DUR Board Meeting
March 5, 2012
Pioneer Room
State Capitol

North Dakota Medicaid
DUR Board Meeting
Agenda
Pioneer Room
State Capitol
March 5, 2012
1pm

1. Administrative items
    - Travel vouchers

2. Old business
    - Review and approval of minutes of 12/5/11 meeting — Chair
    - Budget update — Brendan
    - Second review of Pulmonary Arterial Hypertension Agents — Brendan
    - Second review of Topical Acne Agents — Brendan
    - Second review of Benign Prostatic Hyperplasia Agents — Brendan
    - Second review of Juvisync/Combination Products — Brendan
    - Second review of Gralise — Brendan
    - Yearly PA review — HID
        - Antihistamines
        - PPIs
        - COX-II/NSAIDs
        - Revatio
        - Actoplus Met
        - Azasite/Quixin
        - Carisoprodol
        - Blood Factors
        - Relistor
        - Sancuso
        - Nuvigil
        - Nucynta

3. New business
    - Review of Lorzone — HID
    - Review of Provigil — HID
    - Review of Kapvay — HID
    - Review of Dexpak/Zemapak — HID
    - Review of Xifaxan — HID
    - Review of Vanos
    - Concurrent use of SSRIs and SNRIs — 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 5, 2011

Members Present: Norman Byers, John Savageau, Russ Sobotta, Cheryl Huber, Greg Pfister, Patricia Churchill, Carrie Sorenson, Leann Ness, Jeffrey Hostetter
Members Absent: Kim Krohn, David Clinkenbeard, Steve Irsfeld, James Carlson, Todd Twogood, Carlotta McCleary
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 September 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 have been no budget updates from fiscal since the last DUR Board meeting.

Dificid Second Review
A motion and second were made at the September meeting to place Dificid 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.

Hereditary Angioedema Second Review
A motion and second were made at the September meeting to place agents used to treat hereditary angioedema 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.

Oral Anticoagulants Second Review
A motion and second were made at the September meeting to place Pradaxa on prior authorization. The topic was brought up for a second review. J. Savageau made a motion to add Xarelto to the prior authorization. N. Byers seconded the motion. J. Robinson, representing Boehringer Ingelheim, spoke regarding Pradaxa. J. Stoffel, representing Janssen Scientific Affairs, spoke regarding Xarelto. Chair, G. Pfister called for a voice vote to approve the amendment. The motion passed with no audible dissent. Chair, G. Pfister called for a voice vote to approve the amended original motion. The motion passed with no audible dissent.

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. Solodyn, Oracea, Oxycontin, Short-Acting Beta$_2$ Agonists, Soma 250, Vusion, Targeted Immunomodulators, Moxatag, Uloric, Smoking Cessation, Topical Anesthetic Agents, Name Brand Narcotics, Ribapak, Metozolv, Suboxone/Subutex, Ampyra, Ultram/Rybix/Ryzolt, and Xolair were reviewed. No changes were made.

Pulmonary Arterial Hypertension Agents Review
B. Joyce reviewed PAH information with the Board. W. Braden, representing United Therapeutics, spoke regarding Adcirca and Tyvaso. P. Miner, representing Gilead, spoke regarding Letairis. After discussion, N. Byers made a motion to place agents used to treat PAH on

prior authorization. J. Hostetter seconded the motion. This topic will be brought up at the next meeting for finalization.

Topical Acne Agents Review
B. Joyce reviewed topical acne agents information with the Board. There was no public comment. After discussion, N. Byers made a motion to place an age restriction on topical acne agents for patients less than 10 and greater than 35 to have a dermatologist involved in therapy. G. Pfister seconded the motion. J. Hostetter made a motion to place topical acne agents on prior authorization. C. Sorenson seconded the motion. This topic will be brought up at the next meeting for finalization.

Benign Prostatic Hyperplasia Review
B. Joyce reviewed BPH information with the Board. There was no public comment. After discussion, G. Pfister made a motion to place BPH agents on prior authorization. N. Byers seconded the motion. This topic will be brought up at the next meeting for finalization.

Juvisync Review
B. Joyce reviewed Juvisync with the Board. S. Carlson, representing Merck, spoke regarding Juvisync. After discussion, J. Hostetter made a motion to place combination products that are more expensive than their individual components, such as Juvisync, on prior authorization. G. Pfister seconded the motion. This topic will be brought up at the next meeting for finalization.

Gralise Review
B. Joyce reviewed Gralise with the Board. There was no public comment. N. Byers made a motion to place Gralise on prior authorization, with failure of gabapentin. G. Pfister 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. P. Churchill moved to approve the new criteria and J. Savageau 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 5, 2012. P. Churchill made a motion to adjourn the meeting. N. Byers seconded. The motion passed with no audible dissent. Chair G. Pfister adjourned the meeting at 2:25 pm.

