DUR Board Meeting
March 7, 2018
Heritage Center
Lecture Rooms A & B

north dakota
department of
human services

North Dakota Medicaid
DUR Board Meeting Agenda
Brynhild Haugland Room
State Capitol
600 East Boulevard Avenue
Bismarck, ND
March 7, 2018
1:00 pm

1. Administrative items
    - Travel vouchers

2. Old business
    - Review and approval of 12/17 meeting minutes
    - Budget update
    - Review top 15 therapeutic categories/top 25 drugs
    - Prior authorization/PDL update
    - Second review of Skelaxin
    - Second review of Eucrisa
    - Review of first fill of narcotics

3. New business
    - Review of Anzemet and Zuplenz
    - Review of biosimilar agents
    - Review of Dupixent
    - Review of Duzallo
    - Review of Gocovri
    - Review of Tussicaps
    - Review of topical corticosteroid agents
    - Review of codeine and tramadol utilization
    - Review of Adderall utilization
    - Review of Proton Pump Inhibitor utilization
    - Criteria recommendations
    - Upcoming meeting date/agenda. Next meeting is June 6, 2018 in the Sakakawea Room

4. Adjourn

Please remember to silence all cellular phones during the meeting.

Drug Utilization Review (DUR) Meeting Minutes

December 6, 2017

Members Present: Wendy Brown, Tanya Schmidt, Laura Schield, Michael Quast, Zach Marty, LeNeika Roehrich, Andrea Honeyman, Carlotta McCleary, Peter Woodrow, Michael Booth

Members Absent: Gaylord Kavlie, Katie Kram, Jeffrey Hostetter, Russ Sobotta

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

Old Business

Chair W. Brown called the meeting to order at 1:04 p.m. Chair W. Brown asked for a motion to approve the minutes of the September meeting. T. Schmidt moved that the minutes be approved and A. Honeyman seconded the motion. Chair W. Brown called for a voice vote to approve the minutes. The motion passed with no audible dissent.

Announcements

A. Murphy informed the board of new functionalities in the MMIS claims system that allow for a diagnosis field to be used during claims processing, as well as the ability for the system to automatically scan for concurrent medications. The board was informed that these new functionalities have since been utilized to create edits to check for diagnoses and/or concurrent medications for a select few medication classes such as stimulants and SGLT-2 inhibitors. The board was further informed that additional edits will be implemented in the future for medications on the Preferred Drug List that only require concurrent therapy and/or FDA approved diagnoses. A. Murphy also informed the board that a class review of topical corticosteroids would be presented at the next DUR board meeting to later designate prior authorization criteria for this class of medications.

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 2017.

PDL Update

A. Murphy shared with the Board all of changes made to the Preferred Drug List since the most recent 2017 version of the Preferred Drug List was posted. A total of twenty-one medications were added to the list of PDL medications requiring prior authorization and Moviprep will no longer require prior authorization. Kymriah, Parsabiv, Renflexis, and Xiaflex were added to the Medical Billing Only list of medications.

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. L. Schield spoke to difficulties with navigating the website used to house the forms, criteria, and Preferred Drug List. T. DeRuiter and A. Murphy agreed to provide consolidated,

searchable criteria and review potential ways the website can be restructured to simplify navigation. No changes were recommended during the review of the forms and criteria.

New Business

Discussion on Opioid and Benzodiazepine Abuse and Overdose Diagnoses

A. Murphy and B. Joyce presented statistics on opioid, benzo, heroin, and other psychotropic drug overdoses in the North Dakota Medicaid population during 2017. A. Murphy and B. Joyce presented recommended claims processing edits that could be put into place to try to reduce overdoses of benzodiazepines and opioids in the North Dakota Medicaid population, as well as a step-wise approach in which the edits could be implemented. The board agreed that the presented edits would be beneficial.

Emflaza

B. Joyce briefly discussed Emflaza with the board for the purpose of removing it from the PA criteria for medications >$3,000 to have its own separate criteria. A motion was made by P. Woodrow to manage the medication separately through prior authorization. The motion was seconded by L. Schield.

Skelaxin

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

Eucrisa

T. DeRuiter and B. Joyce reviewed Eucrisa with the Board. A motion was made by M. Quast to manage the medication through prior authorization. The motion was seconded by L. Roehrich. This topic will be reviewed at the next meeting

Criteria Recommendations

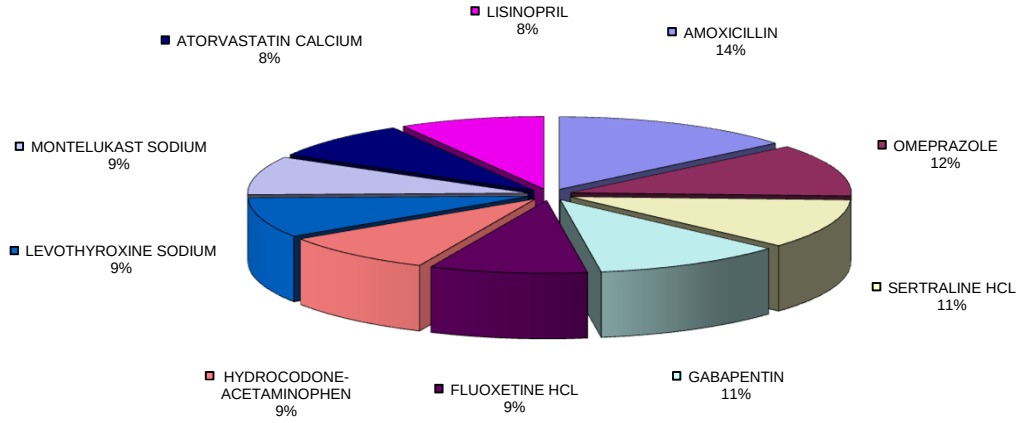
The recommended RDUR criteria enclosed in the packet were developed from product information provided by the manufacturers and are usually consistent with new indications, new drugs added, and new warnings. These proposed criteria will be added to the current set of criteria and will be used in future DUR cycles. L. Roehrich moved to approve the new criteria and T. Schmidt seconded the motion. The motion passed with no audible dissent. The next DUR Board meeting will be held March 7, 2018 at the Capitol in the Brynhild Haugland room in Bismarck. W. Brown adjourned the meeting.

TOP 25 DRUGS BASED ON NUMBER OF CLAIMS FROM 10/01/2017 - 12/31/2017

Drug	AHFS Therapeutic Class	Rx	Paid	Paid/Rx	% Total Claims
AMOXICILLIN	PENICILLINS	3,341	$ 114,852.65	$ 34.38	2.22%
OMEPRAZOLE	PROTON-PUMP INHIBITORS	2,779	$ 53,085.31	$ 19.10	1.85%
SERTRALINE HCL	ANTIDEPRESSANTS	2,619	$ 49,560.47	$ 18.92	1.74%
GABAPENTIN	ANTICONVULSANTS, MISCELLANEOUS	2,612	$ 80,446.91	$ 30.80	1.74%
FLUOXETINE HCL	ANTIDEPRESSANTS	2,162	$ 37,299.26	$ 17.25	1.44%
HYDROCODONE-ACETAMINOPHEN	OPIATE AGONISTS	2,141	$ 60,531.33	$ 28.27	1.43%
LEVOTHYROXINE SODIUM	THYROID AGENTS	2,124	$ 42,517.45	$ 20.02	1.41%
MONTELUKAST SODIUM	LEUKOTRIENE MODIFIERS	2,036	$ 35,908.21	$ 17.64	1.36%
ATORVASTATIN CALCIUM	HMG-COA REDUCTASE INHIBITORS	2,005	$ 53,508.41	$ 26.69	1.33%
LISINOPRIL	ANGIOTENSIN-CONVERTING ENZYME INHIBITORS	1,992	$ 41,411.53	$ 20.79	1.33%
TRAZODONE HCL	ANTIDEPRESSANTS	1,891	$ 28,147.94	$ 14.89	1.26%
METHYLPHENIDATE ER	RESPIRATORY AND CNS STIMULANTS	1,806	$ 337,902.25	$ 187.10	1.20%
AZITHROMYCIN	MACROLIDES	1,645	$ 40,607.29	$ 24.69	1.09%
CLONIDINE HCL	CENTRAL ALPHA-AGONISTS	1,638	$ 28,606.08	$ 17.46	1.09%
VYVANSE	AMPHETAMINES	1,549	$ 320,058.64	$ 206.62	1.03%
ESCITALOPRAM OXALATE	ANTIDEPRESSANTS	1,514	$ 28,020.71	$ 18.51	1.01%
METFORMIN HCL	BIGUANIDES	1,506	$ 24,192.11	$ 16.06	1.00%
PROAIR HFA	BETA-ADRENERGIC AGONISTS	1,457	$ 110,467.65	$ 75.82	0.97%
ALBUTEROL SULFATE	BETA-ADRENERGIC AGONISTS	1,433	$ 57,900.01	$ 40.40	0.95%
AMOXICILLIN-CLAVULANATE POTASS	PENICILLINS	1,401	$ 49,903.02	$ 35.62	0.93%
BUPROPION XL	ANTIDEPRESSANTS	1,382	$ 33,022.56	$ 23.89	0.92%
RISPERIDONE	ANTIPSYCHOTIC AGENTS	1,365	$ 19,946.47	$ 14.61	0.91%
QUETIAPINE FUMARATE	ANTIPSYCHOTIC AGENTS	1,328	$ 23,806.33	$ 17.93	0.88%
IBUPROFEN	NONSTEROIDAL ANTI-INFLAMMATORY AGENTS	1,309	$ 50,581.30	$ 38.64	0.87%
CLONAZEPAM	BENZODIAZEPINES (ANTICONVULSANTS)	1,268	$ 27,050.53	$ 21.33	0.84%
TOTAL TOP 25		46,303	$ 1,749,334.42	$ 37.78	30.82%

Total Rx Claims From 10/01/2017 - 12/31/2017	150,244

Top 10 Drugs
Based on Number of Claims

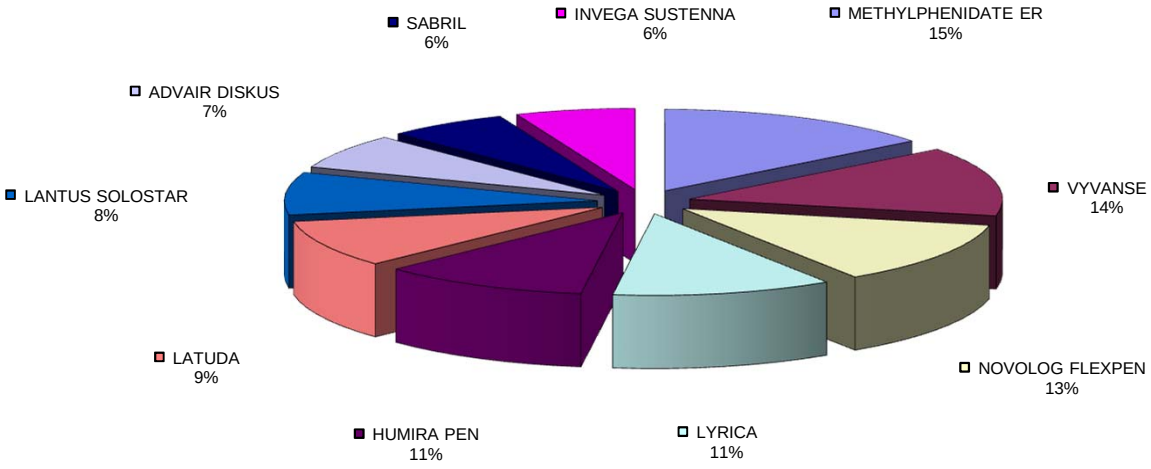


TOP 25 DRUGS BASED ON TOTAL CLAIMS COST FROM 10/01/2017 - 12/31/2017

Drug	AHFS Therapeutic Class	Rx	Paid	Paid/Rx	% Total Claims
METHYLPHENIDATE ER	RESPIRATORY AND CNS STIMULANTS	1,806	$ 337,902.25	$ 187.10	1.20%
VYVANSE	AMPHETAMINES	1,549	$ 320,058.64	$ 206.62	1.03%
NOVOLOG FLEXPEN	INSULINS	570	$ 290,514.63	$ 509.67	0.38%
LYRICA	ANTICONVULSANTS, MISCELLANEOUS	625	$ 264,636.83	$ 423.42	0.42%
HUMIRA PEN	DISEASE-MODIFYING ANTIRHEUMATIC AGENTS	56	$ 249,889.77	$ 4,462.32	0.04%
LATUDA	ANTIPSYCHOTIC AGENTS	305	$ 217,323.81	$ 712.54	0.20%
LANTUS SOLOSTAR	INSULINS	505	$ 196,161.64	$ 388.44	0.34%
ADVAIR DISKUS	CORTICOSTEROIDS (RESPIRATORY TRACT)	502	$ 161,082.55	$ 320.88	0.33%
SABRIL	ANTICONVULSANTS, MISCELLANEOUS	8	$ 145,563.63	$ 18,195.45	0.01%
INVEGA SUSTENNA	ANTIPSYCHOTIC AGENTS	82	$ 143,894.77	$ 1,754.81	0.05%
VIMPAT	ANTICONVULSANTS, MISCELLANEOUS	210	$ 121,908.15	$ 580.52	0.14%
AMOXICILLIN	PENICILLINS	3,341	$ 114,852.65	$ 34.38	2.22%
NORDITROPIN FLEXPRO	PITUITARY	31	$ 113,280.07	$ 3,654.20	0.02%
PROAIR HFA	BETA-ADRENERGIC AGONISTS	1,457	$ 110,467.65	$ 75.82	0.97%
ONFI	BENZODIAZEPINES (ANTICONVULSANTS)	104	$ 110,391.06	$ 1,061.45	0.07%
LEVEMIR FLEXTOUCH	INSULINS	365	$ 109,925.83	$ 301.17	0.24%
LICE KILLING	SCABICIDES AND PEDICULICIDES	282	$ 109,089.00	$ 386.84	0.19%
ADDERALL XR	AMPHETAMINES	587	$ 108,621.40	$ 185.04	0.39%
GILENYA	IMMUNOMODULATORY AGENTS	14	$ 99,725.15	$ 7,123.23	0.01%
NIX	SCABICIDES AND PEDICULICIDES	274	$ 97,691.44	$ 356.54	0.18%
SYMBICORT	CORTICOSTEROIDS (RESPIRATORY TRACT)	340	$ 96,782.40	$ 284.65	0.23%
COPAXONE	IMMUNOMODULATORY AGENTS	14	$ 95,839.36	$ 6,845.67	0.01%
SPIRIVA	ANTIMUSCARINICS/ANTISPASMODICS	300	$ 93,240.17	$ 310.80	0.20%
FOCALIN XR	RESPIRATORY AND CNS STIMULANTS	282	$ 83,312.02	$ 295.43	0.19%
GABAPENTIN	ANTICONVULSANTS, MISCELLANEOUS	2,612	$ 80,446.91	$ 30.80	1.74%
TOTAL TOP 25		16,221	$ 3,872,601.78	$ 238.74	10.80%

Total Rx Claims From 10/01/2017 - 12/31/2017	150,244

Top 10 Drugs
Based on Total Claims Cost



Prior Authorization/PDL Update

Criteria update
Hepatitis C

Added to PA	Category
DUZALLO	antihyperuricemic
NITYR	>3000
XHANCE	nasal steroid
PREVYMIS	>3000
OZEMPIC	GLP-1
XIMINO	Acne
BYDUREON BCISE	GLP-1 Agonist
QTERN	DPP-4 Inhibitor/SGLT2 Inhibtor
TRACLEER	Pulmonary Hypertension
REBINYN	Antihemophilia
HEMLIBRA	Antihemophilia
BEVYXXA	Oral Anticoagulant
ADMELOG	Insulin
ADMELOG SOLOSTAR	Insulin
STEGLATRO	SGLT2 Inhibtor
STEGLUJAN	DPP-4 Inhibitor/SGLT2 Inhibtor
ODACTRA	Allergenic Extracts
TOLMETIN SODIUM	NSAIDs
PIROXICAM	NSAIDs
ETODOLAC	NSAIDs
ETODOLAC ER	NSAIDs
DICLOFENAC SODIUM	NSAIDs
DICLOFENAC SODIUM ER	NSAIDs
DICLOFENAC POTASSIUM	NSAIDs
SUBLOCADE	buprenorphine

Removed from PA	Category
Naltrexone	Naltrexone
Alteplase	Alteplase
Pradaxa	Oral Anticoagulants
Xarelto	Oral Anticoagulants
Eliquis	Oral Anticoagulants
Savaysa	Oral Anticoagulants

Spiriva	COPD
Performoist	COPD
Anoro Ellilpta	COPD
Bevespi Aerosphere	COPD
Victoza	GLP-1 Agonists
Cosentyx	Immunomodulators
Enbrel	Immunomodulators
Humira	Immunomodulators
Androderm	Androgens
Androgel	Androgens
Adempas	PAH
Traceer	PAH
Orenitram ER	PAH
Ventavis 10 mg/ml	PAH
Pegasys	Hep C Interferon
Pegintron	Hep C Interferon
Sylatron	Hep C Interferon
Marinol	Dronabinol
Provigil	Provigil/Nuvigil
Arcalyst	>$3000
Benlysta	>$3000
Buphenyl	>$3000
Carbaglu	>$3000
Cerdelga	>$3000
Chenodal	>$3000
Cholbam	>$3000
Cuprimine	>$3000
Daraprim	>$3000
Esbriet	>$3000
Ilaris	>$3000
Keveyis	>$3000
Korlym	>$3000
Natpara	>$3000
Nityr	>$3000
Ocaliva	>$3000
Orfadin	>$3000
Orkambi	>$3000
Phenoxybenzamine Hcl	>$3000
Promacta	>$3000
Ravicti	>$3000

Samsca	>$3000
Somavert	>$3000
Strensiq	>$3000
Zavesca	>$3000

Bill Medical Side VIA 837I AND 837P TRANSACTIONS
ACTEMRA
ADASUVE
ARTISS
CINVANTI
FLOLAN
JETREA
KENGREAL
LEXTURNA
MEPSEVII
PREVYMIS
PROLASTIN C
QUTENZA
RADICAVA
SIMPONI ARIA
SOLIRIS
VARUBI
VELETRI
YESCARTA
ZILRETTA

North Dakota Department of Human Services
Skelaxin Prior Authorization Criteria

Initial and Renewal Requests: All requests are limited to a 3 month approval

- Patient must have had two 30-day trials of other skeletal muscle relaxants, one of which must be methocarbamol, as evidenced by paid claims or pharmacy print-outs.

health information designs

Skelaxin
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 Skelaxin must meet the following criteria:

- **Patient must have had two 30-day trials of other skeletal muscle relaxants, one of which must be methocarbamol, as evidenced by paid claims or pharmacy print-outs.**

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: □ SKELAXIN	**Diagnosis for this request:**

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

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

Prescriber (or Staff) / Pharmacy Signature**	Date

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

Part II: TO BE COMPLETED BY PHARMACY

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

North Dakota Department of Human Services
Eucrisa Prior Authorization Criteria

Initial Requests: Limited to 3 month approval

- Patient must have a diagnosis of a FDA-approved indication for use of Eucrisa
- Patient must have had a 6-week trial of at least one of the following, as evidenced by paid claims or pharmacy print-outs:
    - 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 print-outs.
    B. Patient must meet both of the following (1 and 2):
        1. Affected area is be on face, groin, axilla, or under occlusion OR patient is under 12 years of age
        2. Patient must have had two 2-week trials of topical corticosteroids of low or higher potency, as evidenced by paid claims or pharmacy print-outs.

Renewal Requests: Limited to 3 month approval

- Documentation from the prescriber must be provided showing that the patient has achieved a significant reduction in severity of atopic dermatitis.

health information designs

Eucrisa
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 Eucrisa must meet the following criteria:

Initial Requests:

- Patient must have an FDA-approved diagnosis for use
- Patient must have had a 6-week trial of at least one of the following: 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.
  - B. Patient must meet both of the following (1 and 2):
    1. Affected area is be on face, groin, axilla, or under occlusion OR patient is under 12 years of age
    2. Patient must have had two 2-week trials of topical corticosteroids of low or higher potency.

Renewal Requests:

- Documentation from the prescriber must be provided showing that the patient has achieved a significant reduction in severity of atopic dermatitis (please attach documentation to this request)

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: □ EUCRISA	**Diagnosis for this request:**	**Is the affected area is on the face, groin, axilla, or under occlusion?** □ YES □ NO

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

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

Prescriber (or Staff) / Pharmacy Signature**	Date

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

Part II: TO BE COMPLETED BY PHARMACY

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

State	Lookback	Day Supply limit	Cumulative Limits	Limits on Rx	Exceptions
Arizona	60 days	5 days			cancer, hospice, palliative, end-of-life, children weaning post hospitalization, skilled nursing facility care, traumatic injury post surgical 14 days
Arkansas	60 days	7 days		50 MME/day	cancer
Colorado	365 days	7 days (for first 3 fills), 4th requires PA			Palliative care
Florida		7 days			excluding sickle cell, cancer, chronic non-malignant pain
Kansas		7 days, as of May 2018			
Missouri	90 days	7 days	60 days out of 90 days	50 MME/day (plan for March/April 18)	
Nevada	45 days	7 days	Total of 13 seven day prescriptions in rolling 12 month period	60 MME/day	cancer, post surgical with anticipated recovery longer than 3 months, palliative care, HIV/AIDS, residing in LTC facility, Rxs written by pain specialist
Ohio		7 days	no more than 14 days of therapy in rolling 45 d	60 MED/Rx	
Pennsylvania		3 days or more than 1 RX in 365 days for children 5 days or more than 1 RX in 180 days for adults		50 MME/day	excluding sickle cell, cancer, palliative care
Tennessee	180 days	5 days	After first fill, up to 10 additional days at 40 MME/day in each 180 day period	40MME/day	
Utah	60 days	7 days			
Virginia		7 days	2 seven day supplys in 60 day period	120 MME/day cumulative opioids	post op 14 days
Washington			Provider must attest to follow best practices for chronic use after 6 weeks	42 pills for 21 and older 18 pills for 20 and younger	

PRODUCT DETAILS OF Anzemet (dolasetron)

INDICATIONS AND USE:

- Anzemet is a selective serotonin receptor (5-HT3) antagonist, indicated for the prevention of nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy in adults and children 2 years and older

DOSAGE AND ADMINISTRATION:

- Max dose is 100 mg
    - Adult Dosing:
        - 100 mg given within 1 hour before chemotherapy
    - Pediatric Dosing:
        - 1.8 mg/kg given within 1 hour before chemotherapy

DOSAGE FORM AND STRENGTHS:

- 50 and 100 mg tablets

CONTRAINDICATIONS:

- Hypersensitivity to dolasetron or any component of the formulation

WARNINGS AND PRECAUTIONS:

- Dose-dependent QT interval prolongation: Avoid in patients with congenital long QT syndrome, hypomagnesemia, or hypokalemia. Hypokalemia and hypomagnesemia must be corrected prior to administration.
- **Dose-dependent PR and QRS interval prolongation**: Patients with underlying structural heart disease and preexisting conduction system abnormalities or patients receiving drugs known to prolong the PR interval and QRS interval at high risk. Avoid in patients with complete heart block or at risk for complete heart block, unless they have an implanted pacemaker.
- Serotonin syndrome: 5-HT3 receptor antagonists are known to cause serotonin syndrome, particularly when used in combination with other serotonergic agents.

ADVERSE REACTIONS:

- Headache (18-23%)
- Cardiovascular: Bradycardia (4% to 5%), tachycardia (≤3%)
- Central nervous system: Fatigue (3-6%), dizziness (1-6%), pain (≤3%)
- Gastrointestinal: Diarrhea (2-5%), dyspepsia (≤3%)

DRUG INTERACTIONS

- Drugs that prolong the QTc interval (e.g. quetiapine, clozapine, amitriptyline, doxepin)
- Serotonergic modulators (e.g. SSRIs, SNRIs, tramadol, TCAs, Triptans).

COST

Drug	Strength	Package Size	WAC Pkg Price	AWP Unit Price
Anzemet Tablet	50 mg	5 tabs	360.27	86.46
Anzemet Tablet	100 mg	5 tabs	477.53	114.61
Anzemet IV sln	20 mg/1 ml	6s (0.625 mL)	140.89	45.09
Anzemet IV sln	20 mg/1 ml	25 mL	293.13	14.07
Anzemet IV sln	20 mg/1 ml	5 mL	58.63	14.07

CURRENT UTILIZATION

ND Medicaid Anzemet Utilization (10/2017 – 12/2017)		
Label Name	**Rx Num**	**Total Reimb Amt**
ANZEMET	0	N/A

REFERENCES:

1. Facts & Comparisons eAnswers. Available at http://online.factsandcomparisons.com. Accessed on February 10. 2018.
2. Anzemet (dolasetron) tablets [prescribing information]. Bridgewater, NJ: Sanofi-Aventis; June 2016.

OVERVIEW OF BIOSIMILAR PRODUCTS

BIOSIMILAR DEFINITION

- The biological product is **highly similar** to the reference product notwithstanding minor differences in clinically inactive components
    - Extensively analyzing the structure and function of both the reference product and the proposed biosimilar (purity, chemical identity, and bioactivity)
    - Minor differences between the reference product and the proposed biosimilar product in clinically inactive components are acceptable
- There are **no clinically meaningful differences** between the biological product and the reference product in terms of the safety, purity, and potency of the product.
    - Generally demonstrated through human and animal pharmacokinetic and pharmacodynamic studies, an assessment of clinical immunogenicity, and (if needed) additional clinical studies

Biosimilar Approval	Biosimilar Product	Original Product	Available
03/06/15	Zarxio (filgrastim-sndz)	Neupogen (filgrastim)	Yes
04/05/2016	Inflectra (infliximab-dyyb)	Remicade (infliximab)	Yes
08/30/2016	Erelzi (etanercept-szzs)	Enbrel (etanercept)	No
09/23/2016	Amjevita (adalimumab-atto)	Humira (adalimumab)	No
04/21/2017	Renflexis (infliximab-abda)	Remicade (infliximab)	Yes
08/25/2017	Cyltezo (adalimumab-adbm)	Humira (adalimumab)	No
09/14/2017	Mvasi (bevacizumab-awwb)	Avastin (bevacizumab)	No
12/01/2017	Ogivri (trastuzumab-dkst)	Herceptin (trastuzumab)	No
12/13/2017	Ixifi (infliximab-qbtx)	Remicade (infliximab)	No

DIFFERENCES BETWEEN REFERENCE AND BIOSIMILAR & INTERCHANGABILITY

- Currently, no biosimilar products are deemed as “interchangeable” with their reference product
- An interchangeable product is a biosimilar product that meets additional requirements outlined by the Biologics Price Competition and Innovation Act
    - Must show that an interchangeable product is expected to produce the same clinical result as the reference product in any given patient
    - For products administered to a patient more than once, the risk in terms of safety and reduced efficacy of switching back and forth between an interchangeable product and a reference product will have been evaluated
    - An interchangeable product may be substituted for the reference product without the involvement of the prescriber
- Biosimilar agents do not necessarily carry all of the same FDA indications as their reference product
    - Sometimes have small but potentially significant differences in the wording of their indications compared to their reference product

Biosimilar	Original	Differences
Zarxio	Neupogen	Acute hematopoietic radiation injury syndrome (Neupogen only) Myelosuppressive chemotherapy recipients with nonmyeloid malignancies: • decrease the duration of severe neutropenia (Zarxio) • decrease the incidence of infection (Neupogen)
Inflectra, Ixifi, & Renflexis	Remicade	Ulcerative Colitis (Remicade only)
Erelzi	Enbrel	Treatment of patients 4 years and older (Enbrel) or 18 years and older (Erelzi) with chronic moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy
Amjevita & Cyltezo	Humira	Hidradenitis suppurativa (Humira only) Uveitis (Humira only)
Mvasi	Avastin	Glioblastoma, progressive (Mvasi) vs. Glioblastoma, recurrent (Avastin) Ovarian (epithelial), fallopian tube, or primary peritoneal cancer (Avastin only)

CURRENT UTILIZATION

ND Medicaid Biosimilar Utilization (10/2017-12/2017)		
Label Name	**Rx Num**	**Total Reimb Amt**
Zarxio	1	$2,769.06

REFERENCES:

1. Facts & Comparisons eAnswers. Available at http://online.factsandcomparisons.com. Accessed on February 10, 2018.
2. Cyltezo (adalimumab) [prescribing information]. Ridgefield, CT; Boehringer Ingelheim Pharmaceuticals Inc: August 2017.
3. Erelzi (etanercept) [prescribing information]. Princeton, NJ: Sandoz Inc; August 2016.
4. Inflectra (infliximab dyyb) [prescribing information]. New York, NY: Pfizer; November 2017.
5. Ixifi (infliximab-qbtx) [prescribing information]. New York, NY: Pfizer; December 2017.
6. Renflexis (infliximab) [prescribing information]. Kenilworth, NJ: Merck Sharp & Dohme; April 2017.
7. Granix (tbo-filgrastim) [prescribing information]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; June 2017.
8. Amjevita (adalimumab-atto) [prescribing information]. Thousand Oaks, CA: Amgen Inc; September 2016.
9. Mvasi (bevacizumab-awwb) [prescribing information]. Thousand Oaks, CA: Amgen Inc; September 2017.

PRODUCT DETAILS OF Dupixent (dupilumab)

INDICATIONS AND USE:

- Moderate to severe atopic dermatitis, not adequately controlled with topical therapies or when those therapies are inadvisable.
- Orphan drug designation: Treatment of short bowel syndrome

DOSAGE AND ADMINISTRATION:

- Adults
  - Initial: 600 mg subQ, divided in 2 different injection sites
  - Maintenance: 300 mg subQ every other week
- Pediatric
  - Safety and effectiveness have not been established

DOSAGE FORM AND STRENGTHS:

- 300 mg/2 mL prefilled syringe

CONTRAINDICATIONS:

- Hypersensitivity to the product or any component of the formulation

WARNINGS AND PRECAUTIONS:

- **Ocular effects**: Conjunctivitis and keratitis have been reported; report new onset or worsening eye symptoms to health care provider
- **Asthma**: Safety and efficacy have not been established in the treatment of asthma. Discontinuation or adjustment of asthma medications in patients with comorbid asthma should not be done without consulting health care provider
- **Appropriate use:** May be used in combination with or without topical corticosteroids. Topical calcineurin inhibitors may be used, but should be reserved for problem areas only (eg, face, neck intertriginous and genital areas)
- **Immunogenicity**: Dupilumab antibodies, including neutralizing antibodies, may develop (may be associated with lower serum dupilumab concentrations)

ADVERSE REACTIONS:

- Dermatologic: Herpes simplex infection (2%)
- Gastrointestinal: Oral herpes (4%)
- Immunologic: Antibody development (7%; neutralizing: 2%)
- Injection site reaction (10%)
- Ophthalmic: Conjunctivitis (10%), eye pruritus (1%)

DRUG INTERACTIONS

- Live Vaccines

COST

Drug	Strength	Package Size	WAC Pkg Price	AWP Unit Price
Dupixent sln	300 mg/2 ml	2 syr (2 mL)	2846.16	853.84750

CURRENT UTILIZATION

ND Medicaid Dupixent Utilization (10/2017 – 12/2017)		
Label Name	**Rx Num**	**Total Reimb Amt**
DUPIXENT	0	N/A

REFERENCES:

1. Facts & Comparisons eAnswers. Available at http://online.factsandcomparisons.com. Accessed on February 10, 2018.
2. Dupixent (dupilumab) [prescribing information]. Tarrytown, NY: Regeneron Pharmaceuticals; March 2017.

PRODUCT DETAILS OF DUZALLO (lesinurad/allopurinol)

INDICATIONS AND USE:

- Treatment of hyperuricemia associated with gout in patients who have not achieved target serum uric acid levels with a medically appropriate daily dose of allopurinol alone.

DOSAGE AND ADMINISTRATION:

- Max dose of lesinurad is 200 mg once daily
- Recommended dosing
    - ADULTS:
        - 1 tablet daily at an allopurinol dose equivalent to patient's current dose
    - PEDIATRIC:
        - Safety and efficacy have not been established

DOSAGE FORM AND STRENGTHS:

- lesinurad/allopurinol 200/200 mg and 200/300 mg tablets

CONTRAINDICATIONS:

- Hypersensitivity to the product or any component of the formulation
- Severe renal impairment (CrCl <30 mL/minute), ESRD, kidney transplant recipients, dialysis
- Tumor lysis syndrome
- Lesch-Nyhan syndrome

WARNINGS AND PRECAUTIONS:

- **Renal Impairment:** Lesinurad, when used concurrently with a xanthine oxidase inhibitor, is associated with an increased incidence of serum creatinine elevations and may cause renal failure or nephrolithiasis. Contraindicated if CrCl <30 mL/min and should be avoided if CrCl is <45 mL/min.
- **Cardiovascular events:** Major cardiac adverse events (cardiovascular deaths, nonfatal MI, or nonfatal strokes) were observed in clinical trials.
- **Secondary hyperuricemia:** Lesinurad has not been studied in patients with secondary hyperuricemia.
- **Gout flare:** Following initiation therapy. Use gout flare prophylaxis when initiating treatment.
- **CYP2C9 poor metabolizers:** Use with caution in CYP2C9 poor metabolizers and patients taking concomitant moderate CYP2C9 inhibitors.
- **Hepatotoxicity:** Cases of reversible hepatotoxicity (allopurinol). Asymptomatic elevations of serum alkaline phosphatase or AST and ALT have been observed.
- **Bone marrow suppression:** Bone marrow suppression (allopurinol)

ADVERSE REACTIONS:

- Increased serum creatinine (6%), ALT/AST increases
- Headache (5%)
- GERD (3%)
- Hypersensitivity (~3% rash, discontinue immediately)
- Gout flare (6%)

DRUG INTERACTIONS

- Vitamin K antagonists
- Moderate CYP2C9 inhibitors: use with caution
- Mercaptopurine and azathioprine: will require dose reductions (1/3-1/4 normal dose)

COST

Drug	Strength	Package Size	WAC Pkg Price	AWP Unit Price
Duzallo Tablet	300-200 mg	30 tablets	371.00	14.84
Duzallo Tablet	200-200 mg	30 tablets	371.00	14.84

CURRENT UTILIZATION

ND Medicaid Duzallo Utilization (10/2017 – 12/2017)		
Label Name	**Rx Num**	**Total Reimb Amt**
DUZALLO	0	N/A

REFERENCES:

1. Facts & Comparisons eAnswers. Available at http://online.factsandcomparisons.com. Accessed on February 10, 2018.
2. Duzallo (lesinurad and allopurinol) [prescribing information]. Cambridge, MA: Ironwood Pharmaceuticals, Inc; November 2017.

PRODUCT DETAILS OF GOCOVRI (amantadine ER)

INDICATIONS AND USE:

- Treatment of dyskinesia in patients with Parkinson disease receiving levodopa-based therapy, with or without concomitant dopaminergic medications.

DOSAGE AND ADMINISTRATION:

- Max dose of lesinurad is 200 mg once daily
- Recommended dosing
    - ADULTS:
        - 1 tablet daily at an allopurinol dose equivalent to what the patient is currently taking
    - PEDIATRIC:
        - Safety and efficacy have not been established

DOSAGE FORM AND STRENGTHS:

- 68.5 and 137 mg capsules

CONTRAINDICATIONS:

- Patients with ESRD

WARNINGS AND PRECAUTIONS:

- **Falling Asleep During Activities of Daily Living:** Advise patients prior to treatment; ordinarily discontinue if occurs.
- **Suicidality and Depression:** Monitor patients for depressed mood, depression, or suicidal ideation or behavior.
- **Hallucinations/Psychotic Behavior:** Patients with major psychotic disorder should ordinarily not be treated with GOCOVRI; observe patients for the occurrence of hallucinations throughout treatment, especially at initiation and after dose increases.
- **Dizziness and Orthostatic Hypotension:** Monitor patients for dizziness and orthostatic hypotension, especially after starting GOCOVRI or increasing the dose.
- **Withdrawal-Emergent Hyperpyrexia and Confusion:** Avoid sudden discontinuation.
- **Impulse Control/Compulsive Behaviors:** Ask patients about increased gambling urges, sexual urges, uncontrolled spending or other urges; consider dose reduction or discontinuation if occurs.

ADVERSE REACTIONS:

- Frequency of >10%
    - Hallucination, Dizziness
    - Dry mouth
    - Peripheral edema
    - Constipation
    - Fall, Orthostatic hypotension

DRUG INTERACTIONS

- **Other Anticholinergic Drugs:** Doses should be reduced if atropine-like effects occur.
- **Drugs Affecting Urinary pH:** Excretion increases with acidic urine; possible accumulation with urine change towards alkaline.
- **Live Attenuated Influenza Vaccines**: Not recommended during use.
- **Alcohol**: Concomitant use not recommended.

COST

Drug	Strength	Package Size	WAC Pkg Price	AWP Unit Price
Gocovri Caps	68.5 mg	60 caps	2375.00	47.50
Gocovri Caps	137 mg	60 caps	2375.00	47.50

CURRENT UTILIZATION

ND Medicaid Gocovri Utilization (10/2017 – 12/2017)		
Label Name	**Rx Num**	**Total Reimb Amt**
GOCOVRI	0	N/A

REFERENCES:

1. Facts & Comparisons eAnswers. Available at http://online.factsandcomparisons.com. Accessed on February 10, 2018.
2. Gocovri (amantadine hydrochloride extended-release) [prescribing information]. Emeryville, CA: Adams Pharma LLC; August 2017.

PRODUCT DETAILS OF TOPICAL CORTICOSTEROIDS

OVERVIEW

- Topical corticosteroids are anti-inflammatory agents approved for the treatment of inflammatory and pruritic manifestations of dermatoses.
    - Preferred in many cases to minimize systemic adverse events
- Classified based on their relative potency: very high (Class I), high (Class II), high-medium (Class III), medium (Class IV), medium-low (Class V), low (Class VI), and very-low (Class VII).
    - Very high potency agents: used to treat severe dermatoses over non-facial/intertriginous areas.
    - Medium to high potency agents: often used for the treatment of mild to moderate non-facial and non-intertriginous dermatoses.
    - Low to medium potency agents: used when large areas need to be treated
    - Low potency agents: used on the eyelids and genital areas.

Topical Corticosteroid Potency Classification			
	Drug	**Formulation**	**Strength**
Very High Potency	augmented betamethasone dipropionate (Diprolene)	Ointment Lotion Gel	0.05%
	clobetasol propionate (Clobex, Cormax, Temovate/E, Olux/E)	Lotion Shampoo Spray Cream Gel Ointment Solution Foam	0.05%
	fluocinonide (Vanos)	Cream	0.1%
	flurandrenolide (Cordran)	Tape	4mcg/cm^2
	halobetasol propionate (Ultravate)	Ointment Cream	0.05%
High Potency	amcinonide (Cyclocort)	Ointment	0.1%
	augmented betamethasone dipropionate (Diprolene AF)	Cream	0.05%
	betamethasone dipropionate (Diprolene)	Ointment	0.05%
	desoximetasone (Topicort, Topicort LP)	Ointment Cream Gel	Ointment: 0.25% Cream: 0.25% Gel: 0.05%
	diflorasone diacetate (ApexiCon E, Psorcon)	Ointment	0.05%
	fluocinonide (Lidex/E)	Ointment Gel Cream Solution	0.05%
	halcinonide (Halog)	Ointment Cream	0.1%
	mometasone furoate (Elocon)	Ointment	0.1%
	triamcinolone acetonide (Trianex)	Ointment	0.5%

High-Medium Potency	amcinonide (Cyclocort)	Cream Lotion	0.1%
	betamethasone dipropionate (Diprolene)	Cream	0.05%
	betamethasone valerate (Valisone)	Ointment	0.1%
	diflorasone diacetate (ApexiCon E, Psorcon)	Cream	0.05%
	fluocinonide (Lidex/E)	Emollient Cream	0.05%
	fluticasone propionate (Cutivate)	Ointment	0.005%
	triamcinolone acetonide (Triderm)	Cream	0.5%
Medium Potency	betamethasone valerate (Luxiq)	Foam	0.12%
	clocortolone pivalate (Cloderm)	Cream	0.1%
	desoximetasone (Topicort)	Emollient Cream	0.05%
	fluocinolone acetonide (Synalar)	Ointment	0.025%
	flurandrenolide (Cordran)	Ointment	0.05%
	hydrocortisone valerate (Westcort)	Ointment	0.2%
	mometasone furoate (Elocon)	Cream Lotion Solution	0.1%
	prednicarbate (Dermatop)	Ointment	0.1%
	triamcinolone acetonide (Kenalog)	Ointment	0.1%
Medium-Low Potency	betamethasone dipropionate (Diprosone)	Lotion	0.05%
	betamethasone valerate (Valisone)	Cream Lotion	0.1%
	Desonide (DesOwen)	Ointment	0.05%
	fluocinolone acetonide (Synalar)	Cream	0.025%
	flurandrenolide (Cordran)	Cream Lotion Ointment	Cream/Lotion: 0.05% Ointment: 0.025%
	fluticasone proprionate (Cutivate)	Cream Lotion	0.05%
	hydrocortisone butyrate (Locoid/Lipocream, Cortizone 10)	Ointment Cream Lotion Solution	0.1%
	hydrocortisone probutate (Pandel)	Cream	0.1%
	hydrocortisone valerate (Westcort)	Cream	0.2%
	prednicarbate (Dermatop)	Cream	0.1%
	triamcinolone acetonide (Kenalog)	Lotion Ointment Cream	Cream/Lotion: 0.1% Ointment: 0.025%

Low Potency	alclometasone dipropionate (Aclovate)	Ointment Cream	0.05%
	desonide (Desonate, Desowen, Lokara, Verdeso)	Cream Gel Lotion Foam	0.05%
	fluocinolone acetonide (Capex Shampoo, Derma-Smoothe/FS)	Solution Shampoo Oil (Scalp) Oil (Body)	0.01%
	flurandrenolide (Cordran)	Cream	0.025%
	triamcinolone acetonide (Kenalog)	Cream Lotion	0.025%
Very Low Potency	hydrocortisone (Ala-Cort, Ala-Scalp, Nuzon, Scalacort, Scalacort-DK Kit, Texacort, Pediaderm HC, Pramosone, Analpram, Epifoam, Cortaid, Cortizone-10, Noble, Scalp Relief)	Ointment Cream Lotion Solution foam Spray	Ointment: 0.5%, 1%, or 2.5% Cream: 0.5%, 1%, or 2.5% Lotion: 1% or 2.5% Solution: 1% or 2.5% Aerosol foam: 1% Spray: 1%

PHARMACOLOGY

- Topical corticosteroids share anti-inflammatory, antipruritic, and vasoconstrictive actions that make them effective treatments in dermatological conditions. The exact mechanisms of action for the topical corticosteroids are not completely understood.

CONTRAINDICATIONS/WARNINGS

- HPA axis suppression, manifestations of Cushing's syndrome, hyperglycemia, glucosuria, and growth retardation in children can result from the systemic absorption of topical corticosteroids. Conditions which augment systemic absorption include the application of the more potent steroids, use over large surface areas, prolonged use, and the addition of occlusive dressings. If these effects are seen, the medications should be discontinued.

ADVERSE REACTIONS

- Local:
    - Burning; itching; irritation; erythema; dryness; folliculitis; hypertrichosis; pruritus; acneiform eruptions; hypopigmentation; perioral dermatitis; allergic contact dermatitis; numbness of fingers; stinging and cracking/tightening of skin; maceration of the skin; secondary infection; skin atrophy; striae; miliaria; telangiectasia. These may occur more frequently with occlusive dressings.
- Systemic:
    - Reversible HPA axis suppression, manifestations of Cushing's syndrome, hyperglycemia and glycosuria.

ND Medicaid Utilization (10/2017 – 12/2017)			
Label Name	**Rx Num**	**Total Reimb Amt**	**Avg Cost per Script**
ALCLOMETASONE DIPR 0.05% OINT	2	$48.58	$24.29
ALCLOMETASONE DIPRO 0.05% CRM	1	$60.64	$60.64
BETAMETHASONE DP 0.05% CRM	18	$945.34	$52.52
BETAMETHASONE DP 0.05% LOT	4	$467.25	$116.81
BETAMETHASONE DP 0.05% OINT	7	$1,084.49	$154.93
BETAMETHASONE DP AUG 0.05% GEL	2	$122.26	$61.13
BETAMETHASONE VA 0.1% CREAM	4	$177.94	$44.49
BETAMETHASONE VA 0.1% LOTION	5	$610.20	$122.04
BETAMETHASONE VALER 0.1% OINTM	4	$107.19	$26.80
BETAMETHASONE VALER 0.12% FOAM	1	$442.13	$442.13
CAPEX SHAMPOO	2	$789.02	$394.51
CLOBETASOL 0.05% CREAM	16	$1,193.90	$74.62
CLOBETASOL 0.05% OINTMENT	27	$3,014.00	$111.63
CLOBETASOL 0.05% SHAMPOO	1	$202.37	$202.37
CLOBETASOL 0.05% SOLUTION	14	$861.72	$61.55
CLOBETASOL 0.05% TOPICAL LOTN	1	$195.93	$195.93
DESONIDE 0.05% CREAM	30	$2,972.41	$99.08
DESONIDE 0.05% LOTION	5	$748.60	$149.72
DESONIDE 0.05% OINTMENT	26	$3,180.95	$122.34
DESOXIMETASONE 0.05% GEL	1	$15.00	$15.00
DESOXIMETASONE 0.25% CREAM	2	$89.73	$44.87
FLUOCINOLONE 0.01% BODY OIL	23	$2,851.94	$124.00
FLUOCINOLONE 0.01% CREAM	1	$95.21	$95.21
FLUOCINOLONE 0.01% SOLUTION	3	$277.41	$92.47
FLUOCINOLONE 0.025% CREAM	1	$95.02	$95.02
FLUOCINOLONE 0.025% OINTMENT	3	$102.36	$34.12
FLUOCINOLONE OIL 0.01% EAR DRP	2	$301.76	$150.88
HALOBETASOL PROP 0.05% CREAM	1	$98.90	$98.90
HALOBETASOL PROP 0.05% OINTMNT	1	$57.12	$57.12
HYDROCORTISONE VAL 0.2% CREAM	4	$467.18	$116.80
HYDROCORTISONE VAL 0.2% OINTMT	14	$1,506.19	$107.59
MOMETASONE FUROATE 0.1% CREAM	16	$1,061.85	$66.37
MOMETASONE FUROATE 0.1% OINT	11	$217.97	$19.82
MOMETASONE FUROATE 50 MCG SPRY	2	$177.68	$88.84
TRIAMCINOLONE 0.025% CREAM	23	$302.99	$13.17
TRIAMCINOLONE 0.025% LOTION	2	$416.54	$208.27
TRIAMCINOLONE 0.025% OINT	20	$326.02	$16.30
TRIAMCINOLONE 0.1% CREAM	256	$4,833.86	$18.88
TRIAMCINOLONE 0.1% LOTION	12	$355.82	$29.65
TRIAMCINOLONE 0.1% OINTMENT	146	$2,239.92	$15.34

TRIAMCINOLONE 0.1% PASTE	9	$435.09	$48.34
TRIAMCINOLONE 0.147 MG/G SPRAY	1	$197.65	$197.65
TRIAMCINOLONE 0.5% CREAM	10	$156.52	$15.65
TRIAMCINOLONE 0.5% OINTMENT	13	$595.97	$45.84

REFERENCES:

1. Facts & Comparisons eAnswers. Available at http://online.factsandcomparisons.com. Accessed on February 10. 2018.
2. Bolognia JL, Jorizzo JL, Schaffer JV. Glucocorticosteroids. Dermatology. 3rd ed. 2012. Ch 125, 2075-88

PRODUCT DETAILS OF Tussicaps (hydrocodone polistirex/chlorpheniramine polistirex)

INDICATIONS AND USE:

- Treatment of cough associated with upper respiratory symptoms due to allergy or the common cold

DOSAGE AND ADMINISTRATION:

- Max dose is 2 capsules (20 mg hydrocodone & 16 mg chlorpheniramine) per day
- Recommended dosing
    - Adults and pediatrics 12 years of age and older:
        - 1 capsule (10 mg hydrocodone & 8 mg chlorpheniramine) every 12 hours
    - Pediatric patients 6 to 11 years of age:
        - 1 half-strength capsule (5 mg hydrocodone & 4 mg chlorpheniramine) every 12 hours

DOSAGE FORM AND STRENGTHS:

- hydrocodone-chlorpheniramine 5/4 mg and 10/8 mg capsules

CONTRAINDICATIONS:

- Hypersensitivity to the product or any component of the formulation
- Pediatric patients less than 6 years (increased risk of fatal respiratory depression)

WARNINGS AND PRECAUTIONS:

- Avoid use in patients with head trauma
- Use with caution in the following patients:
    - Patients with any of the following diagnoses/conditions: abdominal conditions, obstructive bowel disease, respiratory disease/depression, adrenocortical insufficiency, biliary tract impairment, delirium tremens, psychosis, seizures, thyroid dysfunction, obesity, and prostatic hyperplasia/urinary obstruction
    - Patients with severe renal or hepatic impairment
    - Elderly patients
    - Patients with a history of drug abuse or acute alcoholism
    - Cachectic or debilitated patients

ADVERSE REACTIONS:

- Frequency not defined
    - Anxiety, dizziness, drowsiness, dysphoria, euphoria, fear, impaired mental and physical performance, lethargy, mental clouding, mood change, psychic dependence, sedation.
    - Constipation, nausea, vomiting
    - Respiratory depression

DRUG INTERACTIONS

- Other CNS depressants (e.g. benzodiazepines, hypnotics, azelastine)
- Constipating agents (e.g. eluxadoline,
- CYP2D6 and CYP3A4 inhibitors
- CYP3A4 inducers
- Anticholinergic agents (e.g. umeclidinium, amantadine, glycopyrrolate)

COST

Drug	Strength	Package Size	WAC Pkg Price	AWP Unit Price
TussiCaps	4 mg-5 mg	100 caps	3641.43	43.70
TussiCaps	8 mg-10 mg	100 caps	3641.43	43.70
TussiCaps	4 mg-5 mg	20 caps	728.29	43.70
TussiCaps	8 mg-10 mg	20 caps	728.29	43.70

CURRENT UTILIZATION

ND Medicaid TussiCaps Utilization (10/2017-12/2017)		
Label Name	**Rx Num**	**Total Reimb Amt**
TUSSICAPS	0	N/A

REFERENCES:

1. Facts & Comparisons eAnswers. Available at http://online.factsandcomparisons.com. Accessed on February 10, 2018.
2. Product Information: TussiCaps(R) extended-release capsules, hydrocodone polistirex and chlorpheniramine polistirex extended-release capsules. Valeant Pharmaceuticals (per DailyMed), Bridgewater, NJ, 2014.

PRODUCT DETAILS OF Zuplenz (ondansetron)

INDICATIONS AND USE:

- Prevention of nausea and vomiting associated with moderate and highly emetogenic chemotherapy.
- Prevention of nausea and vomiting from radiotherapy in patients receiving total body irradiation, single high-dose fraction to abdomen, or daily fractions to the abdomen.
- Prevention of postoperative nausea and/or vomiting.

DOSAGE AND ADMINISTRATION:

- Max dose is 100 mg
    - Adult & Pediatric Patients 12 and Older Dosing:
        - 8 mg given twice daily
            - 1st dose 30 minutes prior to chemo, 2nd dose 8 hours later
            - Every 12 hours for 1-2 days after completion of chemo
    - Pediatric Dosing (ages 4 – 11 years): only for prevention of nausea and vomiting associated with moderately emetogenic cancer chemotherapy
        - 4 mg film given three times a day
            - 1st dose 30 minutes prior to chemo, then 4 and 8 hours later
            - Every 8 hours for 1-2 days after completion of chemo

DOSAGE FORM AND STRENGTHS:

- 4 and 8 mg dissolving film

CONTRAINDICATIONS:

- Hypersensitivity to ondansetron or any component of the formulation
- Concomitant use of apomorphine

WARNINGS AND PRECAUTIONS:

- **Dose-dependent QT interval prolongation:** Avoid in patients with congenital long QT syndrome, hypomagnesemia, or hypokalemia. Hypokalemia and hypomagnesemia must be corrected prior to administration.
- **Serotonin syndrome:** 5-HT3 receptor antagonists are known to cause serotonin syndrome, particularly when used in combination with other serotonergic agents.

ADVERSE REACTIONS:

- Headache, malaise/fatigue, constipation, diarrhea

DRUG INTERACTIONS

- Drugs that prolong the QTc interval (e.g. quetiapine, clozapine, amitriptyline, doxepin)
- Serotonergic modulators (e.g. SSRIs, SNRIs, tramadol, TCAs, Triptans)
- Apomorphine: profound hypotension and loss of consciousness

COST

Drug	Strength	Package Size	WAC Pkg Price	AWP Unit Price
Zuplenz Film	4 mg	10 films	325.31	39.04
Zuplenz Film	8 mg	10 films	325.31	39.04
Zuplenz Film	4 mg	30 films	965.30	38.61
Zuplenz Film	8 mg	30 films	965.30	38.61

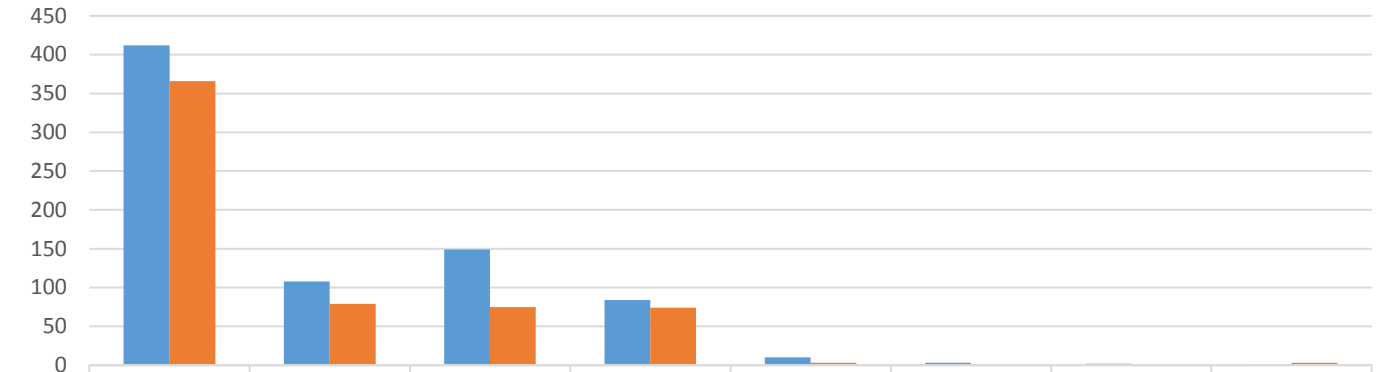
CURRENT UTILIZATION

ND Medicaid Zuplenz Utilization (10/2017-12/2017)		
Label Name	**Rx Num**	**Total Reimb Amt**
ZUPLENZ	0	N/A

REFERENCES:

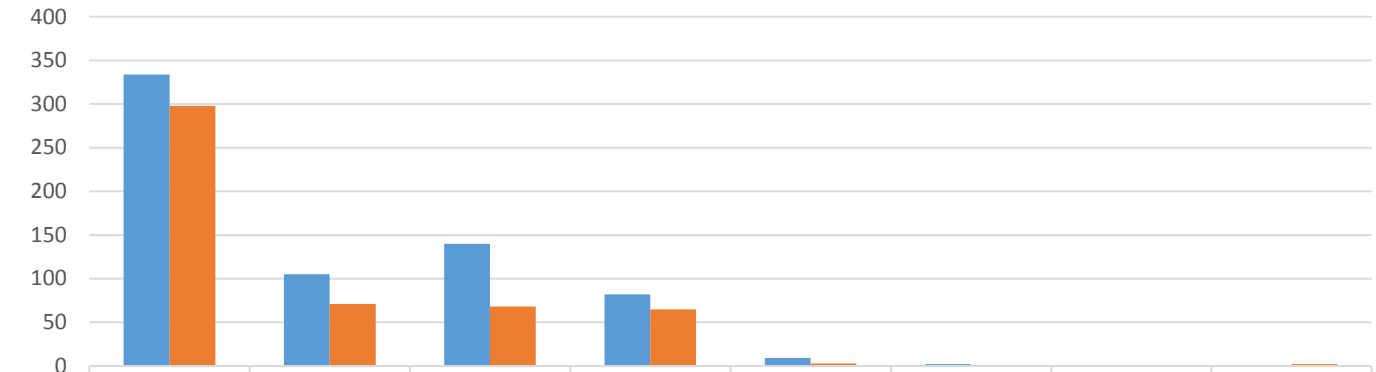
1. Facts & Comparisons eAnswers. Available at http://online.factsandcomparisons.com. Accessed on October 31, 2017.
2. Zuplenz oral soluble film (ondansetron) [prescribing information]. Raleigh, NC: Midatech Pharma US Inc.; January 2017.

Number of Claims per Month



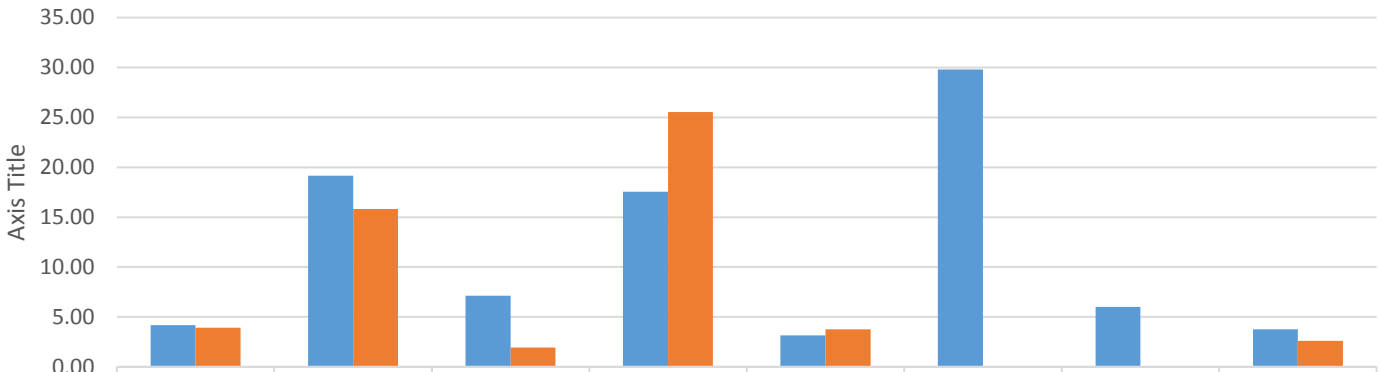
	TRAMADOL	PROMETH/ CODEINE	APAP/ CODEINE	CODEINE/ GUAIFENESIN	APAP/ TRAMADOL	PROMETH/ PHENYLEPH/ CODEINE	CODEINE SULFATE	BUTALBIT/ APAP/ CAFF/ CODEINE
2016	412	108	149	84	10	3	2	1
2017	366	79	75	74	3	0	0	3

Number of Patients per Month

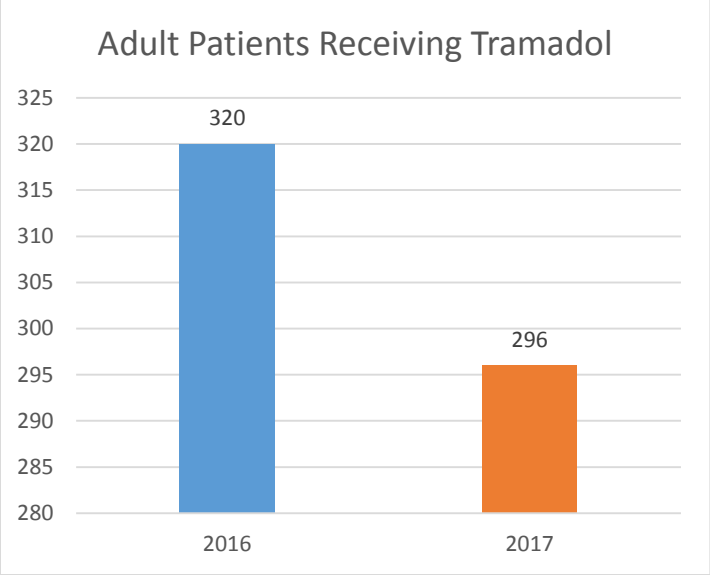


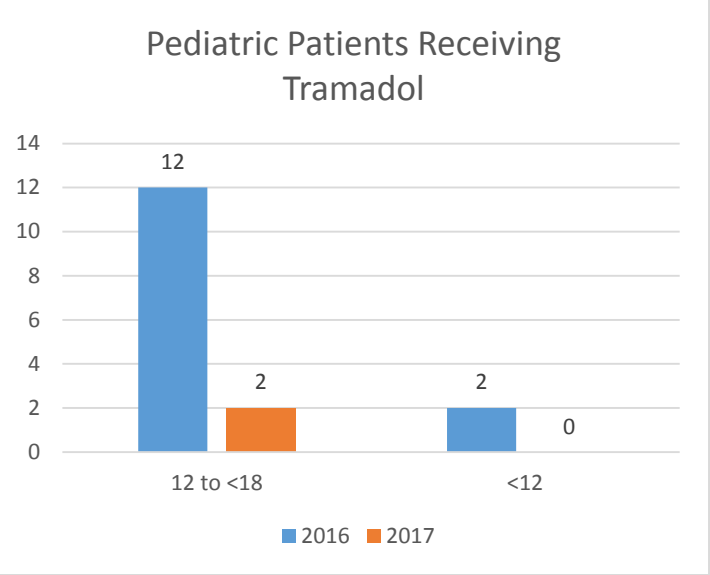
	TRAMADOL	PROMETH/ CODEINE	APAP/ CODEINE	CODEINE/ GUAIFENESIN	APAP/ TRAMADOL	PROMETH/ PHENYLEPH/ CODEINE	CODEINE SULFATE	BUTALBIT/ APAP/ CAFF/ CODEINE
2016	334	105	140	82	9	2	1	1
2017	298	71	68	65	3	0	0	2

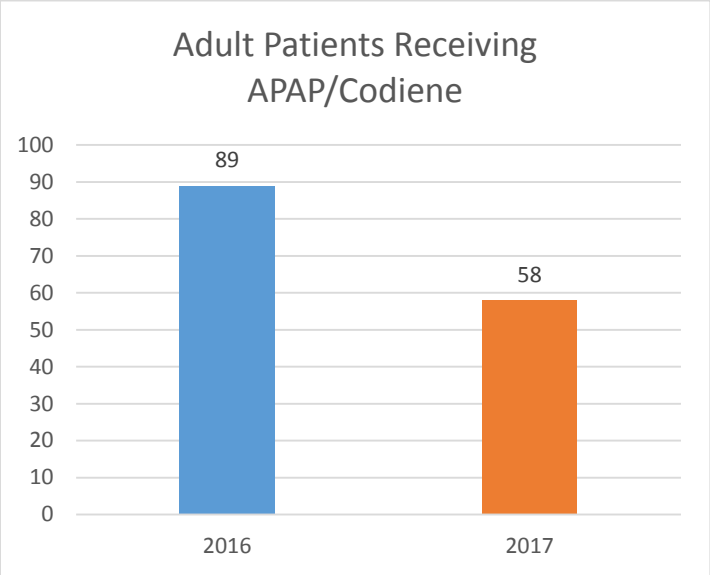
Quantity per Day of Each Product (mL, tablets, or capsules)

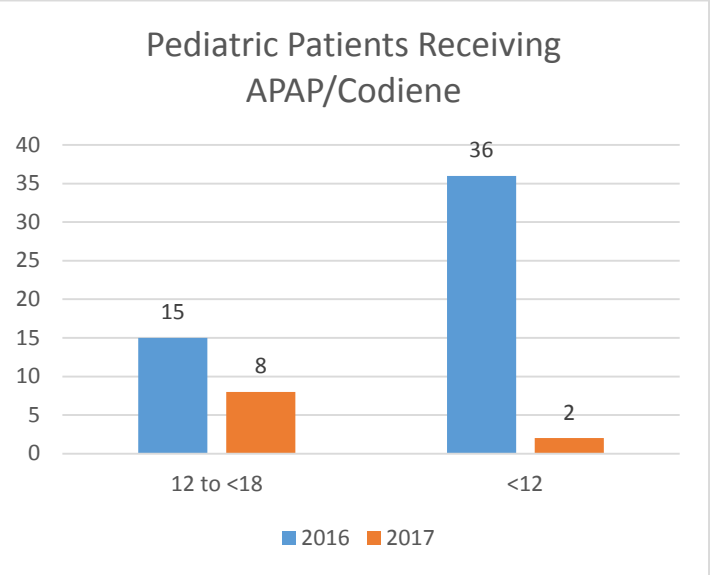


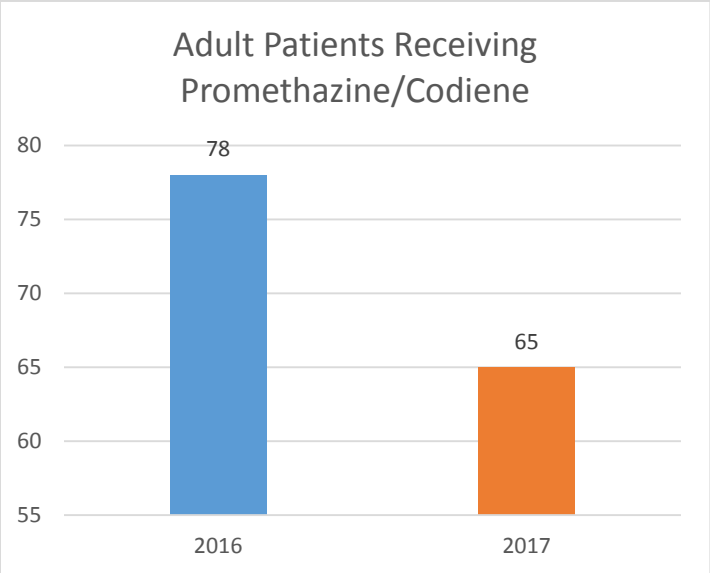
	TRAMADOL	PROMETH/ CODEINE	APAP/ CODEINE	CODEINE/ GUAIFENESIN	APAP/ TRAMADOL	PROMETH/ PHENYLEPH/ CODEINE	CODEINE SULFATE	BUTALBIT/ APAP/ CAFF/ CODEINE
2016	4.18	19.14	7.12	17.53	3.17	29.80	6.00	3.75
2017	3.91	15.81	1.94	25.53	3.75	0.00	0	2.61

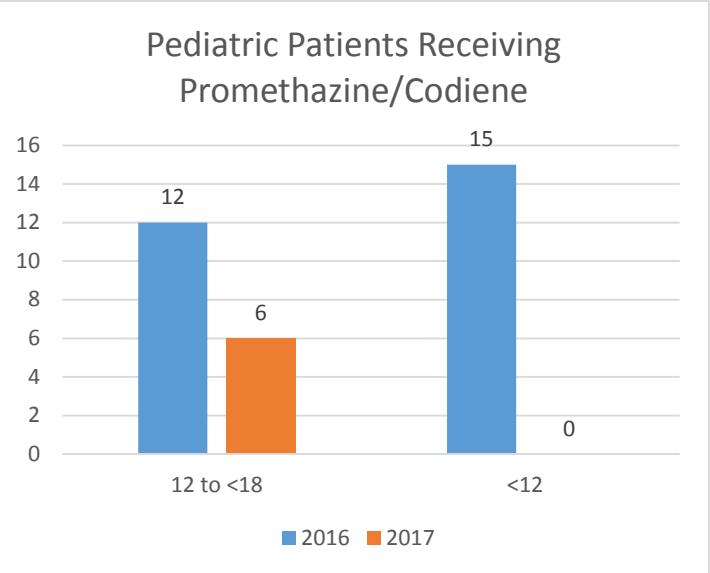

Adult Patients Receiving Tramadol
325
320
315
310
305
300
295
290
285
280
320
296
2016
2017

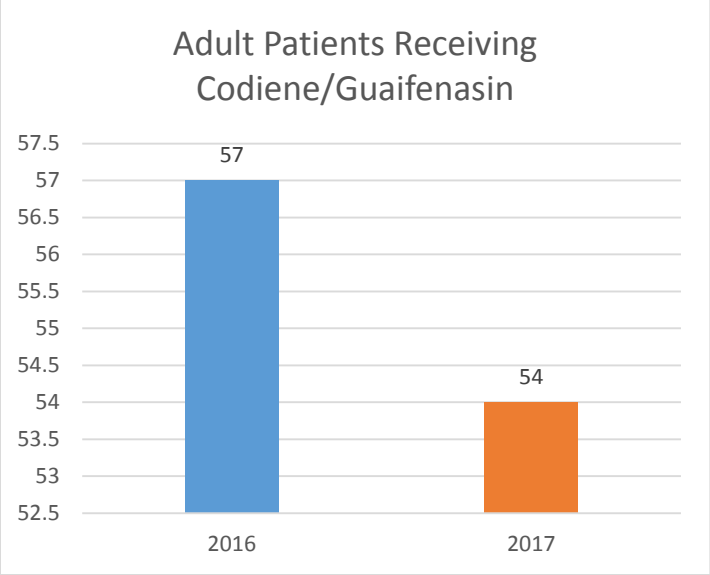

Pediatric Patients Receiving Tramadol
14
12
10
8
6
4
2
0
12
2
2
0
12 to <18
<12
2016
2017

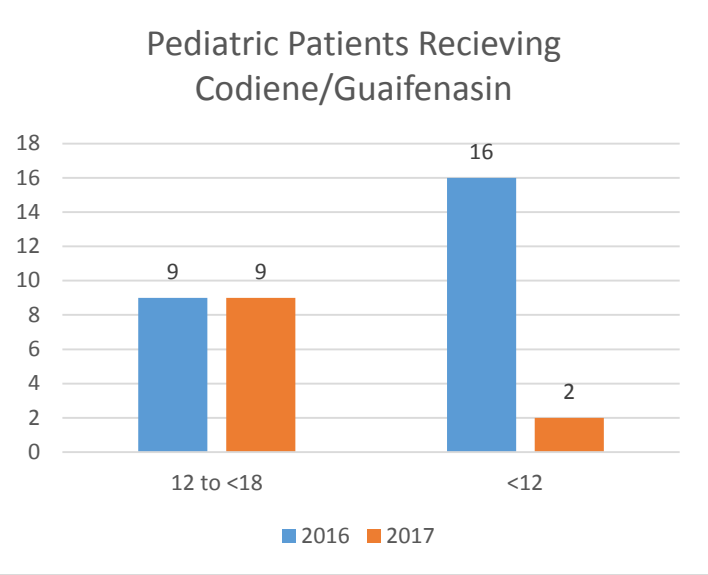

Adult Patients Receiving APAP/Codiene
100
90
80
70
60
50
40
30
20
10
0
89
58
2016
2017

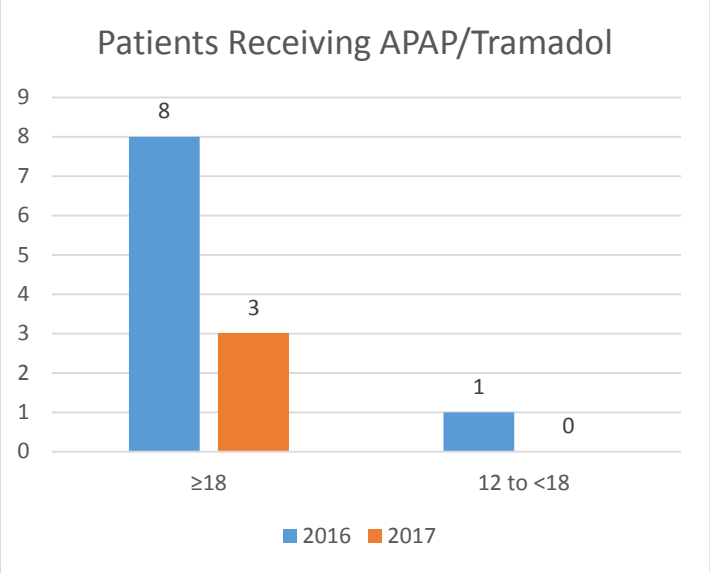

Pediatric Patients Receiving APAP/Codiene
40
35
30
25
20
15
10
5
0
15
8
36
2
12 to <18
<12
2016
2017

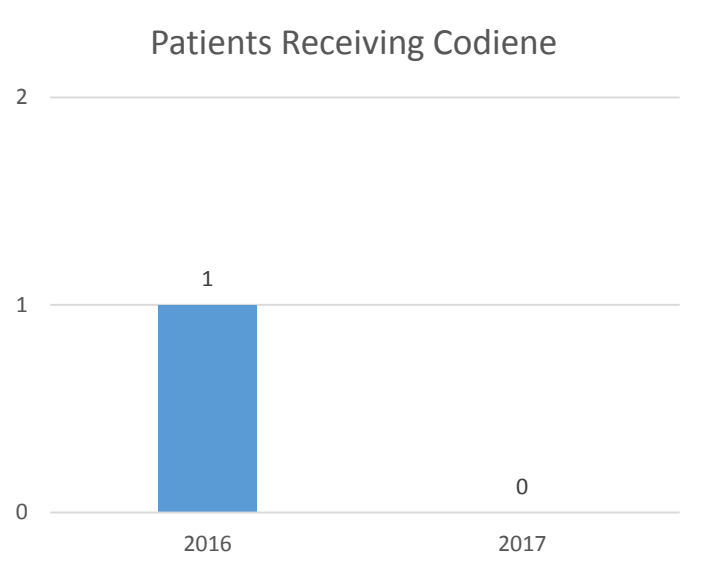

Adult Patients Receiving Promethazine/Codiene
80
75
70
65
60
55
78
65
2016
2017

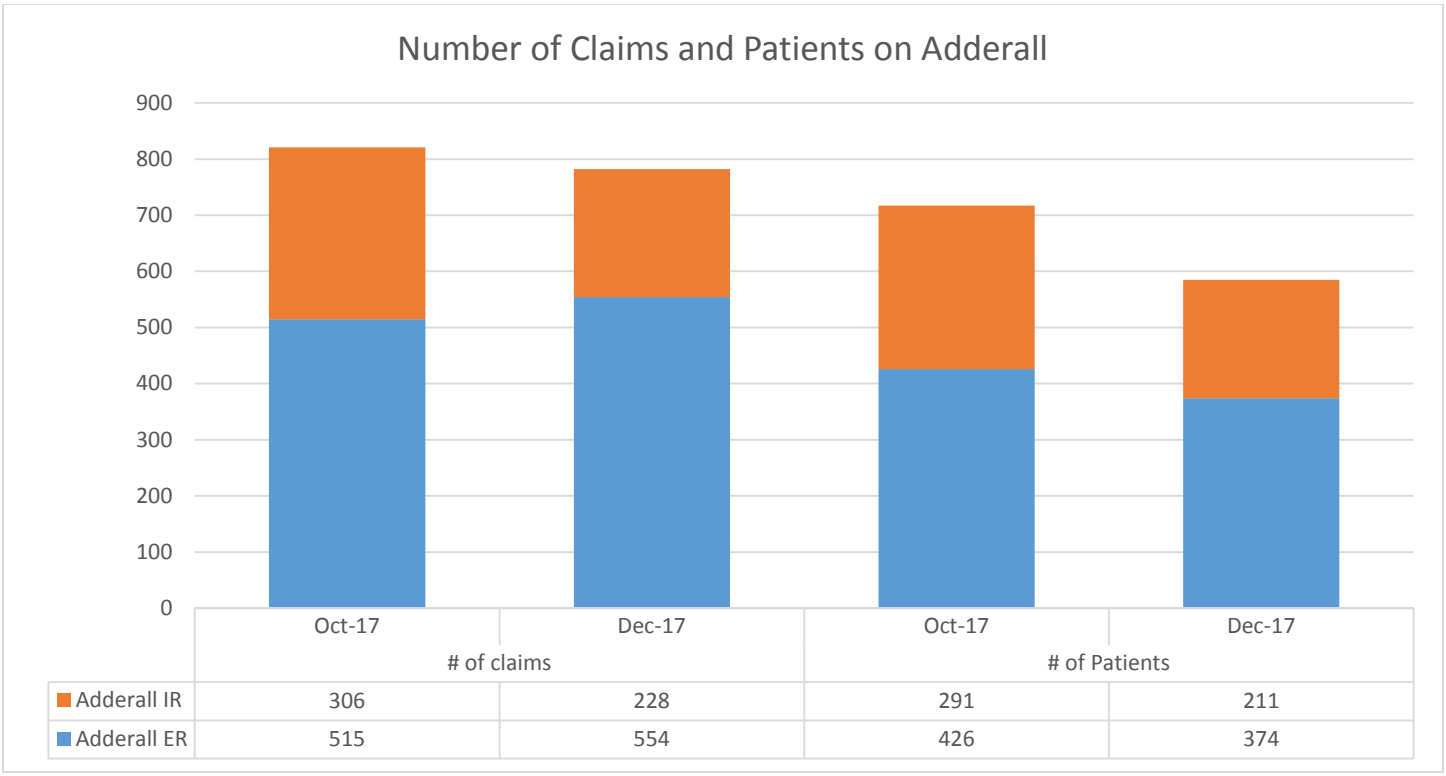

Pediatric Patients Receiving Promethazine/Codiene
16
14
12
10
8
6
4
2
0
12
6
15
0
12 to <18
<12
2016
2017


