DUR Board Meeting
September 13, 2010
Pioneer Room
State Capitol

North Dakota Medicaid
DUR Board Meeting
Agenda
Pioneer Room
State Capitol
September 13, 2010
1:00 P.M.

1. Administrative items
    - Travel vouchers
    - Board members sign in

2. Old business

• Review and approval of minutes of 06/14/10 meeting	Chair
• Budget update	Brendan
• Review of Intuniv	Brendan
• Review of Xolair	Brendan
• Review of Ampyra	Brendan
• Review of Ribapak	Brendan
• Review of Emla	Brendan
• Review of Narcotics	Brendan
• Review of Metozolv	Brendan
• Yearly PA review	HID
o DAW	
o Amrix/Fexmid	
o Xenical	
o Zanaflex capsules	
o Ketek	
o Aczone	

3. New business

• Election of Chair and Vice-Chair	Chair
• Review of agents used to treat Hepatitis C	HID
• Review of ODT preparations	HID
• Review of Oravig	HID
• Review of Zyclara	HID
• Review of Clorpres	HID
• Review of Livalo	
• 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
June 14, 2010

Members Present: Norman Byers, Carrie Sorenson, Jeffrey Hostetter, John Savageau, Carlotta McCleary, David Clinkenbeard, Russ Sobotta, Cheryl Huber
Members Absent: Kim Krohn, James Carlson, Steve Irsfeld, Greg Pfister, Patricia Churchill, Leann Ness, Todd Twogood
Medicaid Pharmacy Department: Brendan Joyce, Gary Betting
HID Staff Present: Candace Rieth

Chair, J. Hostetter called the meeting to order at 1:00 p.m. Chair, J. Hostetter asked for a motion to approve the minutes from the March 15th meeting. C. Huber moved that the minutes be approved and J. Savageau seconded the motion. Chair, J. Hostetter called for a voice vote to approve the minutes. The motion passed with no audible dissent.

Budget Update
B. Joyce informed the Board that the department is currently putting together the budget for the next biennium. Enrollment is estimated to be approximately 62,700. This number does not include any changes in enrollment due to Health Care Reform.

Xolair Review
B. Joyce reviewed Xolair utilization. At the March meeting, the Board suggested that Xolair have a patient safety model similar to hemophilia to ensure compliance. The Board reviewed the prior authorization form that was included in the DUR Pack and made a recommendation that a box be included on the form asking for the specialist involved in treatment. C. Sorenson asked that 'serum' be added to the form before IgE. N. Byers made a motion to place Xolair on prior authorization. C. Sorenson seconded the motion. This topic will be brought up at the next meeting for finalization.

Specialty Medication Review
In March, the Board asked that a review of all specialty medications suitable for criteria-based prior authorizations be reviewed and presented with Xolair at the next board meeting. A list of commonly prior authorized medications was included in the DUR pack. The committee recommended that two meetings be held for each specialty drug considered for prior authorization. The department will review the list and include specialty medications on future agendas.

Suboxone/Subutex Review
A motion and second were made at the March meeting to place Suboxone and Subutex on prior authorization. The topic was brought up for a second review. Brendan reviewed Suboxone and Subutex utilization with the Board. There was no public comment. After discussion, Chair, J. Hostetter 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. Sedative/Hypnotics, Qualaquin, ACE-Inhibitors, ARBs, Renin Inhibitors, Synagis, Growth Hormone, and Triptan forms and criteria were reviewed. C. Rieth gave an update on Synagis utilization for the 2009/2010 season. Dr. Patel spoke regarding the registration process and informed the Board that the process worked well this season.

Ampyra Review
B. Joyce reviewed Ampyra information with the Board. A letter from the National MS Society was circulated to Board members asking that minimal restrictions be placed on Ampyra. Brian Hutchinson of Acorda Therapeutics spoke to the Board regarding Ampyra. A motion was made by N. Byers to place Ampyra on prior authorization with a neurologist involved in therapy. C. Huber seconded the motion. This topic will be brought up at the next meeting for finalization.

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

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

Narcotic Review
B. Joyce reviewed narcotic utilization with the Board. There was no public comment. After discussion, C. Sorenson made a motion that name brand narcotic and tramadol prior authorization forms be brought to the Board for approval. N. Byers seconded the motion. This topic will be brought up at the next meeting for finalization.

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

Intuniv Review
B. Joyce reviewed Intuniv utilization in North Dakota. At the March meeting, the Board asked that additional information be brought to the next meeting including the specialty of providers currently prescribing Intuniv as well as any studies of guanfacine IR in children that are available. Studies were sent to the Board members after the March meeting. C. McCleary asked for clarification on current legislation that states that stimulant medications for ADD/ADHD cannot be placed on prior authorization and the potential that legislative intent could have been that no ADHD medications should be placed on prior authorization. Since Intuniv is not a stimulant medication, it does not fall under the letter of the law, but B. Joyce informed the Board that legislative intent would be researched by the Department's legal staff prior to any implementation of prior authorization on this drug if the DUR Board recommended prior authorizing this drug. There was no public comment. J. Savageau made a motion to place Intuniv on prior authorization. C. Sorenson seconded the motion. This topic will be brought up at the next meeting for finalization.

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

Adjournment
The next DUR board meeting will be held September 13, 2010. C. Huber made a motion to adjourn the meeting. C. Sorenson seconded. The motion passed with no audible dissent. Chair J. Hostetter adjourned the meeting at 3 p.m.

INTUNIV 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 Intuniv must meet the following criteria:

- **Patient must be between 6-17 years of age**
- **Patient must first try guanfacine**

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:

□ INTUNIV

□ FAILED GUANFACINE	START DATE	END DATE	DOSE	FREQUENCY

Physician Signature	Date

Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

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

XOLAIR 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 Xolair must meet the following criteria:

- **Patient must have moderate to severe persistent asthma**
- **Patient must have serum IgE level between 30 and 700 IU/mL**

Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name	**Recipient Date of Birth**	Recipient Medicaid ID Number	
Physician Name	Specialist Involved in Therapy (if not treating physician)		
Physician Medicaid Provider Number	Telephone Number	Fax Number	
Address	City	State	ZIP Code

Requested Drug and Dosage: □ XOLAIR	**Diagnosis for this Request:**	**Serum IgE Level:**
Physician Signature		Date

Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

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

AMPYRA PA FORM

HEALTH INFORMATION DESIGNS

Prior Authorization Vendor for ND Medicaid

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

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

- **Patient must be 18 years or older.**
- **Patient must have a confirmed diagnosis of multiple sclerosis**
- **Patient must not have a history of seizures**
- **Patient's CrCl (creatinine clearance) must be greater than 50mL/min**

Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name	**Recipient Date of Birth**	Recipient Medicaid ID Number	
Physician Name	Specialist involved in therapy (if not treating physician)		
Physician Medicaid Provider Number	Telephone Number	Fax Number	
Address	City	State	ZIP Code
Requested Drug and Dosage: □ AMPYRA	**FDA approved indication for this request:**		
Does the patient have a CrCL greater than 50mL/min?	□ YES	□ NO	
Does the patient have a history of seizures?	□ YES	□ NO	
What is the patient's baseline Timed 25-foot Walk (T25FW)?			
Physician Signature	Date		

Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

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

RIBAPAK PA FORM

HEALTH INFORMATION DESIGNS

Prior Authorization Vendor for ND Medicaid

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

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

- **Patient must first try Ribavirin or Ribasphere.**

Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name	**Recipient Date of Birth**	Recipient Medicaid ID Number	
Physician Name	**(SAMHSA ID)**		
Physician Medicaid Provider Number	Telephone Number	Fax Number	
Address	City	State	ZIP Code
Requested Drug and Dosage: □ RIBAPAK	**FDA Approved Indication for this request:**		
□ **Failed therapy with Ribavirin or Ribasphere**	**Start Date**	**End Date**	**Dose**
WHAT IS THE HCV GENOTYPE? (I-IV)			
***TREATMENT WILL BE COVERED FOR 24 TO 48 WEEKS BASED UPON GENOTYPE AND DIAGNOSIS.**			
□ Treatment regimen for Hepatitis C will include pegylated or non-pegylated interferon in combination with oral ribavirin.			
Physician Signature	Date		

Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

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

EMLA 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 Emla must meet the following criteria:

- **Patient must be 12 years of age or younger**

Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name	**Recipient Date of Birth**	Recipient Medicaid ID Number	
Physician Name			
Physician Medicaid Provider Number	Telephone Number	Fax Number	
Address	City	State	ZIP Code
Requested Drug and Dosage: □ EMLA			
Physician Signature		Date	

Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

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

BRAND-NAME NARCOTICS PA FORM

Prior Authorization Vendor for ND Medicaid

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

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

- **Documented failure of a 30-day trial of a generic brand-name narcotic at a dose equivalent to the brand name narcotic being prescribed**

Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name	**Recipient Date of Birth**	Recipient Medicaid ID Number	
Physician Name			
Physician Medicaid Provider Number	Telephone Number	Fax Number	
Address	City	State	ZIP Code

Requested Drug and Dosage:

□ EMBEDA □ OPANA □ KADIAN □ AVINZA □ EXALGO □ FENTORA □ COMBUNOX □ ONSOLIS

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

Physician Signature	Date

Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

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

TRAMADOL PA FORM

HEALTH INFORMATION DESIGNS

Prior Authorization Vendor for ND Medicaid

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

ND Medicaid requires that patients receiving a new prescription for tramadol ER (Ultram ER/Ryzolt) or tramadol ODT (Rybix) must meet the following criteria:

- **Documented failure of a 30-day trial of generic immediate release tramadol at maximum daily dosage of 400mg per day**

Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name	**Recipient Date of Birth**	Recipient Medicaid ID Number	
Physician Name			
Physician Medicaid Provider Number	Telephone Number	Fax Number	
Address	City	State	ZIP Code

Requested Drug and Dosage:	**Diagnosis for this request:**
□ ULTRAM ER OR GENERIC □ RYZOLT □ RYBIX	

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

Physician Signature	Date

Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

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

METOZOLV ODT 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 Metozolv must meet the following criteria:

- **Patient must try metoclopramide**

Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name	**Recipient Date of Birth**	Recipient Medicaid ID Number	
Physician Name			
Physician Medicaid Provider Number	Telephone Number	Fax Number	
Address	City	State	ZIP Code

Requested Drug and Dosage: □ METOZOLV		**Diagnosis for this request:**	
□ **FAILED METOCLOPRAMIDE THERAPY**	**START DATE**	**END DATE**	**DOSE**
□ *I confirm that I have considered a generic or other alternative and that the requested drug is expected to result in the successful medical management of the recipient.*			
Physician Signature		Date	

Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

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

DISPENSE AS WRITTEN PA FORM

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

Prior Authorization Vendor for ND Medicaid

North Dakota Medicaid requires that patients receiving a brand name drug, when there is a generic equivalent available, must first try and fail the generic product for one of the following reasons:

- **The generic product was not effective**
- **There was an adverse reaction with the generic product**

Part I: TO BE COMPLETED BY PRESCRIBER

Recipient Name		Recipient Date of Birth	Recipient Medicaid ID Number	
Prescriber Name				
Prescriber Medicaid Provider Number		Telephone Number	Fax Number	
Address		City	State	ZIP Code
Requested Drug:	**DOSAGE:**	**Diagnosis for this request:**		
QUALIFICATIONS FOR COVERAGE: □ FAILED GENERIC EQUIVALENT		**Start Date**	**End Date**	**Dose** / **Frequency**
ADVERSE REACTION TO GENERIC EQUIVALENT (ATTACH FDA MEDWATCH FORM) OR CONTRAINDICATED (PROVIDE DESCRIPTION):				
□ *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)	

AMRIX PA FORM

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

HEALTH INFORMATION DESIGNS

Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that patients try and fail generic cyclobenzaprine.

