DUR Board Meeting
December 3rd, 2007
Heritage Center
Rooms A and B
1pm

October 12th, 2007

The next North Dakota Drug Utilization Review (DUR) Board Meeting will be held December 3rd, 2007 at 1:00pm

Heritage Center
Rooms A and B
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
Heritage Center
Rooms A and B
December 3rd, 2007
1pm

1. Administrative items
   - Travel vouchers
   - Board Members Sign In

2. Old Business

• Review and approval of minutes of 10/01/07 meeting	Chairman
• Budget update	Brendan
• Review of Antineoplastic Agents	HID
• Review of ADHD	HID
• Review of Antidepressants	HID
• Yearly PA Review (Zanaflex capsules, Solodyn, Oracea, ophthalmic anti-infectives-expand to cover broad spectrum ophthalmic antibiotics)	HID
• Conflict of Interest Policy	Brendan

3. New Business

• Review of Antipsychotic Agents	HID
• Criteria Recommendations	Brendan
• Upcoming meeting date/agenda	Chairman

4. Adjourn — Chairman

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

Drug Utilization Review (DUR) Meeting Minutes
October 1st, 2007

Members Present: Albert Samuelson, Patricia Churchill, Cheryl Huber, Norman Byers, Carrie Sorenson, Todd Twogood, Greg Pfister, Scott Setzepfandt, Bob Treitline, Kim Krohn, Jeffrey Hostetter, Leann Ness and Carlotta McCleary.
Medicaid Pharmacy Department: Brendan Joyce, Gary Betting
HID Staff Present: Candace Rieth
Members Absent: John Savageau

Chairman, C. Huber, called the meeting to order at 1:00pm. New members were introduced to the Board. C. Huber asked for a motion to approve the minutes from the August 20th meeting. S. Setzepfandt asked for a change to the wording of the minutes. The minutes state that Board members have received letters from Pfizer and S. Setzepfandt said that it should read Board members have received letters from physicians. N. Byers moved that the minutes be approved with modifications and K. Krohn seconded the motion. Chair, C. Huber, called for a voice vote to approve the minutes, which passed with no audible dissent.

Budget Update
B. Joyce made available a spreadsheet showing the top 21 drug classes based on amount reimbursed. Antipsychotics, Anticonvulsants, Antidepressants and ADHD make up 42.97% of the total drug spend for North Dakota Medicaid.

High Cost Medications
House Bill 1459 directs the Department to review expensive medical procedures for prior authorizations. The Department would also like to extend this review to medications. This would allow reconciliation of data to determine incorrect billings. B. Joyce provided more information to the Board on this topic including claims with a minimum billed amount of three thousand dollars, strength of medications, quantities dispensed and days' supply. After reviewing the list, G. Pfister made a motion to allow an edit on agents costing more than three thousand dollars excluding all products listed in the High Cost Drug Claims table. B. Treitline seconded the motion. The chair called for a voice vote and the motion passed with no audible dissent.

Yearly Review of Prior Authorization
Once a year, the Board reviews products that were placed on prior authorization. This allows the Board a chance to review the prior authorization forms and criteria. DAW-1 products were reviewed. B. Joyce provided the Board with a list of all DAW-1 claims that were billed in June, 2007. No action will be taken regarding the DAW-1 form or criteria.

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 criteria will be added to the current set of criteria, and will be used in future DUR cycles. P. Churchill moved to approve the new criteria and N. Byers seconded the motion. C. Huber called for a voice vote and the motion passed with no audible dissent.

Legislative Update
House Bill 1422 restricts placing the following classes of medications on Prior Authorization. These include AIDS, Cancer, Anti-psychotics, Anti-depressants, ADHD and Mood-Stabilizers. Over the next year, the DUR Board will be responsible for reviewing these classes and making recommendations to the Department regarding the plan of action the Board would take, if any. The DUR Board recommendations will be reported, periodically, to the Legislative Council.

Oral Antineoplastic Review
At the June meeting, A. Samuelson suggested getting a consult from one of the Oncology physicians currently prescribing to North Dakota Medicaid patients. B. Joyce had no luck asking for guidance regarding this class of medications. At this time, there is no new information to review and B. Joyce asked Board members for suggestions of oncologists that would be willing to help the Board in this capacity. K. Krohn suggested an oncologist in Minot and she will ask for his guidance.

