DUR Board Meeting
December 3, 2013
Bismarck State College

National Energy Center of Excellence

north dakota
**department of
human services**

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

1. Administrative items
   - Travel vouchers

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

3. New business
   - Annual PA Review   HID
   - Criteria Recommendations   HID
   - Upcoming Meeting Date/Agenda   Chair

4. Adjourn   Chair

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

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

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

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

Medicaid Pharmacy Department: Brendan Joyce, Gary Betting

HID Staff Present: Candace Rieth

Chair G. Pfister called the meeting to order at 1:00 pm. Chair G. Pfister asked for a motion to approve the minutes from the June meeting. N. Byers moved that the minutes be approved, and G. Betting seconded the motion. Chair G. Pfister called for a voice vote to approve the minutes. The motion passed with no audible dissent. New board member, Peter Woodrow was introduced to the Board.

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

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

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

Sitavig Second Review
A motion and second were made at the June meeting to place Sitavig on prior authorization. The topic was brought up for a second review. There was no public comment. After discussion, Chair G. Pfister called for a voice vote to approve the motion. The motion passed with no audible dissent. This will be added to the Orally Disintegrating Tablets PA form.

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

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

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

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

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

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

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

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

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

Statin Review
B. Joyce reviewed statin information with the board. This topic was tabled until the next meeting.

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

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

CHAPTER 50-24.6
MEDICAL ASSISTANCE DRUG USE REVIEW AND AUTHORIZATION

50-24.6-01. Definitions.

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

50-24.6-02. Drug use review board.

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

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

50-24.6-03. Duties of the board.
The board shall:
1. Cooperate with the department to create and implement a prospective and retrospective drug use review program for outpatient prescription drugs under the medical assistance program. This drug use review program must be based on a compendium and drug use review criteria and must comply with 42 U.S.C. 1396r-8(g) (3).
2. Advise and make recommendations regarding any rule proposed for adoption by the department to implement the provisions of state and federal law related to drug use review.
3. Receive and consider information regarding the drug use review process which is provided by the department and by interested parties, including prescribers who treat significant numbers of patients under the department's medical assistance program.
4. Review and recommend to the department any drugs to be included on prior authorization status.
5. Review no less than once each year the status of the list of drugs that have been placed on prior authorization.
6. Review and approve the prior authorization program process used by the department, including the process to accommodate the provision of a drug benefit in an emergency situation.
7. Propose remedial strategies to improve the quality of care and to promote effective use of medical assistance program funds or recipient expenditures.

50-24.6-04. Prior authorization program.
1. The department shall develop and implement a prior authorization program that meets the requirements of 42 U.S.C. 1396r-8(d) to determine coverage of drug products when a medical assistance recipient's health care provider prescribes a drug that is identified as requiring prior authorization. Authorization must be granted for provision of the drug if:
   a. The drug not requiring prior authorization has not been effective, or with reasonable certainty is not expected to be effective, in treating the recipient's condition;
   b. The drug not requiring prior authorization causes or is reasonably expected to cause adverse or harmful reactions to the health of the recipient; or
   c. The drug is prescribed for a medically accepted use supported by a compendium or by approved product labeling unless there is a therapeutically equivalent drug that is available without prior authorization.
2. For any drug placed on the prior authorization program, the department shall provide medical and clinical criteria, cost information, and utilization data to the drug use review board for review and consideration. The board may consider department data and information from other sources to make a decision about placement of the drug on prior authorization.
3. Except for quantity limits that may be no less than the pharmaceutical manufacturer's package insert, or brand name drugs with a generic equivalent drug for which the cost to the state postrebate is less than the brand name drugs, in the aggregate, the department may not prior authorize the following medication classes:
   a. Antipsychotics;
   b. Antidepressants;
   c. Anticonvulsants;
   d. Antiretrovirals, for the treatment of human immunodeficiency virus;
   e. Antineoplastic agents, for the treatment of cancer; and

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

4. The department may use contractors to collect and analyze the documentation required under this section and to facilitate the prior authorization program.

5. The department shall consult with the board in the course of adopting rules to implement the prior authorization program. The rules must:

  a. Establish policies and procedures necessary to implement the prior authorization program.

  b. Develop a process that allows prescribers to furnish documentation required to obtain approval for a drug without interfering with patient care activities.

  c. Allow the board to establish panels of physicians and pharmacists which provide expert guidance and recommendations to the board in considering specific drugs or therapeutic classes of drugs to be included in the prior authorization program.

50-24.6-05. Public notice - Applicability.

1. The department shall provide thirty days' notice of all meetings of the board. The notice requirement is met if the department provides notice of the meeting on the department's website and provides, by written or electronic means, individual notice to each person that has requested such notice. If the meeting agenda includes board consideration of a change to the prior authorization program, the department shall include in the notice a list of the affected drugs, and upon request the board shall provide background information. Any interested party may attend a meeting of the board and provide information or recommendations related to the inclusion of a drug in a prior authorization program.

2. The department shall post on the department's website:

  a. The most current and applicable list of drugs requiring prior authorization, together with any limits on coverage of these drugs.

  b. In downloadable format, forms necessary to complete prior authorization requests.

  c. Decisions regarding changes to the prior authorization program list. The department shall allow a period of no less than thirty days for public comment following posting on the website.

  d. Meeting notice.

3. The department may not discontinue the provision of prescription drug benefits being provided to medical assistance recipients before April 14, 2003, based solely on the subsequent placement of the drug on the prior authorization program.

50-24.6-06. Grievances.

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

50-24.6-07. Appeals.

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

50-24.6-08. Financial incentives prohibited.

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

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

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

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

50-24.6-10. Adoption of rules.
The department shall adopt rules to implement this chapter.

North Dakota

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Medicaid Provider Information

Pharmacy Provider Drug Utilization Review Board

Members

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

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

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

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

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

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

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HEALTH INFORMATION DESIGNS

**Sirturo
Prior Authorization**

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

Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that patients receiving Sirturo must meet the following criteria:
- *Sirturo cannot be billed for outpatient use*
- *Sirturo must be billed by physician*

Part I: TO BE COMPLETED BY PHYSICIAN

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

QUALIFICATIONS FOR COVERAGE:

Requested Drug and Dosage: □ **Sirturo**	Diagnosis for this request:

SIRTURO MUST BE GIVEN/BILLED BY PHYSICIAN

Physician Signature	Date

Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

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

HEALTH INFORMATION DESIGNS

**Brisdelle
Prior Authorization**

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

Prior Authorization Vendor for ND Medicaid

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

- *Patient must first try paroxetine*

Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name	Recipient Date of Birth	Recipient Medicaid ID Number
Physician Name:		
Physician Medicaid Provider Number	Telephone Number	Fax Number

Address	City	State	Zip Code

QUALIFICATIONS FOR COVERAGE:

Requested Drug and Dosage: □ **Brisdelle**	Diagnosis for this request:
Failed Therapy:	Start Date: End Date:
Physician Signature	Date

Part II: TO BE COMPLETED BY PHARMACY

PHARMACY NAME:		ND MEDICAID PROVIDER NUMBER:

PHONE NUMBER	FAX NUMBER	DRUG	NDC #

Part III: FOR OFFICIAL USE ONLY

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

North Dakota Department of Human Services
Brisdelle Authorization Algorithm

Has patient failed a trial of paroxetine?

—YES—▶ PA may be approved

NO

Deny PA

HEALTH INFORMATION DESIGNS
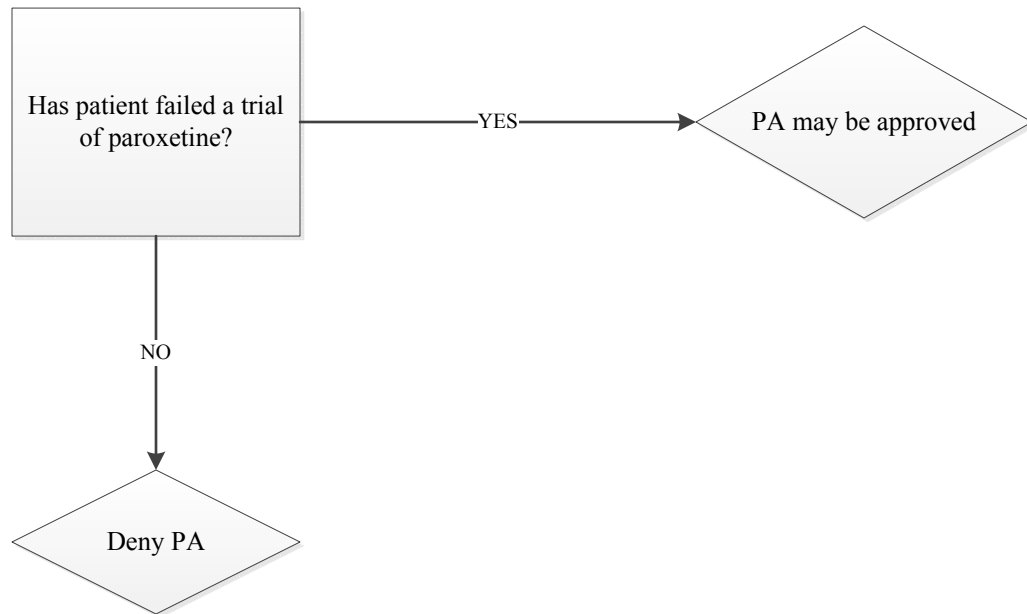
**Nitrolingual Spray
Prior Authorization**

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

Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that patients receiving a new prescription for Nitrolingual Spray must meet the following criteria:
- *Patient must first try sublingual tablets*

Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name	Recipient Date of Birth	Recipient Medicaid ID Number
Physician Name:		

Physician Medicaid Provider Number	Telephone Number	Fax Number	
Address	City	State	Zip Code

QUALIFICATIONS FOR COVERAGE:

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

Part II: TO BE COMPLETED BY PHARMACY

PHARMACY NAME:		ND MEDICAID PROVIDER NUMBER:

PHONE NUMBER	FAX NUMBER	DRUG	
			NDC #

Part III: FOR OFFICIAL USE ONLY

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

North Dakota Department of Human Services
Nitrolingual Spray Authorization Algorithm

Has patient failed a trial of sublingual tablets? —YES→ PA may be approved

NO

Deny PA

HEALTH INFORMATION DESIGNS
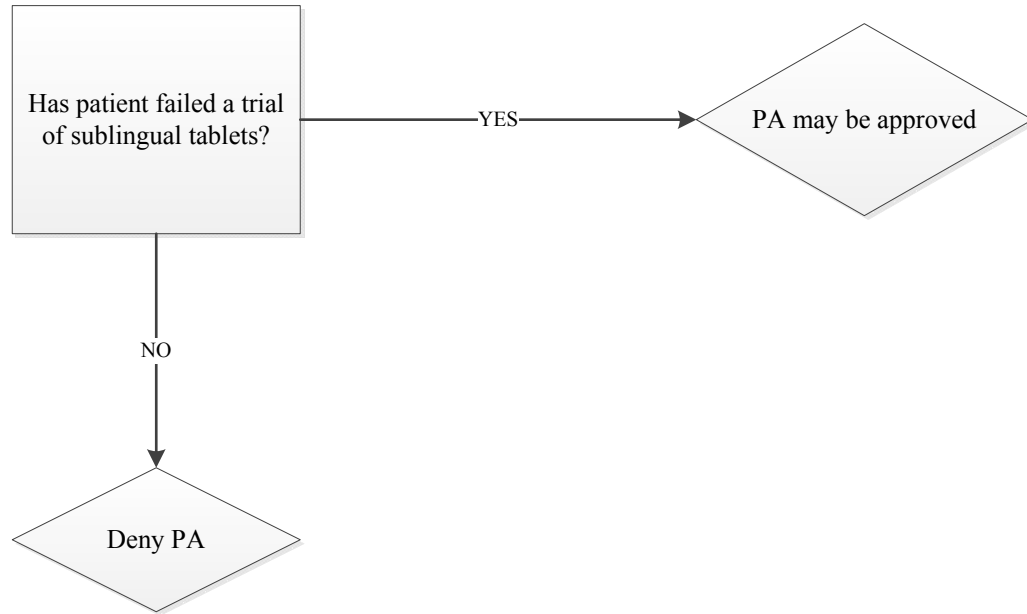
Agents Used to Treat COPD
Prior Authorization

Prior Authorization Vendor for ND Medicaid

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

ND Medicaid requires that patients receiving a new prescription for Arcapta, Brovana, Spiriva, Tudorza, or Breo Ellipta must meet the following criteria:

- *Patient must have a diagnosis of COPD.*

Part I: TO BE COMPLETED BY PHYSICIAN

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

QUALIFICATIONS FOR COVERAGE:

Requested Drug and Dosage:	Diagnosis for this request:
□ **Arcapta**　　　　　□ **Tudorza** □ **Brovana**　　　　　□ **Breo Ellipta** □ **Spiriva**	
Physician Signature	Date

Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

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

North Dakota Department of Human Services
Agents Used to Treat COPD
Authorization Algorithm

Does patient have a diagnosis of COPD?