**Notes:*

- **Cyclobenzaprine does not require PA**
- **Patient must fail therapy on generic cyclobenzaprine before a PA will be considered for Amrix**

Part I: TO BE COMPLETED BY PRESCRIBER

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

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

Qualifications for coverage:

❑ Failed cyclobenzaprine therapy	Start Date:	Dose:
	End Date:	Frequency:

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

Prescriber Signature: Date:

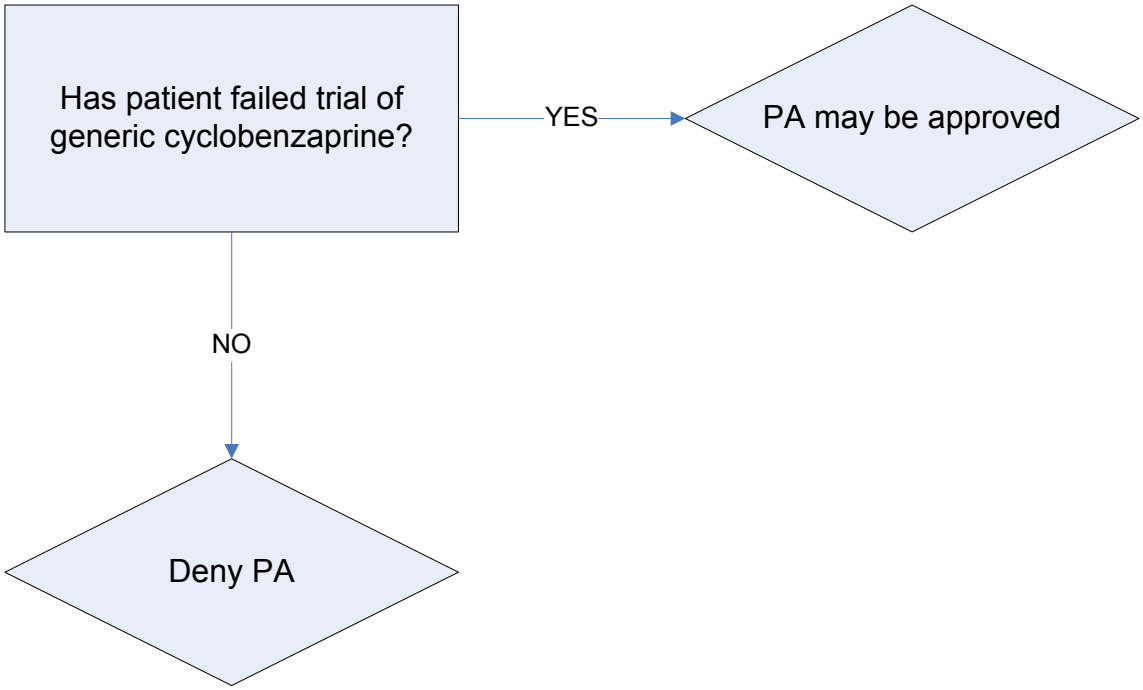
Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

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

North Dakota Department of Human Services
Amrix Authorization Algorithm



HEALTH INFORMATION DESIGNS

Xenical Prior Authorization

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

Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that patients receiving a prescription for Xenical must be seen by a dietician.
Notes:

- ***Patient must have dietician evaluation attached to PA form including height and weight***
- ***BMI must be equal to or greater than 40***
- ***5% weight loss must be realized for continued approval (every 6 months)***

Part I: TO BE COMPLETED BY PRESCRIBER

Recipient Name	Recipient Date of Birth	Recipient Medicaid ID Number	
Prescriber Name			
Prescriber Medicaid Provider Number	Telephone Number	Fax Number	
Address	City	State	ZIP Code
Requested Drug and Dosage: □ XENICAL	**Diagnosis for this request:**		
Qualifications for coverage:			
□ Dietician evaluation attached	Height:	Weight:	BMI:
Prescriber Signature		Date	

Part II: TO BE COMPLETED BY PHARMACY

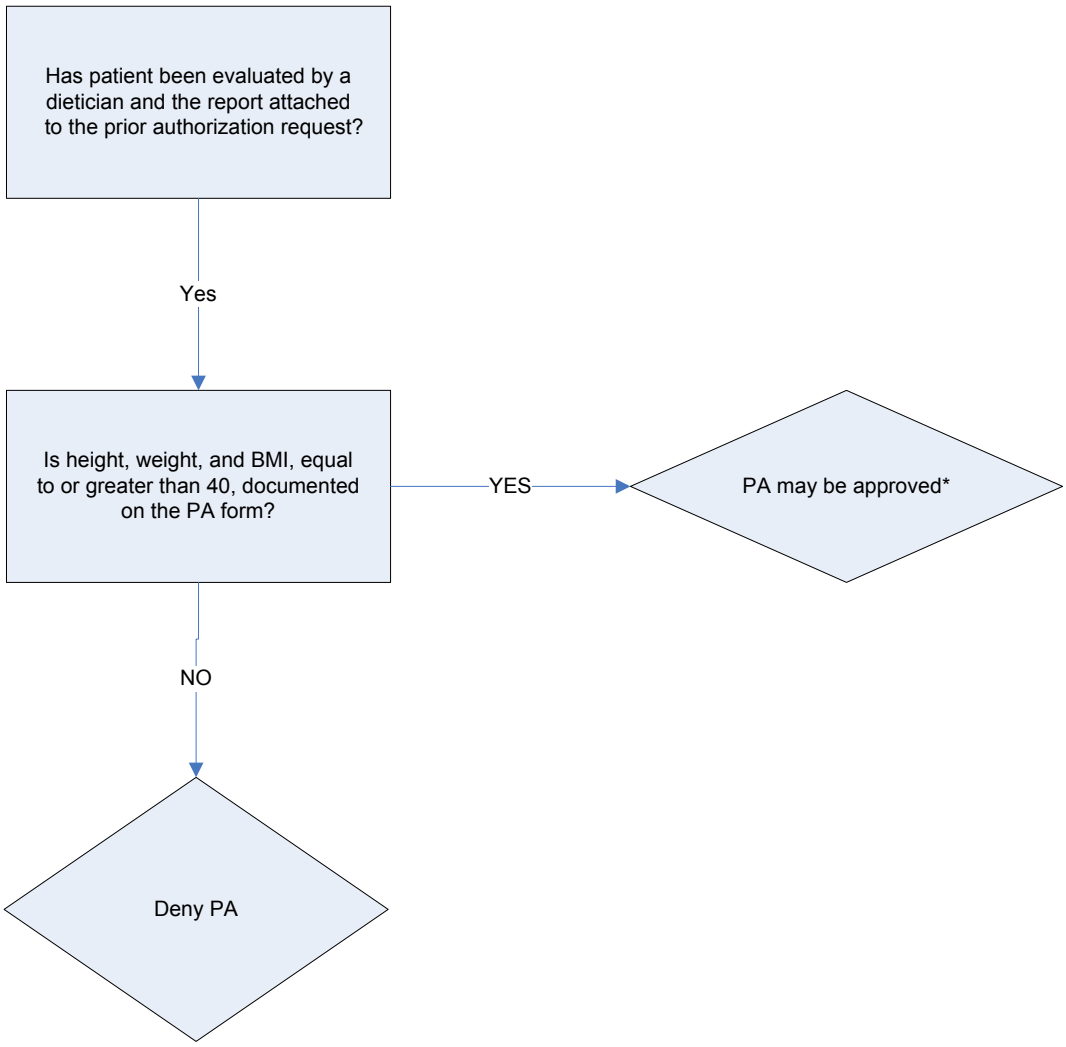
PHARMACY NAME:			ND MEDICAID PROVIDER NUMBER:
TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #

Part III: FOR OFFICIAL USE ONLY

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

North Dakota Department of Human Services

Xenical Prior Authorization Criteria



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

HEALTH INFORMATION DESIGNS

Prior Authorization Vendor for ND Medicaid

Zanaflex Capsule PA Form

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

ND Medicaid requires that patients receiving Zanaflex capsules must use tizanidine tablets first line.
**Notes:*

- **Tizanidine tablets do not require a PA.**
- **Patient must fail therapy on tizanidine tablets before a PA may be granted.**

Part I: TO BE COMPLETED BY PRESCRIBER

Recipient Name	Recipient Date of Birth	Recipient Medicaid ID Number	
Prescriber Name			
Prescriber Medicaid Provider Number	Telephone Number	Fax Number	
Address	City	State	ZIP Code
Requested Drug and Dosage:	**Diagnosis for this request:**		
Qualifications for coverage:			
☐ Failed generic drug	Start Date: End Date:	Dose: Frequency:	
☐ *I confirm that I have considered a generic or other alternative and that the requested drug is expected to result in the successful medical management of the recipient.*			
Prescriber Signature		Date	

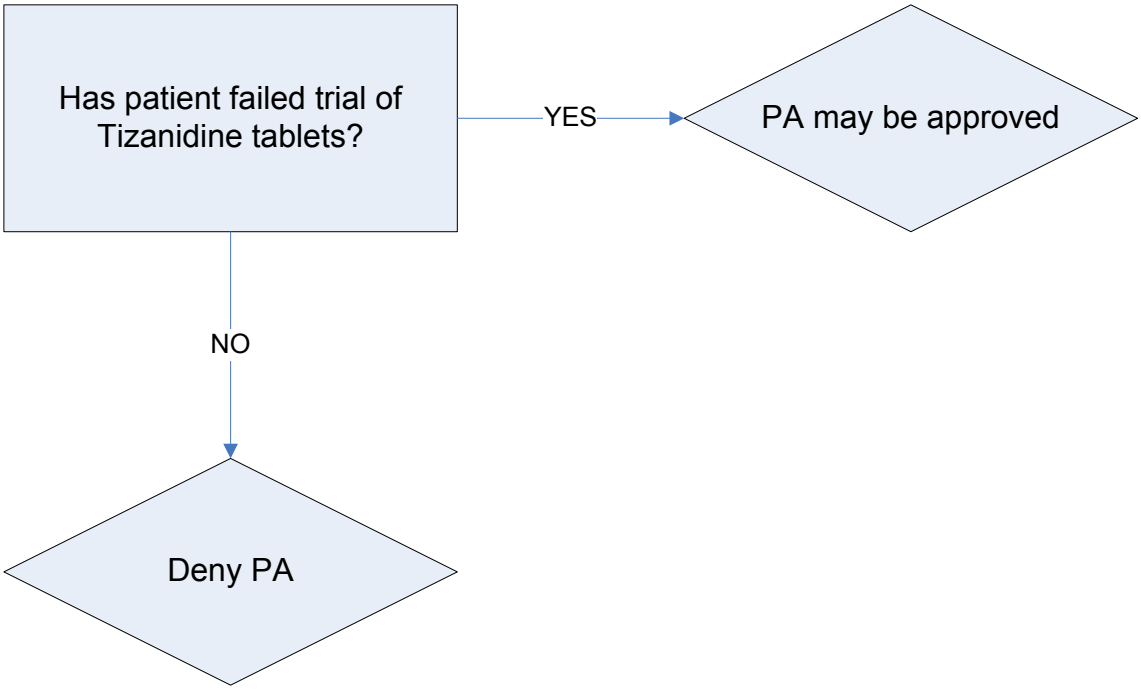
Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

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

North Dakota Department of Human Services
Zanaflex Authorization Algorithm



KETEK PA FORM

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

Prior Authorization Vendor for ND Medicaid

- ND Medicaid will cover Ketek with a diagnosis of community-acquired pneumonia (of mild to moderate severity) due to Streptococcus pneumoniae for patients 18 years and older.
- ND Medicaid will cover Ketek for patients with an allergy to fluoroquinolones or tetracyclines.

Part I: TO BE COMPLETED BY PRESCRIBER

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

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

Qualifications for coverage:

□ Community acquired pneumonia (of mild to moderate severity) due to Streptococcus pneumoniae, (including multi-drug resistant isolates, Haemophilus influenzae, Moraxella catarrhalis, Chlamydophila pneumoniae, or Mycoplasma pneumoniae) for patients 18 years and older.

