant use with these drugs has been shown to significantly increase the AUC and Cmax of lemborexant, increasing the risk of lemborexant-related adverse reactions.

Drugs/Diseases

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

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Dayvigo Prescribing Information, Dec. 2019, Eisai Inc.

10. Lemborexant 10 mg / Weak CYP3A4 Inhibitors _____ _____

Alert Message: The maximum recommended dosage of Dayvigo (lemborexant) is 5 mg no more than once per night when coadministered with weak CYP3A inhibitors. Lemborexant is a CYP3A4 substrate, and physiologically-based pharmacokinetic (PBPK) modeling predicted that concomitant use of weak CYP3A inhibitors increased lemborexant exposure by less than 2-fold.

Drugs/Diseases

Util A	Util B	Util C
Lemborexant 10 mg	Chlorzoxazone	
	Cilostazol	
	Fosaprepitant	
	Ivacaftor	
	Lomitapide	
	Ranitidine	
	Ranolazine	
	Tacrolimus	
	Ticagrelor	

Max Dose: 5 mg/day

References:

Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Dayvigo Prescribing Information, Dec. 2019, Eisai Inc.
FDA: Drug Development and Drug Interactions: Tables of Substrates, Inhibitors and Inducers. Available at: http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/DrugInteractionaLabeling/ucm093664.htm

11. Lemborexant / Moderate & Strong CYP3A4 Inducers _____ _____

Alert Message: The concurrent use of Dayvigo (lemborexant) with moderate or strong CYP3A4 inducers should be avoided. Lemborexant is a CYP3A4 substrate, and concomitant use with these inducers has been shown to decrease lemborexant exposure and may reduce lemborexant efficacy.

Drugs/Diseases

Util A	Util B		Util C
Lemborexant	Apalutamide	Bosentan	
	Carbamazepine	Efavirenz	
	Enzalutamide	Etravirine	
	Lumacaftor	Dexamethasone	
	Mitotane	Modafinil	
	Phenobarbital		
	Phenytoin		
	Primidone		
	Rifabutin		
	Rifampin		
	Rifapentine		

References:

Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Dayvigo Prescribing Information, Dec. 2019, Eisai Inc.
FDA: Drug Development and Drug Interactions: Tables of Substrates, Inhibitors and Inducers. Available at: http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/DrugInteractionaLabeling/ucm093664.htm

12. Lemborexant / CYP2B6 Substrates _____ _____

Alert Message: The concurrent use of Dayvigo (lemborexant) with a CYP2B6 substrate may result in the reduced efficacy of the substrate. Lemborexant is CYP2B6 inducer, and concomitant use with a CYP2B6 substrate can lead to decreased substrate exposure. Monitor the patient for adequate CYP2B6 substrate clinical response. Increasing the dose of the substrate may be considered as needed.

Drugs/Diseases

Util A	Util B	Util C
Lemborexant	Bupropion	
	Cyclophosphamide	
	Efavirenz	
	Methadone	

References:

Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Facts & Comparisons, 2020 Updates, Wolters Kluwer health.
Dayvigo Prescribing Information, Dec. 2019, Eisai Inc.
Hedrich WD, Hassan HE, Wang H. Insights into CYP2B6-mediated Drug-drug Interactions. Acta Pharm Sin B. 2016;6(5):413–425. doi:10.1016/j.apsb.2016.07.016

13. Lemborexant / Therapeutic Appropriateness _____ _____

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

Drugs/Diseases

Util A	Util B	Util C
Lemborexant		

Age Range: 0 – 17 yoa

References:

Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Dayvigo Prescribing Information, Dec. 2019, Eisai Inc.

14. Lemborexant / Lactation _____ _____

Alert Message: There are no data on the presence of Dayvigo (lemborexant) in human milk, the effects on the breastfed infant, or the effects on milk production. Lemborexant and its metabolites are present in the milk of lactating rats. Infants exposed to lemborexant through breastmilk should be monitored for excessive sedation. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for lemborexant and any potential adverse effects on the breastfed infant from lemborexant or the underlying maternal condition.

Drugs/Diseases

Util A	Util B	Util C
Lemborexant	Lactation	

Age Range: 11 – 50 yoa
Gender: Female

References:

Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Dayvigo Prescribing Information, Dec. 2019, Eisai Inc.

15. Lemborexant / Pregnancy / Pregnancy Negating _____ _____

Alert Message: There are no available data on Dayvigo (lemborexant) use in pregnant women to evaluate for drug-associated risks of major birth defects, miscarriage, or adverse maternal or fetal outcomes. There is a pregnancy exposure registry that monitors pregnancy outcomes in women who are exposed to lemborexant during pregnancy. Healthcare providers are encouraged to register patients in the DAYVIGO pregnancy registry.

Drugs/Diseases

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

Age Range: 11 – 50 yoa
Gender: Female

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Dayvigo Prescribing Information, Dec. 2019, Eisai Inc.

16. **Bempedoic Acid / Overuse** _____ _____

Alert Message: Nexletol (bempedoic acid) may be over-utilized. The recommended dosage of bempedoic acid, in combination with maximally tolerated statin therapy, is 180 mg orally once daily.

Drugs/Diseases

Util A	Util B	Util C
Bempedoic Acid		

Max Dose: 180 mg/day

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Nexletol Prescribing Information, Feb. 2020, Esperion Therapeutics, Inc.

17. Bempedoic Acid / Therapeutic Appropriateness _____ _____

Alert Message: The safety and effectiveness of Nexletol (bempedoic acid) have not been established in pediatric patients.

Drugs/Diseases

Util A	Util B	Util C
Bempedoic Acid		

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Nexletol Prescribing Information, Feb. 2020, Esperion Therapeutics, Inc.

18. Bempedoic Acid / Therapeutic Appropriateness _____ _____

Alert Message: Nexletol (bempedoic acid) inhibits renal tubular OAT2 and may increase blood uric acid levels. In clinical trials, 26% of bempedoic acid-treated patients with normal baseline uric acid values (versus 9.5% placebo) experienced hyperuricemia one or more times, and 3.5% of patients experienced clinically significant hyperuricemia reported as an adverse reaction (versus 1.1% placebo). Elevated blood uric acid may lead to the development of gout. Monitor patients for signs and symptoms of hyperuricemia, and initiate treatment with urate-lowering drugs as appropriate.

Drugs/Diseases

Util A	Util B	Util C
Bempedoic Acid		

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Nexletol Prescribing Information, Feb. 2020, Esperion Therapeutics, Inc.

19. Bempedoic Acid / Tendon Rupture _____ _____

Alert Message: Nexletol (bempedoic acid) is associated with an increased risk of tendon rupture or injury. In clinical trials, tendon rupture occurred in 0.5% of patients treated with bempedoic acid versus 0% of placebo-treated patients and involved the rotator cuff (the shoulder), biceps tendon, or Achilles tendon. Discontinue bempedoic acid immediately if the patient experiences rupture of a tendon. Consider discontinuing bempedoic acid if the patient experiences joint pain, swelling, or inflammation. Consider alternative therapy in patients with a history of tendon disorders or tendon rupture.

Drugs/Diseases

Util A	Util B	Util C
Bempedoic Acid		

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Nexletol Prescribing Information, Feb. 2020, Esperion Therapeutics, Inc.

20. Bempedoic Acid / Simvastatin 40 & 80 mg _____ _____

Alert Message: The concurrent use of Nexletol (bempedoic acid) with simvastatin causes an increase in simvastatin concentration and may increase the risk of simvastatin-related myopathy. Avoid concomitant use of bempedoic acid with simvastatin greater than 20 mg.

Drugs/Diseases

Util A	Util B	Util C
Bempedoic Acid	Simvastatin 40mg	
	Simvastatin 80mg	

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Nexletol Prescribing Information, Feb. 2020, Esperion Therapeutics, Inc.

21. Bempedoic Acid / Pravastatin 80 mg _____ _____

Alert Message: The concurrent use of Nexletol (bempedoic acid) with pravastatin causes an increase in pravastatin concentration and may increase the risk of pravastatin-related myopathy. Avoid concomitant use of bempedoic acid with pravastatin greater than 40 mg.

Drugs/Diseases

Util A	Util B	Util C
Bempedoic Acid	Pravastatin 80 mg	

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Nexletol Prescribing Information, Feb. 2020, Esperion Therapeutics, Inc.

22. Bempedoic Acid / Pregnancy / Pregnancy Negating _____ _____

Alert Message: Nexletol (bempedoic acid) therapy should be discontinued when pregnancy is recognized unless the benefits of therapy outweigh the potential risks to the fetus. There are no available data on bempedoic acid use in pregnant women to evaluate for a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes. Bempedoic acid decreases cholesterol synthesis and possibly the synthesis of other biologically active substances derived from cholesterol; therefore, bempedoic acid may cause fetal harm when administered to pregnant women based on the mechanism of action.

Drugs/Diseases

Util A	Util B	Util C (Negating)
Bempedoic Acid	Pregnancy	Abortion
		Delivery
		Miscarriage

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Nexletol Prescribing Information, Feb. 2020, Esperion Therapeutics, Inc.

23. Bempedoic Acid / Therapeutic Appropriateness _____ _____

Alert Message: There is no information regarding the presence of Nexletol (bempedoic acid) in human or animal milk, the effects of the drug on the breastfed infant, or the effects of the drug on milk production. Bempedoic acid decreases cholesterol synthesis and possibly the synthesis of other biologically active substances derived from cholesterol and may cause harm to the breastfed infant. Because of the potential for serious adverse reactions in a breastfed infant, based on the mechanism of action, advise patients that breastfeeding is not recommended during treatment with bempedoic acid.

Drugs/Diseases

Util A	Util B	Util C
Bempedoic Acid	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Nexletol Prescribing Information, Feb. 2020, Esperion Therapeutics, Inc.

24. Bempedoic Acid / Non-adherence _____ _____

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

Drugs/Diseases

Util A	Util B	Util C
Bempedoic Acid		

References:

Osterberg L, Blaschke T. Adherence to Medication. N Engl J Med. 2005;353:487-97.
Kumbhani DJ, Steg PG, Cannon CP, et al., Adherence to Secondary Prevention Medications for Four-Year Outcomes in Outpatients with Atherosclerosis. Am J Med. 2013 Aug;126(8):693-700.
Simpson RJ, Mendys P. The Effects of Adherence and Persistence on Clinical Outcomes in Patients Treated with Statins: A Systematic Review. Jrnl Clin Lipidol. 2010 Nov-Dec;4(6):462-471.
Blackburn DF, Dobson RT, Blackburn JL, et al. Cardiovascular Morbidity Associated with Nonadherence to Statin Therapy. Pharmacotherapy 2005;25(8):1035-1043.
Lindgren P, Eriksson J, Buxton M, et al., The Economic Consequences of Non-Adherence to Lipid-Lowering Therapy: Results from the Anglo-Scandinavian Cardia Outcomes Trial. Int J Clin Pract. 2010 May 24.

25. Asenapine Transdermal / Overuse _____ _____

Alert Message: Secuado (asenapine) transdermal system may be over-utilized. The recommended maximum dosage of transdermal asenapine is 7.6 mg/24 hours. The safety of doses above 7.6 mg/24 hours has not been evaluated in clinical studies.

Drugs/Diseases

Util A	Util B	Util C
Asenapine Transdermal		

Max Dose: 7.6 mg patch per day

References:

Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Secuado Prescribing Information, Oct. 2019, Noven Therapeutics, LLC.

26. Asenapine Transdermal / Therapeutic Appropriateness _____ _____

Alert Message: Secuado (asenapine) transdermal system is contraindicated in patients with severe hepatic impairment (Child-Pugh C). In clinical studies, asenapine exposure was shown to be 7-fold higher in subjects with severe hepatic impairment compared to the exposure observed in subjects with normal hepatic function. No dosage adjustment for transdermal asenapine is required in patients with mild to moderate hepatic impairment (Child-Pugh A and B) because asenapine exposure is similar to that in subjects with normal hepatic function.

Drugs/Diseases

Util A	Util B	Util C
Asenapine Transdermal	Cirrhosis Hepatic Failure	

References:

Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Secuado Prescribing Information, Oct. 2019, Noven Therapeutics, LLC.

27. Asenapine Transdermal / Therapeutic Appropriateness _____ _____

Alert Message: The safety and effectiveness of Secuado (asenapine) transdermal system in pediatric patients have not been established.

Drugs/Diseases

Util A	Util B	Util C
Asenapine Transdermal		

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Secuado Prescribing Information, Oct. 2019, Noven Therapeutics, LLC.

28. Asenapine Transdermal / Tardive Dyskinesia _____ _____

Alert Message: Tardive dyskinesia, a syndrome of potentially irreversible, involuntary, dyskinetic movements, may develop in patients treated with antipsychotic drugs, including Secuado (asenapine) transdermal system. The risk appears to be highest among the elderly, especially elderly women, but it is not possible to predict which patients are likely to develop the syndrome. If signs and symptoms of tardive dyskinesia appear in a patient on asenapine, drug discontinuation should be considered. However, some patients may require treatment with asenapine despite the presence of the syndrome.

Drugs/Diseases

Util A	Util B	Util C
Asenapine Transdermal	Tardive Dyskinesia	

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Secuado Prescribing Information, Oct. 2019, Noven Therapeutics, LLC.

29. Asenapine Transdermal / Orthostatic Hypotension _____ _____

Alert Message: Atypical antipsychotics, including Secuado (asenapine) transdermal system, cause orthostatic hypotension and syncope. Generally, the risk is greatest during initial dose titration and when increasing the dose. Orthostatic vital signs should be monitored in patients who are vulnerable to hypotension (elderly patients, patients with dehydration, hypovolemia, concomitant treatment with antihypertensive medications), patients with known cardiovascular disease (history of myocardial infarction or ischemic heart disease, heart failure, or conduction abnormalities), and patients with cerebrovascular disease.

Drugs/Diseases

Util A	Util B	Util C
Asenapine Transdermal	Orthostatic Hypotension	

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Secuado Prescribing Information, Oct. 2019, Noven Therapeutics, LLC.

30. Asenapine Transdermal / QT Prolongation _____ _____

Alert Message: Asenapine has been shown to prolong the QT/QTc interval. The use of Secuado (asenapine) transdermal system should be avoided in patients with a history of cardiac arrhythmias and in other conditions that may increase the risk of the occurrence of torsade de pointes. The use of asenapine transdermal should also be avoided in combination with drugs that increase the QT interval.

Drugs/Diseases

Util A	Util B	Util C
Asenapine Transdermal	Long QT Syndrome	
	Hypokalemia	
	Hypomagnesemia	
	Bradycardia	

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Secuado Prescribing Information, Oct. 2019, Noven Therapeutics, LLC.

31. Asenapine Transdermal / Seizures _____ _____

Alert Message: As with other antipsychotic drugs, Secuado (asenapine) transdermal system should be used with caution in patients with a history of seizures or with conditions that potentially lower the seizure threshold. Conditions that lower the seizure threshold may be more prevalent in patients 65 years or older.

Drugs/Diseases

Util A	Util B	Util C
Asenapine Transdermal	Seizures	

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Secuado Prescribing Information, Oct. 2019, Noven Therapeutics, LLC.

32. Asenapine Transdermal / Strong CYP1A2 Inhibitors _____ _____

Alert Message: The concurrent use of Secuado (asenapine) transdermal system with a strong CYP1A2 inhibitor may result in increases in the AUC and Cmax of asenapine. Asenapine is metabolized by CYP1A2. Dosage reduction for asenapine transdermal based on clinical response may be necessary.

Drugs/Diseases

Util A	Util B	Util C
Asenapine Transdermal	Fluvoxamine	
	Ciprofloxacin	

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Secuado Prescribing Information, Oct. 2019, Noven Therapeutics, LLC.

33. Asenapine Transdermal / Drugs That Cause QT Prolongation _____ _____

Alert Message: The use of Secuado (asenapine) transdermal system should be avoided in combination with other drugs known to prolong the QTc interval, including Class 1A or Class 3 antiarrhythmics, antipsychotic medications, and antibiotics. Asenapine has been associated with increases in the QTc interval.

Drugs/Diseases

Util A	Util B				Util C
Asenapine Transdermal	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	
	Atazanavir	Ezogabine	Midostaurin	Solifenacin	
	Atomoxetine	Famotidine	Mifepristone	Sotalol	
	Azithromycin	Felbamate	Mirabegron	Sunitinib	
	Bedaquiline	Fingolimod	Mirtazapine	Tacrolimus	
	Bortezomib	Flecainide	Moexipril	Tamoxifen	
	Bendamustine	Fluconazole	Moxifloxacin	Telavancin	
	Bosutinib	Fluoxetine	Nelfinavir	Tetrabenazine	
	Buprenorphine	Fluvoxamine	Nilotinib	Thioridazine	
	Ceritinib	Foscarnet	Nortriptyline	Tizanidine	
	Chloroquine	Galantamine	Ofloxacin	Tolterodine	
	Chlorpromazine	Ganciclovir	Ondansetron	Toremifene	
	Cilostazol	Gemifloxacin	Osimertinib	Tramadol	
	Ciprofloxacin	Gilteritinib	Oxaliplatin	Trazodone	
	Citalopram	Glasdegib	Paliperidone	Trimipramine	
	Clarithromycin	Granisetron	Panobinostat	Valbenazine	
	Clomipramine	Haloperidol	Paroxetine	Vandetanib	
	Clozapine	Hydroxychloroquine	Pasireotide	Vemurafenib	
	Crizotinib	Hydroxyzine	Pazopanib	Venlafaxine	
	Dabrafenib	Ibutilide	Pentamidine	Voriconazole	
	Dasatinib	Iloperidone	Pimavanserin		
	Desipramine	Imipramine	Pimozide		
	Deutetrabenazine	Indapamide	Pitolisant		
	Diphenhydramine	Indinavir	Posaconazole		
	Disopyramide	Ivabradine	Procainamide		
	Dofetilide	Itraconazole	Promethazine		
	Dolasetron	Ivosidenib	Propafenone		
	Droperidol	Ketoconazole	Quetiapine		
	Doxepin	Lapatinib	Quinidine		
	Dronedarone	Lefamulin	Quinine		
	Droperidol	Lenvatinib	Ranolazine		

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Secuado Prescribing Information, Oct. 2019, Noven Therapeutics, LLC.

34. Asenapine Transdermal / Paroxetine _____ _____

Alert Message: The concurrent use of Secuado (asenapine) transdermal system with paroxetine may enhance the inhibitory effects of paroxetine on its own metabolism by CYP2D6. Concomitant use of these agents may cause increases in paroxetine AUC and Cmax. Reduce the paroxetine dose by half when paroxetine is used in combination with asenapine.

Drugs/Diseases

Util A	Util B	Util C
Asenapine Transdermal	Paroxetine	

References:

Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Secuado Prescribing Information, Oct. 2019, Noven Therapeutics, LLC.

35. Asenapine Transdermal / Non-adherence _____ _____

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

Drugs/Diseases

Util A	Util B	Util C
Asenapine Transdermal		

References:

Osterberg L, Blaschke T. Adherence to Medication. N Engl J Med 2005;353:487-97.
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.
Theida P, et.al., An Economic Review of Compliance with Medication Therapy in the Treatment of Schizophrenia, Psychiatric Services, 2003;54:508-516.
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.

36. Ubrogepant / Overuse _____ _____

Alert Message: Ubrelvy (ubrogepant) may be over-utilized. The recommended dose of ubrogepant is 50 mg or 100 mg orally with or without food. If needed, a second dose may be taken at least 2 hours after the initial dose. The maximum dose of ubrogepant in a 24-hour period is 200 mg. The safety of treating more than 8 migraines in a 30-day period has not been established.

Drugs/Diseases

Util A	Util B	Util C (Negate)
Ubrogepant		Cirrhosis
		CKD 4
		CKD 5

Max Dose: 200 mg/day

References:

Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Ubrelvy Prescribing Information, Dec. 2019, Allergan.

37. Ubrogepant / Overuse _____ _____

Alert Message: Ubrelvy (ubrogepant) may be over-utilized. The recommended initial dose of ubrogepant in patients with severe hepatic impairment (Child-Pugh C) or severe renal impairment (CLcr 15-29 mL/min) is 50 mg. If needed, a second dose may be taken at least 2 hours after the initial dose. The maximum dose of ubrogepant in a 24-hour period is 100 mg. The safety of treating more than 8 migraines in a 30-day period has not been established.

Drugs/Diseases

Util A	Util B	Util C (Include)
Ubrogepant		Cirrhosis
		CKD 4
		CKD 5

Max Dose: 100 mg/day

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Ubrelvy Prescribing Information, Dec. 2019, Allergan.

38. Ubrogepant / ESRD _____ _____

Alert Message: The use of Ubrelvy (ubrogepant) should be avoided in patients with end-stage renal disease (CLcr < 15mL/min). Ubrogepant has not been studied in patients with ESRD, and no dosing recommendations can be made for this patient population.

Drugs/Diseases

Util A	Util B	Util C (Include)
Ubrogepant		ESRD

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Ubrelvy Prescribing Information, Dec. 2019, Allergan.

39. Ubrogepant / Therapeutic Appropriateness _____ _____

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

Drugs/Diseases

Util A	Util B	Util C
Ubrogepant		

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Ubrelvy Prescribing Information, Dec. 2019, Allergan.

40. Ubrogepant / Strong CYP3A4 Inhibitors _____ _____

Alert Message: The co-administration of Ubrelvy (ubrogepant) with strong CYP3A4 inhibitors is contraindicated. Ubrogepant is a CYP3A4 substrate, and concurrent use with a strong inhibitor may lead to significant increases in ubrogepant exposure. In in vivo studies, the co-administration of ubrogepant with ketoconazole (a strong CYP3A4 inhibitor) resulted in a 9.7-fold and 5.3-fold increase in the AUCinf and Cmax of ubrogepant, respectively.

Drugs/Diseases

Util A	Util B		Util C
Ubrogepant	Clarithromycin	Nelfinavir	
	Cobicistat	Posaconazole	
	Conivaptan	Ritonavir	
	Indinavir	Saquinavir	
	Itraconazole	Voriconazole	
	Ketoconazole		

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Ubrelvy Prescribing Information, Dec. 2019, Allergan.

41. Ubrogepant 100 mg / Moderate CYP3A4 Inhibitors _____ _____

Alert Message: When Ubrelvy (ubrogepant) is co-administered with a moderate CYP3A4 inhibitor, the initial dose of ubrogepant should be limited to 50 mg, and the use of a second dose within 24 hours should be avoided. In in vivo drug studies, the co-administration of ubrogepant (a CYP3A4 substrate) with the moderate CYP3A4 inhibitor, verapamil, resulted in an approximate 3.5-fold and 2.8-fold increase in the AUCinf and Cmax of ubrogepant, respectively.

Drugs/Diseases

Util A	Util B		Util C
Ubrogepant 100 mg	Aprepitant	Erythromycin	
	Ciprofloxacin	Fluconazole	
	Crizotinib	Fluvoxamine	
	Cyclosporine	Imatinib	
	Diltiazem	Verapamil	
	Dronedarone		

References:
IBM Micromedex DRUGDEX (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA 2020.
Facts & Comparisons, 2020 Updates, Wolters Kluwer Health.
Ubrelvy Prescribing Information, Dec. 2019, Allergan.

42. Ubrogepant 100 mg / Weak CYP3A4 Inhibitors _____ _____

Alert Message: When Ubrelvy (ubrogepant) is co-administered with a weak CYP3A4 inhibitor the initial dose of ubrogepant should be limited to 50 mg and the second dose, if needed, should be limited to 50 mg also. No dedicated drug interaction study has been conducted with ubrogepant (a CYP3A4 substrate) and a weak CYP3A4 inhibitor, but the conservative prediction of the maximal potential increase in ubrogepant exposure with weak CYP3A4 inhibitors is not expected to be more than 2-fold.

Drugs/Diseases

Util A	Util B		Util C
Ubrogepant 100 mg	Amiodarone	Lapatinib	
	Chlorzoxazone	Lomitapide	
	Cilostazol	Ranitidine	
	Fosaprepitant	Ranolazine	
	Istradefylline	Tacrolimus	
	Ivacaftor	Ticagrelor	

References:
IBM Micromedex DRUGDEX (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA 2020.
Facts & Comparisons, 2020 Updates, Wolters Kluwer Health.
Ubrelvy Prescribing Information, Dec. 2019, Allergan.

43. Ubrogepant / Strong CYP3A4 Inducers _____ _____

Alert Message: The concurrent use of Ubrelvy (ubrogepant) with strong CYP3A4 inducers should be avoided. Ubrogepant is a CYP3A4 substrate, and concurrent use with a strong CYP3A4 inducer may result in decreased ubrogepant exposure and loss of efficacy. In in vivo drug studies, the co-administration of ubrogepant with the strong CYP3A4 inducer, rifampin, resulted in an approximate 80% reduction in ubrogepant exposure.

Drugs/Diseases

Util A	Util B		Util C
Ubrogepant	Carbamazepine	Phenytoin	
	Enzalutamide	Primidone	
	Mitotane	Rifampin	
	Phenobarbital		

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Ubrelvy Prescribing Information, Dec. 2019, Allergan.

44. Ubrogepant 100 mg / BCRP and/or P-gp Only Inhibitors _____ _____

Alert Message: When Ubrelvy (ubrogepant) is co-administered with a BCRP and/or P-gp only inhibitor, the initial dose of ubrogepant should be limited to 50 mg and the second dose, if needed, should be limited to 50 mg also. No dedicated drug interaction study has been conducted with ubrogepant (a BCRP and P-gp substrate) and BCRP and P-gp efflux inhibitors, but an increase in ubrogepant exposure may result from co-administration of these drugs.

Drugs/Diseases

Util A	Util B	Util C
Ubrogepant 100 mg	Carvedilol	
	Eltrombopag	
	Quinidine	

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Ubrelvy Prescribing Information, Dec. 2019, Allergan.

45. Ubrogepant / Lactation _____ _____

Alert Message: There are no data on the presence of Ubrelvy (ubrogepant) in human milk, the effects ubrogepant on the breastfed infant, or the effects of ubrogepant on milk production. In lactating rats, oral dosing with ubrogepant resulted in levels of ubrogepant in milk comparable to peak plasma concentrations. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for ubrogepant and any potential adverse effects on the breastfed infant from ubrogepant or underlying maternal condition.

Drugs/Diseases

Util A	Util B	Util C
Ubrogepant	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Ubrelvy Prescribing Information, Dec. 2019, Allergan.

46. Ubrogepant / Pregnancy / Pregnancy Negating _____ _____

Alert Message: There are no adequate data on the developmental risk associated with the use of Ubrelvy (ubrogepant) in pregnant women. In animal studies, adverse effects on embryofetal development were observed following administration of ubrogepant during pregnancy (increased embryofetal mortality in rabbits) or during pregnancy and lactation (decreased body weight in offspring in rats) at doses greater than those used clinically and which were associated with maternal toxicity.

Drugs/Diseases

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

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Ubrelvy Prescribing Information, Dec. 2019, Allergan.

47. Larotrectinib / Overutilization _____ _____

Alert Message: Vitrakvi (larotrectinib) may be over-utilized. The recommended dosage of larotrectinib in adult and pediatric patients with a body surface area (BSA) of at least 1.0 m2 is 100 mg orally twice daily, with or without food, until disease progression or until unacceptable toxicity. The recommended dosage in pediatric patients with a BSA area less than 1.0 m2 is 100 mg/m2 orally twice daily, with or without food, until disease progression or until unacceptable toxicity.

Drugs/Diseases

Util A	Util B	Util C
Larotrectinib		

Max Dose: 200 mg/day

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Vitrakvi Prescribing Information, July 2019, Bayer HealthCare Pharmaceuticals Inc.

48. Larotrectinib / Strong CYP3A4 Inhibitors _____ _____

Alert Message: The concurrent use of Vitrakvi (larotrectinib), a CYP3A4 substrate, with strong CYP3A4 inhibitors should be avoided. If coadministration of a strong CYP3A4 inhibitor cannot be avoided, reduce the larotrectinib dose by 50%. After the inhibitor has been discontinued for 3 to 5 elimination half-lives, resume the larotrectinib dose taken prior to initiating the CYP3A4 inhibitor.

Drugs/Diseases

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

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Vitrakvi Prescribing Information, July 2019, Bayer HealthCare Pharmaceuticals Inc.

49. Larotrectinib / Strong CYP3A4 Inducers _____ _____

Alert Message: The concurrent use of Vitrakvi (larotrectinib), a CYP3A4 substrate, with strong CYP3A4 inducers should be avoided. If coadministration of a strong CYP3A4 inducer cannot be avoided, the larotrectinib dose should be double. After the inducer has been discontinued for 3 to 5 elimination half-lives, resume the larotrectinib dose taken prior to initiating the CYP3A4 inducer.

Drugs/Diseases

Util A	Util B		Util C
Larotrectinib	Carbamazepine	Primidone	
	Enzalutamide	Rifabutin	
	Mitotane	Rifampin	
	Phenytoin	Rifapentine	
	Phenobarbital		

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Vitrakvi Prescribing Information, July 2019, Bayer HealthCare Pharmaceuticals Inc.

50. Larotrectinib / Sensitive CYP3A4 Substrates _____ _____

Alert Message: The concurrent use of Vitrakvi (larotrectinib), a CYP3A4 inhibitor, with sensitive CYP3A4 substrates should be avoided. If coadministration of a sensitive CYP3A4 substrate cannot be avoided, monitor the patient for substrate-related adverse reactions.

Drugs/Diseases

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

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Vitrakvi Prescribing Information, July 2019, Bayer HealthCare Pharmaceuticals Inc.
FDA: Drug Development and Drug Interactions: Tables of Substrates, Inhibitors and Inducers. Available at: http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/DrugInteractionaLabeling/ucm093664.htm

51. Larotrectinib / Pregnancy / Pregnancy Negating _____ _____

Alert Message: Based on literature reports in human subjects with congenital mutations leading to changes in TRK signaling, findings from animal studies, and its mechanism of action, Vitrakvi (larotrectinib) can cause fetal harm when administered to a pregnant woman. Larotrectinib resulted in malformations in rats and rabbits at maternal exposures that were approximately 11- and 0.7- times, respectively, those observed at the clinical dose of 100 mg twice daily. Advise women of the potential risk to a fetus. Advise females of reproductive potential to use an effective method of contraception during treatment and for 1 week after the final dose of larotrectinib.

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Drugs/Diseases

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

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Vitrakvi Prescribing Information, July 2019, Bayer HealthCare Pharmaceuticals Inc.

52. Larotrectinib / Lactation _____ _____

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

Drugs/Diseases

Util A	Util B	Util C
Larotrectinib	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Vitrakvi Prescribing Information, July 2019, Bayer HealthCare Pharmaceuticals Inc.

53. Larotrectinib / Reproductive Potential _____ _____

Alert Message: Vitrakvi (larotrectinib) can cause fetal harm. The manufacturer advises the use of effective contraception during treatment with larotrectinib and for at least 1 week after the final dose.

Drugs/Diseases

Util A	Util B	Util C (Negating)
Larotrectinib		Contraceptives

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Vitrakvi Prescribing Information, July 2019, Bayer HealthCare Pharmaceuticals Inc.

54. Larotrectinib / Reproductive Potential _____ _____

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

Drugs/Diseases

Util A	Util B	Util C
Larotrectinib		

Gender: Male

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Vitrakvi Prescribing Information, July 2019, Bayer HealthCare Pharmaceuticals Inc.

55. Voxelotor / Overuse _____ _____

Alert Message: Oxbryta (voxelotor) may be over-utilized. The recommended maximum daily dose of voxelotor in adults and pediatric patients 12 years of age and older is 1500 mg once daily with or without food.

Drugs/Diseases

Util A	Util B	Util C (Negating)
Voxelotor		Cirrhosis
		Strong or Moderate CYP3A4 Inducers
		Strong CYP3A4 Inhibitors & Fluconazole

Max Dose: 1500 mg/day

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Oxbryta Prescribing Information, Nov. 2019, Global Blood Therapeutics, Inc.

56. Voxelotor / Overuse – Hepatic Impairment _____ _____

Alert Message: Oxbryta (voxelotor) may be over-utilized. The recommended dosage of voxelotor in patients with severe hepatic impairment (Child-Pugh C) is 1000 mg taken once daily with or without food. No dosage adjustment of voxelotor is required for patients with mild or moderate hepatic impairment.

Drugs/Diseases

Util A	Util B	Util C (Include)
Voxelotor		Cirrhosis

Max Dose: 1000 mg/day

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Oxbryta Prescribing Information, Nov. 2019, Global Blood Therapeutics, Inc.

57. Voxelotor / Strong CYP3A4 Inhibitors & Fluconazole _____ _____

Alert Message: The co-administration of Oxbryta (voxelotor) with strong CYP3A4 inhibitors or fluconazole should be avoided due to the increased risk of voxelotor toxicity. If concurrent use is warranted, decrease the voxelotor dosage to 1000 mg once daily.

Drugs/Diseases

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

Max Dose: 1000 mg/day

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Oxbryta Prescribing Information, Nov. 2019, Global Blood Therapeutics, Inc.

58. Voxelotor / Moderate & Strong CYP3A4 Inducers _____ _____

Alert Message: The co-administration of Oxbryta (voxelotor) with moderate or strong CYP3A4 inducers should be avoided. Concurrent use of these agents with voxelotor, a CYP3A4 substrate, may result in decreased voxelotor plasma concentrations and loss of efficacy. If concurrent use is warranted, increase the voxelotor dosage to 2500 mg once daily.

Drugs/Diseases

Util A	Util B			Util C
Voxelotor	Bosentan	Mitotane	Rifapentine	
	Butabarbital	Modafinil	Rifampin	
	Carbamazepine	Nevirapine		
	Dexamethasone	Phenobarbital		
	Enzalutamide	Phenytoin		
	Efavirenz	Primidone		
	Etravirine	Rifabutin		

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Oxbryta Prescribing Information, Nov. 2019, Global Blood Therapeutics, Inc.

59. Voxelotor / Sensitive CYP3A4 Substrates w/ NTI _____ _____

Alert Message: The co-administration of Oxbryta (voxelotor) with sensitive CYP3A4 substrates with a narrow therapeutic index should be avoided. In vivo drug studies have shown that concurrent use of voxelotor, a weak CYP3A4 inhibitor, with midazolam resulted in increased midazolam exposure by 1.6-fold and the predicted increase in patients after multiple dosing is 2-fold. If concomitant use is unavoidable, consider a dose reduction of the sensitive CYP3A4 substrate(s).

Drugs/Diseases

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

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Oxbryta Prescribing Information, Nov. 2019, Global Blood Therapeutics, Inc.
1398 / FDA: Drug Development and Drug Interactions: Tables of Substrates, Inhibitors and Inducers. Available at: http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/DrugInteractionaLabeling/ucm093664.htm

60. Voxelotor / Therapeutic Appropriateness _____ _____

Alert Message: The safety and efficacy of Oxbryta (voxelotor) in pediatric patients below the age of 12 years have not been established.

Drugs/Diseases

Util A	Util B	Util C
Voxelotor		

Age Range: 0 – 11 yoa

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Oxbryta Prescribing Information, Nov. 2019, Global Blood Therapeutics, Inc.

61. Voxelotor / Pregnancy / Pregnancy Negating _____ _____

Alert Message: There are no available data on Oxbryta (voxelotor) use in pregnant women to evaluate for a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes. Voxelotor should only be used during pregnancy if the benefit of the drug outweighs the potential risk.

Drugs/Diseases

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

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Oxbryta Prescribing Information, Nov. 2019, Global Blood Therapeutics, Inc.

62. Voxelotor / Lactation _____ _____

Alert Message: There are no data on the presence of Oxbryta (voxelotor) in human milk, the effects on the breastfed child, or the effects on milk production. Because of the potential for serious adverse reactions in the breastfed child, including changes in the hematopoietic system, advise patients that breastfeeding is not recommended during treatment with voxelotor, and for at least 2 weeks after the last dose.

Drugs/Diseases

Util A	Util B	Util C
Voxelotor	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Oxbryta Prescribing Information, Nov. 2019, Global Blood Therapeutics, Inc.

63. Levamlodipine / Overuse _____ _____

Alert Message: Conjupri (levamlodipine) may be over-utilized. The recommended maximum daily adult dose is 5 mg once daily.

Drugs/Diseases

Util A	Util B	Util C
Levamlodipine		

Max Dose: 5 mg/day
Age Range: 18 – 999 yoa

References:
Facts & Comparisons, 2020 Updates, Wolters Kluwer Health.
Conjupri Prescribing Information, Dec. 2019, CSPC Ouyi Pharmaceutical Co., Ltd.

64. Levamlodipine / Therapeutic Appropriateness _____ _____

Alert Message: Conjupri (levamlodipine) may be over-utilized. The effective antihypertensive oral dose in pediatric patients 6 to 17 years of age is 2.5 mg once daily. Doses in excess of 2.5 mg daily have not been studied in pediatric patients.

Drugs/Diseases

Util A	Util B	Util C
Levamlodipine		

Age Range: 6 – 17 yoa
Max Dose: 2.5 mg/day

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Conjupri Prescribing Information, Dec. 2019, CSPC Ouyi Pharmaceutical Co., Ltd.

65. Levamlodipine / Simvastatin _____ _____

Alert Message: The dose of simvastatin should be limited to 20 mg daily in patients co-administered Conjupri (levamlodipine). Levamlodipine is the pharmacologically active enantiomer of amlodipine. In a drug study, co-administration of amlodipine with simvastatin resulted in a 77% increase in exposure to simvastatin compared to simvastatin alone.

Drugs/Diseases

Util A	Util B	Util C
Levamlodipine	Simvastatin 40 & 80	

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Conjupri Prescribing Information, Dec. 2019, CSPC Ouyi Pharmaceutical Co., Ltd.

66. Levamlodipine / Moderate & Strong CYP3A4 Inhibitors _____ _____

Alert Message: Co-administration of Conjupri (levamlodipine) with moderate or strong CYP3A inhibitors may result in increased systemic exposure to amlodipine and may require levamlodipine dose reduction. Monitor the patient for symptoms of hypotension and edema when amlodipine is co-administered with CYP3A inhibitors to determine the need for dose adjustment.

Drugs/Diseases

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

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Conjupri Prescribing Information, Dec. 2019, CSPC Ouyi Pharmaceutical Co., Ltd.

67. Levamlodipine / Cyclosporine & Tacrolimus _____ _____

Alert Message: The concurrent use of Conjupri (levamlodipine) with cyclosporine or tacrolimus may increase the systemic exposure of the immunosuppressive agent. Frequent monitoring of trough blood levels of cyclosporine and tacrolimus is recommended and adjust the dose when appropriate.

Drugs/Diseases

Util A	Util B	Util C
Levamlodipine	Cyclosporine	
	Tacrolimus	

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Conjupri Prescribing Information, Dec. 2019, CSPC Ouyi Pharmaceutical Co., Ltd.

68. Amifampridine / Overutilization _____ _____

Alert Message: Firdapse (amifampridine) may be over-utilized. The recommended maximum total daily dosage of amifampridine is 80 mg.

Drugs/Diseases

Util A	Util B	Util C
Amifampridine		

Max Dose: 80 mg/day

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Firdapse Prescribing Information, November 2018, Catalyst Pharmaceuticals.

69. Amifampridine / History of Seizures _____ _____

Alert Message: Firdapse (amifampridine) is contraindicated in patients with a history of seizures. Seizures have been observed in patients without a history of seizures taking amifampridine at the recommended doses, at various times after initiation of treatment, at an incidence of approximately 2%. Many of the patients were taking medications or had comorbid medical conditions that may have lowered the seizure threshold. Seizures may be dose-dependent. Consider discontinuation or dose-reduction of amifampridine in patients who have a seizure while on treatment.

