DUR Board Meeting
June 4, 2012
Pioneer Room
State Capitol

North Dakota Medicaid
DUR Board Meeting
Agenda
Pioneer Room
State Capitol
June 4, 2012
1pm

1. Administrative items
    - Travel vouchers

2. Old business

• Review and approval of minutes of 03/05/12 meeting	Chair
• Budget update	Brendan
• Second review of Lorzone	Brendan
• Second review of Provigil	Brendan
• Second review of Kapvay	Brendan
• Second review of Dexpak/Zemapak	Brendan
• Second review of Xifaxan	Brendan
• Second review of Vanos	Brendan
• Update on SSRI/SNRI combinations	Brendan
• Yearly PA review	HID
o Sed/Hyps	
o Qualaquin	
o ACE-I/ARBs/Renin Inhibitors	
o Synagis	
o GH/IGF1	
o Triptans	

3. New business

• Review of Topical Steroids	HID
• Review of Kalydeco	HID
• Review of Kuvan	HID
• Review of Elaprase	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 5, 2012

Members Present: Norman Byers, John Savageau, Russ Sobotta, Cheryl Huber, Greg Pfister, Tanya Schmidt, Carrie Sorenson, Leann Ness, Jeffrey Hostetter, Todd Twogood, Carlotta McCleary, David Clinkenbeard
Members Absent: Kim Krohn, Steve Irsfeld, 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 the spending for the biennium (July-Dec data) is under budget compared to the last biennium. Rebate changes from PPACA are still being determined. The cost of brand name drugs ten years ago was approximately 73 dollars, today it is approximately 220 dollars. The cost of generic drugs ten years ago was approximately 17 dollars, today it is approximately 22 dollars. The generic rate ten years ago was 46%, today it is 80%.

Pulmonary Arterial Hypertension Second Review
A motion and second were made at the December meeting to place agents used to treat pulmonary arterial hypertension on prior authorization. The topic was brought up for a second review. The Revatio/Adcirca PA form will be combined with the new PAH form. 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.

Topical Acne Agents Second Review
A motion and second were made at the December meeting to place Topical Acne Agents 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.

Cialis for Benign Prostatic Hyperplasia Second Review
A motion and second were made at the December meeting to place Cialis for BPH on prior authorization. The topic was brought up for a second review. There was no public comment. A suggestion was made to include 'unless contraindicated' after 'patient must try and fail all alpha blockers and 5-alpha reductase inhibitors and combinations'. J. Hostetter made a motion to amend the form. G. Pfister seconded the motion. Chair G. Pfister called for a voice vote to approve the amendment of the form. The motion passed with no audible dissent. Chair G. Pfister called for a voice vote to approve the motion. The motion passed with no audible dissent.

Combination Products Second Review
A motion and second were made at the December meeting to place combination products that are more costly to the state than their individual ingredients 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.

Gralise Second Review
A motion and second were made at the December meeting to place Gralise 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.

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. Antihistamines, PPIs, COX-II/NSAIDs, Revatio, Actoplus Met, Azasite/Quixin, Carisoprodol, Blood Factors, Relistor, Sancuso, Nuvigil, and Nucynta were reviewed. Changes made:

1. Remove Allegra from antihistamine form
2. PPIs-add duration edits as an agenda item for June meeting
3. COX-II/NSAIDs-add long term utilization information as an agenda item for June meeting
4. Revatio/Adcirca will be combined with PAH form
5. Actoplus Met will be combined with combination products form
6. Merge Carisoprodol and Soma 250 form

Lorzone Review
B. Joyce reviewed Lorzone information with the Board. There was no public comment. After discussion, N. Byers made a motion to place Lorzone on prior authorization with criteria of trial and failure of chlorzoxazone. J. Hostetter seconded the motion. This topic will be brought up at the next meeting for finalization.

Provigil Review
B. Joyce reviewed Provigil information with the Board. There was no public comment. After discussion, N. Byers made a motion to place Provigil on prior authorization for FDA approved indication. C. Sorenson seconded the motion. This topic will be brought up at the next meeting for finalization.

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

Dexpak/Zemapak Review
B. Joyce reviewed Dexpak/Zemapak with the Board. There was no public comment. After discussion, T. Twogood made a motion to place Dexpak/Zemapak on prior authorization. J. Hostetter seconded the motion. This topic will be brought up at the next meeting for finalization.

Xifaxan Review
B. Joyce reviewed Xifaxan with the Board. There was no public comment. J. Hostetter made a motion to place Xifaxan on prior authorization for approved indication. T. Twogood seconded the motion. This topic will be brought up at the next meeting for finalization.

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

SSRI/SNRI Combination Review
Brendan reviewed SSRI/SNRI combination information with the Board. There was no public comment. A suggestion was made that an educational letter, with a survey, be sent to prescribers of these combinations.

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 T. Twogood 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 4, 2012. G. Hostetter made a motion to adjourn the meeting. N. Byers seconded. The motion passed with no audible dissent. Chair G. Pfister adjourned the meeting at 2:45 pm.

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	

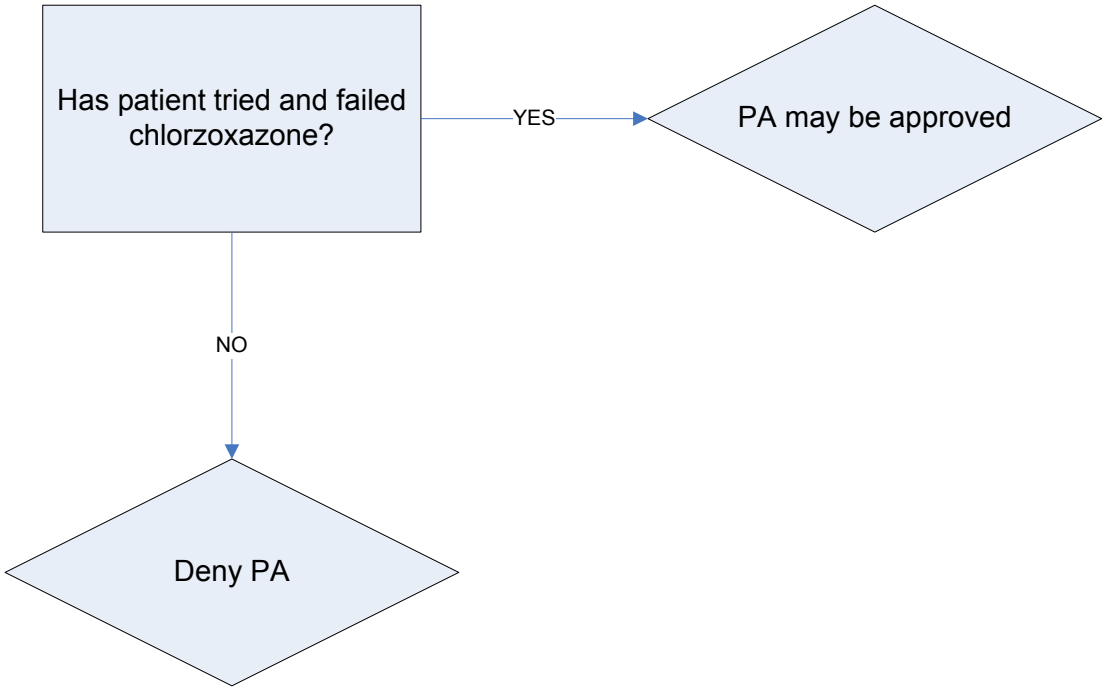
Part II: TO BE COMPLETED BY PHARMACY

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



PROVIGIL 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 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	