Adult Patients Receiving Codiene/Guaifenasin
57.5
57
56.5
56
55.5
55
54.5
54
53.5
53
52.5
57
54
2016
2017

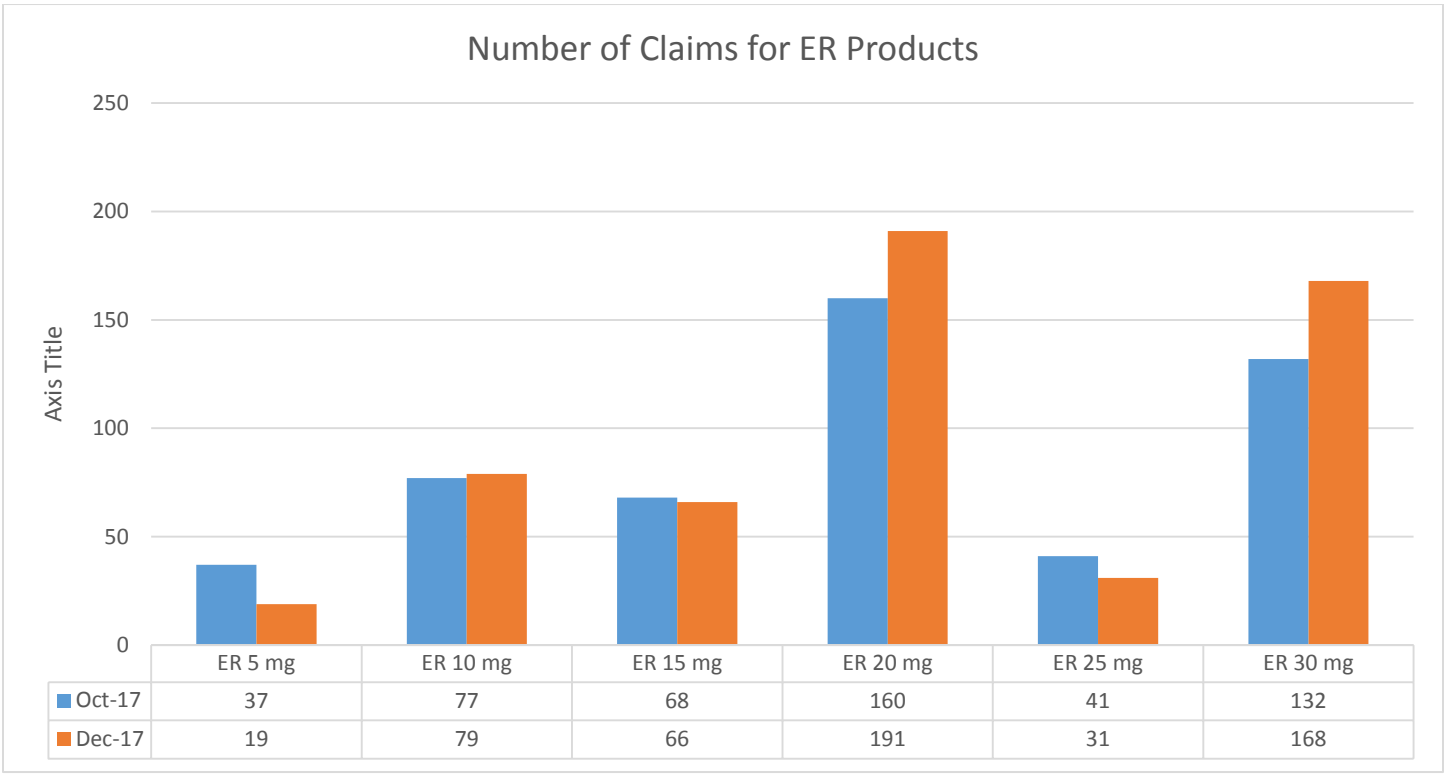

Pediatric Patients Recieving Codiene/Guaifenasin
18
16
14
12
10
8
6
4
2
0
9
9
16
2
12 to <18
<12
2016
2017


Patients Receiving APAP/Tramadol
9
8
7
6
5
4
3
2
1
0
8
3
1
0
≥18
12 to <18
2016
2017

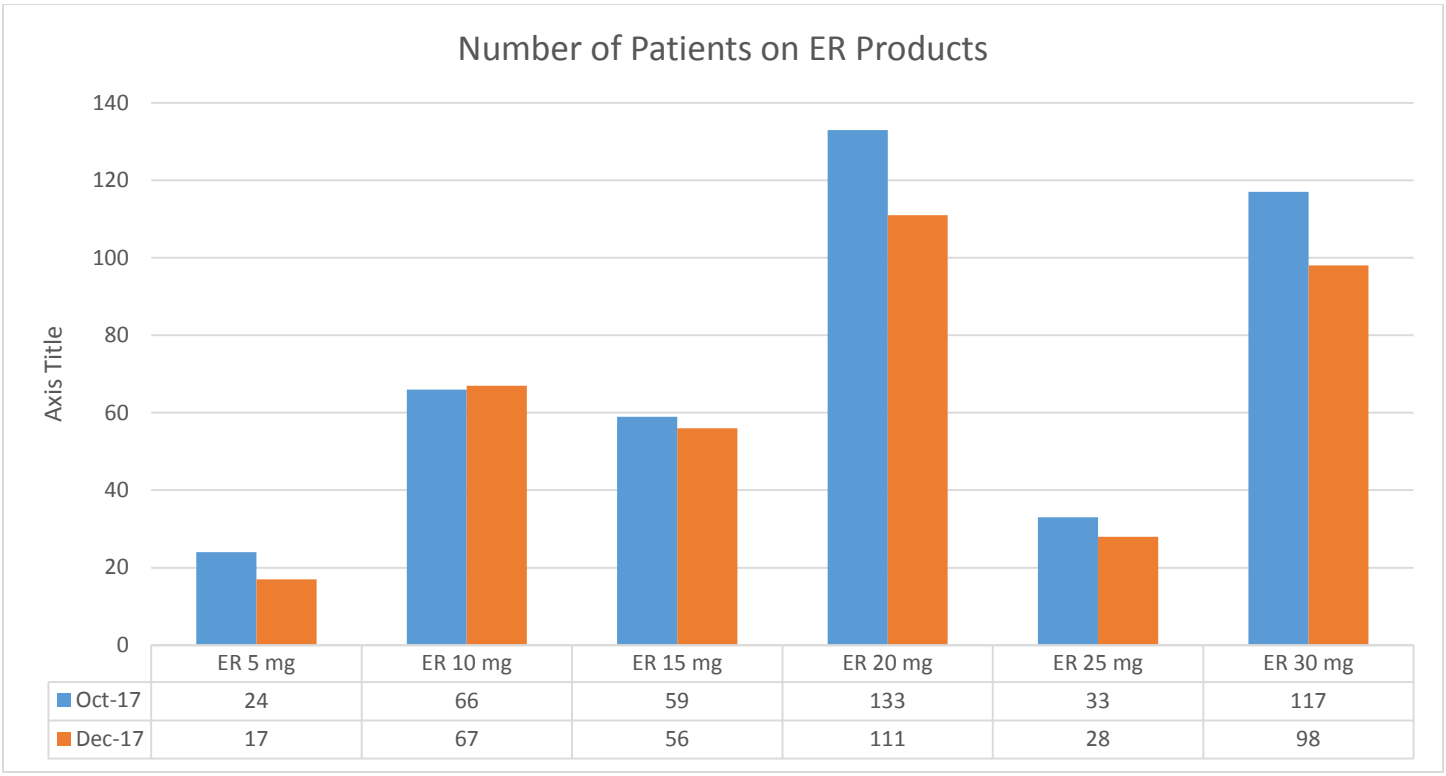

Patients Receiving Codiene
2
1
0
1
0
2016
2017



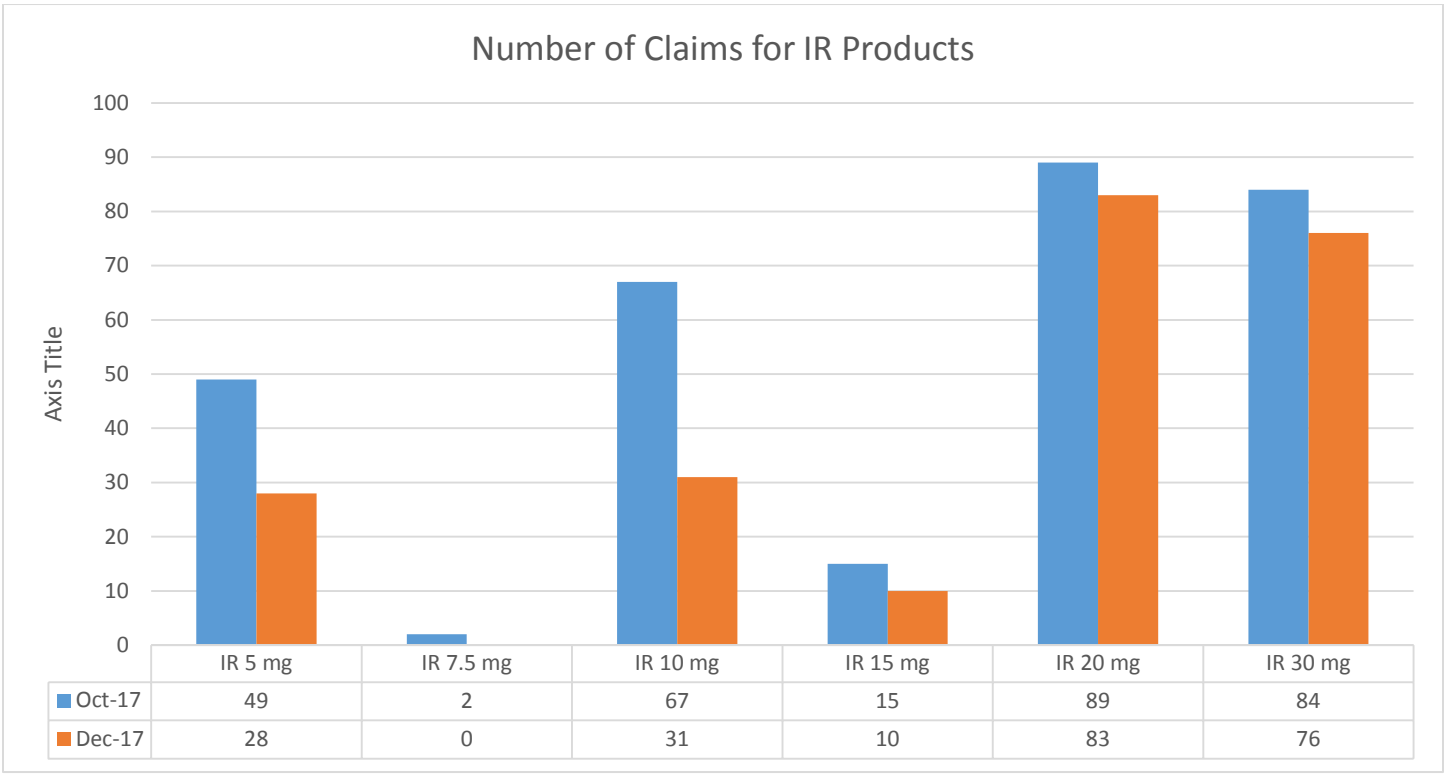
	# of claims		# of Patients	
	Oct-17	Dec-17	Oct-17	Dec-17
Adderall IR	306	228	291	211
Adderall ER	515	554	426	374



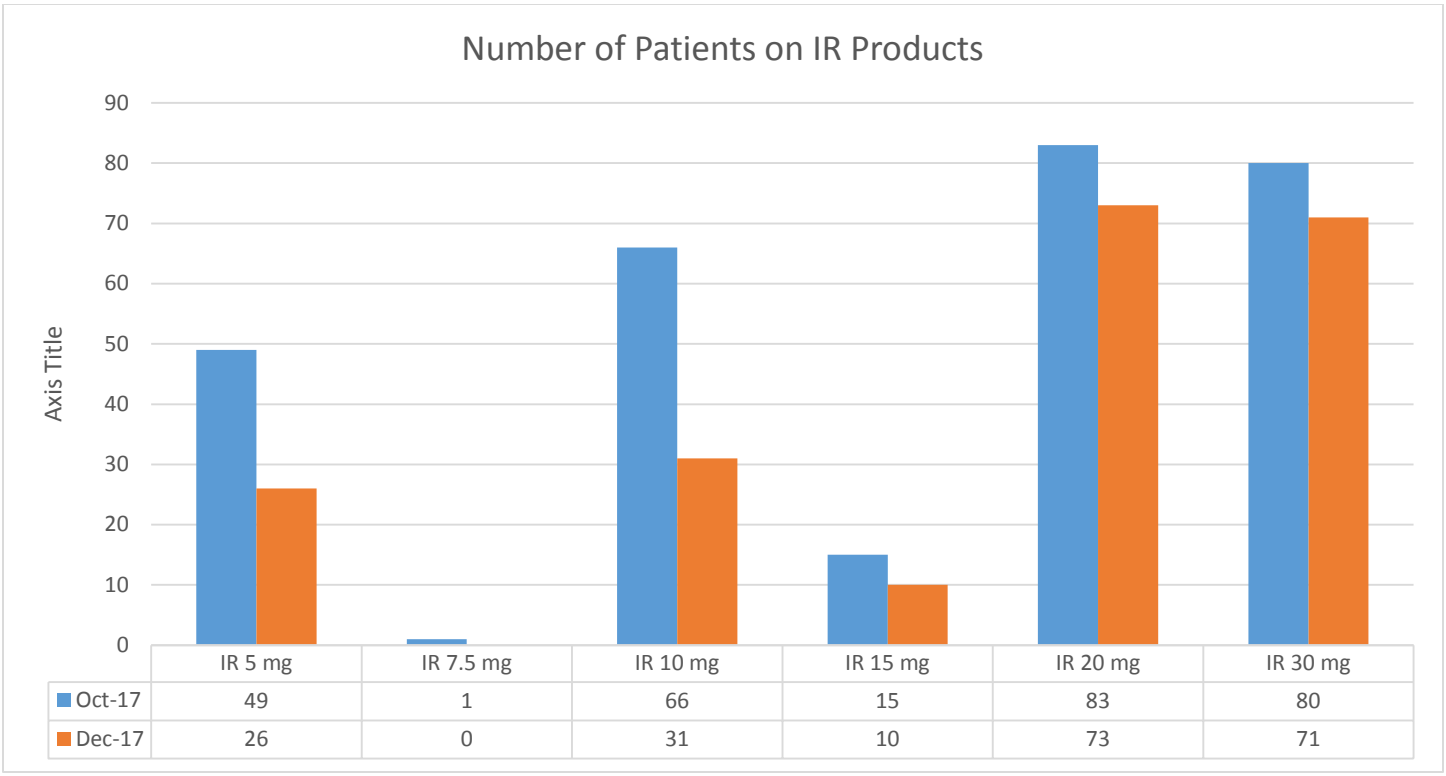
	ER 5 mg	ER 10 mg	ER 15 mg	ER 20 mg	ER 25 mg	ER 30 mg
Oct-17	37	77	68	160	41	132
Dec-17	19	79	66	191	31	168



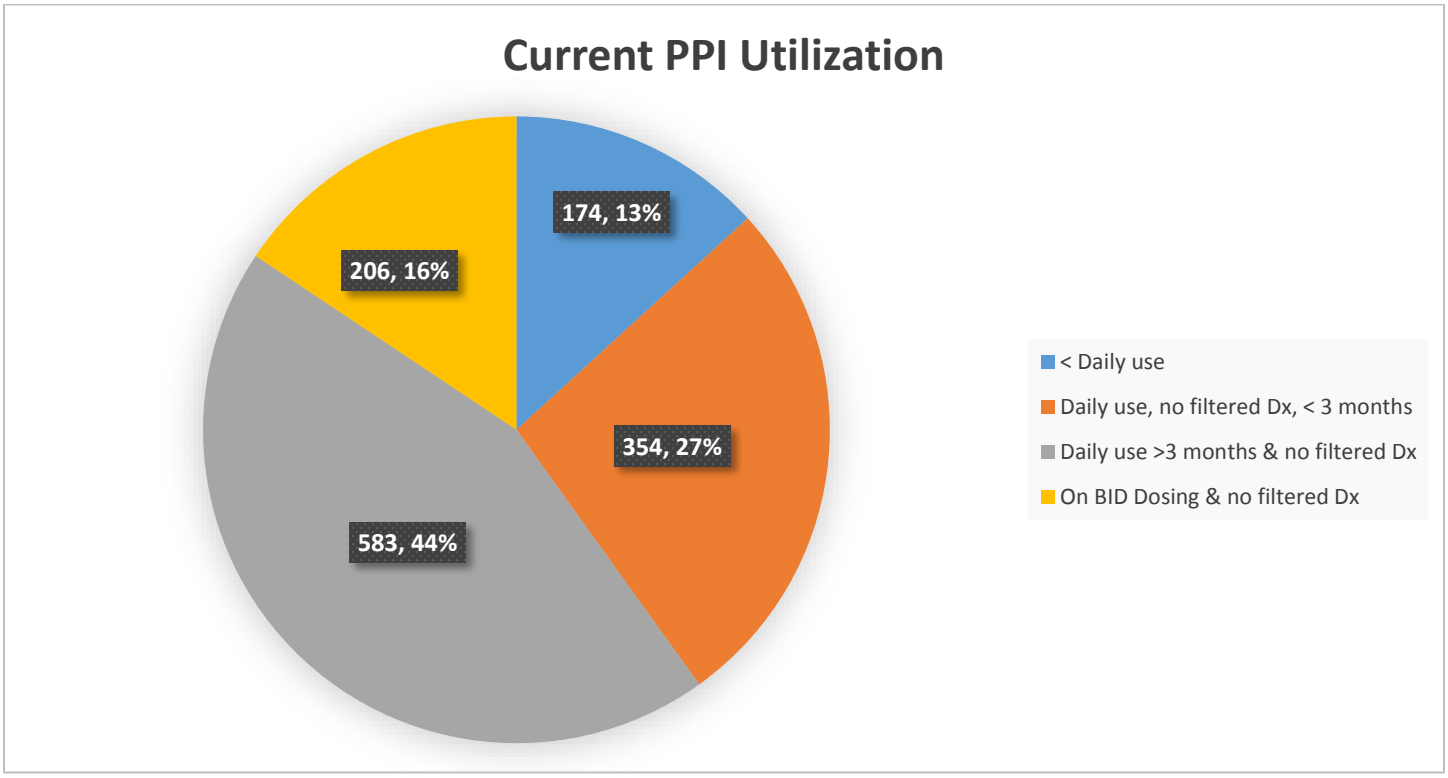
	ER 5 mg	ER 10 mg	ER 15 mg	ER 20 mg	ER 25 mg	ER 30 mg
Oct-17	24	66	59	133	33	117
Dec-17	17	67	56	111	28	98



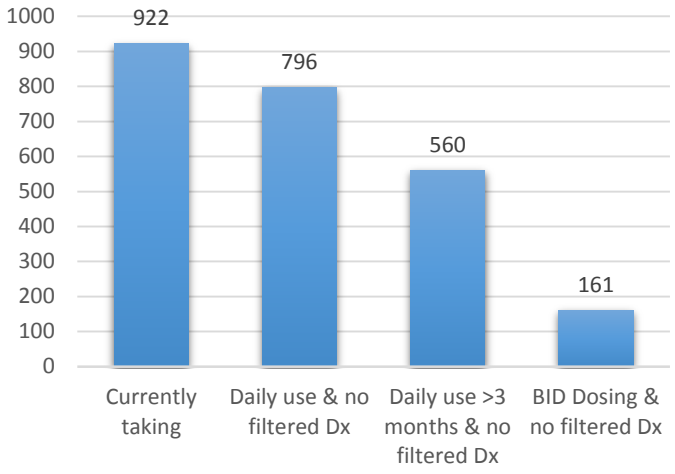
	IR 5 mg	IR 7.5 mg	IR 10 mg	IR 15 mg	IR 20 mg	IR 30 mg
Oct-17	49	2	67	15	89	84
Dec-17	28	0	31	10	83	76



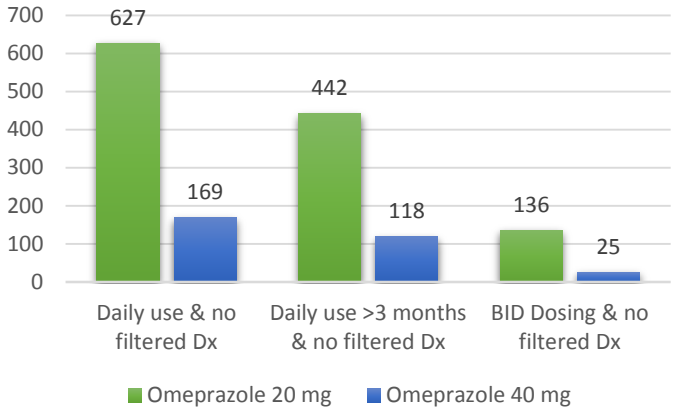
	IR 5 mg	IR 7.5 mg	IR 10 mg	IR 15 mg	IR 20 mg	IR 30 mg
Oct-17	49	1	66	15	83	80
Dec-17	26	0	31	10	73	71



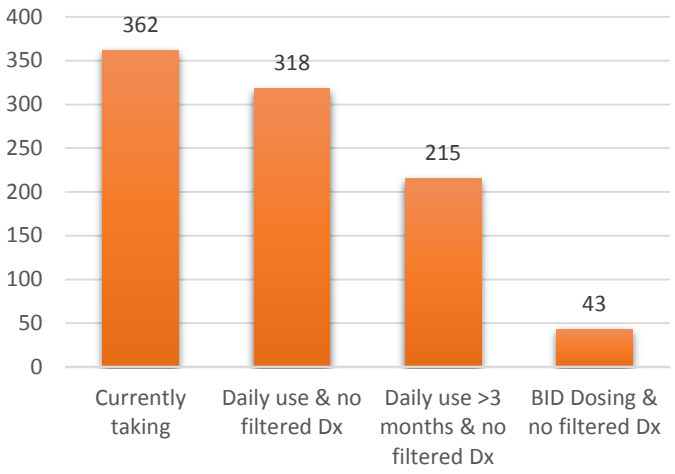
Patients Taking Omeprazole



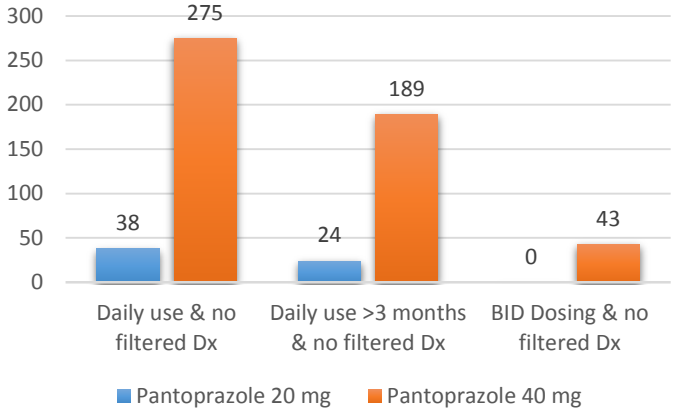
Patients Taking Omeprazole by Dose



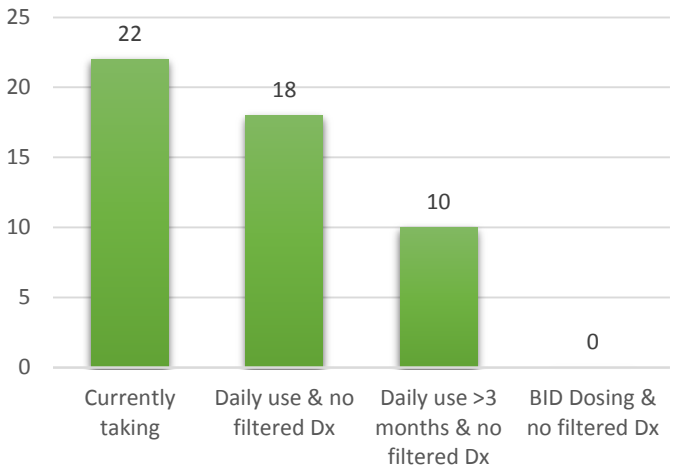
Patients Taking Pantoprazole



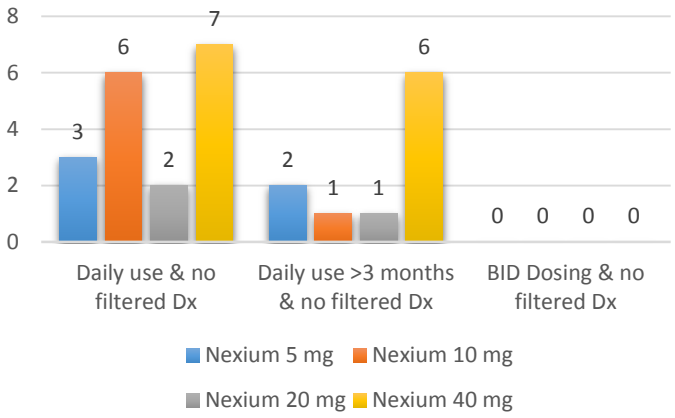
Patients Taking Pantoprazoloe by Dose

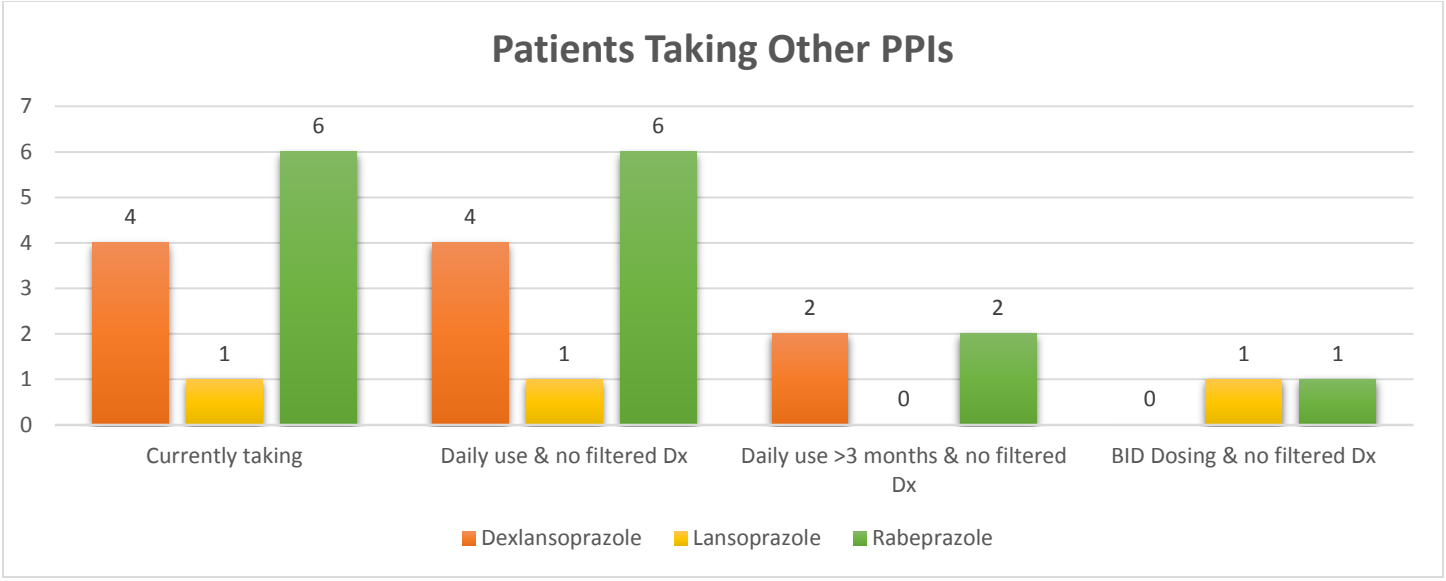


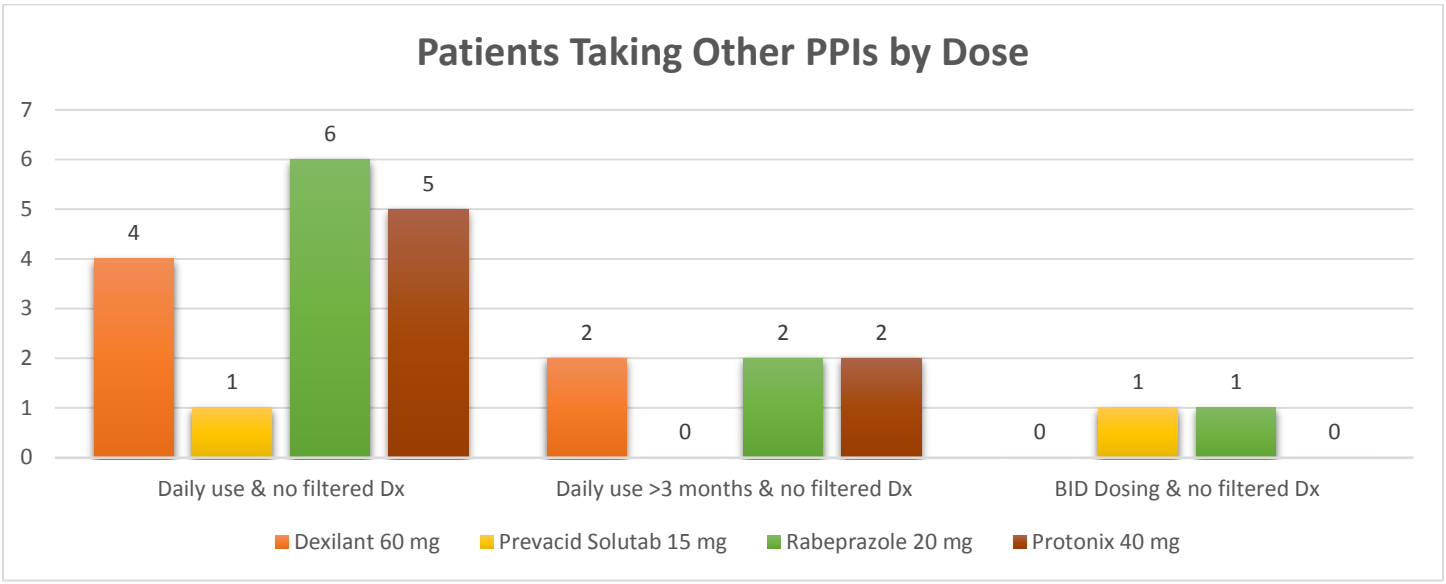
Patients Taking Esomeprazole



Patients Taking Esomeprazole by Dose




Patients Taking Other PPIs
7
6
5
4
3
2
1
0
4
1
6
4
1
6
2
0
2
0
1
1
Currently taking
Daily use & no filtered Dx
Daily use >3 months & no filtered Dx
BID Dosing & no filtered Dx
Dexlansoprazole
Lansoprazole
Rabeprazole


Patients Taking Other PPIs by Dose
7
6
5
4
3
2
1
0
4
1
6
5
2
0
2
2
0
1
1
0
Daily use & no filtered Dx
Daily use >3 months & no filtered Dx
BID Dosing & no filtered Dx
Dexilant 60 mg
Prevacid Solutab 15 mg
Rabeprazole 20 mg
Protonix 40 mg

NORTH DAKOTA MEDICAID
RETROSPECTIVE DRUG UTILIZATION REVIEW
CRITERIA RECOMMENDATIONS
1ST QUARTER 2018

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

1. Fluticasone-Umeclidinium-Vilanterol / Overutilization _____ _____

Alert Message: The manufacturer's recommended dose of Trelegy Ellipta (fluticasone/umeclidinium/vilanterol) is 1 inhalation (100 mcg fluticasone/62.5mcg umeclidinium/25mcg vilanterol) once daily by orally inhaled route only. Clinically significant cardiovascular effects and fatalities have been reported in association with excessive use of inhaled sympathomimetic-containing drugs.

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C
Fluticasone/Umeclidinium/Vilanterol		

Max Dose: 100mcg fluticasone/62.5 mcg umeclidinium/25mcg vilanterol per day

References:
Trelegy Ellipta Prescribing Information, September 2017, GlaxoSmithKline.
Clinical Pharmacology, 2017 Elsevier/Gold Standard.

2. Fluticasone-Umeclidinium-Vilanterol / Black Box Warning _____ _____

Alert Message: Trelegy Ellipta (fluticasone/umeclidinium/vilanterol) contains the long-acting beta-2 adrenergic agonist (LABL) vilanterol and all LABAs increase the risk of asthma-related death. The safety and efficacy of fluticasone/umeclidinium/vilanterol) in patients with asthma have not been established. Fluticasone/umeclidinium/vilanterol is not indicated for the treatment of asthma.

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C **(Include)**
Fluticasone/Umeclidinium/Vilanterol		Asthma

References:
Trelegy Ellipta Prescribing Information, September 2017, GlaxoSmithKline.
Clinical Pharmacology, 2017 Elsevier/Gold Standard.

3. Fluticasone-Umeclidinium-Vilanterol/ Cardiovascular, Diabetes, Thyrotoxicosis & Convulsive Disorders _____ _____

Alert Message: Trelegy Ellipta (fluticasone/umeclidinium/vilanterol) should be used with caution in patients with cardiovascular or convulsive disorders, thyrotoxicosis or sensitivity to sympathomimetic drugs. The vilanterol component is a sympathomimetic amine and can exacerbate these conditions.

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C
Fluticasone/Umeclidinium/Vilanterol	Hypertension Arrhythmias Heart Failure Diabetes Seizures Epilepsy	

References:
Clinical Pharmacology, 2017 Elsevier/Gold Standard.
Trelegy Ellipta Prescribing Information, September 2017, GlaxoSmithKline.

4. Fluticasone-Umeclidinium-Vilanterol / Strong CYP3A4 Inhibitors _____ _____

Alert Message: Concurrent use of Trelegy Ellipta (fluticasone/umeclidinium/vilanterol) with a strong CYP3A4 inhibitor may result in increased systemic exposure to both fluticasone and vilanterol. Both vilanterol and fluticasone are CYP3A4 substrates and inhibition of their CYP3A4-mediated metabolism may increase exposure and risk of adverse effects.

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

Util A	Util B		Util C
Fluticasone/Umeclidinium/Vilanterol	Nefazodone	Saquinavir	
	Clarithromycin	Ritonavir	
	Cobicistat	Nelfinavir	
	Ketoconazole	Indinavir	
	Itraconazole	Boceprevir	
	Posaconazole		
	Voriconazole		

References:
Trelegy Ellipta Prescribing Information, September 2017, GlaxoSmithKline.
Clinical Pharmacology, 2017 Elsevier/Gold Standard.

5. Fluticasone-Umeclidinium-Vilanterol / MAOIs, TCA & QT Prolong Meds _____ _____

Alert Message: Trelegy Ellipta (fluticasone/umeclidinium/vilanterol) should be administered with extreme caution to patients being treated with MAOIs, TCAs, or drugs known to prolong the QTc interval or within 2 weeks of such agents. The action of the adrenergic agonist component of the combo product, vilanterol, on the cardiovascular system may be potentiated by these agents.

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

Util A	Util B				Util C
Trelegy	Albuterol	Disopyramide	Imipramine	Pazopanib	Thioridazine
	Alfuzosin	Dofetilide	Indapamide	Pentamidine	Tizanidine
	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	Ziprasidone
	Azithromycin	Felbamate	Methadone	Risperidone	Zolmitriptan
	Chloral Hydrate	Flecainide	Moexipril/HCTZ	Ritonavir	Ezogabine
	Chloroquine	Fluconazole	Moxifloxacin	Salmeterol	Isocarboxazid
	Chlorpromazine	Fluoxetine	Nicardipine	Saquinavir	Phenelzine
	Ciprofloxacin	Foscarnet	Nilotinib	Sertraline	Tranylcypromine
	Citalopram	Fosphenytoin	Norfloxacin	Solifenacin	Linezolid
	Clarithromycin	Galantamine	Nortriptyline	Sotalol	
	Clomipramine	Gemifloxacin	Octreotide	Sunitinib	
	Clozapine	Granisetron	Ofloxacin	Tacrolimus	
	Dasatinib	Haloperidol	Ondansetron	Tamoxifen	
	Desipramine	Ibutilide	Paliperidone	Terbutaline	
	Diphenhydramine	Iloperidone	Paroxetine	Rasagiline	

References:
Trelegy Ellipta Prescribing Information, September 2017, GlaxoSmithKline.
Clinical Pharmacology, 2017 Elsevier/Gold Standard.

6. Fluticasone-Umeclidinium-Vilanterol / Non-Potassium Sparing Diuretics _____ _____

Alert Message: Caution should be exercised when Trelegy Ellipta (fluticasone/umeclidinium/vilanterol), a beta-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 administration of the diuretic.

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

Util A	Util B		Util C
Fluticasone/Umeclidinium/Vilanterol	Furosemide	Indapamide	
	Bumetanide	Methyclothiazide	
	Torsemide	Metolazone	
	Chlorothiazide		
	Chlorthalidone		
	HCTZ		

References:
Trelegy Ellipta Prescribing Information, September 2017, GlaxoSmithKline.
Clinical Pharmacology, 2017 Elsevier/Gold Standard.

7. Fluticasone-Umeclidinium-Vilanterol / Nonselective Beta Blockers _____ _____

Alert Message: Concurrent use of a beta-adrenergic blocker with Trelegy Ellipta (fluticasone/umeclidinium/vilanterol), a beta2-agonist containing combo product, may diminish the pulmonary effect of the beta-agonist component, vilanterol. Beta-blockers not only block the therapeutic effects of beta-agonists, but may produce severe bronchospasm in patients with asthma and COPD. If concomitant therapy cannot be avoided, consider a cardioselective beta-blocker, but administer with caution.

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

Util A	Util B	Util C **(Negating)**
Fluticasone/Umeclidinium/Vilanterol	Carvedilol	Acebutolol
	Nadolol	Atenolol
	Labetalol	Betaxolol
	Penbutolol	Bisoprolol
	Pindolol	Metoprolol
	Propranolol	Nebivolol
	Sotalol	
	Timolol	

References:
Trelegy Ellipta Prescribing Information, September 2017, GlaxoSmithKline.
Clinical Pharmacology, 2017 Elsevier/Gold Standard.

8. Fluticasone-Umeclidinium-Vilanterol / Narrow Angle Glaucoma _____ _____

Alert Message: Trelegy Ellipta (fluticasone/umeclidinium/vilanterol) should be used with caution in patients with narrow-angle glaucoma. The umeclidinium component of this combo product is an anticholinergic agent and its use in this patient population can worsen the condition.

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C **(Include)**
Fluticasone/Umeclidinium/Vilanterol		Narrow Angle Glaucoma

References:
Trelegy Ellipta Prescribing Information, September 2017, GlaxoSmithKline.
Clinical Pharmacology, 2017 Elsevier/Gold Standard.

9. Fluticasone-Umeclidinium-Vilanterol / Urinary Retention _____ _____

Alert Message: Trelegy Ellipta (fluticasone/umeclidinium/vilanterol) should be used with caution in patients with urinary retention. The umeclidinium component of this combo product is an anticholinergic agent and its use can worsen urinary retention, especially in patients with prostatic hyperplasia or bladder neck obstruction.

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C **(Include)**
Fluticasone/Umeclidinium/Vilanterol		Urinary Retention
		Bladder Neck Obstruction
		Prostatic Hyperplasia

References:
Trelegy Ellipta Prescribing Information, September 2017, GlaxoSmithKline.
Clinical Pharmacology, 2017 Elsevier/Gold Standard.

10. Fluticasone-Umeclidinium-Vilanterol / Anticholinergics _____ _____

Alert Message: The concurrent use of Trelegy Ellipta (fluticasone/umeclidinium/vilanterol) with anticholinergic agents should be avoided. The umeclidinium component of the combo product is an anticholinergic agent and concomitant use with other anticholinergics may lead to an increase in anticholinergic adverse effects.

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

Util A	Util B	Util C
Fluticasone/Umeclidinium/Vilanterol	Trihexyphenidyl	
	Benztropine	
	Orphenadrine	
	Darifenacin	
	Fesoterodine	
	Flavoxate	
	Oxybutynin	
	Solifenacin	
	Tolterodine	
	Trospium	
	Hyoscyamine	
	Scopolamine	
	Propantheline	
	Glycopyrrolate	
	Mepenzolate	
	Methscopolamine	
	Dicyclomine	

References:
Trelegy Ellipta Prescribing Information, September 2017, GlaxoSmithKline.
Clinical Pharmacology, 2017 Elsevier/Gold Standard.

11. Fluticasone-Umeclidinium-Vilanterol / Hepatic Impairment _____ _____

Alert Message: Use of Trelegy Ellipta (fluticasone/umeclidinium/vilanterol) in patients with hepatic impairment may result in increased systemic exposure to the fluticasone component in the combo agent. Fluticasone is primarily cleared in the liver and studies have shown fluticasone systemic exposure can increase by up to 3-fold in patients with hepatic impairment as compared to healthy subjects. Monitor patients for corticosteroid-related side effects.

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C **(Include)**
Fluticasone/Umeclidinium/Vilanterol		Hepatic Impairment

References:
Trelegy Ellipta Prescribing Information, September 2017, GlaxoSmithKline.
Clinical Pharmacology, 2017 Elsevier/Gold Standard.

12. Fluticasone-Umeclidinium-Vilanterol / Non-adherence _____ _____

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

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C
Fluticasone/Umeclidinium/Vilanterol		

References:

Trelegy Ellipta Prescribing Information, September 2017, GlaxoSmithKline.
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. 2014 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 of COPD. 2010 Nov 24;5:401-406.

13. Fluticasone-Umeclidinium-Vilanterol / Therapeutic Appropriateness _____ _____

Alert Message: Trelegy Ellipta (fluticasone/umeclidinium/vilanterol) is not indicated for use in children. The safety and efficacy in pediatric patients have not been established.

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C **(Include)**
Fluticasone/Umeclidinium/Vilanterol		

Age Range: < 18 yoa

References:

Trelegy Ellipta Prescribing Information, September 2017, GlaxoSmithKline.
Clinical Pharmacology, 2017 Elsevier/Gold Standard.

14. QVAR Redihaler / Nonadherence _____ _____

Alert Message: Non-adherence with prescribed asthma therapy may significantly increase the risk of asthma exacerbations, emergency room visits, hospitalization, and asthma-related deaths. Always verify at each office visit that the patient understands their condition, the treatment plan, and the importance of adherence.

Conflict Code: LR - Nonadherence
Drugs/Diseases

Util A	Util B	Util C
Beclomethasone breath actuated		

References:

Osterberg L, Blaschke T. Adherence to medication. N Engl J Med 2005;353:487-97.
Williams LK, Pladevall M, XI Hy, et al., Relationship between Adherence to Inhaled Corticosteroids and Poor Outcomes Among Adults with Asthma. J Allerg Clin Immunol. December 2004;114(6):1288-1293.
Tan H, Sarawate C, Singer J et al., Impact of Asthma Controller Medications on Clinical, Economic, and Patient-Reported Outcomes. Mayo Clinic Proc. August 2009;84(8):675-684.

15. Armonair Respiclick / Nonadherence _____ _____

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

Conflict Code: LR - Nonadherence
Drugs/Diseases
Util A Util B Util C
Fluticasone Inhalation Powder

References:
Iuga AO, McGuire MJ. Adherence and Health Care Costs. Risk Manag Healthc Policy. 2014 Feb 20;7:35-44.
Osterberg L, Blaschke T. Adherence to medication. N Engl J Med 2005;353:487-97.
Tan H, Sarawate C, Singer J et al., Impact of Asthma Controller Medications on Clinical, Economic, and Patient-Reported Outcomes. Mayo Clinic Proc. August 2009;84(8):675-684.
LI JT, et al. Attaining Optimal Asthma Control: A Practice Parameter. J Allerg Clin Immunol. 2005;116"S3-11.
Bender BG, Overcoming Barriers to Nonadherence in Asthma Treatment. J Allerg Clin Immuno. June 2002;109(6):S554-559.

16. Armonair Respiclick / Therapeutic Appropriateness _____ _____

Alert Message: The safety and effectiveness of Armonair Respiclick (fluticasone) in pediatric patients below the age of 12 years have not been established.

Conflict Code: TA - Therapeutic Appropriateness
Drugs/Diseases
Util A Util B Util C
Fluticasone Inhalation Powder

Age Range: 0 – 11 yoa

References:
Armonair Prescribing Information, Jan. 2017, Teva Respiratory, LLC.
Clinical Pharmacology, 2017 Elsevier Gold Standard.

17. AirDuo Respiclick / Therapeutic Appropriateness _____ _____

Alert Message: The safety and effectiveness of AirDuo Respiclick (fluticasone/fluticasone) in pediatric patients below the age of 12 years have not been established.

Conflict Code: TA - Therapeutic Appropriateness
Drugs/Diseases
Util A Util B Util C
Fluticasone/Salmeterol Inhalation Powder

References:
AirDuo Prescribing Information, Jan. 2017, Teva Respiratory, LLC.
Clinical Pharmacology, 2017 Elsevier Gold Standard.

18. AirDuo Respiclick / Nonadherence _____ _____

Alert Message: Non-adherence with prescribed asthma therapy may significantly increase the risk of asthma exacerbations, emergency room visits, hospitalization, and asthma-related deaths. Always verify at each office visit that the patient understands their condition, the treatment plan, and the importance of adherence.

Conflict Code: LR - Nonadherence
Drugs/Diseases

Util A	Util B	Util C
Fluticasone/Salmeterol Inhalation Powder		

References:
Osterberg L, Blaschke T. Adherence to medication. N Engl J Med 2005;353:487-97.
Williams LK, Pladevall M, XI Hy, et al., Relationship between Adherence to Inhaled Corticosteroids and Poor Outcomes Among Adults with Asthma. J Allerg Clin Immunol. December 2004;114(6):1288-1293.
Tan H, Sarawate C, Singer J et al., Impact of Asthma Controller Medications on Clinical, Economic, and Patient-Reported Outcomes. Mayo Clinic Proc. August 2009;84(8):675-684.

19. Lesinurad/Allopurinol / Overutilization _____ _____

Alert Message: Duzallo (lesinurad/allopurinol) may be over-utilized. The manufacturer's recommended maximum dose is one 200 mg lesinurad/300mg allopurinol tablet once daily.

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C (Negate)
Lesinurad/Allopurinol		CKD Stage 4 & 5 ESRD Dependence on Renal Dialysis Kidney Replace by Transplant

Max Dose: 200mg/300mg per day

References:
Duzallo Prescribing Information, Aug. 2017, Ironwood Pharmaceuticals, Inc.
Clinical Pharmacology, 2017, Elsevier/Gold Standard.

20. Lesinurad/Allopurinol / Lesinurad _____ _____

Alert Message: Therapeutic duplication of lesinurad-containing products may be occurring.

Conflict Code: TD – Therapeutic Duplication
Drugs/Diseases

Util A	Util B	Util C
Lesinurad/Allopurinol	Lesinurad	

References:
Duzallo Prescribing Information, Aug. 2017, Ironwood Pharmaceuticals, Inc.
Clinical Pharmacology, 2017, Elsevier/Gold Standard.

Criteria Recommendations *Approved* *Rejected*

21. Lesinurad/Allopurinol / Severe Renal Impairment _____ _____

Alert Message: The use of Duzallo (lesinurad/allopurinol) is contraindicated in patients with severe renal impairment (eCLcr < 30 mL/min), end-stage renal disease, kidney transplant recipients, or patients on dialysis. Lesinurad/allopurinol is not expected to be effective in these patient populations.

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C **(Include)**
Lesinurad/Allopurinol		CKD Stage 4 & 5
		ESRD
		Dependence on Renal Dialysis
		Kidney Replace by Transplant

References:
Duzallo Prescribing Information, Aug. 2017, Ironwood Pharmaceuticals, Inc.
Clinical Pharmacology, 2017, Elsevier/Gold Standard.

22. Lesinurad/Allopurinol / Mild to Moderate Renal Impairment _____ _____

Alert Message: Patients with moderate renal impairment receiving lesinurad have been shown to have a higher occurrence of renal related adverse reactions compared to patients with mild renal impairment or normal renal function. No dosage adjustment is recommended in patients with an eCLcr 45 to less than 60 mL/min, however frequent renal function monitoring is recommended. A lesinurad-containing agent should not be initiated in patients with an eCLcr less than 45 mL/min and should be discontinued when eCLcr is persistently less than 45 mL/min.

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C **(Include)**
Lesinurad		CKD 2 & 3

References:
Duzallo Prescribing Information, Aug. 2017, Ironwood Pharmaceuticals, Inc.
Clinical Pharmacology, 2017, Elsevier/Gold Standard.

23. Lesinurad/Allopurinol / Tumor Lysis Syndrome & Lesch-Nyhan Syndrome _____ _____

Alert Message: The use of Duzallo (lesinurad/allopurinol) is contraindicated in patients with tumor lysis syndrome or Lesch-Nyhan syndrome, where the rate of uric acid formation is greatly increased.

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

Util A	Util B	Util C
Lesinurad/Allopurinol	Tumor Lysis Syndrome	
	Lesch-Nyhan Syndrome	

References:
Duzallo Prescribing Information, Aug. 2017, Ironwood Pharmaceuticals, Inc.
Clinical Pharmacology, 2017, Elsevier/Gold Standard.

24. Lesinurad/Allopurinol / Severe Hepatic Impairment _____ _____

Alert Message: The use of Duzallo (lesinurad/allopurinol) is not recommended in patients with severe hepatic impairment as it has not been studied in this patient population. No dosage adjustment is required in patients with mild or moderate hepatic impairment (Child-Pugh classes A and B).

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

Util A	Util B	Util C
Lesinurad/Allopurinol	Cirrhosis	
	Hepatic Fibrosis	

References:

Duzallo Prescribing Information, Aug. 2017, Ironwood Pharmaceuticals, Inc.
Clinical Pharmacology, 2017, Elsevier/Gold Standard.

25. Lesinurad/Allopurinol / Nonadherence _____ _____

Alert Message: Based on refill history, your patient may be underutilizing Duzallo (lesinurad/allopurinol). 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
Allopurinol		

References:

Osterberg L, Blaschke T. Adherence to Medication. N Engl J Med 2005; 353:487- 497.
Duzallo Prescribing Information, Aug. 2017, Ironwood Pharmaceuticals, Inc.
Harrold LR, Andrade SE, Briesacher BA, et al., Adherence with Urate-Lowering Therapies for the Treatment of Gout. Arthritis Res Ther. 2009;11(2).
De Vera MA, Marcotte G, Rai S, et al., Medication Adherence in Gout: A Systemic Review. Arthritis Care & Research. Vol. 66, No.10, October 2014, pp 1551-1559.

26. Lesinurad/Allopurinol / Moderate CYP2C9 Inhibitors _____ _____

Alert Message: Concurrent use of Duzallo (lesinurad/allopurinol) with moderate CYP2D9 inhibitors (e.g., fluconazole, amiodarone, and miconazole) should be done with caution. The lesinurad component of the combo product is a CYP2C9 substrate and concomitant use with a CYP2C9 inhibitor may result in increased lesinurad exposure and risk of lesinurad-related adverse effects

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

Util A	Util B	Util C
Lesinurad/Allopurinol	Fluconazole	
	Amiodarone	
	Abiraterone	
	Sorafenib	
	Miconazole	

References:

Duzallo Prescribing Information, Aug. 2017, Ironwood Pharmaceuticals, Inc.
Clinical Pharmacology, 2017, Elsevier/Gold Standard.

27. Lesinurad/Allopurinol / CYP2C9 Inducers _____ _____

Alert Message: Concurrent use of Duzallo (lesinurad/allopurinol) with CYP2C9 inducers (e.g., carbamazepine, rifampin, and enzalutamide) should be done with caution. The lesinurad component of the combo product is a CYP2C9 substrate and concomitant use with these agents may result in decreased lesinurad exposure and diminished therapeutic effect. Monitor patients for reduction in lesinurad/allopurinol efficacy or consider therapy modification.

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

Util A	Util B	Util C
Lesinurad/Allopurinol	Carbamazepine	
	Rifampin	
	Enzalutamide	

References:
Duzallo Prescribing Information, Aug. 2017, Ironwood Pharmaceuticals, Inc.
Clinical Pharmacology, 2017, Elsevier/Gold Standard.

28. Lesinurad/Allopurinol / Epoxide Hydrolase Inhibitors _____ _____

Alert Message: Duzallo (lesinurad/allopurinol) should not be administered with an epoxide hydrolase inhibitor (i.e., valproic acid). Concurrent use of these agents may interfere with metabolism of lesinurad component of the combo product.

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

Util A	Util B	Util C
Lesinurad/Allopurinol	Valproic Acid	

References:
Duzallo Prescribing Information, Aug. 2017, Ironwood Pharmaceuticals, Inc.
Clinical Pharmacology, 2017, Elsevier/Gold Standard.

29. Lesinurad/Allopurinol / Hormonal Contraceptives _____ _____

Alert Message: Hormonal contraceptives including oral, injectable, transdermal, and implantable forms may not be reliable when co-administered with Duzallo (lesinurad/allopurinol). Females should use additional methods of contraception and not rely on hormonal contraception alone when taking a lesinurad-containing product.

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

Util A	Util B	Util C
Lesinurad/Allopurinol	Oral Contraceptives	
	Injectable Contraceptives	
	Transdermal Contraceptives	
	Implantable Contraceptives	

References:
Duzallo Prescribing Information, Aug. 2017, Ironwood Pharmaceuticals, Inc.
Clinical Pharmacology, 2017, Elsevier/Gold Standard.

30. Lesinurad/Allopurinol / Aspirin > 325 mg/day _____ _____

Alert Message: Aspirin, at doses higher than 325 mg per day may decrease the efficacy of Duzallo (lesinurad/allopurinol). Aspirin at doses of 325 mg or less per day (i.e., for cardiovascular protection) does not decrease the efficacy of lesinurad and can be co-administered with lesinurad.

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

Util A	Util B	Util C
Aspirin	Lesinurad/Allopurinol	

Max Dose: > 325 mg/day

References:
Duzallo Prescribing Information, Aug. 2017, Ironwood Pharmaceuticals, Inc.
Clinical Pharmacology, 2017, Elsevier/Gold Standard.

31. Allopurinol / Thiazides _____ _____

Alert Message: Concurrent use of an allopurinol-containing agent and thiazide diuretics may contribute to the enhancement of allopurinol toxicity in some patients. Although a causal mechanism and a cause-and-effect relationship have not been established, current evidence suggests that renal function should be monitored in patients on thiazide diuretics and allopurinol even in the absence of renal failure, and dosage levels should be even more conservatively adjusted in those patients on such combined therapy if diminished renal function is detected.

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

Util A	Util B	Util C
Allopurinol	HCTZ	
Lesinurad/Allopurinol	Chlorothiazide	
	Methyclothiazide	
	Bendroflumethiazide	
	Chlorthalidone	
	Indapamide	
	Metolazone	

References:
Duzallo Prescribing Information, Aug. 2017, Ironwood Pharmaceuticals, Inc.
Clinical Pharmacology, 2017, Elsevier/Gold Standard.

32. Lesinurad/Allopurinol / Therapeutic Appropriateness - Pediatrics _____ _____

Alert Message: The safety and effectiveness of Duzallo (lesinurad/allopurinol) have not been established in patients under 18 years of age.

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C
Lesinurad		

Age Range: 0-17 yoa

References:
Duzallo Prescribing Information, Aug. 2017, Ironwood Pharmaceuticals, Inc.
Clinical Pharmacology, 2017, Elsevier/Gold Standard.

33. Sumatriptan/Naproxen / Overutilization _____ _____

Alert Message: Treximet (sumatriptan/naproxen) may be over-utilized. The manufacturer's recommended maximum daily dose in adults is two 85mg sumatriptan/500mg naproxen tablets taken at least 2 hours apart. The safety of treating an average of more than 5 migraine headaches in adults in in a 30-day period has not been established.

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C
Sumatriptan/Naproxen		

Max Dose: 2 tablets per day
Age Range: 18-999 yoa

References:
Clinical Pharmacology, 2017 Elsevier/Gold Standard.
Facts & Comparisons, 2017 Updates, Wolters Kluwer Health.

34. Sumatriptan/Naproxen / Overutilization 12 – 17 yoa _____ _____

Alert Message: Treximet (sumatriptan/naproxen) may be over-utilized. The manufacturer's recommended maximum daily dose in patients 12 to 17 years of age is one (85mg sumatriptan/500mg naproxen) tablet per day. The safety of treating an average of more than 2 migraine headaches in pediatric patients in a 30-day period has not been established.

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C
Sumatriptan/Naproxen		

Max Dose: 1 tablet per day
Age Range: 12 – 17 yoa

References:
Clinical Pharmacology, 2017 Elsevier/Gold Standard.
Facts & Comparisons, 2017 Updates, Wolters Kluwer Health.

35. Sumatriptan/Naproxen / Overutilization _____ _____

Alert Message: Treximet (sumatriptan/naproxen) use is contraindicated in patients with severe hepatic impairment.

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

Util A	Util B	Util C
Sumatriptan/Naproxen	Severe Hepatic Impairment	

References:
Clinical Pharmacology, 2017 Elsevier/Gold Standard.
Facts & Comparisons, 2017 Updates, Wolters Kluwer Health.

36. Sumatriptan/Naproxen / Overutilization _____ _____

Alert Message: Treximet (sumatriptan/naproxen) may be over-utilized. The manufacturer's recommended maximum daily dose in patients with mild to moderate hepatic impairment is one 10mg sumatriptan/60mg naproxen tablet per day.

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C **(Include)**
Sumatriptan/Naproxen		Hepatic Impairment

Max Dose: 10mg sumatriptan/60mg naproxen

References:
Clinical Pharmacology, 2017 Elsevier/Gold Standard.
Facts & Comparisons, 2017 Updates, Wolters Kluwer Health.

37. Sumatriptan/Naproxen / Therapeutic Appropriateness _____ _____

Alert Message: The safety and effectiveness of Treximet (sumatriptan/naproxen) in pediatric patients under 12 years of age have not been established.

Conflict Code: TA - **T**herapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C
Sumatriptan/Naproxen		

Age Range: 0-11 yoa

References:
Clinical Pharmacology, 2017 Elsevier/Gold Standard.
Facts & Comparisons, 2017 Updates, Wolters Kluwer Health.

38. Itraconazole Tabs / Dofetilide _____ _____

Alert Message: Concurrent use of Onmel (itraconazole tablets) with dofetilide is contraindicated. Concomitant use of these agents may result in serious and/or life-threatening events. Itraconazole is a potent CYP3A4 inhibitor and use with dofetilide, a CYP3A4 substrate, may result in elevated dofetilide plasma concentrations.

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

Util A	Util B	Util C
Itraconazole Tabs	Dofetilide	

References:
Facts & Comparisons, 2017 Wolters Kluwer Health.
Onmel Prescribing Information, Nov. 2012, Merz Pharmaceuticals, LLC.

39. Itraconazole Tabs / Ticagrelor _____ _____

Alert Message: Concurrent use of Onmel (itraconazole tablets) with Brilinta (ticagrelor) is contraindicated. Concomitant use of these agents may result in serious and/or life-threatening events. Itraconazole is a potent CYP3A4 inhibitor and use with ticagrelor, a CYP3A4 substrate, may result in elevated ticagrelor plasma concentrations.

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

Util A	Util B	Util C
Itraconazole Tabs	Ticagrelor	

References:
Facts & Comparisons, 2017 Wolters Kluwer Health.
Onmel Prescribing Information, Nov. 2012, Merz Pharmaceuticals, LLC.

40. Itraconazole Tabs / Triazolam _____ _____

Alert Message: Concurrent use of Onmel (itraconazole tablets) with triazolam is contraindicated. Concurrent use of these agents may result in serious and/or life-threatening events. Itraconazole if a potent CYP3A4 inhibitor and use with triazolam, a CYP3A4 substrate, may result in elevated triazolam plasma concentrations.

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

Util A	Util B	Util C
Itraconazole Tabs	Triazolam	

References:
Facts & Comparisons, 2017 Wolters Kluwer Health.
Onmel Prescribing Information, Nov. 2012, Merz Pharmaceuticals, LLC.

41. Itraconazole Tabs / Midazolam (Oral) _____ _____

Alert Message: Concurrent use of Onmel (itraconazole tablets) with oral midazolam is contraindicated. Concomitant use of these agents may result in serious and/or life-threatening events. Itraconazole is a potent CYP3A4 inhibitor and use with oral midazolam, a CYP3A4 substrate, may result in elevated midazolam plasma concentrations.

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

Util A	Util B	Util C
Itraconazole Tabs	Midazolam - oral	

References:
Facts & Comparisons, 2017 Wolters Kluwer Health.
Onmel Prescribing Information, Nov. 2012, Merz Pharmaceuticals, LLC.

42. Dupilumab / Overutilization _____ _____

Alert Message: The recommended dose of Dupixent (dupilumab) for adult patients is an initial dose of 600 mg (two 300 mg injections), followed by 300 mg given every other week.

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C
Dupilumab		

Maintenance Max Dose: 300mg every other week.

References:
Clinical Pharmacology, 2017 Elsevier/Gold Standard.
Dupixent Prescribing Information, March 2017, Regeneron Pharmaceuticals, Inc.

43. Dupilumab / Asthma _____ _____

Alert Message: Dupixent (dupilumab) is an interleukin-4 receptor alpha antagonist which may improve asthma symptoms. Advise patients with co-morbid asthma receiving dupilumab not to adjust or stop their asthma treatments without consultation with their physicians. Safety and efficacy of dupilumab have not been established in the treatment of asthma.

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C (Include)
Dupilumab		Asthma

References:
Clinical Pharmacology, 2017 Elsevier/Gold Standard.
Dupixent Prescribing Information, March 2017, Regeneron Pharmaceuticals, Inc.

44. Dupilumab / Therapeutic Appropriateness - Age _____ _____

Alert Message: Safety and efficacy of Dupixent (dupilumab) in pediatric patients (<18 years of age) have not been established.

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C
Dupilumab		

Age Range: < 18 yoa

References:
Clinical Pharmacology, 2017 Elsevier/Gold Standard.
Dupixent Prescribing Information, March 2017, Regeneron Pharmaceuticals, Inc.

45. QVAR Redihaler / Therapeutic Appropriateness _____ _____

Alert Message: The safety and effectiveness of Qvar Redihaler (beclomethasone) in pediatric patients below the age of 4 years have not been established.

Conflict Code: TA - Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C
Beclomethasone breath actuated		

Age Range: < 4 yoa

References:
QVAR Redihaler Prescribing Information, August 2017, Teva Pharmaceuticals, LLC,
Clinical Pharmacology, 2017 Elsevier Gold Standard.

46. Naldemedine / Overutilization _____ _____

Alert Message: Symproic (naldemedine) may be over-utilized. The manufacturer's recommended dosage of naldemedine, for the treatment of opioid-induced constipation in patients with chronic non-cancer pain, is 0.2 mg once daily.

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C
Naldemedine		

Max Dose: 0.2 mg/day

References:
Facts & Comparisons, 2017 Wolters Kluwer Health.
Symproic Prescribing Information, March 2017, Shionogi Inc.

47. Naldemedine / Opiate Agonists _____ _____

Alert Message: The review of the patient's drug history did not reveal current use of opioid medication. Symproic (naldemedine) is approved for the treatment of opioid-induced constipation (OIC) in adults with chronic non-cancer pain. Naldemedine should be discontinued if treatment with the opioid medication is discontinued.

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C **(Negating)**
Naldemedine		Meperidine
		Morphine
		Codeine
		Hydrocodone
		Oxycodone
		Oxymorphone
		Levorphanol
		Fentanyl
		Tramadol
		Tapentadol

References:
Facts & Comparisons, 2017 Wolters Kluwer Health.
Symproic Prescribing Information, March 2017, Shionogi Inc.

48. Naldemedine / Gastrointestinal Obstruction _____ _____

Alert Message: Symproic (naldemedine) use is contraindicated in patients with known or suspected gastrointestinal obstruction and patients at increased risk of recurrent obstruction, due to the potential for gastrointestinal perforation. Monitor patients for development of severe, persistent, or worsening abdominal pain and discontinue in patients who develop this symptom.

Conflict Code: TA – Therapeutic Appropriateness (Contraindication)
Drugs/Diseases

Util A	Util B	Util C **(Negating)**
Naldemedine		Gastrointestinal Obstruction

References:
Facts & Comparisons, 2017 Wolters Kluwer Health.
Symproic Prescribing Information, March 2017, Shionogi Inc.

49. Naldemedine / Reduction in GI Wall Integrity _____ _____

Alert Message: Symproic (naldemedine), a peripherally acting opioid antagonist, should be used with caution in patients with conditions that may result in impaired integrity of the gastrointestinal tract wall. Cases of gastrointestinal perforation have been reported in patients receiving another peripherally acting opioid antagonist who had conditions associated with localized reduction of structural integrity in the wall of the gastrointestinal tract. Monitor patients for the development of severe, persistent, or worsening abdominal pain and discontinue naldemedine in patients who develop these symptoms.

Conflict Code: TA – Therapeutic Appropriateness (Warning)
Drugs/Diseases

Util A	Util B	Util C **(Include)**
Naldemedine		Crohn's Disease
		Peptic, Gastric, Duodenal & Gastrojejunal Ulcer Disease
		Perforation of Intestine
		Diverticular Disease of Intestine
		Malignant Neoplasm of Intestine
		Malignant Neoplasm of Stomach

References:
Facts & Comparisons, 2017 Wolters Kluwer Health.
Symproic Prescribing Information, March 2017, Shionogi Inc.

50. Naldemedine / Therapeutic Appropriateness _____ _____

Alert Message: Safety and effectiveness of Symproic (naldemedine) have not been established in pediatric patients.

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C
Naldemedine		

Age Range: 0 – 17 yoa

References:
Facts & Comparisons, 2017 Wolters Kluwer Health.
Symproic Prescribing Information, March 2017, Shionogi Inc.

51. Naldemedine / Severe Hepatic Impairment _____ _____

Alert Message: Symproic (naldemedine) has not been studied in patients with severe hepatic impairment and use should be avoided in these patients. No dose adjustment of naldemedine is required in patients with mild or moderate hepatic impairment.

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C **(Include)**
Naldemedine		Severe Hepatic Impairment

References:
Facts & Comparisons, 2017 Wolters Kluwer Health.
Symproic Prescribing Information, March 2017, Shionogi Inc.

52. Naldemedine / Strong CYP3A4 Inducers _____ _____

Alert Message: Concomitant use of Symproic (naldemedine) with strong CYP3A4 inducers (e.g., phenytoin, rifampin, and carbamazepine) should be avoided. Naldemedine is a CYP3A4 substrate and concomitant use with a strong CYP3A4 inducer may result in decreased exposure of naldemedine leading to reduced efficacy.

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

Util A	Util B	Util C
Naldemedine	Phenobarbital	
	Primidone	
	Phenytoin	
	Carbamazepine	
	Rifampin	
	Rifabutin	
	Rifapentine	

References:
Facts & Comparisons, 2017 Wolters Kluwer Health.
Symproic Prescribing Information, March 2017, Shionogi Inc.

53. Naldemedine / Other Opioid Antagonists _____ _____

Alert Message: The concurrent use of opioid antagonists should be avoided. Concomitant use of these agents may have an additional effect of opioid receptor antagonism and increased risk of opioid withdrawal.

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

Util A	Util B	Util C
Naldemedine	Methylnaltrexone	
	Naloxegol	

References:
Facts & Comparisons, 2017 Wolters Kluwer Health.
Symproic Prescribing Information, March 2017, Shionogi Inc.

54. Naldemedine / Moderate & Strong CYP3A4 inhibitors _____ _____

Alert Message: The concurrent use of Symproic (naldemedine), a CYP3A4 substrate, with a moderate or strong CYP3A4 inhibitor may result in increased naldemedine plasma concentrations. Monitor patients in concurrent therapy for naldemedine-related adverse reactions (e.g., gastroenteritis, diarrhea, abdominal pain).

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

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

References:
Facts & Comparisons, 2017 Wolters Kluwer Health.
Symproic Prescribing Information, March 2017, Shionogi Inc.
FDA: Drug Development and Drug Interactions: Tables of Substrates, Inhibitors\and Inducers. Available at: http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/Drug\InteractionaLabeling/ucm093664.htm

55. Naldemedine / P-Glycoprotein Inhibitors _____ _____

Alert Message: The concurrent use of Symproic (naldemedine), a P-gp substrate, with a P-gp inhibitor (e.g., amiodarone, verapamil, and ranolazine) may result in increased naldemedine plasma concentrations. Monitor patients on concurrent therapy for naldemedine-related adverse reactions (e.g., gastroenteritis, diarrhea, abdominal pain).

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

Util A	Util B		Util C
Naldemedine	Amiodarone	Propafenone	
	Captopril	Quinidine	
	Carvedilol	Ranolazine	
	Clarithromycin	Ritonavir	
	Cyclosporine	Verapamil	
	Dronedarone	Itraconazole	
	Lapatinib	Ketoconazole	

References:
Facts & Comparisons, 2017 Wolters Kluwer Health.
Symproic Prescribing Information, March 2017, Shionogi Inc.
FDA: Drug Development and Drug Interactions: Tables of Substrates, Inhibitors and Inducers. Available at: http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/Drug\InteractionaLabeling/ucm093664.htm

56. Naldemedine / Pregnancy / Pregnancy Negating _____ _____

Alert Message: There is no available data with Symproic (naldemedine) in pregnant women to inform a drug-associated risk of major birth defects and miscarriage. There is a potential for opioid withdrawal in a fetus when naldemedine is used in pregnant women. Naldemedine should be used during pregnancy only if the potential benefit justifies the potential risk.

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C **(Negate)**
Naldemedine	Pregnancy	Delivery
		Miscarriage
		Abortion

Gender: Female
Age Range 11 – 50 yoa

References:
Facts & Comparisons, 2017 Wolters Kluwer Health.
Symproic Prescribing Information, March 2017, Shionogi Inc.

57. Naldemedine / Lactation & Disorders of Lactation _____ _____

Alert Message: There is no information regarding the presence of Symproic (naldemedine) in human milk. Naldemedine has been shown to be present in the milk of rats. Because of the potential for serious adverse reactions, including opioid withdrawal in breastfed infants, a decision should be made to discontinue breastfeeding or discontinue the drug, taking into account the importance of the drug to the mother. If the drug is discontinued in order to minimize drug exposure to a breasted infant, advise women that breastfeeding may be resumed 3 days after the final dose of naldemedine.

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C
Naldemedine	Lactation	
	Other Disorder of Lactation	

Gender: Female
Age Range 11 – 50 yoa

References:
Facts & Comparisons, 2017 Wolters Kluwer Health.
Symproic Prescribing Information, March 2017, Shionogi Inc.

58. Glecaprevir/Pibrentasvir / Overutilization _____ _____

Alert Message: The manufacturer's recommended maximum daily dose of Mavyret (glecaprevir/pibrentasvir) is three tablets taken once daily with food (total daily dose: glecaprevir 300 mg and pibrentasvir 120 mg).

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C
Glecaprevir/Pibrentasvir		

Max Dose: 3 tablets/day

References:
Clinical Pharmacology, 2017 Elsevier/Gold Standard.
Mavyret Prescribing Information, August 2017, AbbVie Inc.

59. Glecaprevir/Pibrentasvir / Hepatic Impairment _____ _____

Alert Message: Mavyret (glecaprevir/pibrentasvir) is not recommended in patients with moderate hepatic impairment (Child-Pugh B) as safety and efficacy has not been established. Glecaprevir/pibrentasvir is contraindicated in patients with severe hepatic impairment (Child-Pugh C) due to higher exposure of glecaprevir and pibrentasvir. No dosage adjustment is required in patients with mild hepatic impairment.

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C **(Include)**
Glecaprevir/Pibrentasvir		Hepatic Impairment

References:
Clinical Pharmacology, 2017 Elsevier/Gold Standard.
Mavyret Prescribing Information, August 2017, AbbVie Inc.

60. Glecaprevir/Pibrentasvir / Atazanavir _____ _____

Alert Message: Concurrent use of Mavyret (glecaprevir/pibrentasvir) with atazanavir-containing agents is contraindicated due to the increased risk of ALT elevations. In a drug interaction study co-administration of atazanavir/rtv with glecaprevir/pibrentasvir resulted in a significant increase in both glecaprevir and pibrentasvir exposure.

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

Util A	Util B	Util C
Glecaprevir/Pibrentasvir	Atazanavir	

References:
Clinical Pharmacology, 2017 Elsevier/Gold Standard.
Mavyret Prescribing Information, August 2017, AbbVie Inc.

61. Glecaprevir/Pibrentasvir / Rifampin _____ _____

Alert Message: Concurrent use of Mavyret (glecaprevir/pibrentasvir) with rifampin is contraindicated due to the potential for loss of antiviral efficacy. Both components of the antiviral agent are P-gp substrates and co-administration with rifampin, a P-gp inducer, has been shown to significantly decrease glecaprevir and pibrentasvir exposure.

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

Util A	Util B	Util C
Glecaprevir/Pibrentasvir	Rifampin	

References:
Clinical Pharmacology, 2017 Elsevier/Gold Standard.
Mavyret Prescribing Information, August 2017, AbbVie Inc.

62. Glecaprevir/Pibrentasvir / Carbamazepine _____ _____

Alert Message: Concurrent use of Mavyret (glecaprevir/pibrentasvir) with carbamazepine is not recommended due to the potential for loss of antiviral efficacy. Both components of the antiviral agent are P-gp substrates and co-administration with carbamazepine, a P-gp inducer, has been shown to decrease glecaprevir and pibrentasvir exposure.

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

Util A	Util B	Util C
Glecaprevir/Pibrentasvir	Carbamazepine	

References:
Clinical Pharmacology, 2017 Elsevier/Gold Standard.
Mavyret Prescribing Information, August 2017, AbbVie Inc.

63. Glecaprevir/Pibrentasvir / Efavirenz _____ _____

Alert Message: Concurrent use of Mavyret (glecaprevir/pibrentasvir) with an efavirenz-containing agent is not recommended due to the potential for loss of antiviral efficacy. Both components of the antiviral agent are P-gp substrates and co-administration with efavirenz, a P-gg inducer, has been shown to decrease glecaprevir and pibrentasvir exposure.

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

Util A	Util B	Util C
Glecaprevir/Pibrentasvir	Efavirenz	

References:
Clinical Pharmacology, 2017 Elsevier/Gold Standard.
Mavyret Prescribing Information, August 2017, AbbVie Inc.

64. Glecaprevir/Pibrentasvir / Lopinavir/rtv _____ _____

Alert Message: Concurrent use of Mavyret (glecaprevir/pibrentasvir) with Kaletra (lopinavir/rtv) is not recommended due to the risk of increased glecaprevir and pibrentasvir exposure. Both components of the antiviral agent are substrates for P-gp and BCRP transporters and glecaprevir is also an OATP1B1/3 substrate. Lopinavir/rtv can inhibit OATP, P-gp, and BCRP transporters and co-administration with the antiviral agent may result in elevated antiviral plasma concentrations.

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

Util A	Util B	Util C
Glecaprevir/Pibrentasvir	Lopinavir/rtv	

References:
Clinical Pharmacology, 2017 Elsevier/Gold Standard.
Mavyret Prescribing Information, August 2017, AbbVie Inc.
Mavyret (glecaprevir/pibrentasvir) Drug Approval Package. Clinical Pharmacology and Biopharmaceutics Review(s). Center for Drug Evaluation and Research. App No. 209395Orig1s000. August 3, 2017.
Available at: https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/209394Orig1s000ClinPharmR.pdf

65. Glecaprevir/Pibrentasvir / Darunavir / Ritonavir _____ _____

Alert Message: Concurrent use of Mavyret (glecaprevir/pibrentasvir) with ritonavir-boosted Prezista (darunavir) is not recommended due to the risk of increased glecaprevir and pibrentasvir exposure. Both components of the antiviral agent are substrates for P-gp and BCRP transporters and glecaprevir is also an OATP1B1/3 substrate. Co-administration with the antiviral agent with the protease inhibitor regimen may result in elevated antiviral plasma concentrations.

