DUR Board Meeting
March 11, 2013
Minervas (Kelly Inn)
1800 North 12th Street
Bismarck, ND

North Dakota Medicaid
DUR Board Meeting Agenda
Minervas (Kelly Inn)
1800 North 12th Street
Bismarck, ND
March 11, 2013
1pm

1. Administrative items
    - Travel vouchers

2. Old business
    - Review and Approval of Minutes of 12/12 Meeting — Chair
    - Budget Update — Brendan
    - Second Review of Genitourinary Smooth Muscle Relaxants — Brendan
    - Second Review of Agents Used to Treat Multiple Sclerosis — Brendan
    - Update on medications greater than $3,000 (i.e., Juxtapid, Gattex) — Brendan

3. New business
    - Review of Fulyzaq — HID
    - Review of Xeljanz — HID
    - Asthma Management — HID
    - Criteria Recommendations — HID
    - Upcoming Meeting Date/Agenda — Chair

4. Adjourn — Chair

Please remember to silence all cellular phones and pagers during the meeting.

Drug Utilization Review (DUR) Meeting Minutes
December 3, 2012

Members Present: Norman Byers, John Savageau, Russ Sobotta, Tanya Schmidt, Leann Ness, David Clinkenbeard, Carrie Sorenson, Cheryl Huber, Carlotta McCleary, James Carlson, Greg Pfister, Michael Booth, Jeffrey Hostetter

Members Absent: Steve Irsfeld, Todd Twogood

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 D. Clinkenbeard seconded the motion. Chair G. Pfister called for a voice vote to approve the minutes. The motion passed with no audible dissent. Dr. Michael Booth has filled the open position on the DUR Board. Introductions were made.

Budget Update
B. Joyce informed the board members that there is no new information from fiscal since the last board meeting. B. Joyce also informed the board that the rebate owed to the government by the state is larger than was originally anticipated.

Actinic Keratosis Second Review
A motion and second were made at the September meeting to place agents used to treat Actinic Keratosis 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.

Moxeza Second Review
A motion and second were made at the September meeting to place Moxeza on prior authorization. The topic was brought up for a second review. There was no public comment. Chair G. Pfister called for a voice vote to approve the motion. The motion passed with no audible dissent. Moxeza will be added to the ophthalmic anti-infective form.

Patients Taking Multiple Long-Acting Narcotics Second Review
B. Joyce reviewed recipients taking multiple long-acting narcotics and Oxycontin three times daily. After discussion, the board agreed that edits should be put in to place to decrease the chance of diversion and to improve patient care.

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 – M. Booth made a motion to remove losartan from prior authorization. C. Huber seconded the motion. There was no public comment. Motion passed with no audible dissent.
2. Gilenya – Add "specialist involved in therapy" to form.
3. Livalo – J. Hostetter made a motion to require adequate dosing of existing generics (simvastation/atorvastatin) for 3 months or side effects as criteria for coverage. C. Sorenson seconded the motion. There was no public comment. Motion passed with no audible dissent.

4. Nuedexta – Add 'specialist involved in therapy' to form.
5. Metozolv – Add to ODT form.
6. Oral Anticoagulants – Update form and criteria with new indications.
7. Solodyn – Add to Doryx/Oracea form.
8. Soma 250 – Add to Carisoprodol form.

Kathleen Karnick, representing Janssen, spoke about Nucynta and Nucynta ER. Randy Troxell, representing Novartis, spoke about Gilenya and ACE-I/ARB/Renin Inhibitor prior authorization.

Genitourinary Smooth Muscle Relaxants Review
B. Joyce reviewed genitourinary smooth muscle relaxants (GSM) clinical information and data with the Board. There was no public comment. After discussion, N. Byers made a motion to place GSMs on prior authorization. T. Schmidt seconded the motion. This topic will be brought up at the next meeting for finalization.

Agents Used to Treat Multiple Sclerosis (MS) Review
B. Joyce reviewed Aubagio clinical information and data with the Board. There was no public comment. After discussion, J. Hostetter made a motion to place Aubagio on prior authorization. D. Clinkenbeard seconded the motion. This topic will be brought up at the next meeting for finalization.

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 D. Clinkenbeard 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 11, 2013 in Bismarck. N. Byers made a motion to adjourn the meeting. G. Pfister seconded. The motion passed with no audible dissent. G. Pfister adjourned the meeting.

HEALTH INFORMATION DESIGNS

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 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	

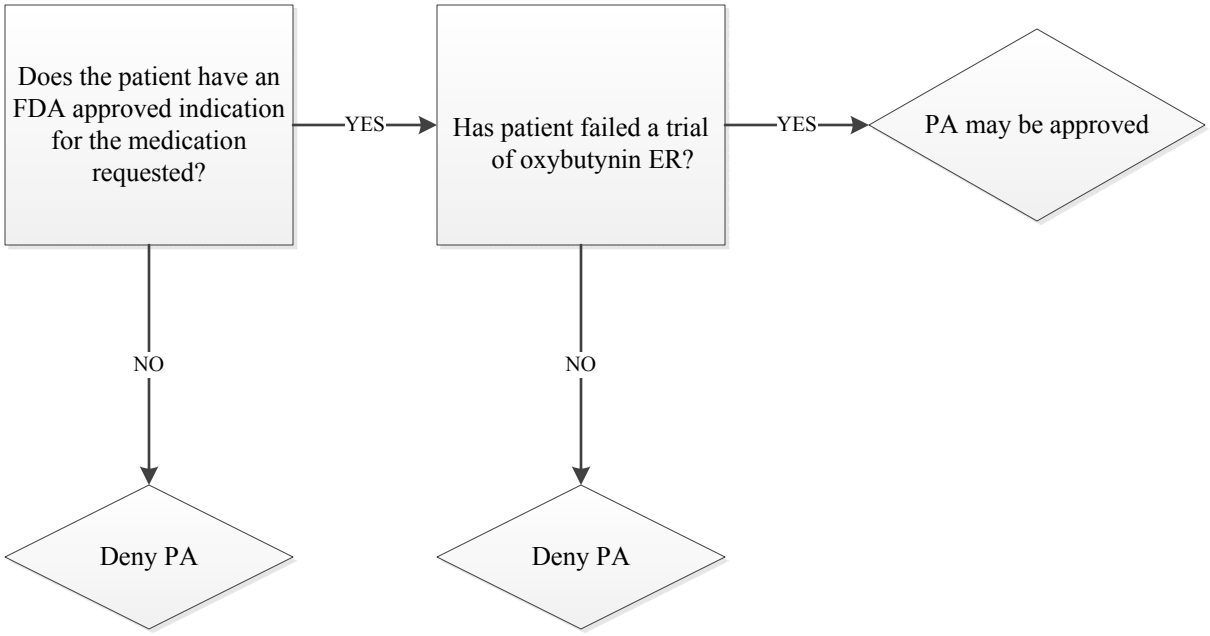
Part II: TO BE COMPLETED BY PHARMACY

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)	

North Dakota Department of Human Services
Genitourinary Smooth Muscle Relaxants
Authorization Algorithm



HEALTH INFORMATION DESIGNS

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	

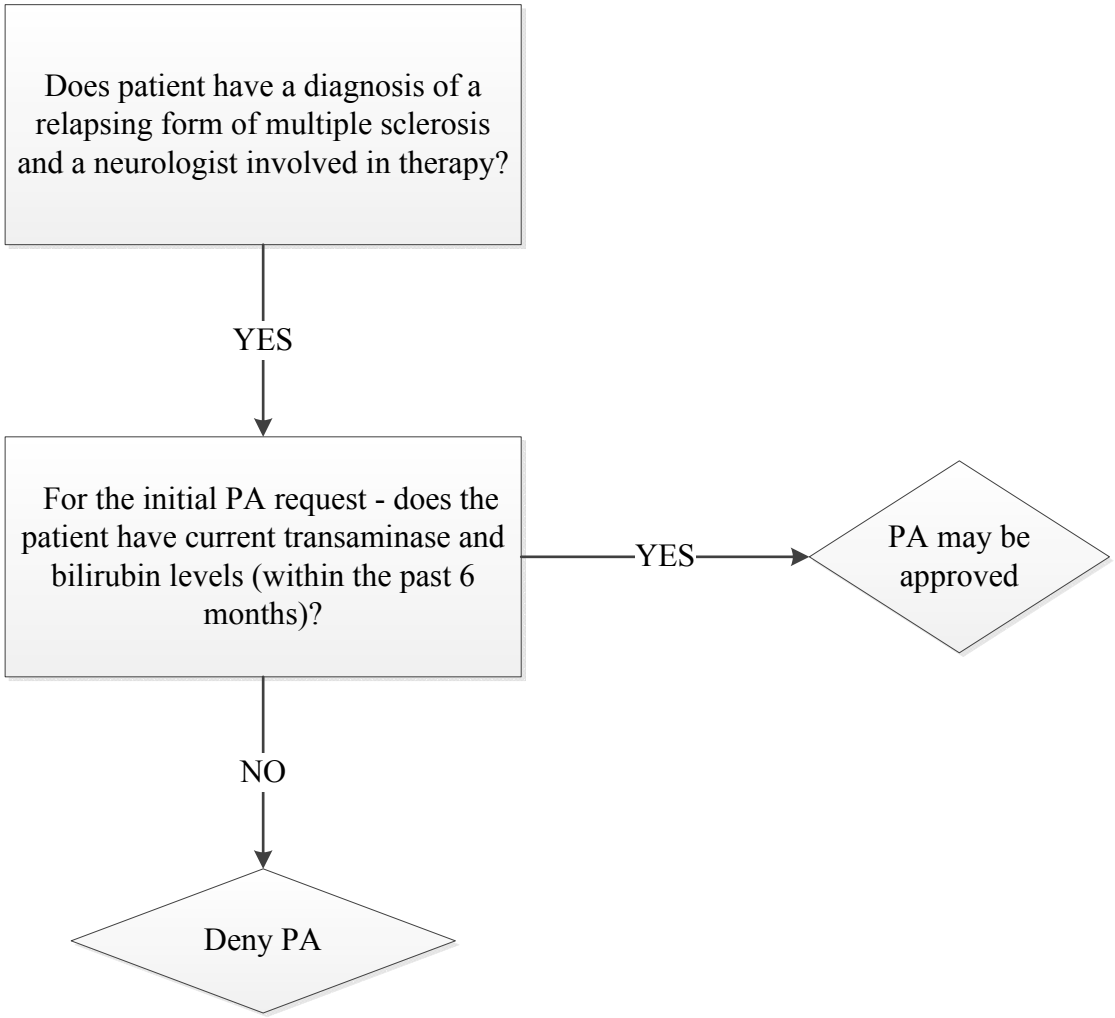
Part II: TO BE COMPLETED BY PHARMACY

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)	

North Dakota Department of Human Services
Aubagio* Authorization Algorithm



Aubagio is contraindicated in pregnant women or women of childbearing potential who are not using reliable contraception.

ND Medicaid Utilization			
Drugs over $3,000/RX for all of 2012			
Drug	**Rx Count**	**Dollar Total**	**Dollar/Rx**
HP ACTHAR GEL 80 UNIT/ML VIAL	1	$29,136.20	$29,136.20
HELIXATE FS 2,000 UNIT VIAL	7	$195,121.36	$27,874.48
FIRAZYR 30 MG/3 ML SYRINGE	1	$22,033.60	$22,033.60
HELIXATE FS 1,000 UNIT VIAL	12	$259,998.99	$21,666.58
INCIVEK 375 MG TABLET	12	$222,369.29	$18,530.77
VENTAVIS 20 MCG/1 ML SOLUTION	5	$79,571.60	$15,914.32
STELARA 90 MG/ML SYRINGE	5	$58,811.45	$11,762.29
STIVARGA 40 MG TABLET	2	$20,194.60	$10,097.30
REVLIMID 15 MG CAPSULE	1	$9,005.85	$9,005.85
TASIGNA 200 MG CAPSULE	1	$8,652.53	$8,652.53
AFINITOR 10 MG TABLET	5	$40,832.85	$8,166.57
XTANDI 40 MG CAPSULE	2	$16,065.20	$8,032.60
AFINITOR 5 MG TABLET	5	$38,717.63	$7,743.53
ZEMAIRA 1,000 MG VIAL	12	$72,537.26	$6,044.77
GLEEVEC 400 MG TABLET	4	$23,763.14	$5,940.79
STELARA 45 MG/0.5 ML SYRINGE	2	$11,857.28	$5,928.64
SUTENT 25 MG CAPSULE	1	$5,899.63	$5,899.63
NEXAVAR 200 MG TABLET	2	$11,761.05	$5,880.53
SENSIPAR 60 MG TABLET	1	$5,545.89	$5,545.89
ZYTIGA 250 MG TABLET	2	$10,959.60	$5,479.80
ELAPRASE 6 MG/3 ML VIAL	40	$218,992.02	$5,474.80
HUMIRA CROHN'S STARTER PACK	1	$5,358.15	$5,358.15
VICTRELIS 200 MG CAPSULE	14	$69,165.48	$4,940.39
GLEEVEC 100 MG TABLET	7	$33,888.14	$4,841.16
SABRIL 500 MG POWDER PACKET	2	$9,358.80	$4,679.40
TARCEVA 100 MG TABLET	7	$31,484.98	$4,497.85
NUTROPIN AQ NUSPIN 20 PEN CART	3	$13,292.85	$4,430.95
GILENYA 0.5 MG CAPSULE	26	$113,569.03	$4,368.04
VANCOCIN HCL 250 MG PULVULE	11	$47,421.20	$4,311.02
HUMIRA PSORIASIS STARTER PACK	2	$8,074.39	$4,037.20
NEUPOGEN 300 MCG/ML VIAL	17	$65,593.08	$3,858.42
AVONEX ADMIN PACK 30 MCG VL	13	$49,889.80	$3,837.68
COPAXONE 20 MG INJECTION KIT	63	$234,507.37	$3,722.34
TEMODAR 100 MG CAPSULE	6	$21,504.85	$3,584.14
AVONEX PREFILLED SYR 30 MCG	49	$172,855.25	$3,527.66
ZYVOX 600 MG TABLET	1	$3,442.64	$3,442.64
CUBICIN 500 MG VIAL	14	$47,297.29	$3,378.38
TASIGNA 200 MG CAPSULE	2	$6,188.30	$3,094.15
BETASERON 0.3 MG KIT	5	$15,366.05	$3,073.21
LOVENOX 80 MG PREFILLED SYRN	10	$30,526.85	$3,052.69
MERREM IV 1 GM VIAL	3	$9,137.55	$3,045.85
Totals	**379**	**$2,349,749.07**	**$6,199.87**

Recently Approved Drugs Over $3,000/Rx

1. Juxtapid (lomitapide) capsules – Microsomal triglyceride transfer protein inhibitor indicated as an adjunct to a low-fat diet and other lipid-lowering treatments, including LDL apheresis where available, to reduce low density lipoprotein-cholesterol (LDL-C), apolipoprotein B (apo B), total cholesterol (TC), and non-high density lipoprotein-cholesterol (non-HDL-C) in patients with homozygous familial hypercholesterolemia (HoFH). **$695.44/capsule**

2. Gattex (teduglutide [rDNA origin]) injection – Glucagon-like peptide-2 (GLP-2) analog indicated for the treatment of adult patients with Short Bowel Syndrome (SBS) who are dependent on parenteral support. **$6,186/kit**

3. Kynamro (mipomersen sodium) injection – Oligonucleotide inhibitor of apolipoprotein B-100 synthesis indicated as an adjunct to lipid-lowering medications and diet to reduce LDL-C, TC, apo B, and non-HDL-C in patients with HoFH. Pricing expected to be similar to Juxtapid. **$176,000/year**

North Dakota Medicaid Department of Human Services
DUR Board Meeting
Fulyzaq® Review

I. Indication

Fulyzaq (crofelemer) is a botanical derived anti-diarrheal indicated for the symptomatic relief of non-infectious diarrhea in adult patients with HIV/AIDS on anti-retroviral therapy.

II. Dosage and Administration

One 125mg delayed-release tablet taken orally two times a day, with or without food.

III. Warnings and Precautions

- Rule out infectious etiologies of diarrhea before starting crofelemer.
- If infectious etiologies are not considered, there is a risk that patients will not receive the appropriate therapy and their disease may worsen.

IV. Adverse Reactions

The most common adverse reactions (incidence ≥3%) are upper respiratory tract infection, bronchitis, cough, flatulence and increased bilirubin.

Reference

1. Fulyzaq® [prescribing information]. Raleigh, NC. Salix Pharmaceuticals, Inc.; Jan 2013.

North Dakota Medicaid Department of Human Services
DUR Board Meeting
Xeljanz® Review

I. Overview

Xeljanz (tofacitinib) was recently approved by the FDA as a new treatment option for adult patients with moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response or intolerance to methotrexate. Xeljanz is an inhibitor of Janus kinase (JAK). Blocking JAK mutes the inflammation responses responsible for RA. Xeljanz may be used as monotherapy or in combination with methotrexate or other nonbiologic disease-modifying antirheumatic drugs (DMARDs). Xeljanz should not be used in combination with biologic DMARDs or potent immunosuppressants such as azathioprine and cyclosporine.

II. Warnings and Precautions

- Serious Infections – Do not administer Xeljanz during an active infection, including localized infections. If a serious infection develops, interrupt Xeljanz until the infection is controlled.
- Lymphomas and other malignancies have been reported in patients treated with Xeljanz.
- Gastrointestinal Perforations – Use with caution in patients that may be at increased risk.
- Laboratory monitoring – Recommended due to potential changes in lymphocytes, neutrophils, hemoglobin, liver enzymes and lipids.
- Immunizations – Live vaccines should not be given concurrently with Xeljanz.
- Severe hepatic impairment – Not recommended.

III. Drug Interactions

- Potent inhibitors of CYP3A4 (e.g., ketoconazole): Reduce dose to 5 mg once daily.
- One or more concomitant medications that result in both moderate inhibition of CYP3A4 and potent inhibition of CYP2C19 (e.g., fluconazole): Reduce dose to 5 mg once daily.
- Potent CYP inducers (e.g., rifampin): May result in loss of or reduced clinical response.

IV. Adverse Reactions

The most commonly reported adverse reactions during the first 3 months in controlled clinical trials (occurring in greater than or equal to 2% of patients treated with Xeljanz monotherapy or in combination with DMARDs) were upper respiratory tract infections, headache, diarrhea and nasopharyngitis.

V. Dosage and Cost

The recommended dose of Xeljanz is 5 mg twice daily. Xeljanz will cost approximately $27,000 annually ($36.99 per pill).

Reference

1. Xeljanz® [prescribing information]. NY, NY. Pfizer Labs; November 2012.

NORTH DAKOTA MEDICAID
RETROSPECTIVE DRUG UTILIZATION REVIEW
CRITERIA RECOMMENDATIONS
MARCH 2013

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

1. Stribild / Contraindicated Drugs _____ _____

Alert Message: Coadministration of Stribild (elvitegravir/cobicistat/emtricitabine/tenofovir) is contraindicated with drugs that are highly dependent on CYP3A4 for clearance and for which elevated plasma concentrations are associated with serious and/or life-threatening adverse events.

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

Util A	Util B	Util C
Stribild	Alfuzosin	
	Ergot Derivatives	
	Lovastatin	
	Simvastatin	
	Pimozide	
	Revatio	
	Triazolam	
	Midazolam - Oral	

References:
Stribild Prescribing Information, August 2012, Gilead Sciences, Inc.
Clinical Pharmacology, 2012 Elsevier/Gold Standard.

2. Stribild / Rifampin _____ _____

Alert Message: Coadministration of Stribild (elvitegravir/cobicistat/emtricitabine/tenofovir) is contraindicated with the potent CYP3A4 inducer rifampin. Concurrent use of these agents may result in significant decreases in the plasma concentrations of cobicistat and elvitegravir (CYP3A4 substrates), leading to loss of virologic response and possible resistance.

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

Util A	Util B	Util C
Stribild	Rifampin	

References:
Stribild Prescribing Information, August 2012, Gilead Sciences, Inc.
Clinical Pharmacology, 2012 Elsevier/Gold Standard.

3. Stribild / Renal Impairment _____ _____

Alert Message: Stribild (elvitegravir/cobicistat/emtricitabine/tenofovir) should not be initiated in patients with estimated creatinine clearance below 70 ml/min. Because Stribild is a fixed-dose combination tablet, it should be discontinued if estimated creatinine clearance declines below 50 mL/min during treatment as dose interval adjustment required for emtricitabine and tenofovir cannot be achieved.

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

Util A	Util B	Util C
Stribild	Renal Impairment	

References:
Stribild Prescribing Information, August 2012, Gilead Sciences, Inc.
Clinical Pharmacology, 2012 Elsevier/Gold Standard.

4. Stribild / Hepatic Impairment _____ _____

Alert Message: Stribild (elvitegravir/cobicistat/emtricitabine/tenofovir) use has not been evaluated in patients with severe hepatic impairment (Child-Pugh Class C) and therefore its use is not recommended in this population. No dose adjustment of Stribild is required in patients with mild (Child-Pugh Class A) or moderate (Child-Pugh Class B) hepatic impairment.

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

Util A	Util B	Util C
Stribild	Hepatic Impairment	

References:
Stribild Prescribing Information, August 2012, Gilead Sciences, Inc.
Clinical Pharmacology, 2012 Elsevier/Gold Standard.

5. Stribild / CYP3A4 Inducers _____ _____

Alert Message: Coadministration of Stribild (elvitegravir/cobicistat/emtricitabine/tenofovir) with the CYP3A4 inducers rifabutin or rifapentine is not recommended. Concurrent use with either inducer may result in significant decreases in the plasma concentrations of cobicistat and elvitegravir (CYP3A4 substrates), leading to loss of virologic response and possible resistance.

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

Util A	Util B	Util C
Stribild	Rifabutin	
	Rifapentine	

References:
Stribild Prescribing Information, August 2012, Gilead Sciences, Inc.
Clinical Pharmacology, 2012 Elsevier/Gold Standard.

6. Stribild / Anticonvulsants _____ _____

Alert Message: Coadministration of Stribild (elvitegravir/cobicistat/emtricitabine/tenofovir) with the CYP3A4 inducers carbamazepine, oxcarbazepine, phenytoin or phenobarbital may significantly decrease plasma concentrations of elvitegravir and cobicistat (CYP3A4 substrates), which may result in loss of therapeutic effect and development of resistance. Alternative anticonvulsants should be considered.

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

Util A	Util B	Util C
Stribild	Carbamazepine	
	Oxcarbazepine	
	Phenytoin	
	Phenobarbital	

References:
Stribild Prescribing Information, August 2012, Gilead Sciences, Inc.

7. Stribild / Clarithromycin _____ _____

Alert Message: Coadministration of Stribild (elvitegravir/cobicistat/emtricitabine/tenofovir) with clarithromycin may increase plasma concentrations of both clarithromycin and cobicistat. Patients with a CrCl between 50mL/min and 60mL/min should have the clarithromycin dose reduced by 50%. No dose adjustment is required for CrCl of 60mL/min or greater.

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

Util A	Util B	Util C
Stribild	Clarithromycin	

References:
Stribild Prescribing Information, August 2012, Gilead Sciences, Inc.

8. Stribild / Telithromycin _____ _____

Alert Message: Coadministration of Stribild (elvitegravir/cobicistat/emtricitabine/tenofovir) with telithromycin may increase plasma concentrations of both telithromycin and cobicistat. Monitor patient for adverse effects of either agent.

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

Util A	Util B	Util C
Stribild	Telithromycin	

References:
Stribild Prescribing Information, August 2012, Gilead Sciences, Inc.

9. Stribild / Neuroleptics _____ _____

Alert Message: Coadministration of Stribild (elvitegravir/cobicistat/emtricitabine/tenofovir) with a neuroleptic agent may increase plasma concentrations of the neuroleptic. A decrease in the dose of the neuroleptic may be needed when co-administered with Stribild.

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

Util A	Util B	Util C
Stribild	Antipsychotics 1st & 2nd Generation	

References:
Stribild Prescribing Information, August 2012, Gilead Sciences, Inc.

10. Stribild / Ketoconazole and Itraconazole _____ _____

Alert Message: Coadministration of Stribild (elvitegravir/cobicistat/emtricitabine/tenofovir) with ketoconazole or itraconazole may increase plasma concentrations of the antifungal due to inhibition by cobicistat of CYP3A4-mediated antifungal metabolism. The maximum daily dose of ketoconazole or itraconazole should not exceed 200mg per day.

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

Util A	Util B	Util C **(Include)**
Ketoconazole		Stribild
Itraconazole		

Max Dose: 200mg/day

References:
Stribild Prescribing Information, August 2012, Gilead Sciences, Inc.

11. Stribild / Voriconazole _____ _____

Alert Message: An assessment of benefit/risk ratio is recommended to justify use of Stribild (elvitegravir/cobicistat/emtricitabine/tenofovir) with Vfend (voriconazole). Concurrent use of these agents may increase plasma concentrations of voriconazole due to inhibition by cobicistat of CYP3A4-mediated voriconazole metabolism.

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

Util A	Util B	Util C
Stribild	Voriconazole	

References:
Stribild Prescribing Information, August 2012, Gilead Sciences, Inc.

12. Stribild / Colchicine / Renal & Hepatic Impairment _____ _____

Alert Message: Stribild (elvitegravir/cobicistat/emtricitabine/tenofovir) should not be administered with colchicine to patients with renal or hepatic impairment. Concurrent use of these agents in patients with these disease states may significantly increase the plasma concentrations of colchicine.

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

Util A	Util B	Util C **(Include)**
Stribild	Colchicine	Renal Impairment
		Hepatic Impairment

References:
Stribild Prescribing Information, August 2012, Gilead Sciences, Inc.

13. Colchicine / Stribild _____ _____

Alert Message: Coadministration of Stribild (elvitegravir/cobicistat/emtricitabine/tenofovir) with colchicine may increase colchicine plasma concentrations and dosage adjustment of colchicine is required. If used to treat gout flares, administer a single 0.6mg dose of colchicine, followed by 0.3mg 1 hour later (repeat no sooner than 3 days). If used for gout prophylaxis and the original regimen was 0.6mg BID, reduce dose to 0.3mg QD, if regimen was 0.6mg QD, reduce to 0.3mg QOD. If used for familial Mediterranean fever the maximum daily dose is 0.6mg daily.

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

Util A	Util B	Util C (Include)
Colchicine		Stribild

Max Dose: 0.6mg/day
References:
Stribild Prescribing Information, August 2012, Gilead Sciences, Inc.

14. Stribild / Dexamethasone _____ _____

Alert Message: Caution is advised when co-administering Stribild (elvitegravir/ cobicistat/emtricitabine/tenofovir) with the CYP3A4 inducer dexamethasone. Concurrent use may significantly decrease plasma concentrations of elvitegravir and cobicistat (CYP3A4 substrates) leading to loss of therapeutic effect and development of resistance.

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

Util A	Util B	Util C
Stribild	Dexamethasone	

References:
Stribild Prescribing Information, August 2012, Gilead Sciences, Inc.

15. Stribild / Fluticasone _____ _____

Alert Message: Coadministration of Stribild (elvitegravir/cobicistat/emtricitabine/tenofovir) with an inhaled or nasal fluticasone product may increase plasma concentrations of fluticasone resulting in reduced serum cortisol concentrations. Alternative corticosteroids should be considered, particularly for long term use.

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

Util A	Util B	Util C
Stribild	Fluticasone Inhaled & Nasal	

References:
Stribild Prescribing Information, August 2012, Gilead Sciences, Inc.

16. Stribild / Salmeterol _____ _____

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

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

Util A	Util B	Util C
Stribild	Salmeterol	

References:
Stribild Prescribing Information, August 2012, Gilead Sciences, Inc.

17. Stribild / Atorvastatin _____ _____

Alert Message: Coadministration of Stribild (elvitegravir/cobicistat/emtricitabine/tenofovir) with an atorvastatin-containing product (Lipitor and Caduet) should be initiated at the lowest starting dose of atorvastatin and titrated carefully while monitoring for atorvastatin-related adverse effects. Concurrent use of these agents may result in increased atorvastatin plasma concentrations due to inhibition by cobicistat of CYP3A4-mediated atorvastatin metabolism.

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

Util A	Util B	Util C
Stribild	Atorvastatin	

References:
Stribild Prescribing Information, August 2012, Gilead Sciences, Inc.

18. Stribild / CYP3A4, 2D6, P-gp, BCRP, OATP1B1 or OATP1B3 Substrates & Agents undergoing Active Tubular Secretion _____ _____

Alert Message: Caution is advised when co-administering Stribild (elvitegravir/ cobicistat/emtricitabine/tenofovir) with drugs that are primarily metabolized by CYP3A4 or CYP2D6, or are substrates of P-gp, BCRP, OATP1B1 or OATP1B3 as concurrent use may result in increased plasma concentrations of the substrate. Clinical and/or therapeutic drug concentration monitoring is advised during coadministration.

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

Util A	Util B*				Util C
Stribild	SSRIs	Pitavastatin	Salicylates	Saxagliptin	
	TCAs	Rosuvastatin	Thiazides	Linagliptin	
	Trazodone	Tamoxifen	Acyclovir	Clonazepam	
	Bupropion	Valsartan	Cidofovir	Ethosuximide	
	CCBs	Olmesartan	Ganciclovir	Cyclosporine	
	Carvedilol	Telmisartan	Valacyclovir	Tacrolimus	
	Metoprolol	Digoxin	Valganciclovir	Sirolimus	
	Nebivolol	Warfarin	Ezetimibe		
	Propranolol	Metformin	Glyburide		
	Timolol	Morphine	Repaglinide		
	Antiarrhythmics	Vancomycin	Nateglinide		

References:
Stribild Prescribing Information, August 2012, Gilead Sciences, Inc.
FDA: Drug Development and Drug Interactions: Table of Substrates, Inhibitors and Inducers. [Accessed 10/17/2012] Available at:
http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/DrugInteractionsLabeling/ucm093664.htm#4

Drugs that are substrates but are contraindicated or have other more specific alerts are not included in this group.

19. Stribild / Nephrotoxic Drugs _____ _____

Alert Message: Avoid administering Stribild (elvitegravir/cobicistat/emtricitabine/tenofovir) with concurrent or recent use of nephrotoxic agents. Renal impairment, including cases of acute renal failure and Fanconi syndrome, has been reported with Stribild use.

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

Util A	Util B			Util C
Stribild	Acetaminophen	Adefovir	Zoledronate	
	Aspirin	Cidofovir	Bea Lactams	
	NSAIDs	Indinavir	Clopidogrel	
	Amitriptyline	Benzodiazepines	Tetracycline	
	Doxepin	Cyclosporine	Statins	
	Fluoxetine	Tacrolimus	Gemfibrozil	
	Lithium	ACEIs	Mesalamine	
	Acyclovir	ARBs		
	Neomycin	Statins		
	Paromomycin	Carmustine		
	Foscarnet	Methotrexate		
	Ganciclovir	Loop Diuretics		
	Pentamidine	Triamterene		
	Quinolones	Proton Pump Inhibitors		
	Rifampin	Allopurinol		
	Sulfonamides	Haloperidol		
	Vancomycin	Pamidronate		
	Doxylamine	Phenytoin		
	Diphenhydramine	Ranitidine		

References:
Stribild Prescribing Information, August 2012, Gilead Sciences, Inc.
Naughton CA. Drug-Induced Nephrotoxicity. Am Fam Physician. 2008 Sep.15;78(6):743-750.

20. Stribild / CYP3A4 Sedative Hypnotics _____ _____

Alert Message: Coadministration of Stribild (elvitegravir/cobicistat/emtricitabine/tenofovir) and a sedative/hypnotic agent that is a CYP3A4 substrate may result in elevated plasma concentrations of the sedative/hypnotic due to inhibition by cobicistat of CYP3A4-mediated metabolism. Dose reduction and clinical monitoring of the sedative/hypnotic agent is recommended when used currently with Stribild.

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

Util A	Util B	Util C
Stribild	Clorazepate	
	Diazepam	
	Estazolam	
	Flurazepam	
	Chlordiazepoxide	
	Alprazolam	
	Buspirone	
	Zolpidem	
	Clobazam	

References:
Stribild Prescribing Information, August 2012, Gilead Sciences, Inc.

21. Stribild / Ethinyl Estradiol-Norgestimate _____ _____

Alert Message: Coadministration of Stribild (elvitegravir/cobicistat/emtricitabine/tenofovir) and an ethinyl estradiol/norgestimate contraceptive may result in elevated norgestimate and reduced ethinyl estradiol concentrations. Risk associated with these altered levels may include insulin resistance, dyslipidemia and venous thrombosis. Consider the risk/benefits associated with concurrent use, particularly in women who have risk factors for these events. Alternative (non-hormonal) methods of contraception can be considered.

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

Util A	Util B	Util C
Stribild	Ethinyl Estradiol/Norgestimate	

References:
Stribild Prescribing Information, August 2012, Gilead Sciences, Inc.

22. Atazanavir / PR Interval Prolongation _____ _____

Alert Message: Reyataz (atazanavir) has been shown to prolong the PR interval in some patients. Atazanavir should be used with caution in patients with preexisting conduction system disease or when administered with other drugs that may prolong the PR interval.

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

Util A	Util B	Util C
Atazanavir	PR Prolongation	
	Conduction Disorder	

References:
Reyataz Prescribing Information, March 2012, Bristol-Myers Squibb.

23. Atazanavir / PR Interval Prolongation _____ _____

Alert Message: Reyataz (atazanavir) has been shown to prolong the PR interval in some patients. Atazanavir should be used with caution in patients with preexisting conduction system disease or when administered with other drugs that may prolong the PR interval.

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

Util A	Util B		Util C
Atazanavir	Digoxin	Labetalol	
	Quinidine	Timolol	
	Procainamide	Pindolol	
	Disopyramide	Bisoprolol	
	Flecainide	Acebutolol	
	Amiodarone	Betaxolol	
	Propafenone	Penbutolol	
	Verapamil	Carteolol	
	Lacosamide	Sotalol	
	Propranolol	Nebivolol	
	Metoprolol	Ritonavir	
	Nadolol	Atazanavir	

References:
Reyataz Prescribing Information, March 2012, Bristol-Myers Squibb.

24. Omega-3-Acid Ethyl Esters / Therapeutic Appropriateness _____ _____
Alert Message: The safety and effectiveness of Lovaza (omega-3-acid ethyl esters) 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
Omega-3-acid ethyl esters		

Age Range: 0 – 18 yoa

References:
Lovaza Prescribing Information, August 2012, GlaxoSmithKline.
Clinical Pharmacology, 2012 Elsevier / Gold Standard.

25. Omega-3-Acid Ethyl Esters / Overuse _____ _____
Alert Message: Lovaza (omega-3-acid ethyl esters) may be over-utilized. The manufacturer's maximum recommended dose is 4 grams per day, taken as a single 4 gram dose or 2 grams twice daily.

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C
Omega-3-acid ethyl esters		

Max Dose: 4 grams daily

References:
Lovaza Prescribing Information, August 2012, GlaxoSmithKline.
Clinical Pharmacology, 2012 Elsevier / Gold Standard.

26. Omega-3-Acid Ethyl Esters / Therapeutic Duplication _____ _____
Alert Message: Therapeutic duplication of omega-3 acids may be occurring. The safety and efficacy of coadministration of these agents has not been studied and, therefore, is not recommended.

Conflict Code: TD – Therapeutic Duplication
Drugs/Diseases

Util A	Util B	Util C
Omega-3-acid ethyl esters	Icosapent ethyl	

References:
Vascepa Prescribing Information, July 2012, Amarin Pharma Inc.
Lovaza Prescribing Information, August 2012, GlaxoSmithKline.
Clinical Pharmacology, 2012 Elsevier / Gold Standard.

27. Omega-3-Acid Ethyl Esters / Anticoagulants _____ _____

Alert Message: Some studies have demonstrated prolongation of bleeding time when anticoagulants and omega-3 fatty acids are used concurrently. Patients receiving treatment with Lovaza (omega-3-acid ethyl esters) and drugs affecting coagulation should be monitored periodically.

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

Util A	Util B	Util C
Omega-3-acid ethyl esters	Anticoagulants	

References:
Lovaza Prescribing Information, August 2012, GlaxoSmithKline.
Clinical Pharmacology, 2012 Elsevier / Gold Standard.

28. Omega-3-Acid Ethyl Esters / Pregnancy / Pregnancy Negating _____ _____

Alert Message: Lovaza (omega-3-acid ethyl esters) is FDA pregnancy category C. There are no adequate and well-controlled studies in pregnant women and it is unknown if omega-3-acid ethyl esters can cause fetal harm. Omega-3-acid ethyl esters should be used during pregnancy only if the potential benefit to the patient justifies the potential risk to the fetus.

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

Util A	Util B	Util C **(Negating)**
Omega-3-Acid Ethyl Esters	Pregnancy ICD-9s	Delivery Miscarriage Abortion

References:
Lovaza Prescribing Information, August 2012, GlaxoSmithKline.
Clinical Pharmacology, 2012 Elsevier / Gold Standard.

29. Omega-3-Acid Ethyl Esters / Hepatic Impairment _____ _____

Alert Message: Patients taking Lovaza (omega-3-acid ethyl esters) that have hepatic impairment should have ALT and AST levels monitored periodically.

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C (Include)
Omega-3-acid ethyl esters		Chronic Liver Disease Cirrhosis

References:
Lovaza Prescribing Information, August 2012, GlaxoSmithKline.
Clinical Pharmacology, 2012 Elsevier / Gold Standard.

30. Omega-3-Acid Ethyl Esters / Atrial Fibrillation or Flutter _____ _____

Alert Message: In clinical trials with Lovaza (omega-3-acid ethyl esters), recurrent atrial fibrillation (AF) or persistent AF was seen in some patients with symptomatic paroxysmal AF or persistent AF. The clinical significance of these results is uncertain, but there may be an association between omega-3-acid ethyl esters and more frequent recurrences of symptomatic AF or flutter in these patients.

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C (Include)
Omega-3-acid ethyl esters		Atrial Fibrillation
		Atrial Flutter

References:
Lovaza Prescribing Information, August 2012, GlaxoSmithKline.
Clinical Pharmacology, 2012 Elsevier / Gold Standard.

31. Omega-3-Acid Ethyl Esters / Non-adherence _____ _____

Alert Message: Based on refill history, your patients may be under-utilizing Lovaza (omega-3-acid ethyl esters). 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
Omega-3-acid ethyl esters		

References:
Schedlbauer A, Davis P, Fahey T. Interventions to Improve Adherence to Lipid Lowering Medication (Review). Cochrane Database System Rev. 2010 Mar 17;(3):CD004371.
Bersot T, Haffner S, Harris WS, et al., Hypertriglyceridemia: Management of Atherogenic Dyslipidemia. Jrnl of Fam Pract. 2006 Jul;55(7):S1-S8.
Osterberg L and Blaschke T. Adherence to Medication. N Engl J Med 2005;353:487-497.

32. Dronedarone / Therapeutic Appropriateness _____ _____

Alert Message: The safety and effectiveness of Multaq (dronedarone) 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
Dronedarone		

Age Range: 0 – 17 yoa

References:
Multaq Prescribing Information, September 2012, Sanofi-Aventis U.S.
Clinical Pharmacology, 2012 Elsevier / Gold Standard.

33. Dronedarone / Pulmonary Toxicity _____ _____

Alert Message: Cases of interstitial lung disease (including pneumonitis and pulmonary fibrosis) have been reported in patients treated with Multaq (dronedarone). Onset of dyspnea or non-productive cough may be related to pulmonary toxicity and patients should be carefully evaluated. In the event that pulmonary toxicity is confirmed, dronedarone should be discontinued.

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

Drugs/Diseases

Util A	Util B	Util C
Dronedarone	Pneumonitis	
	Pulmonary Fibrosis	
	Dyspnea	

References:
Multaq Prescribing Information, September 2012, Sanofi-Aventis U.S.
Clinical Pharmacology, 2012 Elsevier / Gold Standard.

34. Forfivo XL / Overutilization _____ _____

Alert Message: Forfivo XL (extended-release bupropion) may be over-utilized. The manufacturer's maximum recommended dose is 450 mg once daily. Exceeding the recommended dose increases the risk of dose-related seizures.

Drugs/Diseases

Util A	Util B	Util C
Forfivo XL		

References:
Forfivo XL Prescribing Information, Nov. 2011, Intelgenx Corp.
Facts & Comparisons, 2012 Updates Wolters Kluwer Health.

35. Forfivo XL / Therapeutic Appropriateness (0-18 yoa) _____ _____

Alert Message: Safety and effectiveness of Forfivo XL (extended-release bupropion) in pediatric patients have not been established. Anyone considering the use of bupropion in a child or adolescent must balance the potential risks with the clinical need.

Drugs/Diseases

Util A	Util B	Util C
Forfivo XL		

Age Range: 0-18 yoa
References:
Forfivo XL Prescribing Information, Nov. 2011, Intelgenx Corp.
Facts & Comparisons, 2012 Updates Wolters Kluwer Health.

36. Bupropion / Ticlopidine & Clopidogrel _____ _____

Alert Message: Concurrent use of a bupropion-containing agent with clopidogrel or ticlopidine (CYP2B6 Inhibitors) is not recommended. Co-administration of these agents may result in elevated bupropion (CYP2B6 substrate) plasma concentrations and risk of bupropion-related adverse effects (e.g., seizures, nausea, tremor and insomnia).

Drugs/Diseases

Util A	Util B	Util C
Bupropion-All	Ticlopidine	
	Clopidogrel	

References:

Forfivo XL Prescribing Information, Nov. 2011, Intelgenx Corp.
Facts & Comparisons, 2012 Updates Wolters Kluwer Health.
Clinical Pharmacology, 2012 Elsevier/Gold Standard.

DUR Board Meeting
June 3, 2013
Pioneer Room
State Capitol

North Dakota Medicaid
DUR Board Meeting Agenda
Pioneer Room
State Capitol
600 East Blvd. Avenue
Bismarck, ND
June 3, 2013
1pm

1. Administrative items
    - Travel vouchers

2. Old business
    - Review and Approval of Minutes of 3/13 Meeting — Chair
    - Budget Update — Brendan
    - Second Review of Fulyzaq — Brendan
    - Second Review of Xeljanz — Brendan

3. New business
    - Review of Immediate Release Narcotic Utilization — HID
    - Review of Rayos — HID
    - Review of Diclegis — HID
    - Review of Sitavig — HID
    - Review of Onmel — HID
    - Review of Giazo — HID
    - Review of Delzicol — HID
    - Criteria Recommendations — HID
    - Upcoming Meeting Date/Agenda — Chair

4. Adjourn — Chair

Please remember to silence all cellular phones and pagers during the meeting.

Drug Utilization Review (DUR) Meeting Minutes
March 11, 2013

Members Present: Norman Byers, John Savageau, Leann Ness, David Clinkenbeard, Carrie Sorenson, Cheryl Huber, Carlotta McCleary, Greg Pfister, Michael Booth, Jeffrey Hostetter

Members Absent: Steve Irsfeld, Todd Twogood, Russ Sobotta, Tanya Schmidt, James Carlson

Medicaid Pharmacy Department: Brendan Joyce, Gary Betting

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 December meeting. N. Byers moved that the minutes be approved and C. Huber 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 there is no new information since the last board meeting.

Genitourinary Smooth Muscle Relaxants (GSM) Second Review
A motion and second were made at the December meeting to place Genitourinary Smooth Muscle Relaxants 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.

Multiple Sclerosis Second Review
A motion and second were made at the December meeting to place agents used to treat multiple sclerosis (i.e., Aubagio) on prior authorization. The topic was brought up for a second review. Susan Grindle, representing Teva, spoke regarding Copaxone. Chair G. Pfister called for a voice vote to approve the motion. The motion passed with no audible dissent.

Update on Medications Greater than $3,000
B. Joyce reviewed medications that cost greater than $3,000. Recently, three specialty medications came to market that prompted a closer review of high dollar agents. Utilization and new medication to market information was provided to the Board. B. Joyce informed the Board that the State is being vigilant to add these drugs to the PA list as soon as they come on the market. This not only ensures appropriate use, but also cost management when appropriate.

Fulyzaq Review
B. Joyce reviewed Fulyzaq clinical information with the board. There was no public comment. J. Hostetter made a motion to place Fulyzaq on prior authorization. C. Sorenson seconded the motion. This topic will be brought up at the next meeting for finalization.

Xeljanz Review
B. Joyce reviewed Xeljanz clinical information with the board. There was no public comment. T. Hartman, representing Pfizer, spoke regarding Xeljanz. J. Hostetter made a motion to place Xeljanz on prior authorization. G. Pfister seconded the motion. This topic will be brought up at the next meeting for finalization.

Asthma Management
Wendy Brown, Associate Professor at the NDSU College of Pharmacy and Clinical Coordinator of About the Patient, spoke regarding asthma management in the ND Medicaid population. About the Patient is currently writing a grant proposal to develop a Medication Therapy Management (MTM) program, for ND Medicaid recipients, designed to help build collaboration between prescribing health professionals, pharmacists, and patients with asthma in order to optimize medication use and disease control.

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 G. Pfister 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 June 3, 2013 in Bismarck. C. Sorenson made a motion to adjourn the meeting. J. Hostetter seconded. The motion passed with no audible dissent. G. Pfister adjourned the meeting.

HEALTH INFORMATION DESIGNS

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 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	

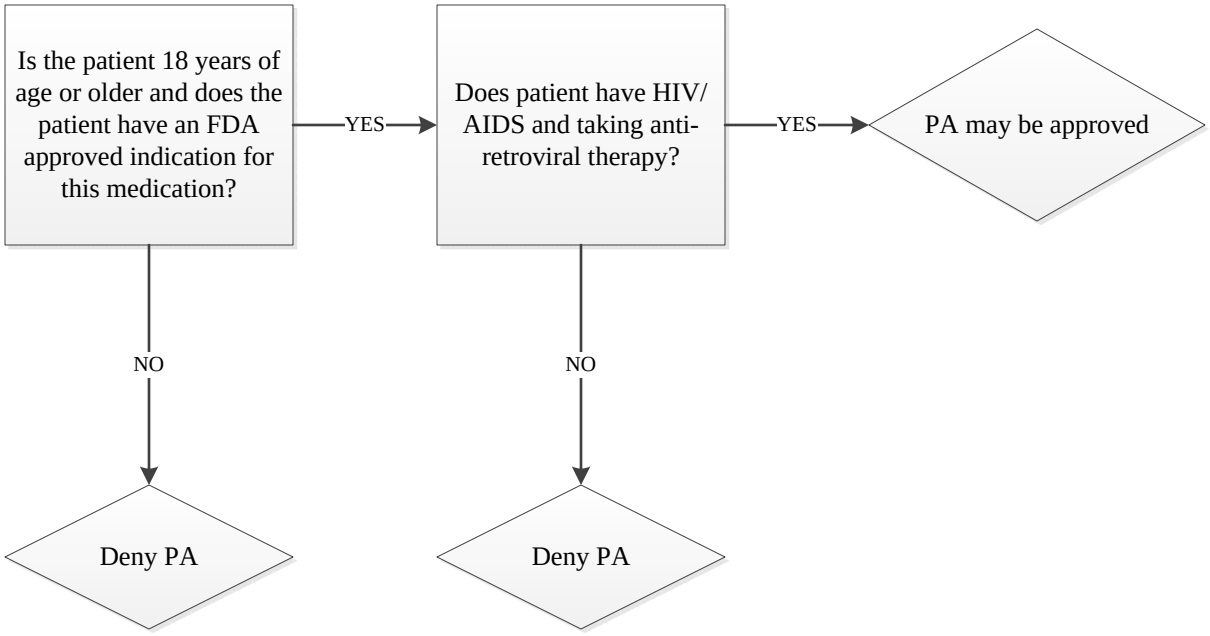
Part II: TO BE COMPLETED BY PHARMACY

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)	

North Dakota Department of Human Services
Fulyzaq Authorization Algorithm



HEALTH INFORMATION DESIGNS

Prior Authorization Vendor for ND Medicaid

Xeljanz
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 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 increase 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 Have or have had active hepatitis B or C virus □ Yes □ NO	Failed methotrexate therapy Start date: End date:
Physician Signature	Date

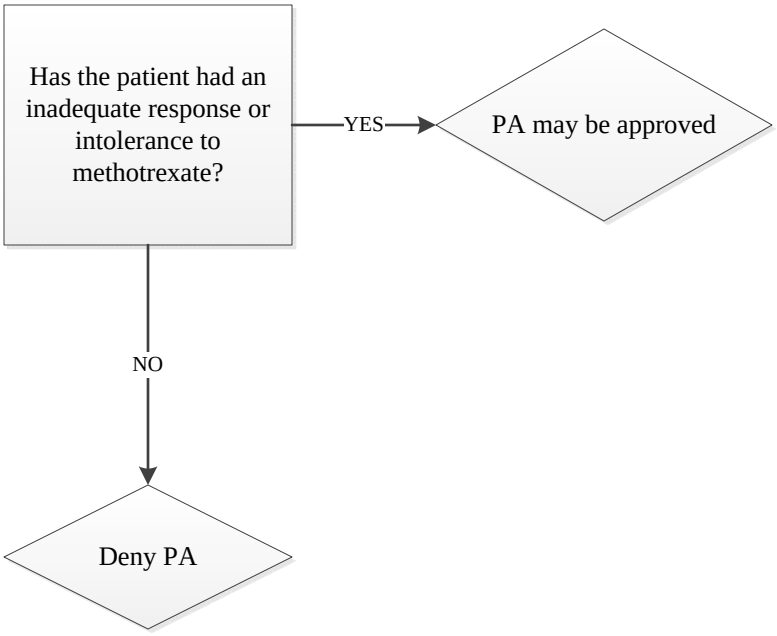
Part II: TO BE COMPLETED BY PHARMACY

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)	

North Dakota Department of Human Services
Xeljanz Authorization Algorithm



North Dakota Immediate Release Narcotic Utilization		
02/26/12 - 02/25/13		
Label Name	**Rx Count**	**Reimb Amt**
HYDROMORPHONE 2 MG TABLET	625	$6,638.42
HYDROMORPHONE 4 MG TABLET	517	$11,691.12
HYDROMORPHONE 8 MG TABLET	74	$7,329.75
MEPERIDINE 50 MG TABLET	80	$1,634.03
METHADONE HCL 10 MG TABLET	356	$6,863.51
METHADONE HCL 5 MG TABLET	157	$1,382.07
MORPHINE SULFATE IR 15 MG TAB	198	$2,464.55
MORPHINE SULFATE IR 30 MG TAB	50	$1,269.29
OXYCODONE HCL 10 MG TABLET	553	$17,905.43
OXYCODONE HCL 15 MG TABLET	158	$5,327.05
OXYCODONE HCL 20 MG TABLET	57	$3,830.71
OXYCODONE HCL 30 MG TABLET	55	$2,956.72
OXYCODONE HCL 5 MG CAPSULE	5	$98.54
OXYCODONE HCL 5 MG TABLET	1717	$31,544.78
OXYMORPHONE HCL 5 MG TABLET	8	$2,497.08
Total Recipients 1062	**4610**	**$103,433.05**

Top 10 Counties by Script Count	
County	**Percentage**
Cass	19.96%
Burleigh	12.80%
Grand Forks	8.42%
Rolette	8.24%
Stutsman	6.82%
Morton	6.70%
Ward	5.17%
Stark	3.69%
Barnes	3.17%
Walsh	2.83%

Top 20 Prescribers by Script Count	
Specialty	**Script Count**
NP	131
Family Practice	124
PA	118
Physiatrist	116
Physical Med and Rehab	90
Family Practice	84
Physical Med and Rehab	71
Family Practice	68
Family Practice	59
Physical Med and Rehab	54
Orthopedics	53
Family Practice	50
Orthopedics	50
NP	48
Family Practice	47
Family Practice	44
Family Practice	44
NP	43
Internal Medicine	42
Family Practice	41

Scripts Filled For 20 Pills Per Day Or Higher			
Unique Scripts	**Qty Disp**	**Days Supply**	**Average Pills per Day**
HYDROMORPHONE 8 MG TABLET	360	4	90.00
OXYCODONE HCL 10 MG TABLET	150	3	50.00
OXYCODONE HCL 5 MG TABLET	480	10	48.00
OXYCODONE HCL 5 MG TABLET	200	6	33.33
OXYCODONE HCL 5 MG TABLET	250	8	31.25
METHADONE HCL 10 MG TABLET	900	30	30.00
OXYCODONE HCL 5 MG TABLET	120	4	30.00
OXYCODONE HCL 5 MG TABLET	140	5	28.00
OXYCODONE HCL 5 MG TABLET	250	9	27.78
HYDROMORPHONE 8 MG TABLET	360	14	25.71
HYDROMORPHONE 2 MG TABLET	200	8	25.00
HYDROMORPHONE 2 MG TABLET	200	8	25.00
HYDROMORPHONE 2 MG TABLET	200	8	25.00
HYDROMORPHONE 2 MG TABLET	200	8	25.00
HYDROMORPHONE 2 MG TABLET	200	8	25.00
OXYCODONE HCL 5 MG TABLET	200	8	25.00
HYDROMORPHONE 4 MG TABLET	360	15	24.00
HYDROMORPHONE 8 MG TABLET	360	15	24.00
HYDROMORPHONE 8 MG TABLET	360	15	24.00
HYDROMORPHONE 8 MG TABLET	360	15	24.00
HYDROMORPHONE 8 MG TABLET	360	15	24.00
HYDROMORPHONE 8 MG TABLET	360	15	24.00
HYDROMORPHONE 8 MG TABLET	360	15	24.00
OXYCODONE HCL 5 MG TABLET	24	1	24.00
OXYCODONE HCL 5 MG TABLET	240	10	24.00
OXYCODONE HCL 5 MG TABLET	240	10	24.00
OXYCODONE HCL 5 MG TABLET	240	10	24.00
OXYCODONE HCL 5 MG TABLET	240	10	24.00
OXYCODONE HCL 5 MG TABLET	336	14	24.00
OXYCODONE HCL 5 MG TABLET	336	14	24.00
OXYCODONE HCL 5 MG TABLET	336	14	24.00
OXYCODONE HCL 5 MG TABLET	336	14	24.00
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OXYCODONE HCL 5 MG TABLET	336	14	24.00
OXYCODONE HCL 5 MG TABLET	336	14	24.00
OXYCODONE HCL 5 MG TABLET	336	14	24.00
OXYCODONE HCL 5 MG TABLET	360	15	24.00

Scripts Filled For 20 Pills Per Day Or Higher			
Unique Scripts	**Qty Disp**	**Days Supply**	**Average Pills per Day**
OXYCODONE HCL 5 MG TABLET	360	15	24.00
OXYCODONE HCL 5 MG TABLET	70	3	23.33
HYDROMORPHONE 2 MG TABLET	300	13	23.08
OXYCODONE HCL 5 MG TABLET	45	2	22.50
OXYCODONE HCL 5 MG TABLET	90	4	22.50
OXYCODONE HCL 5 MG TABLET	224	10	22.40
OXYCODONE HCL 5 MG TABLET	224	10	22.40
OXYCODONE HCL 5 MG TABLET	336	15	22.40
HYDROMORPHONE 2 MG TABLET	200	9	22.22
HYDROMORPHONE 4 MG TABLET	200	9	22.22
HYDROMORPHONE 4 MG TABLET	200	9	22.22
HYDROMORPHONE 4 MG TABLET	200	9	22.22
HYDROMORPHONE 4 MG TABLET	200	9	22.22
HYDROMORPHONE 4 MG TABLET	200	9	22.22
HYDROMORPHONE 4 MG TABLET	200	9	22.22
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HYDROMORPHONE 4 MG TABLET	200	9	22.22
HYDROMORPHONE 4 MG TABLET	200	9	22.22
OXYCODONE HCL 5 MG TABLET	200	9	22.22
HYDROMORPHONE 2 MG TABLET	100	5	20.00
HYDROMORPHONE 2 MG TABLET	100	5	20.00
HYDROMORPHONE 2 MG TABLET	100	5	20.00
HYDROMORPHONE 2 MG TABLET	200	10	20.00
METHADONE HCL 5 MG TABLET	280	14	20.00
MORPHINE SULFATE IR 15 MG TAB	100	5	20.00
OXYCODONE HCL 10 MG TABLET	40	2	20.00
OXYCODONE HCL 10 MG TABLET	60	3	20.00
OXYCODONE HCL 10 MG TABLET	100	5	20.00
OXYCODONE HCL 10 MG TABLET	100	5	20.00
OXYCODONE HCL 10 MG TABLET	100	5	20.00
OXYCODONE HCL 10 MG TABLET	100	5	20.00
OXYCODONE HCL 10 MG TABLET	100	5	20.00
OXYCODONE HCL 10 MG TABLET	100	5	20.00
OXYCODONE HCL 10 MG TABLET	600	30	20.00

Scripts Filled For 20 Pills Per Day Or Higher			
Unique Scripts	**Qty Disp**	**Days Supply**	**Average Pills per Day**
OXYCODONE HCL 5 MG TABLET	40	2	20.00
OXYCODONE HCL 5 MG TABLET	60	3	20.00
OXYCODONE HCL 5 MG TABLET	100	5	20.00
OXYCODONE HCL 5 MG TABLET	100	5	20.00

Top 20 Diagnoses for Patients Receiving 10 or more IR scripts 02/26/12 – 02/25/13		
DX Code	**DX Description**	**Count**
25000	DIABETES UNCOMPL TYPE II	2,161
4019	UNSPECIFIED ESSENTIAL HYPERTENSION	1,718
33829	OTHER CHRONIC PAIN	1,468
5856	END STAGE RENAL DISEASE	1,400
78900	ABDOMINAL PAIN UNS SITE	1,381
3051	TOBACCO USE DISORDER	1,182
28521	ANEMIA CHRONIC KIDNEY DISEASE	1,169
V560	ENCOUNTER FOR EXTRACORP DIALYSIS	1,155
7242	LUMBAGO	1,093
40391	UNS KID HYPER W CKD STAGE V-ESRD	1,043
78650	UNSPEC CHEST PAIN	1,025
58881	SEC HYPERPARATHYROIDISM RENAL	987
496	CHRONIC AIRWAY OBSTRUCTION OTHER	986
78701	NAUSEA WITH VOMITING	960
7840	HEADACHE	959
311	DEPRESSIVE DISORDER OTHER	923
V5869	ENCOUNTER LONG TERM USE OTH DRUGS	839
3384	CHRONIC PAIN SYNDROME	803
30000	ANXIETY STATE UNSPECIFIED	784
25040	DIABETES RENAL MANIF TYPE II	769

North Dakota Medicaid
Pharmacotherapy Review
Rayos®

I. Indication

Rayos is a new extended release dosage form for prednisone indicated:

- As an anti-inflammatory or immunosuppressive agent for certain allergic, dermatologic, gastrointestinal, hematologic, ophthalmologic, nervous system, renal, respiratory, rheumatologic, specific infectious diseases or conditions and organ transplantation.
- For the treatment of certain endocrine conditions.
- For palliation of certain neoplastic conditions.