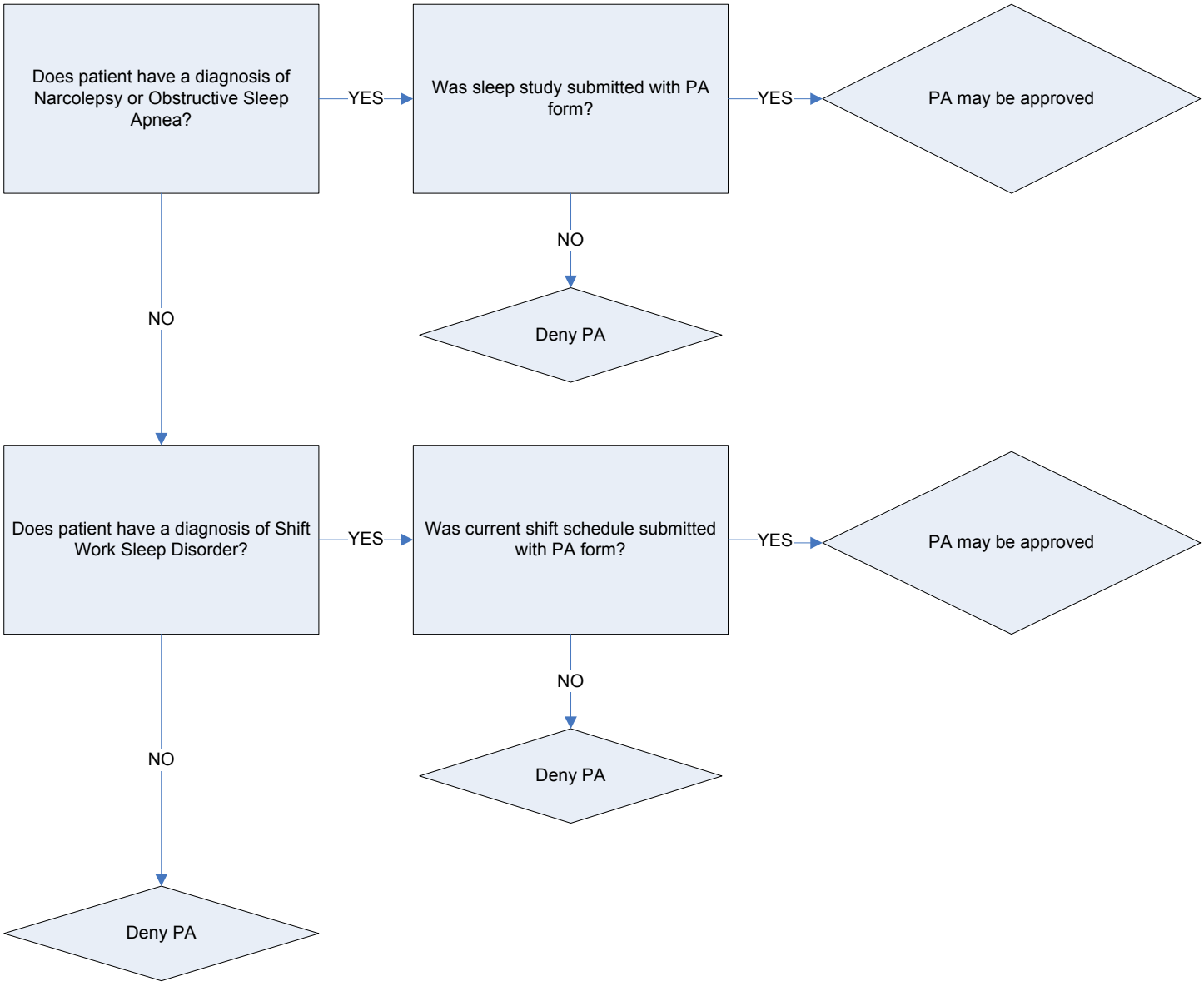
Part II: TO BE COMPLETED BY PHARMACY

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



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	

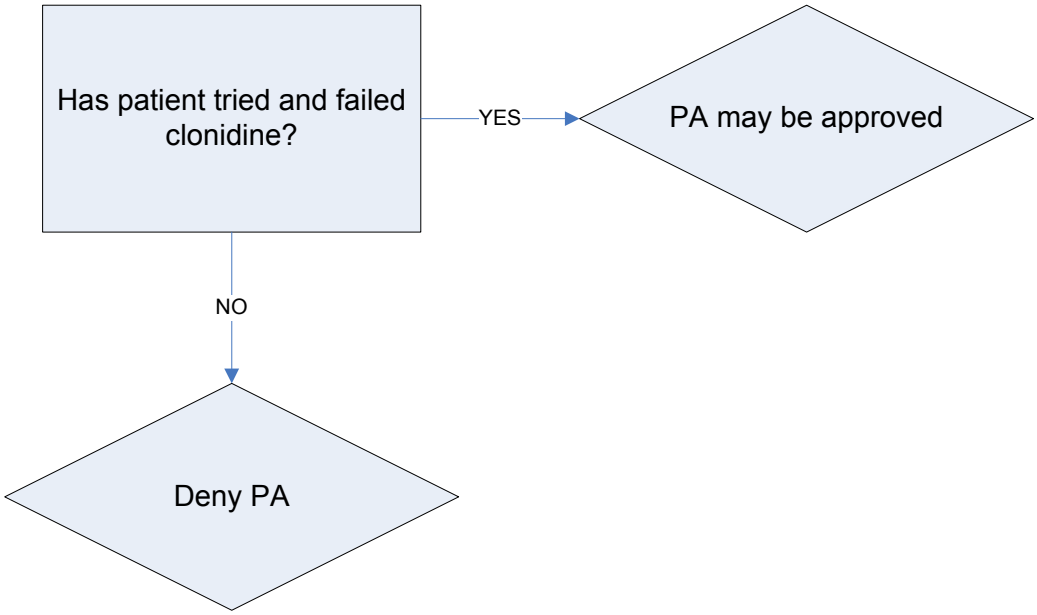
Part II: TO BE COMPLETED BY PHARMACY

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



DEXPAK/ZEMAPAK PA FORM

HEALTH INFORMATION DESIGNS

Prior Authorization Vendor for ND Medicaid

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

ND Medicaid requires that patients receiving a new prescription for DexPak or Zema-Pak must meet the following criteria:

- **Patient must first try and fail with dexamethasone**

Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name	**Recipient Date of Birth**	Recipient Medicaid ID Number	
Physician Name			
Physician Medicaid Provider Number	Telephone Number	Fax Number	
Address	City	State	Zip Code
Requested Drug and Dosage: □ DEXPAK □ ZEMA-PAK	**Diagnosis for this Request:**		
Failed Therapy (dose and frequency): □ DEXAMETHASONE	**Start Date:** **End Date:**		
□ *I confirm that I have considered a generic or other alternative and that the requested drug is expected to result in the successful medical management of the recipient.*			
Prescriber Signature		Date	

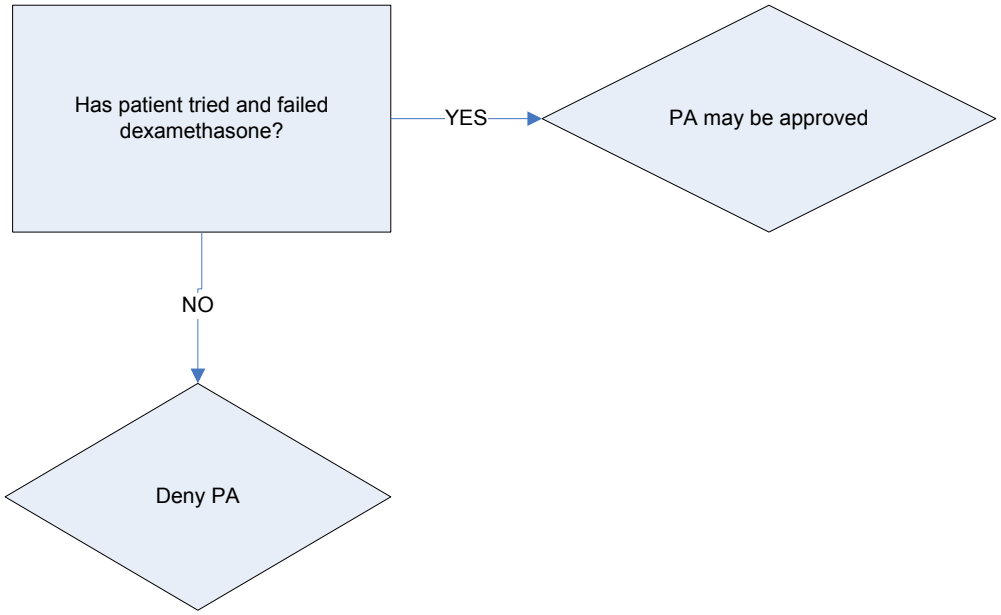
Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