ADHD Review
At the August meeting, the DUR Board suggested a prior authorization on Vyvanse and also suggested broadening prior authorization guidelines for other agents in this class by incorporating step therapy. There was public comment by Rose Mullen, representing Eli Lilly. She reviewed Strattera related prescribing information with the Board. There was public comment by Susan Helgeland, representing Mental Health America of North Dakota. She spoke against restricting ADHD medications for ND Medicaid recipients. B. Joyce stated that post-rebate, Strattera and Daytrana are much more expensive than the other agents in this class. The Department suggests a prior authorization on Daytrana and Strattera. J. Hostetter asked for specific information regarding rebates. B. Joyce stated that he was unable to reveal that information. J. Hostetter said that it is very hard to give an opinion if not all of the information is presented. S. Setzepfandt was asked to explain to the Board the process involved with sharing rebate information. S. Setzepfandt said that it would be very difficult to reveal this information without legal involvement and closed door sessions. G. Pfister made a motion to modify the current proposed form, ADHD PA Form, to read ADHD Stimulant PA form and to remove Strattera. T. Twogood seconded the motion. Regarding the legislative review process for exempted classes, A. Samuelson made a motion to allow the DUR Board to manage and review ADHD. N. Byers seconded the motion. Chair, C. Huber, called for a voice vote. Individual votes were counted with 1 opposed, 2 abstaining and 9 yes votes. Motion passed.

Antidepressant Review
The Antidepressant review is based on the 2007 legislative session requesting information on classes of medications that currently are exempt from prior authorization. B. Joyce reviewed utilization data of the Antidepressant meds including a market share report. Based on post-rebate information, Cymbalta, Effexor XR, Lexapro, Paxil CR and Prozac weekly are the most costly medications in this class. There was public comment by Rose Mullen, representing Eli Lilly. She reviewed Cymbalta prescribing information with the Board. B. Joyce asked the Board if they would like the ability to review and manage antidepressants. B. Joyce stated that the Board could authorize a lifetime PA for these medications and review previous history to look for failure of other medications in the class, making the prior authorization process simpler for providers. C. Huber suggested that the form be reworked and called an SSRI PA form. B. Joyce said that he would have the form reworked and this information would be brought to the next DUR meeting.

Conflict of Interest
Ryan Bernstein, Legal Counsel to Governor John Hoeven of North Dakota has asked that the DUR Board adopt a conflict of interest policy that would require members to disclose financial relationships with drug companies and recuse themselves from voting, in some cases. After much discussion, it was decided that B. Joyce will draft a conflict of interest form and bring it to the December meeting for Board review.

The next DUR board meeting will be December 3rd, 2007. B. Joyce reviewed future agenda items. These include Antidepressants, ADHD agents, Antineoplastic agents and Antipsychotics. G. Pfister made a motion to adjourn the meeting and K. Krohn seconded. Chair C. Huber adjourned the meeting at 3:50 pm.

HEALTH INFORMATION DESIGNS

ADHD Stimulant PA FORM

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

Prior Authorization Vendor for ND Medicaid

ND Medicaid requires the use of one of the following products as first line ADHD therapy: Generic amphetamines, generic methylphenidates, Adderall XR, Metadate CD, Concerta, Focalin XR, or Ritalin LA.

****Note:***

- **Daytrana requires a Prior Authorization.**

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

Qualifications for coverage:

- ❑ Failed first line ADHD therapy — Start Date:
- ❑ NPO status — End Date:

Physician Signature: Date:

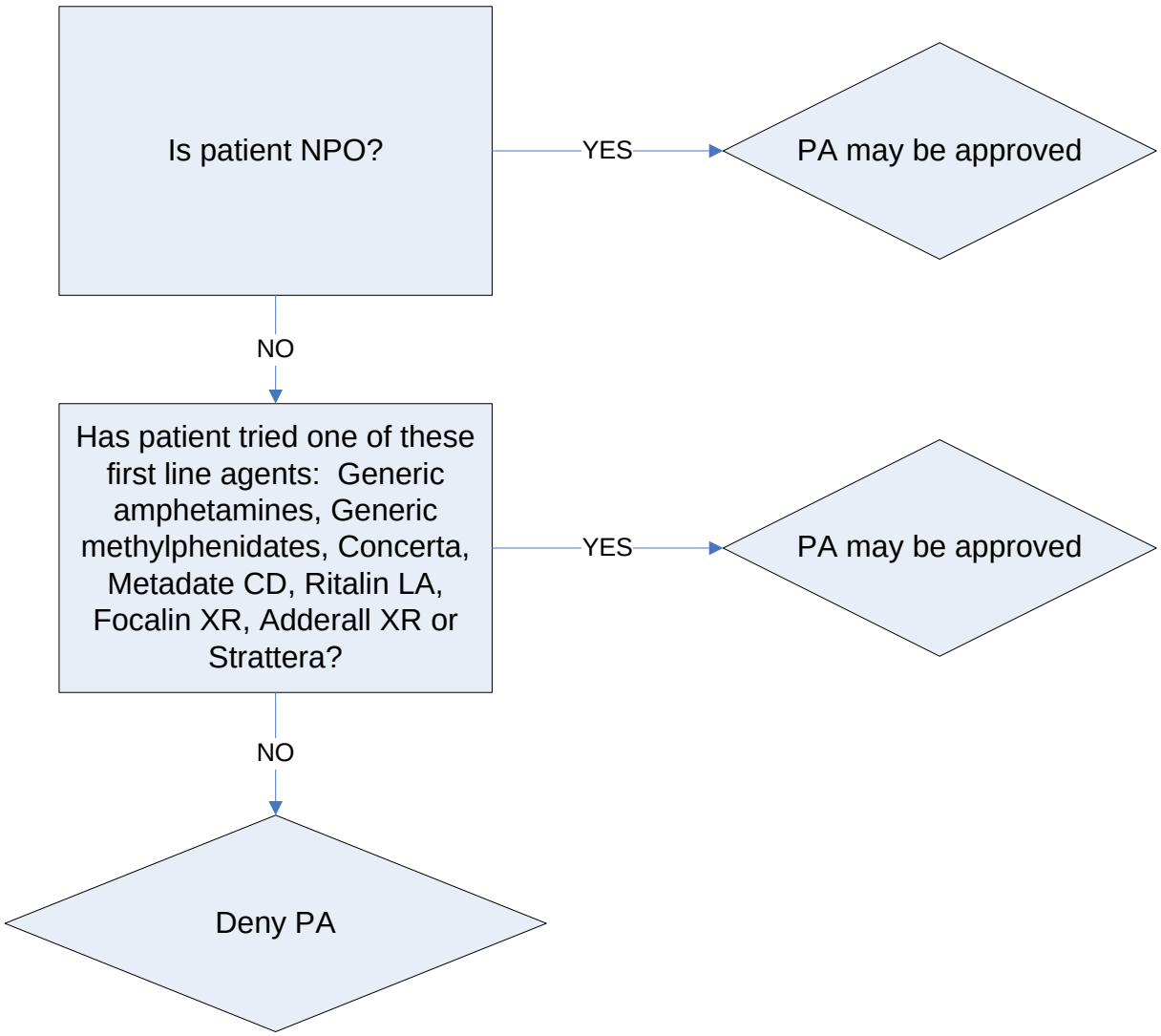
Part II: TO BE COMPLETED BY PHARMACY

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
ADHD Stimulant Authorization Algorithm



Cost of Product (smallest to greatest)

Immediate Release ADHD products < Concerta (low strengths)< Metadate CD (low strengths) < Ritalin LA < Focalin XR < Concerta (high strengths) < Adderall XR < Metadate CD (high strengths)

<<< Daytrana and Strattera

HEALTH INFORMATION DESIGNS

SSRI PA Form

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

Prior Authorization Vendor for ND Medicaid

ND Medicaid requires the use of one of the following products as first line SSRI therapy: Citalopram, Paroxetine, Fluoxetine or Sertraline.

****Note:***

- **Lexapro, Paxil CR, and Prozac Weekly all require a Prior Authorization.**

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:

- ❑ First line antidepressant therapy tried: Start: Dose:
  End: 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:

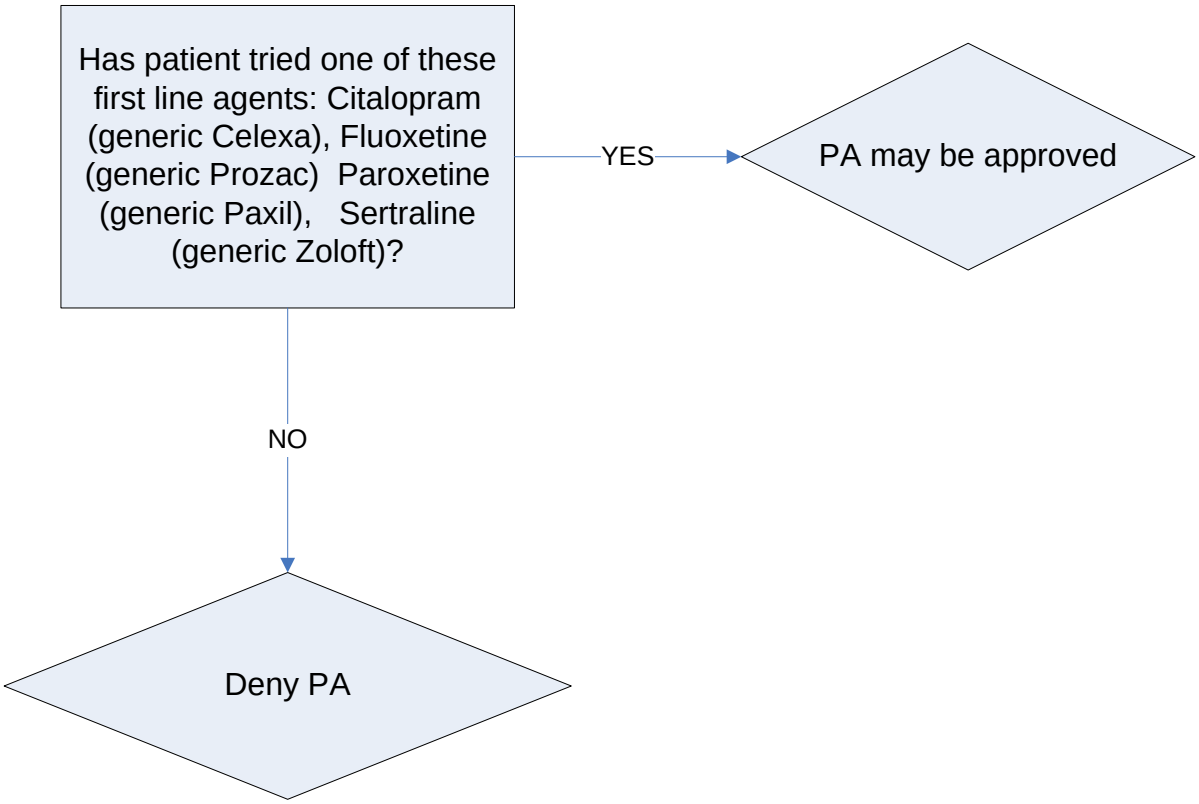
Part II: TO BE COMPLETED BY PHARMACY

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
SSRI Authorization Algorithm



Zanaflex Capsule PRIOR AUTHORIZATION

HEALTH INFORMATION DESIGNS

Prior Authorization Vendor for ND Medicaid

Clear Fields

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

ND Medicaid requires that patients receiving Zanaflex capsules must use Tizanidine tablets first line.

**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 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 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#:

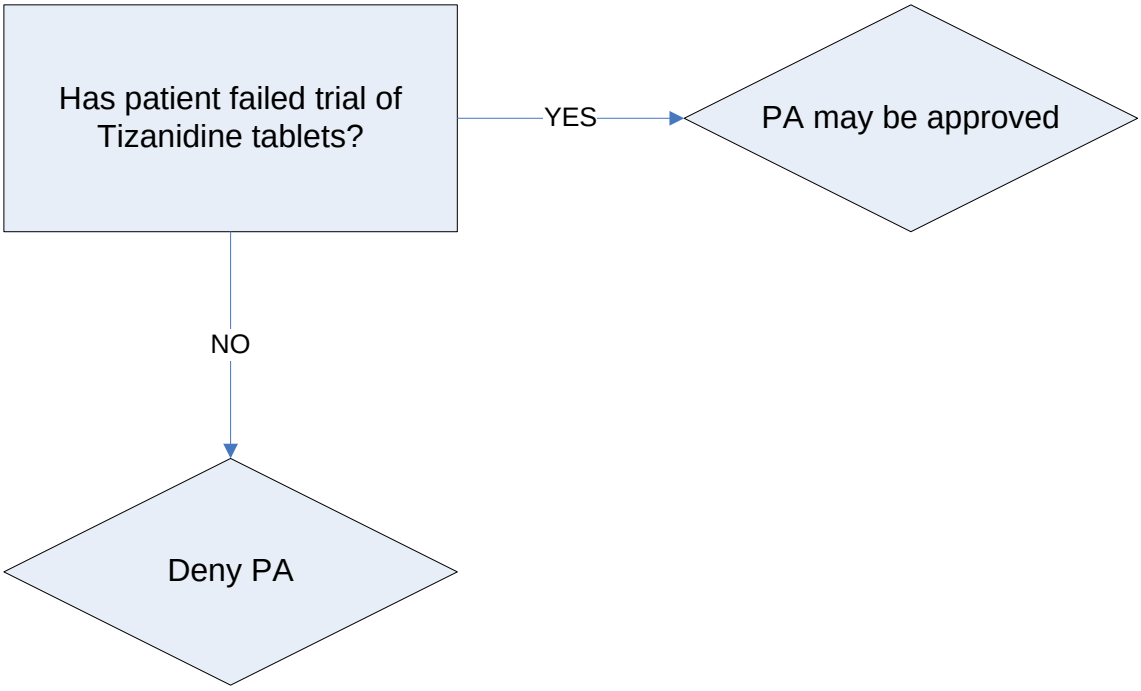
Part III: FOR OFFICIAL USE ONLY

Date: / / Initials: _____

Approved -
Effective dates of PA: From: / / To: / /

Denied: (Reasons)