II. Warnings and Precautions

- Hypothalamic-pituitary-adrenal (HPA) axis suppression, Cushing's syndrome, and hyperglycemia: Monitor patients for these conditions with chronic use. Taper doses gradually for withdrawal after chronic use.
- Infections: Increased susceptibility to new infection and increased risk of exacerbation, dissemination, or reactivation of latent infection. Signs and symptoms of infection may be masked.
- Elevated blood pressure, salt and water retention, and hypokalemia: Monitor blood pressure and sodium, potassium serum levels.
- GI perforation: Increased risk in patients with certain GI disorders. Signs and symptoms may be masked.
- Behavioral and mood disturbances: May include euphoria, insomnia, mood swings, personality changes, severe depression, and psychosis. Existing conditions may be aggravated.
- Decreases in bone density: Monitor bone density in patients receiving long term corticosteroid therapy.
- Ophthalmic effects: May include cataracts, infections, and glaucoma. Monitor intraocular pressure if corticosteroid therapy is continued for more than 6 weeks.
- Live or live attenuated vaccines: Do not administer to patients receiving immunosuppressive doses of corticosteroids.
- Negative effects on growth and development: Monitor pediatric patients on long-term corticosteroid therapy.
- Use in pregnancy: Fetal harm can occur with first trimester use. Apprise women of potential harm to fetus.

III. Drug Interactions

- Anticoagulant agents: May enhance or diminish anticoagulant effects.
- Antidiabetic agents: May increase blood glucose concentrations. Dose adjustments of antidiabetic agents may be required.

- CYP3A4 inducers and inhibitors: May, respectively, increase or decrease clearance of corticosteroids, necessitating dose adjustment.
- Cyclosporine: Increase in activity of both cyclosporine and corticosteroid when administered concurrently. Convulsions have been reported with concurrent use.
- NSAIDs including aspirin and salicylates: Increased risk of gastrointestinal side effects.

IV. Adverse Reactions

Common adverse reactions for corticosteroids include fluid retention, alteration in glucose tolerance, elevation in blood pressure, behavioral and mood changes, increased appetite and weight gain.

V. Dosage and Administration

Individualize dosing based on disease severity and patient response. The timing of administration should take into account the delayed-release pharmacokinetics and the disease or condition being treated:

- Initial dose: RAYOS 5 mg administered once per day. Patients currently on immediate-release prednisone, prednisolone, or methylprednisolone should be switched to RAYOS at an equivalent dose based on relative potency.
- Maintenance dose: Use lowest dosage that will maintain an adequate clinical response.
- Discontinuation: Withdraw gradually if discontinuing long-term or high-dose therapy.
- RAYOS should be taken daily with food.
- RAYOS should be swallowed whole and not broken, divided, or chewed.

VI. Cost

Rayos costs approximately $7.50 per 5mg tablet.

Reference

1. Rayos® [prescribing information]. Deerfield, IL. Horizon Pharma USA, Inc.; January 2013.

North Dakota Medicaid
Pharmacotherapy Review
Diclegis®

I. Indication

Diclegis is a fixed dose combination drug of doxylamine succinate (antihistamine) and pyridoxine hydrochloride (vitamin B6 analog) indicated for the treatment of nausea and vomiting of pregnancy in women who do not respond to conservative management.

II. Warnings and Precautions

- Avoid engaging in activities requiring complete mental alertness, such as driving or operating heavy machinery.
- Concurrent use with alcohol or other CNS depressants is not recommended.
- Use with caution in patients with asthma, increased intraocular pressure, narrow angle glaucoma, stenosing peptic ulcer, pyloroduodenal obstruction and urinary bladder-neck obstruction.

III. Contraindications

- Known hypersensitivity to doxylamine succinate, other ethanolamine derivative antihistamines, pyridoxine hydrochloride or any inactive ingredient in the formulation.
- Monoamine oxidase (MAO) inhibitors.

IV. Drug Interactions

- Severe drowsiness can occur when used in combination with alcohol or other sedating medications.

V. Adverse Reactions

The most common adverse reaction with Diclegis (≥5% and exceeding the rate in placebo) is somnolence.

VI. Dosage and Administration

Take two tablets daily at bedtime. If symptoms are not adequately controlled, the dose can be increased to a maximum recommended dose of four tablets daily (one in the morning, one mid-afternoon and two at bedtime).

VII. Cost

Diclegis costs approximately $5 per tablet.

Reference

1. Diclegis® [prescribing information]. Bryn Mawr, PA. Duchesnay USA, Inc.; April 2013.

North Dakota Medicaid
Pharmacotherapy Review
Sitavig®

I. Indication

Sitavig (acyclovir) is an antiviral medication indicated for the treatment of recurrent herpes labialis (cold sores) in immunocompetent adults.

II. Contraindications

- Known hypersensitivity to acyclovir, milk protein concentrate, or any other component of the product.

III. Drug Interactions

- Due to the low dose and minimal systemic absorption of Sitavig, drug interactions are unlikely.

IV. Adverse Reactions

The most common adverse reactions (≥1%) are headache and application site pain.

V. Dosage and Administration

- Application of one Sitavig 50mg buccal tablet as a single dose to the upper gum (canine fossa) region.
- Sitavig should be applied within one hour after the onset of prodromal symptoms and before the appearance of any signs of herpes labialis.
- Do not crush, chew, suck, or swallow tablets.

Reference

1. Sitavig® [prescribing information]. Bioalliance Pharma SA.; April 2013.

North Dakota Medicaid
Pharmacotherapy Review
Onmel®

I. Indication

Onmel (itraconazole) is an azole antifungal indicated for the treatment of onychomycosis of the toenail caused by *Trichophyton rubrum* or *T. mentagrophytes*.

II. Warnings and Precautions

Black Box Warning

WARNING: CONGESTIVE HEART FAILURE, CARDIAC EFFECTS AND DRUG INTERACTIONS

See full prescribing information for complete boxed warning.

- **Do not administer for the treatment of onychomycosis in patients with evidence of ventricular dysfunction such as congestive heart failure (CHF) or a history of CHF.**
- If signs or symptoms of congestive heart failure occur during administration, discontinue administration.
- Negative inotropic effects were seen when itraconazole was administered intravenously to dogs and healthy human volunteers.

- **Drug Interactions: Co-administration of certain drugs is contraindicated. See complete boxed warning.**
- May increase plasma concentrations of drugs metabolized by thecytochrome P450 3A4 isoenzyme system (CYP3A4) pathway.
- Serious cardiovascular events, including QT prolongation, torsades de pointes, ventricular tachycardia, cardiac arrest, and/or sudden death have occurred in patients using certain drugs. See complete boxed warning.

- Cases of congestive heart failure (CHF), peripheral edema, and pulmonary edema have been reported with itraconazole administration among patients being treated for onychomycosis and/or systemic fungal infections.
- Cardiac dysrhythmias
- Cardiac disease
- Hepatic effects
- Calcium channel blockers
- Neuropathy
- Hearing loss

III. Contraindications

- Do not administer for the treatment of onychomycosis in patients with evidence of ventricular dysfunction such as CHF or a history of CHF.
- Do not administer for the treatment of onychomycosis to pregnant patients or to women contemplating pregnancy.
- Co-administration of cisapride, dofetilide, ergot alkaloids such as dihydroergotamine, ergotamine, ergometrine (ergonovine), and methylergometrine (methylergonovine); felodipine, levacetylmethadol (levomethadyl), lovastatin, methadone, oral

midazolam, nisoldipine, pimozide, quinidine, simvastatin, and triazolam with Onmel is contraindicated.
- Anaphylaxis and hypersensitivity have been reported with use of itraconazole.

IV. Drug Interactions

- Concomitant administration of ONMEL Tablets with certain drugs metabolized by the cytochrome P450 3A4 isoenzyme system (CYP3A4) or transported by P-glycoprotein may result in increased plasma concentrations of those drugs, leading to potentially serious and/or life-threatening adverse events.
- Drug Interactions with the following drugs or classes of drugs may occur: Antiarrhythmics, Anticonvulsants, Anti-HIV Agents, Antimycobacterials, Antineoplastics, Antipsychotics, Benzodiazepines, Calcium Channel Blockers, Gastric Acid Suppressors/Neutralizers, Gastrointestinal Motility Agents, HMG CoA-Reductase Inhibitors, Macrolide Antibiotics, Oral Hypoglycemic Agents, Polyenes, Opiate Analgesics. Not all drug interactions are included in Highlights. See Full Prescribing Information for complete listing.

V. Adverse Reactions

- Most common adverse reactions observed in the treatment phase of the onychomycosis clinical trial (>1%) are upper respiratory tract infections, increased hepatic enzymes, hypoacusis, headache, abdominal pain, diarrhea, nausea, fatigue, arrhythmia, cough, sore throat and back pain.
- Itraconazole has been associated with rare cases of serious hepatotoxicity, including liver failure and death.

VI. Dosage and Administration

Onychomycosis of the toenail: recommended dose is 200mg once daily for 12 consecutive weeks.

VII. Cost

The cost of Onmel is approximately $30 per tablet.

Reference

1. Onmel® [prescribing information]. Greensboro, NC. Merz Pharmaceuticals, LLC; November 2012.

North Dakota Medicaid
Pharmacotherapy Review
Giazo®

I. Indication

Giazo is locally acting aminosalicylate indicated for the treatment of mildly to moderately active ulcerative colitis in male patients 18 years of age and older.

II. Warnings and Precautions

- Exacerbation of the symptoms of ulcerative colitis was reported. Observe patients closely for worsening of these symptoms while on treatment.
- Renal impairment may occur. Assess renal function at the beginning of treatment and periodically during treatment.
- Use with caution with pre-existing liver disease.

III. Contraindications

Giazo is contraindicated in patients with hypersensitivity to salicylates or to any of the components of Giazo tablets or balsalazide metabolites.

IV. Adverse Reactions

Most common adverse reactions (incidence ≥2%) in male ulcerative colitis patients are anemia, diarrhea, pharyngolaryngeal pain, and urinary tract infection.

V. Dosage and Administration

Three 1.1g Giazo tablets 2 times a day (6.6 g/day) with or without food for up to 8 weeks.

VI. Cost

Giazo costs approximately $5 per tablet.

Reference

1. Giazo® [prescribing information]. Raleigh, NC. Salix Pharmaceuticals, Inc.; June 2012.

North Dakota Medicaid
Pharmacotherapy Review
Delzicol®

I. Indication

Delzicol is an aminosalicylate indicated for the treatment of mildly to moderately active ulcerative colitis and for the maintenance of remission of ulcerative colitis.

II. Warnings and Precautions

- Renal impairment may occur. Assess renal function at the beginning of treatment and periodically during treatment.
- Mesalamine-induced acute intolerance syndrome has been reported. Observe patients closely for worsening of these symptoms while on treatment.
- Use caution when treating patients who are hypersensitive to sulfasalazine.
- Mesalamine-induced cardiac hypersensitivity reactions (myocarditis and pericarditis) have been reported.
- Hepatic failure has been reported in patients with pre-existing liver disease. Use caution when treating patients with liver disease.
- Upper gastrointestinal (GI) tract obstruction may delay onset of action.

III. Contraindications

Delzicol is contraindicated in patients with known hypersensitivity to salicylates or aminosalicylates or to any of the ingredients of Delzicol.

IV. Adverse Reactions

The most common adverse reactions (observed in ≥5% of patients) were abdominal pain, eructation, pain, headache, back pain, diarrhea, rash, dyspepsia, rhinitis, flu syndrome, asthenia, flatulence, vomiting, fever, arthralgia, constipation, and gastrointestinal bleeding.

V. Drug Interactions

- Nephrotoxic agents including NSAIDs (renal reactions)
- Azathioprine or 6-mercaptopurine (blood disorders)

VI. Dosage and Administration

- For the treatment of mildly to moderately active ulcerative colitis, 800mg three times daily.
- For the maintenance of remission of ulcerative colitis, 1.6g daily, in divided doses.
- Swallow whole without cutting, breaking, or chewing.
- Dose at least 1 h before or 2 h after a meal.
- Two Delzicol 400mg capsules have not been shown to be bioequivalent to one Asacol HD delayed-release 800mg tablet.

VII. Cost

Delzicol costs approximately $3 per tablet.

Reference

1. Delzicol® [prescribing information]. Rockaway, NJ. Warner Chilcott (US), LLC; February 2013.

NORTH DAKOTA MEDICAID
RETROSPECTIVE DRUG UTILIZATION REVIEW
CRITERIA RECOMMENDATIONS
2nd QUARTER 2013

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

1. Zolpidem IR / Therapeutic Appropriateness _____ _____

Alert Message: The zolpidem-containing product may be over-utilized. The recommended dosing range for immediate-release zolpidem in non-elderly adults is 5 to10 mg daily, immediately before bedtime. A dose greater than 5 mg is more likely to cause next-morning impairment especially in women due to a slower rate of elimination, therefore the lower dose of 5 mg is recommended for females and should be considered for males.

Conflict Code: ER - Overutilization
Drugs/Diseases
Util A Util B Util C
Zolpidem IR

Gender: Female
Max Dose: 5mg/day

References:
MedWatch FDA Safety Information and Adverse Event Reporting Program Safety Information. Zolpidem Containing Products: Drug Safety Communication – FDA Requires Lower Recommended Doses Including Ambien, Ambien CR, Edluar and Zolpimist. [Posted 01/10/2013].
Available at :
http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm334738.htm?source=govdelivery
http://www.fda.gov/Drugs/DrugSafety/ucm334033.htm

2. Zolpidem IR / Therapeutic Appropriateness _____ _____

Alert Message: The zolpidem-containing product may be over-utilized. The recommended dosing range for immediate-release zolpidem in non-elderly adults is 5 to10 mg daily, immediately before bedtime. A dose greater than 5 mg is more likely to cause next-morning impairment especially in women due to a slower rate of elimination, therefore the lower dose of 5 mg is recommended for females and should be considered for males.

Conflict Code: ER - Overutilization
Drugs/Diseases
Util A Util B Util C
Zolpidem IR

Gender: Male
Max Dose: 10mg/day

References:
MedWatch FDA Safety Information and Adverse Event Reporting Program Safety Information. Zolpidem Containing Products: Drug Safety Communication – FDA Requires Lower Recommended Doses Including Ambien, Ambien CR, Edluar and Zolpimist. [Posted 01/10/2013].
Available at :
http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm334738.htm?source=govdelivery
http://www.fda.gov/Drugs/DrugSafety/ucm334033.htm

3. Zolpidem CR / Overutilization _____ _____

Alert Message: Extended-release zolpidem may be over-utilized. The recommended dosing range for zolpidem ER in non-elderly adults is 6.25 to 12.5 mg daily, immediately before bedtime. A dose greater than 6.25 mg is more likely to cause next-morning impairment especially in women due to a slower rate of elimination, therefore the lower dose of 6.25 mg is recommended for females and should be considered for males.

Conflict Code: ER - Overutilization
Drugs/Diseases
Util A Util B Util C
Zolpidem CR

Gender: Female
Max Dose: 6.25mg/day

References:
MedWatch FDA Safety Information and Adverse Event Reporting Program Safety Information. Zolpidem Containing Products: Drug Safety Communication – FDA Requires Lower Recommended Doses Including Ambien, Ambien CR, Edluar and Zolpimist. [Posted 01/10/2013].
Available at :
http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm334738.htm?source=govdelivery
http://www.fda.gov/Drugs/DrugSafety/ucm334033.htm

4. Zolpidem CR / Overutilization _____ _____

Alert Message: Extended-release zolpidem may be over-utilized. The recommended dosing range for zolpidem ER in non-elderly adults is 6.25 to12.5 mg daily, immediately before bedtime. A dose greater than 6.25 mg is more likely to cause next-morning impairment especially in women due to a slower rate of elimination, therefore the lower dose of 6.25 mg is recommended for females and should be considered for males.

Conflict Code: ER - Overutilization
Drugs/Diseases
Util A Util B Util C
Zolpidem CR

Gender: Male
Max Dose: 12.5mg/day

References:
MedWatch FDA Safety Information and Adverse Event Reporting Program Safety Information. Zolpidem Containing Products: Drug Safety Communication – FDA Requires Lower Recommended Doses Including Ambien, Ambien CR, Edluar and Zolpimist. [Posted 01/10/2013].
Available at :
http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm334738.htm?source=govdelivery
http://www.fda.gov/Drugs/DrugSafety/ucm334033.htm

5. Intermezzo / Overutilization Females 18-64 yoa _____ _____

Alert Message: The maximum recommended daily dose of Intermezzo (sublingual zolpidem) for women is 1.75 mg. In clinical studies female subjects exhibited decreased clearance of the same dose of sublingual zolpidem as compared to male subjects, leading to a lower dose recommendation for females. The maximum daily dose for men is 3.5mg.

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C (Negating)
Intermezzo		Hepatic Impairment

Max Dose: 1.75mg/day
Gender: Female
Age Rage: 18-64 yoa

References:
Intermezzo Prescribing Information, July 2012, Purdue Pharma.

6. Intermezzo / Overutilization Males 18-64 yoa _____ _____

Alert Message: The maximum recommended daily dose of Intermezzo (sublingual zolpidem) for men is 3.5 mg. In clinical studies female subjects exhibited decreased clearance of the same dose of sublingual zolpidem as compared to male subjects, leading to a lower dose recommendation for females. The maximum daily dose for females is 1.75 mg.

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C (Negating)
Intermezzo		Hepatic Impairment

Max Dose: 3.5 mg/day
Gender: Male
Age Rage: 18-64 yoa

References:
Intermezzo Prescribing Information, July 2012, Purdue Pharma.

7. Intermezzo / Overutilization 65 yoa and older _____ _____

Alert Message: The maximum recommended daily dose of Intermezzo (sublingual zolpidem) for geriatric patients is 1.75 mg. A pharmacokinetic study of 1.75 and 3.5 mg doses of sublingual zolpidem showed that the plasma Cmax and AUC in elderly subjects following the 3.5 mg dose was higher by 34% and 30%, respectively, than the non-elderly subjects.

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C (Negating)
Intermezzo		Hepatic Impairment

Max Dose: 1.75mg/day
Age Range: ≥65 yoa

References:
Intermezzo Prescribing Iq3207nformation, 2012, Purdue Pharma.

8. Intermezzo / Overutilization Hepatic Impairment _____ _____

Alert Message: The maximum recommended daily dose of Intermezzo (sublingual zolpidem) for patients with hepatic impairment is 1.75 mg. In a pharmacokinetic study patients with chronic hepatic insufficiency or cirrhosis taking oral zolpidem exhibited increased pharmacokinetic parameters as compared to subjects with normal hepatic function.

Conflict Code: ER - Overutilization
Drugs/Diseases

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

Max Dose: 1.75mg/day

References:
Intermezzo Prescribing Information, July 2012, Purdue Pharma.

9. Intermezzo / CNS Depressants _____ _____

Alert Message: The maximum recommended daily dose of Intermezzo (sublingual zolpidem) when taken concurrently with a CNS depressant is 1.75 mg. Concomitant use of these agents may result in additive CNS depression.

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C **(Include)**
Intermezzo		Narcotics
		Benzodiazepines
		Barbiturates
		Sedative/Hypnotics
		Muscle Relaxants
		Antipsychotics
		Antihistamines

Max Dose: 1.75mg/day

References:
Intermezzo Prescribing Information, July 2012, Purdue Pharma.

10. Pioglitazone / Gemfibrozil _____ _____

Alert Message: The maximum recommended dose of a pioglitazone-containing product is 15 mg once daily when used in combination with strong CYP2C8 inhibitors (e.g., gemfibrozil).

Conflict Code: ER – Overutilization
Drugs/Diseases

Util A	Util B	Util C (Include)
Pioglitazone		Gemfibrozil
Pioglitazone/Metformin IR		
Pioglitazone/Alogliptin		

Max Dose: 15 mg/day of pioglitazone

References:
Facts & Comparison, 2013 Updates, Wolters Kluwer Health.
Clinical Pharmacology, 2013 Elsevier/Gold Standard.
Actos Prescribing Information, August 2012, Takeda Pharmaceuticals.
ActoPlus Met Prescribing Information, September 2012, Takeda Pharmaceuticals.
Oseni Prescribing Information, January 2013, Takeda Pharmaceuticals.

11. Actoplus Met XR & Duetact / Gemfibrozil _____ _____

Alert Message: The concurrent use of a pioglitazone-containing agent with a CYP2C8 inhibitor (e.g., gemfibrozil) can cause a significant increase in pioglitazone plasma concentrations. If an inhibitor of CYP2C8 is started or stopped during pioglitazone therapy dosage adjustment of the diabetic treatment may be needed based on clinical response.

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

Util A	Util B	Util C
Pioglitazone/Metformin XR	Gemfibrozil	
Pioglitazone/Glimepiride		

References:
ActoPlus Met XR Prescribing Information, October 2012, Takeda Pharmaceuticals.
Duetact Prescribing Information, October 2012, Takeda Pharmaceuticals.

12. Pioglitazone - All / Rifampin _____ _____

Alert Message: The concurrent use of a pioglitazone-containing agent with a CYP2C8 inducer (e.g., rifampin) can cause a significant decrease in pioglitazone plasma concentrations. If an inducer of CYP2C8 is started or stopped during pioglitazone therapy dosage adjustment of the diabetic treatment may be needed based on clinical response, without exceeding the maximum recommended daily dose of 45 mg for pioglitazone.

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

Util A	Util B	Util C
Pioglitazone-All	Rifampin	

References:
Actos Prescribing Information, August 2012, Takeda Pharmaceuticals.
ActoPlus Met Prescribing Information, September 2012, Takeda Pharmaceuticals.
Oseni Prescribing Information, January 2013, Takeda Pharmaceuticals.
ActoPlus Met XR Prescribing Information, October 2012, Takeda Pharmaceuticals.
Duetact Prescribing Information, October 2012, Takeda Pharmaceuticals.
Flockhart DA. Drug Interactions: Cytochrome P450 Drug Interaction Table. Indiana University School of Medicine. Available at: http://medicine.iupui.edu/clinpharm/ddos/table.asp.

13. Rosiglitazone - All / Rifampin _____ _____

Alert Message: The concurrent use of a rosiglitazone-containing agent with a CYP2C8 inducer (e.g., rifampin) can cause a significant decrease in rosiglitazone plasma concentrations. If an inducer of CYP2C8 is started or stopped during rosiglitazone therapy dosage adjustment of the diabetic treatment may be needed based on clinical response.

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

Util A	Util B	Util C
Rosiglitazone-All	Rifampin	

References:
Avandia Prescribing Information, May 2011, GlaxoSmithKline.
Flockhart DA. Drug Interactions: Cytochrome P450 Drug Interaction Table. Indiana University School of Medicine. Available at: http://medicine.iupui.edu/clinpharm/ddos/table.asp.

14. Rosiglitazone - All / Gemfibrozil _____ _____

Alert Message: The concurrent use of a rosiglitazone-containing agent with a CYP2C8 inhibitor (e.g., gemfibrozil) can cause a significant increase in rosiglitazone plasma concentrations. If an inhibitor of CYP2C8 is started or stopped during rosiglitazone therapy dosage adjustment of the diabetic treatment may be needed based on clinical response.

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

Util A	Util B	Util C
Rosiglitazone- All	Gemfibrozil	

References:
Avandia Prescribing Information, May 2011, GlaxoSmithKline.
Flockhart DA. Drug Interactions: Cytochrome P450 Drug Interaction Table. Indiana University School of Medicine. Available at: http://medicine.iupui.edu/clinpharm/ddos/table.asp.

15. Alogliptin / Overutilization _____ _____

Alert Message: The manufacturer's maximum recommended dose of Nesina (alogliptin) in patients with normal renal function or mild renal impairment is 25 mg once daily.

Conflict Code: ER – Overutilization
Drugs/Diseases

Util A	Util B	Util C (Negate)
Alogliptin		CKD Stage 3-5
		ESRD
		Hypertensive CKD

Max Dose: 25mg/day

References:
Nesina Prescribing Information, January 2013, Takeda Pharmaceuticals.
Facts& Comparisons, 2013 Updates, Wolters Kluwer Health.

16. Alogliptin / Moderate Renal Impairment Dosing _____ _____

Alert Message: The maximum recommended dose of Nesina (alogliptin) in patients with moderate renal impairment (CrCl 30 to < 60 mL/min) is 12.5 mg once daily. Patients with severe renal impairment or ESRD should not receive more than 6.25 mg once daily.

Conflict Code: ER – Overutilization
Drugs/Diseases

Util A	Util B	Util C (Include)
Alogliptin		CKD Stage 3
		CKD unspecified
		Hypertensive CKD

Max Dose: 12.5mg/day

References:
Nesina Prescribing Information, January 2013, Takeda Pharmaceuticals.
Facts& Comparisons, 2013 Updates, Wolters Kluwer Health.

17. Alogliptin / Severe Renal Impairment or ESRD Dosing _____ _____

Alert Message: The maximum recommended dose of Nesina (alogliptin) in patients with severe renal impairment or ESRD (CrCl< 30 mL/min) is 6.25 mg once daily.

Conflict Code: ER – Overutilization
Drugs/Diseases

Util A	Util B	Util C (Include)
Alogliptin		CKD Stage 4-5
		ESRD
		Hypertensive CKD

Max Dose: 6.25mg/day

References:
Nesina Prescribing Information, January 2013, Takeda Pharmaceuticals.
Facts& Comparisons, 2013 Updates, Wolters Kluwer Health.

18. Alogliptin-All / Pancreatitis _____ _____

Alert Message: There have been postmarketing reports of acute pancreatitis in patients taking Nesina (alogliptin). After initiation of any alogliptin-containing product, patients should be observed carefully for signs and symptoms of pancreatitis. If pancreatitis is suspected the alogliptin-containing agent should be promptly discontinued and appropriate management should be initiated.

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

Util A	Util B	Util C
Alogliptin	Pancreatitis	
Alogliptin/Metformin		
Alogliptin/Pioglitazone		

References:
Nesina Prescribing Information, January 2013, Takeda Pharmaceuticals.
Kazano Prescribing Information, January 2013, Takeda Pharmaceuticals.
Oseni Prescribing Information, January 2013, Takeda Pharmaceuticals.

19. Alogliptin-All / Hepatic Effects _____ _____

Alert Message: There have been postmarketing reports of fatal and non-fatal hepatic failure in patients taking Nesina (alogliptin). If liver injury is detected, promptly interrupt alogliptin-containing therapy and assess patient for probable cause. Do not restart the alogliptin-containing product if liver injury is confirmed and no alterative etiology can be found.

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

Util A	Util B	Util C
Alogliptin		
Alogliptin/Metformin		
Alogliptin/Pioglitazone		

References:
Nesina Prescribing Information, January 2013, Takeda Pharmaceuticals.
Kazano Prescribing Information, January 2013, Takeda Pharmaceuticals.
Oseni Prescribing Information, January 2013, Takeda Pharmaceuticals.

20. Alogliptin-All / Insulin & Sulfonylureas _____ _____

Alert Message: The concurrent use of an alogliptin-containing product (Nesina, Kazano and Oseni) with insulin or an insulin secretagogue (e.g., sulfonylurea) may result in hypoglycemia. A lower dose of the sulfonylurea or insulin may be required to minimize the risk of hypoglycemia.

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

Util A	Util B	Util C
Alogliptin	Insulin	
Alogliptin/Metformin	Sulfonylureas	
Alogliptin/Pioglitazone		

References:
Nesina Prescribing Information, January 2013, Takeda Pharmaceuticals.
Kazano Prescribing Information, January 2013, Takeda Pharmaceuticals.
Oseni Prescribing Information, January 2013, Takeda Pharmaceuticals.

21. Alogliptin-Pioglitazone / Overutilization _____ _____

Alert Message: The manufacturer's maximum recommended daily dose of Oseni (alogliptin/pioglitazone) in patients with normal renal function or mild renal impairment is 25 mg alogliptin and 45mg pioglitazone.

Conflict Code: ER – Overutilization
Drugs/Diseases

Util A	Util B	Util C (Negate)
Alogliptin/Pioglitazone		CKD Stage 3-5
		ESRD
		Hypertensive CKD

Max Dose: 25mg/day alogliptin

References:
Oseni Prescribing Information, January 2013, Takeda Pharmaceuticals.

22. Alogliptin-Pioglitazone / Moderate Renal Impairment Dosing _____ _____

Alert Message: The manufacturer's maximum recommended dose of Oseni (alogliptin/pioglitazone) in patients with moderate renal impairment (CrCl 30 to < 60 mL/min) is 12.5 mg of alogliptin once daily. Alogliptin/pioglitazone use is not recommended for patients with severe renal impairment or ESRD requiring dialysis.

Conflict Code: ER – Overutilization
Drugs/Diseases

Util A	Util B	Util C (Include)
Alogliptin/Pioglitazone		CKD Stage 3
		CKD unspecified
		Hypertensive CKD

Max Dose: 12.5mg/day

References:
Oseni Prescribing Information, January 2013, Takeda Pharmaceuticals.

23. Alogliptin-Metformin / Overutilization _____ _____
Alert Message: The manufacturer's maximum recommended daily dose of Kazano (alogliptin/metformin) is 25 mg alogliptin and 2000mg metformin.

Conflict Code: ER – Overutilization
Drugs/Diseases

Util A	Util B	Util C (Negate)
Alogliptin/Metformin		Renal Impairment

Max Dose: 25mg/day alogliptin

References:
Kazano Prescribing Information, January 2013, Takeda Pharmaceuticals.

24. Alogliptin-Metformin / Metabolic Acidosis _____ _____
Alert Message: Kazano (alogliptin/metformin) use is contraindicated in patients with acute or chronic metabolic acidosis, including diabetic ketoacidosis.

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

Util A	Util B	Util C
Alogliptin/Metformin	Acidosis	

References:
Kazano Prescribing Information, January 2013, Takeda Pharmaceuticals.

25. Alogliptin-All / Duplicate Therapy _____ _____
Alert Message: Therapeutic duplication of alogliptin-containing products may be occurring.

Conflict Code: TD – Therapeutic Duplication
Drugs/Diseases

Util A	Util B	Util C
Alogliptin		
Alogliptin/Pioglitazone		
Alogliptin/Metformin		

References:
Nesina Oseni Prescribing Information, January 2013, Takeda Pharmaceuticals.
Oseni Prescribing Information, January 2013, Takeda Pharmaceuticals.
Kazano Prescribing Information, January 2013, Takeda Pharmaceuticals.

26. Alogliptin / Nonadherence _____ _____
Alert Message: Based on refill history, your patient may be under-utilizing Nesina (alogliptin). 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
Alogliptin		

References:
Nesina Prescribing Information, January 2013, Takeda Pharmaceuticals.
Osterberg L, Blaschke T. Adherence to medication. N Engl J Med 2005;353:487-97.
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.
Ho PM, Rumsfeld JS, Masoudi FA, et al., Effect of Medication Nonadherence in Diabetes Mellitus. Cardiology Review, April 2007.

27. Alogliptin-Pioglitazone / Nonadherence _____ _____

Alert Message: Based on refill history, your patient may be under-utilizing Oseni (alogliptin/pioglitazone). 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
Alogliptin/Pioglitazone		

References:
Oseni Prescribing Information, January 2013, Takeda Pharmaceuticals.
Osterberg L, Blaschke T. Adherence to medication. N Engl J Med 2005;353:487-97.
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.
Ho PM, Rumsfeld JS, Masoudi FA, et al., Effect of Medication Nonadherence in Diabetes Mellitus. Cardiology Review, April 2007.

28. Alogliptin-Metformin / Nonadherence _____ _____

Alert Message: Based on refill history, your patient may be under-utilizing Kazano (alogliptin/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
Alogliptin/Metformin		

References:
Kazano Prescribing Information, January 2013, Takeda Pharmaceuticals.
Osterberg L, Blaschke T. Adherence to medication. N Engl J Med 2005;353:487-97.
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.
Ho PM, Rumsfeld JS, Masoudi FA, et al., Effect of Medication Nonadherence in Diabetes Mellitus. Cardiology Review, April 2007.

29. Alogliptin-All / Therapeutic Appropriateness _____ _____

Alert Message: Safety and effectiveness of alogliptin-containing products (Nesina, Kazano and Oseni) in pediatric patients have not been established.

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C
Alogliptin Alogliptin/Metformin Alogliptin/Pioglitazone		

Age Range: 0-18 yoa

References:
Nesina Prescribing Information, January 2013, Takeda Pharmaceuticals.
Oseni Prescribing Information, January 2013, Takeda Pharmaceuticals.
Kazano Prescribing Information, January 2013, Takeda Pharmaceuticals.

30. Metformin – All / Hepatic Impairment _____ _____

Alert Message: The use of metformin-containing products should be avoided in patients with clinical or laboratory evidence of hepatic disease. Metformin can, rarely, cause lactic acidosis and impaired hepatic function can significantly limit clearance of lactate. Metformin use in this patient population may increase the risk of lactic acidosis..

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

Util A	Util B	Util C
Metformin-All	Hepatic Impairment	

References:

Facts & Comparisons, 2013 Updates, Wolters Kluwer Health.
Clinical Pharmacology, 3013 Elsevier/Gold Standard.

DUR Board Meeting
September 9, 2013
Bismarck State College

National Energy Center of Excellence

North Dakota Medicaid
DUR Board Meeting Agenda
Bismarck State College
National Energy Center of Excellence
1200 Schafer Street
Bismarck, ND
September 9, 2013
1pm

1. Administrative items
    - Travel vouchers

2. Old business

• Review and Approval of Minutes of 6/13 Meeting	Chair
• Budget Update	Brendan
• Second Review of Rayos	Brendan
• Second Review of Diclegis	Brendan
• Second Review of Sitavig	Brendan
• Second Review of Onmel	Brendan
• Second Review of Giazo	Brendan

3. New business

• Review of Sirturo	HID
• Review of Brisdelle	HID
• Review of Vecamyl	HID
• Review of Sublingual and Spray Nitroglycerin	HID
• Review of COPD Specific Products	HID
• Review of Epinephrine Injection Devices	HID
• Review of Pulmozyme	HID
• Step therapy for Statins	HID
• Criteria Recommendations	HID
• Upcoming Meeting Date/Agenda	Chair

4. Executive Session (closed)
    - Review of Immediate Release Narcotic Patient Profiles

5. Adjourn — Chair

Please remember to silence all cellular phones and pagers during the meeting.

Drug Utilization Review (DUR) Meeting Minutes
June 3, 2013

Members Present: Norman Byers, John Savageau, Leann Ness, Cheryl Huber, Greg Pfister, Jeffrey Hostetter, Tanya Schmidt, Steve Irsfeld

Members Absent: Todd Twogood, Russ Sobotta, James Carlson, Carrie Sorenson, Carlotta McCleary, Michael Booth

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 March meeting. C. Huber moved that the minutes be approved, and J. Savageau 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 the pharmacy program is performing well and appears to be under budget at this time. This is partly attributed to the brand/generic split. The generic utilization is approximately 84%. Over the next few years, the pharmacy budget will start growing, due to specialty pharmacy growth. Currently, specialty pharmacy is growing approximately 20% per year. B. Joyce also discussed Medicaid Expansion. The legislature passed Medicaid Expansion and it will be put out for bid to MCOs at a per capita rate. State staff will oversee this operation. Expansion will begin January 1, 2014. There should be approximately 20,000 recipients.

Fulyzaq Second Review
A motion and second were made at the March meeting to place Fulyzaq 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.

Xeljanz Second Review
A motion and second were made at the March meeting to place Xeljanz 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.

Immediate Release Narcotic Utilization
B. Joyce reviewed utilization for immediate release narcotics. The goal is to ensure appropriate utilization and decrease diversion with these products. Examples of changes that can be made include quantity limits, drug-drug edits, and criteria for use of extended release products for patients using immediate release products long term. The future goal for these products would be one long-acting agent, one short-acting agent and one combo agent with acetaminophen. The board will review patient profiles during an executive session at the next meeting.

Rayos Review
B. Joyce reviewed Rayos clinical information with the board. There was no public comment. J. Hostetter made a motion to place Rayos on prior authorization. J. Savageau seconded the motion. This topic will be brought up at the next meeting for finalization.

Diclegis Review
B. Joyce reviewed Diclegis clinical information with the board. There was no public comment. J. Savageau made a motion to place Diclegis on prior authorization. G. Pfister seconded the motion. This topic will be brought up at the next meeting for finalization.

Sitavig Review
B. Joyce reviewed Sitavig clinical information with the board. There was no public comment. G. Pfister made a motion to place Sitavig on prior authorization. N. Byers seconded the motion. This topic will be brought up at the next meeting for finalization.

Onmel Review
B. Joyce reviewed Onmel clinical information with the board. There was no public comment. S. Irsfeld made a motion to place Onmel on prior authorization. T. Schmidt seconded the motion. This topic will be brought up at the next meeting for finalization.

Giazo Review
B. Joyce reviewed Giazo clinical information with the board. There was no public comment. J. Hostetter made a motion to place Giazo on prior authorization. C. Huber seconded the motion. This topic will be brought up at the next meeting for finalization.

Delzicol Review
B. Joyce reviewed Delzicol clinical information with the board. There was no public comment. The department will review post rebate data to determine which drug is the best option (Asacol HD or Delzicol).

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. Savageau moved to approve the new criteria and N. Byers 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 September 9, in Bismarck. C. Huber made a motion to adjourn the meeting. J. Hostetter seconded. The motion passed with no audible dissent. G. Pfister adjourned the meeting.

HEALTH INFORMATION DESIGNS

Prior Authorization Vendor for ND Medicaid

Rayos
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 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

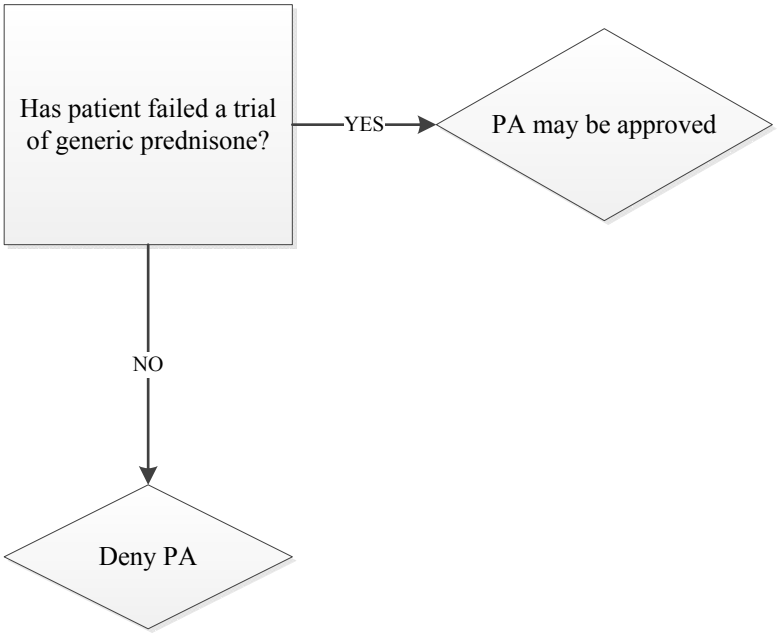
Part II: TO BE COMPLETED BY PHARMACY

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)	

North Dakota Department of Human Services
Rayos Authorization Algorithm



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

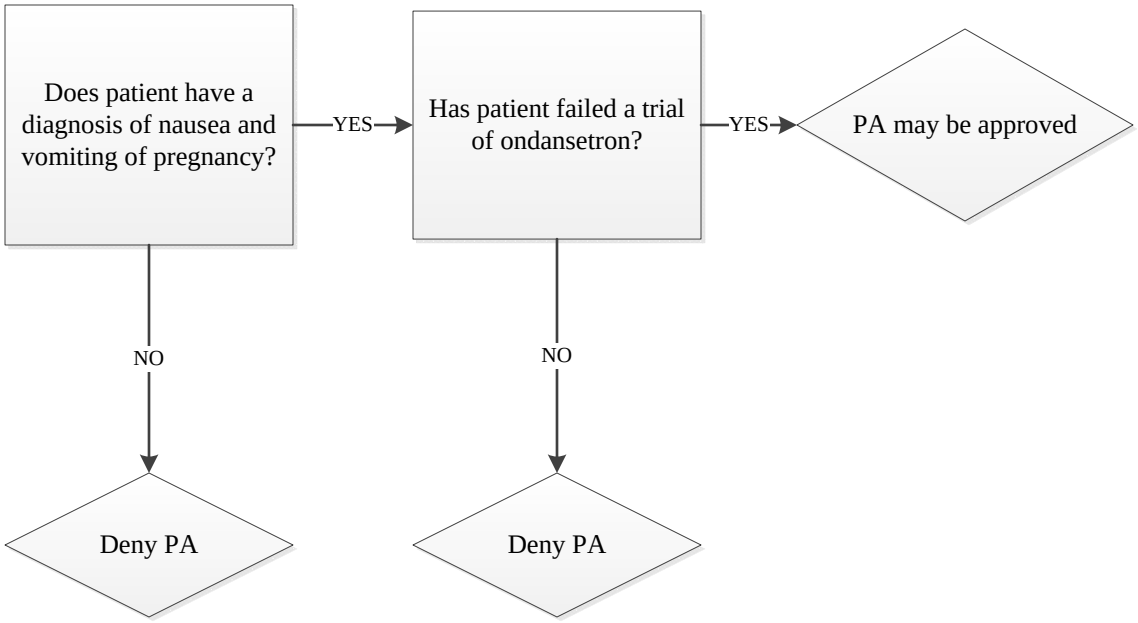
Part II: TO BE COMPLETED BY PHARMACY

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)	

North Dakota Department of Human Services
Diclegis Authorization Algorithm



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)	

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

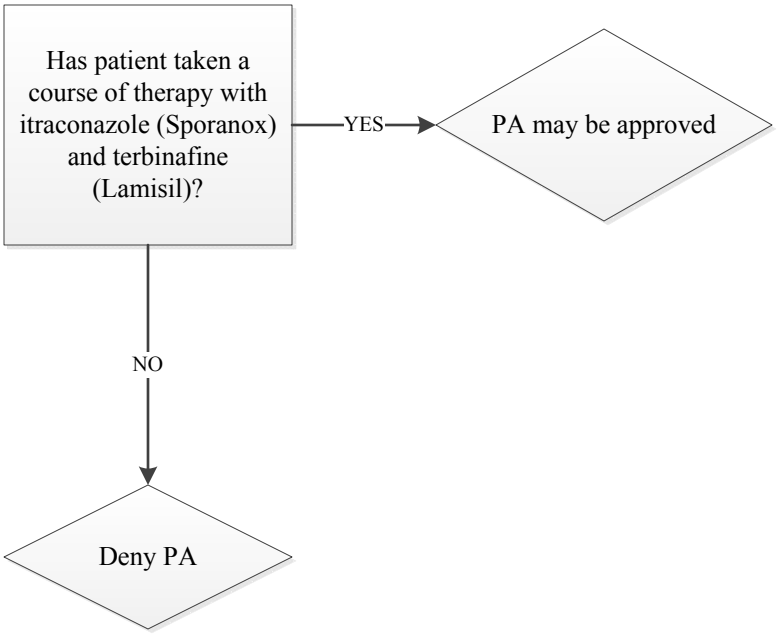
Part II: TO BE COMPLETED BY PHARMACY

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)	

North Dakota Department of Human Services
Onmel Authorization Algorithm



HEALTH INFORMATION DESIGNS

Prior Authorization Vendor for ND Medicaid

Giazo
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 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:	Diagnosis for this request:
□ Giazo	
□ Failed trial of balsalazide 750mg capsules Dose:	
Physician Signature	Date

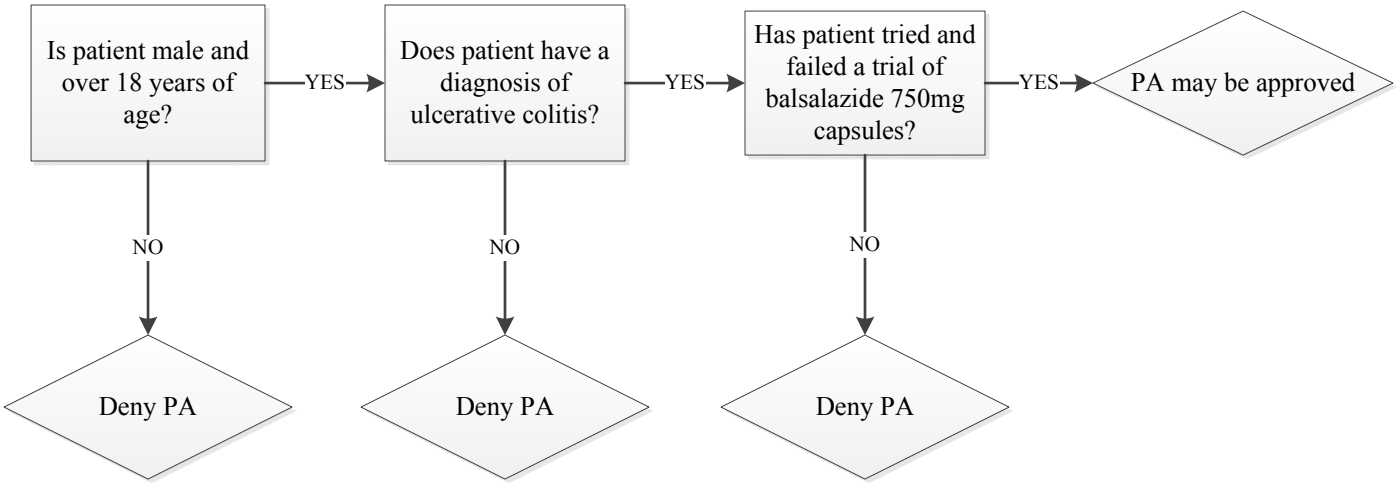
Part II: TO BE COMPLETED BY PHARMACY

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)	

North Dakota Department of Human Services
Giazo Authorization Algorithm



North Dakota Medicaid
Pharmacotherapy Review
Sirturo®

I. Indication

Sirturo (bedaquiline) is a diarylquinoline antimycobacterial drug indicated as part of combination therapy in adults (≥18 years) with pulmonary multi-drug resistant tuberculosis (MDR-TB). Reserve Sirturo for use when an effective treatment regimen cannot otherwise be provided. Sirturo is not indicated for the treatment of latent, extra-pulmonary or drug-sensitive tuberculosis.

II. Dosage and Administration

Sirturo should only be used in combination with at least 3 other drugs to which the patient's MDR-TB isolate has been shown to be susceptible *in vitro*. If in vitro testing results are unavailable, treatment may be initiated with Sirturo in combination with at least 4 other drugs to which the patient's MDR-TB isolate is likely to be susceptible. Sirturo should be taken 400mg once daily for 2 weeks followed by 200mg 3 times per week for 22 weeks with food.

III. Warnings and Precautions

- An increased risk of death was seen in the Sirturo treatment group compared to the placebo treatment group. Only use Sirturo when an effective treatment regimen cannot otherwise be provided.
- QT prolongation can occur with Sirturo. Monitor ECGs frequently.
- Discontinue Sirturo if significant ventricular arrhythmia or a QTcF interval > 500ms develops.
- Use with drugs that prolong QT interval may cause additive QT prolongation. Monitor ECGs more frequently.
- Hepatic-related adverse drug reactions have been reported with use of Sirturo. Monitor liver-related laboratory tests.
- Non-adherence to the treatment regimen could result in failure or resistance.

IV. Adverse Reactions

- The most common adverse reactions reported in ≥10% of patients treated with Sirturo are nausea, arthralgia, and headache.
- Additional adverse events reported in ≥10% of patients treated with Sirturo and with a higher frequency than the placebo treatment group are hemoptysis and chest pain.

V. Drug Interactions

- Avoid use of systemic potent CYP3A4 inducers with Sirturo.
- Avoid use for more than 14 consecutive days of systemic strong CYP3A4 inhibitors with Sirturo unless the benefit outweighs the risk. Appropriate clinical monitoring for Sirturo-related adverse reactions is recommended.

VI. Cost

The current EAC for Sirturo is approximately $172 per tablet.

Reference

1. Sirturo® [prescribing information]. Titusville, NY. Janssen Therapeutics, Division of Janssen Products, LP; December 2012.

North Dakota Medicaid
Pharmacotherapy Review
Brisdelle®

I. Indication

Brisdelle (paroxetine) is a selective serotonin reuptake inhibitor (SSRI) indicated for the treatment of moderate to severe vasomotor symptoms associated with menopause (VMS). Brisdelle is not indicated for the treatment of any psychiatric condition.

II. Dosage and Administration

The recommended dosage of Brisdelle is 7.5mg once daily, at bedtime.

III. Contraindications

- Concurrent use with monoamine oxidase inhibitors (MAOI) or use within 14 days of MAOI use
- Use with thioridazine
- Use with pimozide
- Pregnancy

IV. Warnings and Precautions

- Suicidality: Monitor for suicidality or unusual changes in behavior.
- Serotonin Syndrome: Serotonin syndrome, which is potentially life-threatening, has been reported with SSRIs. Discontinue Brisdelle and initiate supportive treatment.
- Tamoxifen: Efficacy of tamoxifen may be reduced when administered concomitantly with Brisdelle.
- Abnormal Bleeding: Caution patients about the risk of bleeding associated with the concomitant use of Brisdelle and non-steroidal anti-inflammatory drugs (NSAIDs), aspirin, or other drugs that affect coagulation.
- Hyponatremia: Can occur in association with syndrome of inappropriate antidiuretic hormone secretion (SIADH).
- Bone Fracture: Epidemiological studies have reported an association between SSRI treatment and fractures.
- Activation of Mania/Hypomania: Screen for bipolar disorder and monitor for mania/hypomania.
- Seizures: Use cautiously in patients with a history of seizures or with conditions that potentially lower the seizure threshold.
- Akathisia: Can occur, most likely in the first few weeks of treatment.
- Acute Angle Closure Glaucoma: May cause acute angle closure in patients with narrow angle glaucoma.
- Cognitive and Motor Impairment: May cause impairment; patients should not operate machinery or motor vehicles until certain that Brisdelle does not affect them adversely.

V. Adverse Reactions

The most common adverse reactions (≥2%) reported in clinical trials were: headache, fatigue, and nausea/vomiting.

VI. Drug Interactions

Paroxetine is a strong CYP2D6 inhibitor. Co-administration of Brisdelle can alter concentrations of other drugs that are metabolized by CYP2D6. Consider potential drug interactions prior to and during therapy.

Reference

1. Brisdelle® [prescribing information]. Miami, FL. Noven Therapeutics, LLC; June 2013.

North Dakota Medicaid
Pharmacotherapy Review
Vecamyl®

I. Indication

Vecamyl (mecamylamine) is indicated for the management of moderately severe to severe essential hypertension and uncomplicated cases of malignant hypertension.

II. Dosage and Administration

Therapy is usually started with one 2.5mg tablet mecamylamine twice a day. This initial dosage should be modified by increments of one 2.5mg tablet at intervals of not less than 2 days until the blood pressure response occurs. The average total daily dosage of mecamylamine is 25mg, usually in three divided doses. However, as little as 2.5mg daily may be sufficient to control hypertension in some patients. Close supervision and education of the patient, as well as critical adjustment of dosage, are essential to successful therapy.

III. Contraindications

Mecamylamine should not be used in mild, moderate, labile hypertension and may prove unsuitable in uncooperative patients. It is contraindicated in coronary insufficiency or recent myocardial infarction.

Mecamylamine should be given with great discretion, if at all, when renal insufficiency is manifested by a rising or elevated BUN. The drug is contraindicated in uremia. Patients receiving antibiotics and sulfonamides should generally not be treated with ganglion blockers. Other contraindications are glaucoma, organic pyloric stenosis or hypersensitivity to the product.

IV. Warnings and Precautions

Mecamylamine, a secondary amine, readily penetrates into the brain and thus may produce central nervous system effects. Tremor, choreiform movements, mental aberrations, and convulsions may occur rarely. These have occurred most often when large doses of mecamylamine were used, especially in patients with cerebral or renal insufficiency.

When ganglion blockers or other potent antihypertensive drugs are discontinued suddenly, hypertensive levels return. In patients with malignant hypertension and others, this may occur abruptly and may cause fatal cerebral vascular accidents or acute congestive heart failure. When mecamylamine is withdrawn, this should be done gradually and other antihypertensive therapy usually must be substituted. The effects of mecamylamine sometimes may last from hours to days after therapy is discontinued.

The patient's condition should be evaluated carefully, particularly as to renal and cardiovascular function. When renal, cerebral, or coronary blood flow is deficient, any additional impairment, which might result from added hypotension, must be avoided. The use of mecamylamine in patients with marked cerebral and coronary arteriosclerosis or after a recent cerebral accident requires caution.

The action of mecamylamine may be potentiated by excessive heat, fever, infection, hemorrhage, pregnancy, anesthesia, surgery, vigorous exercise, other antihypertensive drugs,

alcohol, and salt depletion as a result of diminished intake or increased excretion due to diarrhea, vomiting, excessive sweating, or diuretics.

During therapy with mecamylamine, sodium intake should not be restricted but, if necessary, the dosage of the ganglion blocker must be adjusted.

Since urinary retention may occur in patients on ganglion blockers, caution is required in patients with prostatic hypertrophy, bladder neck obstruction, and urethral stricture.

Frequent loose bowel movements with abdominal distention and decreased borborygmi may be the first signs of paralytic ileus. If these are present, mecamylamine should be discontinued immediately and remedial steps taken.

V. Adverse Reactions

The following adverse reactions have been reported and within each category are listed in order of decreasing severity.

Gastrointestinal: Ileus, constipation (sometimes preceded by small, frequent liquid stools), vomiting, nausea, anorexia, glossitis and dryness of mouth

Cardiovascular: Orthostatic dizziness and syncope, postural hypotension
Nervous System/Psychiatric: Convulsions, choreiform movements, mental aberrations, tremor, and paresthesias

Respiratory: Interstitial pulmonary edema and fibrosis

Urogenital: Urinary retention, impotence, decreased libido

Special Senses: Blurred vision, dilated pupils

Miscellaneous: Weakness, fatigue, sedation

VI. Drug Interactions

Patients receiving antibiotics and sulfonamides generally should not be treated with ganglion blockers.
The action of mecamylamine may be potentiated by anesthesia, other hypertensive drugs, and alcohol.

Reference

1. Vecamyl® [prescribing information]. Fort Collins, CO. Manchester Pharmaceuticals, Inc.; September 2012.

North Dakota Medicaid
Pharmacotherapy Review
Nitroglycerin Lingual Spray/Sublingual Tablet

I. Indication

Nitroglycerin lingual spray and sublingual tablets are indicated for the acute relief of an attack or acute prophylaxis of angina pectoris caused by coronary artery disease.

II. Dosage and Administration

Spray: One or two metered dose sprays onto or under the tongue. A spray may be repeated approximately every 5 minutes as needed. If chest pain persists, prompt medical attention is recommended. May be used prophylactically 5 to 10 minutes prior to engaging in activities that might precipitate an acute attack. Maximum dose is 3 metered doses per 15-minute period.

Sublingual tablets: Dissolve 1 tablet under tongue or in buccal pouch at first sign of an acute angina attack. Dose may be repeated approximately every 5 minutes until relief is obtained. If pain continues, prompt medical attention is recommended. May be used prophylactically 5 to 10 minutes prior to engaging in activities that might precipitate an acute attack. Maximum dose is 3 tablets per 15-minute period.

III. Contraindications

- Allergic reactions to organic nitrates.
- Concomitant use with a phosphodiesterase type 5 inhibitor (e.g., sildenafil, tadalafil, vardenafil) because of the risk of potentiation of nitrate-induced hypotension.
- Sublingual nitroglycerin therapy is contraindicated in patients with early myocardial infarction, severe anemia, increased intracranial pressure, and those with a known hypersensitivity to nitroglycerin.
- Nitroglycerin lingual spray is contraindicated in patients who have shown purported hypersensitivity or idiosyncrasy to it or other nitrates or nitrites; patients with severe anemia or increased intracranial pressure.

IV. Warnings and Precautions

Myocardial infarction: The use of nitroglycerin during the early course of acute myocardial infarction requires particular attention to hemodynamic monitoring and clinical status.

Hypotension: Severe hypotension, particularly with upright posture, may occur even with small doses of nitroglycerin. Therefore, use with caution in subjects who may have volume depletion from diuretic therapy or in patients who have low systolic blood pressure (e.g., below 90mm Hg). Paradoxical bradycardia and increased angina pectoris may accompany nitroglycerin-induced hypotension.

Tolerance: Nitrate therapy may aggravate the angina caused by hypertrophic cardiomyopathy. Tolerance to this drug and cross-tolerance to other nitrates and nitrites may occur. Tolerance to the vascular and antianginal effects of nitrates has been demonstrated in clinical trials, experience through occupational exposure, and in isolated tissue experiments in the laboratory.

V. Adverse Reactions

Cardiovascular: Cutaneous vasodilation with flushing may occur.

CNS: Headache, which may be severe and persistent, is the most commonly reported side effect. Headache may be recurrent with each daily dose, especially at higher doses. Transient episodes of dizziness and weakness, as well as other signs of cerebral ischemia associated with postural hypotension, may occasionally develop.

Dermatologic: Drug rash or exfoliate dermatitis have been reported in patients receiving nitrate therapy.

Hypersensitivity: Occasionally, an individual may exhibit marked sensitivity to the hypotensive effects of nitrates and severe responses (nausea, vomiting, weakness, restlessness, pallor, perspiration, and collapse) may occur even with therapeutic doses.