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

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



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	

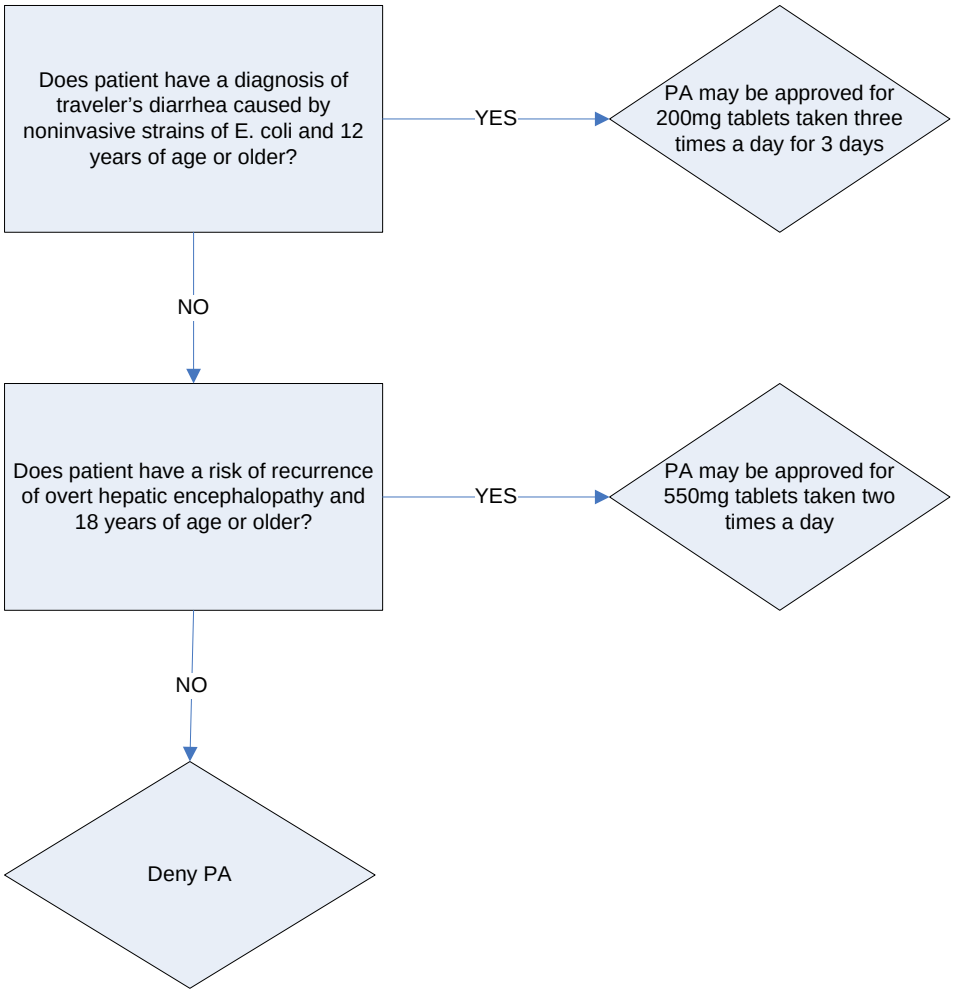
Part II: TO BE COMPLETED BY PHARMACY

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



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	

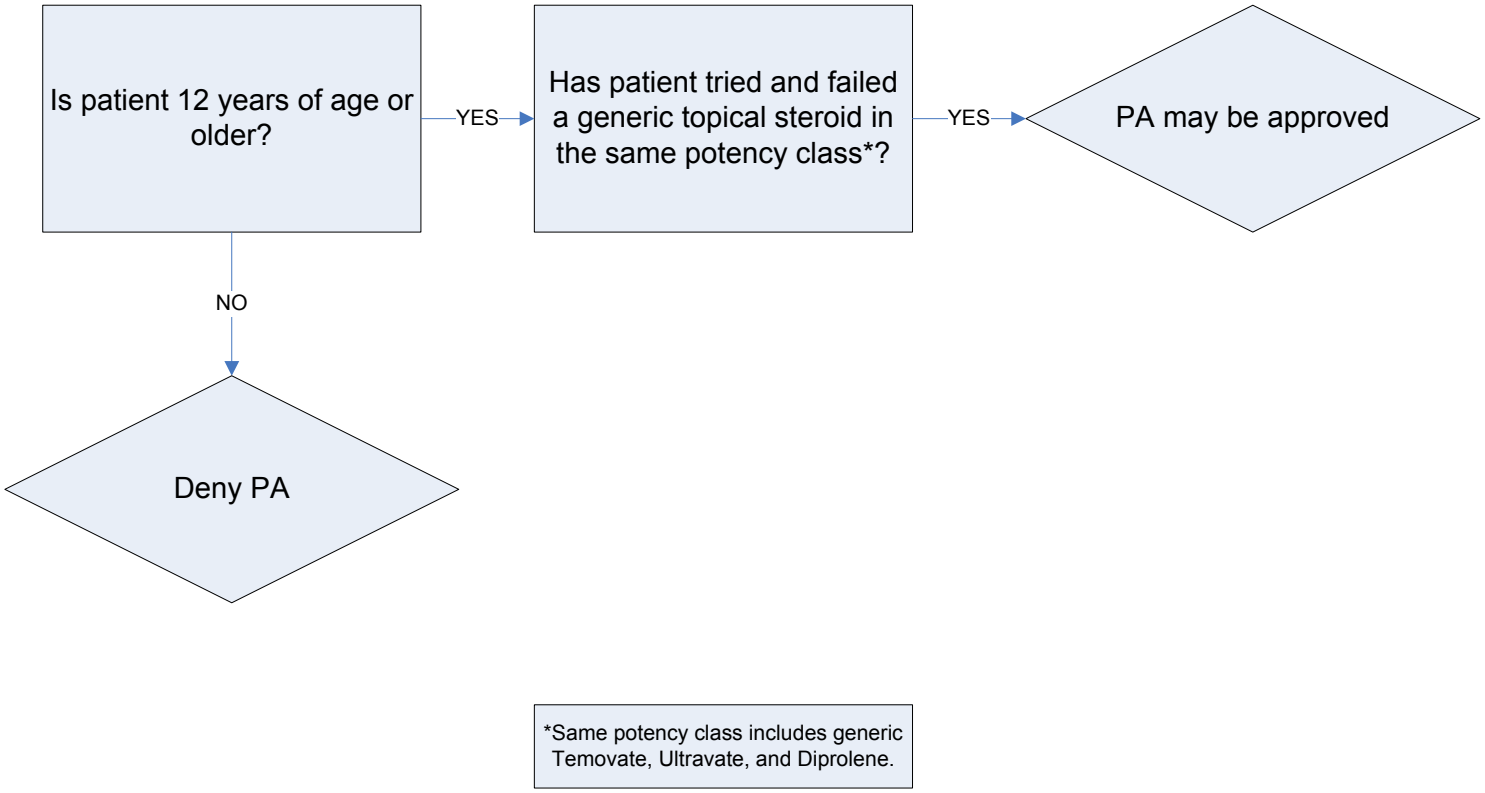
Part II: TO BE COMPLETED BY PHARMACY

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



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	

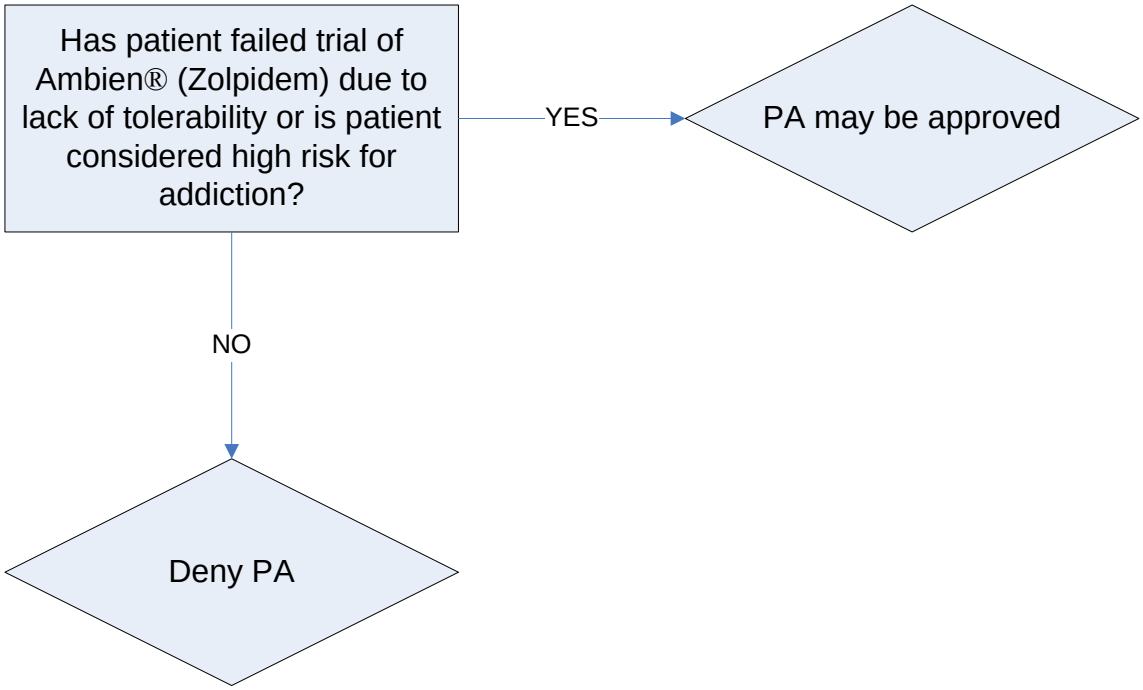
Part II: TO BE COMPLETED BY PHARMACY

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



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:

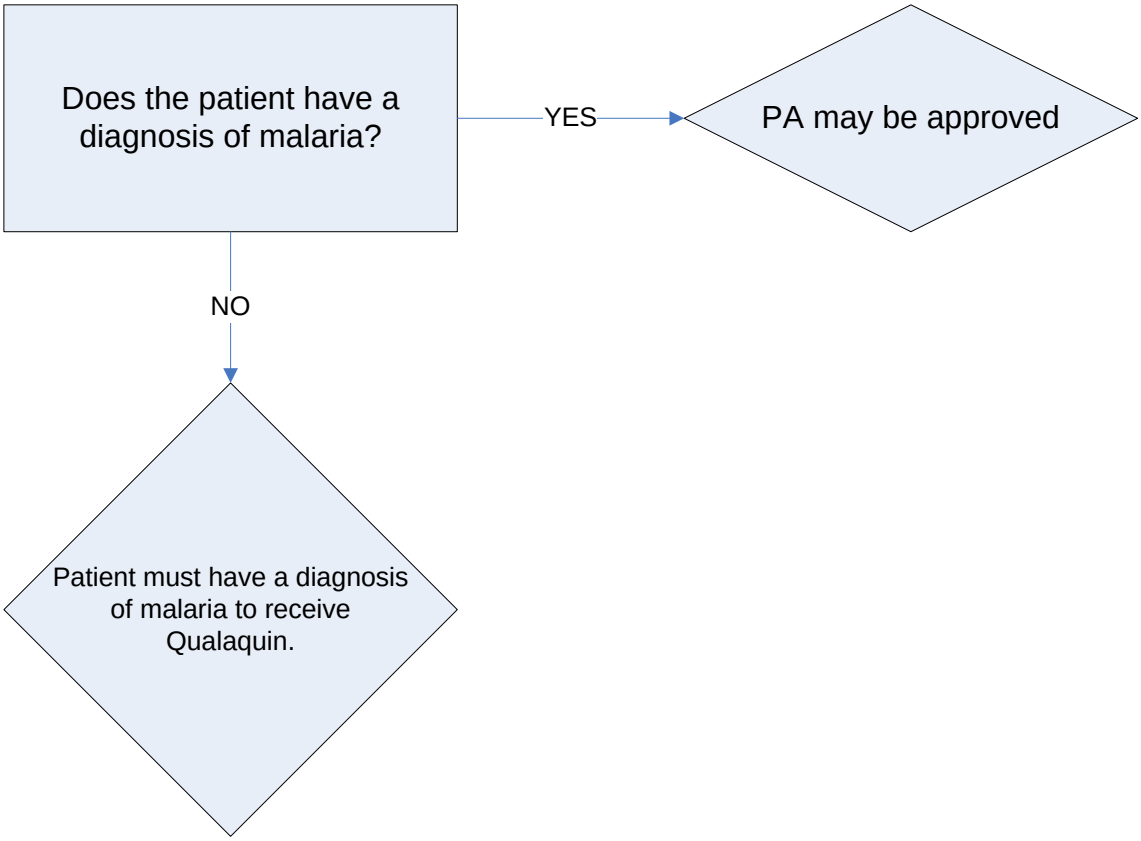
Part II: TO BE COMPLETED BY PHARMACY

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



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

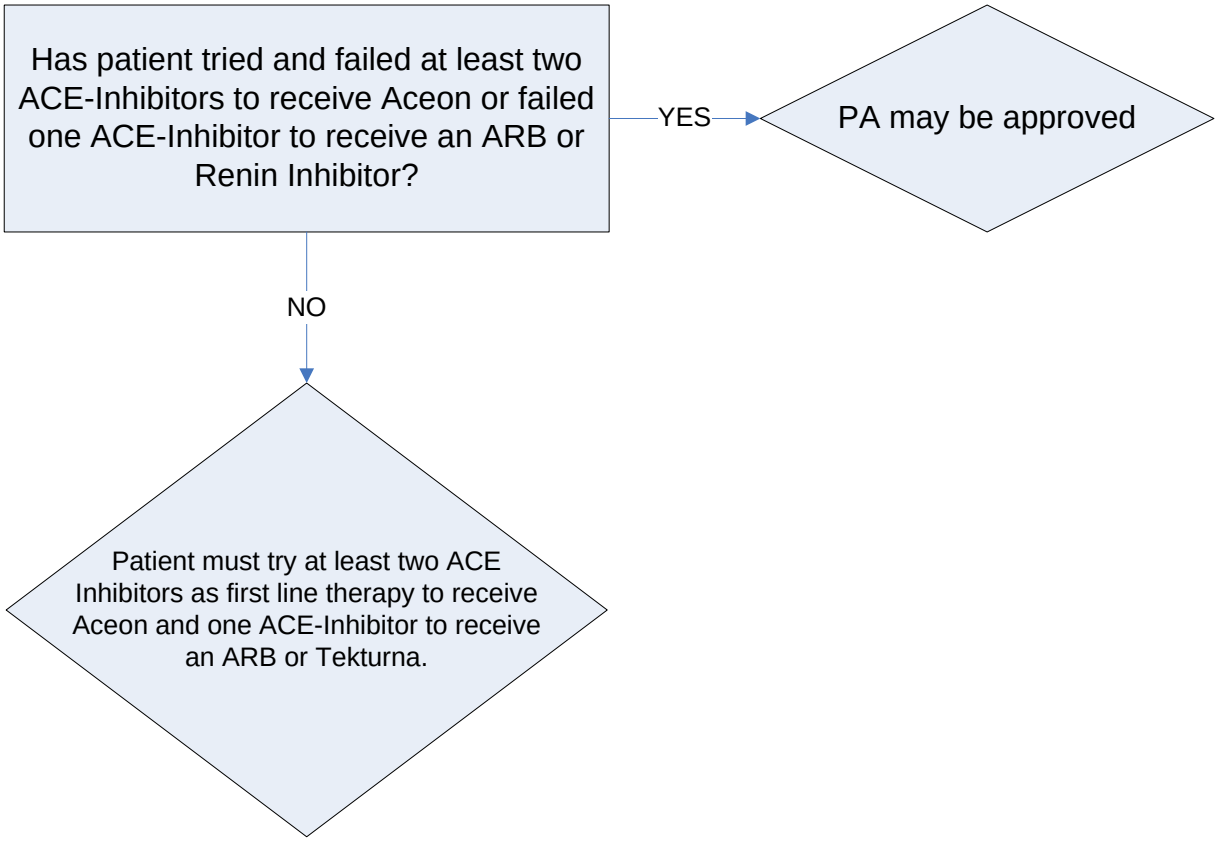
Part II: TO BE COMPLETED BY PHARMACY

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

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.

Growth Hormone PA Form

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

Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that patients receiving Growth Hormone meet one of the criteria below:

- **Growth Hormone Deficiency in children and adults with a history of hypothalamic pituitary disease**
- **Short stature associated with chronic renal insufficiency before renal transplantation**
- **Short stature in patients with Turners Syndrome (TS) or Prader-Willi Syndrome (PWS)**
- **Human Immunodeficiency Virus (HIV) associated wasting in adults**

Part I: TO BE COMPLETED BY PRESCRIBER

RECIPIENT NAME:		RECIPIENT MEDICAID ID NUMBER:
Recipient Date of birth: / /		
PRESCRIBER NAME		PRESCRIBER MEDICAID ID NUMBER:
Address:		Phone: ( )
City:		FAX: ( )
State: Zip:		
REQUESTED DRUG:	**Requested Dosage:** (must be completed)	
Qualifications for coverage:		
Criteria met:	Diagnosis Date: Drug:	Dose: Frequency:
PRESCRIBER SIGNATURE	DATE:	

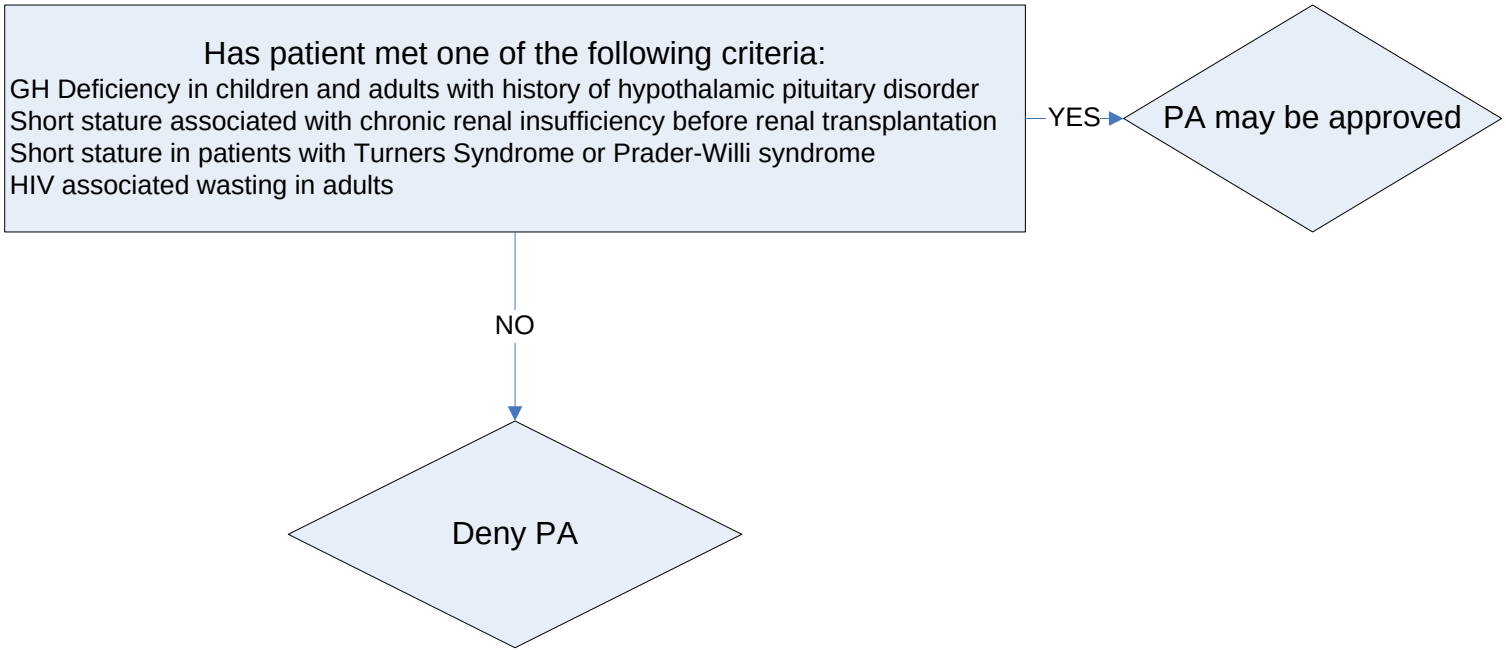
Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

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

North Dakota Department of Human Services
Growth Hormone 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: □ RELPAX □ MAXALT □ AXERT □ TREXIMET □ FROVA □ ZOMIG	**Diagnosis for this request:**		

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

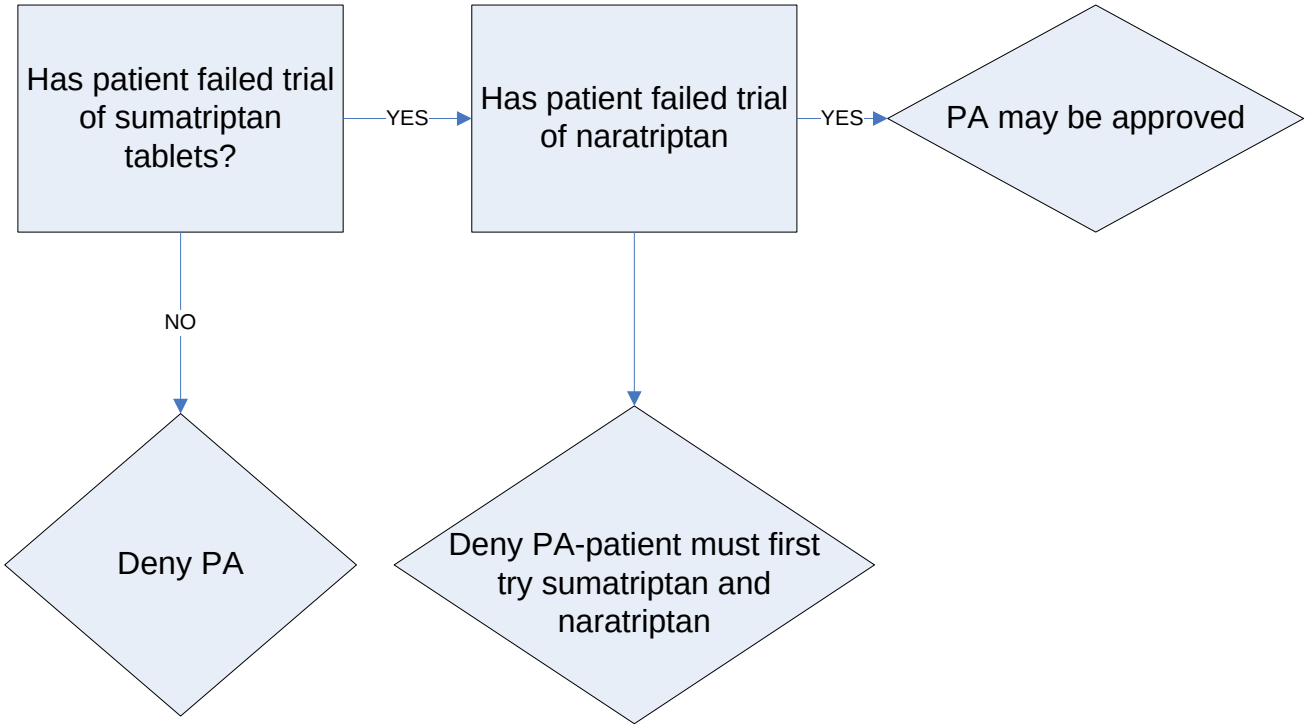
Part II: TO BE COMPLETED BY PHARMACY

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



North Dakota Medicaid
DUR Board Meeting
Topical Corticosteroids® Review

I. Overview

Topical corticosteroids are anti-inflammatory agents approved for the treatment of inflammatory and pruritic manifestations of corticosteroid dermatoses. In an effort to minimize systemic adverse events, topical treatment is preferred in most cases.

The topical corticosteroids are classified based on their relative potency: super high potency (Class I), high potency (Classes II-III), medium potency (Classes IV-V), and low potency (Classes VI-VII). The super high potency agents are used to treat severe dermatoses over non-facial and non-intertriginous areas. Medium to high potency agents are often used for the treatment of mild to moderate non-facial and non-intertriginous dermatoses. Low to medium potency agents are used when large areas need to be treated due to the potential for systemic absorption. Only low potency agents should be used on the eyelids and genital areas.

