DUR Board Meeting
March 6, 2019
Heritage Center

North Dakota Medicaid
DUR Board Meeting Agenda
Heritage Center
612 East Boulevard Avenue
Bismarck, ND
April 9, 2019
1:00 pm

1. Administrative items
    - Travel vouchers

2. Old business
    - Review and approval of 12/2018 meeting minutes
    - Budget update
    - Review top 15 therapeutic categories/top 25 drugs
    - Prior authorization/PDL update
    - Second review of Orilissa
    - Second review of agents for treatment of vaginal candidiasis
    - Second review of agents for treatment of glaucoma
    - Second review of agents for treatment of dry eye syndrome

3. New business
    - Review of estrogen agents
    - Review of Sivextro
    - Review of Nuzyra
    - Review of agents for treatment of osteoporosis
    - Review of agents for treatment of hyperkalemia
    - Review of agents for treatment of Parkinson's disease
    - Report on utilization of long-acting beta agonist/inhaled corticosteroid inhaler combination products without use of a rescue inhaler
    - Increase in Guideline supported use of metformin after intervention
    - Update on provider education and academic detailing programs
    - Retrospective DUR criteria recommendations
    - Upcoming meeting date.
        - Next meeting is June 5, 2019 at the Capitol

4. Adjourn

Please remember to silence all cellular phones during the meeting.

Drug Utilization Review (DUR) Meeting Minutes
December 5, 2018

Members Present: Katie Kram, Tanya Schmidt, LeNeika Roehrich, Andrea Honeyman, Jesse Rue, Peter Woodrow, Laura Schield, Michael Booth, Gaylord Kavlie

Members Absent: Zach Marty, Michael Quast, Jeffrey Hostetter, Russ Sobotta

Medicaid Pharmacy Department: Brendan Joyce, Alexi Murphy, Gary Betting

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

Old Business
Chair L. Roehrich called the meeting to order at 1:09 p.m. Chair L. Roehrich asked for a motion to approve the minutes of the September meeting. T. Schmidt moved that the minutes be approved and P. Woodrow seconded the motion. Chair L. Roehrich called for a voice vote to approve the minutes. The motion passed with no audible dissent.

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 3rd quarter of 2018.

PDL Update
A. Murphy shared with the Board all of changes made to the Preferred Drug List since the most recent 2018 version of the Preferred Drug List was posted. Notable changes included adding Rytary, Daxbia, Millipred, Millipred DP, Taperdex to the Non-Preferred Dosage Form prior authorization criteria; adding Mentax, natifine, Naftin, nystatin-triamcinolone, oxiconazole, and Oxistat to prior authorization required under the the topical antifungals PDL category; and moving Emgality, Aimovig, and Altreno to prior authorization required under the Migraine Prophylaxis PDL category.

Second Review of Glyburide and Avandia
A motion and second was made at the September meeting to place Glyburide and Avandia on prior authorization. The topics were brought up for a second review. There was no public comment. Chair L. Roehrich called for a voice vote and the motion passed with no audible dissent.

Second Review of Lucemyra
A motion and second was made at the September meeting to generate prior authorization criteria for Lucemyra. The topic was brought up for a second review. There was no public comment. Chair L. Roehrich called for a voice vote and the motion passed with no audible dissent.

Second Review of Palynziq
A motion and second was made at the September meeting to place Palynziq on prior authorization. The topics were brought up for a second review to place Palynziq into a prior authorization criteria category for Phenylketonuria with Kuvan. There was no public comment. Chair L. Roehrich called for a voice vote and the motion passed with no audible dissent.

Second Review of Roxybond & Siklos
A motion and second was made at the September meeting to place Roxybond and Siklos on prior authorization. B. Joyce spoke to the Board about the growing number of existing products with new dosage formulations of the same dose and route coming to market and the costs associated with many of these new formulations, such as Roxybond and Siklos. B. Joyce proposed that the Board allow Medicaid the ability to automatically place new formulation products on prior authorization under the Non-Preferred Dosage Formulation prior authorization criteria. The placement of new formulations on prior authorization automatically would be limited to only those agents that have the same active pharmaceutical ingredient, route, and FDA-approved indication as a currently available product. G. Kavlie made a motion to amend the Roxybond and Siklos criteria to an expanded Non-Preferred Dosage Form criteria as stated above. P. Woodrow seconded the motion. Chair L. Roehrich called for a voice vote on the motion to amend the criteria and the motion passed with no audible dissent. Chair L. Roehrich 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. K. Duhrkopf of Sanofi spoke on a new indication for Dupixent for add-on therapy for moderate to severe eosinophilic asthma and asked that the Board consider adjusting eosinophil count requirements in the Dupixent prior authorization criteria. B. Joyce proposed monitoring requests for Dupixent moving forward to determine whether adjustments to the criteria should be made, to which the Board agreed. No changes were recommended during the review of the forms and criteria. A. Murphy highlighted the consolidation of multiple request forms to a "General" prior authorization request form, as well as the consolidation of many other single agent forms to single drug class specific request forms that occurred throughout the year. No changes to forms or criteria were requested or recommended by the Board. A motion was made by G. Kavlie to approve of the reviewed forms as they are, which was seconded by K. Kram. Chair L. Roehrich then called for a voice vote for approval of the reviewed forms and criteria, which passed with no audible dissent.

<u>New Business</u>
Agents for Treatment of Dry Eye Syndrome
T. DeRuiter and A. Murphy reviewed agents for treatment of dry eye syndrome with the Board. A motion was made by P. Woodrow to create this new PA criteria class and manage these medications through prior authorization. The motion was seconded by L. Schield. This topic will be reviewed at the next meeting.

Agents for Treatment of Glaucoma
T. DeRuiter and B. Joyce reviewed agents for treatment of glaucoma with the Board. A motion was made by P. Woodrow to manage the medications through prior authorization. The motion was seconded by K. Kram. This topic will be reviewed at the next meeting.

Orilissa
T. DeRuiter and B. Joyce reviewed Orilissa with the Board. A motion was made by P. Woodrow to manage the medication through prior authorization. The motion was seconded by A. Honeyman. This topic will be reviewed at the next meeting.

Vaginal Anti-Infective Agents
T. DeRuiter and B. Joyce reviewed vaginal anti-infective agents with the Board. A motion was made by G. Kavlie to manage the medication through prior authorization. The motion was seconded by P. Woodrow. This topic will be reviewed at the next meeting.

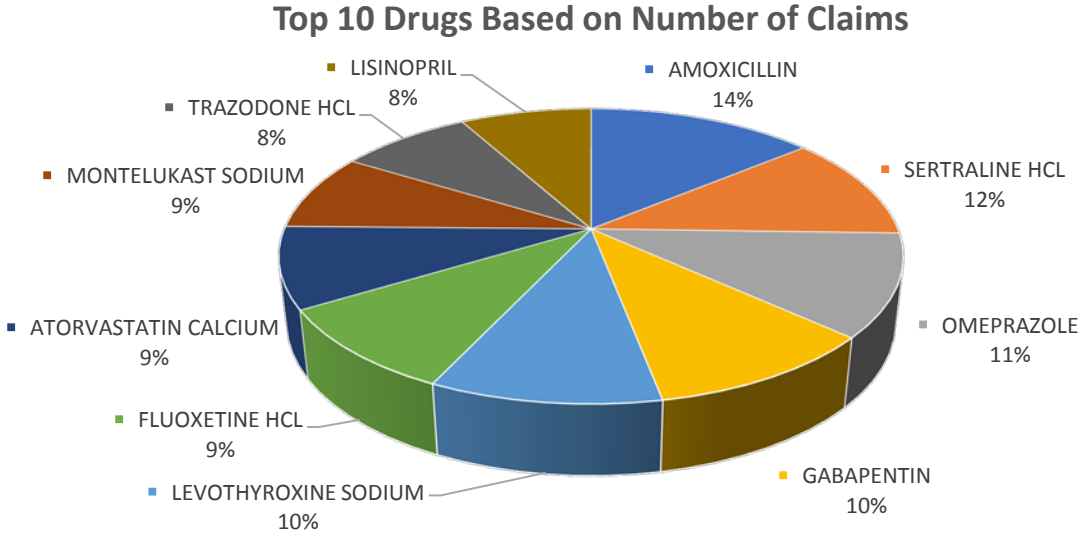
Retrospective Drug Utilization Review (RDUR) Criteria Recommendations
The recommended RDUR criteria enclosed in the packet were developed from product information provided by the manufacturers and are usually consistent with new indications, new drugs added, and new warnings. These proposed criteria will be added to the current set of criteria and will be used in future DUR cycles. Laura Hill of Abbvie requested that RDUR criteria #36 be corrected to apply to patients with a Child-Pugh class of C. K. Kram moved to amend the new criteria as stated above and approve it. P. Woodrow seconded the motion. The motion passed with no audible dissent.

Adjournment and Upcoming Meeting Date
Chair L. Roehrich adjourned the meeting at 3:00 pm. The next DUR Board meeting will be held March 6, 2019 at 1:00 pm at the Heritage Center in Bismarck.

TOP 25 DRUGS BASED ON NUMBER OF CLAIMS FROM 10/01/2018 – 12/31/2018

Drug	AHFS Therapeutic Class	Rx	Paid	Paid/Rx	% Total Claims
AMOXICILLIN	PENICILLIN ANTIBIOTICS	3,290	$123,143.55	$37.43	2.25%
SERTRALINE HCL	ANTIDEPRESSANTS	2,672	$50,180.72	$18.78	1.83%
OMEPRAZOLE	PROTON-PUMP INHIBITORS	2,626	$59,408.64	$22.62	1.80%
GABAPENTIN	ANTICONVULSANTS, MISCE	2,407	$74,152.53	$30.81	1.65%
LEVOTHYROXINE SODIUM	THYROID AGENTS	2,371	$46,474.02	$19.60	1.62%
FLUOXETINE HCL	ANTIDEPRESSANTS	2,181	$34,425.42	$15.78	1.49%
ATORVASTATIN CALCIUM	HMG-COA REDUCTASE INHI	2,085	$49,684.49	$23.83	1.43%
MONTELUKAST SODIUM	LEUKOTRIENE MODIFIERS	1,970	$34,874.32	$17.70	1.35%
TRAZODONE HCL	ANTIDEPRESSANTS	1,916	$28,364.91	$14.80	1.31%
LISINOPRIL	ANGIOTENSIN-CONVERTING	1,903	$49,718.76	$26.13	1.30%
HYDROCODONE-ACETAMINOPHE	OPIATE AGONISTS	1,795	$43,796.92	$24.40	1.23%
VYVANSE	AMPHETAMINES	1,785	$406,186.06	$227.56	1.22%
ESCITALOPRAM OXALATE	ANTIDEPRESSANTS	1,755	$37,387.44	$21.30	1.20%
CLONIDINE HCL	CENTRAL ALPHA-AGONISTS	1,626	$33,026.99	$20.31	1.11%
RISPERIDONE	ANTIPSYCHOTIC AGENTS	1,555	$22,715.63	$14.61	1.06%
METFORMIN HCL	BIGUANIDES	1,530	$24,460.42	$15.99	1.05%
PROAIR HFA	BETA-ADRENERGIC AGONIS	1,515	$114,361.76	$75.49	1.04%
CONCERTA	RESPIRATORY AND CNS ST	1,466	$436,997.79	$298.09	1.00%
AZITHROMYCIN	MACROLIDE ANTIBIOTICS	1,455	$40,234.24	$27.65	1.00%
AMOXICILLIN-CLAVULANATE	PENICILLIN ANTIBIOTICS	1,378	$66,252.38	$48.08	0.94%
QUETIAPINE FUMARATE	ANTIPSYCHOTIC AGENTS	1,339	$27,096.77	$20.24	0.92%
DULOXETINE HCL	ANTIDEPRESSANTS	1,328	$27,556.49	$20.75	0.91%
PANTOPRAZOLE SODIUM	PROTON-PUMP INHIBITORS	1,291	$22,396.35	$17.35	0.88%
LAMOTRIGINE	ANTICONVULSANTS, MISCE	1,273	$19,158.37	$15.05	0.87%
BUPROPION XL	ANTIDEPRESSANTS	1,265	$27,838.32	$22.01	0.87%
TOTAL TOP 25		45,777	$1,899,893.29	$41.50	31.35%

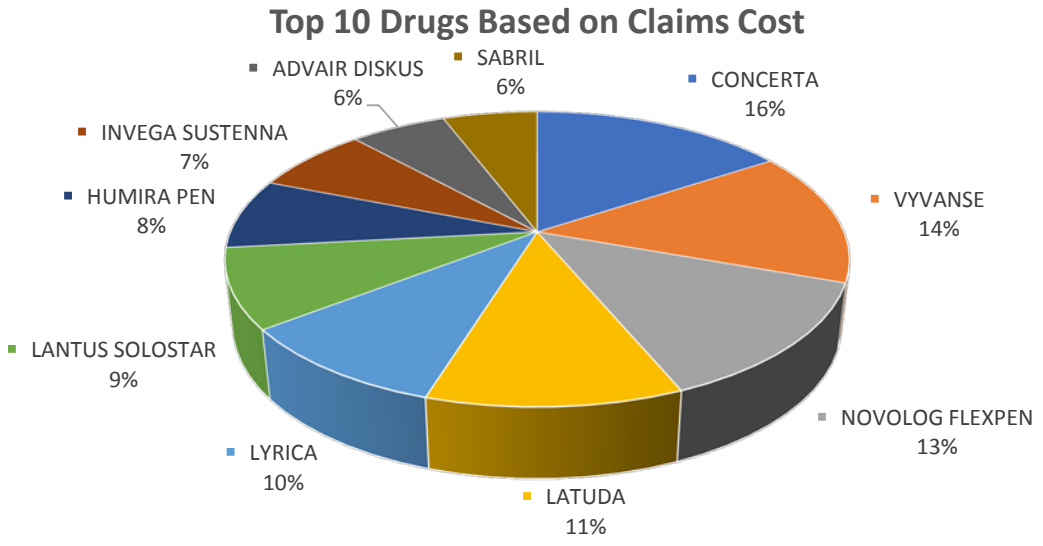
Total Rx Claims From 10/01/2018 - 12/31/2018	146,038



TOP 25 DRUGS BASED ON TOTAL CLAIMS COST FROM 10/01/2018 - 12/31/2018

Drug	AHFS Therapeutic Class	Paid	Rx	Paid/Rx	% Total Cost
CONCERTA	RESPIRATORY AND CNS STIMULANTS	$436,997.79	1,466	$298.09	3.63%
VYVANSE	AMPHETAMINES	$406,186.06	1,785	$227.56	3.38%
NOVOLOG FLEXPEN	INSULINS	$364,881.43	626	$582.88	3.03%
LATUDA	ANTIPSYCHOTIC AGENTS	$310,175.22	494	$627.89	2.58%
LYRICA	ANTICONVULSANTS, MISCELLANEOUS	$269,651.19	578	$466.52	2.24%
LANTUS SOLOSTAR	INSULINS	$241,175.55	541	$445.80	2.00%
HUMIRA PEN	DISEASE-MODIFYING ANTIRHEUMATIC AGENTS	$212,890.14	42	$5,068.81	1.77%
INVEGA SUSTENNA	ANTIPSYCHOTIC AGENTS	$200,357.34	102	$1,964.29	1.67%
ADVAIR DISKUS	CORTICOSTEROIDS (RESPIRATORY TRACT)	$164,635.00	442	$372.48	1.37%
SABRIL	ANTICONVULSANTS, MISCELLANEOUS	$161,652.22	9	$17,961.36	1.34%
NORDITROPIN FLEXPRO	PITUITARY	$161,126.70	47	$3,428.23	1.34%
GENVOYA	ANTIRETROVIRALS	$142,319.34	115	$1,237.56	1.18%
LEVEMIR FLEXTOUCH	INSULINS	$123,831.58	327	$378.69	1.03%
AMOXICILLIN	PENICILLIN ANTIBIOTICS	$123,143.55	3,290	$37.43	1.02%
VIMPAT	ANTICONVULSANTS, MISCELLANEOUS	$121,672.79	192	$633.71	1.01%
PROAIR HFA	BETA-ADRENERGIC AGONISTS	$114,361.76	1,515	$75.49	0.95%
FOCALIN XR	RESPIRATORY AND CNS STIMULANTS	$109,215.66	352	$310.27	0.91%
MAPAP	ANALGESICS AND ANTIPYRETICS, MISC.	$104,880.32	554	$189.31	0.87%
SYMBICORT	CORTICOSTEROIDS (RESPIRATORY TRACT)	$104,625.07	354	$295.55	0.87%
FLOVENT HFA	CORTICOSTEROIDS (RESPIRATORY TRACT)	$102,792.19	475	$216.40	0.85%
ABILIFY MAINTENA	ANTIPSYCHOTIC AGENTS	$99,471.83	53	$1,876.83	0.83%
NIX	SCABICIDES AND PEDICULICIDES	$92,968.90	238	$390.63	0.77%
SYMDEKO	CYSTIC FIBROSIS (CFTR) CORRECTORS	$89,649.84	4	$22,412.46	0.75%
NOVOLOG	INSULINS	$87,874.31	157	$559.71	0.73%
SPIRIVA	ANTIMUSCARINICS/ANTISPASMODICS	$87,590.20	259	$338.19	0.73%
TOTAL TOP 25		$4,434,125.98	14,017	$16.34	36.86%

Total Rx Claims From 10/01/2018 - 12/31/2018	146,038



PDL Update

ADDED TO PA	
ACTEMRA ACTPEN	Cytokine Modulators
AFREZZA	Insulin
AJOVY	Migraine Prophylaxis – CGRP Inhibitors
ALTRENO	Acne
ALVESCO	Corticosteroids – Inhaled
ARAKODA	Antimalarial
ARIKAYCE	CYSTIC FIBROSIS INHALED ANTIBIOTICS
BRYHALI	Topical Corticosteroids
LONG-ACTING OPIOID ANALGESICS	Non-preferred Dosage forms
CIPROFLOXACIN HCL	Ophthalmic Anti-Infectives
COLCHICINE	Non-preferred Dosage forms
DAXBIA	Non-preferred Dosage forms
doxycycline monohydrate tablet	acne
DUPIXENT	Atopic Dermatitis
EMGALITY	Migraine Prophylaxis – CGRP Inhibitors
EMGALITY SYRINGE	Migraine Prophylaxis – CGRP Inhibitors
EPIPEN	Epinephrine Autoinjectors
EPIPEN JR 2-PAK	Epinephrine Autoinjectors
EURAX	Lice
KETOPROFEN	NSAIDs
KRINTAFEL	Antimalarial
MENTAX	Antifungals – Topical
MILLIPRED	Non-preferred Dosage forms
MILLIPRED DP	Non-preferred Dosage forms
MINOLIRA ER	Acne
MULPLETA	over $3000
NAFTIFINE HCL	Antifungals – Topical
NAFTIN	Antifungals – Topical
NEOMYCIN-BACITRACIN-POLYMYXIN	Ophthalmic Anti-Infectives
NOCDURNA	Non-preferred Dosage forms
NOVOLIN 70-30 FLEXPEN	Insulin
NYSTATIN-TRIAMCINOLONE	Antifungals – Topical
OMNARIS	Nasal Steroids
OXICONAZOLE NITRATE	Antifungals – Topical
OXISTAT	Antifungals – Topical
PANZYGA	Immune Globulins

PATADAY	Ophthalmic Anti-Infectives
ROXYBOND	Non-preferred Dosage forms
RYTARY	Non-preferred Dosage forms
SEYSARA	Acne
SIKLOS	Non-preferred Dosage forms
SYMJEPI	Epinephrine Autoinjectors
TAPERDEX	Steroids - Oral
TOLSURA	Antifungals - Oral
TRACLEER	Pulmonary Hypertension
TRESIBA	insulin
UDENYCA	Hematopoietic, Colony Stimulating Factors
VANCOCIN HCL	Non-preferred Dosage forms
YUPELRI	COPD (Chronic Obstructive Pulmonary Disease)
ZEMBRACE SYMTOUCH	Migraine Treatment
ZETONNA	Nasal Steroids
ZYCLARA	Actinic Keratosis

Removed from PA	
AMLODIPINE-OLMESARTAN	ARBs (Angiotensin Receptor Blockers)
AMLODIPINE-VALSARTAN	ARBs (Angiotensin Receptor Blockers)
BENAZEPRIL-HYDROCHLOROTHIAZIDE	ACE (Angiotensin-converting enzyme) Inhibitors
CANDESARTAN CILEXETIL	ARBs (Angiotensin Receptor Blockers)
CANDESARTAN-HYDROCHLOROTHIAZIDE	ARBs (Angiotensin Receptor Blockers)
CAPTOPRIL	ACE (Angiotensin-converting enzyme) Inhibitors
CAPTOPRIL-HYDROCHLOROTHIAZIDE	ACE (Angiotensin-converting enzyme) Inhibitors
DALFAMPRIDINE ER	Multiple Sclerosis
DOXYCYCLINE HYCLATE CAPSULE	Acne
FABIOR	Acne
FOSINOPRIL-HYDROCHLOROTHIAZIDE	ACE (Angiotensin-converting enzyme) Inhibitors
LETAIRIS	Endothelin Receptor Antagonists
MOVANTIK	Constipation – IBS/Opioid Induced
QVAR REDIHALER	Corticosteroids – Inhaled
RELISTOR SYRINGE	Constipation – IBS/Opioid Induced
SEVELAMER CARBONATE	Phosphate Binders
SORILUX	Antipsoriatics – Topical
SPIRIVA RESPIMAT	Long Acting Anticholinergics
STRIVERDI RESPIMAT	Long Acting Beta Agonists
TOBRAMYCIN	Cystic Fibrosis Inhaled Antibiotics
TOLTERODINE TARTRATE	Urinary Antispasmodics
TROSPIUM CHLORIDE	Urinary Antispasmodics
UTIBRON NEOHALER	Combination Anticholinergics/Beta Agonists

Orilissa PA Criteria

Approval:

Initial: 6 months
Renewal (150mg strength ONLY): 18 months

Criteria:

- Patient must be 18 years or older
- Patient must have a diagnosis of moderate to severe pain associated with endometriosis
- Must be prescribed by or in consult with an obstetrician/gynecologist or endocrinologist
- Documented pain scores must be attached.
- Pregnancy test must be performed prior to initiation of treatment, and a non-combination hormone birth control method must be used throughout treatment
- Patient must not have osteoporosis or severe liver disease (Child-Pugh Class C).
- Patient must have failed the following trials:
  A 3-cycle trial of two different types of Non-Steroidal Anti-Inflammatory agent (NSAIDs):
  - A phenylproprionic acid derivative at the upper end of the dose range (e.g. ibuprofen 400mg - 800mg every 6 hours)
  - A fenamate (such as mefenamic acid)

  AND

  A 3-cycle trial of two oral estrogen-progestin or progestin contraceptives

Renewal Criteria:

- Documented improvement in pain scores must be attached.

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
- Must be prescribed by or in consult with an obstetrician/gynecologist or endocrinologist
- Documented pain scores must be attached (updated pain scores must be attached to renewals)
- Pregnancy test must be performed prior to initiation of treatment, and a non-combination hormone birth control method must be used throughout treatment
- Patient must not have osteoporosis or severe liver disease (Child-Pugh Class C).
- Patient must have failed trials of a 3-cycle trial of the following:
  - A phenylproprionic acid derivative NSAID
  - A fenamate NSAID (such as mefenamic acid)
  - 2 oral estrogen-progestin or progestin contraceptives

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:**

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 #

Vaginal Anti-Infectives PA Criteria

Category PA Criteria: A 30-day trial of 3 preferred agents will be required before a non-preferred agent will be authorized. Non-preferred agents require an FDA-approved indication.

PREFERRED AGENTS	NON-PREFERRED AGENTS
AVC (sulfanilamide)	clindamycin cream
CLEOCIN (clindamycin) SUPPOSITORY	CLEOCIN (clindamycin) CREAM
CLINDESSE (clindamycin) CREAM	GYNAZOLE 1 (butoconazole) CREAM
metronidazole gel	NUVESSA (metronidazole) GEL
terconazole cream	METROGEL-VAGINAL (metronidazole)
VANDAZOLE (metronidazole) GEL	MICONAZOLE 3 (miconazole) suppository
	terconazole suppository

Dry Eye Syndrome PA Criteria

Category PA Criteria: A 60-day trial of the preferred agents will be required before a non-preferred agent will be authorized. Non-preferred agents require an FDA-approved indication.

PREFERRED AGENTS	NON-PREFERRED AGENTS
RESTASIS (Cyclosporine)	RESTASIS MULTIDOSE (Cyclosporine)
	XIIDRA (Lifitegrast)

Glaucoma PA Criteria

Glaucoma – Alpha Adrenergic

Group PA Criteria:
Branded non-preferred agents: A 30-day trial of all accessible pharmaceutically equivalent preferred agents will be required before a non-preferred agent will be authorized.

Generic non-preferred agents: A 30-day trial of a pharmaceutically equivalent preferred agent will be required before a non-preferred agent will be authorized.

PREFERRED AGENTS	NON-PREFERRED AGENTS
ALPHAGAN P 0.1% (brimonidine)	apraclonidine
ALPHAGAN P 0.15% (brimonidine)	brimonidine 0.15%
IOPIDINE (apraclonidine)	
brimonidine 0.2%	
COMBIGAN (brimonidine/timolol)	
SIMBRINZA (brinzolamide/brimonidine)	

Glaucoma – Beta Blockers

Group PA Criteria:
A 30-day trial of 2 preferred ingredients will be required before a non-preferred agent will be authorized.

PREFERRED AGENTS	NON-PREFERRED AGENTS
BETOPTIC S (Betaxolol) 0.25%	Betaxolol 0.5%
Carteolol	COSOPT (Dorzolamide/Timolol)
COMBIGAN (brimonidine/timolol)	ISTALOL (Timolol) Daily
Dorzolamide/Timolol	Timolol Daily
Levobunolol	Timolol gel forming solution
Timolol	TIMOPTIC (timolol)
TIMOPTIC OCUDOSE (timolol)	TIMOPTIC-XE (Timolol gel forming solution)

Glaucoma - Prostaglandin

Group PA Criteria:
A 30-day trial of 2 preferred ingredients will be required before a non-preferred agent will be authorized.

PREFERRED AGENTS	NON-PREFERRED AGENTS
Latanoprost	Bimatoprost 0.03%
LUMIGAN (Bimatoprost) 0.01%	VYZULTA (latanoprostene)
TRAVATAN Z (Travoprost)	XALATAN (Latanoprost)
ZIOPTAN (Tafluprost)	XELPROS (Latanoprost)

Glaucoma - Other

Group PA Criteria:
Branded non-preferred agents: A 30-day trial of all accessible pharmaceutically equivalent preferred agents will be required before a non-preferred agent will be authorized.

PREFERRED AGENTS	NON-PREFERRED AGENTS
AZOPT (Brinzolamide)	ISOPTO CARPINE (Pilocarbine)
Dorzolamide	TRUSOPT (Dorzolamide)
PHOSPHOLINE (Echothiophate Iodide)	
Pilocarpine	
RHOPRESSA (netarsudil)	

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 ESTROGEN AGENTS

INDICATIONS AND USE:

- Treatment of breast cancer (for palliation only) in appropriately selected women and men with metastatic disease.
- Hypoestrogenism caused by hypogonadism, castration, or primary ovarian failure
- Vasomotor symptoms associated with menopause
- Postmenopausal osteoporosis prevention
- Treatment of advanced androgen-dependent prostate carcinoma (for palliation only)
- Vulval and vaginal atrophy associated with menopause

DOSAGE FORMS AND ADMINISTRATION:

Dosage Form	Product	Strengths
Ring	Femring*	Femring: 0.05, 0.1 mg/24 hr
Top. Spray	Evamist*	Evamist: 1.52 mg/spray
Top. Patch	Climara, Menostar*, Vivelle-Dot*, Minivelle*, Alora	**Weekly:** • Climara: 0.025, 0.0375, 0.05, 0.06, 0.075, 0.1 mg/24 hr • Menostat: 14 mcg/hr **Twice Weekly:** • Minivelle, Alora, Vivelle-Dot: 0.025, 0.0375, 0.05, 0.075, 0.1 mg/24 hr
Top. Gel	Estrogel*, Divigel*, Elestrin*	Estrogel: 0.06% Divigel: 0.25, 0.5, 0.75, 1 mg/g Elestrin: 0.06%
Top. Cream	Estrace, EC-RX Estradiol*, Premarin*	EC-RX Estradiol: 0.4%, 0.6% Premarin: 0.625 mg/g
Oral Tablet	Estrace*, Premarin*, Menest*	Estrace: 0.5, 1, 2 mg Premarin: 0.3, 0.45, 0.625, 0.9, 1.25 mg Menest: 0.3, 0.625, 1.25, 2.5 mg
IM	Depo-Estradiol*, Delestrogen	Delestrogen: 10, 20, 40 mg/mL Depo-Estradiol: 5 mg/mL

CONTRAINDICATIONS:

- Undiagnosed abnormal genital bleeding
- Known, suspected, or history of breast cancer; known or suspected estrogen-dependent neoplasia
- Active DVT, PE, or a history of these conditions
- Active or history (within past year) of arterial thromboembolic disease (eg, stroke, MI)
- Anaphylactic reaction or angioedema or hypersensitivity to estradiol or any component of the formulation
- Known or suspected pregnancy
- Liver impairment or disease
- Known protein C, protein S, or antithrombin deficiency, or other known thrombophilic disorders (except Alora)

WARNINGS AND PRECAUTIONS:

- **Risks versus benefits**
  - Estrogens should be used for the shortest duration possible at the lowest effective dose consistent with treatment goals and risks for the patient. Patients should be reevaluated as clinically appropriate to determine if treatment is still necessary.
- **Increased risk of disease**
  - May increase risk of ovarian cancer, breast cancer, dementia, endometrial cancer (when used unopposed), gallbladder disease, DVT and stroke.
- **Osteoporosis use**
  - For use only in women at significant risk of osteoporosis and for who other non-estrogen medications are not considered appropriate.
- **Metabolic effects**
  - May increase thyroid-binding globulin levels leading to increased circulating total thyroid hormone levels. Those on thyroid replacement therapy may require higher doses of thyroid hormone while receiving estrogens. May cause increased HDL-C and decreased LDL-C and may have adverse effects on glucose tolerance.
- **Retinal vascular thrombosis**
  - Estrogens may cause retinal vascular thrombosis. Discontinue if migraine, loss of vision, proptosis, diplopia, or other visual disturbances occur; discontinue permanently if papilledema or retinal vascular lesions are observed on examination.
- **Use with caution in patients with the following conditions (exacerbation risk)**
  - Systemic lupus erythematosus (SLE), porphyria, migraine, epilepsy, asthma, hepatic hemangiomas, severe hypocalcemia, hypoparathyroidism, diseases that may be exacerbated by fluid retention, diabetes
- **Secondary exposure**
  - Estradiol may be transferred to another person following skin-to-skin contact with the application site.

COST

Drug	Strength	Package Size	AWP Pkg Price	AWP Unit Price
EVAMIST	1.53 mg/actuation	8.1 ml	148.52	18.33580
FEMRING	0.05 mg/24 hr 0.1 mg/24 hr	1 1	532.40 567.35	532.40 567.35
CLIMARA	All strengths	4	158.17	39.54
VIVELLE-DOT	All strengths	24	~437	~18.20
ALORA	All strengths	8	~130	~17
ESTROGEL	0.06%	93	102.22	1.10
PREMARIN CREAM	0.625 mg/g	30	448.27	14.94
ESTRADIOL CREAM	0.1 mg/g	42.5	337.41	7.93906
ESTRACE TAB	0.5 & 1 mg 2 mg	100 100	654.12 839.63	6.54
ESTRADIOL TAB	All strengths	100	~~70	~0.70
DEPO-ESTRADIOL	5 mg/mL	5 mL	126.35	25.27
DELESTROGEN	10 mg/mL 20 mg/mL 40 mg/mL	5 ml 5 ml 5 ml	159.28 224.48 372.37	31.86 44.90 74.47

CURRENT UTILIZATION

ND Medicaid Utilization (01/2018 – 01/2019)		
Label Name	**Rx Num**	**Total Reimb Amt**
ALORA	3	$431.97
CLIMARA	2	$540.48
DELESTROGEN	1	$368.99
DEPO-ESTRADIOL	18	$2,736.82
ESTRACE CREAM	2	$779.58
ESTRACE TAB	-	-
ESTRADIOL CREAM	30	$10,881.07
ESTRADIOL PATCH	146	$15,804.80
ESTRADIOL TAB	293	$7,162.78
ESTROGEL	-	-
EVAMIST	-	-
FEMRING	3	$1,727.85
PREMARIN CREAM	97	$42,144.17
PREMARIN TAB	161	$33,479.00
VIVELLE-DOT	17	$2,239.79

REFERENCES:

1. Facts & Comparisons eAnswers. Available at http://online.factsandcomparisons.com. Accessed on February 6. 2019.
2. Vivelle-Dot (estradiol transdermal system) [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; May 2013.
3. Femring (estradiol acetate vaginal) [prescribing information]. Rockaway, NJ: Warner Chilcott (US) LLC; May 2016.
4. Alora (estradiol transdermal system) [prescribing information]. Parsippany, NJ: Watson Pharma; August 2012.
5. Evamist (estradiol transdermal spray) [prescribing information]. Minneapolis, MN: Perrigo; November 2017.
6. Climara (estradiol transdermal system) [prescribing information]. Whippany, NJ: Bayer; October 2013.
7. Estrace (estradiol oral) [prescribing information]. North Wales, PA: Teva Pharmaceuticals USA Inc; May 2016.
8. Delestrogen (estradiol valerate) [prescribing information]. Spring Valley, NY: Par Pharmaceutical; September 2015.
9. Premarin tablets [prescribing information]. Philadelphia, PA: Wyeth-Ayerst; October 2011.
10. Menest (estrogens, esterified) [prescribing information]. Bristol, TN: Monarch Pharmaceuticals; September 2011.
11. Estring (estradiol vaginal) [prescribing information]. New York, NY: Pharmacia & Upjohn Company; November 2017.
12. Premarin Vaginal Cream [prescribing information]. Philadelphia, PA: Wyeth Pharmaceuticals Inc; November 2017.
13. Depo-Estradiol (estradiol cypionate) [prescribing information]. New York, NY: Pharmacia and Upjohn Company; October 2006.
14. Estrace (estradiol vaginal) [prescribing information]. Rockaway, NJ: Warner Chilcott; December 2011.

15. Divigel (estradiol gel) [prescribing information]. Maple Grove, MN: Upsher-Smith Laboratories; November 2017.
16. Elestrin (estradiol gel) [prescribing information]. Somerset, NJ: Meda Pharmaceuticals Inc; November 2017.
17. EstroGel (estradiol gel) [prescribing information]. Herndon, VA: ASCEND Therapeutics; November 2017.
18. Estraderm (estradiol transdermal system) [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals; November 2017.
19. Vivelle (estradiol) [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Inc; November 2017.
20. Minivelle (estradiol transdermal system) [prescribing information]. Miami, FL: Noven Pharmaceuticals; September 2014.
21. Menostar (estradiol transdermal system) [prescribing information]. Wayne, NJ: Bayer HealthCare; March 2007.

REVIEW OF SIVEXTRO (TEDIZOLID PHOSPHATE)

INDICATIONS AND USE:

- Acute bacterial skin and skin structure infections
  - Treatment of adult patients with acute bacterial skin and skin structure infections caused by susceptible isolates of the following gram-positive microorganisms: S. aureus (including MRSA), S. pyogenes, S. agalactiae, S. anginosus group, and E .faecalis.

DOSAGE AND ADMINISTRATION:

- 200 mg once daily for 6 days
- Not for pediatric use

DOSAGE FORM AND STRENGTHS:

- 200 mg tablets
- 200 mg IV solution

CONTRAINDICATIONS:

- None

WARNINGS AND PRECAUTIONS:

- **Neutropenia**
  - Not recommended for use in patients with neutrophil counts less than 1,000 cells/mm3

ADVERSE REACTIONS:

- **Most common (>1-10%)**
  - **CV:** Flushing (<2%), HTN (<2%), palpitations (<2%), tachycardia (<2%)
  - **CNS**: HA (6%), dizziness (2%), facial paralysis (<2%), hypoesthesia (<2%), insomnia (<2%), paresthesia (<2%), peripheral neuropathy (1%)
  - **Dermatologic**: Dermatitis (<2%), pruritus (<2%), urticaria (<2%)
  - **GI**: Nausea (8%), diarrhea (4%), vomiting (3%), oral candidiasis (<2%), pseudomembranous colitis (<2%).
  - **Hematologic & oncologic**: dec hemoglobin (males <10.1 g/dL; females <9 g/dL: 3%), dec platelet count (<112,000/mm3: 2%), anemia (<2%), dec WBC (<2%)
  - **Hepatic**: Increased serum transaminases (<2%)
  - **Hypersensitivity** (<2%)
  - **Ophthalmic**: Asthenopia (<2%), blurred vision (<2%), vitreous opacity (<2%)

DRUG INTERACTIONS:

- **Avoid with the following medications**
  - Myelosuppressive agents
  - Alpha-2 agonists
  - MAOIs
  - Triptans
  - Meperidine
  - Methadone
  - Cyclobenzaprine
  - Stimulants

COST

Drug	Strength	Package Size	AWP Pkg Price	AWP Unit Price
SIVEXTRO	200 mg	6 Tablets 30 Tablets	$2,165.94 $12,995.64	$433.19
SIVEXTRO	200 mg IV	10 Doses	$2,875.50	$345.06

CURRENT UTILIZATION

ND Medicaid Utilization (01/2018 – 01/2019)		
Label Name	**Rx Num**	**Total Reimb Amt**
SIVEXTRO	13	$27,262.30

REFERENCES:

1. Facts & Comparisons eAnswers. Available at http://online.factsandcomparisons.com. Accessed on February 2. 2019.
2. Sivextro (tedizolid phosphate) [prescribing information]. Whitehouse Station, NJ: Merck & Company, Inc.; August 2017.

REVIEW OF NUZYRA (OMADACYCLINE)

INDICATIONS AND USE:

- Treatment of community-acquired bacterial pneumonia (CAP) in adult patients caused by susceptible S. pneumoniae, S. aureus (methicillin-susceptible isolates), H. influenzae, H. parainfluenzae, K. pneumoniae, L. pneumophila, M. pneumoniae, and C. pneumoniae
- Treatment of acute bacterial skin and skin structure infections (SSTIs) in adult patients caused by susceptible S. aureus (including MRSA), S. lugdunensis, S. pyogenes, S. anginosus, S. intermedius, and S. constellatus, E. faecalis, E. cloacae, and K. pneumoniae.

DOSAGE AND ADMINISTRATION:

- CAP:
  - IV infusion loading dose on day 1, followed by 300 mg once daily
  - Duration of 7-14 days
- SSTIs:
  - 450 mg once daily on days 1 and 2, followed by 300 mg once daily
  - Duration of 7-14 days
- No dose adjustments for renal/hepatic impairment

DOSAGE FORM AND STRENGTHS:

- 5, 10, 23 mg tablets

CONTRAINDICATIONS:

- Hypersensitivity to omadacycline, tetracycline-class antibacterial drugs, or any component of the formulation

WARNINGS AND PRECAUTIONS:

- **Antianabolic effects**
  - May be associated with antianabolic effects observed with the tetracycline class (including increased BUN, azotemia, acidosis, and hyperphosphatemia); discontinue use if suspected.
- **Hepatotoxicity**
  - May be associated with abnormal liver function tests due to structural similarities with tetracyclines; discontinue use when suspected.
- **CAP**
  - Mortality rate was higher in patients treated with omadacycline for community acquired bacterial pneumonia compared to patients treated with moxifloxacin.
- **Pancreatitis**
  - May be associated with pancreatitis due to structural similarities with tetracyclines; discontinue use if suspected
- **Pseudotumor cerebri**
  - May be associated with pseudotumor cerebri due to structural similarities with tetracyclines; discontinue use if suspected

ADVERSE REACTIONS:

- **Most common (>10%)**
  - Nausea and vomiting

COST

Drug	Strength	Package Size	AWP Pkg Price	AWP Unit Price
NUZYRA	150 mg	6 Tablets 14 Tablets 16 Tablets	$1,422.00 $2,765.00 $3,160.00	$237.00
NUZYRA	100 mg Vials	90 Tablets	$414.00	$414.00

CURRENT UTILIZATION

ND Medicaid Utilization (01/2018 – 01/2019)		
Label Name	**Rx Num**	**Total Reimb Amt**
NUZYRA	-	-

REFERENCES:

1. Facts & Comparisons eAnswers. Available at http://online.factsandcomparisons.com. Accessed on February 2. 2019.
2. Nuzyra (omadacycline) [prescribing information]. Boston, MA: Paratek Pharmaceuticals Inc; October 2018.

REVIEW OF AGENTS FOR TREATMENT OF OSTEOPOROSIS

OSTEOPOROSIS:

- Osteoporosis is characterized by low bone mass and structural deterioration of bone tissue, leading to bone fragility and an increased risk of fractures of the hip, spine, and wrist.
- In the United States, more than 53 million people either already have osteoporosis or are at high risk due to low bone mass.
- Numerous potential causes:
    - Natural reduction of endogenous estrogen (e.g. postmenopausal women)
    - Age
    - Hyperparathyroidism
    - Drug induced (e.g. glucocorticoids)
    - Chronic kidney disease
    - Cancer (e.g. prostate and breast cancer)
    - Diet
- Diagnosed via bone mineral density (BMD) tests.
- Patient with osteoporosis are encouraged to get adequate calcium and vitamin D (based on age) through diet and/or supplements, as well as exercise and reduce smoking, alcohol intake, and avoid medications that can cause bone loss (e.g. steroids, some cancer treatments, aluminum containing antacids).

AGENTS:

- **Bisphosphonates**
    - **Oral**
        - **Fosamax, Binosto (alendronate)**
            - **Treatment:** 10 mg once daily or 70 mg once weekly
            - **Prevention:** 5 mg once daily or 35 mg once weekly
        - **Boniva (ibandronate)**
            - Once monthly, 150 mg tablets
        - **Actonel (risedronate)**
            - **IR Tablet:** 5 mg once daily; or 35 mg once weekly; or 75 mg for 2 consecutive days every month; or 150 mg once monthly.
            - **ER Tablet:** Once weekly, 35 mg once weekly
    - **IV**
        - **Reclast (zoledronic acid)**
            - **Once yearly, 5 mg**
        - **Boniva (ibandronate**
            - **Every 3 months, 3 mg**
- **Prolia (denosumab):**
    - Every 6 months, 60 mg SQ injection
- **Parathyroid hormone**
    - **Forteo (teriparatide)**
        - Once daily, 20 mcg SQ injection
    - **Tymlos (abaloparatide)**
        - Once daily, 80 mcg SQ injection
- **Miacalcin (calcitonin)**
    - Once daily, 0.5 mL (100 units) SQ or IM injection
- **SERMS**
    - **Evista (raloxifene)**
        - Once daily, 60 mg tablets
    - **Duavee (conjugated estrogens/bazedoxifene)**
        - Once daily tablets of conjugated estrogens 0.45 mg/bazedoxifene 20 mg

	Indication for Osteoporosis	Warnings	Contraindications	Notes
Bisphosphonates	PM Women, Men (all but Boniva), glucocorticoid induced (Actonel and Reclast)	Esophageal erosions (oral), ONJ, atypical femur fractures (AFF), and musculoskeletal pain. Correct Ca prior to therapy initiation.	Abnormalities of the esophagus that delay esophageal emptying (oral); inability to stant or sit upright for at least 30 minutes (oral); hypocalcemia	CrCl <53 mL/min
Prolia	PM Women	ONJ, atypical femur fractures (AFF), and musculoskeletal pain. Correct Ca prior to therapy initiation.	HSR; preexisting hypocalcemia; pregnancy	eGFR<15 (Prolia)
Tymlos & Forteo	PM Women, Men (all but Boniva), glucocorticoid induced (Actonel and Reclast)	Osteosarcoma, hypercalcemia, orthostatic hypotension	HSR	Do not use for >2 years
Miacalcin	Men and PM Women, glucocorticoid induced, prostate cancer, breast cancer	Malignancy, hypocalcemia	HSR	Fracture reduction efficacy has not been demonstrated
Evista	PM Women	DVT, PE, stroke, ↑TG	History of VTE; pregnancy	use ≤5 years
Duavee	PM Women	May exacerbate dx of CV disease, dementia, hypoparathyroidism, asthma, hereditary angioedema, epilepsy, migraine, porphyria, SLE, DM, and dx of fluid retention. May cause breast CA, endometrial CA, Ovarian CA, and gallbladder disease.	Undiagnosed abnormal uterine bleeding; hx of VTE; hx of stroke, MI; carcinoma of the breast; estrogen-dependent tumor; hepatic impairment; known thrombophilic disorders; pregnancy; breast-feeding	For use only in women at significant risk of postmenopausal osteoporosis in women with a uterus.

COST

Drug	Strength	Package Size	AWP Pkg Price	AWP Unit Price
ALENDRONATE	5, 10, 35, 70 mg tablets	12-100 tablets	12.78-292.25	1.07-2.92
ALENDRONATE	70 mg/75 mL sln	300 mL	229.00	57.25
RISEDRONATE	5, 30, 35, 150 tablets	3-30 tablets	265.67 - 1858.53	8.86-233.40
RISEDRONATE	35 mg ER tablets	4 tablets	209.22	52.31
BINOSTO	70 mg	4 tablets	241.92	60.48
IBANDRONATE	150 mg tablets	3 tablets	416.60	138.87
RECLAST	5 mg/100 mL	100 mL	1300.60	13.01
PROLIA	60 mg/mL	1 mL	1462.87	1462.87
TYMLOS	3120 mcg/1.56 mL	1.56 mL	2186.89	1401.85
FORTEO	600 mcg/2.4 mL	2.4 mL	3953.64	1647.35
MIACALCIN	200 units/mL	2 mL	3243.68	1621.84
DUAVEE	0.45/20 mg	30 tablets	212.15	7.07

CURRENT UTILIZATION

ND Medicaid Utilization (01/2018 – 01/2019)		
Label Name	**Rx Num**	**Total Reimb Amt**
ALENDRONATE	572	$32,145.22
RISEDRONATE	67	$7,411.81
BINOSTO	-	-
IBANDRONATE	27	$2,208.06
PROLIA	8	$11,272.86
TYMLOS	-	-
FORTEO	47	$192,729.51
MIACALCIN	270	$5,911.00
DUAVEE	12	$3,987.12

REFERENCES:

1. Facts & Comparisons eAnswers. Available at http://online.factsandcomparisons.com. Accessed on February 2. 2019.
2. Fosamax (alendronate) [prescribing information]. Whitehouse Station, NJ: Merck & Co Inc; March 2016.
3. Binosto (alendronate) [prescribing information]. San Antonio, TX: Mission Pharmacal Company; January 2017.
4. Tymlos (abaloparatide) [prescribing information]. Waltham, MA: Radius Health; October 2018.
5. Miacalcin injection (calcitonin-salmon) [prescribing information]. Rockford, IL: Mylan Institutional LLC; September 2017.
6. Forteo (teriparatide) [prescribing information]. Indianapolis, IN: Eli Lilly and Company; October 2016.
7. Prolia (denosumab) [prescribing information]. Thousand Oaks, CA: Amgen Inc; June 2018.
8. Duavee (conjugated estrogens and bazedoxifene acetate) [prescribing information]. New York, NY: Pfizer Inc; November 2017.
9. Actonel (risedronate) [prescribing information]. Irvine, CA: Allergan; Janaury 2018.
10. Boniva tablets (ibandronate) [prescribing information]. South San Francisco, CA: Genetech USA Inc; December 2016.

REVIEW OF AGENTS FOR TREATMENT OF HYPERKALEMIA

HYPERKALEMIA:

- Condition in which there is an elevated level of potassium in the blood serum
  - Normal potassium levels are between 3.5 and 5.0 mmol/L (3.5 and 5.0 mEq/L)
- Depending on the extent of hyperkalemia, symptoms vary from asymptomatic to malaise, palpitations, and muscle weakness, and may include hyperventilation, palpitations, muscle pain, muscle weakness, or numbness, cardiac arrhythmia or sudden cardiac death in cases of severe hyperkalemia.
- Common causes of hyperkalemia include
  - Potassium-retaining drugs
  - Renal insufficiency
  - Adrenal insufficiency
  - Disorders involving cellular breakdown (eg, rhabdomyolysis, burns, bleeding into soft tissue or the GI tract).
- Mild
  - Patients with serum potassium < 6 mEq/L and no ECG abnormalities
- Moderate-Severe
  - Serum potassium between 6 and 6.5 mEq/L
  - Treated with IV insulin, glucose, and calcium, and possibly an inhaled beta 2-agonist for moderate to severe hyperkalemia

DRUG TREATMENTFOR MILD HYPERKALEMIA:

- **Veltassa (patiromer):**
  - Non-absorbed, cation exchange polymer that increases fecal potassium excretion through binding of potassium in the lumen of the GI tract.
- **Lokelma (Sodium Zirconium Cyclosilicate):**
  - Potassium binder that preferentially exchanges potassium for hydrogen and sodium. Binding of potassium reduces the concentration of free potassium in the gastrointestinal lumen, lowering serum potassium levels.
- **Sodium Polystyrene Sulfonate (SPS):**
  - Removes potassium by exchanging sodium ions for potassium ions in the intestine (especially the large intestine) before the resin is passed from the body; the practical exchange capacity is 1 mEq potassium per 1 g of resin in vivo, and in vitro capacity is 3.1 mEq of potassium per 1 g of resin, therefore, a wide range of exchange capacity exists such that close monitoring of serum electrolytes is necessary.

	SPS	**VELTASSA**	**LOKELMA**
MoA	Non-absorbed, cation exchange polymer that increases fecal potassium excretion through binding of potassium in the lumen of the GI tract		
Correct Use	Should not be used as an emergency treatment for life-threatening hyperkalemia because of its delayed onset of action		
GI Warnings	Avoid use in patients with severe constipation, bowel obstruction or impaction, including abnormal postoperative bowel motility disorders (may be ineffective and may worsen GI conditions).		
Electrolyte Disturbances	Severe hypokalemia may occur High sodium content	Hypomagnesemia	High sodium content
Other Warnings	Sodium load may exacerbate edema, CHF, and HTN.		
	Intestinal necrosis (including fatalities) and other serious GI events		

	have been reported, especially when administered with sorbitol.		
Dosage Form(s)	Oral Powder Packet Oral Suspension Rectal Enema	Oral Packet Packet	Oral Packet Packet
Dosing	15 g 1 to 4 times daily	8.4-25.2 g daily	Initial: 10 g TID Maintenance: Max 15 g daily
Pediatric use	Yes	No	No

COST

Drug	Strength	Package Size	AWP Pkg Price	AWP Unit Price
VELTASSA	8.4 g / packet	30 packets	984.90	32.83
VELTASSA	16.8 g / packet	30 packets	984.90	32.83
VELTASSA	25.2 g / packet	30 packets	984.90	32.83
LOKELMA	5 g / packet	30 packets	786.00	26.20
LOKELMA	10 g / packet	30 packets	786.00	26.20
SPS	15 g/60 mL suspension	120 mL	44.10	0.37

CURRENT UTILIZATION

ND Medicaid Utilization (01/2018 – 01/2019)		
Label Name	**Rx Num**	**Total Reimb Amt**
VELTASSA	16	$12,305.86
LOKELMA	-	-
Sodium Polystyrene Sulfonate	17	$827.88

REFERENCES:

1. Facts & Comparisons eAnswers. Available at http://online.factsandcomparisons.com. Accessed on February 2. 2019.
2. Lokelma (sodium zirconium cyclosilicate) [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; July 2018.
3. Veltassa (patiromer) [prescribing information]. Redwood City, CA: Relypsa Inc; May 2018.
4. Sodium polystyrene sulfonate suspension [prescribing information]. Eatontown, NJ: West-Ward Pharmaceuticals Corp; May 2016.

REVIEW OF AGENTS FOR TREATMENT OF PARKINSON'S DISEASE

Parkinson's Disease Overview

- Parkinson's disease is a progressive nervous system disorder that affects movement.
    - Caused by cell death in the basal ganglia of the brain and presence of Lewy bodies in the remaining neurons, which results in a reduced dopamine secretion
        - Reduced dopamine secretion causes an imbalance in the inhibition of motor symptoms, resulting in the impaired motor system control seen in Parkinson's disease
- Signs and symptoms are variable, with worsening symptoms as the disease progresses.
    - Early signs may be mild and go unnoticed
    - Symptoms often begin on one side of your body and usually remain worse on that side, even after symptoms begin to affect both sides
    - Symptoms include
        - Tremor
        - Bradykinesia
        - Rigid muscles
        - Impaired posture and balance
        - Loss of automatic movements
        - Speech changes
        - Writing changes
        - Thinking and behavioral changes
- Epidemiology:
    - ~6.2 million people affected globally
    - Typically occurs in people over the age of 60, of which about on1% are affected
        - Prior to age 50 is considered "early onset"
    - More prevalent in males (ratio of around 3:2)
- Management:
    - There is no cure for Parkinson's disease, but medications, surgery, and physical treatment can provide relief and are much more effective than treatments available for other neurological disorders like Alzheimer's disease, motor neuron disease, and Parkinson plus syndromes.
        - **Exogenous dopamine (levodopa-carbidopa)**
            - Generic tablets, ODT, and ER tablets
            - Rytary: ER capsules
        - **catechol-O-methyltransferase (COMT) inhibitors**
            - increases bioavilibility of levodopa and dopamine by preventing the methylation of levodopa
                - entacapone
                - tolcapone
        - **Monoamine oxidase inhibitors (MAOIs)**
            - inhibiting the activity of monoamine oxidase B (MAO-B), an enzyme which breaks down dopamine
                - Xadago (safinamide)
                - selegiline
                - rasagiline
        - **Dopamine agonists**
            - bind to dopamine receptors in the brain have similar effects to levodopa
                - Apokyn (apomorphine)
                - Amantadine (Gocovri, Osmolex ER)
                - Neupro (rotigotine transdermal)
                - Bromocriptine
                - pramipexole
                - ropinirole

	Drug	Dosing	Special Populations	Contraindications
Levo-Carb	**Rytary**	Up to 2,450/612.5 mg daily	None	HSR; use of MAOI within 14 days; narrow-angle glaucoma
	Levodopa-carbidopa	IR: Up to 2000/200 mg daily ER: up to 2400/600 mg daily	None	HSR; use of MAOI within 14 days; narrow-angle glaucoma
COMTIs	**Entacapone**	Up to 1,600 mg QD	Caution in hepatic impairment	HSR
	Tolcapone	Up to 200 md TID	Avoid if ALT/AST is 2x ULN	Liver disease; prior tolcapone-induced hepatocellular injury; HSR; history of rhabdomyolysis or hyperpyrexia and confusion related to medication
MAOIs	**Xadago**	Up to 100 mg QD	CTP B: 50 mg daily Avoid in CTP C	HSR; severe hepatic impairment; concomitant use with MAOIs or inhibit MAO, meperidine, methadone, propoxyphene, tramadol, SNRIs, TCAs, cyclobenzaprine, methylphenidate, amphetamine, and their derivatives, St. John's wort, dextromethorphan.
	Selegiline	Caps/tabs: 5 mg BID ODT: 1.25mg QD	CrCl <30: not recommended CTP A: 1.25 mg QD Avoid in CTP B or C	HSR; Concomitant use of above drugs listed for Xadago
	Rasagiline	Up to 1 mg QD	CTP A: 0.5 mg daily Avoid in CTP B or C	Concomitant use of above drugs listed for Xadago
Dopamine Agonists	**Apokyn**	SQ: 2 mg once	None	HSR
	Amantadine	Up to 100 mg BID	Dose adjustments for CrCl <50 mL/min	HSR
	Bromocriptine	Up to 50 mg BID	None	HSR
	Neupro	2-8 mg patch QD	None	HSR
	Osmolex ER	Up to 322 mg QD	Dose adjustments for CrCl <60 mL/min	HSR; ESRD
	Gocovri	Up to 274 mg QD	Dose adjustments for CrCl <60 mL/min	HSR; ESRD
	Pramipexole	IR: 0.125-1.5 mg TID ER: 4.5 mg QD	Dose adjustments for CrCl <50 mL/min	None
	Ropinirole	IR: Up to 8 mg TID ER: 24 mg QD	Dose adjustment in ESRD	HSR

Levodopa-carbidopa	COMT Inhibitors	MAOIs	Dopamine Agonists

• May worsen CV disease • May cause urine discoloration • May worsen PUD • May cause peripheral neuropathy • Distribute dietary protein throughout the day • Use with caution in patients with respiratory and endocrine disease as well as glaucoma	• May cause urine discoloration • May cause severe rhabdomyolysis, liver damage, diarrhea, and fibrotic complications	• May cause serotonin syndrome, HTN. • Avoid foods with high tyramine content • Significant drug interactions with drugs affecting monoamine neurotransmitters	• May worsen CV disease • May cause fibrotic complications • Application site reactions (patch)
Avoid rapid discontinuation			
Somnolence			
Neuroleptic malignant syndrome			
Abnormal thinking/behavioral changes			
Reduced impulse control			
Risk for melanoma development may be increased			
May exacerbate dyskinesia			
Orthostatic hypotension			
Psychosis exacerbation/hallucinations			

COST

Drug	Strength	Package Size	AWP Pkg Price	AWP Unit Price
Apokyn	10 mg/mL sln	3 mL	1269.60	423.20
Rytary	23.75 mg-95 mg 36.25 mg-145 mg 48.75 mg-195 mg 61.25 mg-245 mg tab	100 100 100 100	384.67 384.67 384.67 483.35	3.85 3.85 3.85 4.83
Levodopa-carbidopa	10 mg-100 mg tab 25 mg-250 mg tab 50 mg-200 mg tab	100 100 100	77.23 87.20 174.15	0.77 0.87 1.75
Entacapone	200 mg tab	100	395.00	3.95
Tolcapone	100 mg tab	90	9516.80	105.74
Xadago	50-100 mg	30	936.68	31.22
Selegiline	5 mg tab 5 mg cap	60 60	122.45 138.10	2.04 2.30
Rasagiline	0.5-1 mg tab	30	749.50	24.98
Amantadine	100 mg cap	100	193.82	1.94
Bromocriptine	5 mg cap 2.5 mg tab	100 100	931.04 375.47	9.31 3.75
Neupro	1-8 mg patch	30	806.98	26.89
Osmolex ER	129-258 mg ER tab	90	1620.00	18.00
Gocovri	68.5 ER cap 137 mg ER cap	60 60	3070.80 3070.80	51.18 51.18
Pramipexole	0.125-1.5 mg tab	90	265.47	2.95
Ropinirole	0.25-5 mg tab 6 mg ER tab 12 mg ER tab	100 90 30	249.98 738.48 410.47	2.50 8.21 13.69

CURRENT UTILIZATION

ND Medicaid Utilization (01/2018 – 01/2019)		
Label Name	**Rx Num**	**Total Reimb Amt**
Rytary	-	-
Levodopa-carbidopa	239	$6,219.11
Entacapone	38	$2,603.85
Tolcapone	-	-
Xadago	-	-
Selegiline	-	-
Rasagiline	13	$3,440.93
Apokyn	-	-
Amantadine	280	$8,063.71
Bromocriptine	49	$8,114.03
Neupro	12	$7,525.51
Osmolex ER	-	-
Gocovri	-	-
Pramipexole	472	$6,538.51
Ropinrole	660	$9,830.74

REFERENCES:

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5. Neupro (rotigotine) [prescribing information]. Smyrna, GA: UCB Inc; January 2019.
6. Osmolex ER (amantadine) [prescribing information]. Bridgewater, NJ: Vertical Pharmaceuticals; February 2018.
7. Gocovri (amantadine hydrochloride extended-release) [prescribing information]. Emeryville, CA: Adams Pharma LLC; August 2017.
8. Selegiline Hydrochloride Tablets [prescribing information]. Montgomery, AL: Libertas Pharma Inc; May 2014.
9. Azilect (rasagiline) [prescribing information]. North Wales, PA: Teva Pharmaceuticals USA; December 2018.
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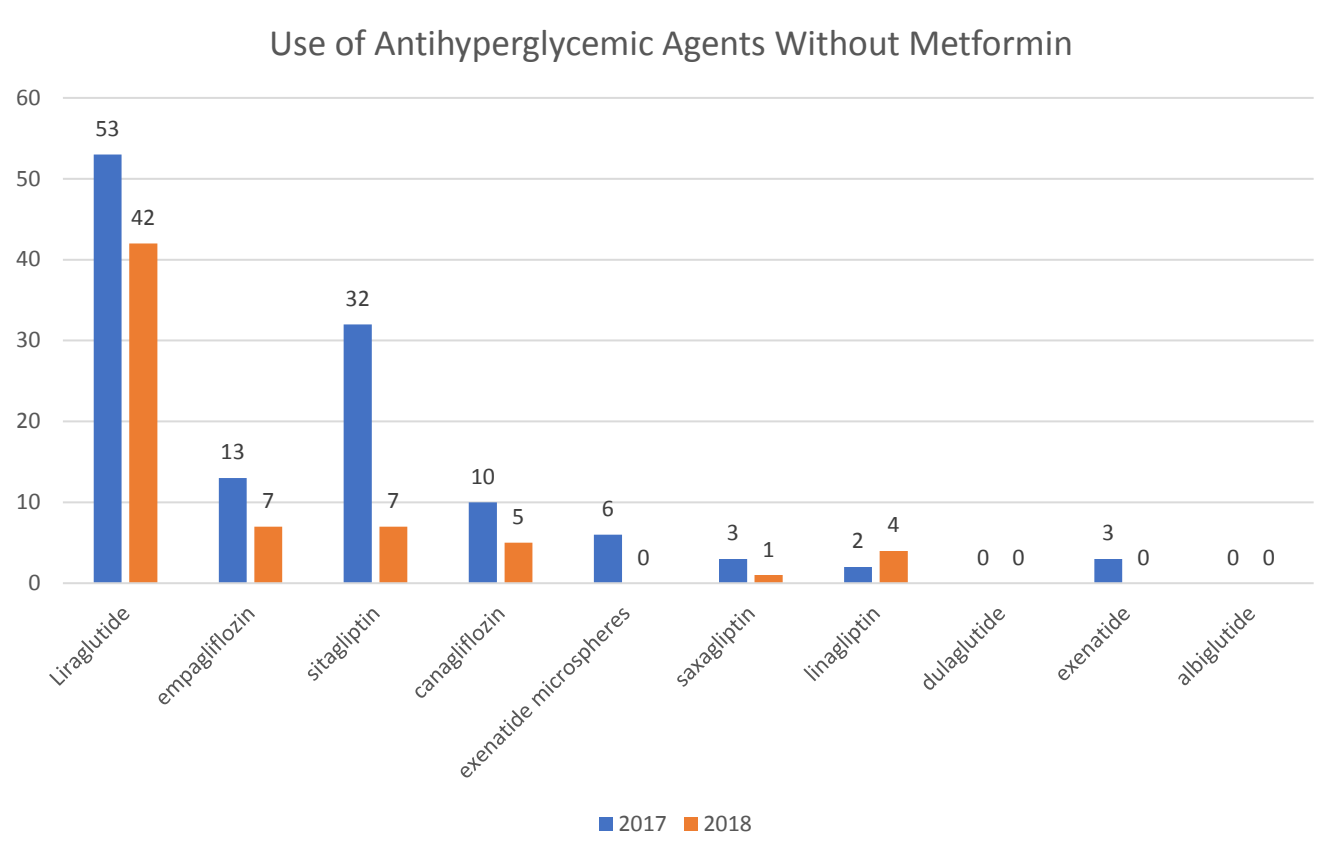
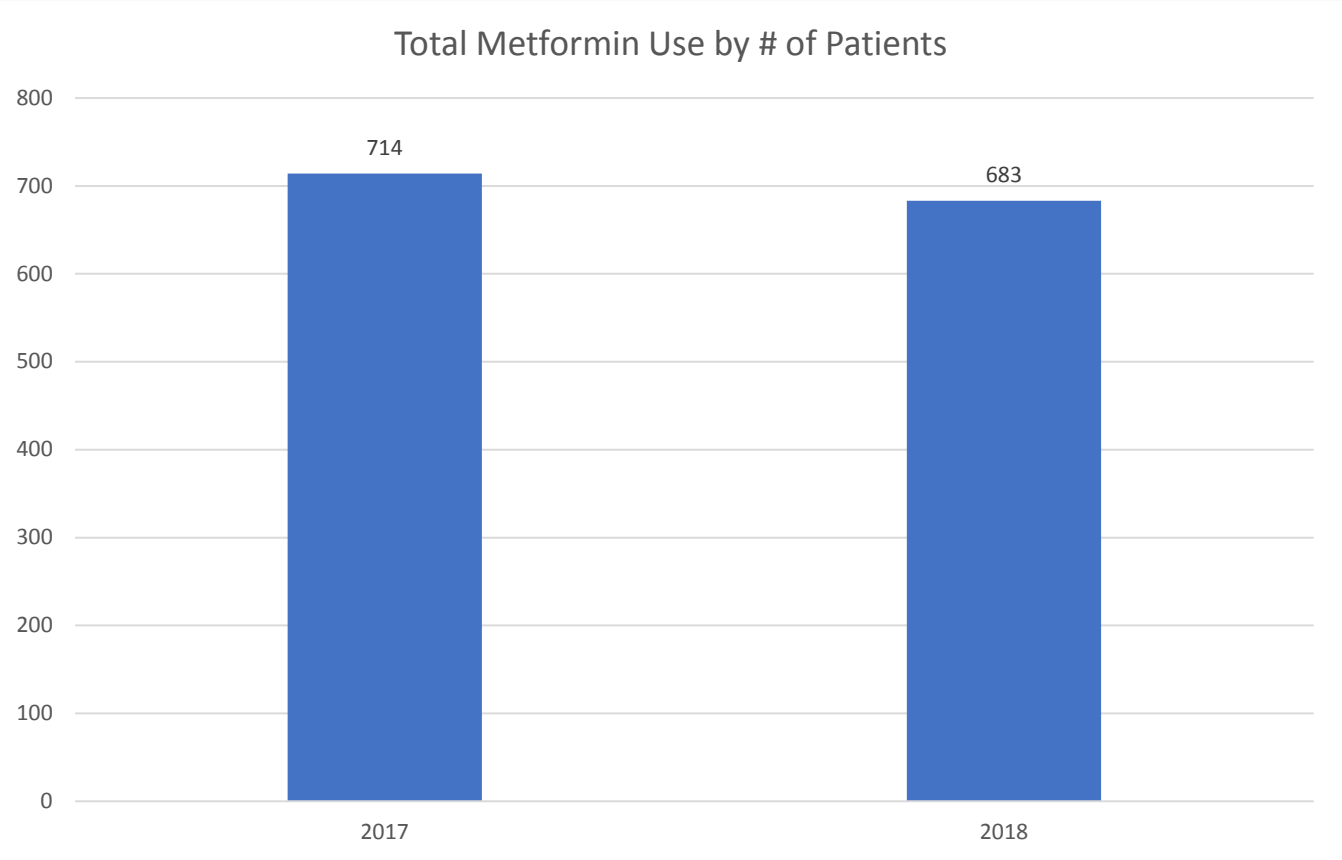
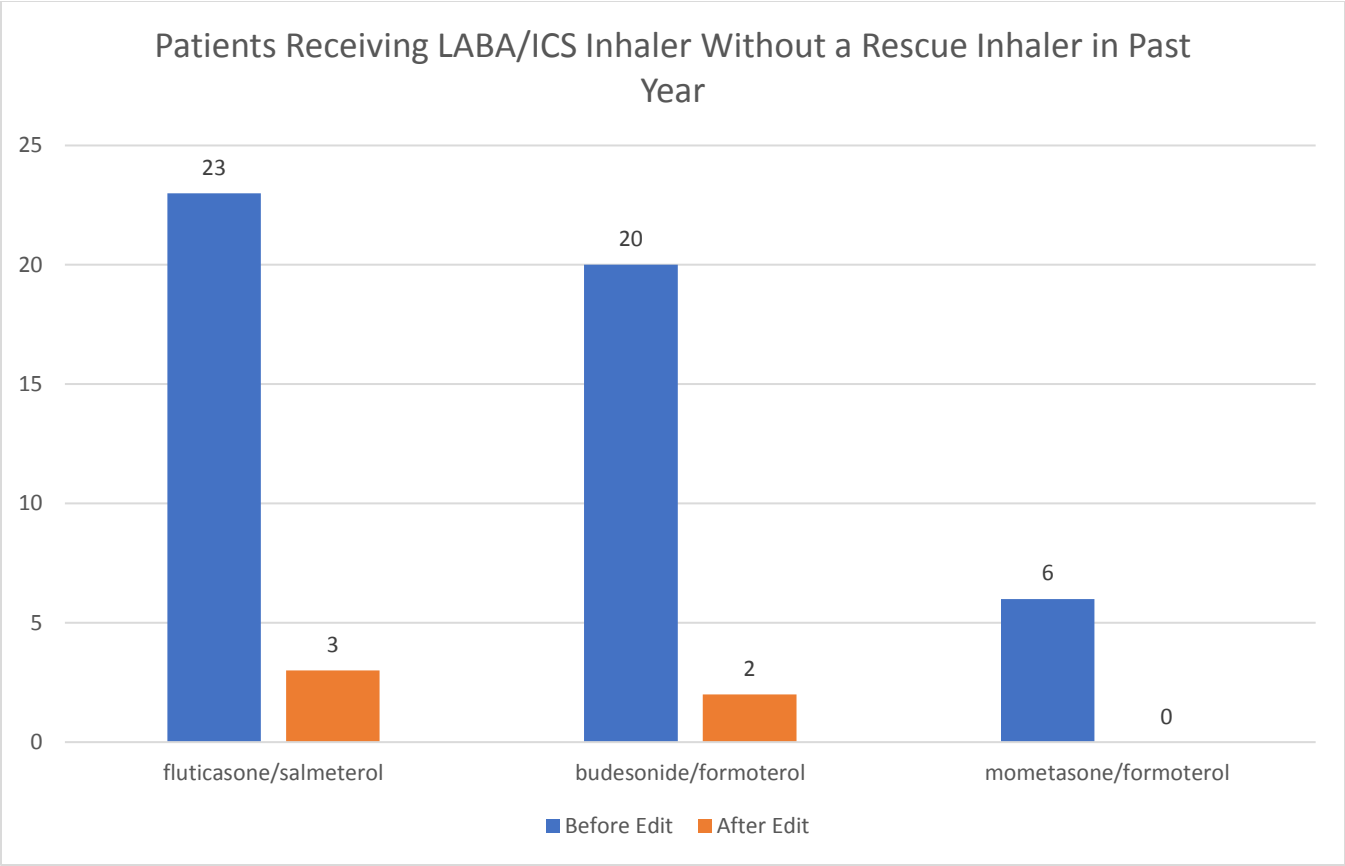
11. Carbidopa and Levodopa. Lexi-Drugs [database online]. Hudson, OH: Lexicomp Inc; 2015. http://online.lexi.com. Accessed February 27, 2015.
12. Rytary (carbidopa/levodopa) [prescribing information]. Hayward, CA: Impax Pharmaceuticals; October 2016.
13. Comtan (entacapone) [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corp; June 2018.
14. Tasmar (tolcapone) [prescribing information]. Bridgewater, NJ: Valeant Pharmaceuticals; August 2015.

15. Requip XL (ropinirole) [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; February 2018.
16. Mirapex (pramipexole dihydrochloride) [prescribing information]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; May 2018.
17. Mirapex ER (pramipexole dihydrochloride) [prescribing information]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; May 2018.


Use of Antihyperglycemic Agents Without Metformin
60
50
40
30
20
10
0
53
42
13
7
32
7
10
5
6
0
3
1
2
4
0 0
3
0
0 0
Liraglutide
empagliflozin
sitagliptin
canagliflozin
exenatide microspheres
saxagliptin
linagliptin
dulaglutide
exenatide
albiglutide
2017
2018


Total Metformin Use by # of Patients
800
700
600
500
400
300
200
100
0
714
683
2017
2018


Patients Receiving LABA/ICS Inhaler Without a Rescue Inhaler in Past Year
25
20
15
10
5
0
23
3
20
2
6
0
fluticasone/salmeterol
budesonide/formoterol
mometasone/formoterol
Before Edit
After Edit

NORTH DAKOTA MEDICAID
RETROSPECTIVE DRUG UTILIZATION REVIEW
CRITERIA RECOMMENDATIONS
1ST QUARTER 2019

Criteria Recommendations ***Approved Rejected***

1. Fluoroquinolones / Therapeutic Appropriateness _____ _____

Alert Message: The FDA has issued a safety alert warning that systemic (oral, injectable) fluoroquinolone use can increase the occurrence of aortic dissections or ruptures. Unless there are no other treatment options available, the use of systemic fluoroquinolones should be avoided in patients with an increased risk for developing an aortic aneurysm, including patients with peripheral atherosclerotic vascular disease, hypertension, genetic disorders involving blood vessel changes, and the elderly.

Drugs/Diseases

Util A	Util B	Util C **(Include)**
Ciprofloxacin		Aortic Aneurysm
Delafloxacin		Peripheral Atherosclerosis
Ofloxacin		Hypertension
Levofloxacin		Marfan's Syndrome
Moxifloxacin		Ehlers-Danlos Syndrome

References:

Food and Drug Administration. FDA Drug Safety Communication: FDA warns about increased risk of ruptures or tears in the aorta blood vessel with fluoroquinolone antibiotics in certain patients. [12-20-2018].
Clinical Pharmacology, 2019 Elsevier/Gold Standard.

2. Opioid / Antipsychotics _____ _____

Alert Message: Concurrent use of an opioid with an antipsychotic may cause hypotension, profound sedation, respiratory depression, coma, and death. Because of these risks, reserve concomitant prescribing of these drugs for use in patients for whom alternative treatment options are inadequate. If co-administration is required consider dosage reduction of one or both agents. The SUPPORT Act of 2018 requires that Medicaid monitor the concurrent use of opioids and antipsychotics.

