
September 1st, 2005

The next North Dakota Drug Utilization Review (DUR) Board Meeting will be held:

November 7th, 2005 at 1:00pm

Pioneer Room
State Capital
612 East Blvd
Bismarck, ND

**Please remember to silence all pagers and cell phones prior to the start of the meeting.**

**North Dakota Medicaid**
**DUR Board Meeting**
**Agenda**
**Pioneer Room**
**November 7th, 2005**
**1pm**

| | | |
|---|---|---|
| 1. | Administrative items<br>-Travel vouchers | |
| 2. | Old Business | |
| | - Review and approval of minutes of 08/08/05 meeting | Chairman |
| | - Budget update | Brendan Joyce |
| | - Review Policy and Procedures | HID |
| | - Review Guidelines ADD/ADHD | HID |
| | - 2nd Review for Revatio | HID |
| 3. | New Business | |
| | - Review of Statins | HID |
| | - Review Sustained Release Opioid Agents | HID |
| | - Review of Actoplus Met | HID |
| | - Review of Fosamax Plus D | HID |
| | - Review of Actonel with Calcium | HID |
| | - Criteria Recommendations | HID |
| | - Meeting Dates 2006 | HID |
| 4. | Upcoming meeting agenda | Chairman |
| 5. | Adjourn | Chairman |

**Please remember to turn all cellular phones and pagers to silent mode during the meeting.**

# Drug Utilization Review (DUR) Meeting Minutes
# August 8th, 2005

**Members Present**: Albert Samuelson, Greg Pfister, John Savageau, Patricia Churchill, Carrie Sorenson, Cheryl Huber, Leann Ness, Norma Byers, Scott Setzepfandt, Gary Betting

**Medicaid Pharmacy Department**: Brendan Joyce

**HID Staff Present**: Candace Rieth, Steve Espy

**Members Absent**: Jay Huber, Bob Treitline

Chair John Savageau called the meeting to order at 1:05pm and asked for a motion to approve the minutes from the June 6, 2005 meeting. Norman Byers moved that the minutes be approved and Albert Samuelson seconded the motion. The chair called for a voice vote to approve the minutes, which passed with no audible dissent.

**Budget Update**:
Brendan Joyce reported the expenditures for FY 2004 were 45,974,797. There was 2.8% increase between FY 2004 and the projected FY 2005 budget. He further explained that the Department had to maintain only a 2.5% growth to stay within the upcoming biennium budget. Previous growth projections were 11%.

**Review of Zanaflex**:
This is the 2nd review of Zanaflex capsules for PA implementation. Brendan Joyce distributed a handout from the manufacturer. Steve Espy explained that he spoke with a representative from Acorda and offered the opportunity for the representative to present to the Board. Instead, a handout about Zanaflex capsules was sent to Brendan. Brendan noted the difference in price between Zanaflex capsules and Tizanidine tablets was $1.61./capsule and .55 /tablet. John Savageau explained the criteria for Prior Authorization for Zanaflex capsules. Scott Setzepfandt suggested that dysphagia be included as a criteria. John Savageau moved to accept the prior authorization form and algorithm as presented. Carrie Sorenson seconded the motion. The motion was approved by voice vote with no audible dissent.

**Review of Board Policy and Procedures**:
John Saveageau, at the previous meeting, asked for a review of the Board Policy and Procedures. John explained to the Board the need to accelerate the decisions the Board makes. HID gave examples in the DUR pak of several states Board Policy and Procedures for the Board to review. John Saveageau explained the difference between the current and the proposed Board Procedures. After much discussion, Albert Samuelson moved to accept the new procedures. Patricia Churchill seconded the motion. The motion carried by voice vote with one dissenting vote.

**Public Comment**:
There was public comment from Joel Gilbertson, an attorney speaking on behalf of PhRMA. Mr. Gilbertson raised concerns about the period of time the Board has to discuss recommendations as well as the language of the proposed Policy and Procedures. Brendan explained that even though the Board voted to accept the new procedures that until the Department agreed, the Board would operate under the old procedures. This topic will be brought up again at the next Board meeting for finalization. Brendan also stated that the Department will be requiring that in the future, the DUR pack will be posted on the internet 8 weeks in advance. Brendan also stated that all future meetings will be held quarterly. Representative Bill Devlin suggested that the Board stay with the current Policy and Procedures and let the legislature make the changes to the Policy and Procedures down the road.

**Review of Impact of Cox II inhibitors on GI Bleed**:
Steve Espy reviewed the graphs enclosed in the DUR pack. The graphs indicated that the increased utilization of Cox II inhibitors did not alter the incidence of GI bleed.

**Review of Average Daily Consumption of ADHD Agents**:
Steve Espy reviewed the table provided that reported all but one sustained release ADHD agent was being prescribed more than once daily. Steve also reviewed the graphs that depicted the utilization of immediate release and sustained release products. There was discussion concerning the increase in utilization of these agents and Cheryl Huber shared points of interest from several pediatric psychiatrists:

- ADHD is not just a school time disease
- Multiple dosing of sustained release products is necessary to prevent abrupt changes throughout the day
- Multiple dosing is necessary when patients are in after school programs and also for homework at night
- Many of the patients using multiple doses of a sustained release product also have co-morbidities
- Education should be directed at family practice rather than psychiatrists

The Board instructed HID to obtain guidelines and standards of care for use of the ADHD agents. There was public comment that followed. Dr. Byers asked if there was a way to know which prescriptions were being written by family practice doctors and which were written by specialists.

**Utilization of SROA agents**:
Steve Espy reviewed the graphs of several specific sustained release narcotics, indicating the dramatic increase in utilization of Oxycontin and Duragesic. There was much discussion on the appropriate use of these drugs and if there are ways to control utilization. Brendan Joyce asked the Board to recommend to the Department that he do a survey of the providers to find out diagnoses, directions and whether or not the doctor is using a contract on the patients taking these medications. John Savageau asked HID to produce a report that indicated the number of single prescriptions for the SROA agents.

**Summary of state actions of Oxycontin**:
Steve Espy reviewed the list of states provided and their actions on Oxycontin. Ten out of thirteen states require a prior authorization for Oxycontin.

