DUR Board Meeting
March 3, 2014
Pioneer Room
State Capitol

North Dakota Medicaid
DUR Board Meeting Agenda
Pioneer Room
State Capitol
600 East Blvd. Avenue
Bismarck, ND
March 3, 2014
1pm

1. Administrative items
    - Select Chair to Replace Greg Pfister for Balance of Term
    - Travel vouchers

2. Old business

• Review and Approval of Minutes of 12/13 Meeting	Chair
• Budget Update	Brendan
• Second Review of Statins	Brendan
• Second Review of Vecamyl	Brendan
• Coverage Clarification	Brendan

3. New business

• Review of Sylatron	HID
• Review of Cathflo	HID
• Review of Ketamine powder (agents that should not be used in an outpatient setting)	HID
• Review of Intranasal Cyanocobalamin Products	HID
• Review of Luzu	HID
• Review of Noxafil	HID
• Review of Bethkis	HID
• Update of New Drug Lookup Website	HID
• Criteria Recommendations	HID
• Upcoming Meeting Date/Agenda	Chair

4. Adjourn — Chair

Please remember to silence all cellular phones during the meeting.

Drug Utilization Review (DUR) Meeting Minutes
September 9, 2013

Members Present: Norman Byers, John Savageau, Greg Pfister, Jeffrey Hostetter, Peter Woodrow, Carlotta McCleary, Carrie Sorenson, Russ Sobotta, Tanya Schmidt

Members Absent: Cheryl Huber, Todd Twogood, Leann Ness, Steve Irsfeld, James Carlson, Michael Booth, Gary Betting

Medicaid Pharmacy Department: Brendan Joyce

HID Staff Present: Candace Rieth

Chair G. Pfister called the meeting to order at 1:00 pm. Chair G. Pfister asked for a motion to approve the minutes from the September meeting. N. Byers moved that the minutes be approved, and J. Hostetter seconded the motion. Chair G. Pfister called for a voice vote to approve the minutes. The motion passed with no audible dissent.

Budget Update
B. Joyce informed the board members that he has nothing new to share.

Board Update
The state law creating the DUR Board was reviewed with the members. Appointment to the board and term end dates were provided. Members were asked to help find replacements for their positions when their terms end. Board members were reminded that the executive director of the department may replace an appointed member of the board who fails to attend a DUR Board meeting three consecutive times without advance excuse.

Sirturo Second Review
A motion and second were made at the September meeting to place Sirturo on prior authorization. The topic was brought up for a second review. There was no public comment. After discussion, Chair G. Pfister called for a voice vote to approve the motion. The motion passed with no audible dissent.

Brisdelle Second Review
A motion and second were made at the September meeting to place Brisdelle on prior authorization. The topic was brought up for a second review. There was no public comment. After discussion, Chair G. Pfister called for a voice vote to approve the motion. The motion passed with no audible dissent.

Nitroglycerin Lingual Spray/Sublingual Tablets Second Review
A motion and second were made at the September meeting to place Nitroglycerin Lingual Spray on prior authorization. The topic was brought up for a second review. There was no public comment. After discussion, Chair G. Pfister called for a voice vote to approve the motion. The motion passed with no audible dissent.

Agents Used to Treat COPD Second Review
A motion and second were made at the September meeting to place agents used to treat COPD on prior authorization. The topic was brought up for a second review. After review of the data, B. Joyce recommended handling this with an age-based prior authorization (no PA required for those 40 years or older). There was no public comment. P. Woodrow made a motion to amend the original motion to state that an age-based prior authorization will be placed on these agents. G. Pfister seconded the motion. After discussion, Chair G. Pfister called for a voice vote to approve the motion. The motion passed with no audible dissent.

Epinephrine Auto-Injection Devices Second Review
A motion and second were made at the September meeting to place Epinephrine Auto-Injection Devices on prior authorization. The topic was brought up for a second review. There was no public comment. After discussion, Chair G. Pfister called for a voice vote to approve the motion. The motion passed with no audible dissent.

Pulmozyme Second Review
A motion and second were made at the December meeting to place Pulmozyme on prior authorization. The topic was brought up for a second review. D. Evans, representing Genentech spoke regarding Pulmozyme. After discussion, Chair G. Pfister called for a voice vote to approve the motion. The motion passed with no audible dissent.

Statin Review
B. Joyce reviewed statin information with the board. There was no public comment. J. Hostetter made a motion to place name-brand statins on prior authorization. G. Pfister seconded the motion. This topic will be reviewed at the next meeting.

Vecamyl Review
B. Joyce reviewed Vecamyl clinical information with the board. There was no public comment. G. Pfister made a motion to place Vecamyl on prior authorization. T. Schmidt seconded the motion. This topic will be reviewed at the next meeting.

Yearly PA Review
The Board reviews products annually that have previously been placed on prior authorization. This allows the Board a chance to update the prior authorization forms and criteria. All forms and criteria were reviewed. Changes include:

1. ACE-I/ARB/Renin Inhibitors PA form - include generic ARBs
2. Actoplus Met - add to combination form
3. Aczone - add to acne form
4. Carisoprodol and Soma 250 - combine into one form
5. Clorpress - add to combination form
6. Daliresp - add to COPD form
7. Gilenya - add specialist box on form
8. Hep C - add new products to market
9. Narcotics/APAP - add combo products with lower APAP dose to PA criteria
10. Moxeza - add to ophthalmic anti-infective form
11. PAH - add new products to market and add Revatio
12. Provigil/Nuvigil - combine into one form
13. Solodyn - combine with Doryx and Oracea
14. Tecfidera - add neurologist on form

Criteria Recommendations
The recommended RDUR criteria enclosed in the packet were developed from product information provided by the manufacturers and usually are consistent with new indications, new drugs added, new warnings, etc. These proposed criteria will be added to the current set of criteria and will be used in future DUR cycles. G. Pfister moved to approve the new criteria and C. Sorenson seconded the motion. Chair G. Pfister called for a voice vote. The motion passed with no audible dissent.

The next DUR board meeting will be held March 3, in Bismarck. N. Byers made a motion to adjourn the meeting. J. Hostetter seconded. The motion passed with no audible dissent. G. Pfister adjourned the meeting.

Statins
Prior Authorization

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-773-0695

Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that patients who are prescribed a name-brand statin must first try a generic statin.
Note:

- ***Generic statins already on the market do not require a prior authorization***

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:**		
Qualifications for coverage:			
□ Medication Failed _____	Start Date: End Date:	Dose: Frequency:	
Physician Signature		Date	

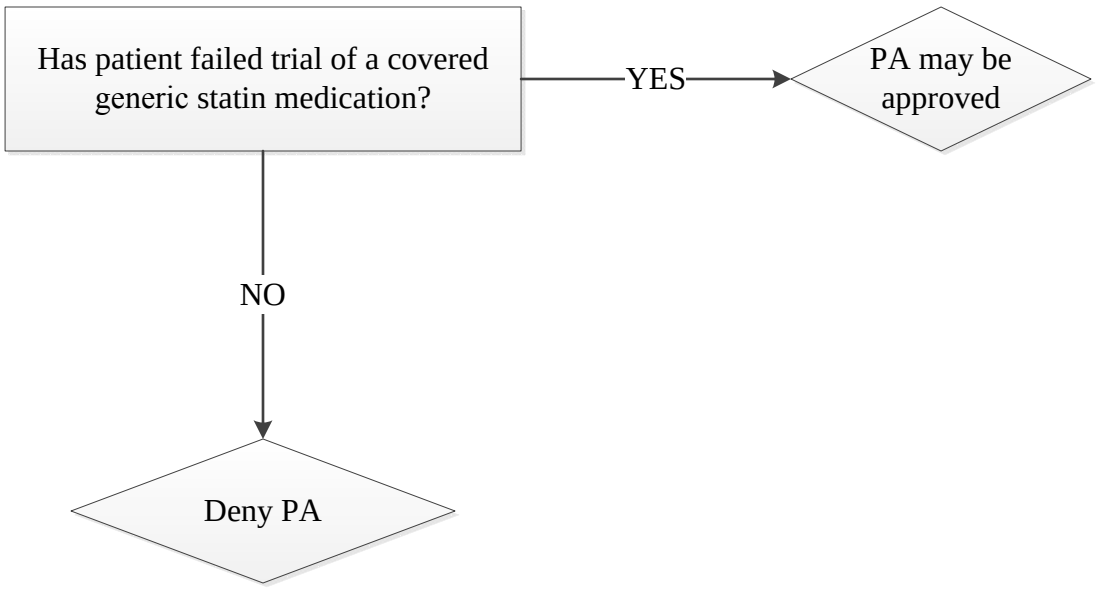
Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

Date Received	Initials:
Approved - Effective dates of PA: From: / / To: / /	Approved by:
Denied: (Reasons)	

North Dakota Department of Human Services
Statins Authorization Algorithm



VECAMYL
PA FORM

Prior Authorization Vendor for ND Medicaid

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-773-0695

ND Medicaid requires that patients receiving a new prescription for Vecamyl must meet the following criteria:

- **Patient must have an FDA approved indication.**
- **Must be prescribed by or in consultation with a hypertension specialist.**
- **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.**

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: □ VECAMYL	**Diagnosis for this Request:**		
Failed Therapy:	**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 Signature		Date	

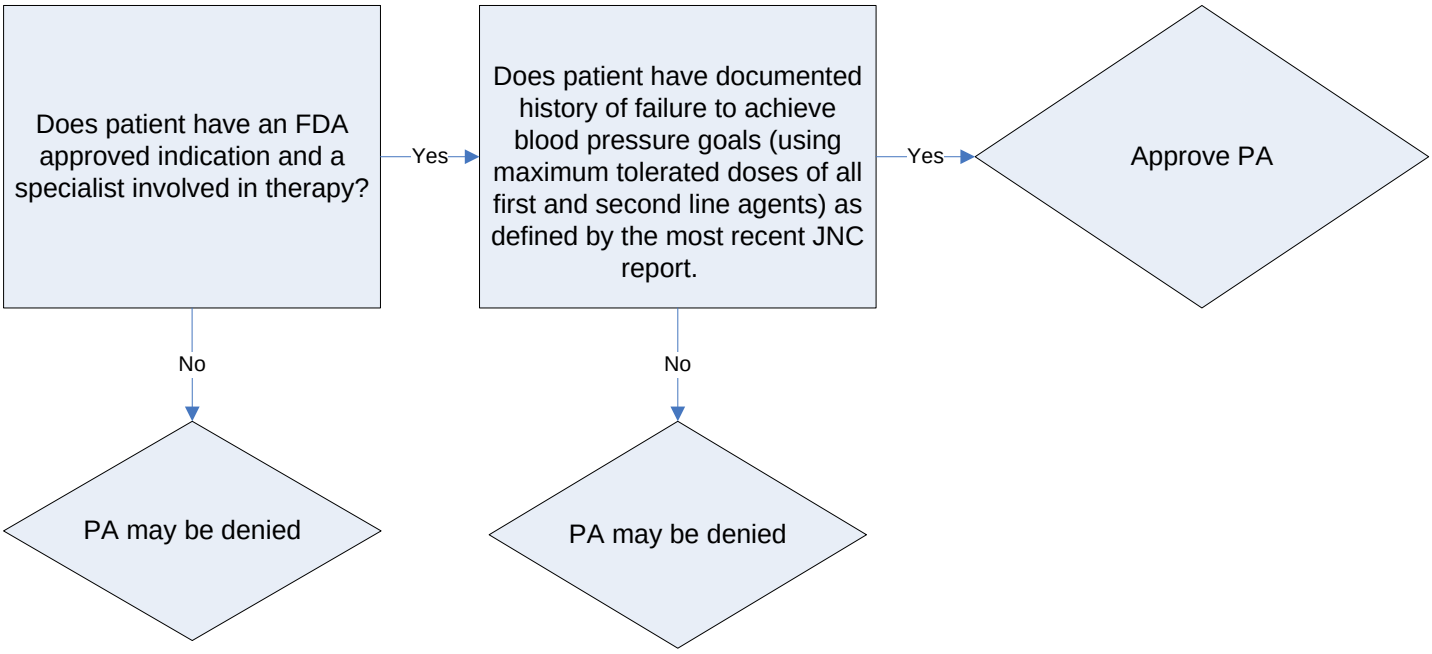
Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

Date Received	Initials:
Approved - Effective dates of PA: From: / / To: / /	Approved by:
Denied: (Reasons)	

North Dakota Department of Human Services
Vecamyl Prior Authorization Algorithm



Notice of Drug Coverage

The drug you selected is not covered under pharmacy services for North Dakota Medicaid. However, it is allowed under physician buy and bill services and should be billed by the physician's office.

North Dakota Department of Human Services
Sylatron Review

I. Indication

Sylatron is an alpha interferon indicated for the adjuvant treatment of melanoma with microscopic or gross nodal involvement within 84 days of definitive surgical resection including complete lymphadenectomy.

II. Dosage and Administration

- 6 mcg/kg/week subcutaneously for 8 doses followed by;
- 3 mcg/kg/week subcutaneously for up to 5 years.

III. Contraindications

1. Known serious hypersensitivity reactions to peginterferon alfa-2b or interferon alfa-2b.
2. Autoimmune hepatitis.
3. Hepatic decompensation (Child-Pugh score >6 [class B and C]).

IV. Warnings and Precautions

1. Depression and other serious neuropsychiatric adverse reactions.
2. History of significant or unstable cardiac disease.
3. Retinal disorders.
4. Child-Pugh score >6 (class B and C).
5. Hypothyroidism, hyperthyroidism, hyperglycemia, diabetes mellitus that cannot be effectively treated by medication.

V. Adverse Reactions

Most common adverse reactions (>60%) are fatigue, increased ALT, increased AST, pyrexia, headache, anorexia, myalgia, nausea, chills, and injection site reaction.

VI. Drug Interactions

- Drug metabolized by cytochrome P-450 (CYP) enzymes; monitor closely when used in combination with drugs metabolized by CYP2C9 or CYP2D6.

VII. Use in Specific Populations

1. Pregnancy: Based on animal data, may cause fetal harm.
2. Pediatrics: Safety and efficacy in patients <18 years old have not been established.
3. Renal Impairment: Increase frequency of monitoring for toxicity in patients with moderate and severe renal impairment.

VIII. Utilization

Sylatron Utilization			
12/24/2012 - 12/23/2013			
Label Name	**Rx Num**	**Total Reimb Amt**	**Average Cost per Script**
SYLATRON 444 MCG 4-PACK	4	$47,755.49	$11,938.87

References:

1. Sylatron® [package insert]. Whitehouse Station, NJ: Merck & Co., Inc.; December 2013.

North Dakota Department of Human Services
Cathflo Activase Review

I. Indication

Cathflo Activase (alteplase) is indicated for the restoration of function to central venous access devices as assessed by the ability to withdraw blood.

II. Dosage and Administration

Cathflo Activase is for instillation into the dysfunctional catheter at a concentration of 1 mg/mL.

- Patients weighing ≥ 30 kg: 2 mg in 2 mL
- Patients weighing < 30 kg: 110% of the internal lumen volume of the catheter, not to exceed 2 mg in 2 mL

If catheter function is not restored at 120 minutes after 1 dose, a second dose may be instilled. There is no efficacy or safety information on dosing in excess of 2 mg per dose for this indication. Studies have not been performed with administration of total doses greater than 4 mg (two 2 mg doses).

III. Precautions

- Catheter dysfunction may be caused by a variety of conditions other than thrombus formation, such as catheter malposition, mechanical failure, constriction by a suture, and lipid deposits or drug precipitates within the catheter lumen. These types of conditions should be considered before treatment.
- Because of the risk of damage to the vascular wall or collapse of soft-walled catheters, vigorous suction should not be applied during attempts to determine catheter occlusion.
- Excessive pressure should be avoided when Cathflo is instilled into the catheter. Such force could cause rupture of the catheter or expulsion of the clot into the circulation.
- Caution should be exercised with patients who have active internal bleeding or who have had any of the following within 48 hours: surgery, obstetrical delivery, percutaneous biopsy of viscera or deep tissues, or puncture of non-compressible vessels. In addition, caution should be exercised with patients who have thrombocytopenia, other hemostatic defects (including those secondary to severe hepatic or renal disease), or any condition for which bleeding constitutes a significant hazard or would be particularly difficult to manage because of its location, or who are at high risk for embolic complications (e.g., venous thrombosis in the region of the catheter). Death and permanent disability have been reported in patients who have experienced stroke and other serious bleeding episodes when receiving pharmacologic doses of a thrombolytic.
- Should be used with caution in the presence of known or suspected infection in the catheter.

IV. Adverse Reactions

In clinical trials, the most serious adverse events reported after treatment were sepsis, gastrointestinal bleeding, and venous thrombosis.

V. Utilization

Cathflo Activase Utilization			
12/24/2012 - 12/23/2013			
Label Name	**Rx Num**	**Total Reimb Amt**	**Average Cost per Script**
Cathflo Activase	6	$12,275.37	$2,045.90

References:

1. Cathflo Activase® [package insert]. South San Francisco, CA: Genentech, Inc.; March 2010.

KETAMINE COMPOUNDING

KETAMINE

Several Medicaid plans covers compounding for Ketamine cream. It can be used recreationally and for date rape.

There are early indicators that Ketamine powder (trade name Ketalar) is being compounded by pharmacies into a topical cream for chronic pain. This drug has potential for personal recreational abuse, as well as being a known "date rape" drug (along with Rohypnol and GHB). OI regional offices are encouraged to analyze Medicaid databases for use of this potentially dangerous drug.

Background

This drug was first discovered in the 1960's. Used primarily as an anesthetic, it causes "dissociative states" and makes patients unaware of their surroundings. Medically it can be used for general anesthesia or for quick "conscious sedation" procedures, such as suturing small children or reducing dislocations. However, the drug has a distressing side effect of causing terrifying hallucinations. It is a schedule III controlled substance. Chemically, it is similar to propofol. Because of the hallucinatory side effects and existence of superior modern medications, Ketamine is now used less regularly in humans. It remains routinely used in veterinary medicine to sedate animals.

Coverage

Ketamine is covered by several Medicaid formularies (sometimes by prior-auth). However, it is not covered under Medicare Part D. The Medicare program has determined there is insufficient literature to support outpatient use of this product, thus classifying it as "experimental". It is primarily supplied as an injection. However, it is also available as a crystalline powder and is compounded into a topical vehicle for transdermal absorption.

Recreational Use

Ketamine can be injected or the powder can be insufflated (snorted). It can be mixed in a cream vehicle by a compounding pharmacist along with other topical medications, like lidocaine or anti-inflammatory agents. The resulting concoction is applied topically to an affected extremity experiencing Peripheral Neuropathy pain syndromes. Literature is mixed on the efficacy of this. Applying more than prescribed results in enhanced absorption; leading to the dissociative side effects. Drug blogs indicate rectal abuse is becoming common as well.

A recent state case in New York found a pharmacy billed Medicaid for the total weight of the compounded cream, rather than just the Ketamine component. A USAO indicated they have seen pharmacies using their own "sales reps" soliciting physicians to write for this compound.

North Dakota Department of Human Services
Intranasal Cyanocobalamin

I. Overview

Nascobal is an intranasal solution containing cyanocobalamin (vitamin B_{12}) for patients with a B_{12} deficiency. Vitamin B_{12} plays an important role in growth, cell reproduction, hematopoiesis and nucleoprotein and myelin synthesis. Deficiency can lead to a wide spectrum of hematologic and neuropsychiatric disorders that can often be reversed by early diagnosis and prompt treatment.

II. Indication

Nascobal is indicated for the maintenance of normal hematologic status in pernicious anemia patients who are in remission following intramuscular vitamin B_{12} therapy and who have no nervous system involvement. Nascobal is also indicated as a supplement for other vitamin B_{12} deficiencies, including:

1. Dietary deficiency of vitamin B_{12} occurring in strict vegetarians.
2. Malabsorption of vitamin B_{12} resulting from structural or functional damage to the stomach or ileum.
3. Inadequate secretion of intrinsic factor resulting from lesions that destroy the gastric mucosa and a number of conditions associated with a variable degree of gastric atrophy.
4. Competition for vitamin B_{12} by intestinal parasites or bacteria.
5. Inadequate utilization of vitamin B_{12}.

III. Contraindications/Warnings

1. Sensitivity to cobalt and/or vitamin B_{12}.
2. Patients with early Leber's disease (hereditary optic nerve atrophy) who were treated with vitamin B_{12} suffered severe and swift optic atrophy.
3. Hypokalemia and sudden death may occur in severe megaloblastic anemia which is treated intensely with vitamin B_{12}.

IV. Drug/Laboratory Test Interactions

1. Persons taking most antibiotics, methotrexate or pyrimethamine invalidate folic acid and vitamin B_{12} diagnostic blood assays.
2. Colchicine, para-aminosalicylic acid and heavy alcohol intake for longer than 2 weeks may produce malabsorption of vitamin B_{12}.

V. Adverse Reactions

The most common adverse experiences, based on data from a short-term clinical trial, were asthenia, headache, infection, glossitis, nausea, paresthesia, and rhinitis.

VI. Dosage and Administration

Nascobal – the recommended initial dose of Nascobal is one spray administered in ONE nostril once weekly. Nascobal should be administered at least one hour before or one hour after ingestion of hot foods or liquids. Periodic monitoring of serum B_{12} levels should be obtained to establish adequacy of therapy.

VII. How Supplied

Nascobal is available as a spray in a dosage strength of 500 mcg per actuation. One bottle delivers 4 doses.

VIII. Cost Comparisons and Utilization

The approximate cost of one bottle of Nascobal is $360.

Label Name	Rx Num	Total Reimb Amt	Avg Cost Per Script
CYANOCOBALAMIN 1,000 MCG/ML	2,218	$16,305.51	$7.35
TOTAL 320 Recipients			

IX. Conclusion

Intranasal cyanocobalamin offers an additional route of administration for patients receiving vitamin B_{12}. The primary disadvantage of the nasal cyanocobalamin agents is the cost. Therefore, Nascobal should be reserved for those patients who are unable to absorb oral vitamin B_{12} or have a well-documented reason why they cannot use the injectable form.

References:

1. Nascobal® [package insert]. Spring Valley, NY: Par Pharmaceutical Companies, Inc.; July 2011.

North Dakota Department of Human Services
Luzu Review

I. Indication

Luzu (luliconazole) is an azole antifungal topical cream indicated for the topical treatment of interdigital tinea pedis, tinea cruris, and tinea corporis caused by the organisms *Trichophyton rubrum* and *Epidermophyton floccosum*, in patients 18 years of age and older.

II. Dosage and Administration

Apply to affected area(s), and approximately 1 inch of the immediate surrounding areas, once daily for 2 weeks in tinea pedis and 1 week in tinea cruris/tinea corporis.

III. Warnings/Precautions

For topical use only; not for oral, ophthalmic, or intravaginal use.

IV. Adverse Reactions

The most common adverse reactions observed in clinical trials were application site reactions, which occurred in less than 1% of subjects.

References:

1. Luzu® [package insert]. Bridgewater, NJ: Valeant Pharmaceuticals; November 2013.

North Dakota Department of Human Services
Noxafil Review

I. Indication

Noxafil is an azole antifungal agent indicated for:

Delayed-release tablets and oral suspension

- Prophylaxis of invasive Aspergillus and Candida infections in patients, 13 years of age and older, who are at high risk of developing these infections due to being severely immunocompromised, such as HSCT recipients with GVHD or those with hematologic malignancies with prolonged neutropenia from chemotherapy.

Oral suspension

- Treatment of oropharyngeal candidiasis (OPC), including OPC refractory (rOPC) to itraconazole and/or fluconazole.

II. Dosage and Administration

Indication	Dose and Duration of Therapy
Prophylaxis of invasive *Aspergillus* and *Candida* infections	Delayed-Release Tablets: Loading dose: 300 mg (three 100 mg delayed-release tablets) twice a day on the first day. Maintenance dose: 300 mg (three 100 mg delayed-release tablets) once a day, starting on the second day. Duration of therapy is based on recovery from neutropenia or immunosuppression. Oral Suspension: 200 mg (5 mL) three times a day. Duration of therapy is based on recovery from neutropenia or immunosuppression.
Oropharyngeal Candidiasis (OPC)	Oral Suspension: Loading dose: 100 mg (2.5 mL) twice a day on the first day. Maintenance dose: 100 mg (2.5 mL) once a day for 13 days.
OPC Refractory (rOPC) to Itraconazole and/or Fluconazole	Oral Suspension: 400 mg (10 mL) twice a day. Duration of therapy is based on the severity of the patient's underlying disease and clinical response.

III. Contraindications

- Do not administer to persons with known hypersensitivity to posaconazole, any component of Noxafil, or other azole antifungal agents.
- Do not coadminister Noxafil with the following drugs:
    - Sirolimus: can result in sirolimus toxicity.
    - CYP3A4 substrates (pimozide, quinidine): can result in QTc interval prolongation and cases of TdP.
    - HMG-CoA reducatse inhibitors primarily metabolized through CYP3A4: can lead to rhabdomyolysis.
    - Ergot alkaloids: can result in ergotism.

IV. Warnings/Precautions

- Calcineurin Inhibitor Toxicity: Noxafil increases concentrations of cyclosporine or tacrolimus; reduce dose of cyclosporine and tacrolimus and monitor concentrations frequently.
- Arrhythmias and QTc Prolongation: Noxafil has been shown to prolong the QTc interval and cause cases of TdP. Administer with caution to patients with potentially proarrhythmic conditions. Do not administer with drugs known to prolong QTc interval and metabolized through CYP3A4. Correct K+, Mg++, and Ca++ before starting Noxafil.
- Hepatic Toxicity: Elevations in LFTs may occur. Discontinuation should be considered in patients who develop abnormal LFTs or monitor LFTs during treatment.
- Midazolam: Noxafil can prolong hypnotic/sedative effects. Monitor patients and ensure that benzodiazepine receptor antagonists are available.

V. Adverse Reactions

Common treatment-emergent adverse reactions (>25%) in prophylaxis studies with posaconazole are fever, diarrhea and nausea.

VI. Utilization

Noxafil costs approximately 50 dollars per 100 mg tablet and approximately 950 dollars per bottle of suspension.

References:

1. Noxafil® [package insert]. Whitehouse Station, NJ: Merck & Co., Inc.; November 2013.

North Dakota Department of Human Services
Bethkis Review

I. Indication

Bethkis is an inhaled aminoglycoside antibacterial indicated for the management of cystic fibrosis patients with *Pseudomonas aeruginosa.* Safety and efficacy have not been demonstrated in patients under the age of six years, patients with a forced expiratory volume in less than one second (FEV1) less than 40% or greater than 80% predicted, or patients colonized with *Burkholderia cepacia.*

II. Dosage and Administration

Administer the entire contents of one ampule twice daily by oral inhalation in repeated cycles of 28 days on drug, followed by 28 days off drug.

III. Contraindications

Bethkis is contraindicated in patients with a known hypersensitivity to any aminoglycoside.

IV. Warnings/Precautions

- Caution should be exercised when prescribing to patients with known or suspected auditory, vestibular, renal, or neuromuscular dysfunction.
- Aminoglycoside may aggravate muscle weakness because of a potential curare-like effect on neuromuscular function.
- Bronchospasm can occur with inhalation of Bethkis.
- Audiograms, serum concentration, and renal function should be monitored as appropriate.
- Fetal harm can occur when aminoglycosides are administered to a pregnant woman. Apprise women of the potential hazard to the fetus.

V. Adverse Reactions

Common adverse reactions (more than 5%) occurring more frequently in Bethkis patients are forced expiratory volume decreased, rales, red blood cell sedimentation rate increased, and dysphonia.

VI. Drug Interactions

- Concurrent and/or sequential use of Bethkis with other drugs with neurotoxic or ototoxic potential should be avoided.
- Bethkis should not be administered concomitantly with ethacrynic acid, furosemide, urea, or mannitol.

VII. Cost

Bethkis costs approximately 100 dollars per 4ml vial (300mg dose).

References:

1. Bethkis® [package insert]. Woodstock, IL: Cornerstone Therapeutics Inc.; May 2013.

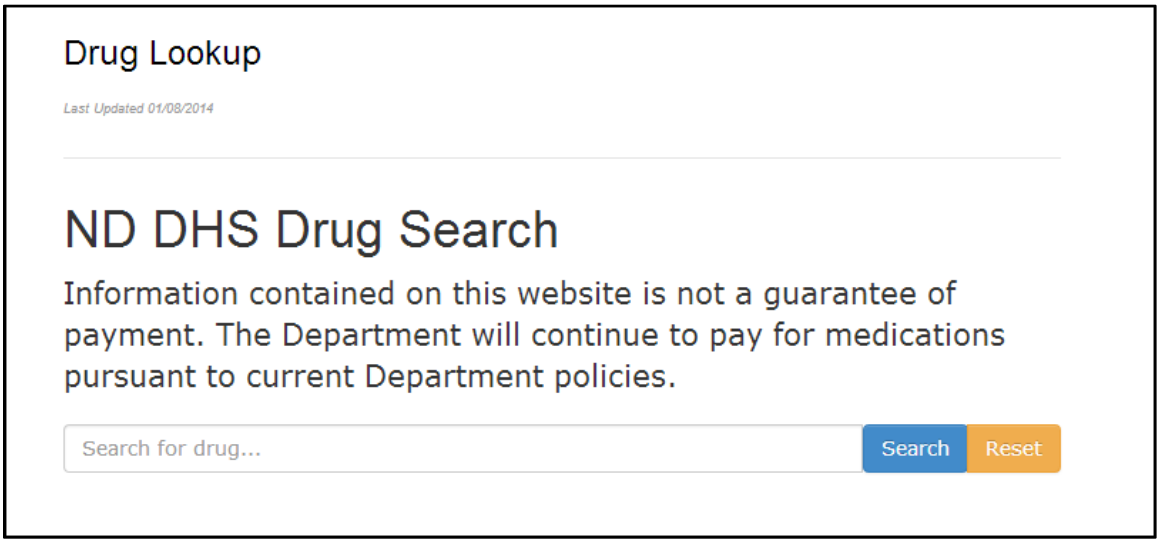
Using the NDC Drug Lookup Application

Presented to North Dakota DUR Board

About the Application

The North Dakota Department of Human Services Prior Authorization website has recently been updated to give you several new features. The updated NDC Drug Lookup application allows users to search for a drug by drug name or NDC number, and it displays easy-to-understand results and each drug's required PA forms.

After accessing the application (via direct link or the prior authorization website), you will see the search page.



The page heading displays when the drug information and PA forms were last updated, and the Search function is clearly visible in the center of the page.

Drug Search

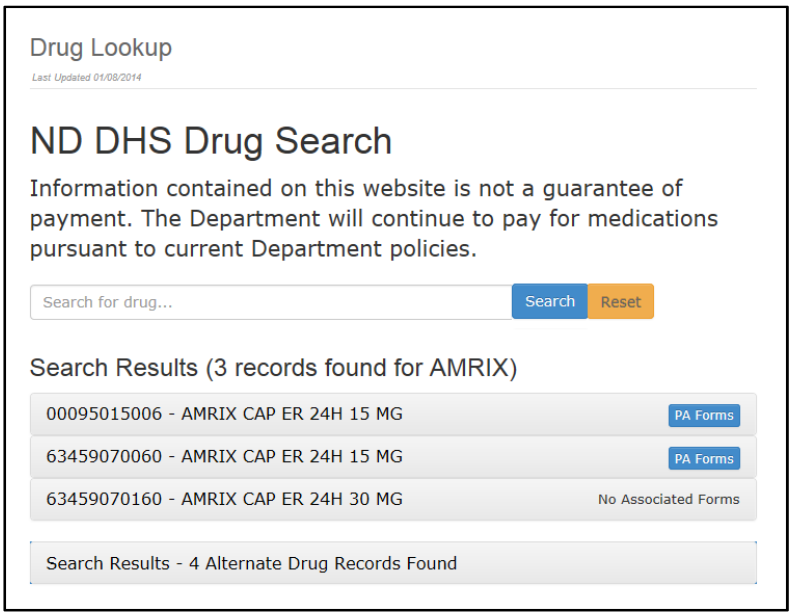
To perform a search, follow the steps below:

1 Type in the NDC number or drug name into the Search bar on the home page.

2 Click **Search**.

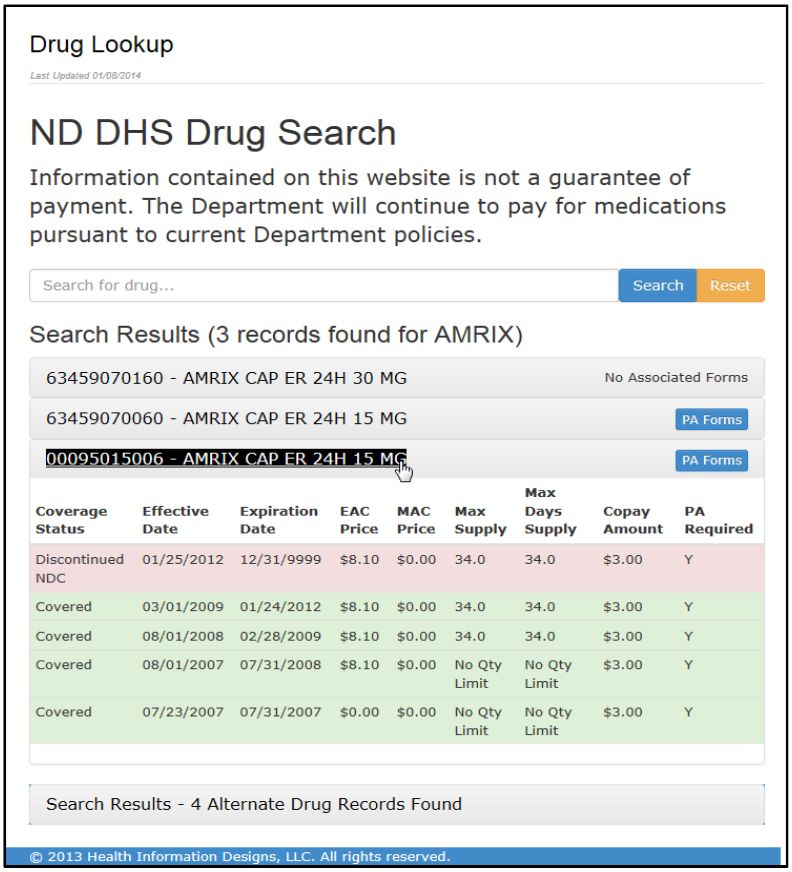
The matching results are displayed in a list below the search bar.

Alternate Drug Records based on the drug you searched are available in a separate expandable list at the bottom of the page.



3 Click on the drug name to expand the search result to show the drug information.

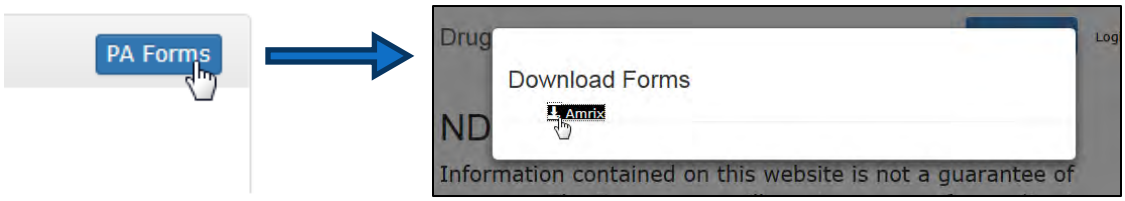
The drug information is color-coded to show you whether the drug is covered, not covered, or discontinued. A "**Y**" in the **PA Required** column indicates that the drug requires a PA.



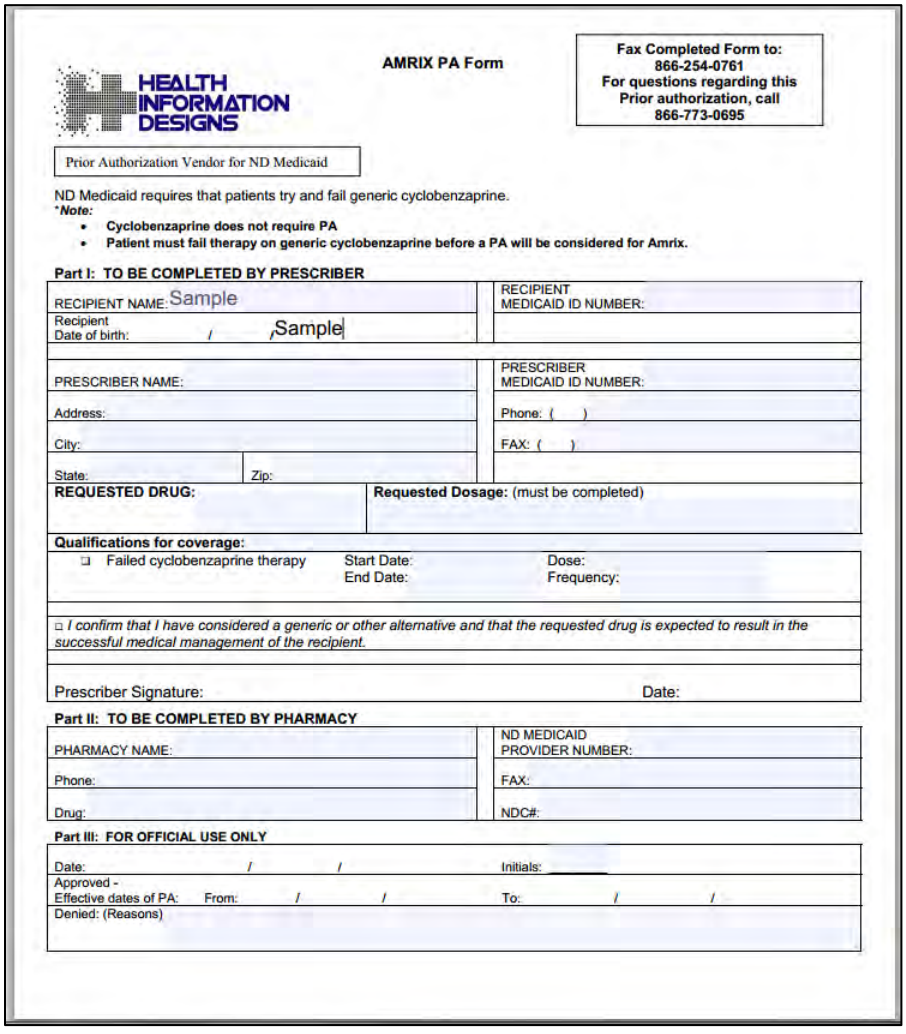
PA Forms

If one or more PA forms are linked to the drug you searched, a blue **PA Forms** button displays to the right of the search result.

1 Click **PA Forms** to display a list of the forms linked to the drug.



2 Click on one of the form names to open that form.



AMRIX PA Form

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-773-0695

HEALTH INFORMATION DESIGNS

Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that patients try and fail generic cyclobenzaprine.
Note:
- **Cyclobenzaprine does not require PA**
- **Patient must fail therapy on generic cyclobenzaprine before a PA will be considered for Amrix.**

Part I: TO BE COMPLETED BY PRESCRIBER

RECIPIENT NAME: Sample	RECIPIENT MEDICAID ID NUMBER:
Recipient Date of birth: / / Sample	
PRESCRIBER NAME:	PRESCRIBER MEDICAID ID NUMBER:
Address:	Phone: ( )
City:	FAX: ( )
State: Zip:	

REQUESTED DRUG: **Requested Dosage:** (must be completed)

Qualifications for coverage:

☐ Failed cyclobenzaprine 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 Signature: Date:

Part II: TO BE COMPLETED BY PHARMACY

PHARMACY NAME:	ND MEDICAID PROVIDER NUMBER:
Phone:	FAX:
Drug:	NDC#:

Part III: FOR OFFICIAL USE ONLY

Date: / /	Initials:
Approved - Effective dates of PA: From: / /	To: / /
Denied: (Reasons)	

3 Complete the form electronically and save it to your computer. You can fax the completed form to 1-866-254-0761 or e-mail it to ndpa@hidinc.com.

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Website: http://www.hidinc.com

NORTH DAKOTA MEDICAID
RETROSPECTIVE DRUG UTILIZATION REVIEW
CRITERIA RECOMMENDATIONS
1st QUARTER 2014

Criteria Recommendations ***Approved Rejected***

1. Roflumilast / Overutilization _____ _____

Alert Message: The manufacturer's recommended dosage of Daliresp (roflumilast) for patients with COPD is one 500 mg tablet per day. Exceeding the recommended dose may increase the occurrence of roflumilast-related adverse effects (e.g., headache, gastrointestinal disorders, insomnia, anxiety, and depression).

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C
Roflumilast		

Max Dose: 500mg/day

References:
Daliresp Prescribing Information, Aug. 2013, Forest Pharmaceuticals, Inc.
Facts & Comparisons, 2013 Updates, Wolters Kluwer Health.

2. Roflumilast / Non-adherence _____ _____

Alert Message: A review of the patient's refill history suggests that the patient may not be taking the drug in the manner it was prescribed. Non-adherence to the prescribed dosing regimen may result in sub-therapeutic effects and recurrence of symptoms. Daliresp (roflumilast) is not a bronchodilator and should not to be used for the relief of acute bronchospasm.

Conflict Code: LR – Non-adherence
Drugs/Diseases

Util A	Util B	Util C
Roflumilast		

References:
Daliresp Prescribing Information, Aug. 2013, Forest Pharmaceuticals, Inc.
Ramsey SD. Suboptimal Medical Therapy in COPD: Exploring the Causes and Consequences. Chest 2000;117:33S-37S.
Bourbeau J and Bartlett SJ. Patient Adherence in COPD. Thorax. 2008;63:831-838.

3. Roflumilast / Hepatic Impairment _____ _____

Alert Message: Daliresp (roflumilast) is extensively metabolized by the liver and its use is contraindicated in patients with moderate to severe liver impairment (Child-Pugh B or C). Clinicians should consider the risk-benefit of administering roflumilast to patients who have mild liver impairment (Child-Pugh A).

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

Util A	Util B	Util C
Roflumilast	Hepatic Impairment	

References:
Daliresp Prescribing Information, Aug. 2013, Forest Pharmaceuticals, Inc.
Facts & Comparisons, 2013 Updates, Wolters Kluwer Health.

4. Roflumilast / Strong CYP3A4 Inducers _____ _____

Alert Message: The concurrent use of Daliresp (roflumilast) with a strong CYP3A4 inducer is not recommended. Roflumilast is extensively metabolized by the liver and coadministration with strong CYP3A4 inducers may decrease systemic exposure and therapeutic effectiveness of roflumilast.

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

Util A	Util B		Util C
Roflumilast	Carbamazepine	Rifabutin	
	Phenytoin	Rifapentine	
	Phenobarbital	Dexamethasone	
	Rifampin		

References:
Daliresp Prescribing Information, Aug. 2013, Forest Pharmaceuticals, Inc..
Clinical Pharmacology, 2013 Elsevier/Gold Standard.
Facts & Comparisons, 2013 Updates, Wolters Kluwer Health.

5. Roflumilast / CYP3A4 Inhibitors or CYP3A4/CYP1A2 Dual* Inhibitors _____ _____

Alert Message: The concurrent use of Daliresp (roflumilast) with CYP3A4 inhibitors or dual inhibitors of CYP3A4 and CYP1A2 may increase roflumilast systemic exposure and result in increased adverse reactions (e.g., diarrhea, weight loss, insomnia, anxiety, and depression). The risk of such concurrent use should be weighed carefully against benefit.

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

Util A	Util B				Util C
Roflumilast	Ketoconazole	Verapamil*	Atazanavir	Zafirlukast	
	Itraconazole	Diltiazem	Fosamprenavir	Dronedarone	
	Fluconazole	Nefazodone	Lapatinib	Delavirdine	
	Voriconazole	Aprepitant	Imatinib	Fluvoxamine*	
	Posaconazole	Saquinavir	Nilotinib	Amiodarone*	
	Telithromycin	Indinavir	Boceprevir	Cimetidine*	
	Clarithromycin	Nelfinavir	Telaprevir	Enoxacin*	
	Erythromycin	Ritonavir	Boceprevir	Zileuton*	

References:
Daliresp Prescribing Information, Aug. 2013, Forest Pharmaceuticals, Inc.
Flockhart DA. Drug Interactions: Cytochrome P450 Drug Interaction Table. Indiana University School of Medicine. Available at: http://medicine.iupui.edu/clinpharm/ddos/table.asp.
FDA: Drug Development and Drug Interactions: Tables of Substrates, Inhibitors and Inducers. [7/28/2011]. Available at: http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/DrugInteractionLabeling/ucm093664.htm#potency
Clinical Pharmacology, 2013 Elsevier/Gold Standard.
Facts & Comparisons, 2013 Updates, Wolters Kluwer Health.

6. Roflumilast / Depression, Suicidality, Anxiety, Insomnia _____ _____

Alert Message: Daliresp (roflumilast) should be used with caution in patients with a history of depression and/or suicidal thoughts or behavior. Treatment with roflumilast is associated with an increase in psychiatric adverse reactions which include anxiety, depression, suicidal thoughts, and mood changes.

Conflict Code: DB - Drug Disease Warning (ICD-9s and/or Drug Inferred Disease)
Drugs/Diseases

Util A	Util B	Util C
Roflumilast	Suicidality	
	Depression	
	Insomnia	
	Anxiety	
	Antidepressants	
	Anxiolytics	

References:
Daliresp Prescribing Information, Aug. 2013, Forest Pharmaceuticals, Inc.
Facts & Comparisons, 2013 Updates, Wolters Kluwer Health.

7. Roflumilast / Weight Loss _____ _____

Alert Message: Daliresp (roflumilast) is associated with weight loss and therefore patient weight should be monitored regularly. If unexplained or clinically significant weight loss occurs, weight loss should be evaluated and discontinuation of roflumilast should be considered.

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

Util A	Util B	Util C
Roflumilast	Loss of weight (783.21)	

References:
Daliresp Prescribing Information, Aug. 2013, Forest Pharmaceuticals, Inc.
Facts & Comparisons, 2013 Updates, Wolters Kluwer Health.

8. ADHD Medications / Peripheral Vasculopathy _____ _____

Alert Message: Stimulants used to treat ADHD are associated with peripheral vasculopathy, including Raynaud's phenomenon. Signs and symptoms are usually intermittent and mild but rarely can include digital ulceration and or soft tissue breakdown. Signs and symptoms generally improve after dose reduction or discontinuation of drug. Careful observation for digital changes should occur during treatment with these agents.

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

Util A	Util B	Util C
Methylphenidate	Raynaud's	
Dexmethylphenidate	Peripheral Vascular Disease Unspecified	
Amphetamine	Cyanosis	
Dextroamphetamine	Pallor	
Lisdexamfetamine		

References:
Clinical Pharmacology, 2013 Elsevier/Gold Standard.
Ritalin & Ritalin SR Prescribing Information, June 2013, Novartis Pharmaceuticals Corporation.
Yu ZJ, Parker-Kotler C, Tran L, et al. Peripheral Vasculopathy associated with Psychostimulant Treatment in Children with Attention-Deficit/Hyperactivity Disorder. Curr Psychiatric Rep (2010) 12:111-115.
Adderall Prescribing Information, June 2013, Shire US Inc.
Dexedrine Prescribing Information, May 2013, Amedra Pharmaceuticals.
Focalin XR Prescribing Information, June 2013, Novartis Pharmaceuticals Corporation.
Facts & Comparisons, 2013 Updates, Wolters Kluwer Health.

9. Long-Acting Opioids / Pregnancy / Pregnancy Negating _____ _____

Alert Message: Chronic maternal use of extended-release and long-acting opioid analgesics during pregnancy can result in neonatal opioid withdrawal syndrome (NOWS), which may be life-threatening and require management by neonatology experts. Symptoms associated with NOWS include tachypnea, trembling, poor feeding, and excessive or high-pitched crying.

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

Util A	Util B	Util C **(Negating)**
Morphine LA	Pregnancy	Miscarriage
Oxycodone LA		Delivery
Methadone		Abortion
Fentanyl LA		
Hydromorphone LA		
Tramadol LA		
Buprenorphine LA		
Oxymorphone LA		
Tapentadol LA		

Age: 11-55
Gender: Female

References:
US Food and Drug Administration (FDA). FDA News Release: FDA announces safety and labeling changes and postmarket study requirements for extended-release and long-acting opioid analgesics. Retrieved September 11, 2013.
Available on the World Wide Web at:
http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm367726.htm
Clinical Pharmacology, 2013 Elsevier/Gold Standard.
Facts & Comparisons, 2013 Updates, Wolters Kluwer Health.

10. Long-acting Opioids / Therapeutic Appropriateness _____ _____

Alert Message: Because of the risks of addiction, abuse, and misuse, even at recommended doses, and because of the greater risks of overdose and death, extended-release or long-acting opioids should be reserved for use in patients for whom alternative treatment options (e.g., nonopioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain; ER/LA opioid analgesics are not indicated for as-needed pain relief.

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C **(Negating)**
Morphine LA		Cancer Diagnoses
Oxycodone LA		Antineoplastic Medications
Methadone		
Fentanyl LA		
Hydromorphone LA		
Tramadol LA		
Buprenorphine LA		
Oxymorphone LA		
Tapentadol LA		

References:
US Food and Drug Administration (FDA). FDA News Release: FDA Announces Safety and Labeling Changes and Postmarket Study Requirements for Extended-release and Long-acting Opioid Analgesics. Retrieved September 11, 2013.
Available on the World Wide Web at:
http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm367726.htm
Clinical Pharmacology, 2013 Elsevier/Gold Standard.
Facts & Comparisons, 2013 Updates, Wolters Kluwer Health.

11. Levomilnacipran / Overutilization _____ _____

Alert Message: Fetzima (levomilnacipran) may be over-utilized. The manufacturer's recommended maximum dose of levomilnacipran is 120 mg once daily.

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C **(Negating)**	
Levomilnacipran		CKD Stage 3, 4, 5 & ESRD	
		Ketoconazole	Telaprevir
		Itraconazole	Boceprevir
		Nefazodone	Posaconazole
		Saquinavir	Voriconazole
		Ritonavir	Clarithromycin
		Indinavir	Telithromycin
		Nelfinavir	

Max Dose: 120mg/day

References:
Fetzima Prescribing Information, July 2013, Forest Pharmaceuticals, Inc.
Clinical Pharmacology, 2013 Elsevier/Gold Standard.

12. Levomilnacipran 120mg / Strong CYP3A4 Inhibitors _____ _____

Alert Message: The dose of Fetzima (levomilnacipran) should not exceed 80 mg once daily when used with strong CYP3A4 inhibitors. Levomilnacipran is a CYP3A4 substrate and concurrent use with a strong CYP3A4 inhibitor may cause a clinically significant increase in levomilnacipran exposure.

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

Util A	Util B		Util C
Levomilnacipran 120mg	Ketoconazole	Telaprevir	
	Itraconazole	Boceprevir	
	Nefazodone	Posaconazole	
	Saquinavir	Voriconazole	
	Ritonavir	Clarithromycin	
	Indinavir	Telithromycin	
	Nelfinavir		

References:
Fetzima Prescribing Information, July 2013, Forest Pharmaceuticals, Inc.
Clinical Pharmacology, 2013 Elsevier/Gold Standard.

13. Levomilnacipran / Moderate Renal Impairment _____ _____

Alert Message: Fetzima (levomilnacipran) is predominately excreted by the kidney; for patients with moderate renal impairment (CrCl 30-59 mL/min), the maintenance dose of levomilnacipran should not exceed 80 mg once daily. For patients with severe renal impairment (CrCl 15-29 mL/min), the maintenance dose should not exceed 40 mg once daily. No dosage adjustment is recommended in mild renal impairment. Levomilnacipran is not recommended for patients with ESRD.

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C **(Include)**
Levomilnacipran		CKD Stage 3

Max Dose: 80mg/day

References:
Fetzima Prescribing Information, July 2013, Forest Pharmaceuticals, Inc.
Clinical Pharmacology, 2013 Elsevier/Gold Standard.

14. Levomilnacipran / Severe Renal Impairment & ESRD _____ _____

Alert Message: Fetzima (levomilnacipran) is predominately excreted by the kidney; for patients with severe renal impairment (CrCl 15-29 mL/min), the maintenance dose should not exceed 40 mg once daily. Levomilnacipran is not recommended for patients with ESRD. For patients with moderate renal impairment (CrCl 30-59 mL/min), the maintenance dose of levomilnacipran should not exceed 80 mg once daily. No dosage adjust ment is recommended in mild renal impairment.

Conflict Code: ER - Overutilization

Drugs/Diseases

Util A	Util B	Util C **(Include)**
Levomilnacipran		CKD Stage 4
		CKD Stage 5
		ESRD

Max Dose: 40 mg/day

References:
Fetzima Prescribing Information, July 2013, Forest Pharmaceuticals, Inc.
Clinical Pharmacology, 2013 Elsevier/Gold Standard.

15. Levomilnacipran / Non-adherence _____ _____

Alert Message: Based on the refill history, your patient may be under-utilizing Fetzima (levomilnacipran). 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 – Non-adherence

Drugs/Diseases

Util A	Util B	Util C
Levomilnacipran		

References:
Fetzima Prescribing Information, July 2013, Forest Pharmaceuticals, Inc.
Osterberg L, Blaschke T. Adherence to Medication. N Engl J Med 2005;353:487-97.
Keene MS. Confusion and Complaints: The True Cost of Noncompliance in Antidepressant Therapy. Medscape Psychiatry & Mental Health. 2005;10(2).\Available at: http://www.medscape.com/viewarticle/518273

16. Levomilnacipran / Pediatric Use (Black Box) _____ _____

Alert Message: The safety and effectiveness of Fetzima (levomilnacipran) in the pediatric population have not been established.

Conflict Code: TA – Therapeutic Appropriateness

Util A	Util B	Util C
Levomilnacipran		

Age Range: 0-18 yoa

References:
Fetzima Prescribing Information, July 2013, Forest Pharmaceuticals, Inc.
Clinical Pharmacology, 2013 Elsevier/Gold Standard.

17. Levomilnacipran / MAOIs _____ _____

Alert Message: Fetzima (levomilnacipran) is contraindicated for concurrent use in patients receiving MAOI therapy intended to treat psychiatric disorders. At least 14 days should elapse between discontinuation of an MAOI to treat psychiatric disorders and initiation of therapy with levomilnacipran. Conversely, at least 7 days should be allowed after stopping levomilnacipran before starting an MAOI antidepressant.

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

Util A	Util B	Util C
Levomilnacipran	Isocarboxazid	
	Phenelzine	
	Tranylcypromine	
	Selegiline Transdermal	

References:
Fetzima Prescribing Information, July 2013, Forest Pharmaceuticals, Inc.
Clinical Pharmacology, 2013 Elsevier/Gold Standard.

18. Levomilnacipran / Linezolid _____ _____

Alert Message: Starting Fetzima (levomilnacipran) in a patient who is being treated with Zyvox (linezolid), a reversible, non-selective MAOI, is contraindicated due to the risk of serotonin syndrome. There may be circumstances when it is necessary to initiate treatment with linezolid in a patient taking levomilnacipran; if so, levomilnacipran should be discontinued before initiating linezolid treatment.

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

Util A	Util B	Util C
Levomilnacipran	Linezolid	

References:
Fetzima Prescribing Information, July 2013, Forest Pharmaceuticals, Inc.
Clinical Pharmacology, 2013 Elsevier/Gold Standard.

19. Levomilnacipran / Serotonergic Agents _____ _____

Alert Message: Caution should be exercised when Fetzima (levomilnacipran) is administered with other serotonergic drugs due to the risk of serotonin syndrome. Levomilnacipran is a serotonin and norepinephrine reuptake inhibitor and concomitant therapy with other serotonergic drugs may cause accumulation of serotonin. If concurrent use is clinically warranted, monitor closely for signs and symptoms of serotonin syndrome.

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

Util A	Util B			Util C
Levomilnacipran	SSRIs	Nefazodone	Buspirone	
	SNRIs	Mirtazapine	Tramadol	
	TCAs	Trazodone	Fentanyl	
	Triptans	Lithium	Cyclobenzaprine	
	Ergot Alkaloids	Meperidine	Rasagiline	

References:
Fetzima Prescribing Information, July 2013, Forest Pharmaceuticals, Inc.
Clinical Pharmacology, 2013 Elsevier/Gold Standard.

20. Levomilnacipran / Drugs Affecting Coagulation _____ _____

Alert Message: Concurrent use of Fetzima (levomilnacipran) and medications that enhance bleeding potential (e.g., anticoagulants, thrombolytics and NSAIDS) may increase the risk of a bleeding complication. Levomilnacipran, which inhibits serotonin reuptake, may cause impaired platelet aggregation due to platelet serotonin depletion.

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

Util A	Util B			Util C
Levomilnacipran	NSAIDS	Dipyridamole	Dabigatran	
	Aspirin	Cilostazol	Dalteparin	
	Warfarin	Clopidogrel	Anagrelide	
	Apixaban	Prasugrel	Enoxaparin	
	Fondaparinux	Ticagrelor		
	Rivaroxaban	Ticlopidine		

References:
Fetzima Prescribing Information, July 2013, Forest Pharmaceuticals, Inc.
Clinical Pharmacology, 2013 Elsevier/Gold Standard.
Bismuth-Evenzal Y, Gonopolsky Y, Gurwitz D, et al. Decreased Serotonin Content and Reduced Agonist-induced Aggregation in Platelets of Patients Chronically Medicated with SSRI Drugs. J Affect Disord. 2012 Jan;136(1-2):99-103.

21. Levomilnacipran / Hypertension, Cardiovascular Disorders _____ _____

Alert Message: Caution should be exercised in treating patients with pre-existing hypertension, cardiovascular, or cerebrovascular conditions that might be compromised by increases in blood pressure and/or heart rate, as Fetzima (levomilnacipran) has been shown to increase both. For patients who experience a sustained increase in heart rate and/or blood pressure while receiving levomilnacipran, discontinuation or other medical intervention should be considered.

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

Util A	Util B		Util C
Levomilnacipran	Hypertension	Ischemic Heart Disease	
	Stroke	Heart Failure	
	Conduction Disorders	Cerebral Ischemia	
	Dysrhythmias	Myocardial Infarction	

References:
Fetzima Prescribing Information, July 2013, Forest Pharmaceuticals, Inc.
Clinical Pharmacology, 2013 Elsevier/Gold Standard.

22. Axitinib / Therapeutic Appropriateness _____ _____

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

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C
Axitinib		

Age Range: 0 – 17 yoa

References:
Inlyta Prescribing Information, September 2013, Pfizer, Inc.
Clinical Pharmacology, 2013 Elsevier / Gold Standard.

23. Axitinib / Overuse _____ _____

Alert Message: Inlyta (axitinib) may be over-utilized. The manufacturer's maximum recommended dose is 10mg twice daily, approximately 12 hours apart.

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C **(Negating)**			
Axitinib		Chronic Liver Disease	Ketoconazole	Itraconazole	Clarithromycin
		Cirrhosis	Nefazodone	Ritonavir	Saquinavir
		Nelfinavir	Indinavir	Telithromycin	Voriconazole
		Atazanavir	Carbamazepine	Phenytoin	Rifabutin
		Phenobarbital	Pioglitazone	Rifampin	Efavirenz
		Dexamethasone	Modafinil	Oxcarbazepine	Nevirapine
		Bosentan	Nafcillin	Etravirine	Boceprevir
		Telaprevir	Delavirdine		

Max Dose: 20mg/day

References:
Inlyta Prescribing Information, September 2013, Pfizer, Inc.
Clinical Pharmacology, 2013 Elsevier / Gold Standard.
Flockhart DA. Drug Interactions: Cytochrome P450 Drug Interaction Table. Indiana University School of Medicine. Available at: http://medicine.iupui.edu/clinpharm/ddos/table.asp.

24. Axitinib / Moderate Hepatic Impairment _____ _____

Alert Message: Inlyta (axitinib) may be over-utilized. Patients with moderately impaired hepatic function (Child-Pugh class B) should have their starting dose decreased by approximately half and subsequent doses increased or decreased based on safety and tolerability. Axitinib has not been studied in patients with severe hepatic impairment (Child-Pugh class C).

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C (Include)
Axitinib		Chronic Liver Disease
		Cirrhosis

Max Dose: 20mg/day

References:
Inlyta Prescribing Information, September 2013, Pfizer, Inc.
Clinical Pharmacology, 2013 Elsevier / Gold Standard.

25. Axitinib / Strong CYP3A4/5 Inhibitors _____ _____

Alert Message: Inlyta (axitinib) may be over-utilized. The concomitant use of axitinib and strong CYP3A4/5 inhibitors should be avoided. If these agents must be co-administered, it is recommended that the dose of axitinib be reduced by approximately half and subsequent doses increased or decreased based on safety and tolerability.

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C (Include)
Axitinib		Ketoconazole
		Itraconazole
		Voriconazole
		Nefazodone
		Nelfinavir
		Saquinavir
		Ritonavir
		Indinavir
		Atazanavir
		Clarithromycin
		Telithromycin
		Boceprevir
		Telaprevir
		Delavirdine

Max Dose: 20mg/day

References:
Inlyta Prescribing Information, September 2013, Pfizer, Inc.
Clinical Pharmacology, 2013 Elsevier / Gold Standard.
Flockhart DA. Drug Interactions: Cytochrome P450 Drug Interaction Table. Indiana University School of Medicine. Available at: http://medicine.iupui.edu/clinpharm/ddos/table.asp. Accessed 10/2013.

26. Axitinib / Strong or Moderate CYP3A4/5 Inducers _____ _____

Alert Message: The manufacturer recommends that concurrent use of Inlyta (axitinib) with strong or moderate CYP3A4/5 inducers be avoided. In clinical studies co-administration of axitinib with rifampin, a strong inducer of CYP3A4/5, reduced plasma exposure of axitinib in healthy volunteers.

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

Util A	Util B				Util C
Axitinib	Carbamazepine	Phenytoin	Rifabutin	Phenobarbital	
	Pioglitazone	Rifampin	Efavirenz	Dexamethasone	
	Modafinil	Oxcarbazepine	Nevirapine	Bosentan	
	Nafcillin	Etravirine			

References:
Inlyta Prescribing Information, September 2013, Pfizer, Inc.
Clinical Pharmacology, 2013 Elsevier / Gold Standard.
Flockhart DA. Drug Interactions: Cytochrome P450 Drug Interaction Table. Indiana University School of Medicine. Available at: Http://medicine.iupui.edu/clinpharm/ddos/table.asp.
Pithavala YK, Tortorici M, Toh M, et al. Effect of Rifampin on the Pharmacokinetics of Axitinib (AG-013736) in Japanese and Caucasian Healthy Volunteers. Cancer Chemother Pharmacol. 2010 February;65(3):563-570.

27. Axitinib / Non-adherence _____ _____

Alert Message: Based on refill history, your patient may be under-utilizing Inlyta (axitinib). 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 – Non-adherence
Drugs/Diseases

Util A	Util B	Util C
Axitinib		

References:
Osterberg L, Blaschke T. Adherence to Medication. N Engl J Med 2005; 353:487-497.
Ruddy K, Mayer E, Partridge A. Patient Adherence and Persistence With Oral Anticancer Treatment. CA Cancer J Clin 2009;59:56-66.
Hershman DL, Shao T, Kushi LH, et al. Early discontinuation and non-adherence to adjuvant hormonal therapy are associated with increased mortality in women with breast cancer. Breast Cancer Res Treat (2011) 126:529-537.

28. Axitinib / Pregnancy / Pregnancy Negating _____ _____

Alert Message: Inlyta (axitinib) is FDA pregnancy category D. If axitinib is used during pregnancy, or if the patient becomes pregnant while receiving this drug, the patient should be apprised of the potential hazard to the fetus.

Conflict Code: MC – Drug/Diagnosis Precaution/Warning/Contraindication
Drugs/Diseases

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

References:
Inlyta Prescribing Information, September 2013, Pfizer, Inc.
Clinical Pharmacology, 2013 Elsevier / Gold Standard.

29. Axitinib / Hypertension & Hypertensive Crisis _____ _____

Alert Message: In a controlled clinical study with Inlyta (axitinib), hypertension was reported in 40% of patients and hypertensive crisis reported in <1%. In the case of severe and persistent hypertension despite use of anti-hypertensive medication and axitinib dose reduction, consider discontinuing axitinib.

Conflict Code: DB – Drug-Drug Marker and/or Diagnosis
Drugs/Diseases

Util A	Util B	Util C
Axitinib	Hypertension	
	Hypertensive Crisis	
	Antihypertensive Medications	

References:
Inlyta Prescribing Information, September 2013, Pfizer, Inc.
Clinical Pharmacology, 2013 Elsevier / Gold Standard.

30. Axitinib / Thromboembolic Events _____ _____

Alert Message: In clinical trials with Inlyta (axitinib), thromboembolic events were reported, including deaths. Axitinib should be used with caution in patients who are at risk for, or who have a history of, these events.

Conflict Code: MC – Drug/Diagnosis Precaution/Warning/Contraindication
Drugs/Diseases

Util A	Util B	Util C
Axitinib	TIA	
	Cerebrovascular Accident	
	Myocardial Infarction	
	Retinal Artery/Vein Occlusion	
	Retinal Vein Thrombosis	
	Pulmonary Embolism	
	Deep Vein Thrombosis	

References:
Inlyta Prescribing Information, September 2013, Pfizer, Inc.
Clinical Pharmacology, 2013 Elsevier / Gold Standard.

31. Axitinib / Hemorrhage _____ _____

Alert Message: In clinical trials with Inlyta (axitinib), hemorrhagic events were reported in 16% of patients. Axitinib has not been studied in patients who have evidence of untreated brain metastasis or recent active gastrointestinal bleeding and should not be used in these patients.

Conflict Code: MC – Drug/Diagnosis Precaution/Warning/Contraindication
Drugs/Diseases

Util A	Util B	Util C
Axitinib	Cerebral Hemorrhage	
	Hematuria	
	Hemoptysis	
	Lower GI hemorrhage	
	Melena	

References:
Inlyta Prescribing Information, September 2013, Pfizer, Inc.
Clinical Pharmacology, 2013 Elsevier / Gold Standard.

32. Axitinib / Reversible Posterior Leukoencephalopathy Syndrome _____ _____

Alert Message: In clinical trials with Inlyta (axitinib), reversible posterior leukoencephalopathy syndrome (RPLS) was reported in <1% of patients. If symptoms of RPLS develop (headache, seizure, lethargy, etc.), and magnetic resonance imaging confirms the diagnosis, therapy with axitinib should be discontinued.

Conflict Code: MC – Drug/Diagnosis Precaution/Warning/Contraindication
Drugs/Diseases

Util A	Util B	Util C
Axitinib	Seizure	
	Confusion	
	Blindness	

References:
Inlyta Prescribing Information, September 2013, Pfizer, Inc.
Clinical Pharmacology, 2013 Elsevier / Gold Standard.