Drugs/Diseases

Util A	Util B	Util C
Opioids	Antipsychotics	

References:

Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Facts & Comparisons, 2019 Updates, Wolters Kluwer Health.
Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act. (SUPPORT Act; P.L. 115-271, 24 October 2018).

3. Atorvastatin / Atazanavir/Cobicistat _____ _____

Alert Message: Coadministration of an atorvastatin-containing agent with Evotaz (atazanavir/cobicistat) is not recommended due to the increased risk of atorvastatin-related adverse effects (e.g., myopathy and rhabdomyolysis). Both atazanavir and cobicistat are CYP3A4 inhibitors and concurrent use with atorvastatin, a CYP3A4 substrate, may result in elevated atorvastatin plasma concentrations.

Drugs/Diseases

Util A	Util B	Util C
Atazanavir/Cobicistat	Atorvastatin	
	Atorvastatin/Amlodipine	

References:

Evotaz Prescribing Information, March 2018, Bristol-Myers Squibb.
Clinical Pharmacology, 2019 Elsevier/Gold Standard.

4. Rosuvastatin 20 & 40 / Atazanavir/Cobicistat _____ _____

Alert Message: The dosage of rosuvastatin should not exceed 10 mg/day in patients receiving concurrent therapy with Evotaz (atazanavir/cobicistat). Cobicistat is an OATP1B1 transport inhibitor and concurrent use of rosuvastatin, an OATP1B1 substrate, may result in increased rosuvastatin plasma concentrations and increased risk of rosuvastatin-related adverse reactions (e.g., myopathy and rhabdomyolysis).

Drugs/Diseases

Util A	Util B	Util C
Rosuvastatin 20 & 40mg	Atazanavir/cobicistat	

References:

Evotaz Prescribing Information, March 2018, Bristol-Myers Squibb.
Clinical Pharmacology, 2019 Elsevier/Gold Standard

5. Proton Pump Inhibitors / Fundic Gland Polyps _____ _____

Alert Message: PPI use is associated with an increased risk of fundic gland polyps that increases with long-term use, especially beyond one year. Most PPI users who developed fundic gland polyps were asymptomatic, and fundic gland polyps were identified incidentally on endoscopy. Use the shortest duration of PPI therapy appropriate to the condition being treated.

Drugs/Diseases

Util A	Util B	Util C **(Include)**
Dexlansoprazole		Polys of Stomach and Duodenum
Omeprazole		
Esomeprazole		
Rabeprazole		
Lansoprazole		
Pantoprazole		

References:

Clinical Pharmacology. 2018, Elsevier/Gold Standard.
Facts & Comparisons, 2018 Updates, Wolters Kluwer Health.

6. Proton Pump Inhibitors / PPI Negating _____ _____

Alert Message: Our records do not indicate a supporting diagnosis for the use of a proton pump inhibitor (PPI). PPIs are very effective agents but are not without adverse effects especially with long-term use. The agents have been associated with increased risk of Clostridium difficile, bone fractures and hospital- and community-acquired pneumonia. Consider the risks and benefits of proton pump inhibitor therapy and fully inform patients of side effects before prescribing.

Drugs/Diseases

Util A	Util B	Util C **(Negating)**
Dexlansoprazole		Ulcers
Omeprazole		GERD
Esomeprazole		Heartburn
Rabeprazole		Barrett's Esophagus
Lansoprazole		Perforation of Esophagus
Pantoprazole		Esophagitis

References:
Clinical Pharmacology. 2018, Elsevier/Gold Standard.
Facts & Comparisons, 2018 Updates, Wolters Kluwer Health.

7. Proton Pump Inhibitors / PPI Negating _____ _____

Alert Message: Our records do not indicate a supporting diagnosis for the long-term use of a proton pump inhibitor (PPI). PPIs are very effective agents to treat several gastrointestinal conditions. The maximum duration of therapy for most patients is up to 60 days for GERD and acute ulcers. Long-term use of PPIs has been associated with increased risk of fractures. Consider the risks and benefits for prolonged use in this patient.

Drugs/Diseases

Util A	Util B	Util C **(Negating)**
Dexlansoprazole		Ulcers
Omeprazole		GERD
Esomeprazole		Heartburn
Rabeprazole		Barrett's Esophagus
Lansoprazole		Perforation of Esophagus
Pantoprazole		Esophagitis

Duration: 90 days or more

References:
Clinical Pharmacology. 2018, Elsevier/Gold Standard.
Facts & Comparisons, 2018 Updates, Wolters Kluwer Health.

8. Atomoxetine / Pheochromocytoma _____ _____

Alert Message: Strattera (atomoxetine) is contraindicated in patients with pheochromocytoma or a history of pheochromocytoma. Serious reactions, including elevated blood pressure and tachyarrhythmia, have been reported in patients with pheochromocytoma or a history of pheochromocytoma who received atomoxetine.

Drug/Disease:

Util A	Util B	Util C
Atomoxetine	Pheochromocytoma	

Reference:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Facts & Comparisons, 2018 Updates, Wolters Kluwer Health.

9. Ribociclib / Overutilization _____ _____

Alert Message: The recommended dose of Kisqali (ribociclib) is 600 mg (three 200 mg film-coated tablets) taken orally, once daily for 21 consecutive days followed by 7 days off treatment resulting in a complete cycle of 28 days. Ribociclib can be taken with or without food.

Drugs/Diseases

Util A	Util B	Util C
Ribociclib		

Max Dose: 600 mg/day

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Kisqali Prescribing Information, July 2018, Novartis Pharmaceuticals Corp.

10. Ribociclib / Strong CYP3A4 Inhibitors _____ _____

Alert Message: Concurrent use of Kisqali (ribociclib), a CYP3A4 substrate, with a strong CYP3A4 inhibitor may increase exposure to ribociclib, increasing the risk of ribociclib toxicity (e.g., QT prolongation). Consider alternative therapies that do not strongly inhibit CYP3A4. If coadministration of ribociclib with a strong CYP3A4 inhibitor cannot be avoided, reduce the dose of ribociclib to 400 mg once daily.

Drugs/Diseases

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

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Kisqali Prescribing Information, July 2018, Novartis Pharmaceuticals Corp.

11. Ribociclib / Strong CYP3A4 Inducers _____ _____

Alert Message: Concurrent use of Kisqali (ribociclib), a CYP3A4 substrate, with a strong CYP3A4 inducer should be avoided as concomitant use may result in decreased ribociclib concentrations and reduced efficacy. Consider an alternative concomitant medication with no or minimal potential to induce CYP3A4.

Drugs/Diseases

Util A	Util B		Util C
Ribociclib	Carbamazepine	Rifampin	
	Phenobarbital	Enzalutamide	
	Primidone	Phenytoin	
	Mitotane		

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Kisqali Prescribing Information, July 2018, Novartis Pharmaceuticals Corp.

12. Ribociclib / CYP3A4 Substrates with NTI _____ _____

Alert Message: Caution is recommended when Kisqali (ribociclib) is administered with CYP3A4 substrates with a narrow therapeutic index. The dose of a sensitive CYP3A4 substrate with a narrow therapeutic index may need to be reduced as ribociclib can increase their exposure.

Drugs/Diseases

Util A	Util B	Util C
Ribociclib	Cyclosporine	
	Dihydroergotamine	
	Ergotamine	
	Everolimus	
	Fentanyl	
	Pimozide	
	Quinidine	
	Sirolimus	
	Tacrolimus	
	Midazolam	

References:

IBM Micromedex DRUDEX (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA, 2018.
Kisqali Prescribing Information, July 2018, Novartis Pharmaceuticals Corp.

13. Ribociclib / QT Prolongation _____ _____

Alert Message: Avoid using Kisqali (ribociclib) with drugs known to prolong the QT interval due to an increased risk of QT prolongation. Ribociclib has been shown to prolong the QT interval in a concentration-dependent manner.

Drugs/Diseases

Util A	Util B				Util C
Ribociclib	Albuterol	Disopyramide	Imipramine	Pazopanib	Vardenafil
	Alfuzosin	Deutetrabenazine	Pentamidine	Tizanidine	Venlafaxine
	Amantadine	Dolasetron	Pimavanserin	Tolterodine	Ziprasidone
	Amiodarone	Doxepin	Itraconazole	Posaconazole	
	Amitriptyline	Ketoconazole	Procainamide	TMP/SMZ	
	Amphetamine	Lapatinib	Propafenone	Trimipramine	
	Arsenic Trioxide	Efavirenz	Levalbuterol	Protriptyline	
	Asenapine	Eliglustat	Levofloxacin	Quetiapine	
	Atazanavir	Erythromycin	Lithium	Quinidine	
	Atomoxetine	Escitalopram	Metaproterenol	Ranolazine	
	Azithromycin	Felbamate	Methadone	Risperidone	
	Ceritinib	Flecainide	Midostaurin	Ritonavir	
	Chloroquine	Fluconazole	Moxifloxacin	Salmeterol	
	Chlorpromazine	Fluoxetine	Maprotiline	Sertraline	
	Ciprofloxacin	Foscarnet	Nilotinib	Solifenacin	
	Citalopram	Fosphenytoin	Dofetilide	Sotalol	
	Clarithromycin	Galantamine	Nortriptyline	Sunitinib	
	Clomipramine	Gemifloxacin	Octreotide	Tacrolimus	
	Clozapine	Granisetron	Ofloxacin	Tamoxifen	
	Dasatinib	Haloperidol	Ondansetron	Terbutaline	
	Desipramine	Mexiletine	Paliperidone	Trazodone	
	Diphenhydramine	Iloperidone	Paroxetine	Vandetanib	

References:

Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Kisqali Prescribing Information, July 2018, Novartis Pharmaceuticals Corp.

14. Ribociclib / Tamoxifen _____ _____

Alert Message: Kisqali (ribociclib) is not indicated for concomitant use with tamoxifen. In a randomized clinical trial, an increase in the QTcF interval of greater than 60 msec from baseline occurred in 16% of patients receiving ribociclib plus tamoxifen compared with 7% of those who received ribociclib plus a non-steroidal aromatase inhibitor (NSAI).

Drugs/Diseases

Util A	Util B	Util C
Ribociclib	Tamoxifen	

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Kisqali Prescribing Information, July 2018, Novartis Pharmaceuticals Corp.

15. Ribociclib / QT Prolongation _____ _____

Alert Message: Avoid the use of Kisqali (ribociclib) in patients who already have or who are at significant risk of developing QT prolongation. Ribociclib has been shown to prolong the QT interval in a concentration-dependent manner. Based on the observed QT prolongation during treatment, ribociclib may require dose interruption, reduction, or discontinuation.

Drugs/Diseases

Util A	Util B	Util C **(Include)**
Ribociclib		Long QT Syndrome
		Congestive Heart Failure
		Unstable Angina
		Bradyarrhythmias
		Myocardial Infarction
		Hypomagnesemia
		Hypokalemia

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Kisqali Prescribing Information, July 2018, Novartis Pharmaceuticals Corp.

16. Ribociclib / Therapeutic Appropriateness _____ _____

Alert Message: Based on findings from animal studies and the mechanism of action, Kisqali (ribociclib) can cause fetal harm when administered to a pregnant woman. Advise women of reproductive potential to use effective contraception during therapy with ribociclib and for at least 3 weeks after the last dose.

Drugs/Diseases

Util A	Util B	Util C
Ribociclib		

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Kisqali Prescribing Information, July 2018, Novartis Pharmaceuticals Corp.

17. Ribociclib / Lactation _____ _____

Alert Message: It is not known if Kisqali (ribociclib) is present in human milk. There are no data on the effects of ribociclib on the breastfed infant or on milk production. Ribociclib and its metabolites readily passed into the milk of lactating rats. Because of the potential for serious adverse reactions in breastfed infants from ribociclib, advise lactating women not to breastfeed while taking ribociclib and for at least 3 weeks after the last dose.

Drugs/Diseases

Util A	Util B	Util C
Ribociclib	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Kisqali Prescribing Information, July 2018, Novartis Pharmaceuticals Corp.

18. Ribociclib / Therapeutic Appropriateness _____ _____

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

Drugs/Diseases

Util A	Util B	Util C
Ribociclib		

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Kisqali Prescribing Information, July 2018, Novartis Pharmaceuticals Corp.

19. Osimertinib / P-gp Substrates _____ _____

Alert Message: Concurrent use of Tagrisso (osimertinib) with a P-gp substrate may result in increased exposure to the P-gp substrate and risk of exposure-related toxicity. Monitor the patient for adverse reactions associated with the P-gp substrate.

Drugs/Diseases

Util A	Util B				Util C
Osimertinib	Dapagliflozin	Aliskiren	Ledipasvir	Venetoclax	
	Empagliflozin	Ambrisentan	Levomilnacipran	Fosamprenavir	
	Sitagliptin	Apixaban	Linagliptin	Maraviroc	
	Saxagliptin	Atorvastatin	Lovastatin	Glecaprevir	
	Loperamide	Nelfinavir	Lapatinib	Ritonavir	
	Morphine	Carvedilol	Nilotinib	Grazoprevir	
	Paliperidone	Cimetidine	Ombitasvir	Sirolimus	
	Dabigatran	Cyclosporine	Paclitaxel	Imatinib	
	Rivaroxaban	Daclatasvir	Paritaprevir	Everolimus	
	Edoxaban	Dexamethasone	Pibrentasvir	Indinavir	
	Tolvaptan	Digoxin	Pravastatin	Fexofenadine	
	Colchicine	Diltiazem	Ranitidine	Ivermectin	
	Methotrexate	Erythromycin	Rifaximin	Pazopanib	
	Afatinib	Etoposide	Estradiol		

References:
Tagrisso Prescribing Information, August 2018, AstraZeneca.
Clinical Pharmacology, 2018 Elsevier/Gold Standard.

Criteria Recommendations *Approved* *Rejected*

20. Ramelteon / Donepezil _____ _____

Alert Message: The concurrent use of a donepezil-containing agent with ramelteon may result in increased ramelteon exposure. In a drug interaction study, the AUC0-inf and Cmax of ramelteon increased by approximately 100% and 87%, respectively, upon coadministration of donepezil with ramelteon. Patients should be closely monitored when ramelteon is coadministered with a donepezil-containing agent.

Drugs/Diseases

Util A	Util B	Util C
Ramelteon	Donepezil	
	Donepezil/Memantine	

References:

Clinical Pharmacology, 2018 Elsevier/Gold Standard.
IBM Micromedex DRUGDEX (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. 2018.

21. Ramelteon / Doxepin _____ _____

Alert Message: The concurrent use of doxepin with ramelteon may result in increased ramelteon exposure. In a drug interaction study, the AUC0-inf and Cmax of ramelteon increased by approximately 66% and 69%, respectively, upon coadministration of doxepin with ramelteon. Patients should be closely monitored when ramelteon is coadministered with doxepin.

Drugs/Diseases

Util A	Util B	Util C
Ramelteon	Doxepin	

References:

Clinical Pharmacology, 2018 Elsevier/Gold Standard.
IBM Micromedex DRUGDEX (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. 2018.

22. Sarilumab / Overutilization _____ _____

Alert Message: Kevzara (sarilumab) may over-utilized. The recommended maximum daily dose of sarilumab is 200 mg once every two weeks given as a subcutaneous injection.

Drugs/Diseases

Util A	Util B	Util C
Sarilumab		

Max Dose: 2 pens/28 days

References:

Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Kevzara Prescribing Information, April 2018, Sanofi-Aventis.

23. Sarilumab / Serious Infection Black Box Warning _____ _____

Alert Message: Serious and sometimes fatal infections due to bacterial, mycobacterial, invasive fungal, viral, or other opportunistic pathogens have been reported in rheumatoid arthritis patients receiving Kevzara (sarilumab). If a serious infection develops, interrupt sarilumab therapy until the infection is controlled.

Drugs/Diseases

Util A	Util B	Util C
Sarilumab	Pneumonia	
	Herpes Zoster	
	Urinary Tract Infection	
	Esophageal Candidiasis	
	Pneumocystosis	
	Acute Histoplasmosis	
	Cryptococcosis	
	Cytomegalovirus	
	Hepatitis	

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Kevzara Prescribing Information, April 2018, Sanofi-Aventis.

24. Sarilumab / Therapeutic Appropriateness (0 – 17 yoa) _____ _____

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

Drugs/Diseases

Util A	Util B	Util C
Sarilumab		

Age Range: 0 - 17 yoa

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Kevzara Prescribing Information, April 2018, Sanofi-Aventis.

25. Sarilumab / GI Perforations Risk Factors _____ _____

Alert Message: Kevzara (sarilumab) should be used with caution in patients who may be at increased risk for gastrointestinal perforation (e.g., patients with a history of diverticulitis, use of corticosteroids or NSAIDs). Events of gastrointestinal perforation have been reported in clinical studies with sarilumab. Patients presenting with new onset abdominal symptoms should be evaluated promptly for early identification of gastrointestinal perforation.

Drugs/Diseases

Util A	Util B	Util C **(Include)**	
Sarilumab		Diverticulitis	Methylprednisolone
		NSAIDS	Prednisolone
		Budesonide	Prednisone
		Cortisone	Deflazacort
		Deflazacort	Dexamethasone
		Hydrocortisone	

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Kevzara Prescribing Information, April 2018, Sanofi-Aventis.

26. Sarilumab / Tuberculosis _____ _____

Alert Message: Evaluate patients for tuberculosis (TB) risk factors and test for latent infection prior to initiating treatment with Kevzara (sarilumab). Treat patients with latent TB with standard antimycobacterial therapy before initiating sarilumab. Consider anti-TB therapy prior to initiation of sarilumab in patients with a past history of latent or active TB in whom an adequate course of treatment cannot be confirmed, and for patients with a negative test for latent TB but having risk factors for TB infection. Closely monitor patients for active tuberculosis during sarilumab treatment, even if the initial latent tuberculosis test is negative.

Drugs/Diseases

Util A	Util B	Util C **(Include)**
Sarilumab		Tuberculosis
		History of Tuberculosis

References:

Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Kevzara Prescribing Information, April 2018, Sanofi-Aventis.

27. Sarilumab / Nonadherence _____ _____

Alert Message: Based on refill history, your patient may be under-utilizing Kevzara (sarilumab). 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
Sarilumab		

References:

Osterberg L, Blaschke T. Adherence to Medication. N Engl J Med. 2005; 353(5):487–497.
Marengo MF, Suarez-Almazor ME. Improving Treatment Adherence in Patients with Rheumatoid Arthritis: What are the Options? International Journal of Clinical Rheumatology. 2015;10(5):345-356.
van den Bemt BJ, Zwikker HE, van den Ende CH. Medication Adherence in Patients with Rheumatoid Arthritis: A Critical Appraisal of the Existing Literature. *Expert Rev Clin Immunol*. 2012;8(4):337–351.

28. Sarilumab / Hepatic Impairment _____ _____

Alert Message: Treatment with Kevzara (sarilumab) is not recommended in patients with active hepatic disease or hepatic impairment, as treatment with sarilumab was associated with transaminase elevations.

Drugs/Diseases

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

References:

Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Kevzara Prescribing Information, April 2018, Sanofi-Aventis.

29. Sarilumab / Pregnancy / Pregnancy Negating _____ _____

Alert Message: The limited human data with Kevzara (sarilumab) in pregnant women are not sufficient to inform drug-associated risk for major birth defects and miscarriage. Monoclonal antibodies, such as sarilumab, are actively transported across the placenta during the third trimester of pregnancy and may affect immune response in the in utero exposed infant. Sarilumab should be used in pregnancy only if the potential benefit justifies the potential risk to the fetus.

Drugs/Diseases

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

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Kevzara Prescribing Information, April 2018, Sanofi-Aventis.

30. Sarilumab / Lactation _____ _____

Alert Message: No information is available on the presence of Kevzara (sarilumab) in human milk, the effects of the drug on the breastfed infant, or the effects of the drug on milk production. The lack of clinical data during lactation precludes clear determination of the risk of sarilumab to an infant during lactation. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for sarilumab and the potential adverse effects on the breastfed child from sarilumab or from the underlying maternal condition.

Drugs/Diseases

Util A	Util B	Util C
Sarilumab	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Kevzara Prescribing Information, April 2018, Sanofi-Aventis.

31. Sarilumab / Biological DMARDs _____ _____

Alert Message: Avoid using Kevzara (sarilumab) with biological DMARDs because of the possibility of increased immunosuppression and increased risk of infection. The concurrent use of sarilumab with biological DMARDs such as TNF antagonists, IL-1R antagonists, anti-CD20 monoclonal antibodies, and selective co-stimulation modulators has not been studied.

Drugs/Diseases

Util A	Util B	Util C
Sarilumab	Adalimumab	Baricitinib
	Certolizumab	Tofacitinib
	Etanercept	Rituximab
	Golimumab	Canakinumab
	Infliximab	Tocilizumab
	Abatacept	Anakinra

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Kevzara Prescribing Information, April 2018, Sanofi-Aventis.

32. Sarilumab / CYP3A4 Substrates _____ _____

Alert Message: Caution should be exercised when Kevzara (sarilumab) is coadministered with CYP3A4 substrates (e.g., oral contraceptives or statins) as there may be a reduction in substrate exposure, which may reduce the substrate efficacy. Sarilumab is an IL-6 antagonist and modulation of IL-6 can influence the expression and activity of CYP enzymes. The effect of sarilumab on CYP450 enzyme activity may persist for several weeks after stopping therapy.

Drugs/Diseases

Util A	Util B	Util C
Sarilumab	Oral Contraceptives	
	Lovastatin	
	Atorvastatin	
	Simvastatin	
	Warfarin	
	Theophylline	

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Kevzara Prescribing Information, April 2018, Sanofi-Aventis.

33. Dupilumab / Therapeutic Appropriateness _____ _____

Alert Message: The safety and efficacy of Dupixent (dupilumab) in pediatric patients less than 12 years of age with asthma have not been established.

Conflict Code: TA - Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C **(Include)**
Dupilumab		Asthma

Age Range: 0 – 11 yoa

References:
Dupixent Prescribing Information, Oct. 2018, Regeneron Pharmaceuticals, Inc.

34. Venetoclax / Overutilization _____ _____

Alert Message: Venclexta (venetoclax) may be over-utilized. The manufacturer's recommended maximum daily dose of venetoclax in combination with low-dose cytarabine after the ramp-up phase for the treatment of newly diagnosed acute myeloid leukemia is 600 mg.

Drugs/Diseases

Util A	Util B	Util C **(Include)**
Venetoclax		Cytarabine

Max Dose: 600 mg/day

References:
Venclexta Prescribing Information, Nov. 2018, AbbVie Inc.
Clinical Pharmacology, 2018 Updates, Elsevier/Gold Standard.

35. Venetoclax / Overutilization _____ _____

Alert Message: Venclexta (venetoclax) may be over-utilized. The manufacturer's recommended maximum daily dose of venetoclax in combination with azacitidine or decitabine after the ramp-up phase for the treatment of newly diagnosed acute myeloid leukemia is 400 mg.

Drugs/Diseases

Util A	Util B	Util C **(Include)**
Venetoclax		Azacitidine
		Decitabine

Max Dose: 400 mg/day

References:
Venclexta Prescribing Information, Nov. 2018, AbbVie Inc.
Clinical Pharmacology, 2018 Updates, Elsevier/Gold Standard.

36. Venetoclax / Overutilization - Posaconazole _____ _____

Alert message: The total steady daily dose of Venclexta (venetoclax) should not exceed 70 mg per day when coadministered with posaconazole. Venetoclax is a CYP3A4 substrate, and posaconazole is a strong CYP3A4 inhibitor. Concomitant use of these drugs may result in increased venetoclax exposure and risk of venetoclax-related toxicities. Concurrent use of a strong CYP3A4 inhibitor with venetoclax is contraindicated at initiation and during the ramp-up phase of venetoclax therapy.

Drugs/Diseases

Util A	Util B	Util C
Venetoclax 100mg	Posaconazole	

Max Dose: 70 mg/day

References:
Venclexta Prescribing Information, Nov. 2018, AbbVie Inc.
Clinical Pharmacology, 2018 Updates, Elsevier/Gold Standard.

37. Cannabidiol / Therapeutic Appropriateness _____ _____

Alert Message: Epidiolex (cannabidiol) causes dose-related elevations of liver transaminases (alanine aminotransferase [ALT] and/or aspartate aminotransferase [AST]). Prior to starting treatment with cannabidiol, obtain serum transaminases (ALT and AST) and total bilirubin levels. Serum transaminases and total bilirubin levels should be obtained at 1 month, 3 months, and 6 months after initiation of treatment with cannabidiol, and periodically thereafter or as clinically indicated.

Drugs/Diseases

Util A	Util B	Util C
Cannabidiol		

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Epidiolex Prescribing Information, June 2018, Greenwich Biosciences.

38. Cannabidiol /Nonadherence _____ _____

Alert Message: Based on the refill history, your patient may be underutilizing Epidiolex (cannabidiol). 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
Cannabidiol		

References:

Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Epidiolex Prescribing Information, June 2018, Greenwich Biosciences.
Faught E, Duh MS, Weiner JR, et al. Nonadherence to Antiepileptic Drugs and Increased Mortality, Findings from the RANSOM Study. Neurology 2008;71(20): 1572-1578.
Osterberg L, Blaschke T. Adherence to Medication. N Engl J Med 2005; 353:487- 497.

39. Cannabidiol / Moderate & Strong CYP3A4 & CYP2C19 Inhibitors _____ _____

Alert Message: Epidiolex (cannabidiol) is metabolized by CYP3A4 and CYP2C19. Therefore, coadministration with a moderate or strong inhibitor of CYP3A4 or CYP2C19 will increase cannabidiol plasma concentrations, which may result in a greater risk of adverse reactions. Consider a reduction in the cannabidiol dosage when coadministered with a moderate or strong inhibitor of CYP3A4 or CYP2C19.

Drugs/Diseases

Util A	Util B				Util C
Cannabidiol	Nefazodone	Diltiazem	Ticlopidine	Fosamprenavir	
	Clarithromycin	Verapamil	Cobicistat		
	Ketoconazole	Fluconazole	Fluoxetine		
	Itraconazole	Aprepitant	Atazanavir		
	Posaconazole	Cimetidine	Imatinib		
	Voriconazole	Ciprofloxacin	Indinavir		
	Saquinavir	Crizotinib	Fluvoxamine		
	Ritonavir	Cyclosporine	Erythromycin		
	Nelfinavir	Dronedarone	Delavirdine		

References:

Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Epidiolex Prescribing Information, June 2018, Greenwich Biosciences.

40. Cannabidiol / Strong CYP3A4 & CYP2C19 Inducers _____ _____

Alert Message: Epidiolex (cannabidiol) is metabolized by CYP3A4 and CYP2C19. Coadministration with a strong CYP3A4 or CYP2C19 inducer will decrease cannabidiol plasma concentrations, which may lower the efficacy of cannabidiol. Consider an increase in the cannabidiol dosage (based on clinical response and tolerability) when coadministered with a strong CYP3A4 or CYP2C19 inducer.

Drugs/Diseases

Util A	Util B	Util C
Cannabidiol	Carbamazepine	
	Phenytoin	
	Primidone	
	Phenobarbital	
	Rifampin	
	Mitotane	
	Enzalutamide	

References:

Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Epidiolex Prescribing Information, June 2018, Greenwich Biosciences.

41. Cannabidiol / Clobazam _____ _____

Alert Message: Coadministration of Epidiolex (cannabidiol) with clobazam produces a 3-fold increase in plasma concentrations of N-desmethylclobazam, the active metabolite of clobazam (a substrate of CYP2C19). This may increase the risk of clobazam-related adverse reactions. Consider a reduction in the dosage of clobazam if adverse reactions known to occur with clobazam are experienced when co-administered with cannabidiol.

Drugs/Diseases

Util A	Util B	Util C
Cannabidiol	Clobazam	

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Epidiolex Prescribing Information, June 2018, Greenwich Biosciences.

42. Cannabidiol / Sensitive CYP2C19 Substrates _____ _____

Alert Message: In vivo data show that coadministration of Epidiolex (cannabidiol) with a drug that is a CYP2C19 substrate will result in an increase in the plasma concentrations of the substrate and may increase the risk of substrate-related adverse reactions. Consider a reduction in the dosage of sensitive CYP2C19 substrates, as clinically appropriate, when coadministered with cannabidiol.

Drugs/Diseases

Util A	Util B	Util C
Cannabidiol	Diazepam	
	Omeprazole	
	Lansoprazole	
	Rabeprazole	

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Epidiolex Prescribing Information, June 2018, Greenwich Biosciences.
FDA: Drug Development and Drug Interactions: Tables of Substrates, Inhibitors and Inducers. Available at: http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResourcesDrugInteractionaLabeling/ucm093664.htm

43. Cannabidiol / Valproate _____ _____

Alert Message: Concomitant use of Epidiolex (cannabidiol) and valproate may increase the risk of hepatotoxicity. Discontinuation or reduction of cannabidiol and/or concomitant valproate should be considered if liver enzyme elevations occur.

Drugs/Diseases

Util A	Util B	Util C
Cannabidiol	Valproate	

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Epidiolex Prescribing Information, June 2018, Greenwich Biosciences.

44. Cannabidiol / Pregnancy / Pregnancy Negating _____ _____

Alert Message: There are no adequate data on the development risks associated with the use of Epidiolex (cannabidiol) in pregnant women. Administration of cannabidiol to pregnant animals produced evidence of developmental toxicity at maternal plasma exposure similar to (rabbit) or greater than (rat) that in humans at therapeutic doses. Encourage women who are taking cannabidiol to enroll in the North American Antiepileptic Drug (NAAED) Pregnancy Registry if they become pregnant.

Drugs/Diseases

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

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Epidiolex Prescribing Information, June 2018, Greenwich Biosciences.

45. Cannabidiol / Lactation _____ _____

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

Drugs/Diseases

Util A	Util B	Util C
Cannabidiol	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Epidiolex Prescribing Information, June 2018, Greenwich Biosciences.

46. Fremanezumab-vfrm / Therapeutic Appropriateness (0 - 17 yoa) _____ _____

Alert Message: The safety and effectiveness of Ajovy (fremanezumab-vfrm) in pediatric patients have not been established.

Drugs/Diseases

Util A	Util B	Util C
Fremanezumab-vfrm		

Age Range: 0 - 17 yoa

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Ajovy Prescribing Information, Sept. 2018, Teva Pharmaceuticals.

47. Fremanezumab-vfrm / Lactation _____ _____

Alert Message: There are no data on the presence of Ajovy (fremanezumab-vfrm) 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 fremanezumab-vfrm and any potential adverse effects on the breastfed infant from fremanezumab-vfrm or from the underlying maternal condition.

Drugs/Diseases

Util A	Util B	Util C
Fremanezumab-vfrm	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Ajovy Prescribing Information, Sept. 2018, Teva Pharmaceuticals.

48. Fremanezumab-vfrm / Pregnancy / Pregnancy Negating _____ _____

Alert Message: There are no adequate data on the developmental risk associated with the use of Ajovy (fremanezumab-vfrm) in pregnant women. Fremanezumab-vfrm has a long half-life. This should be taken into consideration for women who are pregnant or plan to become pregnant while using this drug.

Drugs/Diseases

Util A	Util B	Util C **(Negating)**
Fremanezumab-vfrm	Pregnancy	Miscarriage
		Delivery
		Abortion

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Ajovy Prescribing Information, Sept. 2018, Teva Pharmaceuticals.

49. Itraconazole 65 mg Caps / Overutilization _____ _____

Alert Message: Tolsura (itraconazole) may be over-utilized. The maximum recommended daily dose is 260 mg/day.

Drugs/Diseases

Util A	Util B	Util C
Itraconazole 65 mg Caps		

Max Dose: 260 mg/day

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Tolsura Prescribing Information, Dec. 2018, Mayne Pharma.

50. Itraconazole 65 mg Caps / Drugs that Reduce Gastric Acidity _____ _____

Alert Message: The concurrent use of Tolsura (itraconazole) with a drug that reduces gastric acidity (e.g., aluminum hydroxide, H2-receptor antagonists, and proton pump inhibitors) may result in an increase in the systemic exposure to itraconazole and risk for adverse reactions. Itraconazole dose reduction may be necessary.

Drugs/Diseases

Util A	Util B	Util C
Itraconazole 65 mg Caps	Antacids	
	H-2 Antagonists	
	Proton Pump Inhibitors	

References:

Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Tolsura Prescribing Information, Dec. 2018, Mayne Pharma.

DUR Board Meeting
June 5, 2019
Brynhild Haugland Room

North Dakota Medicaid
DUR Board Meeting Agenda
Brynhild Haugland Room
State Capitol
600 East Boulevard Avenue
Bismarck, ND
June 5, 2019
1:00 pm

1. Administrative items
    - Travel vouchers

2. Old business
    - Review and approval of 04/2019 meeting minutes
    - Budget update
    - Legislative Update
    - Review top 15 therapeutic categories/top 25 drugs
    - Prior authorization/PDL update
    - Second review of Sivextro
    - Second review of Nuzyra
    - Second review of estrogen agents
    - Second review of agents for treatment of osteoporosis
    - Second review of agents for treatment of hyperkalemia
    - Second review of agents for treatment of Parkinson's disease

3. New business
    - Review of short-acting opioid analgesic agents
    - Review of agents for the treatment of thrombocytopenia
    - Review of agents for the treatment of interstitial cystitis
    - Review of agents for the treatment of narcolepsy
    - Report on utilization data from select drugs and drug classes
    - Retrospective DUR criteria recommendations

    - Upcoming meeting date/agenda.
        - Next meeting is September 4, 2019 in the Brynhild Haugland Room

4. Adjourn

Please remember to silence all cellular phones during the meeting.

Drug Utilization Review (DUR) Meeting Minutes
April 9, 2019

Members Present: Michael Booth, Gabriela Balf, Tanya Schmidt, Andrea Honeyman, Peter Woodrow, Jesse Rue, Katie Kram, LeNeika Roehrich, Kayli Bardell

Members Absent: Michael Quast, Jeffrey Hostetter, Russ Sobotta, Laura Schield

Medicaid Pharmacy Department: Brendan Joyce, Alexi Murphy

Old Business

Chair L. Roehrich called the meeting to order at 1:07 p.m. Chair L. Roehrich asked for a motion to approve the minutes of the December meeting. P. Woodrow moved that the minutes be approved and K. Kram seconded the motion. Chair L. Roehrich called for a voice vote to approve the minutes. The motion passed with no audible dissent.

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 2018.

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 from 7 ACE/ARB containing agents, as well as from QVAR RediHaler, Relistor syringe, Spiriva Respimat, Striverdi Respimat, and trospium. Other notable changes including adding the following agents to PA: colchicine, Dupixent, Emgality, Novolin 70-30 Flexpen, Nystatin-Triamcinolone, Omnaris, Pataday, and Tracleer. 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 Orilissa

A motion and second was made at the December meeting to place Orilissa on prior authorization. The topics were brought up for a second review. A. Murphy explained to the board that examples of specific agents would be added to the form for the sake of clarity. Margaret Olman of AbbVie offered to provide the Board with any information they would like regarding Orilissa. Chair L. Roehrich called for a voice vote to approve the presented criteria, and the motion passed with no audible dissent.

Second Review of Vaginal Anti-Infective Agents

A motion and second was made at the December meeting to generate prior authorization criteria for vaginal anti-infective agents. The topic was brought up for a second review. A. Murphy proposed that the Board remove the 30-day requirement listed in the criteria. J. Rue motioned to amend the criteria as suggested and P. Woodrow seconded the motion. There was no public comment. Chair L. Roehrich called for a voice vote on the amended criteria, and the motion passed with no audible dissent.

Second Review of Agents for the Treatment of Glaucoma
A motion and second was made at the December meeting to place agents for the treatment of glaucoma on prior authorization. The topic was brought up for a second review. There was no public comment. Chair L. Roehrich called for a voice vote and the motion passed with no audible dissent.

Second Review of Agents for the Treatment of Dry Eye Syndrome
A motion and second was made at the December meeting to place agents for the treatment of dry eye syndrome on prior authorization. The topic was brought up for a second review. There was no public comment. Chair L. Roehrich called for a voice vote and the motion passed with no audible dissent.

New Business

Review of Estrogen Agents
A. Murphy presented a review of estrogen agents to the Board. A motion was made by J. Rue to create a new PA criteria class and manage these medications through prior authorization. The motion was seconded by K. Kram. This topic will be reviewed at the next meeting.

Review of Sivextro
A. Murphy presented a review of Sivextro to the Board. A motion was made by K. Kram to create PA criteria for the use of this agent and manage this medication through prior authorization. The motion was seconded by A. Honeyman. This topic will be reviewed at the next meeting.

Review of Nuzyra
A. Murphy presented a review of Nuzyra to the Board. A motion was made by P. Woodrow to create PA criteria for the use of this agent and manage this medication through prior authorization. The motion was seconded by K. Kram. This topic will be reviewed at the next meeting.

Agents for Treatment of Osteoporosis
A. Murphy presented a review of agents for treatment of osteoporosis to the Board. A motion was made by J. Rue to create a new PA criteria class and manage these medications through prior authorization. The motion was seconded by K. Kram. This topic will be reviewed at the next meeting.

Agents for Treatment of Hyperkalemia
A. Murphy presented a review of agents for treatment of hyperkalemia to the Board. A motion was made by J. Rue to create a new PA criteria class and manage these medications through prior authorization. The motion was seconded by A. Honeyman. This topic will be reviewed at the next meeting.

Agents for Treatment of Parkinson's Disease
A. Murphy presented a review of agents for treatment of Parkinson's disease to the Board. A motion was made by M. Booth to create a new PA criteria class and manage these medications through prior authorization. The motion was seconded by J. Rue. This topic will be reviewed at the next meeting.

Report on Utilization of Long-Acting Beta Agonist/Inhaled Corticosteroid Inhaler Combination Products Without Use of a Rescue Inhaler

In 2018, a claims processing edit was put in place requiring that patients receiving a long-acting beta agonist/inhaled corticosteroid (LABA/ICS) combination inhaler must also have a paid claim for a rescue inhaler within the past year to ensure the patient has access to a rescue inhaler. To evaluate the effect of this edit, T. DeRuiter presented utilization data showing the number of FFS patients receiving a (LABA/ICS) combination inhaler without having a paid claim for a rescue inhaler within the past year, comparing the number of patients before and after the claims processing edit was put in place. The data showed that only 5 patients are currently receiving a LABA/ICA inhaler without also having paid claims for a rescue inhaler, as compared to 49 patients prior to the edit being put in place.

Report on Utilization of Guideline Supported Use of Metformin

To promote appropriate, guideline supported use of metformin as a first-line agent for patients with diabetes mellitus type 2, a claims processing edit was put in place on preferred DPP-4 inhibitor, GLP-1 agonist, or SGLT-2 inhibitors. The edit requires that, for claims of these preferred agents to pay automatically at the point of sale and not require PA approval, the patient must be currently stable on a metformin-containing agent with good compliance over the past 3 months. To evaluate the impact of this edit, T. DeRuiter presented utilization data showing the number of FFS patients receiving one of these agents without concomitant use of a metformin-containing agent, comparing the number of patients before and after the claims processing edit was put in place. The data showed a reduction in the number of patients receiving one of these agents without metformin for all of these agents with the exception of linagliptin, resulting in 53 fewer patients receiving these medications without using metformin.

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. J. Rue moved to amend the new criteria as stated above and approve it. K. Kram seconded the motion. The motion passed with no audible dissent.

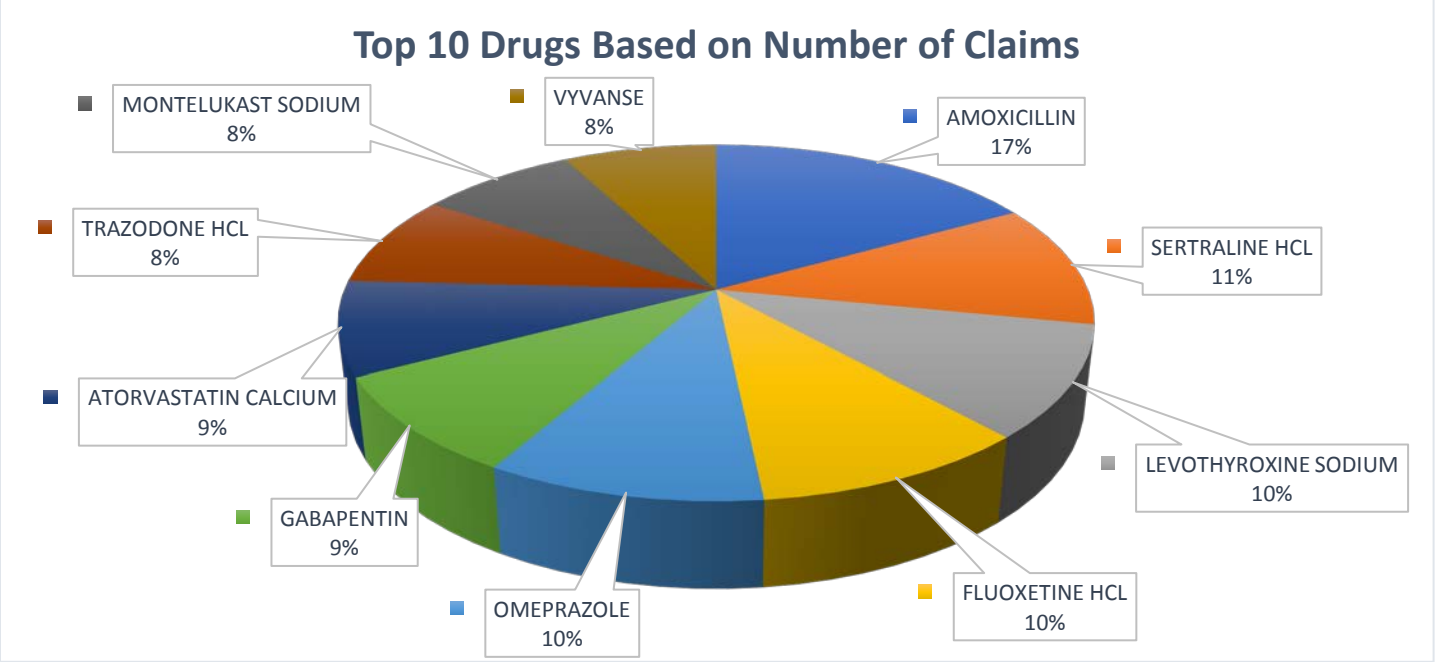
Adjournment and Upcoming Meeting Date

Chair L. Roehrich adjourned the meeting at 2:20 pm. The next DUR Board meeting will be held June 5, 2019 at 1:00 pm at the State Capitol building in the Brynhild -Haugland room.

TOP 25 DRUGS BASED ON NUMBER OF CLAIMS FROM 01/01/2019 – 03/31/2019

Drug	AHFS Class	Claims	Claims Cost	Total Patients	Cost Per Claim	% Total Claims
AMOXICILLIN	PENICILLIN ANTIBIOTICS	4,009	$160,026.16	3,708	$39.92	2.70%
SERTRALINE	ANTIDEPRESSANTS	2,664	$61,741.84	1,202	$23.18	1.79%
LEVOTHYROXINE	THYROID AGENTS	2,402	$45,552.31	879	$18.96	1.62%
FLUOXETINE	ANTIDEPRESSANTS	2,391	$43,817.77	1,040	$18.33	1.61%
OMEPRAZOLE	PROTON-PUMP INHIBITORS	2,383	$44,870.84	1,124	$18.83	1.61%
GABAPENTIN	ANTICONVULSANTS, MISC	2,122	$40,017.54	895	$18.86	1.43%
ATORVASTATIN	HMG-COA INHIBITORS	2,023	$54,138.14	816	$26.76	1.36%
TRAZODONE	ANTIDEPRESSANTS	1,980	$33,048.50	864	$16.69	1.33%
MONTELUKAST	LEUKOTRIENE MODIFIERS	1,895	$36,742.23	938	$19.39	1.28%
VYVANSE	AMPHETAMINES	1,861	$419,470.94	720	$225.40	1.25%
LISINOPRIL	ACE INHIBITORS	1,833	$47,685.41	786	$26.01	1.23%
ESCITALOPRAM	ANTIDEPRESSANTS	1,755	$37,910.34	833	$21.60	1.18%
CLONIDINE	CENTRAL ALPHA-AGONISTS	1,626	$30,701.73	673	$18.88	1.10%
HYDROCODONE-APAP	OPIATE AGONISTS	1,593	$37,122.43	1,018	$23.30	1.07%
AMOXICILLIN-CLAVULANATE	PENICILLIN ANTIBIOTICS	1,548	$80,186.54	1,432	$51.80	1.04%
AZITHROMYCIN	MACROLIDE ANTIBIOTICS	1,547	$46,497.95	1,418	$30.06	1.04%
PROAIR HFA	BETA-ADRENERGIC AGONISTS	1,526	$118,343.75	1,506	$77.55	1.03%
METFORMIN	BIGUANIDES	1,487	$27,112.99	647	$18.23	1.00%
CONCERTA	CNS STIMULANTS	1,462	$464,554.61	599	$317.75	0.99%
RISPERIDONE	ANTIPSYCHOTIC AGENTS	1,453	$21,004.15	479	$14.46	0.98%
LAMOTRIGINE	ANTICONVULSANTS, MISC	1,371	$24,195.97	470	$17.65	0.92%
DULOXETINE	ANTIDEPRESSANTS	1,356	$33,716.49	518	$24.86	0.91%
ARIPIPRAZOLE	ANTIPSYCHOTIC AGENTS	1,306	$30,991.98	516	$23.73	0.88%
ALBUTEROL	BETA-ADRENERGIC AGONISTS	1,290	$54,308.74	1,042	$42.10	0.87%
ASPIRIN	NSAIDS	1,289	$64,481.90	515	$50.02	0.87%

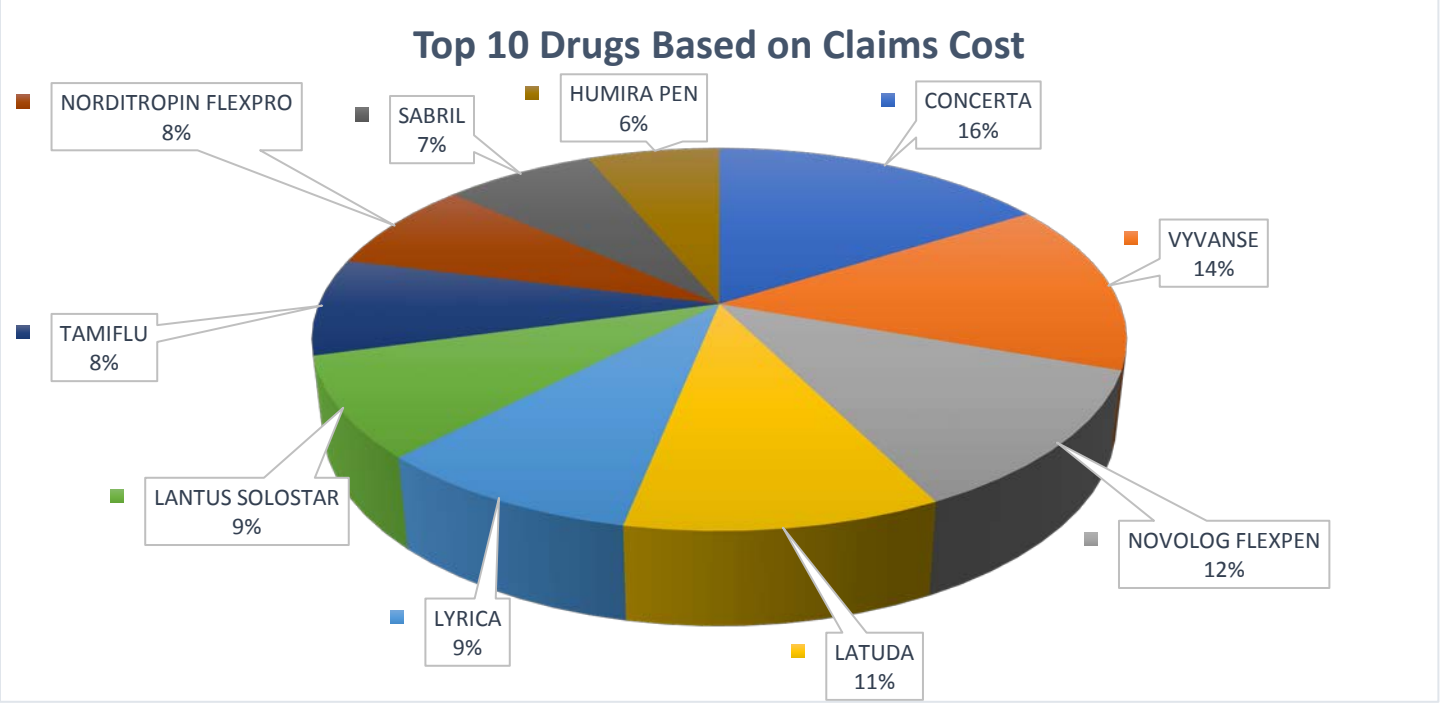
Total Rx Claims From 01/01/2019 – 03/31/2019	148,423



TOP 25 DRUGS BASED ON TOTAL CLAIMS COST FROM 01/01/2019 – 03/31/2019

Drug	AHFS Class	Claims Cost	Claims	Total Patients	Cost Per Claim	% Total Cost
CONCERTA	CNS STIMULANTS	$464,554.61	1,462	599	$775.55	3.61%
VYVANSE	AMPHETAMINES	$419,470.94	1,861	720	$582.60	3.26%
NOVOLOG FLEXPEN	INSULINS	$349,800.28	611	338	$1,034.91	2.72%
LATUDA	ANTIPSYCHOTIC AGENTS	$307,028.31	461	163	$1,883.61	2.39%
LYRICA	ANTICONVULSANTS, MISC	$262,553.24	534	212	$1,238.46	2.04%
LANTUS SOLOSTAR	INSULINS	$246,641.39	564	284	$868.46	1.92%
TAMIFLU	NEURAMINIDASE INHIBITOR	$237,668.85	1,244	1,224	$194.17	1.85%
NORDITROPIN FLEXPRO	PITUITARY	$222,580.85	68	30	$7,419.36	1.73%
SABRIL	ANTICONVULSANTS, MISC	$207,099.76	15	6	$34,516.63	1.61%
HUMIRA PEN	IMMUNOMODULATORS	$181,758.59	34	17	$10,691.68	1.41%
INVEGA SUSTENNA	ANTIPSYCHOTIC AGENTS	$172,005.99	84	31	$5,548.58	1.34%
GENVOYA	ANTIRETROVIRALS	$167,119.03	134	59	$2,832.53	1.30%
AMOXICILLIN	PENICILLIN ANTIBIOTICS	$160,026.16	4,009	3,708	$43.16	1.24%
VIMPAT	ANTICONVULSANTS, MISC	$138,117.38	212	61	$2,264.22	1.07%
LEVEMIR FLEXTOUCH	INSULINS	$132,797.15	309	180	$737.76	1.03%
ADVAIR DISKUS	ICS	$129,051.88	343	191	$675.66	1.00%
LICE KILLING	SCABICIDES & PEDICULICIDES	$121,940.00	276	206	$591.94	0.95%
PROAIR HFA	BETA-ADRENERGIC AGONISTS	$118,343.75	1,526	1,506	$78.58	0.92%
FLOVENT HFA	ICS	$113,178.49	510	330	$342.97	0.88%
MAPAP	ANALGESICS, MISC.	$113,098.38	489	356	$317.69	0.88%
FOCALIN XR	CNS STIMULANTS	$108,838.00	326	129	$843.71	0.85%
SYMBICORT	ICS	$95,692.10	309	177	$540.63	0.74%
TRIUMEQ	ANTIRETROVIRALS	$93,578.56	61	28	$3,342.09	0.73%
NIX	SCABICIDES & PEDICULICIDES	$92,920.62	217	193	$481.45	0.72%
ZUBSOLV	OPIATE PARTIAL AGONISTS	$88,909.41	512	95	$935.89	0.69%

Total Claims Cost From 01/01/2019 – 03/31/2019	$12,869,942.46



PDL Update

ADDED TO PA	
ARNUITY ELLIPTA 100 MCG INH	Inhaled Corticosteroids
BETAXOLOL HCL	Ophthalmic Glaucoma - Beta Blockers
BIMATOPROST	Ophthalmic Glaucoma - Prostaglandin
BRIMONIDINE TARTRATE	Ophthalmic Glaucoma - Alpha Adrenergic
CLINDAMYCIN PHOSPHATE	Vaginal Anti-infectives
DEXAMETHASONE 0.1% EYE DROP	Ophthalmic Anti-Inflammatory
DICLOFENAC SOD EC 50 MG TAB	NSAIDS
DONEPEZIL 23mg	Antidementia
DUOBRII 0.01%-0.045% LOTION	Antipsoriatics - Topical
DUREZOL	Ophthalmic Anti-Inflammatory
ENVARSUS XR	Preferred Dosage Forms
ESOMEP-EZS	Proton Pump Inhibitor
GATTEX	Meds over $3000/month
GYNAZOLE 1	Vaginal Anti-infectives
HALOBETASOL PROPIONATE	Corticosteroids - Topical
INGREZZA INITIATION PACK	Tardive Dyskinesia
INVELTYS	Ophthalmic Anti-Inflammatory
LOTEMAX SM	Ophthalmic Anti-Inflammatory
MAVENCLAD	Multiple Sclerosis - Oral Non-Interferons
MAYZENT	Multiple Sclerosis - Oral Non-Interferons
METRONIDAZOLE	Vaginal Anti-infectives
MICONAZOLE 3	Vaginal Anti-infectives
NORGESIC FORTE	Skeletal Muscle Relaxants
OXERVATE	Meds over $3000/month
QMIIZ ODT	NSAIDS
ROCKLATAN	Ophthalmic Glaucoma - Other
SKYRIZI	Cytokine Modulators
TAKHZYRO	Hereditary Angioedema
TERCONAZOLE	Vaginal Anti-infectives
TESTOPEL	Androgens
TIMOLOL MALEATE	Ophthalmic Glaucoma - Beta Blockers
TIROSINT	Preferred Dosage Forms
TIROSINT-SOL	Preferred Dosage Forms
TREMFYA	Cytokine Modulators
VYZULTA	Ophthalmic Glaucoma - Prostaglandin
XELPROS	Ophthalmic Glaucoma - Prostaglandin

Removed from PA	
ARCAPTA NEOHALER	COPD-Long Acting Beta Agonists
INCRUSE ELLIPTA	COPD-Long Acting Anticholinergics
MENTAX	Antifungals - Topical
SEEBRI NEOHALER	COPD-Long Acting Anticholinergics
TOLTERODINE TARTRATE ER	Unirnary Antispasmodics

Antibiotics - Resistance Prevention

Approval Duration:
Initial: 5 days
Renewal: 5 days

Initial Criteria:

- Patient must be of an appropriate age for use per manufacturer label
- Patient must have an FDA approved indication for use, proven to be caused by a susceptible microorganism by culture and susceptibility testing
- Medication must be prescribed by, or in consultation with, an infection disease specialist.
- One of the following criteria 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

Renewal Criteria:

- 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).

Methicillin-Resistant *Staphylococcus aureus* (MRSA):

Preferred	Non-Preferred
Clindamycin	BAXDELA (Delafloxacin)
Doxycycline	NUZYRA (Omadacycline)
Linezolid	SIVEXTRO (Tedizolid)
Minocycline	
Trimethoprim-Sulfamethoxazole	

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, or in consultation with, an infection disease specialist
- 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 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:**		

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 #

Estrogens

Criteria:

- Patient must have failed 30-day trials of at least two preferred products, as evidenced by paid claims or pharmacy printouts.

Preferred	Non-Preferred
CLIMARA PRO (estradiol-levonorgestrel) PATCH	Estradiol patch
COMBIPATCH (Estradiol- Norethindrone)	Estradiol vaginal cream
DIVIGEL (estradiol) GEL	Estradiol vaginal tablet
ELESTRIN (estradiol) GEL	FEMRING (estradiol)
Estradiol- Norethindrone tablet	MINOSTAR (estradiol) PATCH
Estradiol tablet	PREFEST (estradiol-norgestimate) TABLET
ESTRING (estradiol)	
EVAMIST (estradiol) SPRAY	
MENEST (estrogens, esterified) TABLET	
Norethindrone-Ethinyl Estradiol tablet	
PREMARIN (estrogens, conjugated) TABLET	
PREMARIN (estrogens, conjugated) VAGINAL CREAM	
PREMPHASE (estrogen, conj.,m-progest) TABLET	
PREMPRO (estrogen, conj.,m-progest) TABLET	
VAGIFEM (estradiol) VAGINAL TABLET	
YUVAFEM (estradiol) VAGINAL TABLET	

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 #

Osteoporosis

Approval Duration:

Authorization will be for 2 years (1 year for Evenity)

Criteria:

- Patient must have an FDA approved indication for use
- 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 print-outs:
    - Alendronate or Risedronate
    - Denosumab
- Patient must be at high risk of fracture, confirmed by at least one of the following:
    - BMD T-score ≤ -2.5 based on BMD measurements from lumbar spine, hip, or radius
    - History of low trauma fracture
    - Multiple risk factors for fracture

Additional Criteria for Forteo and Miacalcin:

- 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 print-outs:
    - Evenity (Romosozumab)
    - Tymlos (Abaloparatide)

Preferred	Non-Preferred
Alendronate	EVENITY (Romosozumab)
Calcitonin, Salmon Nasal Spray	FORTEO (Teriparatide)
Ibandronate	MIACALCIN (Calcitonin, Salmon)
PROLIA (Denosumab)	TYMLOS (Abaloparatide)
Risedronate	

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 non-preferred osteoporosis agents must meet the following criteria:

- Patient must have an FDA approved indication for use
  - Patient must have a current BMD T-score ≤ -2.5 OR new fracture after 6-month trials of each of the following:
    - Denosumab AND either Alendronate or Risedronate
- Patient must be at high risk of fracture, confirmed by at least one of the following:
  - BMD T-score ≤ -2.5 based on BMD measurements from lumbar spine, hip, or radius
  - History of low trauma fracture OR multiple risk factors for fracture
- Additional Criteria for Forteo and Miacalcin:
  - Patient must have a current BMD T-score ≤ -2.5 OR new fracture after 6-month trials of each of the following:
    - Evenity (Romosozumab) AND Tymlos (Abaloparatide)

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:**

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

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Part II: TO BE COMPLETED BY PHARMACY

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

Hyperkalemia

Approval Duration:
Initial: 3 months
Renewal: 6 months

Initial Criteria:

- Patient must be 18 years of age or older.
- Medication must be prescribed by, or in consultation with, a cardiologist or nephrologist
- 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
- 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:
    - Patient must have failed a 30-day trial with at least one preferred product
    - Provider has submitted evidenced-based, medical justification explaining why the patient is unable to use all available preferred agents.
- 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:

- 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	Non-Preferred
Bumetanide	LOKELMA (Sodium Zirconium Cyclosilicate)
Chlorothiazide	VELTASSA (Patiromer)
Fludrocortisone	
Furosemide	
Hydrochlorothiazide	
Indapamide	
Metolazone	
Torsemide	

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 cardiologist or 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 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

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

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Part II: TO BE COMPLETED BY PHARMACY

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

Parkinson's disease

Initial Criteria:

- Patient must have an FDA approved indication for use
- Patient must be currently taking carbidopa – levodopa, as evidenced by paid claims or pharmacy print-outs, and will continue taking carbidopa – levodopa concurrently with requested agent

Additional Criteria for Gocovri, Osmolex ER, Rytary, and Pramipexole ER:

- Patient is not currently residing in a long-term care facility
- The prescriber must submit medical justification explaining why the patient cannot use the preferred product (subject to clinical review)

Additional Criteria for apomorphine, Duopa and Inbrija

- The provider must submit documentation of a swallow study or other medical documentation (e.g. chart notes) indicating that the patient has a proven inability to ingest solid dosage formulations.

Additional Criteria for Xadago

- Medication must be prescribed by, or in consultation with, a psychiatrist or neurologist
- Patient must be currently experiencing intermittent hypomobility or "off" episodes
- Patient must be exhibiting deterioration in quality of response, intermittent hypomobility, or "off" episodes during levodopa/carbidopa therapy
- Patient must have had inadequate response to rasagiline and selegiline, as evidenced by paid claims or pharmacy print-outs

Additional Criteria for Nuplazid

- Medication must be prescribed by, or in consultation with, a psychiatrist or neurologist
- Patient must be experiencing recurrent or continuous hallucinations and/or delusions for the past 30 days
- Patient must have experienced an inadequate response to a 30-day trial of quetiapine or clozapine, as evidenced by paid claims or pharmacy print-outs
- Patient must not have experienced a reduction in symptoms of psychosis, despite documented medication dosage reduction and discontinuation trials (with a goal of levodopa monotherapy)

Additional Criteria for Tolcapone

- Patient must have failed a 30-day trial of entacapone

health information designs

General
Prior Authorization Form

Fax Completed Form to:
855-207-0250
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866-773-0695

Prior Authorization Vendor for ND

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- 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 #

Renewal Criteria:

- Patient has experienced disease stabilization or improvement in disease since initiation of treatment

Preferred	Non-Preferred
Amantadine	DUOPA (levodopa/carbidopa)
AZILECT (Rasagiline)	APOKYN (Apomorphine)
Benztropine	GOCOVRI (amantadine ER)
Bromocriptine	INBRIJA (Levodopa)
Carbidopa-levadopa-entacapone	Pramipexole ER
Carbidopa-Levadopa	NUPLAZID (pimavanserin)
Carbidopa-Levadopa ER	OSMOLEX ER (amantadine ER)
Entacapone	Rasagiline
Levodopa	RYTARY (levodopa/carbidopa)
NEUPRO (rotigotine) PATCH	Tolcapone
Pramipexole	XADAGO (Safinamide)
Ropinirole	
Ropinirole ER	
Selegiline	
Trihexyphenidyl	

REVIEW OF SHORT ACTING OPIOID ANALGESICS

SHORT-ACTING OPIOIDS:

- Opioid analgesic agents are the most commonly used pharmacologic agents for the treatment of moderate to severe pain
- **Mechanism**: Agonists at μ-opiate receptors in the CNS, causing inhibition of ascending pain pathways, altering the perception of and response to pain.
- Overall, evidence from comparative clinical trials suggests similar rates of efficacy between short acting agents when dosed at equipotent doses (see table of morphine equivalence)
- Unintentional drug overdose death rates in the United States have increased five-fold since 1990 and this has been driven by increased use of opioid analgesics
    - Pain management with short-acting opioids should be individualized for each patient and include an evaluation of patient patient specific factors that determine the best agent from a safety perspective.
- Short-acting opioid analgesic products are available in many dosage forms, varying potencies and differing durations of action
    - Available Oral Dosage Formulations for Pain (excluding IV)

	Tablet/Capsule	Solution	Suspension	Other
Benzhydrocodone/ APAP	X			
Codeine	X	X		
Codeine/APAP	X	X	X	
Fentanyl				**Fentora**: Buccal tablets: **Subsys**: SL spray **Lazanda**: Nasal spray **Actiq**: Transmucosal lozenge **Abstral**: SL tabs
Hydrocodone/ APAP	X	X		Elixer
Hydrocodone/ ibuprofen	X			
Hydromorphone	X	X		Suppository
Meperidine	X	X		
Morphine	X	X		Suppository
Oxycodone	X	X		
Oxycodone/ APAP	X	X		
Oxycodone/ ASA	X			
Oxycodone/ ibuprofen	X			
Oxymorphone	X			
Tapentadol	X			
Tramadol	X			
Tramadol/ APAP	X			

SAFETY PROFILE:

- **All Short-Acting Agents:**
    - HSR
    - Addiction, abuse, and misuse
    - Respiratory depression
        - Contraindicated in those with acute or severe bronchial asthma in an unmonitored setting
    - Risks from concomitant use with benzodiazepines or other CNS depressants
    - Neonatal withdrawal syndrome
    - Contraindicated in patients with GI obstruction due to constipation
    - CNS depression and sedation
    - Hypotension

- **Contraindicated in patients <12 years of age or <18 years for postoperative tonsillectomy and/or adenoidectomy management:**
    - Codeine
    - Tramadol

- **Use is contraindicated with concomitant monoamine oxidase inhibitor (MAOI) therapy or use within the last 14 days:**
    - Codeine
    - Meperidine
    - Morphine
    - Tapentadol
    - Tramadol

- **Recommended limited duration of use:**
    - Meperidine: avoid use for >48 hours
    - Benzhydrocodone: should not be used for >14 days

- **CYP 3A4 Interactions:**
    - Benzhydrocodone
    - Hydrocodone
    - Meperidine
    - Oxycodone
    - Tramadol
    - Hydromorphone, morphine, oxymorphone, oxycodone, and fentanyl are potent schedule II controlled opioid agonists that have the highest potential for abuse and risk of producing respiratory depression.

- **Other Safety Concerns:**
    - **Meperidine, Tramadol & Tapentadol**
        - Serotonin syndrome (due to SNRI effects)
    - **Oxycodone:**
        - Contraindicated in patients with moderate to severe hepatic impairment
    - **Oxymorphone:**
        - Contraindicated in hypercarbia
    - **Meperidine:**
        - Use with caution in patients with atrial flutter and other supraventricular tachycardias
        - Generates an active metabolite (normeperidine) which can accumulate and precipitate anxiety, tremors, or seizures
            - Risk increases with preexisting CNS or renal dysfunction, prolonged use (more than 48 hours), and cumulative dose (>600 mg/24 hours in adults)
            - **PER LABEL:** Oral meperidine should not be used since first-pass metabolism decreases efficacy while increasing normeperidine concentrations
                - Naloxone does not reverse, and may even worsen, neurotoxicity.

MME CONVERSION FACTORS

Drug name (strength units) MME Conversion Factor	Type of Opioid (strength units) MME Conversion Factor
Benzhydrocodone (mg)	1.2
Codeine (mg)	0.15
Hydrocodone (mg)	1
Hydromorphone (mg)	4
Levorphanol tartrate (mg)	11
Meperidine hydrochloride (mg)	0.1
Morphine	1
Oxycodone (mg)	1.5
Oxymorphone (mg)	3
Tapentadol (mg)	0.4
Tramadol (mg)	0.1

CURRENT UTILIZATION

ND Medicaid Utilization (06/2018 – 05/2019)		
Label Name	**Rx Num**	**Total Reimb Amt**
Benzhydrocodone/ APAP	-	-
Codeine	-	-
Codeine/APAP	662	$11,353.32
Fentora	-	-
Actiq	-	-
Subsya	-	-
Lazanda	-	-
Abstral	-	-
Hydrocodone/ APAP	6,559	$164,206.16
Hydrocodone/ ibuprofen	71	$1,758.44
Hydromorphone	234	$42,78.17
Meperidine	9	$155.81
Morphine	185	$5,207.16
Oxycodone	1,837	$34,412.04
Oxycodone/ APAP	2,972	$81,575.14

Oxymorphone	-	-
Tapentadol	5	$2,042.33
Tramadol	2,452	$37,990.69
Tramadol/ APAP	78	$1,141.7

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REVIEW OF AGENTS FOR TREATMENT OF THROMBOCYTOPENIA

THROMBOCYTOPENIA:

- Thrombocytopenia is defined as a platelet count below the lower limit of normal (<150,000/µL).
  - Mild: PLT of 100,000 to 150,000/µL
  - Moderate: PLT of 50,000 to 99,000/µL
  - Severe: PLT of <50,000/µL)
- Associated low platelet counts carry risks that may range from life-threatening bleeding to no risk at all, depending on comorbid conditions and the cause of thrombocytopenia.
  - Clinical predictors of bleeding include prior bleeding at a similar platelet count and the presence of wet purpura (eg, in mucosal membranes).
    - Surgical bleeding generally may be a concern with platelet counts <50,000/µL (<100,000/µL for some high-risk procedures such as neurosurgery or major cardiac or orthopedic surgery).
    - Severe spontaneous bleeding is most likely with platelet counts <20,000 to 30,000/µL, especially below 10,000/µL.
- Often caused by one of a variety of conditions, with associated risks that range from life-threatening to none.
  - Typically caused by:
    - **Decreased platelet production in the bone marrow:**
      - Bone marrow disorders that impair platelet production (eg, nutrient deficiencies, myelodysplastic syndromes, infection/sepsis)
    - **Peripheral platelet destruction by antibodies:**
      - Anti-platelet antibodies occur in primary immune thrombocytopenia ITP and also in secondary ITP (e.g. from another autoimmune syndrome such as SLE).
    - **Platelet consumption in thrombi:**
      - Occurs in disseminated intravascular coagulation (DIC), thrombocytopenic purpura (TTP), & hemolytic uremic syndrome (HUS).
    - **Dilution:**
      - Typically caused by fluid resuscitation or massive transfusion.
    - **Sequestration (pooling) of platelets in the spleen:**
      - Conditions that increase spleen size or cause splenic congestion through portal hypertension (eg, cirrhosis, alcoholic liver disease) can decrease the platelet count without altering the total platelet mass in the body.
- **Immune thrombocytopenia (ITP):**
  - Common cause of moderate to severe thrombocytopenia in an otherwise asymptomatic adult.
  - Other cell lines are unaffected (ie, ITP does not cause anemia or leukopenia).
  - The prevailing understanding of the mechanism of ITP is antibody-mediated platelet destruction. However, anti-platelet antibodies are not always detected, and their testing is not clinically useful.
  - A presumptive diagnosis of ITP is made when the history, physical examination, and laboratory data do not suggest an alternative diagnosis.

DRUG TREATMENTS:

- **Chronic immune thrombocytopenia (ITP)**
  - **FIRST-LINE AGENTS:**
    - **Glucocorticoids** raise the platelet count in approximately 2/3 of patients, with complete long-term remissions with glucocorticoids have been reported in approximately 20%.
      - Long-term glucocorticoid administration should be avoided, as the consequences may be severe and several alternatives are available.
    - **IVIG** can raise the platelet count within 24 to 48 hours in most patients with ITP, which will usually persist for 2-6 weeks
    - **Anti-D** (anti-D, WinRho, RhoGAM, Rho(D) immune globulin) is an alternative to conventional IVIG for patients whose red blood cells (RBCs) are Rh(D) positive.

- **2ND LINE:**
  - **THROMBOPOIETIN RECEPTOR AGONISTS (TPO-RAs)**
    - Small-molecule peptide and non-peptide agents that bind to and activate TPO receptor, stimulating the production of platelets in the bone marrow.
    - Generally, platelet counts increase in approximately 7 to 14 days.
    - Once treatment is D/C, PLT generally return to baseline levels or even below baseline.

- **Promacta (eltrombopag):**
  - Treatment of thrombocytopenia in adult & pediatric patients ≥1 year of age with who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy.
    - Should only be used if the degree of thrombocytopenia & clinical condition increase the risk for bleeding.
    - Use the lowest dose necessary to achieve & maintain platelet count ≥50,000/mm3.
    - D/C if platelet count does not respond to a level to avoid clinically important bleeding after 4 weeks at the maximum recommended dose.

- **Nplate (romiplostim):**
  - Treatment of adult patients with chronic ITP (pediatric patients with ITP for ≥6 months) who have had insufficient response to corticosteroids, immunoglobulins, or splenectomy.
    - D/C if platelet count does not increase to a level sufficient to avoid clinically important bleeding after 4 weeks at the maximum recommended dose of 10 mcg/kg/week.
    - Should only be used when the degree of thrombocytopenia & clinical condition increase the bleeding risk; should not be used in attempt to normalize platelet counts.
    - REMS Program: Risks of progression of myelodysplastic syndromes to AML, thrombotic/thromboembolic complications, bone marrow fibrosis/reticulin formation, worsened thrombocytopenia after cessation of romiplostim therapy, & medication errors associated with serious outcomes.

  - **SPLEEN TYROSINE KINASE (Syk) INHIBITOR:**
    - Inhibits the signal transduction of Syk, which affects cellular proliferation, differentiation, survival and immune regulation via IgG and B-cell receptor signaling and autoantibody production. Through this action, Syk inhibitors reduce antibody-mediated destruction of platelets.
    - **Tavalisse (fostamatinib):**
      - Treatment of thrombocytopenia in adults with chronic immune thrombocytopenia (ITP) who have had an insufficient response to a previous treatment.
        - D/C after 12 weeks if platelet count does not increase to a level sufficient to avoid clinically important bleeding.
        - Dose adjustments on to achieve & maintain platelet count of at least 50,000/mm3 & based on experienced ADRs.
        - If ADRs would cause dose reduction below 100 mg/day is required, D/C.

- **<u>Chronic liver disease-associated thrombocytopenia</u>**
  - Treatment primarily consists of non-pharmacologic therapies (weight loss, control of DM, etc), with pharmacologic treatments limited to those areas.
  - **TPO-RAs:** Used only when a patient is scheduled to undergo a procedure that puts the patient at risk of bleeding:
    - **Doptelet (avatrombopag):**
      - Do not use to normalize platelet counts.
      - Begin 10 to 13 days prior to the procedure.
      - Obtain a platelet count prior to therapy & on the day of the procedure.
    - **Mulpleta (lusutrombopag):**
      - Do not use to normalize platelet counts in patients with chronic liver disease.
      - Begin 8 to 14 days prior to the procedure.
      - Obtain a platelet count prior to therapy & within 2 days of the procedure.

- **Chronic hepatitis C infection-associated thrombocytopenia**
  - **Promacta (eltrombopag):**
    - Treatment of thrombocytopenia in patients with chronic hepatitis C to allow the initiation & maintenance of interferon-based therapy.
      - Should only be used if the degree of thrombocytopenia prevents initiation of or limits the ability to maintain interferon-based therapy (d/c if antiviral therapy is D/Cd).