Drugs/Diseases

Util A	Util B	Util C (Include)
Amifampridine		Seizures
		Convulsions

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Firdapse Prescribing Information, November 2018, Catalyst Pharmaceuticals.

70. Amifampridine / Cholinergic Drugs _____ _____

Alert Message: The concomitant use of Firdapse (amifampridine) and drugs with cholinergic effects (e.g., direct or indirect cholinesterase inhibitors) may increase the risk of adverse reactions due to additive cholinergic effects.

Drugs/Diseases

Util A	Util B	Util C
Amifampridine	Donepezil	
	Galantamine	
	Pyridostigmine	
	Rivastigmine	

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Firdapse Prescribing Information, November 2018, Catalyst Pharmaceuticals.

71. Amifampridine / Therapeutic Appropriateness _____ _____

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

Drugs/Diseases

Util A	Util B	Util C
Amifampridine		

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Firdapse Prescribing Information, November 2018, Catalyst Pharmaceuticals.

72. Amifampridine / Drugs that Lower Seizure Threshold _____ _____

Alert Message: The concomitant use of Firdapse (amifampridine) with drugs that lower seizure threshold may lead to an increased risk of seizures. The decision to administer amifampridine concomitantly with drugs that lower the seizure threshold should be carefully considered in light of the severity of the associated risks.

Drugs/Diseases

Util A	Util B		Util C
Amifampridine	1st Generation Antipsychotics	SNRIs	
	Aripiprazole	SSRIs	
	Asenapine	Steroids	
	Baclofen	Stimulants	
	Bupropion	Tacrolimus	
	Clozapine	TCAs	
	Diphenhydramine	Tramadol	
	Olanzapine	Ziprasidone	
	Paliperidone		
	Quetiapine		
	Quinolones		

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Firdapse Prescribing Information, November 2018, Catalyst Pharmaceuticals.

73. Amifampridine / Pregnancy / Pregnancy Negating _____ _____

Alert Message: There are no data on the developmental risk associated with the use of Firdapse (amifampridine) in pregnant women. In animal studies, administration of amifampridine phosphate to rats during pregnancy and lactation resulted in developmental toxicity (increase in stillbirths and pup deaths, reduced pup weight, and delayed sexual development) at doses associated with maternal plasma drug levels lower than therapeutic drug levels.

Drugs/Diseases

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

Age Range: 11 – 50 yoa
Gender: Female

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Firdapse Prescribing Information, November 2018, Catalyst Pharmaceuticals.

74. Amifampridine / Lactation _____ _____

Alert Message: There are no data on the presence of Firdapse (amifampridine) in human milk, the effects on the breastfed infant, or the effects on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for amifampridine and any potential adverse effects on the breastfed infant from amifampridine or the underlying maternal condition. In lactating rats, amifampridine was excreted in milk and reached levels similar to those in maternal plasma.

Drugs/Diseases

Util A	Util B	Util C
Amifampridine	Lactation	

Age Range: 11 – 50 yoa
Gender: Female

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Firdapse Prescribing Information, November 2018, Catalyst Pharmaceuticals.

75. Amifampridine / Nonadherence _____ _____

Alert Message: Based on the refill history, your patient may be underutilizing Firdapse (amifampridine). 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
Amifampridine		

References:
Osterberg L, Blaschke T. Adherence to Medication. N Engl J Med 2005; 353:487- 497.
Marcum ZA, Sevick MA, Handler SM. Medication Nonadherence: A Diagnosable and Treatable Medical Condition. *JAMA*. 2013;309(20):2105–2106. doi:10.1001/jama.2013.4638.
Kleinsinger F. The Unmet Challenge of Medication Nonadherence. Perm J. 2018;22:18–033. doi:10.7812/TPP/18-033.

76. Lasmiditan / Overuse _____ _____

Alert Message: Reyvow (lasmiditan) may be over-utilized. The maximum dose of lasmiditan is 200 mg. The recommended dose of lasmiditan is 50 mg, 100 mg, or 200 mg taken orally, as needed. No more than one dose should be taken in a 24 hour period. A second dose of lasmiditan has not been shown to be effective for the same migraine attack. The safety of treating more than 4 migraine attacks in a 30-day period has not been established.

Drugs/Diseases

Util A	Util B	Util C
Lasmiditan		

Max Dose: 200 mg/day

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Reyvow Prescribing Information, Oct. 2019, Eli Lilly and Company.

77. Lasmiditan / Therapeutic Appropriateness _____ _____

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

Drugs/Diseases

Util A	Util B	Util C
Lasmiditan		

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Reyvow Prescribing Information, Oct. 2019, Eli Lilly and Company.

78. Lasmiditan / Therapeutic Appropriateness _____ _____

Alert Message: Reyvow (lasmiditan) has not been studied in patients with severe hepatic impairment (Child-Pugh C), and its use in these patients is not recommended.

Drugs/Diseases

Util A	Util B	Util C
Lasmiditan	Cirrhosis	

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Reyvow Prescribing Information, Oct. 2019, Eli Lilly and Company.

79. Lasmiditan / CNS Depressants _____ _____

Alert Message: Reyvow (lasmiditan) can cause central nervous system (CNS) depression, including dizziness and sedation. Because of the potential for lasmiditan to cause sedation, other cognitive and/or neuropsychiatric adverse reactions, and driving impairment, lasmiditan should be used with caution if used in combination with alcohol or other CNS depressants.

Drugs/Diseases

Util A	Util B	Util C
Lasmiditan	Anticonvulsants	
	Antidepressants	
	Antihistamines	
	Antipsychotics	
	Barbiturates	
	Benzodiazepines	
	Cannabidiol	
	Muscle Relaxants	
	Narcotics	
	Sedative/Hypnotics	

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Reyvow Prescribing Information, Oct. 2019, Eli Lilly and Company.

80. Lasmiditan / Serotonergic Agents _____ _____

Alert Message: Caution should be exercised when Reyvow (lasmiditan) is co-administered with drugs that increase serotonin (i.e., SSRIs, SNRIs, TCAs, and MAOIs) due to the increased risk for serotonin syndrome. In clinical trials, the use of lasmiditan (a 5-HT1F receptor agonist) has been associated with reactions consistent with serotonin syndrome. Lasmiditan should be discontinued if serotonin syndrome is suspected.

Drugs/Diseases

Util A	Util B	Util C
Lasmiditan	Buspirone	
	Bupropion	
	Fentanyl	
	Linezolid	
	MAOIs	
	Meperidine	
	SNRIs	
	SSRIs	
	TCA's	
	Trazodone	
	Tramadol	
	Triptans	

References:

Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Reyvow Prescribing Information, Oct. 2019, Eli Lilly and Company.

81. Lasmiditan / P-gp and BCRP Substrates _____ _____

Alert Message: Concomitant use of Reyvow (lasmiditan) and drugs that are P-gp or BCRP substrates should be avoided. Lasmiditan has been shown to inhibit P-gp and BCRP transport in vitro. Concurrent use of lasmiditan with these substrates would be expected to decrease substrate exposure and efficacy.

Drugs/Diseases

Util A	Util B		Util C
Lasmiditan	Afatinib	Methotrexate	
	Apixaban	Morphine	
	Aliskiren	Nilotinib	
	Alpelisib	Quinidine	
	Ambrisentan	Paliperidone	
	Canagliflozin	Pazopanib	
	Colchicine	Pibrentasvir	
	Dabigatran	Prazosin	
	Digoxin	Ranolazine	
	Dolutegravir	Rivaroxaban	
	Edoxaban	Rosuvastatin	
	Empagliflozin	Saxagliptin	
	Erythromycin	Sirolimus	
	Everolimus	Sitagliptin	
	Fexofenadine	Sulfasalazine	
	Fluvastatin	Talazoparib	
	Gefitinib	Tenofovir	
	Glyburide	Topotecan	
	Imatinib	Verapamil	
	Indinavir		
	Lapatinib		
	Loperamide		
	Maraviroc		

References:

Reyvow Prescribing Information, Oct. 2019, Eli Lilly and Company.
Lee CA, O'Connor MA, Ritchie TK, et al., Breast Cancer Resistance Protein (ABCG2) in Clinical Pharmacokinetics and Drug Interactions: Practical Recommendations for Clinical Victim and Perpetrator Drug-Drug Interaction Study Design. Drug Metab Dispos. 2015 Apr;43(4):490-509. doi:10.1124/dmd.114.062174.

82. Lasmiditan / Heart Rate Lowering Drugs _____ _____

Alert Message: Caution should be exercised when Reyvow (lasmiditan) is co-administered with drugs that lower heart rate, due to the risk of decreased heart rate. In clinical trials, lasmiditan use was associated with a mean decrease in heart rate of 5 to 10 beats per minute (bpm).

Drugs/Diseases

Util A	Util B		Util C
Lasmiditan	Amiodarone	Flecainide	
	Beta Blockers	Galantamine	
	Brigatinib	Ivabradine	
	Carbamazepine	Lacosamide	
	CCBs	Lanreotide	
	Ceritinib	Lithium	
	Clonidine	Mexiletine	
	Crizotinib	Pasireotide	
	Digoxin	Procainamide	
	Disopyramide	Propafenone	
	Donepezil	Quinidine	
	Dronedarone	Rivastigmine	
	Fingolimod	Siponimod	
		Thalidomide	

References:

Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Reyvow Prescribing Information, Oct. 2019, Eli Lilly and Company.

83. CDK 4/6 Inhibitors / ILD Symptoms and Interstitial Pneumonitis _____ _____

Alert Message: Severe, life-threatening, or fatal interstitial lung disease (ILD) and/or pneumonitis can occur in patients treated with CDK 4/6 inhibitors (abemaciclib, palbociclib, and ribociclib). Monitor patients for pulmonary symptoms indicative of ILD/pneumonitis. Symptoms may include hypoxia, cough, dyspnea, or interstitial infiltrates on radiologic exams. Dose interruption or dose reduction is recommended for patients who develop persistent or recurrent Grade 2 ILD/pneumonitis. Permanently discontinue the CDK 4/6 inhibitor in all patients with Grade 3 or 4 ILD or pneumonitis.

Drugs/Diseases

Util A	Util B	Util C
Abemaciclib	Acute Interstitial Pneumonitis	
Palbociclib	Cough	
Ribociclib	Dyspnea	
	Fever	
	Hypoxemia	

References:

Clinical Pharmacology, 2019 Elsevier/Gold Standard.
US Food & Drug Administration. FDA Drug Safety Communications. FDA Warns About Rare But Severe Lung Inflammation with Ibrance, Kisqali, and Verzenio for Breast Cancer. Safety Announcement. [09-13-2019]. Available at: https://www.fda.gov/drugs/drug-safety-and-availability/fda-warns-about-rare-severe-lung-inflammation-ibrance-kisqali-and-verzenio-breast-cancer.

North Dakota Medicaid
Drug Utilization Review Board
Meeting
December 2, 2020
Via Teleconference

North Dakota Medicaid
DUR Board Meeting Agenda
Join Microsoft Teams Meeting

(Click on link)
Join by phone: 1 701-328-0950, Conference ID: 312 304 233#
December 2, 2020
1:00 pm

1. Administrative items
    - DHS announcements

2. Old business
    - Review and approval of September 2020 meeting minutes
    - Budget update
    - Review top 25 drugs for Third quarter of 2020
    - Prior authorization/PDL update
    - Second review of agents for the treatment of diabetic gastroparesis
    - Second review of Ohriahnn (elagolix/estradiol/norethindrone)
    - Second review of Dojolvi (triheptanoin)
    - Update to criteria for Nucala (mepolizumab) for hypereosinophilic syndrome & EGPA
    - Annual prior authorization review of prior authorization forms and criteria

3. New business
    - Review of Evrysdi (risdiplam)
    - Retrospective DUR criteria recommendations
    - Upcoming meeting date/agenda.
        - Next meeting is March 3, 2021
4. Adjourn

Please remember to silence all cellular phones during the meeting.

Drug Utilization Review (DUR) Meeting Minutes
September 3, 2020

Members Present: Andrea Honeyman, Mary Aaland, Joshua Askvig, Gabriela Balf, Jennifer Iverson, Katie Kram, Cory Miller, Laura Schield, Tanya Schmidt, Amy Werremeyer, Peter Woodrow

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

Old Business

Chair A. Honeyman called the meeting to order at 1:01 p.m. B. Joyce announced the appointment of Joshua Askvig to the DUR Board. Chair A. Honeyman asked for a motion to approve the minutes of the June meeting. K. Kram moved that the minutes be approved, and P. Woodrow seconded the motion. The chair called for a voice vote to approve the minutes. The motion passed with no audible dissent. B. Joyce presented the quarterly budget update to the DUR Board.

Review Top 25 Drugs

T. DeRuiter and B. Joyce presented the quarterly review of the top 25 drugs based on total cost od claims, as well as the top AHFS drug classes by cost and claims count based on the total number of claims for the 2nd quarter of 2020.

PDL/PA Criteria Updates

A. Murphy presented the updates and changes to medications requiring prior authorization to the Board since the most recent version of the Preferred Drug List was posted. Changes included additions to the PA criteria approved by the Board at the prior DUR Board meeting, as well as adding new agents and formulations to prior authorization class criteria, where applicable. Notable changes included Nurtec ODT, Reyvow, Ajovy, Harvoni Pallet, and Sovaldi Pallet being added require prior authorization, as well as Harvoni 45 mg/200mg tablet and Sovaldi 200 mg tablet being added to the preferred list of Hepatits C treatment agents. All PDL updates are listed in the handouts for the June 2020 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 Palforzia

A motion and second was made at the June 2020 DUR Board meeting to place Palforzia on prior authorization. The topic was brought up for a second review. Prior authorization criteria were presented to the Board by T. DeRuiter. S. Payne from Aimmune made herself available to the Board for questions. During Board discussion, M. Aaland requested that the Prior Authorization request forms be changed from “to be completed by physician”, to make the request forms more accurate. P. Woodrow made a motion that the state amend and update the prior authorization request forms accordingly to reflect that the forms may be filled out by prescribers or their representatives at the states discretion, and K. Kram seconded the motion. The chair called for a voice vote to approve the motion to update the request forms, which passed without audible dissent. Chair A. Honeyman called for a voice vote to approve the criteria, which passed with no audible dissent.

Second Review of Mytesi
A motion and second was made at the June 2020 DUR Board meeting to place Mytesi on prior authorization. The topic was brought up for a second review. Prior authorization criteria were presented to the Board by T. DeRuiter. There were no public comments. Chair A. Honeyman called for a voice vote to approve the updated criteria, which passed with no audible dissent.

Second Review of Antifibrinolytic Agents
A motion and second was made at the June 2020 DUR Board meeting to place antifibrinolytic agents on prior authorization. The topic was brought up for a second review. Prior authorization criteria were presented to the Board by T. DeRuiter. There were no public comments. Chair A. Honeyman called for a voice vote to approve the updated criteria, which passed with no audible dissent.

Second Review of ACL Inhibitors
A motion and second was made at the June 2020 DUR Board meeting to place the ACL inhibitors on prior authorization. The topic was brought up for a second review. T. DeRuiter presented Prior authorization criteria for all lipid lowering agents that combines previously approved prior authorization criteria for lipid lowering agents with new prior authorization criteria for ACL inhibitors. There were no public comments. Chair A. Honeyman called for a voice vote to approve the updated criteria, which passed with no audible dissent.

Second Review of Cystic Fibrosis Agents (CFTR Inhibitors)
A motion and second was made at the June 2020 DUR Board meeting to place CFTR inhibitors for cystic fibrosis on prior authorization. The topic was brought up for a second review. Prior authorization criteria were presented to the Board by T. DeRuiter. There were no public comments. Chair A. Honeyman called for a voice vote to approve the updated criteria, which passed with no audible dissent.

New Business
Review of Agents for the Treatment of Diabetic Gastroparesis
T. DeRuiter presented a review of agents for the treatment of diabetic gastroparesis to the Board.. A motion was made by A. Werremeyer to manage this class of medications through prior authorization. The motion was seconded by L. Schield. Prior authorization criteria for these agents will be presented, reviewed, and voted on by the Board at the next meeting.

Review of Oriahnn
T. DeRuiter a review of Oriahnn to the Board. During public comment, J. Gianninoto from Abbvie presented an overview of clinical information to the Board. During Board discussion, G. Balf requested that future pricing data also reflect the cost of treatment over a period of time as opposed to just cost per package or unit cost. T. DeRuiter agreed to add this information to future presentations. A motion was made by P. Woodrow to manage this medication through prior authorization. The motion was seconded by K. Kram. Prior authorization criteria for these agents will be presented, reviewed, and voted on by the Board at the next meeting.

Review of Dojolvi

T. DeRuiter and A. Murphy presented a review of antifibrinolytic agents to the Board. During public comment, T. Arnhart Rusinak from Ultragenyx presented an overview of clinical information on Dojolvi to the Board, including explaining the difference between Dojolvi and medical foods. A motion was made by K. Kram to manage this agent through prior authorization. The motion was seconded by A. Werremeyer. Prior authorization criteria for these agents will be presented, reviewed, and voted on by the Board at the next meeting.

Report on Utilization of Benzodiazepines and Opioids Concurrently

Since 2017, North Dakota Medicaid has put claims processing edits and prior authorization criteria on skeletal muscle relaxants to promote safe and effective use of these agents. T. DeRuiter presented utilization data comparing the use of skeletal muscle relaxants in 2017 vs 2020, including total patient and prescription counts during this time. The data showed that use of all skeletal muscle relaxants other than orphenadrine has been lowered since implementing these utilization requirements, with the largest drop being in cyclobenzaprine utilization.

North Dakota Medicaid implemented prior authorization class criteria for topical steroids in 2017. T. DeRuiter presented utilization data comparing the use of topical corticosteroids by potency class in 2017 vs 2018 (after criteria had been implemented), including total prescription counts and claims cost information. The data showed that utilization in each potency category remained roughly the same in 2018 as in 2017, however claims cost was reduced in each category (16%-38% reduction in cost by potency category and overall claims cost reduction of ~25%).

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. M. Aaland moved to approve the new criteria and L. Schield seconded the motion. The motion passed with no audible dissent.

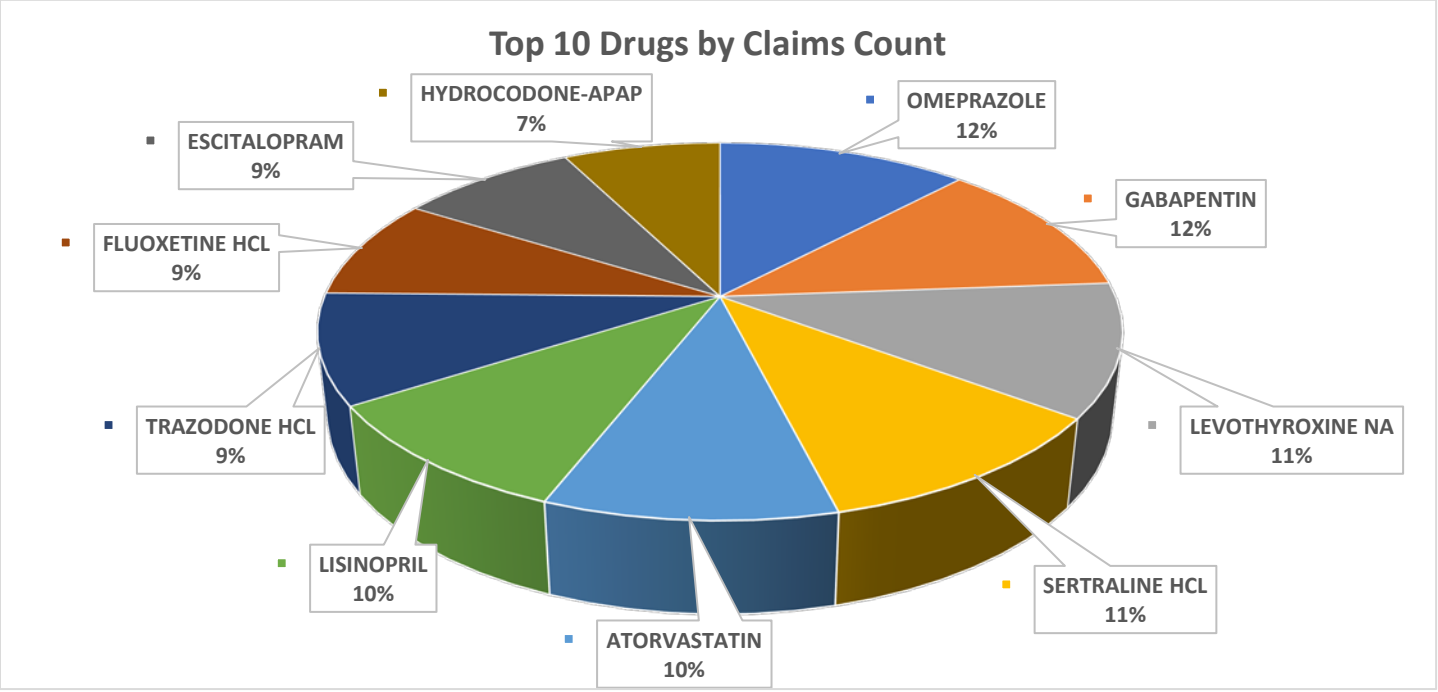
Adjournment and Upcoming Meeting Date

K. Kram made a motion to adjourn, which was seconded by A. Werremeyer. Chair A. Honeyman adjourned the meeting at 3:00 pm. The next DUR Board meeting will be held December 2, 2020 at 1:00 pm via teleconference.

Top 25 Drugs Based on Number of Claims from 07/01/2020 – 09/30/2020

Drug	Claims	Patients	Claims Cost	Cost Per Claim	% Total Claims
OMEPRAZOLE	4,421	2,173	$57,716.90	$13.06	1.92%
GABAPENTIN	4,369	1,833	$81,280.27	$18.60	1.90%
LEVOTHYROXINE	4,316	1,669	$70,284.45	$16.28	1.87%
SERTRALINE HCL	4,141	2,115	$55,929.71	$13.51	1.80%
ATORVASTATIN	3,856	1,874	$54,671.99	$14.18	1.67%
LISINOPRIL	3,733	1,891	$47,482.79	$12.72	1.62%
TRAZODONE HCL	3,587	1,715	$49,919.95	$13.92	1.56%
FLUOXETINE HCL	3,369	1,655	$46,725.57	$13.87	1.46%
ESCITALOPRAM	3,365	1,756	$44,832.14	$13.32	1.46%
HYDROCODONE-APAP	2,815	1,788	$40,149.52	$14.26	1.22%
MONTELUKAST	2,725	1,402	$34,036.58	$12.49	1.18%
METFORMIN HCL	2,536	1,321	$46,535.48	$18.35	1.10%
PANTOPRAZOLE	2,518	1,217	$43,984.52	$17.47	1.09%
BUPROPION XL	2,500	1,177	$40,685.84	$16.27	1.08%
DULOXETINE HCL	2,490	1,090	$33,985.61	$13.65	1.08%
PROAIR HFA	2,285	2,290	$28,810.56	$12.61	0.99%
AMLODIPINE BESYLATE	2,201	1,135	$34,545.56	$15.70	0.96%
VYVANSE	2,180	856	$27,460.74	$12.60	0.95%
CYCLOBENZAPRINE HCL	2,162	1,298	$124,696.96	$57.68	0.94%
LAMOTRIGINE	2,107	795	$537,697.83	$255.20	0.91%
BUPRENORPHINE-NALOXONE	2,076	464	$28,404.11	$13.68	0.90%
CLONIDINE HCL	2,010	982	$33,804.42	$16.82	0.87%
ARIPIPRAZOLE	1,994	925	$26,756.14	$13.42	0.87%
VENLAFAXINE HCL ER	1,988	820	$28,299.07	$14.23	0.86%
CLONAZEPAM	1,925	868	$22,883.22	$11.89	0.84%

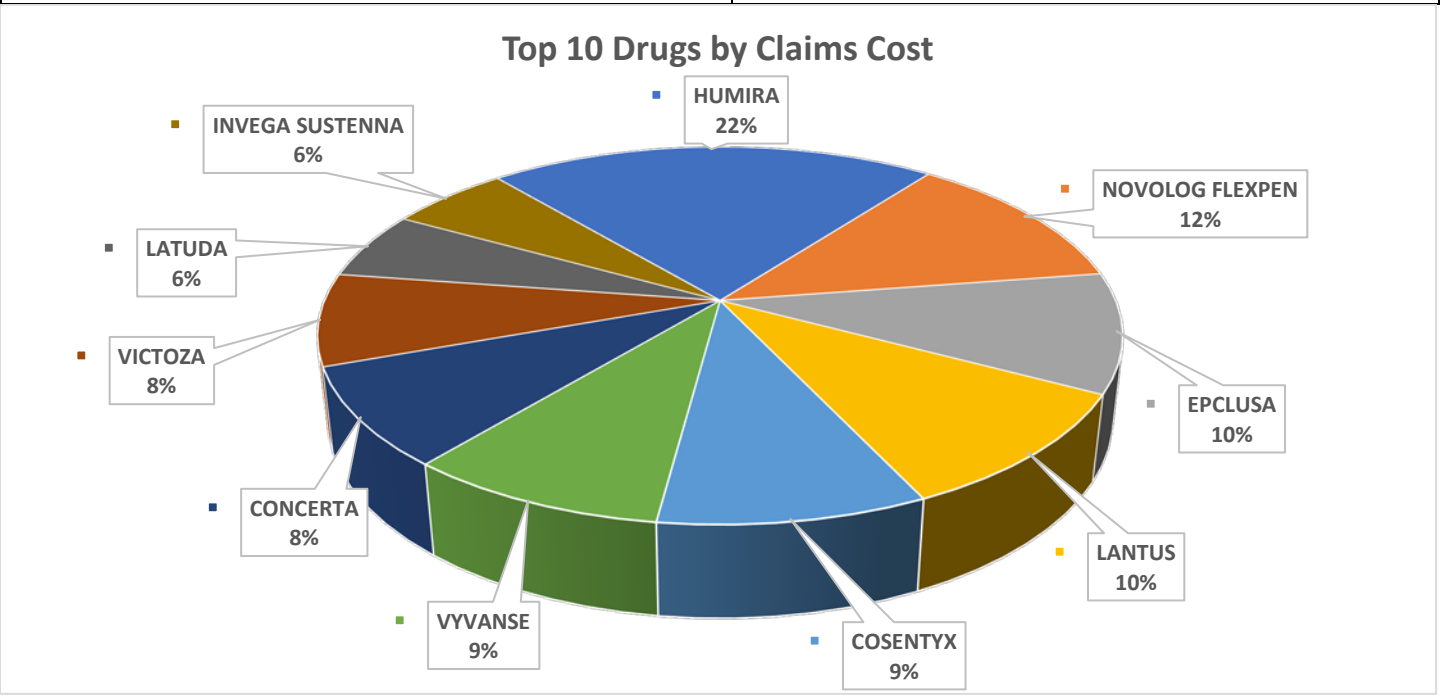
Total Claims From 07/01/2020 – 09/30/2020	252,990



Top 25 Drugs Based on Total Claims Cost from 07/01/2020 – 09/30/2020

Drug	Claims Cost	Claims	Patients	Cost Per Claim	% Total Cost
HUMIRA	$1,327,982.27	213	92	$6,234.66	5.13%
NOVOLOG FLEXPEN	$758,610.23	1,087	586	$697.89	2.93%
EPCLUSA	$632,990.80	26	12	$24,345.80	2.45%
LANTUS	$628,718.57	1326	714	$474.15	2.43%
COSENTYX	$565,542.14	90	35	$6,283.80	2.18%
VYVANSE	$551,971.82	2,247	856	$245.65	2.13%
CONCERTA	$522,532.58	1,568	627	$333.25	2.02%
VICTOZA	$488,520.13	643	286	$759.75	1.89%
LATUDA	$357,545.53	488	187	$732.68	1.38%
INVEGA SUSTENNA	$357,307.69	159	64	$2,247.22	1.38%
TRIKAFTA	$334,720.26	14	4	$23,908.59	1.29%
NORDITROPIN FLEXPRO	$332,481.59	90	43	$3,694.24	1.28%
LEVEMIR	$326,662.89	596	316	$548.09	1.26%
JARDIANCE	$325,967.42	718	298	$453.99	1.26%
STELARA	$324,289.61	15	11	$21,619.31	1.25%
ENBREL	$309,567.02	61	23	$5,074.87	1.20%
MAVYRET	$297,435.24	26	19	$11,439.82	1.15%
SYMBICORT	$288,124.52	884	469	$325.93	1.11%
ADVAIR DISKUS	$265,621.40	754	436	$352.28	1.03%
SABRIL	$249,777.36	13	5	$19,213.64	0.96%
XIFAXAN	$238,578.58	109	52	$2,188.79	0.92%
ADDERALL XR	$233,490.79	1,337	538	$174.64	0.90%
BIKTARVY	$226,643.76	129	53	$1,756.93	0.88%
NOVOLOG	$204,660.23	309	138	$662.33	0.79%
ABILIFY MAINTENA	$196,194.77	95	38	$2,065.21	0.76%

Total Claims Cost From 07/01/2020 – 09/30/2020	**$25,884,220.60**



Top 15 Therapeutic Classes Based on Number of Claims from 07/01/2020 – 09/30/2020

Therapeutic Class Description	Claims	Patients	Claims Cost	Cost/Claim	% Total Claims
ANTIDEPRESSANTS	28,567	10,230	$579,160	$20.27	11.96%
ANTICONVULSANTS, MISC	13,631	4,349	$887,697	$65.12	5.65%
ANTIPSYCHOTIC AGENTS	9,146	3,034	$1,540,012	$168.38	3.90%
PROTON-PUMP INHIBITORS	7,966	3,539	$137,836	$17.30	3.21%
OPIATE AGONISTS	7,652	3,602	$150,397	$19.65	2.83%
NSAIDS	6,999	4,025	$99,698	$14.24	2.77%
STATINS	6,492	3,015	$93,534	$14.41	2.76%
SEDATIVE/HYPNOTICS	6,020	2,787	$94,471	$15.69	2.44%
BETA BLOCKERS	5,779	2,612	$106,966	$18.51	2.41%
ACE INHIBITORS	5,022	2,391	$74,239	$14.78	2.08%
THYROID AGENTS	4,830	1,735	$93,279	$19.31	2.02%
AMPHETAMINES	4,663	1,801	$826,747	$177.30	1.88%
NON-AMPHETAMINE STIMULANTS	4,164	1,495	$734,890	$176.49	1.73%
BIGUANIDES	4,137	1,972	$55,081	$13.31	1.72%
BENZODIAZEPINES	3,665	1,718	$57,606	$15.72	1.57%

Top 15 Therapeutic Classes Based on Claims Cost from 07/01/2020 – 09/30/2020

Therapeutic Class Description	Claims Cost	Claims	Patients	Cost/Claim	% Total Cost
INSULINS	$2,065,971	3,615	1,239	$568.04	7.98%
DMARDS	$1,903,321	373	151	$4,943.69	7.35%
ANTIPSYCHOTIC AGENTS	$1,540,012	8,986	3,034	$168.38	5.95%
SKIN & MUCOUS MEMBRANE AGENTS, MISC	$1,180,057	437	290	$2,448.25	4.56%
HCV ANTIVIRALS	$930,426	13,019	31	$17,892.81	3.59%
INHALED CORTICOSTEROIDS	$911,582	750	1,808	$275.24	3.52%
ANTICONVULSANTS, MISC	$887,697	3,982	4,349	$65.12	3.43%
AMPHETAMINES	$826,747	3,069	1,801	$177.30	3.19%
ANTIRETROVIRALS	$818,909	4,342	229	$1,246.44	3.16%
NON-AMPHETAMINE STIMULANTS	$734,890	880	1,495	$176.49	2.84%
INCRETIN MIMETICS	$690,797	32	412	$715.11	2.67%
ANTINEOPLASTIC AGENTS	$627,960	27,567	195	$1,156.46	2.43%
ANTIDEPRESSANTS	$579,160	518	10,230	$20.27	2.24%
IMMUNOMODULATORY AGENTS MISC	$470,770	61	24	$7,132.88	1.82%
SGLT2 INHIBITORS	$402,427	1,614	376	$450.14	1.55%

Prior Authorization/PDL Update

ADDED TO PA	
Drug	**Class**
Byetta	Prophylaxis of Migraine – CGRP Inhibitors
Conjupri	Calcium Channel Blockers
Cresemba	Antifungals - Aspergillus and Candidiasis Infections
Cystadrops	>$3000/month
Cystaran	>$3000/month
Enspryng	>$3000/month
Evrysdi	>$3000/month
Nexizet	Lipid-Lowering Agents
Nexletol	Lipid-Lowering Agents
Ongentyx	Parkinson's Agents - COMT inhibitor
Repatha	Lipid-Lowering Agents
trientine	>$3000/month
Vumerity	Multiple Sclerosis
Xarelto 2.5mg	Anticoagulants - Oral
Zerviate	Antihistamines

REMOVED FROM PA	
Drug	**Class**
Acanya	Acne
clindamycin-benzoyl peroxide 1%-5%	Acne
Evoclin	Acne
fondaparinux	Anticoagulants - Injectable
Namzaric	Alzheimer's agents
Omnaris	Steroids-Nasal
Onasl Children's	Steroids-Nasal
Otezla	Cytokine Modulators
tolterodine	Urinary Antispasmodics
tolterodine ER	Urinary Antispasmodics
Toujeo Max Solostar	Insulin
Tresiba 200unit/mL	Insulin
Xeljanz	Cytokine Modulators
Xeljanz XR	Cytokine Modulators
Zalapar ODT	Parkinson's Agents - MAO-B inhibitors
Zepatier	Hepatitis C
Zyclara 3.75% cream pump	Acne

Diabetic Gastroparesis

General Prior Authorization Form

Non-Preferred Agents Criteria:

- **Initial Criteria:** *Approval Duration = 3 months*
  - The patient must have an FDA-approved indication for use (meets label recommendations for diagnosis and age)
  - Clinical justification must be provided explaining why the patient is unable to use the solid dosage formulation, with relevant medical documentation (e.g. swallow study) attached to the request (subject to clinical review)
  - The patient must not have any of the following contraindications to treatment with metoclopramide:
    - Diagnosis of epilepsy
    - Gastrointestinal hemorrhage, mechanical obstruction, or perforation
    - Tardive dyskinesia
- **Renewal Criteria:** *Approval Duration = 3 months*
  - The patient 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)

Oriahnn

General Prior Authorization Form

Group Criteria:

- **Initial Criteria:** *Approval Duration = 12 months*
  - The patient must have an FDA-approved indication for use (meets label recommendations for diagnosis and age)
  - The patient must not be pregnant
  - The provider must attest that the patient does not have any contraindications to treatment with Oriahnn
- The patient must have failed the following trials (A and B), as evidenced by paid claims or pharmacy printouts:
  - A. A 3-cycle trial of mefenamic acid or meclofenamate, celecoxib, ibuprofen 1800mg/day or equivalent high dose NSAID
  - B. A 3-cycle trial of an oral estrogen-progestin or progestin contraceptives
- **Renewal Criteria:** *Approval Duration = 12 months*
  - The patient must not have received ≥24 months of Oriahnn, as evidenced by paid claims or pharmacy printouts
  - The provider must attest that the patient does not have any contraindications to treatment with Oriahnn
  - The patient 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)

PA REQUIRED
ORIAHNN (elagolix/estradiol/norethindrone)

Dojolvi

General Prior Authorization Form

Group Criteria:

- **Non-Preferred Agents Criteria:** *Approval Duration = 12 months*
  - The patient must have an FDA-approved indication for use (meets label recommendations for diagnosis and age)
  - The provider must attach documentation of DNA testing confirming the patient's diagnosis of a long-chain fatty acid oxidation disorder

PA REQUIRED
DOJOLVI (triheptanoin)

Nucala

Eosinophilic Granulomatosis with Polyangiitis (EGPA)

General Prior Authorization Form

Group Criteria:

- **Initial Criteria:** *Approval Duration = 6 months*
  - The prescription must be written by, or in consultation with, a hematologist, pulmonolgist, or allergy/immunology specialist
  - The patient must be 18 years of age or older
  - The patient must have a diagnosis of eosinophilic granulomatosis with polyangiitis (EGPA) characterized by the following (A-C), as evidenced by medical documentation attached to the request:
    A. Patient has asthma that is poorly controlled on moderate doses of inhaled glucocorticoids
    B. Patient has a blood eosinophilia count >1000 cells/mcL or 10% eosinophils on differential leukocyte count, as evidenced by laboratory documentation attached to the request
    C. 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 patient must have experienced relapsing or recurring disease requiring systemic corticosteroids in the past year, despite a 3-month trial of one of the following medications, as evidenced by paid claims or pharmacy printouts:
    - Cyclophosphamide
    - Azathioprine
    - Methotrexate
    - Leflunomide
- **Renewal Criteria:** *Approval Duration = 12 months*
  - The patient 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)

Hypereosinophilic Syndrome

General Prior Authorization Form

Group Criteria:

- **Initial Criteria:** *Approval Duration = 6 months*
  - The patient 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 patient must have a diagnosis of hypereosinophilic syndrome (HES) characterized by the following:
    - The patient must have experienced hypereosinophilic syndrome for ≥6 months
    - The provider must attest that there is no identifiable nonhematologic secondary cause
  - The patient 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 patient 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 patient 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 Drug List (PDL)

Including:

Prior Authorization Criteria
Therapeutic Duplication
Electronic Step Care and Concurrent Medications
First Fill
Underutilization

Published By:

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North Dakota Department of Human Services
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Bismarck, ND 58505-0250

NORTH Dakota | Human Services
Be Legendary.™

Version 2021.1

Effective: January 1, 2021

Please use the NDC Drug Lookup to find Prior Authorization (PA) Forms

Guiding Rules of the Preferred Drug List (PDL):

THIS LIST REFERS TO MEDICATIONS PROCESSED BY PHARMACY POINT OF SALE SYSTEMS.

For Clinic Administered Drugs - Prior authorization criteria for medication claims processed by physician/clinic billing using 837P codes can be found at the end of this document or by using this link:
Clinic Administered Drugs - Prior Authorization Criteria.
For medications not on this list, FDA or compendia supported indications are required.

- Prior authorization criteria apply in addition to the general Drug Utilization Review policy that is in effect for the entire pharmacy program
    - Other documents explaining coverage rules can be found at www.hidesigns.com/ndmedicaid:
        - Preferred Diabetic Supply List (PDSL)
        - Coverage Rules on Medications

- Please use the NDC Drug Lookup tool to access PA form, view coverage status, quantity limits, copay, and prior authorization information for all medications.

- Length of prior authorizations is a year unless otherwise specified.

- The use of pharmaceutical samples will not be considered when evaluating the member's medical condition or prior prescription history for drugs that require prior authorization.

- Prior authorization for a non-preferred agent in any category will be given only if all other criteria is met, including clinical criteria and step therapy specific to that category. Requests for non-preferred brand name agents with a generic formulation available must meet the Dispense as Written (DAW1) criteria for approval in addition to as any other applicable coverage criteria/rule (unless otherwise noted).

- A trial will be considered a failure if a product was not effective at maximum tolerated dose with good compliance, as evidenced by paid claims or pharmacy print outs or patient has a documented contraindication, intolerance, or adverse reaction to an ingredient

- Unless otherwise specified, the listing of a brand or generic name includes all legend forms of that drug. OTC drugs are not covered unless specified.