Comparison of topical corticosteroid preparations

Drug	Formulation	Strength
Low Potency		
alclometasone dipropionate (Aclovate)	Ointment Cream	0.05%
betamethasone valerate (Beta-Val)	Lotion	0.1%
desonide (Desonate, Desowen, Lokara, Verdeso)	Cream Lotion Foam	0.05%
fluocinolone acetonide (Capex Shampoo, Derma-Smoothe/FS)	Cream Solution Shampoo Oil (Scalp) Oil (Body)	0.01%
hydrocortisone (Ala-Cort, Ala-Scalp, Nuzon, Scalacort, Scalacort-DK Kit, Texacort, Pediaderm HC, Pramosone, Analpram, Epifoam, Cortaid, Cortizone-10, Noble, Scalp Relief)	Ointment Cream Lotion Solution Aerosol foam Spray	Ointment: 0.5%, 1%, or 2.5% Cream: 0.5%, 1%, or 2.5% Lotion: 1% or 2.5% Solution: 1% or 2.5% Aerosol foam: 1% Spray: 1%
triamcinolone acetonide (Kenalog)	Cream Lotion	0.025%

Medium Potency		
betamethasone dipropionate (Diprosone)	Lotion	0.05%
betamethasone valerate (Beta-Val, Valisone)	Cream	0.1%
clocortolone pivalate (Cloderm)	Cream	0.1%
desonide	Ointment Gel	0.05%
fluocinolone acetonide (Synalar)	Ointment Cream	0.025%
flurandrenolide (Cordran)	Ointment Cream Lotion	Cream/Lotion: 0.05% Ointment: 0.05%
fluticasone proprionate (Cutivate)	Cream Lotion	0.05%
hydrocortisone butyrate (Locoid/Lipocream, Cortizone 10)	Ointment Cream Lotion, spray Lotion Solution	0.1%
hydrocortisone probutate (Pandel)	Cream	0.1%
hydrocortisone valerate (Westcort)	Ointment Cream	0.2%
mometasone furoate (Elocon, Momexin)	Cream Lotion Solution	0.1%
prednicarbate (Dermatop)	Cream, emollient Ointment	0.1%
triamcinolone acetonide (Kenalog)	Lotion Ointment Cream Aerosol spray	Lotion: 0.1% Ointment: 0.025% Cream: 0.1% Aerosol spray: 0.2mg per 2 second spray
High Potency		
amcinonide (Cyclocort)	Ointment Cream	0.1%
betamethasone dipropionate (Diprosone, Diprolene AF)	Ointment Cream, augmented formulation Cream, hydrophilic emollient Lotion	0.05%
betamethasone valerate (Valisone, Luxiq)	Ointment Foam	Ointment: 0.1% Foam: 0.12%
desoximetasone (Topicort, Topicort LP)	Ointment Cream Gel	Ointment: 0.25% Cream: 0.25% or 0.05% Gel: 0.05%
diflorasone diacetate (ApexiCon/E, Florone)	Ointment, emollient Cream, emollient Cream	0.05%

High Potency (cont'd)		
fluocinonide (Lidex/E)	Ointment Gel Cream anhydrous Cream aqueous emollient Solution	0.05%
fluticasone propionate (Cutivate)	Ointment	0.005%
halcinonide (Halog)	Ointment Cream	0.1%
mometasone furoate (Elocon)	Ointment	0.1%
triamcinolone acetonide (Kenalog, Triderm)	Ointment Cream	0.5%
Very High Potency		
betamethasone dipropionate augmented (Diprolene)	Ointment, optimized Lotion Gel	0.05%
clobetasol propionate (Clobex, Cormax, Temovate/E, Olux/E)	Lotion Shampoo Spray Cream Cream, emollient base Gel Ointment Solution Foam	0.05%
diflorasone diacetate (Apexicon)	Ointment (petrolatum)	0.05
fluocinonide (Vanos)	Cream	0.1%
flurandrenolide (Cordran)	Tape	4mcg/cm^2
halobetasol propionate (Ultravate)	Ointment Cream	0.05%

II. Pharmacology

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

III. Contraindications/Warnings

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

IV. Adverse Reactions

Local:
Burning; itching; irritation; erythema; dryness; folliculitis; hypertrichosis; pruritus; acneiform eruptions; hypopigmentation; perioral dermatitis; allergic contact dermatitis; numbness of fingers; stinging and cracking/tightening of skin; maceration of the skin; secondary infection; skin atrophy; striae; miliaria; telangiectasia. These may occur more frequently with occlusive dressings.

Systemic:
Systemic absorption of topical corticosteroids has produced reversible HPA axis suppression, manifestations of Cushing's syndrome, hyperglycemia, and glycosuria. This is more likely to occur with occlusive dressings and with the more potent steroids. Patients with liver failure or children may be at a higher risk.

The risk of adverse reactions may be minimized by changing to a less potent agent, reducing the dosage or using intermittent therapy.

V. Utilization

ND Medicaid Utilization			
02/01/11 - 01/31/12			
Label Name	**Rx Num**	**Total Reimb Amt**	**Avg Cost per Script**
ALCLOMETASONE DIPR 0.05% OINT	1	$39.58	$39.58
ALCLOMETASONE DIPRO 0.05% CRM	9	$208.40	$23.16
BETAMETHASONE DP 0.05% CRM	82	$4,103.49	$50.04
BETAMETHASONE DP 0.05% LOT	23	$1,071.99	$46.61
BETAMETHASONE DP 0.05% OINT	13	$425.42	$32.72
BETAMETHASONE DP AUG 0.05% CRM	36	$1,209.42	$33.60
BETAMETHASONE DP AUG 0.05% LOT	15	$866.72	$57.78
BETAMETHASONE DP AUG 0.05% OIN	18	$1,293.22	$71.85
BETAMETHASONE VA 0.1% CREAM	71	$1,577.45	$22.22
BETAMETHASONE VA 0.1% LOTION	24	$432.90	$18.04
BETAMETHASONE VALER 0.1% OIN	8	$128.58	$16.07
BETA-VAL 0.1% LOTION	1	$10.60	$10.60
CAPEX SHAMPOO	13	$2,645.42	$203.49
CLOBETASOL 0.05% CREAM	180	$3,059.93	$17.00
CLOBETASOL 0.05% GEL	5	$102.88	$20.58
CLOBETASOL 0.05% OINTMENT	166	$2,873.73	$17.31
CLOBETASOL 0.05% SOLUTION	70	$1,389.53	$19.85
CLOBETASOL 17 PROP POWDER	1	$25.30	$25.30
CLOBETASOL EMOLLIENT 0.05% CRM	3	$61.39	$20.46
CLOBETASOL PROP 0.05% FOAM	44	$6,498.84	$147.70
CLOBETASOL PROPIONATE POWDER	1	$8.72	$8.72
CLOBEX 0.05% SHAMPOO	24	$8,663.31	$360.97

ND Medicaid Utilization			
02/01/11 - 01/31/12			
Label Name	**Rx Num**	**Total Reimb Amt**	**Avg Cost per Script**
CLOBEX 0.05% SPRAY	1	$493.92	$493.92
CLOBEX 0.05% TOPICAL LOTION	3	$1,028.92	$342.97
CLODERM 0.1% CREAM	4	$573.66	$143.42
CORDRAN 4 MCG/SQ CM TAPE	17	$2,365.94	$139.17
CORTIFOAM 10% AEROSOL	1	$268.36	$268.36
DERMA-SMOOTHE-FS BODY OIL	106	$3,925.74	$37.04
DERMA-SMOOTHE-FS SCALP OIL	76	$2,868.71	$37.75
DERMATOP 0.1% OINTMENT	7	$403.98	$57.71
DESONATE 0.05% GEL	3	$818.74	$272.91
DESONIDE 0.05% CREAM	166	$3,820.72	$23.02
DESONIDE 0.05% LOTION	50	$2,938.01	$58.76
DESONIDE 0.05% OINTMENT	213	$5,759.56	$27.04
DESOXIMETASONE 0.05% CREAM	27	$2,762.54	$102.32
DESOXIMETASONE 0.05% GEL	15	$1,520.22	$101.35
DESOXIMETASONE 0.25% CREAM	36	$3,335.10	$92.64
DESOXIMETASONE 0.25% OINTMENT	10	$1,195.54	$119.55
DIFLORASONE 0.05% OINTMENT	3	$421.97	$140.66
FLUOCINOLONE 0.01% BODY OIL	7	$234.52	$33.50
FLUOCINOLONE 0.01% CREAM	4	$142.71	$35.68
FLUOCINOLONE 0.01% SCALP OIL	3	$68.13	$22.71
FLUOCINOLONE 0.01% SOLUTION	17	$405.23	$23.84
FLUOCINOLONE 0.025% OINT	16	$365.22	$22.83
FLUOCINONIDE 0.05% CREAM	99	$1,272.54	$12.85
FLUOCINONIDE 0.05% GEL	9	$163.69	$18.19
FLUOCINONIDE 0.05% OINTMENT	67	$1,537.12	$22.94
FLUOCINONIDE 0.05% SOLUTION	21	$329.81	$15.71
FLUOCINONIDE-E 0.05% CREAM	4	$47.75	$11.94
FLUOCINONIDE-EMOL 0.05% CREAM	4	$44.30	$11.08
FLUTICASONE PROP 0.005% OINT	10	$159.17	$15.92
FLUTICASONE PROP 0.05% CREAM	78	$3,031.19	$38.86
HALOBETASOL PROP 0.05% CREAM	15	$342.80	$22.85
HALOBETASOL PROP 0.05% OINTMNT	25	$713.80	$28.55
HALOG 0.1% OINTMENT	1	$163.61	$163.61
HYDROCORTISONE 0.1% SOLN	3	$48.77	$16.26
HYDROCORTISONE 1% CREAM	136	$1,331.58	$9.79
HYDROCORTISONE 1% OINTMENT	62	$577.93	$9.32
HYDROCORTISONE 2.5% CREAM	360	$3,819.78	$10.61
HYDROCORTISONE 2.5% LOTION	62	$2,597.59	$41.90
HYDROCORTISONE 2.5% OINTMENT	200	$2,282.09	$11.41
HYDROCORTISONE BUTY 0.1% CREAM	5	$197.22	$39.44