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

Util A	Util B	Util C **(Include)**
Glecaprevir/Pibrentasvir	Darunavir	Ritonavir

References:
Clinical Pharmacology, 2017 Elsevier/Gold Standard.
Mavyret Prescribing Information, August 2017, AbbVie Inc.
Mavyret (glecaprevir/pibrentasvir) Drug Approval Package. Clinical Pharmacology and Biopharmaceutics Review(s). Center for Drug Evaluation and Research. App No. 209395Orig1s000. August 3, 2017.
Available at: https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/209394Orig1s000ClinPharmR.pdf

66. Glecaprevir/Pibrentasvir / Digoxin _____ _____

Alert Message: Concurrent use of Mavyret (glecaprevir/pibrentasvir) with digoxin may result in increased digoxin plasma concentrations. Digoxin serum concentrations should be measured before initiating glecaprevir/pibrentasvir and monitored during therapy. If digoxin concentrations need to be reduced the manufacturer recommends decreasing the digoxin dose by approximately 50% or by modifying the dosing frequency and continue monitoring.

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

Util A	Util B	Util C
Glecaprevir/Pibrentasvir	Digoxin	

References:
Clinical Pharmacology, 2017 Elsevier/Gold Standard.
Mavyret Prescribing Information, August 2017, AbbVie Inc.

67. Glecaprevir/Pibrentasvir / Ethinyl Estradiol-Containing Products _____ _____

Alert Message: Concurrent use of Mavyret (glecaprevir/pibrentasvir) with an ethinyl estradiol-containing product is not recommended due to the increased risk of ALT elevations. The mechanism of this interaction is unknown.

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

Util A	Util B	Util C
Glecaprevir/Pibrentasvir	Ethinyl Estradiol-Containing Products	

References:
Clinical Pharmacology, 2017 Elsevier/Gold Standard.
Mavyret Prescribing Information, August 2017, AbbVie Inc.

68. Glecaprevir/Pibrentasvir / Atorvastatin - All _____ _____

Alert Message: Concurrent use of Mavyret (glecaprevir/pibrentasvir) with an atorvastatin-containing agent is not recommended. Co-administration of these agents may result in elevated atorvastatin plasma concentrations and risk of myopathy, including rhabdomyolysis. Atorvastatin is a substrate of CYP3A4 isozyme and P-gp and OATP1B1 transporters and both glecaprevir and pibrentasvir are P-gp and OATP1B1 transport inhibitors as well as weak inhibitors of CYP3A-mediated metabolism.

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

Util A	Util B	Util C
Glecaprevir/Pibrentasvir	Atorvastatin	
	Atorvastatin/Amlodipine	

References:
Clinical Pharmacology, 2017 Elsevier/Gold Standard.
Mavyret Prescribing Information, August 2017, AbbVie Inc.
Mavyret (glecaprevir/pibrentasvir) Drug Approval Package. Clinical Pharmacology and Biopharmaceutics Review(s). Center for Drug Evaluation and Research. App No. 209395Orig1s000. August 3, 2017.
Available at: https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/209394Orig1s000ClinPharmR.pdf

69. Glecaprevir/Pibrentasvir / Lovastatin _____ _____

Alert Message: Concurrent use of Mavyret (glecaprevir/pibrentasvir) with lovastatin is not recommended. Co-administration of these agents may result in elevated lovastatin plasma concentrations and risk of myopathy, including rhabdomyolysis. Lovastatin is a substrate of CYP3A4 isozyme, and P-gp and OATP1B1 transporters and both glecaprevir and pibrentasvir are P-gp and OATP1B1 transport inhibitors as well as weak inhibitors of CYP3A-mediated metabolism.

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

Util A	Util B	Util C
Glecaprevir/Pibrentasvir	Lovastatin	

References:
Clinical Pharmacology, 2017 Elsevier/Gold Standard.
Mavyret Prescribing Information, August 2017, AbbVie Inc.
Mavyret (glecaprevir/pibrentasvir) Drug Approval Package. Clinical Pharmacology and Biopharmaceutics Review(s). Center for Drug Evaluation and Research. App No. 209395Orig1s000. August 3, 2017.
Available at: https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/209394Orig1s000ClinPharmR.pdf

70. Glecaprevir/Pibrentasvir / Simvastatin - All _____ _____

Alert Message: Concurrent use of Mavyret (glecaprevir/pibrentasvir) with a simvastatin-containing agent is not recommended. Co-administration of these agents may result in elevated simvastatin plasma concentrations and risk of myopathy, including rhabdomyolysis. Simvastatin is a substrate for CYP3A4 isozyme and P-gp and OATP1B1 transporters and both glecaprevir and pibrentasvir are P-gp and OATP1B1 transport inhibitors as well as weak inhibitors of CYP3A4-mediated metabolism.

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

Util A	Util B	Util C
Glecaprevir/Pibrentasvir	Simvastatin	
	Simvastatin/Ezetimibe	

References:
Clinical Pharmacology, 2017 Elsevier/Gold Standard.
Mavyret Prescribing Information, August 2017, AbbVie Inc.
Mavyret (glecaprevir/pibrentasvir) Drug Approval Package. Clinical Pharmacology and Biopharmaceutics Review(s). Center for Drug Evaluation and Research. App No. 209395Orig1s000. August 3, 2017.
Available at: https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/209394Orig1s000ClinPharmR.pdf

71. Glecaprevir/Pibrentasvir / Pravastatin _____ _____

Alert Message: Concurrent use of Mavyret (glecaprevir/pibrentasvir) with pravastatin may result in increased pravastatin plasma concentrations and risk of myopathy, including rhabdomyolysis. The manufacturer recommends that the pravastatin dose be reduce by 50% when co-administered with glecaprevir/pibrentasvir. Pravastatin is a substrate for P-gp, OATP1B1/3, and BCRP transporters and both glecaprevir and pibrentasvir are inhibitors of P-gp, OATP1B1/3, and BCRP transport.

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

Util A	Util B	Util C
Glecaprevir/Pibrentasvir	Pravastatin	

References:
Clinical Pharmacology, 2017 Elsevier/Gold Standard.
Mavyret Prescribing Information, August 2017, AbbVie Inc.
Mavyret (glecaprevir/pibrentasvir) Drug Approval Package. Clinical Pharmacology and Biopharmaceutics Review(s). Center for Drug Evaluation and Research. App No. 209395Orig1s000. August 3, 2017.
Available at: https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/209394Orig1s000ClinPharmR.pdf

72. Glecaprevir/Pibrentasvir / Rosuvastatin _____ _____

Alert Message: The dose of rosuvastatin should not exceed 10 mg per day when co-administered with Mavyret (glecaprevir/pibrentasvir). The concurrent use of rosuvastatin with glecaprevir/pibrentasvir has been shown to increase rosuvastatin plasma concentrations which may increase the risk of rosuvastatin-related myopathy, including rhabdomyolysis. Rosuvastatin is a substrate for OATP1B1/3 and BCRP transporters and both glecaprevir and pibrentasvir are OATP1B1 and BCRP transport inhibitors.

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

Util A	Util B	Util C
Glecaprevir/Pibrentasvir	Rosuvastatin 20 & 40mg	

References:
Clinical Pharmacology, 2017 Elsevier/Gold Standard.
Mavyret Prescribing Information, August 2017, AbbVie Inc.
Mavyret (glecaprevir/pibrentasvir) Drug Approval Package. Clinical Pharmacology and Biopharmaceutics Review(s). Center for Drug Evaluation and Research. App No. 209395Orig1s000. August 3, 2017.
Available at: https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/209394Orig1s000ClinPharmR.pdf

73. Glecaprevir/Pibrentasvir / Fluvastatin _____ _____

Alert Message: The concurrent use of Mavyret (glecaprevir/pibrentasvir) with fluvastatin may result in increased fluvastatin plasma concentrations and risk of myopathy, including rhabdomyolysis. The manufacturer recommends using the lowest approved fluvastatin dose and if higher doses are needed, use the lowest necessary dose based on risk/benefit assessment. Fluvastatin is a substrate for OATP1B1/3 and BCRP transporters and the glecaprevir and pibrentasvir are inhibitors of both OATP1B1/3 and BCRP transporters.

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

Util A	Util B	Util C
Glecaprevir/Pibrentasvir	Fluvastatin	

References:
Clinical Pharmacology, 2017 Elsevier/Gold Standard.
Mavyret Prescribing Information, August 2017, AbbVie Inc.
Mavyret (glecaprevir/pibrentasvir) Drug Approval Package. Clinical Pharmacology and Biopharmaceutics Review(s). Center for Drug Evaluation and Research. App No. 209395Orig1s000. August 3, 2017.
Available at: https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/209394Orig1s000ClinPharmR.pdf
Kellick KA, Bottorff M, Toth PP. A Clinician's Guide to Statin Drug-Drug Interactions. Jrnl of Clin Lipidol. 2014;8, S30-S46.

74. Glecaprevir/Pibrentasvir / Pitavastatin _____ _____

Alert Message: Concurrent use of Mavyret (glecaprevir/pibrentasvir) with pitavastatin may result in increased pitavastatin plasma concentrations and risk of myopathy, including rhabdomyolysis. The manufacturer recommends using the lowest approved pitavastatin dose and if higher doses are needed, use the lowest necessary dose based in risk/benefit assessment. Pitavastatin is a substrate for OATP1B1/3, and BCRP transporters and both glecaprevir and pibrentasvir are inhibitors of OATP1B1/3 and BCRP transport.

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

Util A	Util B	Util C
Glecaprevir/Pibrentasvir	Pitavastatin	

References:
Clinical Pharmacology, 2017 Elsevier/Gold Standard.
Mavyret Prescribing Information, August 2017, AbbVie Inc.
Mavyret (glecaprevir/pibrentasvir) Drug Approval Package. Clinical Pharmacology and Biopharmaceutics Review(s). Center for Drug Evaluation and Research. App No. 209395Orig1s000. August 3, 2017.
Available at: https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/209394Orig1s000ClinPharmR.pdf
Kellick KA, Bottorff M, Toth PP. A Clinician's Guide to Statin Drug-Drug Interactions. Jrnl of Clin Lipidol. 2014;8, S30-S46.

75. Glecaprevir/Pibrentasvir / Therapeutic Appropriateness _____ _____

Alert Message: The safety and effectiveness of Mavyret (glecaprevir/pibrentasvir) have not been established in children less than 18 years of age.

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C
Glecaprevir/Pibrentasvir		

Age Range: 0-17 yoa

References:
Clinical Pharmacology, 2017 Elsevier/Gold Standard.
Mavyret Prescribing Information, August 2017, AbbVie Inc.

76. Vosevi / Overutilization _____ _____

Alert Message: The manufacturer's recommended maximum dose of Vosevi (sofosbuvir/velpatasvir/voxilaprevir) is one table per day.

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C
Sofosbuvir/Velpatasvir/Voxilaprevir		

Max Dose: 1 tablet per day

References:
Clinical Pharmacology, 2017 Elsevier/Gold Standard.
Vosevi Prescribing Information, Nov. 2017, Gilead Science, Inc.

77. Vosevi / Hepatic Impairment _____ _____

Alert Message: Vosevi (sofosbuvir/velpatasvir/voxilaprevir) use is not recommended in patients with moderate to severe hepatic impairment (Child-Pugh B or C) due to higher exposure of the voxilaprevir component (up to 6-fold in non-HCV infected subjects).

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C **(Include)**
Sofosbuvir/Velpatasvir/Voxilaprevir		Hepatic Impairment

References:
Clinical Pharmacology, 2017 Elsevier/Gold Standard.
Vosevi Prescribing Information, Nov. 2017, Gilead Science, Inc.

78. Vosevi / Therapeutic Appropriateness _____ _____

Alert Message: The safety and effectiveness of Vosevi (sofosbuvir/velpatasvir/voxilaprevir) have not been established in pediatric patients.

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C
Sofosbuvir/Velpatasvir/Voxilaprevir		

Age Range: 0-17 yoa

References:
Clinical Pharmacology, 2016 Elsevier/Gold Standard.
Vosevi Prescribing Information, Nov. 2017, Gilead Science, Inc.

79. Vosevi / Rifampin _____ _____

Alert Message: The concurrent use of Vosevi (sofosbuvir/velpatasvir/voxilaprevir) with rifampin is contraindicated. Concomitant use of these agents may result in a significant decrease in the plasma concentrations of each of the components of the antiviral combination product leading to reduced therapeutic effect. Rifampin is a P-gp inducer as well as a potent CYP3A4 inducer. Each component of the antiviral is a P-gp substrate and velpatasvir and voxilaprevir are CYP3A4 substrates.

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

Util A	Util B	Util C
Sofosbuvir/Velpatasvir/Voxilaprevir	Rifampin	

References:
Clinical Pharmacology, 2017 Elsevier/Gold Standard.
Vosevi Prescribing Information, Nov. 2017, Gilead Science, Inc.

80. Vosevi / Amiodarone _____ _____

Alert Message: Concurrent use of Vosevi (sofosbuvir/velpatasvir/voxilaprevir) with amiodarone is not recommended. Serious symptomatic bradycardia may occur in patients taking amiodarone, particularly in patients also receiving beta-blockers, or those with underlying cardiac comorbidities, and/or advanced liver disease. In patients without alternative viable treatment options, cardiac monitoring is recommended.

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

Util A	Util B	Util C
Sofosbuvir/Velpatasvir/Voxilaprevir	Amiodarone	

References:
Clinical Pharmacology, 2017 Elsevier/Gold Standard.
Vosevi Prescribing Information, Nov. 2017, Gilead Science, Inc.

81. Vosevi / P-gp Inducers, Mod to Potent CYP2B6, 2C8 & 3A4 Inducers _____ _____

Alert Message: The concurrent use of Vosevi (sofosbuvir/velpatasvir/voxilaprevir) with inducers of P-gp and/or moderate or potent inducers of CYP2B6, CYP2C8, or CYP3A4 is not recommended. Co-administration of these agents may significantly decrease plasma concentrations of sofosbuvir, velpatasvir and/or voxilaprevir leading to potentially reduced antiviral therapeutic effects.

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

Util A	Util B		Util C
Sofosbuvir/Velpatasvir	Carbamazepine	Enzalutamide	
	Phenobarbital	Bosentan	
	Primidone	Efavirenz	
	Phenytoin	Etravirine	
	Oxcarbazepine	Nevirapine	
	Rifapentine	Modafinil	
	Rifabutin		

References:
Clinical Pharmacology, 2017 Elsevier/Gold Standard.
Vosevi Prescribing Information, Nov. 2017, Gilead Science, Inc.
Drug Development and Drug Interactions: Tables of Substrates, Inhibitors and Inducers. Available at: http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/Drug\InteractionaLabeling/ucm093664.htm

82. Vosevi / Antacids _____ _____

Alert Message: It is recommended to separate the administration of an antacid and Vosevi (sofosbuvir/velpatasvir/voxilaprevir) by 4 hours. The velpatasvir component of the antiviral combo product is pH dependent and use with drugs that increase gastric pH are expected to decreased velpatasvir, and therefore its bioavailability.

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

Util A	Util B	Util C
Sofosbuvir/Velpatasvir/Voxilaprevir	Aluminum hydroxide	
	Magnesium hydroxide	
	Calcium Carbonate	
	Sodium Bicarbonate	

References:
Clinical Pharmacology, 2017 Elsevier/Gold Standard.
Vosevi Prescribing Information, Nov. 2017, Gilead Science, Inc.

83. Vosevi / H2 Blockers _____ _____

Alert Message: Caution should be exercised when using Vosevi (sofosbuvir/velpatasvir/voxilaprevir) with an H-2 receptor antagonist. These agents may be administered simultaneously or separated by 12 hours. The H-2 antagonist dose should not exceed a dose that is comparable to famotidine 40 mg twice daily. The velpatasvir component of the antiviral combo product is pH dependent and drugs that increase gastric pH are expected to decrease velpatasvir solubility, and therefore it bioavailability.

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

Util A	Util B	Util C **(Include)**
Cimetidine > 1600mg/day		Sofosbuvir/Velpatasvir/Voxilaprevir
Famotidine > 80mg/day		
Ranitidine > 600mg/day		
Nizatidine > 600mg/day		

References:
Clinical Pharmacology, 2017 Elsevier/Gold Standard.
Vosevi Prescribing Information, Nov. 2017, Gilead Science, Inc.

84. Vosevi / Proton Pump Inhibitors _____ _____

Alert Message: The concurrent use of Vosevi (sofosbuvir/velpatasvir/voxilaprevir) with proton pump inhibitors is not recommended. The solubility of the velpatasvir component of the antiviral combo product is pH dependent and drugs that increase the gastric pH are expected to decrease velpatasvir solubility, and therefore its bioavailability. If concomitant use is considered medically necessary, sofosbuvir/velpatasvir/voxilaprevir can be administered with omeprazole 20 mg. Use with other PPIs has not been studied.

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

Util A	Util B	Util C
Sofosbuvir/Velpatasvir/Voxilaprevir	Omeprazole 40 mg	
	Esomeprazole	
	Lansoprazole	
	Dexlansoprazole	
	Rabeprazole	
	Pantoprazole	

References:
Clinical Pharmacology, 2017 Elsevier/Gold Standard.
Vosevi Prescribing Information, Nov. 2017, Gilead Science, Inc.

85. Vosevi / Digoxin _____ _____

Alert Message: The concurrent use of Vosevi (sofosbuvir/velpatasvir/voxilaprevir) with digoxin, a P-gp substrate, may result in an increase in the plasma concentration of digoxin due to inhibition, by the velpatasvir and voxilaprevir antiviral components, of the P-gp efflux transporter system. Refer to digoxin prescribing information for monitoring and dose modification recommendations.

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

Util A	Util B	Util C
Sofosbuvir/Velpatasvir/Voxilaprevir	Digoxin	

References:
Clinical Pharmacology, 2017 Elsevier/Gold Standard.
Vosevi Prescribing Information, Nov. 2017, Gilead Science, Inc.

86. Vosevi / Tipranavir / Ritonavir _____ _____

Alert Message: The concurrent use of Vosevi (sofosbuvir/velpatasvir/voxilaprevir) with ritonavir-boosted tipranavir is not recommended. Tipranavir is a P-gp inducer and co-administration with the P-gp substrates velpatasvir and sofosbuvir has been shown to result in decreased velpatasvir and sofosbuvir plasma concentrations, leading to reduced antiviral efficacy. The effect on voxilaprevir is unknown.

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

Util A	Util B	Util C **(Include)**
Sofosbuvir/Velpatasvir/Voxilaprevir	Tipranavir	Ritonavir

References:
Clinical Pharmacology, 2017 Elsevier/Gold Standard.
Vosevi Prescribing Information, Nov. 2017, Gilead Science, Inc.

87. Vosevi / Atazanavir & Lopinavir _____ _____

Alert Message: The concurrent user of Vosevi (sofosbuvir/velpatasvir/voxilaprevir) with atazanavir- or lopinavir-containing regimens is not recommended. Both atazanavir and lopinavir are OATP1B1 inhibitors and co-administration with the OATP1B1 substrate voxilaprevir may result in increased voxilaprevir plasma concentrations.

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

Util A	Util B	Util C
Sofosbuvir/Velpatasvir/Voxilaprevir	Atazanavir Lopinavir	

References:
Clinical Pharmacology, 2017 Elsevier/Gold Standard.
Vosevi Prescribing Information, Nov. 2017, Gilead Science, Inc.

88. Vosevi / Tenofovir Disoproxil Fumarate _____ _____

Alert Message: The concurrent use of Vosevi (sofosbuvir/velpatasvir/voxilaprevir) with a tenofovir disoproxil fumarate (DF)-containing regimen may result in increased tenofovir DF plasma concentrations and risk for tenofovir-associated adverse reactions. Tenofovir DF is a BCRP and P-gp substrate and the velpatasvir and voxilaprevir components of the antiviral agent inhibit both BCRP- and P-gp-mediated transport.

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

Util A	Util B	Util C
Sofosbuvir/Velpatasvir/Voxilaprevir	Tenofovir Disoproxil fumarate - All	

References:
Clinical Pharmacology, 2017 Elsevier/Gold Standard.
Vosevi Prescribing Information, Nov. 2017, Gilead Science, Inc.

89. Pravastatin / Vosevi _____ _____

Alert Message: The dose of pravastatin should not exceed 40 mg per day with co-administered with Vosevi (sofosbuvir/velpatasvir/voxilaprevir). The concurrent use of sofosbuvir/velpatasvir/voxilaprevir with pravastatin has been shown to increase pravastatin plasma concentrations which may increase the risk of pravastatin-related myopathy, including rhabdomyolysis. Pravastatin is a OATP1B1/3 substrate and the velpatasvir and voxilaprevir components of the antiviral agent are OATP1B1/3 inhibitors.

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

Util A	Util B	Util C
Pravastatin 80 mg	Sofosbuvir/Velpatasvir/Voxilaprevir	

References:
Clinical Pharmacology, 2017 Elsevier/Gold Standard.
Vosevi Prescribing Information, Nov. 2017, Gilead Science, Inc.

90. Vosevi / Rosuvastatin _____ _____

Alert Message: The concurrent use of Vosevi (sofosbuvir/velpatasvir/voxilaprevir) with rosuvastatin is not recommended due to the increased risk of myopathy, including rhabdomyolysis. The velpatasvir and voxilaprevir components of the antiviral agent are inhibitors of BCRP, OATP1B1/3 transporters and concurrent use with rosuvastatin (both a BCRP and OATP1B1/3 substrate) may result in a significant increase in the plasma concentration of rosuvastatin.

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

Util A	Util B	Util C
Sofosbuvir/Velpatasvir/Voxilaprevir	Rosuvastatin	

References:
Clinical Pharmacology, 2017 Elsevier/Gold Standard.
Vosevi Prescribing Information, Nov. 2017, Gilead Science, Inc.

91. Vosevi / Pitavastatin _____ _____

Alert Message: The concurrent use of Vosevi (sofosbuvir/velpatasvir/voxilaprevir) with pitavastatin is not recommended due to increased risk of myopathy, including rhabdomyolysis. The velpatasvir and voxilaprevir component of the antiviral agent are inhibitors or OATP1B1/3 transport and concurrent use with the OAT1B1/3 substrate, pitavastatin, may result in increased pitavastatin plasma concentration.

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

Util A	Util B	Util C
Sofosbuvir/Velpatasvir/Voxilaprevir	Pitavastatin	

References:
Clinical Pharmacology, 2017 Elsevier/Gold Standard.
Vosevi Prescribing Information, Nov. 2017, Gilead Science, Inc.

92. Vosevi / Atorvastatin _____ _____

Alert Message: The concurrent use of Vosevi (sofosbuvir/velpatasvir/voxilaprevir) with atorvastatin may result in increased atorvastatin plasma concentration and risk of myopathy, including rhabdomyolysis. The manufacturer recommends using the lowest approved atorvastatin dose and if higher doses are needed, use the lowest necessary dose based on risk/benefit assessment. Atorvastatin is a substrate of the P-gp and OATP1B1 transporters and the velpatasvir and voxilaprevir components of the antiviral agent are inhibitors of both P-gp and OATP1B1 transporters.

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

Util A	Util B	Util C
Sofosbuvir/Velpatasvir/Voxilaprevir	Atorvastatin	

References:
Clinical Pharmacology, 2017 Elsevier/Gold Standard.
Vosevi Prescribing Information, Nov. 2017, Gilead Science, Inc.

93. Vosevi / Fluvastatin _____ _____

Alert Message: The concurrent use of Vosevi (sofosbuvir/velpatasvir/voxilaprevir) with fluvastatin may result in increased fluvastatin plasma concentration and risk of myopathy, including rhabdomyolysis. The manufacturer recommends using the lowest approved fluvastatin dose and if higher doses are needed, use the lowest necessary dose based on risk/benefit assessment. Fluvastatin is a substrate of OATP1B1 and BCRP transporters and the velpatasvir and voxilaprevir components of the antiviral agent are inhibitors of both OATP1B1 and BCRP transporters.

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

Util A	Util B	Util C
Sofosbuvir/Velpatasvir/Voxilaprevir	Fluvastatin	

References:
Clinical Pharmacology, 2017 Elsevier/Gold Standard.
Vosevi Prescribing Information, Nov. 2017, Gilead Science, Inc.

94. Vosevi / Lovastatin _____ _____

Alert Message: The concurrent use of Vosevi (sofosbuvir/velpatasvir/voxilaprevir) with lovastatin may result in increased lovastatin plasma concentration and risk of myopathy, including rhabdomyolysis. The manufacture recommends using the lowest approved lovastatin dose based on risk/benefit assessment. Lovastatin is a substrate of P-gp and OATP1B1/3 transporters and both the velpatasvir and voxilaprevir components of the antiviral agent are inhibitors pf P-gp and OATP1B1 transporters.

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

Util A	Util B	Util C
Sofosbuvir/Velpatasvir/Voxilaprevir	Lovastatin	

References:
Clinical Pharmacology, 2017 Elsevier/Gold Standard.
Vosevi Prescribing Information, Nov. 2017, Gilead Science, Inc.
Kellick KA, Bottorff M, Toth PP. A Clinician's Guide to Statin Drug-Drug Interactions. Jrnl of Clin Lipidol. 2014;8, S30-S46.

95. Vosevi / Simvastatin _____ _____

Alert Message: The concurrent use of Vosevi (sofosbuvir/velpatasvir/voxilaprevir) with simvastatin may result in increased simvastatin plasma concentration and risk of myopathy, including rhabdomyolysis. The manufacturer recommends using the lowest approved simvastatin dose based on risk/benefit assessment. Simvastatin is a substrate of P-gp and OATP1B1 transporters and both the velpatasvir and voxilaprevir components of the antiviral agent are inhibitors of P-gp and OATP1B1 transporters.

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

Util A	Util B	Util C
Sofosbuvir/Velpatasvir/Voxilaprevir	Simvastatin	

References:
Clinical Pharmacology, 2017 Elsevier/Gold Standard.
Vosevi Prescribing Information, Nov. 2017, Gilead Science, Inc.
Vosevi (sofosbuvir/velpatasvir/voxilaprevir) Drug Approval Package. Clinical Pharmacology and Biopharmaceutics Review(s). Center for Drug Evaluation and Research. App No. 209195Orig1s000. May 8, 2017.
Available at:https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/209195Orig1s000ClinPharmR.pdf

96. Vosevi / Cyclosporine _____ _____

Alert Message: The concurrent use of Vosevi (sofosbuvir/velpatasvir/voxilaprevir) with cyclosporine is not recommended. Co-administration of these agents has been shown to substantially increase the plasma concentration of the voxilaprevir component of the antiviral agent, the safety of which has not been established. Cyclosporine is an OATP transport inhibitor and a voxilaprevir is a substrate of OATP1B1 and OATP1B3.

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

Util A	Util B	Util C
Sofosbuvir/Velpatasvir/Voxilaprevir	Cyclosporine	

References:
Clinical Pharmacology, 2017 Elsevier/Gold Standard.
Vosevi Prescribing Information, Nov. 2017, Gilead Science, Inc.

97. Vosevi / BCRP Substrates _____ _____

Alert Message: The concurrent use of Vosevi (sofosbuvir/velpatasvir/voxilaprevir) with drugs that are BCRP transporter substrates (e.g., methotrexate, sulfasalazine, and topotecan) is not recommended. Both the velpatasvir and voxilaprevir components of the antiviral agent are inhibitors of BCRP drug transport and co-administration with BCRP substrates may result in increased substrate plasma concentrations.

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

Util A	Util B	Util C
Sofosbuvir/Velpatasvir/Voxilaprevir	Methotrexate	
	Mitoxantrone	
	Imatinib	
	Irinotecan	
	Lapatinib	
	Sulfasalazine	
	Topotecan	

References:
Vosevi Prescribing Information, Nov. 2017, Gilead Science, Inc.

98. Lesinurad/Allopurinol / CYP3A4 Substrates _____ _____

Alert Message: Concurrent use of Duzallo (lesinurad/allopurinol) with a CYP3A4 substrate (e.g., aprepitant, buspirone, and simvastatin) may result in a decrease in systemic exposure and therapeutic effect of the CYP3A4 substrate. The lesinurad component of the combo product is a weak CYP3A4 inducer. The manufacturer recommended monitoring the patient for potential reduction in CYP3A substrate efficacy when co-administered with lesinurad.

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

Util A	Util B			Util C
Lesinurad/Allopurinol	Quinidine	Budesonide	Ticagrelor	
	Amiodarone	Eplerenone	Apixaban	
	Ivabradine	Tolvaptan	Aprepitant	
	Eletriptan	Ifosfamide	Olaparib	
	Sildenafil	Vinblastine	Quetiapine	
	Tadalafil	Vincristine	Palbociclib	
	Vardenafil	Vinorelbine	Lurasidone	
	Avanafil	Etoposide	Dapsone	
	Isradipine	Docetaxel	Solifenacin	
	Felodipine	Abiraterone	Atazanavir	
	Amlodipine	Imatinib	Alfuzosin	
	Disulfiram	Bortezomib	Bedaquiline	
	Eszopiclone	Erlotinib	Silodosin	
	Flurazepam	Sunitinib	Tacrolimus	
	Alprazolam	Dasatinib	Simvastatin	
	Triazolam	Lapatinib	Tofacitinib	
	Midazolam	Nilotinib	Lovastatin	
	Buspirone	Pazopanib	Cilostazol	
	Quazepam	Vandetanib		
	Vilazodone	Crizotinib		
	Hydrocodone	Axitinib		
	Oxycodone	Bosutinib		
	Buprenorphine	Cabozantinib		
	Ethosuximide	Ibrutinib		
	Clonazepam	Ceritinib		
	Tiagabine	Irinotecan		

References:
Duzallo Prescribing Information, Aug. 2017, Ironwood Pharmaceuticals, Inc.
Clinical Pharmacology, 2017, Elsevier/Gold Standard.

DUR Board Meeting
June 6, 2018
Sakakawea Room
State Capitol

North Dakota Medicaid
DUR Board Meeting Agenda
Sakakawea Room
State Capitol
600 East Boulevard Avenue
Bismarck, ND
June 6, 2018
1:00 pm

1. Administrative items
    - Travel vouchers

2. Old business
    - Review and approval of 03/2018 meeting minutes
    - Budget update
    - Review top 15 therapeutic categories/top 25 drugs
    - Prior authorization/PDL update
    - Second review of Anzemet and Zuplenz
    - Second review of biosimilar agents
    - Second review of topical corticosteroid agents
    - Second review of Dupixent
    - Second review of Gocovri
    - Second review of Tussicaps

3. New business
    - Review of Rytary
    - Review of Daxbia
    - Review of Millipred DP
    - Review of Eosinophilic Asthma agents
    - Review of Dermatophytosis (Tinea infections) agents
    - Review of Migraine prophylaxis (CGRP Inhibitors)
    - Utilization review of GLP-1 agents
    - Medication Therapy Management (MTM) program update
    - Retrospective DUR Criteria recommendations
    - Upcoming meeting date/agenda.
        - Next meeting is September 5, 2018 in the Brynhild Haugland Room

4. Adjourn

Please remember to silence all cellular phones during the meeting.

Drug Utilization Review (DUR) Meeting Minutes

March 7, 2018

Members Present: Wendy Brown, Katie Kram, Tanya Schmidt, Laura Schield, Michael Quast, Zach Marty, LeNeika Roehrich, Andrea Honeyman, Carlotta McCleary, Peter Woodrow, Michael Booth, Russ Sobotta

Members Absent: Gaylord Kavlie, Jeffrey Hostetter,

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

Old Business

Chair W. Brown called the meeting to order at 1:04 p.m. Chair W. Brown asked for a motion to approve the minutes of the December meeting. T. Schmidt moved that the minutes be approved and L. Roehrich seconded the motion. Chair W. Brown 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 2017.

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. A total of forty-nine medications were removed from requiring prior authorization and nineteen medications were added to the Medical Billing Only list of medications. The following medications will now require an approved prior authorization: Admelog, Bevyxxa, Bydureon BCISE, diclofenac potassium, diclofenac sodium, diclofenac sodium ER, Duzallo, etodolac, etodolac ER, Hemlibra, Nityr, Odactra, Ozempic, piroxicam, Prevymis, Qtern, Rebinyn, Steglatro, Steglujan, Sublocade, tolmetin, Tracleer, Xhance, and Ximino.

Second Review of Skelaxin

A motion and second was made at the December meeting to place Skelaxin on prior authorization. The topics were brought up for a second review. There was no public comment. It was proposed to add a checkbox for methocarbamol and add verbiage that methocarbamol is also less sedating to the form. A motion to approve amended form and prior authorization criteria was made by K. Kram and seconded by P. Woodrow. Chair W. Brown called for a voice vote and the motion passed with no audible dissent.

Second Review of Eucrisa

A motion and second was made at the December meeting to place Eucrisa on prior authorization. The topics were brought up for a second review. Rob Hansen of Pfizer made public comment regarding drug information on Eucrisa. A motion to approve form and prior authorization criteria was made by J. Hostetter and seconded by L. Schield. Chair W. Brown called for a voice vote and the motion passed with no audible dissent.

Review of First Fill of Narcotics

B. Joyce presented information on day supply limitations and edits of other state Medicaid programs for the first fill of narcotics. The Board discussed whether any changes should be made to North Dakota's current policy. The Board requested that data be brought to the next board meeting on the current average day supply of first narcotic fills to determine if any changes needed to be made to the state policy.

New Business

Anzemet and Zuplenz

T. DeRuiter and A. Murphy reviewed Anzemet and Zuplenz with the Board. The Board proposed the creation of a chemotherapy induced nausea and vomiting criteria set and form, which Anzemet and Zuplenz would fall into. A motion was made by M. Quast to create this new PA criteria class and manage these medications through prior authorization. The motion was seconded by J. Hostetter. This topic will be reviewed at the next meeting

Biosimilar Agents

T. DeRuiter and A. Murphy reviewed biosimilar agents with the Board. A motion was made by K. Kram to manage the medications through prior authorization. The motion was seconded by P. Woodrow. This topic will be reviewed at the next meeting

Dupixent

T. DeRuiter and A. Murphy reviewed Dupixent with the Board. A motion was made by K. Kram to manage the medication through prior authorization. The motion was seconded by J. Hostetter. This topic will be reviewed at the next meeting

Gocovri

T. DeRuiter and A. Murphy reviewed Gocovri with the Board. A motion was made by K. Kram to manage the medication through prior authorization. The motion was seconded by J. Hostetter. This topic will be reviewed at the next meeting

Tussicaps

T. DeRuiter and A. Murphy reviewed Tussicaps with the Board. A motion was made by J. Hostetter to manage the medication through prior authorization. The motion was seconded by P. Woodrow. This topic will be reviewed at the next meeting

Topical Corticosteroid Agents

T. DeRuiter and A. Murphy reviewed topical corticosteroid agents with the Board. A motion was made by L. Roehrich to manage the medication through prior authorization. The motion was seconded by K. Kram. This topic will be reviewed at the next meeting

Review of Codeine and Tramadol Utilization

T. DeRuiter and B. Joyce reviewed the utilization of codeine and tramadol agents with the Board. The presented information showed utilization of the available codeine and tramadol products by age group and further evaluated utilization based on number of patients, average dose, and number of claims per month.

Review of Adderall Utilization

T. DeRuiter and B. Joyce reviewed the utilization of Adderall products with the Board. The presented information showed utilization of the available immediate release and extended release Adderall products based on number of claims and number of patients based on product and dosing strength.

Review of Proton Pump Inhibitor Utilization

T. DeRuiter and B. Joyce reviewed the utilization of proton pump inhibitors with the Board. The presented information showed utilization by drug and evaluate the number of patients on each agent that were receiving greater than once daily dose, those that had been on the medication for greater than 3 months, and those without an appropriate diagnosis for long-term PPI therapy.

Review of Hormone Therapy

B. Joyce discussed a claims processing edit in place for hormone therapies based on gender that prevented males from receiving estrogen hormone therapy and females from receiving testosterone therapy. The Board approved of the removal of these claims processing edits to allow patients of either gender to receive these products.

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 L. Schield seconded the motion. The motion passed with no audible dissent.

Adjournment and Upcoming Meeting Date

K. Kram moved to adjourn the meeting at and P. Woodrow seconded. Chair W. Brown adjourned the meeting at 3:10 pm. The next DUR Board meeting will be held June 6, 2018 at the Capitol in the Sakakawea room in Bismarck.

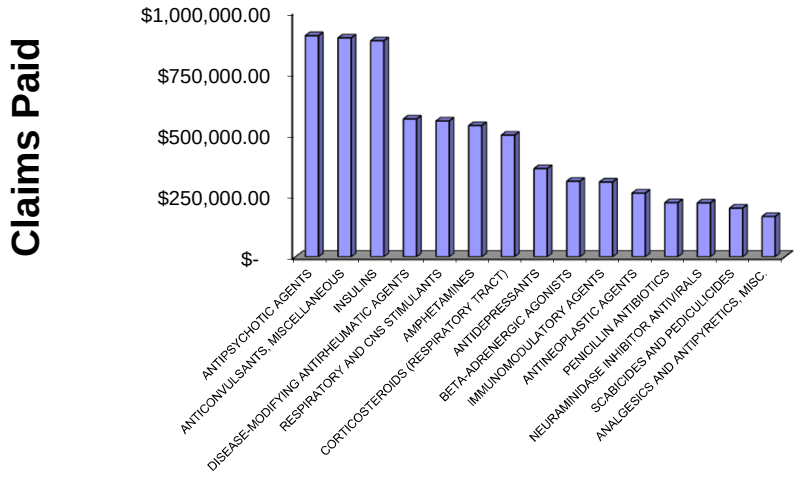
NORTH DAKOTA MEDICAID
Cost Management Analysis

TOP 15 THERAPEUTIC CLASSES BY TOTAL COST OF CLAIMS FROM 01/01/2018 - 03/31/2018

AHFS Therapeutic Class	Rx	Paid	Paid/Rx	% Total Claims
ANTIPSYCHOTIC AGENTS	6,507	$ 902,950.48	$ 138.77	4.33%
ANTICONVULSANTS, MISCELLANEOUS	8,725	$ 893,574.51	$ 102.42	5.80%
INSULINS	1,935	$ 882,141.37	$ 455.89	1.29%
DISEASE-MODIFYING ANTIRHEUMATIC AGENTS	138	$ 563,386.81	$ 4,082.51	0.09%
RESPIRATORY AND CNS STIMULANTS	4,213	$ 555,190.85	$ 131.78	2.80%
AMPHETAMINES	3,524	$ 536,646.88	$ 152.28	2.34%
CORTICOSTEROIDS (RESPIRATORY TRACT)	2,084	$ 497,492.33	$ 238.72	1.39%
ANTIDEPRESSANTS	15,232	$ 361,123.66	$ 23.71	10.12%
BETA-ADRENERGIC AGONISTS	4,221	$ 309,206.09	$ 73.25	2.81%
IMMUNOMODULATORY AGENTS	46	$ 305,848.71	$ 6,648.89	0.03%
ANTINEOPLASTIC AGENTS	276	$ 260,477.69	$ 943.76	0.18%
PENICILLIN ANTIBIOTICS	5,827	$ 221,522.93	$ 38.02	3.87%
NEURAMINIDASE INHIBITOR ANTIVIRALS	1,758	$ 220,394.72	$ 125.37	1.17%
SCABICIDES AND PEDICULICIDES	639	$ 199,162.88	$ 311.68	0.42%
ANALGESICS AND ANTIPYRETICS, MISC.	1,423	$ 164,889.39	$ 115.87	0.95%
Total Top 15	56,548	$ 6,874,009.30	$ 121.56	37.59%

Total Rx Claims From 01/01/2018 - 03/31/2018	150,440

Top 15 Therapeutic Classes
Based on Total Cost of Claims

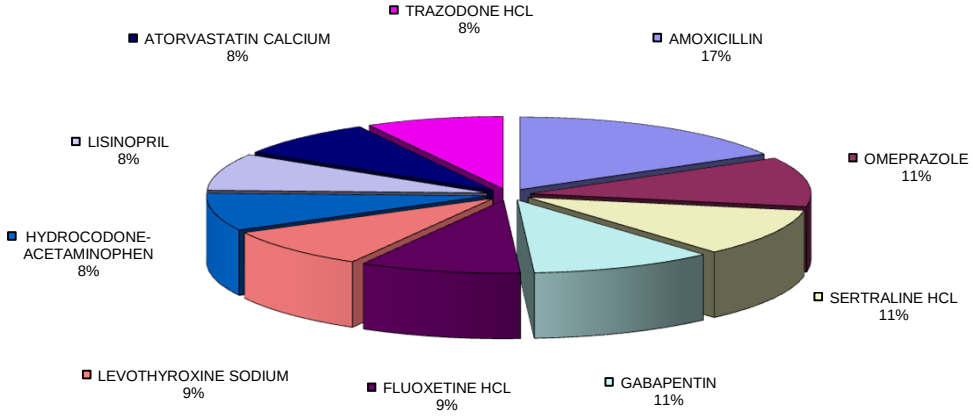


TOP 25 DRUGS BASED ON NUMBER OF CLAIMS FROM 01/01/2018 - 03/31/2018

Drug	AHFS Therapeutic Class	Rx	Paid	Paid/Rx	% Total Claims
AMOXICILLIN	PENICILLIN ANTIBIOTICS	4,080	$ 150,202.46	$ 36.81	2.71%
OMEPRAZOLE	PROTON-PUMP INHIBITORS	2,678	$ 52,547.58	$ 19.62	1.78%
SERTRALINE HCL	ANTIDEPRESSANTS	2,565	$ 49,749.76	$ 19.40	1.70%
GABAPENTIN	ANTICONVULSANTS, MISCELLANEOUS	2,561	$ 91,351.90	$ 35.67	1.70%
FLUOXETINE HCL	ANTIDEPRESSANTS	2,248	$ 32,970.94	$ 14.67	1.49%
LEVOTHYROXINE SODIUM	THYROID AGENTS	2,161	$ 42,123.65	$ 19.49	1.44%
HYDROCODONE-ACETAMINOPHEN	OPIATE AGONISTS	2,021	$ 62,192.87	$ 30.77	1.34%
LISINOPRIL	ANGIOTENSIN-CONVERTING ENZYME INHIBITORS	1,998	$ 46,065.99	$ 23.06	1.33%
ATORVASTATIN CALCIUM	HMG-COA REDUCTASE INHIBITORS	1,998	$ 55,173.27	$ 27.61	1.33%
TRAZODONE HCL	ANTIDEPRESSANTS	1,924	$ 29,229.52	$ 15.19	1.28%
MONTELUKAST SODIUM	LEUKOTRIENE MODIFIERS	1,881	$ 34,512.03	$ 18.35	1.25%
METHYLPHENIDATE ER	RESPIRATORY AND CNS STIMULANTS	1,849	$ 327,065.34	$ 176.89	1.23%
VYVANSE	AMPHETAMINES	1,689	$ 374,960.52	$ 222.00	1.12%
ALBUTEROL SULFATE	BETA-ADRENERGIC AGONISTS	1,673	$ 78,095.31	$ 46.68	1.11%
ESCITALOPRAM OXALATE	ANTIDEPRESSANTS	1,637	$ 32,032.49	$ 19.57	1.09%
CLONIDINE HCL	CENTRAL ALPHA-AGONISTS	1,630	$ 29,855.46	$ 18.32	1.08%
AZITHROMYCIN	MACROLIDE ANTIBIOTICS	1,630	$ 43,901.87	$ 26.93	1.08%
METFORMIN HCL	BIGUANIDES	1,533	$ 22,449.21	$ 14.64	1.02%
AMOXICILLIN-CLAVULANATE POTASS	PENICILLIN ANTIBIOTICS	1,495	$ 59,181.40	$ 39.59	0.99%
OSELTAMIVIR PHOSPHATE	NEURAMINIDASE INHIBITOR ANTIVIRALS	1,468	$ 160,909.80	$ 109.61	0.98%
PROAIR HFA	BETA-ADRENERGIC AGONISTS	1,406	$ 112,504.25	$ 80.02	0.93%
RISPERIDONE	ANTIPSYCHOTIC AGENTS	1,360	$ 19,732.39	$ 14.51	0.90%
QUETIAPINE FUMARATE	ANTIPSYCHOTIC AGENTS	1,347	$ 25,352.12	$ 18.82	0.90%
VITAMIN D3	VITAMIN D	1,333	$ 20,330.15	$ 15.25	0.89%
LAMOTRIGINE	ANTICONVULSANTS, MISCELLANEOUS	1,302	$ 19,337.12	$ 14.85	0.87%
TOTAL TOP 25		47,467	$ 1,971,827.40	$ 41.54	31.55%

Total Rx Claims From 01/01/2018 - 03/31/2018	150,440

Top 10 Drugs
Based on Number of Claims

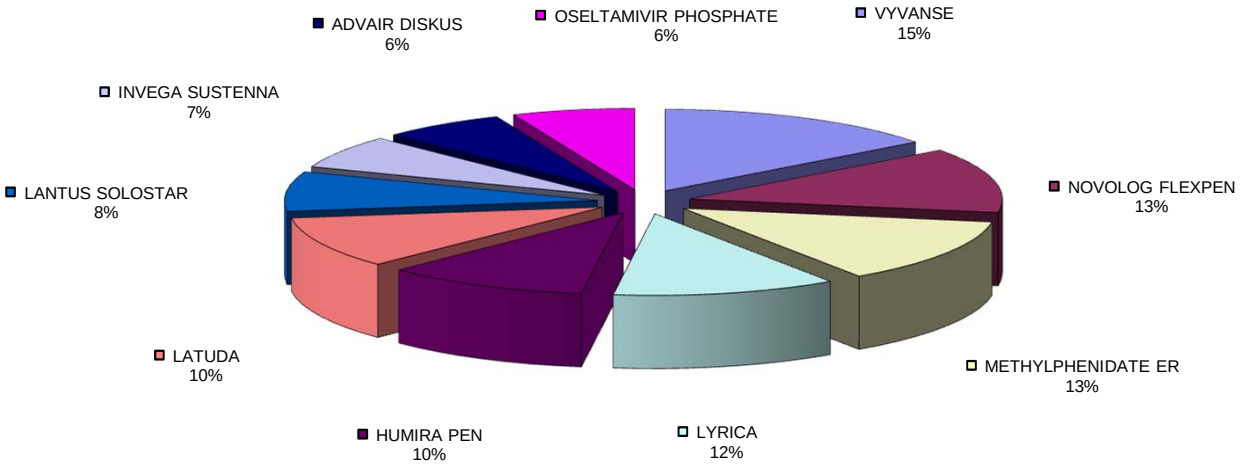


TOP 25 DRUGS BASED ON TOTAL CLAIMS COST FROM 01/01/2018 - 03/31/2018

Drug	AHFS Therapeutic Class	Rx	Paid	Paid/Rx	% Total Claims
VYVANSE	AMPHETAMINES	1,689	$ 374,960.52	$ 222.00	1.12%
NOVOLOG FLEXPEN	INSULINS	615	$ 327,430.18	$ 532.41	0.41%
METHYLPHENIDATE ER	RESPIRATORY AND CNS STIMULANTS	1,849	$ 327,065.34	$ 176.89	1.23%
LYRICA	ANTICONVULSANTS, MISCELLANEOUS	665	$ 293,496.22	$ 441.35	0.44%
HUMIRA PEN	DISEASE-MODIFYING ANTIRHEUMATIC AGENTS	51	$ 267,736.88	$ 5,249.74	0.03%
LATUDA	ANTIPSYCHOTIC AGENTS	325	$ 258,613.62	$ 795.73	0.22%
LANTUS SOLOSTAR	INSULINS	512	$ 199,385.74	$ 389.43	0.34%
INVEGA SUSTENNA	ANTIPSYCHOTIC AGENTS	90	$ 166,577.59	$ 1,850.86	0.06%
ADVAIR DISKUS	CORTICOSTEROIDS (RESPIRATORY TRACT)	457	$ 161,977.55	$ 354.44	0.30%
OSELTAMIVIR PHOSPHATE	NEURAMINIDASE INHIBITOR ANTIVIRALS	1,468	$ 160,909.80	$ 109.61	0.98%
AMOXICILLIN	PENICILLIN ANTIBIOTICS	4,080	$ 150,202.46	$ 36.81	2.71%
MAPAP	ANALGESICS AND ANTIPYRETICS, MISC.	821	$ 133,309.40	$ 162.37	0.55%
LEVEMIR FLEXTOUCH	INSULINS	363	$ 129,625.54	$ 357.10	0.24%
VIMPAT	ANTICONVULSANTS, MISCELLANEOUS	199	$ 121,006.37	$ 608.07	0.13%
ONFI	BENZODIAZEPINES (ANTICONVULSANTS)	122	$ 116,890.98	$ 958.12	0.08%
PROAIR HFA	BETA-ADRENERGIC AGONISTS	1,406	$ 112,504.25	$ 80.02	0.93%
BLINCYTO	ANTINEOPLASTIC AGENTS	12	$ 111,247.82	$ 9,270.65	0.01%
SYMBICORT	CORTICOSTEROIDS (RESPIRATORY TRACT)	346	$ 103,235.73	$ 298.37	0.23%
LICE KILLING	SCABICIDES AND PEDICULICIDES	243	$ 96,502.00	$ 397.13	0.16%
COPAXONE	IMMUNOMODULATORY AGENTS	14	$ 95,833.36	$ 6,845.24	0.01%
ABILIFY MAINTENA	ANTIPSYCHOTIC AGENTS	50	$ 92,967.95	$ 1,859.36	0.03%
FOCALIN XR	RESPIRATORY AND CNS STIMULANTS	294	$ 92,956.02	$ 316.18	0.20%
ADDERALL XR	AMPHETAMINES	526	$ 92,382.61	$ 175.63	0.35%
VIGABATRIN	ANTICONVULSANTS, MISCELLANEOUS	6	$ 92,056.77	$ 15,342.80	0.00%
GABAPENTIN	ANTICONVULSANTS, MISCELLANEOUS	2,561	$ 91,351.90	$ 35.67	1.70%
TOTAL TOP 25		18,764	$ 4,170,226.60	$ 222.25	12.47%

Total Rx Claims From 01/01/2018 - 03/31/2018	150,440

Top 10 Drugs
Based on Total Claims Cost



Chemo Induced Nausea/Vomiting Agents
Prior Authorization Criteria

Approval Duration: 6 months OR until the last day of chemotherapy
Criteria:

- Patient must have diagnosis of nausea and/or vomiting
- Prescriber must be an oncologist
- Patient must be receiving a moderately or highly emetogenic chemotherapy
- The number of cycles of chemotherapy must be indicated
- The final date of chemotherapy treatment must be indicated
- Patient must have failed a trial of the preferred oral product(s) in the same class within the last 30 days as evidenced by paid claims or pharmacy print outs.

SANCUSO (Additional Criteria):

- The patient must have inability to tolerate oral medications.
- The granisetron tablet failure must not be due to side effects.

ZUPLENZ (Additional Criteria):

- The patient must failed a trial of both the ondansetron ODT and solution.
- The ondansetron failures must not be due to side effects.

Preferred	Non-Preferred
Aprepitant	AKYNZEO (netupitant/palonosetron)
	VARUBI (rolapitant) TABLET
Preferred	**Non-Preferred**
Granisetron tablet	ANZEMET (dolasetron)
Ondansetron ODT	SANCUSO (granisetron) PATCH
Ondansetron solution	ZUPLENZ (ondansetron) FILM
Ondansetron tablet	
Palonestron	

health information designs

Chemo Induced Nausea/Vomiting 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 prescription for non-preferred agents to treat chemotherapy induced nausaea/vomiting must meet the following prior authorization criteria:

- Patient must have diagnosis of nausea and/or vomiting
- Prescriber must be an oncologist
- Patient must be receiving a moderately or highly emetogenic chemotherapy and
- The number of cycles and final date of chemotherapy must be indicated
- Patient must have failed a trial of the preferred oral product(s) in the same class within the last 30 days
- For additional criteria specific to Sancuso or Zuplenz, please see the Chemo Induced Nausea/Vomiting Agents Prior Authorization Criteria at 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 and Dosage: □ AKYNZEO □ ANZEMET □ SANCUSO □ VARUBI □ ZUPLENZ	**Diagnosis for this request:** □ NAUSEA AND/OR VOMITING □ OTHER _____

Number of Cycles of Chemotherapy: _____	**Final date of chemotherapy:**_____	**Chemotherapy Regimen:**

List all failed medications:	**Dates:**	**Reason for Failure:**

• **Does the patient have an inability to tolerate oral medications?**	□ YES □ NO
• **Was the patient's trial failure of granisetron tablets due to side effects? (Sancuso)**	□ YES □ NO
• **Was the patient's trial failure of ondansetron ODT and solution due to side effects? (Zuplenz)**	□ 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 #

Biosimilar Agents Prior Authorization Criteria

Criteria:

- The prescriber must submit medical justification explaining why the patient cannot use the preferred product (subject to clinical review)
- Patient must have FDA indication
- Patient must not have contraindications to requested product
- Patient must have failed a therapeutic course of all preferred agents
    - Trial must have been 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

health information designs

Biosimilar 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 prescription for non-preferred biosimilar agents 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 #

Topical Corticosteroid Agents
Prior Authorization Criteria

Criteria:

- **For non-preferred agents not labeled as "STEP 2" (Step 1):**
  - 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.
- **For non-preferred agents labeled as "STEP 2":**
  - 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.

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%
		Clobex (*Brand Required*) Lotion	0.05%	Clobetasol emulsion foam	0.05%
		Clobex (*Brand Required*) Shampoo	0.05%	Clobetasol propionate foam	0.05%
		Clobex (*Brand Required*) Spray	0.05%	Topicort spray	0.25%
		Clobetasol Propionate Gel	0.05%	STEP2* Cordran Tape	4MCG/SQ CM
				STEP 2* Ultravate lotion	0.05%
Class 2 & 3 - High Potency	**Class 2 & 3 - High Potency**				
	Cream	Betamethasone, augmented	0.05%	Apexicon E	0.05%
		Desoximetasone	0.25%	Betamethasone Dipropionate	0.05%
		Diflorasone Diacetate	0.05%	Halog	0.10%
		Fluocinonide	0.05%	Fluocinonide-E	0.05%
		Triamcinolone Acetonide	0.50%	STEP2* Amcinonide	0.10%
	Ointment	Betamethasone Dipropionate	0.05%	Amcinonide	0.10%
		Betamethasone Valerate	0.10%	Diflorasone Diacetate	0.05%
		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%	Betamethasone dipropionate gel	0.05%
		Fluocinonide solution	0.05%	Desoximetasone gel	0.05%
				STEP2* Amcinonide Lotion	0.10%

Class 4 & 5 - Medium Potency	**Class 4 & 5 - Medium Potency**				
	Cream	Betamethasone Valerate	0.10%	Clocortolone Pivalate	0.10%
		Fluticasone Propionate	0.05%	Fluocinolone Acetonide	0.025%
		Mometasone Furoate	0.10%	Pandel	0.10%
		Synalar	0.025%	Prednicarbate	0.10%
		Triamcinolone Acetonide	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	0.05%
Class 6 & 7 - Low Potency	**Class 6 & 7 - 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%		

health information designs

Topical Corticosteroid 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 a non-preferred topical corticosteroid agent must meet the following criteria (for a list of preferred, non-preferred, and step 2 agents, please see the Topical Corticosteroids Prior authorization criteria located at http://www.hidesigns.com/assets/files/ndmedicaid/2018/Criteria/PA_Criteria.pdf):

- **For non-preferred agents not labeled as "STEP 2" (Step 1):**
  - 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.
- **For non-preferred agents labeled as "STEP 2":**
  - 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.

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: □	**Requested Dosage Form:**	**Diagnosis for this request:**
List all failed medications (including dosage form):	**Start Date:**	**End Date:**

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

Prescriber (or Staff) / Pharmacy Signature**	Date

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

Part II: TO BE COMPLETED BY PHARMACY

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

Dupixent Prior Authorization Criteria

Criteria:

- The patient must have an FDA approved indication for use
- Patient must have had a 6-week trial of at least one of the following, as evidenced by paid claims or pharmacy print-outs:
    - 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 print-outs.
    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 print-outs.

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 the following criteria:

- Patient must have had a 6-week trial of at least one of the following: 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.
  - B. Patient must meet both of the following (1 and 2):
    1. Affected area is be on face, groin, axilla, or under occlusion OR patient is under 12 years of age
    2. Patient must have had two 2-week trials of topical corticosteroids of low or higher potency.

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: □ DUPIXENT	**Diagnosis for this request:**	**Is the affected area is on the face, groin, axilla, or under occlusion?** □ YES □ NO
List all failed medications:	**Start Date:**	**End Date:**

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

Prescriber (or Staff) / Pharmacy Signature**	Date

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

Part II: TO BE COMPLETED BY PHARMACY

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

Non-Preferred Dosage Forms
Prior Authorization Criteria

Criteria:

- The prescriber must submit medical justification explaining why the patient cannot use the preferred product (subject to clinical review)
- Patient must have FDA indication
- Patient must not have contraindications to requested product
- Patient must have failed a therapeutic course of all preferred agents
    - Trial must have been 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

Tussicaps:

Preferred	Non-Preferred
Hydrocodone/chlorpheniramine ER suspension	TUSSICAPS (hydrocodone/chlorpheniramine)
Promethazine/codeine	
ZODRYL AC (chlorpheniramine/codeine)	

Gocovri/Osmolex ER:

Additional Criteria: Patient must not be in long term care facility

Preferred	Non-Preferred
Amantadine IR	Amantadine ER

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 #

PRODUCT DETAILS OF Rytary (carbidopa/levodopa ER)

INDICATIONS AND USE:

- Treatment of Parkinson disease, postencephalitic Parkinsonism, and symptomatic Parkinsonism that may follow carbon monoxide and/or manganese intoxication.

DOSAGE AND ADMINISTRATION:

- Max dose is Carbidopa 612.5 mg/levodopa 2,450 mg per day.
    - **Adult Dosing:**
        - Initial:
            - Carbidopa 23.75 mg/levodopa 95 mg 3 times daily for 3 days
            - Day 4: ↑ to 36.25 mg/145 mg 3 times daily.
        - Maintenance:
            - Adjust as needed. May increase up to 97.5 mg/ 390 mg 3 times daily, followed by 5 times daily if needed and tolerated.
    - **Pediatric Dosing:**
        - Safety and efficacy not established.
    - **Renal or Hepatic Impairment**
        - No adjustments provided. Use with caution.

DOSAGE FORM AND STRENGTHS:

- Carbidopa/levodopa ER Capsules in strengths of 23.75/95 mg, 36.25/145 mg, 48.75/195 mg, and 61.25/245 mg

CONTRAINDICATIONS:

- Hypersensitivity to levodopa, carbidopa, or any component of the formulation.
- Concurrent use with nonselective MAOIs or use within the last 14 days.

WARNINGS AND PRECAUTIONS:

- **Psychosis/ Hallucinations:** Abnormal thinking and behavior changes have been reported, as well as hallucinations and confusion. Avoid use in patients with a major psychotic disorder (exacerbation risk)
- **Impulse control disorders:** Dopamine agonists have been associated with compulsive behaviors and/or loss of impulse control. Dose reduction or discontinuation of therapy has been reported to reverse these behaviors in some but not all cases.
- **Somnolence:** Somnolence and falling asleep while engaged in activities of daily living have been reported.
- **Cardiovascular Ischemic Events:** Use with caution in patients with severe cardiovascular disease, including a history of MI with who have residual atrial, nodal, or ventricular arrhythmias.
- **Peptic ulcer disease:** Use with caution in patients with peptic ulcer disease (↑ GI bleed risk).
- **Neuroleptic malignant syndrome:** Symptoms resembling neuroleptic malignant syndrome has been reported in association with rapid dose reduction or abrupt withdrawal. Avoid sudden d/c or rapid dose reduction and monitor patients closely.
- **Glaucoma:** Use with caution in patients with glaucoma. Monitor IOP carefully.
- **Dyskinesias:** May cause or exacerbate dyskinesias. May require dosage reduction.
- **Melanoma:** Risk for melanoma development is increased in Parkinson disease patients. Monitor patients monitored closely and perform periodic skin examinations.

ADVERSE REACTIONS:

- **CV**: Orthostatic hypotension (1-5%)
- **CNS**: Dizziness (9-19%), HA (7-17%), insomnia (2-9%), abnormal dreams (2-6%), anxiety (2-5%)
- **GI:** Nausea (14-20%), constipation (2-6%), vomiting (2-5%), dry mouth (3-7%)
- **Neuromuscular & skeletal:** Dyskinesia (2% to 5%)

DRUG INTERACTIONS

- Non-selective MAOIs (contraindicated)
- MAO-B inhibitors (e.g., rasagiline and selegiline): use with caution (HoTN)
- Dopamine D2 Receptor Antagonists and Isoniazid: reduced effectiveness.
- Iron Salts: reduced absorption

COST

Drug	Strength	Package Size	WAC Pkg Price	AWP Unit Price
Rytary	23.75/95 mg	100	291.68	3.50
Rytary	36.25/145 mg	100	291.68	3.50
Rytary	48.75/195 mg	100	291.68	3.50
Rytary	61.25/245 mg	100	366.51	4.40

CURRENT UTILIZATION

ND Medicaid Utilization (02/2018 – 03/2018)		
Label Name	**Rx Num**	**Total Reimb Amt**
Rytary	0	N/A

REFERENCES:

1. Facts & Comparisons eAnswers. Available at http://online.factsandcomparisons.com. Accessed on May 20. 2018.
2. Rytary (carbidopa/levodopa) [prescribing information]. Hayward, CA: Impax Pharmaceuticals; April 2016.

PRODUCT DETAILS OF Daxbia (cephalexin)

INDICATIONS AND USE:

- Daxbia is a cephalosporin indicated for the treatment of the following infections caused by susceptible isolates of designated bacteria:
    - Respiratory tract infection (*S. pneumoniae & S. pyogenes*)
    - Otitis media (*S. pneumoniae, H. influenzae, S. aureus, S. pyogenes, & M. catarrhalis*)
    - Skin and skin structure infections (*S. aureus & S. pyogenes*)
    - Bone infections (*S. aureus & P. mirabilis*)
    - Genitourinary tract infections (*E. coli, P. mirabilis, & K. pneumoniae*)

DOSAGE AND ADMINISTRATION:

- Dosing ≥15 years of age:
    - 1 to 4 grams per total daily dose in equally divided doses
- Dosing for 1 to 14 years of age:
    - Usual: 25 to 50 mg/kg given in equally divided doses for 7-14 days
    - Severe infections: 50 to 100 mg/kg in equally divided doses
    - Otitis Media: 75 to 100 mg/kg in equally divided doses

DOSAGE FORM AND STRENGTHS:

- 50 and 100 mg tablets

CONTRAINDICATIONS:

- Hypersensitivity to cephalexin or other cephalosporins

WARNINGS AND PRECAUTIONS:

- Dose adjustments required for renal impairment (CrCl <60 mL/min)
- **Hypersensitivity reactions:** Medication should be d/c if occurring in patient. Cross hypersensitivity with other beta-lactam antibacterial drugs ~10%.
- **CDAD:** Risk with antimicrobial therapy
- **Direct Coombs ' Test Seroconversion:** Acute intravascular hemolysis induced by cephalexin therapy has been reported
- **Seizure**: Cephalosporin related warning/precaution
- **Prolonged prothrombin time:** Cephalosporin related warning/precaution
- **Drug resistant bacteria:** Appropriate use.

ADVERSE REACTIONS:

- Diarrhea was most common followed by N/V, dyspepsia, gastritis, and abdominal pain
- Other notable reactions included:
    - Hypersensitivity reactions, pruritus, reversible interstitial nephritis, eosinophilia, neutropenia, thrombocytopenia, hemolytic anemia, aplastic anemia, hemorrhage, renal dysfunction, toxic nephropathy, and slight AST and ALT elevations.

DRUG INTERACTIONS

- Metformin: increased metformin concentrations
- Probenecid: reduced renal excretion of Daxbia

COST

Drug	Strength	Package Size	WAC Pkg Price	AWP Unit Price
Daxbia	333 mg	100 caps	950.00	11.40

CURRENT UTILIZATION

ND Medicaid Utilization (02/2018 – 03/2018)		
Label Name	**Rx Num**	**Total Reimb Amt**
DAXBIA	0	N/A

REFERENCES:

1. Facts & Comparisons eAnswers. Available at http://online.factsandcomparisons.com. Accessed on May 20. 2018.
2. Daxbia (cephalexin) tablets [prescribing information]. Johnson City, TN: Crown Laboratories, Inc.-Aventis; February 2017.

PRODUCT DETAILS OF Millipred DP (prednisolone)

INDICATIONS AND USE:

- **Endocrine disorders:**
  - Primary or secondary adrenocortical insufficiency
  - Congenital adrenal hyperplasia Nonsuppurative thyroiditis
  - Hypercalcemia associated with cancer
- **Rheumatic disorders**: Adjunctive therapy for short term administration (to tide the patient over an acute episode or exacerbation) in numerous rheumatic disorders.
- **Collagen diseases:** During an exacerbation or as maintenance therapy in selected cases of:
  - Systemic lupus erythematosus Acute rheumatic carditis
  - Systemic dermatomyositis
- **Dermatologic diseases**
  - Pemphigus
  - Bullous dermatitis herpetiformis
  - Severe erythema multiforme (Stevens-Johnson syndrome);
  - Exfoliative dermatitis
  - Mycosis fungoides
  - Severe psoriasis
  - Severe seborrheic dermatitis.
- **Allergic states:** Control of severe or incapacitating allergic conditions intractable to adequate trials of conventional treatment.
- **Ophthalmic diseases:** Severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa.
- **Respiratory diseases:**
  - Symptomatic sarcoidosis
  - Loeffler's syndrome not manageable by other means
  - Berylliosis
  - Fulminating or disseminated pulmonary tuberculosis when used concurrently with appropriate antituberculous
  - Aspiration pneumonitis
- **Hematologic disorders:**
  - Idiopathic thrombocytopenic purpura in adults
  - Secondary thrombocytopenia in adults
  - Acquired (autoimmune) hemolytic anemia
  - Erythroblastopenia (RBC anemia)
  - Congenital (erythroid) hypoplastic anemia
- **Neoplastic diseases: For palliative management of:**
  - Leukemias and lymphomas in adults
  - Acute leukemia of childhood
- **Edematous states:** To induce a diuresis or remission of proteinuria in the nephrotic syndrome, without uremia, of the idiopathic type or that due to lupus erythematosus.
- **Gastrointestinal diseases:** To tide the patient over a critical period of the disease in:
  - Ulcerative colitis
  - Regional enteritis
- **Nervous system:** Acute exacerbations of multiple sclerosis.
- **Miscellaneous:**
  - Tuberculous meningitis with subarachnoid block or impending block when used concurrently with appropriate antituberculous chemotherapy

- Trichinosis with neurologic or myocardial involvement

DOSAGE AND ADMINISTRATION:

- Initial Dose: varies depending on diagnosis, usual dosing between 5-60 mg/day.

DOSAGE FORM AND STRENGTHS:

- 5 mg tablets

CONTRAINDICATIONS:

- Systemic fungal infections; hypersensitivity to prednisolone or any component of the formulation

WARNINGS AND PRECAUTIONS:

- Withdraw therapy with gradual dose tapering.
- Chronic use: immunosuppression, adrenal suppression, suppression of the hypothalamic-pituitary-adrenal (HPA) axis, and Kaposi sarcoma.
- Use with caution in patients with diabetes, seizure disorder, osteoporosis, myasthenia gravis, GI disease, and cataracts and/or glaucoma.
- Use may cause psych disturbances and myopathy.
- Use with caution in renal and hepatic impairment.

ADVERSE REACTIONS:

- Cardiovascular: HR changes, arrhythmias, CHF, embolism
- CNS: behavioral and mood changes, depression, convulsions, headache, emotional instability
- Dermatologic: acne, cutaneous atrophy, dry scalp, pigmentation changes, urticaria
- Endocrine: abnormal fat disposition, cushingoid state, hirsutism, manifestations of latent DM, moon facies, growth suppression.
- GI: Abdominal distention, LFT elevations, hepatomegaly, increased appetite, nausea, pancreatitis, peptic ulcer, ulcerative esophagitis, weight gain.
- Musculoskeletal: osteoporosis, tendon rupture, myopathy, loss of muscle mass.
- Other: increased IOP, edema, glucose tolerance alterations, sodium retention, potassium loss.

DRUG INTERACTIONS

- Numerous:
  - Therapy modification:
    - Vaccines, Tofacitinib, Tisagenlecleucel, Telaprevir, Tacrolimus, Roflumilast, Ritonavir, Nivolumab, neuromuscular blocking agents, mitotane, Leflunomide, Hyaluronidase, fosaprepitant, fingolimod, desirudin, Aprepitant, antacids, Aldesleukin
  - Avoid
    - Pimecrolimus, natalizumab, mifepristone, Mifamurtide, Macimorelin, desmopressin

COST

Drug	Strength	Package Size	WAC Pkg Price	AWP Unit Price
Millipred DP	5 mg	21 tabs	180.73	7.17
Millipred DP	5 mg	48 tabs	413.45	7.17

CURRENT UTILIZATION

ND Medicaid Utilization (02/2018 – 03/2018)		
Label Name	**Rx Num**	**Total Reimb Amt**
Millipred DP	0	N/A

REFERENCES:

1. Facts & Comparisons eAnswers. Available at http://online.factsandcomparisons.com. Accessed on May 20. 2018.
2. Millipred Tablets and DP (prednisolone) [prescribing information]. Research Triangle Park, NC: Zylera Pharmaceuticals; September 2016.

PRODUCT DETAILS OF EOSINOPHILIC ASTHMA AGENTS

INDICATIONS AND USE:

- **Fasenra (benralizumab)**
  - Add-on maintenance treatment of severe asthma in adults and children ≥12 years of age with an eosinophilic phenotype
- **Nucala (mepolizumab)**
  - Add-on maintenance treatment of severe asthma in adults and pediatric patients ≥12 years of age with an eosinophilic phenotype
  - Treatment of adult patients with eosinophilic granulomatosis with polyangiitis
- **Cinqair (reslizumab)**
  - Add-on maintenance treatment of severe asthma in adults with an eosinophilic phenotype

Drug Information Comparison:

<table>
<tr><th></th><th>Cinqair</th><th>Nucala</th><th>Fasenra</th></tr>
<tr><td>Adult Dosing</td><td>3 mg/kg IV once every 4 weeks.</td><td colspan="2">Asthma:
• 100 mg SQ every 4 weeks
Eosinophilic granulomatosis:
• 300 mg SQ every 4 weeks</td><td>• Initial: 30 mg SQ every 4 weeks for the first 3 doses
• 30 mg once every 8 weeks</td></tr>
<tr><td>Peds Dose</td><td>N/A</td><td colspan="2">Asthma: >11 years old only; same as adult</td><td>>11 years old only; same as adult</td></tr>
<tr><td>CIs</td><td colspan="4">Hypersensitivity to the product or any component of the formulation</td></tr>
<tr><td rowspan="5">Warnings/Precautions</td><td colspan="4">Not indicated for the treatment of acute asthma symptoms or acute exacerbations, including status asthmaticus.</td></tr>
<tr><td colspan="4">Do not rapidly d/c corticosteroids when therapy is initiated.</td></tr>
<tr><td colspan="4">May increase risk of helminth infection. Patients with preexisting helminth infections should undergo treatment of the infection prior to initiation of therapy.</td></tr>
<tr><td colspan="3">Not indicated for the treatment of other eosinophilic conditions</td><td>N/A</td></tr>
<tr><td>Malignancies were observed during clinical trials.</td><td colspan="2">Use may result in an opportunistic infection of herpes zoster.</td><td>N/A</td></tr>
<tr><td>DIs</td><td colspan="3">N/A</td><td>Belimumab: MAbs may enhance the adverse/toxic effect of Belimumab</td></tr>
</table>

ADRs	Antibody Development (5%)	Antibody Development (asthma: 6%, eosinophilic granulomatosis: <2%)	Antibody development (13%; neutralizing: 12%)
	↑ Creatine Phosphokinase (20%); Myalgia (1%)	Injection site rxn (8-15%); Back pain (5%); muscle spasm (3%); HA (19%)	HA (8%); Pharyngitis (5%)
Product	IV solution 100 mg/10mL	SQ solution reconsituted 100 mg	SQ prefilled syringe 30 mg/mL

- **No dose adjustments for renal or hepatic impairment**

COST

Drug	Strength	Package Size	WAC Pkg Price	AWP Unit Price
Cinqair	10 mg/mL	10 mL	878.00	105.36
Fasenra	30 mg/mL	1 mL syr	4,752.11	5,702.53
Nucala	100 mg	100 mg	2,868.67	3,442.40

CURRENT UTILIZATION

ND Medicaid Utilization (01/2018 – 03/2018)		
Label Name	**Rx Num**	**Total Reimb Amt**
Cinqair	0	N/A
Fasenra	0	N/A
Nucala	0	N/A

REFERENCES:

1. Facts & Comparisons eAnswers. Available at http://online.factsandcomparisons.com. Accessed on May 20. 2018.
2. Cinqair (reslizumab) [prescribing information]. Frazer, PA: Teva; March 2016.
3. Nucala (mepolizumab) [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; December 2017.
4. Fasenra (benralizumab) [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; November 2017.

Dermatophytosis (Tinea infections)

Tinea Infections

- Tinea is the name given to a fungal infection of the skin, caused by dermatophytes. These infections are typically superficial, involving only the epidermis and can lead to a variety of clinical manifestations, the most common of which are tinea pedis, tinea corporis, and tinea cruris.
- **Dermatophytes**
    - Filamentous fungi which metabolize and subsist upon keratin in the skin, hair, and nails.
    - Made up of the genera *Trichophyton*, *Microsporum*, and *Epidermophyton*,
- **Treatment**
    - Most tinea infections can be managed with topical antifungals such as azoles, allylamines, butenafine, ciclopirox, and tolnaftate.
        - Extensive or refractory infections or infections extending into follicles or dermis may require treatment with oral agents such as terbinafine, itraconazole, fluconazole, and griseofulvin.

TINEA PEDIS (athlete's foot)

- Most common dermatophyte infection.
- Tinea pedis may manifest as an interdigital, hyperkeratotic, or vesiculobullous eruption, and rarely as an ulcerative skin disorder.
- **Common pathogen**: T. rubrum, T. interdigitale, and E. floccosum.
- **Infection**: usually acquired by means of direct contact with the causative organism (e.g. walking barefoot in locker rooms or swimming pool facilities).
- **Treatment:** Topical treatment with azoles, allylamines, butenafine, ciclopirox, or tolnaftate,
    - Generally applied once or twice daily and continued for 4 weeks.

TINEA CORPORIS (ringworm)

- Occurs in sites other than the feet, groin, face, or hand.
    - **Common pathogen**: *T. rubrum, T. tonsurans*, *M. canis*, *T. interdigitale, M. gypseum*, *T. violaceum*, and *M. audouinii*.
    - **Infection**: occurs by direct skin contact with an infected individual or animal, contact with fomites, or from secondary spread from other sites of dermatophyte infection.
    - **Treatment:** Topical treatment with azoles, allylamines, butenafine, ciclopirox, and tolnaftate.
        - Generally applied once or twice daily and continued for 1-4 weeks.

TINEA CRURIS (jock itch)

- Occurs in the crural fold. More common in men than women.
    - **Common pathogen**: *T. rubrum, E. floccosum* and *T. interdigitale.*
    - **Infection:** usually results from the spread of the dermatophyte infection from concomitant tinea pedis.
    - **Treatment:** Topical treatment with azoles, allylamines, butenafine, ciclopirox, and tolnaftate.
        - Generally applied once or twice daily and continued for 1-4 weeks.