33. Axitinib / Hyper/Hypothyroidism _____ _____

Alert Message: In clinical trials with Inlyta (axitinib), hypothyroidism was reported in 19% of patients and hyperthyroidism in 1% of patients. Thyroid function should be monitored before initiation of, and periodically throughout, treatment with axitinib.

Conflict Code: MC – Drug/Diagnosis Precaution/Warning/Contraindication
Drugs/Diseases

Util A	Util B	Util C
Axitinib	Hyperthyroidism	
	Hypothyroidism	

References:
Inlyta Prescribing Information, September 2013, Pfizer, Inc.
Clinical Pharmacology, 2013 Elsevier / Gold Standard.

34. Non First-line Antihypertensives / Hypertension / JNC 8 4 Classes _____ _____

Alert Message: The JNC 8 recommends the use of either a CCB, ACEI, ARB or thiazide-type diuretic as initial therapy to control hypertension in non-black adult patients 18 years of age and older, if no contraindications exist. Recommended initial therapy in black patients is a thiazide-type diuretic or CCB, alone or in combination. If goal blood pressure is not achieved with an initial drug refer to the JNC 8 for recommended strategies for adding antihypertensive agents.

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C **(Negating)**
Other Antihypertensives:	Hypertension	Chronic Kidney Disease
Alpha/Beta-Adrenergic Blockers		ACE Inhibitors
Antiadrenergics-Centrally Acting		ARBs
Antiadrenergics-Peripherally Acting		CCBs
Selective Aldosterone Receptor Antagonist		Thiazide-type Diuretics
Beta-Blockers		
Direct Renin Inhibitors		
Loop Diuretics		

Age Range: 18 – 999 yoa

References:
James PA, Oparil S, Carter BL, et al. 2014 Evidence-based Guideline for the Management of High Blood Pressure in Adults: Report from the Panel Members Appointed to the Eight Joint National Committee (JNC 8). JAMA 2014; DOI:10.1001/jama.2013.284427. Available at: http://jama.jamanetwork.com/journal.aspx.

35. Dolutegravir / Overutilization _____ _____

Alert Message: Tivicay (dolutegravir) may be over-utilized. The manufacturer's maximum recommended dose of dolutegravir in treatment-naïve or treatment-experienced INSTI-naïve patients, not receiving potent UGT1A/CYP3A inducers, is 50 mg once daily.

Conflict Code: ER – Overutilization
Drugs/Diseases

Util A	Util B	Util C **(Negating)**
Dolutegravir		Efavirenz
		Fosamprenavir/ritonavir
		Tipranavir/ritonavir
		Rifampin

Max Dose: 50 mg/day
Age Range: 12-999 yoa

References:
Tivicay Prescribing Information, August 2013, ViiV Healthcare.

36. Dolutegravir / Overutilization _____ _____

Alert Message: Tivicay (dolutegravir) may be over-utilized. The manufacturer's maximum recommended dose of dolutegravir in treatment-naïve or treatment-experienced INSTI-naïve patients when co-administered with the following potent UGT1A/CYP3A inducers: efavirenz, fosamprenavir/rtv, tipranavir/rtv or rifampin, is 50 mg twice daily. The safety and efficacy of doses above 50 mg twice daily have not been evaluated.

Conflict Code: ER – Overutilization
Drugs/Diseases

Util A	Util B	Util C **(Include)**
Dolutegravir		Efavirenz
		Fosamprenavir/ritonavir
		Tipranavir/ritonavir
		Rifampin

Max Dose: 100 mg/day
Age Range: 12-999 yoa

References:
Tivicay Prescribing Information, August 2013, ViiV Healthcare.
Cottrel ML, Hadzic T, Kashuba AD. Clinical Pharmacokinetic, Pharmacodynamic and Drug-Interaction Profile of the Integrase Inhibitor Dolutegravir. Clin Pharmacokinet. 04 July 2013 (Online). [Epub ahead of print].

37. Dolutegravir / Therapeutic Appropriateness _____ _____

Alert Message: Single agent antiretroviral therapy is not recommended in HIV-1-infected patients. Monotherapy does not demonstrate potent and sustained antiretroviral activity when compared to combination therapy with three or more antiretrovirals.

Conflict Code: TA - Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C **(Negating)**
Dolutegravir		All Other HIV Antiretroviral Meds

References:
Tivicay Prescribing Information, August 2013, ViiV Healthcare.
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. Feb 12, 2013.
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. November 5, 2012;pp1-333.
Available at: http://aidsinfo.nih.gov/contentfiles/lvguidelines/pediatricguidelines.pdf

38 Dolutegravir / Therapeutic Appropriateness – Age < 12 yoa _____ _____

Alert Message: Safety and effectiveness of Tivicay (dolutegravir) have not been established in pediatric patients younger than 12 years or weighing less than 40 kg, or in pediatric patients who are INST-experienced with documented or clinically suspected resistance to other INSTIs (raltegravir, elvitegravir).

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C
Dolutegravir		

Age Range: 0-11 yoa

References:
Tivicay Prescribing Information, August 2013, ViiV Healthcare.
Clinical Pharmacology, 2013 Elsevier/Gold Standard.

39. Dolutegravir / Dofetilide _____ _____

Alert Message: Co-administration of Tivicay (dolutegravir) with Tikosyn (dofetilide) is contraindicated due to the potential for increased dofetilide plasma concentrations and the risk of serious and/or life-threatening events (e.g., QT prolongation and torsades de pointes). Dolutegravir inhibits the renal organic transporter OCT2 which is responsible for dofetilide elimination.

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

Util A	Util B	Util C
Dolutegravir	Dofetilide	

References:
Tivicay Prescribing Information, August 2013, ViiV Healthcare.
Clinical Pharmacology, 2013 Elsevier/Gold Standard.

40. Dolutegravir /Hepatitis B & C _____ _____

Alert Message: Patients with underlying hepatitis B or C may be at increased risk for worsening or development of transaminase elevations with use of Tivicay (dolutegravir). Appropriate laboratory testing prior to initiating therapy and monitoring for hepatotoxicity during dolutegravir therapy are recommended in patients with underlying hepatic disease such as hepatitis B or C.

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

Util A	Util B	Util C
Dolutegravir	Hepatitis B	
	Hepatitis C	

References:
Tivicay Prescribing Information, August 2013, ViiV Healthcare.
Clinical Pharmacology, 2013 Elsevier/Gold Standard.

41. Dolutegravir / Inducers of CYP3A, UGT1A1, UGT1A3, UGT1A9, BCRP & P-gp _____ _____

Alert Message: Co-administration of Tivicay (dolutegravir) with drugs that induce CYP3A4, UGT1A1, UGT1A3, UGT1A9, BCRP or P-gp should be avoided because there is insufficient data to make dosing recommendations. Concurrent use of dolutegravir with drugs that induce the above enzymes and transporters may decrease dolutegravir plasma concentrations reducing the therapeutic effect.

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

Util A	Util B	Util C
Dolutegravir	Carbamazepine	
	Phenytoin	
	Oxcarbazepine	
	Phenobarbital	
	Modafinil	
	Dexamethasone	
	Nevirapine	

References:
Tivicay Prescribing Information, August 2013, ViiV Healthcare.
Clinical Pharmacology, 2013 Elsevier/Gold Standard.

*No marketed BCRP or UGT1A3 inducers at this time – will be added if/when inducers are marketed. Inducers which have specific dosing recommendations are not included in this criterion (see #4).

42. Dolutegravir / Etravirine / Negating Combo PI Therapy _____ _____

Alert Message: Co-administration of Tivicay (dolutegravir) and etravirine should be avoided, unless also administered with atazanavir/ritonavir, darunavir/ritonavir, or lopinavir/ritonavir. The concurrent use of etravirine and dolutegravir, without one of these ritonavir-boosted protease inhibitors, significantly reduces the plasma concentrations of dolutegravir resulting in decreased therapeutic effect.

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

Util A	Util B	Util C **(Negating)**
Dolutegravir	Etravirine	Atazanavir
		Darunavir
		Ritonavir
		Lopinavir/Ritonavir

References:
Tivicay Prescribing Information, August 2013, ViiV Healthcare.
Clinical Pharmacology, 2013 Elsevier/Gold Standard.
Cottrel ML, Hadzic T, Kashuba AD. Clinical Pharmacokinetic, Pharmacodynamic and Drug-Interaction Profile of the Integrase Inhibitor Dolutegravir. Clin Pharmacokinet. 04 July 2013 (Online). [Epub ahead of print].

43. Dolutegravir / Metformin _____ _____

Alert Message: Close monitoring is recommended when starting or stopping Tivicay (dolutegravir) and metformin together as metformin dose adjustment may be required. Concurrent use of these agents may result in increased metformin concentrations due to inhibition, by dolutegravir, of the renal organic cation transporter OCT2 which is responsible for metformin elimination.

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

Util A	Util B	Util C
Dolutegravir	Metformin	

References:
Tivicay Prescribing Information, August 2013, ViiV Healthcare.
Clinical Pharmacology, 2013 Elsevier/Gold Standard.

44. Dolutegravir / Medications Containing Polyvalent Cations _____ _____

Alert Message: Tivicay (dolutegravir) should be administered 2 hours before or 6 hours after taking medications containing polyvalent cations. Polyvalent cations can bind dolutegravir in the GI tract and reduce its bioavailability.

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

Util A	Util B	Util C
Dolutegravir	Buffered Aspirin	
	Aluminum Hydroxide	
	Oral Calcium Supplements	
	Magnesium Hydroxide	
	Oral Iron Supplements	
	Sucralfate	
	Cation-containing Laxatives	
	Multivitamins	

References:
Tivicay Prescribing Information, August 2013, ViiV Healthcare.
Clinical Pharmacology, 2013 Elsevier/Gold Standard.
Cottrel ML, Hadzic T, Kashuba AD. Clinical Pharmacokinetic, Pharmacodynamic and Drug-Interaction Profile of the Integrase Inhibitor Dolutegravir. Clin Pharmacokinet. 04 July 2013 (Online). [Epub ahead of print].

45. Dolutegravir / Inhibitors of CYP3A, UGT1A1, UGT1A3, UGT1A9, BCRP & P-gp _____ _____

Alert Message: Co-administration of Tivicay (dolutegravir) with drugs that inhibit CYP3A4, UGT1A1, UGT1A3, UGT1A9, BCRP or P-gp may result in increased dolutegravir plasma concentration as dolutegravir is a substrate of these enzymes and transporters. Potential for interaction is low and no dosage adjustment is recommended but monitoring may be appropriate.

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

Util A	Util B	Util C
Dolutegravir	Cyclosporine (3A4 & P-gp & BCRP)	
	Gemfibrozil (UGT1A1 & UGT1A3)	
	Ketoconazole (3A4 & UGT1A1 & P-gp)	
	Itraconazole (3A4 & P-gp)	
	Voriconazole (3A4 & P-gp)	
	Posaconazole (3A4 & P-gp)	
	Diltiazem (3A4 & P-gp)	
	Nicardipine (3A4 & P-gp)	
	Verapamil (3A4 & P-gp)	
	Nefazodone (3A4 & P-gp)	
	Clarithromycin (3A4 & P-gp)	

References:
Tivicay Prescribing Information, August 2013, ViiV Healthcare.
The Liverpool HIV Pharmacology Group (LHPG). Drug Interaction Charts. The University of Liverpool. Accessed Oct 15, 2013. Available at: http://www.hiv-druginteractions.org/Interactions.aspx
Pharmacology Weekly's Medication and Herbal Table of Substrates, Inhibitors and Inducers of UGT Enzymes in Phase II Metabolism. UGT Drug Reference Table. Accessed 10 2013.
Available at:
http://www.pharmacologyweekly.com/content/pages/drug-reference-table-cyp-p450-ugt-enzymes-transporters-ab

* Dolutegravir (DTG) is primarily metabolized via UGT1A1 with CYP3A4 as a secondary metabolic pathway (approximately 10%). DTG is also a substrate for UGT1A3, UGT1A9, BCRP or P-gp. Dolutegravir is a substrate for P-gp but because of its high permeability, significant alterations in absorption due to inhibition or induction is not expected (except with the HIV protease inhibitors). Interaction studies were conducted with boceprevir and telaprevir (potent CYP3A4 & P-gp inhibitors) and the increased DTG exposure was not considered clinically significantly as adverse events of DTG were mild and not exposure-dependent. There is no known UGT1A9 inhibitor, yet.

DUR Board Meeting
June 2, 2014
Brynhild Haugland Room

State Capitol

north dakota
department of
human services

North Dakota Medicaid
DUR Board Meeting Agenda
Brynhild Haugland Room
State Capitol
600 East Blvd. Avenue
Bismarck, ND
June 2, 2014
1pm

1. Administrative items
    - Travel vouchers

2. Old business
    - Review and Approval of Minutes of 03/14 Meeting — Chair
    - Budget Update — Brendan
    - Second Review of Cathflo — Brendan
    - Second Review of Intranasal Cyanocobalamin Products — Brendan
    - Second Review of Luzu — Brendan
    - Second Review of Noxafil — Brendan
    - Second Review of Bethkis — Brendan
    - Name Brand Narcotics (Zohydro, Fentanyl, Suboxone) — Brendan

3. New business
    - Medicaid Expansion Drug Coverage-Formulary and PA Processes — Dr. Crandell
    - Review of Cayston — HID
    - Review of Procysbi — HID
    - Review of Ravicti — HID
    - Review of Gastrointestinal Agents (Linzess, Amitiza) — HID
    - Review of Myalept — HID
    - Review of Northera — HID
    - Review of Oral Allergen Extracts (Ragwitek, Grastek) — HID
    - Criteria Recommendations — HID
    - Upcoming Meeting Date/Agenda — Chair

4. Adjourn — Chair

Please remember to silence all cellular phones during the meeting.

Drug Utilization Review (DUR) Meeting Minutes
March 3, 2014

Members Present: Norman Byers, John Savageau, Jeffrey Hostetter, Peter Woodrow, Carrie Sorenson, Russ Sobotta, Tanya Schmidt, Steve Irsfeld, James Carlson, Michael Booth, Cheryl Huber

Members Absent: Todd Twogood, Leann Ness, Gary Betting, Carlotta McCleary

Medicaid Pharmacy Department: Brendan Joyce

J. Hostetter called the meeting to order at 1:00 p.m. J. Hostetter made a motion for J. Savageau to complete the chairman position vacated by G. Pfister. P. Woodrow seconded the motion. The motion passed with no audible dissent. Chair J. Savageau asked for a motion to approve the minutes from the December meeting. N. Byers moved that the minutes be approved, and J. Hostetter seconded the motion. Chair J. Savageau called for a voice vote to approve the minutes. The motion passed with no audible dissent.

Budget Update
B. Joyce gave the budget update. For calendar year 2013, the net spend was approximately 19.5 million dollars. Prior to rebates, the amount was approximately 36.8 million dollars. Approximately 17.3 million dollars was received in rebates. January 2012 showed 80% generic utilization with the average paid per brand script costing approximately $208 and the average paid per generic script costing approximately $26. In January 2014, generic utilization was 85% with the average paid per brand script costing approximately $290 and the average paid per generic script costing $28.

Statins Second Review
A motion and second were made at the December meeting to place name-brand statins on prior authorization. The topic was brought up for a second review. There was no public comment. After discussion, Chair J. Savageau called for a voice vote to approve the motion. The motion passed with no audible dissent.

Vecamyl Second Review
A motion and second were made at the December meeting to place Vecamyl on prior authorization. The topic was brought up for a second review. There was no public comment. After discussion, Chair J. Savageau called for a voice vote to approve the motion. The motion passed with no audible dissent.

Coverage Clarification
B. Joyce informed the board that drugs that are not covered under pharmacy services will now be linked to a 'coverage clarification' document on the NDC drug lookup website. The document states, "The drug you selected is not covered under pharmacy services for North Dakota Medicaid. However, it is allowed under physician buy and bill services and should be billed by the physician's office."

Sylatron Review
This topic was tabled.

Cathflo Review
B. Joyce reviewed Cathflo information with the board. There was no public comment. P. Woodrow made a motion to place Cathflo on prior authorization. T. Schmidt seconded the motion. This topic will be reviewed at the next meeting.

Ketamine Powder Review
B. Joyce reviewed a Pharmaceutical Alert Bulletin from the U.S. Department of Health and Human Services/OIG discussing Ketamine powder. The board was informed that Ketamine will not be paid through pharmacy services.

Intranasal Cyanocobalamin Products Review
B. Joyce reviewed Nascobal information with the board. There was no public comment. M. Booth made a motion to place intranasal cyanocobalamin products on prior authorization. C. Huber seconded the motion. This topic will be reviewed at the next meeting.

Luzu Review
B. Joyce reviewed Luzu information with the board. There was no public comment. N. Byers made a motion to place Luzu on prior authorization. C. Sorenson seconded the motion. This topic will be reviewed at the next meeting.

Noxafil Review
B. Joyce reviewed Noxafil information with the board. There was no public comment. N. Byers made a motion to place Noxafil on prior authorization. S. Irsfeld seconded the motion. This topic will be reviewed at the next meeting.

Bethkis Review
B. Joyce reviewed Bethkis information with the board. There was no public comment. M. Booth made a motion to place Bethkis on prior authorization. N. Byers seconded the motion. This topic will be reviewed at the next meeting.

Update of New Drug Lookup Website
C. Rieth reviewed the enhanced NDC drug lookup website with the board. The website allows users to search for a drug by name or NDC number and it displays easy to understand results along with each drug's PA form.

Criteria Recommendations
The recommended RDUR criteria enclosed in the packet were developed from product information provided by the manufacturers and usually are consistent with new indications, new drugs added, new warnings, etc. These proposed criteria will be added to the current set of criteria and will be used in future DUR cycles. C. Huber moved to approve the new criteria and N. Byers seconded the motion. Chair J. Savageau called for a voice vote. The motion passed with no audible dissent.

The next DUR board meeting will be held June 2 in Bismarck. N. Byers made a motion to adjourn the meeting. J. Hostetter seconded. The motion passed with no audible dissent. J. Savageau adjourned the meeting.

CATHFLO ACTIVASE
PA FORM

HEALTH INFORMATION DESIGNS

Prior Authorization Vendor for ND Medicaid

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-773-0695

ND Medicaid requires that patients receiving a new prescription for Cathflo Activase must meet the following criteria:

- **Patient must have an FDA approved indication.**
- **Cathflo Activase is indicated for restoration of function to central venous access devices as assessed by the ability to withdraw blood.**

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: □ CATHFLO ACTIVASE	**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 Signature		Date	

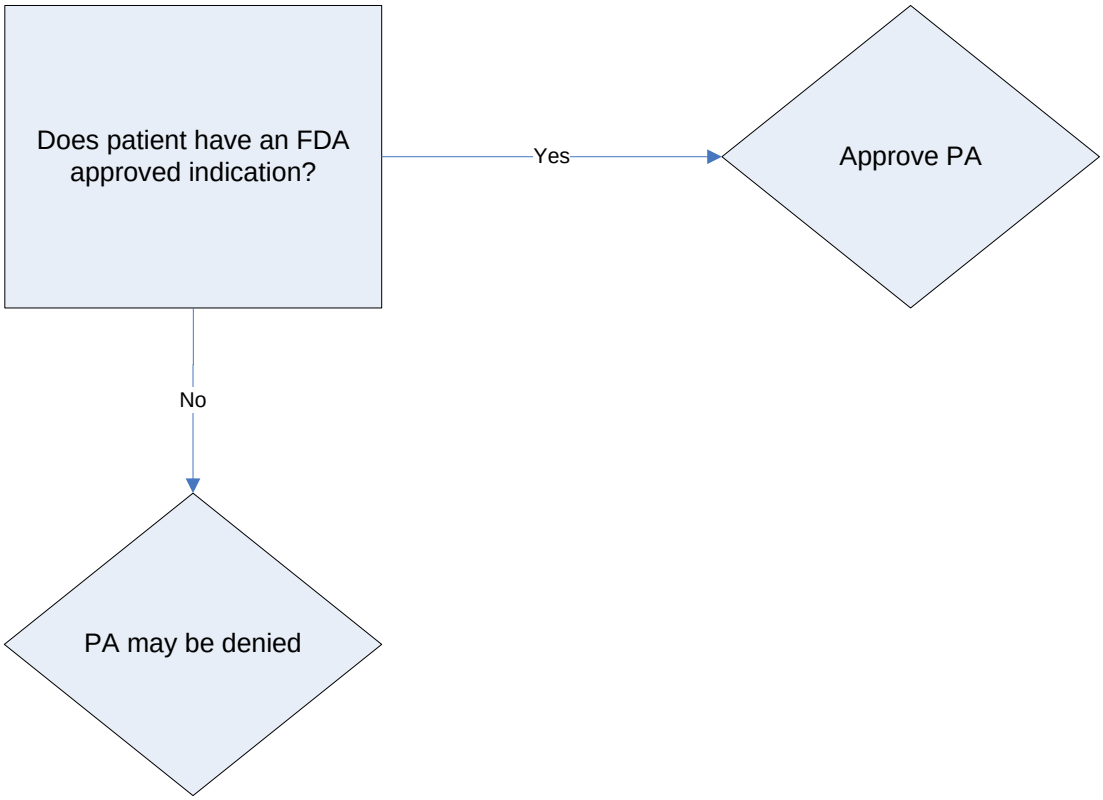
Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

Date Received	Initials:
Approved - Effective dates of PA: From: / / To: / /	Approved by:
Denied: (Reasons)	

North Dakota Department of Human Services
Cathflo Activase Prior Authorization Algorithm



INTRANASAL CYANOCOBALAMIN PRODUCTS
PA FORM

HEALTH INFORMATION DESIGNS

Prior Authorization Vendor for ND Medicaid

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-773-0695

ND Medicaid requires that patients receiving a new prescription for intranasal cyanocobalamin products must try injectable cyanocobalamin as first line therapy.

- **Injectable B-12 does not require a prior authorization.**

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: □ NASCOBAL	**Diagnosis for this Request:**		
Failed Therapy:	**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 Signature		Date	

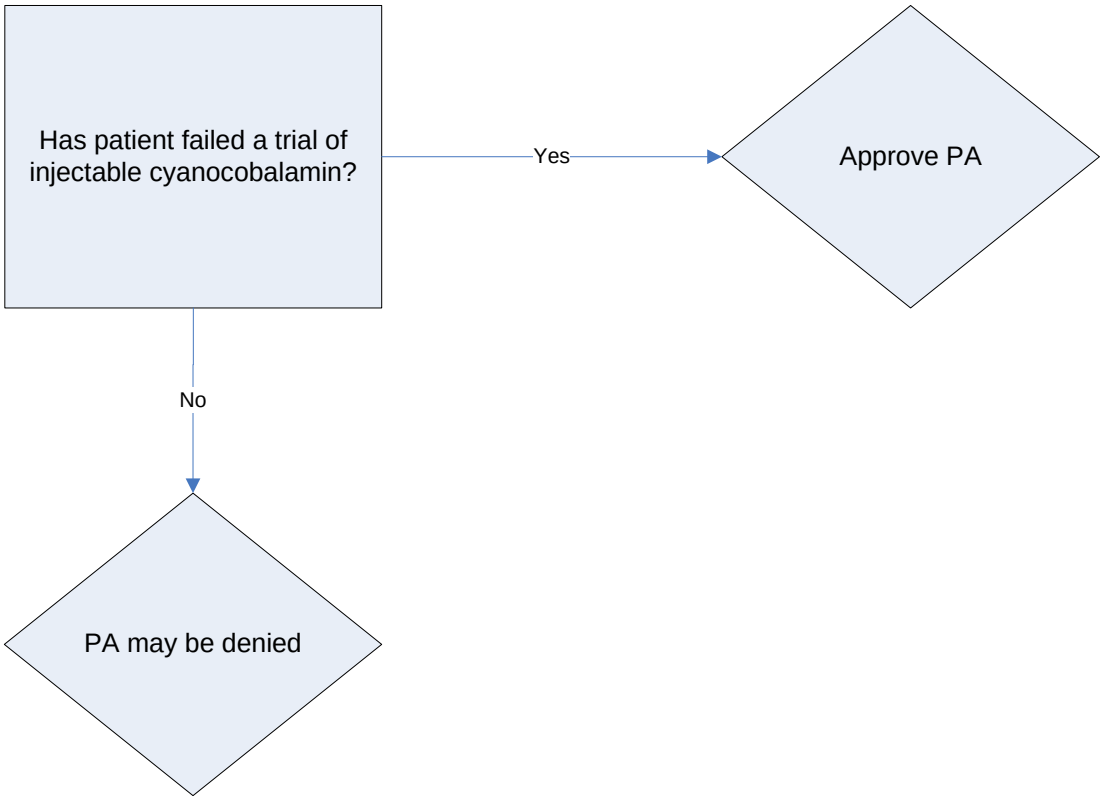
Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

Date Received	Initials:
Approved - Effective dates of PA: From: / / To: / /	Approved by:
Denied: (Reasons)	

North Dakota Department of Human Services
Intranasal Cyanocobalamin Prior Authorization Algorithm



LUZU
PA FORM

HEALTH INFORMATION DESIGNS

Prior Authorization Vendor for ND Medicaid

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-773-0695

ND Medicaid requires that patients receiving a new prescription for Luzu must meet the following criteria:

- **Patient must have an FDA approved indication.**
- **Patient must be 18 years of age or older.**
- **Patient must have documented history of failure of two topical antifungal agents (clotrimazole, econazole) and two oral antifungal agents (terbinafine, fluconazole, itraconazole).**

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: □ LUZU	**Diagnosis for this Request:**
Failed Therapy: **1.** **2.** **3.** **4.**	**Start Date:** **End Date:** **1.** **2.** **3.** **4.**
□ *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 Signature	Date

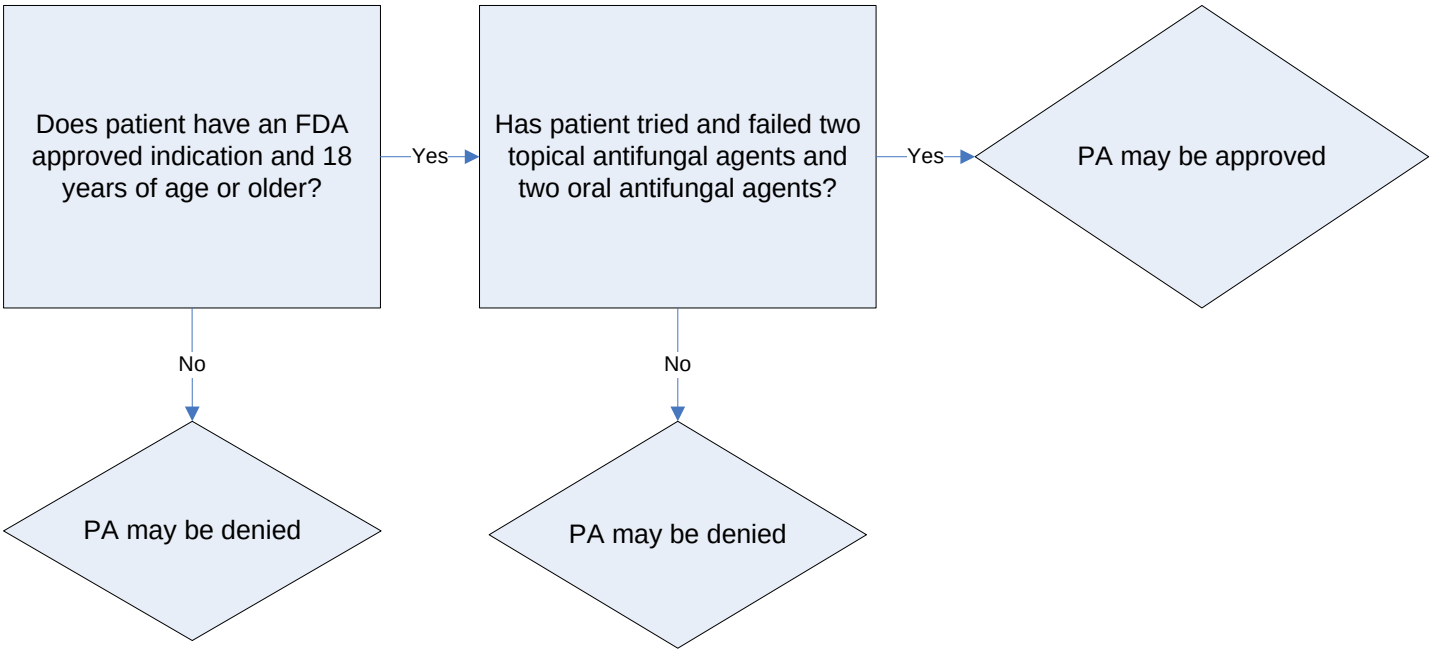
Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

Date Received	Initials:
Approved - Effective dates of PA: From: / / To: / /	Approved by:
Denied: (Reasons)	

North Dakota Department of Human Services
Luzu Prior Authorization Algorithm



NOXAFIL
PA FORM

HEALTH INFORMATION DESIGNS

Prior Authorization Vendor for ND Medicaid

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-773-0695

ND Medicaid requires that patients receiving a new prescription for Noxafil must meet the following criteria:

- **Patient must have an FDA approved indication.**
- **Patient must have documented history of failure of two agents (itraconazole, fluconazole) to receive Noxafil suspension for oropharyngeal candidiasis.**

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: □ NOXAFIL TABLET □ NOXAFIL SUSPENSION	**Diagnosis for this Request:**
Failed Therapy for Oropharyngeal Candidiasis (suspension only): **1.** **2.**	**Start Date:** **End Date:** **1.** **2.**
□ *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 Signature	Date

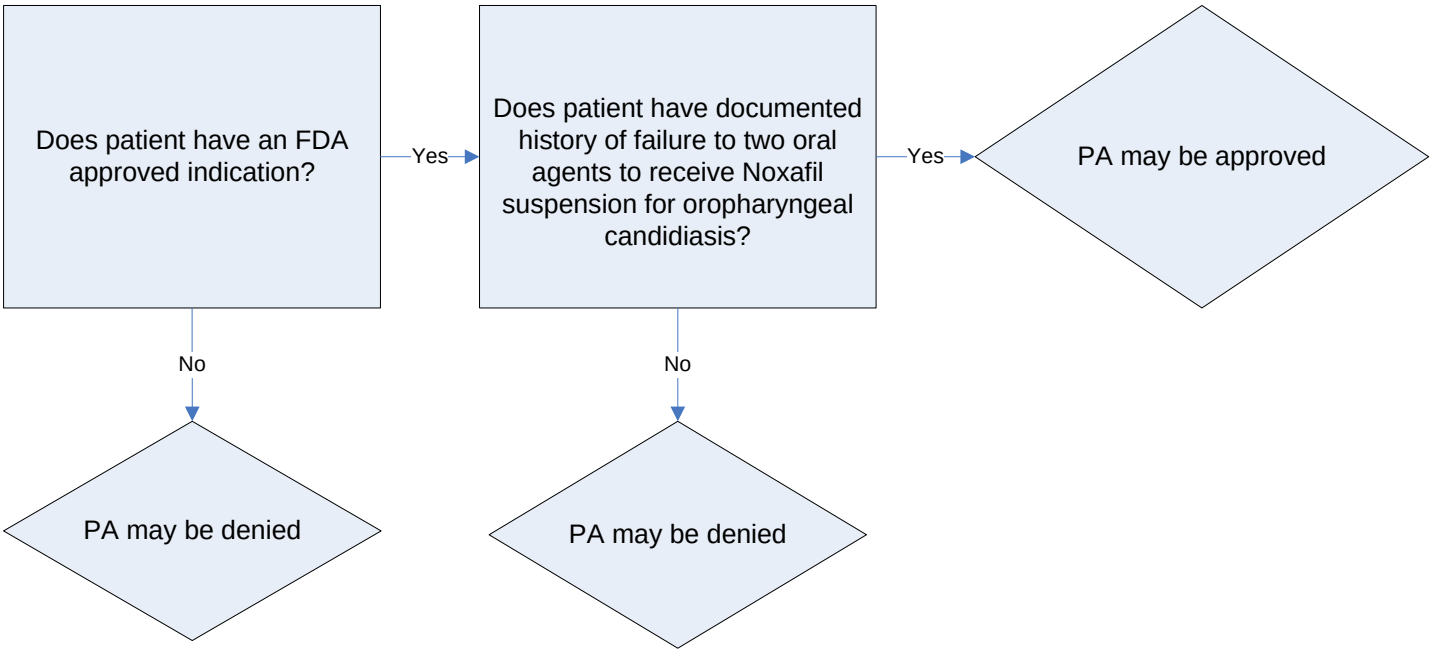
Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

Date Received	Initials:
Approved - Effective dates of PA: From: / / To: / /	Approved by:
Denied: (Reasons)	

North Dakota Department of Human Services
Noxafil Prior Authorization Algorithm



Approved indications:

Tablets and suspension
Prophylaxis of invasive *Aspergillus* and *Candida* infections in patients who are at high risk of developing these infections due to being severely immunocompromised, such as hematopoietic stem cell transplantation (HSCT) recipients with Graft vs. Host Disease (GVHD) or those with hematologic malignancies with prolonged neutropenia from chemotherapy.

Suspension
Treatment of oropharyngeal candidiasis.

BETHKIS
PA FORM

HEALTH INFORMATION DESIGNS

Prior Authorization Vendor for ND Medicaid

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-773-0695

ND Medicaid requires that patients receiving a new prescription for Bethkis must meet the following criteria:

- **Patient must have an FDA approved indication.**

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: □ BETHKIS	**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 Signature		Date	

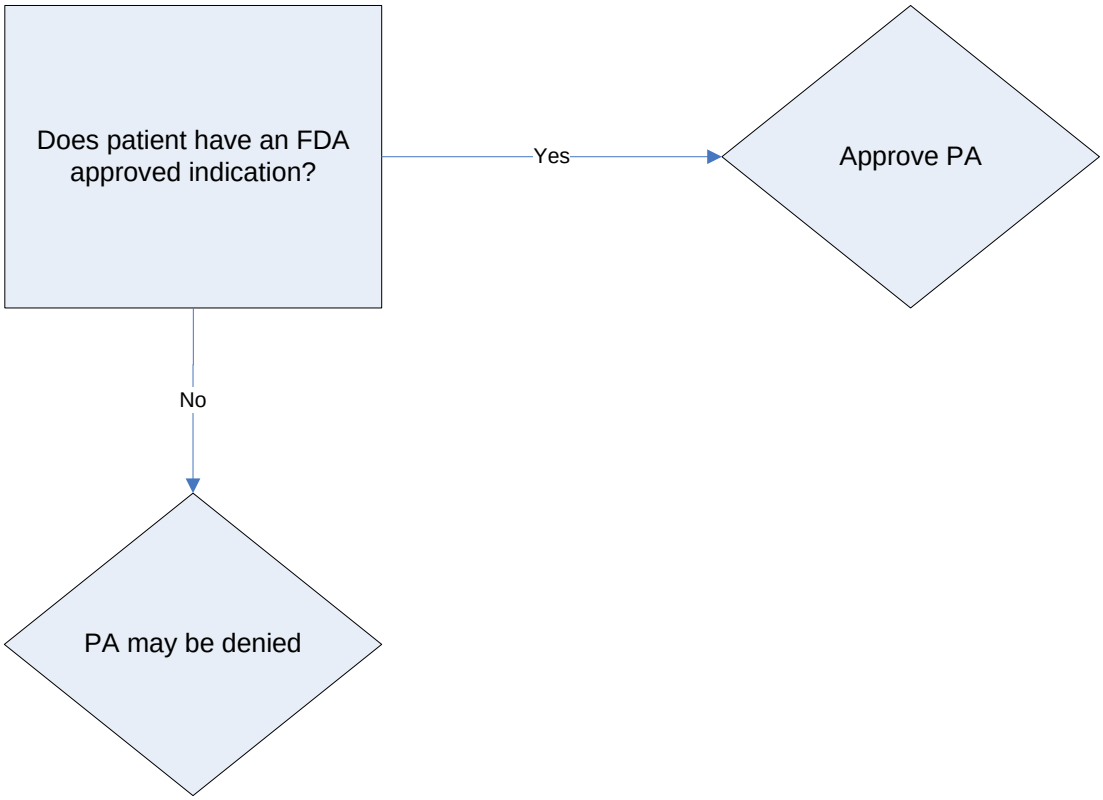
Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

Date Received	Initials:
Approved - Effective dates of PA: From: / / To: / /	Approved by:
Denied: (Reasons)	

North Dakota Department of Human Services
Bethkis Prior Authorization Algorithm



BRAND-NAME NARCOTICS PA FORM

HEALTH INFORMATION DESIGNS

Prior Authorization Vendor for ND Medicaid

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-773-0695

ND Medicaid requires that patients receiving a new prescription for a brand-name narcotic must meet the following criteria:

- **Documented failure of a 30-day trial of a generic narcotic.**

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:

□ EMBEDA □ OPANA ER □ KADIAN □ AVINZA □ EXALGO □ FENTORA □ ONSOLIS □ MAGNACET □ BUTRANS

□ OTHER BRAND NAME PRODUCT _____

FAILED THERAPY	**START DATE**	**END DATE**	**DOSE**	**FREQUENCY**

Physician Signature	Date

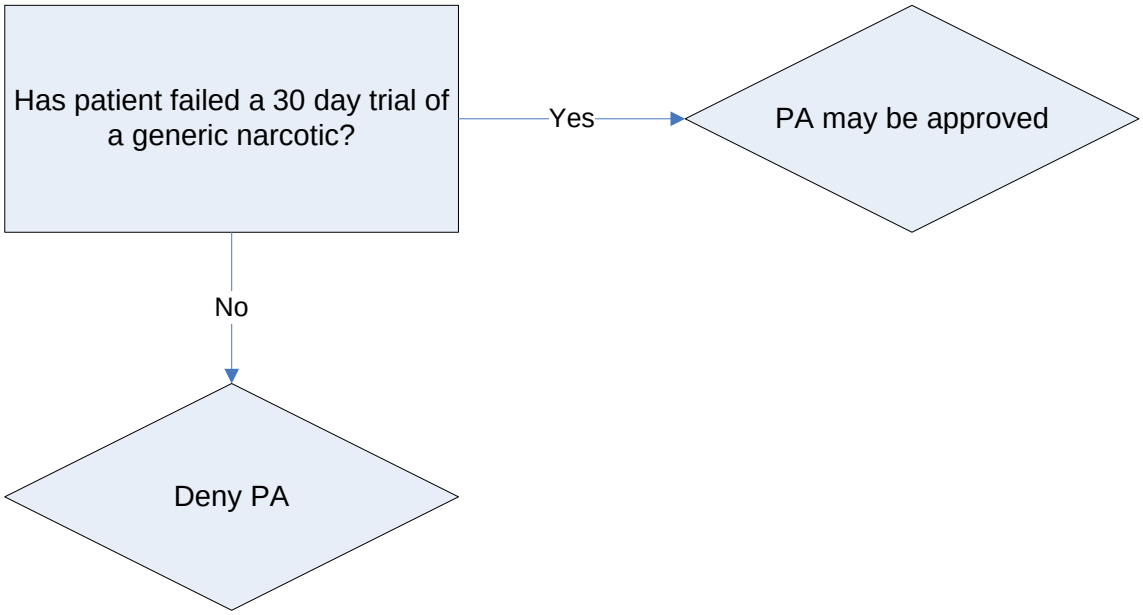
Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

Date Received	Initials:
Approved - Effective dates of PA: From: / / To: / /	Approved by:
Denied: (Reasons)	

North Dakota Department of Human Services
Name-brand Narcotics Prior Authorization Algorithm



SANFORD
HEALTH PLAN

Sanford Health Plan

Michael P. Crandell, MD, MS
Chief Medical Officer

June 2 , 2014

Health Plan History

- South Dakota Certificate of Authority
  - 1997
- Iowa/Minnesota Certificates of Authority
  - 1998
- North Dakota Certificate of Authority
  - February 2010
- Plan established as a Non-Gatekeeper Model
- Community-Based HMO
- A Non-profit owned exclusively by Sanford Health

SANFORD HEALTH PLAN

Key Statistics

- Provider Network in excess of 14,000 providers
- Total Service Area
  - South Dakota – Statewide
  - North Dakota – Statewide
  - Iowa – 10 counties including Sioux City
  - Minnesota – 36 western Minnesota counties.

    (Pending approval for 10 additional counties)

SANFORD HEALTH PLAN

Key Statistics

Membership (all states)

- Fully Insured: 42,573
- Sanford Group Health: 38,495
- Sioux Empire Healthcare Coalition TPA (SD only): 2,971

Total 87,102

SANFORD HEALTH PLAN

Sanford Health

- 27,000 employees
- 1,359 physicians in more than 80 sub-specialty areas
- 39 hospitals
- 32 long-term care facilities
- 225 clinic sites

- Serving 2.3 million people, 132 communities, over 260,000 square miles, 6 states
- Each year, Sanford provides more than…
  - 5.5 million clinic visits
  - 79,000 admissions
  - 75,000 surgical procedures
  - 8,600 births

SANFORD HEALTH PLAN

SANFORD HEALTH
SYSTEM LOCATIONS

Successes

- Integrated health system able to draw on internal resources to develop solutions for identified problems
- Health Plan RN case managers make calls after discharge to ensure medication being taken and/or follow-up appointments scheduled and kept
- Monitor medication compliance with analytics tool

SANFORD HEALTH PLAN

Affordable Care Act

- Medical Homes
- Behavioral Health Triage
- Health Plan – Clinic collaboration
- Medicaid Expansion in North Dakota began January 1, 2014 with Sanford Health Plan

SANFORD HEALTH PLAN

Sanford Health Plan
Pharmacy Services

- 15 year partnership with Express Scripts
- Formulary Management
- Drug Step Management
- Drug Quantity Management
- Care Continuum
  - Utilization Management
  - Therapy Adherence

SANFORD
HEALTH PLAN

Sanford Health Plan
Formulary Development

- Custom-based on efficacy, safety, and cost effectiveness
- Consulting Pharmacist
- Express Scripts recommendations
- Annual presentation to Physician Quality Committee
- Notice of changes and publication
- Modifications throughout the year

SANFORD
HEALTH PLAN

Medicaid Expansion Key Diagnoses

- Hypertension: 142
- Hyperlipidemia: 51
- COPD: 34
- Chronic Renal Failure: 17
- Asthma: 38
- Rheumatoid Arthritis: 12
- Osteoarthritis: 100
- Diabetes: 161
- Bipolar Disorder: 19
- Chronic Liver and Biliary Disease: 19
- Cancer: 10
- Major Depression: 43

(figures as of April 29, 2014)

SANFORD HEALTH PLAN

Top 20 Medications by Volume

Drug Name	Most Common Use	Brand/ Generi
HYDROCODONE-ACETAMINO		G
LISINOPRIL	High Blood Pressure	G
OMEPRAZOLE	Heartburn or Ulcers	G
GABAPENTIN	Seizures	G
TRAMADOL HCL	Pain	G
CYCLOBENZAPRINE HCL		G
CLONAZEPAM	Seizures	G
SERTRALINE HCL	Depression	G
SIMVASTATIN	High Cholesterol	G
METFORMIN HCL	Diabetes	G
LEVOTHYROXINE SODIUM	Thyroid	G
TRAZODONE HCL		G
AMLODIPINE BESYLATE	Hypertension	G
ALPRAZOLAM	Anxiety	G
AZITHROMYCIN	Antibiotic	G
LORAZEPAM	Anxiety	G
CITALOPRAM HBR	Depression	G
METOPROLOL SUCCINATE	Hypertension	G
PREDNISONE	Inflammation	G
ATORVASTATIN CALCIUM	High Cholesterol	G

The information on this report represents the most common indication of each drug listed. However, please keep in mind that many drugs have multiple purposes and may be taken for conditions other than indicated on this report. The indications are provided for the top drugs processed with members enrolled in Sanford Health Plan.

Top 20

B = Brand
G = Generic
N = Non-Specified
O = Over the Counter (ie. Diabetic Supplies)
S = Single-source Brand

SANFORD HEALTH PLAN

Thank You . . . .

Questions

SANFORD HEALTH PLAN

Pharmacy Handbook

for non-grandfathered members

Table of Contents

Sanford Health Plan Formulary

It is agreed that this prescription drug rider is attached to and made a part of the contract between Sanford Health Plan and the member or Plan Sponsor. However, nothing in this rider will alter or affect any of the terms of the contract, unless specifically stated.

To be covered by the Plan, drugs must be:

1. Prescribed by a licensed health care professional within the scope of his or her practice;
2. Listed in the Plan Formulary, unless certification is given by the Plan;
3. Provided by a Participating Pharmacy except in the event of a medical emergency. If the prescription is obtained at a Non-Participating Pharmacy the Member is responsible for the prescription drug cost in full.
4. Approved by the Federal Food and Drug Administration (FDA) for use in the United States.

This information about the Sanford Health Plan Formulary applies only to those drugs, including injectable drugs that may be covered under this Policy.

The Sanford Health Plan Formulary is a list of FDA approved brand-name and generic drugs chosen by health care providers on the Physician Quality Committee. Selection criteria include clinical efficacy, safety, and cost effectiveness. Additions are made throughout the year as warranted with a complete review once a year.
For a complete listing of the formulary, pharmacy locator, health news, generic substitution information, drug side effect and interaction information, personal reminders, price check, benefit information and your current medication usage, log into your myHealthPlan account at www.sanfordhealthplan.com/myhealthplan.

Following the Sanford Health Plan Formulary, especially asking your healthcare Practitioner for generic medications, will save you money and help control the costs of health care. If you request a brand-name drug when there is an equivalent generic alternative available, you will be required to pay the price difference between the brand and the generic in addition to your copay. When your Practitioner prescribes a drug for you, you can ask that he or she refer to the Sanford Health Plan Formulary found on their myHealthPlan account at www.sanfordhealthplan.com/providerlogin.

Open Formulary

An Open Formulary is a list of medications that are recommended by Express Scripts Inc., on behalf of Sanford Health Plan. This list is used only to encourage Practitioners to prescribe appropriate medications. All drugs are covered as defined by The Plan.

Closed Formulary

A Closed Formulary is a list of certain medications that are covered and others that are not covered by The Plan. If a prescription is written for a medication that is not on the formulary list, the Member is responsible in full for the cost of the medication. If you receive an adverse determination for your request for a formulary exception, you may request a review of that decision through the *Complaints and Appeals Procedure.*

Pharmacy Programs

Please review the following information concerning the drug exclusion list, certification, quantity limits, step therapy and injectable medication programs. Additional drugs may be added throughout the year to any listing. Sanford Health Plan will publish these changes on the Sanford Health Plan website and will notify you of any formulary changes that impact your cost sharing or accessibility. If you have any questions or concerns, contact our Pharmacy Management Team at (800) 805-7938.

Injectable Drug Program

Sanford Health Plan has contracted with *CuraScript* for your injectable medication needs. *CuraScript* will ship your drug and all the supplies you need for your injection directly to your home or Practitioner's office within 24 to 48 hours after the request is approved and medication is ordered. Administration supplies (syringes, needles etc.) are free; you are not required to pay additional copays for those supplies. Prior to all shipments, a Patient Admission Specialist will contact you to discuss your copay for your drug and arrange delivery.

CuraScript offers toll-free customer service available 24 hours a day, 365 days a year. Specially trained staff offers support services for you, your caregivers, and your Practitioners that include:

- Injectable drug order information;
- Consultation with an experienced, knowledgeable pharmacist;

- Specially trained nurses available to answer questions about injectable drugs and the disease states they treat.

To enroll in the *CuraScript* program, call toll-free at *1-866-333-9721* and a customer service representative will ask the following information:

- **Your name and date of birth**
- **Your phone number and address**
- **The name of your injectable medication to be filled**
- **Your doctor's name and phone number**

CuraScript will mail your Practitioner a letter explaining the program and how to send your prescriptions to *CuraScript*. By participating in Specialty Care, you are automatically enrolled in a drug therapy management program. This program entitles you to receive the following benefits at no additional charge:

- Access to nurses and pharmacists 24 hours/day, 7 days/week for questions related to your injectable drug and the illness the drug is treating.
- Injectable drug refill reminders if you forget to call for your refill, and convenient refill process.
- Free delivery of your medication and supplies to your home, Practitioner's office or designated location.

Injectable and High Cost Medications

- **The following medications (injectable and high cost medications) must be obtained from CuraScript by calling (866) 333-9721. If these medications are obtained from a retail pharmacy or Practitioner's office without certification by Sanford Health Plan Pharmacy Management Team the Member will be responsible for the full cost of the medication.** All medications obtained from CuraScript are prior authorized by CuraScript using criteria approved by the Sanford Health Plan. Most of these medications are covered under the medical benefit and are subject to payment with deductible, coinsurance or a medical copay, dependent upon your benefit package.

Name	Disease State	Coverage	Preferred Alternatives
8-MOP	MISCELLANEOUS SPECIALTY CONDITIONS	MEDICAL	
ABRAXANE	CANCER	MEDICAL	
ACTEMRA	INFLAMMATORY CONDITIONS	MEDICAL	
ACTHAR H.P.	MULTIPLE SCLEROSIS	MEDICAL	
ACTIMMUNE	IMMUNE DEFICIENCY	MEDICAL	
ADAGEN	*ENZYME DEFICIENCIES*	*MEDICAL - LIMITED DISTRIBUTION*	
ADCIRCA	VASODILATOR	PHARMACY- TIER 3	
ADRIAMYCIN	CANCER	MEDICAL	
ADRUCIL	CANCER	MEDICAL	
ADVATE	HEMOPHILIA	MEDICAL	
AFINITOR	CANCER	MEDICAL	
ALDURAZYME	ENZYME DEFICIENCIES	MEDICAL	
ALFERON N	CANCER	MEDICAL	
ALIMTA	CANCER	MEDICAL	
ALKERAN	CANCER	MEDICAL	
ALPHANATE	HEMOPHILIA	MEDICAL	
ALPHANINE SD	HEMOPHILIA	MEDICAL	
AMEVIVE	INFLAMMATORY CONDITIONS	MEDICAL	
AMIFOSTINE	CANCER	MEDICAL	
AMPYRA	MULTIPLE SCLEROSIS	PHARMACY- TIER 3	
APOKYN	*MISCELLANEOUS SPECIALTY CONDITIONS*	*PHARMACY- TIER 3 - LIMITED DISTRIBUTION*	
ARALAST/NP	RESPIRATORY CONDITIONS	MEDICAL	
ARANESP	BLOOD CELL DEFICIENCY	PHARMACY - TIER 2	
ARCALYST	*INFLAMMATORY CONDITIONS*	*MEDICAL -LIMITED DISTRIBUTION*	
AREDIA	CANCER	MEDICAL	
ARRANON	*CANCER*	*MEDICAL - LIMITED DISTRIBUTION*	
ARZERRA	CANCER	MEDICAL	
ATGAM	TRANSPLANT	MEDICAL	
AUBAGIO	MULTIPLE SCLEROSIS	TIER 2	
AVASTIN	CANCER, OPTHALMIC DISORDERS	MEDICAL	

Name	Disease State	Coverage	Preferred Alternatives
AVONEX	MULTIPLE SCLEROSIS	PHARMACY - TIER 3- STEP THERAPY RULES APPPLY	BETASERON- TIER 1 COPAXONE OR REBIF- TIER 2
BEBULIN VH IMMUNO	HEMOPHILIA	MEDICAL	
BENEFIX	HEMOPHILIA	MEDICAL	
BENLYSTA	SYSTEMIC LUPUS ERYTHEMATOUS	MEDICAL	
BERINERT	*HEREDITARY ANGIOEDEMA*	*MEDICAL- LIMITED DISTRIBUTION*	
BETASERON	MULTIPLE SCLEROSIS	PHARMACY -TIER 2	
BEXXAR	*CANCER*	*MEDICAL - LIMITED DISTRIBUTION*	
BICNU	CANCER	MEDICAL	
BLEOMYCIN SULFATE	CANCER	MEDICAL	
BOSULIF	CANCER	MEDICAL	
BOTOX	MISCELLANEOUS SPECIALTY CONDITIONS	MEDICAL	
BRAVELLE	INFERTILITY	PHARMACY 100% COPAY	
BUSULFEX	CANCER	MEDICAL	
CAMPATH	CANCER	MEDICAL	
CAMPTOSAR	CANCER	MEDICAL	
CAPRELSA	CANCER	MEDICAL	
CARBAGLU	*GENETIC DISORDER*	*MEDICAL - LIMITED DISTRIBUTION*	
CARBOPLATIN	CANCER	MEDICAL	
CARIMUNE	*IMMUNE DEFICIENCY*	*MEDICAL - LIMITED DISTRIBUTION*	
CAYSTON	*RESPIRATORY CONDITIONS*	*PHARMACY TIER 3- LIMITED DISTRIBUTION*	
CELLCEPT INJ	TRANSPLANT	MEDICAL	
CEPROTIN	*MISCELLANEOUS SPECIALTY CONDITIONS*	*MEDICAL- LIMITED DISTRIBUTION*	
CEREDASE	*ENZYME DEFICIENCIES*	*MEDICAL - LIMITED DISTRIBUTION*	
CEREZYME	ENZYME DEFICIENCIES	MEDICAL	
CERUBIDINE	CANCER	MEDICAL	
CETROTIDE	INFERTILITY	PHARMACY 100% COPAY	
CHENODAL	*MISCELLANEOUS SPECIALTY CONDITIONS*	*PHARMACY TIER 3- LIMITED DISTRIBUTION*	
CHORIONIC GONADOTROPIN	INFERTILITY	PHARMACY 100% COPAY	
CIMZIA	INFLAMMATORY CONDITIONS	PHARMACY TIER 3- STEP THERAPY RULES APPPLY	ENBREL OR HUMIRA - TIER 2
CINRYZE	HEREDITARY ANGIOEDEMA	MEDICAL	
CISPLATIN	CANCER	MEDICAL	
CLADRIBINE	CANCER	MEDICAL	
CLOLAR	CANCER	MEDICAL	
COPAXONE	MULTIPLE SCLEROSIS	PHARMACY - TIER 2	
COPEGUS	HEPATITIS C	PHARMACY - TIER 2	
CORIFACT	*HEMOPHILIA*	*MEDICAL - LIMITED DISTRIBUTION*	
COSMEGEN	CANCER	MEDICAL	
CYCLOPHOSPHAMIDE	CANCER	MEDICAL	
CYCLOSPORINE INJ	TRANSPLANT	MEDICAL	
CYSTAGON	*MISCELLANEOUS SPECIALTY CONDITIONS*	*PHARMACY TIER 3 - LIMITED DISTRIBUTION*	
CYTARABINE	CANCER	MEDICAL	
CYTOGAM	IMMUNE DEFICIENCY	MEDICAL	
DACARBAZINE	CANCER	MEDICAL	
DACOGEN	CANCER	MEDICAL	
DACTINOMYCIN	CANCER	MEDICAL	
DAUNORUBICIN HCL	CANCER	MEDICAL	
DAUNOXOME	CANCER	MEDICAL	

Name	Disease State	Coverage	Preferred Alternatives
DDAVP (injection only)	ENDOCRINE DISORDERS	MEDICAL	
DEFEROXAMINE MESYLATE	IRON TOXICITY	MEDICAL	
DEPOCYT	CANCER	MEDICAL	
DESFERAL, MESYLATE	IRON TOXICITY	MEDICAL	
DESMOPRESSIN ACETATE INJ	OTHER ENDOCRINE DRUGS	MEDICAL	
DEXRAZOXANE	CANCER	MEDICAL	
DOCETAXEL	CANCER	MEDICAL	
DOXIL	CANCER	MEDICAL	
DOXORUBICIN HCL	CANCER	MEDICAL	
DYSPORT	*NEUROMUSCULAR CONDITIONS*	*MEDICAL- LIMITED DISTRIBUTION*	
EGRIFTA	*IMMUNE DEFICIENCY GROWTH HORMONE*	*PHARMACY- TIER 3 LIMITED DISTRIBUTION*	
ELAPRASE	*ENZYME DEFICIENCIES*	*MEDICAL - LIMITED DISTRIBUTION*	
ELELYSO	OTHER ENDOCRINE DRUGS	MEDICAL	
ELIGARD	CANCER	MEDICAL	
ELITEK	CANCER	MEDICAL	
ELLENCE	CANCER	MEDICAL	
ELOXATIN	CANCER	MEDICAL	
ELSPAR	CANCER	MEDICAL	
ENBREL	INFLAMMATORY CONDITIONS	PHARMACY - TIER 2	
ENOXAPARIN	ANTICOAGULANT	PHARMACY - AVAIL THRU RETAIL - TIER 1	
EPIRUBICIN	CANCER	MEDICAL	
EPOGEN	BLOOD CELL DEFICIENCY	PHARMACY - TIER 3	ARANESP OR PROCRIT – TIER 2
EPOPROSTENOL	*PULMONARY HYPERTENSION*	*MEDICAL- LIMITED DISTRIBUTION*	
ERBITUX	CANCER	MEDICAL	
ERIVEDGE	CANCER	MEDICAL	
ETHYOL	CANCER	MEDICAL	
ETOPOPHOS	CANCER	MEDICAL	
ETOPOSIDE	CANCER	MEDICAL	
EUFLEXXA	OSTEOARTHRITIS	MEDICAL	
EXJADE	*IRON TOXICITY*	*MEDICAL - LIMITED DISTRIBUTION*	
EYLEA	OPHTHALMIC CONDITIONS	MEDICAL	
FABRAZYME	ENZYME DEFICIENCIES	MEDICAL	
FASLODEX	CANCER	MEDICAL	
FEIBA NH	HEMOPHILIA	MEDICAL	
FEIBA VH IMMUNO	HEMOPHILIA	MEDICAL	
FIRAZYR	HEREDITARY ANGIOEDEMA	PHARMACY - TIER 3	
FIRMAGON	CANCER	MEDICAL	
FLEBOGAMMA/DIF	IMMUNE DEFICIENCY	MEDICAL	
FLOLAN	*PULMONARY HYPERTENSION*	*MEDICAL - LIMITED DISTRIBUTION*	
FLOXURIDINE	CANCER	MEDICAL	
FLUDARA	CANCER	MEDICAL	
FLUDARABINE PHOSPHATE	CANCER	MEDICAL	
FLUOROURACIL	CANCER	MEDICAL	
FOLLISTIM AQ	INFERTILITY	PHARMACY 100% COPAY	
FOLOTYN	*CANCER*	*MEDICAL - LIMITED DISTRIBUTION*	
FORTEO	OSTEOPOROSIS	PHARMACY - TIER 2	
FRAGMIN	ANTICOAGULANT	PHARMACY - AVAIL THRU RETAIL - TIER 2	
FUDR	CANCER	MEDICAL	
FUSILEV	CANCER	MEDICAL	
FUZEON	IMMUNE DEFICIENCY	MEDICAL	

Name	Disease State	Coverage	Preferred Alternatives
GAMASTAN S/D	IMMUNE DEFICIENCY	MEDICAL	
GAMMAGARD	IMMUNE DEFICIENCY	MEDICAL	
GAMMAKED	IMMUNE DEFICIENCY	MEDICAL	
GAMUNEX, -C	IMMUNE DEFICIENCY	MEDICAL	
GANIRELIX ACETATE	INFERTILITY	PHARMACY 100% COPAY	
GEMCITABINE HCL	CANCER	MEDICAL	
GEMZAR	CANCER	MEDICAL	
GENOTROPIN	GROWTH DEFICIENCY	MEDICAL	
GILENYA	MULTIPLE SCLEROSIS	PHARMACY- TIER 3	STEP THERAPY
GILOTRIF	CANCER	MEDICAL	
GLASSIA	RESPIRATORY CONDITIONS	MEDICAL	
GLEEVEC	CANCER	MEDICAL	
GONAL-F/RFF	INFERTILITY	PHARMACY 100% COPAY	
HALAVEN	CANCER	MEDICAL	
HELIXATE FS	HEMOPHILIA	MEDICAL	
HEMOFIL M	HEMOPHILIA	MEDICAL	
HEPAGAM B	HEPATITIS B	MEDICAL	NABI-HB - TIER 2
HERCEPTIN	CANCER	MEDICAL	
HIZENTRA	IMMUNE DEFICIENCY	MEDICAL	
HUMATE-P	HEMOPHILIA	MEDICAL	
HUMATROPE	GROWTH DEFICIENCY	MEDICAL	
HUMIRA	INFLAMMATORY CONDITIONS	PHARMACY - TIER 2	
HYALGAN	OSTEOARTHRITIS	MEDICAL	
HYCAMTIN	CANCER	MEDICAL	
HYPERHEP S/D	HEPATITIS B	MEDICAL	NABI-HB - TIER 2
HYPERRAB S/D	IMMUNE DEFICIENCY	MEDICAL	
HYPERRHO S/D	IMMUNE DEFICIENCY	MEDICAL	
IDAMYCIN PFS	CANCER	MEDICAL	
IDARUBICIN HCL	CANCER	MEDICAL	
IFEX	CANCER	MEDICAL	
IFOSFAMIDE	CANCER	MEDICAL	
IFOSFAMIDE/MESNA	CANCER	MEDICAL	
ILAIRS	AUTOINFLAMMATORY CONDITION	MEDICAL	
IMOGAM RABIES-HT	IMMUNE DEFICIENCY	MEDICAL	
INCIVEK	HEPATITIS C	MEDICAL	
INCRELEX	GROWTH DEFICIENCY	MEDICAL	
INFERGEN	HEPATITIS C	PHARMACY - TIER 3	INTRON A, ROFERON A-TIER 2
INLYTA	CANCER	MEDICAL	
INNOHEP	ANTICOAGULANT	PHARMACY - AVAIL THRU RETAIL - TIER 3	ENOXAPARIN-TIER 1, ARIXTRA OR FRAGMIN- TIER 2
INTRON A	CANCER	MEDICAL	
IPRIVASK	ANTICOAGULANT	PHARMACY - AVAIL THRU RETAIL - TIER 3	
IRESSA	CANCER	MEDICAL	
IRINOTECAN	CANCER	MEDICAL	
ISTODAX	CANCER	MEDICAL	
IXEMPRA	CANCER	MEDICAL	
JEVTANA	CANCER	MEDICAL	
KALBITOR	*HEREDITARY ANGIOEDEMA*	*MEDICAL - LIMITED DISTRIBUTION*	
KALYDECO	RESPIRATORY CONDITIONS	MEDICAL	
KEPIVANCE	*CANCER*	*MEDICAL - LIMITED DISTRIBUTION*	
KINERET	INFLAMMATORY CONDITIONS	PHARMACY - TIER 3	ENBREL - TIER 2
KOATE-DVI	HEMOPHILIA	MEDICAL	
KOGENATE FS	HEMOPHILIA	MEDICAL	
KRYSTEXXA	INFLAMMATORY CONDITIONS	MEDICAL	
KUVAN	PKU	MEDICAL	
KYPROLIS	CANCER	MEDICAL	

Name	Disease State	Coverage	Preferred Alternatives
LETAIRIS	PULMONLARY HYPERTENSION	PHARMACY - TIER 3	
LEUCOVORIN CALCIUM	CANCER	MEDICAL	
LEUKINE	BLOOD CELL DEFICIENCY	MEDICAL	
LEUPROLIDE ACETATE	CANCER	MEDICAL	
LEUSTATIN	CANCER	MEDICAL	
LOVENOX	ANTICOAGULANT	PHARMACY TIER 3	ENOXAPARIN-TIER 1
LUCENTIS	OPTHALMIC CONDITIONS	MEDICAL	
LUMIZYME	*POMPE'S DISEASE*	*MEDICAL - LIMITED DISTRIBUTION*	
LUPRON	CANCER	MEDICAL	
LUPRON DEPOT	CANCER	MEDICAL	
LUVERIS	INFERTILITY	PHARMACY 100% COPAY	
MACUGEN	OPTHALMIC CONDITIONS	MEDICAL	
MELPHALAN	CANCER	MEDICAL	
MENOPUR	INFERTILITY	PHARMACY 100% COPAY	
MESNA	CANCER	MEDICAL	
MESNEX	CANCER	MEDICAL	
METHOTREXATE	CANCER	PHARMACY - TIER 1	
MICRHOGAM PLUS	IMMUNE DEFICIENCY	MEDICAL	
MITOMYCIN	CANCER	MEDICAL	
MITOXANTRONE, HCL	CANCER	MEDICAL	
MONOCLATE-P	HEMOPHILIA	MEDICAL	
MONONINE	HEMOPHILIA	MEDICAL	
MOZOBIL	BLOOD CELL DEFICIENCY	MEDICAL	
MUSTARGEN	CANCER	MEDICAL	
MYLOTARG	CANCER	MEDICAL	
MYOBLOC	MISCELLANEOUS SPECIALTY CONDITIONS	MEDICAL	
MYOZYME	ENZYME DEFICIENCIES	MEDICAL	
NABI-HB	HEPATITIS B	MEDICAL	
NAGLAZYME	ENZYME DEFICIENCIES	MEDICAL	
NAVELBINE	CANCER	MEDICAL	
NEULASTA	BLOOD CELL DEFICIENCY	PHARMACY - TIER 3	NEUPOGEN – TIER 2
NEUMEGA	BLOOD CELL DEFICIENCY	MEDICAL	
NEUPOGEN	BLOOD CELL DEFICIENCY	PHARMACY - TIER 2	
NEXAVAR	CANCER	MEDICAL	
NIPENT	CANCER	MEDICAL	
NORDITROPIN	GROWTH DEFICIENCY	MEDICAL	
NOVANTRONE	CANCER	MEDICAL	
NOVAREL	INFERTILITY	PHARMACY 100% COPAY	
NOVOSEVEN/RT	HEMOPHILIA	MEDICAL	
NPLATE	BLOOD CELL DEFICIENCY	MEDICAL	
NULOJIX	TRANSPLANT	MEDICAL	
NUTROPIN, AQ, NUSPIN	GROWTH DEFICIENCY	MEDICAL	
OCTAGAM	IMMUNE DEFICIENCY	MEDICAL	
OCTREOTIDE ACETATE	ENDOCRINE DISORDERS	MEDICAL	
OFORTA	CANCER	MEDICAL	
OMNITROPE	GROWTH DEFICIENCY	MEDICAL	
ONCASPAR	CANCER	MEDICAL	
ONSOLIS	PAIN MANAGEMENT	PHARMACY – TIER 3	
ONTAK	CANCER	MEDICAL	
ONXOL	CANCER	MEDICAL	
ORENCIA	INFLAMMATORY CONDITIONS	INFUSION- MEDICAL SELF INJECTABLE- PHARMACY- TIER 3	
ORFADIN	*ENZYME DEFICIENCIES*	*MEDICAL - LIMITED DISTRIBUTION*	
ORTHOCLONE OKT-3	*TRANSPLANT*	*MEDICAL - LIMITED DISTRIBUTION*	
ORTHOVISC	OSTEOARTHRITIS	MEDICAL	
OVIDREL	INFERTILITY	PHARMACY 100% COPAY	
OXALIPLATIN	CANCER	MEDICAL	

Name	Disease State	Coverage	Preferred Alternatives
PACLITAXEL	CANCER	MEDICAL	
PAMIDRONATE DISODIUM	CANCER	MEDICAL	
PANRETIN	MISCELLANEOUS SPECIALTY CONDITIONS	MEDICAL	
PEGASYS	HEPATITIS C	PHARMACY –TIER 2	
PEG-INTRON/REDIPEN	HEPATITIS C	PHARMACY –TIER 2	
PERJETA	CANCER	MEDICAL	
PHOTOFRIN	CANCER	MEDICAL	
PLENAXIS	CANCER	MEDICAL	
PREGNYL	INFERTILITY	PHARMACY 100% COPAY	
PRIALT	*MISCELLANEOUS SPECIALTY CONDITIONS*	*MEDICAL - LIMITED DISTRIBUTION*	
PRIVIGEN	IMMUNE DEFICIENCY	MEDICAL	
PROCRIT	BLOOD CELL DEFICIENCY	PHARMACY - TIER 2	
PROFILNINE SD	HEMOPHILIA	MEDICAL	
PROGESTERONE IN OIL	INFERTILITY	PHARMACY 100% COPAY	
PROGRAF	*TRANSPLANT*	*INFUSION-MEDICAL - LIMITED DISTRIBUTION ORAL- PHARMACY- TIER 2*	
PROLASTIN/C	*RESPIRATORY CONDITIONS*	*MEDICAL - LIMITED DISTRIBUTION*	
PROLEUKIN	CANCER	MEDICAL	
PROLIA	OSTEOPOROSIS	PHARMACY – TIER 3	
PROMACTA	BLOOD CELL DEFICIENCY	PHARMACY – TIER 3	
PROVENGE	*IMMUNE DEFICIENCY*	*MEDICAL- LIMITED DISTRIBUTION*	
PULMOZYME	RESPIRATORY CONDITIONS	PHARMACY - TIER 3	
REBETOL	HEPATITIS C	PHARMACY - TIER 1	
REBIF	MULTIPLE SCLEROSIS	PHARMACY - TIER 2	
RECLAST	PAGET'S DISEASE/ OSTEOPORSIS	MEDICAL	ALENDRONATE- TIER 1
RECOMBINATE	HEMOPHILIA	MEDICAL	
REFACTO	HEMOPHILIA	MEDICAL	
REFLUDAN	ANTICOAGULANT	PHARMACY - AVAIL THRU RETAIL- TIER 3	ENOXAPARIN- TIER 1, ARIXTRA OR FRAGMIN- TIER 2
REMICADE	INFLAMMATORY CONDITIONS	MEDICAL	
REMODULIN	*PULMONARY HYPERTENSION*	*PHARMACY - TIER 3 - LIMITED DISTRIBUTION*	
REPRONEX	INFERTILITY	PHARMACY 100% COPAY	
RETROVIR IV	IMMUNE DEFICIENCY	MEDICAL	
REVATIO	PULMONARY HYPERTENSION	PHARMACY - TIER 3	
REVLIMID	CANCER	MEDICAL	
RHOGAM PLUS	IMMUNE DEFICIENCY	MEDICAL	
RHOPHYLAC	IMMUNE DEFICIENCY	MEDICAL	
RIBAPAK	HEPATITIS C	PHARMACY - TIER 1	
RIBASPHERE	HEPATITIS C	PHARMACY - TIER 1	
RIBATAB	HEPATITIS C	PHARMACY - TIER 1	
RIBAVIRIN- ORAL	HEPATITIS C	PHARMACY - TIER 1	
RILUTEK	MISCELLANEOUS SPECIALTY CONDITIONS	MEDICAL	
RITUXAN	CANCER	MEDICAL	
SABRIL	ANTICONVULSANT	PHARMACY – TIER 3	
SAIZEN	GROWTH DEFICIENCY	MEDICAL	
SANDOSTATIN, LAR	ENDOCRINE DISORDERS	MEDICAL	
SEROSTIM	GROWTH DEFICIENCY	MEDICAL	
SIMPONI	INFLAMMATORY CONDITIONS	PHARMACY – TIER 3	
SIMULECT	TRANSPLANT	MEDICAL	
SOLIRIS	MISCELLANEOUS SPECIALTY CONDITIONS	MEDICAL	
SOMATULINE DEPOT	ENDOCRINE DISORDERS	PHARMACY – TIER 3	
SOMAVERT	*GROWTH DEFICIENCY*	*MEDICAL - LIMITED DISTRIBUTION*	
SPRYCEL	CANCER	MEDICAL	

Name	Disease State	Coverage	Preferred Alternatives
STELARA	INFLAMMATORY CONDITIONS	PHARMACY – TIER 3	
STIVARGA	CANCER	MEDICAL	
SUCRAID	ENZYME DEFICIENCY	PHARMACY – TIER 2	
SUPARTZ	OSTEOARTHRITIS	MEDICAL	
SUPPRELIN LA	ENDOCRINE DISORDERS	MEDICAL	
SUTENT	CANCER	MEDICAL	
SYLATRON	CANCER	MEDICAL	
SYNAGIS	RSV PREVENTION	MEDICAL	
SYNVISC, -ONE	OSTEOARTHRITIS	MEDICAL	
TARCEVA	CANCER	MEDICAL	
TASIGNA	CANCER	MEDICAL	
TAXOTERE	CANCER	MEDICAL	
TEMOZOLOMIDE	CANCER	MEDICAL	
TESTOPEL	*HYPOTESTOSTERONE*	*MEDICAL - LIMITED DISTRIBUTION*	
TEV-TROPIN	GROWTH DEFICIENCY	MEDICAL	
THALOMID	CANCER	MEDICAL	
THERACYS	CANCER	MEDICAL	
THIOTEPA	CANCER	MEDICAL	
THYMOGLOBULIN	*TRANSPLANT*	*MEDICAL - LIMITED DISTRIBUTION*	
THYROGEN	CANCER	MEDICAL	
TOBI	RESPIRATORY CONDITIONS	PHARMACY - TIER 3	
TOPOSAR	CANCER	MEDICAL	
TORISEL	CANCER	MEDICAL	
TRACLEER	PULMONARY HYPERTENSION	PHARMACY - TIER 3	
TREANDA	CANCER	MEDICAL	
TRELSTAR, -DEPOT	CANCER	MEDICAL	
TRELSTAR LA	CANCER	MEDICAL	
TRISENOX	CANCER	MEDICAL	
TYKERB	CANCER	MEDICAL	
TYSABRI	MULTIPLE SCLEROSIS	MEDICAL	
TYVASO	PULMONARY HYPERTENSION	MEDICAL	
VANDETANIB	CANCER	MEDICAL	
VANTAS	CANCER	MEDICAL	
VECTIBIX	CANCER	MEDICAL	
VELCADE	CANCER	MEDICAL	
VELETRI	PULMONARY HYPERTENSION	MEDICAL	
VELETRI	*PULMONARY HYPERTENSION*	*MEDICAL - LIMITED DISTRIBUTION*	
VENTAVIS	*PULMONARY HYPERTENSION*	*MEDICAL - LIMITED DISTRIBUTION*	
VICTRELIS	HEPATITIS C	MEDICAL	
VIDAZA	CANCER	MEDICAL	
VINBLASTINE SULFATE	CANCER	MEDICAL	
VINCRISTINE SULFATE	CANCER	MEDICAL	
VINORELBINE TARTRATE	CANCER	MEDICAL	
VISUDYNE	OPHTHALMIC CONDITIONS	MEDICAL	
VIVAGLOBIN	IMMUNE DEFICIENCY	MEDICAL	
VIVITROL	MISCELLANEOUS CNS DISORDER	MEDICAL	
VOTRIENT	CANCER	MEDICAL	
VPRIV	RESPIRATORY CONDITIONS	MEDICAL	
VUMON	CANCER	MEDICAL	
WINRHO SDF	IMMUNE DEFICIENCY	MEDICAL	
XELJANZ	INFLAMMATORY CONDITIONS	TIER 2	
XELODA	CANCER	MEDICAL	
XENAZINE	MISCELLANEOUS CNS DISORDER	MEDICAL	
XEOMIN	MISCELLANEOUS CNS DISORDER	MEDICAL	
XGEVA	CANCER	MEDICAL	
XIAFLEX	MISCELLANEOUS SPECIALTY CONDITIONS	MEDICAL	
XOLAIR	RESPIRATORY CONDITIONS	MEDICAL	

Name	Disease State	Coverage	Preferred Alternatives
XGEVA	ENDOCRINE CONDITIONS	MEDICAL	
XTANDI	CANCER	MEDICAL	
XYNTHA	HEMOPHILIA	MEDICAL	
XYREM	*MISCELLANEOUS SPECIALTY CONDITIONS*	*PHARMACY – TIER 2 - LIMITED DISTRIBUTION*	
YERVOY	CANCER	MEDICAL	
ZALTRAP	CANCER	MEDICAL	
ZANOSAR	CANCER	MEDICAL	
ZAVESCA	ENZYME DEFICIENCIES	MEDICAL	
ZEMAIRA	*RESPIRATORY CONDITIONS*	*MEDICAL - LIMITED DISTRIBUTION*	
ZENAPAX	TRANSPLANT	MEDICAL	
ZEVALIN	CANCER	MEDICAL	
ZINECARD	CANCER	MEDICAL	
ZOLADEX	CANCER	MEDICAL	
ZOLINZA	CANCER	MEDICAL	
ZOMETA	CANCER	MEDICAL	
ZORBTIVE	GROWTH DEFICIENCY	MEDICAL	
ZYTIGA	CANCER	MEDICAL	

Step Therapy Program

The step therapy program was developed to encourage the use of first-line alternatives before more expensive second-line medications. If a Member does not obtain the desired clinical effect or experiences side effects at one step, then the drug choice at another step may be tried. If a step therapy rule is not met at the pharmacy, coverage will be determined by prospective (pre-service) review. You can request prospective (pre-service) review and/or certification by calling the Pharmacy Management Team at 1-800-805-7938. The following step therapy programs are listed and their clinical criteria are as follows.