Summary of Available TPO-RAs and Syk Inhibitors					
	Promacta	**Doptelet**	**Mulpleta**	**Nplate**	**Tavalisse**
Chronic ITP	X			X	X (refractory)
Chronic liver disease-associated thrombocytopenia		X	X		
Chronic HCV-associated thrombocytopenia	X				
Administration	Oral w/o food	Oral w/ food	Oral w/ or w/o food	SubQ	Oral w/ or w/o food
Normal Dosing	≥18: 25/100 mg 1-17: 12.5-75 mg	40-60 mg	3 mg	1-10 mcg/kg	100-150 mg
Frequency	Daily	Daily for 5 days	Daily for 7 days	Weekly	Twice daily
Adjustments	Based on PLT, genetics, & hepatic function	Based on PLT	None	Based on PLT	Based on PLT & ADRs
Ages	≥1 years	≥18 years	≥18 years	≥1 years	≥18 years
Additional concerns	▪ Hepatotoxicity ▪ Thromboembolism ▪ Cataract	▪ Thromboembolism	▪ Thromboembolism	▪ Malignancy ▪ Thromboembolism ▪ Bone marrow reticulin fiber form.	▪ Hypertension ▪ GI Toxicity ▪ Neutropenia ▪ Hepatotoxicity

COST

Drug	Strength	Package Size	AWP Pkg Price	AWP Unit Price
Doptelet	20 mg tab	10	$11,328.00	$1,132.80
Mulpleta	3 mg tab	7	$10,200.00	$1,457.15
Promacta	12.5 mg powder	30 packets	$5,911.76	$197.06
Promacta	12.5 mg tab	30	$5,911.76	$197.06
Promacta	25 mg tab	30	$5,911.76	$197.06
Promacta	50 mg tab	30	$10,698.41	$356.61
Promacta	75 mg tab	30	$16,047.61	$534.92
Tavalisse	100 mg tab	60	$11,793.60	$196.56
Tavalisse	150 mg tab	60	$11,793.60	$196.56
Nplate	250 mcg injection	1	$2,230.30	$2,230.30
Nplate	500 mcg injection	1	$4,460.59	$4,460.59

CURRENT UTILIZATION

ND Medicaid Utilization (06/2018 – 05/2019)		
Label Name	**Rx Num**	**Total Reimb Amt**
Doptelet	-	-
Mulpleta	-	-
Promacta	5	$31,345.59
Tavalisse	-	-
Nplate	-	-

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REVIEW OF AGENTS FOR TREATMENT OF INTERSTITIAL CYSTITIS

INTERSTITIAL CYSTITIS:

- Interstitial cystitis/bladder pain syndrome (IC/BPS) is a condition involving chronic bladder pain or discomfort that can have a profound detrimental impact on quality of life
- Diagnosis of IC/BPS applies to patients with chronic bladder pain in the absence of other etiologies of the symptoms, and the American Urological Association definition of IC/BPS requires that the duration of symptoms is at least 6 weeks
- Symptoms:
    - Persistent unpleasant sensations (described as pain, pressure, or discomfort) that are attributable to the bladder that can vary
        - Most consistent feature is an increase in discomfort with bladder filling and a relief with voiding. This can vary from mild pressure to severe, debilitating pain.
        - Other symptoms:
            - Urinary urgency
            - Increased frequency of urination
            - Suprapubic, urethral, and/or perineal pain
            - Dysuria
            - Sensation of bladder spasms/pressure
            - Gross hematuria
    - Majority of patients' symptoms that are of gradual onset, with worsening of discomfort, urgency and frequency over a period of months
- The pathophysiology of IC/BPS bladder pain is not well understood, and it is likely that such symptoms represent more than one underlying etiology

TREATMENT FOR INTERSTITIAL CYSTITIS:

- Treatment goal of providing symptomatic relief

First-line: Self-care and behavior modification

- Application of local heat or cold over the bladder or perineum.
- Avoidance of activities or food or beverages that exacerbate symptoms
- Fluid management (restriction or increased fluid intake)
- Bladder training with urge suppression
- Non-absorbed, cation exchange polymer that increases fecal potassium excretion through binding of potassium in the lumen of the GI tract.

Second-Line: Oral medications

- There are no large comparative studies of oral medications for IC/BPS.
- **Amitriptyline:**
    - **Effects**: Believed to have analgesic properties and relieves the depressive symptoms associated with chronic pain
    - **Use**: Most widely used agent for initial pharmacologic therapy of IC/BPS, as the effects can be observed soon after therapy.
    - **Data**: A randomized trial (n = 50) found that 4 months of amitriptyline (25-100 mg daily) resulted in a significantly higher proportion of patients than placebo with a >30% decrease in a symptom score (42% vs. 13%). Another randomized trial (n = 271) of 12 weeks of amitriptyline therapy (10-75 mg once daily) failed to demonstrate significant increase in the rate of moderate or marked symptom improvement against placebo (55% vs. 45%), however, a significantly higher rate of improvement was observed in the subgroup of patients (n = 106) who were able to tolerate doses of ≥50 mg daily (77% vs. 53%).
    - **Dosing**: Amitriptyline appears to be most effective at higher doses but use of these doses is limited by bothersome or dangerous adverse effects.
        - Typical dosing regimen: starts at 10 mg qhs, escalating at weekly intervals to 25, 50, and 75 mg (or to the maximum tolerated dose).
    - **ADRs**: Adverse effects include anticholinergic effects (eg, dry mouth, urinary retention); sedation; weight gain; orthostatic hypotension; and cardiac conduction abnormalities.

- **Warnings/Precautions:** Do not use with MAOIs or cisapride. Avoid use with CYP 450 inhibitors.

- **Elmiron (pentosan polysulfate sodium):**
  - **Effects**: the drug appears to adhere to the bladder wall mucosa where it may act as a buffer to protect the tissues from irritating substances in the urine
  - **Use**: Only agent that is specifically FDA-approved for treatment of IC/BPS. The typical regimen is 100 mg three times daily. May take 3-6 months after initiation to experience symptom relief.
  - **Data**: A meta-analysis of five randomized trials found that PPS resulted in a significantly higher rate of clinical improvement than placebo, although the magnitude of effect was modest (relative risk [RR] 1.69, 95% CI 1.16-2.46).
  - **Dosing:** Recommended dosing is 100 mg three times daily.
  - **ADRs**: May be associated with hair loss, although this side effect is mild and reversible. Rarely, it has been associated with mild elevation in liver function enzymes, and it is recommended to obtain these blood tests after six months of therapy. In our practice, we do not continue monitoring liver function enzymes if the initial testing at six months is normal.
  - **Warnings/Precautions:** Bleeding complications of ecchymosis, epistaxis, and gum hemorrhage have been reported (mild anticoagulant); May cause immunoallergic thrombocytopenia; Alopecia is associated with Elmiron; Do not use in patients with known history of HSR to heparin agents.
- **Antihistamines:**
  - Hydroxyzine is the most commonly used antihistamine for the treatment of IC/BPS
  - **Use:** Most commonly used in patients who patients who also have an allergic disorder, and it those who complain of insomnia because they void frequently during the night.
  - **Effects:** reduces histaminergic reactions, and potential benefit is hypothesis that hypersensitivity is a part of the pathogenesis of IC/BPS.
  - **Data:** The only randomized trial (31 patient assigned to hydroxyzine, 31 to placebo) to evaluate this therapy did not find a significantly higher response rate with hydroxyzine compared with placebo (31% versus 20%).
  - **Dosing:** 25 to 50 mg at bedtime.
  - **ADRs:** Most common include sedation, dizziness, and drowsiness.
  - **Warnings/Precautions:** QT prolongation; Acute generalized exanthematous pustulosis; May worsen glaucoma; May cause respiratory depression.

COST

Drug	Strength	Package Size	AWP Pkg Price	AWP Unit Price
Amitriptyline	10 mg tab	100	$31.80	$0.32
Amitriptyline	25 mg tab	100	$63.60	$0.64
Amitriptyline	50 mg tab	100	$127.00	$1.27
Amitriptyline	75 mg tab	100	$190.80	$1.91
Amitriptyline	100 mg tab	100	$254.00	$2.54
Amitriptyline	150 mg tab	100	$381.00	$3.81
Elmiron	100 mg caps	100	$1,105.42	$11.05
Hydroxyzine	10 mg tab	100	$63.50	$0.64
Hydroxyzine	25 mg tab	100	$91.98	$0.92
Hydroxyzine	50 mg tab	100	$111.55	$1.12

CURRENT UTILIZATION

ND Medicaid Utilization (06/2018 – 05/2019)		
Label Name	**Rx Num**	**Total Reimb Amt**
Amitriptyline	2,017	$64,759.06
Elmiron	51	$30,364.73
Hydroxyzine	2,450	$77,930.36

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REVIEW OF AGENTS FOR TREATMENT OF NARCOLEPSY

NARCOLEPSY:

- Narcolepsy is a chronic sleep disorder characterized by overwhelming daytime drowsiness and sudden attacks of sleep. People with narcolepsy often find it difficult to stay awake for long periods of time, regardless of the circumstances, and can occur with a sudden loss of muscle tone (type 1 narcolepsy) or without this cataplexy (type 2 narcolepsy)
- Narcolepsy is a chronic condition for which there's no cure. However, medications and lifestyle changes can help you manage the symptoms.
- **Symptoms**
  - Excessive daytime sleepiness/sudden falling asleep
  - Decreased alertness and focus throughout the day
  - In type 1 narcolepsy: sudden loss of muscle tone (cataplexy) including slurred speech to complete weakness of most muscles, and may last up to a few minutes
    - Triggered by intense emotions (e.g. laughter, excitement, fear, surprise or anger)
  - Sleep paralysis: a temporary inability to move or speak while falling asleep or upon waking
  - Rapid transition to REM sleep, usually within 15 minutes of falling asleep
  - Hallucinations when falling asleep or waking
- **Causes**
  - The exact cause of narcolepsy is unknown. Potentially due to low levels of hypocretin, which helps regulate wakefulness and REM sleep
- **Normal sleep pattern vs. narcolepsy**
  - Normal sleep: process begins with non-rapid eye movement (NREM) sleep, in which brain waves slow considerably. This transitions to REM sleep after ~1 hour
  - Narcolepsy: suddenly entering into REM sleep without first experiencing NREM sleep, both at night and during the day

DRUG TREATMENT FOR NARCOLEPSY:

- Goals: To obtain "normal" alertness during conventional waking hours or to maximize alertness at important times of the day (eg, during work, school, or while driving)

- **Currently Available, FDA-Approved Agents:**

	modafinil (Provigil) / armodafinil (Nuvigil)	**Methylphenidate**	**Amphetamines**	**sodium oxybate (Xyrem)**
MoA	Blocks reuptake of DA into presynaptic neurons	Blocks reuptake of DA & NE into presynaptic neurons	Blocks reuptake of DA & NE into presynaptic neurons	Metabolite of GABA; inhibitory effects on GABA-B receptors
Effects	Promotes wakefulness into early evening	Promotes wakefulness	Most potent wakefulness-promoting drugs	Reduces cataplexy and may decrease daytime sleepiness
Dosing	Dosed once daily	Dosed once or multiple times daily depending on product used	Dosed once or multiple times daily depending on product used	6-9 g in 2 divided doses at night: 1st qhs; 2nd 2.5-4 hours later
CIs	HSR	HSR; use during or within 14 days following MAOI; marked anxiety, tension, and agitation; glaucoma; Tourette syndrome or tics	HSR; use during or within 14 days following MAOI; marked anxiety, tension, and agitation; glaucoma; Tourette syndrome or tics	Coadministration with alcohol or sedative hypnotic agents; succinic semialdehyde dehydrogenase deficiency
Warning	SJS; potential for abuse	Potential for abuse and dependence.	High potential for abuse and dependence.	↑ anxiety, confusion, psychosis, agitation, depression, sleepwalking; Abuse potential
Caution	Psychosis, depression, or mania; CV disease; Tourette syndrome	CV disease; pre-existing psychosis; Seizure; PVD	CV disease; pre-existing psychosis; Seizure; PVD	Compromised respiratory function; CV Disease
ADRs	HA, nausea, dry mouth, anorexia, and diarrhea	↑ BP, palpitations, HA, insomnia, nervousness, restlessness, anxiety, anorexia	↑ BP, palpitations, HA, insomnia, nervousness, restlessness, anxiety, anorexia	Confusion, HA, Dizziness, N/V, weight loss, urinary incontinence, worsening of depression, sleepwalking

Newly FDA-Approved Agent:

- **Sunosi (solriamfetol):** FDA approved in March 2019, expected to be on the market in 2019.
  - **MoA:** selective dopamine and norepinephrine reuptake inhibitor with wake-promoting effects
  - **Indication:** To improve wakefulness in adult patients with excessive daytime sleepiness associated with narcolepsy or obstructive sleep apnea (OSA).
  - **Dosing:**
    - Initial dose: 75 mg once daily in the morning
      - May be increased to a max dose of 150 mg daily after 3 days (as tolerated)
  - **CI:** Concomitant use with/within 14 days of an MAOI
  - **Warnings/Precautions:**
    - May cause dose-dependent increases in blood pressure and heart rate
    - Psychiatric symptoms including anxiety, insomnia, and irritability have been reported with use
  - **ADRs:** Most common are headache, nausea, and decreased appetite

COST

Drug	Strength	Package Size	AWP Pkg Price	AWP Unit Price
armodafinil	250 mg tab	60	$1,967.73	$21.86
modafinil	200 mg tab	100	$3,994.48	$39.90
Concerta ER	54 mg tabs	100	$1,599.83	$15.99
Vyvanse	70 mg caps	100	$1,215.36	$12.15
Xyrem	500 mg/mL sln	180 mL	$5,540.93	$30.78
Sunosi	N/A	N/A	N/A	N/A

CURRENT UTILIZATION

ND Medicaid Utilization (06/2018 – 05/2019)		
Label Name	**Rx Num**	**Total Reimb Amt**
armodafinil	45	$1,607.72
modafinil	80	$2,605.81
Methylphenidate	12,610	$1,865,026.96
Vyvanse	6,398	$1,451,091.17
Amphetamine/ dextroamphetamine	5,965	$478,601.14
Xyrem	2	$24,875.40
Sunosi	-	-

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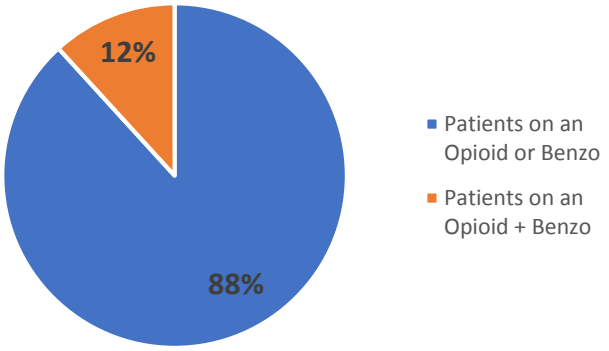
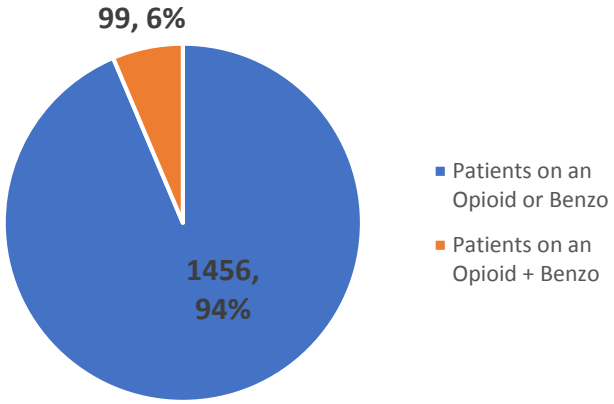
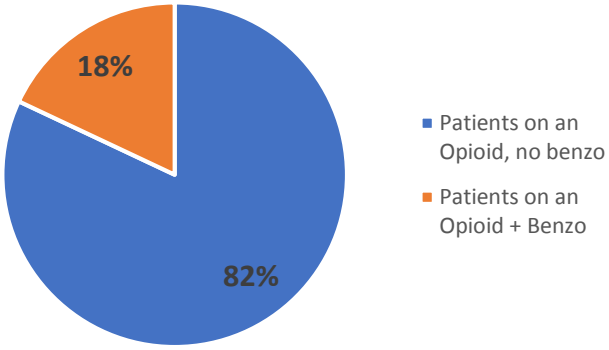
2018: % of Patients on Opioid or Benzo



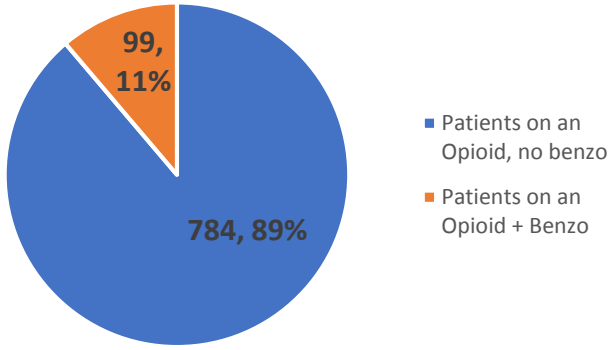
% of Patients on Opioid or Benzo



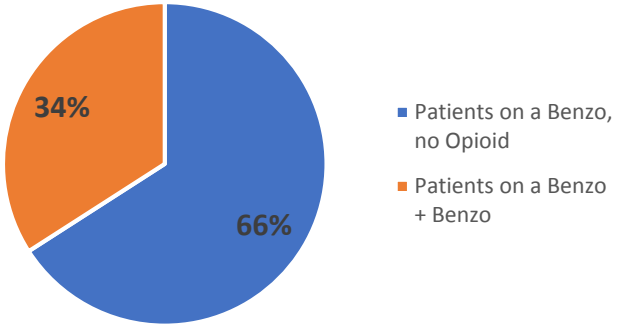
2018: % of Patients on Opioid also on Benzo



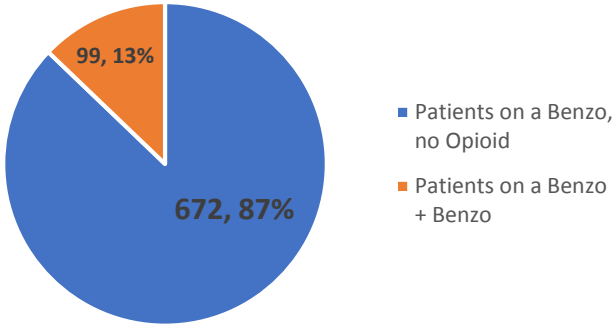
2019: % of Patients on Opioid also on Benzo

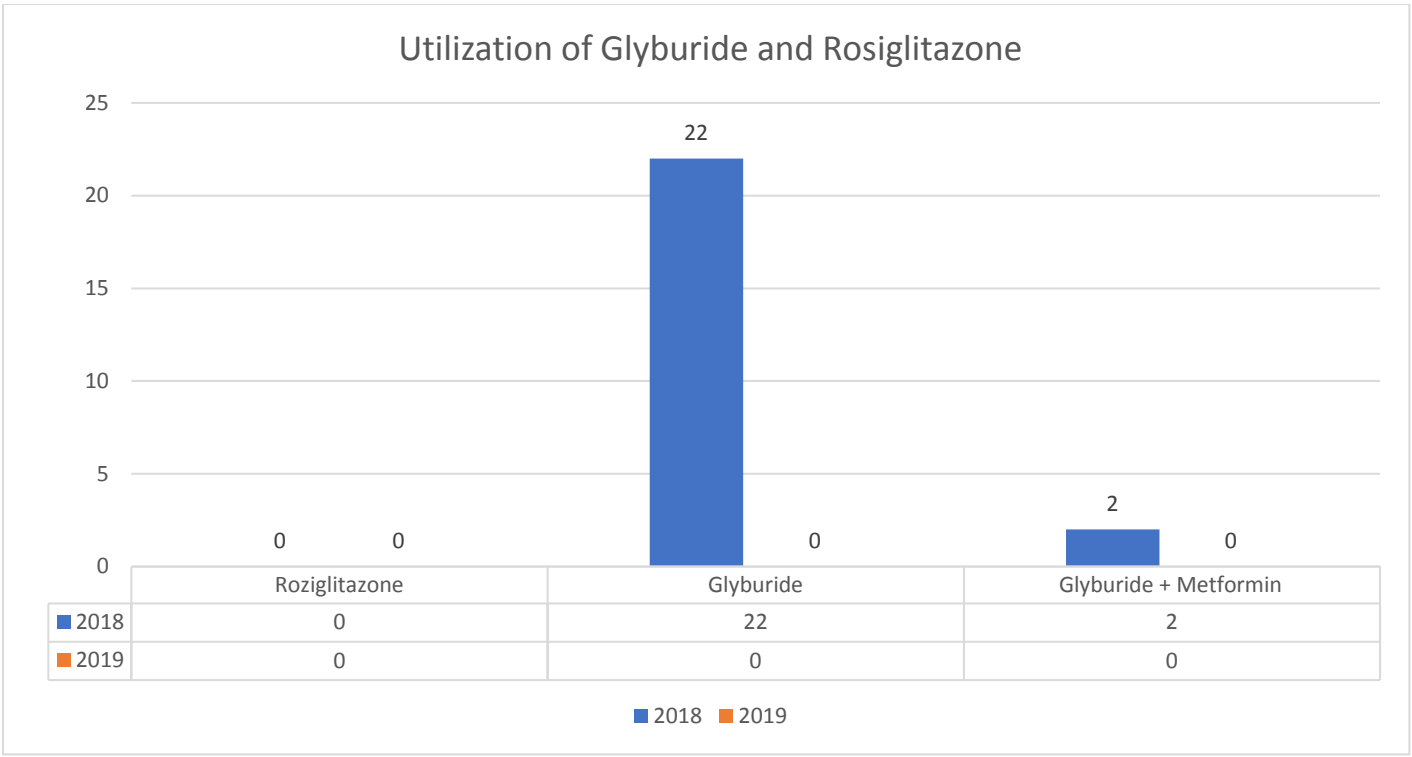


2018: % of Patients on Benzo also on Opioid



2019: % of Patients on Benzo also on Opioid




Utilization of Glyburide and Rosiglitazone
25
20
15
10
5
0
22
2
0
0
0
0
Roziglitazone
Glyburide
Glyburide + Metformin
2018
0
22
2
2019
0
0
0
2018
2019

NORTH DAKOTA MEDICAID
RETROSPECTIVE DRUG UTILIZATION REVIEW
CRITERIA RECOMMENDATIONS
2ND QUARTER 2019

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

1. Talazoparib / Overutilization _____ _____
Alert Message: The recommended dose of Talzenna (talazoparib) is 1 mg orally once daily.

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C **(Negating)**
Talazoparib		CKD Stage 3

Max Dose: 1 mg/day

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Talzenna Prescribing Information, October 2018, Pfizer, Inc.

2. Talazoparib / Therapeutic Appropriateness _____ _____
Alert Message: Talzenna (talazoparib) may be over-utilized. For patients with moderate renal impairment (CLcr 30 - 59 mL/min), the recommended dose of talazoparib is 0.75 mg once daily. Talazoparib has not been studied in patients with severe renal impairment (CLcr < 30 mL/min) or patients requiring hemodialysis.

Conflict Code: TA - Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C **(Include)**
Talazoparib 1mg		CKD Stage 3

Max Dose: 0.75mg/day

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Talzenna Prescribing Information, October 2018, Pfizer, Inc.

3. Talazoparib / Pregnancy / Pregnancy Negating _____ _____
Alert Message: Based on its mechanism of action and findings from animal data, Talzenna (talazoparib) can cause fetal harm when administered to a pregnant woman. Apprise pregnant women and females of reproductive potential of the potential risk to a fetus.

Conflict Code: MC – Drug (Actual) Disease Precaution
Drugs/Diseases

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

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Talzenna Prescribing Information, October 2018, Pfizer, Inc.

4. Talazoparib / Therapeutic Appropriateness _____ _____

Alert Message: Advise females of reproductive potential to use effective contraception during treatment and for at least 7 months following the last dose of Talzenna (talazoparib). Based on its mechanism of action and findings from animal data, talazoparib can cause fetal harm when administered to a pregnant woman.

Conflict Code: MC – Drug (Actual) Disease Precaution
Drugs/Diseases

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

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Talzenna Prescribing Information, October 2018, Pfizer, Inc.

5. Talazoparib / Lactation _____ _____

Alert Message: There are no data on the presence of Talzenna (talazoparib) in human milk, the effects of the drug on milk production, or the effects of the drug on the breastfed child. Because of the potential for serious adverse reactions in a breastfed child from talazoparib, advise lactating women not to breastfeed during treatment with talazoparib and for at least 1 month after the final dose.

Conflict Code: MC – Drug (Actual) Disease Precaution
Drugs/Diseases

Util A	Util B	Util C
Talazoparib	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Talzenna Prescribing Information, October 2018, Pfizer, Inc.

6. Talazoparib / Males _____ _____

Alert Message: Based on genotoxicity and animal reproduction studies, advise male patients with female partners of reproductive potential and pregnant partners to use effective contraception during treatment with Talzenna (talazoparib) and for at least 4 months following the last dose.

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C
Talazoparib		

Gender: Male

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Talzenna Prescribing Information, October 2018, Pfizer, Inc.

7. Talazoparib / Certain P-gp Inhibitors _____ _____

Alert Message: Coadministration with certain P-gp inhibitors (i.e., amiodarone, carvedilol, clarithromycin, itraconazole, or verapamil) may significantly increase Talzenna (talazoparib) exposure. If coadministration of talazoparib with one of these P-gp inhibitors cannot be avoided, reduce the talazoparib dose to 0.75 mg once daily. When the P-gp inhibitor is discontinued, increase the talazoparib dose (after 3 - 5 half-lives of the inhibitor) to the dose used prior to the initiation of the P-gp inhibitor.

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

Util A	Util B	Util C
Talazoparib 1 mg	Amiodarone	
	Carvedilol	
	Clarithromycin	
	Itraconazole	
	Verapamil	

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Talzenna Prescribing Information, October 2018, Pfizer, Inc.

8. Talazoparib / Other P-gp Inhibitors _____ _____

Alert Message: Coadministration of Talzenna (talazoparib), a P-gp substrate, with the identified P-gp inhibitor may result in increased talazoparib exposure. Monitor the patient for talazoparib-related adverse reactions.

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

Util A	Util B		Util C
Talazoparib	Dronedarone	Cobicistat	
	Lapatinib	Ritonavir	
	Propafenone	Saquinavir	
	Quinidine	Ranolazine	

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Talzenna Prescribing Information, October 2018, Pfizer, Inc.

9. Talazoparib / BCRP Inhibitors _____ _____

Alert Message: Coadministration of Talzenna (talazoparib), a BCRP substrate, with a BCRP inhibitor may result in increased talazoparib exposure. If coadministration cannot be avoided, monitor the patient for talazoparib-related adverse reactions.

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

Util A	Util B			Util C
Talazoparib	Cyclosporine	Elbasvir/Grazoprevir	Rolapitant	Teriflunomide
	Nelfinavir	Eltrombopag	Safinamide	Vemurafenib
	Atazanavir	Fostamatinib	Sirolimus	Velpatasvir/Sofosbuvir
	Daclatasvir	Glecaprevir/Pibrentasvir	Sulfasalazine	
	Leflunomide	Ledipasvir/Sofosbuvir	Tacrolimus	
	Osimertinib	Regorafenib	Tedizolid	

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Talzenna Prescribing Information, October 2018, Pfizer, Inc.

10. Talazoparib / Therapeutic Appropriateness _____ _____

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

Conflict Code: TA - Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C
Talazoparib		

Age Range: 0-17 yoa

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Talzenna Prescribing Information, October 2018, Pfizer, Inc.

11. Apalutamide / Overutilization _____ _____

Alert Message: Erleada (apalutamide) may be over-utilized. The recommended dosage of apalutamide is 240 mg (four 60 mg tablets) orally once daily.

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C
Apalutamide		

Max Dose: 240 mg/day

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Erleada Prescribing Information, Feb. 2018, Janssen Products.

12. Apalutamide / Pregnancy / Pregnancy Negating _____ _____

Alert Message: Erleada (apalutamide) is contraindicated for use in pregnant women because the drug can cause fetal harm and potential loss of pregnancy. Apalutamide is not indicated for use in females, so animal embryo-fetal developmental toxicology studies were not conducted with apalutamide. Based on its mechanism of action, apalutamide may cause fetal harm when administered during pregnancy.

Conflict Code: MC – Drug (Actual) Disease Precaution/Warning
Drugs/Diseases

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

Gender: Female
Age Range: 11 – 50

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Erleada Prescribing Information, Feb. 2018, Janssen Products.

13. Apalutamide / Falls & Fractures _____ _____

Alert Message: Falls and fractures occurred in patients receiving Erleada (apalutamide). Evaluate patients for fracture and fall risk. Monitor and manage patients at risk for fractures according to established treatment guidelines and consider use of bone-targeted agents. In clinical trials, fractures occurred in 12% of patients treated with apalutamide and in 7% of patients treated with placebo.

Conflict Code: MC – Drug (Actual) Disease Precaution/Warning
Drugs/Diseases

Util A	Util B	Util C
Apalutamide	Falls	
	Fractures	

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Erleada Prescribing Information, Feb. 2018, Janssen Products.

14. Apalutamide / Seizures _____ _____

Alert Message: Seizures have been reported in patients receiving Erleada (apalutamide). Permanently discontinue apalutamide in patients who develop a seizure during treatment. It is unknown whether anti-epileptic medications will prevent seizures with apalutamide. Advise patients of the risk of seizures while receiving apalutamide and of engaging in any activity where sudden loss of consciousness could cause harm to themselves or others.

Conflict Code: MC – Drug (Actual) Disease Precaution/Warning
Drugs/Diseases

Util A	Util B	Util C **(Include)**
Apalutamide		Seizures
		Epilepsy

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Erleada Prescribing Information, Feb. 2018, Janssen Products.

15. Apalutamide / Strong CYP2C8 and CYP3A4 Inhibitors _____ _____

Alert Message: Co-administration of Erleada (apalutamide) with a strong CYP2C8 or CYP3A4 inhibitor is predicted to increase the steady-state exposure of the active moieties (sum of unbound apalutamide plus the potency-adjusted unbound N-desmethyl-apalutamide) of apalutamide. No initial dose adjustment is necessary; however, reduce the apalutamide dose based on tolerability.

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

Util A	Util B		Util C
Apalutamide	Clarithromycin	Voriconazole	
	Nefazodone	Ketoconazole	
	Cobicistat	Itraconazole	
	Saquinavir	Posaconazole	
	Ritonavir	Gemfibrozil	
	Nelfinavir	Clopidogrel	
	Indinavir		

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Erleada Prescribing Information, Feb. 2018, Janssen Products.

16. Apalutamide / Therapeutic Effectiveness _____ _____

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

Conflict Code: TA - Therapeutic Effectiveness
Drugs/Diseases

Util A	Util B	Util C
Apalutamide		

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Erleada Prescribing Information, Feb. 2018, Janssen Products.

17. Apalutamide / Nonadherence _____ _____

Alert Message: Based on refill history, your patient may be under-utilizing Erleada (apalutamide). Non-adherence to the prescribed dosing regimen may result in subtherapeutic effects, which may lead to decreased patient outcomes and additional medical cost.

Conflict Code: LR - Nonadherence
Drugs/Diseases

Util A	Util B	Util C
Apalutamide		

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

18. Apalutamide / P-gp, BCRP or OATP1B1 Substrates _____ _____

Alert Message: Erleada (apalutamide) was shown to be a weak inducer of P-glycoprotein (P-gp), breast cancer resistance protein (BCRP), and organic anion transporting polypeptide 1B1 (OATP1B1) clinically. Concomitant use of apalutamide with medications that are substrates of P-gp, BCRP, or OATP1B1 can result in lower exposure of these medications. Use caution if substrates of P-gp, BCRP, or OATP1B1 must be co-administered with apalutamide and evaluate for loss of activity if medication is continued.

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

Util A	Util B	Util C
Apalutamide	Sulfasalazine	
	Dabigatran	
	Digoxin	
	Fexofenadine	
	Pibrentasvir	
	Sofosbuvir	
	Pravastatin	
	Prazosin	
	Chlorothiazide	
	Methotrexate	
	Topotecan	
	Dantrolene	
	Cimetidine	
	Nitrofurantoin	

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Erleada Prescribing Information, Feb. 2018, Janssen Products.

19. Apalutamide / Substrates of CYP 3A4, 2C19, and 2C9 _____ _____

Alert Message: Erleada (apalutamide) is a strong inducer of CYP3A4 and CYP2C19, and a weak inducer of CYP2C9 in humans. Concomitant use of apalutamide with medications that are primarily metabolized by CYP3A4, CYP2C19, or CYP2C9 can result in lower exposure to these medications. Substitution for these medications is recommended when possible or evaluate for loss of activity if medication is continued.

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

Util A	Util B				
Apalutamide	Amiodarone	Buprenorphine	Budesonide	Etoposide	Dexamethasone
	Fentanyl	Cabozantinib	Buspirone	Estrogens	Dexlansoprazole
	Omeprazole	Midazolam	Disopyramide	Cariprazine	Copanlisib
	Quinidine	Warfarin	Abemaciclib	Amlodipine	Ceritinib
	Crizotinib	Diazepam	Lansoprazole	Acalabrutinib	Atazanavir
	Chlordiazepoxide	Dabrafenib	Diltiazem	Rabeprazole	Oxycodone
	Bedaquiline	Cilostazol	Saxagliptin	Rilpivirine	Celecoxib
	Hydrocodone	Bortezomib	Etravirine	Dapsone	Lovastatin
	Glimepiride	Carbamazepine	Bosutinib	Citalopram	Darifenacin
	Duvelisib	Phenytoin	Lansoprazole	Brexpiprazole	Clarithromycin
	Darunavir	Efavirenz	Fluticasone	Brigatinib	Clonazepam
	Dasatinib	Elbasvir	Brentuximab	Bromocriptine	Clorazepate
	Eletriptan	Everolimus	Felodipine	Encorafenib	Eplerenone
	Erlotinib	Estazolam	Estradiol	Eszopiclone	Ethosuximide
	Etoposide	Flurazepam	Fosamprenavir	Gefitinib	Glasdegib
	Guanfacine	Haloperidol	Idelalisib	Imatinib	Isradipine
	Ixabepilone	Lapatinib	Larotrectinib	Levomilnacipran	Macitentan
	Maraviroc	Mefloquine	Repaglinide	Midostaurin	Mifepristone
	Mirtazapine	Nelfinavir	Torsemide	Nevirapine	Nifedipine
	Nilotinib	Nisoldipine	Ospemifene	Paclitaxel	Palbociclib
	Panobinostat	Pazopanib	Pimavanserin	Vilazodone	Zolpidem
	Quetiapine	Ranolazine	Regorafenib	Ribociclib	Rifabutin
	Roflumilast	Romidepsin	Ruxolitinib	Saquinavir	Sildenafil
	Silodosin	Solifenacin	Sunitinib	Suvorexant	Tadalafil
	Tasimelteon	Temsirolimus	Ticagrelor	Tipranavir	Tolterodine
	Toremifene	Trabectedin	Trazodone	Triazolam	Valbenazine
	Verapamil	Vardenafil	Vemurafenib	Venlafaxine	
	Vinblastine	Vincristine	Vinorelbine	Vorapaxar	
	Avatrombopag	Carvedilol	Simvastatin	Dronabinol	
	Glyburide	Nateglinide	Ospemifene	Terbinafine	
	Valproic Acid	Bictegravir	Pantoprazole	Atorvastatin	

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Erleada Prescribing Information, Feb. 2018, Janssen Products.

20. Apalutamide / UGT Substrates _____ _____

Alert Message: Concomitant administration of Erleada (apalutamide) with medications that are substrates of UDP-glucuronosyl transferase (UGT) can result in decreased substrate exposure. Use caution if substrates of UGT must be co-administered with apalutamide and evaluate for loss of activity.

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

Util A	Util B			
Apalutamide	Canagliflozin	Deferasirox	Indacaterol	Irinotecan
	Imipramine	Acetaminophen	Vorinostat	Pitavastatin
	Lamotrigine	Lorazepam	Olanzapine	
	Mycophenolate	Raloxifene	Oxazepam	

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Erleada Prescribing Information, Feb. 2018, Janssen Products.
Knights KM, Rowland A, Miners JO. Renal Drug Metabolism in Humans: The Potential for Drug-Endobiotic Interaction involving P-450 (CYP) and UDP-Glucuronosyltransferase (UGT). Br J Clin Pharmacol. 2013 Oct;76(4):587-602.

21. Apalutamide / Therapeutic Appropriateness _____ _____

Alert Message: Based on the mechanism of action and findings in an animal reproduction study, advise male patients with female partners of reproductive potential to use effective contraception during treatment and for 3 months after the last dose of Erleada (apalutamide).

Conflict Code: TA - Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C
Apalutamide		

Gender: Male

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Erleada Prescribing Information, Feb. 2018, Janssen Products.

22. Galcanezumab-gnlm / Overutilization _____ _____

Alert Message: Emgality (galcanezumab-gnlm) may be over-utilized. The recommended dosage of galcanezumab-gnlm is 240 mg once as a loading dose, followed by doses of 120 mg injected subcutaneously once monthly.

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C
Galcanezumab-gnlm		

Max Dose:1 pen per month after loading dose

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Emgality Prescribing Information, September 2018, Eli Lilly and Company.

Criteria Recommendations *Approved* *Rejected*

23. Galcanezumab-gnlm / Therapeutic Appropriateness (0 – 17 yoa) _____ _____
Alert Message: The safety and effectiveness of Emgality (galcanezumab-gnlm) in pediatric patients have not been established.

Conflict Code: TA - Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C
Galcanezumab-gnlm		

Age Range: 0 - 17 yoa

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Emgality Prescribing Information, September 2018, Eli Lilly and Company.

24. Galcanezumab-gnlm / Lactation _____ _____
Alert Message: There are no data on the presence of Emgality (galcanezumab-gnlm) in human milk, the effects on the breastfed infant, or the effects on milk production. The development and health benefits of breastfeeding should be considered along with the mother's clinical need for galcanezumab-gnlm and any potential adverse effects on the breastfed infant from galcanezumab-gnlm or from the underlying maternal condition.

Conflict Code: MC – Drug (actual) Disease Precaution
Drugs/Diseases

Util A	Util B	Util C
Galcanezumab-gnlm	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Emgality Prescribing Information, September 2018, Eli Lilly and Company.

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

Conflict Code: LR Nonadherence
Drugs/Diseases

Util A	Util B	Util C
Galcanezumab-gnlm		

References:
Osterberg L, Blaschke T. Adherence to Medication. N Engl J Med. 2005; 353(5):487–497.
Emgality Prescribing Information, September 2018, Eli Lilly and Company.
Clinical Pharmacology, 2019 Elsevier/Gold Standard.

26. Symtuza / Overutilization _____ _____

Alert Message: The manufacturer's recommended dose of Symtuza (darunavir/cobicistat/emtricitabine/tenofovir alafenamide) is one tablet taken orally once daily.

Conflict Code: ER - Overutilization

Drugs/Diseases		
Util A	Util B	Util C
Darunavir/Cobicistat/Emtricitabine/Tenofovir Alafenamide		

Max Dose: 1 tablet/day

References:
Symtuza Prescribing Information, Feb. 2019, Janssen Products, LP.
Clinical Pharmacology, 2019 Elsevier/Gold Standard.

27. Symtuza / Severe Renal Impairment _____ _____

Alert Message: Symtuza (darunavir/cobicistat/emtricitabine/tenofovir alafenamide) is not recommended for use in patients with severe renal impairment (creatinine clearance below 30 mL per minute).

Conflict Code: TA – Therapeutic Appropriateness

Drugs/Diseases		
Util A	Util B	Util C **(Include)**
Darunavir/Cobicistat/Emtricitabine/Tenofovir Alafenamide		CKD 4 CKD 5 ESRD

References:
Symtuza Prescribing Information, Feb. 2019, Janssen Products, LP.
Clinical Pharmacology, 2019 Elsevier/Gold Standard.

28. Symtuza / Severe Hepatic Impairment _____ _____

Alert Message: Symtuza (darunavir/cobicistat/emtricitabine/tenofovir alafenamide) is not for use in patients with severe hepatic impairment (Child-Pugh Class C). This fixed dose combination antiretroviral agent has not been studied in patients with severe hepatic impairment, and there are only limited data regarding the use of the individual components in patients with severe hepatic impairment.

Conflict Code: TA – Therapeutic Appropriateness

Drugs/Diseases		
Util A	Util B	Util C **(Include)**
Darunavir/Cobicistat/Emtricitabine/Tenofovir Alafenamide		Cirrhosis Hepatic Failure

References:
Symtuza Prescribing Information, Feb. 2019, Janssen Products, LP.
Clinical Pharmacology, 2019 Elsevier/Gold Standard.

29. Symtuza / Contraindicated Drugs _____ _____

Alert Message: A review of recent pharmacy claims shows that the patient is receiving concurrent therapy with Symtuza (darunavir/cobicistat/emtricitabine/tenofovir alafenamide) and a drug that is contraindicated with the fixed-dose combination agent. Concurrent use of Symtuza with the identified drug may result in serious and/or life-threatening events.

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

Util A	Util B		Util C
Darunavir/Cobicistat/Emtricitabine/Tenofovir Alafenamide	Alfuzosin	Elbasvir/Grazoprevir	
	Ranolazine	Lovastatin	
	Dronedarone	Simvastatin	
	Carbamazepine	Revatio	
	Phenobarbital	Midazolam	
	Phenytoin	Triazolam	
	Rifampin	Dihydroergotamine	
	Lurasidone	Ergotamine	
	Pimozide	Methylergonovine	

References:
Symtuza Prescribing Information, Feb. 2019, Janssen Products, LP.
Clinical Pharmacology, 2019 Elsevier/Gold Standard.

30. Symtuza / Colchicine / Hepatic & Renal Impairment _____ _____

Alert Message: Coadministration of Symtuza (darunavir/cobicistat/emtricitabine/tenofovir alafenamide) with colchicine is contraindicated in patients with renal and/or hepatic impairment due to the potential for serious and/or life-threatening reactions.

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

Util A	Util B	Util C **(Include)**
Darunavir/Cobicistat/Emtricitabine/Tenofovir Alafenamide	Colchicine	Renal Impairment
		Hepatic Impairment

References:
Symtuza Prescribing Information, Feb. 2019, Janssen Products, LP.
Clinical Pharmacology, 2019 Elsevier/Gold Standard.

31. Symtuza / Colchicine / Hepatic & Renal Impairment Negating _____ _____

Alert Message: Coadministration of Symtuza (darunavir/cobicistat/emtricitabine/tenofovir alafenamide) with colchicine may increase colchicine plasma concentrations, and dosage adjustment of colchicine is required. Please refer to the official prescribing Information for the recommended dosage adjustments. The concurrent use of Symtuza with colchicine in patients with renal or hepatic impairment is contraindicated.

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

Util A	Util B	Util C **(Negating)**
Darunavir/Cobicistat/Emtricitabine/Tenofovir Alafenamide	Colchicine	Renal Impairment
		Hepatic Impairment

References:
Symtuza Prescribing Information, Feb. 2019, Janssen Products, LP.
Clinical Pharmacology, 2019 Elsevier/Gold Standard

32. Symtuza / Therapeutic Appropriateness _____ _____

Alert Message: The safety and effectiveness of Symtuza (darunavir/cobicistat/emtricitabine/tenofovir alafenamide) in pediatric patients less than 18 years of age have not been established. Darunavir, a component of the combination antiretroviral product, is not recommended in pediatric patients below the age of 3 years of age because of toxicity and mortality in juvenile rats dosed with darunavir.

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C
Darunavir/Cobicistat/Emtricitabine/Tenofovir Alafenamide		

Age Range: 0 – 17 yoa

References:
Symtuza Prescribing Information, Feb. 2019, Janssen Products, LP.

33. Symtuza / Pregnancy / Pregnancy Negating _____ _____

Alert Message: Symtuza (darunavir/cobicistat/emtricitabine/tenofovir alafenamide) is not recommended for use during pregnancy because of substantially lower exposures of darunavir and cobicistat during pregnancy. Symtuza should not use initiated in pregnant individuals. An alternative regimen is recommended for individuals who become pregnant during therapy with Symtuza.

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C **(Negating)**
Darunavir/Cobicistat/Emtricitabine/Tenofovir Alafenamide	Pregnancy	Miscarriage Delivery Abortion

Age Range: 11 - 50
Gender: Female

References:
Symtuza Prescribing Information, Feb. 2019, Janssen Products, LP.
Clinical Pharmacology, 2019 Elsevier/Gold Standard

34. Symtuza / All Other Antiretrovirals _____ _____

Alert Message: Symtuza (darunavir/cobicistat/emtricitabine/tenofovir alafenamide) is a complete regimen for the treatment of HIV-1 infection and coadministration with other antiretroviral medications is not recommended.

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B
Darunavir/Cobicistat/Emtricitabine/Tenofovir Alafenamide	Cellular Chemokine Receptor (CCR5) Antagonist Fusion Inhibitors Integrase Inhibitors NNRTIs NRTIs Nucleotide Analog Reverse Transcriptase Inhibitors Protease Inhibitors Other Antiretroviral Combos

References:
Symtuza Prescribing Information, Feb. 2019, Janssen Products, LP.
Clinical Pharmacology, 2019 Elsevier/Gold Standard

35. Symtuza / Nonadherence _____ _____

Alert Message: Based on the refill history, your patient may be under-utilizing Symtuza (darunavir/cobicistat/emtricitabine/tenofovir alafenamide). 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.

Conflict Code: LR - Nonadherence
Drugs/Diseases

Util A	Util B	Util C
Darunavir/Cobicistat/Emtricitabine/Tenofovir Alafenamide		

References:
Symtuza Prescribing Information, Feb. 2019, Janssen Products, LP.
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. May 30, 2018.
Available at: http://www.aidsinfo.nih.gov/guidelines/ht,l/1/adult-and-adolescent-arv/0
Hoffman C, Mulcahy F, Goals and Principles of Therapy - Eradication, Cost, Prevention and Adherence. Hoffman C, Rockstroh J, Kamps BS, eds. HIV Medicine, Flying Publishers-Paris, Cagliari, Wuppertal, Sevilla, 2005:167-173.

36. Symtuza / Antiarrhythmic Agents that are CYP3A4 Substrates _____ _____

Alert Message: Caution should be exercised when administering Symtuza (darunavir/cobicistat/emtricitabine/tenofovir alafenamide) with antiarrhythmic drugs that are CYP3A4 and/or CYP2D6 substrates. Concurrent use of these agents may result in an increase in the antiarrhythmic plasma concentrations due to inhibition of CYP3A4- and/or CYP2D6-mediated metabolism by the darunavir and cobicistat components of the antiretroviral agent. Clinical monitoring is recommended upon coadministration with these antiarrhythmics.

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

Util A	Util B	Util C
Darunavir/Cobicistat/Emtricitabine/Tenofovir Alafenamide	Amiodarone Disopyramide Flecainide Propafenone Quinidine Mexiletine	

References:
Symtuza Prescribing Information, Feb. 2019, Janssen Products, LP.
Clinical Pharmacology, 2019 Elsevier/Gold Standard

37. Symtuza / Digoxin _____ _____

Alert Message: Caution should be exercised when administering Symtuza (darunavir/cobicistat/emtricitabine/tenofovir alafenamide) with digoxin, a P-gp substrate. Concurrent use of these agents may result in an increase in digoxin plasma concentrations due to inhibition of P-gp-mediated transport by the cobicistat component of the antiretroviral.

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

Util A	Util B	Util C
Darunavir/Cobicistat/Emtricitabine/Tenofovir Alafenamide	Digoxin	

References:
Symtuza Prescribing Information, Feb. 2019, Janssen Products, LP.
Clinical Pharmacology, 2019 Elsevier/Gold Standard.

38. Symtuza / Clarithromycin & Erythromycin _____ _____

Alert Message: Caution should be exercised when administering Symtuza (darunavir/cobicistat/emtricitabine/tenofovir alafenamide) with clarithromycin or erythromycin. Concurrent use of these agents may result in an increase in the plasma concentrations of the antibacterial as well as the darunavir and cobicistat components of the antiretroviral. The antibacterial and antiretroviral agents are both CYP3A4 substrates and inhibitors. Consider alternative antibiotic therapy with concomitant use of Symtuza.

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

Util A	Util B	Util C
Darunavir/Cobicistat/Emtricitabine/Tenofovir Alafenamide	Clarithromycin Erythromycin	

References:
Symtuza Prescribing Information, Feb. 2019, Janssen Products, LP.
Clinical Pharmacology, 2019 Elsevier/Gold Standard.

39. Symtuza / Dasatinib _____ _____

Alert Message: Caution should be exercised when administering Symtuza (darunavir/cobicistat/emtricitabine/tenofovir alafenamide) with dasatinib. Concurrent use of these agents may result in an increase in dasatinib plasma concentrations due to the inhibition of dasatinib CYP3A4-mediated metabolism by the cobicistat and darunavir components of the antiretroviral. A decrease in the dasatinib dosage may be necessary. Consult the official prescribing Information for dasatinib for the recommended dosage adjustment.

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

Util A	Util B	Util C
Darunavir/Cobicistat/Emtricitabine/Tenofovir Alafenamide	Dasatinib	

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Symtuza Prescribing Information, Feb. 2019, Janssen Products, LP.

40. Symtuza / Eslicarbazepine & Oxcarbazepine _____ _____

Alert Message: The concurrent use of Symtuza (darunavir/cobicistat/emtricitabine/tenofovir alafenamide) with eslicarbazepine or oxcarbazepine may cause a significant decrease in the plasma concentrations or the darunavir and cobicistat components of the combination antiretroviral agent, leading to the potential loss of virologic efficacy and development of resistance. Consider alternative anticonvulsant or antiretroviral therapy to avoid changes in exposure. If coadministration is necessary, monitor the patient for lack of virologic response.

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

Util A	Util B	Util C
Darunavir/Cobicistat/Emtricitabine/Tenofovir Alafenamide	Eslicarbazepine Oxcarbazepine	

References:
Symtuza Prescribing Information, Feb. 2019, Janssen Products, LP.

41. Symtuza / Clonazepam _____ _____

Alert Message: Caution should be exercised when coadministering Symtuza (darunavir/cobicistat/emtricitabine/tenofovir alafenamide) with clonazepam. Concurrent use of these agents may result in an increase in clonazepam plasma concentrations due to inhibition of clonazepam CYP3A4-mediated metabolism by the darunavir and cobicistat components of the antiretroviral. Clinical monitoring of clonazepam is recommended when these agents are coadministered.

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

Util A	Util B	Util C
Darunavir/Cobicistat/Emtricitabine/Tenofovir Alafenamide	Clonazepam	

References:
Symtuza Prescribing Information, Feb. 2019, Janssen Products, LP.
Clinical Pharmacology, 2019 Elsevier/Gold Standard.

42. Symtuza / SSRIs, TCAs & Trazodone _____ _____

Alert Message: Caution should be exercised when coadministering Symtuza (darunavir/cobicistat/emtricitabine/tenofovir alafenamide) with a selective serotonin reuptake inhibitor, tricyclic antidepressant, or trazodone. The cobicistat component of the antiretroviral agent is a CYP3A4 and CYP2D6 inhibitor, and concurrent use with drugs that are CYP3A4 and CYP2D6 substrates may result in elevated substrate plasma concentrations. Careful dose titration of the antidepressant and monitoring for response are recommended.

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

Util A	Util B	Util C
Darunavir/Cobicistat/Emtricitabine/Tenofovir Alafenamide	SSRIs TCAs Trazodone	

References:
Symtuza Prescribing Information, Feb. 2019, Janssen Products, LP.
Clinical Pharmacology, 2019 Elsevier/Gold Standard.

43. Symtuza / Ketoconazole & Itraconazole _____ _____

Alert Message: Coadministration of Symtuza (darunavir/cobicistat/emtricitabine/tenofovir alafenamide) with ketoconazole or itraconazole may result in increased plasma concentrations of the antifungal as well as the plasma concentrations of the antiretroviral components, darunavir and cobicistat. Darunavir, cobicistat, and both of the antifungals are CYP3A4 substrates and inhibitors. Monitor the patient for increased antifungal and antiretroviral-related adverse effect.

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

Util A	Util B	Util C
Darunavir/Cobicistat/Emtricitabine/Tenofovir Alafenamide	Ketoconazole Itraconazole	

References:
Symtuza Prescribing Information, Feb. 2019, Janssen Products, LP.
Clinical Pharmacology, 2019 Elsevier/Gold Standard.

44. Symtuza / Voriconazole _____ _____

Alert Message: Concurrent use of Symtuza (darunavir/cobicistat/emtricitabine/tenofovir alafenamide) with voriconazole is not recommended unless the benefit/risk assessment justifies the use of voriconazole. Voriconazole and the antiretroviral components, darunavir and cobicistat, are CYP3A4 substrates and inhibitors. The effects of concurrent use if unknown.

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

Util A	Util B	Util C
Darunavir/Cobicistat/Emtricitabine/Tenofovir Alafenamide	Voriconazole	

References:
Symtuza Prescribing Information, Feb. 2019, Janssen Products, LP.
Clinical Pharmacology, 2019 Elsevier/Gold Standard.

45. Rifabutin / Symtuza _____ _____

Alert Message: The concurrent use of Symtuza darunavir/cobicistat/emtricitabine/tenofovir alafenamide) with rifabutin is not recommended. If the combination is warranted, the recommended dose of rifabutin is 150 mg every other day. Coadministration may result in increased rifabutin plasma concentrations and decreased tenofovir plasma concentrations. Monitor the patient for rifabutin-related adverse reactions including neutropenia and uveitis.

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C **(Include)**
Rifabutin		Darunavir/Cobicistat/Emtricitabine/Tenofovir Alafenamide

Max Dose: 1 capsule every other day

References:
Symtuza Prescribing Information, Feb. 2019, Janssen Products, LP.
Clinical Pharmacology, 2019 Elsevier/Gold Standard.

46. Symtuza / Rifapentine _____ _____

Alert Message: The concurrent use of Symtuza (darunavir/cobicistat/emtricitabine/tenofovir alafenamide) with rifapentine is not recommended due to the potential for loss of virologic efficacy and development of resistance to the antiretroviral agent. The darunavir and tenofovir components of the antiretroviral combination product are CYP3A4 substrates, and coadministration with rifapentine, a CYP3A4 inducer, can result in decreased plasma concentrations of both tenofovir and darunavir.

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

Util A	Util B	Util C
Darunavir/Cobicistat/Emtricitabine/Tenofovir Alafenamide	Rifapentine	

References:
Symtuza Prescribing Information, Feb. 2019, Janssen Products, LP.
Clinical Pharmacology, 2019 Elsevier/Gold Standard.

47. Symtuza / Antipsychotics Metabolized by 3A4 or 2D6 _____ _____

Alert Message: Coadministration of Symtuza (darunavir/cobicistat/emtricitabine/tenofovir alafenamide) with an antipsychotic agent that is metabolized by CYP3A4 or CYP2D6 may result in increased plasma concentrations of the antipsychotic. The darunavir and cobicistat components of the combination antiretroviral agent are CYP3A4 and CYP2D6 inhibitors. Dose reduction of the antipsychotic may be needed when coadministered with Symtuza.

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

Util A	Util B		Util C
Darunavir/Cobicistat/Emtricitabine/Tenofovir Alafenamide	Perphenazine	Pimavanserin	
	Risperidone	Lurasidone	
	Thioridazine	Aripiprazole	
	Quetiapine	Brexpiprazole	
	Chlorpromazine	Cariprazine	
	Fluphenazine	Iloperidol	
	Haloperidol	Clozapine	

References:
Symtuza Prescribing Information, Feb. 2019, Janssen Products, LP.
Clinical Pharmacology, 2019 Elsevier/Gold Standard.

48. Symtuza / Beta-Blockers Metabolized by 2D6 _____ _____

Alert Message: Coadministration of Symtuza (darunavir/cobicistat/emtricitabine/tenofovir alafenamide) with a beta-blocker that is metabolized by CYP2D6 may result in increased plasma concentrations of the beta-blocker. The darunavir and cobicistat components of the combination antiretroviral agent are CYP2D6 inhibitors. Clinical monitoring for signs of increased pharmacologic and adverse effects of the beta-blocker is recommended.

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

Util A	Util B	Util C
Darunavir/Cobicistat/Emtricitabine/Tenofovir Alafenamide	Carvedilol	
	Metoprolol	
	Propranolol	
	Timolol	

References:
Symtuza Prescribing Information, Feb. 2019, Janssen Products, LP.
Clinical Pharmacology, 2019 Elsevier/Gold Standard.

49. Symtuza / Calcium Channel Blockers Metabolized by 3A4 _____ _____

Alert Message: Coadministration of Symtuza (darunavir/cobicistat/emtricitabine/tenofovir alafenamide) with a calcium channel blocker (CCB) that is metabolized by CYP3A4 may result in increased plasma concentrations or the calcium channel blocker. The darunavir and cobicistat components of the combination antiretroviral agent are CYP3A4 inhibitors. Clinical monitoring for signs of increased pharmacologic and adverse effects of the CCB is recommended.

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

Util A	Util B		Util C
Darunavir/Cobicistat/Emtricitabine/Tenofovir Alafenamide	Amlodipine	Nicardipine	
	Diltiazem	Nimodipine	
	Felodipine	Nisoldipine	
	Verapamil	Nifedipine	
	Isradipine		

References:
Symtuza Prescribing Information, Feb. 2019, Janssen Products, LP.
Clinical Pharmacology, 2019 Elsevier/Gold Standard.

50. Symtuza / Atorvastatin 40 & 80 mg _____ _____

Alert Message: The dosage of atorvastatin should not exceed 20 mg/day in patients receiving concurrent therapy with Symtuza (darunavir/cobicistat/emtricitabine/tenofovir alafenamide). Cobicistat and darunavir are both CYP3A4 inhibitors and concurrent use with atorvastatin, a CYP3A4 substrate, may result in increased atorvastatin plasma concentrations and increased risk for atorvastatin-related adverse reactions (e.g., myopathy and rhabdomyolysis).

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

Util A	Util B	Util C
Darunavir/Cobicistat/Emtricitabine/Tenofovir Alafenamide	Atorvastatin 40 & 80 mg	

References:
Symtuza Prescribing Information, Feb. 2019, Janssen Products, LP.
Clinical Pharmacology, 2019 Elsevier/Gold Standard.

51. Symtuza / Rosuvastatin 20 & 40 mg _____ _____

Alert Message: The dosage of rosuvastatin should not exceed 10 mg/day in patients receiving concurrent therapy with Symtuza (darunavir/cobicistat/emtricitabine/tenofovir alafenamide). Cobicistat is an OATP1B1 transport inhibitor and concurrent use with rosuvastatin, an OATP1B1 substrate, may result in increased rosuvastatin plasma concentrations and increased risk of rosuvastatin-related adverse reactions (e.g., myopathy and rhabdomyolysis).

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

Util A	Util B	Util C
Darunavir/Cobicistat/Emtricitabine/Tenofovir Alafenamide	Rosuvastatin 20 & 40 mg	

References:
Symtuza Prescribing Information, Feb. 2019, Janssen Products, LP.
Clinical Pharmacology, 2019 Elsevier/Gold Standard.

52. Symtuza / Dexamethasone _____ _____

Alert Message: The concurrent use of Symtuza (darunavir/cobicistat/emtricitabine/tenofovir alafenamide with dexamethasone may result in decreased plasma concentrations of the cobicistat and darunavir components of the combo antiretroviral which may result in loss of antiretroviral efficacy and the potential development of viral resistance. Darunavir and cobicistat are CYP3A4 substrates and dexamethasone is a CYP3A4 inducer. Dexamethasone concentrations may be increased. Alternative corticosteroid therapy should be considered for patients prescribed Symtuza.

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

Util A	Util B	Util C
Darunavir/Cobicistat/Emtricitabine/Tenofovir Alafenamide	Dexamethasone	

References:
Symtuza Prescribing Information, Feb. 2019, Janssen Products, LP.
Clinical Pharmacology, 2019 Elsevier/Gold Standard.

53. Symtuza / Methylprednisolone _____ _____

Alert Message: The concurrent use of Symtuza (darunavir/cobicistat/emtricitabine/tenofovir alafenamide with methylprednisolone may result in increased methylprednisolone plasma concentrations and the potential for Cushing's syndrome and adrenal suppression. Darunavir and cobicistat are CYP3A4 inhibitors and methylprednisolone is a CYP3A4 substrate. Alternative corticosteroids whose concentrations are less affected by CYP3A4 inhibitors should be considered, especially for long-term use.

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

Util A	Util B	Util C
Darunavir/Cobicistat/Emtricitabine/Tenofovir Alafenamide	Methylprednisolone	

References:
Symtuza Prescribing Information, Feb. 2019, Janssen Products, LP.
Clinical Pharmacology, 2019 Elsevier/Gold Standard.

54. Symtuza / Prednisone _____ _____

Alert Message: The concurrent use of Symtuza (darunavir/cobicistat/emtricitabine/tenofovir alafenamide) with prednisone may result in increased prednisone plasma concentrations and the potential for Cushing's syndrome and adrenal suppression. Darunavir and cobicistat are CYP3A4 inhibitors and prednisone is a CYP3A4 substrate. Alternative corticosteroids whose concentrations are less affected by CYP3A4 inhibitors should be considered, especially for long-term use.

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

Util A	Util B	Util C
Darunavir/Cobicistat/Emtricitabine/Tenofovir Alafenamide	Prednisone	

References:
Symtuza Prescribing Information, Feb. 2019, Janssen Products, LP.
Clinical Pharmacology, 2019 Elsevier/Gold Standard.

55. Symtuza / Fluticasone _____ _____

Alert Message: The concurrent use of Symtuza (darunavir/cobicistat/emtricitabine/tenofovir alafenamide) with a fluticasone-containing product may result in increased fluticasone plasma concentrations due to inhibition of fluticasone CYP3A4-mediated metabolism by the cobicistat and darunavir components of the antiretroviral product. Concomitant therapy may result in adverse systemic corticosteroid effects.

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

Util A	Util B	Util C
Darunavir/Cobicistat/Emtricitabine/Tenofovir Alafenamide	Fluticasone	

References:
Symtuza Prescribing Information, Feb. 2019, Janssen Products, LP.
Clinical Pharmacology, 2019 Elsevier/Gold Standard.

56. Symtuza / Mometasone _____ _____

Alert Message: The concurrent use of Symtuza (darunavir/cobicistat/emtricitabine/tenofovir alafenamide) with mometasone may result in increased mometasone plasma concentrations due to inhibition of mometasone CYP3A4-medicated metabolism by the cobicistat and darunavir components of the antiretroviral product. Concomitant therapy may result in adverse systemic corticosteroid effects. Alternative corticosteroids should be considered, particularly for long-term use.

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

Util A	Util B	Util C
Darunavir/Cobicistat/Emtricitabine/Tenofovir Alafenamide	Mometasone	

References:
Symtuza Prescribing Information, Feb. 2019, Janssen Products, LP.
Clinical Pharmacology, 2019 Elsevier/Gold Standard.

57. Symtuza / CYP3A4 Metabolized Sedatives _____ _____

Alert Message: Coadministration of Symtuza (darunavir/cobicistat/emtricitabine/tenofovir alafenamide) with a sedative/hypnotic that is metabolized by CYP3A4 may result in increased plasma concentrations of the sedative/hypnotic. The darunavir and cobicistat components of the combination antiretroviral agent are CYP3A4 inhibitors. Dose reduction and clinical monitoring of the sedative/hypnotic agent should be considered when coadministered with Symtuza.

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

Util A	Util B	Util C
Darunavir/Cobicistat/Emtricitabine/Tenofovir Alafenamide	Buspirone Diazepam Estazolam Zolpidem Flurazepam Chlordiazepoxide Clorazepate	

References:
Symtuza Prescribing Information, Feb. 2019, Janssen Products, LP.
Clinical Pharmacology, 2019 Elsevier/Gold Standard.

58. Symtuza / Salmeterol _____ _____

Alert Message: Coadministration of Symtuza (darunavir/cobicistat/emtricitabine/tenofovir alafenamide) with a salmeterol-containing agent is not recommended. Concurrent use may result in increased risk of cardiovascular adverse events associated with salmeterol, including QT prolongation, palpitations, and sinus tachycardia.

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

Util A	Util B	Util C
Darunavir/Cobicistat/Emtricitabine/Tenofovir Alafenamide	Salmeterol	

References:
Symtuza Prescribing Information, Feb. 2019, Janssen Products, LP.
Clinical Pharmacology, 2019 Elsevier/Gold Standard.

59. Symtuza / Bosentan _____ _____

Alert Message: The concurrent use of Symtuza (darunavir/cobicistat/emtricitabine/tenofovir alafenamide) with Tracleer (bosentan) may result in increased plasma concentrations of bosentan and decreased plasma concentrations of cobicistat and darunavir. All three agents are CYP3A4 substrates while bosentan is a potent CYP3A4 inducer and cobicistat and darunavir are CYP3A inhibitors. Refer to the official cobicistat prescribing Information for the appropriate dosing upon initiation of concomitant therapy with these agents.

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

Util A	Util B	Util C
Darunavir/Cobicistat/Emtricitabine/Tenofovir Alafenamide	Bosentan	

References:
Symtuza Prescribing Information, Feb. 2019, Janssen Products, LP.
Clinical Pharmacology, 2019 Elsevier/Gold Standard.

60. Symtuza / Everolimus _____ _____

Alert Message: Coadministration of Symtuza (darunavir/cobicistat/emtricitabine/tenofovir alafenamide) with everolimus (a CYP3A4 and P-gp substrate) is not recommended. The cobicistat and darunavir components of the antiretroviral agent are strong inhibitors of CYP3A4 and also inhibit P-gp transport. Concurrent use of these drugs may result in a significant increase in everolimus plasma concentrations.

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

Util A	Util B	Util C
Darunavir/Cobicistat/Emtricitabine/Tenofovir Alafenamide	Everolimus	

References:
Symtuza Prescribing Information, Feb. 2019, Janssen Products, LP.
Clinical Pharmacology, 2019 Elsevier/Gold Standard.

61. Symtuza / CYP3A4 Metabolized Immunosuppressants _____ _____

Alert Message: Caution should be exercised when coadministering Symtuza (darunavir/cobicistat/emtricitabine/tenofovir alafenamide) with an immunosuppressant that is a CYP3A4 substrate. The cobicistat and darunavir components of the antiretroviral agent are inhibitors of CYP3A4, and concurrent use of these agents may result in increased immunosuppressant plasma concentrations. Therapeutic drug monitoring is recommended with concomitant use.

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

Util A	Util B	Util C
Darunavir/Cobicistat/Emtricitabine/Tenofovir Alafenamide	Cyclosporine Sirolimus Tacrolimus	

References:
Symtuza Prescribing Information, Feb. 2019, Janssen Products, LP.
Clinical Pharmacology, 2019 Elsevier/Gold Standard.

62. Symtuza / Tramadol _____ _____

Alert Message: The concurrent use of Symtuza (darunavir/cobicistat/emtricitabine/tenofovir alafenamide) with a tramadol-containing agent may result in increased plasma concentrations of the parent drug tramadol and decreased levels of the active metabolite of tramadol. A dose decrease for tramadol may be needed when these agents are coadministered. Tramadol is a CPY3A4 and CYP2D6 substrate, and the cobicistat and darunavir components of the antiretroviral agent inhibit both CYP3A4- and CYP2D6-mediated metabolism.

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

Util A	Util B	Util C
Darunavir/Cobicistat/Emtricitabine/Tenofovir Alafenamide	Tramadol	

References:
Symtuza Prescribing Information, Feb. 2019, Janssen Products, LP.
Clinical Pharmacology, 2019 Elsevier/Gold Standard.

63. Symtuza / Avanafil _____ _____

Alert Message: The concurrent use of Stendra (avanafil) with Symtuza (darunavir/cobicistat/emtricitabine/tenofovir alafenamide) is not recommended because a safe and effective avanafil dosage regimen has not been established. Consider an alternative PDE-5 inhibitor that has dosing recommendations established and provided in the official prescribing Information.

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

Util A	Util B	Util C
Darunavir/Cobicistat/Emtricitabine/Tenofovir Alafenamide	Avanafil	

References:
Symtuza Prescribing Information, Feb. 2019, Janssen Products, LP.
Clinical Pharmacology, 2019 Elsevier/Gold Standard.

64. Symtuza / Buprenorphine _____ _____

Alert Message: The concurrent use of Symtuza (darunavir/cobicistat/emtricitabine/tenofovir alafenamide) with a buprenorphine-containing agent may result in increased buprenorphine plasma concentrations. Buprenorphine is a CYP3A4 substrate, and the cobicistat and darunavir components of the antiretroviral agent inhibit CYP3A4-mediated metabolism. If buprenorphine is initiated in a patient taking Symtuza, titrate the buprenorphine dose to the desired effect. If Symtuza is initiated in a patient taking buprenorphine, a dose adjustment of buprenorphine may be needed.

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

Util A	Util B	Util C
Darunavir/Cobicistat/Emtricitabine/Tenofovir Alafenamide	Buprenorphine	

References:
Symtuza Prescribing Information, Feb. 2019, Janssen Products, LP.
Clinical Pharmacology, 2019 Elsevier/Gold Standard.

65. Symtuza / Drospirenone/Ethinyl Estradiol _____ _____

Alert Message: The concurrent use of Symtuza (darunavir/cobicistat/emtricitabine/tenofovir alafenamide) with a drospirenone-containing agent may result in increased drospirenone plasma concentrations, putting the patients at risk of drospirenone-related adverse effects (e.g., hyperkalemia). Clinical monitoring is recommended when these agents are coadministered.

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

Util A	Util B	Util C
Darunavir/Cobicistat/Emtricitabine/Tenofovir Alafenamide	Drospirenone	

References:
Symtuza Prescribing Information, Feb. 2019, Janssen Products, LP.
Clinical Pharmacology, 2019 Elsevier/Gold Standard.

66. Symtuza / Estrogen-based Contraceptives _____ _____

Alert Message: The concurrent use of Symtuza (darunavir/cobicistat/emtricitabine/tenofovir alafenamide) with estrogen-based contraceptives may result in decreased pharmacologic effects of the contraceptive agent. Additional or alternative (non-hormonal) forms of contraception should be considered in these patients.

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

Util A	Util B	Util C
Darunavir/Cobicistat/Emtricitabine/Tenofovir Alafenamide	Estrogen-Based Contraceptives	

References:
Symtuza Prescribing Information, Feb. 2019, Janssen Products, LP.
Clinical Pharmacology, 2019 Elsevier/Gold Standard.

67. Erenumab-aooe / Overutilization _____ _____

Alert Message: Aimovig (erenumab-aooe) may be over-utilized. The recommended dosage of erenumab-aooe is 70 mg injected subcutaneously once monthly. Some patients may benefit from a dosage of 140 mg injected subcutaneously once monthly, which is administered as two consecutive subcutaneous injections of 70 mg each.

Drugs/Diseases

Util A	Util B	Util C
Erenumab-aooe		

Max Dose: 2 pens per month

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Aimovig Prescribing Information, May 2018, Amgen Inc.

68. Erenumab-aooe / Therapeutic Appropriateness (0 – 17 yoa) _____ _____

Alert Message: The safety and effectiveness of Aimovig (erenumab-aooe) in pediatric patients have not been established.

Drugs/Diseases

Util A	Util B	Util C
Erenumab-aooe		

Age Range: 0 - 17 yoa

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Aimovig Prescribing Information, May 2018, Amgen Inc.

69. Erenumab-aooe / Lactation _____ _____

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

Drugs/Diseases

Util A	Util B	Util C
Erenumab-aooe	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Aimovig Prescribing Information, May 2018, Amgen Inc.

70. Erenumab-aooe / Nonadherence _____ _____

Alert Message: Based on refill history, your patient may be underutilizing Aimovig (erenumab-aooe). 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
Erenumab-aooe		

References:
Osterberg L, Blaschke T. Adherence to Medication. N Engl J Med. 2005; 353(5):487–497.
Aimovig Prescribing Information, May 2018, Amgen Inc.
Clinical Pharmacology, 2019 Elsevier/Gold Standard.

71. Pimavanserin / Nonadherence _____ _____

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

Conflict Code: LR - Nonadherence
Drugs/Diseases

Util A	Util B	Util C
Pimavanserin		

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.
Fleisher JE, Stern MB. Medication Non-adherence in Parkinson's Disease. Curr Neurol Neurosci Rep. 2013;13(10):382. doi 10 01007/s11910-013-0382-z

72. Ibalizumab-uiyk / Nonadherence _____ _____

Alert Message: Based on refill history, your patient may be under-utilizing Trogarzo (ibalizumab-uiyk). Nonadherence to the 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
Ibalizumab-uiyk		

References:
Trogarzo Prescribing Information, May 2018, Theratechnologies, Inc.
Clinical Pharmacology, 2019 Elsevier/Gold Standard.

73. Ibalizumab-uiyk / Therapeutic Appropriateness _____ _____

Alert Message: A review of recent pharmacy claims reveals that the patient is not receiving an optimal background regimen (OBR) of antiretroviral medications in addition to Trogarzo (ibalizumab-uiyk). Ibalizumab-uiyk is FDA approved to be used in combination with other antiretroviral agents for the treatment of HIV-1 infection.

Drugs/Diseases

Util A	Util B	Util C **(Negating)**
Ibalizumab-uiyk		Antiretrovirals

References:
Trogarzo Prescribing Information, May 2018, Theratechnologies, Inc.
Clinical Pharmacology, 2019 Elsevier/Gold Standard.

74. Ibalizumab-uiyk / Therapeutic Appropriateness _____ _____

Alert Message: The safety and effectiveness of Trogarzo (ibalizumab-uiyk) in pediatric patients have not been established.

Drugs/Diseases

Util A	Util B	Util C
Ibalizumab-uiyk		

Age Range: 0 – 17 yoa

References:
Trogarzo Prescribing Information, May 2018, Theratechnologies, Inc.
Clinical Pharmacology, 2019 Elsevier/Gold Standard.

75. Amantadine ER / Overutilization _____ _____

Alert Message: The manufacturer's recommended maximum daily dose of Osmolex ER (amantadine extended-release) is 322 mg, taken in the morning.

Drugs/Diseases

Util A	Util B	Util C **(Negating)**
Amantadine ER		CKD 3, 4, & 5
		ESRD

Max Dose: 322 mg/day

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Osmolex ER Prescribing Information, Feb. 2018, Vertical Pharmaceuticals, LLC.

76. Amantadine ER / Overutilization Moderate Renal Impairment _____ _____

Alert Message: The manufacturer's recommended maximum daily dose of Osmolex ER (amantadine extended-release) in patients with moderate renal impairment (CrCl 30 - 59 mL/min/1.73m2) is 322 mg once every 48 hours.