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		

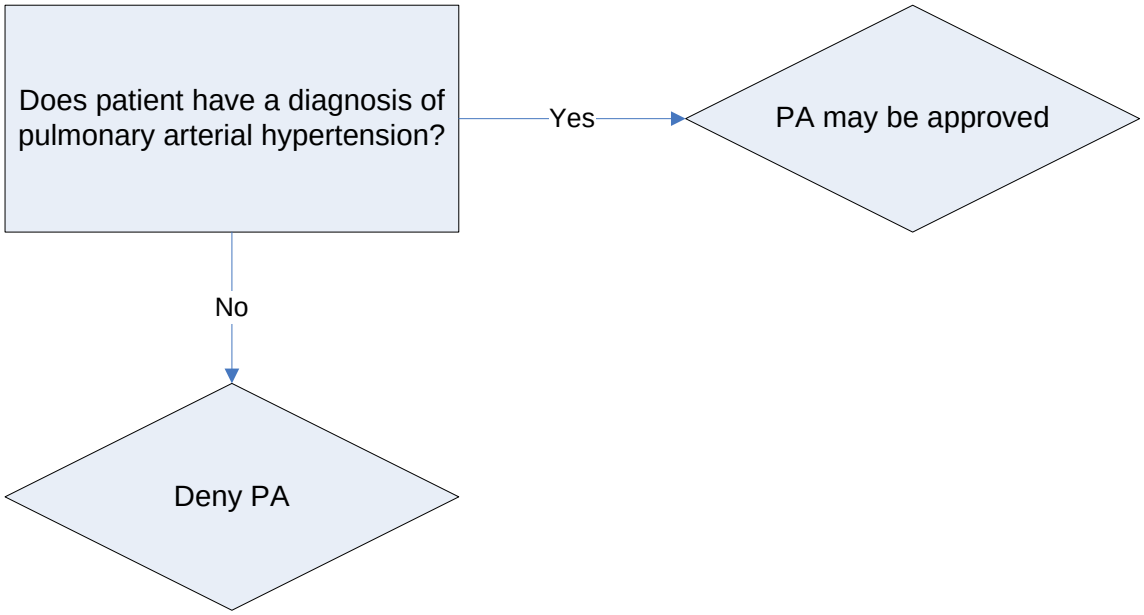
Part II: TO BE COMPLETED BY PHARMACY

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



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		

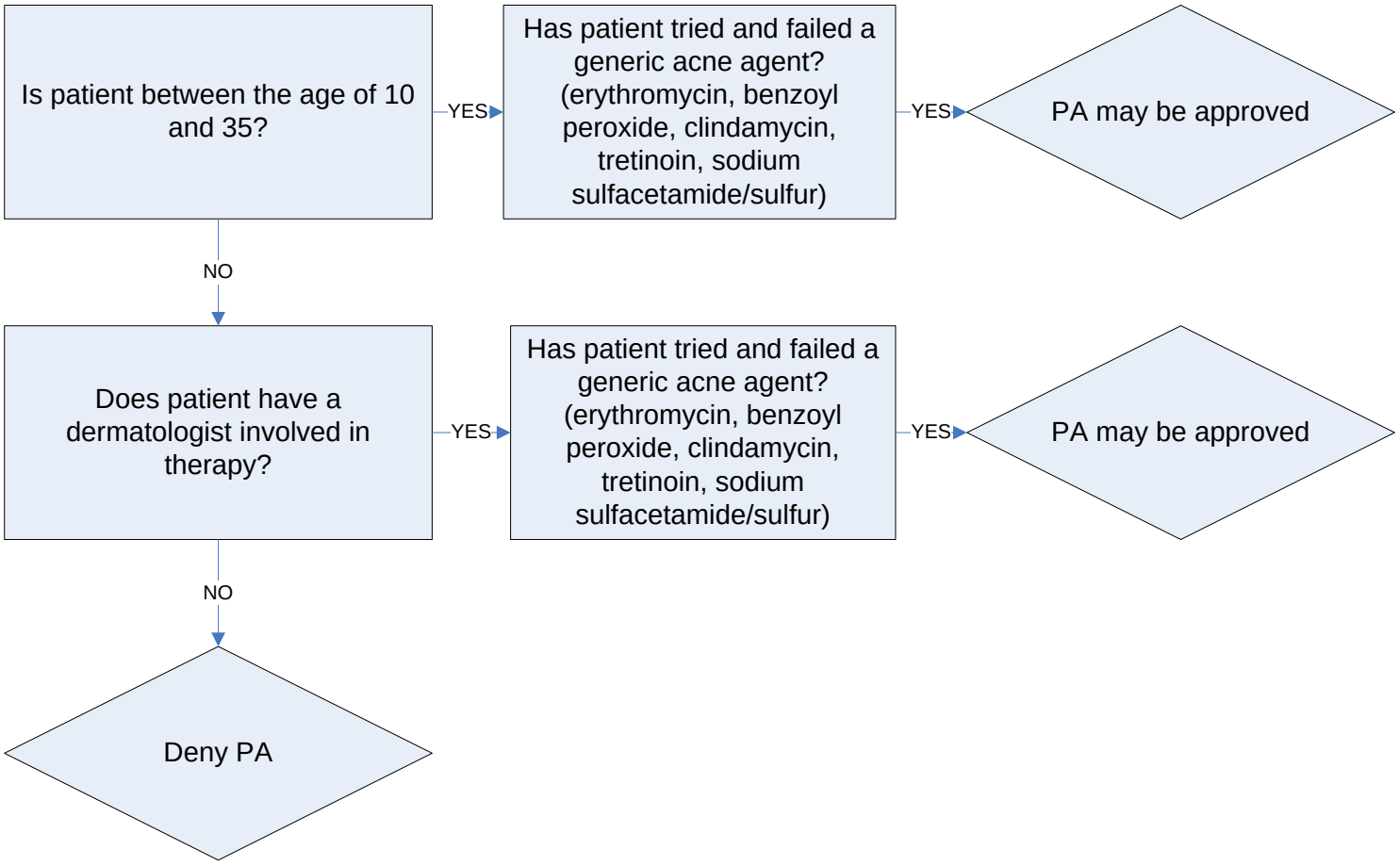
Part II: TO BE COMPLETED BY PHARMACY

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



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**

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	

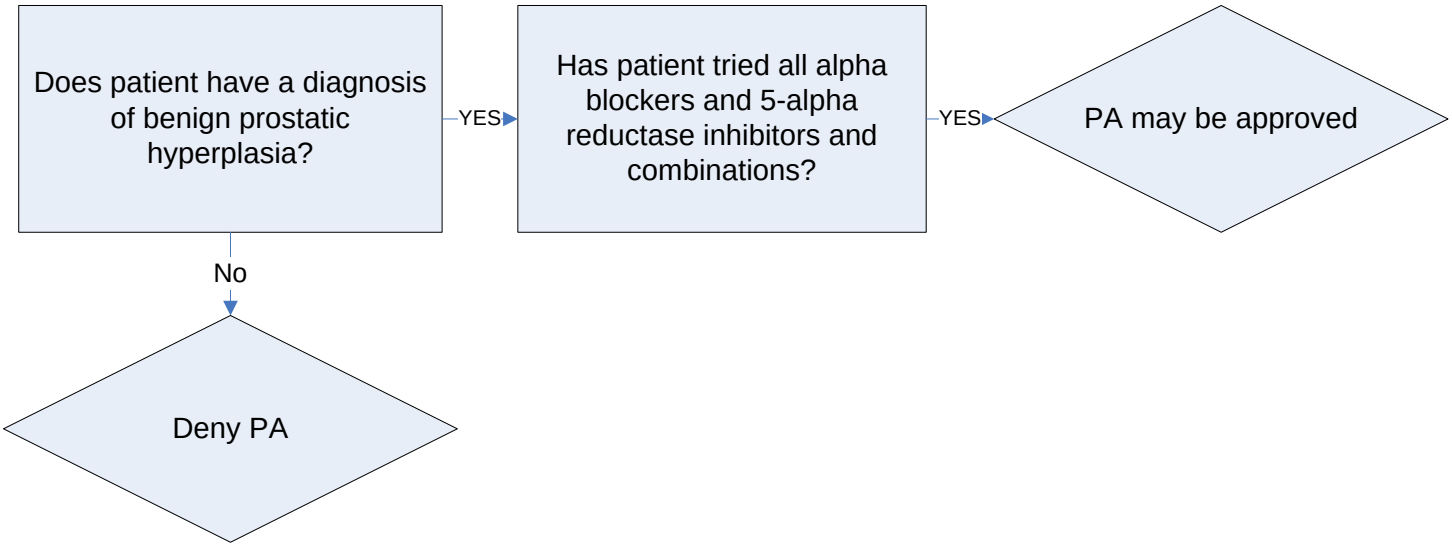
Part II: TO BE COMPLETED BY PHARMACY

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



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	

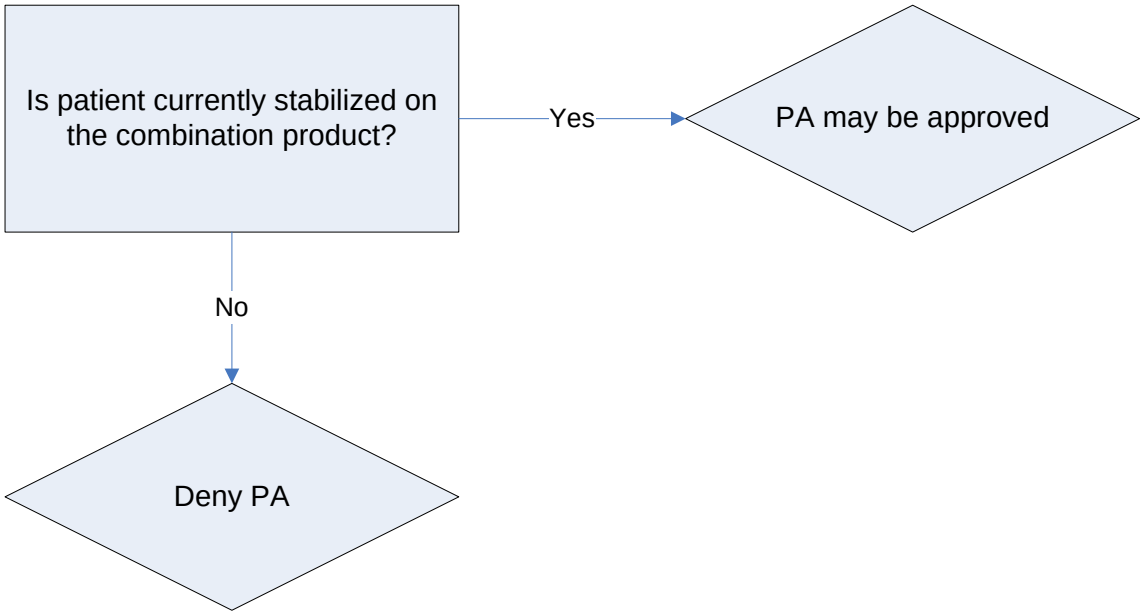
Part II: TO BE COMPLETED BY PHARMACY

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



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	

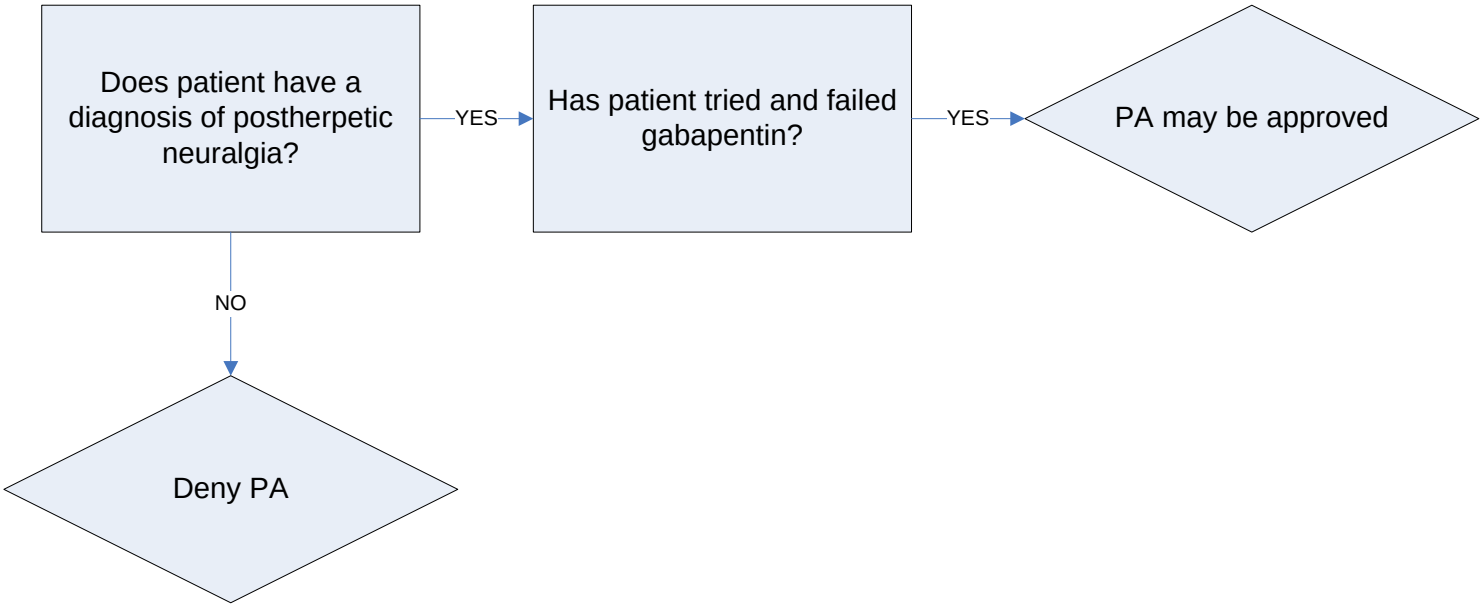
Part II: TO BE COMPLETED BY PHARMACY

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



ANTIHISTAMINE PA FORM

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

Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that patients receiving 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:

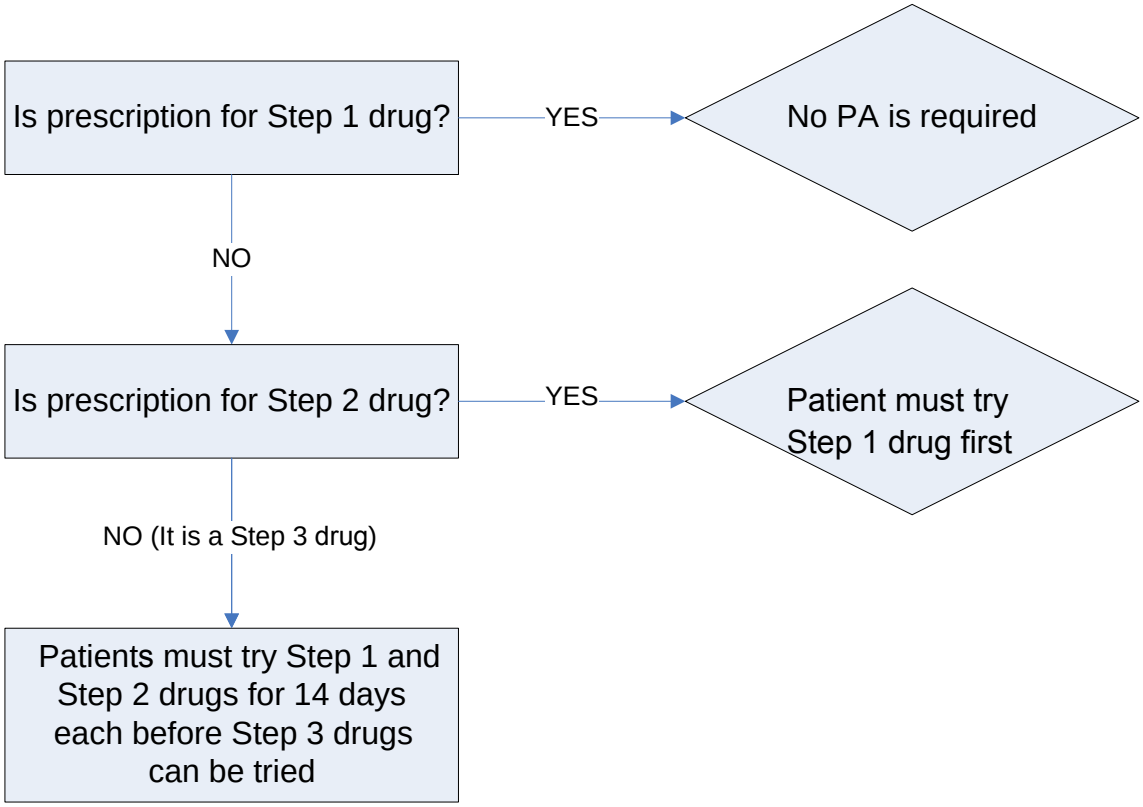
Part II: TO BE COMPLETED BY PHARMACY

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

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.**
- **Prior Authorization is NOT required for patients < 13 years of age.**
- **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:

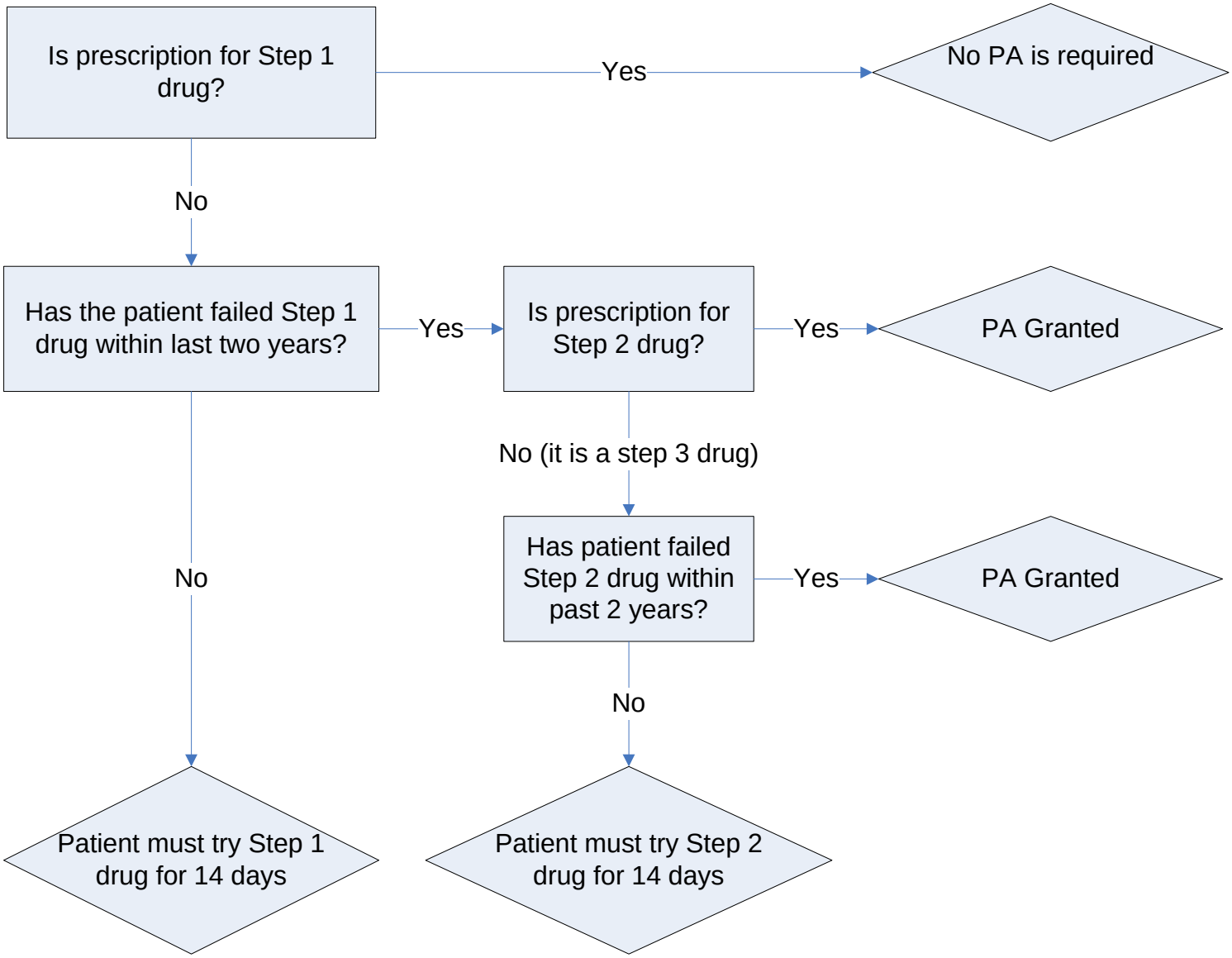
Part II: TO BE COMPLETED BY PHARMACY

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)