Step Therapy

- Antidepressent Therapy (SSRI and SNRI)
- Avonex
- Celebrex
- Cimzia
- Crestor
- Proton Pump Inhibitors (PPIs)
- Zetia / Liptruzet

Antidepressent (SSRI and SNRI) Step Therapy

1. One generic drug will be required before a brand name drug is authorized. Generic drugs will have to have been prescribed at an effective dose for a minimum of 30 days. Documentation of attempt and failure of a generic within the last 12 months will be considered as fulfilling this requirement.
   - Bupropion sr, xl
   - Citalopram
   - Escitalopram
   - FluvoxamineFluoxetine 20 mg
   - Mirtazapine
   - Paroxetine ir, cr
   - Sertraline
   - Venlafaxine ir, xr capsules and tablets
2. Cymbalta will be covered (after a generic SSRI/ SNRI is tried a minimum of 30 days) at the 2nd tier copay level. This medication will also be covered if being used for chronic pain, diabetes neuropathy or fibromyalgia, PA will still be required, no step therapy necessary.
3. Pristiq will be covered (after a generic SSRI/ SNRI is tried a minimum of 30 days) at the 2nd tier copay level.
4. Viibryd will be covered (after a generic SSRI/ SNRI is tried a minimum of 30 days) at the 2nd tier copay level.

Avonex Step Therapy

- Trial and/or failure of Betaseron, Copaxone or Rebif is required prior to approval. This medication will be covered at the Members 3nd tier copay through CuraScripts.

Celebrex Step Therapy

1. Celebrex is covered without authorization at a limit of 30 pills per month for Members at 3rd tier copay.
2. Exceptions for formulary coverage at a 2nd tier copay can be approved for Members if one of the following criteria has been met:
   - Age >= 65 years of age
   - Past history of a GI bleed, perforation, obstruction
   - Requires use of long-term (>1 month) oral corticosteroid therapy
   - Currently taking warfarin (Coumadin) or dicumarol
   - Diagnosis of rheumatoid arthritis
   - Members with reduced platelet counts <75,000
3. Members with the diagnosis of rheumatoid arthritis will be granted approval for >30 pills per month.

Cimzia Step Therapy

- Trial and/or failure of Enbrel , Humira or Simponi is required prior to approval. Drug will be covered at the Member's 3rd tier copay.

Crestor Step Therapy

- The Member must have a minimum 30 day trial of one of the following medications in the last 12 months for possible consideration
  - Atorvastatin
  - Lovastatin
  - Pravastatin
  - Simvatatin

Proton Pump Inhibitors (PPIs) Step Therapy

- A minimum 30 day trial of generic omeprazole and pantoprazole are required before use of a non-formulary PPI will be considered.
- Prior authorization is required for lansoprazole solutabs. This is based on medical necessity for all members over the age of 12 years.

Zetia/Liptruzet Step Therapy

1. The Member must have tried and failed one of the following drugs (may be brand or generic) or combination of drugs at the following dosage:

Brand Name	Daily Dose
Advicor	≥2000 mg/40 mg
Atorvastin	≥20 mg
Lovastatin	≥40 mg
Pravastatin	≥40 mg
Simvastatin	≥40 mg

2. The Member has tried one of the drugs from the above list and cannot tolerate the side effects.
3. The Member is taking or will be taking a medication that has drug interactions with a drug from the above listing.
4. Children or adolescents <17 years of age must have tried a drug from the above list at the clinically appropriate pediatric dose.
5. Members with severe renal impairment of creatinine clearance ≤30 mL/minute.
6. Homozygous familial hypercholesterolemia.
7. Homozygous familial sitosterolemia.
8. Pregnant women.
9. Active liver disease or unexplained persistent elevations of serum transaminases.

Certification

Drugs that Require Prospective (Pre-service) Review and Certification

To be considered for coverage by Sanford Health Plan, the following medications require a written certification of medical necessity for a formulary exception. Fax the written certification of Medical Necessity to Pharmacy Management at (605) 328-6813.

Medications

- Byetta; failure of covered oral medications.
- Bydueron: failure of covered oral medications
- Lovaza; Triglyceride level must be greater than 500
- Testosterone Products (Androderm, Androgel, Axiron, Testoderm, Testosterone Injectable); requires a below normal testosterone level within the last 6 months with symptoms of testosterone deficiency other than erectile dysfunction.
- Symlin; failure of covered oral medications .
- Uloric: failure of generic allopurinol .
- Victoza; failure of covered oral medications .

Limited and Non-Covered Services

Excluded Drugs and Supplies

Requests for coverage of Non-Preferred Brand-Name Drugs will not be considered unless the Member has tried and failed a Formulary alternative.

The following medications are specifically **EXCLUDED** from coverage under the Plan unless regulation, a formulary exception, or a previous certification has been granted by the Plan:

- Drugs not listed in the Sanford Health Plan Formulary or without Prior-Authorization or a formulary exception from The Plan;
- Replacement of a prescription drug due to loss, damage, or theft;
- Outpatient drugs dispensed in a Provider's office or non-retail pharmacy location;
- Drugs that may be received without charge under a federal, state, or local program;
- Drugs for cosmetic purposes, including baldness, removal of facial hair, or pigmenting or anti-pigmenting of the skin;
- Refills of any prescription older than one year;
- Compound medications with no legend (prescription) medication;
- Acne medication for Members over age thirty (30) (e.g. Retin-A Microgel);
- B-12 injection (except for pernicious anemia);
- Drug Efficacy Study Implementation ("DESI") drugs;
- Experimental or Investigational drugs or drug usage if not recognized by the Food and Drug Administration;
- Growth hormone, except when medically indicated and Prior-Approved by the Plan;
- Orthomolecular therapy, including nutrients, vitamins (including but not limited to prenatal vitamins),multi-vitamins with iron and/or fluoride, food supplements and baby formula (except to treat PKU or otherwise required to sustain life), nutritional and electrolyte substances;
- Medications, equipment or supplies available over-the-counter (OTC) (except for insulin and select diabetic supplies, e.g., insulin syringes, needles, test strips and lancets) that by federal or state law do not require a prescription order; any medication that is equivalent to an OTC medication except for drugs that have a rating of "A" or "B" in the current recommendations of the United States Preventive Services Task Force and only when prescribed by a healthcare Practitioner and/or Provider;
- Drugs and associated expenses and devices not approved by the FDA for a particular use except as required by law (unless Provider certifies off-label use with a letter of medical necessity);
- Anorexiants or Weight management drugs except when Medically Necessary ;
- Whole Blood and Blood Components Not Classified as Drugs in the United States Pharmacopoeia;
- Medication used to treat infertility;
- Smoking deterrant products such as Chantix except when Medically Necessary and per Plan guidelines; and
- Unit dose packaging.

Drug Exclusion List

The following drugs (and their generic equivalent, if listed) are excluded by the Sanford Health Plan, as there are similar drugs in this category available for coverage. Brand name products will not be covered when an A-B rated generic is available.

Excluded Drug	Formulary Alternative
Aciphex	omeprazole, pantoprazole
Actonel	alendronate
Adrenaclick	Epipen/Jr., Auvi-Q
Aerobid/-M	Flovent, Pulmicort, Qvar
Alamast	generics, Patanol, Pataday
Allegra/-D	OTC products available
Alocril	generics, Patanol, Pataday
Alomide	generics, Patanol, Pataday
Alora	estrogen patches,, Vivelle-DOT
Alrex	generics, Patanol, Pataday
Altoprev	lovastatin
Alvesco	Flovent, Pulmicort, QVAR
Ambien, CR	zolpidem
Angelig	Prempro/Premphase, Fem HRT
Anzemet	ondansetron
Antara	gemfibrozil, fenofibrate, TriLipix
Apidra	Humalog, Novolog
Apriso	Asacol, Lialda, Pentasa
Asmanex	Flovent, Pulmicort, Qvar
Atacand/HCT	generics
Atralin	tretinoin, adapalene, Differin, Retin-A Microgel, Epiduo
Avinza	morphine sulfate, oxycodone
Avita	tretinoin, adapalene, Differin, Retin-A Microgel, Epiduo
Azmacort	Flovent, Pulmicort, Qvar
Azelex	tretinoin, Differin
Azor	amlodipine + losartan
Beclovent	Flovent, Pulmicort, Qvar
Beconase/AQ	flunisolide, fluticasone, Nasonex
Benicar/HCT	generics
Binosto	alendronate
Boniva	alendronate
Brisdelle	paroxetine
Bromday	diclofenac, ketorolac
Brovana	Perforomist
Cambia	diclofenac
Cardene SR	felodipine, amlodipine
Cardura XL	doxazosin, finasteride, Uroxatral
Cedax	cefprozil, cefuroxine, amoxicillin/clavulanate
Cenestin	generics, Premarin
Cetraxal	ofloxacin, Ciprodex
Cipro HC	ofloxacin, Ciprodex
Clarinex/-D	OTC products available
ClimaraPro	Combipatch
Colazal	Asacol, Lialda, Pentasa
Cyclessa	generic oral contraceptives
Dexilant	omeprazole, pantoprazole
Dipentum	Asacol, Lialda, Pentasa
Dulera	Advair, Symbicort
Durezol	generics, Lotemax
DynaCirc/CR	felodipine, amlopidine, nifedipine ER

Excluded Drug	Formulary Alternative
Edarbi	losartan
Edular	zolpidem, zaleplon
Elestat	generics, Patanol, Pataday
Emadine	generics, Patanol, Pataday
Enablex	oxybutynin/ er, Detrol LA, Toviaz, Vesicare
Enjuvia	generics, Premarin
Epinephrine-Auto Injector	Epipen/Jr., Auvi-Q
Estraderm	estrogen patches, Vivell-DOT
Exforge	amlodipine + losartan
Fanapt	Abilify, Geodon, Risperdal, Seroquel, Zyprexa
Femcon FE	generic oral contraceptives
Femtrace	generics, Premarin
Fexofenadine	OTC products available
FML Forte	generics, Lotemax
Fortesta	Androderm, Androgel, Axiron
Fosamax-D	alendronate
Gelnique	oxybutynin er, Detrol LA, Toviaz, Vesicare
Generese	generic oral contraceptives
Helidac	Bismuth Subsalicylate + generic metronidazole + tetracycline
Invega	olanzapine, quetiapine, risperidone, ziprasidone, Abilify tab, Latuda Seroquel XR
Iquix	generics, Vigamox
Kadian	morphine sulfate, oxycodone
Kombiglyze XR	Januvia, Onglyza
lansoprazole caps	omeprazole, pantoprazole
Lastacaft	generics, Patanol, Pataday
LescolXL	atorvastatin, simvastatin, p ravastatin, lovastatin
Lipofen	simvastatin, pravastatin, lovastatin
Livalo	atorvastatin, simvastatin, pravastatin, lovastatin
Loestrin 24 Fe	generic oral contraceptives
Lofibra	fenofibrate
LoSeasonique	generic oral contraceptives
Lunesta	zolpidem, zaleplon
Luvox CR	fluvoxamine
Maxair Autohaler	Ventolin HFA, ProAir HFA
Menest	generics, Premarin
Menostar	estrogen patches, Vivelle-DOT
Micardis/HCT	generics
Moxatag	amoxicillin
Moxeza	generics, Vigamox
Myrbetriq	generics, Detrol, Vesicare
Naprelan CR	ibuprofen, naproxen sodium
Nasocort/ AQ	flunisolide, fluticasone, Nasonex
Natazia	generic oral contraceptives
Nevenac	diclofenac, ketorolac, Acuvail

Excluded Drug	Formulary Alternative
Nexium	omeprazole, pantoprazole
Omnaris	flunisolide, fluticasone, Nasonex
Opana, ER	morphine sulfate, oxycodone
Optivar	generics, Patanol, Pataday
Oracea	doxycycline 20mg caps x2
Oxytrol	oxybutynin er, Detrol LA, Toviaz, Vesicare
Patanase	azelastine, Astepro
PrevPac	generic clarithromycin + amoxicillin + lansoprazole
Prefest	Prempro, Premphase, FemHRT
Prilosec	omeprazole, pantoprazole
Protonix	omeprazole, pantoprazole
Proventil HFA	Ventolin HFA, Proair HFA
Prozac Weekly	fluoxetine
Quixin	generics, Vigamox
Rapaflo	generics, Uroxatrol
Renova	tretinoin, Retin-A Microgel, Differin
Ritalin LA	generics, Vyvanse
Rhinocort/AQ	flunisolide, fluticasone , Nasonex
Rozerem	zaleplon, zolpidem
Rynatan	OTC products available
Safyral	generic oral contraceptives
Sancuso	ondansetron, granisetron
Silenor	zolpidem, zaleplon
Solodyn ER	minocycline
Spectracef	cefprozil, cefuroxime, amoxicillin/clavulante
Sular	generic felodipine, generic amlodipine (Norvasc)
Suprax	cefprozil, cefuroxime, amoxicillin/clavulanate
Symbyax	fluoxetine + Zyprexa
Tecfidera	Avonex, Betaseron, Rebif
Testim	Androderm, Androgel, Axiron
Teveten/HCT	generics
TravatanZ	lantanoprost, Lumigan
Treximet	sumatriptan + naproxen
Tribenzor	amlodipine + losartan/HCT
Triglide	gemfibrozil, fenofibrate, TriLipix
Tussionex	promethazine-codeine
Twinject	Epipen/ Jr., Auvi-Q
Twynsta	amlodipine + losartan
Vascepa	Lovaza
Vexol	generics, Lotemax
Vimovo	naproxen + omeprazole
Vytorin	atorvastatin, simvastatin , pravastatin, lovastatin
Xopenex HFA	ProAir HFA, Ventolin HFA
Xyzal	OTC products available
Zegerid	omeprazole
Zioptan	lantanoprost, Lumigan
Zolpimist	zolipdem
Zuplenz	ondansetron

Compounded drug products that contain any combination of baclofen, cyclobenzaprine, ketamine, bupivacaine, orphendadrine, gabapentin, or ketoprofen are **NOT COVERED** due to lack of good quality scientific evidence of effectiveness or safety for these specific ingredient combinations and mode of administration.

Quantity Limit List*

The following drugs do not require certification but have a quantity limit:

Anzemet—1 tablets/ prescription (not covered unless part of step therapy program)
Axert—6 tablets/prescription
butorphanol tartrate- nasal spray —2 spray bottles/ prescription
Emend—3 pills/prescription (3rd tier copay)
Frova—9 tablets/prescription
granisetron (generic Kytril)—2 tablets/prescription (not covered unless medically necessary)
Lysteda- 30 tablets/prescription
Migranal—4 spray/prescription
naratriptan (generic Amerge)—9 tablets/prescription
Relpax—12 tablets/prescription
rizatriptan(generic Maxalt)—12 tablets/prescription
sumatriptan (generic Imitrex)—12 tablets/ 6 nasal spray or 1 kit for injections/prescription or 2 injections
Zomig—6 ampules/sprays/prescription
zolmitriptan(generic Zomig)—12 tablets / prescription

**There is a 30-day prescription limit excluding maintenance medications. If you would like a complete listing or information about a specific drug please contact the Pharmacy Management Team at 1-800-805-7938, or log into myHealthPlan at www.sanfordhealthplan.com/myhealthplan.*

Special Quantity Limits

The following drugs, when approved by authorization, are only available in quantities of 30 per prescription for one copay. Additional quantities will generate additional copays.

Formulary Drugs:

Cymbalta 60 mg daily limitation

Non-Formulary Drugs

Nexium
Aciphex
Dexilant

Complaints and Appeals Procedure

If you receive an adverse determination to your request for an exception to the formulary, please follow the *Complaints and Appeals Procedure* and the *External Review Rights* in the Policy. This applies to requests for coverage of non-covered medications, generic substitutions, therapeutic interchanges and step-therapy protocols.

Definitions

4-Tier Formulary

A 4-Tier drug program uses a copayment structure that reduces your out-of-pocket costs when using Generic Drugs and Preferred Brand Name Drugs. When a prescription is filled, your copayment will be at least one of these tiers: *

Tier 1: Generic Drugs
Tier 2: Preferred Brand Name Drugs
Tier 3: Non-Preferred Brand Name Drugs
Tier 4: Formulary or Specialty Name Brand Drugs exceeding a contracted value of $400

3-Tier Formulary

A 3-Tier drug program uses a copayment structure that reduces your out-of-pocket costs when using Generic Drugs and Preferred Brand Name Drugs. When a prescription is filled, your copayment will be at least one of these tiers: *

Tier 1: Generic Drugs
Tier 2: Preferred Brand Name Drugs
Tier 3: Non-Preferred Brand Name Drugs

2-Tier Formulary

A 2-Tier drug program uses a copayment structure that reduces your out-of-pocket costs when using Generic Drugs and Preferred Brand Name Drugs. When a prescription is filled, your copayment will be at one of these tiers: *

Tier 1: Generic Drugs
Tier 2: All covered Brand Name Drugs

*The higher the tier, the higher the copay

Brand Name Drug

A drug manufactured and marketed under a trademark or name by a specific drug manufacturer.

Certification Process

The process of obtaining prior authorization for coverage of certain prescription drug products prior to their being dispensed, using guidelines approved by the Sanford Health Plan. Refer to the section on *Drugs that Require Prospective (pre-service) Review and Certification* in this booklet.

Clinic/Office/Hospital Outpatient Administered Injectables

Injectable medications that may be given in a variety of settings but must be given by a healthcare professional. These drugs are considered to be a medical benefit with coverage at the deductible and coinsurance level.

Copay (also known as Copayment)

The specified charge (flat dollar amount or percentage) that the Member is required to pay for a Prescription Drug Product.

Covered Drugs

The following types of drugs are covered unless subject to an exception listed under “Excluded Drugs and Supplies:”

1. Federal Legend Drugs: any medicinal substance which bears the legend, "Caution: Federal Law prohibits dispensing without a prescription," except for those medicinal substances classified as exempt narcotics pursuant to State law;
2. An injectable drug can be prescribed to either be self-administered or administered by a healthcare professional. Covered injectable drugs include insulin. Refer to the Injectable Drug Listing in this book for additional covered drugs.
3. State Restricted Drugs: any medicinal substance which may only be dispensed with a prescription according to State law;
4. Compound Medications: any medicinal substance which must be mixed, compounded, or otherwise prepared by a registered pharmacist and has at least one ingredient that is a Federal legend or State restricted drug in a therapeutic quantity. Claims must be submitted electronically from the pharmacy for coverage consideration. *refer to the compound section on *Drug Exclusion List* to see policy exclusions;
5. Diabetic Treatment: Items listed below are available in a 90 day supply. A supply that is meant to last 30 days or less will generate 1 copay, a supply that lasts 31-60 days will generate 2 copays and a supply that lasts from 61-90 days will generate 3 copays.
    - needles
    - injectable insulin
    - syringes
    - lancets
    - test strips - maximum amount of 205 strips per month with a healthcare Practitioner order

Drug Exclusion
Sanford Health Plan reserves the right to maintain a drug listing of medications which are specifically not covered under benefit packages per Plan policy. Payment for the drugs on this list will be the Member's responsibility in full. Members may request a review of an adverse determination based on issues of medical necessity as it relates to non-covered medications, generic substitution, therapeutic interchanges and step-therapy protocols. Refer to *Drug Exclusion List* and *Complaints and Appeals Procedure* in this book.

Drug Formulary
A list which identifies those Prescription Drug Products which are preferred by the Plan for dispensing to Members when appropriate. This list is subject to periodic review and modifications.

Generic Drug
Drugs that (1) are approved by the Food and Drug Administration (FDA) as a therapeutic equivalent to the Brand Name Drug, (2) contain the same active ingredient as the Brand Name Drug, and (3) cost less than the Brand Name equivalent.

Maintenance Drug List
A list of drug products, typically used for chronic conditions, approved by Sanford Health Plan, allowed to be dispensed in 90 day quantities.

Medical Benefit
Refers to drugs which are covered at the deductible/coinsurance level instead of with a copay.

Member
An individual eligible for benefits under the Plan.

Non-Participating Pharmacy
A pharmacy that does not have a contract with Express Scripts Inc., on behalf of Sanford Health Plan. **If a Sanford Health Plan Member utilizes a Non-Participating Pharmacy, except in an emergency, the Member is responsible for the full cost of the prescription drug.**

Non-Preferred Brand-Name Drug
Brand-Name drug not on Sanford Health Plan's Formulary.
Requests for coverage of Non-Preferred Brand-Name Drugs will not be considered unless the Member has tried and failed a Formulary alternative. These drugs are provided at a higher cost share to the Member. This is the 3rd or 4th Tier Copay in a 3-Tier or 4- Tier Formulary.

Over-the-Counter (OTC) Drug
A drug product that does not require a prescription order under Federal or State law. Sanford Health Plan does not cover any medications that can be obtained over-the-counter.

Participating Pharmacy
A pharmacy that has contracted with Express Scripts Inc., on behalf of Sanford Health Plan to deliver prescription drug services to Members. The Participating Pharmacy may be a hospital, pharmacy or other facility that has contractually

accepted the terms and conditions set forth by the Health Plan. Refer to the Sanford Health Plan Participating Pharmacy Listing or Express Scripts website found on www.sanfordhealthplan.com/myhealthplan. **If a Sanford Health Plan Member does not utilize their prescription card, except in an emergency, the Member is responsible for the full cost of the prescription drug.**

Preferred Brand-Name Drug
A prescription drug that is available only as a name brand medication, is preferred by Sanford Health Plan and is listed in the Drug Formulary. A preferred brand name drug is typically available at the 2nd tier copay in a 3- Tier or 4- Tier Formulary.

Prescription Drug Product
A medication, product or device approved by the Food and Drug Administration (FDA) and dispensed under Federal or State law only, pursuant to a prescription order or refill.

Reasonable Costs
Costs that do not exceed the lesser of: (a) negotiated schedule of payment developed by the Plan which is accepted as payment in full by Participating Practitioner and/or Providers within the Plan's Service Area or (b) the prevailing marketplace charges.

Self-Injectable
Self-administered injectable drugs can be given at home by the patient or caregiver. Typically these drugs are covered under the pharmacy benefit.

Specialty Drugs
Specialty drugs are defined as injectable and non-injectable drugs that have one or more of several key characteristics, including:

- Requirement for frequent dosing adjustments and intensive clinical monitoring to decrease the potential for drug toxicity and increase the probability for beneficial treatment outcomes.
- Need for intensive patient training and compliance assistance to facilitate therapeutic goals.
- Limited or exclusive product availability and distribution.
- Specialized product handling and/or administration requirements.
- Cost in excess of $500 for a 30-day supply

Step Therapy Program
Program using protocols that specify the order in which different drugs for a given condition are prescribed. If a Member does not obtain the desired clinical effect or experiences side effects at one step, then the drug choice at another step may be tried. Step therapy requires the use of first-line alternatives before more expensive second-line drugs are covered by the pharmacy benefit.

Supply
- Drugs are typically dispensed in quantities of 30 days or less for one copay, unless otherwise approved by the Plan. In some instances, if more than a typical 30 day supply is dispensed an additional copay will be charged. Examples include: all brand name Proton Pump Inhibitors and Cymbalta.
- Maintenance drugs may be dispensed in a 90-day supply, but a copayment applies to each 30-day supply received.

Affordable Care Act (ACA) Mandated Drug Coverage
The Affordable Care Act requires all non-grandfathered health plans to cover ten categories of essential health benefits; one of these essential health benefits categories include prescription drugs. Sanford Health Plan is required to cover the following over the counter (OTC) medications prescribed by a physician/practitioner and filled by a participating pharmacy for its *Simplicity* members.

Essential Health Benefits (EHB)

Drug Category	Dosage Form	Criteria
Aspirin to prevent cardiovascular disease	Generic OTC agents 81mg and 325mg only	Men ages 45 to 79 Women ages 55 to 79
Fluoride	Generic Rx and Generic OTC (single entity and combo products)	Children older than 6 months of age through 5 years old

Folic Acid	Generic Rx and Generic OTC 0.4mg and 0.8mg only	Women through age of 50 years
Iron Supplements	Generic Rx and Generic OTC (single entity and combo products)	Children older than 6 months of age through 12 months
Vitamin D	Generic Rx and Generic OTC (single entity with calcium ≤1,000 units of Vit D)	Age ≥ 65 years
Bowel Preparation Agents	Generic Rx only with primary indication of colonoscopy preparation	Adults; ages 50 to 75 years (2 prescriptions per 365 days)

The ACA mandates that FDA approved contraceptive methods be covered by Health Plans for women as prescribed by Practioners. Sanford Health Plan has a formulary listing for the covered generic contraceptive oral medications. This can be found under chapter 13.7 of the formulary. Coverage is also offered for the following preferred brand medications at the 3rd tier copay; Ortho Tri-Cyclen Lo, NuvaRing and Ortho Evra. Also covered at the pharmacy with a prescription are the following barrier methods; diaphragms and cervical caps.

Formulary

for North Dakota Medicaid members

The following is a list of the most commonly prescribed drugs. It represents an abbreviated version of the drug formulary that is the core of your pharmacy benefit coverage. In addition to using this list, allowing substitution of generic products is encouraged when appropriate.

Generic drugs are indicated in bold. Tier 2 co-payment will apply to all of the covered brands listed on this formulary. Brand name drugs are listed in CAPITAL letters.

This is NOT a complete listing of covered drugs. For a complete list of medications, you can go to "find a pharmacy" at www.sanfordhealthplan.com/myhealthplan and link to the Express Scripts website.

"PA Required" indicates that prior authorization is required on that specific medication. "Step therapy" indicates the medication requires the use of first-line alternatives before more expensive second-line drugs are covered by the pharmacy benefit. Drugs marked with an asterisk (*) must be obtained from CuraScript.

If you are currently taking or are prescribed an injectable medication, please contact CuraScript Injectable Drug Program at (866) 333-9721 to order your drugs. Refer to the Pharmacy Handbook for a complete listing of drugs and instructions.

If you have questions regarding coverage call (855)-276-7214.

Table of Contents

DRUG NAME	PA/STEP/QLL	TIER 1	TIER 2	SUGGESTED PREFFERED ALTERNATIVES
CHAPTER 1: ANESTHETICS				
1.2 TOPICAL ANESTHETICS				
lidocaine hcl		X		
lidocaine-prilocaine		X		
LIDODERM			X	
CHAPTER 2: ANTIINFECTIVES				
2.1.1 CEPHALOSPORINS				
cefaclor er		X		
cefadroxil		X		
cefdinir		X		
cefpodoxime proxetil		X		
cefprozil		X		
cefuroxime		X		
cephalexin		X		
CEDAX			X	**cefprozil, cefuroxime, amox/clav**
SUPRAX			X	**cefprozil, cefuroxime, amox/clav**
2.1.3 CLINDAMYCINS				
clindamycin hcl		X		
clindamycin phosphate		X		
2.1.4 ERYTHROMYCINS				
erythromycin		X		
2.1.4.1 OTHER MACROLIDES				
azithromycin		X		
clarithromycin/er		X		
2.1.5 PENICILLINS				
amox tr-potassium clavulanate		X		
amoxicillin		X		
amoxicillin-clavulanate er		X		
dicloxacillin sodium		X		
penicillin v potassium		X		
2.1.6 SULFONAMIDES				
sulfamethoxazole-trimethoprim		X		
2.1.7 TETRACYCLINES				
doxycycline hyclate		X		
doxycycline monohydrate		X		
minocycline hcl		X		
tetracycline hcl		X		
DORYX			X	
2.1.8 URINARY ANTIINFECTIVES				
nitrofurantoin		X		
nitrofurantoin mono-macro		X		
trimethoprim		X		
2.1.9 QUINOLONES				
ciprofloxacin, -er		X		
levofloxacin		X		
ofloxacin		X		
AVELOX/ABC PACK			X	
FACTIVE			X	
NOROXIN			X	**ciprofloxacin, levofoxacin, ofloxacin**
2.2 TOPICAL ANTIBACTERIAL DRUGS				
gentamicin sulfate		X		
mupirocin		X		

DRUG NAME	PA/STEP/QLL	TIER		SUGGESTED PREFFERED ALTERNATIVES
		1	2	
silver sulfadiazine		X		
ALTABAX			X	
BACTROBAN NASAL OINTMENT			X	
2.3 ORAL ANTIFUNGAL DRUGS				
fluconazole		X		
griseofulvin		X		
itraconazole		X		
ketoconazole		X		
nystatin		X		
terbinafine hcl		X		
voriconazole		X		
GRIFULVIN V			X	
ONMEL			X	
ORAVIG			X	
2.4.1 VAGINAL ANTIFUNGALS				
clotrimazole		X		
terconazole		X		
2.4.2 OTHER TOPICAL ANTIFUNGALS				
ciclopirox		X		
clotrimazole		X		
econazole nitrate		X		
ketoconazole		X		
nystatin		X		
ERTACZO			X	**generic**/OTC ANTIFUNGAL
EXELDERM			X	**generic**/OTC ANTIFUNGAL
NAFTIN			X	**generics**, LOROX
OXISTAT			X	**generic**/OTC ANTIFUNGAL
2.4.3 TOPICAL ANTIFUNGAL-CORTICOSTEROID COMB.				
clotrimazole-betamethasone		X		
nystatin-triamcinolone		X		
2.5.1 ANTIRETROVIRALS & PROTEASE INHIBITORS				
lamivudine		X		
lamivudine-zidovudine		X		
nevirapine		X		
ATRIPLA			X	
COMBIVIR			X	
COMPLERA			X	
EPIVIR			X	
EPZICOM			X	
INCIVEK	PA		X	
INTELENCE			X	
ISENTRESS			X	
KALETRA			X	
LEXIVA			X	
NORVIR			X	
PREZISTA			X	
REYATAZ			X	
SUSTIVA			X	
TRUVADA			X	
VICTRELIS	PA		X	
VIRAMUNE			X	
VIRAMUNE XR			X	

DRUG NAME	PA/STEP/QLL	TIER		SUGGESTED PREFFERED ALTERNATIVES
		1	2	
VIREAD			X	
ZIAGEN			X	
2.5.2 OTHER ANTIVIRAL DRUGS				
acyclovir		X		
amantadine		X		
famciclovir		X		
ribapak		X		
ribavirin		X		
valacyclovir		X		
BARACLUDE			X	
DENAVIR			X	
EPIVIR HBV			X	
RELENZA	QLL		X	
TAMIFLU	QLL		X	
2.6 TOPICAL ANTIVIRAL DRUGS				
XERESE			X	
ZOVIRAX			X	
2.7.2 ANTITUBERCULOSIS DRUGS				
isoniazid		X		
rifampin		X		
MYCOBUTIN			X	
2.7.3 PLASMODICIDES				
atovaquone-proguanil hcl		X		
hydroxychloroquine sulfate		X		
mefloquine hcl		X		
QUALAQUIN			X	
2.7.4 SULFONES				
DAPSONE			X	
2.7.5 TRICHOMONOCIDES				
metronidazole		X		
tinidazole		X		
2.8 OTHER ANTIINFECTIVE DRUGS				
bacitracin		X		
vancomycin hcl		X		
DIFICID			X	
MEPRON			X	
NEBUPENT			X	
VANCOCIN PULVULE	PA		X	
XIFAXAN			X	
ZYVOX	PA		X	
2.8.2 AMINOGLYCOSIDES				
gentamicin sulfate		X		
tobramycin sulfate		X		
TOBI			X	
CHAPTER 3: ANTINEOPLASTIC/IMMUNOSUPPRESSANT DRUGS				
3.0 ANTINEOPLASTIC/IMMUNOSUPPRESSANT DRUGS				
anagrelide hcl		X		
azathioprine		X		
cyclosporine modified		X		
hydroxyurea		X		
leflunomide		X		
megestrol acetate		X		

DRUG NAME	PA/STEP/QLL	TIER		SUGGESTED PREFFERED ALTERNATIVES
		1	2	
mercaptopurine		X		
methotrexate		X		
mycophenolate mofetil		X		
tacrolimus		X		
tamoxifen citrate		X		
tretinoin		X		
ENBREL	PA		X	
HUMIRA	PA		X	
MEGACE ES			X	
MYFORTIC			X	
RAPAMUNE			X	
SIMPONI	PA		X	
STELARA	PA		X	
CHAPTER 4: CARDIOVASCULAR MEDICATIONS				
4.1 CARDIAC GLYCOSIDES				
digoxin		X		
LANOXIN			X	
4.2 CALCIUM ANTAGONISTS				
amlodipine besylate		X		
cartia xt		X		
diltiazem/er		X		
felodipine er		X		
nifediac cc		X		
nifedical xl		X		
nifedipine er		X		
nisoldipine		X		
verapamil/er pm		X		
CARDENE SR			X	**generics, amlodipine**
CARDIZEM LA			X	
SULAR			X	**nisoldipine**
4.3.1 LOOP DIURETICS				
bumetanide		X		
furosemide		X		
torsemide		X		
4.3.2 THIAZIDE AND RELATED DRUGS				
chlorthalidone		X		
hydrochlorothiazide		X		
indapamide		X		
metolazone		X		
4.3.3 POTASSIUM SPARING DIURETICS				
amiloride hcl		X		
eplerenone		X		
spironolactone		X		
spironolactone-hctz		X		
triamterene-hctz		X		
triamterene-hydrochlorothiazid		X		
4.4 BETA-ADRENERGIC ANTAGONIST DRUGS				
acebutolol hcl		X		
atenolol		X		
bisoprolol fumarate		X		
carvedilol		X		
labetalol hcl		X		

DRUG NAME	PA/STEP/QLL	TIER		SUGGESTED PREFFERED ALTERNATIVES
		1	2	
metoprolol succinate		X		
metoprolol tartrate		X		
nadolol		X		
pindolol		X		
propranolol hcl		X		
timolol maleate		X		
BYSTOLIC			X	
COREG CR			X	**carvedilol**
INNOPRAN XL			X	
4.5.1 VASODILATOR ANTIHYPERTENSIVES				
doxazosin mesylate		X		
minoxidil		X		
prazosin hcl		X		
terazosin hcl		X		
4.5.2 CENTRALLY ACTING ANTIHYPERTENSIVES				
clonidine, hcl		X		
guanfacine hcl		X		
methyldopa		X		
4.5.4.1 ANGIOTENSIN CONVERTING ENZYME INHIBITORS				
benazepril hcl		X		
captopril		X		
enalapril maleate		X		
fosinopril sodium		X		
lisinopril		X		
moexipril hcl		X		
quinapril hcl		X		
ramipril		X		
trandolapril		X		
4.5.4.2 ANGIOTENSIN II RECEPTOR ANTAGONISTS				
candesartan, -hctz		X		
eprosartan mesylate		X		
irbesartan, -hctz		X		
losartan, -hctz		X		
valsartan hctz		X		
DIOVAN			X	
EDARBI			X	**Generics**
MICARDIS, -HCT			X	**Generics**
TEVETEN HCT			X	**generics**
4.5.6 OTHER ANTIHYPERTENSIVES				
amlodipine besylate-benazepril		X		
atenolol-chlorthalidone		X		
benazepril-hydrochlorothiazide		X		
bisoprolol-hydrochlorothiazide		X		
captopril-hydrochlorothiazide		X		
enalapril-hydrochlorothiazide		X		
fosinopril-hydrochlorothiazide		X		
irbesartan-hydrochlorothiazide		X		
lisinopril-hydrochlorothiazide		X		
losartan-hydrochlorothiazide		X		
metoprolol-hydrochlorothiazide		X		
moexipril-hydrochlorothiazide		X		
AMTURNIDE			X	

DRUG NAME	PA/STEP/QLL	TIER		SUGGESTED PREFFERED ALTERNATIVES
		1	2	
AZOR			X	
EXFORGE/HCT			X	
TARKA ER			X	**trandolapril/verapamil**
TEKAMLO			X	
TEKTURNA/HCT			X	
TRIBENZOR			X	
4.6.1 NITRATES				
isosorbide		X		
isosorbide dinitrate		X		
nitroglycerin		X		
nitroglycerin patch		X		
NITROSTAT			X	
4.7.1.3 CLASS 1C				
flecainide acetate		X		
propafenone hcl		X		
RYTHMOL SR			X	**propafenone**
4.7.3 AMIODARONES				
amiodarone hcl		X		
4.7.5 OTHER ANTIARRHYTHMICS				
sotalol		X		
MULTAQ			X	
TIKOSYN			X	
4.8.1 HYPOLIPOPROTEINEMICS				
cholestyramine		X		
colestipol hcl		X		
fenofibrate		X		
fenofibric acid		X		
gemfibrozil		X		
LOVAZA	PA		X	
WELCHOL			X	
ZETIA	ST		X	
4.8.2 HMG-COA REDUCTASE INHIBITORS				
atorvastatin		X		
fluvastatin	ST	X		
lovastatin		X		
pravastatin		X		
simvastatin		X		
CRESTOR	ST		X	
LIVALO	ST		X	**generic HMGs**
4.8.2.1 HMG-COA COMBINATIONS				
amlodipine-atorvastatin		X		
ADVICOR			X	
CADUET	ST		X	
LIPTRUZET	ST		X	
4.9 OTHER CARDIOVASCULAR DRUGS				
pentoxifylline		X		
RANEXA			X	
CHAPTER 5: AUTONOMIC AND CNS MEDICATIONS				
5.1.1 ANALGESICS				
butorphanol tartrate		X		
tramadol hcl/er		X		
tramadol hcl-acetaminophen		X		

DRUG NAME	PA/STEP/QLL	TIER		SUGGESTED PREFFERED ALTERNATIVES
		1	2	
5.1.1.1 CLASS II NARCOTICS				
endocet		X		
fentanyl		X		
hydromorphone hcl		X		
methadone hcl		X		
morphine sulfate/er		X		
oxycodone hcl		X		
oxycodone-acetaminophen		X		
oxymorphone hcl		X		
ROXICET		X		
NUCYNTA, -ER	PA		X	
OPANA ER	PA		X	
OXYCONTIN			X	
5.1.1.2 CLASS III NARCOTICS				
acetaminophen-codeine		X		
buprenorphine hcl		X		
hydrocodone bit-ibuprofen		X		
hydrocodone-acetaminophen		X		
reprexain		X		
zamicet		X		
BUTRANS			X	
SUBOXONE			X	
5.1.2 DRUGS TO PREVENT AND TREAT HEADACHES				
butalbital compound-codeine		X		
butalbital-aspirin-caffeine		X		
dihydroergotamine nasal spray		X		
naratriptan tab	9/rx	X		
rizatriptan tab	12/rx	X		
sumatriptan tab	12/rx	X		
sumatriptan inj	1 kit/rx	X		
sumatriptan nasal spray	6/rx	X		
zolmitriptan -zmt tab	12/rx	X		
AXERT	6/rx		X	**naratriptan, rizatriptan, sumatriptan, zolmitritan**
FROVA	9/rx		X	**naratriptan, rizatriptan, sumatriptan, zolmitritan**
RELPAX	12/rx		X	
ZOMIG NASAL SPRAY	6/rx		X	
5.2.1 ANXIOLYTICS				
alprazolam/er/xr		X		
buspirone hcl		X		
chlordiazepoxide hcl		X		
clorazepate dipotassium		X		
diazepam		X		
lorazepam		X		
oxazepam		X		
5.2.2 SEDATIVE/HYPNOTIC DRUGS				
estazolam		X		
flurazepam		X		
temazepam		X		
triazolam		X		
zaleplon		X		
zolpidem tartrate, -er		X		
LUNESTA			X	**zolpidem, zaleplon**

DRUG NAME	PA/STEP/QLL	TIER		SUGGESTED PREFFERED ALTERNATIVES
		1	2	
ROZEREM			X	**zolpidem, zaleplon**
5.3 ANTIMANIA DRUGS				
lithium carbonate		X		
5.4.1 CARBAMAZEPINES				
carbamazepine, -xr		X		
oxcarbazepine		X		
TEGRETOL XR			X	**carbamazepine xr**
5.4.2 ANTICONVULSANT BENZODIAZEPINES				
clonazepam		X		
diazepam		X		
5.4.3 HYDANTOINS				
phenytoin sodium extended		X		
DILANTIN			X	
PHENYTEK			X	
5.4.4 VALPROIC ACID AND DERIVATIVES				
divalproex sodium, -er		X		
valproic acid		X		
5.4.6 ANTICONVULSANT BARBITURATES				
phenobarbital		X		
primidone		X		
5.4.7 OTHER ANTICONVULSANTS				
gabapentin		X		
lamotrigine		X		
levetiracetam		X		
topiramate		X		
zonisamide		X		
GRALISE			X	
HORIZANT			X	
KEPPRA, XR			X	
LAMICTAL, -ODT, -XR			X	**lamotrigine**
LYRICA			X	
POTIGA			X	
VIMPAT			X	
5.5.1.1 TERTIARY AMINES				
amitriptyline hcl		X		
clomipramine hcl		X		
doxepin hcl		X		
imipramine hcl		X		
5.5.1.2 SECONDARY AMINES				
desipramine hcl		X		
nortriptyline hcl		X		
5.5.1.3 SELECTIVE SEROTONIN REUPTAKE INHIBITORS				
citalopram, - hbr		X		
escitalopram oxalate		X		
fluoxetine hcl		X		
fluvoxamine maleate		X		
paroxetine hcl		X		
sertraline hcl		X		
VIIBRYD	ST		X	
5.5.1.4 OTHER ANTIDEPRESSANTS				
bupropion hcl,- sr, -xl		X		
mirtazapine		X		

DRUG NAME	PA/STEP/QLL	TIER		SUGGESTED PREFFERED ALTERNATIVES
		1	2	
nefazodone hcl		X		
trazodone hcl		X		
venlafaxine hcl, -er	ST	X		
CYMBALTA	ST/QLL		X	
PRISTIQ ER	ST		X	
SAVELLA			X	
5.5.2 MAO INHIBITORS				
tranylcypromine sulfate		X		
5.6 ANTIVERTIGO AND ANTIEMETIC DRUGS				
dronabinol		X		
granisetron hcl	LIMIT 2/rx	X		
meclizine hcl		X		
ondansetron hcl		X		
ondansetron odt		X		
prochlorperazine maleate		X		
promethazine hcl		X		
promethegan		X		
ANZEMET	LIMIT 1/rx		X	
EMEND	LIMIT 3/rx		X	**granisetron, ondansetron**
TRANSDERM-SCOP			X	
5.7.1 ANTIPARKINSON ANTICHOLINERGIC DRUGS				
benztropine mesylate		X		
trihexyphenidyl hcl		X		
5.7.2 OTHER ANTIPARKINSON DRUGS				
bromocriptine mesylate		X		
carbidopa-levodopa		X		
carbidopa-levodopa-entacapone		X		
pramipexole dihydrochloride		X		
ropinirole hcl		X		
AZILECT			X	
COMTAN			X	
MIRAPEX ER			X	
NEUPRO			X	
REQUIP XL			X	
STALEVO			X	**use generic**
5.8 ANTIPSYCHOTIC DRUGS				
clozapine		X		
fluphenazine hcl		X		
haloperidol		X		
olanzapine, -odt		X		
perphenazine		X		
quetiapine fumarate		X		
risperidone		X		
thioridazine hcl		X		
thiothixene		X		
trifluoperazine hcl		X		
ziprasidone hcl		X		
ABILIFY			X	
FANAPT			X	**generics**
GEODON			X	
INVEGA ER	PA		X	**generics**
LATUDA			X	

DRUG NAME	PA/STEP/QLL	TIER		SUGGESTED PREFFERED ALTERNATIVES
		1	2	
SAPHRIS	PA		X	**generics**
SEROQUEL XR			X	
5.8.1 ALIPHATIC PHENOTHIAZINES				
chlorpromazine hcl		X		
5.8.1.1 PSYCHOTHERAPEUTIC COMBINATIONS				
olanzapine-fluoxetine hcl		X		
SYMBYAX			X	
5.9.1 CNS STIMULANT DRUGS				
amphetamine salt combo		X		
dexmethylphenidate hcl, -sulfate		X		
dextroamphetamine-amphetamine		X		
methylphenidate er, -hcl, -sr		X		
modafinil		X		
DAYTRANA			X	
FOCALIN XR			X	
NUVIGIL			X	
QUILLIVANT XR			X	
RITALIN LA			X	**methylphenidate**
VYVANSE			X	
5.9.2 OTHER CNS/AUTONOMIC DRUGS				
atropine sulfate		X		
naltrexone hcl		X		
pyridostigmine bromide		X		
NUEDEXTA			X	
5.9.3 ANTIDEMENTIA DRUGS				
donepezil hcl		X		
galantamine hbr		X		
rivastigmine		X		
ARICEPT/ODT			X	donepezil
EXELON SOLUTION, PATCHES			X	rivastigmine
NAMENDA			X	
NAMENDA XR			X	
5.9.6 OTHER DRUGS FOR ADHD				
INTUNIV			X	
KAPVAY			X	
STRATTERA			X	
CHAPTER 6: DERMATOLOGICAL MEDICATIONS				
6.1 TOPICAL CORTICOSTEROID DRUGS				
alclometasone dipropionate		X		
betamethasone dipropionate		X		
betamethasone valerate		X		
clobetasol		X		
desonide		X		
desoximetasone		X		
fluocinolone		X		
fluticasone propionate		X		
halobetasol propionate		X		
hydrocortisone butyrate, -valerate		X		
mometasone furoate		X		
triamcinolone acetonide		X		

DRUG NAME	PA/STEP/QLL	TIER		SUGGESTED PREFFERED ALTERNATIVES
		1	2	
CLOBEX			X	
HALOG			X	**generics**
KENALOG			X	**halobetasol propionate**
OLUX-E			X	**clobetasol propionate**
ULTRAVATE PAC			X	**halobetasol propionate**
6.2 ANTIPRURITIC DRUGS				
hydroxyzine		X		
6.3 ANTIACNE DRUGS				
adapalene		X		
benzoyl peroxide		X		
clindamycin phosphate		X		
clindamycin-benzoyl peroxide		X		
erythromycin		X		
erythromycin-benzoyl peroxide		X		
metronidazole		X		
sodium sulfacetamide-sulfur		X		
tretinoin	PA	X		
ACANYA			X	
BENZACLIN			X	
DIFFERIN 0.1% LOTION & 0.3% GEL			X	**adapalene**
DUAC			X	
EPIDUO			X	
FINACEA			X	
METROGEL			X	
RETIN-A MICRO/PUMP	PA		X	
6.3.1 ACCUTANES				
isotretinoin		X		
6.7 KERATOLYTIC DRUGS				
CONDYLOX			X	**podofilox**
6.8 ANTIPSORIASIS AND ANTIECZEMA DRUGS				
calcipotriene		X		
calcitrene		X		
selenium sulfide		X		
sulfacetamide sodium		X		
DOVONEX			X	
SORILUX			X	
TACLONEX			X	
TAZORAC			X	
VECTICAL			X	**calcipotriene ointment**
6.9.2 TOPICAL DERMATOLOGICAL DRUGS				
fluorouracil		X		
imiquimod		X		
tretinoin		X		
CARAC			X	
ELIDEL			X	
EPICERAM			X	
FLUOROPLEX			X	
PICATO			X	
PROTOPIC			X	
SANTYL			X	
SOLARAZE			X	**fluorouracil**

DRUG NAME	PA/STEP/QLL	TIER		SUGGESTED PREFFERED ALTERNATIVES
		1	2	
VEREGEN			X	**podofilox**
ZYCLARA			X	
6.9.3 SCABICIDES				
permethrin		X		
EURAX			X	
ULESFIA			X	
6.9.5 TOPICAL ANTI-INFLAMMATORY DRUGS				
FLECTOR			X	
VOLTAREN			X	
CHAPTER 7: EAR-NOSE-THROAT MEDICATIONS				
7.1 DRUGS AFFECTING THE EAR				
antipyrine-benzocaine		X		
neomycin-polymyxin-hc		X		
neomycin-polymyxin-hydrocort		X		
ofloxacin		X		
CIPRODEX			X	**generic otic quinolone**
7.2 DRUGS AFFECTING THE NOSE				
azelastine hcl		X		
flunisolide		X		
fluticasone propionate		X		
ipratropium bromide		X		
ASTELIN			X	
ASTEPRO			X	
DYMISTA			X	
NASONEX			X	
QNASL	PA		X	
VERAMYST	PA		X	**fluticasone**
ZETONNA	PA		X	
7.3 DRUGS AFFECTING THE THROAT AND MOUTH				
doxycycline hyclate		X		
pilocarpine hcl		X		
triamcinolone acetonide		X		
CHAPTER 8: ENDOCRINE MEDICATIONS				
8.1.1 INSULIN				
APIDRA/SOLOSTAR			X	
HUMALOG		X		
HUMULIN		X		
LANTUS/SOLOSTAR			X	
LEVEMIR/FLEXPEN			X	
NOVOLIN		X		
NOVOLOG/FLEXPEN			X	
NOVOLOG MIX 70-30/FLEXPEN			X	
8.1.2 ORAL HYPOGLYCEMIC DRUGS				
acarbose		X		
glimepiride		X		
glipizide, -er, -xl, -w/metformin		X		
glyburide, -micronized, -w/metformin		X		
metformin hcl/er		X		
nateglinide		X		
FORTAMET			X	
PRANDIMET			X	

DRUG NAME	PA/STEP/QLL	TIER		SUGGESTED PREFFERED ALTERNATIVES
		1	2	
PRANDIN			X	
RIOMET			X	**metformin**
8.1.3 INSULIN SENSITIZERS				
pioglitazone		X		
pioglitazone-metformin		X		
ACTOPLUS MET XR			X	
AVANDAMET			X	**pioglitazone-metformin**
AVANDARYL			X	**pioglitazone + sulfonylurea**
AVANDIA			X	**pioglitazone**
DUETACT			X	
8.1.4 AMYLIN ANALOGUES				
SYMLINPEN VIAL	PA		X	
SYMLINPEN PEN	PA		X	
8.1.5.1 INCRETIN MIMETICS				
BYDUREON	ST		X	
BYETTA	ST		X	
VICTOZA	ST		X	
8.1.5.2 DIPEPTIDYL PEPTIDASE-IV INHIBITORS				
JANUMET/XR			X	
JANUVIA			X	
JENTADUETO			X	
JUVISYNC			X	
KOMBIGLYZE XR			X	
ONGLYZA			X	
TRADJENTA			X	
8.2 GLUCOSE ELEVATING DRUGS				
GLUCAGEN			X	
GLUCAGON EMERGENCY KIT			X	
8.3.1 GLUCOCORTICOID DRUGS				
dexamethasone		X		
dexamethasone sodium phosphate		X		
hydrocortisone		X		
methylprednisolone		X		
prednisolone		X		
prednisone		X		
veripred 20 solution		X		
8.3.2 MINERALOCORTICOID DRUGS				
fludrocortisone acetate		X		
8.4.1 THYROID SUPPLEMENTS				
levothyroxine sodium		X		
ARMOUR THYROID			X	
CYTOMEL			X	**liothyronine**
SYNTHROID			X	
8.4.2 ANTITHYROID DRUGS				
methimazole		X		
propylthiouracil		X		
8.6 OTHER ENDOCRINE DRUGS				
alendronate sodium		X		
desmopressin acetate		X		
etidronate disodium		X		
ibandronate sodium		X		

DRUG NAME	PA/STEP/QLL	TIER		SUGGESTED PREFFERED ALTERNATIVES
		1	2	
ACTONEL	PA		X	**alendronate**
CHAPTER 9: GASTROINTESTINAL MEDICATIONS				
9.2 ANTIDIARRHEAL DRUGS				
diphenoxylate-atropine		X		
loperamide		X		
9.3 ANTISPASMODICS/DRUGS AFFECT GI MOTILITY				
chlordiazepoxide-clidinium		X		
dicyclomine hcl		X		
hyoscyamine sulfate		X		
metoclopramide hcl		X		
9.4.1 OTHER ANTIULCER DRUGS				
misoprostol		X		
sucralfate		X		
CARAFATE			X	
9.4.2 PROTON PUMP INHIBITORS				
omeprazole		X		
pantoprazole sodium		X		
ACIPHEX	PA		X	**pantoprazole, omeprazole**
DEXILANT	PA		X	**pantoprazole, omeprazole**
NEXIUM	PA		X	**pantoprazole, omeprazole**
9.4.3 HELICOBACTER PYLORI DRUGS				
HELIDAC			X	**generic equivalents**
OMECLAMOX-PAK			X	**generic equivalents**
PREVPAC			X	**generic equivalents**
PYLERA			X	**generic equivalents**
9.5 LAXATIVES AND CATHARTICS				
OSMOPREP			X	
9.6 OTHER GI DRUGS				
anucort-hc		X		
balsalazide disodium		X		
budesonide ec		X		
hydrocortisone, -acetate		X		
pancrelipase 5,000		X		
peg 3350-electrolyte		X		
proctosol-hc		X		
proctozone-hc		X		
sulfasalazine		X		
trilyte with flavor packets		X		
ursodiol		X		
ANALPRAM E			X	
ANALPRAM HC			X	
ASACOL HD			X	
CANASA			X	
CREON DR			X	
DELZICOL			X	
DIPENTUM			X	**sulfasalazine**
GOLYTELY			X	
HALFLYTELY-BISACODYL			X	**peg electrolyte**
LIALDA			X	
MOVIPREP			X	**peg electrolyte**
NULYTELY WITH FLAVOR PACKS			X	
PANCREAZE			X	

DRUG NAME	PA/STEP/QLL	TIER		SUGGESTED PREFFERED ALTERNATIVES
		1	2	
PENTASA			X	
PERTZYE			X	
PREPOPIK			X	
RECTIV			X	
SUPREP			X	
ULTRESA			X	
ZENPEP			X	
9.7 IRRITABLE BOWEL DRUGS				
AMITIZA			X	
LINZESS			X	
CHAPTER 11: MUSCULOSKELETAL MEDICATIONS				
11.1.1 SALICYLATES AND RELATED DRUGS				
aspirin, -ec		X		$0 with Rx, age restriction applies
choline mag trisalicylate		X		
diflunisal		X		
salsalate		X		
11.1.2 NON-STEROIDAL ANTIINFLAMMATORY AGENTS				
diclofenac potassium, -sodium		X		
etodolac		X		
flurbiprofen		X		
ibuprofen		X		
indomethacin		X		
ketoprofen		X		
ketorolac tromethamine		X		
meloxicam		X		
nabumetone		X		
naproxen		X		
oxaprozin		X		
piroxicam		X		
sulindac		X		
CELEBREX	QLL		X	
NAPRELAN CR			X	**naproxen**
11.2 DRUGS TO PREVENT AND TREAT GOUT				
allopurinol		X		
probenecid		X		
COLCRYS			X	
ULORIC	PA		X	
11.3.1 DIRECT MUSCLE RELAXANTS				
baclofen		X		
tizanidine hcl		X		
11.3.2 CNS MUSCLE RELAXANTS				
carisoprodol		X		
chlorzoxazone		X		
cyclobenzaprine hcl		X		
metaxalone		X		
methocarbamol		X		
orphenadrine citrate		X		
AMRIX ER			X	**cyclobenzaprine**
CHAPTER 12: NUTRITION,BLOOD				
12.1.3 THERAPEUTIC VITAMINS & MINERALS				
calcitriol		X		
calcium acetate		X		

DRUG NAME	PA/STEP/QLL	TIER		SUGGESTED PREFFERED ALTERNATIVES
		1	2	
eliphos		X		
folic acid		X		$0 with Rx for females age 50 & younger
levocarnitine		X		
vitamin d		X		$0 with Rx for age 65 years & older
12.1.4 FLUORIDE PRODUCTS				
sodium fluoride		X		
12.2 POTASSIUM SUPPLEMENTS				
potassium chloride		X		
12.3.1 ORAL ANTICOAGULANTS, VITAMIN K				
warfarin sodium		X		
COUMADIN			X	
12.3.2 HEPARIN AND HEPARIN ANTAGONISTS				
enoxaparin sodium		X		
fondaparinux sodium		X		
ARIXTRA			X	
FRAGMIN			X	
12.3.3 OTHER DRUGS AFFECTING COAGULATION				
ELIQUIS			X	
XARELTO			X	
12.3.5 THROMBIN INHIBITORS				
PRADAXA			X	
12.4 ANTIPLATELET DRUGS				
cilostazol		X		
clopidogrel		X		
dipyridamole		X		
AGGRENOX			X	
BRILINTA			X	
EFFIENT			X	
12.5 HEMOSTATICS				
LYSTEDA			X	
12.7 BLOOD DETOXICANTS				
enulose		X		
lactulose		X		
FOSRENOL			X	
KRISTALOSE			X	
RENAGEL			X	
RENVELA			X	
CHAPTER 13: OBSTETRICAL & GYNECOLOGICAL MEDICATIONS				
13.1.3 OB/GYN TOPICAL ANTIINFECTIVES				
clindamycin phosphate		X		
metronidazole		X		
vandazole		X		
13.3 ANDROGEN DRUGS				
testosterone cypionate	PA	X		
ANDRODERM	PA		X	
ANDROGEL	PA		X	
AXIRON	PA		X	
STRIANT	PA		X	
13.4 ESTROGEN DRUGS				
estradiol		X		