Drugs/Diseases

Util A	Util B	Util C **(Include)**
Amantadine ER		CKD 3

Max Dose: 322 mg/48 hrs

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Osmolex ER Prescribing Information, Feb. 2018, Vertical Pharmaceuticals, LLC.

77. Amantadine ER / Overutilization Severe Renal Impairment _____ _____

Alert Message: The manufacturer's recommended maximum daily dose of Osmolex ER (amantadine extended-release) in patients with severe renal impairment (CrCl 15 - 29 mL/min/1.73m2) is 322 mg every 96 hours.

Drugs/Diseases

Util A	Util B	Util C **(Include)**
Amantadine ER		CKD 4 & 5

Max Dose: 68.5 mg/day

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Osmolex ER Prescribing Information, Feb. 2018, Vertical Pharmaceuticals, LLC.

78. Amantadine ER / End Stage Renal Disease _____ _____

Alert Message: The use of Osmolex ER (amantadine extended-release) in patients with end-stage renal disease (CrCl < 15 mL/min/1.73m2) is contraindicated. The clearance of amantadine is significantly reduced in patients with renal insufficiency.

Drugs/Diseases

Util A	Util B	Util C **(Include)**
Amantadine ER		ESRD

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Osmolex ER Prescribing Information, Feb. 2018, Vertical Pharmaceuticals, LLC.

79. Revefenacin / Overutilization _____ _____

Alert Message: The recommended dose of Yupelri (revefenacin) inhalation solution is one 175 mcg unit-dose vial administered once daily by nebulizer using a mouthpiece.

Drugs/Diseases

Util A	Util B	Util C
Revefenacin		

Max Dose: 1 inhalation/day

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Yupelri Prescribing Information, November 2018, Mylan.

80. Revefenacin / Glaucoma _____ _____

Alert Message: Yupelri (revefenacin) should be used with caution in patients with narrow-angle glaucoma. Revefenacin is a long-acting muscarinic antagonist, and its use in this patient population can worsen the condition.

Drugs/Diseases

Util A	Util B	Util C (Include)
Revefenacin		Glaucoma

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Yupelri Prescribing Information, November 2018, Mylan.

81. Revefenacin / Urinary Retention, Prost Hyperplasia & Bladder Neck Obs _____ _____

Alert Message: Yupelri (revefenacin) should be used with caution in patients with urinary retention. Prescribers and patients should be alert for signs and symptoms of urinary retention (e.g., difficulty passing urine, painful urination), especially in patients with prostatic hyperplasia or bladder-neck obstruction. Instruct patients to consult a healthcare provider immediately if any of these signs or symptoms develop.

Drugs/Diseases

Util A	Util B	Util C
Revefenacin	Urinary Retention Prostatic Hyperplasia Bladder-Neck Obstruction	

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Yupelri Prescribing Information, November 2018, Mylan.

82. Revefenacin / Anticholinergics _____ _____

Alert Message: The concurrent use of Yupelri (revefenacin) with anticholinergic agents should be avoided. Revefenacin is a long-acting muscarinic antagonist, and co-administration with anticholinergics may lead to an increase in anticholinergic adverse effects.

Drugs/Diseases

Util A	Util B				Util C
Revefenacin	Trihexyphenidyl	Trospium	Cyclizine	Oxybutynin	
	Benztropine	Hyoscyamine	Dicyclomine	Trimethobenzamide	
	Orphenadrine	Scopolamine	Diphenhydramine	Flavoxate	
	Darifenacin	Propantheline	Meclizine	Metscopolamine	
	Fesoterodine	Mepenzolate	Solifenacin	Tolterodine	

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Yupelri Prescribing Information, November 2018, Mylan.

83. Revefenacin / OATP1B1 & OATP1B3 Inhibitors _____ _____

Alert Message: The concurrent use of Yupelri (revefenacin) with OATP1B1 and OATP1B3 inhibitors is not recommended. The active metabolite of revefenacin is a substrate or OATP1B1 and OATP1B3. Coadministration of revefenacin with an inhibitor of these uptake transporters can result in increased systemic exposure to the active metabolite.

Drugs/Diseases

Util A	Util B	Util C
Revefenacin	Rifampicin	Letermovir
	Cyclosporine	Lopinavir
	Clarithromycin	Obeticholic Acid
	Atazanavir	Paritaprevir/Ombitasvir/Ritonavir
	Cobicistat	Rifampin
	Daclatasvir	Velpatasvir/Sofosbuvir/Voxilaprevir
	Eltrombopag	Velpatasvir/Sofosbuvir
	Erythromycin	Teriflunomide
	Gemfibrozil	
	Glecaprevir/Pibrentasvir	

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Yupelri Prescribing Information, November 2018, Mylan.

84. Revefenacin / Therapeutic Appropriateness _____ _____

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

Drugs/Diseases

Util A	Util B	Util C
Revefenacin		

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Yupelri Prescribing Information, November 2018, Mylan.

85. Revefenacin / Hepatic Impairment _____ _____

Alert Message: Yupelri (revefenacin) is not recommended for use in patients with any degree of hepatic impairment. In a pharmacokinetic study, the systemic exposure of revefenacin was unchanged while that of its active metabolite was increased in subjects with moderate hepatic impairment. The safety of revefenacin has not been evaluated in COPD patients with mild-to-severe hepatic impairment.

Drugs/Diseases

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

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Yupelri Prescribing Information, November 2018, Mylan.

86. Revefenacin / Pregnancy / Pregnancy Negating _____ _____

Alert Message: There are no adequate and well-documented studies with Yupelri (revefenacin) in pregnant women. Women should be advised to contact their physician if they become pregnant while taking revefenacin.

Drugs/Diseases

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

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Yupelri Prescribing Information, November 2018, Mylan.

87. Revefenacin / Lactation _____ _____

Alert Message: There is no information regarding the presence of Yupelri (revefenacin) in human milk, the effects on the breastfed infant, or the effects on milk production. However, revefenacin was present in the milk of lactating rats following dosing during pregnancy and lactation. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for revefenacin, and any potential adverse effects on the breastfed infant from revefenacin or from the underlying maternal condition.

Drugs/Diseases

Util A	Util B	Util C
Revefenacin	Lactation	

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Yupelri Prescribing Information, November 2018, Mylan.

88. Revefenacin / Nonadherence _____ _____

Alert Message: Based on refill history, your patient may be under-utilizing Yupelri (revefenacin). 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
Revefenacin		

References:

van Boven JF, Chavannes NH, van der Molen T, et al. Clinical and Economic Impact of Non-adherence in COPD: A Systematic Review. Respir Med. 2015 Jan;108(1):103-113.
Restrepo RD, Alvarez MT, Wittnebel LD, et al., Medication Adherence Issues in Patients Treated for COPD. International Journal of COPD. 2008;3(3):371-384.
Simoni-Wastila L, Wei Y, Qian J, et al., Association of Chronic Obstructive Pulmonary Disease Maintenance Medication Adherence With All-Cause Hospitalization and Spending in a Medicare Population. Am Jrnl Geriatr Pharmacother. 2012 Jun;10(3):201-210.
Lareau SC, Yawn BP. Improving Adherence with Inhaler Therapy in COPD. International Journal COPD. 2010 Nov 24;5:401-406.

89. Amantadine ER / Alcohol Dependence _____ _____

Alert Message: Concomitant use of Osmolex ER (amantadine extended-release) with alcohol is not recommended, as it may increase the potential for CNS effects such as dizziness, confusion, lightheadedness, and orthostatic hypotension.

Drugs/Diseases

Util A	Util B	Util C
Amantadine ER	Alcohol Dependence	

References:

Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Osmolex ER Prescribing Information, Feb. 2018, Vertical Pharmaceuticals, LLC.

90. Amantadine ER / Drugs Decreasing Urinary pH _____ _____

Alert Message: Concurrent use of Osmolex ER (amantadine extended-release) with a urinary acidifying agent may decrease amantadine serum concentrations due to increased amantadine elimination. The pH of urine influences the excretion rate of amantadine. Monitor the patient for decreased amantadine efficacy.

Drugs/Diseases

Util A	Util B	Util C
Amantadine ER	Methenamine Potassium Phosphate Ascorbic Acid	

References:

Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Osmolex ER Prescribing Information, Feb. 2018, Vertical Pharmaceuticals, LLC.

91. Amantadine ER / Drugs Increasing Urinary pH _____ _____

Alert Message: Concurrent use of Osmolex ER (amantadine extended-release) with a urinary alkalinizing agent may lead to an accumulation of amantadine and risk of amantadine-related adverse effects. The pH of urine influences the excretion rate of amantadine. Alterations of urine pH towards the alkaline condition may lead to accumulation of the drug.

Drugs/Diseases

Util A	Util B		Util C
Amantadine ER	Acetazolamide	Chlorothiazide	
	Dichlorphenamide	Chlorthalidone	
	Methazolamide	Hydrochlorothiazide	
	Potassium Citrate	Methyclothiazide	
	Sodium Citrate	Metolazone	
	Calcium Acetate		
	Sodium Bicarbonate		

References:

Facts & Comparison, 2018 Updates. Wolters Kluwer Health.
Osmolex ER Prescribing Information, Feb. 2018, Vertical Pharmaceuticals, LLC.

DUR Board Meeting
September 4, 2019
Heritage Center

North Dakota Medicaid
DUR Board Meeting Agenda
Brynhild Haugland Room
State Capitol
600 East Boulevard Avenue
Bismarck, ND
September 4, 2019
1:00 pm

1. Administrative items
    - DHS announcements

2. Old business
    - Review and approval of June 2019 meeting minutes
    - Budget update
    - Review top 25 drugs for second quarter of 2019
    - Prior authorization/PDL update
    - Second review of short-acting opioid analgesic agents
    - Second review of agents for the treatment of thrombocytopenia
    - Second review of agents for the treatment of interstitial cystitis
    - Second review of agents for the treatment of narcolepsy
    - Sanford Medicaid Expansion update

3. New business
    - Review of antifungal agents for aspergillus and candidiasis infections
    - Report on utilization data from select drugs and drug classes
    - DUR Board discussion regarding medication adherence
    - Retrospective DUR criteria recommendations
    - Case Reviews
    - Upcoming meeting date/agenda.
        - Next meeting is December 4, 2019 in the Brynhild Haugland Room

4. Adjourn

Please remember to silence all cellular phones during the meeting.

Drug Utilization Review (DUR) Meeting Minutes
June 5, 2019

Members Present: Michael Quast, Gabriela Balf, Tanya Schmidt, Andrea Honeyman, Peter Woodrow, Jesse Rue, LeNeika Roehrich, Kayli Bardell, Michael Quast, Jeffrey Hostetter

Members Absent: Michael Booth, Russ Sobotta, Laura Schield, Katie Kram

Medicaid Pharmacy Department: Brendan Joyce, Alexi Murphy

Old Business

Chair L. Roehrich called the meeting to order at 1:07 p.m. Chair L. Roehrich asked for a motion to approve the minutes of the December meeting. T. Schmidt moved that the minutes be approved and G. Balf seconded the motion. Chair L. Roehrich called for a voice vote to approve the minutes. The motion passed with no audible dissent.

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 1st 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 a number of COPD inhalers and 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 Sivextro and Nuzyra

A motion and second was made at the December meeting to place Sivextro and Nuzyra on prior authorization. The topics were brought up for a second review. J. Hostetter made a motion to amend the prescriber requirements to include following stewardship or per protocol, and J. Rue seconded the motion. Chair L. Roehrich called for a voice vote to approve the amendment, and the motion passed with no audible dissent. Chair L. Roehrich called for a voice vote to approve the amended criteria, and the motion passed with no audible dissent.

Second Review of Estrogen Agents

A motion and second was previously made to place estrogen agents on prior authorization. The topic was brought up for a second review. There was no public comment. Chair L. Roehrich called for a voice vote and the motion passed with no audible dissent.

Second Review of Agents for Treatment of Osteoporosis

A motion and second was made at the December meeting to place agents for the treatment of osteoporosis on prior authorization. The topic was brought up for a second review. P. Woodrow made a motion to amend the criteria to account for FRAX scores to be included and considered, and J. Hostetter seconded the motion. Chair L. Roehrich called for a voice vote to approve the

amendment, and the motion passed with no audible dissent. There was no public comment. Chair L. Roehrich called for a voice vote to approve the amended criteria, and the motion passed with no audible dissent.

Second Review of Agents for the Treatment of Hyperkalemia
A motion and second was made at the December meeting to place agents for the treatment of hyperkalemia on prior authorization. The topic was brought up for a second review. There was no public comment. Chair L. Roehrich called for a voice vote and the motion passed with no audible dissent.

Second Review of Agents for the Treatment of Parkinsons's Disease
A motion and second was made at the December meeting to place agents for the treatment of Parkinson's disease on prior authorization. The topic was brought up for a second review. There was no public comment. Chair L. Roehrich called for a voice vote and the motion passed with no audible dissent.

New Business
Review of Short Acting Opioids
A. Murphy presented a review of short-acting opioid agents to the Board. A motion was made by M. Quast to create PA criteria for the use of these agents and manage these medications through prior authorization. The motion was seconded by J. Rue. This topic will be reviewed at the next meeting.

Review of Agents for Treatment of Thrombocytopenia
A. Murphy presented a review of agents for treatment of thrombocytopenia to the Board. A motion was made by J. Hostetter. Woodrow to create PA criteria for the use of this agent and manage this medication through prior authorization. The motion was seconded by J. Rue. This topic will be reviewed at the next meeting.

Review of Agents for Treatment of Interstitial Cystitis
A. Murphy presented a review of agents for treatment of interstitial cystitis to the Board. A motion was made by P. Woodrow to create a new PA criteria class and manage these medications through prior authorization. The motion was seconded by J. Rue. This topic will be reviewed at the next meeting.

Review of Agents for Treatment of Narcolepsy
A. Murphy presented a review of agents for treatment of hyperkalemia to the Board. A motion was made by J. Rue to create a new PA criteria class and manage these medications through prior authorization. The motion was seconded by G. Balf. This topic will be reviewed at the next meeting.

Report on Utilization of Benzodiazepines and Opioids Concurrently
To reduce the risk of respiratory depression, a claims processing edit was put in place limiting the concurrent use of these agents to requiring a prior authorization in 2018. T. DeRuiter presented utilization data showing the number of FFS patients receiving an opioid and benzodiazepine concurrently from 2018 to 2019. The data showed that the number of patients receiving an agent from both of these drug classes was reduced by ~50% since this edit was put in place.

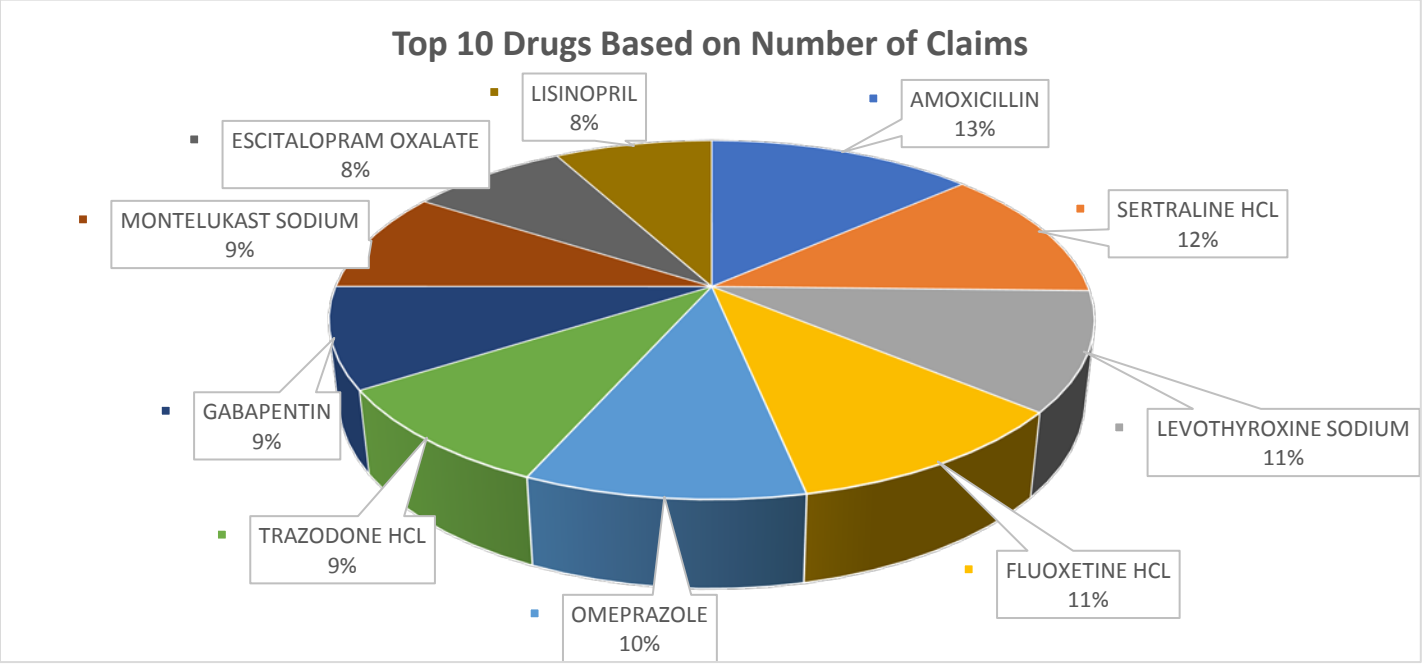
Retrospective Drug Utilization Review (RDUR) Criteria Recommendations
The recommended RDUR criteria enclosed in the packet were developed from product information provided by the manufacturers and are usually consistent with new indications, new drugs added, and new warnings. These proposed criteria will be added to the current set of criteria and will be used in future DUR cycles. J. Hostetter moved to amend the new criteria as stated above and approve it. J. Rue seconded the motion. The motion passed with no audible dissent.

Adjournment and Upcoming Meeting Date
Chair L. Roehrich adjourned the meeting at 2:45 pm. The next DUR Board meeting will be held September 4, 2019 at 1:00 pm at the State Capitol building in the Brynhild -Haugland room.

TOP 25 DRUGS BASED ON NUMBER OF CLAIMS FROM 04/01/2019 – 06/30/2019

Drug	AHFS Class	Claims	Claims Cost	Patients	Cost Per Claim	% Total Claims
AMOXICILLIN	PENICILLIN ANTIBIOTICS	2,951	$112,358.97	2,756	$38.07	2.13%
SERTRALINE HCL	ANTIDEPRESSANTS	2,616	$59,423.73	1,149	$22.72	1.89%
LEVOTHYROXINE SODIUM	THYROID AGENTS	2,348	$45,020.71	855	$19.17	1.70%
FLUOXETINE HCL	ANTIDEPRESSANTS	2,328	$40,012.16	1,014	$17.19	1.68%
OMEPRAZOLE	PROTON-PUMP INHIBITORS	2,192	$42,181.41	995	$19.24	1.58%
TRAZODONE HCL	ANTIDEPRESSANTS	2,027	$38,873.32	887	$19.18	1.46%
GABAPENTIN	ANTICONVULSANTS, MISC	1,993	$46,446.36	867	$23.30	1.44%
MONTELUKAST SODIUM	LEUKOTRIENE MODIFIERS	1,990	$43,819.73	1,005	$22.02	1.44%
ESCITALOPRAM OXALATE	ANTIDEPRESSANTS	1,749	$40,011.21	833	$22.88	1.26%
LISINOPRIL	ACE INHIBITORS	1,744	$53,336.34	758	$30.58	1.26%
ATORVASTATIN CALCIUM	STATINS	1,728	$46,295.00	723	$26.79	1.25%
VYVANSE	AMPHETAMINES	1,708	$406,421.89	686	$237.95	1.23%
HYDROCODONE-APAP	OPIATE AGONISTS	1,564	$33,578.89	1,002	$21.47	1.13%
CLONIDINE HCL	CENTRAL ALPHA-AGONISTS	1,488	$25,296.12	622	$17.00	1.08%
RISPERIDONE	ANTIPSYCHOTIC AGENTS	1,443	$21,399.41	472	$14.83	1.04%
PROAIR HFA	SABAS	1,412	$107,212.00	1,394	$75.93	1.02%
DULOXETINE HCL	ANTIDEPRESSANTS	1,401	$32,096.94	544	$22.91	1.01%
CONCERTA	CNS STIMULANTS	1,396	$460,715.08	575	$330.03	1.01%
FLUTICASONE PROPIONATE	CORTICOSTEROIDS (EENT)	1,340	$31,147.39	930	$23.24	0.97%
ASPIRIN EC	NSAIDS	1,339	$55,531.24	520	$41.47	0.97%
METFORMIN HCL	BIGUANIDES	1,324	$23,476.60	582	$17.73	0.96%
LAMOTRIGINE	ANTICONVULSANTS, MISC	1,321	$24,277.39	451	$18.38	0.95%
AMOXICILLIN-CLAVULANATE	PENICILLIN ANTIBIOTICS	1,295	$53,582.26	1,219	$41.38	0.94%
CETIRIZINE HCL	ANTIHISTAMINES	1,259	$44,983.43	740	$35.73	0.91%
ARIPIPRAZOLE	ANTIPSYCHOTIC AGENTS	1,257	$28,185.31	517	$22.42	0.91%

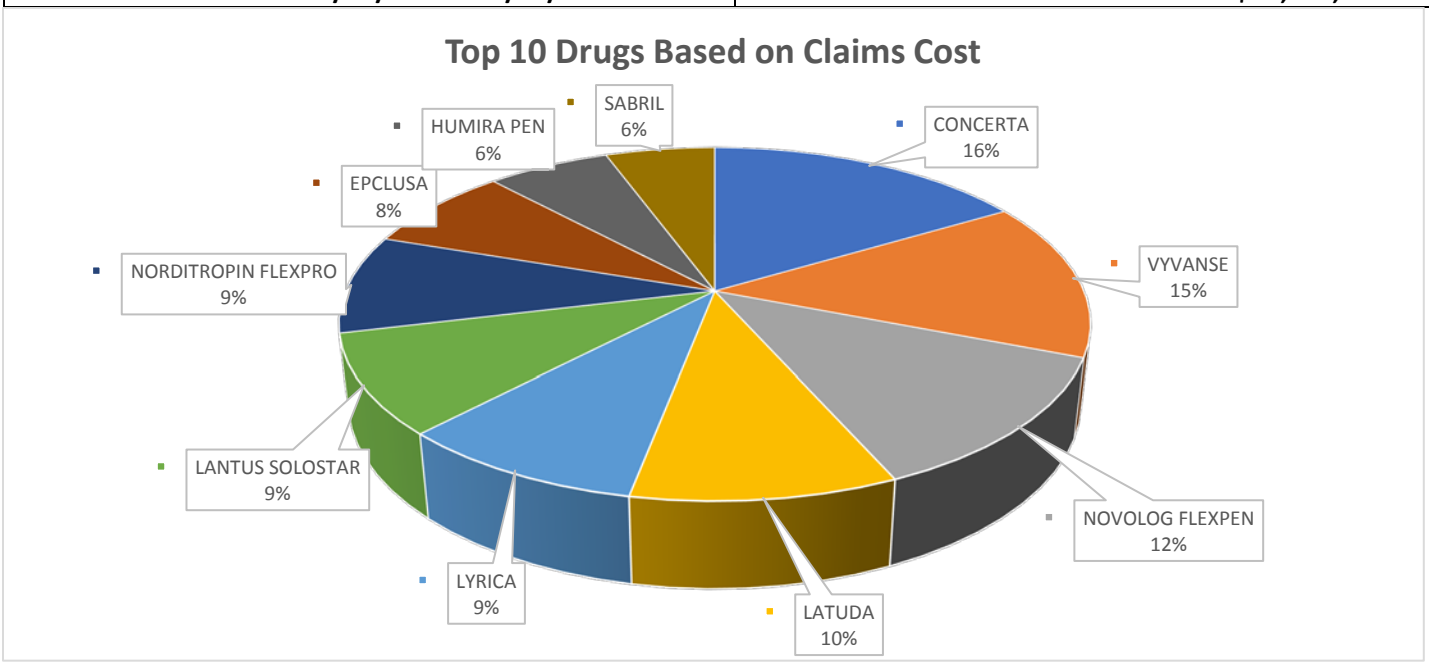
Total Claims From 04/01/2019 – 06/30/2019	**138,365**



TOP 25 DRUGS BASED ON TOTAL CLAIMS COST FROM 04/01/2019 – 06/30/2019

Drug	AHFS Class	Claims Cost	Claims	Patients	Cost Per Claim	% Total Cost
CONCERTA	CNS STIMULANTS	$460,715.08	1,396	575	$330.03	3.81%
VYVANSE	CNS STIMULANTS	$406,421.89	1,708	686	$237.95	3.36%
NOVOLOG FLEXPEN	INSULINS	$347,521.87	606	320	$573.47	2.88%
LATUDA	ANTIPSYCHOTIC AGENTS	$271,119.92	395	140	$686.38	2.24%
LYRICA	ANTICONVULSANTS, MISC	$254,692.27	525	213	$485.13	2.11%
LANTUS SOLOSTAR	INSULINS	$254,003.07	568	286	$447.19	2.10%
NORDITROPIN FLEXPRO	PITUITARY	$253,628.51	73	33	$3,474.36	2.10%
EPCLUSA	HCV ANTIVIRALS	$218,961.99	9	6	$24,329.11	1.81%
HUMIRA PEN	IMMUNOMODULATORS	$176,790.38	32	14	$5,524.70	1.46%
SABRIL	ANTICONVULSANTS, MISC	$157,489.36	9	4	$17,498.82	1.30%
INVEGA SUSTENNA	ANTIPSYCHOTIC AGENTS	$145,398.65	74	31	$1,964.85	1.20%
GENVOYA	ANTIRETROVIRALS	$144,140.90	124	52	$1,162.43	1.19%
ADVAIR DISKUS	INHALED CORTICOSTEROIDS	$140,359.64	382	200	$367.43	1.16%
VIMPAT	ANTICONVULSANTS, MISC	$125,599.57	203	59	$618.72	1.04%
LEVEMIR FLEXTOUCH	INSULINS	$120,746.57	304	172	$397.19	1.00%
FOCALIN XR	CNS STIMULANTS	$116,244.44	344	142	$337.92	0.96%
AMOXICILLIN	PENICILLIN ANTIBIOTICS	$112,358.97	2,951	2,756	$38.07	0.93%
PROAIR HFA	BETA-ADRENERGIC AGONISTS	$107,212.00	1,412	1,394	$75.93	0.89%
FLOVENT HFA	INHALED CORTICOSTEROIDS	$106,661.65	479	303	$222.68	0.88%
MAVYRET	HCV ANTIVIRALS	$102,857.48	8	6	$12,857.19	0.85%
COSENTYX PEN (2 PENS)	IMMUNOMODULATORS	$101,317.03	18	9	$5,628.72	0.84%
ABILIFY MAINTENA	ANTIPSYCHOTIC AGENTS	$98,984.50	48	18	$2,062.18	0.82%
NOVOLOG	INSULINS	$92,575.40	179	89	$517.18	0.77%
SYMBICORT	INHALED CORTICOSTEROIDS	$91,588.98	292	168	$313.66	0.76%
COSENTYX PEN	IMMUNOMODULATORS	$91,474.83	9	4	$10,163.87	0.76%

Total Claims Cost From 04/01/2019 – 06/30/2019	**$12,087,420.13**



PDL Update

ADDED TO PA	
Drug	**Criteria Category**
APOKYN	Parkinson's Disease
ASMANEX TWISTHALER	Inhaled Corticosteroids
BAXDELA	Antibiotics - Resistance Prevention
CANDESARTAN - HCTZ	ARBs (Angiotensin Receptor Blockers)
CEQUA	Ophthalmic – Dry Eye Syndrome
DUOBRII	Antipsoriatics – Topical
DUOPA	Parkinson's Disease
ESTRADIOL VAGINAL CREAM	Estrogens
ESTRADIOL VAGINAL TABLET	Estrogens
ESTRADIOL PATCH	Estrogens
EVENITY	Osteoporosis
FEMRING	Estrogens
FORTEO	Osteoporosis
GOCOVRI	Parkinson's Disease
INBRIJA	Parkinson's Disease
LEVORPHANOL	Opioid Analgesics – Long Acting
LOKELMA	Hyperkalemia
MAVENCLAD	Multiple Sclerosis - Oral Non-Interferons
MIACALCIN	Osteoporosis
MINOSTAR	Estrogens
NASCOBAL	Preferred Dosage Forms
NATROBA	Lice
NEOMYCIN/POLYMYXIN B/GRAMICIDIN DROPS	Ophthalmic Anti-Infectives
NEULASTA	Hematopoietic, Colony Stimulating Factors
NORGESIC FORTE	Skeletal Muscle Relaxants
NUPLAZID	Parkinson's Disease
NUZYRA	Antibiotics - Resistance Prevention
OSMOLEX ER	Parkinson's Disease
OTOVEL	Otic Anti-infectives – Fluoroquinolones
OXERVATE	Meds over $3000/month
PRAMIPEXOLE ER	Parkinson's Disease
PREFEST	Estrogens
RASAGILINE	Parkinson's Disease
RYTARY	Parkinson's Disease
SIVEXTRO	Antibiotics - Resistance Prevention
SKYRIZI	Cytokine Modulators
TOLCAPONE	Parkinson's Disease
TOLTERODINE	Urinary Antispasmodics
TOLTERODINE ER	Urinary Antispasmodics
TREPROSTINIL	Pulmonary Hypertension - Prostacyclins
TYMLOS	Osteoporosis
VELTASSA	Hyperkalemia
XADAGO	Parkinson's Disease

Removed from PA	
Drug	**Criteria Category**
ARMODAFINIL	Nuvigil
BELBUCA	Opioid Analgesics – Long Acting
CANDESARTAN	ARBs (Angiotensin Receptor Blockers)
DALIRESP	COPD - PDE4-Inhibitor
DICLOFENAC	NSAIDS
ETODOLAC	NSAIDS
FULPHILA	Ophthalmic Glaucoma - Beta Blockers
GENTAK	Tardive Dyskinesia
JENTADUETO XR	Diabetes - DPP4-Inhibitors
MODAFINIL	Nuvigil
NYSTATIN-TRIAMCINOLONE	Antifungals - Topical
OLOPATADINE 0.2%	Ophthalmic - Antihistamines
ORALAIR	Allergen Extracts
ORAVIG	Noxafil & Tolsura
ORENITRAM	Pulmonary Hypertension - Prostacyclins
OXAPROZIN	NSAIDS
PIROXICAM	NSAIDS
PRASUGREL	Platelet Aggregation Inhibitors
REVATIO	Pulmonary Hypertension - PDE-5 Inhibitors
SILDENAFIL	Pulmonary Hypertension - PDE-5 Inhibitors
SYMJEPI	Epinephrine Autoinjectors
TADALAFIL	Pulmonary Hypertension - PDE-5 Inhibitors
TOLMETIN	NSAIDS
TYVASO	Pulmonary Hypertension - Prostacyclins
UDENYCA	Hematopoietic, Colony Stimulating Factors
UPTRAVI	Pulmonary Hypertension - Prostacyclins
VENTAVIS	Pulmonary Hypertension - Prostacyclins
ZALAPAR	Parkinson’s Disease
ZORVOLEX	NSAIDS

SHORT-ACTING OPIOID ANALGESIC AGENTS

- **Criteria for coverage of Subsys, Fentora, 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 print-outs
    - 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
- **Criteria for coverage of ALL other non-preferred short-acting opioid analgesics:**
  - Initial Criteria:
    - The patient must have required around-the-clock pain relief for the past 90 days, as evidenced by paid claims or pharmacy print-outs
    - 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)
  - Additional criteria for coverage of 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 print-outs:
      - **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
  - Additional criteria for coverage of 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).
  - Renewal Criteria:
    - Documentation noting progress toward therapeutic goal must be included with request (including pain level and function).

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 long-acting opioid analgesic must meet the following criteria:

- Patient must have required around-the-clock pain relief for the past 90 days
- The past 3 months of North Dakota PDMP reports must have been reviewed by the prescriber.
- Patient must be in consult with oncologist or pain management specialist with a pain management contract (with treatment plan including goals for pain and function, and urine and/or blood screens) if:
  - Cumulative daily dose of narcotics exceed 90 MED/day
  - Patient is using benzodiazepine concurrently with narcotic medication
- 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.)

*** For additional and agent-specific criteria, please see criteria for coverage in the Preferred Drug List at www.hidesigns.com/assets/files/ndmedicaid/NDPDL.pdf**

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
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.*

INTERSTITIAL CYSTITIS

- **Elmiron:**
  - Initial Criteria: Duration of Approval = 3 months
    - The prescriber must attest that all other potential causes for bladder pain/discomfort have been ruled out.
    - The patient must have a diagnosis of pain or discomfort due to interstitial cystitis.
    - The patient must be 16 years of age or older.
    - The patient must have not experienced adequate symptom relief after implementing self-care practices and behavior modification (e.g. avoiding food/beverages and activities that exacerbate symptoms, fluid management, etc).
    - The patient must have failed a 30-day trial of amitriptyline, as evidenced by paid claims or pharmacy print-outs.
  - Renewal Criteria: Duration of approval = 12 months
    - The patient must have experienced a significant reduction in bladder pain/discomfort since initiating therapy (supported by clinical documentation).

PREFERRED AGENTS	NON-PREFERRED AGENTS
amitriptyline	ELMIRON (pentosan polysulfate sodium)

NARCOLEPSY

- **Criteria for coverage for all non-preferred agents:**
  - The patient must have an FDA-approved indication for use (meets label recommendations for diagnosis and age).
- **Additional criteria for coverage of Xyrem**
  - The patient must be experiencing one of the following, and meet any additional criteria for coverage (if applicable):
    - Cataplexy
    - Excessive Daytime Sleepiness:
      - The patient must have failed 30-day trials of modafinil and at least 1 additional CNS stimulant indicated for treatment of narcolepsy, as evidenced by paid claims or pharmacy print-outs
- **Additional criteria for coverage of Sunosi**
  - The patient must meet have a diagnosis of Narcolepsy or obstructive sleep apnea.
  - The patient must have failed 30-day trials of each preferred agent, as evidenced by paid claims or pharmacy print-outs
  - 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

PREFERRED AGENTS	NON-PREFERRED AGENTS
modafinil	SUNOSI
NUVIGIL (armodafinil)	XYREM

THROMBOCYTOPENIA

- **Criteria for initial and renewal requests for all agents and indications**
  - 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
- **Chronic immune thrombocytopenia (ITP)**
  - Criteria for coverage of Promacta, Doptelet, Nplate, and 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

- **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

- **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

- **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

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 #

SANFORD HEALTH PLAN

PBM Quarterly Review: Mid-Year 2019
Prepared by: Axia Strategies

Medicaid

AXIA STRATEGIES

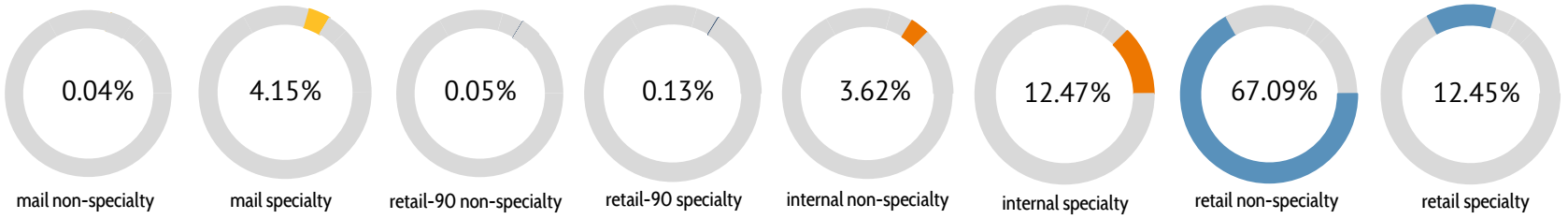
SPECIALTY & NON-SPECIALTY: SUMMARY

	Mid-Year 2018	Mid-Year 2019	Trend
membership			
Avg. Members / Month	20,325	19,226	-5.4%
Total Utilizing Members	15,279	15,020	-1.7%
utilization			
Total Rx Volume	219,806	208,976	-4.9%
% Specialty Rx Volume	0.5%	0.6%	7.5%
Rx Volume / Member	10.8	10.9	0.5%
Generic Dispensing Rate	86.0%	86.1%	0.0%
Mail Dispensing Rate	0.1%	0.1%	-33.2%
cost			
Total Gross Cost	$17,888,055	$17,437,974	-2.5%
Total Plan Cost	$17,816,282	$17,129,452	-3.9%
% Specialty Plan Cost	26.5%	29.2%	10.3%
Plan Cost PMPM	$146.09	$148.49	1.6%
Member Cost Share %	0.4%	0.4%	1.6%
Non-SRx Mbr Cost Share %	0.5%	0.5%	5.1%
Specialty Mbr Cost Share %	0.0%	0.0%	0.8%

Costs & Trends

- SHP's total Rx volume fell by 10,830 claims, which was a decrease of 4.9% over the prior period
- SHP total plan cost decreased by 3.9% to $17,129,452 for Mid-Year 2019
- Plan cost on a PMPM basis increased by 1.6%
- Specialty plan cost continues to make up a large portion of total spend at 29.2% for Mid-Year 2019
- Member cost share is currently 0.4%, which represents a positive trend of 1.6% from Mid-Year 2018

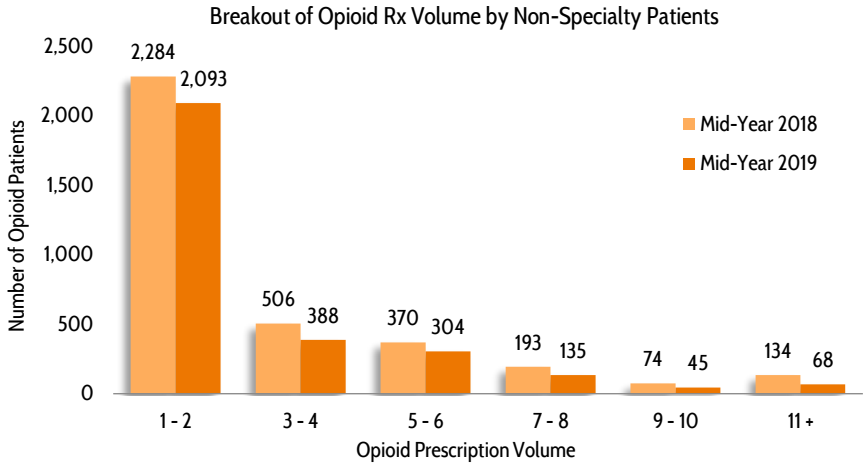
Breakout of Total Plan Costs: Mid-Year 2019



NON-SPECIALTY: SUMMARY

network pharmacies	Mid-Year 2018	Mid-Year 2019	Trend
utilization			
Avg. Members / Month	20,325	19,226	-5.4%
Total Rx Volume	218,635	207,779	-5.0%
Rx Volume / Member	10.8	10.8	0.5%
Generic Dispensing Rate	86.3%	86.4%	0.1%
cost			
Total Gross Cost	$13,164,264	$12,367,949	-6.0%
Total Plan Cost	$13,098,325	$12,126,749	-7.4%
Plan Cost PMPM	$107.41	$105.12	-2.1%
Member Cost Share %	0.5%	0.5%	5.1%

Opioids



	Total Rx Volume	Total # of Patients	Avg. Days Supply/Rx
Mid-Year 2018	10,741	3,561	13.2
Mid-Year 2019	7,964	3,033	12.4

Top 10 New Drugs by Total Plan Cost: Non-Specialty

Drug Name	Common Indication	Drug Type	Rx Volume	# Patients	Total Plan Cost
Bupropion Hydrochloride E	Depression	Generic	3699	1053	$79,361
Concerta	Attention Disorders	Brand	192	56	$71,188
Albuterol Sulfate Hfa	Asthma	Brand	1611	1018	$70,669
Fluticasone Propionate/Sa	Asthma	Generic	379	191	$70,546
Wixela Inhub	Asthma	Generic	125	69	$19,922
Ingrezza	Tardive Dyskinesia	Brand	3	1	$19,529
Advair Hfa	Asthma	Brand	48	26	$19,277
Aprepitant	Nausea/Vomiting	Generic	24	1	$13,140
Buprenorphine Hydrochlori	Pain	Generic	59	30	$10,928
Lotronex	Gi Disorders	Brand	5	1	$10,204

* Indicates that the product has been used in compounds during the reporting time period

NON-SPECIALTY Rx
AWP Prices: Then & Now

48%

The baseline AWP/unit **increased** for 479 drugs (48% of the claims dispensed during both periods)

The average AWP/unit increase was $2.60.

Top 10 Non-Specialty Drugs: By Dollar Increase in Average AWP Per Unit

			Rx Volume	Total AWP	Avg. AWP/Unit		
Drug Name	Drug Type	Common Indication	Mid-Year 2019		Mid-Year 2018	Mid-Year 2019	$ Change
INVEGA SUSTENNA	Brand	ANTIPSYCHOTICS	72	$201,178	$1,997	$2,132	$134
ZYPREXA RELPREVV	Brand	MENTAL/NEURO DISORDERS	27	$29,063	$1,011	$1,101	$90
ARISTADA	Brand	MENTAL/NEURO DISORDERS	22	$61,563	$874	$953	$80
RISPERDAL CONSTA	Brand	MENTAL/NEURO DISORDERS	41	$55,658	$972	$1,008	$36
BYETTA	Brand	DIABETES	29	$27,142	$507	$532	$24
EPINEPHRINE	Brand	ANAPHYLAXIS	102	$42,705	$188	$210	$22
VICTOZA	Brand	DIABETES	652	$621,112	$108	$123	$15
BYDUREON PEN	Brand	DIABETES	216	$181,380	$198	$210	$12
NUVARING	Brand	CONTRACEPTIVES	217	$43,120	$186	$195	$10
SPIRIVA RESPIMAT	Brand	COPD	109	$56,174	$119	$129	$10

31%

The baseline AWP/unit **decreased** for 316 drugs (31% of the claims dispensed during both periods)

The average AWP/unit decrease was $0.80.

Top 10 Non-Specialty Drugs: By Dollar Decrease in Average AWP Per Unit

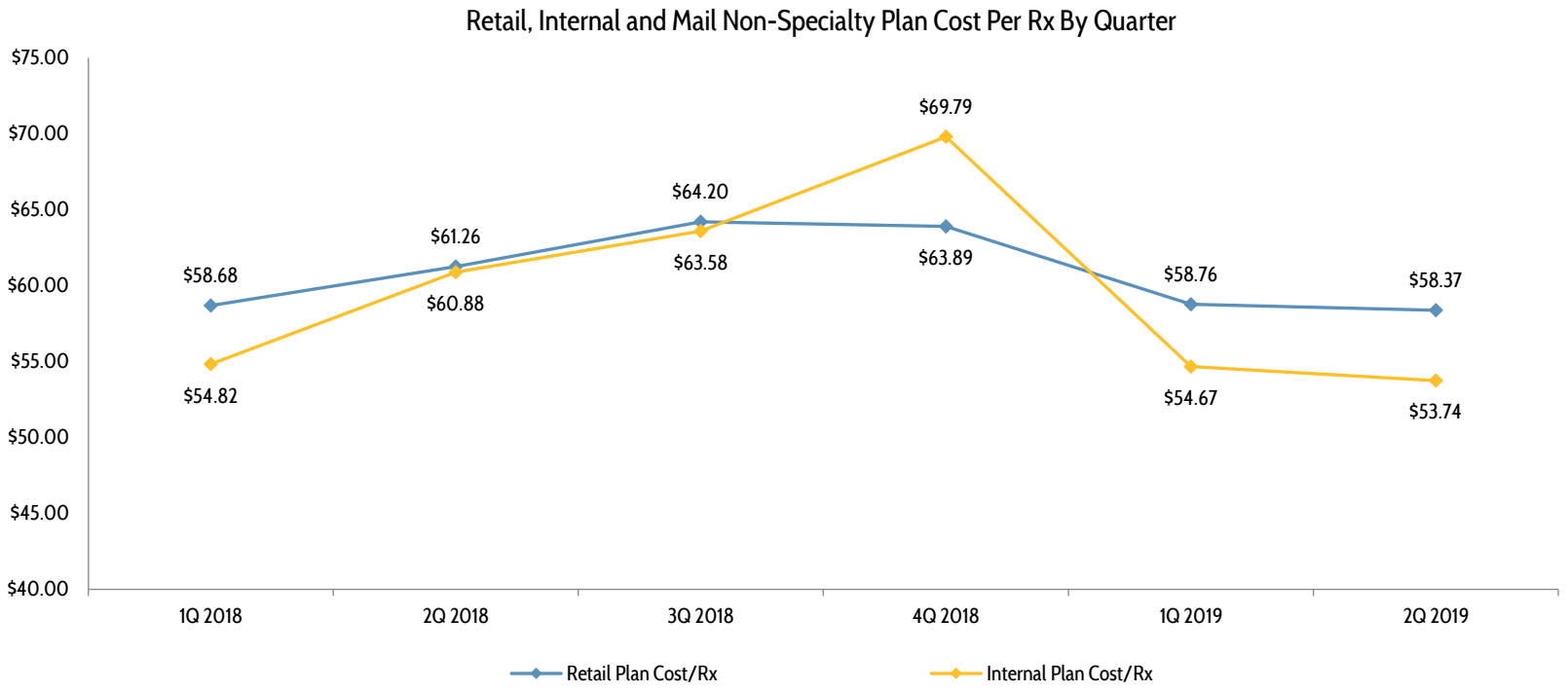
			Rx Volume	Total AWP	Avg. AWP/Unit		
Drug Name	Drug Type	Common Indication	Mid-Year 2019		Mid-Year 2018	Mid-Year 2019	$ Change
NALTREXONE HCL	Generic*	MENTAL/NEURO DISORDERS	360	$28,663	$28	$3	-$25
OLOPATADINE HCL	Generic	EYE CONDITIONS	139	$31,525	$47	$38	-$9
ABILIFY MAINTENA	Brand	MENTAL/NEURO DISORDERS	93	$230,885	$2,437	$2,431	-$6
PALIPERIDONE ER	Generic	ANTIPSYCHOTICS	80	$71,576	$33	$31	-$2
METHYLPHENIDATE HYDROCHLO	Generic	ATTENTION DISORDERS	472	$70,608	$5	$4	-$1
ESOMEPRAZOLE MAGNESIUM	Generic	ULCER DISEASE	322	$79,406	$9	$8	-$1
MIDODRINE HCL	Generic	LOW BLOOD PRESSURE	72	$25,779	$5	$5	-$1
RANITIDINE HCL	Generic	ULCER DISEASE	468	$36,489	$3	$2	-$1
SUMATRIPTAN SUCCINATE	Generic	MIGRAINE HEADACHES	658	$153,436	$26	$26	-$1
ONDANSETRON ODT	Generic	NAUSEA/VOMITING	999	$537,773	$26	$25	-$1

* Indicates that the product has been used in compounds during the reporting time period

** Top drugs tables reviewed only the top 200 non-specialty drugs by total AWP

NON-SPECIALTY: SUMMARY

Non-Specialty Claims by Quarter												
	Rx Volume				Plan Cost/Rx				Member Cost/Rx			
	Retail	Retail-90	Internal	Mail	Retail	Retail-90	Internal	Mail	Retail	Retail-90	Internal	Mail
1Q 2018	103,683	37	5,951	0	$58.68	$335.24	$54.82	$0.00	$0.29	$0.57	$0.22	$0.00
2Q 2018	102,753	40	6,171	0	$61.26	$136.86	$60.88	$0.00	$0.31	$0.23	$0.23	$0.00
3Q 2018	99,765	38	5,592	0	$64.20	$139.48	$63.58	$0.00	$0.32	$0.47	$0.23	$0.00
4Q 2018	100,620	28	5,625	0	$63.89	$132.58	$69.79	$0.00	$0.31	$0.32	$0.25	$0.00
1Q 2019	97,154	53	5,641	25	$58.76	$80.66	$54.67	$305.57	$0.32	$0.11	$0.24	$0.60
2Q 2019	99,063	54	5,789	0	$58.37	$67.53	$53.74	$0.00	$0.30	$0.06	$0.24	$0.00



NON-SPECIALTY:

Top 25 Drugs by Gross Cost

Top 25 Non-Specialty Drugs by Gross Cost

Rank '18	Rank '19	Drug Name	Drug Type	Common Indication	Rx Volume Mid-Year 2018	Rx Volume Mid-Year 2019	Rx Volume Trend	Total Gross Cost Mid-Year 2018	Total Gross Cost Mid-Year 2019	Total Gross Cost Trend	Total Plan Cost Mid-Year 2018	Total Plan Cost Mid-Year 2019	Total Plan Cost Trend
1	1	NOVOLOG FLEXPEN	Brand	DIABETES	1,545	1,368	-11.5%	$870,390	$761,698	-12.5%	$867,198	$754,585	-13.0%
2	2	LYRICA	Brand	SEIZURES	1,294	1,084	-16.2%	$617,137	$547,953	-11.2%	$614,098	$537,114	-12.5%
4	3	LANTUS SOLOSTAR	Brand	DIABETES	1,281	1,286	0.4%	$473,851	$485,532	2.5%	$470,590	$479,136	1.8%
5	4	VICTOZA	Brand	DIABETES	572	652	14.0%	$391,752	$474,519	21.1%	$390,318	$459,146	17.6%
3	5	LEVEMIR FLEXTOUCH	Brand	DIABETES	1,010	910	-9.9%	$476,636	$428,907	-10.0%	$475,094	$425,671	-10.4%
7	6	LATUDA	Brand	MENTAL/NEURO DISORDERS	265	333	25.7%	$316,125	$389,607	23.2%	$315,555	$363,415	15.2%
11	7	ZUBSOLV	Brand	OPIOID DEPENDENCE	985	1,494	51.7%	$199,333	$279,705	40.3%	$197,167	$275,619	39.8%
8	8	XIFAXAN	Brand	INFECTIONS	136	128	-5.9%	$279,390	$265,090	-5.1%	$279,081	$264,790	-5.1%
16	9	JARDIANCE	Brand	DIABETES	378	623	64.8%	$147,835	$246,102	66.5%	$146,935	$241,797	64.6%
9	10	SYMBICORT	Brand	ASTHMA	812	750	-7.6%	$251,547	$243,710	-3.1%	$249,363	$238,544	-4.3%
10	11	VYVANSE	Brand	ATTENTION DISORDERS	779	812	4.2%	$220,419	$232,643	5.5%	$218,607	$221,838	1.5%
20	12	ABILIFY MAINTENA	Brand	MENTAL/NEURO DISORDERS	61	93	52.5%	$122,341	$180,633	47.6%	$122,185	$175,136	43.3%
13	13	CONTOUR NEXT BLOOD GLUCOS	Brand	DIABETES	1,864	1,846	-1.0%	$161,744	$178,777	10.5%	$156,767	$172,175	9.8%
28	14	INVEGA SUSTENNA	Brand	ANTIPSYCHOTICS	44	72	63.6%	$91,579	$158,161	72.7%	$91,456	$157,972	72.7%
23	15	ELIQUIS	Brand	ANTICOAGULANT	253	359	41.9%	$104,265	$152,964	46.7%	$103,608	$151,573	46.3%
14	16	SPIRIVA HANDIHALER	Brand	COPD	445	410	-7.9%	$160,060	$146,838	-8.3%	$158,827	$143,660	-9.5%
12	17	JANUVIA	Brand	DIABETES	490	363	-25.9%	$194,299	$142,025	-26.9%	$193,057	$141,008	-27.0%
30	18	BYDUREON PEN	Brand	DIABETES	136	216	58.8%	$84,876	$134,266	58.2%	$84,600	$133,063	57.3%
15	19	NOVOLOG	Brand	DIABETES	303	228	-24.8%	$159,804	$131,940	-17.4%	$159,075	$126,286	-20.6%
18	20	GABAPENTIN	Generic	SEIZURES	6,624	5,991	-9.6%	$138,935	$110,671	-20.3%	$138,935	$110,493	-20.5%
39	21	TRINTELLIX	Brand	DEPRESSION	177	286	61.6%	$63,344	$103,702	63.7%	$62,921	$98,583	56.7%
27	22	XARELTO	Brand	ANTICOAGULANT	226	244	8.0%	$94,486	$102,406	8.4%	$93,850	$97,182	3.6%
17	23	PROAIR HFA	Brand	ASTHMA	2,449	1,378	-43.7%	$141,022	$92,123	-34.7%	$135,451	$88,182	-34.9%
35	24	ANORO ELLIPTA	Brand	COPD	177	226	27.7%	$70,336	$89,257	26.9%	$69,829	$88,618	26.9%
42	25	LEVOTHYROXINE SODIUM	Generic*	THYROID DISORDERS	4,041	3,999	-1.0%	$59,921	$83,783	39.8%	$59,921	$83,516	39.4%

* Indicates that the product has been used in compounds during the reporting time period

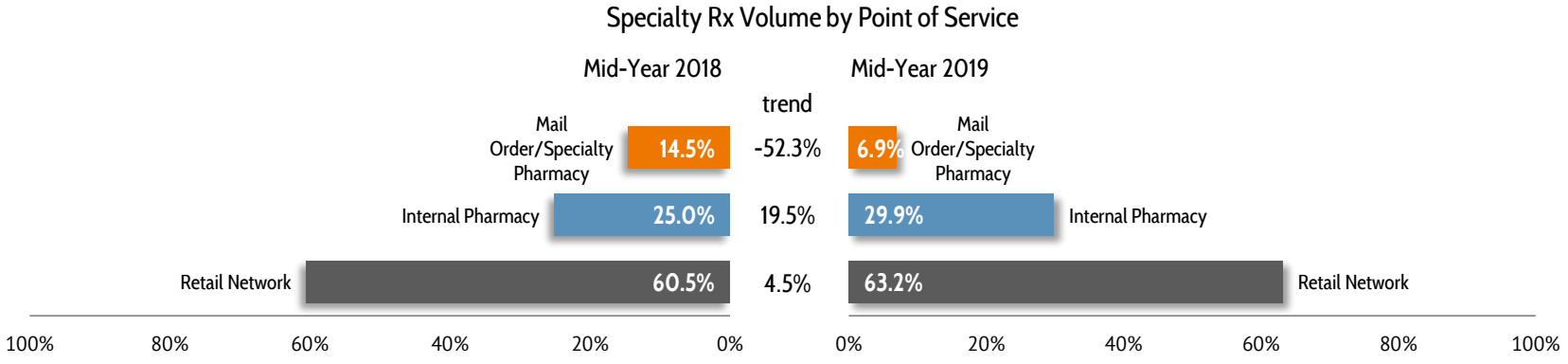
SPECIALTY: SUMMARY

	Mid-Year 2018	Mid-Year 2019	Trend
membership			
Avg. Members / Month	20,325	19,226	-5.4%
Total Utilizing Members	323	328	1.5%
utilization			
Total Rx Volume	**1,171**	**1,197**	**2.2%**
Retail Network SRx Volume	708	756	6.8%
Internal Pharmacy SRx Volume	293	358	22.2%
Mail Order SRx Volume	170	83	-51.2%
Rx Volume/Utilizing SRx Member	3.6	3.6	0.7%
Generic Dispensing Rate	28.7%	29.3%	2.2%
cost			
Total Gross Cost	$4,723,791	$5,070,025	7.3%
Total Plan Cost	$4,717,958	$5,002,703	6.0%
Plan Cost PMPM	**$38.69**	**$43.37**	**12.1%**
Retail Network	$16.56	$18.49	11.7%
Internal Pharmacy	$12.91	$18.52	43.4%
Mail Order/SRx Pharmacy	$9.22	$6.17	-33.1%
Member Cost Share $	$2,094	$2,265	8.2%
Member Cost Share %	**0.0%**	**0.0%**	**0.8%**
Retail Network	0.1%	0.1%	12.1%
Internal Pharmacy	0.0%	0.0%	-7.4%
Mail Order/SRx Pharmacy	0.0%	0.0%	-29.7%

Top 10 New Drugs by Total Plan Cost: Specialty

Drug Name	Common Indication	Drug Type	Rx Volume	# Patients	Total Plan Cost
Bexarotene	Cancer	Generic	6	1	$161,314
Symdeko	Cystic Fibrosis	Brand	4	1	$93,065
Imbruvica	Cancer	Brand	6	1	$72,540
Letairis	Pulmonary Hypertension	Brand	7	2	$70,527
Sutent	Cancer	Brand	4	1	$68,318
Taltz	Psoriasis	Brand	6	1	$60,678
Gleevec	Cancer	Brand	5	1	$49,086
Lynparza	Cancer	Brand	4	2	$42,651
Dupixent	Atopic Dermatitis	Brand	10	3	$33,895
Kuvan	Endocrine Disorders	Brand	2	1	$32,571

* Indicates that the product has been used in compounds during the reporting time period



SPECIALTY Rx
AWP Prices: Then & Now

66%

The baseline AWP/unit **increased** for 41 drugs (66% of the claims dispensed during both periods)

The average AWP/unit increase was $132.46.

Top 10 Specialty Drugs: By Dollar Increase in Average AWP Per Unit

			Rx Volume	Total AWP	Avg. AWP/Unit		
Drug Name	Drug Type	Common Indication	Mid-Year 2019		Mid-Year 2018	Mid-Year 2019	$ Change
STELARA	Brand	RHEUMATOID ARTHRITIS	6	$132,028	$24,701	$26,406	$1,704
HUMIRA PEN-CD/UC/HS START	Brand	ULCER DISEASE	2	$37,254	$2,923	$3,725	$802
HUMIRA PEN-PS/UV STARTER	Brand	RHEUMATOID ARTHRITIS	5	$62,089	$2,923	$3,684	$761
NATPARA	Brand	HYPOPARATHYROIDISM	5	$58,810	$5,609	$5,830	$221
PROMACTA	Brand	BLOOD CELL DEFICIENCY	2	$32,095	$330	$519	$189
HUMIRA PEN	Brand	RHEUMATOID ARTHRITIS	137	$968,590	$2,923	$3,104	$181
HUMIRA	Brand	RHEUMATOID ARTHRITIS	31	$228,488	$2,923	$3,104	$181
AVONEX PEN	Brand	MULTIPLE SCLEROSIS	3	$24,933	$8,148	$8,311	$163
AVONEX	Brand	MULTIPLE SCLEROSIS	1	$8,311	$8,148	$8,311	$163
SPRYCEL	Brand	CANCER	4	$65,697	$392	$547	$155

15%

The baseline AWP/unit **decreased** for 9 drugs (15% of the claims dispensed during both periods)

The average AWP/unit decrease was $27.63.

Top 10 Specialty Drugs: By Dollar Decrease in Average AWP Per Unit

			Rx Volume	Total AWP	Avg. AWP/Unit		
Drug Name	Drug Type	Common Indication	Mid-Year 2019		Mid-Year 2018	Mid-Year 2019	$ Change
REPATHA SURECLICK	Brand	HIGH BLOOD CHOLESTEROL	10	$7,802	$670	$483	-$188
TEMOZOLOMIDE	Generic	CANCER	10	$43,099	$288	$256	-$31
ENOXAPARIN SODIUM	Generic	DVT/ANTICOAGULATION	72	$100,257	$86	$69	-$17
TENOFOVIR DISOPROXIL FUMA	Generic	HIV	16	$13,827	$40	$31	-$9
SIROLIMUS	Generic	TRANSPLANT	8	$5,339	$17	$14	-$3
MYCOPHENOLATE MOFETIL	Generic	TRANSPLANT	77	$63,531	$7	$6	$0
TRETINOIN	Generic	ACNE	106	$22,133	$5	$5	$0
CAPECITABINE	Generic	CANCER	8	$25,730	$39	$39	$0
ENTECAVIR	Generic	HEPATITIS B	6	$7,998	$44	$44	$0
-	-	-	-	-	-	-	-

* Indicates that the product has been used in compounds during the reporting time period

** Top drugs tables reviewed only the top 200 specialty drugs by total AWP

SPECIALTY:

Top 25 Drugs by Gross Cost

Top 25 Specialty Drugs by Gross Cost

Rank '18	Rank '19	Drug Name	Drug Type	Common Indication	Rx Volume Mid-Year 2018	Rx Volume Mid-Year 2019	Rx Volume Trend	Total Gross Cost Mid-Year 2018	Total Gross Cost Mid-Year 2019	Total Gross Cost Trend	Total Plan Cost Mid-Year 2018	Total Plan Cost Mid-Year 2019	Total Plan Cost Trend
1	1	HUMIRA PEN	Brand	RHEUMATOID ARTHRITIS	159	137	-13.8%	$829,642	$790,012	-4.8%	$829,270	$767,586	-7.4%
22	2	COSENTYX SENSOREADY PEN	Brand	PSORIASIS	9	68	655.6%	$58,369	$470,956	706.9%	$58,336	$470,752	707.0%
3	3	MAVYRET	Brand	HEPATITIS C	32	36	12.5%	$431,285	$437,113	1.4%	$431,219	$437,026	1.3%
2	4	EPCLUSA	Brand	HEPATITIS C	17	14	-17.6%	$436,760	$286,189	-34.5%	$436,715	$286,147	-34.5%
4	5	GILENYA	Brand	MULTIPLE SCLEROSIS	35	30	-14.3%	$276,676	$240,229	-13.2%	$276,574	$240,139	-13.2%
19	6	HUMIRA	Brand	RHEUMATOID ARTHRITIS	14	31	121.4%	$69,779	$187,337	168.5%	$69,758	$187,244	168.4%
6	7	ENBREL SURECLICK	Brand	RHEUMATOID ARTHRITIS	27	33	22.2%	$132,858	$165,856	24.8%	$132,777	$165,775	24.9%
-	8	BEXAROTENE	Generic	CANCER	0	6	-	$0	$161,314	-	-	$161,314	-
5	9	COPAXONE	Brand	MULTIPLE SCLEROSIS	31	18	-41.9%	$224,035	$123,909	-44.7%	$224,005	$123,855	-44.7%
7	10	AUBAGIO	Brand	MULTIPLE SCLEROSIS	19	17	-10.5%	$125,432	$115,397	-8.0%	$125,375	$115,346	-8.0%
27	11	STELARA	Brand	RHEUMATOID ARTHRITIS	2	6	200.0%	$42,489	$106,936	151.7%	$42,477	$106,918	151.7%
13	12	STRIBILD	Brand	HIV	27	31	14.8%	$85,853	$94,347	9.9%	$85,787	$94,290	9.9%
-	13	SYMDEKO	Brand	CYSTIC FIBROSIS	0	4	-	$0	$93,077	-	-	$93,065	-
24	14	GENVOYA	Brand	HIV	18	29	61.1%	$51,373	$85,255	66.0%	$51,319	$67,861	32.2%
8	15	TRUVADA	Brand	HIV	69	45	-34.8%	$116,974	$75,674	-35.3%	$116,791	$75,548	-35.3%
-	16	IMBRUVICA	Brand	CANCER	0	6	-	$0	$72,558	-	-	$72,540	-
-	17	LETAIRIS	Brand	PULMONARY HYPERTENSION	0	7	-	$0	$70,548	-	-	$70,527	-
15	18	REVLIMID	Brand	CANCER	6	7	16.7%	$85,126	$70,360	-17.3%	$85,108	$70,339	-17.4%
-	19	SUTENT	Brand	CANCER	0	4	-	$0	$68,330	-	-	$68,318	-
25	20	XELJANZ	Brand	RHEUMATOID ARTHRITIS	12	14	16.7%	$50,510	$61,310	21.4%	$50,474	$61,268	21.4%
-	21	TALTZ	Brand	PSORIASIS	0	6	-	$0	$60,696	-	-	$60,678	-
-	22	KUVAN	Brand	ENDOCRINE DISORDERS	0	2	-	$0	$53,606	-	-	$32,571	-
20	23	TRIUMEQ	Brand	HIV	23	19	-17.4%	$66,136	$53,320	-19.4%	$66,085	$50,505	-23.6%
12	24	SPRYCEL	Brand	CANCER	9	4	-55.6%	$91,055	$52,812	-42.0%	$91,037	$52,800	-42.0%
42	25	NATPARA	Brand	HYPOPARATHYROIDISM	2	5	150.0%	$19,294	$49,547	156.8%	$19,288	$49,532	156.8%

* Indicates that the product has been used in compounds during the reporting time period

SPECIALTY & NON-SPECIALTY:

Top 20 High Cost Claimants

Top 20 High Cost Claimants by Total YTD Plan Cost										
		2019 Totals		Patient's Highest Cost Drug: 2019						
Patient Rank '19	New to List*	Total Rx Volume	Total Plan Cost	Drug Name	Common Indication	Rx Volume	Plan Cost	% Patient's Total Plan Cost	Specialty Indicator	Drug Type
1	Yes	76	$175,759	BEXAROTENE	CANCER	6	$161,314	91.8%	Specialty	Generic
2	Yes	41	$109,558	SYMDEKO	CYSTIC FIBROSIS	4	$93,065	84.9%	Specialty	Brand
3	Yes	13	$85,504	STELARA	RHEUMATOID ARTHRITIS	4	$85,363	99.8%	Specialty	Brand
4	Yes	42	$75,725	IMBRUVICA	CANCER	6	$72,540	95.8%	Specialty	Brand
5	Yes	10	$73,154	EPCLUSA	HEPATITIS C	3	$72,987	99.8%	Specialty	Brand
6	Yes	45	$72,200	REVLIMID	CANCER	7	$70,339	97.4%	Specialty	Brand
7	Yes	55	$71,955	GILENYA	MULTIPLE SCLEROSIS	7	$55,466	77.1%	Specialty	Brand
8	Yes	24	$69,307	SUTENT	CANCER	4	$68,318	98.6%	Specialty	Brand
9	Yes	7	$60,744	TALTZ	PSORIASIS	6	$60,678	99.9%	Specialty	Brand
10	Yes	40	$59,810	EPCLUSA	HEPATITIS C	2	$48,658	81.4%	Specialty	Brand
11	Yes	43	$56,598	HUMIRA PEN	RHEUMATOID ARTHRITIS	6	$40,394	71.4%	Specialty	Brand
12	Yes	17	$56,544	COSENTYX SENSOREADY PEN	PSORIASIS	1	$43,052	76.1%	Specialty	Brand
13	Yes	50	$54,446	LETAIRIS	PULMONARY HYPERTENSION	5	$50,116	92.0%	Specialty	Brand
14	Yes	29	$52,952	HUMIRA	RHEUMATOID ARTHRITIS	9	$50,496	95.4%	Specialty	Brand
15	Yes	5	$52,867	SPRYCEL	CANCER	4	$52,800	99.9%	Specialty	Brand
16	Yes	85	$52,791	HUMIRA	RHEUMATOID ARTHRITIS	5	$50,459	95.6%	Specialty	Brand
17	Yes	34	$50,948	GLEEVEC	CANCER	5	$49,086	96.3%	Specialty	Brand
18	Yes	11	$50,561	HUMIRA PEN	RHEUMATOID ARTHRITIS	5	$50,469	99.8%	Specialty	Brand
19	Yes	11	$50,535	HUMIRA PEN	RHEUMATOID ARTHRITIS	7	$50,446	99.8%	Specialty	Brand
20	Yes	40	$50,236	NATPARA	HYPOPARATHYROIDISM	5	$49,532	98.6%	Specialty	Brand

* Indicates that this patient was not on the top 20 high cost claimant list as of year end 2018

REVIEW OF ANTIFUNGAL AGENTS FOR ASPERGILLUS AND CANDIDA INFECTIONS

ASPERGILLUS AND CANDIDA INFECTIONS:

- Both are broad terms to describe a host of fungal infections caused by species of Aspergillus or Candida.
- These infections are most common in immunosuppressed patients, most commonly:
  - Hematopoietic cell transplant (HCT) recipients
  - Solid organ transplant (especially lung, heart-lung, and liver) recipients
  - Patients who experience prolonged neutropenia
  - Patients with hematologic malignancies
  - Patients with AIDs
- **Aspergillus**:
  - Invasive aspergillosis most frequently occurs in the lungs or sinuses after inhalation, although, less commonly, disease can spread from the gastrointestinal tract or result from direct inoculation into the skin.
    - "aspergillosis" refers to illness due to allergy, airway or lung invasion, cutaneous infection, or extrapulmonary dissemination caused by species of Aspergillus, most commonly A. fumigatus, A. flavus, and A. terreus
    - Aspergillus species are ubiquitous in nature, and inhalation is common
      - Tissue invasion is uncommon (typically due to immunosuppression)
  - Invasive focal infections most often occur after spreading in the blood or when anatomic abnormalities or devices are present
- **Candida**:
  - The clinical manifestations of infection with Candida species range from local mucous membrane infections to widespread dissemination with multisystem organ failure
  - The different Candida species are capable of producing all of the clinical syndromes (infection with Candida albicans is the most common)
    - The most benign infections are characterized by local overgrowth on mucous membranes (oropharyngeal involvement, vaginitis) as a result of changes in the normal flora.
  - More extensive persistent mucous membrane infections occur in individuals with deficiencies in cell-mediated immunity, in which widespread visceral dissemination occurs after Candida species gain access to the bloodstream

TREATMENT:

- **Candida:**
  - **General Guideline Recommendations**
    - **Treatment** options depend on the type of infection (location, species, and susceptibility), but generally, the Infectious Diseases Society of America (IDSA) recommendations that fall under outpatient (pharmacy) care include the following:
      - **Oropharyngeal candidiasis (thrush):** Topical antifungal agents (Nystatin or clotrimazole lozenges)
      - **Other candida infections:** systemic azole antifungals and echinocandins (caspofungin, micafungin, and anidulafungin)
    - **Prophylaxis** recommendations are for use of fluconazole or an echinocandin.
- **Aspergillus:**
  - **General Guideline Recommendations**
    - **Treatment** options depend on the type of infection (location, species, and susceptibility), but generally, the Infectious Diseases Society of America (IDSA) recommendations that fall under outpatient (pharmacy) care include the following:
      - **Triazoles — Triazole antifungal agents include voriconazole, posaconazole, itraconazole, and fluconazole**
    - **Prophylaxis:** posaconazole, voriconazole, itraconazole, micafungin, and caspofungin

- **Newer agents**
  - **Cresemba (isavuconazonium)**
    - Azole antifungal derivative, indicated for the treatment of invasive aspergillosis in adults
  - **Noxafil (posaconazole)**
  - Suspension formulation of posaconazole
    - Indicated for prophylaxis of invasive Aspergillus and Candida infections in patients 13 years and older, and Treatment of oropharyngeal candidiasis, including oropharyngeal candidiasis refractory to itraconazole and/or fluconazole in patients 13 years and older
  - **Tolsura (itraconazole):**
    - Formulation of itraconazole in a 65 mg capsule
    - Indications for the following:
      - **Blastomycosis**, pulmonary and extrapulmonary
      - **Histoplasmosis**, including chronic cavitary pulmonary disease and disseminated, non-meningeal histoplasmosis
      - **Aspergillosis**, pulmonary and extrapulmonary, in patients who are intolerant of or who are refractory to amphotericin B therapy

COST

Drug	Strength	Package Size	AWP Pkg Price	AWP Unit Price
CLOTRIMAZOLE LOZENGE	10 mg	140	408.84	2.92
CRESEMBA	186 mg caps	14	1555.09	111.08
FLUCONAZOLE TABLET	50, 100, 150, 200 mg tablet	various	Various	1.02-14.32
ITRACONAZOLE SOLUTION	10 mg/mL	3 supp	347.12	2.31
ITRACONAZOLE CAPSULE	100 mg	various	various	5.66-24.06
NYSTATIN SUSPENSION	100,000 u/mL	various	various	0.24-0.28
NOXAFIL	40 mg/mL	105 mL	1,727.46	82.23
TOLSURA	65 mg	60 caps	2,482.25	41.37
VORICONAZOLE	50, 200 mg tab	various	various	19.87-139.31

CURRENT UTILIZATION

ND Medicaid Utilization (08/01/18 – 07/31/19)			
Label Name	**Rx Num**	**Quantity**	**Total Reimb Amt**
CLOTRIMAZOLE LOZENGE	46	2,778	$2,128.83
CRESEMBA	0	0	0
FLUCONAZOLE TABLET	1,879	6,408	$39,399.15
FLUCONAZOLE SUSPENSION	237	9,720	$6,087.24
ITRACONAZOLE SOLUTION	1	28	$67.30
ITRACONAZOLE CAPSULE	22	2.472	$5,428.83
NYSTATIN SUSPENSION	588	65,386	$18,374.01
NOXAFIL	0	0	0
TOLSURA	0	0	0
VORICONAZOLE	22	1,455	$9,161.23

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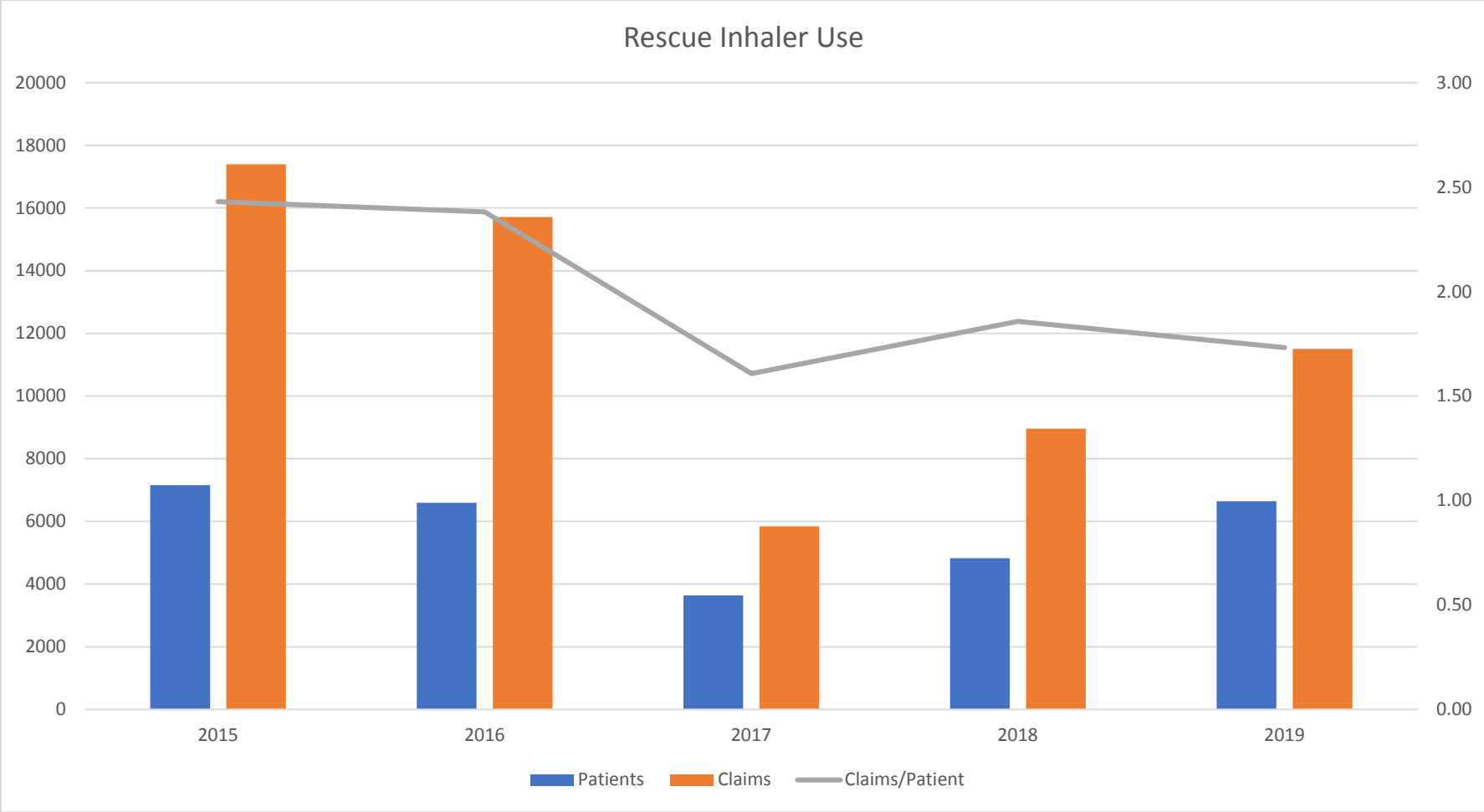
1. Facts & Comparisons eAnswers. Available at http://online.factsandcomparisons.com. Accessed on August 5. 2019.
2. Patterson TF, Thompson III GR, Denning DW, Fishman JA, Hadley S, Herbrecht R, Kontoyiannis DP, Marr KA, Morrison VA, Nguyen MH, Segal BH. Practice guidelines for the diagnosis and management of aspergillosis: 2016 update by the Infectious Diseases Society of America. Clinical Infectious Diseases. 2016 Jun 29;63(4):e1-60.
3. Pappas PG, Kauffman CA, Andes DR, Clancy CJ, Marr KA, Ostrosky-Zeichner L, Reboli AC, Schuster MG, Vazquez JA, Walsh TJ, Zaoutis TE. Clinical practice guideline for the management of candidiasis: 2016 update by the Infectious Diseases Society of America. Clinical Infectious Diseases. 2015 Dec 16;62(4):e1-50.