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

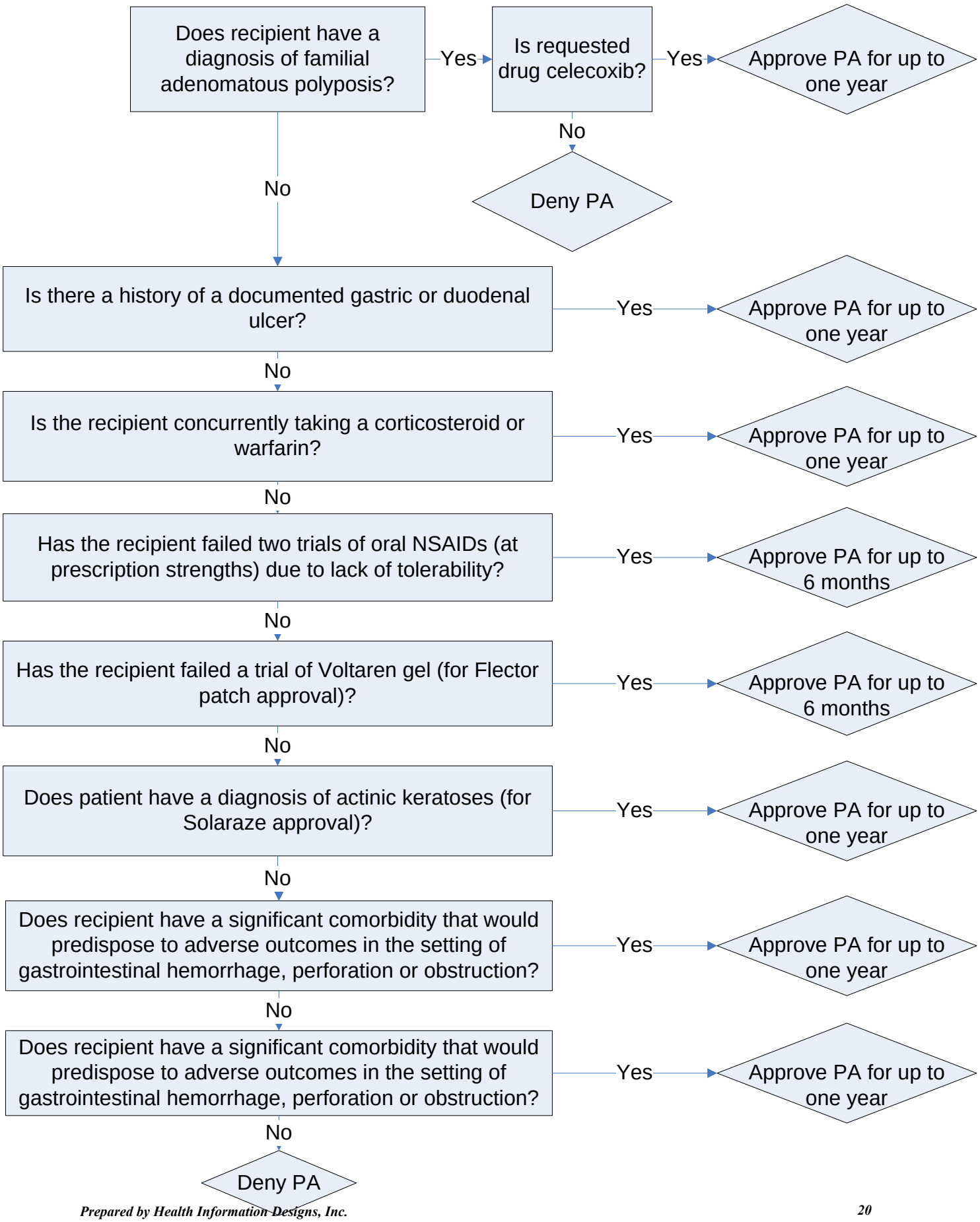
Part II: TO BE COMPLETED BY PHARMACY

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



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		

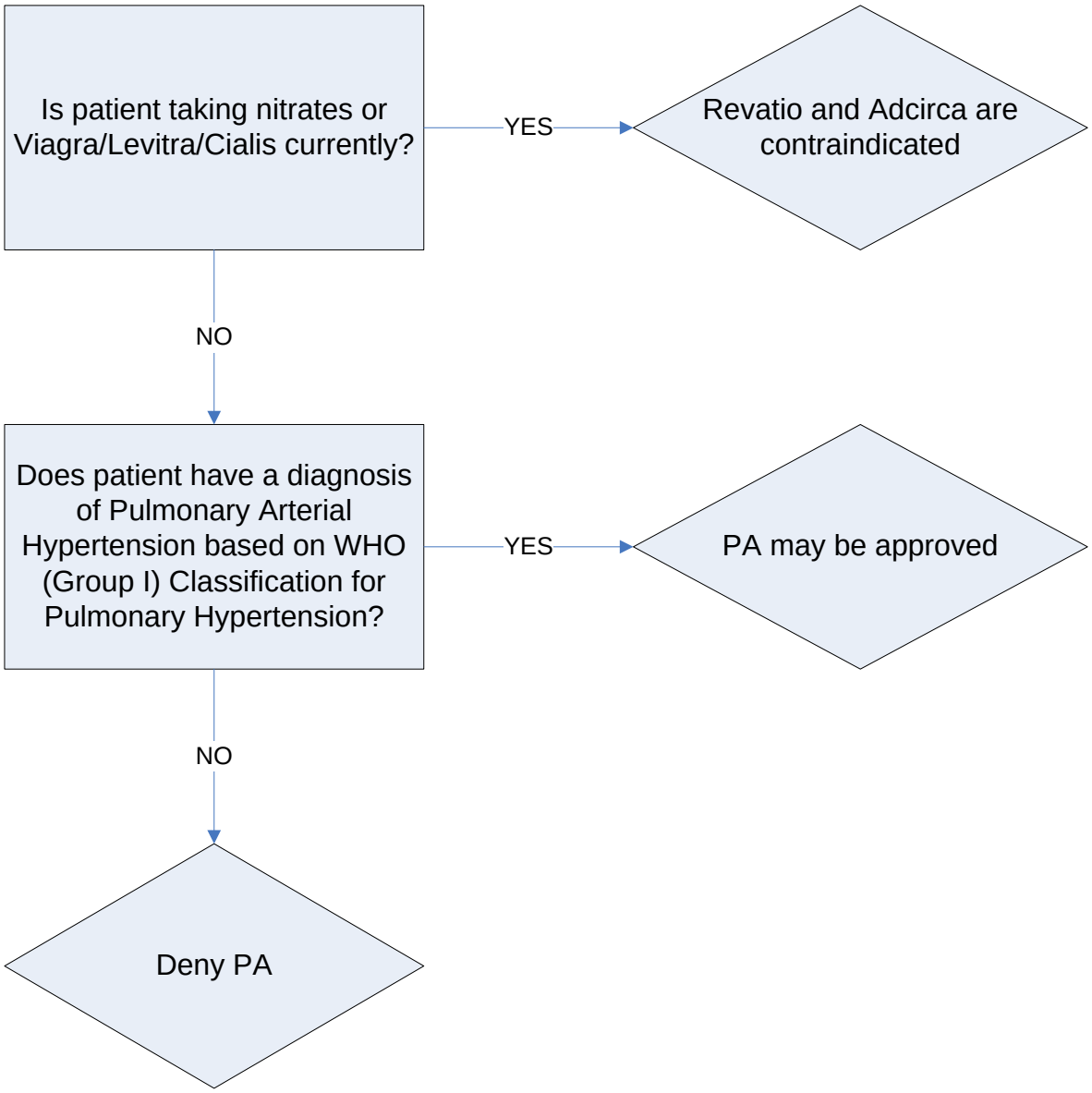
Part II: TO BE COMPLETED BY PHARMACY

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



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	

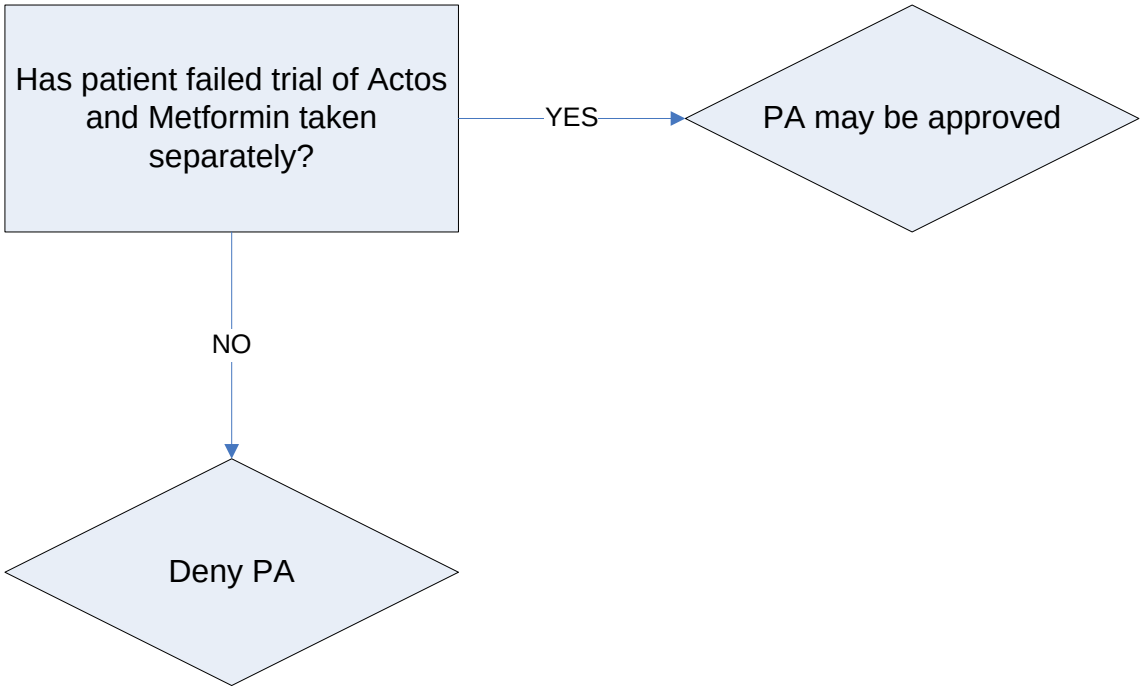
Part II: TO BE COMPLETED BY PHARMACY

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



OPHTHALMIC ANTI-INFECTIVE PA FORM

Prior Authorization Vendor for ND Medicaid

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

ND Medicaid will not pay for Azasite 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		

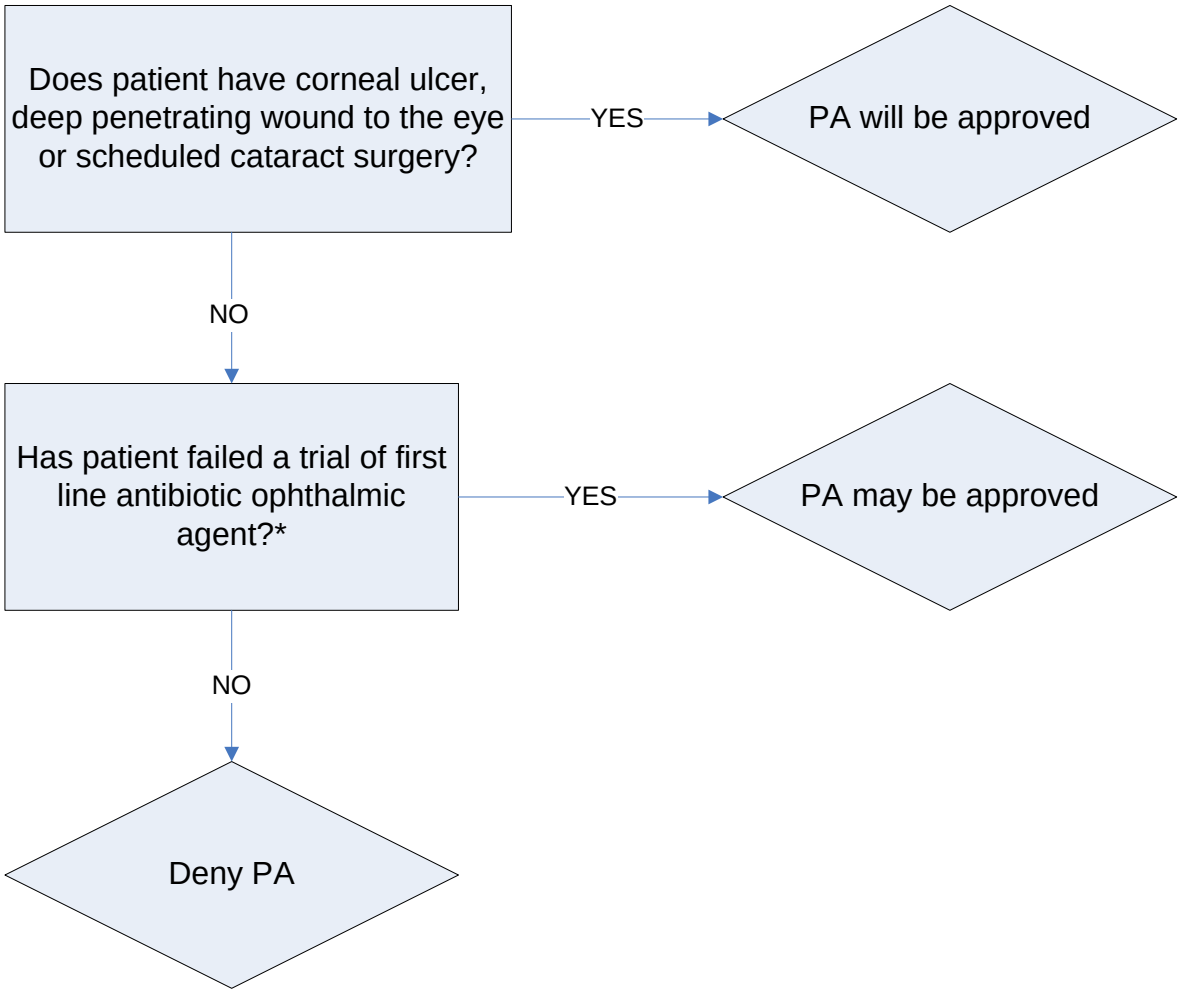
Part II: TO BE COMPLETED BY PHARMACY

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).

