DUR Board Meeting
March 12th, 2007
Radisson Hotel
Manhattan Room
1pm

HEALTH INFORMATION DESIGNS

January 12th, 2007

The next North Dakota Drug Utilization Review (DUR) Board Meeting will be held March 12th, 2007 at 1:00pm

Radisson Hotel
Manhattan Room
605 East Broadway Ave
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
Radisson Hotel
Manhattan Room
March 12th, 2007
1pm

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

2. Old Business

• Review and approval of minutes of 12/11/06 meeting	Chairman
• Budget update	Brendan
• Chair and Vice-Chair Elections	Brendan
• Yearly review of Antihistamines, COXII/NSAIDs, PPIs, Revatio and Acto*plus* met	HID
• Tablet Splitting Update	HID
• Methadone Utilization	HID
• Name Brand Mandate (Wellbutrin XL)	Brendan

3. New Business

• Hepatitis C product adherence review	HID
• Ophthalmic Antihistamines Review	HID
• Qualaquin Review	HID
• Criteria Recommendations	Brendan
• Legislation Update	Brendan
• Upcoming meeting date/agenda June 4th, 2007	Chairman
• Executive Session-review Provigil profiles	

4. Adjourn — Chairman

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

Drug Utilization Review (DUR) Meeting Minutes
December 11th, 2006

Members Present: Albert Samuelson, John Savageau, Patricia Churchill, Cheryl Huber, Leann Ness, Norman Byers, Carlotta McCleary, Carrie Sorenson, and Bob Treitline.

Medicaid Pharmacy Department: Brendan Joyce, Gary Betting

HID Staff Present: Candace Rieth

Members Absent: Scott Setzepfandt, and Todd Twogood

Chairman, J. Savageau, called the meeting to order at 1:03pm. He asked for a motion to approve the minutes from the November 13th, 2006 meeting. N. Byers moved that the minutes be approved and B. Treitline seconded the motion. The chair called for a voice vote to approve the minutes, which passed with no audible dissent.

Budget Update:
B. Joyce reported that there was no updated budget information, at this time.

Review of Oxycontin
Since Oxycontin became available generically, the number of patients, tablets and scripts each has decreased. Recent court rulings will remove the generic product from the market. The Department would like to implement a prior authorization status for Oxycontin to ensure appropriate utilization and avoid questionable brand utilization increases. B. Joyce stated that one function of the DUR Board is to address abuse potential within Medicaid. At this time, the other sustained release opioids do not exhibit inappropriate utilization. C. Huber suggested that a pain contract not be required for a prior authorization of Oxycontin. J. Savageau suggested that cancer pain be included as criteria for coverage of Oxycontin. A. Samuelson believes that a prior authorization on Oxycontin will be a deterrent of the product to the street market. A Samuelson also asked the State to review Methadone data. There was no public comment. At the November DUR meeting, a motion and second was made to place Oxycontin on prior authorization. This motion was amended to include cancer diagnoses as criteria and to remove the pain contract request. A voice vote was taken with no audible dissent. Motion passed.

Review of Oracea and Solodyn
C. Rieth reviewed Oracea and Solodyn. These are two new extended release formulations of tetracyclines that were approved by the FDA in May 2006. At this time, there is no evidence that Oracea and Solodyn are superior to their generic counterparts for treating acne or rosacea. There was no public comment. A motion and second were made at the November meeting to prior authorize Oracea and Solodyn. A voice vote was taken with no audible dissent. Motion passed.

Review of Exubera
B. Joyce reviewed Exubera. Exubera is an inhaled short acting recombinant regular insulin product indicated for the treatment of diabetes mellitus in adults. At the November meeting, the Board made no recommendation for prior authorization of Exubera. B. Joyce had one paid claim and profile to share with the Board. The profile exhibited inappropriate utilization of Exubera. The Department will watch Exubera utilization and bring the information to the Board if inappropriate utilization continues.

Yearly Review of Prior Authorization and Zanaflex capsules
B. Joyce reviewed the PA response data with the Board. From January 1, 2006 through November 30, 2006, 1,966 prior authorizations were processed. Of these, 1,858 were responded to in less than 8 hours. This is 94.51% of the claims, with 5.49% (108) with a response rate between 8 and 24 hours. C. Rieth reviewed Zanaflex capsule 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. The Board reviewed the information and no action was taken. There will be no changes to the Zanaflex capsule prior authorization.

Tablet Splitting Initiative
C. Rieth reviewed tablet splitting data that shows a significant savings if a tablet splitting initiative were implemented. Currently, the State provides a monetary incentive to pharmacies that split tablets. B. Treitline suggested that the Department send letters to physicians and pharmacies asking for assistance with tablet splitting. B. Joyce stated that letters have been sent in the past with no significant changes. C. Huber asked if a patient incentive could be offered. B. Joyce said that he would discuss this with CMS and see if removing the copay on these prescriptions would be allowed. C. Rieth stated that in South Dakota, the state began a tablet splitting initiative with the statin class of medications and that the Department is reimbursing pharmacies for tablet splitters. B. Joyce said that a pharmacy incentive has been tried, that letters have been mailed and he asked that the Board give more suggestions regarding tablet splitting.

Criteria Recommendations
The enclosed recommended RDUR criteria are 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 RDUR cycles. B. Treitline moved to approve the new criteria and C. Huber seconded the motion. The motion was approved by voice vote with no audible dissent

The next DUR board meeting will be March 12th, 2007. C. Huber made a motion to adjourn the meeting and A. Samuelson seconded. Chair J. Savageau adjourned the meeting at 2:00 pm.

HEALTH INFORMATION DESIGNS

Prior Authorization Vendor for ND Medicaid

Antihistamine PA Form

Clear Fields

Fax Completed Form to:
866-254-0761 or 334-321-2199
For questions regarding this prior authorization, call
866-773-0695 or 334-321-0268

North Dakota Medicaid requires that patients receiving antihistamines must use **Loratadine*** as first line.

***Note:**

- **Loratadine OTC may be prescribed WITHOUT prior authorization. Loratadine OTC is covered by Medicaid when prescribed by a physician.**
- **Prior authorization is NOT required for patients < 13 years of age.**
- **Patients must use loratadine OTC for a minimum of 14 days for the trial to be considered a failure. Patient preference does not constitute a failure.**
- **Net cost to Medicaid: Loratadine<<<Zyrtec<Clarinex<Allegra.**

Part I: TO BE COMPLETED BY PHYSICIAN - *COMPLETE PART I AND FAX TO PATIENT'S PHARMACY*

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: ☐ Allegra ☐ Clarinex ☐ Zyrtec	Diagnosis for this request	Requested Dosage (must be completed)	

Qualifications for coverage:

☐ Failed Loratadine	Start Date	End Date	Dose	Frequency
☐ Adverse reaction (attach FDA Medwatch form) to loratadine or contraindicated: (provide description below)				
☐ Diagnosis of Urticaria				
☐ *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 - *COMPLETE PART II AND FAX TO NUMBER AT TOP OF FORM*

Pharmacy Name			ND Medicaid Provider Number
Telephone Number	Fax Number	Drug	NDC #

Part III: FOR STATE USE ONLY

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

NORTH DAKOTA MEDICAID
Percentage Market Share Within Sub-Classes
Antihistamine

	FEB 04	OCT 06
All Antihistamine(No Subclass)		
ALLEGRA	25.95	0.22
ALLEGRA-D	0.00	0.00
ALLEGRA-D 12 HOUR	8.65	2.25
ALLEGRA-D 24 HOUR	0.00	0.45
CLARINEX	6.51	1.12
CLARINEX-D 24 HOUR	0.00	0.00
CLARITIN	0.84	2.25
CLARITIN-D 12 HOUR	0.37	0.00
CLARITIN-D 24 HOUR	0.09	1.12
LORATADINE	9.58	51.69
LORATADINE D	0.00	0.00
LORATADINE-D	0.00	0.00
ZYRTEC	42.42	38.88
ZYRTEC-D	5.58	2.02

Class added to PA Mar 2004

HEALTH INFORMATION DESIGNS

Prior Authorization Vendor for ND Medicaid

Brand Name NSAID/COX2 PA Form

Clear Fields

Fax Completed Form to:
866-254-0761 or 334-321-2199
For questions regarding this prior authorization, call
866-773-0695 or 334-321-0268

North Dakota Medicaid requires that patients using brand name NSAIDs or Cox II drugs must use a generic NSAID as first line.

***Note: The PA will be approved if one of the following criteria is met.**

- **Failed two trials of prescribed NSAIDs**
- **Recipient is 65 years old**
- **Recipient has history of gastric or duodenal ulcer or has comorbidity of GI bleed, perforation or obstruction**
- **Recipient has history of endoscopically documented NSAID induced gastritis with GI bleed**
- **Recipient is on warfarin or corticosteroid 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:	**Requested Dosage**	**Diagnosis for the request**	
☐ Celebrex		☐ Warfarin/Corticosteroid therapy	☐ GI Bleed, perofration or obstruction
		☐ Gastric or duodenal ulcer	☐ Endoscopically documented NSAID gastritis with GI bleed

Qualifications for coverage:

☐ Failed NSAID therapy	Start Date	End Date	Dose	Frequency
☐ Failed NSAID 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.*				
Physician Signature			Date	

Part II: TO BE COMPLETED BY PHARMACY

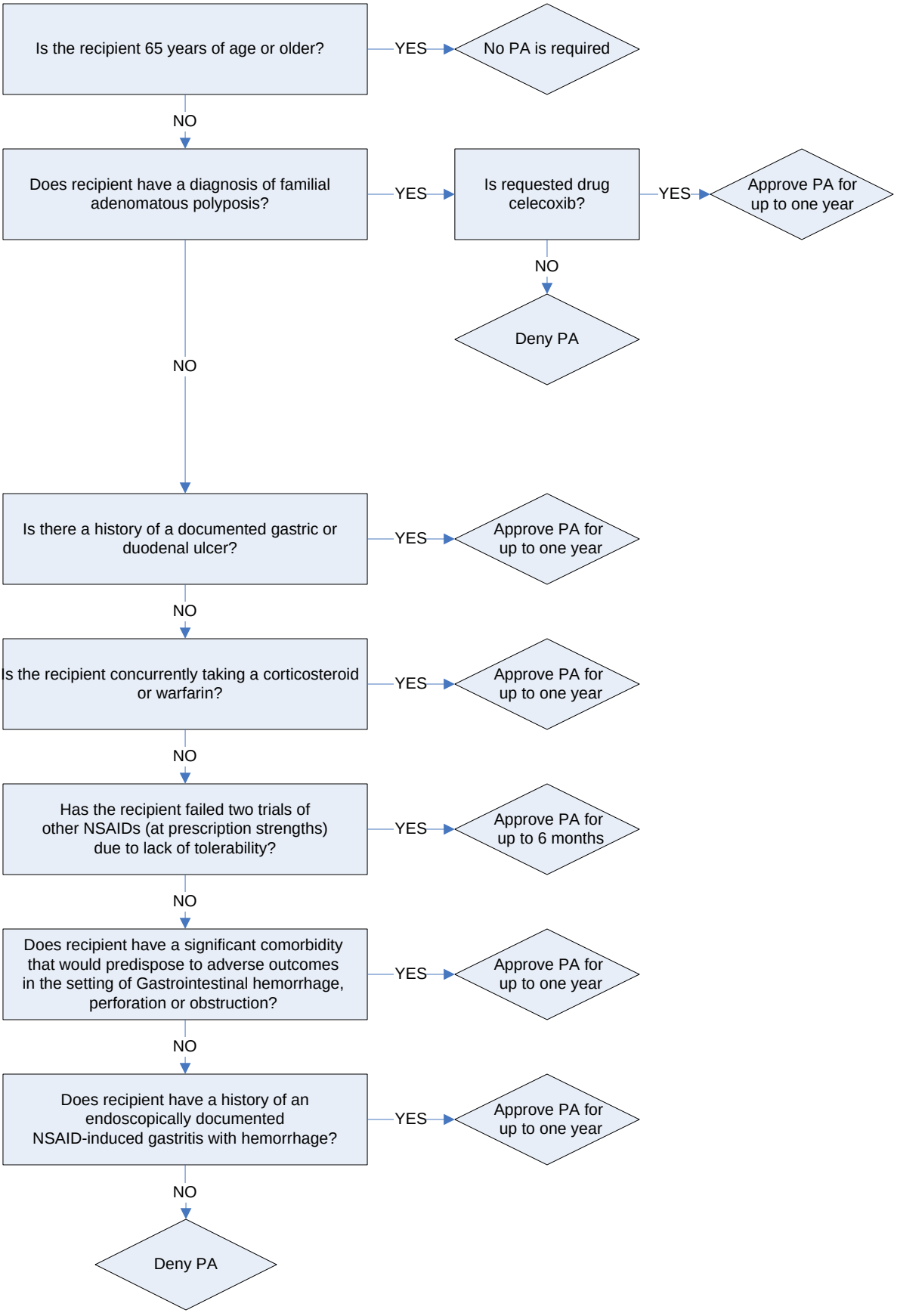
Pharmacy Name			ND Medicaid Provider Number
Telephone Number	Fax Number	Drug	NDC #

Part III: FOR STATE USE ONLY

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

North Dakota Department of Human Services

Cox-2 Inhibitor Authorization Criteria Algorithm



NORTH DAKOTA MEDICAID
Percentage Market Share Within Sub-Classes
NSAIDS/COXII

	FEB 04	FEB 05	OCT 06
All NSAIDS/COXII (No Subclass)			
ARTHROTEC 50	0.68	0.84	0.00
ARTHROTEC 75	0.47	0.74	0.23
BEXTRA	13.95	15.03	0.00
CELEBREX	30.08	28.59	4.08
CLINORIL	0.00	0.00	0.00
DICLOFENAC POTASSIUM	0.64	1.29	3.74
DICLOFENAC SODIUM	0.77	1.88	5.33
DIFLUNISAL	0.04	0.20	0.00
DOLOBID	0.00	0.00	0.00
EC-NAPROSYN	0.00	0.00	0.00
ETODOLAC	0.60	1.38	1.59
FELDENE	0.00	0.00	0.00
FENOPROFEN CALCIUM	0.00	0.00	0.00
FLURBIPROFEN	0.09	0.74	0.79
FLURBIPROFEN SODIUM	0.00	0.00	0.00
HYDROCODONE BIT-IBUPROFEN	3.00	3.41	7.37
IBUPROFEN	16.99	23.59	41.16
IBUPROFEN CHILD	0.00	0.00	0.00
IBUPROFEN IB	0.00	0.00	0.11
IBUPROFEN INFANT	0.00	0.05	0.11
IBUPROFEN M	0.00	0.00	0.00
IBUPROFEN PMR	0.00	0.00	0.00
INDOCIN	0.00	0.00	0.00
INDOCIN SR	0.00	0.00	0.00
INDOMETHACIN	1.41	1.68	1.81
KETOPROFEN	1.67	1.83	1.70
KETOROLAC TROMETHAMINE	2.05	1.73	3.17
LODINE	0.00	0.00	0.00
LODINE XL	0.00	0.00	0.00
MECLOFENAMATE SODIUM	0.04	0.20	0.68
MECLOMEN	0.00	0.00	0.00
MOBIC	0.86	3.21	0.68
MOTRIN	0.81	0.49	2.15
MOTRIN IB	0.00	0.00	0.00
MOTRIN MIGRAINE	0.00	0.00	0.00
NABUMETONE	1.63	3.02	3.74
NAPRELAN	0.00	0.00	0.00
NAPROSYN	0.17	0.10	0.00
NAPROXEN	5.13	6.53	16.67
NAPROXEN SODIUM	0.94	1.04	1.13
OXAPROZIN	0.39	0.49	0.68
PIROXICAM	0.26	0.84	1.59
PONSTEL	0.04	0.10	0.45
RELAFEN	0.04	0.00	0.00
SULINDAC	0.56	0.54	0.91
TOLECTIN 200	0.00	0.00	0.00

Class added to PA Mar 2005

TOLECTIN 600	0.00	0.00	0.00
TOLECTIN DS	0.00	0.00	0.00
TOLMETIN SODIUM	0.17	0.05	0.00
TORADOL	0.00	0.00	0.00
VICOPROFEN	0.34	0.10	0.00
VIOXX	15.92	0.00	0.00
VOLTAREN	0.26	0.30	0.11
VOLTAREN-XR	0.00	0.00	0.00

Class added to PA Mar 2005

HEALTH INFORMATION DESIGNS

Prior Authorization Vendor for ND Medicaid

Proton Pump Inhibitor PA Form

Clear Fields

Fax Completed Form to:
866-254-0761 or 334-321-2199
For questions regarding this prior authorization, call
866-773-0695 or 334-321-0268

North Dakota Medicaid requires that patients receiving proton pump inhibitors must use **Prilosec OTC*** as first line.

*Note:

- **Prilosec OTC may be prescribed WITHOUT prior authorization. Prilosec OTC is covered by Medicaid when prescribed by a physician.**
- **Prior Authorization is NOT required for patients < 13 years of age.**
- **Patients must use Prilosec OTC for a minimum of 14 days for the trial to be considered a failure. Patient preference does not constitute a failure.**
- **Net cost to Medicaid: Prilosec OTC <<< Protonix < Prevacid < Omeprazole << Aciphex < Prilosec RX << Nexium.**

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:

☐ Protonix ☐ Aciphex ☐ Prevacid
☐ Nexium ☐ Prilosec

Requested Dosage (must be completed)

Diagnosis for this request

Qualifications for coverage:

☐ Failed omeprazole OTC	Start Date	End Date	Dose	Frequency

☐ Adverse Reaction to omeprazole OTC (attach FDA Medwatch form) or Contraindicated: (provide description below)

☐ Pregnancy - Due Date:

☐ Inability to take or tolerate oral tablets (must check a box below)

- ☐ Tube Fed
- ☐ Requires soft food or liquid administration
- ☐ Other (provide description)

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

Physician Signature	Date

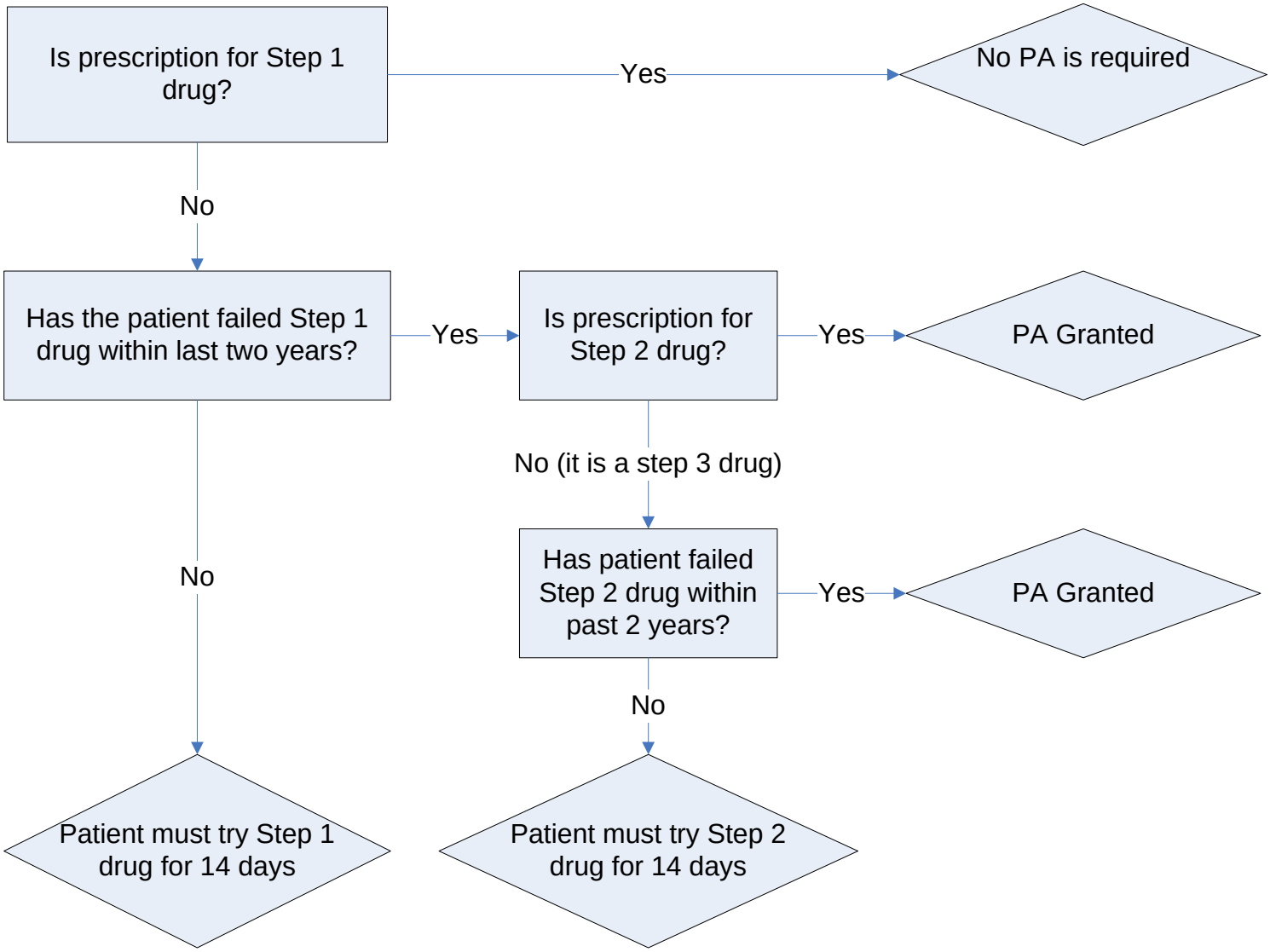
Part II: TO BE COMPLETED BY PHARMACY - *COMPLETE PART II AND FAX TO NUMBER AT TOP OF PAGE*

Pharmacy Name			ND Medicaid Provider Number
Telephone Number	Fax Number	Drug	NDC #

Part III: FOR STATE USE ONLY

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

North Dakota Department of Human Services
Proton Pump Inhibitor Authorization Criteria Algorithm



Please Note:

Step 1 drug is defined as Prilosec OTC

Step 2 drug is defined as Protonix, Prevacid (which is 3 times more expensive)

Step 3 drug is defined as Nexium, Aciphex (which is 5-8 times more expensive)

NORTH DAKOTA MEDICAID
Percentage Market Share Within Sub-Classes
Proton Pump Inhibitors

	FEB 04	OCT 06
All Proton Pump Inhibitors(No Subclass)		
ACIPHEX	4.93	2.76
NEXIUM	12.23	4.51
NEXIUM I.V.	0.00	0.00
OMEPRAZOLE	8.29	7.27
PREVACID	23.88	14.66
PREVACID IV	0.00	0.00
PRILOSEC	2.06	0.00
PRILOSEC OTC	20.88	62.53
PROTONIX	27.73	8.27
PROTONIX IV	0.00	0.00

Class added to PA Mar 2004

HEALTH INFORMATION DESIGNS

Prior Authorization Vendor for ND Medicaid

Revatio PA Form

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 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) **Diagnosis for this request:**

Qualifications for coverage:

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

Physician Signature: Date:

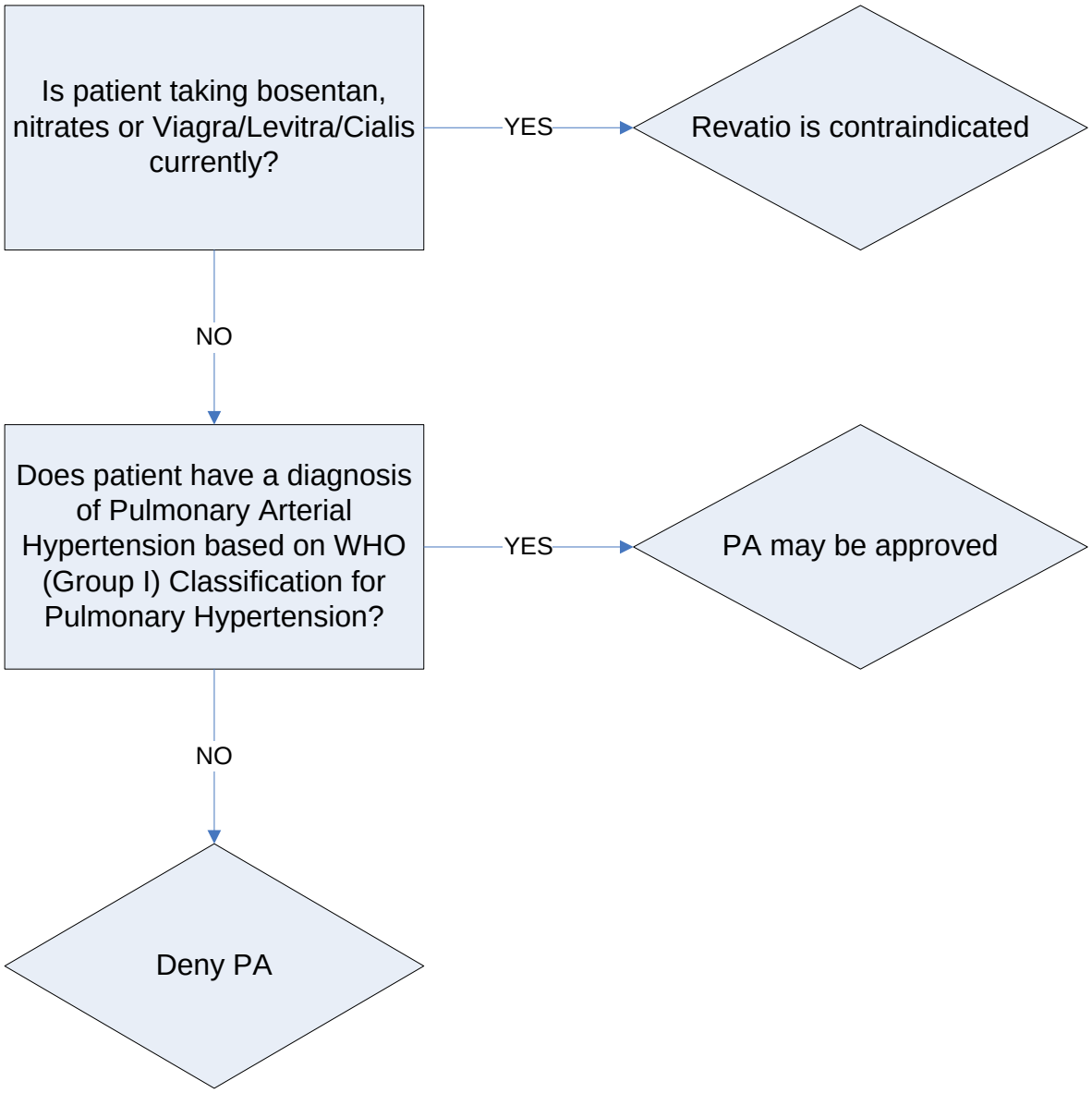
Part II: TO BE COMPLETED BY PHARMACY

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
Revatio Authorization Algorithm