TREATMENT AGENTS

- **Allylamines**
  - **MoA:** Inhibits the enzyme squalene epoxidase, resulting in inhibition of ergosterol synthesis and subsequent weakening of fungal cell membranes.
  - **Topical Agents:**
    - Generics:
      - butenafine cream
      - naftifine cream/gel
      - terbinafine cream/gel/solution
    - Select Brand Agents:
      - Mentax (butenafine) cream
- **Ciclopirox**
  - **MoA:** Inhibiting active membrane transport of essential elements into the fungal cell disrupting the synthesis of DNA, RNA, and proteins.
  - **Topical Agents:**
    - Generics:
      - Ciclopirox cream/gel/shampoo/solution/suspension
- **Azoles:**
  - **MoA:** Alters the permeability of the cell wall by blocking fungal cytochrome P450 which inhibits biosynthesis of triglycerides and phospholipids by fungi.
  - **Topical Agents:**
    - Generics:
      - ketoconazole cream/foam/gel/shampoo
      - clotrimazole cream/ointment/solution
      - econazole cream
      - miconazole aerosol/cream/ointment/powder/solution
      - oxiconazole cream
    - Select Brand Agents:
      - Extina (ketoconazole) foam
      - Ecoza (econazole) foam
      - Luzu (luliconazole) cream
      - Ertaczo (sertaconazole) cream
      - Exelderm (sulconazole) cream/solution
      - Oxistat (oxiconazole) cream/lotion
- **Tolnaftate**
  - **MoA: I**nhibits fungal squalene epoxidase and distorts the hyphae and stunts mycelial growth in susceptible fungi
  - **Topical Agents:**
    - Generics:
      - Tolnaftate aerosol/cream/solution
- **Undecylenic Acid**
  - **MoA:** Fungistatic, unsaturated fatty acid that inhibits fungal fatty acid synthesis.
  - **Topical Agents:**
    - Generics:
      - undecylenic acid aerosol/liquid.ointment/solution

Table of Select Antifungals and Common Tinea Infections					
	Tinea pedis	Tinea cruris	Tinea corporis	Tinea pityriasis	Seborrheic dermatitis
butenafine	4	2	2	2	
ciclopirox	4	4	4	4	4
clotrimazole	4	2	4	4	
ketoconazole	6	2	2	2	4
miconazole	4	2	4		
naftifine	2-4	2-4	2-4		
terbinafine	2	1	1		
tolnaftate	4	2	4		
undecylenic acid	4	2	4		
Ecoza Cream	4	2	2	2	
Ecoza Foam	4				
Ertaczo	4				
Exelderm cream	4	3	3		
Exelderm sln		3	3		
Extina					4
Luzu	2	1	1		
Mentax				2	
Oxistat	4	2	2	2	
Number above represents the number of weeks of treatment with the product, as recommended by the drug label.					

COST OF SELECT BRAND PRODUCTS

Drug	Strength	Package Size	WAC Pkg Price	AWP Unit Price
Ecoza	1% foam	70 grams	560.27	9.60
Ertaczo	2% cream	60 grams	899.51	17.99
Exelderm	1% cream	15 grams	60.31	4.82
Exelderm	1% cream	30 grams	343.80	13.75
Exelderm	1% cream	60 grams	569.49	11.39
Exelderm	1% solution	30 mL	343.83	13.75
Extina	2% foam	50 grams	784.97	18.84
Extina	2% foam	100 grams	918.64	11.02
Luzu	1% cream	60 grams	492.11	9.84
Mentax	1% cream	15 grams	98.07	7.84
Mentax	1% cream	30 grams	196.11	7.84
Oxistat	1% cream	30 grams	643.23	25.73
Oxistat	1% cream	60 grams	652.69	13.05
Oxistat	1% cream	90 grams	978.56	13.05
Oxistat	1% lotion	30 mL	643.26	25.73
Oxistat	1% lotion	60 mL	782.72	13.04

UTILIZATION

ND Medicaid Utilization (02/2018 – 03/2018)		
Label Name	**Rx Num**	**Total Reimb Amt**
Ecoza	0	N/A
Ertaczo	0	N/A
Exelderm	0	N/A
Extina	0	N/A
Luzu	0	N/A
Mentax	0	N/A
Oxistat	0	N/A

REFERENCES:

1. Facts & Comparisons eAnswers. Available at http://online.factsandcomparisons.com. Accessed on May 20. 2018.
2. Ecoza (econazole) [prescribing information]. Jamison, PA: Quinnova Pharmaceuticals LLC; October 2013.
3. Ertaczo [package insert]. Bridgewater, NJ: Valeant Pharmaceuticals; January 2014.
4. Exelderm (sulconazole) 1% cream [prescribing information]. Jacksonville, FL: Ranbaxy; December 2012.
5. Exelderm (sulconazole) solution [prescribing information]. Jacksonville, FL: Ranbaxy; March 2013.
6. Extina (ketoconazole foam) [prescribing information]. Newtown, PA: Prestium Pharma; June 2013.
7. Luzu (luliconazole) [prescribing information]. Bridgewater, NJ: Valeant Pharmaceuticals; February 2018.
8. Mentax (butenafine hydrochloride cream) [prescribing information]. Morgantown, WV: Mylan; November 2013.
9. Oxistat (oxiconazole) [prescribing information]. Melville, NY: PharmaDerm; January 2012.

PRODUCT DETAILS OF Migraine prophylaxis (CGRP Inhibitors)

INDICATIONS AND USE:

- Aimovig (erenumab-aooe)
  - Preventive treatment of migraine in adults.
- Agents on the horizon:
  - Eptinezumab (Alder BioPharmaceuticals)
  - Fremanezumab (Teva):
  - Galcanezumab (Eli Lilly)

DOSAGE AND ADMINISTRATION:

- Initial dose of 70 mg SQ once monthly, then either 70 or 140 mg SQ once monthly

DOSAGE FORM AND STRENGTHS:

- Subcutaneous auto-injectors at 70 mg/mL with 1 mL (70 mg) and 2 mL (140 mg) available
-

CONTRAINDICATIONS:

- No contraindications listed in prescribing information

WARNINGS AND PRECAUTIONS:

- The packaging (needle shield of auto-injector and needle cap of prefilled syringe) may contain latex.

ADVERSE REACTIONS:

- Constipation (3%)
- Antibody development (3% to 6%)
- Injection site reaction (5% to 6%)
- Muscle cramps (≤2%)

COST

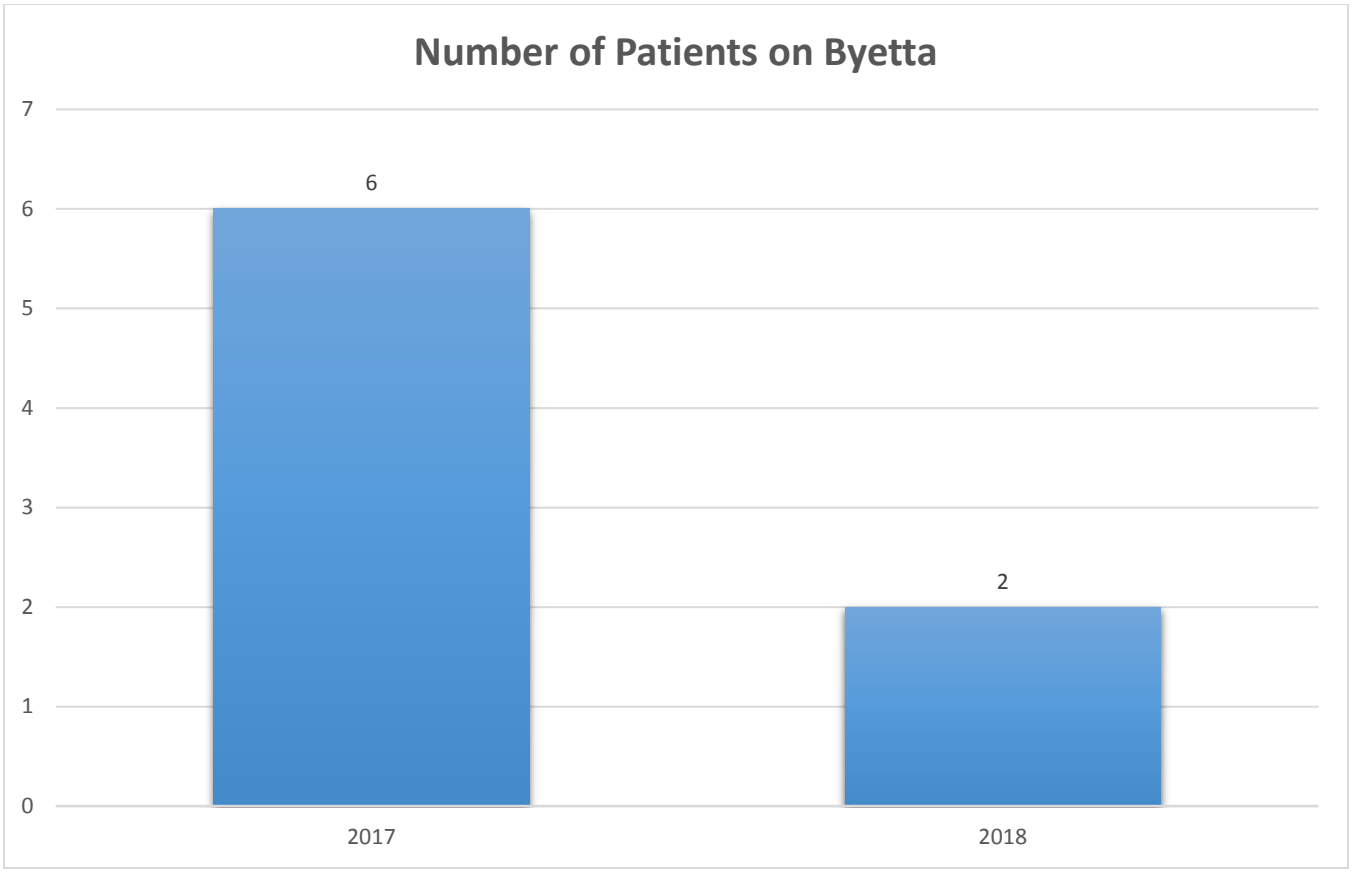
Drug	Strength	Package Size	WAC Pkg Price	AWP Unit Price
Aimovig	140 mg	Two 1 mL syr	$575.00	$345.00
Aimovig	70 mg	One 1 mL sry	$575.00	$690.00

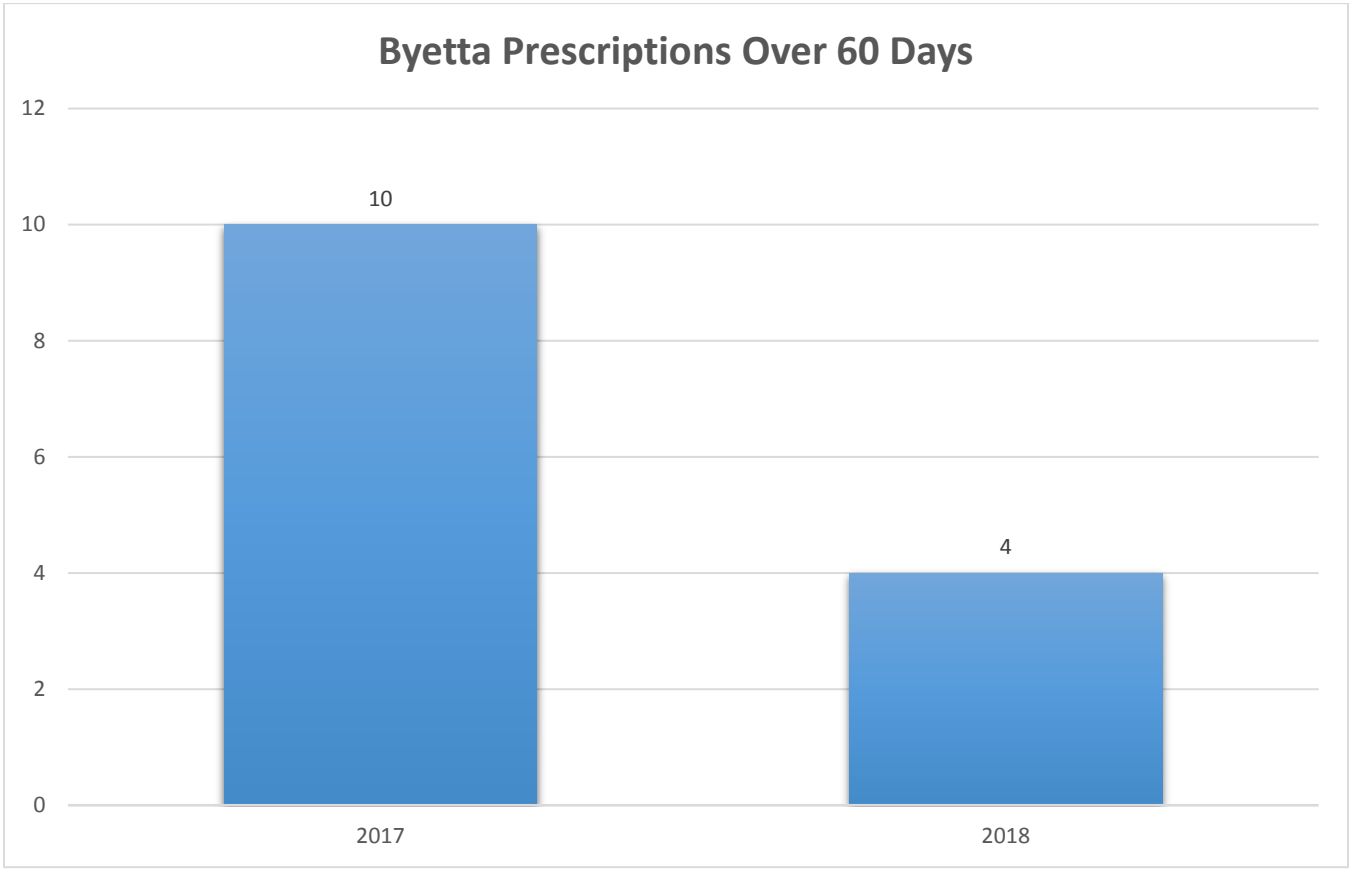
CURRENT UTILIZATION

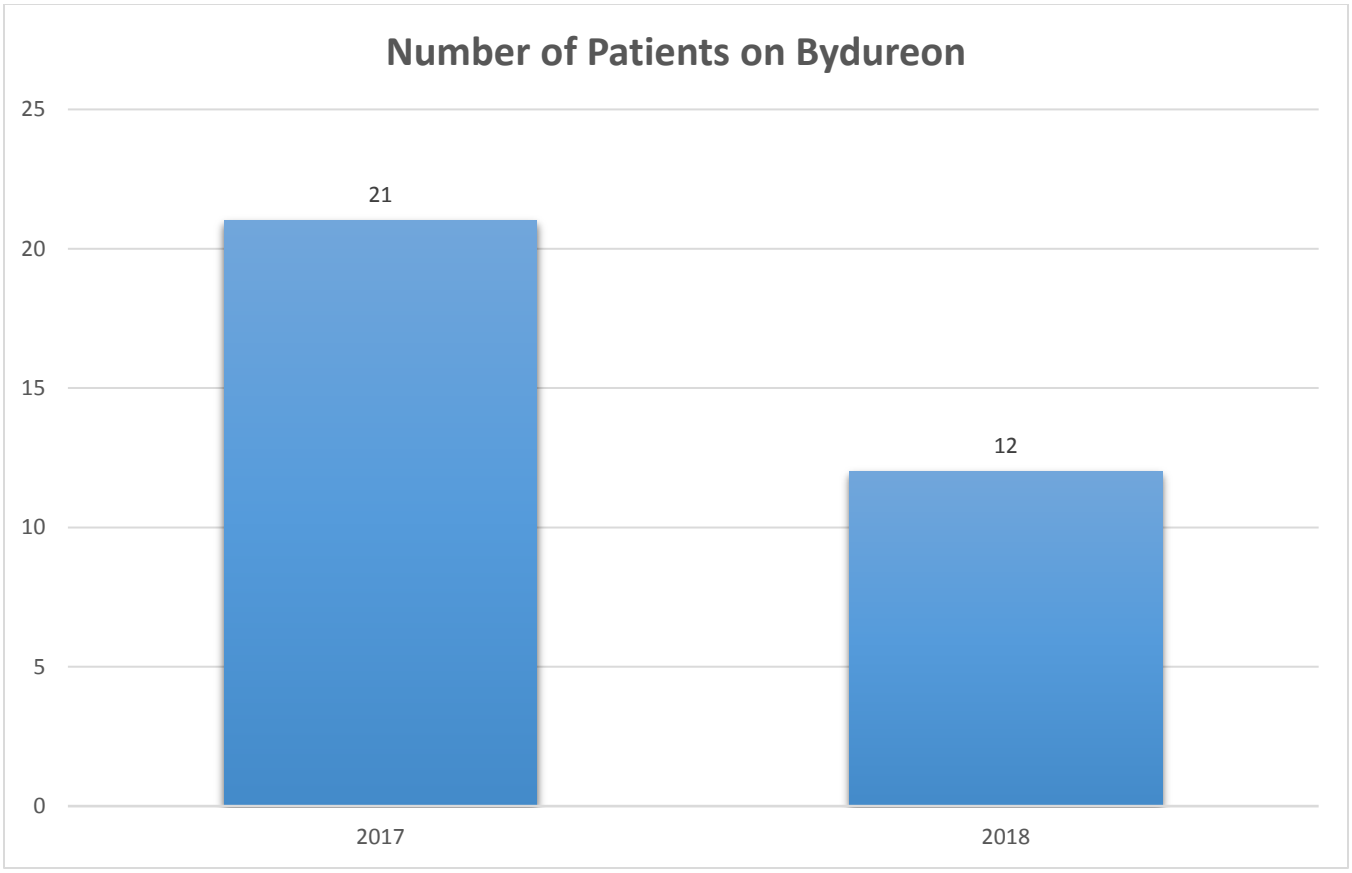
ND Medicaid Utilization (02/2018 – 03/2018)		
Label Name	**Rx Num**	**Total Reimb Amt**
Aimovig	0	N/A

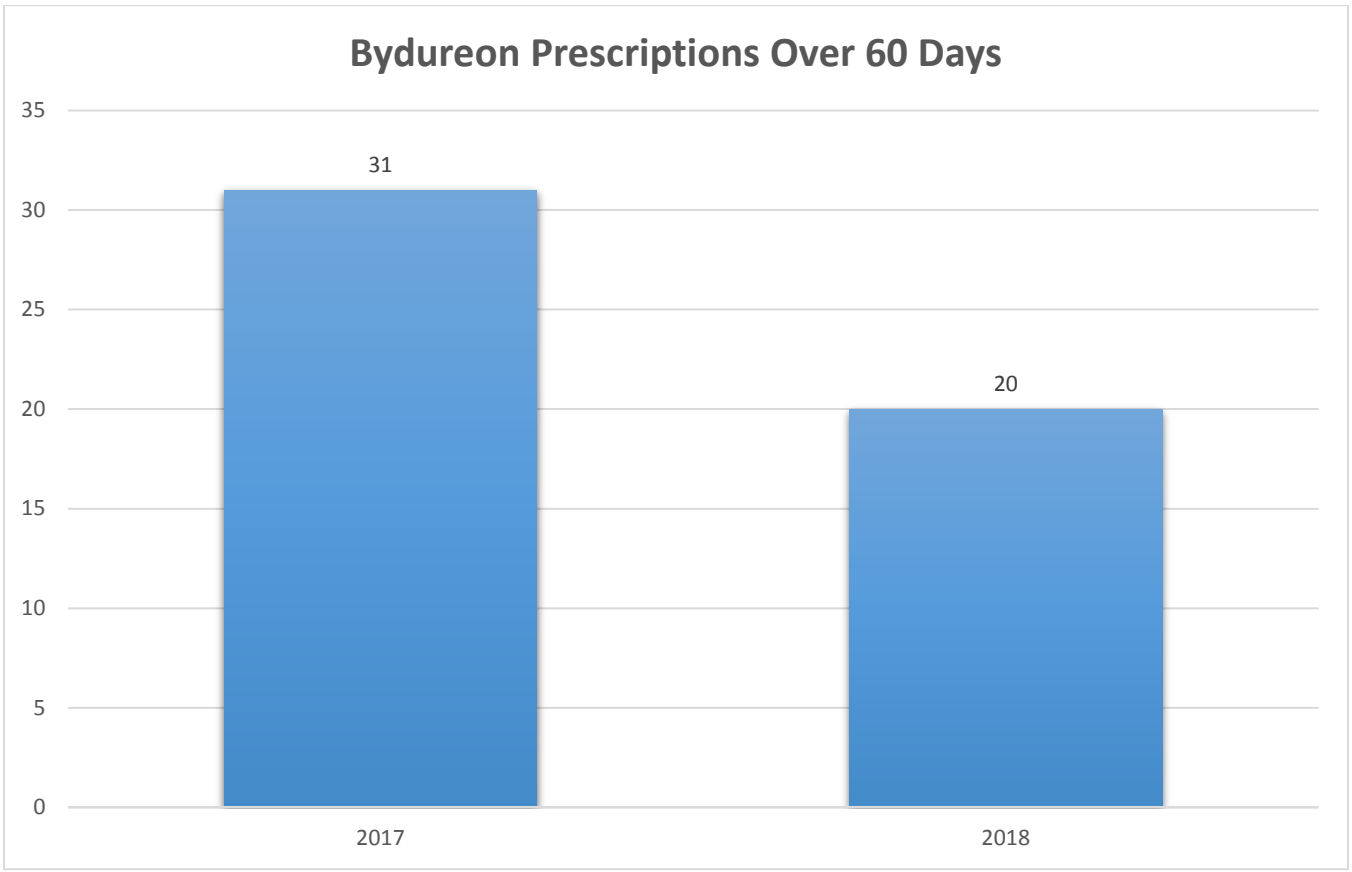
REFERENCES:

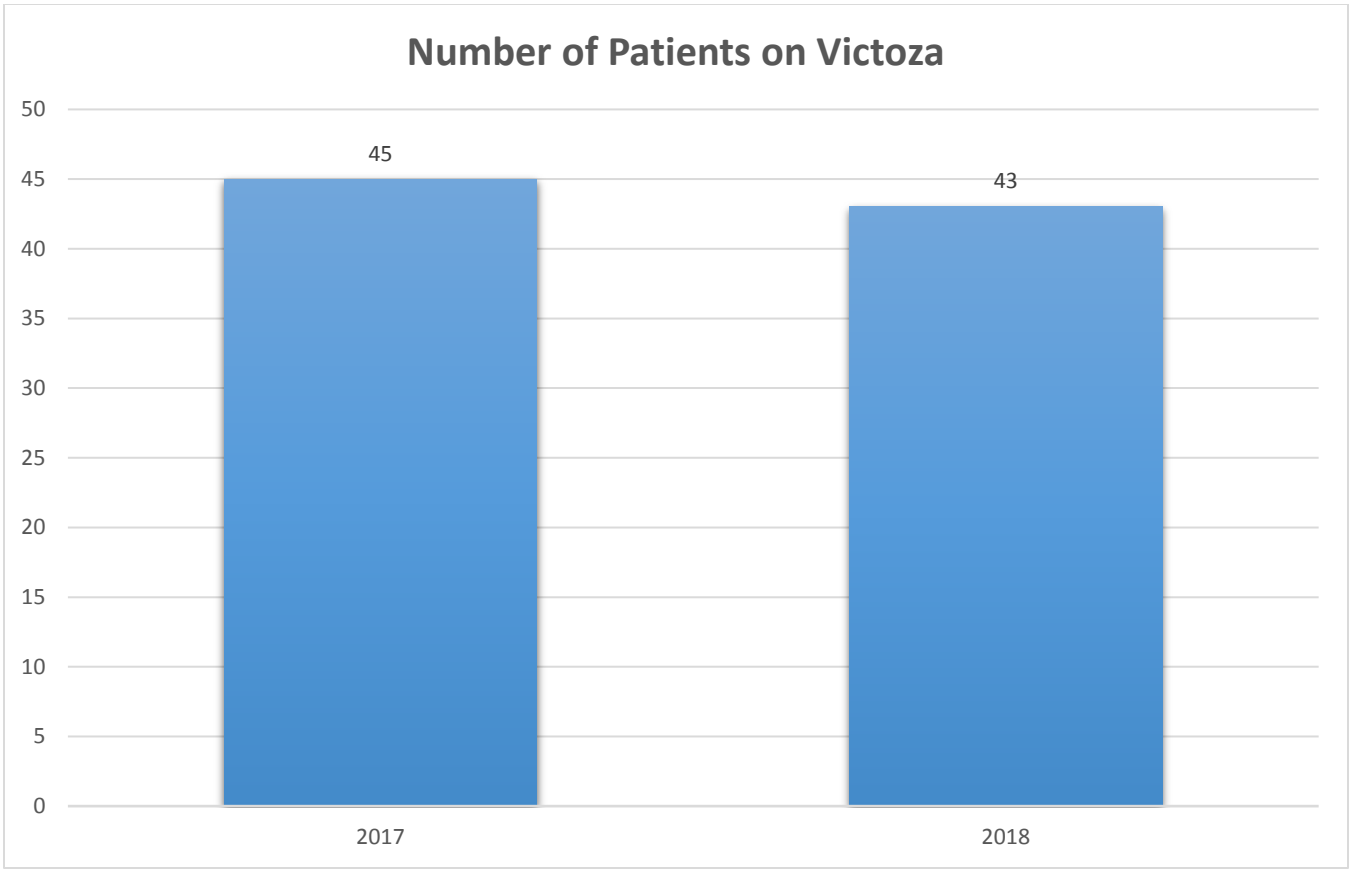
1. Facts & Comparisons eAnswers. Available at http://online.factsandcomparisons.com. Accessed on May 20. 2018.
2. Aimovig (erenumab-aooe) [prescribing information]. Thousand Oaks, CA: Amgen Inc; May 2018.

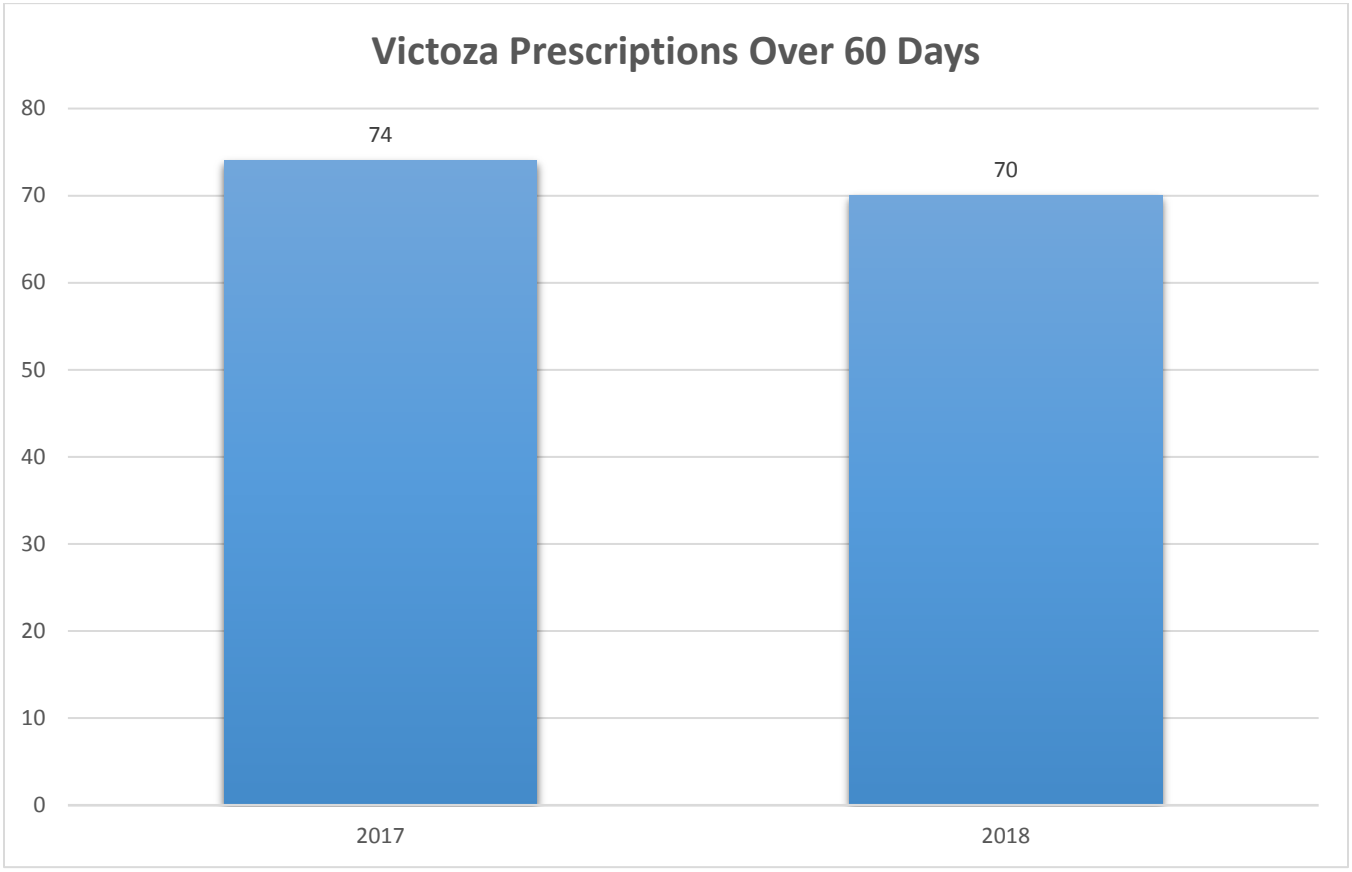

Number of Patients on Byetta
7
6
5
4
3
2
1
0
6
2
2017
2018


Byetta Prescriptions Over 60 Days
12
10
8
6
4
2
0
10
4
2017
2018


Number of Patients on Bydureon
25
20
15
10
5
0
21
12
2017
2018


Bydureon Prescriptions Over 60 Days
35
30
25
20
15
10
5
0
31
20
2017
2018


Number of Patients on Victoza
50
45
40
35
30
25
20
15
10
5
0
45
43
2017
2018


Victoza Prescriptions Over 60 Days
80
70
60
50
40
30
20
10
0
74
70
2017
2018

NORTH DAKOTA MEDICAID
RETROSPECTIVE DRUG UTILIZATION REVIEW
CRITERIA RECOMMENDATIONS
2ND QUARTER 2018

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

1. Semaglutide / Overutilization _____ _____

Alert Message: The recommended maximum dose of Ozempic (semaglutide) is 1 mg subcutaneous injection once weekly.

Conflict Code: ER - Overutilization

Drugs/Diseases		
Util A	Util B	Util C
Semaglutide		

Max Dose: 1mg injection/week

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Ozempic Prescribing Information, December 2017, Novo Nordisk Inc.

2. Semaglutide / Nonadherence _____ _____

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

Conflict Code: LR - Nonadherence

Drugs/Diseases		
Util A	Util B	Util C
Semaglutide		

References:
Ho PM, Rumsfeld JS, Masoudi FA, et al., Effect of Medication Nonadherence on Hospitalization and Mortality Among Patients with Diabetes Mellitus. Arch Intern Med. 2006;166:1836-1841.
Currie CJ, Peyrot M, Morgan CL, et al. The Impact of Treatment Noncompliance on Mortality in People With Type 2 Diabetes. Diabetes Care 35:1279-1284, June 2012.
Butler RJ, Davis TK, Johnson WL, et al. Effects of Non adherence with Prescription Drugs Among Older Adults. Am J Manag Care. 2011 Feb; 17(2):153-60.

3. Semaglutide / Medullary Thyroid Carcinoma & MENS II _____ _____

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

Conflict Code: TA – Therapeutic Appropriateness

Drugs/Diseases		
Util A	Util B	Util C (Include)
Semaglutide		Medullary Thyroid Carcinoma II
		Thyroid Carcinoma
		History of Thyroid Carcinoma

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Ozempic Prescribing Information, December 2017, Novo Nordisk Inc.

4. Semaglutide / Therapeutic Appropriateness (Black Box) _____ _____

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

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C
Semaglutide		

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Ozempic Prescribing Information, December 2017, Novo Nordisk Inc.

5. Semaglutide / Pancreatitis _____ _____

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

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

Util A	Util B	Util C
Semaglutide	Pancreatitis	

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Ozempic Prescribing Information, December 2017, Novo Nordisk Inc.

6. Semaglutide / Therapeutic Appropriateness _____ _____

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

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C
Semaglutide		

Age Range: 0 – 17 yoa

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Ozempic Prescribing Information, December 2017, Novo Nordisk Inc.

7. Semaglutide / Insulin and Insulin Secretagogues _____ _____

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

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

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

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Ozempic Prescribing Information, December 2017, Novo Nordisk Inc.

8. Semaglutide / Pregnancy / Delivery, Miscarriage & Abortion _____ _____

Alert Message: There are limited data with Ozempic (semaglutide) use in pregnant women. Based on animal reproduction studies, there may be potential risks to the fetus from exposure to semaglutide during pregnancy. Semaglutide should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

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

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

Age Range: 11 – 50 yoa
Gender: Female

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Ozempic Prescribing Information, December 2017, Novo Nordisk Inc.

9. Semaglutide / Therapeutic Appropriateness _____ _____

Alert Message: Females of reproductive potential should be informed to discontinue the use of Ozempic (semaglutide) at least 2 months before a planned pregnancy due to the long washout period for semaglutide.

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C
Semaglutide		

Age Range: 11 – 50 yoa
Gender: Female

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Ozempic Prescribing Information, December 2017, Novo Nordisk Inc.

10. Semaglutide / Renal Impairment _____ _____

Alert Message: There have been postmarketing reports of acute kidney injury and worsening of chronic renal failure, which may sometimes require hemodialysis, in patients treated with GLP-1 receptor agonists. A majority of reported events occurred in patients who had experienced nausea, vomiting, diarrhea, or dehydration. Monitor renal function when initiating or escalating doses of Ozempic (semaglutide) in patients reporting severe adverse gastrointestinal reactions.

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

Util A	Util B	Util C
Semaglutide	Renal Impairment/Failure	

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.

11. Biktarvy / Overutilization _____ _____

Alert Message: The manufacturer's recommended dose of Biktarvy (bictegravir/emtricitabine/tenofovir alafenamide) is one tablet once daily.

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C
Bictegravir/Emtricitabine/Tenofovir alafenamide		

Max Dose: 1 tablet/day

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Biktarvy Prescribing Information, Feb. 2018, Gilead Sciences, Inc.

12. Biktarvy / All Other Antiretrovirals _____ _____

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

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C
Bictegravir/Emtricitabine/Tenofovir alafenamide	Cellular Chemokine Receptor (CCR5) Antagonist Fusion Inhibitors Integrase Inhibitors NNRTIs NRTIs Nucleotide Analog Reverse Transcriptase Inhibitors Protease Inhibitors Antiretroviral Combos	

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Biktarvy Prescribing Information, Feb. 2018, Gilead Sciences, Inc.

13. Biktarvy / Severe Renal Impairment _____ _____

Alert Message: Biktarvy (bictegravir/emtricitabine/tenofovir alafenamide) use is not recommended in patients with estimated creatinine clearance below 30 mL per minute, (estimated by Cockcroft-Gault (C-G)). No dosage adjustment of bictegravir/emtricitabine/tenofovir alafenamide is recommended in patients with CLcr greater than or equal to 30 mL per minute.

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C **(Include)**
Bictegravir/Emtricitabine/Tenofovir alafenamide		CKD 5 ESRD

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Biktarvy Prescribing Information, Feb. 2018, Gilead Sciences, Inc.

14. Biktarvy / Hepatic Impairment _____ _____

Alert Message: Biktarvy (bictegravir/emtricitabine/tenofovir alafenamide) has not been studied in patients with severe hepatic impairment (Child-Pugh Class C) and therefore, it is not recommended for use in this patient population. No dosage adjustment of bictegravir/emtricitabine/tenofovir alafenamide is recommended in patients with mild (Child-Pugh Class A) or moderate (Child-Pugh Class B) hepatic impairment.

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C **(Include)**
Bictegravir/Emtricitabine/Tenofovir alafenamide		Cirrhosis Hepatic Fibrosis

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Biktarvy Prescribing Information, Feb. 2018, Gilead Sciences, Inc.

15. Biktarvy / Dofetilide _____ _____

Alert Message: The concurrent use of Biktarvy (bictegravir/emtricitabine/tenofovir alafenamide) with dofetilide is contraindicated due to the risk of dofetilide-related serious and/or life-threatening events. The bictegravir component of the antiretroviral is an inhibitor of renal organic cation transporter (OCT2) and multidrug and toxin extrusion transporter (MATE1) which are responsible for dofetilide elimination and co-administration of these agents may result in increased dofetilide plasma concentrations.

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

Util A	Util B	Util C
Bictegravir/Emtricitabine/Tenofovir alafenamide	Dofetilide	

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Biktarvy Prescribing Information, Feb. 2018, Gilead Sciences, Inc.

16. Biktarvy / Rifampin _____ _____

Alert Message: The concurrent use of Biktarvy (bictegravir/emtricitabine/tenofovir alafenamide) with rifampin is contraindicated due to the risk for the loss of therapeutic efficacy and development of resistance to bictegravir/emtricitabine/tenofovir alafenamide. The bictegravir component of the antiretroviral is a CYP3A4 substrate and UGT1A1 substrate and rifampin is a strong inducer of both CYP3A4 and UGT1A1. Co-administration of these agents may lead to substantially decreased bictegravir plasma concentrations.

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

Util A	Util B	Util C
Bictegravir/Emtricitabine/Tenofovir alafenamide	Rifampin	

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Biktarvy Prescribing Information, Feb. 2018, Gilead Sciences, Inc.

17. Biktarvy / P-gp & BCRP Inhibitors _____ _____

Alert Message: The tenofovir alafenamide (TAF) component of Biktarvy (bictegravir/emtricitabine/tenofovir alafenamide) is a substrate of both P-gp and BCRP transport. Concurrent use of a TAF-containing agent with a P-gp and/or BCRP transport inhibitor may result in increased TAF absorption and plasma concentrations and risk of TAF-related adverse effects.

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

Util A	Util B	Util C
Bictegravir/Emtricitabine/Tenofovir alafenamide	Amiodarone Cobicistat Cyclosporine Glecaprevir/Pibrentasvir Ledipasvir/Sofosbuvir Osimertinib Regorafenib Rolapitant Simeprevir Tedizolid Velpatasvir Vemurafenib	

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Biktarvy Prescribing Information, Feb. 2018, Gilead Sciences, Inc.

18. Biktarvy / Anticonvulsants CYP3A4 Inducers _____ _____

Alert Message: Concurrent use of Biktarvy (bictegravir/emtricitabine/tenofovir alafenamide) with drugs that induce CYP3A4 may cause a decrease in the plasma concentrations of the bictegravir and tenofovir alafenamide components (both CYP3A4 substrates) of the antiretroviral. Decreased plasma concentrations of the antiretrovirals may lead to loss of antiretroviral therapeutic effect and development of resistance. Alternative anticonvulsants should be considered.

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

Util A	Util B	Util C
Bictegravir/Emtricitabine/Tenofovir alafenamide	Carbamazepine Oxcarbazepine Phenobarbital Primidone Phenytoin	

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Biktarvy Prescribing Information, Feb. 2018, Gilead Sciences, Inc.

19. Biktarvy / Rifabutin & Rifapentine _____ _____

Alert Message: Concurrent use of Biktarvy (bictegravir/emtricitabine/tenofovir alafenamide) with rifabutin or rifapentine is not recommended. The bictegravir component of the combination antiretroviral is a CYP3A4 substrate and induction of its CYP3A4 metabolism by rifabutin or rifapentine may result in decreased plasma concentrations of the antiretroviral and may lead to loss of antiretroviral therapeutic effect and development of resistance.

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

Util A	Util B	Util C
Bictegravir/Emtricitabine/Tenofovir alafenamide	Rifabutin Rifapentine	

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Biktarvy Prescribing Information, Feb. 2018, Gilead Sciences, Inc.

20. Biktarvy / Al & Mg & Ca Antacids _____ _____

Alert Message: Caution should be exercised when Biktarvy (bictegravir/emtricitabine/tenofovir alafenamide) is prescribed concomitantly with antacids containing the polyvalent cations aluminum, magnesium, or calcium as the bioavailability of the bictegravir component of the antiretroviral may be decreased. Bictegravir/emtricitabine/tenofovir alafenamide can be taken under fasting conditions 2 hours before these antacids. Routine administration of bictegravir/emtricitabine/tenofovir alafenamide with, or 2 hours after, these antacids is not recommended.

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

Util A	Util B	Util C
Bictegravir/Emtricitabine/Tenofovir alafenamide	Aluminum Hydroxide Magnesium Hydroxide Calcium Carbonate Antacid	

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Biktarvy Prescribing Information, Feb. 2018, Gilead Sciences, Inc.

21. Biktarvy / Calcium & Iron Supplements _____ _____

Alert Message: Caution should be exercised when Biktarvy (bictegravir/emtricitabine/tenofovir alafenamide) is prescribed concomitantly with supplements containing polyvalent calcium (Ca) or iron (Fe) as the bioavailability of the bictegravir component of the antiretroviral may be decreased. Bictegravir/emtricitabine/tenofovir alafenamide and Ca or Fe supplements can be taken together with food. Routine administration of bictegravir/emtricitabine/tenofovir alafenamide under fasting conditions simultaneously with, or 2 hours after, these supplements is not recommended.

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

Util A	Util B	Util C
Bictegravir/Emtricitabine/Tenofovir alafenamide	Calcium Carbonate Supplements Calcium Citrate Calcium Gluconate Calcium Lactate Iron Supplements	

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Biktarvy Prescribing Information, Feb. 2018, Gilead Sciences, Inc.

22. Biktarvy / Metformin _____ _____

Alert Message: The concurrent use of Biktarvy (bictegravir/emtricitabine/tenofovir alafenamide) with dofetilide is contraindicated due to the risk of dofetilide-related serious and/or life-threatening events. The bictegravir component of the antiretroviral is an inhibitor of renal organic cation transporter (OCT2) and multidrug and toxin extrusion transporter (MATE1) which are responsible for dofetilide elimination and co-administration of these agents may result in increased dofetilide plasma concentrations.

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

Util A	Util B	Util C
Bictegravir/Emtricitabine/Tenofovir alafenamide	Metformin	

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Biktarvy Prescribing Information, Feb. 2018, Gilead Sciences, Inc.

23. Biktarvy / Nonadherence _____ _____

Alert Message: 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
Bictegravir/Emtricitabine/Tenofovir alafenamide		

References:
Clinical Pharmacology, 2017 Elsevier/Gold Standard.
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 17, 2017. 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 27, 2017. Available at: http://aidsinfo.nih.gov/contentfiles/lvguidelines/pediatricguidelines.pdf

24. Biktarvy / Therapeutic Appropriateness _____ _____

Alert Message: Safety and effectiveness of Biktarvy (bictegravir/emtricitabine/tenofovir alafenamide) in pediatric patients less than 18 years of age have not been established.

Conflict Code: TA - Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C
Bictegravir/Emtricitabine/Tenofovir alafenamide		

Age Range 0 -17 yoa

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Biktarvy Prescribing Information, Feb. 2018, Gilead Sciences, Inc.

25. Lurasidone / Overutilization _____ _____

Alert Message: The maximum recommended daily dose of Latuda (lurasidone) in pediatric patients 10 to 17 years of age with bipolar depression is 80 mg per day.

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C **(Include)**
Lurasidone		Bipolar Disorder

Max Dose: 80 mg/day
Age Range: 10 - 17 yoa

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Latuda Prescribing Information, March 2018, Sunovion Pharmaceuticals, Inc.

26. Pasireotide / Bromocriptine _____ _____

Alert Message: Co-administration of somatostatin analogues with bromocriptine may increase the blood levels of bromocriptine. Dose reduction of bromocriptine may be necessary.

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

Util A	Util B	Util C
Pasireotide	Bromocriptine	

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Signifor Prescribing Information, March 2018, Novartis Pharmaceuticals Corporation.
Signifor LAR Prescribing Information, March 2018, Novartis Pharmaceuticals Corporation.

27. Metformin / Carbonic Anhydrase Inhibitors _____ _____

Alert Message: Concurrent use of a metformin-containing agents with a carbonic anhydrase inhibitor may increase the risk of lactic acidosis associated with metformin use. Carbonic anhydrase inhibitors can decrease serum bicarbonate and induce non-anion gap, hyperchloremic metabolic acidosis. Consider more frequent monitoring of patients receiving these agents concomitantly.

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

Util A	Util B	Util C
Metformin	Acetazolamide	
	Zonisamide	
	Dichlorphenamide	
	Methazolamide	

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

28. Ertugliflozin / Overutilization _____ _____

Alert Message: The manufacturer's recommended dose of Steglatro (ertugliflozin) is 15 mg once daily.

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C
Ertugliflozin		

Max Dose: 15 mg/day

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Steglatro Prescribing Information, Dec. 2017, Merck Sharp & Dohme Corp.

29. Ertugliflozin / Severe Renal Impairment, ESRD & Dialysis _____ _____

Alert Message: Steglatro (ertugliflozin) is contraindicated in patients with severe renal impairment, end stage renal disease, or patients in dialysis. Based on its mechanism of action (inhibition of SGLT2 in the proximal renal tubules), ertugliflozin is not expected to be effective in these patients.

Conflict Code: TA - Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C **(Include)**
Ertugliflozin		CKD Stage 4 & 5
		ESRD
		Dialysis

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Steglatro Prescribing Information, Dec. 2017, Merck Sharp & Dohme Corp.

30. Ertugliflozin / Mild to Moderate Renal impairment _____ _____

Alert Message: Assessment of renal function is recommended prior to initiation of Steglatro (ertugliflozin) therapy and periodically thereafter. Initiation of ertugliflozin is not recommended in patients with an eGFR of 30 to less than 60 mL/min/1.73m2 and continued use is not recommended in patients with an eGFR persistently between 30 and less than 60 mL/min/1.73m2.

Conflict Code: TA - Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C **(Include)**
Ertugliflozin		CKD Stage 1, 2, & 3

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Steglatro Prescribing Information, Dec. 2017, Merck Sharp & Dohme Corp.

31. Ertugliflozin / Nonadherence _____ _____

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

Conflict Code: LR - Nonadherence
Drugs/Diseases

Util A	Util B	Util C
Ertugliflozin		

References:
Steglatro Prescribing Information, Dec. 2017, Merck Sharp & Dohme Corp.
Osterberg L, Blaschke T. Adherence to medication. N Engl J Med 2005;353:487-97.
Ho PM, Rumsfeld JS, Masoudi FA, et al., Effect of Medication Nonadherence in Diabetes Mellitus. Cardiology Review, April 2007.
Currie CJ, Peyrot M, Morgan CL, et al. The Impact of Treatment Noncompliance on Mortality in People with Type 2 Diabetes. Diabetes Care 35:1279-1284, June 2012.

32. Ertugliflozin / Hypotension _____ _____

Alert Message: Steglatro (ertugliflozin) causes osmotic diuresis which can lead to volume depletion and hypotension, particularly in patients with impaired renal function, elderly patients, or patients on diuretics. Monitor patients for signs and symptoms during therapy. Before initiating ertugliflozin in patients with one or more of these characteristics, volume status should be assessed and corrected.

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

Util A	Util B	Util C
Ertugliflozin	Hypotension	
	Hypovolemia	
	CKD Stage 3	
	Dehydration	

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Steglatro Prescribing Information, Dec. 2017, Merck Sharp & Dohme Corp.

33. Ertugliflozin / Diuretics _____ _____

Alert Message: Steglatro (ertugliflozin) causes osmotic diuresis which can lead to volume depletion and hypotension, particularly in patients with impaired renal function, elderly patients, or patients on diuretics. Monitor patients for signs and symptoms during therapy. Before initiating ertugliflozin in patients with one or more of these characteristics, volume status should be assessed and corrected.

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

Util A	Util B			Util C
Ertugliflozin	Furosemide	Chlorthalidone	Triamterene	
	Torsemide	Indapamide	Eplerenone	
	Ethacrynate	Methyclothiazide		
	Bumetanide	Metolazone		
	HCTZ	Amiloride		
	Chlorothiazide	Spironolactone		

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Steglatro Prescribing Information, Dec. 2017, Merck Sharp & Dohme Corp.

34. Ertugliflozin / Insulin & Insulin Secretagogues _____ _____

Alert Message: The concurrent use of Steglatro (ertugliflozin) with insulin and insulin secretagogues 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 ertugliflozin.

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

Util A	Util B	Util C
Ertugliflozin	Insulins	
	Sulfonylureas	

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Steglatro Prescribing Information, Dec. 2017, Merck Sharp & Dohme Corp.

35. Ertugliflozin / LDL-C Increases _____ _____

Alert Message: The use of Steglatro (ertugliflozin) can cause dose-related increases in LDL-C levels. Patients receiving ertugliflozin should have their LDL-C levels monitored and treated per standard of care.

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C **(Include)**
Ertugliflozin		Hypercholesterolemia

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Steglatro Prescribing Information, Dec. 2017, Merck Sharp & Dohme Corp.

36. Ertugliflozin / Pregnancy / Pregnancy Negating _____ _____

Alert Message: Based on animal data showing adverse renal effects, Steglatro (ertugliflozin) use is not recommended during the second and third trimesters of pregnancy. In animal studies, adverse renal changes were observed in rats when ertugliflozin was administered during a period of renal development corresponding to the late second and third trimesters of human pregnancy.

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

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

References:
Steglatro Prescribing Information, Dec. 2017, Merck Sharp & Dohme Corp.
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Blumer I, Hadar E, Hadden DR, et al. Diabetes and Pregnancy: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. 2013;98(11):4227-4249.
American Diabetes Association (ADA). 13. Management of Diabetes in Pregnancy. In Standards of Medical Care in Diabetes - 2017. Diabetes Care. 2017c;40(Suppl. 1):S114-S119.

37. Ertugliflozin / Therapeutic Appropriateness _____ _____

Alert Message: Safety and effectiveness of Steglatro (ertugliflozin) in pediatric patients under 18 years of age have not been established.

Conflict Code: TA - Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C
Ertugliflozin		

Age Range 0 -17 yoa

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Steglatro Prescribing Information, Dec. 2017, Merck Sharp & Dohme Corp.

38. Dolutegravir/Rilpivirine / Overutilization _____ _____

Alert Message: The recommended daily dose of Juluca (dolutegravir/rilpivirine) is one 50 mg dolutegravir/25 mg rilpivirine tablet per day.

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C
Dolutegravir/rilpivirine		

Max Dose: 1 tablet per day

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Juluca Prescribing Information, Nov. 2017, ViiV Healthcare.

39. Dolutegravir/Rilpivirine / Rifabutin / Rilpivirine _____ _____

Alert Message: If Juluca (dolutegravir/rilpivirine) is co-administered with rifabutin, the patient should take an additional 25 mg rilpivirine tablet once daily with dolutegravir/rilpivirine for the duration of the rifabutin therapy. Rifabutin is a CYP3A4 inducer and concomitant use with a rilpivirine-containing agent may result in decreased plasma concentrations of rilpivirine and loss of virologic response or possible resistance to rilpivirine.

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

Util A	Util B	Util C **(Negate)**
Dolutegravir/rilpivirine	Rifabutin	Rilpivirine

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Juluca Prescribing Information, Nov. 2017, ViiV Healthcare.

40. Dolutegravir/Rilpivirine / Dofetilide _____ _____

Alert Message: The concurrent use of Juluca (dolutegravir/rilpivirine) with dofetilide is contraindicated due to the potential for serious and life-threatening adverse events, such as QT prolongation and torsade de pointes. Dofetilide is a substrate of the renal organic cation transporter 2 (OCT2) and the dolutegravir component of the combination antiretroviral product inhibits elimination via OCT2.

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

Util A	Util B	Util C
Dolutegravir/rilpivirine	Dofetilide	

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Juluca Prescribing Information, Nov. 2017, ViiV Healthcare.

41. Dolutegravir/Rilpivirine / Contraindicated Drugs _____ _____

Alert Message: Co-administration of Juluca (dolutegravir/rilpivirine) is contraindicated with drugs that significantly decrease rilpivirine plasma concentrations as concurrent use may result in loss of virologic response and possible resistance and cross-resistance to the antiretroviral.

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

Util A	Util B		Util C
Dolutegravir/rilpivirine	Carbamazepine	Omeprazole	
	Oxcarbazepine	Esomeprazole	
	Phenobarbital	Lansoprazole	
	Phenytoin	Pantoprazole	
	Rifampin	Rabeprazole	
	Rifapentine	Dexlansoprazole	
		Dexamethasone	

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Juluca Prescribing Information, Nov. 2017, ViiV Healthcare.

42. Dolutegravir/Rilpivirine / All Other Antiretrovirals _____ _____

Alert Message: Juluca (dolutegravir/rilpivirine) is a complete regimen; co-administration with other antiretroviral medications for the treatment of HIV-1 infection is not recommended.

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

Util A	Util B	Util C
Dolutegravir/rilpivirine	Cellular Chemokine Receptor (CCR5) Antagonist	
	Fusion Inhibitors	
	Integrase Inhibitors	
	NNRTIs	
	NRTIs	
	Nucleotide Analog Reverse Transcriptase Inhibitors	
	Protease Inhibitors	
	Antiretroviral Combos	

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Juluca Prescribing Information, Nov. 2017, ViiV Healthcare.

43. Dolutegravir/Rilpivirine / Antacids _____ _____

Alert Message: Caution should be exercised when Juluca (dolutegravir/rilpivirine) is prescribed concomitantly with antacids (e.g., aluminum or magnesium hydroxide, calcium carbonate) as antacids increase gastric pH which may cause a significant decrease in the plasma concentrations of the rilpivirine component of the antiretroviral combination product. Rilpivirine requires an acidic environment for optimal absorption. Antacids should be administered either at least 4 hours before or at least 6 hours after dolutegravir/rilpivirine.

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

Util A	Util B	Util C
Dolutegravir/rilpivirine	Aluminum Hydroxide	
	Magnesium Hydroxide	
	Calcium Carbonate	

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Juluca Prescribing Information, Nov. 2017, ViiV Healthcare.

44. Dolutegravir/Rilpivirine / Metformin _____ _____

Alert Message: Concurrent use of Juluca (dolutegravir/rilpivirine) and metformin may result in increased metformin concentrations due to inhibition, by dolutegravir, of the renal organic cation transporter 2 (OCT2) and multidrug and toxin extrusion transporter (MATE1) which are responsible for metformin elimination. Monitoring blood glucose is recommended when initiation concomitant use and after withdrawal of dolutegravir/rilpivirine.

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

Util A	Util B	Util C
Dolutegravir/rilpivirine	Metformin	

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Juluca Prescribing Information, Nov. 2017, ViiV Healthcare.

45. Dolutegravir/Rilpivirine / Certain Macrolides _____ _____

Alert Message: Concurrent use of Juluca (dolutegravir/rilpivirine) with clarithromycin or erythromycin may cause an increase in the plasma concentrations of the rilpivirine component of the antiretroviral combination product, due to inhibition by the macrolide of rilpivirine CYP3A4-mediated metabolism. When possible, consider alternatives, such as azithromycin.

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

Util A	Util B	Util C
Dolutegravir/rilpivirine	Erythromycin	
	Clarithromycin	

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Juluca Prescribing Information, Nov. 2017, ViiV Healthcare.

46. Dolutegravir/Rilpivirine / Medications Containing Polyvalent Cations _____ _____

Alert Message: Juluca (dolutegravir/rilpivirine) should be administered 4 hours before or 6 hours after taking medications containing polyvalent cations. Polyvalent cations can bind the dolutegravir component of the antiretroviral combination product in the GI tract and reduce its bioavailability.

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

Util A	Util B	Util C
Dolutegravir/rilpivirine	Sucralfate	
	Cation-containing Laxatives	

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Juluca Prescribing Information, Nov. 2017, ViiV Healthcare.

47. Dolutegravir/Rilpivirine / Oral Calcium & Iron Supplements _____ _____

Alert Message: Concurrent use of Juluca (dolutegravir/rilpivirine) with supplements containing calcium or iron may result in the decreased absorption of the dolutegravir component in the antiretroviral combination product. Dolutegravir/rilpivirine may be administered with supplements if taken together with a meal or take dolutegravir/rilpivirine 4 hours before or 6 hours after taking these supplements.

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

Util A	Util B	Util C
Dolutegravir/rilpivirine	Iron Supplements	
	Calcium Supplements	
	Multivitamins w/ Iron & Calcium	

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Juluca Prescribing Information, Nov. 2017, ViiV Healthcare.

48. Dolutegravir/Rilpivirine / Depression _____ _____

Alert Message: Depressive disorders have been reported with rilpivirine use. Promptly evaluate patients with severe depressive symptoms to assess whether the symptoms are related to the rilpivirine-containing agent and to determine whether the risks of continued therapy outweigh the benefits.

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

Util A	Util B	Util C
Dolutegravir/rilpivirine	Major Depressive Disorder	
	Suicidal Ideation	

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Juluca Prescribing Information, Nov. 2017, ViiV Healthcare.

49. Dolutegravir/Rilpivirine / Nonadherence _____ _____

Alert Message: Based on the refill history, your patient may be underutilizing Juluca (dolutegravir/rilpivirine). 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
Dolutegravir/rilpivirine		

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 17, 2017. 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 27, 2017. Available at: http://aidsinfo.nih.gov/contentfiles/lvguidelines/pediatricguidelines.pdf

50. Pregabalin CR / Overutilization - DPN _____ _____

Alert Message: Lyrica CR (pregabalin extended-release) may be over-utilized. The manufacturer's recommended dose for patients with diabetic peripheral neuropathy is 330 mg per day. Higher doses have not been shown to confer significant additional benefit and are less well tolerated. In view of the dose-dependent adverse reactions with pregabalin, treatment with doses above 330 mg per day are not recommended in this patient population.

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C **(Include)**
Pregabalin CR		Diabetic Peripheral Neuropathy

Max Dose: 330 mg/day

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Lyrica CR Prescribing Information, Oct. 2017, Pfizer Inc.

51. Pregabalin CR / Overutilization - PHN _____ _____

Alert Message: Lyrica CR (pregabalin extended-release) may be over-utilized. The manufacturer's recommended maximum dose for patients with postherpetic neuralgia is 660 mg once daily. In view of the dose-dependent adverse effects and the higher rate of treatment discontinuation caused by adverse reactions, dosing above 330 mg per day should be reserved for those patients who have ongoing pain and are tolerating 330 mg daily.

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C **(Include)**
Pregabalin CR		Postherpetic Neuralgia

Max Dose: 660 mg/day

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Lyrica CR Prescribing Information, Oct. 2017, Pfizer Inc.

52. Pregabalin CR / CKD 4, 5, ESRD & Hemodialysis _____ _____

Alert Message: Use of Lyrica CR (pregabalin extended-release) is not recommended for patients with creatinine clearance (CLcr) less than 30 mL/min or who are undergoing hemodialysis; those patients should receive pregabalin immediate-release.

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C **(Include)**
Pregabalin CR		CKD 4
		CKD 5
		ESRD
		Hemodialysis

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Lyrica CR Prescribing Information, Oct. 2017, Pfizer Inc.

53. Pregabalin CR / CKD 3 _____ _____

Alert Message: Lyrica CR (pregabalin extended-release) is eliminated primarily by renal excretion and dose adjustment is recommended in patients with a CLcr between 30 - 59 mL/min. Refer to the official prescribing information for recommended total daily dose based on the patient's estimated CLcr. Patients with CLcr greater than or equal to 60 mL/min do not require dosage adjustment.

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C **(Include)**
Pregabalin CR		CKD 3

Max Dose: 660 mg/day

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Lyrica CR Prescribing Information, Oct. 2017, Pfizer Inc.

54. Pregabalin CR / Thiazolidinediones _____ _____

Alert Message: The thiazolidinedione class of antidiabetic drugs can cause weight gain and/or fluid retention, possibly exacerbating or leading to heart failure. Monitor patients for the development of edema when co-administering Lyrica CR (pregabalin extended-release) and these agents.

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

Util A	Util B	Util C **(Include)**
Pregabalin CR	Rosiglitazone	
	Pioglitazone	

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Lyrica CR Prescribing Information, Oct. 2017, Pfizer Inc.

55. Pregabalin CR / Heart Failure _____ _____

Alert Message: Lyrica CR (pregabalin extended-release) may cause peripheral edema. Because there are limited data on congestive heart failure patients with New York Association (NYHA) Class III or IV cardiac status, monitor these patients for possible exacerbation of congestive heart failure symptoms when using pregabalin extended-release.

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C **(Include)**
Pregabalin CR		Heart Failure

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Lyrica CR Prescribing Information, Oct. 2017, Pfizer Inc.

56. Pregabalin CR / Nonadherence _____ _____

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

Conflict Code: LR - Nonadherence
Drugs/Diseases

Util A	Util B	Util C
Pregabalin		

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.
Faught ER, Weiner JR, Guerin A, et al. Impact of Nonadherence to Antiepileptic Drugs on Health Care Utilization and Costs: Findings from the RANSOM Study. Epilepsia 2009;50(3):501-509.

57. Opioid Cough & Cold Medications / Therapeutic Appropriateness _____ _____

Alert Message: Opioid cough and cold medications containing codeine or hydrocodone are not approved for use in children younger than 18 years of age. The serious risks associated with these medications (i.e., respiratory depression, death, abuse and addiction) outweigh their potential benefits in this population. Cough due to a cold or upper respiratory infection is self-limited and generally does not need to be treated. For those children in whom cough treatment is necessary, alternative medicines are available.

Conflict Code: TA - Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C
Codeine Cough and Cold Products		
Hydrocodone Cough and Cold Products		

Age Range: <18 yoa

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
FDA Drug Safety Communication: FDA requires labeling changes for prescription opioid cough and cold medicines to limit their use to adults 18 years and older. Safety Announcement [01-11-2018].
Available at:
https://www.fda.gov/Drugs/DrugSafety/ucm590435.htm?utm_campaign=Prescription%20Opioid%20Cough%20and%20Cold%20Medicines%3A%20Drug%20Safety%20Communication

58. Amantadine ER / Overutilization _____ _____

Alert Message: The manufacturer's recommended dose of Gocovri (amantadine extended release) is 274 mg (two 137 mg capsules) once daily at bedtime.

Conflict Code: ER - Overutilization
Drugs/Diseases

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

Max Dose: 274 mg/day

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Gocovri Prescribing Information, August 2017, Adamas Pharma, LLC.

59. Amantadine ER / Overutilization Moderate Renal Impairment _____ _____

Alert Message: The manufacturer's recommended maximum dose of Gocovri (amantadine extended release) in patients with moderate renal impairment (CrCl 30 - 59 mL/min/1.73 m2) is 137 mg once daily at bedtime.

Conflict Code: ER - Overutilization
Drugs/Diseases

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

Max Dose: 137 mg/day

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Gocovri Prescribing Information, August 2017, Adamas Pharma, LLC.

60. Amantadine ER / Overutilization Severe Renal Impairment _____ _____

Alert Message: The manufacturer's recommended dose of Gocovri (amantadine extended release) in patients with severe renal impairment (CrCl 15 - 29 mL/min/1.73 m2) is 68.5 mg once daily at bedtime.

Conflict Code: ER - Overutilization
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.
Gocovri Prescribing Information, August 2017, Adamas Pharma, LLC.

61. Amantadine ER / End Stage Renal Disease _____ _____

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

Conflict Code: TA - Therapeutic Appropriateness
Drugs/Diseases

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

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Gocovri Prescribing Information, August 2017, Adamas Pharma, LLC.

62. Amantadine ER / Alcohol Dependence _____ _____

Alert Message: Concomitant use of Gocovri (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, and may result in dose-dumping (premature exaggerated release of drug).

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

Util A	Util B	Util C
Amantadine ER	Alcohol Dependence	

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Gocovri Prescribing Information, August 2017, Adamas Pharma, LLC.

63. Amantadine ER / Drugs Decreasing Urinary pH _____ _____

Alert Message: Concurrent use of Gocovri (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 patient for decreased amantadine efficacy.

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

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

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Gocovri Prescribing Information, August 2017, Adamas Pharma, LLC.

64. Amantadine ER / Drugs Increasing Urinary pH _____ _____

Alert Message: Concurrent use of Gocovri (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 and alterations of urine pH towards the alkaline condition may lead to amantadine accumulation.

Conflict Code: DD – Drug/Drug Interaction
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:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Gocovri Prescribing Information, August 2017, Adamas Pharma, LLC.

65. Ertugliflozin-Metformin / Overutilization _____ _____

Alert Message: The manufacturer's recommended dose of Segluromet (ertugliflozin/metformin) is 7.5 mg ertugliflozin/1000 mg metformin twice daily.

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C
Ertugliflozin/Metformin		

Max Dose: 15/2000mg per day

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Segluromet Prescribing Information, Dec. 2017, Merck Sharp & Dohme Corp.

66. Ertugliflozin-Metformin / Severe Renal Impairment, ESRD & Dialysis _____ _____

Alert Message: Segluromet (ertugliflozin/metformin) is contraindicated in patients with severe renal impairment, end-stage renal disease, or patients on dialysis. Based on the mechanism of action of the ertugliflozin component (inhibition of SGLT2 in the proximal renal tubules), ertugliflozin is not expected to be effective in these patients.

Conflict Code: TA - Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C **(Include)**
Ertugliflozin/Metformin		CKD Stage 4 & 5
		ESRD
		Dialysis

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Segluromet Prescribing Information, Dec. 2017, Merck Sharp & Dohme Corp.

67. Ertugliflozin-Metformin / Mild to Moderate Renal impairment _____ _____

Alert Message: Assessment of renal function is recommended prior to initiation of Segluromet (ertugliflozin/metformin) therapy and periodically thereafter. Initiation of ertugliflozin/metformin is not recommended in patients with an eGFR of 30 to less than 60 mL/min/1.73m2. Continued use is not recommended when eGFR is persistently between 30 and less than 60 mL/min/1.73m2.

Conflict Code: TA - Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C **(Include)**
Ertugliflozin/Metformin		CKD Stage 1, 2, & 3

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Segluromet Prescribing Information, Dec. 2017, Merck Sharp & Dohme Corp.

68. Ertugliflozin-Metformin / Hypotension _____ _____

Alert Message: The ertugliflozin component of Segluromet (ertugliflozin/metformin) can cause intravascular volume contraction. Therefore, symptomatic hypotension may occur after initiating ertugliflozin/metformin particularly in patients with impaired renal function, elderly patients, or patients on diuretics. Before initiating ertugliflozin/metformin, volume status should be assessed and corrected if indicated. Monitor for signs and symptoms of hypotension after initiating therapy.

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

Util A	Util B	Util C
Ertugliflozin/Metformin	Hypotension	
	Hypovolemia	
	CKD Stage 3	
	Dehydration	

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Segluromet Prescribing Information, Dec. 2017, Merck Sharp & Dohme Corp.

69. Ertugliflozin-Metformin / Diuretics _____ _____

Alert Message: The ertugliflozin component of Segluromet (ertugliflozin/metformin) can cause intravascular volume contraction. Therefore, symptomatic hypotension may occur after initiating ertugliflozin/metformin particularly in patients with impaired renal function, elderly patients, or patients on diuretics. Before initiating ertugliflozin/metformin, volume status should be assessed and corrected if indicated. Monitor for signs and symptoms of hypotension after initiating therapy.

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

Util A	Util B			Util C
Ertugliflozin/Metformin	Furosemide	Chlorthalidone	Triamterene	
	Torsemide	Indapamide	Eplerenone	
	Ethacrynate	Methyclothiazide		
	Bumetanide	Metolazone		
	HCTZ	Amiloride		
	Chlorothiazide	Spironolactone		

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Segluromet Prescribing Information, Dec. 2017, Merck Sharp & Dohme Corp.

70. Ertugliflozin-Metformin / Insulin & Insulin Secretagogues _____ _____

Alert Message: The concurrent use of Segluromet (ertugliflozin/metformin) with insulin and insulin secretagogues 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 ertugliflozin/metformin.

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

Util A	Util B	Util C
Ertugliflozin/Metformin	Insulins	
	Sulfonylureas	

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Segluromet Prescribing Information, Dec. 2017, Merck Sharp & Dohme Corp.

71. Ertugliflozin-Metformin / LDL-C Increases _____ _____

Alert Message: Dose-related increases in LDL-C levels can occur with the use of ertugliflozin, a component of Segluromet (ertugliflozin/metformin). Patients receiving ertugliflozin/metformin should have their LDL-C levels monitored and treated per standard of care.

Conflict Code: TA - Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C **(Include)**
Ertugliflozin/Metformin		Hypercholesterolemia

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Segluromet Prescribing Information, Dec. 2017, Merck Sharp & Dohme Corp.

72. Ertugliflozin-Metformin / Pregnancy / Pregnancy Negating _____ _____

Alert Message: Based on animal data showing adverse renal effects, Segluromet (ertugliflozin/metformin) use is not recommended during the second and third trimesters of pregnancy. In animal studies, adverse renal changes were observed in rats when ertugliflozin was administered during a period of renal development corresponding to the late second and third trimesters of human pregnancy.

Conflict Code: TA - Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C **(Negating)**
Ertugliflozin/Metformin	Pregnancy	Delivery
		Abortion
		Miscarriage

Age Range: 11 - 50 yoa
Gender: Female

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Segluromet Prescribing Information, Dec. 2017, Merck Sharp & Dohme Corp.
Blumer I, Hadar E, Hadden DR, et al. Diabetes and Pregnancy: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. 2013;98(11):4227-4249.
American Diabetes Association (ADA). 13. Management of Diabetes in Pregnancy. In Standards of Medical Care in Diabetes - 2017. Diabetes Care. 2017c;40(Suppl. 1):S114-S119.

73. Ertugliflozin-Metformin / Nonadherence _____ _____

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

Conflict Code: LR - Nonadherence
Drugs/Diseases

Util A	Util B	Util C
Ertugliflozin/Metformin		

References:
Osterberg L, Blaschke T. Adherence to medication. N Engl J Med 2005;353:487-97.
Ho PM, Rumsfeld JS, Masoudi FA, et al., Effect of Medication Nonadherence in Diabetes Mellitus. Cardiology Review, April 2007.
Currie CJ, Peyrot M, Morgan CL, et al. The Impact of Treatment Noncompliance on Mortality in People With Type 2 Diabetes. Diabetes Care 35:1279-1284, June 2012.
Segluromet Prescribing Information, Dec. 2017, Merck Sharp & Dohme Corp.

74. Ertugliflozin-Metformin / Therapeutic Appropriateness _____ _____

Alert Message: Safety and effectiveness of Segluromet (ertugliflozin/metformin) in pediatric patients under 18 years of age have not been established.

Conflict Code: TA - Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C
Ertugliflozin/Metformin		

Age Range 0 -17 yoa

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Segluromet Prescribing Information, Dec. 2017, Merck Sharp & Dohme Corp.

75. Nuedexta / Pseudobulbar Affect (Negating) _____ _____

Alert Message: A recent review of the patient's medical profile does not reveal a supporting diagnosis for the use of Nuedexta (dextromethorphan/quinidine). Dextromethorphan/quinidine is only approved for the treatment of pseudobulbar affect (PBA). Clinical research on the safety and efficacy of dextromethorphan/quinidine for other indications has not been conducted. This agent has serious adverse effects as well as significant drug interactions and should only be used for the FDA approved indication.

Conflict Code: TA - Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C **(Negating)**
Dextromethorphan/quinidine		Pseudobulbar Affect

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Facts & Comparisons, 2018 Updates, Wolters Kluwer Health.
Nuedexta Prescribing Information, Jan. 2015, Avanir Pharmaceuticals, Inc.

76. Sumatriptan Injection 3 mg / Overutilization _____ _____

Alert Message: Zembrace SymTouch (sumatriptan) may be over-utilized. The manufacturer's recommended maximum cumulative dose that may be given in 24 hours is 12 mg subcutaneously, with doses separated by at least 1 hour.

Conflict Code: ER - Overutilization
Drugs/Diseases
Util A Util B Util C
Sumatriptan Injection

Max Dose: 12 mg/day

References:
Clinical Pharmacology, 2017 Elsevier/Gold Standard.
Facts & Comparisons, 2017 Updates, Wolters Kluwer Health.

77. Sumavel / Overutilization _____ _____

Alert Message: Sumavel DosePro (sumatriptan) may be over-utilized. The manufacturer's recommended maximum cumulative dose that may be given in 24 hours is 12 mg subcutaneously (2 - 6mg doses), with doses separated by at least 1 hour.

Conflict Code: ER - Overutilization
Drugs/Diseases
Util A Util B Util C
Sumatriptan Inj.

Max Dose: 12 mg/day

References:
Clinical Pharmacology, 2017 Elsevier/Gold Standard.
Facts & Comparisons, 2017 Updates, Wolters Kluwer Health.

78. Ertugliflozin-Sitagliptin / Overutilization _____ _____

Alert Message: The manufacturer's recommended dose of Steglujan (ertugliflozin/sitagliptin) is 15 mg ertugliflozin/100 mg sitagliptin once daily.

Conflict Code: ER - Overutilization
Drugs/Diseases
Util A Util B Util C
Ertugliflozin/Sitagliptin

Max Dose: 15 mg/100mg per day

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Steglujan Prescribing Information, Dec. 2017, Merck Sharp & Dohme Corp.

79. Ertugliflozin-Sitagliptin / Severe Renal Impairment, ESRD & Dialysis _____ _____

Alert Message: Steglujan (ertugliflozin/sitagliptin) is contraindicated in patients with severe renal impairment, end-stage renal disease, or patients on dialysis. Based on the mechanism of action of the ertugliflozin component (inhibition of SGLT2 in the proximal renal tubules), the agent is not expected to be effective in these patients.

Conflict Code: TA - Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C **(Include)**
Ertugliflozin/Sitagliptin		CKD Stage 4 & 5
		ESRD
		Dialysis

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Steglujan Prescribing Information, Dec. 2017, Merck Sharp & Dohme Corp.

80. Ertugliflozin-Sitagliptin / Mild to Moderate Renal impairment _____ _____

Alert Message: Assessment of renal function is recommended prior to initiation of Steglujan (ertugliflozin/sitagliptin) therapy and periodically thereafter. Initiation of an ertugliflozin-containing agent is not recommended in patients with an eGFR of 30 to less than 60 mL/min/1.73m2 and continued use is not recommended in patients with an eGFR persistently between 30 and less than 60 ml/min/1.73m2.

Conflict Code: TA - Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C **(Include)**
Ertugliflozin/Sitagliptin		CKD Stage 1, 2, & 3

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Steglujan Prescribing Information, Dec. 2017, Merck Sharp & Dohme Corp.

81. Ertugliflozin-Sitagliptin / Nonadherence _____ _____

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

Conflict Code: LR - Nonadherence
Drugs/Diseases

Util A	Util B	Util C
Ertugliflozin/Sitagliptin		

References:
Steglujan Prescribing Information, Dec. 2017, Merck Sharp & Dohme Corp.
Osterberg L, Blaschke T. Adherence to medication. N Engl J Med 2005;353:487-97.
Ho PM, Rumsfeld JS, Masoudi FA, et al., Effect of Medication Nonadherence in Diabetes Mellitus. Cardiology Review, April 2007.
Currie CJ, Peyrot M, Morgan CL, et al. The Impact of Treatment Noncompliance on Mortality in People With Type 2 Diabetes. Diabetes Care 35:1279-1284, June 2012.

82. Ertugliflozin-Sitagliptin / Hypotension _____ _____

Alert Message: The ertugliflozin component of Steglujan (ertugliflozin/sitagliptin) can cause intravascular volume contraction. Therefore, symptomatic hypotension may occur after initiating ertugliflozin/sitagliptin particularly in patients with impaired renal function, elderly patients, or patients on diuretics. Before initiating ertugliflozin/sitagliptin, volume status should be assessed and corrected if indicated. Monitor for signs and symptoms of hypotension after initiating therapy.

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

Util A	Util B	Util C
Ertugliflozin/Sitagliptin	Hypotension	
	Hypovolemia	
	CKD Stage 3	
	Dehydration	

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Steglujan Prescribing Information, Dec. 2017, Merck Sharp & Dohme Corp.

83. Ertugliflozin-Sitagliptin / Diuretics _____ _____

Alert Message: The ertugliflozin component of Steglujan (ertugliflozin/sitagliptin) can cause intravascular volume contraction. Therefore, symptomatic hypotension may occur after initiating ertugliflozin/sitagliptin particularly in patients with impaired renal function, elderly patients, or patients on diuretics. Before initiating ertugliflozin/sitagliptin, volume status should be assessed and corrected if indicated. Monitor for signs and symptoms of hypotension after initiating therapy.

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

Util A	Util B			Util C
Ertugliflozin/Sitagliptin	Furosemide	Chlorthalidone	Triamterene	
	Torsemide	Indapamide	Eplerenone	
	Ethacrynate	Methyclothiazide		
	Bumetanide	Metolazone		
	HCTZ	Amiloride		
	Chlorothiazide	Spironolactone		

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Steglujan Prescribing Information, Dec. 2017, Merck Sharp & Dohme Corp.

84. Ertugliflozin-Sitagliptin / Insulin & Insulin Secretagogues _____ _____

Alert Message: The concurrent use of Steglujan (ertugliflozin/sitagliptin) with insulin and insulin secretagogues 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 ertugliflozin/sitagliptin.

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

Util A	Util B	Util C
Ertugliflozin/Sitagliptin	Insulins	
	Sulfonylureas	

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Steglujan Prescribing Information, Dec. 2017, Merck Sharp & Dohme Corp.

85. Ertugliflozin-Sitagliptin / LDL-C Increases _____ _____

Alert Message: The use of Steglujan (ertugliflozin/sitagliptin) can cause dose-related increases in LDL-C levels. Patients receiving ertugliflozin/sitagliptin should have their LDL-C levels monitored and treated per standard of care.