□ Please list fluoroquinolone or tetracycline that patient is allergic to: _____

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

Prescriber Signature: Date:

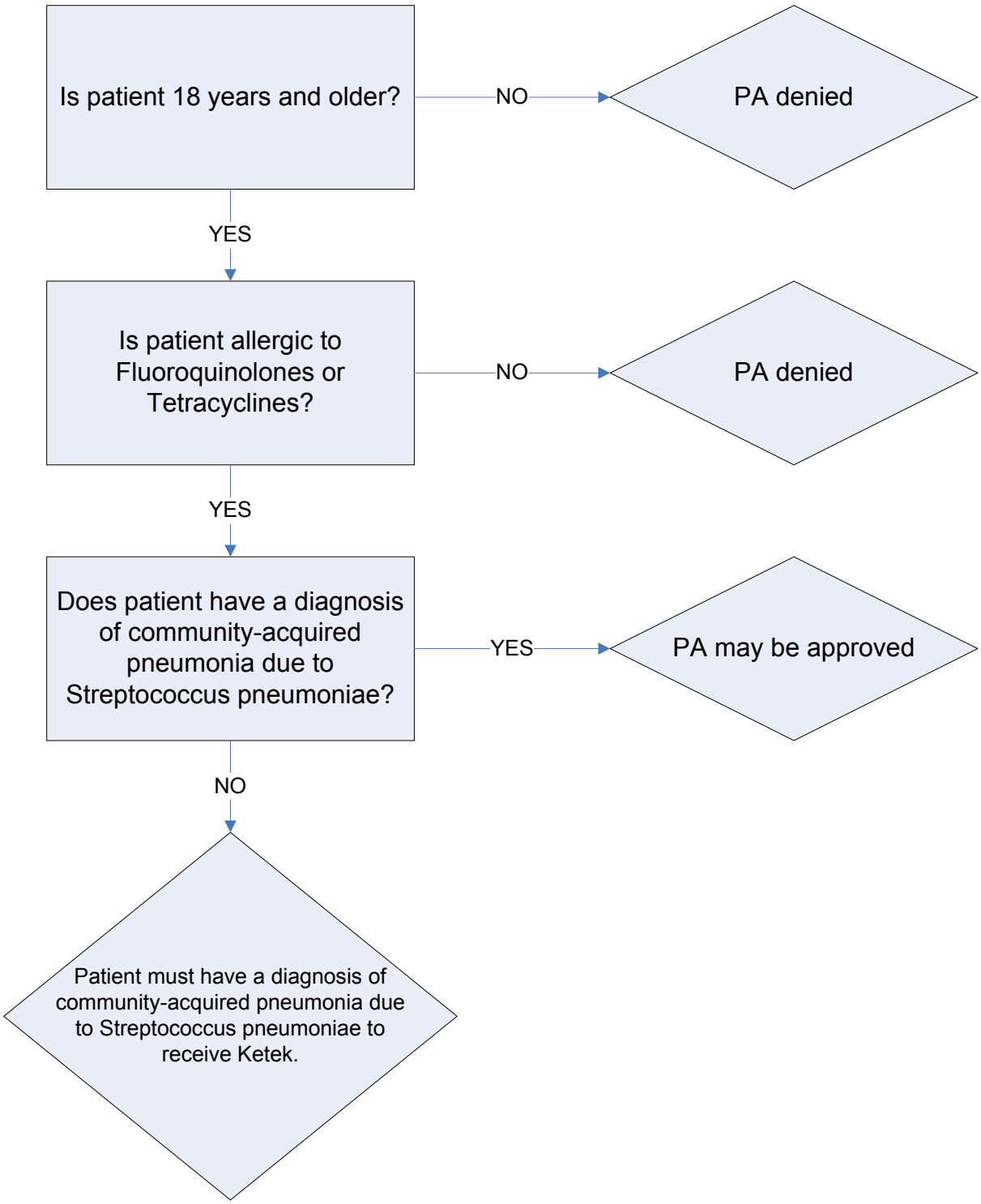
Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

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

North Dakota Department of Human Services
Ketek Criteria Algorithm



Aczone Gel PA FORM

HEALTH INFORMATION DESIGNS

Prior Authorization Vendor for ND

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 Aczone gel must try other topical acne agents as first line therapy.

Part I: TO BE COMPLETED BY PRESCRIBER

Recipient Name	Recipient Date of Birth	Recipient Medicaid ID Number	
Prescriber Name			
Prescriber Medicaid Provider Number	Telephone Number	Fax Number	
Address	City	State	Zip Code
Requested Drug and Dosage: □ ACZONE GEL	**Diagnosis for this request:**		

Qualifications for coverage:

□ Failed acne therapy Name of medication failed: _____	Start Date	End Date	Dose	Frequency

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

Prescriber Signature	Date

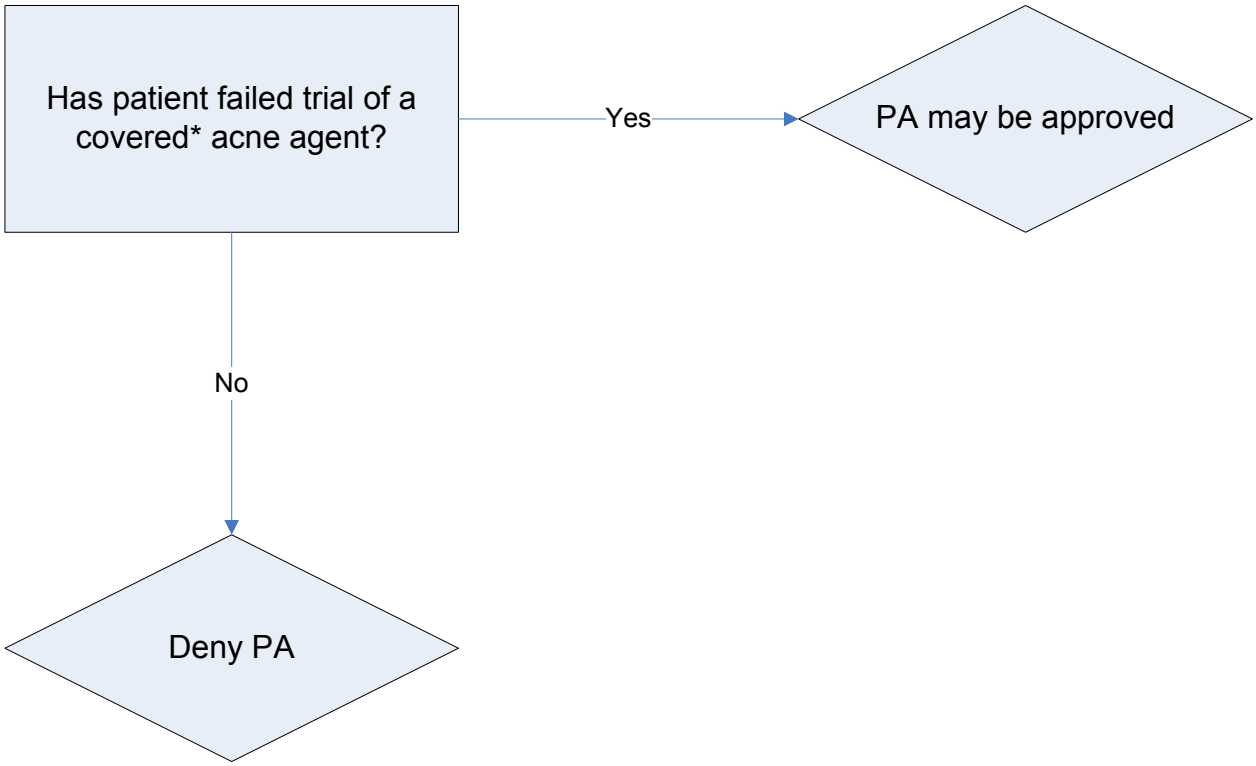
Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

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

North Dakota Department of Human Services
Aczone Authorization Algorithm



*Tretinoin and benzoyl peroxide products do not require a PA

North Dakota Department of Human Services
DUR Board Meeting
Interferons Review
September 13, 2010

I. Overview

Interferons are naturally occurring proteins that are made and secreted by cells of the immune system. Interferons modulate the response of the immune system to viruses, bacteria, cancer, and other foreign substances that invade the body. Interferons do not directly kill viral or cancerous cells; they boost the immune system response and reduce the growth of cancer cells by regulating the action of several genes that control the secretion of numerous cellular proteins that affect growth.

The interferons are primarily used for the treatment of chronic hepatitis B and hepatitis C. The hepatitis B virus (HBV) is a DNA virus that is transmitted through exposure with infected blood and body fluids, and is a leading cause of death from liver disease. The hepatitis C virus (HCV) is a RNA virus that is also transmitted through exposure with infected blood.

Interferons included in this review

Generic Name	Formulation	Example Brand Name
Interferon alfa-2b	injection	Intron A
Interferon alfacon-1	injection	Infergen
Interferon alfa-n3	injection	Alferon N
Peginterferon alfa-2a	injection	Pegasys
Peginterferon alfa-2b	injection	PegIntron

II. Treatment Guidelines

Clinical Guideline	Recommendation
American Association for the Study of Liver Diseases (AASLD): **Chronic Hepatitis B: An Update (2009)**	<u>General Information</u> • The aims of treatment of chronic hepatitis B are to achieve sustained suppression of HBV replication and remission of liver disease. The ultimate goal is to prevent cirrhosis, hepatic failure and hepatocellular carcinoma. • Parameters used to assess treatment response include normalization of serum ALT, decrease in serum HBV DNA level, loss of hepatitis B e antigen (HBeAg) with or without detection of anti-HBe, and improvement in liver histology. • Responses to antiviral therapy of chronic hepatitis B are categorized as biochemical (BR), virologic (VR), or histologic (HR), and as on therapy or sustained off therapy. • Seven therapeutic agents have been approved for the treatment of adults with chronic hepatitis B in the United States. While interferons are administered for predefined durations, the nucleoside/nucleotide analogues (NAs) are usually administered until specific endpoints are achieved. The difference in approach is related to the additional immune modulatory effects of the

Clinical Guideline	Recommendation
	interferons. General Treatment Recommendations • Patients with HBeAg-positive chronic hepatitis B with ALT >2 times normal or moderate/severe hepatitis on biopsy and HBV DNA >20,000 IU/mL should be considered for treatment. o Treatment should be delayed for 3 to 6 months in persons with compensated liver disease to determine if spontaneous HBeAg seroconversion occurs. o Patients with icteric ALT flares should be promptly treated. o Treatment may be initiated with any of the 7 approved antiviral medications, but peginterferon alfa or entecavir are preferred. o Clinical trials suggest that the efficacy of peginterferon alfa is similar to or slightly better than standard interferon alfa. • Patients with HBeAg-positive chronic hepatitis B and ALT persistently normal or minimally elevated (<2 times normal) generally should not be initiated on treatment. • Children with elevated ALT >2 times normal should be considered for treatment if ALT levels remain elevated at this level for longer than 6 months. (Treatment may be initiated with interferon alfa or lamivudine. • Patients with HBeAg-negative chronic hepatitis B (serum HBV DNA >20,000 IU/mL and elevated ALT>2 times normal) should be considered for treatment. o Liver biopsy may be considered for HBeAg-negative patients with lower HBV DNA levels (2,000-20,000 IU/mL) and borderline normal or minimally elevated ALT levels. o Treatment may be initiated if there is moderate/severe inflammation or significant fibrosis on biopsy. o Treatment may be initiated with any of the 7 approved antiviral medications, but peginterferon alfa, tenofovir or entecavir are preferred in view of the need for long-term treatment. • Patients who failed to respond to prior interferon alfa (standard or pegylated) therapy may be retreated with nucleoside/nucleotide analogues (NA). • Patients who failed to achieve primary response as evidenced by <2 log decrease in serum HBV DNA level after at least 6 months of NA therapy should be switched to an alternative treatment or receive additional treatment. • In patients with inactive HBsAg carrier state, antiviral treatment is not indicated, but these patients should be monitored. Patients Who Develop Breakthrough Infection While Receiving NA Therapy • All patients with virologic breakthrough should be considered for rescue therapy. • For patients in whom there was no clear indication for hepatitis B treatment and who continue to have compensated liver disease, withdrawal of therapy may be considered but these patients need to be closely monitored and treatment reinitiated if they experience severe hepatitis flares.