HEALTH INFORMATION DESIGNS

Prior Authorization Vendor for ND Medicaid

ACTO*plus* met PA Form

Clear Fields

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:

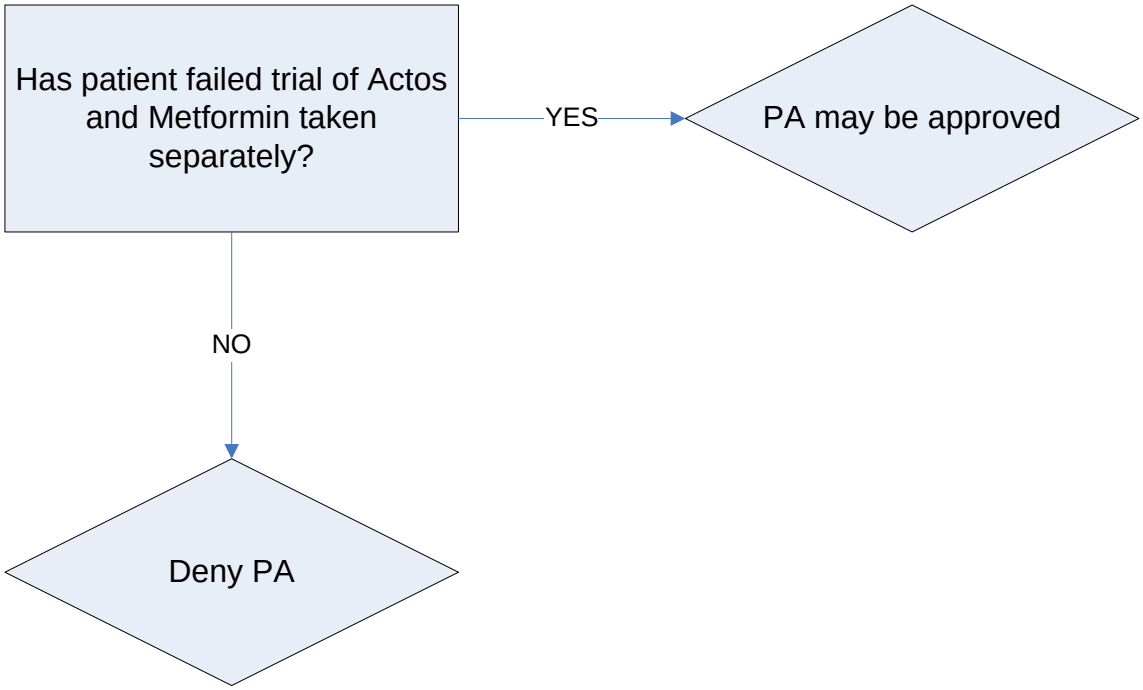
Part II: TO BE COMPLETED BY PHARMACY

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



NORTH DAKOTA MEDICAID
Cost Avoidance Review

PA Class	Implementation Date	Cost Avoidance* Through Dec-05	Cost Avoidance** January 2006 Through October 2006	Total Cost Avoidance
Antihistamine	Mar-04	$620,619	$275,756	$896,375
Proton Pump Inhibitors	Mar-04	$2,315,836	$513,537	$2,829,373
NSAIDS/COXII	Mar-05	$178,655	$203,433	$382,088
ACE Inhibitors	May-05	-$18,880	$10,336	-$8,544
ARBS	Sep-05	$48,095	$71,702	$119,797
Sedative/Hypnotics	Jun-06	Not Implemented	$20,209	$20,209
All Classes		$3,144,325	$1,094,973	$4,239,298

***Cost Avoidance through December 2005 was calculated as follows: 1) Pre PA Actual Costs were projected using a linear trend line based on the actual cost for the most recent 12 months prior to the implementation of the PA; 2) Post PA Actual Costs were subtracted from the projection in (1) for each month after the implementation of the PA; 3) Cost Avoidance through December 2005 is the sum of the differences calculated in (2) for the months after PA implementation.**

****Cost Avoidance January 2006 through October 2006 was calculated by deducting the official state percentage of Part D recipients from the actual data through December 2005 then use the following: 1) Pre PA Actual Costs were projected using a linear trend line based on the actual cost for the most recent 12 months prior to the implementation of the PA; 2) Post PA Actual Costs were subtracted from the projection in (1) for each month after the implementation of the PA; 3) Cost Avoidance January 2006 through October 2006 is the sum of the differences calculated in (2) for the months after PA implementation.**

Cost Savings-Tablet Splitting
01/01/06-06/30/06

Name of Drug	Number of tablets dispensed	Total Cost	Cost Savings
Zoloft 25mg	3714	$8,911.33	
Zoloft 50mg (1/2 tab)	1857	$4,698.21	$4,213.12
Zoloft 50mg	19199	$48,659.12	
Zoloft 100mg (1/2 tab)	9599	$23,901.51	$24,757.61
Lexapro 5mg	180	$431.17	
Lexapro 10mg (1/2 tab)	90	$207.00	$224.17
Lexapro 10mg	21842	$50,225.55	
Lexapro 20mg (1/2 tab)	10921	$26,756.45	$23,469.10
Crestor 5mg	1560	$4,267.80	
Crestor 10mg (1/2 tab)	780	$2,254.20	$2,013.60
Crestor 10mg	6848	$19,762.58	
Crestor 20mg (1/2 tab)	3424	$10,100.80	$9,661.78
Crestor 20mg	2283	$6,731.02	
Crestor 40mg (1/2 tab)	1142	$3,437.42	$3,293.60
Lipitor 10mg	20963	$49,813.56	
Lipitor 20mg (1/2 tab)	10481	$35,320.97	$14,492.59
Lipitor 20mg	13934	$46,967.93	
Lipitor 40mg (1/2 tab)	6967	$26,056.58	$20,911.35
Lipitor 40mg	6162	$21,225.32	
Lipitor 80mg (1/2 tab)	3081	$10,136.49	$11,088.83
Zocor 10mg	721	$1,708.41	
Zocor 20mg (1/2 tab)	360	$1,461.60	$246.81
Zocor 20mg	4417	$17,922.51	
Zocor 40mg (1/2 tab)	2208	$9,648.96	$8,273.55
Zocor 40mg	4355	$19,046.48	
Zocor 80mg (1/2 tab)	2177	$10,014.20	$9,032.28
Toprol XL 25mg	4236	$3,892.81	
Toprol XL 50mg (1/2 tab)	2118	$1,736.76	$2,156.05
Toprol XL 50mg	7061	$5,791.02	
Toprol XL 100mg (1/2 tab)	3530	$4,306.60	$1,484.42

Toprol XL 100mg	4786	$5,828.18	
Toprol XL 200mg (1/2 tab)	2393	$4,474.91	$1,353.27
Provigil 100mg	1288	$6,646.16	
Provigil 200mg (1/2 tab)	644	$4,565.96	$2,080.20

Annualized Cost Savings

Zoloft	$57,941.46
Lexapro	$47,386.54
Crestor	$29,937.96
Lipitor	$92,985.54
Zocor	$35,105.28
Toprol	$9,987.48
Provigil	$4,160.40
Total	$277,504.66

HEALTH INFORMATION DESIGNS

2006 Methadone Utilization

NDC USAGE for nd_methadone from 01/01/06 to 11/27/06 for Program All				
NDC Code	**Rx Num**	**Qty Dispensed**	**Total Claim Cost**	**Label Name**
54355563	1	10	$1.67	METHADONE 5 MG/5 ML SOLUTION
54457025	53	2814	$631.26	METHADONE HCL 5 MG TABLET
54457125	371	46918	$10,951.71	METHADONE HCL 10 MG TABLET
54855424	1	56	$11.79	METHADONE HCL 10 MG TABLET
406054034	17	1048	$447.57	METHADOSE 40 MG TABLET DISPR
406345434	192	22547	$4,802.37	METHADOSE 10 MG TABLET
406575501	3	183	$34.40	METHADONE HCL 5 MG TABLET
406577101	132	15243	$3,046.60	METHADONE HCL 10 MG TABLET
406697434	27	2205	$385.59	METHADOSE 5 MG TABLET
TOTAL	797	91024	$20,312.96	
139 Patients				
94 Physicians				

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Wellbutrin Memo to Pharmacies

The DUR Board recently voted that ND Medicaid should prior authorize generics when they are significantly more expensive than their brand counterparts (net of rebates to the state). The DUR Board wants the Department to spend their funds in the most efficient way possible and they also feel that the ND Medicaid pharmacy providers have proven to be excellent partners in cost saving initiatives.

Since the Wellbutrin XL generics are currently significantly more expensive to Medicaid than the brand, ND Medicaid will prior authorize the generic. Also, since ND Medicaid considers the less expensive product a 'generic'for co-pay determination (much like Septra DS and other brands that are used as generics), there will be no co-pay on Wellbutrin XL 300 mg until the pricing difference between the two changes and the generic is less expensive.

Brendan K. Joyce, PharmD
Administrator, Pharmacy Services
North Dakota Department of Human Services Phone 701-328-4023 Fax 701-328-1544

Hepatitis C Agents

NDC USAGE for nd_hepatitis C from 01/01/04 to 11/27/06 for Program All			
Rx Num	**Qty Dispensed**	**Total Claim Cost**	**Label Name**
1	84	$189.99	RIBAVIRIN 200 MG CAPSULE
1	42	$491.80	REBETOL 200 MG CAPSULE
3	3	$1,172.40	PEG-INTRON REDIPEN 150 MCG
2	240	$1,677.38	RIBAVIRIN 200 MG TABLET
2	300	$2,513.98	RIBAVIRIN 200 MG CAPSULE
2	224	$2,528.45	REBETOL 200 MG CAPSULE
2	252	$2,700.05	REBETOL 200 MG CAPSULE
4	504	$3,071.80	RIBASPHERE 200 MG CAPSULE
5	17	$7,116.96	PEG-INTRON 150 MCG KIT
6	672	$4,061.22	RIBASPHERE 200 MG CAPSULE
8	32	$13,158.20	PEG-INTRON REDIPEN 150 MCG 4PK
8	991	$7,789.03	RIBAVIRIN 200 MG TABLET
4	16	$8,663.97	PEG-INTRON REDIPEN 120 MCG
6	900	$7,527.60	RIBAVIRIN 200 MG TABLET
9	1260	$7,788.60	RIBAVIRIN 200 MG CAPSULE
10	1480	$10,666.80	RIBASPHERE 200 MG CAPSULE
14	1568	$9,905.55	RIBAVIRIN 200 MG CAPSULE
9	35	$14,287.35	PEG-INTRON 80 MCG KIT
10	39	$15,649.59	PEG-INTRON REDIPEN 80 MCG
10	40	$20,731.35	PEG-INTRON REDIPEN 120 MCG 4PK
19	3136	$32,333.98	RIBAVIRIN 200 MG CAPSULE
22	3267	$36,084.09	REBETOL 200 MG CAPSULE
29	4690	$39,506.01	RIBAVIRIN 200 MG CAPSULE
23	23	$38,292.83	PEGASYS 180 MCG/ML CONV.PACK
36	100	$40,591.53	PEGASYS 180 MCG/ML VIAL
35	138	$58,504.91	PEG-INTRON 120 MCG KIT
80	11958	$107,943.47	COPEGUS 200 MG TABLET
116	128	$224,478.36	PEGASYS 180 MCG/0.5 ML CONV.PK
476	32139	$719,427.25	

Patient compliance with Hepatitis C Agents

Dispensed	Rx Number	Patient PCN	Rx Provider #	Prescribing Physician	Qty Dispensed	Days Supply	Reimburse Amount
7/15/2005	823768	A	20121	18006	4	28	$1,466.58
8/8/2005	823768		20121	18006	4	28	$1,466.58
9/8/2005	823768		20121	18006	4	28	$1,466.58
9/30/2005	836473		20121	18006	4	28	$1,466.58
10/24/2005	836473		20121	18006	4	28	$1,466.58
7/15/2005	823766		20121	18006	168	34	$1,005.20
8/25/2005	823766		20121	18006	168	34	$1,005.20
9/28/2005	823766		20121	18006	112	22	$672.00
2/2/2006	823701	B	20914	18517	1	28	$1,608.46
3/8/2006	823701		20914	18517	1	28	$1,608.46
4/7/2006	823701		20914	18517	1	28	$1,688.81
5/5/2006	823701		20914	18517	1	28	$1,688.81
5/30/2006	823701		20914	18517	1	28	$1,688.81
6/24/2006	823701		20914	18517	1	28	$1,688.81
7/22/2006	823701		20914	18517	1	28	$1,688.81
8/20/2006	823701		20914	18517	1	28	$1,688.81
2/2/2006	823702		20914	18517	154	30	$921.90
3/8/2006	823702		20914	18517	154	30	$921.90
4/7/2006	823702		20914	18517	168	34	$1,005.20
5/5/2006	823702		20914	18517	154	34	$921.90
6/2/2006	823702		20914	18517	168	30	$1,005.20
7/10/2006	823702		20914	18517	168	33	$1,005.20
8/9/2006	823702		20914	18517	154	33	$921.90
10/6/2006	166218	C	21101	11191	1	28	$1,688.81
10/6/2006	166217		21101	11191	120	30	$900.44
4/7/2005	838518	D	20090	16003	112	28	$768.33
5/2/2005	838518		20090	16003	112	28	$844.24
5/31/2005	838518		20090	16003	112	28	$844.24
6/27/2005	843329		20090	16003	112	28	$844.24
7/21/2005	843329		20090	16003	112	28	$886.38
8/22/2005	843329		20090	16003	112	28	$886.38
4/7/2005	838519		20090	16003	4	28	$1,517.52
5/2/2005	840239		20090	16003	1	28	$1,517.52
5/31/2005	840239		20090	16003	1	28	$1,517.52
6/27/2005	843330		20090	16003	1	28	$1,517.52
7/29/2005	843330		20090	16003	1	28	$1,517.52
8/22/2005	843330		20090	16003	1	28	$1,517.52
11/17/2006	882058	E	20145	11978	4	28	$1,716.62
11/17/2006	882059		20145	11978	168	28	$1,258.37
1/6/2004	750745	F	20079	12707	168	28	$339.38
1/27/2004	750745		20079	12707	168	28	$339.38
1/6/2004	752611		20079	12707	4	26	$298.59
1/27/2004	752611		20079	12707	4	25	$44.45

Patient compliance with Hepatitis C Agents

2/23/2004	796487	G	20656	14441	168	28	$1,006.49
3/23/2004	796487		20656	14441	168	28	$1,006.49
4/20/2004	796487		20656	14441	168	28	$1,056.74
5/20/2004	796487		20656	14441	168	28	$1,056.74
6/16/2004	796487		20656	14441	168	28	$1,056.74
7/14/2004	796487		20656	14441	168	28	$1,056.74
8/11/2004	796487		20656	14441	168	28	$1,056.74
9/8/2004	796487		20656	14441	168	28	$1,056.74
10/6/2004	796487		20656	14441	168	28	$1,056.74
11/2/2004	796487		20656	14441	168	28	$1,151.70
12/2/2004	796487		20656	14441	168	28	$1,151.70
1/5/2005	830375		20656	14441	168	28	$1,151.70
1/27/2005	830375		20656	14441	168	28	$1,151.70
2/23/2004	796486		20656	14441	1	28	$1,376.58
3/23/2004	796486		20656	14441	1	28	$1,376.58
4/20/2004	796486		20656	14441	1	28	$1,376.58
5/20/2004	796486		20656	14441	1	28	$1,445.33
6/17/2004	796486		20656	14441	1	28	$1,445.33
7/14/2004	796486		20656	14441	1	28	$1,445.33
8/13/2004	815165		20656	14441	1	28	$1,445.33
9/9/2004	815165		20656	14441	1	28	$1,445.33
10/6/2004	815165		20656	14441	1	28	$1,445.33
11/2/2004	815165		20656	14441	1	28	$1,517.52
12/2/2004	815165		20656	14441	1	28	$1,517.52
12/29/2004	815165		20656	14441	1	28	$1,517.52
1/27/2005	830374		20656	14441	1	28	$1,517.52

9/13/2006	708323	H	20680	18517	1	28	$1,688.81
10/9/2006	708323		20680	18517	1	28	$1,688.81
11/8/2006	708323		20680	18517	1	28	$1,688.81
9/13/2006	708324		20680	18517	210	30	$1,255.10
10/9/2006	708324		20680	18517	210	30	$1,255.10
11/8/2006	708324		20680	18517	210	30	$1,255.10

10/4/2004	859063	I	21174	12486	1	30	$1,231.33
11/3/2004	859063		21174	12486	1	30	$1,246.52
11/29/2004	859063		21174	12486	1	30	$1,517.52
1/3/2005	859063		21174	12486	1	30	$1,227.52
1/27/2005	859063		21174	12486	1	30	$1,517.52
2/24/2005	859063		21174	12486	1	30	$1,517.52
3/31/2005	859063		21174	12486	1	30	$1,517.02
4/25/2005	859063		21174	12486	1	30	$1,517.52
6/1/2005	859063		21174	12486	1	30	$1,227.52
6/27/2005	859063		21174	12486	1	30	$1,517.52
7/21/2005	859063		21174	12486	1	30	$1,453.57
10/4/2004	859061		21174	12486	120	30	$715.60
11/29/2004	859061		21174	12486	120	30	$715.60
2/8/2005	859061		21174	12486	120	30	$429.60
4/20/2005	859061		21174	12486	120	30	$459.30
6/21/2005	859061		21174	12486	120	30	$719.60

Patient compliance with Hepatitis C Agents

2/10/2005	824931	J	20145	11978	4	28	$1,466.58
3/8/2005	824931		20145	11978	4	28	$1,466.58
4/12/2005	824931		20145	11978	4	28	$1,466.58
5/3/2005	824931		20145	11978	4	28	$1,466.58
5/31/2005	824931		20145	11978	4	28	$1,466.58
6/28/2005	824931		20145	11978	4	28	$1,466.58
7/18/2005	824931		20145	11978	4	28	$1,466.58
8/15/2005	824931		20145	11978	4	28	$1,466.58
9/15/2005	824931		20145	11978	4	28	$1,466.58
10/11/2005	824931		20145	11978	4	28	$1,466.58
11/8/2005	824931		20145	11978	4	28	$1,466.58
12/8/2005	824931		20145	11978	4	28	$1,466.58
1/11/2006	854016		20145	11978	4	28	$1,554.46
2/10/2005	824932		20145	11978	112	28	$672.00
3/8/2005	824932		20145	11978	112	28	$672.00
4/12/2005	824932		20145	11978	112	28	$672.00
5/10/2005	824932		20145	11978	112	28	$672.00
6/9/2005	824932		20145	11978	112	28	$672.00
7/7/2005	824932		20145	11978	112	28	$672.00
8/8/2005	824932		20145	11978	112	28	$672.00
9/6/2005	824932		20145	11978	112	28	$672.00
10/7/2005	824932		20145	11978	112	28	$672.00
11/7/2005	824932		20145	11978	112	28	$672.00
12/6/2005	824932		20145	11978	112	28	$672.00
1/2/2006	824932		20145	11978	112	28	$672.00
2/1/2006	855970		20145	11978	112	28	$672.00

6/20/2005	836279	K	20145	11640	4	28	$1,466.58
7/18/2005	836279		20145	11640	4	28	$1,466.58
8/15/2005	836279		20145	11640	4	28	$1,466.58
9/19/2005	836279		20145	11640	4	28	$1,466.58
10/24/2005	836279		20145	11640	4	28	$1,466.58
11/15/2005	836279		20145	11640	3	21	$1,100.34
6/20/2005	836286		20145	11640	140	28	$838.60
7/21/2005	836286		20145	11640	140	28	$838.60
8/23/2005	836286		20145	11640	140	28	$838.60
9/22/2005	836286		20145	11640	140	28	$838.60
10/24/2005	836286		20145	11640	140	28	$838.60

3/22/2006	857726	L	20121	13181	4	28	$1,554.46
4/24/2006	876257		20121	13181	4	28	$1,632.08
5/25/2006	882413		20121	13181	4	28	$1,632.08
7/12/2006	884826		20121	13181	4	28	$1,632.08
1/25/2006	857726		20121	13181	4	28	$1,554.47
2/22/2006	857726		20121	13181	4	28	$1,554.47
1/25/2006	857728		20121	13181	140	28	$838.60
2/22/2006	857728		20121	13181	140	28	$838.60
3/22/2006	857728		20121	13181	140	28	$838.60
4/24/2006	857728		20121	13181	140	28	$838.60
5/24/2006	857728		20121	13181	140	28	$838.60

Patient compliance with Hepatitis C Agents

7/12/2006	857728		20121	13181	140	28	$838.60

1/20/2006	629167	M	20176	18006	3	21	$221.37
1/20/2006	629169		20176	18006	112	28	$145.68

9/9/2005	467081	N	21168	18517	1	28	$1,517.52
10/11/2005	467081		21168	18517	1	28	$1,517.52
11/10/2005	467081		21168	18517	1	28	$1,517.52
12/8/2005	467081		21168	18517	1	28	$1,517.52
1/6/2006	467081		21168	18517	1	28	$1,608.46
2/1/2006	467081		21168	18517	1	28	$1,608.46
9/12/2005	467082		21168	18517	120	30	$719.60
10/11/2005	467082		21168	18517	120	30	$719.60
11/10/2005	467082		21168	18517	120	30	$719.60
12/8/2005	467082		21168	18517	120	30	$719.60
1/6/2006	467082		21168	18517	120	30	$719.60
2/1/2006	467082		21168	18517	120	30	$719.60

3/16/2005	1351852	O	20589	17502	180	30	$1,233.85
4/13/2005	1358891		20589	17502	180	30	$1,233.85
5/9/2005	942518		21149	17502	168	28	$1,265.56
6/13/2005	945367		21149	17502	168	28	$1,265.56
7/7/2005	945367		21149	17502	168	28	$1,265.56
3/18/2005	1353369		20589	17502	4	28	$1,517.52
4/13/2005	1358892		20589	17502	4	28	$1,517.52
5/9/2005	942527		21149	17502	4	28	$1,517.52
6/13/2005	942527		21149	17502	4	28	$1,517.52
7/7/2005	942527		21149	17502	4	28	$1,517.52

1/15/2004	693431	P	20914	11973	4	30	$1,376.58
2/16/2004	697971		20914	11973	1	30	$1,376.58
3/11/2004	697971		20914	18976	1	30	$1,376.58
4/12/2004	697971		20914	18976	1	30	$1,376.58
1/15/2004	686414		20914	11973	120	30	$1,193.69
1/15/2004	686414		20914	11973	84	21	$0.00
3/3/2004	686414		20914	18976	153	34	$1,521.51
3/3/2004	686414		20914	18976	84	21	$0.00
4/9/2004	686414		20914	18976	168	34	$0.00
4/9/2004	706589		20914	18976	140	34	$1,392.37

4/1/2004	6315875	Q	20251	11007	168	30	$1,006.49
4/30/2004	6315875		20251	11007	168	30	$1,056.74
6/1/2004	6315875		20251	11007	168	30	$1,056.74
6/30/2004	6315875		20251	11007	168	30	$1,056.74
8/2/2004	6315875		20251	11007	168	30	$1,056.74
9/20/2004	6324242		20251	11007	168	30	$1,056.74
11/26/2004	6324242		20251	11007	168	30	$1,151.70
4/1/2004	6315874		20251	11007	1	28	$1,376.58
4/30/2004	6315874		20251	11007	1	28	$1,445.33
6/1/2004	6315874		20251	11007	1	28	$1,445.33
6/30/2004	6315874		20251	11007	1	28	$1,445.33

Patient compliance with Hepatitis C Agents

7/29/2004	6315874		20251	11007	1	28	$1,445.33
9/20/2004	6324243		20251	11007	1	28	$1,445.33
11/13/2004	6324243		20251	11007	1	28	$1,445.33

1/16/2004	193435	R	20013	11536	4	30	$1,466.55
1/16/2004	193434		20013	11536	168	30	$1,670.50
8/30/2004	6132393		21025	12486	120	30	$755.27
9/27/2004	6132393		21025	12486	120	30	$755.27
11/3/2004	6132393		21025	12486	120	30	$823.10
11/29/2004	6132393		21025	12486	120	30	$823.10
12/30/2004	6132393		21025	12486	120	30	$823.10
2/22/2005	6132393		21025	12486	120	30	$823.10
3/21/2005	6132393		21025	12486	120	30	$823.10
4/18/2005	6132393		21025	12486	120	30	$823.10
6/8/2005	6132393		21025	12486	120	30	$904.43
8/30/2004	6132392		21025	12486	4	28	$5,714.54
9/27/2004	6132392		21025	12486	4	28	$5,776.50
11/3/2004	6132392		21025	12486	4	28	$6,065.26
11/29/2004	6132392		21025	12486	1	28	$1,517.52
12/30/2004	6132392		21025	12486	1	28	$1,517.52
1/26/2005	6132392		21025	12486	1	28	$1,517.52
2/22/2005	6132392		21025	12486	1	28	$1,517.52
3/21/2005	6132392		21025	12486	1	28	$1,517.52
4/18/2005	6132392		21025	12486	1	28	$1,517.52
5/19/2005	6132392		21025	12486	1	28	$1,517.52
6/17/2005	6132392		21025	12486	1	28	$1,517.52