*** - Indicates that additional PA criteria applies as indicated in the Product PA Criteria

Contents

Please use the NDC Drug Lookup to find Prior Authorization (PA) Forms

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Please use the NDC Drug Lookup to find Prior Authorization (PA) Forms

General

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 (1-3):
   1. The requested brand-name product must not have an authorized generic available
   2. The patient 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 patient
      b. The patient or prescriber preference is NOT criteria considered for approval
   3. 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:

o The patient must have a diagnosis of an FDA-approved indication for use in line with label recommendations

PA REQUIRED
CYSTADROPS (cysteamine)
CYSTARAN (cysteamine)
ENSPRYNG (satralizumab-mwge)
EVRYSDI (risdiplam)
GATTEX (teduglutide)
INCRELEX (mecasermin)
OXERVATE (cenegermin-bkbj)
SYPRINE (Trientine)

Non-solid dosage preparations

General Prior Authorization Form

Electronic Age Verification

A. Non-solid dosage preparations of preferred products are automatically covered for all patients younger than 9 years old. For coverage of these products in patients 9 years of age or older, one of the following criteria must be met (A or B): The patient 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:

Prior Authorization Form - Non-Preferred Dosage Form

See Preferred Dosage Forms List

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).

Blood Modifying Agents

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** - Patient must have an FDA approved indication

Non-Preferred Agents Criteria:

- The patient must have a diagnosis of an FDA-approved indication.
- The patient 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***}	

Anticoagulants - Injectable

General Prior Authorization Form

Electronic Diagnosis Verification

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

Non-Preferred Agents Criteria:

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

Antifibrinolytic Agents

Prior Authorization Form - Antihemophilic Factors

Group Criteria:

- **Non-Preferred Agents Criteria:** *Approval Duration = 12 months*
  - The patient must have an FDA-approved indication for use (meets label recommendations for diagnosis and age)
  - The patient 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 patient is unable to use all other products (subject to clinical review)

Product Specific Criteria:

- **Non-Solid Dosage Formulations:** The patient must be unable to ingest solid dosage form as evidenced by swallow study documentation

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AMICAR (aminocaproic acid) tablet – *Brand Preferred*	aminocaproic acid oral solution

AMICAR (aminocaproic acid) oral solution– *Brand Preferred*	aminocaproic acid tablet
tranexamic acid tablet	LYSTEDA (tranexamic acid)

Antihemophilic Factor Products

Prior Authorization Form - Antihemophilic Factors

Group Criteria:

- The provider must attest that the patient visits an accredited Hemophilia Treatment Center once per year
- The date of the patient's last appointment with treatment center must be provided
- Contact information for treatment center must be provided

Non-Preferred Agents Criteria:

- Clinical justification must be provided explaining why the patient is unable to use the PREFERRED AGENTS (subject to clinical review).
- The patient 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)	
FACTOR VIII – HEMOPHILIA A	
PREFERRED AGENTS (CLINICAL PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**
ADVATE (factor VIII recombinant)	ADYNOVATE (factor VIII recombinant, PEGylated)
AFSTYLA (factor VIII recombinant, single chain)	ELOCTATE (factor VIII recombinant, Fc fusion protein)
HEMOFIL M (factor VIII plasma derived; mAb-purified)	ESPEROCT (factor VIII recombinant, glycopegylated – exei)
KOATE (factor VIII plasma derived, chromatography purified)	JIVI (factor VIII recombinant, pegylated-aucl)
KOGENATE FS (factor VIII recombinant)	KOVALTRY (factor VIII recombinant)
NOVOEIGHT (factor VIII recombinant)	OBIZUR (recombinant, B domain-deleted porcine factor VIII)
NUWIQ (factor VIII recombinant)	
RECOMBINATE (factor VIII recombinant)	
XYNTHA (factor VIII recombinant)	
XYNTHA SOLOFUSE (factor VIII recombinant)	
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)**
ALPHANINE SD (factor IX, plasma-derived)	ALPROLIX (factor IX recombinant, Fc fusion)
BENEFIX (factor IX recombinant)	IDELVION (factor IX recombinant, albumin fusion)
IXINITY (factor IX recombinant)	REBINYN (factor IX recombinant, glycol-PEGylated)
MONONINE (factor IX, plasma-derived mAb purified)	

PROFILNINE (factor IX complex)	
RIXUBIS (factor IX recombinant)	
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)	

Hematopoietic, Colony Stimulating Factors

General Prior Authorization Form

Group Criteria:

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

Non-Preferred Agents Criteria:

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

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
FULPHILA (Pegfilgrastrim-JMDB)	GRANIX (TBO-Filgrastim)
LEUKINE (Sargramostim)	NEULASTA (Pegfilgrastim)
NEUPOGEN (Filgrastim)	NIVESTYM (Figrastim-AAFI)
UDENYCA (Pegfligrastim-CBQV)	ZARXIO (Filgrastim-SNDZ)
ZIEXTENZO (Pegfligrastim-BMEZ)	

Platelet Aggregation Inhibitors

General Prior Authorization Form

Non-Preferred Agents Criteria:

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

Thrombocytopenia

General Prior Authorization Form

Group Criteria:

- The patient must have an FDA-approved indication for use (meets label recommendations for diagnosis and age).
- Documentation of the patient's current platelet count must be attached to the request

Non-Preferred Agents Criteria:

- The patient 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.

Diagnosis Specific Criteria: Chronic immune thrombocytopenia (ITP):

- Criteria for coverage of **Promacta, Doptelet, Nplate, Tavalisse**:
    - **Initial Criteria:**
        - The provider must attest that the patient's degree of thrombocytopenia and clinical condition increase the risk for bleeding
            - The patient must have experienced an inadequate response after one of the following (A or B):
                A. The patient must have failed a trial of appropriate duration of a corticosteroid or immunoglobulins as evidenced by paid claims or pharmacy print outs
                B. The patient must have undergone a splenectomy
    - **Renewal Criteria:**
        - The patient must be experiencing a significant increase in platelet count and bleeding reduction risk on therapy (supported by documentation)
        - If on maximum dose: The patient's platelet count must have increased to a level sufficient to avoid clinically important bleeding after the recommended duration for the product*
          *Promacta, Nplate, Doptelet: 4 weeks
          *Tavalisse: 12 weeks

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

Diagnosis Specific Criteria: Chronic liver disease-associated thrombocytopenia

- Criteria for coverage of **Doptelet** and **Mulpleta**
    - The patient must have a diagnosis of chronic liver disease
    - The patient must be scheduled to undergo a procedure that puts the patient 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*
      *Doptelet: given from 10-13 to 5-8 days prior to procedure
      *Mulpleta: given from 8-14 to 2-8 days prior to procedure

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

Diagnosis Specific Criteria: Chronic hepatitis C infection-associated thrombocytopenia

- Criteria for coverage of **Promacta**
    - The patient must have a diagnosis of hepatitis C and be currently receiving or planning to initiate interferon-based treatment
        - Prescriber must attest that the patient's degree of thrombocytopenia prevents continuation or initiation of interferon

Diagnosis Specific Criteria: Aplastic Anemia

- Criteria for coverage of **Promacta**
    - One of the following must be met (A or B):
        A. The patient must be receiving Promacta as first-line treatment in combination with standard immunosuppressive therapy (e.e. corticosteroid, Atgam, cyclosporin)

B. The patient must have had an insufficient response to treatment with prior immunosuppressive therapy

Hypertension

Calcium Channel Blockers

General Prior Authorization Form

Group Criteria:

- **Non-Preferred Agents Criteria:** *Approval Duration = 12 months*
  - The patient must have an FDA-approved indication for use (meets label recommendations for diagnosis and age).
  - The patient must have had a 30-day trial of each preferred calcium channel blocker of a unique active ingredient, as evidenced by paid claims or pharmacy printouts.
  - Clinical justification must be provided explaining why the patient is unable to use all other products to treat hypertension (subject to clinical review).

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
Amlodipine	CONJUPRI (levamlodipine)
Felodipine	
Isradipine	
Nicardipine	
Nifedipine	
Nisoldipine	

Vecamyl

General Prior Authorization Form

Group Criteria:

- The patient 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.

Heart Failure

Edecrin

General Prior Authorization Form

Product Specific Criteria:

- **Ethacrynic acid**: One of the following must be met (A or B)
  - The patient must have a documented sulfa allergy
  - The patient 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	

Entresto/Farxiga

Diagnosis

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

AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ENTRESTO (sacubitril/valsartan)	

FARXIGA (dapagliflozin)	

Lipid-Lowering Agents

General Prior Authorization Form

Group Criteria:

- **Initial Criteria:** *Approval Duration = 3 months*
  - The patient must have an FDA-approved indication for use (meets label recommendations for diagnosis and age)
  - The patient must have LDL levels of >130 mg/dL after a 90-day trial of each of the following, as evidenced by paid claims or pharmacy printouts:
    - A lipid lowering agent other than a statin combined with either Crestor (rosuvastatin) ≥20 mg or Lipitor (atorvastatin) ≥ 40 mg
    - A PCSK9 Inhibitor combined with either Crestor (rosuvastatin) ≥20 mg or Lipitor (atorvastatin) ≥ 40 mg
  - The patient must currently be receiving a maximally tolerated statin (HMG-CoA reductase inhibitor) agent, as evidenced by paid claims or pharmacy printouts
  - Clinical justification must be provided explaining why the patient is unable to use all other products to lower their cholesterol (subject to clinical review)
- **Renewal Criteria:** *Approval Duration = 12 months*
  - The patient must currently be receiving a maximally tolerated statin (HMG-CoA reductase inhibitor) agent, as evidenced by paid claims or pharmacy printouts
  - The patient 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)
MTP (Microsomal Triglyceride Transfer Protein) INHIBITOR	
PREFERRED AGENTS (NO PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**
	JUXTAPID (lomitapide)
PCSK9 (Proprotien Convertase Subtilisin/Kexin Type 9) INHIBITORS	
PREFERRED AGENTS (NO PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**
PRALUENT PEN (Alirocumab) – Labeler 72733	PRALUENT PEN (Alirocumab) – Labeler 00024
	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)
JUVISYNC (sitaglipitin/simvastatin)	Fluvastatin ER
LIVALO (pitavastatin)	LESCOL XL (Fluvastatin)
Lovastatin	LIPITOR (atorvastatin)
Pravastatin	PRAVACHOL (pravastatin)
Rosuvastatin	VYTORIN (ezetimibe/simvastatin)
Simvastatin	ZOCOR (simvastatin)

	ZYPITAMAG (pitavastatin)

Pulmonary Hypertension

General Prior Authorization Form

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

Group Criteria:

- The patient 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.
    - o

PREFERRED AGENTS (CLINCAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ALYQ (Tadalafil)	ADCIRCA (Tadalafil) TABLET
REVATIO (Sildenafil) SUSPENSION*** - *Brand Required*	REVATIO (Sildenafil) TABLET
Sildenafil tablet	Sildenafil Suspension
Tadalafil tablet	

Soluble Guanylate Cyclase Stimulators

Electronic Diagnosis Verification

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

Prior Authorization Criteria

Group Criteria:

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

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

Prostacyclins

Electronic Diagnosis Verification

- The patient 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	
VENTAVIS (Iloprost) INHALATION	

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 patient 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 patient is unable to use the preferred agents (subject to clinical review)

CLINDAMYCIN-BENZOYL PEROXIDE	
PREFERRED AGENTS (NO PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**
ACANYA (Clindamycin-benzoyl peroxide) 1.2%-2.5% - *Brand Preferred*	BENZACLIN (Clindamycin/benzoyl peroxide without pump) 1%-5%
Clindamycin-benzoyl peroxide 1%-5% with pump	BENZACLIN (Clindamycin/benzoyl peroxide with pump) 1%-5%
Clindamycin-benzyl peroxide 1.2%-5%	Clindamycin-benzoyl peroxide 1.2%-2.5%
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 Preferred*	CLINDAGEL (Clindamycin) GEL DAILY
ZIANA (Clindamycin-tretinoin 1.2%-0.025%) - *Brand Preferred*	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
RETIN-A (Tretinoin) GEL 0.01%, 0.025% - *Brand Preferred*	ARAZLO (Tazarotene) 0.045% LOTION
RETIN-A (Tretinoin) CREAM - *Brand Preferred*	Clindamycin-tretinoin 1.2%-0.025%
RETIN-A MICRO (Tretinoin Microsphere) GEL WITHOUT PUMP 0.4%, 0.1% - *Brand Preferred* (45 gram size)	FABIOR (Tazarotene) 0.1% FOAM

RETIN-A MICRO PUMP (Tretinoin Microsphere) 0.4%, 0.1% - *Brand Preferred* (45 gram size)	RETIN-A (Tretinoin) GEL 0.05%
RETIN-A MICRO PUMP (Tretinoin Microsphere) 0.08%	RETIN-A MICRO PUMP (Tretinoin Microsphere) 0.06%
Tretinoin gel (Generic co-preferred)	tretinoin microsphere with pump
Tretinoin cream (Generic co-preferred)	tretinoin microsphere without pump
ZIANA (Clindamycin-tretinoin 1.2%-0.025%) - *Brand Preferred*	
ADAPALENE	
PREFERRED AGENTS (NO PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**
Adapalene gel	Adapalene 0.1% cream
Adapalene/Benzoyl Peroxide 0.1%-2.5%	Adapalene 0.3% gel with pump
DIFFERIN (adapalene) CREAM - *Brand Preferred*	DIFFERIN (adapalene) GEL
DIFFERIN (adapalene) GEL W/ PUMP - *Brand Preferred*	EPIDUO (adapalene/benzoyl peroxide) 0.1%-2.5%
DIFFERIN (adapalene) LOTION	
EPIDUO FORTE (adapalene/benzoyl peroxide) 0.3%-2.5%	
OTHER	
PREFERRED AGENTS (NO PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**
ACZONE (Dapsone) GEL WITHOUT PUMP 5% - *Brand Required*	ACZONE (Dapsone) GEL WITH PUMP 7.5%
Cleansing Wash (Sulfacetamide sodium/Sulfur/Urea) 10%-4%-10%	AKLIEF (Trifarotene) CREAM 0.005%
SSS 10-5 (Sulfacetamide) FOAM	BP 10-1 (Sulfacetamide sodium/Sulfur) CLEANSER
Sulfacetamide 10% suspension	Dapsone gel without pump 5%
Sodium Sulfacetamide/Sulfur Cleanser 10%-5% (W/W)	Dapsone gel pump 7.5%
Sodium Sulfacetamide/Sulfur Cleanser 9%-4%	SSS 10-5 (Sulfacetamide) CLEANSER
Sodium Sulfacetamide/Sulfur Cleanser 9%-4.5%	Sodium sulfacetamide/sulfur pads 10%-4%
Sodium Sulfacetamide/Sulfur Cleanser 10%-2%	Sodium Sulfacetamide/Sulfur Cream 10%-2%
Sodium Sulfacetamide/Sulfur Suspension 8%-4%	SUMADAN (Sodium Sulfacetamide/Sulfur) CLEANSER 9%-4.5%
Sodium Sulfacetamide/Sulfur Cleanser 9.8% -4.8%	SUMAXIN (Sodium sulfacetamide/sulfur pads) PADS 10%-4%
SUMAXIN (Sodium Sulfacetamide/Sulfur) CLEANSER 9%-4%	SUMAXIN TS (Sodium Sulfacetamide/Sulfur) SUSPENSION 8%-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
VIBRAMYCIN (Doxycycline calcium) 50 mg/5mL SYRUP	Doxycycline monohydrate tablet 75mg, 150 mg
	Doxycycline hyclate tablet DR
	MINOCIN (Minocycline) CAPSULE
	Minocycline tablet
	Minocycline Tablet ER

Please use the NDC Drug Lookup to find Prior Authorization (PA) Forms

	MINOLIRA ER (Minocycline) TABLET
	MORGIDOX (Doxycycline hyclate) CAPSULE
	SEYSARA (Sarecycline)
	SOLODYN ER (Minocycline) TABLET
	Tetracycline
	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 patient must have an FDA-approved indication for use (meets label recommendations for diagnosis and age).
- The patient 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 Preferred*	ALDARA (Imiquimod) 0.5% CREAM
Diclofenac 3% sodium gel	EFUDEX (Fluorouracil) 5% CREAM
Imiquimod 5% cream packet	Fluorouracil 0.5% cream
Fluorouracil 5% cream	Fluorouracil 2% solution
ZYCLARA (imiquimod) 3.75% CREAM PUMP – *Brand Preferred*	Fluorouracil 5% solution
	Imiquimod 3.75% cream pump
	PICATO (ingenol mebutate)
	TOLAK (Fluorouracil) 4% CREAM
	ZYCLARA (imiquimod) 3.75% CREAM PACKET
	ZYCLARA (imiquimod) 2.5% CREAM PUMP

Antifungals – Topical

General Prior Authorization Form

Diagnosis Specific Criteria:

- **Onychomycosis:** *Approval Duration = 12 months*
  - The patient must have a diagnosis of an FDA approved indication for use
    - Diagnosis must be confirmed by potassium hydroxide (KOH) preparation
  - The patient must have had a trial of one oral agent (terbinafine, fluconazole, or itraconazole), for the length of recommended treatment time for patient'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 patient 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 patient must have had a trial of 3 preferred agents, for the length of recommended treatment time for patient'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 patient 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 Preferred*	LUZU (Luliconazole) Cream
EXELDERM SOLUTION (sulconazole) – *Brand Preferred*	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	VUSION (Miconazole/Zinc/White Petrolatum) OINTMENT
NYAMYC (Nystatin) POWDER	
Nystatin – triamcinolone cream	
Nystatin – triamcinolone ointment	
NYSTOP (Nystatin) POWDER	

Antipsoriatics – Topical

General Prior Authorization Form

Non-Preferred Agents Criteria:

- **For Foams and Sprays:**
  - Patient must have failed 30-day trials of the preferred solution and shampoo formulations, as evidenced by paid claims or pharmacy print outs
- **For Lotions:**
  - Patient must have failed a 30-day trial of a preferred agent, as evidenced by paid claims or pharmacy print outs
- **For Ointments:**
  - Patient 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	calcitriol ointment
SORILUX (calcipotriene) FOAM	DOVONEX (Calcipotriene) CREAM
TACLONEX (calcipotriene/betamethasone) SUSPENSION – *Brand Preferred*	DUOBRII (halobetasol/tazarotene) LOTION
TACLONEX (calcipotriene/betamethasone) OINTMENT – *Brand Preferred*	ENSTILAR (calcipotriene/betamethasone) FOAM
TAZORAC (Tazarotene) CREAM 0.1% - *Brand Preferred*	Tazarotene 0.1% cream
TAZORAC (Tazarotene) GEL	
VECTICAL (Calcitriol) OINTMENT – *Brand Preferred*	

Eczema / Atopic Dermatitis

Electronic Age Verification

Product Specific: Protopic (tacrolimus) ointment 0.1%

- The patient must be 16 years of age or older

Prior Authorization Criteria

Prior Authorization Form - Eczema

Topical Corticosteroids: Please see the Preferred Drug List of Topical Corticosteroids at the end of this document

Category PA Criteria:

- Patient must meet FDA label recommendations for indication and age

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

- **Dupixent and Eucrisa**
    - Patient 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. Patient must have had two 2-week trials of topical corticosteroids of medium or higher potency, as evidenced by paid claims or pharmacy printouts.
        - B. Patient must meet both of the following (1 AND 2):
            1. Affected area is on face, groin, axilla, or under occlusion
            2. Patient 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*

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

PREFERRED AGENTS (NO PA REQUIRED)	PREFERRED AGENTS (CLINCAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ELIDEL (pimecrolimus) CREAM – *Brand Preferred*	DUPIXENT (dupilumab)***	Pimecrolimus
PROTOPIC (tacrolimus) OINTMENT 0.03% – *Brand Preferred*	EUCRISA (crisaborole) OINTMENT***	Tacrolimus 0.03%
PROTOPIC (tacrolimus) OINTMENT 0.1% – *Brand Preferred*		Tacrolimus 0.1%
Topical Corticosteroids		

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 patient 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)
	SKLICE (ivermectin)

Steroids - Topical

General Prior Authorization Form

Non-Preferred Agents Criteria:

- **Non-preferred Step 1 agents (not labeled as "STEP 2"):**
    - The patient 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 patient 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.

See Topical Corticosteroids Preferred Medication List

Endocrinology

Androgens

General Prior Authorization Form

Group Criteria:

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

- The patient 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 patient is unable to use the preferred products (subject to clinical review).

Injectable/Implantable

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS:
Testosterone Cypionate injection	AVEED (Testosterone Undecanoate)
Testosterone Enanthate injection	DEPO-TESTOSTERONE (Testosterone Cypionate)
	TESTOPEL (Testosterone)
	XYOSTED (Testosterone Enanthate)

Oral

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

Diabetes

References:

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

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 patients 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
  - Thiazolidinediones with Insulins or Sulfonylureas
    - Thiazolidinediones increases the adverse effects of hypoglycemia, fluid retention, and heart failure when used concomitantly with sulfonylureas and insulin.
- **COVERED options in combination WITH INSULIN** therapy: GLP-1 Agonists, SGLT-2 inhibitors, 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)

    - Metformin is recommended throughout treatment escalation
- Humulin R U-500 is not allowed with any other insulin (basal or prandial)
    - Humulin R U-500 is indicated for monotherapy. It acts differently than regular insulin (U-100). It provides both basal and prandial coverage. Injections can be increased to 3 times per day for prandial coverage.

Underutilization

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

DPP4-Inhibitors

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-Inhibitors 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.
        - Patients 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 patient must have an FDA-approved indication for use (meets label recommendations for diagnosis and age).
- The patient 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)
    - Victoza
- One of the following must be met (A OR B):
    A. The requested agent is a combination product containing metformin
    B. The patient is currently stable on a metformin-containing agent, with good compliance in the past 3 months, as evidenced by paid claims or pharmacy printouts (patients with GI intolerances to high dose IR metformin should trial at minimum a dose of 500mg ER).

++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/pioglitizone
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

Group Criteria:

Please use the NDC Drug Lookup to find Prior Authorization (PA) Forms

- The prescriber must provide medical justification explaining why the patient 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)
	GLYXAMBI (Empagliflozin/linagliptin)
	STEGLUJAN (Ertugliflozin/Sitagliptin)
	TRIJARDY XR (Empagliflozin/Linagliptan/Metformin)
	++QTERN (Dapagliflozin/Saxagliptin)

GLP-1 Agonists

General Prior Authorization Form

Non-Preferred Step 1 Agents Criteria:

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

- The patient must have an FDA-approved indication for use (meets label recommendations for diagnosis and age).
- The patient 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
  - Ozempic titrated to max dose

Product Specific Criteria:

- ***Adlyxin and Rybelsus:
  - The patient must have had 90-day trials of each of the following, as evidenced by paid claims or pharmacy printouts:
    - Bydureon BCISE
    - Trulicity

++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)	OZEMPIC (semaglutide)	ADLYXIN (lixisenatide)***
BYDUREON (exenatide microspheres)		BYDUREON BCISE (exenatide microspheres)
		++BYETTA (exenatide)
		RYBELSUS (semaglutide)***
		TRULICITY (dulaglutide)

Glucose Rescue Medications

Duration Coverage

- 2 doses (initial and replacement doses) are covered every 180 days without prior authorization

General Prior Authorization Form

Group Criteria (Initial):

- Glucose Rescue medications do NOT require prior authorization for the initial or replacement dose

Group Criteria (Renewal):

- The provider must attest if it is known that the previous dose was taken by the patient (and not diverted or given to another person)
- One of the following criteria must be met (A, B, or C)
    - The previous dose has expired
    - The dose was used by patient for a hypoglycemic episode
    - The patient 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.

Non-Preferred Criteria

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

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
BAQSIMI (Glucagon)	GVOKE (Glucagon)
Glucagon Kit	GLUCOGEN (Glucagon) HYPOKIT

Insulin/GLP-1 Agonist Combination

General Prior Authorization Form

Group Criteria:

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

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS:
	SOLIQUA (Insulin glargine/lixisenatide)
	XULTOPHY (insulin degludec/liraglutide)

Insulin

Duration Coverage

- Products containing NPH insulin are limited to 210 days of coverage for every 365 days to allow for use in pregnancy.
    - Lantus and Levemir have been demonstrated to reduce the risk of symptomatic and nocturnal hypoglycemia compared with NPH insulin.

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).
    - **For dose <100 unit/day**, the same criteria as Toujeo Solostar 100 unit/mL or Tresiba 100 unit/mL must be met as outlined below.
    - **For dose >200 units of insulin per day**, clinical justification must be provided explaining why the patient is not a candidate for U-500R (Toujeo and Tresiba are not intended as replacements for U500 insulin).

Prior Authorization

Insulin Prior Authorization Form

Group Criteria:

- **Non-preferred insulins:**
    - Clinical justification must be provided explaining why the patient is unable to use the preferred products (subject to clinical review).
- **Insulin syringe/pens:**
    - Clinical justification must be provided explaining why the patient is unable to use the preferred insulin vial/pen products (subject to clinical review).

Product Specific Criteria:

- ***Humulin N/Novolin N Vial/Novolin 70/30:** One of the following must be met (A or B):
    A. The patient must be pregnant or breastfeeding
    B. Clinical justification must be provided explaining why the patient is unable to use the preferred NPH products (subject to clinical review).
- ***Fiasp:** The patient 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
- ***Toujeo Solostar 100 unit/mL and 300 unit/mL and Tresiba 100 unit/mL:**
    - **Initial Criteria:** *Approval 6 months*
        - The requested agent must be prescribed by or in consultation with an endocrinologist or diabetes specialist.
        - One of the following must be met, as evidenced by provided clinical notes or labs:
            - The patient experiences recurrent episodes of hypoglycemia on Insulin glargine U100 and insulin detemir U100 despite adjustments to current regimen (prandial insulin, interacting drugs, meal and exercise timing).
            - The patient must be experiencing inconsistent blood sugars after a 90-day trial with good compliance, as evidenced by paid claims or pharmacy printouts of each of the following:
                - Lantus
                - Levemir
        - 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).
- **Toujeo Solostar 100 unit/mL and 300 unit/mL and Tresiba 100 unit/mL Renewal Criteria:** *Approval 12 months*
    - The patient 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)

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
HUMULIN R (insulin regular, human) VIAL	AFREZZA (insulin regular, human)
Insulin aspart flexpen	FIASP (insulin aspart) CARTRIDGE***
Insulin aspart cartridge	FIASP (insulin aspart) SYRINGE***
Insulin aspart syringe	FIASP (insulin aspart) VIAL***
Insulin aspart vial	HUMALOG U-100 (insulin lispro) KWIKPEN
Insulin lispro junior	HUMALOG (insulin lispro) VIAL
Insulin lispro vial	HUMALOG (insulin lispro) CARTRIDGE
Insulin lispro insulin pen	HUMALOG U-200 (insulin lispro) KWIKPEN
NOVOLIN R (insulin regular, human) VIAL	HUMALOG JUNIOR KWIKPEN (insulin lispro)
	LYUMJEV (Insulin lispro-aabc) KWIKPEN
	LYUMJEV (Insulin lispro-aabc) VIAL

	NOVOLOG (insulin aspart) CARTRIDGE
	NOVOLOG (insulin aspart) FLEXPEN
	NOVOLOG (insulin aspart) VIAL
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	TOUJEO SOLOSTAR (insulin glargine)***
LEVEMIR (insulin detemir) VIAL	TRESIBA (insulin degludec) FLEXTOUCH U-100***
LEVEMIR (insulin detemir) FLEXTOUCH	TRESIBA (insulin degludec) VIAL***
TOUJEO MAX SOLOSTAR (insulin glargine)	
TRESIBA (insulin degludec) FLEXTOUCH U-200	
Mixed Insulin	
PREFERRED AGENTS (NO PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**
HUMALOG MIX 50/50 (insulin NPL/insulin lispro) KWIKPEN	Insulin lispro mix 75/25 kwikpen
HUMALOG MIX 75/25 (insulin NPL/insulin lispro) KWIKPEN – *Brand Preferred*	NOVOLIN 70-30 (insulin NPH human/regular insulin human) VIAL
HUMALOG MIX 50/50 (insulin NPL/insulin lispro) VIAL	NOVOLIN 70-30 (insulin NPH human/regular insulin human) FLEXPEN
HUMALOG MIX 75/25 (insulin NPL/insulin lispro) VIAL	NOVOLOG MIX 70/30 (insulin aspart protamine/insulin aspart) FLEXPEN
HUMULIN 70/30 (insulin NPH human/regular insulin human) VIAL	NOVOLOG MIX 70/30 (insulin aspart protamine/insulin aspart) VIAL
HUMULIN 70/30 (insulin NPH human/regular insulin human) KWIKPEN	
Insulin aspart protamine/insulin aspart insulin pen	
Insulin aspart protamine/insulin aspart vial	

Rosiglitazone

General Prior Authorization Form

Product Specific Criteria:

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

++ Clinically Non-preferred: Pioglitazone has a potential benefit over rosiglitazone for ASCVD.

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
Pioglitazone	++Rosiglitazone

SGLT2 Inhibitors

General Prior Authorization Form

Non-Preferred Agents Criteria:

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

- The patient is currently stable on a metformin-containing agent, with good compliance in the past 3 months, as evidenced by paid claims or pharmacy printouts (patients with GI intolerances to high dose IR metformin should trial at minimum a dose of 500mg ER).

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 patient 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 patient 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

Group Criteria:

- Patients new to GH therapy must meet the criteria below and be started on a preferred growth hormone.
    - Patients continuing GH therapy and having met the criteria listed below must be switched to a preferred growth hormone.
- **For Initial or Renewal Requests:**
    - Patient 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:
        - Patient must not have active malignancy
        - Prescriber must be an endocrinologist or nephrologist, or prescriber must have at least one annual consultation about the patient with the pediatric specialty.

        - Patient must not have epiphyseal closure and must still be growing, unless one of the below exceptions is present:
            - Exceptions:
                - Patient has a diagnosis of Prader-Willi syndrome
                - Patient 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.
    - Diagnosis of chronic renal insufficiency (additional criteria):
        - Patient must not have received a renal transplant.
        - Patient 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 patients.
        - Patient 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. Patients 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. Patient 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:
        - Patient must have been compliant with growth hormone (last 6 fills must have been on time).
    - Diagnosis of Prader–Willi syndrome (additional criteria):
        - If patient is obese, BMI must have decreased. If patient is not obese, BMI must have maintained or decreased.

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

Serostim

Prior Authorization Form - Growth Hormone

Product Specific Criteria (Initial):

- Patient must have a diagnosis of treatment of HIV with wasting cachexia
- Patient must not have an active malignancy
- Prescriber must be experienced in the diagnosis and management of HIV infection
- Patient must be on concomitant antiretroviral therapy
- Patient 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
- Patient must not have completed 48 weeks of continuous treatments

Zorbtive

Prior Authorization Form - Growth Hormone

Product Specific Criteria:

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

Osteoporosis

Electronic Diagnosis Verification

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

Prior Authorization Form - Osteoporosis

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

- The patient must have a diagnosis of an FDA-approved indication for use
- The patient must have a current BMD T-score ≤ -2.5 OR new fracture after a 6-month trial of each of the following, as evidenced by paid claims or pharmacy printouts:
  - Alendronate or Risedronate
  - Denosumab
- Patient must be at high risk of fracture, confirmed by at least one of the following:
  - The patient with a history of hip or vertebral fracture
  - The patient with a T-score of −2.5 or lower at the femoral neck or spine
  - The patient who have 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

Product Specific Criteria:

- ***** Alendronate oral solution:**
  - The patient must be unable to ingest solid dosage form as evidenced by swallow study documentation
- *****Tymlos and Miacalcin:**
  - The patient must have a current BMD T-score ≤ -2.5 OR new fracture after a 6-month trial of Forteo (Teriparatide), as evidenced by paid claims or pharmacy printouts
- ***** Teriparatide:**
  - Clinical justification must be provided explaining why Forteo is unable to be used (subject to clinical review).

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
Alendronate	ACTONEL (risedronate)
Alendronate oral solution PA***	EVISTA (Raloxifene)
Calcitonin, Salmon Nasal Spray	FORTEO (Teriparatide)
Ibandronate	MIACALCIN (Calcitonin, Salmon)***
PROLIA (Denosumab)	Teriparatide***
Raloxifene	TYMLOS (Abaloparatide)***
Risedronate	

Pituitary Suppressants

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ELIGARD (leuprolide)	
LUPRON DEPOT (leuprolide)	
SUPPRELIN LA (histrelin)	
SYNAREL (nafarelin)	
TRESTAR (triptorelin)	
TRIPTODUR (triptorelin)	
VANTAS (histrelin)	
ZOLADEX (goserelin)	

Gastrology

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 patient must be 18 years of age or older.
- The patient must have an FDA-approved indication for use (meets label recommendations for diagnosis and age).
- The patient must have had 30-day trials of each of the following, as evidenced by paid claims or pharmacy printouts:
    - Amitiza and Linzess

Product Specific Criteria

- ***Motegrity: The patient 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)	LINZESS (linaclotide) 72 mcg
LINZESS (linaclotide) 145 mcg, 290 mcg	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 30 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 patient must be 18 years of age or older.
- The patient must have an FDA-approved indication for use (meets label recommendations for diagnosis and age).

- The patient must be currently receiving an opioid agent, as evidenced by paid claims or pharmacy printouts.
- The patient must have had 30-day trials of each of the following, as evidenced by paid claims or pharmacy printouts:
    - Amitiza and Movantik

Non-Oral Dose Formulations Criteria:

- The patient must be unable to ingest solid dosage form as evidenced by swallow study documentation

Solid Oral Dose Formulations	
PREFERRED AGENTS (NO PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**
AMITIZA (lubiprostone)	RELISTOR (methylnaltrexone) TABLET
MOVANTIK (naloxegol)	SYMPROIC (naldemedine)
Non-Oral Dose Formulations	
PREFERRED AGENTS (CLINICAL PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**
RELISTOR (methylnaltrexone) SYRINGE	
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

Prior Authorization Criteria

General Prior Authorization Form

Non-Preferred Agents Criteria:

- Initial Criteria: *Approval Duration = 3 months*
    - The patient 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 patient must have had a 30-day trial of each preferred agent, as evidenced by paid claims or pharmacy printouts.
- Renewal Criteria: *Approval Duration = 12 months*
    - The patient 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

Product Specific Criteria:

- ***alosetron**:
    - The patient must be a female.
- ***** **dicylclomine Oral Syrup:** The patient must be unable to ingest solid dosage form as evidenced by swallow study documentation

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 Preferred*	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 patient 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)

Nausea/Vomiting

Chemo Induced

Prior Authorization Form - Nausea/Vomiting

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

- The patient must have diagnosis of nausea and/or vomiting
- Prescriber must be an oncologist
- The patient must be receiving a moderately or highly emetogenic chemotherapy
- The final date of chemotherapy treatment must be provided with the request
- Patient 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
- Patient 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
VARUBI (Rolapitant) TABLET	EMEND (Aprepitant) CAPSULE
	EMEND (Aprepitant) SUSPENSION
5-HT3 RECEPTOR ANTAGONISTS	
PREFERRED AGENTS (NO PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**
AKYNZEO (Netupitant/Palonosetron)	SANCUSO (Granisetron) PATCH
Granisetron tablet	ZOFRAN (Ondansetron) TABLET
Ondansetron ODT	SUSTOL (granisetron) SYRINGE
Ondansetron solution	
Ondansetron tablet	
CANNABINOIDS	
PREFERRED AGENTS (NO PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**
Dronabinol Capsule	MARINOL (Dronabinol) CAPSULE

Pregnancy

Prior Authorization Form - Nausea/Vomiting

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

- Patient must have diagnosis of nausea and vomiting of pregnancy
- Patient's due date must be provided
- The prescriber must submit medical justification explaining why the patient cannot use a preferred product (subject to clinical review)

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
BONJESTA (doxylamine/vitamin B6)	Doxylamine/Vitamin B6
DICLEGIS (doxylamine/vitamin B6) – *Brand Required*	
meclizine	
metoclopramide	
ondansetron	

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:
  - H2 Blockers
  - 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

Electronic Age Verification

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

Electronic Step Care and Concurrent Medications

- Non-Preferred Step 1 Agents: Use least expensive proton pump inhibitors must be trialed first
  - A total of 28 days of 2 preferred agents at max dose must be paid within 90 days prior to step 1 agents date of service.

Prior Authorization Criteria

General Prior Authorization Form

Group Criteria: *Approval Duration = 6 months*

Non-Preferred Agents Criteria: Step 2 Agents:

- Clinical justification must be provided explaining why the patient is unable to use the other agents (subject to clinical review).
- Non-Solid Dosage Forms: The patient must have feeding tube in place

Solid Dosage Forms

SOLID DOSAGE FORMS

Please use the NDC Drug Lookup to find Prior Authorization (PA) Forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED STEP 1 AGENTS (ELECTRONIC STEP)	NON-PREFERRED STEP 2 AGENTS (PA REQUIRED)
DEXILANT (dexlansoprazole)	Esomeprazole magnesium	NEXIUM (esomeprazole)
Lansoprazole	Rabeprazole	Omeprazole-Sodium bicarbonate
Omeprazole		PREVACID (Lansoprazole)
Pantoprazole		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 Preferred*	PRILOSEC PACKET (omeprazole)	ACIPHEX SPRINKLE (rabeprazole)
Omeprazole ODT		Esomeprazole solution packet
PREVACID (Lansoprazole) SOLUTAB *– Brand Preferred*		Lansoprazole ODT
PROTONIX (pantoprazole) PACKET		Omeprazole-sodium bicarbonate packet
		Pantoprazole packet
		Rabeprazole Sprinkle

Vancomycin - Oral

General Prior Authorization Form

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

- The patient must have diagnosis of *Clostridium difficile*-associated diarrhea (CDAD)
- The patient must be 18 years of age or older
- The patient must have failed a 10-day trial with a preferred agent, as evidenced by paid claims or pharmacy printouts
- Request must be for treatment of the first recurrence for a patient whose initial episode was treated with Dificid

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

Genetic and Rare Disease

Cystic Fibrosis

Cystic Fibrosis - Inhaled Antibiotics

General Prior Authorization Form

Product Specific Criteria:

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

- The patient must be colonized with *Pseudomonas aeruginosa.*
- The patient must have had a 28-day trial of TOBI Podhaler, as evidenced by paid claims or pharmacy printouts.

- ***Arikayce:**
  - The patient must be colonized with *Mycobacterium avium* complex (MAC).
  - The patient 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 Preferred*	CAYSTON (aztreonam)***
TOBI PODHALER (tobramycin) PA***	tobramycin
TOBI (tobramycin) – *Brand Preferred*	tobramycin/nebulizer

Cystic Fibrosis – CFTR Modulators

General Prior Authorization Form

Group Criteria: *Approval Duration = 12 months*

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

Hereditary Angioedema

General Prior Authorization Form

Category Criteria:

- The patient must have diagnosis of hereditary angioedema, confirmed by a specialist.