**Summary of State actions on statins**:
Steve Espy reviewed the list of states provided and their action on the drug class statins. The majority of the states require a prior authorization on statins. The Board instructed HID to bring back, as an agenda item, utilization data, cost analysis and proposed criteria for potential prior authorization of the statin drug class.

**Review of Revatio**:
Brendan Joyce reviewed the enclosed information provided for Revatio, including the PA form and criteria. He mentioned the necessity of the prior authorization in relation to the federal mandate concerning sexual offenders. Norman Byers moved to consider the recommendation to place Revatio on PA. Greg Pfister seconded the motion; the motion was approved by voice vote with no audible dissent. Brendan Joyce reminded the Board that this would be brought back for a second consideration at the next Board meeting.

**Review of Recommended Criteria**:
Brendan Joyce advised the Board that the enclosed recommended RDUR criteria are developed from product information provided be the manufactures and usually are consistent with new indications, new drugs added, new warnings, etc. These criteria will be added to the current set of critieria and will be used in future RDUR cycles. Patricia Churchill moved to approve the new criteria and Carrie Sorenson seconded the motion. The motion was approved by voice vote with no audible dissent

Steve Espy suggested the next meeting date of 11/7/05 and also recommended to set the four quarterly meetings for 2006; 1/9, 4/10, 7/10 and 10/9. These dates can be approved at the next meeting. Acting Chair Cheryl Huber adjourned the meeting at 3:35.

Budget Info:

With the start of the new biennium, the Department is working on evaluating previous utilization in the program and the projected impact of Part D. This is obviously complex, so no projections on expenditures are available as of September 1, 2005. We assume that projections will be available in time for the DUR Board meeting in November.

# ND Medicaid DUR Board
# Procedures
(Developed 7/28/03)
(Modified 7/28/03)

1. All information to be distributed to DUR Board members must be sent to the Administrator of Pharmacy Services for distribution.
   a. All information received 14 days prior to the subsequent meeting will be forwarded to DUR Board members.
   b. Electronic format as an attachment to an e-mail is the preferred format.
   c. Electronic format as a CD-ROM or diskette is considered the second best option.
   d. If the format must be paper, 15 copies must be supplied to the Administrator of Pharmacy Services.
   e. The Department of Human Services will forward e-mail attachments to DUR Board members upon receipt of the e-mail.
   f. The Department of Human Services will mail all information received via hardcopy, CD-ROM, or diskette weekly on Thursday afternoons as well as one last mailing 14 days prior to the scheduled DUR Board meeting.
   g. The majority of communication from the Department of Human Services will be via e-mail and e-mail attachments.

2. Only one person may represent an interested party for presentations made during DUR Board meetings.

3. Presentations made by interested parties are limited to five (5) minutes (does not include Q&A or discussion generated by DUR Board members).

4. Process for DUR Board recommendations.
   a. The first meeting in which a discussion is held on specific medication(s), the DUR Board will draft a proposal for any action on the medication(s) after reviewing information supplied by the Department of Human Services and interested parties.
   b. This draft will be distributed to DUR Board members and those that have notified the Department of Human Services that they wish to receive such information.
   c. Comments on the proposal will be accepted in the same process as the general information (send to Department of Human Services at least 14 days prior to the next meeting).
   d. The subsequent meeting will involve a review of the comments received and will allow public comments per DUR Board guidelines mentioned above.
   e. The DUR Board will then develop and vote on a finalized proposal.

**ND Medicaid DUR Board**
**Procedures**
**(Developed 7/28/03)**
**(Modified 7/29/05)**

1. All information to be distributed to DUR Board members must be sent to the Administrator of Pharmacy Services for distribution.
   a. Information presented at the DUR Board meeting will be placed on the DHS website at least 8 weeks prior to the scheduled DUR meeting.
   b. Electronic format as an attachment to an e-mail is the next preferred format.
   c. If the format must be paper, 15 copies must be supplied to the Administrator of Pharmacy Services. The Department of Human Services will mail this information to DUR Board members weekly on Thursday afternoons as well as one last mailing 14 days prior to the scheduled DUR Board meeting.
   d. The Department of Human Services will forward the website link to DUR Board members, and interested parties, upon notice of posted DUR information on the website.
   e. The majority of communication from the Department of Human Services will be via DHS website, e-mail and e-mail attachments.

2. Only one person may represent an interested party for presentations made during DUR Board meetings.

3. Presentations made by interested parties are limited to five (5) minutes. This does not include Q&A or discussion generated by DUR Board members.

4. Process for DUR Board recommendations:
   a. Posting of information on DHS website will give DUR Board members and the public 8 weeks to draft a proposal for any action on the medication(s) after reviewing information supplied by the Department of Human Services and interested parties.
   b. This draft will be distributed to DUR Board members and those that have notified the Department of Human Services that they wish to receive such information.
   c. Comments on the proposal will be accepted. Send to DHS at least 14 days prior to the scheduled meeting.
   d. At the scheduled meeting, the DUR Board will review the comments received and will allow public comments per DUR Board guidelines mentioned above.
   e. The DUR Board will then develop and vote on a finalized proposal

# Specialty Codes for ADD Medications filled
# January 1, 2005 to June 28th, 2005

| Drug Name | Rx Num | Total Price |
|---|---|---|
| Adderall XR | 2525 | $240,148.11 |
| Concerta, Metadate CD, Ritalin LA | 5100 | $433,906.35 |
| **TOTAL** | 7625 | $674,054.46 |

**Summary by Specialty**

| Specialty | Claims Count | Qty Dispensed | Total Dollars |
|---|---|---|---|
| 01-General Practice | 1642 | 51995 | $138,461.82 |
| 13-Neurology | 1 | 30 | $80.51 |
| 16-OB/GYN | 1 | 30 | $74.95 |
| 19-Dentist | 1 | 30 | $97.77 |
| 20-Orthopedic Surgery | 5 | 150 | $25.00 |
| 26-Psychiatry | 3519 | 124747 | $321,908.82 |
| 30-Radiology | 1 | 16 | $27.22 |
| 37-Pediatrics | 1487 | 50059 | $128,654.16 |
| 41-Internal Medicine | 248 | 7312 | $21,218.57 |
| 42-Oncology | 1 | 30 | $97.77 |
| 70-Clinic | 148 | 4486 | $12,518.83 |
| 82-Emergency Medical Service | 3 | 120 | $234.13 |
| 93-Nurse Practitioner | 568 | 18754 | $50,654.91 |
| | | Grand Total | $674,054.46 |

In 2003, the 3rd World Symposium on Pulmonary Hypertension was convened in Venice to modify classification based on the new understanding of disease mechanisms. The revised system developed by this group provides the current frame work for understanding pulmonary hypertension.