8/31/2005	201906	S	21264	53168	150	30	$1,186.57
9/28/2005	201906		21264	53168	150	30	$1,186.57
11/3/2005	201906		21264	53168	150	30	$1,245.81
12/7/2005	201906		21264	53168	150	30	$1,245.81
1/4/2006	201906		21339	53168	150	30	$1,245.81
2/2/2006	201906		21339	53168	150	30	$1,245.81
8/31/2005	201905		21264	53168	1	28	$1,517.52
9/28/2005	201905		21264	53168	1	28	$1,517.52
11/1/2005	201905		21264	53168	1	28	$1,517.52
11/29/2005	201905		21264	53168	1	28	$1,517.52
12/27/2005	201905		21264	53168	1	28	$1,608.46
1/20/2006	201905		21339	53168	1	28	$1,608.46

2/16/2004	793570	T	20145	11805	42	28	$418.83
3/11/2004	795556		20145	11805	56	28	$557.90

1/16/2006	819861	U	20914	18517	1	28	$1,608.46
2/22/2006	819861		20914	18517	1	28	$1,608.46
3/3/2006	830100		20914	18517	4	28	$1,480.44
4/6/2006	830100		20914	18517	4	28	$1,554.37
4/30/2006	830100		20914	18517	4	28	$1,554.37
6/1/2006	830100		20914	18517	4	28	$1,554.37
7/3/2006	830100		20914	18517	4	28	$1,554.37
1/16/2006	819859		20914	18517	126	31	$755.30

Patient compliance with Hepatitis C Agents

2/22/2006	819859		20914	18517	126	31	$755.30
4/6/2006	819859		20914	18517	126	31	$755.30
4/30/2006	819859		20914	18517	126	31	$755.30

6/15/2006	854302	V	20012	12141	120	30	$1,095.51
8/3/2006	854302		20012	12141	120	30	$1,095.51
8/29/2006	854302		20012	12141	120	30	$1,095.51
9/26/2006	854302		20012	12141	120	30	$1,095.51
10/30/2006	854302		20012	12141	120	30	$1,095.51
11/27/2006	854302		20012	12141	120	30	$512.80
6/15/2006	854295		20012	12141	1	28	$1,688.81
8/3/2006	854295		20012	12141	1	28	$1,688.81
8/29/2006	854295		20012	12141	1	28	$1,688.81
9/26/2006	854295		20012	12141	1	28	$1,688.81
10/24/2006	854295		20012	12141	1	28	$1,688.81
11/15/2006	854295		20012	12141	1	28	$1,688.81

1/8/2004	6157297	W	20834	11210	120	30	$719.38
6/15/2004	2005872		21414	17435	120	30	$755.27
7/13/2004	2005872		21414	17435	120	30	$755.27
8/10/2004	2005872		21414	17435	120	30	$755.27
8/10/2004	2008259		21414	17435	1	7	$362.54
6/15/2004	2005873		21414	17435	1	28	$1,445.33
7/12/2004	2005873		21414	17435	1	28	$1,445.33
8/12/2004	2008336		21414	17435	1	28	$1,445.33

12/2/2004	472715	X	20793	18517	1	28	$1,517.52
1/4/2005	472715		20793	18517	1	28	$1,517.52
2/1/2005	472715		20793	18517	1	28	$1,517.52
2/28/2005	472715		20793	18517	1	28	$1,517.52
3/29/2005	472715		20793	18517	1	28	$1,517.52
4/27/2005	472715		20793	18517	1	28	$1,517.52
12/2/2004	472716		20793	18517	112	28	$672.00
1/4/2005	472716		20793	18517	112	28	$672.00
2/1/2005	472716		20793	18517	112	28	$672.00
2/28/2005	472716		20793	18517	112	28	$672.00
3/29/2005	472716		20793	18517	112	28	$672.00
4/27/2005	472716		20793	18517	112	28	$672.00

10/3/2006	1006619	Y	20121	13181	4	30	$1,635.12
10/27/2006	1006619		20121	13181	4	30	$1,635.12
11/25/2006	1006619		20121	13181	4	30	$1,635.12
10/3/2006	1006618		20121	13181	210	30	$1,255.10
11/14/2006	1006618		20121	13181	210	30	$1,255.10

11/22/2006	2051460	Z	21414	15372	1	30	$423.41
11/22/2006	2051442		21414	15372	84	11	$189.99

10/13/2004	518343	AA	21364	12141	168	28	$1,056.74
11/4/2004	518343		21364	12141	168	28	$1,151.70
12/6/2004	518343		21364	12141	168	28	$1,151.70

Patient compliance with Hepatitis C Agents

1/5/2005	518343		21364	12141	168	28	$1,151.70
1/31/2005	518343		21364	12141	168	28	$1,151.70
2/28/2005	518343		21364	12141	168	28	$1,151.70
3/23/2005	518343		21364	12141	168	28	$1,151.70
5/13/2005	518343		21364	12141	168	28	$1,265.56
6/6/2005	518343		21364	12141	168	28	$1,265.56
7/5/2005	518343		21364	12141	168	28	$1,265.56
7/28/2005	518343		21364	12141	168	28	$1,328.76
8/29/2005	518343		21364	12141	168	28	$1,328.76
10/13/2004	518342		21364	12141	1	28	$830.67
11/4/2004	518342		21364	12141	1	28	$832.79
12/6/2004	518342		21364	12141	1	28	$980.40
1/5/2005	518342		21364	12141	1	28	$993.06
1/31/2005	518342		21364	12141	1	28	$1,517.52
2/28/2005	518342		21364	12141	1	28	$1,459.03
3/23/2005	518342		21364	12141	1	28	$921.30
5/13/2005	518342		21364	12141	1	28	$1,517.52
6/6/2005	518342		21364	12141	1	28	$1,517.52
7/5/2005	518342		21364	12141	1	28	$1,517.52
7/28/2005	518342		21364	12141	1	28	$1,517.52
8/29/2005	518342		21364	12141	1	28	$1,517.52

1/12/2004	540511	BB	20066	17435	4	28	$1,376.58
1/19/2004	546329		20066	17435	112	28	$1,114.21

2/16/2004	648289	CC	20123	18006	154	30	$1,531.45
2/16/2004	648289		20123	18006	150	30	$0.00
3/8/2004	648289		20123	18006	154	30	$1,531.45
4/7/2004	648289		20123	18006	154	30	$1,531.45
5/6/2004	648289		20123	18006	154	30	$1,531.45
6/5/2004	648289		20123	18006	154	30	$1,531.45
7/16/2004	648289		20123	18006	154	30	$1,531.45
2/16/2004	648296		20123	18006	4	30	$1,466.58
2/16/2004	648296		20123	18006	2	30	$0.00
2/16/2004	648296		20123	18006	8	30	$0.00
3/8/2004	648296		20123	18006	4	30	$1,466.58
4/7/2004	648296		20123	18006	4	30	$1,466.58
5/6/2004	648296		20123	18006	4	30	$1,466.58
6/5/2004	648296		20123	18006	4	30	$1,466.58
7/2/2004	648296		20123	18006	4	30	$1,466.58
8/5/2004	648296		20123	18006	4	30	$1,466.58

2/8/2005	795259	DD	20121	18006	4	28	$1,466.58
3/7/2005	795259		20121	18006	4	28	$1,466.58
4/4/2005	795259		20121	18006	4	28	$1,466.58
5/6/2005	812391		20121	18006	4	28	$1,466.58
5/31/2005	812391		20121	18006	4	28	$1,466.58
6/23/2005	812391		20121	18006	4	28	$1,466.58
7/26/2005	812391		20121	18006	1	7	$367.85
2/8/2005	795258		20121	18006	168	34	$1,005.20
3/18/2005	795258		20121	18006	168	34	$1,005.20

Patient compliance with Hepatitis C Agents

4/14/2005	795258		20121	18006	168	34	$1,005.20
5/31/2005	795258		20121	18006	168	34	$1,005.20
6/23/2005	819041		20121	18006	168	19	$1,005.20

2/3/2004	696178	EE	20914	16482	336	33	$2,011.39
2/3/2004	696178		20914	16482	336	33	$0.00
4/22/2004	420378		20789	12707	150	30	$943.69
5/18/2004	420378		20789	12707	150	30	$943.69
6/22/2004	420378		20789	12707	150	30	$943.69
2/3/2004	696176		20914	16482	1	28	$1,376.58
4/22/2004	420377		20789	12707	1	28	$1,376.58
5/19/2004	422479		20789	12707	1	28	$1,445.33
6/15/2004	422479		20789	12707	1	28	$1,445.33

9/18/2006	146106	FF	21095	13181	4	28	$1,713.60
11/10/2006	146106		21095	13181	4	28	$1,713.60
9/18/2006	146108		21095	13181	168	28	$1,005.20
11/10/2006	146108		21095	13181	168	28	$1,005.20

5/19/2004	2238048	GG	20967	53168	1	30	$0.00
8/6/2004	2296507		20967	53168	1	28	$1,445.33

3/19/2004	796217	HH	20145	11978	168	28	$1,670.52
4/26/2004	796217		20145	11978	168	28	$1,670.52
4/26/2004	796217		20145	11978	168	28	$0.00
5/17/2004	796217		20145	11978	168	28	$1,670.52
6/23/2004	796217		20145	11978	168	28	$1,670.52
3/19/2004	796216		20145	11978	1	28	$386.15
7/15/2004	796376		20145	11978	4	28	$1,396.74
8/6/2004	796376		20145	11978	4	28	$1,396.74
8/30/2004	796376		20145	11978	4	28	$1,396.74
10/7/2004	796376		20145	11978	4	28	$1,396.74
11/9/2004	796376		20145	11978	4	28	$1,396.74
12/10/2004	796376		20145	11978	4	28	$1,396.74
1/10/2005	796376		20145	11978	4	28	$1,396.74
2/15/2005	796376		20145	11978	4	28	$1,396.74
3/9/2005	796376		20145	11978	3	21	$1,047.96
3/22/2004	796376		20145	11978	4	28	$1,396.74
4/26/2004	796376		20145	11978	4	28	$1,396.74
5/17/2004	796376		20145	11978	4	28	$1,396.74
6/23/2004	796376		20145	11978	4	28	$1,396.74
8/5/2004	796217		20145	11978	168	28	$1,415.50
9/7/2004	796217		20145	11978	168	28	$1,415.50
10/7/2004	796217		20145	11978	168	28	$1,005.20
11/8/2004	796217		20145	11978	168	28	$1,005.20
12/10/2004	796217		20145	11978	168	28	$1,005.20
1/10/2005	796217		20145	11978	168	28	$1,005.20
2/11/2005	796217		20145	11978	168	28	$1,005.20
3/14/2005	796217		20145	11978	168	28	$1,005.20

3/9/2004	652717	II	21349	19680	150	30	$898.83

Patient compliance with Hepatitis C Agents

4/23/2004	654828		21349	19680	150	30	$943.69
1/22/2004	637886		21349	19680	1	28	$1,376.58
3/9/2004	652715		21349	19680	1	28	$1,376.58
4/23/2004	654827		21349	19680	1	28	$1,376.58

7/25/2005	2024385	JJ	21414	12622	100	17	$791.58
7/25/2005	2024386		21414	12622	1	28	$1,517.52

1/15/2004	895915	KK	20129	11730	4	30	$0.00

1/6/2004	961914	LL	20007	19678	2	28	$689.09
2/2/2004	982379		20007	19678	2	28	$689.09
3/4/2004	982379		20007	19678	2	28	$689.09
9/23/2004	1027306		20007	18517	4	28	$1,445.34
10/22/2004	1027306		20007	18517	4	28	$1,445.34
12/4/2004	1041470		20007	18517	2	28	$759.56
1/3/2005	1041470		20007	18517	2	28	$759.56
2/1/2005	1041470		20007	18517	2	28	$759.56
3/3/2005	1041470		20007	18517	2	28	$725.16
3/25/2005	1041470		20007	18517	2	28	$759.56
4/25/2005	1041470		20007	18517	2	28	$759.56
5/20/2005	1041470		20007	18517	2	28	$759.56
6/18/2005	1041470		20007	18517	2	28	$759.56
7/18/2005	1041470		20007	18517	2	28	$759.56
8/15/2005	1041470		20007	18517	2	28	$759.56
9/13/2005	1041470		20007	18517	2	28	$759.56
10/10/2005	1041470		20007	18517	2	28	$759.56
11/7/2005	1109868		20007	18517	2	28	$759.56
12/2/2005	1109868		20007	18517	2	28	$759.56
9/23/2004	1027308		20007	18517	150	30	$898.10
10/22/2004	1027308		20007	18517	150	30	$898.10

8/3/2004	6037753	MM	21119	18006	1	1	$386.15
8/10/2004	6037753		21119	18006	1	1	$381.55
8/17/2004	6037753		21119	18006	1	1	$381.55
8/3/2004	6037754		21119	18006	168	28	$1,385.61

10/20/2004	651722	NN	20817	18517	56	14	$356.31
11/12/2004	651722		20817	18517	56	14	$383.37
11/26/2004	653566		20817	18517	112	28	$771.33
10/20/2004	651721		20817	18517	2	14	$726.47
11/12/2004	651721		20817	18517	2	14	$721.87
11/27/2004	653565		20817	18517	4	28	$1,701.05

1/26/2004	685880	OO	20914	18517	4	28	$0.00
1/26/2004	694928		20914	18517	1	30	$0.00
1/26/2004	694928		20914	18517	1	30	$0.00
1/26/2004	690488		20914	18517	168	30	$0.00

4/29/2005	744330	PP	20851	18517	1	30	$1,517.52
5/24/2005	744330		20851	18517	1	30	$1,517.52

Patient compliance with Hepatitis C Agents

6/28/2005	744330		20851	18517	1	30	$1,517.52
7/28/2005	744330		20851	18517	1	30	$1,517.52
8/24/2005	744330		20851	18517	1	30	$1,517.52
9/21/2005	744330		20851	18517	1	30	$1,517.52
10/25/2005	744330		20851	18517	1	30	$1,517.52
11/19/2005	744330		20851	18517	1	30	$1,517.52
12/15/2005	744330		20851	18517	1	30	$1,608.46
4/29/2005	744331		20851	18517	140	30	$838.60
5/24/2005	744331		20851	18517	140	30	$838.60
6/29/2005	744331		20851	18517	140	30	$838.60
7/28/2005	744331		20851	18517	140	30	$838.60
8/24/2005	744331		20851	18517	140	30	$838.60
9/21/2005	744331		20851	18517	140	30	$838.60
10/25/2005	744331		20851	18517	140	30	$838.60
11/19/2005	744331		20851	18517	140	30	$838.60
12/15/2005	744331		20851	18517	140	30	$838.60

8/11/2006	440482	QQ	21131	17502	1	30	$1,688.81
9/8/2006	443488		21131	17502	1	30	$1,688.81
10/2/2006	446412		21131	17502	1	28	$1,688.81
10/30/2006	449532		21131	17502	1	28	$1,688.81
8/11/2006	440483		21131	17502	35	7	$167.61
8/22/2006	441667		21131	17502	105	21	$491.62
9/7/2006	443513		21131	17502	105	21	$491.62
10/2/2006	446410		21131	17502	150	30	$699.91
10/30/2006	449533		21131	17502	140	28	$1,048.72

8/17/2006	861612	RR	20914	18517	1	28	$1,688.81
8/17/2006	861615		20914	18517	168	28	$783.23

6/29/2006	510204	SS	21168	18517	1	28	$1,688.81
7/24/2006	510204		21168	18517	1	28	$1,688.81
10/26/2006	527690		21168	18517	1	28	$1,688.81
6/29/2006	510203		21168	18517	180	30	$1,076.60
7/31/2006	510203		21168	18517	180	30	$1,076.60
10/26/2006	527691		21168	18517	180	30	$1,076.60

9/27/2005	691191	TT	20123	13181	4	30	$317.49
10/27/2005	691191		20123	13181	4	30	$317.49
11/25/2005	691191		20123	13181	4	30	$81.09
12/21/2005	691191		20123	13181	4	30	$12.00
1/20/2006	691191		20123	13181	4	30	$314.88
2/20/2006	691191		20123	13181	4	30	$314.88
9/27/2005	691193		20123	13181	210	30	$132.00
11/14/2005	691193		20123	13181	210	30	$132.00
12/21/2005	691193		20123	13181	210	30	$15.00
2/6/2006	691193		20123	13181	210	30	$132.00

11/18/2005	1410239	UU	20589	11936	120	30	$996.97
11/21/2005	1410831		20589	11936	4	28	$1,517.52
12/20/2005	1410831		20589	11936	4	28	$1,608.46

Patient compliance with Hepatitis C Agents

1/16/2006	1410831		20589	11936	4	28	$1,608.46
1/2/2006	1420471		20589	11936	120	30	$838.69
1/28/2006	1420471		20589	11936	120	30	$838.69

5/23/2006	285753	VV	21128	15482	1	28	$1,389.72
7/7/2006	285753		21128	15482	1	28	$1,428.81
8/3/2006	285753		21128	15482	1	28	$1,428.81
9/5/2006	292974		21128	15482	1	28	$1,688.81
10/2/2006	292974		21128	15482	1	28	$1,428.81
10/24/2006	292974		21128	15482	1	28	$1,688.81
5/23/2006	285755		21128	15482	150	30	$1,122.56
7/11/2006	285755		21128	15482	150	30	$1,122.56
8/4/2006	285755		21128	15482	150	30	$1,122.56
9/5/2006	292973		21128	15482	150	30	$862.56
10/2/2006	292973		21128	15482	150	30	$1,122.56
10/27/2006	292973		21128	15482	150	30	$1,122.56

Antihistamine/Mast Cell Stabilizer Ophthalmics

There are two forms of allergic conjunctivitis, seasonal and perennial. Seasonal is more common and related to exposure to airborne allergens such as grass, tree and weed pollens, and molds. The perennial form persists throughout the year and is usually triggered by dust mites, animal dander, and feathers.

One class of medications used to treat allergic conjunctivitis is the antihistamine/mast cell stabilizer ophthalmics. The products included within this class are Patanol (Olopatadine), Zaditor (Ketotifen), Elestat (Epinastine) and Optivar (Azelastine). These medications are popular because of their dual mechanism of action. The antihistamine action is quick and the mast cell stabilizing action is more delayed. These products are indicated for the temporary prevention of itching of the eye due to allergic conjunctivitis and are safe and effective for both short- and long-term use.

Recently, Zaditor was approved to be sold without a prescription. The OTC product costs about $15 per bottle for a 30 day supply. This is compared to the prescription products that range in price (WAC) from approximately 68-75 dollars per month. There are no head to head trials that compare antihistamine/mast cell stabilizers, so it is impossible to conclude that one drug is superior to another.

DRUG USAGE for nd_antihistamine eyedrops from 01/01/06 to 11/27/06				
Generic Name	**Brand Name**	**Rx Num**	**Qty Dispensed**	**Total Claim Cost**
AZELASTINE HCL	OPTIVAR	7	41	$676.72
EPINASTINE HCL	ELESTAT	3	15	$250.52
KETOTIFEN FUMARATE	ZADITOR	11	55	$794.37
OLOPATADINE HCL	PATANOL	533	2670	$45,631.20
TOTAL		554	2781	$47,352.81

HEALTH INFORMATION DESIGNS

Prior Authorization Vendor for ND Medicaid

Antihistamine Ophthalmic PA Form

Clear Fields

Fax Completed Form to:
866-254-0761 or 334-321-2199
For questions regarding this prior authorization, call
866-773-0695 or 334-321-0268

North Dakota Medicaid requires that patients receiving antihistamine ophthalmics must use Zaditor OTC as first line.

***Note:**

- **Zaditor OTC may be prescribed WITHOUT prior authorization. Zaditor OTC is covered by Medicaid when prescribed by a physician.**
- **Patients must use Zaditor OTC for a minimum of 30 days for the trial to be considered a failure. Patient preference does not constitute a failure.**

Part I: TO BE COMPLETED BY PHYSICIAN - *COMPLETE PART I AND FAX TO PATIENT'S PHARMACY*

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: ☐ Elestat ☐ Optivar ☐ Patanol	Diagnosis for this request	Requested Dosage (must be completed)	

Qualifications for coverage:

☐ Failed Zaditor OTC	Start Date	End Date	Dose	Frequency

Physician Signature	Date

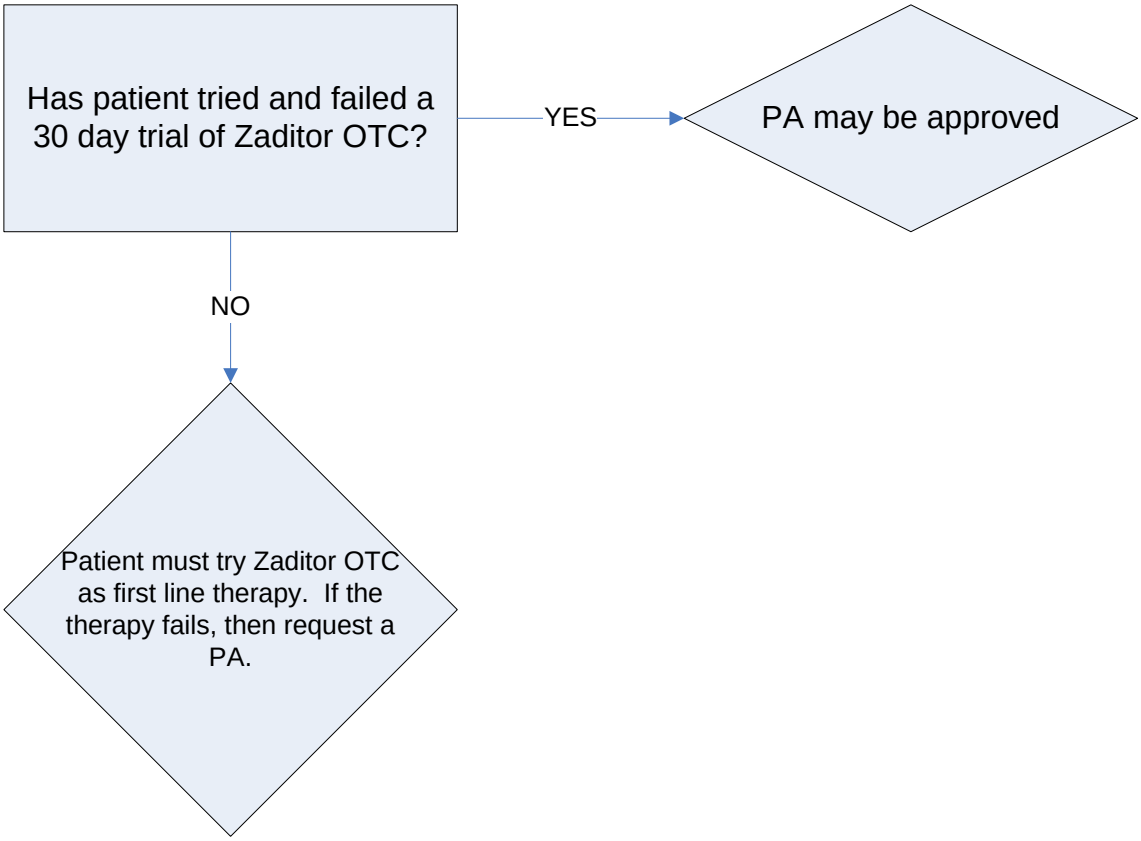
Part II: TO BE COMPLETED BY PHARMACY - *COMPLETE PART II AND FAX TO NUMBER AT TOP OF FORM*

Pharmacy Name			ND Medicaid Provider Number
Telephone Number	Fax Number	Drug	NDC #

Part III: FOR STATE USE ONLY

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

North Dakota Department of Human Services
Antihistamine Ophthalmic Criteria Algorithm



CDER Quinine and Unapproved Products

The Division of Drug Information (DDI) is CDER's focal point for public inquiries. We serve the public by providing information on human drug products and drug product regulation by FDA.

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FDA has ordered firms to stop marketing unapproved drug products containing quinine, a drug used to treat malaria, citing serious safety concerns, including deaths, associated with quinine products. There are multiple unapproved products containing quinine currently marketed. However, there is only one quinine product approved by the FDA. As part of its action, FDA is also cautioning consumers about off-label use of quinine to treat leg cramps. Quinine is approved for treatment of malaria, but is also commonly prescribed to treat leg cramps and similar conditions. Because malaria is life-threatening, the risks associated with quinine use are justified for that condition. But because of the drug's risks, FDA believes it should not be used to prevent or treat leg cramps.

Mutual Pharmaceutical Company, Inc.'s Qualaquin, is FDA-approved to treat certain types of malaria without complications. Unlike the approved product, many unapproved quinine drug products are marketed without labeling cautioning against use of the product for treatment of leg cramps. The FDA-approved labeling for the product provides extensive warnings regarding serious adverse events associated with use of quinine, potentially serious interactions with other drugs, and conditions under which quinine should not be used. Quinine is a drug with a narrow margin between an effective dose and a toxic dose. The dosing for the approved drug is supported by data to maximize the safety and efficacy of the product. The dosing for the unapproved drugs has not been reviewed and approved by FDA.

In June, 2006, FDA issued a new guidance, "Marketed Unapproved Drugs – Compliance Policy Guide," which makes clear that firms illegally marketing drugs without FDA approval need to submit applications showing that their products are safe and effective before continuing to market those products. FDA's actions against unapproved drugs are part of the agency's broader initiative, launched last year, to ensure that consumers and the health care community are provided with established and emerging drug safety information so that they can make the best possible medical decisions about the safe and effective use of drugs. Since the FDA announced this initiative, the agency has issued warning letters to several companies that are manufacturing unapproved drugs and federal courts have entered permanent injunctions against two others. FDA expects to further accelerate its enforcement efforts against marketed unapproved drugs in 2007.