North Dakota Department of Human Services
Zanaflex Authorization Algorithm



HEALTH INFORMATION DESIGNS

Prior Authorization Vendor for ND Medicaid

SOLODYN PRIOR AUTHORIZATION

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

Note: ND Medicaid will not pay for Solodyn without documented failure of a first line tetracycline agent.

- First line agents include: doxycycline, minocycline, and tetracycline.

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:	**Indication:**
☐ Solodyn	
☐ *Patient has failed a 90 day trial of which first line agent* _____	
Physician Signature:	Date:

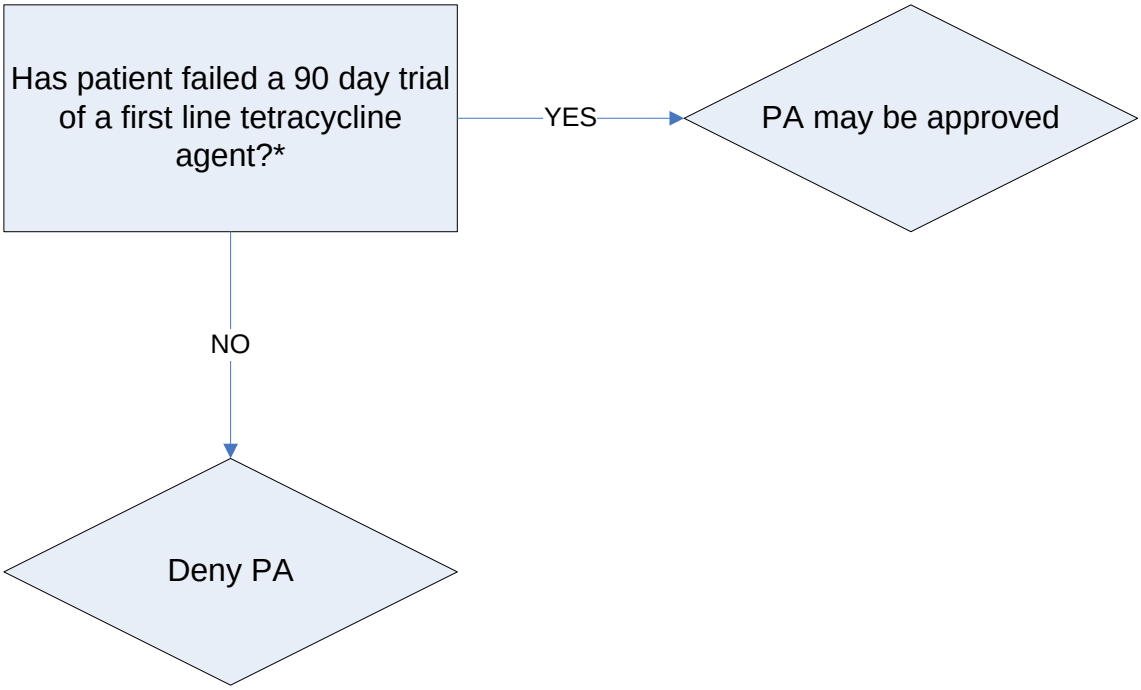
Part II: TO BE COMPLETED BY PHARMACY

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 Service
Solodyn Authorization Algorithm



*First line agents include: doxycycline, minocycline, and tetracycline.

HEALTH INFORMATION DESIGNS

Prior Authorization Vendor for ND Medicaid

ORACEA PRIOR AUTHORIZATION

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

Note: ND Medicaid will not pay for Oracea without documented failure of a first line tetracycline agent.

- First line agents include: doxycycline, minocycline, and tetracycline.