CARISOPRODOL PA FORM

Prior Authorization Vendor for ND Medicaid

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

ND Medicaid requires that patients using carisoprodol 350mg longer than two times per year (272 tablets) must receive a prior authorization. Cyclobenzaprine, chlorzoxazone, methocarbamol and orphenadrine do not require a prior authorization.

***Note:**

- **PA will be approved if recipient is currently taking carisoprodol on a chronic basis and provider is weaning patient.**

Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name	Recipient Date of Birth	Recipient Medicaid ID Number	
Physician Name			
Physician Medicaid Provider Number	Telephone Number	Fax Number	
Address	City	State	Zip Code
Requested Drug and Dosage: □ CARISOPRODOL	**Diagnosis for this request:**		
Qualifications for coverage:			
□ CHRONIC CARISOPRODOL RECIPIENT BEING WEANED (PLEASE INCLUDE WEANING SCHEDULE)	Dose	Frequency	
□ *I confirm that I have considered a generic or other alternative and that the requested drug is expected to result in the successful medical management of the recipient.*			
Physician Signature	Date		

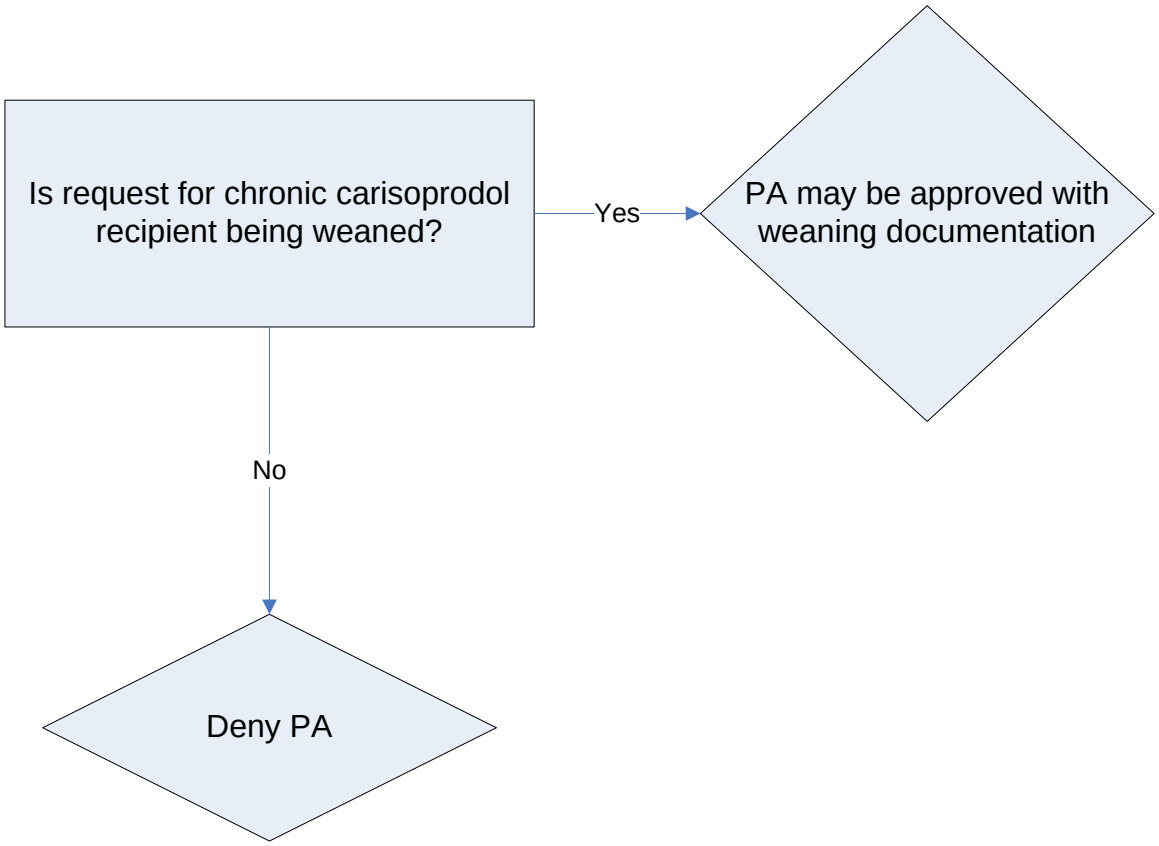
Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

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

North Dakota Department of Human Services
Carisoprodol Authorization Algorithm



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:	