Quinine and Leg Cramps

Mutual Pharmaceutical Company/AR Scientific has introduced Qualaquin (quinine sulfate capsules USP, 324 mg) to the US commercial market for the treatment of malaria. Qualaquin is the first formulation of quinine sulfate to be evaluated and approved by the FDA.

With the approval of Qualaquin, the FDA will soon remove all unapproved quinine products from the market. Since 1969, the FDA has received 665 reports of serious adverse events tied to quinine, including 93 deaths.[1] In 1995, the FDA discouraged using quinine for leg cramps based on the risk to benefit ratio. Quinine can cause severe thrombocytopenia, GI disturbances, visual changes, ringing in the ears, deafness and CV abnormalities. Most of quinine's adverse effects are dose-dependent, but thrombocytopenia can occur at any dose, and at any time during treatment.

Today, many clinicians prescribe quinine for leg cramps because it has the most evidence supporting its use. A meta-analysis showed that quinine reduced the average number of cramps by 3.6 over a four week period (95% CI 2.15-5.05). However, it did not affect the duration of the cramps that occurred. In a trial not included in the meta-analysis, quinine led to an average of two fewer cramps over a two-week time frame, compared to placebo.[2] Quinine sulfate is commonly used off-label to treat leg cramps. But quinine products are only approved for malaria. The package insert for Qualaquin specifically says NOT to use quinine for leg cramps. As a result, many third party insurers as well as State Medicaid plans are giving Qualaquin prior authorization status.

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[1] *@WebMD, Dec. 12, 2006*

[2] *Off-label use of quinine: things to consider. Pharmacist's Letter/Prescriber's Letter 2007;23(1):230101*

DRUG USAGE for nd_quinine from 01/01/06 to 11/27/06 for Program			
Generic Name	**Rx Num**	**Qty Dispensed**	**Total Claim Cost**
QUININE SULFATE	234	7977	$6,260.77
TOTAL	234	7977	$6,260.77

HEALTH INFORMATION DESIGNS

Qualaquin Form

Clear Fields

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

Prior Authorization Vendor for ND Medicaid

ND Medicaid will cover Qualaquin with a diagnosis of Malaria.

Part I: TO BE COMPLETED BY 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:

- ❑ Malaria

.

Physician Signature: Date:

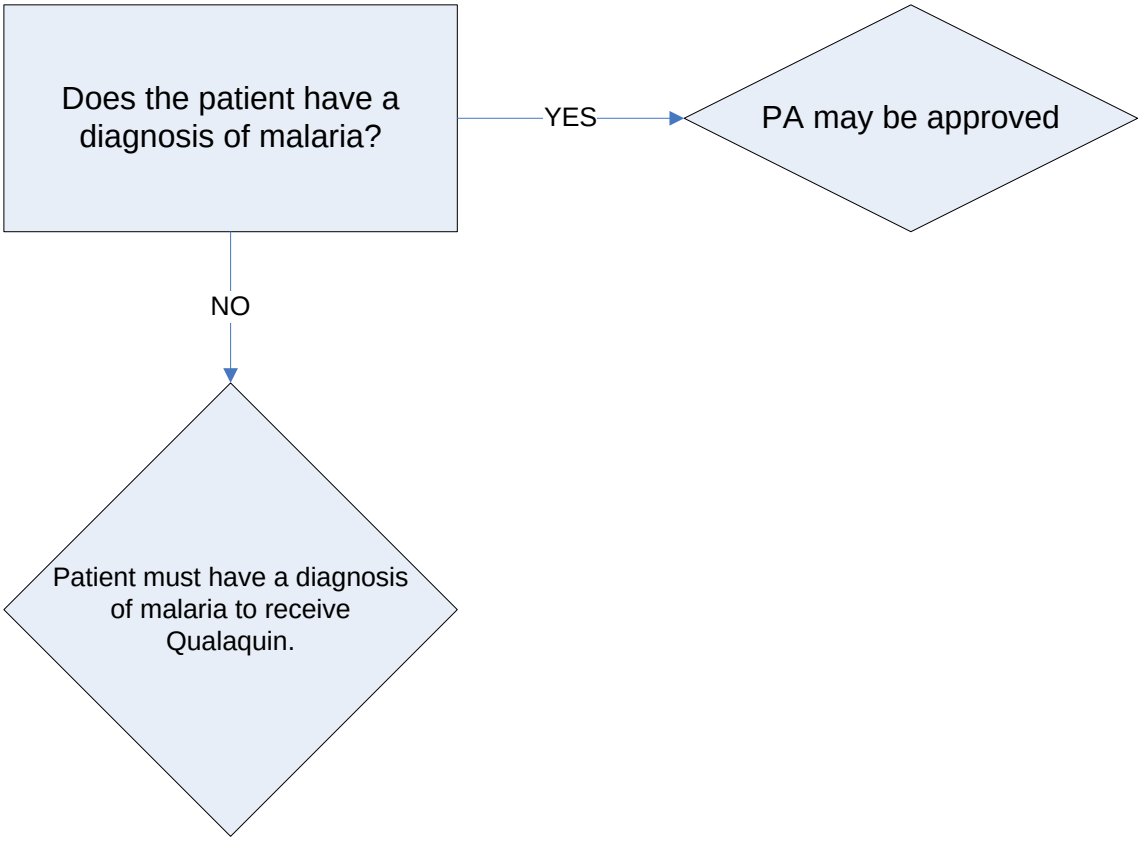
Part II: TO BE COMPLETED BY PHARMACY

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
Qualaquin Criteria Algorithm



NORTH DAKOTA MEDICAID
DRUG UTILIZATION REVIEW CRITERIA RECOMMENDATIONS
1st QUARTER 2007

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

1. Bisphosphonates /Therapeutic Appropriateness _____ _____

Alert Message: Osteonecrosis of the jaw (ONJ) has been reported in patients treated with bisphosphonates. Most cases have been in cancer patients receiving IV bisphosphonates undergoing dental procedures, but some have occurred in patients with other diagnoses and on oral bisphosphonates. The American Association of Endodontists recommends that all patients taking bisphosphonates be considered at some risk for ONJ. Consider recommending dental examination with appropriate preventative dentistry prior to treatment with a bisphosphonate.

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Disease:

Util A	Util B	Util C
Alendronate		
Etidronate		
Ibandronate		
Pamidronate		
Risedronate		
Tiludronate		
Zoledronate		

References:
Facts & Comparisons, 2006 Updates.
Weinberg, M. Bisphosphonate-Associated Osteonecrosis of the Jaws: Impact on Oral Health U.S. Pharm 2006;5:62-69.
Position Statement: Bisphosphonates may put patients at risk for deterioration of the Jaw, American Association of Endodontists. April 2006.

2. Contraceptives / Smoking _____ _____

Alert Message: Cigarette smoking increases the risk of serious cardiovascular side effects from hormonal contraceptive use. This risk increases with age and with heavy smoking (15 or more cigarettes per day) and is quite marked in women over 35 years of age. Women who use hormonal contraceptives should be strongly advised not to smoke.

Conflict Code: MC - Drug (Actual) Disease Precaution (Black Box Warning)
Drugs/Disease:

Util A	Util B	Util C
Hormonal Contraceptives	Smoking	
	Tobacco Abuse	

References:
Ortho Evra Prescribing Information, Sept. 2006, Ortho-McNeil Pharmaceutical, Inc.
Facts & Comparisons, 2006 Updates.

Criteria Recommendations	*Approved*	*Rejected*

3. Methadone / Therapeutic Appropriateness _____ _____

Alert Message: Methadone can cause significant toxicities. Vigilance is necessary during treatment initiation, dose titration, and drug conversion from other opioids to methadone. It is critical to understand the pharmacokinetics of methadone when converting patients to methadone. Methadone's half-life (8-59 hours) is longer than its duration of action (4-8 hours). Incomplete cross-tolerance makes conversion complex and does not eliminate the possibility of overdose.

Conflict Code: TA – Therapeutic Appropriateness (Black Box Warning)
Drugs/Disease:

Util A	Util B	Util C
Methadone		

References:
MedWatch – The Safety Information and Adverse Event Reporting Program, 2006.
Dolophine Prescribing Information, Oct. 2006, Roxane Laboratories, Inc.

4. Rituximab / Therapeutic Appropriateness _____ _____

Alert Message: Rituxan (rituximab) may cause exacerbations of viral infections or viral reactivation, including reactivation of the JC virus, which can lead to PML (progressive multifocal leukoencephalopathy) a rare and usually fatal disease. Physicians and patients should be aware of the development of new neurological symptoms (major vision changes, lack of coordination, or disorientation) that could be warning signs of PML.

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Disease:

Util A	Util B	Util C
Rituximab		

References:
MedWatch – The Safety Information and Adverse Event Reporting Program, 2006.

5. Oseltamivir / Therapeutic Appropriateness _____ _____

Alert Message: There have been postmarketing reports of self-injury and delirium with the use of Tamiflu (oseltamivir) in patients with influenza. The reports were primarily among pediatric patients. The relative contribution of the drug to these events is not known. Patients with influenza should be closely monitored for signs of abnormal behavior throughout the treatment period.

Conflict Code: TA – Therapeutic Appropriateness
Drugs/Disease:

Util A	Util B	Util C
Oseltamivir		

References:
MedWatch – The Safety Information and Adverse Event Reporting Program, 2006.
Tamiflu Prescribing Information, Nov. 2006, Roche Laboratories Inc.

DUR Board Meeting
June 4th, 2007
Heritage Center
Rooms A and B
1pm

HEALTH INFORMATION DESIGNS

April 4th, 2007

The next North Dakota Drug Utilization Review (DUR) Board Meeting will be held June 4th, 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
June 4th, 2007
1pm

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

2. Old Business

• Review and approval of minutes of 03/12/07 meeting	Chairman
• Budget update	Brendan
• Methadone Utilization	HID
• Qualaquin Review	HID
• Yearly Review of Sedative/Hypnotics and ACE-I	HID
• Legislative Update	Brendan

3. New Business

• Review of Amrix	HID
• Review of Janumet	HID
• Review of Tekturna	HID
• Review of Xopenex HFA	HID
• Review of Ketek	HID
• Review of Synagis	HID
• Prior Authorization of High Cost/Low Utilization Drugs	Brendan
• Review of various HIV/AIDS Medications	HID
• Review of various Cancer medications	HID
• Criteria Recommendations	Brendan
• Upcoming meeting date/agenda August 6th, 2007	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
March 12th, 2007

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

Chairman, J. Savageau, called the meeting to order at 1:00pm. He asked for a motion to approve the minutes from the December 11th, 2006 meeting. N. Byers moved that the minutes be approved and C. Huber seconded the motion. The chair called for a voice vote to approve the minutes, which passed with no audible dissent.

Budget Update:
B. Joyce reported that the department spends approximately 2.3 million per month (pre-rebates). The last 6 months average of people picking up medications is 15,900 per month. There are approximately 49,000 people eligible in any given month to pick up medications.

Chair/Vice-Chair Elections:
Cheryl Huber will be the new chair of the North Dakota DUR Board and Robert Treitline will be the Vice-Chair.

Legislative Update
Currently, there is legislation in place that 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 two years, 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.

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. Antistamines were reviewed. No action will be taken regarding the Antihistamine form or criteria. Brand Name NSAID/COX2s were reviewed. A motion was made by Pat Churchill to remove 'recipient is 65 years old' as a criterion. Todd Twogood seconded the motion. Motion passed with no audible dissent. Forms and criteria for PPIs, Revatio and Actoplus met were also reviewed. No actions were taken.

Tablet Splitting Initiative
C. Rieth reviewed tablet splitting data that shows a significant savings if a tablet splitting initiative were implemented. Currently, the State provides a monetary incentive to pharmacies that split tablets. At the December meeting, C. Huber asked if a patient incentive could be offered. B. Joyce stated that removing the copay on these prescriptions would not be allowed. C. Rieth reviewed results of the Zoloft tablet splitting letter that was mailed to pharmacies in 2006. Two hundred and fifty three patient letters were mailed and only five changes to implement tablet splitting have been made. A motion was made by A. Samuelson to implement a mandatory tablet splitting program that would be phased in slowly with the Board updated on a regular basis. S. Setzepfandt suggested that only scored tablets be split. C. Huber asked that exceptions be made for patients that refuse to take split tablets. Brendan said that overrides would be granted on a case by case basis. Tablet splitting will be implemented with quantity limits. B. Treitline seconded the motion. Motion passed with no audible dissent.

Review of Methadone
At the December meeting A Samuelson asked the State to review methadone data. C. Rieth reviewed utilization data from 1/1/06-11/27/06. A. Samuelson asked for more information including methadone trends over time, the distribution of patients using methadone and patients using methadone with multiple prescribers. This information will be presented at the June meeting.

Review Name Brand Mandate
B. Joyce reviewed the first drug to receive name brand mandated status since the Board approved this process for cost containment. Included in the pack was the memo to pharmacists regarding Wellbutrin XL 300mg. Since the Wellbutrin XL 300mg generics are currently significantly more expensive to Medicaid than the brand, ND Medicaid will prior authorize the generic. Until further notice, there will be no co-pay on Wellbutrin XL 300mg.

Review of Hepatitis C
B. Joyce stated that Dr. Martin, an infectious disease doctor at Medcenter One asked that the Board review compliance issues regarding Hepatitis C. S. Setzepfandt recused himself from the discussion. Jeff Chevalier spoke on behalf of Roche. He stated that there were manufacturer sponsored patient compliance programs available. Providers would need to enroll patients in these programs. Jeff stated from the data provided, usage in North Dakota Medicaid appears to be very well managed. Ken Hesterman spoke on behalf of Schering-Plough. He stated that his company also has patient compliance programs available. B. Joyce asked that both companies encourage doctors to enroll their patients in these compliance programs. B. Joyce also told these representatives that providers may request, from ND Medicaid, profiles of their patients to verify compliance.

Review of Antihistamine/Mast Cell Stabilizer Ophthalmics
B. Joyce stated that Zaditor is now available OTC. In the DUR pack that was sent to Board members, the statement was made that there are no head to head trials that compare the antihistamine/mast cell stabilizer agents. That was an inaccurate statement and trials have been provided to all Board members. At this time, B. Joyce does not know if Zaditor OTC will be a rebatable product. T. Twogood stated that he was afraid that limiting the antihistamine/mast cell stabilizer products would cause an increase in utilization of steroid ophthalmics. This topic was tabled.

Review of Qualaquin
B. Joyce informed the Board that all quinine products will eventually leave the market with Qualaquin being the only remaining product. Qualaquin is approved for malaria. Cost information was provided to the Board regarding the use of Requip and Qualaquin in restless leg syndrome. A motion was made by B. Treitline to place Qualaquin on prior authorization with malaria as the qualifying criteria. P. Churchill seconded the motion. This topic will be brought before the Board in June for finalization.

Criteria Recommendations
The enclosed recommended RDUR criteria are 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. C. Huber moved to approve the new criteria and J. Savageau seconded the motion. The motion was approved by voice vote with no audible dissent

The next DUR board meeting will be June 4th, 2007. B. Joyce reviewed future agenda items. These include Amrix, Albuterol HFA, Ketek, HIV/AIDS and Cancer. C. Huber made a motion to adjourn the meeting and A. Samuelson seconded. Chair J. Savageau adjourned the meeting at 3:30 pm.

2006-2007 Methadone Utilization

DRUG USAGE for nd_methadone from 01/01/06 to 01/29/07 for Program			
Generic Name	**Rx Num**	**Qty Dispensed**	**Total Claim Cost**
METHADONE HCL	965	109982.4	$24,596.90
TOTAL	965	109982.4	$24,596.90

151 patients
101 physicians

391 Industry Drive • Auburn, AL 36832 • Phone: (334)502-3262 • Fax: (334) 466-6947
Auburn, Alabama • Jackson, Mississippi • Little Rock, Arkansas • Salisbury, Maryland

HEALTH INFORMATION DESIGNS

Methadone Scripts per Patient

Sex	Rx Count	Sex	Rx Count	Sex	Rx Count	Sex	Rx Count
F	1	F	1	F	24	M	4
M	1	F	1	M	7	F	10
F	4	F	5	F	1	F	2
F	1	F	1	M	1	F	2
F	3	M	12	F	13	F	13
F	1	F	16	F	9	F	13
F	18	F	17	F	21	F	2
M	30	M	17	F	2	F	7
F	11	F	1	M	13	F	1
F	27	M	3	F	6	M	1
M	1	F	4	M	11	F	1
F	20	F	2	F	12	F	1
F	13	M	3	M	15	M	28
F	12	F	2	F	4	M	1
M	18	F	10	M	5	F	1
F	6	F	3	M	6	F	8
F	6	F	28	F	1	M	4
F	1	F	2	F	12	F	2
F	8	M	10	F	12	F	1
F	1	M	1	F	1	F	13
F	2	F	1	F	9	F	1
M	7	F	6	M	3	M	6
M	7	F	8	M	7	M	5
F	1	M	1	F	14	M	14
M	18	M	1	F	1	M	1
F	5	M	17	F	4	M	11
M	6	F	6	F	1	F	1
F	3	F	2	F	6	F	2
F	1	F	1	M	1	M	5
F	12	F	1	F	1	F	2
F	13	F	1	F	1	M	4
F	1	F	4	M	14	F	1
F	1	M	1	F	1	F	2
F	2	F	13	F	4	F	1
M	14	F	1	F	3	M	1
F	6	M	12	F	1	F	17
M	13	F	1	F	1	F	2
M	13	F	1	F	1		

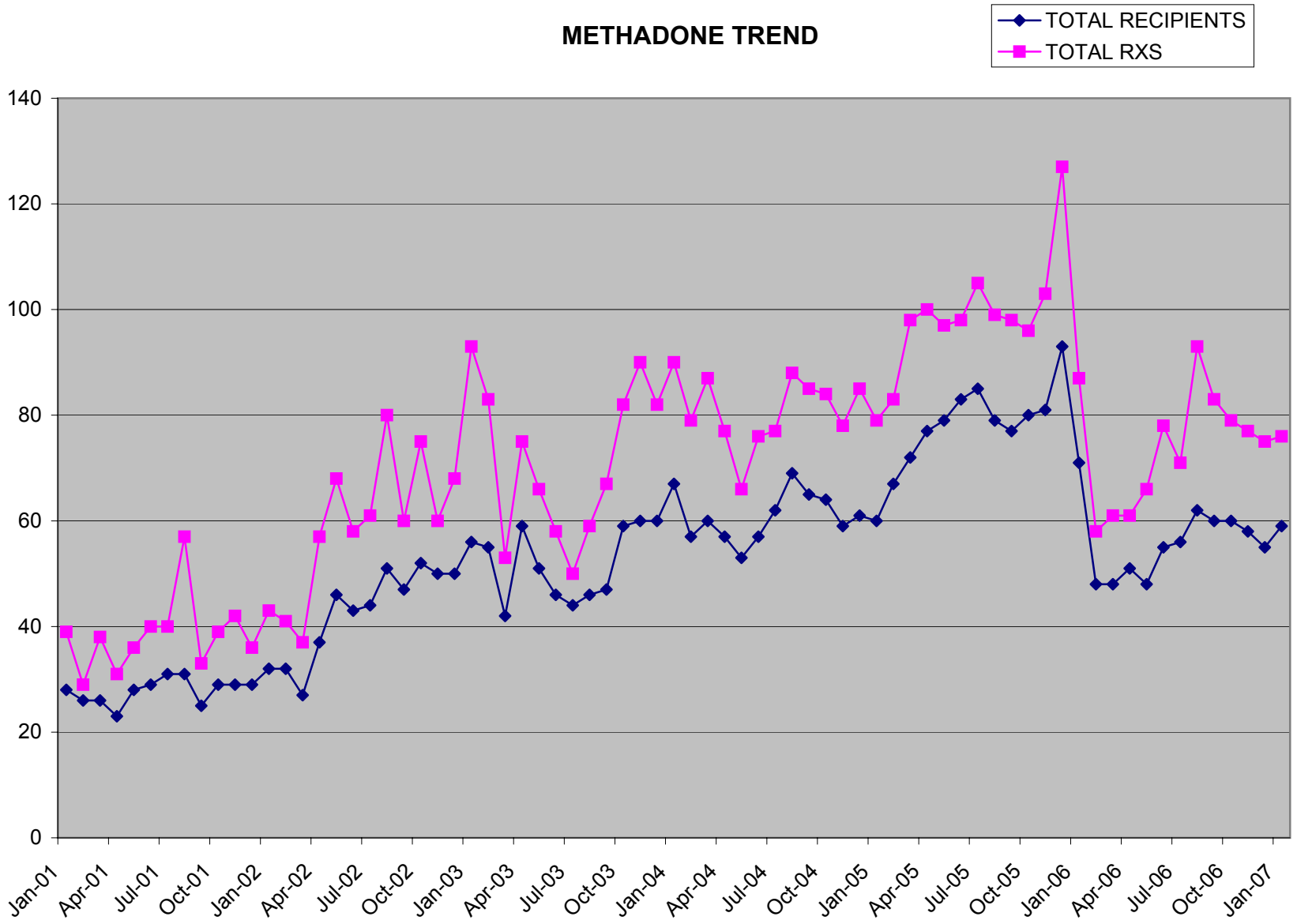
391 Industry Drive • Auburn, AL 36832 • Phone: (334)502-3262 • Fax: (334) 466-6947
Auburn, Alabama • Jackson, Mississippi • Little Rock, Arkansas • Salisbury, Maryland

North Dakota Medicaid		
Number of Physicians Prescribing		
Methadone to Each Patient		
01/01/2006 to 01/29/2007		
Health Information Designs		
Patient	**# of Physicians**	**# of scripts**
000000001	1	1
000000002	1	1
000000003	1	4
000000004	1	1
000000005	1	3
000000006	1	1
000000007	2	18
000000008	2	30
000000009	6	11
000000010	1	27
000000011	1	1
000000012	2	20
000000013	1	13
000000014	2	12
000000015	5	18
000000016	1	6
000000017	2	6
000000018	1	1
000000019	1	8
000000020	1	1
000000021	1	2
000000022	1	1
000000023	1	1
000000024	1	5
000000025	1	1
000000026	1	12
000000027	4	16
000000028	1	17
000000029	2	17
000000030	1	1
000000031	1	3
000000032	1	4
000000033	1	2
000000034	1	3
000000035	1	2
000000036	1	10
000000037	1	3
000000038	2	28
000000039	1	2
000000040	1	10
000000041	1	1
000000042	1	1
000000043	1	24
000000044	1	7
000000045	1	1
000000046	1	1

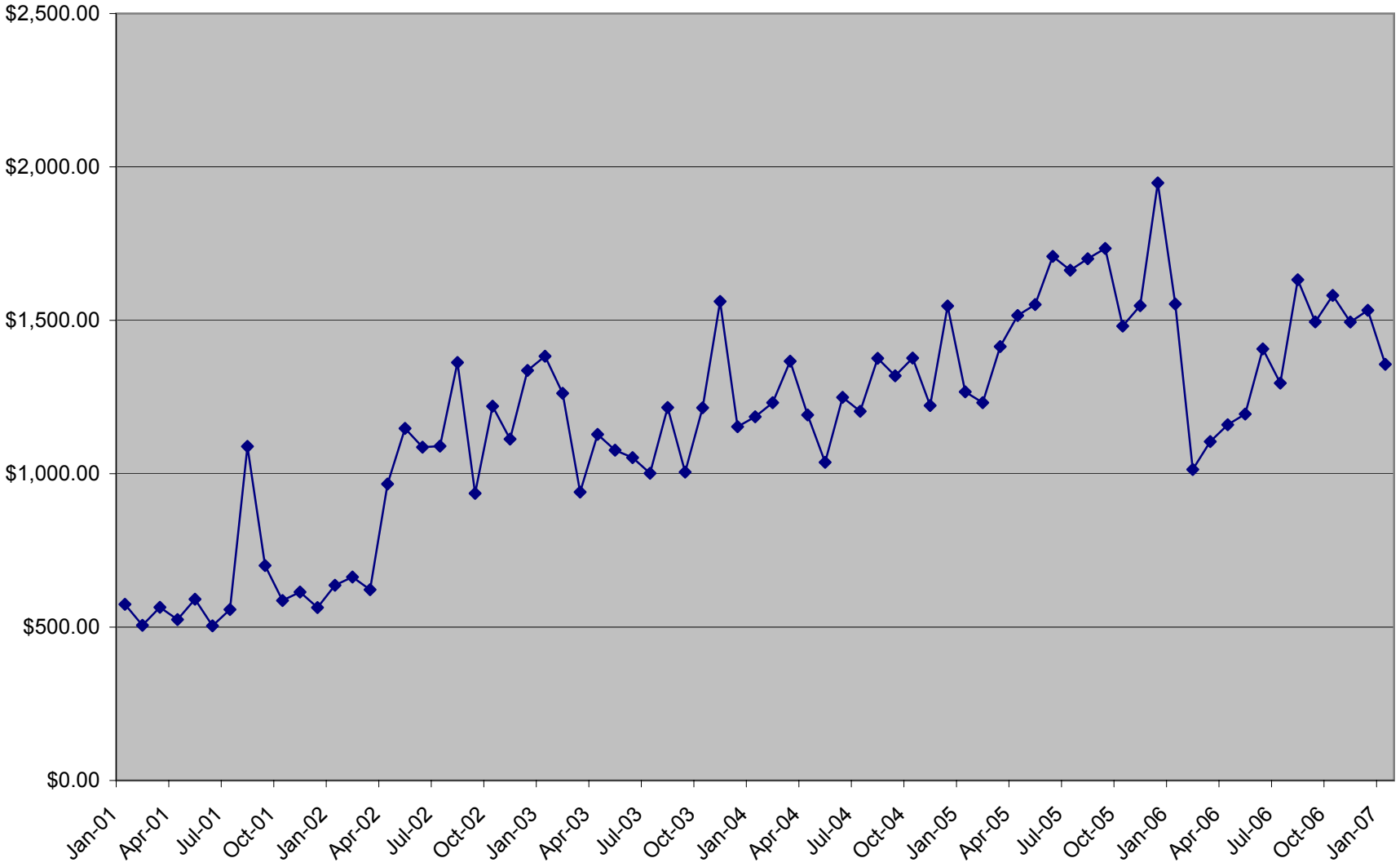
North Dakota Medicaid		
Number of Physicians Prescribing		
Methadone to Each Patient		
01/01/2006 to 01/29/2007		
Health Information Designs		
Patient	**# of Physicians**	**# of scripts**
000000047	2	13
000000048	3	9
000000049	3	21
000000050	1	2
000000051	1	13
000000052	5	6
000000053	3	11
000000054	2	12
000000055	1	15
000000056	1	4
000000057	4	5
000000058	2	6
000000059	1	1
000000060	1	12
000000061	3	12
000000062	1	1
000000063	2	9
000000064	1	4
000000065	1	10
000000066	1	2
000000067	1	2
000000068	1	13
000000069	1	13
000000070	1	2
000000071	1	7
000000072	1	1
000000073	1	1
000000074	1	1
000000075	1	1
000000076	2	28
000000077	1	1
000000078	1	1
000000079	1	8
000000080	2	4
000000081	1	2
000000082	1	1
000000083	1	13
000000084	1	1
000000085	1	7
000000086	4	7
000000087	1	1
000000088	1	18
000000089	1	5
000000090	2	6
000000091	1	3
000000092	1	1