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
BERINERT (C1 Esterase Inhibitor)	FIRAZYR (icatibant)
CINRYZE (C1 Esterase Inhibitor)	
HAEGARDA (C1 Esterase Inhibitor)	
icatibant	
KALBITOR (ecallantide)	
RUCONEST (C1 Esterase Inhibitor)	
TAKHZYRO (lanadelumab-FLYO)	

Idiopathic Pulmonary Fibrosis / Interstitial Lung Disease

Prior Authorization Form - Idiopathic Pulmonary Fibrosis

Category Criteria:

- The patient 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 patient must have forced vital capacity (FVC) ≥ 40% of predicted within prior 60 days
- The patient 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)

ESBRIET (Pirfenidone)	
OFEV (Nintedanib)	

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 patient must have a diagnosis of hyperphenylalaninemia
- The patient must be following a PHE restricted diet
- The patient's weight must be provided
- The patient must be 4 years of age or older
- The patient must not have been known to have two null mutations in TRANS
- Baseline PHE levels must be attached
    - For females of child bearing 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
- Requested initial dose must be 10 mg/kg or less

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

- The patient'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 patient's PHE level must be greater than 360 micromoles per liter
    - For increase > 10 mg/kg - patient must have failed a trial of 1 month of 10 mg/kg

Palynziq:

Prior Authorization Form - Phenylketonuria

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

- The patient must have a diagnosis of hyperphenylalaninemia
- The patient must be following a PHE restricted diet
- The patient must be 18 years of age or older
- PHE levels must be above 600 micromoles/liter
- The patient must have been compliant with 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 patient's PHE level must be greater than 360 micromoles per liter

Immunology

Biosimilar Agents

General Prior Authorization Form

Group Criteria:

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

Cytokine Modulators

General Prior Authorization Form

Non-Preferred Agents Criteria:

- The patient must have had a 3-month trial of 2 preferred cytokine modulator agents, as evidenced by paid claims or pharmacy printouts.

Product Specific Criteria:

- **Skyrizi:**
  - The patient must have had a 3-month trial of 1 non-preferred agent, as evidenced by paid claims or pharmacy printouts.

ANKYLOSING SPONDYLITIS	
PREFERRED AGENTS (NO PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**
ENBREL (etanercept)	CIMZIA (certolizumab)
HUMIRA (adalimumab)	COSENTYX (secukinumab)
TALTZ (ixekizumab)	SIMPONI (golimumab)
BEHCET'S SYNDROME	
PREFERRED AGENTS (NO PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**
HUMIRA (adalimumab)	
OTEZLA (apremilast)	
CHRONIC INFANTILE NEUROLOGICAL, CUTANEOUS AND ARTICULAR SYNDROME	
PREFERRED AGENTS (PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**
KINERET (anakinra)	
CROHN'S DISEASE	
PREFERRED AGENTS (NO PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**
HUMIRA (adalimumab)	CIMZIA (certolizumab)
	STELARA (ustekinumab)
CYTOKINE RELEASE SYNDROME	
PREFERRED AGENTS (PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**
ACTEMRA (tocilizumab)	
GIANT CELL ARTERITIS	
PREFERRED AGENTS (PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**
ACTEMRA (tocilizumab)	
HIDRADENITIS SUPPURATIVA	
PREFERRED AGENTS (NO PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**
HUMIRA (adalimumab)	
NON-RADIOGRAPHIC AXIAL SPONDYLARTHRITIS	
PREFERRED AGENTS (NO PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**

HUMIRA (adalimumab)	CIMZIA (certolizumab)
TALTZ (ixekizumab)	COSENTYX (secukinumab)
PLAQUE PSORIASIS	
PREFERRED AGENTS (NO PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**
ENBREL (etanercept)	CIMZIA (certolizumab)
HUMIRA (adalimumab)	COSENTYX (secukinumab)
TALTZ (ixekizumab)	OTEZLA (apremilast)
	SILIQ (brodalumab)***
	SKYRIZI (risankizumab-rzaa)***
	STELARA (ustekinumab)
	TREMFYA (guselkumab)
PSORIATIC ARTHRITIS	
PREFERRED AGENTS (NO PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**
ENBREL (etanercept)	CIMZIA (certolizumab)
HUMIRA (adalimumab)	COSENTYX (secukinumab)
TALTZ (ixekizumab)	ORENCIA (abatacept)
	OTEZLA (apremilast)
	SIMPONI (golimumab)
	STELARA (ustekinumab)
	TREMFYA (guselkumab)
	XELJANZ (tofacitinib)
	XELJANZ XR (tofacitinib)
RHEUMATOID ARTHRITIS	
PREFERRED AGENTS (NO PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**
ENBREL (etanercept)	ACTEMRA (tocilizumab)
HUMIRA (adalimumab)	CIMZIA (certolizumab)
XELJANZ (tofacitinib)	COSENTYX (secukinumab)
	KEVZARA (sarilumab)
	KINERET (anakinra)
	OLUMIANT (baricitinib)
	ORENCIA (abatacept)
	RINVOQ (upadacitinib)
	SIMPONI (golimumab)
	XELJANZ XR (tofacitinib)
SCHNITZLER SYNDROME	
PREFERRED AGENTS (PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**
KINERET (anakinra)	
ULCERATIVE COLITIS	
PREFERRED AGENTS (NO PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**
HUMIRA (adalimumab)	SIMPONI (golimumab)
XELJANZ (tofacitinib)	STELARA (ustekinumab)
XELJANZ XR (tofacitinib)	
UVEITIS	
PREFERRED AGENTS (NO PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**
HUMIRA (adalimumab)	

Dupixent

Prior Authorization Form - Dupixent

Please use the NDC Drug Lookup to find Prior Authorization (PA) Forms

Asthma

Click to Jump to Criteria

Eczema

Click to Jump to Criteria

Chronic Rhinosinusitis

General Prior Authorization Form

Initial Criteria: *Approval Duration = 3 months*

- The patient must meet label recommendations for indication and age.
- Diagnosis has been confirmed by anterior rhinoscopy, nasal endoscopy, or computed tomography (CT)
- The patient must still be experiencing inflammation of paranasal sinuses after 12 weeks of treatment with intranasal or oral corticosteroids and nasal saline irrigations, as evidenced by paid claims or pharmacy printouts.

Renewal Criteria: *Approval Duration = 9 months*

- The prescriber must provide documentation showing that the patient has achieved a significant reduction in systemic or intranasal corticosteroids and reduction in inflammation.

Eosinophilic Asthma

Prior Authorization Form – Eosinophilic Asthma

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

- The patient must meet label recommendations for indication and age.
- Must be prescribed by, or in consult with, a pulmonologist or allergist/immunologist
- The patient must have had 2 or more asthma exacerbations 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

Non-Preferred Agents Criteria:

- The patient 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 = 3 months*

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

Self-Injectable Products

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

Health Professional Administration Only Products

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
CINQUAIR (reslizumab)	
XOLAIR (omalizumab)	

Epinephrine

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

General Prior Authorization Form

Category Criteria:

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

Product Specific Criteria:

- **Uloric:**
  - The patient must have had a 30-day trial of allopurinol, as evidenced by paid claims or pharmacy printouts
- **Gloperba:**
  - The patient must be unable to ingest solid dosage form as evidenced by swallow study documentation

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
Allopurinol Tablet	Colchicine Capsules
COLCRYS (Colchicine) TABLETS – *Brand Preferred*	Colchicine Tablets
MITIGARE (Colchicine) CAPSULE – *Brand Preferred*	Febuxostat
Probenecid-Colchicine Tablets	GLOPERBA (Colchicine) ORAL SOLUTION
Probenecid Tablets	ULORIC (Febuxostat) TABLET
	ZYLOPRIM (Allopurinol) TABLET

Immune Globulins

Prior Authorization Form - Immune Globulins

Category Criteria:

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

Product Specific Criteria:

- **Gammagard S/D:**
  - The patient must be intolerant to IgA (i.e., treatment of an autoimmune process in a patient with undetectable levels of IgA)
- **Cutaquig, Cuvitru, Hizentra, Hyqvia or Xembify:**
  - The patient must be unable to tolerate SQ administration with preferred products that can be given subcutaneously.
  - The patient must have failed a trial of at least two of the following, as evidenced by paid claims or pharmacy printouts:
    - Gamunex-C
    - Gammaked
    - Gammagard
- **Other Products:**
  - The patient must have failed a trial of at least two of the following, as evidenced by paid claims or pharmacy printouts:
    - Gammagard

- Gamunex-C
- Privigen

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)	CUTAQUIG (human immune globulin G solution)
GAMASTAN (human immunoglobulin)	CUVITRU (human immunoglobulin gamma)
GAMASTAN S-D (human immunoglobulin)	GAMMAGARD S-D (human immunoglobulin gamma)
GAMMAGARD LIQUID (human immunoglobulin gamma)	HIZENTRA (human immunoglobulin gamma)
GAMMAKED (human immunoglobulin gamma)	HYQVIA (human immune globulin G and hyaluronidase)
GAMMAPLEX (human immunoglobulin gamma)	PANZYGA (Immune Globulin- IFAS)
GAMUNEX-C (human immunoglobulin gamma)	XEMBIFY (human immune globulin-klhw)
OCTAGAM (human immunoglobulin gamma)	
PRIVIGEN (human immunoglobulin gamma)	

Palforzia

Palforzia Prior Authorization Form

Group Criteria:

- **Initial Criteria:** *Approval Duration = 6 months*
  - The patient must have an FDA-approved indication for use (meets label recommendations for diagnosis and age)
  - The patient 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 patient has access to injectable epinephrine, and that the patient/caregiver has been instructed and trained on its appropriate use
  - The patient 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 patient must have a clinical history of allergy to peanuts or peanut-containing foods AND one of the following:
    - The patient 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 patient 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 patient must not have any of the following:
    - Uncontrolled asthma
    - Severe or persistent GI symptoms
    - Eosinophilic esophagitis
  - The patient must have experienced and maintained clinical benefit since starting treatment with Palforzia, as evidenced by the following:
    - The patient continues to have a peanut allergy and has been/is being monitored for resolution of their allergy
    - The patient 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 patient 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 patient 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)	

Ulcerative Colitis Agents

General Prior Authorization Form

Category PA Criteria:

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

Cytokine Modulators

See Cytokine Modulators Criteria

Oral

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

Rectal

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
Mesalamine enema	Mesalamine enema kit

Mesalamine rectal suppository	ROWASA (mesalamine) ENEMA KIT
	SF ROWASA (mesalamine) ENEMA
	UCERIS (budesonide) RECTAL FOAM

Infectious Disease

Antibiotics - Resistance Prevention

Prior Authorization Form – Antibiotics – Resistance Prevention

Non-Preferred Agents Criteria:

- **Initial Criteria:** *Approval Duration = 5 days*
  - Patient 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 a preferred antibiotic is not an option due to susceptibility, previous failed trials, or other contraindications (subject to clinical review)
    - B. The patient is continuing treatment upon discharge from an acute care facility
- **Renewal Criteria:** *Approval Duration = 5 days*
  - Prescriber must attest that the patient's condition is improving and that it is medically necessary to continue treatment course after re-evaluation of the patient'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)
OMECLAMOX-PAK (Omeprazole/Clarithromycin/Amoxicillin)	HELIDAC (bismuth ssal/metronidazole/tetracycline)
PYLERA (Bismuth Subcitrate Potassium/Metronidazole/Tetracycline)	TALICIA (Omeprazole/Amoxicillin/Rifabutin)
PREVPAC (Lansoprazole/Amoxicillin/Clarithromycin)	

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 patient must meet one of the following (A or B):
    - The patient 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)
Fluconazole	DIFLUCAN (Fluconazole)
Itraconazole	Posaconazole
NOXAFIL (Posaconazole) – *Brand Required*	SPORANOX (Itraconazole)
Nystatin	TOLSURA (itraconazole) CAPSULE
ORAVIG (miconazole)	VFEND (Voriconazole)
Terbinafine	
Voriconazole	

Non-solid oral formulations

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

Antimalarial Agents

Electronic Step Care and Concurrent Medications

- A total of 30 days of same active ingredient must be paid within 99 days prior to current claim for hydroxychloroquine and chloroquine. Prior authorization required to initiate treatment.

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 patient 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 patient must be less than 18 years old

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
daraprim	ARAKODA (tafenoquine)
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 patient 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 patient 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)	
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)
ATRIPLA (efavirenz/emtricitabine/tenofovir) – *Brand Preferred*	efavirenz/emtricitabine/tenofovir
COMPLERA (emtricitabine/rilpivirine/tenofovir)	SUSTIVA (efavirenz)
EDURANT (rilpivirine)	
efavirenz	
JULUCA (dolutegravir/rilpivirine)	
ODEFSEY (emtricitabine/rilpivirine/tenofovir)	
PIFELTRO (doravirine)	
rilpivirine	

SYMFI (efavirenz/lamivudine/tenofovir)	
SYMFI LO (efavirenz/lamivudine/tenofovir)	
NOT RECOMMENDED FOR FIRST LINE USE	
Etravirine: Guidelines do not recommend for treatment-naïve patients due to insufficient data. FDA indication is for treatment experienced patients and so should be reserved for salvage therapy, pretreated patients 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 patients. 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.	
etravirine	
INTELENCE (etravirine)	
nevirapine	
nevirapine ER	

Nucleoside Reverse Transcriptase Inhibitors

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
abacavir	efavirenz/emtricitabine/tenofovir
abacavir/lamivudine	emtricitabine/tenofovir
ATRIPLA (efavirenz/emtricitabine/tenofovir) – *Brand Preferred*	EPIVIR (lamivudine)
BIKTARVY (bictegravir/Emtricitabine/Tenofovir)	EPZICOM (abacavir)
CIMDUO (lamivudine/tenofovir)	TRIZIVIR (abacavir/lamivudine)
COMPLERA (emtricitabine/rilpivirine/tenofovir)	VIREAD (tenofovir)
DELSTRIGO (doravirine/lamivudine/tenofovir)	ZERIT (stavudine) CAPSULE
DESCOVY (emtricitabine/tenofovir)	ZIAGEN (abacavir)
EMTRIVA (emtricitabine)	
GENVOYA (elvitegravir/cobicistat/emtricitabine/tenofovir)	
lamivudine	
ODEFSEY (emtricitabine/rilpivirine/tenofovir)	
SYMFI (efavirenz/lamivudine/tenofovir)	
SYMFI LO (efavirenz/lamivudine/tenofovir)	
STRIBILD (elvitegravir/cobicistat/emtricitabine/tenofovir)	
SYMTUZA (darumavir/cobicistat/emtricitabine/tenofovir)	
tenofovir	
TEMIXYS (Lamivudine/Tenofovir)	
TRIUMEQ (abacavir/dolutegravir/lamivudine)	
TRUVADA (emtricitabine/tenofovir) – *Brand Preferred*	
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 patients, 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	REYATAZ (atazanavir) CAPSULE
EVOTAZ (atazanavir/cobicistat)	Ritonavir

Please use the NDC Drug Lookup to find Prior Authorization (PA) Forms

NORVIR (ritonavir)	
PREZCOBIX (darunavir/cobicistat)	
PREZISTA (darunavir)	
REYATAZ (atazanavir) POWDER PACK	
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)	
KALETRA (lopinavir/ritonavir) TABLET	
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 patients 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 claim if patient has decompensated cirrhosis (Child Pugh B or C).
    - Epclusa requires prior authorization and after prior authorization is approved, Epclusa 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

Please use the NDC Drug Lookup to find Prior Authorization (PA) Forms

Antivirals

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

- The patient must have an FDA-approved indication for use (meets label recommendations for diagnosis and age).
- 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.
- The patient must be drug (drugs of abuse by injection) and alcohol free as documented by 2 drug and alcohol tests, dated at least 3 months apart, with the most current test completed within 60 days of the request date, in addition to meeting criteria below as applicable:
- **If the patient has a history of alcohol use disorder**, one of the following must be met (A or B)
    A. The patient must submit an additional alcohol test dated 12 months (+/- 3 months) prior to request date
    B. All of the following must be met:
        - The patient must have abstained from alcohol for the past 3 months, as evidenced by alcohol tests dated 3 months apart, with most recent test within 30 days of the request date
        - The patient must be receiving treatment from an enrolled addiction medicine/chemical dependency treatment provider, and the provider/facility name must be provided with the request
        - Chart notes must be attached regarding assessment of patient's readiness for treatment including readiness for abstinence from alcohol use during and after treatment
- **If the patient has a history of illicit use of drugs by injection**, one of the following must be met (A or B)
    A. The patient must submit an additional alcohol test dated 12 months (+/- 3 months) prior to request date
    B. All of the following must be met
        - The patient must have abstained from illicit use of drugs by injection for the past 3 months, as evidenced by drug tests dated 3 months apart, with most recent test within 30 days of the request date
        - The patient must be receiving treatment from an enrolled addiction medicine/chemical dependency treatment (or buprenorphine waived) provider, and the provider/facility name must be provided with the request
        - Chart notes must be attached regarding assessment of readiness for treatment of the patient including readiness for abstinence from illicit drug use by injection during and after treatment
- The patient must not be receiving a known recreationally used high risk combination of drugs (e.g. "the holy trinity") for the past 6 months.
- Prescriber must be a hepatology, gastroenterology, or infectious disease specialist if the patient has any of the following:
    - 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
    - Prior hepatitis C treatment with a Direct Acting Antiviral Regimen
    - 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) if the patient has any of the following:
    - Compensated cirrhosis (Child's Pugh A)
    - Prior hepatitis C treatment with a Direct Acting Antiviral Regimen
- Females using ribavirin must have a negative pregnancy test in the last 30 days and receive monthly pregnancy tests during treatment.
- Patient must have established compliant behavior including attending scheduled provider visits (defined as 1 or less no-shows) and filling maintenance medications on time as shown in the prescription medication history for the past 6 months.

- Patient must be tested for hepatitis B, and if the test is positive, hepatitis B must either be treated or closely monitored if patient does not need treatment.
- Patient must not have life expectancy of less than 12 months due to non-liver related comorbid conditions.
- Patient and Prescriber attestation forms must be attached to request

Non-Preferred Agents Criteria:

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

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
EPCLUSA (sofosbuvir/velpatasvir) *Brand Preferred****	HARVONI (ledipasvir/sofosbuvir) 90mg/400mg tablet
HARVONI (ledipasvir/sofosbuvir) 45 mg/200mg tablet	HARVONI (ledipasvir/sofosbuvir) ORAL PALLET
MAVYRET (glecaprevir/pibrentasvir)***	ledipasvir/sofosbuvir 90mg/400mg tablet
SOVALDI (sofosbuvir) 200 MG TABLET	sofosbuvir/velpatasvir
	SOVALDI (sofosbuvir) 400MG TABLET
	SOVALDI (sofosbuvir) ORAL PALLET
	VIEKIRA PAK (dasabuvir/ombitasvir/paritaprevir/ritonavir)
	VOSEVI (sofosbuvir/velpatasvir/voxilaprevir)***
	ZEPATIER (elbasvir/grazoprevir)

Ribavirin

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

Influenza

Electronic Age Verification

- Xofluza: The patient 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 patient must have diagnosis of benign prostatic hyperplasia (BPH)
- The patient 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	

Hematopoietic, Erythropoiesis Stimulating Agents

General Prior Authorization Form

Non-Preferred Agents Criteria:

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

Prior Authorization Form - Hyperkalemia

Group Criteria:

- **Initial criteria**: *Approval Duration = 3 months*
  - The patient must be 18 years of age or older.
  - Medication must be prescribed by, or in consultation with, a nephrologist
  - The patient's current serum potassium level must be exceeding the upper limit of normal, as evidenced by documentation from at least two separate lab values, submitted with the request
  - The patient must not have gastrointestinal motility disorders (e.g. severe constipation, bowel obstruction or impaction, abnormal postoperative bowel motility disorders)
  - One of the following criteria must be met:
    - The patient must have failed 30-day trials with at least two of the following products
      - Bumetanide, Chlorothiazide, Fludrocortisone, Furosemide, Hydrochlorothiazide, Indapamide, Metolazone, Torsemide
  - The patient 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 patient:
    - angiotensin-converting enzyme inhibitor
    - angiotensin II receptor blocker
    - aldosterone antagonist
    - nonsteroidal anti-inflammatory drugs (NSAIDs)
- **Renewal Criteria**: *Approval Duration = 6 months*
  - The patient'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 (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
LOKELMA (Sodium Zirconium Cyclosilicate)	VELTASSA (Patiromer)

Phosphate Binders

General Prior Authorization Form

Category Criteria:

- The patient must have had 30-day trials of at least 3 preferred agents of a unique active ingredient, as evidenced by paid claims or pharmacy printouts.
- The patient must have a diagnosis of end-stage renal disease or chronic kidney disease.

Solid dosage form

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
Calcium acetate	AURYXIA (ferric citrate) TABLET
FOSRENOL (lanthanum) CHEWABLE TABLET – *brand preferred*	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

Urinary Antispasmodics

Step Care and Concurrent Medications

- Non-Preferred Step 1 Agents: Use least 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

Non-Preferred Agents Criteria:

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

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED STEP 1 AGENTS (ELECTRONIC STEP)	NON-PREFERRED AGENTS (PA REQUIRED)
flavoxate	tolterodine	darifenacin ER
GELNIQUE (oxybutynin)	tolterodine ER	DETROL (tolterodine)
oxybutynin ER		DITROPAN XL (oxybutynin)
oxybutynin syrup		dutasteride/tamsulosin
oxybutynin tablet		FLOMAX (tamsulosin)
OXYTROL (oxybutynin) PATCH		JALYN (dutasteride/tamsulosin)

Please use the NDC Drug Lookup to find Prior Authorization (PA) Forms

solifenacin		MYRBETRIQ (mirabegron)
tamsulosin		trospium ER
TOVIAZ (fesoterodine)		VESICARE (solifenacin)
trospium		

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 Age Verification

- Patients must be greater than 30 years old or documentation of diagnosis must be provided.

Prior Authorization Criteria

General Prior Authorization Form

Non-Preferred Product Criteria:

- The patient must have a diagnosis of an FDA-approved indication for use
- The patient must have had a 30-day trial of a pharmaceutically equivalent preferred agent, as evidenced by paid claims or pharmacy printouts.
- The patient must not reside in facility with skilled nursing care.

Product Specific Criteria:

- Donepezil 23mg:
  - Clinical justification must be provided explaining why the patient 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 Preferred*	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 relaxant, or narcotic tablets or capsules
    - If a patient can swallow, they should be transitioned to a tablet or capsule formulation

Electronic Diagnosis Verification

- **Diacomit, Epidiolex, Fentepla:** The patient must have a 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 patient 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 patient 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 XR tablet
carbamazepine ER capsule	CARBATROL (carbamazepine)
carbamazepine oral suspension	EPITOL (carbamazepine)
carbamazepine tablet	EQUETRO (carbamazepine)
oxcarbazepine tablet	oxcarbazepine oral solution
OXTELLAR XR (oxcarbazepine)	TEGRETROL (carbamazepine oral suspension)
TEGRETOL (carbamazepine)	TRILEPTAL (oxcarbazepine)
TRILEPTAL (oxcarbazepine) ORAL SUSPENSION – *Brand Preferred*	
TEGRETOL XR (carbamazepine) – *Brand Preferred*	
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
divalproex ER	DEPAKOTE ER (divalproex sodium)
divalproex sprinkle	DEPAKOTE SPRINKLE (divalproex sodium)
divalproex tablet	DILANTIN (phenytoin) CHEWABLE TABLET
ethosuximide capsule	DILANTIN (phenytoin) ORAL SUSPENSION
ethosuximide oral solution	DILANTIN ER (phenytoin)
FELBATOL (felbamate) TABLET– *Brand Preferred*	felbamate oral suspension
FELBATOL (felbamate) ORAL SUSPENSION - *Brand Preferred*	felbamate tablet
PEGANONE (ethotoin)	MYSOLINE (primidone)
phenobarbital elixir	ONFI (clobazam)
phenobarbital tablet	ONFI (clobazam) ORAL SOLUTION
phenytoin chewable tablet	PHENYTEK (phenytoin)

Please use the NDC Drug Lookup to find Prior Authorization (PA) Forms

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	KEPPRA (levetiracetam)
BANZEL (rufinamide) TABLET	KEPPRA (levetiracetam) ORAL SOLUTION
BRIVIACT (brivaracetam)	KEPPRA XR (levetiracetam)
DIACOMIT (stiripentol)	LAMICTAL (lamotrigine)
EPIDIOLEX (cannabidiol)	LAMICTAL (lamotrigine) DOSE PACK
FINTEPLA (fenfluramine) ORAL SOLUTION	LAMICTAL ODT (lamotrigine)
FYCOMPA (perampanel)	lamotrigine chewable tablet
FYCOMPA (perampanel) ORAL SUSPENSION	lamotrigine ER
gabapentin capsule	LYRICA (pregabalin)
gabapentin oral solution	LYRICA (pregabalin) ORAL SOLUTION
gabapentin tablet	NEURONTIN (gabapentin) CAPSULE
GABITRIL (tiagabine) - *Brand Preferred*	NEURONTIN (gabapentin) ORAL SOLUTION
LAMICTAL ODT (lamotrigine) DOSE PACK	NEURONTIN (gabapentin) TABLET
LAMICTAL ER (lamotrigine) DOSE PACK	QUDEXY XR (topiramate)
LAMICTAL XR (lamotrigine) - *Brand Preferred*	SPRITAM (levetiracetam)
LAMICTAL (lamotrigine) CHEWABLE TABLET- *Brand Preferred*	SUBVENITE (lamotrigine)
lamotrigine dose pack	tiagabine
lamotrigine ODT	TOPAMAX (topiramate)
lamotrigine tablet	TOPAMAX (topiramate) SPRINKLE CAPSULE
levetiracetam ER	VIGADRONE (vigabatrin)
levetiracetam oral solution	vigabatrin
levetiracetam tablet	vigabatrin powder pack
pregabalin	ZONEGRAN (zonisamide)
pregabalin oral solution	
SABRIL (vigabatrin) - *Brand Preferred*	
SABRIL (vigabatrin) POWDER PACK - *Brand Preferred*	
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 Preferred*	Diazepam pediatric rectal gel
DIASTAT ACUDIAL (diazepam) RECTAL GEL – *Brand Preferred*	Diazepam rectal gel
NAYZILAM (midazolam) SPRAY	
VALTOCO (diazepam) SPRAY	

Emflaza

Prior Authorization Form - Emflaza

Please use the NDC Drug Lookup to find Prior Authorization (PA) Forms

Initial Criteria: *Approval Duration = 6 months*

- The patient must be 2 years of age or older
- The patient 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 patient must have serum creatinine kinase activity of at least 10 times the upper limit of normal (ULN) prior to initiating treatment
- The patient 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 patient 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 patient 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 patient 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)

Headache/Migraine

Prophylaxis of Migraine – CGRP Inhibitors

Prior Authorization Form –Migraine/Cluster Headache Prophylaxis

Group Criteria:

- **Initial (approval duration: 3 months):**
    - Patient must experience 3 or more migraine days per month.
    - The patient 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.

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

Non-Preferred Agents Criteria:

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

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AJOVY (fremanezumab-vfrm)	AIMOVIG (erenumab-aooe)
EMGALITY (galcanazumab-gnlm)	

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

Non-Triptan Agents

PREFERRED AGENTS (CLINCAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
NURTEC ODT (rimegepant)	CAMBIA (diclofenac potassium) POWDER PACK
	D.H.E.45 (dihydroergotamine) INJECTION
	dihydroergotamine injection
	dihydroergotamine nasal spray
	ERGOMAR (ergotamine) SL TABLET
	MIGERGOT (ergotamine/caffeine) RECTAL SUPPOSITORY
	MIGRANAL (dihydroergotamine) SPRAY
	REYVOW (Lasmiditan)
	UBRELVY (Ubrogepant)

Triptans (5HT-1 agonists)

Approval Duration = 6 months

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

- Patients must not able to take oral medications (as evidenced by swallow study documentation):

Non-Preferred Step 1 Agents Criteria:

- Patients 18 years old or older: The patient must have had a 30-day trial of each preferred agent, as evidenced by paid claims or pharmacy printouts.
- Patients 6 to 17 years of age: The patient must have had a 30-day trial of rizatriptan, as evidenced by paid claims or pharmacy printouts.

Non-preferred step 2 agents:

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

Solid Oral Dosage Forms		
PREFERRED AGENTS (NO PA REQUIRED)	**PREFERRED STEP 1 AGENTS (PA REQUIRED)**	**NON-PREFERRED STEP 2 AGENTS (PA REQUIRED)**
RELPAX (eletriptan) TABLET – *Brand Preferred*	Naratriptan Tablet	Almotriptan Tablet
Rizatriptan tablet	Zolmitriptan Tablet	AMERGE (naratriptan) TABLET
Sumatriptan tablet		Eletriptan Tablet
		FROVA (frovatriptan) TABLET
		Frovatriptan Tablet
		IMITREX (sumatriptan) TABLET
		MAXALT (rizatriptan) TABLET
		Sumatriptan/Naproxen Tablet
		TREXIMET (Sumatriptan/Naproxen) TABLET
		ZOMIG (zolmitriptan) TABLET
Non-Solid Oral Dosage Form		
PREFERRED AGENTS (NO PA REQUIRED)	**PREFERRED STEP 1 AGENTS (PA REQUIRED)**	**NON-PREFERRED STEP 2 AGENTS (PA REQUIRED)**
Rizatriptan ODT	Zolmitriptan ODT	MAXALT MLT (rizatriptan)
		ZOMIG ODT (zolmitriptan)
Non-Oral Dosage Forms		
PREFERRED AGENTS (CLINICAL PA REQUIRED)	**PREFERRED STEP 1 AGENTS (PA REQUIRED)**	**NON-PREFERRED STEP 2 AGENTS (PA REQUIRED)**
ONZETRA XSAIL (sumatriptan) NASAL SPRAY	ZOMIG (zolmitriptan) NASAL SPRAY	IMITREX (sumatriptan) CARTRIDGE
		IMITREX (sumatriptan) PEN INJCTR
		IMITREX (sumatriptan) SPRAY
		Sumatriptan Cartridge
		Sumatriptan Pen Injctr
		Sumatriptan Spray
		Sumatriptan Syringe
		Sumatriptan Vial
		TOSYMRA (Sumatriptan) NASAL SPRAY
		ZEMBRACE SYMTOUCH (Sumatriptan)

Cluster Headache

Initial PA Criteria: *Approval Duration: 3 months*

- Patient 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:

- Patient 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
- Patient must have had a 2-month trial with verapamil

Renewal PA Criteria: *Approval Duration: 9 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 patient headache journal

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
Topiramate	EMGALITY (Galcanazumab-gnlm)
Verapamil	

Cluster Headache Treatment

Non-preferred agents:

- The patient 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
ZOMIG (Zolmitriptan) NASAL SPRAY	Dihydroergotamine (DHE) intranasal
Zolmitriptan oral	Dihydroergotamine Injection
Zolmitriptan ODT	Dihydroergotamine Nasal Spray
	ERGOMAR (ergotamine) SL TABLET
	IMITREX (sumatriptan) CARTRIDGE
	IMITREX (sumatriptan) PEN INJCTR
	IMITREX (sumatriptan) SPRAY
	IMITREX (sumatriptan) VIAL
	MIGRANAL (dihydroergotamine) SPRAY
	Sumatriptan Cartridge
	Sumatriptan intranasal
	Sumatriptan Pen Injctr
	Sumatriptan Spray
	Sumatriptan subcutaneous
	Sumatriptan Syringe
	Sumatriptan Vial
	TOSYMRA (Sumatriptan) NASAL SPRAY
	ZEMBRANCE SYMTOUCH (Sumatriptan)

Multiple Sclerosis

Interferons

General Prior Authorization Form

Non-Preferred Agents Criteria:

- The patient must have an FDA-approved indication for use (meets label recommendations for diagnosis and age).
- The patient 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 patient must have an FDA-approved indication for use (meets label recommendations for diagnosis and age).
- The patient must have had a 3-month trial of each of the following, as evidenced by paid claims or pharmacy printouts.
    - Copaxone 20mg/mL, Aubagio, Gilenya, Tecfidera, Vumerity, Zeposia,
- Clinical justification must be provided explaining why the patient is unable to use the preferred products (subject to clinical review).

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

Oral Non-Interferons

General Prior Authorization Form

Non-Preferred Agents Criteria:

- The patient must have an FDA-approved indication for use (meets label recommendations for diagnosis and age).
- The patient must have had a 3-month trial of each preferred agent, as evidenced by paid claims or pharmacy printouts.
- One of the following must be met (A OR B):
    - The patient must have had a 3-month trial of Copaxone, as evidenced by paid claims or pharmacy printouts.
    - If patient has a documented intolerance, hypersensitivity, or labeled contraindication to Copaxone, the patient must have had a 3-month trial interferon beta-1, as evidenced by paid claims or pharmacy printouts.

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
AUBAGIO (teriflunomide)	MAVENCLAD (cladribine)
dimethyl fumarate	MAYZENT (siponimod)
GILENYA (fingolimod)	TECFIDERA (dimethyl fumarate)
	VUMERITY (diroximel fumarate)
	ZEPOSIA (ozanimod)

Narcolepsy

Therapeutic Duplication

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

Electronic Step Care and Concurrent Medications

- Wakix requires titration to 17.8 mg dose with 4.45 mg tablets.

Underutilization

- Wakix and Sunosi 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:

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

Diagnosis Specific Criteria:

- **Narcolepsy:**
  - The patient 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
- **Obstructive Sleep Apnea:**
  - The requested agent must be Sunosi
  - The patient must have failed 30-day trials of each preferred agent, 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

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)
Modafinil	Armodafinil
NUVIGIL (Armodafinil) – *Brand Preferred*	PROVIGIL (Modafinil)
	SUNOSI (Solriamfetol)
	WAKIX (Pitolisant)
	XYREM (Sodium Oxybate)

Nuedexta

Prior Authorization Form - Nuedexta

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

- The patient must be 18 years of age or older
- The patient 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 patient 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
    - Patient 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

Non-Preferred Agents Criteria (Renewal):

Documentation of disease stabilization or improvement in disease since initiation of treatment must be provided

Parkinson's Agents – Adenosine Receptor Agonist

- **Non-Preferred Agents Criteria:**
    - The patient 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 patient must be currently experiencing intermittent hypomobility or "off" episodes
    - The patient 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 patient must be exhibiting deterioration in quality of response to during levodopa/carbidopa therapy for intermittent hypomobility, or "off" episodes

- The patient must have had inadequate response to rasagiline and selegiline, as evidenced by paid claims or pharmacy printouts

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 patient 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 patient 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
  - Documentation of intermittent hypomobility or "off" episodes (number and frequency) must be provided
  - The patient must have had inadequate response to medications in two of the following classes to reduce number and frequency of OFF episodes, as evidenced by paid claims or pharmacy printouts
    - A monoamine oxidase-B (MAO-B) inhibitor (e.g. rasagiline and selegiline)
    - A dopamine agonist (e.g. pramipexole IR, ropinirole IR)
    - A catechol-O-methyltransferase (COMT) inhibitor (e.g. entacapone)

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

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

- **Non-Preferred Agents Criteria**
  - The patient must have a diagnosis of an FDA-approved indication for use
  - The patient is must not currently be residing in a facility with skilled nursing care
  - Clinical justification must be provided explaining why the patient 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 patient must have a diagnosis of an FDA-approved indication for use
  - The patient is must not currently be residing in a facility with skilled nursing care

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

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
Carbidopa-levodopa-entacapone	Carbidopa-Levodopa ODT
Carbidopa-Levodopa capsules	RYTARY (Levodopa/Carbidopa)
Carbidopa-Levodopa ER	

Parkinson's Agents –MAO-B Inhibitors

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

Product Specific Criteria:

- ***Xadago:**
  - The patient 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 patient must be currently experiencing intermittent hypomobility or "off" episodes
  - The patient 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 patient must be exhibiting deterioration in quality of response to during levodopa/carbidopa therapy for intermittent hypomobility, or "off" episodes
  - The patient must have had inadequate response to rasagiline and selegiline, as evidenced by paid claims or pharmacy printouts

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

Parkinson's Agents – COMT inhibitor

- **Non-Preferred Agents Criteria**
  - The patient 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 patient must have a diagnosis of an FDA-approved indication for use
  - The patient is must not currently be residing in a facility with skilled nursing care
  - Clinical justification must be provided explaining why the patient 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	

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

Category Criteria

- The patient must be 18 years of age or older.
- The prescription must be written by/in consultation with a specialist (neurologist or psychiatrist).
- The patient 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 patient must not be taking monoamine oxidase inhibitor (MAOI)
- The patient is not pregnant or breastfeeding

Product Specific Criteria:

- *** **Austedo/tetrabenazine:**
    - The patient must have a diagnosis of Huntington's disease or Tardive Dyskinesia.
    - The patient must not have hepatic impairment

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

Ophthalmic

Antihistamines

General Prior Authorization Form

Non-Preferred Agents Criteria:

- The patient 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)	Epinastine

ALOMIDE (lodoxamide)	Olopatadine 0.2%
Azelastine	ZERVIATE (cetirizine)
BEPREVE (bepotastine)	
Cromolyn	
LASTACAFT (alcaftadine)	
Olopatadine 0.1%	
PAZEO (olopatadine)	

Anti-infectives

General Prior Authorization Form

Non-Preferred Agents Criteria:

- The patient must have had 3-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)
Bacitracin/polymyxin B ointment	AZASITE (azithromycin)
BESIVANCE (besifloxacin) DROPS	Bacitracin ointment
CILOXAN (ciprofloxacin) OINTMENT	BLEPH-10 (sulfacetamide) DROPS
Ciprofloxacin drops	CILOXAN (ciprofloxacin) DROPS
Erythromycin ointment	Gatifloxacin drops
GENTAK (gentamicin sulfate) OINTMENT	Levofloxacin drops
Gentamicin sulfate drops	MOXEZA (moxifloxacin) DROPS
Gentamicin sulfate ointment	NEO-POLYCIN (neomycin SU/bacitracin/polymyxin B) OINTMENT
Moxifloxacin drops	NEOSPORIN (neomycin SU/polymyxin B/gramicidin) DROPS
Neomycin SU/bacitracin/polymyxin B ointment	OCUFLOX (ofloxacin) DROPS
Neomycin SU/polymyxin B/gramicidin drops	POLYCIN (bacitracin/polymyxin) OINTMENT
Ofloxacin drop	POLYTRIM (polymyxin B/trimethoprim) DROPS
Polymyxin B/trimethoprim drops	Sulfacetamide ointment
Sulfacetamide drops	TOBREX (tobramycin) DROPS
Tobramycin drops	VIGAMOX (moxifloxacin) DROPS
TOBREX (tobramycin) OINTMENT	ZYMAXID (gatifloxacin) DROPS

Anti-infectives/Anti-inflammatories

General Prior Authorization Form

Non-Preferred Agents Criteria:

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

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
BLEPHAMIDE (sulfacetamide/prednisolone) DROPS	BLEPHAMIDE S.O.P. (sulfacetamide/prednisolone) ointment
Neomycin/polymyxin b/dexamethasone drops	MAXITROL (neomycin/polymyxin b/dexamethasone) DROPS
Neomycin/polymyxin b/dexamethasone ointment	MAXITROL (neomycin/polymyxin b/dexamethasone) OINTMENT
PRED-G (gentamicin/prednisol ac) DROPS	Neomycin/bacitracin/polymyxin b/hydrocortisone ointment
PRED-G (gentamicin/prednisol ac) OINTMENT	Neomycin/polymyxin b/hydrocortisone drops
Sulfacetamide/prednisolone drops	NEO-POLYCIN HC (neomycin SU/bacitracin/polymyxin B/hydrocortisone) OINTMENT
TOBRADEX (tobramycin/dexamethasone) DROPS	TOBRADEX ST (tobramycin/dexamethasone) DROPS
TOBRADEX (tobramycin/dexamethasone) OINTMENT	Tobramycin/dexamethasone
ZYLET (tobramycin/lotepred etab) DROPS	

Anti-inflammatories

General Prior Authorization Form

Non-Preferred Agents Criteria:

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

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ACUVAIL (ketorolac)	ACULAR (ketorolac)
ALREX (loteprednol)	ACULAR LS (ketorolac)
Diclofenac sodium	Bromfenac sodium
DUREZOL (Difluprednate)	BROMSITE (bromfenac sodium)
FLAREX (fluorometholone)	Dexamethasone sodium phosphate
Fluorometholone	INVELTYS (Loteprednol)
Flurbiprofen sodium	FML (fluorometholone)
FML FORTE (fluorometholone)	LOTEMAX SM (Loteprednol)
FML S.O.P. (fluorometholone)	Loteprednol eye drops
ILEVRO (nepafenac)	OMNIPRED 1% (prednisolone acetate)
ketorolac tromethamine 0.4%	PRED FORTE 1% (prednisolone acetate)
ketorolac tromethamine 0.5%	PROLENSA (bromfenac)
LOTEMAX (loteprednol) DROPS – *Brand Preferred*	
LOTEMAX (loteprednol) GEL DROPS	
LOTEMAX (loteprednol) OINTMENT	
MAXIDEX (dexamethasone)	
NEVANAC (nepafenac)	
PRED MILD 0.12% (prednisolone acetate)	
Prednisolone acetate 1%	
Prednisolone sodium phosphate 1%	

Dry Eye Syndrome

General Prior Authorization Form

Non-Preferred Agents Criteria:

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

Product Specific Criteria:

- **Cequa, Restasis Multidose**
  - The patient 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 patient 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 patient 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 patient 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)	brimonidine 0.15%
ALPHAGAN P 0.15% (brimonidine) – *Brand Preferred*	
apraclonidine 0.5%	
IOPIDINE (apraclonidine) 1%	
brimonidine 0.2%	
COMBIGAN (brimonidine/timolol)	
SIMBRINZA (brinzolamide/brimonidine)	

Beta Blockers

General Prior Authorization Form

Non-Preferred Agents Criteria:

- The patient 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%	betaxolol 0.5%
carteolol	ISTALOL (timolol maleate) Daily
COMBIGAN (brimonidine/timolol)	timolol daily
dorzolamide/timolol	timolol gel forming solution
levobunolol	TIMOPTIC (timolol maleate)
timolol maleate	TIMOPTIC-XE (timolol gel forming solution)
TIMOPTIC OCUDOSE (timolol)	

Prostaglandins

General Prior Authorization Form

Non-Preferred Agents Criteria:

- The patient 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 Preferred*	XALATAN (Latanoprost)
ZIOPTAN (Tafluprost)	XELPROS (Latanoprost)

Other

Non-Preferred Agents Criteria:

- **Branded non-preferred agents:** The patient 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 patient 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)	ISOPTO CARPINE (Pilocarbine)
Dorzolamide	TRUSOPT (Dorzolamide)

PHOSPHOLINE (Echothiophate Iodide)	
Pilocarpine	
RHOPRESSA (Netarsudil)	
ROCKLATAN (Netarsudil/Latanoprost)	

Otic

Anti-infectives/Anti-inflammatories – Fluoroquinolones

General Prior Authorization Form

Non-Preferred Agents Criteria:

- The patient 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 Preferred*	Ciprofloxacin/Fluocinolone
	OTOVEL (ciprofloxacin/fluocinolone)

Pain

Lidocaine topical cream

Prior Authorization Form - Anesthetics - Topical

Group Criteria:

- The request must be for patient home use of cream, prior to injection pain from a medically necessary procedure

Lidocaine patch

General Prior Authorization Form

- **Generic non-preferred agents:** The patient 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)
LIDODERM (lidocaine) 5% PATCH – *Brand Required*	Lidocaine 5% patch
ZTLIDO (Lidocaine) 1.8% PATCH	

NSAIDS

Therapeutic Duplication

- One strength of one medication is allowed at a time (topical and oral formulations are not allowed together)

Electronic Diagnosis Verification

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

Solid Oral Dosage Forms

Prior Authorization Form - NSAIDs

Non-Preferred Agents Criteria:

- The patient 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 patient 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)
fenoprofen 600mg	DAYPRO (oxaprozin)
flurbiprofen	diclofenac sodium ER 100mg
ibuprofen	diclofenac sodium 35mg capsule
indomethacin	diclofenac/misoprostol
indomethacin ER	DUEXIS (famotidine/ibuprofen)
ketoprofen 50mg, 75mg	etodolac ER
ketorolac	FELDENE (piroxicam)
meclofenamate	fenoprofen 400mg
mefenamic acid	INDOCIN (indomethacin)
meloxicam	ketoprofen 25mg
nabumetone	ketoprofen ER 200mg
naproxen 220mg, 250mg, 500mg	MOBIC (meloxicam)
piroxicam	NALFON (fenoprofen)
Sulindac	NAPRELAN (naproxen)
tolmetin 200mg, 400mg	naproxen ER 375 mg
VIMOVO (naproxen/esomeprazole) – *Brand preferred*	naproxen 275mg, 550mg
	naproxen/esomeprazole
	oxaprozin
	RELAFEN DS (nabumetone)
	tolmetin 600mg
	VIVLODEX (meloxicam, submicronized)
	ZIPSOR (diclofenac)
	ZORVOLEX (diclofenac, submicronized)

Non-Solid Oral Dosage Forms

Prior Authorization Form - NSAIDs

Non-Preferred Agents Criteria:

- The patient 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 patient is unable to use the preferred products (subject to clinical review).