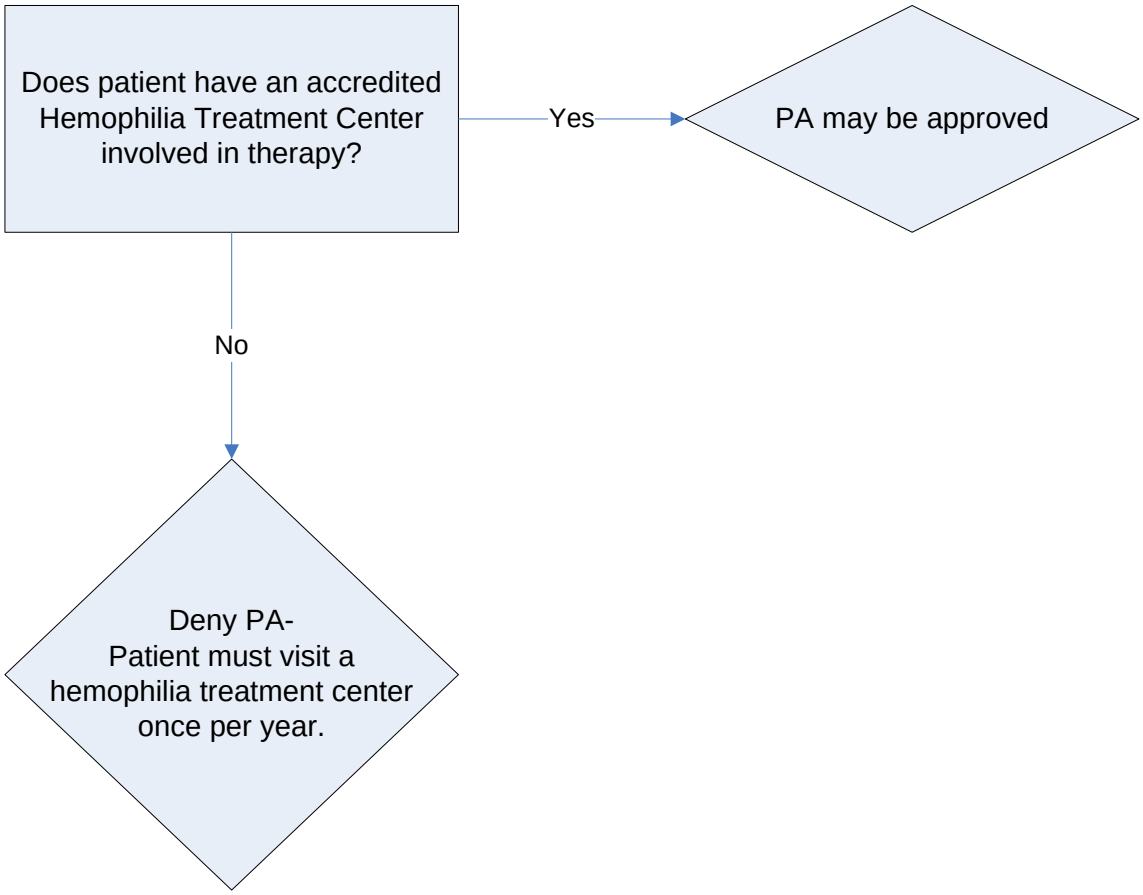
Part II: TO BE COMPLETED BY PHARMACY

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



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	

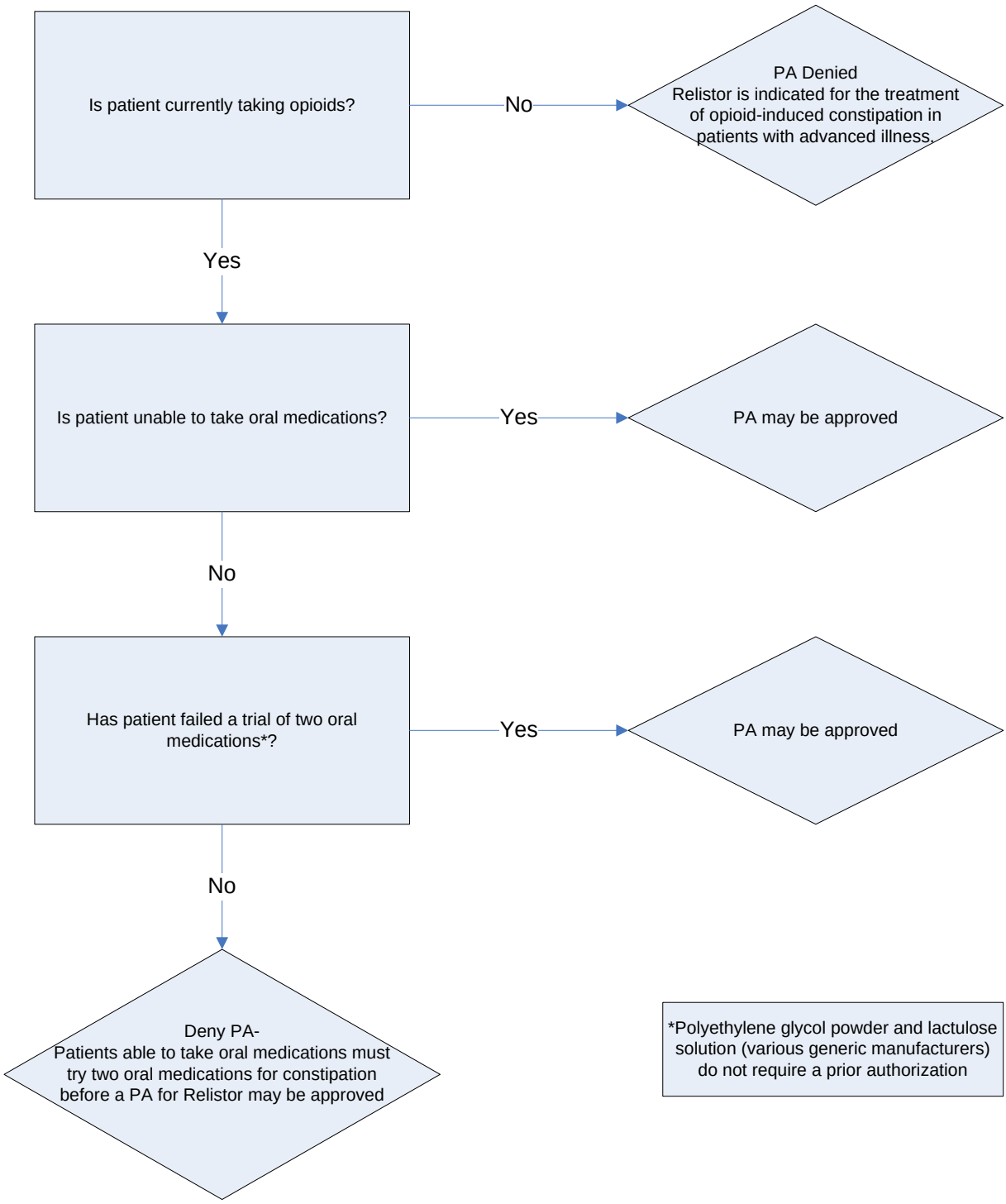
Part II: TO BE COMPLETED BY PHARMACY

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



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	

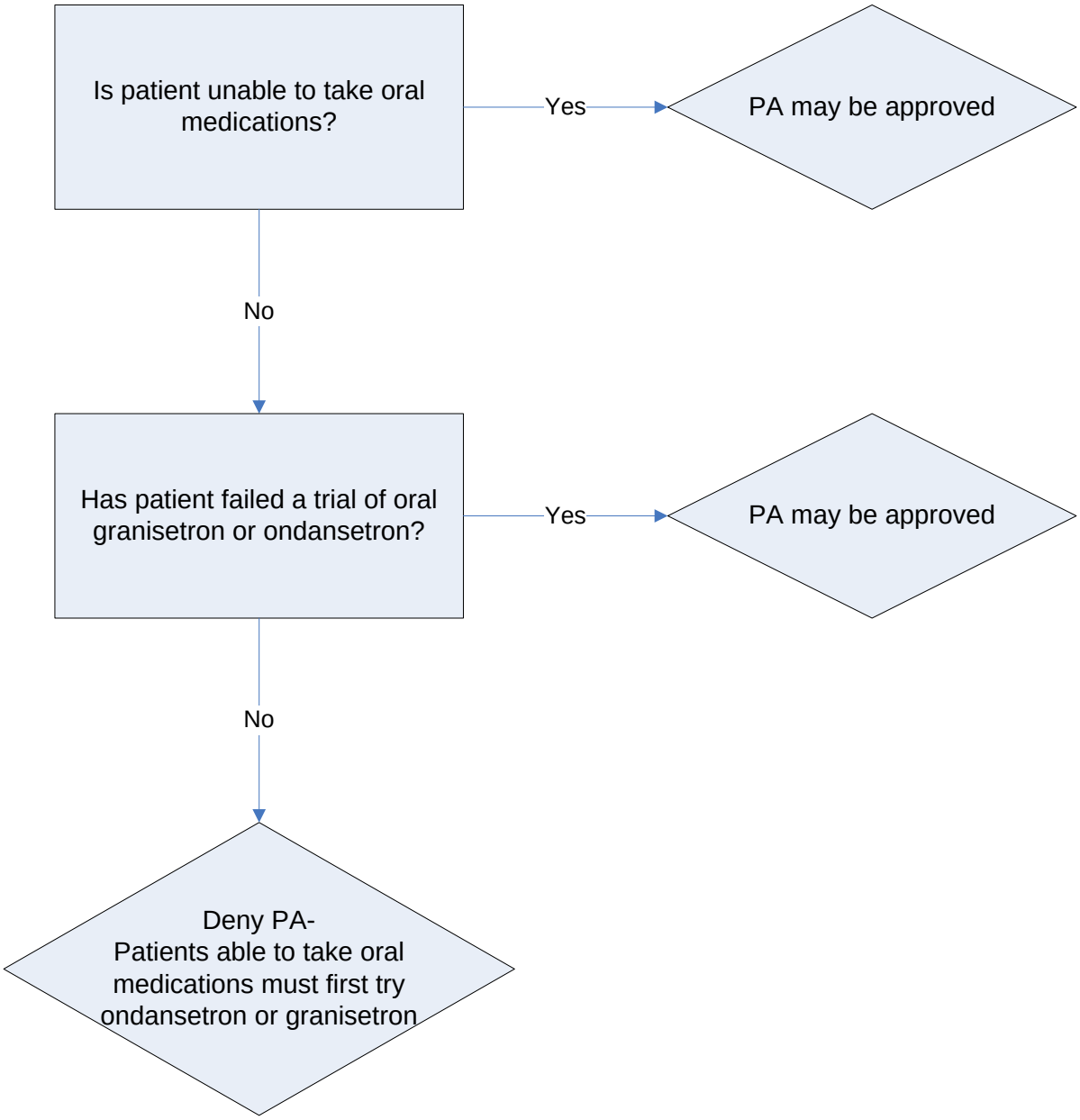
Part II: TO BE COMPLETED BY PHARMACY

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

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	

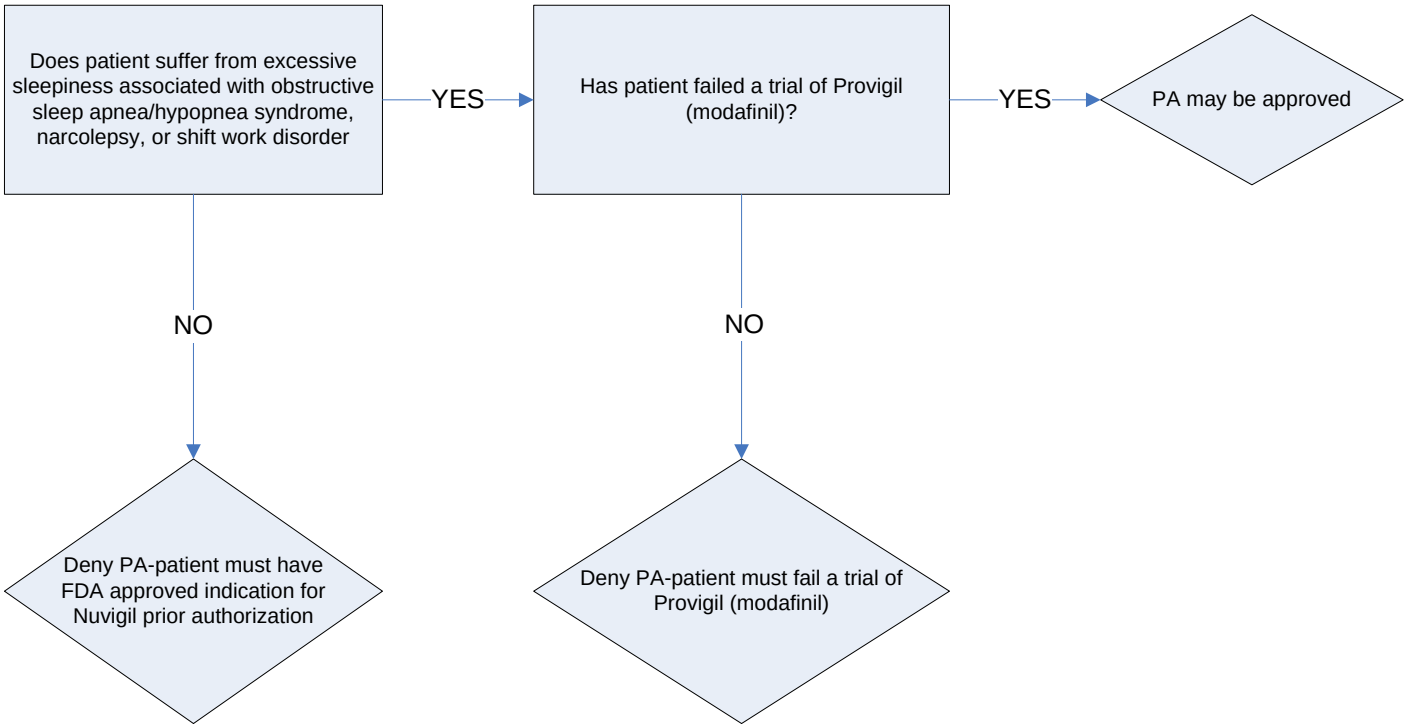
Part II: TO BE COMPLETED BY PHARMACY

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



Nucynta Prior Authorization

Prior Authorization Vendor for ND Medicaid

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

ND Medicaid requires that patients receiving a new prescription for Nucynta must be unable to tolerate other opioids due to gastrointestinal side effects.

- **Oxycodone is covered without a prior authorization.**

Part I: TO BE COMPLETED BY PRESCRIBER

Recipient Name	Recipient Date of Birth	Recipient Medicaid ID Number	
Prescriber Name			
Prescriber Medicaid Provider Number	Telephone Number	Fax Number	
Address	City	State	Zip Code
Requested Drug and Dosage: □ **Nucynta**	**Diagnosis for this request:**		
Qualifications for coverage:			
□ UNABLE TO TOLERATE OTHER OPIOIDS DUE TO GASTROINTESTINAL SIDE EFFECTS OPIOID TRIED_____ START DATE: DOSE: END DATE: FREQUENCY:			
Prescriber Signature		Date	

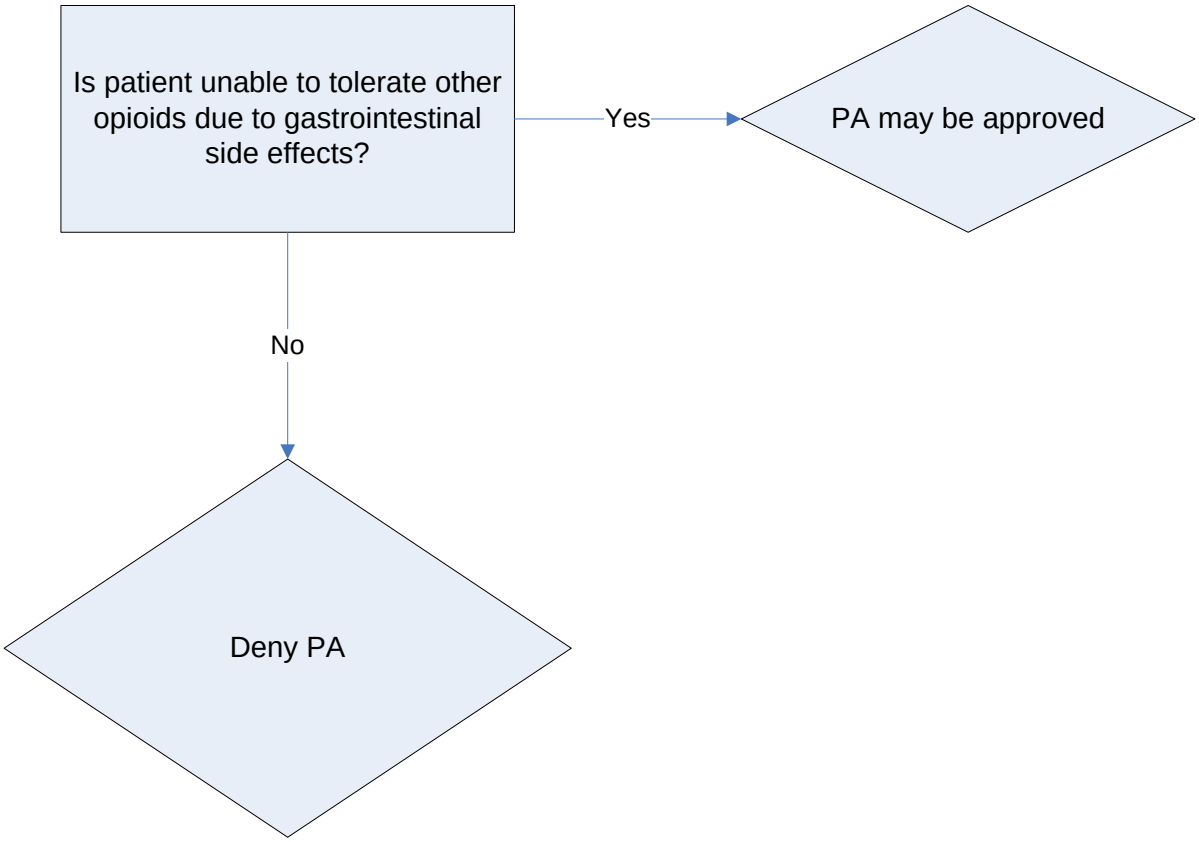
Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

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

North Dakota Department of Human Services
Nucynta Authorization Algorithm



North Dakota Medicaid
DUR Board Meeting
Lorzone™ Review

I. Overview

Lorzone is indicated as an adjunct to rest, physical therapy, and other measures, for the relief of discomfort associated with acute, painful musculoskeletal conditions. The mode of action of this drug has not been clearly identified, but may be related to its sedative properties. Chlorzoxazone does not directly relax tense skeletal muscles in man.

II. Pharmacology

Chlorzoxazone is a centrally-acting agent for painful musculoskeletal conditions. Data available from animal experiments as well as human study indicate that chlorzoxazone acts primarily at the level of the spinal cord and subcortical areas of the brain where it inhibits multisynaptic reflex arcs involved in producing and maintaining skeletal muscle spasm of varied etiology. The clinical result is a reduction of the skeletal muscle spasm with relief of pain and increased mobility of the involved muscles. Blood levels of chlorzoxazone can be detected in people during the first 30 minutes and peak levels may be reached, in the majority of the subjects, in about 1 to 2 hours after oral administration of chlorzoxazone. Chlorzoxazone is rapidly metabolized and is excreted in the urine, primarily in a conjugated form as the glucuronide. Less than one percent of a dose of chlorzoxazone is excreted unchanged in the urine in 24 hours.