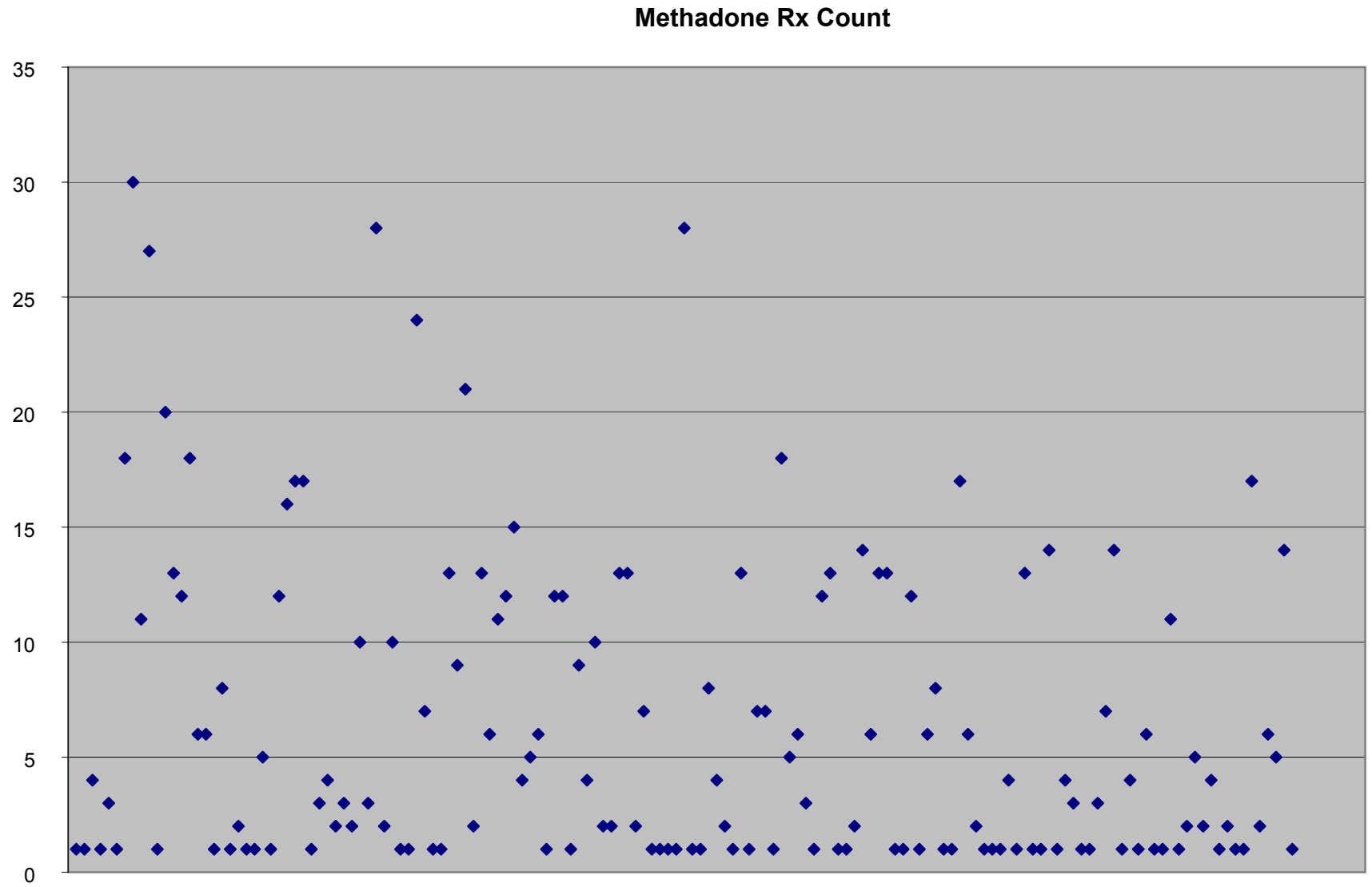
North Dakota Medicaid		
Number of Physicians Prescribing		
Methadone to Each Patient		
01/01/2006 to 01/29/2007		
Health Information Designs		
Patient	**# of Physicians**	**# of scripts**
000000093	1	12
000000094	3	13
000000095	1	1
000000096	1	1
000000097	2	2
000000098	2	14
000000099	2	6
000000100	2	13
000000101	1	13
000000102	1	1
000000103	1	1
000000104	1	1
000000105	1	12
000000106	1	1
000000107	1	6
000000108	1	8
000000109	1	1
000000110	1	1
000000111	3	17
000000112	1	6
000000113	1	2
000000114	1	1
000000115	1	1
000000116	1	1
000000117	1	4
000000118	1	1
000000119	2	13
000000120	1	1
000000121	1	1
000000122	1	14
000000123	1	1
000000124	2	4
000000125	1	3
000000126	1	1
000000127	1	1
000000128	1	3
000000129	3	7
000000130	2	14
000000131	1	1
000000132	2	4
000000133	1	1
000000134	2	6
000000135	1	1
000000136	1	1
000000137	1	1
000000138	2	11

North Dakota Medicaid		
Number of Physicians Prescribing		
Methadone to Each Patient		
01/01/2006 to 01/29/2007		
Health Information Designs		
Patient	**# of Physicians**	**# of scripts**
000000139	1	1
000000140	1	2
000000141	1	5
000000142	1	2
000000143	1	4
000000144	1	1
000000145	1	2
000000146	1	1
000000147	1	1
000000148	1	17
000000149	1	2
000000150	2	6
000000151	1	5
000000152	3	19
000000153	2	3


METHADONE TREND
TOTAL RECIPIENTS
TOTAL RXS
140
120
100
80
60
40
20
0
Jan-01
Apr-01
Jul-01
Oct-01
Jan-02
Apr-02
Jul-02
Oct-02
Jan-03
Apr-03
Jul-03
Oct-03
Jan-04
Apr-04
Jul-04
Oct-04
Jan-05
Apr-05
Jul-05
Oct-05
Jan-06
Apr-06
Jul-06
Oct-06
Jan-07

METHADONE TOTAL CLAIMS COST




Methadone Rx Count
35
30
25
20
15
10
5
0

HEALTH INFORMATION DESIGNS

Qualaquin Form

Clear Fields

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

Prior Authorization Vendor for ND Medicaid

ND Medicaid will cover Qualaquin with a diagnosis of Malaria.

Part I: TO BE COMPLETED BY 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:

- ❑ Malaria

.

Physician Signature: Date:

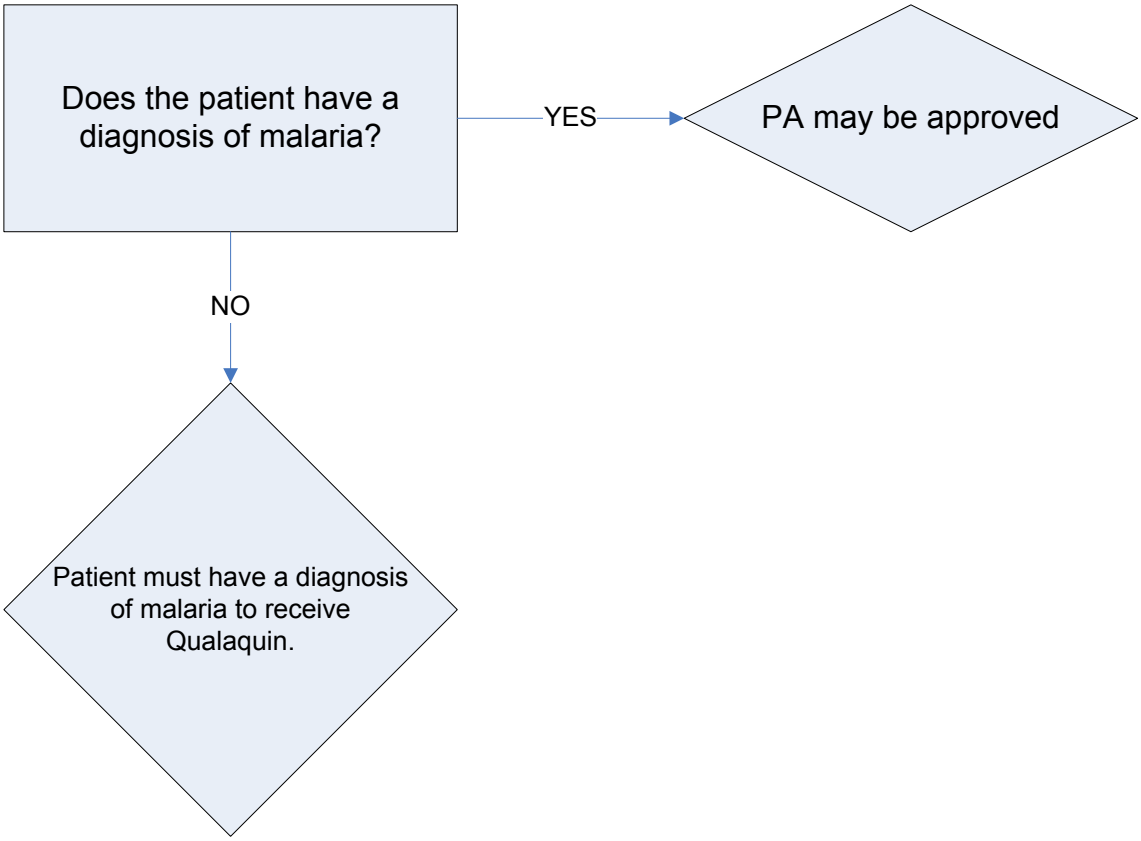
Part II: TO BE COMPLETED BY PHARMACY

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
Qualaquin Criteria Algorithm



HEALTH INFORMATION DESIGNS

Prior Authorization Vendor for ND Medicaid

ACE Inhibitor PA Form

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 an ACE Inhibitor must use at least two generics as first line.

**Note:*

- **Captopril, Enalapril, Lisinopril, Moexipril, Benazepril, Quinapril or Fosinopril do not require a PA**
- **If the patient has not failed two generics but has subsequently had a successful trial of a brand drug, the PA will be approved.**
- **Altace should be reserved for a recipient who is > 55 years old with previous CV disease or diabetes plus one other risk factor for CV disease.**

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:

☐ Failed generic drug

☐ *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

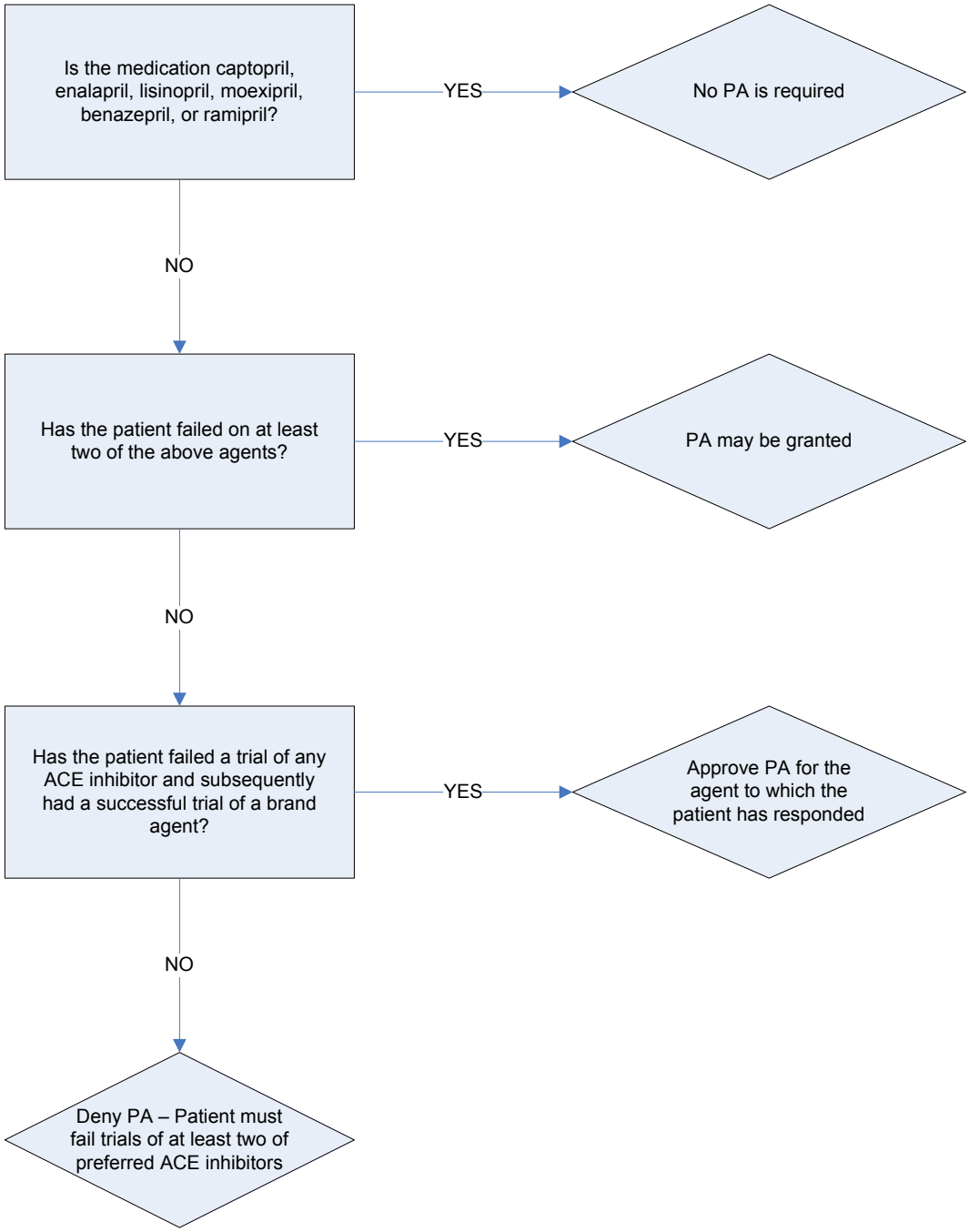
Date: / / Initials: _____

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

Denied: (Reasons)

North Dakota Department of Human Services

Ace Inhibitor Authorization Criteria Algorithm



PLEASE NOTE: ramilpril (Altace) is considerably more expensive than other preferred ACE inhibitors. DHS recommends that the use of ramipril be reserved for patients 55 years of age or older with previous cardiovascular (CV) disease or diabetes plus one other risk factor for CV disease.

NORTH DAKOTA MEDICAID
Percentage Market Share Within Sub-Classes
ACE Inhibitors

	FEB 04	APR 05	DEC 06
All ACE Inhibitors(No Subclass)			
ACCUPRIL	8.39	0.46	0.16
ACCURETIC	0.33	0.11	0.00
ACEON	0.33	0.42	0.00
ALTACE	7.61	8.61	7.19
BENAZEPRIL HCL	0.29	5.27	4.08
BENAZEPRIL HCL-HCTZ	0.00	0.98	1.47
CAPOTEN	0.00	0.00	0.00
CAPOZIDE	0.00	0.00	0.00
CAPTOPRIL	1.99	1.62	1.63
CAPTOPRIL/HYDROCHLOROTHIAZIDE	0.00	0.00	0.00
ENALAPRIL MALEATE	18.87	18.18	12.58
ENALAPRIL MALEATE-HCTZ	0.00	0.00	0.00
ENALAPRIL MALEATE/HCTZ	0.81	0.74	0.33
FOSINOPRIL SODIUM	1.77	2.57	1.14
FOSINOPRIL-HYDROCHLOROTHIAZIDE	0.00	0.18	0.33
LEXXEL	0.00	0.04	0.00
LISINOPRIL	37.70	41.67	57.03
LISINOPRIL-HCTZ	3.64	4.43	4.41
LISINOPRIL-HYDROCHLOROTHIAZIDE	0.00	0.00	1.14
LOTENSIN	5.22	0.04	0.00
LOTENSIN HCT	1.36	0.07	0.00
LOTREL	4.38	3.97	1.63
MAVIK	0.37	0.60	0.16
MOEXIPRIL HCL	2.83	0.14	0.16
MONOPRIL	1.58	0.07	0.00
MONOPRIL HCT	0.40	0.11	0.00
PRINIVIL	0.11	0.04	0.16
PRINZIDE	0.00	0.00	0.00
QUINAPRIL	0.00	1.30	0.16
QUINAPRIL HCL	0.00	4.54	3.59
QUINARETIC	0.00	0.18	0.16
TARKA	0.15	0.25	0.16
UNIRETIC	1.58	1.30	0.33
UNIVASC	0.00	2.00	1.96
VASERETIC	0.00	0.00	0.00
VASOTEC	0.07	0.00	0.00
VASOTEC I.V.	0.00	0.00	0.00
ZESTORETIC	0.18	0.11	0.00
ZESTRIL	0.04	0.04	0.00

Class added to PA May 2005

HEALTH INFORMATION DESIGNS

Prior Authorization Vendor for ND Medicaid

Sedative/Hypnotic PA Form

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 a new prescription for a name brand Sedative/Hypnotic must use Ambien® (zolpidem) as first line therapy.

****Note:***

- **The PA will be approved if there is a failed trial of Ambien® (zolpidem)**
- **Estazolam, flurazepam, temazepam, triazolam, quazepam and Ambien® (zolpidem) do not require a PA**

Part I: TO BE COMPLETED BY 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 Ambien® (zolpidem) 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:

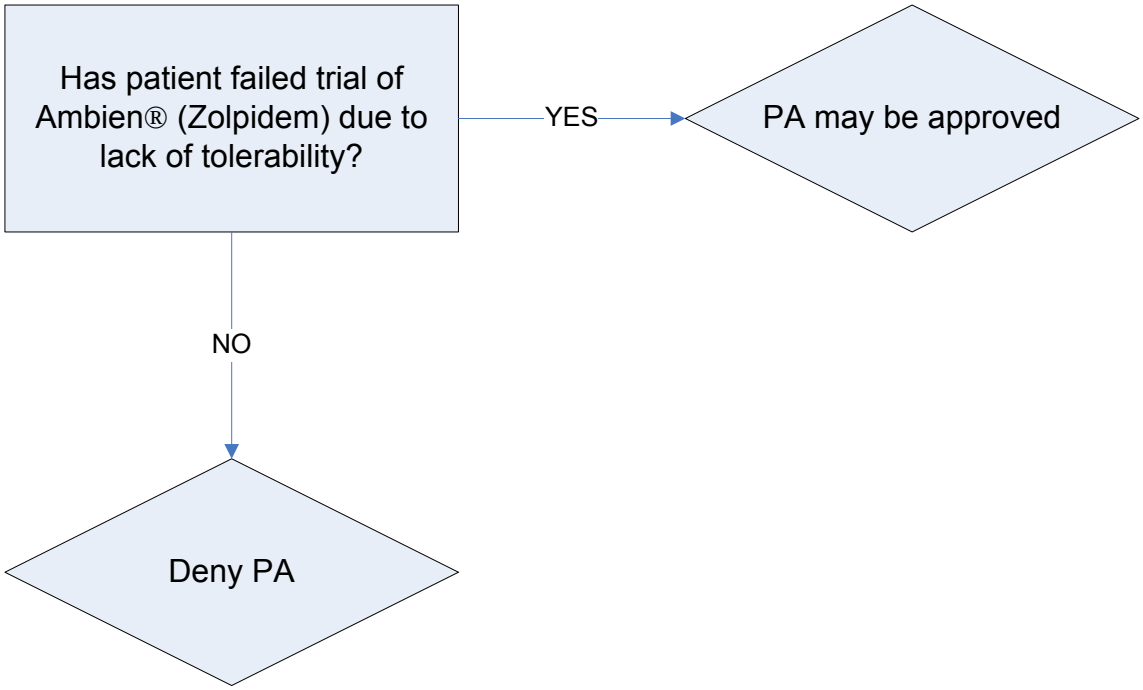
Part II: TO BE COMPLETED BY PHARMACY

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
Sedative/Hypnotic Authorization Algorithm



NORTH DAKOTA MEDICAID
Percentage Market Share Within Sub-Classes
Sedative/Hypnotics

	FEB 04	MAY 06	DEC 06
All Sedative/Hypnotics(No Subclass)			
AMBIEN	91.22	56.59	73.44
AMBIEN CR	0.00	17.51	9.93
LUNESTA	0.00	18.71	10.39
ROZEREM	0.00	4.80	4.16
SONATA	8.78	2.40	2.08

Class added to PA June 2006

NORTH DAKOTA MEDICAID
Cost Avoidance Review

PA Class	Implementation Date	Cost Avoidance* Through Dec-05	Cost Avoidance** January 2006 Through December 2006	Total Cost Avoidance
Antihistamine	Mar-04	$620,608	$343,228	$963,836
Proton Pump Inhibitors	Mar-04	$2,315,836	$618,974	$2,934,810
NSAIDS/COXII	Mar-05	$178,649	$253,744	$432,392
ACE Inhibitors	May-05	-$18,880	$21,254	$2,374
ARBS	Sep-05	$48,095	$89,406	$137,501
Sedative/Hypnotics	Jun-06	Not Implemented	$17,450	$17,450
All Classes		$3,144,307	$1,344,057	$4,488,364

***Cost Avoidance through December 2005 was calculated as follows: 1) Pre PA Actual Costs were projected using a linear trend line based on the actual cost for the most recent 12 months prior to the implementation of the PA; 2) Post PA Actual Costs were subtracted from the projection in (1) for each month after the implementation of the PA; 3) Cost Avoidance through December 2005 is the sum of the differences calculated in (2) for the months after PA implementation.**

****Cost Avoidance January 2006 through December 2006 was calculated by deducting the official state percentage of Part D recipients from the actual data through December 2005 then use the following: 1) Pre PA Actual Costs were projected using a linear trend line based on the actual cost for the most recent 12 months prior to the implementation of the PA; 2) Post PA Actual Costs were subtracted from the projection in (1) for each month after the implementation of the PA; 3) Cost Avoidance January 2006 through December 2006 is the sum of the differences calculated in (2) for the months after PA implementation.**

Amrix®[1]

Amrix is a new extended release skeletal muscle relaxant containing cyclobenzaprine hydrochloride.

Indication
Amrix is indicated as an adjunct to rest and physical therapy for relief of muscle spasm associated with acute, painful musculoskeletal conditions. Improvement is manifested by relief of muscle spasm and its associated signs and symptoms, namely, pain, tenderness, and limitation of motion. *Amrix should be used only for short periods (up to two or three weeks) because adequate evidence of effectiveness for more prolonged use is not available and because muscle spasm associated with acute, painful musculoskeletal conditions is generally of short duration and specific therapy for longer periods is seldom warranted.*

Amrix has not been found effective in the treatment of spasticity associated with cerebral or spinal cord disease or in children with cerebral palsy.

How Supplied
Amrix extended-release capsules are available in 15 and 30 mg strengths. Amrix 15 mg capsules are orange/orange and Amrix 30 mg are blue/orange.

Dosage
The recommended adult dose for most patients is one Amrix 15 mg capsule taken once daily. Some patients may require up to 30 mg/day. It is recommended that doses be taken at approximately the same time each day.

Adverse Effects
The most common adverse reactions were dry mouth, dizziness, fatigue, constipation, somnolence, nausea, dyspepsia, headache, vision blurred, dysgeusia, palpitations, tremor, dry throat, acne and disturbance in attention.

Drug Abuse and Dependence
Pharmacologic similarities among the tricyclic drugs require that certain withdrawal symptoms be considered when Amrix is administered, even though they have not been reported to occur with this drug. Abrupt cessation of treatment after prolonged administration rarely may produce nausea, headache, and malaise. These are not indicative of addiction.

Drug Interactions
Amrix may have life-threatening interactions with MAO inhibitors. Amrix may enhance the effects of alcohol, barbiturates, and other CNS depressants. Tricyclic antidepressants may block the antihypertensive action of guanethidine and similarly acting compounds. Tricyclic antidepressants may enhance the seizure risk in patients taking tramadol or tramadol/acetaminophen.

Precautions
Because of its atropine-like action, Amrix should be used with caution in patients with a history of urinary retention, angle-closure glaucoma, increased intraocular pressure and in patients taking anticholinergic medication.

Pregnancy
Amrix is Pregnancy Category B. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Manufacturer
ECR Pharmaceuticals
Richmond, Virginia 23255

[1] Product information for Amrix. ECR Pharmaceuticals, Richmond, Virginia 23255. www.fda.gov/cder/foi/label/2007/021777ll.pdf (accessed April 2nd, 2007).