The system includes several improvements over the former 1998 Evian Classification system. The terms "primary" and "secondary" were discontinued because they had limited diagnostic value. In addition, new classifications were added, including primary veno-occlusive disease (PVOD). Risk factor descriptions were updated, and the classification of congenital systemic-to pulmonary shunts was revised. A new classification of genetic factors in PH was recommended, but not implemented because available data were judged to be inadequate.

The Venice 2003 Revised Classification system can be summarized as follows:

- WHO Group I - Pulmonary arterial hypertension (PAH)
- WHO Group II - Pulmonary hypertension with left heart disease
- WHO Group III - Pulmonary hypertension associated with lung diseases and/or hypoxemia
- WHO Group IV - Pulmonary hypertension due to chronic thrombotic and/or embolic disease
- WHO Group V - Miscellaneous

These terms are currently in use, but they are not yet as commonly used as the old terms of PPH and SPH[1]

[1] Executive Summary from the World Symposium on Primary Pulmonary Hypertension 1998, Evian France 6 - 10 September 1998 (Modified Venice 2003).

**Revatio PRIOR AUTHORIZATION**
ND DEPARTMENT OF HUMAN SERVICES
MEDICAL SERVICES DIVISION

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

ND Medicaid requires that patients receiving Revatio must have a diagnosis of Pulmonary Arterial Hypertension based on WHO (Group I) Classification for Pulmonary Hypertension.

****Note:***

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

**Part I: TO BE COMPLETED BY PHYSICIAN**

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

| | |
|---|---|
| **REQUESTED DRUG:** | **Requested Dosage:** (must be completed)<br><br>**Diagnosis for this request:** |

**Qualifications for coverage:**

- ❑ Indication for the treatment of Pulmonary Arterial Hypertension (WHO Group I Classification)

□ *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:

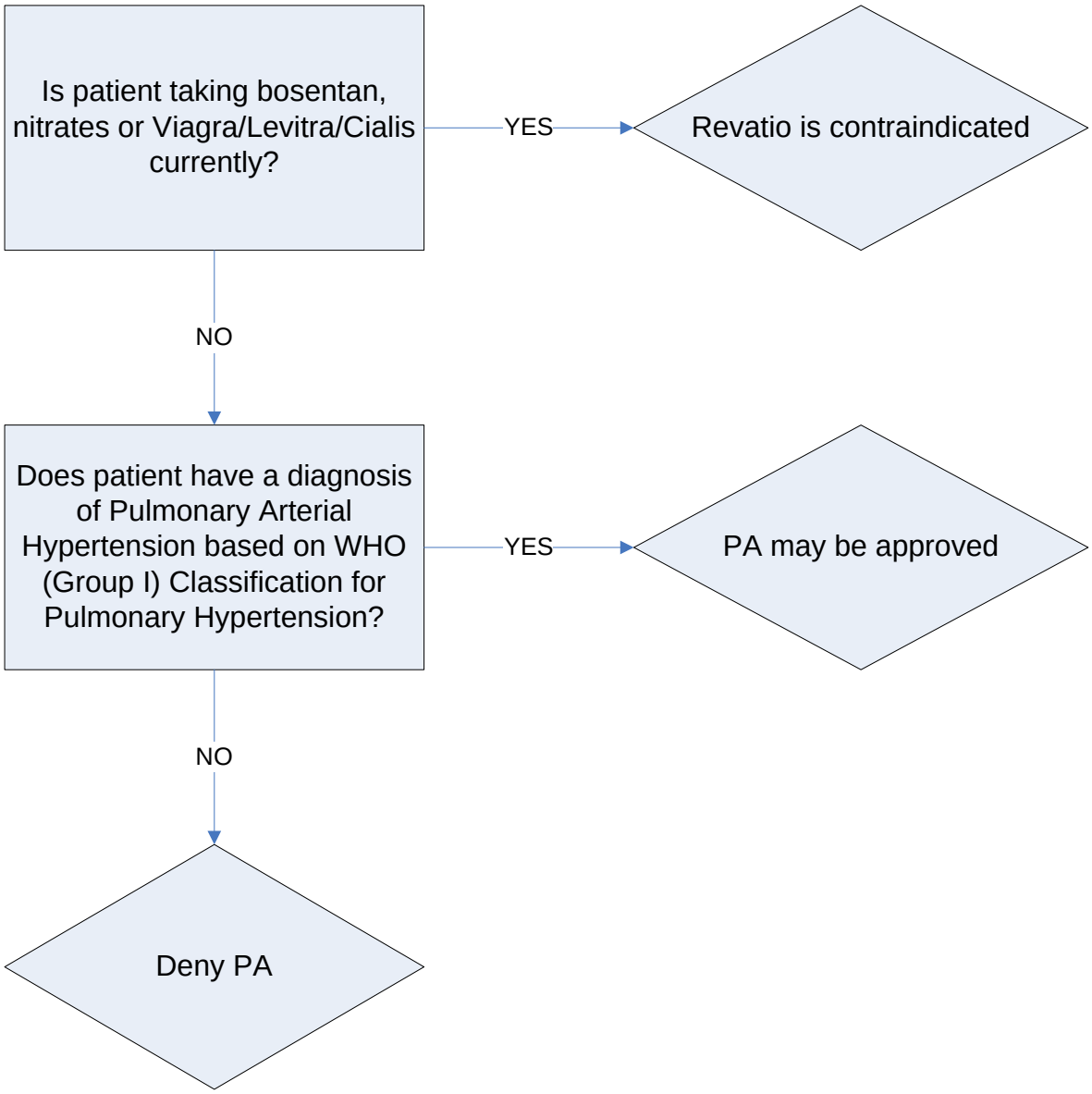
**Part II: TO BE COMPLETED BY PHARMACY**