DRUG NAME	PA/STEP/QLL	TIER		SUGGESTED PREFFERED ALTERNATIVES
		1	2	
estrogen-methyltestosterone		X		
estropipate		X		
CENESTIN			X	
DIVIGEL			X	orals or patches
ELESTRIN			X	orals or patches
ENJUVIA			X	
ESTRACE			X	
ESTRASORB			X	orals or patches
ESTRING	QLL		X	
ESTROGEL			X	orals or patches
EVAMIST			X	orals or patches
MENEST			X	
MINIVELLE			X	
PREMARIN			X	
VAGIFEM			X	
VIVELLE-DOT			X	
13.4.1 ESTROGEN/PROGESTIN COMBINATIONS				
jinteli		X		
ACTIVELLA			X	
CLIMARA PRO			X	
COMBIPATCH			X	
FEMHRT			X	
PREFEST			X	
PREMPHASE			X	
PREMPRO			X	
13.4.3 SELECTIVE ESTROGEN RECEPTOR MODULATOR				
EVISTA			X	
13.5 PROGESTIN DRUGS				
camila		X		
errin		X		
jolivette		X		
nora-be		X		
norethindrone		X		
CRINONE GEL			X	
PROMETRIUM			X	
13.7 CONTRACEPTIVES				
gildess/fe, lutera, marlissa, heather, introvale, jolessa, jolivette, junel/fe, kariva, kelnor, kurvelo, leena, lessina, levonest, levonor-eth estrad, levora		X		
low-ogestrel, microgestin/fe, mono-linya, mononessa, myzilra, necon, nora-be, norethindrone, norgestimate-eth estradiol, norg-ethin estr, nortrel, ocella, orsythia		X		
portia, previfem, quasense, reclipsen, solia, sprintec, sronyx, syeda, tri-estarylla, tri-linyah, trinessa, tri-previfem, tri-sprintec, trivora, velivet, viorele, wera, zarah, zovia		X		
NUVARING	QLL		X	
ORTHO EVRA	QLL		X	
ORTHO TRI-CYCLEN LO	QLL		X	
CHAPTER 14: OPHTHALMIC MEDICATIONS				
14.1.1 OPHTHALMIC TOPICAL ANTIBACTERIAL DRUGS				

DRUG NAME	PA/STEP/QLL	TIER		SUGGESTED PREFFERED ALTERNATIVES
		1	2	
bacitracin		X		
bacitracin-polymyxin		X		
ciprofloxacin hcl		X		
erythromycin		X		
gentamicin sulfate		X		
neomycin-bacitracin-polymyxin		X		
ofloxacin		X		
polymyxin b sul-trimethoprim		X		
sulfacetamide sodium		X		
AZASITE			X	
BESIVANCE	PA		X	
MOXEZA	PA		X	
VIGAMOX			X	
14.1.2 OPHTHALMIC TOPICAL ANTIVIRAL DRUGS				
trifluridine		X		
14.2 OPHTHALMIC CORTICOSTEROID DRUGS				
fluorometholone		X		
prednisolone acetate		X		
DUREZOL			X	
LOTEMAX			X	
VEXOL			X	
14.3 OPHTHALMIC ANTIINFECTIVE/CORTICOSTEROIDS				
neomycin-polymyxin-dexameth		X		
neomycin-polymyxin-hc		X		
tobramycin-dexamethasone		X		
ZYLET			X	
14.5 ANTIGLAUCOMA DRUGS				
acetazolamide		X		
brimonidine tartrate		X		
dorzolamide hcl		X		
dorzolamide-timolol		X		
latanoprost		X		
levobunolol hcl		X		
pilocarpine hcl		X		
timolol maleate		X		
ALPHAGAN P			X	
AZOPT			X	**generics**
BETIMOL			X	**betaxolol, timolol**
BETOPTIC S			X	**betaxolol**
COMBIGAN			X	**generics**
COSOPT PF			X	
ISTALOL			X	**timolol maleate**
LUMIGAN	PA		X	
TRAVATAN Z	PA		X	
14.6 OTHER OPHTHALMIC DRUGS				
atropine sulfate		X		
azelastine hcl		X		
cromolyn sodium		X		
diclofenac sodium		X		
epinastine hcl		X		
ACUVAIL	PA		X	
ALOCRIL	PA		X	**OTC ketotifen**

DRUG NAME	PA/STEP/QLL	TIER		SUGGESTED PREFFERED ALTERNATIVES
		1	2	
ALOMIDE	PA		X	**OTC ketotifen**
BEPREVE	PA		X	**OTC ketotifen**
EMADINE	PA		X	**OTC ketotifen**
LASTACAFT	PA		X	
PATADAY			X	
PATANOL			X	
RESTASIS			X	
CHAPTER 15: RESPIRATORY MEDICATIONS				
15.1.1 BETA-2 ADRENERGIC DRUGS				
albuterol sulfate		X		
metaproterenol sulfate		X		
ARCAPTA NEOHALER			X	
BROVANA	PA		X	
FORADIL			X	
MAXAIR AUTOHALER	PA		X	
PERFOROMIST			X	
PROAIR HFA			X	
SEREVENT DISKUS			X	
VENTOLIN HFA			X	
XOPENEX SOLUTION			X	
15.1.2 METHYL XANTHINE DRUGS				
theophylline		X		
theophylline anhydrous		X		
15.1.3 OTHER DRUGS FOR ASTHMA				
budesonide		X		
cromolyn sodium		X		
epinephrine		X		
ipratropium bromide		X		
ipratropium-albuterol		X		
ADVAIR DISKUS			X	
ADVAIR HFA			X	
ASMANEX			X	
ATROVENT HFA			X	
AUVI-Q			X	
COMBIVENT, -RESPIMAT			X	
DULERA			X	
EPIPEN, -JR			X	
FLOVENT HFA, -DISKUS			X	
PULMICORT FLEXHALER			X	
QVAR			X	
SPIRIVA			X	
SYMBICORT			X	
TUDORZA PRESSAIR			X	
15.1.4 LEUKOTRIENE MODIFIERS				
montelukast sodium		X		
zafirlukast		X		
15.2.1 ANTIHISTAMINES				
arbinoxa		X		
cyproheptadine hcl		X		
desloratadine		X		
fexofenadine hcl		X		
levocetirizine dihydrochloride		X		

DRUG NAME	PA/STEP/QLL	TIER		SUGGESTED PREFFERED ALTERNATIVES
		1	2	
promethazine hcl		X		
15.2.3 ANTIHISTAMINE/DECONGESTANT COMBINATIONS				
promethazine vc		X		
15.3 ANTITUSSIVE AND EXPECTORANT DRUGS				
benzonatate		X		
guaifenesin-codeine		X		
promethazine vc-codeine		X		
promethazine-codeine		X		
promethazine-dm		X		
REZIRA			X	
ZUTRIPRO			X	
15.4 OTHER RESPIRATORY DRUGS				
DALIRESP			X	
CHAPTER 16: UROLOGICAL MEDICATIONS				
16.1.1 ANTICHOLINERGIC ANTISPASMODICS				
oxybutynin chloride, -er		X		
tolterodine tartrate		X		
trospium chloride, -er				
DETROL LA	ST		X	
ENABLEX	ST		X	**generics**
TOVIAZ	ST		X	
VESICARE	ST		X	
16.1.2 CHOLINERGIC STIMULANTS				
bethanechol chloride		X		
16.1.3 URINARY ANESTHETICS				
phenazopyridine hcl		X		
16.1.4 OTHER GENITOURINARY PRODUCTS				
alfuzosin hcl		X		
finasteride		X		
potassium citrate		X		
tamsulosin hcl		X		
AVODART			X	
ELMIRON			X	
FLOMAX			X	**tamsulosin**
JALYN			X	
RAPAFLO			X	
CHAPTER 18: MEDICAL (MISCELLANEOUS) SUPPLIES				
18.1 DIABETIC SUPPLIES				
ACCU-CHEK		X		
ONE TOUCH		X		

INDEX

metronidazole	13.1.3
metronidazole	2.7.5
MICARDIS, -HCT	4.5.4.2
microgestin/fe	13.7
MINIVELLE	13.4
minocycline hcl	2.1.7
minoxidil	4.5.1
MIRAPEX ER	5.7.2
mirtazapine	5.5.1.4
misoprostol	9.4.1
modafinil	5.9.1
moexipril hcl	4.5.4.1
moexipril-hydrochlorothiazide	4.5.6
mometasone furoate	6.1
mono-linya	13.7
mononessa	13.7
montelukast sodium	15.1.4
morphine sulfate/er	5.1.1.1
MOVIPREP	9.6
MOXEZA	14.1.1
MULTAQ	4.7.5
mupirocin	2.2
MYCOBUTIN	2.7.2
mycophenolate mofetil	3
MYFORTIC	3
myzilra	13.7
nabumetone	11.1.2
nadolol	4.4
NAFTIN	2.4.2
naltrexone hcl	5.9.2
NAMENDA	5.9.3
NAMENDA XR	5.9.3
NAPRELAN CR	11.1.2
naproxen	11.1.2
naratriptan tab	5.1.2
NASONEX	7.2
nateglinide	8.1.2
NEBUPENT	2.8
necon	13.7
nefazodone hcl	5.5.1.4
neomycin-bacitracin-polymyxin	14.1.1
neomycin-polymyxin-dexameth	14.3
neomycin-polymyxin-hc	7.1
neomycin-polymyxin-hc	14.3
neomycin-polymyxin-hydrocort	7.1
NEUPRO	5.7.2
nevirapine	2.5.1
NEXIUM	9.4.2
nifediac cc	4.2
nifedical xl	4.2
nifedipine er	4.2
nisoldipine	4.2
nitrofurantoin	2.1.8
nitrofurantoin mono-macro	2.1.8
nitroglycerin	4.6.1
nitroglycerin patch	4.6.1
NITROSTAT	4.6.1
nora-be	13.7
nora-be	13.5
norethindrone	13.7
norethindrone	13.5
norg-ethin estr	13.7
norgestimate-eth estradiol	13.7
NOROXIN	2.1.9
nortrel	13.7
nortriptyline hcl	5.5.1.2
NORVIR	2.5.1
NOVOLIN	8.1.1
NOVOLOG MIX 70-30/FLEXPEN	8.1.1
NOVOLOG/FLEXPEN	8.1.1
NUCYNTA, -ER	5.1.1.1
NUEDEXTA	5.9.2
NULYTELY WITH FLAVOR PACKS	9.6
NUVARING	13.7
NUVIGIL	5.9.1
nystatin	2.3
nystatin	2.4.2
nystatin-triamcinolone	2.4.3
ocella	13.7
ofloxacin	7.1
ofloxacin	14.1.1
ofloxacin	2.1.9
olanzapine, -odt	5.8
olanzapine-fluoxetine hcl	5.8.1.1
OLUX-E	6.1
OMECLAMOX-PAK	9.4.3
omeprazole	9.4.2
ondansetron hcl	5.6
ondansetron odt	5.6
ONE TOUCH	18.1
ONGLYZA	8.1.5.2
ONMEL	2.3
OPANA ER	5.1.1.1
ORAVIG	2.3
orphenadrine citrate	11.3.2
orsythia	13.7
ORTHO EVRA	13.7
ORTHO TRI-CYCLEN LO	13.7
OSMOPREP	9.5
oxaprozin	11.1.2
oxazepam	5.2.1
oxcarbazepine	5.4.1
OXISTAT	2.4.2
oxybutynin chloride, -er	16.1.1
oxycodone hcl	5.1.1.1
oxycodone-acetaminophen	5.1.1.1
OXYCONTIN	5.1.1.1
oxymorphone hcl	5.1.1.1
PANCREAZE	9.6
pancrelipase 5,000	9.6
pantoprazole sodium	9.4.2
paroxetine hcl	5.5.1.3
PATADAY	14.6
PATANOL	14.6
peg 3350-electrolyte	9.6
penicillin v potassium	2.1.5
PENTASA	9.6
pentoxifylline	4.9
PERFOROMIST	15.1.1
permethrin	6.9.3
perphenazine	5.8
PERTZYE	9.6
phenazopyridine hcl	16.1.3
phenobarbital	5.4.6
PHENYTEK	5.4.3
phenytoin sodium extended	5.4.3
PICATO	6.9.2
pilocarpine hcl	7.3
pilocarpine hcl	14.5
pindolol	4.4

pioglitazone	8.1.3
pioglitazone-metformin	8.1.3
piroxicam	11.1.2
polymyxin b sul-trimethoprim	14.1.1
portia	13.7
potassium chloride	12.2
potassium citrate	16.1.4
POTIGA	5.4.7
PRADAXA	12.3.5
pramipexole dihydrochloride	5.7.2
PRANDIMET	8.1.2
PRANDIN	8.1.2
pravastatin	4.8.2
prazosin hcl	4.5.1
prednisolone	8.3.1
prednisolone acetate	14.2
prednisone	8.3.1
PREFEST	13.4.1
PREMARIN	13.4
PREMPHASE	13.4.1
PREMPRO	13.4.1
PREPOPIK	9.6
previfem	13.7
PREVPAC	9.4.3
PREZISTA	2.5.1
primidone	5.4.6
PRISTIQ ER	5.5.1.4
PROAIR HFA	15.1.1
probenecid	11.2
prochlorperazine maleate	5.6
proctosol-hc	9.6
proctozone-hc	9.6
promethazine hcl	5.6
promethazine hcl	15.2.1
promethazine vc	15.2.3
promethazine vc-codeine	15.3
promethazine-codeine	15.3
promethazine-dm	15.3
promethegan	5.6
PROMETRIUM	13.5
propafenone hcl	4.7.1.3
propranolol hcl	4.4
propylthiouracil	8.4.2
PROTOPIC	6.9.2
PULMICORT FLEXHALER	15.1.3
PYLERA	9.4.3
pyridostigmine bromide	5.9.2
QNASL	7.2
QUALAQUIN	2.7.3
quasense	13.7
quetiapine fumarate	5.8
QUILLIVANT XR	5.9.1
quinapril hcl	4.5.4.1
QVAR	15.1.3
ramipril	4.5.4.1
RANEXA	4.9
RAPAFLO	16.1.4
RAPAMUNE	3
reclipsen	13.7
RECTIV	9.6
RELENZA	2.5.2
RELPAX	5.1.2
RENAGEL	12.7
RENVELA	12.7
reprexain	5.1.1.2
REQUIP XL	5.7.2
RESTASIS	14.6
RETIN-A MICRO/PUMP	6.3
REYATAZ	2.5.1
REZIRA	15.3
ribapak	2.5.2
ribavirin	2.5.2
rifampin	2.7.2
RIOMET	8.1.2
risperidone	5.8
RITALIN LA	5.9.1
rivastigmine	5.9.3
rizatriptan tab	5.1.2
ropinirole hcl	5.7.2
ROXICET	5.1.1.1
ROZEREM	5.2.2
RYTHMOL SR	4.7.1.3
salsalate	11.1.1
SANTYL	6.9.2
SAPHRIS	5.8
SAVELLA	5.5.1.4
selenium sulfide	6.8
SEREVENT DISKUS	15.1.1
SEROQUEL XR	5.8
sertraline hcl	5.5.1.3
silver sulfadiazine	2.2
SIMPONI	3
simvastatin	4.8.2
sodium fluoride	12.1.4
sodium sulfacetamide-sulfur	6.3
SOLARAZE	6.9.2
solia	13.7
SORILUX	6.8
sotalol	4.7.5
SPIRIVA	15.1.3
spironolactone	4.3.3
spironolactone-hctz	4.3.3
sprintec	13.7
sronyx	13.7
STALEVO	5.7.2
STELARA	3
STRATTERA	5.9.6
STRIANT	13.3
SUBOXONE	5.1.1.2
sucralfate	9.4.1
SULAR	4.2
sulfacetamide sodium	6.8
sulfacetamide sodium	14.1.1
sulfamethoxazole-trimethoprim	2.1.6
sulfasalazine	9.6
sulindac	11.1.2
sumatriptan inj	5.1.2
sumatriptan nasal spray	5.1.2
sumatriptan tab	5.1.2
SUPRAX	2.1.1
SUPREP	9.6
SUSTIVA	2.5.1
syeda	13.7
SYMBICORT	15.1.3
SYMBYAX	5.8.1.1
SYMLINPEN PEN	8.1.4
SYMLINPEN VIAL	8.1.4
SYNTHROID	8.4.1
TACLONEX	6.8
tacrolimus	3

TAMIFLU	2.5.2
tamoxifen citrate	3
tamsulosin hcl	16.1.4
TARKA ER	4.5.6
TAZORAC	6.8
TEGRETOL XR	5.4.1
TEKAMLO	4.5.6
TEKTURNA/HCT	4.5.6
temazepam	5.2.2
terazosin hcl	4.5.1
terbinafine hcl	2.3
terconazole	2.4.1
testosterone cypionate	13.3
tetracycline hcl	2.1.7
TEVETEN HCT	4.5.4.2
theophylline	15.1.2
theophylline anhydrous	15.1.2
thioridazine hcl	5.8
thiothixene	5.8
TIKOSYN	4.7.5
timolol maleate	4.4
timolol maleate	14.5
tinidazole	2.7.5
tizanidine hcl	11.3.1
TOBI	2.8.2
tobramycin sulfate	2.8.2
tobramycin-dexamethasone	14.3
tolterodine tartrate	16.1.1
topiramate	5.4.7
torsemide	4.3.1
TOVIAZ	16.1.1
TRADJENTA	8.1.5.2
tramadol hcl/er	5.1.1
tramadol hcl-acetaminophen	5.1.1
trandolapril	4.5.4.1
TRANSDERM-SCOP	5.6
tranylcypromine sulfate	5.5.2
TRAVATAN Z	14.5
trazodone hcl	5.5.1.4
tretinoin	3
tretinoin	6.3
tretinoin	6.9.2
triamcinolone acetonide	6.1
triamcinolone acetonide	7.3
triamterene-hctz	4.3.3
triamterene-hydrochlorothiazid	4.3.3
triazolam	5.2.2
TRIBENZOR	4.5.6
tri-estarylla	13.7
trifluoperazine hcl	5.8
trifluridine	14.1.2
trihexyphenidyl hcl	5.7.1
tri-linyah	13.7
trilyte with flavor packets	9.6
trimethoprim	2.1.8
trinessa	13.7
tri-previfem	13.7
tri-sprintec	13.7
trivora	13.7
trospium chloride, -er	16.1.1
TRUVADA	2.5.1
TUDORZA PRESSAIR	15.1.3
ULESFIA	6.9.3
ULORIC	11.2
ULTRAVATE PAC	6.1
ULTRESA	9.6
ursodiol	9.6
VAGIFEM	13.4
valacyclovir	2.5.2
valproic acid	5.4.4
valsartan hctz	4.5.4.2
VANCOCIN PULVULE	2.8
vancomycin hcl	2.8
vandazole	13.1.3
VECTICAL	6.8
velivet	13.7
venlafaxine hcl, -er	5.5.1.4
VENTOLIN HFA	15.1.1
VERAMYST	7.2
verapamil/er pm	4.2
VEREGEN	6.9.2
veripred 20 solution	8.3.1
VESICARE	16.1.1
VEXOL	14.2
VICTOZA	8.1.5.1
VICTRELIS	2.5.1
VIGAMOX	14.1.1
VIIBRYD	5.5.1.3
VIMPAT	5.4.7
viorele	13.7
VIRAMUNE	2.5.1
VIRAMUNE XR	2.5.1
VIREAD	2.5.1
vitamin d	12.1.3
VIVELLE-DOT	13.4
VOLTAREN	6.9.5
voriconazole	2.3
VYVANSE	5.9.1
warfarin sodium	12.3.1
WELCHOL	4.8.1
wera	13.7
XARELTO	12.3.3
XERESE	2.6
XIFAXAN	2.8
XOPENEX SOLUTION	15.1.1
zafirlukast	15.1.4
zaleplon	5.2.2
zamicet	5.1.1.2
zarah	13.7
ZENPEP	9.6
ZETIA	4.8.1
ZETONNA	7.2
ZIAGEN	2.5.1
ziprasidone hcl	5.8
zolmitriptan -zmt tab	5.1.2
zolpidem tartrate, -er	5.2.2
ZOMIG NASAL SPRAY	5.1.2
zonisamide	5.4.7
zovia	13.7
ZOVIRAX	2.6
ZUTRIPRO	15.3
ZYCLARA	6.9.2
ZYLET	14.3
ZYVOX	2.8

Medication Request Form

PO Box 91110
Sioux Falls, SD 57109
(605) 328-6800 • 1-800-752-5863
Fax: (605) 328-6813
sanfordhealthplan.com

SANFORD HEALTH PLAN

This form can be completed by a member or practitioner when seeking coverage for a medication that qualifies as a non-formulary drug, meaning not covered, or one requiring a prior authorization.

Review Criteria

The following criteria will be used in determining whether or not a formulary exception or prior authorization request is approved:

1. Has the member failed an appropriate trial of formulary (covered) medications or over the counter options prior to this request?
2. Are the choices available on the drug formulary not appropriate or recommended for the member's medical needs?
3. Has the member had unacceptable side effects from the formulary drug?

Required Information

All information MUST be completed or the form will be returned to sender. Please be **very specific** in all areas to speed the process.

Name: _____ ID: _____ Date of Birth: _____

Phone #: _____ Diagnosis: _____ Drug Requested: _____

Dosage, quantity requested (per month) and length of treatment, if known: _____

_____

Reason for medication request: _____

_____

Other medications (prescription or over the counter) tried and/or failed; please describe nature of failure including details. Check here if none ☐:_____

_____

For provider use only:

Other pertinent history and labs (relative or pertaining to this request): _____

_____

Prescribing Practitioner Name/Specialty: _____

Prescribing Practitioner Address, City, State, Zip: _____

Prescribing Practitioner Phone #: ( ) _____ Prescribing Practitioner Fax #: ( ) _____

Pharmacy Name: _____ Pharmacy Phone #: ( ) _____

Who filled out this form: _____

Relationship to member: _____ Date: _____

PRODUCT DETAILS OF CAYSTON® (AZTREONAM)

INDICATIONS AND USE: Cayston (aztreonam for inhalation solution) is a monobactam antibacterial indicated to improve respiratory symptoms in cystic fibrosis (CF) patients with *Pseudomonas aeruginosa.* Safety and effectiveness have not been established in pediatric patients below the age of 7 years, patients with FEV_1 <25% or >75% predicted, or patients colonized with *Burkholderia cepacia.*

DOSAGE FORMS: Each kit for a 28-day course of Cayston contains 84 sterile vials of Cayston and 88 ampules of sterile diluent packed in 2 cartons, each carton containing a 14-day supply.

ADMINISTRATION: The recommended dose of Cayston for both adults and pediatric patients 7 years of age and older is one single-use vial (75mg of aztreonam) reconstituted with 1 mL of sterile diluent administered 3 times a day for a 28-day course (followed by 28 days off therapy). Dosage is not based on weight or adjusted for age. Doses should be taken at least 4 hours apart. Cayston is administered by inhalation using an Altera® Nebulizer System. Patients should use a bronchodilator before administration of Cayston.

CONTRAINDICATIONS: Do not administer to patients with a known allergy to aztreonam.

SPECIAL POPULATIONS:

- Cayston is classified as pregnancy category B. No adequate and well-controlled studies of aztreonam for injection or Cayston in pregnant women have been conducted. Cayston should be used during pregnancy only if clearly needed.
- Use of Cayston during breastfeeding is unlikely to pose a risk to infants.
- The safety and effectiveness in pediatric patients below the age of 7 have not been established.
- Clinical trials of Cayston did not include Cayston-treated patients aged 65 years of age and older to determine whether they respond differently from younger patients.
- Cayston may be administered to patients with mild, moderate, and severe renal impairment with no dosage adjustment.

WARNINGS AND PRECAUTIONS:

- Allergic reaction to Cayston was seen in clinical trials. Stop treatment if an allergic reaction occurs. Use caution when Cayston is administered to patients with known allergic reaction to beta-lactams.
- Bronchospasm has been reported with Cayston. Stop treatment if chest tightness develops during nebulizer use.
- Healthcare providers should consider a patient's baseline FEV_1 measured prior to Cayston therapy and the presence of other symptoms when evaluating whether post-treatment changes in FEV_1 are caused by a pulmonary exacerbation.
- Prescribing Cayston in the absence of known *Pseudomonas aeruginosa* infection in patients with CF is unlikely to provide benefit and increases the risk of development of drug-resistant bacteria.

ADVERSE REACTIONS: Common adverse reactions (more than 5%) occurring more frequently in Cayston patients are cough, nasal congestion, wheezing, pharyngolaryngeal pain, pyrexia, chest discomfort, abdominal pain, and vomiting.

DRUG INTERACTIONS: No formal clinical studies of drug interactions with Cayston have been conducted.

PATIENT COUNSELING INFORMATION:

- Cayston is a prescription inhaled antibiotic used to improve breathing symptoms in people with cystic fibrosis who have *Pseudomonas aeruginosa* in their lungs.
- Cayston is only for infections caused by bacteria. It is not for infections caused by viruses, such as the common cold.
- Cayston is used only with the Altera® Nebulizer System.
- Patients should complete the full 28-day course of Cayston even if they are feeling better.
- If a dose is missed, take all 3 daily doses as long as the doses are at least 4 hours apart.
- Use a bronchodilator prior to administration of Cayston.
- Patients taking several inhaled medications should be advised to use the medications in the following order of administration: bronchodilator, mucolytics, and lastly, Cayston.
- Patients who believe they are experiencing an allergic reaction to Cayston should be advised to contact their doctor immediately.

References:

1. Cayston® [package insert]. Foster City, CA: Gilead Sciences, Inc.; September 2012.

PRODUCT DETAILS OF PROCYSBI™ (CYSTEAMINE BITARTRATE)

INDICATIONS AND USE: Procysbi (cysteamine bitartrate) is a cysteine-depleting agent indicated for the management of nephropathic cystinosis in adults and children ages 6 years and older.

DOSAGE FORMS: Procysbi is available as 25 mg and 75 mg delayed-release capsules.

ADMINISTRATION: Procysbi should be prescribed by a physician experienced in management of nephropathic cystinosis.

- Swallow capsules whole or after sprinkling on food or in recommended liquids. Administer via gastrostomy tube (12 F or larger) after mixing with food.
- Total daily dose is 1.3 gm/m^2/day in two divided doses, every 12 hours.
- Take Procysbi at least 2 hours after and at least 30 minutes before eating.
- Goal of therapy is to maintain a white blood cell (WBC) cysteine level <1 nmol ½ cysteine/mg protein or a plasma cysteamine concentration >0.1 mg/L.
- Patients switching from immediate-release cysteamine to Procysbi should take a total daily dose of Procysbi equal to their previous total daily dose of immediate-release cysteamine bitartrate.
- Starting dose in cysteamine-naïve patients is ⅛ to ¼ of the maintenance dose of Procysbi. The dose should be raised gradually over 4 to 6 weeks to help reduce the risk of side effects.
- If a dose is missed, it should be taken as soon as possible. However, if a patient has missed a dose and the next scheduled dose is due in less than 4 hours, the patient should be instructed to not take the missed dose, and to take the next dose on time.

CONTRAINDICATIONS: The use of Procysbi is contraindicated in patients who are hypersensitive to penicillamine.

SPECIAL POPULATIONS:

- Procysbi is classified as pregnancy category C. Procysbi should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.
- Because of the potential for serious adverse reactions in nursing infants, nursing is not recommended.
- Procysbi therapy should be initiated as soon as the diagnosis of nephropathic cystinosis has been confirmed in children greater than 6 years and adults. The risks and benefits of treatment with Procysbi in children under 6 years old are not yet established.

WARNINGS AND PRECAUTIONS:

- Ehlers-Danlos like Syndrome: Reduce dosage if skin and bone lesions occur.
- Skin Rash: Discontinue if severe skin rash such as erythema multiforme bullosa or toxic epidermal necrolysis occurs.
- Gastrointestinal: Monitor for symptoms of gastrointestinal ulceration and bleeding.
- Central Nervous System: Monitor for seizures, lethargy, somnolence, depression, and encephalopathy.

- Leukopenia and Elevated Alkaline Phosphatase Levels: Monitor white blood cell count and elevated alkaline phosphatase levels.
- Benign Intracranial Hypertension: Monitor for signs and symptoms of benign intracranial hypertension.

ADVERSE REACTIONS: Common adverse reactions (more than 5%) are vomiting, abdominal pain/discomfort, headaches, nausea, diarrhea, anorexia/decreased appetite, breath odor, fatigue, dizziness, skin odor, and rash.

DRUG INTERACTIONS: Procysbi can be administered with electrolyte (except bicarbonate) and mineral replacements necessary for management of Fanconi Syndrome as well as vitamin D and thyroid hormone.

PATIENT COUNSELING INFORMATION:

- Procysbi requires extensive laboratory monitoring to determine the correct dose.
- Take Procysbi consistently and do not miss doses. If a missed dose is within 4 hours of the next dose, skip the missed dose and take the next regularly scheduled dose. Do not double the dose.
- Take Procysbi at least 2 hours after and at least 30 minutes before eating.
- Immediately contact physician if pregnancy is suspected.
- Breastfeeding is not recommended.
- Exercise caution in driving a car or engaging in other hazardous activities after taking Procysbi.
- Procysbi may cause ulcers and bleeding. Contact physician immediately if stomach pain, nausea, vomiting, loss of appetite, or vomiting blood is experienced.
- Contact physician immediately if a skin rash is experienced.
- Lab testing to monitor for low white blood cell count and elevated alkaline phosphatase will be needed while taking Procysbi.
- Contact physician immediately if experiencing headache, tinnitus, dizziness, nausea, double vision, blurry vision, loss of vision, or eye pain.
- Report any skin changes to physician.

References:

1. Procysbi® [package insert]. Novato, CA: Raptor Pharmaceuticals, Inc.; April 2013.

PRODUCT DETAILS OF RAVICTI® (GLYCEROL PHENYLBUTYRATE)

INDICATIONS AND USE: Ravicti (glycerol phenylbutyrate) is indicated for use as a nitrogen-binding agent for chronic management of adult and pediatric patients 2 years of age and older with urea cycle disorders (UCD) who cannot be managed by dietary protein restriction and/or amino acid supplementation alone.

DOSAGE FORMS: Ravicti is available as an oral liquid containing 1.1 g/mL of glycerol phenylbutyrate.

ADMINISTRATION: Ravicti should be prescribed by a physician experienced in management of UCDs.

- Take with food and administer directly into mouth via oral syringe or dosing cup.
- Give Ravicti in 3 equally divided doses, each rounded up to the nearest 0.5 mL.
- The maximum total daily dosage is 17.5 mL (19g).
- Ravicti must be used with dietary protein restriction and, in some cases, dietary supplements (e.g., essential amino acids, arginine, citrulline, protein-free calorie supplements).
- Patients switching from sodium phenylbutyrate to Ravicti should receive the dosage of Ravicti that contains the same amount of phenylbutyric acid. The conversion is daily dosage of Ravicti (mL) = daily dosage of sodium phenylbutyrate (g) x 0.86.
- The recommended dosage range, based upon body surface area, in patients naïve to phenylbutyrate (PBA) is 4.5 to 11.2 mL/m^2/day (5 to 12.4 g/m^2/day).
- For patients with some residual enzyme activity who are not adequately controlled with dietary restriction, recommended starting dose is 4.5 mL/m^2/day.

CONTRAINDICATIONS:

- Do not administer to patients with a known hypersensitivity to phenylbutyrate.
- Do not administer to patients younger than 2 months of age.

SPECIAL POPULATIONS:

- Ravicti is classified as pregnancy category C. Ravicti should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.
- Because of the potential for adverse reactions from Ravicti in nursing infants, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into consideration the importance of the drug to the health of the mother.
- The safety and effectiveness in pediatric patients 2 to under 18 years of age were established in 2 open-label, sodium phenylbutyrate to Ravicti, fixed-sequence, switchover clinical trials. The safety and efficacy of Ravicti in patients 2 months of age to under 2 years of age have not been established. Ravicti is contraindicated in patients <2 months of age.
- Clinical trials of Ravicti did not include sufficient numbers of subjects aged 65 years of age and older to determine whether they respond differently from younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range.

- Dosage for patients with moderate to severe hepatic impairment should be started at the lower end of the recommended dosing range and should be kept on the lowest dose necessary to control their ammonia levels.
- The efficacy and safety of Ravicti in patients with renal impairment are unknown. Monitor ammonia levels closely when starting patients with impaired renal function on Ravicti.
- Cayston may be administered to patients with mild, moderate, and severe renal impairment with no dosage adjustment.

WARNINGS AND PRECAUTIONS:

- Neurotoxicity - (phenylacetate [PAA] the active moiety of Ravicti, may be toxic) therefore reduce dosage for symptoms of neurotoxicity.
- Reduced phenylbutyrate absorption in pancreatic insufficiency or intestinal malabsorption-monitor ammonia levels closely.

ADVERSE REACTIONS: Common adverse reactions in ≥10% of patients are diarrhea, flatulence, and headache.

DRUG INTERACTIONS:

- Use of corticosteroids may cause the breakdown of body protein and increase plasma ammonia levels. Monitor ammonia levels closely when corticosteroids and Ravicti are used concomitantly.
- Hyperammonemia may be induced by haloperidol and by valproic acid. Monitor ammonia levels closely when use of valproic acid or haloperidol is necessary in UCD patients.
- Probenecid may inhibit the renal excretion of metabolites of Ravicti including phenylacetylglutamine (PAGN) and PAA.

PATIENT COUNSELING INFORMATION:

- Ravicti is a prescription medicine used in adults and children 2 years of age and older for long-term management of high blood levels of ammonia caused by a condition called urea cycle disorder (UCD). Ravicti should be used if the UCD cannot be managed with a low-protein diet and dietary supplements alone.
- Ravicti may cause serious side effects. Call your doctor or go to the nearest emergency room if you experience wheezing, shortness of breath, cough, low blood pressure, flushing, nausea, or a rash while taking Ravicti.
- Take Ravicti with food.
- Ravicti is an oral liquid that is taken by mouth using an oral syringe or measuring cup.
- Talk to your doctor about participating in a UCD registry. The purpose of the registry is to collect information about people with UCD to improve care.

References:

1. Ravicti® [package insert]. South San Francisco, CA: Hyperion Therapeutics, Inc.; January 2013.

PRODUCT DETAILS OF LINZESS® (LINACLOTIDE)

INDICATIONS AND USE: Linzess is a guanylate cyclase-C agonist indicated in adults for the treatment of irritable bowel syndrome with constipation (IBS-C) and chronic idiopathic constipation (CIC).

DOSAGE FORMS: Linzess is available as 145 mcg and 290 mcg capsules.

ADMINISTRATION:

- IBS-C: Take 290 mcg orally once daily.
- CIC: Take 145 mcg orally once daily.
- Take on empty stomach at least 30 minutes prior to first meal of the day.

CONTRAINDICATIONS: Linzess is contraindicated in patients up to 6 years of age and patients with known or suspected mechanical gastrointestinal obstruction.

SPECIAL POPULATIONS:

- Linzess is classified as pregnancy category C. There are no adequate and well-controlled studies of Linzess in pregnant women. Linzess should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.
- Caution should be exercised when Linzess is administered to a nursing woman.
- The safety and effectiveness in pediatric patients have not been established.
- Chronic Idiopathic Constipation and Irritable Bowel Syndrome with Constipation-Clinical trials of Linzess did not include sufficient numbers of patients aged 65 years of age and older to determine whether they respond differently from younger patients.

WARNINGS AND PRECAUTIONS:

- Linzess is contraindicated in pediatric patients up to 6 years of age.
- Avoid the use of Linzess in pediatric patients 6 through 17 years of age.
- Stop Linzess if severe diarrhea occurs and contact a healthcare provider.

ADVERSE REACTIONS:

- Most common adverse reactions (incidence of at least 2%) are diarrhea, abdominal pain, abdominal distension, and flatulence.

DRUG INTERACTIONS: No drug-drug interaction studies have been conducted with Linzess.

PATIENT COUNSELING INFORMATION:

- Linzess is a prescription medication used in adults to treat irritable bowel syndrome with constipation and chronic idiopathic constipation.
- Do not give Linzess to children under the age of 6. You should not give Linzess to children 6 to 17 years of age.
- Keep Linzess in the original container.
- Take once daily on an empty stomach as prescribed.

- Swallow the capsule whole and do not break apart or chew.
- If you miss a dose, skip the missed dose. Take the next dose at the regular time. Do not take 2 doses at the same time.
- Stop Linzess and contact physician if you experience severe diarrhea.
- Seek immediate medical attention if you develop unusual or severe stomach-area pain, and/or severe diarrhea.

UTILIZATION 03/26/13 – 03/26/14

Label Name	Rx Num	Total Reimb Amt	Avg Cost per Script
Linzess 145 mcg	75	$15,360.82	$204.81
Linzess 290 mcg	24	$5,623.28	$234.30
Total 36 recipients	**99**	**$20,984.1**	

References:

1. Linzess® [package insert]. St. Louis, MO: Forest Pharmaceuticals, Inc.; August 2013.

PRODUCT DETAILS OF AMITIZA® (LUBIPROSTONE)

INDICATIONS AND USE: Amitiza is a chloride channel activator indicated for treatment of chronic idiopathic constipation in adults, treatment of opioid-induced constipation in adults with chronic, non-cancer pain, and treatment of irritable bowel syndrome with constipation in women ≥ 18 years old.

DOSAGE FORMS: Amitiza is available as 8 mcg and 24 mcg capsules.

ADMINISTRATION:

- Take Amitiza orally with food or water.
- Swallow capsules whole and do not break apart or chew.
- The recommended dose for chronic idiopathic constipation and opioid-induced constipation is 24 mcg twice daily orally with food and water.
- The recommended dose for irritable bowel syndrome with constipation is 8 mcg twice daily orally with food and water.

CONTRAINDICATIONS: Amitiza is contraindicated in patients with known or suspected mechanical gastrointestinal obstruction.

SPECIAL POPULATIONS:

- Amitiza is classified as pregnancy category C. There are no adequate and well-controlled studies of Amitiza in pregnant women. Amitiza should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.
- Caution should be exercised when Amitiza is administered to a nursing woman.
- The safety and effectiveness in pediatric patients have not been established.
- Chronic Idiopathic Constipation-The efficacy of Amitiza in the elderly subpopulation was consistent with the efficacy in the overall study population.
- Opioid-induced Constipation and Irritable Bowel Syndrome with Constipation-Clinical trials of Amitiza did not include sufficient numbers of patients aged 65 years of age and older to determine whether they respond differently from younger patients.
- In case of chronic idiopathic constipation or opioid-induced constipation indications, the starting dosage of Amitiza should be reduced in patients with moderate hepatic impairment. The starting dose of Amitiza should be reduced in all patients with severe hepatic impairment, regardless of the indication. No dosing adjustment is required in patients with mild hepatic impairment (Child-Pugh Class A).

WARNINGS AND PRECAUTIONS:

- Patients may experience nausea; concomitant administration of food may reduce this symptom.
- Do not prescribe for patients that have severe diarrhea.
- Patients taking Amitiza may experience dyspnea within an hour of first dose. This symptom generally resolves within 3 hours, but may recur with repeat dosing.

- Evaluate patients with symptoms suggestive of mechanical gastrointestinal obstruction prior to initiating treatment with Amitiza.

ADVERSE REACTIONS:

- Most common adverse reactions (more than 4%) in chronic idiopathic constipation are nausea, diarrhea, headache, abdominal pain, abdominal distension, and flatulence.
- Most common adverse reactions (more than 4%) in opioid-induced constipation are nausea and diarrhea.
- Most common adverse reactions (more than 4%) in irritable bowel syndrome with constipation are nausea, diarrhea, and abdominal pain.

DRUG INTERACTIONS: Concomitant use of diphenylheptane opioids (e.g., methadone) may interfere with the efficacy of Amitiza.

PATIENT COUNSELING INFORMATION:

- Take Amitiza twice daily with food and water to reduce the occurrence of nausea.
- Patients taking Amitiza may experience dyspnea within an hour of the first dose.
- Patients on treatment who experience severe nausea, dyspnea, or diarrhea should notify their physician.
- Lactating women should monitor their milk-fed infants for diarrhea while taking Amitiza.

UTILIZATION 03/26/13 – 03/25/14

Label Name	Rx Num	Total Reimb Amt	Avg Cost per Script
Amitiza 8 mcg	22	$5,870.23	$266.83
Amitiza 24 mcg	84	$15,957.75	$189.97
Total 33 recipients	**106**	**$21,827.98**	

References:

1. Amitiza® [package insert]. Deerfield, IL: Takeda Pharmaceuticals America, Inc.; April 2013.

PRODUCT DETAILS OF MYALEPT™ (METRELEPTIN)

INDICATIONS AND USE: Myalept (metreleptin) is a leptin analog indicated as an adjunct to diet as replacement therapy to treat the complications of leptin deficiency in patients with congenital or acquired generalized lipodystrophy.
Limitations of Use:

- The safety and effectiveness of Myalept for the treatment of complications of partial lipodystrophy have not been established.
- The safety and effectiveness of Myalept for the treatment of liver disease, including nonalcoholic steatohepatitis (NASH), have not been established.
- Myalept is not indicated for use in patients with HIV-related lipodystrophy.
- Myalept is not indicated for use in patients with metabolic disease, without concurrent evidence of generalized lipodystrophy.

DOSAGE FORMS: Myalept is available as a sterile, white, solid, lyophilized cake of 11.3 mg metreleptin per vial to deliver 5 mg per mL when reconstituted in 2.2 mL of Bacteriostatic Water for Injection (BWFI) or preservative-free sterile Water for Injection (WFI).

ADMINISTRATION: Administer as a subcutaneous injection once daily after the lyophilized cake is reconstituted with BWFI or WFI. The recommended daily dosages in mg per kg of body weight are:

- Body weight 40 kg or less: starting dose 0.06 mg/kg/day, increase or decrease by 0.02 mg/kg to a maximum daily dose of 0.13 mg/kg.
- Males greater than 40 kg body weight: starting dose 2.5 mg/day, increase or decrease by 1.25 mg to 2.5 mg/day to a maximum dose of 10 mg/day.
- Females greater than 40 kg body weight: starting dose 5 mg/day, increase or decrease by 1.25 mg to 2.5 mg/day to a maximum dose of 10 mg/day.

CONTRAINDICATIONS:

- General obesity not associated with congenital leptin deficiency.
- Hypersensitivity to metreleptin.

SPECIAL POPULATIONS:

- Myalept is classified as pregnancy category C. No adequate and well-controlled studies of Myalept in pregnant women have been conducted. Myalept should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.
- Because of the potential for serious adverse reactions in nursing infants from Myalept, a decision should be made whether to discontinue nursing or discontinue the drug, taking into account the importance of drug to the mother.
- No clinically meaningful differences were observed in the efficacy and safety of Myalept between pediatric and adult patients.
- Clinical trials of Myalept did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. In general, dose selection should be cautious, usually starting at the low end of the dosing range.

WARNINGS AND PRECAUTIONS:

- Anti-metreleptin antibodies with neutralizing activity could inhibit endogenous leptin action and/or result in loss of Myalept efficacy. Test for neutralizing antibodies in patients with severe infections or loss of efficacy during Myalept treatment.
- T-cell lymphoma-carefully consider benefits and risks of treatment with Myalept in patients with significant hematologic abnormalities and/or acquired generalized lipodystrophy.
- Hypoglycemia-a dose adjustment, including possible large reductions, of insulin or insulin secretagogue may be necessary. Closely monitor blood glucose in patients on concomitant insulin or insulin secretagogue therapy.
- Autoimmunity-Autoimmune disorder progression has been observed in patients treated with Myalept. Carefully consider benefits and risks of Myalept treatment in patients with autoimmune disease.
- Hypersensitivity-Hypersensitivity reactions (e.g., urticarial or generalized rash) have been reported. Patient should promptly seek medical advice regarding suspected reactions.
- Benzyl Alcohol Toxicity-Preservative-free sterile WFI recommended for neonates and infants.

ADVERSE REACTIONS: Common adverse reactions (≥ 10%) are headache, hypoglycemia, decreased weight, and abdominal pain.

DRUG INTERACTIONS: No formal drug interaction studies were performed.

PATIENT COUNSELING INFORMATION:

- Myalept is a prescription medicine used with a diet recommended by your healthcare provider to treat problems caused by not having enough leptin in your body (leptin deficiency) in people with congenital or acquired generalized lipodystrophy.
- Talk to your healthcare provider right away if you have any symptoms of an allergic reaction including a rash or itching (hives).
- Myalept may cause serious side effects including risk for loss of endogenous leptin activity/loss of Myalept efficacy due to neutralizing antibodies and lymphoma.
- Take Myalept exactly as the healthcare provider tells you to. Do not change your dose or suddenly stop taking Myalept.
- Myalept is injected 1 time per day at the same time each day under the skin (subcutaneous) of your stomach, thigh, or upper arm.
- Myalept can be used with or without food.
- If you miss a dose, take it as soon as you remember. Do not take an extra dose or increase the amount of your dose to make up for a missed dose.
- Do not mix Myalept and insulin in the same syringe or vial or inject in the same injection site.
- Possible side effects include low blood sugar, autoimmunity, allergic reactions, benzyl alcohol toxicity, headache, decreased weight, and abdominal pain.

References:

1. Myalept® [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; February 2014.

PRODUCT DETAILS OF NORTHERA™ (DROXIDOPA)

INDICATIONS AND USE: Northera (droxidopa) is indicated for the treatment of orthostatic dizziness, lightheadedness, or the 'feeling that you are about to black out' in adult patients with symptomatic neurogenic orthostatic hypotension caused by primary autonomic failure (Parkinson's disease, multiple system atrophy, and pure autonomic failure), dopamine beta-hydroxylase deficiency, and non-diabetic autonomic neuropathy. Effectiveness beyond 2 weeks of treatment has not been demonstrated.

DOSAGE FORMS: Northera is available as 100 mg, 200 mg, and 300 mg capsules.

ADMINISTRATION: The recommended starting dose of Northera is 100 mg three times during the day: upon arising in the morning, at midday, and in the late afternoon at least 3 hours prior to bedtime (to reduce the potential for supine hypertension during sleep). Titrate by 100 mg three times daily, up to a maximum dose of 600 mg three times daily.

SPECIAL POPULATIONS:

- Northera is classified as pregnancy category C. There are no adequate and well-controlled studies of Northera in pregnant women.
- Choose nursing or Northera.
- The safety and effectiveness of Northera in pediatric patients have not been established.
- No overall differences in safety or effectiveness were observed between these subjects and younger subjects, and other reported clinical experience has not identified difference in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.
- Clinical experience with Northera in patients with severe renal function impairment (GFR less than 30 mL/min) is limited.

WARNINGS AND PRECAUTIONS:

- Northera can cause or exacerbate supine hypertension and may increase cardiovascular risk if supine hypertension is not well-managed.
- Postmarketing cases of a symptom complex resembling neuroleptic malignant syndrome (NMS) have been reported. NMS is an uncommon but life-threatening syndrome characterized by fever or hyperthermia, muscle rigidity, involuntary movements, altered consciousness, and mental status changes. The early diagnosis of this condition is important for the appropriate management of these patients.
- Northera may exacerbate existing ischemic heart disease, arrhythmias, and congestive heart failure. Careful consideration should be given to this potential risk prior to initiating therapy in patients with these conditions.
- Northera contains FD+C Yellow No. 5 (tartrazine) which may cause allergic-type reactions in certain susceptible persons.

ADVERSE REACTIONS: Common adverse reactions (greater than 5%) are headache, dizziness, arrhythmias, and congestive heart failure.

DRUG INTERACTIONS:

- Use of dopa-decarboxylase inhibitors may require dose adjustments of Northera.
- Administering Northera in combination with other agents that increase blood pressure (e.g., norepinephrine, ephedrine, midodrine, and triptans) would be expected to increase the risk for supine hypertension.

PATIENT COUNSELING INFORMATION:

- Northera is a prescription medicine used for lightheadedness or the feeling that you are going to 'black out'.
- Northera causes elevations in blood pressure and increases the risk of supine (lying face up) hypertension, which could lead to strokes, heart attacks, and death. Rest and sleep in an upper body elevated position and monitor blood pressure.
- Take the late afternoon dose at least three hours before bedtime to reduce the risk of supine hypertension.
- Consult a physician if you are pregnant or nursing.
- Take Northera the same way each time, either with food or without food.
- If a dose is missed, patients should take the next dose at the regularly scheduled time and should not double the dose.

References:

1. Northera® [package insert]. Charlotte, NC: Chelsea Therapeutics; February 2014.

PRODUCT DETAILS OF RAGWITEK™ (SHORT RAGWEED POLLEN ALLERGEN EXTRACT)

INDICATIONS AND USE: Ragwitek (short ragweed pollen allergen extract) is an allergen extract indicated as immunotherapy for the treatment of short ragweed pollen-induced allergic rhinitis, with or without conjunctivitis, confirmed by positive skin test or *in vitro* testing for pollen-specific IgE antibodies for short ragweed pollen.

DOSAGE FORMS: Ragwitek is available as 12 Amb a 1-Unit (Amb a 1-U) tablets.

ADMINISTRATION:

- One tablet daily.
- Initiate treatment at least 12 weeks before the expected onset of each ragweed pollen season and continue treatment throughout the season.
- Place the tablet immediately under the tongue. Allow it to remain there until completely dissolved. Do not swallow for at least 1 minute.
- Administer the first dose of Ragwitek under the supervision of a physician with experience in the diagnosis and treatment of allergic diseases. Observe patients in the office for at least 30 minutes following the initial dose.

CONTRAINDICATIONS:

- Severe, unstable, or uncontrolled asthma.
- History of any severe systemic allergic reaction or any severe local reaction to sublingual allergen immunotherapy.
- A history of eosinophilic esophagitis.
- Hypersensitivity to any of the inactive ingredients contained in this product.

SPECIAL POPULATIONS:

- Ragwitek is classified as pregnancy category C. Because systemic and local adverse reactions with immunotherapy may be poorly tolerated during pregnancy, Ragwitek should be used during pregnancy only if clearly needed.
- Caution should be exercised when Ragwitek is administered to a nursing woman.
- Ragwitek is not approved for use in pediatric patients.
- Ragwitek is not approved for use in patients over 65 years of age because safety and efficacy have not been established.

WARNINGS AND PRECAUTIONS:

Ragwitek can cause life-threatening allergic reactions such as anaphylaxis and severe laryngopharyngeal restriction.
Do not administer Ragwitek to patients with severe, unstable or uncontrolled asthma.
Observe patients in the office for at least 30 minutes following the initial dose.
Prescribe auto-injectable epinephrine, instruct and train patients on its appropriate use, and instruct patients to seek immediate medical care upon its use.
Ragwitek may not be suitable for patients with certain underlying medical conditions that may reduce their ability to survive a serious allergic reaction.
Ragwitek may not be suitable for patients who may be unresponsive to epinephrine or inhaled bronchodilators, such as those taking beta-blockers.

- Inform patients of the signs and symptoms of serious allergic reactions and instruct them to seek immediate medical care and discontinue therapy should any of these occur.
- Prescribe auto-injectable epinephrine to patients receiving Ragwitek.
- Ragwitek can cause local reactions in the mouth or throat that could compromise the upper airway. Consider discontinuation of Ragwitek in patients who experience persistent and escalating adverse reactions in the mouth or throat.
- Eosinophilic esophagitis has been reported in association with sublingual tablet immunotherapy. Discontinue Ragwitek and consider a diagnosis of eosinophilic esophagitis in patients who experience severe or persistent gastro-esophageal symptoms including dysphagia or chest pain.
- Ragwitek has not been studied in subjects with moderate or severe asthma. Withhold immunotherapy with Ragwitek if the patient is experiencing an acute asthma exacerbation. Re-evaluate patients who have recurrent asthma exacerbations and consider discontinuation of Ragwitek.
- Concomitant dosing with other allergen immunotherapy may increase the likelihood of local or systemic adverse reactions to either subcutaneous or sublingual allergen immunotherapy.
- Stop treatment with Ragwitek to allow complete healing of the oral cavity in patients with oral inflammation (e.g., oral lichen planus, mouth ulcers, or thrush) or oral wounds, such as those following oral surgery or dental extraction.

ADVERSE REACTIONS:

- Most common adverse reactions (≥5% of patients) were throat irritation, oral pruritus, ear pruritus, oral paraesthesia, mouth edema, and tongue pruritus.

PATIENT COUNSELING INFORMATION:

- Ragwitek is used to treat ragweed pollen induced allergic reactions.
- Carefully remove the tablet from the blister package with dry hands and put the tablet under your tongue. Do not swallow for at least 1 minute.

- Take the first tablet of Ragwitek in your doctor's office.
- Ragwitek may cause life-threatening allergic reactions. The signs and symptoms may include trouble breathing, throat tightness or swelling, trouble swallowing or speaking, dizziness or fainting, rapid or weak heartbeat, severe stomach cramps/vomiting/diarrhea, or severe flushing/itching of the skin.
- Keep an auto-injectable epinephrine with you at all times.

References:

1. Ragwitek® [package insert]. Whitehouse Station, NJ: Merck & Co., Inc.; April 2014.

PRODUCT DETAILS OF GRASTEK® (TIMOTHY GRASS POLLEN ALLERGEN EXTRACT)

INDICATIONS AND USE: Grastek (timothy grass pollen allergen extract) is an allergen extract indicated as immunotherapy for the treatment of grass pollen-induced allergic rhinitis, with or without conjunctivitis, confirmed by positive skin test or *in vitro* testing for pollen-specific IgE antibodies for Timothy grass or cross-reactive grass pollens.

DOSAGE FORMS: Grastek is available as 2800 Bioequivalent Allergy Units (BAUs) tablets.

ADMINISTRATION:

- One tablet daily.
- Initiate treatment at least 12 weeks before the expected onset of each grass pollen season and continue treatment throughout the season. For sustained effectiveness for one grass pollen season after cessation of treatment, Grastek may be taken daily for three consecutive years.
- Place the tablet immediately under the tongue. Allow it to remain there until completely dissolved. Do not swallow for at least 1 minute.
- Administer the first dose of Grastek under the supervision of a physician with experience in the diagnosis and treatment of allergic diseases. Observe patients in the office for at least 30 minutes following the initial dose.

CONTRAINDICATIONS:

- Severe, unstable, or uncontrolled asthma.
- History of any severe systemic allergic reaction or any severe local reaction to sublingual allergen immunotherapy.
- A history of eosinophilic esophagitis.
- Hypersensitivity to any of the inactive ingredients contained in this product.

SPECIAL POPULATIONS:

- Grastek is classified as pregnancy category B. There are no adequate and well-controlled studies of Grastek in pregnant women. Grastek should be used during pregnancy only if clearly needed.
- Caution should be exercised when Grastek is administered to a nursing woman.
- The safety and effectiveness in children and adolescents 5 through 17 years of age have been established. The safety and efficacy in pediatric patients below 5 years of age have not been established.
- There is no clinical trial experience with Grastek in patients over 65 years of age.

WARNINGS AND PRECAUTIONS:

Grastek can cause life-threatening allergic reactions such as anaphylaxis and severe laryngopharyngeal restriction.
Do not administer Grastek to patients with severe, unstable or uncontrolled asthma.
Observe patients in the office for at least 30 minutes following the initial dose.
Prescribe auto-injectable epinephrine, instruct and train patients on its appropriate use, and instruct patients to seek immediate medical care upon its use.
Grastek may not be suitable for patients with certain underlying medical conditions that may reduce their ability to survive a serious allergic reaction.
Grastek may not be suitable for patients who may be unresponsive to epinephrine or inhaled bronchodilators, such as those taking beta-blockers.

- Inform patients of the signs and symptoms of serious allergic reactions and instruct them to seek immediate medical care and discontinue therapy should any of these occur.
- In case of oral inflammation or wounds, stop treatment with Grastek to allow complete healing of the oral cavity.
- Prescribe auto-injectable epinephrine to patients receiving Grastek.
- Continue discontinuation of Grastek and consider a diagnosis of eosinophilic esophagitis in patients who experience severe or persistent gastro-esophageal symptoms including dysphagia or chest pain.
- Withhold immunotherapy with Grastek if the patient is experiencing an acute asthma exacerbation. Re-evaluate patients who have recurrent asthma exacerbations and consider discontinuation of Grastek.
- Concomitant dosing with other allergen immunotherapy may increase the likelihood of local or systemic adverse reactions to either subcutaneous or sublingual allergen immunotherapy.
- Grastek can cause local reactions in the mouth or throat that could compromise the upper airway. Consider discontinuation of Grastek in patients who experience persistent and escalating adverse reactions in the mouth or throat.

ADVERSE REACTIONS:

- Most common adverse reactions (≥5% of patients) were ear pruritus, oral pruritus, tongue pruritus, mouth edema, and throat irritation.

PATIENT COUNSELING INFORMATION:

- Grastek is used to treat grass pollen induced allergic reactions.
- Carefully remove the foil from the blister unit with dry hands and put the tablet under your tongue. Do not swallow for at least 1 minute.
- Grastek may cause life-threatening allergic reactions. The signs and symptoms may include trouble breathing, throat tightness or swelling, trouble swallowing or

speaking, dizziness or fainting, rapid or weak heartbeat, severe stomach cramps/vomiting/diarrhea, or severe flushing/itching of the skin.

- Keep an auto-injectable epinephrine with you at all times.
- The first dose must be administered in a doctor's office.
- If you have persistent reactions in the mouth or throat, discontinue Grastek and contact a healthcare professional.
- If you have asthma and experience difficulty breathing, stop Grastek and contact a healthcare professional.

References:

1. Grastek® [package insert]. Whitehouse Station, NJ: Merck & Co., Inc.; April 2014.

NORTH DAKOTA MEDICAID
RETROSPECTIVE DRUG UTILIZATION REVIEW
CRITERIA RECOMMENDATIONS
2ND QUARTER 2014

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

1. Vortioxetine / Overutilization / Negating CYP Inducers & Inhibitors _____ _____

Alert Message: The manufacturer's maximum recommended daily dose of Brintellix (vortioxetine) is 20 mg in extensive CYP2D6 metabolizers. The efficacy and safety of doses above 20 mg/day have not been evaluated in controlled clinical trials. The vortioxetine dose should not exceed 10mg/day in CYP2D6 poor metabolizers.

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C **(Negating)**			
Vortioxetine		Bupropion	Rifampin	Phenytoin	Carbamazepine
		Fluoxetine	Rifabutin	Phenobarbital	Quinidine
		Paroxetine	Rifapentine	Primidone	

Max Dose: 20mg/day

References:
Brintellix Prescribing Information, September 2013, Takeda Pharmaceuticals.
Clinical Pharmacology, 2013 Elsevier/Gold Standard.

2. Vortioxetine 15 & 20 mg / Strong CYP2D6 Inhibitors _____ _____

Alert Message: The manufacture recommends that the daily dose of Brintellix (vortioxetine) be reduced by half when patients are receiving a strong CYP2D6 inhibitor (i.e., bupropion, fluoxetine, paroxetine and quinidine) concomitantly. The dose should be increased to the original level when the CYP2D6 inhibitor is discontinued.

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

Util A	Util B	Util C
Vortioxetine 15mg	Bupropion	
Vortioxetine 20mg	Fluoxetine	
	Paroxetine	
	Quinidine	

References:
Brintellix Prescribing Information, September 2013, Takeda Pharmaceuticals.
Clinical Pharmacology, 2013 Elsevier/Gold Standard.

3. Vortioxetine / Strong CYP Inducers _____ _____

Alert Message: The concurrent use of Brintellix (vortioxetine) with a strong CYP inducer (e.g., rifampin, carbamazepine, and phenytoin) for greater than 14 days may necessitate an increase in the vortioxetine dose but the dose should not exceed three times the original dose. Vortioxetine is extensively metabolized via multiple cytochrome isozymes (e.g., CYP2D6, CYP3A4/5, CYP2C9 and CYP2C8) and use with CYP inducers may result in decreased vortioxetine plasma concentrations.

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

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

References:
Brintellix Prescribing Information, September 2013, Takeda Pharmaceuticals.
FDA Drug Development and Approval Process (Drugs): Drug Development ad Drug Interactions: Table of Substrates, Inhibitors and Inducers. Available at:
http://www.fda.gov/drugs/developmentapprovalprocess/developmentresources/druginteractionslabeling/ucm093664.htm

4. Vortioxetine / Non-adherence _____ _____

Alert Message: Based on the refill history, your patient may be underutilizing Brintellix (vortioxetine). 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 – Non-adherence
Drugs/Diseases

Util A	Util B	Util C
Vortioxetine		

References:
Brintellix Prescribing Information, September 2013, Takeda Pharmaceuticals.
Osterberg L, Blaschke T. Adherence to Medication. N Engl J Med 2005;353:487-97.
Keene MS. Confusion and Complaints: The True Cost of Noncompliance in Antidepressant Therapy. Medscape Psychiatry & Mental Health. 2005;10(2).\Available at: http://www.medscape.com/viewarticle/518273

5. Vortioxetine / Pediatric Use (Black Box) _____ _____

Alert Message: The safety and effectiveness of Brintellix (vortioxetine) in the pediatric population have not been established.

Conflict Code: TA – Therapeutic Appropriateness

Util A	Util B	Util C
Vortioxetine		

Age Range: 0-18 yoa

References:
Brintellix Prescribing Information, September 2013, Takeda Pharmaceuticals.
Clinical Pharmacology, 2013 Elsevier/Gold Standard.

6. Vortioxetine / MAOIs _____ _____

Alert Message: Brintellix (vortioxetine) is contraindicated for concurrent use in patients receiving MAOI therapy intended to treat psychiatric disorders, due to risk of serotonin syndrome. Vortioxetine should not be used within 14 days of discontinuing treatment with an MAOI and treatment with an MAOI should not be initiated within 21 days of discontinuation of vortioxetine.

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

Util A	Util B	Util C
Vortioxetine	Isocarboxazid	
	Phenelzine	
	Tranylcypromine	
	Selegiline Transdermal	

References:
Brintellix Prescribing Information, September 2013, Takeda Pharmaceuticals.
Clinical Pharmacology, 2013 Elsevier/Gold Standard.

7. Vortioxetine / Linezolid _____ _____

Alert Message: Brintellix (vortioxetine) is contraindicated for concurrent use with Zyvox (linezolid), a reversible, non-selective MAOI, due to risk of serotonin syndrome. There may be circumstances when it is necessary to initiate treatment with linezolid in a patient taking vortioxetine, if so vortioxetine should be discontinued before initiating linezolid treatment.

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

Util A	Util B	Util C
Vortioxetine	Linezolid	

References:
Brintellix Prescribing Information, September 2013, Takeda Pharmaceuticals.
Clinical Pharmacology, 2013 Elsevier/Gold Standard.

8. Vortioxetine / Serotonergic Agents _____ _____

Alert Message: Caution should be exercised when Brintellix (vortioxetine) is administered with other serotonergic drugs. Vortioxetine is a serotonin modulator/stimulator and concomitant therapy with other serotonergic drugs may cause accumulation of serotonin and increase the risk of serotonin syndrome (e.g., mental status changes, hypertension, vasoconstriction, and neuronal aberrations).

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

Util A	Util B		Util C
Vortioxetine	SSRIs	Nefazodone	
	SNRIs	Mirtazapine	
	TCAs	Trazodone	
	Triptans	Lithium	
	Ergot Alkaloids	Meperidine	
	Buspirone	Fentanyl	
	Tramadol		

References:
Brintellix Prescribing Information, September 2013, Takeda Pharmaceuticals.
Clinical Pharmacology, 2013 Elsevier/Gold Standard.

9. Vortioxetine / Drugs affecting Coagulation _____ _____

Alert Message: Concurrent use of Brintellix (vortioxetine) and medications that enhance bleeding potential (e.g., anticoagulants, thrombolytics and NSAIDS) may increase the risk of a bleeding complication. Vortioxetine, which inhibits serotonin reuptake, may cause impaired platelet aggregation due to platelet serotonin depletion.

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

Util A	Util B		Util C
Vortioxetine	NSAIDS	Dipyridamole	
	Aspirin	Cilostazol	
	Warfarin	Clopidogrel	
	Apixaban	Prasugrel	
	Fondaparinux	Ticagrelor	
	Rivaroxaban	Ticlopidine	
	Dabigatran	Anagrelide	
	Dalteparin	Enoxaparin	

References:
Brintellix Prescribing Information, September 2013, Takeda Pharmaceuticals.
Clinical Pharmacology, 2013 Elsevier/Gold Standard.

10. Perampanel / Overuse _____ _____

Alert Message: The manufacturer's maximum recommended dose of Fycompa (perampanel) is 12 mg once daily at bedtime.

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C **(Negate)**
Perampanel		Hepatic Impairment

Max Dose: 12mg/day

References:
Fycompa Prescribing Information, June 2013, Eisai.
Clinical Pharmacology, 2013 Elsevier/Gold Standard.

11. Perampanel / Overuse Hepatic Impairment _____ _____

Alert Message: The manufacture's maximum recommended daily dose of Fycompa (perampanel) is 6 mg and 4 mg once daily at bedtime for patients with mild and moderate hepatic impairment, respectively. Perampanel use is not recommended in patients with severe hepatic impairment.

Conflict Code: ER - Overutilization
Drugs/Diseases

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

Max Dose: 6mg/day

References:
Fycompa Prescribing Information, June 2013, Eisai.
Clinical Pharmacology, 2013 Elsevier/Gold Standard.

12. Perampanel / Renal Impairment & Hemodialysis _____ _____

Alert Message: Fycompa (perampanel) use is not recommended in patients with severe renal impairment or on hemodialysis.

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C
Perampanel	CKD Stage 4 & 5 Hemodialysis	

References:
Fycompa Prescribing Information, June 2013, Eisai.
Clinical Pharmacology, 2013 Elsevier/Gold Standard.

13. Perampanel / Levonorgestrel Contraceptives _____ _____

Alert Message: Use of Fycompa (perampanel) with oral or implant contraceptives containing levonorgestrel may render them less effective. Concurrent use of perampanel at a dose of 12mg/day reduced levonorgestrel exposure by approximately 40%. Additional non-hormonal forms of contraception are recommended.

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

Util A	Util B	Util C
Perampanel	Levonorgestrel Contraceptives	

References:
Fycompa Prescribing Information, June 2013, Eisai.
Clinical Pharmacology, 2013 Elsevier/Gold Standard.

14. Perampanel / CYP3A4 Inducers Anticonvulsants _____ _____

Alert Message: The concurrent use of Fycompa (perampanel) with an antiepileptic drug (AED) that induces CYP3A4-mediated metabolism can result in decreased plasma levels of perampanel and loss of therapeutic effect. The starting dose of perampanel should be increased in the presence of enzyme-inducing AEDs. When an enzyme-inducing AED is introduced or withdrawn, patients should be closely monitored and perampanel dose adjusted if needed.

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

Util A	Util B	Util C
Perampanel	Carbamazepine	
	Oxcarbazepine	
	Phenytoin	
	Phenobarbital	
	Primidone	

References:
Fycompa Prescribing Information, June 2013, Eisai.
Clinical Pharmacology, 2013 Elsevier/Gold Standard.