AMRIX 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 try and fail generic cyclobenzaprine.
**Note:*
- **Cyclobenzaprine does not require PA**
- **Patient must fail therapy on generic cyclobenzaprine before a PA will be considered for Amrix.**

Part I: TO BE COMPLETED BY 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 cyclobenzaprine therapy Start Date: Dose:
End Date: Frequency:

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

Physician Signature: Date:

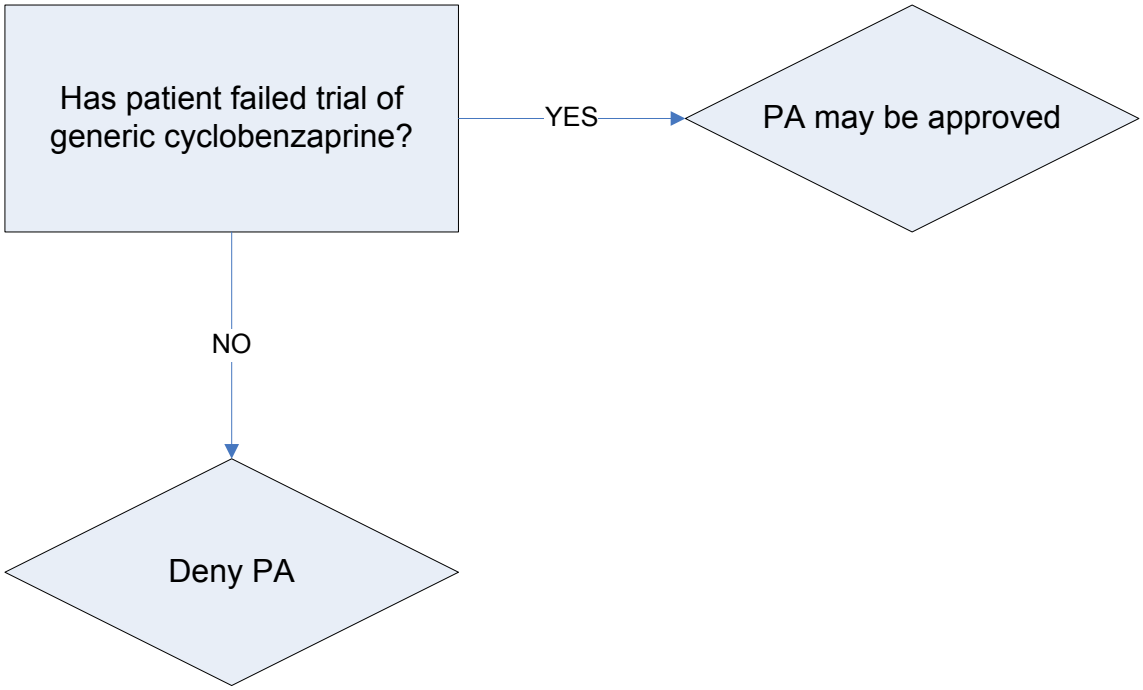
Part II: TO BE COMPLETED BY PHARMACY

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
Amrix Authorization Algorithm



Press Release

FDA Approves JANUMET™ for Type 2 Diabetes, Offering Powerful Glucose Control of a DPP-4 Inhibitor and Metformin in a Single Tablet

JANUMET (sitagliptin/metformin HCl) provides significantly greater A1C[1] reduction than metformin alone and helped more than twice as many patients get to A1C goal

WHITEHOUSE STATION, N.J., April 2, 2007—Merck & Co., Inc. announced today that the U.S. Food and Drug Administration (FDA) approved JANUMET™, the first and only tablet combining a dipeptidyl peptidase-4 (DPP-4) inhibitor, sitagliptin (also known as JANUVIA™), and metformin for the treatment of type 2 diabetes.

JANUMET has been approved, as an adjunct to diet and exercise, to improve blood sugar (glucose) control in adult patients with type 2 diabetes who are not adequately controlled on metformin or sitagliptin alone, or in patients already being treated with the combination of sitagliptin and metformin. JANUMET should not be used in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis.

The FDA approved JANUMET based upon clinical data including sitagliptin plus metformin as separate tablets. A clinical bioequivalence study has demonstrated the equivalence between JANUMET and sitagliptin plus metformin as separate tablets.

“JANUMET is the latest advance in Merck’s longstanding commitment to developing effective medicines for type 2 diabetes,” said Adam Schechter, president, United States Human Health, Merck & Co., Inc. “With JANUMET and JANUVIA, Merck now has a growing family of products that provides physicians with important treatment options for patients with type 2 diabetes.”

Full prescribing information can be found at www.janumet.com.

Janumet®[1]

Janumet is a combination medication containing sitagliptin phosphate (Januvia) with metformin for treating type 2 diabetes.

Indication
Janumet is indicated as an adjunct to diet and exercise to improve glycemic control in adult patients with type 2 diabetes mellitus who are not adequately controlled on metformin or sitagliptin alone or in patients already being treated with the combination of sitagliptin and metformin.
Important Limitations of Use
Janumet should not be used in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis.

How Supplied
Janumet is available as light pink or red, capsule-shaped, film-coated tablets containing 50 mg/500 mg or 50 mg/1000 mg of sitagliptin/metformin.

Dosage
The dosage of antihyperglycemic therapy with Janumet should be individualized on the basis of the patient's current regimen, effectiveness, and tolerability while not exceeding the maximum recommended daily dose of 100 mg sitagliptin and 2000 mg metformin. Janumet should generally be given twice daily with meals, with gradual dose escalation, to reduce the gastrointestinal (GI) side effects due to metformin.

Adverse Effects
The most common adverse experience in sitagliptin monotherapy reported regardless of investigator assessment of causality in >5% of patients and more commonly than in patients given placebo was nasopharyngitis.
The most common adverse (>5%) established adverse reactions due to initiation of metformin therapy are diarrhea, nausea/vomiting, flatulence, abdominal discomfort, indigestion, asthenia, and headache.

Precautions
Lactic Acidosis due to metformin accumulation, patients with evidence of hepatic disease, patients with evidence of renal impairment, decrease in Vitamin B12 levels, alcohol use, surgical procedures, change in lab values or clinical status, use with medications known to cause hypoglycemia, use with medications affecting renal function or metformin disposition, use during radiologic studies with IV iodinated contrast materials, hypoxic states and loss of blood glucose control.

Drug Interactions
Cationic drugs (e.g., amiloride, digoxin, morphine, procainamide, quinidine, quinine, ranitidine, triamterene, trimethoprim, or vancomycin) that are eliminated by renal tubular secretion theoretically have the potential for interaction with metformin by competing for common renal tubular transport systems.
Co-administration of metformin and glyburide did not result in any changes in either metformin pharmacokinetics or pharmacodynamics. Decreases in glyburide AUC and Cmax were observed, but were highly variable.
A single-dose, metformin-furosemide drug interaction study in healthy subjects demonstrated that pharmacokinetic parameters of both compounds were affected by co-administration.
Nifedipine appears to enhance the absorption of metformin.
Certain drugs tend to produce hyperglycemia and may lead to loss of glycemic control. These drugs include the thiazides and other diuretics, corticosteroids, phenothiazines, thyroid products, estrogens, oral contraceptives, phenytoin, nicotinic acid, sympathomimetics, calcium channel blocking drugs and isoniazid. When such drugs are administered to a patient receiving Janumet the patient should be closely observed to maintain adequate glycemic control.

Pregnancy
Janumet is Pregnancy Category B. There are no adequate and well-controlled studies in pregnant women with Janumet or its individual components; therefore, the safety of Janumet in pregnant women is not known. Janumet should be used during pregnancy only if clearly needed.

Manufacturer
Merck and Co., Inc.
Whitehouse Station, NJ 08889

[1] Product information for sitagliptin/metformin (Janumet). Merck and Co., Inc., Whitehouse Station, NJ 08999. www.janumet.com. (Accessed April 2nd, 2007).

Janumet 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 Januvia and Metformin separately.
Note:

- **Januvia does not require PA**
- **Metformin does not require PA**
- **Patient must fail therapy on Januvia 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:

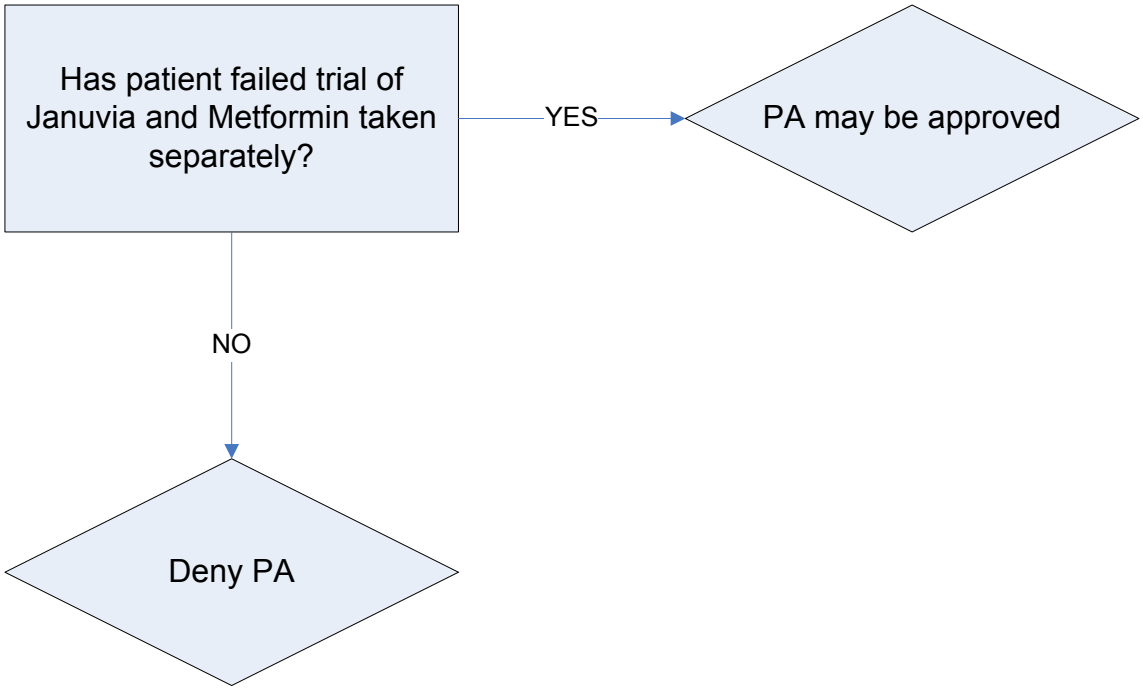
Part II: TO BE COMPLETED BY PHARMACY

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
Janumet Authorization Algorithm



Press Releases

Tekturna® - the first new type of high blood pressure medicine in more than a decade - receives its first approval in the US

- *Tekturna, the first approved direct renin inhibitor, acts on one of the body's key regulators of blood pressure by targeting renin*
- *Tekturna provides significant blood pressure reduction for a full 24 hours and is generally well tolerated*
- *Important additional blood pressure lowering observed when Tekturna added to other high blood pressure medicines*
- *High blood pressure is a leading contributor to cardiovascular disease, the world's No. 1 killer*

East Hanover, March 6, 2007 - Novartis announced today that the United States has become the first country in the world to approve Tekturna® (aliskiren) tablets, the first new type of medicine in more than a decade for treating high blood pressure - a condition estimated to affect nearly one billion people worldwide and remains uncontrolled in nearly 70% of patients.

The Food and Drug Administration (FDA) issued the approval for Tekturna as the first in a new class of drugs called direct renin inhibitors. A once-daily oral therapy, Tekturna acts by targeting renin - an enzyme responsible for triggering a process that can contribute to high blood pressure. This condition is a leading contributor to cardiovascular disease, considered the world's leading cause of death.

Tekturna received FDA approval for treatment of high blood pressure as monotherapy or in combination with other high blood pressure medications. The use of Tekturna with maximal doses of ACE inhibitors has not been adequately studied. Tekturna is expected to be available in March in pharmacies as 150 mg and 300 mg tablets.

"Renin angiotensin system activity contributes to many of the complications associated with high blood pressure," said Marc A. Pfeffer, M.D., PhD, Professor of Medicine, Harvard Medical School and Cardiologist, at Brigham & Women's Hospital. "By inhibiting this important system at its origin, renin production, a direct rennin inhibitor, such as Tekturna, offers an exciting therapeutic option for treating hypertension."

In an extensive clinical trial program involving more than 6,400 patients, Tekturna provided significant blood pressure reductions for a full 24 hours. Furthermore, Tekturna provided added efficacy when used in combination with other commonly used blood pressure medications. In clinical trials, the approved doses of Tekturna were generally well tolerated and the most common side effect experienced by more patients taking Tekturna than patients taking a sugar pill was diarrhea. Other less common reactions to Tekturna include cough and rash.

Tekturna should be discontinued as soon as pregnancy is detected as it may harm an unborn baby, causing injury and even death. Women who plan to become pregnant should talk to their doctor about other treatment options before taking Tekturna.

Angioedema has been rarely reported in patients taking Tekturna.

"Many patients require two or more medicines to control their blood pressure. As a new treatment approach, Tekturna has the potential to help these patients manage their disease," said James Shannon, MD, Global Head of Development at Novartis Pharma AG. "Tekturna demonstrates our commitment to developing innovative medicines to help the millions of patients suffering from high blood pressure."

Novartis is committed to conducting a large outcome trial program to evaluate the long-term effects of Tekturna and direct renin inhibition.

Tekturna was developed in collaboration with Speedel.

For more information about Tekturna call 1-888-TEKTURNA (1-888-835-8876) or visit www.tekturna.com.

Tekturna®

Tekturna is a new antihypertensive medication that is the first direct renin inhibitor approved by the FDA.

Indication
Tekturna is indicated for the treatment of hypertension. It may be used alone or in combination with other antihypertensive agents.

How Supplied
Tekturna is available as an unscored tablet containing 150mg or 300mg of aliskiren.

Dosage
The usual recommended starting dose of Tekturna is 150mg once daily. In patients whose blood pressure is not adequately controlled, the daily dose may be increased to 300mg. Doses above 300mg did not give an increased blood pressure response but increased the rate of diarrhea.

Patients should establish a routine pattern for taking Tekturna with regards to meals. High fat meals decrease absorption substantially.

Adverse Effects
Aliskiren produces dose-related gastrointestinal (GI) adverse effects. Diarrhea was reported by 2.3% of patients at 300mg, compared to 1.2% in placebo patients. Other GI symptoms included abdominal pain, dyspepsia, and gastroesophageal reflux, although increased rates for abdominal pain and dyspepsia were distinguished from placebo only at 600mg daily. Diarrhea and other GI symptoms were typically mild and rarely led to discontinuation.

Aliskiren was associated with a slight increase in cough in the placebo-controlled studies (1.1% for any aliskiren use vs. 0.6% for placebo). In active-controlled trials with ACE inhibitor (ramipril, lisinopril) arms, the rates of cough for the aliskiren arms were about one-third to one-half the rates in the ACE inhibitor arms.

Two cases of angioedema with respiratory symptoms were reported with aliskiren use in the clinical studies. Two other cases of periorbital edema without respiratory symptoms were reported as possible angioedema and resulted in discontinuation. The rate of these angioedema cases in the completed studies was 0.06%. In addition, 26 other cases of edema involving the face, hands, or whole body were reported with aliskiren use, including 4 leading to discontinuation.

Drug Interactions
Aliskiren is metabolized by cytochrome P450 3A4. Co-administration of lovastatin, atenolol, warfarin, furosemide, digoxin, celecoxib, hydrochlorothiazide, ramipril, valsartan, metformin and amlodipine did not result in clinically significant increases in aliskiren exposure. Co-administration with irbesartan led to a 50% reduction in the maximum concentration of aliskiren and co-administration with atorvastin led to a 50% increase in the maximum concentration of aliskiren. Following the administration of ketoconazole 200mg twice daily, an 80% increase in aliskiren plasma level was noted.

Precautions
Angioedema of the head and neck has been reported in patients taking aliskiren. If this occurs, aliskiren should be discontinued immediately and supportive treatment should be initiated.

Excessive hypotension has rarely occurred, more commonly in patients who are receiving other antihypertensive agents or in those who are salt or volume depleted. If excessive hypotension occurs, the patient should be put in the supine position, and normal saline should be given, if necessary.

Tekturna has not been studied in patients with greater than moderate renal dysfunction, in those receiving dialysis, or in those with nephritic syndrome or renovascular hypertension.

Use in Pregnancy
Aliskiren is Pregnancy Category C during the first trimester and Pregnancy Category D during the second and third trimesters. When used in pregnancy during the second and third trimesters, drugs that act directly on the rennin-angiotensin system can cause injury and even death to the developing fetus. When pregnancy is detected, Tekturna should be discontinued as soon as possible.

Manufacturer
Novartis Pharmaceuticals Corporation
East Hanover, NJ 07936[1]
www.tekturna.com

[1] Product information for aliskiren (Tekturna). Novartis Pharmaceuticals Corporation. East Hanover, NJ 07936. www.tekturna.com. (Accessed April 2nd, 2007).

HEALTH INFORMATION DESIGNS

ARB and Renin Inhibitor PA Form

Clear Fields

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 an ARB or Renin Inhibitor, must use and fail one ACE Inhibitor.

- Angiotensin II receptor antagonists: Hyzaar, Micardis, Micardis/HCT, Teveten, Teveten/HCT, Atacand, Atacand/HCT, Avapro, Avalide, Benicar, Benicar/HCT, Cozaar, Diovan, Diovan/HCT
- Renin Inhibitor: Tekturna

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:

Qualifications for coverage:

☐ Failed ACE Inhibitor	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:

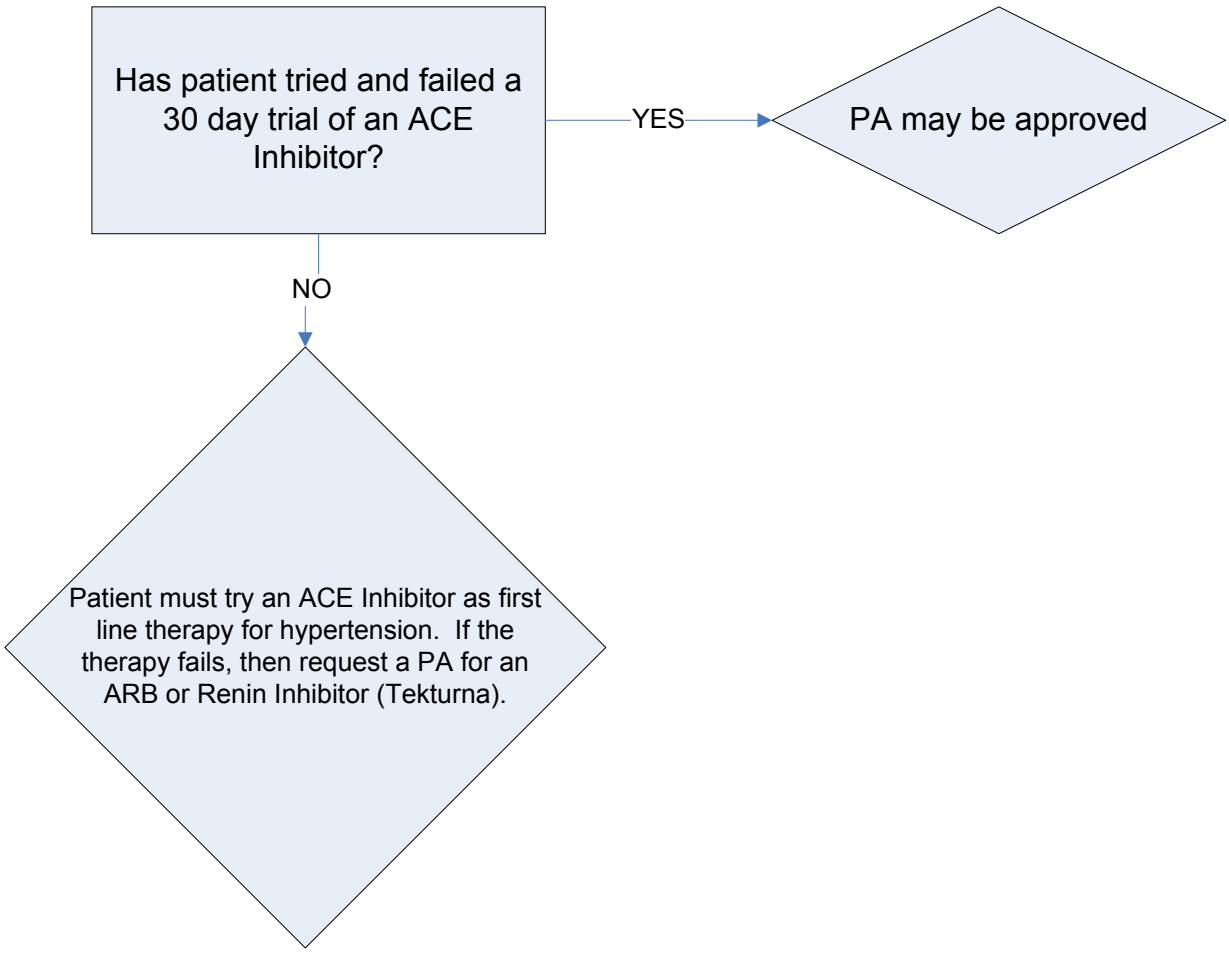
Part II: TO BE COMPLETED BY PHARMACY

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
ARB and Renin Inhibitor (Tekturna) Authorization Criteria Algorithm



Xopenex HFA®[1]

Xopenex HFA (Levalbuterol) inhalation is a selective beta2-adrenergic receptor agonist administered via nebulization. Levalbuterol is the (R)-isomer of albuterol. Levalbuterol binds to the beta2-adrenergic receptor on the airway smooth muscle leading to relaxation of the smooth muscle of the airways.

Indication

Xopenex HFA Inhalation Aerosol is indicated for the treatment or prevention of bronchospasm in adults, adolescents, and children 4 years of age and older with reversible obstructive airway disease.

How Supplied

Xopenex HFA Inhalation Aerosol is supplied as a pressurized aluminum canister in a box.

Dosage

Adults and Pediatric Asthma: For treatment of acute episodes of bronchospasm or prevention of asthmatic symptoms, the usual dosage of Xopenex HFA Inhalation Aerosol for adults and children 4 years of age and older is 2 inhalations repeated every 4 to 6 hours; in some patients, 1 inhalation every 4 hours may be sufficient. More frequent administration or a larger number of inhalations is not routinely recommended.

If a previously effective dosage regimen fails to provide the usual response, this may be a marker of destabilization of asthma and requires reevaluation of the patient and the treatment regimen, giving special consideration to the possible need for anti-inflammatory treatment, e.g., corticosteroids.

Adverse Effects

The most common adverse effects of treatment with inhaled beta-agonists include palpitations, chest pain, rapid heart rate, tremor and nervousness.

Drug Interactions

Other short-acting sympathomimetic aerosol bronchodilators or epinephrine should be used with caution with Xopenex HFA Inhalation Aerosol. If additional adrenergic drugs are to be administered by any route, they should be used with caution to avoid deleterious cardiovascular effects.

1. Beta-blockers: Beta-adrenergic receptor blocking agents not only block the pulmonary effect of beta-adrenergic agonists, but may produce severe bronchospasm in asthmatic patients. Therefore, patients with asthma should not normally be treated with beta blockers.

2. Diuretics: The ECG changes and/or hypokalemia that may result from the administration of non-potassium-sparing diuretics (such as loop and thiazide diuretics) can be acutely worsened by beta-agonists, especially when the recommended dose of the beta-agonist is exceeded. Although the clinical significance of these effects is not known, caution is advised in the co administration of beta-agonists with non-potassium-sparing diuretics.
3. Digoxin: Mean decreases of 16% to 22% in serum digoxin levels were demonstrated after single-dose intravenous and oral administration of racemic albuterol, respectively, to normal volunteers who had received digoxin for 10 days. The clinical significance of these findings for patients with obstructive airway disease is unclear.
4. Monoamine Oxidase Inhibitors or Tricyclic Antidepressants: Xopenex HFA Inhalation Aerosol should be administered with extreme caution to patients being treated with monoamine oxidase inhibitors or tricyclic antidepressants, or within 2 weeks of discontinuation of such agents, because the action of albuterol on the vascular system may be potentiated.

Precautions
Xopenex HFA Inhalation Aerosol, like all sympathomimetic amines, should be used with caution in patients with cardiovascular disorders, especially coronary insufficiency, hypertension, and cardiac arrhythmias; in patients with convulsive disorders, hyperthyroidism, or diabetes mellitus; and in patients who are unusually responsive to sympathomimetic amines. Clinically significant changes in systolic and diastolic blood pressure have been seen in individual patients and could be expected to occur in some patients after the use of any beta-adrenergic bronchodilator.

Large doses of intravenous racemic albuterol have been reported to aggravate preexisting diabetes mellitus and ketoacidosis. As with other beta-adrenergic agonist medications, Xopenex HFA Inhalation Aerosol may produce significant hypokalemia in some patients, possibly through intracellular shunting, which has the potential to produce adverse cardiovascular effects. The decrease is usually transient, not requiring supplementation.

Pregnancy
Xopenex HFA Inhalation Aerosol is Pregnancy Category C.

Manufacturer
Sepracor
Marlborough, MA 01752

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[1] Product information for Xopenex HFA. Sepracor Inc., Marlborough, MA 01752. www.xopenex.com/xopenexProviders/XopenexMDI_PI.pdf (accessed April 5th, 2007).

NDC USAGE from 01/01/06 to 02/26/07 for Program All					
Rx Num	**Qty Dispensed**	**Total Remb Amt**	**Total Claim Cost**	**Label Name**	**Cost Per Rx**
7893	151148	$127,487.97	$189,435.15	ALBUTEROL 90 MCG INHALER	$16.15
981	9321.2	$37,253.89	$45,068.88	PROAIR HFA 90 MCG INHALER	$37.98
212	1642.4	$8,253.19	$10,120.11	PROVENTIL HFA 90 MCG INHALER	$38.93
13	233	$510.99	$535.64	VENTOLIN HFA 90 MCG INHALER	$39.31
30	540	$1,151.41	$1,293.65	VENTOLIN HFA 90 MCG INHALER	$38.38
250	3797	$18,044.34	$13,600.61	XOPENEX HFA 45 MCG INHALER	$72.18
9379	166681.6	$192,701.79	$260,054.04	**Totals**	

Proventil HFA Less Expensive to North Dakota Medicaid

In March 2005, the FDA announced that the albuterol inhalers containing chlorofluorocarbons (CFCs) as propellants would be phased out and be replaced with more ozone-friendly HFA inhalers. The final discontinuation date for the CFC inhalers is December 31, 2008. The FDA does not consider the CFC and the HFA inhalers clinically interchangeable. North Dakota Medicaid encourages pharmacies to exhaust their supplies of generic albuterol before converting patients to HFA alternatives.