VI. Drug Interactions

Alcohol: Concomitant use of nitrates and alcohol may cause hypotension. Alcohol may enhance sensitivity to the hypotensive effects of nitrates. Nitroglycerin acts directly on vascular muscle. Therefore, any other agents that depend on vascular smooth muscle as the final common path can be expected to have decreased or increased effect depending upon the agent.

Antihypertensives, phenothiazines: Patients receiving antihypertensive drugs, beta-adrenergic blockers, or phenothiazines should be observed for possible additive hypotensive effects. Marked orthostatic hypotension has been reported when calcium channel blockers and organic (controlled-release) nitrates were used concomitantly. Dose adjustment of either class of agent may be necessary.

Aspirin: Aspirin may decrease the clearance and enhance the hemodynamic effects of sublingual nitroglycerin.

Phosphodiesterase type 5 inhibitors: The risk of nitrate-induced hypotension may be increased by coadministration. Concurrent use is contraindicated.

Other nitrates: A decrease in therapeutic effect of nitroglycerin may result from use of long-acting nitrates.

Tissue-type plasminogen activator (t-PA): A decrease thrombolytic effect may result.

Heparin: Anticoagulant effect of heparin may be reduced. Monitor APTT.

Ergotamine: Increased bioavailability of ergotamine. Avoid concomitant use.

VII. Nitroglycerin Utilization

ND Medicaid Nitroglycerin Utilization			
05/30/12 - 05/29/13			
Label Name	**Rx Num**	**Total Reimb Amt**	**Average Cost per Script**
NITRO-BID 2% OINTMENT	2	$51.41	$25.71
NITROGLYCERIN 0.1 MG/HR PATCH	20	$627.36	$31.37
NITROGLYCERIN 0.2 MG/HR PATCH	28	$720.16	$25.72
NITROGLYCERIN 0.4 MG/HR PATCH	7	$194.43	$27.78
NITROGLYCERIN LINGUAL 0.4 MG	4	$1,032.90	$258.23
NITROLINGUAL 0.4 MG SPRAY	30	$8,461.87	$282.06
NITROSTAT 0.3 MG TABLET SL	2	$38.55	$19.28
NITROSTAT 0.4 MG TABLET SL	280	$2,809.34	$10.03
RECTIV 0.4% OINTMENT	6	$2,475.40	$412.57
166 recipients	379	$16,411.42	

Example Nitrolingual Patient's Refill History		
Patient A	**Patient B**	**Patient C**
7/9/2012	**6/20/2012**	**6/5/2012**
NITROLINGUAL 0.4 MG SPRAY	NITROLINGUAL 0.4 MG SPRAY	NITROLINGUAL 0.4 MG SPRAY
8/29/2012	**7/19/2012**	**7/5/2012**
NITROLINGUAL 0.4 MG SPRAY	NITROLINGUAL 0.4 MG SPRAY	NITROLINGUAL 0.4 MG SPRAY
11/8/2012	**8/16/2012**	**8/7/2012**
NITROLINGUAL 0.4 MG SPRAY	NITROLINGUAL 0.4 MG SPRAY	NITROLINGUAL 0.4 MG SPRAY
2/5/2013	**9/15/2012**	**9/5/2012**
NITROLINGUAL 0.4 MG SPRAY	NITROLINGUAL 0.4 MG SPRAY	NITROLINGUAL 0.4 MG SPRAY
3/5/2013	**10/15/2012**	**9/29/2012**
NITROLINGUAL 0.4 MG SPRAY	NITROLINGUAL 0.4 MG SPRAY	NITROLINGUAL 0.4 MG SPRAY
4/3/2013	**11/14/2012**	**11/6/2012**
NITROLINGUAL 0.4 MG SPRAY	NITROLINGUAL 0.4 MG SPRAY	NITROLINGUAL 0.4 MG SPRAY
5/10/2013	**12/12/2012**	**12/5/2012**
NITROLINGUAL 0.4 MG SPRAY	NITROLINGUAL 0.4 MG SPRAY	NITROLINGUAL 0.4 MG SPRAY
	1/9/2013	**1/7/2013**
	NITROLINGUAL 0.4 MG SPRAY	NITROLINGUAL 0.4 MG SPRAY
	2/8/2013	**1/31/2013**
	NITROLINGUAL 0.4 MG SPRAY	NITROLINGUAL 0.4 MG SPRAY
	3/6/2013	**3/1/2013**
	NITROLINGUAL 0.4 MG SPRAY	NITROLINGUAL 0.4 MG SPRAY
	4/3/2013	**4/2/2013**
	NITROLINGUAL 0.4 MG SPRAY	NITROLINGUAL 0.4 MG SPRAY
	5/3/2013	
	NITROLINGUAL 0.4 MG SPRAY	

Reference

1. Nitrolingual® [prescribing information]. Raleigh, NC. Arbor Pharmaceuticals, Inc.; www.nitrolingual.com accessed August, 2013.
2. Nitromist® [prescribing information]. Cranford, NJ. Akrimax Pharmaceuticals, LLC; February 2012.
3. Wolters Kluwer Facts & Comparisons. Accessed August, 2013.

North Dakota Medicaid
Pharmacotherapy Review
Breo Ellipta®

I. Indication

Breo Ellipta is a combination of fluticasone furoate, an inhaled corticosteroid (ICS), and vilanterol, a long-acting beta$_2$-adrenergic agonist (LABA), indicated for long-term, once-daily, maintenance treatment of airflow obstruction and for reducing exacerbations in patients with chronic obstructive pulmonary disease. Breo Ellipta is not indicated for relief of acute bronchospasm or for treatment of asthma.

II. Dosage and Administration

Breo Ellipta should be administered as one inhalation once daily by the orally inhaled route only. After inhalation, the patient should rinse his/her mouth with water without swallowing to help reduce the risk of oropharyngeal candidiasis. Breo Ellipta should be taken at the same time every day and should not be used more than one time every 24 hours.

III. Contraindications

The use of Breo Ellipta is contraindicated in patients with severe hypersensitivity to milk proteins or who have demonstrated hypersensitivity to either fluticasone furoate, vilanterol, or any of the excipients.

IV. Warnings and Precautions

- LABA increase the risk of asthma-related death. **(BLACK BOX WARNING)**
- Do not initiate in acutely deteriorating COPD or to treat acute symptoms.
- Do not use in combination with an additional medicine containing LABA because of risk of overdose.
- *Candida albicans* infection of the mouth and pharynx may occur. Monitor patients periodically. Advise the patient to rinse his/her mouth without swallowing after inhalation to help reduce the risk.
- Increased risk of pneumonia in patients with COPD taking Breo Ellipta. Monitor patients for signs and symptoms of pneumonia.
- Potential worsening of infections (e.g., existing tuberculosis; fungal, bacterial, viral, or parasitic infection; ocular herpes simplex). Use with caution in patients with these infections. More serious or even fatal course of chickenpox or measles can occur in susceptible patients.
- Risk of impaired adrenal function when transferring from systemic corticosteroids. Taper patients slowly from systemic corticosteroids if transferring to Breo Ellipta.
- Hypercorticism and adrenal suppression may occur with very high dosages or at the regular dosage in susceptible individuals. If such changes occur, discontinue Breo Ellipta slowly.
- If paradoxical bronchospasm occurs, discontinue Breo Ellipta and institute alternative therapy.
- Use with caution in patients with cardiovascular disorders because of beta-adrenergic stimulation.
- Assess for decrease in bone mineral density initially and periodically thereafter.
- Close monitoring for glaucoma and cataracts is warranted.

- Use with caution in patients with convulsive disorders, thyrotoxicosis, diabetes mellitus, and ketoacidosis.
- Be alert to hypokalemia and hyperglycemia.

V. Adverse Reactions

Most common adverse reactions (incidence ≥3%) are nasopharyngitis, upper respiratory tract infection, headache, and oral candidiasis.

VI. Drug Interactions

- Strong cytochrome P450 3A4 (e.g., ketoconazole): Use with caution. May cause systemic corticosteroid and cardiovascular effects.
- Monoamine oxidase inhibitors and tricyclic antidepressants: Use with extreme caution. May potentiate effect of vilanterol on vascular system.
- Beta-blockers: Use with caution. May block bronchodilatory effects of beta-agonists and produce severe bronchospasm.
- Diuretics: Use with caution. Electrocardiographic changes and/or hypokalemia associated with non-potassium-sparing diuretics may worsen with concomitant beta-agonists.

VII. Cost

The current cost of Breo Ellipta is approximately $289.

Reference

1. Breo Ellilpta® [prescribing information]. Research Triangle Park, NC. GlaxoSmithKline; May 2013.

North Dakota Medicaid
Pharmacotherapy Review
Long-Acting Beta-Agonists for Chronic Obstructive Pulmonary Disease

I. Indication

Arcapta (indacaterol) and Brovana (arformoterol) are long-acting beta$_2$-adrenergic agonists (LABA) indicated for the long term maintenance treatment of chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema. Arcapta and Brovana are not indicated to treat acute deteriorations of COPD or asthma.

II. Dosage and Administration

Arcapta: The recommended dose is once-daily inhalation of the contents of one 75mcg capsule. Arcapta should be administered once daily ever day at the same time of the day by the orally inhaled route only using the NEOHALER inhaler only. If a dose is missed, the next dose should be taken as soon as it is remembered. Do not use more than one time every 24 hours.

Brovana: The recommended dose is one 15mcg unit-dose vial administered twice daily (morning and evening) by nebulization. A total daily dose of greater than 30mcg is not recommended. For use with a standard jet nebulizer (with a face mask or mouthpiece) connected to an air compressor.

III. Contraindications

All LABA are contraindicated in patients with asthma without use of a long-term asthma control medication.

IV. Warnings and Precautions

- LABA increase the risk of asthma-related death. **(BLACK BOX WARNING)**
- Do not initiate in acutely deteriorating COPD patients.
- Do not use for relief of acute symptoms. Concomitant short-acting beta$_2$-agonists can be used as needed for acute relief.
- Do not exceed the recommended dose. Excessive use, or use in conjunction with other medications containing LABA can result in clinically significant cardiovascular effects, and may be fatal.
- Immediate hypersensitivity reactions may occur.
- Life-threatening paradoxical bronchospasm can occur.
- Use with caution in patients with cardiovascular or convulsive disorders, thyrotoxicosis, or with sensitivity to sympathomimetic drugs.

V. Adverse Reactions

Arcapta: Most common adverse reactions (≥2% and more common than placebo) are cough, oropharyngeal pain, nasopharyngitis, headache and nausea.

Brovana: Most common adverse reactions (≥2% and more common than placebo) are pain, chest pain, back pain, diarrhea, sinusitis, leg cramps, dyspnea, rash, flu syndrome, peripheral edema and lung disorder.

VI. Drug Interactions

- Other adrenergic drugs may potentiate effect: Use with caution.
- Xanthine derivatives, steroids, diuretics or non-potassium sparing diuretics may potentiate hypokalemia or ECG changes. Use with caution.
- MAO inhibitors, tricyclic antidepressants, and drugs that prolong QTc interval may potentiate effect on cardiovascular system. Use with extreme caution.
- Beta-blockers may decrease effectiveness: Use with caution and only when medically necessary.

VII. Utilization

ND Medicaid LABA for COPD Utilization			
05/30/12 - 05/29/13			
Label Name	**Rx Num**	**Total Reimb Amt**	**Average Cost per Script**
BROVANA 15 MCG/2 ML	58	$25,178.09	$434.11
11 recipients			

Reference

1. Brovana® [prescribing information]. Marlborough, MA. Sunovion Pharmaceuticals, Inc.; February 2012.
2. Arcapta® [prescribing information]. East Hanover, NJ. Novartis Pharmaceuticals, Corporation; September 2012.

North Dakota Medicaid
Pharmacotherapy Review
Inhaled Anticholinergics

I. Indication

The inhaled anticholinergics are approved for the long-term, maintenance treatment of bronchospasm associated with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema. Tiotropium is also approved to reduce exacerbations in patients with COPD.

II. Dosage and Administration

Spiriva (tiotropium): Two inhalations of the powder contents of a single capsule once daily.

Tudorza (aclidinium): One oral inhalation of 400mcg twice daily.

III. Warnings and Precautions

- Not for acute use: Not for use as a rescue medication.
- Immediate hypersensitivity reactions: Discontinue at once and consider alternatives if immediate hypersensitivity reactions, including angioedema, bronchospasm, or anaphylaxis, occur. Use with caution in patients with severe hypersensitivity to milk proteins.
- Paradoxical bronchospasm: Discontinue and consider other treatments if paradoxical bronchospasm occurs.
- Worsening of narrow-angle glaucoma may occur. Use with caution in patients with narrow-angle glaucoma and instruct patients to consult a physician immediately if this occurs.
- Worsening of urinary retention may occur. Use with caution in patients with prostatic hyperplasia or bladder-neck obstruction and instruct patients to consult a physician immediately if this occurs.

IV. Adverse Reactions

Spiriva: Most common adverse reactions (≥5% incidence in the one year placebo-controlled trials) were upper respiratory tract infection, dry mouth, sinusitis, pharyngitis, non-specific chest pain, urinary tract infection, dyspepsia, and rhinitis.

Tudorza: Most common adverse reactions (≥3% incidence and greater than placebo) are headache, nasopharyngitis, and cough.

V. Drug Interactions

Anticholinergics may interact additively with concomitantly used anticholinergic medications.

VI. Utilization

ND Medicaid Inhaled Anticholinergic Utilization			
05/30/12 - 05/29/13			
Label Name	**Rx Num**	**Total Reimb Amt**	**Average Cost per Script**
TUDORZA PRESSAIR 400 MCG INH	1	$236.50	$236.50
SPIRIVA 18 MCG CP-HANDIHALER	1129	$278,303.50	$246.50
Total recipients 217	**1130**	**$278,540.00**	

Reference

1. Spiriva® [prescribing information]. Ridgefield, CT. Boehringer Ingelheim Pharmaceuticals, Inc.; June 2013.
2. Tudorza® [prescribing information].St. Louis, MO. Forest Pharmaceuticals, Inc.; July 2012.

North Dakota Medicaid
Pharmacotherapy Review
Epinephrine Auto-Injection Devices

I. Indication

Epinephrine auto-injection is indicated in the emergency treatment of allergic reactions (Type 1), including anaphylaxis to stinging insects (e.g., order Hymenoptera, which includes bees, wasps, hornets, yellow jackets, and fire ants) and biting insects (e.g., triatoma, mosquitos), allergen immunotherapy, foods, drugs, diagnostic testing substances (e.g., radiocontrast media) and other allergens, as well as idiopathic anaphylaxis or exercise-induced anaphylaxis.

Epinephrine auto-injection is intended for immediate administration in patients who are determined to be at increased risk for anaphylaxis, including individuals with a history of anaphylactic reactions. Such reactions may occur within minutes after exposure and consist of flushing, apprehension, syncope, tachycardia, thread or unobtainable pulse associated with a fall in blood pressure, convulsions, vomiting, diarrhea and abdominal cramps, involuntary voiding, wheezing, dyspnea due to laryngeal spasm, pruritus, rashes, urticaria or angioedema.

II. Dosage and Administration

Patients greater than or equal to 30kg (66 lbs) inject 0.3mg. Patients 15 to 30 kg (33 lbs – 66 lbs) inject 0.15mg. Inject intramuscularly or subcutaneously into the anterolateral aspect of the thigh, through clothing if necessary. Each device is a single-use injection.

III. Warnings and Precautions

- In conjunction with use, seek immediate medical or hospital care.
- Do not inject intravenously, into buttock, or into digits, hands or feet.
- The presence of a sulfite in this product should not deter use.
- Administer with caution in patients with heart disease, including patients with cardiac arrhythmias, coronary artery or organic heart disease, or hypertension. In such patients, or in patients who are on drugs that may sensitize the heart to arrhythmias, epinephrine may precipitate or aggravate angina pectoris as well as produce ventricular arrhythmias.
- Some patients may be at greater risk of developing adverse reactions after epinephrine administration. These include the following: hyperthyroid persons, persons with cardiovascular disease, hypertension, or diabetes, elderly patients, pregnant women and pediatric patients.

IV. Adverse Reactions

Adverse reactions to epinephrine include anxiety, apprehensiveness, restlessness, tremor, weakness, dizziness, sweating, palpitations, pallor, nausea and vomiting, headache, and/or respiratory difficulties.

V. Drug Interactions

- Patients who receive epinephrine while concomitantly taking cardiac glycosides or diuretics should be observed carefully for the development of cardiac arrhythmias.
- The effects of epinephrine may be potentiated by tricyclic antidepressants, monoamine oxidase inhibitors, levothyroxine sodium, and certain antihistamines.

- The cardiostimulating and bronchodilating effects of epinephrine are antagonized by beta-adrenergic blocking drugs.
- The vasoconstricting and hypertensive effects of epinephrine are antagonized by alpha-adrenergic blocking drugs.
- Ergot alkaloids may reverse the pressor effects of epinephrine.

VI. Utilization

ND Medicaid Epinephrine Auto-Injector Utilization			
05/30/12 - 05/29/13			
Label Name	**Rx Num**	**Total Reimb Amt**	**Average Cost per Script**
AUVI-Q 0.3 MG AUTO-INJECTOR	1	$264.88	$264.88
EPIPEN 0.3 MG AUTO-INJECTOR	1	$93.69	$93.69
EPIPEN 2-PAK 0.3 MG AUTO-INJCT	367	$80,692.95	$219.87
EPIPEN JR 0.15 MG AUTO-INJCT	2	$151.57	$75.79
EPIPEN JR 2-PAK 0.15 MG INJCTR	206	$44,905.40	$217.99
476 recipients	**577**	**$126,108.49**	

Reference

1. EpiPen® [prescribing information]. Basking Ridge, NJ. Mylan Specialty L.P.; August 2012.
2. Auvi-Q® [prescribing information]. Bridgewater, NJ. Sanofi-Aventis U.S. LLC; September 2012.

North Dakota Medicaid
Pharmacotherapy Review
Pulmozyme®

I. Indication

Pulmozyme (dornase alfa) inhalation solution, in conjunction with standard therapies, is indicated in the management of cystic fibrosis (CF) patients to improve pulmonary function. In patients with an FVC ≥40% of predicted, daily administration of Pulmozyme has also been shown to reduce the risk of respiratory tract infections requiring parenteral antibiotics.

Safety and efficacy of daily administration have not been demonstrated in patients for longer than twelve months.

II. Clinical Pharmacology

In cystic fibrosis (CF) patients, retention of viscous purulent secretions in the airways contributes both to reduced pulmonary function and exacerbations of infection. Purulent pulmonary secretions contain very high concentrations of extracellular DNA released by degenerating leukocytes that accumulate in response to infection. In vitro, Pulmozyme hydrolyzes the DNA in sputum of CF patients and reduces sputum viscoelasticity.

III. Dosage and Administration

The recommended dose for use in most CF patients 5 years of age and older is one 2.5mg single-use ampule inhaled once daily using a recommended nebulizer. Some patients may benefit from twice daily administration.

IV. Contraindications

Pulmozyme is contraindicated in patients with known hypersensitivity to dornase alfa, Chinese Hamster Ovary cell products, or any component of the product.

V. Precautions

Pulmozyme should be used in conjunction with standard therapies for CF.

VI. Adverse Reactions

In a randomized, placebo-controlled clinical trial in patients with FVC greater than or equal to 40% of predicted, over 600 patients received dornase alfa once or twice daily for 6 months; most adverse events were not more common on dornase alfa than on placebo and probably reflected the sequelae of the underlying lung disease. In most cases, events that were increased were mild, transient in nature, and did not require alterations in dosing. Few patients experienced adverse events resulting in permanent discontinuation from dornase alfa, and the discontinuation rate was similar for placebo (2%) and dornase alfa (3%). Events that were more frequent (greater than 3%) in dornase alfa-treated patients than in placebo-treated patients are listed in the table below.

Adverse Reactions Increased ≥ 3% in Dornase Alfa-Treated Patients Over Placebo in Cystic Fibrosis Clinical Trials					
Adverse event	Trial in mild to moderate cystic fibrosis patients (FVC greater than or equal to 40% of predicted) treated for 24 weeks			Trial in advanced cystic fibrosis patients (FVC less than 40% of predicted) treated for 12 weeks	
	Placebo (n=325)	Dornase alfo every day (n=322)	Dornase alfa twice a day (n=321)	Placebo (n=159)	Dornase alfa every day (n=161)
Voice alteration	7%	12%	16%	6%	18%
Pharyngitis	33%	36%	40%	28%	32%
Rash	7%	10%	12%	1%	3%
Laryngitis	1%	3%	4%	1%	3%
Chest pain	16%	18%	21%	23%	25%
Conjunctivitis	2%	4%	5%	0%	1%
Rhinitis	<3%	<3%	<3%	24%	30%
FVC decrease of ≥10% of predicted	<3%	<3%	<3%	17%	22%
Fever	<3%	<3%	<3%	28%	32%
Dyspepsia	<3%	<3%	<3%	0%	3%
Dyspnea (when reported as serious)	<3%	<3%	<3%	12%	17%

VII. Drug Interactions

No formal drug interaction studies have been performed.

VIII. Utilization

ND Medicaid Pulmozyme Utilization			
05/30/12 - 05/29/13			
Label Name	**Rx Num**	**Total Reimb Amt**	**Average Cost per Script**
PULMOZYME 1 MG/ML AMPUL	83	$170,502.73	$2,054.25
Total recipients 17			

Reference

1. Pulmozyme® [prescribing information]. South San Francisco, CA. Genentech, Inc.; October 2010.

ND Medicaid Statin Utilization (AHFS 240608)			
05/30/12 - 05/29/13			
Label Name	**Rx Num**	**Total Reimb Amt**	**Average Cost per Script**
AMLODIPINE-ATORVAST 10-10 MG	7	$886.34	$126.62
AMLODIPINE-ATORVAST 10-20 MG	4	$684.76	$171.19
AMLODIPINE-ATORVAST 10-40 MG	11	$1,883.09	$171.19
AMLODIPINE-ATORVAST 10-80 MG	12	$2,080.36	$173.36
ATORVASTATIN 10 MG TABLET	64	$662.30	$10.35
ATORVASTATIN 20 MG TABLET	1289	$14,421.53	$11.19
ATORVASTATIN 40 MG TABLET	951	$11,143.43	$11.72
ATORVASTATIN 80 MG TABLET	942	$12,366.17	$13.13
CRESTOR 10 MG TABLET	423	$60,229.98	$142.39
CRESTOR 20 MG TABLET	332	$53,318.16	$160.60
CRESTOR 40 MG TABLET	160	$24,531.76	$153.32
CRESTOR 5 MG TABLET	134	$20,519.91	$153.13
FLUVASTATIN SODIUM 40 MG CAP	2	$206.94	$103.47
LESCOL XL 80 MG TABLET	1	$42.00	$42.00
LIPITOR 20 MG TABLET	1	$25.86	$25.86
LIPITOR 40 MG TABLET	2	$67.15	$33.58
LIVALO 1 MG TABLET	3	$384.84	$128.28
LIVALO 2 MG TABLET	2	$256.56	$128.28
LOVASTATIN 10 MG TABLET	19	$117.59	$6.19
LOVASTATIN 20 MG TABLET	48	$382.38	$7.97
LOVASTATIN 40 MG TABLET	104	$976.93	$9.39
PRAVASTATIN SODIUM 10 MG TAB	54	$528.36	$9.78
PRAVASTATIN SODIUM 20 MG TAB	142	$1,289.32	$9.08
PRAVASTATIN SODIUM 40 MG TAB	214	$2,023.54	$9.46
PRAVASTATIN SODIUM 80 MG TAB	49	$681.70	$13.91
SIMCOR 1,000-20 MG TABLET	6	$1,924.36	$320.73
SIMCOR 500-20 MG TABLET	6	$731.19	$121.87
SIMCOR 500-40 MG TABLET	8	$754.69	$94.34
SIMVASTATIN 10 MG TABLET	702	$4,410.04	$6.28
SIMVASTATIN 20 MG TABLET	1976	$13,270.90	$6.72
SIMVASTATIN 40 MG TABLET	1179	$8,492.59	$7.20
SIMVASTATIN 5 MG TABLET	54	$445.87	$8.26
SIMVASTATIN 80 MG TABLET	209	$1,693.35	$8.10
1,333 recipients	**9112**	**$241,433.95**	

HEALTH INFORMATION DESIGNS

Prior Authorization Vendor for ND Medicaid

HMG-CoA Reductase Inhibitors (Statins) 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 HMG-CoA Reductase Inhibitors must meet the following criteria:

- *Patient must have paid claims that show two trials of generic statins*

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:
Medication Failed and Dose 1._____ Start Date: End Date: 2._____ 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)	

NORTH DAKOTA MEDICAID
RETROSPECTIVE DRUG UTILIZATION REVIEW
CRITERIA RECOMMENDATIONS
3RD QUARTER 2013

Criteria Recommendations ***Approved Rejected***

1. Icosapent Ethyl / Therapeutic Appropriateness _____ _____

Alert Message: The safety and effectiveness of Vascepa (icosapent ethyl) in pediatric patients have not been established.

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C
Icosapent ethyl		

Age Range: 0 – 18 yoa

References:
Vascepa Prescribing Information, November 2012, Amarin Pharma Inc.
Clinical Pharmacology, 2013 Elsevier / Gold Standard.

2. Icosapent Ethyl / Overuse _____ _____

Alert Message: Vascepa (icosapent ethyl) may be over-utilized. The manufacturer's maximum recommended dose is 4 grams per day, taken as 2 grams twice daily with food.

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C
Icosapent ethyl		

Max Dose: 4 grams daily

References:
Vascepa Prescribing Information, November 2012, Amarin Pharma Inc.
Clinical Pharmacology, 2013 Elsevier / Gold Standard.

3. Icosapent Ethyl / Drugs Affecting Coagulation _____ _____

Alert Message: Some published studies have demonstrated prolongation of bleeding time when anticoagulants and omega-3 fatty acids are used concurrently. Patients receiving treatment with Vascepa (icosapent ethyl) and drugs affecting coagulation should be monitored periodically.

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

Util A	Util B	Util C
Icosapent Ethyl	Anticoagulants	
	Thrombin Inhibitors	
	Platelet Aggregation Inhibitors	
	Direct Factor Xa Inhibitors	
	Low Molecular Weight Heparins	

References:
Vascepa Prescribing Information, November 2012, Amarin Pharma Inc.
Clinical Pharmacology, 2013 Elsevier / Gold Standard.

4. Icosapent Ethyl / Pregnancy / Pregnancy Negating _____ _____

Alert Message: Vascepa (icosapent ethyl) is FDA pregnancy category C. There are no adequate and well-controlled studies in pregnant women and it is unknown if icosapent ethyl can cause fetal harm. Icosapent ethyl should be used during pregnancy only if the potential benefit to the patient justifies the potential risk to the fetus.

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

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

References:
Vascepa Prescribing Information, November 2012, Amarin Pharma Inc.
Clinical Pharmacology, 2013 Elsevier / Gold Standard.

5. Icosapent Ethyl / Hepatic Impairment _____ _____

Alert Message: Patients taking Vascepa (icosapent ethyl) who have hepatic impairment should have ALT and AST levels monitored periodically.

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C (Include)
Icosapent Ethyl		Chronic Liver Disease
		Cirrhosis

References:
Vascepa Prescribing Information, November 2012, Amarin Pharma Inc.
Clinical Pharmacology, 2013 Elsevier / Gold Standard.

6. Icosapent Ethyl / Non-adherence _____ _____

Alert Message: Based on refill history, your patient may be under-utilizing Vascepa (icosapent ethyl). 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
Icosapent ethyl		

References:
Schedlbauer A, Davis P, Fahey T. Interventions to Improve Adherence to Lipid Lowering Medication (Review). Cochrane Database System Rev. 2010 Mar 17;(3):CD004371.
Bersot T, Haffner S, Harris WS, et al., Hypertriglyceridemia: Management of Atherogenic Dyslipidemia. Jrnl of Fam Pract. 2006 Jul;55(7):S1-S8.
Osterberg L and Blaschke T. Adherence to Medication. N Engl J Med 2005;353:487-497.

7. Voriconazole / Efavirenz Tablets - Single Entity _____ _____

Alert Message: If Sustiva (efavirenz) is co-administered with Vfend (voriconazole), the voriconazole maintenance dose should be increased to 400 mg q12h and the efavirenz dose should be decreased to 300 mg q24h using the capsule formulation. Efavirenz tablets should not be broken. Concurrent use of these agents at standard doses, poses the risk for voriconazole therapeutic failure and increased efavirenz-related toxicities.

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

Util A	Util B	Util C
Voriconazole	Efavirenz 600mg Tablet	

References:
Clinical Pharmacology, 2013 Elsevier / Gold Standard.
Facts & comparisons, 2013 Updates, Wolters Kluwer Health.

8. Darunavir / Pediatric Patients (0-2 yoa) _____ _____

Alert Message: Prezista (darunavir) should not be used in pediatric patients below 3 years of age in view of toxicity and mortality observed in animal trials. In juvenile rats, single doses of darunavir (at ages 5-11 days) or multiple doses of darunavir (at age 12 days) caused mortality. The exposures and toxicity profile in the older animals (day 23 or day 26) were comparable to those observed in adult rats. Due to uncertainties regarding the rate of development of the human blood-brain barrier and liver enzymes, darunavir should not be given to patients below 3 years of age.

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C
Darunavir		

Age Range: 0 – 2 yoa

References:
Prezista Prescribing Information. February 2013. Janssen Products, LP.
Clinical Pharmacology, 2013 Elsevier / Gold Standard.

9. Voriconazole / Atripla _____ _____

Alert Message: Coadministration of Vfend (voriconazole) with Atripla (efavirenz/ emtricitabine/tenofovir) is contraindicated because Atripla is a fixed-dose combination product and the dose of efavirenz cannot be altered. Concurrent use of these agents at standard doses, poses the risk for voriconazole therapeutic failure and increased efavirenz-related toxicities.

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

Util A	Util B	Util C
Voriconazole	Efavirenz/Emtricitabine/Tenofovir	

References:
Vfend Prescribing Information, Oct. 2011, Pfizer Inc.
Atripla Prescribing Information, June 2012, Gilead Science, Inc.
Facts & comparisons, 2013 Updates, Wolters Kluwer Health.

10. Canagliflozin / CKD Stage 3, 4 & 5, ESRD & Dialysis-Negating _____ _____

Alert Message: The recommended starting dose of Invokana (canagliflozin) is 100 mg once daily taken before the first meal of the day. For patients who have an eGFR of 60 mL/min/1.73 m^2 or greater and require additional glycemic control, the dose can be increased to a maximum of 300 mg once daily. Monitor renal function during canagliflozin therapy.

Conflict Code: ER – Overutilization
Drugs/Diseases

Util A	Util B	Util C (Negating)
Canagliflozin		CKD Stage 3, 4 & 5
		ESRD
		Dialysis

Max Dose: 300 mg/day

References:
Invokana Prescribing Information, March 2013, Janssen Pharmaceuticals, Inc.
Clinical Pharmacology, 2013 Elsevier/Gold Standard.

11. Canagliflozin / CKD Stage 3 _____ _____

Alert Message: The dose of Invokana (canagliflozin) is limited to 100 mg daily in patients with moderate renal impairment with an eGFR of 45 to less than 60 mL/min/1.73 m^2. Renal function should be monitored frequently during canagliflozin therapy and canagliflozin discontinued when eGFR is persistently less than 45 mL/min/1.73 m^2.

Conflict Code: ER – Overutilization
Drugs/Diseases

Util A	Util B	Util C (Include)
Canagliflozin		CKD Stage 3

Max Dose: 100 mg/day

References:
Invokana Prescribing Information, March 2013, Janssen Pharmaceuticals, Inc.
Clinical Pharmacology, 2013 Elsevier/Gold Standard.

12. Canagliflozin / Stage 4 & 5 CKD _____ _____

Alert Message: Invokana (canagliflozin) is contraindicated in patients with severe renal impairment (eGFR less than 30 mL/min/1.73 m^2), end stage renal disease or patients on dialysis. Canagliflozin is not expected to be effective in these patient populations.

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

Util A	Util B	Util C
Canagliflozin	CKD Stage 4 & 5	
	ESRD	
	Dialysis	

References:
Invokana Prescribing Information, March 2013, Janssen Pharmaceuticals, Inc.
Clinical Pharmacology, 2013 Elsevier/Gold Standard.

13. Canagliflozin / Hypotension, Hypovolemia Dehydration & CKD State 3 _____ _____

Alert Message: Invokana (canagliflozin) can cause symptomatic hypotension after initiating therapy. Patients at risk are those with dehydration or hypovolemia, impaired renal function (eGFR < 60mL/min/1.73 m^2), the elderly, patients with low systolic blood pressure or if on diuretics, an ACEI, or ARB. Monitor patient for signs and symptoms after initiating therapy.

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

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

References:
Invokana Prescribing Information, March 2013, Janssen Pharmaceuticals, Inc.
Clinical Pharmacology, 2013 Elsevier/Gold Standard.

14. Canagliflozin / Diuretics, ACEIs & ARBs _____ _____

Alert Message: Invokana (canagliflozin) can cause symptomatic hypotension after initiating therapy. Patients at risk are those with dehydration or hypovolemia, impaired renal function (eGFR < 60 mL/min/1.73 m^2), the elderly, patients with low systolic blood pressure or if on diuretics, an ACEI, or ARB. Monitor patient for signs and symptoms after initiating therapy.

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

Util A	Util B	Util C
Canagliflozin	ACEIs	
	ARBs	
	Aliskiren	
	Diuretics	

References:
Invokana Prescribing Information, March 2013, Janssen Pharmaceuticals, Inc.
Clinical Pharmacology, 2013 Elsevier/Gold Standard.

15. Canagliflozin / Hyperkalemia _____ _____

Alert Message: Invokana (canagliflozin) can cause hyperkalemia. Monitor serum potassium levels periodically after initiating canagliflozin in patients with impaired renal function and in patients predisposed to hyperkalemia due to medication or other medical conditions.

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

Util A	Util B	Util C
Canagliflozin	Hyperkalemia	
	CKD Stage 3	
	Heart Failure	
	Addison's Disease	
	SLE	

References:
Invokana Prescribing Information, March 2013, Janssen Pharmaceuticals, Inc.
Clinical Pharmacology, 2013 Elsevier/Gold Standard.

16. Canagliflozin / Hyperkalemia Inducing Drugs _____ _____

Alert Message: Invokana (canagliflozin) can cause hyperkalemia. Monitor serum potassium levels periodically after initiating canagliflozin in patients with impaired renal function and in patients predisposed to hyperkalemia due to medication or other medical conditions.

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

Util A	Util B	Util C
Canagliflozin	Potassium-Sparing Diuretics	
	ACEIs	
	ARBs	
	Aliskiren	
	Eplerenone	
	Drospirenone	
	NSAIDS	
	Cyclosporine	
	Potassium	
	Tacrolimus	
	Trimethoprim	

References:
Invokana Prescribing Information, March 2013, Janssen Pharmaceuticals, Inc.
Clinical Pharmacology, 2013 Elsevier/Gold Standard.

17. Canagliflozin / Insulin & Insulin Secretagogues _____ _____

Alert Message: The concurrent use of Invokana (canagliflozin) 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 canagliflozin.

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

Util A	Util B	Util C
Canagliflozin	Insulins	
	Sulfonylureas	

References:
Invokana Prescribing Information, March 2013, Janssen Pharmaceuticals, Inc.
Clinical Pharmacology, 2013 Elsevier/Gold Standard.

18. Canagliflozin / LDL-C Increases _____ _____

Alert Message: The use of Invokana (canagliflozin) can cause dose-related increases in LDL-C levels. Patients receiving canagliflozin 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
Canagliflozin		

References:
Invokana Prescribing Information, March 2013, Janssen Pharmaceuticals, Inc.
Clinical Pharmacology, 2013 Elsevier/Gold Standard.

19. Canagliflozin 100mg / UGT Inducers _____ _____

Alert Message: Concurrent use of Invokana (canagliflozin) with a UGT inducer may result in decreased canagliflozin exposure and loss of efficacy. Consider increasing the canagliflozin dose to 300 mg once daily in patients currently taking 100 mg once daily who have an eGFR of 60 mL/min/1.73m^2 or greater and require additional glycemic control. Consider another antihyperglycemic agent in patients with an eGFR of 45 to less than 60 mL/min/1.73m^2 receiving concurrent therapy with a UGT inducer.

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

Util A	Util B	Util C
Canagliflozin 100mg	Rifampin	
	Phenytoin	
	Phenobarbital	
	Ritonavir	

References:
Invokana Prescribing Information, March 2013, Janssen Pharmaceuticals, Inc.
Clinical Pharmacology, 2013 Elsevier/Gold Standard.

20. Canagliflozin 300mg / UGT Inducers _____ _____

Alert Message: Concurrent use of Invokana (canagliflozin) 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 300mg	Rifampin	
	Phenytoin	
	Phenobarbital	
	Ritonavir	

References:
Invokana Prescribing Information, March 2013, Janssen Pharmaceuticals, Inc.
Clinical Pharmacology, 2013 Elsevier/Gold Standard.

21. Canagliflozin / Digoxin _____ _____

Alert Message: The concurrent use of Invokana (canagliflozin) with digoxin may result in increased AUC and Cmax of digoxin. Patients taking canagliflozin with concomitant digoxin should be monitored appropriately.

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

Util A	Util B	Util C
Canagliflozin	Digoxin	

References:
Invokana Prescribing Information, March 2013, Janssen Pharmaceuticals, Inc.
Clinical Pharmacology, 2013 Elsevier/Gold Standard.

22. Canagliflozin / Therapeutic Appropriateness _____ _____

Alert Message: Safety and effectiveness of Invokana (canagliflozin) 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		

Age Range: 0-17 yoa

References:
Invokana Prescribing Information, March 2013, Janssen Pharmaceuticals, Inc.
Clinical Pharmacology, 2013 Elsevier/Gold Standard.

23. Canagliflozin / Liver Disease _____ _____

Alert Message: The use of Invokana (canagliflozin) has not been studied in patients with severe hepatic impairment and is therefore not recommended. No dosage adjustment is necessary in patients with mild or moderate hepatic impairment.

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

Util A	Util B	Util C
Canagliflozin	Cirrhosis	
	Chronic Liver Disease	
	Necrosis of the Liver	

References:
Invokana Prescribing Information, March 2013, Janssen Pharmaceuticals, Inc.
Clinical Pharmacology, 2013 Elsevier/Gold Standard.

24. Canagliflozin / Pregnancy / Miscarriage, Abortion, Delivery Negating _____ _____

Alert Message: Invokana (canagliflozin) should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. No adequate and well-controlled studies of canagliflozin use in pregnant women have been conducted. Canagliflozin is classified as pregnancy category C.

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

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

References:
Invokana Prescribing Information, March 2013, Janssen Pharmaceuticals, Inc.
Clinical Pharmacology, 2013 Elsevier/Gold Standard.

25. Ezogabine / FDA Safety Warning _____ _____

Alert Message: Potiga can cause blue skin discoloration and eye abnormalities characterized by pigment changes in the retina. All patients taking ezogabine or about to start ezogabine should have an eye exam, followed by periodic eye exams thereafter. Discontinue ezogabine if ophthalmic changes are observed unless no other treatment options are available. If skin discoloration develops, give serious consideration to changing to an alternative medication.

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C
Ezogabine		

References:
FDA Drug Safety Communication: Antiseizure Drug Potiga (ezogabine) Linked to Retinal Abnormalities and Blue Skin Discoloration. [04/26/2013].
Available at: http://www.fda.gov/Drugs/DrugSafety/ucm349538.htm

26. Valproate / Migraine / Epilepsy (Negating) _____ _____

Alert Message: A recent study has shown that valproate sodium and related products, valproic acid and divalproex sodium, can cause decreased IQ scores in children whose mothers took these agents while pregnant. Valproate products are contraindicated and should not be taken by pregnant women for prevention of migraines. Valproate products are pregnancy category X for migraine prevention in pregnant women. All non-pregnant women of childbearing age taking valproate products should use effective birth control.

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

Util A	Util B	Util C **(Negating)**
Valproate Agents	Migraine	Epilepsy

Gender: Females
Age Range: 11 – 50 yoa

References:
FDA Drug Safety Communication: Valproate Anti-seizure Products Contraindicated for Migraine Prevention in Pregnant Women due to Decreased IQ Scores in Exposed Children. Safety Announcement [05-06-2013].

27. Olmesartan Products / Severe Sprue-Like Enteropathy _____ _____

Alert Message: Olmesartan-containing products can cause severe sprue-like enteropathy, which may develop months to years after starting olmesartan. Patients experience severe, chronic diarrhea with substantial weight loss. If no other etiology is identified for intestinal problems olmesartan should be discontinued and another antihypertensive therapy started.

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C
Olmesartan		

References:
FDA Drug Safety Communication: FDA Approves Label Changes to Include Intestinal Problems (Sprue-Like Enteropathy) Linked to Blood Pressure Medicine Olmesartan Medoxomil. [07/03/2013].
Rubio-Tapia A, Herman ML, Ludvigsson JF et al. Severe Spruelike Enteropathy Associated with Olmesartan. Mayo Clin Proc. 2012 Aug;87(8):732-8.

28. Saxagliptin-Metformin XR / Overutilization _____ _____

Alert Message: Kombiglyze XR (saxagliptin/metformin extended-release) may be over-utilized. The manufacturer's maximum recommended dose of extended-release saxagliptin/metformin is 5 mg saxagliptin/2000 mg metformin once daily.

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C **(Negating)**		
Saxagliptin/Metformin XR		Nefazodone	Indinavir	Telaprevir
		Clarithromycin	Nelfinavir	Boceprevir
		Telithromycin	Atazanavir	
		Ketoconazole	Imatinib	
		Itraconazole	Delavirdine	
		Saquinavir	Voriconazole	
		Ritonavir	Posaconazole	

Max: 5/2000mg per day
References:
Kombiglyze XR Prescribing Information, May 2013, Bristol-Myers Scribb.
Facts & Comparisons, 2013 Updates, Wolters Kluwer Health.

29. Saxagliptin-Metformin XR / Strong CYP3A4 Inhibitors _____ _____

Alert Message: The dose of Kombiglyze XR (saxagliptin/metformin extended-release) should be limited to 2.5 mg/1000 mg once daily when co-administered with strong CYP3A4/5 inhibitors (e.g., ketoconazole, atazanavir, clarithromycin, indinavir, itraconazole, nefazodone, ritonavir, saquinavir, and telithromycin). Concurrent use of saxagliptin with a strong 3A4/5 inhibitor may result in significantly elevated saxagliptin levels and risk of adverse events.

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

Util A	Util B			Util C
Saxagliptin/Metformin 5/500 XR	Nefazodone	Indinavir	Telaprevir	
Saxagliptin/Metformin 5/1000 XR	Clarithromycin	Nelfinavir	Boceprevir	
	Telithromycin	Atazanavir		
	Ketoconazole	Imatinib		
	Itraconazole	Delavirdine		
	Saquinavir	Voriconazole		
	Ritonavir	Posaconazole		

References:
Kombiglyze XR Prescribing Information, May 2013, Bristol-Myers Scribb.
Facts & Comparisons, 2013 Updates, Wolters Kluwer Health
FDA: Drug Development and Drug Interactions: Tables of Substrates, Inhibitors and Inducers. Available at: http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/DrugInteractionLabeling/ucm093664.htm

30. Tofacitinib / Therapeutic Appropriateness _____ _____

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

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C
Tofacitinib		

Age Range: 0 – 18 yoa

References:
Xeljanz Prescribing Information, November 2012, Pfizer, Inc.
Clinical Pharmacology, 2013 Elsevier / Gold Standard.

31. Tofacitinib / Pregnancy / Pregnancy Negating _____ _____

Alert Message: There are no adequate and well-controlled studies for use of Xeljanz (tofacitinib) in pregnant women. Tofacitinib (Pregnancy Category C) should only be used during pregnancy if the potential benefit justifies the potential risk to the fetus.

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

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

References:
Xeljanz Prescribing Information, November 2012, Pfizer, Inc.
Clinical Pharmacology, 2013 Elsevier / Gold Standard.

32. Tofacitinib / Overuse _____ _____

Alert Message: Xeljanz (tofacitinib) may be over-utilized. The manufacturer's maximum recommended dose is 5 mg twice daily.

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C **(Negating)**		
Tofacitinib		Moderate/Severe Renal Insufficiency	Ketoconazole	Nefazodone
		Moderate Hepatic Impairment	Clarithromycin	Nelfinavir
		Ritonavir	Saquinavir	Boceprevir
		Indinavir	Telithromycin	Fluvoxamine
		Telaprevir	Voriconazole	Fluconazole
		Delavirdine	Posaconazole	
		Imatinib	Itraconazole	

Max Dose: 10 mg per day

References:
Xeljanz Prescribing Information, November 2012, Pfizer, Inc.
Clinical Pharmacology, 2013 Elsevier / Gold Standard.
FDA: Drug Development and Drug Interactions: Tables of Substrates, Inhibitors and Inducers. Available at:
http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/DrugInteractionLabeling/ucm093664.htm

33. Tofacitinib / Overuse in Specific Diseases States or w/ Certain Drugs _____ _____

Alert Message: The dosage of Xeljanz (tofacitinib) should be reduced to 5 mg once daily in patients with moderate or severe renal insufficiency, moderate hepatic impairment (Child-Pugh Class B) or those patients receiving concomitant therapy with potent inhibitors of CYP3A4 (e.g., ketoconazole).

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C **(Include)**		
Tofacitinib		Moderate/Severe Renal Insufficiency	Ketoconazole	Nefazodone
		Moderate Hepatic Impairment	Clarithromycin	Nelfinavir
		Ritonavir	Saquinavir	Boceprevir
		Indinavir	Telithromycin	
		Telaprevir	Voriconazole	
		Delavirdine	Posaconazole	
		Imatinib	Itraconazole	

Max Dose: 5 mg per day

References:
Xeljanz Prescribing Information, November 2012, Pfizer, Inc.
Clinical Pharmacology, 2013 Elsevier / Gold Standard.
FDA: Drug Development and Drug Interactions: Tables of Substrates, Inhibitors and Inducers. Available at: http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/DrugInteractionLabeling/ucm093664.htm

34. Tofacitinib / Fluconazole _____ _____

Alert Message: The dosage of Xeljanz (tofacitinib) should be reduced to 5 mg once daily in patients receiving concomitant therapy with a potent inhibitor of CYP2C19 and a moderate inhibitor of CYP3A4 (e.g., fluconazole).

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C **(Include)**
Tofacitinib		Fluconazole

Max Dose: 5mg per day

References:
Xeljanz Prescribing Information, November 2012, Pfizer, Inc.
Clinical Pharmacology, 2013 Elsevier / Gold Standard.
FDA: Drug Development and Drug Interactions: Tables of Substrates, Inhibitors and Inducers. Available at: http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/DrugInteractionLabeling/ucm093664.htm

35. Tofacitinib / Fluvoxamine _____ _____

Alert Message: The dosage of Xeljanz (tofacitinib) should be reduced to 5 mg once daily in patients receiving concomitant therapy with a potent inhibitor of CYP2C19 and a moderate inhibitor of CYP3A4 (e.g., fluvoxamine).

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C **(Include)**
Tofacitinib		Fluvoxamine

Max Dose: 5mg per day

References:
Xeljanz Prescribing Information, November 2012, Pfizer, Inc.
Clinical Pharmacology, 2013 Elsevier / Gold Standard.
FDA: Drug Development and Drug Interactions: Tables of Substrates, Inhibitors and Inducers. Available at: http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/DrugInteractionLabeling/ucm093664.htm

36. Tofacitinib / Ticlopidine / Moderate CYP3A4 Inhibitors _____ _____

Alert Message: The dosage of Xeljanz (tofacitinib) should be reduced to 5 mg once daily in patients receiving concomitant therapy with a potent inhibitor of CYP2C19 (e.g., ticlopidine) and a moderate inhibitor of CYP3A4.

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

Util A	Util B	Util C **(Include)**		
Tofacitinib	Ticlopidine	Erythromycin	Amiodarone	Aprepitant
		Diltiazem	Verapamil	Darunavir
		Atazanavir	Crizotinib	Lapatinib
		Ciprofloxacin	Fosamprenavir	

References:
Xeljanz Prescribing Information, November 2012, Pfizer, Inc.
Clinical Pharmacology, 2013 Elsevier / Gold Standard.

37. Tofacitinib / Severe Hepatic Impairment _____ _____

Alert Message: The safety and efficacy of Xeljanz (tofacitinib) have not been studied in patients with severe hepatic impairment (Child-Pugh Class C) or in patients with positive hepatitis B virus or hepatitis C virus serology and is not recommended for use in these populations.

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

Util A	Util B	Util C
Tofacitinib	Chronic Liver Disease	
	Cirrhosis	

References:
Xeljanz Prescribing Information, November 2012, Pfizer, Inc.
Clinical Pharmacology, 2013 Elsevier / Gold Standard.

38. Tofacitinib / Biologic DMARDS - Immunosuppressants _____ _____

Alert Message: Xeljanz (tofacitinib) should not be used in combination with biologic DMARDs or potent immunosuppressants (e.g., azathioprine or cyclosporine).

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

Util A	Util B			Util C
Tofacitinib	Anakinra	Rituximab	Tocilizumab	
	Abatacept	Azathioprine	Cyclosporine	
	Certolizumab	Etanercept	Adalimumab	
	Infliximab	Golimumab		

References:
Xeljanz Prescribing Information, November 2012, Pfizer, Inc.
Clinical Pharmacology, 2013 Elsevier / Gold Standard.

39. Tofacitinib / Potent CYP3A4 Inducers _____ _____

Alert Message: Coadministration of Xeljanz (tofacitinib) with potent inducers of CYP3A4 (e.g., rifampin) may result in loss of or reduced clinical response to tofacitinib. Consider monitoring patient for decreased tofacitinib response.

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

Util A	Util B	Util C
Tofacitinib	Rifampin	Etravirine
	Rifabutin	Carbamazepine
	Rifapentine	Phenytoin
	Nevirapine	Phenobarbital
	Efavirenz	Dexamethasone

References:
Xeljanz Prescribing Information, November 2012, Pfizer, Inc.
Clinical Pharmacology, 2013 Elsevier / Gold Standard.

40. Tofacitinib / Gastrointestinal Perforations _____ _____

Alert Message: Xeljanz (tofacitinib) should be used with caution in patients who may be at increased risk for gastrointestinal perforation. The role of JAK inhibition in these events is not known, but episodes of GI perforation have been reported in clinical studies.

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

Util A	Util B	Util C
Tofacitinib	Diverticulitis	
	Peptic Ulcer Disease	
	Ulcerative Colitis	

References:
Xeljanz Prescribing Information, November 2012, Pfizer, Inc.
Clinical Pharmacology, 2013 Elsevier / Gold Standard.

41. Tofacitinib / Malignancy (Black Box Warning) _____ _____

Alert Message: Xeljanz (tofacitinib) may not be appropriate therapy for patients with a current or past malignancy, as studies have shown that tofacitinib may precipitate a secondary malignancy. Carefully consider the risks and benefits of tofacitinib therapy before initiating the drug in patients with a known malignancy other than a successfully treated non-melanoma skin cancer.

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

Util A	Util B	Util C
Tofacitinib	Malignancy	

References:
Xeljanz Prescribing Information, November 2012, Pfizer, Inc.
Clinical Pharmacology, 2013 Elsevier / Gold Standard.

42. Tofacitinib / Serious Infections (Black Box Warning) _____ _____

Alert Message: Patients treated with Xeljanz (tofacitinib) may be at increased risk for developing serious infections (including tuberculosis, invasive fungal infections and other bacterial and/or viral infections) that may lead to hospitalization or death. If a serious infection develops, interrupt tofacitinib therapy until the infection is controlled. The risks and benefits of treatment with tofacitinib should be carefully considered prior to initiating therapy in patients with chronic or recurrent infection.

Conflict Code: TA – Therapeutic Appropriateness

Drugs/Diseases		
Util A	Util B	Util C
Tofacitinib		

References:
Xeljanz Prescribing Information, November 2012, Pfizer, Inc.
Clinical Pharmacology, 2013 Elsevier / Gold Standard.

43. Tofacitinib / Tuberculosis (Black Box Warning) _____ _____

Alert Message: Patients being treated with Xeljanz (tofacitinib) should be evaluated and tested for latent or active tuberculosis prior to initiation of tofacitinib therapy. Once therapy has been started, patients should be closely monitored for the development of signs and symptoms of tuberculosis, including patients who tested negative for latent tuberculosis infection prior to initiating therapy.

Conflict Code: TA – Therapeutic Appropriateness

Drugs/Diseases		
Util A	Util B	Util C
Tofacitinib		

References:
Xeljanz Prescribing Information, November 2012, Pfizer, Inc.
Clinical Pharmacology, 2013 Elsevier / Gold Standard.

44. Tofacitinib / Epstein Barr Virus (Black Box Warning) _____ _____

Alert Message: In clinical trials, renal transplant patients being treated with Xeljanz (tofacitinib) in combination with immunosuppressant medications had an increased rate of developing Epstein Barr Virus-associated post-transplant lymphoproliferative disorder.

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

Drugs/Diseases		
Util A	Util B	Util C
Tofacitinib	Renal Transplant	

References:
Xeljanz Prescribing Information, November 2012, Pfizer, Inc.
Clinical Pharmacology, 2013 Elsevier / Gold Standard.

45. Liptruzet / Overutilization _____ _____

Alert Message: Liptruzet (ezetimibe/atorvastatin) may be over-utilized. The manufacturer's maximum recommended daily dose is 10mg ezetimibe / 80 mg atorvastatin.

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C **(Negating)**	
Ezetimibe/Atorvastatin		Clarithromycin	Cyclosporine
		Itraconazole	Tipranavir
		Saquinavir	Telaprevir
		Darunavir	Gemfibrozil
		Fosamprenavir	Nelfinavir

Max Dose: 10/80mg per day

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

46. Atorvastatin-All / Boceprevir _____ _____

Alert Message: In patients taking Victrelis (boceprevir), therapy with Liptruzet (ezetimibe/atorvastatin) should be limited to 10mg ezetimibe/40 mg atorvastatin and appropriate clinical assessment is recommended to ensure that the lowest dose necessary of ezetimibe/atorvastatin is employed. Boceprevir is a CYP3A4 inhibitor and use with atorvastatin, a CYP3A4 substrate, may elevate atorvastatin levels and increase the risk of statin-related myopathy and rhabdomyolysis,

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

Util A	Util B	Util C
Atorvastatin 40mg containing agents	Boceprevir	

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

DUR Board Meeting
December 3, 2013
Bismarck State College

National Energy Center of Excellence

North Dakota Medicaid
DUR Board Meeting Agenda
Bismarck State College
National Energy Center of Excellence
Room 431/433
1200 Schafer Street
Bismarck, ND
December 3, 2013
1pm

1. Administrative items
    - Travel vouchers

2. Old business

• Review and Approval of Minutes of 9/13 Meeting	Chair
• Budget Update	Brendan
• Second Review of Sirturo	Brendan
• Second Review of Brisdelle	Brendan
• Second Review of Nitroglycerin Lingual Spray/Sublingual Tablets	Brendan
• Second Review of Agents Used to Treat COPD	Brendan
• Second Review of Epinephrine Auto-Injection Devices	Brendan
• Second Review of Pulmozyme	Brendan
• Review of Statins	Brendan
• Review of Vecamyl	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 and pagers during the meeting.

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

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

Members Absent: Todd Twogood, Leann Ness, Tanya Schmidt, Steve Irsfeld, James Carlson, Michael Booth

Medicaid Pharmacy Department: Brendan Joyce, Gary Betting

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 June meeting. N. Byers moved that the minutes be approved, and G. Betting seconded the motion. Chair G. Pfister called for a voice vote to approve the minutes. The motion passed with no audible dissent. New board member, Peter Woodrow was introduced to the Board.

Budget Update
B. Joyce informed the board members that for the 2011-2013 biennium, the net spend was 37.8 million dollars; 72.9 million dollars spend pre-rebate. There was approximately 35 million collected in rebates. This includes approximately 64,000 recipients and 1.43 million pharmacy claims.

Rayos Second Review
A motion and second were made at the June meeting to place Rayos 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.

Diclegis Second Review
A motion and second were made at the June meeting to place Diclegis 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.

Sitavig Second Review
A motion and second were made at the June meeting to place Sitavig 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. This will be added to the Orally Disintegrating Tablets PA form.

Onmel Second Review
A motion and second were made at the June meeting to place Onmel 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.

Giazo Second Review
A motion and second were made at the June meeting to place Giazo 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.

Sirturo Review
B. Joyce reviewed Sirturo clinical information with the board. There was no public comment. J. Hostetter made a motion to make Sirturo unavailable in the retail setting. C. Huber seconded the motion. This topic will be brought up at the next meeting for finalization.

Brisdelle Review
B. Joyce reviewed Brisdelle clinical information with the board. There was no public comment. N. Byers made a motion to place Brisdelle on prior authorization. P. Woodrow seconded the motion. This topic will be brought up at the next meeting for finalization.

Vecamyl Review
B. Joyce reviewed Vecamyl clinical information with the board. There was no public comment. J. Hostetter made a motion to review more information at the December meeting. G. Pfister seconded the motion. This topic will be reviewed at the next meeting.

Nitroglycerin Lingual Spray/Sublingual Tablet Review
B. Joyce reviewed nitroglycerin spray/sublingual tablet clinical information with the board. There was no public comment. P. Woodrow made a motion to place Nitroglycerin Lingual Spray on prior authorization. J. Savageau seconded the motion. This topic will be brought up at the next meeting for finalization.

COPD Review
B. Joyce reviewed agents used to treat COPD clinical information with the board. There was no public comment. J. Savageau made a motion to place agents used to treat COPD on prior authorization. P. Woodrow seconded the motion. This topic will be brought up at the next meeting for finalization.

Epinephrine Auto-Injections Review
B. Joyce reviewed epinephrine auto-injections clinical information with the board. R. Sobotta, representing Sanofi, spoke regarding Auvi Q. N. Byers made a motion to place epinephrine auto-injectors on prior authorization. G. Pfister seconded the motion. The department will review post rebate data to determine which drug is the best option (EpiPen or Auvi Q). This topic will be brought up at the next meeting for finalization.