15. Perampanel / Strong CYP3A4 Inducers (Non-AEDs) _____ _____

Alert Message: The concurrent use of Fycompa (perampanel) with a strong CYP3A4 inducer (e.g., rifampin and nevirapine) should be avoided. Perampanel is a CYP3A4 substrate and concomitant use with a potent inducer may result in significantly decreased perampanel plasma levels and loss of therapeutic effect.

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

Util A	Util B	Util C
Perampanel	Rifampin	
	Rifapentine	
	Rifabutin	
	Nevirapine	

References:
Fycompa Prescribing Information, June 2013, Eisai.
Clinical Pharmacology, 2013 Elsevier/Gold Standard.

16. Perampanel / CNS Depressants _____ _____

Alert Message: The concurrent use of Fycompa (perampanel) and CNS depressants including alcohol may increase CNS depression. Patients should limit activity until they have experience with concomitant use of CNS depressants.

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

Util A	Util B	Util C
Perampanel	Antidepressants	
	Antihistamines - Sedating	
	Antipsychotics	
	Barbiturates	
	Benzodiazepines	
	Muscle Relaxants	
	Narcotics	
	Hypnotics	

References:
Fycompa Prescribing Information, June 2013, Eisai.
Clinical Pharmacology, 2013 Elsevier/Gold Standard.

17. Perampanel / Therapeutic Appropriateness (0-11 yoa) _____ _____

Alert Message: The safety and effectiveness of Fycompa (perampanel) in pediatric patients less than12 years old have not been established.

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C
Perampanel		

Age Range 0-11 yoa

References:
Fycompa Prescribing Information, June 2013, Eisai.
Clinical Pharmacology, 2013 Elsevier/Gold Standard.

18. Perampanel / Black Box Warning _____ _____

Alert Message: Serious or life-threatening psychiatric and behavioral adverse reactions including aggression, hostility, homicidal ideation and threats have been reported in patients taking Fycompa (perampanel). Perampanel dosage should be reduced if these symptoms occur and should be discontinued immediately if symptoms are severe or are worsening.

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C
Perampanel		

References:
Fycompa Prescribing Information, June 2013, Eisai.
Clinical Pharmacology, 2013 Elsevier/Gold Standard.

19. Perampanel / Non-adherence _____ _____

Alert Message: Based on refill history, your patient may be under-utilizing Fycompa (perampanel). 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 – Non-adherence

Drugs/Diseases		
Util A	Util B	Util C
Perampanel		

References:

Fycompa Prescribing Information, June 2013, Eisai.
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.
Osterberg L, Blaschke T. Adherence to Medication. N Engl J Med 2005; 353:487- 497.

20. Canagliflozin / Nonadherence _____ _____

Alert Message: Based on refill history, your patient may be under-utilizing Invokana (canagliflozin). 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
Canagliflozin		

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.

21. Testosterone / History of Cardiovascular/Cerebrovascular Disease _____ _____

Alert Message: The FDA is evaluating the risk of stroke, heart attack and death in men taking FDA-approved testosterone products. Reassessment of this testosterone safety issue is based on the recent publication of two separate studies that suggested an increased risk of cardiovascular events among groups of men prescribed testosterone therapy. Prescribers should consider whether the benefits of testosterone treatment is likely to exceed the potential risks of treatment.

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C **(Include)**
Testosterone		Myocardial Infarction
		Stroke
		Angina
		Arrhythmia
		Heart Failure
		Hypertension
		Peripheral Vascular Disease
		Ischemic Heart Disease

Gender: Male

References:
FDA Drug Safety Communications; FDA Evaluating Risk of Stroke, Heart Attack and Death with FDA-approved Testosterone Products. [01-21-2014].
Vigen R, O'Donnell CI, Baron AE, et al. Association of Testosterone Therapy with Mortality, Myocardial Infarction and Stroke in Men with Low Testosterone Levels. JAMA 2013;310(17):1829-1836.
Finkle WD, Greenland S, Ridgeway GK, Adams JL, Frasco MA, et al. (2014) Increased Risk of Non-Fatal Myocardial Infarction Following Testosterone Therapy Prescription in Men. PLoS ONE 9(1): e85805. doi:10.1371/journal.pone.0085805

22. Posaconazole / CY3A4 Substrates that Prolong QT Interval _____ _____

Alert Message: Noxafil (posaconazole) is contraindicated with CYP3A4 substrates that prolong the QT interval. Posaconazole is a strong CYP3A4 inhibitor and concurrent use with a CYP3A4 substrate may result in increased substrate plasma concentrations, leading to QTc prolongation and torsades de pointes. In addition, posaconazole has been associated with prolongation of the QT interval.

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

Util A	Util B				Util C
Posaconazole	Trazodone	Sunitinib	Erythromycin	Solifenacin	
	Vardenafil	Dasatinib	Clarithromycin		
	Pimozide	Lapatinib	Mifepristone		
	Venlafaxine	Nilotinib	Haloperidol		
	Disopyramide	Indacaterol	Chloroquine		
	Amiodarone	Rilpivirine	Mefloquine		
	Telithromycin	Clozapine	Iloperidone		
	Alfuzosin	Quetiapine	Ondansetron		
	Crizotinib	Dofetilide	Propafenone		
	Ziprasidone	Methadone	Quinine		
	Asenapine	Citalopram	Vemurafenib		
	Dronedarone	Ranolazine	Saquinavir		

References:
Noxafil Prescribing Information, Nov. 2013, Merck Sharp & Dohme Corp.
Clinical Pharmacology, 2013 Elsevier/Gold Standard.
Facts & Comparisons, 2013 Updates, Wolters Kluwer Health.

23. Posaconazole / Sirolimus _____ _____

Alert Message: The concurrent use of Noxafil (posaconazole) is contraindicated with Rapamune (sirolimus) due to risk of sirolimus toxicity. Co-administration of these agents has been shown to increase sirolimus blood concentrations by approximately 9-fold. Posaconazole is a strong inhibitor of sirolimus CYP3A4-mediated metabolism and both drugs are substrates for P-gp efflux protein.

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

Util A	Util B	Util C
Posaconazole	Sirolimus	

References:
Noxafil Prescribing Information, Nov. 2013, Merck Sharp & Dohme Corp.
Clinical Pharmacology, 2013 Elsevier/Gold Standard.

24. Posaconazole / Cyclosporine & Tacrolimus _____ _____

Alert Message: Caution should be exercised when co-administering Noxafil (posaconazole) with a calcineurin-inhibitor (cyclosporine and tacrolimus). Concurrent use of posaconazole with these agents has been shown to increase the whole blood trough concentrations of the calcineurin-inhibitor. Frequent monitoring of cyclosporine or tacrolimus whole blood concentrations should be performed during and at discontinuation of posaconazole treatment and the calcineurin-inhibitor dose adjusted accordingly.

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

Util A	Util B	Util C
Posaconazole	Cyclosporine Tacrolimus	

References:
Noxafil Prescribing Information, Nov. 2013, Merck Sharp & Dohme Corp.
Clinical Pharmacology, 2013 Elsevier/Gold Standard.

25. Non First-line Antihypertensives / Hypertension / JNC 8 4 Classes _____ _____

Alert Message: The JNC 8 recommends the use of either a CCB, ACEI, ARB or thiazide-type diuretic as initial therapy to control hypertension in non black adult patients 18 years of age and older, if no contraindications exist. Recommended initial therapy in black patients is a thiazide-type diuretic or CCB, alone or in combination. If goal blood pressure is not achieved with an initial drug refer to the JNC 8 for recommended strategies for adding antihypertensive agents.

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C **(Negating)**
Other Antihypertensives: Alpha/Beta-Adrenergic Blockers Antiadrenergics-Centrally Acting Antiadrenergics-Peripherally Acting Selective Aldosterone Receptor Antagonist Beta-Blockers Direct Renin Inhibitors Loop Diuretics	Hypertension	Chronic Kidney Disease ACE Inhibitors ARBs CCBs Thiazide-type Diuretics

Age Range: 18 – 999 yoa

References:
James PA, Oparil S, Carter BL, et al. 2014 Evidence-based Guideline for the Management of High Blood Pressure in Adults: Report from the Panel Members Appointed to the Eight Joint National Committee (JNC 8). JAMA 2014; DOI:10.1001/jama.2013.284427. Available at: http://jama.jamanetwork.com/journal.aspx.

26. Dapagliflozin / Overutilization _____ _____

Alert Message: The manufacturer's maximum recommended dose of Farxiga (dapagliflozin) is 10 mg once daily.

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C **(Negating)**
Dapagliflozin		Renal Impairment

Max Dose: 10mg/day

References:
Farxiga Prescribing Information, Jan. 2014, Bristol-Myers Squibb.
Clinical Pharmacology, 2014 Elsevier/Gold Standard.

27. Dapagliflozin / Moderate Renal impairment _____ _____

Alert Message: Assessment of renal function is recommended prior to initiation of Farxiga (dapagliflozin) therapy and periodically thereafter. Dapagliflozin should not be initiated in patients with an eGFR less than 60 mL/min/1.73m^2 and should be discontinued when eGFR is persistently less than 60mL/ min/1.73m^2.

Conflict Code: TA - Therapeutic Appropriateness
Drugs/Diseases

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

References:
Farxiga Prescribing Information, Jan. 2014, Bristol-Myers Squibb.
Clinical Pharmacology, 2014 Elsevier/Gold Standard.

28. Dapagliflozin / Severe Renal Impairment, ESRD & Dialysis _____ _____

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

Conflict Code: TA - Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C **(Include)**
Dapagliflozin		CKD Stage 4, & 5
		End-Stage Renal Disease
		Dialysis

References:
Farxiga Prescribing Information, Jan. 2014, Bristol-Myers Squibb.
Clinical Pharmacology, 2014 Elsevier/Gold Standard.

29. Dapagliflozin / Nonadherence _____ _____

Alert Message: Based on refill history, your patient may be under-utilizing Farxiga (dapagliflozin). 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
Dapagliflozin		

References:
Farxiga Prescribing Information, Jan. 2014, Bristol-Myers Squibb.
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.

30. Dapagliflozin / Hypotension _____ _____

Alert Message: Farxiga (dapagliflozin) causes osmotic diurese which can lead to volume depletion and hypotension, particularly in patients with impaired renal function, elderly patients or patients on loop diuretics. Monitor patients for signs and symptoms during therapy. Before initiating dapagliflozin 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
Dapagliflozin	Hypotension	
	Hypovolemia	
	CKD Stage 3	
	Dehydration	

References:
Farxiga Prescribing Information, Jan. 2014, Bristol-Myers Squibb.
Clinical Pharmacology, 2014 Elsevier/Gold Standard.

31. Dapagliflozin / Loop Diuretics _____ _____

Alert Message: Farxiga (dapagliflozin) causes osmotic diurese which can lead to volume depletion and hypotension, particularly in patients with impaired renal function, elderly patients or patients on loop diuretics. Monitor patients for signs and symptoms during therapy. Before initiating dapagliflozin 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
Dapagliflozin	Furosemide	
	Torsemide	
	Ethacrynate	
	Bumetanide	

References:
Farxiga Prescribing Information, Jan. 2014, Bristol-Myers Squibb.
Clinical Pharmacology, 2014 Elsevier/Gold Standard.

32. Dapagliflozin / Insulin & Insulin Secretagogues _____ _____

Alert Message: The concurrent use of Farxiga (dapagliflozin) 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 dapagliflozin.

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

Util A	Util B	Util C
Dapagliflozin	Insulins	
	Sulfonylureas	

References:
Farxiga Prescribing Information, Jan. 2014, Bristol-Myers Squibb.
Clinical Pharmacology, 2014 Elsevier/Gold Standard.

33. Dapagliflozin / LDL-C Increases _____ _____

Alert Message: The use of Farxiga (dapagliflozin) can cause dose-related increases in LDL-C levels. Patients receiving dapagliflozin 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
Dapagliflozin	Hypercholesterolemia	

References:
Farxiga Prescribing Information, Jan. 2014, Bristol-Myers Squibb.
Clinical Pharmacology, 2014 Elsevier/Gold Standard.

34. Dapagliflozin / Bladder Cancer _____ _____

Alert Message: An imbalance in bladder cancers was observed in Farxiga (dapagliflozin) clinical trials. Dapagliflozin should not be used in patients with active bladder cancer and used with caution in patients with a prior history of bladder cancer.

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

Util A	Util B	Util C
Dapagliflozin		Neoplasm of Bladder
		History of Malignant Neoplasm of Bladder

References:
Farxiga Prescribing Information, Jan. 2014, Bristol-Myers Squibb.
Clinical Pharmacology, 2014 Elsevier/Gold Standard.

35. SGLT2 Inhibitors / Therapeutic Duplication _____ _____

Alert Message: Therapeutic duplication of sodium-glucose co-transporter 2 (SGLT2) inhibitors may be occurring.

Conflict Code: TD – Therapeutic Duplication
Drugs/Diseases

Util A	Util B	Util C
Dapagliflozin		
Canagliflozin		

References:
Farxiga Prescribing Information, Jan. 2014, Bristol-Myers Squibb.
Clinical Pharmacology, 2014 Elsevier/Gold Standard.

36. ASCVD Inferring Drugs / High-Intensity Statin Therapy (Negating) _____ _____

Alert Message: The ACC/AHA Blood Cholesterol Guidelines recommend the use of high-intensity statin therapy, which lowers LDL-C at least 50%, to reduce atherosclerotic cardiovascular risk in adults 75 years of age and younger who have clinical ASCVD (e.g., CHD, stroke, and PAD), unless contraindicated. Moderate-intensity statin therapy should be used as a second-line option if high-intensity statin therapy is not tolerated. Refer to the ACC/AHA guidelines for agents and dosage.

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C **(Negating if High-Intensity Therapy Present)**
Nitrates		Atorvastatin 40mg & 80 mg
Cilostazol		Rosuvastatin 20 mg, 40 mg & 80 mg
Clopidogrel		
Prasugrel		
Ticagrelor		
Ticlopidine		
Dipyridamole/Aspirin		

Age Range: ≤ 75 yoa

References:
Stone NJ, Robinson J, Lichtenstein AH, et.al., 2013 ACC/AHA Guideline on the Treatment of Blood Cholesterol to Reduce Atherosclerotic Cardiovascular Risk in Adults, Jrnl Am Coll Cardiol (2013), doi:10.1016/j.jacc.2013.11.002.

37. ASCVD Inferring Drugs / Statins (Negating) - No therapy at all (>75 yoa) _____ _____

Alert Message: The ACC/AHA Blood Cholesterol Guidelines state that it is reasonable to consider moderate-intensity statin therapy, which lowers LDL-C 30% to 49%, to reduce atherosclerotic cardiovascular risk in patients > 75 years of age with clinical ASCVD (e.g., CHD, stroke, and PAD), unless contraindicated. Refer to the ACC/AHA guidelines for agents and dosage.

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C **(Negating)**
Nitrates		Atorvastatin
Cilostazol		Rosuvastatin
Clopidogrel		Lovastatin
Prasugrel		Fluvastatin
Ticagrelor		Pravastatin
Ticlopidine		Simvastatin
Dipyridamole/Aspirin		Pitavastatin

Age Range: >75 yoa

References:
Stone NJ, Robinson J, Lichtenstein AH, et.al., 2013 ACC/AHA Guideline on the Treatment of Blood Cholesterol to Reduce Atherosclerotic Cardiovascular Risk in Adults, Jrnl Am Coll Cardiol (2013), doi:10.1016/j.jacc.2013.11.002.

38. Antidiabetic Agents / Statins & ASCVD Inferring (Negating) _____ _____

Alert Message: The ACC/AHA Blood Cholesterol Guidelines recommend the use moderate-intensity statin therapy as primary prevention to reduce the risk of atherosclerotic cardiovascular disease in diabetic patients 40 to 75 years of age with a LDL-C of 70 - 189 mg/dL, unless contraindicated. If the diabetic patient has an estimated 10-year ASCVD risk of 7.5% or greater high-intensity statin therapy is recommended. Refer to the ACC/AHA guidelines for agents and dosage.

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C **(Negating)**
Insulin		Lovastatin
Sulfonylureas		Fluvastatin
Alpha-Glucosidase Inhibitors		Simvastatin
Amylin Analogs		Pravastatin
Biguanide		Atorvastatin
DPP4 Inhibitors		Rosuvastatin
Glucagon-like Peptide 1 Receptor Agonist		Pitavastatin
Insulin		Nitrates
Meglitinides		Cilostazol
Sodium-Glucose Co-Transporter 2 Inhibitors		Clopidogrel
Thiazolidinediones		Prasugrel
		Ticagrelor
		Ticlopidine
		Dipyridamole/Aspirin

Age Range: 40 -75 yoa

References:
Stone NJ, Robinson J, Lichtenstein AH, et.al., 2013 ACC/AHA Guideline on the Treatment of Blood Cholesterol to Reduce Atherosclerotic Cardiovascular Risk in Adults, Jrnl Am Coll Cardiol (2013), doi:10.1016/j.jacc.2013.11.002.

39. Antidiabetic Agents / Statins & ASCVD Inferring (Negating) _____ _____

Alert Message: The patient may benefit from the addition of a statin to their drug regimen, if no contraindications exist. The ACC/AHA Blood Cholesterol Guidelines state that it is reasonable to initiate, continue, or intensify statin therapy in diabetic patients < 40 years of age if the patient may derive ASCVD risk reduction benefits. Refer to the ACC/AHA guidelines for agents and dosage.

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C **(Negating)**
Insulin		Lovastatin
Sulfonylureas		Fluvastatin
Alpha-Glucosidase Inhibitors		Simvastatin
Amylin Analogs		Pravastatin
Biguanide		Atorvastatin
DPP4 Inhibitors		Rosuvastatin
Glucagon-like Peptide 1 Receptor Agonist		Pitavastatin
Insulin		Nitrates
Meglitinides		Cilostazol
Sodium-Glucose Co-Transporter 2 Inhibitors		Clopidogrel
Thiazolidinediones		Prasugrel
		Ticagrelor
		Ticlopidine
		Dipyridamole/Aspirin

Age Range: 21 -39 yoa

References:
Stone NJ, Robinson J, Lichtenstein AH, et.al., 2013 ACC/AHA Guideline on the Treatment of Blood Cholesterol to Reduce Atherosclerotic Cardiovascular Risk in Adults, Jrnl Am Coll Cardiol (2013), doi:10.1016/j.jacc.2013.11.002.

40. Antidiabetic Agents / Statins & ASCVD Inferring (Negating) _____ _____

Alert Message: The patient may benefit from the addition of a statin to their drug regimen, if no contraindications exist. The ACC/AHA Blood Cholesterol Guidelines state that it is reasonable to initiate, continue, or intensify statin therapy in diabetic patients > 75 years if the patient may derive ASCVD risk reduction benefit. Refer to the ACC/AHA guidelines for agents and dosage.

Conflict Code: TA – Therapeutic Appropriateness

Drugs/Diseases

Util A	Util B	Util C **(Negating)**
Insulin		Lovastatin
Sulfonylureas		Fluvastatin
Alpha-Glucosidase Inhibitors		Simvastatin
Amylin Analogs		Pravastatin
Biguanide		Atorvastatin
DPP4 Inhibitors		Rosuvastatin
Glucagon-like Peptide 1 Receptor Agonist		Pitavastatin
Insulin		Nitrates
Meglitinides		Cilostazol
Sodium-Glucose Co-Transporter 2 Inhibitors		Clopidogrel
Thiazolidinediones		Prasugrel
		Ticagrelor
		Ticlopidine
		Dipyridamole/Aspirin

Age Range: > 75 yoa

References:

Stone NJ, Robinson J, Lichtenstein AH, et.al., 2013 ACC/AHA Guideline on the Treatment of Blood Cholesterol to Reduce Atherosclerotic Cardiovascular Risk in Adults, Jrnl Am Coll Cardiol (2013), doi:10.1016/j.jacc.2013.11.002.

DUR Board Meeting
September 3, 2014
Pioneer Room
State Capitol

North Dakota Medicaid
DUR Board Meeting Agenda
Pioneer Room
State Capitol
600 East Blvd. Avenue
Bismarck, ND
September 3, 2014
1pm

1. Administrative items
    - Travel vouchers
    - Introduction of new members

2. Old business

• Review and approval of minutes of 06/14 meeting	Chair
• Budget update	Brendan
• Second review of Northera	Brendan
• Second review of oral allergen extracts	Brendan
• Updated AAP Guidelines-Synagis	Brendan
• Update on NDQuits protocol	Health Department

3. New business

• Hepatitis C treatment and compliance	HID
• Review of benzodiazepine utilization	HID
• Review of testosterone products	HID
• Review of phosphate binders	HID
• Review of Zontivity	HID
• Review of Evzio	HID
• Criteria recommendations	HID
• Upcoming meeting date/agenda	Chair

4. Adjourn — Chair

Please remember to silence all cellular phones during the meeting.

Drug Utilization Review (DUR) Meeting Minutes
June 2, 2014

Members Present: Norman Byers, John Savageau, Jeffrey Hostetter, Peter Woodrow, Carrie Sorenson, Russ Sobotta, Tanya Schmidt, Steve Irsfeld, Michael Booth, Cheryl Huber, Gary Betting, Leann Ness

Members Absent: Todd Twogood, Carlotta McCleary, James Carlson

Medicaid Pharmacy Department: Brendan Joyce

J. Savageau called the meeting to order at 1:00 p.m. Chair J. Savageau asked for a motion to approve the minutes from the March meeting. T. Schmidt moved that the minutes be approved, and N. Byers seconded the motion. Chair J. Savageau called for a voice vote to approve the minutes. The motion passed with no audible dissent.

Cathflo Second Review
A motion and second were made at the March meeting to place Cathflo on prior authorization. The topic was brought up for a second review. There was no public comment. After discussion, Chair J. Savageau called for a voice vote to approve the motion. The motion passed with no audible dissent. The form will be labeled "Alteplase."

Intranasal Cyanocobalamin Products Second Review
A motion and second were made at the March meeting to place intranasal cyanocobalamin products on prior authorization. The topic was brought up for a second review. There was no public comment. After discussion, Chair J. Savageau called for a voice vote to approve the motion. The motion passed with no audible dissent.

Luzu Second Review
A motion and second were made at the March meeting to place Luzu on prior authorization. The topic was brought up for a second review. There was no public comment. After discussion, Chair J. Savageau called for a voice vote to approve the motion. The motion passed with no audible dissent.

Noxafil Second Review
A motion and second were made at the March meeting to place Noxafil on prior authorization. The topic was brought up for a second review. There was no public comment. After discussion, Chair J. Savageau called for a voice vote to approve the motion. The motion passed with no audible dissent.

Bethkis Second Review
A motion and second were made at the March meeting to place Bethkis on prior authorization. The topic was brought up for a second review. There was no public comment. After discussion, Chair J. Savageau called for a voice vote to approve the motion. The motion passed with no audible dissent.

Name Brand Narcotics
B. Joyce discussed with the board changing the name of the form to "Narcotics PA." All narcotics will require a prior authorization except generic MS Contin. In the future, PDMP reports may be required from prescribers when requesting a narcotic.

Medicaid Expansion Drug Coverage
Michael Crandell, Chief Medical Officer of Sanford Health Plan, spoke with the committee about Medicaid expansion in North Dakota.

Cayston Review
B. Joyce reviewed Cayston information with the board. There was no public comment. P. Woodrow made a motion to place Cayston on prior authorization. J. Hostetter seconded the motion. This topic will be reviewed at the next meeting.

Procysbi Review
B. Joyce reviewed Procysbi information with the board. There was no public comment. The committee agreed that Procysbi should be included in the >$3,000 prior authorization.

Ravicti Review
B. Joyce reviewed Ravicti information with the board. There was no public comment. Ravicti is also >$3,000. The board agreed that the state should PA all high cost medications $3,000 and over and report back to the board on drugs that were added.

Gastrointestinal Agents Review
B. Joyce reviewed gastrointestinal agents with the board. There was no public comment. This topic was tabled.

Myalept Review
B. Joyce reviewed Myalept information with the board. There was no public comment. This topic was tabled.

Northera Review
B. Joyce reviewed Northera information with the board. There was no public comment. M. Booth made a motion to place Northera on prior authorization. C. Sorenson seconded the motion. This topic will be reviewed at the next meeting.

Oral Allergen Extracts Review
B. Joyce reviewed oral allergen extracts with the board. There was no public comment. M. Booth made a motion to place oral allergen extracts on prior authorization. J. Hostetter seconded the motion. 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 usually are consistent with new indications, new drugs added, new warnings, etc. These proposed criteria will be added to the current set of criteria and will be used in future DUR cycles. J. Hostetter asked that criterion #36 dealing with high doses of statins and diabetes be brought back to the next meeting. J. Hostetter moved to approve the new criteria (without #36) and P. Woodrow seconded the motion. Chair J. Savageau called for a voice vote. The motion passed with no audible dissent.

The next DUR board meeting will be held September 3, in Bismarck. N. Byers made a motion to adjourn the meeting. J. Hostetter seconded. The motion passed with no audible dissent. J. Savageau adjourned the meeting.

NORTHERA
PA FORM

HEALTH INFORMATION DESIGNS

Prior Authorization Vendor for ND Medicaid

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-773-0695

ND Medicaid requires that patients receiving a new prescription for Northera must meet the following criteria:

- **Patient must have an FDA approved indication.**

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: □ NORTHERA	**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 Signature		Date	

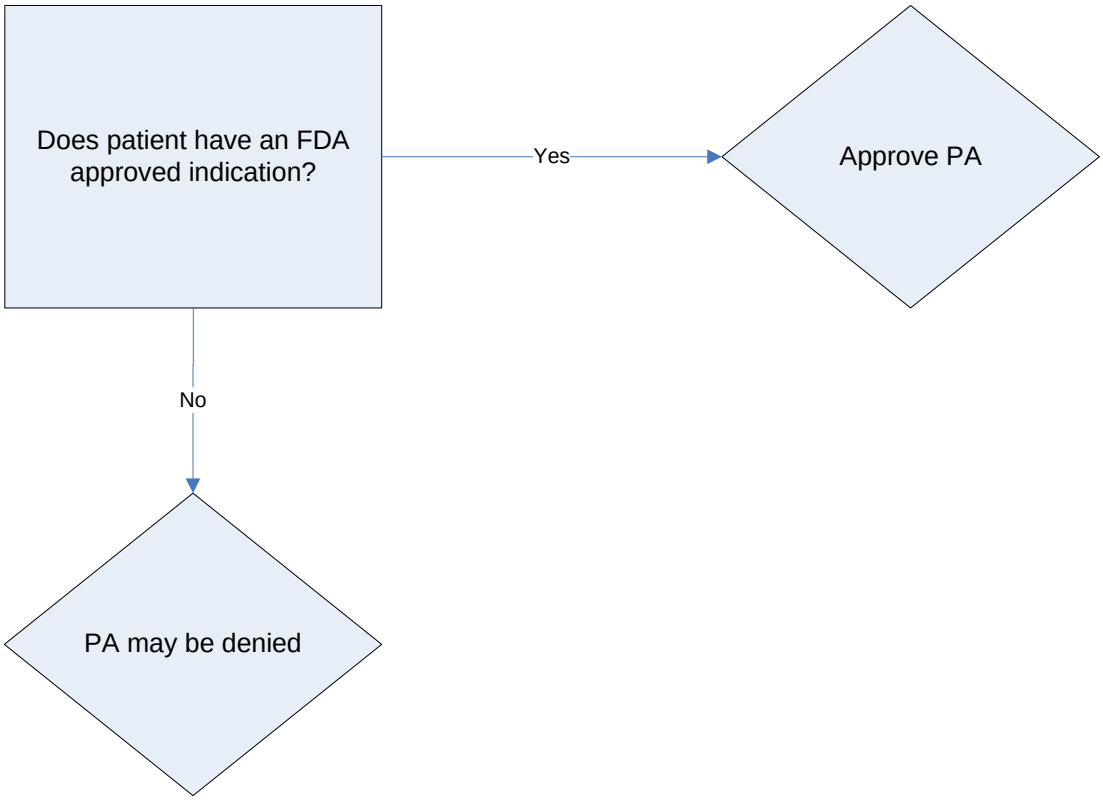
Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

Date Received	Initials:
Approved - Effective dates of PA: From: / / To: / /	Approved by:
Denied: (Reasons)	

North Dakota Department of Human Services
Northera Prior Authorization Algorithm



ORAL ALLERGEN EXTRACTS
PA FORM

HEALTH INFORMATION DESIGNS

Prior Authorization Vendor for ND Medicaid

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-773-0695

ND Medicaid requires that patients receiving a new prescription for oral allergen extracts must meet the following criteria:

- **Patient must have the FDA approved indication for the drug requested.**
- **Diagnosis confirmed by positive skin test or *in vitro* testing for pollen-specific IgE antibodies.**
- **History of failure, contraindication, or intolerance to two of the following: oral antihistamine, intranasal antihistamine, intranasal corticosteroid, or leukotriene inhibitors.**
- **History of failure or intolerance to subcutaneous allergen immunotherapy (allergy shots).**
- **Patient must not have severe, unstable, or uncontrolled asthma.**

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:	**Diagnosis for this Request:**	**History of Failure:**
□ GRASTEK	□ GRASS POLLEN-INDUCED ALLERGIC RHINITIS	**1.**
□ ORALAIR	□ RAGWEED POLLEN-INDUCED ALLERGIC RHINITIS	**2.**
□ RAGWITEK		**3.**

□ *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 Signature	Date

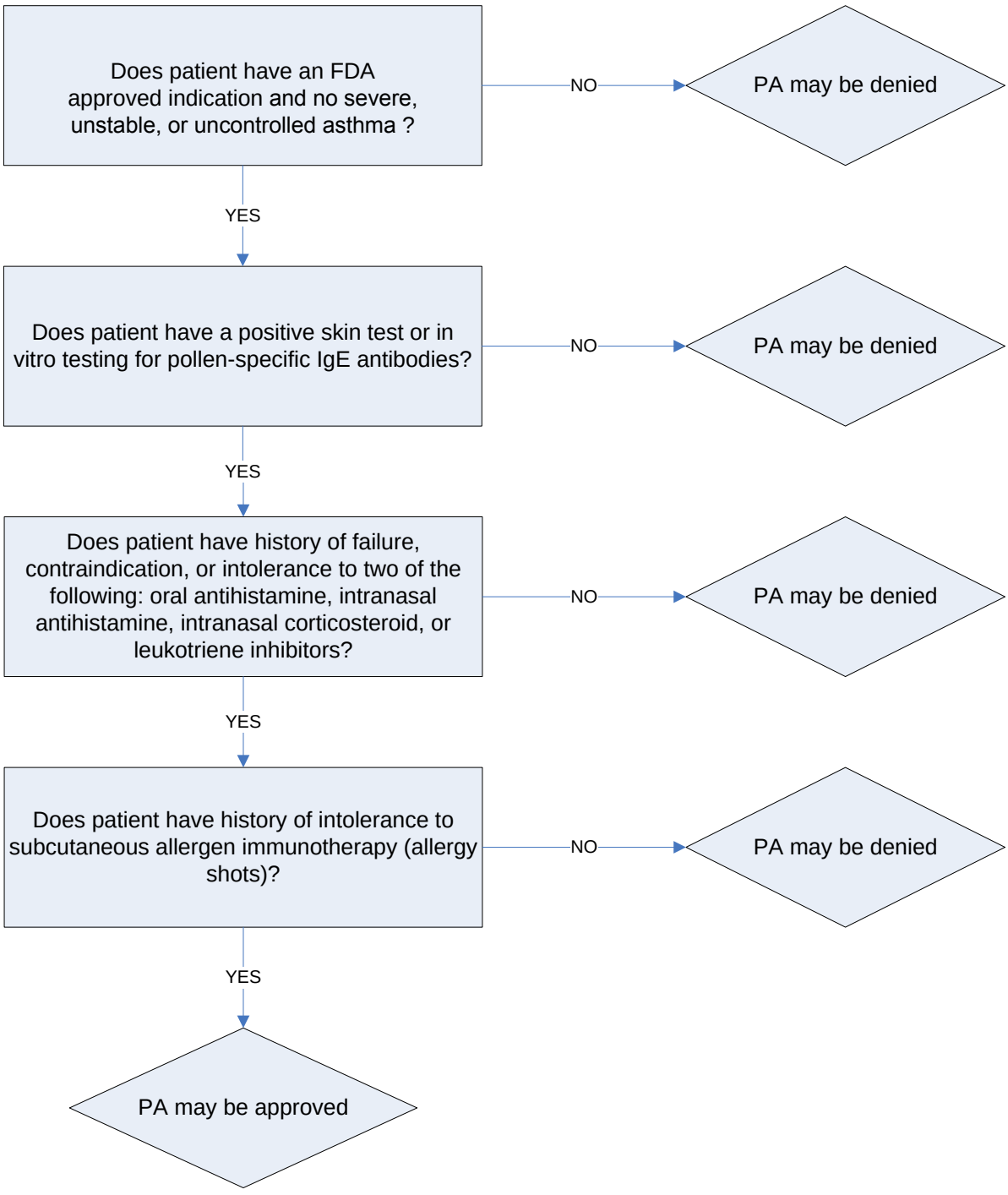
Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

Date Received	Initials:
Approved - Effective dates of PA: From: / / To: / /	Approved by:
Denied: (Reasons)	

North Dakota Department of Human Services
Oral Allergen Extracts Prior Authorization Algorithm



PEDIATRICS®
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Updated Guidance for Palivizumab Prophylaxis Among Infants and Young Children at Increased Risk of Hospitalization for Respiratory Syncytial Virus Infection

COMMITTEE ON INFECTIOUS DISEASES AND BRONCHIOLITIS GUIDELINES COMMITTEE

Pediatrics; originally published online July 28, 2014;
DOI: 10.1542/peds.2014-1665

American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN™

POLICY STATEMENT

Updated Guidance for Palivizumab Prophylaxis Among Infants and Young Children at Increased Risk of Hospitalization for Respiratory Syncytial Virus Infection

COMMITTEE ON INFECTIOUS DISEASES AND BRONCHIOLITIS GUIDELINES COMMITTEE

KEY WORDS
RSV, respiratory syncytial virus, palivizumab, bronchiolitis, infants and young children, chronic lung disease, congenital heart disease

ABBREVIATIONS
AAP—American Academy of Pediatrics
CHD—congenital heart disease
CLD—chronic lung disease
COID—Committee on Infectious Diseases
RSV—respiratory syncytial virus

(Continued on last page)

abstract

FREE

Palivizumab was licensed in June 1998 by the Food and Drug Administration for the reduction of serious lower respiratory tract infection caused by respiratory syncytial virus (RSV) in children at increased risk of severe disease. Since that time, the American Academy of Pediatrics has updated its guidance for the use of palivizumab 4 times as additional data became available to provide a better understanding of infants and young children at greatest risk of hospitalization attributable to RSV infection. The updated recommendations in this policy statement reflect new information regarding the seasonality of RSV circulation, palivizumab pharmacokinetics, the changing incidence of bronchiolitis hospitalizations, the effect of gestational age and other risk factors on RSV hospitalization rates, the mortality of children hospitalized with RSV infection, the effect of prophylaxis on wheezing, and palivizumab-resistant RSV isolates. This policy statement updates and replaces the recommendations found in the 2012 *Red Book*. *Pediatrics* 2014;134:415–420

Policy statements from the American Academy of Pediatrics (AAP) are designed to provide updated guidance for child health care topics, with an emphasis on evidence-based recommendations whenever possible. Policy statements are reviewed at least every 3 years and updated when appropriate. In following this procedure, the AAP Committee on Infectious Diseases (COID) has undertaken a systematic review of all recent and older peer-reviewed literature relating to the burden of respiratory syncytial virus (RSV) disease in infants and children, focusing on publications that delineate children at greatest risk of serious RSV disease and studies that define pharmacokinetics, safety, and efficacy. Detailed input regarding this guidance has been solicited from 21 committees, councils, sections, and advisory groups within the AAP, as well as organizations outside the AAP. Outside groups include the American College of Chest Physicians, American College of Emergency Physicians, American Thoracic Society, Emergency Nurses Association, National Association of Neonatal Nurses, National Association of Neonatal Nurse Practitioners, and Society of Hospital

Medicine. In addition, this review includes all data presented to the COID by the manufacturer of palivizumab.

As part of this deliberative review of palivizumab use, the COID judged the quality of the available data, as well as the impact of palivizumab prophylaxis to reach a unanimous consensus on guidance for the use of palivizumab in the United States. Cost was considered during deliberations by the COID and Bronchiolitis Guideline Committee, but the final guidance as presented here is driven by the limited clinical benefit derived from palivizumab prophylaxis.[1–3]

As detailed in the accompanying technical report,[4] the benefit resulting from this drug is limited. Palivizumab prophylaxis has limited effect on RSV hospitalizations on a population basis, no measurable effect on mortality, and a minimal effect on subsequent wheezing.

This policy statement updates and replaces the most recent AAP recommendations for the use of palivizumab prophylaxis published in 2012 in the 29th edition of the *Red Book*.[5] This policy statement offers specific guidance for the use of palivizumab on the basis of available evidence, as well as expert opinion. A detailed discussion of the foundation of the updated guidance for each category as well as the references for each section may be found in the accompanying technical report,[4] and AAP guidelines for the diagnosis and management of bronchiolitis, which were published in 2006[6] (for which a revision is forthcoming).

The palivizumab package insert states: "Synagis is indicated for the prevention of serious lower respiratory tract disease caused by RSV in children at high risk of RSV disease."[7] In the absence of a specific definition of "high risk" by the US Food and Drug Administration, the AAP has endeavored to provide pediatricians and other health care providers with more precise guidance for determining who is at increased risk since palivizumab was first licensed.[5,8–11]

The informed opinion of the COID and the Bronchiolitis Guidelines Committee, as well as others participating in the current statement, is that palivizumab use should be restricted to the populations detailed below.

PRETERM INFANTS WITHOUT CHRONIC LUNG DISEASE OF PREMATURITY OR CONGENITAL HEART DISEASE

Palivizumab prophylaxis may be administered to infants born before 29 weeks, 0 days' gestation who are younger than 12 months at the start of the RSV season. For infants born during the RSV season, fewer than 5 monthly doses will be needed.

Available data for infants born at 29 weeks, 0 days' gestation or later do not identify a clear gestational age cutoff for which the benefits of prophylaxis are clear. For this reason, infants born at 29 weeks, 0 days' gestation or later are not universally recommended to receive palivizumab prophylaxis. Infants 29 weeks, 0 days' gestation or later may qualify to receive prophylaxis on the basis of congenital heart disease (CHD), chronic lung disease (CLD), or another condition.

Palivizumab prophylaxis is not recommended in the second year of life on the basis of a history of prematurity alone.

Some experts believe that on the basis of the data quantifying a small increase in risk of hospitalization, even for infants born earlier than 29 weeks, 0 days' gestation, palivizumab prophylaxis is not justified.

PRETERM INFANTS WITH CLD

Prophylaxis may be considered during the RSV season during the first year of life for preterm infants who develop CLD of prematurity defined as gestational age <32 weeks, 0 days and a requirement for >21% oxygen for at least the first 28 days after birth.

During the second year of life, consideration of palivizumab prophylaxis is recommended only for infants who satisfy this definition of CLD of prematurity and continue to require medical support (chronic corticosteroid therapy, diuretic therapy, or supplemental oxygen) during the 6-month period before the start of the second RSV season. For infants with CLD who do not continue to require medical support in the second year of life prophylaxis is not recommended.

INFANTS WITH HEMODYNAMICALLY SIGNIFICANT CHD

Certain children who are 12 months or younger with hemodynamically significant CHD may benefit from palivizumab prophylaxis. Children with hemodynamically significant CHD who are most likely to benefit from immunoprophylaxis include infants with acyanotic heart disease who are receiving medication to control congestive heart failure and will require cardiac surgical procedures and infants with moderate to severe pulmonary hypertension.

Decisions regarding palivizumab prophylaxis for infants with cyanotic heart defects in the first year of life may be made in consultation with a pediatric cardiologist.

These recommendations apply to qualifying infants in the first year of life who are born within 12 months of onset of the RSV season.

The following groups of infants with CHD are not at increased risk of RSV infection and generally should not receive immunoprophylaxis:

- Infants and children with hemodynamically insignificant heart disease (eg, secundum atrial septal

defect, small ventricular septal defect, pulmonic stenosis, uncomplicated aortic stenosis, mild coarctation of the aorta, and patent ductus arteriosus)

- Infants with lesions adequately corrected by surgery, unless they continue to require medication for congestive heart failure
- Infants with mild cardiomyopathy who are not receiving medical therapy for the condition
- Children in the second year of life

Because a mean decrease in palivizumab serum concentration of 58% was observed after surgical procedures that involve cardiopulmonary bypass, for children who are receiving prophylaxis and who continue to require prophylaxis after a surgical procedure, a postoperative dose of palivizumab (15 mg/kg) should be considered after cardiac bypass or at the conclusion of extracorporeal membrane oxygenation for infants and children younger than 24 months.

Children younger than 2 years who undergo cardiac transplantation during the RSV season may be considered for palivizumab prophylaxis.

CHILDREN WITH ANATOMIC PULMONARY ABNORMALITIES OR NEUROMUSCULAR DISORDER

No prospective studies or population-based data are available to define the risk of RSV hospitalization in children with pulmonary abnormalities or neuromuscular disease. Infants with neuromuscular disease or congenital anomaly that impairs the ability to clear secretions from the upper airway because of ineffective cough are known to be at risk for a prolonged hospitalization related to lower respiratory tract infection and, therefore, may be considered for prophylaxis during the first year of life.

IMMUNOCOMPROMISED CHILDREN

No population based data are available on the incidence of RSV hospitalization in children who undergo solid organ or hematopoietic stem cell transplantation. Severe and even fatal disease attributable to RSV is recognized in children receiving chemotherapy or who are immunocompromised because of other conditions, but the efficacy of prophylaxis in this cohort is not known. Prophylaxis may be considered for children younger than 24 months of age who are profoundly immunocompromised during the RSV season.

CHILDREN WITH DOWN SYNDROME

Limited data suggest a slight increase in RSV hospitalization rates among children with Down syndrome. However, data are insufficient to justify a recommendation for routine use of prophylaxis in children with Down syndrome unless qualifying heart disease, CLD, airway clearance issues, or prematurity (<29 weeks, 0 days' gestation) is present.

CHILDREN WITH CYSTIC FIBROSIS

Routine use of palivizumab prophylaxis in patients with cystic fibrosis, including neonates diagnosed with cystic fibrosis by newborn screening, is not recommended unless other indications are present. An infant with cystic fibrosis with clinical evidence of CLD and/or nutritional compromise in the first year of life may be considered for prophylaxis. Continued use of palivizumab prophylaxis in the second year may be considered for infants with manifestations of severe lung disease (previous hospitalization for pulmonary exacerbation in the first year of life or abnormalities on chest radiography or chest computed tomography that persist when stable) or weight for length less than the 10th percentile.

RECOMMENDATIONS FOR TIMING OF PROPHYLAXIS FOR ALASKA NATIVE AND AMERICAN INDIAN INFANTS

On the basis of the epidemiology of RSV in Alaska, particularly in remote regions where the burden of RSV disease is significantly greater than the general US population, the selection of Alaska Native infants eligible for prophylaxis may differ from the remainder of the United States. Clinicians may wish to use RSV surveillance data generated by the state of Alaska to assist in determining onset and end of the RSV season for qualifying infants.

Limited information is available concerning the burden of RSV disease among American Indian populations. However, special consideration may be prudent for Navajo and White Mountain Apache infants in the first year of life.

DISCONTINUATION OF PALIVIZUMAB PROPHYLAXIS AMONG CHILDREN WHO EXPERIENCE BREAKTHROUGH RSV HOSPITALIZATION

If any infant or young child receiving monthly palivizumab prophylaxis experiences a breakthrough RSV hospitalization, monthly prophylaxis should be discontinued because of the extremely low likelihood of a second RSV hospitalization in the same season (<0.5%).

USE OF PALIVIZUMAB IN THE SECOND YEAR OF LIFE

Hospitalization rates attributable to RSV decrease during the second RSV season for all children. A second season of palivizumab prophylaxis is recommended only for preterm infants born at <32 weeks, 0 days' gestation who required at least 28 days of oxygen after birth and who continue to require

supplemental oxygen, chronic systemic corticosteroid therapy, or bronchodilator therapy within 6 months of the start of the second RSV season.

LACK OF THERAPEUTIC EFFICACY OF PALIVIZUMAB

Passive antibody administration is not effective in treatment of RSV disease and is not approved or recommended for this indication.

PREVENTION OF HEALTH CARE-ASSOCIATED RSV DISEASE

No rigorous data exist to support palivizumab use in controlling outbreaks of health care-associated disease, and palivizumab use is not recommended for this purpose. Infants in a neonatal unit who qualify for prophylaxis because of CLD, prematurity, or CHD may receive the first dose 48 to 72 hours before discharge to home or promptly after discharge.

Strict adherence to infection-control practices is the basis for reducing health care-associated RSV disease.

RSV SEASONALITY

Because 5 monthly doses of palivizumab at 15 mg/kg per dose will provide more than 6 months (>24 weeks) of serum palivizumab concentrations above the desired level for most children, administration of more than 5 monthly doses is not recommended within the continental United States. For qualifying infants who require 5 doses, a dose beginning in November and continuation for a total of 5 monthly doses will provide protection for most infants through April and is recommended for most areas of the United States. If prophylaxis is initiated in October, the fifth and final dose should be administered in February, which will provide protection for most infants through March. If prophylaxis is initiated in December, the fifth and final dose should be administered in April, which will provide protection for most infants through May.

Variation in the onset and offset of the RSV season in different regions of Florida may affect the timing of palivizumab administration. Data from the Florida Department of Health may be used to determine the appropriate timing for administration of the first dose of palivizumab for qualifying infants. Despite varying onset and offset dates of the RSV season in different regions of Florida, a maximum of 5 monthly doses of palivizumab should be adequate for qualifying infants for most RSV seasons in Florida.

Sporadic RSV infections occur throughout the year in most geographic locations. During times of low RSV prevalence (regardless of proportion of positive results), prophylaxis with palivizumab provides the least benefit because of the large number of children who must receive prophylaxis to prevent 1 RSV hospitalization.

EFFECT OF PALIVIZUMAB PROPHYLAXIS ON SUBSEQUENT WHEEZING

Prophylaxis is not recommended for primary asthma prevention or to reduce subsequent episodes of wheezing.

SUMMARY OF GUIDANCE

- In the first year of life, palivizumab prophylaxis is recommended for infants born before 29 weeks, 0 days' gestation.
- Palivizumab prophylaxis is not recommended for otherwise healthy infants born at or after 29 weeks, 0 days' gestation.
- In the first year of life, palivizumab prophylaxis is recommended for preterm infants with CLD of prematurity, defined as birth at <32 weeks, 0 days' gestation and a requirement for >21% oxygen for at least 28 days after birth.
- Clinicians may administer palivizumab prophylaxis in the first year of life to certain infants with hemodynamically significant heart disease.
- Clinicians may administer up to a maximum of 5 monthly doses of palivizumab (15 mg/kg per dose) during the RSV season to infants who qualify for prophylaxis in the first year of life. Qualifying infants born during the RSV season may require fewer doses. For example, infants born in January would receive their last dose in March.
- Palivizumab prophylaxis is not recommended in the second year of life except for children who required at least 28 days of supplemental oxygen after birth and who continue to require medical intervention (supplemental oxygen, chronic corticosteroid, or diuretic therapy).
- Monthly prophylaxis should be discontinued in any child who experiences a breakthrough RSV hospitalization.
- Children with pulmonary abnormality or neuromuscular disease that impairs the ability to clear secretions from the upper airways may be considered for prophylaxis in the first year of life.
- Children younger than 24 months who will be profoundly immunocompromised during the RSV season may be considered for prophylaxis.
- Insufficient data are available to recommend palivizumab prophylaxis for children with cystic fibrosis or Down syndrome.
- The burden of RSV disease and costs associated with transport from remote locations may result in a broader use of palivizumab for RSV prevention in Alaska Native

populations and possibly in selected other American Indian populations.

- Palivizumab prophylaxis is not recommended for prevention of health care-associated RSV disease.

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(Continued from first page)

www.pediatrics.org/cgi/doi/10.1542/peds.2014-1665

doi:10.1542/peds.2014-1665

PEDIATRICS (ISSN Numbers: Print, 0031-4005; Online, 1098-4275).

Updated Guidance for Palivizumab Prophylaxis Among Infants and Young Children at Increased Risk of Hospitalization for Respiratory Syncytial Virus Infection

COMMITTEE ON INFECTIOUS DISEASES AND BRONCHIOLITIS GUIDELINES COMMITTEE

Pediatrics; originally published online July 28, 2014;
DOI: 10.1542/peds.2014-1665

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
- Based on the 2009 American Academy of Pediatrics *Policy Statement – Modified Recommendations for Use of Palivizumab for Prevention of Respiratory Syncytial Virus Infections**, a maximum of 5 or 3 doses will be allowed during the Synagis season determined by gestational age.
- Providers will choose when to start dosing Synagis based on prevalence of RSV in the community

TO BE COMPLETED BY PRESCRIBER

Recipient Medicaid ID Number	Recipient Date of Birth	Prescriber NPI	Prescriber Fax Number

Diagnosis (qualification for Synagis)

___ Prematurity

≤28 weeks, 6 days gestational age – Synagis allowed if younger than 12 months of age at start of RSV season (max of 5 doses)

29-31 weeks, 6 days gestational age – Synagis allowed if younger than 6 months of age at start of RSV season (max of 5 doses)

32-34 weeks, 6 days gestational age – Synagis allowed during RSV season up to 6 months of life (max of 3 doses)

Gestational Age (e.g. 32 weeks, 4 days)

Weeks _____ **Days** _____

Risk Factor(s) (for those 32-34 weeks, 6 days)

___ Daycare attendance

___ Sibling younger than 5 years of age

___ Chronic Lung Disease of Prematurity (CLD)

Must be less than 24 months of age and receive medical therapy within six months before start of RSV season

___ Supplemental Oxygen

___ Bronchodilator

___ Diuretic

___ Chronic corticosteroid therapy

___ Congenital Heart Disease (CHD)

Must be less than 24 months of age and requiring medical therapy for CHD

Medical Therapy Required _____

___ Neuromuscular disease

___ Congenital abnormalities of the airways

***Accessed online at http://aappolicy.aappublications.org/cgi/reprint/pediatrics;124/6/1694.pdf.**

HEALTH INFORMATION DESIGNS

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Gestational Age (e.g. 32 weeks, 4 days)

Weeks _____ **Days** _____

~~Risk Factor(s) (for those 32-34 weeks, 6 days)~~

___ ~~Daycare attendance~~

___ ~~Sibling younger than 5 years of age~~

___ Chronic Lung Disease of Prematurity (CLD) – gestational age <32 weeks, 0 days and a requirement for >21% oxygen for at least the first 28 days of birth.

Must be less than 24 months of age and receive medical therapy within six months before start of RSV season

___ Supplemental Oxygen

___ ~~Bronchodilator~~

___ Diuretic

___ Chronic corticosteroid therapy

___ Congenital Heart Disease (CHD)

Must be less than 12 months of age and requiring medical therapy for hemodynamically significant 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)

___ Congenital abnormalities of the airways (may be considered for prophylaxis during the first year of life)

___ Profoundly Immunocompromised children (children <24 months may be considered for prophylaxis during the RSV season)

***Accessed online at http://aappolicy.aappublications.org/cgi/reprint/pediatrics;124/6/1694.pdf.**

NORTH DAKOTA
DEPARTMENT of HEALTH

COMMUNITY HEALTH SECTION
600 East Boulevard Avenue, Dept. 301
Bismarck, N.D. 58505-0200
www.ndhealth.gov
TTY 800.366.6888

Memorandum

To: North Dakota Medicaid Drug Utilization Review Board

From: Krista Fremming, Tobacco Program Director

Date: 8/5/2014

Re: Training Protocol for Rehabilitative Services providers

The steps below outline a proposed process for the Department of Health to provide training and distribution of prior authorization forms to Medicaid rehabilitative services providers. The purpose of the new process is to expand tobacco dependence treatment coverage options for ND Medicaid members by providing a way for FDA-approved tobacco cessation medications to be covered through ND Medicaid when the member participates in face to face or group counseling through a rehabilitative services provider.

Currently, ND Medicaid members who wish to use tobacco cessation medications are required to enroll in phone counseling provided by NDQuits. The new proposed process (below) will allow coverage for medications when participating in face to face or group counseling, which will encourage more successful quit attempts by ND Medicaid members.

1. DoH develops a webinar that will be housed on the NDQuits website for rehab providers (and others) that will include the basics of brief cessation interventions, motivational interviewing, neurobiology of nicotine and pharmacology.
2. After providers complete the webinar, they will be prompted to take a test to demonstrate their knowledge. The test results will be forwarded to DoH Tobacco program staff for documentation and certification of pass/fail.
3. Providers who successfully pass the webinar post-test will be provided with the current ND Medicaid prior authorization form for cessation medications as well as a template enrollment letter in counseling services. The DoH will coordinate the distribution of the PA forms and enrollment letter templates.
4. Providers will be required to complete the webinar or another approved tobacco cessation training (minimum of 2 hours in length) at least every 2 years to maintain their eligibility to receive the Medicaid cessation medications forms. The DoH will track and remind providers who are getting close to having their eligibility expire.

For any questions on the proposed process or tobacco cessation activity in North Dakota, please contact Krista at 701.328.2315 or kfremming@nd.gov.

PL Detail-Document **#300204**
−This PL Detail-Document gives subscribers additional insight related to the Recommendations published in−
PHARMACIST'S LETTER / PRESCRIBER'S LETTER
February 2014

Comparison of Hepatitis C Drugs

For years, peginterferon alpha plus ribavirin was the only treatment for hepatitis C. Now protease inhibitors (boceprevir, telaprevir, simeprevir) and a polymerase inhibitor (sofosbuvir) are available **for use with peginterferon alpha and ribavirin** to improve efficacy for genotype 1 infections. Sofosbuvir is also indicated for genotypes 2, 3, and 4, and can be used without peginterferon alpha in some patients. The newest agents (simeprevir, sofosbuvir) have convenient dosing regimens, fewer drugs interactions, and seem to be better tolerated than boceprevir and telaprevir. The following chart compares hepatitis C drugs in regard to dosing, common adverse effects, contraindicated drugs, safety monitoring, and cost. Patient assistance programs are also listed. Information in the chart is from U.S. product labeling unless otherwise noted. Information from Canadian labeling is included when it differs significantly (e.g., more conservative) from U.S. labeling.

Abbreviations: ALT = alanine aminotransferase; CBC = complete blood count; LFTs = liver function tests

Adult Dosing[a]	Common Adverse Effects[a]	Drug Interactions	Safety Monitoring[a]	Cost[b]
PROTEASE INHIBITORS				
Boceprevir (*Victrelis*; *Victrelis Triple* [Canada] kit includes ribavirin and peginterferon alpha-2b): For genotype 1 infections. Must use with peginterferon alpha and ribavirin.				
800 mg three times daily (every 7 to 9 hours) with food starting on week five of peginterferon alpha plus weight-based ribavirin. For patients with compensated cirrhosis, treatment is continued for 44 more weeks (48 weeks total treatment duration). For patients without cirrhosis, total treatment duration 28 to 48 weeks, depending on viral response and response history.	Over 35% of patients when used with peginterferon and ribavirin: fatigue, anemia (over 40% of patients need erythropoiesis-stimulating agent), nausea, headache, dysgeusia.	• CYP3A substrate and strong inhibitor. • P-glycoprotein substrate and inhibitor. **Contraindicated Drugs**: alfuzosin, amiodarone (Canada), carbamazepine, cisapride, drospirenone, ergots, lovastatin, midazolam (oral), pimozide, phenobarbital, phenytoin, propafenone (Canada), quinidine (Canada), rifampin, sildenafil (*Revatio*), simvastatin, St. John's wort, tadalafil (*Adcirca*), triazolam (Boceprevir interacts with many other drugs. See U.S. MedGuide and product labeling for a complete list of all interacting drugs, dosing adjustments, and monitoring).	Check CBC at baseline and at weeks two, four, eight, and 12, and as clinically indicated. Decreased white blood cell, neutrophil, or platelet count may require peginterferon dosage decrease or treatment discontinuation. Reductions in hemoglobin may require peginterferon and/or ribavirin dose reduction or treatment discontinuation. If peginterferon or ribavirin is discontinued, boceprevir must also be discontinued.	U.S.: $40,120.32 for 24 weeks or $73,553.92 for 44 weeks Canada: $26,460 for 24 weeks or $48,510 for 44 weeks Patient assistance programs: U.S.: http://www.merck.com/merckhelps/act-program/ Canada: 866-872-5773 (Merck Care)

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Adult Dosing[a]	**Common Adverse Effects**[a]	**Drug Interactions**	**Safety Monitoring**[a]	**Cost**[b]
Simeprevir (*Olysio* [U.S.], *Galexos* [Canada]): For genotype 1 infections. Must use with peginterferon alpha and ribavirin. Dosed once daily. Has fewer drug interactions and appears better tolerated than telaprevir or boceprevir. May cause rash and sun sensitivity, especially in patients of East Asian ancestry. Check the virus for a specific genetic mutation before using *Olysio*. About 35% of patients are infected with a virus containing a Q80K polymorphism that makes *Olysio* less effective, but doesn't change susceptibility to other antivirals. Caution should be exercised when using *Olysio* in severely sulfa-allergic patients; contains a sulfonamide moiety.				
150 mg once daily with food plus peginterferon alfa plus ribavirin* for 12 weeks. This is followed by an additional 12 to 36 weeks of peginterferon alfa plus ribavirin,* based on viral response and response history (24 to 48 weeks total treatment duration). *Ribavirin dose: 1000 mg divided twice daily (e.g., 400 mg qAM, 600 mg qPM) if <75 kg, or 1200 mg divided twice daily if ≥75 kg.[1]	Over 20% of patients when used with peginterferon and ribavirin: rash (including photosensitivity), itching, nausea	• CYP3A substrate and weak intestinal CYP3A4 inhibitor. • Weak CYP1A2 inhibitor. • P-glycoprotein inhibitor. • Inhibits an organic anion transporter protein (OATP1B1). No contraindicated drugs. (See product labeling for a complete list of all interacting drugs, dosing adjustments, and monitoring).	See monitoring as for peginterferon alpha and ribavirin. If peginterferon or ribavirin is discontinued, simeprevir must also be discontinued.	*Olysio* (U.S.): $66,360 for 12 weeks *Galexos* (Canada): $39,422.40 for 12 weeks Patient assistance program for *Olysio*: http://www.olysio.com/support/financial-assistance *Galexos* program not available at press time. Contact Janssen Medical Information at 800-567-3331.

Adult Dosing[a]	**Common Adverse Effects**[a]	**Drug Interactions**	**Safety Monitoring**[a]	**Cost**[b]
Telaprevir (*Incivek*): For genotype 1 infections. Must use with peginterferon alpha and ribavirin.				
1125 mg twice daily (every 10 to 14 hours) with food (not low fat), plus peginterferon alfa plus weight-based ribavirin for 12 weeks. This is followed by an additional 12 to 36 weeks of peginterferon alfa plus ribavirin, based on viral response and response history (24 to 48 weeks total treatment duration).	Over 35% of patients when used with peginterferon and ribavirin: rash (discontinue all treatment components if progressive or severe), fatigue, itching, nausea, anemia	• Strong CYP3A inhibitor. • CYP3A substrate. • P-glycoprotein substrate and inhibitor. • Inhibits organic anion transporter proteins OATP1B1 and OATP2B1. **Contraindicated Drugs**: alfuzosin, amiodarone (Canada), atorvastatin (U.S.), carbamazepine, cisapride, eletriptan (Canada), eplerenone (Canada), ergots, flecainide (Canada), lovastatin, midazolam (oral), phenobarbital, phenytoin, pimozide, propafenone (Canada), quinidine (Canada), rifampin, sildenafil (*Revatio*), simvastatin, St. John's wort, tadalafil (*Adcirca*)(U.S.), triazolam, vardenafil (Canada) (Telaprevir interacts with many other drugs. See U.S. MedGuide and product labeling for a complete list of all interacting drugs, dosing adjustments, and monitoring).	Check CBC, blood chemistry, LFTs, TSH, and lipids (Canada) at baseline, at weeks two, four, eight, and 12, and as clinically indicated. Decreased white blood cell, neutrophil, or platelet count may require peginterferon dosage decrease or treatment discontinuation. Reductions in hemoglobin may require peginterferon and/or ribavirin dose reduction or treatment discontinuation. If peginterferon or ribavirin is discontinued, telaprevir must also be discontinued.	U.S.: $66,155.10 for 12 weeks Canada: $36,716.40 for 12 weeks Patient assistance program: U.S.: www.incivek.com/help-paying-for-incivek Canada: 877-574-4298 (*Incivek* Care)

Adult Dosing[a]	Common Adverse Effects[a]	Drug Interactions	Safety Monitoring[a]	Cost[b]
POLYMERASE INHIBITOR				
Sofosbuvir (*Sovaldi*): For genotype 1 and 4 infections, with peginterferon alpha and ribavirin. For genotypes 2 and 3, must use with ribavirin. For genotype 1 infections, use with only ribavirin can be considered if peginterferon cannot be used. Seems better tolerated than the protease inhibitors, and usually requires a shorter treatment duration. Indicated for patients co-infected with HIV. Sofosbuvir plus ribavirin can be used for up to 48 weeks pre-liver transplant to prevent reinfection (U.S.).				
Genotypes 1 and 4: 400 mg once daily with or without food plus ribavirin* and peginterferon alfa for 12 weeks. (For **genotype 1**, use with only ribavirin* can be considered if peginterferon cannot be used [U.S.]). **Genotypes 2 and 3**: 400 mg once daily with or without food plus ribavirin* for 12 weeks for genotype 2, or 24 weeks for genotype 3 (16 to 24 weeks, Canada). *Ribavirin dose: 1000 mg divided twice daily (e.g., 400 mg qAM, 600 mg qPM) if <75 kg, or 1200 mg divided twice daily if ≥75 kg.	Over 20% of patients when used with peginterferon and ribavirin: fatigue, headache, nausea, insomnia, anemia	• P-glycoprotein substrate. • BCRP (breast cancer resistance protein) drug transporter substrate. No contraindicated drugs. (See product labeling for a complete list of all interacting drugs, dosing adjustments, and monitoring).	See monitoring as for peginterferon alpha and ribavirin. If the other agents used with sofosbuvir are discontinued, sofosbuvir must also be discontinued.	U.S.: $84,000 for 12 weeks Canada: price not available at press time. Patient assistance programs: U.S: www.mysupportpath.com Canada: 866-207-4267 (Momentum Support Program)

Adult Dosing[a]	Common Adverse Effects[a]	Drug Interactions	Safety Monitoring[a]	Cost[b]
INTERFERONS				
Peginterferon alfa-2a (*Pegasys*; *Pegasys RBV* kit [Canada] includes ribavirin [*Copegus*]): For use with ribavirin. For genotype 1 infections, add a protease inhibitor or polymerase inhibitor to improve efficacy.				
180 mcg subcutaneously once weekly for 12 to 48 weeks, depending on antiviral regimen, patient history, and response. Reduce dose to 135 mcg once weekly if CrCl <30 mL/min. (Canada: reduce dose to 135 mcg once weekly in hemodialysis patients).	Over 35% of patients when used with ribavirin: fatigue, weakness, fever, myalgia, headache	• CYP1A2 inhibitor. No contraindicated drugs. (See product labeling for a complete list of all interacting drugs, dosing adjustments, and monitoring).	Check CBC at baseline, at weeks two and four, and periodically. Check blood chemistry and LFTs at baseline, at week four, and periodically. In clinical trials, CBC, blood chemistry, and LFTs were checked at weeks one, two, four, six, and eight. Thyroid function should be checked at baseline. In clinical trials, it was checked every 12 weeks. Dose reduction or discontinuation may be required in the event of reduced neutrophil or platelet count, or elevated ALT. Patients with cardiac disease should have a baseline EKG. Monitor for depression/suicidal ideation. Dose reduction (U.S. only) or discontinuation may be indicated.	U.S.: $21,595.56 for 28 weeks Canada: $11,970.28 (*Pegasys*) or $11,637.92 (*Pegasys RBV* kit) for 28 weeks Patient assistance programs: U.S.: http://www.genentech-access.com/pegasys/hcp/find-patient-assistance Canada: 888-748-8926 (Pegassist)

Adult Dosing[a]	Common Adverse Effects[a]	Drug Interactions	Safety Monitoring[a]	Cost[b]
Peginterferon alfa-2b (*PegIntron* [U.S.]; *Pegetron* kit [Canada] includes ribavirin): For use with ribavirin. For genotype 1 infections, add a protease inhibitor or polymerase inhibitor to improve efficacy.				
1.5 mcg/kg subcutaneously once weekly for 12 to 48 weeks, depending on antiviral regimen, patient history, and response. Reduce dose by 25% if CrCl is 30 to 50 mL/min. Reduce dose by 50% if CrCl 10 to 29 mL/min. (Canada: contraindicated if CrCl <50 mL/min).	Over 35% of patients when used with ribavirin: injection site reaction, fatigue, weakness, headache, rigors, fever, nausea, myalgia, insomnia, mood instability, hair loss	• May induce CYP2C8/9. • May increase or decrease CYP2D6 activity. No contraindicated drugs. (See product labeling for a complete list of all interacting drugs, dosing adjustments, and monitoring).	Check CBC, blood chemistry, and LFTs at baseline and periodically (Canada: at baseline, weeks two and four, then periodically). In clinical trials, these tests were measured at weeks 2, 4, 8, and 12, then every six weeks, and as clinically indicated. Check thyroid function at baseline. In clinical trials, TSH was checked every 12 weeks. Decreased white blood cell, neutrophil, or platelet count or hemoglobin may require dosage decrease or treatment discontinuation. Discontinue treatment if liver or renal function deteriorates. Patients with cardiac disease should have a baseline EKG. Monitor for depression/suicidal ideation. Dose reduction (U.S. only) or discontinuation may be indicated.	U.S.: $21,699.16 for 120 mcg for 28 weeks Canada: $12,585.02 (*Pegetron* 120 mcg kit) for 28 weeks Patient assistance programs (U.S.): http://www.merck.com/merckhelps/act-program/ (ACT Program) Canada: 866-872-5773 (Merck Care)

Adult Dosing[a]	Common Adverse Effects[a]	Drug Interactions	Safety Monitoring[a]	Cost[b]
NUCLEOSIDE ANALOGUE				
Ribavirin (*Copegus*, *Rebetol*, *Ribasphere* tablets and capsules [U.S.]; *Pegetron* kit [Canada] includes peginterferon alpha-2b, *Pegasys RBV* kit [Canada] includes Peginterferon): For use with peginterferon alpha. For genotype 1 infections, add a protease inhibitor or polymerase inhibitor to improve efficacy.				
Duration is 12 to 48 weeks depending on genotype, antiviral regimen, patient history, and response. ***Copegus***, ***Ribasphere*** **tablets [U.S.]** (indicated for use with peginterferon alpha-2a)**:**[c] Genotype 2 or 3: 400 mg twice daily Genotypes 1 and 4: weight <75 kg, 400 mg qAM and 600 mg qPM. Weight ≥75 kg, 600 mg twice daily. For CrCl 30 to 50 mL/min., reduce dose to alternating 200 mg/400 mg once daily. For patients with CrCl <30 mL/min., reduce dose to 200 mg once daily (U.S.). *Continued…*	Over 35% of patients when used with peginterferon: fatigue, weakness, fever, myalgia, headache, rigors, nausea, insomnia, mood instability, alopecia	• Contraindicated with didanosine (Canada, not recommended). (See product labeling for a complete list of all interacting drugs, dosing adjustments, and monitoring).	Pregnancy test at baseline, then monthly during treatment and for six months after discontinuation. Patients with cardiac disease should have a baseline EKG. Check CBC at baseline, at weeks two and four, then periodically. Check blood chemistry and LFTs at baseline, (week two [*Pegetron*], week four [*Copegus*, *Pegasys RBV*, *Pegetron*]), then periodically. Check thyroid function at baseline. In clinical trials of *Copegus*/*Pegasys*, CBC, blood chemistry, and LFTs were checked at weeks one, two, four, six, and eight, then every four to six weeks and as clinically indicated. TSH was checked every 12 weeks. Reductions in hemoglobin may require ribavirin dose reduction or treatment discontinuation.	U.S.: $21,016.66 (*Copegus*) for 600 mg twice daily for 28 weeks $8,653.68 (*Rebetol*) or $3,831.80 (*Ribasphere*) for 1000 mg divided twice daily for 28 weeks Canada: $12,585.02 (*Pegetron* 120 mcg kit) or $11,637.92 (*Pegasys RBV* kit) for 1000 mg divided twice daily for 28 weeks Patient assistance program for *Rebetol*: http://www.merck.com/merckhelps/act-program/ (ACT program) Canada: for *Pegetron*, 866-872-

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Adult Dosing[a]	**Common Adverse Effects**[a]	**Drug Interactions**	**Safety Monitoring**[a]	**Cost**[b]
Ribavirin, continued ***Rebetol* [U.S]**, ***Ribasphere* capsules [U.S.], *Pegetron* kit [Canada]** (indicated for use with peginterferon alpha-2b):[c] 800 to 1400 mg (divided twice daily), depending on weight. Contraindicated if CrCl <50 mL/min.				5773; for *Pegasys*, 877-734-2897

The following product labeling was used in the preparation of this chart: *Victrelis* (September 2013), *Pegasys* (July 2013), *PegIntron* (November 2013), *Copegus* (February 2013), *Rebetol* (November 2013), *Ribasphere* tablets (December 2013), *Ribasphere* capsules (October 2012), *Olysio* (November 2013), *Sovaldi* (December 2013), *Incivek* (October 2013), *Victrelis* Canada (May 2013), *Pegasys* Canada (August 2013), *Pegetron* (March 2013), *Pegasys RBV* (August 2013), *Galexos* (November 2013), *Sovaldi* Canada (December 2013), *Incivek* Canada (December 2013)

a. See product labeling for dose reduction and other management recommendations in the event of moderate to severe clinical adverse reactions or laboratory abnormalities.
b. U.S. cost is wholesale average cost (WAC). Canadian cost is wholesale price.
c. Although each ribavirin product/dose is indicated for use with a specific peginterferon alpha product, some experts use the ribavirin dose used in the clinical trials for each specific protease or polymerase inhibitor, regardless of the peginterferon product used.