Albuterol products that are available HFA include, ProAir HFA, Proventil HFA and Ventolin HFA. (Long-acting bronchodilators should not be substituted as rescue inhalers for albuterol or albuterol HFA products). Proventil HFA currently offers the best price to North Dakota Medicaid of the available Albuterol HFA products.

Xopenex HFA MDI formulation became available in 2005. The main ingredient is levalbuterol. Because of the cost and limited trials showing efficacy over albuterol, Xopenex HFA should be reserved for those patients who do not tolerate albuterol.

Cost Impact to ND Medicaid

Switch from Albuterol to Proair HFA/Proventil HFA/Ventolin HFA	approx. $152, 222/year
Switch from Albuterol to Xopenex HFA	approx. $379,067/year

HEALTH INFORMATION DESIGNS

Prior Authorization Vendor for ND Medicaid

Xopenex HFA PA Form

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 a new prescription for Albuterol HFA must use Proventil HFA as first line therapy.
__Note:__

- Proventil HFA does not require 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: **XOPENEX HFA**	**Requested Dosage:** (must be completed)

Qualifications for coverage:

☐ Failed Proventil HFA 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:

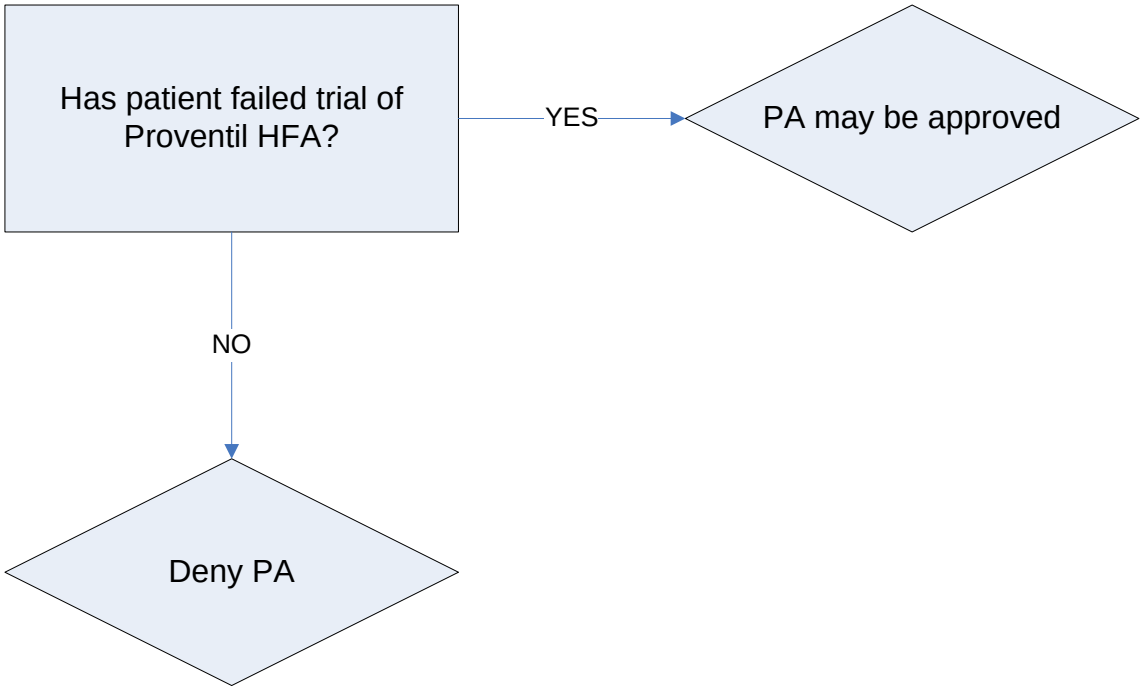
Part II: TO BE COMPLETED BY PHARMACY

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
Xopenex HFA Authorization Algorithm



Telithromycin (marketed as Ketek) Information[1]

On February 12, 2007, the FDA and the sponsor agreed on an updated label for Ketek (telithromycin), an antibiotic, and to distribute a Medication Guide (MedGuide) for patients.

The new label narrows the usage for Ketek by dropping two previously approved indications (acute bacterial exacerbation of chronic bronchitis due to *Streptococcus pneumoniae*, *Haemophilus, influenzae*, or *Moraxella catarrhalis*; and acute bacterial sinusitis due to Streptococcus pneumoniae, Haemophilus influenzae, Moraxella catarrhalis, or Staphylococcus aureus.)

Ketek is now indicated for the treatment of community-acquired pneumonia (of mild to moderate severity) due to Streptococcus pneumoniae, (including multi-drug resistant isolates, *Haemophilus influenzae, Moraxella catarrhalis, Chlamydophila pneumoniae,* or *Mycoplasma pneumoniae,* for patients 18 years and older.

The updated label includes a boxed warning and a contraindication stating that no one with myasthenia gravis should take Ketek. In addition, warnings were strengthened for hepatotoxicity (liver injury), loss of consciousness, and visual disturbances.

On June 29, 2006, the Food and Drug Administration notified healthcare professionals and patients that it completed its safety assessment of Ketek (telithromycin). FDA determined that additional warnings about the risk of liver toxicity are required and the manufacturer has revised the drug labeling to address this safety concern. In addition, the WARNINGS for patients with myasthenia gravis are being strengthened.

On January 20, 2006, the FDA advised the public that the *Annals of Internal Medicine* had published an article reporting three patients who experienced serious liver toxicity following administration of Ketek (telithromycin). These cases had also been reported to FDA MedWatch. Telithromycin is marketed and used extensively in many other countries, including countries in Europe and Japan.

[1] US Food and Drug Administration Retrieved March 20, 2007, from http://www.fda.gov/cder/drug/infopage/telithromycin/default.htm

IMPORTANT PRESCRIBING INFORMATION

KETEK® (telithromycin) DEAR HEALTHCARE PROFESSIONAL LETTER

March 2007

IMPORTANT INFORMATION ABOUT KETEK® (telithromycin)

Dear Healthcare Professional:

Sanofi-aventis U.S. would like to inform you of important updated information regarding KETEK® (telithromycin) tablets. **The prescribing information has been revised to add a boxed warning and contraindication for myasthenia gravis patients**. **In addition, the indications for the treatment of acute exacerbation of chronic bronchitis (AECB) and acute bacterial sinusitis (ABS) have been removed from the labeling.** These revisions follow discussions with the Food and Drug Administration (FDA) regarding its decision to follow recommendations of a December 2006 Advisory Committee that the balance of the benefits and risks no longer support continued marketing of Ketek for these two indications. It is important to note that Ketek continues to be indicated only for the treatment of community-acquired pneumonia (CAP) of mild to moderate severity due to *Streptococcus pneumoniae,* (including multi-drug resistant isolates [MDRSP*]), *Haemophilus influenzae, Moraxella catarrhalis, Chlamydophila pneumoniae, or Mycoplasma pneumoniae,* for patients 18 years old and older.

Safety information regarding visual disturbances and loss of consciousness, previously in the precautions section, has been added to the warnings section. **In prescribing KETEK, it is important for healthcare professionals to inform and discuss with patients the four highlighted toxicities: exacerbation of myasthenia gravis, hepatotoxicity, visual disturbances, and loss of consciousness**.

A Medication Guide has been developed that replaces the Patient Information section of the US prescribing information for KETEK, to better inform and educate patients. The Medication Guide must be provided by pharmacists to patients when KETEK® is dispensed. Healthcare professionals should advise patients to read the medication guide prior to taking KETEK.

Important changes to the updated KETEK® Prescribing Information include:

IMPORTANT DRUG SAFETY INFORMATION:

1. Add a **BOXED WARNING** regarding what is now a **CONTRAINDICATION** for patients with myasthenia gravis;
2. Include a **WARNING** concerning visual disturbances and loss of consciousness, including information previously listed in the **PRECAUTIONS** section;
3. Include a Medication Guide for patients that replaces the Patient Information section

sanofi-aventis U.S., 55 Corporate Drive, PO Box 5925, Bridgewater, NJ 08807-0890
Tel. (908) 981-5000 – www.sanofi-aventis.com

IMPORTANT PRESCRIBING INFORMATION:

1. ***Remove*** from the labeling recommendations for the use of Ketek in the treatment of acute exacerbations of chronic bronchitis (AECB) and acute bacterial sinusitis (ABS) in the **INDICATIONS AND USAGE, DOSAGE AND ADMINISTRATION and CLINICAL STUDIES** sections.

These changes have been approved by the US Food and Drug Administration.

The most important changes in the prescribing information relating to the above are as follows:

MYASTHENIA GRAVIS

Clinicians are advised to review carefully the Boxed Warning shown below, which has been added to the prescribing information.

Ketek is contraindicated in patients with myasthenia gravis. There have been reports of fatal and life-threatening respiratory failure in patients with myasthenia gravis associated with the use of Ketek. (See **CONTRAINDICATIONS**.)

CONTRAINDICATIONS

Added:

"KETEK is contraindicated in patients with myasthenia gravis. Exacerbations of myasthenia gravis have been reported in patients and sometimes occurred within a few hours of the first dose of telithromycin. Reports have included fatal and life-threatening acute respiratory failure with a rapid onset and progression."

VISUAL DISTURBANCES AND SYNCOPE

WARNINGS

Added 2 new subsections:

"**Visual disturbances*"**

KETEK may cause visual disturbances particularly in slowing the ability to accommodate and the ability to release accommodation. Visual disturbances included blurred vision, difficulty focusing, and diplopia. Most events were mild to moderate; however, severe cases have been reported.

"**Loss of Consciousness*"**

There have been post-marketing adverse event reports of transient loss of consciousness including some cases associated with vagal syndrome.

***Because of potential visual difficulties or loss of consciousness, patients should attempt to minimize activities such as driving a motor vehicle, operating heavy machinery or engaging in other hazardous activities during treatment with KETEK. If patients experience visual disorders or loss of consciousness while taking KETEK, patients should not drive a motor vehicle, operate heavy machinery or engage in other hazardous activities.** (See **PRECAUTIONS, Information for Patients**.)"

REMOVED*: ACUTE EXACERBATION of CHRONIC BRONCHITIS (AECB) and ACUTE BACTERIAL SINUSITIS (ABS) INDICATIONS*

INDICATIONS AND USAGE

***Removed* from the indications section acute exacerbation of chronic bronchitis (AECB) and acute bacterial sinusitis (ABS).**

DOSAGE AND ADMINISTRATION

Revised the dosing information to delete references to infection type and to be specific for the community acquired-pneumonia indication as follows:

"The dose of KETEK tablets is 800 mg (2 tablets of 400 mg) taken orally once every 24 hours, for 7–10 days. KETEK tablets can be administered with or without food."

We also remind healthcare professionals of the June 2006 labeling changes concerning hepatotoxicity. The current version of the warning follows.

"**WARNINGS**

"Acute hepatic failure and severe liver injury, in some cases fatal, have been reported in patients treated with KETEK. These hepatic reactions included fulminant hepatitis and hepatic necrosis leading to liver transplant, and were observed during or immediately after treatment. In some of these cases, liver injury progressed rapidly and occurred after administration of a few doses of KETEK**.**

"Physicians and patients should monitor for the appearance of signs or symptoms of hepatitis, such as fatigue, malaise, anorexia, nausea, jaundice, bilirubinuria, acholic stools, liver tenderness or hepatomegaly. **Patients with signs or symptoms of hepatitis must be advised to discontinue KETEK and immediately seek medical evaluation, which should include liver function tests**. If clinical hepatitis or transaminase elevations combined with other systemic symptoms occur, KETEK should be permanently discontinued.

"Ketek must not be re-administered to patients with a previous history of hepatitis and/or jaundice associated with the use of KETEK tablets, or any macrolide antibiotic.

"In addition, less severe hepatic dysfunction associated with increased liver enzymes, hepatitis and in some cases jaundice was reported with the use of KETEK. These events associated with less severe forms of liver toxicity were reversible."

At sanofi-aventis U.S., patient safety is our highest priority and we are committed to ensuring that healthcare professionals continue to have the information necessary to prescribe KETEK appropriately. Please carefully review this information and the revised labeling including the Medication Guide which are enclosed. Contact sanofi-aventis if you have any questions about this information or the safe and effective use of KETEK.

We also encourage you to report any adverse events experienced by your patients. Call sanofi-aventis U.S. at 1-800-633-1610 (option #2) to report adverse events occurring in connection with the use of KETEK. Alternatively, this information may be reported to FDA's MedWatch Reporting System by phone at 1-800-FDA-1088, by facsimile at 1-800-FDA-0178, or by mail using the Form 3500 at http://www.fda.gov/medwatch/index.html.

The revised product information including the Medication Guide will be included in Ketek® (telithromycin) packages manufactured after February 12, 2007, and is available on the company and product websites (www.sanofi-aventis.us and www.ketek.com) or by contacting Medical Information Services at 1-800-633-1610 (option #1) from 9 am to 5 pm (EST) Monday–Friday.

Sincerely,

Douglas Greene, MD

Senior Vice President US Medical Affairs & Chief Medical Officer
Sanofi-aventis U.S.

Enclosures: KETEK® (telithromycin) Full Prescribing Information

US.TEL.07.02.022

About Ketek

Ketek is contraindicated in patients with myasthenia gravis. There have been reports of fatal and life-threatening respiratory failure in patients with myasthenia gravis associated with the use of Ketek.

KETEK tablets are indicated for the treatment of community-acquired pneumonia (of mild to moderate severity) due to *Streptococcus pneumoniae*, (including multi-drug resistant isolates [MDRSP*]), *Haemophilus influenzae*, *Moraxella catarrhalis*, *Chlamydophila pneumoniae*, or *Mycoplasma pneumoniae*, for patients 18 years old and above.

*MDRSP, Multi-drug resistant *Streptococcus pneumoniae* includes isolates known as PRSP (penicillin-resistant *Streptococcus pneumoniae*), and are isolates resistant to two or more of the following antibiotics: penicillin, 2nd generation cephalosporins, e.g., cefuroxime, macrolides, tetracyclines and trimethoprim/sulfamethoxazole.

To reduce the development of drug-resistant bacteria and maintain the effectiveness of KETEK and other antibacterial drugs, KETEK should be used only to treat infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

KETEK is contraindicated in patients with myasthenia gravis. Exacerbations of myasthenia gravis have been reported in patients and sometimes occurred within a few hours of the first dose of telithromycin. Reports have included fatal and life-threatening acute respiratory failure with a rapid onset and progression.

KETEK is contraindicated in patients with previous history of hepatitis and/or jaundice associated with the use of KETEK tablets, or any macrolide antibiotic.

KETEK is contraindicated in patients with a history of hypersensitivity to telithromycin and/or any components of KETEK tablets, or any macrolide antibiotic.

Concomitant administration of KETEK with cisapride or pimozide is contraindicted.

Acute hepatic failure and severe liver injury, in some cases fatal, have been reported in patients treated with KETEK. These hepatic reactions included fulminant hepatitis and hepatic necrosis leading to liver transplant, and were observed during or immediately after treatment. In some of these cases, liver injury progressed rapidly and occurred after administration of a few doses of KETEK**.**

Physicians and patients should monitor for the appearance of signs or symptoms of hepatitis, such as fatigue, malaise, anorexia, nausea, jaundice, bilirubinuria, acholic stools, liver tenderness or hepatomegaly. **Patients with signs or symptoms of hepatitis must be advised to discontinue KETEK and immediately seek medical evaluation, which should include liver function tests**. If clinical hepatitis or transaminase elevations combined with other systemic symptoms occur, KETEK should be permanently discontinued.

Ketek must not be re-administered to patients with a previous history of hepatitis and/or jaundice associated with the use of KETEK tablets, or any macrolide antibiotic.

In addition, less severe hepatic dysfunction associated with increased liver enzymes, hepatitis and in some cases jaundice was reported with the use of KETEK. These events associated with less severe forms of liver toxicity were reversible.

Telithromycin has the potential to prolong the QTc interval of the electrocardiogram in some patients. QTc prolongation may lead to an increased risk for ventricular arrhythmias, including torsades de pointes. Thus, telithromycin should be avoided in patients with congenital prolongation of the QTc interval, and in patients with ongoing proarrhythmic conditions such as uncorrected hypokalemia or hypomagnesemia, clinically significant bradycardia, and in patients receiving Class IA (e.g., quinidine and procainamide) or Class III (e.g., dofetilide) antiarrhythmic agents.

Cases of torsades de pointes have been reported post-marketing with KETEK. In clinical trials, no cardiovascular morbidity or mortality attributable to QTc prolongation occurred with telithromycin treatment in 4780 patients in clinical trials, including 204 patients having a prolonged QTc at baseline.

KETEK may cause visual disturbances particularly in slowing the ability to accommodate and the ability to release accommodation. Visual disturbances included blurred vision, difficulty focusing, and diplopia. Most events were mild to moderate; however, severe cases have been reported.

There have been post-marketing adverse event reports of transient loss of consciousness including some cases associated with vagal syndrome.

Because of potential visual difficulties or loss of consciousness, patients should attempt to minimize activities such as driving a motor vehicle, operating heavy machinery or engaging in other hazardous activities during treatment with KETEK. If patients experience visual disorders or loss of consciousness while taking KETEK, patients should not drive a motor vehicle, operate heavy machinery or engage in other hazardous activities.

Clostridium difficile associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including KETEK, and may range in severity from mild diarrhea to fatal colitis. Treatment with antibacterial agents alters the normal flora of the colon leading to overgrowth of *C. difficile*.

C. difficile produces toxins A and B which contribute to the development of CDAD. Hypertoxin producing strains of *C. difficile* cause increased morbidity and mortality, as these infections can be refractory to antimicrobial therapy and may require colectomy. CDAD must be considered in all patients who present with diarrhea following antibiotic use. Careful medical history is necessary since CDAD has been reported to occur over two months after the administration of antibacterial agents.

If CDAD is suspected or confirmed, ongoing antibiotic use not directed against *C. difficile* may need to be discontinued. Appropriate fluid and electrolyte management, protein supplementation, antibiotic treatment of *C difficile,* and surgical evaluation should be instituted as clinically indicated.

Therapy with simvastatin, lovastatin, or atorvastatin should be suspended during the course of KETEK treatment. Concomitant treatment of KETEK with rifampin, a CYP 3A4 inducer, should be avoided.

Most adverse events were mild to moderate and included diarrhea, nausea, headache, dizziness, and vomiting.

HEALTH INFORMATION DESIGNS

Ketek

NDC USAGE for ketek from 01/01/06 to 02/26/07 for Program All					
NDC Code	**Rx Num**	**Qty Dispensed**	**Total Remb Amt**	**Total Claim Cost**	**Label Name**
00088222507	186	2221	$11,126.18	$14,174.17	KETEK PAK 400 MG TABLET
00088222541	87	1026	$5,537.41	$6,456.25	KETEK 400 MG TABLET
TOTAL	273	3247	$16,663.59	$20,630.42	**233 Recipients**

North Dakota Medicaid
Trend Summary Analysis
01/01/06 - 02/26/07

PERIOD COVERED	TOTAL RECIPIENTS	% CHANGE	TOTAL RXS	% CHANGE	TOTAL CLAIMS COST	% CHANGE
Jan-06	40		41		2,352.94	
Feb-06	40	0	41	0	2,467.01	4.85
Mar-06	44	10	45	9.76	3,093.56	25.4
Apr-06	35	-20.45	35	-22.22	1,961.60	-36.59
May-06	23	-34.29	23	-34.29	1,370.26	-30.15
Jun-06	12	-47.83	12	-47.83	789.49	-42.38
Jul-06	4	-66.67	4	-66.67	212.24	-73.12
Aug-06	2	-50	2	-50	132.79	-37.43
Sep-06	12	500	14	600	886.52	567.61
Oct-06	21	75	21	50	1,203.31	35.73
Nov-06	18	-14.29	18	-14.29	1,110.77	-7.69
Dec-06	7	-61.11	7	-61.11	399.58	-64.03
Jan-07	6	-14.29	7	0	516.72	29.32
Feb-07	3	-50	3	-57.14	166.8	-67.72

HEALTH INFORMATION DESIGNS

Ketek PA Form

Clear Fields

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

Prior Authorization Vendor for ND Medicaid

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

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:

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

Physician Signature: Date:

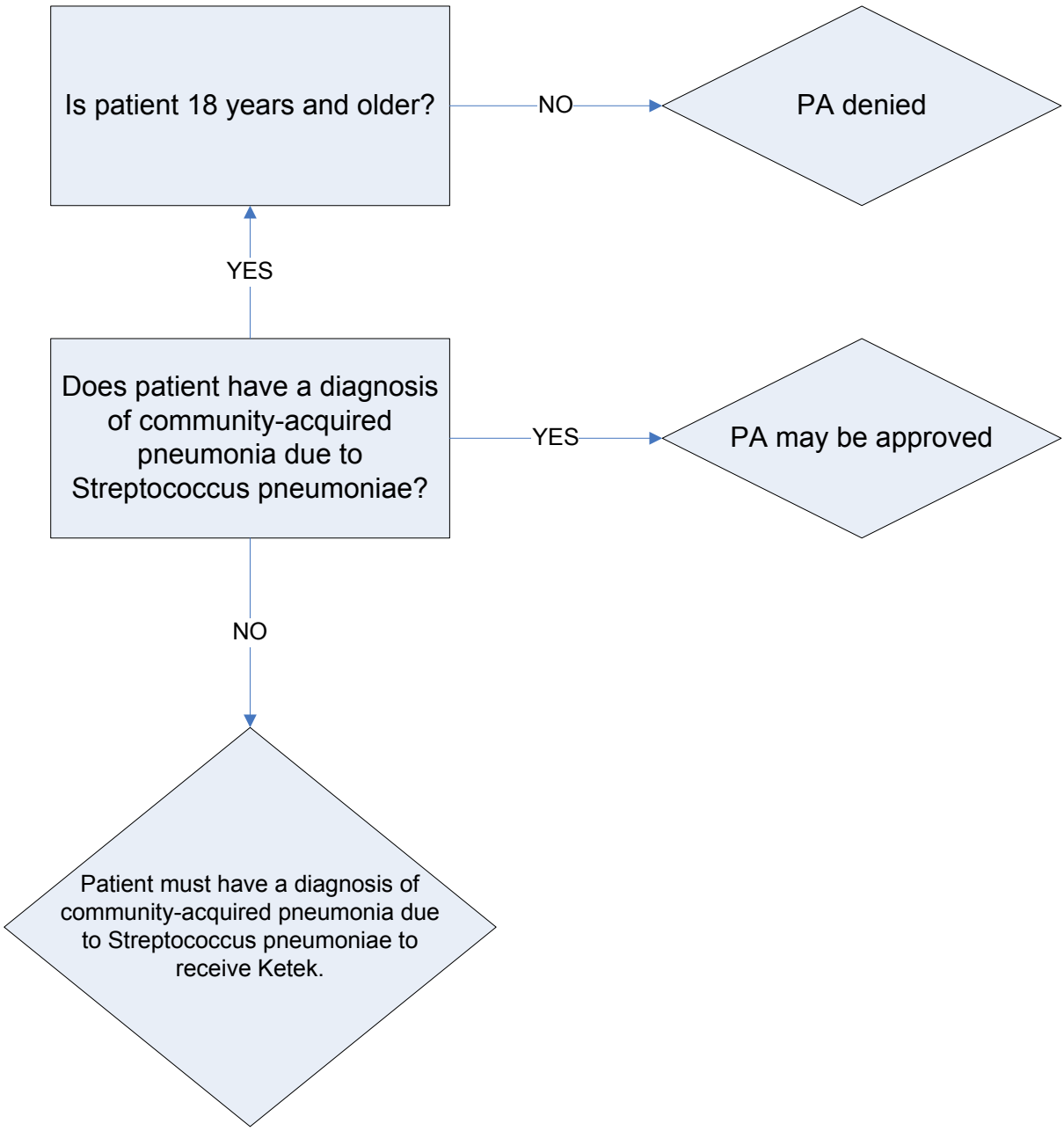
Part II: TO BE COMPLETED BY PHARMACY

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
Ketek Criteria Algorithm



AAP 2006 REDBOOK RECOMMENDATIONS FOR THE PREVENTION OF RSV

CLINICAL MANIFESTATIONS: Respiratory syncytial virus (RSV) causes acute respiratory tract illness in patients of all ages. In infants and young children, RSV is the most important cause of bronchiolitis and pneumonia. During the first few weeks of life, particularly among preterm infants, infection with RSV may produce minimal respiratory tract signs. Lethargy, irritability, and poor feeding, sometimes accompanied by apneic episodes, may be the presenting manifestations in infants. Most previously healthy infants infected with RSV do not require hospitalization, and many who are hospitalized improve with supportive care and are discharged in fewer than 5 days. Characteristics that increase the risk of severe or fatal RSV infection are preterm birth; cyanotic or complicated congenital heart disease, especially conditions causing pulmonary hypertension; underlying pulmonary disease, especially chronic lung disease of prematurity; and immunodeficiency disease or therapy causing immunosuppression at any age. The association between RSV bronchiolitis early in life and subsequent reactive airway disease remains poorly understood. After RSV bronchiolitis, many children will have episodes of recurrent wheezing, which usually diminish in subsequent years. Some children may develop wheezing at older ages or develop long-term abnormalities in pulmonary function. This association may reflect an underlying predisposition to reactive airway disease rather than a direct consequence of RSV infection.

Almost all children are infected at least once by 2 years of age, and reinfection throughout life is common. Respiratory syncytial virus infection in older children and adults usually manifests as upper respiratory tract illness, but more serious disease involving the lower respiratory tract also can develop in immunocompromised patients or in the elderly. Exacerbation of acute asthmatic bronchitis or other chronic lung conditions may occur.