ND Medicaid Utilization			
02/01/11 - 01/31/12			
Label Name	**Rx Num**	**Total Reimb Amt**	**Avg Cost per Script**
HYDROCORTISONE BUTYR 0.1% OINT	4	$94.38	$23.60
HYDROCORTISONE POWDER	11	$231.43	$21.04
HYDROCORTISONE VAL 0.2% CREAM	137	$3,322.85	$24.25
HYDROCORTISONE VAL 0.2% OINTMT	65	$3,063.89	$47.14
KENALOG AEROSOL SPRAY	8	$1,246.39	$155.80
LIDOCAINE-HC 3-0.5% CREAM	1	$116.69	$116.69
MOMETASONE FUROATE 0.1% CREAM	135	$4,680.69	$34.67
MOMETASONE FUROATE 0.1% OINT	67	$2,792.77	$41.68
MOMETASONE FUROATE 0.1% SOLN	9	$345.27	$38.36
OLUX-E 0.05% FOAM	1	$354.14	$354.14
PREDNICARBATE 0.1% CREAM	9	$252.51	$28.06
PROCTOFOAM-HC FOAM	27	$1,682.65	$62.32
PROCTOSOL-HC 2.5% CREAM	130	$1,261.54	$9.70
PROCTOZONE-HC 2.5% CREAM	60	$574.71	$9.58
TRIAMCINOLONE 0.025% CREAM	123	$972.40	$7.91
TRIAMCINOLONE 0.025% LOTION	23	$697.45	$30.32
TRIAMCINOLONE 0.025% OINT	27	$372.52	$13.80
TRIAMCINOLONE 0.05% OINT	2	$37.76	$18.88
TRIAMCINOLONE 0.1% CREAM	1582	$19,926.72	$12.60
TRIAMCINOLONE 0.1% LOTION	104	$3,684.08	$35.42
TRIAMCINOLONE 0.1% OINTMENT	504	$4,818.33	$9.56
TRIAMCINOLONE 0.1% PASTE	68	$3,623.72	$53.29
TRIAMCINOLONE 0.5% CREAM	143	$1,743.72	$12.19
TRIAMCINOLONE 0.5% OINTMENT	49	$544.50	$11.11
VANOS 0.1% CREAM	1	$599.77	$599.77
Total 3,556 recipients	**6044**	**$148,115.88**	

References

1. Goldstein BG, Goldstein AO. General principles of dermatologic therapy and topical corticosteroid use. Accessed online April, 2012.
2. Wolters Kluwer Health, Inc. Drug Facts and Comparisons. St. Louis, MO. 2012.

North Dakota Medicaid
DUR Board Meeting
Kalydeco® Review

I. Indication

Kalydeco is indicated for the treatment of cystic fibrosis (CF) in patients age 6 years and older who have a G551D mutation in the cystic fibrosis conductance regulator (CFTR) gene. If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of the G551D mutation.

II. Dosage and Administration

Adults and pediatric patients age 6 years and older: one 150mg tablet taken orally every 12 hours with fat-containing food.

III. Pharmacology

Kalydeco is a potentiator of the CFTR protein. The CFTR protein is a chloride channel present at the surface of epithelial cells in multiple organs. Kalydeco facilitates increased chloride transport by potentiating the channel-open probability (or gating) of the G551D-CFTR protein.

IV. Warnings/Precautions

Elevated transaminases (ALT or AST): Transaminases (ALT and AST) should be assessed prior to initiating Kalydeco, every 3 months during the first year of treatment, and annually thereafter. Patients who develop increased transaminase levels should be closely monitored until the abnormalities resolve. Dosing should be interrupted in patients with ALT or AST of greater than 5 times the upper limit of normal (ULN). Following resolution of transaminase elevations, consider the benefits and risks of resuming Kalydeco dosing.

Use with CYP3A inducers: Concomitant use with strong CYP3A inducers (e.g., rifampin, St. John's Wort) substantially decreases exposure of Kalydeco which may diminish effectiveness. Therefore, co-administration is not recommended.

V. Adverse Reactions

The most common adverse drug reactions to Kalydeco (occurring ≥8% of patients with CF who have a G551D mutation in the CFTR gene) were headache, oropharyngeal pain, upper respiratory tract infection, nasal congestion, abdominal pain, nasopharyngitis, diarrhea, rash, nausea, and dizziness.

VI. Drug Interactions

CYP3A inhibitors: Reduce Kalydeco dose to 150 mg twice-a-week when co-administered with strong CYP3A inhibitors (e.g., ketoconazole). Reduce Kalydeco dose to 150 mg once daily when co-administered with moderate CYP3A inhibitors (e.g., fluconazole). Avoid food containing grapefruit or Seville oranges.

References

1. Kalydeco [prescribing information]. Cambridge, MA: Vertex Pharmaceuticals, Inc; January 2012.

North Dakota Medicaid
DUR Board Meeting
Kuvan® Review

I. Indication

Kuvan is indicated to reduce blood phenylalanine (Phe) levels in patients with hyperphenylalaninemia (HPA) due to tetrahydrobiopterin- (BH4-) responsive Phenylketonuria (PKU). Kuvan is to be used in conjunction with a Phe-restricted diet.

II. Dosage and Administration

The recommended starting dose of Kuvan is 10mg/kg/day taken once daily. Doses of Kuvan may be adjusted in the range of 5 to 20mg/kg taken once daily. Blood Phe must be monitored regularly. Kuvan should be taken orally with food to increase the absorption. Kuvan tablets should be dissolved in 4 to 8 oz. of water or apple juice and taken within 15 minutes.

III. Pharmacology

Kuvan is a synthetic form of BH4, the cofactor for the enzyme phenylalanine hydroxylase (PAH). PAH hydroxylates Phe through an oxidative reaction to form tyrosine. In patients with PKU, PAH activity is absent or deficient. Treatment with BH4 can activate residual PAH enzyme, improve the normal oxidative metabolism of Phe, and decrease Phe levels in some patients.

IV. Warnings/Precautions

Monitor Blood Phe Levels During Treatment:
Prolonged exposure to elevated blood Phe levels can injure the brain and reduce brain function. To ensure adequate blood Phe control, blood Phe levels must still be carefully monitored even though patients are receiving Kuvan which can reduce blood Phe levels.

Treat All Patients With a Phe-restricted Diet:
The initiation of Kuvan therapy does not eliminate the need for ongoing dietary management.

V. Adverse Reactions

The most common adverse reactions (incidence ≥4%) in patients treated with Kuvan are headache, diarrhea, abdominal pain, upper respiratory tract infection, pharyngolaryngeal pain, vomiting, and nausea.

VI. Drug Interactions

No drug interaction studies were performed.

References

1. Kuvan [prescribing information]. Novato, CA: BioMarin Pharmaceuticals, Inc; December 2007.

North Dakota Medicaid
DUR Board Meeting
Elaprase® Review

I. Indication

Elaprase is indicated for patients with Hunter syndrome (Mucopolysaccharidosis II, MPS II). Elaprase has been shown to improve walking capacity in these patients.

II. Dosage and Administration

The recommended dosage regimen of Elaprase is 0.5 mg/kg of body weight administered every week as an intravenous infusion.

III. Pharmacology

Hunter syndrome is an X-linked recessive disease caused by insufficient levels of the lysosomal enzyme iduronate-2-sulfatase. Treatment of Hunter syndrome patients with Elaprase provides exogenous enzyme for uptake into cellular lysosomes.

IV. Warnings/Precautions

Elaprase labeling contains a black-box warning. Life-threatening anaphylactic reactions have been observed in some patients during Elaprase infusions. Because of the potential for severe infusion reactions, appropriate medical support should be readily available when Elaprase is administered. Patients with compromised respiratory function or acute respiratory disease may be at higher risk of life-threatening complications from infusion reactions.

V. Adverse Reactions

The most serious infusion-related adverse reactions reported with Elaprase were anaphylactic and allergic reactions. In clinical studies, the most frequent serious adverse events related to the use of Elaprase were hypoxic episodes. Adverse reactions were commonly reported in association with infusions. The most common infusion-related reactions were headache, fever, cutaneous reactions (rash, pruritus, erythema, and urticaria), and hypertension.

VI. Drug Interactions

No formal drug interaction studies have been conducted with Elaprase.

References

1. Elaprase [prescribing information]. Cambridge, MA: Shire Human Genetic Therapies, Inc; November 2011.

NORTH DAKOTA MEDICAID
RETROSPECTIVE DRUG UTILIZATION REVIEW
CRITERIA RECOMMENDATIONS
2ND QUARTER 2012

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

1. Tapentadol ER / Overutilization _____ _____

Alert Message: The manufacturer's recommended maximum daily dose of Nucynta ER (tapentadol extended-release) is 500mg (250mg twice daily).

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C **(Negating)**
Tapentadol ER		Hepatic Impairment

Max Dose: 500 mg/day

References:
Nucynta ER Prescribing Information, August 2011, Janssen Pharmaceuticals, Inc.
Facts & Comparisons, 2012 Update

2. Tapentadol ER / Overutilization – Hepatic Impairment _____ _____

Alert Message: Nucynta ER (tapentadol extended-release) should be used with caution in patients with moderate hepatic impairment. Initiate treatment in these patients using 50 mg tapentadol extended-release and administer no more frequently than once every 24 hours. The maximum recommended dose for patients with moderate hepatic impairment is 100 mg once daily.

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C **(Including)**
Tapentadol ER		Hepatic Impairment

Max Dose: 100 mg/day

References:
Nucynta ER Prescribing Information, August 2011, Janssen Pharmaceuticals, Inc.
Facts & Comparisons, 2012 Updates.

3. Tekturna HCT / Overutilization _____ _____

Alert Message: The manufacturer's recommended maximum dose of Tekturna HCT (aliskiren/hydrochlorothiazide) is 300/25 mg per day. Exceeding the recommended dose may result in the potential for adverse effects (e.g., diarrhea, influenza, and dizziness).

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C
Tekturna HCT		

Max Dose : 300/25mg/day

References:
Tekturna HCT Prescribing Information, Feb. 2012, Novartis Pharmaceuticals, Corp.

4. Valturna / Overutilization _____ _____

Alert Message: The manufacturer's recommended maximum dose of Valturna (aliskiren/valsartan) is 300/320 mg per day. Exceeding the recommended dose may result in the potential for adverse effects (e.g., diarrhea, fatigue, and nasopharyngitis).

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

Max Dose: 300/320mg/day

References:
Valturna Prescribing Information, Dec. 2011, Novartis Pharmaceuticals Corp.
Facts & Comparisons, 2012 Updates.

5. Amturnide / Overutilization _____ _____

Alert Message: The manufacturer's recommended maximum dose of Amturnide (aliskiren/amlodipine/hctz) is 300/10/25 mg per day. Exceeding the recommended dose may result in the potential for adverse effects (e.g., diarrhea, peripheral edema, and headache).