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

**Part III: FOR OFFICIAL USE ONLY**

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

# North Dakota Department of Human Services
# Revatio Authorization Algorithm



## Statin Overview[i]

| Trade Name | Generic Name | Release |
|---|---|---|
| Lipitor | Atorvastatin | ER |
| Lescol, Lescol XL | Fluvastatin | ER/IR |
| Altocor ER, Mevacor | Lovastatin | ER/IR |
| Pravachol | Pravastatin | ER |
| Crestor | Rosuvastatin | ER |
| Zocor | Simvastatin | ER |

**Equivalent doses of statins:**

| Atorvastatin | Fluvastatin | Lovastatin | Pravastatin | Rosuvastatin | Simvastatin |
|---|---|---|---|---|---|
| -- | 40mg | 20mg | 20mg | -- | 10mg |
| 10mg | 80mg | 40 or 80mg | 40mg | -- | 20mg |
| 20mg | -- | 80mg | 80mg | 5 or 10mg | 40mg |
| 40mg | -- | -- | -- | -- | 80mg |
| 80mg | -- | -- | -- | 20mg | -- |
| -- | -- | -- | -- | 40mg | -- |

**What these drugs have in common**

- All statins lower cholesterol and lower LDL. All but Crestor have been shown to improve heart disease
- All statins may cause serious harm in muscles or liver
- No differences exist among statins by age, sex, or diabetes. Little data exists about use in African-Americans, Hispanics, or other ethnic groups

**How statins compare in their ability to reduce LDL-c**

- For patients who require LDL-c reductions of up to 40% to meet their goal, any of the statins are effective
- In patients requiring an LDL-c reduction of 40% or greater to meet the National Cholesterol Education Program goals, atorvastatin 20mg or more, lovastatin 80mg, rosuvastatin 10mg or more, and simvastatin 20mg or more daily are likely to meet the goal

**Key Differences**

- Atorvastatin, pravastatin, and simvastatin lower risk of stroke
- Pravastatin has the least drug interactions
- Atorvastatin, lovastatin, and simvastatin have the most drug interactions. This concerns people who have HIV or had a transplant; then fluvastatin or pravastatin are better due to fewer drug interactions.
- Lovastatin currently available in generic form, pravastatin and simvastatin will be available generically by spring 2006.

**How do statins work**

- Statins block the enzyme HMG-CoA reductase that is the rate-limiting step in the manufacture of cholesterol
- Reduce LDL-cholesterol, total cholesterol and triglycerides and slightly increase high-density lipoprotein (HDL-c)
- May have anti-inflammatory effects
- Equally effective at lowering C-reactive protein levels

**Usual starting doses/max doses**

- Rosuvastain 10mg, atorvastatin 10mg and 20mg of the other statins
- Taking a statin at bedtime or with the evening meal improves its ability to lower LDL
- Maximum daily dose for rosuvastatin is 40mg
- All other statins, maximum FDA-approved daily dose is 80mg
- For lovastatin and pravastatin, the maximum dose usually is prescribed as 40mg twice a day

[i] Drug Class Review on HMG-CoA Reductase Inhibitors (statins) 2005 by Oregon Health & Science University

Health Information Designs, Inc.