Rescue Inhaler Use
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2017
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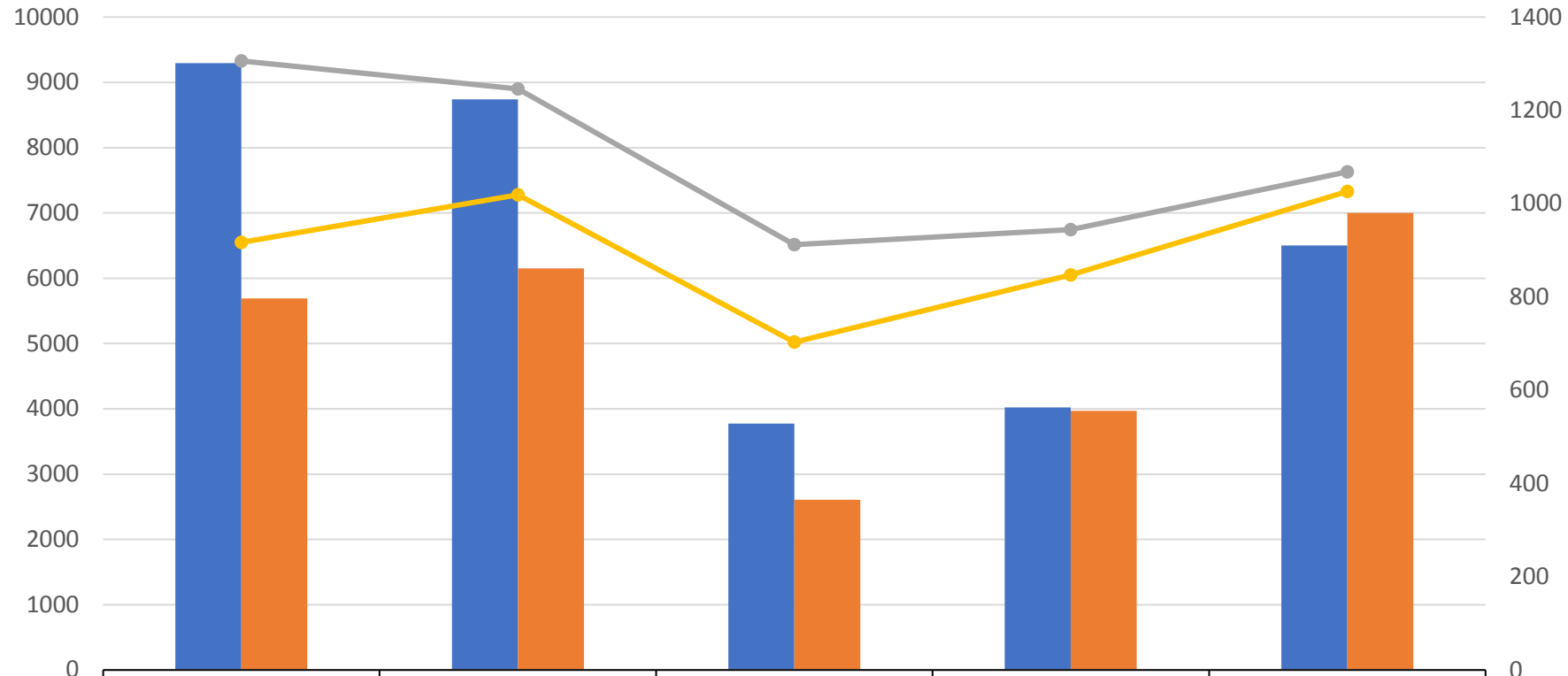
Patients
Claims
Claims/Patient

Adderall vs. Vyvanse Utilization Over 5 Years



	2015	2016	2017	2018	2019
Adderall (rx)	9296	8739	3776	4022	6503
Vyvanse (rx)	5689	6150	2608	3970	7001
Adderall (pts)	1306	1246	912	944	1068
Vyvanse (pts)	917	1019	703	847	1026

NORTH DAKOTA MEDICAID
RETROSPECTIVE DRUG UTILIZATION REVIEW
CRITERIA RECOMMENDATIONS
3RD QUARTER 2019

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

1. Esketamine / Overutilization _____ _____

Alert Message: The recommended maximum maintenance dosage of Spravato (esketamine) is 84 mg once weekly. Evidence of therapeutic benefit should be evaluated at the end of the induction phase to determine the need for continued treatment.

Drugs/Diseases

Util A	Util B	Util C
Esketamine		

Max Dose: 84 mg once weekly

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Spravato Prescribing Information, March 2019, Janssen Pharmaceuticals, Inc.

2. Esketamine / Antidepressants (Negating) _____ _____

Alert Message: A review of the patient's drug profile does not reveal a prescription for an oral antidepressant. Spravato (esketamine) is approved to be used in conjunction with an oral antidepressant.

Drugs/Diseases

Util A	Util B	Util C **(Negating)**
Esketamine		Antidepressants

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Spravato Prescribing Information, March 2019, Janssen Pharmaceuticals, Inc.

3. Esketamine / Contraindications _____ _____

Alert Message: Spravato (esketamine) is contraindicated in patients with; aneurysmal vascular disease (including thoracic and abdominal aorta, intracranial, and peripheral arterial vessels), arteriovenous malformation, or a history of intracerebral hemorrhage.

Drugs/Diseases

Util A	Util B	Util C
Esketamine	Abdominal Aortic Aneurysm	
	Thoracic Aortic Aneurysm	
	Peripheral Arterial Vessels	
	Arteriovenous Malformation	

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Spravato Prescribing Information, March 2019, Janssen Pharmaceuticals, Inc.

Criteria Recommendations *Approved* *Rejected*

4. Esketamine / Contraindications _____ _____

Alert Message: Spravato (esketamine) is contraindicated in patients with a history of intracerebral hemorrhage. Esketamine causes increases in the systolic and/or diastolic blood pressure at all recommended doses. In clinical trials, approximately 8% to 17% of esketamine-treated patients and 1% to 3% of placebo-treated patients experienced an increase of more than 40 mmHg in systolic BP and/or 25 mmHg in diastolic BP in the first 1.5 hours after administration at least once during the first 4 weeks of treatment.

Drugs/Diseases

Util A	Util B	Util C **(Include)**
Esketamine		History of Intracranial Hemorrhage

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Spravato Prescribing Information, March 2019, Janssen Pharmaceuticals, Inc.

5. Esketamine / CNS Depressants _____ _____

Alert Message: Concomitant use of Spravato (esketamine) with CNS depressants (e.g., benzodiazepines, opioids, alcohol) may increase sedation. Closely monitor the patient for sedation with concomitant use of esketamine with CNS depressants.

Drugs/Diseases

Util A	Util B	Util C
Esketamine	Benzodiazepines	
	Opioids	
	Skeletal Muscle Relaxants	
	Sedative/Hypnotics	

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Spravato Prescribing Information, March 2019, Janssen Pharmaceuticals, Inc.

6. Esketamine / Dissociation (Black Box Warning) _____ _____

Alert Message: Given its potential to induce dissociative effects, carefully assess patients with psychosis before administering Spravato (esketamine). Treatment with esketamine should be initiated only if the benefit outweighs the risk. Because of the risks of dissociation and sedation, patients must be monitored by a healthcare provider for at least 2 hours at each treatment session, followed by an assessment to determine when the patient is considered clinically stable and ready to leave the healthcare setting.

Drugs/Diseases

Util A	Util B	Util C
Esketamine		

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Spravato Prescribing Information, March 2019, Janssen Pharmaceuticals, Inc.

Criteria Recommendations *Approved* *Rejected*

7. Esketamine / Abuse and Misuse (Black Box Warning) _____ _____

Alert Message: Spravato (esketamine) contains esketamine, a Schedule III controlled substance (CIII), and may be subject to abuse and diversion. Assess each patient's risk for abuse or misuse prior to prescribing esketamine and monitor all patients receiving esketamine for the development of these behaviors or conditions, including drug-seeking behavior, while on therapy. Individuals with a history of drug abuse or dependence are at greater risk.

Drugs/Diseases

Util A	Util B	Util C **(Include)**
Esketamine		Drug Abuse
		Drug Dependence

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Spravato Prescribing Information, March 2019, Janssen Pharmaceuticals, Inc.

8. Esketamine / Pregnancy / Pregnancy Negating _____ _____

Alert Message: Based on published findings from pregnant animals treated with ketamine, the racemic mixture of arketamine and esketamine, Spravato (esketamine) may cause fetal harm when administered to pregnant women. Advise pregnant women of the potential risk to an infant exposed to esketamine in utero. Advise women of reproductive potential to consider pregnancy planning and prevention.

Drugs/Diseases

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

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Spravato Prescribing Information, March 2019, Janssen Pharmaceuticals, Inc.

9. Esketamine / Lactation _____ _____

Alert Message: Spravato (esketamine) is present in human milk. There are no data on the effects of esketamine on the breastfed infant or on milk production. Published studies in juvenile animals report neurotoxicity. Because of the potential for neurotoxicity, advise patients that breastfeeding is not recommended during treatment with esketamine.

Drugs/Diseases

Util A	Util B	Util C
Esketamine	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Spravato Prescribing Information, March 2019, Janssen Pharmaceuticals, Inc.

Criteria Recommendations *Approved* *Rejected*

10. Esketamine / Hypertension _____ _____

Alert Message: Spravato (esketamine) can cause increases in systolic and/or diastolic blood pressure (BP) at all recommended doses. Increases in BP peak approximately 40 minutes after esketamine administration and last approximately 4 hours. Carefully assessed to determine whether the potential benefits of esketamine therapy outweigh its risks.

Drugs/Diseases

Util A	Util B	Util C **(Include)**
Esketamine		Hypertension

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Spravato Prescribing Information, March 2019, Janssen Pharmaceuticals, Inc.

11. Esketamine /Therapeutic Appropriateness _____ _____

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

Drugs/Diseases

Util A	Util B	Util C
Esketamine		

Age Range: 0 - 17 yoa

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Spravato Prescribing Information, March 2019, Janssen Pharmaceuticals, Inc.

12. Esketamine / Therapeutic Appropriateness _____ _____

Alert Message: The mean Spravato (esketamine) AUC and t1/2 values were higher in patients with moderate hepatic impairment compared to those with normal hepatic function. Esketamine-treated patients with moderate hepatic impairment may need to be monitored for adverse reactions for a longer period of time. Esketamine has not been studied in patients with severe hepatic impairment (Child-Pugh class C). Use in this population is not recommended.

Drugs/Diseases

Util A	Util B	Util C
Esketamine		

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Spravato Prescribing Information, March 2019, Janssen Pharmaceuticals, Inc.

13. Esketamine / Psychostimulants _____ _____

Alert Message: Concomitant use of Spravato (esketamine) with psychostimulants (e.g., amphetamines, methylphenidate, modafinil, armodafinil) may increase blood pressure. Closely monitor blood pressure with concomitant use of esketamine with psychostimulants.

Drugs/Diseases

Util A	Util B	Util C
Esketamine	Amphetamine	
	Dextroamphetamine	
	Lisdexamfetamine	
	Methylphenidate	
	Dexmethylphenidate	
	Modafinil	
	Armodafinil	

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Spravato Prescribing Information, March 2019, Janssen Pharmaceuticals, Inc.

14. Esketamine / MAO Inhibitors _____ _____

Alert Message: Concomitant use of Spravato (esketamine) with monoamine oxidase inhibitors (MAOIs) may increase blood pressure. Closely monitor blood pressure with concomitant use of esketamine with MAOIs.

Drugs/Diseases

Util A	Util B	Util C
Esketamine	Isocarboxazid	
	Phenelzine	
	Tranylcypromine	

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Spravato Prescribing Information, March 2019, Janssen Pharmaceuticals, Inc.

15. Doravirine / Overutilization _____ _____

Alert Message: Pifeltro (doravirine) may be over-utilized. The recommended dosage of doravirine is 100 mg orally once daily.

Drugs/Diseases

Util A	Util B	Util C
Doravirine		

Max Dose: 1 tablet/day

References:
Pifeltro Prescribing Information, August 2018, Merck Sharp & Dohme Corp.
Clinical Pharmacology, 2019 Elsevier/Gold Standard.

16. Doravirine / Nonadherence _____ _____

Alert Message: Based on the refill history, your patient may be under-utilizing Pifeltro (doravirine). 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
Doravirine		

References:

Clinical Pharmacology, 2019 Elsevier/Gold Standard.
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. October 25, 2018. Available at: http://www.aidsinfo.nih.gov/guidelines/ht,l/1/adult-and-adolescent-arv/0
Nachega JB, Marconi VC, van Zyl GU, et al. HIV Treatment Adherence, Drug Resistance, Virologic Failure: Evolving Concepts. Infect Disord Drug Targets. 2011 April;11(2):167-174.
Schaecher KL. The Importance of Treatment Adherence in HIV. Am J Manag Care. 2013 Sep;19(12 Suppl):231-7.

17. Doravirine / Rifabutin _____ _____

Alert Message: If Pifeltro (doravirine) is co-administered with rifabutin, increase the doravirine dosage to one tablet twice daily (approximately 12 hours apart) for the duration of rifabutin co-administration.

Drugs/Diseases

Util A	Util B	Util C
Doravirine	Rifabutin	

References:

Pifeltro Prescribing Information, August 2018, Merck Sharp & Dohme Corp.
Clinical Pharmacology, 2019 Elsevier/Gold Standard.

18. Doravirine / Contraindicated Drugs _____ _____

Alert Message: The concurrent use of Pifeltro (doravirine) with a drug that is a strong CYP3A4 inducer is contraindicated. Doravirine is a CYP3A4 substrate, and co-administration with a strong CYP3A4 inducer may result in a significant decrease in doravirine plasma concentrations, a decrease doravirine efficacy, and possible development of resistance. At least a 4-week cessation period is recommended for the strong inducer prior to initiation of doravirine.

Drugs/Diseases

Util A	Util B	Util C
Doravirine	Enzalutamide	
	Carbamazepine	
	Oxcarbazepine	
	Phenobarbital	
	Phenytoin	
	Rifampin	
	Rifapentine	
	Mitotane	

References:

Pifeltro Prescribing Information, August 2018, Merck Sharp & Dohme Corp.
Clinical Pharmacology, 2019 Elsevier/Gold Standard.

19. Doravirine / Therapeutic Appropriateness _____ _____

Alert Message: The safety and effectiveness of Pifeltro (doravirine) in pediatric patients less than 18 years of age have not been established.

Drugs/Diseases

Util A	Util B	Util C
Doravirine		

Age Range: 0 – 17 yoa

References:

Pifeltro Prescribing Information, August 2018, Merck Sharp & Dohme Corp.
Clinical Pharmacology, 2019 Elsevier/Gold Standard.

20. Doravirine / Therapeutic Appropriateness _____ _____

Alert Message: Monotherapy with an NNRTI is not recommended in HIV-1-infected patients. Drug-resistant virus emerges rapidly when an NNRTI is administered as single agent therapy. Achieving viral suppression requires the use of antiretroviral (ARV) regimens with at least two, and preferably three, active drugs from two or more ARV drug classes.

Drugs/Diseases

Util A	Util B	Util C **(Negating)**
Doravirine		All Other Antiretrovirals

References:

Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Pifeltro Prescribing Information, August 2018, Merck Sharp & Dohme Corp.
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. Oct. 25, 2018. Available at: http://www.aidsinfo.nih.gov/guidelines/ht,l/1/adult-and-adolescent-arv/0

21. Doravirine / Efavirenz _____ _____

Alert Message: The concurrent use of Pifeltro (doravirine) with an efavirenz-containing drug is not recommended. Doravirine is a CYP3A substrate, and co-administration with efavirenz, a CYP3A4 inducer, may result in decreased doravirine exposure and decreased doravirine efficacy. Both drugs are non-nucleoside reverse transcriptase inhibitors, and the concomitant use represents unnecessary duplication of therapy.

Drugs/Diseases

Util A	Util B	Util C
Doravirine	Efavirenz	
	Efavirenz/Lamivudine/Tenofovir Dis	
	Efavirenz/Emtricitabine/Tenofovir Dis	

References:

Pifeltro Prescribing Information, August 2018, Merck Sharp & Dohme Corp.
Clinical Pharmacology, 2019 Elsevier/Gold Standard.

22. Doravirine / Etravirine _____ _____

Alert Message: The concurrent use of Pifeltro (doravirine) with (Intelence) etravirine is not recommended. Doravirine is a CYP3A substrate, and co-administration with etravirine, a CYP3A4 inducer, may result in decreased doravirine exposure and decreased doravirine efficacy. Both drugs are non-nucleoside reverse transcriptase inhibitors, and the concomitant use represents unnecessary duplication of therapy.

Drugs/Diseases

Util A	Util B	Util C
Doravirine	Etravirine	

References:
Pifeltro Prescribing Information, August 2018, Merck Sharp & Dohme Corp.
Clinical Pharmacology, 2019 Elsevier/Gold Standard.

23. Doravirine / Nevirapine _____ _____

Alert Message: The concurrent use of Pifeltro (doravirine) with nevirapine is not recommended. Doravirine is a CYP3A substrate, and co-administration with nevirapine, a CYP3A4 inducer, may result in decreased doravirine exposure and decreased doravirine efficacy. Both drugs are non-nucleoside reverse transcriptase inhibitors, and the concomitant use represents unnecessary duplication of therapy.

Drugs/Diseases

Util A	Util B	Util C
Doravirine	Nevirapine	

References:
Pifeltro Prescribing Information, August 2018, Merck Sharp & Dohme Corp.
Clinical Pharmacology, 2019 Elsevier/Gold Standard.

24. Delstrigo / Overutilization _____ _____

Alert Message: Delstrigo (doravirine/lamivudine/tenofovir disoproxil fumarate) may be over-utilized. The recommended dosage of doravirine 100 mg/lamivudine 300 mg/tenofovir disoproxil fumarate 300 mg is one tablet once daily.

Drugs/Diseases

Util A	Util B	Util C
Doravirine/Lamivudine/Tenofovir DF		

Max Dose: 1 tablet/day

References:
Delstrigo Prescribing Information, August 2018, Merck Sharp & Dohme Corp.
Clinical Pharmacology, 2019 Elsevier/Gold Standard.

Criteria Recommendations *Approved* *Rejected*

25. Delstrigo / Nonadherence _____ _____

Alert Message: Based on the refill history, your patient may be under-utilizing Delstrigo (doravirine/lamivudine/tenofovir disoproxil fumarate). 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
Doravirine/Lamivudine/Tenofovir DF		

References:

Delstrigo Prescribing Information, August 2018, Merck Sharp & Dohme Corp.
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. Octeber25, 2018. Available at: http://www.aidsinfo.nih.gov/guidelines/ht,l/1/adult-and-adolescent-arv/0
Nachega JB, Marconi VC, van Zyl GU, et al. HIV Treatment Adherence, Drug Resistance, Virologic Failure: Evolving Concepts. Infect Disord Drug Targets. 2011 April;11(2):167-174.
Schaecher KL. The Importance of Treatment Adherence in HIV. Am J Manag Care. 2013 Sep;19(12 Suppl):231-7.

26. Delstrigo / Renal Impairment _____ _____ _____

Alert Message: Delstrigo (doravirine/lamivudine/tenofovir disoproxil fumarate) is not recommended in patients with estimated creatinine clearance less than 50 mL/min. Doravirine/lamivudine/tenofovir disoproxil fumarate is a fixed-dose combination tablet, and the dosage of lamivudine and tenofovir cannot be adjusted.

Drugs/Diseases

Util A	Util B	Util C
Doravirine/Lamivudine/Tenofovir DF	CKD 3, 4, 5 ESRD	

References:

Delstrigo Prescribing Information, August 2018, Merck Sharp & Dohme Corp.
Clinical Pharmacology, 2019 Elsevier/Gold Standard.

27. Delstrigo / Rifabutin / Doravirine (Negating) _____ _____

Alert Message: If Delstrigo (doravirine/lamivudine/tenofovir disoproxil fumarate) is co-administered with rifabutin, take one tablet of doravirine/lamivudine/tenofovir disoproxil once daily, followed by one tablet of doravirine 100 mg approximately 12 hours after the fixed-dose combination product for the duration of rifabutin co-administration. Doravirine is a CYP3A4 substrate, and concurrent use with a CYP3A4 inducer may decrease doravirine exposure, resulting in potential loss of virologic response.

Drugs/Diseases

Util A	Util B	Util C **(Negating)**
Doravirine/Lamivudine/Tenofovir DF	Rifabutin	Doravirine

References:

Delstrigo Prescribing Information, August 2018, Merck Sharp & Dohme Corp.
Clinical Pharmacology, 2019 Elsevier/Gold Standard.

28. Delstrigo / Contraindicated Drugs _____ _____

Alert Message: The concurrent use of Delstrigo (doravirine/lamivudine/tenofovir disoproxil fumarate) with a drug that is a strong CYP3A4 inducer is contraindicated. The doravirine component of the fixed-dose combination product is a CYP3A substrate, and co-administration with a strong CYP3A4 inducer may result in a significant decrease in doravirine plasma concentrations, a decrease doravirine efficacy, and possible development of resistance. At least a 4-week cessation period is recommended for the strong inducer prior to initiation of doravirine/lamivudine/tenofovir disoproxil fumarate.

Drugs/Diseases

Util A	Util B	Util C
Doravirine/Lamivudine/Tenofovir DF	Enzalutamide	
	Carbamazepine	
	Oxcarbazepine	
	Phenobarbital	
	Phenytoin	
	Rifampin	
	Rifapentine	
	Mitotane	

References:
Delstrigo Prescribing Information, August 2018, Merck Sharp & Dohme Corp.
Clinical Pharmacology, 2019 Elsevier/Gold Standard.

29. Delstrigo / Ledipasvir/Sofosbuvir _____ _____

Alert Message: The concurrent use of Delstrigo (doravirine/lamivudine/tenofovir disoproxil fumarate) with ledipasvir/sofosbuvir may result in elevated tenofovir disoproxil plasma concentrations. Monitor the patient for adverse reactions associated with tenofovir disoproxil fumarate.

Drugs/Diseases

Util A	Util B	Util C
Doravirine/Lamivudine/Tenofovir DF	Ledipasvir/Sofosbuvir	

References:
Delstrigo Prescribing Information, August 2018, Merck Sharp & Dohme Corp.
Clinical Pharmacology, 2019 Elsevier/Gold Standard.

30. Delstrigo / Therapeutic Appropriateness _____ _____

Alert Message: The safety and effectiveness of Delstrigo (doravirine/lamivudine/tenofovir disoproxil fumarate) in pediatric patients less than 18 years of age have not been established.

Drugs/Diseases

Util A	Util B	Util C
Doravirine/Lamivudine/Tenofovir DF		

Age Range: 0 – 17 yoa

References:
Delstrigo Prescribing Information, August 2018, Merck Sharp & Dohme Corp.
Clinical Pharmacology, 2019 Elsevier/Gold Standard.

31. Delstrigo / Therapeutic Appropriateness _____ _____

Alert Message: Delstrigo (doravirine/lamivudine/tenofovir disoproxil) is a complete regimen for the treatment of HIV-1 infection, co-administration with other antiretroviral medications for the treatment of HIV-1 infection is not recommended.

Drugs/Diseases

Util A	Util B	Util C
Doravirine/Lamivudine/Tenofovir DF	All Other Antiretrovirals	

References:

Delstrigo Prescribing Information, August 2018, Merck Sharp & Dohme Corp.
Clinical Pharmacology, 2019 Elsevier/Gold Standard.

32. Metformin - All / Vitamin B 12 _____ _____

Alert Message: The use of metformin is associated with vitamin B12 deficiency. Certain individuals (those with inadequate vitamin B12 or calcium intake or absorption) appear to be predisposed to developing subnormal vitamin B12 levels. Consider measuring hematologic parameters on an annual basis and vitamin B12 at 2 to 3-year intervals in patients receiving a metformin-containing medication and manage any abnormalities.

Drugs/Diseases

Util A	Util B	Util C
Metformin		

References:

Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Facts & Comparisons, 2019 Updates, Wolters Kluwer Health.
Aroda VR, Edelstein SL. Goldberg RB, et al., Long-term Metformin Use and Vitamin B12 Deficiency in the Diabetes Prevention Program Outcomes Study. J Clin Endocrinol Metab. 2016 Apr;101(4):1754-1761.

33. DPP-4 Inhibitors / Bullous Pemphigoid _____ _____

Alert Message: Postmarketing cases of bullous pemphigoid requiring hospitalization have been reported with DPP-4 inhibitor use (sitagliptin, saxagliptin, linagliptin, and alogliptin). In reported cases, patients typically recovered with topical or systemic immunosuppressive treatment and discontinuation of the DPP-4 inhibitor. Tell patients to report the development of blisters or erosions while receiving a DPP-4 inhibitor containing medication. If bullous pemphigoid is suspected, the DPP-4 inhibitor should be discontinued, and referral to a dermatologist should be considered for diagnosis and appropriate treatment.

Drugs/Diseases

Util A	Util B	Util C
Sitagliptin	Bullous Pemphigoid	
Saxagliptin		
Linagliptin		
Alogliptin		

References:

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

34. Galcanezumab-gnlm / Overutilization _____ _____

Alert Message: Emgality (galcanezumab-gnlm) may be over-utilized. The recommended dosage of galcanezumab-gnlm for the treatment of episodic cluster headaches is 300 mg (three consecutive 100 mg subcutaneous injections) at the onset of the cluster period, then monthly until the end of the cluster period.

Drugs/Diseases

Util A	Util B	Util C **(Include)**
Galcanezumab-gnlm		Cluster Headache

Max Dose: 3 pens per month

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Emgality Prescribing Information, June 2019, Eli Lilly and Company.

35. Galcanezumab-gnlm / Overutilization _____ _____

Alert Message: Emgality (galcanezumab-gnlm) may be over-utilized. The recommended dosage of galcanezumab-gnlm for the preventative treatment of migraine in adults is 240 mg once as a loading dose, followed by doses of 120 mg injected subcutaneously once monthly.

Drugs/Diseases

Util A	Util B	Util C **(Include)**
Galcanezumab-gnlm		Migraine

Max Dose:1 pen per month after loading dose

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Emgality Prescribing Information, June 2019, Eli Lilly and Company.

36. Pitavastatin / Therapeutic Appropriateness _____ _____

Alert Message: The safety and effectiveness of Livalo (pitavastatin) have not been established in pediatric patients younger than 8 years of age with HeFH or in pediatric patients with other types of hyperlipidemia (other than HeFH).

Drug/Disease:

Util A	Util B	Util C
Pitavastatin		

Age Range: 0 - 7 yoa

References:
Livalo Prescribing Information, May 2019, Kowa Pharmaceuticals America, Inc.
Facts & Comparisons, 2019 Updates, Wolters Kluwer Health.

37. Pitavastatin / Overuse _____ _____

Alert Message: The recommended maximum dose of Zypitamag (pitavastatin magnesium) is 4 mg once daily. Doses exceeding 4 mg per day have been associated with an increased risk for severe myopathy in premarketing clinical studies.

Drug/Disease:

Util A	Util B	Util C **(Negate)**
Pitavastatin		Severe Renal Impairment
		Hemodialysis

Max Dose: 4 mg per day

References:
Zypitamag Prescribing Information, August 2018, Medicure.

38. Pitavastatin / Moderate to Severe Renal Impairment & ESRD _____ _____

Alert Message: The recommended maximum dose of Zypitamag (pitavastatin magnesium) in patients with moderate and severe renal impairment (GFR 30-59 mL/min/1.73m2 and 15-29 mL/min/1.73m2 not receiving hemodialysis, respectively) as well as end-stage renal disease receiving hemodialysis is 2 mg once daily.

Drug/Disease:

Util A	Util B	Util C **(Include)**
Pitavastatin		Severe Renal Impairment
		Hemodialysis

Max Dose: 2 mg/day

References:
Zypitamag Prescribing Information, August 2018, Medicure.

39. Pitavastatin / Cyclosporine _____ _____

Alert Message: Co-administration of Zypitamag (pitavastatin magnesium) with cyclosporine is contraindicated. The concurrent use of these agents has been shown to cause significant increases the AUC (4.6-fold increase) and Cmax (6.6-fold increase) of pitavastatin.

Drug/Disease:

Util A	Util B	Util C
Pitavastatin	Cyclosporine	

References:
Zypitamag Prescribing Information, August 2018, Medicure.

40. Pitavastatin / Active Liver Disease _____ _____

Alert Message: Zypitamag (pitavastatin magnesium) is contraindicated in patients with active liver disease, which may include unexplained persistent transaminase elevations.

Drug/Disease:

Util A	Util B	Util C
Pitavastatin	Hepatitis	
	Cirrhosis	
	Hemochromatosis	
	Non-alcoholic Fatty Liver Disease	
	Hepatic Cancer	
	Wilson's Disease	
	Budd-Chiari Syndrome	
	Gilbert's Syndrome	

References:
Zypitamag Prescribing Information, August 2018, Medicure.

41. Erythromycin / Pitavastatin _____ _____

Alert Message: In patients taking erythromycin, the dose of Zypitamag (pitavastatin magnesium) should not exceed 1 mg per day. In clinical trials, concurrent use of pitavastatin 4 mg QD with erythromycin 500 mg QID for 6 days resulted in a significant increase in pitavastatin exposure (2.8-fold increase in AUC and 3.6-fold increase in Cmax).

Drug/Disease:

Util A	Util B	Util C
Erythromycin	Pitavastatin 2 & 4 mg	

References:
Zypitamag Prescribing Information, August 2018, Medicure.

42. Pitavastatin / Rifampin _____ _____

Alert Message: In patients taking rifampin, the dose of Zypitamag (pitavastatin magnesium) should not exceed 2 mg once daily. In clinical trials, concurrent use of pitavastatin 4 mg QD with rifampin 600 mg QID for 5 days resulted in a significant increase in pitavastatin exposure (29% increase in AUC and 2.0-fold increase in Cmax).

Drug/Disease:

Util A	Util B	Util C
Pitavastatin	Rifampin	

Max Dose: 2 mg/day

References:
Zypitamag Prescribing Information, August 2018, Medicure.

43. Pitavastatin / Therapeutic Appropriateness _____ _____

Alert Message: The safety and effectiveness of Zypitamag (pitavastatin magnesium) in pediatric patients have not been established.

Drug/Disease:

Util A	Util B	Util C
Pitavastatin		

Age Range: 0 - 17 yoa

References:
Zypitamag Prescribing Information, August 2018, Medicure.

44. Dapagliflozin-Saxagliptin-Metformin / Overutilization _____ _____

Alert Message: Qternmet XR (dapagliflozin/saxagliptin/metformin) may be over-utilized. The recommended maximum daily dose of dapagliflozin/saxagliptin/metformin is 10 mg dapagliflozin/5 mg saxagliptin/2000 metformin once daily.

Drugs/Diseases

Util A	Util B	Util C **(Negate)**
Dapagliflozin/Saxagliptin/Metformin		CKD Stage 3, 4 & 5 ESRD Dialysis

Max Dose: 10 mg/5 mg/2000mg per day

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Qternmet XR Prescribing Information, June 2019, AstraZeneca.

45. Dapagliflozin-Saxagliptin-Metformin / CKD Stage 3, 4 & 5 & ESRD _____ _____

Alert Message: Qternmet XR (dapagliflozin/saxagliptin/metformin) use is contraindicated in patients with moderate to severe renal impairment (eGFR < 45 mL/min/1.73m2), end-stage renal disease or on dialysis. The dapagliflozin component of the combo product causes intravascular volume contraction and can cause renal impairment.

Drugs/Diseases

Util A	Util B	Util C **(Include)**
Dapagliflozin/Saxagliptin/Metformin		CKD Stage 3, 4 & 5 ESRD Dialysis

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Qternmet XR Prescribing Information, June 2019, AstraZeneca.

46. Dapagliflozin-Saxagliptin-Metformin/ Therapeutic Appropriateness _____ _____

Alert Message: Qternmet XR (dapagliflozin/saxagliptin/metformin) use is contraindicated in patients with ketoacidosis. Reports of ketoacidosis, a serious life-threatening condition requiring urgent hospitalization, have been identified in postmarketing surveillance in patients with type 1 and type 2 diabetes mellitus receiving sodium glucose cotransporter-2 (SGLT2) inhibitors, including dapagliflozin. Fatal cases of ketoacidosis have been reported in patients taking dapagliflozin. Dapagliflozin/saxagliptin/metformin is not indicated for the treatment of patients with type 1 diabetes mellitus.

Drugs/Diseases

Util A	Util B	Util C
Dapagliflozin/Saxagliptin/Metformin	Ketoacidosis	

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Qternmet XR Prescribing Information, June 2019, AstraZeneca.

47. Dapagliflozin-Saxagliptin-Metformin / Strong CYP3A4/5 Inhibitors _____ _____

Alert Message: Do not co-administer Qternmet XR (dapagliflozin/saxagliptin/metformin) with strong CYP3A4/5 inhibitors (e.g., ketoconazole, atazanavir, nefazodone, ritonavir, and clarithromycin). The saxagliptin component of the combo product is a CYP3A4/5 substrate and use with a strong CYP3A4/5 inhibitor is expected to result in a significant increase in saxagliptin plasma concentrations.

Drugs/Diseases

Util A	Util B		Util C
Dapagliflozin/Saxagliptin/Metformin	Itraconazole	Indinavir	
	Ketoconazole	Nelfinavir	
	Atazanavir	Telithromycin	
	Clarithromycin	Nefazodone	
	Saquinavir	Cobicistat	
	Ritonavir		

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Qternmet XR Prescribing Information, June 2019, AstraZeneca.

48. Dapagliflozin-Saxagliptin-Metformin/ Insulin & Insulin Secretagogues _____ _____

Alert Message: The concurrent use of Qternmet XR (dapagliflozin/saxagliptin/metformin) 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 dapagliflozin/saxagliptin/metformin.

Drugs/Diseases

Util A	Util B	Util C
Dapagliflozin/Saxagliptin/Metformin	Insulin	
	Chlorpropamide	
	Tolbutamide	
	Tolazamide	
	Glyburide	
	Glipizide	
	Glimepiride	

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Qternmet XR Prescribing Information, June 2019, AstraZeneca.

49. Dapagliflozin-Saxagliptin-Metformin/ Bladder Cancer _____ _____

Alert Message: In clinical trials, an increased occurrence of bladder cancer was observed in subjects receiving dapagliflozin (0.17%) as compared to placebo (0.03%). Qternmet XR (dapagliflozin/saxagliptin/metformin) should not be used in patients with active bladder cancer and used with caution in patients with a prior history of bladder cancer.

Drugs/Diseases

Util A	Util B	Util C **(Include)**
Dapagliflozin/Saxagliptin/Metformin		Neoplasm of Bladder
		History of Malignant Neoplasm of Bladder

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Qternmet XR Prescribing Information, June 2019, AstraZeneca.

50. Dapagliflozin-Saxagliptin-Metformin/ Hypotension (Loop Diuretics) _____ _____

Alert Message: The dapagliflozin component of Qternmet XR (dapagliflozin/saxagliptin/metformin) can cause osmotic diuresis which can lead to volume depletion and hypotension, particularly in patients with impaired renal function, elderly patients or patients on loop diuretics. Before initiating a dapagliflozin-containing agent in a patient with one or more of these characteristics, volume status should be assessed and corrected. Patients should be monitored for signs and symptoms during therapy.

Drugs/Diseases

Util A	Util B	Util C
Dapagliflozin/Saxagliptin/Metformin	Furosemide	
	Torsemide	
	Ethacrynate	
	Bumetanide	

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Qternmet XR Prescribing Information, June 2019, AstraZeneca.

51. Dapagliflozin-Saxagliptin-Metformin / Therapeutic Appropriateness _____ _____

Alert Message: The safety and effectiveness of Qternmet XR (dapagliflozin/saxagliptin/metformin) in patients under 18 years of age have not been established.

Drugs/Diseases

Util A	Util B	Util C
Dapagliflozin/Saxagliptin/Metformin		

Age Range: 0 - 17 yoa

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Qternmet XR Prescribing Information, June 2019, AstraZeneca.

52. Dapagliflozin-Saxagliptin-Metformin / Therapeutic Appropriateness _____ _____

Alert Message: The use of Qternmet XR (dapagliflozin/saxagliptin/metformin) can cause an increase in LDL-C levels. Patients receiving dapagliflozin/saxagliptin/metformin should have their LDL-C monitored and treated per standard of care.

Drugs/Diseases

Util A	Util B	Util C **(Include)**
Dapagliflozin/Saxagliptin/Metformin		Hypercholesterolemia

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Qternmet XR Prescribing Information, June 2019, AstraZeneca.

53. Dapagliflozin-Saxagliptin-Metformin / Nonadherence _____ _____

Alert Message: Based on refill history, your patient may be under-utilizing Qternmet XR (dapagliflozin/saxagliptin/metformin). 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
Dapagliflozin/Saxagliptin/Metformin		

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.
Qternmet XR Prescribing Information, June 2019, AstraZeneca.

54. Dapagliflozin-Saxagliptin-Metformin / Pregnancy / Pregnancy Negating _____ _____

Alert Message: Based on animal data showing renal effects, from dapagliflozin, Qternmet XR (dapagliflozin/saxagliptin/metformin) is not recommended during the second and third trimesters of pregnancy. The limited available data with dapagliflozin and saxagliptin in pregnant women are not sufficient to determine a drug-associated risk for major birth defects or miscarriage. During pregnancy, consider appropriate alternative therapies.

Drugs/Diseases

Util A	Util B	Util C **(Negating)**
Dapagliflozin/Saxagliptin/Metformin	Pregnancy	Delivery Abortion Miscarriage

Gender: Female
Age Range: 11 – 50 yoa

References:

Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Qternmet XR Prescribing Information, June 2019, AstraZeneca.
American College of Obstetricians and Gynecologists (ACOG), Committee on Practice Bulletins - Obstetrics. Practice Bulletin No. 137: Gestational Diabetes Mellitus. Obstet Gynecol. 2013:122(2 Pt 1):406-416.
Blumer I, Hadar E, Hadden DR, et al. Diabetes and Pregnancy: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. 2013;98(11):406-416.

55. Dapagliflozin-Saxagliptin-Metformin /OAT2 & MATE Inhibitors _____ _____

Alert Message: Concurrent use of Qternmet XR (dapagliflozin/saxagliptin/metformin) with drugs that interfere with common renal tubular transport systems involved in the renal elimination of metformin (e.g., OCT2 and MATE inhibitors) may result in reduced metformin clearance and increased risk of metformin-related adverse effects (e.g., lactic acidosis). Consider the benefits and risks of concomitant use.

Drugs/Diseases

Util A	Util B	Util C
Dapagliflozin/Saxagliptin/Metformin	Ranolazine Vandetanib Dolutegravir Cimetidine	

References:

Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Qternmet XR Prescribing Information, June 2019, AstraZeneca.

56. Dapagliflozin-Saxagliptin-Metformin / Alcohol Use _____ _____

Alert Message: Alcohol is known to potentiate the effect of metformin on lactate metabolism. Patients should be warned against excessive alcohol intake (ethanol intoxication) while taking a metformin-containing medication due to the increased risk for lactic acidosis.

Drugs/Diseases

Util A	Util B	Util C
Dapagliflozin/Saxagliptin/Metformin	Alcohol Related	Disorders

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Qternmet XR Prescribing Information, June 2019, AstraZeneca.

57. Dapagliflozin-Saxagliptin-Metformin / Lactation _____ _____

Alert Message: Because of the potential for serious adverse reactions in a breastfed infant, advise women that use of Qternmet XR (dapagliflozin/saxagliptin/metformin) is not recommended while breastfeeding. There is limited information regarding the presence of dapagliflozin/saxagliptin/metformin or its components (dapagliflozin, saxagliptin, and metformin) in human milk, the effects on the breastfed infant, or the effects on milk production. Limited published studies report that metformin is present in human milk.

Drugs/Diseases

Util A	Util B	Util C
Dapagliflozin/Saxagliptin/Metformin	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Qternmet XR Prescribing Information, June 2019, AstraZeneca.

58. Lamivudine/Tenofovir Disoproxil / Overutilization _____ _____

Alert Message: The recommended dosage of Cimduo (lamivudine/tenofovir disoproxil fumarate) in HIV-1-infected adult and pediatric patients weighing at least 35 kg is one tablet taken orally once daily with or without food.

Drugs/Diseases

Util A	Util B	Util C
Lamivudine/Tenofovir Disoproxil		

Max dose: 1 tablet/day

References:
Cimduo Prescribing Information, Feb. 2018, Mylan Specialty LP.
Clinical Pharmacology, 2019 Elsevier/Gold Standard.

59. Lamivudine/Tenofovir Disoproxil / Renal Impairment _____ _____

Alert Message: Because Cimduo (lamivudine/tenofovir disoproxil fumarate) is a fixed-dose combination tablet and cannot be dose adjusted, it is not recommended for use in patients with impaired renal function (creatinine clearance less than 50 mL/min) or patients with end-stage renal disease (ESRD) requiring hemodialysis. The tenofovir disoproxil fumarate (TDF) component of the combination antiretroviral agent is primarily eliminated by the kidney. Renal impairment, including cases of acute renal failure and Fanconi syndrome, has been reported with the use of TDF.

Drugs/Diseases

Util A	Util B	Util C **(Include)**
Lamivudine/Tenofovir Disoproxil		CKD 3, 4, & 5 ESRD Dialysis

References:
Cimduo Prescribing Information, Feb. 2018, Mylan Specialty LP.
Clinical Pharmacology, 2019 Elsevier/Gold Standard.

60. Lamivudine/Tenofovir Disoproxil / Lactic Acidosis or Hepatomegaly _____ _____

Alert Message: Lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, have been reported with the use of nucleoside analogs and other antiretrovirals. Treatment with the nucleoside analog should be suspended in any patient who develops clinical or laboratory findings suggestive of lactic acidosis or pronounced hepatotoxicity (which may include hepatomegaly and steatosis even in the absence of marked transaminase elevations).

Drugs/Diseases

Util A	Util B	Util C
Lamivudine/Tenofovir Disoproxil	Lactic Acidosis Hepatomegaly	

References:
Cimduo Prescribing Information, Feb. 2018, Mylan Specialty LP.
Clinical Pharmacology, 2019 Elsevier/Gold Standard.

61. Lamivudine/Tenofovir Disoproxil / Pancreatitis _____ _____

Alert Message: Cimduo (lamivudine/tenofovir disoproxil fumarate), should be used with caution in pediatric patients with a history of prior antiretroviral nucleoside exposure, a history of pancreatitis, or other significant risk factors for the development of pancreatitis. Pancreatitis, which has been fatal in some cases, has been observed in antiretroviral nucleoside-experienced pediatric subjects receiving lamivudine alone or in combination with other antiretroviral agents. Treatment with lamivudine/tenofovir disoproxil fumarate should be stopped immediately if clinical signs, symptoms, or laboratory abnormalities suggestive of pancreatitis occur.

Drugs/Diseases

Util A	Util B	Util C **(Include)**
Lamivudine/Tenofovir Disoproxil		Pancreatitis

References:
Cimduo Prescribing Information, Feb. 2018, Mylan Specialty LP.
Clinical Pharmacology, 2019 Elsevier/Gold Standard.

62. Lamivudine/Tenofovir Disoproxil / Bone Effects _____ _____

Alert Message: In clinical trials in HIV-1-infected adults, tenofovir disoproxil fumarate (TDF) was associated with slightly greater decreases in bone mineral density (BMD) and increases in biochemical markers of bone metabolism, suggesting increased bone turnover relative to comparators. For patients receiving Cimduo (lamivudine/tenofovir disoproxil fumarate), assessment of BMD should be considered for adults who have a history of pathologic bone fracture or other risk factors for osteoporosis or bone loss. If bone abnormalities are suspected, then appropriate consultation should be obtained.

Drugs/Diseases

Util A	Util B	Util C
Lamivudine/Tenofovir Disoproxil	Osteoporosis w/ Fractures	
	Osteoporosis w/o Fractures	

References:

Cimduo Prescribing Information, Feb. 2018, Mylan Specialty LP.
Clinical Pharmacology, 2019 Elsevier/Gold Standard.

63. Lamivudine/Tenofovir Disoproxil / Atazanavir + Ritonavir _____ _____

Alert Message: When atazanavir is co-administered with Cimduo (lamivudine/tenofovir disoproxil fumarate), it is recommended that atazanavir 300 mg is given with ritonavir 100 mg. Tenofovir disoproxil fumarate should not be coadministered with atazanavir without ritonavir.

Drugs/Diseases

Util A	Util B	Util C **(Negate)**
Lamivudine/Tenofovir Disoproxil	Atazanavir	Ritonavir

References:

Cimduo Prescribing Information, Feb. 2018, Mylan Specialty LP.
Clinical Pharmacology, 2019 Elsevier/Gold Standard.

64. Lamivudine/Tenofovir Disoproxil / Lopinavir/Ritonavir _____ _____

Alert Message: The concurrent use of lopinavir/ritonavir with tenofovir disoproxil fumarate (TDF) has been shown to increase TDF concentrations. Patients receiving Cimduo (lamivudine/tenofovir disoproxil fumarate) concomitantly with lopinavir/ritonavir should be monitored for TDF-associated adverse reactions. Lamivudine/TDF should be discontinued in patients who develop TDF-associated adverse reactions.

Drugs/Diseases

Util A	Util B	Util C
Lamivudine/Tenofovir Disoproxil	Lopinavir/rtv	

References:

Cimduo Prescribing Information, Feb. 2018, Mylan Specialty LP.
Clinical Pharmacology, 2019 Elsevier/Gold Standard.

65. Lamivudine/Tenofovir Disoproxil / Atazanavir or Darunavir + Ritonavir _____ _____

Alert Message: Atazanavir coadministered with ritonavir and darunavir coadministered with ritonavir have been shown to increase tenofovir disoproxil fumarate (TDF) concentrations. Patients receiving Cimduo (lamivudine/tenofovir disoproxil fumarate) concomitantly with atazanavir and ritonavir or darunavir and ritonavir should be monitored for TDF-associated adverse reactions. Lamivudine/TDF should be discontinued in patients who develop TDF-associated adverse reactions.

Drugs/Diseases

Util A	Util B	Util C **(Include)**
Lamivudine/Tenofovir Disoproxil	Atazanavir Darunavir	Ritonavir

References:
Cimduo Prescribing Information, Feb. 2018, Mylan Specialty LP.
Clinical Pharmacology, 2019 Elsevier/Gold Standard.

66. Lamivudine/Tenofovir Disoproxil / Sofosbuvir/Velpatasvir _____ _____

Alert Message: Coadministration of tenofovir disoproxil fumarate (TDF), a component of Cimduo (lamivudine/tenofovir disoproxil fumarate), and Epclusa (sofosbuvir/velpatasvir) has been shown to increase TDF exposure. In patients receiving TDF concomitantly with sofosbuvir/velpatasvir, monitor for adverse reactions associated with TDF.

Drugs/Diseases

Util A	Util B	Util C
Lamivudine/Tenofovir Disoproxil	Sofosbuvir/Velpatasvir	

References:
Cimduo Prescribing Information, Feb. 2018, Mylan Specialty LP.
Clinical Pharmacology, 2019 Elsevier/Gold Standard.

67. Lamivudine/Tenofovir Disoproxil / Ledipasvir/Sofosbuvir w/o RTV _____ _____

Alert Message: Coadministration of tenofovir disoproxil fumarate (TDF), a component of Cimduo (lamivudine/tenofovir disoproxil fumarate), and Harvoni (ledipasvir/sofosbuvir) has been shown to increase TDF exposure. In patients receiving (lamivudine/TDF concomitantly with ledipasvir/sofosbuvir without an HIV-1 protease inhibitor/ritonavir or an HIV-1 protease inhibitor/cobicistat combination, monitor for adverse reactions associated with TDF.

Drugs/Diseases

Util A	Util B	Util C **(Negate)**
Lamivudine/Tenofovir Disoproxil	Ledipasvir/Sofosbuvir	Ritonavir Cobicistat

References:
Cimduo Prescribing Information, Feb. 2018, Mylan Specialty LP.
Clinical Pharmacology, 2019 Elsevier/Gold Standard.

68. Lamivudine/Tenofovir Disoproxil / Ledipasvir/Sofosbuvir w/ RTV _____ _____

Alert Message: Coadministration of tenofovir disoproxil fumarate (TDF), a component of Cimduo (lamivudine/tenofovir disoproxil fumarate), and Harvoni (ledipasvir/sofosbuvir) has been shown to increase TDF exposure. In patients receiving lamivudine/TDF, concomitantly with ledipasvir/sofosbuvir and an HIV-1 protease inhibitor/ritonavir or an HIV-1 protease inhibitor/cobicistat combination, consider an alternative HCV or antiretroviral therapy, as the safety of increased TDF concentrations in this setting has not been established.

Drugs/Diseases

Util A	Util B	Util C **(Include)**
Lamivudine/Tenofovir Disoproxil	Ledipasvir/Sofosbuvir	Ritonavir
		Cobicistat

References:
Cimduo Prescribing Information, Feb. 2018, Mylan Specialty LP.
Clinical Pharmacology, 2019 Elsevier/Gold Standard.

69. Lamivudine/Tenofovir Disoproxil / Drugs that Reduce Renal Function _____ _____

Alert Message: Co-administration of Cimduo (lamivudine/tenofovir disoproxil fumarate) with drugs that reduce renal function or compete for active tubular secretion may increase serum concentrations of the tenofovir component of the combination antiretroviral and/or increase the concentrations of other renally eliminated drugs. Tenofovir disoproxil fumarate (TDF) is principally eliminated by the kidney by glomerular filtration and active renal tubular secretion.

Drugs/Diseases

Util A	Util B	Util C
Lamivudine/Tenofovir Disoproxil	Adefovir	
	Cidofovir	
	Acyclovir	
	Valacyclovir	
	Valganciclovir	

References:
Cimduo Prescribing Information, Feb. 2018, Mylan Specialty LP.
Clinical Pharmacology, 2019 Elsevier/Gold Standard.

70. Lamivudine/Tenofovir Disoproxil / NSAIDs _____ _____

Alert Message: The use of Cimduo (lamivudine/tenofovir disoproxil fumarate) should be avoided with concurrent or recent use of a nephrotoxic agent (e.g., high-dose or multiple non-steroidal anti-inflammatory drugs). Cases of acute renal failure after initiation of high dose or multiple NSAIDs have been reported in HIV-infected patients with risk factors for renal dysfunction who appeared stable on tenofovir disoproxil fumarate. Some patients required hospitalization and renal replacement therapy. Alternatives to NSAIDs should be considered, if needed, in patients at risk for renal dysfunction.

Drugs/Diseases

Util A	Util B	Util C
Lamivudine/Tenofovir Disoproxil	NSAIDs	

References:
Cimduo Prescribing Information, Feb. 2018, Mylan Specialty LP.
Clinical Pharmacology, 2019 Elsevier/Gold Standard.

71. Lamivudine/Tenofovir Disoproxil / Nephrotoxic Agents _____ _____

Alert Message: The use of Cimduo (lamivudine/tenofovir disoproxil fumarate) should be avoided with concurrent or recent use of a nephrotoxic agent. Renal impairment, including cases of acute renal failure and Fanconi syndrome (renal tubular injury with severe hypophosphatemia), has been reported with the use of tenofovir disoproxil fumarate (TDF). Coadministration of TDF with nephrotoxic agents may increase the risk nephrotoxicity.

Drugs/Diseases

Util A	Util B		Util C
Lamivudine/Tenofovir Disoproxil	ACE Inhibitor	Pamidronate	
	ARBs	Probenecid	
	Methotrexate	Tacrolimus	
	Cyclosporine	Zoledronic Acid	
	Penicillins	Salicylates	
	Amikacin		

References:
Cimduo Prescribing Information, Feb. 2018, Mylan Specialty LP.
Clinical Pharmacology, 2019 Elsevier/Gold Standard.

72. Lamivudine/Tenofovir Disoproxil / Nonadherence _____ _____

Alert Message: Based on the refill history, your patient may be underutilizing Cimduo (lamivudine/tenofovir disoproxil fumarate). 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
Lamivudine/Tenofovir Disoproxil		

References:
Osterberg L, Blaschke T. Adherence to Medication. N Engl J Med 2005; 353:487- 497.
Beer L, Heffelfinger J, Frazier E, et al. Use of and Adherence to Antiretroviral Therapy in a Large U.S. Sample of HIV-Infected Adults in Care, 2007-2008. Open AIDS J.2012;6:213-223.
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. October 25, 2018. Available at: http://www.aidsinfo.nih.gov/contentfiles/adultandadolescentgl.pdf.
Panel on Antiretroviral Therapy and Medical Management of HIV-Infected Children. Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection. April 16, 2018. Available at: http://aidsinfo.nih.gov/contentfiles/lvguidelines/pediatricguidelines.pdf

73. Acalabrutinib / Overutilization _____ _____

Alert Message: The recommended dose of Calquence (acalabrutinib) is 100 mg taken approximately every 12 hours until disease progression or unacceptable toxicity.

Drugs/Diseases

Util A	Util B	Util C
Acalabrutinib		

Max Dose: 200 mg/day

References:
Calquence Prescribing Information, Oct. 2017, AstraZeneca.
Clinical Pharmacology 2019, Elsevier/Gold Standard.

74. Acalabrutinib / Strong CYP3A4 Inhibitors _____ _____

Alert Message: Coadministration of Calquence (acalabrutinib), a CYP3A4 substrate, with strong CYP3A4 inhibitors should be avoided. Concurrent use of these agents may cause increased acalabrutinib plasma concentrations and result in acalabrutinib toxicity. Alternatively, if the CYP3A4 inhibitor will be used short-term, interrupt acalabrutinib therapy.

Drugs/Diseases

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

References:
Calquence Prescribing Information, Oct. 2017, AstraZeneca.
Clinical Pharmacology 2019, Elsevier/Gold Standard.

75. Acalabrutinib / Moderate CYP3A4 Inhibitors _____ _____

Alert Message: Coadministration of Calquence (acalabrutinib), a CYP3A4 substrate, with moderate CYP3A4 inhibitors may increase acalabrutinib plasma concentrations and result in acalabrutinib toxicity. If acalabrutinib is co-administered with a moderate CYP3A4 inhibitor, reduce the acalabrutinib dose to 100 mg once daily.

Drugs/Diseases

Util A	Util B		Util C
Acalabrutinib	Aprepitant	Ciprofloxacin	
	Crizotinib	Imatinib	
	Diltiazem	Cyclosporine	
	Verapamil	Dronedarone	
	Fluconazole	Erythromycin	
	Fluvoxamine	Fosamprenavir	

Max Dose: 100 mg/day

References:
Calquence Prescribing Information, Oct. 2017, AstraZeneca.
Clinical Pharmacology 2019, Elsevier/Gold Standard.

76. Acalabrutinib / Strong CPY3A4 Inducers _____ _____

Alert Message: Coadministration of Calquence (acalabrutinib), a CYP3A4 substrate, with strong CYP3A4 inducers should be avoided. Concurrent use of these agents may cause decreased acalabrutinib plasma concentrations and result in reduced acalabrutinib activity. If a strong CYP3A4 inducer cannot be avoided, increase the acalabrutinib dose to 200 mg twice daily.

Drugs/Diseases

Util A	Util B	Util C
Acalabrutinib	Carbamazepine	
	Phenytoin	
	Phenobarbital	
	Rifampin	
	Enzalutamide	
	Mitotane	

References:
Calquence Prescribing Information, Oct. 2017, AstraZeneca.
Clinical Pharmacology 2019, Elsevier/Gold Standard.

77. Acalabrutinib / Proton Pump Inhibitors _____ _____

Alert Message: Concurrent use of Calquence (acalabrutinib) with a proton pump inhibitor should be avoided. Co-administration of these agents may result in decreased acalabrutinib plasma concentrations. Acalabrutinib solubility decreases with increasing pH. If treatment with a gastric acid reducing agents is required, consider an H2-receptor antagonist or an antacid.

Drugs/Diseases

Util A	Util B	Util C
Acalabrutinib	Dexlansoprazole	
	Omeprazole	
	Esomeprazole	
	Rabeprazole	
	Lansoprazole	
	Pantoprazole	

References:
Calquence Prescribing Information, Oct. 2017, AstraZeneca.
Clinical Pharmacology 2019, Elsevier/Gold Standard.

78. Acalabrutinib / H2-Receptor Antagonists _____ _____

Alert Message: Concurrent use of Calquence (acalabrutinib) with an H2-receptor antagonist may decrease acalabrutinib plasma concentrations. Acalabrutinib solubility decreases with increasing pH. If the use of an H2-receptor antagonist is required, administer acalabrutinib 2 hours before taking an H2-receptor antagonist.

Drugs/Diseases

Util A	Util B	Util C
Acalabrutinib	Cimetidine	
	Famotidine	
	Ranitidine	
	Nizatidine	

References:
Calquence Prescribing Information, Oct. 2017, AstraZeneca.
Clinical Pharmacology 2019, Elsevier/Gold Standard.

79. Acalabrutinib / Antacids _____ _____

Alert Message: Concurrent use of Calquence (acalabrutinib) with an antacid may decrease acalabrutinib plasma concentrations. Acalabrutinib solubility decreases with increasing pH. If the use of an antacid is required, separate the dosing of acalabrutinib and the antacid by at least 2 hours.

Drugs/Diseases

Util A	Util B	Util C
Acalabrutinib	Aluminum Hydroxide	
	Magnesium Hydroxide	
	Magnesium Carbonate	
	Calcium Carbonate	

References:
Calquence Prescribing Information, Oct. 2017, AstraZeneca.
Clinical Pharmacology 2019, Elsevier/Gold Standard.

80. Acalabrutinib / Therapeutic Appropriateness _____ _____

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

Drugs/Diseases

Util A	Util B	Util C
Acalabrutinib		

Age Range: 0 – 17 yoa

References:
Calquence Prescribing Information, Oct. 2017, AstraZeneca.
Clinical Pharmacology 2019, Elsevier/Gold Standard.

81. Acalabrutinib / Lactation _____ _____

Alert Message: No data are available regarding the presence of Calquence (acalabrutinib) or its active metabolite in human milk, its effects on the breastfed child, or on milk production. Acalabrutinib and its active metabolite were present in the milk of lactating rats. Due to the potential for adverse reactions in a breastfed child from acalabrutinib, advise lactating women not to breastfeed while taking acalabrutinib and for at least 2 weeks after the final dose.

Drugs/Diseases

Util A	Util B	Util C
Acalabrutinib	Lactation	

Gender: Female
Age Range: 11 – 50 yoa

References:
Calquence Prescribing Information, Oct. 2017, AstraZeneca.
Clinical Pharmacology 2019, Elsevier/Gold Standard.

82. Acalabrutinib / Pregnancy / Pregnancy Negating _____ _____

Alert Message: Based on findings in animals, Calquence (acalabrutinib) may cause fetal harm when administered to a pregnant woman. There are no available data in pregnant women to inform the drug-associated risk. In animal reproduction studies, administration of acalabrutinib to pregnant rabbits during organogenesis resulted in reduced fetal growth at maternal exposures (AUC) approximately 4 times exposures in patients at the recommended dose of 100 mg twice daily. Advise pregnant women of the potential risk to a fetus.

Drugs/Diseases

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

Gender: Female
Age Range: 11 – 50 yoa

References:
Calquence Prescribing Information, Oct. 2017, AstraZeneca.
Clinical Pharmacology 2019, Elsevier/Gold Standard.

83. Acalabrutinib / Infections _____ _____

Alert Message: Serious infections (bacterial, viral or fungal), including fatal events and opportunistic infections have occurred in the combined safety database of 612 patients with hematologic malignancies treated with Calquence (acalabrutinib) monotherapy. Monitor patients for signs and symptoms of infection and treat as medically appropriate. Consider prophylaxis in patients who are at increased risk for opportunistic infections.

Drugs/Diseases

Util A	Util B		Util C
Acalabrutinib	Pneumonia	Cryptococcosis	
	Herpes Zoster	Cytomegalovirus	
	Urinary Tract Infection	Hepatitis	
	Esophageal Candidiasis	Fever	
	Acute Histoplasmosis	Pneumocystosis	

References:
Calquence Prescribing Information, Oct. 2017, AstraZeneca.
Clinical Pharmacology, 2019 Elsevier/Gold Standard.

84. Acalabrutinib / Atrial Fib & Flutter / Afib Tx (negating) _____ _____

Alert Message: In the combined safety database of 612 patients with hematologic malignancies treated with Calquence (acalabrutinib) monotherapy, atrial fibrillation and atrial flutter of any grade occurred in 3% of patients, and Grade 3 in 1% of patients. Monitor for atrial fibrillation and atrial flutter and manage as appropriate.

Drugs/Diseases

Util A	Util B	Util C **(Negating)**		
Acalabrutinib	Atrial Fibrillation	Apixaban	Dofetilide	Flecainide
	Atrial Flutter	Dabigatran	Dronedarone	Propranolol
		Digoxin	Edoxaban	Propafenone
		Diltiazem	Sotalol	
		Quinidine	Rivaroxaban	
		Verapamil	Warfarin	

References:
Calquence Prescribing Information, Oct. 2017, AstraZeneca.
Clinical Pharmacology, 2019 Elsevier/Gold Standard.

85. Acalabrutinib / Bleeding _____ _____

Alert Message: Serious hemorrhagic events, including fatal events, have occurred with Calquence (acalabrutinib) therapy. Grade 3 or higher bleeding events, including gastrointestinal, intracranial, and epistaxis have been reported in 2% of patients. The mechanism for the bleeding events is not well understood. Acalabrutinib may further increase the risk of hemorrhage in patients receiving antiplatelet or anticoagulant therapies, and patients should be monitored for signs of bleeding.

Drugs/Diseases

Util A	Util B	Util C **(Include)**
Acalabrutinib	Anticoagulants	Gastrointestinal Bleeding
	Antiplatelets	Intracranial Bleeding
		Epistaxis

References:
Calquence Prescribing Information, Oct. 2017, AstraZeneca.
Clinical Pharmacology 2019, Elsevier/Gold Standard.

86. Clobazam / Overutilization (≥ 10 yoa) _____ _____

Alert Message: Sympazan (clobazam) may be over-utilized. Patients weighing greater than 30 kg should have therapy initiated at 5 mg twice daily and titrated as tolerated to a maximum of 40 mg (20 mg twice daily). Patients weighing 30 kg or less should have clobazam therapy initiated at 5 mg daily and titrated as tolerated to 20 mg (10 mg twice daily).

Drugs/Diseases
Util A Util B Util C
Clobazam

Max Dose: 40 mg/day
Age Range: ≥ 10 yoa

References:
Sympazan Prescribing Information, Nov. 2018, Aquestive Therapeutics.
Clinical Pharmacology, 2019 Elsevier/Gold Standard.

87. Clobazam / Overutilization (2-9 yoa) _____ _____

Alert Message: Sympazan (clobazam) may be over-utilized. Patients weighing 30 kg or less should have clobazam therapy initiated at 5 mg daily and titrated as tolerated to 20 mg daily. Patients weighing greater than 30 kg should have therapy initiated at 10 mg daily and titrated as tolerated to a maximum of 40 mg daily.

Drugs/Diseases
Util A Util B Util C
Clobazam

Max Dose: 20 mg/day
Age Range: 2-9 yoa

References:
Sympazan Prescribing Information, Nov. 2018, Aquestive Therapeutics.
Clinical Pharmacology, 2019 Elsevier/Gold Standard.

88. Clobazam / TA - Therapeutic Appropriateness (<2 yoa) _____ _____

Alert Message: The safety and effectiveness of Sympazan (clobazam) in patients less than 2 years of age have not been established.

Drugs/Diseases
Util A Util B Util C
Clobazam

Age Range: 0-1 yoa

References:
Sympazan Prescribing Information, Nov. 2018, Aquestive Therapeutics.
Clinical Pharmacology, 2019 Elsevier/Gold Standard.

89. Clobazam / Nonadherence _____ _____

Alert Message: Based on the refill history, your patient may be underutilizing Sympazan (clobazam). Non-adherence to the prescribed dosing regimen may result in sub-therapeutic effects, which may lead to decreased patient outcomes and additional healthcare costs. If the patient is discontinuing clobazam, it should be withdrawn gradually by decreasing the total daily dose by 5 - 10 mg/day on a weekly basis until discontinued in order to avoid seizure occurrence or withdrawal symptoms.

Drugs/Diseases

Util A	Util B	Util C
Clobazam		

References:

Sympazan Prescribing Information, Nov. 2018, Aquestive Therapeutics.
Faught E, Duh MS, Weiner JR, et al. Nonadherence to Antiepileptic Drugs and Increased Mortality, Findings from the RANSOM Study. Neurology 2008;71(20): 1572-1578.
Hodges JC, Treadwell J, Malphrus AD, et al., Identification and Prevention of Antiepileptic Drug Noncompliance: The Collaborative Use of State-Supplied Pharmaceutical Data. ISRN Pediatr. 2014 Feb 19:1-8.
Viswanathan M, Golin CE, Jones DC, et al., Interventions to Improve Adherence to Self-administered Medications for Chronic Disease in the United States: A Systemic Review. Ann Intern Med. 2012:157:785-792.

90. Clobazam / Moderate & Strong CYP2C19 Inhibitors _____ _____

Alert Message: Sympazan (clobazam) is a CYP2C19 substrate, and concurrent use with a strong or moderate CYP2C19 inhibitor may result in increased exposure to the active metabolite of clobazam (N-desmethylclobazam). Dosage adjustment of clobazam may be necessary.

Drugs/Diseases

Util A	Util B	Util C
Clobazam	Fluconazole	
	Fluvoxamine	
	Ticlopidine	
	Omeprazole	
	Esomeprazole	
	Fluoxetine	
	Voriconazole	

References:

Sympazan Prescribing Information, Nov. 2018, Aquestive Therapeutics.
Clinical Pharmacology, 2019 Elsevier/Gold Standard.

91. Clobazam / CNS Depressants _____ _____

Alert Message: Sympazan (clobazam) has a CNS depressant effect, and concurrent use with other CNS depressants may result in potentiated depressants effects.

Drugs/Diseases

Util A	Util B	Util C
Clobazam	Narcotics	
	Barbiturates	
	Benzodiazepines	
	Sedative/Hypnotics	
	Muscle Relaxants	
	Antihistamines	
	Antipsychotics	

References:

Sympazan Prescribing Information, Nov. 2018, Aquestive Therapeutics.
Clinical Pharmacology, 2019 Elsevier/Gold Standard.

92. Clobazam / CYP3A4 Metabolized Hormonal Contraceptives _____ _____

Alert Message: Sympazan (clobazam) is a weak CYP3A4 inducer and concurrent use with CYP3A4-mediated hormonal contraceptives may diminish the effectiveness of the contraceptive agent. The manufacturer recommends the use of additional non-hormonal form of contraception when using clobazam.

Drugs/Diseases

Util A	Util B	Util C
Clobazam	CYP3A4 Metabolized Hormonal Contraceptives	

References:
Sympazan Prescribing Information, Nov. 2018, Aquestive Therapeutics.
Clinical Pharmacology, 2019 Elsevier/Gold Standard.

93. Clobazam / Substance Abuse _____ _____

Alert Message: Sympazan (clobazam) should be used with caution in patients with a history of substance abuse because of the predisposition of such patients to habituation and dependence. Clobazam is a benzodiazepine. In clinical trials, cases of dependency were reported following abrupt discontinuation of clobazam.

Drugs/Diseases

Util A	Util B	Util C
Clobazam	Substance Abuse	

References:
Sympazan Prescribing Information, Nov. 2018, Aquestive Therapeutics.
Clinical Pharmacology, 2019 Elsevier/Gold Standard.

94. Clobazam / CYP2D6 Metabolized Drugs _____ _____

Alert Message: Sympazan (clobazam) is a CYP2D6 inhibitor, and concurrent use with drugs metabolized by CYP2D6 may cause increased plasma concentrations of the substrate. Dosage adjustment of the CYP2D6 substrate may be required.

Drugs/Diseases

Util A	Util B			Util C
Clobazam	Dextromethorphan	Aripiprazole	Paroxetine	Ondansetron
	Atomoxetine	Carvedilol	Donepezil	Promethazine
	Metoprolol	Duloxetine	Propafenone	Chlorpheniramine
	Nebivolol	Flecainide	Propranolol	
	Perphenazine	Fluoxetine	Risperidone	
	Tolterodine	Fluvoxamine	Tamoxifen	
	Venlafaxine	Haloperidol	Timolol	
	Thioridazine	Mexiletine	Tramadol	
	Tricyclic Antidepressants	Oxycodone	Amphetamine	

References:
Sympazan Prescribing Information, Nov. 2018, Aquestive Therapeutics.
Clinical Pharmacology, 2019 Elsevier/Gold Standard.

95. Clobazam / Alcohol Abuse/Dependence _____ _____

Alert Message: A review of the patient's diagnostic profile reveals that they may consume alcohol. The concurrent use of Sympazan (clobazam) with alcohol has been reported to increase the maximum plasma exposure of clobazam by approximately 50%. Caution patients against the use of alcohol while taking clobazam.

Drugs/Diseases

Util A	Util B	Util C
Clobazam	Alcohol Dependence	
	Acute Alcohol Intoxication	
	Other/Unspecified Alcohol Dependence	

References:

Sympazan Prescribing Information, Nov. 2018, Aquestive Therapeutics.
Clinical Pharmacology, 2019 Elsevier/Gold Standard.

96. Cariprazine / Overutilization _____ _____

Alert Message: Vraylar (cariprazine) may be over-utilized. The manufacturer's recommended maximum daily dose of cariprazine for the treatment of depressive episodes associated with bipolar 1 disorder is 3 mg once daily.

Drugs/Diseases

Util A	Util B	Util C **(Include)**
Cariprazine		Bipolar Depression

Max Dose: 3 mg/day

References:

Vraylar Prescribing Information, May 2019, Allergan.
Clinical Pharmacology, 2019, Elsevier/Gold Standard.

97. Nuedexta / Elderly _____ _____

Alert Message: A review of the patient's diagnostic profile does not reveal a recent diagnosis of pseudobulbar affect. Nuedexta (dextromethorphan/quinidine) should be used with caution in older patients because it has limited efficacy in alleviating behavioral symptoms of dementia in patients without pseudobulbar affect and because it potentially increases the risk for falls and drug-drug interactions.

Drugs/Diseases

Util A	Util B	Util C **(Negating)**
Dextromethorphan/quinidine		Pseudobulbar Affect

Age Range: ≥ 65 yoa

References:

2019 American Geriatrics Society Beers Criteria Update Expert Panel. American Geriatrics Society 2019 Updated AGS Beers Criteria for Potentially Inappropriate Medication Use in Older Adults. J Am Geriatr Soc. 2019;67(4):674-694.

98. Rivaroxaban / Elderly _____ _____

Alert Message: Xarelto (rivaroxaban) should be used with caution for the treatment of venous thromboembolism or atrial fibrillation in patients 75 years or older. This patient population may be at increased risk of both thrombotic and bleeding events.

Drugs/Diseases

Util A	Util B	Util C
Rivaroxaban		

Age Range: ≥ 75 yoa

References:

2019 American Geriatrics Society Beers Criteria Update Expert Panel. American Geriatrics Society 2019 Updated AGS Beers Criteria for Potentially Inappropriate Medication Use in Older Adults. J Am Geriatr Soc. 2019;67(4):674-694.

99. TMP-SMX / Elderly _____ _____

Alert Message: Trimethoprim-Sulfamethoxazole should be used with caution by older patients with reduced kidney function and taking an angiotensin-converting enzyme inhibitor (ACEI) or angiotensin receptor blocker (ARB) because of an increased risk of hyperkalemia.