─YES─→ PA may be approved

NO ↓

Deny PA

HEALTH INFORMATION DESIGNS
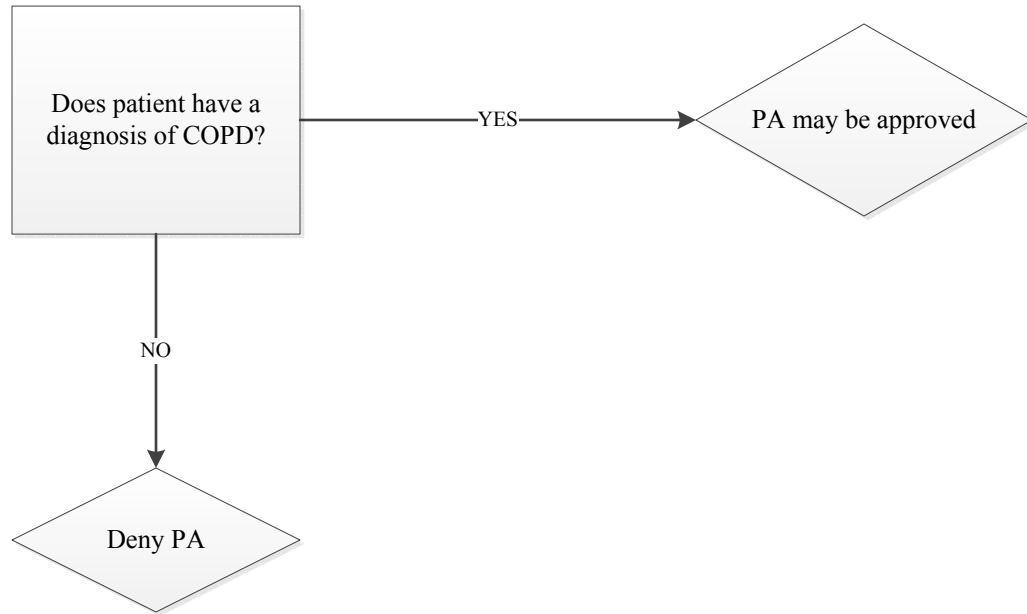
**Epinephrine Auto Injectors
Prior Authorization**

Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that patients receiving a new prescription for epinephrine auto injectors must use Auvi-Q as first line therapy.

- *Auvi-Q does not require a prior authorization*

Part I: TO BE COMPLETED BY PHYSICIAN

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

QUALIFICATIONS FOR COVERAGE:

Requested Drug and Dosage: □	Diagnosis for this request:
Failed Therapy:	Start Date: End Date:
Physician Signature	Date

Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

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

North Dakota Department of Human Services
Epinephrine Auto Injector
Authorization Algorithm

Has patient failed a trial of Auvi-Q? —YES→ PA may be approved

NO ↓

Deny PA

HEALTH INFORMATION DESIGNS
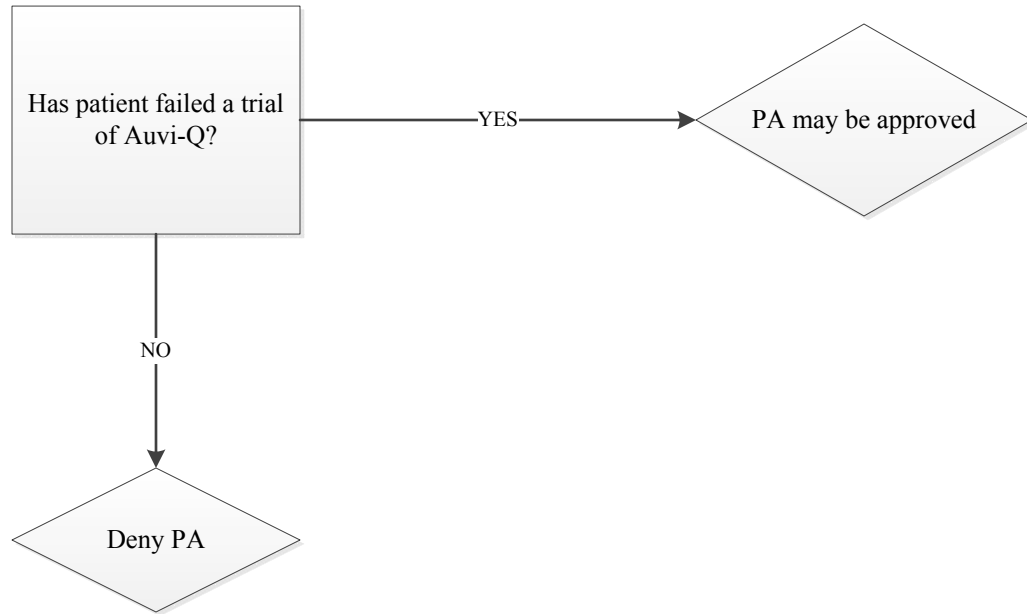
**Pulmozyme
Prior Authorization**

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

Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that patients receiving a new prescription for Pulmozyme must meet the following criteria:
- *Patient must have a confirmed diagnosis of cystic fibrosis*

Part I: TO BE COMPLETED BY PHYSICIAN

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

QUALIFICATIONS FOR COVERAGE:

Requested Drug and Dosage: □ **Pulmozyme**	Diagnosis for this request:
Physician Signature	Date

Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

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

North Dakota Department of Human Services
Pulmozyme Authorization Algorithm

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┌─────────────────────────┐
│  Does patient have a    │
│  confirmed diagnosis of │────YES────▶  PA may be approved
│  cystic fibrosis?       │
└─────────────────────────┘
            │
            NO
            │
            ▼
         Deny PA
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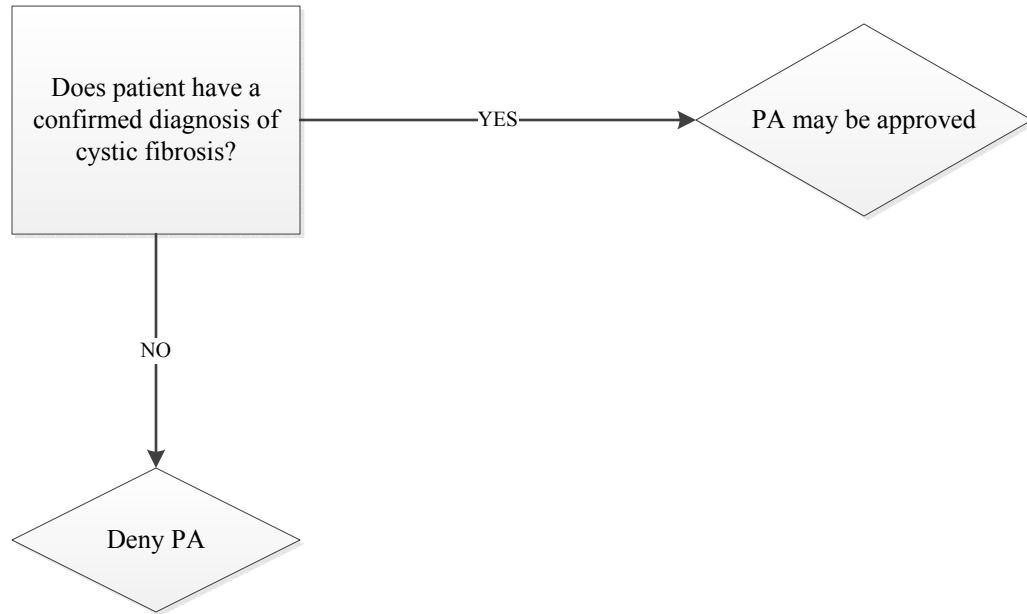
ND Medicaid Statin Utilization (AHFS 240608)			
05/30/12 - 05/29/13			
Label Name	Rx Num	Total Reimb Amt	Average Cost per Script
AMLODIPINE-ATORVAST 10-10 MG	7	$886.34	$126.62
AMLODIPINE-ATORVAST 10-20 MG	4	$684.76	$171.19
AMLODIPINE-ATORVAST 10-40 MG	11	$1,883.09	$171.19
AMLODIPINE-ATORVAST 10-80 MG	12	$2,080.36	$173.36
ATORVASTATIN 10 MG TABLET	64	$662.30	$10.35
ATORVASTATIN 20 MG TABLET	1289	$14,421.53	$11.19
ATORVASTATIN 40 MG TABLET	951	$11,143.43	$11.72
ATORVASTATIN 80 MG TABLET	942	$12,366.17	$13.13
CRESTOR 10 MG TABLET	423	$60,229.98	$142.39
CRESTOR 20 MG TABLET	332	$53,318.16	$160.60
CRESTOR 40 MG TABLET	160	$24,531.76	$153.32
CRESTOR 5 MG TABLET	134	$20,519.91	$153.13
FLUVASTATIN SODIUM 40 MG CAP	2	$206.94	$103.47
LESCOL XL 80 MG TABLET	1	$42.00	$42.00
LIPITOR 20 MG TABLET	1	$25.86	$25.86
LIPITOR 40 MG TABLET	2	$67.15	$33.58
LIVALO 1 MG TABLET	3	$384.84	$128.28
LIVALO 2 MG TABLET	2	$256.56	$128.28
LOVASTATIN 10 MG TABLET	19	$117.59	$6.19
LOVASTATIN 20 MG TABLET	48	$382.38	$7.97
LOVASTATIN 40 MG TABLET	104	$976.93	$9.39
PRAVASTATIN SODIUM 10 MG TAB	54	$528.36	$9.78
PRAVASTATIN SODIUM 20 MG TAB	142	$1,289.32	$9.08
PRAVASTATIN SODIUM 40 MG TAB	214	$2,023.54	$9.46
PRAVASTATIN SODIUM 80 MG TAB	49	$681.70	$13.91
SIMCOR 1,000-20 MG TABLET	6	$1,924.36	$320.73
SIMCOR 500-20 MG TABLET	6	$731.19	$121.87
SIMCOR 500-40 MG TABLET	8	$754.69	$94.34
SIMVASTATIN 10 MG TABLET	702	$4,410.04	$6.28
SIMVASTATIN 20 MG TABLET	1976	$13,270.90	$6.72
SIMVASTATIN 40 MG TABLET	1179	$8,492.59	$7.20
SIMVASTATIN 5 MG TABLET	54	$445.87	$8.26
SIMVASTATIN 80 MG TABLET	209	$1,693.35	$8.10
1,333 recipients	9112	$241,433.95	

HEALTH INFORMATION DESIGNS

HMG-CoA Reductase Inhibitors (Statins) Prior Authorization

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

Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that patients receiving a new prescription for HMG-CoA Reductase Inhibitors must meet the following criteria:

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

Part I: TO BE COMPLETED BY PHYSICIAN

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

QUALIFICATIONS FOR COVERAGE:

Requested Drug and Dosage:	Diagnosis for this request:

Medication Failed and Dose

1._____	Start Date:	End Date:
2._____	Start Date:	End Date:

Physician Signature	Date

Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

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

North Dakota Medicaid
Pharmacotherapy Review
Vecamyl®

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Respiratory: Interstitial pulmonary edema and fibrosis.