# North Dakota Medicaid
## Statin Utilization
## Excluding Dual Eligibles
## 11/01/2004 - 06/27/2005

9/2/2005

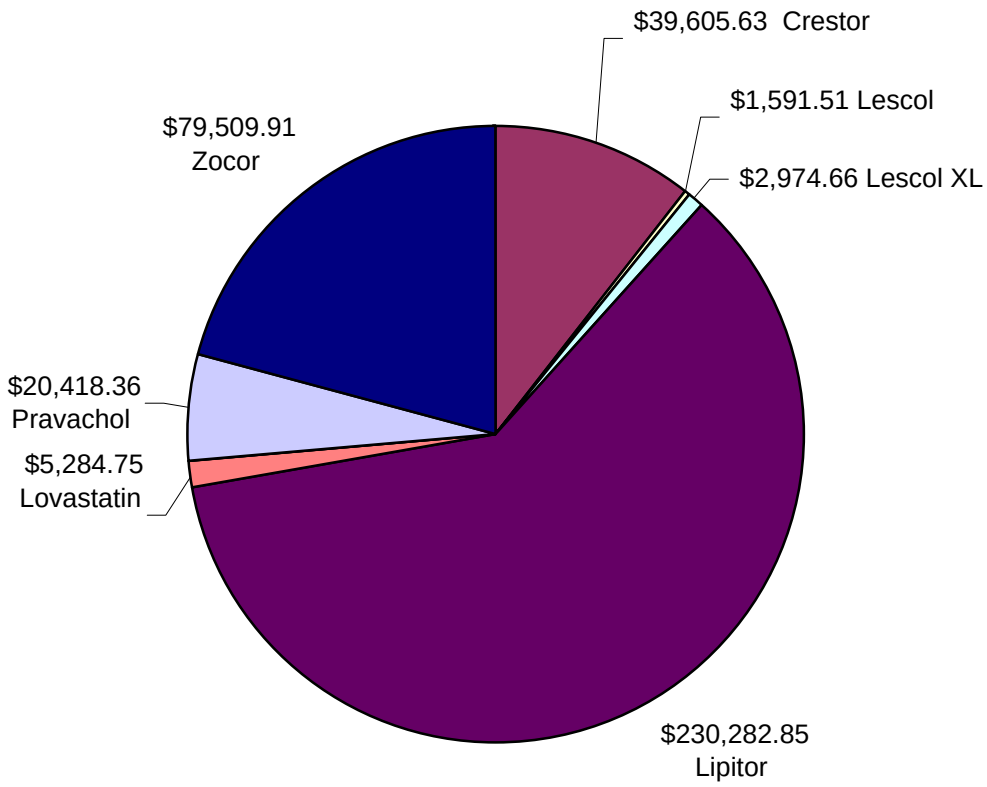
**By Cost**

| | 200411 | 200412 | 200501 | 200502 | 200503 | 200504 | 200505 | 200506 |
|---|---|---|---|---|---|---|---|---|
| **ALTOCOR** | $ - | $ - | $ - | $ - | $ - | $ - | $ - | $ - |
| **CRESTOR** | $ 3,939.57 | $ 4,812.00 | $ 4,192.50 | $ 3,268.88 | $ 5,780.43 | $ 4,741.23 | $ 6,386.32 | $ 6,484.70 |
| **LESCOL** | $ 172.05 | $ 117.53 | $ 121.86 | $ - | $ 243.93 | $ 123.51 | $ 443.97 | $ 368.66 |
| **LESCOL XL** | $ 327.91 | $ 365.93 | $ 295.28 | $ 233.80 | $ 404.35 | $ 354.80 | $ 486.17 | $ 506.42 |
| **LIPITOR** | $ 22,607.53 | $ 24,396.92 | $ 24,591.11 | $ 23,588.51 | $ 37,667.29 | $ 30,661.15 | $ 33,571.66 | $ 33,198.68 |
| **LOVASTATIN** | $ 458.83 | $ 686.02 | $ 527.67 | $ 750.22 | $ 791.97 | $ 636.02 | $ 791.41 | $ 642.61 |
| **MEVACOR** | $ - | $ - | $ - | $ - | $ - | $ - | $ - | $ - |
| **PRAVACHOL** | $ 1,688.75 | $ 2,095.43 | $ 2,084.33 | $ 1,982.25 | $ 3,203.14 | $ 3,467.08 | $ 2,510.48 | $ 3,386.90 |
| **ZOCOR** | $ 7,718.42 | $ 7,067.18 | $ 7,606.65 | $ 7,469.73 | $ 11,399.56 | $ 10,039.13 | $ 14,527.94 | $ 13,681.30 |
| **Total** | $ 36,913.06 | $ 39,541.01 | $ 39,419.40 | $ 37,293.39 | $ 59,490.67 | $ 50,022.92 | $ 58,717.95 | $ 58,269.27 |

**By Number of Prescriptions**

| | 200411 | 200412 | 200501 | 200502 | 200503 | 200504 | 200505 | 200506 |
|---|---|---|---|---|---|---|---|---|
| **ALTOCOR** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **CRESTOR** | 61 | 72 | 62 | 53 | 80 | 65 | 87 | 88 |
| **LESCOL** | 4 | 2 | 4 | 0 | 4 | 2 | 7 | 6 |
| **LESCOL XL** | 6 | 7 | 5 | 4 | 6 | 5 | 7 | 7 |
| **LIPITOR** | 299 | 335 | 342 | 311 | 494 | 412 | 435 | 446 |
| **LOVASTATIN** | 13 | 18 | 13 | 19 | 20 | 17 | 21 | 15 |
| **MEVACOR** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **PRAVACHOL** | 17 | 21 | 23 | 21 | 30 | 33 | 29 | 32 |
| **ZOCOR** | 79 | 75 | 78 | 78 | 114 | 98 | 136 | 127 |
| **Total** | 479 | 530 | 527 | 486 | 748 | 632 | 722 | 721 |

## Statin Utilization (Non-Dual) Cost 11/01/04 - 06/27/05



**STATIN PRIOR AUTHORIZATION**
ND DEPARTMENT OF HUMAN SERVICES
MEDICAL SERVICES DIVISION

**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 statin must first fail a trial of a generic statin.
****Note: These preferred medications do not require a PriorAuthorization-lovastatin, pravastatin, or simvastatin***

**Part I: TO BE COMPLETED BY PHYSICIAN**

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

**REQUESTED DRUG:**

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

**Diagnosis for this request:**

**Other CV Risk Factors:**

**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.*

Physician Signature: Date:

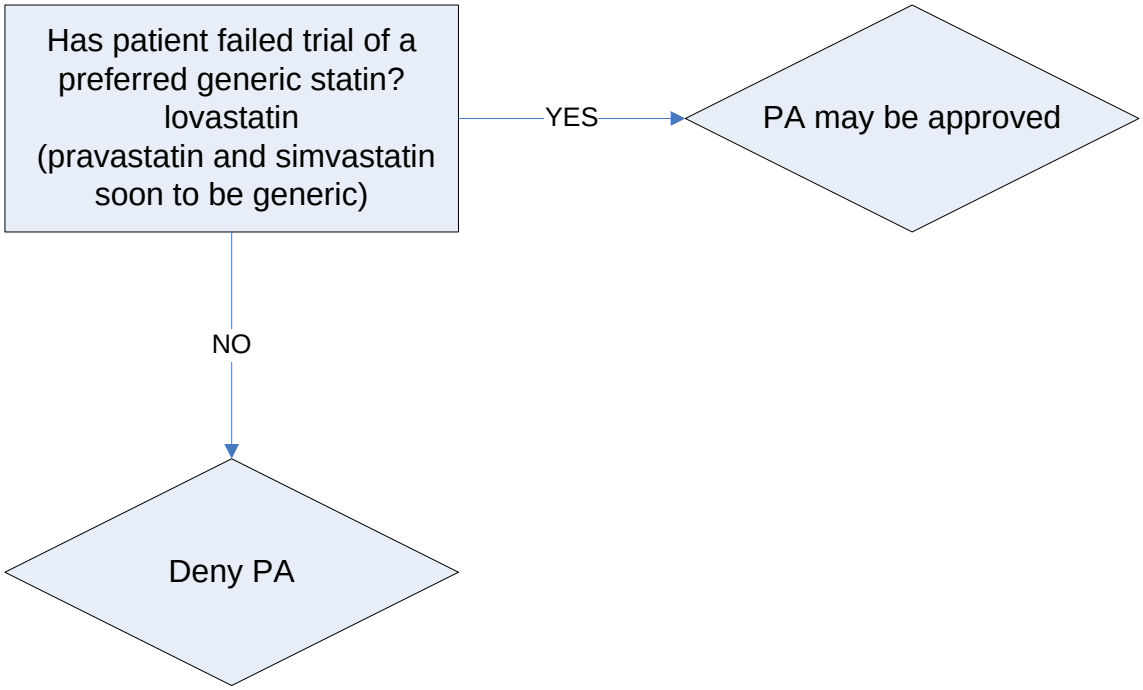
**Part II: TO BE COMPLETED BY PHARMACY**

| | |
|---|---|
| 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
# Statin Authorization Algorithm



HEALTH INFORMATION DESIGNS

## Review PRN use of Sustained Release Opioid Analgesics (SROA)

- List of medications used for review: Oxycontin, MS Contin, Kadian, Avinza, Duragesic, Oramorph
- Criteria used: patients receiving only one prescription for SROA in the time period from November 1st, 2004 - June 27th, 2005
- Number of scripts per medication:
- Avinza-10
- Duragesic-49
- Fentanyl-46
- Morphine-21
- Oxycontin-64
- Approximately 190 prescriptions for prn SROA's were written during this time frame. Of these 190 prescriptions, approximately 120 providers were responsible for the prn SROA prescriptions.