Drugs/Diseases

Util A	Util B	Util C
Trimethoprim-Sulfamethoxazole	ACE Inhibitors	
	ARBs	
	Renal Impairment	

Age Range: ≥ 75 yoa

References:

2019 American Geriatrics Society Beers Criteria Update Expert Panel. American Geriatrics Society 2019 Updated AGS Beers Criteria for Potentially Inappropriate Medication Use in Older Adults. J Am Geriatr Soc. 2019;67(4):674-694.

100. Tramadol / Elderly _____ _____

Alert Message: Tramadol-containing medication should be used with caution in older patients because tramadol may exacerbate or cause hyponatremia or SIADH. Sodium levels should be monitored closely when starting or changing tramadol dosages in this patient population.

Drugs/Diseases

Util A	Util B	Util C
Tramadol		

Age Range: ≥ 65 yoa

References:

2019 American Geriatrics Society Beers Criteria Update Expert Panel. American Geriatrics Society 2019 Updated AGS Beers Criteria for Potentially Inappropriate Medication Use in Older Adults. J Am Geriatr Soc. 2019;67(4):674-694.

101. Glimepiride / Elderly _____ _____

Alert Message: Glimepiride-containing medications can produce severe prolonged hypoglycemia in older adults. If no contraindications exist, consider discontinuing the glimepiride-containing agent and switching to a short-acting sulfonylurea (e.g., glipizide) or metformin.

Drugs/Diseases
Util A Util B Util C
Glimepiride

Age Range: ≥ 65 yoa

References:
2019 American Geriatrics Society Beers Criteria Update Expert Panel. American Geriatrics Society 2019 Updated AGS Beers Criteria for Potentially Inappropriate Medication Use in Older Adults. J Am Geriatr Soc. 2019;67(4):674-694.
American Diabetes Association (ADA). 12. Older Adults: Standards of Medical Care-2019. Diabetes Care. 2019 Jan;42(Suppl 1):S139.-147. Available at: http://care.diabetesjournals.org/content/42//Supplement_1

102. Oxaprozin / Overutilization _____ _____

Alert Message: In pediatric patients 6 to 16 years of age with juvenile rheumatoid arthritis, oxaprozin dosing is weight based. In children, doses greater than 1,200 mg have not been studied. The recommended once-daily dose of oxaprozin for pediatric patients weighing 22 to 31 kg is 600 mg and 900 mg once daily for patients weighing 32 to 54 kg. For patients weighing 55 kg or more, the dose is 1200 mg once daily.

Drugs/Diseases
Util A Util B Util C
Oxaprozin

Age Range: 6 - 16 yoa
Max Dose: 1200 mg/day

References:
Daypro Prescribing Information, May 2016, Pfizer.
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Facts & Comparisons, 2019 updates, Wolters Kluwer Health.

103. Oxaprozin / Therapeutic Appropriateness _____ _____

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

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases
Util A Util B Util C
Oxaprozin

Age Range: 0 - 5 yoa

References:
Daypro Prescribing Information, May 2016, Pfizer.
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Facts & Comparisons, 2019 updates, Wolters Kluwer Health.

104. Meloxicam Tabs & ODT / Overutilization - Hemodialysis _____ _____
Alert Message: Meloxicam may be over-utilized. The maximum recommended daily dose of meloxicam in adults on hemodialysis is 7.5 mg.

Drugs/Diseases

Util A	Util B	Util C (**Include)**
Meloxicam Tabs & ODT		Hemodialysis

Max Dose: 7.5 mg/day
Age Range: 18 - 999 yoa

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

105. Meloxicam Tabs & ODT / Overutilization _____ _____
Alert Message: Meloxicam may be over-utilized. The maximum recommended daily dose of meloxicam in pediatric patients with juvenile rheumatoid arthritis who weigh greater than or equal to 60 kg is 7.5 mg. Meloxicam should not be used in children who weigh less than 60 kg.

Drugs/Diseases

Util A	Util B	Util C
Meloxicam Tabs & ODT		

Max Dose: 7.5 mg/day
Age Range: 2 – 17 yoa

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

106. Meloxicam Tabs & ODT / Overutilization _____ _____
Alert Message: The safety and effectiveness of meloxicam tablets in pediatric patients under 2 years of age have not been established.

Conflict Code: ER – Overutilization
Drugs/Diseases

Util A	Util B	Util C
Meloxicam Tabs & ODT		

Age Range: 0 - 1 yoa

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

107. Meloxicam Capsule / Therapeutic Appropriateness _____ _____
Alert Message: The safety and effectiveness of Vivlodex (meloxicam) in pediatric patients have not been established.

Drugs/Diseases

Util A	Util B	Util C
Meloxicam Caps		

Age Range: 0 – 17 yoa

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

108. Meloxicam - All / Severe Renal Disease _____ _____

Alert Message: Avoid the use of meloxicam in patients with advanced renal disease unless the benefits are expected to outweigh the risk of worsening renal function. Long-term administration of NSAIDs has resulted in renal papillary necrosis and other renal injury. No information is available from controlled clinical studies regarding the use of meloxicam in patients with advanced renal disease. The renal effects of meloxicam may hasten the progression of renal dysfunction in patients with pre-existing renal disease.

Drugs/Diseases

Util A	Util B	Util C **(Negate)**
Meloxicam - All	CKD Stage 4	Hemodialysis
	CKD Stage 5	

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

109. Meloxicam Capsules 10 mg / Overutilization - Hemodialysis _____ _____

Alert Message: Vivlodex (meloxicam capsules) may be over-utilized. The maximum recommended daily dose of meloxicam in adults on hemodialysis is 5 mg.

Drugs/Diseases

Util A	Util B	Util C
Meloxicam Caps 10mg	Hemodialysis	

Max Dose: 5 mg/day

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

110. Canagliflozin - All / Black Box Warning _____ _____

Alert Message: An approximately 2-fold increased risk of lower limb amputations has been associated with canagliflozin use in patients with type 2 diabetes who have either established cardiovascular disease or who are at risk for cardiovascular disease. Before initiating a canagliflozin-containing product, consider factors in the patient history that may predispose to the need for amputations, such as a history of prior amputation, peripheral vascular disease, neuropathy and diabetic foot ulcers. Counsel patients about the importance of routine preventative foot care.

Drugs/Diseases

Util A	Util B	Util C
Canagliflozin		
Canagliflozin/Metformin		

Reference:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Facts & Comparisons, 2019 Updates, Wolters Kluwer Health.
MedWatch: FDA Drug Safety Communication: FDA Confirms Increased Risk of Leg and Foot Amputations with the Diabetes Medicine Canagliflozin (Invokana, Invokamet, Invokamet XR). [5-16-2017].
Available at: https://www.fda.gov/Drugs/DrugSafety/ucm557507.htm

111. Ribociclib;Letrozole / Overutilization _____ _____

Alert Message: The recommended dose of Kisqali Femara Co-Pack (ribociclib;letrozole) is 600 mg (three 200 mg film-coated tablets) of ribociclib taken orally, once daily for 21 consecutive days followed by 7 days off ribociclib treatment resulting in a complete cycle of 28 days. The letrozole 2.5 mg tablet is to be taken once daily throughout the 28-day cycle.

Drugs/Diseases

Util A	Util B	Util C
Ribociclib;Letrozole		

Max Dose: 600 mg/day ribociclib; 2.5mg letrozole

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Kisqali Femara Co-Pack Prescribing Information, Feb. 2019, Novartis Pharmaceuticals Corp.

112. Ribociclib;Letrozole / Strong CYP3A4 Inhibitors _____ _____

Alert Message: Concurrent use of Kisqali Femara Co-Pack (ribociclib;letrozole) with a strong CYP3A4 inhibitor may increase exposure to ribociclib, increasing the risk of ribociclib toxicity (e.g., QT prolongation). Concomitant use of these drugs should be avoided. Consider alternative therapies that do not strongly inhibit CYP3A4. If coadministration of ribociclib with a strong CYP3A4 inhibitor cannot be avoided, reduce the dose of ribociclib to 400 mg once daily.

Drugs/Diseases

Util A	Util B		Util C
Ribociclib;Letrozole	Clarithromycin	Nefazodone	
	Cobicistat	Ketoconazole	
	Conivaptan	Itraconazole	
	Ritonavir	Posaconazole	
	Saquinavir	Voriconazole	
	Indinavir	Nelfinavir	

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Kisqali Femara Co-Pack Prescribing Information, Feb. 2019, Novartis Pharmaceuticals Corp.

113. Ribociclib;Letrozole / Strong CYP3A4 Inducers _____ _____

Alert Message: Concurrent use of Kisqali Femara Co-Pack (ribociclib;letrozole) with a strong CPY3A4 inducer should be avoided as concomitant use may result in decreased ribociclib concentrations and reduce efficacy. Consider an alternative concomitant medication with no or minimal potential to induce CYP3A4.

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

Util A	Util B		Util C
Ribociclib;Letrozole	Carbamazepine	Rifampin	
	Phenobarbital	Enzalutamide	
	Primidone	Phenytoin	
	Mitotane		

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Kisqali Femara Co-Pack Prescribing Information, Feb. 2019, Novartis Pharmaceuticals Corp.

114. Ribociclib;Letrozole / CYP3A4 Substrates with NTI _____ _____

Alert Message: Caution is recommended when Kisqali Femara Co-Pack (ribociclib;letrozole) is administered with drugs that are CYP3A4 substrates with a narrow therapeutic index. The ribociclib component in the co-packaged product is a CYP3A4 inhibitor. The dose of a sensitive CYP3A4 substrate with a narrow therapeutic index may need to be reduced as ribociclib can increase substrate exposure.

Drugs/Diseases

Util A	Util B	Util C
Ribociclib;Letrozole	Cyclosporine	
	Dihydroergotamine	
	Ergotamine	
	Everolimus	
	Fentanyl	
	Pimozide	
	Quinidine	
	Sirolimus	
	Tacrolimus	
	Midazolam	

References:

IBM Micromedex DRUDEX (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA, 2019.
Kisqali Femara Co-Pack Prescribing Information, Feb. 2019, Novartis Pharmaceuticals Corp.

115. Ribociclib;Letrozole / QT Prolongation _____ _____

Alert Message: Avoid using Kisqali Femara Co-Pack (ribociclib;letrozole) with drugs known to prolong the QT interval due to an increased risk of QT prolongation. The ribociclib component in the co-packaged product has been shown to prolong the QT interval in a concentration-dependent manner.

Drugs/Diseases

Util A	Util B				Util C
Ribociclib;Letrozole	Albuterol	Disopyramide	Imipramine	Pazopanib	Vardenafil
	Alfuzosin	Deutetrabenazine	Pentamidine	Tizanidine	Venlafaxine
	Amantadine	Dolasetron	Pimavanserin	Tolterodine	Ziprasidone
	Amiodarone	Doxepin	Itraconazole	Posaconazole	
	Amitriptyline	Ketoconazole	Procainamide	TMP/SMZ	
	Amphetamine	Lapatinib	Propafenone	Trimipramine	
	Arsenic Trioxide	Efavirenz	Levalbuterol	Protriptyline	
	Asenapine	Eliglustat	Levofloxacin	Quetiapine	
	Atazanavir	Erythromycin	Lithium	Quinidine	
	Atomoxetine	Escitalopram	Metaproterenol	Ranolazine	
	Azithromycin	Felbamate	Methadone	Risperidone	
	Ceritinib	Flecainide	Midostaurin	Ritonavir	
	Chloroquine	Fluconazole	Moxifloxacin	Salmeterol	
	Chlorpromazine	Fluoxetine	Maprotiline	Sertraline	
	Ciprofloxacin	Foscarnet	Nilotinib	Solifenacin	
	Citalopram	Fosphenytoin	Dofetilide	Sotalol	
	Clarithromycin	Galantamine	Nortriptyline	Sunitinib	
	Clomipramine	Gemifloxacin	Octreotide	Tacrolimus	
	Clozapine	Granisetron	Ofloxacin	Tamoxifen	
	Dasatinib	Haloperidol	Ondansetron	Terbutaline	
	Desipramine	Mexiletine	Paliperidone	Trazodone	
	Diphenhydramine	Iloperidone	Paroxetine	Vandetanib	

References:

Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Kisqali Femara Co-Pack Prescribing Information, Feb. 2019, Novartis Pharmaceuticals Corp.

116. Ribociclib;Letrozole / QT Prolongation _____ _____

Alert Message: Avoid the use of Kisqali Femara Co-Pack (ribociclib;letrozole) in patients who already have or who are at significant risk for developing QT prolongation. The ribociclib component of the co-packaged product has been shown to prolong the QT interval in a concentration-dependent manner. Based on the observed QT prolongation during treatment, ribociclib may require dose interruption, reduction, or discontinuation.

Drugs/Diseases

Util A	Util B	Util C **(Include)**
Ribociclib;Letrozole		Long QT Syndrome
		Congestive Heart Failure
		Unstable Angina
		Bradyarrhythmias
		Myocardial Infarction
		Hypomagnesemia
		Hypokalemia

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Kisqali Femara Co-Pack Prescribing Information, Feb. 2019, Novartis Pharmaceuticals Corp.

117. Ribociclib;Letrozole / Therapeutic Appropriateness _____ _____

Alert Message: Advise women of reproductive potential to use effective contraception during therapy with Kisqali Femara Co-Pack (ribociclib;letrozole) and for at least 3 weeks after the last dose. Based on findings from animal studies and the mechanisms of action, ribociclib;letrozole can cause fetal harm when administered to a pregnant woman.

Conflict Code: TA - Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C **(Negating)**
Ribociclib;Letrozole		Contraceptives

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Kisqali Femara Co-Pack Prescribing Information, Feb. 2019, Novartis Pharmaceuticals Corp.

118. Ribociclib;Letrozole / Pregnancy / Pregnancy Negating _____ _____

Alert Message: Based on findings from animal studies and the mechanisms of action, Kisqali Femara Co-Pack (ribociclib;letrozole) can cause fetal harm when administered to a pregnant woman. Advise pregnant women of potential risk to a fetus.

Drugs/Diseases

Util A	Util B	Util C **(Negating)**
Ribociclib;Letrozole	Pregnancy	Miscarriage
		Delivery
		Abortion

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Kisqali Femara Co-Pack Prescribing Information, Feb. 2019, Novartis Pharmaceuticals Corp.

119. Ribociclib;Letrozole / Lactation _____ _____

Alert Message: It is not known if the components of Kisqali Femara Co-Pack (ribociclib;letrozole) are present in human milk. There are no data on the effects of ribociclib or letrozole on the breastfed infant or on milk production. Because of the potential for serious adverse reactions in breastfed infants from these drugs, advise lactating women not to breastfeed while taking ribociclib;letrozole therapy and for at least 3 weeks after the last dose.

Drugs/Diseases

Util A	Util B	Util C
Ribociclib;Letrozole	Lactation	

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Kisqali Femara Co-Pack Prescribing Information, Feb. 2019, Novartis Pharmaceuticals Corp.

120. Ribociclib;Letrozole / Therapeutic Appropriateness _____ _____

Alert Message: The safety and efficacy of Kisqali Femara Co-Pack (ribociclib;letrozole) in pediatric patients have not been established.

Drugs/Diseases

Util A	Util B	Util C
Ribociclib;Letrozole		

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Kisqali Femara Co-Pack Prescribing Information, Feb. 2019, Novartis Pharmaceuticals Corp.

DUR Board Meeting
December 4, 2019
Capitol Buliding
Brynhild-Haugland Room

North Dakota Medicaid
DUR Board Meeting Agenda
Brynhild Haugland Room
State Capitol
600 East Boulevard Avenue
Bismarck, ND
December 4, 2019
1:00 pm

1. Administrative items
    - DHS announcements

2. Old business
    - Review and approval of September 2019 meeting minutes
    - Budget update
    - Review top 25 drugs for third quarter of 2019
    - Prior authorization/PDL update
    - Second review of antifungal agents for aspergillus and candidiasis infections
    - Second review of eosinophilic asthma agents
    - Annual prior authorization review of prior authorization forms and criteria

3. New business
    - Review of Glucagon agents
    - Retrospective DUR criteria recommendations
    - Upcoming meeting date/agenda.
        - Next meeting is March 4, 2020 in the Brynhild Haugland Room

4. Adjourn

Please remember to silence all cellular phones during the meeting.

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

Members Present: Michael Quast, Gabriela Balf, Tanya Schmidt, Andrea Honeyman, Peter Woodrow, Laura Schield, Jennifer Iverson

Members Absent: Michael Booth, Russ Sobotta, Katie Kram, LeNeika Roehrich

Medicaid Pharmacy Department: Brendan Joyce, Alexi Murphy

Old Business

T. Schmidt served as interim chair and the meeting to order at 1:05 p.m. Chair T. Schmidt asked for a motion to approve the minutes of the June meeting. G. Balf moved that the minutes be approved, and A. Honeyman seconded the motion. The chair called for a voice vote to approve the minutes. The motion passed with no audible dissent.

Review Top 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 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 a number of pulmonary hypertension agents and NSAIDs, 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 Short-Acting Opioid Analgesic Agents

A motion and second was made at the June meeting to place select short-acting opioid analgesic agents on prior authorization. The topic was brought up for a second review. There was no public comment. Chair T. Schmidt called for a voice vote and the motion passed with no audible dissent.

Second Review of Agents for the Treatment of Thrombocytopenia

A motion and second was previously made to place agents for the treatment of thrombocytopenia on prior authorization. The topic was brought up for a second review. There was no public comment. Chair T. Schmidt called for a voice vote and the motion passed with no audible dissent.

Second Review of Agents for Treatment of Interstitial Cystitis

A motion and second was made at the June meeting to place agents for the treatment of interstitial cystitis on prior authorization. The topic was brought up for a second review. There was no public comment. Chair T. Schmidt called for a voice vote and the motion passed with no audible dissent.

Second Review of Agents for the Treatment of Narcolepsy
A motion and second was made at the June meeting to place agents for the treatment of narcolepsy on prior authorization. The topic was brought up for a second review. There was no public comment. Chair T. Schmidt called for a voice vote and the motion passed with no audible dissent.

Sanford Health Plan Update
Danny Weiss, representing Sanford Health Plan, spoke regarding ND Medicaid Expansion. In mid-year 2019, there were 19,226 average members per month with 78% of members utilizing benefits. The generic fill rate was 86.1%. The cost of specialty medications during that time accounted for 29.2% of total costs. The presentation focused on breakdowns of costs associated with specialty vs. non-specialty medications.

New Business

Review of Antifungal Agents for Aspergillus and Candidiasis Infections
A. Murphy presented a review of short-acting opioid agents to the Board. A motion was made by P. Woodrow to create PA criteria for the use of these agents and manage these medications through prior authorization. The motion was seconded by M. Quast. This topic will be reviewed at the next meeting.

Utilization Review of Rescue Inhalers and ADHD Products
T. DeRuiter presented data on the utilization of rescue inhalers and ADHD Products in the fee-for-service Medicaid population. The data indicated an overall reduction in rescue inhaler use per patient since 2015. Data also indicated that the utilization of Adderall as compared to Vyvanse has decreased drastically over the years with 2019 being the first year where Vyvanse is being used at a higher rate than Adderall. of therapeutic duplication with benzodiazepine and or sedative agents, drilled down to most commonly duplicated agents and regimen.

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. T. Schmidt moved to approve the new criteria and G. Balf seconded the motion. The motion passed with no audible dissent.

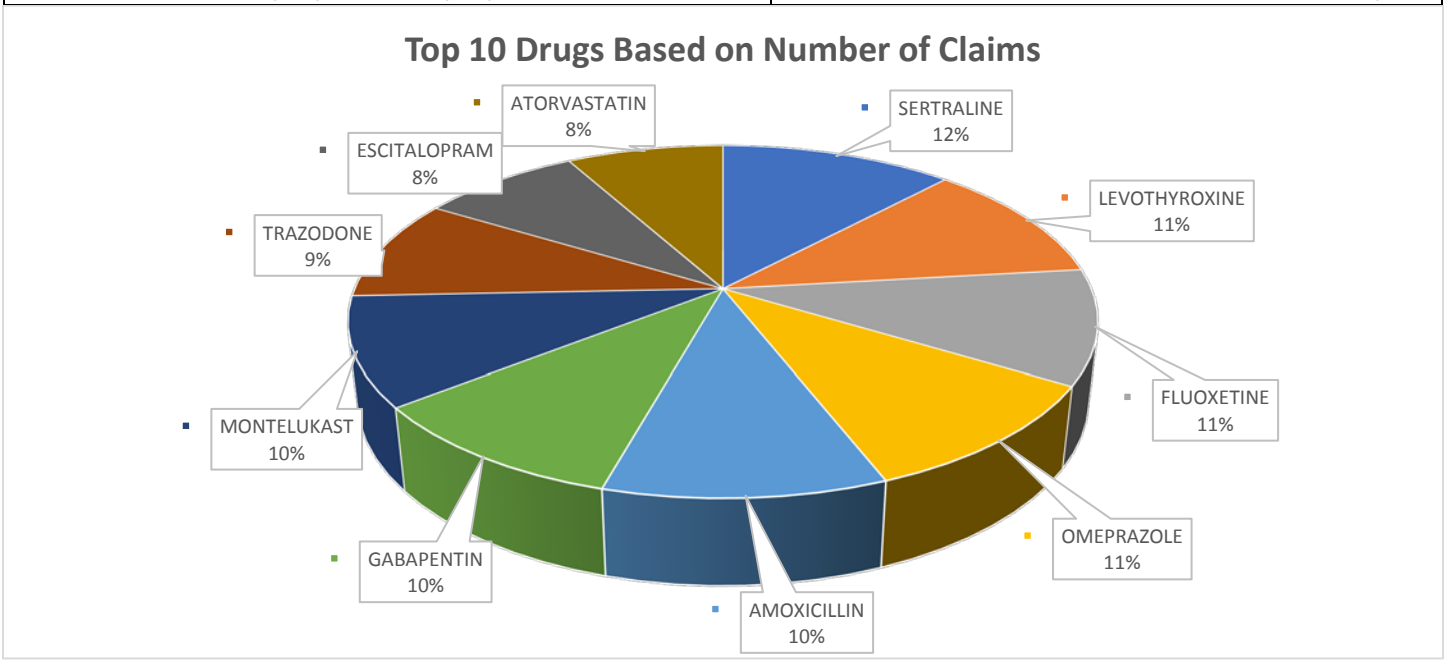
Case Reviews
B. Joyce and A. Murphy presented cases for the DUR Board to review for any potential areas for improvement through targeted interventions, claims processing edits, or other intervention methods.

Adjournment and Upcoming Meeting Date
Chair T. Schmidt adjourned the meeting at 2:45 pm. The next DUR Board meeting will be held December 4, 2019 at 1:00 pm at the State Capitol building in the Brynhild -Haugland room.

TOP 25 DRUGS BASED ON NUMBER OF CLAIMS FROM 07/01/2019 – 09/30/2019

Drug	AHFS Class	Claims	Claims Cost	Patients	Cost Per Claim	% Total Claims
SERTRALINE HCL	ANTIDEPRESSANTS	2,436	$49,017.05	1,123	$20.12	1.83%
LEVOTHYROXINE SODIUM	THYROID AGENTS	2,269	$44,395.01	838	$19.57	1.71%
FLUOXETINE HCL	ANTIDEPRESSANTS	2,132	$37,804.45	960	$17.73	1.60%
OMEPRAZOLE	PROTON-PUMP INHIBITORS	2,106	$38,730.94	973	$18.39	1.58%
AMOXICILLIN	PENICILLIN ANTIBIOTICS	2,091	$80,140.35	1,972	$38.33	1.57%
GABAPENTIN	ANTICONVULSANTS, MISC	2,038	$51,176.40	847	$25.11	1.53%
MONTELUKAST SODIUM	LEUKOTRIENE MODIFIERS	2,023	$39,924.42	1,000	$19.74	1.52%
TRAZODONE HCL	ANTIDEPRESSANTS	1,896	$34,113.38	848	$17.99	1.43%
ESCITALOPRAM OXALATE	ANTIDEPRESSANTS	1,673	$38,279.42	803	$22.88	1.26%
ATORVASTATIN CALCIUM	STATINS	1,640	$42,364.91	714	$25.83	1.23%
VYVANSE	AMPHETAMINES	1,613	$368,030.99	632	$228.17	1.21%
LISINOPRIL	ACE INHIBITORS	1,573	$45,390.24	725	$28.86	1.18%
HYDROCODONE-APAP	OPIATE AGONISTS	1,536	$40,913.42	976	$26.64	1.16%
CLONIDINE HCL	CENTRAL ALPHA-AGONISTS	1,505	$26,452.37	638	$17.58	1.13%
PROAIR HFA	BETA AGONISTS	1,433	$112,108.77	1,412	$78.23	1.08%
RISPERIDONE	ANTIPSYCHOTIC AGENTS	1,366	$19,819.70	442	$14.51	1.03%
LAMOTRIGINE	ANTICONVULSANTS, MISC	1,340	$23,106.20	451	$17.24	1.01%
CONCERTA	CNS STIMULANTS	1,335	$433,087.83	538	$324.41	1.00%
DULOXETINE HCL	ANTIDEPRESSANTS	1,292	$27,451.04	496	$21.25	0.97%
METFORMIN HCL	BIGUANIDES	1,286	$22,116.88	570	$17.20	0.97%
ASPIRIN EC	NSAIDS	1,282	$63,023.96	512	$49.16	0.96%
ARIPIPRAZOLE	ANTIPSYCHOTIC AGENTS	1,264	$26,811.63	516	$21.21	0.95%
FLUTICASONE PROPIONATE	CORTICOSTEROIDS (EENT)	1,247	$28,731.56	870	$23.04	0.94%
PANTOPRAZOLE SODIUM	PROTON-PUMP INHIBITORS	1,219	$18,948.79	524	$15.54	0.92%
VITAMIN D3	VITAMIN D	1,214	$19,970.48	517	$16.45	0.91%

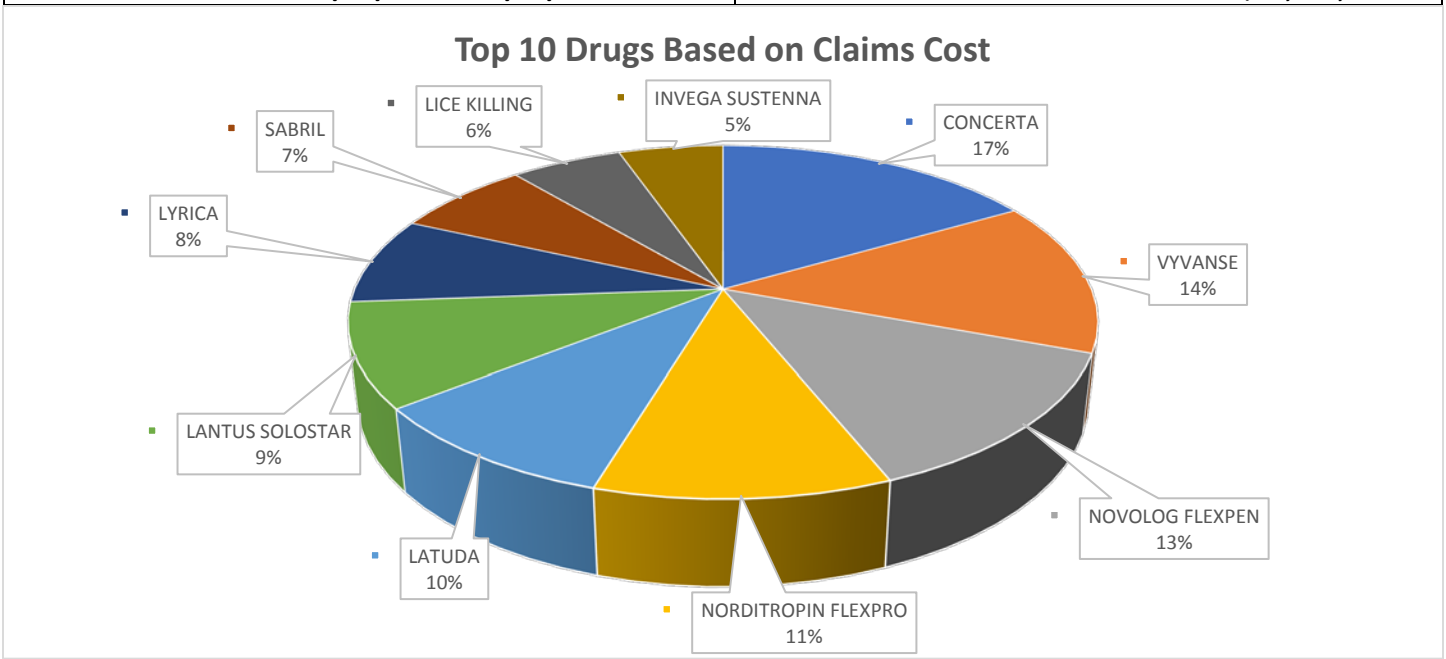
Total Claims From 07/01/2019 – 09/30/2019	132,943



TOP 25 DRUGS BASED ON TOTAL CLAIMS COST FROM 07/01/2019 – 09/30/2019

Drug	AHFS Class	Claims Cost	Claims	Patients	Cost Per Claim	% Total Cost
CONCERTA	CNS STIMULANTS	$433,087.83	1,335	538	$805.00	3.70%
VYVANSE	AMPHETAMINES	$368,030.99	1,613	632	$582.33	3.14%
NOVOLOG FLEXPEN	INSULINS	$342,269.64	583	312	$1,097.02	2.92%
NORDITROPIN FLEXPRO	PITUITARY	$281,234.26	79	33	$8,522.25	2.40%
LATUDA	ANTIPSYCHOTIC AGENTS	$252,157.23	329	117	$2,155.19	2.15%
LANTUS SOLOSTAR	INSULINS	$247,206.50	591	294	$840.84	2.11%
LYRICA	ANTICONVULSANTS, MISC	$208,391.72	456	192	$1,085.37	1.78%
SABRIL	ANTICONVULSANTS, MISC	$183,736.41	9	3	$61,245.47	1.57%
LICE KILLING	SCABICIDES AND LICE	$149,695.00	343	265	$564.89	1.28%
INVEGA SUSTENNA	ANTIPSYCHOTIC AGENTS	$140,220.16	73	30	$4,674.01	1.20%
VIMPAT	ANTICONVULSANTS, MISC	$130,987.99	206	59	$2,220.14	1.12%
GENVOYA	ANTIRETROVIRALS	$123,026.42	105	45	$2,733.92	1.05%
EPCLUSA	HCV ANTIVIRALS	$121,600.25	5	3	$40,533.42	1.04%
NIX	SCABICIDES AND LICE	$120,245.64	274	255	$471.55	1.03%
MAVYRET	HCV ANTIVIRALS	$115,717.14	9	6	$19,286.19	0.99%
HUMIRA PEN	DMARDS	$114,589.01	24	10	$11,458.90	0.98%
PROAIR HFA	BETA-ADRENERGIC AGONISTS	$112,108.77	1,433	1,412	$79.40	0.96%
LEVEMIR FLEXTOUCH	INSULINS	$111,359.58	282	164	$679.02	0.95%
FLOVENT HFA	INHALED CORTICOSTEROIDS	$110,195.46	503	324	$340.11	0.94%
HUMIRA(CF) PEN	DMARDS	$100,938.12	18	7	$14,419.73	0.86%
FOCALIN XR	CNS STIMULANTS	$97,712.49	286	122	$800.92	0.83%
NOVOLOG	INSULINS	$95,186.15	181	90	$1,057.62	0.81%
ZUBSOLV	OPIATE PARTIAL AGONISTS	$90,966.20	357	80	$1,137.08	0.78%
XIFAXAN	ANTIBACTERIALS, MISC	$90,057.88	53	22	$4,093.54	0.77%
SYMBICORT	INHALED CORTICOSTEROIDS	$89,841.83	284	166	$541.22	0.77%

Total Claims Cost From 07/01/2019 – 09/30/2019	$11,705,810.83



PDL Update

ADDED TO PA	
Apokyn	Parkinson's Disease
Aprepitant	Nausea/Vomiting
Asmanex	Corticosteroids – Inhaled
Astagraf XL	Preferred Dosage Forms
Baxdela	Antibiotics - Resistance Prevention
Candesartan-Hydrochlorothiazide	ARBs (Angiotensin Receptor Blockers)
Cutaquig (Human Ig G Solution)	Immune Globulins
Divigel	Estrogens
Duopa	Parkinson's Disease
Emsam	Parkinson's Disease
Femring	Estrogens
Forteo	Osteoporosis
Lokelma	Hyperkalemia
Loprox	Preferred Dosage Forms
Menest	Estrogens
Motegrity	Idiopathic Constipation
Natroba	Lice
Neulasta	Hematopoietic, Colony Stimulating Factors
Nucala	Eosinophilic Asthma
Nuzyra	Antibiotics - Resistance Prevention
Otovel	Otic Anti-infectives/Anti-inflammatories
Oxaprozin	NSAIDS
Pancreaze	Digestive Enzymes
Pennsaid	NSAIDS
Prefest	Estrogens
Qtern	DPP4/SGLT2 Inhibitors Combination
Rasagiline Patch	Parkinson's Disease
Sivextro	Antibiotics - Resistance Prevention
Tazarotene	Antipsoriatics - Topical
Tolcapone	Parkinson's Disease
Tolterodine Tartrate	Urinary Antispasmodics
Tolterodine Tartrate ER	Urinary Antispasmodics
Uloric	Gout
Veltassa	Hyperkalemia
Vivelle-Dot	Estrogens

Removed from PA	
Aliskiren	Renin Inhibitors
Armodafinil	Narcolepsy
Belbuca	Opioid Analgesics – Long Acting
Duaklir Pressair	Anticholinergic/Beta Agonists Combinations
Fasenra	Eosinophilic Asthma
Fiasp	Insulins
Jentadueto XR	DPP4-Inhibitors
Moxifloxacin	Antibiotics - Resistance Prevention
Nourianz	Parkinson's Disease
Orenitram ER	Pulmonary Hypertension
Ozobax	Skeletal Muscle Relaxants
Panzyga	Immune Globulins
Proair Respiclick	Albuterol/Levalbuterol Rescue Inhalers
Retin-A Micro Pump	Acne
Rinvoq	Cytokine Modulators
Rybelsus	GLP-1 Agonists
Sunosi	Narcolepsy
Tolmetin Sodium	NSAIDs
Tosymra	Treatment of Migraine - Triptans - 5HT(1) Agonist
Treprostinil	Pulmonary Hypertension
Tyvaso	Pulmonary Hypertension
Uptravi	Pulmonary Hypertension
Varubi	Nausea/Vomiting
Ventavis	Pulmonary Hypertension
Wakix	Narcolepsy

ANTIFUNGAL AGENTS FOR ASPERGILLUS AND CANDIDA INFECTIONS

Group Criteria: *Approval Duration = 2 weeks*

- The patient must have an FDA-approved indication for use (meets label recommendations for diagnosis and age).
- The patient must have documented history of failure to all preferred agents in last 30-days, as evidenced by paid claims or pharmacy print-outs

Product Specific Criteria

- **Tolsura**:
  - The patient must be intolerant of or refractory to amphotericin B therapy.
- **Cresemba**:
  - For use in prophylaxis of invasive Aspergillus and Candida infections:
    - The patient must be severely immunocompromised (e.g. hematopoietic stem cell transplant (HSCT) recipients with graft-versus-host disease (GVHD), patients with hematologic malignancies with prolonged neutropenia from chemotherapy).

PREFERRED AGENTS	NON-PREFERRED AGENTS
Clotrimazole	NOXAFIL (posaconazole)
Fluconazole	TOLSURA (itraconazole)
Itraconazole	CRESEMBA (isavuconazonium)
Nystatin	
ORAVIG (miconazole)	

EOSINOPHILIC ASTHMA

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).
    - **Cinqair**: The patient must be 18 years of age or older
    - **All others**: The patient must be 12 years of age or older
  - The patient must have had 2 or more asthma exacerbations in previous year despite continued compliant use of one of the following combination therapies, as evidenced by paid claims or pharmacy print-outs (A or B):
    A. A moderate to high dose inhaled steroid in combination with a long-acting beta agonist (LABA)
    B. A moderate to high dose inhaled steroid in combination with a long-acting muscarinic antagonist (LAMA)
  - One of the following must be met (A or B):
    A. The patient must have baseline eosinophil level of ≥ 300 cells/mcL within past 12 months
    B. The patient must have oral corticosteroid dependent asthma and has required at least 30 days of oral steroid use in past 120 days, as evidenced by paid claims or pharmacy print-outs
- **Renewal Criteria:** *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

PREFERRED AGENTS	NON-PREFERRED AGENTS
DUPIXENT (dupilumab)	CINQAIR (reslizumab)
NUCALA (mepolizumab)	
FASENRA (benralizumab)	

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 #

health information designs

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 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:**

• **Does the patient have any contraindications to therapy with the requested agent?**	□ YES □ NO
• **Is medical justification explaining why the patient cannot use the preferred product attached?** *(please attach any relevant documentation to the 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

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 for one of the following reasons.

- **The generic product(s) are not effective (attach MedWatch form for ALL available different generic manufacturers)**
- **There was an adverse reaction with the generic product(s) (attach MedWatch form for ALL available different generic manufacturers)**
- **Primary insurance requires a ND Medicaid non-preferred brand product.**

****DAW not allowed for drugs with an authorized generic available.**

Part I: TO BE COMPLETED BY PRESCRIBER

Recipient Name		Recipient Date of Birth	Recipient Medicaid ID Number	
Prescriber Name				
Prescriber NPI		Telephone Number	Fax Number	
Address		City	State	Zip Code
Requested Drug:	**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

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 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 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

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

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 PHYSICIAN

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 #

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 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:**

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 PREFFERED AGENTS (no PA required) (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 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:**
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 following criteria:

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

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

Recipient Name	Recipient Date of Birth	Recipient Medicaid ID Number
Prescriber Name	Pain, Palliative Care, or Oncology/Hematology Specialist involved in therapy (if not treating 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 following criteria:

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

Part I: TO BE COMPLETED BY PRESCRIBER OF THE BENZODIAZEPINE

Recipient Name	Recipient Date of Birth	Recipient Medicaid ID Number
Prescriber Name	Specialist involved in therapy (if not treating 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 at **http://hidesigns.com/assets/files/ndmedicaid/2019/Criteria/PA_Criteria.pdf**

Part I: TO BE COMPLETED BY PRESCRIBER

Recipient Name	Recipient Date of Birth	Recipient Medicaid ID Number	
Prescriber Name	Specialist involved in therapy (if not treating 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 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 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

Dupixent
Prior Authorization Form

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

Prior Authorization Vendor for ND

ND Medicaid requires that patients receiving a new prescription for Dupixent must meet criteria for coverage, as stated in the PA Criteria page of the North Dakota Medicaid Prior Authorization website (www.hidesigns.com/ndmedicaid) or directly at the following link: http://www.hidesigns.com/assets/files/ndmedicaid/2018/Criteria/PA_Criteria.pdf

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:	**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

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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 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:**

- **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

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Part II: TO BE COMPLETED BY PHARMACY

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

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

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

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Part II: TO BE COMPLETED BY PHARMACY

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

health information designs

Hemangeol
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 Hemangeol must meet the following criteria:

- The patient must have a diagnosis of proliferating infantile hemangioma requiring systemic therapy
- The patient must be between 5 weeks and 1 year of age
- The patient must weigh at least 2 kg
- The provider must attest that the patient does not have any of the following contraindications to treatment:
  - Asthma or history of bronchospasm
  - Bradycardia (<80 beats per minute)
  - Greater than first-degree heart block
  - Decompensated heart failure
  - Blood pressure <50/30 mmHg
  - Pheochromocytoma

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: □ HEMANGEOL	Diagnosis: Patient's weight:	Does patient have ANY contraindications to Hemangeol?	
□ *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

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 PHYSICIAN

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 is drug (illicit use by injection) and alcohol free for past 3 months:** □ YES □ NO
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:

Will the requested medication be given with ribavirin to a patient of child bearing potential? If yes, has the patient had a negative pregnancy test in the last 30 days? Will the receive pregnancy tests monthly during treatment?	□ YES □ NO □ YES □ NO □ N/A □ YES □ NO □ N/A
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 patient have a diagnosis of alcohol use disorder?	□ YES □ NO
Does patient have a history of illicit use of drugs by injection?	□ YES □ NO
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

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 attestation form
- □ 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 agree to complete the entire course of treatment and have laboratory tests before starting, during, and after completing treatment as ordered by my healthcare provider.
- ☐ I understand that for the medication to work, it is important that I take my medication each day for the entire course of treatment.
- ☐ I understand the importance to not drink alcohol or use illicit drugs during and after my treatment for Hepatitis C.
- ☐ I understand how to avoid being re-infected with Hepatitis C during and after my treatment.
- ☐ (Females) I understand that these drugs are harmful to babies. I will use two methods to avoid getting pregnant. I understand that this medication may cause serious birth defects to an unborn child for up to 6 months after I have completed my treatment.
- ☐ (Males) I understand that while I am taking the medication, I must avoid getting my partner pregnant. If my partner becomes pregnant, the baby may have serious birth defects. My partner and I will prevent pregnancy using two forms of birth control for up to 6 months after my treatment is complete. If I have a committed partner, I have discussed these risks with her.

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.

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 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

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 be 18 years of age or older
- The patient must have documented diagnosis of idiopathic pulmonary fibrosis
- The patient must have a specialist involved in therapy
- The patient must have forced vital capacity (FVC) ≥ 50% of predicted within prior 60 days

Product Specific Criteria

- **Alternative Ofev Products:**
  - The patient must have documented diagnosis of systemic sclerosis-associated interstitial lung disease

Part I: TO BE COMPLETED BY PHYSICIAN

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.**
- **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 PHYSICIAN

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 a non-preferred insulin must meet the following criteria:

- **For pens/syringes when vials are available:** Prescriber must provide medical justification explaining why the patient cannot use a vial
- **For Fiasp:** Patient must have failed a 30-day trial with Novolog, Humalog, and Apidra
- **For Basaglar:** Prescriber must provide medical justification explaining why the patient cannot use a preferred products
- **For Tresiba and Toujeo:**
  - Initial Criteria
    - Must be prescribed by or in consultation with an endocrinologist or diabetes specialist
    - Patient must have one of the following (A or B):
      A. Recurrent episodes of hypoglycemia on preferred basal insulin product despite adjustments to current regimen (prandial insulin, interacting drugs, meal and exercise timing).
      B. 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.
    - **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
    - Must provide clinical notes or labs documenting either an improvement in frequency and/or severity of hypoglycemia or documented improved glycemic control (A1C)

Part I: TO BE COMPLETED BY PHYSICIAN

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

Juxtapid
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 Juxtapid must meet the following criteria:

- 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 the following:
  - A lipid lowering agent other than a statin combined with either Crestor (rosuvastatin) ≥20 mg or Lipitor (atorvastatin) ≥ 40 mg
- The patient must meet one of the following (A, B, or C):
  - A. Patient must have genetic confirmation of 2 mutant alleles at the LDLR, APOB, PCSK9, or LDLRAP1 gene locus
  - B. The patient's current untreated LDL and total cholesterol level is > 500 mg/dl or >300 mg/dl with cutaneous or tendon xanthoma before 10 years of age
  - C. The patient has a current untreated LDL level consistent with Heterozygous Familial Hypercholesterolemia (HeFH) in both parents

Part I: TO BE COMPLETED BY PHYSICIAN

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:**		

Patient's Current LDL:

Does the patient have genetic confirmation of 2 mutant alleles at the LDLR, APOB, PCSK9, or LDLRAP1 gene locus?
□ YES □ NO

Untreated LDL and total cholesterol level of > 500 mg/dl or >300 mg/dl with cutaneous or tendon xanthoma before 10 years of age?
□ YES □ NO

Does the patient have an untreated LDL level consistent with HeFH in both parents?
□ 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

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

Part I: TO BE COMPLETED BY 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:**		
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 a new prescription for Mifeprex must meet the following criteria:

- **Patient must have an FDA approved indication for the medication requested.**
- **Prescriber must provide signed written statement as listed in the Mifeprex Prior Authorization Criteria at www.hidesigns.com/assets/files/ndmedicaid/2018/Criteria/PA_Criteria.pdf**

Part I: TO BE COMPLETED BY PHYSICIAN

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 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)			
□ *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 using non-preferred NSAIDs 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 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
Requested Drug and Dosage:	**Diagnosis for this request:**	

List all failed medications:	**Start Date:**	**End Date:**	**Reason for Failure:**

Qualifications for coverage:

Is the patient unable to ingest solid dosage forms (please attach swallow study documentation)?	□ YES □NO
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 postoperative nausea and vomiting?	□ 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

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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 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

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

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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 the following criteria:

Initial Criteria

- Patient must be 18 years of age or older
- Patient must not have a prolonged QT interval, heart failure, or complete atrioventricular block
- Patient's baseline CNS-LS and weekly PBA episode count must be provided
- Patient must have a diagnosis of PBA due to one of the following conditions: ALS, MS, Alzheimer's disease, or stroke
- **For PBA due to Alzheimer's disease or stroke**
  - Neurologic condition must have been stable for at least 3 months
  - Patient must have failed a 3-month trial of one medication from BOTH classes listed: SSRIs (sertraline, fluoxetine, citalopram and paroxetine) and Tricyclic Antidepressants (nortriptyline or amitriptyline)
    - A PBA episode count and CNS-LS score must be provided for before and after each trial

Renewal Criteria

- Benefit of renewal must be assessed
- Baseline and current PBA episode count must be included with request
- Current PBA episode count must be a 75 percent decrease from baseline
- **For PBA due to Alzheimer's disease or stroke**
  - Baseline and current Center for Neurological Studies lability (CNS-LS) must be included with request
  - Current CNS-LS score must be a 30% decrease from baseline

Part I: TO BE COMPLETED BY 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 (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 long-acting opioid analgesic must meet the following criteria:

- Patient must have required around-the-clock pain relief for the past 90 days
- The past 3 months of North Dakota PDMP reports must have been reviewed by the prescriber.
- Patient must be in consult with oncologist or pain management specialist with a pain management contract (with treatment plan including goals for pain and function, and urine and/or blood screens) if:
  - Cumulative daily dose of narcotics exceed 90 MED/day
  - Patient is using benzodiazepine concurrently with narcotic medication
- 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.)

*** For additional and agent-specific criteria, please see criteria for coverage in the Preferred Drug List at www.hidesigns.com/assets/files/ndmedicaid/NDPDL.pdf**

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
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

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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:

- Patient must be 16 years or older.
- Indicated for use in treatment of documented opioid dependence.
- Must not be taking other opioids, tramadol, or carisoprodol concurrently.
- Prescriber must be registered to prescribe buprenorphine and buprenorphine/naloxone combinations under the Substance Abuse and Mental Health Services Administration (SAMHSA).
- For non-preferred agents, the presciber must submit medical justification explaining why preferred agents cannot be used.

Part I: TO BE COMPLETED BY PHYSICIAN

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.

Has a contract between the prescriber and patient been signed?	□ YES	□ NO
Does the prescriber perform routine drug screens?	□ YES	□ NO
Does the prescriber routinely check the PDMP system?	□ YES	□ NO
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

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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
- Documented pain scores must be attached (updated pain scores must be attached to renewals)
- Patient must not have osteoporosis or severe liver disease (Child-Pugh Class C).
- Patient must have failed trials of the following (A and B):
  - A 3-cycle trial of mefenamic acid (or similar fenamate Non-Steroidal Anti-Inflammatory agent (NSAIDs))
  - A 3-cycle trial of twoan oral estrogen-progestin or progestin contraceptives

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:**	

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

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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 non-preferred osteoporosis agents must meet the following criteria:

- Patient must have a diagnosis of an FDA approved indication for use
- Patient must have a current BMD T-score ≤ -2.5 OR new fracture after 6-month trials of each of the following:
  - Denosumab AND either Alendronate or Risedronate
- Patient must be at high risk of fracture, confirmed by at least one of the following:
  - History of hip or vertebral fracture
  - T-score of BMD measurements at the femoral neck or spine is ≤ -2.5 OR between −1.0 and −2.5 & a 10-year hip fracture risk ≥3% as assessed with the FRAX
  - 10-year risk of a major osteoporosis-related fracture of ≥20% as assessed with the FRAX
- Additional Criteria for Forteo and Miacalcin:
  - Patient must have a current BMD T-score ≤ -2.5 OR new fracture after 6-month trials of each of the following:
    - Evenity (Romosozumab) AND Tymlos (Abaloparatide)

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:**

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

PCSK9 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 Medicaid

ND Medicaid requires that patients receiving a new prescription for PCSK9 inhibitors must meet the following criteria:

Group Criteria:

- Patient's LDL must have remained greater than 70 mg/dL after an 8-week trial of Rosuvastatin 20-40 mg or Atorvastatin 40-80 mg with good compliance, as evidenced by paid claims or pharmacy printouts.
- Clinical documentation of the patient's LDL during prior trials must be provided with the request.

Non-Preferred Agents Criteria:

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

Part I: TO BE COMPLETED BY PHYSICIAN

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:**		
	LDL level:		

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

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 PHYSICIAN

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 PHYSICIAN

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

Spinraza PA 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 prescription for Spinraza must meet the following criteria:

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

Part I: TO BE COMPLETED BY PHYSICIAN

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**			
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 (SMA Type 3 only)?** □ **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

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

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**

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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:

- **All Agents**
  - Patient is 18 years of age or older
  - Patient must have a specialist (neurologist or physiatrist) involved in therapy
  - Patient has been diagnosed with tardive dyskinesia
    - Involuntary athetoid or choreiform movements
    - History of treatment with dopamine receptor blocking agent (DRBA)
    - Symptom duration lasting longer than 4-8 weeks
  - Patient must not be taking monoamine oxidase inhibitor (MAOI)
  - Patient is not pregnant or breastfeeding
- **Additional Criteria for Austedo/tetrabenazine:**
  - Patient must have chorea associated with Huntington's disease or Tardive Dyskinesia
  - Patient must not have hepatic impairment

Part I: TO BE COMPLETED BY PHYSICIAN

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 #

Preferred Drug List (PDL)

& Prior Authorization Criteria

Published By:

Medical Services Division
North Dakota Department of Human Services
600 E Boulevard Ave Dept 325
Bismarck, ND 58505-0250

December 2019

Version 2020.1

Effective: January 1, 2020

Please use the Prior Authorization Form 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
        - Preferred Diabetic Supply List (PDSL)
        - Coverage Rules on Medications
        - Therapeutic Duplication Edits

- Please use the NDC Drug Lookup tool to view coverage status, quantity limits, copay, and prior authorization information for all medications.

- To access PA forms, please use:
    - Prior Authorization Form Lookup Tool
    - PA Forms Link

- 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 with a preferred brand/generic equivalent in any category will be given only if all other criteria is met, including all DAW criteria, clinical criteria, and step therapy specific to that category.

- 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 particular brand or generic name includes all legend forms of that drug. OTC drugs are not covered unless specified.

- Rational of inability to swallow a solid dosage form must be provided after age 9 for all non-solid oral dosage forms.

- Clinical justification must be provided for combination products that are comprised of components available and more cost effective when prescribed separately

*** - Indicates that additional PA criteria applies as indicated in the Product PA Criteria

Contents

Please use the Prior Authorization Form Lookup to find Prior Authorization (PA) Forms

General

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
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:

- The patient must have a diagnosis of an FDA-approved indication for use in line with label recommendations

PA REQUIRED
GATTEX (teduglutide)
INCRELEX (mecasermin)
OXERVATE (cenegermin-bkbj)

Non-solid dosage preparations

General Prior Authorization Form

Group Criteria:

- The patient must have failed treatment with a more cost-effect dosage form in the last 30 days, as evidenced by paid claims or pharmacy printouts

    OR

- The patient must be unable to ingest solid dosage form as evidenced by swallow study documentation

Preferred Dosage Forms List:

Prior Authorization Form - Non-Preferred Dosage Form

See Preferred Dosage Forms List

Cardiology

Angina:

Non-Preferred Agents Criteria:

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

PREFFERED AGENTS (NO PA REQUIRED)	NON-PREFFERED AGENTS (PA REQUIRED)
RANEXA (ranolazine)	Ranolazine ER

Blood Modifying Agents

Anticoagulants - Oral:

General Prior Authorization Form

Group Criteria:

- The patient must have a diagnosis of an FDA-approved indication.

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.

PREFFERED AGENTS (NO PA REQUIRED)	NON-PREFFERED AGENTS (PA REQUIRED)
ELIQUIS (Apixaban)	SAVAYSA (edoxaban)
PRADAXA (dabigatran)	
XARELTO (rivaroxaban)	

Anticoagulants - Injectable

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).
- One of the following must be met (A or B)
    A. The patient must have had a 30-day trial of enoxaparin, as evidenced by paid claims or pharmacy printouts.
    B. The request must be for fondaparinux and the patient must have a diagnostic history of heparin-induced thrombocytopenia (HIT)

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

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 PREFFERED AGENTS (no PA required) (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	
PREFFERED AGENTS (CLINICAL PA REQUIRED)	NON-PREFFERED AGENTS (PA REQUIRED)
NOVOSEVEN RT (Coagulation Factor VIIa recombinant)	
FACTOR VIII – HEMOPHILIA A	
PREFFERED AGENTS (CLINICAL PA REQUIRED)	NON-PREFFERED AGENTS (PA REQUIRED)
ADVATE (factor VIII recombinant)	ADYNOVATE (factor VIII recombinant, PEGylated)

HEMOFIL M (factor VIII plasma derived; mAb-purified)	AFSTYLA (factor VIII recombinant, single chain)
KOATE (factor VIII plasma derived, chromatography purified)	ELOCTATE (factor VIII recombinant, Fc fusion protein)
KOGENATE FS (factor VIII recombinant)	JIVI (factor VIII recombinant, pegylated-aucl)
NOVOEIGHT (factor VIII recombinant)	KOVALTRY (factor VIII recombinant)
NUWIQ (factor VIII recombinant)	OBIZUR (recombinant, B domain-deleted porcine factor VIII)
RECOMBINATE (factor VIII recombinant)	
XYNTHA (factor VIII recombinant)	
XYNTHA SOLOFUSE (factor VIII recombinant)	
FACTOR VIII:C – HEMOPHILIA A	
PREFFERED AGENTS (CLINICAL PA REQUIRED)	**NON-PREFFERED AGENTS (PA REQUIRED)**
MONOCLATE-P (Antihemophilic Factor VIII:C (human))	
FACTOR VIII – HEMOPHILIA A/vWF	
PREFFERED AGENTS (CLINICAL PA REQUIRED)	**NON-PREFFERED 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	
PREFFERED AGENTS (CLINICAL PA REQUIRED)	**NON-PREFFERED AGENTS (PA REQUIRED)**
	VONVENDI (Recombinant human vWF)
FACTOR IX – HEMOPHILIA B	
PREFFERED AGENTS (CLINICAL PA REQUIRED)	**NON-PREFFERED 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	
PREFFERED AGENTS (CLINICAL PA REQUIRED)	**NON-PREFFERED AGENTS (PA REQUIRED)**
HEMLIBRA (Emicizumab-kxwh)	
FACTOR X	
PREFFERED AGENTS (CLINICAL PA REQUIRED)	**NON-PREFFERED AGENTS (PA REQUIRED)**
COAGADEX (Coagulation Factor X (Human))	
FACTOR X	
PREFFERED AGENTS (CLINICAL PA REQUIRED)	**NON-PREFFERED AGENTS (PA REQUIRED)**
CORIFACT (Factor XIII Concentrate (Human))	
FACTOR XIII A – SUBUNIT, RECOMBINANT	
PREFFERED AGENTS (CLINICAL PA REQUIRED)	**NON-PREFFERED AGENTS (PA REQUIRED)**
TRETTEN (Factor XIII A-Subunit, recombinant)	
ANTI-INHIBITOR COAGULANT COMPLEX	
PREFFERED AGENTS (CLINICAL PA REQUIRED)	**NON-PREFFERED 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).

Please use the Prior Authorization Form Lookup to find Prior Authorization (PA) Forms

Non-Preferred Agents Criteria:

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

PREFFERED AGENTS (NO PA REQUIRED)	NON-PREFFERED AGENTS (PA REQUIRED)
FULPHILA (Pegfilgrastrim-JMDB)	GRANIX (TBO-Filgrastim)
LEUKINE (Sargramostim)	NEULASTA (Pegfilgrastim)
NEUPOGEN (Filgrastim)	NIVESTYM (Figrastim-AAFI)
UDENYCA (pegfligrastim-CBQV)	ZARXIO (Filgrastim-SNDZ)

Platelet Aggregation Inhibitors

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:

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

Product Specific Criteria:

- ***Yosprala DR/Durlaza**: Clinical justification must be provided explaining why the patient is unable to use the preferred products (subject to clinical review).

PREFFERED AGENTS (NO PA REQUIRED)	NON-PREFFERED AGENTS (PA REQUIRED)
AGGRENOX (aspirin/dipyridamole)	Aspirin/Dipyridamole ER
Aspirin	Aspirin/Omeprazole DR
BRILINTA (ticagrelor)	Clopidogrel 300mg
Clopidogrel 75 mg	DURLAZA (aspirin ER)***
Dipyridamole	EFFIENT (prasugrel)
Prasugrel	PLAVIX (clopidogrel)
	YOSPRALA DR (aspirin/omeprazole)***
	ZONTIVITY (vorapaxar)

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

PREFFERED AGENTS (CLINICAL PA REQUIRED)	NON-PREFFERED 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

PREFFERED AGENTS (CLINICAL PA REQUIRED)	NON-PREFFERED 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

ARBs (Angiotensin Receptor Blockers)

General Prior Authorization Form

Non-Preferred Agents Criteria:

- The patient must have had 30-day trials of 3 preferred agents at their highest tolerable therapeutic dose, as evidenced by paid claims or pharmacy printouts.

Product Specific Criteria:

- **Combination agents:**
  - Clinical justification must be provided explaining why the patient is unable to use a preferred combination product or the individual agents separately (subject to clinical review).

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

Amlodipine-olmesartan	Amlodipine-Valsartan-Hydrochlorothiazide
Amlodipine-valsartan	ATACAND (Candesartan)
Candesartan 4mg, 32mg	ATACAND HCT (Candesartan-Hydrochlorothiazide)
EDARBI (azilsartan)	AVALIDE (Irbesartan-Hydrochlorothiazide)
EDARBYCLOR (azilsartan/chlorothalidone)	AVAPRO (irbesartan)
Irbesartan	AZOR (Amlodipine/Olmesartan)
Irbesartan-hydrochlorothiazide	BYVALSON (Nebivolol/Valsartan)
Losartan	Candesartan 8mg, 16mg
Losartan-hydrochlorothiazide	Candesartan-hydrochlorothiazide
Olmesartan	COZAAR (Losartan)
Olmesartan-hydrochlorothiazide	DIOVAN HCT (Valsartan-Hydrochlorothiazide)
Telmisartan	Eprosartan
Valsartan	EXFORGE (Amlodipine-Valsartan)
Valsartan-hydrochlorothiazide	EXFORGE HCT (Amlodipine-Valsartan-Hydrochlorothiazide)
	HYZAAR (Losartan-Hydrochlorothiazide)
	Telmisartan-Amlodipine
	Telmisartan-Hydrochlorothiazide
	TRIBENZOR (Olmesartan-Amlodipine-Hydrochlorothiazide)

Renin Inhibitors

General Prior Authorization Form

Non-Preferred Agents Criteria:

- The patient must have had 30-day trials of 2 different ACE-inhibitors and 2 different ARBs, each at the highest tolerable therapeutic dose, as evidenced by paid claims or pharmacy printouts.

PREFERRED AGENTS	NON-PREFERRED AGENTS
TEKTURNA (aliskiren)	aliskirin
	TEKTURNA HCT (aliskiren-hydrochlorothiazide)

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)
  - A. The patient must have a documented sulfa allergy
  - B. The patient must have failed a 30-day trial of all preferred agents, as evidenced by paid claims or pharmacy print outs.

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

Entresto

Product Specific Criteria:

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

PREFFERED AGENTS (NO PA REQUIRED)	NON-PREFFERED AGENTS (PA REQUIRED)
ENTRESTO (sacubitril/valsartan)	

Lipid-Lowering Agents

Juxtapid

Prior Authorization Form - Juxtapid

Product Specific Criteria:

- 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 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
- The patient must meet one of the following (A, B, or C):
    - A. The patient must have genetic confirmation of two mutant alleles at the LDLR, APOB, PCSK9, or LDLRAP1 gene locus
    - B. The patient's current untreated LDL and total cholesterol level is > 500 mg/dl or >300 mg/dl with cutaneous or tendon xanthoma before 10 years of age
    - C. The patient has a current untreated LDL level consistent with Heterozygous Familial Hypercholesterolemia (HeFH) in both parents

PCSK9 Inhibitors

PCSK9 Inhibitors Prior Authorization Form

Group Criteria:

- Patient's LDL must have remained greater than 70 mg/dL after an 8-week trial of Rosuvastatin 20-40 mg or Atorvastatin 40-80 mg with good compliance, as evidenced by paid claims or pharmacy printouts.
- Clinical documentation of the patient's LDL during prior trials must be provided with the request.

Non-Preferred Agents Criteria:

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

PREFFERED AGENTS (CLINICAL PA REQUIRED)	NON-PREFFERED AGENTS (PA REQUIRED)
PRALUENT PEN (Alirocumab)	REPATHA SURECLICK (Evolocumab)
REPATHA PUSHTRONEX (Evolocumab)	REPATHA SYRINGE (Evolocumab)

Statins

General Prior Authorization Form

Product Specific Criteria:

- **Livalo**:
    - Statin intensity treatment goal must be "moderate" or "low"
    - The patient must have failed 3-month trials of one of the below drug regimens (based on their intensity treatment goal), as evidenced by paid claims or pharmacy print outs:
        - "Moderate" treatment goal
            - atorvastatin 10-20mg, rosuvastatin 5-10mg, and one of the following:
                - Simvastatin 20 - 40mg a day

        - Pravastatin 40 - 80mg a day
        - Lovastatin 40mg a day
        - Fluvastatin XL 80mg a day
        - Fluvastatin 40mg twice a day
    - "Low" treatment goal
        - Two of the following:
            - Simvastatin 10mg a day
            - Pravastatin 10 - 20mg a day
            - Lovastatin 20mg a day
            - Fluvastatin 20 - 40mg a day
- **Altoprev (lovastatin) ER/Fluvastatin/Fluvastatin ER/Zypitamag:**
    - Clinical justification must be provided explaining why the patient is unable to use the preferred agents (subject to clinical review).

PREFFERED AGENTS (NO PA REQUIRED)	NON-PREFFERED AGENTS (PA REQUIRED)
atorvastatin	ALTOPREV (lovastatin)
lovastatin	ALTOPREV (lovastatin) ER
pravastatin	Amlodipine-atorvastatin
rosuvastatin	CRESTOR (rosuvastatin)
simvastatin	EZALLOR SPRINKLE (rosuvastatin)
	Ezetimibe-simvastatin
	fluvastatin
	fluvastatin ER
	LESCOL XL (fluvastatin)
	LIPITOR (atorvastatin)
	LIVALO (pitavastatin)
	PRAVACHOL (pravastatin)
	ZOCOR (simvastatin)
	ZYPITAMAG (pitavastatin)

Pulmonary Hypertension

General Prior Authorization Form

PDE-5 Inhibitors

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.

Product Specific Criteria:

- **Sildenafil/Tadalafil:**
    - One of the following must be met (A or B):
        A. The patient must be less than 12 years of age
        B. The provider must submit clinical documentation to support patient's diagnosis
- **Revatio Suspension:**
    - The provider must submit clinical documentation to support patient's diagnosis
    - One of the following must be met (A or B):
        A. The patient must be less than 9 years of age.

B. The provider must submit clinical documentation of the patient's inability to ingest a solid dosage form.

PREFFERED AGENTS (PA REQUIRED)	NON-PREFFERED 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

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.

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

Endothelin Receptor Antagonists

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.

Product Specific Criteria:

- **Tracleer Suspension**
  - One of the following must be met (A or B):
    A. The patient must be less than 9 years of age
    B. The provider must submit clinical documentation of the patient's inability to ingest a solid dosage form

PREFFERED AGENTS (NO PA REQUIRED)	NON-PREFFERED AGENTS (PA REQUIRED)
Ambrisentan	Bosentan
TRACLEER (bosentan) SUSPENSION***	LETAIRIS (ambrisentan)
TRACLEER (bosentan) TABLETS - *Brand Preferred*	OPSUMIT (macitentan)

Prostacyclins

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.

PREFFERED AGENTS (NO PA REQUIRED)	NON-PREFFERED AGENTS (PA REQUIRED)
ORENITRAM ER (Treprostinil) TABLET	REMODULIN (Treprostinil) INJECTION
UPTRAVI (Selexipag) TABLET	
Treprostinil injection	
TYVASO (Treprostinil) INHALATION	
VENTAVIS (Iloprost) INHALATION	

Dermatology

Acne

General Prior Authorization Form

Group Criteria:

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

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	
PREFFERED AGENTS (NO PA REQUIRED)	**NON-PREFFERED AGENTS (PA REQUIRED)**
Clindamycin-benzyl peroxide 1.2%-5%	ACANYA (Clindamycin-benzoyl peroxide) 1.2%-2.5%
Clindamycin/benzoyl peroxide 1%-5% without pump	BENZACLIN (Clindamycin/benzoyl peroxide without pump) 1%-5%
ONEXTON (Clindamycin/benzoyl peroxide) 1.2%-3.75%	BENZACLIN (Clindamycin/benzoyl peroxide with pump) 1%-5%
	Clindamycin/benzoyl peroxide 1%-5% with pump
	Clindamycin-benzoyl peroxide 1.2%-2.5%
	DUAC (lindamycin/benzoyl peroxide) 1.2%-5%
	NEUAC (Clindamycin/benzoyl peroxide) 1.2%-5%
TRETINOIN MICROSPHERES	
PREFFERED AGENTS (NO PA REQUIRED)	**NON-PREFFERED AGENTS (PA REQUIRED)**
RETIN-A MICRO PUMP (Tretinoin Microsphere) 0.06%	RETIN-A MICRO (Tretinoin Microsphere) GEL WITHOUT PUMP
RETIN-A MICRO PUMP (Tretinoin Microsphere) 0.08%	RETIN-A MICRO PUMP (Tretinoin Microsphere) 0.04%
	RETIN-A MICRO PUMP (Tretinoin Microsphere) 0.10%
	tretinoin microsphere without pump
	tretinoin microsphere with pump
TRETINOIN	
PREFFERED AGENTS (NO PA REQUIRED)	**NON-PREFFERED AGENTS (PA REQUIRED)**
ALTRENO (tretinoin) LOTION	ATRALIN (Tretinoin) 0.05% GEL
AVITA (tretinoin) CREAM *(brand preferred)*	Clindamycin-tretinoin 1.2%-0.025%
RETIN-A (tretinoin) CREAM *(brand preferred)*	FABIOR (tazarotene) 0.1% FOAM
Tretinoin gel 0.01%, 0.03%	Tretinoin cream
ZIANA (Clindamycin-tretinoin 1.2%-0.025%) *(brand preferred)*	Tretinoin gel 0.05%
ADAPALENE	
PREFFERED AGENTS (NO PA REQUIRED)	**NON-PREFFERED AGENTS (PA REQUIRED)**
DIFFERIN (adapalene) CREAM (*brand preferred*)	Adapalene 0.1% cream
Adapalene gel	Adapalene 0.3% gel with pump
DIFFERIN (adapalene) GEL W/ PUMP *(brand preferred)*	Adapalene/Benzoyl Peroxide 0.1%-2.5%
DIFFERIN (adapalene) LOTION	
EPIDUO (adapalene/benzoyl peroxide) 0.1%-2.5% *(brand preferred)*	
EPIDUO FORTE (adapalene/benzoyl peroxide) 0.3%-2.5%	
OTHER	

PREFFERED AGENTS (NO PA REQUIRED)	NON-PREFFERED AGENTS (PA REQUIRED)
ACZONE (Dapsone) GEL WITH PUMP 7.5%	ACZONE (Dapsone) GEL WITHOUT PUMP 5%
AZELEX (Azelaic Acid)	AKLIEF (Trifarotene) CREAM 0.005%
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
Sulfacetamide suspension	CLINDAGEL (Clindamycin) GEL DAILY
	Clindamycin Gel Daily
	Clindamycin foam
	Dapsone gel without pump 5%
	EVOCLIN (Clindamycin) FOAM
TETRACYCLINES	
PREFFERED AGENTS (NO PA REQUIRED)	**NON-PREFFERED AGENTS (PA REQUIRED)**
Doxycycline hyclate capsule	Demeclocycline
Doxycycline hyclate tablet 20mg, 100mg	DORYX (Doxycycline hyclate) TABLET DR
Doxycycline monohydrate 25 mg/5mL suspension	DORYX MPC (Doxycycline hyclate) TABLET DR
Doxycycline monohydrate tablet 50 mg, 75mg, 100mg	Doxycycline monohydrate capsule 75mg, 150mg
Doxycycline monohydrate capsule 50 mg, 100mg	Doxycycline hyclate tablet 75mg, 150 mg
Minocycline capsule	Doxycycline monohydrate tablet 75mg, 150 mg
Minocycline tablet	Doxycycline hyclate tablet DR
VIBRAMYCIN (Doxycycline) 25mg/5mL SUSPENSION	MINOCIN (Minocycline) CAPSULE
VIBRAMYCIN (Doxycycline calcium) 50 mg/5mL SYRUP	Minocycline Tablet ER
	MINOLIRA ER (Minocycline) TABLET
	MORGIDOX (Doxycycline hyclate) CAPSULE
	SEYSARA (Sarecycline)
	SOLODYN ER (Minocycline) TABLET
	Tetracycline
	XIMINO (Minocycline) CAPSULE ER

Actinic Keratosis

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 6-month trial of each preferred agent of a unique active ingredient, as evidenced by paid claims or pharmacy printouts.

PREFFERED AGENTS (NO PA REQUIRED)	NON-PREFFERED AGENTS (PA REQUIRED)
CARAC (Fluorouracil) 0.5% CREAM	Fluorouracil 0.5% cream
Diclofenac 3% sodium gel	Imiquimod 3.75% cream pump
Imiquimod 5% cream packet	PICATO (ingenol mebutate)
Fluorouracil 5% cream	ZYCLARA (imiquimod) 3.75% CREAM PUMP
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

PREFFERED AGENTS (NO PA REQUIRED)	NON-PREFFERED AGENTS (PA REQUIRED)
Ciclopirox cream	CICLODAN (Ciclopirox) CREAM
Ciclopirox gel	CICLODAN (Ciclopirox) SOLUTION
Ciclopirox shampoo	EXTINA (Ketoconazole) FOAM
Ciclopirox solution	JUBLIA (efinaconazole) SOLUTION
Clotrimazole cream	KERYDIN (tavaborole) SOLUTION
Clotrimazole solution	Ketoconazole foam
Econazole cream	LOPROX (Ciclopirox) CREAM
ERTACZO (sertraconazole) CREAM	LOPROX (Ciclopirox) SHAMPOO
EXELDERM CREAM (sulconazole)	LOPROX (Ciclopirox/Skin Cleanser) KIT
EXELDERM SOLUTION (sulconazole)	LOPROX (Ciclopirox) SUSPENSION
Ketoconazole cream	LUZU (Luliconazole) Cream
Ketoconazole shampoo	Naftifine Cream
Luliconazole cream	Natfifine Gel
MENTAX (butenafine) CREAM	NAFTIN (Naftifine) CREAM
Miconazole	NAFTIN (Naftifine) GEL
Miconazole/zinc oxide/white petrolatum ointment	NIZORAL (Ketoconazole) SHAMPOO
Nystatin cream	NYAMYC (Nystatin) POWDER
Nystatin ointment	NYSTOP (Nystatin) POWDER
Nystatin powder	Oxiconazole cream
Nystatin – triamcinolone cream	OXYSTAT (Oxiconazole) CREAM
Nystatin – triamcinolone ointment	OXISTAT (oxiconazole) LOTION
	PENLAC (Ciclopirox) SOLUTION

	VUSION (Miconazole/Zinc/White Petrolatum) OINTMENT

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

PREFFERED AGENTS (NO PA REQUIRED)	NON-PREFFERED AGENTS (PA REQUIRED)
calcipotriene ointment	calcipotriene/betamethasone ointment
calcipotriene solution	Calcitriol ointment
calcipotriene cream	DOVONEX (Calcipotriene) CREAM
SORILUX (calcipotriene) FOAM	DUOBRII (halobetasol/tazarotene) LOTION
TACLONEX (calcipotriene/betamethasone) SUSPENSION	ENSTILAR (calcipotriene/betamethasone) FOAM
TAZORAC (Tazarotene) CREAM 0.05%	TACLONEX (calcipotriene/betamethasone) OINTMENT
TAZORAC (Tazarotene) GEL	Tazarotene cream
VECTICAL (Calcitriol) OINTMENT	TAZORAC (Tazarotene) CREAM 0.1%

Eczema / Atopic Dermatitis

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*

- **Eucrisa**:
  - Patient must have had a 30-day trial of at least one of the following within the past 180 days, as evidenced by paid claims or pharmacy printouts:
    - A topical calcineurin inhibitor (tacrolimus or pimecrolimus) OR a topical corticosteroid
- **Dupixent**
  - 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 = 3 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

PREFFERED AGENTS (CLINICAL PA REQUIRED)	NON-PREFFERED AGENTS (PA REQUIRED)
DUPIXENT (dupilumab)***	Tacrolimus 0.03%
EUCRISA (crisaborole) OINTMENT***	Tacrolimus 0.1%
Pimecrolimus – Labeler 68682	ELIDEL (pimecrolimus) CREAM
PROTOPIC (tacrolimus) OINTMENT 0.03%	Pimecrolimus – Labeler 00591
PROTOPIC (tacrolimus) OINTMENT 0.1%***	

Hemangeol

Prior Authorization Form - Hemangeol

Product Specific Criteria:

- The patient must have a diagnosis of proliferating infantile hemangioma requiring systemic therapy
- The patient must be between 5 weeks and 1 year of age
- The patient must weigh at least 2 kg
- The provider must attest that the patient does not have any of the following contraindications to treatment:
    - Asthma or history of bronchospasm
    - Bradycardia (<80 beats per minute)
    - Greater than first-degree heart block
    - Decompensated heart failure
    - Blood pressure <50/30 mmHg
    - Pheochromocytoma

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).*

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

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

Diabetes

DPP4-Inhibitors

General Prior Authorization Form

Group Criteria:

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

Non-Preferred Agents Criteria:

- 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

PREFFERED AGENTS (NO PA REQUIRED)	NON-PREFFERED AGENTS (PA REQUIRED)
JANUMET (sitagliptin/metformin)	alogliptan/pioglitizone
JANUMET XR (sitagliptin/metformin)	alogliptin
JANUVIA (sitagliptin)	alogliptin/metformin
JENTADUETO (linagliptin/metformin)	JUVISYNC (sitagliptin/simvastatin)
JENTADUETO XR (linagliptin/metformin)	KAZANO (alogliptin/metformin)
TRADJENTA (linagliptin)	KOMBIGLYZE XR (saxagliptin/metformin)
	NESINA (alogliptin)
	ONGLYZA (saxagliptin)
	OSENI (alogliptin/pioglitazone)

DPP4-Inhibitors/SGLT2 Inhibitors Combination

General Prior Authorization Form

Group Criteria:

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

PREFFERED AGENTS (NO PA REQUIRED)	NON-PREFFERED AGENTS (PA REQUIRED)
	GLYXAMBI (Empagliflozin/linagliptin)
	STEGLUJAN (Ertugliflozin/Sitagliptin)
	QTERN (Dapagliflozin/Saxagliptin)

GLP-1 Agonists

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 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).