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

Max Dose: 300/10/25mg/day

References:
Amturnide Prescribing Information, Feb. 2012, Novartis Pharmaceuticals Corp.
Facts & Comparisons, 2012 Updates.

6. Tekamlo / Overutilization _____ _____

Alert Message: The manufacturer's recommended maximum dose of Tekamlo (aliskiren/amlodipine) is 300/10 mg per day. Exceeding the recommended dose may result in the potential for adverse effects (e.g., diarrhea, peripheral edema, and dyspepsia).

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

Max Dose: 300/10 mg/day

References:
Tekamlo Prescribing Information, Feb. 2012, Novartis Pharmaceuticals Corp.

7. Aliskiren-All / Cyclosporine & Itraconazole _____ _____

Alert Message: The concurrent use of aliskiren-containing products with cyclosporine or itraconazole should be avoided. In clinical studies when aliskiren was given with cyclosporine or itraconazole, the blood concentrations of aliskiren were significantly increased.

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

Util A	Util B	Util C
Aliskiren-All	Cyclosporine	
	Itraconazole	

References:
Facts & Comparisons, 2012 Updates.
Clinical Pharmacology, 2012 Elsevier/Gold Standard.
Tekturna Prescribing Information, Dec. 2011 Novartis Pharmaceutical Corp.
Tekamlo Prescribing Information, Feb. 2012, Novartis Pharmaceuticals Corp.
Amturnide Prescribing Information, Feb. 2012, Novartis Pharmaceuticals Corp.
Valturna Prescribing Information, Dec. 2011, Novartis Pharmaceuticals Corp.
Tekturna HCT Prescribing Information, Feb. 2012, Novartis Pharmaceuticals, Corp.

8. Aliskiren-All / ACEIs, K+ Sparing Diuretics & K+ Supplements/Diabetes _____ _____

Alert Message: Caution should be exercised when aliskiren-containing products are co-administered with ACE inhibitors, potassium-sparing diuretics, potassium supplements or other potassium containing salt substances. The concurrent use of aliskiren with these agents may lead to increases in serum potassium.

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

Util A	Util B	Util C **(Negating)**
Aliskiren-All	ACE Inhibitors	Type 2 Diabetes
	Potassium-Sparing Diuretics	Oral Hypoglycemics
	Potassium Acetate	Exenatide
	Potassium Chloride	Liraglutide
		Pramlintide

References:
Tekamlo Prescribing Information, Feb. 2012, Novartis Pharmaceuticals Corp.
Tekturna Prescribing Information, Dec. 2011 Novartis Pharmaceutical Corp.
Amturnide Prescribing Information, Feb. 2012, Novartis Pharmaceuticals Corp.
Valturna Prescribing Information, Dec. 2011, Novartis Pharmaceuticals Corp.
Tekturna HCT Prescribing Information, Feb. 2012, Novartis Pharmaceuticals, Corp.
Facts & Comparisons, 2012 Updates.
Clinical Pharmacology, 2012 Elsevier/Gold Standard.

9. Aliskiren-All / ACEIs & ARBs / Type 2 Diabetes _____ _____

Alert Message: Due to interim results from the ALTITUDE study, as a precautionary measure, it is advised that aliskiren or aliskiren-containing fixed combination products not be used in combination with ACE inhibitors or ARBs in patients with diabetes. This population is at risk of cardiovascular and renal adverse events if the combination is used. Patients should be switched to alternative antihypertensive treatment.

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

Util A	Util B	Util C **(Include)**
Aliskiren-All	ACE Inhibitors	Diabetes
	ARBs	Insulin
		Oral Hypoglycemics
		Exenatide
		Liraglutide
		Pramlintide

References:
Direct Healthcare Professional Communication on Potential Risks of Cardiovascular and Renal adverse Events in Patients with Type 2 Diabetes and Real impairment and/or Cardiovascular Disease Treated with Aliskiren (Tekturna) Tablets and Aliskiren-containing Combination Products. January 2012
Available at: http://www.pharma.us.novartis.com/assets/pdf/TKT-1118923%20Dear_HCP_Letter_email_with%20Tek-Val%20PIs_vf.pdf

10. Valturna / Type 2 Diabetes _____ _____

Alert Message: Due to interim results from the ALTITUDE study, as a precautionary measure, it is advised that healthcare professionals stop the use of Valturna (aliskiren/valsartan) in patients with diabetes. This population is at risk of cardiovascular and renal adverse events if the combination is used. Patients should be switched to alternative antihypertensive treatment.

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

Util A	Util B	Util C
Aliskiren/Valsartan	Diabetes	
	Insulin	
	Oral Hypoglycemics	
	Exenatide	
	Liraglutide	
	Pramlintide	

References:
Direct Healthcare Professional Communication on Potential Risks of Cardiovascular and Renal adverse Events in Patients with Type 2 Diabetes and Real impairment and/or Cardiovascular Disease Treated with Aliskiren (Tekturna) Tablets and Aliskiren-containing Combination Products. January 2012
Available at: http://www.pharma.us.novartis.com/assets/pdf/TKT-1118923%20Dear_HCP_Letter_email_with%20Tek-Val%20PIs_vf.pdf

11. Aliskiren-All / NSAIDS & COX-2 Inhibitors _____ _____

Alert Message: The concurrent use of aliskiren-containing products (Tekturna, Tekturna HCT, Valturna, Tekamlo and Amturnide) with an NSAID may lead to increased risk of renal impairment and loss of antihypertensive effect. Monitor renal function periodically in patients receiving aliskiren and NSAID therapy.

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

Util A	Util B	Util C
Aliskiren-All	NSAIDS	
	COX-2 Inhibitors	

References:
Tekturna Prescribing Information, Dec. 2011 Novartis Pharmaceutical Corp.
Facts & Comparisons, 2012 Updates.
Clinical Pharmacology, 2012 Elsevier/Gold Standard.
Tekamlo Prescribing Information, Feb. 2012, Novartis Pharmaceuticals Corp.
Amturnide Prescribing Information, Feb. 2012, Novartis Pharmaceuticals Corp.
Valturna Prescribing Information, Dec. 2011, Novartis Pharmaceuticals Corp.
Tekturna HCT Prescribing Information, Feb. 2012, Novartis Pharmaceuticals, Corp.

12. Tekturna HCT & Amturnide / Severe Renal Impairment _____ _____

Alert Message: The use of the aliskiren-containing products, Tekturna HCT and Amturnide, is not recommended in patients with severe renal impairment (GFR < 30mL/min).

Conflict Code: DC – Drug /Disease and/or Drug (Drug Inferred) Warning
Drugs/Diseases

Util A	Util B	Util C
Tekturna HCT	Stage IV CKD	
	Stage V CKD	

References:
Tekturna HCT Prescribing Information, Feb. 2012, Novartis Pharmaceuticals, Corp.
Amturnide Prescribing Information, Feb. 2012, Novartis Pharmaceuticals Corp.

*Other aliskiren-containing products state use with caution in patients with severe renal impairment – criteria 2976 already turned on.

13. Aliskiren / Pregnancy / Delivery-Miscarriage-Abortion _____ _____

Alert Message: When pregnancy is detected, discontinue the aliskiren-containing product (Tekturna, Tekturna HCT, Tekamlo, Valturna & Amturnide) as soon as possible. Aliskiren is a direct renin inhibitor and drugs acting directly on the renin-angiotensin system can cause injury and death to the developing fetus. All aliskiren-containing products are FDA pregnancy category D.

Conflict Code: Drugs (Actual) Diseases Precaution
Drugs/Diseases

Util A	Util B	Util C (Negating)
Aliskiren-All	Pregnancy	Delivery
		Miscarriage
		Abortion

References:
Tekturna HCT Prescribing Information, Dec. 2011, Novartis Pharmaceuticals, Corp.
Tekamlo Prescribing Information, Feb. 2012, Novartis Pharmaceuticals, Corp.
Valturna Prescribing Information, Feb. 2012, Novartis Pharmaceuticals, Corp.
Amturnide Prescribing Information, Feb. 2012, Novartis Pharmaceuticals, Corp.
FDA Tekturna (aliskiren) Label Revision Pregnancy Approval Letter. [02/02/2012].
Available at: http://www.accessdata.fda.gov/drugsatfda_docs/appletter/2012/021985s022ltr.pdf

14. Lovastatin / Ranolazine _____ _____

Alert Message: The risk of myopathy, including rhabdomyolysis, may be increased by concomitant administration of Ranexa (ranolazine) and lovastatin. Dose adjustment of lovastatin may be considered during coadministration with ranolazine.

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

Util A	Util B	Util C
Lovastatin	Ranolazine	

References:
Mevacor Prescribing Information, Feb. 2012, Merck & Co., Inc.
Clinical Pharmacology, 2012 Elsevier/Gold Standard.

15. Lovastatin / Colchicine _____ _____

Alert Message: Cases of myopathy, including rhabdomyolysis, have been reported with lovastatin co-administered with colchicine, and caution should be exercised when prescribing lovastatin with colchicine.

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

Util A	Util B	Util C
Lovastatin	Colchicine	

References:
Mevacor Prescribing Information, Feb. 2012, Merck & Co., Inc.

16. Lovastatin / Strong CYP3A4 Inhibitors _____ _____

Alert Message: The concurrent use of lovastatin, a CYP3A4 substrate, with a strong CYP3A4 inhibitor is contraindicated due to the increased risk of lovastatin-related myopathy and rhabdomyolysis.

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

Util A	Util B	Util C
Lovastatin	Ketoconazole	
	Itraconazole	
	Posaconazole	
	Nefazodone	
	Boceprevir	
	Telaprevir	
	Clarithromycin	
	Telithromycin	
	Erythromycin	

References:
Mevacor Prescribing Information, Feb. 2012, Merck & Co., Inc.