Pulmozyme Review
B. Joyce reviewed Pulmozyme clinical information with the board. D. Evans, representing Genentech, spoke regarding Pulmozyme. J. Hostetter made a motion to place Pulmozyme on prior authorization. J. Savageau seconded the motion. This topic will be brought up at the next meeting for finalization.

Statin Review
B. Joyce reviewed statin information with the board. This topic was tabled until 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. C. Huber moved to approve the new criteria and N. Byers 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 December 3, in Bismarck. C. Huber made a motion to adjourn the meeting. J. Hostetter seconded. The motion passed with no audible dissent. G. Pfister adjourned the meeting.

CHAPTER 50-24.6
MEDICAL ASSISTANCE DRUG USE REVIEW AND AUTHORIZATION

50-24.6-01. Definitions.

As used in this chapter, unless the context otherwise requires:

1. "Board" means the drug use review board.
2. "Compendium" means the American hospital formulary service drug information, United States pharmacopeia-drug information, the DRUGDEX information system, American medical association drug evaluations, or nonproprietary peer-reviewed medical literature.
3. "Department" means the department of human services.
4. "Drug use review" means a program as described in 42 U.S.C. 1396r-8(g)(2).
5. "Drug use review criteria" means standards approved by the board for use in determining whether use of a drug is likely to be medically appropriate, to be medically necessary, and not result in adverse medical outcomes.
6. "Prior authorization" means a process requiring the prescriber or the dispenser to verify with the department or the department's contractor that proposed medical use of a particular drug for a medical assistance program recipient meets predetermined criteria for coverage by the medical assistance program.

50-24.6-02. Drug use review board.

1. The board is established within the department for the implementation of a drug use review program.
2. The board consists of seventeen members. The pharmacy administrator of the department and the medical consultant to the department are ex officio nonvoting board members who shall provide administrative services to the board. A majority of the appointed members must be physicians and pharmacists participating in the medical assistance program. Four or more of the appointed members must have experience with a drug use review process or have participated in programs in which prior authorization is used. The appointed members of the board must be:
   a. Four physicians licensed in this state and actively engaged in the practice of medicine, one of whom is a psychiatrist, appointed by the North Dakota medical association;
   b. Two physicians licensed in this state and actively engaged in the practice of medicine, appointed by the executive director of the department;
   c. Four pharmacists licensed in this state and actively engaged in the practice of pharmacy, appointed by the North Dakota pharmaceutical association;
   d. Two pharmacists licensed in this state and actively engaged in the practice of pharmacy, appointed by the executive director of the department;
   e. One individual who represents consumer interests, appointed by the governor;
   f. One pharmacist or physician representing the brand pharmaceutical industry appointed by the pharmaceutical research and manufacturers of America; and
   g. One pharmacist or physician representing the generic pharmaceutical industry appointed by the generic pharmaceutical association.
3. Appointed board members shall serve staggered three-year terms. An appointed member may be reappointed for a period not to exceed three 3-year terms. A vacancy on the board must be filled for the balance of the unexpired term from the appropriate board category as provided under subsection 2. The executive director of the department may replace an appointed member of the board who fails to attend three consecutive meetings of the board without advance excuse or who fails to perform the duties expected of a board member. The pharmaceutical industry representatives are nonvoting board members.
4. Voting board members shall select a chairman and a vice chairman on an annual basis from the board's voting membership.
5. The board shall meet in person at least once every three months and may meet at other times by teleconference or electronically at the discretion of the chairman. A

board member is entitled to receive from the department per diem compensation and reimbursement of expenses as determined by the department, except that no compensation under this section may be paid to any board member who receives compensation or salary as a state employee or official.

50-24.6-03. Duties of the board.

The board shall:

1. Cooperate with the department to create and implement a prospective and retrospective drug use review program for outpatient prescription drugs under the medical assistance program. This drug use review program must be based on a compendium and drug use review criteria and must comply with 42 U.S.C. 1396r-8(g)(3).
2. Advise and make recommendations regarding any rule proposed for adoption by the department to implement the provisions of state and federal law related to drug use review.
3. Receive and consider information regarding the drug use review process which is provided by the department and by interested parties, including prescribers who treat significant numbers of patients under the department's medical assistance program.
4. Review and recommend to the department any drugs to be included on prior authorization status.
5. Review no less than once each year the status of the list of drugs that have been placed on prior authorization.
6. Review and approve the prior authorization program process used by the department, including the process to accommodate the provision of a drug benefit in an emergency situation.
7. Propose remedial strategies to improve the quality of care and to promote effective use of medical assistance program funds or recipient expenditures.

50-24.6-04. Prior authorization program.

1. The department shall develop and implement a prior authorization program that meets the requirements of 42 U.S.C. 1396r-8(d) to determine coverage of drug products when a medical assistance recipient's health care provider prescribes a drug that is identified as requiring prior authorization. Authorization must be granted for provision of the drug if:
   a. The drug not requiring prior authorization has not been effective, or with reasonable certainty is not expected to be effective, in treating the recipient's condition;
   b. The drug not requiring prior authorization causes or is reasonably expected to cause adverse or harmful reactions to the health of the recipient; or
   c. The drug is prescribed for a medically accepted use supported by a compendium or by approved product labeling unless there is a therapeutically equivalent drug that is available without prior authorization.
2. For any drug placed on the prior authorization program, the department shall provide medical and clinical criteria, cost information, and utilization data to the drug use review board for review and consideration. The board may consider department data and information from other sources to make a decision about placement of the drug on prior authorization.
3. Except for quantity limits that may be no less than the pharmaceutical manufacturer's package insert, or brand name drugs with a generic equivalent drug for which the cost to the state postrebate is less than the brand name drugs, in the aggregate, the department may not prior authorize the following medication classes:
   a. Antipsychotics;
   b. Antidepressants;
   c. Anticonvulsants;
   d. Antiretrovirals, for the treatment of human immunodeficiency virus;
   e. Antineoplastic agents, for the treatment of cancer; and

f. Stimulant medication used for the treatment of attention deficit disorder and attention deficit hyperactivity disorder.

4. The department may use contractors to collect and analyze the documentation required under this section and to facilitate the prior authorization program.
5. The department shall consult with the board in the course of adopting rules to implement the prior authorization program. The rules must:
   a. Establish policies and procedures necessary to implement the prior authorization program.
   b. Develop a process that allows prescribers to furnish documentation required to obtain approval for a drug without interfering with patient care activities.
   c. Allow the board to establish panels of physicians and pharmacists which provide expert guidance and recommendations to the board in considering specific drugs or therapeutic classes of drugs to be included in the prior authorization program.

50-24.6-05. Public notice - Applicability.

1. The department shall provide thirty days' notice of all meetings of the board. The notice requirement is met if the department provides notice of the meeting on the department's website and provides, by written or electronic means, individual notice to each person that has requested such notice. If the meeting agenda includes board consideration of a change to the prior authorization program, the department shall include in the notice a list of the affected drugs, and upon request the board shall provide background information. Any interested party may attend a meeting of the board and provide information or recommendations related to the inclusion of a drug in a prior authorization program.
2. The department shall post on the department's website:
   a. The most current and applicable list of drugs requiring prior authorization, together with any limits on coverage of these drugs.
   b. In downloadable format, forms necessary to complete prior authorization requests.
   c. Decisions regarding changes to the prior authorization program list. The department shall allow a period of no less than thirty days for public comment following posting on the website.
   d. Meeting notice.
3. The department may not discontinue the provision of prescription drug benefits being provided to medical assistance recipients before April 14, 2003, based solely on the subsequent placement of the drug on the prior authorization program.

50-24.6-06. Grievances.

Expired under S.L. 2003, ch. 430, § 12.

50-24.6-07. Appeals.

A medical assistance recipient who is aggrieved by the placement of a drug on prior authorization may appeal as authorized under chapter 28-32.

50-24.6-08. Financial incentives prohibited.

The department may not offer or pay, directly or indirectly, any material inducement, bonus, or other financial incentive to a participating provider based on the denial or delay of medically necessary and appropriate prescription drug therapy or based on a reduction in the proportion of recipients who receive prescription drug therapy under the medical assistance program.

50-24.6-09. Maximum allowable costs and use of edits.

To promote efficiency and savings in the department's service to eligible medical assistance program recipients, the department shall create and implement the broadest possible list of drugs that can be paid at the maximum allowable costs. To further promote efficiency and savings, the department shall maximize use of edit programs that pertain to payment of medical

assistance program pharmaceutical claims. Upon request of a member of the legislative assembly, the department shall provide to that member a summary of edit programs available to the medical assistance program and a description of the department's progress in implementing the edit programs.

50-24.6-10. Adoption of rules.

The department shall adopt rules to implement this chapter.

Medicaid Provider Information

Pharmacy Provider Drug Utilization Review Board

Members

Health Information Designs (HID) - North Dakota DUR/PA website

The HID Website for ND Medicaid also contains the DUR Board Meeting Agenda & Minutes, along with the Policy and Procedures.

Per federal law, each state must establish a Drug Use Review (DUR) Board. North Dakota Medicaid's DUR Board has been active for many years. The DUR Board's functions include but are not limited to serving as an advisory board for various policies, identifying and developing educational topics for practitioners to improve drug therapy, and assisting the department in identifying patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care.

The DUR Board includes six physicians, six pharmacists, and three non-voting members as outlined by State Law and Administrative Rules. Meetings are held at least quarterly, and the meetings are open to the public. If you have any questions regarding N.D. Medicaid's DUR Board or the Medication Prior Authorization Program, please contact Brendan Joyce, PharmD, Administrator, Pharmacy Services at bjoyce@nd.gov.

DUR Board members serve staggered three year terms with a maximum of three renewals as described in state law. Below is a table showing the current schedule of the staggered terms and the board members serving those terms. All terms begin July 1 and end June 30 of the specified years. The Position column shows the member subset as well as the entity that appointed that member (e.g. RPh DHS 1 is one of two pharmacists appointed by the Department of Human Services). The number of remaining renewals (if applicable) are shown, and the Appointment Ends column is populated with the year the member would end service on the Board if they exhaust all available renewals.

Position	Member Name	Member Type	Appointed Date	Renewals Left	Appointment Ends
Ex-Officio	Betting, Gary, MD	MD		N/A	OPEN
Ex-Officio	Joyce, Brendan, PharmD	Pharm		N/A	OPEN
Gov Appt	McCleary, Carlotta	Cons. Int.	7/1/2006	1	2018
GPhA	Carlson, James, PharmD	GPhA	9/1/2009	2	2021
MD DHS 1	Byers, Norman, MD	MD	7/1/2003	0	2015
MD DHS 2	Woodrow, Peter, MD	MD	7/1/2013	3	2025
MD NDMA 1	Booth, Michael, MD	MD	12/1/2012	3	2024
MD NDMA 2	Hostetter, Jeffrey, MD	MD	9/1/2007	1	2019
MD NDMA 3	Huber, Cheryl, MD	MD	7/1/2004	0	2014
MD NDMA 4	Twogood, Todd, MD	MD	5/1/2006	1	2017
PhRMA	Sobotta, Russ, PhRMA	PhRMA	7/1/2009	2	2018
RPh DHS 1	Ness, Leann, PharmD	Pharm	7/1/2003	0	2015
RPh DHS 2	Pfister, Greg, PharmD	Pharm	7/1/2003	0	2014
RPh NDPhA 1	Irsfeld, Steve, RPh	Pharm	7/1/2009	1	2019
RPh NDPhA 2	Savageau, John, RPh	Pharm	7/1/2003	0	2015
RPh NDPhA 3	Schmidt, Tanya, PharmD	Pharm	4/1/2012	2	2022
RPh NDPhA 4	Sorenson, Carrie, PharmD	Pharm	7/1/2004	0	2014

Top of page Back to previous page

Sirturo
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 Sirturo must meet the following criteria:

- *Sirturo cannot be billed for outpatient use*
- *Sirturo must be billed by physician*

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: □ **Sirturo**	Diagnosis for this request:
SIRTURO MUST BE GIVEN/BILLED BY PHYSICIAN	
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

Brisdelle
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 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

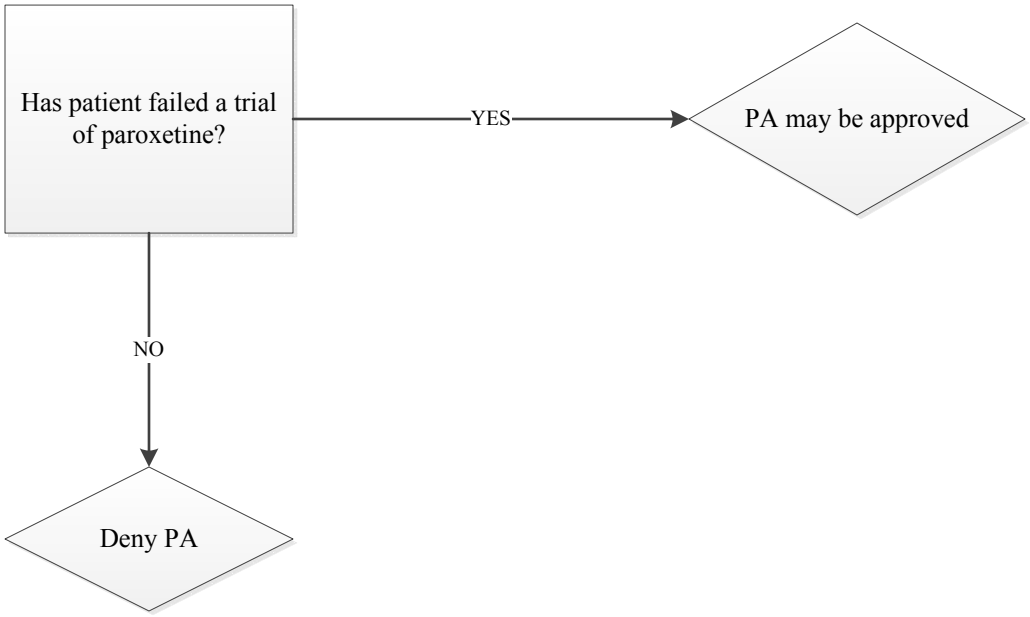
Part II: TO BE COMPLETED BY PHARMACY

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)	

North Dakota Department of Human Services
Brisdelle Authorization Algorithm



HEALTH INFORMATION DESIGNS

Prior Authorization Vendor for ND Medicaid

Nitrolingual 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: □ **Nitrolingual Spray**	Diagnosis for this request:
Failed Therapy:	Start Date: End Date:
Physician Signature	Date

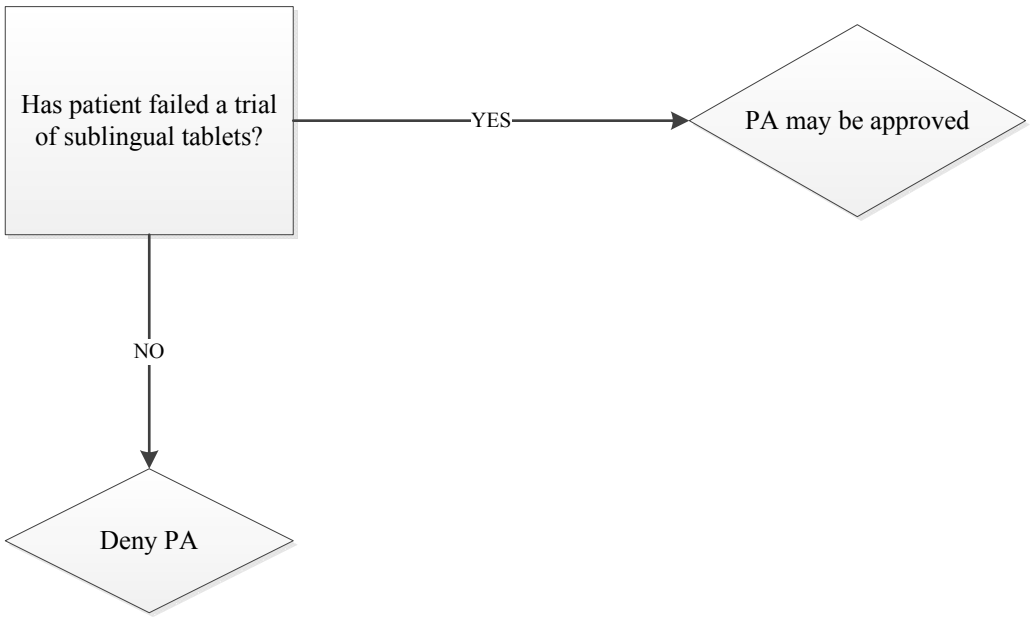
Part II: TO BE COMPLETED BY PHARMACY

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)	

North Dakota Department of Human Services
Nitrolingual Spray Authorization Algorithm



HEALTH INFORMATION DESIGNS

Prior Authorization Vendor for ND Medicaid

Agents Used to Treat COPD
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 Arcapta, Brovana, Spiriva, Tudorza, 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**	
Physician Signature	Date

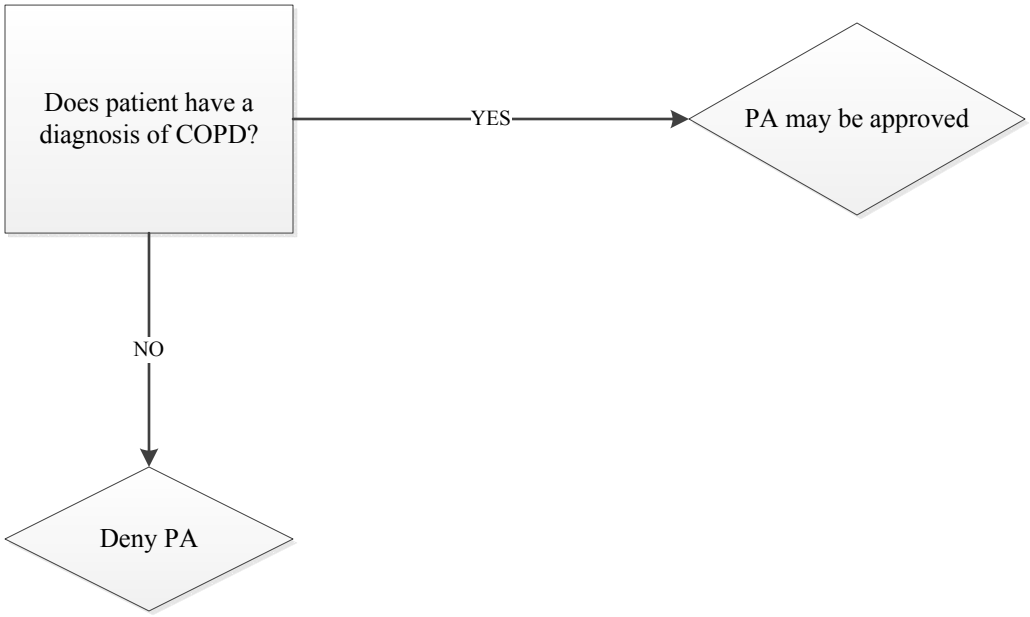
Part II: TO BE COMPLETED BY PHARMACY

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
Agents Used to Treat COPD
Authorization Algorithm



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

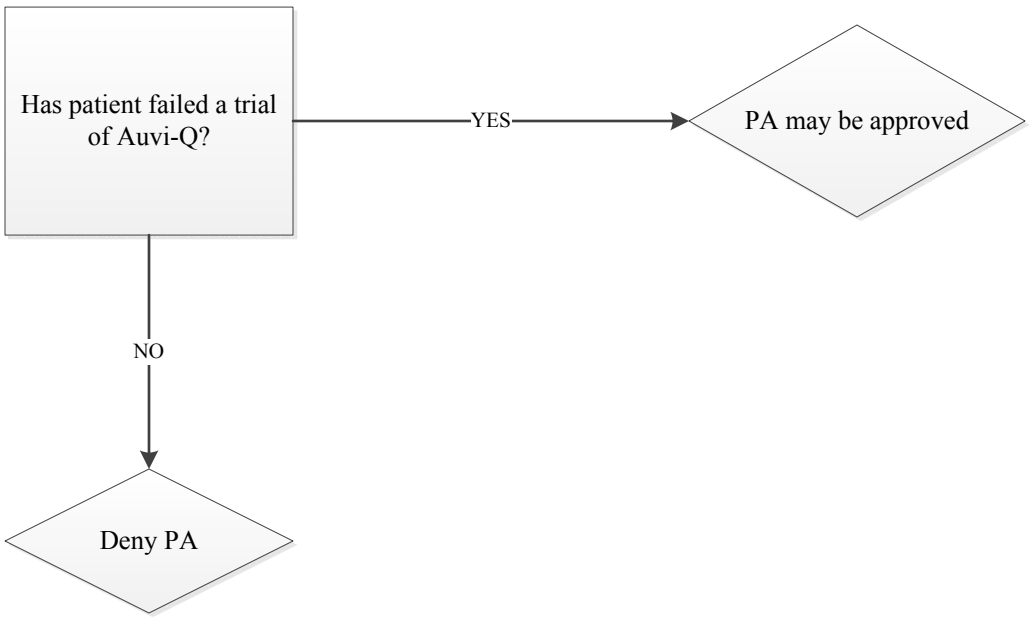
Part II: TO BE COMPLETED BY PHARMACY

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)	

North Dakota Department of Human Services
Epinephrine Auto Injector
Authorization Algorithm



HEALTH INFORMATION DESIGNS

Prior Authorization Vendor for ND Medicaid

Pulmozyme
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 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

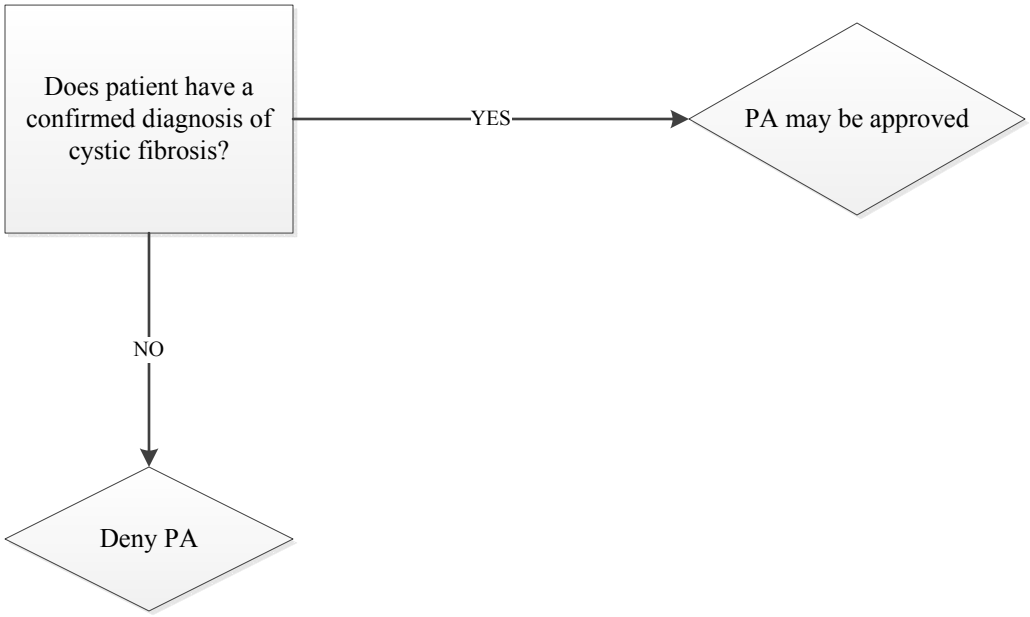
Part II: TO BE COMPLETED BY PHARMACY

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)	

North Dakota Department of Human Services
Pulmozyme Authorization Algorithm



ND Medicaid Statin Utilization (AHFS 240608)			
05/30/12 - 05/29/13			
Label Name	**Rx Num**	**Total Reimb Amt**	**Average Cost per Script**
AMLODIPINE-ATORVAST 10-10 MG	7	$886.34	$126.62
AMLODIPINE-ATORVAST 10-20 MG	4	$684.76	$171.19
AMLODIPINE-ATORVAST 10-40 MG	11	$1,883.09	$171.19
AMLODIPINE-ATORVAST 10-80 MG	12	$2,080.36	$173.36
ATORVASTATIN 10 MG TABLET	64	$662.30	$10.35
ATORVASTATIN 20 MG TABLET	1289	$14,421.53	$11.19
ATORVASTATIN 40 MG TABLET	951	$11,143.43	$11.72
ATORVASTATIN 80 MG TABLET	942	$12,366.17	$13.13
CRESTOR 10 MG TABLET	423	$60,229.98	$142.39
CRESTOR 20 MG TABLET	332	$53,318.16	$160.60
CRESTOR 40 MG TABLET	160	$24,531.76	$153.32
CRESTOR 5 MG TABLET	134	$20,519.91	$153.13
FLUVASTATIN SODIUM 40 MG CAP	2	$206.94	$103.47
LESCOL XL 80 MG TABLET	1	$42.00	$42.00
LIPITOR 20 MG TABLET	1	$25.86	$25.86
LIPITOR 40 MG TABLET	2	$67.15	$33.58
LIVALO 1 MG TABLET	3	$384.84	$128.28
LIVALO 2 MG TABLET	2	$256.56	$128.28
LOVASTATIN 10 MG TABLET	19	$117.59	$6.19
LOVASTATIN 20 MG TABLET	48	$382.38	$7.97
LOVASTATIN 40 MG TABLET	104	$976.93	$9.39
PRAVASTATIN SODIUM 10 MG TAB	54	$528.36	$9.78
PRAVASTATIN SODIUM 20 MG TAB	142	$1,289.32	$9.08
PRAVASTATIN SODIUM 40 MG TAB	214	$2,023.54	$9.46
PRAVASTATIN SODIUM 80 MG TAB	49	$681.70	$13.91
SIMCOR 1,000-20 MG TABLET	6	$1,924.36	$320.73
SIMCOR 500-20 MG TABLET	6	$731.19	$121.87
SIMCOR 500-40 MG TABLET	8	$754.69	$94.34
SIMVASTATIN 10 MG TABLET	702	$4,410.04	$6.28
SIMVASTATIN 20 MG TABLET	1976	$13,270.90	$6.72
SIMVASTATIN 40 MG TABLET	1179	$8,492.59	$7.20
SIMVASTATIN 5 MG TABLET	54	$445.87	$8.26
SIMVASTATIN 80 MG TABLET	209	$1,693.35	$8.10
1,333 recipients	**9112**	**$241,433.95**	

HEALTH INFORMATION DESIGNS

Prior Authorization Vendor for ND Medicaid

HMG-CoA Reductase Inhibitors (Statins) 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 HMG-CoA Reductase Inhibitors must meet the following criteria:

- *Patient must have paid claims that show two trials of generic statins*

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:
Medication Failed and Dose 1._____ Start Date: End Date: 2._____ 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)	

North Dakota Medicaid
Pharmacotherapy Review
Vecamyl®

I. Indication

Mecamylamine is a potent oral antihypertensive agent and ganglion blocker indicated for the management of moderately severe to severe essential hypertension and uncomplicated cases of malignant hypertension.

II. Dosage and Administration

Therapy is usually started with one 2.5mg tablet mecamylamine twice a day. This initial dosage should be modified by increments of one 2.5mg tablet at intervals of not less than 2 days until the blood pressure response occurs. The average total daily dosage of mecamylamine is 25mg, usually in three divided doses. However, as little as 2.5mg daily may be sufficient to control hypertension in some patients. Close supervision and education of the patient, as well as critical adjustment of dosage, are essential to successful therapy.

III. Contraindications

Mecamylamine should be used in mile, moderate, labile hypertension and may prove unsuitable in uncooperative patients. It is contraindicated in coronary insufficiency or recent myocardial infarction.

Mecamylamine should be given with great discretion, if at all, when renal insufficiency is manifested by a rising or elevated BUN. The drug is contraindicated in uremia. Patients receiving antibiotics and sulfonamides should generally not be treated with ganglion blockers. Other contraindications are glaucoma, organic pyloric stenosis or hypersensitivity to the product.

IV. Warnings and Precautions

Mecamylamine, a secondary amine, readily penetrates into the brain and thus may produce central nervous system effects. Tremor, choreiform movements, mental aberrations, and convulsions may occur rarely. These have occurred most often when large doses of mecamylamine were used, especially in patients with cerebral or renal insufficiency.

When ganglion blockers or other potent antihypertensive drugs are discontinued suddenly, hypertensive levels return. In patients with malignant hypertension and others, this may occur abruptly and may cause fatal cerebral vascular accidents or acute congestive heart failure. When mecamylamine is withdrawn, this should be done gradually and other antihypertensive therapy usually must be substituted. The effects of mecamylamine sometimes may last from hours to days after therapy is discontinued.

The patient's condition should be evaluated carefully, particularly as to renal and cardiovascular function. When renal, cerebral, or coronary blood flow is deficient, any additional impairment, which might result from added hypotension, must be avoided. The use of mecamylamine in patients with marked cerebral and coronary arteriosclerosis or after a recent cerebral accident requires caution.

The action of mecamylamine may be potentiated by excessive heat, fever, infection, hemorrhage, pregnancy, anesthesia, surgery, vigorous exercise, other antihypertensive drugs, alcohol, and salt depletion as a result of diminished intake or increased excretion due to diarrhea, vomiting, excessive sweating, or diuretics.

During therapy with mecamylamine, sodium intake should not be restricted but, if necessary, the dosage of the ganglion blocker must be adjusted.

Since urinary retention may occur in patients on ganglion blockers, caution is required in patients with prostatic hypertrophy, bladder neck obstruction, and urethral stricture.

Frequent loose bowel movements with abdominal distention and decreased borborygmi may be the first signs of paralytic ileus. If these are present, mecamylamine should be discontinued immediately and remedial steps taken.

V. Adverse Reactions

The following adverse reactions have been reported and within each category are listed in order of decreasing severity.

Gastrointestinal: Ileus, constipation (sometimes preceded by small, frequent liquid stools), vomiting, nausea, anorexia, glossitis and dryness of mouth.

Cardiovascular: Orthostatic dizziness and syncope, postural hypotension.
Nervous System/Psychiatric: Convulsions, choreiform movements, mental aberrations, tremor, and paresthesias.

Respiratory: Interstitial pulmonary edema and fibrosis.

Urogenital: Urinary retention, impotence, decreased libido.

Special Senses: Blurred vision, dilated pupils.

Miscellaneous: Weakness, fatigue, sedation.

VI. Drug Interactions

Patients receiving antibiotics and sulfonamides generally should not be treated with ganglion blockers.
The action of mecamylamine may be potentiated by anesthesia, other hypertensive drugs, and alcohol.

VII. Cost

The cost of mecamylamine is approximately 54 dollars per tablet.

Reference

1. Vecamyl® [prescribing information]. Fort Collins, CO. Manchester Pharmaceuticals, Inc.; September 2012.

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

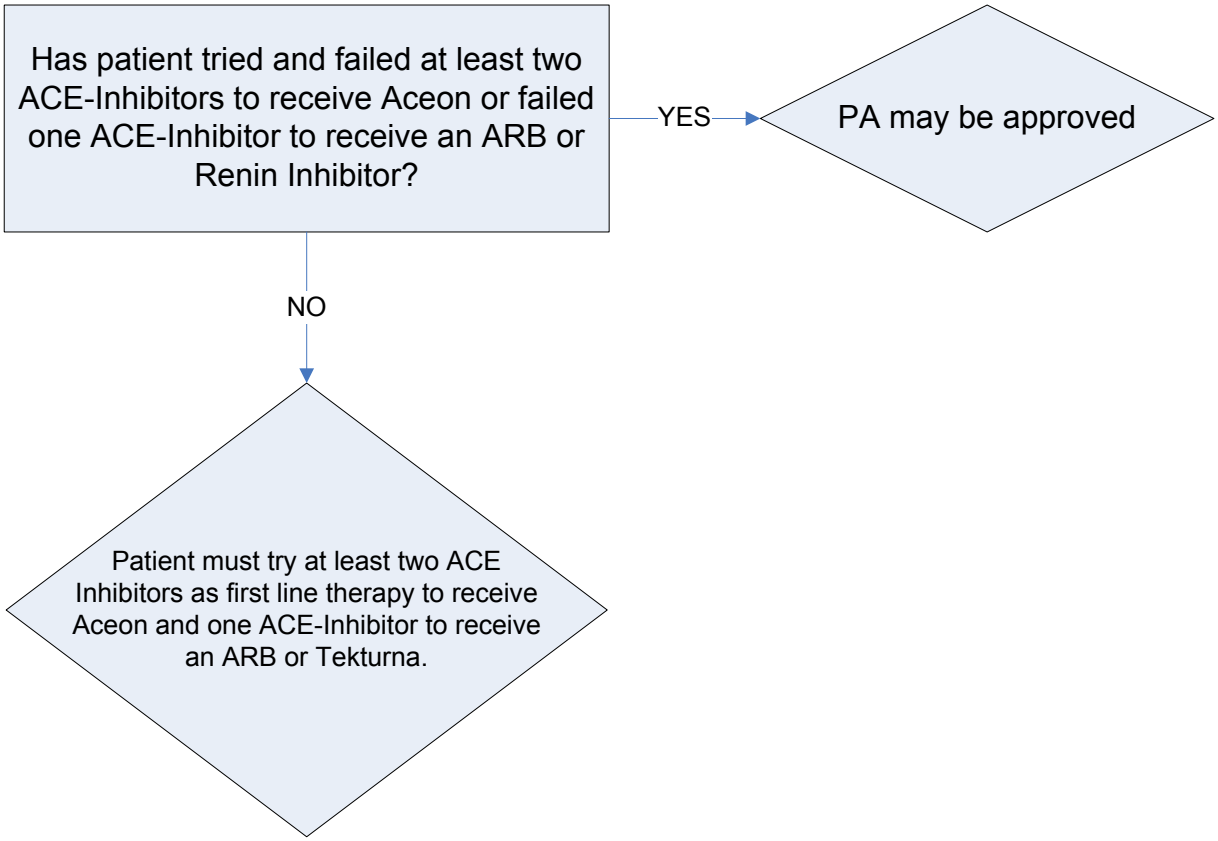
Part II: TO BE COMPLETED BY PHARMACY

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)	

North Dakota Department of Human Services
ACE-Is, ARBs and Renin Inhibitor (Tekturna) Authorization Criteria Algorithm



ACE-I: Captopril, enalapril, moexipril, ramipril, lisinopril, trandolapril, quinapril, benazepril or fosinopril and hydrochlorothiazide combinations

ARB: Micardis, Teveten, Atacand, Avapro, Benicar, Cozaar, Diovan, Edarbi, and hydrochlorothiazide combinations

Renin Inhibitor: Tekturna and hydrochlorothiazide combination

ACTINIC KERATOSIS 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 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	

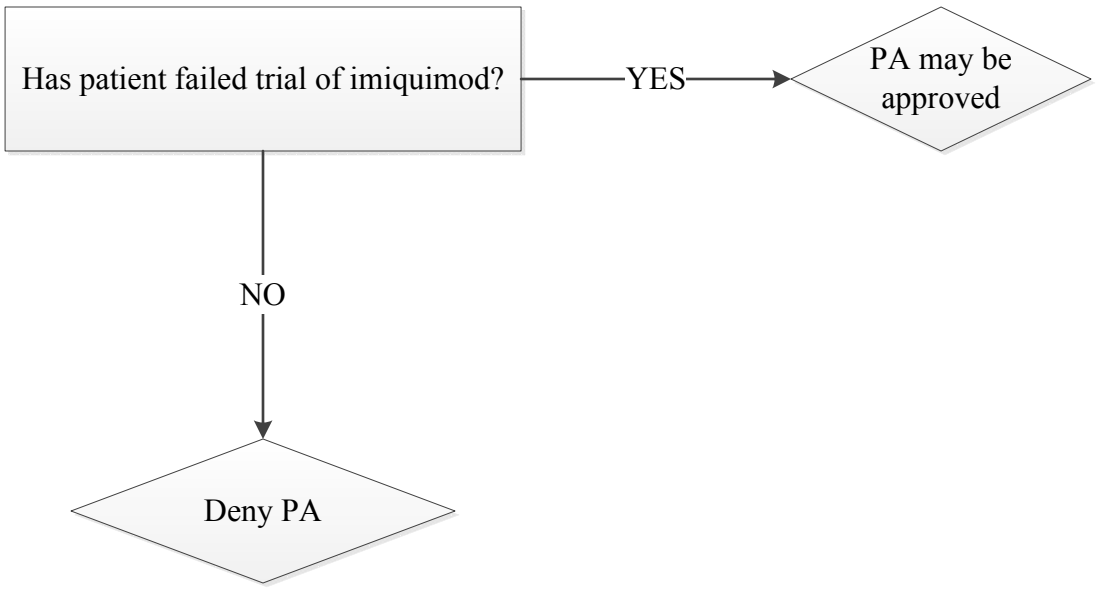
Part II: TO BE COMPLETED BY PHARMACY

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)	

North Dakota Department of Human Services
Actinic Keratosis Authorization Algorithm



HEALTH INFORMATION DESIGNS

ACTO*plus* met 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 receive Actos and Metformin separately.
Note:

- ***Actos does not require PA***
- ***Metformin does not require PA***
- ***Patients must fail therapy on Actos and Metformin separately 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: □ **ACTO*plus* met**	**Diagnosis for this request:**		
Qualifications for coverage:			
□ Failed both drugs separately	Start Date: End Date:	Dose: Frequency:	
Prescriber Signature		Date	

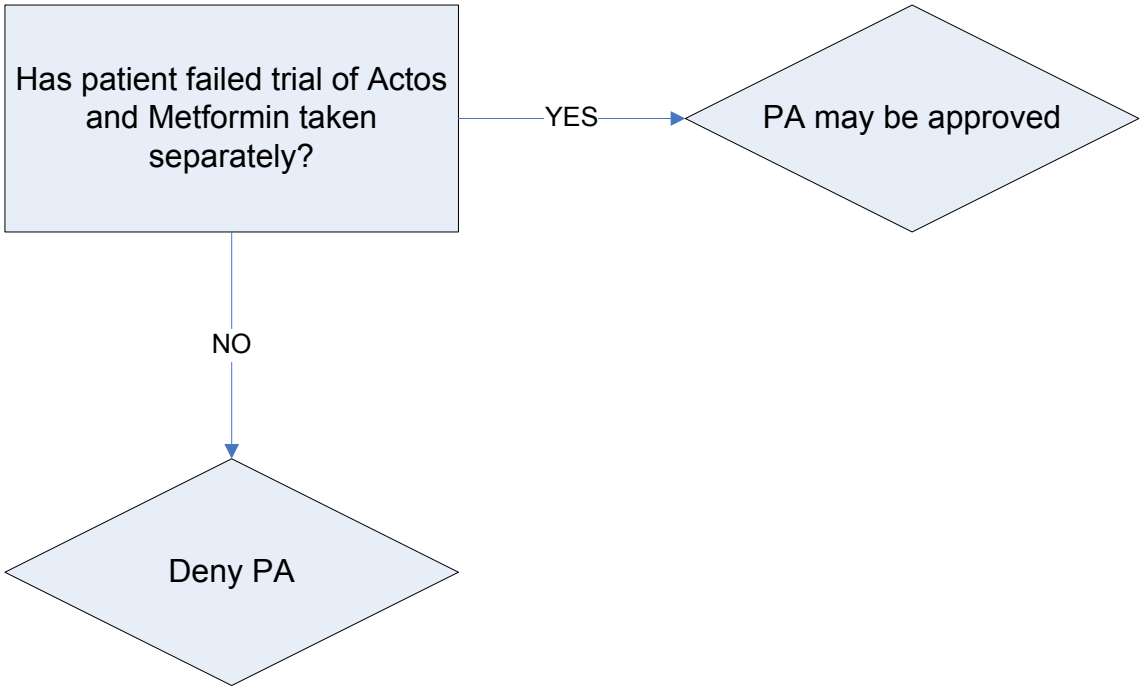
Part II: TO BE COMPLETED BY PHARMACY

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)	

North Dakota Department of Human Services
ACTO*plus met* Authorization Algorithm



Aczone Gel 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 new prescription for Aczone gel must try other topical acne agents as first line therapy.

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: □ ACZONE GEL	**Diagnosis for this request:**		

Qualifications for coverage:

□ Failed acne 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

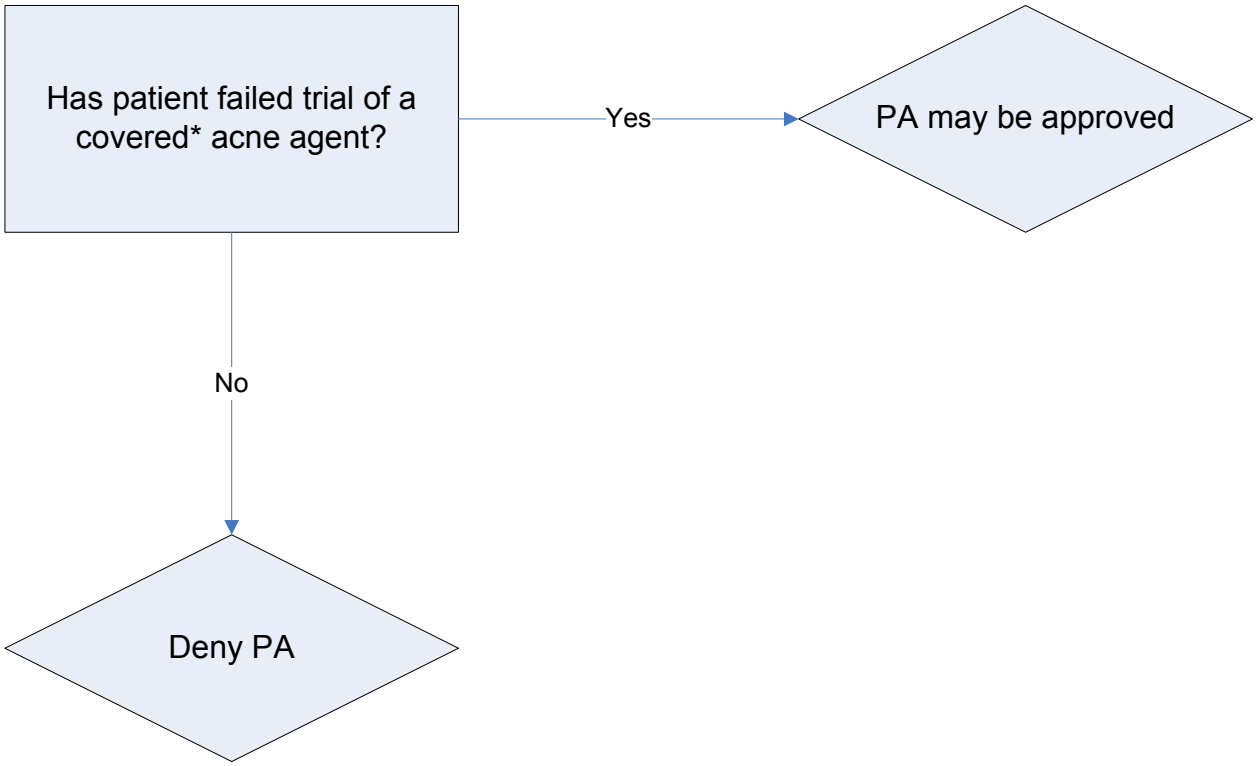
Part II: TO BE COMPLETED BY PHARMACY

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)	

North Dakota Department of Human Services
Aczone Authorization Algorithm



*Tretinoin and benzoyl peroxide products do not require a PA

AMPYRA 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 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	

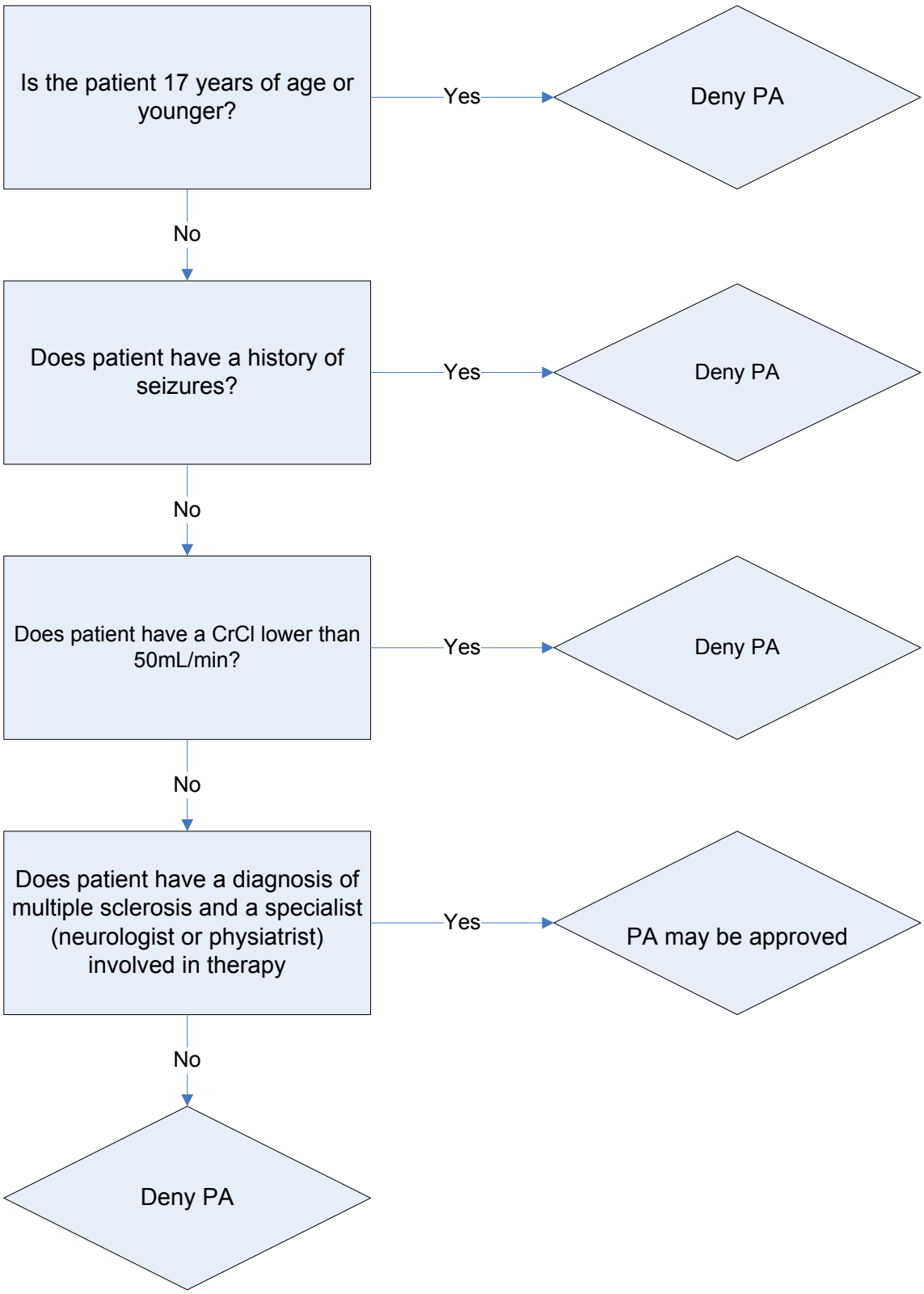
Part II: TO BE COMPLETED BY PHARMACY

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)	

North Dakota Department of Human Services
Ampyra Prior Authorization Algorithm



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:			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: 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:

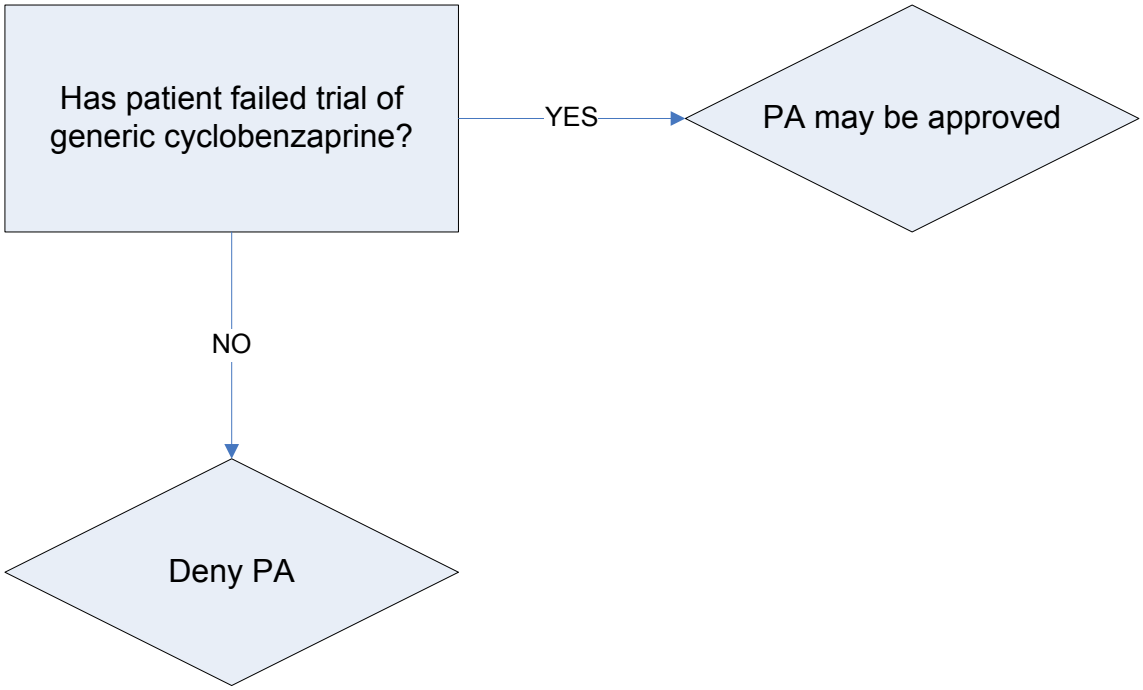
Part II: TO BE COMPLETED BY PHARMACY

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)					

North Dakota Department of Human Services
Amrix Authorization Algorithm



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:

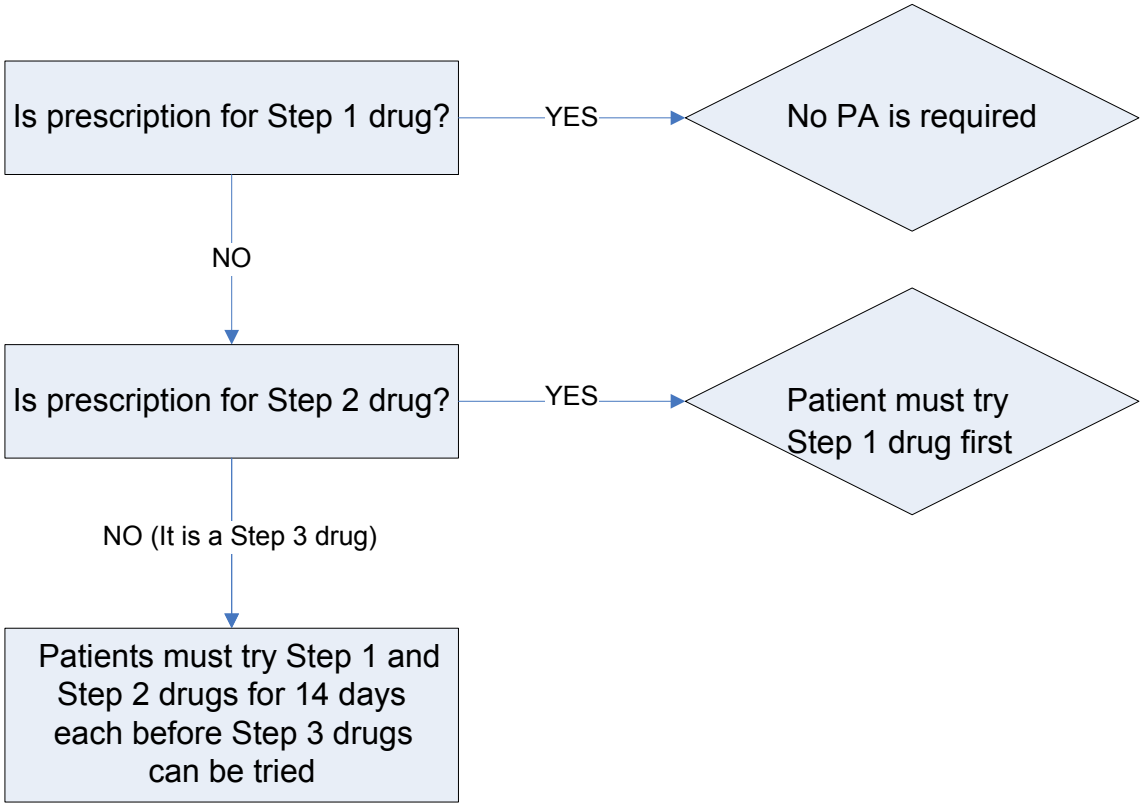
Part II: TO BE COMPLETED BY PHARMACY

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)	

North Dakota Department of Human Services
Antihistamine Authorization Criteria Algorithm



Please Note:

Step 1 drug is defined as Loratadine OTC or Cetirizine
Step 2 drug is defined as Allegra (generic)
Step 3 drug is defined as Clarinex or Xyzal-must try Step 1 and Step 2 drugs before trying Step 3.

Net cost to Medicaid: Loratadine = cetirizine << Allegra (generic) << Clarinex = Xyzal

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	

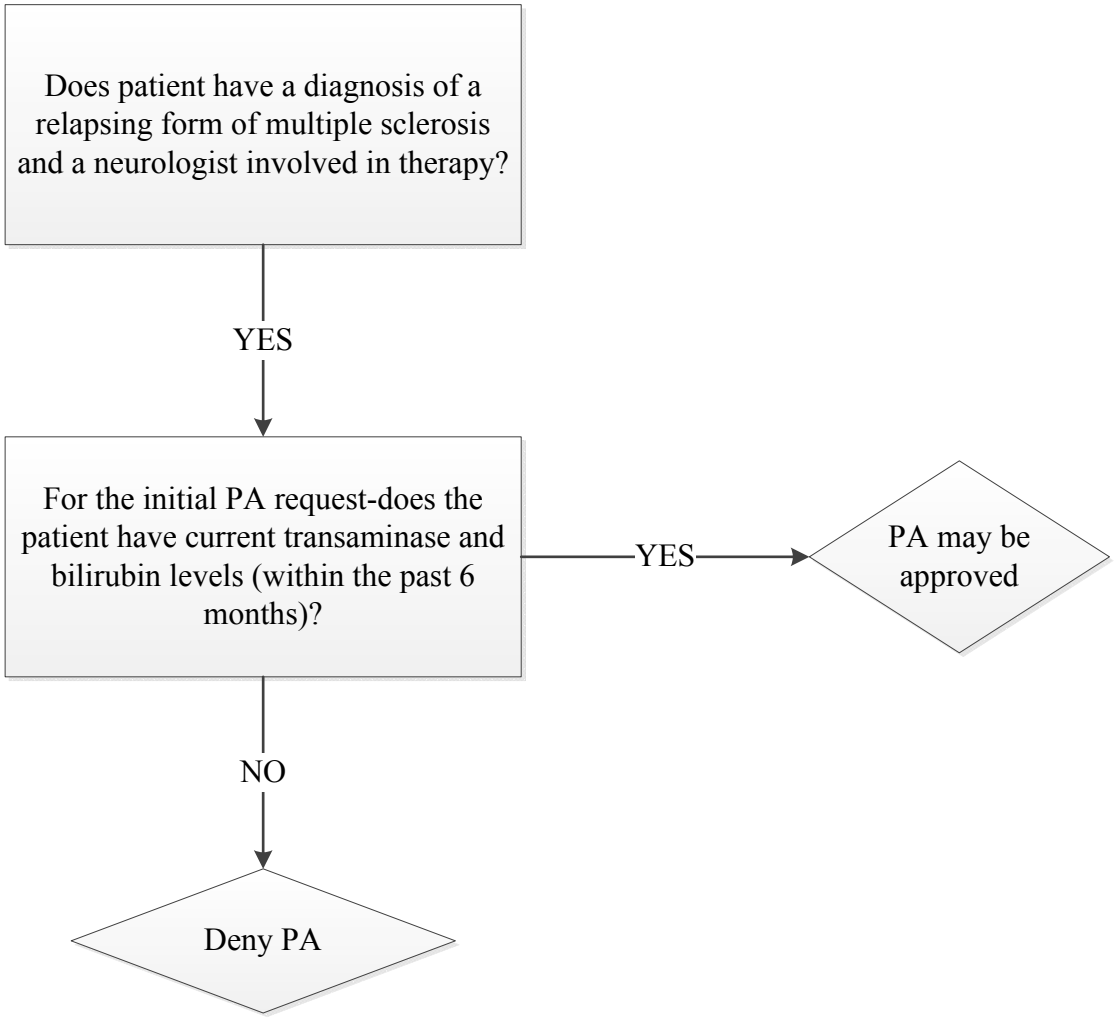
Part II: TO BE COMPLETED BY PHARMACY

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)	

North Dakota Department of Human Services
Aubagio Authorization Algorithm



Aubagio is contraindicated in pregnant women or women of childbearing potential who are not using reliable contraception.