Non-Preferred Agents Criteria:

- The patient must have had a 30-day trial of each GLP-1 agonist of a unique active ingredient, as evidenced by paid claims or pharmacy printouts.

PREFFERED AGENTS (NO PA REQUIRED)	NON-PREFFERED AGENTS (PA REQUIRED)
VICTOZA (liraglutide)	ADLYXIN (lixisenatide)
BYDUREON (exenatide microspheres)	BYDUREON BCISE (exenatide microspheres)
BYETTA (exenatide)	OZEMPIC (semaglutide)
	RYBELSUS (semaglutide)
	TRULICITY (dulaglutide)

Insulin/GLP-1 Agonist Combination

General Prior Authorization Form

Group Criteria:

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

PREFFERED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS:
	SOLIQUA (Insulin glargine/lixisenatide)
	XULTOPHY (insulin degludec/liraglutide)

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:

- ***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)
            -

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 (insulin lispro) VIAL	AFREZZA (insulin regular, human)
HUMALOG (insulin lispro) CARTRIDGE	BASAGLAR KWIKPEN U-100 (insulin glargine)***
HUMALOG MIX 50/50 (insulin NPL/insulin lispro) VIAL	FIASP (insulin aspart) FLEXTOUCH***
HUMALOG MIX 75/25 (insulin NPL/insulin lispro) VIAL	FIASP (insulin aspart) VIAL***
HUMULIN 70/30 (insulin NPH human/regular insulin human) VIAL	Insulin lispro vial
HUMULIN R (insulin regular, human) VIAL	Insulin lispro syringe
HUMULIN R U-500 (insulin regular, human) VIAL	HUMALOG JUNIOR KWIKPEN (insulin lispro)
LANTUS (insulin glargine) SOLOSTAR	HUMALOG MIX 50/50 (insulin NPL/insulin lispro) KWIKPEN
LANTUS (insulin glargine) VIAL	HUMALOG MIX 75/25 (insulin NPL/insulin lispro) KWIKPEN

Please use the Prior Authorization Form Lookup to find Prior Authorization (PA) Forms

LEVEMIR (insulin detemir) VIAL	HUMALOG U-100 (insulin lispro) KWIKPEN
LEVEMIR (insulin detemir) FLEXTOUCH	HUMALOG U-200 (insulin lispro) KWIKPEN
NOVOLIN R (insulin regular, human) VIAL	HUMULIN 70/30 (insulin NPH human/regular insulin human) KWIKPEN
NOVOLOG (insulin aspart) CARTRIDGE	HUMULIN N (insulin NPH human isophane) VIAL
NOVOLOG (insulin aspart) FLEXPEN	HUMULIN N (insulin NPH human isophane) KWIKPEN
NOVOLOG (insulin aspart) VIAL	HUMULIN R (Insulin regular, human) U-500 KWIKPEN
NOVOLOG MIX 70/30 (insulin aspart protamine/insulin aspart) FLEXPEN – Labeler 00002	NOVOLOG MIX 70/30 (insulin aspart protamine/insulin aspart) FLEXPEN – Labeler 00169
NOVOLOG MIX 70/30 (insulin aspart protamine/insulin aspart) VIAL	NOVOLIN 70-30 (insulin NPH human/regular insulin human) VIAL
	NOVOLIN 70-30 (insulin NPH human/regular insulin human) FLEXPEN
	NOVOLIN N (insulin NPH human isophane) VIAL
	TOUJEO MAX SOLOSTAR (insulin glargine)***
	TOUJEO SOLOSTAR (insulin glargine)***
	TRESIBA (insulin degludec) FLEXTOUCH U-100***
	TRESIBA (insulin degludec) FLEXTOUCH U-200***
	TRESIBA (insulin degludec) 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)

PREFFERED AGENTS (NO PA REQUIRED)	NON-PREFFERED AGENTS (PA REQUIRED)
Pioglitazone	Rosiglitazone

SGLT2 Inhibitors

General Prior Authorization Form

Group PA Criteria:

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

Non-Preferred Agents Criteria:

- The patient must have had a 30-day trial of an empagliflozin agent, as evidenced by paid claims or pharmacy printouts.

Product Specific Criteria:

- ***Steglatro/Steglatromet:** The patient must have had a 30-day trial of each of the following, as evidenced by paid claims or pharmacy printouts: a dapagliflozin agent AND a canagliflozin agent.

PREFFERED AGENTS (NO PA REQUIRED)	NON-PREFFERED AGENTS (PA REQUIRED)
JARDIANCE (empagliflozin)	FARXIGA (dapagliflozin)
SYNJARDY (empagliflozin/metformin)	INVOKANA (canagliflozin)
SYNJARDY XR (empagliflozin/metformin)	INVOKAMET (canagliflozin)

	INVOKAMET XR (canagliflozin/metformin)
	STEGLATRO (ertugliflozin)***
	STEGLATROMET (ertugliflozin/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).

PREFFERED AGENTS (NO PA REQUIRED)	NON-PREFFERED AGENTS (PA REQUIRED)
Glimepiride	Glyburide
Glipizide	Glyburide/Metformin
Glipizide/Metformin	
Glipizide ER	

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.

PREFFERED AGENTS (CLINICAL PA REQUIRED)	NON-PREFFERED AGENTS (PA REQUIRED)
GENOTROPIN (somatropin)	HUMATROPE (somatropin)
GENOTROPIN MINIQUICK (somatropin)	NUTROPIN AQ (somatropin)
NORDITROPIN FLEXPRO (somatropin)	OMNITROPE (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

Pituitary Suppressants

PREFFERED AGENTS (NO PA REQUIRED)	NON-PREFFERED 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

Category PA 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).

Idiopathic Constipation

General Prior Authorization Form

Non-Preferred Agents Criteria:

- The patient must have had 30-day trials of each of the following, as evidenced by paid claims or pharmacy printouts:
    - Amitiza and Linzess

PREFFERED AGENTS (NO PA REQUIRED)	NON-PREFFERED AGENTS (PA REQUIRED)
AMITIZA (lubiprostone)	LINZESS (linaclotide) 72 mcg
LINZESS (linaclotide) 145 mcg, 290 mcg	MOTEGRITY (prucalopride)
	TRULANCE (plecanatide)
	ZELNORM (Tegaserod)

Opioid-Induced Constipation:

General Prior Authorization Form

Non-Preferred Agents Criteria:

- 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

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

Diarrhea – Irritable Bowel Syndrome

General Prior Authorization Form

Non-Preferred Agents Criteria:

- Patient must be 18 years of age or older.
- 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.

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

Digestive Enzymes

General Prior Authorization Form

Non-Preferred Agents Criteria:

- A 30-day trial of all PREFFERED AGENTS (no PA required) 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

PREFFERED AGENTS (NO PA REQUIRED)	NON-PREFFERED AGENTS (PA REQUIRED)
CREON (lipase/protease/amylase)	PANCREAZE (lipase/protease/amylase)
ZENPEP (lipase/protease/amylase)	PANCRELIPASE (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

Product Specific Criteria:

- **Syndros**

- The patient must have one of the following diagnoses and meet required trial for their diagnosis:
  - Loss of appetite due to HIV/AIDS:
    - The patient must have tried and failed a 3-month trial with Megace, as evidenced by paid claims or pharmacy printouts
  - Chemotherapy-induced nausea and vomiting:
    - The patient must have tried and failed a 3-day trial of ondansetron ODT in combination with aprepitant suspension and a glucocorticoid, as evidenced by paid claims or pharmacy printouts

NK1 RECEPTOR ANTAGONISTS	
PREFFERED AGENTS (NO PA REQUIRED)	**NON-PREFFERED AGENTS (PA REQUIRED)**
VARUBI (Rolapitant) TABLET	AKYNZEO (Netupitant/Palonosetron)
	Aprepitant Capsule
	EMEND (Aprepitant) CAPSULE
	EMEND (Aprepitant) SUSPENSION
5-HT3 RECEPTOR ANTAGONISTS	
PREFFERED AGENTS (NO PA REQUIRED)	**NON-PREFFERED AGENTS (PA REQUIRED)**
Granisetron tablet	AKYNZEO (Netupitant/Palonosetron)
Ondansetron ODT	SANCUSO (Granisetron) PATCH
Ondansetron solution	ZOFRAN (Ondansetron) TABLET
Ondansetron tablet	ZUPLENZ (Ondansetron) FILM
CANNABINOIDS	
PREFFERED AGENTS (NO PA REQUIRED)	**NON-PREFFERED AGENTS (PA REQUIRED)**
Dronabinol Capsule	CESAMET (Nabilone) CAPSULE
	MARINOL (Dronabinol) CAPSULE
	SYNDROS (Dronabinol) SOLUTION

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 must have failed a 3-day trial of all preferred products
- Patient's due date must be provided
- Bonjesta: The prescriber must submit medical justification explaining why the patient cannot use a preferred product (subject to clinical review)

PREFFERED AGENTS (NO PA REQUIRED)	NON-PREFFERED AGENTS (PA REQUIRED)
DICLEGIS (doxylamine/vitamin B6) – *Brand Required*	BONJESTA (doxylamine/vitamin B6)
meclizine	Doxylamine/Vitamin B6
metoclopramide	
ondansetron	

Proton Pump Inhibitor

Solid Dosage Forms

General Prior Authorization Form

Group Criteria: *Approval Duration = 6 months*

Please use the Prior Authorization Form Lookup to find Prior Authorization (PA) Forms

Non-Preferred Agents Criteria: Step 1 Agents (Esomeprazole Magnesium, Lansoprazole 15mg, rabeprazole):

- Patient must have failed a 25-day trial of at least one of the preferred or Step 1 Solid Dosage Form agents in the past 90 days, as evidenced by paid claims or pharmacy printouts

Non-Preferred Agents Criteria: Step 2 Agents (Esomeprazole strontium, Esomeprazole magnesium/glycerin, Omeprazole-sodium bicarbonate):

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

SOLID DOSAGE FORMS		
PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED STEP 1 AGENTS (ELECTRONIC STEP)	NON-PREFERRED STEP 2 AGENTS (PA REQUIRED)
DEXILANT (dexlansoprazole)	Esomeprazole magnesium	Esomeprazole magnesium/glycerin
Lansoprazole 30mg	Lansoprazole 15mg	Esomeprazole strontium
omeprazole	Rabeprazole	NEXIUM (esomeprazole)
pantoprazole		Omeprazole-Sodium bicarbonate
		PREVACID (Lansoprazole)
		PRILOSEC (Omeprazole)
		PROTONIX (Pantoprazole)

Non-Solid Dosage Forms

General Prior Authorization Form

Group Criteria: *Approval Duration = 6 months*

Non-Preferred Agents Criteria:

- The patient must have feeding tube in place
- The patient must have failed a 30-day trial of all Preferred Non-Solid Dosage form agents (Nexium Packet and Protonix Packet) in the past 2 years, as evidenced by paid claims or pharmacy printouts

Product Specific Criteria:

- **Prilosec Packet:**
  - The patient must have had a 30-day trial of lansoprazole ODT in the past 2 years, as evidenced by paid claims or pharmacy printouts
- **Omeprazole-sodium bicarbonate packet/Aciphex Sprinkle:**
  - Clinical justification must be provided explaining why the patient is unable to use the other proton-pump inhibitor agents (subject to clinical review)

NON-SOLID DOSAGE FORMS		
PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED STEP 1 AGENTS (PA REQUIRED)	NON-PREFERRED STEP 2 AGENTS (PA REQUIRED)
NEXIUM (esomeprazole) PACKET	Lansoprazole 15mg ODT	ACIPHEX SPRINKLE (rabeprazole)
PROTONIX (pantoprazole) PACKET	PRILOSEC PACKET (omeprazole)	Lansoprazole 30mg ODT
		Omeprazole-sodium bicarbonate packet
		PREVACID (Lansoprazole) SOLUTAB

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 vancomycin, 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

PREFFERED AGENTS (NO PA REQUIRED)	NON-PREFFERED AGENTS (PA REQUIRED)
FIRVANQ (vancomycin) SOLUTION	DIFICID (fidaxomicin) TABLET
Vancomycin capsule	VANCOCIN (vancomycin) CAPSULE

Genetic and Rare Disease

Cystic Fibrosis Inhaled Antibiotics

General Prior Authorization Form

Product Specific Criteria:

- ***Tobramycin:
  - The patient must be stable on tobramycin, as evidenced by a paid claim or pharmacy printouts in the past 75 days
- ***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 *Mycrobacterium 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.

PREFFERED AGENTS (NO PA REQUIRED)	NON-PREFFERED AGENTS (PA REQUIRED)
BETHKIS (Tobramycin)	ARIKAYCE (Amikacin/Nebulizer) ***
KITABIS PAK (Tobramycin/Nebulizer) (*Brand Preferred)*	CAYSTON (Aztreonam)***
TOBI PODHALER (Tobramycin) ***	TOBI (Tobramycin)
	Tobramycin***
	Tobramycin/Nebulizer

Hereditary Angioedema

General Prior Authorization Form

Category Criteria:

- The patient must have diagnosis of hereditary angioedema, confirmed by a specialist.

PREFFERED AGENTS (CLINICAL PA REQUIRED)	NON-PREFFERED AGENTS (PA REQUIRED)
BERINERT (C1 Esterase Inhibitor)	
CINRYZE (C1 Esterase Inhibitor)	
FIRAZR (Icatibant)	
HAEGARDA (C1 Esterase Inhibitor)	
KALBRITOR (Ecallantide)	
RUCONEST (C1 Esterase Inhibitor)	
TAKHZYRO (Lanadelumab-FLYO)	

Idiopathic Pulmonary Fibrosis

Prior Authorization Form - Idiopathic Pulmonary Fibrosis

Category Criteria:

- The patient must be 18 years of age or older
- The patient must have documented diagnosis of idiopathic pulmonary fibrosis
- The patient must have a specialist involved in therapy
- The patient must have forced vital capacity (FVC) ≥ 50% of predicted within prior 60 days

Product Specific Criteria

- **Alternative Ofev Products:**
  - The patient must have documented diagnosis of systemic sclerosis-associated interstitial lung disease

PREFFERED AGENTS (NO PA REQUIRED)	NON-PREFFERED AGENTS (PA REQUIRED)
ESBRIET (Pirfenidone)	
OFEV (Nintedanib)	

Phenylketonuria

Kuvan:

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:

- ***Stelara, 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	
PREFFERED AGENTS (NO PA REQUIRED)	**NON-PREFFERED AGENTS (PA REQUIRED)**
COSENTYX (secukinumab)	CIMZIA (certolizumab)
ENBREL (etanercept)	SIMPONI (golimumab)
HUMIRA (adalimumab)	TALTZ (ixekizumab)
BEHCET'S SYNDROME	
PREFFERED AGENTS (NO PA REQUIRED)	**NON-PREFFERED AGENTS (PA REQUIRED)**
HUMIRA (adalimumab)	OTEZLA (apremilast)
CHRONIC INFANTILE NEUROLOGICAL, CUTANEOUS AND ARTICULAR SYNDROME	
PREFFERED AGENTS (PA REQUIRED)	**NON-PREFFERED AGENTS (PA REQUIRED)**
KINERET (anakinra)	
CROHN'S DISEASE	
PREFFERED AGENTS (NO PA REQUIRED)	**NON-PREFFERED AGENTS (PA REQUIRED)**
HUMIRA (adalimumab)	CIMZIA (certolizumab)
	STELARA (ustekinumab)***
CYTOKINE RELEASE SYNDROME	

PREFFERED AGENTS (PA REQUIRED)	NON-PREFFERED AGENTS (PA REQUIRED)
ACTEMRA (tocilizumab)	
GIANT CELL ARTERITIS	
PREFFERED AGENTS (PA REQUIRED)	**NON-PREFFERED AGENTS (PA REQUIRED)**
ACTEMRA (tocilizumab)	
HIDRADENITIS SUPPURATIVA	
PREFFERED AGENTS (NO PA REQUIRED)	**NON-PREFFERED AGENTS (PA REQUIRED)**
HUMIRA (adalimumab)	
NON-RADIOGRAPHIC AXIAL SPONDYLARTHRITIS	
PREFFERED AGENTS (NO PA REQUIRED)	**NON-PREFFERED AGENTS (PA REQUIRED)**
HUMIRA (adalimumab)	CIMZIA (certolizumab)
PLAQUE PSORIASIS	
PREFFERED AGENTS (NO PA REQUIRED)	**NON-PREFFERED AGENTS (PA REQUIRED)**
COSENTYX (secukinumab)	CIMZIA (certolizumab)
ENBREL (etanercept)	OTEZLA (apremilast)
HUMIRA (adalimumab)	SILIQ (brodalumab)***
	SKYRIZI (risankizumab-rzaa)***
	STELARA (ustekinumab)***
	TALTZ (ixekizumab)***
	TREMFYA (guselkumab)***
PSORIATIC ARTHRITIS	
PREFFERED AGENTS (NO PA REQUIRED)	**NON-PREFFERED AGENTS (PA REQUIRED)**
COSENTYX (secukinumab)	CIMZIA (certolizumab)
ENBREL (etanercept)	ORENCIA (abatacept)
HUMIRA (adalimumab)	OTEZLA (apremilast)
	SIMPONI (golimumab)
	STELARA (ustekinumab)***
	TALTZ (ixekizumab)***
	XELJANZ (tofacitinib)
	XELJANZ XR (tofacitinib)
RHEUMATOID ARTHRITIS	
PREFFERED AGENTS (NO PA REQUIRED)	**NON-PREFFERED AGENTS (PA REQUIRED)**
COSENTYX (secukinumab)	ACTEMRA (tocilizumab)
ENBREL (etanercept)	CIMZIA (certolizumab)
HUMIRA (adalimumab)	KEVZARA (sarilumab)
	KINERET (anakinra)
	OLUMIANT (baricitinib)
	ORENCIA (abatacept)
	RINVOQ (upadacitinib)
	SIMPONI (golimumab)
	XELJANZ (tofacitinib)
	XELJANZ XR (tofacitinib)
SCHNITZLER SYNDROME	
PREFFERED AGENTS (PA REQUIRED)	**NON-PREFFERED AGENTS (PA REQUIRED)**
KINERET (anakinra)	
ULCERATIVE COLITIS	
PREFFERED AGENTS (NO PA REQUIRED)	**NON-PREFFERED AGENTS (PA REQUIRED)**
HUMIRA (adalimumab)	SIMPONI (golimumab)

Please use the Prior Authorization Form Lookup to find Prior Authorization (PA) Forms

	STELARA (ustekinumab)
	XELJANZ (tofacitinib)
	XELJANZ XR (tofacitinib)
UVEITIS	
PREFFERED AGENTS (NO PA REQUIRED)	**NON-PREFFERED AGENTS (PA REQUIRED)**
HUMIRA (adalimumab)	

Dupixent

Prior Authorization Form - Dupixent

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.
- The patient must have had 2 or more asthma exacerbations in previous year despite continued compliant use of a moderate to high dose inhaled steroid in combination with a long-acting beta agonist (LABA) or long-acting muscarinic antagonist (LAMA) as evidenced by paid claims or pharmacy printouts
- One of the following must be met (A or B):
    A. The patient must have baseline eosinophil level of ≥ 300 cells/mcL within past 12 months
    B. The patient must have oral corticosteroid dependent asthma and has required at least 30 days of oral steroid use in past 120 days, 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

PREFERRED AGENTS	NON-PREFERRED AGENTS
DUPIXENT (Dupilumab)	
FASENRA (Benralizumab)	

NUCALA (Mepolizumab)	

Epinephrine

General Prior Authorization Form

PREFFERED AGENTS (CLINICAL PA REQUIRED)	NON-PREFFERED 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

PREFFERED AGENTS (NO PA REQUIRED)	NON-PREFFERED AGENTS (PA REQUIRED)
Allopurinol Tablet	COLCRYS (Colchicine) TABLETS
Colchicine Capsules	Febuxostat
Colchicine Tablets	MITIGARE (Colchicine) CAPSULE
Probenecid-Colchicine Tablets	ULORIC (Febuxostat) TABLET
Probenecid Tablets	ZYLOPRIM (Allopurinol) TABLET

Immune Globulins

Prior Authorization Form - Immune Globulins

Non-Preferred Agents 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 IV administration
  - 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:**

Please use the Prior Authorization Form Lookup to find Prior Authorization (PA) Forms

- 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

PREFFERED AGENTS (NO PA REQUIRED)	NON-PREFFERED AGENTS (PA REQUIRED)
BIVIGAM (human immunoglobulin gamma)	CUTAQUIG (human immune globulin G solution)
FLEBOFAMMA DIF (human immunoglobulin gamma)	CUVITRU (human immunoglobulin gamma)
GAMANEX-C (human immunoglobulin gamma)	GAMMAGARD S-D (human immunoglobulin gamma)
GAMASTAN S-D	HIZENTRA (human immunoglobulin gamma)
GAMMAGARD LIQUID (human immunoglobulin gamma)	HYQVIA (human immune globulin G and hyaluronidase)
GAMMAKED (human immunoglobulin gamma)	XEMBIFY (human immune globulin-klhw)
GAMMAPLEX (human immunoglobulin gamma)	
OCTAGAM (human immunoglobulin gamma)	
PANZYGA (Immune Globulin- IFAS)	
PRIVIGEN (human immunoglobulin gamma)	

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) and Zetonna (ciclesonide):**
    - Clinical justification must be provided explaining why the patient is unable to use another product with the same active ingredient (subject to clinical review)

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

Oral

PREFFERED AGENTS (NO PA REQUIRED)	NON-PREFFERED AGENTS (PA REQUIRED)
APRISO (mesalamine) CAPSULE	AZULFIDINE (sulfasalazine)
ASACOL HD (mesalamine)	AZULFIDINE DR (sulfasalazine)

Balsalazide capsule	COLAZAL (balsalazide)
DELZICOL (mesalamine) CAPSULE	Mesalamine DR
DIPENTUM (olsalazine)	Mesalamine HD
LIALDA (mesalamine) TABLET	SULFAZINE (sulfasalazine)
PENTASA (mesalamine)	
Sulfasalazine DR tablet	
Sulfasalazine tablet	

Rectal

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

Infectious Disease

Antimalarial Agents

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
- The patient must be less than 18 years old to qualify for atovaquone/proguanil 62.5-25 MG

PREFFERED AGENTS (NO PA REQUIRED)	NON-PREFFERED 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)

Serostim - Wasting Cachexia

Dronabinol/Syndros - Loss of Appetitie

Antiretrovirals

Category Criteria:

Please use the Prior Authorization Form Lookup to find Prior Authorization (PA) Forms

- **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

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

PREFFERED AGENTS (NO PA REQUIRED)	NON-PREFFERED AGENTS (PA REQUIRED)
ATRIPLA (Efavirenz/Emtricitabine/Tenofovir)	SUSTIVA (Efavirenz)
COMPLERA (Emtricitabine/Rilpivirine/tenofovir)	VIRAMUNE (Nevirapine)
EDURANT (Rilpivirine)	VIRAMUNE XR (Nevirapine)
Efavirenz	
Etravirine	
INTELENCE (Etravirine)	
JULUCA (dolutegravir/rilpivirine)	
Nevirapine	
Nevirapine ER	
ODEFSEY (Emtricitabine/Rilpivirine/Tenofovir)	
PIFELTRO (Doravirine)	
Rilpivirine	
SYMFI (efavirenz/lamivudine/tenofovir)	
SYMFI LO (efavirenz/lamivudine/tenofovir)	

Nucleoside Reverse Transcriptase Inhibitors

PREFFERED AGENTS (NO PA REQUIRED)	NON-PREFFERED AGENTS (PA REQUIRED)
Abacavir	COMBIVIR (lamivudine/zidovudine)
Abacavir/lamivudine	EPIVIR (lamivudine)
Abacavir/lamivudine/zidovudine	EPZICOM (abacavir)
ATRIPLA (efavirenz/emtricitabine/tenofovir)	RETROVIR (zidovudine)
BIKTARVY (bictegravir/Emtricitabine/Tenofovir)	TRIZIVIR (abacavir/lamivudine)
CIMDUO (lamivudine/tenofovir)	VIDEX EC (didanosine)
COMPLERA (emtricitabine/rilpivirine/tenofovir)	VIREAD (tenofovir)
DELSTRIGO (doravirine/lamivudine/tenofovir)	ZERIT (stavudine) CAPSULE
DESCOVY (emtricitabine/tenofovir)	ZIAGEN (abacavir)
Didanosine	
EMTRIVA (emtricitabine)	
GENVOYA (elvitegravir/cobicistat/emtricitabine/tenofovir)	
Lamivudine	
Lamivudine/zidovudine	
ODEFSEY (emtricitabine/rilpivirine/tenofovir)	
SYMFI (efavirenz/lamivudine/tenofovir)	
SYMFI LO (efavirenz/lamivudine/tenofovir)	
Stavudine	
STRIBILD (elvitegravir/cobicistat/emtricitabine/tenofovir)	
SYMTUZA (darumavir/cobicistat/emtricitabine/tenofovir)	
Tenofovir	
TRIUMEQ (abacavir/dolutegravir/lamivudine)	

Please use the Prior Authorization Form Lookup to find Prior Authorization (PA) Forms

TRUVADA (emtricitabine/tenofovir)	
VIDEX (didanosine)	
Zidovudine	

Post-Attachment Inhibitor

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

Protease Inhibitor

PREFFERED AGENTS (NO PA REQUIRED)	NON-PREFFERED AGENTS (PA REQUIRED)
APTIVUS (tipranavir)	KALETRA (lopinavir/ritonavir) SOLUTION
Atazanavir	LEXIVA (Fosamprenavir)
CRIXIVAN (indinavir)	REYATAZ (atazanavir) CAPSULE
EVOTAZ (atazanavir/cobicistat)	Ritonavir
Fosamprenavir	
INVIRASE (saquinavir)	
KALETRA (lopinavir/ritonavir) TABLET	
Lopinavir/ritonavir solution	
NORVIR (ritonavir)	
PREZCOBIX (darunavir/cobicistat)	
PREZISTA (darunavir)	
REYATAZ (atazanavir) POWDER PACK	
SYMTUZA (darumavir/cobicistat/emtricitabine/tenofovir)	
VIRACEPT (nelfinavir)	

Lipodystrophy – Growth Hormone-Releasing Hormone Analogue

PREFFERED AGENTS (NO PA REQUIRED)	NON-PREFFERED AGENTS (PA REQUIRED)
EGRIFTA (Tesamorelin)	

Hepatitis C Treatments

Prior Authorization From – 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.
- HCV RNA level must be taken on week 4 and sent with a renewal request for any duration of treatment 12 weeks or longer.
- PA approval duration will be based on label recommendation.

Product Specific Criteria:

- ***Epclusa:**
  - Must be used with ribavirin for patients with decompensated cirrhosis (Child-Pugh B C).
- ***Mavyret/Vosevi:**
  - Patient must not have decompensated cirrhosis (Child-Pugh B or Child-Pugh C).

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)
MAVYRET (glecaprevir/pibrentasvir)***	Ledipasvir/sofosbuvir
	Sofosbuvir/velpatasvir
	SOVALDI (sofosbuvir)
	VIEKIRA PAK (dasabuvir/ombitasvir/paritaprevir/ritonavir)
	VOSEVI (sofosbuvir/velpatasvir/voxilaprevir)***
	ZEPATIER (elbasvir/grazoprevir)

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

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	

Antifungals - Aspergillius and Candidiasis Infections

General Prior Authorization Form

Non-Preferred Agents Criteria: *Approval Duration = 2 weeks*

- The request must be for use as prophylaxis of invasive Aspergillus and Candida infections or Oropharyngeal Candidiasis
- The patient must have documented history of failure to all preferred agents in last 30-days, as evidenced by paid claims or pharmacy printouts

PREFFERED AGENTS (NO PA REQUIRED)	NON-PREFFERED AGENTS (PA REQUIRED)
Clotrimazole	DIFLUCAN (Fluconazole)
CRESEMBA (Isavuconazonium)	NOXAFIL (posaconazole)
Fluconazole	SPORANOX (Itraconazole)
Itraconazole	TOLSURA (itraconazole)
Nystatin	VFEND (Voriconazole)
ORAVIG (miconazole)	
Voriconazole	

Men's Health

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

PREFFERED 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

PREFFERED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS:
	ANDROID (Methyltestosterone)
	Methyltestosterone
	METHITEST (Methyltestosterone)
	STRIANT (Testosterone)
	TESTRED (Methyltestosterone)

Topical

PREFFERED AGENTS (NO PA REQUIRED)	NON-PREFFERED AGENTS (PA REQUIRED)
ANDRODERM (testosterone) PATCH	ANDROGEL (testosterone)
Testosterone 1% gel packet	AXIRON (testosterone) TOPICAL SOLUTION
Testosterone 1% gel tube	FORTESTA (testosterone) 2% Gel MD PMP CANISTER
Testosterone 12.5/1.25G gel MD PMP Bottle	TESTIM (testosterone) GEL TUBE
	Testosterone 2% Gel MD PMP Canister
	Testosterone 20.25/1.25G Gel MD PMP Bottle
	Testosterone 1.25G-1.62% Gel Packet
	Testosterone 2.5G-1.62% Gel Packet
	VOGELXO (Testosterone)

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

PREFFERED AGENTS (NO PA REQUIRED)	NON-PREFFERED AGENTS (PA REQUIRED)
alfuzosin ER	AVODART (Dutasteride)
CARDURA XL (doxazosin)	CARDURA (Doxazosin)
doxazosin	FLOMAX (Tamsulosin)

dutasteride	MINIPRESS (Prazosin)
finasteride	PROSCAR (Finasteride)
prazosin	sildenafil
RAPAFLO (silodosin) – *brand required*	tadalafil
tamsulosin	
terazosin	

Nephrology/Urology

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.

PREFFERED AGENTS (PA REQUIRED)	NON-PREFFERED AGENTS (PA REQUIRED)
ARANESP (darbepoetin alfa)	EPOGEN (epoetin alfa)
PROCRIT (epoetin alfa)	MIRCERA (methoxy polyethylene glycol-epoetin beta)
	RETACRIT (epoetin alfa - epbx)

Hyperkalemia

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

PREFFERED AGENTS (CLINICAL PA REQUIRED)	NON-PREFFERED AGENTS (PA REQUIRED)
LOKELMA (Sodium Zirconium Cyclosilicate)	VELTASSA (Patiromer)

Interstitial Cystitis

General Prior Authorization Form

Non-Preferred Agents Criteria:

- **Initial Criteria:** *Duration of Approval = 3 Months*
  - The prescriber must attest that all other potential causes for bladder pain/discomfort have been ruled out.
  - The patient must have a diagnosis of pain or discomfort due to interstitial cystitis.
  - The patient must be 16 years of age or older.
  - The patient must have not experienced adequate symptom relief after implementing self-care practices and behavior modification (e.g. avoiding food/beverages and activities that exacerbate symptoms, fluid management, etc).
  - The patient must have failed a 30-day trial of amitriptyline, as evidenced by paid claims or pharmacy printouts.
- **Renewal Criteria:** *Duration of Approval = 12 months*
  - The patient must have experienced a significant reduction in bladder pain/discomfort since initiating therapy (supported by clinical documentation).

PREFFERED AGENTS (PA REQUIRED)	NON-PREFFERED AGENTS (PA REQUIRED)
Amitriptyline	ELMIRON (Pentosan Polysulfate Sodium)

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.

PREFFERED AGENTS (NO PA REQUIRED)	NON-PREFFERED AGENTS (PA REQUIRED)
Calcium acetate	AURYXIA (ferric citrate) TABLET
FOSRENOL (lanthanum) CHEWABLE TABLET *– brand preferred*	FOSRENOL (lanthanum) POWDER PACK
PHOSLYRA (calcium acetate) ORAL solution	Lanthanum chew tab
RENVELA (sevelamer) POWDER PACK	RENAGEL (Sevelamer HCl) TABLET
Sevelamer Carbonate Tablet	RENVELA (sevelamer carbonate) TABLET
Sevelamer Powder Pack - Labeler 00955	Sevelamer HCl 400mg Tablet
	Sevelamer HCl 800mg Tablet
	Sevelamer Powder Pack - Labeler 65862, 43598
	VELPHORO (Sucroferric oxyhydroxide)

Urinary Antispasmodics

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.

Product Specific Criteria:

- ***** Trospium ER:** The patient must have had a 30-day trial of each of the following, as evidenced by paid claims or pharmacy printouts:
    - Trospium and tolterodine ER

PREFFERED AGENTS (NO PA REQUIRED)	NON-PREFFERED AGENTS (PA REQUIRED)
Darifenacin ER – Labeler 10370	Darifenacin ER
ENABLEX (darifenacin ER)	DETROL (tolterodine)
Flavoxate	DETROL LA (tolterodine)
GELNIQUE (oxybutynin)	DITROPAN XL (oxybutynin)
Oxybutynin ER	MYRBETRIQ (mirabegron)
Oxybutynin syrup	SANCTURA (trospium)
Oxybutynin tablet	SANCTURA ER (trospium)***
OXYTROL (oxybutynin) PATCH	Tolterodine
Solifenacin	Tolterodine ER
TOVIAZ (fesoterodine)	Trospium ER***
Trospium	VESICARE (solifenacin)

Neurology

Anticonvulsants

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.

PREFFERED AGENTS (NO PA REQUIRED)	NON-PREFERRED AGENTS:
APTIOM (Eslicarbazepine)	CARBATROL (Carbamazepine)
BANZEL (Rufinamide) ORAL SUSPENSION	DEPAKENE (Valproic acid) CAPSULE
BANZEL (Rufinamide) TABLET	DEPAKENE (Valproic acid) ORAL SOLUTION
BRIVIACT (Brivaracetam)	DEPAKOTE (Divalproex sodium) TABLET
Carbamazepine chewable tablet	DEPAKOTE ER (Divalproex sodium)
Carbamazepine ER capsule	DEPAKOTE SPRINKLE (Divalproex sodium)
Carbamazepine oral suspension	DILANTIN (Phenytoin) CHEWABLE TABLET
Carbamazepine tablet	DILANTIN (Phenytoin) ORAL SUSPENSION
Carbamazepine XR tablet	DILANTIN ER (Phenytoin)
CELONTIN (Methsuximide)	EPITOL (Carbamazepine)
Divalproex ER	Felbamate Tablet
Divalproex sprinkle	Felbamate Oral Suspension
Divalproex tablet	KEPPRA (Levetiracetam)
Ethosuximide capsule	KEPPRA (Levetiracetam) ORAL SOLUTION
Ethosuximide oral solution	KEPPRA XR (Levetiracetam)
FELBATOL (Felbamate) (*Brand Preferred)*	LAMICTAL (Lamotrigine)
FELBATOL (Felbamate) ORAL SUSPENSION (*Brand Preferred)*	LAMICTAL (Lamotrigine) CHEWABLE TABLET
FYCOMPA (Perampanel)	LAMICTAL (Lamotrigine) DOSE PACK
FYCOMPA (Perampanel) ORAL SUSPENSION	MYSOLINE (Primidone)
Gabapentin capsule	NEURONTIN (Gabapentin) CAPSULE
Gabapentin oral solution	NEURONTIN (Gabapentin) ORAL SOLUTION
Gabapentin tablet	NEURONTIN (Gabapentin) TABLET

GABITRIL (Tiagabine) (*Brand Preferred)*	Pregabalin
LAMICTAL ER (Lamotrigine) DOSE PACK	Pregabalin oral solution
LAMICTAL ODT (Lamotrigine)	QUDEXY XR (Topiramate)
LAMICTAL ODT (Lamotrigine) DOSE PACK	TEGRETOL XR (Carbamazepine)
LAMICTAL XR (Lamotrigine)	TEGRETROL (Carbamazepine oral suspension)
Lamotrigine chewable tablet	Tiagabine
Lamotrigine dose pack	TOPAMAX (Topiramate)
Lamotrigine ER	TOPAMAX (Topiramate) SPRINKLE CAPSULE
Lamotrigine ODT	TRILEPTAL (Oxcarbazepine)
Lamotrigine tablet	TRILEPTAL (Oxcarbazepine) ORAL SUSPENSION
Levetiracetam ER	Vigabatrin
Levetiracetam oral solution	Vigabatrin powder pack
Levetiracetam tablet	VIGADRONE (Vigabatrin)
LYRICA (Pregabalin) *(Brand Preferred)*	ZARONTIN (Ethosuximide)
LYRICA (Pregabalin) ORAL SOLUTION (*Brand Preferred)*	ZARONTIN (Ethosuximide) ORAL SOLUTION
Oxcarbazepine oral solution	ZONEGRAN (Zonisamide)
Oxcarbazepine tablet	
OXTELLAR XR (Oxcarbazepine)	
PEGANONE (Ethotoin)	
Phenobarbital elixir	
Phenobarbital tablet	
PHENYTEK (phenytoin)	
Phenytoin chewable tablet	
Phenytoin ER capsule	
Phenytoin suspension	
Primidone	
SABRIL (Vigabatrin) (*Brand Preferred)*	
SABRIL (Vigabatrin) POWDER PACK (*Brand Preferred)*	
SPRITAM (Levetiracetam)	
TEGRETOL (Carbamazepine)	
Topiramate ER	
Topiramate sprinkle capsule	
Topiramate tablet	
TROKENDI XR (Topiramate)	
Valproic acid capsule	
Valproic acid oral solution	
VIMPAT (lacosamide)	
VIMPAT (lacosamide) ORAL SOLUTION	
Zonisamide	

Dementia

General Prior Authorization Form

Category PA Criteria:

- One of the following (A OR B) must be met:
  A. The patient must have a diagnosis of an FDA-approved indication for use
  B. The patient is greater than 30 years of age.
- **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.
  - **Non-Solid Dosage Forms:** The patient must be unable to ingest solid dosage form as evidenced by swallow study documentation

Product Specific Criteria:

- ***Memantine ER**:

- The patient must have had a 30-day trial of memantine IR, as evidenced by paid claims or pharmacy printouts.
- The patient must not reside in facility with skilled nursing care.

PREFFERED AGENTS (NO PA REQUIRED)	NON-PREFFERED AGENTS (PA REQUIRED)
Donepezil 5mg, 10mg Tablet	ARICEPT (donepezil)
Galantamine Tablet	Donepezil ODT
Galantamine ER	Donepezil 23mg Tablet
Memantine	EXELON (rivastigmine) PATCH
Rivastigmine Capsule	Galantamine oral solution
	Memantine oral solution
	Memantine ER
	NAMENDA (memantine)
	NAMENDA XR (memantine)
	NAMZARIC (memantine/donepezil)
	RAZADYNE (galantamine)
	RAZADYNE ER (galantamine)
	Rivastigmine patch

Emflaza

Prior Authorization Form - Emflaza

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)
    A. 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

B. 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

Headache/Migraine

Prophylaxis of Migraine – CGRP Inhibitors

Prior Authorization Form – CGRP Inhibitors

Group Criteria:

- **Initial (approval duration: 3 months):**
  - Patient must experience 4 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.

PREFFERED AGENTS (CLINICAL PA REQUIRED)	NON-PREFFERED AGENTS (PA REQUIRED)
AIMOVIG (Erenumab-aooe)	AJOVY (Fremanezumab-vfrm)
EMGALITY (Galcanazumab-gnlm)	

Cluster Headache – Emgality

Prior Authorization Form – CGRP Inhibitors

Initial PA Criteria: *Approval Duration: 3 months*

- Patient must meet ICHD-3 criteria for diagnosis of cluster headache
- Patient must use medication as preventative treatment during episodic cluster headache episodes, as medication is not indicated for chronic use

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

Treatment of Migraine - Triptans - 5HT(1) Agonist

General Prior Authorization Form

Non-Preferred Agents Criteria:

- **Patients able to take oral medications:**
  - 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.

- 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):**
  - The patient must have had a 30-day trial of rizatriptan within the past 24 months, as evidenced by paid claims or pharmacy printouts.

Product Specific Criteria:

Cambia Powder Pack -Migraine Treatment

- ***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).

PREFFERED AGENTS (NO PA REQUIRED)	NON-PREFFERED AGENTS (PA REQUIRED)
RELPAX (eletriptan) – *Brand Preferred*	Almotriptan Tablet***
Rizatriptan	ALSUMA (sumatriptan) PEN INJCTR***
Rizatriptan ODT	AMERGE (naratriptan) TABLET
Sumatriptan tablet	Eletriptan 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)
	Naratriptan Tablet
	ONZETRA XSAIL (sumatriptan)
	Sumatriptan Cartridge***
	Sumatriptan Pen Injctr***
	Sumatriptan Spray***
	Sumatriptan Syringe***
	Sumatriptan Vial
	Sumatriptan/Naproxen Tablet***
	TOSYMRA (Sumatriptan) NASAL SPRAY***
	TREXIMET (Sumatriptan/Naproxen) TABLET
	ZEMBRANCE SYMTOUCH (Sumatriptan)***
	Zolmitriptan Tablet***
	Zolmitriptan ODT
	ZOMIG (zolmitriptan) TABLET***
	ZOMIG (zolmitriptan) SPRAY

	ZOMIG ODT (zolmitriptan)

Dihydroergotamine

General Prior Authorization Form

Non-Preferred Agents Criteria:

- **Non-preferred step 1 agents:**
  - The patient must have a diagnosis of migraine or cluster headache
  - Within the past 2 years, the patient must have had 30-day trials of at least two 'Preferred Agents', as evidenced by paid claims or pharmacy printouts
- **Non-preferred step 2 agents:**
  - The patient must meet criteria for Step 1 agents
  - 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

PREFERRED AGENTS (NO PA REQUIRED)	NON-PREFERRED STEP 1 AGENTS (PA REQUIRED)	NON-PREFERRED STEP 2 AGENTS (PA REQUIRED)
RELPAX (eletriptan)	ONZETRA XSAIL (sumatriptan) NASAL SPRAY	CAFERGOT (ergotamine/caffeine) TABLET
Rizatriptan Tablets	ZOMIG (zolmitriptan) NASAL SPRAY	D.H.E.45 (dihydroergotamine) INJECTION
Rizatriptan ODT	zolmitriptan ODT	Dihydroergotamine Injection
Sumatriptan Tablets		Dihydroergotamine Nasal Spray
		ERGOMAR (ergotamine) SL TABLET
		MIGERGOT (ergotamine/caffeine) RECTAL SUPPOSITORY
		MIGRANAL (dihydroergotamine) SPRAY

Multiple Sclerosis

General Prior Authorization Form

Interferons

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.

PREFFERED AGENTS (NO PA REQUIRED)	NON-PREFFERED 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, and Tecfidera

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

PREFFERED AGENTS (NO PA REQUIRED)	NON-PREFFERED 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):
  - **A.** The patient must have had a 3-month trial of Copaxone, as evidenced by paid claims or pharmacy printouts.
  - **B.** 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.

PREFFERED AGENTS (NO PA REQUIRED)	NON-PREFFERED AGENTS (PA REQUIRED)
AUBAGIO (teriflunomide)	MAVENCLAD (Cladribine)
GILENYA (fingolimod)	MAYZENT (Siponimod)
	TECFIDERA (dimethyl fumarate)

Narcolepsy

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:

Please use the Prior Authorization Form Lookup to find Prior Authorization (PA) Forms

- 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	NON-PREFERRED AGENTS
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

General Prior Authorization Form

Product Specific Criteria:

- **Gocovri, Osmolex ER, Rytary, and Pramipexole ER:**
  - 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).
- **Inbrija, Apokyn, Duopa:**
  - 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)
- **Xadago and Nourianz:**
  - 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
- **Nuplazid**:
  - 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 experiencing recurrent or continuous hallucinations and/or delusions for the past 30 days
  - The patient must have experienced an inadequate response to a 30-day trial of quetiapine or clozapine, as evidenced by paid claims or pharmacy printouts
  - The patient must not have experienced a reduction in symptoms of psychosis, despite documented medication dosage reduction and discontinuation trials (with a goal of levodopa monotherapy)
- **Tolcapone**
  - The patient must have failed a 30-day trial of entacapone, as evidenced by paid claims or pharmacy printouts

- **Rasagiline and Emsam**
    - The patient must have failed a 30-day trial of selegiline, as evidenced by paid claims or pharmacy printouts

Non-Preferred Agents Criteria (Renewal):

- Documentation of disease stabilization or improvement in disease since initiation of treatment must be provided

PREFERRED AGENTS	NON-PREFERRED AGENTS
Amantadine IR	APOKYN (Apomorphine)
AZILECT (Rasagiline)	Carbidopa-Levodopa ODT
Benztropine	DUOPA (Levodopa/Carbidopa)
Bromocriptine	EMSAM (Selegiline) PATCH
Carbidopa-levodopa-entacapone	GOCOVRI (Amantadine ER)
Carbidopa-Levodopa Capsules	INBRIJA (Levodopa)
Carbidopa-Levodopa ER	NOURIANZ (Istradefylline)
Entacapone	NUPLAZID (Pimavanserin)
Levodopa	OSMOLEX ER (Amantadine ER)
NEUPRO (Rotigotine) PATCH	Pramipexole ER
Pramipexole IR	Rasagiline
Ropinirole	RYTARY (Levodopa/Carbidopa)
Ropinirole ER	Tolcapone
Selegiline	XADAGO (Safinamide)
Trihexyphenidyl	

Tardive Dyskinesia

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

PREFFERED AGENTS (CLINICAL PA REQUIRED)	NON-PREFFERED 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.

PREFFERED AGENTS (NO PA REQUIRED)	NON-PREFFERED AGENTS (PA REQUIRED)
ALOMIDE (lodoxamide)	ALOCRIL (nedocromil)
Azelastine	ELESTAT (epinastine)
BEPREVE (bepotastine)	Epinastine
Cromolyn	Olopatadine 0.2% - Labeler 17478, 00093, 60505
LASTACAFT (alcaftadine)	PATANOL 0.1% (olopatadine)
Olopatadine 0.1%	PATADAY 0.2% (olopatadine)
Olopatadine 0.2% - Labeler 61314	
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.

PREFFERED AGENTS (NO PA REQUIRED)	NON-PREFFERED 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	Neomycin SU/bacitracin/polymyxin B ointment
Gentamicin sulfate ointment	Neomycin SU/polymyxin B/gramicidin drops
Moxifloxacin drops	NEO-POLYCIN (neomycin SU/bacitracin/polymyxin B) OINTMENT
MOXEZA (moxifloxacin) DROPS	NEOSPORIN (neomycin SU/polymyxin B/gramicidin) DROPS
Ofloxacin drop	OCUFLOX (ofloxacin) DROPS
Polymyxin B/trimethoprim drops	POLYCIN (bacitracin/polymyxin) OINTMENT
Sulfacetamide drops	POLYTRIM (polymyxin B/trimethoprim) DROPS
Tobramycin drops	Sulfacetamide ointment
TOBREX (tobramycin) OINTMENT	TOBREX (tobramycin) DROPS
	VIGAMOX (moxifloxacin) DROPS
	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.

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

Neomycin/bacitracin/polymyxin b/hydrocortisone ointment	BLEPHAMIDE S.O.P. (sulfacetamide/prednisolone) ointment
BLEPHAMIDE (sulfacetamide/prednisolone) DROPS	MAXITROL (neomycin/polymyxin b/dexamethasone) DROPS
Neomycin/polymyxin b/dexamethasone drops	MAXITROL (neomycin/polymyxin b/dexamethasone) OINTMENT
Neomycin/polymyxin b/dexamethasone ointment	Neomycin/polymyxin b/hydrocortisone drops
Neomycin/polymyxin b/hydrocortisone ointment	NEO-POLYCIN HC (neomycin SU/bacitracin/polymyxin B/hydrocortisone) OINTMENT
PRED-G (gentamicin/prednisol ac) DROPS	TOBRADEX ST (tobramycin/dexamethasone) DROPS
PRED-G (gentamicin/prednisol ac) OINTMENT	Tobramycin/dexamethasone
Sulfacetamide/prednisolone drops	
TOBRADEX (tobramycin/dexamethasone) DROPS	
TOBRADEX (tobramycin/dexamethasone) OINTMENT	
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.

PREFFERED AGENTS (NO PA REQUIRED)	NON-PREFFERED 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)	ILEVRO (nepafenac)
FML S.O.P. (fluorometholone)	LOTEMAX SM (Loteprednol)
ketorolac tromethamine 0.4%	Loteprednol eye drops
Ketorolac tromethamine 0.5%	OCUFEN (flurbiprofen)
LOTEMAX (loteprednol) GEL DROPS	OMNIPRED 1% (prednisolone acetate)
LOTEMAX (loteprednol) OINTMENT	PRED FORTE 1% (prednisolone acetate)
MAXIDEX (dexamethasone)	PROLENSA (bromfenac)
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).

PREFFERED AGENTS (NO PA REQUIRED)	NON-PREFFERED AGENTS (PA REQUIRED)
RESTASIS (Cyclosporine)	CEQUA (Cyclosporine)***
	RESTASIS MULTIDOSE (Cyclosporine)***
	XIIDRA (Lifitegrast)

Glaucoma

Alpha Adrenergics

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.

PREFFERED AGENTS (NO PA REQUIRED)	NON-PREFFERED AGENTS (PA REQUIRED)
ALPHAGAN P 0.1% (brimonidine)	Apraclonidine 0.5%
ALPHAGAN P 0.15% (brimonidine)	Brimonidine 0.15%
IOPIDINE (apraclonidine) 1%	
IOPIDINE (apraclonidine) 0.5%	
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.

PREFFERED AGENTS (NO PA REQUIRED)	NON-PREFFERED AGENTS (PA REQUIRED)
BETOPTIC S (Betaxolol) 0.25%	Betaxolol 0.5%
Carteolol	COSOPT (Dorzolamide/Timolol)
COMBIGAN (brimonidine/timolol)	ISTALOL (Timolol) Daily
Dorzolamide/Timolol	Timolol Daily
Levobunolol	Timolol gel forming solution
Timolol Maleate	TIMOPTIC (Timolol Maleate)
TIMOPTIC OCUDOSE (timolol)	TIMOPTIC-XE (Timolol gel forming solution)

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.

PREFFERED AGENTS (NO PA REQUIRED)	NON-PREFFERED AGENTS (PA REQUIRED)
Latanoprost	Bimatoprost 0.03%
LUMIGAN (Bimatoprost) 0.01%	VYZULTA (latanoprostene)

TRAVATAN Z (Travoprost)	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.

PREFFERED AGENTS (NO PA REQUIRED)	NON-PREFFERED 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.

PREFFERED AGENTS (NO PA REQUIRED)	NON-PREFFERED AGENTS (PA REQUIRED)
CIPRO HC (ciprofloxacin/hydrocortisone)	OTOVEL (ciprofloxacin/fluocinolone)
CIPRODEX (ciprofloxacin/dexamethasone)	

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

NSAIDS

Prior Authorization Form - NSAIDs

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:

- **Mefanemic acid:**
  - The patient must have diagnosis of dysmenorrhea
- **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)

PREFFERED AGENTS (NO PA REQUIRED)	NON-PREFFERED AGENTS (PA REQUIRED)
Celecoxib 50mg, 100mg, 200mg	ARTHROTEC (Diclofenac/Misoprostol)
Diclofenac potassium	Celecoxib 400mg
Diclofenac sodium 50mg, 75mg	CELEBREX (Celecoxib)
Etodolac	DAYPRO (Oxaprozin)
Fenoprofen 600mg	Diclofenac sodium ER 100mg
Flurbiprofen	Diclofenac sodium 25mg
Ibuprofen	Diclofenac/Misoprostol
Indomethacin	DUEXIS (Famotidine/Ibuprofen)
Indomethacin ER	Etodolac ER
Ketoprofen 50mg, 75mg	FELDENE (Piroxicam)
Ketorolac	Fenoprofen 400mg
Meloxicam	INDOCIN (Indomethacin)
Nabumetone	Ketoprofen 25mg
Naproxen 220mg, 250mg, 500mg	Ketoprofen ER 200mg
Piroxicam	Meclofenamate
Sulindac	Mefenamic acid
Tolmetin 200mg, 400mg	MOBIC (Meloxicam)
ZIPSOR (diclofenac)	NALFON (Fenoprofen)
	NAPRELAN (Naproxen)
	Naproxen ER 375 mg
	Naproxen 275mg, 550mg
	Oxaprozin
	TIVORBEX (indomethacin, submicronized)
	Tolmetin 600mg
	VIMOVO (Naproxen/Esomeprazole)
	VIVLODEX (meloxicam, submicronized)
	ZORVOLEX (diclofenac, submicronized)

Non-Solid Oral Dosage Forms

Prior Authorization Form - NSAIDs

Product Specific Criteria:

- **Indomethacin oral solution**:
  - The patient must be unable to ingest solid dosage form as evidenced by swallow study documentation
  - The patient must have failed a 30-day trial of naproxen oral solution, as evidenced by paid claims or pharmacy print outs

PREFERRED AGENTS	NON-PREFERRED AGENTS
Ibuprofen	CAMBIA (Diclofenac Potassium) POWDER PACK
Naproxen	Indomethacin
	QMIIZ ODT (meloxicam)

Please use the Prior Authorization Form Lookup to find Prior Authorization (PA) Forms

Nasal

Prior Authorization Form - NSAIDs

Product Specific Criteria:

- **Sprix**:
  - The patient must be 18 years of age or older
  - The patient must have a diagnosis of postoperative nausea and vomiting
  - The patient must not have a documented history of gastric or duodenal ulcer or comorbidities of GI bleed, perforation, or obstruction

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).

PREFFERED AGENTS (NO PA REQUIRED)	NON-PREFFERED AGENTS (PA REQUIRED)
Diclofenac 1.5% Topical Solution	Diclofenac Patch
Diclofenac Gel	PENNSAID (Diclofenac) 2% PUMP
FLECTOR (diclofenac) PATCH *(Brand Preferred)*	VOLTAREN (diclofenac) GEL

Opioid Analgesics – Long Acting

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 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 narcotics exceeds 90 MED/day
  - Patient is using benzodiazepine concurrently with narcotic medication
- **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

PREFFERED AGENTS (NO PA REQUIRED)	NON-PREFFERED AGENTS (PA REQUIRED)
BELBUCA (Buprenorphine)	buprenorphine patches
Butorphanol	
BUTRANS (buprenorphine) PATCHES	

Abuse Deterrent Formulations/Unique Mechanisms from Full Agonist Opioids

Prior Authorization Form – Opioid Analgesics

Additional Group Criteria:

- The patient must have 30-day trials of both an NSAID and an immediate release opioid, as evidenced by paid claims or pharmacy printouts

PREFFERED AGENTS (CLINICAL PA REQUIRED)	NON-PREFFERED AGENTS (PA REQUIRED)
NUCYNTA ER (tapentadol)	ARYMO ER (morphine)***
OXYCONTIN (oxycodone)	CONZIP (tramadol ER) CAPSULES
Tramadol ER Tablets	HYSINGLA ER (hydrocodone)
	Levorphanol
	Methadone***
	MORPHABOND ER (morphine)***
	Tramadol ER Capsules
	ULTRAM ER (tramadol ER) TABLETS
	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
- **Morphine ER Tablets:**
  - Patients have reached the max dose of Oxycontin and are switching to Morphine ER Tablets for an Opioid Rotation strategy

Full Agonist Opioids Without Abuse Deterrent Formulations	
PREFFERED AGENTS (CLINICAL PA REQUIRED)	NON-PREFFERED AGENTS (PA REQUIRED)
Fentanyl 12 mcg/hr***	DURAGESIC (Fentanyl) Patch
Fentanyl 25 mcg/hr, 50 mcg/hr, 75 mcg/hr, 100 mcg/hr	EXALGO (hydromorphone)
	Fentanyl patch 37.5 mcg/hr, 62.5 mcg/hr, 87.5 mcg/hr
	Hydromorphone ER tablets
	KADIAN (morphine)
	Morphine ER capsules
	Morphine ER tablets
	MS CONTIN (morphine)
	Oxycodone ER
	Oxymorphone ER tablets
	ZOHYDRO ER (hydrocodone)

Opioid Analgesic – Short Acting

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

Please use the Prior Authorization Form Lookup to find Prior Authorization (PA) Forms

        - 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)
- **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
- **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).
- **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).

PREFFERED AGENTS (CLINICAL PA REQUIRED)	NON-PREFFERED AGENTS (PA REQUIRED)
Acetaminophen/Codeine Solution	ABSTRAL (Fentanyl) SUBLINGUAL TABLET
Acetaminophen/Codeine Tablets	ACTIQ (Fentanyl) LOZENGE
Benzhydrocodone/Acetaminophen	Butalbital-Codeine
Codeine Tablets	CONZIP (Tramadol)
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	Fentanyl Citrate Buccal Tablet
Hydromorphone Liquid	Fentanyl Lozenge
Hydromorphone Tablet	Hydrocodone/Acetaminophen 5-163mg/7.5mL Solution
Morphine Tablets	hydrocodone-acetaminophen 2.5-325 MG
Morphine Solution	hydrocodone-acetaminophen 10MG-300MG
NUCYNTA (Tapentadol) TABLETS	hydrocodone-acetaminophen 5 MG-300MG
Oxycodone 5mg, 10mg Tablets	hydrocodone-acetaminophen 7.5-300 MG
Oxycodone Solution	LAZANDA (Fentanyl) SPRAY
oxycodone-acetaminophen 5-325 MG	LORCET (Hydrocodone/Acetaminophen)
oxycodone-acetaminophen 10 -325 MG	LORTAB (Hydrocodone/Acetaminophen) SOLUTION
Oxymorphone Tablets	Meperidine

Please use the Prior Authorization Form Lookup to find Prior Authorization (PA) Forms

Tramadol Tablets	NALOCET (Oxycodone/Acetaminophen)
Tramadol/Acetaminophen Tablets	NORCO (Hydrocodone/Acetaminophen)
	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)
	ROXYBOND (Oxycodone)
	SUBSYS (Fentanyl) SPRAY
	ULTRACET (Tramadol/Acetaminophen)
	ULTRAM (Tramadol)
	VICODIN (Hydrocodone/Acetaminophen)

Skeletal Muscle Relaxants

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)

PREFFERED AGENTS (NO PA REQUIRED)	NON-PREFFERED AGENTS (PA REQUIRED)
Baclofen	AMRIX (Cyclobenzaprine)
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

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	
PREFFERED AGENTS (NO PA REQUIRED)	**NON-PREFFERED AGENTS (PA REQUIRED)**
Atomoxetine	Clonidine ER***
Clonidine	INTUNIV (guanfacine ER)
Guanfacine	STRATTERA (atomoxetine)
Guanfacine ER	
Stimulants - Methylphenidates	
PREFFERED AGENTS (NO PA REQUIRED)	**NON-PREFFERED AGENTS (PA REQUIRED)**
ADHANSIA XR (methylphenidate)	Dexmethylphenidate ER
APTENSIO XR (methylphenidate)	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 tablet
FOCALIN XR (dexmethylphenidate) – *Brand Preferred*	Methylphenidate LA capsules - 50-50 – 20mg, 30mg, 40mg, 60mg
Methylphenidate solution	METHYLIN (methylphenidate) solution
Methylphenidate CD 30-70	RELEXXII (methylphenidate)
Methylphenidate chew tablet	RITALIN (methylphenidate)
Methylphenidate ER capsules 50-50	RITALIN LA (methylphenidate LA capsules - 50-50) 10mg
Methylphenidate LA capsules - 50-50 – 10mg	
Methylphenidate tablet	
QUILLICHEW ER (methylphenidate)	
QUILLIVANT XR (methylphenidate)	
RITALIN LA (methylphenidate LA capsules - 50-50) 20mg, 30mg, 40mg – *Brand Preferred*	
Stimulants - Amphetamines	
PREFFERED AGENTS (NO PA REQUIRED)	**NON-PREFFERED AGENTS (PA REQUIRED)**
ADZENYS ER (Amphetamine) SOLUTION	ADDERALL (Dextroamphetamine/amphetamine)
ADZENYS XR - ODT (Amphetamine)	ADDERALL XR (Dextroamphetamine/amphetamine)
DESOXYN (Methamphetamine) – *Brand Preferred*	Amphetamine
Dextroamphetamine	DEXEDRINE (Dextroamphetamine)
Dextroamphetamine ER	Dextroamphetamine 5 mg/5 ml
Dextroamphetamine/amphetamine	Methamphetamine
Dextroamphetamine/amphetamine ER	ZENZEDI (Dextroamphetamine)
DYANAVEL XR (Amphetamine)	
EVEKEO (Amphetamine) – *Brand Preferred*	

Non-Stimulants	
PREFFERED AGENTS (NO PA REQUIRED)	**NON-PREFFERED AGENTS (PA REQUIRED)**
EVEKEO ODT (Amphetamine)	
MYDAYIS (Dextroamphetamine/dextroamphetamine)	
PROCENTRA (Dextroamphetamine) – *Brand Preferred*	
VYVANSE (Lisdexamfetamine)	
VYVANSE (lLsdexamfetamine) CHEW TABLET	

Atypical Antipsychotics

Oral

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).

PREFFERED AGENTS (NO PA REQUIRED)	NON-PREFFERED AGENTS (PA REQUIRED)
Aripiprazole solution	ABILIFY (aripiprazole)
Aripiprazole	ABILIFY DISCMELT (aripiprazole)
Aripiprazole ODT	CLOZARIL (clozapine)
Clozapine	FAZACLO (clozapine) RAPDIS
Clozapine ODT	GEODON (ziprasidone)
FANAPT (iloperidone)	INVEGA ER (paliperidone)
LATUDA (lurasidone)	Olanzapine/Fluoxetine***
Olanzapine	RISPERDAL (risperidone)
Olanzapine ODT	RISPERDAL (risperidone) ORAL SOLUTION
Paliperidone ER	RISPERDAL M-TAB (risperidone)
Quetiapine	SEROQUEL (quetiapine)
Quetiapine ER	SEROQUEL XR (quetiapine)
REXULTI (brexpiprazole)	SYMBYAX (olanzapine/fluoxetine) ***
Risperidone	ZYPREXA (olanzapine)
Risperidone ODT	ZYPREXA ZYDIS (olanzapine)
Risperidone oral solution	
SAPHRIS (asenapine)	
VRAYLAR (cariprazine)	
Ziprasidone	

Long Acting Injectable

PREFFERED AGENTS (NO PA REQUIRED)	NON-PREFFERED 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

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
- **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:**
  - 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	Ramelteon
ROZEREM (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)	EDLUAR (Zolpidem)
	Estazolam
	Flurazepam
	LUNESTA (Eszopiclone)
	SECONAL SODIUM (Secobarbital)
	Temazepam
	Triazolam
	Zolpidem ER
	Zolpidem 10mg (for females)
	ZOLPIMIST (Zolpidem)
	Zolpidem SL tab

Respiratory

Albuterol/Levalbuterol Rescue Inhalers

General Prior Authorization Form
MedWatch Form

Product Specific Criteria

- **Albuterol HFA, ProAir Respiclick:**
  - The patient must currently be receiving an inhaled corticosteroid product, as evidenced by paid claims or pharmacy printouts (see Coverage Rules for Medications).

PREFFERED AGENTS (NO PA REQUIRED)	NON-PREFFERED AGENTS (PA REQUIRED)
Albuterol HFA – Labeler 66993***	Albuterol HFA – Labeler 00933 and 00254
PROAIR (albuterol) HFA – *Brand Preferred*	PROVENTIL (albuterol) HFA
PROAIR RESPICLICK (albuterol)***	VENTOLIN (albuterol) HFA***
XOPENEX (levalbuterol) HFA - *Brand Preferred*	

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.

PREFFERED AGENTS (NO PA REQUIRED)	NON-PREFFERED 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)	
UTIBRON NEOHALER (glycopyrrolate/indacaterol)	

Corticosteroids – Inhaled

General Prior Authorization Form

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.

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

PREFFERED AGENTS (NO PA REQUIRED)	NON-PREFFERED AGENTS (PA REQUIRED)
SPIRIVA HANDIHALER (tiotropium)	INCRUSE ELLIPTA (umeclidinium)
SPIRIVA RESPIMAT 2.5 MG (tiotropium)	LONHALA MAGNAIR (glycopyrrolate)***
TUDORZA PRESSAIR (aclidinium)	SEEBRI NEOHALER (glycopyrrolate)
	YUPELRI (revefenacin)

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.

PREFFERED AGENTS (NO PA REQUIRED)	NON-PREFFERED AGENTS (PA REQUIRED)
ARCAPTA NEOHALER (indacaterol)	BROVANA (arformoterol)***
PERFOROMIST (formoterol)	
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, Spiriva Respimat, Incruse Ellipta, or Seebri Neohaler
            - II. Brovana, Arcapta Neohaler, 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, Utibron NeoHaler, Bevespi Aerosphere, or Trelegy Ellipta
    - **For asthma diagnosis:**
        - The patient must have been reviewed for step down therapy for all renewal requests.

PREFFERED AGENTS (NO PA REQUIRED)	NON-PREFFERED AGENTS (PA REQUIRED)
ADVAIR HFA (Fluticasone/Salmeterol)	ADVAIR DISKUS (Fluticasone/Salmeterol)
DULERA (Mometasone/Formoterol)	AIRDUO RESPICLICK (Fluticasone/Salmeterol)
Fluticasone/Salmeterol – Labeler 66993	BREO ELLIPTA (Fluticasone/Vilanterol)
SYMBICORT (Budesonide/Formoterol)	Fluticasone/Salmeterol – Labeler - 00093
	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).
- 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

PREFFERED AGENTS (NO PA REQUIRED)	NON-PREFFERED AGENTS (PA REQUIRED)
	TRELEGY ELLIPTA (Fluticasone Furoate/Umeclidinium/Vilanterol)

Substance Use

Nicotine / Tobacco Dependence Treatment

General Prior Authorization Form

A total of 24 consecutive weeks of Chantix will be covered, every 2 years.

A total of 12 consecutive weeks will be covered for all other products, every 2 years.

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.

PREFFERED AGENTS (NO PA REQUIRED)	NON-PREFFERED 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)

PREFFERED AGENTS (NO PA REQUIRED)	NON-PREFFERED 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

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

Opioid Partial Antagonist

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).
- DAW (Dispense As Written) Criteria must be met in addition to Opioid Partial Antagonist 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).
    - DAW (Dispense As Written) Criteria must be met in addition to Opioid Partial Antagonist Group PA Criteria.

ORAL AGENTS	
PREFFERED AGENTS (NO PA REQUIRED)	NON-PREFFERED 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	
PREFFERED AGENTS (NO PA REQUIRED)	NON-PREFFERED AGENTS (PA REQUIRED)
SUBLOCADE (buprenorphine)	
PROBUPHENE (buprenorphine)	

Women's Health

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.

PREFFERED AGENTS (CLINICAL PA REQUIRED)	NON-PREFFERED AGENTS (PA REQUIRED)
CLIMARA PRO (estradiol-levonorgestrel) PATCH	ALORA (Estradiol) PATCH TWICE WEEKLY
COMBIPATCH (Estradiol- Norethindrone)	CLIMARA (Estradiol) PATCH WEEKLY
ELESTRIN (estradiol) GEL	DELESTROGEN (Estradiol Valerate) INJECTION
Estradiol Tablet	DEPO-ESTRADIOL (Estradiol Cypionate) INJECTION
ESTRING (estradiol)	DIVIGEL (estradiol) GEL
EVAMIST (estradiol) SPRAY	Estradiol Valerate Injection
MENOSTAR (estradiol) PATCH	Estradiol- Norethindrone Tablet

Norethindrone-Ethinyl Estradiol tablet	Estradiol Patch Twice Weekly
PREMARIN (estrogens, conjugated) INJECTION	Estradiol Patch Weekly
PREMARIN (estrogens, conjugated) TABLET	Estradiol Vaginal Cream
PREMARIN (estrogens, conjugated) VAGINAL CREAM	Estradiol Vaginal Tablet
PREMPHASE (estrogen, conj.,m-progest) TABLET	FEMRING (estradiol)
PREMPRO (estrogen, conj.,m-progest) TABLET	MENEST (estrogens, esterified) TABLET
VAGIFEM (estradiol) VAGINAL TABLET	MINIVELLE (Estradiol) PATCH TWICE WEEKLY
YUVAFEM (estradiol) VAGINAL TABLET	PREFEST (estradiol-norgestimate) TABLET
	VIVELLE-DOT (Estradiol) PATCH

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

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 (or similar fenamate Non-Steroidal Anti-Inflammatory agent (NSAIDs))
    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).

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:

- ***Forteo and Miacalcin:**
  - The patient must have a current BMD T-score ≤ -2.5 OR new fracture after a 6-month trial of Tymlos (Abaloparatide), as evidenced by paid claims or pharmacy printouts
- ***Binosto and alendronate oral solution:**
  - The patient must be unable to ingest solid dosage form as evidenced by swallow study documentation

PREFFERED AGENTS (CLINICAL PA REQUIRED)	NON-PREFFERED AGENTS (PA REQUIRED)
Alendronate	Alendronate oral solution
Calcitonin, Salmon Nasal Spray	BINOSTO (Alendronate) EFFERVESCENT TAB
Ibandronate	FORTEO (Teriparatide)***
PROLIA (Denosumab)	MIACALCIN (Calcitonin, Salmon)***
Risedronate	TYMLOS (Abaloparatide)

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.

PREFFERED AGENTS (CLINICAL PA REQUIRED)	NON-PREFFERED AGENTS (PA REQUIRED)
MAKENA (hydroxyprogesterone caproate)	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 agents, as evidenced by paid claims or pharmacy printouts.