Clinical Guideline	Recommendation
	Treatment of Patients with Lamivudine (or telbivudine)-resistant HBV • If adefovir is used, lamivudine (or telbivudine) should be continued indefinitely to decrease the risk of hepatitis flares during the transition period and to reduce the risk of subsequent adefovir resistance. • If tenofovir is used, continuation of lamivudine (or telbivudine) is recommended to decrease the risk of subsequent antiviral resistance. • If entecavir is used, lamivudine or telbivudine should be stopped as continued presence of lamivudine- (or telbivudine-) resistant mutations will increase the risk of entecavir resistance. Entecavir is not an optimal therapy because of increasing risk of resistance to entecavir over time. Treatment of Patients with Adefovir-resistant HBV • In patients with no prior exposure to other NA, lamivudine, telbivudine, or entecavir may be added. Alternatively, adefovir may be stopped, and tenofovir plus lamivudine or emtricitabine may be used. • In patients with prior lamivudine resistance in whom lamivudine had been stopped when treatment was switched to adefovir, adefovir may be stopped and tenofovir plus lamivudine, emtricitabine or entecavir may be used but the durability of response to this combination is unknown. Treatment of Patients with Entecavir-resistant HBV • Adefovir or tenofovir can be used as it has been shown to have activity against entecavir-resistant HBV in *in vitro* studies, but clinical data are lacking. Treatment of Patients with Compensated Cirrhosis • Treatment should be considered for patients with ALT >2 times normal, and for patients with normal or minimally elevated ALT if serum HBV DNA levels are high (>2,000 IU/mL). • Patients with compensated cirrhosis are best treated with NAs because of the risk of hepatic decompensation associated with interferon alfa–related flares of hepatitis. In view of the need for long-term therapy, tenofovir or entecavir is preferred. Treatment of Patients with Decompensated Cirrhosis • Treatment should be promptly initiated with an NA that can produce rapid viral suppression with low risk of drug resistance. • Lamivudine or telbivudine may be used as initial treatment in combination with adefovir or tenofovir to reduce the risk of drug resistance. • Entecavir or tenofovir alone would be an appropriate treatment in this setting but clinical data documenting their safety and efficacy in patients with decompensated cirrhosis are lacking. • Treatment should be coordinated with a transplant center. • Interferon alfa or peginterferon alfa should not be used in patients with decompensated cirrhosis. Treatment Duration • The recommended treatment duration for HBeAg-positive chronic hepatitis B is 16 weeks for standard interferon alfa and 48 weeks for peginterferon alfa. • The recommended treatment duration for HBeAg-negative chronic hepatitis B is 48 weeks for both standard and peginterferon alfa.

Clinical Guideline	Recommendation
	• Treatment with NAs should be continued until the patient has achieved HBeAg seroconversion and undetectable serum HBV (for patients with HBeAg-positive chronic hepatitis B). For patients with HBeAg negative chronic hepatitis B, treatment should be continued until the patient has achieved HBsAg clearance. For patients with compensated cirrhosis, treatment should be received long-term. However, treatment may be stopped in HBeAg-positive patients if they have confirmed HBeAg seroconversion and have completed at least 6 months of consolidation therapy and in HBeAg-negative patients if they have confirmed HBsAg clearance. For patients with decompensated cirrhosis and recurrent hepatitis B post–liver transplantation, life-long treatment is recommended. <u>Recommendations for Treatment of Patients with HBV/HIV Coinfection</u> • Patients who meet criteria for chronic hepatitis B should be treated. • Patients who are not on HAART and are not anticipated to require HAART in the near future should be treated with an antiviral therapy that does not target HIV, such as peginterferon alfa or adefovir. Although telbivudine does not target HIV, it should not be used in this circumstance. • Patients in whom treatment for both HBV and HIV is planned should receive therapies that are effective against both viruses: lamivudine plus tenofovir or emtricitabine plus tenofovir are preferred. • Patients who are already on effective HAART that does not include a drug active against HBV may be treated with peginterferon alfa or adefovir. • In patients with lamivudine resistance, tenofovir should be added. <u>Recommendations for Treatment of Hepatitis B Carriers Who Require Immunosuppressive or Cytotoxic Therapy</u> • Prophylactic antiviral therapy is recommended for HBV carriers at the onset of cancer chemotherapy or of a finite course of immunosuppressive therapy. • Patients with baseline HBV DNA<2,000 IU/mL level should continue treatment for 6 months after completion of chemotherapy or immunosuppressive therapy. • Patients with high baseline HBV DNA (>2,000 IU/mL) level should continue treatment until they reach treatment endpoints as in immunocompetent patients. • Lamivudine or telbivudine can be used if the anticipated duration of treatment is short (<12 months) and baseline serum HBV DNA is not detectable. • Tenofovir or entecavir is preferred if longer duration of treatment is anticipated. • Interferon alfa should be avoided in view of the bone marrow suppressive effect. <u>Recommendations for Treatment of Patients with Acute Symptomatic Hepatitis B</u> • Treatment is only indicated for patients with fulminant hepatitis B and those with protracted, severe acute hepatitis B. • Lamivudine or telbivudine may be used when the anticipated duration of treatment is short; otherwise, entecavir is preferred.

Clinical Guideline	Recommendation
	• Treatment should be continued until HBsAg clearance is confirmed or indefinitely in those who undergo liver transplantation. • Interferon alfa therapy is contraindicated.
American Association for the Study of Liver Diseases (AASLD): **Diagnosis, Management, and Treatment of Hepatitis C: An Update (2009)**	General Information • The goal of therapy is to prevent complications and death from HCV infection. Treatment responses are defined by a surrogate virological parameter rather than a clinical endpoint. Short-term outcomes can be measured biochemically (normalization of serum ALT levels), virologically (absence of HCV RNA from serum by a sensitive PCRbased assay), and histologically (point improvement in necroinflammatory score with no worsening in fibrosis score). • Several types of virological responses may occur, labeled according to their timing relative to treatment. The most important is the sustained virological response (SVR), defined as the absence of HCV RNA from serum by a sensitive PCR assay 24 weeks following discontinuation of therapy (virological cure). Undetectable virus at the end of either a 24-week or 48-week course of therapy is referred to as an end-of treatment response (ETR). An ETR does not accurately predict that an SVR will be achieved, but is necessary for it to occur. • The currently recommended therapy of chronic HCV infection is the combination of a pegylated interferon alfa and ribavirin. • Treatment decisions should be individualized based on the severity of liver disease, the potential for serious side effects, the likelihood of treatment response, the presence of comorbid conditions, and the patient's readiness for treatment. <u>Genotype1 and Genotype 4 HCV Infection</u> • Treatment with peginterferon plus ribavirin should be planned for 48 weeks. • Treatment may be discontinued in patients who do not achieve an early virological response (EVR; >2 log reduction in HCV RNA at week 12 of treatment). • Patients who do not achieve a complete EVR (undetectable HCV RNA at week 12 of treatment) should be re-tested at week 24, and if HCV RNA remains positive, treatment should be discontinued. • For patients with genotype 1 infection who have delayed virus clearance (HCV RNA test becomes negative between weeks 12 and 24); consideration should be given to extending therapy to 72 weeks. <u>Genotype 2 or Genotype 3 HCV Infection</u> • Treatment with peginterferon plus ribavirin should be administered for 24 weeks. <u>Retreatment</u> • Retreatment with peginterferon plus ribavirin in patients who did not achieve an SVR after a prior full course of peginterferon plus ribavirin not recommended, even if a different type of peginterferon is administered. • Retreatment with peginterferon plus ribavirin can be considered for non-responders or relapsers who have previously been treated with non-pegylated interferon with or without ribavirin, or with peginterferon monotherapy, particularly if they have bridging fibrosis or cirrhosis.

Clinical Guideline	Recommendation
	• Maintenance therapy is not recommended for patients with bridging fibrosis or cirrhosis who have failed a prior course of peginterferon and ribavirin. <u>Treatment of Persons with Normal Serum Aminotransferase Values</u> • Regardless of the serum alanine aminotransferase level, the decision to initiate therapy with pegylated interferon and ribavirin should be individualized based on the severity of liver disease by liver biopsy, the potential for serious side effects, the likelihood of response, and the presence of comorbid conditions. • The treatment regimen for HCV-infected persons with normal aminotransferase levels should be the same as that used for persons with elevated serum aminotransferase levels. <u>Treatment of Children</u> • Children aged 2-17 years who are infected with HCV should be considered appropriate candidates for treatment using the same criteria as that used for adults. • Children should be treated with pegylated interferon alfa-2b, 60mcg/m2 weekly in combination with ribavirin, 15 mg/kg daily for a duration of 48 weeks. <u>Treatment of HIV-infected Persons</u> • Hepatitis C should be treated in the HIV/HCV co-infected patient in whom the likelihood of serious liver disease and a treatment response are judged to outweigh the risk of morbidity from the adverse effects of therapy. • Initial treatment of hepatitis C in most HIV-infected patients should be peginterferon alfa plus ribavirin for 48 weeks at doses recommended for HCV mono-infected patients. • When possible, patients receiving zidovudine (AZT) and especially didanosine (ddI) should be switched to an equivalent antiretroviral agent before beginning therapy with ribavirin. • HIV-infected patients with decompensated liver disease (CTP Class B or C) should not be treated with peginterferon alfa and ribavirin and may be candidates for liver transplantation.

III. Indications

Indication	Interferon alfa-2b	Interferon alfacon-1	Interferon alfa-n3	Peginterferon alfa-2a	Peginterferon alfa-2b
AIDS-related Kaposi's sarcoma	√				
Chronic hepatitis B	√			√	
Chronic hepatitis C	√	√		√	√
Condylomata acuminate	√		√		
Follicular lymphoma	√				
Hairy cell leukemia	√				
Malignant melanoma	√				

IV. Pharmacokinetics

Generic Name	Bioavailability (%)	Metabolism	Excretion (%)	Half-Life (hours)
Interferon alfa-2b	>90	Kidney-extensive	Not reported	2-3
Interferon alfacon-1	83-100	Not reported	Renal	1.3-3.4
Interferon alfa-n3	Not reported	Kidney-extensive	Not reported	4.43-6.76
Peginterferon alfa-2a	>60	Liver	Renal	60-90

Generic Name	Bioavailability (%)	Metabolism	Excretion (%)	Half-Life (hours)
Peginterferon alfa-2b	Not reported	Liver	Renal	22-60