PREFERRED AGENTS	NON-PREFERRED AGENTS
Ibuprofen	INDOCIN (Indomethacin) SOLUTION
Naproxen	

Nasal

Prior Authorization Form - NSAIDs

Non-Preferred Agents Criteria:

- The patient 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 patient 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:

Prior Authorization Form - NSAIDs

Non-Preferred Agents Criteria:

- The patient 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 patient is unable to use the preferred products (subject to clinical review).

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
Diclofenac 1% Gel	Diclofenac Patch
Diclofenac 1.5% Topical Solution	LICART (Diclofenac) PATCH 1.3%
FLECTOR (diclofenac) PATCH *(Brand Preferred)*	PENNSAID (Diclofenac) 2% PACKET
	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:
  - Quetiapine ER: Due to guidance in The SUPPORT for Patients and Communities Act (H.R. 6) on CNS depression risk between antipsychotics and opioids.
  - Benzodiazepines: See Exception Criteria
  - 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
- 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
- Patient must meet Prior Authorization Criteria

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 patient's North Dakota PDMP reports.
- The patient 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 patient 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 patient 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 patient 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 Preferred*	

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 Preferred*	CONZIP (tramadol ER) CAPSULES
Tramadol 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:**

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

A. The patient 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 patient 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 Tablets
	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 patient 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 patient's age must be within label recommendations
  - The patient must have a diagnosis of cancer pain
  - The patient 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 patient 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 patient's North Dakota PDMP reports
  - The patient 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)

o **Oxycodone IR**
- The above Initial Criteria must be met
- The patient 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
- **Solution:** The patient must be unable to ingest solid dosage form as evidenced by swallow study documentation

o **Meperidine, butalbital-codeine products:**
- The above Initial Criteria must be met
- Clinical justification must be provided explaining why the patient is unable to use other opioid and non-opioid analgesic products (subject to clinical review).

o **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 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)
	ROXICODONE (oxycodone)

Please use the NDC Drug Lookup to find Prior Authorization (PA) Forms

	ROXYBOND (oxycodone)
	SUBSYS (fentanyl) SPRAY
	ULTRACET (tramadol/acetaminophen)
	ULTRAM (tramadol)
	VICODIN (hydrocodone/acetaminophen)

Skeletal Muscle Relaxants

Therapeutic Duplication

- One strength of one medication is allowed at a time
- 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 patients 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 = 3 months*

- The patient 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 = 3 months*
  - One of the required 30-day trials must be methocarbamol, as evidenced by paid claims or pharmacy printouts.
- **Carisoprodol:** *Approval Duration = 1 week*
  - Clinical justification must be provided explaining why the patient is unable to use the preferred agents (subject to clinical review)

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 is not allowed with the following 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 with benzodiazepines or sedatives
    - Insomnia has been reported in 25-56% of patients receiving Mydayis. Patients 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

Prior Authorization Criteria

Non-Preferred Agents Criteria:

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

Product Specific Criteria:

- *** **Clonidine ER**: Patient must have had a 30-day trial of immediate release clonidine, as evidenced by pharmacy claims or pharmacy printouts.

Non-Stimulants

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
clonidine	atomoxetine
guanfacine	clonidine ER***
guanfacine ER	INTUNIV (guanfacine ER)
STRATTERA (atomoxetine) – *Brand Preferred*	

Stimulants

Stimulants - Methylphenidates	
PREFERRED AGENTS (NO PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**
ADHANSIA XR (methylphenidate)	Dexmethylphenidate ER
APTENSIO XR (methylphenidate) – *Brand Preferred*	FOCALIN (dexmethylphenidate)
CONCERTA (methylphenidate) – *Brand Preferred*	METADATE ER (methylphenidate)
COTEMPLA XR - ODT (methylphenidate)	METHYLIN (methylphenidate) chew tablets
DAYTRANA (methylphenidate)	Methylphenidate ER 72 mg
Dexmethylphenidate	Methylphenidate ER capsule
FOCALIN XR (dexmethylphenidate) – *Brand Preferred*	Methylphenidate ER tablet
JORNAY PM (methylphenidate)	Methylphenidate LA capsules - 50-50
Methylphenidate solution	METHYLIN (methylphenidate) solution
Methylphenidate CD 30-70	RITALIN (methylphenidate)
Methylphenidate chew tablet	
Methylphenidate ER capsules 50-50	
Methylphenidate tablet	
QUILLICHEW ER (methylphenidate)	
QUILLIVANT XR (methylphenidate)	
RITALIN LA (methylphenidate LA capsules - 50-50)– *Brand Preferred*	

Stimulants - Amphetamines	
PREFERRED AGENTS (NO PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**
ADDERALL XR (Dextroamphetamine/amphetamine) – *Brand Preferred*	ADZENYS ER (Amphetamine) SOLUTION
ADZENYS XR - ODT (Amphetamine)	ADDERALL (Dextroamphetamine/amphetamine)
Amphetamine	DEXEDRINE (Dextroamphetamine)
Amphetamine ER solution	Dextroamphetamine 5 mg/5 ml
DESOXYN (Methamphetamine) – *Brand Preferred*	EVEKEO (Amphetamine)

Please use the NDC Drug Lookup to find Prior Authorization (PA) Forms

Stimulants - Amphetamines	
PREFERRED AGENTS (NO PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**
Dextroamphetamine	Methamphetamine
Dextroamphetamine ER	ZENZEDI (Dextroamphetamine)
Dextroamphetamine/amphetamine	Dextroamphetamine/amphetamine ER
DYANAVEL XR (Amphetamine)	
EVEKEO ODT (Amphetamine)	
MYDAYIS (Dextroamphetamine/dextroamphetamine)	
PROCENTRA (Dextroamphetamine) – *Brand Preferred*	
VYVANSE (Lisdexamfetamine)	
VYVANSE (Lisdexamfetamine) CHEW TABLET	

Atypical Antipsychotics

Therapeutic Duplication

- Long acting injections are not allowed with oral tablets of the same active ingredient or prodrug
    - In some cases (e.g. missed/delayed dose or during initiation), time-limited concomitant therapy with oral formulation may be indicated.
- First generation antipsychotics: Chloropromazine, Fluphenazine, Perphenazine, Thioridazine, Trifluoperazine, Haloperidol
    - One strength allowed at a time
    - No other antipsychotic medication is allowed concurrently
- Second generation antipsychotics:
    - Aripiprazole: one strength is allowed at a time
    - Risperidone: not allowed with paliperidone concurrently
    - Caplyta, Fanapt, Latuda, Paliperidone, Rexulti, Saphris, Secuado, Vraylar, Ziprasidone: one strength is allowed at a time and no other antipsychotic medication is allowed concurrently
    - Quetiapine:
        - Immediate release: 200mg, 300mg, and 400mg are not allowed together
        - Extended release: 200mg, 300mg, and 400mg are not allowed together or with immediate release. 150mg is not allowed with 50mg.
        - Opioids are not allowed with quetiapine IR due to risk of CNS depression.
    - Olanzapine:
        - Olanzapine 2.5mg is not allowed with olanzapine 5mg or 7.5mg
        - Olanzapine 5mg not allowed with 10mg or 15mg
        - All other olanzapine tablet strengths are allowed together
        - ODT and tablets are not allowed concurrently
        - Olanzapine/Fluoxetine is not allowed with any other product containing olanzapine.

      Additional information:
        - 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
- Tizanidine is not allowed with antipsychotics due to visual hallucinations being reported in 3% of patients receiving tizanidine, psychosis has also been reported.

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 patient 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 patient 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 patient is unable to use the preferred, individual products separately (subject to clinical review).

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
Aripiprazole solution	ABILIFY (aripiprazole)
Aripiprazole	ABILIFY DISCMELT (aripiprazole)
Aripiprazole ODT	CLOZARIL (clozapine)
CAPLYTA (Lumateperone)	GEODON (ziprasidone)
Clozapine	INVEGA ER (paliperidone)
Clozapine ODT	Olanzapine/Fluoxetine***
FANAPT (Iloperidone)	RISPERDAL (risperidone)
LATUDA (Lurasidone)	RISPERDAL (risperidone) ORAL SOLUTION
Olanzapine	RISPERDAL M-TAB (risperidone)
Olanzapine ODT	SEROQUEL (quetiapine)
Paliperidone ER	SEROQUEL XR (quetiapine)
Quetiapine	ZYPREXA (olanzapine)
Quetiapine ER	ZYPREXA ZYDIS (olanzapine)
REXULTI (Brexpiprazole)	
Risperidone	
Risperidone ODT	
Risperidone oral solution	
SAPHRIS (Asenapine)	
SECUADO (Asenapine)	
VRAYLAR (Cariprazine)	
Ziprasidone	

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.

Please use the NDC Drug Lookup to find Prior Authorization (PA) Forms

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ABILIFY MAINTENA (aripiprazole)	
ARISTADA (aripiprazole lauroxil)	
ARISTADA INITIO (aripiprazole lauroxil)	
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 patients receiving Mydayis. Patients 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: See Exception Criteria

Electronic Step Care and Concurrent Medications

- Zolpidem: Initiation with trial of 5 mg must be used for 7 days prior to 10 mg tablets
    - Zolpidem is recommended to be used at lowest dose possible.

Prior Authorization Criteria

Prior Authorization Form - Sedative/Hypnotics

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

- **Zolpidem 10mg** (prior authorization required for females only):
    - The patient must have failed a 25-day trial of zolpidem 5 mg within the last 30 days, as evidenced by paid claims or pharmacy print outs
- **Belsomra, Dayvigo:**
    - The patient's insomnia must be characterized by difficulty with sleep onset and maintenance
    - The patient must have had the following 25-day trials with the most recent failure within the last 30 days, as evidenced by paid claims or pharmacy printouts
        - Silenor (doxepin)
        - Eszopiclone
        - Zolpidem ER
- **Temazepam, zolpidem SL:**
    - The patient's insomnia must be characterized by difficulty with sleep onset and maintenance

- The patient must have had the following 25-day trials with the most recent failure within the last 30 days, as evidenced by paid claims or pharmacy printouts
    - Zolpidem ER
    - Eszopiclone
    - Silenor (doxepin)
    - Belsomra

- **Edluar (Zolpidem):**
    - The patient's insomnia must be characterized by difficulty with sleep onset
    - The patient must have had the following 25-day trials with the most recent failure within the last 30 days, as evidenced by paid claims or pharmacy printouts
        - Zolpidem IR
        - Zaleplon
        - Eszopiclone
- **Triazolam, fluazepam, estazolam, Seconal sodium, Zolpimist:**
    - Clinical justification must be provided explaining why the patient 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 patient must be undergoing dose tapering

NON - DEA SCHEDULED (NON-ADDICTIVE) MEDICATION:	
PREFERRED AGENTS (NO PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**
Mirtazapine	Doxepin
ROZEREM (ramelteon)	Ramelteon
SILENOR (doxepin) – *Brand Preferred*	
Trazodone	
DEA SCHEDULED MEDICATIONS	
PREFERRED AGENTS (NO PA REQUIRED)	**NON-PREFERRED AGENTS (PA REQUIRED)**
Eszopiclone	AMBIEN (Zolpidem)
Zaleplon	AMBIEN CR (Zolpidem)
Zolpidem	BELSOMRA (Suvorexant)
Zolpidem ER	DAYVIGO (Lemborexant)
	EDLUAR (Zolpidem)
	Estazolam
	Flurazepam
	INTERMEZZO (Zolpidem) SL TABLET
	LUNESTA (Eszopiclone)
	SECONAL SODIUM (Secobarbital)
	Temazepam
	Triazolam
	ZOLPIMIST (Zolpidem)
	Zolpidem SL tab

Respiratory

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

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 patient receives multiple forms of rescue medication, the risk of unidentified uncontrolled asthma and rescue inhaler dependence is increased.
    - Exceptions:
      - Maximally treated patients with end-stage COPD will be allowed an ongoing override
      - Acutely ill children will be allowed a one-time 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 25 days of an inhaled short or long acting anticholinergic must be paid within 45 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 patients experiencing exacerbations while on antimuscarinic therapy.

Albuterol/Levalbuterol Rescue Inhalers

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, patient 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

- Exception:
  - If primary insurance will only pay for Ventolin HFA or ProAir Respiclick and patient is well-controlled without steroid inhaler (i.e. uses less than 2 canisters per 6 months).

Prior Authorization

General Prior Authorization Form
MedWatch Form

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
Albuterol HFA – Labeler 66993, 50090	Albuterol HFA – Labeler 00933, 00254, 45802, 69097, 71205
PROAIR (albuterol) HFA – *Brand Preferred*	ProAir Digihaler
PROAIR RESPICLICK (albuterol)	PROVENTIL (albuterol) HFA
XOPENEX (levalbuterol) HFA - *Brand Preferred*	VENTOLIN (albuterol) HFA

Anticholinergics/Beta Agonists Combinations

General Prior Authorization Form

Non-Preferred Agents Criteria:

- The patient must have an FDA-approved indication for use (meets label recommendations for diagnosis and age).
- The patient 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 patient must have had a 30-day trial of Stiolto Respimat, as evidenced by paid claims or pharmacy printouts.
  - Clinical justification must be provided explaining why the patient is unable to use the preferred products (subject to clinical review).

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

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.

Prior Authorization

General Prior Authorization Form

Please use the NDC Drug Lookup to find Prior Authorization (PA) Forms

Non-Preferred Agents Criteria:

- The patient 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:

- *** **Asmanex Twisthaler, Alvesco**: Patient must have had a 30-day trial of Asmanex HFA, as evidenced by pharmacy claims or pharmacy printouts.

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

Long Acting Anticholinergics

General Prior Authorization Form

Non-Preferred Agents Criteria:

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

Product Specific Criteria:

- ***Lonhala Magnair**:
    - The patient 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 patient 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)	YUPELRI (revefenacin)
SPIRIVA RESPIMAT 2.5 MCG (tiotropium)	
TUDORZA PRESSAIR (aclidinium)	

Spiriva Respimat 1.25 mcg

General Prior Authorization Form

Criteria for coverage:

- The patient must have a diagnosis of asthma
- The patient must have failed a 30-day trial of a steroid inhaler and a long acting beta agonist

Long Acting Beta Agonists

General Prior Authorization Form

Group Criteria:

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

Product Specific Criteria:

- ***Brovana**: The patient must have had a 30-day trial of Perforomist, as evidenced by paid claims or pharmacy printouts.

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
PERFOROMIST (formoterol)	BROVANA (arformoterol)***
SEREVENT DISKUS (salmeterol)	

STRIVERDI RESPIMAT (olodaterol)	

Steroid/Long Acting Beta Agonist (LABA) Combination Inhalers

General Prior Authorization Form

Criteria for coverage:

- The patient must have had 30-day trials of each preferred agent, as evidenced by paid claims or pharmacy printouts
- The patient must have a diagnosis of an FDA-approved indication for use and meet the criteria for that diagnosis
    - **For COPD diagnosis: one of the following must be met (A or B):**
        - A. The patient must have failed 30-day trials of at least 1 agent from each of the below lists (I and II)
            - I. Tudorza Pressair, Spiriva Handihaler, Spiriva Respimat, or Incruse Ellipta
            - II. Brovana, Striverdi Respimat, Perforomist, or Serevent.
        - B. The patient must have failed 30-day trials of at least 1 of the following agents below:
            - Anoro Ellipta, Stiolto Respimat, Bevespi Aerosphere, or Trelegy Ellipta
    - **For asthma diagnosis:**
        - The patient 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 Preferred*	AIRDUO RESPICLICK (Fluticasone/Salmeterol)
ADVAIR HFA (Fluticasone/Salmeterol)	BREO ELLIPTA (Fluticasone/Vilanterol)
DULERA (Mometasone/Formoterol)	Budesonide/Formoterol
SYMBICORT (Budesonide/Formoterol)	Fluticasone/Salmeterol
	WIXELA INHUB (Fluticasone/Salmeterol)

Steroid/Anticholinergics/Long Acting Beta Agonists Combinations

General Prior Authorization Form

Non-Preferred Agents Criteria:

- The patient must have an FDA-approved indication for use (meets label recommendations for diagnosis and age).
- **For COPD diagnosis:** the patient must have had a 30-day trial of the following combinations (both 1 AND 2), as evidenced by paid claims or pharmacy printouts:
    1. Steroid/Long Acting Beta Agonist (LABA) Combination Inhalers + Long Acting Anticholinergics
    2. Combination Anticholinergics/Long Acting Beta Agonist + Inhaled Steroid
- **For asthma diagnosis:** the patient must have had at least two 30-day trials of a steroid/LABA combination inhaler (unique ingredients for each trial) + Spiriva Respimat 1.25 mg inhaler, as evidenced by paid claims or pharmacy printouts

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
	TRELEGY ELLIPTA (Fluticasone Furoate/Umeclidinium/Vilanterol)

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 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.

Duration Coverage

- A total of 12 consecutive weeks will be covered for all other products, every 6 months (Chantix may be extended to 24 consecutive weeks if abstinent)

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

Naloxone Rescue Medications

General Prior Authorization Form

Group Criteria (Initial):

- Narcan Nasal Spray does NOT require prior authorization for the initial dose

Group Criteria (Renewal):

- The provider must attest that it is known that the previous dose was taken by the patient (and not diverted or given to another patient)
- One of the following criteria must be met (A, B, or C)
    A. The previous dose has expired
    B. The dose was used by patient for illicit drug use

C. The patient 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

Opioid Antagonist

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

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

Underutilization

- Buprenorphine and buprenorphine/naloxone must be used compliantly and will reject on point of sale for late fill

Prior Authorization Criteria

General Prior Authorization Form

Product Specific Criteria:

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

Non-Preferred Agents Criteria:

- The patient 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 patient 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.
- For all non-preferred agents OTHER than Zubsolv (buprenorphine/naloxone):
  - The patient must have failed a 30-day trial of Zubsolv (buprenorphine/naloxone)
  - Clinical justification must be provided explaining why the patient is unable to use Zubsolv (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.

PREFERRED AGENTS (NO PA REQUIRED)		NON-PREFERRED AGENTS (PA REQUIRED)
Buprenorphine-naloxone tablets		BUNAVAIL FILM (buprenorphine/naloxone)
Buprenorphine tablets***		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 patient must have failed 30-day trials of at least two preferred products, as evidenced by paid claims or pharmacy printouts.

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
CLIMARA PRO (estradiol-levonorgestrel) PATCH	ACTIVELLA (Estradiol/Norethindrone) TABLET
COMBIPATCH (Estradiol- Norethindrone)	ALORA (Estradiol) PATCH TWICE WEEKLY
ELESTRIN (estradiol) GEL	AMABELZ (Estradiol/Norethindrone) TABLET
Estradiol Tablet	BIJUVA (Estradiol/Progesterone)
ESTRING (estradiol)	CLIMARA (Estradiol) PATCH WEEKLY
EVAMIST (estradiol) SPRAY	DELESTROGEN (Estradiol Valerate) INJECTION
MENOSTAR (estradiol) PATCH	DEPO-ESTRADIOL (Estradiol Cypionate) INJECTION
Norethindrone-Ethinyl Estradiol tablet	DIVIGEL (estradiol) GEL
PREMARIN (estrogens, conjugated) INJECTION	DOTTI (Estradiol) PATCH TWICE WEEKLY
PREMARIN (estrogens, conjugated) TABLET	ESTRACE (Estradiol) TABLET
PREMARIN (estrogens, conjugated) VAGINAL CREAM	Estradiol Valerate Injection
PREMPHASE (estrogen, conj.,m-progest) TABLET	Estradiol- Norethindrone Tablet
PREMPRO (estrogen, conj.,m-progest) TABLET	Estradiol Patch Twice Weekly
VAGIFEM (estradiol) VAGINAL TABLET	Estradiol Patch Weekly
	Estradiol Vaginal Cream
	Estradiol Vaginal Tablet
	FEMRING (estradiol)
	FYAVOLV (Norethindrone-Ethinyl Estradiol) TABLET
	JINTELI (Norethindrone-Ethinyl Estradiol) TABLET
	LOPREEZA (Estradiol/Norgestimate) TABLET
	MENEST (estrogens, esterified) TABLET
	MIMVEY (Estradiol/Norgestimate) TABLET
	MINIVELLE (Estradiol) PATCH TWICE WEEKLY
	PREFEST (Estradiol/Norgestimate) TABLET
	VIVELLE-DOT (Estradiol) PATCH TWICE WEEKLY
	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

Oriahnn

Diagnosis

- The patient must have an FDA approved indication

Age

- The patient must be 18 years of age or older

PREFERRED AGENTS (CLINICAL PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
ORIAHNN (Elagolix, Estradiol, and Norethindrone acetate)	

Orilissa

Prior Authorization Form - Orilissa

Initial Criteria: *Approval Duration = 6 months*

- The patient must be 18 years of age or older
- The patient must have a diagnosis of moderate to severe pain associated with endometriosis
- The patient must not have osteoporosis or severe liver disease (Child-Pugh Class C).
- The patient must have failed the following trials (A and B), as evidenced by paid claims or pharmacy printouts:
  - A. A 3-cycle trial of mefenamic acid, meclofenamate, celecoxib, ibuprofen 1800mg/day or equivalent high dose NSAID
  - B. A 3-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

Non-Preferred Agents Criteria:

- The patient must have an FDA-approved indication for use (meets label recommendations for diagnosis and age).
- The patient 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 medication is medically necessary

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

MAKENA (hydroxyprogesterone caproate) – *Brand Preferred*	hydroxyprogesterone caproate

Vaginal Anti-Infectives

General Prior Authorization Form

Non-Preferred Agents Criteria:

- The patient must have an FDA-approved indication for use (meets label recommendations for diagnosis and age).
- The patient 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	METROGEL-VAGINAL (Metronidazole)
GYNAZOLE 1 (butoconazole) CREAM	MICONAZOLE 3 (miconazole) suppository
Metronidazole gel	terconazole suppository
NUVESSA (Metronidazole) GEL	VANDAZOLE (Metronidazole) GEL
terconazole cream	

Preferred Dosage Forms List:

Prior Authorization Form - Non-Preferred Dosage Form

Criteria for coverage:

- Clinical justification must be provided explaining why the patient is unable to use the preferred agents (subject to clinical review).
- The patient must have a diagnosis of an FDA-approved indication for use
- The patient must not have any contraindication to the requested product
- The patient 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 patient 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 patient*

***: 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
GOLYTELY 236-22.74G	GAVILYTE-C
MOVIPREP	GAVILYTE-N
OSMOPREP	NULYTELY
PEG-3350 AND ELECTROLYTES 236-22.74G	PEG 3350-ELECTROLYTE 240-22.72G
	PEG 3350-ELECTROLYTE 420 G
	PEG 3350/SOD SUL/NACL/KCL/ASB/C
	PLENVU
	PREPOPIK
	SUPREP
	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

Daxbia (Cephalexin)

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

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)

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)
	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)
	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)
	INFAMMACIN (diclofenac/capsicum)
	KETODAN (ketoconazole/skin cleanser 28)
	LIDOPURE PATCH 5% COMBO PAC (lidocaine/kinesiology tape)
	LIDOTIN (gabapentin/lidocaine/silicone)

Please use the NDC Drug Lookup to find Prior Authorization (PA) Forms

	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)
	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)
	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)
	TREXALL (methotrexate)

Mupirocin

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
Mupirocin Ointment	Mupirocin Calcium Cream

Nascobal (Cyanocobalamin) Nasal Spray

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

Nitroglycerin Spray

Required trial duration: 1 dose while on preventative medication

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

Please use the NDC Drug Lookup to find Prior Authorization (PA) Forms

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 Preferred*	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	

Statins (HMG-CoA 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)
JUVISYNC (sitaglipitin/simvastatin)	Fluvastatin ER
LIVALO (pitavastatin)	LESCOL XL (Fluvastatin)
Lovastatin	LIPITOR (atorvastatin)
Pravastatin	PRAVACHOL (pravastatin)
Rosuvastatin	VYTORIN (ezetimibe/simvastatin)
Simvastatin	ZOCOR (simvastatin)
	ZYPITAMAG (pitavastatin)

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	Budesonide 9 mg ER Tablet
Cortisone	DEXPAK (dexamethasone)
Dexamethasone	DXEVO (dexamethasone)
Hydrocortisone	EMFLAZA (deflazacort)
Methylprednisone	MILLIPRED (Prednisolone)
Prednisolone sodium phosphate 5mg/5ml, 15mg/5ml, 25mg/5ml	Prednisone Intensol
Prednisone Solution	Prednisolone sodium phosphate ODT
Prednisone Tablets	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	TIROSINT (levothyroxine)

Tussicaps

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

Topical Corticosteroids Preferred Medication List

Potency	Dosage Form	Preferred		Non-Preferred	
Class 1 - Very High Potency	**Class 1 - Very High Potency**				
	Cream	Clobetasol Propionate	0.05%	Clobetasol Emollient	0.05%
				Halobetasol Propionate	0.05%
				STEP2* Fluocinonide	0.10%
	Ointment	Betamethasone, augmented	0.05%	Halobetasol Propionate	0.05%

Please use the NDC Drug Lookup to find Prior Authorization (PA) Forms

		Clobetasol Propionate	0.05%		
	Foam, Gel, Lotion, Shampoo, Solution, Spray, Tape	Clobetasol Propionate Solution	0.05%	Betamethasone, augmented lotion	0.05%
		Clobetasol Propionate Lotion	0.05%	Betamethasone, augmented gel	0.05%
		Clobex (*Brand Required*) Shampoo	0.05%	Clobetasol emulsion foam	0.05%
		Clobex (*Brand Required*) Spray	0.05%	Clobetasol propionate foam	0.05%
		Clobetasol Propionate Gel	0.05%	Lexette (Halobetasol) foam	0.05%
				Desoximetasone spray	0.25%
				STEP2* Cordran (Flurandrenolide) Tape	4MCG/SQ CM
				STEP 2* Ultravate (Halobetasol) lotion	0.05%
Class 2 - High Potency	**Class 2 - High Potency**				
	Cream	Betamethasone, augmented	0.05%	Apexicon E	0.05%
		Desoximetasone	0.25%	Fluocinonide-E	0.05%
		Diflorasone Diacetate	0.05%	STEP2* Amcinonide	0.10%
		Fluocinonide	0.05%		
		Halog-*brand required*	0.10%		
		Triamcinolone Acetonide	0.50%		
	Ointment	Betamethasone Dipropionate	0.05%	Diflorasone Diacetate	0.05%
		Betamethasone Valerate	0.10%		
		Desoximetasone	0.25%		
		Fluocinonide	0.05%		
		Fluticasone Propionate	0.01%		
		Halog (halcinonide)	0.10%		
		Mometasone Furoate	0.10%		
		Triamcinolone Acetonide	0.50%		
	Gel, Lotion Solution	Fluocinonide gel	0.05%	STEP2* Amcinonide Lotion	0.10%
		Fluocinonide solution	0.05%	Bryhali (halobetasol)	0.01%
				Desoximetasone gel	0.05%
				Halog (halcinonide) Solution	0.1%
Class 3 - Medium Potency	**Class 3 - Medium Potency**				
	Cream	Betamethasone Valerate	0.10%	Betamethasone Dipropionate	0.05%
		Fluticasone Propionate	0.05%	Clocortolone Pivalate	0.10%
		Mometasone Furoate	0.10%	Fluocinolone Acetonide	0.025%
		Synalar	0.025%	Pandel	0.10%
		Triamcinolone Acetonide	0.10%	Prednicarbate	0.10%
				STEP2* Desoximetasone	0.05%
				STEP2* Flurandrenolide	0.05%

Please use the NDC Drug Lookup to find Prior Authorization (PA) Forms

				STEP2* Hydrocortisone Butyrate	0.10%
				STEP2* Hydrocortisone Butyrate Emollient	0.10%
				STEP2* Hydrocortisone Valerate	0.20%
	Ointment	Fluocinolone Acetonide	0.025%	Desoximetasone	0.05%
		Desonide	0.05%	Hydrocortisone Valerate	0.20%
		Hydrocortisone Butyrate	0.10%	Triamcinolone	0.05%
		Prednicarbate	0.10%	STEP2* Flurandrenolide	0.05%
		Triamcinolone Acetonide	0.10%		
		Triamcinolone Acetonide	0.025%		
	Aerosol, Foam, Lotion, Solution, Spray	Mometasone Furoate Solution	0.10%	Betamethasone Valerate Foam	0.12%
		Betamethasone Dipropionate Lotion	0.05%	Triamcinolone Acetonide Aerosol	0.147MG/G
		Hydrocortisone Butyrate Solution	0.10%	STEP2* Flurandrenolide Lotion	0.05%
		Triamcinolone Acetonide Lotion	0.10%	STEP2* Fluticasone Propionate Lotion	0.05%
				STEP2* Sernivo spray (Betamethasone)	0.05%
Class 4 - Low Potency	**Class 4 - Low Potency**				
	Cream	Alclometasone Dipropionate	0.05%		
		Desonide	0.05%		
		Fluocinolone Acetonide	0.01%		
		Hydrocortisone	2.50%		
		Hydrocortisone	1.00%		
		Triamcinolone Acetonide	0.025%		
	Ointment	Alclometasone Dipropionate	0.05%		
		Hydrocortisone	1.00%		
		Hydrocortisone	2.50%		
	Oil, Lotion, Gel Shampoo, Solution	Betamethasone Valerate Lotion	0.10%	Desonide Gel	0.05%
		Capex Shampoo	0.01%		
		Desonide Lotion	0.05%		
		Fluocinolone Acetonide Oil	0.01%		
		Fluocinolone Acetonide Solution	0.01%		
		Hydrocortisone Lotion	2.50%		
		Texacort Solution	2.50%		
		Triamcinolone Acetonide Lotion	0.025%		

Clinic Administered Drugs

Brineura

Prior Authorization Form - Brineura

Initial Criteria: *Approval Duration = 6 months*

- Patient must be between 3 and 8 years of age.

- The patient must have diagnosis of late infantile neuronal ceroid lipofuscinosis type 2 (CLN2), also known as tripeptidyl peptidase 1 (TPP1) deficiency confirmed by the following:
    - A genetic test confirming CLN2 disease
    - An enzyme assay confirming deficiency of tripeptidyl peptidase 1 (TPP1)
- Brineura must be prescribed by or in consultation with a metabolic specialist, geneticist, or pediatric neurologist.
- Patient must not have ventriculoperitoneal shunts
- Baseline results of motor and language domains of the Hamburg CLN2 Clinical Rating Scale must be submitted and meet the following parameters
    - Results must show a combined score of less than 6 in the motor and language domains
    - Results must show a score of at least 1 in each of these domains

Renewal Criteria: *Approval Duration = 12 months*

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

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

Duchenne Muscular Dystrophy (DMD)

Exondys / Vyondys

Category Criteria (Initial): *Approval Duration: 8 weeks*

- The patient must be a male between ages of 4 and 19 years old
- The prescriber must be, or in consult with, a neurologist specializing in treatment of DMD (submit documentation of formal consultation with specialist)
- The patient must have an FDA-approved diagnosis confirmed by genetic test as recommended by manufacturer
- The prescriber must submit medical records confirming the patient has
    - A baseline 6-Minute Walk Time (6MWT) ≥ 300 meters while walking independently (e.g. without side-by-side assist, cane, walker, wheelchair, etc.)
    - Stable respiratory function – FVC predicted > 50%, not requiring ventilatory assistance
    - Stable cardiac function – LVEF > 40 % by ECHO
    - Inadequate treatment response with standard corticosteroid therapy for a minimum of 6 months with adherence, as evidenced by paid claims or pharmacy printouts
- The patient must be currently taking corticosteroids, as evidenced by paid claims or pharmacy printouts, and will continue taking with requested agent
- Weight and calculated dose must be provided consistent with approved FDA dose of 30 mg/kg infused once weekly
- The patient must not be taking any other RNA antisense agent or any other gene therapy

Category Criteria (Renewal): *Approval Duration: 6 months*

- The prescriber must be, or in consult with, a neurologist specializing in treatment of DMD (submit documentation of formal consultation with specialist)
- The prescriber must submit medical records confirming the patient has maintained
    - A 6MWT ≥ 300 meters while walking independently (e.g. without side-by-side assist, cane, walker, wheelchair, etc.)
    - Stable respiratory function – FVC predicted > 50%, not requiring ventilatory assistance
    - Stable cardiac function – LVEF > 40 % by ECHO

Eosinophilic Asthma

Please see Clinical Criteria if being dispensed by a pharmacy

If billed by medical/physician billing, does not require prior authorization if being used for an FDA approved indication.

Self-Injectable Products

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
FASENRA (benralizumab)	DUPIXENT (dupilumab)
	NUCALA (mepolizumab)

Health Professional Administration Only Products

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS (PA REQUIRED)
CINQUAIR (reslizumab)	
XOLAIR (omalizumab)	

Gamifant

Category Criteria (Initial): *Approval Duration: 3 months or up to the hematopoietic stem cell transplantation (HSCT) date*

- The prescriber must be, or in consultation with, a hematologist, oncologist, immunologist, or transplant specialist
- The patient must have diagnosis of primary hemophagocytic lymphohistiocytosis (HLH)
- The patient has refractory, recurrent or progressive disease or intolerance with conventional HLH therapy (i.e., etoposide + dexamethasone, cyclosporine A, or Anti-thymocyte globulin)
- The patient must be a candidate for stem cell transplant
- The patient must have one of the following:
  - Confirmation of a gene mutation known to cause primary HLH (e.g. PRF1, UNC13D, STX11 RAB27A, or STXBP2)
  - Confirmation of 5 of the following clinical characteristics:
    - Fever ≥ 101.3F for over 7 days
    - Splenomegaly
    - Two of the following cytopenias in the peripheral blood:
      - Hemoglobin < 9 g/dL (or < 10 g/dL in infants less than 4 weeks of age)
      - Platelet count < 100,000/microL
      - ANC <1000/microL
    - One of the following:
      - Hypertriglyceridemia defined as fasting triglycerides ≥ 265 mg/dL (2 mmol/L)
      - Hypofibrinogenemia defined as fibrinogen ≤ 1.5 g/L
    - Hemophagocytosis in bone marrow or spleen or lymph nodes with no evidence of malignancy
    - Low or absent natural killer cell activity
    - Ferritin ≥ 500 mg/L
    - Soluble CD25 (i.e., soluble IL-2 receptor) ≥ 2,400 U/mL
- The requested medication must be administered with dexamethasone as part of the induction or maintenance phase of stem cell transplant, which is to be discontinued at the initiation of conditioning for stem cell transplant

Category Criteria (Renewal): *Approval Duration: 3 months or up to the HSCT date*

- At least 3 HLH abnormalities must be improved by at least 50% from baseline.