Urogenital: Urinary retention, impotence, decreased libido.

Special Senses: Blurred vision, dilated pupils.

Miscellaneous: Weakness, fatigue, sedation.

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

VII. Cost
The cost of mecamylamine is approximately 54 dollars per tablet.

Reference

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

ACE-Inhibitors (ACE-I), Angiotensin II Receptor Blockers (ARB) and Renin Inhibitor PA Form

HEALTH INFORMATION DESIGNS

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
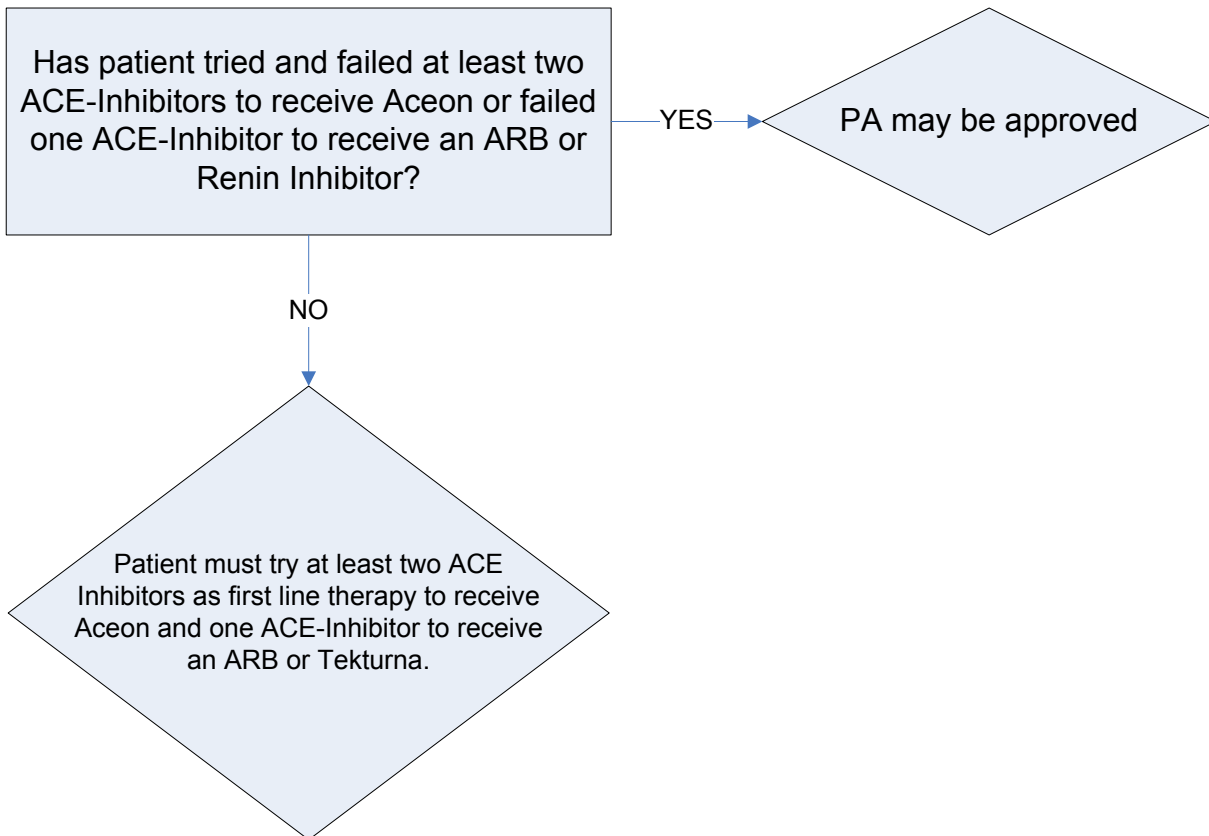
Has patient tried and failed at least two ACE-Inhibitors to receive Aceon or failed one ACE-Inhibitor to receive an ARB or Renin Inhibitor?

YES → PA may be approved

NO ↓

Patient must try at least two ACE Inhibitors as first line therapy to receive Aceon and one ACE-Inhibitor to receive an ARB or Tekturna.

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

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

Renin Inhibitor: Tekturna and hydrochlorothiazide combination

ACTINIC KERATOSIS PA FORM

HEALTH INFORMATION DESIGNS

Prior Authorization Vendor for ND Medicaid

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

ND Medicaid requires that patients receiving a new prescription for Solaraze, Zyclara, or Picato must first try imiquimod.
- *Imiquimod does not require prior authorization*

Part I: TO BE COMPLETED BY PHYSICIAN

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

Requested Drug and Dosage: □ ZYCLARA □ SOLARAZE □ PICATO	**Diagnosis for this Request:**	
Physician Signature		Date

Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

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

North Dakota Department of Human Services
Actinic Keratosis Authorization Algorithm

| Has patient failed trial of imiquimod? | —YES→ | PA may be approved |

NO
↓

Deny PA

HEALTH INFORMATION DESIGNS
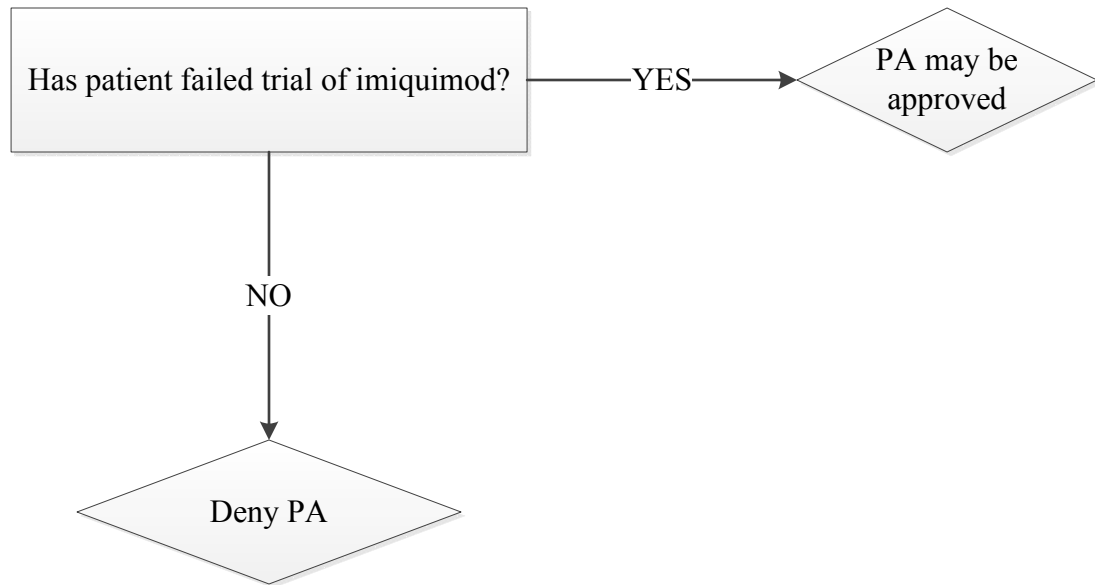
ACTO*plus* met Prior Authorization

Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that patients receive Actos and Metformin separately.
*Note:
- *Actos does not require PA*
- *Metformin does not require PA*
- *Patients must fail therapy on Actos and Metformin separately before a PA may be granted*

Part I: TO BE COMPLETED BY PRESCRIBER

Recipient Name	Recipient Date of Birth	Recipient Medicaid ID Number	
Prescriber Name			
Prescriber Medicaid Provider Number	Telephone Number	Fax Number	
Address	City	State	Zip Code

Requested Drug and Dosage: □ **ACTO*plus* met**	**Diagnosis for this request:**

Qualifications for coverage:		
□ Failed both drugs separately	Start Date:	Dose:
	End Date:	Frequency:
Prescriber Signature		Date

Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

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

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

Has patient failed trial of Actos and Metformin taken separately?

YES → PA may be approved

NO → Deny PA
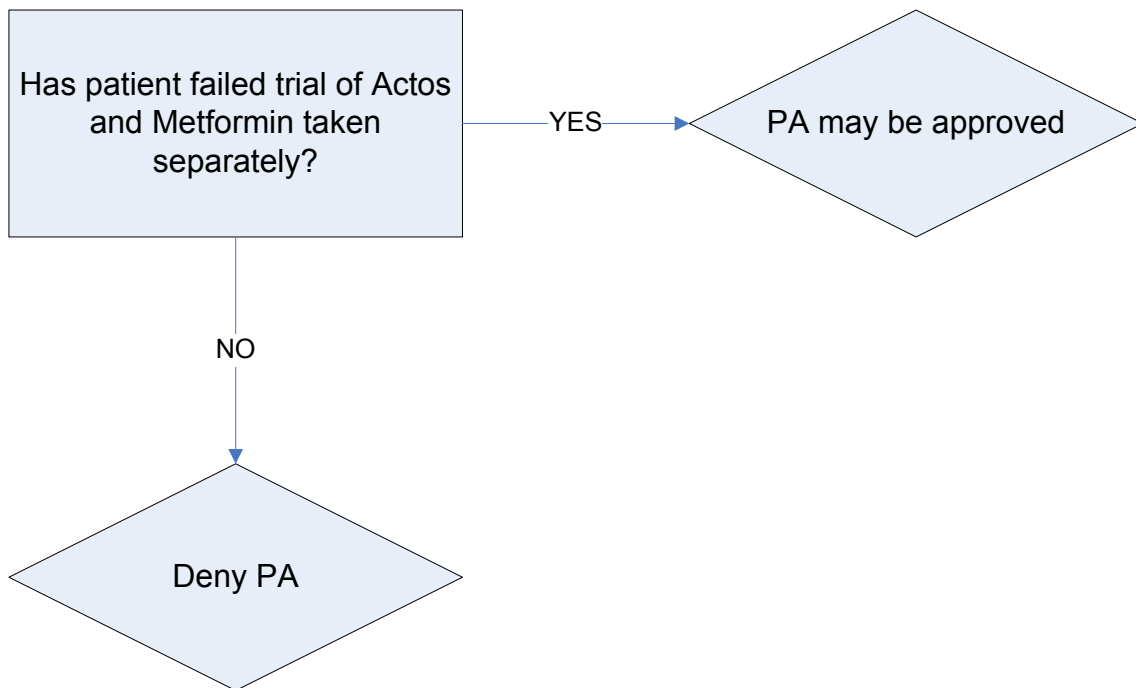
North Dakota Department of Human Services
Local Anesthetics (Topical) Prior Authorization Algorithm

Is the patient 12 years of age or younger

Yes → No PA required

No ↓

Is the medical procedure listed on the prior authorization form?