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: END DATE:	DOSE: FREQUENCY:		
Physician Signature		Date	

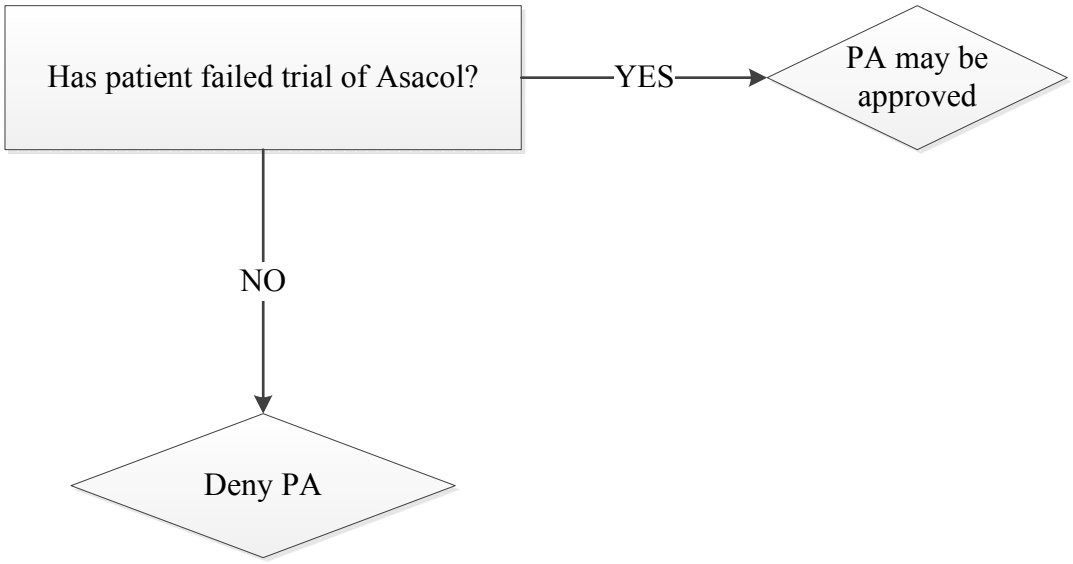
Part II: TO BE COMPLETED BY PHARMACY

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
Asacol HD Authorization Algorithm



For the treatment of moderately active ulcerative colitis: The recommended dose of Asacol HD in adults is two 800 mg tablets to be taken three times daily with or without food, for a total daily dose of 4.8 g for a duration of 6 weeks. $987.84

For the treatment of mildly to moderately active ulcerative colitis: The usual dosage in adults is two 400-mg tablets to be taken three times a day for a total daily dose of 2.4 grams for a duration of 6 weeks. $493.92

For the maintenance of remission of ulcerative colitis: The recommended dosage in adults is 1.6 grams daily, in divided doses.

BLOOD FACTOR 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 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:	

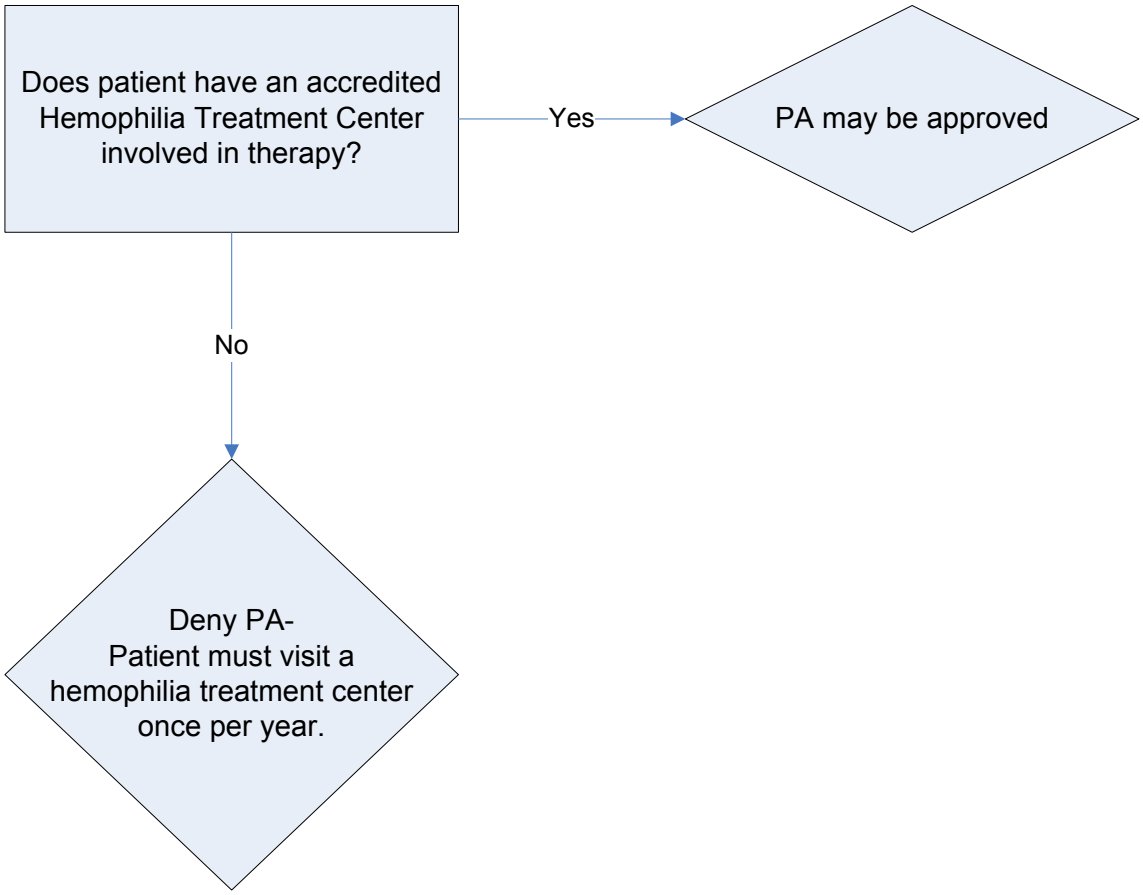
Part II: TO BE COMPLETED BY PHARMACY

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)	

North Dakota Department of Human Services
Blood Factor Products Authorization Algorithm



CARISOPRODOL 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 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		

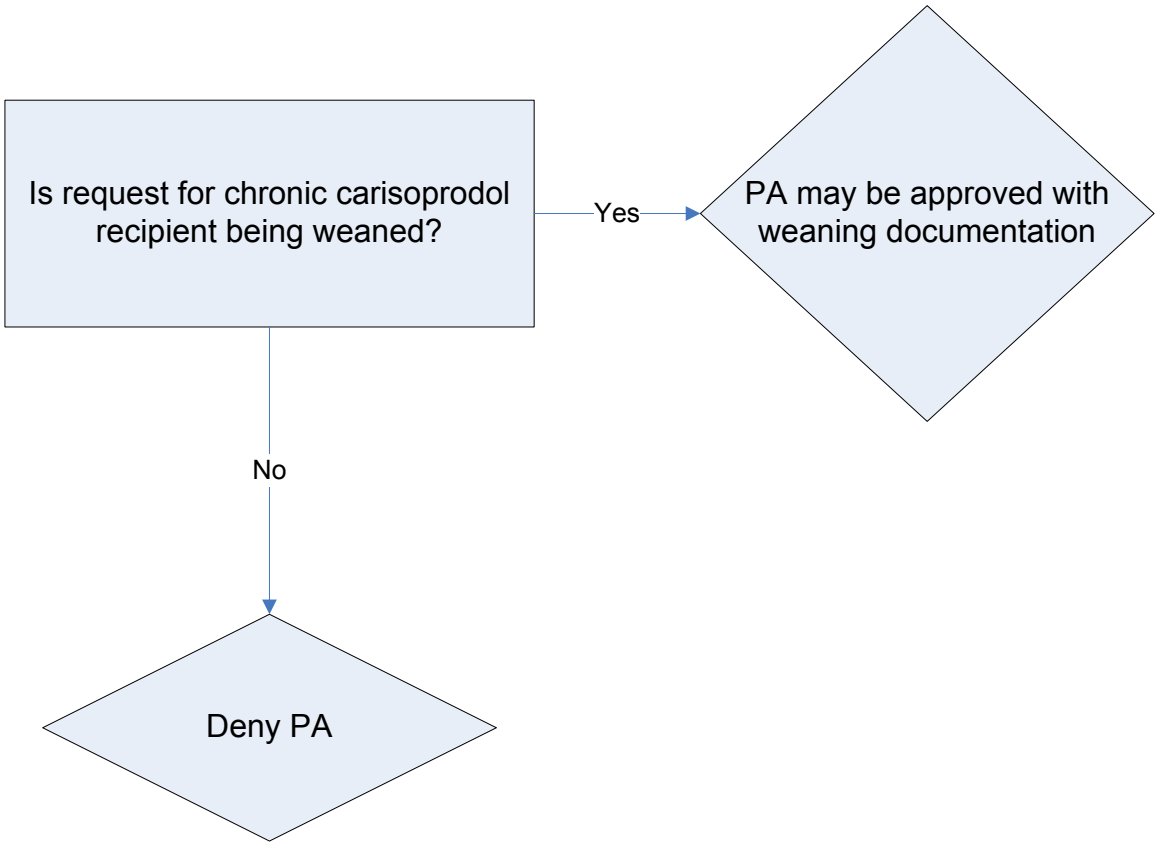
Part II: TO BE COMPLETED BY PHARMACY

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)	

North Dakota Department of Human Services
Carisoprodol Authorization Algorithm



CIALIS for BENIGN PROSTATIC HYPERPLASIA
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 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	

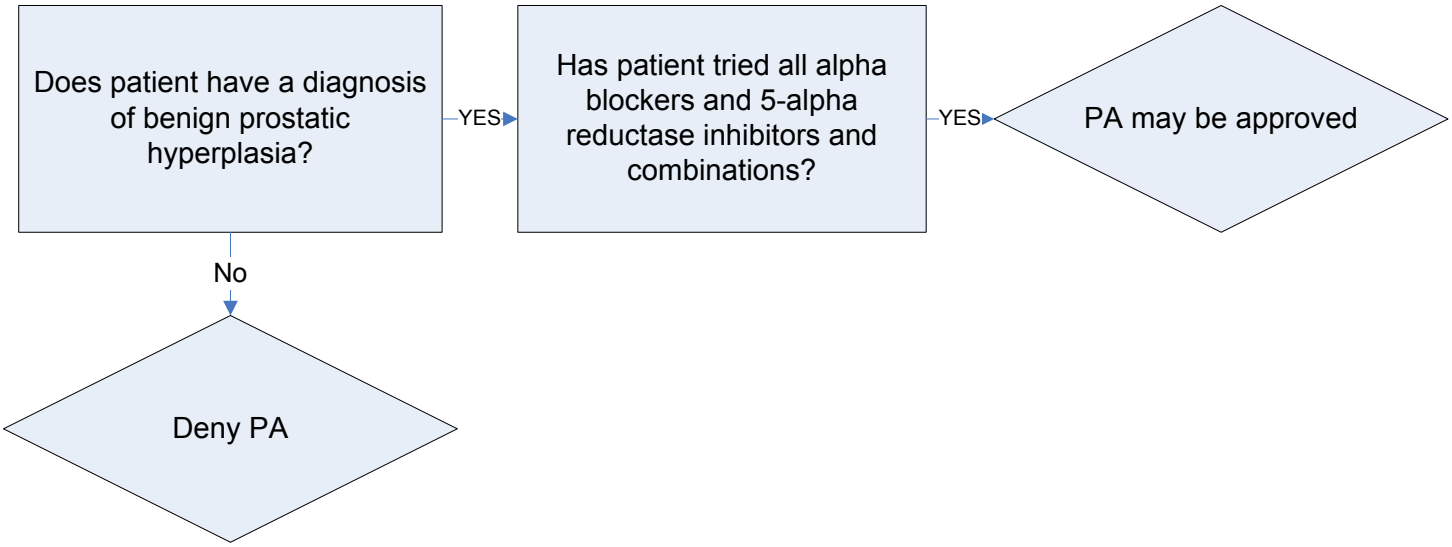
Part II: TO BE COMPLETED BY PHARMACY

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)	

North Dakota Department of Human Services
CIALIS for Benign Prostatic Hyperplasia
Prior Authorization Algorithm



Clorpres 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 receive clonidine and chlorthalidone separately.
Note:

- ***Clonidine does not require PA***
- ***Chlorthalidone 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: □ **Clorpres**	**Diagnosis for this request:**		
Qualifications for coverage:			
□ Failed both drugs separately	Start Date: End Date:	Dose: Frequency:	
Physician Signature		Date	

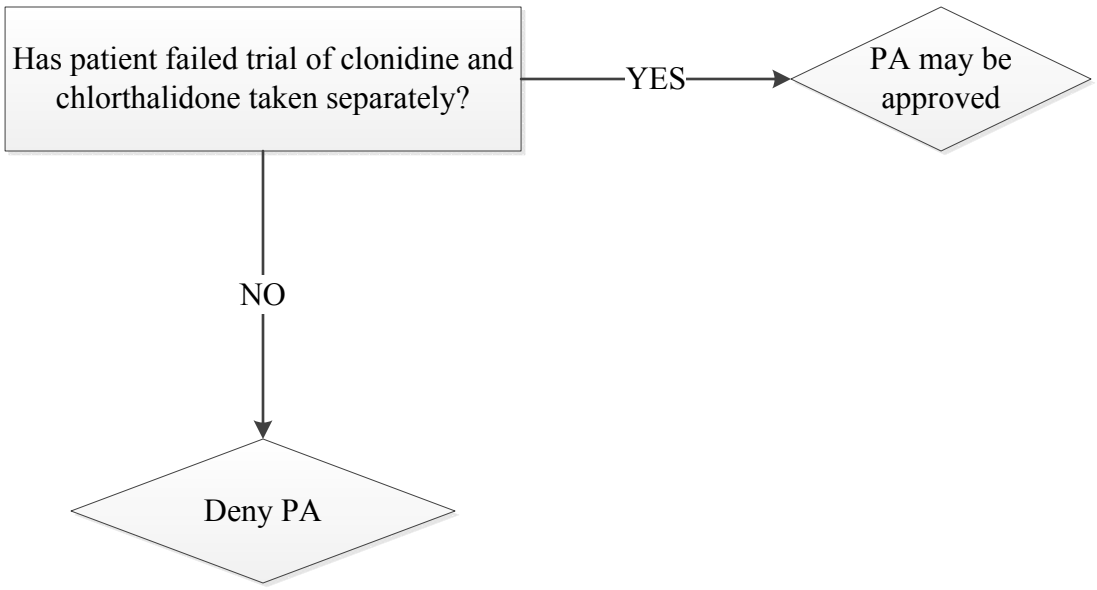
Part II: TO BE COMPLETED BY PHARMACY

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
Clorpres Authorization Algorithm



COMBINATION 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 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	

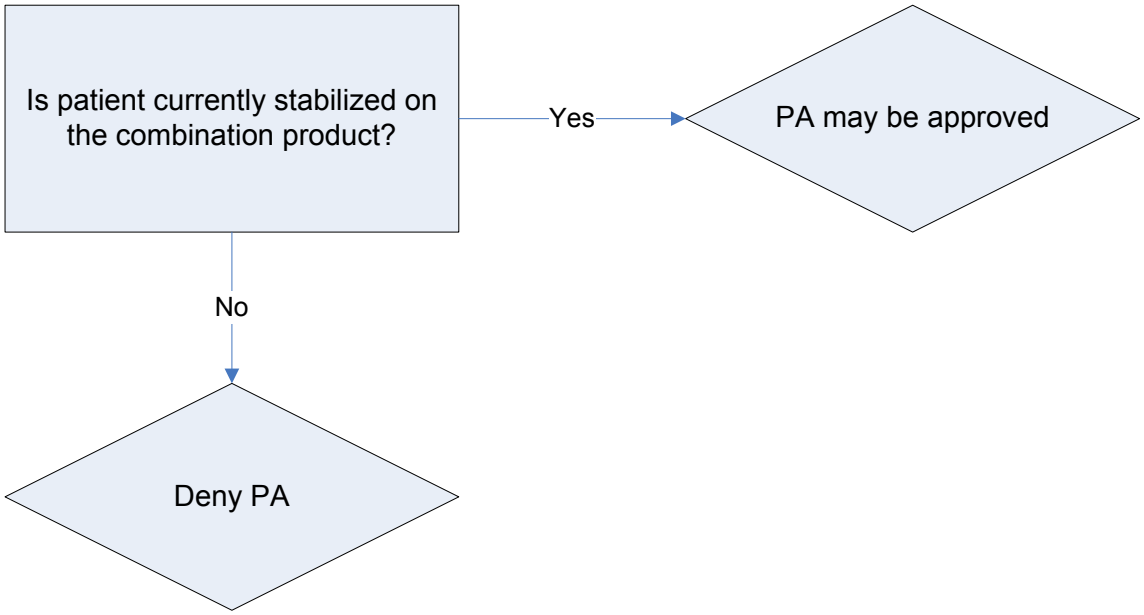
Part II: TO BE COMPLETED BY PHARMACY

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)	

North Dakota Department of Human Services
Combination Products
Prior Authorization Algorithm



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

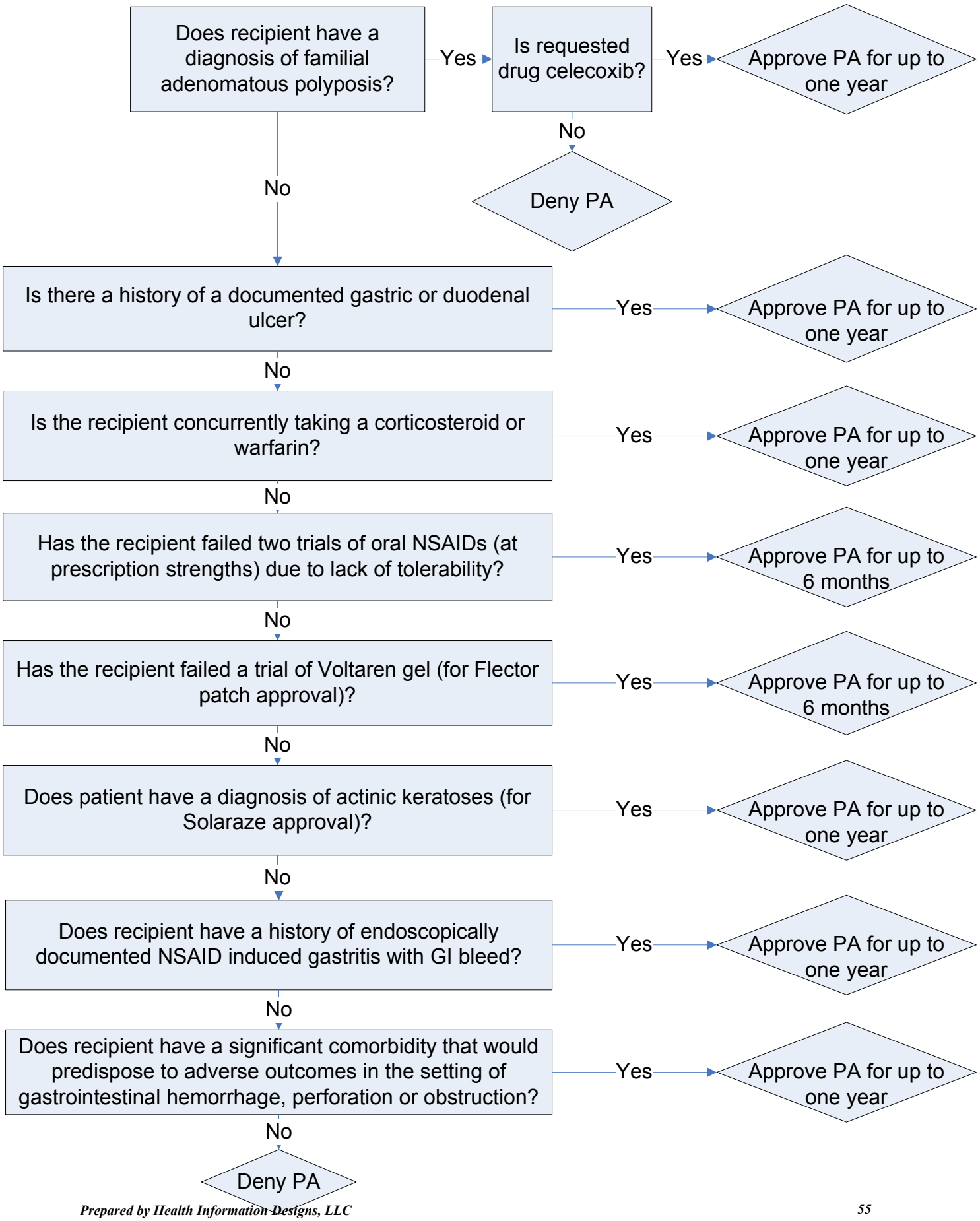
Part II: TO BE COMPLETED BY PHARMACY

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)	

North Dakota Department of Human Services
Name Brand NSAID/COX-II Authorization Algorithm



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	

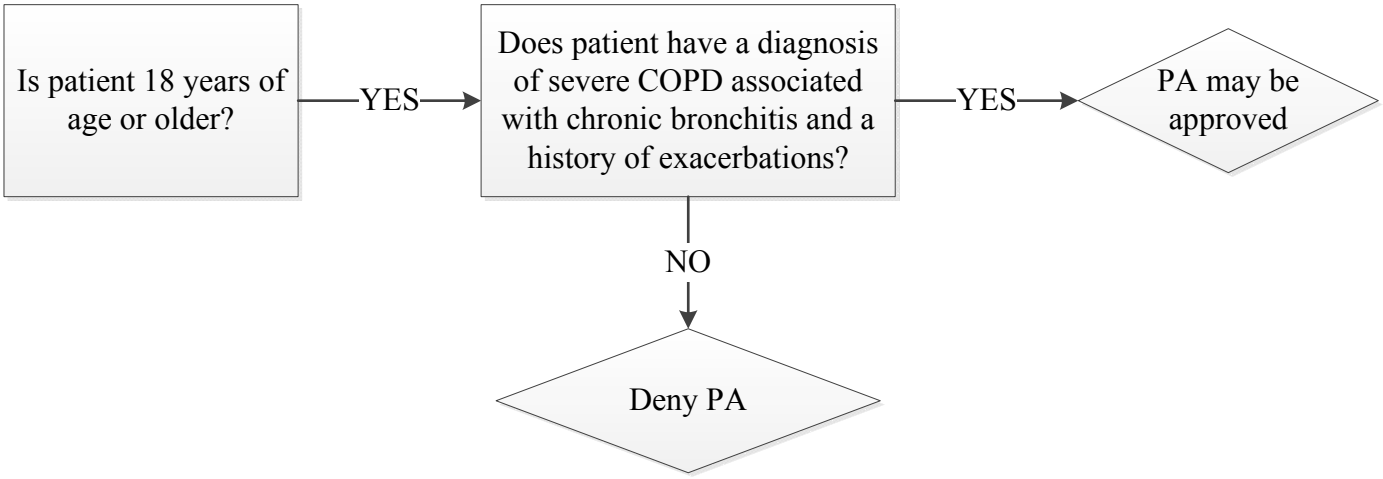
Part II: TO BE COMPLETED BY PHARMACY

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)	

North Dakota Department of Human Services
Daliresp Authorization Algorithm



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

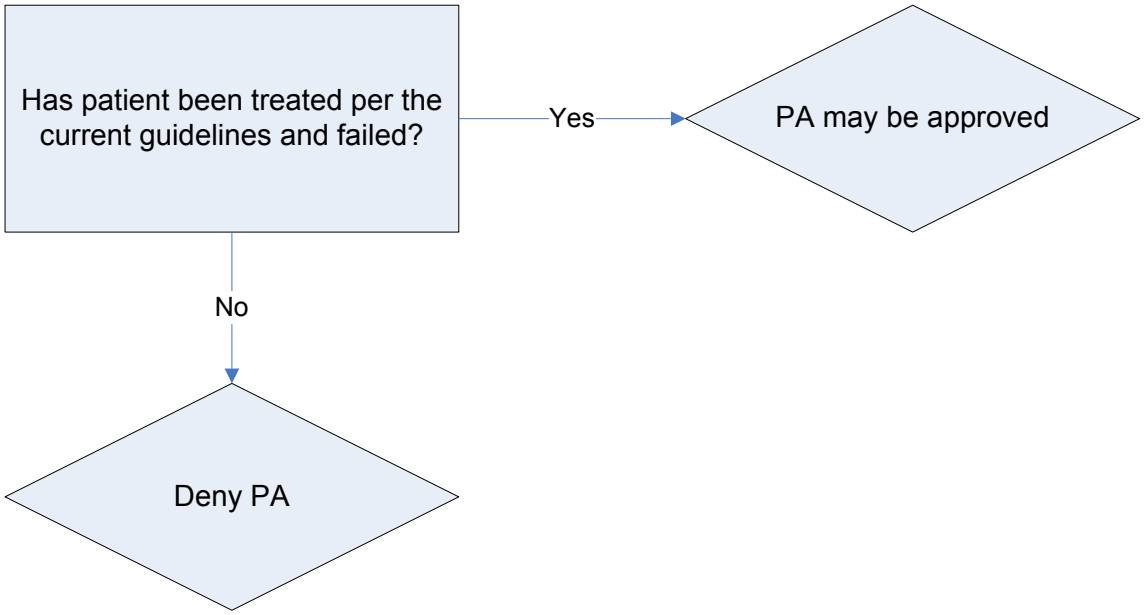
Part II: TO BE COMPLETED BY PHARMACY

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)	

North Dakota Department of Human Services
Dificid Prior Authorization Algorithm



- 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:
  - Initial episode (mild to moderate severity)-metronidazole
  - Initial episode (severe)-vancomycin*
  - Initial episode (severe, complicated)-vancomycin* and metronidazole)
  - First recurrence-same regimen as first episode
  - Second recurrence-oral vancomycin* in tapered regimen

*Compounded oral vancomycin is covered without prior authorization

*Metronidazole is covered without prior authorization

DEXPAK/ZEMAPAK 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 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	

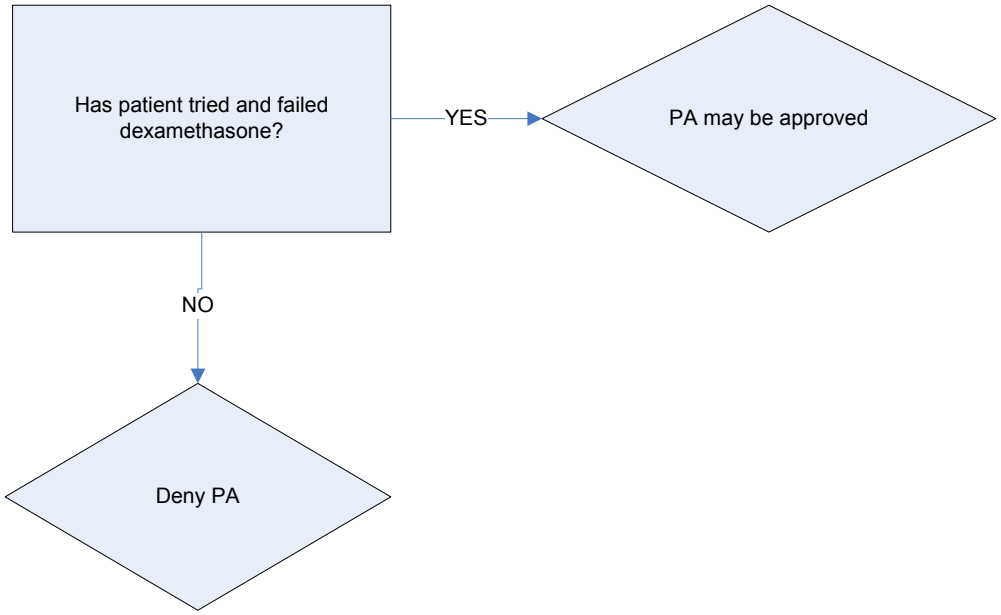
Part II: TO BE COMPLETED BY PHARMACY

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)	

North Dakota Department of Human Services
Dexpak/Zemapak Prior Authorization Algorithm



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	

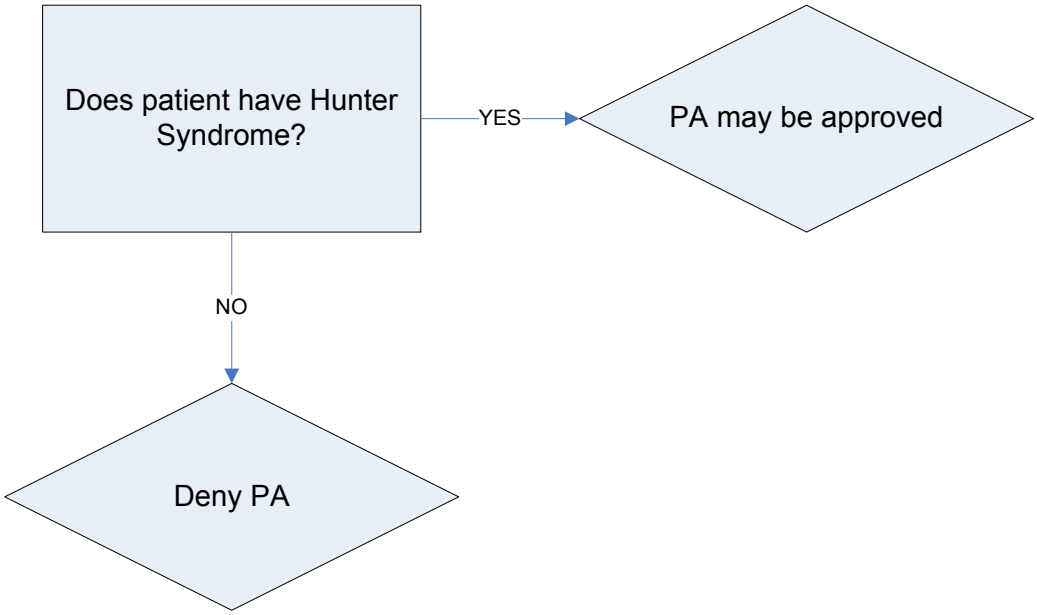
Part II: TO BE COMPLETED BY PHARMACY

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)	

North Dakota Department of Human Services
Elaprase Prior Authorization Algorithm



HEALTH INFORMATION DESIGNS

Prior Authorization Vendor for ND Medicaid

Fulyzaq
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 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		

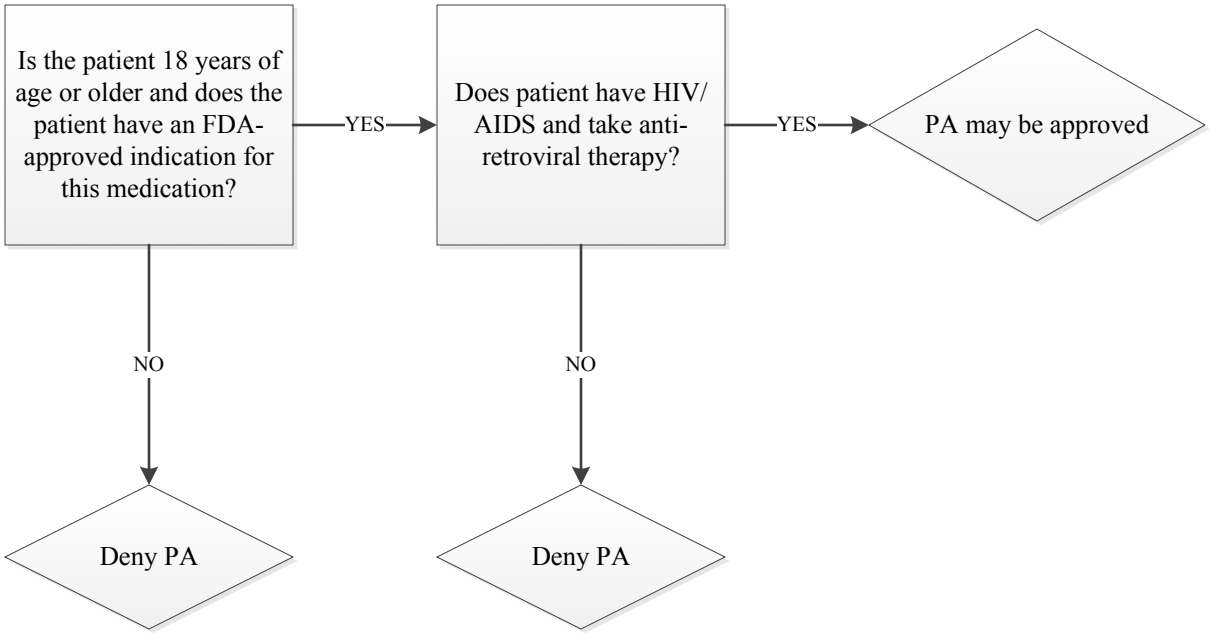
Part II: TO BE COMPLETED BY PHARMACY

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)	

North Dakota Department of Human Services
Fulyzaq Authorization Algorithm



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	

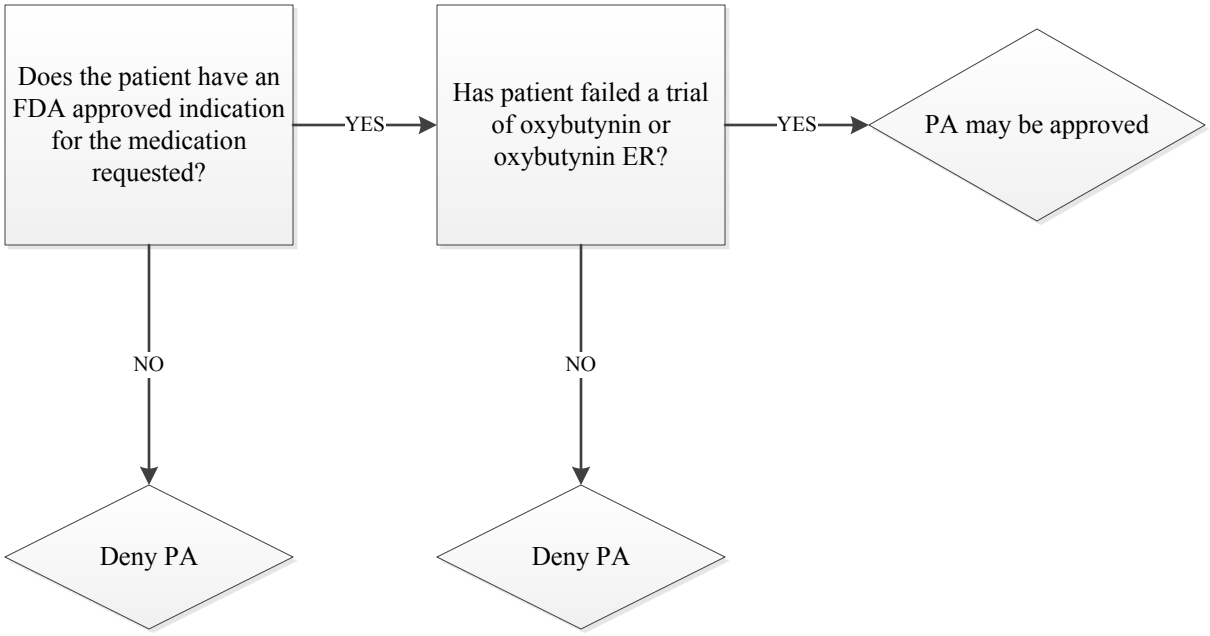
Part II: TO BE COMPLETED BY PHARMACY

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)	

North Dakota Department of Human Services
Genitourinary Smooth Muscle Relaxants
Authorization Algorithm



HEALTH INFORMATION DESIGNS

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

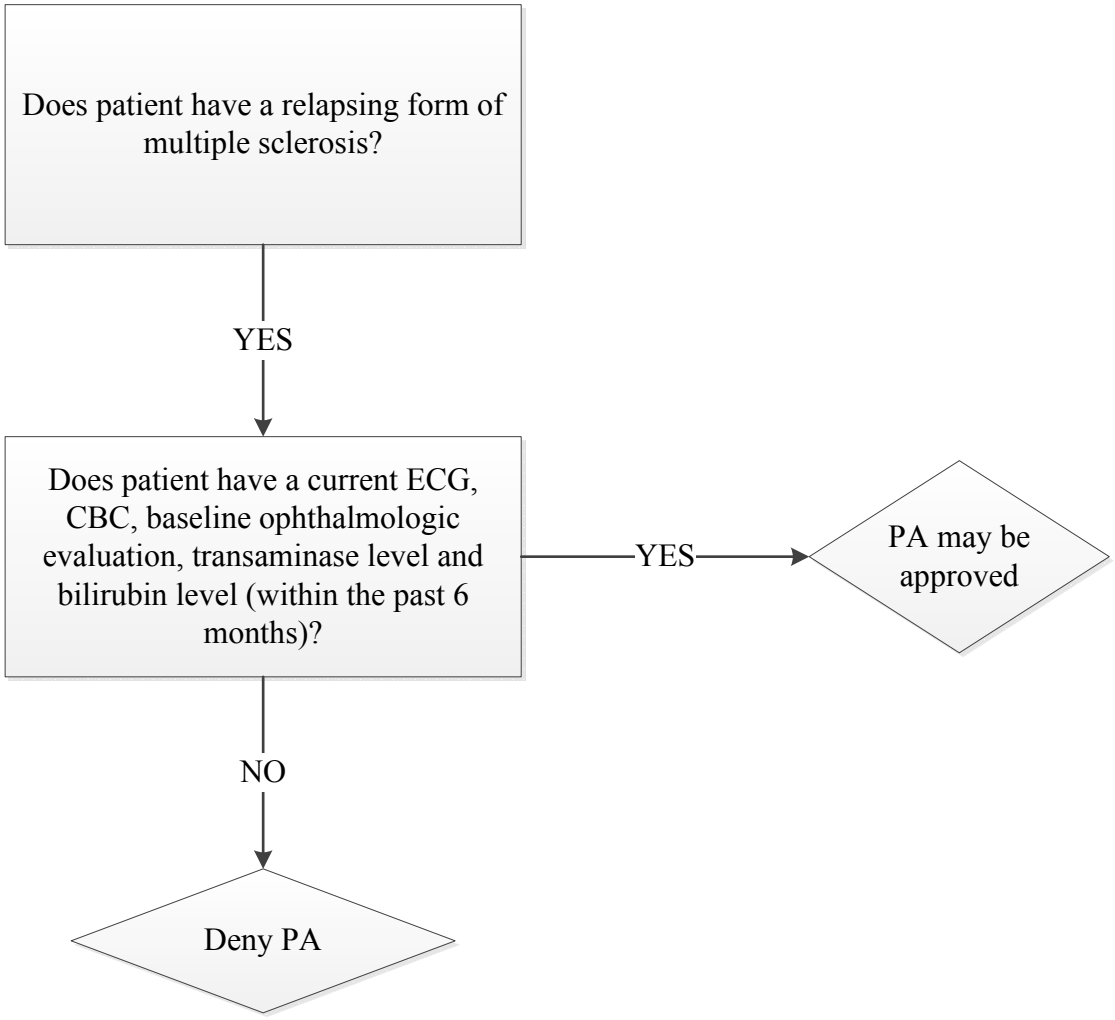
Part II: TO BE COMPLETED BY PHARMACY

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)	

North Dakota Department of Human Services
Gilenya Authorization Algorithm



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	

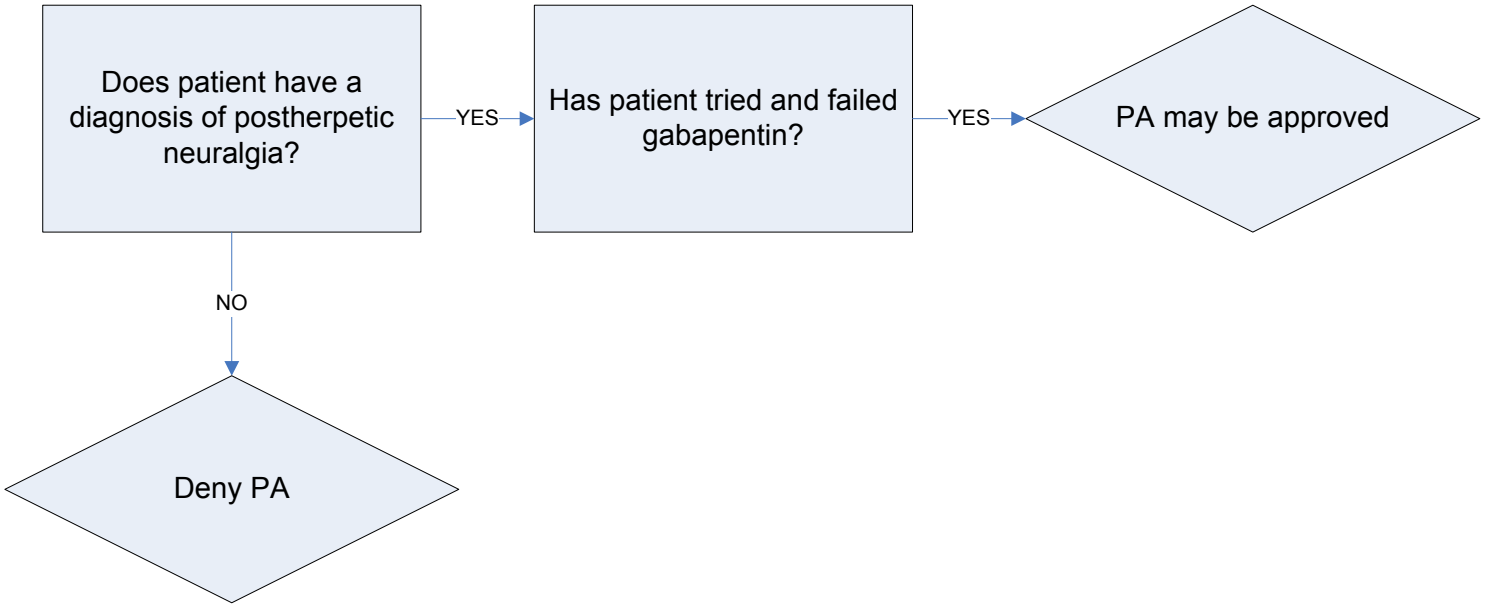
Part II: TO BE COMPLETED BY PHARMACY

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)	

North Dakota Department of Human Services
Gralise Prior Authorization Algorithm



Growth Hormone 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 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:	

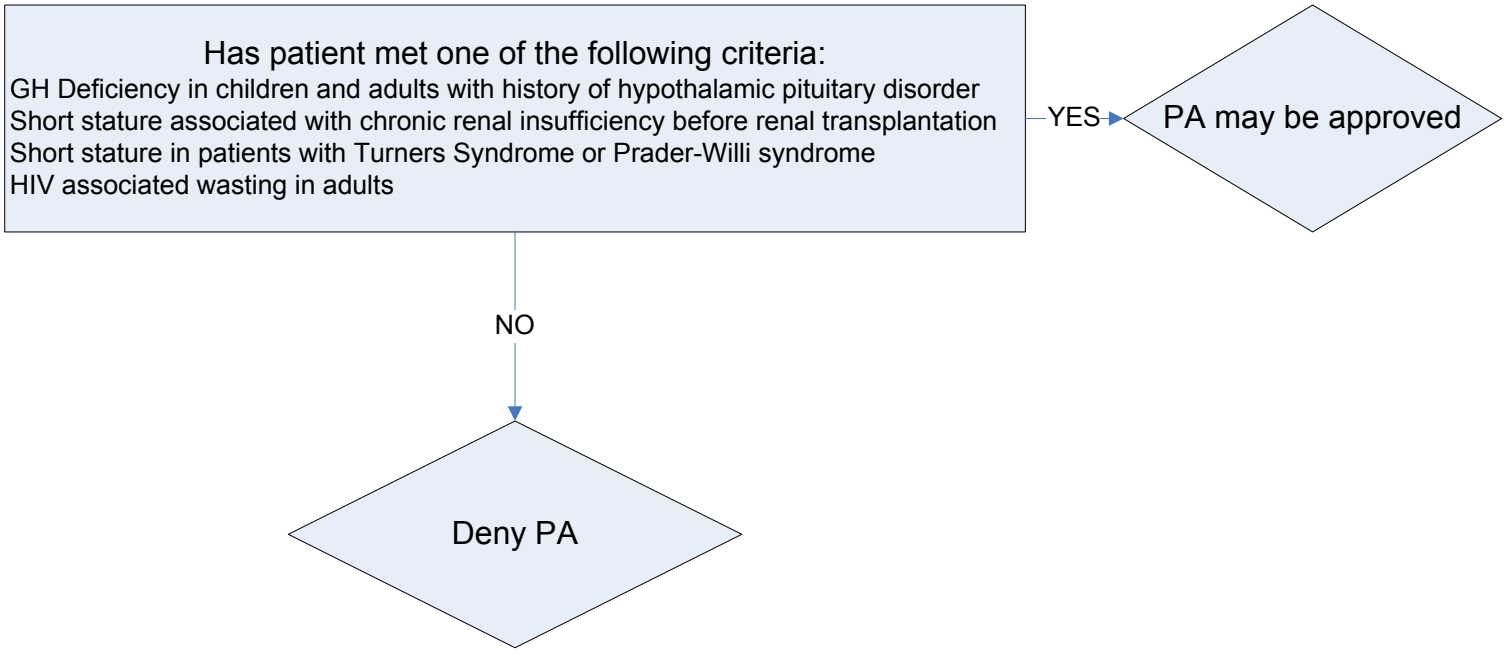
Part II: TO BE COMPLETED BY PHARMACY

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)	

North Dakota Department of Human Services
Growth Hormone Authorization Algorithm



HEALTH INFORMATION DESIGNS

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:** **Ribavirin dose:** **Peg-interferon dose:**	**Genotype:**	
Physician Signature		Date	

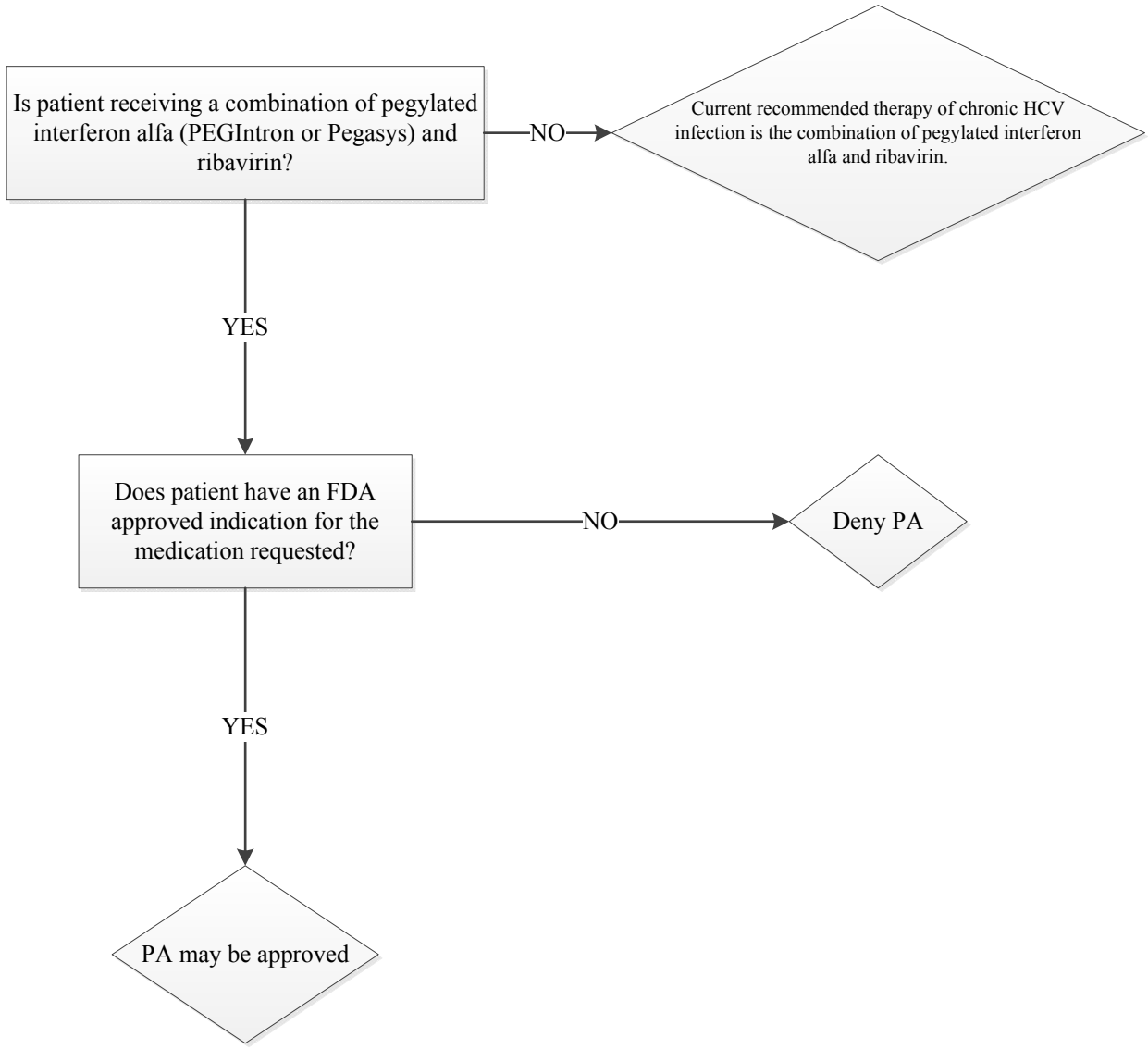
Part II: TO BE COMPLETED BY PHARMACY

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
Hepatitis C Virus (HCV) Medication Authorization Algorithm



HEREDITARY ANGIOEDEMA
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 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		

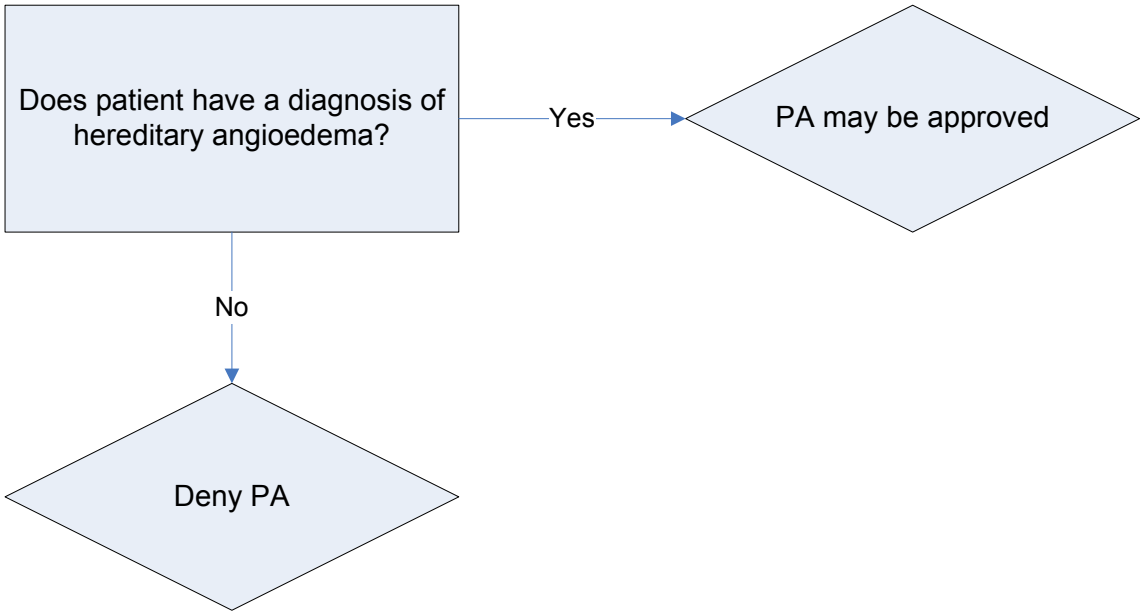
Part II: TO BE COMPLETED BY PHARMACY

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)	

North Dakota Department of Human Services
Hereditary Angioedema Prior Authorization Algorithm



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	

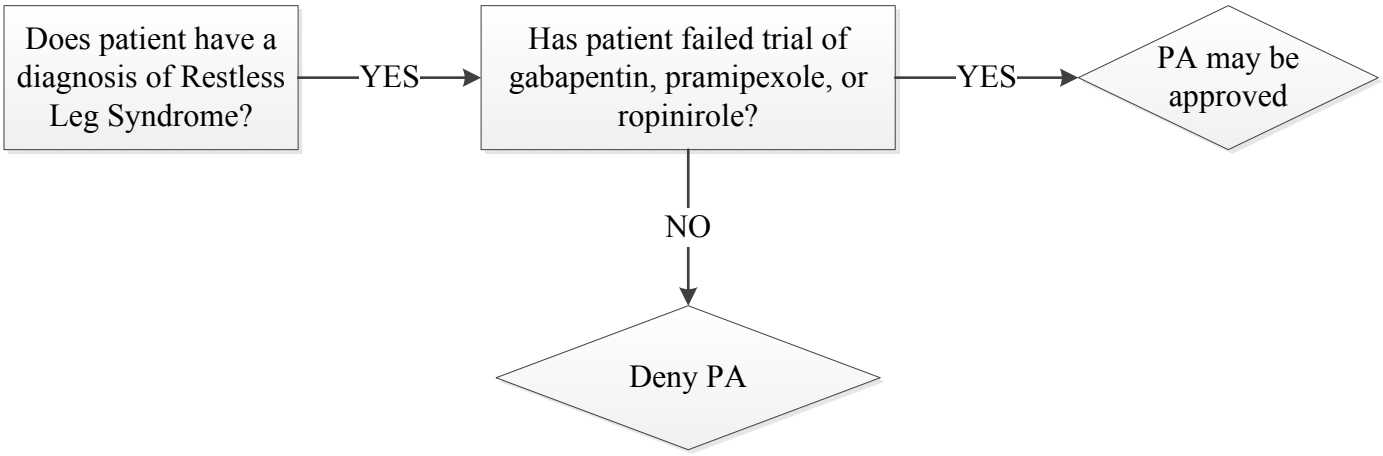
Part II: TO BE COMPLETED BY PHARMACY

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)	

North Dakota Department of Human Services
Horizant Authorization Algorithm



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

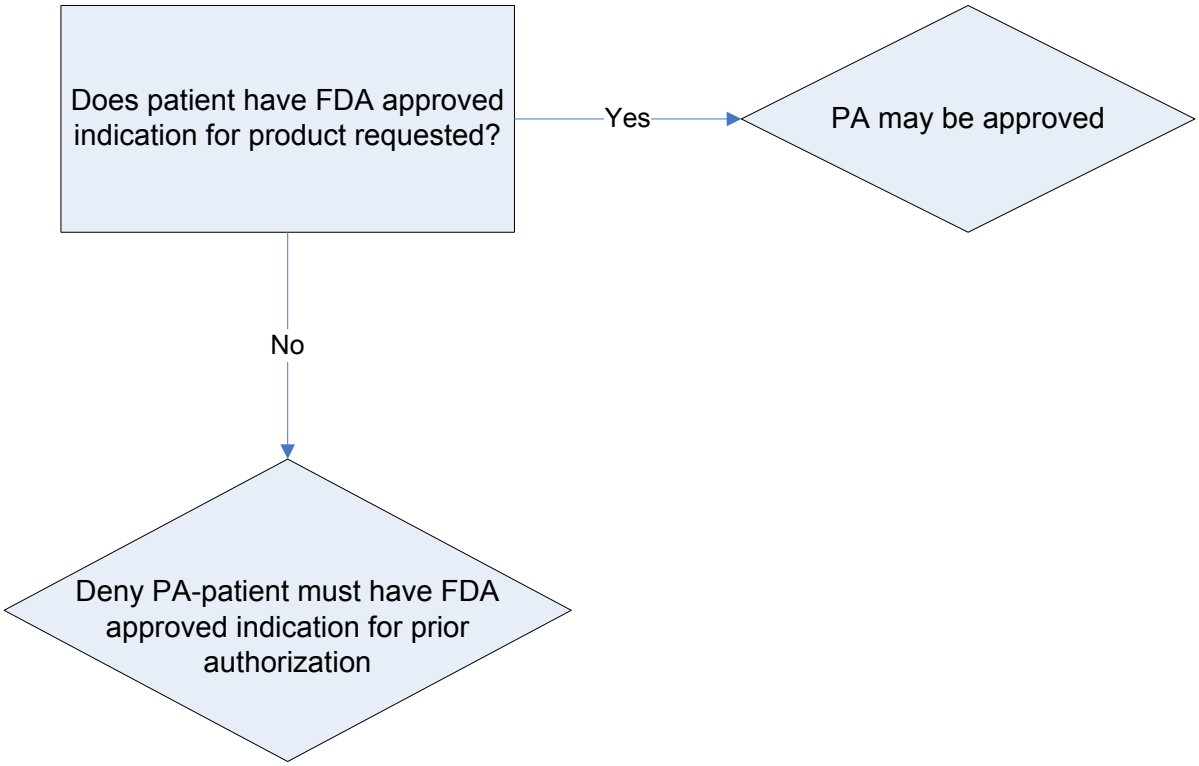
Part II: TO BE COMPLETED BY PHARMACY

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)	

North Dakota Department of Human Services
Targeted Immune Modulators Authorization Algorithm



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	

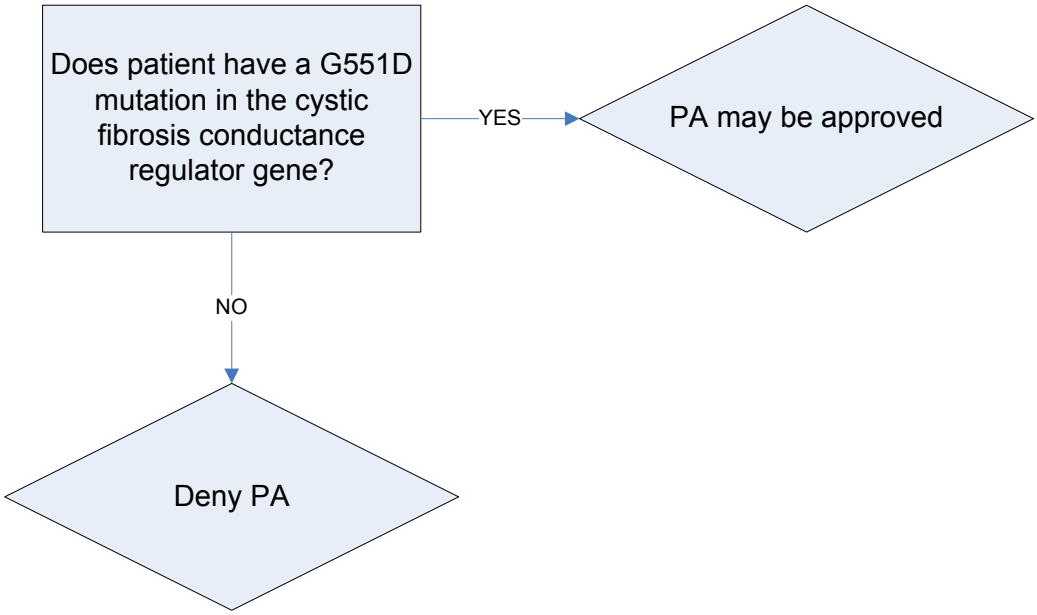
Part II: TO BE COMPLETED BY PHARMACY

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)	