More. . . PRESCRIBER'S LETTER

Project Leader in preparation of this PL Detail-Document: *Melanie Cupp, Pharm.D., BCPS*

References

1. Fried MW, Buti M, Dore GJ, et al. Once-daily simeprevir (TMC435) with pegylated interferon and ribavirin in treatment-naïve genotype 1 hepatitis C: the randomized PILLAR study. *Hepatology* 2013;58:1918-29.

Cite this document as follows: PL Detail-Document, Comparison of Hepatitis C Drugs. Pharmacist's Letter/Prescriber's Letter. February 2014.

PHARMACIST'S LETTER *Evidence and Recommendations You Can Trust…* PRESCRIBER'S LETTER

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ND Medicaid - Agents Used to Treat Hep C Utilization			
01/01/14 - 05/31/14			
Label Name	**Rx Num**	**Total Reimb Amt**	**Avg Cost per Script**
RIBAVIRIN 200 MG TABLET	14	$1,409.99	$100.71
PEGINTRON REDIPEN 120	2	$6,178.16	$3,089.08
PEGASYS 180 MCG/0.5 ML	9	$27,678.06	$3,075.34
SOVALDI 400 MG TABLET	9	$227,867.22	$25,318.58
8 recipients/4 prescribers (infectious disease specialists/gastroenterologist/NP/internist)			
Sovaldi Recipient	**Doses**	**Pegasys**	**Ribavirin**
1	3	yes	yes
2	2	yes	yes
3	2	no	yes
4	1	no	no
5	1	yes	yes

SOVALDI PA FORM

HEALTH INFORMATION DESIGNS

Prior Authorization Vendor for ND Medicaid

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-773-0695

ND Medicaid requires that patients receiving a new prescription for Sovaldi must meet the following criteria:

- Patient must be ≥ 18 years old.
- Must have a diagnosis of chronic hepatitis C (genotypes 1, 2, 3, or 4) with compensated liver disease.
- Liver biopsy showing fibrosis corresponding to a Metavir score of greater than or equal to 2 or Ishak score of greater than or equal to 3 or other accepted test demonstrating liver fibrosis.
- Must be prescribed by or in consultation with a hepatologist, gastroenterologist, or infectious disease specialist.
- Must be used in combination with ribavirin or in combination with pegylated interferon and ribavirin **(must not be used as monotherapy).**
- Female patients must have a negative pregnancy test within 30 days prior to initiation of therapy and monthly during treatment.
- Absence of renal impairment (eGFR must be >30mL/min/1.73m^2) and absence of end stage renal disease (ESRD).
- Documentation showing that patient is drug and alcohol free for the past 12 months.

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 □ **Sovaldi** Dosage _____	**Documented liver fibrosis**	**Diagnosis for this request** **Genotype** **Pegylated interferon dose** **Ribavirin dose**	**Patient is drug and alcohol free for past 12 months** □ YES □ NO **Negative pregnancy test in the past 30 days** □ YES □ NO	**eGFR**
Physician Signature			Date	

Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

Date Received	Initials:
Approved - Effective dates of PA: From: / / To: / /	Approved by:
Denied: (Reasons)	

OLYSIO PA FORM

HEALTH INFORMATION DESIGNS

Prior Authorization Vendor for ND Medicaid

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-773-0695

ND Medicaid requires that patients receiving a new prescription for Olysio must meet the following criteria:

- Patient must be ≥ 18 years old.
- Must have a diagnosis of chronic hepatitis C, genotype 1, with compensated liver disease.
- Liver biopsy showing fibrosis corresponding to a Metavir score of greater than or equal to 2 or Ishak score of greater than or equal to 3 or other accepted test demonstrating liver fibrosis.
- Must be prescribed by or in consultation with a hepatologist, gastroenterologist, or infectious disease specialist.
- Must be used in combination with pegylated interferon and ribavirin **(must not be used as monotherapy).**
- Female patients must have a negative pregnancy test within 30 days prior to initiation of therapy and monthly during treatment.
- Documentation showing that patient is drug and alcohol free for the past 12 months.
- Alternative therapy should be considered for patients infected with HCV genotype 1a containing the Q80K polymorphism.

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 □ **Olysio** Dosage _____	**Documented liver fibrosis** **Presence of Q80K polymorphism?** □ YES □ NO	**Diagnosis for this request** **Genotype** **Pegylated interferon dose** **Ribavirin dose**	**Patient is drug and alcohol free for past 12 months** □ YES □ NO **Negative pregnancy test in the past 30 days** □ YES □ NO
Physician Signature			Date

Part II: TO BE COMPLETED BY PHARMACY

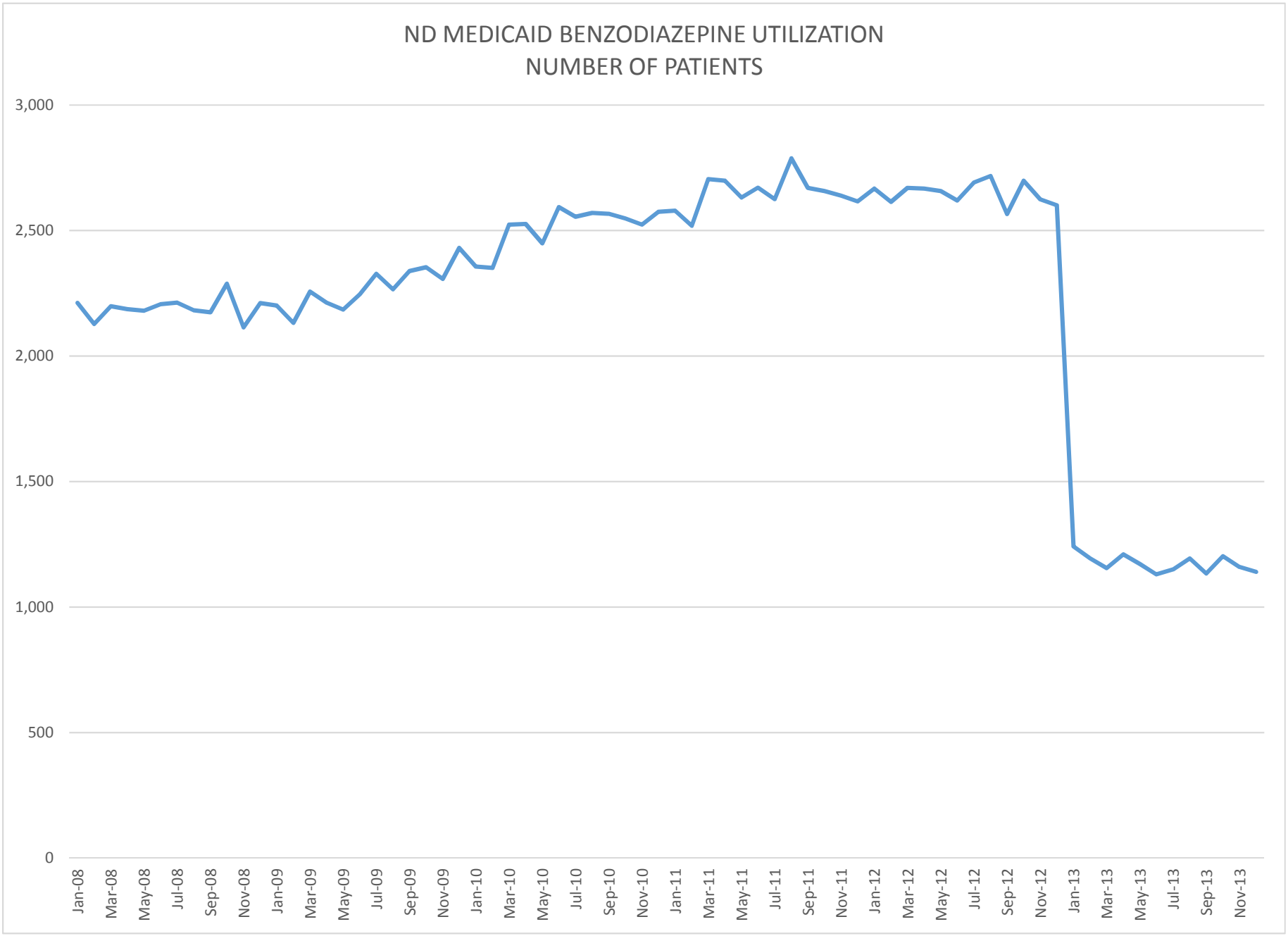
PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #

Part III: FOR OFFICIAL USE ONLY

Date Received	Initials:
Approved - Effective dates of PA: From: / / To: / /	Approved by:
Denied: (Reasons)	

ND Medicaid Benzodiazepine Utilization			
06/01/13 - 05/31/14			
Label Name	**Rx Num**	**Total Reimb Amt**	**Average Cost per Script**
ALPRAZOLAM 0.25 MG TABLET	631	$4,575.18	$7.25
ALPRAZOLAM 0.5 MG TABLET	1598	$11,264.32	$7.05
ALPRAZOLAM 1 MG TABLET	1515	$11,706.03	$7.73
ALPRAZOLAM 2 MG TABLET	181	$2,603.02	$14.38
ALPRAZOLAM ER 0.5 MG TABLET	6	$92.75	$15.46
ALPRAZOLAM ER 1 MG TABLET	9	$158.41	$17.60
ALPRAZOLAM ER 2 MG TABLET	15	$523.31	$34.89
ALPRAZOLAM ER 3 MG TABLET	13	$386.00	$29.69
ALPRAZOLAM XR 0.5 MG TABLET	1	$16.69	$16.69
ALPRAZOLAM XR 1 MG TABLET	6	$118.50	$19.75
ALPRAZOLAM XR 2 MG TABLET	15	$428.68	$28.58
ALPRAZOLAM XR 3 MG TABLET	1	$34.78	$34.78
ATIVAN 0.5 MG TABLET	3	$5.39	$1.80
CHLORDIAZEPOXIDE 10 MG CAPSULE	12	$122.78	$10.23
CHLORDIAZEPOXIDE 25 MG CAPSULE	26	$273.79	$10.53
CHLORDIAZEPOXIDE 5 MG CAPSULE	2	$21.80	$10.90
CLONAZEPAM 0.125 MG DIS TAB	32	$137.15	$4.29
CLONAZEPAM 0.25 MG ODT	41	$114.40	$2.79
CLONAZEPAM 0.5 MG DIS TABLET	49	$410.16	$8.37
CLONAZEPAM 0.5 MG TABLET	2478	$18,188.70	$7.34
CLONAZEPAM 1 MG DIS TABLET	5	$33.20	$6.64
CLONAZEPAM 1 MG TABLET	2541	$20,966.77	$8.25
CLONAZEPAM 2 MG TABLET	384	$3,121.88	$8.13
CLORAZEPATE 3.75 MG TABLET	60	$680.06	$11.33
CLORAZEPATE 7.5 MG TABLET	48	$448.33	$9.34
DIASTAT 2.5 MG PEDI SYSTEM	7	$1,618.75	$231.25
DIASTAT ACUDIAL 12.5-15-20 MG	4	$832.27	$208.07
DIASTAT ACUDIAL 5-7.5-10 MG KT	54	$13,811.67	$255.77
DIAZEPAM 10 MG RECTAL GEL SYST	104	$21,588.96	$207.59
DIAZEPAM 10 MG TABLET	330	$2,602.70	$7.89
DIAZEPAM 2 MG TABLET	129	$738.42	$5.72
DIAZEPAM 2.5 MG RECTAL GEL SYS	30	$6,581.88	$219.40
DIAZEPAM 20 MG RECTAL GEL SYST	9	$2,220.84	$246.76
DIAZEPAM 5 MG TABLET	682	$4,655.63	$6.83
DIAZEPAM 5 MG/5 ML SOLUTION	180	$3,885.52	$21.59
ESTAZOLAM 1 MG TABLET	2	$62.44	$31.22
ESTAZOLAM 2 MG TABLET	6	$82.81	$13.80
FLURAZEPAM 15 MG CAPSULE	5	$60.10	$12.02
FLURAZEPAM 30 MG CAPSULE	22	$207.02	$9.41
LORAZEPAM 0.5 MG TABLET	1706	$12,281.59	$7.20
LORAZEPAM 1 MG TABLET	2646	$19,062.81	$7.20
LORAZEPAM 2 MG TABLET	341	$3,617.22	$10.61
LORAZEPAM 2 MG/ML ORAL CONCENT	150	$6,324.80	$42.17
MIDAZOLAM HCL 10 MG/2 ML VIAL	1	$6.27	$6.27

ND Medicaid Benzodiazepine Utilization			
06/01/13 - 05/31/14			
Label Name	**Rx Num**	**Total Reimb Amt**	**Average Cost per Script**
MIDAZOLAM HCL 2 MG/ML SYRUP	2	$16.72	$8.36
MIDAZOLAM HCL 5 MG/ML VIAL	2	$20.70	$10.35
ONFI 10 MG TABLET	44	$15,473.24	$351.66
ONFI 2.5 MG/ML SUSPENSION	22	$6,568.44	$298.57
ONFI 20 MG TABLET	22	$12,549.97	$570.45
ONFI 5 MG TABLET	8	$675.39	$84.42
OXAZEPAM 15 MG CAPSULE	3	$48.99	$16.33
TEMAZEPAM 15 MG CAPSULE	175	$1,516.85	$8.67
TEMAZEPAM 22.5 MG CAPSULE	11	$304.17	$27.65
TEMAZEPAM 30 MG CAPSULE	276	$2,436.51	$8.83
TEMAZEPAM 7.5 MG CAPSULE	1	$170.60	$170.60
TRIAZOLAM 0.25 MG TABLET	52	$922.82	$17.75
XANAX 0.5 MG TABLET	1	$2.07	$2.07
3,193 recipients	**16704**	**$217,380.25**	


ND MEDICAID BENZODIAZEPINE UTILIZATION
NUMBER OF PATIENTS
3,000
2,500
2,000
1,500
1,000
500
0
Jan-08
Mar-08
May-08
Jul-08
Sep-08
Nov-08
Jan-09
Mar-09
May-09
Jul-09
Sep-09
Nov-09
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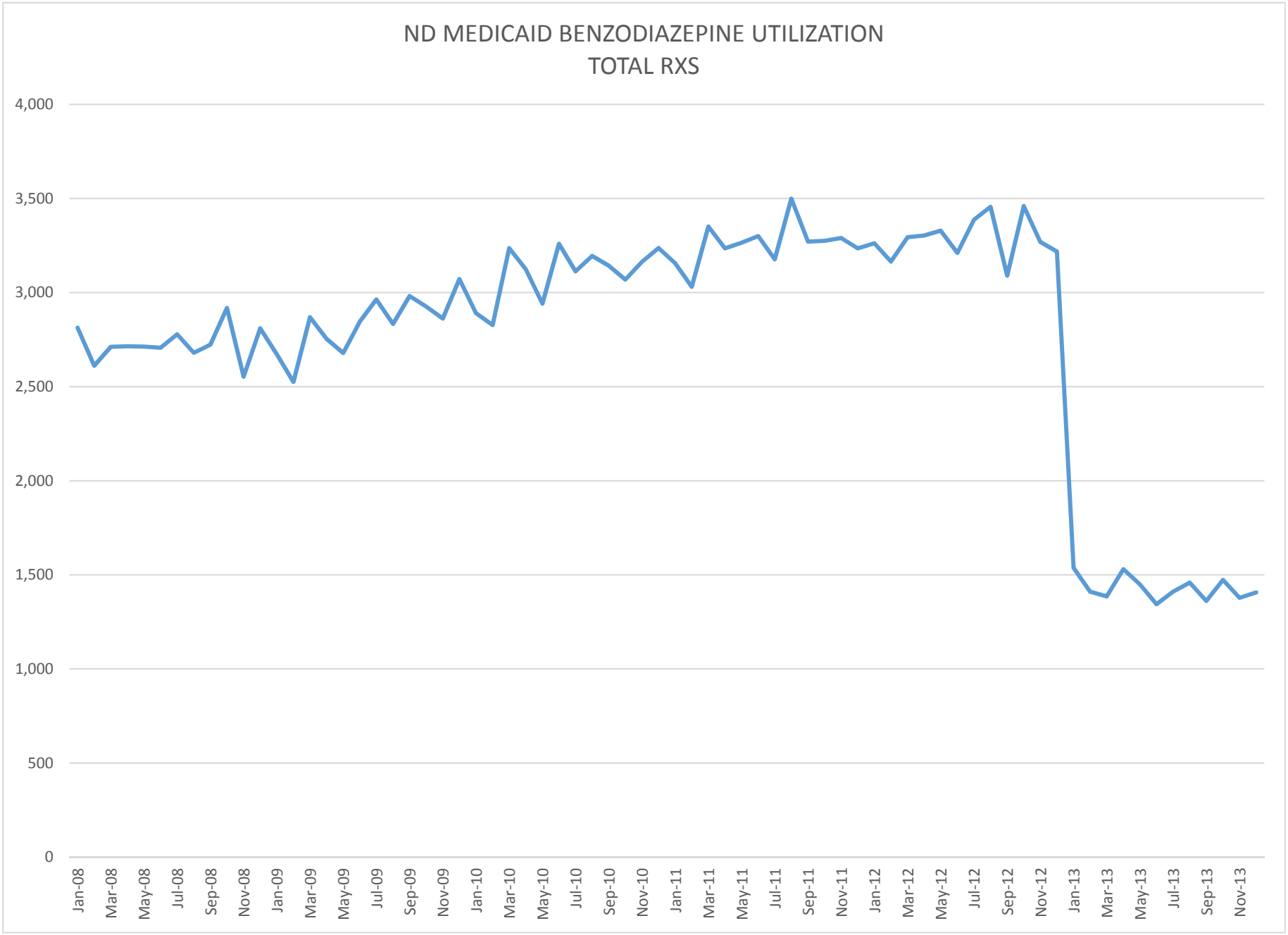
Jul-13
Sep-13
Nov-13


ND MEDICAID BENZODIAZEPINE UTILIZATION
TOTAL RXS
4,000
3,500
3,000
2,500
2,000
1,500
1,000
500
0
Jan-08
Mar-08
May-08
Jul-08
Sep-08
Nov-08
Jan-09
Mar-09
May-09
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Nov-09
Jan-10
Mar-10
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Jul-10
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May-11
Jul-11
Sep-11
Nov-11
Jan-12
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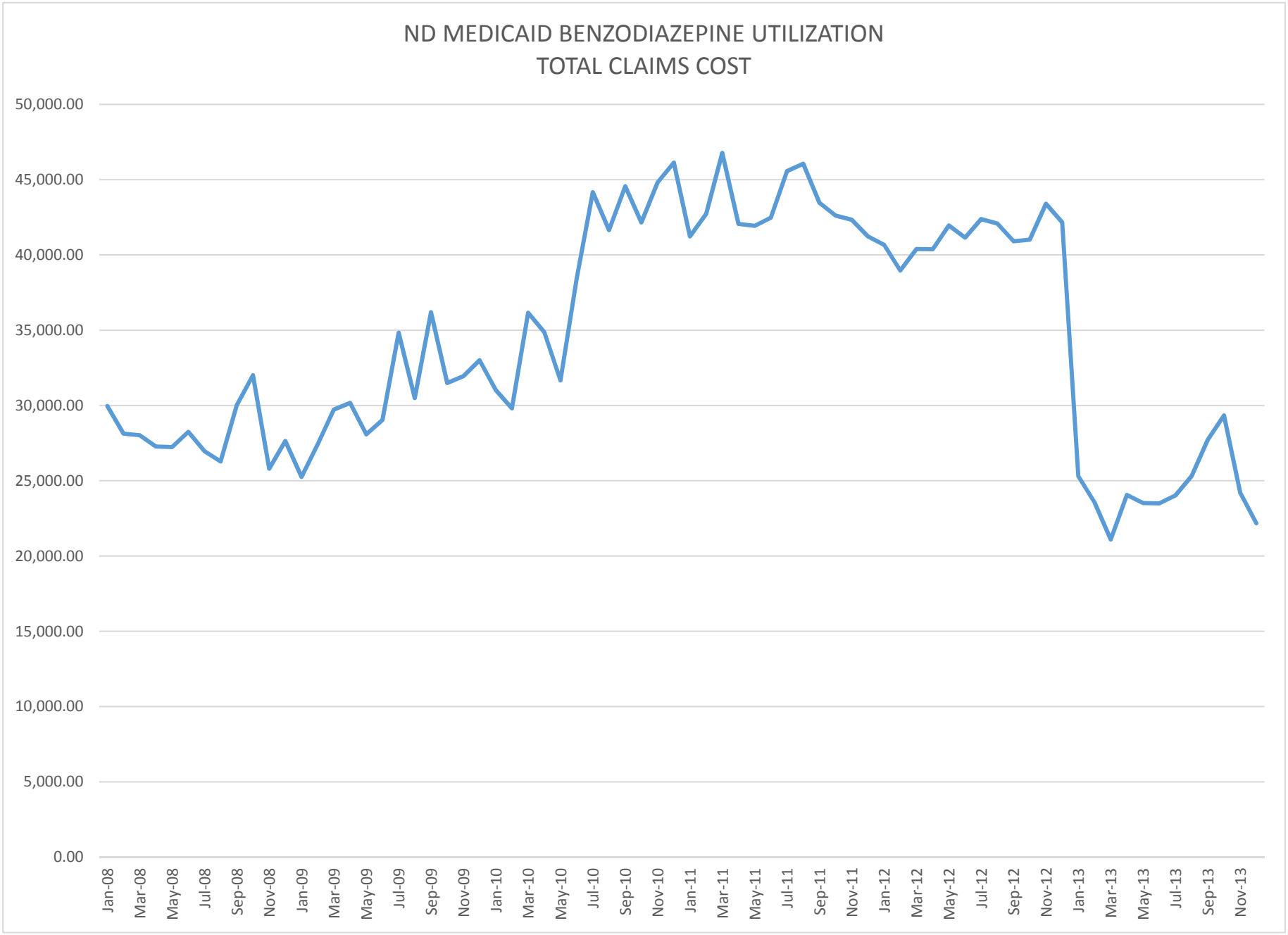
May-12
Jul-12
Sep-12
Nov-12
Jan-13
Mar-13
May-13
Jul-13
Sep-13
Nov-13


ND MEDICAID BENZODIAZEPINE UTILIZATION
TOTAL CLAIMS COST
50,000.00
45,000.00
40,000.00
35,000.00
30,000.00
25,000.00
20,000.00
15,000.00
10,000.00
5,000.00
0.00
Jan-08
Mar-08
May-08
Jul-08
Sep-08
Nov-08
Jan-09
Mar-09
May-09
Jul-09
Sep-09
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Nov-13

PRODUCT DETAILS OF TRANSDERMAL ANDROGENS

INDICATIONS AND USE: Transdermal androgens are indicated for the management of male hypogonadism. Hypogonadism is a defect of the reproductive system which results in a lack of function of the gonads (testes). It can be categorized by the level of the reproductive system that is defective. Primary hypogonadism results from a defect of the gonads while secondary hypogonadism (hypogonadotropic hypogonadism) results from defects in the hypothalamus or pituitary.

DOSAGE FORMS: Transdermal androgens are available as patches, gels, and solutions.

ADMINISTRATION:

- AndroGel 1% – initial, 50 mg once daily in the morning; maintenance, 50 to 100 mg/day.
- AndroGel 1.62% – initial, 40.5 mg applied topically once daily in the morning; maintenance, 20.25 to 81 mg/day.
- Androderm – initial, 4 mg/day applied nightly for 24 hours; maintenance, 2 to 6 mg/day applied at night.
- Fortesta – initial, 40 mg applied once daily in the morning; maintenance, 10 to 70 mg/day.
- Testim – initial, 5 g once daily; maintenance, 5 to 10 g/day.
- Axiron – initial, 60 mg applied once daily in the morning; maintenance, 30 to 120 mg/day.
- Vogelxo – initial, 50 mg applied topically once daily; maintenance 50 to 100 mg/day.

SPECIAL POPULATIONS:

- Safety and efficacy in patients younger than 18 years have not been established.

WARNINGS AND PRECAUTIONS:

- Black Box Warning – Virilization has been reported in children who were secondarily exposed to transdermal testosterone. Ensure that children avoid contact with unwashed or unclothed application sites in men using transdermal testosterone.
- Monitor patients with benign prostatic hyperplasia (BPH) for worsening signs and symptoms.
- Venous thromboembolism (VTE), including deep vein thrombosis (DVT) and pulmonary embolism (PE) have been reported in patients using testosterone products.
- Exogenous administration of androgens may lead to azoospermia.
- Edema, with or without congestive heart failure, may be a complication in patients with preexisting cardiac, renal, or hepatic disease.
- Sleep apnea may occur in those with risk factors.
- Monitor serum testosterone, prostate specific antigen (PSA), hematocrit, hemoglobin, liver function, and lipid concentrations periodically.

ADVERSE REACTIONS: Most common adverse reactions (incidences ≥ 5%) are acne, application site reaction, abnormal lab tests, and prostatic disorders.

PATIENT COUNSELING INFORMATION:

- Men with known or suspected carcinoma of the breast or prostrate should not use testosterone gel.
- Know signs and symptoms of secondary exposure in children and women.
- Wash hands with soap and water after application.
- Cover the application site with clothing after the gel has dried.
- Wash the application site thoroughly with soap and water prior to any situation where skin-to-skin contact of the application site with another person is anticipated.
- Testosterone gel is an alcohol-based product and is flammable; therefore, avoid fire, flame, or smoking until the gel has dried.
- Be aware of the potential adverse reactions with androgens: changes in urinary habits, breathing disturbances, too frequent or persistent erections of the penis, nausea, vomiting, changes in skin color, or ankle swelling.
- Wait 2 hours before swimming or washing following application.

UTILIZATION:

ND Medicaid Testosterone Utilization			
06/01/13 - 05/31-14			
Label Name	**Rx Num**	**Total Reimb Amt**	**Avg Cost per Script**
ANDROGEL 1% GEL PUMP	10	$3,968.45	$396.85
ANDROGEL 1%(2.5G) GEL PACKET	4	$5,326.42	$1,331.61
ANDROGEL 1%(5G) GEL PACKET	2	$844.38	$422.19
ANDROGEL 1.62% GEL PUMP	31	$14,585.16	$470.49
ANDROGEL 1.62%(2.5G) GEL PCKT	5	$1,921.45	$384.29
AXIRON 30 MG/ACTUATION SOLN	3	$1,278.27	$426.09
DEPO-TESTOSTERONE 200 MG/ML	19	$843.26	$44.38
METHITEST 10 MG TABLET	3	$118.05	$39.35
TESTIM 1% (50MG) GEL	3	$1,204.77	$401.59
TESTOSTERON CYP 2,000 MG/10 ML	20	$1,402.90	$70.15
26 recipients	**100**	**$31,493.11**	

References:

1. Vogelxo [package insert]. Maple Grove, MN: Upsher-Smith Laboratories, Inc.; June 2014.
2. Axiron [package insert]. Indianapolis, IN: Lilly USA, LLC: June 2014.
3. Fortesta [package insert]. Malvern, PA: Endo Pharmaceuticals, Inc.; June 2014.
4. Androderm [package insert]. Parsippany, NY: Watson; November 2013.
5. Androgel [package insert]. North Chicago, IL: AbbVie, Inc.; June 2014.
6. Testim [package insert]. Chesterbrook, PA: Auxilium Pharmaceuticals, Inc.; June 2014.

PRODUCT DETAILS OF PHOSPHATE BINDERS

INDICATIONS AND USE: The mainstay of therapy for patients with chronic kidney disease (CKD) unable to excrete phosphate is dietary restriction of phosphate. However, high concentrations of phosphorous are found in many foods including dairy products, nuts, and meat. Consequently, most patients with chronic kidney disease (CKD) will require a phosphate-binding medication. Maintaining serum phosphorus levels of 2.7 to 4.6 mg/dL in patients who are not receiving dialysis and 3.5 to 5.5 mg/dL in those receiving dialysis is generally considered a clinically acceptable outcome of treatment with phosphate binders.

Drug	Indication
Calcium acetate (Phoslo, Eliphos, others)	To reduce serum phosphate in patients with end-stage renal disease (ESRD).
Lanthanum carbonate (Fosrenol)	To reduce serum phosphate in patients with end-stage renal disease (ESRD).
Sevelamer hydrochloride (Renagel)	Control of serum phosphorous levels in patients with CKD on dialysis.
Sevelamer carbonate (Renvela)	Control of serum phosphorous levels in patients with CKD on dialysis.
Sucroferric oxyhydroxide (Velphoro)	Control of serum phosphorous levels in patients with CKD on dialysis.

DOSAGE FORMS: Phosphate binders are available in capsules, solution, tablets, suspension, and chewable tablets.

ADMINISTRATION:

- Calcium acetate – 1334 mg three times daily with meals
- Lanthanum carbonate – 500 mg three times daily with meals
- Sevelamer hydrochloride – 800 to 1600 mg three times daily with meals
- Sevelamer carbonate – 800 to 1600 mg three times daily with meals
- Sucroferric oxyhydroxide – 500 mg three times daily with meals.

SPECIAL POPULATIONS:

- Safety and efficacy have not been established in pediatric patients.
- Pregnancy category B (sucroferric oxyhydroxide)
- Pregnancy category C (sevelamer, lanthanum, calcium acetate)

WARNINGS AND PRECAUTIONS:

- Patients with peritonitis during peritoneal dialysis, significant gastric or hepatic disorders, following major gastrointestinal surgery, or with a history of hemochromatosis or other diseases with iron accumulation have not been included in clinical studies with sucroferric oxyhydroxide. Monitor effect and iron homeostasis.

- Serious cases of dysphagia, bowel obstruction, and perforation have been associated with sevelamer use, some requiring hospitalization and surgery.
- Chew or crush lanthanum carbonate completely to reduce the risk of serious adverse effects.
- Serious cases of gastrointestinal obstruction, ileus, and fecal impaction have been associated with lanthanum use, some requiring surgery or hospitalization. Risk factors include altered gastrointestinal anatomy, hypomotility disorders and concomitant medications.
- Lanthanum has radio-opaque properties and therefore may give the appearance typical of an imaging agent during abdominal X-ray procedures.
- Patients with end stage renal disease (ESRD) may develop hypercalcemia while treated with calcium. Monitor calcium levels regularly.

ADVERSE REACTIONS: Most common adverse reactions include discolored feces, diarrhea, hypercalcemia (calcium acetate), nausea, vomiting, and abdominal pain.

PATIENT COUNSELING INFORMATION:

- Take with or immediately after meals.
- Chew or crush completely before swallowing (lanthanum carbonate)
- Report new onset or worsening of existing constipation promptly to a physician.
- Tablets must be chewed and not swallowed whole (sucroferric oxyhydroxide)

UTILIZATION:

ND Medicaid Phosphate-Binder Utilization			
06/01/13 - 05/31/14			
Label Name	**Rx Num**	**Total Remb Amt**	**Avg Cost per Script**
CALCIUM ACETATE 667 MG CAPSULE	108	$10,215.64	$94.59
CALCIUM ACETATE 667 MG GELCAP	4	$403.49	$100.87
CALCIUM ACETATE 667 MG TABLET	6	$452.04	$75.34
FOSRENOL 1,000 MG TABLET CHEW	14	$11,177.29	$798.38
FOSRENOL 500 MG TABLET CHEW	3	$4,635.33	$1,545.11
RENAGEL 800 MG TABLET	15	$23,520.88	$1,568.06
RENVELA 0.8 GM POWDER PACKET	1	$346.20	$346.20
RENVELA 800 MG TABLET	79	$36,397.23	$460.72
36 recipients	**230**	**$87,148.10**	

References:

1. Velphoro [package insert]. Waltham, MA: Fresenius Medical Care North America; December 2013.
2. Renagel [package insert]. Cambridge, MA: Genzyme: May 2011.
3. Renvela [package insert]. Cambridge, MA: Genzyme; May 2011.
4. Fosrenol [package insert]. Wayne, PA: Shire US, Inc.; October 2012.

PRODUCT DETAILS OF ZONTIVITY (VORAPAXAR)

INDICATIONS AND USE: Zontivity is a protease-activated receptor-1 (PAR-1) antagonist indicated for the reduction of thrombotic cardiovascular events in patients with a history of myocardial infarction (MI) or with peripheral arterial disease (PAD). Zontivity has been shown to reduce the rate of a combined endpoint of cardiovascular death, MI, stroke, and urgent coronary revascularization.

DOSAGE FORMS: Zontivity is available as 2.08 mg tablets.

ADMINISTRATION: Take one tablet of Zontivity 2.08 mg orally once daily, with or without food. There is no experience with use of Zontivity alone as the only administered antiplatelet agent. Zontivity has been studied only as an addition to aspirin and/or clopidogrel. There is limited clinical experience with other antiplatelet drugs.

SPECIAL POPULATIONS:

- Zontivity is classified as pregnancy category B. There are no adequate and well-controlled studies of Zontivity use in pregnant women.
- It is unknown whether Zontivity or its metabolites are excreted in human milk, but it is actively secreted in milk of rats. Because many drugs are excreted in human milk, and because of the potential for serious adverse reactions in nursing infants from Zontivity, discontinue nursing or discontinue Zontivity.
- The safety and effectiveness of Zontivity in pediatric patients have not been established.
- Because older patients are generally at a higher risk of bleeding, consider patient age before initiating Zontivity.

WARNINGS AND PRECAUTIONS:

- Like other antiplatelet agents, Zontivity increases the risk of bleeding.
- Avoid use with strong CYP3A inhibitors or inducers.

ADVERSE REACTIONS:

- Black Box Warning-Do not use Zontivity in patients with a history of stroke, transient ischemic attack (TIA), intracranial hemorrhage (ICH), or active pathological bleeding.
- Bleeding, including life-threatening and fatal bleeding, is the most commonly reported adverse reaction.

PATIENT COUNSELING INFORMATION:

- Take medication exactly as prescribed.
- Do not discontinue Zontivity without discussing with the prescribing physician.
- Report any unanticipated, prolonged, or excessive bleeding, or blood in the stool or urine.
- Inform physicians and dentists of Zontivity use before surgery or dental procedures.

- List all prescription medications, over-the-counter medications, or dietary supplements they are taking or plan to take so that the physician knows about other treatments that may affect bleeding risk.

References:

1. Zontivity© [package insert]. Whitehouse Station, NJ: Merck & Co., Inc.; May 2014.

PRODUCT DETAILS OF EVZIO (NALOXONE HYDROCHLORIDE INJECTION)

INDICATIONS AND USE: Evzio is an opioid antagonist indicated for the emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression. Evzio is intended for immediate administration as emergency therapy in settings where opioids may be present.

DOSAGE FORMS: Evzio is available as a 0.4mg/0.4mL naloxone hydrochloride solution in a pre-filled auto-injector.

ADMINISTRATION: Administer the initial dose of Evzio to adult or pediatric patients intramuscularly or subcutaneously into the anterolateral aspect of the thigh, through clothing if necessary, and seek emergency medical assistance. Administer Evzio as quickly as possible because prolonged respiratory depression may result in damage to the central nervous system or death. The requirement for repeat doses of Evzio depends upon the amount, type, and route of administration of the opioid being antagonized.

If the desired response is not obtained after 2 or 3 minutes, another Evzio dose may be administered. If there is still no response and additional doses are available, additional Evzio doses may be administered every 2 to 3 minutes until emergency medical assistance arrives. Additional supportive and/or resuscitative measures may be helpful while awaiting emergency medical assistance.

Reversal of respiratory depression by partial agonists or mixed agonist/antagonists, such as buprenorphine and pentazocine, may be incomplete or require higher doses of naloxone.

SPECIAL POPULATIONS:

- Evzio is classified as pregnancy category B. There are no adequate and well-controlled studies of Evzio in pregnant women.
- Exercise caution when Evzio is administered to a nursing woman.
- The safety and effectiveness of Evzio have been established in pediatric patients for known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression.
- Geriatric patients have a greater frequency of decreased hepatic, renal, or cardiac function and of concomitant disease or other drug therapy. Therefore, the systemic exposure of naloxone can be higher in these patients.

WARNINGS AND PRECAUTIONS:

- Due to the duration of action, keep the patient under continued surveillance and repeated doses of naloxone should be administered, as necessary, while awaiting emergency medical assistance.
- Other supportive and/or resuscitative measures may be helpful while awaiting emergency medical assistance.

- Reversal of respiratory depression by partial agonists or mixed agonists/ antagonists, such as buprenorphine and pentazocine, may be incomplete.
- Use in patients who are opioid dependent may precipitate acute abstinence syndrome.
- Patients with pre-existing cardiac disease or patients who have received medications with potential adverse cardiovascular effects should be monitored in an appropriate healthcare setting.
- In neonates, opioid withdrawal may be life-threatening if not recognized and properly treated.

ADVERSE REACTIONS: The following adverse reactions have been identified during use of naloxone hydrochloride in the post-operative setting: Hypotension, hypertension, ventricular tachycardia and fibrillation, dyspnea, pulmonary edema, and cardiac arrest. Death, coma, and encephalopathy have been reported as sequelae of these events. Excessive doses of naloxone hydrochloride in post-operative patients have resulted in significant reversal of analgesia and have caused agitation.

Abrupt reversal of opioid effects in persons who were physically dependent on opioids has precipitated signs and symptoms of opioid withdrawal including: body aches, fever, sweating, runny nose, sneezing, piloerection, yawning, weakness, shivering or trembling, nervousness, restlessness or irritability, diarrhea, nausea or vomiting, abdominal cramps, increased blood pressure, tachycardia. In the neonate, opioid withdrawal signs and symptoms also included: convulsions, excessive crying, hyperactive reflexes.

PATIENT COUNSELING INFORMATION:

- Become familiar with the Evzio instructions for use.
- Practice using the trainer before Evzio is needed.
- Each Evzio can only be used one time; however, the trainer (which is black and white) can be re-used for training purposes and its red safety guard can be removed and replaced.
- Make sure Evzio is present whenever persons may be intentionally or accidentally exposed to an opioid to treat serious opioid overdose (i.e., opioid emergencies).
- Instruct the patients and their family members or caregivers how to recognize the signs and symptoms of an opioid overdose requiring the use of Evzio.
- When in doubt, if a patient is unresponsive, and an opioid overdose is suspected, administer Evzio as quickly as possible because prolonged respiratory depression may result in damage to the central nervous system or death.
- Seek emergency medical assistance after administering the first dose of Evzio.

References:

1. Evzio [package insert]. Richmond, VA: Kaleo, Inc.; April 2014.

NORTH DAKOTA MEDICAID
RETROSPECTIVE DRUG UTILIZATION REVIEW
CRITERIA RECOMMENDATIONS
3RD QUARTER 2014

Criteria Recommendations ***Approved Rejected***

1. Eslicarbazepine / Overutilization _____ _____

Alert Message: The manufacturer's maximum recommended dose of Aptiom (eslicarbazepine) is 1200 mg once daily (after a minimum of one week at 800 mg once daily). This dosage is associated with an increase in adverse reactions.

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C **(Negating)**
Eslicarbazepine		CKD Stage 3, 4 & 5
		ESRD

Max Dose: 1200 mg/day

References:
Aptiom Prescribing Information, Nov. 2013, Sunovion.
Clinical Pharmacology, 2014 Elsevier/Gold Standard.

2. Eslicarbazepine / Overutilization – Moderate & Severe Renal Impairment _____ _____

Alert Message: The manufacturer's maximum recommended dose of Aptiom (eslicarbazepine) in patients with moderate to severe renal impairment is 600 mg once daily. These patients should be titrated starting at 200 mg once daily and after two weeks, increase dosage to 400 mg once daily, which is the recommended maintenance dosage.

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C **(Include)**
Eslicarbazepine		CKD Stage 3, 4 & 5
		ESRD

Max Dose: 600 mg/day

References:
Aptiom Prescribing Information, Nov. 2013, Sunovion.
Clinical Pharmacology, 2014 Elsevier/Gold Standard.

3. Eslicarbazepine / Non-adherence _____ _____

Alert Message: Based on refill history, your patients may be under-utilizing Aptiom (eslicarbazepine). 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 – Non-adherence
Drugs/Diseases

Util A	Util B	Util C
Eslicarbazepine		

References:
Aptiom Prescribing Information, Nov. 2013, Sunovion.
Faught E, Duh MS, Weiner JR., Nonadherence to Antiepileptic Drugs and Increased Mortality. 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.

4. Eslicarbazepine / Therapeutic Appropriateness _____ _____

Alert Message: Aptiom (eslicarbazepine) can cause clinically significant, and in some cases, serious, life-threatening hyponatremia. Measurement of serum sodium and chloride levels should be considered during maintenance treatment with eslicarbazepine, particularly if the patient is receiving medications known to decrease serum sodium levels.

Conflict Code: TA - Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C
Eslicarbazepine		

References:
Aptiom Prescribing Information, Nov. 2013, Sunovion.
Clinical Pharmacology, 2014 Elsevier/Gold Standard.

5. Eslicarbazepine / Therapeutic Appropriateness _____ _____

Alert Message: Serious dermatologic reactions including Steven-Johnson Syndrome (SJS) have been reported in association with Aptiom (eslicarbazepine) use. If a patient develops a dermatologic reaction while taking eslicarbazepine, discontinue eslicarbazepine, unless the reaction is clearly not drug-related.

Conflict Code: TA - Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C
Eslicarbazepine		

References:
Aptiom Prescribing Information, Nov. 2013, Sunovion.
Clinical Pharmacology, 2014 Elsevier/Gold Standard.

6. Eslicarbazepine / Jaundice _____ _____

Alert Message: Aptiom (eslicarbazepine) can cause liver injury and baseline evaluations of liver laboratory tests are recommended. Eslicarbazepine should be discontinued in patients with jaundice or other evidence of significant liver injury (e.g., laboratory evidence).

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

Util A	Util B	Util C
Eslicarbazepine	Jaundice	

References:
Aptiom Prescribing Information, Nov. 2013, Sunovion.
Clinical Pharmacology, 2014 Elsevier/Gold Standard.

7. Eslicarbazepine / Oral Hormonal Contraceptives _____ _____

Alert Message: Concurrent use of Aptiom (eslicarbazepine) with oral hormonal contraceptives (OC) may result in decreased plasma levels of the OC and loss of contraceptive efficacy. Females of reproductive potential should use additional or alternative non-hormonal birth control.

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

Util A	Util B	Util C
Eslicarbazepine	Hormonal Oral Contraceptives	

Gender: Females
Age: 11-55 yoa

References:
Aptiom Prescribing Information, Nov. 2013, Sunovion.
Clinical Pharmacology, 2014 Elsevier/Gold Standard.

8. Eslicarbazepine / Warfarin _____ _____

Alert Message: Concurrent use of Aptiom (eslicarbazepine) with warfarin may result in decreased warfarin plasma concentrations. Patients receiving concurrent therapy with these agents should have INR monitored, particularly during eslicarbazepine initiation or upon discontinuation of concomitant therapy.

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

Util A	Util B	Util C
Eslicarbazepine	Warfarin	

References:
Aptiom Prescribing Information, Nov. 2013, Sunovion.
Clinical Pharmacology, 2014 Elsevier/Gold Standard.

9. Eslicarbazepine / Carbamazepine _____ _____

Alert Message: Concurrent use of Aptiom (eslicarbazepine) with carbamazepine may require dosage adjustment of one or both drugs, based on efficacy and tolerability. Both agents increase the clearance of the other. The agents are also chemically related and concomitant use has been shown to increase the incidence of adverse reactions.

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

Util A	Util B	Util C
Eslicarbazepine	Carbamazepine	

References:
Aptiom Prescribing Information, Nov. 2013, Sunovion.
Clinical Pharmacology, 2014 Elsevier/Gold Standard.

10. Eslicarbazepine / Phenytoin _____ _____

Alert Message: Concurrent use of Aptiom (eslicarbazepine) with phenytoin may require dosage adjustment of one or both agents. Phenytoin may induce eslicarbazepine metabolism decreasing plasma concentrations while eslicarbazepine may inhibit phenytoin metabolism increasing phenytoin concentrations. Phenytoin plasma concentrations should be monitored during concurrent therapy and dose adjustment made based on clinical response and serum levels.

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

Util A	Util B	Util C
Eslicarbazepine	Phenytoin	

References:
Aptiom Prescribing Information, Nov. 2013, Sunovion.
Clinical Pharmacology, 2014 Elsevier/Gold Standard.

11. Eslicarbazepine / Phenobarbital & Primidone _____ _____

Alert Message: Concurrent use of Aptiom (eslicarbazepine) with phenobarbital or primidone may require an increase in the eslicarbazepine dose. Phenobarbital and primidone may induce eslicarbazepine metabolism decreasing plasma concentrations.

Conflict Code: DD – Drug/Drug Interaction

Drugs/Diseases

Util A	Util B	Util C
Eslicarbazepine	Phenobarbital Primidone	

References:
Aptiom Prescribing Information, Nov. 2013, Sunovion.
Clinical Pharmacology, 2014 Elsevier/Gold Standard.

12. Eslicarbazepine / Simvastatin & Rosuvastatin _____ _____

Alert Message: Concurrent use of Aptiom (eslicarbazepine) with either simvastatin or rosuvastatin may result in decreased systemic exposure of the statin due to inhibition, by eslicarbazepine, of statin CYP3A4-mediated metabolism. Dose adjustment of simvastatin or rosuvastatin may be needed, if clinically significant changes in serum lipids are noted.

Conflict Code: DD – Drug/Drug Interaction

Drugs/Diseases

Util A	Util B	Util C
Eslicarbazepine	Simvastatin Rosuvastatin	

References:
Aptiom Prescribing Information, Nov. 2013, Sunovion.
Clinical Pharmacology, 2014 Elsevier/Gold Standard.

13. Eslicarbazepine / Oxcarbazepine _____ _____

Alert Message: Aptiom (eslicarbazepine) should not be taken as an adjunctive therapy with oxcarbazepine. Eslicarbazepine is a prodrug for the active metabolite of oxcarbazepine and concurrent use may result in increased active metabolite levels.

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

Util A	Util B	Util C
Eslicarbazepine	Oxcarbazepine	

References:
Aptiom Prescribing Information, Nov. 2013, Sunovion.
Clinical Pharmacology, 2014 Elsevier/Gold Standard.

14. Tolvaptan / Liver Disease _____ _____

Alert Message: Samsca (tolvaptan) can cause serious and potentially fatal liver injury. The use of tolvaptan should be avoided in patients with underlying liver disease, including cirrhosis, because the ability to recover from liver injury may be impaired.

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

Util A	Util B	Util C
Tolvaptan	Cirrhosis	
	Necrosis of Liver	
	Hepatitis	
	Liver Disorders	

References:
Clinical Pharmacology, 2014 Elsevier/Gold Standard.
Facts & Comparisons, 2014 Updates, Wolters Kluwer Healthcare.
Samsca Prescribing Information, Feb. 2014, Otsuka Pharmaceuticals Co., Ltd.

15. Tolvaptan / Therapeutic Appropriateness – Duration _____ _____

Alert Message: Samsca (tolvaptan) should not be administered for more than 30 days to minimize the risk of liver injury.

Conflict Code: TA - Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C
Tolvaptan		

Day Supply: > 30 days

References:
Clinical Pharmacology, 2014 Elsevier/Gold Standard.
Facts & Comparisons, 2014 Updates, Wolters Kluwer Healthcare.
Samsca Prescribing Information, Feb. 2014, Otsuka Pharmaceuticals Co., Ltd.

16. ARBs / Lithium _____ _____

Alert Message: Concurrent use of lithium with an angiotensin II receptor antagonist (ARB) may result in substantially increased steady-state plasma lithium levels, sometimes resulting in lithium toxicity. If concurrent use is required, monitor lithium concentrations and adjust lithium dosage as needed.

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

Util A	Util B	Util C
Losartan	Lithium	
Valsartan		
Candesartan		
Eprosartan		
Irbesartan		
Olmesartan		
Telmisartan		
Azilsartan		

References:
Clinical Pharmacology, 2014 Elsevier/Gold Standard.
Facts & Comparisons, 2014 Updates, Wolters Kluwer Healthcare.

17. Econazole / Warfarin _____ _____

Alert Message: Concurrent use of econazole 1% cream or foam with warfarin has resulted in enhanced anticoagulant effect. Most cases reported product application with the use under occlusion, genital application or application to large body surface area which may increase the systemic absorption of econazole. If concomitant therapy is clinically indicated, monitor INR and/or prothrombin time especially for patients who apply econazole to large body surface area, or under occlusion.

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

Util A	Util B	Util C
Econazole	Warfarin	

References:
Clinical Pharmacology, 2014 Elsevier/Gold Standard.
Micromedex DrugDex Drug Evaluations, 2014 Truven Health Analytics, Inc.
Spectazole 1% Topical Cream Feb. 2014, Merz Pharmaceuticals LLC.
Facts & Comparisons, 2014 Updates, Wolters Kluwer Health.

18. Ketoconazole / Disopyramide _____ _____

Alert Message: Concurrent use of ketoconazole and disopyramide is contraindicated due to risk of serious cardiovascular adverse events including QT prolongation. Disopyramide is a CYP3A4 substrate and use with the potent CYP3A4 inhibitor ketoconazole may result in elevated disopyramide plasma concentrations and associated toxicity.

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

Util A	Util B	Util C
Ketoconazole	Disopyramide	

References:
Clinical Pharmacology, 2014 Elsevier/Gold Standard.
Nizoral Prescribing Information, Feb. 2014, Janssen Pharmaceuticals, Inc.

19. Ketoconazole / Colchicine _____ _____

Alert Message: Concurrent use of ketoconazole and colchicine is contraindicated due to risk of colchicine toxicity. Colchicine is a CYP3A4 substrate and use with the potent CYP3A4 inhibitor ketoconazole may result in elevated colchicine plasma concentrations and associated toxicity.

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

Util A	Util B	Util C
Ketoconazole	Colchicine	

References:
Clinical Pharmacology, 2014 Elsevier/Gold Standard.
Nizoral Prescribing Information, Feb. 2014, Janssen Pharmaceuticals, Inc.

20. Ketoconazole / Felodipine & Nisoldipine _____ _____

Alert Message: Concurrent use of ketoconazole with felodipine or nisoldipine is contraindicated due to risk of calcium channel blocker (CCB) negative inotropic effects. Felodipine and nisoldipine are CYP3A4 substrates and use with the potent CYP3A4 inhibitor ketoconazole may result in increased CCB plasma concentrations and risk of edema and congestive heart failure.

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

Util A	Util B	Util C
Ketoconazole	Nisoldipine Felodipine	

References:
Clinical Pharmacology, 2014 Elsevier/Gold Standard.
Nizoral Prescribing Information, Feb. 2014, Janssen Pharmaceuticals, Inc.

21. Dapagliflozin / Overutilization _____ _____

Alert Message: The manufacturer's maximum recommended dose of Farxiga (dapagliflozin) is 10 mg once daily.

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C **(Negating)**
Dapagliflozin		Renal Impairment

Max Dose: 10mg/day

References:
Farxiga Prescribing Information, Jan. 2014, Bristol-Myers Squibb.
Clinical Pharmacology, 2014 Elsevier/Gold Standard.

22. Dapagliflozin / Moderate Renal impairment _____ _____

Alert Message: Assessment of renal function is recommended prior to initiation of Farxiga (dapagliflozin) therapy and periodically thereafter. Dapagliflozin should not be initiated in patients with an eGFR less than 60 mL/min/1.73m^2 and should be discontinued when eGFR is persistently less than 60mL/ min/1.73m^2.

Conflict Code: TA - Therapeutic Appropriateness
Drugs/Diseases

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

References:
Farxiga Prescribing Information, Jan. 2014, Bristol-Myers Squibb.
Clinical Pharmacology, 2014 Elsevier/Gold Standard.

23. Dapagliflozin / Severe Renal Impairment, ESRD & Dialysis _____ _____

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

Conflict Code: TA - Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C **(Include)**
Dapagliflozin		CKD Stage 4, & 5 End-Stage Renal Disease Dialysis

References:
Farxiga Prescribing Information, Jan. 2014, Bristol-Myers Squibb.
Clinical Pharmacology, 2014 Elsevier/Gold Standard.

24. Dapagliflozin / Nonadherence _____ _____

Alert Message: Based on refill history, your patient may be under-utilizing Farxiga (dapagliflozin). 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
Dapagliflozin		

References:
Farxiga Prescribing Information, Jan. 2014, Bristol-Myers Squibb.
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.

25. Dapagliflozin / Hypotension _____ _____

Alert Message: Farxiga (dapagliflozin) causes osmotic diurese which can lead to volume depletion and hypotension, particularly in patients with impaired renal function, elderly patients or patients on loop diuretics. Monitor patients for signs and symptoms during therapy. Before initiating dapagliflozin 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
Dapagliflozin	Hypotension	
	Hypovolemia	
	CKD Stage 3	
	Dehydration	

References:
Farxiga Prescribing Information, Jan. 2014, Bristol-Myers Squibb.
Clinical Pharmacology, 2014 Elsevier/Gold Standard.

26. Dapagliflozin / Loop Diuretics _____ _____

Alert Message: Farxiga (dapagliflozin) causes osmotic diurese which can lead to volume depletion and hypotension, particularly in patients with impaired renal function, elderly patients or patients on loop diuretics. Monitor patients for signs and symptoms during therapy. Before initiating dapagliflozin 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
Dapagliflozin	Furosemide	
	Torsemide	
	Ethacrynate	
	Bumetanide	

References:
Farxiga Prescribing Information, Jan. 2014, Bristol-Myers Squibb.
Clinical Pharmacology, 2014 Elsevier/Gold Standard.

27. Dapagliflozin / Insulin & Insulin Secretagogues _____ _____

Alert Message: The concurrent use of Farxiga (dapagliflozin) 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 dapagliflozin.

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

Util A	Util B	Util C
Dapagliflozin	Insulins	
	Sulfonylureas	

References:
Farxiga Prescribing Information, Jan. 2014, Bristol-Myers Squibb.
Clinical Pharmacology, 2014 Elsevier/Gold Standard.

28. Dapagliflozin / LDL-C Increases _____ _____

Alert Message: The use of Farxiga (dapagliflozin) can cause dose-related increases in LDL-C levels. Patients receiving dapagliflozin 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
Dapagliflozin	Hypercholesterolemia	

References:
Farxiga Prescribing Information, Jan. 2014, Bristol-Myers Squibb.
Clinical Pharmacology, 2014 Elsevier/Gold Standard.

29. Dapagliflozin / Bladder Cancer _____ _____

Alert Message: An imbalance in bladder cancers was observed in Farxiga (dapagliflozin) clinical trials. Dapagliflozin should not be used in patients with active bladder cancer and used with caution in patients with a prior history of bladder cancer.

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

Util A	Util B	Util C
Dapagliflozin		Neoplasm of Bladder
		History of Malignant Neoplasm of Bladder

References:
Farxiga Prescribing Information, Jan. 2014, Bristol-Myers Squibb.
Clinical Pharmacology, 2014 Elsevier/Gold Standard.

30. SGLT2 Inhibitors / Therapeutic Duplication _____ _____

Alert Message: Therapeutic duplication of sodium-glucose co-transporter 2 (SGLT2) inhibitors may be occurring.

Conflict Code: TD – Therapeutic Duplication
Drugs/Diseases

Util A	Util B	Util C
Dapagliflozin		
Canagliflozin		

References:
Farxiga Prescribing Information, Jan. 2014, Bristol-Myers Squibb.
Clinical Pharmacology, 2014 Elsevier/Gold Standard.

31. Ketoconazole / Methadone _____ _____

Alert Message: Concurrent use of ketoconazole and methadone is contraindicated due to risk of serious cardiovascular adverse events including QT prolongation and respiratory and/or CNS depression. Methadone is a CYP3A4 substrate and use with the potent CYP3A4 inhibitor ketoconazole may result in elevated methadone plasma concentrations.

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

Util A	Util B	Util C
Ketoconazole	Methadone	

References:
Clinical Pharmacology, 2014 Elsevier/Gold Standard.
Nizoral Prescribing Information, Feb. 2014, Janssen Pharmaceuticals, Inc.

32. Testosterone / Venous Thrombosis _____ _____

Alert Message: There have been postmarketing reports of venous thromboembolism (VTE), including deep vein thrombosis (DVT) and pulmonary embolism (PE), in patients using testosterone products. The risk of venous clots is unrelated to polycythemia that can occur with testosterone therapy. Evaluate patients who report symptoms of pain, edema, warmth, and erythema in the lower extremity for DVT and those who present with acute shortness of breath for PE. If a VTE is suspected, discontinue testosterone treatment and initiate appropriate management.

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C
Testosterone		

References:
Natesto Prescribing Information, May 2014, Trimel BioPharma SRL.
Vogelxo Prescribing Information, June 2014, Upsher-Smith Laboratories, Inc.
FDA Drug Safety and Availability: Testosterone Products: FDA/CDER Statement – Risk of Venous Blood Clots. [6-20-2014].

TABLED CRITERIA

1. ASCVD Inferring Drugs / High-Intensity Statin Therapy (Negating) _____ _____

Alert Message: The ACC/AHA Blood Cholesterol Guidelines recommend the use of high-intensity statin therapy, which lowers LDL-C at least 50%, to reduce atherosclerotic cardiovascular risk in adults 75 years of age and younger who have clinical ASCVD (e.g., CHD, stroke, and PAD), unless contraindicated. Moderate-intensity statin therapy should be used as a second-line option if high-intensity statin therapy is not tolerated. Refer to the ACC/AHA guidelines for agents and dosage.

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C **(Negating if High-Intensity Therapy Present)**
Nitrates		Atorvastatin 40mg & 80 mg
Cilostazol		Rosuvastatin 20 mg, 40 mg & 80 mg
Clopidogrel		
Prasugrel		
Ticagrelor		
Ticlopidine		
Dipyridamole/Aspirin		

Age Range: ≤ 75 yoa

References:
Stone NJ, Robinson J, Lichtenstein AH, et.al., 2013 ACC/AHA Guideline on the Treatment of Blood Cholesterol to Reduce Atherosclerotic Cardiovascular Risk in Adults, Jrnl Am Coll Cardiol (2013), doi:10.1016/j.jacc.2013.11.002.

DUR Board Meeting
December 3, 2014
Pioneer Room
State Capitol

North Dakota Medicaid
DUR Board Meeting Agenda
Pioneer Room
State Capitol
600 East Blvd. Avenue
Bismarck, ND
December 3, 2014
1pm

1. Administrative items
    - Travel vouchers
    - Introduction of new members

2. Old business

• Review and approval of minutes of 09/14 meeting	Chair
• Budget update	Brendan
• Update on Synagis	Brendan
• Update on benzodiazepine utilization	Brendan
• Second review of testosterone products	Brendan
• Second review of phosphate binders	Brendan
• Second review of Zontivity	Brendan
• Second review of Evzio	Brendan

3. New business

• Annual PA review	HID
• Criteria recommendations	HID
• Upcoming meeting date/agenda	Chair

4. Adjourn — Chair

Please remember to silence all cellular phones during the meeting.

Drug Utilization Review (DUR) Meeting Minutes
September 3, 2014

Members Present: John Savageau, Jeffrey Hostetter, Peter Woodrow, Russ Sobotta, Tanya Schmidt, Steve Irsfeld, Michael Booth, Carlotta McCleary, Laura Schield, Katie Kram, Wendy Brown, Emmet Kenney

Members Absent: Todd Twogood, James Carlson, Leann Ness

Medicaid Pharmacy Department: Brendan Joyce, Gary Betting

J. Savageau called the meeting to order at 1:00 p.m. Chair J. Savageau asked for a motion to approve the minutes from the June meeting. M. Booth moved that the minutes be approved, and P. Woodrow seconded the motion. Chair J. Savageau called for a voice vote to approve the minutes. The motion passed with no audible dissent.

Budget update
B. Joyce distributed and discussed a table showing drug rebate amounts from 1st quarter 2010 through 4th quarter 2013. Approximately 8-9 million dollars are paid out to pharmacies each quarter. Approximately 4-4.5 million dollars are recouped from drug rebates.

Northera second review
A motion and second were made at the June meeting to place Northera on prior authorization. The topic was brought up for a second review. There was no public comment. After discussion, Chair J. Savageau called for a voice vote to approve the motion. The motion passed with no audible dissent.

Oral allergen extracts second review
A motion and second were made at the June meeting to place oral allergen extracts on prior authorization. The topic was brought up for a second review. There was no public comment. After discussion, Chair J. Savageau called for a voice vote to approve the motion. The motion passed with no audible dissent.

Updated AAP guidelines for palivizumab prophylaxis
B. Joyce discussed the updated guidelines for palivizumab (Synagis). The updated guidelines were incorporated into a prior authorization form for the board to review. L. Willshaw, representing MedImmune, spoke regarding Synagis. A motion was made by K. Kram to accept the changes to the current Synagis form to reflect the updated AAP guidelines. W. Brown seconded the motion. Chair J. Savageau called for a voice vote to approve the motion. The motion passed with no audible dissent. The board asked that data be brought back to the December meeting showing how many children during the 2013-2014 Synagis season would not have received medication based on the new guidelines. The board also asked for RSV hospitalization information from the 2013-2014 season, if available. B. Joyce stated that hospitalization data would be virtually impossible to obtain because the diagnosis is not always used for billing purposes.

NDQuits protocol update
B. Joyce informed the board of changes in how the recipients receive the form with the updated protocol. Currently, ND Medicaid members who wish to use tobacco cessation medications are required to enroll in phone counseling provided by NDQuits. The new proposed process will allow coverage for medications when participating in face to face or group counseling, which will encourage more successful quit attempts.

Hepatitis C treatment and compliance
B. Joyce reviewed current treatment guidelines as well as utilization data for Sovaldi and Olysio. Board members reviewed prior authorization forms for Sovaldi and Olysio. The department would like guidance from the board on criteria for approval as well as long-term oversight to ensure compliance. The board made a recommendation that to demonstrate drug and alcohol free for the past 12 months that all PA requests would be accompanied by 12 months of urine screens.

Benzodiazepine review
B. Joyce reviewed benzodiazepine utilization with the board. Data regarding duplicate therapy of benzodiazepines was also discussed. The board asked that more information be provided at the December meeting including ages of recipients, prescribers, and diagnoses.

Transdermal androgen review
B. Joyce reviewed transdermal androgen information with the board. Mike Gonzales, representing Abbvie, spoke regarding Androgel. P. Woodrow made a motion to place transdermal androgens on prior authorization. J. Hostetter seconded the motion. This topic will be reviewed at the next meeting.

Phosphate binders review
B. Joyce reviewed phosphate binder information with the board. There was no public comment. M. Booth made a motion to place Velphoro on prior authorization. P. Woodrow seconded the motion. This topic will be reviewed at the next meeting.

Zontivity Review
B. Joyce reviewed Zontivity information with the board. There was no public comment. W. Brown made a motion to place Zontivity on prior authorization. P. Woodrow seconded the motion. This topic will be reviewed at the next meeting.

Evzio Review
B. Joyce reviewed Evzio information with the board. There was no public comment. J. Hostetter made a motion to place Evzio on prior authorization. L. Schield seconded the motion. 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 usually are consistent with new indications, new drugs added, new warnings, etc. 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 M. Booth seconded the motion. Chair J. Savageau called for a voice vote. The motion passed with no audible dissent.