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:	**Indication:**
☐ Oracea	

☐ *Patient has failed a 90 day trial of which first line agent* _____

Physician Signature:	Date:

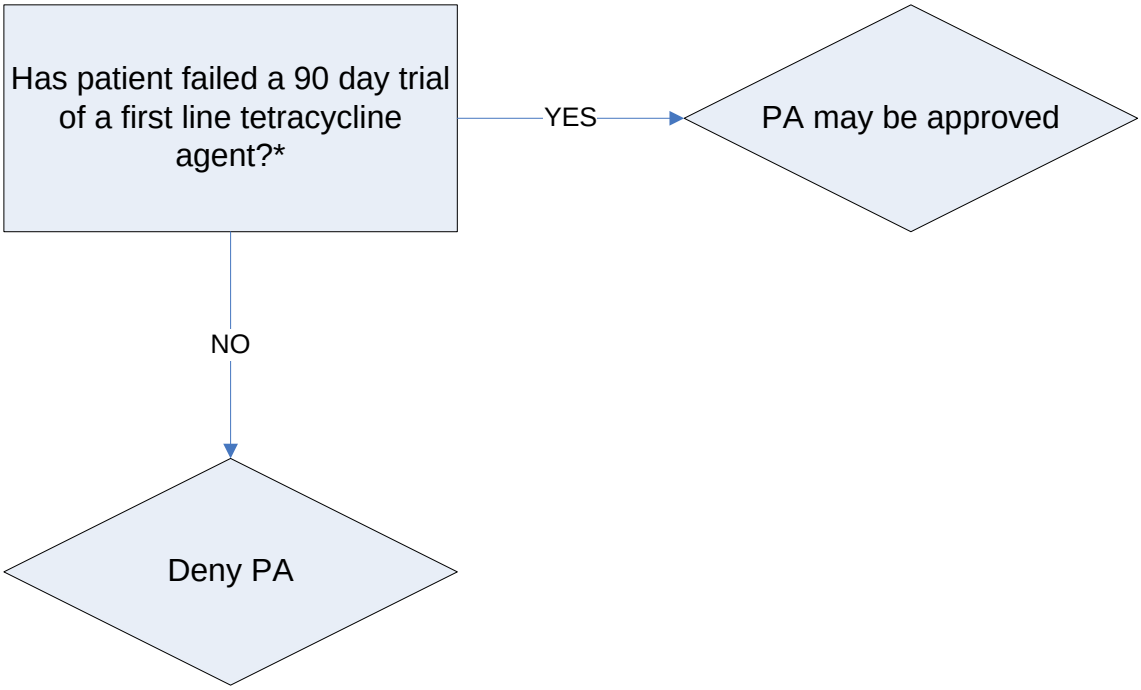
Part II: TO BE COMPLETED BY PHARMACY

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 Service
Oracea Authorization Algorithm



*First line agents include: doxycycline, minocycline, and tetracycline.

HEALTH INFORMATION DESIGNS

Prior Authorization Vendor for ND Medicaid

Ophthalmic Anti-infective PA Form

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

Note: ND Medicaid will not pay for Zymar or Vigamox without documented failure of a first line antibiotic ophthalmic agent.

- First line agents include: sulfacetamide (Bleph10, etc.), erythromycin, bacitracin-polymixin B (Polysporin), polymyxin B-neomycin-gramicidin (Neosporin), trimethoprim-polymyxin B (Polytrim) and gentamicin (Garamycin, etc.).

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:	**Indication:**
☐ Zymar ☐ Vigamox	☐ Deep penetrating wound ☐ Pre/Post Cataract Surgery ☐ Corneal ulcer
Physician Signature:	Date:

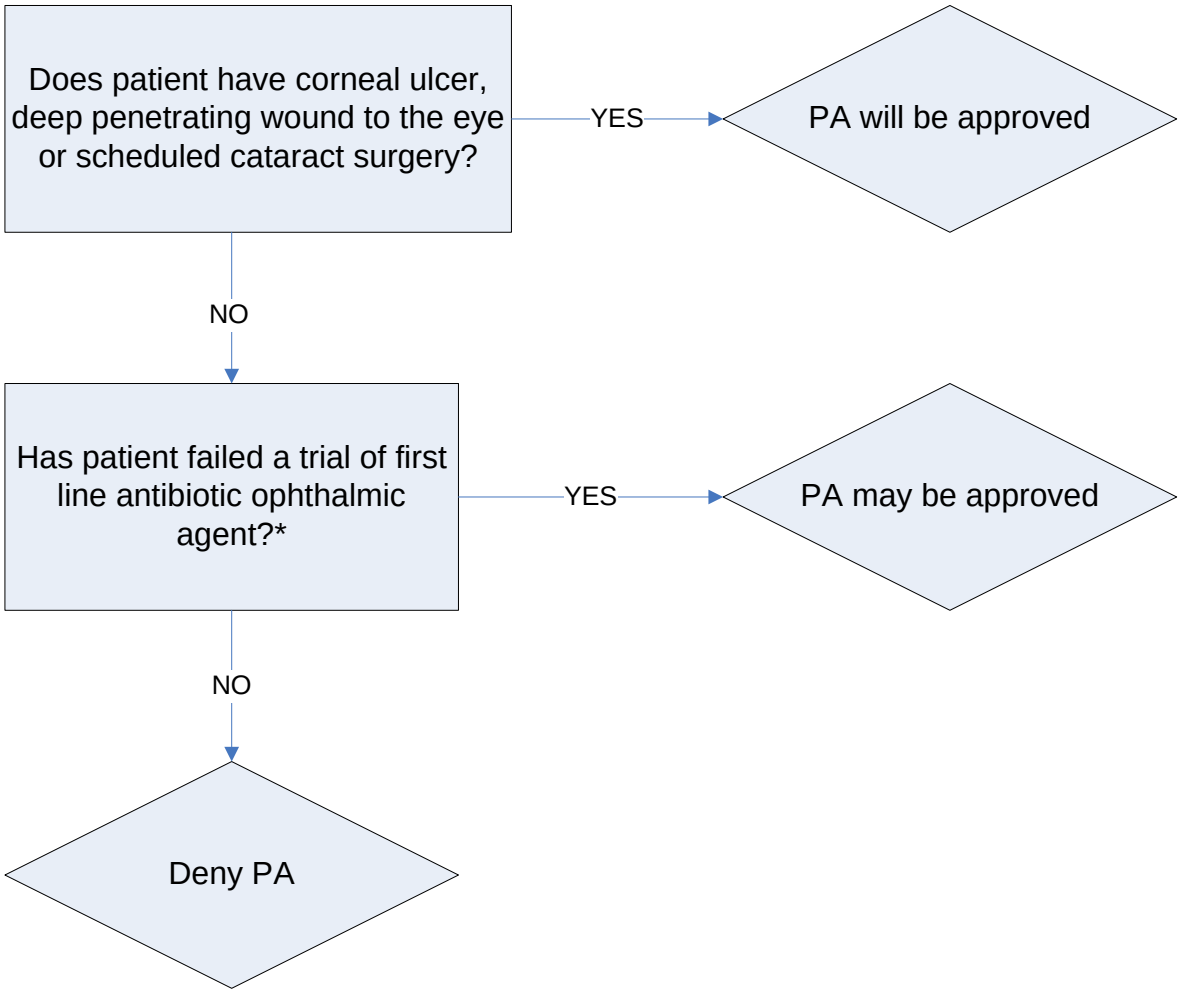
Part II: TO BE COMPLETED BY PHARMACY

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
Ophthalmic Anti-infective Authorization Algorithm



*First line agents include: sulfacetamide (Bleph 10, etc.), erythromycin, bacitracin-polymixin B (Polysporin), polymyxin B-neomycin-gramicidin (Neosporin), trimethoprim-polymyxin B (Polytrim), gentamicin (Garamycin, etc.), ofloxacin (Ocuflox), and ciprofloxacin (Ciloxan).

State of
North Dakota
Office of the Governor

John Hoeven
Governor

September 14, 2007

Brendan Joyce
600 East Blvd. Ave. - Dept 325
Bismarck, ND 58505-325

Dear Brendan:

The Drug Utilization Review Board has an important role in implementing a drug use review program for outpatient prescription drugs under the medical assistance program.

Because the Board reviews the utilization, cost, and effectiveness of drugs and recommend the drugs which are placed on the prior authorization program, it is important the Board and its members ensure the board is free of any conflict of interest with drug companies. Even the perception of a conflict may undermine the Board's trustworthiness with the public.

To prevent a conflict of interest, I recommend the Board adopt a conflict-of-interest policy that would require members to disclose financial relationships with drug companies and recuse themselves from voting in some cases.

The Board's work of finding affordable and effective medication for our citizens is a vitally important role, and the adoption of a conflict-of-interest policy would help further the publics trust in the Board's work.

Sincerely,

Ryan Bernstein
Legal Counsel

34:58

SEP 17 2007
Medical Services

600 E Boulevard Ave
Bismarck, ND 58505-0001
Phone: 701.328.2200
Fax: 701.328.2205
www.nd.gov

NORTH DAKOTA MEDICAID
RETROSPECTIVE DRUG UTILIZATION REVIEW
CRITERIA RECOMMENDATIONS
ADDITIONAL RDUR MEETING 2007

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

1. Fentora / Therapeutic Appropriateness _____ _____

Alert Message: Fentora (buccal fentanyl) is only approved for the treatment of breakthrough pain in patients with cancer who are already receiving and are tolerant to opioid therapy. Buccal fentanyl must not be used in opioid non-tolerant patients. The improper selection of patients, incorrect dosing and improper product substitution may result in a fatal overdose with this agent.
Conflict Code: TA - Therapeutic Appropriateness
Drugs/Disease

Util A	Util B	Util C (Negating)
Fentora		Cancer ICD-9s
		Antineoplastic Agents

References:
Fentora Prescribing Information, April 2007, Cephalon, Inc.
FDA News: FDA Warns of Potential Serious Side Effects with Breakthrough Cancer Pain Drug. September 26, 2007.