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C **(Include)**
Ertugliflozin/Sitagliptin		Hypercholesterolemia

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Steglujan Prescribing Information, Dec. 2017, Merck Sharp & Dohme Corp.

86. Ertugliflozin-Sitagliptin / Pregnancy / Pregnancy Negating _____ _____

Alert Message: Based on animal data showing adverse renal effects Steglujan (ertugliflozin/sitagliptin) use is not recommended during the second and third trimesters of pregnancy. In animal studies, adverse renal changes were observed in rates when ertugliflozin was administered during a period of renal development corresponding to the late second and third trimesters of human pregnancy. During pregnancy consider appropriate alternative therapy.

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

Util A	Util B	Util C **(Negating)**
Ertugliflozin/Sitagliptin	Pregnancy	Delivery
		Abortion
		Miscarriage

Age Range: 11 - 50 yoa
Gender: Female

References:
Steglujan Prescribing Information, Dec. 2017, Merck Sharp & Dohme Corp.
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Blumer I, Hadar E, Hadden DR, et al. Diabetes and Pregnancy: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. 2013;98(11):4227-4249.
American Diabetes Association (ADA). 13. Management of Diabetes in Pregnancy. In Standards of Medical Care in Diabetes - 2017. Diabetes Care. 2017c;40(Suppl. 1):S114-S119.

87. Ertugliflozin-Sitagliptin / Therapeutic Appropriateness _____ _____

Alert Message: Safety and effectiveness of Steglujan (ertugliflozin/sitagliptin) in pediatric patients under 18 years of age have not been established.

Conflict Code: TA - Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C
Ertugliflozin/Sitagliptin		

Age Range 0 -17 yoa

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Steglujan Prescribing Information, Dec. 2017, Merck Sharp & Dohme Corp.

88. Glycopyrrolate / Overutilization _____ _____

Alert Message: The manufacturer's recommended maximum daily dose of Lonhala Magnair (glycopyrrolate) is one vial (25 mcg) inhaled twice daily (total 50 mcg per day). More frequent administration or greater number of inhalations (more than one vial twice daily) is not recommended.

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C
Glycopyrrolate Inhalation Solution		

Max Dose: 50 mcg/day

References:
Lonhala Magnair, Dec. 2017, Sunovion Pharmaceuticals Inc.
Clinical Pharmacology, 2018 Elsevier/Gold Standard.

89. Glycopyrrolate / Anticholinergic Agents _____ _____

Alert Message: The concurrent use of Lonhala Magnair (glycopyrrolate) with other anticholinergic agents should be avoided. Glycopyrrolate is an anticholinergic agent and co-administration with other anticholinergics may lead to an increase in anticholinergic adverse effects.

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

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

References:
Lonhala Magnair, Dec. 2017, Sunovion Pharmaceuticals Inc.
Clinical Pharmacology, 2018 Elsevier/Gold Standard.

90. Glycopyrrolate / Non-adherence _____ _____

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

Conflict Code: LR - Nonadherence
Drugs/Diseases

Util A	Util B	Util C
Glycopyrrolate Inhalation Solution		

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.

91. Glycopyrrolate / Narrow Angle Glaucoma _____ _____

Alert Message: Lonhala Magnair (glycopyrrolate) should be used with caution in patients with narrow-angle glaucoma. Glycopyrrolate is an anticholinergic agent and its use in this patient population can worsen the condition.

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C **(Include)**
Glycopyrrolate Inhalation Solution		Narrow Angle Glaucoma

References:
Lonhala Magnair, Dec. 2017, Sunovion Pharmaceuticals Inc.
Clinical Pharmacology, 2018 Elsevier/Gold Standard.

92. Glycopyrrolate / Urinary Retention, Prost Hyperplasia/Bladder Neck Obst. _____ _____

Alert Message: Lonhala Magnair (glycopyrrolate) should be used with caution in patients with urinary retention. Glycopyrrolate is an anticholinergic agent and its use can worsen urinary retention, especially in patient with prostatic hyperplasia or bladder neck obstruction.

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C **(Include)**
Glycopyrrolate Inhalation Solution		Urinary Retention Prostatic Hyperplasia Bladder Neck Obstruction

References:
Lonhala Magnair, Dec. 2017, Sunovion Pharmaceuticals Inc.
Clinical Pharmacology, 2018 Elsevier/Gold Standard.

93. Glycopyrrolate /Therapeutic Appropriateness _____ _____

Alert Message: The safety and effectiveness of Lonhala Magnair (glycopyrrolate) have not been established in pediatric patients.

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C
Glycopyrrolate Inhalation Solution		

Age Range: 0 – 17 yoa

References:
Lonhala Magnair, Dec. 2017, Sunovion Pharmaceuticals Inc.
Clinical Pharmacology, 2018 Elsevier/Gold Standard.

DUR Board Meeting
September 5, 2018
Brynhild Haugland Room

North Dakota Medicaid
DUR Board Meeting Agenda
Brynhild Haugland Room
State Capitol
600 East Boulevard Avenue
Bismarck, ND
September 5, 2018
1:00 pm

1. Administrative items
    - Travel vouchers

2. Old business
    - Review and approval of 06/2018 meeting minutes
    - Budget update
    - Review top 15 therapeutic categories/top 25 drugs
    - Prior authorization/PDL update
    - Second review of Daxbia
    - Second review of dermatophytosis (Tinea infections) agents
    - Second review of eosinophilic asthma agents
    - Second review of migraine prophylaxis (CGRP Inhibitors)
    - Second review of Millipred DP
    - Second review of Rytary
    - Sanford Update

3. New business
    - Review of glyburide and Avandia
    - Review of Lucemyra
    - Review of Palynziq
    - Review of Roxybond
    - Review of Siklos
    - Utilization review of concomitant sedative/hypnotic and benzodiazepine agents
    - Update on CAR T-cell Therapies
    - Retrospective DUR criteria recommendations
    - Upcoming meeting date/agenda.
        - Next meeting is December 5, 2018 in the Lecture Room A of the Heritage Center

4. Adjourn

Please remember to silence all cellular phones during the meeting.

Drug Utilization Review (DUR) Meeting Minutes
June 6, 2018

Members Present: Katie Kram, Tanya Schmidt, Zach Marty, LeNeika Roehrich, Andrea Honeyman, Carlotta McCleary, Peter Woodrow, Jeffrey Hostetter

Members Absent: Gaylord Kavlie, Laura Schield, Michael Quast, Michael Booth, Wendy Brown, Russ Sobotta

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

Old Business

T. Schmidt served as Chair in the absence of W. Brown, and called the meeting to order at 1:00 p.m. Chair T. Schmidt asked for a motion to approve the minutes of the March meeting. K. Kram moved that the minutes be approved and L. Roehrich seconded the motion. Chair T. Schmidt 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 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. Changes included classifying Epipen (epinephrine) and Epipen Jr (epinephrine) as preferred agents, ritonavir, Azasite (azithromycin), and Advair HFA (fluticasone/salmeterol) being classified as a non-preferred agents, and PDL category criteria updates to hepatitis C treatments and for partial opioid antagonists for opioid dependence.

Second Review of Chemotherapy Induced Nausea and Vomiting Agents

A motion and second was made at the March meeting to place the chemotherapy induced nausea and vomiting agents, Anzemet and Zuplenz on prior authorization along with other agents used for the treatment of chemotherapy induced nausea and vomiting. The topics were brought up for a second review. There was no public comment. A motion to approve amended form and prior authorization criteria was made by K. Kram and seconded by J. Hostetter. Chair T. Schmidt called for a voice vote and the motion passed with no audible dissent.

Second Review of Biosimilar Agents

A motion and second was made at the March meeting to generate prior authorization criteria for biosimilar agents. 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 Topical Corticosteroid Agents

A motion and second was made at the March meeting to place non-preferred topical corticosteroid agents on prior authorization. The topics were 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 Dupixent
A motion and second was made at the March meeting to place Dupixent on prior authorization. The topics were brought up for a second review. Chair T. Schmidt called for a voice vote and the motion passed with no audible dissent.

Second Review of Gocovri and Tussicaps (Non-Preferred Dosage Forms)
A motion and second was made at the March meeting to place Eucrisa on prior authorization. The topics were 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.

Discussion of First Fill of Narcotics
B. Joyce presented information on national quality measure updates regarding first fills of narcotics. These measures will require the first fill of narcotics to be for a 7 day supply or less, which will result in North Dakota Medicaid adjusting the claims processing edit for first fills of narcotics from a limit of 14 days to 7 days. The Board vocalized no issues with this change.

New Business

Rytary
T. DeRuiter and A. Murphy reviewed Rytary with the Board. A motion was made by K. Kram to create this new PA criteria class and manage these medications through prior authorization. The motion was seconded by J. Hostetter. This topic will be reviewed at the next meeting

Daxbia
T. DeRuiter and A. Murphy reviewed Daxbia with the Board. A motion was made by K. Kram to manage the medications through prior authorization. The motion was seconded by L. Roehrich. This topic will be reviewed at the next meeting

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

Eosinophilic Asthma Agents
T. DeRuiter and B. Joyce reviewed the eosinophilic asthma agents Cinqair, Fasenra, and Nucala with the Board. Ted Sheedy of GlaxoSmithKline spoke regarding clinical trial data of Nucala. A motion was made by K. Kram to manage the medication through prior authorization. The motion was seconded by J. Hostetter. This topic will be reviewed at the next meeting

Dermatophytosis (Tinea infections) Agents
T. DeRuiter and B. Joyce reviewed agents used for the treatment of tinea infections with the Board. A motion was made by P. Woodrow to manage the medication through prior authorization. The motion was seconded by K. Kram. This topic will be reviewed at the next meeting

Migraine Prophylaxis (CGRP Inhibitors)

T. DeRuiter and B. Joyce reviewed the class of CGRP inhibitors for migraine prophylaxis with the Board. A motion was made by K. Kram to manage the medication through prior authorization. The motion was seconded by J. Hostetter. This topic will be reviewed at the next meeting

Review of GLP-1 Receptor Agonist Utilization

T. DeRuiter and B. Joyce reviewed the utilization of GLP-1 receptor agonist agents with the Board. The presented information showed utilization of the available GLP-1 receptor agonists during the 1st quarter 2018 as compared to the utilization of the same agents during 3rd quarter 2017. The data was presented in terms of number of monthly prescriptions for and number of patients receiving each GLP-1 receptor agonist.

Medication Therapy Management (MTM) Program Update

A. Murphy updated the Board on the status of the state MTM program. The Board was informed that the program would be starting up within the next few months and will focus on proper use of inhaled asthma products, compliance with mental health medications, diabetes treatment, and transitioning care between inpatient and outpatient facilities.

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 approve the new criteria and K. Kram seconded the motion. The motion passed with no audible dissent.

Adjournment and Upcoming Meeting Date

J. Hostetter moved to adjourn the meeting at and K. Kram seconded. Chair T. Schmidt adjourned the meeting at 2:35 pm. The next DUR Board meeting will be held September 5, 2018 at 1:00 pm in the Brynhild Haugland Room at the State Capitol.

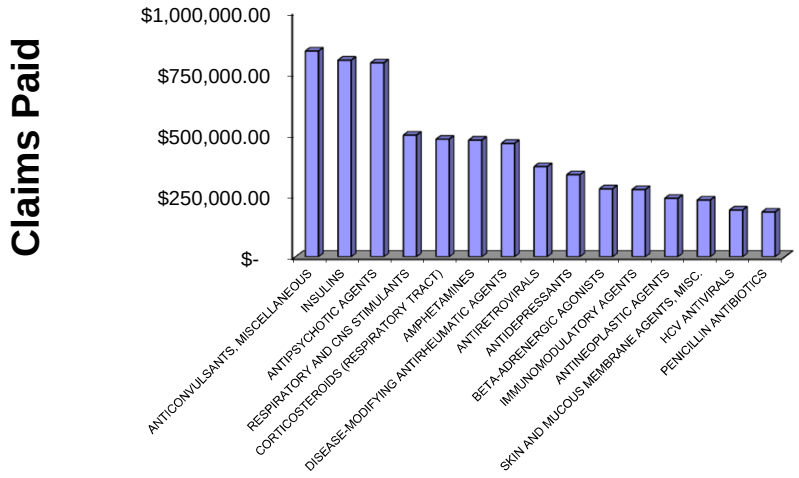
NORTH DAKOTA MEDICAID
Cost Management Analysis

TOP 15 THERAPEUTIC CLASSES BY TOTAL COST OF CLAIMS FROM 04/01/2018 - 06/30/2018

AHFS Therapeutic Class	Rx	Paid	Paid/Rx	% Total Claims
ANTICONVULSANTS, MISCELLANEOUS	8,294	$ 840,324.50	$ 101.32	5.94%
INSULINS	1,789	$ 803,137.88	$ 448.93	1.28%
ANTIPSYCHOTIC AGENTS	6,326	$ 792,155.56	$ 125.22	4.53%
RESPIRATORY AND CNS STIMULANTS	3,731	$ 497,602.56	$ 133.37	2.67%
CORTICOSTEROIDS (RESPIRATORY TRACT)	1,958	$ 481,136.71	$ 245.73	1.40%
AMPHETAMINES	3,063	$ 477,427.20	$ 155.87	2.19%
DISEASE-MODIFYING ANTIRHEUMATIC AGENTS	125	$ 463,945.45	$ 3,711.56	0.09%
ANTIRETROVIRALS	516	$ 368,969.53	$ 715.06	0.37%
ANTIDEPRESSANTS	14,776	$ 335,901.08	$ 22.73	10.57%
BETA-ADRENERGIC AGONISTS	3,376	$ 278,095.81	$ 82.37	2.42%
IMMUNOMODULATORY AGENTS	41	$ 275,118.58	$ 6,710.21	0.03%
ANTINEOPLASTIC AGENTS	269	$ 239,282.44	$ 889.53	0.19%
SKIN AND MUCOUS MEMBRANE AGENTS, MISC.	255	$ 232,218.06	$ 910.66	0.18%
HCV ANTIVIRALS	12	$ 191,481.60	$ 15,956.80	0.01%
PENICILLIN ANTIBIOTICS	4,152	$ 183,253.77	$ 44.14	2.97%
Total Top 15	48,683	$ 6,460,050.73	$ 132.70	34.84%

Total Rx Claims From 04/01/2018 - 06/30/2018	139,731

Top 15 Therapeutic Classes
Based on Total Cost of Claims

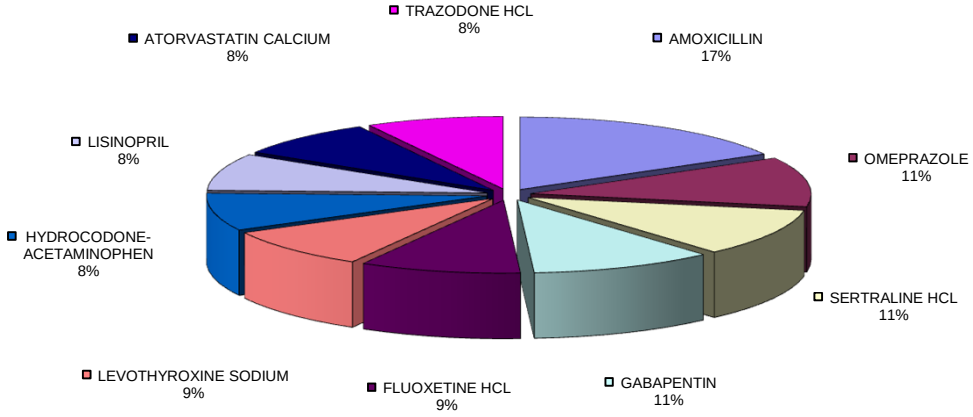


TOP 25 DRUGS BASED ON NUMBER OF CLAIMS FROM 04/01/2018 - 06/30/2018

Drug	AHFS Therapeutic Class	Rx	Paid	Paid/Rx	% Total Claims
AMOXICILLIN	PENICILLIN ANTIBIOTICS	4,080	$ 150,202.46	$ 36.81	2.92%
OMEPRAZOLE	PROTON-PUMP INHIBITORS	2,678	$ 52,547.58	$ 19.62	1.92%
SERTRALINE HCL	ANTIDEPRESSANTS	2,565	$ 49,749.76	$ 19.40	1.84%
GABAPENTIN	ANTICONVULSANTS, MISCELLANEOUS	2,561	$ 91,351.90	$ 35.67	1.83%
FLUOXETINE HCL	ANTIDEPRESSANTS	2,248	$ 32,970.94	$ 14.67	1.61%
LEVOTHYROXINE SODIUM	THYROID AGENTS	2,161	$ 42,123.65	$ 19.49	1.55%
HYDROCODONE-ACETAMINOPHEN	OPIATE AGONISTS	2,021	$ 62,192.87	$ 30.77	1.45%
LISINOPRIL	ANGIOTENSIN-CONVERTING ENZYME INHIBITORS	1,998	$ 46,065.99	$ 23.06	1.43%
ATORVASTATIN CALCIUM	HMG-COA REDUCTASE INHIBITORS	1,998	$ 55,173.27	$ 27.61	1.43%
TRAZODONE HCL	ANTIDEPRESSANTS	1,924	$ 29,229.52	$ 15.19	1.38%
MONTELUKAST SODIUM	LEUKOTRIENE MODIFIERS	1,881	$ 34,512.03	$ 18.35	1.35%
METHYLPHENIDATE ER	RESPIRATORY AND CNS STIMULANTS	1,849	$ 327,065.34	$ 176.89	1.32%
VYVANSE	AMPHETAMINES	1,689	$ 374,960.52	$ 222.00	1.21%
ALBUTEROL SULFATE	BETA-ADRENERGIC AGONISTS	1,673	$ 78,095.31	$ 46.68	1.20%
ESCITALOPRAM OXALATE	ANTIDEPRESSANTS	1,637	$ 32,032.49	$ 19.57	1.17%
CLONIDINE HCL	CENTRAL ALPHA-AGONISTS	1,630	$ 29,855.46	$ 18.32	1.17%
AZITHROMYCIN	MACROLIDE ANTIBIOTICS	1,630	$ 43,901.87	$ 26.93	1.17%
METFORMIN HCL	BIGUANIDES	1,533	$ 22,449.21	$ 14.64	1.10%
AMOXICILLIN-CLAVULANATE POTASS	PENICILLIN ANTIBIOTICS	1,495	$ 59,181.40	$ 39.59	1.07%
OSELTAMIVIR PHOSPHATE	NEURAMINIDASE INHIBITOR ANTIVIRALS	1,468	$ 160,909.80	$ 109.61	1.05%
PROAIR HFA	BETA-ADRENERGIC AGONISTS	1,406	$ 112,504.25	$ 80.02	1.01%
RISPERIDONE	ANTIPSYCHOTIC AGENTS	1,360	$ 19,732.39	$ 14.51	0.97%
QUETIAPINE FUMARATE	ANTIPSYCHOTIC AGENTS	1,347	$ 25,352.12	$ 18.82	0.96%
VITAMIN D3	VITAMIN D	1,333	$ 20,330.15	$ 15.25	0.95%
LAMOTRIGINE	ANTICONVULSANTS, MISCELLANEOUS	1,302	$ 19,337.12	$ 14.85	0.93%
TOTAL TOP 25		47,467	$ 1,971,827.40	$ 41.54	33.97%

Total Rx Claims From 04/01/2018 - 06/30/2018	139,731

Top 10 Drugs
Based on Number of Claims

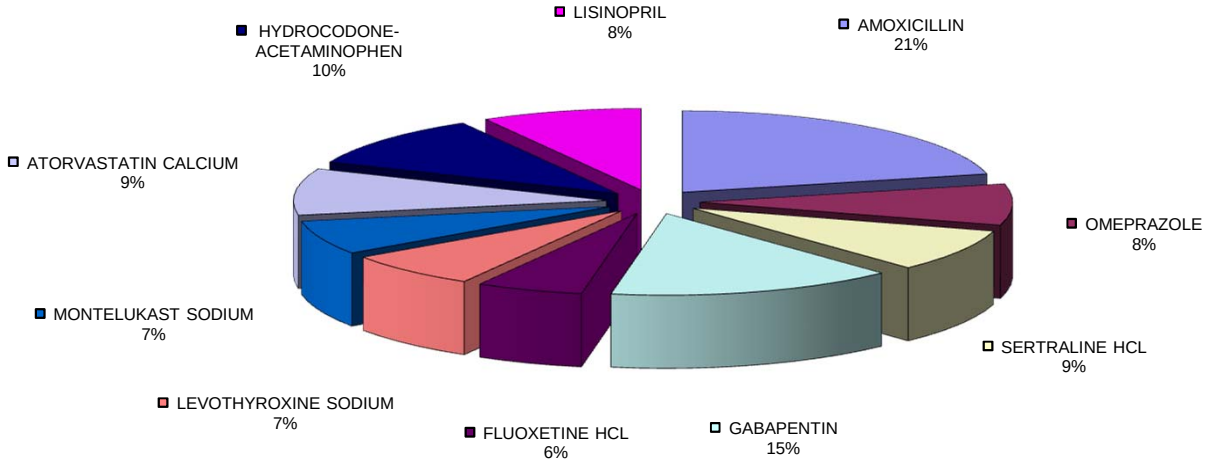


TOP 25 DRUGS BASED ON TOTAL CLAIMS COST FROM 04/01/2018 - 06/30/2018

Drug	AHFS Therapeutic Class	Rx	Paid	Paid/Rx	% Total Claims
AMOXICILLIN	PENICILLIN ANTIBIOTICS	2,788	$ 122,517.84	$ 43.94	2.00%
OMEPRAZOLE	PROTON-PUMP INHIBITORS	2,579	$ 46,713.49	$ 18.11	1.85%
SERTRALINE HCL	ANTIDEPRESSANTS	2,553	$ 48,364.92	$ 18.94	1.83%
GABAPENTIN	ANTICONVULSANTS, MISCELLANEOUS	2,408	$ 85,100.37	$ 35.34	1.72%
FLUOXETINE HCL	ANTIDEPRESSANTS	2,157	$ 31,575.27	$ 14.64	1.54%
LEVOTHYROXINE SODIUM	THYROID AGENTS	2,137	$ 40,278.25	$ 18.85	1.53%
MONTELUKAST SODIUM	LEUKOTRIENE MODIFIERS	2,005	$ 38,657.95	$ 19.28	1.43%
ATORVASTATIN CALCIUM	HMG-COA REDUCTASE INHIBITORS	2,002	$ 52,858.42	$ 26.40	1.43%
HYDROCODONE-ACETAMINOPHEN	OPIATE AGONISTS	1,932	$ 59,411.72	$ 30.75	1.38%
LISINOPRIL	ANGIOTENSIN-CONVERTING ENZYME INHIBITORS	1,907	$ 47,448.92	$ 24.88	1.36%
TRAZODONE HCL	ANTIDEPRESSANTS	1,871	$ 26,692.90	$ 14.27	1.34%
METHYLPHENIDATE ER	RESPIRATORY AND CNS STIMULANTS	1,671	$ 296,224.81	$ 177.27	1.20%
ESCITALOPRAM OXALATE	ANTIDEPRESSANTS	1,549	$ 32,211.08	$ 20.79	1.11%
METFORMIN HCL	BIGUANIDES	1,518	$ 23,182.01	$ 15.27	1.09%
CLONIDINE HCL	CENTRAL ALPHA-AGONISTS	1,503	$ 27,756.22	$ 18.47	1.08%
VYVANSE	AMPHETAMINES	1,492	$ 345,116.56	$ 231.31	1.07%
PROAIR HFA	BETA-ADRENERGIC AGONISTS	1,370	$ 116,518.28	$ 85.05	0.98%
RISPERIDONE	ANTIPSYCHOTIC AGENTS	1,318	$ 20,043.33	$ 15.21	0.94%
QUETIAPINE FUMARATE	ANTIPSYCHOTIC AGENTS	1,315	$ 23,124.78	$ 17.59	0.94%
VITAMIN D3	VITAMIN D	1,285	$ 19,417.31	$ 15.11	0.92%
LAMOTRIGINE	ANTICONVULSANTS, MISCELLANEOUS	1,273	$ 18,739.40	$ 14.72	0.91%
FLUTICASONE PROPIONATE	CORTICOSTEROIDS (EENT)	1,248	$ 24,830.53	$ 19.90	0.89%
ARIPIPRAZOLE	ANTIPSYCHOTIC AGENTS	1,212	$ 30,239.54	$ 24.95	0.87%
CETIRIZINE HCL	SECOND GENERATION ANTIHISTAMINES	1,207	$ 53,813.67	$ 44.58	0.86%
DULOXETINE HCL	ANTIDEPRESSANTS	1,193	$ 25,894.09	$ 21.71	0.85%
TOTAL TOP 25		43,493	$ 1,656,731.66	$ 38.09	31.13%

Total Rx Claims From 04/01/2018 - 06/30/2018	139,731

Top 10 Drugs
Based on Total Claims Cost



Added to PA	Category
ACZONE	Acne
AMCINONIDE	Topical Steroids
AMLODIPINE-VALSARTAN	Combination
ANZEMET	Chemo Induced Nausea/Vomiting
APEXICON E	Topical Steroids
ARNUITY ELLIPTA	Steroid Inhaler
Auvi Q	Epinephrine pens
BETAMETHASONE DIPROPIONATE	Topical Steroids
BETAMETHASONE VALERATE	Topical Steroids
BONJESTA	Diclegis/Bonjesta
CAPTOPRIL	ACE Inhibitors
CAPTOPRIL-HYDROCHLOROTHIAZIDE	Combination
Cinryze	Hereditary Angioedema
CLENPIQ	Bowel Prep Agents
CLOBETASOL EMOLLIENT	Topical Steroids
CLOBETASOL PROPIONATE EMOLLIENT FOAM	Topical Steroids
CLOBETASOL PROPIONATE FOAM	Topical Steroids
CLOCORTOLONE PIVALATE	Topical Steroids
CORDRAN	Topical Steroids
DESOXIMETASONE	Topical Steroids
DIFLORASONE DIACETATE	Topical Steroids
doptelet	> $3000
EUCRISA	Eucrisa
FLUOCINOLONE ACETONIDE	Topical Steroids
FLUOCINONIDE	Topical Steroids
FLURANDRENOLIDE	Topical Steroids
FLUTICASONE PROPIONATE	Topical Steroids
FLUVASTATIN ER	Statins
FLUVASTATIN SODIUM	Statins
FULPHILA	Biosimilars
GOCOVRI	Extended Release Amantadine
HALOBETASOL PROPIONATE	Topical Steroids
HALOG	Topical Steroids
HYDROCORTISONE BUTYRATE	Topical Steroids
HYDROCORTISONE VALERATE	Topical Steroids
IDELVION	Antihaemophilia
JADENU	Jadenu
JADENU SPRINKLE	Jadenu
JUVISYNC	Combination
KEVZARA PEN	Cytokine Modulators
LONHALA MAGNAIR	COPD
LUCEMYRA	> $3000
MAKENA	> $3000

MEFLOQUINE HCL	Malaria
METAXALONE	Skelaxin
MIRCERA	Biosimilars
OLUMIANT	Cytokine Modulators
OSMOLEX ER	Extended Release Amantadine
PALYNZIQ	> $3000
PANDEL	Topical Steroids
PREDNICARBATE	Topical Steroids
PRESTALIA	Combination
PROVENTIL HFA	Rescue Inhalers
RETACRIT	Biosimilars
RETIN-A MICRO PUMP	Acne
SERNIVO	Topical Steroids
SORILUX	Plaque Psoriasis
Tavalisse	> $3000
TAZAROTENE	Acne
TELMISARTAN-AMLODIPINE	Combination
TOPICORT	Topical Steroids
TRANDOLAPRIL-VERAPAMIL ER	Combination
TRETINOIN	Acne
TRIAMCINOLONE ACETONIDE	Topical Steroids
TRIANEX	Topical Steroids
TUSSICAPS	Tussicaps
ULTRAVATE	Topical Steroids
ZARXIO	Biosimilars
ZUPLENZ	Chemo Induced Nausea/Vomiting

Removed from PA	**Category**
ACTIVASE	Activase
ADVAIR HFA	Steroid/LABA Inhalers
BILTRICIDE	Biltricide
calcipotriene cream	Plaque Psoriasis
CARDURA XL	BPH
CATHFLO ACTIVASE	Activase
CELECOXIB	NSAIDs
DARAPRIM	> $3000
DIFFERIN	Acne
EPIPEN 2-PAK	epinephrine pens
EPIPEN JR	epinephrine pens
ESZOPICLONE	Sedative/Hypnotic
FLOVENT DISKUS	Steroid Inhalers
HETLIOZ	Sedative/Hypnotic
INTRON A	Interferon - Hep C
JUBLIA	Onychomycosis
MYTESI	Fulyzaq

NAPROXEN SODIUM CR	NSAIDs
NORTHERA	Northera
PROGLYCEM	> $3000
PROMACTA	> $3000
Sorilux (calcipotriene) Foam	Plaque Psoriasis
TUDORZA PRESSAIR	COPD
VALSARTAN-HYDROCHLOROTHIAZIDE	combination
VENTOLIN HFA	Rescue Inhalers
XIFAXAN	IBS
XOPENEX HFA	Rescue Inhalers
ZALEPLON	Sedative/Hypnotic
ZETONNA	Steroid Inhalers
ZYCLARA	Actinic Keratosis

Non-Preferred Dosage Forms
Prior Authorization Criteria

Criteria:

- The prescriber must submit medical justification explaining why the patient cannot use the preferred product (subject to clinical review)
- Patient must have FDA indication
- Patient must not have contraindications to requested product
- Patient must have failed a therapeutic course of all preferred agents
    - Trial must have been 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

Daxbia (Cephalexin):

Preferred	Non-Preferred
Cephalexin	Dexbia (Cephalexin)

Oral Steroids:

Additional Criteria:

- Emflaza: See Emflaza Criteria on this document
- Rayos: Trial of 12 weeks with 2AM dosing of prednisone

Preferred	Non-Preferred
Budesonide EC	DEXPAK (dexamethasone)
Cortisone	EMFLAZA (deflazacort)
Dexamethasone	MILLIPRED (Prednisolone)
Hydrocortisone	Prednisolone sodium phosphate ODT
Methylprednisone	Prednisolone sodium phosphate 10mg/5ml, 20mg/5ml solution
Prednisolone sodium phosphate 5mg/5ml, 15mg/5ml, 25mg/5ml	RAYOS (prednisone)
Prednisone	TAPERDEX (dexamethasone)
	UCERIS (budesonide)

Rytary (Carbidopa/Levodopa):

Additional Criteria: Patient is not in a long term care facility

Preferred	Non-Preferred
Carbidopa/Levodopa	RYTARY (carbidopa/levodopa)
Carbidopa/Levodopa ER	
Carbidopa/Levodopa/Entacapone	

Emflaza Criteria:

- Patient must be 5 years of age or older
- 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
- **Additional Initial Criteria: Approval 6 months**
    - Onset of weakness before 5 years of age
    - Must be prescribed by or in consultation with a physician who specializes in the treatment of Duchenne Muscular Dystrophy (DMD) and/or neuromuscular disorders
    - Serum creatinine kinase activity at least 10 times the upper limit of normal (ULN) prior to initiating treatment
    - Inadequate treatment response, intolerance, or contraindication to a 6-month trial of prednisone
    - Obtain a baseline motor milestone score from ONE the following assessments:
        - 6-minute walk test (6MWT)
        - North Star Ambulatory Assessment (NSAA)
        - Motor Function Measure (MFM)
        - Hammersmith Functional Motor Scale (HFMS)
    - Patient must have ONE of the following significant intolerable adverse effects supported by documentation:
        - Cushingoid appearance
        - Central (truncal) obesity
        - Undesirable weight gain (>10% of body weight gain increase over 6-month period)
        - Diabetes and/or hypertension that is difficult to manage
        - Severe behavioral adverse effect
- **Additional Renewal Criteria: Approval 1 year**
    - Patient must have ONE of the following:
        - Improvement in motor milestone score from baseline from ONE the following assessments:
        - 6MWT – improvement of 20 meters from baseline
        - NSAA – improvement of 2 points from baseline
        - MFM – improvement of 2 points from baseline
        - HFMS – improvement of 2 points from baseline
    - Patient must have had improvement of adverse effects experienced on prednisone supported by documentation:
        - Cushingoid appearance
        - Central (truncal) obesity
        - Undesirable weight gain (>10% of body weight gain increase over 6-month period)
        - Diabetes and/or hypertension that is difficult to manage
        - Severe behavioral adverse effect

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 #

Topical Antifungals
Prior Authorization Criteria

Approval Duration

Onychomycosis: 1 year
Dermatophytosis: 1 month

Criteria:

- Patient must have an FDA approved diagnosis confirmed by potassium hydroxide (KOH) preparation.
- Patient must have failed a trial of 3 preferred agents including at least one oral agent (terbinafine, fluconazole, or itraconazole) for the length of recommended treatment time for patient's particular infection.
- The prescriber must submit medical justification explaining why the patient cannot use a preferred product cannot be used if requested product ingredient is available in a preferred formulation (subject to clinical review).
- **Additional Criteria for Treatment of Onychomycosis:**
    - There must have been enough time since treatment cessation to assess healthy toenail outgrow (≥ 6 months)

Preferred	Non-Preferred
Ciclopirox cream	Ciclopirox gel
Ciclopirox shampoo	Ciclopirox solution
Ciclopirox suspension	KERYDIN (tavaborole)
Clotrimazole cream	Ketoconazole foam
Econazole cream	MENTAX (butenafine) CREAM
ERTACZO (sertraconazole) CREAM	Naftifine cream
EXELDERM CREAM (sulconazole)	NAFTIN (naftifine) GEL
EXELDERM SOLUTION (sulconazole)	Nystatin – triamcinolone cream
JUBLIA (efinaconazole)	Nystatin – triamcinolone ointment
Ketoconazole cream	Oxiconazole cream
Ketoconazole shampoo	OXISTAT (oxiconazole) LOTION
LUZU (luliconazole) CREAM	PENLAC (ciclopirox)
MENTAX (butenafine) CREAM	
Miconazole	
Nystatin cream	
Nystatin ointment	
Nystatin powder	
VUSION (miconazole/zinc oxide/white petrolatum)	

health information designs

Topical Antifungals
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 non-preferred topical antifungal agent must meet the following criteria:

Criteria for all agents:

- Patient must have an FDA approved diagnosis confirmed by potassium hydroxide (KOH) preparation.
- Patient must have failed a trial of 3 preferred agents including at least one oral agent (terbinafine, fluconazole, or itraconazole) for the length of recommended treatment time for patient's particular infection.
- The prescriber must submit medical justification explaining why the patient cannot use a preferred product cannot be used if requested product ingredient is available in a preferred formulation.

Additional criteria for treatment of onychomycosis:

- There must have been enough time since treatment cessation to assess healthy toenail outgrow (≥ 6 months)

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 #

Eosinophilic Asthma Agents

- All agents will now only be approved when requested via medical billing only.

Migraine Prophylaxis (CGRP Inhibitors)
Prior Authorization Criteria

Approval Duration

Initial Approval: 3 months
Renewal Approval: 1 year

Criteria:

- **Initial**
  - Patient must experience 4 or more migraine days per month.
  - Prescriber must submit documentation of treatment failure of a 2 month trial of two preferred agents from different therapeutic classes.
    - Documentation must include clinical notes regarding failure to reduce migraine frequency.
- **Renewal**
  - Patient must experience a reduction in migraines of at least 50%

Preferred	Non-Preferred
Amitriptyline	AIMOVIG (erenumab-aooe)
Atenolol	
BOTOX (Onabotulinumtoxin A)	
Divalproex Sodium	
Metoprolol	
Nadolol	
Propranolol	
Timolol	
Topiramate	
Venlafaxine	

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 following criteria:

Initial Requests:

- Patient must experience 4 or more migraine days per month.
- Prescriber must submit documentation of treatment failure of a 2 month trial of two preferred agents from different therapeutic classes. Documentation must include clinical notes regarding failure to reduce migraine frequency.

Renewal Requests: Patient must experience a reduction in migraines 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:**		
Number of experienced migraine days per month:			
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 #

Medicaid Expansion

Top Line Performance Metrics

- Generic Fill Rate (GFR) decreased 0.2 percentage points to 86.2%

	Medicaid Expansion			Medicaid - Ages 35-65	
Description	1/18 - 6/18	1/17 - 6/17	Change	1/18 - 6/18	Change
Avg Members per Month	20,333	20,087	1.2%		
Number of Unique Patients	15,352	15,517	-1.1%		
Pct Members Utilizing Benefit	75.5%	77.2%	-1.7		
Total Days	5,523,788	5,381,086	2.7%		
Total Rxs	219,680	217,070	1.2%		
Average Member Age	39.3	39.1	0.5%	49.0	0.2%
Nbr Rxs PMPM	1.80	1.80	0.0%	2.64	0.6%
Generic Fill Rate	86.2%	86.3%	-0.2	85.2%	-0.5
Home Delivery Utilization	0.0%	0.0%	0.0	0.2%	0.0
Member Cost %	0.4%	0.3%	0.1	0.5%	0.0
Specialty Percent of Plan Cost	26.6%	21.4%	5.2	45.9%	1.6
Formulary Compliance Rate	99.7%	98.7%	1.0	98.9%	-0.2

Key Statistics: Specialty Detailed

- You have 331 unique specialty patients, an increase of 29 specialty patients

Medicaid Expansion						
	Non-Specialty			Specialty		
Description	1/18 - 6/18	1/17 - 6/17	Change	1/18 - 6/18	1/17 - 6/17	Change
Avg Members per Month	20,333	20,087	1.2%	20,333	20,087	1.2%
Number of Unique Patients	15,325	15,495	-1.1%	331	302	9.6%
Pct Members Utilizing Benefit	75.4%	77.1%	-1.8	1.6%	1.5%	0.1
Total Days	5,491,061	5,350,425	2.6%	32,727	30,661	6.7%
Total Rxs	218,492	215,968	1.2%	1,188	1,102	7.8%
Percent of Total Rxs	99.46%	99.49%	0.0	0.54%	0.51%	0.0
Nbr Rxs PMPM	1.79	1.79	-0.1%	0.010	0.009	6.5%
Generic Fill Rate	86.5%	86.6%	-0.2	30.0%	29.6%	0.4
Member Cost %	0.5%	0.4%	0.1	0.0%	0.1%	0.0

Specialty	
Medicaid - Ages 35-65	
1/18 - 6/18	Change
0.04	4.0%
17.9%	4.9
0.0%	0.0

Top 10 Indications

- The highest trend is in Multiple Sclerosis at 22.1%

REPRESENT

68.2%

OF YOUR TOTAL PLAN COST

Top Indications by Plan Cost

1/18 - 6/18							1/17 - 6/17			
Rank	Peer Rank	Indication	Rxs	Patients	Generic Fill Rate	Peer Generic Fill Rate	Rank	Rxs	Patients	Generic Fill Rate
1	2	DIABETES	17,019	2,158	38.7%	42.0%	1	15,744	2,047	38.2%
2	3	INFLAMMATORY CONDITIONS	840	213	59.2%	50.3%	3	884	216	59.6%
3	6	PAIN/INFLAMMATION	29,470	6,670	94.9%	96.6%	2	32,462	7,144	94.1%
4	4	ASTHMA	8,836	2,513	25.5%	23.4%	5	8,229	2,403	25.2%
5	8	MENTAL/NEURO DISORDERS	5,641	1,429	90.9%	91.3%	4	5,004	1,260	90.2%
6	7	HEPATITIS C	53	29	1.9%	1.7%	6	37	16	10.8%
7	9	MULTIPLE SCLEROSIS	107	27	1.9%	16.6%	8	98	20	11.2%
8	1	HIV	289	59	6.9%	12.1%	10	300	57	0.0%
9	19	ATTENTION DISORDERS	3,443	815	63.9%	77.6%	9	3,710	824	72.7%
10	14	DEPRESSION	24,043	5,437	98.1%	98.5%	7	22,439	5,290	97.7%
		Total Top 10:	**89,741**		**76.0%**			**88,907**		**76.8%**
		Differences Between Periods:	**834**		**-0.8%**					

Peer = Express Scripts Peer 'Medicaid - Ages 35-65' market segment

Top 25 Drugs

- Represent 44.5% of your total Plan Cost and comprise 13 indications
- 6 of your top 25 are specialty drugs

Top Drugs by Plan Cost								
				1/18 - 6/18		1/17 - 6/17		
Rank	Peer Rank	Brand Name	Indication	Rxs	Pts.	Prev Rank	Rxs	Pts.
1	40	NOVOLOG FLEXPEN	DIABETES	1,540	499	1	1,408	476
2	4	HUMIRA PEN*	INFLAMMATORY CONDITIONS	157	43	2	148	36
3	9	LYRICA	PAIN/INFLAMMATION	1,293	351	3	1,293	355
4	98	LEVEMIR FLEXTOUCH	DIABETES	1,005	316	5	904	306
5	11	LANTUS SOLOSTAR	DIABETES	1,286	408	7	834	276
6	50	EPCLUSA*	HEPATITIS C	17	9	4	16	7
7	2	MAVYRET*	HEPATITIS C	32	18			
8	16	ADVAIR DISKUS	ASTHMA	893	324	9	805	286
9	15	LATUDA	MENTAL/NEURO DISORDERS	268	88	12	231	81
10	20	VICTOZA 3-PAK	DIABETES	376	118	11	345	99
11	53	GILENYA*	MULTIPLE SCLEROSIS	36	9	24	19	5
12	49	XIFAXAN	GI DISORDERS	135	50	16	97	43
13	22	SYMBICORT	ASTHMA	815	312	13	708	273
14	56	COPAXONE*	MULTIPLE SCLEROSIS	31	8	25	22	4
15	90	VYVANSE	ATTENTION DISORDERS	780	213	15	765	205
16	183	ZUBSOLV	CHEMICAL DEPENDENCE	982	156	213	39	9
17	19	JANUVIA	DIABETES	488	134	20	429	116
18	35	CHANTIX	SMOKING CESSATION	489	271	21	446	260
19	72	NOVOLOG	DIABETES	310	81	17	375	104
20	36	SPIRIVA	COPD	446	146	19	495	145
21	158	CONTOUR NEXT TEST STRIP	DIAGNOSTIC AIDS	1,756	672	342	72	27
22	43	JARDIANCE	DIABETES	379	104	487	8	2
23	42	GABAPENTIN	PAIN/INFLAMMATION	6,617	1,801	26	6,509	1,810
24	59	PROAIR HFA	ASTHMA	2,448	1,211	31	2,087	1,111
25	13	ENBREL SURECLICK*	INFLAMMATORY CONDITIONS	27	7	10	53	16
			Total Top 25:	22,606			18,108	
			Differences Between Periods:	4,498				

*Specialty Drugs

Peer = Express Scripts Peer 'Medicaid - Ages 35-65' market segment

Top 25 Specialty Drugs

- Represent 21.6% of your total Plan Cost and comprise 7 indications

Top Specialty Drugs by Plan Cost								
				1/18 - 6/18		1/17 - 6/17		
Overall Rank	Overall Peer Rank	Brand Name	Indication	Rxs	Pts.	Overall Rank	Rxs	Pts.
2	4	HUMIRA PEN	INFLAMMATORY CONDITIONS	157	43	2	148	36
6	50	EPCLUSA	HEPATITIS C	17	9	4	16	7
7	2	MAVYRET	HEPATITIS C	32	18			
11	53	GILENYA	MULTIPLE SCLEROSIS	36	9	24	19	5
14	56	COPAXONE	MULTIPLE SCLEROSIS	31	8	25	22	4
25	13	ENBREL SURECLICK	INFLAMMATORY CONDITIONS	27	7	10	53	16
27	58	AUBAGIO	MULTIPLE SCLEROSIS	19	6	38	16	4
29	8	TRUVADA	HIV	70	23	33	66	16
30	76	ENBREL	INFLAMMATORY CONDITIONS	23	5	49	13	4
32	154	HUMIRA PEN CROHN-UC-HS START	INFLAMMATORY CONDITIONS	7	7	154	2	2
39	17	ATRIPLA	HIV	39	8	55	32	8
41	84	SPRYCEL	CANCER	9	2			
44	29	STRIBILD	HIV	27	5	48	26	7
45	542	ORKAMBI	CYSTIC FIBROSIS	4	1			
46	38	REVLIMID	CANCER	6	1			
47	52	ENOXAPARIN SODIUM	ANTICOAGULANT	104	45	56	101	64
49	70	VOSEVI	HEPATITIS C	3	1			
51	306	LONSURF	CANCER	9	2			
55	62	HUMIRA	INFLAMMATORY CONDITIONS	14	3	61	14	3
59	3	TRIUMEQ	HIV	22	6	111	12	4
65	139	XELJANZ	INFLAMMATORY CONDITIONS	13	3	89	11	2
69	92	IMATINIB MESYLATE	CANCER	6	2			
70	1	GENVOYA	HIV	18	5	29	42	12
77	55	IBRANCE	CANCER	4	1			
82	63	COSENTYX PEN (2 PENS)	INFLAMMATORY CONDITIONS	6	4			
			Total Top 25:	703			593	
			Differences Between Periods:	110				

Peer = Express Scripts Peer 'Medicaid - Ages 35-65' market segment

Advanced Opioid Management Activity

Sanford Health Plan - Medicaid

2018-01-01 - 2018-06-30

EXPRESS SCRIPTS®

Opioid Metrics

Opioids	All Patients			Cancer/PC*			Without Cancer/PC*		
	2017 (1-2Q)	2018 (1-2Q)	% Diff	2017 (1-2Q)	2018 (1-2Q)	% Diff	2017 (1-2Q)	2018 (1-2Q)	% Diff
Patients	4,341	3,564	-19.6%	49	38	-25.2%	4,292	3,526	- 19.5%
% Members	21.6%	17.5%	- 4.1%	0.2%	0.2%	0%	21.4%	17.3%	- 4.1%
% Patients	28.0%	23.2%	- 4.8%	0.3%	0.2%	- 0.1%	27.7%	23.0%	- 4.7%
New Patients	2,886	2,419	- 17.6%	19	20	5.1%	2,867	2,399	- 17.7%
Total Rx Count	14,036	10,808	- 25.9%	232	154	-40.4%	13,804	10,654	- 25.7%
% Rxs	6.3%	4.8%	- 1.5%	0.1%	0.1%	0%	6.2%	4.7%	- 1.5%
Rxs per Patient	3.23	3.03	- 6.3%	4.73	4.05	-15.4%	3.22	3.02	- 6.41%-
Total Plan Cost	$431,326	$277,967	- 43.2%	$11,875	$7,809	-41.3%	$419,451	$270,158	-43.2%
% of Total Plan Cost	2.4%	1.5%	- 0.9%	0.1%	0.0%	- 0.1%	2.4%	1.5%	- 0.9%
% Patients with long acting and short acting opioid use	5.3%	3.1%	-2.2%	12.2%	10.5%	- 1.7%	5.2%	3.0%	- 2.2%
Average days per patient SA:LA ratio (for patients taking both)	104:91	101:96	N/A	113:157	111:163	N/A	104:89	101:93	N/A
Prescribers per Patient	1.65	1.52	- 8.2%	1.73	1.76	1.7%	1.65	1.52	-8.2%
Pharmacies per Patient	1.29	1.25	-3.1%	1.27	1.24	-2.3%	1.29	1.25	-3.1%
Patients filling 3 drug combination**	23	25	8.3%	0	0	0%	23	25	8.3%

*Palliative Care

**(Benzodiazepines, Opioids and Skeletal Muscle Relaxants)

Long Acting Opioid Metrics

Long Acting Opioids	All Patients			Cancer/PC*			Without Cancer/PC*		
	2017 (1-2Q)	2018 (1-2Q)	% Diff	2017 (1-2Q)	2018 (1-2Q)	% Diff	2017 (1-2Q)	2018 (1-2Q)	% Diff
Patients	269	121	-75.8%	7	5	-33.3%	262	116	-77.2%
% Opioid Patients	6.2%	3.4%	- 2.8%	14.3%	13.2%	- 1.1%	6.1%	3.3%	- 2.8%
Days per Rx	25.68	24.24	-5.7%	26.79	29.70	10.3%	25.63	23.92	-6.9%
Days per Patient	93.67	96.17	2.6%	160.71	160.40	-0.1%	91.87	93.40	1.6%
Rxs per Patient	3.65	3.97	8.3%	6.00	5.40	-10.5%	3.58	3.91	8.8%
Total Rx Count	981	480	-68.5%	42	27	-43.4%	939	453	-69.8%
Total Plan Cost	$160,908	$75,750	-71.9%	$7,317	$5,001	-37.6%	$153,591	$70,750	-73.8%

*Palliative Care

Short Acting Opioid Metrics

Short Acting Opioids	All Patients			Cancer/PC*			Without Cancer/PC*		
	2017 (1-2Q)	2018 (1-2Q)	% Diff	2017 (1-2Q)	2018 (1-2Q)	% Diff	2017 (1-2Q)	2018 (1-2Q)	% Diff
Patients	4,301	3,552	- 19%	48	37	-25.8%	4,253	3,515	-19%
% Opioid Patients	99.1%	99.7%	0.6%	98.0%	97.4%	-0.6%	99.1%	99.7%	0.6%
New Patients	2,860	2,405	-17.2%	19	20	5.1%	2,841	2,385	-17.4%
Days per Rx	12.97	12.75	-1.7%	19.30	16.65	-14.7%	12.88	12.70	-1.4%
Days per Patient	39.37	37.07	- 6.0%	76.40	57.16	-28.8%	38.95	36.86	-5.5%
Rxs per Patient	3.04	2.91	-4.3%	3.96	3.43	-14.3%	3.02	2.90	- 4.0%
Days per New Patient First Fill	6.56	4.27	-42.2%	9.21	3.95	- 79.9%	6.55	4.28	-41.9%
Total Rx Count	13,055	10,328	-23.3%	190	127	-39.7%	12,865	10,201	-23.0%
Total Plan Cost	$270,418	$202,216	-28.6%	$4,558	$2,808	-47.5%	$265,860	$199,408	-28.5%
Patients getting more than 7 days supply	1,919	1,276	-40.2%	34	17	- 66.6%	1,885	1,259	-39.8%
% Patients getting more than 7 days supply	44.6%	35.9%	-8.7%	70.8%	45.9%	- 24.9%	44.3%	35.8%	-8.5%
Patients getting 7 days supply or less	2,382	2,276	-4.5%	14	20	35.2%	2,368	2,256	-4.8%
% Patients getting 7 days supply or less	55.4%	64.1%	8.7%	29.2%	54.1%	24.9%	55.7%	64.2%	8.5%

*Palliative Care

Antidotes/Addiction Treatment Metrics

Antidotes	All Patients			Cancer/PC*			Without Cancer/PC*		
	2017 (1-2Q)	2018 (1-2Q)	% Diff	2017 (1-2Q)	2018 (1-2Q)	% Diff	2017 (1-2Q)	2018 (1-2Q)	% Diff
Patients	12	19	45.1%	1	0	- 100%	11	19	53.3%
Rxs per Patient	1.50	1.11	-29.8%	1.00	0.00	- 100%	1.55	1.11	-33.0%
Total Rx Count	18	21	15.3%	1	0	- 100%	17	21	21.0%
Total Plan Cost	$2,340	$2,540	8.1%	$126	0	- 100%	$2,178	$2,540	15.3%

Addiction Treatment	All Patients			Cancer/PC*			Without Cancer/PC*		
	2017 (1-2Q)	2018 (1-2Q)	% Diff	2017 (1-2Q)	2018 (1-2Q)	% Diff	2017 (1-2Q)	2018 (1-2Q)	% Diff
Patients	134	191	35.0%	1	0	-100%	133	191	35.8%
Rxs per Patient	5.89	6.93	16.2%	6.00	0.00	-100%	5.89	6.93	16.2%
Total Rx Count	789	1,324	50.6%	6	0	-100%	783	1,324	51.3%
Total Plan Cost	$264,024	$317,166	18.2%	$1,519	$0	-100%	$262,505	$317,166	18.8%

*Palliative Care

Morphine Equivalent Dose (MEqD)

MEqD	
Number of Unique Opioid Patients That Hit >200mg Accumulated MEqD Edit At Least Once	31
% of Total Opioid Patients That Hit >200mg Accumulated MEqD Edit At Least Once	0.9%
Number of Opioid Claims That Hit >200mg Accumulated MEqD Edit	51
% of Total Opioid Claims That Hit >200mg Accumulated MEqD Edit	0.5%
Total Primary Coverage Reviews	20
Total Primary Approvals	19
Total Primary Denials	1
Total Appeals	0
Total Appeal Approvals	0
Total Appeal Denials	0
Total Rejects With A Subsequent Fill	47
Total Successful Reductions in Accumulated MEqD	0
Success Rate	0.0%
Average Rejected Accumulated MEqD Reduction (Reject vs 1st Fill)	0.0%
Median Rejected Accumulated MEqD Reduction (Reject vs 1st Fill)	0.0%

Data based on enrollment activity in the Express Scripts standard MEqD edit

Short Acting Edit

Short Acting 7 Day Edit	
Number of Unique Opioid Patients That Hit the 7 Day Short Acting Edit	388
% of Total Opioid Patients That Hit the 7 Day Short Acting Edit	10.9%
Number of Opioid Claims That Hit the 7 Day Short Acting Edit	424
% of Total Opioid Claims That Hit the 7 Day Short Acting Edit	3.9%
Total Primary Coverage Reviews	16
Total Primary Approvals	9
Total Primary Denials	7
Total Appeals	0
Total Appeal Approvals	0
Total Appeal Denials	0
Total Rejects With A Subsequent Fill	333
Total Successful Reductions to 7 Days Supply or Less	316
Success Rate	94.9%
Average Rejected Days Supply	16.40
Average Days Supply on 1st Subsequent Fill	7.29
Average Days Supply Reduction (Reject vs 1st Fill)	-55.5%
Median Days Supply Reduction (Reject vs 1st Fill)	-46.2%

Data based on enrollment activity in the Express Scripts standard Short Acting 7Day Edit

Long Acting Edit

Long Acting PA Edit	
Number of Unique Opioid Patients that Hit the Long Acting PA Edit	38
% of Total Opioid Patients that Hit the Long Acting PA Edit	1.1%
Number of Opioid Claims that Hit the Long Acting PA Edit	48
% of Total Opioid Claims that Hit the Long Acting PA Edit	0.4%
Total Primary Coverage Reviews	28
Total Primary Approvals	20
Total Primary Denials	8
Total Appeals	0
Total Appeal Approvals	0
Total Appeal Denials	0
Total Rejects With A Subsequent Fill	38
Total Successful Switches to a Short Acting Opioid	26
Success Rate	68.4%

Data based on enrollment activity in the Express Scripts standard Long Acting PA Edit

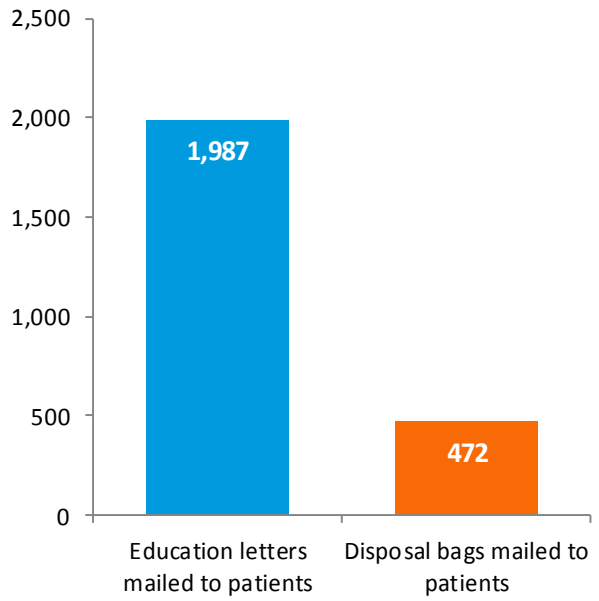
Member Interventions

Member outreach as part of Advanced Opioid Management Solution.

1987 Education letters mailed to patients

472 Disposal bags mailed to patients

264 Opioid alerts sent to Physicians

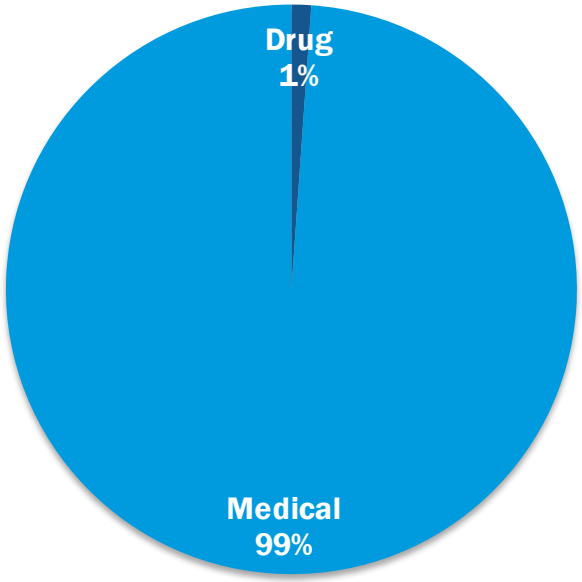


Advanced Opioid Management Savings Analysis

Drug Cost Savings	
Long Acting Edit	$1,167
Short Acting Edit	($136)
Total	$1,031

Medical Cost Avoidance	
Total	$91,726

Total Program Savings



Total Estimated Savings $92.8K

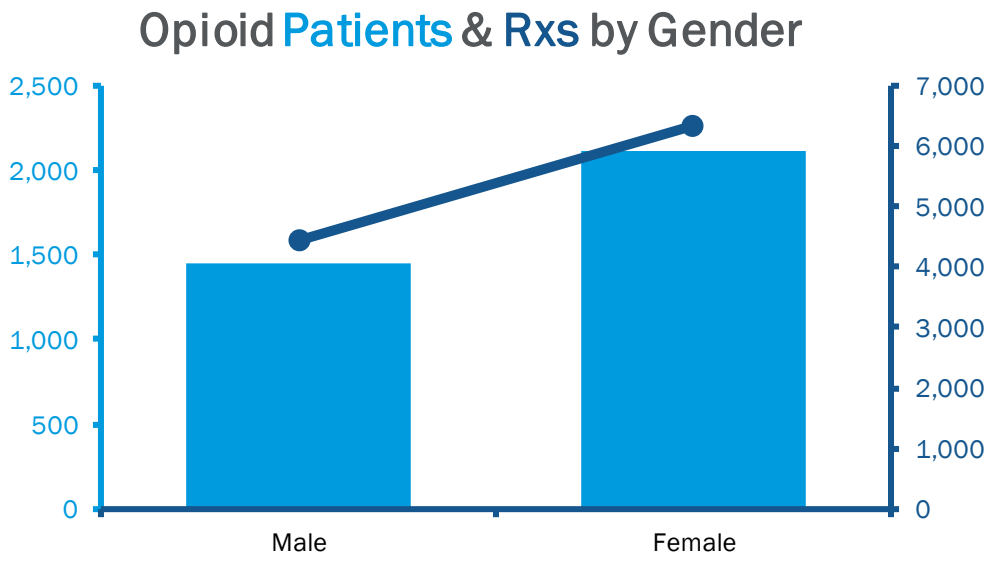
~ $0.76 PMPM Savings

Estimated Pharmacy plan savings $0.01 PMPM

Estimated Medical plan savings $0.75 PMPM

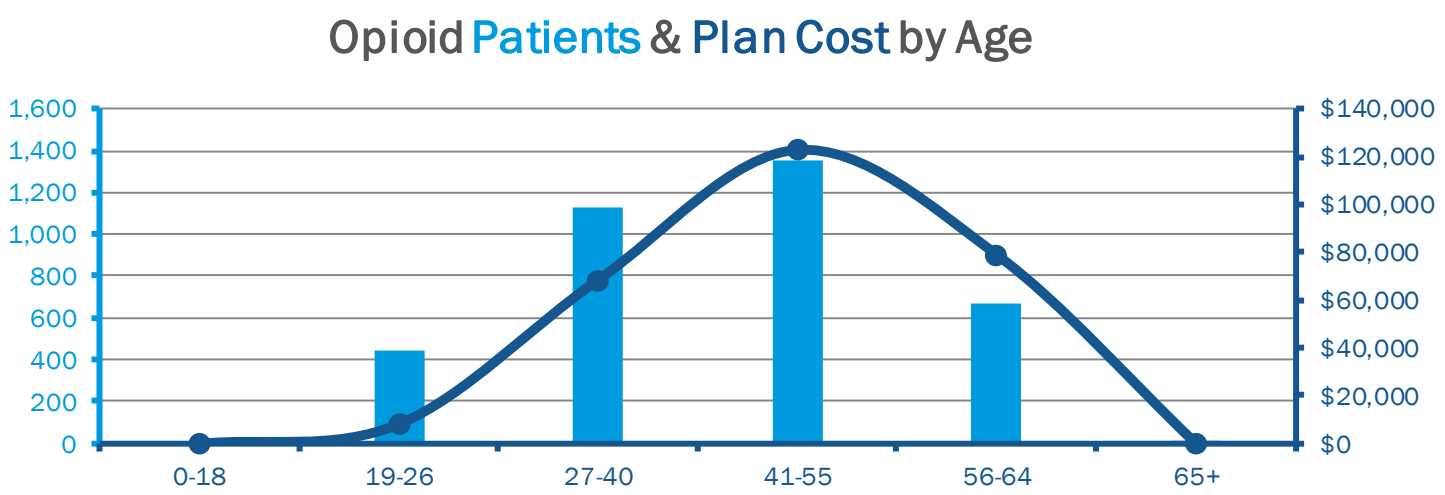
Gender Distribution

Gender	Patients Filling Opioids	% Patients filling Opioids	Opioid RXs /Opioid Patient
Male	1,449	40.7%	3.1
Female	2,115	59.3%	3.0



Age Distribution

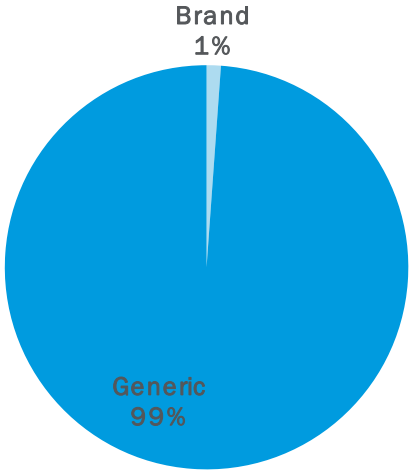
Age Range	Patients	Plan Cost	Female Patients	% Female
0-18	0	$0	0	0.0%
19-26	441	$8,154	289	65.5%
27-40	1,128	$68,338	685	60.7%
41-55	1,353	$122,555	783	57.9%
56-64	665	$78,832	372	55.9%
65+	3	$88	2	66.7%



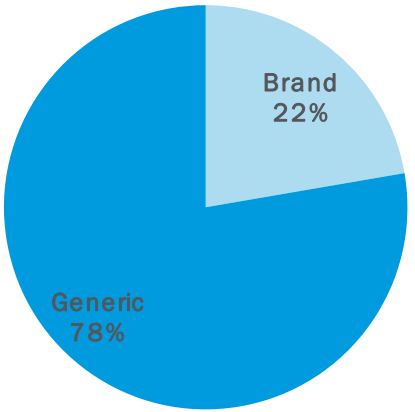
Brand vs Generic Utilization

	Opioid RXs	% Opioid RXs	Total Plan Cost	% Plan Cost	Cost/Rx
Brand Opioids	123	1.1%	$61,979	22.3%	$503.90
Generic Opioids	10,685	98.9%	$215,987	77.7%	$20.21

Brand vs Generic (by Rx Count)



Brand vs Generic (by Plan Cost)



Top 10 Opioids by Rx Count

Rank	Drug Name	Brand(A/B) Generic(G)	RX Count	% Opioid RXs	Overall Medication Rank by RX Count
1	HYDROCODONE-ACETAMINOPHEN	G	4,182	38.7%	6
2	TRAMADOL HCL	G	2,404	22.2%	22
3	OXYCODONE-ACETAMINOPHEN	G	1,680	15.5%	33
4	OXYCODONE HCL	G	1,157	10.7%	53
5	ACETAMINOPHEN-CODEINE	G	440	4.1%	111
6	MORPHINE SULFATE ER	G	236	2.2%	175
7	HYDROMORPHONE HCL	G	230	2.1%	178
8	FENTANYL	G	157	1.5%	223
9	NUCYNTA	A	51	0.5%	376
10	MORPHINE SULFATE	G	51	0.5%	377
		Top 10 Total	**10,588**		

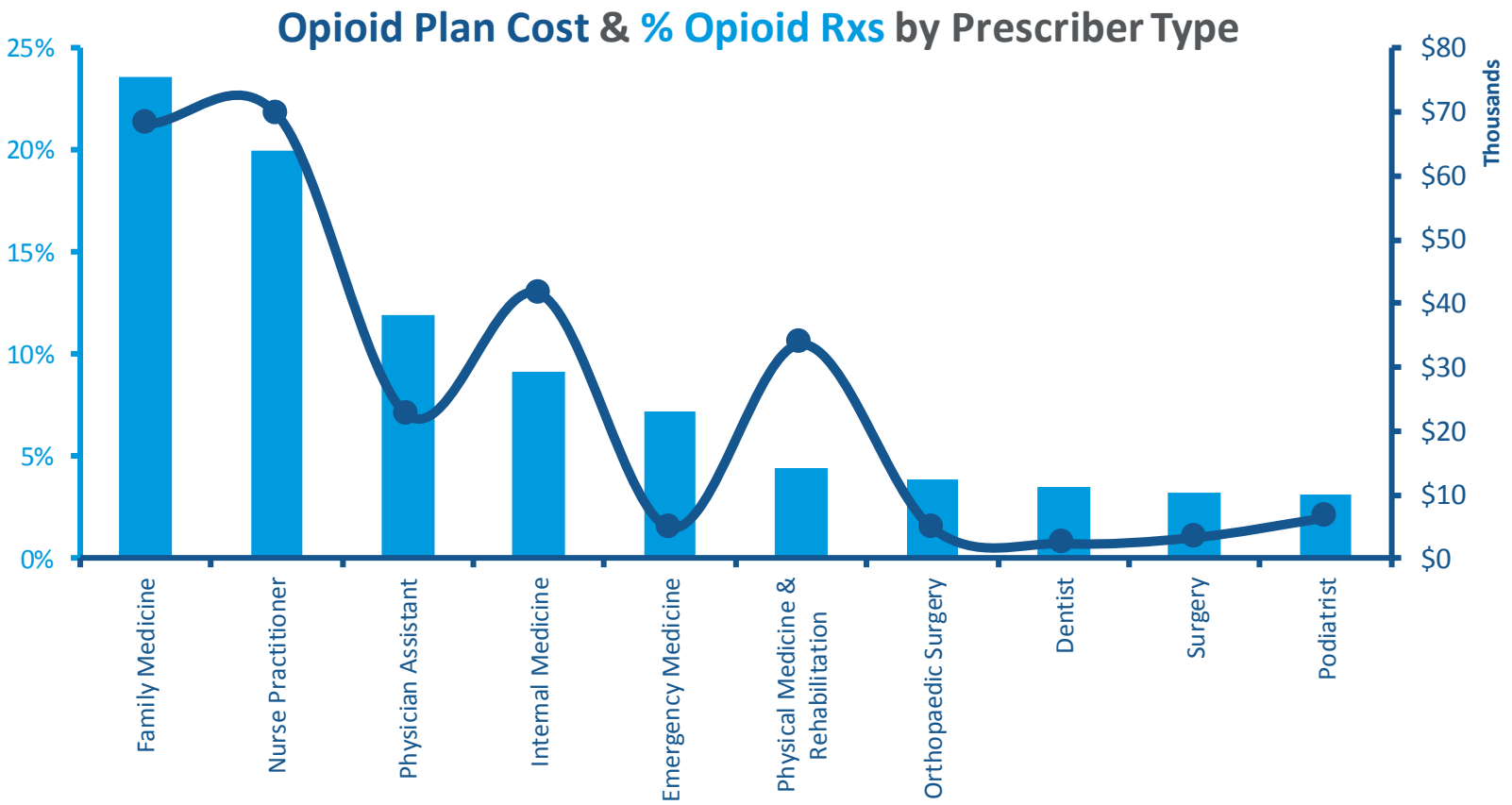
Top 10 Long Acting Opioids by Rx Count

Rank	Drug Name	Brand(A/B) Generic(G)	RX Count	% Opioid RXs	Overall Medication Rank by RX Count
1	MORPHINE SULFATE ER	G	236	2.2%	175
2	FENTANYL	G	157	1.5%	223
3	OXYCONTIN	A	39	0.4%	416
4	BUTRANS	A	18	0.2%	589
5	NUCYNTA ER	A	10	0.1%	721
6	METHADONE HCL	G	8	0.1%	784
7	TRAMADOL HCL ER	G	7	0.1%	808
8	OXYCODONE HCL ER	A	2	0.0%	1,081
9	EMBEDA	A	1	0.0%	1,162
10	DURAGESIC	B	1	0.0%	1,160
		Top 10 Total	**479**		

Top 10 Short Acting Opioids by Rx Count

Rank	Drug Name	Brand(A/B) Generic(G)	RX Count	% Opioid RXs	Overall Medication Rank by RX Count
1	HYDROCODONE-ACETAMINOPHEN	G	4,182	38.7%	6
2	TRAMADOL HCL	G	2,404	22.2%	22
3	OXYCODONE-ACETAMINOPHEN	G	1,680	15.5%	33
4	OXYCODONE HCL	G	1,157	10.7%	53
5	ACETAMINOPHEN-CODEINE	G	440	4.1%	111
6	HYDROMORPHONE HCL	G	230	2.1%	178
7	NUCYNTA	A	51	0.5%	376
8	MORPHINE SULFATE	G	51	0.5%	377
9	HYDROCODONE-IBUPROFEN	G	50	0.5%	379
10	TRAMADOL HCL-ACETAMINOPHEN	G	31	0.3%	476
		Top 10 Total	**10,276**		

Top Prescriber Types



Avandia and Actos[1-22]

Cardiovascular Effects

- Avandia (rosiglitazone) and Actos (pioglitazone) both increase the risk of HF (Boxed Warning for both products.
- Potential that Avandia use is associated with a higher risk of adverse cardiovascular events than Actos.
    - Based off of retrospective analyses of prescription data obtained from national databases, Avandia was associated with an increase in heart failure and all-cause mortality compared with Actos.
        - The largest study included 227,571 patients 65 years or older who initiated treatment with Avandia or Actos.
            - Avandia use was associated with a significantly ↑risk of stroke, HF, and all-cause mortality [HR of 1.27, 1.25, and 1.14, respectively].
- In September 2010, the FDA restricted Avandia to those already taking it and to new patients who cannot control their Type 2 diabetes with other medications, and instituted a REMS program.
    - RECORD study
        - *The Rosiglitazone Evaluated for Cardiac Outcomes and Regulation of Glycaemia in Diabetes study*: Designed to evaluate the effects of Avandia on cardiovascular events and mortality
            - 321 patients in the Avandia group and 323 in the control group, experienced the cardiovascular hospitalization or cardiovascular death.
                - ↑ Incidence of HF in 61 subjects assigned to Avandia compared with 29 in the control group [HR=2.10, 95% CI=1.35-3.27].
                - The effect of Avandia on MI was inconclusive due to the small number of events and possibly affected by greater statin use in the Avandia group [HR=1.14, 95% CI=0.80-1.63].
- In 2012, the FDA removed restrictions on Avandia and in 2015, the FDA removed the REMS requirement.
- **Risk of Myocardial Infarction:**
    - **Effect of Avandia on the risk of MI is uncertain.**
        - Some analyses have shown no or inconclusive evidence of Avandia use effecting MI risk, while many others have shown an increased risk of MI with Avandia use.
            - Ex 1: One meta-analysis of 42 trials of Avandia demonstrated an ↑in MI compared with placebo, metformin, sulfonylurea, or insulin (86 and 72 MIs in the Avandia and control groups respectively [HR=1.43, 95% CI=1.03-1.98]).
            - Ex 2: An independent meta-analysis performed by the manufacturers of Avandia showed similar findings [HR for events related to ischemia=1.31, 95% CI=1.01-1.70].
            - Ex. 3: The RECORD study showed inconclusive results for MI risk.
    - **Actos effects on MI risk**
        - Meta-analysis of 19 trials of Actos for the treatment of diabetes:
            - MI occurred in 1.5% of patients in the Actos group and 2% in the comparator group (placebo, metformin, sulfonylurea, rosiglitazone) [HR=0.81, 95% CI=0.64-1.02].
        - *Prospective Pioglitazone Clinical Trial in Macrovascular Events (PROactive)* trial
            - Patients with DM2 and high risk for macrovascular complications, managed with DM medications + either placebo or Actos.
            - Significant ↓in the incidence of all-cause mortality, MI, or stroke in the Actos treated group [HR=0.84, 95% CI=0.72-0.98].
            - Subanalysis showed Actos use in patients with previous MI results in a decreased incidence of fatal/nonfatal MI [HR=0.72, 95% CI=0.52-0.99].

Effects on Lipids

- Avandia and Actos have demonstrated differing effects on serum lipid concentrations in multiple studies, with most randomized trials finding that Actos produces a more favorable lipid profile.
    - Multiple randomized trials have shown that LDL levels typically remained constant when Actos added to a DM regimen while increases in LDL cholesterol levels ranging from 8 to 16 percent were noted in studies of Avandia.

        - In those same studies, HDL levels increased ~10% with both products, but reductions in serum TG were observed more often with Actos than with Avandia.
    - In the largest randomized trial that directly compared the two drugs, 735 patients with DLD and DM2 were assigned to receive either Avandia or Actos as monotherapy.
        - TG reductions were significantly greater in the Actos vs Avandia group [52 vs. 13 mg/dL].
        - HDL increases were greater in the Actos vs Avandia group [5.2 vs. 2.4 mg/dL]
        - LDL increases were greater in the Avandia vs Actos group [21.3 vs. 21.3 mg/dL

Current Utilization of Thiazoladinediones	
Agent	**Number of Patients**
Actos	24
Avandia	0

Glyburide and Other Sulfonylureas[23-28]

Hypoglycemia Risks:

- Incidence of hypoglycemia appears to be less common with shorter-acting than longer-acting sulfonylureas (SUs)
    - In a four-year, retrospective study of 14,000 patients 65 years or older with type 2 diabetes treated with different SUs, episodes of serious hypoglycemia were rare. The incidence was highest in those patients taking glyburide and lowest among those taking tolbutamide [19.9 vs. 3.5 episodes/1000 person-years].

Use in Chronic Kidney Disease:

- SU metabolites are renally excreted after undergoing metabolism. Agents such as glyburide and glimepiride have active metabolites that retain some hypoglycemic activity.
- Glipizide's metabolites are inactive.
- Therefore, the risk of hypoglycemia is higher in patients with chronic kidney disease in patients receiving a SU with active metabolites.

Cardiovascular Risk:

- Newer SUs, such as glipizide and glimepiride, are selective for the pancreatic SU receptors over the cardiac receptors (unlike glyburide)
    - Do not appear to be associated with ↑cardiovascular mortality compared with metformin or other diabetes medications, although direct controlled clinical trials have not been performed.
- Research:
    - Retrospective study using pharmaceutical data for 5795 subjects who received initial monotherapy with either a SU or metformin.
        - Evaluated deaths per 1000 person-years during the follow-up period
            - 61.4 for glyburide vs 39.6 for metformin
            - Risk of death or an acute ischemic event was greater for subjects exposed to higher doses of the SU, but not metformin
    - A meta-analysis of 47 trials comparing 2nd generation SUs (glimepiride and glipizide) with diet, placebo, or an active comparator, the SUs were not associated with ↑risk of overall mortality, CV mortality, MI, or stroke.
    - In a study of 1310 patients with DM who were hospitalized for MI, mortality rates were significantly ↓ in patients previously treated with a SU compared with other oral medications, insulin, or no medication [3.9, 6.4, 9.4, and 8.4% respectively].
        - Among the SU-treated patients, mortality was significantly lower in patients receiving second-generation sulfonylureas compared to glyburide.