North Dakota Department of Human Services
Kalydeco Prior Authorization Algorithm



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	

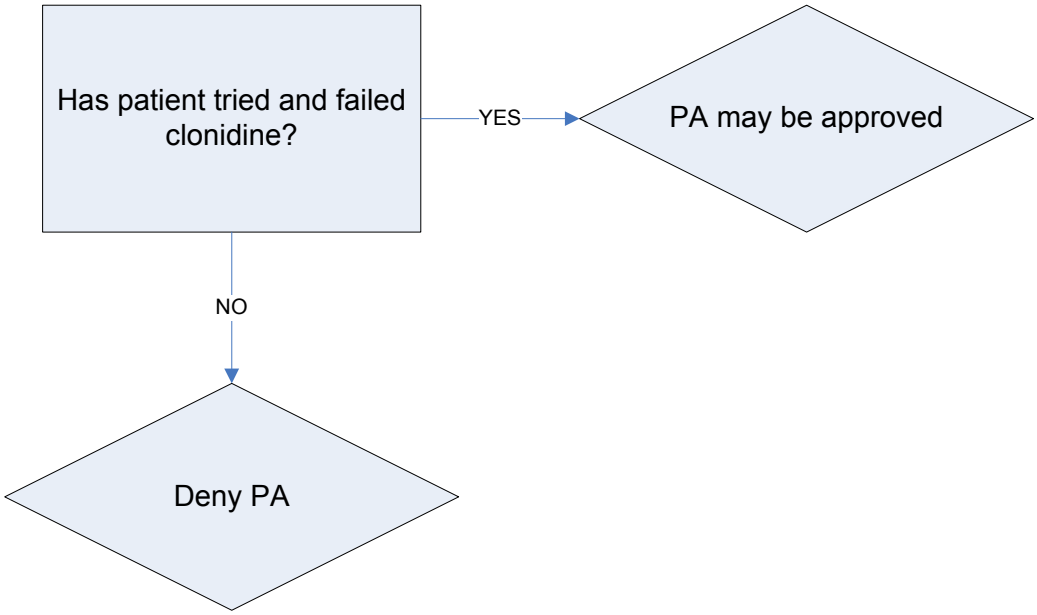
Part II: TO BE COMPLETED BY PHARMACY

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)	

North Dakota Department of Human Services
Kapvay Prior Authorization Algorithm



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:

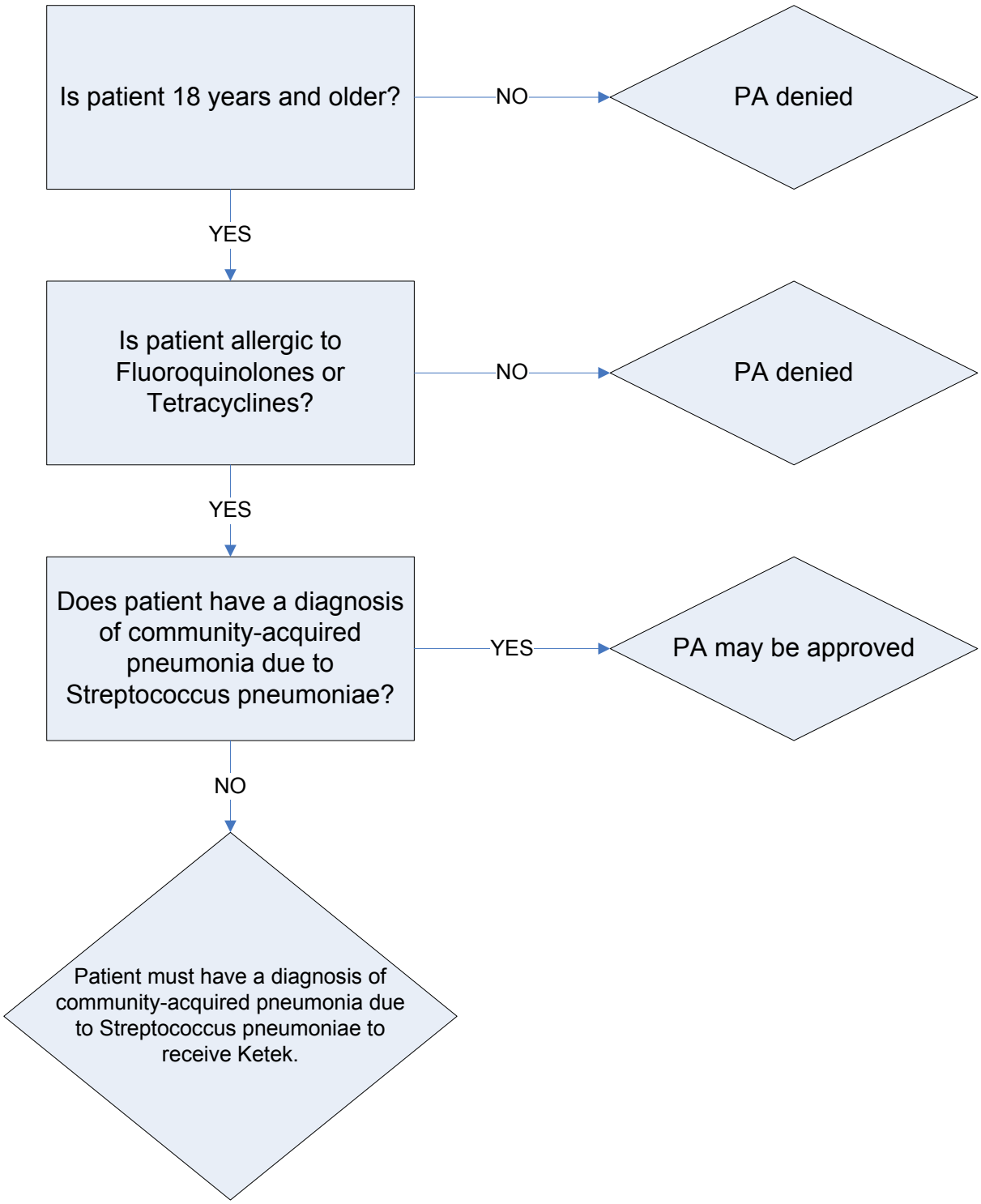
Part II: TO BE COMPLETED BY PHARMACY

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)	

North Dakota Department of Human Services
Ketek Criteria Algorithm



KUVAN 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 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	

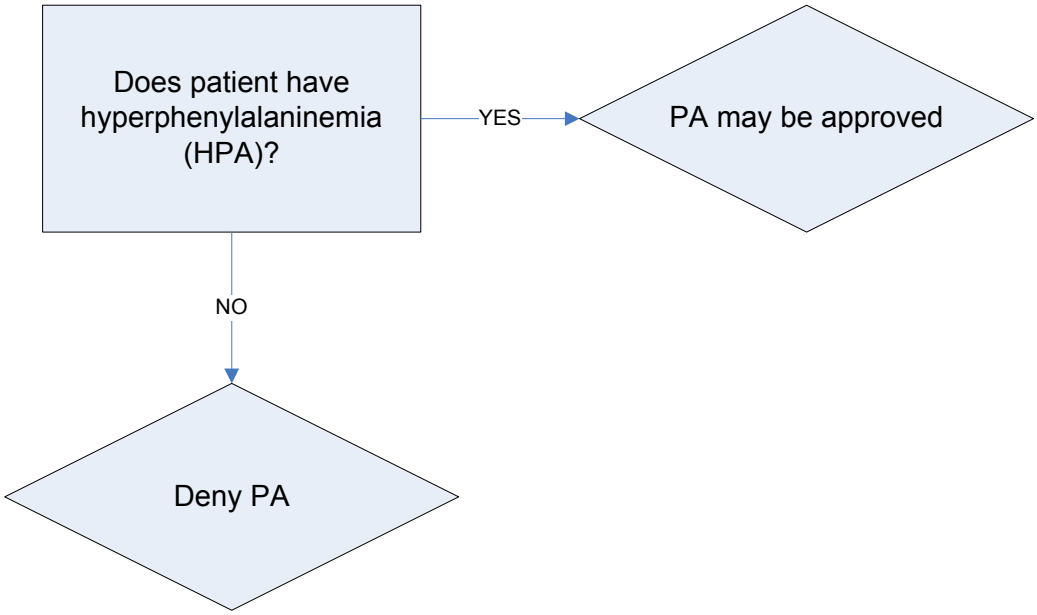
Part II: TO BE COMPLETED BY PHARMACY

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)	

North Dakota Department of Human Services
Kuvan Prior Authorization Algorithm



Livalo 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 Livalo must first try a covered statin medication
Note:

- ***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: □ **Livalo**	**Diagnosis for this request:**		
Qualifications for coverage:			
□ Medication Failed _____	Start Date: End Date:	Dose: Frequency:	
Physician Signature		Date	

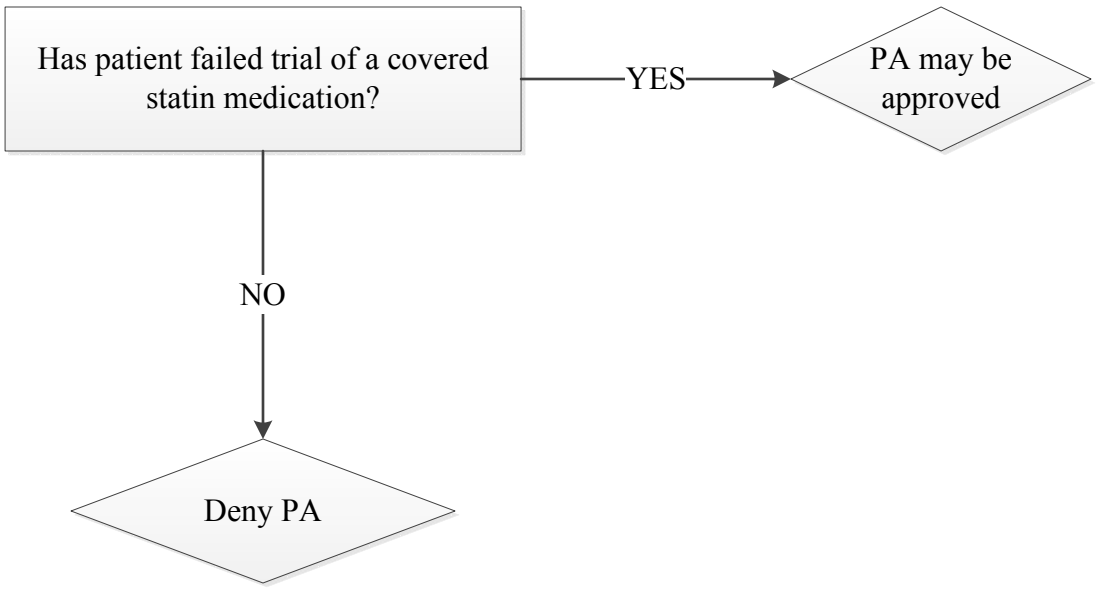
Part II: TO BE COMPLETED BY PHARMACY

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
Livalo Authorization Algorithm



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	

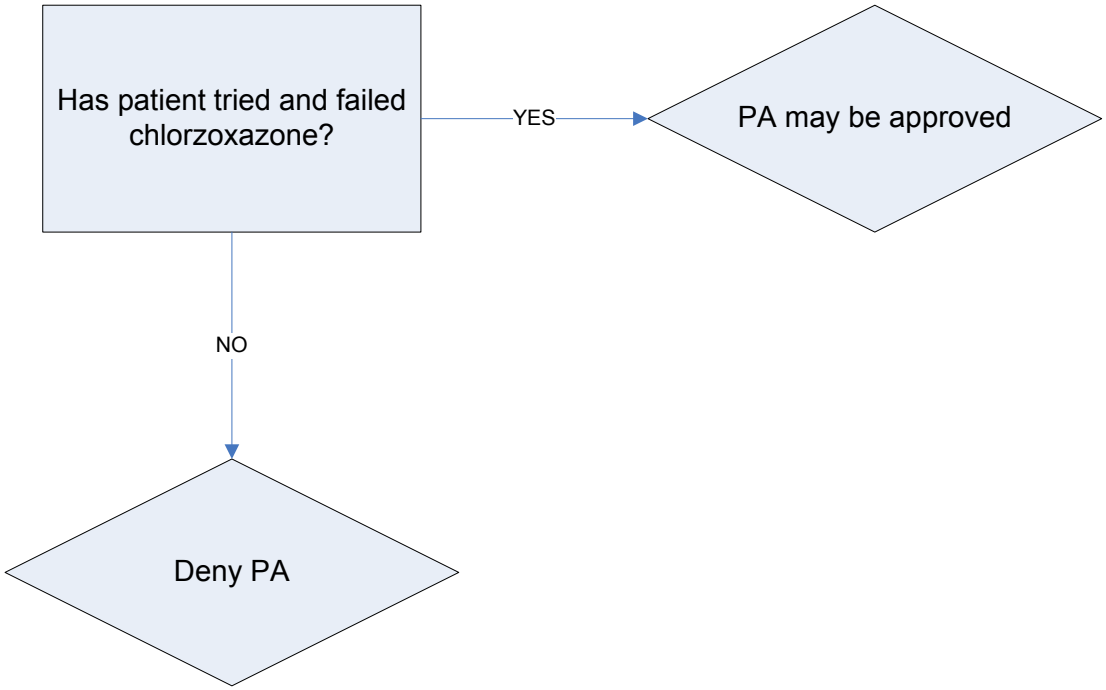
Part II: TO BE COMPLETED BY PHARMACY

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)	

North Dakota Department of Human Services
Lorzone Prior Authorization Algorithm



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	

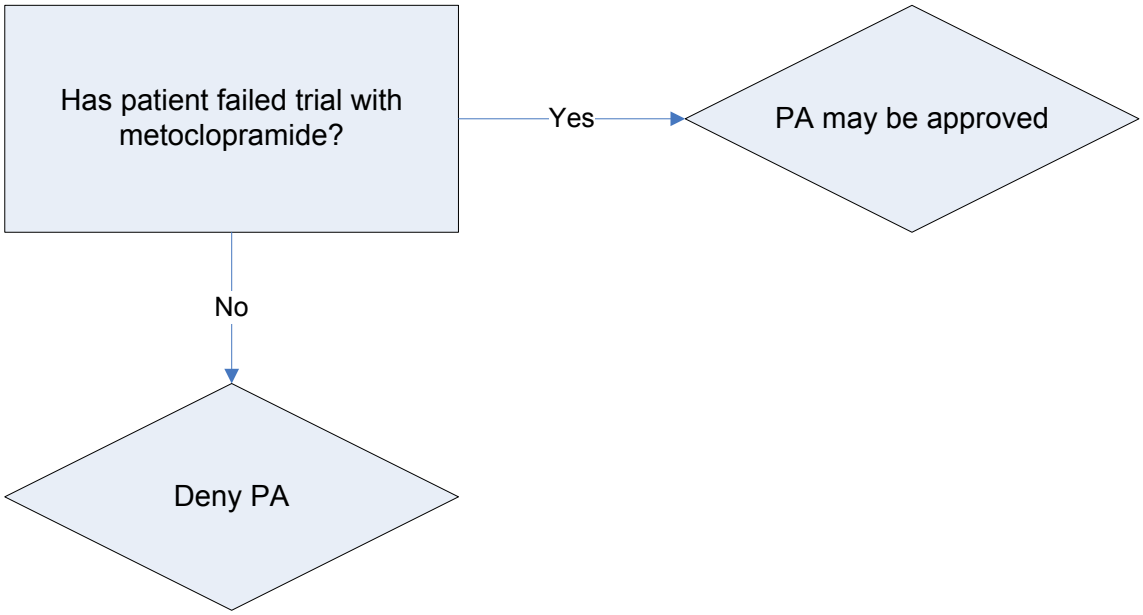
Part II: TO BE COMPLETED BY PHARMACY

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)	

North Dakota Department of Human Services
Metozolv Prior Authorization Algorithm



MOXATAG 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 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

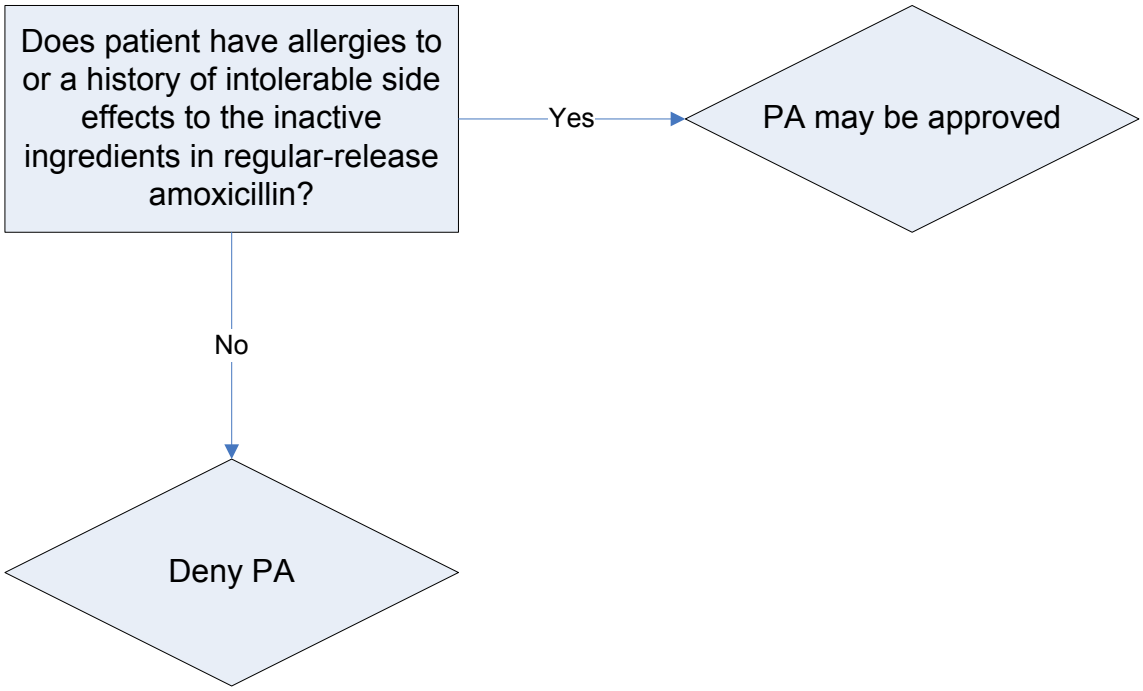
Part II: TO BE COMPLETED BY PHARMACY

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)	

North Dakota Department of Human Services
Moxatag Authorization Algorithm



Regular-release amoxicillin does not require a prior authorization and costs approximately $4.40 for a course of therapy compared to $84.40 for a course of Moxatag therapy.

MOXEZA 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 Moxeza must have a documented failure of a first line 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 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: □ MOXEZA	**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	

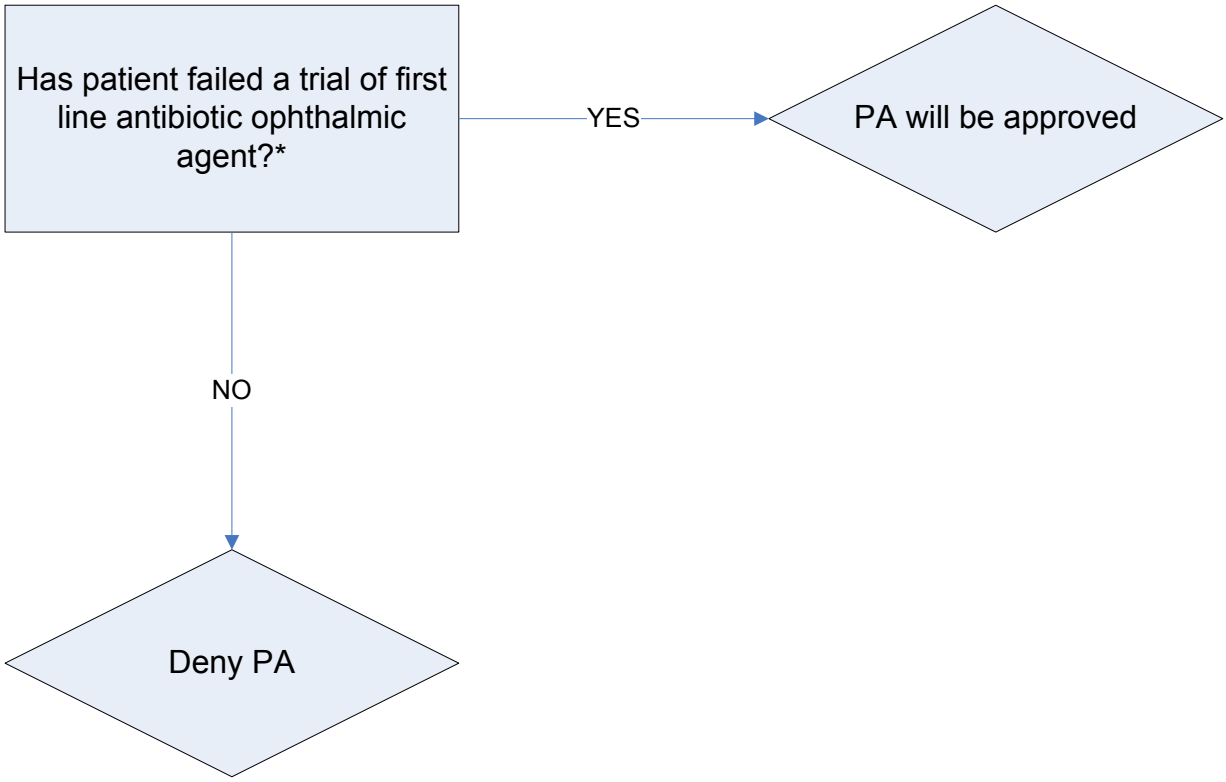
Part II: TO BE COMPLETED BY PHARMACY

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
Moxeza Authorization Algorithm



*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).

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

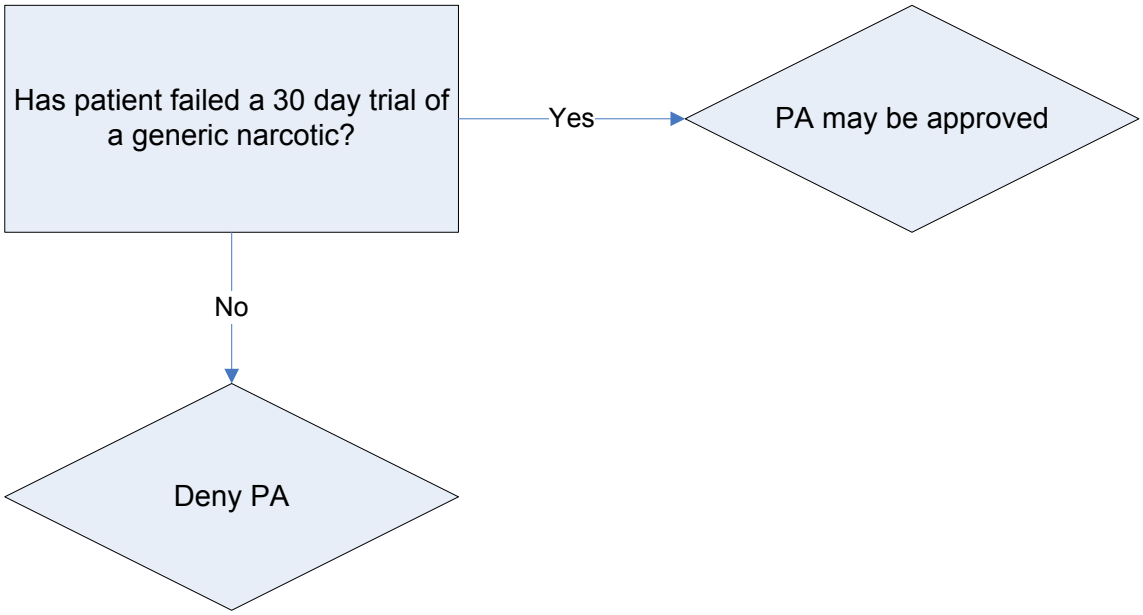
Part II: TO BE COMPLETED BY PHARMACY

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



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	

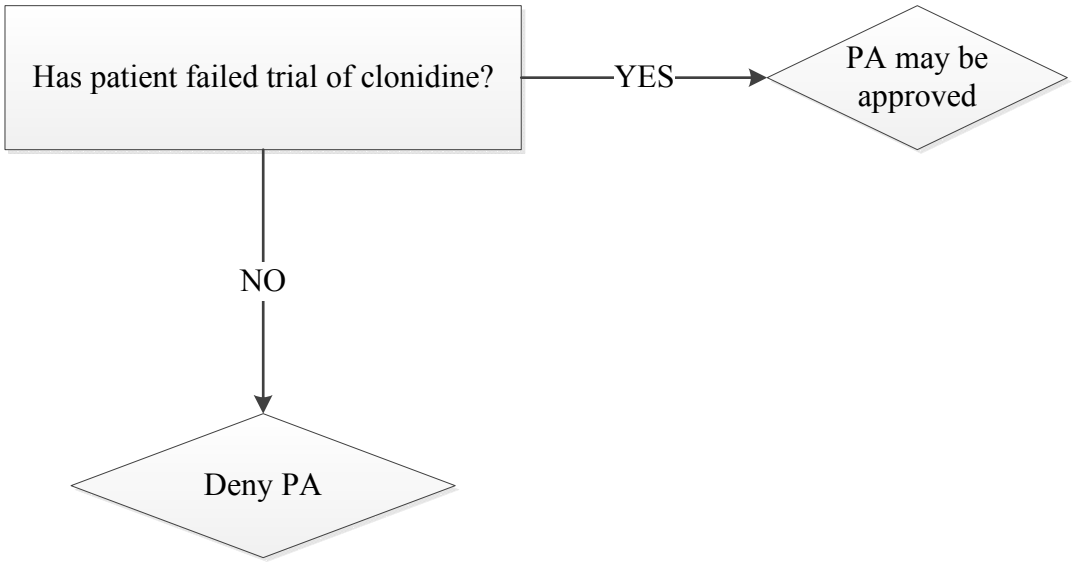
Part II: TO BE COMPLETED BY PHARMACY

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)	

North Dakota Department of Human Services
Nexiclon Authorization Algorithm



HEALTH INFORMATION DESIGNS

Prior Authorization Vendor for ND Medicaid

Nucynta 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 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	

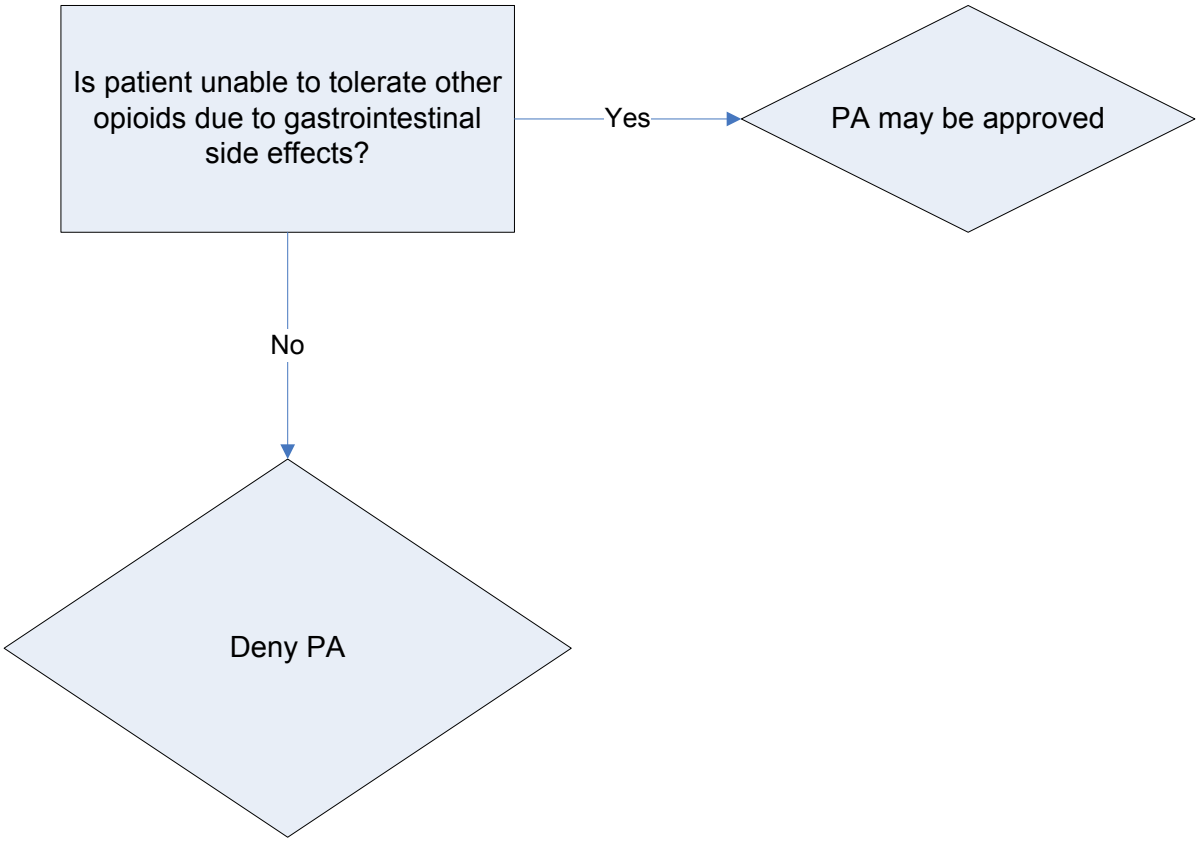
Part II: TO BE COMPLETED BY PHARMACY

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)	

North Dakota Department of Human Services
Nucynta Authorization Algorithm



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	

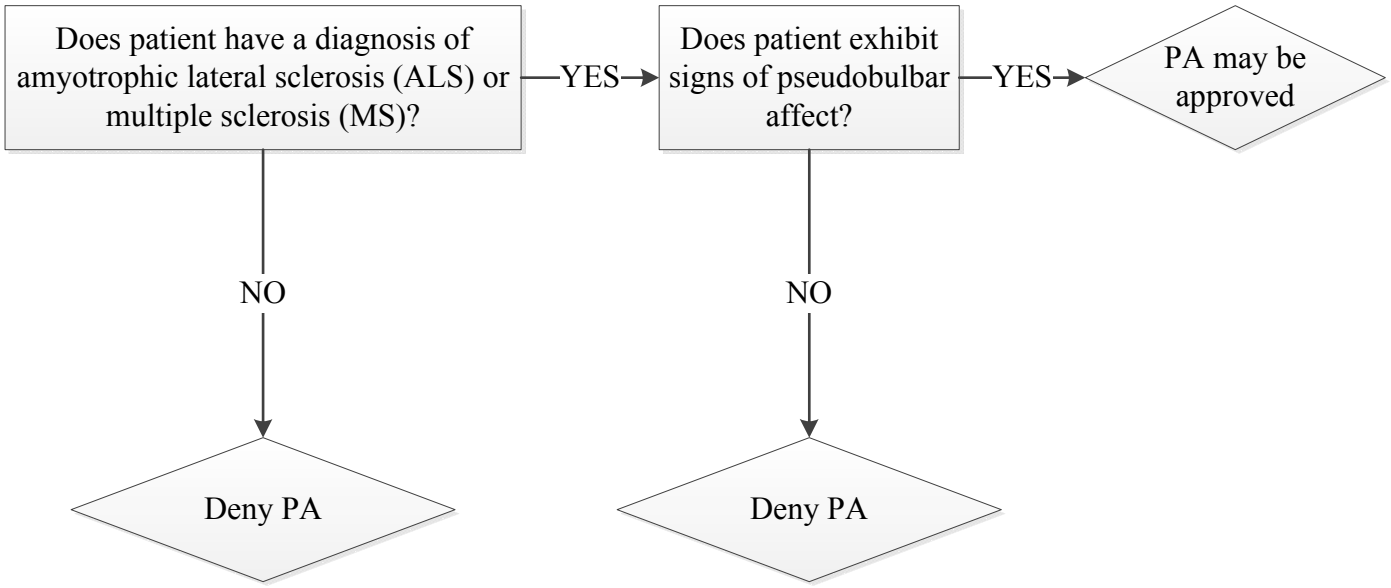
Part II: TO BE COMPLETED BY PHARMACY

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)	

North Dakota Department of Human Services
Nuedexta Authorization Algorithm



HEALTH INFORMATION DESIGNS

Prior Authorization Vendor for ND Medicaid

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 Nuvigil must suffer from excessive sleepiness associated with obstructive sleep apnea/hypopnea syndrome, narcolepsy, or shift work disorder.

- **Provigil 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: □ **Nuvigil**	**Diagnosis for this request:**		
Qualifications for coverage:			
□ FAILED PROVIGIL (MODAFINIL)	START DATE: END DATE:	DOSE: FREQUENCY:	
□ EXCESSIVE SLEEPINESS ASSOCIATED WITH OBSTRUCTIVE SLEEP APNEA/HYPOPNEA SYNDROME □ NARCOLEPSY □ SHIFT WORK SLEEP DISORDER			
Prescriber Signature		Date	

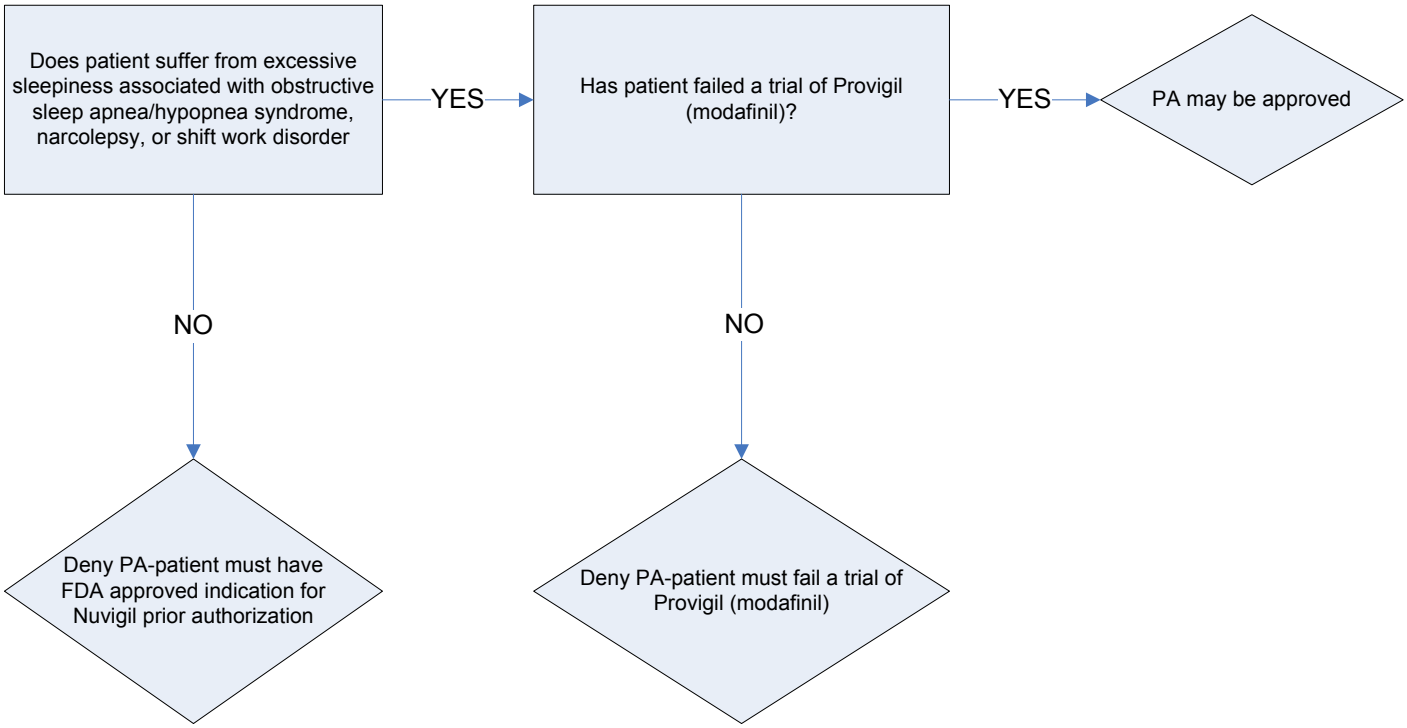
Part II: TO BE COMPLETED BY PHARMACY

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)	

North Dakota Department of Human Services
Nuvigil Authorization Algorithm



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	

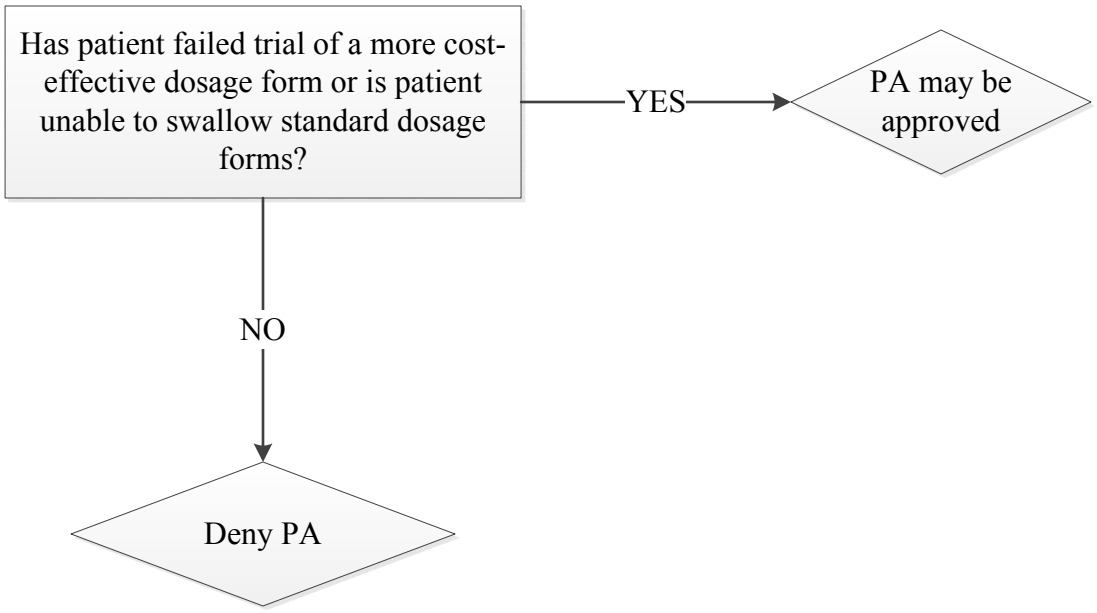
Part II: TO BE COMPLETED BY PHARMACY

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)	

North Dakota Department of Human Services
Orally Disintegrating Tablets (ODT) Authorization Algorithm



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	

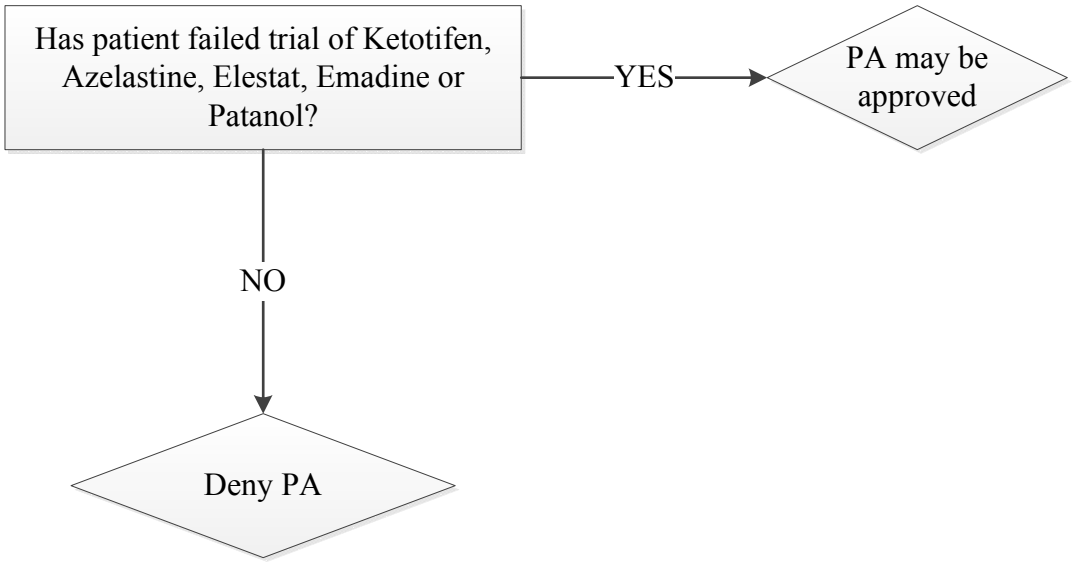
Part II: TO BE COMPLETED BY PHARMACY

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)	

North Dakota Department of Human Services
Ophthalmic Antihistamine Authorization Algorithm



OPHTHALMIC ANTI-INFECTIVE 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 will not pay for Azasite or Quixin 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 □ 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		

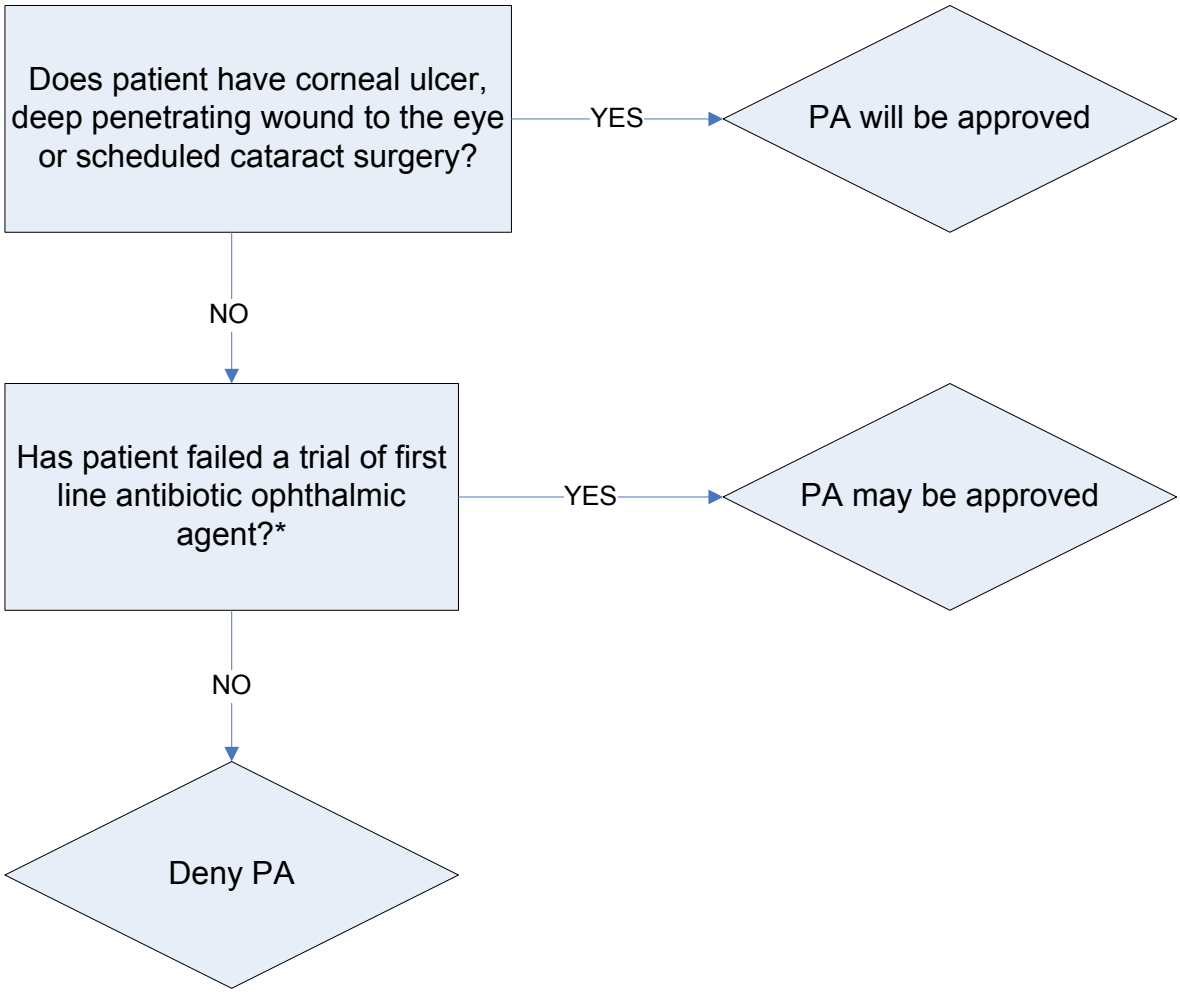
Part II: TO BE COMPLETED BY PHARMACY

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)	

North Dakota Department of Human Services
Ophthalmic Anti-infective Authorization Algorithm



*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).

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:

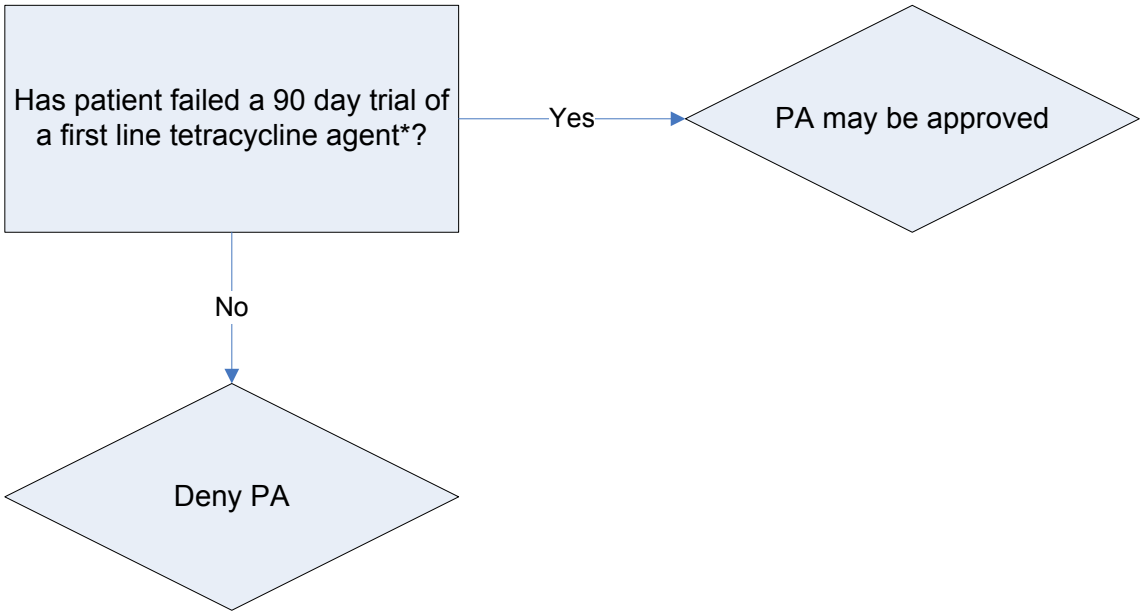
Part II: TO BE COMPLETED BY PHARMACY

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)	

North Dakota Department of Human Services
Doryx and Oracea Prior Authorization Algorithm



**Doxycycline, minocycline, and tetracycline do not require a PA and cost approximately $3 - $40 for a course of therapy compared to $353 dollars for Oracea and $331 dollars for Doryx.

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		

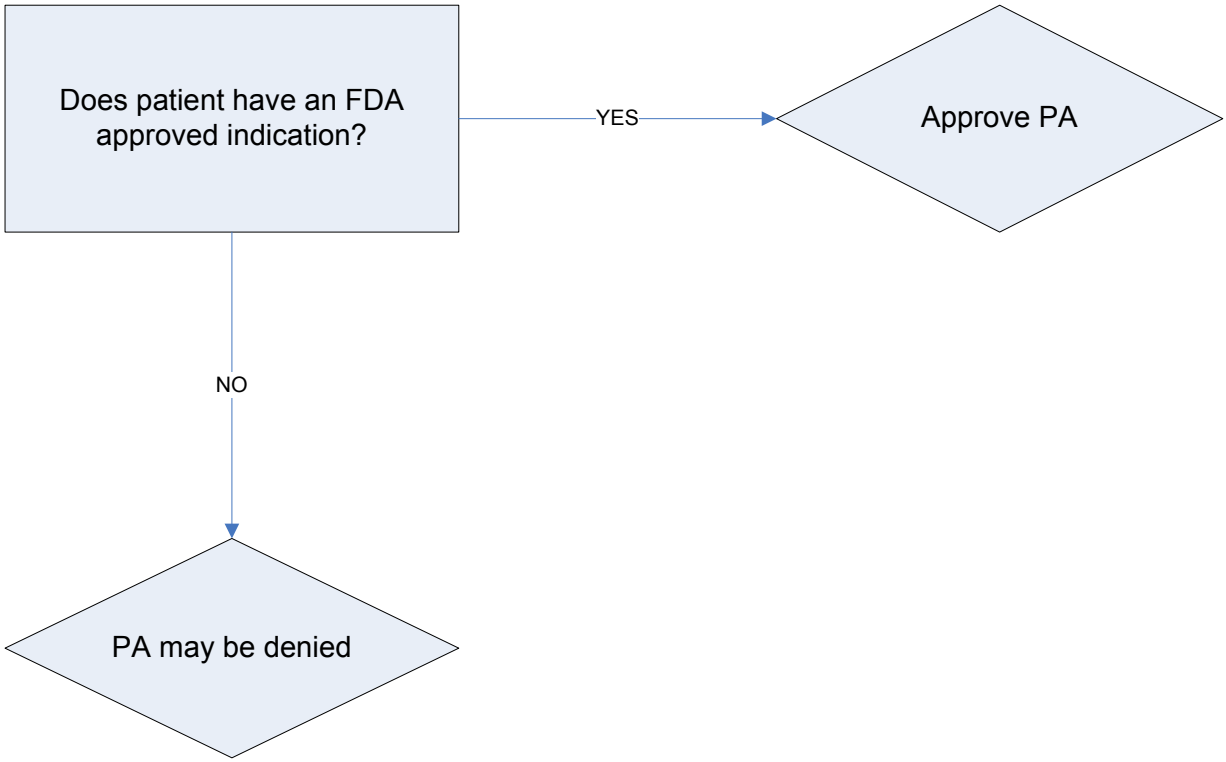
Part II: TO BE COMPLETED BY PHARMACY

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)	

North Dakota Department of Human Services
Oral Anticoagulants Prior Authorization Algorithm



- Pradaxa is indicated to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation.
- Xarelto is indicated to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation.
- Xarelto is indicated for the treatment of deep vein thrombosis (DVT), pulmonary embolism (PE), and for the reduction in the risk of recurrence of DVT and of PE.
- Xarelto is indicated for the prophylaxis of DVT, which may lead to PE in patients undergoing knee or hip replacement surgery.
- Eliquis is indicated to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation.