The next DUR board meeting will be held December 3, in Bismarck. J. Hostetter made a motion to adjourn the meeting. P. Woodrow seconded. The motion passed with no audible dissent. J. Savageau adjourned the meeting.

Synagis Overview (2004 – 2014)

RSV Season	Amt Paid	# of Doses	Cost of Synagis	# of Patients Treated	# of PA's Approved	Total Costs	Preemies	# </= 2
2004-2005	$219,058.35	314	$ 332,411.82	61	-	$ 551,470.17	75	9958
2005-2006	$378,547.65	305	$ 376,323.11	63	-	$ 754,870.76	78	10301
2006-2007	$168,277.25	457	$ 551,636.87	98	-	$ 719,914.12	71	10412
2007-2008	$356,790.93	351	$ 480,680.57	76	-	$ 837,471.50	87	11014
2008-2009	$245,849.75	339	$ 475,015.41	73	-	$ 720,865.16	79	11797
2009-2010	$535,789.44	170	$ 264,035.47	54	87	$ 799,824.91	93	12665
2010-2011	$581,963.75	227	$ 405,387.46	67	99	$ 987,351.21	78	12937
2011-2012	$699,033.05	211	$ 382,138.46	65	117	$1,081,171.51	97	13025
2012-2013	$798,530.85	188	$ 376,351.47	60	92	$1,174,882.32	90	12963
2013-2014	$510,168.26	164	$ 333,557.31	61	114	$ 843,725.57	55	13259

RSV Season	Count of Premature Babies	Overall Recipient Count ≤ 2
2004-2005	75	9,958
2005-2006	78	10,301
2006-2007	71	10,412
2007-2008	87	11,014
2008-2009	79	11,797
2009-2010	93	12,665
2010-2011	78	12,937
2011-2012	97	13,025
2012-2013	90	12,963
2013-2014	55*	13,259

*providers may still bill for premature babies for this time period

Synagis Data – 2013/2014 season

138 total IDs (114 PA approvals and 24 billed medical with no PA)	
114 PAs approved	
61 billed on pharmacy side	
83 billed on medical side	
OVERALL PICTURE (114 PA approvals)	
51 do not meet guidelines	45%
51 meet guidelines	45%
12 TPL	
Breakdown of those that do not meet 2014 AAP guidelines	
29-31/6	18
32-34/6	33
Breakdown of those that meet 2014 AAP guidelines	
Pulmonary abnormalities	1
CLD	12
CHD	5
<29	33

Participants in Updated Guidance

- Bronchiolitis Guidelines Committee
- Committee on Infectious Diseases
- 21 Committees, Councils, Sections & Advisory Groups within the AAP
- Outside Groups
    - American Academy of Family physicians
    - American College of Chest Physicians
    - American College of Emergency Physicians
    - American Thoracic Society
    - Emergency Nurses Association
    - Society of Hospital Medicine

Need for Updated Guidance

- Data on seasonality of RSV circulation
- Data showing risk of RSV hospitalization by gestational age
- Data regarding palivizumab pharmacokinetics
- Data showing a decline in incidence of bronchiolitis hospitalizations
- Data showing no difference in RSV hospitalization rates or RSV attack rates between African-American and white children <24 m of age
- Data showing mortality rates among children hospitalized with RSV are lower than previously estimated
- Data showing a statistically significant but clinically limited episodes of wheezing
- Reports indicating little benefit from prophylaxis among children with Down syndrome and cystic fibrosis
- Reports describing palivizumab resistant RSV isolates among children hospitalized with breakthrough infection
- Independently conducted cost-analyses demonstrating high cost versus limited benefit
- Need to simplify guidance

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Updated Guidance for Palivizumab Prophylaxis Among Infants and Young Children at Increased Risk of Hospitalization for Respiratory Syncytial Virus Infection

COMMITTEE ON INFECTIOUS DISEASES AND BRONCHIOLITIS GUIDELINES COMMITTEE

Pediatrics; originally published online July 28, 2014;
DOI: 10.1542/peds.2014-1665

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POLICY STATEMENT

Updated Guidance for Palivizumab Prophylaxis Among Infants and Young Children at Increased Risk of Hospitalization for Respiratory Syncytial Virus Infection

COMMITTEE ON INFECTIOUS DISEASES AND BRONCHIOLITIS GUIDELINES COMMITTEE

KEY WORDS

RSV, respiratory syncytial virus, palivizumab, bronchiolitis, infants and young children, chronic lung disease, congenital heart disease

ABBREVIATIONS

AAP—American Academy of Pediatrics
CHD—congenital heart disease
CLD—chronic lung disease
COID—Committee on Infectious Diseases
RSV—respiratory syncytial virus

(Continued on last page)

abstract

FREE

Palivizumab was licensed in June 1998 by the Food and Drug Administration for the reduction of serious lower respiratory tract infection caused by respiratory syncytial virus (RSV) in children at increased risk of severe disease. Since that time, the American Academy of Pediatrics has updated its guidance for the use of palivizumab 4 times as additional data became available to provide a better understanding of infants and young children at greatest risk of hospitalization attributable to RSV infection. The updated recommendations in this policy statement reflect new information regarding the seasonality of RSV circulation, palivizumab pharmacokinetics, the changing incidence of bronchiolitis hospitalizations, the effect of gestational age and other risk factors on RSV hospitalization rates, the mortality of children hospitalized with RSV infection, the effect of prophylaxis on wheezing, and palivizumab-resistant RSV isolates. This policy statement updates and replaces the recommendations found in the 2012 *Red Book. Pediatrics* 2014;134:415–420

Policy statements from the American Academy of Pediatrics (AAP) are designed to provide updated guidance for child health care topics, with an emphasis on evidence-based recommendations whenever possible. Policy statements are reviewed at least every 3 years and updated when appropriate. In following this procedure, the AAP Committee on Infectious Diseases (COID) has undertaken a systematic review of all recent and older peer-reviewed literature relating to the burden of respiratory syncytial virus (RSV) disease in infants and children, focusing on publications that delineate children at greatest risk of serious RSV disease and studies that define pharmacokinetics, safety, and efficacy. Detailed input regarding this guidance has been solicited from 21 committees, councils, sections, and advisory groups within the AAP, as well as organizations outside the AAP. Outside groups include the American College of Chest Physicians, American College of Emergency Physicians, American Thoracic Society, Emergency Nurses Association, National Association of Neonatal Nurses, National Association of Neonatal Nurse Practitioners, and Society of Hospital

Medicine. In addition, this review includes all data presented to the COID by the manufacturer of palivizumab.

As part of this deliberative review of palivizumab use, the COID judged the quality of the available data, as well as the impact of palivizumab prophylaxis to reach a unanimous consensus on guidance for the use of palivizumab in the United States. Cost was considered during deliberations by the COID and Bronchiolitis Guideline Committee, but the final guidance as presented here is driven by the limited clinical benefit derived from palivizumab prophylaxis.[1–3]

As detailed in the accompanying technical report,[4] the benefit resulting from this drug is limited. Palivizumab prophylaxis has limited effect on RSV hospitalizations on a population basis, no measurable effect on mortality, and a minimal effect on subsequent wheezing.

This policy statement updates and replaces the most recent AAP recommendations for the use of palivizumab prophylaxis published in 2012 in the 29th edition of the *Red Book*.[5] This policy statement offers specific guidance for the use of palivizumab on the basis of available evidence, as well as expert opinion. A detailed discussion of the foundation of the updated guidance for each category as well as the references for each section may be found in the accompanying technical report,[4] and AAP guidelines for the diagnosis and management of bronchiolitis, which were published in 2006[6] (for which a revision is forthcoming).

The palivizumab package insert states: "Synagis is indicated for the prevention of serious lower respiratory tract disease caused by RSV in children at high risk of RSV disease."[7] In the absence of a specific definition of "high risk" by the US Food and Drug Administration, the AAP has endeavored to provide pediatricians and other health care providers with more precise guidance for determining who is at increased risk since palivizumab was first licensed.[5,8–11]

The informed opinion of the COID and the Bronchiolitis Guidelines Committee, as well as others participating in the current statement, is that palivizumab use should be restricted to the populations detailed below.

PRETERM INFANTS WITHOUT CHRONIC LUNG DISEASE OF PREMATURITY OR CONGENITAL HEART DISEASE

Palivizumab prophylaxis may be administered to infants born before 29 weeks, 0 days' gestation who are younger than 12 months at the start of the RSV season. For infants born during the RSV season, fewer than 5 monthly doses will be needed.

Available data for infants born at 29 weeks, 0 days' gestation or later do not identify a clear gestational age cutoff for which the benefits of prophylaxis are clear. For this reason, infants born at 29 weeks, 0 days' gestation or later are not universally recommended to receive palivizumab prophylaxis. Infants 29 weeks, 0 days' gestation or later may qualify to receive prophylaxis on the basis of congenital heart disease (CHD), chronic lung disease (CLD), or another condition.

Palivizumab prophylaxis is not recommended in the second year of life on the basis of a history of prematurity alone.

Some experts believe that on the basis of the data quantifying a small increase in risk of hospitalization, even for infants born earlier than 29 weeks, 0 days' gestation, palivizumab prophylaxis is not justified.

PRETERM INFANTS WITH CLD

Prophylaxis may be considered during the RSV season during the first year of life for preterm infants who develop CLD of prematurity defined as gestational age <32 weeks, 0 days and a requirement for >21% oxygen for at least the first 28 days after birth.

During the second year of life, consideration of palivizumab prophylaxis is recommended only for infants who satisfy this definition of CLD of prematurity and continue to require medical support (chronic corticosteroid therapy, diuretic therapy, or supplemental oxygen) during the 6-month period before the start of the second RSV season. For infants with CLD who do not continue to require medical support in the second year of life prophylaxis is not recommended.

INFANTS WITH HEMODYNAMICALLY SIGNIFICANT CHD

Certain children who are 12 months or younger with hemodynamically significant CHD may benefit from palivizumab prophylaxis. Children with hemodynamically significant CHD who are most likely to benefit from immunoprophylaxis include infants with acyanotic heart disease who are receiving medication to control congestive heart failure and will require cardiac surgical procedures and infants with moderate to severe pulmonary hypertension.

Decisions regarding palivizumab prophylaxis for infants with cyanotic heart defects in the first year of life may be made in consultation with a pediatric cardiologist.

These recommendations apply to qualifying infants in the first year of life who are born within 12 months of onset of the RSV season.

The following groups of infants with CHD are not at increased risk of RSV infection and generally should not receive immunoprophylaxis:

- Infants and children with hemodynamically insignificant heart disease (eg, secundum atrial septal

defect, small ventricular septal defect, pulmonic stenosis, uncomplicated aortic stenosis, mild coarctation of the aorta, and patent ductus arteriosus)

- Infants with lesions adequately corrected by surgery, unless they continue to require medication for congestive heart failure
- Infants with mild cardiomyopathy who are not receiving medical therapy for the condition
- Children in the second year of life

Because a mean decrease in palivizumab serum concentration of 58% was observed after surgical procedures that involve cardiopulmonary bypass, for children who are receiving prophylaxis and who continue to require prophylaxis after a surgical procedure, a postoperative dose of palivizumab (15 mg/kg) should be considered after cardiac bypass or at the conclusion of extracorporeal membrane oxygenation for infants and children younger than 24 months.

Children younger than 2 years who undergo cardiac transplantation during the RSV season may be considered for palivizumab prophylaxis.

CHILDREN WITH ANATOMIC PULMONARY ABNORMALITIES OR NEUROMUSCULAR DISORDER

No prospective studies or population-based data are available to define the risk of RSV hospitalization in children with pulmonary abnormalities or neuromuscular disease. Infants with neuromuscular disease or congenital anomaly that impairs the ability to clear secretions from the upper airway because of ineffective cough are known to be at risk for a prolonged hospitalization related to lower respiratory tract infection and, therefore, may be considered for prophylaxis during the first year of life.

IMMUNOCOMPROMISED CHILDREN

No population based data are available on the incidence of RSV hospitalization in children who undergo solid organ or hematopoietic stem cell transplantation. Severe and even fatal disease attributable to RSV is recognized in children receiving chemotherapy or who are immunocompromised because of other conditions, but the efficacy of prophylaxis in this cohort is not known. Prophylaxis may be considered for children younger than 24 months of age who are profoundly immunocompromised during the RSV season.

CHILDREN WITH DOWN SYNDROME

Limited data suggest a slight increase in RSV hospitalization rates among children with Down syndrome. However, data are insufficient to justify a recommendation for routine use of prophylaxis in children with Down syndrome unless qualifying heart disease, CLD, airway clearance issues, or prematurity (<29 weeks, 0 days' gestation) is present.

CHILDREN WITH CYSTIC FIBROSIS

Routine use of palivizumab prophylaxis in patients with cystic fibrosis, including neonates diagnosed with cystic fibrosis by newborn screening, is not recommended unless other indications are present. An infant with cystic fibrosis with clinical evidence of CLD and/or nutritional compromise in the first year of life may be considered for prophylaxis. Continued use of palivizumab prophylaxis in the second year may be considered for infants with manifestations of severe lung disease (previous hospitalization for pulmonary exacerbation in the first year of life or abnormalities on chest radiography or chest computed tomography that persist when stable) or weight for length less than the 10th percentile.

RECOMMENDATIONS FOR TIMING OF PROPHYLAXIS FOR ALASKA NATIVE AND AMERICAN INDIAN INFANTS

On the basis of the epidemiology of RSV in Alaska, particularly in remote regions where the burden of RSV disease is significantly greater than the general US population, the selection of Alaska Native infants eligible for prophylaxis may differ from the remainder of the United States. Clinicians may wish to use RSV surveillance data generated by the state of Alaska to assist in determining onset and end of the RSV season for qualifying infants.

Limited information is available concerning the burden of RSV disease among American Indian populations. However, special consideration may be prudent for Navajo and White Mountain Apache infants in the first year of life.

DISCONTINUATION OF PALIVIZUMAB PROPHYLAXIS AMONG CHILDREN WHO EXPERIENCE BREAKTHROUGH RSV HOSPITALIZATION

If any infant or young child receiving monthly palivizumab prophylaxis experiences a breakthrough RSV hospitalization, monthly prophylaxis should be discontinued because of the extremely low likelihood of a second RSV hospitalization in the same season (<0.5%).

USE OF PALIVIZUMAB IN THE SECOND YEAR OF LIFE

Hospitalization rates attributable to RSV decrease during the second RSV season for all children. A second season of palivizumab prophylaxis is recommended only for preterm infants born at <32 weeks, 0 days' gestation who required at least 28 days of oxygen after birth and who continue to require

supplemental oxygen, chronic systemic corticosteroid therapy, or bronchodilator therapy within 6 months of the start of the second RSV season.

LACK OF THERAPEUTIC EFFICACY OF PALIVIZUMAB

Passive antibody administration is not effective in treatment of RSV disease and is not approved or recommended for this indication.

PREVENTION OF HEALTH CARE-ASSOCIATED RSV DISEASE

No rigorous data exist to support palivizumab use in controlling outbreaks of health care-associated disease, and palivizumab use is not recommended for this purpose. Infants in a neonatal unit who qualify for prophylaxis because of CLD, prematurity, or CHD may receive the first dose 48 to 72 hours before discharge to home or promptly after discharge.

Strict adherence to infection-control practices is the basis for reducing health care-associated RSV disease.

RSV SEASONALITY

Because 5 monthly doses of palivizumab at 15 mg/kg per dose will provide more than 6 months (>24 weeks) of serum palivizumab concentrations above the desired level for most children, administration of more than 5 monthly doses is not recommended within the continental United States. For qualifying infants who require 5 doses, a dose beginning in November and continuation for a total of 5 monthly doses will provide protection for most infants through April and is recommended for most areas of the United States. If prophylaxis is initiated in October, the fifth and final dose should be administered in February, which will provide protection for most infants through March. If prophylaxis is initiated in December, the fifth and final dose should be administered in April, which will provide protection for most infants through May.

Variation in the onset and offset of the RSV season in different regions of Florida may affect the timing of palivizumab administration. Data from the Florida Department of Health may be used to determine the appropriate timing for administration of the first dose of palivizumab for qualifying infants. Despite varying onset and offset dates of the RSV season in different regions of Florida, a maximum of 5 monthly doses of palivizumab should be adequate for qualifying infants for most RSV seasons in Florida.

Sporadic RSV infections occur throughout the year in most geographic locations. During times of low RSV prevalence (regardless of proportion of positive results), prophylaxis with palivizumab provides the least benefit because of the large number of children who must receive prophylaxis to prevent 1 RSV hospitalization.

EFFECT OF PALIVIZUMAB PROPHYLAXIS ON SUBSEQUENT WHEEZING

Prophylaxis is not recommended for primary asthma prevention or to reduce subsequent episodes of wheezing.

SUMMARY OF GUIDANCE

- In the first year of life, palivizumab prophylaxis is recommended for infants born before 29 weeks, 0 days' gestation.
- Palivizumab prophylaxis is not recommended for otherwise healthy infants born at or after 29 weeks, 0 days' gestation.
- In the first year of life, palivizumab prophylaxis is recommended for preterm infants with CLD of prematurity, defined as birth at <32 weeks, 0 days' gestation and a requirement for >21% oxygen for at least 28 days after birth.
- Clinicians may administer palivizumab prophylaxis in the first year of life to certain infants with hemodynamically significant heart disease.
- Clinicians may administer up to a maximum of 5 monthly doses of palivizumab (15 mg/kg per dose) during the RSV season to infants who qualify for prophylaxis in the first year of life. Qualifying infants born during the RSV season may require fewer doses. For example, infants born in January would receive their last dose in March.
- Palivizumab prophylaxis is not recommended in the second year of life except for children who required at least 28 days of supplemental oxygen after birth and who continue to require medical intervention (supplemental oxygen, chronic corticosteroid, or diuretic therapy).
- Monthly prophylaxis should be discontinued in any child who experiences a breakthrough RSV hospitalization.
- Children with pulmonary abnormality or neuromuscular disease that impairs the ability to clear secretions from the upper airways may be considered for prophylaxis in the first year of life.
- Children younger than 24 months who will be profoundly immunocompromised during the RSV season may be considered for prophylaxis.
- Insufficient data are available to recommend palivizumab prophylaxis for children with cystic fibrosis or Down syndrome.
- The burden of RSV disease and costs associated with transport from remote locations may result in a broader use of palivizumab for RSV prevention in Alaska Native

populations and possibly in selected other American Indian populations.

- Palivizumab prophylaxis is not recommended for prevention of health care-associated RSV disease.

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(Continued from first page)

www.pediatrics.org/cgi/doi/10.1542/peds.2014-1665

doi:10.1542/peds.2014-1665

PEDIATRICS (ISSN Numbers: Print, 0031-4005; Online, 1098-4275).

Updated Guidance for Palivizumab Prophylaxis Among Infants and Young Children at Increased Risk of Hospitalization for Respiratory Syncytial Virus Infection

COMMITTEE ON INFECTIOUS DISEASES AND BRONCHIOLITIS GUIDELINES COMMITTEE

Pediatrics; originally published online July 28, 2014;
DOI: 10.1542/peds.2014-1665

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

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**

Report Dates: 01/01/14 - 06/30/14	
Overlapping Timeframe: 60	
Total Days Supply: 1	
Consecutive Days Difference in Prescriptions: 10	
Number of Therapies: At Least 2	
Number of Recipients: 99	
Drug Names	**Count of Overlaps**
ALPRAZOLAM , ALPRAZOLAM ER	1
ALPRAZOLAM , ALPRAZOLAM ER , LORAZEPAM , TEMAZEPAM	4
ALPRAZOLAM , CLONAZEPAM	31
ALPRAZOLAM , CLONAZEPAM , DIAZEPAM	3
ALPRAZOLAM , CLONAZEPAM , DIAZEPAM , TEMAZEPAM	1
ALPRAZOLAM , CLONAZEPAM , LORAZEPAM	4
ALPRAZOLAM , DIAZEPAM	5
ALPRAZOLAM , DIAZEPAM , LORAZEPAM	2
ALPRAZOLAM , LORAZEPAM	11
ALPRAZOLAM , TEMAZEPAM	4
ALPRAZOLAM , TRIAZOLAM	3
ALPRAZOLAM ER , CLONAZEPAM	7
CHLORDIAZEPOXIDE HCL , CLONAZEPAM	4
CHLORDIAZEPOXIDE HCL , LORAZEPAM	2
CHLORDIAZEPOXIDE HCL , LORAZEPAM , TEMAZEPAM	2
CLONAZEPAM , DIAZEPAM	19
CLONAZEPAM , DIAZEPAM , LORAZEPAM	6
CLONAZEPAM , LORAZEPAM	42
CLONAZEPAM , LORAZEPAM , LORAZEPAM INTENSOL	6
CLONAZEPAM , LORAZEPAM , TEMAZEPAM	3
CLONAZEPAM , LORAZEPAM INTENSOL	2
CLONAZEPAM , MIDAZOLAM HCL	3
CLONAZEPAM , TEMAZEPAM	4
CLONAZEPAM , TRIAZOLAM	1
DIAZEPAM , LORAZEPAM	10
DIAZEPAM , TEMAZEPAM	3
DIAZEPAM , TEMAZEPAM , TRIAZOLAM	3
FLURAZEPAM HCL , LORAZEPAM	1
LORAZEPAM , TEMAZEPAM	3

Top 20 Prescribers of duplicate benzodiazepine therapy	
Prescriber	**City**
Neurologist	Fargo
Pediatrician	Jamestown
Psychiatrist	Fargo
Psychiatrist	Bismarck
Psychiatrist	Fargo
NP	Fargo
Psychiatrist	Grand Forks
Family Medicine	Bismarck
Psychiatrist	Grand Forks
Psychiatrist	Fargo
NP	Bismarck
Internal Medicine	Fargo
NP	Bismarck
Psychiatrist	Bismarck
NP	Minot
Family Medicine	Valley City
PA	Fargo
Family Medicine	Wahpeton
Psychiatrist	Bismarck
Neurologist	Grand Forks
Duplicate benzodiazepine therapy - age ranges	
Age Range	**Recipient Count**
0-10	4
11-20	5
21-30	11
31-40	23
41-50	27
51-60	19
61+	10
Top 20 diagnoses	**Count**
ENCOUNTER LONG TERM USE OTH DRUGS	551
ANXIETY STATE UNSPECIFIED	462
UNSPECIFIED ESSENTIAL HYPERTENSION	456
TOBACCO USE DISORDER	370
DEPRESSIVE DISORDER OTHER	349
ABDOMINAL PAIN UNS SITE	322
LUMBAGO	304
UNSPEC CHEST PAIN	301
DIABETES UNCOMPL TYPE II	301
HEADACHE	299
PNEUMONIA ORGANISM UNSPECIFIED	284
URINARY TRACT INFECTION UNSPEC	236
UNS MYALGIA/MYOSITIS	230
DIARRHEA	223
POSTTRAUMATIC STRESS DISORDER	215
CERVICALGIA	212
RHEUMATOID ARTHRITIS	210
ASTHMA UNSPECIFIED	210
PAIN IN LIMB	200
GENERALIZED ANXIETY DISORDER	192

TOPICAL TESTOSTERONE
PA FORM

HEALTH INFORMATION DESIGNS

Prior Authorization Vendor for ND Medicaid

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-773-0695

ND Medicaid requires that patients receiving a new prescription for a topical testosterone must meet the following criteria:

- **Patient must have an FDA approved indication.**

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:**
□ ANDRODERM_____ □ ANDROGEL_____ □ FORTESTA_____ □ TESTIM_____ □ AXIRON_____ □ VOGELXO_____	**Testosterone Level:** **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 Signature	Date

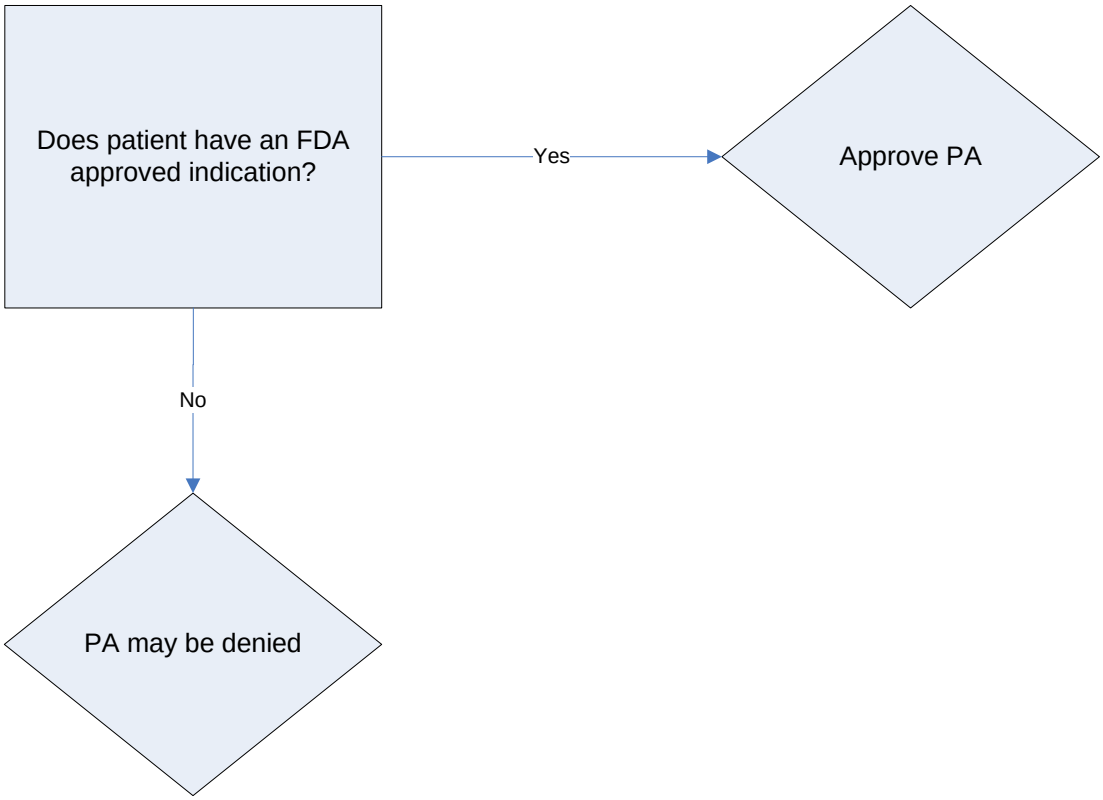
Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

Date Received	Initials:
Approved - Effective dates of PA: From: / / To: / /	Approved by:
Denied: (Reasons)	

North Dakota Department of Human Services
Topical Testosterone Prior Authorization Algorithm



PHOSPHATE BINDERS
PA FORM

HEALTH INFORMATION DESIGNS

Prior Authorization Vendor for ND Medicaid

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-773-0695

ND Medicaid requires that patients receiving a new prescription for phosphate binders must meet the following criteria:

- **Patient must have an FDA approved indication.**

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:**
□ RENAGEL _____ □ FOSRENOL_____ □ RENVELA _____ □ VELPHORO _____	

□ *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 Signature	Date

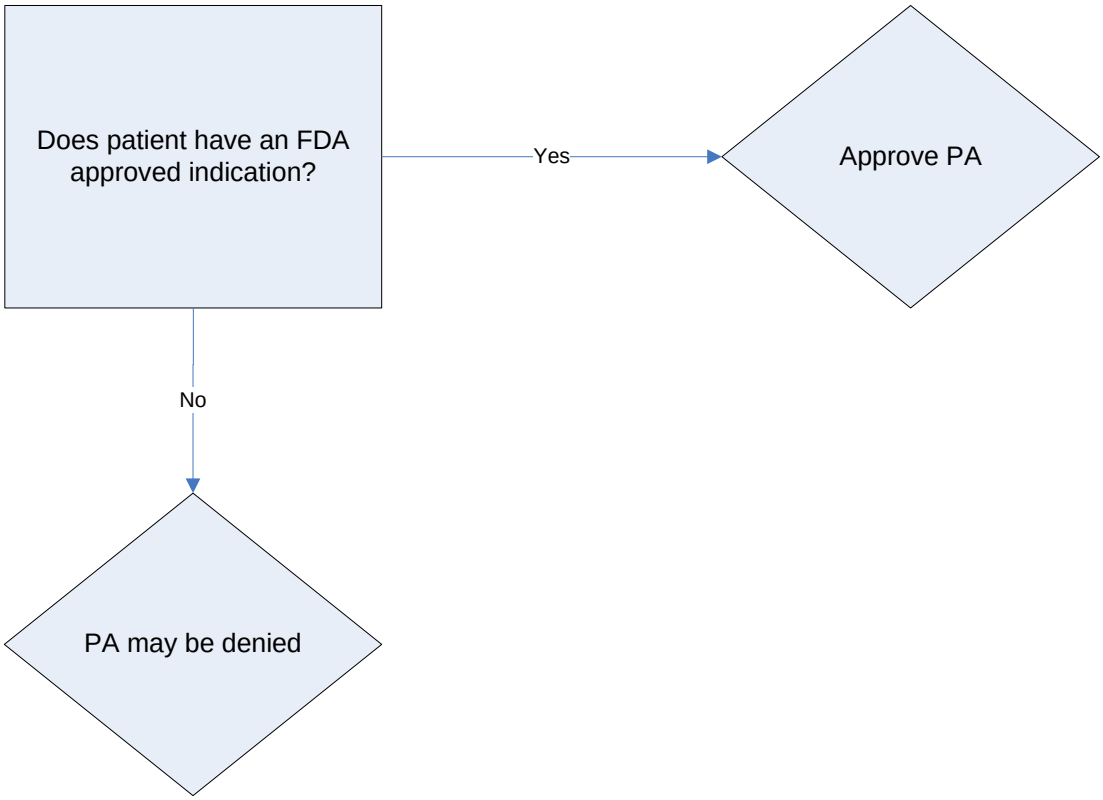
Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

Date Received	Initials:
Approved - Effective dates of PA: From: / / To: / /	Approved by:
Denied: (Reasons)	

North Dakota Department of Human Services
Phosphate Binders Authorization Algorithm



ZONTIVITY
PA FORM

Prior Authorization Vendor for ND Medicaid

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-773-0695

ND Medicaid requires that patients receiving a new prescription for Zontivity must meet the following criteria:

- **Patient must have an FDA approved indication.**
- **Patient must be 18 years of age or older.**
- **Use with aspirin and/or clopidogrel (limited clinical experience with Zontivity as the only antiplatelet agent).**
- **Contraindicated in patients with a history of stroke, transient ischemic attack, or intracranial hemorrhage.**

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: □ ZONTIVITY	**Diagnosis for this Request:**		
Using in combination with: □ ASA □ ASA/CLOPIDOGREL □ CLOPIDOGREL			
□ *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 Signature	Date		

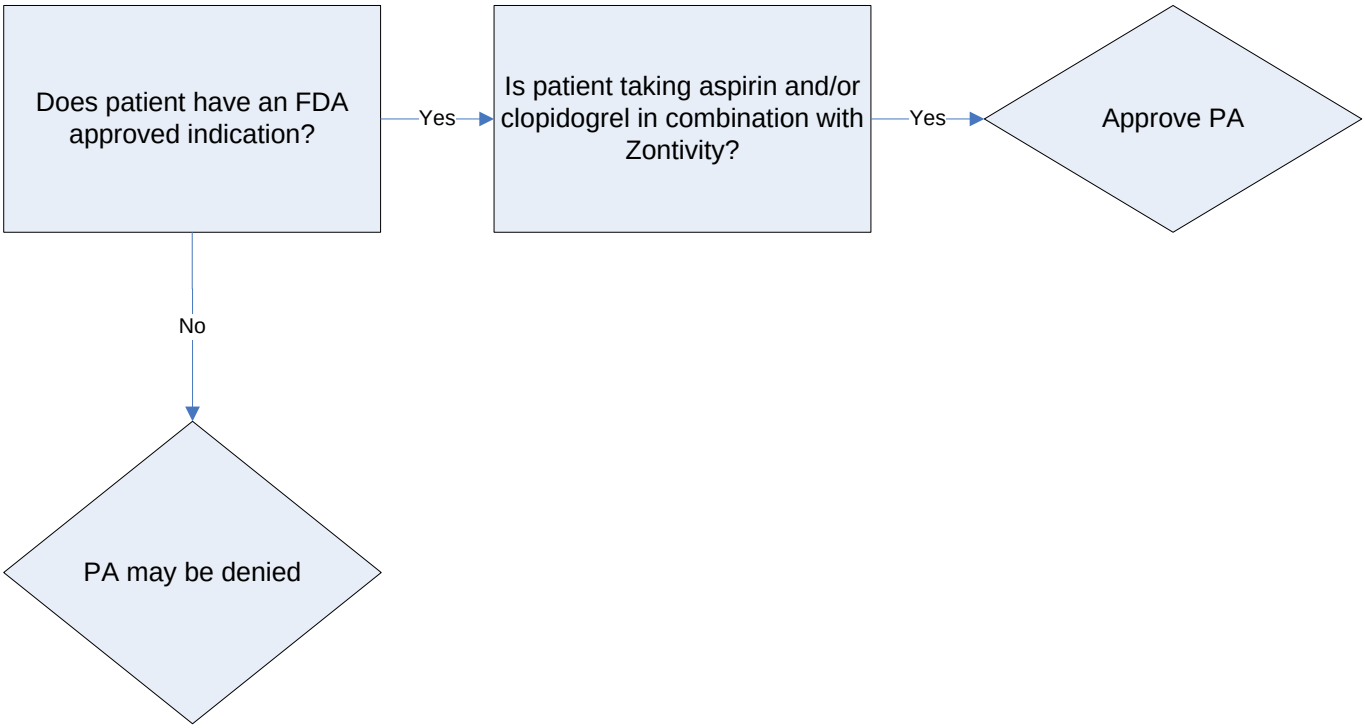
Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

Date Received	Initials:
Approved - Effective dates of PA: From: / / To: / /	Approved by:
Denied: (Reasons)	

North Dakota Department of Human Services
Zontivity Prior Authorization Algorithm



EVZIO
PA FORM

Prior Authorization Vendor for ND Medicaid

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-773-0695

ND Medicaid requires that patients receiving a new prescription for Evzio must meet the following criteria:

- **Patient must have an FDA approved indication.**

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: □ EVZIO	**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 Signature		Date	

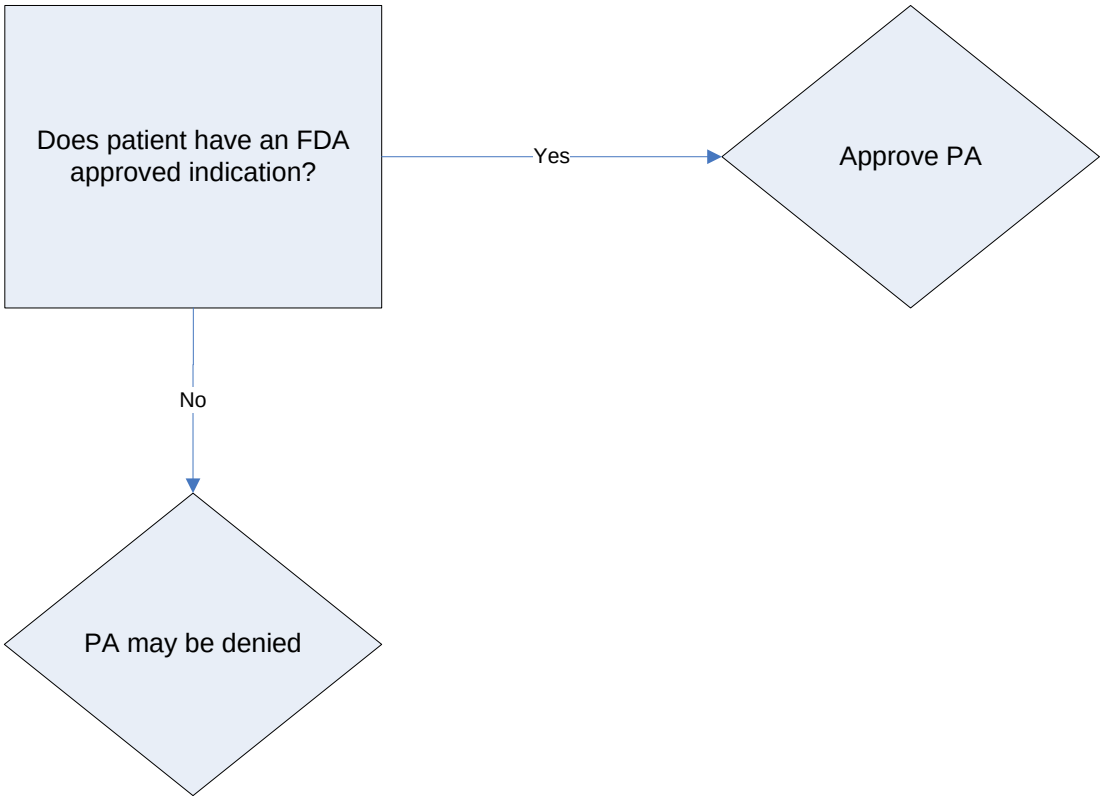
Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

Date Received	Initials:
Approved - Effective dates of PA: From: / / To: / /	Approved by:
Denied: (Reasons)	

North Dakota Department of Human Services
Evzio Prior Authorization Algorithm



ACE-Inhibitors (ACE-I), Angiotensin II Receptor Blockers (ARB) and Renin Inhibitor PA Form

Fax Completed Form to: 866-254-0761
For questions regarding this Prior authorization, call 866-773-0695

Prior Authorization Vendor for ND

ND Medicaid requires that patients receiving a prescription for Aceon must try at least two generic ACE-Is as first line.
ND Medicaid requires that patients receiving an ARB or Renin Inhibitor must try and fail one ACE-I.

***Note:**

- **ACE-I: Captopril, enalapril, moexipril, ramipril, lisinopril, trandolapril, quinapril, benazepril, and fosinopril and their hydrochlorothiazide containing combinations do not require a prior authorization.**
- **Angiotensin II receptor antagonists: Cozaar, Micardis, Teveten, Atacand, Diovan, Avapro, Benicar, Edarbi and their hydrochlorothiazide containing combinations.**
- **Renin Inhibitor: Tekturna and Tekturna HCT.**

Part I: TO BE COMPLETED BY PRESCRIBER

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

Qualifications for coverage:

□ Failed ACE-I therapy (list two ACE-I to receive Aceon)	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 Signature	Date

Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

Date Received	Initials:
Approved - Effective dates of PA: From: / / To: / /	Approved by:
Denied: (Reasons)	

ACTINIC KERATOSIS PA FORM

HEALTH INFORMATION DESIGNS

Prior Authorization Vendor for ND Medicaid

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-773-0695

ND Medicaid requires that patients receiving a new prescription for Solaraze, Zyclara, or Picato must first try imiquimod.

- ***Imiquimod does not require prior authorization***

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: □ ZYCLARA □ SOLARAZE □ PICATO	**Diagnosis for this Request:**		
Physician Signature		Date	

Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

Date Received	Initials:
Approved - Effective dates of PA: From: / / To: / /	Approved by:
Denied: (Reasons)	

AMPYRA PA FORM

HEALTH INFORMATION DESIGNS

Prior Authorization Vendor for ND Medicaid

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-773-0695

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**

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:**		
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)?			
Physician Signature		Date	

Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

Date Received	Initials:
Approved - Effective dates of PA: From: / / To: / /	Approved by:
Denied: (Reasons)	

AMRIX PA Form

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-773-0695

Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that patients try and fail generic cyclobenzaprine.
****Note:***

- **Cyclobenzaprine does not require PA**
- **Patient must fail therapy on generic cyclobenzaprine before a PA will be considered for Amrix.**

Part I: TO BE COMPLETED BY PRESCRIBER

RECIPIENT NAME:	RECIPIENT MEDICAID ID NUMBER:
Recipient Date of birth: / /	
PRESCRIBER NAME:	PRESCRIBER MEDICAID ID NUMBER:
Address:	Phone: ( )
City:	FAX: ( )
State: Zip:	
REQUESTED DRUG:	**Requested Dosage:** (must be completed)

Qualifications for coverage:

❑ Failed cyclobenzaprine therapy	Start Date:	Dose:
	End Date:	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 Signature: Date:

Part II: TO BE COMPLETED BY PHARMACY

PHARMACY NAME:	ND MEDICAID PROVIDER NUMBER:
Phone:	FAX:
Drug:	NDC#:

Part III: FOR OFFICIAL USE ONLY

Date: / /	Initials: _____
Approved - Effective dates of PA: From: / /	To: / /
Denied: (Reasons)	

HEALTH INFORMATION DESIGNS

Prior Authorization Vendor for ND Medicaid

ANTIHISTAMINE PA FORM

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-773-0695

ND Medicaid requires that patients receiving antihistamines must use loratadine (Claritin generic) and cetirizine (Zyrtec generic) as step therapy.

***Note:**

- ***Loratadine OTC and cetirizine OTC (or prescription generic) may be prescribed WITHOUT prior authorization.***
- ***Loratadine OTC and cetirizine OTC are covered by Medicaid when prescribed by a physician.***
- ***Patients must use loratadine or cetirizine for a minimum of 14 days for the trial to be considered a failure. Patient preference does not constitute a failure. Patients must use fexofenadine as step 2 after loratadine or cetirizine failure.***
- ***Net cost to Medicaid: Loratadine = cetirizine << Allegra (generic) << Clarinex = Xyzal***

Part I: TO BE COMPLETED BY PRESCRIBER

RECIPIENT NAME:		RECIPIENT MEDICAID ID NUMBER:
Recipient Date of birth: / /		
PRESCRIBER NAME:		PRESCRIBER MEDICAID ID NUMBER:
Address:		Phone: ( )
City:		FAX: ( )
State: Zip:		

REQUESTED DRUG: □ **ALLEGRA (GENERIC)** □ **CLARINEX** □ **XYZAL**	**Requested Dosage:** (must be completed) **Diagnosis for this request:**

Qualifications for coverage:

□ Failed loratadine or cetirizine (include which agent failed)_____	Start Date:	End Date:
□ Failed Allegra (generic) Step 2	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 Signature: Date:

Part II: TO BE COMPLETED BY PHARMACY

PHARMACY NAME:		ND MEDICAID PROVIDER NUMBER:
Phone:		FAX:
Drug:		NDC#:

Part III: FOR OFFICIAL USE ONLY

Date: / /	Initials: _____
Approved - Effective dates of PA: From: / /	To: / /
Denied: (Reasons)	

Aubagio Prior Authorization

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-773-0695

Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that patients who are prescribed Aubagio must follow these guidelines:

***Note:**

- ***Patient must have a confirmed diagnosis of a relapsing form of multiple sclerosis.***
- ***Patient must have a neurologist involved in therapy.***
- ***Obtain transaminase and bilirubin levels within 6 months before initiation of Aubagio and monitor ALT levels at least monthly for 6 months.***
- ***Aubagio is contraindicated in pregnant women or women of childbearing potential who are not using reliable contraception.***

Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name	Recipient Date of Birth	Recipient Medicaid ID Number	
Physician Name	Neurologist involved in therapy:		
Physician Medicaid Provider Number	Telephone Number	Fax Number	
Address	City	State	Zip Code
Qualifications for coverage:			
Requested Drug and Dosage: □ **Aubagio**	**Diagnosis for this request:**		
Physician Signature		Date	

Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

Date Received	Initials:
Approved - Effective dates of PA: From: / / To: / /	Approved by:
Denied: (Reasons)	

Asacol HD Prior Authorization

Fax Completed Form to:
866-254-0761
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 Asacol HD must try and fail Asacol.
Note:

- ***Asacol is FDA approved to treat mild to moderate flares and maintain remission of ulcerative colitis.***
- ***Asacol HD is FDA approved to treat flares in patients with moderately active ulcerative colitis.***

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: □ **Asacol HD**	**Diagnosis for this request:**		
Qualifications for coverage:			
□ FAILED ASACOL THERAPY START DATE: DOSE: END DATE: FREQUENCY:			
Physician Signature		Date	

Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

Date Received	Initials:
Approved - Effective dates of PA: From: / / To: / /	Approved by:
Denied: (Reasons)	

BLOOD FACTOR PRODUCTS PA FORM

Prior Authorization Vendor for ND Medicaid

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-773-0695

ND Medicaid requires that patients receiving a new prescription for blood factor products 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

Part I: TO BE COMPLETED BY PRESCRIBER

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 :	**DOSAGE:**		
Qualifications for coverage:			
TREATMENT CENTER CONTACT INFORMATION:	DATE OF LAST APPOINTMENT WITH TREATMENT CENTER: _____		
Prescriber Signature:		Date:	

Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

Date Received	Initials:
Approved - Effective dates of PA: From: / / To: / /	Approved by:
Denied: (Reasons)	

Brisdelle
Prior Authorization

Fax Completed Form to:
866-254-0761
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 Brisdelle must meet the following criteria:

- *Patient must first try paroxetine*

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

QUALIFICATIONS FOR COVERAGE:	
Requested Drug and Dosage: □ **Brisdelle**	Diagnosis for this request:
Failed Therapy:	Start Date: End Date:
Physician Signature	Date

Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

Date Received	Initials:
Approved - Effective dates of PA: From: / / To: / /	Approved by:
Denied: (Reasons)	

BUPRENORPHINE OR BUPRENORPHINE/NALOXONE COMBINATIONS PA FORM

Fax Completed Form to:
866-254-0761
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 buprenorphine containing products 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 under the Substance Abuse and Mental Health Services Administration (SAMHSA).**

Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name	**Recipient Date of Birth**	Recipient Medicaid ID Number	
Physician Name	**(SAMHSA ID)**		
Physician Medicaid Provider Number	Telephone Number	Fax Number	
Address	City	State	Zip Code
Requested Drug and Dosage: □ SUBOXONE/ZUBSOLV □ SUBUTEX	**FDA Approved Indication for this request:**		
□ Patient is not taking other opioids, tramadol, or carisoprodol concurrently with buprenorphine containing products.			
Physician Signature	Date		

Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

Date Received	Initials:
Approved - Effective dates of PA: From: / / To: / /	Approved by:
Denied: (Reasons)	

CARISOPRODOL PA FORM

Prior Authorization Vendor for ND Medicaid

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-773-0695

ND Medicaid requires that patients using carisoprodol 350mg longer than two times per year (272 tablets) must receive a prior authorization. Cyclobenzaprine, chlorzoxazone, methocarbamol and orphenadrine do not require a prior authorization.

***Note:**

- **PA will be approved if recipient is currently taking carisoprodol on a chronic basis and provider is weaning patient.**

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: □ CARISOPRODOL	**Diagnosis for this request:**		
Qualifications for coverage:			
□ CHRONIC CARISOPRODOL RECIPIENT BEING WEANED (PLEASE INCLUDE WEANING SCHEDULE)	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.*			
Physician Signature	Date		

Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

Date Received	Initials:
Approved - Effective dates of PA: From: / / To: / /	Approved by:
Denied: (Reasons)	

CIALIS for BENIGN PROSTATIC HYPERPLASIA
PA FORM

Prior Authorization Vendor for ND Medicaid

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-773-0695

ND Medicaid requires that patients receiving a prescription for Cialis used to treat benign prostatic hyperplasia (BPH) must meet the following criteria:

- **Patient must have diagnosis of BPH**
- **Patient must try and fail all alpha blockers and 5-alpha reductase inhibitors and combinations, unless contraindicated.**

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:**	**Attach additional notes listing all products 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 Signature		Date	

Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

Date Received	Initials:
Approved - Effective dates of PA: From: / / To: / /	Approved by:
Denied: (Reasons)	

COMBINATION PRODUCTS
PA FORM

Prior Authorization Vendor for ND Medicaid

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-773-0695

ND Medicaid requires that patients receiving a new prescription for a combination product that is more expensive than the individual components must meet the following criteria:

- **Patient must be currently stable on the combination product**

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:**		
□ *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 Signature		Date	

Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

Date Received	Initials:
Approved - Effective dates of PA: From: / / To: / /	Approved by:
Denied: (Reasons)	

Agents Used to Treat COPD
Prior Authorization

Fax Completed Form to:
866-254-0761
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 Arcapta, Brovana, Spiriva, Tudorza, Anoro Ellipta, or Breo Ellipta must meet the following criteria:

- *Patient must have a diagnosis of COPD.*

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

QUALIFICATIONS FOR COVERAGE:

Requested Drug and Dosage:	Diagnosis for this request:
□ **Arcapta** □ **Tudorza** □ **Brovana** □ **Breo Ellipta** □ **Spiriva** □ **Anoro Ellipta**	
Physician Signature	Date

Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

Date Received	Initials:
Approved - Effective dates of PA: From: / / To: / /	Approved by:
Denied: (Reasons)	

HEALTH INFORMATION DESIGNS

Prior Authorization Vendor for ND Medicaid

BRAND NAME NSAID/COX-II PA FORM

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-773-0695

ND Medicaid requires that patients using brand name NSAIDs or COX-II drugs must use a generic NSAID as first line.

***Note: The PA will be approved if one of the following criteria is met:**

- **Failed two trials of prescribed oral NSAIDs to receive brand name oral NSAIDs**
- **Failed trial of Voltaren gel to receive brand name topical NSAIDs for inflammation**
- **Recipient is on warfarin or corticosteroid therapy**
- **Recipient has history of gastric or duodenal ulcer or has comorbidities of GI bleed, perforation or obstruction**
- **Recipient has history of endoscopically documented NSAID induced gastritis with GI bleed**
- **Solaraze will be covered for patients with a diagnosis of actinic keratoses**

Part I: TO BE COMPLETED BY PRESCRIBER

Recipient Name	Recipient Date of Birth	Recipient Medicaid ID Number	
Prescriber Name			
Prescriber Medicaid Provider Number	Telephone Number	Fax Number	
Address	City	State	Zip Code

Requested Drug and Dosage:	**Diagnosis for this request:**	
□ Celebrex	□ Warfarin/Corticosteroid therapy	□ GI bleed, perforation or obstruction
□ Other _____	□ Gastric or duodenal ulcer	□ Endoscopically documented NSAID gastritis with GI Bleed
	□ Actinic keratoses **(Solaraze)**	

Qualifications for coverage:

□ Failed NSAID therapy	Start Date	End Date	Dose	Frequency
□ Failed NSAID 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 Signature	Date

Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

Date Received	Initials:
Approved - Effective dates of PA: From: / / To: / /	Approved by:
Denied: (Reasons)	

Daliresp Prior Authorization

Fax Completed Form to:
866-254-0761
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 Daliresp must follow the following guidelines:

- ***Patient must be 18 years of age or older.***
- ***Patient must have a diagnosis of severe COPD associated with chronic bronchitis and a history of exacerbations.***

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: □ **Daliresp**	**Diagnosis for this request:**		
Physician Signature		Date	

Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

Date Received	Initials:
Approved - Effective dates of PA: From: / / To: / /	Approved by:
Denied: (Reasons)	

HEALTH INFORMATION DESIGNS

Prior Authorization Vendor for ND Medicaid

Diclegis
Prior Authorization

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-773-0695

ND Medicaid requires that patients receiving a new prescription for Diclegis must meet the following criteria:

- *Patient must have diagnosis of nausea and vomiting of pregnancy*
- *Patient must first try ondansetron*

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

QUALIFICATIONS FOR COVERAGE:

Requested Drug and Dosage: □ **Diclegis**	Diagnosis for this request:
Failed Therapy:	Start Date: End Date:
Physician Signature	Date

Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

Date Received	Initials:
Approved - Effective dates of PA: From: / / To: / /	Approved by:
Denied: (Reasons)	

DISPENSE AS WRITTEN PA FORM

Fax Completed Form to:
866-254-0761
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 was not effective (attach MedWatch form)**
- **There was an adverse reaction with the generic product (attach MedWatch form)**
- **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 Medicaid Provider Number		Telephone Number	Fax Number	
Address		City	State	Zip Code
Requested Drug:	**DOSAGE:**	**Diagnosis for this request:**		

QUALIFICATIONS FOR COVERAGE: □ FAILED GENERIC EQUIVALENT**(ATTACH FDA MEDWATCH FORM)**	**Start Date**	**End Date**	**Dose**	**Frequency**

ADVERSE REACTION TO GENERIC EQUIVALENT (ATTACH FDA MEDWATCH FORM)

□ *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 Signature	Date

Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

Date Received	Initials:
Approved - Effective dates of PA: From: / / To: / /	Approved by:
Denied: (Reasons)	

DIFICID PA FORM

Prior Authorization Vendor for ND Medicaid

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-773-0695

ND Medicaid requires that patients receiving a new prescription for Dificid must meet the following criteria:

- **Patient must have diagnosis of *Clostridium difficile*-associated diarrhea (CDAD)**
- **Patient must be ≥ 18 years of age**
- **Patient must have been treated per the current guidelines and failed**
- **Compounded oral vancomycin is covered without prior authorization**
- **Metronidazole is covered without prior authorization**

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: □ DIFICID	**Diagnosis for this Request:**	**Failed therapy:** **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 Signature		Date

Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

Date Received	Initials:
Approved - Effective dates of PA: From: / / To: / /	Approved by:
Denied: (Reasons)	

DEXPAK/ZEMAPAK PA FORM

HEALTH INFORMATION DESIGNS

Prior Authorization Vendor for ND Medicaid

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-773-0695

ND Medicaid requires that patients receiving a new prescription for DexPak or Zema-Pak must meet the following criteria:

- **Patient must first try and fail with dexamethasone**

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: □ DEXPAK □ ZEMA-PAK	**Diagnosis for this Request:**		
Failed Therapy (dose and frequency): □ DEXAMETHASONE	**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 Signature		Date	

Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

Date Received	Initials:
Approved - Effective dates of PA: From: / / To: / /	Approved by:
Denied: (Reasons)	

ELAPRASE PA FORM

Prior Authorization Vendor for ND Medicaid

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-773-0695

ND Medicaid requires that patients receiving a new prescription for Elaprase must meet the following criteria:

- **Patient must have Hunter Syndrome.**

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: □ ELAPRASE	**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 Signature		Date	

Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

Date Received	Initials:
Approved - Effective dates of PA: From: / / To: / /	Approved by:
Denied: (Reasons)	

Epinephrine Auto Injectors
Prior Authorization

Fax Completed Form to:
866-254-0761
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 epinephrine auto injectors must use Auvi-Q as first line therapy.

- *Auvi-Q does not require a prior authorization*

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

QUALIFICATIONS FOR COVERAGE:	
Requested Drug and Dosage: □	Diagnosis for this request:
Failed Therapy:	Start Date: End Date:
Physician Signature	Date

Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

Date Received	Initials:
Approved - Effective dates of PA: From: / / To: / /	Approved by:
Denied: (Reasons)	

Fulyzaq
Prior Authorization

Fax Completed Form to:
866-254-0761
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 Fulyzaq must meet the following criteria:

Note:

- **Patient must be 18 years of age or older.**
- **Patient must have non-infectious diarrhea.**
- **Patient must have HIV/AIDS and be taking anti-retroviral therapy.**

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
QUALIFICATIONS FOR COVERAGE:			
Requested Drug and Dosage: □ **Fulyzaq**	Diagnosis for this request: Anti-retroviral therapy		
Physician Signature	Date		

Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

Date Received	Initials:
Approved - Effective dates of PA: From: / / To: / /	Approved by:
Denied: (Reasons)	

Genitourinary Smooth Muscle Relaxants (GSM) Prior Authorization

Fax Completed Form to: 866-254-0761
For questions regarding this Prior authorization, call 866-773-0695

Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that patients who are prescribed GSMs must follow these guidelines:
Note:

- **Patient must have an FDA approved indication for the medication requested.**
- **Patient must try oxybutynin or oxybutynin ER.**

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
Qualifications for coverage:			
Requested Drug and Dosage: □ **Enablex** □ **Detrol LA** □ **Toviaz** □ **Gelnique** □ **Myrbetriq** □ **Oxytrol** □ **Detrol** □ **Sanctura** □ **Vesicare** □ **Sanctura XR**	**Diagnosis for this request:** **Failed therapy (Drug and Dose)** **Start Date:** **End Date:**		
Physician Signature		Date	

Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

Date Received	Initials:
Approved - Effective dates of PA: From: / / To: / /	Approved by:
Denied: (Reasons)	

Giazo
Prior Authorization

Fax Completed Form to:
866-254-0761
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 Giazo must meet the following criteria:

- *Patient must be male.*
- *Patient must be > 18 years of age.*
- *Patient must have a diagnosis of ulcerative colitis.*
- *Patient has tried and failed balsalazide 750mg capsules.*

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
QUALIFICATIONS FOR COVERAGE:			
Requested Drug and Dosage: □ Giazo		Diagnosis for this request:	
□ Failed trial of balsalazide 750mg capsules Dose:			
Physician Signature		Date	

Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

Date Received	Initials:
Approved - Effective dates of PA: From: / / To: / /	Approved by:
Denied: (Reasons)	

Gilenya Prior Authorization

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-773-0695

Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that patients who are prescribed Gilenya must follow these guidelines:

Note:

- ***Must have relapsing forms of multiple sclerosis.***
- ***Must have a current electrocardiogram (within 6 months) for patients taking anti-arrhythmics, beta-blockers, or calcium channel blockers; patients with cardiac risk factors; and patients with a slow or irregular heart beat.***
- ***Must have a recent CBC (within 6 months).***
- ***Must have an adequate ophthalmologic evaluation at baseline and 3-4 months after treatment initiation.***
- ***Must have recent (within 6 months) transaminase and bilirubin levels before initiation of therapy.***
- ***Will not be approved for use in combination therapy***

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: □ **Gilenya**		**Diagnosis for this request:**	
Qualifications for coverage:			
Current electrocardiogram **Date:**	**Current CBC** **Date:**	**Ophthalmologic Evaluation** **Date:**	**Transaminase/Bilirubin levels** **Date:**
Physician Signature			Date

Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

Date Received	Initials:
Approved - Effective dates of PA: From: / / To: / /	Approved by:
Denied: (Reasons)	

GRALISE PA FORM

Prior Authorization Vendor for ND Medicaid

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-773-0695

ND Medicaid requires that patients receiving a new prescription for Gralise must meet the following criteria:

- **Patient must have a diagnosis of postherpetic neuralgia**
- **Patient must first try gabapentin**

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: □ GRALISE	**Diagnosis for this Request:**		
Failed Therapy (dose and frequency): □ GABAPENTIN	**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 Signature		Date	

Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

Date Received	Initials:
Approved - Effective dates of PA: From: / / To: / /	Approved by:
Denied: (Reasons)	

Growth Hormone PA Form

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-773-0695

Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that patients receiving Growth Hormone meet one of the criteria below:

- **Growth Hormone Deficiency in children and adults with a history of hypothalamic pituitary disease**
- **Short stature associated with chronic renal insufficiency before renal transplantation**
- **Short stature in patients with Turners Syndrome (TS) or Prader-Willi Syndrome (PWS)**
- **Human Immunodeficiency Virus (HIV) associated wasting in adults**

Part I: TO BE COMPLETED BY PRESCRIBER

RECIPIENT NAME:		RECIPIENT MEDICAID ID NUMBER:
Recipient Date of birth: / /		
PRESCRIBER NAME		PRESCRIBER MEDICAID ID NUMBER:
Address:		Phone: ( )
City:		FAX: ( )
State: Zip:		
REQUESTED DRUG:	**Requested Dosage:** (must be completed)	
Qualifications for coverage:		
Criteria met:	Diagnosis Date: Drug:	Dose: Frequency:
PRESCRIBER SIGNATURE	DATE:	

Part II: TO BE COMPLETED BY PHARMACY

PHARMACY NAME:	ND MEDICAID PROVIDER NUMBER:
Phone:	FAX:
Drug:	NDC#:

Part III: FOR OFFICIAL USE ONLY

Date: / /	Initials: _____
Approved - Effective dates of PA: From: / /	To: / /
Denied: (Reasons)	

HARVONI PA FORM

Prior Authorization Vendor for ND Medicaid

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-773-0695

ND Medicaid requires that patients receiving a new prescription for Harvoni must meet the following criteria:

- Patient must be ≥ 18 years old.
- Must have a diagnosis of chronic hepatitis C (genotypes 1) with compensated liver disease.
- Liver biopsy showing fibrosis corresponding to a Metavir score of greater than or equal to 2 or Ishak score of greater than or equal to 3 or other accepted test demonstrating liver fibrosis.
- Must be prescribed by or in consultation with a hepatologist, gastroenterologist, or infectious disease specialist.
- Absence of renal impairment (eGFR must be >30mL/min/1.73m^2) and absence of end stage renal disease (ESRD).
- Documentation showing that patient is drug and alcohol free for the past 12 months
- The concomitant use of Harvoni and P-gp inducers (rifampin, St. John's wort), certain anticonvulsants, certain antiretrovirals, and rosuvastatin is not recommended.

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	**Documented liver fibrosis:**	**Diagnosis for this request:**	**Patient is drug and alcohol free for past 12 months:**
□ **Harvoni** Dosage: _____		**Genotype:**	□ YES □ NO **eGFR:**

Has the patient been previously treated for chronic hepatitis C? □ YES □ NO If yes, please indicate past treatment regimen(s), dates of treatment, and response to therapy:	Baseline HCV RNA: HCV RNA 4 weeks after starting therapy:
Physician Signature	Date

Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

Date Received	Initials:
Approved - Effective dates of PA: From: / / To: / /	Approved by:
Denied: (Reasons)	

Hepatitis C Virus (HCV) Medication Prior Authorization

Fax Completed Form to:
866-254-0761
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 Intron, Infergen, Pegasys, PegIntron, Incivek, or Victrelis must submit a prior authorization form.

Note:

- ***Prior authorization will be granted if the requested product has been approved by the FDA for the indication listed below.***
- ***Current recommended therapy of chronic HCV infection is the combination of pegylated interferon alfa (PEGIntron or Pegasys) and ribavirin.***
- ***Incivek and Victrelis patients must be 18 years of age or older.***
- ***Incivek and Victrelis patients must also be taking ribavirin and peg-interferon.***
- ***Incivek and Victrelis will only be approved for 12 weeks for review of HCV-RNA levels and compliance.***

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: □ **Intron** □ **Pegasys** □ **Infergen** □ **PEGIntron** □ **Incivek** □ **Victrelis**	**Diagnosis for this request:**	**Genotype:**	
	Ribavirin dose: **Peg-interferon dose:**		
Physician Signature		Date	

Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

Date Received	Initials:
Approved - Effective dates of PA: From: / / To: / /	Approved by:
Denied: (Reasons)	

HEREDITARY ANGIOEDEMA
PA FORM

Prior Authorization Vendor for ND Medicaid

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-773-0695

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: □ BERINERT □ FIRAZYR □ CINRYZE □ KALBITOR	**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 Signature	Date		

Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

Date Received	Initials:
Approved - Effective dates of PA: From: / / To: / /	Approved by:
Denied: (Reasons)	

Horizant Prior Authorization

Fax Completed Form to:
866-254-0761
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 Horizant must follow the following guidelines:

- ***Patient must have a diagnosis of Restless Leg Syndrome.***
- ***Patient must have had a trial of gabapentin, pramipexole, or ropinirole.***

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: □ **Horizant**	**Diagnosis for this request:**		
Qualifications for coverage:			
□ FAILED THERAPY START DATE: END DATE:	DOSE: FREQUENCY:		
Physician Signature		Date	

Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

Date Received	Initials:
Approved - Effective dates of PA: From: / / To: / /	Approved by:
Denied: (Reasons)	

TARGETED IMMUNE MODULATORS PA FORM

HEALTH INFORMATION DESIGNS

Prior Authorization Vendor for ND Medicaid

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-773-0695

ND Medicaid requires that patients receiving a new prescription for Actemra, Orencia, Humira, Enbrel, Amevive, Kineret, Cimzia, Remicade, Simponi and Stelara must submit a prior authorization form.

- Prior authorization will be granted if the requested product has been approved by the FDA for the indication listed below.

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:**
□ ORENCIA	□ AMEVIVE	
□ ENBREL	□ CIMZIA	
□ KINERET	□ REMICADE	
□ HUMIRA	□ SIMPONI	
□ STELARA	□ ACTEMRA	

□ *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.*

Physician Signature	Date

Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

Date Received	Initials:
Approved - Effective dates of PA: From: / / To: / /	Approved by:
Denied: (Reasons)	

KALYDECO PA FORM

Prior Authorization Vendor for ND Medicaid

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-773-0695

ND Medicaid requires that patients receiving a new prescription for Kalydeco must meet the following criteria:

- **Patient must have a G551D mutation in the cystic fibrosis conductance regulator (CFTR) gene.**

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: □ KALYDECO	**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 Signature		Date	

Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

Date Received	Initials:
Approved - Effective dates of PA: From: / / To: / /	Approved by:
Denied: (Reasons)	

KAPVAY PA FORM

Prior Authorization Vendor for ND Medicaid

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-773-0695

ND Medicaid requires that patients receiving a new prescription for Kapvay must meet the following criteria:

- **Patient must first try clonidine**

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: □ KAPVAY	**Diagnosis for this Request:**		
Failed Therapy (dose and frequency): □	**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 Signature		Date	

Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

Date Received	Initials:
Approved - Effective dates of PA: From: / / To: / /	Approved by:
Denied: (Reasons)	

KETEK PA FORM

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-773-0695

Prior Authorization Vendor for ND Medicaid

- ND Medicaid will cover Ketek with a diagnosis of community-acquired pneumonia (of mild to moderate severity) due to Streptococcus pneumoniae for patients 18 years and older.
- ND Medicaid will cover Ketek for patients with an allergy to fluoroquinolones or tetracyclines.

Part I: TO BE COMPLETED BY PRESCRIBER

RECIPIENT NAME:	RECIPIENT MEDICAID ID NUMBER:
Recipient Date of birth: / /	
PRESCRIBER NAME:	PRESCRIBER MEDICAID ID NUMBER:
Address:	Phone: ( )
City:	FAX: ( )
State: Zip:	

REQUESTED DRUG: □ **KETEK**	**Requested Dosage:** (must be completed)

Qualifications for coverage:

□ Community acquired pneumonia (of mild to moderate severity) due to Streptococcus pneumoniae, (including multi-drug resistant isolates, Haemophilus influenzae, Moraxella catarrhalis, Chlamydophila pneumoniae, or Mycoplasma pneumoniae) for patients 18 years and older.