Yes → PA may be approved

No ↓

Deny PA
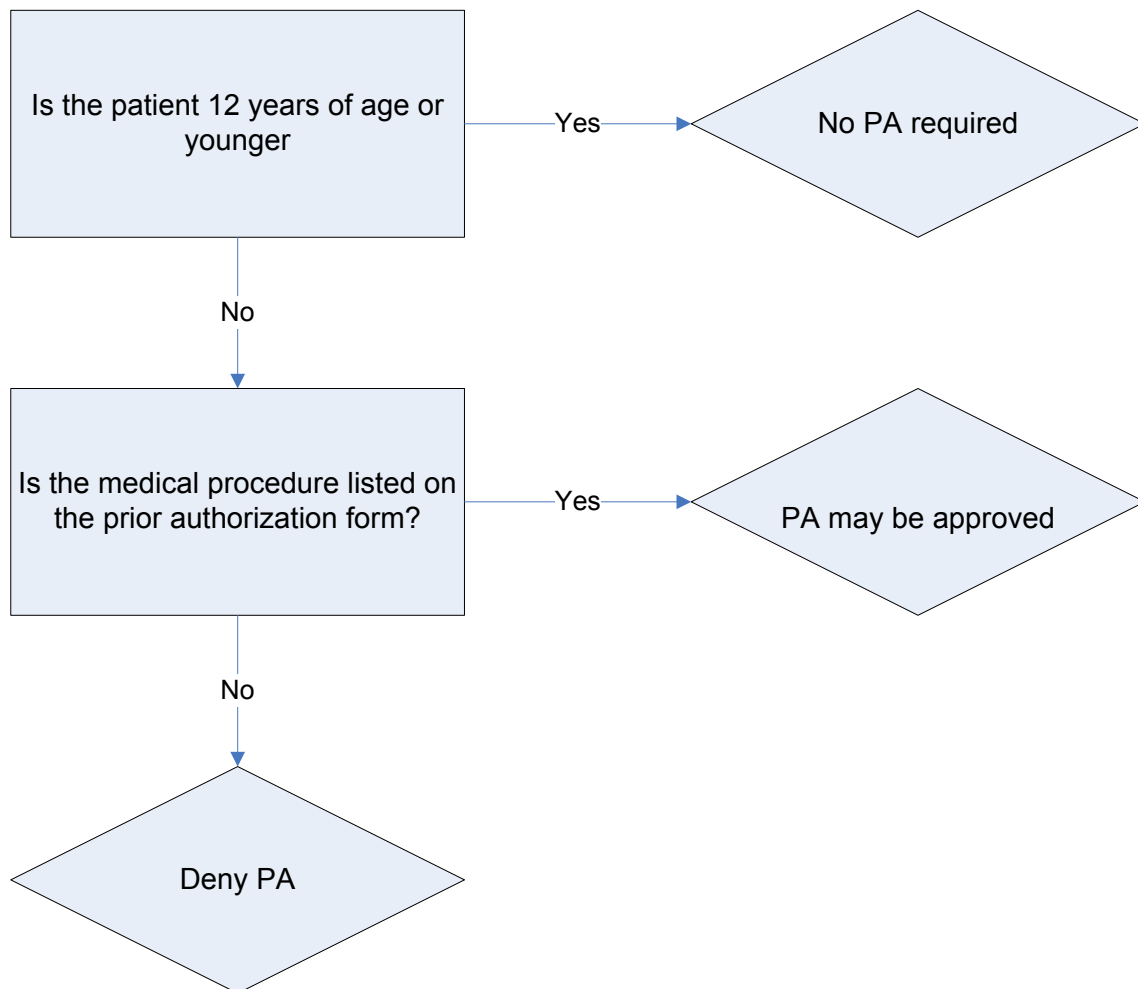
**Topical Ketoconazole Products
Prior Authorization**

HEALTH INFORMATION DESIGNS

Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that patients who are prescribed Extina, Xolegel, and Ketocon Plus must first try a covered ketoconazole medication.
Note:

- *Ketoconazole creams and ketoconazole shampoos do not require a prior authorization.*

Part I: TO BE COMPLETED BY PHYSICIAN

Recipient Name	Recipient Date of Birth	Recipient Medicaid ID Number	
Physician Name			
Physician Medicaid Provider Number	Telephone Number	Fax Number	
Address	City	State	Zip Code
Requested Drug and Dosage: □ **Extina** □ **Xolegel** □ **Ketocon Plus**	**Diagnosis for this request:**		
Qualifications for coverage:			
□ Medication Failed _____	Start Date: End Date:	Dose: Frequency:	
Physician Signature		Date	

Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

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

North Dakota Department of Human Services
Topical Ketoconazole Products Authorization Algorithm
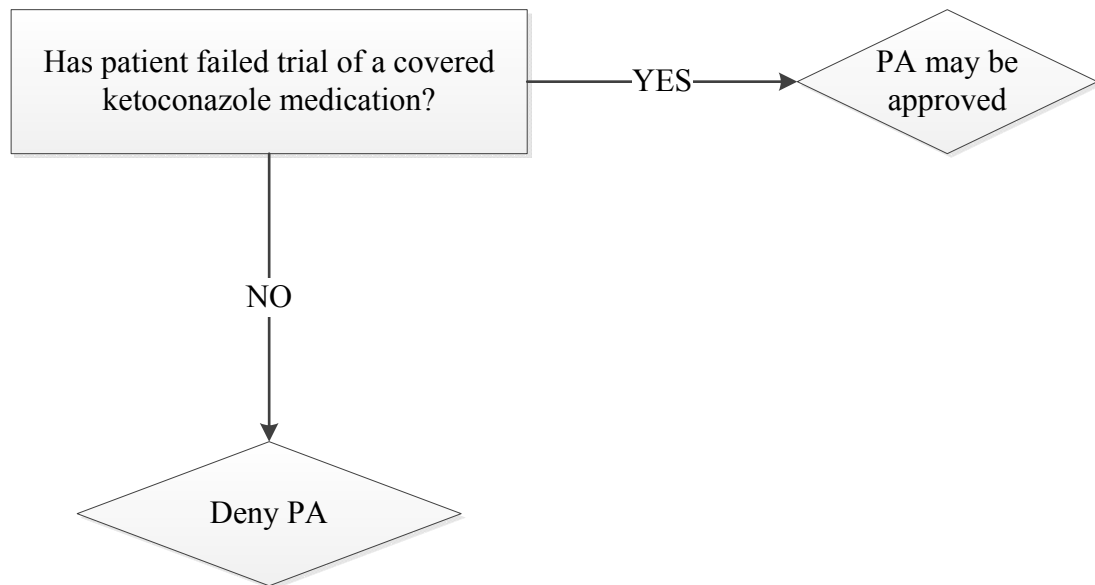
```
┌──────────────────────────────┐
│ Has patient failed trial of a │ ─────YES────▶  ◇ PA may be
│  covered ketoconazole         │                    approved
│  medication?                  │
└──────────────────────────────┘
              │
             NO
              │
              ▼
          ◇ Deny PA
```

TRAMADOL ER PA FORM

HEALTH INFORMATION DESIGNS

Prior Authorization Vendor for ND Medicaid

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

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

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

Part I: TO BE COMPLETED BY PHYSICIAN

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

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

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

Physician Signature	Date

Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

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

North Dakota Department of Human Services
Tramadol ER Prior Authorization Algorithm
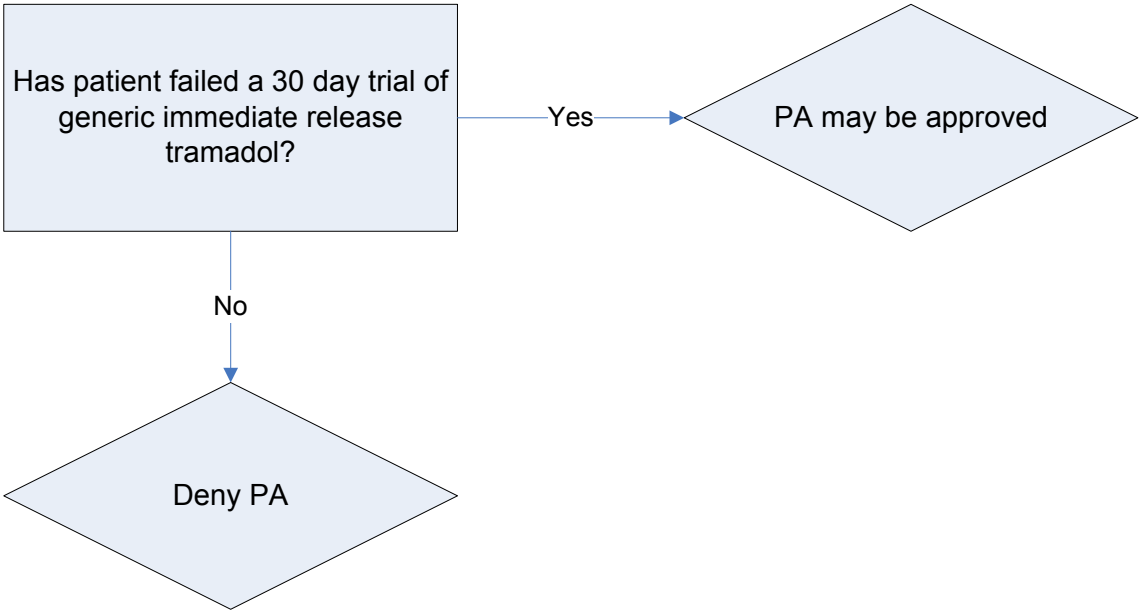
Has patient failed a 30 day trial of generic immediate release tramadol?

Yes → PA may be approved

No → Deny PA

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: □ NARATRIPTAN □ 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
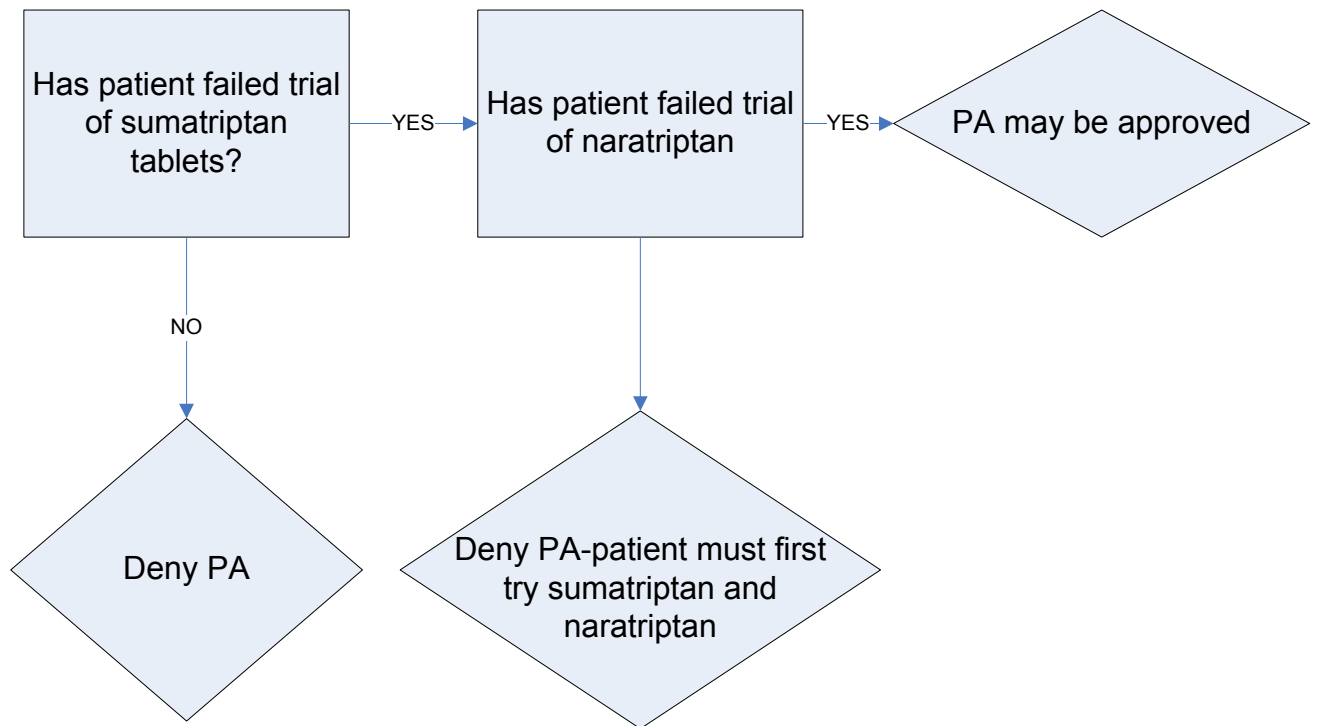
Has patient failed trial of sumatriptan tablets?