# NORTH DAKOTA DEPARTMENT OF HUMAN SERVICES

**Medical Services**

John Hoeven, Governor
Carol K. Olson, Executive Director

(701) 328-2321
Fax (701) 328-1544
Toll Free 1-800-755-2604
Provider Relations (701) 328-4030


[TODAY]

[adrs1]
[adrs2]
[adrs3]
[adrs4]

DEAR [tadrs1]:

In compliance with the OBRA '90 federal legislation, state Medicaid agencies are mandated to have an operating Drug Use Review (DUR) Board. One large part of the DUR Board's duties is physician education. Part of this process is to help assure that Medicaid beneficiaries receive appropriate medications in the most cost-effective manner, thus conserving state expenditures for drugs whenever possible.

**You are receiving this notice** because Department records indicate that you have prescribed Sustained Release Opioid Analgesics on a prn (as needed) basis. These medications are intended for the management of moderate-to-severe pain when a continuous, around-the-clock analgesic is needed for an extended period of time. These medications **are not** intended for use as a prn (as needed) analgesic.

In presenting this information to you, we recognize that the management of each patient's drug therapy depends upon an assessment of the patient's entire clinical situation about which we are not fully aware. Enclosed is a survey to fill out based on your individual treatment plan with each patient(s) listed. Please return the survey to the Department in the enclosed envelope.

Thank you for your professional consideration.

Sincerely,

Brendan K. Joyce, PharmD
Administrator, Pharmacy Services

PRESCRIBER RESPONSE

All information used to generate the enclosed letter, including Prescriber identification, was obtained from Pharmacy Claims Data. If there appears to be an error in the information provided, please note the discrepancy. Thank you for your cooperation.

1. This patient is under my care:
_____ Yes
_____ No

2. This patient has a diagnosis of:
_____

3. The directions for use on patient's prescription:
_____

4. Do you currently have a narcotic contract with this patient:
_____ Yes
_____ No

5. Please check here if you wish to receive reference information on the identified problem___. (Please provide a fax number if available_____-_____-_____.)
Comments: _____
_____
_____

[adrs1] Case# [case_no]
Letter Type [letter_type]
[alert_msg]
[criteria]

*Administered by* Health Information Designs, Inc.
1550 Pumphrey Ave.
Auburn, AL 36832-9956
(800)225-6998 x 3020 Fax (800)881-5573

**ACTO*plus* met PRIOR AUTHORIZATION**
ND DEPARTMENT OF HUMAN SERVICES
MEDICAL SERVICES DIVISION

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

ND Medicaid requires that patients receive Actos and Metformin separately.
****Note:***

- **Actos does not require PA**
- **Metformin does not require PA**
- **Patient must fail therapy on Actos and Metformin separately before a PA may be granted**

**Part I: TO BE COMPLETED BY PHYSICIAN**

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

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

**Qualifications for coverage:**

| | | |
|---|---|---|
| ❑ Failed both drugs separately | 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.*

Physician Signature: Date:

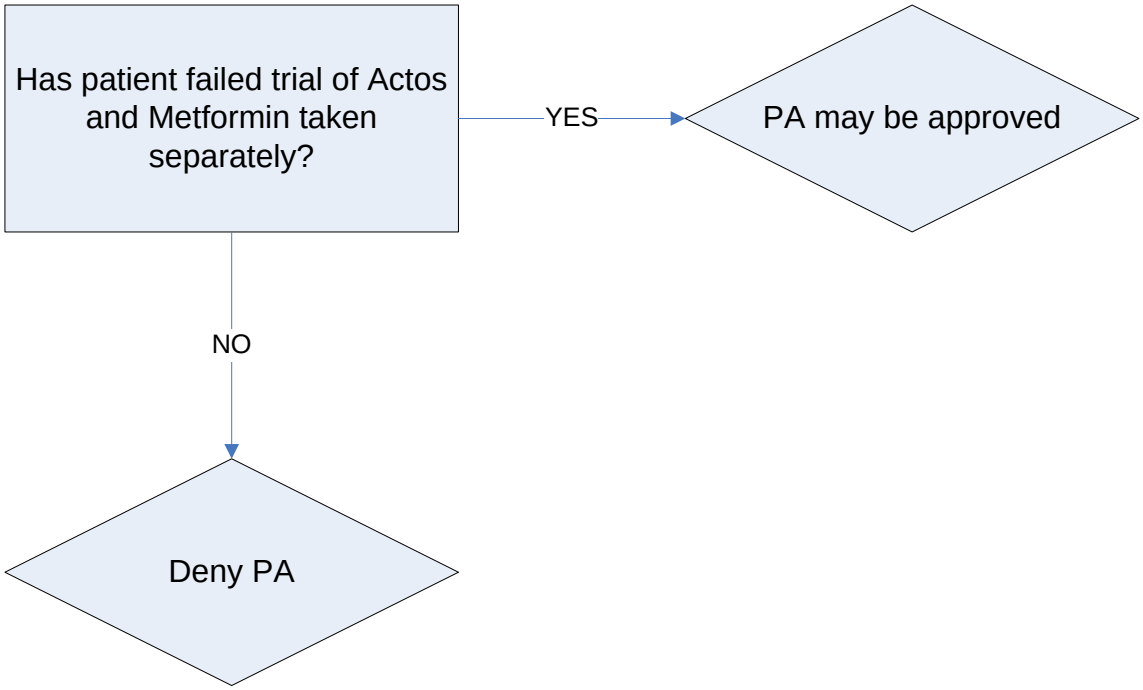
**Part II: TO BE COMPLETED BY PHARMACY**

| | |
|---|---|
| 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
# ACTO*plus met* Authorization Algorithm