III. Warnings/Precautions

1. Serious (including fatal) hepatocellular toxicity has been reported rarely in patients receiving chlorzoxazone. The mechanism is unknown but appears to be idiosyncratic and unpredictable. Factors predisposing patients to this rare event are not known. Patients should be instructed to report early signs and/ or symptoms of hepatoxicity such as fever, rash, anorexia, nausea, vomiting, fatigue, right upper quadrant pain, dark urine, or jaundice. Lorzone™ should be discontinued immediately and a physician consulted if any of these signs or symptoms develop. Lorzone™ use should also be discontinued if a patient develops abnormal liver enzymes (e.g., AST, ALT, alkaline phosphates and bilirubin).
2. The concomitant use of alcohol or other central nervous system depressants may have an additive effect.
3. The safe use of Lorzone has not been established with respect to the possible adverse effects upon fetal development. Therefore, it should be used in women of childbearing potential only when, in the judgement of the physician, the potential benefits outweigh the possible risks.
4. If sensitivity reactions occur such as urticaria, redness, or itching of the skin, the drug should be stopped.

5. If any symptoms suggestive of liver dysfunction are observed, the drug should be discontinued.

IV. Adverse Reactions

Chlorzoxazone-containing products are usually well tolerated. It is possible in rare instances that chlorzoxazone may have been associated with gastrointestinal bleeding. Drowsiness, dizziness, light-headedness, malaise, or overstimulation may be noted by an occasional patient. Rarely, allergic-type skin rashes, petechiae, or ecchymoses may develop during treatment. Angioneurotic edema or anaphylactic reactions are extremely rare. There is no evidence that the drug will cause renal damage. Rarely, a patient may note discoloration of the urine resulting from a phenolic metabolite of chlorzoxazone. This finding is of no known clinical significance.

V. Dosage and Administration

Lorzone 375mg – one tablet three or four times daily. If adequate response is not obtained with this dose, the 375mg tablets may be increased to two tablets (750mg) three or four times daily. As improvement occurs, dosage can usually be reduced.

Lorzone 750mg – 2/3 tablet (500mg) three or four times daily. If adequate response is not obtained with this dose, it may be increased to one tablet (750mg) three or four times daily. As improvement occurs, dosage can usually be reduced.

VI. Drug Interactions

CNS Agents - the concomitant use of alcohol or other CNS depressants may have an additive effect.

References

1. Lorzone™ [prescribing information]. Sayreville, NJ. Vertical Pharmaceuticals., Inc.; October 2010.

North Dakota Medicaid
DUR Board Meeting
Provigil® Review

I. Overview

Provigil (modafinil) is indicated to improve wakefulness in adult patients with excessive sleepiness associated with narcolepsy, obstructive sleep apnea (OSA), and shift work disorder (SWD).

In OSA, Provigil is indicated as an adjunct to standard treatment for the underlying obstruction. If continuous positive airway pressure (CPAP) is the treatment of choice for a patient, a maximal effort to treat with CPAP for an adequate period of time should be made prior to initiating Provigil. If Provigil is used adjunctively with CPAP, the encouragement of and periodic assessment of CPAP compliance is necessary.

In all cases, careful attention to the diagnosis and treatment of the underlying sleep disorder is of utmost importance. Prescribers should be aware that some patients may have more than one sleep disorder contributing to their excessive sleepiness.

The effectiveness of modafinil in long-term use (greater than 9 weeks in narcolepsy clinical trials and 12 weeks in OSA and SWD clinical trials) has not been systematically evaluated in placebo-controlled trials. The physician who elects to prescribe Provigil for an extended time in patients with narcolepsy, OSA, or SWD should periodically reevaluate long-term usefulness for the individual patient.

II. Pharmacology

The precise mechanism through which modafinil promotes wakefulness is unknown. Modafanil has wake-promoting actions similar to sympathomimetic agents like amphetamine and methylphenidate, although the pharmacologic profile is not identical to that of sympathomimetic amines.

III. Dosage and Administration

The recommended dose of modafinil is 200mg given once a day. For patients with narcolepsy and OSA, modafinil should be taken as a single dose in the morning. For patients with SWD, modafinil should be taken approximately 1 hour prior to the start of their work shift. Doses up to 400mg/day, given as a single dose, have been well tolerated, but there is no consistent evidence that this dose confers additional benefit beyond that of the 200mg dose.

IV. Warnings

- Serious Rash, including Stevens-Johnson Syndrome

- Angioedema and Anaphylactoid Reactions
- Multi-organ Hypersensitivity Reactions
- Persistent Sleepiness
- Psychiatric Symptoms

V. Precautions

- Modafanil has not been evaluated in patients with a recent history of myocardial infarction or unstable angina, and such patients should be treated with caution.
- The effectiveness of steroidal contraceptives may be reduced when used with modafinil and for one month after discontinuation of therapy. Alternate or concomitant methods of contraception are recommended for patients treated with modafinil tablets, and for one month after discontinuation.
- The blood levels of cyclosporine may be reduced when used with modafinil. Monitoring of circulating cyclosporine concentrations and appropriate dosage adjustment for cyclosporine should be considered when these drugs are used concomitantly.
- In patients with severe hepatic impairment, with or without cirrhosis, modafinil should be administered at a reduced dose.
- In elderly patients, elimination of modafinil and its metabolites may be reduced as a consequence of aging. Consideration should be given to the use of lower doses in this population.

VI. Drug Interactions

- CYP3A4 inducers (e.g., carbamazepine, phenobarbital, rifampin)/CYP3A4 inhibitors (e.g., itraconazole, ketoconazole)-coadministration with potent inducers or inhibitors could alter the plasma levels of modafinil.
- MAOIs-use caution with coadministration.
- Methylphenidate/Dextroamphetamine-modafanil absorption may be delayed by approximately 1 hour.
- Alcohol-avoid coadministration.
- Clozapine-serum levels may be elevated, increasing the pharmacologic and toxic effects. Monitor closely.
- Contraceptives, hormonal estrogens-effectiveness may be reduced. Alternate or concomitant methods of contraception are recommended for patients treated with modafinil and for 1 month after discontinuation of modafinil.
- Cyclosporine-dosage adjustment may be needed.
- CYP2C9/2C19 (e.g., diazepam, propranolol, phenytoin, SSRIs, certain tricyclic antidepressants)-coadministration may have prolonged elimination and may require dosage reduction and monitoring for toxicity.
- CYP1A2, CYP2B6, and CYP3A4 substrates-use caution when modafinil is coadministered with drugs that depend on these 3 enzymes for their clearance.
- Triazolam-$C_{max,}$ AUC, and half-life may be decreased.

VII. Adverse Reactions

The most commonly observed adverse reactions (5% or more) associated with the use of modafinil more frequently than placebo-treated patients in the placebo-controlled clinical studies in primary disorders of sleep and wakefulness were anxiety, back pain, diarrhea, dizziness, dyspepsia, headache, insomnia, nausea, nervousness, and rhinitis.

VIII. Utilization

Provigil and Nuvigil Utilization		
10/01/10 - 09/30/11		
Label Name	**Rx Num**	**Total Reimb Amt**
NUVIGIL 250 MG TABLET	1	$64.46
NUVIGIL 150 MG TABLET	1	$315.88
PROVIGIL 100 MG TABLET	19	$8,113.20
PROVIGIL 200 MG TABLET	187	$103,173.68
55 recipients	**208**	**$111,667.22**
5 recipients have obstructive sleep apnea diagnosis **3 recipients have narcolepsy diagnosis**		

.

References

1. Provigil® [prescribing information]. Frazer, PA. Cephalon, Inc.; October 2010.

North Dakota Medicaid
DUR Board Meeting
Kapvay® Review

I. Indication

Kapvay is a centrally acting alpha$_2$-adrenergic agonist indicated for the treatment of attention deficit hyperactivity disorder (ADHD) as monotherapy or as adjunctive therapy to stimulant medications.

II. Dosage and Administration

Dosing should be initiated with one 0.1mg tablet at bedtime, and the daily dosage should be adjusted in increments of 0.1mg/day at weekly intervals until the desired response is achieved. Doses should be taken twice a day, with either an equal or higher split dosage being given at bedtime.

III. Pharmacology

Clonidine stimulates alpha$_2$-adrenergic receptors in the brain. The mechanism of action of clonidine in ADHD is not known.

IV. Warnings/Precautions

- Hypotension/bradycardia
- Somnolence/sedation
- Abrupt discontinuation
- Allergic reactions
- Use in patients with vascular disease, cardiac conduction disease, or chronic renal failure
- Concomitant use with other clonidine containing products

V. Adverse Reactions

Common and drug related adverse reactions (incidence at least 5% and twice the rate of placebo) reported with the use of Kapvay include somnolence, fatigue, upper respiratory tract infection, irritability, throat pain, insomnia, nightmares, emotional disorder, constipation, nasal congestion, increased body temperature, dry mouth and ear pain.

VI. Drug Interactions

- Sedating drugs
- Tricyclic antidepressants
- Drugs known to affect sinus node function or AV nodal conduction
- Other clonidine containing products
- Antihypertensive drugs

VII. Utilization

Kapvay Utilization		
10/01/10 - 09/30/11		
Label Name	**Rx Num**	**Total Reimb Amt**
KAPVAY ER 0.1 MG TABLET	19	$2,196.58
4 recipients	**19**	**$2,196.58**

References

1. Kapvay [prescribing information]. Atlanta, GA: Shionogi Pharma, Inc; September 2010.

North Dakota Medicaid
DUR Board Meeting
Dexpak/Zemapak® Review

I. Overview

Dexpak and Zemapak are synthetic glucocorticoids, containing dexamethasone, primarily used for their potent anti-inflammatory effects in disorders of many organ systems. These agents are used to treat allergic states, dermatologic diseases, endocrine disorders, gastrointestinal diseases, hematologic disorders, neoplastic diseases, nervous system diseases, ophthalmic disease, renal diseases, respiratory diseases, rheumatic disorders and other miscellaneous disorders.

II. Pharmacology

Glucocorticoids, naturally occurring and synthetic are adrenocortical steroids that are readily absorbed from the gastrointestinal tract. Glucocorticoids cause varied metabolic effects. In addition, they modify the body's immune responses to diverse stimuli. Naturally occurring glucocorticoids (hydrocortisone and cortisone), which also have sodium-retaining properties, are used as replacement therapy in adrenocortical deficiency states. Their synthetic analogs, including dexamethasone, are primarily used for their anti-inflammatory effects in disorders of many organ systems. At equipotent anti-inflammatory doses, dexamethasone almost completely lacks the sodium-retaining property of hydrocortisone and closely related derivatives of hydrocortisone.

III. Warnings

- Cardio-renal – average and large doses of corticosteroids can cause elevation of blood pressure, sodium and water retention, and increased excretion of potassium.
- Endocrine – Corticosteroids can produce reversible hypothalamic-pituitary adrenal (HPA) axis suppression with the potential for glucocorticosteroid insufficiency after withdrawal of treatment.
- Infections – Corticosteroids may mask some signs of infection, and new infections may appear during their use. Corticosteroids may exacerbate systemic fungal infections and therefore should not be used in the presence of such infections unless they are needed to control life-threatening drug reactions. Chickenpox and measles (viral infection) can have a more serious or even fatal course in pediatric and adult patients on corticosteroids.
- Tuberculosis – The use of corticosteroids in active tuberculosis should be restricted to those cases of fulminating or disseminated tuberculosis in which the corticosteroid is used for the management of the disease in conjunction with an appropriate antituberculous regimen.
- Cerebral Malaria – Corticosteroids should not be used in cerebral malaria.
- Vaccination – Administration of live or live attenuated vaccines is contraindicated in patients receiving immunosuppressive doses of corticosteroids.

- Ophthalmic – Prolonged use of corticosteroids may produce posterior subcapsular cataracts, glaucoma with possible damage to the optic nerves, and may enhance the establishment of secondary ocular infections caused by fungi or viruses.

IV. Precautions

- General – The lowest possible dose of corticosteroids should be used to control the condition under treatment. Reduction should be gradual, when possible.
- Cardio-renal – As some sodium retention with resultant edema and potassium loss may occur in patients receiving corticosteroids, these agents should be used with caution in patients with congestive heart failure, hypertension, or renal insufficiency.
- Endocrine – Drug-induced secondary adrenocortical insufficiency may be minimized by gradual reduction of dosage.
- Gastrointestinal – Steroids should be used with caution in active or latent peptic ulcers, diverticulitis, fresh intestinal anastomoses, and nonspecific ulcerative colitis, since they may increase the risk of perforation.
- Musculoskeletal – Corticosteroids decrease bone formation and increase bone resorption both through their effect on calcium regulation (i.e., decreasing absorption and increasing excretion) and inhibition of osteoblast function. This may lead to inhibition of bone growth in pediatric patients and the development of osteoporosis at any age.
- Neuro-psychiatric – Although controlled clinical trials have shown corticosteroids to be effective in speeding the resolution of acute exacerbations of multiple sclerosis, they do not show that they affect the ultimate outcome or natural history of the disease. Psychic derangements may appear when corticosteroids are used, ranging from euphoria, insomnia, mood swings, personality changes, and severe depression, to frank psychotic manifestations. Also, existing emotional instability or psychotic tendencies may be aggravated by corticosteroids.