Spinal Muscular Atrophy (SMA)

Spinraza

Prior Authorization Form - Spinraza

Criteria: *Approval Duration = 12 months*

- For a diagnosis of Spinal Muscular Atrophy (SMA) Type 1, 2, or 3:

- The patient must not have respiratory insufficiency (need for invasive or noninvasive ventilation for more than 6 hours per 24-hour period)
- The patient must not require gastric feeding tubes for the majority of feeds
- The patient must not have severe contractures or severe scoliosis
- The patient must not have wasting or cachexia

o For a diagnosis of Spinal Muscular Atrophy (SMA) Type 3:
- The patient must be less than 2 years of age
- The patient must be experiencing issues with ambulating (falls, trouble climbing stairs, unable to walk independently)

Zolgensma

Criteria: *Approval Duration = 1 month (Approval is limited to a single intravenous infusion per lifetime)*

- Patient is less than 2 years of age
- The diagnosis is spinal muscular atrophy (SMA) with genetic testing confirming bi-allelic deletions or mutations in the *SMN1 gene*
- Medication is prescriber per the dosing guidelines in the package insert (recommended dose is 1.1×10^{14} vector genomes per kilogram)
- Baseline Documentation has been submitted confirming anti-adeno-associated virus serotype 9 (anti-AAV9) antibody titer is ≤ 1:50 measured by Enzyme-linked Immunosorbent Assay (ELISA) binding immunoassay
- Patient must not have advanced SMA evidenced by one of the following
  - Complete paralysis of limbs
  - Permanent ventilator dependence (defined as requiring invasive ventilation (tracheostomy) or respiratory assistance for 16 of more hours per day (including noninvasive ventilatory support) continuously for 14 or more days in the absence of an acute reversible illness, excluding perioperative ventilation.

Synagis

Prior Authorization Form - Synagis

Criteria: *Approval Duration = 5 months (allows for 5 monthly doses between October 19th through April 21st)*

o Patient must have one of the following diagnoses (A, B, or C) and the additional criteria outlined for diagnosis:
- **Prematurity:**
  - < 29 weeks, 0 days gestational age
  - ≤12 months of age at start of RSV season
- **Chronic Lung Disease of Prematurity (CLD)**
  - ≤12 months of age at start of RSV season
    - ❖ < 32 weeks, 0 days gestational age
    - ❖ Requires supplemental oxygen > 21% for at least the first 28 days after birth
  - 13-24 months of age at start of RSV season
    - ❖ < 32 weeks, 0 days gestational age
    - ❖ Requires supplemental oxygen > 21% for at least the first 28 days after birth
    - ❖ Continues to receive medical support within six months before the start of RSV season with supplemental oxygen, diuretic, or chronic corticosteroid therapy
- **Congenital Heart Disease**
  - ≤12 months of age at start of RSV season
    - ❖ Hemodynamically significant cyanotic or acyanotic congenital heart disease with medical therapy required

Therapeutic Duplication Edits

Therapeutic Duplication Edits for medications on the PDL are embedded within those categories. This is a listing of therapeutic duplication edits on medications that are not managed by the PDL.

Antidepressant Medications

- One strength of one medication per therapeutic class is allowed at a time
  - Therapeutic classes:
    - SSRIs
    - SNRIs
    - Tricyclic Antidepressants
    - Bupropion
    - Mirtazapine
    - Selegiline
- Mirtazapine is not allowed with other alpha 2 agonists (clonidine, clonidine/chlorthalidone, guanfacine, methyldopa)
  - Mirtazapine is also an alpha 2 agonist
- Fetzima, Viibryd, or Brintellix are not allowed with other antidepressant medications
  - Exceptions: trazodone and mirtazapine
- Fluvoxamine, a strong 1A2 inhibitor, is not covered with Ramelteon, a 1A2 Substrate.

Benzodiazepines

- One short acting medication is allowed at a time: alprazolam, lorazepam, oxazepam
- One long acting medication is allowed at a time: chlordiazepoxide, clonazepam, diazepam, alprazolam ER
- Benzodiazepines are not covered with
  - Opioids: See Exception Criteria
  - Xyrem
  - Mydayis
    - Insomnia has been reported in 25-56% of patients receiving Mydayis. Patients reporting insomnia should use a shorter acting product that does not reach steady state.
- Benzodiazepines indicated only for insomnia are not allowed with other non-barbiturate insomnia medications or other benzodiazepines
- Long Acting Benzodiazepines are not covered with sleeping medication due to CNS depression
  - Belsomra and Dayvigo are not covered with short or long acting benzodiazepines
- 3A4 Substrates (alprazolam, clonazepam, midazolam,) are not allowed with strong 3A4 inhibitors. Click here for a full listing of medications included.

Long Acting Contraception

- One strength of one medication is allowed at a time

Therapeutic Duplication Class Expanded Lists

These classes are managed within the PDL. For full explanation of medications included within edit, an expanded list is provided here. Links with detailed explanation of how these edits work are included within the applicable sections within the PDL.

Opioid and Benzodiazepines

Opioid and Benzodiazepines Concurrent Use Form

Includes long acting opioids over 90 MME/day or immediate release opioids over 15 MME/dose due to guidance in The SUPPORT for Patients and Communities Act (H.R. 6) on CNS depression risk between benzodiazepines and opioids

Criteria:

- The prescriber must attest that they have reviewed the past 3 months of the patient's North Dakota PDMP reports.
- The patient 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)
  - Patient 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 benzodiazepine and opioid attest to the following:
      - The patient 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

Anticholinergics and Acetylcholinesterase Inhibitors

Anticholinergics	Acetylcholinesterase Inhibitors
Anoro Ellipta (Umeclidinium Bromide/Vilanterol)	Aricept (donepezil)
Atrovent HFA (Ipratropium Bromide)	Exelon (Rivastigmine)
Benztropine	Razadyne (Galantamine)
Bevespi Aerosphere (glycopyrrolate/formoterol)	Pyridostigmine
Combivent Respimat (Ipratropium/Albuterol)	
Cuvposa (Glycopyrrolate)	
Detrol (tolterodine)	
Dicyclomine	
Enablex (Darifenacin)	
Glycopyrrolate	
Incruse Ellipta (Umeclidinium Bromide)	
Lonhala Magnair (glycopyrrolate)	
Oxybutynin	
Propantheline	
Spiriva (Tiotropium Bromide)	

Spiriva Respimat (Tiotropium Bromide)	
Stiolto Respimat (Tiotropium/Olodaterol)	
Toviaz (Fesoterodine)	
Trelegy Ellipta (Fluticasone/Umeclidinium/Vilanterol)	
Trihexyphenidyl	
Trospium	
Tudorza Pressair (Aclidinium Bromide)	
Vesicare (Solifenacin)	
Yupelri (Revefenacin)	

CYP450 3A4 Interactions

Strong 3A4 Inhibitors	3A4 Substrates
Atazanavir	Alprazolam
Clarithromycin	Clonazepam
Cobicistat	Corlanor
Darunavir	Fentanyl
Dasabuvir	Midazolam
Idelaisib	Methadone
Indinavir	Oxycodone
Itraconazole	
Ketoconazole	
Lopinavir	
Mifepristone	
Nefazodone	
Nelfinavir	
Ombitasvir	
Paritaprevir	
Posaconazole	
Ritonavir	
Saquinavir	
Telithromycin	
Voriconazole	

Electronic Step Care and Concurrent Medications

Electronic Step Care and Concurrent Medications for medications on the PDL are embedded within those categories. This is a listing of Electronic Step Care and Concurrent Medications on medications that are not managed by the PDL.

Antidepressants

- Trintellix: Initiation with 10 mg must be used for 10 days prior to continuing therapy with 20 mg
  - Trintellix recommended starting dose is 10 mg once daily.
- Desvenlafaxine ER: 30 days of 50 mg must be paid within 40 days of 25 mg date of service
  - 25 mg is intended only for gradual titration before discontinuation. It is not a therapeutic dose.

Hepatic Encephalopathy

- 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.

Test strips, Lancets, Meters

- A total of a 25 day supply of Insulin and/or Sulfonylurea therapy must be paid within 150 days prior to diabetic test strip's date of service.
  - The ADA guidelines point out the lack of clinical utility and cost-effectiveness of routine Self-Monitoring of Blood Glucose (SMBG) in non-insulin treated patients. Both the Society of General Internal Medicine and the Endocrine Society recommend against routine SMBG for type 2 diabetes patients not on insulin or agents that cause hypoglycemia.
- Gestational Diabetes is a covered indication for diabetic testing supplies. Patients with gestational diabetes must have prenatal vitamins or folic acid preparations in their prescription claim history for testing supplies to pay.

Potassium Supplements

- A total of a 30-day supply of diuretic must be paid within 100 days prior to potassium supplement's date of service.
  - Potassium labs should be regularly monitored when receiving continuous potassium supplementation to prevent hyperkalemia, especially in the absence of a potassium wasting diuretic.
  - A yearlong override will be granted after confirmation of continued need and monitoring

First Fill

First Fill for medications on the PDL are embedded within those categories. This is a listing of First Fill on medications that are not managed by the PDL.

Antidepressants

- Viibryd and Trintellix must be filled with a 10 day supply if no previous fill within past 99 days

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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 that patients receiving a prescription for non-preferred medications to meet specific diagnosis and step-therapy requirements. Criteria for agents requiring prior authorization 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 physician)		
Prescriber NPI	Telephone Number	Fax Number	
Address	City	State	Zip Code
Requested Drug and Dosage:	**Diagnosis for this request:**		
List all failed medications:		**Start Date:**	**End Date:**

Additional Qualifications for Coverage (e.g. medical justification explaining inability to meet required trials)

□ Patient is pregnant: Due Date _____
□ Patient has inability to take or tolerate solid oral dosage forms (please attach swallow study)
□ Patient has feeding tube in place: (please state specific type of feeding tube _____)
□ 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 patient's medical records. I also understand that any misrepresentations or concealment of any information requested in the prior authorization request may subject me to audit and recoupment.*

Part II: TO BE COMPLETED BY PHARMACY

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

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Non-Preferred Dosage Forms
Prior Authorization Form

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

Prior Authorization Vendor for ND

ND Medicaid requires that patients receiving a prescription for non-preferred dosage form of a preferred agent must meet the following prior authorization criteria:

- The prescriber must submit medical justification explaining why the patient cannot use the preferred product (subject to clinical review)
- Patient must have FDA approved indication for use
- Patient must not have contraindications to requested product
- Patient must have failed a therapeutic course of all preferred agents within the last 2 years
  - Trials must have been at least 30 days in duration unless otherwise indicated
  - A failure is defined as product was not effective at maximum tolerated dose or patient 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 patient

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 physician)		
Prescriber NPI	Telephone Number	Fax Number	
Address	City	State	Zip Code
Requested Drug and Dosage:	**Diagnosis for this request:**		
List all failed medications:	**Start Date:**	**End Date:**	

• **Does the patient have any contraindications to therapy with the requested agent?** • **Is medical justification explaining why the patient cannot use the preferred product attached?** *(please attach any relevant documentation to the request)*	□ YES □ NO □ 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 patient's medical records. I also understand that any misrepresentations or concealment of any information requested in the prior authorization request may subject me to audit and recoupment.*

Part II: TO BE COMPLETED BY PHARMACY

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

health information designs

Concurrent Medication Required Prior Authorization Form

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

Prior Authorization Vendor for ND

ND Medicaid requires that patients receiving a product on the "Concurrent Medications and Step Care" list must also be taking the required concurrent medication listed in the document. Overrides will be considered for patients that are unable to take the required concurrent medication based on medical justification provided by the prescriber (subject to clinical review by ND Medicaid).

For an override to be considered, please complete and fax in this request form to the above number. Please attach any and all documentation (chart notes, pharmacy print-outs, etc.) supporting a medical justification as to why the patient is unable to use the required concurrent medication.

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 physician)		
Prescriber NPI	Telephone Number	Fax Number	
Address	City	State	Zip Code
Requested product(s) and frequency of use:	**Diagnosis for this request:**		
Medical justification for inability to use required concurrent medication (please attach any supporting documentation to 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 patient's medical records. I also understand that any misrepresentations or concealment of any information requested in the prior authorization request may subject me to audit and recoupment.*			

Part II: TO BE COMPLETED BY PHARMACY

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

health information designs

Dispense as Written 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

North Dakota Medicaid requires that patients receiving a brand name drug, when there is a generic equivalent available, must first try and fail the generic product. The Dispense as Written (DAW1) prior authorization criteria can be found in 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				
Prescriber NPI		Telephone Number	Fax Number	
Address		City	State	Zip Code
Requested Drug:	**DOSAGE:**	**Diagnosis for this request:**		

QUALIFICATIONS FOR COVERAGE: □ FAILED TWO GENERIC EQUIVALENTS	**Start Date**	**End Date**	**Dose**	**Frequency**

ADVERSE REACTION TO GENERIC EQUIVALENT: □ FDA MEDWATCH FORM ATTACHED FOR EACH GENERIC FAILED

PRIMARY INSURANCE REQUIRES: □ BRAND NAME PRODUCT

Primary insurance carrier: _____

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

Prescriber (or Staff) / Pharmacy Signature**	Date

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

Part II: TO BE COMPLETED BY PHARMACY

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

health information designs

Antibiotics – Resistance Prevention Prior Authorization Form

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

Prior Authorization Vendor for ND

ND Medicaid requires that patients receiving a prescription for select antibiotics to meet the following criteria:

- Medication must be prescribed by an infection disease specialist, an antibiotic stewardship program, or protocol
- Patient must be of an appropriate age for use per manufacturer label and have a diagnosis of an FDA approved indication for use, proven to be caused by a susceptible microorganism by culture and susceptibility testing
- One of the following must be met:
  - Prescriber must provide evidence-based medical justification for use, explaining why a preferred antibiotic is not an option due to susceptibility, previous failed trials, or other contraindications (subject to clinical review)
  - Patient is continuing treatment upon discharge from an acute care facility

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 physician)		
Prescriber NPI	Telephone Number	Fax Number	
Address	City	State	Zip Code

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

Qualifications for coverage:

Has the provider attached documentation showing that the patient's infection is caused by a susceptible microorganism by culture and susceptibility testing?	□ YES □NO
Is the patient continuing treatment upon discharge from an acute care facility?	□ YES □NO
RENEWAL ONLY: Is the patient's condition improving and continued treatment is required after re-evaluation of their condition?	□ YES □NO

Justification for use over preferred agents (provide below or in documentation attached to 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 patient's medical records. I also understand that any misrepresentations or concealment of any information requested in the prior authorization request may subject me to audit and recoupment.*

Part II: TO BE COMPLETED BY PHARMACY

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

health information designs

Antihemophilic Factors 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 patients receiving a new prescription for antihemophilic factors must meet the following criteria:

Criteria for all agents:

- The provider must attest that the patient visits an accredited Hemophilia Treatment Center once per year.
  - The date of the patient's last appointment with treatment center must be provided.
  - Contact information for treatment center must be provided.

Non-Preferred Agents Criteria:

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

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 physician)		
Prescriber NPI	Telephone Number	Fax Number	
Address	City	State	Zip Code

Requested Drug and Dosage:	**Diagnosis for this Request:**
TREATMENT CENTER CONTACT INFORMATION:	**Date of last appointment with treatment center:**
	Patient visits an accredited Hemophilia Treatment Center for yearly checkups: □ 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 patient's medical records. I also understand that any misrepresentations or concealment of any information requested in the prior authorization request may subject me to audit and recoupment.*

Part II: TO BE COMPLETED BY PHARMACY

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

health information designs

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 patients receiving both an opioid analgesic and a benzodiazepine must meet the "Opioid and Benzodiazepines" criteria listed in 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 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 physician)	
Prescriber NPI	Telephone Number	Fax Number
Requested Opioid Analgesic:	**Diagnosis for use of opioid(s) in this patient:**	
Plan to taper: (dose and length of treatment)	**Clinical justification for concurrent opioid and benzodiazepine treatment and/or reason opioid dose cannot be reduced:**	

Treatment Alternatives:	**Start/End Date:**	**Reason for failure:**
□ NSAIDs □ TCAs □ SNRIs □ Corticosteroids □ Weight Loss □ Physical Therapy □ Cognitive Behavioral Therapy □ Other		

Qualifications for coverage:

Does provider routinely check the PDMP?	□ YES □ NO
Has the provider established a realistic treatment plan with the patient, 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 patient's medical records. I also understand that any misrepresentations or concealment of any information requested in the prior authorization request may subject me to audit and recoupment.*

health information designs

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 patients receiving both an opioid analgesic and a benzodiazepine must meet the "Opioid and Benzodiazepines" criteria listed in 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 OF THE BENZODIAZEPINE

Recipient Name	Recipient Date of Birth	Recipient Medicaid ID Number
Prescriber Name	Specialist involved in therapy (if not treating physician)	
Prescriber NPI	Telephone Number	Fax Number
Requested Benzodiazepine:	**Diagnosis for use of a benzodiazepine in this patient:**	
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 patient, 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 patient undergo routine drug screens?	□ YES □ NO
Has the provider discussed and counseled the patient 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:

□ Patient'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

health information designs

Brineura
Prior Authorization Form

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

Prior Authorization Vendor for ND

ND Medicaid requires that patients receiving Brineura to meet prior authorization criteria. The prior authorization criteria can be found in 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 physician)		
Prescriber NPI	Telephone Number	Fax Number	
Billing Facility Name	Billing Facility NPI	Fax Number	
Address	City	State	Zip Code

Requested Drug and Dosage:	**ICD-10 Diagnosis Code(s) for this request:**

Qualifications for Coverage:

Initial Requests (please answer the questions below):	
Does patient have ventriculoperitoneal shunts?	□ YES □NO
Has the patient's diagnosis been confirmed by a genetic test confirming CLN2 disease?	□ YES □NO
Have results of an enzyme assay confirmed a deficiency of tripeptidyl peptidase 1 (TPP1) in this patient?	□ YES □NO
Have the patient's baseline results of motor and language domains of the Hamburg CLN2 Clinical Rating Scale been attached/faxed in with this request?	□ YES □NO
Renewal Requests (please answer the questions below):	
Does the patient have an acute, unresolved localized infection on or around the device insertion site or suspected or confirmed CNS infection?	□ YES □NO
Have the patient's current results of motor domain of the Hamburg CLN2 Clinical Rating Scale been attached/faxed in with this request?	□ YES □NO
Has the patient responded to therapy compared to pretreatment baseline with stability/lack of decline* in motor function/milestones?	□ YES □NO
**: Decline is defined as having an unreversed (sustained) 2-category decline or an unreversed score of 0 in the Motor domain of the CLN2 Clinical Rating Scale*	

Prescriber (or Staff) / Signature**	Date

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

health information designs

Diabetic Testing Supplies 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

In line with current ADA guidelines, ND Medicaid requires that patients receiving a prescription for diabetic testing supplies that are not receiving an insulin or sulfonylurea product, as evidenced by paid pharmacy claims, will require prior authorization to qualify for coverage.
Overrides for a period of 6 months will be considered for patients that are newly diagnosed, acutely ill, or have a significant change in health status for medically necessary purposes. To obtain an override, please complete this form and fax to the number above for clinical review.

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 physician)		
Prescriber NPI	Telephone Number	Fax Number	
Address	City	State	Zip Code
Requested product(s) and frequency of use:	**Diagnosis for this request:**		
Medical justification for use/ qualifications for coverage (please attach any supporting documentation to 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 patient's medical records. I also understand that any misrepresentations or concealment of any information requested in the prior authorization request may subject me to audit and recoupment.*			

Part II: TO BE COMPLETED BY PHARMACY

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

health information designs

Eczema / Atopic Dermatitis Prior Authorization Form

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

Prior Authorization Vendor for ND

ND Medicaid requires that patients receiving a new prescription for Eczema / Atopic Dermatitis agents that require prior authorization must meet prior authorization criteria. The prior authorization criteria can be found in 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 physician)		
Prescriber NPI	Telephone Number	Fax Number	
Address	City	State	Zip Code

Requested Drug:	**Diagnosis for this request:**	**Is the affected area is on the face, groin, axilla, or under occlusion?** □ 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 patient's medical records. I also understand that any misrepresentations or concealment of any information requested in the prior authorization request may subject me to audit and recoupment.*

Part II: TO BE COMPLETED BY PHARMACY

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

health information designs

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 patients receiving a new prescription for Emflaza must meet the criteria for use available at www.hidesigns.com/assets/files/ndmedicaid/2018/Criteria/PA_Criteria.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 physician)		
Prescriber NPI	Telephone Number	Fax Number	
Address	City	State	Zip Code

Requested Drug and Dosage:	**Diagnosis for this request:**	
List all failed medications:	**Start Date:**	**End Date:**

- **Patient's serum creatinine kinase activity prior to initiating treatment:**
- **Patient's current motor milestone score** (provide score and assessment used):
- **Did the patient experience onset of weakness before 5 years of age?** □ YES □ NO
- *INITIAL*: **Patient 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*: **Patient 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 patient's medical records. I also understand that any misrepresentations or concealment of any information requested in the prior authorization request may subject me to audit and recoupment.*

Part II: TO BE COMPLETED BY PHARMACY

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

health information designs

Gamifant
Prior Authorization Form

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

Prior Authorization Vendor for ND

ND Medicaid requires that patients receiving a new prescription for Gamifant 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. Please fill out this request form in its entirety, answer all questions relevant to the requested product, and attach any required documentation to this request form.

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

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

Requested Drug:	Diagnosis:	ICD-10 Code:

Prior therapies	**Start-end dates**	**Reason for discontinuation**

Is the patient a candidate for stem cell transplant?	□ **YES**	□ **NO**
Does the patient experience the following clinical characteristics?		
• Fever ≥101.3°F for > 7 days	□ YES	□ NO
• Splenomegaly	□ YES	□ NO
• Low or absent natural killer cell activity	□ YES	□ NO
• Ferritin ≥ 500 mg/L	□ YES	□ NO
• Soluble CD25 (i.e., soluble IL-2 receptor) ≥ 2,400 U/mL	□ YES	□ NO
• Fasting triglycerides ≥ 265 mg/dL (2 mmol/L)	□ YES	□ NO
• Fibrinogen ≤ 1.5 g/L	□ YES	□ NO
• ANC <1000/microL	□ YES	□ NO
• Platelet count < 100,000/microL	□ YES	□ NO
• Hemoglobin < 9 g/dL (or < 10 g/dL in infants < 4 weeks of age)	□ YES	□ NO
Has all required documentation been attached to the request (e.g. genetic testing, lab documentation)?	□ **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 patient's medical records. I also understand that any misrepresentations or concealment of any information requested in the prior authorization request may subject me to audit and recoupment.*

health information designs

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 Medicaid

ND Medicaid requires that patients receiving a preferred growth hormone*, Serostim, or Zorbtive must meet the criteria for the specified product listed in the preferred drug list (PDL). Please see the PDL at http://hidesigns.com/assets/files/ndmedicaid/NDPDL.pdf:

**=Patient's receiving a non-preferred growth hormone product must be switched to a preferred agent.*

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 physician)		
Prescriber NPI	Telephone Number	Fax Number	
Address	City	State	Zip Code
Requested Drug and Dosage:	**Diagnosis for this request:**		

Qualifications for coverage:

Does patient have any active malignancy?	□ YES □NO
Has patient attained epiphyseal closure?	□ YES □NO
Does the patient 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 patient have multiple pituitary hormone deficiencies caused by a known, hypothalamic-pituitary Disease*(endogenous GH deficiency only)*?	□ YES □NO
Has the patient received a renal transplant *(chronic renal insufficiency only)?*	□ YES □NO
Has a diagnosis of sleep apnea been ruled out in this patient *(Prader-Willi syndrome only)*?	□ YES □NO
Are all lab values stated as required in the criteria attached to this request?	□ YES □NO

Patient'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 patient's medical records. I also understand that any misrepresentations or concealment of any information requested in the prior authorization request may subject me to audit and recoupment.*

Part II: TO BE COMPLETED BY PHARMACY

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

health information designs

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 patients receiving a prescription for hepatitis C treatments must meet the criteria listed in the preferred drug list (PDL). Please see the PDL at http://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/PRESCRIBER'S OFFICE

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:**	**Patient's liver fibrosis score:** □ F0-F1 □ F3-F4
Diagnosis: □ HCV □ OTHER:	**Genotype:**	**Patient's Child–Pugh Class:** □ A □ B □ C □ N/A

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

Has the patient remained drug (illicit use by injection) and alcohol free for the past 3 months?	□ YES □ NO
Does patient have a diagnosis of alcohol use disorder?	□ YES □ NO
Does patient have a history of illicit use of drugs by injection?	□ YES □ NO
Has patient 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
Does the patient have Hepatitis B?	□ YES □ NO
If the patient has Hepatitis B, has it been treated or will it be closely monitored during treatment?	□ YES □ NO
Is the patient post-liver transplant?	□ YES □ NO
Does the patient's life expectancy greater than one year?	□ YES □ NO
Does patient attended scheduled visits with no more than 1 no-show and fill maintenance medications on time?	□ YES □ NO
Does patient have any contraindications to therapy with the requested agent?	□ YES □ NO
ONLY IF RIBAVIRIN IS BEING USED IN A PATIENT OF CHILD-BEARING POTENTIAL Has the patient had a negative pregnancy test in the last 30 days and will receive monthly pregnancy tests during treatment?	□ YES □ NO □ N/A

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

- □ Baseline HCV RNA
- □ ≥ 2 drug and alcohol tests dated at least 3 months apart
- □ Patient & Prescriber attestation forms
- □ HCV RNA 4 weeks after starting therapy (for renewal)
- □ Chart notes addressing patient's alcohol and drug free status over the past year
- □ Documentation of patient'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 patient's medical records. I also understand that any misrepresentations or concealment of any information requested in the prior authorization request may subject me to audit and recoupment.*

Part II: TO BE COMPLETED BY PHARMACY

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

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** __/__/____

health information designs

Hyperkalemia
Prior Authorization Form

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

Prior Authorization Vendor for ND

ND Medicaid requires that patients receiving a prescription for select agents for hhyperkalemia to meet the following criteria:

- Patient must be 18 years of age or older
- Medication must be prescribed by, or in consultation with, a nephrologist
- Patient's current serum potassium level must be exceeding the upper limit of normal (shown by 2 labs)
- Patient must not have gastrointestinal motility disorders
- One of the following criteria must be met:
  - Patient must have failed a 30-day trial with at least one preferred product
  - Provider has submitted medical justification explaining why the patient cannot use any preferred agents
- The patient must not be receiving the medications known to cause hyperkalemia, OR medical justification must be provided explaining why discontinuation of these agents would be clinically inappropriate in this patient
- **Renewal**: Patient's current serum potassium level must be within normal limits or significantly reduced from baseline

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 physician)		
Prescriber NPI	Telephone Number	Fax Number	
Address	City	State	Zip Code
Requested Drug and Dosage:	**Diagnosis for this request:**		
List all failed medications:		**Start Date:**	**End Date:**

Additional Qualifications for Coverage

Has the provider attached required lab documentation showing 2 of the patient's current potassium levels?	□ YES □NO
Does the patient have a diagnosis of any gastrointestinal motility disorder?	□ YES □NO
Is the patient to continue to receive a medication known to cause hyperkalemia?	□ 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 patient's medical records. I also understand that any misrepresentations or concealment of any information requested in the prior authorization request may subject me to audit and recoupment.*

Part II: TO BE COMPLETED BY PHARMACY

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

health information designs

Idiopathic Pulmonary Fibrosis 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 patients receiving a new prescription for agents used to treat idiopathic pulmonary fibrosis must meet the following criteria:

Category Criteria:

- The patient 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 patient must have forced vital capacity (FVC) ≥ 40% of predicted within prior 60 days
- The patient must have carbon monoxide diffusing capacity (DLCO, corrected for hemoglobin) of 30% to 79% of predicted.

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 different than prescriber)			
Prescriber NPI	Telephone Number	Fax Number		
Address	City	State	Zip Code	
Requested Drug:	Diagnosis:	FVC:	Date of FVC Provided:	
□ *I confirm that I have considered a generic or other alternative and that the requested drug is expected to result in the successful medical management of the recipient.*				
Prescriber (or Staff) / Pharmacy Signature**	Date			
**: *By completing this form, I hereby certify that the above request is true, accurate and complete. That the request is medically necessary, does not exceed the medical needs of the member, and is clinically supported in the patient's medical records. I also understand that any misrepresentations or concealment of any information requested in the prior authorization request may subject me to audit and recoupment.*				

Part II: TO BE COMPLETED BY PHARMACY

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

health information designs

Immune Globulins
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 patients receiving a new prescription for an immune globulin must meet the following criteria:

- If patient's BMI > 30, adjusted body weight must be provided along with the calculated dose.
- **The patient must have a diagnosis of an FDA-approved indication for use**
- **For Gammagard S/D:** Patient must be intolerant to IgA.
- **For Cutaquig, Cuvitru, Hizentra, Hyqvia or Xembify:** Patient must be unable to tolerate IV administration and fail a trial of two of the following: Gamunex-C, Gammaked, or Gammagard.
- **For all other agents:** Patient must try and fail two of the following: Gamunex-C, Privigen, or Gammagard.

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	
Address	City	State	Zip Code
Requested Drug and Dosage:	**Diagnosis for this request:**		
List all failed medications:	**Start Date:**	**End Date:**	

Qualifications for coverage:

Is patient intolerant to IgA?	□ YES □NO
Is patient unable to tolerate IV administration?	□ YES □NO
Is patient BMI over 30?	□ YES □NO
If patient BMI over 30, provide adjusted body weight and calculated dose:	

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

Prescriber (or Staff) / Pharmacy Signature**	Date

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

Part II: TO BE COMPLETED BY PHARMACY

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

health information designs

Prior Authorization Vendor for ND Medicaid

Insulins
Prior Authorization Form

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

ND Medicaid requires that patients receiving a new prescription for non-preferred insulin products must meet prior authorization criteria. The prior authorization criteria can be found in 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:			
Prescriber NPI	Telephone Number	Fax Number	
Address	City	State	Zip Code
Requested Drug and Dosage:	Diagnosis for this request:		
Failed Therapy:	Start Date:	End Date:	
Has all required documentation/medical justification supporting use over preferred agents been attached? □ 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 patient's medical records. I also understand that any misrepresentations or concealment of any information requested in the prior authorization request may subject me to audit and recoupment.*			

Part II: TO BE COMPLETED BY PHARMACY

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

health information designs

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 patients receiving Makena to meet prior authorization criteria. The prior authorization criteria can be found in 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 physician)		
Prescriber NPI	Telephone Number	Fax Number	
Address	City	State	Zip Code
Requested Drug and Dosage:	**Diagnosis for this request:**		
Patient's Estimated Date of Delivery or Gestational Age of Current Pregnancy (weeks and days):			
Does the patient have a history of singleton spontaneous preterm birth?	□ YES	□ NO	
Is the patient 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 patient's medical records. I also understand that any misrepresentations or concealment of any information requested in the prior authorization request may subject me to audit and recoupment.*			

Part II: TO BE COMPLETED BY PHARMACY

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

health information designs

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 Medicaid

ND Medicaid requires that patients receiving Mifeprex to meet prior authorization criteria. The prior authorization criteria can be found in 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	
Physician Name			
Physician Medicaid Provider Number	Telephone Number	Fax Number	
Address	City	State	Zip Code
Requested Drug and Dosage:	**FDA approved indication for this request:**		

- **Is the patient terminating a pregnancy before 70 days of gestation?**
  □ YES □ NO
- **Is the pregnancy 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 patient's medical records. I also understand that any misrepresentations or concealment of any information requested in the prior authorization request may subject me to audit and recoupment.*

Part II: TO BE COMPLETED BY PHARMACY

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

health information designs

Migraine Prophylaxis (CGRP Inhibitors) Prior Authorization Form

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

Prior Authorization Vendor for ND

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

Initial Request Criteria for All Diagnoses:

- The patient must have had a 3-month trial of each preferred agent*.
- The patient must have had the specified 2-month trial(s) of the required prerequisite therapy (stated in the PDL)*.
- **Additional criteria for migraine prevention:** Patient must experience ≥4 migraine days per-month.
- **Additional criteria for episodic cluster headaches:** Prescriber must submit documentation supporting a diagnosis that meets the International Headache Society 3 – beta (IHS-3b) diagnostic criteria for cluster headache (chronic migraine must be ruled out).

**= The prescriber must submit documentation, including clinical notes regarding failure of prior treatments.*

Renewal Requests: Patient must experience a reduction in migraines/weekly cluster headaches of at least 50%

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 physician)		
Prescriber NPI	Telephone Number	Fax Number	
Address	City	State	Zip Code
Requested Drug and Dosage:	**Diagnosis for this request:**		
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 patient's medical records. I also understand that any misrepresentations or concealment of any information requested in the prior authorization request may subject me to audit and recoupment.*			

Part II: TO BE COMPLETED BY PHARMACY

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

health information designs

NSAIDs
Prior Authorization Form

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

Prior Authorization Vendor for ND

ND Medicaid requires that patients receiving a new prescription for non-preferred NSAID agents that require prior authorization must meet prior authorization criteria. The prior authorization criteria can be found in 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 physician)	
Prescriber NPI	Telephone Number	Fax Number
Requested Drug and Dosage:	**Diagnosis for this request:**	

List all failed medications:	**Start Date:**	**End Date:**	**Reason for Failure:**

Qualifications for coverage:

Does the patient have a history of gastric or duodenal ulcer or comorbidities of GI bleed, perforation, or obstruction? □ YES □NO

Does patient have a diagnosis of dysmenorrhea or endometriosis? □ YES □NO

All other needed qualifications for coverage/medical justification for use is attached to this request? □ 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 patient's medical records. I also understand that any misrepresentations or concealment of any information requested in the prior authorization request may subject me to audit and recoupment.*

Part II: TO BE COMPLETED BY PHARMACY

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

health information designs

Nausea/Vomiting Prior Authorization Form

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

Prior Authorization Vendor for ND

ND Medicaid requires that patients receiving a new prescription for a non-preferred agent for nausea/vomiting treatment must meet the criteria for the specified product listed in the preferred drug list (PDL). Please see the PDL at http://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 physician)	
Prescriber NPI	Telephone Number	Fax Number

Requested Drug and Dosage:	**Diagnosis for this request:**	
List all failed medications:	**Dates:**	**Reason for Failure:**

Estimated last day of treatment (ie. pregnancy due date or final date of chemotherapy):

Additional Qualifications for Coverage:
□ Does the patient have an inability to tolerate oral medications (please attach swallow study)? □ YES □ NO
□ Other, Explain:

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

Prescriber (or Staff) / Pharmacy Signature**	Date

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

Part II: TO BE COMPLETED BY PHARMACY

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

health information designs

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 patients receiving a new prescription for Nuedexta must meet prior authorization criteria. The prior authorization criteria can be found in 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 physician)		
Prescriber NPI	Telephone Number	Fax Number	
Address	City	State	Zip Code
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 patient 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 patient's medical records. I also understand that any misrepresentations or concealment of any information requested in the prior authorization request may subject me to audit and recoupment.*

Part II: TO BE COMPLETED BY PHARMACY

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

health information designs

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 patients receiving a new prescription for ALL long-acting opioid analgesics and non-preferred short-acting opioid analgesics must meet prior authorization criteria. The prior authorization criteria can be found in 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	Pain, Palliative Care, or Oncology/Hematology Specialist involved in therapy (if not treating physician):		
Prescriber NPI	Telephone Number	Fax Number	
Requested Opioid Analgesic:	**Diagnosis for use of opioid(s) in this patient:**		
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:	
Has the past 3 months of North Dakota PDMP reports must have been reviewed by the prescriber?	□ YES □ NO
Has the provider established a realistic treatment plan with the patient, addressing expected outcomes and limitations of therapy in totally eliminating pain?	□ YES □ NO
Has the patient established opioid tolerability by using short acting opioids daily for at least 90 days prior to request	□ YES □ NO
Does the patient have access to Narcan and counseled on overdose risk?	□ 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:

□ Patient'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 patient's medical records. I also understand that any misrepresentations or concealment of any information requested in the prior authorization request may subject me to audit and recoupment.*

health information designs

Prior Authorization Vendor for ND Medicaid

Opioid Dependence Agents Prior Authorization Form

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

ND Medicaid requires that patients receiving a new prescription for buprenorphine and buprenorphine/naloxone combinations must meet the following criteria:

Product Specific Criteria:

- **Buprenorphine tablets**: The patient must be pregnant or breastfeeding

Non-Preferred Agents Criteria:

- The patient must have had a 30-day trial of each preferred agent.
- Clinical justification must be provided explaining why the patient is unable to use the preferred products
- A MedWatch form for each trial of each product must be filled out and attached to request
- DAW Criteria must be met in addition to Opioid Partial Agonist Group PA Criteria.
- **For all non-preferred agents OTHER than Zubsolv (buprenorphine/naloxone):**
    - The patient must have failed a 30-day trial of Zubsolv (buprenorphine/naloxone)
    - Clinical justification must be provided explaining why the patient is unable to use Zubsolv
    - A MedWatch form for each trial of each product from the available manufacturer(s) must be filled out and attached to request
    - DAW Criteria must be met in addition to Opioid Partial Agonist Group PA Criteria.

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

Recipient Name	**Recipient Date of Birth**	Recipient Medicaid ID Number	
Prescriber Name	**(SAMHSA ID-X DEA Number)**		
Prescriber NPI	Telephone Number	Fax Number	
Address	City	State	Zip Code
Requested Drug and Dosage:	**FDA Approved Indication for this request:**		
□ Patient is not taking other opioids, tramadol, or carisoprodol concurrently with requested medication.			
Is the patient pregnant?		□ YES	□ NO
Is the patient currently breastfeeding?		□ YES	□ NO
Patient Due Date (if pregnant):			
□ *I confirm that I have considered a generic or other alternative and that the requested drug is expected to result in the successful medical management of the recipient.*			
Prescriber (or Staff) / Pharmacy Signature**		Date	
**: *By completing this form, I hereby certify that the above request is true, accurate and complete. That the request is medically necessary, does not exceed the medical needs of the member, and is clinically supported in the patient's medical records. I also understand that any misrepresentations or concealment of any information requested in the prior authorization request may subject me to audit and recoupment.*			

Part II: TO BE COMPLETED BY PHARMACY

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

health information designs

Orilissa
Prior Authorization Form

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

Prior Authorization Vendor for ND

ND Medicaid requires that patients receiving a prescription for Orilissa to meet the following prior authorization criteria:

- Patient must have an FDA-approved indication for use and be of the FDA approved age for use
- The patient must have a diagnosis of moderate to severe pain associated with endometriosis
- The patient must not have osteoporosis or severe liver disease (Child-Pugh Class C).
- The patient must have failed the following trials (A and B), as evidenced by paid claims or pharmacy printouts:
  - A. A 3-cycle trial of mefenamic acid, meclofenamate, celecoxib, ibuprofen 1800mg/day or equivalent high dose NSAID
  - B. A 3-cycle trial of an oral estrogen-progestin or progestin contraceptives

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 physician)		
Prescriber NPI	Telephone Number	Fax Number	
Address	City	State	Zip Code
Requested Drug and Dosage:	**Diagnosis for this request:**		
List all failed medications:		**Start Date:**	**End Date:**

Qualifications for coverage:

Has the patient had a negative pregnancy test and will use a non-combination hormone birth control method must be used throughout treatment? □ YES □NO

Does the patient have osteoporosis or severe liver disease (Child-Pugh Class C)? □ 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 patient's medical records. I also understand that any misrepresentations or concealment of any information requested in the prior authorization request may subject me to audit and recoupment.*

Part II: TO BE COMPLETED BY PHARMACY

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

health information designs

Osteoporosis 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 patients receiving a new prescription for osteoporosis treatment agents that require prior authorization must meet prior authorization criteria. The prior authorization criteria can be found in 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 physician)		
Prescriber NPI	Telephone Number	Fax Number	
Address	City	State	Zip Code
Requested Drug and Dosage:	**Diagnosis for this request:**		
List all failed medications:	**Start Date:**	**End Date:**	

Qualifications for coverage:

Patient's BMD T-Score:	Site of BMD Measurement:

Does the patient have a history of low trauma fracture?	□ YES □NO
Has the patient had a new fracture within the last 6-months?	□ YES □NO
Does the patient have multiple risk factors for fracture?	□ 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 patient's medical records. I also understand that any misrepresentations or concealment of any information requested in the prior authorization request may subject me to audit and recoupment.*

Part II: TO BE COMPLETED BY PHARMACY

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

health information designs

Out of State Pharmacy 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

Part I

Recipient Name	Recipient Date of Birth	Recipient Medicaid ID Number

Requested Drug and Dosage:

Qualifications for coverage:

Start Date	End Date	Dose	Frequency

Reason for out of state pharmacy request:

Recipient is residing out of state? □ YES □ NO
If yes, please provide recipient residence, city, state, zip code:

Requested drug is only available at out of state pharmacies? □ YES □ NO

Third party requires out of state pharmacy for coverage? □ YES □ NO
If yes, contact State Provider Relations at 1-800-755-2604.