V. Drug Interactions

Precipitant Drug	Object Drug	Description
Interferon alfa-2b	Myelosuppressive agents (e.g., zidovudine)	There may be synergistic adverse reactions. Patients have had a higher incidence of neutropenia than that expected with zidovudine alone. Carefully monitor WBC count in myelosuppressed patients or those receiving myelosuppressive agents.
Interferon alfa-2b	Theophyllines	Concomitant use significantly reduces theophylline clearance, resulting in 100% increase in serum theophylline levels.
Interferon alfacon-1	Myelosuppressive agents	Use caution when administering with other agents known to cause myelosuppression.
Interferon alfacon-1	Drugs metabolized by cytochrome P450	Use caution when administering to patients who are receiving agents metabolized via cytochrome P450, and monitor closely for changes in therapeutic and/or toxic levels of these concomitant drugs.
Peginterferon alfa-2a	Methadone	Concomitant treatment with peginterferon alfa-2a once weekly for 4 weeks was associated with methadone levels that were 10% to 15% higher than at baseline.
Peginterferon alfa-2a	NRTIs (e.g., didanosine, zidovudine, stavudine)	Coadministration may increase toxicities, such as hematologic toxicities. Cases of hepatic decomposition were observed.
Peginterferon alfa-2a	Theophylline	Coadministration with peginterferon alfa-2a was associated with an inhibition of CYP1A2 and a 25% increase in theophylline AUC. Monitor theophylline levels and adjust dose as needed.
Peginterferon alfa-2b	CYP2C8/9 substrates (e.g., phenytoin, warfarin)	Plasma concentrations of these substrates may be reduced, decreasing the pharmacologic effects. Evaluate the response of the patient and adjust the dose of the substrate as needed.
Peginterferon alfa-2b	CYP2D6 substrates (e.g., flecainide)	Plasma concentrations of these substrates may be reduced, decreasing the pharmacologic effects. Evaluate the response of the patient and adjust the dose of the substrate as needed.
Peginterferon alfa-2b	Methadone	Methadone plasma concentrations may be elevated, increasing the pharmacologic effects and adverse reactions. Monitor patients for signs and symptoms of increased narcotic effect and adjust the methadone dose as needed.
Peginterferon alfa-2b with or without ribavirin	NRTIs	Closely monitor for treatment-associated toxicities (e.g., hepatic decompensation, anemia) especially in cirrhotic HIV/HCV coinfected patients. Discontinue the NRTI as medically appropriate. Reduce the dose or discontinue interferon, ribavirin, or both if toxicities develop.
Peginterferon alfa-2b with ribavirin	Didanosine	Coadministration of ribavirin and didanosine is not recommended. Reports of fatal hepatic failure, as well as peripheral neuropathy, pancreatitis, and symptomatic hyperlactatemia/lactic acidosis, have been reported.
Peginterferon alfa-2b with ribavirin	Pyrimidine nucleoside analogs (e.g., lamivudine, stavudine, zidovudine)	Severe neutropenia and severe anemia may develop in HIV/HCV coinfected patients. Closely monitor the patient.

VI. Adverse Reactions

Adverse Events	Interferon alfa-2b	Interferon alfacon-1	Interferon alfa-n3	Peginterferon alfa-2a	Peginterferon alfa-2b
Cardiovascular					
Bradycardia	<5				
Chest pain	<1-28	5-13	10		6-8
Flushing		4-13			4-6
Hypertension	<5-9	2-5			
Hypotension	<5		6		
Palpitations	<5	2-5			
Tachycardia	<5				
Central Nervous System					
Agitation/irritability	1-22	4-6		19-33	2-8
Amnesia	1-14	2-10			
Anxiety	1-9	9-19			28-47
Concentration impaired	<1-14			8-10	10-17
Confusion	1-12	4-5			
Depression	3-40	18-26	2	18-20	29-31
Drowsiness	1-33	4-7		3-5	
Dizziness	7-23	18-25	9	14-16	12-21
Fatigue	8-96	2-71	6-65	56-65	52-66
Headache	21-62	78-82	10-31	43-54	56-62
Insomnia	<1-12	24-39	2-10	19-30	23-40
Lethargy	8-96	2-71	6-65	56-65	52-66
Malaise	8-96	2-71	6-65	56-65	52-66
Paresthesia	1-21	9-13			
Somnolence	1-33	4-7		3-5	
Taste/smell disturbances		3-5			
Dermatological					
Alopecia	8-38	10-14		18-28	22-36
Diaphoresis/sweating	1-21	11-13	2	6	6-11
Dry skin	<1-10	2-6		4-10	11-24
Eczema				1-5	
Injection site reaction	<5	5-23	10-12	22-23	47-75
Pruritus		10-14	2	12-19	12-29
Rash	1-25	10-13		5-8	6-24
Endocrine and Metabolic					
Hyperthyroidism	<5				
Hypothyroidism	<5			3-4	5
Weight decrease	<1-13	2-5		4-16	11-29
Gastrointestinal					
Abdominal cramping	1-23	24-41		8-15	13-15
Abdominal discomfort	1-23	24-41		8-15	13-15
Abdominal pain	1-23	24-41		8-15	13-15
Anorexia	1-69	14-24	68	16-24	20-32
Constipation	<1-14	5-9			1-5
Diarrhea	2-45	24-29	2-6	11-16	18-22
Dry/painful mouth	1-28			4-6	6-12
Dyspepsia/heartburn	2-8	10-21	3	<1-6	6-9
Flatulence	<5	5-8	3		
Nausea	17-66	30-40	4-48	24-25	26-43
Taste alterations	<1-24				<1-9

Adverse Events	Interferon alfa-2b	Interferon alfacon-1	Interferon alfa-n3	Peginterferon alfa-2a	Peginterferon alfa-2b
Vomiting	2-32	11-12	29	24-25	7-14
Hematological					
Hematocrit decreased			7	17-52	
Hemoglobin decreased			7	17-52	
Leukopenia	<5	15-28			<1-6
Neutropenia	<5-14			21-40	6-26
Platelets increased or decreased			3	33-52	
Thrombocytopenia	<5-10	18-19		5-8	5-7
Laboratory Test Abnormalities					
Albuminuria	<5				
Alkaline phosphatase increased			8		
ALT/AST increased	<5-63		3		
Anemia	<5	2-6		2-14	12
Bilirubin increased or decreased	<5		4		10-14
BUN increased	<5				
LDH increased	<5				
Proteinuria	<5				
Uric acid increased					33-38
Musculoskeletal					
Arthralgia	3-19	43-51	5-10	22-28	23-34
Asthenia	5-63	7-10			
Back pain	1-15	23-42	4	5-9	
Myalgia	16-75	51-58	16-45	37-40	54-56
Respiratory					
Asthma	<5				
Bronchitis	<5-10	1-6			
Cough	<1-31	11-22		4-10	8-23
Dyspnea	<1-34	7-12		4-13	4-26
Pharyngitis	1-31	17-34			10-12
Rhinitis	<5	7-13			2-8
Sinusitis	1-21	12-17			6-7
Respiratory tract infections		16-31			
Other					
Anaphylaxis	<5	3-7			
Chills	45-54		14-87		
Edema		3-9			
Fever	34-94	55-61	40-81	37-54	22-46
Flu-like syndrome	<1-79	8-15			
Pain	3-18	39-54		10-11	
Visual disturbances	<5	3-5	6	4-5	2-5

Black Box Warning for Interferon Alfa-2B and Interferon Alfacon-1

Alpha interferons, including alfa-2b and interferon alfacon-1, cause or aggravate fatal or life-threatening neuropsychiatric, autoimmune, ischemic, and infectious disorders. Monitor patients closely with periodic clinical and laboratory evaluations. Withdraw therapy from patients with persistently severe or worsening signs or symptoms of these conditions. In many, but not all, cases these disorders resolve after stopping interferon alfa-2b or interferon alfacon-1 therapy.

Black Box Warning for Peginterferon Alfa-2a and Peginterferon Alfa-2b

Alpha interferons, including peginterferon alfa-2a and peginterferon alfa-2b, may cause or aggravate fatal or life-threatening neuropsychiatric, autoimmune, ischemic, and infectious disorders. Monitor patients closely with periodic clinical and laboratory evaluations. Withdraw therapy in patients with persistently severe or worsening signs or symptoms of these conditions. In many, but not all, cases these disorders resolve after stopping peginterferon alfa-2a or peginterferon alfa-2b therapy.

Combination therapy with ribavirin: Ribavirin may cause birth defects and/or death of the fetus. Extreme care must be taken to avoid pregnancy in women taking peginterferon alfa-2a or peginterferon alfa-2b and in female partners of men taking peginterferon alfa-2a or peginterferon alfa-2b. Ribavirin causes hemolytic anemia. The anemia associated with ribavirin therapy may result in a worsening of cardiac disease. Because ribavirin is genotoxic and mutagenic, consider it a potential carcinogen.

VII. Dosage and Administration

Usual Dosing Regimens for Interferons

Generic Name	Usual Adult Dose	Usual Pediatric Dose	Availability
Interferon alfa-2b	AIDS-related Kaposi's sarcoma: 30 MIU/m^2 SC or IM three times a week (TIW) until disease progression or maximal response after 16 weeks. Chronic hepatitis B: 30 to 35 MIU per week, administered SC or IM, either as 5 MIU daily or as 10 MIU TIW for 16 weeks. Chronic hepatitis C: 3 MIU TIW administered SC or IM up to 18-24 months. Patients who do not normalize their ALT after 16 weeks should be considered for treatment discontinuation. Condylomata acuminate: 1 MIU per lesion in a maximum of 5 lesions in a single course. The lesions should be injected TIW on alternate days for 3 weeks. An additional course may be administered at 12 to 16 weeks. Follicular lymphoma: 5 MIU SC TIW for up to	Children ≥1 year of age: Chronic hepatitis B: 3 MIU/m^2 SC TIW for 1 week, then 6MIU/m^2 TIW for a total duration of 16 to 24 weeks.	Pen Injection Kit: 3 MIU/0.2mL 5 MIU/0.2mL 10 MIU/0.2mL Vial: 10 MIU/mL 6 MIU/mL 10 MIU 18 MIU 50 MIU

Generic Name	Usual Adult Dose	Usual Pediatric Dose	Availability
	18 months in conjunction with an anthracycline-containing chemotherapy regimen and following completion of the chemotherapy regimen. Hairy cell leukemia: 2 MIU/m^2 administered IM or SC TIW for up to 6 months. Patients with platelet counts of less than 50,000/mm^3 should not be administered interferon alfa-2b IM, but instead by SC administration. Malignant melanoma: Induction-20 MIU/m^2 as an IV infusion, over 20 minutes, 5 consecutive days per week, for 4 weeks. Maintenance-10 MIU/m^2 as a SC injection TIW for 48 weeks.		
Interferon alfacon-1	Chronic hepatitis C: 9 mcg TIW administered SC as a single injection for 24 weeks. At least 48 hours should elapse between doses of interferon alfacon-1. No response or relapse upon discontinuation: 15 mcg TIW for up to 48 weeks.	Safety and effectiveness of interferon alfacon-1 have not been established in patients younger than 18 years.	Vial: 9 mcg/0.3mL 15 mcg/0.5mL
Interferon alfa-n3	Condylomata acuminate: 0.05mL (250,000 IU) per wart administered twice weekly for up to 8 weeks.	Safety and effectiveness of interferon alfa-n3 have not been established in patients younger than 18 years.	Vial: 5 MIU/mL
Peginterferon alfa-2a	Chronic hepatitis B: 180 mcg once weekly for 48 weeks by SC administration in the abdomen or thigh. Chronic hepatitis C: 180 mcg once weekly for 48 weeks by SC administration in the abdomen or thigh.	Safety and effectiveness have not been established in patients younger than 18 years.	Kit: 180 mcg/0.5mL Vial: 180 mcg/mL

Generic Name	Usual Adult Dose	Usual Pediatric Dose	Availability
	Combination therapy with ribavirin: 180 mcg SC once weekly. The recommended dose of ribavirin and duration for peginterferon therapy is based on viral genotype. The daily dose of ribavirin is 800 to 1,200 mg administered orally in 2 divided doses.		
Peginterferon alfa-2b	Chronic hepatitis C: 1mcg/kg/wk SC for 1 year. Combination with ribavirin: 1.5 mcg/kg/wk SC with ribavirin 800 to 1,400 mg capsules.	Children 3-17 years of age: Chronic hepatitis C: 60 mcg/m^2/wk SC in combination with ribavirin 15 mg/kg/day orally in 2 divided doses.	Kit: 50 mcg/0.5mL 80 mcg/0.5mL 120 mcg/0.5mL 150 mcg/0.5mL Pen Injection Kit: 50 mcg/0.5mL 80 mcg/0.5mL 120 mcg/0.5mL 150 mcg/0.5mL

References

1. Wolters Kluwer Health, Inc. Drug Facts and Comparisons. St. Louis, MO. 2010.
2. Lok A. American Association for the Study of Liver Diseases. Chronic Hepatitis B: Update 2009. Accessed July 2010. Available at http://www.aasld.org.
3. Ghany MG. American Association for the Study of Liver Diseases. Diagnosis, Management, and Treatment of Hepatitis C: Update 2009. Accessed July 2010 at http://www.aasld.org.