→ YES → Has patient failed trial of naratriptan → YES → PA may be approved

↓ NO

Deny PA

Deny PA-patient must first try sumatriptan and naratriptan

ULORIC PA FORM

HEALTH INFORMATION DESIGNS

Prior Authorization Vendor for ND Medicaid

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

ND Medicaid requires that patients receiving a new prescription for Uloric must try allopurinol as first line therapy or have documented renal/hepatic dysfunction.

- Allopurinol does not require a prior authorization.
- Allopurinol doses must be 300 mg or greater to be considered failed therapy.

Part I: TO BE COMPLETED BY PHYSICIAN

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

Requested Drug and Dosage: □ ULORIC	**Diagnosis for this request:**

Qualifications for coverage:

□ FAILED ALLOPURINOL THERAPY	Start Date	End Date	Dose	Frequency

□ RENAL OR HEPATIC IMPAIRMENT

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

Physician Signature	Date

Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

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

North Dakota Department of Human Services
Uloric Authorization Algorithm
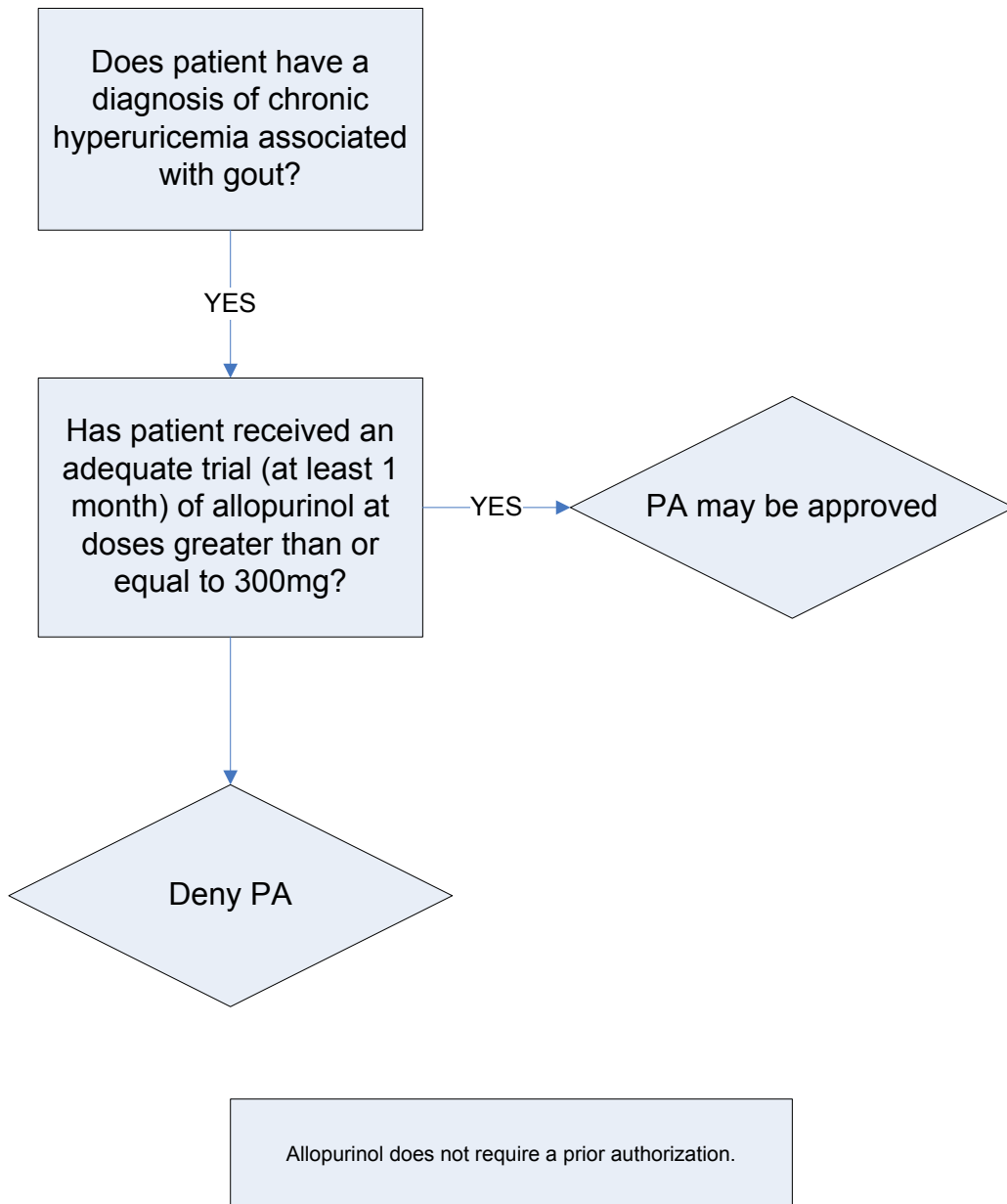
Does patient have a diagnosis of chronic hyperuricemia associated with gout?

YES

Has patient received an adequate trial (at least 1 month) of allopurinol at doses greater than or equal to 300mg?

YES

PA may be approved

Deny PA

Allopurinol does not require a prior authorization.

VANOS PA FORM

HEALTH INFORMATION DESIGNS

Prior Authorization Vendor for ND Medicaid

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

ND Medicaid requires that patients receiving a new prescription for Vanos must meet the following criteria:
- **Patient must be 12 years of age and older.**
- **Patient must have documented failure with a generic topical steroid in the same potency class (Ultravate, Temovate, Diprolene).**

Part I: TO BE COMPLETED BY PHYSICIAN

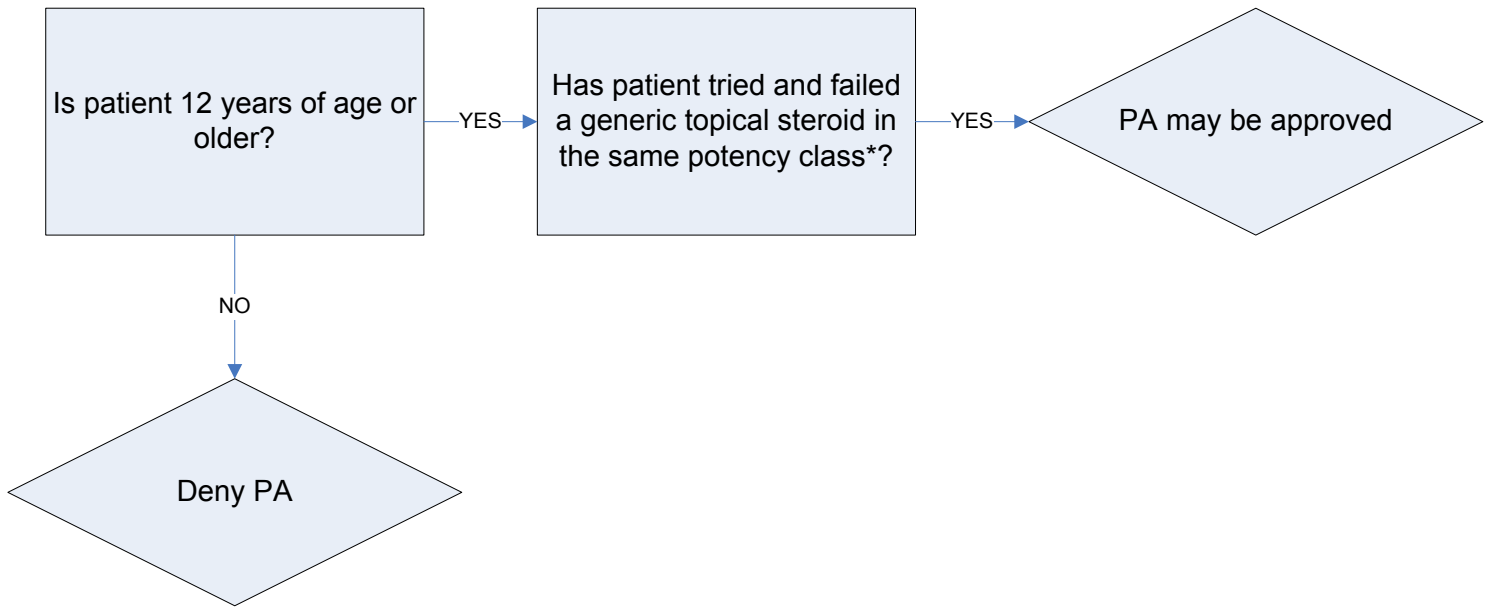| Recipient Name	**Recipient Date of Birth**	Recipient Medicaid ID Number	
Physician Name			
Physician Medicaid Provider Number	Telephone Number	Fax Number	
Address	City	State	Zip Code
Requested Drug and Dosage: □ VANOS	**Diagnosis for this Request:**		
Failed Therapy (dose and frequency): □	**Start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

Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

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

North Dakota Department of Human Services
Vanos Prior Authorization Algorithm

Is patient 12 years of age or older?

—YES→ Has patient tried and failed a generic topical steroid in the same potency class*?

—YES→ PA may be approved

NO ↓

Deny PA

*Same potency class includes generic Temovate, Ultravate, and Diprolene.

Vusion PA FORM

HEALTH INFORMATION DESIGNS

Prior Authorization Vendor for ND Medicaid

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

ND Medicaid requires that patients receiving a new prescription for Vusion must try other topical antifungal products as first line therapy.

***Note: Nystatin and clotrimazole do not require a prior authorization.**

Part I: TO BE COMPLETED BY PRESCRIBER

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

Requested Drug and Dosage: □ VUSION	**Diagnosis for this request:**

Qualifications for coverage:

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

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

Prescriber Signature	Date

Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

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

North Dakota Department of Human Services
Vusion Prior Authorization Algorithm

Has patient failed trial of a covered* antifungal agent?

Yes → PA may be approved

No → Deny PA
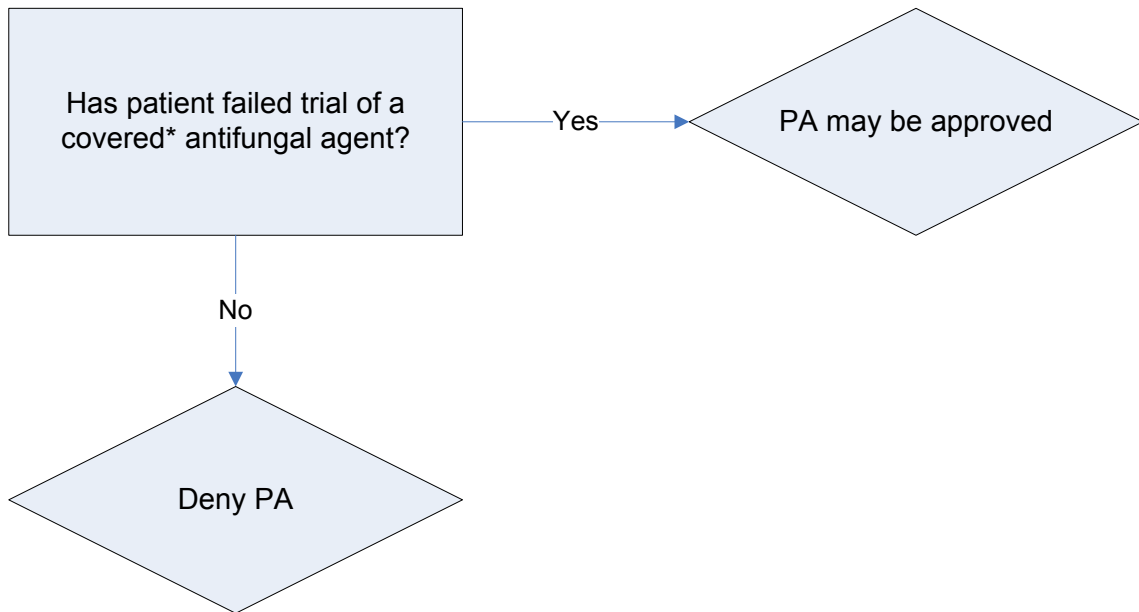
*Nystatin and clotrimazole do not require a PA and cost approximately $6 - $36 for a course of therapy compared to $246 for a course of Vusion therapy.