Part II

PHARMACY NAME (REQUIRED)			ND MEDICAID PROVIDER NUMBER (REQUIRED)
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC # (REQUIRED)

Pharmacy Signature:	Date:

health information designs

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 Medicaid

ND Medicaid requires that patients receiving a new prescription for a phenylketonuria agent must meet the criteria for the specified product listed in the preferred drug list (PDL). Please see the PDL at http://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			
Prescriber NPI	Telephone Number	Fax Number	
Address	City	State	Zip Code:

Requested Drug and Dosage:	**Diagnosis for use:**	**PHE level:**	**Patient's weight:**

Has the patient been known to have two null mutations in TRANS?	□ YES	□ NO
Are baseline PHE levels attached?	□ YES	□ NO
Is patient of child-bearing potential?	□ YES	□ NO
Is this a renewal request?	□ YES	□ NO
Has the patient 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 patient's medical records. I also understand that any misrepresentations or concealment of any information requested in the prior authorization request may subject me to audit and recoupment.*

Part II: TO BE COMPLETED BY PHARMACY

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

health information designs

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 Medicaid

ND Medicaid requires that patients receiving a new prescription for a non-preferred sedative/hypnotic agent must meet the criteria for the specified product listed in the preferred drug list (PDL). Please see the PDL at http://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			
Prescriber NPI	Telephone Number	Fax Number	
Address	City	State	Zip Code
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? Is the patient's insomnia characterized by difficulty with sleep initiation? Is the patient's insomnia characterized by difficulty with sleep maintenance? Does the patient require dose tapering?		□ YES □ NO □ YES □ NO □ YES □ NO □ 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 patient's medical records. I also understand that any misrepresentations or concealment of any information requested in the prior authorization request may subject me to audit and recoupment.*			

Part II: TO BE COMPLETED BY PHARMACY

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

health information designs

Prior Authorization Vendor for ND Medicaid

Spinal Muscular Atrophy Prior Authorization Form

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

ND Medicaid requires that patients receiving a prescription for treatments of spinal muscular atrophy 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. Please fill out this request form in its entirety, answer all questions relevant to the requested product, and attach any required documentation to this request form.

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

Recipient Name	Recipient Date of Birth	Recipient Medicaid ID Number	
Prescriber Name	Prescriber NPI		
Billing Facility NPI	Telephone Number	Fax Number	
Address	City	State	Zip Code
Billing Facility NPI	ICD-10 Code:		
Requested Drug and Dose:			
Diagnosis for this request: □ **SMA Type 1** □ **SMA Type 2** □ **SMA Type 3**			
Patient's weight:	**Baseline motor ability score:**	**Age at SMA symptom onset:**	

Does the patient have respiratory insufficiency?	□ **YES**	□ **NO**
Does the patient require gastric feeding tubes for the majority of feeds?	□ **YES**	□ **NO**
Does the patient have severe contractures or severe scoliosis?	□ **YES**	□ **NO**
Does the patient have wasting or cachexia?	□ **YES**	□ **NO**
Does the patient experience issues with ambulating?	□ **YES**	□ **NO**
Has the patient reached full gestational age?	□ **YES**	□ **NO**
Has all required documentation been attached to the request (e.g. genetic testing, antibody titers, motor ability scores)?	□ **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 patient's medical records. I also understand that any misrepresentations or concealment of any information requested in the prior authorization request may subject me to audit and recoupment.*

health information designs

SYNAGIS WEB BASED FORM

For questions regarding this Prior Authorization Call 701-328-4023

Prior Authorization Vendor for ND Medicaid

Note:

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

TO BE COMPLETED BY PRESCRIBER/PRESCRIBER'S OFFICE

Recipient Medicaid ID Number	Recipient Date of Birth	Prescriber NPI	Prescriber Fax Number
Billing Facility NPI	**Billing Facility Name**		**ICD-10 code**

Diagnosis (qualification for Synagis)

___ **Prematurity**

<29 weeks, 0 days gestational age – Synagis allowed if younger than 12 months of age at start of RSV season (max of 5 doses)

Gestational Age (e.g. 28 weeks, 4 days)

Weeks _____ **Days** _____

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

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

___ Supplemental Oxygen

___ Diuretic

___ Chronic corticosteroid therapy

___ **Congenital Heart Disease (CHD)**

Child ≤12 months old with hemodynamically significant cyanotic or acyanotic CHD

Medical Therapy Required _____

*children less than 24 months who undergo cardiac transplantation during RSV season may be considered for prophylaxis.

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

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

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

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

health information designs

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 patients 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/PRESCRIBER'S OFFICE

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

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

Does the patient have uncontrolled asthma?	□ YES	□ NO
Has the patient experienced severe or life-threatening anaphylaxis in the 60 days?	□ YES	□ NO
Does the patient have a history of eosinophilic esophagitis or another eosinophilic GI disease?	□ YES	□ NO
Has the patient/caregiver been educated on appropriate use of epinephrine?	□ YES	□ NO
RENEWAL ONLY: Does the patient continue to have a peanut allergy and has been/is being monitored for resolution of their allergy?	□ YES	□ NO
RENEWAL ONLY: Has the patient been able to tolerate the maintenance dose of Palforzia (300 mg daily)?	□ 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 patient's medical records. I also understand that any misrepresentations or concealment of any information requested in the prior authorization request may subject me to audit and recoupment.*

Part II: TO BE COMPLETED BY PHARMACY

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

health information designs

Prior Authorization Vendor for ND Medicaid

Tardive Dyskinesia Agents Prior Authorization Form

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

ND Medicaid requires that patients receiving a new prescription for Austedo, Ingrezza, or tetrabenazine must meet the following criteria:

Category Criteria

- The patient must be 18 years of age or older.
- The prescription must be written by/in consultation with a specialist (neurologist or psychiatrist).
- The patient 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 patient must not be taking monoamine oxidase inhibitor (MAOI)
- The patient is not pregnant or breastfeeding

Product Specific Criteria: * Austedo/tetrabenazine:**

- The patient must have a diagnosis of Huntington's disease or Tardive Dyskinesia.
- The patient 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	
Address	City	State	Zip Code
Requested Drug and Dosage:	**FDA approved indication for this request:** Does the patient have hepatic impairment? □ YES □ NO		
List all failed medications (drug name, date of trial, reason for failure):			
□ *I confirm that I have considered a generic or other alternative and that the requested drug is expected to result in the successful medical management of the recipient.*			
Prescriber (or Staff) / Pharmacy Signature**	Date		
**: *By completing this form, I hereby certify that the above request is true, accurate and complete. That the request is medically necessary, does not exceed the medical needs of the member, and is clinically supported in the patient's medical records. I also understand that any misrepresentations or concealment of any information requested in the prior authorization request may subject me to audit and recoupment.*			

Part II: TO BE COMPLETED BY PHARMACY

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

health information designs

Topical Anesthetics
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 patients receiving a new prescription for topical anesthetic must meet the following criteria:

- The request must be for patient home use of cream, prior to injection pain from a medically necessary procedure

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	
Address	City	State	Zip Code
Requested Drug and Dosage:	**FDA approved indication for this request:**		
Is the requested agent being given used at the patient's residence?		□ 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 patient's medical records. I also understand that any misrepresentations or concealment of any information requested in the prior authorization request may subject me to audit and recoupment.*			

Part II: TO BE COMPLETED BY PHARMACY

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

REVIEW OF EVRYSDI (risdiplam)

Spinal muscular atrophy (SMA):

- Genetic, autosomal recessive, disease affecting the central nervous and peripheral nervous system, characterized by degeneration of the anterior horn cells in the spinal cord and motor nuclei in the lower brainstem, which results in progressive muscle weakness and atrophy voluntary muscle movement
    - Typically caused by a mutation in the survival of motor neuron 1 (SMN1) gene, which results in deficiency in functional SMN protein, resulting in progressive motor neuron death and muscle atrophy
        - SMN protein is still made by SMN2 genes, however the majority of the SMN proteins from SMN2 are truncated and non-functional due to SMN2 most mRNA missing exon 7
            - The more functional SMN protein is produced, the milder the disease course
- **Symptoms**
    - Variability between and within SMA types
        - Symmetric proximal voluntary muscle weakness, greater in lower limbs
        - Absent or decreased deep tendon reflexes
        - Restrictive, progressive respiratory insufficiency
- **Types**

Type	Age of Onset	Motor Milestones	Avg/ Life Expectancy	Usual SMN2 Gene Copies
Type 0	Prenatal	No motor milestones are achieved	0-6 months	1
Type 1	0-6 months	Unable to sit unsupported	2 years	2-3
Type 2	3-15 months	Unable to stand or walk unassisted	~25 years	3
Type 3	18 months- adulthood	Progressive limb weakness	Normal	3-4
Type 4	undefined	All milestone achieved; progressive weakness	Normal	4-8

- **Therapy:**
    - **Supportive therapy:**
        - Nutrition assistance
            - Changing food consistency to improve food intake and protect against aspiration
            - Feeding tube placement
        - Respiratory assistance
            - Methods for mobilization and clearance of airway secretions
            - Ventilation support
        - Complications of muscle weakness
            - Physical therapy, spinal bracing, surgical repair of scoliosis
    - **Disease-Modifying Therapy**
        - **Spinraza (nusinersen):** Modifies splicing of the SMN2 gene to increase production of normal, full-length SMN protein
            - Intrathecal injection given in 4 loading doses, then every 4 months
        - **Zolgensma (onasemnogene abeparvovec):** viral vector containing complementary DNA encoding the normal human SMN protein (gene replacement of SMN1)
            - IV infusion, one time
        - **Evrysdi (risdiplam):** SMN2 splicing modifier that binds two sites in SMN2 pre-messenger RNA, thereby correcting the splicing deficit of SMN2, leading to increased levels of full-length SMN protein
            - By mouth, daily

EVRYSDI

- **Indication**: Treatment of spinal muscular atrophy (SMA) in patients 2 months of age and older
- **Mechanism of action:** SMN2 splicing modifier that binds two sites in SMN2 pre-messenger RNA to increase exon 7 inclusion in SMN2 mRNA
    - Corrects the splicing deficit of SMN2 which results to increased levels of full-length SMN protein
        - >2-fold median change in functional SMN protein from baseline
- **Contraindications:** None per label
- **Administration and Dosing:**
    - Given orally, once daily after a meal, using reusable syringe provided
        - If not taken within 5 minutes, dose should be discarded, and a new dose should be given
    - Dose:
        - **2 months - <2 years of age:** 0.2 mg/kg daily
        - **>2 years of age, < 20 kg:** 0.25 mg/kg
        - **>2 years of age, ≥20 kg:** 5 mg
- **Clinical Trial Experience**
    - **Study 1**
        - **Patient demographics:**
            - Type 1 SMA
            - 2 SMN2 copies
        - **Results:**
            - Sit without support for 5 seconds at 12 months
                - 41% able to sit independently (vs 0% expected)
            - Survival without permanent ventilation
                - 90% at 12 months (>15 months old)
                - 81% at 23 months (>28 months old)
                - In the normal population, 25% survive w/o ventilation beyond 14 months
    - **Study 2**
        - **Patient demographics:**
            - Type 2 (71%) and 3 (29%) SMN
            - 2-25 years of age
            - 67% had scoliosis (32% had severe scoliosis)
        - **Results (at 12 months):**
            - Change from baseline in the Motor Function Measure 32 (MFM32) score:
                - +1.36 for treatment group vs. -0.19 in placebo (1.55-point difference)
            - Proportion of patients with ≥3-point change from baseline in MFM32 score:
                - 38.3% in treatment group vs. 23.7% in placebo group (OR: 2.35)
            - Change in Revised Upper Limb Module (RULM) score:
                - 1.61 for treatment group vs. 0.02 in placebo (1.59-point difference)
- **Warnings/Precautions:**
    - Some dosage forms may contain sodium benzoate/benzoic acid, which in large amount may lead to a potentially fatal toxicity (“gasping syndrome”) in neonates
- **Adverse Effects**
    - **Common (>10%)**
        - **Dermatologic**: Skin rash (17%)
        - **Gastrointestinal**: Constipation (≥10%), diarrhea (17%), vomiting (≥10%)
        - **Respiratory**: Pneumonia (≥10%), upper respiratory tract infection (≥10%)
        - **Miscellaneous**: Fever (22%)
    - **Less Common (1-10%):**
    - **Gastrointestinal**: Aphthous stomatitis (≤7%), oral mucosa ulcer (≤7%)
    - **Genitourinary:** Urinary tract infection (5%)
    - **Neuromuscular & skeletal**: Arthralgia (5%)

- **Pregnancy/Lactation/Reproduction:**
  - **Pregnancy:**
    - In animal studies, administration during pregnancy or throughout pregnancy and lactation resulted in adverse effects on development (embryofetal mortality, malformations, decreased fetal body weights, and reproductive impairment in offspring) at or above clinically relevant drug exposures
      - females of reproductive potential should be advised of this potential risk, receive pregnancy testing, and be advised to use effective contraception during treatment and for at least 1 month after her last dose
  - **Lactation:**
    - Excreted in breastmilk of lactating rate. No data on human breastmilk, effects on infant or milk production
  - **Reproduction:**
    - Male fertility may be compromised by treatment
      - Studies in juvenile and adult rats and in monkeys demonstrated adverse effects on the reproductive organs, including germ cells, in males at clinically relevant plasma exposures
      - Patients should be counseled on this potential, and male patients may consider sperm preservation prior to treatment
  - **Drug interactions**
    - May increase plasma concentrations of drugs eliminated via MATE1 or MATE2-K such as metformin (avoid concomitant use with MATE substrates)
      - If coadministration cannot be avoided, monitor for drug-related toxicities and consider dosage reduction of the coadministered drug is needed

COST

Drug	Strength	Package Size	AWP Pkg Price	AWP Price Per Dose	Cost per year*	Cost per 1st 5 years*
Evrysdi	0.75 mg/mL	80 mL	$13,404.52	$1,117.07 #	$407,731 #	$2,038,653 #
Spinraza	2.4 mg/mL	5	$153,000	$153,000	$459,000*	$2,754,000 *
Zolgensma	N/A	1	$2,550,000	$2,550,000	$2,550,000 &	$2,550,000 &

#: Evrysdi based on highest dosing schedule
**: Spinraza initial dose costs: $918,000*
&: Zolgensma given as 1 dose/lifetime

CURRENT UTILIZATION

ND Medicaid Utilization (09/2019 – 09/2020)		
Label Name	**Rx Num**	**Total Reimb Amt**
Evrysdi	0	-

REFERENCES:

1. Facts & Comparisons eAnswers. Available at http://online.factsandcomparisons.com. Accessed on November 14. 2020.
2. UpToDate. Available at https://www.uptodate.com/contents/search. Accessed on November 14. 2020.
3. Evrysdi (risdiplam) [prescribing information]. South San Francisco, CA: Genentech Inc; August 2020.

NORTH DAKOTA MEDICAID
RETROSPECTIVE DRUG UTILIZATION REVIEW
CRITERIA RECOMMENDATIONS
4TH QUARTER 2020

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

1. Celecoxib Oral Solution / Overuse _____ _____

Alert Message: Elyxyb (celecoxib oral solution) may be over-utilized. The recommended maximum dosage of celecoxib oral solution in a 24-hour period is 120 mg. The safety and effectiveness of a second dose in a 24-hour period have not been established. The recommended and maximum dose in patients who are known or suspected to be CYP2C9 poor metabolizers is 60 mg (2.4 mL).

Drugs/Diseases

Util A	Util B	Util C (Negating)
Celecoxib Oral Solution		Hepatic Impairment

Max Dose: 120 mg/day

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Elyxyb Prescribing Information, May 2020, Promius Pharma LLC.

2. Celecoxib Oral Solution / Overuse – Hepatic Impairment _____ _____

Alert Message: Elyxyb (celecoxib oral solution) may be over-utilized. The recommended maximum dosage of celecoxib oral solution in patients with moderate hepatic impairment (Child-Pugh Class B) in a 24-hour period is 60 mg.

Drugs/Diseases

Util A	Util B	Util C (Include)
Celecoxib Oral Solution		Hepatic Impairment

Max Dose: 60 mg/day

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Elyxyb Prescribing Information, May 2020, Promius Pharma LLC.

3. Celecoxib Oral Solution / Therapeutic Appropriateness _____ _____

Alert Message: The safety and effectiveness of Elyxyb (celecoxib oral solution) in pediatric patients have not been established. Disseminated intravascular coagulation has occurred with the use of celecoxib capsules in pediatric patients with systemic onset JRA.

Drugs/Diseases

Util A	Util B	Util C
Celecoxib Oral Solution		

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Elyxyb Prescribing Information, May 2020, Promius Pharma LLC.

4. Celecoxib Oral Solution / Severe Hepatic Impairment _____ _____

Alert Message: The use of Elyxyb (celecoxib oral solution) in patients with severe hepatic impairment (Child-Pugh Class C) is not recommended. The effect of hepatic impairment on the pharmacokinetics of celecoxib oral solution has not been evaluated. A pharmacokinetic study in subjects with mild (Child-Pugh Class A) and moderate (Child-Pugh Class B) hepatic impairment conducted using celecoxib oral capsule has shown that steady-state celecoxib AUC is increased about 40% and 180%, respectively, above that seen in healthy control subjects.

Drugs/Diseases

Util A	Util B	Util C
Celecoxib Oral Solution	Cirrhosis	
	Liver Failure	

References:

Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Elyxyb Prescribing Information, May 2020, Promius Pharma LLC.

5. Celecoxib Oral Solution / Severe Renal Impairment _____ _____

Alert Message: The use of Elyxyb (celecoxib oral solution) in patients with severe renal impairment is not recommended. Patients with severe renal impairment have not been studied.

Drugs/Diseases

Util A	Util B	Util C (Include)
Celecoxib Oral Solution		CKD Stage 4
		CKD Stage 5

References:

Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Elyxyb Prescribing Information, May 2020, Promius Pharma LLC.

6. Celecoxib Oral Solution / Therapeutic Appropriateness _____ _____

Alert Message: Overuse of acute migraine drugs (e.g., ergotamine, triptans, opioids, nonsteroidal anti-inflammatory drugs or a combination of these drugs for 10 or more days per month), including Elyxyb (celecoxib oral solution), may lead to exacerbation of headache (medication overuse headache). Medication overuse headache may present as migraine-like daily headaches or as a marked increase in the frequency of migraine attacks. Detoxification of patients, including withdrawal of the overused drugs and treatment of withdrawal symptoms (which often includes a transient worsening of headache), may be necessary.

Drugs/Diseases

Util A	Util B	Util C (Include)
Celecoxib Oral Solution	Ergotamine	Migraine
	Triptans	
	Opioids	
	NSAIDs	
	CGRP Receptor Antagonist	
	Lasmiditan	

References:

Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Elyxyb Prescribing Information, May 2020, Promius Pharma LLC.

7. Duloxetine / High Dose (MDD & GAD) _____ _____

Alert Message: Drizalma Sprinkle (duloxetine delayed-release) may be over-utilized. The recommended dosing range for patients with MDD or GAD is 40 mg to 60 mg a day. While a 120 mg per day dose was shown to be effective, there is no evidence that doses greater than 60 mg per day confer any additional benefits. The safety of doses above 120 mg per day has not been adequately evaluated. Periodically reassess to determine the need for maintenance treatment and the appropriate dose for such treatment.

Drugs/Diseases

Util A	Util B	Util C (Include)
Duloxetine sprinkle		MDD
		GAD

Max Dose: 120 mg/day

References:
Drizalma Sprinkle Prescribing Information, June 2020, Sun Pharmaceutical Industries, Inc.
Clinical Pharmacology, 2020 Elsevier/Gold Standard.

8. Duloxetine / High Dose (DPNP & CMP) _____ _____

Alert Message: Drizalma Sprinkle (duloxetine delayed-release) may be over-utilized. The recommended daily dose for patients with diabetic peripheral neuropathic pain or chronic musculoskeletal pain is 60 mg a day. There is no evidence that doses higher than 60 mg confer significant additional benefit.

Drugs/Diseases

Util A	Util B	Util C (Include)
Duloxetine sprinkle		Diabetic Peripheral Neuropathic
		Chronic Musculoskeletal Pain

Max Dose: 60 mg/day

References:
Drizalma Sprinkle Prescribing Information, June 2020, Sun Pharmaceutical Industries, Inc.
Clinical Pharmacology, 2020 Elsevier/Gold Standard.

9. Duloxetine / End Stage Renal Disease _____ _____

Alert Message: The use of Drizalma Sprinkle (duloxetine delayed-release) should be avoided in patients with severe renal impairment. Increased plasma concentration of duloxetine, and especially of its metabolites, occur in patients with end-stage renal disease (requiring dialysis).

Drugs/Diseases

Util A	Util B	Util C
Duloxetine sprinkle	Severe Renal Impairment	
	End Stage Renal Disease	

References:
Drizalma Sprinkle Prescribing Information, June 2020, Sun Pharmaceutical Industries, Inc.
Clinical Pharmacology, 2020 Elsevier/Gold Standard.

10. Duloxetine / Hepatic Insufficiency _____ _____

Alert Message: The use of Drizalma Sprinkle (duloxetine delayed-release) should be avoided in patients with mild, moderate, or severe hepatic impairment. Duloxetine should not be prescribed to patients with evidence of chronic liver disease. Patients with clinically evident hepatic impairment have decreased duloxetine metabolism and elimination.

Drugs/Diseases

Util A	Util B	Util C
Duloxetine sprinkle	Hepatic Insufficiency	

References:
Drizalma Sprinkle Prescribing Information, June 2020, Sun Pharmaceutical Industries, Inc.
Clinical Pharmacology, 2020 Elsevier/Gold Standard.

11. Duloxetine / MAO Inhibitors _____ _____

Alert Message: The use of MAOIs intended to treat psychiatric disorders with Drizalma Sprinkle (duloxetine delayed-release), or within 5 days of stopping treatment with duloxetine, is contraindicated because of an increased risk of serotonin syndrome. The use of duloxetine delayed-release within 14 days of stopping an MAOI intended to treat psychiatric disorders is also contraindicated. Starting duloxetine delayed-release in a patient who is being treated with MAOIs such as linezolid or intravenous methylene blue is contraindicated because of an increased risk of serotonin syndrome.

Drugs/Diseases

Util A	Util B	Util C
Duloxetine sprinkle	Isocarboxazid	
	Linezolid	
	Phenelzine	
	Tranylcypromine	

References:

Drizalma Sprinkle Prescribing Information, June 2020, Sun Pharmaceutical Industries, Inc.
Clinical Pharmacology, 2020 Elsevier/Gold Standard.

12. Duloxetine / Thioridazine _____ _____

Alert Message: Drizalma Sprinkle (duloxetine delayed-release) and thioridazine should not be co-administered. Duloxetine is a moderate inhibitor of CYP2D6, and concurrent use with thioridazine (a sensitive CYP2D6 substrate) may increase the risk of serious ventricular arrhythmias and sudden death associated with elevated plasma levels of thioridazine.

Drugs/Diseases

Util A	Util B	Util C
Duloxetine sprinkle	Thioridazine	

References:

Drizalma Sprinkle Prescribing Information, June 2020, Sun Pharmaceutical Industries, Inc.
Clinical Pharmacology, 2020 Elsevier/Gold Standard.

13. Duloxetine / Narrow-Angle Glaucoma _____ _____

Alert Message: The use of Drizalma Sprinkle (duloxetine delayed-release) should be avoided in patients with anatomically narrow angles. The pupillary dilation that occurs following the use of many antidepressant drugs, including duloxetine, may trigger an angle closure attack in a patient with anatomically narrow angles who does not have a patent iridectomy.

Drugs/Diseases

Util A	Util B	Util C
Duloxetine sprinkle	Anatomical Narrow Angle	

References:

Drizalma Sprinkle Prescribing Information, June 2020, Sun Pharmaceutical Industries, Inc.
Clinical Pharmacology, 2020 Elsevier/Gold Standard.

14. Duloxetine / Fluvoxamine _____ _____

Alert Message: The concurrent use of Drizalma Sprinkle (duloxetine delayed-release) with fluvoxamine should be avoided. Duloxetine is a CYP1A2 substrate, and fluvoxamine is a potent CYP1A2 inhibitor. In drug studies, the concurrent use of these agents resulted in an approximately 6-fold increase in the duloxetine AUC, a 2.5-fold increase in the duloxetine Cmax, and the duloxetine t1/2 was increased approximately 3-fold.

Drugs/Diseases

Util A	Util B	Util C
Duloxetine sprinkle	Fluvoxamine	

References:

Drizalma Sprinkle Prescribing Information, June 2020, Sun Pharmaceutical Industries, Inc.
Clinical Pharmacology, 2020 Elsevier/Gold Standard.

15. Duloxetine / Potent 2D6 Inhibitors _____ _____

Alert Message: Drizalma Sprinkle (duloxetine delayed-release) should be used with caution in patients receiving potent CYP2D6 inhibitors (paroxetine, fluoxetine, and quinidine). Concomitant use of duloxetine, a CYP2D6 substrate, with potent CYP2D6 inhibitors increases the AUC of duloxetine.

Drugs/Diseases

Util A	Util B	Util C
Duloxetine sprinkle	Bupropion	
	Fluoxetine	
	Paroxetine	
	Quinidine	

References:

Drizalma Sprinkle Prescribing Information, June 2020, Sun Pharmaceutical Industries, Inc.
Clinical Pharmacology, 2020 Elsevier/Gold Standard.

16. Duloxetine / TCAs that are CYP2D6 Substrates _____ _____

Alert Message: Drizalma Sprinkle (duloxetine delayed-release) should be used with caution in patients receiving tricyclic antidepressants (TCA) that are primarily metabolized by CYP2D6 (i.e., desipramine, amitriptyline, nortriptyline, and imipramine). Duloxetine is a moderate inhibitor of CYP2D6, and concurrent use with these TCAs may result in elevated TCA plasma concentrations. TCA plasma levels may need to be monitored, and TCA dose reduction may be necessary.

Drugs/Diseases

Util A	Util B	Util C
Duloxetine sprinkle	Amitriptyline	
	Desipramine	
	Imipramine	
	Nortriptyline	

References:

Drizalma Sprinkle Prescribing Information, June 2020, Sun Pharmaceutical Industries, Inc.
Clinical Pharmacology, 2020 Elsevier/Gold Standard.

17. Duloxetine / CYP2D6 Metabolized Drugs _____ _____

Alert Message: Drizalma Sprinkle (duloxetine delayed-release) should be used with caution in patients receiving drugs that are extensively metabolized by CYP2D6 isozyme and which have a narrow therapeutic index (e.g., Type 1C antiarrhythmics and phenothiazines). Duloxetine is a moderate inhibitor of CYP2D6, and concurrent use with these agents may result in elevated plasma concentrations of the CYP2D6.

Drugs/Diseases

Util A	Util B	Util C
Duloxetine sprinkle	Chlorpromazine	
	Flecainide	
	Fluphenazine	
	Nebivolol	
	Perphenazine	
	Propafenone	

References:

Drizalma Sprinkle Prescribing Information, June 2020, Sun Pharmaceutical Industries, Inc.
Clinical Pharmacology, 2020 Elsevier/Gold Standard.

18. Duloxetine / Underuse _____ _____

Alert Message: After reviewing your patient's refill frequency for Drizalma Sprinkle (duloxetine delayed-release) we are concerned that they may be non-adherent to the prescribed dosing regimen, which may lead to sub-therapeutic effects.

Drugs/Diseases

Util A	Util B	Util C
Duloxetine sprinkle		

References:

Drizalma Prescribing Information, June 2020, Sun Pharmaceutical Industries, Inc.
Osterberg L, Blaschke T. Adherence to medication. N Engl J Med 2005;353:487-97.
Keene MS. Confusion and Complaints: The True Cost of Noncompliance in Antidepressant Therapy. Medscape Psychiatry & Mental Health. 2005;10(2). Available at: http://www.medscape.com/viewarticle/518273
Chong WW, Aslani P, Chen TF. Effectiveness of Interventions to Improve Antidepressant Medication Adherence: A Systematic Review. Int J Clin Pract. 2011 Sep;65(9)954-975.
Woldu H, Porta G, Goldstein T, et al. Pharmacokinetically and Clinician-Determined Adherence to an Antidepressant Regimen and Clinical Outcome in the TORDIA Trial. J Am Acad Child Adol Psy, 50;5:490-98. May 2011.

19. Duloxetine / Therapeutic Appropriateness _____ _____

Alert Message: The safety and effectiveness of Drizalma Sprinkle (duloxetine delayed-release) have not been established in pediatric patients less than 7 years.

Drugs/Diseases

Util A	Util B	Util C
Duloxetine Sprinkle		

Age Range: 0 – 6 yoa

References:

Drizalma Sprinkle Prescribing Information, June 2020, Sun Pharmaceutical Industries, Inc.
Clinical Pharmacology, 2020 Elsevier/Gold Standard.

20. Duloxetine / Therapeutic Appropriateness _____ _____

Alert Message: The safety and effectiveness of Drizalma Sprinkle (duloxetine delayed-release) have not been established in pediatric patients for any indication other than GAD in patients 7 to 17 years. The use of duloxetine delayed-release capsules in a child or adolescent must balance the potential risks with the clinical need.

Drugs/Diseases

Util A	Util B	Util C (Negating)
Duloxetine Sprinkle	MDD	GAD
	DPN	
	CMP	

Age Range: 0 – 17 yoa

References:
Drizalma Sprinkle Prescribing Information, June 2020, Sun Pharmaceutical Industries, Inc.
Clinical Pharmacology, 2020 Elsevier/Gold Standard.

21. Diroximel / Overuse _____ _____

Alert Message: Vumerity (diroximel) may be over-utilized. The recommended maintenance dose after 7 days of initial treatment is 462 mg twice a day orally (administered as two 231 mg capsules).

Drugs/Diseases

Util A	Util B	Util C
Diroximel		

Max Dose: 924 mg/day

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Facts & Comparisons, 2020 Updates, Wolters Kluwer Health.
Vumerity Prescribing Information, August 2020, Biogen Inc.

22. Diroximel / Therapeutic Appropriateness _____ _____

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

Drugs/Diseases

Util A	Util B	Util C
Diroximel		

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Facts & Comparisons, 2020 Updates, Wolters Kluwer Health.
Vumerity Prescribing Information, August 2020, Biogen Inc.

23. Diroximel / Dimethyl Fumarate _____ _____

Alert Message: The concurrent use of Vumerity (diroximel) with Tecfidera (dimethyl fumarate) is contraindicated. Both drugs are rapidly metabolized to the active metabolite, monomethyl fumarate (MMF). Co-administration of these drugs may result in elevated concentrations of MMF and increase the risk of adverse/toxic effects.

Drugs/Diseases

Util A	Util B	Util C
Diroximel	Dimethyl Fumarate	

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Facts & Comparisons, 2020 Updates, Wolters Kluwer Health.
Vumerity Prescribing Information, August 2020, Biogen Inc.

24. Diroximel / Moderate & Severe Renal Impairment _____ _____

Alert Message: Because of an increase in the exposure of a major metabolite [2-hydroxyethyl succinimide (HES)], the use of Vumerity (diroximel) is not recommended in patients with moderate or severe renal impairment. No dosage adjustment is necessary in patients with mild renal impairment.

Drugs/Diseases

Util A	Util B	Util C
Diroximel	CKD 3, 4, & 5	

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Facts & Comparisons, 2020 Updates, Wolters Kluwer Health.
Vumerity Prescribing Information, August 2020, Biogen Inc.

25. Diroximel / Pregnancy / **Pregnancy Negating** _____ _____

Alert Message: There are no adequate data on the developmental risk associated with the use of Vumerity (diroximel) or dimethyl fumarate (which has the same active metabolite as diroximel) in pregnant patients. In animal studies, administration of diroximel fumarate during pregnancy or throughout pregnancy and lactation resulted in adverse effects on embryofetal and offspring development (increased incidences of skeletal abnormalities, increased mortality, decreased body weights, neurobehavioral impairment) at clinically relevant drug exposures.

Drugs/Diseases

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

Gender: Female
Age Range 11 – 50 yoa

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Facts & Comparisons, 2020 Updates, Wolters Kluwer Health.
Vumerity Prescribing Information, August 2020, Biogen Inc.

26. Diroximel / Lactation _____ _____

Alert Message: There are no data on the presence of Vumerity (diroximel) or metabolites (MMF, HES) 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 diroximel 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
Diroximel	Lactation	

Gender: Female
Age Range 11 – 50 yoa

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Facts & Comparisons, 2020 Updates, Wolters Kluwer Health.
Vumerity Prescribing Information, August 2020, Biogen Inc.

27. Diroximel / Progressive Multifocal Leukoencephalopathy _____ _____

Alert Message: Progressive multifocal leukoencephalopathy (PML) has occurred in patients with MS treated with dimethyl fumarate (which has the same active metabolite as Vumerity (diroximel). At the first sign or symptom suggestive of PML, withhold diroximel and perform an appropriate diagnostic evaluation.

Drugs/Diseases

Util A	Util B	Util C
Diroximel	Visual Disturbances	
	Muscle Weakness	
	Disorientation	
	Altered Mental Status	

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Facts & Comparisons, 2020 Updates, Wolters Kluwer Health.
Vumerity Prescribing Information, August 2020, Biogen Inc.

28. Diroximel / Flushing / Aspirin _____ _____

Alert Message: Vumerity (diroximel) may cause flushing (e.g., warmth, redness, itching, and/or burning sensation). The administration of diroximel with food may reduce the incidence of flushing. Alternatively, the 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 (Negating)
Diroximel	Flushing	Aspirin

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Facts & Comparisons, 2020 Updates, Wolters Kluwer Health.
Vumerity Prescribing Information, August 2020, Biogen Inc.

29. Diroximel / Non-adherence _____ _____

Alert Message: Based on refill history, your patient may be under-utilizing Vumerity (diroximel). 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
Diroximel		

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.

30. Empagliflozin/Linagliptin/Metformin XR / Nonadherence _____ _____

Alert Message: Based on refill history, your patient may be under-utilizing Trijardy XR (empagliflozin/linagliptin/metformin extended-release). Non-adherence to the prescribed dosing regimen may result in sub-therapeutic effects, which may lead to decreased patient outcomes and additional healthcare costs.

Drugs/Diseases

Util A	Util B	Util C
Empagliflozin/Linagliptin/Metformin		

References:

Osterberg L, Blaschke T. Adherence to Medication. N Engl J Med 2005;353:487-97.
Ho PM, Rumsfeld JS, Masoudi FA, et al., Effect of Medication Nonadherence in Diabetes Mellitus. Cardiology Review, April 2007.
Currie CJ, Peyrot M, Morgan CL, et al. The Impact of Treatment Noncompliance on Mortality in People With Type 2 Diabetes. Diabetes Care 35:1279-1284, June 2012.

31. Empagliflozin/Linagliptin/Metformin XR / Overutilization _____ _____

Alert Message: Trijardy XR (empagliflozin/linagliptin/metformin extended-release) may be over-utilized. The recommended maximum dose of the combination agent is empagliflozin 25 mg/linagliptin 5mg/metformin 2000 mg once daily with a meal in the morning.

Drugs/Diseases

Util A	Util B	Util C
Empagliflozin/Linagliptin/Metformin		

Max Dose: 25mg/5mg/2000mg per day

References:

Trijardy Prescribing Information, Jan. 2020, Boehringer Ingelheim Pharmaceuticals, Inc.
Clinical Pharmacology, 2020 Elsevier/Gold Standard.

32. Empagliflozin/Linagliptin/Metformin XR / Therapeutic Appropriateness _____ _____

Alert Message: The safety and effectiveness of Trijardy XR (empagliflozin/linagliptin/metformin extended-release) in pediatric patients under 18 years of age have not been established.

Drugs/Diseases

Util A	Util B	Util C
Empagliflozin/Linagliptin/Metformin		

Age Range: 0-17 yoa

References:
Trijardy Prescribing Information, Jan. 2020, Boehringer Ingelheim Pharmaceuticals, Inc.
Clinical Pharmacology, 2020 Elsevier/Gold Standard.

33. Empagliflozin/Linagliptin/Metformin XR / Mild to Mod. Renal Impairment _____ _____

Alert Message: Assessment of renal function is recommended prior to initiation of Trijardy XR (empagliflozin/linagliptin/metformin extended-release) and periodically thereafter. No dosage adjustment is needed in patients with an eGFR greater than or equal to 45 mL/min/1.73m2. Empagliflozin/linagliptin/metformin ER should not be initiated in patients with an eGFR less than 45 mL/min/1.73m2 or continued in patients with an eGFR less than 45 mL/min/1.73m2.

Drugs/Diseases

Util A	Util B	Util C (Include)
Empagliflozin/Linagliptin/Metformin		CKD Stage 1
		CKD Stage 2
		CKD Stage 3

References:
Trijardy Prescribing Information, Jan. 2020, Boehringer Ingelheim Pharmaceuticals, Inc.
Clinical Pharmacology, 2020 Elsevier/Gold Standard.

34. Empagliflozin/Linagliptin/Metformin XR / CKD 4, 5, ESRD, & Dialysis _____ _____

Alert Message: Trijardy XR (empagliflozin/linagliptin/metformin extended-release) use is contraindicated in patients with severe renal impairment (eGFR less than 30 mL/min/1.73m2), end-stage renal disease, or receiving dialysis. The empagliflozin component of the combination product causes intravascular volume contraction and can cause acute kidney injury. The metformin component of the combination product is associated with the occurrence of lactic acidosis. The risk of metformin accumulation and metformin-associated lactic acidosis increases with the severity of renal impairment.

Drugs/Diseases

Util A	Util B	Util C (Include)
Empagliflozin/Linagliptin/Metformin		CKD Stage 4 & 5
		ESRD
		Dialysis

References:
Trijardy Prescribing Information, Jan. 2020, Boehringer Ingelheim Pharmaceuticals, Inc.
Clinical Pharmacology, 2020 Elsevier/Gold Standard.

35. Empagliflozin/Linagliptin/Metformin XR / Insulin & Sulfonylureas _____ _____

Alert Message: The concurrent use of Trijardy XR (empagliflozin/linagliptin/metformin extended-release) with insulin or an insulin secretagogue can increase the risk of hypoglycemia. A lower dose of insulin or insulin secretagogue may be required to minimize the risk of hypoglycemia when used in combination with empagliflozin/linagliptin/metformin ER.