## Post Part D Utilization Data of Actonel and Fosamax

| | |
|---|---|
| **Fosamax** | **64 scripts per month** |
| **Actonel** | **13 scripts per month** |

### Average Cost

| | |
|---|---|
| **Fosamax** | **$ 68.30/script** |
| **Actonel** | **$ 71.84/script** |

**Fosamax plus D PRIOR AUTHORIZATION**
ND DEPARTMENT OF HUMAN SERVICES
MEDICAL SERVICES DIVISION

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

ND Medicaid requires that patients receive Fosamax without D.
****Note:***

- ***Fosamax does not require a PA***

**Part I: TO BE COMPLETED BY PHYSICIAN**

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

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

**Qualifications for coverage:**

| | | |
|---|---|---|
| ❑ Failed Fosamax without D | Start Date:<br>End Date: | Dose:<br>Frequency: |

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

Physician Signature: Date:

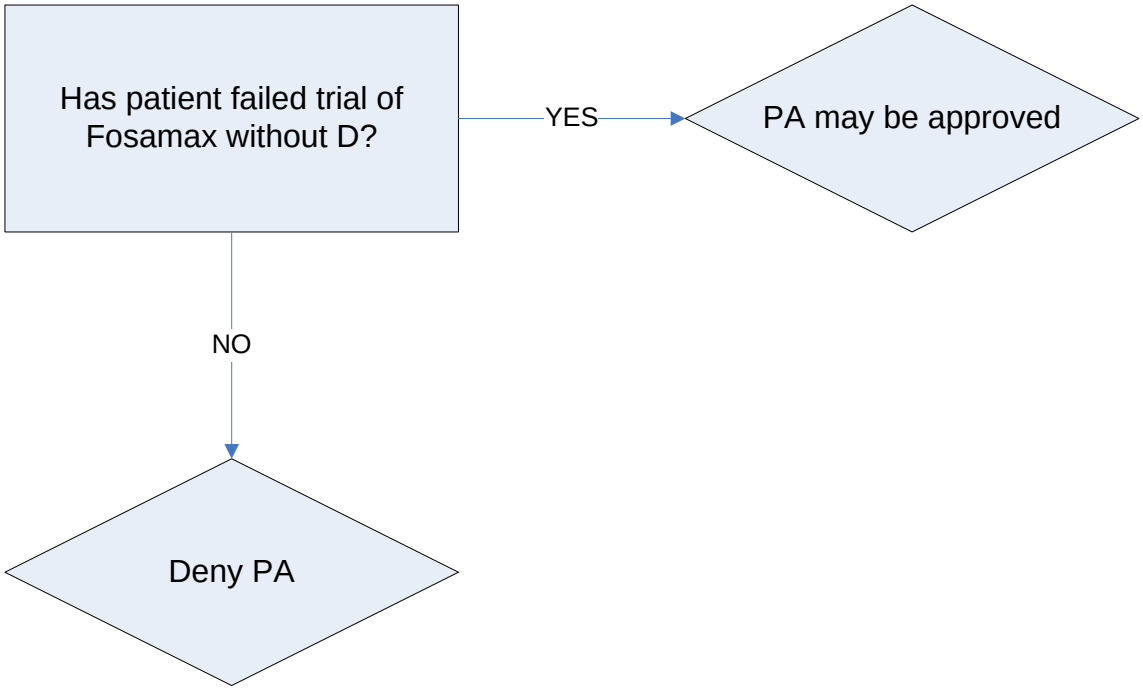
**Part II: TO BE COMPLETED BY PHARMACY**

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

**Part III: FOR OFFICIAL USE ONLY**

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

# North Dakota Department of Human Services
# Fosamax plus D Authorization Algorithm



**Actonel with Calcium PRIOR AUTHORIZATION**
ND DEPARTMENT OF HUMAN SERVICES
MEDICAL SERVICES DIVISION

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

ND Medicaid requires that patients receive Actonel without Calcium.
***Note:**

- ***Actonel does not require a PA***

**Part I: TO BE COMPLETED BY PHYSICIAN**

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

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

**Qualifications for coverage:**

- ❑ Failed Actonel without Calcium — 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.*

Physician Signature: Date:

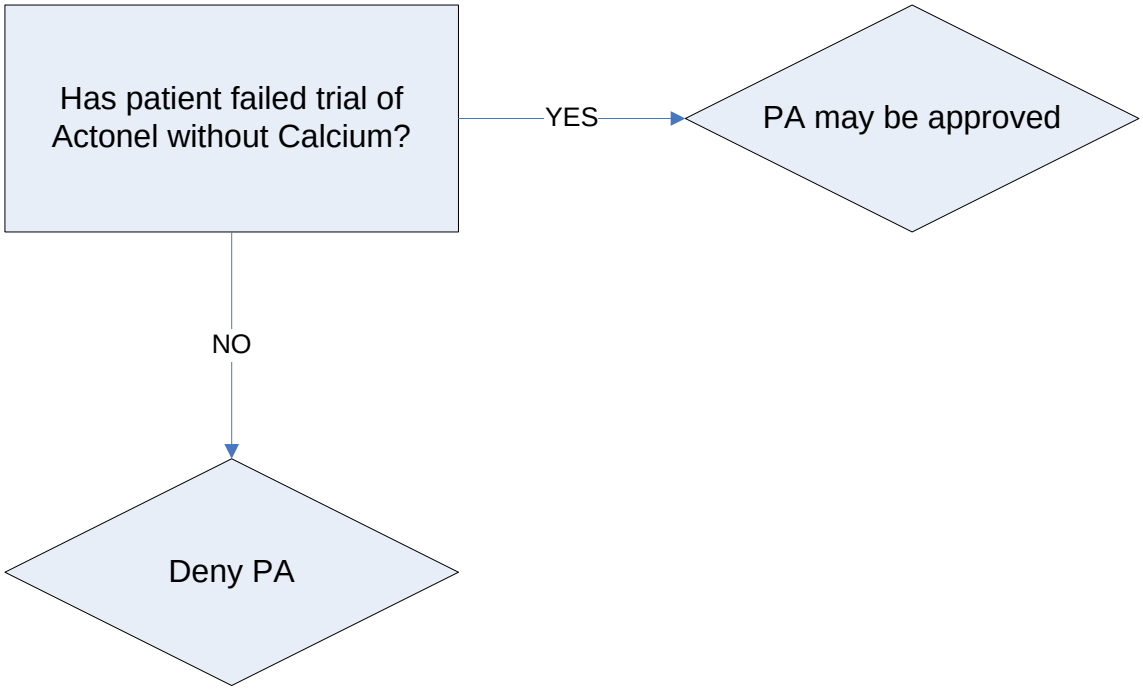
**Part II: TO BE COMPLETED BY PHARMACY**

| | |
|---|---|
| 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
# Actonel with Calcium Authorization Algorithm