2. Fentora / Therapeutic Appropriateness _____ _____

Alert Message: Fentora (buccal fentanyl) is only approved for the treatment of breakthrough pain in patients with cancer who are already receiving and are tolerant to opioid therapy. Buccal fentanyl must not be used in opioid non-tolerant patients. The improper selection of patients, incorrect dosing and improper product substitution may result in a fatal overdose with this agent.
Conflict Code: TA - Therapeutic Appropriateness
Drugs/Disease

Util A	Util B	Util C (Negating)	
Fentora		Meperidine	Levorphanol
		Morphine	Methadone
		Fentanyl Transdermal	Oxycodone
		Fentanyl Lozenges	Oxymorphone
		Hydrocodone	Propoxyphene
		Hydromorphone	Codeine

References:
Fentora Prescribing Information, April 2007, Cephalon, Inc.
Facts & Comparisons, 2007 Updates.

3. Quetiapine / Substance Abuse _____ _____

Alert Message: Seroquel (quetiapine) should be prescribed with caution to patients with a history of substance abuse. The agent has sedative and anxiolytic properties and may be misused by some patients. Closely observe patients for signs of misuse or abuse (e.g., development of tolerance, increases in dose, drug-seeking behavior). Inappropriate use of quetiapine may put patients at risk for arrhythmias, hypotension, weight gain, and diabetes.
Conflict Code: TA - Therapeutic Appropriateness
Drugs/Disease

Util A	Util B	Util C
Quetiapine	Substance Abuse	

References:
Seroquel Prescribing Information, July 2007, AstraZeneca. Pharmaceuticals LP.
Pharmacist's Letter, Seroquel (Quetiapine) Abuse, October 2007 #ISSN #0883-0371.
Pierre JM, Shnayder I, Wirshing DA, et al., Intranasal Quetiapine Abuse, Am J Psychiatry Sept 2004, 161(9):1718.
Reeves RR, Brister JC. Additional Evidence of the Abuse of Potential of Quetiapine, South Med J 2007;100(8):834-6.

Recommendations	*Approved*	*Rejected*

4. Codeine / Pregnancy _____ _____

Alert Message: Nursing infants may be at an increased risk of morphine overdose if their mothers are taking codeine-containing products and are ultra-rapid metabolizers of codeine. If codeine use is necessary in nursing mothers prescribe the lowest effective dose for the shortest amount of time. Inform mothers receiving codeine of the potential risks and signs of morphine overdose in themselves and their infants.
Conflict Code: MC – Drug (Actual) Disease Precaution
Drugs/Disease

Util A	Util B	Util C (Negating)
Codeine	Pregnancy	Miscarriage
	Lactation	Abortion

References:
FDA Public Health Advisory: Use of Codeine by some Breastfeeding Mothers may lead to Life-threatening Side Effects in Nursing Babies. August 17, 2007. Available at: http://www.fda.gov/cder/drug/advisory/codeine.htm

5. Haloperidol / Therapeutic Appropriateness _____ _____

Alert Message: Higher doses and intravenous administration of haloperidol appear to be associated with an increased risk of QT prolongation, torsades de pointes and even sudden death. Particular caution is advised when prescribing haloperidol to patients with predisposing factors (e.g., cardiac abnormalities, hypothyroidism and electrolyte imbalance) that could cause an even greater risk of these serious adverse effects.
Conflict Code: TA – Therapeutic Appropriateness
Drugs/Disease

Util A	Util B	Util C (Negating)
Haloperidol		

Criterion will hit on patients receiving higher doses (8mg.day or above).

References:
MedWatch The FDA Safety Information and Adverse Event Reporting Program, 2007.

6. Haloperidol / Over utilization _____ _____

Alert Message: Haloperidol may be over-utilized. The recommended maximum dose is 100 mg per day. Exceeding this dose may enhance the risk of adverse effects (e.g., QT prolongation, torsades de pointes, extrapyramidal symptoms, seizures, and hypertension).
Conflict Code: HD – High Dose
Drugs/Disease

Util A	Util B	Util C (Negating)
Haloperidol		

Mas Dose: 100 mg/day

References:
Facts & Comparisons, 2007 Updates.
Clinical Pharmacology, Gold Standard, 2007.
MedWatch The FDA Safety Information and Adverse Event Reporting Program, 2007.