HEALTH INFORMATION DESIGNS

Xeljanz
Prior Authorization

Prior Authorization Vendor for ND Medicaid

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

ND Medicaid requires that patients receiving a new prescription for Xeljanz must meet the following criteria:
Note:
- **Patient must have an inadequate response or intolerance to methotrexate.**
- **Patient must have a test for latent tuberculosis prior to starting Xeljanz.**
- **Patient must have current lab monitoring prior to starting Xeljanz (CBC, liver enzymes, lipid panel)**
- **Use with caution in patients that may be at increased risk of gastrointestinal perforations.**

Part I: TO BE COMPLETED BY PHYSICIAN

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

QUALIFICATIONS FOR COVERAGE:

Requested Drug and Dosage: □ **Xeljanz**	Diagnosis for this request:
TB test in the past 6 months □ Yes □ No Lab monitoring has occurred and measurements within acceptable limits (i.e., lymphocytes, neutrophils, hemoglobin, lipids, and liver enzymes) □ Yes □ NO Has or has had active hepatitis B or C virus □ Yes □ NO	Failed methotrexate therapy Start date: End date:
Physician Signature	Date

Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

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

North Dakota Department of Human Services
Xeljanz Authorization Algorithm
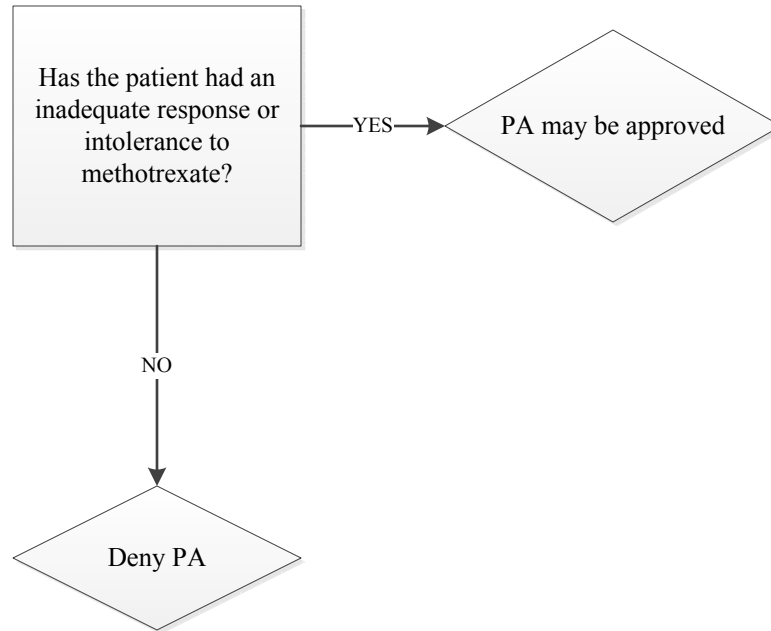
Has the patient had an inadequate response or intolerance to methotrexate?

—YES→ PA may be approved

NO ↓

Deny PA

Xenical Prior Authorization

HEALTH INFORMATION DESIGNS

Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that patients receiving a prescription for Xenical must be seen by a dietician.
Note:
- *Patient must have dietician evaluation attached to PA form including height and weight.*
- *BMI must be equal to or greater than 40.*
- *5% weight loss must be realized for continued approval (every 6 months).*

Part I: TO BE COMPLETED BY PRESCRIBER

Recipient Name	Recipient Date of Birth	Recipient Medicaid ID Number

Prescriber Name		

Prescriber Medicaid Provider Number	Telephone Number	Fax Number	

Address	City	State	Zip Code

Requested Drug and Dosage: □ XENICAL	**Diagnosis for this request:**

Qualifications for coverage:

□ Dietician evaluation attached	Height:	Weight:	BMI:

Prescriber Signature	Date

Part II: TO BE COMPLETED BY PHARMACY

PHARMACY NAME:	ND MEDICAID PROVIDER NUMBER:

TELEPHONE NUMBER	FAX NUMBER	DRUG	NDC #

Part III: FOR OFFICIAL USE ONLY

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

North Dakota Department of Human Services
Xenical Prior Authorization Criteria

Has patient been evaluated by a dietician and the report attached to the prior authorization request?

Yes

Is height, weight, and BMI, equal to or greater than 40, documented on the PA form?

YES

PA may be approved*

NO

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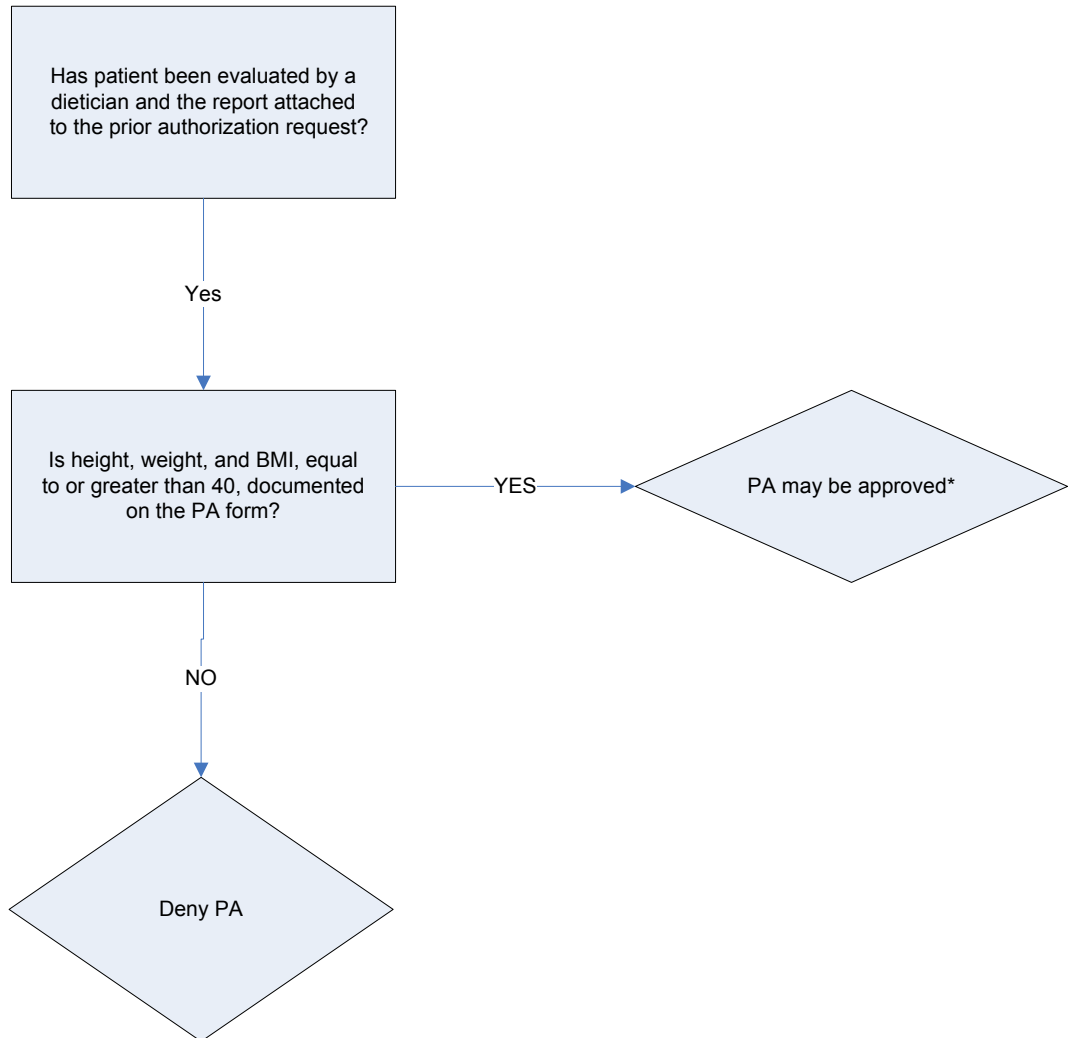
*5% weight loss must be realized for continued approval every 6 months.

XIFAXAN PA FORM

HEALTH INFORMATION DESIGNS

Prior Authorization Vendor for ND Medicaid

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:	**Diagnosis for this Request:**
□ XIFAXAN	□ 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
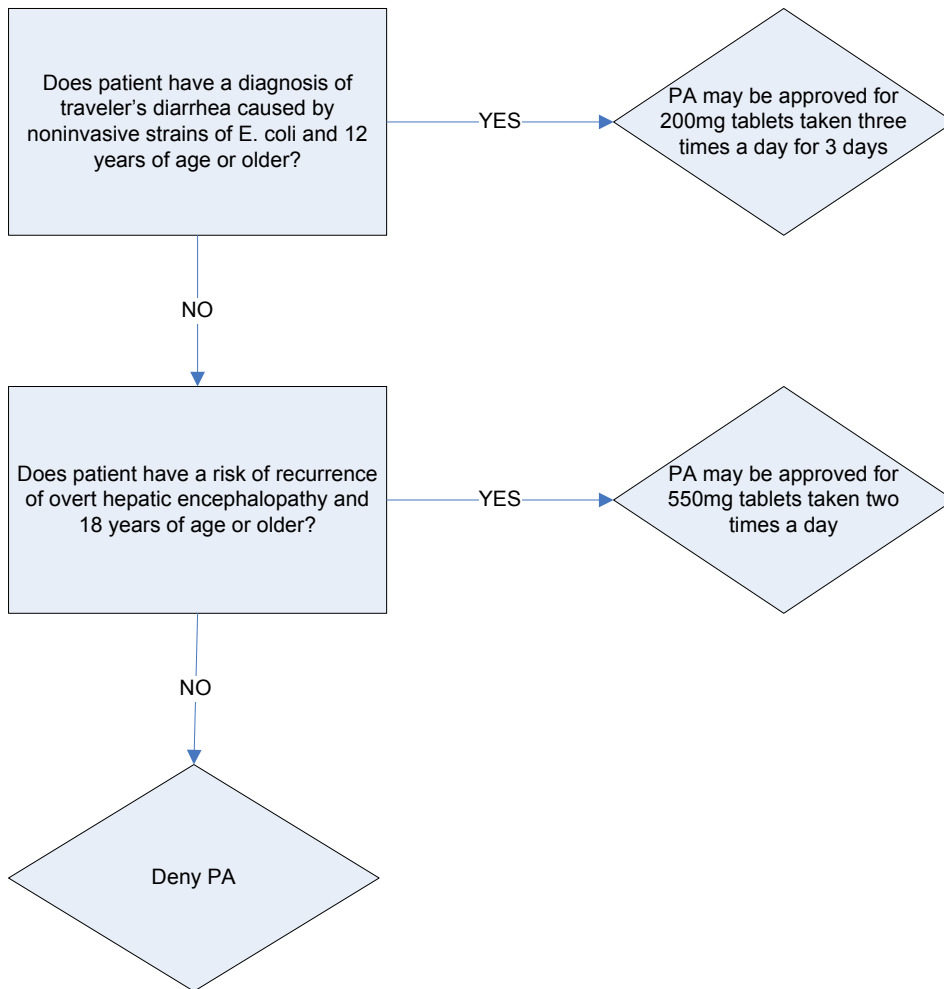
Does patient have a diagnosis of traveler's diarrhea caused by noninvasive strains of E. coli and 12 years of age or older?