PREFFERED AGENTS (NO PA REQUIRED)	NON-PREFFERED 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	
terconazole cream	
VANDAZOLE (Metronidazole) GEL	

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

PREFFERED AGENTS (NO PA REQUIRED)	NON-PREFFERED AGENTS (PA REQUIRED)
Amoxicillin IR	Amoxicillin ER

Antihistamines

PREFFERED AGENTS (NO PA REQUIRED)	NON-PREFFERED AGENTS (PA REQUIRED)
Cetirizine Chew Tablet	Desloratadine ODT
Cetirizine Solution	Levocetirizine solution
Cetirizine Tablet	
Desloratadine Tablet	
Levocetirizine Tablet	
Loratadine Solution	
Loratadine Tablet	

Bactroban

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

Belladonna Alkaloids/Phenobarbital

PREFFERED AGENTS (NO PA REQUIRED)	NON-PREFFERED AGENTS (PA REQUIRED)
Belladonna Alkaloids/Phenobarbital Tablets	Belladonna Alkaloids/Phenobarbital Elixir

Please use the Prior Authorization Form Lookup to find Prior Authorization (PA) Forms

Bowel Prep Agents

Required trial duration: 1 complete dose

PREFFERED AGENTS (NO PA REQUIRED)	NON-PREFFERED 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
	PLENVU
	PREPOPIK
	SUPREP
	TRILYTE

Brisdelle (Paroxetine)

PREFFERED AGENTS (NO PA REQUIRED)	NON-PREFFERED AGENTS (PA REQUIRED)
Paroxetine tablets	Paroxetine Mesylate 7.5mg capsules

Butalbital-Acetaminophen-Caffeine

PREFFERED AGENTS (NO PA REQUIRED)	NON-PREFFERED 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)

PREFFERED AGENTS (NO PA REQUIRED)	NON-PREFFERED AGENTS (PA REQUIRED)
Cephalexin	Daxbia (Cephalexin)

Gabapentin

PREFFERED AGENTS (NO PA REQUIRED)	NON-PREFFERED AGENTS (PA REQUIRED)
Gabapentin	GRALISE (gabapentin)
Gabapentin	HORIZANT (gabapentin)
Pramipexole	
Ropinirole	

Jadenu (Deferasirox)

PREFFERED AGENTS (NO PA REQUIRED)	NON-PREFFERED AGENTS (PA REQUIRED)
Deferasirox tablet for suspension	JADENU (deferasirox)

Kits

PREFFERED AGENTS (NO PA REQUIRED)	NON-PREFFERED AGENTS (PA REQUIRED)
FDA approved products prescribed separately	DERMACINRX ARM PAK (lidocaine/dimethacone)

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	DERMACINRX CINLONE-I CPI (triamcinolone/lidocaine/prilocaine)
	DERMACINRX PHN PAK (lidocaine/emollient cmb No. 102)
	DERMACINRX SILAZONE (triamcinolone/silicones)
	TRIXYLITRAL (diclofenac/lidocaine/tape)
	ELLZIA PAK (triamcinolone/dimethicone)
	INFAMMACIN (diclofenac/capsicum)
	LOPROX (ciclopirox/skin cleanser No. 40)
	MIGRANOW (sumatriptan/menthol/camphor)
	MORGIDOX (Doxycycline/skin cleanser No. 19)
	PRO DNA MEDICATED COLLECTION (lidocaine/glycerin)
	QUTENZA (capsaicin/skin cleanser)
	SILAZONE-II (triamcinolone/silicones)
	TICANSE (fluticasone/sodium chloride/sodium bicarbonate)
	XRYLIX (diclofenac/kinesiology tape)

Metformin

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

Methotrexate

Required trial duration: 6 weeks

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

Mupirocin

PREFFERED AGENTS (NO PA REQUIRED)	NON-PREFFERED AGENTS (PA REQUIRED)
Mupirocin Ointment	Mupirocin Calcium Cream

Nascobal (Cyanocobalamin) Nasal Spray

PREFFERED AGENTS (NO PA REQUIRED)	NON-PREFFERED AGENTS (PA REQUIRED)
Cyanocobalamin Injection	NASCOBAL (Cyanocobalamin) NASAL SPRAY

Nitroglycerin Spray

Required trial duration: 1 dose while on preventative medication

PREFFERED AGENTS (NO PA REQUIRED)	NON-PREFFERED AGENTS (PA REQUIRED)
Nitroglycerin sublingual tablets	GONITRO (Nitroglycerin) SUBLINGUAL PACKET
	Nitroglycerin Spray
	NITROLINGUAL (Nitroglycerin) SPRAY

Nocdurna (desmopressin)

PREFFERED AGENTS (NO PA REQUIRED)	NON-PREFFERED AGENTS (PA REQUIRED)
Desmopressin	Nocdurna (desmopressin)

Please use the Prior Authorization Form Lookup to find Prior Authorization (PA) Forms

Onmel (itraconazole)

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

PREFFERED AGENTS (NO PA REQUIRED)	NON-PREFFERED AGENTS (PA REQUIRED)
Itraconazole capsule	ONMEL (itraconazole) tablet
Terbinafine	

Potassium

PREFFERED AGENTS (NO PA REQUIRED)	NON-PREFFERED AGENTS (PA REQUIRED)
Potassium tablets	Potassium Solution
	Potassium Powder for Solution

Procysbi (cysteamine)

PREFFERED AGENTS (NO PA REQUIRED)	NON-PREFFERED AGENTS (PA REQUIRED)
CYSTAGON (cysteamine)	PROCYSBI (cysteamine)

Ribavirin

PREFFERED AGENTS (NO PA REQUIRED)	NON-PREFFERED AGENTS (PA REQUIRED)
RIBASPHERE (ribavirin)	RIBASPHERE RIBAPAK (ribavirin)
Ribavirin	

Siklos (Hydroxyurea)

PREFFERED AGENTS (NO PA REQUIRED)	NON-PREFFERED AGENTS (PA REQUIRED)
DROXIA (Hydroxyurea capsule)	SIKLOS (Hydroxyurea tablet)
Hydroxyurea capsule	

Steroids - Oral

Additional Criteria for coverage of Emflaza: See Emflaza Criteria on this document

Rayos required trial duration: 12 weeks with 2AM dosing of prednisone

PREFFERED AGENTS (NO PA REQUIRED)	NON-PREFFERED 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

PREFFERED AGENTS (NO PA REQUIRED)	NON-PREFFERED AGENTS (PA REQUIRED)
Tacrolimus	ASTAGRAF XL (Tacrolimus)

	ENVARSUS ER (Tacrolimus)

Tirosint (levothyroxine)

PREFFERED AGENTS (NO PA REQUIRED)	NON-PREFFERED AGENTS (PA REQUIRED)
levothyroxine	TIROSINT (levothyroxine)

Tussicaps

PREFFERED AGENTS (NO PA REQUIRED)	NON-PREFFERED 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%
		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%	Halog	0.10%
		Diflorasone Diacetate	0.05%	Fluocinonide-E	0.05%
		Fluocinonide	0.05%	STEP2* Amcinonide	0.10%
		Triamcinolone Acetonide	0.50%		
	Ointment	Betamethasone Dipropionate	0.05%	Diflorasone Diacetate	0.05%
		Betamethasone Valerate	0.10%		

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		Desoximetasone	0.25%		
		Fluocinonide	0.05%		
		Fluticasone Propionate	0.01%		
		Halog	0.10%		
		Mometasone Furoate	0.10%		
		Triamcinolone Acetonide	0.50%		
	Gel, Lotion Solution	Fluocinonide gel	0.05%	Desoximetasone gel	0.05%
		Fluocinonide solution	0.05%	Bryhali (halobetasol)	0.01%
				STEP2* Amcinonide Lotion	0.10%
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%
				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%	Trianex	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, Shampoo, Solution	Capex Shampoo	0.01%	Betamethasone Valerate Lotion	0.10%
		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*

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

- 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)

Synagis

Prior Authorization Form - Synagis

Criteria: *Approval Duration = 5 months (allows for 5 monthly doses between October 19th through April 21st)*

- Patient must have one of the following diagnoses (A, B, or C) and the additional criteria outlined for diagnosis:

A. Prematurity:
- < 29 weeks, 0 days gestational age
- ≤12 months of age at start of RSV season

B. 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

C. Congenital Heart Disease
- ≤12 months of age at start of RSV season
  - Hemodynamically significant cyanotic or acyanotic congenital heart disease with medical therapy required

REVIEW OF GLUCAGON AGENTS

INDICATIONS:

- Hypoglycemia: Treatment of severe hypoglycemia in pediatric and adult patients*.
- *Products not packaged with a syringe and diluent necessary for rapid preparation and administration during an emergency outside of a health care facility are not indicated for the emergency treatment of hypoglycemia
- Note: The American Diabetes Association (ADA) recommends that glucagon be prescribed for all patients with diabetes at increased risk of level 2 hypoglycemia (less than 54 mg/dL); caregivers, school personnel, or family members of these patients should be trained on when and how to administer glucagon
- **Diagnostic aid:** As a diagnostic aid during radiologic examinations to temporarily inhibit movement of the GI tract in adults.

PRODUCTS:

Drug	**Route**
Glucagon (generic)	SQ, IM or IV
Glucagon Emergency	SQ, IM or IV
GlucaGen Hypokit	SQ, IM or IV
GlucaGen Diagnostic	IM or IV
Gvoke PFS	SQ
Baqsimi	Nasal

DOSING:

- **Hypoglycemia:**

	Adult Dosing	**Pediatric Cutoff**	**Pediatric Dose**
GlucaGen Hypokit	1 mg*	< 6 years or <25 kg	0.5 mg*
Glucagon Emergency Kit	1 mg*	< 20 kg	0.5 mg or 0.02-0.03 mg/kg*
Gvoke PFS	1 mg*	≥2 years, <45 kg	0.5 mg*
Baqsimi	3 mg* (1 actuation)	N/A	N/A
* may repeat in 15 minutes if needed			

- Injection as diagnostic aid:
  - Relaxation of the stomach, duodenal bulb, duodenum, and small bowel:
    - 0.2 to 0.5 mg IV or 1 mg IM
  - Relaxation of the colon:
    - 0.5 to 0.75 mg IV or 1 to 2 mg IM

TIME TO ONSET AND PEAK EFFECT:

Administration	Onset of Effect	Max Peak Effect
IV	<1 minute	5-20 minutes
IM	10 minutes	>90 minutes
SQ	10 minutes	>90 minutes
Nasal*	16 minutes	>90 minutes
**No statistically significant efficacy outcomes noted between Nasal formulation and injection formulations despite delayed onset.*		

COST:

Drug	Strength	Package Size	AWP Pkg Price	AWP Unit Price
Glucagon (generic)	1 mg sln	1	$204.60	$204.60
Glucagon Novaplus	1 mg sln	1 or 10	$162.00-$1,620.00	$162.00
Glucagon Emergency	1 mg sln	1	$336.96	$336.96
GlucaGen Hypokit	1 mg sln	1	$338.46	$338.46
GlucaGen Diagnostic	1 mg sln	1	$205.92	$205.92
Gvoke PFS/Hypopen	0.5 mg/0.1 mL SQ	1 or 2	$336.96-673.92	$1684.80-3369.60
Gvoke PFS/ Hypopen	1 mg.0.2 mL SQ	1 or 2	$336.96-673.92	$1684.80-3369.60
Baqsimi	3 mg/1 actuation	1-2	$336.96-673.92	$336.96

CURRENT UTILIZATION:

ND Medicaid Utilization (09/2018 – 08/2019)		
Label Name	**Rx Num**	**Total Reimb Amt**
Baqsimi	**1**	**$574.06**
Glucagon Emergency	**124**	**$30,615.69**
GlucaGen Hypokit	**11**	**$2,837.15**
GlucaGen Diagnostic	**0**	**0**
Gvoke PFS	**0**	**0**

REFERENCES:

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3. Glucagon Emergency Kit (glucagon) [prescribing information]. Indianapolis, IN: Eli Lilly and Company; July 2018.
4. Glucagen and Glucagen Hypokit (glucagon) [product information]. Mississuaga, Ontario, Canada: Novo Nordisk Canada Inc; February 2014.
5. Glucagon injection [prescribing information]. Lake Zurich, IL: Fresenius Kabi; January 2016.
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7. Baqsimi (glucagon) [prescribing information]. Indianapolis, IN: Eli Lilly and Company; July 2019.
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NORTH DAKOTA MEDICAID
RETROSPECTIVE DRUG UTILIZATION REVIEW
CRITERIA RECOMMENDATIONS
4TH QUARTER 2019

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

1. Solriamfetol / Overutilization _____ _____

Alert Message: Sunosi (solriamfetol) may be overutilized. The recommended dose range for solriamfetol is 75 mg to 150 mg once daily. Based on efficacy and tolerability, the dosage of solriamfetol may be doubled at intervals of at least 3 days. The maximum recommended dose is 150 mg once daily. Dosages above 150 mg daily do not confer increased effectiveness sufficient to outweigh dose-related adverse reactions.

Drugs/Diseases

Util A	Util B	Util C **(Negate)**
Solriamfetol		CKD 3, 4 & 5
		ESRD

Max Dose: 150 mg/day

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

2. Solriamfetol / Overutilization – Moderate Renal Impairment _____ _____

Alert Message: The maximum recommended dosage of Sunosi (solriamfetol) in patients with moderate renal impairment (eGFR 30-59 mL/min/1.73 m2) is 75 mg once daily after at least 7 days of initial dosing at 37.5 once daily. Patients with moderate or severe renal impairment may be at a higher risk of increases in blood pressure and heart rate because of the prolonged half-life of solriamfetol. The maximum dosage of solriamfetol in patients with severe renal impairment (eGFR 15-29 mL/min/1.73 m2) is 37.5 mg once daily.

Drugs/Diseases

Util A	Util B	Util C **(Include)**
Solriamfetol		CKD 3

Max Dose: 75 mg/day

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

3. Solriamfetol / Overutilization – Severe Renal Impairment _____ _____

Alert Message: The maximum recommended dosage of Sunosi (solriamfetol) in patients with severe renal impairment (eGFR 15-29 mL/min/1.73 m2) is 37.5 mg once daily. Patients with moderate or severe renal impairment may be at a higher risk of increases in blood pressure and heart rate because of the prolonged half-life of solriamfetol. The maximum dosage of solriamfetol in patients with moderate renal impairment (eGFR 30-59 mL/min/1.73 m2) is 75 mg once daily after at least 7 days of initial dosing at 37.5 once daily.

Drugs/Diseases

Util A	Util B	Util C **(Include)**
Solriamfetol		CKD 4 & 5

Max Dose: 37.5 mg/day

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

4. Solriamfetol / ESRD _____ _____

Alert Message: The use of Sunosi (solriamfetol) is not recommended in patients with ESRD (eGFR < 15 mL/min/1.73 m2). Solriamfetol is primarily renally eliminated and exposure (AUC) and half-life of solriamfetol are significantly increased in patients with end-stage renal disease.

Drugs/Diseases

Util A	Util B	Util C **(Include)**
Solriamfetol		ESRD

References:

Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Sunosi Prescribing Information, June 2019, Jazz Pharmaceuticals, Inc.

5. Solriamfetol / MAOIs _____ _____

Alert Message: Sunosi (solriamfetol) is contraindicated in patients receiving concomitant treatment with monoamine oxidase (MAO) inhibitors, or within 14 days following discontinuation of monoamine oxidase inhibitor, because of the risk of hypertensive reaction.

Drugs/Diseases

Util A	Util B		Util C
Solriamfetol	Isocarboxazid	Rasagiline	
	Phenelzine	Linezolid	
	Tranylcypromine	Safinamide	

References:

Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Sunosi Prescribing Information, June 2019, Jazz Pharmaceuticals, Inc.

6. Solriamfetol / Dopaminergic Agents _____ _____

Alert Message: Use caution when concomitantly administering dopaminergic drugs with Sunosi (solriamfetol). Solriamfetol is a dopamine and norepinephrine reuptake inhibitor (DNRI), and use with dopaminergic drugs that increase levels of dopamine or that bind directly to dopamine receptors might result in pharmacodynamic interactions with solriamfetol. Interactions with dopaminergic drugs have not been evaluated with solriamfetol.

Drugs/Diseases

Util A	Util B		Util C
Solriamfetol	Amantadine	Ropinirole	
	Bromocriptine	Rotigotine	
	Bupropion	Pramipexole	
	Levodopa	Tolcapone	
	Entacapone		

References:

Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Sunosi Prescribing Information, June 2019, Jazz Pharmaceuticals, Inc.

Criteria Recommendations *Approved* *Rejected*

7. Solriamfetol / Serious Heart Problems _____ _____

Alert Message: The use of Sunosi (solriamfetol) should be avoided in patients with unstable cardiovascular disease, serious heart arrhythmias, or other serious heart problems. Solriamfetol may cause dose-dependent increases in blood pressure and heart rate. If increases in blood pressure or heart rate occur and cannot be managed with dose reduction of solriamfetol or other appropriate medical interventions, consider discontinuation of solriamfetol.

Drugs/Diseases

Util A	Util B	Util **C (Include)**
Solriamfetol		Arrhythmia
		Unstable Angina
		Myocardial Infarction
		Valve Disorders
		Heart Failure

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Sunosi Prescribing Information, March 2019, Jazz Pharmaceuticals, Inc.

8. Solriamfetol / Blood Pressure & Heart Rate Increases _____ _____

Alert Message: Exercise caution when prescribing Sunosi (solriamfetol) to patients at high risk for cardiovascular events (e.g., patients with known cardiovascular or cerebrovascular disease, preexisting hypertension, advanced age). Solriamfetol may cause dose-dependent increases in blood pressure and heart rate. If increases in blood pressure or heart rate occur and cannot be managed with dose reduction of solriamfetol or other appropriate medical interventions, consider discontinuation of solriamfetol.

Drugs/Diseases

Util A	Util B	Util C **(Include)**
Solriamfetol		Hypertension
		Tachycardia
		Diabetes
		Hyperlipidemia
		Obesity

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Sunosi Prescribing Information, March 2019, Jazz Pharmaceuticals, Inc.

9. Solriamfetol / Psychiatric Symptoms _____ _____

Alert Message: Psychiatric adverse reactions have been observed in clinical trials with Sunosi (solriamfetol), including anxiety, insomnia, and irritability. Caution should be exercised when treating patients with solriamfetol who have a history of psychosis or bipolar disorders. Patients treated with solriamfetol should be observed for the possible emergence or exacerbation of psychiatric symptoms. If psychiatric symptoms develop in association with the administration of solriamfetol, consider dose reduction or discontinuation of solriamfetol.

Drugs/Diseases

Util A	Util B	Util C **(Include)**
Solriamfetol		Bipolar Disorder
		Psychosis
		Anxiety
		Agitation
		Irritability
		Insomnia

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

10. Solriamfetol / Drugs the Increase BP or HR _____ _____

Alert Message: Caution should be exercised when prescribing Sunosi (solriamfetol) with other medications that increase blood pressure and/or heart rate. Solriamfetol can cause dose-dependent increases in blood pressure and heart rate, and concurrent use with other medications that increase blood pressure and/or heart rate may increase the risk of the adverse effects.

Drugs/Diseases

Util A	Util B	Util C
Solriamfetol	Amphetamine	Benzphetamine
	Dextroamphetamine	Diethylpropion
	Lisdexamfetamine	Phendimetrazine
	Methamphetamine	Phentermine
	Methylphenidate	Droxidopa
	Dexmethylphenidate	Venlafaxine
	Pseudoephedrine	Esketamine
	Phenylephrine	Triptans
	Indomethacin	Ibuprofen
	Naproxen	Piroxicam

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

11. Solriamfetol / Therapeutic Appropriateness _____ _____

Alert Message: The safety and effectiveness of Sunosi (solriamfetol) in pediatric patients have not been established. Clinical studies of solriamfetol in pediatric patients have not been conducted.

Drugs/Diseases

Util A	Util B	Util C
Solriamfetol		

Age Range 0 – 17 yoa

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

12. Solriamfetol / Pregnancy / Pregnancy Negating _____ _____

Alert Message: There are no available human data regarding the use of Sunosi (solriamfetol) during pregnancy to be informative of any drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes. Results from some animal reproductive studies using doses exceeding the maximum recommended human dose (MRHD) of solriamfetol showed fetal harm and maternal toxicity. Healthcare providers are encouraged to register pregnant patients in the Sunosi Pregnancy Registry.

Drugs/Diseases

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

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

13. Solriamfetol / Lactation _____ _____

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

Drugs/Diseases

Util A	Util B	Util C
Solriamfetol	Lactation	

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

14. Aclidinium/Formoterol / Therapeutic Appropriateness _____ _____

Alert Message: The safety and effectiveness of Duaklir Pressair (aclidinium/formoterol) have not been established in the pediatric population.

Drugs/Diseases

Util A	Util B	Util C
Aclidinium/Formoterol		

Age Range: 0 – 17 yoa

References:
Duaklir Pressair Prescribing Information, March 2019, AstraZeneca.
Clinical Pharmacology, 2019 Elsevier/Gold Standard.

15. Aclidinium/Formoterol / Overuse _____ _____

Alert Message: Duaklir Pressair (aclidinium/formoterol) may be over-utilized. The manufacturer's maximum recommended dose is one oral inhalation (400 mcg/12 mcg) twice daily. Clinically significant cardiovascular effects and fatalities have been reported in association with excessive use of inhaled sympathomimetic drugs.

Drugs/Diseases

Util A	Util B	Util C
Aclidinium/Formoterol		

Max Dose: 800 mcg/24 mcg daily

References:
Duaklir Pressair Prescribing Information, March 2019, AstraZeneca.
Clinical Pharmacology, 2019 Elsevier/Gold Standard.

16. Aclidinium/Formoterol / Therapeutic Appropriateness _____ _____

Alert Message: Duaklir Pressair (aclidinium/formoterol) is indicated for maintenance treatment of patients with chronic obstructive pulmonary disease (COPD) and is not indicated for the relief of acute bronchospasm or for the treatment of asthma. The safety and efficacy of aclidinium/formoterol in patients with asthma has not been established.

Drugs/Diseases

Util A	Util B	Util C **(Negating)**
Aclidinium/Formoterol	Asthma	COPD

References:
Duaklir Pressair Prescribing Information, March 2019, AstraZeneca.
Clinical Pharmacology, 2019 Elsevier/Gold Standard.

17. Aclidinium/Formoterol / Cardiovascular, Convulsive Disorders, Thyrotoxicosis & Diabetes _____ _____

Alert Message: Duaklir Pressair (aclidinium/formoterol) should be used with caution in patients with cardiovascular or convulsive disorders, thyrotoxicosis, diabetes mellitus, or sensitivity to sympathomimetic drugs. The formoterol component is a sympathomimetic amine and can exacerbate these conditions.

Drugs/Diseases

Util A	Util B	Util C
Aclidinium/Formoterol	Hypertension	
	Arrhythmias	
	Heart Failure	
	Diabetes	
	Seizures	
	Epilepsy	

References:
Duaklir Pressair Prescribing Information, March 2019, AstraZeneca.
Clinical Pharmacology, 2019 Elsevier/Gold Standard.

18. Aclidinium/Formoterol / Narrow Angle Glaucoma _____ _____

Alert Message: Duaklir Pressair (aclidinium/formoterol) should be used with caution in patients with narrow-angle glaucoma. Aclidinium is an anticholinergic agent and may worsen this condition. Prescribers and patients should be alert for signs and symptoms of acute narrow-angle glaucoma (e.g., eye pain or discomfort, blurred vision, or visual halos).

Drugs/Diseases

Util A	Util B	Util C
Aclidinium/Formoterol	Narrow-Angle Glaucoma	

References:
Duaklir Pressair Prescribing Information, March 2019, AstraZeneca.
Clinical Pharmacology, 2019 Elsevier/Gold Standard.

19. Aclidinium/Formoterol / Urinary Retention _____ _____

Alert Message: Duaklir Pressair (aclidinium/formoterol) should be used with caution in patients with urinary retention or bladder neck obstruction. Aclidinium is an anticholinergic agent which may worsen urinary retention. Prescribers and patients should be alert for signs and symptoms of urinary retention (e.g., difficulty passing urine, painful urination), especially in patients with prostatic hyperplasia or bladder neck obstruction. Instruct patients to consult a physician immediately should any of these signs or symptoms develop.

Drugs/Diseases

Util A	Util B	Util C
Aclidinium/Formoterol	Urinary Retention	
	Prostatic Hyperplasia	
	Bladder-Neck Obstruction	

References:
Duaklir Pressair Prescribing Information, March 2019, AstraZeneca.
Clinical Pharmacology, 2019 Elsevier/Gold Standard.

20. Aclidinium/Formoterol / Paradoxical Bronchospasm _____ _____

Alert Message: Inhaled medicines, including Duaklir Pressair (aclidinium/formoterol), may cause paradoxical bronchospasm, which may be life-threatening. If paradoxical bronchospasm occurs following dosing with aclidinium/formoterol, it should be treated immediately with an inhaled, short-acting bronchodilator. Aclidinium/formoterol should be discontinued immediately, and alternative therapies should be instituted.

Drugs/Diseases

Util A	Util B	Util C
Aclidinium/Formoterol	Bronchospasm	

References:
Duaklir Pressair Prescribing Information, March 2019, AstraZeneca.
Clinical Pharmacology, 2019 Elsevier/Gold Standard.

21. Aclidinium/Formoterol / Anticholinergic Drugs _____ _____

Alert Message: The concurrent use of Duaklir Pressair (aclidinium/formoterol) with anticholinergic medications should be avoided. The aclidinium component of the combination medication is an anticholinergic drug, and use with another anticholinergic agent may result in additive anticholinergic adverse effects.

Drugs/Diseases

Util A	Util B	Util C
Aclidinium/Formoterol	Anticholinergics	

References:
Duaklir Pressair Prescribing Information, March 2019, AstraZeneca.
Clinical Pharmacology, 2019 Elsevier/Gold Standard.

22. Aclidinium/Formoterol / Adrenergic Drugs _____ _____

Alert Message: Caution should be exercised when Duaklir Pressair (aclidinium/formoterol) is prescribed concurrently with other adrenergic sympathomimetic agents, administered by any route, because the sympathetic effects of the formoterol component of the combination product may be potentiated.

Drugs/Diseases

Util A	Util B			
Aclidinium/Formoterol	Ephedrine	Metaproterenol	Lisdexamfetamine	Oxymetazoline
	Epinephrine	Terbutaline	Diethylpropion	Tetrahydrozoline
	Pseudoephedrine	Methamphetamine	Benzphetamine	
	Phenylephrine	Methylphenidate	Phentermine	
	Albuterol	Amphetamine	Phendimetrazine	
	Pirbuterol	Dextroamphetamine	Naphazoline	

References:
Duaklir Pressair Prescribing Information, March 2019, AstraZeneca.
Clinical Pharmacology, 2019 Elsevier/Gold Standard.

23. Aclidinium/Formoterol / Xanthine Derivatives & Steroids _____ _____

Alert Message: Caution should be exercised when Duaklir Pressair (aclidinium/formoterol) is prescribed concurrently with xanthine derivatives or steroids because concomitant administration may potentiate the hypokalemic effect of the formoterol component of the combination agent.

Drugs/Diseases

Util A	Util B	
Aclidinium/Formoterol	Theophylline	Hydrocortisone
	Aminophylline	Methylprednisolone
	Dyphylline	Prednisone
	Betamethasone	Prednisolone
	Budesonide	Dexamethasone
	Cortisone	

References:
Duaklir Pressair Prescribing Information, March 2019, AstraZeneca.
Clinical Pharmacology, 2019 Elsevier/Gold Standard.

24. Aclidinium/Formoterol / Non-Potassium Sparing Diuretics _____ _____

Alert Message: Caution should be exercised when Duaklir Pressair (aclidinium/formoterol), a beta2-agonist containing combo agent, is prescribed concurrently with non-potassium sparing diuretics because concomitant administration may potentiate the ECG changes or hypokalemia that may result from the administration of the diuretic.

Drugs/Diseases

Util A	Util B		Util C
Glycopyrrolate/Formoterol	Furosemide	Indapamide	
	Bumetanide	Methyclothiazide	
	Torsemide	Metolazone	
	Chlorothiazide		
	Chlorthalidone		
	HCTZ		

References:
Duaklir Pressair Prescribing Information, March 2019, AstraZeneca.
Clinical Pharmacology, 2019 Elsevier/Gold Standard.

25. Aclidinium/Formoterol / MAOIs, TCA & Other QT Prolong Meds _____ _____

Alert Message: Duaklir Pressair (aclidinium/formoterol), as with other drugs containing beta2-agonists, should be administered with caution to patients being treated with monoamine oxidase inhibitors, tricyclic antidepressants, or other drugs known to prolong the QTc interval, because the action of adrenergic agonists on the cardiovascular system may be potentiated by these agents. Drugs that are known to prolong the QTc interval have an increased risk of ventricular arrhythmias.

Drugs/Diseases

Util A	Util B				Util C
Aclidinium/Formoterol	Albuterol	Disopyramide	Imipramine	Pazopanib	
	Alfuzosin	Dofetilide	Indapamide	Pentamidine	
	Amantadine	Dolasetron	Isradipine	Pimozide	
	Tolterodine	Amiodarone	Doxepin	Itraconazole	
	Posaconazole	Trazodone	Amitriptyline	Dronedarone	
	Ketoconazole	Procainamide	TMP/SMZ	Amphetamine	
	Droperidol	Lapatinib	Propafenone	Trimipramine	
	Arsenic Trioxide	Ephedrine	Levalbuterol	Protriptyline	
	Vandetanib	Asenapine	Epinephrine	Levofloxacin	
	Quetiapine	Vardenafil	Atazanavir	Erythromycin	
	Lithium	Quinidine	Venlafaxine	Atomoxetine	
	Escitalopram	Metaproterenol	Ranolazine	Tizanidine	
	Ziprasidone	Azithromycin	Felbamate	Tamoxifen	
	Risperidone	Zolmitriptan	Chloral Hydrate	Flecainide	
	Moexipril/HCTZ	Ritonavir	Ezogabine	Chloroquine	
	Fluconazole	Moxifloxacin	Salmeterol	Rasagiline	
	Chlorpromazine	Fluoxetine	Nicardipine	Saquinavir	
	Phenelzine	Ciprofloxacin	Foscarnet	Nilotinib	
	Sertraline	Tranylcypromine	Citalopram	Fosphenytoin	
	Solifenacin	Linezolid	Clarithromycin	Galantamine	
	Nortriptyline	Sotalol	Thioridazine	Terbutaline	
	Clomipramine	Tacrolimus	Octreotide	Sunitinib	
	Clozapine	Granisetron	Ofloxacin	Artemether/Lumefantrine	
	Dasatinib	Haloperidol	Ondansetron		
	Desipramine	Isocarboxazid	Paliperidone		
	Diphenhydramine	Iloperidone	Paroxetine		

References:

Duaklir Pressair Prescribing Information, March 2019, AstraZeneca.
Clinical Pharmacology, 2019 Elsevier/Gold Standard.

26. Aclidinium/Formoterol / Nonselective Beta Blockers _____ _____

Alert Message: Beta-adrenergic receptor antagonists (beta-blockers) and Duaklir Pressair (aclidinium/formoterol) may antagonize the effect of each other when administered concurrently. Beta-blockers not only block the therapeutic effects of beta2-agonists, such as formoterol, but may produce severe bronchospasm in COPD patients. Therefore, patients with COPD should not normally be treated with beta-blockers. If therapy is warranted, cardioselective beta-blockers could be considered, although they should be administered with caution.

Drugs/Diseases

Util A	Util B	Util C **(Negating)**
Glycopyrrolate/Formoterol	Carvedilol	Acebutolol
	Nadolol	Atenolol
	Labetalol	Betaxolol
	Penbutolol	Bisoprolol
	Pindolol	Metoprolol
	Propranolol	Nebivolol
	Sotalol	
	Timolol	

References:

Duaklir Pressair Prescribing Information, March 2019, AstraZeneca.
Clinical Pharmacology, 2019 Elsevier/Gold Standard.

27. Aclidinium/Formoterol / Non-adherence _____ _____

Alert Message: Based on refill history, your patient may be under-utilizing Duaklir Pressair (aclidinium/formoterol). 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
Aclidinium/Formoterol		

References:

van Boven JF, Chavannes NH, van der Molen T, et al. Clinical and Economic Impact of Non-adherence in COPD: A Systematic Review. Respir Med. 2015 Jan;108(1):103-113.
Restrepo RD, Alvarez MT, Wittnebel LD, et al., Medication Adherence Issues in Patients Treated for COPD. International Journal of COPD. 2008;3(3):371-384.
Simoni-Wastila L, Wei Y, Qian J, et al., Association of Chronic Obstructive Pulmonary Disease Maintenance Medication Adherence With All-Cause Hospitalization and Spending in a Medicare Population. Am Jrnl Geriatr Pharmacother. 2012 Jun;10(3):201-210.
Lareau SC, Yawn BP. Improving Adherence with Inhaler Therapy in COPD. International Journal COPD. 2010 Nov 24;5:401-406.

28. Budesonide ER Tablets / Hepatic Impairment _____ _____

Alert Message: Uceris (budesonide extended-release tablets) is primarily metabolized in the liver. Patients with moderate to severe hepatic impairment (Child-Pugh Class B and C, respectively) could be at increased risk of hypercorticism and adrenal axis suppression due to increased systemic exposure of oral budesonide. Monitor the patient for increased signs and/or symptoms of hypercorticism. Discontinuing the use of budesonide extended-release tablets should be considered in these patients.

Drugs/Diseases

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

References:

Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Uceris Prescribing Information, Nov. 2016, Valeant Pharmaceuticals.

29. Budesonide ER Tablets / Strong CYP3A4 Inhibitors _____ _____

Alert Message: The concurrent use of Uceris (budesonide extended-release tablets) with strong CYP3A4 inhibitors should be avoided. Budesonide is a CYP3A4 substrate, and coadministration with strong CYP3A4 inhibitors can significantly increase the systemic exposure to budesonide.

Drugs/Diseases

Util A	Util B		Util C
Budesonide ER Tabs	Itraconazole	Indinavir	
	Ketoconazole	Nelfinavir	
	Atazanavir	Telithromycin	
	Clarithromycin	Nefazodone	
	Saquinavir	Cobicistat	
	Ritonavir		

References:

Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Uceris Prescribing Information, Nov. 2016, Valeant Pharmaceuticals.

30. Stiripentol / Overutilization _____ _____

Alert Message: Diacomit (stiripentol) may be over-utilized. The recommended maximum total dosage of stiripentol is 3,000 mg/day.

Drugs/Diseases

Util A	Util B	Util C
Stiripentol		

Max Dose: 3000 mg/day

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Diacomit Prescribing Information, August 2018, Biocodex.

31. Stiripentol / Therapeutic Appropriateness _____ _____

Alert Message: A recent review of the patient drug history does not reveal a current prescription for clobazam. Diacomit (stiripentol) is indicated for the treatment of seizures associated with Dravet syndrome (DS) in patients 2 years of age and older taking clobazam. There are no clinical data to support the use of stiripentol as monotherapy in Dravet syndrome.

Drugs/Diseases

Util A	Util B	Util C **(Negating)**
Stiripentol		Clobazam

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Diacomit Prescribing Information, August 2018, Biocodex.

32. Stiripentol / Neutropenia & Thrombocytopenia _____ _____

Alert Message: Diacomit (stiripentol) can cause a significant decline in neutrophil count and platelet count. Hematologic testing should be obtained prior to starting treatment with stiripentol, and then every 6 months.

Drugs/Diseases

Util A	Util B	Util C
Stiripentol	Neutropenia	
	Thrombocytopenia	

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Diacomit Prescribing Information, August 2018, Biocodex.

33. Stiripentol / Clobazam _____ _____

Alert Message: Co-administration of Diacomit (stiripentol), which inhibits CYP3A4 and CYP2C19, with clobazam results in increased plasma concentrations of clobazam (a substrate of CYP3A4) and norclobazam, the active metabolite of clobazam (a substrate of CYP2C19). This may increase the risk of clobazam-related adverse reactions. Consider a reduction in dosage of clobazam if adverse reactions are experienced when co-administered with stiripentol.

Drugs/Diseases

Util A	Util B	Util C
Stiripentol	Clobazam	

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Diacomit Prescribing Information, August 2018, Biocodex.

34. Stiripentol / CYP1A2, 3A4 & 2C19 Inducers _____ _____

Alert Message: Induction-based interactions leading to decreases in Diacomit (stiripentol) concentrations are possible when co-administered with a potent CYP1A2, CYP3A4, or CYP2C19 inducer, such as rifampin, phenytoin, phenobarbital, and carbamazepine, as these enzymes all metabolize stiripentol. Concomitant use of strong inducers with stiripentol should be avoided, or dosage adjustments should be made.

Drugs/Diseases

Util A	Util B	Util C
Stiripentol	Rifampin	
	Phenytoin	
	Phenobarbital	
	Carbamazepine	
	Omeprazole	
	Lansoprazole	

References:

Diacomit Prescribing Information, August 2018, Biocodex.
FDA Drug Development and Drug Interaction: Tables 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

35. Stiripentol / Substrates of CYP2C8, 2C19, P-gp & BCRP _____ _____

Alert Message: Because of potential inhibition of enzyme/transporter activity by Diacomit (stiripentol), consider a reduction in dosage of substrates of CYP2C8, CYP2C19 (e.g., diazepam, clopidogrel), P-gp (e.g., digoxin), and BCRP (e.g., methotrexate, prazosin, glyburide), if adverse reactions are experienced when administered concomitantly with stiripentol.

Drugs/Diseases

Util A	Util B			Util C
Stiripentol	Diazepam	Rabeprazole	Digoxin	
	Clopidogrel	Voriconazole	Fexofenadine	
	Dantrolene	Loperamide	Quinidine	
	Methotrexate	Glyburide	Sulfasalazine	
	Prazosin	Repaglinide	Rosuvastatin	

References:

Diacomit Prescribing Information, August 2018, Biocodex.
FDA Drug Development and Drug Interaction: Tables 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

36. Stiripentol / Substrates of CYP1A2, 2B6 & 3A4 _____ _____

Alert Message: In vitro data show that Diacomit (stiripentol) is both an inhibitor and inducer of CYP1A2, CYP2B6, and CYP3A4. Because of potential drug-drug interactions, consider dose adjustment of CYP1A2 substrates (e.g., theophylline, caffeine), CYP2B6 substrates (e.g., sertraline, thiotepa), and CYP3A4 substrates (e.g., midazolam, triazolam, quinidine), as clinically appropriate, when administered concomitantly with stiripentol.

Drugs/Diseases

Util A	Util B		Util C
Stiripentol	Dexamethasone	Pirfenidone	Crizotinib
	Midazolam	Eszopiclone	Dasatinib
	Alprazolam	Ethosuximide	Erlotinib
	Triazolam	Galantamine	Ibrutinib
	Alosetron	Hydrocodone	Lapatinib
	Bupropion	Loratadine	Nilotinib
	Etoposide	Lurasidone	Pazopanib
	Irinotecan	Maraviroc	Sunitinib
	Cyclophosphamide	Oxycodone	Vandetanib
	Selegiline	Prasugrel	Clozapine
	Imatinib	Quazepam	Tasimelteon
	Methadone	Simvastatin	Ramelteon
	Ketamine	Lovastatin	Fosamprenavir
	Velpatasvir	Tadalafil	Atazanavir
	Apixaban	Tiagabine	Tipranavir
	Bortezomib	Axitinib	Delavirdine
	Bosutinib	Vilazodone	Theophylline
	Buprenorphine	Axitinib	Tizanidine
	Clomipramine	Cabozantinib	Theophylline
	Disulfiram	Ceritinib	Efavirenz
	Avanafil	Darifenacin	Everolimus
	Naloxegol	Nisoldipine	Sirolimus
	Vardenafil	Duloxetine	Tacrolimus
	Buspirone	Dronedarone	Budesonide
	Dasatinib	Eletriptan	Eplerenone
	Felodipine	Indinavir	Lurasidone
	Maraviroc	Quetiapine	Sildenafil
	Ticagrelor	Tolvaptan	Aprepitant
	Atorvastatin	Colchicine	Eliglustat
	Pimozide	Rilpivirine	Rivaroxaban

References:

Diacomit Prescribing Information, August 2018, Biocodex.
FDA Drug Development and Drug Interaction: Tables 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

37. Stiripentol / Therapeutic Appropriateness _____ _____

Alert Message: The safety and effectiveness of Diacomit (stiripentol) in pediatric patients below the age of 2 years have not been established.

Drugs/Diseases

Util A	Util B	Util C
Stiripentol		

Age Range: 0 – 1 yoa

References:

Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Diacomit Prescribing Information, August 2018, Biocodex.

38. Stiripentol / Moderate & Severe Renal Impairment _____ _____

Alert Message: There is no formal study of the pharmacokinetics and metabolism of Diacomit (stiripentol) in patients with renal impairment. However, since stiripentol metabolites are eliminated mainly through the kidney, administration to patients with moderate or severe renal impairment is not recommended.

Drugs/Diseases

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

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Diacomit Prescribing Information, August 2018, Biocodex.

39. Stiripentol / Hepatic Impairment _____ _____

Alert Message: There has been no formal study of the pharmacokinetics of Diacomit (stiripentol) in patients with liver impairment. However, since stiripentol is mainly metabolized by the liver, administration to patients with moderate or severe liver impairment is not recommended.

Drugs/Diseases

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

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Diacomit Prescribing Information, August 2018, Biocodex.

40. Stiripentol / Nonadherence _____ _____

Alert Message: Based on the refill history, your patient may be underutilizing Diacomit (stiripentol). 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
Stiripentol		

References:
Osterberg L, Blaschke T. Adherence to Medication. N Engl J Med 2005; 353:487- 497.
Faught E, Duh MS, Weiner JR, et al. Nonadherence to Antiepileptic Drugs and Increased Mortality, Findings from the RANSOM Study. Neurology 2008;71(20): 1572-1578.
Hodges JC, Treadwell J, Malphrus AD, et al., Identification and Prevention of Antiepileptic Drug Noncompliance: The Collaborative Use of State-Supplied Pharmaceutical Data. ISRN Pediatr. 2014 Feb 19:1-8.
Viswanathan M, Golin CE, Jones DC, et al., Interventions to Improve Adherence to Self-administered Medications for Chronic Disease in the United States: A Systemic Review. Ann Intern Med. 2012:157:785-792.

41. Stiripentol / Pregnancy / Pregnancy Negating _____ _____

Alert Message: There are no adequate data on the developmental risks associated with the use of Diacomit (stiripentol) in pregnant women. Administration of stiripentol to pregnant animals produced evidence of developmental toxicity at maternal doses lower than the recommended clinical dose. Physicians are advised to recommend that pregnant patients taking stiripentol enroll in the North American Antiepileptic Drug (NAAED) Pregnancy Registry.

Drugs/Diseases

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

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Diacomit Prescribing Information, August 2018, Biocodex.

42. Stiripentol / Lactation _____ _____

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

Drugs/Diseases

Util A	Util B	Util C
Stiripentol	Lactation	

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Diacomit Prescribing Information, August 2018, Biocodex.

43. Stiripentol Solution / Phenylketonuria _____ _____

Alert Message: Phenylalanine can be harmful to patients with phenylketonuria (PKU). Diacomit (stiripentol) powder for suspension contains phenylalanine, a component of aspartame. Each 250 mg packet contains 1.40 mg phenylalanine; each 500 mg packet contains 2.80 mg phenylalanine. Before prescribing stiripentol powder for suspension to a patient with PKU, consider the combined daily amount of phenylalanine from all sources, including stiripentol powder for suspension. Stiripentol capsules do not contain phenylalanine.

Drugs/Diseases

Util A	Util B	Util C **(Include)**
Stiripentol Solution		Phenylketonuria

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Diacomit Prescribing Information, August 2018, Biocodex.

44. Efavirenz/Lamivudine/Tenofovir / All Other Antiretrovirals _____ _____

Alert Message: Symfi (efavirenz/lamivudine/tenofovir disoproxil) is a complete regimen for the treatment of HIV-1 infection; therefore, it should not be administered with other antiretroviral medications for the treatment of HIV-1 infection.

Drugs/Diseases

Util A	Util B	Util C
Efavirenz/Lamivudine/Tenofovir	Cellular Chemokine Receptor (CCR5) Antagonist	
	Fusion Inhibitors	
	Integrase Inhibitors	
	NNRTIs	
	NRTIs	
	Nucleotide Analog Reverse Transcriptase Inhibitors	
	Protease Inhibitors	
	Antiretroviral Combos	

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Symfi Prescribing Information, March 2018, Mylan Specialty LP.

45. Efavirenz/Lamivudine/Tenofovir / Overutilization _____ _____

Alert Message: Symfi (efavirenz/lamivudine/tenofovir disoproxil) may be over-utilized. The recommended maximum daily dose in adults and pediatric patients weighing at least 40 kg, and can swallow a solid tablet, is one tablet once daily on an empty stomach, preferably at bedtime.

Drugs/Diseases

Util A	Util B	Util C
Efavirenz/Lamivudine/Tenofovir		

Max Dose: 1 tablet/day

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Symfi Prescribing Information, March 2018, Mylan Specialty LP.

46. Efavirenz/Lamivudine/Tenofovir / Elbasvir/Grazoprevir _____ _____

Alert Message: Concurrent use of Symfi (efavirenz/lamivudine/tenofovir disoproxil) with Zepatier (elbasvir/grazoprevir) is contraindicated due to the potential for loss elbasvir/grazoprevir virologic response. The efavirenz component of the combination antiretroviral product is a CYP3A4 inducer, and both components of the antiviral combination product are CYP3A4 substrates.

Drugs/Diseases

Util A	Util B	Util C
Efavirenz/Lamivudine/Tenofovir	Elbasvir/Grazoprevir	

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Symfi Prescribing Information, March 2018, Mylan Specialty LP.

47. Efavirenz/Lamivudine/Tenofovir / Renal Impairment _____ _____

Alert Message: Because Symfi (efavirenz/lamivudine/tenofovir disoproxil) is a fixed-dose combination tablet and cannot be dose adjusted, the agent is not recommended for use in patients with impaired renal function (CrCl < 50 mL/min) or patients with ESRD requiring hemodialysis. Renal impairment, including cases of acute renal failure and Fanconi syndrome, has been reported with the use of the tenofovir component of this combination tablet.

Drugs/Diseases

Util A	Util B	Util C **(Include)**
Efavirenz/Lamivudine/Tenofovir		CKD 3, 4, & 5 ESRD Dialysis

References:

Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Symfi Prescribing Information, March 2018, Mylan Specialty LP.

48. Efavirenz/Lamivudine/Tenofovir / Hepatic Impairment _____ _____

Alert Message: Symfi (efavirenz/lamivudine/tenofovir disoproxil) use is not recommended in patients with moderate to severe hepatic impairment (Child-Pugh B or C). Efavirenz/lamivudine/tenofovir disoproxil should be used with caution in patients with mild hepatic impairment. Postmarketing cases of hepatitis, including fulminant hepatitis progressing to liver failure requiring transplantation or resulting in death, have been reported in patients treated with efavirenz, a component of the combination product.

Drugs/Diseases

Util A	Util B	Util C **(Include)**
Efavirenz/Lamivudine/Tenofovir		Hepatic Impairment

References:

Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Symfi Prescribing Information, March 2018, Mylan Specialty LP.

49. Efavirenz/Lamivudine/Tenofovir / Seizure Disorders _____ _____

Alert Message: Symfi (efavirenz/lamivudine/tenofovir disoproxil) should be used with caution in patients with a history of seizures. The use of the efavirenz, a component in the combination antiretroviral product, has been associated with the occurrence of convulsions, generally in the presence of a known medical history of seizures.

Drugs/Diseases

Util A	Util B	Util C **(Include)**
Efavirenz/Lamivudine/Tenofovir		Seizures Convulsions

References:

Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Symfi Prescribing Information, March 2018, Mylan Specialty LP.

50. Efavirenz/Lamivudine/Tenofovir / Drugs Causing QT Prolongation _____ _____

Alert Message: Concurrent use of Symfi (efavirenz/lamivudine/tenofovir disoproxil) with drugs that prolong the QTc interval may increase the risk for QTc prolongation. QTc prolongation has been observed with the use of efavirenz, a component in the combination antiretroviral. It is recommended to consider alternatives to products containing efavirenz when coadministered with a drug with a known risk of torsade de pointes or when administered to patients at higher risk of torsade de pointes.

Drugs/Diseases

Util A	Util B			Util C
Efavirenz/Lamivudine/Tenofovir	Albuterol	Disopyramide	Imipramine	Pazopanib
	Alfuzosin	Dofetilide	Indapamide	Pentamidine
	Amantadine	Dolasetron	Isradipine	Pimozide
	Tolterodine	Amiodarone	Doxepin	Itraconazole
	Posaconazole	Trazodone	Amitriptyline	Dronedarone
	Ketoconazole	Procainamide	TMP/SMZ	Amphetamine
	Droperidol	Lapatinib	Propafenone	Trimipramine
	Arsenic Trioxide	Ephedrine	Levalbuterol	Protriptyline
	Vandetanib	Asenapine	Epinephrine	Levofloxacin
	Quetiapine	Vardenafil	Atazanavir	Erythromycin
	Lithium	Quinidine	Venlafaxine	Atomoxetine
	Escitalopram	Metaproterenol	Ranolazine	Tizanidine
	Ziprasidone	Azithromycin	Felbamate	Tamoxifen
	Risperidone	Zolmitriptan	Chloral Hydrate	Flecainide
	Moexipril/HCTZ	Ritonavir	Ezogabine	Chloroquine
	Fluconazole	Moxifloxacin	Salmeterol	Rasagiline
	Chlorpromazine	Fluoxetine	Nicardipine	Saquinavir
	Phenelzine	Ciprofloxacin	Foscarnet	Nilotinib
	Sertraline	Tranylcypromine	Citalopram	Fosphenytoin
	Solifenacin	Linezolid	Clarithromycin	Galantamine
	Nortriptyline	Sotalol	Thioridazine	Terbutaline
	Clomipramine	Tacrolimus	Octreotide	Sunitinib
	Clozapine	Granisetron	Ofloxacin	Artemether/Lumefantrine
	Dasatinib	Haloperidol	Ondansetron	
	Desipramine	Isocarboxazid	Paliperidone	
	Diphenhydramine	Iloperidone	Paroxetine	

References:

Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Symfi Prescribing Information, March 2018, Mylan Specialty LP.

51. Efavirenz/Lamivudine/Tenofovir / Risk Factors for Torsade de Pointes _____ _____

Alert Message: QTc prolongation has been observed with the use of efavirenz, a component in the combination antiretroviral Symfi (efavirenz/lamivudine/tenofovir disoproxil). It is recommended to consider alternative therapy in patients at higher risk of torsade de pointes.

Drugs/Diseases

Util A	Util B	Util C
Efavirenz/Lamivudine/Tenofovir	Long QT Syndrome	
	Bradycardia	
	Hypokalemia	
	Hypomagnesemia	
	Arrhythmias	

References:

Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Symfi Prescribing Information, March 2018, Mylan Specialty LP.
Jatin D. (2017, Jan. 31) Torsade de Pointes. eMedicine, Medscape.com.

52. Efavirenz/Lamivudine/Tenofovir / Bupropion _____ _____

Alert Message: Concurrent use of Symfi (efavirenz/lamivudine/tenofovir disoproxil) with a bupropion-containing agent may result in decreased plasma concentrations and pharmacologic effects of bupropion. Adjustments to the bupropion dosage may be necessary and should be guided by clinical response. The bupropion dose should not exceed the maximum recommended dose.

Drugs/Diseases

Util A	Util B	Util C
Efavirenz/Lamivudine/Tenofovir	Bupropion	

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Symfi Prescribing Information, March 2018, Mylan Specialty LP.

53. Efavirenz/Lamivudine/Tenofovir / Sertraline _____ _____

Alert Message: Concurrent use of Symfi (efavirenz/lamivudine/tenofovir disoproxil) with sertraline may result in decreased plasma concentrations and pharmacologic effects of sertraline. Adjustments to the sertraline dosage may be necessary and should be guided by clinical response. The sertraline dose should not exceed the maximum recommended dose.

Drugs/Diseases

Util A	Util B	Util C
Efavirenz/Lamivudine/Tenofovir	Sertraline	

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Symfi Prescribing Information, March 2018, Mylan Specialty LP.

54. Efavirenz/Lamivudine/Tenofovir / Ketoconazole & Itraconazole _____ _____

Alert Message: Concurrent use of Symfi (efavirenz/lamivudine/tenofovir disoproxil) with ketoconazole or itraconazole (CYP3A4 substrates) can result in decreased plasma concentrations of the antifungal agent due to induction of CYP3A4-mediated metabolism by efavirenz. In addition, both antifungal agents as well as efavirenz are associated with QT prolongation and concomitant use may result in additive effects on the QT interval. Consider alternative antifungal treatment because no dose recommendation for the antifungal can be made.

Drugs/Diseases

Util A	Util B	Util C
Efavirenz/Lamivudine/Tenofovir	Ketoconazole Itraconazole	

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Symfi Prescribing Information, March 2018, Mylan Specialty LP.

55. Efavirenz/Lamivudine/Tenofovir / Posaconazole _____ _____

Alert Message: The concurrent use of Symfi (efavirenz/lamivudine/tenofovir disoproxil) with posaconazole should be avoided unless the benefit outweighs the risk. The efavirenz component of the combination antiretroviral product is a UDP-glucuronidase inducer and coadministration with posaconazole, a UDP-G substrate, can result in a significant decrease in the posaconazole plasma concentrations. In addition, both posaconazole and efavirenz are associated with QT prolongation and concomitant use may result in additive effects on the QT interval.

Drugs/Diseases

Util A	Util B	Util C
Efavirenz/Lamivudine/Tenofovir	Posaconazole	

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Symfi Prescribing Information, March 2018, Mylan Specialty LP.

56. Efavirenz Containing Agents / Certain Statins _____ _____

Alert Message: Concurrent use of Symfi (efavirenz/lamivudine/tenofovir disoproxil) with atorvastatin, pravastatin or simvastatin can result in decreased statin plasma concentrations due to induction, by efavirenz, of the statin CYP3A4-mediated metabolism. Statin dosage adjustment may be necessary, but do not exceed the maximum recommended statin dose.

Drugs/Diseases

Util A	Util B	Util C
Efavirenz/Lamivudine/Tenofovir	Atorvastatin Simvastatin Pravastatin	

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Symfi Prescribing Information, March 2018, Mylan Specialty LP.

57. Efavirenz/Lamivudine/Tenofovir / Velpatasvir-Sofosbuvir _____ _____

Alert Message: Concurrent use of Symfi (efavirenz/lamivudine/tenofovir disoproxil) with Epclusa (velpatasvir/sofosbuvir) is not recommended because it may result in loss of therapeutic effect of velpatasvir-sofosbuvir. The efavirenz component of the antiretroviral agent is a CYP3A4 inducer, and the velpatasvir component of the antiviral is a CYP3A4 substrate.

Drugs/Diseases

Util A	Util B	Util C
Efavirenz/Lamivudine/Tenofovir	Velpatasvir-Sofosbuvir	

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Symfi Prescribing Information, March 2018, Mylan Specialty LP.

58. Efavirenz/Lamivudine/Tenofovir / Immunosuppressants 3A4 Substrate _____ _____

Alert Message: Concurrent use of Symfi (efavirenz/lamivudine/tenofovir disoproxil) with an immunosuppressant drug that is a CYP3A4 substrate may result in decreased immunosuppressant exposure. Dosage adjustment of the immunosuppressant may be required. Close monitoring of the immunosuppressant concentrations for at least 2 weeks is recommended when starting or stopping treatment with an efavirenz-containing drug.

Drugs/Diseases

Util A	Util B	Util C
Efavirenz/Lamivudine/Tenofovir	Cyclosporine	
	Tacrolimus	
	Sirolimus	
	Everolimus	

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Symfi Prescribing Information, March 2018, Mylan Specialty LP.

59. Efavirenz/Lamivudine/Tenofovir / CCBs that are CYP3A4 Substrates _____ _____

Alert Message: Concurrent use of Symfi (efavirenz/lamivudine/tenofovir disoproxil) with a calcium channel blocker (CCB) that is a CYP3A4 substrate can result in a decrease in the CCB plasma concentrations. The efavirenz component of the antiretroviral combination product is a CYP3A4 inducer. Dosage adjustment of the CCB may be necessary and should be guided by clinical response to the CCB.

Drugs/Diseases

Util A	Util B	Util C
Efavirenz/Lamivudine/Tenofovir	Diltiazem	
	Verapamil	
	Felodipine	
	Nicardipine	
	Nifedipine	
	Nimodipine	
	Nisoldipine	
	Amlodipine	
	Isradipine	

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Symfi Prescribing Information, March 2018, Mylan Specialty LP.

60. Efavirenz/Lamivudine/Tenofovir / Rifampin _____ _____

Alert Message: Caution is recommended when using Symfi (efavirenz/lamivudine/tenofovir disoproxil) with rifampin. Both rifampin and the efavirenz component of the antiretroviral are inducers and substrates of CYP3A4 metabolism. Coadministration use of these agents may result in decreased plasma concentrations of both drugs. Monitor the patient for loss of efficacy of efavirenz and rifampin.

Drugs/Diseases

Util A	Util B	Util C
Efavirenz/Lamivudine/Tenofovir	Rifampin	

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Symfi Prescribing Information, March 2018, Mylan Specialty LP.

61. Efavirenz/Lamivudine/Tenofovir / Atovaquone _____ _____

Alert Message: Concurrent use of Symfi (efavirenz/lamivudine/tenofovir disoproxil) with atovaquone is not recommended. Coadministration of these agents may cause a decrease in atovaquone plasma concentrations and result in the reduced efficacy of atovaquone.

Drugs/Diseases

Util A	Util B	Util C
Efavirenz/Lamivudine/Tenofovir	Atovaquone	

References:

Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Symfi Prescribing Information, March 2018, Mylan Specialty LP.

62. Efavirenz/Lamivudine/Tenofovir / Atovaquone-Proguanil _____ _____

Alert Message: Concurrent use of Symfi (efavirenz/lamivudine/tenofovir disoproxil) with atovaquone/proguanil is not recommended. Coadministration of these agents may cause a decrease in both the atovaquone and proguanil plasma concentrations and result in the reduced efficacy of the antimalarial product.

Drugs/Diseases

Util A	Util B	Util C
Efavirenz/Lamivudine/Tenofovir	Atovaquone-Proguanil	

References:

Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Symfi Prescribing Information, March 2018, Mylan Specialty LP.

63. Efavirenz/Lamivudine/Tenofovir / Nonadherence _____ _____

Alert Message: Based on the refill history, your patient may be underutilizing Symfi (efavirenz/lamivudine/tenofovir disoproxil). 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
Efavirenz/Lamivudine/Tenofovir		

References:

Symfi Prescribing Information, March 2018, Mylan Specialty LP.
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. Oct. 25, 2018.
Available at: http://www.aidsinfo.nih.gov/guidelines/ht,l/1/adult-and-adolescent-arv/0
Panel on Antiretroviral Therapy and Medical Management of Children Living with HIV. Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection. Sept. 12, 2019. Available at:
http://aidsinfo.nih.gov/contentfiles/lvguidelines/pe diatricguidelines.pdf

64. Entecavir / Overutilization – Nucleoside Inhibitor Naive _____ _____

Alert Message: Entecavir may be over-utilized. The recommended daily dose of entecavir for chronic hepatitis B virus infection in nucleoside inhibitor-treatment-naïve adults and adolescents 16 years of age and older is 0.5 mg once daily.

Drugs/Diseases

Util A	Util B	Util C **(Negate)**
Entecavir		Lamivudine

Max Dose: 0.5 mg/day
Age Range: 16 – 999 yoa

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Facts & Comparisons, 2019 Updates, Wolters Kluwer Health.
Baraclude Prescribing Information, Dec. 2018. Bristol-Myers Squibb.

65. Entecavir / Overutilization _____ _____

Alert Message: Entecavir may be over-utilized. The recommended daily dose of entecavir in adults and adolescents (at least 16 years of age) with a history of hepatitis B viremia while receiving lamivudine or known lamivudine or telbivudine resistance substitutions rtM204I/V with or without rtL180M, rtL80I/V, or rtV173L is 1 mg once daily.

Drugs/Diseases

Util A	Util B	Util C **(Include)**
Entecavir		Lamivudine

Max Dose: 1.0 mg/day
Age Range: 16 – 999 yoa

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

66. Entecavir / Overutilization – Decompensated Liver Disease _____ _____

Alert Message: Entecavir may be over-utilized. The recommended daily dose of entecavir for chronic hepatitis B virus infection in adults with decompensated liver disease is 1.0 mg once daily.

Drugs/Diseases

Util A	Util B	Util C **(Include)**
Entecavir		Jaundice
		Ascites
		Variceal Hemorrhage
		Hepatic Failure

Max Dose: 1.0 mg/day

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

67. Entecavir / Overutilization – Renal Impairment _____ _____

Alert Message: Entecavir may be over-utilized. In adult subjects with renal impairment, the apparent oral clearance of entecavir decreased as creatinine clearance decreased. Dosage adjustment of entecavir is recommended for patients with creatinine clearance less than 50 mL/min, including patients on hemodialysis or continuous ambulatory peritoneal dialysis (CAPD). Please refer to the official prescribing information for the recommended entecavir dosage adjustment.

Drugs/Diseases

Util A	Util B	Util C **(Include)**
Entecavir		CKD Stage 4
		CDK Stage 5
		ESRD
		Hemodialysis

Max Dose: 0.5 mg/day

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

68. Entecavir / Nonadherence _____ _____

Alert Message: Based on the refill history, your patient may be under-utilizing entecavir. Nonadherence to antiviral therapy may result in insufficient plasma levels and partial suppression of viral load leading to the loss of antiviral efficacy.

Drugs/Diseases

Util A	Util B	Util C
Entecavir		

References:
Osterberg L, Blaschke T. Adherence to Medication. N Engl J Med. 2005; 353(5):487–497.
Lieveld FI, van Vlerken LG, Siersena PD, van Erpecum KJ. Patient Adherence to Antiviral Treatment for Chronic Hepatitis B and C: A Systemic Review. Ann Hepatol. 2013 May-June;12(3):380-391.
Ford N, Scourse R, Lemoine M, et al., Adherence to Nucleoside Analogue Therapies for Chronic Hepatitis B Infection: A Systemic Review and Meta-Analysis. Hepatol Commun. 2018 Sep 25;2(10):11670-1167.

69. Entecavir / Therapeutic Appropriateness _____ _____

Alert Message: The safety and effectiveness of entecavir have not been established in pediatric patients less than 2 years of age.

Drugs/Diseases

Util A	Util B	Util C
Entecavir		

Age Range: 0 – 1 yoa

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

70. Entecavir / Drugs That Reduce Renal Function or Compete for ATS _____ _____

Alert Message: Since entecavir is primarily eliminated by the kidneys, coadministration of entecavir with drugs that reduce renal function or compete for active tubular secretion may increase serum concentrations of either entecavir or the coadministered drug. The effects of coadministration of entecavir with other drugs that are renally eliminated or are known to affect renal function have not been evaluated, and patients should be monitored closely for adverse events when entecavir is coadministered with such drugs.

Drugs/Diseases

Util A	Util B		Util C
Entecavir	Acyclovir	Morphine	
	Amiloride	NSAIDs	
	ACE Inhibitors	Pamidronate	
	Cimetidine	Procainamide	
	Cisplatin	Prochlorperazine	
	Cyclosporine	Ranitidine	
	Quinidine	Tacrolimus	
	Digoxin	Triamterene	
	Dofetilide	Trimethoprim	
	Memantine	Trospium	
	Foscarnet	Valacyclovir	
	Midodrine	Valganciclovir	
	Ketoconazole	Vancomycin	
	Megestrol	Zoledronic Acid	

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

71. Entecavir / Black Box Warning _____ _____

Alert Message: Lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, have been reported with the use of nucleoside analogue inhibitors, including entecavir, alone or in combination with antiretrovirals. Particular caution should be exercised when administering nucleoside analogue inhibitors to any patient with known risk factors for liver disease. Treatment with entecavir 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 **(Include)**
Entecavir		Lactic Acidosis
		Hepatomegaly

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

72. Entecavir / HIV / Antiretroviral Therapy _____ _____

Alert Message: Entecavir has not been evaluated in HIV/HBV co-infected patients who were not simultaneously receiving effective HIV treatment. Limited clinical experience suggests there is a potential for the development of resistance to HIV nucleoside reverse transcriptase inhibitors if entecavir is used to treat chronic hepatitis B virus infection in patients with HIV infection that is not being treated. Therefore, therapy with entecavir is not recommended for HIV/HBV co-infected patients who are not also receiving HAART.

Drugs/Diseases

Util A	Util B	Util C **(Negating)**
Entecavir	HIV	HAART

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

73. Tofacitinib / RA & PsA / Risk Factors for Thrombosis (Black Box) _____ _____

Alert Message: Avoid the use of tofacitinib (Xeljanz/Xeljanz XR) in patients that may be at increased risk of thrombosis. Thrombosis, including pulmonary embolism, deep venous thrombosis, and arterial thrombosis, was observed at an increased incidence in patients with rheumatoid arthritis 50 years of age and older with at least one CV risk factor treated with Xeljanz (tofacitinib) 10 mg twice daily compared to tofacitinib 5 mg twice daily or TNF blockers in a large, ongoing postmarketing study. Many of these events were serious, and some resulted in death.

Drugs/Diseases

Util A	Util B	Util C **(Include)**
Tofacitinib	Rheumatoid Arthritis	Hyperlipidemia
	Psoriatic Arthritis	Smoking
		Diabetes
		Hypertension
		Abdominal Obesity

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Facts & Comparisons, 2019 Wolters Kluwer Health.
Xeljanz/Xeljanz XR Prescribing Information, July 2019, Pfizer, Inc.
Xeljanz, Xeljanz XR (tofacitinib): Drug Safety Communication - Due to an Increased Risk of Blood Clots and Death with Higher Dose. [07/26/2019].

74. 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.
Duobrii Prescribing Information, April 2019, Bausch Health Companies Inc.

75. 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.
Duobrii Prescribing Information, April 2019, Bausch Health Companies Inc.

76. 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.
Duobrii Prescribing Information, April 2019, Bausch Health Companies Inc.

77. 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

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Duobrii Prescribing Information, April 2019, Bausch Health Companies Inc.

78. Buprenorphine Transdermal / CYP3A4 Inhibitors _____ _____

Alert Message: Concurrent use of Butrans (buprenorphine transdermal), a CYP3A4 substrate, with a CYP3A4 inhibitor can increase buprenorphine plasma concentrations resulting in prolonged opioid effects.

Drugs/Diseases

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

Reference:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Facts & Comparisons, 2019 Updates, Wolters Kluwer Health.
Butrans Prescribing Information, Sept. 2018, Endo Pharmaceuticals, Inc.

79. Apalutamide / Ischemic Heart Disease _____ _____

Alert Message: Ischemic cardiovascular events, including events leading to death, occurred in patients receiving Erleada (apalutamide). Monitor for signs and symptoms of ischemic heart disease. Optimize management of cardiovascular risk factors, such as hypertension, diabetes, or dyslipidemia. Consider discontinuation of apalutamide for Grade 3 and 4 events.

Drugs/Diseases

Util A	Util B	Util C
Apalutamide	Syncope	
	Dyspnea	
	Tachycardia	
	Bradycardia	
	Palpitations	
	Angina	

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Erleada Prescribing Information, Sept. 2019, Janssen Products.

80. Delafloxacin / Overutilization _____ _____

Alert Message: Baxdela (delafloxacin) may be over-utilized. The recommended maximum dosage of delafloxacin is 450 mg orally every 12 hours. The recommended duration of treatment is 5 to 14 days for acute bacterial skin and skin structure infections (ABSSSI) and 5 to 10 days for community-acquired bacterial pneumonia (CABP).

Drugs/Diseases

Util A	Util B	Util C
Delafloxacin		

Max Dose: 900 mg/day

References:
Baxdela Prescribing Information, Oct. 2019, Melinta Therapeutics, Inc.
Clinical Pharmacology, 2019 Elsevier/Gold Standard.

81. Delafloxacin / Therapeutic Appropriateness _____ _____

Alert Message: The use of Baxdela (delafloxacin) in patients with end-stage renal disease (ESRD) is not recommended. There is insufficient information to provide dosing recommendations in this patient population.

Drugs/Diseases

Util A	Util B	Util C
Delafloxacin	End-Stage Renal Disease	

References:
Baxdela Prescribing Information, Oct. 2019, Melinta Therapeutics, Inc.
Clinical Pharmacology, 2019 Elsevier/Gold Standard.

82. Delafloxacin / Therapeutic Appropriateness _____ _____

Alert Message: Fluoroquinolones have been associated with disabling and potentially irreversible serious adverse reactions that have occurred together, including; tendinitis and tendon rupture, peripheral neuropathy, and CNS effects. Discontinue Baxdela (delafloxacin) immediately and avoid the use of fluoroquinolones in patients who experience any of these adverse reactions.

Drugs/Diseases

Util A	Util B	Util C
Delafloxacin		

References:
Baxdela Prescribing Information, Oct. 2019, Melinta Therapeutics, Inc.
Clinical Pharmacology, 2019 Elsevier/Gold Standard.

83. 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.

84. Rizatriptan / Therapeutic Appropriateness _____ _____

Alert Message: 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.

85. Triptans / Cardiac & Cerebrovascular Contraindications _____ _____

Alert Message: Triptans are contraindicated in patients with ischemic heart disease, or previous myocardial infarction, stroke or coronary vasospasm (including Prinzmetal's angina) due to their vasoconstrictive effect. There have been reports of serious cardiovascular events, including death, associated with triptan use. Consider using a safer alternative in this patient.

Drugs/Diseases

Util A	Util B	Util C **(Include)**
Almotriptan		Myocardial Infraction
Eletriptan		Ischemic Heart Disease
Frovatriptan		Angina
Naratriptan		Arrhythmias
Rizatriptan		Transient Ischemic Attack
Sumatriptan		
Zolmitriptan		

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

86. Lorlatinib / Overutilization _____ _____

Alert Message: Lorbrena (lorlatinib) may be over-utilized. The recommended dosage of lorlatinib is 100 mg orally once daily.

Drugs/Diseases

Util A	Util B	Util C
Lorlatinib		

Max Dose: 100 mg/day

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Lorbrena Prescribing Information, Nov. 2018, Pfizer, Inc.

87. Lorlatinib / Strong CYP3A Inducers _____ _____

Alert Message: Lorbrena (lorlatinib), a CYP3A4 substrate, is contraindicated in patients taking strong CYP3A inducers. Concurrent use of these agents may result in serious hepatotoxicity, as well as decreased lorlatinib plasma concentrations. Discontinue strong CYP3A inducers for 3 plasma half-lives of the strong CYP3A4 inducer prior to initiating lorlatinib.

Drugs/Diseases

Util A	Util B	Util C
Lorlatinib	Carbamazepine	Apalutamide
	Phenytoin	Enzalutamide
	Phenobarbital	Lumacaftor/Ivacaftor
	Primidone	
	Rifampin	
	Mitotane	

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Lorbrena Prescribing Information, Nov. 2018, Pfizer, Inc.

88. Lorlatinib / Moderate CYP3A Inducers _____ _____

Alert Message: The concurrent use of Lorbrena (lorlatinib) with moderate CYP3A inducers should be avoided. If concomitant use of moderate CYP3A inducers cannot be avoided, monitor AST, ALT, and bilirubin 48 hours after initiating lorlatinib and at least 3 times during the first week after initiating lorlatinib.

Drugs/Diseases

Util A	Util B		Util C
Lorlatinib	Bosentan	Butalbital	
	Efavirenz		
	Etravirine		
	Modafinil		

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Lorbrena Prescribing Information, Nov. 2018, Pfizer, Inc.

89. Lorlatinib / Therapeutic Appropriateness _____ _____

Alert Message: Advise female patients of reproductive potential to use effective non-hormonal contraception during treatment with Lorbrena (lorlatinib) and for at least 6 months after the final dose. Also advise females of reproductive potential to use a non-hormonal method of contraception, because lorlatinib can render hormonal contraceptives ineffective.

Drugs/Diseases

Util A	Util B	Util C
Lorlatinib		

Gender: Female
Age Range: 11 – 55 yoa

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Lorbrena Prescribing Information, Nov. 2018, Pfizer, Inc.

90. Lorlatinib / Pregnancy / Pregnancy Negating _____ _____

Alert Message: Based on findings from animal studies and its mechanism of action, Lorbrena (lorlatinib) can cause embryo-fetal harm when administered to a pregnant woman. There are no available data on lorlatinib use in pregnant women. Advise a pregnant woman of the potential risk to a fetus.

Drugs/Diseases

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

Gender: Female
Age Range: 11 – 55 yoa

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Lorbrena Prescribing Information, Nov. 2018, Pfizer, Inc.

91. Lorlatinib / Therapeutic Appropriateness _____ _____

Alert Message: Based on genotoxicity findings, advise males with female partners of reproductive potential to use effective non-hormonal contraception during treatment with Lorbrena (lorlatinib) and for at least 3 months after the final dose.

Drugs/Diseases

Util A	Util B	Util C
Lorlatinib		

Gender: Male

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Lorbrena Prescribing Information, Nov. 2018, Pfizer, Inc.

92. Lorlatinib / Therapeutic Appropriateness _____ _____

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

Drugs/Diseases

Util A	Util B	Util C
Lorlatinib		

Age Range: 0 - 17 yoa

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Lorbrena Prescribing Information, Nov. 2018, Pfizer, Inc.

93. Lorlatinib / Interstitial Lung Disease _____ _____

Alert Message: Lorbrena (lorlatinib) can cause interstitial lung disease (ILD)/pneumonitis. Promptly investigate for ILD/pneumonitis in any patient who presents with worsening of respiratory symptoms indicative of ILD/pneumonitis (e.g., dyspnea, cough, and fever). Immediately withhold lorlatinib in patients with suspected ILD/pneumonitis. Permanently discontinue lorlatinib for treatment-related ILD/pneumonitis of any severity.

Drugs/Diseases

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

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Lorbrena Prescribing Information, Nov. 2018, Pfizer, Inc.

94. Lorlatinib / Atrioventricular Block _____ _____

Alert Message: PR interval prolongation and atrioventricular (AV) block can occur in patients receiving Lorbrena (lorlatinib). Monitor ECG prior to initiating lorlatinib and periodically thereafter. Withhold and resume at a reduced dose or at the same dose in patients who undergo pacemaker placement. Permanently discontinue lorlatinib for recurrence in patients without a pacemaker.

Drugs/Diseases

Util A	Util B	Util C
Lorlatinib	Atrioventricular Block	

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Lorbrena Prescribing Information, Nov. 2018, Pfizer, Inc.

95. Lorlatinib / Strong CYP3A Inhibitors _____ _____

Alert Message: The concurrent use of Lorbrena (lorlatinib) with strong CYP3A inhibitors should be avoided. Concomitant use of these drugs may result in increased lorlatinib plasma concentrations. If concomitant use with a strong CYP3A inhibitor cannot be avoided, reduce the starting dose of lorlatinib according to the official prescribing information. If concomitant use of a strong CYP3A inhibitor is discontinued, increase the lorlatinib dose (after 3 plasma half-lives of the strong CYP3A inhibitor) to the dose that was used before starting the strong inhibitor.

Drugs/Diseases

Util A	Util B		Util C
Lorlatinib	Nefazodone	Cobicistat	
	Clarithromycin	Saquinavir	
	Ketoconazole	Ritonavir	
	Itraconazole	Indinavir	
	Voriconazole	Saquinavir	
	Itraconazole		

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Lorbrena Prescribing Information, Nov. 2018, Pfizer, Inc.

96. Lorlatinib / CYP3A Substrates _____ _____

Alert Message: Lorbrena (lorlatinib) is a CYP3A4 inducer, and concurrent use with a drug that is a CYP3A4 substrate can result in a decrease in the concentration of the CYP3A substrate. Avoid concomitant use of lorlatinib with CYP3A substrates, where minimal concentration changes may lead to serious therapeutic failures. If concomitant use is unavoidable, increase the CYP3A substrate dosage in accordance with approved product labeling.

Drugs/Diseases

Util A	Util B	Util C
Lorlatinib	Estrogens	
	Oxycodone	
	Tramadol	
	Hydrocodone	
	Amlodipine	
	Amiodarone	
	Avanafil	
	Codeine	
	Dihydrocodeine	
	Diltiazem	
	Doravirine	
	Elbasvir/Grazoprevir	
	Elvitegravir	

References:
Clinical Pharmacology, 2019 Elsevier/Gold Standard
Lorbrena Prescribing Information, Nov. 2018, Pfizer, Inc.

97. Lorlatinib / Hyperlipidemia _____ _____

Alert Message: Increases in serum cholesterol and triglycerides can occur in patients receiving Lorbrena (lorlatinib). Initiate or increase the dose of lipid-lowering agents in patients with hyperlipidemia. Monitor serum cholesterol and triglycerides before initiating lorlatinib, 1 and 2 months after initiating lorlatinib, and periodically thereafter. Withhold and resume at the same dose for the first occurrence; resume at the same or a reduced dose of lorlatinib for recurrence based on severity.

Drugs/Diseases

Util A	Util B	Util C
Lorlatinib	Hyperlipidemia	
	Hypertriglyceridemia	

References:

Clinical Pharmacology, 2019 Elsevier/Gold Standard.
Lorbrena Prescribing Information, Nov. 2018, Pfizer, Inc.