HEALTH INFORMATION DESIGNS

Hepatitis C Virus (HCV) Medication Prior Authorization

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

Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that patients receiving a prescription for Intron, Infergen, Pegasys or PegIntron must submit a prior authorization form.

Note:

- ***Prior authorization will be granted if the requested product has been approved by the FDA for the indication listed below:***
- ***Current recommended therapy of chronic HCV infection is the combination of pegylated interferon alfa (PEGIntron or Pegasys) and ribavirin***

Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name	Recipient Date of Birth	Recipient Medicaid ID Number	
Physician Name			
Physician Medicaid Provider Number	Telephone Number	Fax Number	
Address	City	State	ZIP Code
Requested Drug and Dosage: □ **Intron** □ **Pegasys** □ **Infergen** □ **PEGIntron**	**Diagnosis for this request:** **Ribavirin dose:**		
Physician Signature		Date	

Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

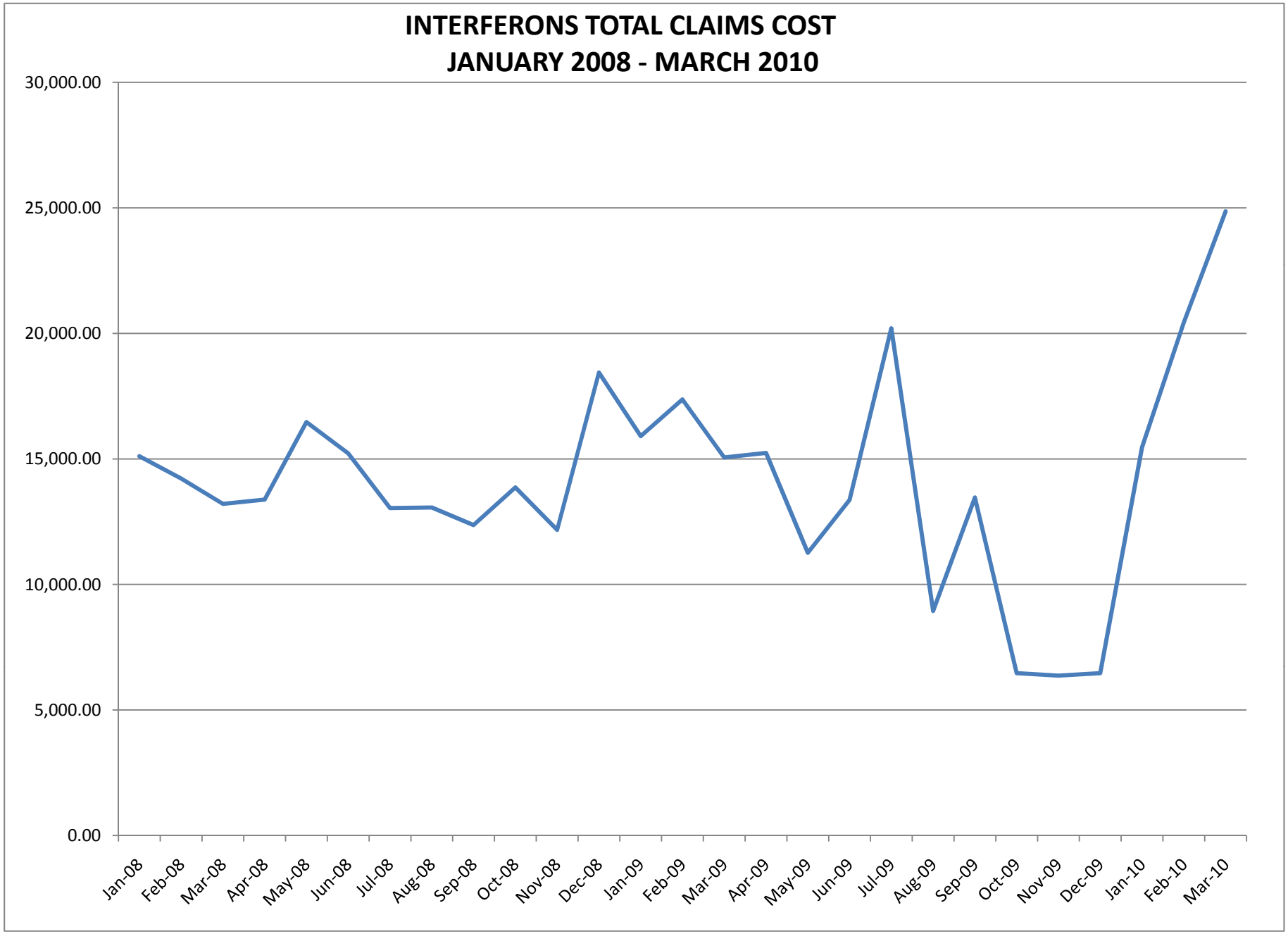
Date Received	Initials:
Approved - Effective dates of PA: From: / / To: / /	Approved by:
Denied: (Reasons)	

Interferon Utilization
05/26/09 - 05/25/10

Label Name	Rx Num	Total Reimb Amt	Cost per Script
PEGASYS 180 MCG/0.5 ML CONV.PK	50	$111,082.51	$2,221.65
PEGASYS 180 MCG/ML VIAL	1	$2,213.78	$2,213.78
PEGINTRON REDIPEN 120 MCG 4PK	4	$8,792.04	$2,198.01
PEGINTRON REDIPEN 150 MCG	2	$4,621.58	$2,310.79
PEGINTRON REDIPEN 150 MCG 4PK	20	$45,836.12	$2,291.81
Total 19 recipients/15 providers	**77**	**$172,546.03**	

Provider Specialty

Family Practice-1
Nurse Practitioner-3
Gastroenterologist-2
Psychiatrist-1
Infectious Disease-5
Nephrologist-2
Internal Medicine-1


INTERFERONS TOTAL CLAIMS COST
JANUARY 2008 - MARCH 2010
30,000.00
25,000.00
20,000.00
15,000.00
10,000.00
5,000.00
0.00
Jan-08
Feb-08
Mar-08
Apr-08
May-08
Jun-08
Jul-08
Aug-08
Sep-08
Oct-08
Nov-08
Dec-08
Jan-09
Feb-09
Mar-09
Apr-09
May-09
Jun-09
Jul-09
Aug-09
Sep-09
Oct-09
Nov-09
Dec-09
Jan-10
Feb-10
Mar-10

Orally Disintegrating Tablets Currently Available

Drug name	Form	Generic name
ABILIFY DISCMELT	TAB RAPDIS	ARIPIPRAZOLE
ALLEGRA ODT	TAB RAPDIS	FEXOFENADINE HCL
ALPRAZOLAM	TAB RAPDIS	ALPRAZOLAM
ARICEPT ODT	TAB RAPDIS	DONEPEZIL HCL
CARBIDOPA-LEVODOPA	TAB RAPDIS	CARBIDOPA/LEVODOPA
CLARINEX	TAB RAPDIS	DESLORATADINE
CLONAZEPAM	TAB RAPDIS	CLONAZEPAM
DISPAS	TAB RAPDIS	HYOSCYAMINE SULFATE
ED-SPAZ	TAB RAPDIS	HYOSCYAMINE SULFATE
EXJADE	TAB DISPER	DEFERASIROX
FAZACLO	TAB RAPDIS	CLOZAPINE
HYOMAX-FT	TAB RAPDIS	HYOSCYAMINE SULFATE
HYOSCYAMINE SULFATE	TAB RAPDIS	HYOSCYAMINE SULFATE
KLONOPIN	TAB RAPDIS	CLONAZEPAM
LAMICTAL	TAB DISPER	LAMOTRIGINE
LAMICTAL ODT	TAB RAPDIS	LAMOTRIGINE
LAMOTRIGINE	TAB DISPER	LAMOTRIGINE
MACUTEK	TAB RAPDIS	VIT A
MAXALT MLT	TAB RAPDIS	RIZATRIPTAN BENZOATE
METOZOLV ODT	TAB RAPDIS	METOCLOPRAMIDE HCL
MIRTAZAPINE	TAB RAPDIS	MIRTAZAPINE
NIRAVAM	TAB RAPDIS	ALPRAZOLAM
NULEV	TAB RAPDIS	HYOSCYAMINE SULFATE
ONDANSETRON ODT	TAB RAPDIS	ONDANSETRON
ORAPRED ODT	TAB RAPDIS	PREDNISOLONE SOD PHOSPHATE
PARCOPA	TAB RAPDIS	CARBIDOPA/LEVODOPA
PEPCID RPD	TAB RAPDIS	FAMOTIDINE
PREVACID	TAB RAP DR	LANSOPRAZOLE
PROBARIMIN QT	TAB RAPDIS	MV
PRO-HYO	TAB RAPDIS	HYOSCYAMINE SULFATE
REMERON	TAB RAPDIS	MIRTAZAPINE
RESCRIPTOR	TAB DISPER	DELAVIRDINE MESYLATE
RISPERDAL M-TAB	TAB RAPDIS	RISPERIDONE
RISPERIDONE ODT	TAB RAPDIS	RISPERIDONE
RYBIX ODT	TAB RAPDIS	TRAMADOL HCL
SYMAX	TAB RAPDIS	HYOSCYAMINE SULFATE
ZELAPAR	TAB RAPDIS	SELEGILINE HCL
ZOFRAN ODT	TAB RAPDIS	ONDANSETRON
ZOMIG ZMT	TAB RAPDIS	ZOLMITRIPTAN
ZYPREXA ZYDIS	TAB RAPDIS	OLANZAPINE

North Dakota Department of Human Services
DUR Board Meeting
Oravig® Review
September 13, 2010

I. Overview

Oravig contains the active ingredient miconazole, an imidazole antifungal agent. Oravig is indicated for the local treatment of oropharyngeal candidiasis (OPC) in adults.

II. Pharmacology

Miconazole inhibits the enzyme cytochrome P450 14α-demethylase which leads to inhibition of ergosterol synthesis, an essential component of the fungal cell membrane. Miconazole also affects the synthesis of triglycerides and fatty acids and inhibits oxidative and peroxidative enzymes, increasing the amount of reactive oxygen species within the cell.

III. Warnings/Precautions

Hypersensitivity: Allergic reactions, including anaphylactic reactions and hypersensitivity, have been reported with the administration of miconazole products, including Oravig. Discontinue therapy immediately at the first sign of hypersensitivity.

IV. Drug Interactions

Warfarin: Concomitant administration of miconazole and warfarin has resulted in enhancement of anticoagulant effect. Cases of bleeding and bruising following the concomitant use of warfarin and topical, intravaginal, or oral miconazole were reported. Closely monitor pro-thrombin time, International Normalized Ratio (INR), or other suitable anticoagulation tests if Oravig is administered concomitantly with warfarin. Also monitor for evidence of bleeding.

Drugs Metabolized through CYP 2C9 and 3A4: No formal drug interaction studies have been performed with Oravig, but miconazole is a known inhibitor of CYP2C9 and CYP3A4. Although the systemic absorption of miconazole following Oravig administration is minimal and plasma concentrations of miconazole are substantially lower than when given intravenously, the potential for interaction with drugs metabolized through CYP2C9 and CYP3A4 such as oral hypoglycemic, phenytoin, or ergot alkaloids cannot be ruled out.

V. Adverse Reactions

Adverse Reactions Reported in ≥ 2% of Patients and Healthy Subjects who Received Oravig in Clinical Trials

Adverse Reaction	**Oravig n=480 (%)**
Patients with at least one Adverse Event	209 (43.5)
Gastrointestinal disorders Diarrhea Nausea Abdominal pain upper Vomiting	20.6 6.0 4.6 2.5 2.5
Infections and infestations	11.9
Nervous system disorders Headache Dysgeusia	10.6 5.0 2.9

VI. Dosage and Administration

The recommended dosing schedule for Oravig is the application of one 50mg buccal tablet to the upper gum region once daily for 14 consecutive days.