—YES→ PA may be approved for 200mg tablets taken three times a day for 3 days

NO

↓

Does patient have a risk of recurrence of overt hepatic encephalopathy and 18 years of age or older?

—YES→ PA may be approved for 550mg tablets taken two times a day

NO

↓

Deny PA

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)	

North Dakota Department of Human Services
Xolair Prior Authorization Algorithm

Does patient have moderate to severe persistent asthma with a serum IgE level between 30 and 700 IU/ml?

Yes → PA may be approved

No → Deny PA

HEALTH INFORMATION DESIGNS
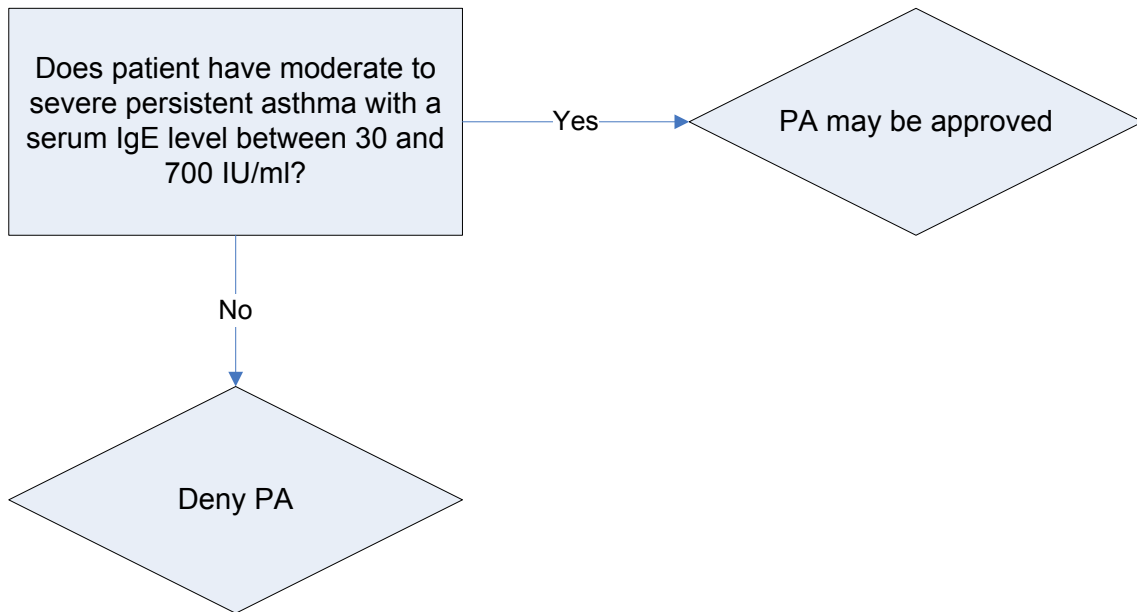
Xyrem Prior Authorization

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

Prior Authorization Vendor for ND Medicaid

ND Medicaid requires that patients who are prescribed Xyrem must meet these guidelines:
Note:
- *Must be 18 years or older.*
- *Must have a diagnosis of excessive daytime sleepiness and cataplexy in patients with narcolepsy.*
- *Must be enrolled in the Xyrem Success Program*

Part I: TO BE COMPLETED BY PHYSICIAN

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

Requested Drug and Dosage:	**Diagnosis for this request:**
□ **Xyrem**	

Qualifications for coverage:

□ Enrolled in Xyrem Success Program	Enrolled Date:	Dose:
Physician Signature		Date

Part II: TO BE COMPLETED BY PHARMACY

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

Part III: FOR OFFICIAL USE ONLY

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

North Dakota Department of Human Services
Xyrem Authorization Algorithm

Does patient have a diagnosis of narcolepsy with excessive daytime sleepiness _and_ cataplexy?

↓ YES

Is patient enrolled in the Xyrem Success Program? —YES→ PA may be approved

↓ NO

Deny PA

HEALTH INFORMATION DESIGNS
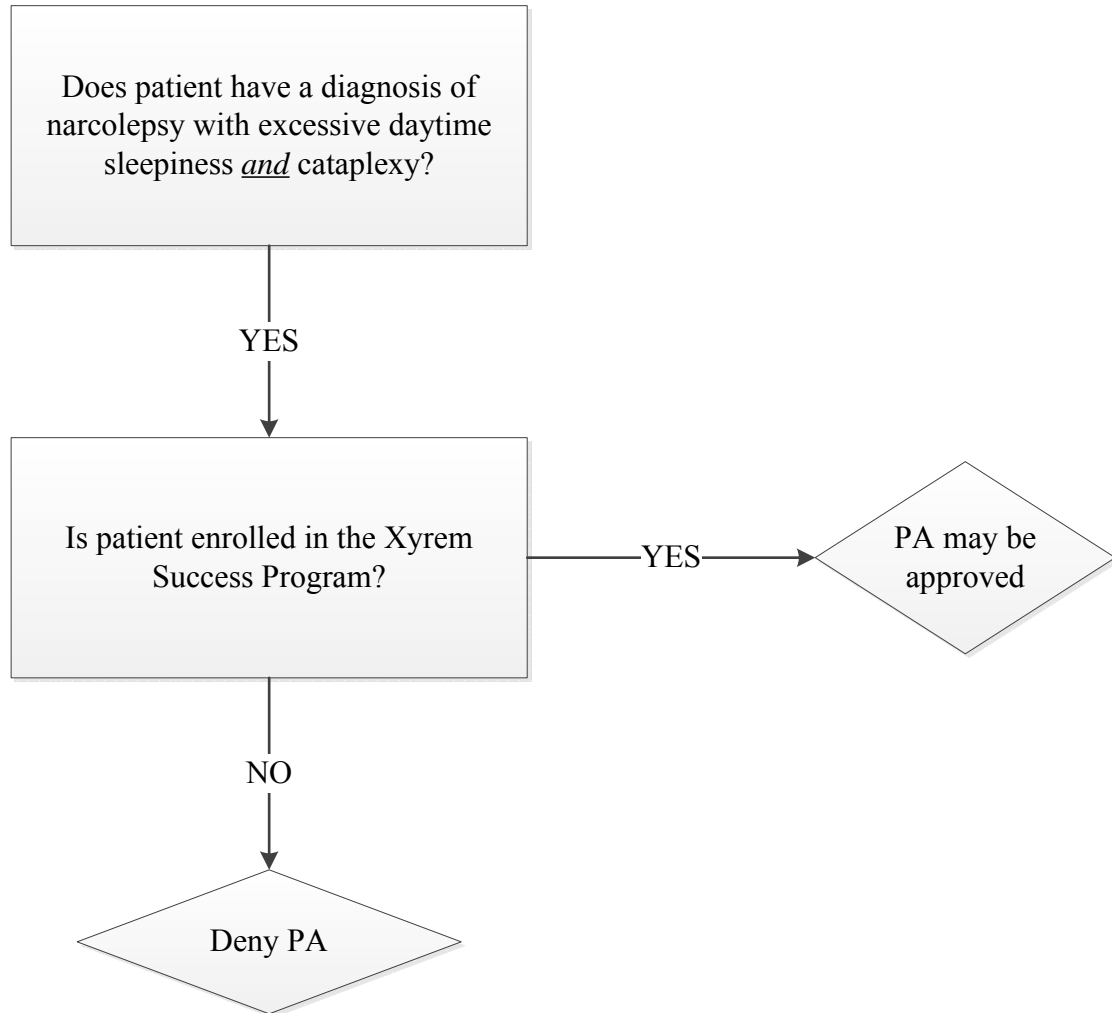
Zanaflex Capsule PA Form

Prior Authorization Vendor for ND Medicaid

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

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

Part I: TO BE COMPLETED BY PRESCRIBER

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

Prescriber Medicaid Provider Number	Telephone Number	Fax Number	
Address	City	State	Zip Code

Requested Drug and Dosage:	**Diagnosis for this request:**

Qualifications for coverage:

□ Failed generic drug	Start Date:	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 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

Has patient failed trial of Tizanidine tablets?

YES → PA may be approved

NO → Deny PA
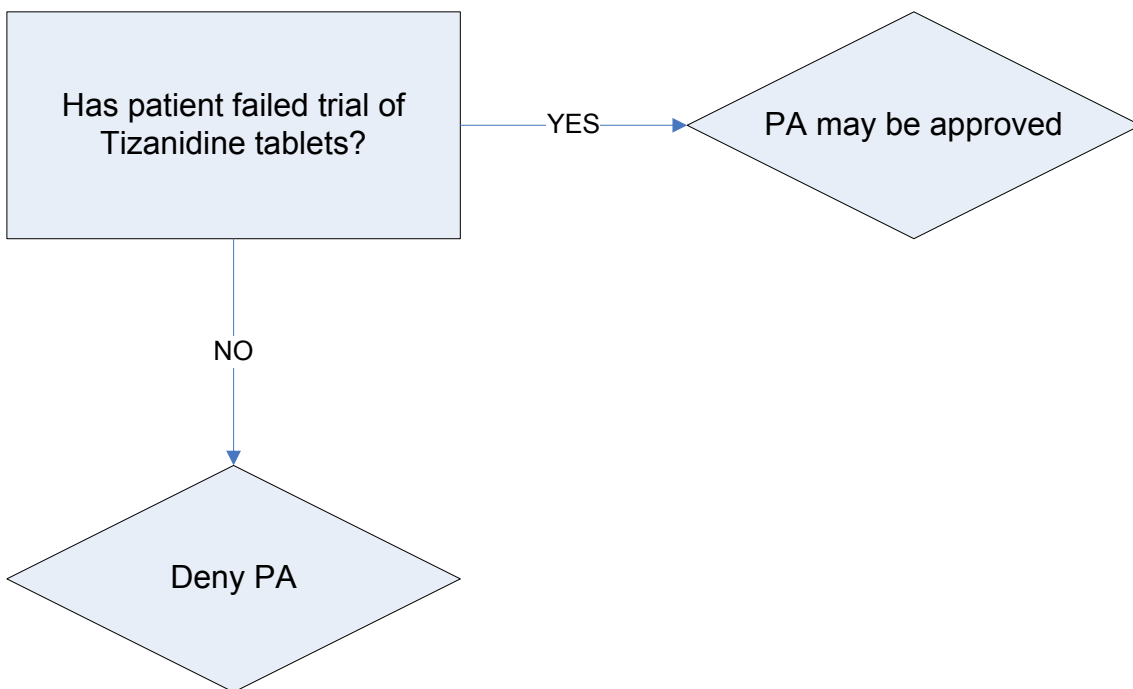
14. Telaprevir / Trazodone   _____   _____
Alert Message: The concurrent use of Incivek (telaprevir), a potent CYP3A4 inhibitor, and CYP3A4 substrate trazodone may result in elevated trazodone plasma concentrations, increasing risk of adverse events. Dosage adjustment of trazodone may be necessary during concurrent therapy with telaprevir.