V. Drug Interactions

- Aminoglutethimide – May diminish adrenal suppression by corticosteroids.
- Amphotericin B injection and potassium-depleting agents – Patients should be observed closely for development of hypokalemia.
- Antibiotics – Macrolide antibiotics have been reported to cause a significant decrease in corticosteroid clearance.
- Anticholinesterases – May produce weakness in patients with myasthenia gravis.
- Anticoagulants, oral – Usually results in inhibition of response to warfarin. Monitor coagulation indices frequently.
- Antidiabetics – Because corticosteroids may increase blood glucose concentrations, dosage adjustments of antidiabetic agents may be required.
- Antitubercular drugs – Serum concentrations of isoniazid may be decreased.
- Cholestyramine – May increase the clearance of corticosteroids.

- Cyclosporine – Increased activity of both cyclosporine and corticosteroids may occur when the two are used concurrently.
- Dexamethasone suppression test – False-negative results in the dexamethasone suppression test in patients being treated with indomethacin have been reported.
- Digitalis glycosides – May be at increased risk of arrhythmias due to hypokalemia.
- Ephedrine – May enhance the metabolic clearance of corticosteroids.
- Estrogens, including oral contraceptives – May decrease the hepatic metabolism of certain corticosteroids.
- Hepatic Enzyme Inducers, Inhibitors, and Substrates - Drugs which induce cytochrome P450 3A4 (CYP 3A4) enzyme activity (e.g., barbiturates, phenytoin, carbamazepine, rifampin) may enhance the metabolism of corticosteroids and require that the dosage of the corticosteroid be increased. Drugs which inhibit CYP 3A4 (e.g., ketoconazole, macrolide antibiotics such as erythromycin) have the potential to result in increased plasma concentrations of corticosteroids. Dexamethasone is a moderate inducer of CYP 3A4. Co-administration with other drugs that are metabolized by CYP 3A4 (e.g., indinavir, erythromycin) may increase their clearance, resulting in decreased plasma concentration.
- Ketoconazole – May decrease the metabolism of certain corticosteroids by up to 60%, leading to increased risk of corticosteroid side effects.
- Nonsteroidal anti-inflammatory agents – Increases the risk of gastrointestinal side effects.
- Phenytoin – Reports of both increases and decreases in phenytoin levels, leading to alterations in seizure control.
- Skin tests – May suppress reactions to skin tests.
- Thalidomide – Toxic epidermal necrolysis has been reported with concomitant use.
- Vaccines – May exhibit a diminished response to toxoids and live or inactivated vaccines due to inhibition of antibody response.

VI. Adverse Reactions

The following adverse reactions have been reported with dexamethasone or other corticosteroids:

Allergic reactions: Anaphylactoid reaction, anaphylaxis, angioedema.

Cardiovascular: Bradycardia, cardiac arrest, cardiac arrhythmias, cardiac enlargement, circulatory collapse, congestive heart failure, fat embolism, hypertension, hypertrophic cardiomyopathy in premature infants, myocardial rupture following recent myocardial infarction, edema, pulmonary edema, syncope, tachycardia, thromboembolism, thrombophlebitis, vasculitis.

Dermatologic: Acne, allergic dermatitis, dry scaly skin, ecchymoses and petechiae, erythema, impaired wound healing, increased sweating, rash, striae, suppression of reactions to skin tests, thin fragile skin, thinning scalp hair, urticaria.

Endocrine: Decreased carbohydrate and glucose tolerance, development of cushingoid state, hyperglycemia, glycosuria, hirsutism, hypertrichosis, increased requirements for insulin or oral hypoglycemic agents in diabetes, manifestations of latent diabetes mellitus, menstrual irregularities, secondary adrenocortical and pituitary unresponsiveness (particularly in times of stress, as in trauma, surgery, or illness), suppression of growth in pediatric patients.

Fluid and electrolyte disturbances: Congestive heart failure in susceptible patients, fluid retention, hypokalemic alkalosis, potassium loss, sodium retention.

Gastrointestinal: Abdominal distention, elevation in serum liver enzyme levels (usually reversible upon discontinuation), hepatomegaly, increased appetite, nausea, pancreatitis, peptic ulcer with possible perforation and hemorrhage, perforation of the small and large intestine (particularly in patients with inflammatory bowel disease), ulcerative esophagitis.

Metabolic: Negative nitrogen balance due to protein catabolism.
Musculoskeletal: Aseptic necrosis of femoral and humeral heads, loss of muscle mass, muscle weakness, osteoporosis, pathologic fracture of long bones, steroid myopathy, tendon rupture, vertebral compression fractures.

Neurological/Psychiatric: Convulsions, depression, emotional instability, euphoria, headache, increased intracranial pressure with papilledema (pseudotumor cerebri) usually following discontinuation of treatment, insomnia, mood swings, neuritis, neuropathy, paresthesia, personality changes, psychic disorders, vertigo.

Ophthalmic: Exophthalmos, glaucoma, increased intraocular pressure, posterior subcapsular cataracts.

Other: Abnormal fat deposits, decreased resistance to infection, hiccups, increased or decreased motility and number of spermatozoa, malaise, moon face, weight gain.

VII. Dosage and Administration

For oral administration
The initial dosage of dexamethasone varies from 0.75 to 9 mg a day depending on the disease being treated. (Dosage requirements are variable and must be individualized on the basis of the disease under treatment and the response of the patient)

After a favorable response is noted, the proper maintenance dosage should be determined by decreasing the initial drug dosage in small decrements at appropriate time intervals until the lowest dosage that maintains an adequate clinical response is reached.

Situations which may make dosage adjustments necessary are changes in clinical status secondary to remissions or exacerbations in the disease process, the patient's individual

drug responsiveness, and the effect of patient exposure to stressful situations not directly related to the disease entity under treatment. In this latter situation it may be necessary to increase the dosage of the corticosteroid for a period of time consistent with the patient's condition. If after long-term therapy the drug is to be stopped, it is recommended that it be withdrawn gradually rather than abruptly.

In the treatment of acute exacerbations of multiple sclerosis, daily doses of 30 mg of dexamethasone for a week followed by 4 to 12 mg every other day for one month have been shown to be effective.

In pediatric patients, the initial dose of dexamethasone may vary depending on the specific disease entity being treated. The range of initial doses is 0.02 to 0.3 mg/kg/day in three or four divided doses.

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References

1. Wolters Kluwer Health, Inc. ed. Drug Facts and Comparisons. St Louis, MO. 2011.
2. Zema-Pak [prescribing information]. Magnolia, TX. Macoven Pharmaceuticals; August 2009.

North Dakota Medicaid
DUR Board Meeting
Xifaxan® Review

I. Overview

Xifaxan (rifaximin) is a rifamycin antibacterial indicated for the treatment of patients (≥12 years of age) with travelers' diarrhea (TD) caused by noninvasive strains of *Escherichia coli.* Xifaxan is also indicated for reduction in risk of overt hepatic encephalopathy (HE) recurrence in patients ≥18 years of age.

Xifaxan should not be used in patients with diarrhea complicated by fever or blood in the stool or diarrhea due to pathogens other than *E. coli.* To reduce the development of drug-resistant bacteria and maintain the effectiveness of Xifaxan and other antibacterial drugs, Xifaxan should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria.

II. Dosage and Administration

- Travelers' Diarrhea – The recommended dose is one 200mg tablet taken orally three times a day for 3 days.
- Hepatic Encephalopathy – The recommended dose is one 550mg tablet taken orally two times a day, with or without food.

III. Warnings/Precautions

- Travelers' Diarrhea not caused by *E. coli.*
- Clostridium difficile-associated diarrhea
- Development of drug resistant bacteria
- Severe (Child-Pugh C) hepatic impairment

IV. Adverse Reactions

All adverse reactions for Xifaxan 200mg three times daily that occurred at a frequency ≥2% in two placebo-controlled trials include flatulence, headache, abdominal pain, rectal tenesmus, defecation urgency, nausea, constipation, pyrexia, and vomiting.

All adverse reactions for Xifaxan 550mg two times daily for reducing the risk of overt hepatic encephalopathy recurrence in adult patients that occurred at a frequency ≥5% in a placebo-controlled trial include peripheral edema, dizziness, fatigue, ascites, muscle spasms, pruritus, abdominal pain, abdominal distension, anemia, cough, depression, insomnia, nasopharyngitis, abdominal pain upper, arthralgia, back pain, constipation, dyspnea, pyrexia, rash, and nausea.

V. Drug Interactions

An *in vitro* study has suggested that rifaximin induces CYP3A4. However, in patients with normal liver function, rifaximin at the recommended dosing regimen is not expected to induce CYP3A4. It is unknown whether rifaximin can have a significant effect on the pharmacokinetics of concomitant CYP3A4 substrates in patients with reduced liver function who have elevated rifaximin concentrations.

An *in vitro* study suggested that rifaximin is a substrate of P-glycoprotein. It is unknown whether concomitant drugs that inhibit P-glycoprotein can increase the systemic exposure of rifaximin.

VI. Utilization

ND Xifaxan Utilization		
10/01/10 - 09/30/11		
Label Name	**Rx Num**	**Total Reimb Amt**
XIFAXAN 200 MG TABLET	46	$3,798.72
XIFAXAN 550 MG TABLET	82	$84,989.62
24 recipients	**128**	**$88,788.34**

References

1. Xifaxan® [prescribing information]. Morrisville, NC. Salix Pharmaceuticals, Inc.; March 2010.

North Dakota Medicaid
DUR Board Meeting
Vanos® Review

I. Overview

Vanos cream is a corticosteroid indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid responsive dermatoses in patients 12 years of age or older. Treatment beyond 2 consecutive weeks is not recommended and the total dosage should not exceed 60g per week because of the potential for the drug to suppress the hypothalamic-pituitary-adrenal (HPA) axis.

II. Dosage and Administration

- Psoriasis: apply a thin layer once or twice daily to the affected skin areas.
- Atopic Dermatitis: apply a thin layer once daily to the affected skin areas.
- Corticosteroid Responsive Dermatoses, other than psoriasis or atopic dermatitis: apply a thin layer once or twice daily to the affected areas.

III. Warnings/Precautions

- Systemic absorption may produce reversible HPA axis suppression, Cushing's syndrome, hyperglycemia and unmask latent diabetes.
- Modify use should HPA axis suppression develop.
- Potent corticosteroids, use on large areas, prolonged use or occlusive use may increase systemic absorption.
- Local adverse reactions with topical steroids may include atrophy, striae, irritation, acneiform eruptions, hypopigmentation and allergic contact dermatitis and may be more likely to occur with occlusive use or more potent corticosteroids.
- Children may be more susceptible to systemic toxicity when treated with topical corticosteroids.

IV. Adverse Reactions

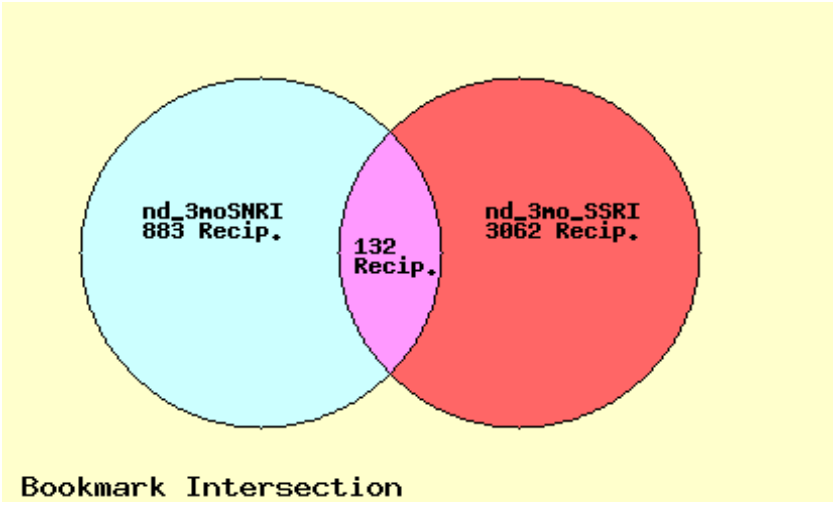
The most commonly reported adverse reactions (≥1%) were headache, application site burning, nasopharyngitis, and nasal congestion.