Oravig should be applied in the morning, after brushing the teeth. The tablet should be applied with dry hands. The rounded side surface of the tablet should be placed against the upper gum just above the incisor tooth and held in place with slight pressure over the upper lip for 20 seconds to ensure adhesion. The tablet is round on one side for comfort, but either side of the tablet can be applied to the gum.

Once applied, Oravig stays in position and gradually dissolves. Subsequent applications of Oravig should be made to alternate sides of mouth. Before applying the next tablet, the patient should clear away any remaining tablet material. In addition:

- Oravig should not be crushed, chewed, or swallowed.
- Food and drink can be taken normally when Oravig is in place but chewing gum should be avoided.
- If Oravig does not adhere or falls off within the first 6 hours, the same tablet should be repositioned immediately. If the tablet still does not adhere, a new tablet should be placed.
- If Oravig is swallowed within the first 6 hours, the patient should drink a glass of water and a new tablet should be applied only once.
- If Oravig falls off or is swallowed after it was in place for 6 hours or more, a new tablet should not be applied until the next regularly scheduled dose.

References

1. Oravig® Prescribing Information, April 2010, Strativa Pharmaceuticals, a Division of Par Pharmaceutical, Inc.
2. Wolters Kluwer Health, Inc. Drug Facts and Comparisons. St. Louis, MO. 2010.

HEALTH INFORMATION DESIGNS

Oravig Prior Authorization

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

Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that patients receiving a prescription for Oravig first try clotrimazole or nystatin.
Notes:

- ***Clotrimazole does not require PA***
- ***Nystatin does not require PA***

Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name	Recipient Date of Birth	Recipient Medicaid ID Number	
Physician Name			
Physician Medicaid Provider Number	Telephone Number	Fax Number	
Address	City	State	ZIP Code
Requested Drug and Dosage: □ **Oravig**	**Diagnosis for this request:**		
Qualifications for coverage:			
□ **Immunosuppressive therapy** □ **Cytotoxic cancer therapy**			
Physician Signature	Date		

Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

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

North Dakota Department of Human Services
DUR Board Meeting
Zyclara® Review
September 13, 2010

I. Overview

Zyclara cream is indicated for the topical treatment of clinically typical, visible or palpable actinic keratosis (AK) of the full face or balding scalp in immunocompetent adults.

II. Pharmacology

The mechanism of action of Zyclara cream in treating AK lesions is unknown.

III. Warnings/Precautions

Local Skin Reactions: Intense local skin reactions including skin weeping or erosion can occur after a few applications of Zyclara cream and may require an interruption of dosing. Zyclara cream has the potential to exacerbate inflammatory conditions of the skin, including chronic graft versus host disease. Administration of Zyclara cream is not recommended until the skin is healed from any previous drug or surgical treatment. Concomitant use of Zyclara and any other imiquimod creams, in the same treatment area, should be avoided since they contain the same active ingredient (imiquimod) and may increase the risk for and severity of local skin reactions.

Systemic Reactions: Flu-like signs and symptoms may accompany, or even precede, local skin reactions and may include fatigue, nausea, fever, myalgias, arthralgias, and chills. An interruption of dosing and an assessment of the patient should be considered.

Ultraviolet Light Exposure: Exposure to sunlight (including sunlamps) should be avoided or minimized during use of Zyclara cream because of concern for heightened sunburn susceptibility. Patients should be warned to use protective clothing when using Zyclara cream. Patients with sunburn should be advised not to use Zyclara cream until fully recovered. Patients who may have considerable sun exposure and those patients with inherent sensitivity to sunlight should exercise caution when using Zyclara cream.

IV. Adverse Reactions

Selected Adverse Reactions Occurring in ≥ 2% of Zyclara Treated Subjects

Adverse Reaction	**Zyclara Cream 3.75% (N=160)**	**Vehicle (N=159)**
Headache	10 (6%)	5 (3%)
Application site pruritus	7 (4%)	1 (<1%)
Fatigue	7 (4%)	0 (0%)
Nausea	6 (3%)	2 (1%)
Application site irritation	5 (3%)	0 (0%)
Application site pain	5 (3%)	0 (0%)

Adverse Reaction	Zyclara Cream 3.75% (N=160)	Vehicle (N=159)
Pyrexia	5 (3%)	0 (0%)
Anorexia	4 (3%)	0 (0%)
Dizziness	4 (3%)	0 (0%)
Herpes simplex	4 (3%)	1 (<1%)
Pain	4 (3%)	0 (0%)
Chest pain	3 (2%)	0 (0%)
Diarrhea	3 (2%)	0 (0%)
Lymphadenopathy	3 (2%)	0 (0%)

V. Dosage and Administration

Zyclara should be applied once daily before bedtime to the skin of the affected area (either the face or balding scalp) for two 2-week treatment cycles separated by 2-week no-treatment period. Zyclara should be applied as a thin film to the entire treatment area and rubbed in until the cream is no longer visible. Up to 2 packets of Zyclara cream may be applied to the treatment area at each application. Zyclara cream should be left on the skin for approximately 8 hours, after which time the cream should be removed by washing the area with mild soap and water.

References

1. Zyclara® Prescribing Information, March 2010, Graceway Pharmaceuticals; Manufactured by 3M Health Care Limited.
2. Wolters Kluwer Health, Inc. Drug Facts and Comparisons. St. Louis, MO. 2010.

HEALTH INFORMATION DESIGNS

Zyclara Prior Authorization

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

Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that patients receiving a prescription for Zyclara first try imiquimod.
Note:

- ***Imiquimod does not require PA***

Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name	Recipient Date of Birth	Recipient Medicaid ID Number	
Physician Name			
Physician Medicaid Provider Number	Telephone Number	Fax Number	
Address	City	State	ZIP Code
Requested Drug and Dosage: □ **Zyclara**	**Diagnosis for this request:**		
Qualifications for coverage:			
□ **Trial of imiquimod** **Start Date** **End Data**			
Physician Signature	Date		

Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

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

North Dakota Department of Human Services
DUR Board Meeting
Clorpres® Review
September 13, 2010

I. Overview

Clorpres is an antihypertensive combination product containing clonidine and chlorthalidone. It has FDA approval for the treatment of hypertension; not indicated for initial therapy.

II. Pharmacology

Clonidine stimulates central alpha-adrenergic receptors to inhibit sympathetic cardioaccelerator and vasoconstrictor centers. Chlorthalidone inhibits reabsorption of sodium and chloride in the proximal portion of the distal convoluted tubules.

III. Warnings/Precautions

- Coronary insufficiency: Use with caution in patients with severe coronary insufficiency, recent MI, or cerebral vascular disease.
- Electrolyte abnormalities: Hypokalemia and other electrolyte abnormalities, including hyponatremia and hypochloremic alkalosis, are common while receiving chlorthalidone. Ensure that serum electrolytes and renal function are monitored before starting therapy and periodically thereafter.
- Perioperative use: Continue clonidine therapy to within 4 hours of surgery and resume as soon as possible thereafter.
- Systemic lupus erythematosus: May be activated or exacerbated.
- Uric acid: Hyperuricemia may occur, or frank gout may be precipitated.
- Withdrawal: Discontinue therapy by reducing the dose gradually over 2-4 days to avoid rapid increase in blood pressure.
- Renal function impairment: Use with caution. Minor alterations of fluid and electrolyte balance may precipitate hepatic coma.
- Children: Safety and efficacy not established.
- Elderly: Per the Beers list, clonidine has the potential for orthostatic hypotension and CNS adverse effects.
- Monitoring:
    - Blood sugar: Monitor blood sugar in diabetic patient when drug is started or dose is changed. Report significant changes to health care provider.
    - Blood pressure: Monitor and record blood pressure and pulse. Should hypotension result, hold medication and notify health care provider.

IV. Drug Interactions

- Alcohol, barbiturates, other sedatives: CNS depressive effects may be enhanced with clonidine.

- Antihypertensive agents: Action may be increased or potentiated by chlorthalidone.
- Insulin, sulfonylureas (e.g., chlorpropamide): Hypoglycemic effect may be decreased by chlorthalidone, necessitating an increase in dosage.
- Lithium: Because renal excretion of lithium may be reduced, avoid use if possible.
- Norepinephrine: Arterial responsiveness to norepinephrine may be decreased.
- Tricyclic antidepressants: Effects on clonidine may be reduced.

V. Adverse Reactions

Cardiovascular:

- Clonidine: Orthostatic hypotension; palpitations; tachycardia; Raynaud phenomena; CHF; ECG abnormalities; arrhythmias.
- Chlorthalidone: Orthostatic hypotension.

CNS:

- Drowsiness; dizziness; sedation
- Clonidine: Malaise; agitation; nervousness; depression; headache; insomnia; vivid dreams; nightmares; restlessness; anxiety; visual and auditory hallucinations; delirium; fatigue; vertigo
- Chlorthalidone: Dizziness; paresthesias; headache; xanthopsia

Dermatologic:

- Clonidine: Rash; pruritus; hives; angioneurotic edema; urticaria; alopecia
- Chlorthalidone: Purpura; photosensitivity; rash; urticaria; necrotizing angiitis; toxic epidermal necrolysis

GI:

- Dry mouth; constipation
- Clonidine: Nausea; vomiting; anorexia
- Chlorthalidone: Anorexia; gastric irritation; nausea; vomiting; cramping; diarrhea; constipation; jaundice; pancreatitis

GU:

- Clonidine: Decreased sexual activity; impotence; loss of libido; nocturia; micturition; urinary retention
- Chlorthalidone: Hyperuricemia; impotence

Hematologic:

- Chlorthalidone: Leukopenia; agranulocytosis; thrombocytopenia; aplastic anemia

Hepatic:

- Clonidine: Transient abnormalities in LFTs.

Metabolic:

- Clonidine: Weight gain.
- Chlorthalidone: Hyperglycemia; hyperuricemia.

Special senses:

- Clonidine: Dryness and burning of eyes; blurred vision; dryness of nasal mucosa.

Miscellaneous:

- Clonidine: Weakness; discontinuation syndrome; muscle and joint pain; cramps of the lower limbs; pallor; weakly positive Coombs test; muscle spasm.
- Chlorthalidone: Weakness; restlessness.

VI. Dosage and Administration

Hypertension: once or twice per day from a minimum dose of clonidine 0.1mg plus chlorthalidone 15mg to a maximum dose of clonidine 0.6mg plus chlorthalidone 30mg.

References

1. Wolters Kluwer Health, Inc. Drug Facts and Comparisons. St. Louis, MO. 2010.

HEALTH INFORMATION DESIGNS

Clorpres Prior Authorization

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

Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that patients receive clonidine and chlorthalidone separately.
Notes:

- ***Clonidine does not require PA***
- ***Chlorthalidone does not require PA***

Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name	Recipient Date of Birth	Recipient Medicaid ID Number	
Physician Name			
Physician Medicaid Provider Number	Telephone Number	Fax Number	
Address	City	State	ZIP Code
Requested Drug and Dosage: □ **Clorpres**	**Diagnosis for this request:**		
Qualifications for coverage:			
□ Failed both drugs separately	Start Date: End Date:	Dose: Frequency:	
Physician Signature		Date	

Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

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

North Dakota Department of Human Services
DUR Board Meeting
Livalo® Review
September 13, 2010

I. Overview

Livalo is a HMG-CoA reductase inhibitor indicated for patients with primary hyperlipidemia and mixed dyslipidemia as an adjunctive therapy to diet to reduce elevated total cholesterol (TC), low-density lipoprotein cholesterol (LDL-C), apolipoprotein B (Apo B), triglycerides (TG), and to increase high-density lipoprotein cholesterol (HDL-C).