Drugs/Diseases

Util A	Util B	Util C
Empagliflozin/Linagliptin/Metformin	Insulins	
	Chlorpropamide	
	Glimepiride	
	Glipizide	
	Glyburide	
	Tolazamide	
	Tolbutamide	

References:
Trijardy Prescribing Information, Jan. 2020, Boehringer Ingelheim Pharmaceuticals, Inc.
Clinical Pharmacology, 2020 Elsevier/Gold Standard.

36. Empagliflozin/Linagliptin/Metformin XR / Ketoacidosis _____ _____

Alert Message: Trijardy XR (empagliflozin/linagliptin/metformin) use is contraindicated in patients with ketoacidosis. Fatal cases of ketoacidosis have been reported in patients receiving SGLT2 inhibitors, including empagliflozin, a component of the combination product. In patients treated with empagliflozin/linagliptin/metformin ER, consider monitoring for ketoacidosis and temporarily discontinuing empagliflozin/linagliptin/metformin ER in clinical situations known to predispose to ketoacidosis (e.g., prolonged fasting due to acute illness or surgery).

Drugs/Diseases

Util A	Util B	Util C
Empagliflozin/Linagliptin/Metformin	Ketoacidosis	

References:
Trijardy Prescribing Information, Jan. 2020, Boehringer Ingelheim Pharmaceuticals, Inc.
Clinical Pharmacology, 2020 Elsevier/Gold Standard.

37. Empagliflozin/Linagliptin/Metformin XR / Pregnancy / Pregnancy Negating _____ _____

Alert Message: Based on animal data showing adverse renal effects from empagliflozin, Trijardy XR (empagliflozin/linagliptin/metformin extended-release) is not recommended during the second and third trimesters of pregnancy.

Drugs/Diseases

Util A	Util B	Util C (Negating)
Empagliflozin/Linagliptin/Metformin	Pregnancy	Abortion
		Delivery
		Miscarriage

Gender: Female
Age Range: 11 – 50 yoa

References:
Trijardy Prescribing Information, Jan. 2020, Boehringer Ingelheim Pharmaceuticals, Inc.
Clinical Pharmacology, 2020 Elsevier/Gold Standard.

38. Empagliflozin/Linagliptin/Metformin XR / Lactation _____ _____

Alert Message: Because of the potential for serious adverse reactions in a breastfed infant, including the potential for empagliflozin to affect postnatal renal development, advise patients that use of Trijardy XR (empagliflozin/linagliptin/metformin extended-release) is not recommended while breastfeeding.

Drugs/Diseases

Util A	Util B	Util C
Empagliflozin/Linagliptin/Metformin	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Trijardy Prescribing Information, Jan. 2020, Boehringer Ingelheim Pharmaceuticals, Inc.
Clinical Pharmacology, 2020 Elsevier/Gold Standard.

39. Forfivo XL / Clopidogrel & Ticlopidine _____ _____

Alert Message: Concurrent use of a Forfivo (bupropion extended-release) with clopidogrel or ticlopidine (CYP2B6 inhibitors) may result in elevated bupropion (CYP2B6 substrate) plasma concentrations and risk of bupropion-related adverse effects (e.g., seizure, nausea, tremor, and insomnia). Coadministration of this bupropion-containing product with ticlopidine or clopidogrel is not recommended.

Drugs/Diseases

Util A	Util B	Util C
Forfivo XL	Clopidogrel Ticlopidine	

References:
Forfivo XL Prescribing Information, Dec. 2019, Almatica Pharma, Inc.
Clinical Pharmacology, 2020 Elsevier/Gold Standard.

40. Istradefylline / Overuse _____ _____

Alert Message: The recommended dosage of Nourianz (istradefylline) is 20 mg administered orally once daily. The dosage may be increased to a maximum of 40 mg once daily, based on individual need and tolerability. Initial dose titration is not required.

Drugs/Diseases

Util A	Util B	Util C
Istradefylline		

Max Dose: 40 mg/day

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Nourianz Prescribing Information, August 2019, Kyowa Kirin Inc.

41. Istradefylline 40 mg / Overuse – Hepatic Impairment _____ _____

Alert Message: The recommended dosage of Nourianz (istradefylline) in patients with moderate hepatic impairment is 20 mg once daily. Closely monitor patients with moderate hepatic impairment (Child-Pugh B) for adverse reactions when on istradefylline treatment. Avoid the use of istradefylline in patients with severe hepatic impairment (Child-Pugh C). No dosage adjustment is needed in patients with mild hepatic impairment (Child-Pugh A).

Drugs/Diseases

Util A	Util B	Util C
Istradefylline 40 mg	Hepatic Impairment	

Max Dose: 20 mg/day

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Nourianz Prescribing Information, August 2019, Kyowa Kirin Inc.

42. Istradefylline / Therapeutic Appropriateness _____ _____

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

Drugs/Diseases

Util A	Util B	Util C
Istradefylline		

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Nourianz Prescribing Information, August 2019, Kyowa Kirin Inc.

43. Istradefylline / Therapeutic Appropriateness _____ _____

Alert Message: Women of childbearing potential should be advised to use contraception during treatment with Nourianz (istradefylline). The use of istradefylline during pregnancy is not recommended.

Drugs/Diseases

Util A	Util B	Util C (Negating)
Istradefylline		Contraceptives

Age Range: 11 – 50 yoa
Gender: Female

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Nourianz Prescribing Information, August 2019, Kyowa Kirin Inc.

Criteria Recommendations *Approved* *Rejected*

44. Istradefylline / Tobacco Use _____ _____

Alert Message: Tobacco smoking has been shown to decrease Nourianz (istradefylline) steady-state systemic exposures by 38% to 54%, which may decrease efficacy. Therefore, the recommended istradefylline dosage in patients who smoke 20 or more cigarettes per day (or the equivalent amount of another tobacco product) is 40 mg once daily.

Drugs/Diseases

Util A	Util B	Util C
Istradefylline 20mg	Tobacco Use	

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Nourianz Prescribing Information, August 2019, Kyowa Kirin Inc.

45. Istradefylline 40 mg / Overuse – Strong CYP3A4 Inhibitors _____ _____

Alert Message: The maximum recommended dosage of Nourianz (istradefylline) with concomitant use of strong CYP3A4 inhibitors is 20 mg once daily. In clinical drug studies, co-administration of istradefylline with a strong CYP3A4 inhibitor (ketoconazole) increased istradefylline AUCinf by 2.5 fold.

Drugs/Diseases

Util A	Util B		Util C
Istradefylline 40mg	Clarithromycin	Nelfinavir	
	Cobicistat	Posaconazole	
	Indinavir	Ritonavir	
	Itraconazole	saquinavir	
	Ketoconazole	Voriconazole	
	Nefazodone		

Max Dose: 20 mg/day

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Nourianz Prescribing Information, August 2019, Kyowa Kirin Inc.

46. Istradefylline / Strong CYP3A4 Inducers _____ _____

Alert Message: In drug studies, co-administration of Nourianz (istradefylline), a CYP3A4 substrate, with a strong CYP3A4 inducer (rifampin) decreased istradefylline Cmax and AUCinf by 45% and 81%, respectively. Therefore, it is recommended to avoid the use of istradefylline with strong CYP3A4 inducers (e.g., carbamazepine, rifampin, and phenytoin).

Drugs/Diseases

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

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Nourianz Prescribing Information, August 2019, Kyowa Kirin Inc.

47. Istradefylline / P-gp Substrates _____ _____

Alert Message: In drug studies, the co-administration of Nourianz (istradefylline) with a P-gp substrate (digoxin) increased the P-gp substrate Cmax and AUCinf by 33% and 21%, respectively. Monitor for an increase in adverse reactions of concomitant drugs that are P-gp substrates when co-administering with istradefylline.

Drugs/Diseases

Util A	Util B	Util C
Istradefylline	Dabigatran	
	Digoxin	
	Fexofenadine	
	Loperamide	
	Quinidine	

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Nourianz Prescribing Information, August 2019, Kyowa Kirin Inc.

48. Istradefylline / Pregnancy / Pregnancy Negating _____ _____

Alert Message: Based on animal data, Nourianz (istradefylline) may cause fetal harm. There are no adequate data on the developmental risk associated with the use of istradefylline in pregnant patients. In animal studies, oral administration of istradefylline during pregnancy resulted in teratogenicity (increased incidences of fetal structural abnormalities, embryofetal and offspring mortality and growth deficits) at clinically relevant exposures and in the absence of maternal toxicity.

Drugs/Diseases

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

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Nourianz Prescribing Information, August 2019, Kyowa Kirin Inc.

49. Istradefylline / Lactation _____ _____

Alert Message: There are no data on the presence of Nourianz (istradefylline) in human milk, the effects of istradefylline on the breastfed infant, or the effects of istradefylline on milk production. Istradefylline was present in the milk of lactating rats at concentrations up to 10 times that in maternal plasma. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for istradefylline, and any potential adverse effects on the breastfed infant from istradefylline or the underlying maternal condition.

Drugs/Diseases

Util A	Util B	Util C
Istradefylline	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Nourianz Prescribing Information, August 2019, Kyowa Kirin Inc.

50. Istradefylline / Non-adherence _____ _____

Alert Message: Based on refill history, your patient may be under-utilizing Nourianz (istradefylline). 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
Istradefylline		

References:

Osterberg L, Blaschke T. Adherence to Medication. N Engl J Med. 2005;353:487-97.
Grosset D, Antonini A, Canesi M, et al. Adherence to Antiparkinson Medication in a Multicenter European Study. Movement Disord. 2009. Vol 24, No. 6:826-832.
Straka I, Minár M, Škorvánek M, et al. Adherence to Pharmacotherapy in Patients With Parkinson's Disease Taking Three and More Daily Doses of Medication. *Front Neurol*. 2019;10:799. Published 2019 Jul 31. doi:10.3389/fneur.2019.00799

51. Bempedoic Acid/Ezetimibe / Overuse _____ _____

Alert Message: Nexlizet (bempedoic acid/ezetimibe) may be over-utilized. The recommended dosage of bempedoic acid/ezetimibe in combination with maximally tolerated statin therapy is 180 mg bempedoic acid/10 mg ezetimibe orally once daily.

Drugs/Diseases

Util A	Util B	Util C
Bempedoic Acid/Ezetimibe		

Max Dose: 180 mg/day

References:

Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Nexlizet Prescribing Information, Feb. 2020, Esperion Therapeutics, Inc.

52. Bempedoic Acid/Ezetimibe / Therapeutic Appropriateness _____ _____

Alert Message: The safety and effectiveness of Nexlizet (bempedoic acid/ezetimibe) have not been established in pediatric patients.

Drugs/Diseases

Util A	Util B	Util C
Bempedoic Acid/Ezetimibe		

Age Range: 0 – 17 yoa

References:

Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Nexlizet Prescribing Information, Feb. 2020, Esperion Therapeutics, Inc.

Criteria Recommendations *Approved* *Rejected*

53. Bempedoic Acid/Ezetimibe / Therapeutic Appropriateness _____ _____

Alert Message: Nexlizet (bempedoic acid/ezetimibe) inhibits renal tubular OAT2 and may increase blood uric acid levels. In clinical trials, 26% of bempedoic acid-treated patients with normal baseline uric acid values (versus 9.5% placebo) experienced hyperuricemia one or more times, and 3.5% of patients experienced clinically significant hyperuricemia reported as an adverse reaction (versus 1.1% placebo). Elevated blood uric acid may lead to the development of gout. Monitor patients for signs and symptoms of hyperuricemia, and initiate treatment with urate-lowering drugs as appropriate.

Drugs/Diseases

Util A	Util B	Util C
Bempedoic Acid/Ezetimibe		

References:

Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Nexlizet Prescribing Information, Feb. 2020, Esperion Therapeutics, Inc.

54. Bempedoic Acid/Ezetimibe / Tendon Rupture _____ _____

Alert Message: Nexlizet (bempedoic acid/ezetimibe) is associated with an increased risk of tendon rupture or injury. In clinical trials, tendon rupture occurred in 0.5% of patients treated with bempedoic acid versus 0% of placebo-treated patients. Discontinue the bempedoic acid-containing drug immediately if the patient experiences rupture of a tendon. Consider discontinuing the bempedoic acid-containing drug if the patient experiences joint pain, swelling, or inflammation. Consider alternative therapy in patients with a history of tendon disorders or tendon rupture.

Drugs/Diseases

Util A	Util B	Util C
Bempedoic Acid/Ezetimibe		

References:

Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Nexlizet Prescribing Information, Feb. 2020, Esperion Therapeutics, Inc.

55. Bempedoic Acid/Ezetimibe / Simvastatin 40 & 80 mg _____ _____

Alert Message: The concurrent use of Nexlizet (bempedoic acid/ezetimibe) with simvastatin causes an increase in the simvastatin concentration and may increase the risk of simvastatin-related myopathy. Avoid concomitant use of a bempedoic acid-containing drug with simvastatin greater than 20 mg.

Drugs/Diseases

Util A	Util B	Util C
Bempedoic Acid/Ezetimibe	Simvastatin 40mg	
	Simvastatin 80mg	

References:

Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Nexlizet Prescribing Information, Feb. 2020, Esperion Therapeutics, Inc.

56. Bempedoic Acid/Ezetimibe / Pravastatin 80 mg _____ _____

Alert Message: The concurrent use of Nexlizet (bempedoic acid/ezetimibe) with pravastatin causes an increase in pravastatin concentration and may increase the risk of pravastatin-related myopathy. Avoid concomitant use of a bempedoic acid-containing drug with pravastatin greater than 40 mg.

Drugs/Diseases

Util A	Util B	Util C
Bempedoic Acid/Ezetimibe	Pravastatin 80 mg	

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Nexlizet Prescribing Information, Feb. 2020, Esperion Therapeutics, Inc.

57. Bempedoic Acid/Ezetimibe / Cyclosporine _____ _____

Alert Message: The concurrent use of Nexlizet (bempedoic acid/ezetimibe) with cyclosporine increases ezetimibe and cyclosporine concentrations. Monitor the cyclosporine concentrations in patients receiving bempedoic acid/ezetimibe and cyclosporine. In patients treated with cyclosporine, the potential effects of the increased exposure to ezetimibe from concomitant use should be carefully weighed against the benefits of alterations in lipid levels provided by bempedoic acid/ezetimibe.

Drugs/Diseases

Util A	Util B	Util C
Bempedoic Acid/Ezetimibe	Cyclosporine	

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Nexlizet Prescribing Information, Feb. 2020, Esperion Therapeutics, Inc.

58. Bempedoic Acid/Ezetimibe / Fenofibrate _____ _____

Alert Message: The concurrent use of Nexlizet (bempedoic acid/ezetimibe) with fenofibrate increases cholesterol excretion into the bile, leading to cholelithiasis. If cholelithiasis is suspected in a patient receiving bempedoic acid/ezetimibe and fenofibrate, gallbladder studies are indicated and alternative lipid-lowering therapy should be considered. Co-administration of bempedoic acid/ezetimibe with fibrates other than fenofibrate is not recommended.

Drugs/Diseases

Util A	Util B	Util C
Bempedoic Acid/Ezetimibe	Fenofibrate	

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Nexlizet Prescribing Information, Feb. 2020, Esperion Therapeutics, Inc.

59. Bempedoic Acid/Ezetimibe / Pregnancy / Pregnancy Negating _____ _____

Alert Message: Discontinue Nexlizet (bempedoic acid/ezetimibe) when pregnancy is recognized unless the benefits of therapy outweigh the potential risks to the fetus. There are no available data on bempedoic acid use in pregnant women to evaluate for a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes. There are insufficient data on ezetimibe use in pregnant women to evaluate for drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes. Bempedoic acid/ezetimibe decreases cholesterol synthesis and may cause fetal harm when administered to pregnant women based on the mechanism of action.

Drugs/Diseases

Util A	Util B	Util C (Negating)
Bempedoic Acid/Ezetimibe	Pregnancy	Abortion
		Delivery
		Miscarriage

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Nexlizet Prescribing Information, Feb. 2020, Esperion Therapeutics, Inc.

60. Bempedoic Acid/Ezetimibe / Lactation _____ _____

Alert Message: Because of the potential for serious adverse reactions in a breastfed infant, based on the mechanism of action, advise patients that breastfeeding is not recommended during treatment with Nexlizet (bempedoic acid/ezetimibe). There is no information regarding the presence of bempedoic acid in human or animal milk, the effects of the drug on the breastfed infant, or the effects of the drug on milk production. There is no information about the presence of ezetimibe in human milk. Bempedoic acid/ezetimibe decreases cholesterol synthesis and may cause harm to the breastfed infant.

Drugs/Diseases

Util A	Util B	Util C
Bempedoic Acid/Ezetimibe	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Nexlizet Prescribing Information, Feb. 2020, Esperion Therapeutics, Inc.

61. Bempedoic Acid/Ezetimibe / Non-adherence _____ _____

Alert Message: Based on refill history, your patient may be under-utilizing Nexlizet (bempedoic acid/ezetimibe). Non-adherence to the prescribed dosing regimen may result in subtherapeutic effects, which may lead to decreased outcomes and additional healthcare costs.

Drugs/Diseases

Util A	Util B	Util C
Bempedoic Acid/Ezetimibe		

References:
Osterberg L, Blaschke T. Adherence to Medication. N Engl J Med. 2005;353:487-97.
Kumbhani DJ, Steg PG, Cannon CP, et al., Adherence to Secondary Prevention Medications for Four-Year Outcomes in Outpatients with Atherosclerosis. Am J Med. 2013 Aug;126(8):693-700.
Simpson RJ, Mendys P. The Effects of Adherence and Persistence on Clinical Outcomes in Patients Treated with Statins: A Systematic Review. Jrn; Clin Lipidol. 2010 Nov-Dec;4(6):462-471.
Lindgren P, Ericksson J, Buxton M, et al., The Economic Consequences of Non-Adherence to Lipid-Lowering Therapy: Results from the Anglo-Scandinavian Cardia Outcomes Trial. Int J Clin Pract. 2010 May 24.

62. Duvelisib / Overuse _____ _____

Alert Message: Copiktra (duvelisib) may be over-utilized. The recommended daily dose of duvelisib is 25 mg twice daily with or without food, for a cycle of 28 days.

Drugs/Diseases

Util A	Util B	Util C
Duvelisib		

Max Dose: 50 mg/day

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Copiktra Prescribing Information, July 2019, Verastem, Inc.

63. Duvelisib / Therapeutic Appropriateness _____ _____

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

Drugs/Diseases

Util A	Util B	Util C
Duvelisib		

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Copiktra Prescribing Information, July 2019, Verastem, Inc.

64. Duvelisib / Pregnancy / Pregnancy Negating _____ _____

Alert Message: Based on findings from animal studies and the mechanism of action, Copiktra (duvelisib) can cause fetal harm when administered to a pregnant patient. Advise patients of reproductive potential and males with partners of reproductive potential to use effective contraception during treatment and for at least 1 month after the last duvelisib dose.

Drugs/Diseases

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

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Copiktra Prescribing Information, July 2019, Verastem, Inc.

65. Duvelisib / Lactation _____ _____

Alert Message: There are no data on the presence of Copiktra (duvelisib) and/or its metabolites in human milk, the effects on the breastfed child, or milk production. Because of the potential for serious adverse reactions from duvelisib in a breastfed child, advise lactating patients not to breastfeed while taking duvelisib and for at least 1 month after the last dose.

Drugs/Diseases

Util A	Util B	Util C
Duvelisib	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Copiktra Prescribing Information, July 2019, Verastem, Inc.

66. Duvelisib / Therapeutic Appropriateness _____ _____

Alert Message: Advise patients of reproductive potential to use effective contraception during treatment with Copiktra (duvelisib) and for at least 1 month after the last dose. Based on findings in animals and its mechanism of action, duvelisib can cause fetal harm when administered to a pregnant patient. Pregnancy testing should be conducted before the initiation of duvelisib treatment.

Drugs/Diseases

Util A	Util B	Util C (Negating)
Duvelisib		Contraceptives

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Copiktra Prescribing Information, July 2019, Verastem, Inc.

67. Duvelisib / Therapeutic Appropriateness _____ _____

Alert Message: Advise male patients with partners of reproductive potential to use effective contraception during treatment with Copiktra (duvelisib) and for at least 1 month after the last dose.

Drugs/Diseases

Util A	Util B	Util C
Duvelisib		

Gender: Male

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Copiktra Prescribing Information, July 2019, Verastem, Inc.

68. Duvelisib / Strong CYP3A Inducers _____ _____

Alert Message: The concurrent use of Copiktra (duvelisib) with strong CYP3A4 inducers should be avoided. Duvelisib is a CYP3A4 substrate, and co-administration with a strong CYP3A4 inducer may result in decreased duvelisib exposure and loss of duvelisib therapeutic efficacy.

Drugs/Diseases

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

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Copiktra Prescribing Information, July 2019, Verastem, Inc.

69. Duvelisib / Strong CYP3A Inhibitors _____ _____

Alert Message: The concurrent use of Copiktra (duvelisib) with strong CYP3A4 inhibitors should be avoided. Duvelisib is a CYP3A4 substrate, and co-administration with a strong CYP3A4 inhibitor may result in increased duvelisib exposure and increased risk of duvelisib-related toxicities.

Drugs/Diseases

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

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Copiktra Prescribing Information, July 2019, Verastem, Inc.

70. Duvelisib / Sensitive CYP3A4 Substrates _____ _____

Alert Message: The concurrent use of Copiktra (duvelisib) with a drug that is a sensitive CYP3A4 substrate may cause an increase in the AUC of a sensitive CYP3A4 substrate, which may increase the risk of toxicities of these drugs. Consider reducing the dose of the sensitive CYP3A4 substrate, and monitor for signs of toxicities of the coadministered sensitive CYP3A substrate.

Drugs/Diseases

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

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Copiktra Prescribing Information, July 2019, Verastem, Inc.

Criteria Recommendations *Approved* *Rejected*

71. Duvelisib / Serious Infections _____ _____

Alert Message: Serious, including fatal, infections have occurred in patients receiving Copiktra (duvelisib). The most common serious infections were pneumonia, sepsis, and lower respiratory infections. Treat infections prior to initiation of duvelisib. Advise patients to report any new or worsening signs and symptoms of infection. Refer to the official prescribing information for dose modification to manage duvelisib toxicities.

Drugs/Diseases

Util A	Util B		Util C
Duvelisib	Herpes Zoster	Cytomegalovirus	
	Urinary Tract Infection	Hepatitis	
	Esophageal Candidiasis	Fever	
	Acute Histoplasmosis	Respiratory Infections	

References:

Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Copiktra Prescribing Information, July 2019, Verastem, Inc.

70. Duvelisib / Hepatotoxicity _____ _____

Alert Message: Copiktra (duvelisib) can cause hepatotoxicity. Monitor hepatic function during treatment with duvelisib. For Grade 2 ALT/AST elevation (greater than 3 to 5 × ULN), maintain duvelisib dose and monitor at least weekly until return to less than 3 × ULN. For Grade 3 ALT/AST elevation (greater than 5 to 20 × ULN), withhold duvelisib and monitor at least weekly until return to less than 3 × ULN. Resume duvelisib at the same dose (first occurrence) or a reduced dose for subsequent occurrence. For grade 4 ALT/AST elevation (greater than 20 × ULN), discontinue duvelisib.

Drugs/Diseases

Util A	Util B	Util C
Duvelisib	Abnormal Liver Function Studies	

References:

Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Copiktra Prescribing Information, July 2019, Verastem, Inc.

73. Duvelisib / Diarrhea or Colitis _____ _____

Alert Message: Serious, including fatal, diarrhea or colitis occurred in 18% of patients receiving Copiktra (duvelisib). Advise patients to report any new or worsening diarrhea. Refer to the official prescribing information for therapy modification to manage duvelisib-related diarrhea or colitis.

Drugs/Diseases

Util A	Util B	Util C
Duvelisib	Diarrhea	
	Colitis	

References:

Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Copiktra Prescribing Information, July 2019, Verastem, Inc.

74. Duvelisib / FDA Approved Indications _____ _____

Alert Message: A review of the patient's diagnosis records did not reveal a supporting diagnosis for Copiktra (duvelisib). Duvelisib is indicated for the treatment of adult patients with relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphomas (SLL) after at least two prior therapies or those with relapsed or refractory follicular lymphoma (FL) after at least two prior systemic therapies. The long-term safety and efficacy of this agent in the treatment of disease states other than the FDA-approved indications are unknown.

Drugs/Diseases

Util A	Util B	Util C (Negating)
Duvelisib		Chronic Lymphocytic Leukemia
		Small Lymphocytic Lymphomas
		Follicular Lymphoma

References:

Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Facts & Comparisons, 2020 Updates, Wolters Kluwer Health.

75. Duvelisib / Nonadherence _____ _____

Copiktra (duvelisib). 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
Duvelisib		

References:

Osterberg L, Blaschke T. Adherence to Medication. N Engl J Med. 2005;353:487-97.
Ruddy K, Mayer E, Partridge A. Patient Adherence and Persistence With Oral Anticancer Treatment. CA Cancer J Clin 2009;59:56-66.
Barillet M, Prevost V, Joly F, Clarisse B. Oral Antineoplastic Agents: How do We Care About Adherence?. Br J Clin Pharmacol. 2015;80(6):1289–1302. doi:10.1111/bcp.12734
Greer JA, Amoyal N, Nisotel L, et al. Systemic Review of Adherence to Oral Antineoplastic Therapies. The Oncologist. 2016;21:354-376.

76. Niraparib / MDS/AML _____ _____

Alert Message: Myelodysplastic Syndrome/Acute Myeloid Leukemia (MDS/AML), including cases with fatal outcome, have been reported in patients who received Zejula (niraparib) monotherapy in clinical trials. Discontinue niraparib if MDS/AML is confirmed.

Drugs/Diseases

Util A	Util B	Util C
Niraparib	Myelodysplastic Syndrome	
	Acute Myeloid Leukemia	

References:

Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Zejula Prescribing Information, April 2020, GlaxoSmithKline.

77. Niraparib / Therapeutic Appropriateness _____ _____

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

Drugs/Diseases

Util A	Util B	Util C
Niraparib		

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Zejula Prescribing Information, April 2020, GlaxoSmithKline.

78. Niraparib / Therapeutic Appropriateness _____ _____

Alert Message: Hypertension and hypertensive crisis have been reported in patients treated with Zejula (niraparib). Monitor blood pressure and heart rate at least weekly for the first two months, then monthly for the first year and periodically thereafter during treatment with niraparib. Closely monitor patients with cardiovascular disorders, especially coronary insufficiency, cardiac arrhythmias, and hypertension. Medically manage hypertension with antihypertensive medications and adjustment of the niraparib dose, if necessary.

Drugs/Diseases

Util A	Util B	Util C
Niraparib	Hypertension	
	Atherosclerotic Heart Disease	
	Cardiac Arrhythmias	

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Zejula Prescribing Information, April 2020, GlaxoSmithKline.

79. Niraparib / Hematologic Adverse Reactions _____ _____

Alert Message: Hematologic adverse reactions (thrombocytopenia, anemia and neutropenia) have been reported in patients treated with Zejula (niraparib). Do not start niraparib until patients have recovered from hematological toxicity caused by previous chemotherapy (≤ Grade 1). Monitor complete blood counts weekly for the first month, monthly for the next 11 months of treatment, and periodically after this time. If hematological toxicities do not resolve within 28 days following interruption, discontinue niraparib, and refer the patient to a hematologist for further investigations, including bone marrow analysis and blood sample for cytogenetics.

Drugs/Diseases

Util A	Util B	Util C
Niraparib	Thrombocytopenia	
	Anemia	
	Neutropenia	

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Zejula Prescribing Information, April 2020, GlaxoSmithKline.

80. Niraparib / Pregnancy / Pregnancy Negating _____ _____

Alert Message: Based on its mechanism of action, Zejula (niraparib) can cause fetal harm when administered to pregnant patients. There are no data regarding the use of niraparib in pregnant patients to inform the drug-associated risk. Niraparib has the potential to cause teratogenicity and/or embryo-fetal death since niraparib is genotoxic and targets actively dividing cells in animals and patients (e.g., bone marrow). Due to the potential risk to a fetus based on its mechanism of action, animal developmental and reproductive toxicology studies were not conducted with niraparib. Apprise pregnant patients of the potential risk to a fetus.

Drugs/Diseases

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

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Zejula Prescribing Information, April 2020, GlaxoSmithKline.

81. Niraparib / Reproductive Potential _____ _____

Alert Message: Advise patients of reproductive potential to use effective contraception during treatment with Zejula (niraparib) and for at least 6 months following the last dose. Niraparib can cause fetal harm when administered to a pregnant patient.

Drugs/Diseases

Util A	Util B	Util C (Negating)
Niraparib		Contraceptives

Gender: Female
Age Range 11 – 50 yoa

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Zejula Prescribing Information, April 2020, GlaxoSmithKline.

82. Niraparib / Lactation _____ _____

Alert Message: No data are available regarding the presence of Zejula (niraparib) or its metabolites in human milk or on its effects on the breastfed infant, or milk production. Because of the potential for serious adverse reactions in breastfed infants from niraparib, advise a lactating patient not to breastfeed during treatment with niraparib for 1 month after receiving the final dose.

Drugs/Diseases

Util A	Util B	Util C
Niraparib	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Zejula Prescribing Information, April 2020, GlaxoSmithKline.

83. Niraparib / Non-adherence _____ _____

Alert Message: Based on refill history, your patient may be under-utilizing Zejula (niraparib). Non-adherence 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
Niraparib		

References:

Osterberg L, Blaschke T. Adherence to Medication. N Engl J Med 2005; 353:487- 497.
Paolella GA, Boyd AD, Wirth SM, Cuellar S, Venepalli NK, Crawford SY. Adherence to Oral Anticancer Medications: Evolving Interprofessional Roles and Pharmacist Workforce Considerations. *Pharmacy (Basel)*. 2018;6(1):23. Published 2018 Mar 8. doi:10.3390/pharmacy6010023.
Greer JA, Amoyal N, Nisotel L, Fishbein JN, et al., A Systematic Review of Adherence to Oral Antineoplastic Therapies. The Oncologist. 2016;21:354–376.

84. Dacomitinib / Overutilization _____ _____

Alert Message: Vizimpro (dacomitinib) may be over-utilized. The recommended dosage of dacomitinib is 45 mg orally once daily.

Drugs/Diseases

Util A	Util B	Util C
Dacomitinib		

Max Dose: 45 mg/day

References:

Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Vizimpro Prescribing Information, Sept. 2018, Pfizer, Inc.

85. Dacomitinib / Interstitial Lung Disease _____ _____

Alert Message: Severe and fatal ILD/pneumonitis occurred in patients treated with Vizimpro (dacomitinib) and occurred in 0.5% of the 394 dacomitinib-treated patients; 0.3% of cases were fatal. Monitor patients for pulmonary symptoms indicative of ILD/pneumonitis. Withhold dacomitinib and promptly investigate for ILD in patients who present with worsening of respiratory symptoms which may be indicative of ILD (e.g., dyspnea, cough, and fever). Permanently discontinue dacomitinib if ILD is confirmed.

Drugs/Diseases

Util A	Util B	Util C
Dacomitinib	Dyspnea	
	Cough	
	Fever	
	Interstitial Pneumonia	

References:

Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Vizimpro Prescribing Information, Sept. 2018, Pfizer, Inc.

86. Dacomitinib / Diarrhea _____ _____

Alert Message: Severe and fatal diarrhea occurred in patients treated with Vizimpro (dacomitinib). Diarrhea occurred in 86% of the 394 dacomitinib-treated patients; Grade 3 or 4 diarrhea was reported in 11% of patients, and 0.3% of cases were fatal. Withhold dacomitinib for Grade 2 or greater diarrhea until recovery to less than or equal to Grade 1 severity, then resume dacomitinib at the same or a reduced dose depending on the severity of diarrhea. Promptly initiate anti-diarrheal treatment (loperamide or diphenoxylate hydrochloride with atropine sulfate) for diarrhea.

Drugs/Diseases

Util A	Util B	Util C
Dacomitinib	Diarrhea	

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Vizimpro Prescribing Information, Sept. 2018, Pfizer, Inc.

87. Dacomitinib / Pregnancy / Pregnancy Negating _____ _____

Alert Message: Based on findings from animal studies and its mechanism of action, Vizimpro (dacomitinib)can cause fetal harm when administered to a pregnant woman. There are no available data on dacomitinib use in pregnant women. Advise a pregnant woman of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with dacomitinib and for at least 17 days after the final dose.

Drugs/Diseases

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

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Vizimpro Prescribing Information, Sept. 2018, Pfizer, Inc.

88. Dacomitinib / Lactation _____ _____

Alert Message: There is no information regarding the presence of Vizimpro (dacomitinib) or its metabolites in human milk or their effects on the breastfed infant or on milk production. Because of the potential for serious adverse reactions in breastfed infants from dacomitinib, advise women not to breastfeed during treatment with dacomitinib and for at least 17 days after the last dose.

Drugs/Diseases

Util A	Util B	Util C
Dacomitinib	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Vizimpro Prescribing Information, Sept. 2018, Pfizer, Inc.

89. Dacomitinib / Therapeutic Appropriateness _____ _____

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

Drugs/Diseases

Util A	Util B	Util C
Dacomitinib		

Age Range: 0 - 17 yoa

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Vizimpro Prescribing Information, Sept. 2018, Pfizer, Inc.

90. Dacomitinib / Therapeutic Appropriateness _____ _____

Alert Message: Vizimpro (dacomitinib) can cause fetal harm when administered to a pregnant woman. Advise females of reproductive potential to use effective contraception during treatment with dacomitinib and for at least 17 days after the final dose.

Drugs/Diseases

Util A	Util B	Util C (Negating)
Dacomitinib		Contraceptives

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Vizimpro Prescribing Information, Sept. 2018, Pfizer, Inc.

91. Dacomitinib / Proton Pump Inhibitors _____ _____

Alert Message: Concomitant use with a PPI decreases dacomitinib concentrations, which may reduce Vizimpro (dacomitinib) efficacy. Avoid the concomitant use of PPIs with dacomitinib. As an alternative to PPIs, use locally-acting antacids or an H2-receptor antagonist. Administer dacomitinib at least 6 hours before or 10 hours after taking an H2-receptor antagonist.

Drugs/Diseases

Util A	Util B	Util C
Dacomitinib	Dexlansoprazole	
	Esomeprazole	
	Lansoprazole	
	Omeprazole	
	Pantoprazole	
	Rabeprazole	

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Vizimpro Prescribing Information, Sept. 2018, Pfizer, Inc.

92. Dacomitinib / CYP2D6 Substrates _____ _____

Alert Message: Concomitant use of Vizimpro (dacomitinib) increases the concentration of drugs that are CYP2D6 substrates, which may increase the risk of toxicities of these drugs. Avoid concomitant use of dacomitinib with CYP2D6 substrates where minimal increases in the concentration of the CYP2D6 substrate may lead to serious or life-threatening toxicities.

Drugs/Diseases

Util A	Util B		Util C
Dacomitinib	Amphetamine	Metoprolol	
	Aripiprazole	Nebivolol	
	Atomoxetine	Paroxetine	
	Brexpiprazole	Perphenazine	
	Codeine	Propafenone	
	Desipramine	Quinidine	
	Dextroamphetamine	Risperidone	
	Dextromethorphan	Thioridazine	
	Dihydrocodeine	Timolol	
	Fluoxetine	Tolterodine	
	Fluvoxamine	Venlafaxine	
	Iloperidone		

References:

Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Vizimpro Prescribing Information, Sept. 2018, Pfizer, Inc.
Straight Healthcare. Cytochrome P450 2D6. Available at: https://www.straighthealthcare.com/cytochrome-p450-2d6.html

93. Secukinumab / Overutilization _____ _____

Alert Message: Cosentyx (secukinumab) may be over-utilized. The recommended maximum dose of secukinumab is 300 mg every 4 weeks.

Drugs/Diseases

Util A	Util B	Util C
Secukinumab		

Max Dose: 300 mg/4 weeks

References:

Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Cosentyx Prescribing Information, June 2020. Novartis Pharmaceuticals Corp.

94. Secukinumab / Serious Infection _____ _____

Alert Message: Cosentyx (secukinumab) may increase the risk of infections. In clinical trials, a higher rate of infections was observed in secukinumab treated subjects compared to placebo-treated subjects. Exercise caution when considering the use of secukinumab in patients with a chronic infection or a history of recurrent infection. If a patient develops a serious infection, the patient should be closely monitored, and secukinumab should be discontinued until the infection resolves.

Drugs/Diseases

Util A	Util B		Util C
Secukinumab	Herpes Zoster	Cytomegalovirus	
	Urinary Tract Infection	Hepatitis	
	Esophageal Candidiasis	Fever	
	Acute Histoplasmosis	Respiratory Infections	

References:

Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Cosentyx Prescribing Information, June 2020. Novartis Pharmaceuticals Corp.

95. Secukinumab / Therapeutic Appropriateness (0 – 17 yoa) _____ _____

Alert Message: The safety and effectiveness of Cosentyx (secukinumab) in pediatric patients have not been evaluated.

Drugs/Diseases

Util A	Util B	Util C
Secukinumab		

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Cosentyx Prescribing Information, June 2020. Novartis Pharmaceuticals Corp.

96. Secukinumab / Inflammatory Bowel Disease _____ _____

Alert Message: Caution should be used when prescribing Cosentyx (secukinumab) to patients with inflammatory bowel disease. Exacerbations, in some cases serious, occurred in secukinumab treated patients during clinical trials in plaque psoriasis, psoriatic arthritis, and ankylosing spondylitis. In addition, new-onset inflammatory bowel disease cases occurred in clinical trials with secukinumab. Patients who are treated with secukinumab should be monitored for signs and symptoms of inflammatory bowel disease.

Drugs/Diseases

Util A	Util B	Util C (Include)
Secukinumab		Inflammatory Bowel Disease

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Cosentyx Prescribing Information, June 2020. Novartis Pharmaceuticals Corp.

97. Secukinumab / CYP3A4 Substrates w/ NTI _____ _____

Alert Message: Upon initiation or discontinuation of Cosentyx (secukinumab) in patients who are receiving concomitant CYP450 substrates, particularly those with a narrow therapeutic index, consider monitoring for therapeutic effect or drug concentration and consider dosage adjustment as needed. The formation of CYP450 enzymes can be altered by increased levels of certain cytokines (e.g., IL-1, IL-6, IL-10, TNFα, IFN) during chronic inflammation. Thus, the formation of CYP450 enzymes could be normalized during secukinumab administration.

Drugs/Diseases

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

References:
Clinical Pharmacology, 2020 Elsevier/Gold Standard.
Cosentyx Prescribing Information, June 2020. Novartis Pharmaceuticals Corp.

98. Secukinumab / Nonadherence _____ _____

Alert Message: Based on refill history, your patient may be under-utilizing Cosentyx (secukinumab). 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
Secukinumab		

References:

Osterberg L, Blaschke T. Adherence to Medication. N Engl J Med 2005;353:487-97.
Soobraty A, Boughdady S, Selinger CP. Current Practice and Clinicians' Perception of Medication Non-adherence in Patients with Inflammatory Bowel Disease: A Survey of 98 Clinicians. World J Gastro Pharma Ther. 2017; 8(1):67-73.
McKay KA, Tremlett H, Patten SB, et al. Determinants of Non-Adherence to Disease-Modifying Therapies in Multiple Sclerosis: A Cross-Canada Prospective Study. Mult Scler. 2016;23(4):588-596.
Joplin S, van der Zwan R, Joshua F, Wong PK. Medication Adherence in Patients with Rheumatoid Arthritis: The Effect of Patient Education, Health Literacy, and Musculoskeletal Ultrasound. Biomed Res Int. 2015;2015:150658.