Current Utilization of Sulfonylureas	
Agent	**Number of Patients**
Glipizide	82
Glimepiride	56
Glyburide	20

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24. Zeller M, Danchin N, Simon D, et al. Impact of type of preadmission sulfonylureas on mortality and cardiovascular outcomes in diabetic patients with acute myocardial infarction. J Clin Endocrinol Metab 2010; 95:4993.
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PRODUCT DETAILS OF LUCEMYRA (LOFEXIDINE)

INDICATIONS AND USE:

- Opioid Withdrawal
    - Mitigation of opioid withdrawal symptoms to facilitate abrupt opioid discontinuation in adults.
        - MoA: Central alpha-2 adrenergic agonist that reduces the release of norepinephrine and decreases sympathetic tone

DOSAGE AND ADMINISTRATION:

- Initial dosing is 0.54 mg 4 times daily, which may be titrated to symptoms
- **Max:** 0.72 mg/dose or 2.88 mg/day
- **Duration:** Administer during peak opioid withdrawal period (generally 5 to 7 days after last opioid use). May continue for up to 14 days if needed
- **Discontinuation:** Decrease dose gradually over 2 to 4 days.
- **Dose Adjustments**
    - **Renal impairment:**
        - eGFR 30-88.9 mL/minute/1.73 m^2: 0.36 mg/dose
        - eGFR <30 mL/minute/1.73 m^2: 0.18 mg/dose
    - **Hepatic impairment:**
        - Moderate impairment (Child-Pugh class B): 0.36 mg/dose
        - Severe impairment (Child-Pugh class C): 0.18 mg/dose

DOSAGE FORM AND STRENGTHS:

- 0.18 mg tablets

CONTRAINDICATIONS:

- None per label

WARNINGS AND PRECAUTIONS:

- **Cardiovascular effects:**
    - Syncope and Decreases in BP or HR
        - Reduce dose or interrupt therapy if clinically significant bradycardia and/or hypotension occur.
        - Avoid use in patients with severe coronary insufficiency, recent myocardial infarction, significant bradycardia, cerebrovascular disease, and chronic renal failure.
    - QT Prolongation
        - Avoid use in patients with congenital long QT syndrome.
- **Accidental opioid overdose**
    - Lofexidine is not a treatment for opioid use disorder, and it should be used only in conjunction with a comprehensive management program for the treatment of opioid use disorder.
    - Patients who had been treated with lofexidine may respond to lower opioid doses than previously used. This could result in potentially life-threatening opioid overdose.
- **Discontinuation of therapy**
    - Discontinuing lofexidine gradually to avoid severe withdrawal symptoms.
- **CYP2D6 poor metabolizers**
    - Exposure to lofexidine may be increased.

ADVERSE REACTIONS:

- **Most common (>10%)**
    - Orthostatic hypotension (29-42%), bradycardia (24-32%), hypotension (30%)
    - Insomnia (51-55%), dizziness (19-23%), sedation/drowsiness (12-13%)
    - Xerostomia (10-11%)

DRUG INTERACTIONS

- Most significant are those that :
    - Agents that significantly lower BP (bromperidol) or HR (ceritinib), or significantly prolong QT interval (e.g. hydroxychloroquine, macimorelin, mifepristone, promazine, etc.)

COST

Drug	Strength	Package Size	AWP Pkg Price	AWP Unit Price
LUCEMYRA	0.18 mg	36 Tablets	893.81	24.83
LUCEMYRA	0.18 mg	96 Tablets	2,383.49	24.83

CURRENT UTILIZATION

ND Medicaid Utilization (06/2018 – 07/2018)		
Label Name	**Rx Num**	**Total Reimb Amt**
LUCEMYRA	0	N/A

REFERENCES:

1. Facts & Comparisons eAnswers. Available at http://online.factsandcomparisons.com. Accessed on July 20. 2018.
2. Lucemyra (lofexidine) [prescribing information]. Louisville, KY: US WorldMeds, LLC; May 2018.

PRODUCT DETAILS OF PALYNZIQ (PEGVALIASE-PQPZ INJECTION)

INDICATIONS AND USE:

- To reduce blood phenylalanine concentrations in adult patients with phenylketonuria (PKU) who have uncontrolled blood phenylalanine concentrations >600 micromol/L on existing management

DOSAGE AND ADMINISTRATION:

- Initial: 2.5 mg once weekly for 4 weeks.
- After initial 4 weeks, double dose weekly to 40 mg weekly, then 10 mg once daily.
    - Followed by 20 mg once daily for 24 weeks, then can go to 40 mg daily has not been achieved on the 20 mg daily dose (if a 20% reduction of blood phenylalanine from baseline does not occur OR if blood phenylalanine concentration 600 micromol/L or less)
- If a response has not been achieved after administering 40 mg once daily for 16 weeks, discontinue therapy

DOSAGE FORM AND STRENGTHS:

- 2.5 mg/0.5 mL, 10 mg/0.5 mL, and 20 mg/mL prefilled syringes for SQ injection

CONTRAINDICATIONS:

- None per label

BOXED WARNING

- Anaphylaxis has been reported after administration and may occur at any time during treatment.
    - Administer the initial dose under the supervision of a healthcare provider
    - Prior to self-injection, confirm patient competency with self-administration

WARNINGS AND PRECAUTIONS:

- Anaphylaxis (see boxed warning)

ADVERSE REACTIONS:

- Most common (>10%)
    - **CNS**: HA (35-50%), fatigue (13-22%), anxiety (5-18%), dizziness (16-17%)
    - **Derm**: Skin changes (21-44%), pruritus (20-24%), alopecia (5-17%), Injection-site reaction (72-88%)
    - **GI**: Nausea (18-26%), vomiting (13-26%), ab pain (14-25%), diarrhea (9-22%)
    - **Hematologic**: Change in serum protein (<LLN: complement factor C3 8-84%; complement factor C4 48-62%), ↑ C-RP (64-68%), ↓ phenylalanin (16-61%)
    - **Hypersensitivity**: Anaphylaxis (9-84%), hypersensitivity reaction (53-69%)
    - **Immunologic**: Antibody development (100%; neutralizing antibodies to PAL enzyme activity: 88%)
    - **Muscoluskeletal**: Arthralgia (61-83%), ↑ creatine phosphokinase (18-43%)
    - **Respiratory**: Sore throat (13-23%), cough (9-22%), nasal congestion (4-18%)

DRUG INTERACTIONS

- No significant interactions

COST

Drug	Strength	Package Size	AWP Pkg Price	AWP Unit Price
PALYNZIQ	2.5 mg/0.5 mL	1 mL	585.60	585.60
PALYNZIQ	10 mg/0.5 mL	1 mL	585.60	585.60
PALYNZIQ	20 mg/1 mL	1 mL	585.60	585.60

CURRENT UTILIZATION

ND Medicaid Utilization (06/2018 – 07/2018)		
Label Name	**Rx Num**	**Total Reimb Amt**
PALYNZIQ	0	N/A

REFERENCES:

1. Facts & Comparisons eAnswers. Available at http://online.factsandcomparisons.com. Accessed on July 20. 2018.
2. Palynziq (pegvaliase-pqpz) [prescribing information]. Novato, CA: BioMarin Pharmaceutical Inc; May 2018.

PRODUCT DETAILS OF ROXYBOND (OXYCODONE ABUSE-DETERRENT TABLET)

INDICATIONS AND USE:

- Opioid agonist indicated for the management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate.
    - Only to be used when alternative treatment options….
        - Have not been tolerated, or are not expected to be tolerated,
        - Have not provided adequate analgesia or are not expected to provide adequate analgesia.
    - Formulated with inactive ingredients that make the tablet more difficult to manipulate for misuse and abuse: Difficult to prepare into solution and forms viscous material that does not pass through a needle easily.

DOSAGE AND ADMINISTRATION:

- Initial: 5 or 15 mg every 4-6 hours as needed and titrate to effect.
- Dosing ≥15 years of age:
    - 1 to 4 grams per total daily dose in equally divided doses
- Dosing for 1 to 14 years of age:
    - Usual: 25 to 50 mg/kg given in equally divided doses for 7-14 days
    - Severe infections: 50 to 100 mg/kg in equally divided doses
    - Otitis Media: 75 to 100 mg/kg in equally divided doses

DOSAGE FORM AND STRENGTHS:

- 5, 15, 30 mg tablets

CONTRAINDICATIONS:

- Significant respiratory depression
- Acute or severe bronchial asthma in an unmonitored setting or in absence of resuscitative equipment
- Known or suspected gastrointestinal obstruction, including paralytic ileus
- Hypersensitivity to oxycodone

BOXED WARNING

- Respiratory depression, addiction/abuse potential, accidental ingestion, neonatal opioid withdrawal, CYP3A4 interactions, risk when used with benzos.

WARNINGS AND PRECAUTIONS:

- See boxed warnings
- Avoid use in cachectic and debilitated patients
- May cause hypotension
- Use with caution in patients with mental health conditions, seizures, head trauma, abdominal conditions, and biliary tract impairment.

ADVERSE REACTIONS:

- Most common adverse reactions: dizziness, nausea, constipation, vomiting, headache, pruritus, insomnia, asthenia, and somnolence.

DRUG INTERACTIONS

- Other CNS depressants, CYP 3A4 inducers and inhibitors

COST

Drug	Strength	Package Size	AWP Price	AWP Unit Price
ROXYBOND	5 mg	100 tablets	667.00	8.00
ROXYBOND	15 mg	100 tablets	933.60	9.34
ROXYBOND	30 mg	100 tablets	1,244.40	12.44

CURRENT UTILIZATION

ND Medicaid Utilization (06/2018 – 07/2018)		
Label Name	**Rx Num**	**Total Reimb Amt**
ROXYBOND	0	N/A

REFERENCES:

1. Facts & Comparisons eAnswers. Available at http://online.factsandcomparisons.com. Accessed on July 20. 2018.
2. Roxybond (oxycodone) [prescribing information]. Basking Ridge, NJ: Daiichi Sankyo Inc; June 2017.

PRODUCT DETAILS OF SIKLOS (HYDROXYUREA)

INDICATIONS AND USE:

- Sickle cell anemia
  - To reduce the frequency of painful crises and to reduce the need for blood transfusions in patients with recurrent moderate to severe painful crises.

DOSAGE AND ADMINISTRATION:

- Dosing ≥2 years of age:
  - **Max:** 35 mg/kg/day (titrated to effect, every 2 weeks if blood labs in acceptable range)
  - Neutrophils ≥2,500 cells/mm^3; platelets ≥95,000/mm^3; hemoglobin >5.3 g/dL; and reticulocytes ≥95,000/mm^3 if hemoglobin is <9 g/dL
  - **Initial:** 20 mg/kg/day
    - **Renal impairment (CrCl <50 mL/min):** Reduce initial dose 50%

DOSAGE FORM AND STRENGTHS:

- 100 mg tablets

CONTRAINDICATIONS:

- Hypersensitivity to hydroxyurea or any component of its formulation

BOXED WARNING

- Bone marrow suppression: Hydroxyurea may cause severe myelosuppression. Monitor blood counts at baseline and throughout treatment. Interrupt treatment and reduce dose as necessary.
- Secondary malignancy: Hydroxyurea is carcinogenic. Advise sun protection and monitor patients for malignancies

WARNINGS AND PRECAUTIONS:

- Cutaneous vasculitic toxicity
  - Vasculitic ulcerations and gangrene have been reported in patients with myeloproliferative disorders during hydroxyurea treatment.
    - Avoid use in patients with leg ulcer wounds and d/c if this occurs.
- HIV-infected patients
  - Pancreatitis, hepatotoxicity, and peripheral neuropathy have occurred when hydroxyurea was administered with antiretroviral medications.
- Macrocytosis
  - Self-limiting macrocytosis may be seen early in treatment. Prophylactic folic acid supplementation is recommended
- Tumor lysis syndrome
  - Hyperuricemia may occur with antineoplastic treatment.
- Radiation therapy recipients
  - Patients with a history of radiation therapy are at risk for exacerbation of post irradiation erythema and myelosuppression
- Avoid use of live vaccines during hydroxyurea therapy

ADVERSE REACTIONS:

- **Common (>5%)**
  - Eczema (infants and children: 13%)
  - Macrocytosis (MCV >97: 42%)
  - Leg ulcer (7%), dermal ulcer (3%)
  - Acute mucocutaneous toxicity (5%)
  - Asthma (infants and children: 9%)

DRUG INTERACTIONS

- Live vaccines, Tacrolimus and pimecrolimus, Antiretroviral therapy, Other immunosuppressants, Other myelosuppressive agents

COST

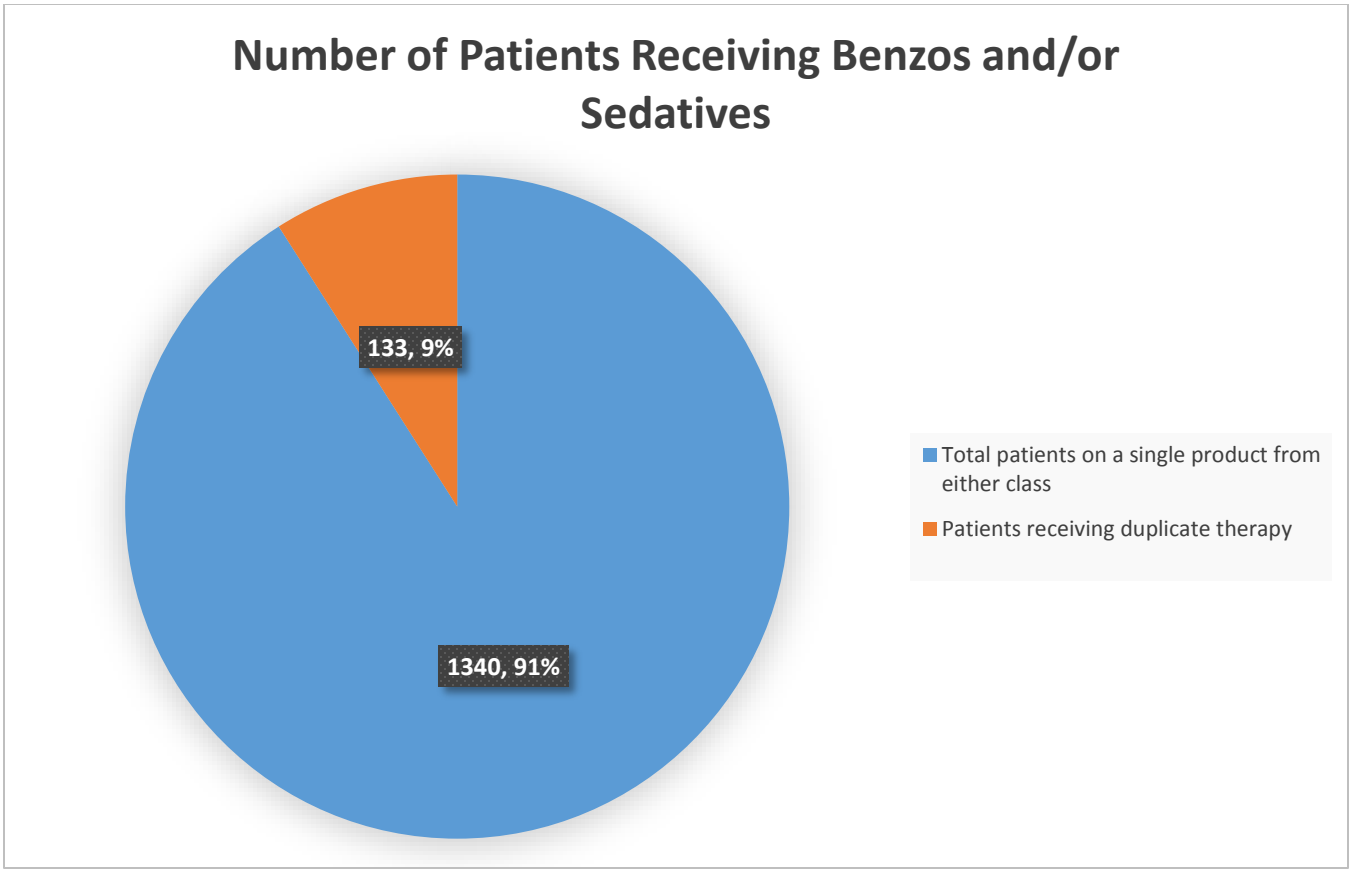
Drug	Strength	Package Size	AMP Pkg Price	AWP Unit Price
SIKLOS	100 mg	100 tablets	360.00	6.00

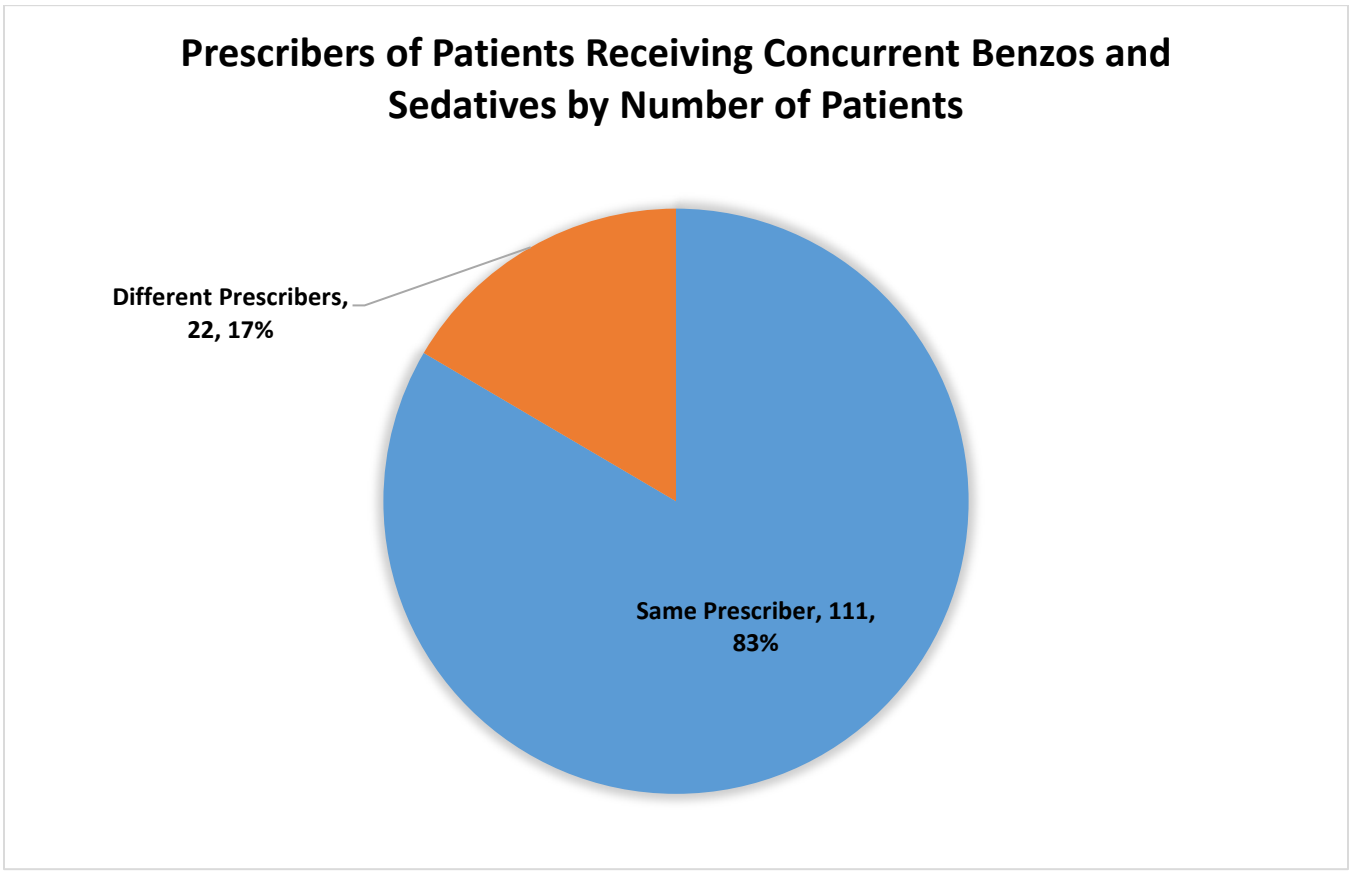
CURRENT UTILIZATION

ND Medicaid Utilization (06/2018 – 07/2018)		
Label Name	**Rx Num**	**Total Reimb Amt**
SIKLOS	0	N/A

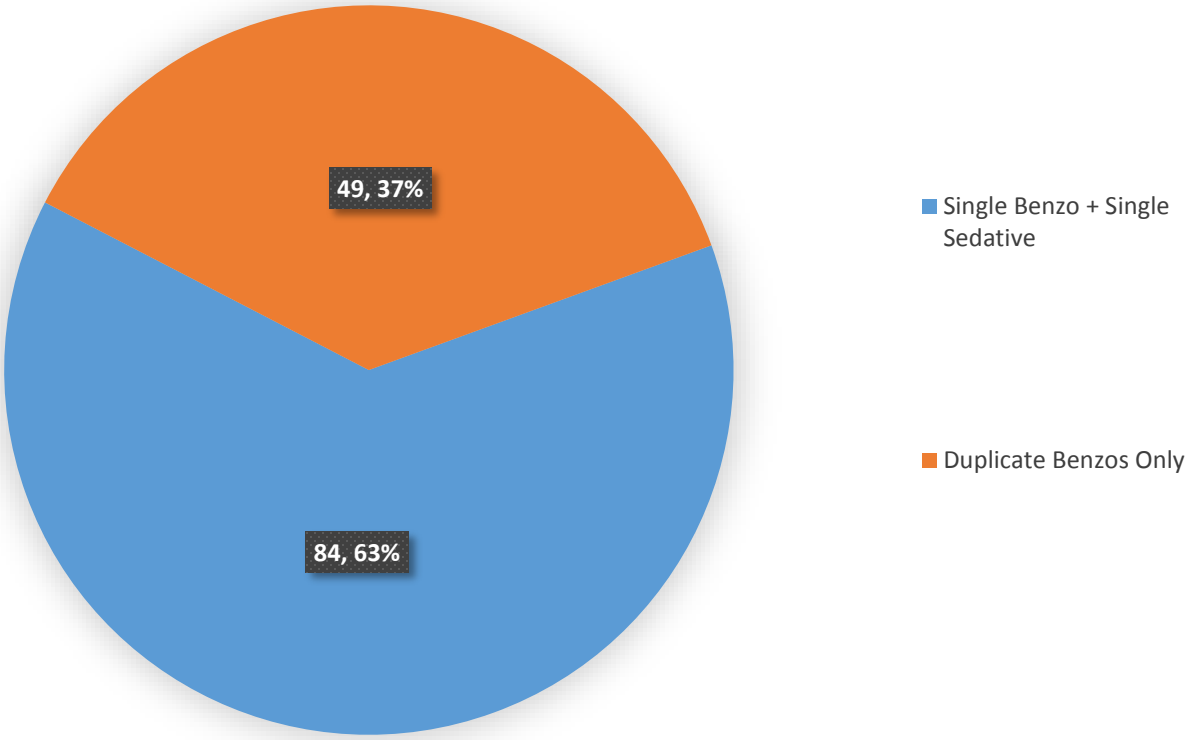
REFERENCES:

1. Facts & Comparisons eAnswers. Available at http://online.factsandcomparisons.com. Accessed on July 20. 2018.
2. Siklos (hydroxyurea) [prescribing information]. Bryn Mawr, PA: Medunik USA Inc; May 2018.

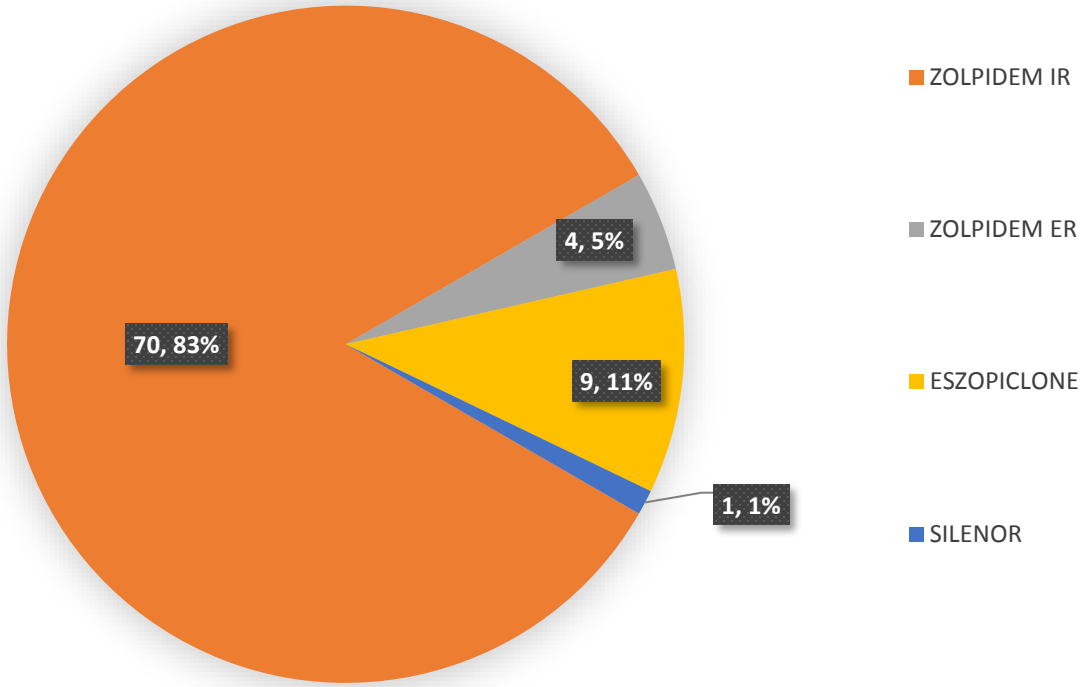

Number of Patients Receiving Benzos and/or Sedatives
133, 9%
1340, 91%
Total patients on a single product from either class
Patients receiving duplicate therapy


Prescribers of Patients Receiving Concurrent Benzos and Sedatives by Number of Patients
Different Prescribers, 22, 17%
Same Prescriber, 111, 83%

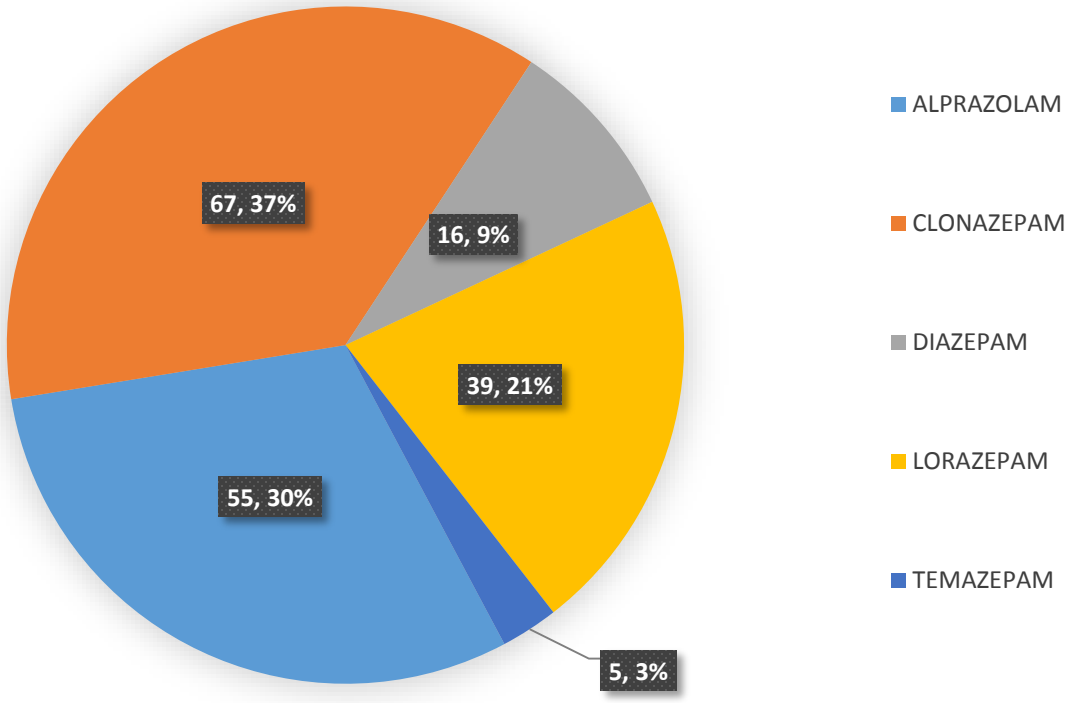
Benzo/Sedative Concurrent Use by Number of Patients



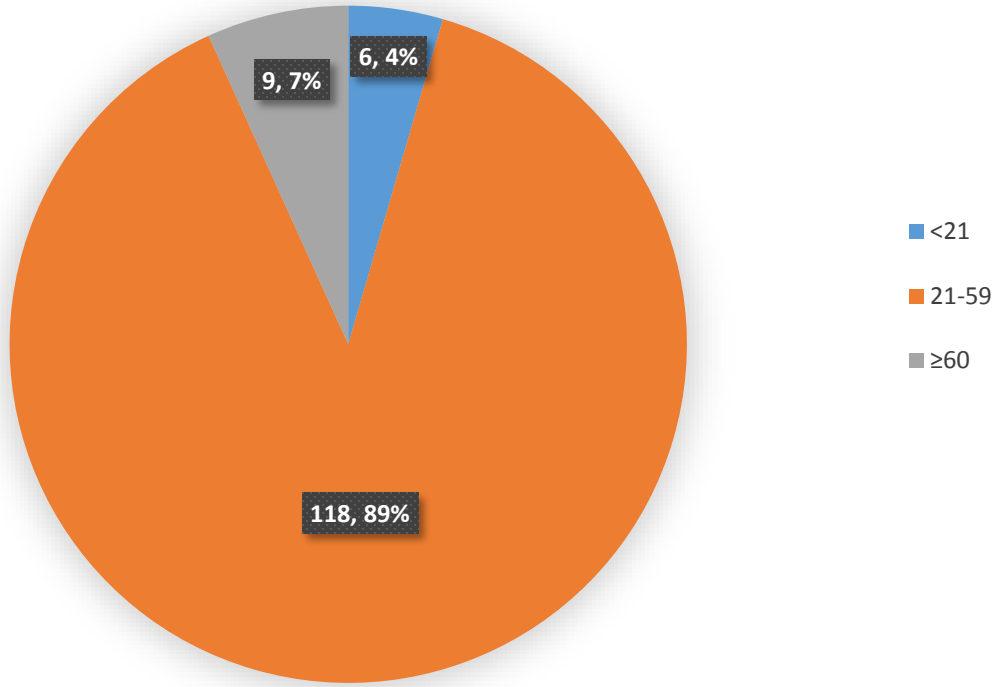
Most Common Sedatives Used Concurrently with Benzos by Number of Patients

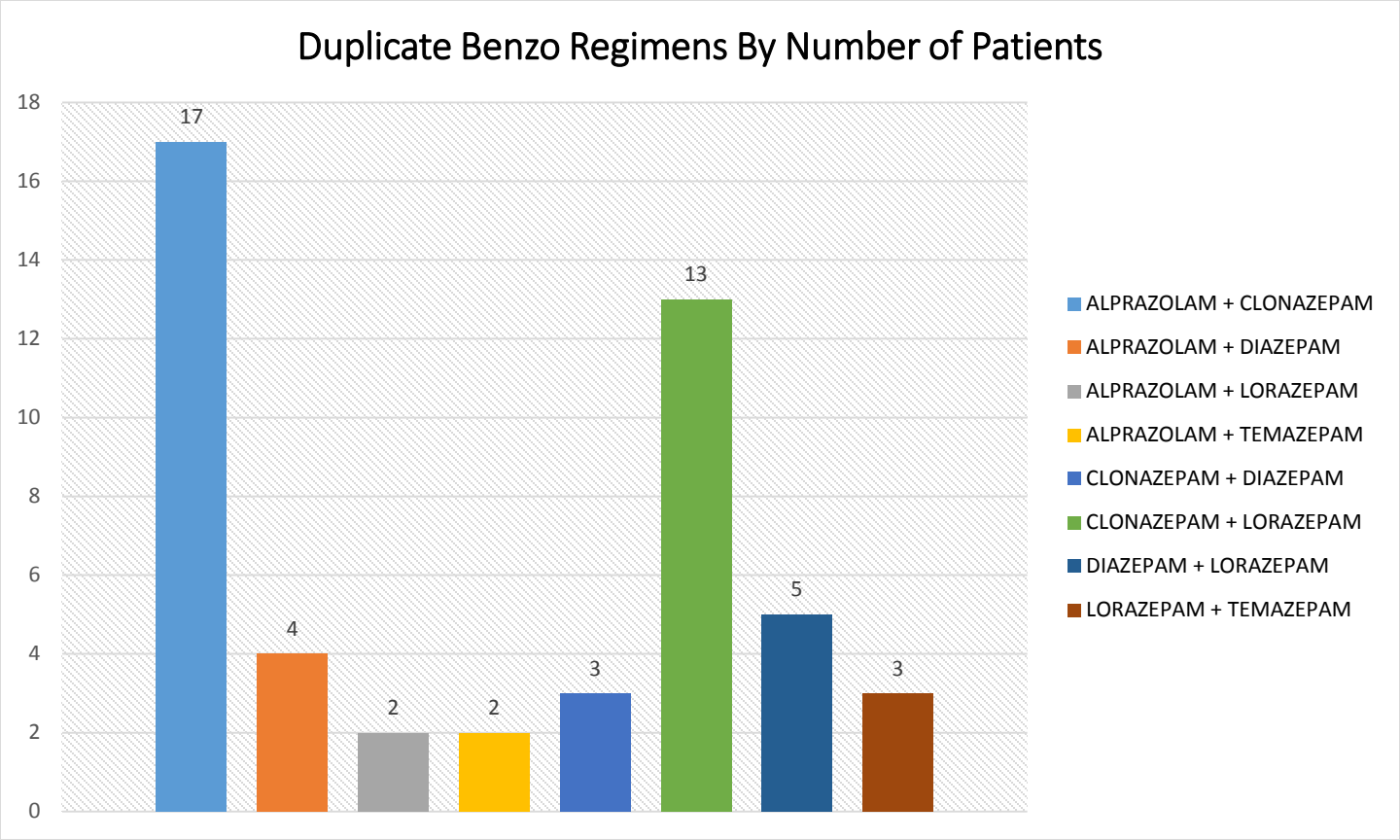


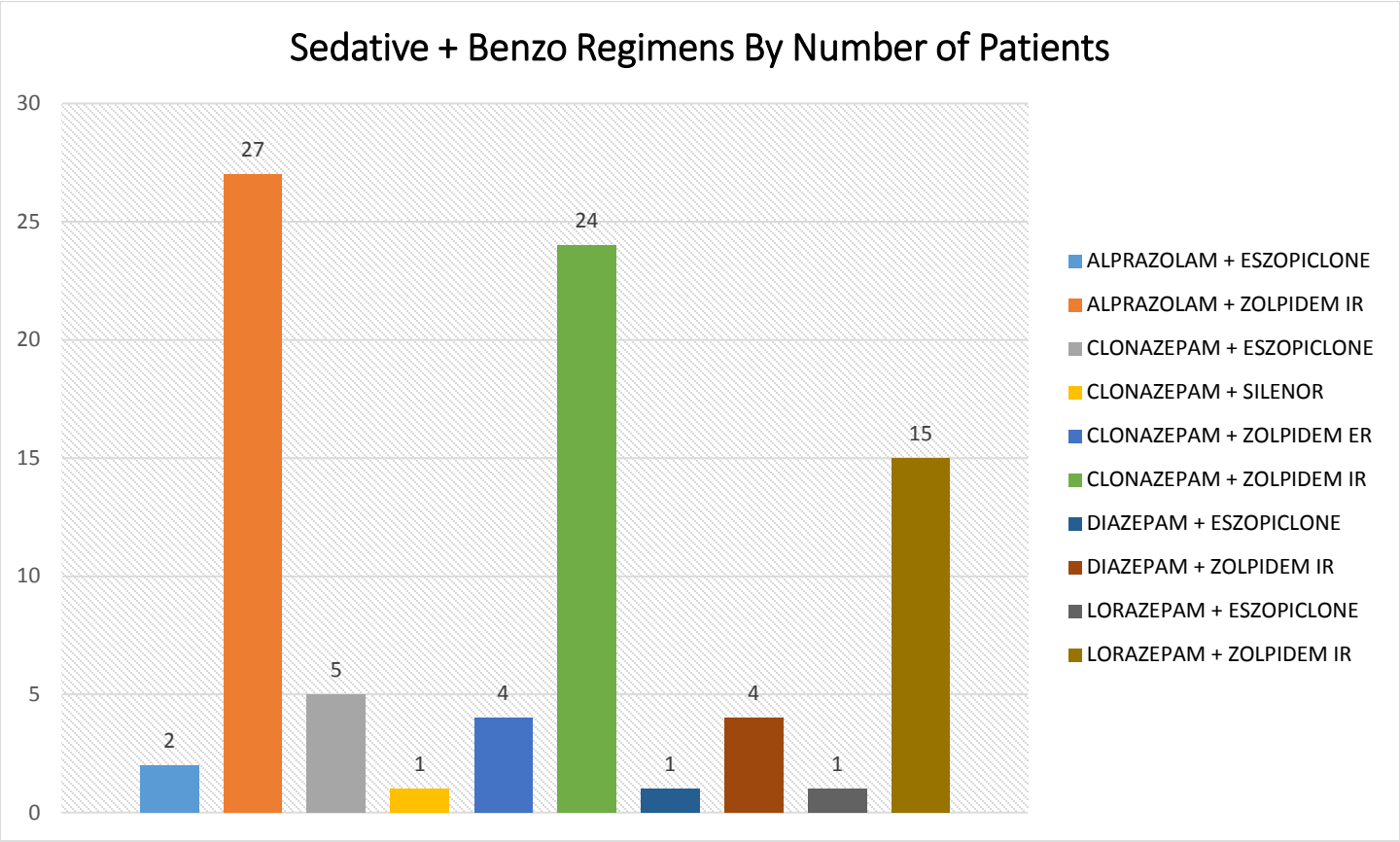
Most Common Benzos Used Concurrently with Sedatives by Number of Patients

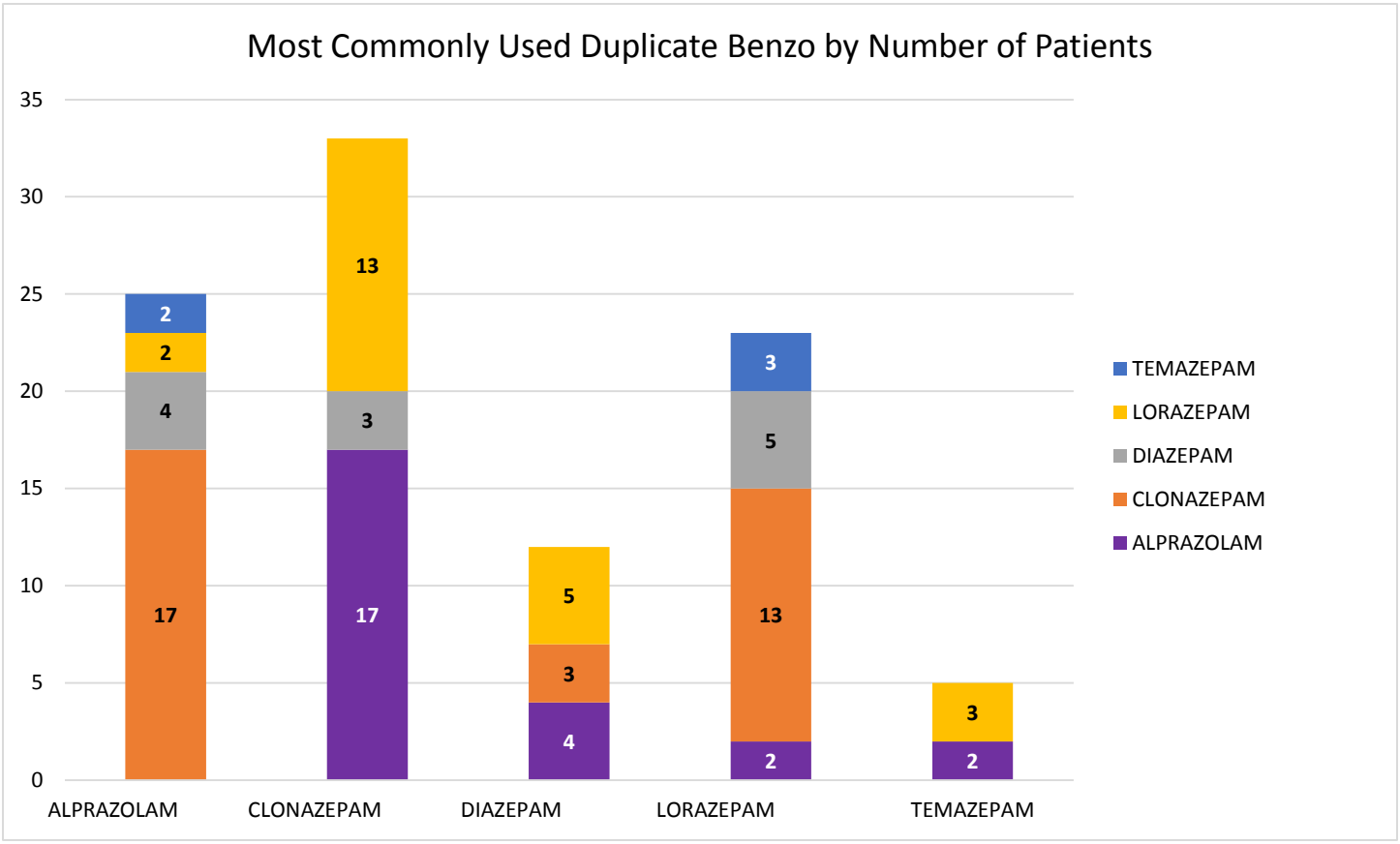


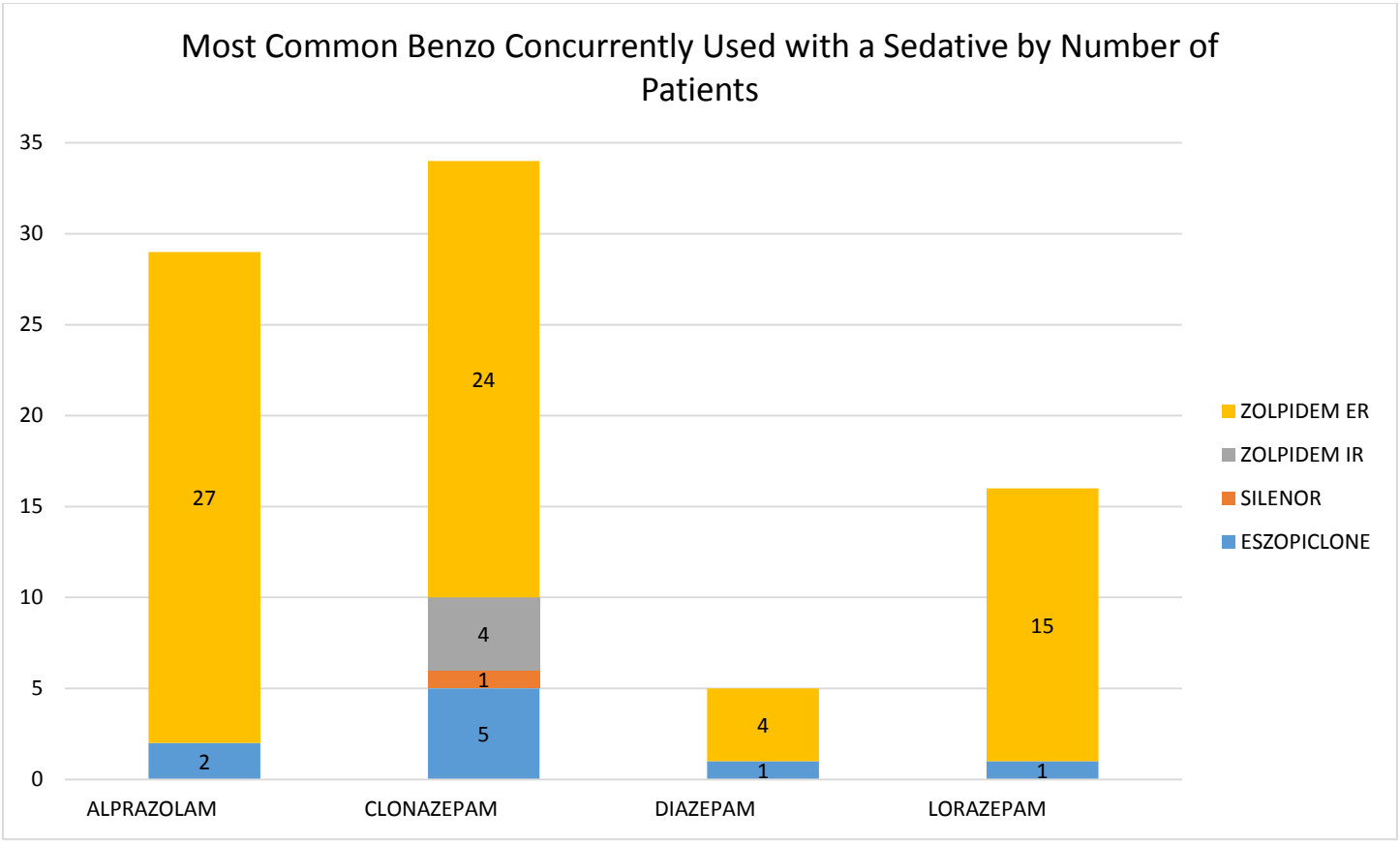
Number of Patients on Concurrent Benzos/Sedatives by Age Group




Duplicate Benzo Regimens By Number of Patients
18
16
14
12
10
8
6
4
2
0
17
4
2
2
3
13
5
3
ALPRAZOLAM + CLONAZEPAM
ALPRAZOLAM + DIAZEPAM
ALPRAZOLAM + LORAZEPAM
ALPRAZOLAM + TEMAZEPAM
CLONAZEPAM + DIAZEPAM
CLONAZEPAM + LORAZEPAM
DIAZEPAM + LORAZEPAM
LORAZEPAM + TEMAZEPAM


Sedative + Benzo Regimens By Number of Patients
30
25
20
15
10
5
0
2
27
5
1
4
24
1
4
1
15
ALPRAZOLAM + ESZOPICLONE
ALPRAZOLAM + ZOLPIDEM IR
CLONAZEPAM + ESZOPICLONE
CLONAZEPAM + SILENOR
CLONAZEPAM + ZOLPIDEM ER
CLONAZEPAM + ZOLPIDEM IR
DIAZEPAM + ESZOPICLONE
DIAZEPAM + ZOLPIDEM IR
LORAZEPAM + ESZOPICLONE
LORAZEPAM + ZOLPIDEM IR


Most Commonly Used Duplicate Benzo by Number of Patients
35
30
25
20
15
10
5
0
2
2
4
17
13
3
17
5
3
4
3
5
13
2
3
2
ALPRAZOLAM
CLONAZEPAM
DIAZEPAM
LORAZEPAM
TEMAZEPAM
TEMAZEPAM
LORAZEPAM
DIAZEPAM
CLONAZEPAM
ALPRAZOLAM


Most Common Benzo Concurrently Used with a Sedative by Number of Patients
35
30
25
20
15
10
5
0
27
2
24
4
1
5
4
1
15
1
ALPRAZOLAM
CLONAZEPAM
DIAZEPAM
LORAZEPAM
ZOLPIDEM ER
ZOLPIDEM IR
SILENOR
ESZOPICLONE

Overview of CAR T-Cell Immunotherapies

How they Work

- Chimeric antigen receptor (CAR) T-cell therapies
    - Unique compared to other chemotherapy agents in that the active product is actually genetically modified versions of a patient's own T-cells
    - Therapies work by reprogramming a patient's T cells to make it produce a CAR on its surface that allows it to target a specified antigen (transgene encoding)
        - CAR is an antibody fragment which recognizes and binds to a specific target "antigen"
        - After antigen binding, the CAR transmits a signal promoting T-cell proliferation, activation, secretion of inflammatory mediators, and ultimately destruction of antigen expressing cells

Preparation of the Active Product

- Because CAR T-cell immunotherapies are genetically enhanced versions of a patient's own T-cells, a multi-step process must take place prior to a patient being able to be treated with them.
    1. Patient's T-cells are removed from their blood using a process called leukapheresis
    2. T-cells are sent to a lab where they are genetically engineered to produce CD19 directed CARs
    3. The number of modified CAR T-cells is augmented by growing cells in the laboratory, which are then frozen
    4. Depending on the agent and the regimen chosen, the patient may be given lymphodepleting regimen*
    5. The patient's modified CAR T-cells are transfused into the patient's blood stream

Available Products

- Kymriah (tisagenlecleucel)
    - Indicated for the treatment of B-cell precursor acute lymphoblastic leukemia (ALL) that is refractory or in second or later relapse in patients up to 25 years of age
    - Efficacy was proven in a trial including 63 pediatric and young adult patients with R/R B-cell precursor ALL.
        - 63% and 19% achieved CR or complete remission with incomplete blood count recovery (CRi) respectively.
        - The median DOR was not reached and the median time to onset of CR/CRi was 29 days.
- Yescarta (axicabtagene ciloleucel)
    - Indicated for the treatment of relapsed or refractory large B-cell lymphoma after 2 or more lines of systemic therapy (includes diffuse large B-cell lymphoma (DLBCL) not otherwise specified, primary mediastinal large B-cell lymphoma, high-grade B-cell lymphoma, and DLBCL arising from follicular lymphoma).
    - Efficacy established in an open-label trial of 101 adult patients with relapsed or refractory aggressive B-cell non-Hodgkin lymphoma.
        - 51% achieved complete remission (CR) and 21% achieved partial remission
        - Median duration of response (DOR) of 9.2 months and a median time to response of 0.9 months
- Both products carry boxed warnings regarding the existence of a REMS program for each product as well as on the risk of potentially fatal or life-threatening cytokine release syndrome (CRS) and neurological toxicities associated with the products.
- Other warning include risk of serious viral, bacterial, and other infections; prolonged cytopenias,; Hypogammaglobulinemia; Hepatitis B virus (HBV) reactivation; and development of secondary malignancies or leukemia recurrence during treatment
- Most common adverse reactions (>10%), include blood pressure changes, tachycardia, headache, fatigue, delirium, hypophosphatemia, GI upset, acute renal failure, hypoxia, cough, myalgia and fever.

References:

1. Fischer, A. "FDA News Release: FDA approves CAR-T cell therapy to treat adults with certain types of large B-cell lymphoma". Press Announcements. United States Food and Drug Administration, 18 October 2017.
2. Fischer, A. "FDA approval brings first gene therapy to the United States". Press Announcements. United States Food and Drug Administration, 30 August 2017.
3. Kymriah (tisagenlecleucel) [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; August 2017.
4. Yescarta (axicabtagene ciloleucel) [prescribing information]. Santa Monica, CA: Kite Pharma Inc; October 2017.

NORTH DAKOTA MEDICAID
RETROSPECTIVE DRUG UTILIZATION REVIEW
CRITERIA RECOMMENDATIONS
3RD QUARTER 2018

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

1. Midostaurin / Overutilization _____ _____

Alert Message: The manufacturer's recommended dose of Rydapt (midostaurin) for patients with acute myeloid leukemia (AML) is 50 mg twice daily.

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C **(Include)**
Midostaurin		Acute Myeloid Leukemia

Max Dose: 100mg/day

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

2. Midostaurin / Overutilization _____ _____

Alert Message: The manufacturer's recommended dose of Rydapt (midostaurin) for patients with aggressive systemic mastocytosis (ASM), systemic mastocytosis with associated hematological neoplasm (SM-AHM) or mast cell leukemia (MCL) is 100 mg twice daily.

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C **(Include)**
Midostaurin		Aggressive Systemic Mastocytosis (ASM) Mast Cell Leukemia

Max Dose: 200mg/day

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

3. Midostaurin / Strong CYP3A4 Inducers _____ _____

Alert Message: Concurrent use of Rydapt (midostaurin), a CYP3A4 substrate, with a strong CYP3A4 inducer should be avoided as concomitant use may result in decreased midostaurin concentrations and reduced efficacy.

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

Util A	Util B		Util C
Midostaurin	Carbamazepine	Rifampin	
	Phenobarbital	Enzalutamide	
	Primidone		
	Phenytoin		

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

4. Midostaurin / Strong CYP3A4 Inhibitors _____ _____

Alert Message: Concurrent use of Rydapt (midostaurin), a CYP3A4 substrate, with a strong CYP3A4 inhibitor may increase exposure to midostaurin and its active metabolites, increasing the risk of midostaurin toxicity. Consider alternative therapies that do not strongly inhibit CYP3A4 or monitor for increased risk of midostaurin-related adverse reactions.

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

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

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

5. Midostaurin / Pregnancy / Pregnancy negating _____ _____

Alert Message: Rydapt (midostaurin) may cause fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to the fetus.

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

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

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Rydapt Prescribing Information, April 2017, Novartis Pharmaceuticals Corp.

6. Midostaurin / Therapeutic Appropriateness _____ _____

Alert Message: Advise males with female sexual partners of reproductive potential that effective contraception should be used during treatment with Rydapt (midostaurin) and for 4 months after the last dose. Based on its mechanism of action and findings from animal reproduction studies, midostaurin may cause embryo-fetal toxicity.

Conflict Code: TA - Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C
Midostaurin		

Gender: Male

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

7. Midostaurin / Therapeutic Appropriateness _____ _____

Alert Message: Based on its mechanism of action and findings from animal reproduction studies, Rydapt (midostaurin) may cause fetal harm when administered to a pregnant woman. Advise females of reproductive potential to use effective contraception during treatment with midostaurin and for at least 4 months after the last dose.

Conflict Code: TA - Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C
Midostaurin		

Gender: Female
Age Range: 11 – 50 yoa

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

8. Midostaurin / Therapeutic Appropriateness _____ _____

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

Conflict Code: TA - Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C
Midostaurin		

Age Range: 0-17 yoa

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

9. Midostaurin / Pulmonary Toxicity _____ _____

Alert Message: Cases of interstitial lung disease and pneumonitis, some fatal, have occurred in patients treated with Rydapt (midostaurin) as monotherapy or with chemotherapy. Monitor patients for pulmonary symptoms. Discontinue midostaurin in patients who experience signs and symptoms of interstitial lung disease or pneumonitis without an infectious etiology.

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

Util A	Util B	Util C
Midostaurin	Acute Interstitial Pneumonia Dyspnea	

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

10. Neratinib / Overutilization _____ _____

Alert Message: The manufacturer's recommended dose of Nerlynx (neratinib) is 240 mg (6 tablets) orally once daily.

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C
Neratinib		

Max Dose: 240 mg/day

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Nerlynx Prescribing Information, June 2018, Puma Biotechnology, Inc.

11. Neratinib / Diarrhea _____ _____

Alert Message: Nerlynx (neratinib) can cause severe diarrhea. Aggressively manage diarrhea occurring despite recommended prophylaxis with additional antidiarrheals, fluids, and electrolytes as clinically indicated. Withhold neratinib in patients who experience severe and/or persistent diarrhea. Permanently discontinue neratinib in patients experiencing Grade 4 diarrhea or Grade >/= 2 diarrhea that occurs after maximal dose reduction.

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

Util A	Util B	Util C
Neratinib	Diarrhea	

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Nerlynx Prescribing Information, June 2018, Puma Biotechnology, Inc.

12. Neratinib / Therapeutic Appropriateness-Hepatotoxicity _____ _____

Alert Message: Nerlynx (neratinib) has been associated with hepatotoxicity characterized by increased liver enzymes. Monitor liver function tests monthly for the first 3 months of treatment, then every 3 months while on treatment and as clinically indicated. Withhold neratinib in patients experiencing Grade 3 liver abnormalities and permanently discontinue neratinib in patients experiencing Grade 4 liver abnormalities.

Conflict Code: TA - Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C
Neratinib		

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Nerlynx Prescribing Information, June 2018, Puma Biotechnology, Inc.

13. Neratinib / Pregnancy / Pregnancy Negating _____ _____

Alert Message: Based on findings from animal studies and its mechanism of action, Nerlynx (neratinib) can cause fetal harm when administered to a pregnant woman. In animal reproductive studies, administration of neratinib to pregnant rabbits during organogenesis caused abortions, embryo-fetal death and fetal abnormalities.

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

Util A	Util B	Util C
Neratinib	Pregnancy	Miscarriage
		Abortion
		Delivery

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Nerlynx Prescribing Information, June 2018, Puma Biotechnology, Inc.

14. Neratinib / Therapeutic Appropriateness _____ _____

Alert Message: Nerlynx (neratinib) may cause fetal harm when administered to a pregnant woman. Advise females of reproductive potential to use effective contraception during treatment with neratinib and for 1 month after the last dose. Females of reproductive potential should have a pregnancy test prior to starting treatment with neratinib.

Conflict Code: TA - Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C
Neratinib		

Gender: Female
Age Range: 11 – 50 yoa

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Nerlynx Prescribing Information, June 2018, Puma Biotechnology, Inc.

15. Neratinib / Therapeutic Appropriateness _____ _____

Alert Message: Based on findings in animal reproductive studies, advise males receiving Nerlynx (neratinib) with female partners of reproductive potential to use effective contraception during treatment and for 3 months after the last dose of neratinib.

Conflict Code: TA - Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C
Neratinib		

Gender: Male

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Nerlynx Prescribing Information, June 2018, Puma Biotechnology, Inc.

16. Neratinib / Proton Pump Inhibitors _____ _____

Alert Message: Concurrent use of Nerlynx (neratinib) with a proton pump inhibitor should be avoided as concomitant use of these agents may result in decreased neratinib exposure and efficacy. Drug interaction studies with neratinib and lansoprazole resulted in a decrease in neratinib Cmax and AUC of 71% and 65%, respectively.

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

Util A	Util B	Util C
Neratinib	Omeprazole	
	Esomeprazole	
	Lansoprazole	
	Rabeprazole	
	Dexlansoprazole	
	Pantoprazole	

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Nerlynx Prescribing Information, June 2018, Puma Biotechnology, Inc.

17. Neratinib / H2-Receptor Antagonists _____ _____

Alert Message: Concurrent use of Nerlynx (neratinib) with an H-2-receptor blocker should be avoided as concomitant use of these agents may result in decreased neratinib exposure and efficacy. The solubility of neratinib is pH dependent and its solubility decreases as gastric pH increases.

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

Util A	Util B	Util C
Neratinib	Cimetidine	
	Famotidine	
	Nizatidine	
	Ranitidine	

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Nerlynx Prescribing Information, June 2018, Puma Biotechnology, Inc.

18. Neratinib / Antacids _____ _____

Alert Message: Concurrent use of Nerlynx (neratinib) with an antacid may result in decreased neratinib exposure and efficacy. The solubility of neratinib is pH dependent and its solubility decreases as gastric pH increases. If concomitant use is warranted separate the dosing of neratinib and antacids by 3 hours.

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

Util A	Util B	Util C
Neratinib	Magnesium Hydroxide	
	Aluminum Hydroxide	
	Calcium Carbonate	

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Nerlynx Prescribing Information, June 2018, Puma Biotechnology, Inc.

19. Neratinib / Moderate & Strong CYP3A4 Inhibitors _____ _____

Alert Message: Concurrent use of Nerlynx (neratinib), a CYP substrate, with a moderate or strong CYP3A4 inhibitor should be avoided as concomitant use may result in increased neratinib plasma concentrations and neratinib toxicity.

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

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

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Nerlynx Prescribing Information, June 2018, Puma Biotechnology, Inc.

20. Neratinib / Moderate & Strong CYP3A4 Inducers _____ _____

Alert Message: Concurrent use of Nerlynx (neratinib), a CYP3A4 substrate, with a moderate or strong CYP3A4 inducer should be avoided as concomitant use may result in decreased neratinib plasma concentrations and loss of neratinib efficacy.

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

Util A	Util B			Util C
Neratinib	Carbamazepine	Rifampin	Bosentan	
	Phenobarbital	Rifabutin	Efavirenz	
	Primidone	Rifapentine	Etravirine	
	Phenytoin	Mitotane	Modafinil	
	Enzalutamide	Nevirapine		

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Nerlynx Prescribing Information, June 2018, Puma Biotechnology, Inc.

21. Neratinib / Digoxin _____ _____

Alert Message: Concurrent use of Nerlynx (neratinib) with digoxin may result in increased digoxin concentrations and risk of digoxin toxicity due to neratinib inhibition of digoxin P-gp-mediated transport. In drug studies, concomitant use of digoxin with multiple oral doses of neratinib in healthy subjects increased the mean digoxin Cmax by 54% and the AUC by 32%. Dosage adjustment of digoxin may be required.

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

Util A	Util B	Util C
Neratinib	Digoxin	

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Nerlynx Prescribing Information, June 2018, Puma Biotechnology, Inc.

22. Neratinib / P-gp Substrates _____ _____

Alert Message: Concurrent use of Nerlynx (neratinib), a P-gp inhibitor, with a P-gp substrate may result in increased concentrations of the substrate. Monitor patient for P-gp substrate-related adverse reactions.

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

Util A	Util B	Util C
Neratinib	Dabigatran	
	Fexofenadine	
	Quinidine	
	Loperamide	
	Afatinib	
	Colchicine	
	Dapagliflozin	
	Edoxaban	
	Empagliflozin	
	Everolimus	
	Maraviroc	
	Methotrexate	
	Morphine	
	Paliperidone	
	Pazopanib	
	Ranolazine	
	Rivaroxaban	
	Saxagliptin	
	Sirolimus	
	Sitagliptin	
	Tacrolimus	
	Tolvaptan	
	Venetoclax	

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Nerlynx Prescribing Information, June 2018, Puma Biotechnology, Inc.

23. Abemaciclib / Overutilization _____ _____

Alert Message: Verzenio (abemaciclib) may be over-utilized. When used as monotherapy, the recommended maximum dose of abemaciclib is 200 mg twice daily.

Conflict Code: ER – Overutilization
Drugs/Diseases

Util A	Util B	Util C **(Negating)**
Abemaciclib		Fulvestrant

Max Dose: 400 mg/day

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Verzenio Prescribing Information, Sept. 2017, Eli Lilly and Company.

24. Abemaciclib / Overutilization _____ _____

Alert Message: Verzenio (abemaciclib) may be over-utilized. When used in combination with fulvestrant, the recommended maximum dose of abemaciclib is 150 mg twice daily.

Conflict Code: ER – Overutilization
Drugs/Diseases

Util A	Util B	Util C **(Include)**
Abemaciclib		Fulvestrant

Max Dose: 300 mg/day

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Verzenio Prescribing Information, Sept. 2017, Eli Lilly and Company.

25. Abemaciclib / Severe Hepatic Impairment _____ _____

Alert Message: Patients with severe hepatic impairment should have the Verzenio (abemaciclib) dosing frequency reduced to one tablet once daily. In a single dose clinical study, the terminal half-life and the systemic exposure of abemaciclib plus its active metabolites doubled in subjects with severe hepatic impairment (Child-Pugh C) relative to those with normal liver function.

Conflict Code: ER – Overutilization
Drugs/Diseases

Util A	Util B	Util C **(Include)**
Abemaciclib		Cirrhosis
		Hepatic Fibrosis

Max Dose: 1 tablet per day

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Verzenio Prescribing Information, Sept. 2017, Eli Lilly and Company.
Center for Drug Evaluation and Research, NDA/BLA Multi-Discipline Review and Evaluation NDA 208716 Abemaciclib. February 1, 2016.

26. Abemaciclib / Ketoconazole _____ _____

Alert Message: Concurrent use of Verzenio (abemaciclib) with ketoconazole should be avoided due to the risk of abemaciclib toxicity. Ketoconazole is a potent CYP3A4 inhibitor and concomitant use with the CYP3A4 substrate, abemaciclib, is predicted to increase the AUC of abemaciclib by up to 16-fold.

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

Util A	Util B	Util C
Abemaciclib	Ketoconazole	

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Verzenio Prescribing Information, Sept. 2017, Eli Lilly and Company.

27. Abemaciclib / Strong CYP3A4 Inhibitors _____ _____

Alert Message: The concurrent use of Verzenio (abemaciclib), a CYP3A4 substrate, with a strong CYP3A4 inhibitor may increase the exposure of abemaciclib and its active metabolites, leading to abemaciclib toxicity. Refer to the official package labeling for the recommended abemaciclib dosage reduction when abemaciclib is used concomitantly with a strong CYP3A4 inhibitor. If the strong CYP3A4 inhibitor is discontinued, increase the abemaciclib dose (after 3-5 half-lives of the inhibitor) to the dose that was used before starting the strong inhibitor.

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

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

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Verzenio Prescribing Information, Sept. 2017, Eli Lilly and Company.

28. Abemaciclib / Strong CYP3A4 Inducers _____ _____

Alert Message: The concurrent use of Verzenio (abemaciclib), a CYP3A4 substrate, with a strong CYP3A4 inducer should be avoided due to the risk of decreased abemaciclib efficacy. In clinical studies, the co-administration of the strong CYP3A4 inducer rifampin with abemaciclib decreased the plasma concentrations of abemaciclib plus its active metabolites by 67% in healthy subjects.

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

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

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Verzenio Prescribing Information, Sept. 2017, Eli Lilly and Company.

29. Abemaciclib / Pregnancy / Pregnancy Negating _____ _____

Alert Message: Based on findings from animal studies and the mechanism of action, Verzenio (abemaciclib) can cause fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to a fetus. Females of reproductive potential should have a negative pregnancy test prior to initiating treatment with abemaciclib and advised to use effective contraception during treatment with abemaciclib and for at least 3 weeks after the last dose.

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

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

Gender: Female
Age Range: 18 – 50 yoa

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Verzenio Prescribing Information, Sept. 2017, Eli Lilly and Company.

30. Arnuity Ellipta / Overutilization (5-11 yoa) _____ _____

Alert Message: Arnuity Ellipta (fluticasone furoate inhalation) may be over-utilized. The manufacturer's recommended maximum dose in patients 5 to 11 years of age is 50 mcg once daily.

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C
Fluticasone Furoate		

Age Range 5 – 11 yoa

References:
Arnuity Ellipta Prescribing Information, May 2018, GlaxoSmithKline.

31. Deutetrabenazine / Tetrabenazine _____ _____

Alert Message: Concurrent use of Austedo (deutetrabenazine) with Ingrezza (valbenazine) is contraindicated. Both deutetrabenazine and valbenazine are VMAT2 inhibitors and concomitant use may cause synergistic or additive toxicity.

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

Util A	Util B	Util C
Deutetrabenazine	Valbenazine	

References:
Austedo Prescribing Information, June 2018, Teva Pharmaceuticals.

32. Dexlansoprazole / Therapeutic Appropriateness - Age _____ _____

Alert Message: The safety and effectiveness of Dexilant (dexlansoprazole) have not been established in pediatric patients less than 12 years of age. Dexlansoprazole is not recommended in pediatric patients less than 12 years of age.

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C
Dexlansoprazole		

Age Range: 0-11 yoa

References:
Dexilant Prescribing Information, June 2018, Takeda Pharmaceuticals.
Clinical Pharmacology. 2018, Elsevier/Gold Standard.

33. Dexlansoprazole / Overutilization _____ _____

Alert Message: The recommended dose of Dexilant (dexlansoprazole) for healing of erosive esophagitis (EE) is 60 mg once daily. For maintenance of healed EE and relief of associated heartburn or symptomatic non-erosive GERD, the recommended dose is 30 mg once daily.

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C **(Negate)**
Dexlansoprazole		Hepatic Impairment

Max Dose: 60 mg/day

References:
Dexilant Prescribing Information, June 2018, Takeda Pharmaceuticals.
Clinical Pharmacology. 2018, Elsevier/Gold Standard.

34. Alectinib / Overutilization _____ _____

Alert Message: The manufacturer's recommended daily dose of Alecensa (alectinib) is 600 mg taken twice daily for a total daily dose of 1200 mg.

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C
Alectinib		

Max Dose: 1200 mg/day

References:
Alecensa Prescribing Information, June 2018, Genentech.
Clinical Pharmacology, 2016 Elsevier/Gold Standard.

35. Alectinib / Overutilization – Hepatic Impairment _____ _____

Alert Message: The recommended daily dose of Alecensa (alectinib) in patients with severe hepatic impairment (Child-Pugh C) is 450 mg twice daily. No dose adjustment is recommended for patients with mild (Child-Pugh A) or moderate (Child-Pugh B) hepatic impairment.

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C (Include)
Alectinib		Cirrhosis
		Hepatic Fibrosis

Max Dose: 900 mg/day

References:
Alecensa Prescribing Information, June 2018, Genentech.

36. Alectinib / Therapeutic Appropriateness _____ _____

Alert Message: Alecensa (alectinib) can cause severe ALT, AST, or bilirubin elevation. Monitor liver function tests and total bilirubin every 2 weeks during the first 3 months of treatment, then once a month and as clinically indicated, with more frequent testing in patients who develop transaminase and bilirubin elevations. Based on the severity of the adverse reaction, modify therapy according to the manufacturer's instructions in the official prescribing information.

Conflict Code: TA -Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C
Alectinib		

References:
Alecensa Prescribing Information, June 2018, Genentech.

37. Alectinib / ILD Symptoms & Interstitial Pneumonitis _____ _____

Alert Message: Alecensa (alectinib) can cause interstitial lung disease (ILD)/pneumonitis. Promptly investigate for ILD/pneumonitis if patient presents with new or worsening respiratory symptoms such as dyspnea, fever, or cough. Immediately withhold treatment with alectinib in patients diagnosed with ILD/pneumonitis and permanently discontinue alectinib if no other potential causes of ILD/pneumonitis have been identified.

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

Util A	Util B	Util C
Alectinib	Dyspnea	
	Fever	
	Cough	
	Wheezing	
	Interstitial pneumonitis	

References:
Alecensa Prescribing Information, June 2018, Genentech.

38. Alectinib / Bradycardia _____ _____

Alert Message: Symptomatic bradycardia can occur with Alecensa (alectinib) therapy. In cases of non-life-threatening, symptomatic bradycardia withhold alectinib until recovery to asymptomatic bradycardia or to a heart rate of 60 bpm or above and evaluate concomitant medications known to cause bradycardia. If attributable to a concomitant medication, resume alectinib at a reduced dose (450 mg BID or 300 mg BID) upon recovery to asymptomatic bradycardia or to a heart rate of 60 bpm or above. If not attributed to a concomitant medication permanently discontinue alectinib. Permanently discontinue in case of recurrence or in cases of life-threatening bradycardia.

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

Util A	Util B	Util C
Alectinib	Bradycardia	

References:
Alecensa Prescribing Information, June 2018, Genentech.

39. Alectinib / Therapeutic Appropriateness _____ _____

Alert Message: Alecensa (alectinib) can cause severe myalgia and creatine phosphokinase (CPK) elevation. Assess CPK every 2 weeks during the first month of therapy and in patients reporting unexplained muscle pain tenderness or weakness. In case of severe CPK elevations (CPK > 5 times ULN), modify therapy according to the manufacturer's instructions in the official prescribing information.

Conflict Code: TA -Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C
Alectinib		

References:
Alecensa Prescribing Information, June 2018, Genentech.

40. Alectinib / Pregnancy / Pregnancy Negating _____ _____

Alert Message: Alecensa (alectinib) can cause fetal harm in a pregnant woman based on its mechanism of action and findings in animals. Advise female patients of childbearing potential receiving alectinib to use effective contraceptive measures during treatment and for 1 week following final alectinib dose. Advise male patients with female partners of reproductive potential to use effective contraception during treatment and for 3 months following the final dose.

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

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

Age Range 11-50 yoa
Gender: Female

References:
Alecensa Prescribing Information, June 2018, Genentech.

41. Tofacitinib IR / Overutilization _____ _____

Alert Message: Xeljanz (tofacitinib) may be over-utilized. The manufacturer's recommended maximum dose of tofacitinib, for patients with ulcerative colitis, is 10 mg twice daily.

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C **(Include)**
Tofacitinib IR		Ulcerative Colitis

Max Dose: 20 mg/day

References:
Xeljanz/Xeljanz XR Prescribing Information, May 2018, Pfizer, Inc.
Clinical Pharmacology, 2018 Elsevier/Gold Standard.

42. Tofacitinib XR / Moderate, Severe Renal Insufficiency & Hepatic Impair. _____ _____

Alert Message: The manufacturer recommends that a patient receiving Xeljanz XR (tofacitinib extended-release) be switched to immediate-release tofacitinib 5 mg once daily if the patient has moderate or severe renal insufficiency or moderate hepatic impairment.

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

Util A	Util B	Util C
Tofacitinib XR	CKD 3, 4, &5	
	Hepatic Impairment	

References:
Xeljanz/Xeljanz XR Prescribing Information, May 2018, Pfizer, Inc.
Clinical Pharmacology, 2018 Elsevier/Gold Standard.

43. Tofacitinib XR / Strong CYP3A4 Inhibitors & Potent CYP2C19 Inhibitors _____ _____

Alert Message: The manufacturer recommends that a patient receiving Xeljanz XR (tofacitinib extended-release) be switched to immediate-release tofacitinib 5 mg once daily if the patient is receiving concurrent therapy with a strong CYP3A4 inhibitor or with one or more concomitant medications that cause both moderate CYP3A4 inhibition and potent CYP2C19 inhibition.

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

Util A	Util B		Util C
Tofacitinib XR	Nefazodone	Voriconazole	
	Saquinavir	Itraconazole	
	Ritonavir	Posaconazole	
	Nelfinavir	Cobicistat	
	Indinavir	Fluconazole	
	Clarithromycin	Fluvoxamine	
	Ketoconazole		

References:
Xeljanz/Xeljanz XR Prescribing Information, May 2018, Pfizer, Inc.
Clinical Pharmacology, 2018 Elsevier/Gold Standard.

DUR Board Meeting
December 5, 2018
Hetitage Center

North Dakota Medicaid
DUR Board Meeting Agenda
Lecture Room A
Heritage Center
612 East Boulevard Avenue
Bismarck, ND
December 5, 2018
1:00 pm

1. Administrative items
    - Travel vouchers

2. Old business
    - Review and approval of 09/2018 meeting minutes
    - Budget update
    - Review top 15 therapeutic categories/top 25 drugs
    - Prior authorization/PDL update
    - Second review of glyburide and Avandia
    - Second review of Lucemyra
    - Second review of Palynziq
    - Second review of Roxybond
    - Second review of Siklos
    - Annual prior authorization review of forms and criteria

3. New business
    - Review of agents for treatment of dry eye syndrome
    - Review of agents for treatment of glaucoma
    - Review of Donepezil 23mg
    - Review of Nascobal
    - Review of Orilissa
    - Review of agents for treatment of vaginal candidas
    - Retrospective DUR criteria recommendations
    - Upcoming meeting date/agenda.
        - Next meeting is March 6, 2019 in the Heritage Center
4. Adjourn

Please remember to silence all cellular phones during the meeting.

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

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

Members Absent: Gaylord Kavlie, Zach Marty, Jeffrey Hostetter

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

Old Business

A. Honeyman served as interim Chair and called the meeting to order at 1:15 p.m. Chair A. Honeyman asked for a motion to approve the minutes of the June meeting. K. Kram moved that the minutes be approved and L. Roehrich seconded the motion. Chair A. Honeyman called for a voice vote to approve the minutes. The motion passed with no audible dissent.

Announcements

Jesse Rue has been appointed to the North Dakota Medicaid DUR Board. The current DUR Board Chair position is now open. The election of a new chair will take place at the next DUR Board meeting in December.

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 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 a number of topical corticosteroid agents, as well as high cost (>$3,000) medications to prior authorization required, as well as removing 30 medications from requiring prior authorization.

Second Review of Daxbia, Millipred DP, and Rytary

A motion and second was made at the June meeting to place Daxbia, Millipred DP, and Rytary on prior authorization. The topics were brought up for a second review to be added to the Non-Preferred Dosage Form PA Criteria. There was no public comment. Chair A. Honeyman called for a voice vote and the motion passed with no audible dissent.

Second Review of Dermatophytosis (Tinea Infections) Agents

A motion and second was made at the June meeting to generate prior authorization criteria for biosimilar agents. The topic was brought up for a second review. There was no public comment. Chair A. Honeyman called for a voice vote and the motion passed with no audible dissent.

Second Review of Eosinophilic Asthma Agents

A motion and second was made at the June meeting to place eosinophilic asthma agents on prior authorization. The topics were brought up for a second review. There was no public comment. Chair A. Honeyman called for a voice vote and the motion passed with no audible dissent.

Second Review of Migraine Prophylaxis (CGRP Inhibitors) Agents
A motion and second was made at the June meeting to place Migraine Prophylaxis (CGRP Inhibitors) Agents on prior authorization. The topic was brought up for a second review. Erin Conley of Amgen spoke regarding expected symptom improvement after treatment with Aimovig. Chair A. Honeyman 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 2017, there were 20,087 average members per month with 77.2% of members utilizing benefits. The generic fill rate was 86.3%. The top 25 drugs represent 44.5% of total plan cost and 6 of the top 25 drugs were specialty drugs. Advanced Opioid Management Activity was also discussed, highlighting claims processing edits put in place as well as targeted interventions, resulting in an overall 19.6% reduction in patients receiving opioids in the 1st half of 2018, as compared to the first two quarters of 2017.