□ 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 Signature: Date:

Part II: TO BE COMPLETED BY PHARMACY

PHARMACY NAME:	ND MEDICAID PROVIDER NUMBER:
Phone:	FAX:
Drug:	NDC#:

Part III: FOR OFFICIAL USE ONLY

Date: / /	Initials: _____
Approved - Effective dates of PA: From: / /	To: / /
Denied: (Reasons)	

KUVAN PA FORM

HEALTH INFORMATION DESIGNS

Prior Authorization Vendor for ND Medicaid

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-773-0695

ND Medicaid requires that patients receiving a new prescription for Kuvan must meet the following criteria:

- **Patient must have hyperphenalaninemia.**

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: □ KUVAN	**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 Signature		Date	

Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

Date Received	Initials:
Approved - Effective dates of PA: From: / / To: / /	Approved by:
Denied: (Reasons)	

LORZONE PA FORM

Prior Authorization Vendor for ND Medicaid

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-773-0695

ND Medicaid requires that patients receiving a new prescription for Lorzone must meet the following criteria:

- **Patient must first try chlorzoxazone**

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: □ LORZONE	**Diagnosis for this Request:**		
Failed Therapy (dose and frequency): □ CHLORZOXAZONE	**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 Signature		Date	

Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

Date Received	Initials:
Approved - Effective dates of PA: From: / / To: / /	Approved by:
Denied: (Reasons)	

METOZOLV ODT PA FORM

Prior Authorization Vendor for ND Medicaid

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-773-0695

ND Medicaid requires that patients receiving a new prescription for Metozolv must meet the following criteria:

- **Patient must try metoclopramide.**

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: □ METOZOLV		**Diagnosis for this request:**	
□ **FAILED METOCLOPRAMIDE THERAPY**	**START DATE**	**END DATE**	**DOSE**
□ *I confirm that I have considered a generic or other alternative and that the requested drug is expected to result in the successful medical management of the recipient.*			
Physician Signature		Date	

Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

Date Received	Initials:
Approved - Effective dates of PA: From: / / To: / /	Approved by:
Denied: (Reasons)	

MOXATAG PA FORM

Prior Authorization Vendor for ND Medicaid

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-773-0695

ND Medicaid requires that patients receiving a new prescription for Moxatag must submit documentation of allergies or show a history of intolerable side effects to the inactive ingredients in regular-release amoxicillin.

- Regular-release amoxicillin does not require a prior authorization.

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 : □ MOXATAG	**Dosage**
Qualifications for coverage:	
□ Allergic/intolerable side effects to inactive ingredients of regular-release amoxicillin. Name of inactive ingredient: _____	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.*	
Physician Signature	Date

Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

Date Received	Initials:
Approved - Effective dates of PA: From: / / To: / /	Approved by:
Denied: (Reasons)	

BRAND-NAME NARCOTICS PA FORM

HEALTH INFORMATION DESIGNS

Prior Authorization Vendor for ND Medicaid

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-773-0695

ND Medicaid requires that patients receiving a new prescription for a brand-name narcotic must meet the following criteria:

- **Documented failure of a 30-day trial of a generic narcotic.**

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:

□ EMBEDA □ OPANA ER □ KADIAN □ AVINZA □ EXALGO □ FENTORA □ ONSOLIS □ MAGNACET □ BUTRANS

□ OTHER BRAND NAME PRODUCT _____

FAILED THERAPY	**START DATE**	**END DATE**	**DOSE**	**FREQUENCY**

Physician Signature	Date

Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

Date Received	Initials:
Approved - Effective dates of PA: From: / / To: / /	Approved by:
Denied: (Reasons)	

Narcotics/APAP
Prior Authorization

Fax Completed Form to:
866-254-0761
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 narcotics containing acetaminophen doses greater than 325mg must use hydrocodone/acetaminophen 5/325-10/325 or oxycodone acetaminophen 5/325-10/325.

- ***FDA is requesting that drug manufacturers limit the amount of acetaminophen in prescription drug products to 325mg per dosage unit.***
- ***Higher-dose formulations of hydrocodone/acetaminophen and oxycodone/acetaminophen should be phased out by 2014.***

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:**		
Qualifications for coverage:			
□ FAILED THERAPY START DATE: END DATE:	DOSE: FREQUENCY:		
Physician Signature		Date	

Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

Date Received	Initials:
Approved - Effective dates of PA: From: / / To: / /	Approved by:
Denied: (Reasons)	

Nexiclon Prior Authorization

Fax Completed Form to:
866-254-0761
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 Nexiclon must try and fail clonidine.
Note:

- ***Clonidine does not require PA***

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: □ **Nexiclon**	**Diagnosis for this request:**		
Qualifications for coverage:			
□ FAILED CLONIDINE THERAPY START DATE: END DATE:	DOSE: FREQUENCY:		
Physician Signature		Date	

Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

Date Received	Initials:
Approved - Effective dates of PA: From: / / To: / /	Approved by:
Denied: (Reasons)	

HEALTH INFORMATION DESIGNS

Prior Authorization Vendor for ND Medicaid

Nitroglycerin Lingual Spray
Prior Authorization

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-773-0695

ND Medicaid requires that patients receiving a new prescription for Nitrolingual Spray must meet the following criteria:

- *Patient must first try sublingual tablets*

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

QUALIFICATIONS FOR COVERAGE:	
Requested Drug and Dosage: □ **Nitroglycerin Lingual Spray**	Diagnosis for this request:
Failed Therapy:	Start Date: End Date:
Physician Signature	Date

Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

Date Received	Initials:
Approved - Effective dates of PA: From: / / To: / /	Approved by:
Denied: (Reasons)	

Nuedexta Prior Authorization

Fax Completed Form to:
866-254-0761
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 Nuedexta must have a diagnosis of amyotrophic lateral sclerosis (ALS) or multiple sclerosis (MS) and exhibit signs of pseudobulbar affect.

Note:

- ***Nuedexta is indicated for the treatment of pseudobulbar affect (PBA).***
- ***Nuedexta has not been shown to be safe or effective in other types of emotional lability that can commonly occur, for example, in Alzheimer's disease and other dementias.***
- ***Nuedexta is contraindicated in patients with a prolonged QT interval, heart failure, or complete atrioventricular (AV) block.***

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: □ **Nuedexta**	**Diagnosis for this request (must check at least 2):** □ **PBA** □ **ALS** □ **MS**		
Physician Signature		Date	

Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

Date Received	Initials:
Approved - Effective dates of PA: From: / / To: / /	Approved by:
Denied: (Reasons)	

Nucynta Prior Authorization

HEALTH INFORMATION DESIGNS

Prior Authorization Vendor for ND Medicaid

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-773-0695

ND Medicaid requires that patients receiving a new prescription for Nucynta must be unable to tolerate other opioids due to gastrointestinal side effects.

- **Oxycodone is covered without a prior authorization.**

Part I: TO BE COMPLETED BY PRESCRIBER

Recipient Name	Recipient Date of Birth	Recipient Medicaid ID Number	
Prescriber Name			
Prescriber Medicaid Provider Number	Telephone Number	Fax Number	
Address	City	State	Zip Code
Requested Drug and Dosage: □ **Nucynta**	**Diagnosis for this request:**		
Qualifications for coverage:			
□ UNABLE TO TOLERATE OTHER OPIOIDS DUE TO GASTROINTESTINAL SIDE EFFECTS OPIOID TRIED_____ START DATE: DOSE: END DATE: FREQUENCY:			
Prescriber Signature		Date	

Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

Date Received	Initials:
Approved - Effective dates of PA: From: / / To: / /	Approved by:
Denied: (Reasons)	

OLYSIO PA FORM

HEALTH INFORMATION DESIGNS

Prior Authorization Vendor for ND Medicaid

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-773-0695

ND Medicaid requires that patients receiving a new prescription for Olysio must meet the following criteria:

- Patient must be ≥ 18 years old.
- Must have a diagnosis of chronic hepatitis C, genotype 1, with compensated liver disease.
- Liver biopsy showing fibrosis corresponding to a Metavir score of greater than or equal to 2 or Ishak score of greater than or equal to 3 or other accepted test demonstrating liver fibrosis.
- Must be prescribed by or in consultation with a hepatologist, gastroenterologist, or infectious disease specialist.
- Must be used in combination with pegylated interferon and ribavirin. **(must not be used as monotherapy)**
- Female patients must have a negative pregnancy test within 30 days prior to initiation of therapy and monthly during treatment.
- Documentation showing that patient is drug and alcohol free for the past 12 months
- Alternative therapy should be considered for patients infected with HCV genotype 1a containing the Q80K polymorphism.

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 □ **Olysio** Dosage _____	**Documented liver fibrosis** **Presence of Q80K polymorphism?** □ YES □ NO	**Diagnosis for this request** **Genotype** **Pegylated interferon dose** **Ribavirin dose**	**Patient is drug and alcohol free for past 12 months** □ YES □ NO **Negative pregnancy test in the past 30 days** □ YES □ NO
Has the patient been previously treated for chronic hepatitis C? □ YES □ NO If yes, please indicate past treatment regimen(s), dates of treatment, and response to therapy:			Baseline HCV RNA: HCV RNA 4 weeks after starting therapy:
Physician Signature			Date

Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

Date Received:	Initials:
Approved - Effective dates of PA: From: / / To: / /	Approved by:
Denied: (Reasons)	

Onmel
Prior Authorization

Fax Completed Form to:
866-254-0761
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 Onmel must meet the following criteria:

- *Patient must receive two medically necessary courses of therapy with itraconazole (Sporanox) and terbinafine (Lamisil)*

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

QUALIFICATIONS FOR COVERAGE:	
Requested Drug and Dosage: □ **Onmel**	Diagnosis for this request:
Physician Signature	Date

Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

Date Received	Initials:
Approved - Effective dates of PA: From: / / To: / /	Approved by:
Denied: (Reasons)	

Orally Disintegrating Tablets (ODT)
Prior Authorization

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-773-0695

Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that patients who are prescribed an orally disintegrating tablet must first try a more cost-effective dosage form.

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:**		
Qualifications for coverage:			
□ Unable to Swallow □ Medication Failed _____	Start Date: End Date:	Dose: Frequency:	
Physician Signature		Date	

Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

Date Received	Initials:
Approved - Effective dates of PA: From: / / To: / /	Approved by:
Denied: (Reasons)	

Ophthalmic Antihistamines
Prior Authorization

Fax Completed Form to:
866-254-0761
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 Lastacaft, Bepreve, and Pataday must first try one of the following:

- ***Ketotifen, Azelastine, Elestat, Emadine, and Patanol do not require a prior authorization.***

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: □ **Lastacaft** □ **Bepreve** □ **Pataday**	**Diagnosis for this request:**		
Qualifications for coverage:			
□ FAILED THERAPY START DATE: END DATE:	DOSE: FREQUENCY:		
Physician Signature		Date	

Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

Date Received	Initials:
Approved - Effective dates of PA: From: / / To: / /	Approved by:
Denied: (Reasons)	

OPHTHALMIC ANTI-INFECTIVE PA FORM

Prior Authorization Vendor for ND Medicaid

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-773-0695

ND Medicaid will not pay for Azasite, Quixin, or Moxeza without documented failure of a first line antibiotic ophthalmic agent.

***Note: First line agents include sulfacetamide (Bleph 10®, etc.), erythromycin, bacitracin-polymixin B (Polysporin®), polymyxin B neomycin-gramicidin (Neosporin®), trimethoprim-polymyxin B (Polytrim®), gentamicin (Garamycin®, etc.), ofloxacin (Ocuflox®) and ciprofloxacin (Ciloxan®).**

Part I: TO BE COMPLETED BY PRESCRIBER

Recipient Name	Recipient Date of Birth	Recipient Medicaid ID Number	
Prescriber Name			
Prescriber Medicaid Provider Number	Telephone Number	Fax Number	
Address	City	State	Zip Code
Requested Drug and Dosage: □ AZASITE □ MOXEZA □ QUIXIN	**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 Signature	Date		

Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

Date Received	Initials:
Approved - Effective dates of PA: From: / / To: / /	Approved by:
Denied: (Reasons)	

DORYX and ORACEA PA FORM

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-773-0695

Prior Authorization Vendor for ND Medicaid

Note: ND Medicaid will not pay for Oracea without documented failure of a first line tetracycline agent.

- First line agents include: doxycycline, minocycline, and tetracycline.

Part I: TO BE COMPLETED BY PRESCRIBER

RECIPIENT NAME:		RECIPIENT MEDICAID ID NUMBER:
Recipient Date of birth: / /		
PRESCRIBER NAME:		PRESCRIBER MEDICAID ID NUMBER:
Address:		Phone: ( )
City:		FAX: ( )
State: Zip:		

REQUESTED DRUG: □ **ORACEA** □ **DORYX**	**Requested Dosage:** (must be completed)

Qualifications for coverage:

□ Patient has failed a 90 day trial of which first line agent _____

□ *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 Signature: Date:

Part II: TO BE COMPLETED BY PHARMACY

PHARMACY NAME:		ND MEDICAID PROVIDER NUMBER:
Phone:		FAX:
Drug:		NDC#:

Part III: FOR OFFICIAL USE ONLY

Date: / /	Initials: _____
Approved - Effective dates of PA: From: / /	To: / /
Denied: (Reasons)	

ORAL ANTICOAGULANTS
PA FORM

Prior Authorization Vendor for ND Medicaid

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-773-0695

ND Medicaid requires that patients receiving a new prescription for Pradaxa, Xarelto or Eliquis must meet the following criteria:

- **Patient must have an FDA approved indication.**

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: □ PRADAXA □ XARELTO □ ELIQUIS	**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 Signature	Date		

Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

Date Received	Initials:
Approved - Effective dates of PA: From: / / To: / /	Approved by:
Denied: (Reasons)	

Oravig Prior Authorization

Fax Completed Form to:
866-254-0761
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 Oravig first try fluconazole.
Note:

- ***Fluconazole does not require PA***

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: □ **Oravig**	**Diagnosis for this request:**		
Qualifications for coverage:			
□ **Medication failed** _____	**Start Date:** **End Date:**	**Dose:** **Frequency:**	
Physician Signature		Date	

Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

Date Received	Initials:
Approved - Effective dates of PA: From: / / To: / /	Approved by:
Denied: (Reasons)	

HEALTH INFORMATION DESIGNS

Prior Authorization Vendor for ND Medicaid

OXYCODONE CR
PA FORM

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-773-0695

***Note: The PA may be approved if all of the following criteria are met.**

- **Patient has a chronic pain indication (includes cancer).**
- **Patient has taken an immediate release narcotic for the past 90 days or is switching from another sustained release opioid analgesic.**

Part I: TO BE COMPLETED BY PRESCRIBER

Recipient Name		Recipient Date of Birth	Recipient Medicaid ID Number
Prescriber Name			
Prescriber Medicaid Provider Number		Telephone Number	Fax Number
Address		City	State / Zip Code
Requested Drug: □ OXYCODONE CR	**DOSAGE:**	**Diagnosis for this request:**	
QUALIFICATIONS FOR COVERAGE: □ CHRONIC MALIGNANT PAIN INDICATION □ CHRONIC NON-MALIGNANT PAIN INDICATION		**LIST IMMEDIATE RELEASE MEDICATION TAKEN:**	
LIST OTHER SUSTAINED RELEASE OPIOID ANALGESIC PATIENT IS SWITCHING FROM:			
□ *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 Signature			Date

Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

Date Received	Initials:
Approved - Effective dates of PA: From: / / To: / /	Approved by:
Denied: (Reasons)	

Proton Pump Inhibitor PA Form

Prior Authorization Vendor for ND Medicaid

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-773-0695

ND Medicaid requires that patients receiving proton pump inhibitors must use Prilosec OTC, Prevacid 24HR, Omeprazole, or Pantoprazole as first line.

****Note:***

- **Prilosec OTC, Prevacid 24HR, Omeprazole and Pantoprazole may be prescribed WITHOUT prior authorization. Prilosec OTC and Prevacid 24HR are covered by Medicaid when prescribed by a physician.**
- **Patients must use Prilosec OTC, Prevacid 24HR, omeprazole, or pantoprazole for a minimum of 14 days for the trial to be considered a failure. Patient preference does not constitute a failure.**
- **Net cost to Medicaid: Prilosec OTC = Prevacid 24HR = Omeprazole = Pantoprazole <<< Lansoprazole << Aciphex << Nexium << Zegerid <<< Dexilant.**

Part I: TO BE COMPLETED BY PRESCRIBER

RECIPIENT NAME:	RECIPIENT MEDICAID ID NUMBER:
Recipient Date of birth: / /	
PRESCRIBER NAME:	PRESCRIBER MEDICAID ID NUMBER:
Address:	Phone: ( )
City:	FAX: ( )
State: Zip:	

REQUESTED DRUG: □ Aciphex □ Lansoprazole □ Nexium □ Zegerid □ Dexilant	**Requested Dosage:** (must be completed) **Diagnosis for this request:**

Qualifications for coverage:

❑ Failed Prilosec OTC/Prevacid 24HR/Omeprazole/Pantoprazole therapy	Start Date: End Date:	Dose: Frequency:
□ Pregnancy – Due Date		
□ Inability to take or tolerate oral tablets (must check a box) □ Tube Fed □ Requires soft food or liquid administration □ Other (provide description)		
□ Adverse reaction (attach FDA Medwatch form) to omeprazole/lansoprazole.		
□ *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 Signature:		Date:

Part II: TO BE COMPLETED BY PHARMACY

PHARMACY NAME:	ND MEDICAID PROVIDER NUMBER:
Phone:	FAX:
Drug:	NDC#:

Part III: FOR OFFICIAL USE ONLY

Date: / /	Initials: _____
Approved - Effective dates of PA: From: / /	To: / /
Denied: (Reasons)	

HEALTH INFORMATION DESIGNS

Prior Authorization Vendor for ND Medicaid

Provigil/Nuvigil Prior Authorization

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-773-0695

ND Medicaid requires that patients receiving a new prescription for Provigil or Nuvigil must suffer from excessive sleepiness associated with obstructive sleep apnea/hypopnea syndrome, narcolepsy, or shift work disorder.

- **Provigil must be used before Nuvigil will be approved.**

Part I: TO BE COMPLETED BY PRESCRIBER

Recipient Name	Recipient Date of Birth	Recipient Medicaid ID Number	
Prescriber Name			
Prescriber Medicaid Provider Number	Telephone Number	Fax Number	
Address	City	State	Zip Code
Requested Drug and Dosage: □ **Nuvigil** □ **Provigil**	**Diagnosis for this request:**		
Qualifications for coverage:			
□ FAILED PROVIGIL (Nuvigil Requests)	START DATE: END DATE:	DOSE: FREQUENCY:	
□ EXCESSIVE SLEEPINESS ASSOCIATED WITH OBSTRUCTIVE SLEEP APNEA/HYPOPNEA SYNDROME □ NARCOLEPSY □ SHIFT WORK SLEEP DISORDER			
Prescriber Signature		Date	

Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

Date Received	Initials:
Approved - Effective dates of PA: From: / / To: / /	Approved by:
Denied: (Reasons)	

PULMONARY ARTERIAL HYPERTENSION AGENTS
PA FORM

Prior Authorization Vendor for ND Medicaid

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-773-0695

ND Medicaid requires that patients receiving a new prescription for an agent used to treat pulmonary arterial hypertension (PAH) must meet the following criteria:

- **Patient must have diagnosis of PAH 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: □ LETAIRIS □ TRACLEER □ VENTAVIS □ REVATIO □ ADCIRCA □ TYVASO □ OTHER_____	**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 Signature	Date		

Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

Date Received	Initials:
Approved - Effective dates of PA: From: / / To: / /	Approved by:
Denied: (Reasons)	

Pulmozyme
Prior Authorization

Fax Completed Form to:
866-254-0761
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 Pulmozyme must meet the following criteria:

- *Patient must have a confirmed diagnosis of cystic fibrosis*

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

QUALIFICATIONS FOR COVERAGE:

Requested Drug and Dosage: □ **Pulmozyme**	Diagnosis for this request:
Physician Signature	Date

Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

Date Received	Initials:
Approved - Effective dates of PA: From: / / To: / /	Approved by:
Denied: (Reasons)	

QUALAQUIN PA FORM

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-773-0695

Prior Authorization Vendor for ND Medicaid

ND Medicaid will cover Qualaquin with a diagnosis of Malaria.

Part I: TO BE COMPLETED BY PRESCRIBER

RECIPIENT NAME:			RECIPIENT MEDICAID ID NUMBER:
Recipient Date of birth: / /			
PRESCRIBER NAME:			PRESCRIBER MEDICAID ID NUMBER:
Address:			Phone: ( )
City:			FAX: ( )
State:	Zip:		

REQUESTED DRUG: □ **QUALAQUIN**	**Requested Dosage:** (must be completed)

Qualifications for coverage:

□ Diagnosis of malaria

□ *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 Signature: Date:

Part II: TO BE COMPLETED BY PHARMACY

PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
Phone:			FAX:
Drug:			NDC#:

Part III: FOR OFFICIAL USE ONLY

Date: / /		Initials: _____
Approved - Effective dates of PA: From: / /		To: / /
Denied: (Reasons)		

Rayos
Prior Authorization

Fax Completed Form to:
866-254-0761
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 Rayos must meet the following criteria:

- *Patient must first try generic prednisone.*

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

QUALIFICATIONS FOR COVERAGE:	
Requested Drug and Dosage: □ **Rayos**	Diagnosis for this request:
Physician Signature	Date

Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

Date Received	Initials:
Approved - Effective dates of PA: From: / / To: / /	Approved by:
Denied: (Reasons)	

RIBAPAK PA FORM

Prior Authorization Vendor for ND Medicaid

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-773-0695

ND Medicaid requires that patients receiving a new prescription for RibaPak must meet the following criteria:

- **Patient must first try Ribavirin or Ribasphere.**

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: □ RIBAPAK	**FDA Approved Indication for this request:**		
□ **Failed therapy with Ribavirin or Ribasphere**	**Start Date**	**End Date**	**Dose**
WHAT IS THE HCV GENOTYPE? (I-IV)			
***TREATMENT WILL BE COVERED FOR 24 TO 48 WEEKS BASED UPON GENOTYPE AND DIAGNOSIS.**			
□ Treatment regimen for Hepatitis C will include pegylated or non-pegylated interferon in combination with oral ribavirin.			
Physician Signature		Date	

Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

Date Received	Initials:
Approved - Effective dates of PA: From: / / To: / /	Approved by:
Denied: (Reasons)	

Relistor Prior Authorization

Fax Completed Form to:
866-254-0761
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 Relistor must meet the following guidelines:

- Diagnosis of opioid-induced constipation
- Inability to tolerate oral medications *or*
- Failed two oral medications

Note:
***Polyethylene glycol powder is covered without a prior authorization.**

Part I: TO BE COMPLETED BY PRESCRIBER

Recipient Name	Recipient Date of Birth	Recipient Medicaid ID Number	
Prescriber Name			
Prescriber Medicaid Provider Number	Telephone Number	Fax Number	
Address	City	State	Zip Code
Requested Drug and Dosage: □ **Relistor**	**Diagnosis for this request:**		
Qualifications for coverage:			
FIRST FAILED MEDICATION	START DATE:	END DATE:	
SECOND FAILED MEDICATION	START DATE:	END DATE:	
□ INABILITY TO TOLERATE ORAL MEDICATIONS			
Prescriber Signature		Date	

Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

Date Received	Initials:
Approved - Effective dates of PA: From: / / To: / /	Approved by:
Denied: (Reasons)	

HEALTH INFORMATION DESIGNS

Sancuso Prior Authorization

Fax Completed Form to:
866-254-0761
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 Sancuso must be unable to take oral medications.
Note:

- ***Dolasetron, oral granisetron, and ondansetron do not require PA.***
- ***Patients must be unable to take oral medications or***
- ***Patients must fail therapy on ondansetron or oral granisetron before a PA may be granted.***

Part I: TO BE COMPLETED BY PRESCRIBER

Recipient Name	Recipient Date of Birth	Recipient Medicaid ID Number	
Prescriber Name			
Prescriber Medicaid Provider Number	Telephone Number	Fax Number	
Address	City	State	Zip Code
Requested Drug and Dosage: □ **Sancuso**	**Diagnosis for this request:**		
Qualifications for coverage:			
□ FAILED MEDICATION	START DATE: END DATE:	DOSE: FREQUENCY:	
□ PATIENT UNABLE TO TAKE ORAL MEDICATIONS			
Prescriber Signature		Date	

Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

Date Received	Initials:
Approved - Effective dates of PA: From: / / To: / /	Approved by:
Denied: (Reasons)	

HEALTH INFORMATION DESIGNS

Prior Authorization Vendor for ND Medicaid

Sedative/Hypnotic PA Form

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-773-0695

ND Medicaid requires that patients receiving a new prescription for a name brand Sedative/Hypnotic must use Ambien® (zolpidem) as first line therapy.

**Note:*

- **The PA will be approved if there is a failed trial of Ambien (zolpidem).**
- **Estazolam, flurazepam, temazepam, triazolam, quazepam and Ambien (zolpidem) do not require a PA.**

Part I: TO BE COMPLETED BY PRESCRIBER

Recipient Name	Recipient Date of Birth	Recipient Medicaid ID Number	
Prescriber Name			
Prescriber Medicaid Provider Number	Telephone Number	Fax Number	
Address	City	State	Zip Code
Requested Drug and Dosage:	**Diagnosis for this request:**		
Qualifications for coverage:			
□ FAILED AMBIEN (ZOLPIDEM)	Start Date: End Date:	Dose: Frequency:	
□ HIGH RISK FOR ADDICTION			
□ *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 Signature		Date	

Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

Date Received	Initials:
Approved - Effective dates of PA: From: / / To: / /	Approved by:
Denied: (Reasons)	

Short-Acting HFA Beta$_2$ Agonist PA FORM

HEALTH INFORMATION DESIGNS

Prior Authorization Vendor for ND Medicaid

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-773-0695

ND Medicaid requires that patients receiving a new prescription for ProAir HFA, Ventolin HFA, or Xopenex HFA must use Proventil HFA as first line therapy.

***Note: Proventil HFA does not require a prior authorization.**

Part I: TO BE COMPLETED BY PRESCRIBER

Recipient Name	Recipient Date of Birth	Recipient Medicaid ID Number	
Prescriber Name			
Prescriber Medicaid Provider Number	Telephone Number	Fax Number	
Address	City	State	Zip Code
Requested Drug and Dosage: □ XOPENEX HFA □ VENTOLIN HFA □ PROAIR HFA	**Diagnosis for this request:**		

Qualifications for coverage:

□ Failed Proventil HFA 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 Signature	Date

Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

Date Received	Initials:
Approved - Effective dates of PA: From: / / To: / /	Approved by:
Denied: (Reasons)	

SOVALDI PA FORM

HEALTH INFORMATION DESIGNS

Prior Authorization Vendor for ND Medicaid

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-773-0695

ND Medicaid requires that patients receiving a new prescription for Sovaldi must meet the following criteria:

- Patient must be ≥ 18 years old.
- Must have a diagnosis of chronic hepatitis C (genotypes 1, 2, 3, or 4) with compensated liver disease.
- Liver biopsy showing fibrosis corresponding to a Metavir score of greater than or equal to 2 or Ishak score of greater than or equal to 3 or other accepted test demonstrating liver fibrosis.
- Must be prescribed by or in consultation with a hepatologist, gastroenterologist, or infectious disease specialist.
- Must be used in combination with ribavirin or in combination with pegylated interferon and ribavirin. **(must not be used as monotherapy)**
- Female patients must have a negative pregnancy test within 30 days prior to initiation of therapy and monthly during treatment.
- Absence of renal impairment (eGFR must be >30mL/min/1.73m^2) and absence of end stage renal disease (ESRD).
- Documentation showing that patient is drug and alcohol free for the past 12 months

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 □ **Sovaldi** Dosage _____	**Documented liver fibrosis**	**Diagnosis for this request** **Genotype** **Pegylated interferon dose** **Ribavirin dose**	**Patient is drug and alcohol free for past 12 months** □ YES □ NO **Negative pregnancy test in the past 30 days** □ YES □ NO	**eGFR**
Has the patient been previously treated for chronic hepatitis C? □ YES □ NO If yes, please indicate past treatment regimen(s), dates of treatment, and response to therapy:			Baseline HCV RNA: HCV RNA 4 weeks after starting therapy:	
Physician Signature			Date	

Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

Date Received	Initials:
Approved - Effective dates of PA: From: / / To: / /	Approved by:
Denied: (Reasons)	

Statins
Prior Authorization

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-773-0695

Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that patients who are prescribed a name-brand statin must first try a generic statin.
Note:

- ***Generic statins already on the market do not require a prior authorization***

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:**		
Qualifications for coverage:			
□ Medication Failed _____	Start Date: End Date:	Dose: Frequency:	
Physician Signature		Date	

Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

Date Received	Initials:
Approved - Effective dates of PA: From: / / To: / /	Approved by:
Denied: (Reasons)	

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

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**

Tecfidera Prior Authorization

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-773-0695

Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that patients who are prescribed Tecfidera must follow these guidelines:

Note:

- ***Must have relapsing forms of multiple sclerosis.***
- ***Must have a recent CBC (within 6 months).***

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: □ **Tecfidera**	**Diagnosis for this request:** **Current CBC (date):**		
Physician Signature		Date	

Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

Date Received	Initials:
Approved - Effective dates of PA: From: / / To: / /	Approved by:
Denied: (Reasons)	

Smoking Cessation Program

NDQuits

1-800-QUIT-NOW

Prior Authorization Vendor for ND Medicaid

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, in order 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 day supply of therapy for patches, gum, lozenges, and bupropion, every two years. Combination therapy with these medications is allowed.

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.

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.

TOPICAL ACNE AGENTS
PA FORM

Prior Authorization Vendor for ND Medicaid

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-773-0695

ND Medicaid requires that patients receiving a new prescription for a branded topical acne agent must meet the following criteria:

- **Patients under the age of 10 or older than 35 must have a dermatologist involved in therapy**
- **Patients must first try and fail a generic topical acne agent (erythromycin, benzoyl peroxide, clindamycin, tretinoin, sodium sulfacetamide/sulfur)**

Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name	**Recipient Date of Birth**	Recipient Medicaid ID Number	
Physician Name	Dermatologist Involved in therapy (if patient is <10 and >35): Next Appointment date:		
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 Signature	Date		

Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

Date Received	Initials:
Approved - Effective dates of PA: From: / / To: / /	Approved by:
Denied: (Reasons)	

LOCAL ANESTHETICS (TOPICAL) PA FORM

HEALTH INFORMATION DESIGNS

Prior Authorization Vendor for ND Medicaid

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-773-0695

ND Medicaid requires that patients receiving a new prescription for a topical local 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	
Physician Name			
Physician Medicaid Provider Number	Telephone Number	Fax Number	
Address	City	State	Zip Code
Requested Drug and Dosage: □ EMLA □ SYNERA	**Medical Procedure:**		
Physician Signature		Date	

Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

Date Received	Initials:
Approved - Effective dates of PA: From: / / To: / /	Approved by:
Denied: (Reasons)	

Topical Ketoconazole Products
Prior Authorization

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-773-0695

Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that patients who are prescribed Extina, Xolegel, and Ketocon Plus must first try a covered ketoconazole medication.

Note:

- ***Ketoconazole creams and ketoconazole shampoos do not require a prior authorization.***

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: □ **Extina** □ **Xolegel** □ **Ketocon Plus**	**Diagnosis for this request:**		
Qualifications for coverage:			
□ Medication Failed _____	Start Date: End Date:	Dose: Frequency:	
Physician Signature		Date	

Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

Date Received	Initials:
Approved - Effective dates of PA: From: / / To: / /	Approved by:
Denied: (Reasons)	

TRAMADOL ER PA FORM

HEALTH INFORMATION DESIGNS

Prior Authorization Vendor for ND Medicaid

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-773-0695

ND Medicaid requires that patients receiving a new prescription for tramadol ER (Ultram ER/Ryzolt) or tramadol ODT (Rybix) must meet the following criteria:

- **Documented failure of a 30-day trial of generic immediate release tramadol at maximum daily dosage of 400mg per 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: □ ULTRAM ER OR GENERIC □ RYZOLT □ RYBIX	**Diagnosis for this request:**

FAILED THERAPY	**START DATE**	**END DATE**	**DOSE**	**FREQUENCY**

Physician Signature	Date

Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

Date Received	Initials:
Approved - Effective dates of PA: From: / / To: / /	Approved by:
Denied: (Reasons)	

Serotonin (5-HT$_1$) Receptor Agonists - Triptan PA FORM

HEALTH INFORMATION DESIGNS

Prior Authorization Vendor for ND Medicaid

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-773-0695

ND Medicaid requires that patients receiving a new prescription for Axert, Frova, Maxalt, Relpax, Treximet, or Zomig must try sumatriptan then naratriptan as first line therapies.

*__Note:__

- **Sumatriptan does not require a PA.**
- **Injectables are not subject to a prior authorization at this time.**

Part I: TO BE COMPLETED BY PRESCRIBER

Recipient Name	Recipient Date of Birth	Recipient Medicaid ID Number	
Prescriber Name			
Prescriber Medicaid Provider Number	Telephone Number	Fax Number	
Address	City	State	Zip Code

Requested Drug and Dosage:	**Diagnosis for this request:**
□ NARATRIPTAN □ RELPAX □ MAXALT □ AXERT □ TREXIMET □ FROVA □ ZOMIG	

Qualifications for coverage:

□ Failed sumatriptan therapy	Start Date	End Date	Dose	Frequency
□ Failed naratriptan 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 Signature	Date

Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

Date Received	Initials:
Approved - Effective dates of PA: From: / / To: / /	Approved by:
Denied: (Reasons)	

ULORIC PA FORM

HEALTH INFORMATION DESIGNS

Prior Authorization Vendor for ND Medicaid

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-773-0695

ND Medicaid requires that patients receiving a new prescription for Uloric must try allopurinol as first line therapy or have documented renal/hepatic dysfunction.

- Allopurinol does not require a prior authorization.
- Allopurinol doses must be 300 mg or greater to be considered failed therapy.

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: □ ULORIC	**Diagnosis for this request:**		

Qualifications for coverage:

□ FAILED ALLOPURINOL THERAPY	Start Date	End Date	Dose	Frequency
□ RENAL OR HEPATIC IMPAIRMENT				
□ *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.*				
Physician Signature			Date	

Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

Date Received	Initials:
Approved - Effective dates of PA: From: / / To: / /	Approved by:
Denied: (Reasons)	

VANOS PA FORM

HEALTH INFORMATION DESIGNS

Prior Authorization Vendor for ND Medicaid

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-773-0695

ND Medicaid requires that patients receiving a new prescription for Vanos must meet the following criteria:

- **Patient must be 12 years of age and older.**
- **Patient must have documented failure with a generic topical steroid in the same potency class (Ultravate, Temovate, Diprolene).**

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: □ VANOS	**Diagnosis for this Request:**		
Failed Therapy (dose and frequency): □	**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 Signature		Date	

Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

Date Received	Initials:
Approved - Effective dates of PA: From: / / To: / /	Approved by:
Denied: (Reasons)	

VECAMYL
PA FORM

HEALTH INFORMATION DESIGNS

Prior Authorization Vendor for ND Medicaid

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-773-0695

ND Medicaid requires that patients receiving a new prescription for Vecamyl must meet the following criteria:

- **Patient must have an FDA approved indication.**
- **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.**

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: □ VECAMYL	**Diagnosis for this Request:**		
Failed Therapy:	**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 Signature		Date	

Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

Date Received	Initials:
Approved - Effective dates of PA: From: / / To: / /	Approved by:
Denied: (Reasons)	

Vusion PA FORM

Prior Authorization Vendor for ND Medicaid

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-773-0695

ND Medicaid requires that patients receiving a new prescription for Vusion must try other topical antifungal products as first line therapy.

***Note: Nystatin and clotrimazole do not require a prior authorization.**

Part I: TO BE COMPLETED BY PRESCRIBER

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: □ VUSION	**Diagnosis for this request:**		

Qualifications for coverage:

□ Failed antifungal therapy Name of medication failed: _____	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 Signature	Date

Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

Date Received	Initials:
Approved - Effective dates of PA: From: / / To: / /	Approved by:
Denied: (Reasons)	

Xeljanz
Prior Authorization

Fax Completed Form to:
866-254-0761
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 Xeljanz must meet the following criteria:

Note:

- **Patient must have an inadequate response or intolerance to methotrexate.**
- **Patient must have a test for latent tuberculosis prior to starting Xeljanz.**
- **Patient must have current lab monitoring prior to starting Xeljanz (CBC, liver enzymes, lipid panel)**
- **Use with caution in patients that may be at increased risk of gastrointestinal perforations.**

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

QUALIFICATIONS FOR COVERAGE:

Requested Drug and Dosage: □ **Xeljanz**	Diagnosis for this request:
TB test in the past 6 months □ Yes □ No Lab monitoring has occurred and measurements within acceptable limits (i.e., lymphocytes, neutrophils, hemoglobin, lipids, and liver enzymes) □ Yes □ NO Has or has had active hepatitis B or C virus □ Yes □ NO	Failed methotrexate therapy Start date: End date:
Physician Signature	Date

Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

Date Received	Initials:
Approved - Effective dates of PA: From: / / To: / /	Approved by:
Denied: (Reasons)	

HEALTH INFORMATION DESIGNS

Xenical Prior Authorization

Fax Completed Form to:
866-254-0761
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 Xenical must be seen by a dietician.
Note:

- ***Patient must have dietician evaluation attached to PA form including height and weight.***
- ***BMI must be equal to or greater than 40.***
- ***5% weight loss must be realized for continued approval (every 6 months).***

Part I: TO BE COMPLETED BY PRESCRIBER

Recipient Name	Recipient Date of Birth	Recipient Medicaid ID Number	
Prescriber Name			
Prescriber Medicaid Provider Number	Telephone Number	Fax Number	
Address	City	State	Zip Code
Requested Drug and Dosage: □ XENICAL	**Diagnosis for this request:**		
Qualifications for coverage:			
□ Dietician evaluation attached	Height:	Weight:	BMI:
Prescriber Signature		Date	

Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

Date Received	Initials:
Approved - Effective dates of PA: From: / / To: / /	Approved by:
Denied: (Reasons)	

XIFAXAN PA FORM

Prior Authorization Vendor for ND Medicaid

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-773-0695

ND Medicaid requires that patients receiving a new prescription for Xifaxan must meet the following guidelines:

- Patient must be 12 years of age or older and have a diagnosis of traveler's diarrhea caused by noninvasive strains of E. coli.
- Patient must be 18 years of age or older and have a risk of recurrence of overt hepatic encephalopathy.
- Do not use in patients with diarrhea complicated by fever or blood in the stool or diarrhea due to pathogens other than E. coli.

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: □ XIFAXAN	**Diagnosis for this Request:** □ TRAVELER'S DIARRHEA: 200 mg three times a day for 3 days □ HEPATIC ENCEPHALOPATHY: 550 mg two times a day		
□ *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 Signature		Date	

Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

Date Received	Initials:
Approved - Effective dates of PA: From: / / To: / /	Approved by:
Denied: (Reasons)	

XOLAIR PA FORM

Prior Authorization Vendor for ND Medicaid

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-773-0695

ND Medicaid requires that patients receiving a new prescription for Xolair must meet the following criteria:

- **Patient must have moderate to severe persistent asthma**
- **Patient must have serum IgE level between 30 and 700 IU/mL**

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: □ XOLAIR	**Diagnosis for this Request:**	**Serum IgE Level:**
Physician Signature		Date

Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

Date Received	Initials:
Approved - Effective dates of PA: From: / / To: / /	Approved by:
Denied: (Reasons)	

Xyrem Prior Authorization

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-773-0695

Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that patients who are prescribed Xyrem must meet these guidelines:
Note:

- ***Must be 18 years or older.***
- ***Must have a diagnosis of excessive daytime sleepiness and cataplexy in patients with narcolepsy.***
- ***Must be enrolled in the Xyrem Success Program***

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: □ **Xyrem**	**Diagnosis for this request:**		
Qualifications for coverage:			
□ Enrolled in Xyrem Success Program	Enrolled Date:	Dose:	
Physician Signature		Date	

Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

Date Received	Initials:
Approved - Effective dates of PA: From: / / To: / /	Approved by:
Denied: (Reasons)	

HEALTH INFORMATION DESIGNS

Prior Authorization Vendor for ND Medicaid

Zanaflex Capsule PA Form

Fax Completed Form to:
866-254-0761
For questions regarding this Prior authorization, call
866-773-0695

ND Medicaid requires that patients receiving Zanaflex capsules must use tizanidine tablets first line.
__Note:__

- **Tizanidine tablets do not require a PA.**
- **Patient must fail therapy on tizanidine tablets before a PA may be granted.**

Part I: TO BE COMPLETED BY PRESCRIBER

Recipient Name	Recipient Date of Birth	Recipient Medicaid ID Number	
Prescriber Name			
Prescriber Medicaid Provider Number	Telephone Number	Fax Number	
Address	City	State	Zip Code
Requested Drug and Dosage:	**Diagnosis for this request:**		
Qualifications for coverage:			
□ Failed generic drug	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 Signature		Date	

Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

Date Received	Initials:
Approved - Effective dates of PA: From: / / To: / /	Approved by:
Denied: (Reasons)	

NORTH DAKOTA MEDICAID
RETROSPECTIVE DRUG UTILIZATION REVIEW
CRITERIA RECOMMENDATIONS
4TH QUARTER 2014

Criteria Recommendations ***Approved Rejected***

1. Albiglutide / Overutilization _____ _____

Alert Message: The recommended dosage of Tanzeum (albiglutide) is 30 mg once weekly given as a subcutaneous injection in the abdomen, thigh, or upper arm region. The dosage may be increased to 50 mg once weekly if the glycemic response is inadequate.

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C
Albiglutide		

Max Dose: 50 mg per week

References:
Tanzeum Prescribing Information, April 2014, GlaxoSmithKline.
Clinical Pharmacology, 2014 Elsevier/Gold Standard.

2. Albiglutide / Insulin and Insulin Secretagogues _____ _____

Alert Message: The risk of hypoglycemia is increased when Tanzeum (albiglutide) 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
Albiglutide	Insulins	
	Chlorpropamide	
	Glimepiride	
	Glipizide	
	Glyburide	
	Tolazamide	
	Tolbutamide	

References:
Tanzeum Prescribing Information, April 2014, GlaxoSmithKline.
Clinical Pharmacology, 2014 Elsevier/Gold Standard.

3. Albiglutide / Non-adherence _____ _____

Alert Message: Non-adherence to Tanzeum (albiglutide) therapy may result in loss of glycemic control and an increased risk of developing adverse diabetic-related complications.

Conflict Code: LR – Non-adherence
Drugs/Diseases

Util A	Util B	Util C
Albiglutide		

References:
Tanzeum Prescribing Information, April 2014, GlaxoSmithKline.
Currie CJ, Peyrot M, Morgan CL, et al. The Impact of Treatment Noncompliance on Mortality in People With Type 2 Diabetes. Diabetes Care 35:1279-1284, June 2012.
Butler RJ, Davis TK, Johnson WL, et al. Effects of Nonadherence with Prescription Drugs Among Older Adults. Am J Manag Care. 2011 Feb; 17(2):153-60.

4. Albiglutide / Thyroid Carcinoma & MENS II _____ _____

Alert Message: The use of Tanzeum (albiglutide), a glucagon-like peptide-1 (GLP-1) receptor agonist, is contraindicated in patients with a personal or family history of medullary thyroid carcinoma (MTC) or with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2). GLP-1 receptor agonists have been shown to increase the incidence of thyroid C-cell tumors in rodents. 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 – Contraindication (Black Box Warning)
Drugs/Diseases

Util A	Util B	Util C **(Included)**
Albiglutide		Medullary Thyroid Carcinoma II
		Thyroid Carcinoma
		History of Thyroid Carcinoma

References:
Tanzeum Prescribing Information, April 2014, GlaxoSmithKline.
Clinical Pharmacology, 2014 Elsevier/Gold Standard.

5. Albiglutide / Therapeutic Appropriateness _____ _____

Alert Message: Tanzeum (albiglutide) is a glucagon-like peptide-1 (GLP-1) receptor agonist and GLP-1 agonists have been shown to cause thyroid C-cell tumors at clinically relevant exposure in rodents. It is unknown whether albiglutide 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 **(Negate)**
Albiglutide		Medullary Thyroid Carcinoma II
		Thyroid Carcinoma
		History of Thyroid Carcinoma

References:
Tanzeum Prescribing Information, April 2014, GlaxoSmithKline.
Clinical Pharmacology, 2014 Elsevier/Gold Standard.

6. Albiglutide / Pancreatitis _____ _____

Alert Message: In clinical trials, acute pancreatitis has been reported in association with Tanzeum (albiglutide) use. Albiglutide should be promptly discontinued if pancreatitis is suspected and should not be restarted if confirmed. Albiglutide 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
Albiglutide	Pancreatitis	

References:
Tanzeum Prescribing Information, April 2014, GlaxoSmithKline.
Clinical Pharmacology, 2014 Elsevier/Gold Standard.

7. Albiglutide / Therapeutic Appropriateness _____ _____

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

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C
Albiglutide		

Age Range: 0-18 yoa

References:
Tanzeum Prescribing Information, April 2014, GlaxoSmithKline.
Clinical Pharmacology, 2014 Elsevier/Gold Standard.

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

Alert Message: There are no adequate and well-controlled studies of Tanzeum (albiglutide) in pregnant women. Nonclinical studies have shown reproductive toxicity, but not teratogenicity, in mice. Albiglutide is Pregnancy Category C and should not be used during pregnancy unless the expected benefit outweighs the potential risks.

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

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

References:
Tanzeum Prescribing Information, April 2014, GlaxoSmithKline.
Clinical Pharmacology, 2014 Elsevier/Gold Standard.

9. Albiglutide / Renal Impairment _____ _____

Alert Message: Use caution when initiating or escalating doses of Tanzeum (albiglutide) in patients with renal impairment. In a trial of albiglutide in patients with renal impairment, the frequency of gastrointestinal events increased as renal function declined. No dosage adjustment is recommended in renal impairment but monitoring renal function is recommended in patients reporting severe adverse gastrointestinal reactions.

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C **(Include)**
Albiglutide		Renal Impairment

References:
Tanzeum Prescribing Information, April 2014, GlaxoSmithKline.
Clinical Pharmacology, 2014 Elsevier/Gold Standard.

10. Albiglutide / Severe Gastrointestinal Disorders _____ _____

Alert Message: Tanzeum (albiglutide), a glucagon-like peptide-1 (GLP-1) receptor agonist, has not been studied in patient with pre-existing severe gastrointestinal disease, including severe gastroparesis. Its use is not recommended in patients with severe GI disease. GLP-1 receptor agonists slow gastric emptying and can exacerbate gastrointestinal disorders.

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C **(Include)**
Albiglutide		Gastroparesis
		Irritable Bowel Syndrome
		Diverticular Disease
		Crohn's Disease
		Ulcerative Colitis

References:
Tanzeum Prescribing Information, April 2014, GlaxoSmithKline.
Clinical Pharmacology, 2014 Elsevier/Gold Standard.

11. Linagliptin-All / Therapeutic Appropriateness _____ _____

Alert Message: There have been post-marketing reports of acute pancreatitis including fatal pancreatitis, in patients taking linagliptin. If pancreatitis is suspected, promptly discontinue the linagliptin-containing product and initiate appropriate management. It is unknown whether patients with a history of pancreatitis are at increased risk while using linagliptin.

Conflict Code: TA - Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C
Linagliptin		

References:
Tradjenta Prescribing Information, June 2013, Boehringer Ingelheim Pharmaceuticals. Inc.
Jentadueto Prescribing Information, June 2013, Boehringer Ingelheim Pharmaceuticals. Inc.

12. Viscous Lidocaine 2% / Black Box Warning _____ _____

Alert Message: Oral viscous lidocaine 2% solution should not be used to treat infants and children with teething pain. This agent is not approved to treat teething pain and its use in infants and young children can cause serious harm, including death.

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C **(Negating)**
Viscous Lidocaine 2%		Neoplasm
		Chemotherapy

Age Range: 0 – 4 yoa

References:
MedWatch The FDA Safety Information and Adverse Event Reporting Program - Lidocaine Viscous: Drug Safety Communication – Boxed Warning Required – Should Not Be Used to Treat Teething Pain. [6/26/2014].

13. Empagliflozin / Overutilization _____ _____

Alert Message: Jardiance (empagliflozin) may be over-utilized. The manufacturer's recommended dose of empagliflozin is 10 mg once daily in the morning, taken with or without food. In patients tolerating empagliflozin, the dose may be increased to 25 mg once daily.

Conflict Code: ER - Overutilization

Drugs/Diseases		
Util A	Util B	Util C
Empagliflozin		

Max Dose: 25mg/day

References:
Jardiance Prescribing Information, Aug. 2014, Boehringer Ingelheim Pharmaceuticals, Inc.

14. Empagliflozin / Mild to Moderate Renal Impairment _____ _____

Alert Message: Assessment of renal function is recommended prior to initiation of Jardiance (empagliflozin) and periodically thereafter. No dosage adjustment is needed in patients with an eGFR greater than or equal to 45 mL/min/1.73m2. Empagliflozin should not be initiated in patients with an eGFR less than 45 mL/min/1.73m2 and should be discontinued if eGFR is persistently less than 45 mL/min/1.73m2.

Conflict Code: TA – Therapeutic Appropriateness

Drugs/Diseases		
Util A	Util B	Util C **(Include)**
Empagliflozin		CKD Stage 1
		CKD Stage 2
		CKD Stage 3

References:
Jardiance Prescribing Information, Aug. 2014, Boehringer Ingelheim Pharmaceuticals, Inc.

15. Empagliflozin / Severe Renal Impairment, ESRD & Dialysis _____ _____

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

Conflict Code: TA – Therapeutic Appropriateness

Drugs/Diseases		
Util A	Util B	Util C **(Include)**
Empagliflozin		ESRD
		CKD Stage 4 & 5
		Dialysis

References:
Jardiance Prescribing Information, Aug. 2014, Boehringer Ingelheim Pharmaceuticals, Inc.

16. Empagliflozin / Non-adherence _____ _____

Alert Message: Based on refill history, your patient may be under-utilizing Jardiance (empagliflozin). 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 – Non-adherence
Drugs/Diseases

Util A	Util B	Util C
Empagliflozin		

References:
Jardiance Prescribing Information, Aug. 2014, Boehringer Ingelheim Pharmaceuticals, Inc.
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.
Butler RJ, Davis TK, Johnson WL, et al. Effects of Nonadherence with\Prescription Drugs Among Older Adults. Am J Manag Care. 2011 Feb; 17(2):153-60.

17. Empagliflozin / Hypotension, Hypovolemia CKD Stage 3 & Dehydration _____ _____

Alert Message: Jardiance (empagliflozin) 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 empagliflozin 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
Empagliflozin	Hypotension	
	Hypovolemia	
	CKD Stage 3	
	Dehydration	

References:
Jardiance Prescribing Information, Aug. 2014, Boehringer Ingelheim Pharmaceuticals, Inc.

18. Empagliflozin / Diuretics _____ _____

Alert Message: Jardiance (empagliflozin) 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 empagliflozin 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
Empagliflozin	Loop Diuretics	
	Thiazide Diuretics	
	Potassium Sparing Diuretics	

References:
Jardiance Prescribing Information, Aug. 2014, Boehringer Ingelheim Pharmaceuticals, Inc.

19. Empagliflozin / Insulin & Sulfonylureas _____ _____

Alert Message: The concurrent use of Jardiance (empagliflozin) with insulin or an insulin secretagogue can increase the risk of hypoglycemia. A lower dose of insulin or insulin secretagogue may be required to minimize the risk of hypoglycemia when used in combination with empagliflozin.

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

Util A	Util B	Util C
Empagliflozin	Insulin	
	Chlorpropamide	
	Glimepiride	
	Glipizide	
	Glyburide	
	Tolazamide	
	Tolbutamide	

References:
Jardiance Prescribing Information, Aug. 2014, Boehringer Ingelheim Pharmaceuticals, Inc.

20. Empagliflozin / LDL-Increases _____ _____

Alert Message: The use of Jardiance (empagliflozin) can cause dose-related increases in LDL-C levels. Patients receiving empagliflozin 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)**
Empagliflozin		Hypercholesterolemia

References:
Jardiance Prescribing Information, Aug. 2014, Boehringer Ingelheim Pharmaceuticals, Inc.

21. Empagliflozin / Pediatric Use _____ _____

Alert Message: The safety and effectiveness of Jardiance (empagliflozin) 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
Empagliflozin		

Age Range: 0-17 yoa

References:
Jardiance Prescribing Information, Aug. 2014, Boehringer Ingelheim Pharmaceuticals, Inc.

22. Canagliflozin/Metformin / Overutilization _____ _____

Alert Message: Invokamet (canagliflozin/metformin) may be over-utilized. The manufacturer's recommended total daily dose of canagliflozin/metforming is 300mg/2000mg in patients with an eGFR of 60 mL/min/1.73m2 or greater.

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	**Util C (Negating)**
Canagliflozin/Metformin		CKD Stage 3, 4 & 5
		ESRD
		Dialysis

Max Dose: 300mg/2000mg per day

References:
Invokamet Prescribing Information, Aug. 2014, Janssen Pharmaceuticals, Inc.
Clinical Pharmacology, 2014 Elsevier/Gold Standard.

23. Canagliflozin/Metformin / Moderate Renal Impairment _____ _____

Alert Message: The dose of Invokamet (canagliflozin/metformin) should be limited to canagliflozin 50 mg twice daily in patients with moderate renal impairment with an eGFR of 45 to less than 60 mL/min/1.723m2.

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C **(Include)**
Canagliflozin/Metformin		CKD Stage 3

Max Dose: 100mg/2000mg per day

References:
Invokamet Prescribing Information, Aug. 2014, Janssen Pharmaceuticals, Inc.
Clinical Pharmacology, 2014 Elsevier/Gold Standard.

24. Canagliflozin/Metformin / Severe Renal Impairment, ESRD & Dialysis _____ _____

Alert Message: Invokamet (canagliflozin/metformin) is contraindicated in patients with renal impairment (e.g., serum creatinine levels greater than or equal to 1.5mg/dL for males or 1.4 mg/dL for females, or eGFR less than 45 mL/min/1.73 m2), end stage renal disease or patients on dialysis.

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

Util A	Util B	Util C
Canagliflozin/Metformin	CKD Stage 4 & 5	
	ESRD	
	Dialysis	

References:
Invokamet Prescribing Information, Aug. 2014, Janssen Pharmaceuticals, Inc.
Clinical Pharmacology, 2014 Elsevier/Gold Standard.

25. Canagliflozin/Metformin 50mg / UGT Inducers _____ _____

Alert Message: Concurrent use of Invokamet (canagliflozin/metformin) with a UGT inducer may result in decreased canagliflozin exposure and loss of efficacy. Consider increasing the canagliflozin dose to 150 mg twice daily in patients currently taking 50 mg twice daily who have an eGFR of 60 mL/min/1.73m2 or greater and require additional glycemic control. Consider another antihyperglycemic agent in patients with an eGFR of 45 to less than 60 mL/min/1.73m2 receiving concurrent therapy with a UGT inducer.

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

Util A	Util B	Util C
Canagliflozin/Metformin 50mg/500mg	Rifampin	
Canagliflozin/Metformin 50mg/1000mg	Phenytoin	
	Phenobarbital	
	Ritonavir	

References:
Invokamet Prescribing Information, Aug. 2014, Janssen Pharmaceuticals, Inc.
Clinical Pharmacology, 2014 Elsevier/Gold Standard.

26. Canagliflozin/Metformin 150mg / UGT Inducers _____ _____

Alert Message: Concurrent use of Invokamet (canagliflozin/metformin) with a UGT inducer may result in decreased canagliflozin exposure and loss of efficacy. Monitor patient for loss of canagliflozin effectiveness.

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

Util A	Util B	Util C
Canagliflozin/Metformin 150mg/500mg	Rifampin	
Canagliflozin/Metformin 150mg/1000mg	Phenytoin	
	Phenobarbital	
	Ritonavir	

References:
Invokamet Prescribing Information, Aug. 2014, Janssen Pharmaceuticals, Inc.
Clinical Pharmacology, 2014 Elsevier/Gold Standard.

27. Canagliflozin/Metformin / Therapeutic Appropriateness _____ _____

Alert Message: Safety and effectiveness of Invokamet (canagliflozin/metformin) 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
Canagliflozin/Metformin		

Age Range: 0-17 yoa

References:
Invokamet Prescribing Information, Aug. 2014, Janssen Pharmaceuticals, Inc.
Clinical Pharmacology, 2014 Elsevier/Gold Standard.

28. Canagliflozin/Metformin / Nonadherence _____ _____

Alert Message: Based on refill history, your patient may be under-utilizing Invokamet (canagliflozin/metformin). 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
Canagliflozin/Metformin		

References:
Osterberg L, Blaschke T. Adherence to medication. N Engl J Med 2005;353:487-97.
Miller KE, Medication Nonadherence Affects Diabetes Treatment. Am Family Phys. Vol. 75 No. 6, March 15, 2007.
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.
Invokamet Prescribing Information, Aug. 2014, Janssen Pharmaceuticals, Inc.

29. Canagliflozin/Metformin / Pregnancy / Miscarriage, Delivery & Abortion _____ _____

Alert Message: Invokamet (canagliflozin/metformin) should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Canagliflozin/metformin is classified pregnancy category C.

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C **(Negating)**
Canagliflozin/Metformin	Pregnancy	Delivery Miscarriage Abortion

Age Range: 11-50 yoa
Gender: Female

References:
Invokamet Prescribing Information, Aug. 2014, Janssen Pharmaceuticals, Inc.
Clinical Pharmacology, 2014 Elsevier/Gold Standard.

30. Canagliflozin/Metformin / Digoxin _____ _____

Alert Message: Caution is warranted and monitoring is recommended when Invokamet (canagliflozin/metformin) is coadministered with digoxin. Concurrent use of canagliflozin and digoxin has been shown to increase digoxin exposure. Metformin and digoxin are both cationic drugs and may compete for renal tubular transport resulting in elevated metformin levels.

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

Util A	Util B	Util C
Canagliflozin/Metformin	Digoxin	

References:
Invokamet Prescribing Information, Aug. 2014, Janssen Pharmaceuticals, Inc.
Micromedex Healthcare Series, DrugDex Drug Evaluations, 2014 Truven health Analytics.

31. Triumeq / Non-adherence _____ _____

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 – Non-adherence
Drugs/Diseases

Util A	Util B	Util C
Abacavir/dolutegravir/lamivudine		

References:
Hoffman C, Mulcahy F, Goals and Principles of Therapy - Eradication, Cost, Prevention and Adherence. Hoffman C, Rockstroh J, Kamps BS, eds. HIV Medicine, Flying Publishers-Paris, Cagliari, Wuppertal, Sevilla, 2005:167-173.
Cheever LW, Chapter V: Adherence to HIV Therapies. In: A Guide to Clinical Care of Women with HIV/AIDS, 2005 Edition, HIV/AIDS Bureau, US Department of Health and Human Services.
http://hab.hrsa.gov/publications/womencare05/WG05chap5.htm
Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the Use of Antiretroviral Agents in HIV-1 Infected Adults and Adolescents. Department of Health and Human Services. May 1, 2014.
Available at: http://www.aidsinfo.nih.gov/ContentFiles/AdultandAdolescentGL.pdf.

32. Omalizumab / Therapeutic Appropriateness _____ _____

Alert Message: A 5-year FDA safety review of Xolair (omalizumab) use found a potential for increased risk of serious cardiovascular and cerebrovascular events including, heart attacks, TIA, pulmonary hypertension and pulmonary embolism/venous thrombosis. Patients should be periodically reassessed for the need for continued therapy with omalizumab.

Conflict Code: TA - Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C
Omalizumab		

References:
Xolair Prescribing Information, September 2014, Genentech.
MedWatch: The FDA Safety Information and Adverse Event Reporting Program. Xolair (omalizumab): Drug Safety Communication – Slightly Elevated Risk of Cardiovascular and Cerebrovascular Serious Adverse Events. [09/26/2014].

33. Indacaterol / Overutilization _____ _____

Alert Message: The manufacturer's recommended maximum daily dose of Arcapta (indacaterol) is 75 mcg inhaled once daily. Excessive use of indacaterol, or use in conjunction with other medications containing a beta-2-agonist can result in clinically significant cardiovascular effects and may be fatal.

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C
Indacaterol		

Max Dose: 75mcg/day

References:
Arcapta Prescribing Information, Sept. 2012, Novartis Pharmaceuticals Corp.
Clinical Pharmacology, 2014 Gold Standard.

34. Long-Acting Beta-2-Agonists / Therapeutic Duplication _____ _____

Alert Message: Therapeutic duplication of long-acting beta agonists may be occurring. Clinically significant cardiovascular effects and fatalities have been reported in association with excessive use of inhaled sympathomimetic drugs.

Conflict Code: TD – Therapeutic Duplication
Drugs/Diseases

Util A	Util B	Util C
Indacaterol		
Arformoterol		
Formoterol		
Levalbuterol		
Salmeterol		
Olodaterol		

References:
Arcapta Prescribing Information, Sept. 2012, Novartis Pharmaceuticals Corp.
Striverdi Respimat Prescribing Information, July 2014, Boehringer Ingelheim Pharmaceuticals. Inc.
Clinical Pharmacology, 2014 Gold Standard.
Facts & Comparisons, 2014 Updates, Wolters Kluwer Health.

35. Indacaterol / Adrenergic Drugs _____ _____

Alert Message: Caution should be exercised when Arcapta (indacaterol) is prescribed concurrently with other adrenergic sympathomimetic agents, administered by any route, because the sympathetic effects of indacaterol may be potentiated.

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

Util A	Util B				Util C
Indacaterol	Ephedrine	Methyldopa	Phentermine	Naphazoline	
	Epinephrine	Tizanidine	Benzphetamine	Pirbuterol	
	Pseudoephedrine	Amphetamine	Diethylpropion	Metaproterenol	
	Phenylephrine	Dextroamphetamine	Phendimetrazine	Terbutaline	
	Clonidine	Lisdexamfetamine	Apraclonidine		
	Guanfacine	Methylphenidate	Brimonidine		

References:
Arcapta Prescribing Information, Sept. 2012, Novartis Pharmaceuticals Corp.
Clinical Pharmacology, 2014 Gold Standard.
Facts & Comparisons, 2014 Updates, Wolters Kluwer Health.

36. Indacaterol / Xanthines Derivatives, Steroids & Diuretics _____ _____

Alert Message: Caution should be exercised when Arcapta (indacaterol) is prescribed concurrently with xanthine derivatives, steroids, or diuretics because concomitant administration may potentiate the hypokalemic effect of indacaterol. The ECG changes or hypokalemia that may result from the administration of non-potassium sparing diuretics can be acutely worsened by beta-agonists.

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

Util A	Util B		Util C
Indacaterol	Theophylline	Dexamethasone	
	Aminophylline	Hydrocortisone	
	Dyphylline	Methylprednisolone	
	Betamethasone	Prednisolone	
	Budesonide	Prednisone	
	Cortisone		

References:
Arcapta Prescribing Information, Sept. 2012, Novartis Pharmaceuticals Corp.
Clinical Pharmacology, 2014 Gold Standard.
Facts & Comparisons, 2014 Updates, Wolters Kluwer Health.

37. Indacaterol / Non-Potassium Sparing Diuretics _____ _____

Alert Message: Caution should be exercised when Arcapta (indacaterol) is prescribed concurrently with non-potassium sparing diuretics because concomitant administration may potentiate the ECG changes or hypokalemia that may result\from the administration of the diuretic.

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

Util A	Util B	Util C
Indacaterol	Chlorothiazide	
	Chlorthalidone	
	HCTZ	
	Indapamide	
	Methyclothiazide	
	Metolazone	
	Furosemide	
	Bumetanide	
	Torsemide	

References:
Arcapta Prescribing Information, Sept. 2012, Novartis Pharmaceuticals Corp.
Clinical Pharmacology, 2014 Gold Standard.
Facts & Comparisons, 2014 Updates, Wolters Kluwer Health.

38. Indacaterol / Nonselective Beta Blockers _____ _____

Alert Message: Concurrent use of Arcapta (indacaterol) with a beta-adrenergic receptor antagonist may interfere with the effect of each other. 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 administered with caution.

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

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

References:
Arcapta Prescribing Information, Sept. 2012, Novartis Pharmaceuticals Corp.
Clinical Pharmacology, 2014 Gold Standard.
Facts & Comparisons, 2014 Updates, Wolters Kluwer Health.

39. Indacaterol / Cardiovascular, Convulsive Disorders, Thyrotoxicosis & Diabetes _____ _____

Alert Message: Arcapta (indacaterol) should be used with caution in patients with cardiovascular or convulsive disorders, thyrotoxicosis or sensitivity to sympathomimetic drugs. Indacaterol is a sympathomimetic amine and can aggravate these conditions.

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

Util A	Util B	Util C
Indacaterol	Arrhythmia	
	Hypertension	
	Heart Failure	
	Epilepsy	
	Seizures	
	Diabetes	

References:
Arcapta Prescribing Information, Sept. 2012, Novartis Pharmaceuticals Corp.
Clinical Pharmacology, 2014 Gold Standard.
Facts & Comparisons, 2014 Updates, Wolters Kluwer Health.

40. Indacaterol / MAOIs, TCAs & QT Prolongation Agents _____ _____

Alert Message: Arcapta (indacaterol) should be administered with extreme caution to patients being treated with MAOIs, TCAs, or drugs know to prolong the QTc interval because the action of the adrenergic agonist, indacaterol, on the cardiovascular system may be potentiated by these agents.

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

Util A	Util B				Util C
Indacaterol	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	Rasagiline
	Clomipramine	Gemifloxacin	Octreotide	Sunitinib	
	Clozapine	Granisetron	Ofloxacin	Tacrolimus	
	Dasatinib	Haloperidol	Ondansetron	Tamoxifen	
	Desipramine	Ibutilide	Paliperidone	Telithromycin	
	Diphenhydramine	Iloperidone	Paroxetine	Terbutaline	

References:
Arcapta Prescribing Information, Sept. 2012, Novartis Pharmaceuticals Corp.
Clinical Pharmacology, 2014 Gold Standard.
Facts & Comparisons, 2014 Updates, Wolters Kluwer Health.

41. Indacaterol / Therapeutic Appropriateness _____ _____

Alert Message: The safety and effectiveness of Arcapta (indacaterol) have not been established in children .

Conflict Code: TA - Therapeutic Appropriateness
Drugs/Diseases
Util A Util B Util C
Indacaterol

Age Range: 0-18 yoa

References:
Arcapta Prescribing Information, Sept. 2012, Novartis Pharmaceuticals Corp.
Clinical Pharmacology, 2014 Gold Standard.
Facts & Comparisons, 2014 Updates, Wolters Kluwer Health.

42. Indacaterol / Therapeutic Appropriateness (Black Box Warning) _____ _____

Alert Message: Arcapta (indacaterol) is a long-acting beta-2-adrenergic agonist (LABA) and all LABAs increase the risk of asthma-related death. The safety and efficacy of indacaterol in patients with asthma have not been established. Indacaterol is not indicated for the treatment of asthma.

Conflict Code: TA - Therapeutic Appropriateness
Drugs/Diseases
Util A Util B Util C
Indacaterol

References:
Arcapta Prescribing Information, Sept. 2012, Novartis Pharmaceuticals Corp.
Clinical Pharmacology, 2014 Gold Standard.
Facts & Comparisons, 2014 Updates, Wolters Kluwer Health.

43. Indacaterol / Non-adherence _____ _____

Alert Message: Based on refill history, your patient may be under-utilizing Arcapta (indacaterol). 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
Indacaterol

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. 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 COPD. 2010 Nov 24;5:401-406.