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	

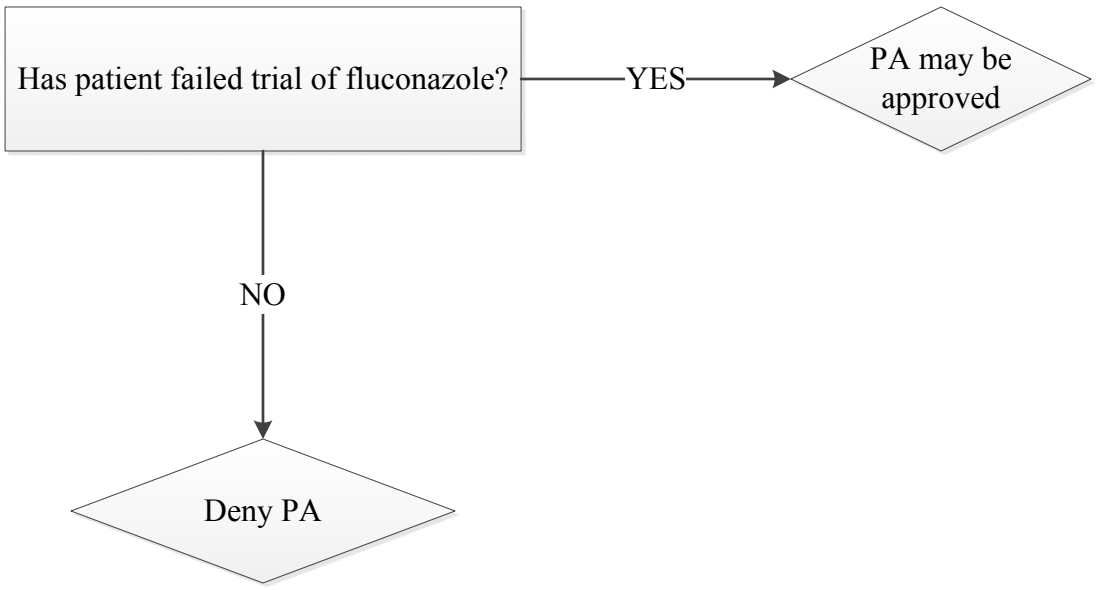
Part II: TO BE COMPLETED BY PHARMACY

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)	

North Dakota Department of Human Services
Oravig Authorization Algorithm



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

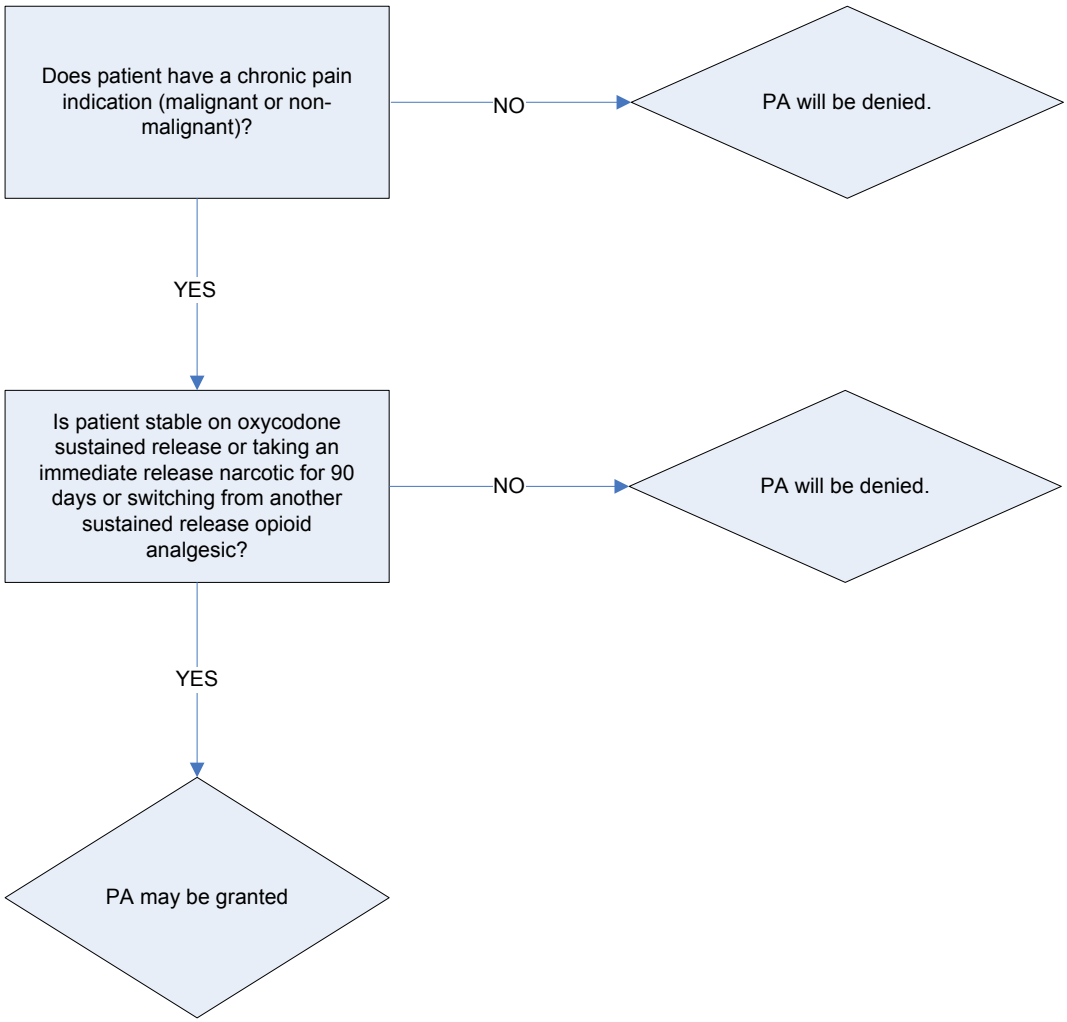
PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #

Part III: FOR OFFICIAL USE ONLY

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

North Dakota Department of Human Services

Oxycodone CR Prior Authorization Criteria Algorithm



HEALTH INFORMATION DESIGNS

Prior Authorization Vendor for ND Medicaid

Proton Pump Inhibitor 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 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:

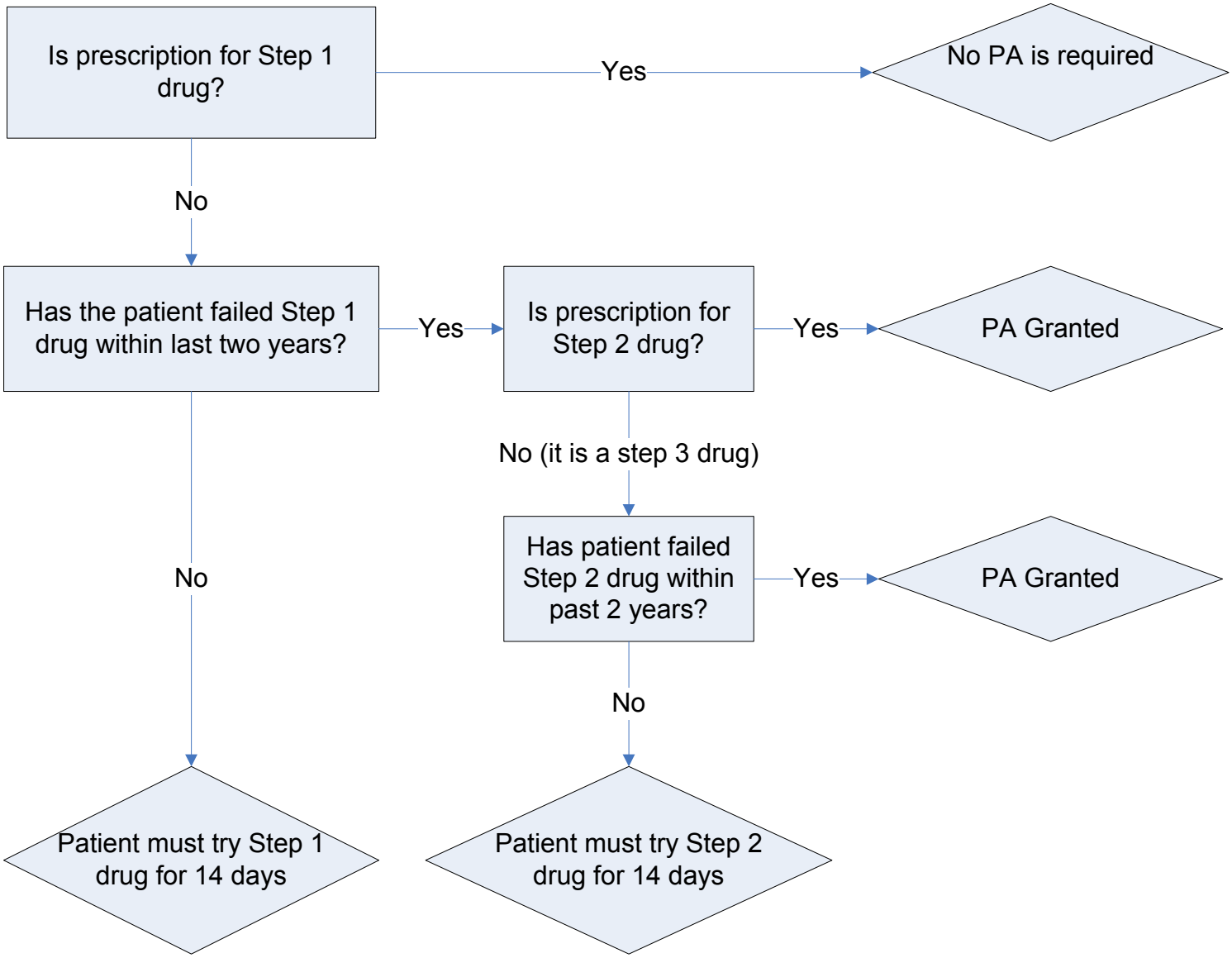
Part II: TO BE COMPLETED BY PHARMACY

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)	

North Dakota Department of Human Services
Proton Pump Inhibitor Authorization Criteria Algorithm



Please Note:

Step 1 drug is defined as Prilosec OTC, Prevacid 24HR, omeprazole, and pantoprazole

Step 2 drug is defined as lansoprazole

Step 3 drug is defined as Nexium, Aciphex, Zegerid and Dexilant (which is 5-8 times more expensive)

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	

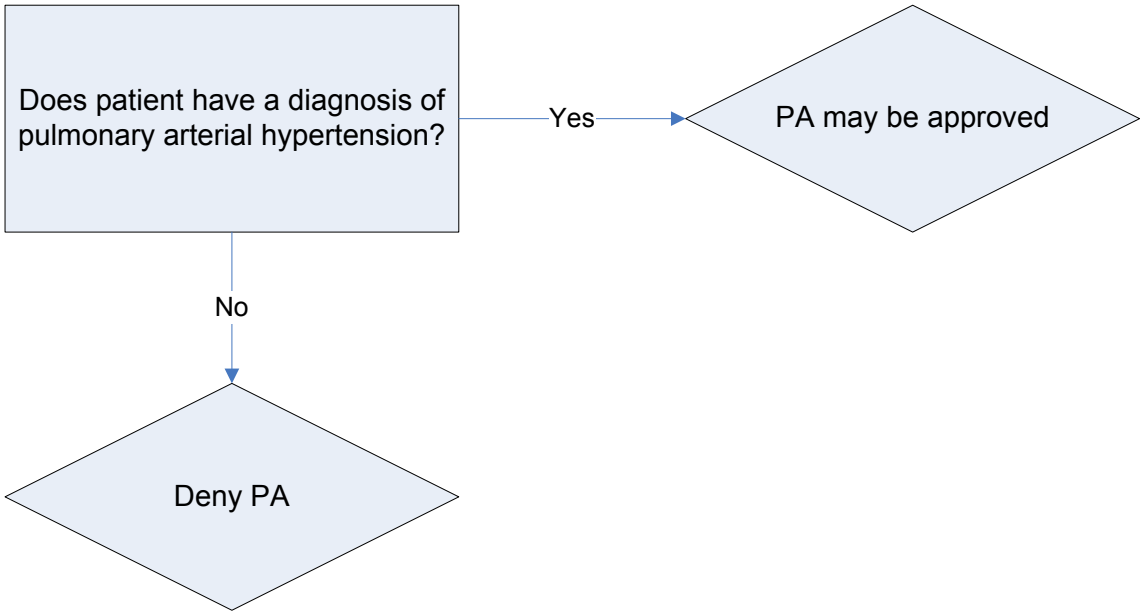
Part II: TO BE COMPLETED BY PHARMACY

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)	

North Dakota Department of Human Services
Pulmonary Arterial Hypertension Agents
Prior Authorization Algorithm



PROVIGIL 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 Provigil must meet the following criteria:

- **Patient must suffer from excessive sleepiness associated with narcolepsy, obstructive sleep apnea, or shift work disorder.**

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: □ PROVIGIL	**Diagnosis for this Request:**		
QUALIFICATIONS FOR COVERAGE: □ Narcolepsy - Sleep study must be attached □ Obstructive Sleep Apnea - Sleep study must be attached □ Shift Work Sleep Disorder – Current shift schedule must be attached			
□ *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	

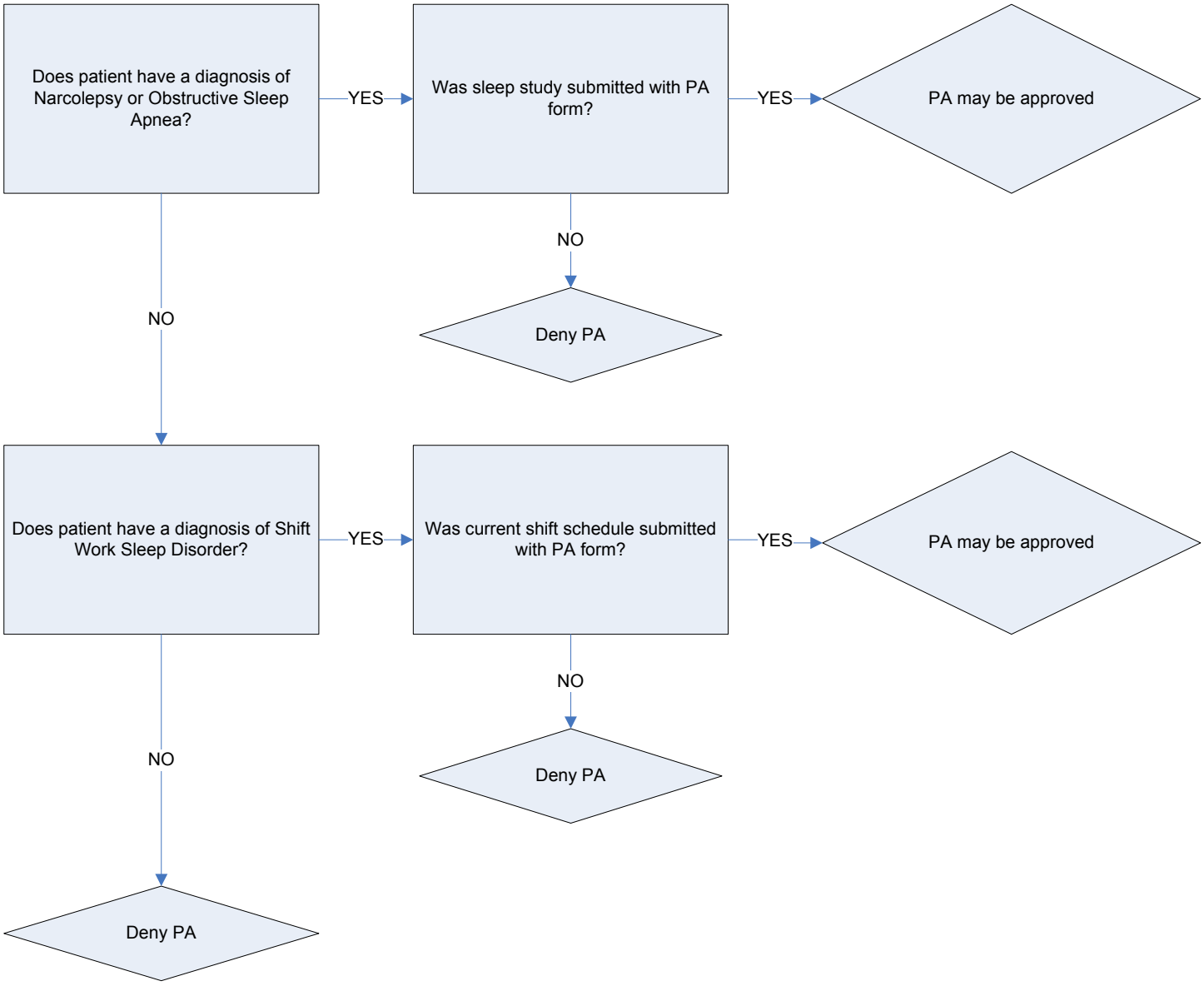
Part II: TO BE COMPLETED BY PHARMACY

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
Provigil Prior Authorization Algorithm



HEALTH INFORMATION DESIGNS

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:

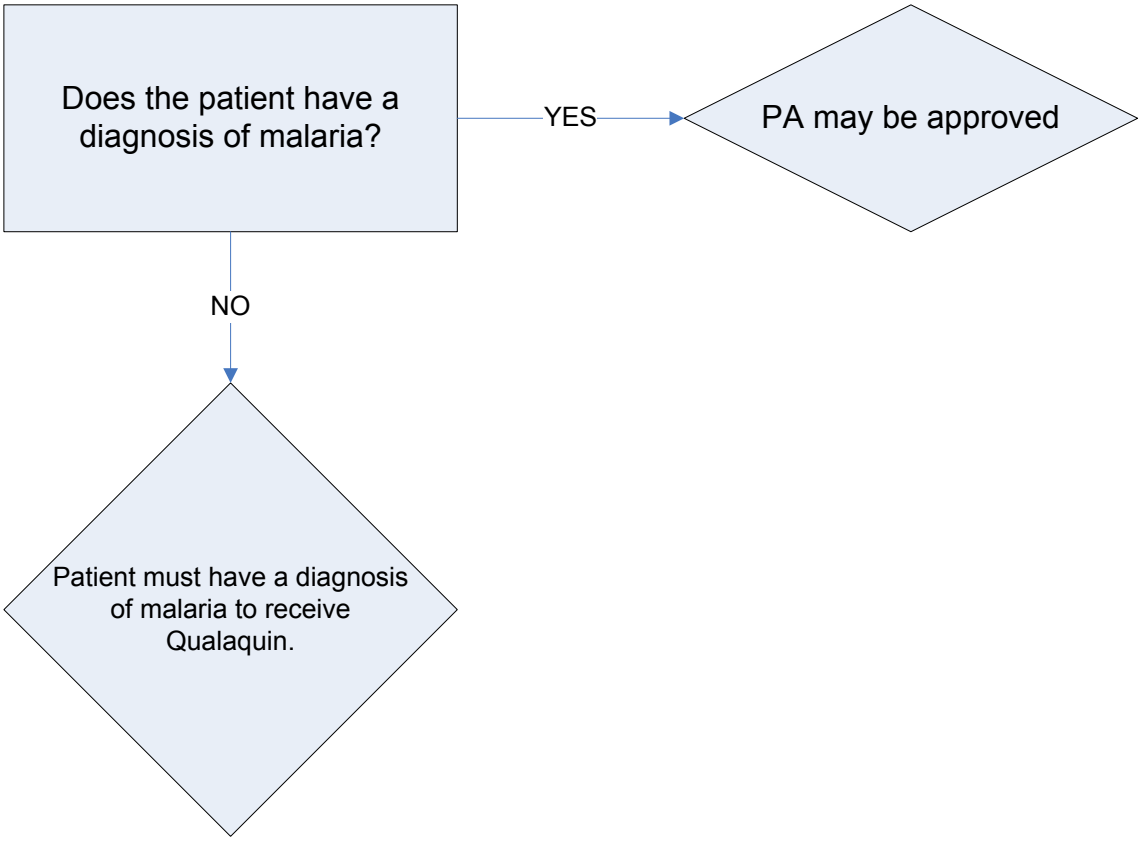
Part II: TO BE COMPLETED BY PHARMACY

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)		

North Dakota Department of Human Services
Qualaquin Criteria Algorithm



RIBAPAK 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 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

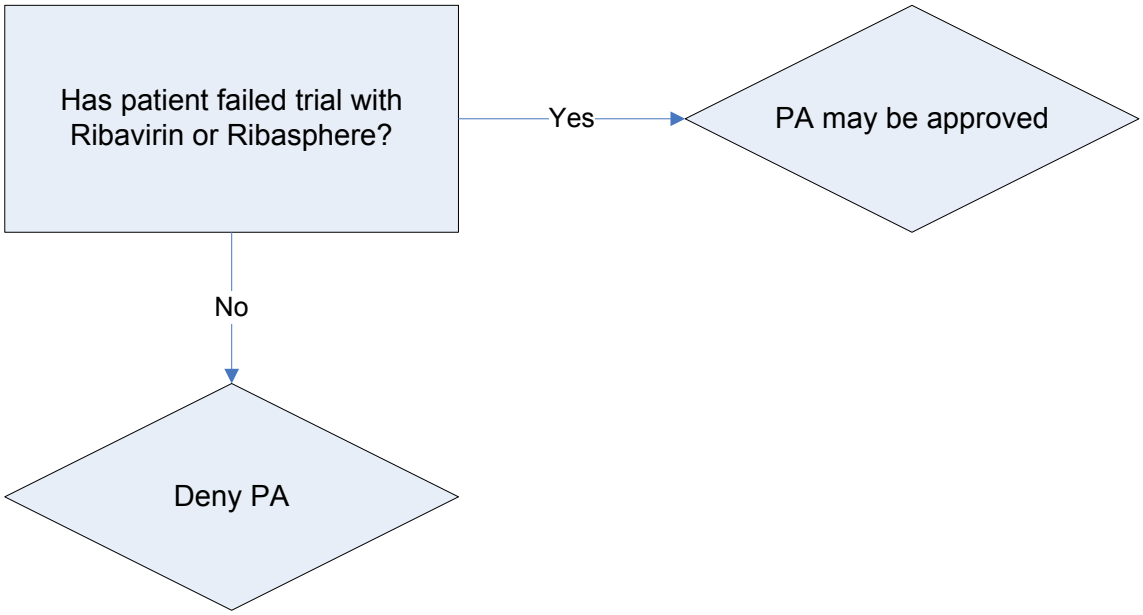
Part II: TO BE COMPLETED BY PHARMACY

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)	

North Dakota Department of Human Services
Ribapak Prior Authorization Algorithm



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	

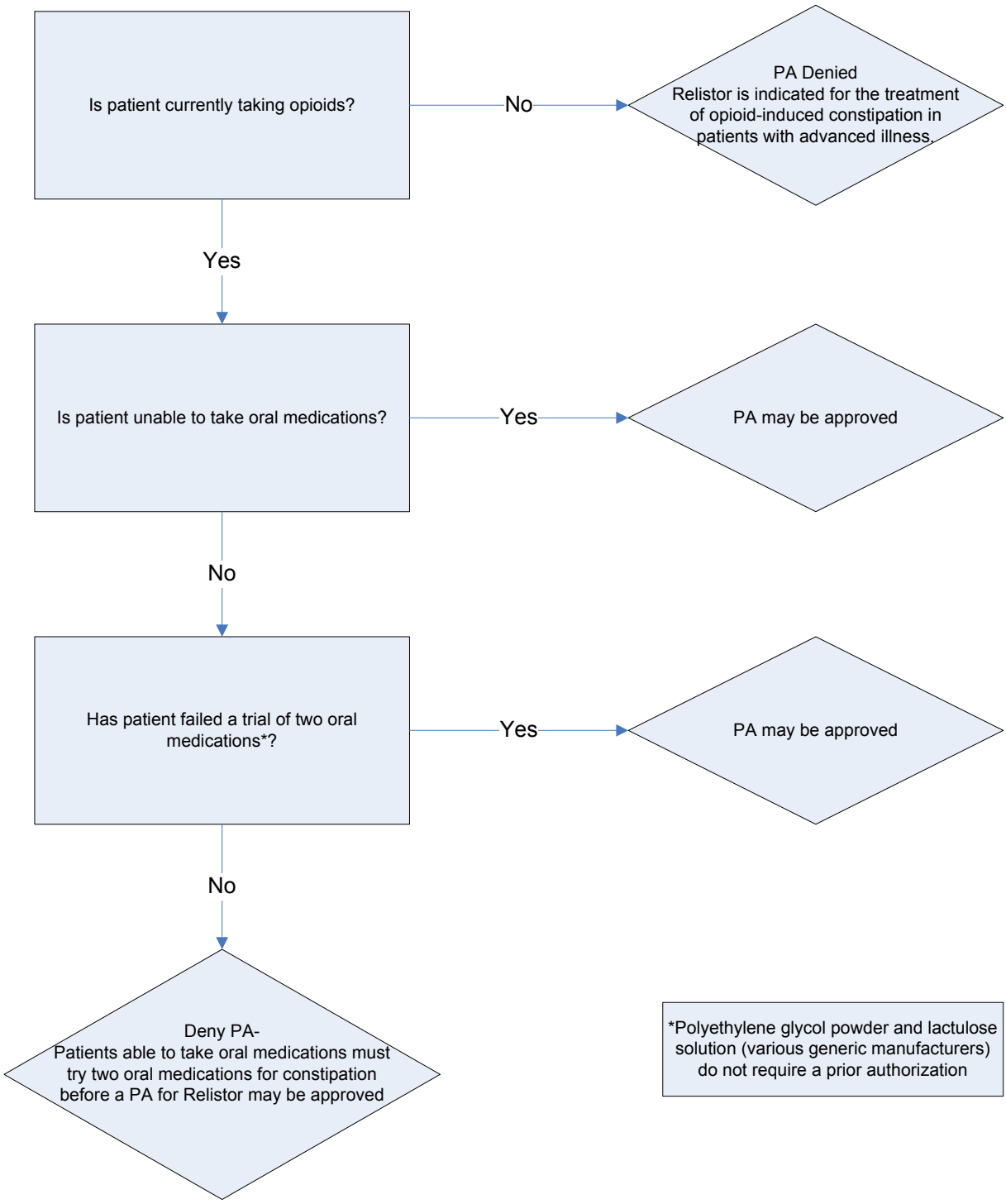
Part II: TO BE COMPLETED BY PHARMACY

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)	

North Dakota Department of Human Services
Relistor Authorization Algorithm



Revatio/Adcirca
Prior Authorization 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 Revatio or Adcirca must have a diagnosis of Pulmonary Arterial Hypertension based on WHO (Group I) Classification for Pulmonary Hypertension.

*__Note:__

- ***Patients taking Nitrates or Viagra/Levitra/Cialis will not receive a PA***

Part I: TO BE COMPLETED BY PRESCRIBER

Recipient Name	Recipient Date of Birth	Recipient Medicaid ID Number	
Prescriber Name			
Prescriber Medicaid Number	Telephone Number	Fax Number	
Address	City	State	Zip Code
Requested Drug and Dosage: □ **Revatio** □ **Adcirca**	**Diagnosis for this request:**		
Qualifications for coverage:			
□ Indication for the treatment of Pulmonary Arterial Hypertension (WHO Group I Classification)			
Prescriber Signature		Date	

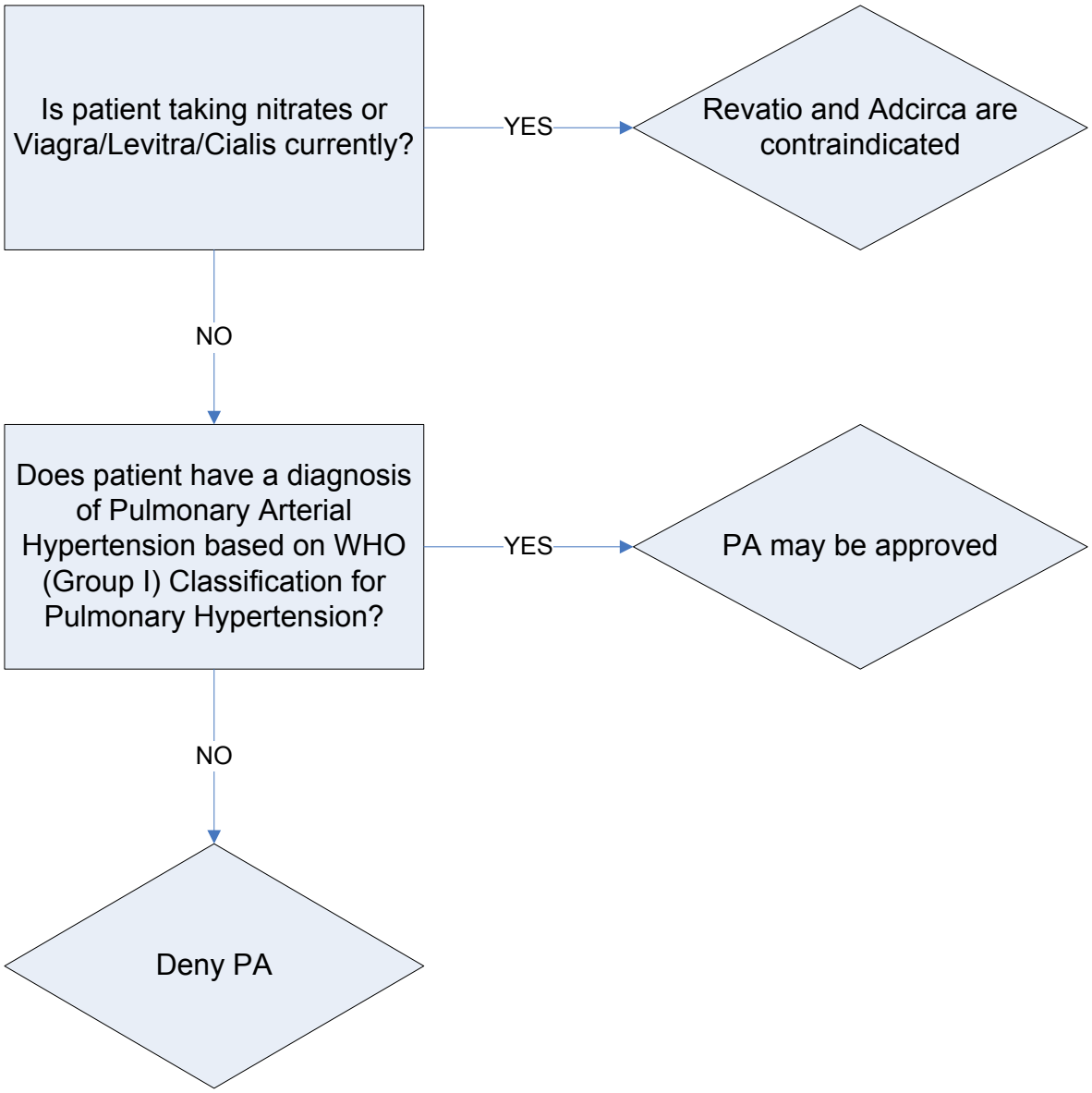
Part II: TO BE COMPLETED BY PHARMACY

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 Department of Human Services
Revatio/Adcirca Authorization Algorithm



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	

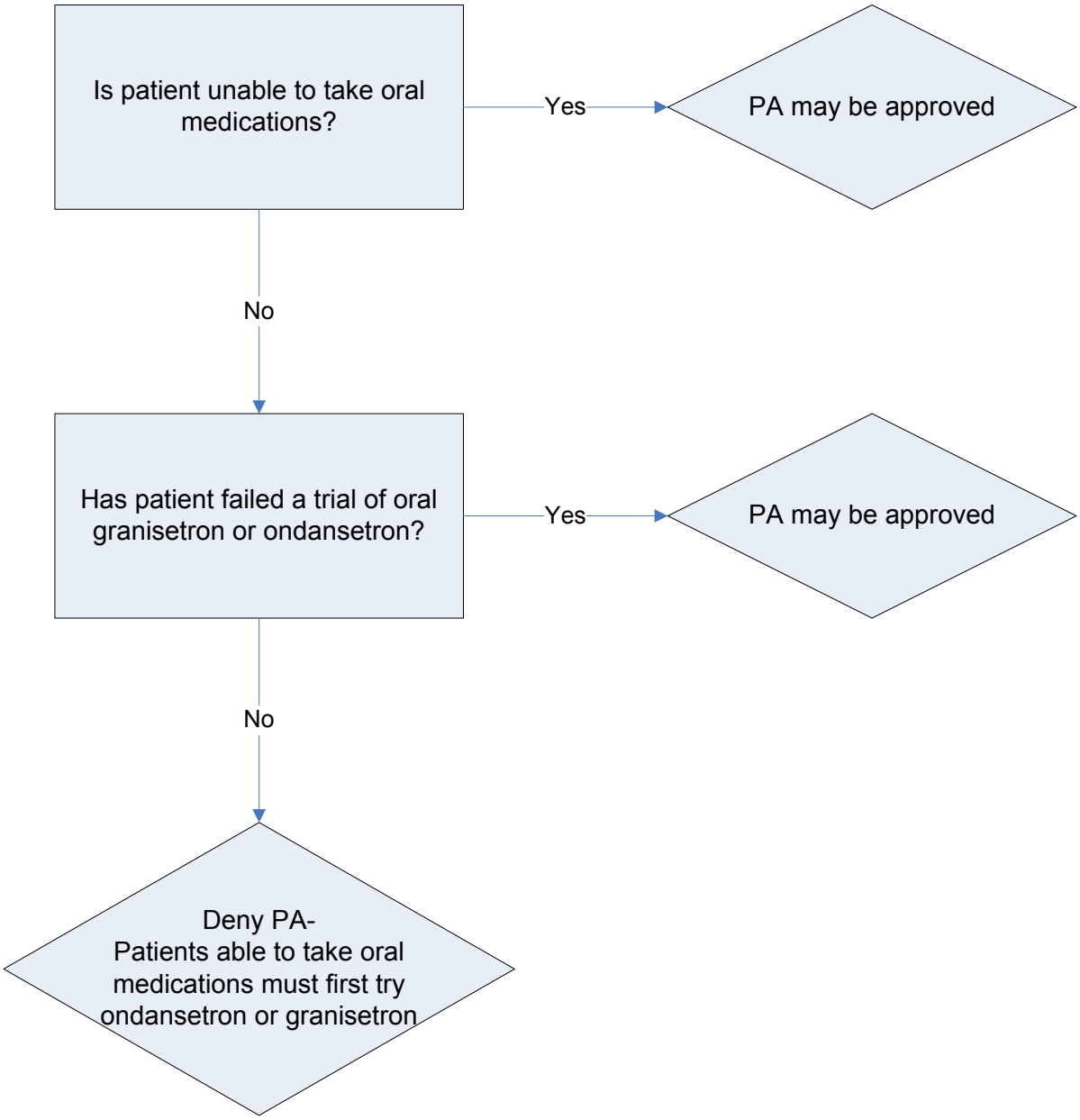
Part II: TO BE COMPLETED BY PHARMACY

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)	

North Dakota Department of Human Services
Sancuso Authorization Algorithm



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	

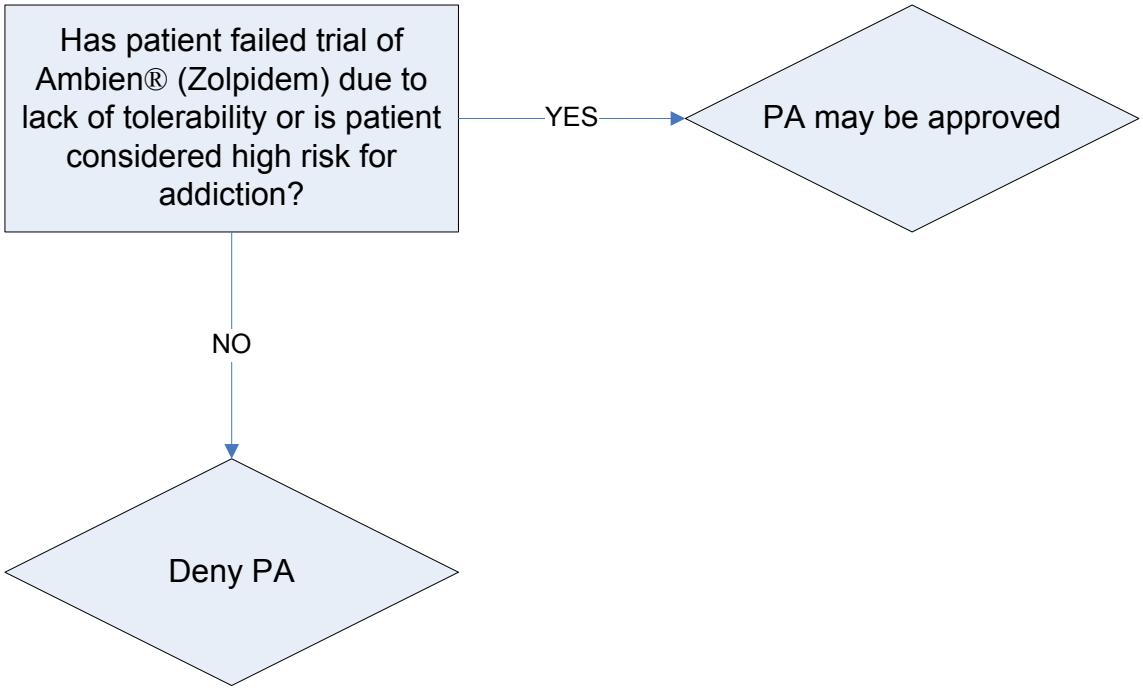
Part II: TO BE COMPLETED BY PHARMACY

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)	

North Dakota Department of Human Services
Sedative/Hypnotic Authorization Algorithm



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

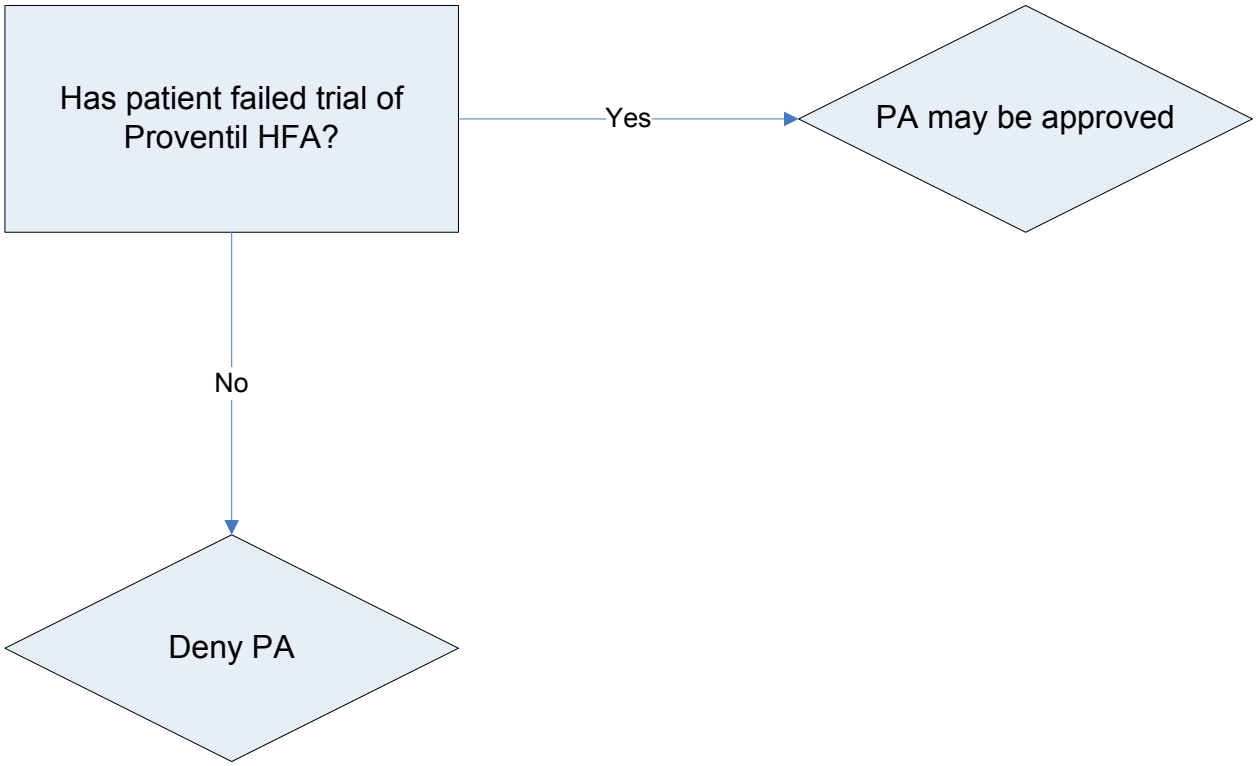
Part II: TO BE COMPLETED BY PHARMACY

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)	

North Dakota Department of Human Services Short-Acting Beta$_2$ Agonist Authorization Algorithm



HEALTH INFORMATION DESIGNS

SOLODYN 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 Solodyn 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: □ **SOLODYN**	**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:

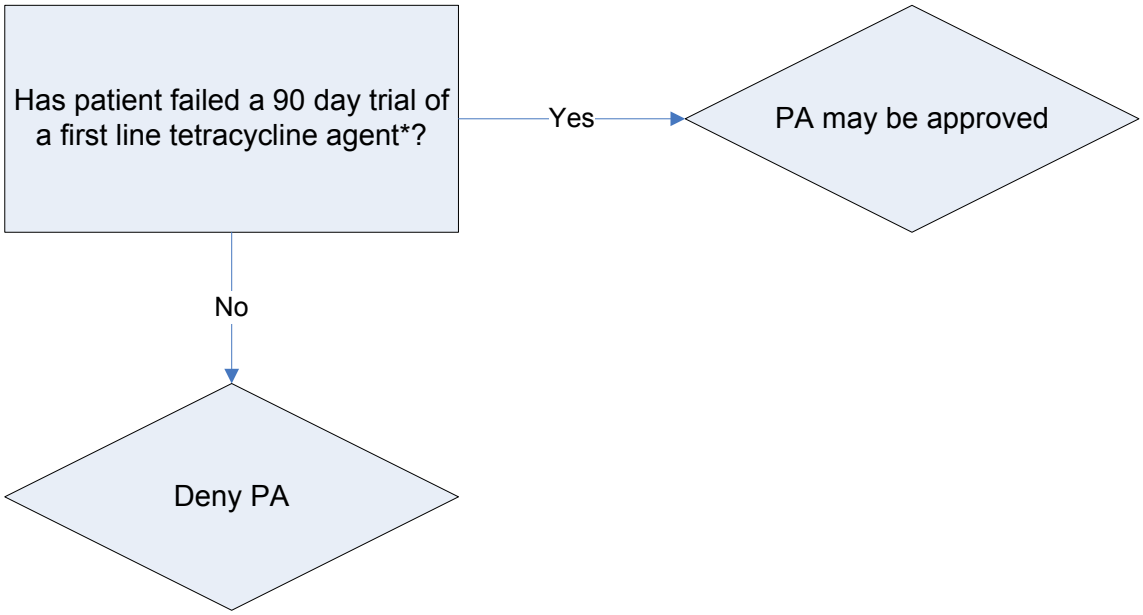
Part II: TO BE COMPLETED BY PHARMACY

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)	

North Dakota Department of Human Services
Solodyn Prior Authorization Algorithm



*Doxycycline, minocycline, and tetracycline do not require a PA and cost approximately $3 - $40 for a course of therapy compared to $775 dollars for Solodyn.

SUBOXONE/SUBUTEX 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 Suboxone and Subutex 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 Suboxone/Subutex 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 □ SUBUTEX	**FDA Approved Indication for this request:**		
□ Patient is not taking other opioids, tramadol, or carisoprodol concurrently with Suboxone or Subutex.			
Physician Signature	Date		

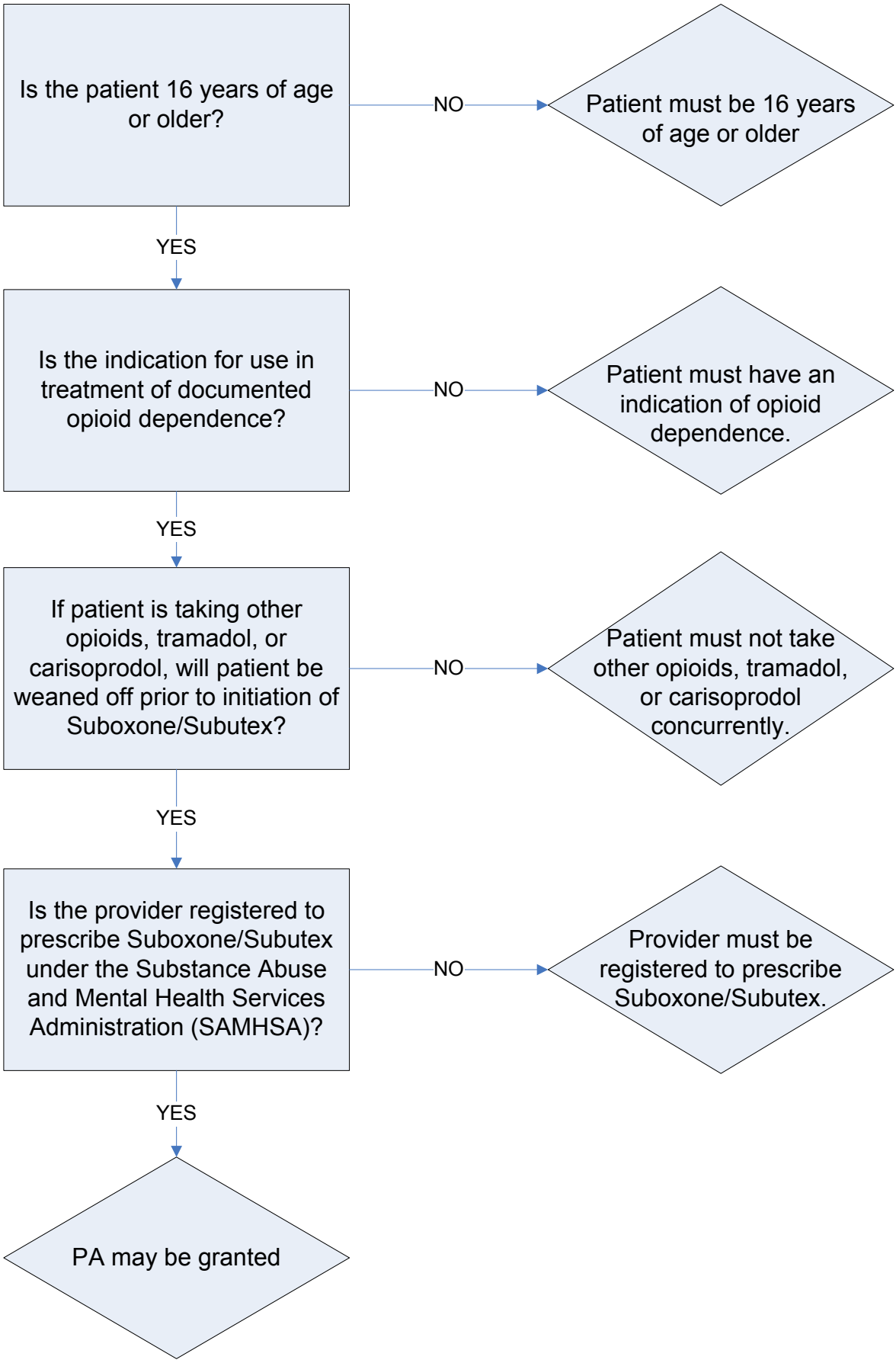
Part II: TO BE COMPLETED BY PHARMACY

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
Suboxone/Subutex Authorization Algorithm



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.

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	

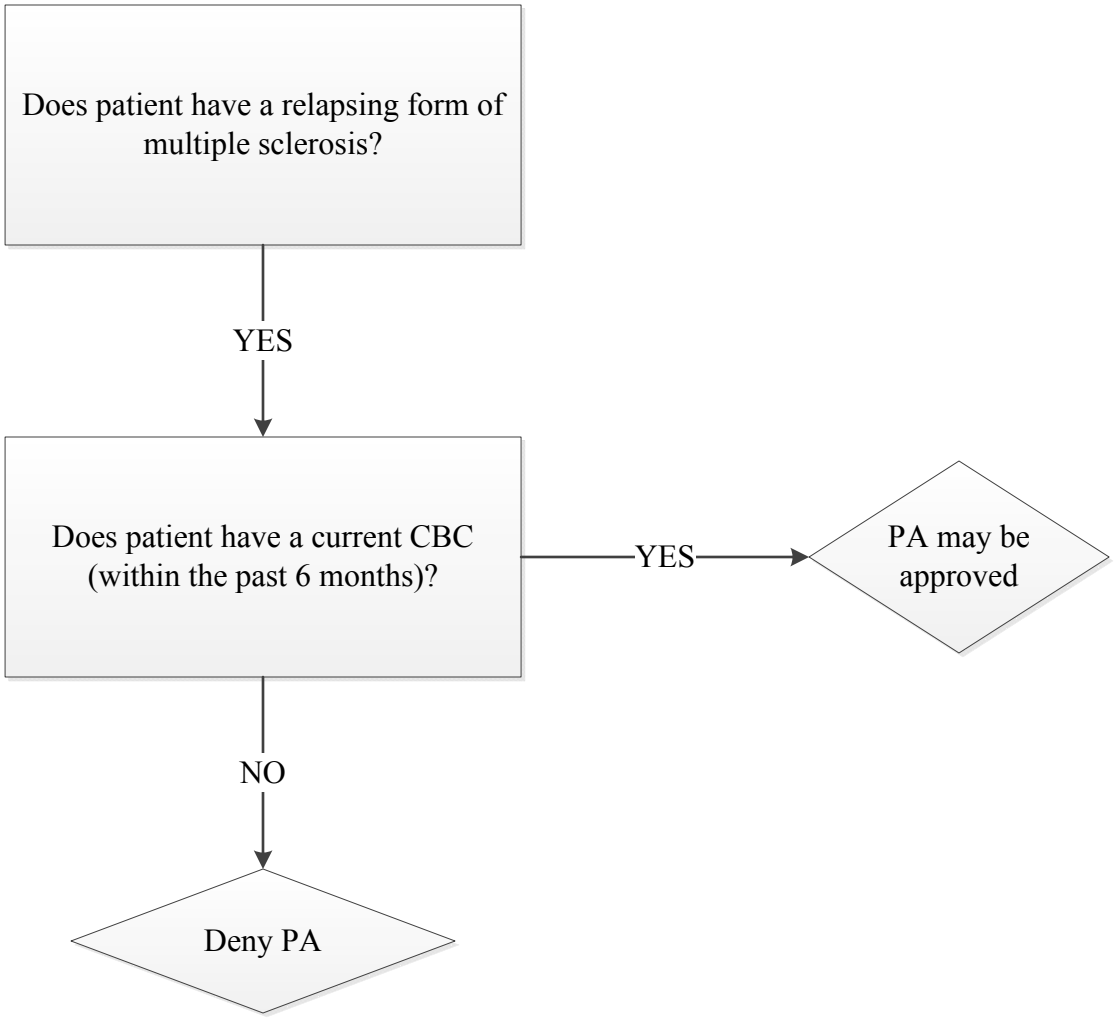
Part II: TO BE COMPLETED BY PHARMACY

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)	

North Dakota Department of Human Services
Tecfidera Authorization Algorithm



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		

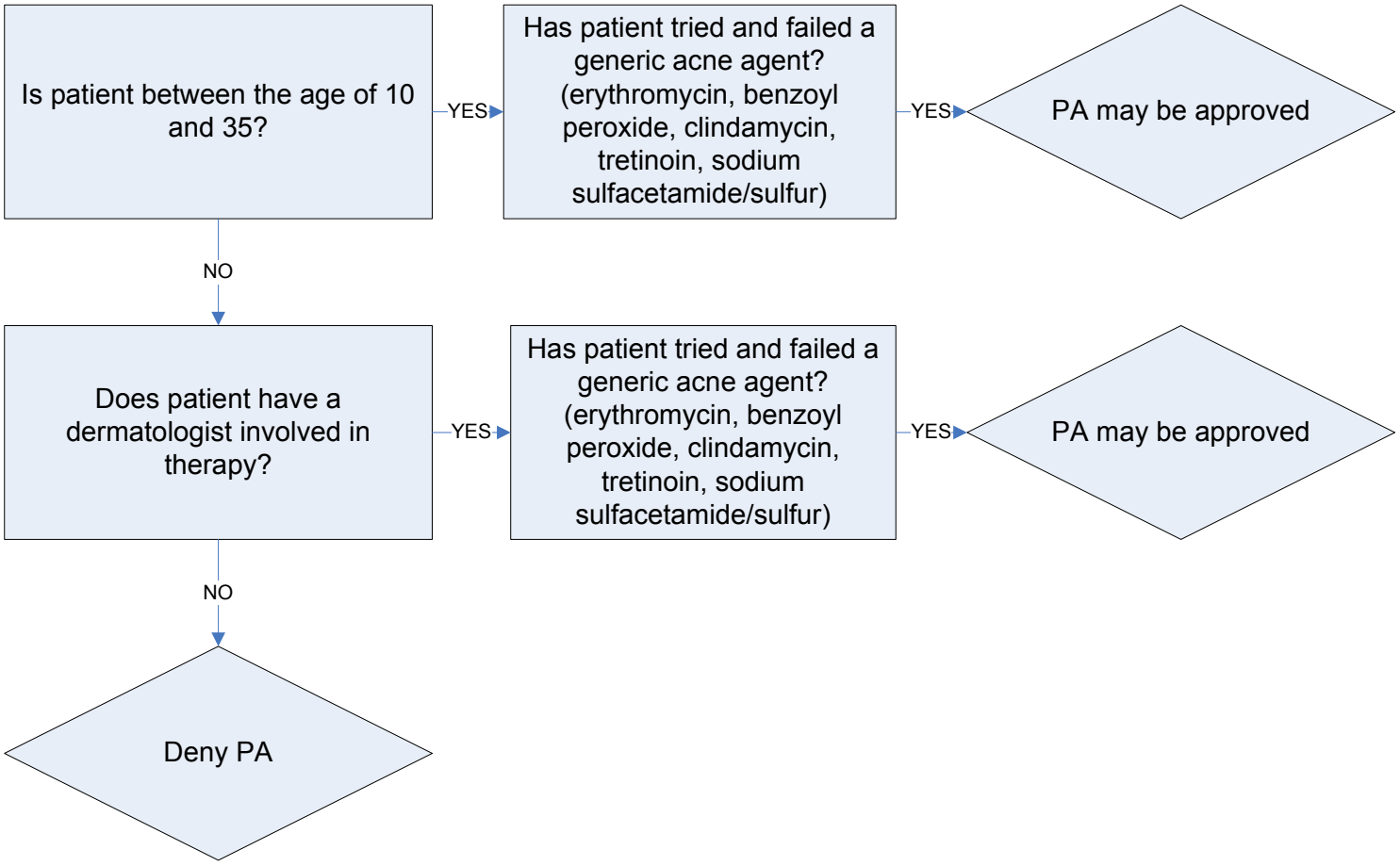
Part II: TO BE COMPLETED BY PHARMACY

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)	

North Dakota Department of Human Services
Topical Acne Agents
Prior Authorization Algorithm



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	

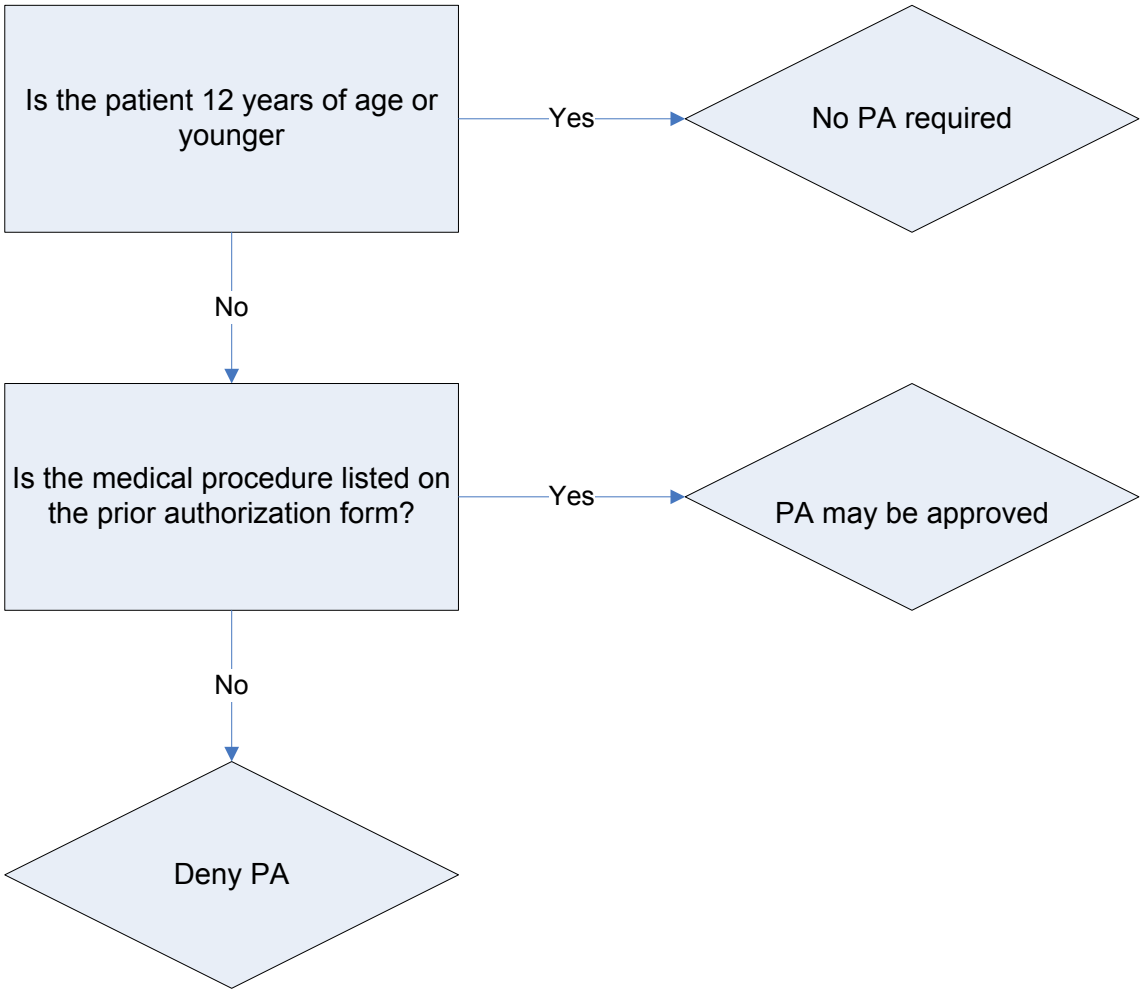
Part II: TO BE COMPLETED BY PHARMACY

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)	

North Dakota Department of Human Services
Local Anesthetics (Topical) Prior Authorization Algorithm



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	

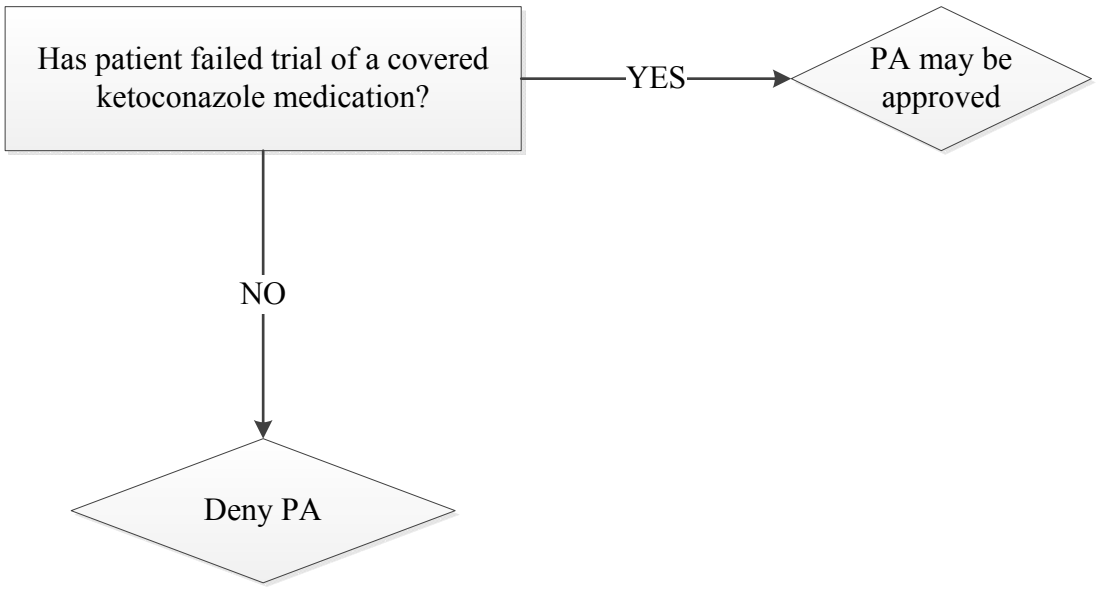
Part II: TO BE COMPLETED BY PHARMACY

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)	

North Dakota Department of Human Services
Topical Ketoconazole Products Authorization Algorithm



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

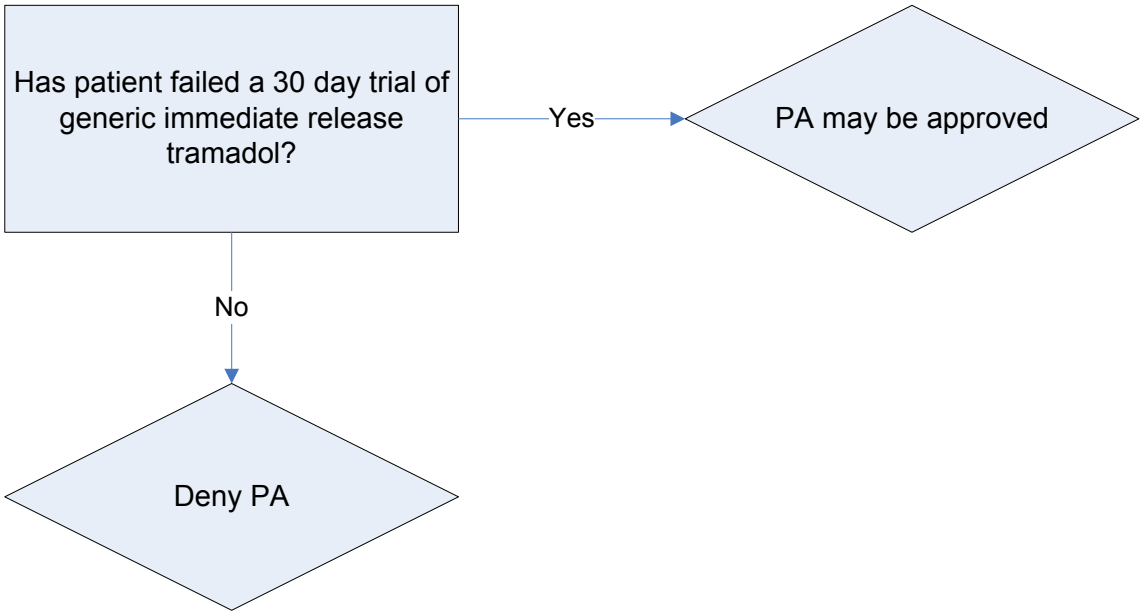
Part II: TO BE COMPLETED BY PHARMACY

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)	

North Dakota Department of Human Services
Tramadol ER Prior Authorization Algorithm



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

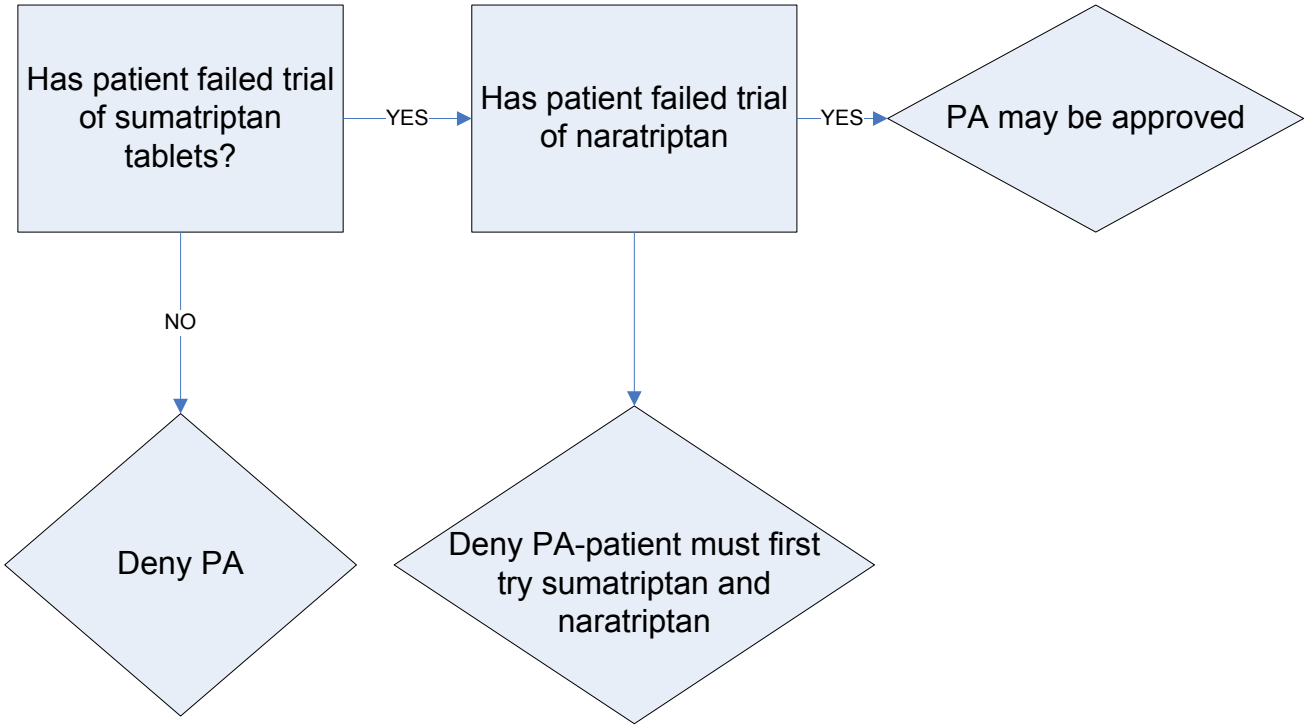
Part II: TO BE COMPLETED BY PHARMACY

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)	

North Dakota Department of Human Services
Serotonin (5-HT_1) Receptor Agonists
Triptan Prior Authorization Algorithm



ULORIC 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 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	

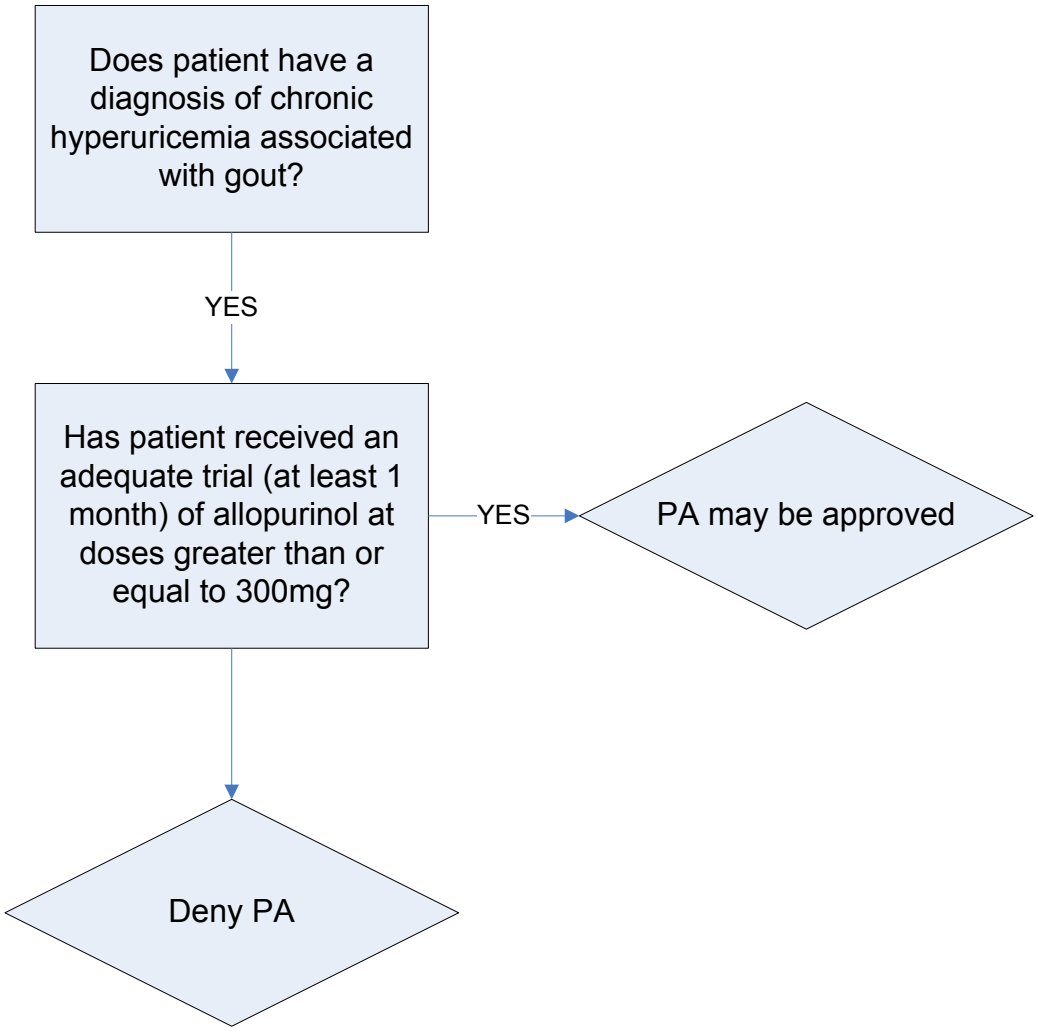
Part II: TO BE COMPLETED BY PHARMACY

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)	

North Dakota Department of Human Services
Uloric Authorization Algorithm



Allopurinol does not require a prior authorization.