New Business
Glyburide and Avandia
T. DeRuiter and A. Murphy reviewed glyburide and rosiglitazone containing products with the Board. A motion was made by K. Kram to create this new PA criteria class and manage these medications through prior authorization. The motion was seconded by T. Schmidt. This topic will be reviewed at the next meeting

Lucemyra
T. DeRuiter and B. Joyce reviewed Lucemyra with the Board. A motion was made by T. Schmidt to manage the medications through prior authorization. The motion was seconded by L. Schield. This topic will be reviewed at the next meeting

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

Roxybond
T. DeRuiter and B. Joyce reviewed Roxybond with the Board. A motion was made by T. Schmidt to manage the medication through prior authorization. The motion was seconded by J. Rue. This topic will be reviewed at the next meeting

Siklos
T. DeRuiter and B. Joyce reviewed Siklos with the Board. A motion was made by K. Kram to manage the medication through prior authorization. The motion was seconded by J. Rue. This topic will be reviewed at the next meeting

Utilization Review of Concomitant Sedative/Hypnotic and Benzodiazepine Agents
T. DeRuiter presented data on the current utilization of sedative/hypnotics in the fee-for-service Medicaid population. Data points included the incidence of therapeutic duplication with benzodiazepine and or sedative agents, drilled down to most commonly duplicated agents and regimen.

Update on CAR T-cell Therapies
T. DeRuiter presented on the available chimeric antigen receptor T-cell therapies currently available. The presentation included which agents were available and their indications for use, as well as a discussion on how the agents are prepared and elicit their therapeutic effects.

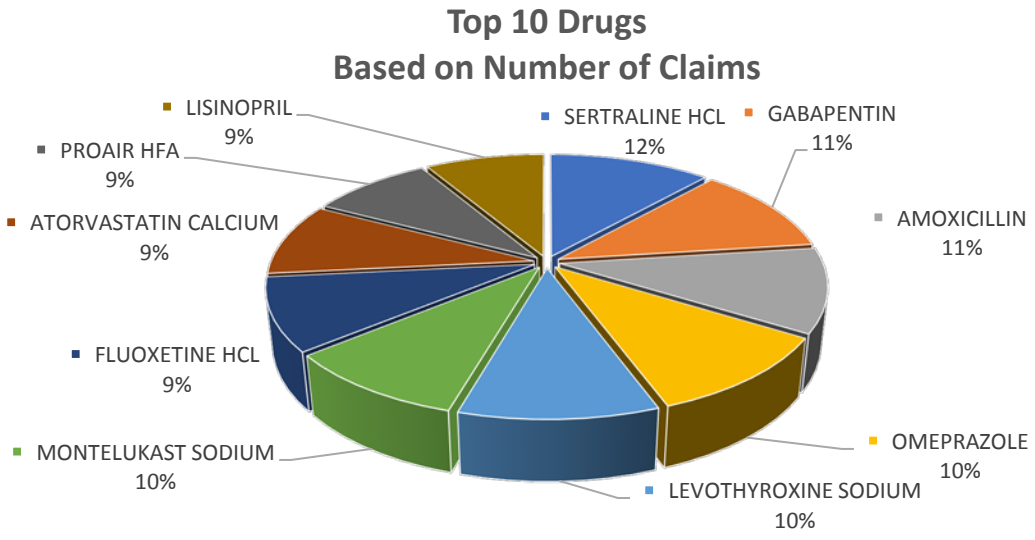
Retrospective Drug Utilization Review (RDUR) Criteria Recommendations
The recommended RDUR criteria enclosed in the packet were developed from product information provided by the manufacturers and are usually consistent with new indications, new drugs added, and new warnings. These proposed criteria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

Adjournment and Upcoming Meeting Date
Interim Chair A. Honeyman adjourned the meeting at 2:35 pm. The next DUR Board meeting will be held December 5, 2018 at 1:00 pm at the Heritage Center in Bismarck.

TOP 25 DRUGS BASED ON NUMBER OF CLAIMS FROM 07/01/2018 - 09/30/2018

Drug	AHFS Therapeutic Class	Rx	Paid	Paid/Rx	% Total Claims
SERTRALINE HCL	ANTIDEPRESSANTS	2,705	$45,097.30	$16.67	1.97%
GABAPENTIN	ANTICONVULSANTS, MISCELLANEOUS	2,633	$91,155.55	$34.62	1.92%
AMOXICILLIN	PENICILLIN ANTIBIOTICS	2,507	$106,053.48	$42.30	1.82%
OMEPRAZOLE	PROTON-PUMP INHIBITORS	2,453	$40,661.51	$16.58	1.78%
LEVOTHYROXINE SODIUM	THYROID AGENTS	2,361	$44,250.28	$18.74	1.72%
MONTELUKAST SODIUM	LEUKOTRIENE MODIFIERS	2,222	$40,186.49	$18.09	1.62%
FLUOXETINE HCL	ANTIDEPRESSANTS	2,167	$30,854.61	$14.24	1.58%
ATORVASTATIN CALCIUM	HMG-COA REDUCTASE INHIBITORS	2,163	$55,330.47	$25.58	1.57%
PROAIR HFA	BETA-ADRENERGIC AGONISTS	2,023	$146,383.81	$72.36	1.47%
LISINOPRIL	ANGIOTENSIN-CONVERTING ENZYME INHIBITORS	1,993	$55,100.91	$27.65	1.45%
HYDROCODONE-ACETAMINOPHEN	OPIATE AGONISTS	1,972	$52,604.17	$26.68	1.43%
TRAZODONE HCL	ANTIDEPRESSANTS	1,943	$28,966.45	$14.91	1.41%
METHYLPHENIDATE ER	RESPIRATORY AND CNS STIMULANTS	1,722	$288,813.95	$167.72	1.25%
ESCITALOPRAM OXALATE	ANTIDEPRESSANTS	1,702	$43,250.47	$25.41	1.24%
VYVANSE	AMPHETAMINES	1,686	$377,752.83	$224.05	1.23%
CLONIDINE HCL	CENTRAL ALPHA-AGONISTS	1,657	$29,078.14	$17.55	1.21%
METFORMIN HCL	BIGUANIDES	1,605	$25,970.52	$16.18	1.17%
RISPERIDONE	ANTIPSYCHOTIC AGENTS	1,553	$22,079.92	$14.22	1.13%
QUETIAPINE FUMARATE	ANTIPSYCHOTIC AGENTS	1,467	$24,149.55	$16.46	1.07%
VITAMIN D3	VITAMIN D	1,422	$19,828.39	$13.94	1.03%
LAMOTRIGINE	ANTICONVULSANTS, MISCELLANEOUS	1,382	$19,405.52	$14.04	1.01%
CETIRIZINE HCL	SECOND GENERATION ANTIHISTAMINES	1,346	$54,306.91	$40.35	0.98%
DULOXETINE HCL	ANTIDEPRESSANTS	1,340	$26,587.26	$19.84	0.97%
FLUTICASONE PROPIONATE	CORTICOSTEROIDS (EENT)	1,328	$29,448.99	$22.18	0.97%
PANTOPRAZOLE SODIUM	PROTON-PUMP INHIBITORS	1,315	$24,105.31	$18.33	0.96%
TOTAL TOP 25		46,667	$1,721,422.79	$36.89	33.95%

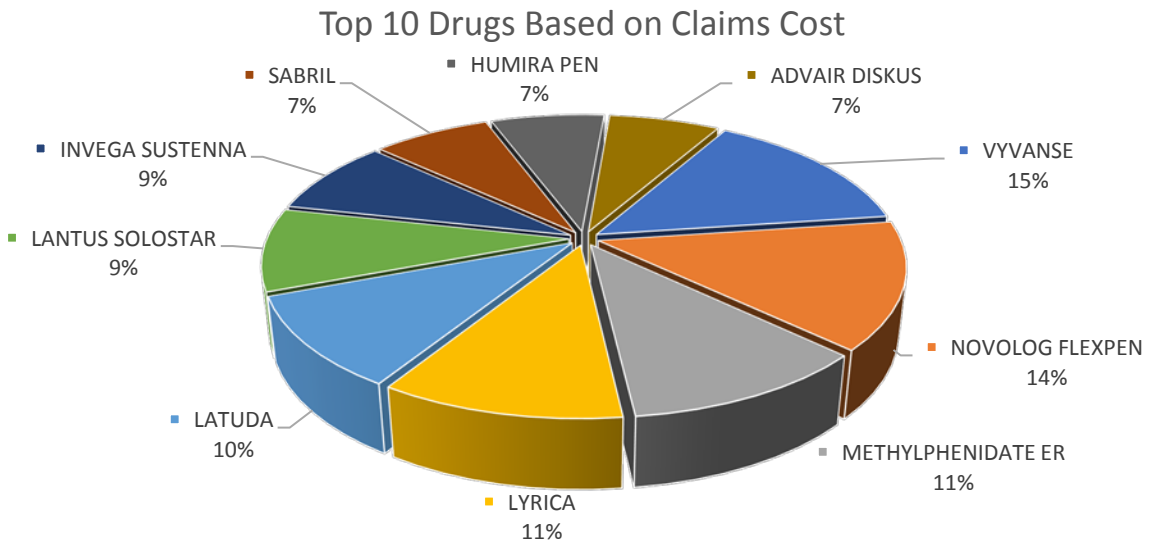
Total Rx Claims From 07/01/2018 - 09/30/2018	137,465



TOP 25 DRUGS BASED ON TOTAL CLAIMS COST FROM 07/01/2018 - 09/30/2018

Drug	AHFS Therapeutic Class	Rx	Paid	Paid/Rx	% Total Cost
VYVANSE	AMPHETAMINES	1,686	$377,752.83	$224.05	3.32%
NOVOLOG FLEXPEN	INSULINS	649	$369,666.49	$569.59	3.25%
METHYLPHENIDATE ER	RESPIRATORY AND CNS STIMULANTS	1,722	$288,813.95	$167.72	2.54%
LYRICA	ANTICONVULSANTS, MISCELLANEOUS	615	$282,002.24	$458.54	2.48%
LATUDA	ANTIPSYCHOTIC AGENTS	413	$266,700.68	$645.76	2.34%
LANTUS SOLOSTAR	INSULINS	554	$240,902.11	$434.84	2.12%
INVEGA SUSTENNA	ANTIPSYCHOTIC AGENTS	110	$219,140.76	$1,992.19	1.93%
SABRIL	ANTICONVULSANTS, MISCELLANEOUS	11	$191,983.69	$17,453.06	1.69%
HUMIRA PEN	DISEASE-MODIFYING ANTIRHEUMATIC AGENTS	37	$185,487.43	$5,013.17	1.63%
ADVAIR DISKUS	CORTICOSTEROIDS (RESPIRATORY TRACT)	477	$181,123.66	$379.71	1.59%
NIX	SCABICIDES AND PEDICULICIDES	402	$162,703.72	$404.74	1.43%
LEVEMIR FLEXTOUCH	INSULINS	376	$147,736.61	$392.92	1.30%
GENVOYA	ANTIRETROVIRALS	117	$146,819.51	$1,254.87	1.29%
PROAIR HFA	BETA-ADRENERGIC AGONISTS	2,023	$146,383.81	$72.36	1.29%
LICE KILLING	SCABICIDES AND PEDICULICIDES	328	$135,359.00	$412.68	1.19%
ONFI	BENZODIAZEPINES (ANTICONVULSANTS)	116	$124,526.60	$1,073.51	1.09%
VIMPAT	ANTICONVULSANTS, MISCELLANEOUS	203	$123,005.58	$605.94	1.08%
SYMBICORT	CORTICOSTEROIDS (RESPIRATORY TRACT)	379	$115,768.87	$305.46	1.02%
NORDITROPIN FLEXPRO	PITUITARY	34	$112,126.82	$3,297.85	0.99%
AMOXICILLIN	PENICILLIN ANTIBIOTICS	2,507	$106,053.48	$42.30	0.93%
FLOVENT HFA	CORTICOSTEROIDS (RESPIRATORY TRACT)	491	$104,850.96	$213.55	0.92%
MAVYRET	HCV ANTIVIRALS	8	$103,392.80	$12,924.10	0.91%
MAPAP	ANALGESICS AND ANTIPYRETICS, MISC.	655	$101,600.22	$155.11	0.89%
FOCALIN XR	RESPIRATORY AND CNS STIMULANTS	314	$96,865.95	$308.49	0.85%
ZUBSOLV	OPIATE PARTIAL AGONISTS	492	$93,795.50	$190.64	0.82%
TOTAL TOP 25		14,719	$4,424,563.27	$300.60	38.87%

Total Rx Claims From 07/01/2018 - 09/30/2018	137,465



PDL Update

ADDED TO PA	
RYTARY	Non-preferred Dosage forms
DAXBIA	Non-preferred Dosage forms
MILLIPRED	Non-preferred Dosage forms
MILLIPRED DP	Non-preferred Dosage forms
TAPERDEX	Non-preferred Dosage forms
MENTAX	Antifungals - Topical
NAFTIFINE HCL	Antifungals - Topical
NAFTIN	Antifungals - Topical
NYSTATIN-TRIAMCINOLONE	Antifungals - Topical
OXICONAZOLE NITRATE	Antifungals - Topical
OXISTAT	Antifungals - Topical
EMGALITY	Migraine Prophylaxis
AIMOVIG	Migraine Prophylaxis
ALTRENO	Migraine Prophylaxis
MINOLIRA ER	Acne

Glyburide

Criteria for non-preferred medication:

- Patient must have failed a 30 day trial of glimepiride and glipizide, as evidenced by paid claims or pharmacy printouts.
- The prescriber must submit medical justification explaining why the patient cannot use a preferred product or another class of medication.

Preferred	Non-Preferred
Glimepiride	Glyburide
Glipizide	Glyburide/Metformin
Glipizide/Metformin	
Glipizide ER	

Rosiglitazone

Criteria for non-preferred medication:

- Patient must have failed a 30 day trial of pioglitazone, as evidenced by paid claims or pharmacy printouts.
- The prescriber must submit medical justification explaining why the patient cannot use a preferred product or another class of medication.

Preferred	Non-Preferred
Pioglitazone	AVANDIA (Rosiglitazone)

Lucemyra

Criteria for non-preferred medication:

- Patient must have an FDA approved diagnosis.
- The prescriber must submit medical justification explaining why the patient cannot use a preferred product (subject to clinical review).

Preferred	Non-Preferred
Clonidine	LUCEMYRA (Lofexidine)
Guanfacine	

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 #

Phenylketonuria

Criteria:

- Patient must have a diagnosis of hyperphenylalaninemia
- Patient must be following a PHE restricted diet

Kuvan:

Approval:

Initial: 2 months
Renewal: 12 months

- Additional Criteria for initial requests:
    - Patient's weight must be provided
    - Patient must be 4 years of age or older
    - 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
- Additional Criteria for renewal requests:
    - 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
        - 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:

Approval:

Initial: 6 months
Renewal: 12 months

- Additional Criteria for initial requests:
    - Patient must be 18 years of age or older
    - PHE levels must be above 600 micromoles/liter after compliance with diet and medication management for past 6 months.
- Additional Criteria for renewal requests:
    - 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 40mg:
        - PHE levels must be attached that were taken after 24 weeks of 20mg
        - Patient's PHE level must be greater than 360 micromoles per liter

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 following criteria:

- Patient must be of FDA-approved age for use of the agent
- Patient's weight must be provided
- Current PHE levels must be attached and within range for approval
- Patient must have hyperphenalaninemia
- Patient must be following a PHE restricted diet
- **For Kuvan:** Patient must not have been known to have two null mutations in TRANS

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 #

Preferred Dosage Forms List:

Criteria:

- The prescriber must submit medical justification explaining why the patient cannot use the preferred product (subject to clinical review)
- Patient must have FDA indication
- Patient must not have contraindications to requested product
- Patient must have failed a therapeutic course of all preferred agents
    - Trial must have been 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

Roxybond (oxycodone)

Preferred	Non-Preferred
Oxycodone	ROXYBOND (oxycodone)

Siklos (Hydroyurea)

Preferred	Non-Preferred
DROXIA (Hydroxyurea capsule)	Hydroxyurea tablet
Hydroxyurea capsule	

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 #

Dupixent

Prior Authorization Form - Dupixent
Approval: 3 months

Atopic Dermatitis

Initial Criteria:

- Patient must have a diagnosis of an FDA-approved indication for use
- Patient must be 18 years of age or older
- Patient must have had a 6-week trial of at least one of the following, as evidenced by paid claims or pharmacy print-outs:
    - 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 print-outs.
    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 print-outs.

Renewal Criteria:

- Documentation from the prescriber must be provided showing that the patient has achieved a significant reduction in severity of atopic dermatitis.

Asthma

Initial Criteria:

- Patient must have a diagnosis of an FDA-approved indication for use
- Patient must be 12 years of age or older
- Patient must have had 2 or more exacerbations in previous year despite continued compliant use of moderate to high dose inhaled steroid plus long-acting beta agonist (LABA) or long-acting muscarinic antagonist (LAMA) as evidenced by paid claims or pharmacy print-outs.
- One of the following must be met (A or B):
    A. Patient must have baseline eosinophil level of ≥ 300 cells/mcL within past 12 months
    B. Patient must have oral corticosteroid dependent asthma with at least 30 days of oral steroid use in past 120 days

Renewal Criteria:

- Documentation from the prescriber must be provided showing that the patient has achieved a significant reduction in exacerbations and utilization of rescue medications.

Prior Authorization Criteria

This is NOT an all-inclusive list of medications that require prior authorization. If you are looking for a medication that requires prior authorization that is not on this list, please see:

- The Preferred Drug List (PDL) and navigate to the most current year and version
- The preferred dosage forms list at the end of this document
- Other documents explaining limitations that may cause a prior authorization denial:
    - Preferred Diabetic Supply List (PDSL)
    - Coverage Rules on Medications
    - Drug Utilization Management List

Contents

ACE-Inhibitors

General Prior Authorization Form

Criteria for non-preferred medication:
EPANED:

- Patient must be less than 9 years of age, or unable to ingest solid dosage form as evidenced by swallow study documentation

QBRELIS:

- Patient must be less than 9 years of age, or unable to ingest solid dosage form as evidenced by swallow study documentation
- The prescriber must submit medical justification explaining why the patient cannot use Epaned (subject to clinical review)

Non-preferred Combination Medications:

- Please prescribe individual medication separately or use a different medication combination

Preferred	Non-Preferred
amlodipine-benazepril	benazepril-hydrochlorothiazide
benazepril	captopril
enalapril	captopril-hydrochlorothiazide
enalapril-hydrochlorothiazide	EPANED (enalapril)
fosinopril	fosinopril-hydrochlorothiazide
lisinopril	PRESTALIA (perindopril/amlodipine)
lisinopril-hydrochlorothiazide	QBRELIS (lisinopril)
moexipril	trandolapril-verapamil ER
moexipril-hydrochlorothiazide	
perindopril	
quinapril	
quinapril-hydrochlorothiazide	
ramipril	
trandolapril	

ARBs (Angiotensin Receptor Blockers)

General Prior Authorization Form

ENTRESTO:

- Please see "Heart Failure-Neprilysin Inhibitor/Angiotensin Receptor Blocker" category on PDL. http://www.hidesigns.com/ndmedicaid/pdl/

Criteria for non-preferred products

Candesartan-hydrochlorothiazide, candesartan, eprosartan:

- Patient must fail three 30-day trials at the highest tolerable therapeutic dose of the following as evidenced by paid claims or pharmacy print outs:
    - Irbesartan

- Telmisartan
- Azilsartan
- Olmesartan
- Valsartan
- Losartan

Combination Medications: (telmisartan-hydrochlorothiazide, Exforge, Exforge Hct, amlodipine-olmesartan, Byvalson, Amlodipine-valsartan, Candesartan-hydrochlorothiazide, Telmisartan-amlodipine):

- Please prescribe individual medication separately or use a different medication combination

Preferred	Non-Preferred
EDARBI (azilsartan)	Amlodipine-olmesartan
EDARBYCLOR (azilsartan/chlorothalidone)	Amlodipine-valsartan
ENTRESTO (sacubitril/valsartan)	BYVALSON (nebivolol/valsartan)
Irbesartan	Candesartan-hydrochlorothiazide
Irbesartan-hydrochlorothiazide	Candesartan
Losartan	Eprosartan
Losartan-hydrochlorothiazide	EXFORGE (amlodipine-valsartan)
Olmesartan	EXFORGE HCT (amlodipine-valsartan-hydrochlorothiazide)
Olmesartan-hydrochlorothiazide	Telmisartan-amlodipine
Telmisartan	Telmisartan-hydrochlorothiazide
Valsartan	
Valsartan-hydrochlorothiazide	

Renin Inhibitor

General Prior Authorization Form

Criteria:

- Patient must have failed 30-day trials at the highest tolerable therapeutic dose of two medications in each of the following groups as evidenced by paid claims or pharmacy print outs:
    - ARB: Azilsartan, candesartan, eprosartan, irbesartan, losartan, olmesartan, telmisartan, valsartan
    - ACE-Inhibitors: Captopril, enalapril, moexipril, ramipril, lisinopril, trandolapril, quinapril, benazepril, perindopril, or fosinopril

Preferred	Non-Preferred
	TEKTURNA (aliskiren)
	TEKTURNA HCT (aliskiren-hydrochlorothiazide)

Acitretin

Prior Authorization Form - Acitretin

Criteria:

- Patient must be male or female permanently unable to bear children

Acne

General Prior Authorization Form

Criteria:

- Patient must be between 12 and 35 years old
- The prescriber must submit medical justification explaining why the patient cannot use the preferred product (subject to clinical review)

Preferred	Non-Preferred
clindamycin-benzoyl peroxide	
ACANYA (clindamycin-benzoyl peroxide) 1.2%-2.5%	BENZACLIN (clindamycin/benzoyl peroxide) 1%-5%
clindamycin-benzyl peroxide 1.2%-5%	clindamycin/benzoyl peroxide 1%-5% with pump - manufacturer 45802
clindamycin/benzoyl peroxide 1%-5% without pump- manufacturers 00378, 00781, 045802, and 68682	clindamycin/benzoyl peroxide 1%-5% without pump - manufacturer 51672
ONEXTON (clindamycin/benzoyl peroxide) 1.2%-3.75%	
TRETINOIN MICROSPHERES	
	tretinoin microsphere
	tretinoin microsphere with pump
TRETINOIN	
AVITA (tretinoin) CREAM *(brand preferred)*	AVITA (tretinoin) GEL
RETIN-A (tretinoin) CREAM *(brand preferred)*	RETIN-A (tretinoin) GEL
tretinoin gel 0.01%, 0.03%	tretinoin cream
	tretinoin gel 0.05%
ADAPALENE	
DIFFERIN (adapalene) CREAM (*brand preferred*)	PLIXDA (adapalene) SWAB
adapalene gel	
DIFFERIN (adapalene) GEL W/ PUMP *(brand preferred)*	
DIFFERIN (adapalene) LOTION	

EPIDUO (adapalene/benzoyl peroxide) 0.1%-2.5% *(brand preferred)*	
EPIDUO FORTE (adapalene/benzoyl peroxide) 0.3%-2.5%	
OTHER	
ACZONE (dapsone) GEL WITH PUMP	FABIOR (tazarotene)
AZELEX (azelaic acid)	dapsone gel
ZIANA (clindamycin-tretinoin 1.2%-0.025%) *(brand preferred)*	tazarotene cream
sulfacetamide	
TETRACYCLINES	
Preferred	Non-Preferred
clindamycin capsule	doxycycline hyclate capsule 50 mg
clindamycin cream	doxycycline hyclate tablet DR 50 mg
clindamycin foam	doxycycline monohydrate tablet 50 mg
clindamycin gel	doxycycline hyclate tablet DR 75 mg
clindamycin lotion	doxycycline hyclate tablet 75 mg
doxycycline monohydrate 25 mg/5mL	doxycycline monohydrate capsule 75 mg
doxycycline monohydrate capsule 50 mg	doxycycline hyclate capsule 100 mg
doxycycline monohydrate tablet 75 mg	doxycycline hyclate tablet DR 100 mg
doxycycline monohydrate capsule 100 mg	DORYX MPC (doxycycline hyclate) 120mg
doxycycline monohydrate tablet 100 mg	doxycycline hyclate tablet 150 mg
metronidazole cream	doxycycline monohydrate capsule 150mg
metronidazole gel	doxycycline monohydrate tablet 150 mg
metronidazole lotion	doxycycline hyclate tablet DR 150 mg
minocycline	doxycycline hyclate tablet DR 200mg
VIBRAMYCIN (doxycycline monohydrate) 25 mg/5mL SUSP	minocycline ER
VIBRAMYCIN (doxycycline monohydrate) 50 mg/5mL SYRUP	MORGIDOX (doxycycline hyclate) 100mg
	MORGIDOX (doxycycline hyclate) 50mg
	tetracycline
	VIBRAMYCIN (doxycycline hyclate)100 mg

Actinic Keratosis

General Prior Authorization Form

Criteria for non-preferred medication:

- Patient must fail a 6-month trial of imiquimod before receiving a non-preferred product as evidenced by paid claims or pharmacy print outs.

Preferred	Non-Preferred

imiquimod	PICATO (ingenol mebutate)
ZYCLARA (imiquimod)	SOLARAZE (diclofenac sodium) GEL

Albuterol/Levalbuterol Rescue Inhalers

General Prior Authorization Form
MedWatch Form

Criteria for non-preferred medications:

ProAir RespiClick:

- Patient must fail a 30-day trials of all the following as evidenced by paid claims or pharmacy print outs:
  - Proventil HFA
  - Ventolin HFA
  - Xopenex HFA
- A MedWatch form documenting the experienced treatment failure for each trial must be provided with authorization request

Ventolin HFA:

- A steroid inhaler must be used with Ventolin HFA. See Coverage Rules for Medications for specifics.

Preferred	Non-Preferred
PROAIR (albuterol) HFA	PROAIR RESPICLICK (albuterol)
VENTOLIN (albuterol) HFA**	PROVENTIL (albuterol) HFA
XOPENEX (levalbuterol) HFA *(brand preferred)*	

Allergenic Extracts – Oral

General Prior Authorization Form

Criteria

- Patient must have an FDA-approved diagnosis of allergic rhinitis confirmed by a positive skin test or in vitro testing for pollen-specific IgE antibodies contained in the requested product
- Patient must be an FDA-approved age
- Patient must have failed a trial of 2 of the following: oral antihistamines, intranasal antihistamines, intranasal corticosteroids, or leukotriene inhibitors as evidenced by paid claims or pharmacy printouts.
- Patient must have failed a trial of have intolerance to subcutaneous allergen immunotherapy (allergy shots) as evidenced by paid claims or pharmacy printouts.

Preferred	Non-Preferred
	ORALAIR (GR POL-ORC/SW VER/RYE/KENT/TIM)

Ampyra

Prior Authorization Form - Ampyra

Approval:

Initial: 3 months

Renewals: 6 months

Initial Criteria:

- Patient must be 18 years or older
- Patient must have a specialist (neurologist or physiatrist) involved in therapy
- Patient must have confirmed diagnosis of multiple sclerosis
- Patient must not have a history of seizures
- Patient's CrCl (creatinine clearance) must be greater than 50mL/min
- Patient must not have experienced any acute exacerbations within the last 60 days
- Patient must have established a baseline ability of walking 25 feet in 8 to 45 seconds

1st Renewal Request Criteria:

- Renewal PA Requests must include patient's baseline and current T25FW
- Current 25-foot walk time must be 20% faster than baseline 25-foot walk time

Subsequent Renewal Request Criteria:

- Renewal PA Requests must include patient's baseline and current T25FW
- Current 25-foot walk time must be faster than baseline 25-foot walk time

Anesthetics - Topical

Prior Authorization Form - Anesthetics - Topical

Criteria:

- Patients must be 12 years of age or older
- Use must be for placement of peripheral or central line or injections through an implanted port

Anticoagulants - Injectable

General Prior Authorization Form

Criteria for non-preferred medication:

- Patient must have FDA Approved Indication
- Patient must have failed a 30-day trial with enoxaparin, as evidenced by paid claims or pharmacy printouts.

- Patients with Heparin-induced thrombocytopenia (HIT) requesting fondaparinux can bypass enoxaparin trial

Preferred	Non-Preferred
enoxaparin	fondaparinux
	FRAGMIN (dalteparin)

Antifungals – Topical

Approval:

Onychomycosis: 1 year
Dermatophytosis: 1 month

Criteria:

- Patient must have an FDA approved diagnosis confirmed by potassium hydroxide (KOH) preparation
- Patient must have failed a trial of 3 preferred agents including at least one oral agent (terbinafine, fluconazole, or itraconazole) for the length of recommended treatment time for patient's particular infection.
- Medical Justification must be provided for why a preferred product cannot be used if requested product ingredient is available in a preferred formulation.

Additional Criteria for onychomycosis:

- There must have been enough time since treatment cessation to assess healthy toenail outgrow (at least 6 months)

Preferred	Non-Preferred
Ciclopirox cream	Ciclopirox solution
Ciclopirox gel	JUBLIA (efinaconazole)
Ciclopirox shampoo	KERYDIN (tavaborole)
Ciclopirox suspension	Ketoconazole foam
Clotrimazole cream	MENTAX (butenafine) CREAM
Econazole cream	Naftifine cream
ERTACZO (sertraconazole) CREAM	NAFTIN (naftifine) GEL
EXELDERM CREAM (sulconazole)	Nystatin – triamcinolone cream
EXELDERM SOLUTION (sulconazole)	Nystatin – triamcinolone ointment
Ketoconazole cream	Oxiconazole cream
Ketoconazole shampoo	OXISTAT (oxiconazole) LOTION
LUZU (luliconazole) CREAM	PENLAC (ciclopirox)
MENTAX (butenafine) CREAM	

Miconazole	
Nystatin cream	
Nystatin ointment	
Nystatin powder	
VUSION (miconazole/zinc oxide/white petrolatum)	

Antihistamines

General Prior Authorization Form

Criteria for non-preferred medication:

- Patient must have failed the following 14-day trials, as evidenced by paid claims or pharmacy printouts.
    - loratadine
    - cetirizine

Preferred	Non-Preferred
cetirizine chew tablet	desloratadine ODT
cetirizine solution	desloratadine tablet
cetirizine tablet	levocetirizine solution
levocetirizine tablet	
loratadine ODT	
loratadine solution	
loratadine tablet	

Antihemophilic Factor Products

Prior Authorization Form - Antihemophilic Factors

Criteria:

- Patient must visit an accredited Hemophilia Treatment Center once per year
- Date of Last Appointment with treatment center must be provided
- Contact information for treatment center must be provided

Criteria for non-preferred medication:

- Medical justification must be given as to why preferred product won't work
- 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)

Preferred	Non-Preferred
ADVATE	ADYNOVATE
AFSTYLA	ELOCTATE
ALPHANATE	HEMLIBRA
ALPHANINE SD	JIVI
ALPROLIX	KOVALTRY
BEBULIN	
BENEFIX	
FEIBA	
HELIXATE FS	
HEMOFIL M	
HUMATE-P	
IDELVION	
IXINITY	
KOATE-DVI	
KOGENATE FS BIO-SET	
KOGENATE FS	
MONOCLATE-P	
MONONINE	
NOVOEIGHT	
NOVOSEVEN	
OBIZURE	
PROFILNINE SD	
RECOMBINATE	
RIXUBIS	
VONVENDI	
WILATE	
XYNTHA	

Antihyperuricemics

General Prior Authorization Form

Criteria for non-preferred medication:

Colchicine tablets:

- Medical justification must be given as to why preferred product won't work

Duzallo:

- Patient must have failed 30-day trials of Uloric and allopurinol, as evidenced by paid claims or pharmacy printouts.

Uloric

- Patient must have failed a 30-day trial of allopurinol, as evidenced by paid claims or pharmacy printouts.

Zurampic:

- Patient must have failed 30-day trials of Uloric and allopurinol, as evidenced by paid claims or pharmacy printouts.
- Zurampic must be used in combination with allopurinol or Uloric

Preferred	Non-Preferred
allopurinol tablet	colchicine tablet
colchicine capsule	DUZALLO (lesinurad/allopurinol)
probenecid-colchicine	ULORIC (febuxostat) TABLET
	ZURAMPIC (lesinurad) TABLET

Antimalarial Agents

General Prior Authorization Form

Preferred and Non-Preferred Agent Criteria:

- Antimalarials are only covered for treatment, *NOT for prophylaxis*

Additional Criteria for Non-Preferred Agent

- Patient must have tried generic quinine in the last 30 days, as evidenced by paid claims or pharmacy print outs
- Patient must be less than 18 years old to qualify for atovaquone/proguanil 62.5-25 MG

Preferred	Non-Preferred
daraprim	atovaquone/proguanil
hydroxychloroquine	chloroquine
quinine	COARTEM (artemether/lumefantrine)
	MALARONE (atovaquone/proguanil)
	mefloquine
	primaquine

Antipsoriatics – Topical

General Prior Authorization Form

Criteria for non-preferred medication:

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

Preferred	Non-Preferred

calcipotriene ointment	calcipotriene/betamethasone ointment
calcipotriene solution	ENSTILAR (calcipotriene/betamethasone) FOAM
calcipotriene cream	SORILUX (calcipotriene) FOAM
TACLONEX (calcipotriene/betamethasone) SUSPENSION	
Preferred	Non-Preferred
Clobetasol Cream	Clobetasol Emollient Cream
Clobetasol Gel	Clobetasol Emollient Foam
CLOBEX (Clobetasol) LOTION *(brand required)*	Clobetasol Foam
Clobetasol Ointment	
CLOBEX (Clobetasol) SHAMPOO *(brand required)*	
Clobetasol Solution	
CLOBEX (Clobetasol) SPRAY *(brand required)*	

Benign Prostatic Hyperplasia

General Prior Authorization Form

Criteria for non-preferred medication:

- Recipient must have diagnosis of benign prostatic hyperplasia (BPH)
- Patient must have failed a 30-day trial of all preferred products, unless contraindicated as evidenced by paid claims or pharmacy print outs

Preferred	Non-Preferred
alfuzosin ER	sildenafil
CARDURA XL (doxazosin)	
doxazosin	
dutasteride	
finasteride	
prazosin	
silodosin	
tamsulosin	
terazosin	

Biosimilar Agents

General Prior Authorization Form

Criteria:

- The prescriber must submit medical justification explaining why the patient cannot use the preferred product (subject to clinical review)
- Patient must have FDA indication

Corticosteroids - Topical

General Prior Authorization Form

Criteria:

For non-preferred agents not labeled as "STEP 2" (Step 1):

- 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.

For non-preferred agents labeled as "STEP 2":

- 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

Dispense as Written (DAW1)

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

Criteria:

- Patient must have failed a 30-day trial of all accessible generic product (s), as evidenced by paid claims or pharmacy print outs
    - 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
    - Patient or prescriber preference is NOT criteria considered for approval
- A MedWatch form for each manufacturer must be filled out and attached to request
- Product must not have an authorized generic

OR

- Primary insurance requires a ND Medicaid non-preferred branded product

Diclegis/Bonjesta

Prior Authorization Form - Diclegis

Approval: Until two weeks past provided due date
Criteria:

- 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

- Diclegis/Bonjesta has not been studied in women with hyperemesis gravidarum
- Bonjesta: The prescriber must submit medical justification explaining why the patient cannot use a preferred product or Diclegis (subject to clinical review)

Preferred	Non-Preferred
meclizine	BONJESTA (doxylamine/vitamin B6)
metoclopramide	DICLEGIS (doxylamine/vitamin B6)
ondansetron	

Dificid

General Prior Authorization Form

Approval: 5 days
Criteria:

- Patient must have diagnosis of *Clostridium difficile*-associated diarrhea (CDAD)
- Patient must be ≥ 18 years of age

Additional Renewal Criteria:

- Must be first recurrence for a patient whose initial episode was treated with Dificid

Preferred	Non-Preferred
metronidazole	DIFICID (fidaxomicin)
vancomycin	

Dupixent

Prior Authorization Form - Dupixent

Approval: 3 months
Initial Criteria**:**

- Patient must have a diagnosis of an FDA-approved indication for use
- Patient must be 18 years of age or older
- Patient must have had a 6-week trial of at least one of the following, as evidenced by paid claims or pharmacy print-outs:
    - 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 print-outs.
    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 print-outs.

Renewal Criteria:

- Documentation from the prescriber must be provided showing that the patient has achieved a significant reduction in severity of atopic dermatitis.

Dihydroergotamine

General Prior Authorization Form

Criteria for non-preferred medications:

- Patient must have a diagnosis of migraine or cluster headache
- Patient must have had two 30 day trials (within the past 2 years) of 'Preferred Agents' and two 30 day trials (within the past 2 years) of 'Non-Preferred Step 1 Agents'

Preferred	Non-Preferred Step 1	Non-Preferred Step 2
RELPAX (eletriptan)	ONZETRA XSAIL (sumatriptan) NASAL SPRAY	CAFERGOT (ergotamine/caffeine) TABLET
rizatriptan	ZOMIG (zolmitriptan) NASAL SPRAY	D.H.E.45 (dihydroergotamine) INJECTION
Rizatriptan ODT	zolmitriptan ODT	dihydroergotamine injection
sumatriptan		ERGOMAR (ergotamine) SL TABLET
		MIGERGOT (ergotamine/caffeine) RECTAL SUPPOSITORY
		MIGRANAL (dihydroergotamine) SPRAY

Edecrin

General Prior Authorization Form

Criteria:

- Patient must have sulfa allergy

OR

- Patient must have failed a 30-day trial of all preferred agents, as evidenced by paid claims or pharmacy print outs

Preferred	Non-Preferred
furosemide	ethacrynic acid
bumetanide	
torsemide	

Emflaza

Criteria:

- Patient must be 5 years of age or older
- 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

Additional Initial Criteria: Approval 6 months

- Onset of weakness before 5 years of age
- Must be prescribed by or in consultation with a physician who specializes in the treatment of Duchenne Muscular Dystrophy (DMD) and/or neuromuscular disorders
- Serum creatinine kinase activity at least 10 times the upper limit of normal (ULN) prior to initiating treatment
- Inadequate treatment response, intolerance, or contraindication to a 6-month trial of prednisone
- Obtain a baseline motor milestone score from 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)
- 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

Additional Renewal Criteria: Approval 1 year

- Patient must have ONE of the following:
    - 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
    - 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

Eucrisa

Prior Authorization Form - Eucrisa

Approval: 3 months
Initial Criteria:

- Patient must have a diagnosis of a FDA-approved indication for use of Eucrisa
- Patient must be 2 years of age or older
- Patient must have had a 6-week trial of at least one of the following, as evidenced by paid claims or pharmacy print-outs:
    - Tacrolimus or Pimecrolimus
- One of the following must be met (A or B):
    C. Patient must have had two 2-week trials of topical corticosteroids of medium or higher potency, as evidenced by paid claims or pharmacy print-outs.
    D. Patient must meet both of the following (1 and 2):
        1. Affected area is on face, groin, axilla, or under occlusion OR patient is under 12 years of age
        2. Patient must have had two 2-week trials of topical corticosteroids of low or higher potency, as evidenced by paid claims or pharmacy print-outs.

Renewal Criteria:

- Documentation from the prescriber must be provided showing that the patient has achieved a significant reduction in severity of atopic dermatitis.

Hemangeol

Prior Authorization Form - Hemangeol

Criteria:

- Patient must have a diagnosis of proliferating infantile hemangioma requiring systemic therapy
- Patient must be between 5 weeks and 1 year of age
- Patient must weigh 2 kg or greater
- Patient must have not have contraindications:
    - 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

Hereditary Angioedema

Prior Authorization - Hereditary Angioedema

Criteria:

- Patient must have diagnosis of hereditary angioedema
- Diagnosis must be confirmed by a specialist

Idiopathic Pulmonary Fibrosis

Prior Authorization Form - Idiopathic Pulmonary Fibrosis

Criteria:

- Patient must be 18 years of age or older
- Patient must have documented diagnosis of idiopathic pulmonary fibrosis
- Patient must have a specialist involved in therapy
- Patient must have forced vital capacity (FVC) ≥ 50% of predicted within prior 60 days

Immune Globulins

Prior Authorization Form - Immune Globulins

Criteria for all products:

- If patient's BMI > 30, adjusted body weight must be provided along with the calculated dose
- The indication has been provided
- 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:

- Patient must be intolerant to IgA (i.e., treatment of an autoimmune process in a patient with undetectable levels of igA)

Cuvitru, Hizentra, or Hyqvia:

- Patient must be unable to tolerate IV administration
- Patient failed a trial of two of the following:
    - Gamunex-C
    - Gammaked
    - Gammagard

Other Products:

- Patient failed a trial of two of the following:
    - Gammagard
    - Gamunex-C
    - Privigen

Preferred	Non-Preferred

BIVIGAM (human immunoglobulin gamma)	CUVITRU (human immunoglobulin gamma)
CARIMUNE NF (human immunoglobulin gamma)	GAMMAGARD S-D (human immunoglobulin gamma)
FLEBOFAMMA DIF (human immunoglobulin gamma)	HIZENTRA (human immunoglobulin gamma)
GAMANEX-C (human immunoglobulin gamma)	HYQVIA (human immune globulin G and hyaluronidase
GAMASTAN S-D	
GAMMAGARD LIQUID (human immunoglobulin gamma)	
GAMMAKED (human immunoglobulin gamma)	
GAMMAPLEX (human immunoglobulin gamma)	
OCTAGAM (human immunoglobulin gamma)	
PRIVIGEN (human immunoglobulin gamma)	

Juxtapid/Kynamro

Prior Authorization Form - Juxtapid/Kynamro

Criteria:

- Patient must have a diagnosis of Homozygous Familial Hypercholesterolemia (HoFH)
- Patient must be 18 years of age or older
- Patient must have LDL levels of >130 mg/dL after a 90-day trial of the following, as evidenced by paid claims or pharmacy print-outs:
    - A lipid lowering agent other than a statin combined with either Crestor (rosuvastatin) ≥20 mg or Lipitor (atorvastatin) ≥ 40 mg
- Patient meets one of the following:
    - genetic confirmation of two mutant alleles at the LDLR, APOB, PCSK9, or LDLRAP1 gene locus
    - an untreated LDL and total cholesterol level of > 500 mg/dl or >300 mg/dl with cutaneous or tendon xanthoma before 10 years of age
    - an untreated LDL level consistent with Heterozygous Familial Hypercholesterolemia (HeFH) in both parents

Kalydeco

Prior Authorization Form - Kalydeco

Criteria:

- Patient must be 2 years of age or older

- Patient must have one of the following mutations in the cystic fibrosis conductance regulator (CFTR) gene: G1244E, G1349D, G178R, G551D, G551S, R117H, S1251N, S1255P, S549N, S549R, A1067T, A455E, D110E, D110H, D1152H, D1270N, D579G, E193K, E56K, F1052V, F1074L, G1069R, K1060T, L206W, P67L, R1070Q, R1070W, R117C, R347H, R352Q, R74W, S945L, S977F, 2789+5G→A, 3272-26A→G, 3849+10kbC→T, 711+3A→G, E831X

Ketek

Prior Authorization Form - Ketek

Approval: 5 days
Criteria:

- Patient must have a diagnosis of community-acquired pneumonia (of mild to moderate severity) due to Streptococcus pneumoniae
- Patient must be 18 years and older
  OR
  Patient must have an allergy to fluoroquinolones or tetracyclines
- Patient must not have myasthenia gravis
- Patient must have tried another antibiotic in the last 3 months

Luzu

General Prior Authorization Form

Approval: 5 days
Criteria:

- Patient must be 18 years of age or older
- Patient must have a diagnosis of interdigital tinea pedistinea cruris, or tinea corporis caused by the organisms *Trichophyton rubrum* and *Epidermophyton floccosum*
- Patient must have failed a 4-week trial of clotrimazole

Preferred	Non-Preferred
Clotrimazole 1% cream	Luzu 1% Cream

Medications that cost over $3000/month

General Prior Authorization Form

Criteria:

- Patient must have FDA approved diagnosis

DOPTELET (avatrombopag)
INCRELEX (mecasermin)

LUCEMYRA (lofexidine)
MULPLETA (lusutrombopag)
TAVALISSE (fostamatinib)

Miacalcin:

Prior Authorization Form - Miacalcin/Tymlos

Criteria:

Patient must have one of the following diagnoses and meet additional criteria for their diagnosis:

- Paget's Disease of the bone
  Additional Criteria:
  - Patient must have failed a 6-month trial of a preferred product (a bisphosphonate)
- Postmenopausal Osteoporosis
  Additional Criteria:
  - Patient must be postmenopausal for ≥ 5 years
  - Patient must have failed a 6-month trial of a preferred product (a bisphosphonate)
- Hypercalcemia

Preferred	Non-Preferred
Alendronate	MIACALCIN (calcitonin)
Ibandronate	TYMLOS (abaloparatide)
Risedronate	

Mifeprex

Prior Authorization Form - Mifeprex

Approval: 1 month
Criteria:

- Patient must not be over 70 days in gestation
- One of the following criteria must be met along with additional criteria:
  - Pregnancy must have resulted from an act of rape or incest
    Additional Criteria: One of the following criteria must be met
    - 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.

- 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
  Additional Criteria:
  - 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

Naloxone Rescue Medications

Prior Authorization Form - Naloxone Rescue Medications

Initial Criteria:

Narcan Nasal Spray does NOT require prior authorization for the initial dose

Evzio:

- Provider has provided medical justification explaining why the patient cannot use Narcan Nasal Spray or injectable naloxone
- Patient must have one of the following diagnosis and must meet additional criteria for their diagnosis
  - Diagnosis of opioid use disorder:
    Additional Criteria:
    - Patient has been referred to addiction counseling services
  - Diagnosis of overdose with opioid pain treatment:
    Additional Criteria:
    - Patient must have chronic pain issue where benefit outweighs risk of continuing treatment
    - Patient must have had paid opioid claim in the last 30 days

Additional Renewal Criteria:

- The provider has answered if 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:
  - The previous dose has expired
  - The dose was used by patient for illicit drug use
  - 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

Preferred	Non-Preferred
Naloxone injection	EVZIO (naloxone) AUTO-INJECTOR

NARCAN (naloxone) NASAL SPRAY	

Nausea/Vomiting – Chemo Induced

Prior Authorization Form - Nausea/Vomiting - Chemo Induced
Approval: 6 months OR until the last day of chemotherapy
Criteria:

- Patient must have diagnosis of nausea and/or vomiting
- Prescriber must be an oncologist
- Patient must be receiving a moderately or highly emetogenic chemotherapy
- The number of cycles of chemotherapy must be indicated
- The final date of chemotherapy treatment must be indicated
- Patient must have failed a trial of the preferred oral product(s) in the same class within the last 30 days as evidenced by paid claims or pharmacy print outs.

SANCUSO (Additional Criteria):

- The patient must have inability to tolerate oral medications.
- The granisetron tablet failure must not be due to side effects.

ZUPLENZ (Additional Criteria):

- The patient must fail a trial of both the ondansetron ODT and solution.
- The ondansetron failures must not be due to side effects.

SYNDROS (Additional Criteria)

- Patient must be less than 7 years of age, or unable to ingest solid dosage form as evidenced by swallow study documentation
- Patient must have one of the following diagnoses and meet required trial for their diagnosis:
    - Loss of appetite due to HIV/AIDS:
        - 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:
        - Patient must have tried and failed a 3-day trial of ondansetron ODT in combination with aprepitant suspension and a glucocorticoid if, as evidenced by paid claims or pharmacy printouts

Preferred	Non-Preferred
Aprepitant	AKYNZEO (netupitant/palonosetron)
	VARUBI (rolapitant) TABLET
Preferred	**Non-Preferred**
Granisetron tablet	ANZEMET (dolasetron)
Ondansetron ODT	SANCUSO (granisetron) PATCH
Ondansetron solution	ZUPLENZ (ondansetron) FILM
Ondansetron tablet	
Palonestron	

Preferred	Non-Preferred
Dronabinol	Cesamet (nabilone) Syndros (Dronabinol) SOLUTION

Nasal Steroids

General Prior Authorization Form

Non-Preferred Agent Criteria:

- Patient must have had 30 day trials (within the past 2 years) of 3 preferred agents

Preferred	Non-Preferred
BECONASE AQ (beclomethasone)	flunisolide
Fluticasone	mometasone
OMNARIS (ciclesonide)	QNASL CHILDREN'S (beclomethasone)
QNASL (beclomethasone)	XHANCE (fluticasone)
ZETONNA (ciclesonide)	

Noxafil

General Prior Authorization Form

Approval: 2 weeks
Criteria:

- Medication indication must be prophylaxis of invasive Aspergillus and Candida infections or Oropharyngeal Candidiasis
- Patient must have documented history of failure to all preferred agents in last 30 days

Preferred	Non-Preferred
itraconazole	NOXAFIL (posaconazole)
fluconazole	

NSAIDS

Prior Authorization Form - NSAIDs

Criteria:

Oral solid dosage forms

Mefanemic acid:

- Patient must have diagnosis of dysmenorrhea
- Patient must have failed a 30-day trial of 3 different oral generic NSAIDs, as evidenced by paid claims or pharmacy print outs

Celecoxib 400mg/Naproxen 275 mg:

- Patient must use another tablet strength

Other oral generic NSAIDs:

- Patient must have failed a 30-day trial of 3 oral generic NSAID, as evidenced by paid claims or pharmacy print outs

Branded NSAIDs

- Provider has provided medical justification explaining why the patient cannot use another NSAID

Generic Solid Oral Dosage Forms	
Preferred	Non-Preferred
celecoxib 50mg, 100mg, 200mg	celecoxib 400mg
flurbiprofen	diclofenac
ibuprofen	diclofenac ER
indomethacin	etodolac
Indomethacin ER	etodolac ER
ketoprofen	fenoprofen
ketorolac	ketoprofen ER
meloxicam	meclofenamate
nabumatone	mefenamic acid
naproxen	Naproxen ER 375 mg
sulindac	Naproxen 275mg
	oxaprozin
	piroxicam
	TIVORBEX (indomethacin, submicronized)
	tolmetin
	VIVLODEX (meloxicam, submicronized)
	ZIPSOR (diclofenac)
	ZORVOLEX (diclofenac, submicronized)

Oral Solutions

Indomethacin and meloxicam oral solution:

- Patient must be unable to ingest solid dosage form and include swallow study documentation
- Patient must have failed a 30-day trial of naproxen oral solution, as evidenced by paid claims or pharmacy print outs

Oral Combination Products:

Arthotec:

- Patient must be at high risk of developing NSAID included gastric and duodenal ulcers
- Patient must not be pregnant

- Patient must have failed the following 30-day trials, as evidenced by paid claims or pharmacy print outs:
    - celecoxib
    - a generic oral NSAID in addition to a proton pump inhibitor

Duexis:

- The prescriber must provide medical justification explaining why the patient cannot use individual products (famotidine + ibuprofen)

Vimovo:

- The prescriber must provide medical justification explaining why the patient cannot use individual products (naproxen + esomeprazole)

Nasal

Sprix:

- Patient must be 18 years of age or older
- Patient must have a diagnosis of postoperative nausea and vomiting
- Patient must be unable to tolerate oral medications
- Patient must not have a history of gastric or duodenal ulcer or comorbidities of GI bleed, perforation, or obstruction

Non-solid dosage preparations

Prior Authorization Form - Non-Solid Dosage Forms

Criteria:

- Patient must have tried a more cost-effect dosage form in the last 30 days
  OR
- Patient must be unable to ingest solid dosage form as evidenced by swallow study documentation

Nuedexta

Prior Authorization Form - Nuedexta

Approval: for 3 months
Initial Criteria:

- Patient must be 18 years of age or older
- Patient must not have a prolonged QT interval, heart failure, or complete atrioventricular (AV) block
- The following information must be provided:

    - Baseline Center for Neurological Studies lability (CNS-LS)
    - Baseline weekly PBA episode count
- 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, as evidenced by paid claims or pharmacy print outs, of one medication from BOTH classes listed:
    - SSRIs: sertraline, fluoxetine, citalopram and paroxetine
    - 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

Renewal Criteria: Approval for 6 months

- 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

Additional renewal 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 a 30 percent decrease from baseline

Nuvigil

General Prior Authorization Form

Criteria:

- Patient must have FDA approved diagnosis

- Patient must have failed a 30-day trial of modafinil, as evidenced by paid claims or pharmacy print outs

Onychomycosis

General Prior Authorization Form

Criteria:

- Patient is 18 years of age or older
- Patient has a diagnosis of onychomycosis of the toenail(s) due to *Trichophyton rubrum* or *Tricophyton mentagrophytes*
- Patient must have confirmed diagnosis by one of the following: KOH prep test, fungal culture, or nail biopsy
- Patient has failed a 12-week trial of all the preferred agents with enough time since treatment cessation to assess healthy toenail outgrown (at least 6 months)

Preferred	Non-Preferred
Itraconazole capsule	KERYDIN (tavaborole)
JUBLIA (efinaconazole)	
Terbinafine	

Opioid Analgesic – Short Acting

Prior Authorization Form - Short Acting Opioids

Subsys, Fentora, Lazanda, Actiq, and Abstral:

- Patient must be an FDA approved age
- Patient must have cancer pain
- 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 60mg oral morphine daily, 25 mcg transdermal fentanyl/hour, 30mg oxycodone daily, 8 mg of oral hydromorphone daily, or equianalgesic dose of another opioid daily

Oxycodone IR:

- The patient must have chronic pain
- The patient must currently be on a long-acting narcotic, as evidenced by paid claims or pharmacy print-outs
- The prescriber must confirm that they have reviewed the North Dakota PDMP reports for the patient
- The Morphine Equivalent Dose (MED) of the requested oxycodone strength must be less than 15% of the total daily Morphine Equivalent Dose (MED) provided by the long acting narcotic as calculated below (Please use an Opioid Dose Calculator to find the MED for specific products):

- Oxycodone 15mg tablet: long acting narcotic must provide at least 150mg MED per day
- Oxycodone 20mg tablet: long acting narcotic must provide at least 200mg MED per day
- Oxycodone 30mg tablet: long acting narcotic must provide at least 300mg MED per day

Oravig

General Prior Authorization Form

Approval: 1 week
Criteria:

- Patient must have failed a 30-day trial of one of the preferred agents, as evidenced by paid claims or pharmacy print-outs

Preferred	Non-Preferred
Clotrimazole	ORAVIG (miconazole)
Fluconazole	
Itraconazole	
Nystatin	

PCSK9 Inhibitors

Prior Authorization Form - PCSK9 Inhibitors

Criteria:

- Patient must have one of the following diagnosis:
  - Heterozygous familial hypercholesterolemia
  - Clinical atherosclerotic cardiovascular disease
  - *Diagnosis for Repatha only*: Homozygous familial hypercholesterolemia
- Patient must have failed** all the following 3-month trials:
  - Crestor 20-40mg
  - Atorvastatin 40-80mg
  - A statin combined with another lipid lowering agent

  **A failure is defined as an LDL level that remained 130 mg/DL or greater

Additional initial criteria:

- Patient's LDL level must be 130 mg/DL or greater

Preferred	Non-Preferred
Praluent Pen	Repatha Sureclick
Repatha Pushtronex	Repatha Syringe

Phenylketonuria

Prior Authorization Form - Kuvan

Criteria:

- Patient must have a diagnosis of hyperphenylalaninemia
- Patient must be following a PHE restricted diet

Kuvan:
Approval:

Initial: 2 months
Renewal: 12 months

- Additional Criteria for initial requests:
    - Patient's weight must be provided
    - Patient must be 4 years of age or older
    - 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
- Additional Criteria for renewal requests:
    - 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
        - 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:
Approval:

Initial: 6 months
Renewal: 12 months

- Additional Criteria for initial requests:
    - Patient must be 18 years of age or older
    - PHE levels must be above 600 micromoles/liter
    - Patient must have been compliant with diet and medication management for past 6 months.
- Additional Criteria for renewal requests:

- 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 40mg:
    - PHE levels must be attached that were taken after 24 weeks of 20mg
    - Patient's PHE level must be greater than 360 micromoles per liter

Proton Pump Inhibitor

Prior Authorization Form - Proton Pump Inhibitor

Approval: 6 months
Criteria:

Esomeprazole:

- Patient must meet one of the following criteria:
    - Patient has had a 30-day trial of all the preferred Solid Dosage Forms (lansoprazole, omeprazole, pantoprazole, and rabeprazole) in the past 2 years

Lansoprazole ODT:

- Patient must have feeding tube
- Patient must have had a 30-day trial of all Preferred Non-Solid Dosage forms (Nexium Packet and Protonix Packet) in the past 2 years

Prilosec Packet:

- Patient must have feeding tube
- Patient must have had a 30-day trial of all Preferred Non-Solid Dosage forms (Nexium Packet and Protonix Packet) and lansoprazole ODT in the past 2 years

Omeprazole-sodium bicarbonate packet/Aciphex Sprinkle:

- Patient must have feeding tube
- Patient must have had a 30-day trial of all the Preferred Solid Dosage forms (lansoprazole, omeprazole, and pantoprazole), Dexilant, esomeprazole, and rabeprazole in the past 2 years

Esomeprazole strontium/Omeprazole-sodium bicarbonate:

- The prescriber must provide medical justification explaining why the patient cannot use another proton pump inhibitor

Solid Dosage Forms	
Preferred	Non-Preferred
DEXILANT (dexlansoprazole)	esomeprazole
lansoprazole	esomeprazole strontium
omeprazole	omeprazole-sodium bicarbonate
pantoprazole	
rabeprazole	

Non-Solid Dosage Forms	
Preferred	Non-Preferred
NEXIUM (esomeprazole) PACKET	ACIPHEX SPRINKLE (rabeprazole)
PROTONIX (pantoprazole) PACKET	Lansoprazole ODT
	Omeprazole-sodium bicarbonate packet
	PRILOSEC PACKET (omeprazole)

Sedatives/Hypnotics

Prior Authorization Form - Sedative/Hypnotics

Approval:

Initial: 1 month

Renewal:

- Benzodiazepines (temazepam, triazolam, flurazepam, estazolam): 2 weeks
- Others: 6 months

Initial Criteria:

Zolpidem 10mg (prior authorization required for females only):

- Patient must have failed a 25-day trial of zolpidem 5mg within the last 30 days, as evidenced by paid claims or pharmacy print outs

Rozerem:

- Patient's insomnia must be characterized by difficulty with sleep initiation
- 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 print-outs
    - Mirtazapine OR Trazodone
    - Silenor

Zolpidem ER:

- Patient's insomnia must be characterized by difficulty with sleep maintenance
- 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 print-outs
    - Eszopiclone
    - Silenor
    - Zolpidem IR

Zolpidem SL tab, Edluar:

- Patient's insomnia must be characterized by difficulty with middle of the night awakening with more than 4 hours left to sleep
- 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 print-outs
    - Eszopiclone

- Silenor
- Zolpidem IR
- Zolpidem ER

Temazepam, triazolam, flurazepam, estazolam, Seconal sodium, Belsomra, and Zolpimist:

- 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 print-outs
  - Edluar
  - Eszopiclone
  - Silenor
  - Zaleplon
  - Zolpidem IR
  - Zolpidem ER

Renewal Criteria:

- Confirmation that other conditions causing sleep issues have been ruled out must be provided

Additional renewal criteria for benzodiazepines (temazepam, triazolam, flurazepam, estazolam):

- Patient must require dose tapering

Non-scheduled (non-addictive) options	
Preferred	Non-Preferred
mirtazapine	ROZEREM (ramelteon)
SILENOR (doxepin)	
trazodone	

Preferred	Non-Preferred
eszopiclone	BELSOMRA (suvorexant)
zaleplon	EDLUAR (zolpidem)
zolpidem 5mg	flurazepam
zolpidem 10mg (for males)	SECONAL SODIUM (secobarbital)
	temazepam
	triazolam
	zolpidem CR
	zolpidem 10mg (for females)
	ZOLPIMIST (zolpidem)
	Zolpidem SL tab

Serostim

Prior Authorization Form - Growth Hormone

Criteria:

- Patient must not have an active malignancy
- Patient must have a diagnosis of treatment of HIV with wasting cachexia
- 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

Additional Renewal Criteria:

- 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

Skeletal Muscle Relaxants

Carisoprodol

Prior Authorization Form - Carisoprodol

Approval: 1 week
Criteria for non-preferred medication:

- Recipient must be taking carisoprodol on a chronic basis
- Provider must be weaning patient

Metaxalone

General Prior Authorization Form

Approval: 3 months
Criteria:

- Patient must have had two 30-day trials of other skeletal muscle relaxants, one of which must be methocarbamol, as evidenced by paid claims or pharmacy print-outs.

Preferred	Non-Preferred
orphenadrine	AMRIX (cyclobenzaprine)
baclofen	carisoprodol-aspirin
chlorzoxazone	carisoprodol-aspirin-codeine
cyclobenzaprine	DANTRIUM (dantrolene)
dantrolene	FEXMID (cyclobenzaprine)
methocarbamol	LORZONE (chlorzoxazone)
tizanidine	metaxalone
	METAXALL (metaxalone)

	ROBAXIN (methocarbamol)
	SOMA (carisoprodol)
	ZANAFLEX (tizanidine)

Spinraza

Must be billed on medical/physician side via 837P transactions
Prior Authorization Form - Spinraza

Approval: 1 year
Criteria:

- For a diagnosis of Spinal Muscular Atrophy (SMA) Type 1, 2, or 3:
    - Patient must not have respiratory insufficiency (need for invasive or noninvasive ventilation 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 (falls, trouble climbing stairs, unable to walk independently)

Spiriva Respimat 1.25 mcg

General Prior Authorization Form

Criteria:

- Patient must have a diagnosis of asthma
- Patient must have failed a 30-day trial of a steroid inhaler

Statins

General Prior Authorization Form

Criteria:
Livalo/Zypitamag:

- Statin intensity treatment goal must be “moderate” or “low”
- Patients must have failed the following 3-month trials 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

Ezetimibe/simvastatin

- Please prescribe individual medication separately or use a different medication combination

Altoprev (lovastatin) ER/Fluvastatin/Fluvastatin ER:

- The prescriber must submit medical justification explaining why the patient cannot use the preferred product (subject to clinical review)

Preferred	Non-Preferred
atorvastatin	ALTOPREV (lovastatin) ER
lovastatin	Ezetimibe/simvastatin
pravastatin	fluvastatin
rosuvastatin	fluvastatin ER
simvastatin	LIVALO (pitavastatin)
	ZYPITAMAG (pitavastatin)

Synagis

Must be billed on medical/physician side using 837p transactions

Prior Authorization Form - Synagis

Approval: 5 monthly doses between October 19th through April 21st

Criteria:

- Patient must have one of the following and additional criteria outlined for diagnosis:
    - Prematurity:
        - < 29 weeks, 0 days gestational age
        - ≤12 months of age at start of RSV season
    - Chronic Lung Disease of Prematurity (CLD)
        - ≤12 months of age at start of RSV season
            - ❖ < 32 weeks, 0 days gestational age
            - ❖ Requires supplemental oxygen > 21% for at least the first 28 days after birth
        - 13-24 months of age at start of RSV season
            - ❖ < 32 weeks, 0 days gestational age

        - ❖ Requires supplemental oxygen > 21% for at least the first 28 days after birth
        - ❖ Continues to receive medical support within six months before the start of RSV season with supplemental oxygen, diuretic, or chronic corticosteroid therapy
    - Congenital Heart Disease
        - ▪ ≤12 months of age at start of RSV season
            - ❖ Hemodynamically significant cyanotic or acyanotic congenital heart disease with medical therapy required
        - ▪ 13-24 months of age at start of RSV season
            - ❖ Has undergone cardiac transplantation during the RSV season
    - Neuromuscular disease
        - ▪ ≤12 months of age at start of RSV season
    - Pulmonary abnormalities
        - ▪ ≤12 months of age at start of RSV season
    - Profoundly Immunocompromised
        - ▪ ≤24 months of age at start of RSV season

Tardive Dyskinesia

Prior Authorization Form - Tardive Dyskinesia

Criteria:

- 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

Austedo/tetrabenazine:

- Patient must have chorea associated with Huntington's disease or Tardive Dyskinesia
- Patient must not have hepatic impairment

Preferred	Non-Preferred
INGREZZA (valbenazine)	AUSTEDO (deutetrabenazine)
tetrabenazine	

Tobacco Cessation

North Dakota Medicaid has joined forces with the Department of Health to provide free, confidential, telephone-based cessation coaching to recipients interested in quitting tobacco. Beginning November 15, 2008, to receive smoking cessation products (patches, gum, lozenges, bupropion, or Chantix®), Medicaid recipients must be signed up with NDQuits (1-800-QUIT-NOW or 1-800-784-8669). Once a recipient is enrolled in coaching, they will work with their coach to determine which medications they wish to use. The complete process is described below:

1. Patient calls NDQuits and enrolls in coaching.
2. Coaches guide patient through quitting process.
3. Individualized treatment plan developed.
4. If medications are used, the patient will receive an enrollment letter which will include the NDQuit's standing orders for the specific medication(s).
5. The HID Prior Authorization form will be included with the letter
6. The client must contact their physician and obtain the prescription.
7. The patient, physician or pharmacy must fax the Prior Authorization form and enrollment letter to HID.
8. Patient takes prescription to pharmacy.
9. Pharmacy fills prescription and the claim is paid.

Patients will be limited to a 90 consecutive days supply of therapy for patches, gum, lozenges, and bupropion, every two years.

Chantix is limited to the initial 12 weeks of therapy with an additional 12 weeks (24 consecutive weeks) allowed if the patient has continuously quit for a minimum of one month (since day 56 of therapy). The Chantix regimen will be allowed once every two years.

Nicotrol inhaler requires a smoking cessation trial with nicotine gum, lozenges, or nasal spray.

Prior authorizations will be entered based upon the recipient's Quit Date. This means that the approval date range will be sufficient to allow recipients to pick up medications at least one week prior to their Quit Date. Compliance will be an important aspect of the patient's success.

Please contact Health Information Designs, Inc. at (334) 502-3262 or toll free at 1-800-225-6998, with questions regarding the smoking cessation prior authorization process.

Tymlos

Prior Authorization Form - Miacalcin/Tymlos

Criteria:

- Patient must have a history of osteoporotic fractures
- Patient must have multiple risk factors for fracture
- Patient has not been taking Tymlos for ≥ 2 years
- Patient must have failed a 6-month trial of a preferred product (a bisphosphonate)

Preferred	Non-Preferred
Alendronate	MIACALCIN (calcitonin)
Ibandronate	TYMLOS (abaloparatide)
Risedronate	

Uceris Rectal Foam

General Prior Authorization Form

Criteria:

- Patient has a diagnosis of ulcerative colitis
- Patient must have failed a 1-month trial of one of the preferred agents

Preferred	Non-Preferred
CANASA (mesalamine) RECTAL SUPPOSITORY	Mesalamine enema kit
Mesalamine enema	UCERIS (budesonide) RECTAL FOAM

Vecamyl

Prior Authorization Form - Vecamyl

Criteria:

- 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.

Xyrem

Prior Authorization Form - Xyrem

Criteria:

- Patient must be 18 years of age or older
- Patient must be enrolled in the Xyrem REMS program
- Patient must not be taking any sedative hypnotics, opioids, or muscle relaxants
- Patient must have one of the following diagnoses and additional criteria for diagnosis:
    - Cataplexy in Patient's with Narcolepsy
    - Excessive Daytime Sleepiness

      Additional Criteria:
        - Patient must have failed a 2-month trial of modafinil

Zorbtive

Prior Authorization Form - Growth Hormone

Criteria:

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

Preferred Dosage Forms List:

Prior Authorization Form - Non-Preferred Dosage Form

Criteria:

- The prescriber must submit medical justification explaining why the patient cannot use the preferred product (subject to clinical review)
- Patient must have FDA indication
- Patient must not have contraindications to requested product
- Patient must have failed a therapeutic course of all preferred agents
    - Trial must have been 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

Altoprev (lovastatin) ER

Trial: 3 months

Preferred	Non-Preferred
lovastatin	ALTOPREV (lovastatin) ER

Amrix (cyclobenzaprine)

Preferred	Non-Preferred
Cyclobenzaprine	AMRIX (cyclobenzaprine)
	Cyclobenzaprine 7.5mg

Bowel Prep Agents

Trial: 1 complete dose

Preferred	Non-Preferred
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)

Preferred	Non-Preferred
Paroxetine tablets	BRISDELLE (paroxetine) CAPSULES

Colchicine

Preferred	Non-Preferred
Colchicine capsules	Colchicine tablets
	COLCRYS (colchicine) TABLETS
	MITIGARE (colchicine) CAPSULES

Daxbia (Cephalexin)

Preferred	Non-Preferred
Cephalexin	Daxbia (Cephalexin)

Fortamet (metformin)
Glumetza (metformin)

Preferred	Non-Preferred
Metformin ER	FORTAMET (metformin)
	GLUMETZA (metformin)

Gocovri (amantadine ER)
Osmolex ER (amantadine ER)

Preferred	Non-Preferred
Amantadine IR	Gocovri (amantadine ER)
	Osmolex ER (amantadine ER)

Gralise (gabapentin)

Preferred	Non-Preferred
gabapentin	GRALISE (gabapentin)

Horizant (gabapentin)

Preferred	Non-Preferred
gabapentin	HORIZANT (gabapentin)
pramipexole	
ropinirole	

Jadenu (deferasirox)

Preferred	Non-Preferred
EXJADE (deferasirox)	JADENU (deferasirox)

Ketoconazole foam

Preferred	Non-Preferred
ketoconazole cream	ketoconazole foam
ketoconazole shampoo	

Kits

Preferred	Non-Preferred
FDA approved products prescribed separately	DERMACINRX ARM PAK (lidocaine/dimethacone)
	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)

Lorzone (chlorzoxazone)

Preferred	Non-Preferred
chlorzoxazone	LORZONE (chlorzoxazone)

methotrexate

Trial: 6 weeks

Preferred	Non-Preferred
methotrexate	OTREXUP (methotrexate)
	RASUVO (methotrexate)
	TREXALL (methotrexate)

Moxatag (amoxicillin)

Amoxicillin IR	MOXATAG (amoxicillin) ER

Narcotic/APAP Criteria

Preferred	Non-Preferred
hydrocodone-acetaminophen	2.5-325 MG
hydrocodone-acetaminophen	7.5-325 MG
hydrocodone-acetaminophen	10MG-300MG
hydrocodone-acetaminophen	5 MG-300MG
hydrocodone-acetaminophen	7.5-300 MG
oxycodone-acetaminophen	2.5-325 MG
oxycodone-acetaminophen	7.5-325 MG
PRIMLEV (oxycodone-acetaminophen)	5 MG-300MG
PRIMLEV (oxycodone-acetaminophen)	7.5-300 MG
PRIMLEV (oxycodone-acetaminophen)	10MG-300MG

Nitroglycerin Spray

Trial: 1 dose while on preventative medication

Preferred	Non-Preferred
Nitroglycerin sublingual tablets	Nitroglycerin Spray

Nuvessa (metronidazole)

Preferred	Non-Preferred
Clindamycin vaginal 2% cream	NUVESSA (metronidazole) 1.3% GEL
Metronidazole 0.75% vaginal gel	

Onmel (itraconazole)

Trial: 12 weeks with 6 months outgrow following treatment for onychomycosis

Preferred	Non-Preferred
Itraconazole capsule	ONMEL (itraconazole) tablet
Terbinafine	

Oxaydo (oxycodone)

Preferred	Non-Preferred
Oxycodone	Oxaydo (oxycodone) Roxybond (oxycodone)

Procysbi (cysteamine)

Preferred	Non-Preferred
CYSTAGON (cysteamine)	PROCYSBI (cysteamine)

Ribavirin

Preferred	Non-Preferred
RIBASPHERE (ribavirin)	COPEGUS (ribavirin)
Ribavirin	MODERIBA (ribavirin)
	RIBASPHERE RIBAPAK (ribavirin)

Rytary (Carbidopa/Levodopa)

Additional Criteria: Patient is not in a long term care facility

Preferred	Non-Preferred
Carbidopa/Levodopa	RYTARY (carbidopa/levodopa)
Carbidopa/Levodopa ER	
Carbidopa/Levodopa/Entacapone	

Steroids - Oral

Additional Criteria:
Emflaza: See Emflaza Criteria on this document
Rayos: Trial of 12 weeks with 2AM dosing of prednisone

Preferred	Non-Preferred
Budesonide 3mg EC	DEXPAK (dexamethasone)
Cortisone	EMFLAZA (deflazacort)
Dexamethasone	MILLIPRED (Prednisolone)
Hydrocortisone	Prednisolone sodium phosphate ODT
Methylprednisone	Prednisolone sodium phosphate 10mg/5ml, 20mg/5ml solution
Prednisolone sodium phosphate 5mg/5ml, 15mg/5ml, 25mg/5ml	RAYOS (prednisone)
Prednisone	TAPERDEX (dexamethasone)
	UCERIS (budesonide)

Testosterone – oral

Preferred	Non-Preferred
ANDROGEL (testosterone) PACKET 1%	METHYLTESTOSTERONE

ANDROGEL (testosterone) PACKET 1.62%	METHITEST (methyltestosterone)
ANDRODERM (testosterone)	

Tirosint (levothyroxine)

Preferred	Non-Preferred
levothyroxine	TIROSINT (levothyroxine)

Tizanidine Capsules

Preferred	Non-Preferred
Tizanidine tablets	Tizanidine capsules

Tussicaps

Preferred Non-Preferred	Preferred Non-Preferred
Hydrocodone/chlorpheniramine ER suspension	TUSSICAPS (hydrocodone/chlorpheniramine)
Promethazine/codeine	
ZODRYL AC (chlorpheniramine/codeine)	

Topical Corticosteroids Preferred Medication List - Page 1 of 2

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%
		Clobex (*Brand Required*) Lotion	0.05%	Clobetasol emulsion foam	0.05%
		Clobex (*Brand Required*) Shampoo	0.05%	Clobetasol propionate foam	0.05%
		Clobex (*Brand Required*) Spray	0.05%	Topicort spray	0.25%
		Clobetasol Propionate Gel	0.05%	STEP2* Cordran Tape	4MCG/SQ CM
				STEP 2* Ultravate lotion	0.05%
Class 2 & 3 - High Potency	**Class 2 & 3 - High Potency**				
	Cream	Betamethasone, augmented	0.05%	Apexicon E	0.05%
		Desoximetasone	0.25%	Betamethasone Dipropionate	0.05%
		Diflorasone Diacetate	0.05%	Halog	0.10%
		Fluocinonide	0.05%	Fluocinonide-E	0.05%
		Triamcinolone Acetonide	0.50%	STEP2* Amcinonide	0.10%
	Ointment	Betamethasone Dipropionate	0.05%	Amcinonide	0.10%
		Betamethasone Valerate	0.10%	Diflorasone Diacetate	0.05%
		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%	Betamethasone dipropionate gel	0.05%
		Fluocinonide solution	0.05%	Desoximetasone gel	0.05%
				STEP2* Amcinonide Lotion	0.10%

Topical Corticosteroids Preferred Medication List - Page 2 of 2

Class 4 & 5 - Medium Potency	**Class 4 & 5 - Medium Potency**				
	Cream	Betamethasone Valerate	0.10%	Clocortolone Pivalate	0.10%
		Fluticasone Propionate	0.05%	Fluocinolone Acetonide	0.025%
		Mometasone Furoate	0.10%	Pandel	0.10%
		Synalar	0.025%	Prednicarbate	0.10%
		Triamcinolone Acetonide	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	0.05%
Class 6 & 7 - Low Potency	**Class 6 & 7 - 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%		

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General
Prior Authorization Form

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

Prior Authorization Vendor for ND

ND Medicaid requires that patients receiving a prescription for non-preferred medications to meet specific diagnosis and step-therapy requirements. Criteria for agents requiring prior authorization can be found 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 #

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Non-Preferred Dosage Forms
Prior Authorization Form

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

Prior Authorization Vendor for ND

ND Medicaid requires that patients receiving a prescription for non-preferred dosage form of a preferred agent must meet the following prior authorization criteria:

- The prescriber must submit medical justification explaining why the patient cannot use the preferred product (subject to clinical review)
- Patient must have FDA approved indication for use
- Patient must not have contraindications to requested product
- Patient must have failed a therapeutic course of all preferred agents within the last 2 years
  - Trials must have been at least 30 days in duration unless otherwise indicated
  - A failure is defined as product was not effective at maximum tolerated dose or patient has a documented intolerance or adverse reaction to inactive ingredients where the non-preferred product is expected to have a different result and other alternatives (e.g. medications in same class) are not an option for the patient

Part I: TO BE COMPLETED BY 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 #

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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 #

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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 #

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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:

Ampyra
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 Ampyra must meet the following criteria:

- **Patient must be 18 years or older.**
- **Patient must have a specialist (neurologist or physiatrist) involved in therapy.**
- **Patient must have a confirmed diagnosis of multiple sclerosis.**
- **Patient must not have a history of seizures**
- **Patient's CrCl (creatinine clearance) must be greater than 50mL/min**
- **Renewal PA requests must include patient's current T25FW.**

Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name	**Recipient Date of Birth**	Recipient Medicaid ID Number	
Physician Name	Specialist involved in therapy (if not treating physician)		
Physician Medicaid Provider Number	Telephone Number	Fax Number	
Address	City	State	Zip Code
Requested Drug and Dosage: □ AMPYRA	**FDA approved indication for this request:**		
Has patient experienced any acute exacerbations within the last 60 days?	□ YES	□ NO	
Does the patient have a CrCL greater than 50mL/min?	□ YES	□ NO	
Does the patient have a history of seizures?	□ YES	□ NO	
What is the patient's baseline Timed 25-foot Walk (T25FW)?	**If this is a renewal PA request, please include patient's current T25FW:**		
Prescriber (or Staff) / Pharmacy Signature**	Date		
**: *By completing this form, I hereby certify that the above request is true, accurate and complete. That the request is medically necessary, does not exceed the medical needs of the member, and is clinically supported in the patient's medical records. I also understand that any misrepresentations or concealment of any information requested in the prior authorization request may subject me to audit and recoupment.*			

Part II: TO BE COMPLETED BY PHARMACY

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

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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 provide the following information:

- **Visit once per year with an accredited Hemophilia Treatment Center**
- **Date of last appointment with treatment center**
- **Contact information for treatment center**
- **For non-preferred agents, medical justification must be provided explaining why the patient cannot use preferred agents**

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:	**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 #

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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.*

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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

Daliresp
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 Daliresp to meet the following criteria for coverage:

- Patient must have a diagnosis of COPD
- Patient must also have had a 30 day trial with a medication in each of the following therapeutic classes, as evidenced by paid claims or pharmacy print-outs:
  - Long acting anticholinergic
  - Long acting beta agonist
  - Inhaled Steroid
- Initial requests: Patient experienced a COPD exacerbation requiring treatment with corticosteroids in the past year
- Renewal requests: Patient must have had a decreased number of COPD exacerbation requiring treatment with corticosteroids since starting therapy with Daliresp

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:**	
Has the patient experienced a COPD exacerbation requiring treatment with corticosteroids in the past year?		□ YES □ NO	
(Renewals only) Has the patient experienced decreased number of COPD exacerbation requiring treatment with corticosteroids since starting therapy with Daliresp?		□ 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

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

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

Part II: TO BE COMPLETED BY PHARMACY

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

health information designs

Emflaza
Prior Authorization Form

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

Prior Authorization Vendor for ND

ND Medicaid requires that patients receiving a new prescription for Emflaza must meet the criteria for use available at www.hidesigns.com/assets/files/ndmedicaid/2018/Criteria/PA_Criteria.pdf

Part I: TO BE COMPLETED BY 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

**: *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

Eucrisa
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 Eucrisa must meet the following criteria:

Initial Requests:

- Patient must be 2 years of age or older
- Patient must have an FDA-approved diagnosis for use
- Patient must have had a 30 day trial within the past 180 days of one of the following:
  - A topical calcineurin inhibitor (tacrolimus or pimecrolimus)
  - A topical corticosteroid.