# NORTH DAKOTA MEDICAID
# RETROSPECTIVE DRUG UTILIZATION REVIEW
# SEPTEMBER 2005

***Recommendation*** ***Approved*** ***Rejected***

**1. Oxcarbazepine / / Therapeutic Appropriateness** _____ _____

Alert Message: Serious dermatological reactions, including Stevens-Johnson Syndrome and toxic epidermal necrolysis, have been reported in both children and adults in association with Trileptal (oxcarbazepine) use. The median onset for reported cases was 19 days. Such serious skin reactions may be life-threatening, and some patients required hospitalization with very rare reports of fatal outcome. Recurrence of serious skin reactions following re-challenge with oxcarbazepine has also been reported.
Conflict Code: TA – Therapeutic Appropriateness – Warning
Drugs/Disease

| Util A | Util B | Util C |
|---|---|---|
| Oxcarbazepine | | |

References:
Trileptal Prescribing Information, March 2005, Novartis Pharmaceuticals Corporation.
MedWatch: The FDA Safety Information and Adverse Event Reporting Program, 2005.

**2. Oxcarbazepine / / Therapeutic Appropriateness** _____ _____

Alert Message: Multi-organ hypersensitivity reactions have occurred in close temporal association (median time to detection 13 days: range 4-60) to the initiation of Trileptal (oxcarbazepine) therapy in adult and pediatric patients. Although there have been a limited number of reports, many of these cases resulted in hospitalization and some were considered life threatening. Signs and symptoms of this disorder were diverse. If reaction is suspected discontinue oxcarbazepine and start alternative treatment.
Conflict Code: TA – Therapeutic Appropriateness – Precaution
Drugs/Disease

| Util A | Util B | Util C |
|---|---|---|
| Oxcarbazepine | | |

References:
Trileptal Prescribing Information, March 2005, Novartis Pharmaceuticals Corporation.
MedWatch: The FDA Safety Information and Adverse Event Reporting Program, 2005.

**3. Fentanyl Transdermal/Potent CYP 450 3A4 inhibitors** _____ _____

Alert message: Concurrent use of fentanyl products with potent CYP 3A4 inhibitors (e.g., ritonavir, ketoconazole, itraconazole, troleandomycin, clarithromycin, nelfinavir, and nefazodone) may result in an increase in fentanyl plasma concentrations, which could increase or prolong adverse effects and may cause potentially fatal respiratory depression. Patients receiving fentanyl and potent CYP 3A4 inhibitors should be monitored for an extended period of time and dosage adjustments made if warranted.
Conflict Code: DD – Drug/Drug Interactions
Severity: Major
Drugs/Disease:

| Util A | Util B | | Util C |
|---|---|---|---|
| Fentanyl | Ritonavir | Clarithromycin | |
| | Ketoconazole | Nelfinavir | |
| | Itraconazole | Nefazodone | |
| | Troleandomycin | Erythromycin | |

References:
MedWatch: The FDA Safety Information and Adverse Event Reporting Program, 2005.
Actiq Prescribing Information, Sept. 2004, Cephalon, Inc.
Duragesic Prescribing Information, Feb. 2005, Janssen Pharmaceutica Products, L.P.

| *Recommendation* | *Approved* | *Rejected* |
|---|---|---|

4**. Isotretinoin / Tetracyclines** _____ _____

Alert Message: The concurrent use of isotretinoin and tetracyclines should be avoided. An increased incidence of pseudotumor cerebri has been reported in patients receiving these agents in combination. Early signs of pseudotumor cerebri include papilledema, severe headache, nausea, vomiting and visual disturbances. If symptoms are present discontinue drug immediately and consult a neurologist.
Conflict Code: DD – Drug-Drug Interaction
Drugs:

| Util A | Util B | Util C |
|---|---|---|
| Isotretinoin | Tetracycline | |
| | Minocycline | |
| | Doxycycline | |

References:
Accutane Product Information, Aug. 2005, Roche Laboratories, Inc.
Micromedex Healthcare Series, Drugdex Drug Evaluations, 2005.
Facts & Comparisons, 2005 Updates.

**5. Salmeterol / High Dose** _____ _____

Alert Message: Salmeterol doses greater than 100 mcg per day (given in two equally divided doses) have been associated with significant increases in heart rate, reductions in diastolic pressure, and prolongation of QTc interval which may potentially produce life-threatening arrhythmias.
Conflict Code: ER - Overutilization
Drugs:

| Util A | Util B | Util C |
|---|---|---|
| Salmeterol | | |

References:
Micromedex Healthcare Series, Drugdex Drug Evaluations, 2005.
Facts & Comparisons, 2005 Updates.
Serevent Product Information, Sept. 2004, GlaxoSmithKline.
Advair Product Information, Sept. 2004, GlaxoSmithKline.

**6. Formoterol / High Dose** _____ _____

Alert Message: Foradil (formoterol fumarate) may be over-utilized. The manufacturer's recommended maximum daily dose is 12 mcg (one capsule) twice daily. The use of higher doses has not shown greater efficacy and may be a sign of worsening respiratory disease.
Conflict Code: ER - Overutilization
Drugs:

| Util A | Util B | Util C |
|---|---|---|
| Formoterol | | |

Max Dose: 24mcg/day
References:
Micromedex Healthcare Series, Drugdex Drug Evaluations, 2005.
Facts & Comparisons, 2005 Updates.
Foradil Product Information, June 2003, Schering Corporation.

# Proposed ND DUR Board Meeting Dates
# 2006

**February 6th**

**May 1st**

**August 7th**

**November 6th**