17. Rosuvastatin / Kaletra or Atazanavir (Ritonavir-Boost or Alone) _____ _____

Alert Message: The dose of Crestor (rosuvastatin) should not exceed 10 mg once daily in patients also receiving HIV protease inhibitors, Kaletra (lopinavir/ritonavir), Reyataz (atazanavir) or ritonavir- boosted atazanavir. Protease inhibitors are CYP3A4 inhibitors and concurrent use with rosuvastatin, a 3A4 substrate, may elevate rosuvastatin 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
Rosuvastatin 20 & 40	Lopinavir/Ritonavir Atazanavir	

References:
Crestor Prescribing Information, Feb. 2012, AstraZeneca.
Reyataz Prescribing Information, Feb. 2012, Bristol-Myers Squibb. *(Reyataz PI Table 13 states - applies to Reyataz with or without ritonavir, unless otherwise indicated).*

18. Atorvastatin / Tipranavir + Ritonavir _____ _____

Alert Message: The concurrent use of Lipitor (atorvastatin) and ritonavir-boosted Aptivus (tipranavir) should be avoided. Both tipranavir and ritonavir are CYP3A4 inhibitors and use with atorvastatin, a 3A4 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	Tipranavir	Ritonavir

References:
Lipitor Prescribing Information, Feb. 2012, Pfizer Pharmaceuticals, Inc.
Aptivus Prescribing Information, Feb. 2012, Boehringer Ingelheim Pharmaceuticals, Inc.
Micromedex Healthcare Series, DrugDex Drug Evaluations, 2012 Thomson Reuters.

19. Atorvastatin-All / Telaprevir _____ _____

Alert Message: The concurrent use of atorvastatin-containing agents (Lipitor and Caduet) with Incivek (telaprevir) should be avoided. Telaprevir is a strong CYP3A4 inhibitor and concurrent use with atorvastatin, a CYP3A4 substrate, may lead to elevated 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-All	Telaprevir	

References:
Incivek Prescribing Information, March 2012, Vertex Pharmaceuticals, Inc.
Facts & Comparisons, 2012 Updates.
Lipitor Prescribing Information, Feb. 2012, Pfizer Pharmaceuticals, Inc.

20. Atorvastatin / Lopinavir + Ritonavir _____ _____

Alert Message: Caution should be exercised when co-administering Lipitor (atorvastatin) with the HIV protease inhibitor Kaletra (lopinavir plus ritonavir). The lowest dose necessary of atorvastatin should be used. Atorvastatin is a CYP3A4 substrate and concurrent use with strong CYP3A4 inhibitors, lopinavir and ritonavir, 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	Lopinavir/Ritonavir	

References:
Lipitor Prescribing Information, Feb. 2012, Pfizer Pharmaceuticals, Inc.

21. Atorvastatin / Ritonavir-Boosted Saquinavir, Darunavir & Fosamprenavir _____ _____

Alert Message: The dose of Lipitor (atorvastatin) should not exceed 20mg daily in patients receiving the ritonavir-boosted HIV protease inhibitors saquinavir, darunavir and fosamprenavir or unboosted fosamprenavir. Protease inhibitors are CYP3A4 inhibitors and concurrent use with atorvastatin, a 3A4 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 40 & 80 mg	Saquinavir Darunavir Fosamprenavir	Ritonavir

References:
Lipitor Prescribing Information, Feb. 2012, Pfizer Pharmaceuticals, Inc.

22. Atorvastatin / Fosamprenavir _____ _____

Alert Message: The dose of Lipitor (atorvastatin) should not exceed 20mg daily in patients receiving the ritonavir-boosted HIV protease inhibitors saquinavir, darunavir and fosamprenavir or unboosted fosamprenavir. Protease inhibitors are CYP3A4 inhibitors and concurrent use with atorvastatin, a 3A4 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 40 & 80mg	Fosamprenavir	

References:
Lipitor Prescribing Information, Feb. 2012, Pfizer Pharmaceuticals, Inc.

**Criterion created so it will hit on patients receiving unboosted fosamprenavir - above criterion requires ritonavir to be present.*

23. Atorvastatin / Clarithromycin & Itraconazole _____ _____

Alert Message: The dose of Lipitor (atorvastatin) should not exceed 20 mg daily in patients receiving the strong CYP3A4 inhibitors clarithromycin or itraconazole. Atorvastatin is a 3A4 substrate and concurrent use with either agent may lead to elevated atorvastatin levels and increase the risk of statin-related myopathy and rhabdomyolysis

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C
Atorvastatin 40 & 80mg	Clarithromycin Itraconazole	

References:
Lipitor Prescribing Information, Feb. 2012, Pfizer Pharmaceuticals, Inc.

24. Atorvastatin / Nelfinavir _____ _____

Alert Message: In patients with HIV taking nelfinavir, therapy with Lipitor (atorvastatin) should be limited to 40 mg, and appropriate clinical assessment is recommended to ensure that the lowest dose necessary of atorvastatin is employed. Nelfinavir is a CYP3A4 inhibitor and use with atorvastatin, a 3A4 substrate, may elevate atorvastatin levels and increase the risk of statin-related myopathy and rhabdomyolysis.

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C (Include)
Atorvastatin		Nelfinavir

Max Dose: 40 mg/day

References:
Lipitor Prescribing Information, Feb. 2012, Pfizer Pharmaceuticals, Inc.

25. Atorvastatin / Strong 3A4 Inhibitors _____ _____

Alert Message: Coadministration of Lipitor (atorvastatin) with strong CYP3A4 inhibitors (e.g., ketoconazole, nefazodone, posaconazole and erythromycin) can lead to increases in atorvastatin plasma concentrations and risk of myopathy and rhabdomyolysis. The extent of interaction and potentiation of effects depend on the variability of effect on CYP3A4.

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

Util A	Util B	Util C
Atorvastatin	Ketoconazole Posaconazole Voriconazole Nefazodone Indinavir Telithromycin	

References:
Lipitor Prescribing Information, Feb. 2012, Pfizer Pharmaceuticals, Inc.

26. Caduet / Protease Inhibitors _____ _____

Alert Message: Caduet (amlodipine/atorvastatin) daily doses exceeding 20 mg of the atorvastatin component, should be used with caution in patients also receiving HIV protease inhibitors. The lowest dose necessary of atorvastatin-containing agent should be used. Protease inhibitors are strong CYP3A4 inhibitors and use with atorvastatin, a 3A4 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
Caduet 5/40	Saquinavir	Darunavir	Lopinavir/Ritonavir	
Caduet 5/80	Ritonavir	Fosamprenavir		
Caduet 10/40	Indinavir	Tipranavir		
Caduet 10/80	Nelfinavir	Atazanavir		
Caduet 2.5/40				

References:
Caduet Prescribing Information, Jan. 2012, Pfizer Pharmaceuticals, Inc.
**Caduet PI states; Therefore, in patients taking HIV protease inhibitors use caution when administering atorvastatin doses > 20mg. It does not split them up like the new Lipitor PI. So all protease inhibitors are included in one criterion (page 32).*

27. Caduet / Clarithromycin & Itraconazole _____ _____

Alert Message: Caduet (amlodipine/atorvastatin) daily doses exceeding 20 mg of the atorvastatin component should be used with caution in patients also receiving clarithromycin or itraconazole. The lowest dose necessary of atorvastatin-containing agent should be used. Clarithromycin and itraconazole are strong CYP3A4 inhibitors and use with atorvastatin, a 3A4 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
Caduet 5/40	Clarithromycin	
Caduet 5/80	Itraconazole	
Caduet 10/40		
Caduet 10/80		
Caduet 2.5/40		

References:
Caduet Prescribing Information, Jan. 2012, Pfizer Pharmaceuticals, Inc.

28. Caduet / Cyclosporine _____ _____

Alert Message: The atorvastatin dose of the combo agent Caduet (amlodipine/atorvastatin) should not exceed 10 mg of atorvastatin daily in patients receiving cyclosporine. Cyclosporine is an OATP1B1 inhibitor and concurrent use with atorvastatin products can increase the bioavailability of atorvastatin thereby increasing the risk of statin-related myopathy and rhabdomyolysis.

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

Util A	Util B	Util C
Caduet 20, 40 & 80mg	Cyclosporine	

References:
Caduet Prescribing Information, Jan. 2012, Pfizer Pharmaceuticals, Inc.

29. Pravastatin / Clarithromycin _____ _____

Alert Message: The dose of pravastatin should not exceed 40 mg once daily in patients also receiving clarithromycin. The concurrent use of these two agents increases the risk of statin-related myopathy and rhabdomyolysis.

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

Util A	Util B	Util C
Pravastatin 80mg	Clarithromycin	

References:
Pravachol Prescribing Information, Feb. 2012, Bristol-Myers Squibb.
Clinical Pharmacology, 2012 Elsevier/Gold Standard.

30. Vytorin / Renal Impairment _____ _____

Alert Message: In patients with chronic kidney disease and estimated glomerular filtration rate < 60 mL/min/1.73 m^2 the manufacturer's recommended dose of Vytorin (ezetimibe/simvastatin) is 10/20mg per day. In such patients, higher doses should be used with caution and close monitoring.

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

Util A	Util B	Util C
Vytorin 10/40 & 10/80	Renal Impairment	

References:
Vytorin Prescribing Information, Feb. 2012, Merck & Co. Inc.

31. Atorvastatin / Atazanavir _____ _____

Alert Message: The concurrent use of Lipitor (atorvastatin) and Reyataz (atazanavir) may result in increased atorvastatin levels due to inhibition, by atazanavir, of atorvastatin CYP3A4-mediated metabolism. Use the lowest possible starting dose of atorvastatin with careful monitoring for toxicities (e.g., myopathy and rhabdomyolysis) or consider a statin with less potential for interaction (i.e., fluvastatin).

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

Util A	Util B	Util C
Atorvastatin	Atazanavir	

References:
Lipitor Prescribing Information, Feb. 2012, Pfizer Pharmaceuticals, Inc.
Reyataz Prescribing Information, Feb. 2012, Bristol-Myers Squibb.

32. Boceprevir / Atorvastatin 40 & 80mg _____ _____

Alert Message: The concurrent use of Victrelis (boceprevir), a potent CYP3A4 inhibitor with Lipitor (atorvastatin), a CYP3A4 substrate, may result in elevated atorvastatin plasma concentrations increasing the risk of atorvastatin-related adverse events (e.g., myopathy and rhabdomyolysis). The atorvastatin dose should be carefully titrated and should not exceed a maximum daily dose of 20 mg during coadministration with boceprevir.

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

Util A	Util B	Util C
Boceprevir	Atorvastatin 40 & 80mg	

References:
Facts & Comparisons, 2012 Updates.
Clinical Pharmacology, 2012 Elsevier/Gold Standard.
Victrelis Prescribing Information, May 2011, Schering Corporation.