Renewal Requests:

- Documentation from the prescriber must be provided showing that the patient has achieved a significant reduction in severity of atopic dermatitis (please attach documentation to this request)

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: □ EUCRISA	**Diagnosis for this request:**	**Is the affected area is on the face, groin, axilla, or under occlusion?** □ YES □ NO

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

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

Prescriber (or Staff) / Pharmacy Signature**	Date

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

Part II: TO BE COMPLETED BY PHARMACY

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

health information designs

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 preferred growth hormone meet one of the criteria below (patient's receiving a non-preferred growth hormone product must be switched to a preferred agent):

- Multiple pituitary hormone deficiencies caused by a known hypothalamic-pituitary disease or its treatment (brain surgery and/or radiation)
- Turner's syndrome
- SHOX syndrome
- Noonan syndrome
- Chronic renal insufficiency
- Prader–Willi syndrome
- See growth hormone criteria for additional information. www.hidesigns.com/assets/files/ndmedicaid/2017/Criteria/growth_hormone_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	
Address	City	State	Zip Code
Requested Drug and Dosage:	**Diagnosis for this request:**		

Qualifications for coverage:

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

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

Prescriber (or Staff) / Pharmacy Signature**	Date

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

Part II: TO BE COMPLETED BY PHARMACY

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

health information designs

Hemangeol
Prior Aurhotization 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:

- **Patient must be between 5 weeks and 1 year of age.**
- **Patient must weigh 2 kg or greater.**
- **Patient must not have contraindications as listed below: asthma or a history of bronchospasm, bradycardia (<80 beats per minute), greater than first-degree heart block, decompensated heart failure, blood pressure <50/30 mmHg, or pheochromocytoma.**
- **Patient must have a diagnosis of proliferating infantile hemangioma requiring systemic therapy.**

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: □ 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

Hereditary Angioedema
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 agent used to treat hereditary angioedema must meet the following criteria:

- **Patient must have diagnosis of hereditary angioedema confirmed by a specialist**

Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name	**Recipient Date of Birth**	Recipient Medicaid ID Number	
Physician Name	Specialist Involved in therapy:		
Physician Medicaid Provider Number	Telephone Number	Fax Number	
Address	City	State	Zip Code
Requested Drug and Dosage:	**Diagnosis for 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

Agents Used to Treat Idiopathic Pulmonary Fibrosis 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:

- **Patient must be 18 years of age or older.**
- **Patient must have documented diagnosis of idiopathic pulmonary fibrosis.**
- **Patient must have a specialist involved in therapy.**
- **Patient must have forced vital capacity (FVC) ≥ 50% of predicted within prior 60 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 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 Hizentra, Cuvitru, or Hyqvia:** 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: **Indication for this request:**	**Is patient BMI over 30? □ YES □ NO** **If yes, provide adjusted body weight and calculated dose:** **Is patient intolerant to IgA (i.e., treatment of an autoimmune process in a patient with undetectable levels of IgA)? □YES □NO** **Is patient unable to tolerate IV administration? □ YES □ NO** **Please list all medications patient has tried and failed:**		
□ *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

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 product
- **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.
    - Must provide clinical explanation for the following (if applicable):
      A. If dose is >200 units of insulin per day, why patient is not a candidate for U-500R.
      B. Need for smaller volume of 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:

- Patient must have a diagnosis of Homozygous Familial Hypercholesterolemia (HoFH)
- Patient must be 18 years of age or older
- Patient's LDL is >130 mg/dL after a 90-day trial of combined therapy with either Crestor ≥20 mg or atorvastatin ≥ 40 mg plus another lipid lowering agent
- Patient meets one of the following:
  - Has genetic confirmation of 2 mutant alleles at the LDLR, APOB, PCSK9, or LDLRAP1 gene locus
  - Has an untreated LDL and total cholesterol level of > 500 mg/dl or >300 mg/dl with cutaneous or tendon xanthoma before 10 years of age
  - Has an untreated LDL level consistent with 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

Ketek
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 Ketek must meet the following criteria:

- One of the following:
  - Patient has a diagnosis of community-acquired pneumonia (of mild to moderate severity) due to Streptococcus pneumoniae and is 18 years and older.
  - Patient has an allergy to fluoroquinolones or tetracyclines, does not have a diagnosis of myasthenia gravis, and has not tried another antibiotic in the last 3 months.

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: (must be completed) □ **KETEK**	**Diagnosis**		

Qualifications for coverage:

Does the patient have community acquired pneumonia (of mild to moderate severity) due to Streptococcus pneumoniae?	□ YES □ NO
Does the patient have myasthenia gravis?	□ YES □ NO
Does the patient have any other antibiotic use in the last 3 months?	□ YES □ NO

Please list fluoroquinolone or tetracycline that patient is allergic to: _____

□ *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

Miacalcin and Tymlos 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 Miacalcin or Tymlos must meet the following criteria:

- **Miacalcin:** *Patient must have one of the below diagnoses and meet the criteria for their diagnosis (if present)*
  - **Paget's Disease of the bone:** Patient must have failed a 6-month trial of a bisphosphonate
  - **Postmenopausal Osteoporosis:** Patient must be postmenopausal for ≥ 5 years and have failed a 6-month trial of a bisphosphonate
  - **Hypercalcemia**
- **Tymlos:**
  - Patient must have a history of osteoporotic fractures and have multiple risk factors for fracture
  - Patient has not been taking Tymlos for ≥ 2 years
  - Patient must have failed a 6-month trial of a bisphosphonate

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:**		
List all failed medications (drug name, date of trial, reason for failure):	Has the patient been postmenopausal for ≥ 5 years? □ 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

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 following criteria:

Initial Requests:

- Patient must experience 4 or more migraine days per month.
- Prescriber must submit documentation of treatment failure of a 2 month trial of two preferred agents from different therapeutic classes. Documentation must include clinical notes regarding failure to reduce migraine frequency.

Renewal Requests: Patient must experience a reduction in migraines 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:**		
Number of experienced migraine days per month:			
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

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 Nausea/Vomiting must meet the following criteria:

- Patient must have diagnosis of nausea and vomiting.
- Patient must have failed a 3-day trial of all preferred products within the last 30 days.
- Estimated last day of treatment must be provided (i.e. due date or last day of chemotherapy)
- For additional criteria specific to Bonjesta, Sancuso, Syndros, or Zuplenz, please see the Nausea/Vomiting Prior Authorization Criteria at 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

Requested Drug and Dosage:	**Diagnosis for this request:** □ Nausea and/or vomiting due to: □ Moderately or highly emetogenic chemotherapy □ Pregnancy

List all failed medications:	**Dates:**	**Reason for Failure:**

Estimated last day of treatment (ie. pregnancy due date or final date of chemotherapy):

Additional Qualifications for Coverage:
□ Does the patient have an inability to tolerate oral medications (please attach swallow study)? □ YES □ NO
□ Other, Explain:

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

Prescriber (or Staff) / Pharmacy Signature**	Date

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

Part II: TO BE COMPLETED BY PHARMACY

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

health information designs

Nuedexta
Prior Authorization Form

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

Prior Authorization Vendor for ND

ND Medicaid requires that patients receiving a new prescription for Nuedexta must meet 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

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 following criteria:

- **For generic non-preferred, solid oral dosage form NSAIDs:**
  - Patient must have failed a 30-day trial of 3 oral generic NSAIDs, as evidenced by paid claims or pharmacy print outs
- **For Branded NSAIDs**
  - Provider must submit medical justification explaining why the patient cannot use all other NSAIDs (subject to clinical review)
- **For Sprix**, please see additional prior authorization criteria for NSAIDs available at **www.hidesigns.com/assets/files/ndmedicaid/2018/Criteria/PA_Criteria.pdf**
- **For Combination NSAIDs:**
  - Provider must submit medical justification explaining individual ingredients cannot be used separately (subject to 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
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
For Sprix Requests: 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

**: *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

Long Acting 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 non-preferred abuse deterrent agents:
  - The patient must have had a 30-day trial of preferred tapentadol, morphine, and oxycodone products
- For non-preferred agents without an abuse deterrent:
  - The patient must have had 30-day trials of preferred fentanyl, morphine, and oxycodone products

*** 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:	**Dose and Frequency:**	**Start/End Date:**	**Reason for failure:**
□ NSAIDs □ TCAs □ SNRIs □ Corticosteroids □ Weight Loss □ Physical Therapy □ Cognitive Behavioral Therapy □ Other:			

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.*

health information designs

Prior Authorization Vendor for ND Medicaid

Short Acting Opioid Analgesics
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 short-acting opioid analgesic must meet the following criteria:

- **Subsys, Fentora, Lazanda, Actiq and Abstral**
  - Patient must be of appropriate age for use per FDA-approved indication of the requested agent
  - The patient must have cancer pain.
  - The patient must currently be on around the clock opioid therapy and have been on round the clock opioid therapy for at least 1 week, as evidenced by paid claims or pharmacy print-outs.
- **Oxycodone IR**
  - The patient must have chronic pain.
  - The patient must currently be on a long-acting narcotic, as evidenced by paid claims or pharmacy print-outs.
  - The prescriber must confirm that they have reviewed the North Dakota PDMP reports for the patient.
  - The patient's current total daily Morphine Equivalent Dose (MED), must be greater than the minimum per tablet strength requested (below), as evidenced by paid claims or pharmacy print-outs.
    - For 15 mg tablet ≥300 MED/day, for 20 mg tablet ≥300 MEDs/day, for 30 mg tablet ≥300 MEDs/day.

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:	**Diagnosis for this Request:**		
Is patient on a long-acting narcotic? □ YES □ NO Does the prescriber routinely check the PDMP system? □ YES □ NO			

FAILED THERAPY	**START DATE**	**END DATE**	**DOSE & FREQUENCY**

□ *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

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

**: *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:

- **Patient must have a confirmed diagnosis of one of the following:**
  - Heterozygous familial hypercholesterolemia (HeFH)
  - Clinical atherosclerotic cardiovascular disease (ASCVD)
  - **Repatha only**: Homozygous familial hypercholesterolemia (HoFH)
- **The patient must have failed (defined as an LDL level that remained >130 mg/dL) after a 3-month trial of each of the following treatments:**
  - Crestor 20-40mg
  - Atorvastatin 40-80mg
  - A statin combined with another lipid lowering agent

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 following criteria:

- **Patient must have hyperphenalaninemia.**
- **Patient must be following a PHE restricted diet.**

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: □ KUVAN	**PHE level:**	**Diagnosis for this Request:**	**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

Pulmonary Arterial Hypertension 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 an agent used to treat pulmonary hypertension must meet the following criteria:

- **Patient must have diagnosis of an FDA-approved indication.**
- **Non--preferred agents will require a 30-day trial of all preferred medications.**
- **Specific criteria for each class of medication will need to be met for approval. Please see criteria for coverage in the Preferred Drug List 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:		
Prescriber NPI	Telephone Number	Fax Number	
Address	City	State	Zip Code
Requested Drug and Dosage:	**Diagnosis for this Request:**		
	Is the patient pregnant? □ Yes □ No Is the patient taking a reliable form of birth control? □ Yes □ No Will patient take monthly pregnancy tests during therapy? □ Yes □ No Is the patient taking nitrates of any form? □ Yes □ No Will LFT's be measured monthly? □ Yes □ No		
List all failed medications:	**Start Date:**	**End Date:**	
□ *I confirm that I have considered a generic or other alternative and that the requested drug is expected to result in the successful medical management of the recipient.*			
Prescriber (or Staff) / Pharmacy Signature**	Date		
**: *By completing this form, I hereby certify that the above request is true, accurate and complete. That the request is medically necessary, does not exceed the medical needs of the member, and is clinically supported in the patient's medical records. I also understand that any misrepresentations or concealment of any information requested in the prior authorization request may subject me to audit and recoupment.*			

Part II: TO BE COMPLETED BY PHARMACY

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

health information designs

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 name brand Sedative/Hypnotic must use Ambien® (zolpidem) as first line therapy.

*__Note:__

- **Requires step therapy. See Sedative/Hypnotic PA criteria for more information.**

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? □ YES □ NO
Does the patient require dose tapering? □ YES □ NO
Is the patient's insomnia characterized by difficulty with sleep maintenance? □ YES □ NO
Is the patient's insomnia characterized by difficulty with sleep initiation? □ YES □ NO
Is the patient's insomnia characterized by difficulty with middle of the night awakening with more than 4 hours left to sleep? □ 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**

health information designs

Prior Authorization Vendor for ND Medicaid

Tardive Dyskinesia Agents Prior Authorization Form

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

ND Medicaid requires that patients receiving a new prescription for Austedo, Ingrezza, or tetrabenazine must meet the following criteria:

- **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
  - For Austedo, the patient must have failed a 30-day trial with Ingrezza

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 #

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:

- **These medications will only be covered when prescribed for use prior to certain procedures (e.g., placement of a peripheral or central line or injections through an implanted port). Medical procedure must be listed on PA form.**
- **PA not required for patients 12 years of age and younger.**

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:** □ Placement of a peripheral or central line □ Injections through an implanted port □ Other:		
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

Topical Antifungals
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 non-preferred topical antifungal agent must meet the following criteria:

Criteria for all agents:

- Patient must have an FDA approved diagnosis confirmed by potassium hydroxide (KOH) preparation.
- Patient must have failed a trial of 3 preferred agents including at least one oral agent (terbinafine, fluconazole, or itraconazole) for the length of recommended treatment time for patient's particular infection.
- The prescriber must submit medical justification explaining why the patient cannot use a preferred product cannot be used if requested product ingredient is available in a preferred formulation.

Additional criteria for treatment of onychomycosis:

- There must have been enough time since treatment cessation to assess healthy toenail outgrow (≥ 6 months)

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 #

REVIEW OF AGENTS FOR TREATMENT OF DRY EYE SYNDROME

KERATOCONJUNCTIVITIS SICCA

- Keratoconjunctivitis sicca is dryness of the conjunctiva and cornea, causing dryness, red eyes, irritation, gritty/burning sensation, blurred vision, and excessive tearing.
- **Epidemiology:** ~5 to 30% of persons ≥50 years old, 6.8% of U.S. population
- **Pathophysiology:** 2 causes:
    - **Decreased Tear Production**
        - **Sjögren's syndrome:** A systemic autoimmune disorder in which there is inflammatory infiltration of the lacrimal glands leading to cell death and tear hyposecretion.
        - **Non-Sjögren's syndrome:** Involves lacrimal dysfunction without associated systemic findings.
            - The most common form is age-related dry eye in which it is believed that there is lacrimal ductal obstruction over time, leading to decreased lacrimal gland function.
                - Can also be due to conjunctival scarring conditions such as trachoma, mucous membrane pemphigoid, and ocular burns.
            - Other common causes include lacrimal gland infiltration due to sarcoidosis, lymphoma, graft versus host disease, and episcleritis.
            - Also due to contact lens use is associated with reduced corneal sensitivity and subsequently reduced reflex sensory tear secretion, as well as diabetes mellitus.
    - **Increased Evaporative Loss**
        - Excessive water loss from the ocular surface.
        - Most commonly caused by posterior blepharitis, in which the accessory lacrimal glands responsible for the lipid component of the tear film are dysfunctional.
        - Structural abnormalities of eyelid position or decreased blink function also increase evaporation of the tear film by increasing the area or the time of tear film exposure.
- **Treatment**
    - Artificial tears:
        - Typically considered first-line treatment for dry eye and have been shown to improve irritative symptoms in patients with dry eye. Multiple products. Available in liquid, gel, and ointment forms. Typical to notice improvement within a few days of initiating treatment but may take up to three to four weeks to note a significant change in symptoms
    - Topical cyclosporine (Restasis)
        - Immunosuppressive agent, indicated for increasing tear production when suppressed tear production is presumed to be due to keratoconjunctivitis sicca-associated ocular inflammation (in patients not already using topical anti-inflammatory drugs or punctal plugs).
    - Topical lifitegrast (Xiidra)
        - Lifitegrast is an integrin antagonist, indicated for the treatment of the signs and symptoms of dry eye disease. It binds to the integrin lymphocyte function-associated antigen-1 (LFA-1) and blocks the interaction of LFA-1 with its cognate ligand intercellular adhesion molecule-1 (ICAM-1)

	Artificial Tears	Restasis	Xiidra
Dosing	Instill 1 to 2 drops into eye(s) 3 or 4 times daily, as needed	Instill 1 drop into each eye every 12 hours	Instill 1 drop into each eye every 12 hours
Age Indicated for Use	All ages	>16 years of age	Adults
Common ADRs		Eye pain/burning sensation	Application site irritations, dysgeusia, reduced visual acuity
Dosage form	Gels, ointments, solutions,	Emulsion	Solution

COST

Drug	Strength	Package Size	AWP Pkg Price	AWP Unit Price
SYSTANE	0.4-0.3%	3.5 gram ointment	8.78	2.50 (per gram)
SYSTANE	0.4-0.3%	30 mL solution	16.68	0.56 (per mL)
SYSTANE	0.4-0.3%	10 mL gel	10.19	1.02 (per gram)
RESTASIS	0.05%	30s emulsion	305.59	10.19 (per drop)
RESTASIS	0.05%	60s emulsion	611.20	10.19 (per drop)
RESTASIS MULTIDOSE	0.05 %	5.5 mL	611.20	111.13 (per mL)
XIIDRA	5%	60s solution	608.40	10.14 (per drop)

CURRENT UTILIZATION

ND Medicaid Utilization (10/2017 – 10/2018)		
Label Name	**Rx Num**	**Total Reimb Amt**
RESTASIS	159	$65,435.44
RESTASIS MULTIDOSE	18	$8,759.55
XIIDRA	28	$13,140.89

REFERENCES:

1. Facts & Comparisons eAnswers. Available at http://online.factsandcomparisons.com. Accessed on October 20. 2018.
2. Xiidra (lifitegrast) [prescribing information]. Lexington, MA: Shire US Inc; December 2017.
3. Restasis (cyclosporine) [prescribing information]. Irvine, CA: Allergan Inc: received July 20, 2017.
4. Restasis Multidose (cyclosporine) [prescribing information]. Irvine, CA: Allergan Inc; October 2016.

REVIEW OF AGENTS FOR TREATMENT OF GLAUCOMA

GLAUCOMA:

- Glaucoma is a group of eye diseases that cause nerve damage, traditionally characterized by elevated intraocular pressure (IOP). Increased IOP can lead to optic nerve damage, causing progressive visual field loss and, ultimately, irreversible blindness if left untreated
    - Open-angle glaucoma: optic neuropathy characterized by progressive peripheral visual field loss followed by central field loss in a typical pattern. Typically occurs with elevated IOP, due to increased aqueous production and/or decreased outflow. The optic nerve takes on a hollowed-out appearance on ophthalmoscopic examination, which is described as "cupping."
    - Angle-closure glaucoma is characterized by narrowing or closure of the anterior chamber angle, causing inadequate drainage of the aqueous humor and elevated IOP. Typically presents as a painful red eye and must be treated within 24 hours to prevent permanent blindness

TREATMENT:

- **Primary Goal:** Lowering intraocular pressure
- **Medication classes and examples:**
    - **Prostaglandins**: Lowers IOP by increasing outflow of aqueous humor through both the trabecular meshwork and uveoscleral routes.
        - latanoprost, bimatoprost, tafluprost, travoprost
        - **Vyzulta (latanoprostene bunod):** metabolized to latanoprost after administration.
    - **Beta blockers:** reduces IOP by reducing aqueous humor production or possibly increases the outflow of aqueous humor
        - **betaxolol, timolol**
        - **Timoptic-XE:** gel formulation of timolol
    - **Alpha agonists:** reduction of aqueous humor formation
        - **apraclonidine, brimonidine**
    - **Carbonic anhydrase inhibitors:** decreases aqueous humor secretion, presumably by slowing the formation of bicarbonate ions with subsequent reduction in sodium and fluid transport.
        - **dorzolamide, brinzolamide**
    - **RhoPressa (netarsudil):** rho kinase inhibitor; it is believed to reduce IOP by increasing the outflow of aqueous humor through the trabecular meshwork.
- **Initiation of therapy:**
    - Prostaglandins and beta blockers are often considered as the 1st line choice. Prostaglandins due to their low side effect profile and potential benefits in efficacy vs other agents, and beta blockers due to their general affordability.

Overview of Representative Drugs from Each Class

	Dosage Form(s)	Dosing	Pediatric Use	Contraindications
latanoprost	Solution	1 drop daily	No	None
Vyzulta	Solution	1 drop daily	No	HSR
timolol	Solution, gel	1 drop twice daily	No	HSR; asthma, COPD; sinus braqdycardia; 2nd or 3rd degree AV block; heart failure; cardiogenic shock
Timoptic-XE	gel	1 drop daily	No	
brimonidine	Solution	1 drop thrice daily	>2	HSR
dorzolamide	Solution	1 drop thrice daily	Yes	HSR
RhoPressa	Solution	1 drop daily	No	None

COST

Drug	Strength	Package Size	AWP Pkg Price	AWP Unit Price
LATANOPROST	0.005 % sln	2.5 ml	19.44	7.78
VYZULTA	0.024 % sln	2.5 ml	216.00	86.40
TIMOLOL	0.5 % sln	5 ml	6.03	1.21
TIMOLOL	0.5 % GFS	5 ml	217.27	43.45
TIMOPTIC-XE	0.5 % GFS	5 ml	252.60	50.52
BRIMONIDINE	0.2 % sln	5 ml	32.65	6.53
BRIMONIDINE	0.15 % sln	5 ml	160.01	32.00
DORZOLAMIDE	0.2 % sln	10 ml	66.75	6.68
RHOPRESSA	0.02 % sln	2.5 ml	274.80	109.92

CURRENT UTILIZATION

ND Medicaid Utilization (10/2017 – 10/2018)		
Label Name	**Rx Num**	**Total Reimb Amt**
LATANOPROST	390	$11,129.60
VYZULTA	0	$0.00
TIMOLOL	147	$3,162.67
TIMOLOL GFS	27	$2,270.54
TIMOPTIC-XE	0	$0.00
BRIMONIDINE	97	$14,354.01
DORZOLAMIDE	19	$3,006.83
RHOPRESSA	0	$0.00

REFERENCES:

1. Facts & Comparisons eAnswers. Available at http://online.factsandcomparisons.com. Accessed on October 20. 2018.
2. Rhopressa (netarsudil) [prescribing information]. Irvine, CA: Aerie Pharmaceuticals; December 2017.
3. Timoptic-XE (timolol maleate) [prescribing information]. Bridgewater, NJ: Valeant Pharmaceuticals; July 2018.
4. Vyzulta (latanoprostene bunod) [prescribing information]. Bridgewater, NJ: Bausch & Lomb; June 2018.

REVIEW OF DONEPEZIL 23 MG

INDICATIONS AND USE:

- Alzheimer disease
    - Treatment of mild, moderate, or severe dementia of the Alzheimer type. 23 mg is specifically indicated for use in severe dementia.

DOSAGE AND ADMINISTRATION:

- Initial Dosing: 5 mg once daily
- Mild-Moderate dementia: 5-10 mg daily
- Moderate to severe dementia: 10 or 23 mg daily
- Titration recommendations:
    - Evidence shows that a higher incidence of cholinergic ADRs are associated with rapid titration, so the recommended titration of dose is as follows:
        - A dose of 10 mg should not be administered until patients have been on a daily dose of 5 mg for 4 to 6 weeks
        - A dosage of donepezil 23 mg once daily can be administered once patients have been on a dosage of donepezil 10 mg once daily for at least 3 months

DOSAGE FORM AND STRENGTHS:

- 5, 10, 23 mg tablets

CONTRAINDICATIONS:

- Hypersensitivity to donepezil, piperidine derivatives, or any component of the formulation

WARNINGS AND PRECAUTIONS:

- **Anorexia/weight loss**
    - May cause anorexia and/or weight loss (dose related)
- **GI effects**
    - May cause dose-related diarrhea, nausea, and/or vomiting; usually resolves in 1 to 3 weeks
- **Neuroleptic malignant syndrome**
    - Rare cases of neuroleptic malignant syndrome (NMS) have been reported
- **Rhabdomyolysis**
    - Rare cases of rhabdomyolysis (including acute renal failure) have been reported after a few months of therapy
- **Altered cardiac conduction**
    - Donepezil may be associated with QT prolongation and torsades de pointes; use with caution in patients at risk of prolonged cardiac repolarization
- **Peptic ulcer disease**
    - Use with caution in patients at risk of ulcer disease
- **Respiratory disease**
    - Use with caution in patients with chronic obstructive pulmonary disease and/or asthma
- **Seizure disorder**
    - Use with caution in patients with a history of seizure disorder
- **Urinary tract obstruction**
    - Use with caution in patients with bladder outlet obstruction or prostatic hyperplasia
- **Low-weight patients may experience greater GI ADRs**

ADVERSE REACTIONS:

- **Most common (>10%)**
    - Insomnia, nausea, dizziness, HA, fatigue

COST

Drug	Strength	Package Size	AWP Pkg Price	AWP Unit Price
DONEPEZIL	5 mg	90 Tablets	699.38	7.77
DONEPEZIL	10 mg	90 Tablets	699.38	7.77
DONEPEZIL	23 mg	90 Tablets	784.34	8.71

CURRENT UTILIZATION

ND Medicaid Utilization (10/2017 – 10/2018)		
Label Name	**Rx Num**	**Total Reimb Amt**
DONEPEZIL 5 MG	87	$1,149.73
DONEPEZIL 10 MG	159	$2,948.44
DONEPEZIL 23 MG	6	$261.00

REFERENCES:

1. Facts & Comparisons eAnswers. Available at http://online.factsandcomparisons.com. Accessed on October 20. 2018.
2. Aricept and Aricept ODT (donepezil) [prescribing information]. Woodcliff Lake, NJ: Eisai Inc; February 2016.

REVIEW OF NASCOBAL (cyanocobalamin intranasal)

INDICATIONS AND USE:

- Pernicious anemia
    - For maintenance of normal hematologic status in pernicious anemia patients who are in remission following intramuscular (IM) vitamin B12 therapy and who have no nervous system involvement.
- B12 deficiency

DOSAGE AND ADMINISTRATION:

- Adult Dosing: 1 spray in 1 nostril once weekly
- No specific pediatric dosing recommendations

DOSAGE FORM AND STRENGTHS:

- 500 mcg/ 0.1 mL nasal spray gel

CONTRAINDICATIONS:

- Hypersensitivity to cyanocobalamin, cobalt, or any component of the formulation

WARNINGS AND PRECAUTIONS:

- **Leber Disease:**
    - Patients with early Leber disease (hereditary optic nerve atrophy) treated with vitamin B12 suffered severe and swift optic atrophy
- **Hypokalemia**
    - Hypokalemia and sudden death may occur in severe megaloblastic anemia that is treated intensely with vitamin B12. Carefully monitor serum potassium levels during therapy.
- **Vitamin B12 deficiency**
    - Vitamin B12 deficiency that is allowed to progress for longer than 3 months may produce permanent degenerative lesions of the spinal cord. Dosages of folic acid of more than 0.1 mg/day may result in hematologic remission in patients with vitamin B12 deficiency. Neurologic manifestations will not be prevented with folic acid, and if not treated with vitamin B12, irreversible damage will result.
    - If a patient is not properly maintained with intranasal vitamin B12, IM vitamin B12 is necessary for adequate treatment of the patient. No single regimen fits all cases, and the status of the patient observed in follow-up is the final criterion for adequacy of therapy.
- **Folate deficiency**
    - Dosages of vitamin B12 exceeding 10 mcg/day may produce a hematologic response in patients with folate deficiency. Indiscriminate administration may mask the true diagnosis.
    - Vitamin B12 is not a substitute for folic acid, and because it might improve folic acid deficient megaloblastic anemia, indiscriminate use of vitamin B12 could mask the true diagnosis.
- **Thrombocytosis**
    - Thrombocytosis could occur upon conversion of severe megaloblastic to normal erythropoiesis with vitamin B12 therapy. Therefore, carefully monitor platelet count during therapy.
- **Polycythemia vera**
    - Vitamin B12 deficiency may suppress the signs of polycythemia vera. Treatment with vitamin B12 may unmask this condition.
- **Nasal symptoms**
    - The effectiveness of intranasal cyanocobalamin in patients with allergic rhinitis, nasal congestion, and upper respiratory tract infections has not been determined. Defer treatment until symptoms have subsided.
- **Stomach carcinoma**
    - Patients with pernicious anemia have about 3 times the incidence of stomach carcinoma when compared with the general population. Perform appropriate tests

ADVERSE REACTIONS:

- **Most common**
    - Infection (4%): sore throat or common cold

DRUG INTERACTIONS

- No significant interactions.

COST

Drug	Strength	Package Size	AWP Pkg Price	AWP Unit Price
NASCOBAL	500 mcg/0.1 mL	4 Sprays	670.10	167.53

CURRENT UTILIZATION

ND Medicaid Utilization (10/2017 – 10/2018)		
Label Name	**Rx Num**	**Total Reimb Amt**
NASCOBAL	12	$6,295.18

REFERENCES:

1. Facts & Comparisons eAnswers. Available at http://online.factsandcomparisons.com. Accessed on October 20. 2018.
2. Nascobal (cyanocobalamin) [prescribing information]. Spring Valley, NY: Par Pharmaceutical Companies; April 2014

REVIEW OF ORILISSA (elagolix)

INDICATIONS AND USE:

- Endometriosis
  - Management of moderate to severe pain associated with endometriosis.
    - MoA: it is a short-acting, nonpeptide, GnRH antagonist that suppresses pituitary and ovarian hormone function in a dose-dependent manner. Concentrations of LH, FSH, and estradiol are decreased during therapy and rapidly return to previous levels once treatment is discontinued. In patients with endometriosis, these actions reduce dysmenorrhea and non-menstrual pelvic pain

DOSAGE AND ADMINISTRATION:

- **Initial:** 150 mg once daily
- **Max:** 200 mg twice daily
- **Duration:**
  - 200 mg twice daily dose: 6 months
  - 150 mg daily dose: 24 months
- **Dose Adjustments**
  - **Hepatic impairment:**
    - Mild impairment (Child-Pugh class A):
      - No dose adjustments needed
    - Moderate impairment (Child-Pugh class B):
      - Max dose is 150 mg daily for no longer than 6 months
    - Severe impairment (Child-Pugh class C):
      - Contraindicated

DOSAGE FORM AND STRENGTHS:

- 150 mg tablets and 200 mg tablets

CONTRAINDICATIONS:

- Pregnancy; known osteoporosis; severe hepatic impairment (Child-Pugh class C); concomitant use of strong organic anion transporting polypeptide (OATP) 1B1 inhibitors (eg, cyclosporine, gemfibrozil).

WARNINGS AND PRECAUTIONS:

- **Bleeding irregularities**
  - Menstrual bleeding patterns may change, causing a decrease in the amount, intensity or duration of bleeding. Changes in bleeding patterns may alter the ability to detect pregnancy.
- **BMD loss**
  - A dose-dependent decrease in BMD. The risk of BMD loss is increased with duration of use and may not be completely reversible following discontinuation of elagolix. Evaluate patients for osteoporosis risk factors (including a history of low-trauma fracture) prior to therapy. Consider supplementation with calcium and vitamin D. Duration of treatment should be limited to prevent BMD loss. Do not use in patients with known osteoporosis.
- **Depression**
  - May increase the risk of depression and mood changes; risk may be increased in patients with a history of suicidality or depression. Suicidal ideation/behavior has been reported.

ADVERSE REACTIONS:

- **Most common (>10%)**
  - Hot flash/night sweats (24-46%
  - Headache (17-20%)
  - Nausea (11-16%)

DRUG INTERACTIONS

- Most significant are:
  - Strong CYP3A4 inhibitiors
  - P-glycoprotein/ABCB1 Inhibitors
  - OATP1B1/SLCO1B1 Inhibitors

COST

Drug	Strength	Package Size	AWP Pkg Price	AWP Unit Price
ORILISSA	150 mg	28 Tablets	1,013.84	36.21
ORILISSA	200 mg	56 Tablets	1,013.84	18.10

CURRENT UTILIZATION

ND Medicaid Utilization (10/2017 – 10/2018)		
Label Name	**Rx Num**	**Total Reimb Amt**
ORILISSA	3	$2,562.99

REFERENCES:

1. Facts & Comparisons eAnswers. Available at http://online.factsandcomparisons.com. Accessed on October 20. 2018.
2. Orilissa (elagolix) [prescribing information]. North Chicago, IL: AbbVie Inc; July 2018.

REVIEW OF AGENTS FOR TREATMENT OF VAGINAL CANDIDAS

VAGINAL CANDIDA INFECTIONS:

- Characterized by inflammation in the setting of Candida species
  - Most commonly C. albicans
- Treatment is indicated for the relief of symptoms
- The treatment regimen is typically based on whether the woman has an uncomplicated infection (90% of patients) or complicated infection (10% of patients).
- **Uncomplicated Infection:**
  - Sporadic, infrequent episodes (≤3 episodes/year)
  - Mild to moderate signs/symptoms
  - Probable infection with Candida albicans
  - Healthy, nonpregnant woman
  - Immunocompetent woman
- **Complicated Infection:**
  - Severe signs/symptoms
  - Candida species other than C. albicans, particularly C. glabrata
  - Pregnancy, poorly controlled diabetes, immunosuppression, debilitation
  - History of recurrent (≥3/year) culture-verified vulvovaginal candidiasis

TREATMENT:

- **Uncomplicated Infection:**
  - Typically used is oral fluconazole due to ease of use and efficacy (single oral dose) but may use topical antifungals as well
- **Complicated Infection:**
  - **Immunocompromised patient or those with severe symptoms:**
    - May use any of the same oral or topical agents, but typically require longer duration of treatment (e.g. 2 to 3 doses of oral fluconazole, 72 hours apart)
  - **Caused by species other than C. albicans, particularly C. glabrata:**
    - C. krusei is usually resistant to fluconazole but is highly susceptible to topical azole creams and suppositories, such as clotrimazole, miconazole, and terconazole
  - **Recurrent Infection:**
    - May require up to 6 months of preventative therapy
  - **Pregnancy**: avoid oral fluconazole

- **Oral Agents:**
  - **Fluconazole 150 mg oral tablet**
    - Single dose, taken by mouth
      - Complicated infections may require repeat dosing
    - Do not use if pregnant
- **Topical Agents**
  - **Gynazole 1 (butoconazole)**
    - **2% Cream:** Dosed as a single application
  - **Clotrimazole**
    - Available as 1% or 2% cream
      - Dosed as 1 application (~5 grams) daily for three days (3%) or 7 days (1%)
  - **Miconazole**
    - **2% Cream:** Dosed as 1 application daily 7 days
    - **4% Cream:** Dosed as 1 application daily for 3 days
    - **Monistat 3:** 200 mg vaginal suppository dosed as 1 daily for 3 days
  - **Terconazole**
    - 80 mg vaginal suppository: 1 suppository daily at bedtime for 3 days
    - 0.4% cream: 1 application, once daily at bedtime for 7 days
    - 0.8% cream: 1 application, once daily at bedtime for 3 days

	Dosage Form(s)	Strength	Dose	Duration (days)
Gynazole 1	Cream	2%	Once daily	1
Clotrimazole	Cream	1%	Once daily	7
Clotrimazole	Cream	2%	Once daily	3
Miconazole 3	Suppository	200 mg	Once daily	3
Miconazole	Cream	2%	Once daily	7
Miconazole	Cream	4%	Once daily	3
Terconazole	Suppository	80 mg	Once daily	3
Terconazole	Cream	0.4%	Once daily	7
Terconazole	Cream	0.8%	Once daily	3

COST

Drug	Strength	Package Size	AWP Pkg Price	AWP Unit Price
GYNAZOLE 1	2%	5 grams	124.93	24.99
CLOTRIMAZOLE	1%	45 grams	48.91	1.09
CLOTRIMAZOLE	2%	21 grams	10.60	0.50
MICONAZOLE 3	200 mg	3 supp	52.57	17.52
MICONAZOLE	2%	24 grams	13.19	0.55
MICONAZOLE	4%	24 grams	13.19	0.55
TERCONAZOLE	80 mg	3 supp	141.51	47.17
TERCONAZOLE	0.4%	45 grams	44.54	0.99
TERCONAZOLE	0.8%	20 grams	40.93	2.05

CURRENT UTILIZATION

ND Medicaid Utilization (10/2017 – 10/2018)		
Label Name	**Rx Num**	**Total Reimb Amt**
GYNAZOLE 1	0	$0.00
CLOTRIMAZOLE	270	$5,911.00
MICONAZOLE CREAM	0	$0.00
MICONAZOLE SUPP	3	$148.37
TERCONAZOLE CREAM	144	$5,024.62
TERCONAZOLE SUPP	4	$319.49

REFERENCES:

1. Facts & Comparisons eAnswers. Available at http://online.factsandcomparisons.com. Accessed on October 20. 2018.
2. Gynazole-1 (butoconazole) [prescribing information]. Allegan, MI: Perrigo; November 2014.
3. Terazol (terconazole) [prescribing information]. Titusville, NJ: Janssen Pharmaceuticals Inc; May 2018.
4. Clotrimazole 3 day vaginal cream [prescribing information]. Hawthorne, NY: Taro Pharmaceuticals U.S.A. Inc; October 2016.
5. Clotrimazole 7 day vaginal cream [prescribing information]. Hawthorne, NY: Taro Pharmaceuticals U.S.A. Inc; July 2012.
6. Monistat Dual-Pak [package insert]. Personal Products Co; July 1999

NORTH DAKOTA MEDICAID
RETROSPECTIVE DRUG UTILIZATION REVIEW
CRITERIA RECOMMENDATIONS
4TH QUARTER 2018

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

1. Tezacaftor/Ivacaftor;Ivacaftor / Overutilization _____ _____

Alert Message: Symdeko (tezacaftor/ivacaftor;ivacaftor) may be over-utilized. The manufacturer's recommended maximum daily dose is one (1) tezacaftor 100 mg/ivacaftor 150 mg fixed-dose combination tablet in the morning and one (1) 150 mg ivacaftor tablet in the evening, given 12 hours apart.

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C
Tezacaftor/Ivacaftor;Ivacaftor		

Max Dose: 1 Box/month = 60 tablets/month

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Symdeko Prescribing Information, Feb. 2018, Vertex Pharmaceuticals Incorporated.

2. Tezacaftor/Ivacaftor;Ivacaftor / Nonadherence _____ _____

Alert Message: Based on refill history, your patient may be under-utilizing Symdeko (tezacaftor/ivacaftor;ivacaftor). 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
Tezacaftor/Ivacaftor;Ivacaftor		

References:
Symdeko Prescribing Information, Feb. 2018, Vertex Pharmaceuticals Incorporated.
Eakin MN, Bilderback A, Boyle MP, Mogayzel PJ, Riekert KA. Longitudinal Association between Medication Adherence and Lung Health in People with Cystic Fibrosis. Jrnl Cyst Fib. 2011;10(4):258-264.
Bishay LC, Sawicki. Strategies to Optimize Treatment Adherence in Adolescent Patients with Cystic Fibrosis. Adolesc Health, Med & Ther. 2016 Oct 21;7:117-124.

3. Tezacaftor/Ivacaftor;Ivacaftor / Therapeutic Appropriateness (0-11 yoa) _____ _____

Alert Message: The safety and efficacy of Symdeko (tezacaftor/ivacaftor;ivacaftor) in patients younger than 12 years of age have not been established.

Conflict Code: TA - Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C
Tezacaftor/Ivacaftor;Ivacaftor		

Age Range: 0 – 11 yoa

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Symdeko Prescribing Information, Feb. 2018, Vertex Pharmaceuticals Incorporated.

4. Tezacaftor/Ivacaftor;Ivacaftor / Strong CYP3A4 Inducers _____ _____

Alert Message: Concurrent use of Symdeko (tezacaftor/ivacaftor;ivacaftor) with a strong CYP3A4 inducer is not recommended. Both tezacaftor and ivacaftor are CYP3A4 substrates, and concomitant use with strong 3A4 inducers may result in reduced exposure and reduced efficacy.

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

Util A	Util B		Util C
Tezacaftor/Ivacaftor;Ivacaftor	Carbamazepine	Rifampin	
	Phenytoin	Mitotane	
	Phenobarbital	Enzalutamide	
	Primidone		

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Symdeko Prescribing Information, Feb. 2018, Vertex Pharmaceuticals Incorporated.

5. Tezacaftor/Ivacaftor;Ivacaftor / Strong CYP3A4 Inhibitors _____ _____

Alert Message: When Symdeko (tezacaftor/ivacaftor;ivacaftor) is co-administered with a strong CYP3A4 inhibitor, the dosing of tezacaftor/ivacaftor should be adjusted to one (1) tezacaftor 100 mg/ivacaftor 150 mg fixed-dose combination tablet twice a week (taken approximately 3 to 4 days apart. The evening dose of ivacaftor 150 mg should not be taken. Both tezacaftor and ivacaftor are CYP3A4 substrates, and concomitant use with strong CYP3A4 inhibitors may significantly increase substrate exposure and risk of adverse effects.

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

Util A	Util B		Util C
Tezacaftor/Ivacaftor;Ivacaftor	Clarithromycin	Indinavir	
	Nefazodone	Ketoconazole	
	Cobicistat	Itraconazole	
	Saquinavir	Posaconazole	
	Ritonavir	Voriconazole	
	Nelfinavir		

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Symdeko Prescribing Information, Feb. 2018, Vertex Pharmaceuticals Incorporated.

6. Tezacaftor/Ivacaftor;Ivacaftor / Moderate CYP3A4 Inhibitors _____ _____

Alert Message: When Symdeko (tezacaftor/ivacaftor;ivacaftor) is co-administered with a moderate CYP3A4 inhibitor, the dosing of tezacaftor/ivacaftor should be adjusted to one (1) tezacaftor 100 mg/ivacaftor 150 mg fixed-dose combination tablet every other day in the morning, and one (1) ivacaftor 150 mg tablet every other day in the morning on alternate days (i.e., tezacaftor/ivacaftor tablet on Day 1 and ivacaftor tablet on Day 2). The evening dose of ivacaftor should not be taken.

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

Util A	Util B			Util C
Tezacaftor/Ivacaftor;Ivacaftor	Diltiazem	Dronedarone	Crizotinib	
	Verapamil	Cyclosporine	Clotrimazole	
	Fluconazole	Imatinib		
	Erythromycin	Fluvoxamine		
	Aprepitant	Cimetidine		

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Symdeko Prescribing Information, Feb. 2018, Vertex Pharmaceuticals Incorporated.

7. Tezacaftor/Ivacaftor;Ivacaftor / Moderate to Severe Hepatic Impairment _____ _____

Alert Message: A reduced dose of Symdeko (tezacaftor/ivacaftor;ivacaftor) is recommended in patients with moderate hepatic impairment (Child-Pugh Class B) and severe hepatic impairment (Child-Pugh Class C). Patients with moderate impairment should receive one (1) tezacaftor 100 mg/ivacaftor 150 mg fixed-dose combination tablet once daily and NO ivacaftor 150 mg dose. Patients with severe impairment should receive one (1) tezacaftor 100 mg/ivacaftor 150 mg fixed-dose combination tablet once daily (or less frequently) and NO ivacaftor 150 mg dose.

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

Util A	Util B	Util C
Tezacaftor/Ivacaftor;Ivacaftor	Cirrhosis	
	Hepatic Failure	

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Symdeko Prescribing Information, Feb. 2018, Vertex Pharmaceuticals Incorporated.

8. Tezacaftor/Ivacaftor;Ivacaftor / P-gp Substrates w/ NTI _____ _____

Alert Message: Caution and appropriate monitoring should be used when Symdeko (tezacaftor/ivacaftor;ivacaftor) is co-administered with a P-gp substrate with a narrow therapeutic index. The ivacaftor component of the co-packaged combination product is a P-gp inhibitor, and concurrent use with a P-gp substrate may result in increased substrate exposure.

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

Util A	Util B	Util C
Tezacaftor/Ivacaftor;Ivacaftor	Digoxin	
	Cyclosporine	
	Everolimus	
	Sirolimus	
	Tacrolimus	

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Symdeko Prescribing Information, Feb. 2018, Vertex Pharmaceuticals Incorporated.

9. Doxylamine/Pyridoxine / Overutilization _____ _____

Alert Message: The maximum recommended dose of Bonjesta (doxylamine/pyridoxine extended-release) is two tablets per day, one in the morning and one at bedtime.

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C
Doxylamine/Pyridoxine		

Max Dose: 2 tablets/day

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Bonjesta Prescribing Information, June 2018. Duchesnay Inc.

10. Doxylamine/Pyridoxine / MAO Inhibitors _____ _____

Alert Message: The use of Bonjesta (doxylamine/pyridoxine extended-release) is contraindicated in women who are taking monoamine oxidase inhibitors (MAOIs). Concurrent use of MAOIs with doxylamine/pyridoxine can prolong and intensify the adverse central nervous system effects of the doxylamine component of the combination antiemetic.

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

Util A	Util B	Util C
Doxylamine/Pyridoxine	Isocarboxazid	
	Phenelzine	
	Tranylcypromine	

References:
Bonjesta Prescribing Information, June 2018. Duchesnay Inc.

11. Doxylamine/Pyridoxine / CNS Depressants _____ _____

Alert Message: Concurrent use of Bonjesta (doxylamine/pyridoxine extended-release) with other CNS depressants, including alcohol, is not recommended. The doxylamine component of the antiemetic may cause somnolence and severe drowsiness. Coadministration with CNS depressants may enhance the sedative effects of doxylamine.

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

Util A	Util B	Util C
Doxylamine/Pyridoxine	Sedatives	
	Anxiolytics	
	Narcotics	
	Barbiturates	
	Muscle Relaxants	

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Bonjesta Prescribing Information, June 2018. Duchesnay Inc.

12. Doxylamine/Pyridoxine / Certain Disease State _____ _____

Alert Message: Bonjesta (doxylamine/pyridoxine extended-release) should be used with caution in patients with asthma, increased intraocular pressure, narrow-angle glaucoma, stenosing peptic ulcer, pyloroduodenal obstruction, and urinary bladder-neck obstruction. The anticholinergic effects of the doxylamine component of the antiemetic product may worsen symptoms of these conditions.

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

Util A	Util B	Util C
Doxylamine/Pyridoxine	Asthma	
	Increased Intraocular Pressure	
	Narrow Angle Glaucoma	
	Peptic Ulcer	
	Obstruction of Duodenum	
	Bladder-neck Obstruction	

References:
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Bonjesta Prescribing Information, June 2018. Duchesnay Inc.

13. Benzhydrocodone/Acetaminophen / Overutilization _____ _____

Alert Message: Apadaz (benzhydrocodone/acetaminophen) may be over-utilized. The manufacturer recommends that the benzhydrocodone/acetaminophen dosage should not exceed 12 tablets in a 24-hour period.

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C
Benzhydrocodone/Acetaminophen		

Max Dose: 12 tabs/day

References:
Apadaz Prescribing Information, Feb. 2018, KemPharm, Inc.

14. Benzhydrocodone/Acetaminophen / CYP3A4 Inhibitors _____ _____

Alert Message: Concomitant use of Apadaz (benzhydrocodone/acetaminophen) with a CYP3A4 inhibitor may result in an increase in hydrocodone plasma concentrations, which could increase or prolong hydrocodone-related adverse reactions and may cause potentially fatal respiratory depression. Consider dosage reduction of benzhydrocodone/acetaminophen until stable drug effects are achieved. After stopping a CYP3A4 inhibitor, as the effects of the inhibitor decline, the hydrocodone plasma concentration will decrease, resulting in decreased opioid efficacy or a withdrawal syndrome in a patient who has developed a physical dependence on hydrocodone.

Conflict Code: DD – Drug/Drug Interaction (Black Box Warning)
Drugs/Diseases

Util A	Util B			Util C
Benzhydrocodone/Acetaminophen	Clarithromycin	Nefazodone	Erythromycin	
	Cobicistat	Ketoconazole	Ciprofloxacin	
	Conivaptan	Itraconazole	Crizotinib	
	Ritonavir	Posaconazole	Cyclosporine	
	Saquinavir	Voriconazole	Dronedarone	
	Indinavir	Diltiazem	Fluvoxamine	
	Nelfinavir	Verapamil	Imatinib	
	Atazanavir	Aprepitant	Clotrimazole	
	Tipranavir	Fluconazole	Idelalisib	
	Cimetidine	Chlorzoxazone	Cilostazol	
	Ivacaftor	Ranitidine		
	Ranolazine	Tacrolimus		
	Idelalisib	Ticagrelor		

References:
Apadaz Prescribing Information, Feb. 2018, KemPharm, Inc.

15. Benzhydrocodone/Acetaminophen / CYP3A4 Inducers _____ _____

Alert Message: Concurrent use of Apadaz (benzhydrocodone/acetaminophen) with a CYP3A4 inducer can cause a decrease in the hydrocodone plasma concentration, resulting in decreased efficacy or onset of a withdrawal syndrome in patients who have developed a physical dependence on hydrocodone. After stopping a CYP3A4 inducer, the hydrocodone plasma concentration will increase, which could increase or prolong both the therapeutic effects and adverse reactions, and may cause serious respiratory depression. If a CYP3A4 inducer is discontinued, consider benzhydrocodone/acetaminophen dosage reduction.

Conflict Code: DD – Drug/Drug Interaction (Black Box Warning)
Drugs/Diseases

Util A	Util B			Util C
Benzhydrocodone/Acetaminophen	Carbamazepine	Rifampin	Bosentan	
	Phenobarbital	Rifabutin	Efavirenz	
	Primidone	Rifapentine	Etravirine	
	Phenytoin	Mitotane	Modafinil	
	Enzalutamide	Nevirapine		

References:
Apadaz Prescribing Information, Feb. 2018, KemPharm, Inc.

16. Benzhydrocodone/Acetaminophen / MAO Inhibitors _____ _____

Alert Message: The use of Apadaz (benzhydrocodone/acetaminophen) is not recommended for patients taking monoamine oxidase inhibitors or within 14 days of stopping MAOI treatment. Concurrent use may manifest as serotonin syndrome or opioid toxicity (e.g., respiratory depression and coma).

Conflict Code: DD – Drug/Drug Interaction (Black Box Warning)
Drugs/Diseases

Util A	Util B	Util C
Benzhydrocodone/Acetaminophen	Isocarboxazid	
	Phenelzine	
	Tranylcypromine	
	Rasagiline	
	Linezolid	

References:
Apadaz Prescribing Information, Feb. 2018, KemPharm, Inc.

17. Benzhydrocodone/Acetaminophen / Dual 3A4/2D6 Inhibitor _____ _____

Alert Message: Concurrent use of Apadaz (benzhydrocodone/acetaminophen) and drugs that inhibit both CYP3A4 and CYP2D6 metabolism can increase the hydrocodone plasma concentration, resulting in increased or prolonged opioid effects. Consider benzhydrocodone/acetaminophen dosage reduction until stable drug effects are achieved. After stopping a dual CYP3A4/CYP2D6 inhibitor, as the effects of the inhibitor decline, the hydrocodone plasma concentration will decrease, resulting in decreased opioid efficacy or a withdrawal syndrome in a patient who had developed a physical dependence on hydrocodone.

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

Util A	Util B	Util C
Benzhydrocodone/Acetaminophen	Fluvoxamine	

References:
Apadaz Prescribing Information, Feb. 2018, KemPharm, Inc.

18. Benzhydrocodone/Acetaminophen / Serotonergic Agents _____ _____

Alert Message: Concurrent use of Apadaz (benzhydrocodone/acetaminophen) with other drugs that affect the serotonergic neurotransmitter system may result in serotonin syndrome. If concomitant use is warranted, carefully observe the patient, particularly during treatment initiation and dose adjustment. Discontinue benzhydrocodone/acetaminophen if serotonin syndrome is suspected.

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

Util A	Util B		Util C
Benzhydrocodone/Acetaminophen	SSRIs	Mirtazapine	
	SNRIs	Trazodone	
	TCAs	Tramadol	
	Triptans		

References:
Apadaz Prescribing Information, Feb. 2018, KemPharm, Inc.
Rastogi R. Swarm RA, Patek TA. Case Scenario: Opioid Association with Serotonin Syndrome. Anesthesiology. 2011 Dec;115(6):1291-1298.
Gillman PK. Monoamine Oxidase Inhibitors, Opioid Analgesics and Serotonin Toxicity. Br J Anaesth. 2005;95:434-441.

19. Benzhydrocodone/Acetaminophen / Muscle Relaxants _____ _____

Alert Message: Concurrent use of Apadaz (benzhydrocodone/acetaminophen) with muscle relaxants may enhance the neuromuscular blocking action of skeletal muscle relaxants and produce an increased degree of respiratory depression. Monitor the patient for signs of respiratory depression that may be greater than otherwise expected. A dosage decrease of benzhydrocodone/acetaminophen and/or the muscle relaxant may be necessary.

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

Util A	Util B		Util C
Benzhydrocodone/Acetaminophen	Baclofen	Methocarbamol	
	Carisoprodol	Orphenadrine	
	Chlorzoxazone	Tizanidine	
	Cyclobenzaprine	Dantrolene	
	Metaxalone		

References:
Apadaz Prescribing Information, Feb. 2018, KemPharm, Inc.

20. Benzhydrocodone/Acetaminophen / Diuretics _____ _____

Alert Message: Concurrent use of Apadaz (benzhydrocodone/acetaminophen) with a diuretic may result in reduced diuretic efficacy due to the opioid-induced release of antidiuretic hormone. If coadministration is warranted, monitor the patient for signs and symptoms of diminished diuresis and/or decreased effects on blood pressure. Dosage adjustment of the diuretic may be necessary.

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

Util A	Util B		Util C
Benzhydrocodone/Acetaminophen	Furosemide	Chlorothiazide	
	Bumetanide	Chlorthalidone	
	Ethacrynic	Hydrochlorothiazide	
	Torsemide	Indapamide	
	Amiloride	Methyclothiazide	
	Spironolactone	Metolazone	
	Triamterene	Eplerenone	

References:
Apadaz Prescribing Information, Feb. 2018, KemPharm, Inc.

21. Benzhydrocodone/Acetaminophen / Anticholinergic Agents _____ _____

Alert Message: Concurrent use of Apadaz (benzhydrocodone/acetaminophen) with anticholinergic drugs may increase the risk of urinary retention and severe constipation, which may lead to paralytic ileus. If concomitant use is warranted, monitor the patient for signs of urinary retention or reduced gastric motility.

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

Util A	Util B			Util C
Benzhydrocodone/Acetaminophen	Trifluoperazine	Thioridazine	Promethazine	
	Trihexyphenidyl	Benztropine	Orphenadrine	
	Clozapine	Olanzapine	Quetiapine	
	Belladonna	Atropine	Propantheline	
	Glycopyrrolate	Mepenzolate	Dicyclomine	
	Flavoxate	Oxybutynin	Trospium	
	Tolterodine	Solifenacin	Darifenacin	
	Fesoterodine	Diphenhydramine	Brompheniramine	
	Meclizine	Clemastine	Chlorpheniramine	
	Hydroxyzine			

References:
Apadaz Prescribing Information, Feb. 2018, KemPharm, Inc.

22. Benzhydrocodone/Acetaminophen / Therapeutic Appropriateness _____ _____

Alert Message: The safety and effectiveness of Apadaz (benzhydrocodone/acetaminophen) in pediatric patients below the age of 18 years have not been established.

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C
Benzhydrocodone/Acetaminophen		

Age Range: 0 – 17 yoa

References:
Apadaz Prescribing Information, Feb. 2018, KemPharm, Inc.

23. Baricitinib / Overutilization _____ _____

Alert Message: The recommended dose of Olumiant (baricitinib) is 2 mg per day.

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C
Baricitinib		

Max Dose: 2mg/day

References:
Olumiant Prescribing Information, May 2018, Eli Lilly and Company.

24. Baricitinib / 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 Olumiant (baricitinib). If a serious infection develops, interrupt baricitinib therapy until the infection is controlled.

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

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

References:
Olumiant Prescribing Information, May 2018, Eli Lilly and Company.

25. Baricitinib / Therapeutic Appropriateness (0 – 17 yoa) _____ _____

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

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C
Baricitinib		

Age Range: 0- 17 yoa

References:
Olumiant Prescribing Information, May 2018, Eli Lilly and Company.

26. Baricitinib / Thrombosis Risk Factors Black Box Warning _____ _____

Alert Message: Olumiant (baricitinib) should be used with caution in patients who are at increased risk for thrombosis. Thrombosis, including deep venous thrombosis (DVT) and pulmonary embolism (PE), has been observed at an increased incidence in patients treated with baricitinib compared to placebo. If clinical features of DVT/PE or arterial thrombosis occur, patients should be evaluated promptly and treated appropriately.

Conflict Code: MC – Drug/Disease Precaution
Drugs/Diseases

Util A	Util B	Util C
Baricitinib	Pregnancy	
	Smoking	
	Cancer	
	Heart Failure	
	Hx of DVT or PE	
	Hypercoagulable State, Secondary	

References:
Olumiant Prescribing Information, May 2018, Eli Lilly and Company.

27. Baricitinib / GI Perforations Risk Factors _____ _____

Alert Message: Olumiant (baricitinib) 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 glucocorticoids or NSAIDs). Events of gastrointestinal perforation have been reported in clinical studies with baricitinib. Patients presenting with new onset abdominal symptoms should be evaluated promptly for early identification of gastrointestinal perforation.

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B		Util C
Baricitinib	Diverticulitis	Methylprednisolone	
	NSAIDS	Prednisolone	
	Budesonide	Prednisone	
	Cortisone	Deflazacort	
	Deflazacort	Dexamethasone	
	Hydrocortisone		

References:
Olumiant Prescribing Information, May 2018, Eli Lilly and Company.

28. Baricitinib / Renal Impairment _____ _____

Alert Message: Olumiant (baricitinib) is not recommended for use in patients with estimated GFR of less than 60 mL/min/1.73m2. Baricitinib is excreted substantially by the kidney, and the risk of baricitinib-related adverse reactions may be greater in patients with impaired renal function.

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C **(Included)**
Baricitinib		CKD 3, 4, & 5
		ESRD

References:
Olumiant Prescribing Information, May 2018, Eli Lilly and Company.

29. Baricitinib / Severe Hepatic Impairment _____ _____

Alert Message: Olumiant (baricitinib) is not recommended in patients with severe hepatic impairment. The drug has not been studied in this population.

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C **(Included)**
Baricitinib		Cirrhosis
		Hepatic Fibrosis

References:
Olumiant Prescribing Information, May 2018, Eli Lilly and Company.

30. Baricitinib / OAT3 Inhibitors _____ _____

Alert Message: Olumiant (baricitinib) is not recommended for use in patients taking strong organic anion transporter 3 (OAT3) inhibitors. Baricitinib is an OAT3 substrate, and concurrent use with a strong inhibitor of OAT transport may result in increased baricitinib exposure.

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

Util A	Util B	Util C
Baricitinib	Probenecid	
	Teriflunomide	
	Leflunomide	

References:
Olumiant Prescribing Information, May 2018, Eli Lilly and Company.

31. Baricitinib / Biologics & DMARDs _____ _____

Alert Message: Use of Olumiant (baricitinib) in combination with other JAK inhibitors, biologic DMARDs, or with potent immunosuppressants such as azathioprine and cyclosporine is not recommended because of the potential for increased immunosuppression and increased infection risk.

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

Util A	Util B		Util C
Baricitinib	Tofacitinib	Guselkumab	
	Cyclosporine	Infliximab	
	Abatacept	Ixekizumab	
	Adalimumab	Rituximab	
	Anakinra	Sarilumab	
	Azathioprine	Secukinumab	
	Canakinumab	Ustekinumab	
	Certolizumab	Golimumab	
	Daclizumab	Etanercept	

References:
Olumiant Prescribing Information, May 2018, Eli Lilly and Company.

32. Baricitinib / Tuberculosis _____ _____

Alert Message: Serious infections leading to hospitalization or death, including tuberculosis, have occurred in patients receiving Olumiant (baricitinib). Prior to starting baricitinib, perform a test for latent tuberculosis; if it is positive, start treatment for tuberculosis prior to starting baricitinib. Monitor all patients for active tuberculosis during baricitinib treatment, even if the initial latent tuberculosis test is negative.

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C
Baricitinib	Tuberculosis	

References:
Olumiant Prescribing Information, May 2018, Eli Lilly and Company.

33. Baricitinib / Nonadherence _____ _____

Alert Message: Based on refill history, your patient may be under-utilizing Olumiant (baricitinib). 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
Baricitinib		

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.

34. Elagolix / Overutilization _____ _____

Alert Message: The recommended maximum dose of Orilissa (elagolix) is 400 mg a day (200 mg twice daily). Treatment duration at this dose should be limited to 6 months due to the risk of bone loss. Bone mineral density (BMD) loss is greater with increasing duration of elagolix use and may not be completely reversible after stopping treatment.

Conflict Code: ER - Overutilization
Drugs/Diseases

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

Max Dose: 400 mg/day

References:
Orilissa Prescribing Information, July 2018, AbbVie Inc.

35. Elagolix / Overutilization _____ _____

Alert Message: Orilissa (elagolix) may be over-utilized. The recommended dose of elagolix in patients with moderate hepatic impairment is 150 mg once daily for a maximum duration of 6 months. Elagolix 200 mg twice a day is not recommended for women with moderate hepatic impairment due to the risk of bone loss. In a clinical study, women with moderate hepatic impairment taking elagolix had approximately 3-fold higher elagolix exposure compared to women with normal hepatic function.

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C **(Include)**
Elagolix		Moderate Hepatic Impairment

Max Dose: 150 mg/day

References:
Orilissa Prescribing Information, July 2018, AbbVie Inc.

36. Elagolix / Severe Hepatic Impairment _____ _____

Alert Message: Treatment with Orilissa (elagolix) is contraindicated in women with severe hepatic disease (Child-Pugh B) due to the risk of bone loss. Elagolix causes a dose-dependent decrease in bone mineral density (BMD). In a clinical study, women with severe hepatic impairment taking elagolix had approximately 7-fold higher elagolix exposure compared to women with normal hepatic function.

Conflict Code: MC - Drug Actual Disease Problem
Drugs/Diseases

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

References:
Orilissa Prescribing Information, July 2018, AbbVie Inc.

37. Elagolix / Pregnancy / Pregnancy Negating _____ _____

Alert Message: Treatment with Orilissa (elagolix) is contraindicated in women who are pregnant. Exposure to elagolix early in pregnancy may increase the risk of early pregnancy loss. Elagolix treatment should be discontinued if the patient becomes pregnant during treatment.

Conflict Code: MC - Drug Actual Disease Problem
Drugs/Diseases

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

References:
Orilissa Prescribing Information, July 2018, AbbVie Inc.

38. Elagolix / Osteoporosis _____ _____

Alert Message: Orilissa (elagolix) use is contraindicated in women with known osteoporosis. Elagolix is a gonadotropin-releasing hormone (GnRH) receptor antagonist which causes a dose-dependent decrease in bone mineral density (BMD).

Conflict Code: MC - Drug Actual Disease Problem
Drugs/Diseases

Util A	Util B	Util C **(Include)**
Elagolix		Osteoporosis

References:
Orilissa Prescribing Information, July 2018, AbbVie Inc.

39. Elagolix / Strong OATP1B1 Inhibitors _____ _____

Alert Message: The concurrent use of Orilissa (elagolix) with strong OATP1B1 inhibitors is contraindicated. Elagolix is an OATP1B1 substrate and concomitant use with drugs that inhibit OATP1B1 transport may increase elagolix plasma concentrations.

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

Util A	Util B	Util C
Elagolix	Cyclosporine	
	Gemfibrozil	
	Cobicistat	
	Clarithromycin	
	Erythromycin	
	Paritaprevir	
	Eltrombopag	
	Glecaprevir	
	Ritonavir	

References:
Orilissa Prescribing Information, July 2018, AbbVie Inc.

40. Elagolix / Digoxin _____ _____

Alert Message: The concurrent use of Orilissa (elagolix) with digoxin may increase digoxin exposure. Elagolix is an inhibitor of the P-glycoprotein (P-gp) efflux transporter, and digoxin is a P-gp substrate with a narrow therapeutic index. In a clinical drug interaction study, concurrent use of elagolix with digoxin resulted in an increase in the digoxin Cmax and AUC, by 71% and 26%, respectively. Clinical monitoring of digoxin is recommended when co-administered with elagolix.

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

Util A	Util B	Util C
Elagolix	Digoxin	

References:
Orilissa Prescribing Information, July 2018, AbbVie Inc.

41. Elagolix 200 mg / Strong CYP3A Inhibitors _____ _____

Alert Message: Coadministration of Orilissa (elagolix) 200 mg twice daily and strong CYP3A inhibitors for more than 1 month is not recommended. Elagolix is a CYP3A substrate, and concurrent use with a strong CYP3A inhibitor may increase elagolix plasma concentrations.

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

Util A	Util B		Util C
Elagolix 200 mg	Nefazodone	Saquinavir	
	Clarithromycin	Ritonavir	
	Ketoconazole	Indinavir	
	Itraconazole	Nelfinavir	
	Posaconazole	Cobicistat	
	Voriconazole		

Duration: > 30 days

References:
Orilissa Prescribing Information, July 2018, AbbVie Inc.

42. Elagolix / CYP3A Inducers _____ _____

Alert Message: The concurrent use of Orilissa (elagolix), a CYP3A substrate, with a CYP3A inducer may decrease elagolix plasma concentrations. Monitor the patient for decreased elagolix efficacy.

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

Util A	Util B	Util C
Elagolix	Carbamazepine	
	Phenytoin	
	Primidone	
	Phenobarbital	

References:
Orilissa Prescribing Information, July 2018, AbbVie Inc.

43. Elagolix 200 mg / Rifampin _____ _____

Alert Message: Concomitant use of Orilissa (elagolix) 200 mg twice daily and rifampin is not recommended. If concurrent therapy with rifampin and elagolix is warranted, the elagolix dose should not exceed 150 mg once daily and the duration of the combined therapy limited to 6 months.

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

Util A	Util B	Util C
Elagolix 200mg	Rifampin	

References:
Orilissa Prescribing Information, July 2018, AbbVie Inc.

44. Elagolix / Midazolam _____ _____

Alert Message: The concurrent use of Orilissa (elagolix) with midazolam may decrease midazolam exposure. In a clinical drug interaction study, coadministration of elagolix with midazolam resulted in a decrease in midazolam AUC and Cmax. Consider increasing the dose of midazolam and individualize therapy based on the patient's response.

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

Util A	Util B	Util C
Elagolix	Midazolam	

References:
Orilissa Prescribing Information, July 2018, AbbVie Inc.

45. Elagolix / Rosuvastatin _____ _____

Alert Message: The concurrent use of Orilissa (elagolix) with rosuvastatin may decrease rosuvastatin exposure. In a clinical drug interaction study, coadministration of elagolix with rosuvastatin resulted in a 40% decrease in rosuvastatin AUC. Monitor lipid panel and adjust rosuvastatin dose if necessary.

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

Util A	Util B	Util C
Elagolix	Rosuvastatin	

References:
Orilissa Prescribing Information, July 2018, AbbVie Inc.
Center for Drug Evaluation and Research, Orilissa and elagolix sodium, Multi-Discipline Review Application Number 201450), 2017.
Available at: https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/210450Orig1s000MultiD.pdf

46. Elagolix / Estrogen-Containing Contraceptives _____ _____

Alert Message: Based on the mechanism of action of Orilissa (elagolix), estrogen-containing contraceptives are expected to reduce the efficacy of elagolix. The effect of progestin-only contraceptives on the efficacy of elagolix is unknown. Advise women of childbearing potential to use non-hormonal contraceptives during treatment with elagolix and for one week after discontinuing elagolix.

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

Util A	Util B	Util C
Elagolix	Estrogen-Containing Contraceptives	

References:
Orilissa Prescribing Information, July 2018, AbbVie Inc.

47. Elagolix / Therapeutic Appropriateness _____ _____

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

Conflict Code: TA - Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C
Elagolix		

Age Range: 0 – 17 yoa

References:
Orilissa Prescribing Information, July 2018, AbbVie Inc.

48. Abemaciclib / Moderate CYP3A4 Inhibitors _____ _____

Alert Message: The concurrent use of Verzenio (abemaciclib), a CYP3A4 substrate, with a moderate CYP3A4 inhibitor may increase the exposure of abemaciclib and its active metabolites, leading to abemaciclib toxicity. With concomitant use of moderate CYP3A4 inhibitors, monitor the patient for adverse reactions and consider reducing the abemaciclib dose in 50 mg decrements as demonstrated in the official package labeling, if necessary.

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

Util A	Util B	Util C
Abemaciclib	Amiodarone	Erythromycin
	Verapamil	Ciprofloxacin
	Diltiazem	Fluconazole
	Aprepitant	Atazanavir
	Lapatinib	Fosamprenavir
	Crizotinib	Darunavir

References:
Verzenio Prescribing Information, August 2018, Eli Lilly and Company.

49. 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

50. Fluoroquinolones / Myasthenia Gravis _____ _____

Alert Message: Fluoroquinolones may exacerbate muscle weakness in patients with myasthenia gravis. Avoid use of fluoroquinolones in patients with known history of myasthenia gravis.

Conflict Code: TA – Therapeutic Appropriateness (Black Box Warning)
Drugs/Diseases

Util A	Util B	Util C (Include)
Ciprofloxacin		Myasthenia Gravis
Delafloxacin		
Gemifloxacin		
Levofloxacin		
Moxifloxacin		
Ofloxacin		

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

51. Fluoroquinolones / Blood Glucose Disturbances _____ _____

Alert Message: Fluoroquinolone antibiotics may cause significant disturbances in blood glucose and certain mental health side effects. The low blood glucose levels can result in serious problems, including coma, particularly in older people and patients with diabetes who are taking medicines to reduce blood glucose.

Conflict Code: TA – Therapeutic Appropriateness

Drugs/Diseases

Util A	Util B	Util C
Ciprofloxacin		
Delafloxacin		
Gemifloxacin		
Levofloxacin		
Moxifloxacin		
Ofloxacin		

References:

Food and Drug Administration. FDA Drug Safety communication: FDA reinforces safety information about serious low blood sugar levels and mental health side effects with fluoroquinolone antibiotics; requires label changes. [07-10-2018]. Available at: https://www.fda.gov/Drugs/DrugSafety/ucm611032.htm
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Facts & Comparisons, 2018 Updates, Wolters Kluwer Health.

52. Fluoroquinolones / Antidiabetic Medications _____ _____

Alert Message: Disturbances of blood glucose, including symptomatic hyperglycemia and hypoglycemia, have been reported in diabetic patients receiving concomitant treatment with an antidiabetic agent. Severe cases of hypoglycemia resulting in coma or death have been reported. Careful monitoring of blood glucose is recommended when these agents are coadministered. Stop the fluoroquinolone immediately if a patient reports glucose disturbances and switch to a non-fluoroquinolone antibiotic if possible.

Conflict Code: MC – Drug (Actual) Disease Warning

Drugs/Diseases

Util A	Util B	Util C
Ciprofloxacin	Insulin	
Delafloxacin	Antidiabetic Medications	
Gemifloxacin		
Levofloxacin		
Moxifloxacin		
Ofloxacin		

References:

Food and Drug Administration. FDA Drug Safety communication: FDA reinforces safety information about serious low blood sugar levels and mental health side effects with fluoroquinolone antibiotics; requires label changes. [07-10-2018]. Available at: https://www.fda.gov/Drugs/DrugSafety/ucm611032.htm
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Facts & Comparisons, 2018 Updates, Wolters Kluwer Health.

53. Fluoroquinolones / Psychiatric Adverse Reactions _____ _____

Alert Message: Fluoroquinolone antibiotics have been associated with an increased risk of psychiatric adverse reactions (e.g., disturbances in attention, memory impairment, delirium, nervousness, agitation, disorientation, hallucinations, and self-injurious behavior). These adverse reactions can occur after just one dose. Stop the fluoroquinolone immediately if a patient reports any central nervous system side effects, including psychiatric reactions and switch to a non-fluoroquinolone antibiotic if possible.

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

Util A	Util B	Util C
Ciprofloxacin	Altered mental Status	
Delafloxacin	Hallucinations	
Gemifloxacin	Intentional Self Harm	
Levofloxacin	Nervousness	
Moxifloxacin	Disorientation	
Ofloxacin	Agitation	

References:
Food and Drug Administration. FDA Drug Safety communication: FDA reinforces safety information about serious low blood sugar levels and mental health side effects with fluoroquinolone antibiotics; requires label changes. [07-10-2018]. Available at: https://www.fda.gov/Drugs/DrugSafety/ucm611032.htm
Clinical Pharmacology, 2018 Elsevier/Gold Standard.
Facts & Comparisons, 2018 Updates, Wolters Kluwer Health.

54. Asenapine / Therapeutic Appropriateness _____ _____

Alert Message: The safety and efficacy of Saphris (asenapine) for the treatment of Bipolar I disorder in pediatric patients below 10 years of age have not been established.

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C **(Include)**
Asenapine		Bipolar I Disorder Mania & Mixed Episodes

Age Range: 0 – 9 yoa

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

55. Mepolizumab / Overutilization _____ _____

Alert Message: The manufacturer's recommended dose of Nucala (mepolizumab) for eosinophilic granulomatosis with polyangiitis (EGPA) is 300 mg administered once every 4 weeks by subcutaneous injection.

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C **(Include)**
Mepolizumab		Polyarteritis with lung involvement [Churg-Strauss]

Max Dose: 3 injections/4 weeks

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

56. Mepolizumab / Therapeutic Appropriateness _____ _____

Alert Message: The manufacturer's recommended dose of Nucala (mepolizumab) for eosinophilic granulomatosis with polyangiitis (EGPA) is 300 mg administered once every 4 weeks by subcutaneous injection.

Conflict Code: TA - Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C **(Include)**
Mepolizumab		Polyarteritis with lung involvement [Churg-Strauss]

Age Range: ≤ 18 yoa

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