Conflict Code: DD – Drug/Drug Interaction
Drugs/Diseases
Util A   Util B   Util C
Telaprevir   Trazodone

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

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

Conflict Code: DD – Drug/Drug Interaction
Drugs/Diseases
Util A   Util B   Util C **(Negating)**
Telaprevir   Colchicine   Renal Impairment
                                Hepatic Impairment

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

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

Conflict Code: DD – Drug/Drug Interaction
Drugs/Diseases
Util A   Util B   Util C **(Include)**
Telaprevir   Colchicine   Renal Impairment
                                Hepatic Impairment

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

17. Telaprevir / CYP3A4 Substrate CCBs   _____   _____

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

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

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

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

18. Telaprevir / Prednisone & Methylprednisolone   _____   _____

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

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

Util A	Util B	Util C
Telaprevir	Prednisone	
	Methylprednisolone	

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

19. Telaprevir / Dexamethasone   _____   _____

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

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

Util A	Util B	Util C
Telaprevir	Dexamethasone	

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

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

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

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

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

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

21. Telaprevir / Bosentan   _____ _____

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

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

Util A	Util B	Util C
Telaprevir	Bosentan	

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

22. Telaprevir / Efavirenz   _____ _____

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

Conflict Code: LR – Low Dose
Drugs/Diseases

Util A	Util B	Util C **(Include)**
Telaprevir		Efavirenz

Dose/day: < 1125mg/day of telaprevir

References:
Facts & Comparisons, 2013 Updates, Wolters Kluwer Health.
Clinical Pharmacology, 2013 Elsevier/Gold Standard.
Incivek Prescribing Information, April 2013, Vertex Pharmaceuticals Inc.
Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the Use of Antiretroviral Agents in HIV-1 Infected Adults and Adolescents. Department of Health and Human Services. February 12, 2013;1-167. Available at http://www.aidsinfo.nih.gov/ContentFiles/AdultandAdolescentGL.pdf.

23. Telaprevir / Atripla   _____   _____

Alert Message: The concurrent use of Incivek (telaprevir) and Atripla (efavirenz/ emtricitabine/tenofovir) may result in the decreased exposure to both efavirenz and telaprevir and increased exposure to tenofovir.

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

Util A	Util B	Util C
Telaprevir	Atripla	

References:
Clinical Pharmacology, 2013 Elsevier/Gold Standard.
Incivek Prescribing Information, April 2013, Vertex Pharmaceuticals Inc.

24. Telaprevir / Tenofovir-Containing Agents   _____   _____

Alert Message: The concurrent use of Incivek (telaprevir) and a tenofovir-containing agent (i.e., Viread, Truvada, Complera or Atripla) may result in increased tenofovir exposure and risk for tenofovir-related adverse effects. Increased clinical and laboratory monitoring are warranted.

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

Util A	Util B	Util C
Telaprevir	Tenofovir	
	Tenofovir/Emtricitabine	
	Tenofovir/Emtricitabine/Efavirenz	
	Tenofovir/Rilpivirine/Emtricitabine	

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

25. Telaprevir / Immunosuppressants   _____   _____

Alert Message: The concurrent use of Incivek (telaprevir), a potent CYP3A4 inhibitor, with a CYP3A4 substrate immunosuppressant may result in elevated plasma concentrations of the CYP3A4 substrate, increasing the risk of immunosuppressant-related adverse events. Close monitoring of immunosuppressant blood levels is recommended.

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

Util A	Util B	Util C
Telaprevir	Cyclosporine	
	Tacrolimus	
	Sirolimus	

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

26. Telaprevir / Salmeterol   _____ _____

Alert Message: The concurrent use of Incivek (telaprevir) with a salmeterol-containing agent is not recommended due to the risk of adverse cardiovascular events associated with salmeterol. Telaprevir is a potent CYP3A4 inhibitor and use with the CYP3A4 substrate salmeterol can result in elevated salmeterol plasma concentrations.

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

Util A	Util B	Util C
Telaprevir	Salmeterol	

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

27. Telaprevir / Methadone   _____ _____

Alert Message: The concurrent use of methadone with Incivek (telaprevir) may result in reduced plasma concentrations of methadone. Clinical monitoring is recommended as the dose of methadone during maintenance therapy may need to be adjusted in some patients.

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

Util A	Util B	Util C
Telaprevir	Methadone	

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

28. Telaprevir / Ethinyl Estradiol Contraceptives   _____ _____

Alert Message: The concurrent use of Incivek (telaprevir) and ethinyl estradiol contraceptives may result in decreased ethinyl estradiol plasma concentrations with the potential of birth control failure in women with childbearing potential. Systemic hormonal contraception must be augmented by 2 alternative effective forms of contraception and may include intrauterine devices and barrier methods during therapy and for 6 months following therapy.

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

Util A	Util B	Util C
Telaprevir	EE- containing contraceptives	

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

29. Telaprevir / PDE5 for ED   _____ _____
Alert Message: The concurrent use of Incivek (telaprevir) and a PDE5 inhibitor for the treatment of ED may result in increased PDE5 inhibitor plasma concentrations and risk of serious PDE5 inhibitor-related adverse events. Do not exceed the following doses for PDE5 inhibitors when used with telaprevir: sildenafil - 25 mg every 48 hours, tadalafil -10 mg every 72 hours and vardenafil - 2.5 mg every 24 hours.

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

Util A	Util B	Util C
Telaprevir	Vardenafil 5, 10 & 20mg	
	Sildenafil 50& 100 mg	
	Tadalafil 20mg	

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

30. Telaprevir / Alprazolam   _____ _____
Alert Message: The concurrent use of Incivek (telaprevir) with alprazolam may result in elevated alprazolam serum concentrations and risk of alprazolam-related adverse events. Clinical monitoring is warranted.

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

Util A	Util B	Util C
Telaprevir	Alprazolam	

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

31. Telaprevir / Zolpidem   _____ _____
result in decreased zolpidem exposure. Clinical monitoring and dose titration of zolpidem is recommended to achieve the desired clinical response.

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

Util A	Util B	Util C
Telaprevir	Zolpidem	

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

32. Telaprevir / Rifabutin   _____   _____
Alert Message: The concurrent use of Incivek (telaprevir) with rifabutin is not recommended.
Co-administration of these agents may result in elevated rifabutin plasma concentrations
and decreased telaprevir concentrations. Both agents are CYP3A4 substrates and telaprevir
is a potent CYP3A4 inhibitor while rifabutin is a CYP3A4 inducer.

Conflict Code: DD – Drug/Drug Interaction
Drugs/Diseases
Util A   Util B   Util C
Telaprevir   Rifabutin

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

33. Telaprevir / Darunavir / Ritonavir   _____   _____
Alert Message: Concurrent use of Incivek (telaprevir) with ritonavir-boosted Prezista
(darunavir) is not recommended. Co-administration of these agents has been shown to
result in reduced steady-state exposure to both telaprevir and darunavir.

Conflict Code: DD – Drug/Drug Interaction
Drugs/Diseases
Util A   Util B   Util C **(Include)**
Telaprevir   Darunavir   Ritonavir

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

34. Telaprevir / Fosamprenavir / Ritonavir   _____   _____
Alert Message: Concurrent use of Incivek (telaprevir) with ritonavir-boosted Lexiva
(fosamprenavir) is not recommended. Co-administration of these agents has been shown
to result in reduced steady-state exposure to both telaprevir and fosamprenavir.

Conflict Code: DD – Drug/Drug Interaction
Drugs/Diseases
Util A   Util B   Util C **(Include)**
Telaprevir   Fosamprenavir   Ritonavir

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

35. Telaprevir / Lopinavir-Ritonavir   _____   _____
Alert Message: Concurrent use of Incivek (telaprevir) with Kaletra (lopinavir/ritonavir) is not recommended. Co-administration of these agents has been shown to result in reduced steady-state exposure to telaprevir.

Conflict Code: DD – Drug/Drug Interaction
Drugs/Diseases
<u>Util A</u>   <u>Util B</u>   <u>Util C</u>
Telaprevir   Lopinavir/Ritonavir

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

36. Telaprevir / Atazanavir / Ritonavir   _____   _____
Alert Message: Concurrent use of Incivek (telaprevir) with ritonavir-boosted Reyataz (atazanavir) has been shown to result in reduced steady-state exposure to telaprevir while steady-state atazanavir exposure was increased. Monitor patient for decreased telaprevir efficacy and atazanavir-related adverse effects.

Conflict Code: DD – Drug/Drug Interaction
Drugs/Diseases
<u>Util A</u>   <u>Util B</u>   <u>Util C</u> **(Include)**
Telaprevir   Atazanavir   Ritonavir

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

37. Telaprevir / Clarithromycin, Erythromycin & Telithromycin   _____   _____
Alert Message: Concurrent use of Incivek (telaprevir) with the antibacterials, clarithromycin, erythromycin or telithromycin, may result in increased plasma concentrations of telaprevir and the antibacterial agent. Caution is warranted and clinical monitoring is recommended when agents are co-administered. All three antibacterials have been shown to increase QT prolongation and clarithromycin and erythromycin are reported to cause torsade de pointes.

Conflict Code: DD – Drug/Drug Interaction
Drugs/Diseases
<u>Util A</u>   <u>Util B</u>   <u>Util C</u>
Telaprevir   Clarithromycin
                  Erythromycin
                  Telithromycin
References:
Facts & Comparisons, 2013 Updates, Wolters Kluwer Health.
Clinical Pharmacology, 2013 Elsevier/Gold Standard.
Incivek Prescribing Information, April 2013, Vertex Pharmaceuticals Inc.

38. Telaprevir / Certain Statins   _____ _____
Alert Message: Concurrent use of Incivek (telaprevir) with fluvastatin, pitavastatin, pravastatin or rosuvastatin may result in increased plasma concentrations of the statin, increasing the risk of statin-related adverse effects. Caution is warranted and clinical monitoring is recommended when telaprevir is co-administered with one of these statins. Telaprevir is an inhibitor of OATP1B1 and OATP2B1 transporters.

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

Util A	Util B	Util C
Telaprevir	Fluvastatin	
	Pravastatin	
	Pitavastatin	
	Rosuvastatin	

References:
Clinical Pharmacology, 2013 Elsevier/Gold Standard.
Incivek Prescribing Information, April 2013, Vertex Pharmaceuticals Inc.

39. Eletriptan / Potent CYP3A4 Inhibitors   _____ _____
Alert Message: Relpax (eletriptan) is a CYP3A4 substrate and should not be used within at least 72 hours of treatment with drugs that have demonstrated potent CYP3A4 inhibition and have this effect described in the contraindications, warning and precaution section of labeling.

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

Util A	Util B			Util C
Eletriptan	Ketoconazole	Saquinavir	Tipranavir	
	Itraconazole	Ritonavir		
	Nefazodone	Indinavir		
	Clarithromycin	Nelfinavir		
	Telithromycin	Atazanavir		
	Boceprevir	Fosamprenavir		
	Telaprevir	Lopinavir/Ritonavir		

References:
Relpax Prescribing Information, Jan. 2012, Pfizer US Pharmaceutical Group.
Facts & Comparisons, 2013 Updates, Wolters Kluwer Health.

40. Topiramate ER / Overutilization   _____ _____
Alert Message: Trokendi XR (topiramate extended-release) may be over-utilized. The manufacturer's recommended maximum dose of extended-release topiramate is 400 mg once daily.

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C
Topiramate XR		

Max Dose: 400mg/day

References:
Trokendi UX Prescribing Information, August 2013, Supernus Pharmaceuticals.

41. Topiramate IR / Migraine / Negating Seizures & Anticonvulsants   _____ _____

Alert Message: The manufacturer's recommended maximum daily dose of topiramate as treatment for adults for prophylaxis of migraine headache is 100 mg per day in two divided doses.

Conflict Code: ER - Overutilization
Drugs/Diseases

Util A	Util B	Util C **(Negating)**
Topiramate IR 100	Migraine	Seizures/Epilepsy
Topiramate IR 200		Anticonvulsants

References:
Facts & Comparisons, 2013 Updates, Wolters Kluwer Health.
Topamax Prescribing Information, Oct. 2012, Janssen Pharmaceuticals, Inc.