VANOS 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 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	

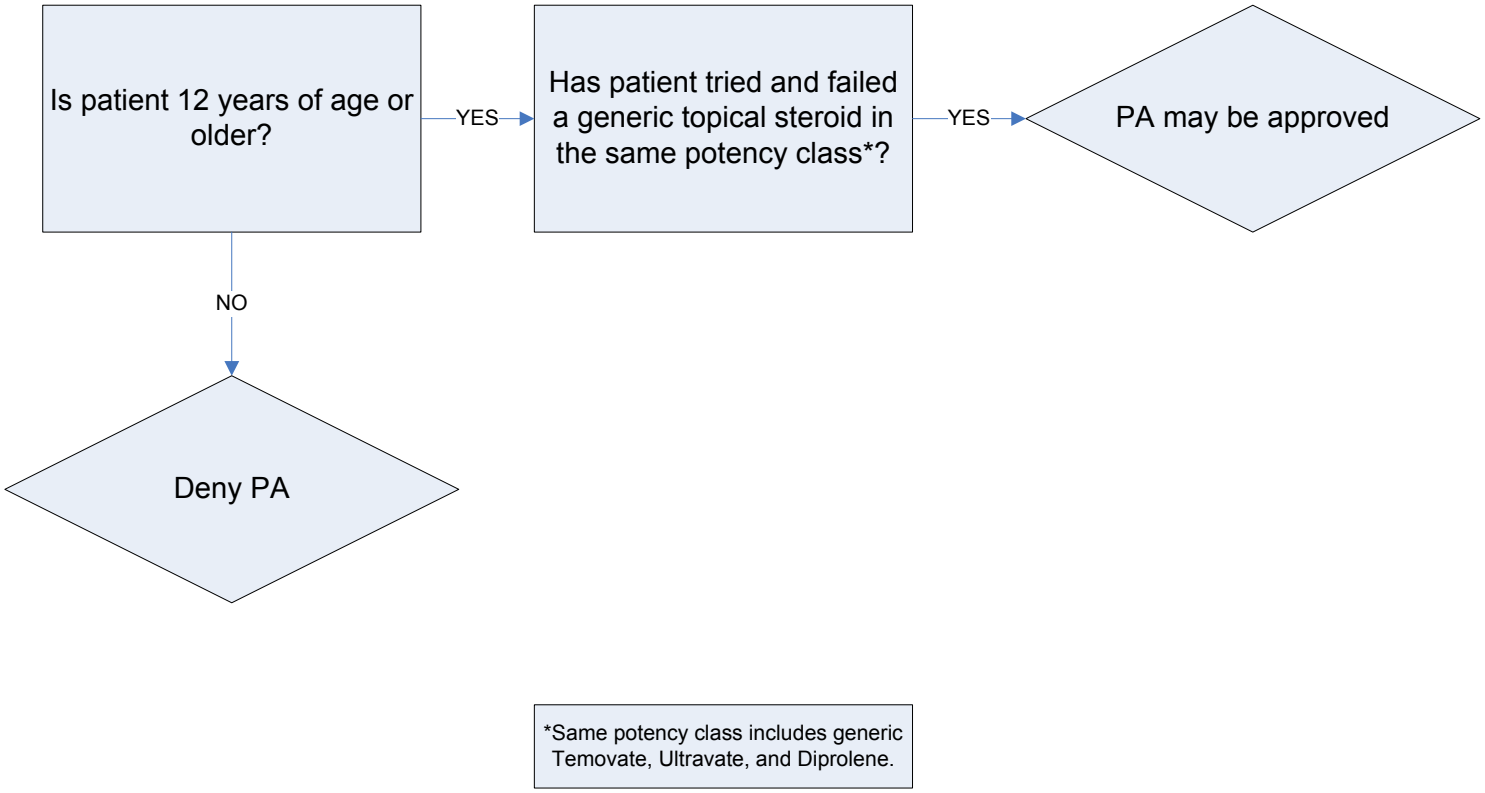
Part II: TO BE COMPLETED BY PHARMACY

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)	

North Dakota Department of Human Services
Vanos Prior Authorization Algorithm



Vusion 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 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

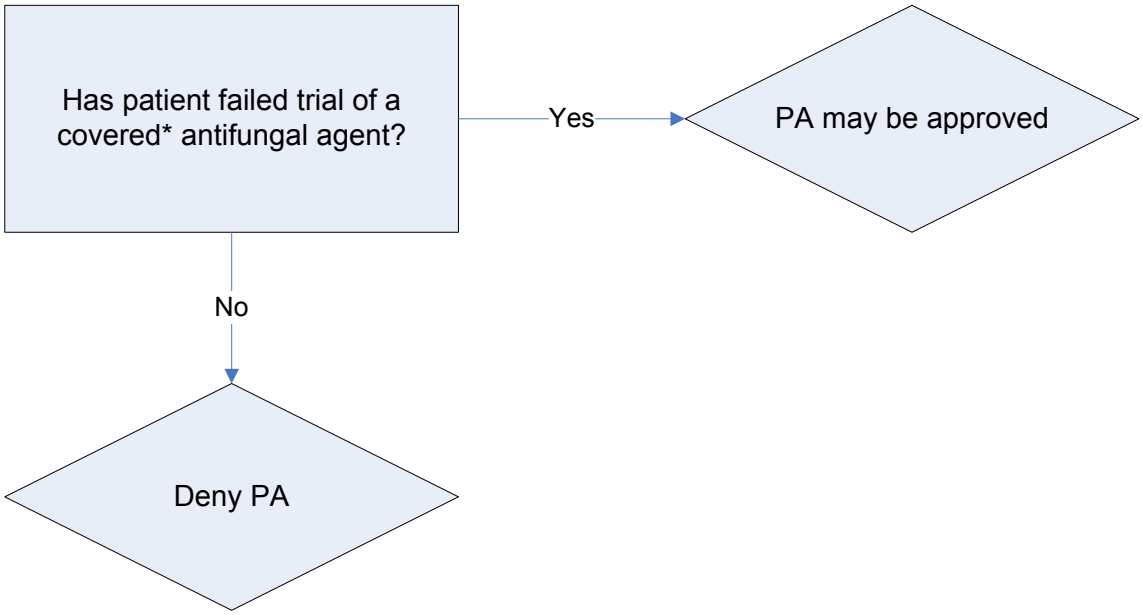
Part II: TO BE COMPLETED BY PHARMACY

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)	

North Dakota Department of Human Services
Vusion Prior Authorization Algorithm



*Nystatin and clotrimazole do not require a PA and cost approximately $6 - $36 for a course of therapy compared to $246 for a course of Vusion therapy.

HEALTH INFORMATION DESIGNS

Prior Authorization Vendor for ND Medicaid

Xeljanz
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 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

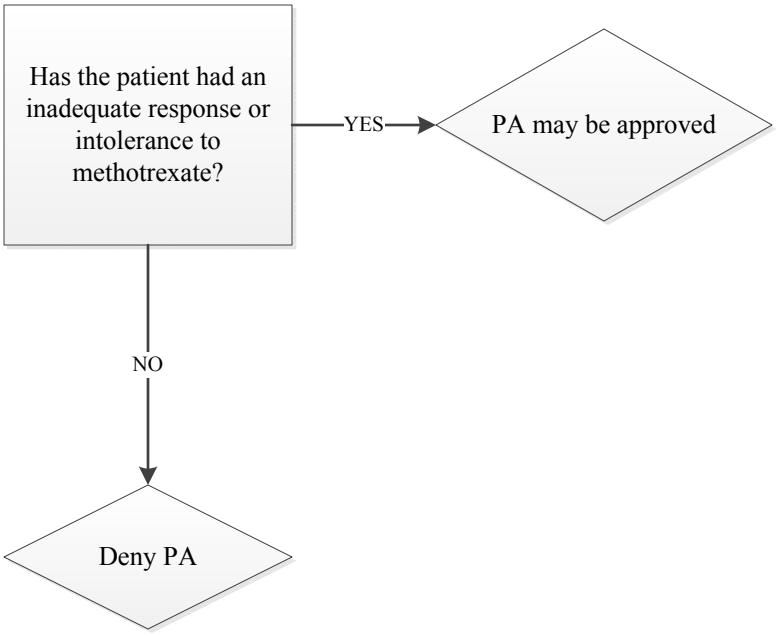
Part II: TO BE COMPLETED BY PHARMACY

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)	

North Dakota Department of Human Services
Xeljanz Authorization Algorithm



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	

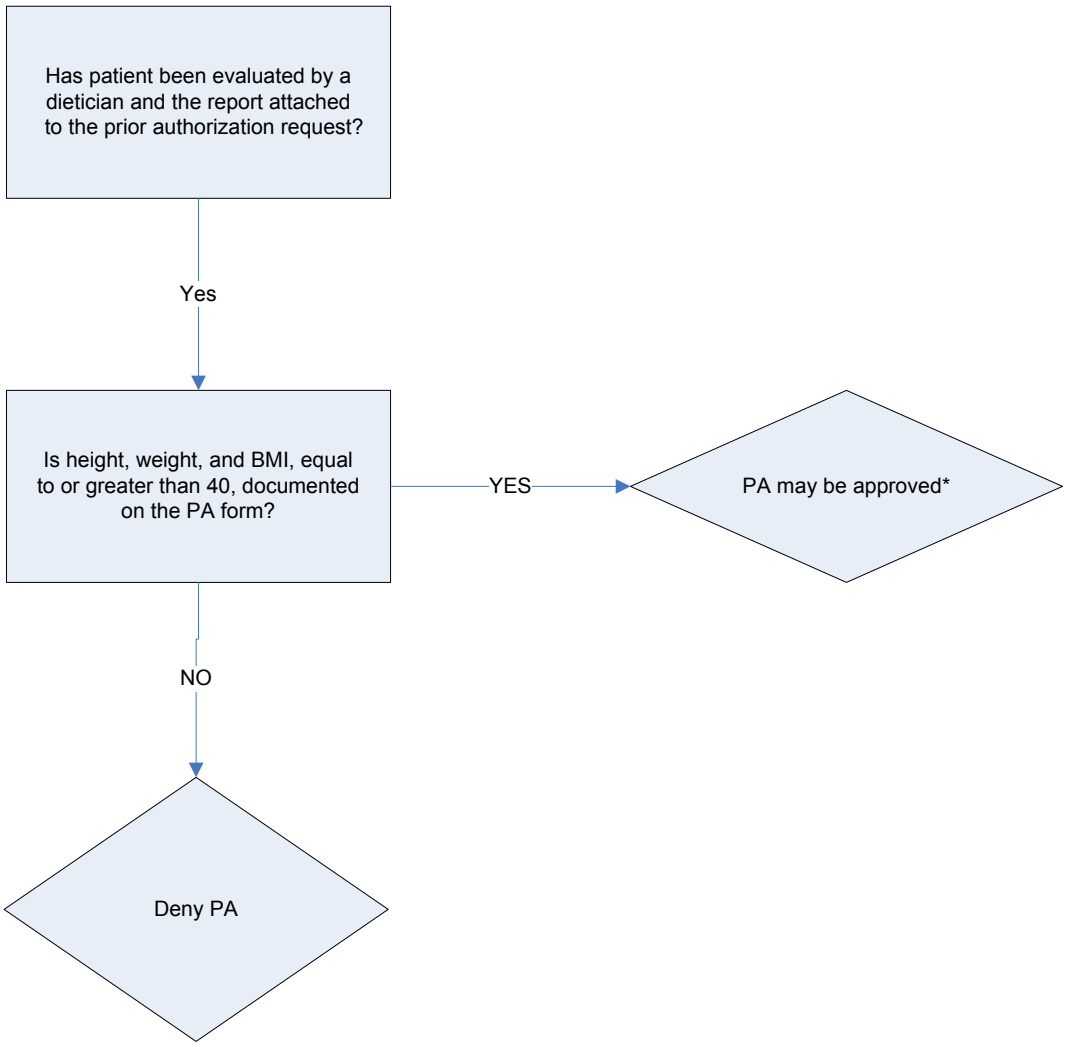
Part II: TO BE COMPLETED BY PHARMACY

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)	

North Dakota Department of Human Services
Xenical Prior Authorization Criteria



*5% weight loss must be realized for continued approval every 6 months.

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	

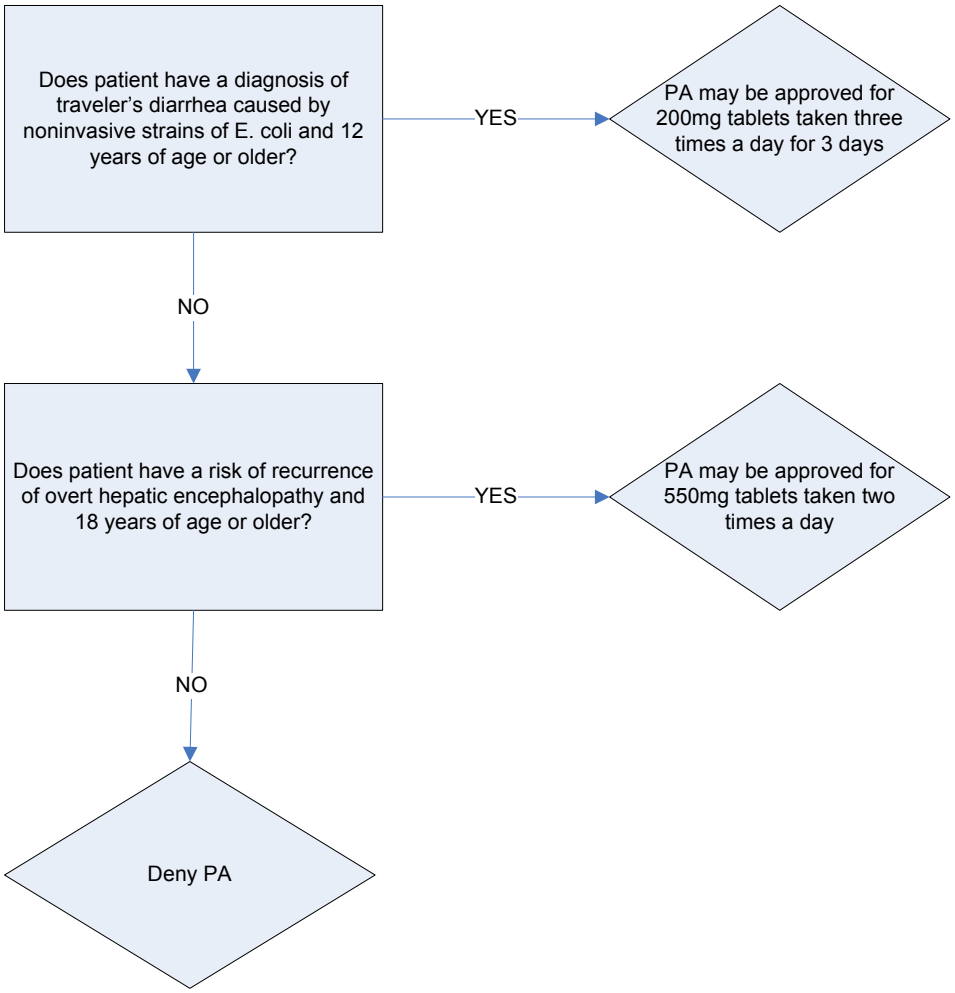
Part II: TO BE COMPLETED BY PHARMACY

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)	

North Dakota Department of Human Services
Xifaxan Prior Authorization Algorithm



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

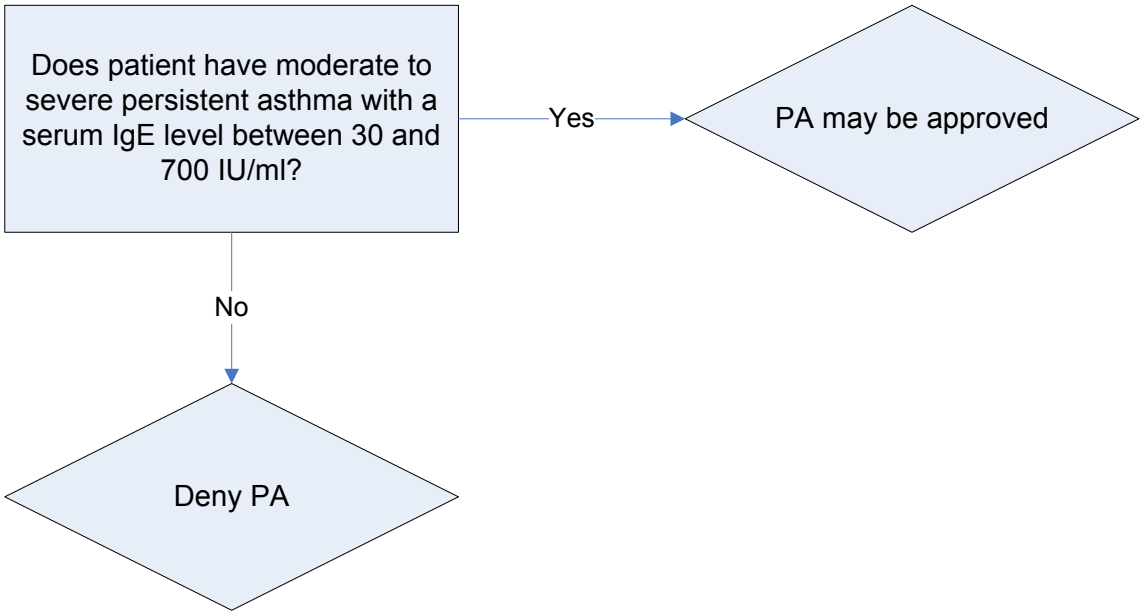
Part II: TO BE COMPLETED BY PHARMACY

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)	

North Dakota Department of Human Services
Xolair Prior Authorization Algorithm



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	

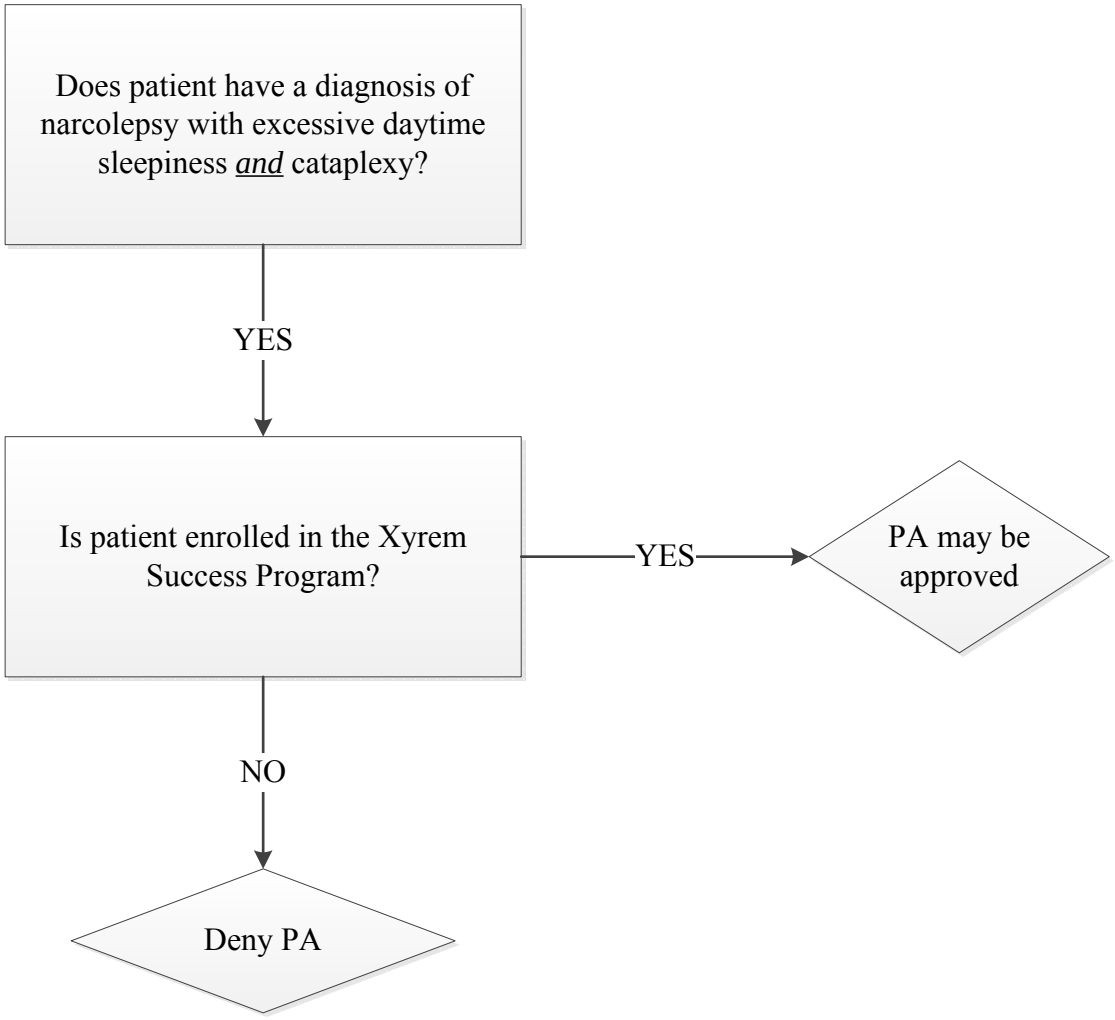
Part II: TO BE COMPLETED BY PHARMACY

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)	

North Dakota Department of Human Services
Xyrem Authorization Algorithm



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	

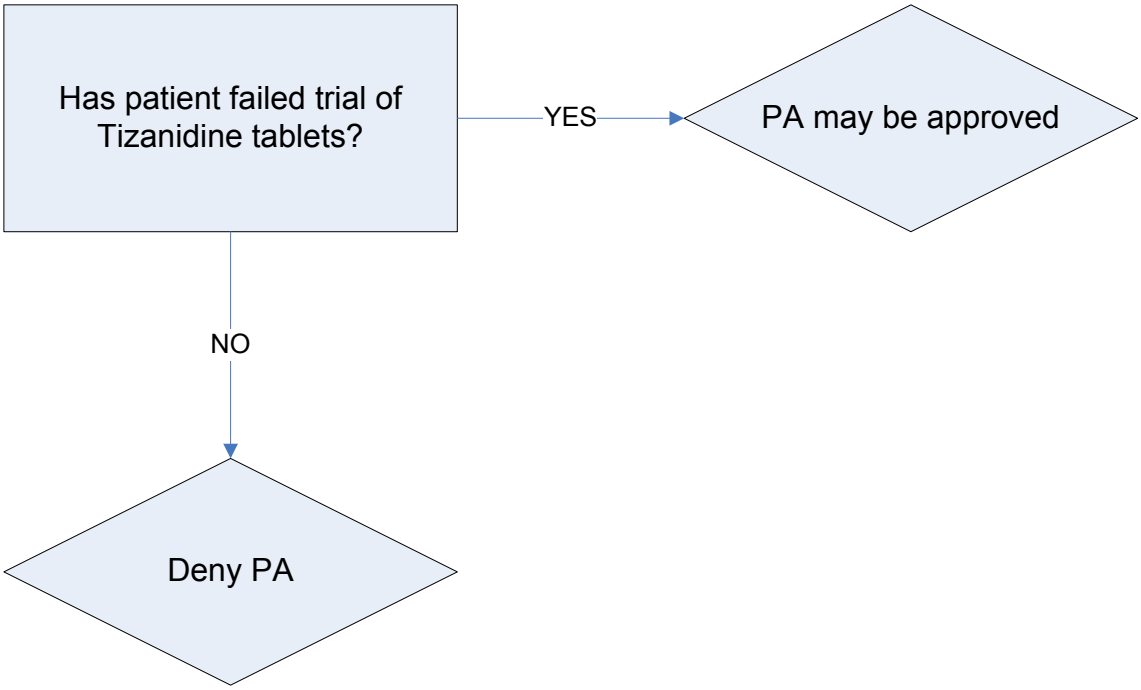
Part II: TO BE COMPLETED BY PHARMACY

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 Department of Human Services
Zanaflex Authorization Algorithm



NORTH DAKOTA MEDICAID
RETROSPECTIVE DRUG UTILIZATION REVIEW
CRITERIA RECOMMENDATIONS
4TH QUARTER 2013

Criteria Recommendations ***Approved Rejected***

1. Telaprevir / Peginterferon Alfa and Ribavirin (Negating) _____ _____

Alert Message: A review of the patient's recent drug history does not indicate the concurrent use of Incivek (telaprevir) with peginterferon alfa and ribavirin. Telaprevir must not be used as monotherapy due to the risk of the selection of resistant mutants which may be followed by viral breakthrough. Combination therapy with peginterferon alfa and ribavirin reduces the frequency of resistance development.

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Diseases

Util A	Util B	Util C **(Negating)**
Telaprevir		Peginterferon alfa
		Ribavirin

References:
Sarrazin C, Zeuzem S. Resistance to Direct Antiviral Agents in Patients with Hepatitis C Infection. Gastroenterology. 2010 Feb;138(2):447-62.
Sarrazin C, Kieffer TL, Bartels D, et al. Dynamic Hepatitis C Virus Genotypic and Phenotypic Changes in Patients Treated with the Protease Inhibitor Telaprevir. Gastroenterology. 2007;132:1767-77
Facts & Comparisons, 2013 Updates, Wolters Kluwer Health.
Clinical Pharmacology, 2013 Elsevier/Gold Standard.
Incivek Prescribing Information, April 2013, Vertex Pharmaceuticals Inc.

2. Telaprevir / Pregnancy / Miscarriage-Delivery-Abortion _____ _____

Alert Message: Incivek (telaprevir) in combination with peginterferon alfa and ribavirin is contraindicated in pregnant women and in men whose female partners are pregnant (Pregnancy Category X). Women of childbearing potential and men must use at least two forms of effective contraception during treatment and for at least 6 months after treatment has concluded.

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

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

References:
Facts & Comparisons, 2013 Updates, Wolters Kluwer Health.
Clinical Pharmacology, 2013 Elsevier/Gold Standard.
Incivek Prescribing Information, April 2013, Vertex Pharmaceuticals Inc.

3. Telaprevir / Drugs Highly Dependent on CYP3A for Clearance _____ _____

Alert Message: The concurrent use of Incivek (telaprevir) is contraindicated with drugs that are highly dependent on CYP3A4/5 for clearance, and for which elevated plasma concentrations are associated with serious and/or life threatening reactions. Telaprevir is a potent CYP3A4 inhibitor and co-administration with drugs requiring CYP3A4 for metabolism may cause large increases in serum concentrations of the CYP3A4/5 substrate.

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

Util A	Util B	Util C
Telaprevir	Alfuzosin	
	Dihydroergotamine	
	Ergotamine	
	Methylergonovine	
	Lovastatin	
	Simvastatin	
	Sildenafil (Revatio)	
	Tadalafil (Adcirca)	
	Pimozide	
	Triazolam	
	Midazolam-oral	

References:
Facts & Comparisons, 2013 Updates, Wolters Kluwer Health.
Clinical Pharmacology, 2013 Elsevier/Gold Standard.
Incivek Prescribing Information, April 2013, Vertex Pharmaceuticals Inc.

4. Telaprevir / Potent CYP3A Inducers _____ _____

Alert Message: The concurrent use of Incivek (telaprevir) with the potent CYP3A4 inducer rifampin is contraindicated. Telaprevir is a CYP3A4 substrate and co-administration with rifampin significantly reduces telaprevir plasma concentrations and may lead to loss of virologic response.

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

Util A	Util B	Util C
Telaprevir	Rifampin	

References:
Facts & Comparisons, 2013 Updates, Wolters Kluwer Health.
Clinical Pharmacology, 2013 Elsevier/Gold Standard.
Incivek Prescribing Information, April 2013, Vertex Pharmaceuticals Inc.

5. Ketoconazole & Itraconazole / Telaprevir _____ _____

Alert Message: The concurrent use of Incivek (telaprevir) with ketoconazole or itraconazole may result in increased plasma concentrations of telaprevir and the antifungal, as all are substrates and inhibitors of CYP3A4. When co-administered with telaprevir the dosages of itraconazole or ketoconazole should not exceed 200 mg /day.

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

Util A	Util B	Util C **(Include)**
Ketoconazole		Telaprevir
Itraconazole		

Max Dose of Antifungal: 200mg/day

References:
Facts & Comparisons, 2013 Updates, Wolters Kluwer Health.
Clinical Pharmacology, 2013 Elsevier/Gold Standard.
Incivek Prescribing Information, April 2013, Vertex Pharmaceuticals Inc.

6. Telaprevir / Posaconazole _____ _____

Alert Message: The concurrent use of Incivek (telaprevir) with Noxafil (posaconazole) may result in elevated plasma concentrations of both telaprevir and posaconazole, increasing the risk of adverse effects which includes posaconazole-related QT interval prolongation and torsade de pointes. Clinical monitoring is advised during concurrent use of these agents.

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

Util A	Util B	Util C
Telaprevir	Posaconazole	

References:
Facts & Comparisons, 2013 Updates, Wolters Kluwer Health.
Clinical Pharmacology, 2013 Elsevier/Gold Standard.
Incivek Prescribing Information, April 2013, Vertex Pharmaceuticals Inc.

7. Telaprevir / Voriconazole _____ _____

Alert Message: The concurrent use of Incivek (telaprevir) with voriconazole is not recommended unless an assessment of the benefit /risk ratio justifies its use.
Co-administration may result in increased plasma concentrations of telaprevir and increased risk of telaprevir-related adverse effects. Voriconazole levels can be increased or decreased leading to either increased risk of voriconazole adverse effects (e.g., QT prolongation or torsade de points) or decreased voriconazole efficacy.

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

Util A	Util B	Util C
Telaprevir	Voriconazole	

References:
Facts & Comparisons, 2013 Updates, Wolters Kluwer Health.
Clinical Pharmacology, 2013 Elsevier/Gold Standard.
Incivek Prescribing Information, April 2013, Vertex Pharmaceuticals Inc.

8. Telaprevir / P-gp, CYP3A4 and/or OATP1B1 & 2 Substrates _____ _____

Alert Message: Incivek (telaprevir) is a strong CYP3A4 inhibitor and an inhibitor of P-glycoprotein (P-gp), OATP1B1 and OATP2B1. Concurrent use of telaprevir with drugs that are substrates of these pathways may result in increased plasma concentrations of the substrate, resulting in increased risk of adverse effects. Dosage adjustment of the substrate may be required during telaprevir therapy and readjustment after completion of telaprevir therapy.

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

Util A	Util B	Util C
Telaprevir	Afatinib (Pg-p)	Trazodone (3A4)
	Aliskiren (3A4)	Ziprasidone (3A4)
	Fexofenadine (3A4 OAT1B1)	Escitalopram (3A4)
	Ondansetron (P-gp & 3A4)	Citalopram (3A4)
	Acetaminophen (3A4)	Repaglinide (3A4 & OAT1B1)
	Almotriptan (3A4)	
	Buprenorphine (3A4)	

References:
Facts & Comparisons, 2013 Updates, Wolters Kluwer Health.
Clinical Pharmacology, 2013 Elsevier/Gold Standard.
Incivek Prescribing Information, April 2013, Vertex Pharmaceuticals Inc.

9. Telaprevir / Digoxin _____ _____

Alert Message: The concurrent use of Incivek (telaprevir), a P-gp inhibitor, and digoxin, a P-gp substrate, may cause elevated digoxin concentrations, increasing the risk of digoxin-related adverse events. If concurrent use is required the lowest dose of digoxin should be prescribed initially. The serum digoxin concentrations should be monitored and used for titration of digoxin to obtain the desired clinical effect.

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

Util A	Util B	Util C
Telaprevir	Digoxin	

References:
Facts & Comparisons, 2013 Updates, Wolters Kluwer Health.
Clinical Pharmacology, 2013 Elsevier/Gold Standard.
Incivek Prescribing Information, April 2013, Vertex Pharmaceuticals Inc.

10. Telaprevir / Antiarrhythmics _____ _____

Alert Message: The concurrent use of Incivek (telaprevir), a potent CYP3A4 inhibitor, and CYP3A4-metabolized antiarrhythmics may result in serious and/or life threatening adverse events. Caution is warranted and clinical monitoring is recommended when these agents are used concomitantly with telaprevir.

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

Util A	Util B	Util C
Telaprevir	Amiodarone	
	Flecainide	
	Propafenone	
	Quinidine	

References:
Facts & Comparisons, 2013 Updates, Wolters Kluwer Health.
Clinical Pharmacology, 2013 Elsevier/Gold Standard.
Incivek Prescribing Information, April 2013, Vertex Pharmaceuticals Inc.

11. Telaprevir / Warfarin _____ _____

Alert Message: The concurrent use of Incivek (telaprevir) and warfarin may cause alterations (increases or decreases) in the warfarin plasma concentrations. When these drugs are co-administered monitor INR closely and adjust warfarin dose if necessary.

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

Util A	Util B	Util C
Telaprevir	Warfarin	

References:
Facts & Comparisons, 2013 Updates, Wolters Kluwer Health.
Clinical Pharmacology, 2013 Elsevier/Gold Standard.
Incivek Prescribing Information, April 2013, Vertex Pharmaceuticals Inc.

12. Telaprevir / Carbamazepine _____ _____

Alert Message: The concurrent use of Incivek (telaprevir) and carbamazepine may result in increased carbamazepine plasma concentrations and decreased telaprevir plasma concentrations. Clinical or laboratory monitoring of carbamazepine concentrations and dose titration are recommended to achieve the desired clinical response.

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

Util A	Util B	Util C
Telaprevir	Carbamazepine	

References:
Facts & Comparisons, 2013 Updates, Wolters Kluwer Health.
Clinical Pharmacology, 2013 Elsevier/Gold Standard.
Incivek Prescribing Information, April 2013, Vertex Pharmaceuticals Inc.

13. Telaprevir / Phenytoin & Phenobarbital _____ _____

Alert Message: The concurrent use of Incivek (telaprevir) and phenytoin or phenobarbital may result in altered phenytoin and phenobarbital plasma concentrations (increase or decrease) and decreased telaprevir plasma concentrations. Clinical or laboratory monitoring of the anticonvulsant concentrations and dose titration are recommended to achieve the desired clinical response.

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

Util A	Util B	Util C
Telaprevir	Phenytoin Phenobarbital	

References:
Facts & Comparisons, 2013 Updates, Wolters Kluwer Health.
Clinical Pharmacology, 2013 Elsevier/Gold Standard.
Incivek Prescribing Information, April 2013, Vertex Pharmaceuticals Inc.

14. Telaprevir / Trazodone _____ _____

Alert Message: The concurrent use of Incivek (telaprevir), a potent CYP3A4 inhibitor, and CYP3A4 substrate trazodone may result in elevated trazodone plasma concentrations, increasing risk of adverse events. Dosage adjustment of trazodone may be necessary during concurrent therapy with telaprevir.

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

Util A	Util B	Util C
Telaprevir	Trazodone	

References:
Facts & Comparisons, 2013 Updates, Wolters Kluwer Health.
Clinical Pharmacology, 2013 Elsevier/Gold Standard.
Incivek Prescribing Information, April 2013, Vertex Pharmaceuticals Inc.

15. Telaprevir / Colchicine / Renal or Hepatic Impairment Negating _____ _____

Alert Message: The concurrent use of Incivek (telaprevir), a potent CYP3A4 inhibitor, and the CYP3A4 substrate colchicine may result in elevated colchicine plasma concentrations, increasing the risk of fatal colchicine toxicity. A reduction in colchicine dosage or an interruption of colchicine treatment is recommended in patients with normal renal or hepatic function. Please see the manufacturer's specific dosing information for the use of colchicine.

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

Util A	Util B	Util C **(Negating)**
Telaprevir	Colchicine	Renal Impairment
		Hepatic Impairment

References:
Facts & Comparisons, 2013 Updates, Wolters Kluwer Health.
Clinical Pharmacology, 2013 Elsevier/Gold Standard.
Incivek Prescribing Information, April 2013, Vertex Pharmaceuticals Inc.

16. Telaprevir / Colchicine / Renal or Hepatic Impairment (Include) _____ _____

Alert Message: The concurrent use of Incivek (telaprevir), a potent CYP3A4 inhibitor, and the CYP3A4 substrate colchicine may result in elevated colchicine plasma concentrations, increasing the risk of fatal colchicine toxicity. Patients with renal or hepatic impairment should not be prescribed colchicine with telaprevir.

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

Util A	Util B	Util C **(Include)**
Telaprevir	Colchicine	Renal Impairment
		Hepatic Impairment

References:
Facts & Comparisons, 2013 Updates, Wolters Kluwer Health.
Clinical Pharmacology, 2013 Elsevier/Gold Standard.
Incivek Prescribing Information, April 2013, Vertex Pharmaceuticals Inc.

17. Telaprevir / CYP3A4 Substrate CCBs _____ _____

Alert Message: The concurrent use of Incivek (telaprevir), a potent CYP3A4 inhibitor, and a CYP3A4 substrate calcium channel blocker (CCB) may result in elevated CCB plasma concentrations, increasing risk of CCB-related adverse events. Caution is warranted and clinical monitoring is recommended. Dosage reductions may be necessary if the CCB co-administered is amlodipine.

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

Util A	Util B	Util C
Telaprevir	Amlodipine	
	Felodipine	
	Nicardipine	
	Nifedipine	
	Nisoldipine	
	Diltiazem	
	Verapamil	

References:
Facts & Comparisons, 2013 Updates, Wolters Kluwer Health.
Clinical Pharmacology, 2013 Elsevier/Gold Standard.
Incivek Prescribing Information, April 2013, Vertex Pharmaceuticals Inc.

18. Telaprevir / Prednisone & Methylprednisolone _____ _____

Alert Message: The concurrent use of Incivek (telaprevir) with prednisone or methylprednisolone is not recommended. The systemic corticosteroids are CYP3A4 substrates and co-administration with telaprevir, a potent CYP3A4 inhibitor, may result in significantly increased corticosteroid plasma concentrations.

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

Util A	Util B	Util C
Telaprevir	Prednisone	
	Methylprednisolone	

References:
Facts & Comparisons, 2013 Updates, Wolters Kluwer Health.
Clinical Pharmacology, 2013 Elsevier/Gold Standard.
Incivek Prescribing Information, April 2013, Vertex Pharmaceuticals Inc.

19. Telaprevir / Dexamethasone _____ _____

Alert Message: The concurrent use of Incivek (telaprevir), a CYP3A4 substrate, and dexamethasone, a CYP3A4 inducer, may result in decreased telaprevir plasma concentrations and loss of virologic activity. The combination of telaprevir and dexamethasone should be used with caution or alternatives should be considered.

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

Util A	Util B	Util C
Telaprevir	Dexamethasone	

References:
Facts & Comparisons, 2013 Updates, Wolters Kluwer Health.
Clinical Pharmacology, 2013 Elsevier/Gold Standard.
Incivek Prescribing Information, April 2013, Vertex Pharmaceuticals Inc.

20. Telaprevir / Inhaled & Nasal Corticosteroids Fluticasone & Budesonide _____ _____

Alert Message: The concurrent use of Incivek (telaprevir) with the inhaled or nasal corticosteroids budesonide or fluticasone may cause increased plasma concentrations of the corticosteroid, resulting in significantly reduced serum cortisol concentrations. Co-administration of these agents is not recommended unless the potential benefit to the patient outweighs the risk of systemic corticosteroid side effects.

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

Util A	Util B	Util C
Telaprevir	Fluticasone-Inhaled & Nasal	
	Budesonide-Inhaled & Nasal	

References:
Facts & Comparisons, 2013 Updates, Wolters Kluwer Health.
Clinical Pharmacology, 2013 Elsevier/Gold Standard.
Incivek Prescribing Information, April 2013, Vertex Pharmaceuticals Inc.

21. Telaprevir / Bosentan _____ _____

Alert Message: The concurrent use of Incivek (telaprevir) with Tracleer (bosentan) may result in elevated bosentan plasma concentrations leading to increased risk of bosentan-related adverse events. Caution is warranted and clinical monitoring is recommended.

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

Util A	Util B	Util C
Telaprevir	Bosentan	

References:
Facts & Comparisons, 2013 Updates, Wolters Kluwer Health.
Clinical Pharmacology, 2013 Elsevier/Gold Standard.
Incivek Prescribing Information, April 2013, Vertex Pharmaceuticals Inc.

22. Telaprevir / Efavirenz _____ _____

Alert Message: The concurrent use of Incivek (telaprevir) and Sustiva (efavirenz) may result in decreased exposure to both telaprevir and efavirenz. HIV guidelines recommend that the telaprevir dose be increased to 1125 mg every 8 hours along with close clinical monitoring during co-administration due to potential for HIV and hepatitis C treatment failure.

Conflict Code: LR – Low Dose
Drugs/Diseases

Util A	Util B	Util C **(Include)**
Telaprevir		Efavirenz

Dose/day: < 1125mg/day of telaprevir

References:
Facts & Comparisons, 2013 Updates, Wolters Kluwer Health.
Clinical Pharmacology, 2013 Elsevier/Gold Standard.
Incivek Prescribing Information, April 2013, Vertex Pharmaceuticals Inc.
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. February 12, 2013;1-167. Available at http://www.aidsinfo.nih.gov/ContentFiles/AdultandAdolescentGL.pdf.

23. Telaprevir / Atripla _____ _____

Alert Message: The concurrent use of Incivek (telaprevir) and Atripla (efavirenz/ emtricitabine/tenofovir) may result in the decreased exposure to both efavirenz and telaprevir and increased exposure to tenofovir.

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

Util A	Util B	Util C
Telaprevir	Atripla	

References:
Clinical Pharmacology, 2013 Elsevier/Gold Standard.
Incivek Prescribing Information, April 2013, Vertex Pharmaceuticals Inc.

24. Telaprevir / Tenofovir-Containing Agents _____ _____

Alert Message: The concurrent use of Incivek (telaprevir) and a tenofovir-containing agent (i.e., Viread, Truvada, Complera or Atripla) may result in increased tenofovir exposure and risk for tenofovir-related adverse effects. Increased clinical and laboratory monitoring are warranted.

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

Util A	Util B	Util C
Telaprevir	Tenofovir	
	Tenofovir/Emtricitabine	
	Tenofovir/Emtricitabine/Efavirenz	
	Tenofovir/Rilpivirine/Emtricitabine	

References:
Facts & Comparisons, 2013 Updates, Wolters Kluwer Health.
Clinical Pharmacology, 2013 Elsevier/Gold Standard.
Incivek Prescribing Information, April 2013, Vertex Pharmaceuticals Inc.

25. Telaprevir / Immunosuppressants _____ _____

Alert Message: The concurrent use of Incivek (telaprevir), a potent CYP3A4 inhibitor, with a CYP3A4 substrate immunosuppressant may result in elevated plasma concentrations of the CYP3A4 substrate, increasing the risk of immunosuppressant-related adverse events. Close monitoring of immunosuppressant blood levels is recommended.

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

Util A	Util B	Util C
Telaprevir	Cyclosporine	
	Tacrolimus	
	Sirolimus	

References:
Facts & Comparisons, 2013 Updates, Wolters Kluwer Health.
Clinical Pharmacology, 2013 Elsevier/Gold Standard.
Incivek Prescribing Information, April 2013, Vertex Pharmaceuticals Inc.

26. Telaprevir / Salmeterol _____ _____

Alert Message: The concurrent use of Incivek (telaprevir) with a salmeterol-containing agent is not recommended due to the risk of adverse cardiovascular events associated with salmeterol. Telaprevir is a potent CYP3A4 inhibitor and use with the CYP3A4 substrate salmeterol can result in elevated salmeterol plasma concentrations.

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

Util A	Util B	Util C
Telaprevir	Salmeterol	

References:
Facts & Comparisons, 2013 Updates, Wolters Kluwer Health.
Clinical Pharmacology, 2013 Elsevier/Gold Standard.
Incivek Prescribing Information, April 2013, Vertex Pharmaceuticals Inc.

27. Telaprevir / Methadone _____ _____

Alert Message: The concurrent use of methadone with Incivek (telaprevir) may result in reduced plasma concentrations of methadone. Clinical monitoring is recommended as the dose of methadone during maintenance therapy may need to be adjusted in some patients.

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

Util A	Util B	Util C
Telaprevir	Methadone	

References:
Facts & Comparisons, 2013 Updates, Wolters Kluwer Health.
Clinical Pharmacology, 2013 Elsevier/Gold Standard.
Incivek Prescribing Information, April 2013, Vertex Pharmaceuticals Inc.

28. Telaprevir / Ethinyl Estradiol Contraceptives _____ _____

Alert Message: The concurrent use of Incivek (telaprevir) and ethinyl estradiol contraceptives may result in decreased ethinyl estradiol plasma concentrations with the potential of birth control failure in women with childbearing potential. Systemic hormonal contraception must be augmented by 2 alternative effective forms of contraception and may include intrauterine devices and barrier methods during therapy and for 6 months following therapy.

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

Util A	Util B	Util C
Telaprevir	EE- containing contraceptives	

References:
Facts & Comparisons, 2013 Updates, Wolters Kluwer Health.
Clinical Pharmacology, 2013 Elsevier/Gold Standard.
Incivek Prescribing Information, April 2013, Vertex Pharmaceuticals Inc.

29. Telaprevir / PDE5 for ED _____ _____

Alert Message: The concurrent use of Incivek (telaprevir) and a PDE5 inhibitor for the treatment of ED may result in increased PDE5 inhibitor plasma concentrations and risk of serious PDE5 inhibitor-related adverse events. Do not exceed the following doses for PDE5 inhibitors when used with telaprevir: sildenafil - 25 mg every 48 hours, tadalafil -10 mg every 72 hours and vardenafil - 2.5 mg every 24 hours.

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

Util A	Util B	Util C
Telaprevir	Vardenafil 5, 10 & 20mg	
	Sildenafil 50& 100 mg	
	Tadalafil 20mg	

References:
Facts & Comparisons, 2013 Updates, Wolters Kluwer Health.
Clinical Pharmacology, 2013 Elsevier/Gold Standard.
Incivek Prescribing Information, April 2013, Vertex Pharmaceuticals Inc.

30. Telaprevir / Alprazolam _____ _____

Alert Message: The concurrent use of Incivek (telaprevir) with alprazolam may result in elevated alprazolam serum concentrations and risk of alprazolam-related adverse events. Clinical monitoring is warranted.

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

Util A	Util B	Util C
Telaprevir	Alprazolam	

References:
Facts & Comparisons, 2013 Updates, Wolters Kluwer Health.
Clinical Pharmacology, 2013 Elsevier/Gold Standard.
Incivek Prescribing Information, April 2013, Vertex Pharmaceuticals Inc.

31. Telaprevir / Zolpidem _____ _____

result in decreased zolpidem exposure. Clinical monitoring and dose titration of zolpidem is recommended to achieve the desired clinical response.

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

Util A	Util B	Util C
Telaprevir	Zolpidem	

References:
Facts & Comparisons, 2013 Updates, Wolters Kluwer Health.
Clinical Pharmacology, 2013 Elsevier/Gold Standard.
Incivek Prescribing Information, April 2013, Vertex Pharmaceuticals Inc.

32. Telaprevir / Rifabutin _____ _____

Alert Message: The concurrent use of Incivek (telaprevir) with rifabutin is not recommended. Co-administration of these agents may result in elevated rifabutin plasma concentrations and decreased telaprevir concentrations. Both agents are CYP3A4 substrates and telaprevir is a potent CYP3A4 inhibitor while rifabutin is a CYP3A4 inducer.

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

Util A	Util B	Util C
Telaprevir	Rifabutin	

References:
Facts & Comparisons, 2013 Updates, Wolters Kluwer Health.
Clinical Pharmacology, 2013 Elsevier/Gold Standard.
Incivek Prescribing Information, April 2013, Vertex Pharmaceuticals Inc.

33. Telaprevir / Darunavir / Ritonavir _____ _____

Alert Message: Concurrent use of Incivek (telaprevir) with ritonavir-boosted Prezista (darunavir) is not recommended. Co-administration of these agents has been shown to result in reduced steady-state exposure to both telaprevir and darunavir.

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

Util A	Util B	Util C **(Include)**
Telaprevir	Darunavir	Ritonavir

References:
Facts & Comparisons, 2013 Updates, Wolters Kluwer Health.
Clinical Pharmacology, 2013 Elsevier/Gold Standard.
Incivek Prescribing Information, April 2013, Vertex Pharmaceuticals Inc.

34. Telaprevir / Fosamprenavir / Ritonavir _____ _____

Alert Message: Concurrent use of Incivek (telaprevir) with ritonavir-boosted Lexiva (fosamprenavir) is not recommended. Co-administration of these agents has been shown to result in reduced steady-state exposure to both telaprevir and fosamprenavir.

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

Util A	Util B	Util C **(Include)**
Telaprevir	Fosamprenavir	Ritonavir

References:
Facts & Comparisons, 2013 Updates, Wolters Kluwer Health.
Clinical Pharmacology, 2013 Elsevier/Gold Standard.
Incivek Prescribing Information, April 2013, Vertex Pharmaceuticals Inc.

35. Telaprevir / Lopinavir-Ritonavir _____ _____

Alert Message: Concurrent use of Incivek (telaprevir) with Kaletra (lopinavir/ritonavir) is not recommended. Co-administration of these agents has been shown to result in reduced steady-state exposure to telaprevir.

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

Util A	Util B	Util C
Telaprevir	Lopinavir/Ritonavir	

References:
Facts & Comparisons, 2013 Updates, Wolters Kluwer Health.
Clinical Pharmacology, 2013 Elsevier/Gold Standard.
Incivek Prescribing Information, April 2013, Vertex Pharmaceuticals Inc.

36. Telaprevir / Atazanavir / Ritonavir _____ _____

Alert Message: Concurrent use of Incivek (telaprevir) with ritonavir-boosted Reyataz (atazanavir) has been shown to result in reduced steady-state exposure to telaprevir while steady-state atazanavir exposure was increased. Monitor patient for decreased telaprevir efficacy and atazanavir-related adverse effects.

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

Util A	Util B	Util C **(Include)**
Telaprevir	Atazanavir	Ritonavir

References:
Facts & Comparisons, 2013 Updates, Wolters Kluwer Health.
Clinical Pharmacology, 2013 Elsevier/Gold Standard.
Incivek Prescribing Information, April 2013, Vertex Pharmaceuticals Inc.

37. Telaprevir / Clarithromycin, Erythromycin & Telithromycin _____ _____

Alert Message: Concurrent use of Incivek (telaprevir) with the antibacterials, clarithromycin, erythromycin or telithromycin, may result in increased plasma concentrations of telaprevir and the antibacterial agent. Caution is warranted and clinical monitoring is recommended when agents are co-administered. All three antibacterials have been shown to increase QT prolongation and clarithromycin and erythromycin are reported to cause torsade de pointes.

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

Util A	Util B	Util C
Telaprevir	Clarithromycin Erythromycin Telithromycin	

References:
Facts & Comparisons, 2013 Updates, Wolters Kluwer Health.
Clinical Pharmacology, 2013 Elsevier/Gold Standard.
Incivek Prescribing Information, April 2013, Vertex Pharmaceuticals Inc.

38. Telaprevir / Certain Statins _____ _____

Alert Message: Concurrent use of Incivek (telaprevir) with fluvastatin, pitavastatin, pravastatin or rosuvastatin may result in increased plasma concentrations of the statin, increasing the risk of statin-related adverse effects. Caution is warranted and clinical monitoring is recommended when telaprevir is co-administered with one of these statins. Telaprevir is an inhibitor of OATP1B1 and OATP2B1 transporters.

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

Util A	Util B	Util C
Telaprevir	Fluvastatin	
	Pravastatin	
	Pitavastatin	
	Rosuvastatin	

References:
Clinical Pharmacology, 2013 Elsevier/Gold Standard.
Incivek Prescribing Information, April 2013, Vertex Pharmaceuticals Inc.

39. Eletriptan / Potent CYP3A4 Inhibitors _____ _____

Alert Message: Relpax (eletriptan) is a CYP3A4 substrate and should not be used within at least 72 hours of treatment with drugs that have demonstrated potent CYP3A4 inhibition and have this effect described in the contraindications, warning and precaution section of labeling.

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

Util A	Util B			Util C
Eletriptan	Ketoconazole	Saquinavir	Tipranavir	
	Itraconazole	Ritonavir		
	Nefazodone	Indinavir		
	Clarithromycin	Nelfinavir		
	Telithromycin	Atazanavir		
	Boceprevir	Fosamprenavir		
	Telaprevir	Lopinavir/Ritonavir		

References:
Relpax Prescribing Information, Jan. 2012, Pfizer US Pharmaceutical Group.
Facts & Comparisons, 2013 Updates, Wolters Kluwer Health.

40. Topiramate ER / Overutilization _____ _____

Alert Message: Trokendi XR (topiramate extended-release) may be over-utilized. The manufacturer's recommended maximum dose of extended-release topiramate is 400 mg once daily.

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C
Topiramate XR		

Max Dose: 400mg/day

References:
Trokendi UX Prescribing Information, August 2013, Supernus Pharmaceuticals.

41. Topiramate IR / Migraine / Negating Seizures & Anticonvulsants _____ _____

Alert Message: The manufacturer's recommended maximum daily dose of topiramate as treatment for adults for prophylaxis of migraine headache is 100 mg per day in two divided doses.

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C **(Negating)**
Topiramate IR 100	Migraine	Seizures/Epilepsy
Topiramate IR 200		Anticonvulsants

References:
Facts & Comparisons, 2013 Updates, Wolters Kluwer Health.
Topamax Prescribing Information, Oct. 2012, Janssen Pharmaceuticals, Inc.