II. Limitations of Use

- Doses of Livalo greater than 4mg once daily were associated with an increased risk for severe myopathy in premarketing clinical studies. Do not exceed 4mg once daily dosing of Livalo.
- The effect of Livalo on cardiovascular morbidity and mortality has not been determined.
- Livalo has not been studied in patients with severe renal impairment (glomerular filtration rate < 30 mL/min/1.73m^2) not on hemodialysis. Livalo should not be used in this patient population.
- Livalo has not been studied with the protease inhibitor combination lopinavir/ritonavir. Livalo should not be used with this combination of protease inhibitors.
- Livalo has not been studied in Fredrickson Type I, III, and V dyslipidemias.

III. Pharmacology

Pitavastatin competitively inhibits HMG-CoA reductase, which is a rate-determining enzyme involved with biosynthesis of cholesterol, in a manner of competition with the substrate so that it inhibits cholesterol synthesis in the liver. As a result, the expression of LDL-receptors followed by the uptake of LDL from blood to liver is accelerated and then the plasma TC decreases. Further, the sustained inhibition of cholesterol synthesis in the liver decreases levels of very low density lipoproteins.

IV. Pharmacokinetics

- Absorption-peak plasma concentrations are achieved about 1 hour after oral administration
- Distribution-more than 99% protein bound and the mean volume of distribution is approximately 148L.
- Metabolism-marginally metabolized by CYP2C9 and to a lesser extent by CYP2C8.
- Excretion-mean plasma elimination half-life is approximately 12 hours.

V. Contraindications

The use of Livalo is contraindicated in the following conditions:

- Patients with a known hypersensitivity to any component of this product.
- Patients with active liver disease which may include unexplained persistent elevations of hepatic transaminase levels.
- Women who are pregnant or may become pregnant.
- Nursing mothers.
- Co-administration with cyclosporine.

VI. Warnings/Precautions

- Skeletal muscle effects
- Liver enzyme abnormalities and monitoring

VII. Drug Interactions

- Cyclosporine: Significantly increased pitavastatin exposure. Co-administration of cyclosporine and Livalo is contraindicated.
- Lopinavir/Ritonavir: Co-administration with Livalo may significantly increase pitavastatin exposure.
- Erythromycin: Significantly increased pitavastatin exposure. A dose of Livalo 1mg once daily should not be exceeded.
- Rifampin: Significantly increased pitavastatin exposure. A dose of Livalo 2mg once daily should not be exceeded.
- Fibrates: Because the risk of myopathy during treatment with HMG-CoA reductase inhibitors may be increased with concurrent administration of fibrates, Livalo should be administered with caution when used concomitantly with gemfibrozil or other fibrates.
- Niacin: The risk of skeletal muscle effects may be enhanced when Livalo is used in combination with niacin; a reduction in Livalo dosage should be considered in this setting.
- Warfarin: no significant pharmacokinetic interaction with R- and S- warfarin. Patients receiving warfarin should have their PT and INR monitored when pitavastatin is added to their therapy.

VIII. Adverse Reactions

Adverse Reactions Reported by ≥ 2% of Patients Treated with Livalo

Adverse Reactions	**Placebo N=208**	**Livalo 1mg N=309**	**Livalo 2mg N=951**	**Livalo 4mg N=1540**
Back Pain	2.9%	3.9%	1.8%	1.4%
Constipation	1.9%	3.6%	1.5%	2.2%
Diarrhea	1.9%	2.6%	1.5%	1.9%
Myalgia	1.4%	1.9%	2.8%	3.1%
Pain in extremity	1.9%	2.3%	0.6%	0.9%

Other adverse reactions reported from clinical studies were arthralgia, headache, influenza, and nasopharyngitis.

The following laboratory abnormalities have also been reported: elevated creatine phosphokinase, transaminases, alkaline phosphatase, bilirubin and glucose.

IX. Dosage and Administration

The dose range for Livalo is 1 to 4mg orally once daily at any time of the day with or without food. The recommended starting dose is 2mg and the maximum dose is 4mg. The starting dose and maintenance doses of Livalo should be individualized according to patient characteristics, such as goal of therapy and response.

After initiation or upon titration of Livalo, lipid levels should be analyzed after 4 weeks and the dosage adjusted accordingly.

References

1. Livalo® Prescribing Information, January 2010, Kowa Pharmaceuticals America, Inc.
2. Wolters Kluwer Health, Inc. Drug Facts and Comparisons. St. Louis, MO. 2010.

HEALTH INFORMATION DESIGNS

Prior Authorization Vendor for ND Medicaid

Livalo Prior Authorization

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

ND Medicaid requires that patients who are prescribed Livalo must first try a covered statin medication

Note:

- ***Statins already on the market do not require PA***

Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name | Recipient Date of Birth | Recipient Medicaid ID Number

Physician Name			
Physician Medicaid Provider Number	Telephone Number	Fax Number	
Address	City	State	ZIP Code
Requested Drug and Dosage:	**Diagnosis for this request:**		
□ **Livalo**			
Qualifications for coverage:			
□ Medication Failed _____	Start Date: End Date:	Dose: Frequency:	
Physician Signature		Date	

Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

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

NORTH DAKOTA MEDICAID
RETROSPECTIVE DRUG UTILIZATION REVIEW
CRITERIA RECOMMENDATIONS
3RD QUARTER 2010

Criteria Recommendations	*Approved*	*Rejected*

1. ActoPlus Met XR /Overutilization _____ _____

Alert Message: ActoPlus Met XR (extended-release pioglitazone/metformin) may be over-utilized. The manufacturer's maximum recommended daily dose is 45 mg pioglitazone / 2000 mg metformin.

Conflict Code: ER – Overutilization
Drug/Disease:

Util A	Util B	Util C
ActoPlus Met XR		

Max Dose: 45mg pioglitazone -2000mg metformin extended-release per day

References:
Facts & Comparisons, 2010 Updates.
ActoPlus Met XR Prescribing Information, March 2009, Takeda Pharmaceuticals.

2. ActoPlus Met XR /Non-adherence _____ _____

Alert Message: Non-adherence to ActoPlus Met XR (extended-release pioglitazone/metformin) therapy may result in loss of glycemic control and an increased risk of developing diabetic-related complications.

Conflict Code: LR – Non-adherence
Drug/Disease:

Util A	Util B	Util C
ActoPlus Met XR		

References:
Facts & Comparisons, 2010 Updates.
ActoPlus Met XR Prescribing Information, March 2009, Takeda Pharmaceuticals.

3. Dutasteride/tamsulosin / Overutilization _____ _____

Alert Message: Jalyn (dutasteride/tamsulosin) may be over-utilized. The manufacturer's maximum recommended daily dose is one capsule (0.5 mg dutasteride/0.4 mg tamsulosin) daily.

Conflict Code: ER - Overutilization
Drug/Disease:

Util A	Util B	Util C
Dutasteride/tamsulosin		

Max Dose: 0.5 mg dutasteride/0.4 mg tamsulosin per day

References:
Jalyn Prescribing Information, June 2010. GlaxoSmithKline.

4. Tamsulosin / Strong CYP 3A4 Inhibitors _____ _____

Alert Message: Tamsulosin-containing products should not be co-administered with strong CYP3A4 Inhibitors (e.g. ketoconazole, itraconazole, and ritonavir). Tamsulosin is metabolized via CYP3A4 isoenzyme and concurrent use with a strong inhibitor can significantly decrease tamsulosin metabolism and increase tamsulosin exposure.

Conflict Code: DD – Drug/Drug Interaction
Drug/Disease:

Util A	Util B		Util C
Tamsulosin-All	Ketoconazole	Ritonavir	
	Itraconazole	Saquinavir	
	Nefazodone	Indinavir	
	Clarithromycin	Nelfinavir	
	Telithromycin	Atazanavir	

References:
Jalyn Prescribing Information, June 2010. GlaxoSmithKline.
Flomax Prescribing Information, Nov. 2009, Boehringer Ingelheim Pharmaceuticals, Inc.

5. Tamsulosin / CYP2D6 Inhibitors & Moderate 3A4 Inhibitors _____ _____

Alert Message: Tamsulosin-containing products should be used with caution when co-administered with moderate CYP3A4 inhibitors, moderate or strong CYP2D6 inhibitors or in patients known to be poor2D6 metabolizers. Tamsulosin is metabolized via CYP3A4 and CYP2D6 and concurrent use with Inhibitors of these isoenzymes or in poor 2D6 metabolizers may result in a significant increase in tamsulosin exposure.

Conflict Code: DD - Drug/Drug Interaction
Drug/Disease:

Util A	Util B			Util C
Tamsulosin-All	Erythromycin	Paroxetine	Terbinafine	
	Aprepitant	Bupropion		
	Fluconazole	Fluoxetine		
	Verapamil	Quinidine		
	Diltiazem	Duloxetine		

References:
Jalyn Prescribing Information, June 2010. GlaxoSmithKline.
Flockhart DA. Drug Interactions: Cytochrome P450 Drug Interaction Table. Indiana University School of Medicine. Available at: http://medicine.iupui.edu/clinpharm/ddos/table.asp.
Flomax Prescribing Information, Nov. 2009, Boehringer Ingelheim Pharmaceuticals, Inc.

6. Tamsulosin-All / Cimetidine _____ _____

Alert Message: Tamsulosin-containing products should be used with caution when co-administered with cimetidine (an inhibitor of both CYP3A4 and 2D6). Concurrent use of these agents has resulted in a moderate increase in tamsulosin AUC (44%) with a 26% decrease in tamsulosin clearance.

Conflict Code: DD - Drug/Drug Interaction
Drug/Disease:

Util A	Util B	Util C
Tamsulosin-All	Cimetidine	

References:
Jalyn Prescribing Information, June 2010. GlaxoSmithKline.
Flockhart DA. Drug Interactions: Cytochrome P450 Drug Interaction Table. Indiana University School of Medicine. Available at: http://medicine.iupui.edu/clinpharm/ddos/table.asp.
Flomax Prescribing Information, Nov. 2009, Boehringer Ingelheim Pharmaceuticals, Inc.

Criteria Recommendations *Approved* *Rejected*

7. Tamsulosin-All / Warfarin _____ _____

Alert Message: Tamsulosin-containing products should be used with caution when co-administered with warfarin. Results from limited in vitro and in vivo studies are inconclusive concerning this interaction, therefore caution should be exercised with concurrent use.

Conflict Code: DD - Drug/Drug Interaction
Drug/Disease:

Util A	Util B	Util C
Tamsulosin-All	Warfarin	

References:
Jalyn Prescribing Information, June 2010. GlaxoSmithKline.
Flockhart DA. Drug Interactions: Cytochrome P450 Drug Interaction Table. Indiana University School of Medicine. Available at: http://medicine.iupui.edu/clinpharm/ddos/table.asp.
Flomax Prescribing Information, Nov. 2009, Boehringer Ingelheim Pharmaceuticals, Inc.

8. Alpha-1-Adrenergic Receptor Blockers/ Duplicate Therapy _____ _____

Alert Message: Therapeutic duplication of alpha-1-adrenergic blockers may be occurring. These agents should not be used concurrently due to the increased risk of hypotension.

Conflict Code: TD – Therapeutic Duplication
Drug/Disease:

Util A	Util B	Util C
Tamsulosin-all		
Prazosin		
Terazosin		
Doxazosin		
Alfuzosin		
Silodosin		

References:
Jalyn Prescribing Information, June 2010. GlaxoSmithKline.
Flomax Prescribing Information, Nov. 2009, Boehringer Ingelheim Pharmaceuticals, Inc.
Minipress Prescribing Information, July 2009, Pfizer Labs.

9. Dutasteride / Pregnancy / Pregnancy Negating _____ _____

Alert Message: Dutasteride-containing products are contraindicated during pregnancy and in women of childbearing potential due to risk for fetal harm. In animal studies dutasteride, an androgen hormone inhibitor, inhibited the normal development of external genitalia in male fetuses. Dutasteride-containing products are pregnancy category X.

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

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

Age: 12 – 999 years of age

References:
Jalyn Prescribing Information, June 2010. GlaxoSmithKline.
Facts & Comparisons, 2010 Updates.
Avodart Prescribing Information, June 2010, GlaxoSmithKline.