References

1. Vanos® [prescribing information]. Scottsdale, AZ. Medicis, The Dermatology Company; November 2011.

SSRI Utilization		
10/01/10 - 09/30/11		
Label Name	**Rx Num**	**Total Reimb**
CELEXA 20 MG TABLET	8	$888.26
CITALOPRAM HBR 10 MG TABLET	618	$5,415.70
CITALOPRAM HBR 10 MG/5 ML SOLN	76	$3,267.29
CITALOPRAM HBR 20 MG TABLET	2231	$21,167.94
CITALOPRAM HBR 40 MG TABLET	1942	$18,457.73
FLUOXETINE 20 MG/5 ML SOLUTION	254	$4,905.47
FLUOXETINE DR 90 MG CAPSULE	76	$7,476.81
FLUOXETINE HCL 10 MG CAPSULE	1116	$8,025.77
FLUOXETINE HCL 10 MG TABLET	350	$2,929.43
FLUOXETINE HCL 20 MG CAPSULE	5108	$47,288.25
FLUOXETINE HCL 20 MG TABLET	104	$910.26
FLUOXETINE HCL 40 MG CAPSULE	9	$121.25
FLUVOXAMINE MALEATE 100 MG TAB	209	$5,605.76
FLUVOXAMINE MALEATE 25 MG TAB	37	$1,006.64
FLUVOXAMINE MALEATE 50 MG TAB	73	$1,256.28
LEXAPRO 10 MG TABLET	355	$29,885.40
LEXAPRO 20 MG TABLET	4021	$366,575.57
LEXAPRO 5 MG TABLET	12	$586.48
LEXAPRO 5 MG/5 ML SOLUTION	16	$2,893.86
LUVOX CR 100 MG CAPSULE	11	$1,856.10
LUVOX CR 150 MG CAPSULE	1	$170.08
PAROXETINE CR 12.5 MG TABLET	8	$575.04
PAROXETINE CR 25 MG TABLET	72	$8,494.93
PAROXETINE CR 37.5 MG TABLET	58	$5,200.92
PAROXETINE HCL 10 MG TABLET	202	$2,001.55
PAROXETINE HCL 20 MG TABLET	681	$7,854.15
PAROXETINE HCL 30 MG TABLET	256	$3,069.93
PAROXETINE HCL 40 MG TABLET	835	$11,397.06
PAXIL 10 MG/5 ML SUSPENSION	5	$925.90
PAXIL CR 25 MG TABLET	26	$4,723.53
PROZAC 20 MG PULVULE	25	$16,973.88
PROZAC 40 MG PULVULE	5	$1,934.50
PROZAC WEEKLY 90 MG CAPSULE	28	$3,335.84
SERTRALINE 20 MG/ML ORAL CONC	39	$2,034.65
SERTRALINE HCL 100 MG TABLET	4534	$43,718.23
SERTRALINE HCL 25 MG TABLET	667	$5,717.53
SERTRALINE HCL 50 MG TABLET	2606	$23,177.91
VIIBRYD 10 MG TABLET	5	$385.14
VIIBRYD 20 MG TABLET	5	$487.52
VIIBRYD 40 MG TABLET	12	$1,496.97
5,456 recipients	**26707**	**$674,195.51**

SNRI Utilization		
10/01/10 - 09/30/11		
Label Name	**Rx Num**	**Total Reimb**
CYMBALTA 20 MG CAPSULE	54	$8,390.31
CYMBALTA 30 MG CAPSULE	1256	$170,653.71
CYMBALTA 60 MG CAPSULE	2929	$474,432.16
PRISTIQ ER 100 MG TABLET	270	$33,781.99
PRISTIQ ER 50 MG TABLET	565	$71,184.89
SAVELLA 100 MG TABLET	49	$4,043.96
SAVELLA 12.5 MG TABLET	4	$302.76
SAVELLA 25 MG TABLET	23	$2,340.13
SAVELLA 50 MG TABLET	120	$12,789.10
SAVELLA TITRATION PACK	27	$2,666.05
VENLAFAXINE HCL 100 MG TABLET	26	$1,114.14
VENLAFAXINE HCL 25 MG TABLET	25	$341.27
VENLAFAXINE HCL 37.5 MG TABLET	63	$1,571.05
VENLAFAXINE HCL 50 MG TABLET	14	$427.20
VENLAFAXINE HCL 75 MG TABLET	110	$2,971.41
VENLAFAXINE HCL ER 150 MG CAP	1462	$157,910.20
VENLAFAXINE HCL ER 225 MG TAB	94	$21,238.54
VENLAFAXINE HCL ER 37.5 MG CAP	432	$25,997.20
VENLAFAXINE HCL ER 75 MG CAP	1237	$99,809.76
1,490 recipients	**8760**	**$1,091,965.83**



NORTH DAKOTA MEDICAID
RETROSPECTIVE DRUG UTILIZATION REVIEW
CRITERIA RECOMMENDATIONS
1ST QUARTER 2012

Criteria Recommendations ***Approved Rejected***

1. Clobazam / Overutilization (≥ 10 yoa) _____ _____

Alert Message: Onfi (clobazam) may be over-utilized. Patients weighing greater than 30 kg should have therapy initiated at 10 mg daily and titrated as tolerated to a maximum of 40 mg daily. Patients weighing 30 kg or less should have clobazam therapy initiated at 5 mg daily and titrated as tolerated to 20 mg daily.

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

Max Dose: 40mg/day
Age Range: ≥ 10 yoa
We do not receive weight data for patients so an age range was chosen to reduce the number of false positives. The age range of 10 years of age and older was selected because the average weight of a 10 year child is 86 pounds (85 for males, 88 for females according to CDC Body Mass Index Report 2000).

References:
Onfi Prescribing Information, October 2011, Lundbeck, Inc.

2. Clobazam / Overutilization (2-9 yoa) _____ _____

Alert Message: Onfi (clobazam) may be over-utilized. Patients weighing 30 kg or less should have clobazam therapy initiated at 5 mg daily and titrated as tolerated to 20 mg daily. Patients weighing greater than 30 kg should have therapy initiated at 10 mg daily and titrated as tolerated to a maximum of 40 mg daily.

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

Max Dose: 20mg/day
Age Range: 2-9 yoa

References:
Onfi Prescribing Information, October 2011, Lundbeck, Inc.

3. Clobazam / TA - Therapeutic Appropriateness (<2 yoa) _____ _____

Alert Message: The safety and effectiveness of Onfi (clobazam) in patients less than 2 years of age have not been established.

Conflict Code: TA - Therapeutic Appropriateness
Drugs/Diseases
Util A Util B Util C
Clobazam

Age Range: 0-1 yoa

References:
Onfi Prescribing Information, October 2011, Lundbeck, Inc.

4. Clobazam / Nonadherence _____ _____

Alert Message: Based on the refill history, your patient may be underutilizing Onfi (clobazam). Non-adherence to the prescribed dosing regimen may result in sub-therapeutic effects, which may lead to decreased patient outcomes and additional healthcare costs. If the patient is discontinuing clobazam it should be withdrawn gradually by decreasing the total daily dose by 5 - 10 mg/day on a weekly basis until discontinued in order to avoid seizure occurrence or withdrawal symptoms.

Conflict Code – LR - Nonadherence
Drugs/Diseases

Util A	Util B	Util C
Clobazam		

References:
Onfi Prescribing Information, October 2011, Lundbeck, Inc.

5. Clobazam / Moderate & Strong CYP2C19 Inhibitors _____ _____

Alert Message: Onfi (clobazam) is a CYP2C19 substrate and concurrent use with a strong or moderate CYP2C19 inhibitor may result in increased exposure to the active metabolite of clobazam (N-desmethylclobazam). Dosage adjustment of clobazam may be necessary.

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

Util A	Util B	Util C
Clobazam	Fluconazole	
	Fluvoxamine	
	Ticlopidine	
	Omeprazole	
	Esomeprazole	
	Fluoxetine	
	Voriconazole	

References:
Onfi Prescribing Information, October 2011, Lundbeck, Inc.
FDA Drug Development and Drug Interactions: Table of Substrates, Inhibitors and Inducers: Table of Substrates, Inhibitors.
Available at:
http://www.fda.gov/drugs/developmentapprovalprocess/developmentresources/druginteractionslabeling/ucm093664.htm

6. Clobazam / CNS Depressants _____ _____

Alert Message: Onfi (clobazam) has a CNS depressant effect and concurrent use with other CNS depressants may result in potentiated depressants effects.

Conflict Code
Drugs/Diseases

Util A	Util B	Util C
Clobazam	Narcotics	
	Barbiturates	
	Benzodiazepines	
	Sedative/Hypnotics	
	Muscle Relaxants	
	Antihistamines	
	Antipsychotics	

References:
Onfi Prescribing Information, October 2011, Lundbeck, Inc.
Micromedex Healthcare Series, DrugDex Drug Evaluations, 2011 Thomson Reuters.

7. Clobazam / CYP3A4 Metabolized Hormonal Contraceptives _____ _____

Alert Message: Onfi (clobazam) is a weak CYP3A4 inducer and concurrent use with CYP3A4-metabolized hormonal contraceptives may diminish the effectiveness of the contraceptive agent. The manufacturer recommends the use an additional non-hormonal form of contraception when using clobazam.

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

Util A	Util B	Util C
Clobazam	CYP3A4 Metabolized Hormonal Contraceptives	

References:
Onfi Prescribing Information, October 2011, Lundbeck, Inc.
Micromedex Healthcare Series, DrugDex Drug Evaluations, 2011 Thomson Reuters.

8. Clobazam / Substance Abuse _____ _____

Alert Message: Onfi (clobazam) should be used with caution in patients with a history of substance abuse because of the predisposition of such patients to habituation and dependence. Clobazam is a benzodiazepine and in clinical trials, cases of dependency were reported following abrupt discontinuation of clobazam.

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

Util A	Util B	Util C
Clobazam	Drug Abuse	

References:
Onfi Prescribing Information, October 2011, Lundbeck, Inc.

9. Clobazam / CYP2D6 Metabolized Drugs _____ _____

Alert Message: Onfi (clobazam) is a CYP2D6 inhibitor and concurrent use with drugs metabolized by CYP2D6 may cause increased plasma concentrations of the substrate. Dosage adjustment of the CYP2D6 substrate may be required.

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

Util A	Util B			Util C
Clobazam	Dextromethorphan	Aripiprazole	Paroxetine	Ondansetron
	Atomoxetine	Carvedilol	Propafenone	Promethazine
	Metoprolol	Duloxetine	Propranolol	Chlorpheniramine
	Nebivolol	Flecainide	Risperidone	
	Perphenazine	Fluoxetine	Tamoxifen	
	Tolterodine	Fluvoxamine	Timolol	
	Venlafaxine	Haloperidol	Tramadol	
	Thioridazine	Mexiletine	Amphetamine	
	Tricyclic Antidepressants	Oxycodone	Donepezil	

References:
Onfi Prescribing Information, October 2011, Lundbeck, Inc.
FDA Drug Development and Drug Interactions: Table of Substrates, Inhibitors and Inducers: Table of Substrates, Inhibitors.
Available at:
http://www.fda.gov/drugs/developmentapprovalprocess/developmentresources/druginteractionslabeling/ucm093664.htm
Micromedex Healthcare Series, DrugDex Drug Evaluations, 2011 Thomson Reuters.

10. Clobazam / Alcohol Abuse/Dependence _____ _____

Alert Message: A review of the patient's diagnostic profile reveals that they may consume alcohol. The concurrent use of Onfi (clobazam) with alcohol has been reported to increase the maximum plasma exposure of clobazam by approximately 50%. Caution patients against use of alcohol while taking clobazam.

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

Util A	Util B	Util C
Clobazam	Alcohol Dependence	
	Acute Alcohol Intoxication	
	Other/Unspecified Alcohol Dependence	

References:
Onfi Prescribing Information, October 2011, Lundbeck, Inc.

11. Dronedarone / Warfarin _____ _____

Alert Message: Post-marketing cases of increased INR with or without bleeding events have been reported in warfarin-treated patients initiated on Multaq (dronedarone). Monitor INR after initiating dronedarone in patients taking warfarin.

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

Util A	Util B	Util C
Dronedarone	Warfarin	

References:
Facts & Comparisons, 2012 Updates.
Clinical Pharmacology, 2012 Elsevier/Gold Standard.
Multaq Prescribing Information, December 2011, Sanofi-Aventis U.S. LLC.

12. Dronedarone / Atrial Fibrillation (Black Box Warning) _____ _____

Alert Message: Multaq (dronedarone) is contraindicated in patients with atrial fibrillation (AF) who will not or cannot be cardioverted into normal sinus rhythm. In patients with permanent AF, dronedarone doubles the risk of death, stroke, and hospitalization for heart failure. Patients treated with dronedarone should undergo monitoring of cardiac rhythm at least once every 3 months.

Conflict Code: MC- Drug/Disease Warning (Black Box)
Drugs/Diseases

Util A	Util B	Util C
Dronedarone	Atrial Fibrillation	

References:
Multaq Prescribing Information, December 2011, Sanofi-Aventis U.S. LLC.
FDA Safety Communication: Review Update of Multaq (dronedarone) and Increased Risk of Death and Serious Cardiovascular Adverse Events. [12-19-2011].
Available at: http://www.fda.gov/Drugs/DrugSafety/ucm283933.htm