ETIOLOGY: Respiratory syncytial virus is an enveloped RNA paramyxovirus that lacks neuraminidase and hemagglutinin surface glycoproteins. Two major strains (groups A and B) have been identified and often circulate concurrently. The clinical and epidemiologic significance of strain variation has not been determined, but some evidence suggests that antigenic differences may affect susceptibility to infection and that some strains may be more virulent than other strains.

EPIDEMIOLOGY: Humans are the only source of infection. Transmission usually is by direct or close contact with contaminated secretions, which may involve droplets or fomites. Respiratory syncytial virus can persist on environmental surfaces for many hours and for a half-hour or more on hands. Infection among hospital personnel and others can occur by self-inoculation with contaminated secretions. Enforcement of infection control policies is important to decrease the risk of health care-related transmission of RSV. Health care-related spread of RSV to organ transplant recipients or patients with cardiopulmonary abnormalities or immunocompromised conditions has been associated with severe and fatal disease in children and adults.

Respiratory syncytial virus usually occurs in annual epidemics during winter and early spring in temperate climates. Spread among household and child care contacts, including adults, is common. The period of viral shedding usually is 3 to 8 days, but shedding may last longer, especially in young infants and in immunosuppressed individuals, in whom shedding may continue for as long as 3 to 4 weeks.

The **incubation period** ranges from 2 to 8 days; 4 to 6 days is most common.

DIAGNOSTIC TESTS: Rapid diagnostic assays, including immunofluorescent and enzyme immunoassay techniques for detection of viral antigen in nasopharyngeal specimens, are available commercially and generally are reliable. The sensitivity of these assays in comparison with culture varies between 53% and 96%, with most in the 80% to 90% range. As with all antigen detection assays, false-positive test results are more likely to occur at the beginning or end of the RSV season when the incidence of disease is low. Therefore, antigen detection assays should not be the solitary basis on which the beginning and end of monthly prophylaxis is determined.

Viral isolation from nasopharyngeal secretions in cell cultures requires 3 to 5 days, but results and sensitivity vary among laboratories, because methods of isolation are exacting and RSV is a labile virus. Experienced viral laboratory personnel should be consulted for optimal methods of collection and transport of specimens. Serologic testing of acute and convalescent serum specimens should not be used to confirm infection; in particular, the sensitivity of serologic diagnosis of infection is low among young infants. The polymerase chain reaction assay has been used for detection of RSV in clinical specimens but is not available commercially.

TREATMENT: Primary treatment is supportive and should include hydration, careful clinical assessment of respiratory status, including measurement of oxygen saturation, use of supplemental oxygen, suction of the upper airway, and if necessary, intubation and mechanical ventilation. Ribavirin has in vitro antiviral activity against RSV, but ribavirin aerosol treatment for RSV infection is not recommended routinely. Ribavirin therapy has been associated with a small but statistically significant increase in oxygen saturation during the acute infection in several small studies. However, a consistent decrease in need for mechanical ventilation, decrease in length of stay in the pediatric intensive care unit, or reduction in days of hospitalization among ribavirin recipients has not been demonstrated. The high cost, aerosol route of administration, concern about potential toxic effects among exposed health care professionals, and conflicting results of efficacy trials have led to controversy about the use of this drug. A decision about ribavirin administration should be made on the basis of the particular clinical circumstances and experience of the physician.

BETA-ADRENERGIC AGENTS. Beta-adrenergic agents are not recommended for routine care of first-time wheezing associated with RSV bronchiolitis. Some physicians elect to use bronchodilator therapy because of concern that reactive airway disease may be misdiagnosed as bronchiolitis. Repeat doses of an inhaled bronchodilator should be

continued only in the small number of infants with well-documented improvement in respiratory function soon after the first dose.

CORTICOSTEROIDS. In hospitalized infants with RSV bronchiolitis, corticosteroids are not effective and are not indicated.

ANTIMICROBIAL AGENTS. Antimicrobial agents rarely are indicated, because bacterial lung infection and bacteremia are uncommon in infants hospitalized with RSV bronchiolitis or pneumonia. Otitis media occurs in infants with RSV bronchiolitis, but oral antibiotic agents can be used if therapy for otitis media is necessary.

PREVENTION OF RSV INFECTIONS. Palivizumab, a humanized mouse monoclonal antibody that is administered intramuscularly, is available to reduce the risk of RSV hospitalization in high-risk children. Respiratory Syncytial Virus Immune Globulin Intravenous (RSV-IGIV), a hyperimmune, polyclonal globulin prepared from donors selected for high serum titers of RSV neutralizing antibody, no longer is available. Palivizumab is licensed for prevention of RSV lower respiratory tract disease in selected infants and children with chronic lung disease of prematurity (CLD [formerly called bronchopulmonary dysplasia]) or with a history of preterm birth (<35 weeks' gestation) or with congenital heart disease. Palivizumab is administered every 30 days, beginning in early November, with 4 subsequent monthly doses (total of 5 doses). The dose of palivizumab is 15 mg/kg, administered intramuscularly. Palivizumab is not effective in the treatment of RSV disease, and it is not approved for this indication.

Recommendations by the American Academy of Pediatrics for the use of palivizumab are as follows:

- Palivizumab prophylaxis should be considered for infants and children younger than 24 months of age with chronic lung disease of prematurity who have required medical therapy (supplemental oxygen, bronchodilator or diuretic or corticosteroid therapy) for CLD within 6 months before the start of the RSV season. Patients with more severe CLD who continue to require medical therapy may benefit from prophylaxis during a second RSV season. Data are limited regarding the effectiveness of palivizumab during the second year of life. Individual patients may benefit from decisions made in consultation with neonatologists, pediatric intensivists, pulmonologists, or infectious disease specialists.
- Infants born at 32 weeks of gestation or earlier may benefit from RSV prophylaxis, even if they do not have CLD. For these infants, major risk factors to consider include their gestational age and chronologic age at the start of the RSV season. Infants born at 28 weeks of gestation or earlier may benefit from prophylaxis during their first RSV season, whenever that occurs during the first 12 months of life. Infants born at 29 to 32 weeks of gestation may benefit most from prophylaxis up to 6 months of age. For the purpose of this recommendation, 32 weeks' gestation refers to an infant born on or before the 32nd week of gestation (ie, 32 weeks, 0 days). Once a child qualifies for initiation of prophylaxis at the

start of the RSV season, administration should continue throughout the season and not stop at the point an infant reaches either 6 months or 12 months of age.

- Although palivizumab has been shown to decrease the likelihood of hospitalization in infants born between 32 and 35 weeks of gestation (ie, between 32 weeks, 1 day and 35 weeks, 0 days), the cost of administering prophylaxis to this large group of infants must be considered carefully. Therefore, most experts recommend that prophylaxis should be reserved for infants in this group who are at greatest risk of severe infection and who are younger than 6 months of age at the start of the RSV season. Epidemiologic data suggest that RSV infection is more likely to lead to hospitalization for these infants when the following risk factors are present: child care attendance, school-aged siblings, exposure to environmental air pollutants, congenital abnormalities of the airways, or severe neuromuscular disease. However, no single risk factor causes a very large increase in the rate of hospitalization, and the risk is additive as the number of risk factors for an individual infant increases. Therefore, prophylaxis should be considered for infants between 32 and 35 weeks of gestation only if 2 or more of these risk factors are present. Passive household exposure to tobacco smoke has not been associated with an increased risk of RSV hospitalization on a consistent basis. Furthermore, exposure to tobacco smoke is a risk factor that can be controlled by the family of an infant at increased risk of severe RSV disease, and preventive measures will be far less costly than palivizumab prophylaxis. High-risk infants never should be exposed to tobacco smoke. In contrast to the well-documented beneficial effect of breastfeeding against many viral illnesses, existing data are conflicting regarding the specific protective effect of breastfeeding against RSV infection. High-risk infants should be kept away from crowds and from situations in which exposure to infected individuals cannot be controlled. Participation in group child care should be restricted during the RSV season for high-risk infants whenever feasible. Parents should be instructed on the importance of careful hand hygiene. In addition, all high-risk infants and their contacts should be immunized against influenza beginning at 6 months of age.
- In the Northern hemisphere and particularly within the United States, RSV circulates predominantly between November and March. The inevitability of the RSV season is predictable, but the severity of the season, the time of onset, the peak of activity, and the end of the season cannot be predicted precisely. There can be substantial variation in timing of community outbreaks of RSV disease from year to year in the same community and between communities in the same year, even in the same region. These variations, however, occur within the overall pattern of RSV outbreaks, usually beginning in November or December, peaking in January or February, and ending by the end of March or sometime in April. Communities in the southern United States tend to experience the earliest onset of RSV activity, and Midwestern states tend to experience the latest. The duration of the season for western and northeast regions typically occurs between that noted in the South and the Midwest. In recent years, the national median duration of the RSV season has been 15 weeks and even in the South, with a seasonal duration of 16 weeks, the range is 13 to 20 weeks. Results from clinical trials indicate that palivizumab trough serum concentrations >30 days after the fifth dose will be well

above the protective concentration for most infants. If the first dose is administered in November, 5 monthly doses of palivizumab will provide substantially more than 20 weeks of protective serum antibody concentrations for most of the RSV season, even with variation in season onset and end. Changes from this recommendation of 5 monthly doses require careful consideration of the benefits and costs.

- Children who are 24 months of age or younger with hemodynamically significant cyanotic and acyanotic congenital heart disease will benefit from palivizumab prophylaxis. Decisions regarding prophylaxis with palivizumab in children with congenital heart disease should be made on the basis of the degree of physiologic cardiovascular compromise. Children younger than 24 months of age with congenital heart disease who are most likely to benefit from immunoprophylaxis include:
- Infants who are receiving medication to control congestive heart failure
- Infants with moderate to severe pulmonary hypertension
- Infants with cyanotic heart disease

Because a mean decrease in palivizumab serum concentration of 58% was observed after surgical procedures that use cardiopulmonary bypass, for children who still require prophylaxis, a postoperative dose of palivizumab (15 mg/kg) should be considered as soon as the patient is medically stable.

The following groups of infants are **not** at increased risk of RSV and generally should not receive immunoprophylaxis:

- Infants and children with hemodynamically insignificant heart disease (eg, secundum atrial septal defect, small ventricular septal defect, pulmonic stenosis, uncomplicated aortic stenosis, mild coarctation of the aorta, and patent ductus arteriosus)
- Infants with lesions adequately corrected by surgery, unless they continue to require medication for congestive heart failure
- Infants with mild cardiomyopathy who are not receiving medical therapy

Dates for initiation and termination of prophylaxis should be based on the same considerations as for high-risk preterm infants.

- Palivizumab prophylaxis has not been evaluated in randomized trials in immunocompromised children. Although specific recommendations for immunocompromised patients cannot be made, children with severe immunodeficiencies (eg, severe combined immunodeficiency or advanced acquired immunodeficiency syndrome) may benefit from prophylaxis.
- Limited studies suggest that some patients with cystic fibrosis may be at increased risk of RSV infection. However, insufficient data exist to determine the effectiveness of palivizumab use in this patient population.
- If an infant or child who is receiving palivizumab immunoprophylaxis experiences a breakthrough RSV infection, monthly prophylaxis should continue through the

RSV season. This recommendation is based on the observation that high-risk infants may be hospitalized more than once in the same season with RSV lower respiratory tract disease and the fact that more than one RSV strain often cocirculates in a community.

- Physicians should arrange for drug administration within 6 hours after opening a vial of palivizumab, because this biological product does not contain a preservative.
- Respiratory syncytial virus is known to be transmitted in the hospital setting and to cause serious disease in high-risk infants. In high-risk hospitalized infants, the major means to prevent RSV disease is strict observance of infection control practices, including prompt isolation of RSV-infected infants. If an RSV outbreak occurs in a high-risk unit (eg, pediatric intensive care unit), primary emphasis should be placed on proper infection control practices, especially hand hygiene. No data exist to support palivizumab use in controlling outbreaks of nosocomial disease.
- Palivizumab does not interfere with response to vaccines.

ISOLATION OF THE HOSPITALIZED PATIENT: In addition to standard precautions, contact precautions are recommended for the duration of RSV-associated illness among infants and young children, including patients treated with ribavirin. The effectiveness of these precautions depends on compliance and necessitates scrupulous adherence to appropriate hand hygiene practices. Patients with RSV infection should be cared for in single rooms or placed in a cohort.

CONTROL MEASURES: The control of nosocomial RSV transmission is complicated by the continuing chance of introduction through infected patients, staff, and visitors. During the peak of the RSV season, many infants and children hospitalized with respiratory tract symptoms will be infected with RSV and should be cared for with contact precautions (see Isolation of the Hospitalized Patient, p 565). Early identification of RSV-infected patients (see Diagnostic Tests, p 561) is important so that appropriate precautions can be instituted promptly. During large outbreaks, a variety of measures have been demonstrated to be effective, including the following: (1) laboratory screening of symptomatic patients for RSV infection; (2) cohorting infected patients and staff; (3) excluding visitors with respiratory tract infections; (4) excluding staff with respiratory tract illness or RSV infection from caring for susceptible infants; and (5) use of gowns, gloves, goggles, and perhaps masks.

A critical aspect of RSV prevention among high-risk infants is education of parents and other caregivers about the importance of decreasing exposure to and transmission of RSV. Preventive measures include limiting, where feasible, exposure to contagious settings (eg, child care centers) and emphasis on hand hygiene in all settings, including the home, especially during periods when the contacts of high-risk children have respiratory infections.

Related text in Red Book:

Preterm and Low Birth Weight Infants

Red Book 2006: 67-69. [Extract] [Full Version]

American Indian/Alaska Native Children

Red Book 2006: 87-90. [Extract] [Full Version]

This topic has been referenced by these articles:

- Uzel, G., Premkumar, A., Malech, H. L., Holland, S. M. (2000). Respiratory Syncytial Virus Infection in Patients With Phagocyte Defects. *Pediatrics* 106: 835-837 [Abstract] [Full Version]
- Gavin, P. J., Katz, B. Z. (2002). Intravenous Ribavirin Treatment for Severe Adenovirus Disease in Immunocompromised Children. *Pediatrics* 110: e9-9 [Abstract] [Full Version]
- Bockova, J., O'Brien, K. L., Oski, J., Croll, J., Reid, R., Weatherholtz, R. C., Santosham, M., Karron, R. A. (2002). Respiratory Syncytial Virus Infection in Navajo and White Mountain Apache Children. *Pediatrics* 110: e20-20 [Abstract] [Full Version]
- Titus, M. O., Wright, S. W. (2003). Prevalence of Serious Bacterial Infections in Febrile Infants With Respiratory Syncytial Virus Infection. *Pediatrics* 112: 282-284 [Abstract] [Full Version]
- Thatayatikom, A., Liu, A. H. (2005). Vascular Endothelial Growth Factor (VEGF) Induces Remodeling and Enhances Th2-Mediated Sensitization and Inflammation in the Lung. *Pediatrics* 116: 556-557 [Full Version]
- Choudhuri, J. A., Ogden, L. G., Ruttenber, A. J., Thomas, D. S.K., Todd, J. K., Simoes, E. A.F. (2006). Effect of Altitude on Hospitalizations for Respiratory Syncytial Virus Infection. *Pediatrics* 117: 349-356 [Abstract] [Full Version]
- Pinto, R. A., Arredondo, S. M., Bono, M. R., Gaggero, A. A., Diaz, P. V. (2006). T Helper 1/T Helper 2 Cytokine Imbalance in Respiratory Syncytial Virus Infection Is Associated With Increased Endogenous Plasma Cortisol. *Pediatrics* 117: e878-e886 [Abstract] [Full Version]

HEALTH INFORMATION DESIGNS

Synagis

NDC USAGE for synagis from 08/01/05 to 05/01/06 for Program All				
NDC Code	**Rx Num**	**Qty Dispensed**	**Total Price**	**Label Name**
60574411101	141	159	$201,775.83	SYNAGIS 100 MG VIAL
60574411201	83	91	$59,432.00	SYNAGIS 50 MG VIAL
60574411301	35	38	$48,549.18	SYNAGIS 100 MG/1 ML VIAL
60574411401	20	25	$33,700.00	SYNAGIS 50 MG/0.5 ML VIAL
TOTAL	279	313	$343,457.01	
60 patients/30 physicians				

NDC USAGE for synagis from 08/01/06 to 02/26/07 for Program All				
NDC Code	**Rx Num**	**Qty Dispensed**	**Total Claim Cost**	**Label Name**
60574411301	152	160	$268,195.15	SYNAGIS 100 MG/1 ML VIAL
60574411401	68	34	$60,529.34	SYNAGIS 50 MG/0.5 ML VIAL
TOTAL	220	194	$328,724.49	
77 patients/28 physicians				

BlueCross BlueShield Of North Dakota

4510 13th Avenue S.W.
Fargo, North Dakota 58121-0001

An independence license of the
Blue Cross & Blue Shield Association.

Synagis Benefit Inquiry
(For review: contact the Onsite Coordinator or Fax to (701)277-2253)

Name: _____ Date: _____

DOB: _____ Physician: _____

Benefit Plan #: _____

Criteria:
_____ 32 weeks gestation or less

_____ Between 32 1/7 and 35 0/7 weeks gestation
And 2 of the following:
_____ Child Care attendance
_____ School-aged siblings
_____ Exposure to environmental air pollutants
_____ Congenital abnormalities of the airways
_____ Severe neuromuscular disease

Approved _____

Approval determinations are based on medical necessity provided coverage is in force for the patient and the provider is eligible for reimbursement at the time the services are rendered. Benefits for approved services are subject to the definitions, conditions, limitations and exclusions of this Benefit Plan.

Denied _____
Denied Explanation:
_____
_____

Providers can obtain benefit information by calling the Provider Service Department at 701-282-1090 or 1-800-368-2312 or for Federal Employee Program ("R" contract #), please call 1-800-548-4026 or 701-282-1468.

Authorizing Signature: _____ Date: _____

Ref. # _____

Provider, **if you wish a reconsideration of this decision, it must be requested in writing.** Please send your request letter to the Medical Management and attach further documentation to support the request.

1/14/2004

Iowa Medicaid Drug Prior Authorization Criteria

The drug prior authorization unit will consider other conditions as listed in the compendia on an individual basis after reviewing documentation submitted regarding the medical necessity.

Updated 01/16/2006

Palivizumab (RSV Prophylaxis) *Use Palivizumab PA form*	Prior authorization is required for therapy with palivizumab. Payment for palivizumab shall be authorized for patients who meet one of the following criteria: 1. Patient is less than 24 months of age at start of therapy and has chronic lung disease requiring medication or oxygen within the last six months. 2. Patient is less than 12 months of age at start of therapy with a gestational age of less than or equal to 28 weeks. 3. Patient is less than 6 months of age at start of therapy with a gestational age between 28 weeks and 31 weeks. 4. Patient is less than 6 months of age at start of therapy with a gestational age of 32 weeks to 35 weeks and has at least one additional risk factor.

New York Medicaid GUIDELINES

Following are guidelines for identifying children who should be considered for RSV prophylaxis adapted from the American Academy of Pediatrics' Policy Statement[1]:

- Infants and children less than 24 months of age with CLD who have required medical therapy for CLD within the past 6 months before the anticipated start of the RSV season.
- Neonates born at greater than 28 weeks and less than 32 weeks gestation with or without CLD who are less than 6 months of age at the start of the RSV season.
- Neonates born at 28 weeks of gestation or less with or without CLD and who are less than 12 months of age at the start of the RSV season.
- Neonates born between 32 and 35 weeks gestation with or without CLD who are less than 6 months of age at the start of the RSV season only if two or more additional risk factors are present including: school-age siblings, child-care attendance, exposure to environmental air pollutants, congenital abnormalities of the airways or severe neuromuscular disease.
- Children who are 24 months of age or younger with hemodynamically significant cyanotic and acyanotic congenital heart disease.

Palivizumab should not be used for the treatment of RSV disease.

Palivizumab (Synagis®) Medicaid Prior Authorization Criteria [1]

Approval Criteria

- Treatment is being administered at the start or within the RSV season for Idaho AND
- Patient is < 2 years old with chronic lung disease that has required treatment within the past 6 months OR
- Patient is being treated for hemodynamically significant congenital heart disease OR
- Patient was born at less than 29 weeks of gestation and is currently younger than one year of age OR
- Patient was born between 29 and 32 weeks gestation and is currently less than six months of age OR
- Patient was born between 32 and 35 weeks gestation and is currently six months of age or less and has multiple risk factors present:
    - neurological disease,
    - low birth weight,
    - more than 1 young sibling,
    - child care center attendance,
    - exposure to tobacco smoke,
    - anticipated cardiac surgery,
    - and/or long distance from hospital care

Denial Criteria

- Agent is being used for second season prophylaxis
  Exception: the patient has chronic lung disease or hemodynamically significant congenital heart disease requiring medical therapy..

1. Criteria are based on: Revised indications for the use of palvizumab and respiratory syncytial virus immune globulin intravenous for the prevention of respiratory syncytial virus infections. American Academy of Pediatrics Policy Statement. Pediatrics 2003;112:1442-1446. www.aap.org/policy/s020305.html

SD EForm - 1000 V2

HELP

DEPARTMENT OF SOCIAL SERVICES
DIVISION OF MEDICAL SERVICES
700 Governors Drive
Pierre, South Dakota 57501-2291
(605) 773-3495
Pierre: Nicki Bartel, RN, RHIT - Fax (605) 773-5246
Sioux Falls: Ellen Brubeck, RN - Fax (605) 367-5253
Rapid City: Myrna Laumbach, RN - Fax (605) 394-2699

Complete and use the button at the end to print for mailing.

SYNAGIS/RESPIGAM PRIOR AUTHORIZATION

Patient Name: _____ DOB: _____

Medicaid #_____ Request Date:_____

Provider Name: _____ Provider #:_____

Provider Address: _____

Provider Phone: _____ Fax: _____ Email: _____

Submitted by/Contact Person: _____ Phone: _____ Fax: _____

****

Synagis and Respigam are covered by the South Dakota Medicaid Program when a child meets one of the following criteria and **it has been recommended by a Neonatologist, Pediatric Pulmonologist, or Pediatric Cardiologist**:

☐ A Children under 6 months of age at the onset of the RSV season who were 35 weeks and less gestational age at birth.

☐ B Children under two years of age at the onset of the RSV season with evidence of ongoing lung disease such as bronchopulmonary dysplasia or cystic fibrosis requiring treatment with oral bronchodilators, supplemental oxygen, diuretics, or nebulized or inhaled medications to stabilize the disease in the last 6 months.

☐ C Children under two years of age at the onset of the RSV season with immunodeficiences that may make them more susceptible to severe lower respiratory tract disease related to RSV.

☐ D Any child under two years of age at the onset of the RSV season felt to be at high risk for significant lower respiratory tract illness related to RSV.

DIAGNOSIS:_____

HOSPITALIZATIONS/TREATMENT/MEDICATIONS USED IN THE LAST 6 MONTHS:

Medication: Synagis ☐ Respigam ☐ Gestational age at birth _____

Neonatologist, Pediatric Pulmonologist, or Pediatric Cardiologist: (*REQUIRED)*

Printed Name: _____ Signature: _____

(Both physician signatures are required.)

Prescribing physician: *(REQUIRED)*

Printed Name: _____ Signature: _____

Location: Clinic _____ Home Health _____ Outpatient Hospital _____

1 PRINT FOR MAILING CLEAR FORM

Medicaid Pharmacy Request Form
Synagis® Prior Authorization

FAX: (800) 748-0116
Phone: (800) 748-0130

Fax or Mail to
HEALTH INFORMATION DESIGNS

P.O. Box 3210
Auburn, AL 36832-3210

PATIENT INFORMATION

Patient Name _____ Patient Medicaid # _____

Patient DOB _____ Patient phone # with area code _____

PRESCRIBER INFORMATION

Prescribing physician _____ License # _____

Phone # with area code _____ Fax # with area code _____

Address (Optional) _____
(Address/City/State/Zip)

I certify that this treatment is indicated and necessary and meets the guidelines for use as outlined by the Alabama Medicaid Agency. I will be supervising the patient's treatment. Supporting documentation is available in the patient record.

_____
Physician's signature Date

DRUG/CLINICAL INFORMATION

Drug requested _____ Strength _____

J Code _____ (if applicable) Qty. per month _____ NDC # _____

Diagnosis or ICD-9 Code* _____ Diagnosis or ICD-9 Code* _____

Current weight _____ kg. Number of doses requested _____

(Check applicable age, condition and risk factors)

- ❒ Gestational age ≤ 28 wks & infant is < 12 months
- ❒ Gestational age 29-32 wks & infant is < 6 months
- ❒ Gestational age 33-35 wks & infant < 6 months with AAP risk factors*
  AND
- ❒ Currently outpatient with no inpatient stay in the last 2 weeks.
- ❒ Child is < 24 months old with Chronic Lung Disease*
- ❒ Child is < 24 months old with Congenital Heart Disease*

*Document AAP risk factor(s) and/or other required medical justification .

Medical justification _____

❒ **Additional medical justification attached.**

❒ A dose of Synagis® was administered while patient was hospitalized. Date dose administered _____

PHARMACY INFORMATION

Dispensing pharmacy _____ Provider # _____

Phone # with area code _____ Fax # with area code _____

FOR HID USE ONLY

❒ Approve request ❒ Deny request ❒ Modify request ❒ Medicaid eligibility verified

Comments _____

_____ _____
Reviewer's Signature Response Date/Hour

SYNAGIS® (PALVIZUMAB)

MS Medicaid will approve the administration of Synagis® for children meeting the American Academy of Pediatrics (AAP) Redbook recommendations for RSV immunoprophylaxis. The criteria detailed below are based on the AAP recommendations.

Beneficiaries must meet criteria in one of four categories:

Category 1 Prematurity of ≤ 28 weeks gestation Age: ≤ 1 year	Category 2 Prematurity of 29-32 weeks gestation Age: ≤ 6 months at the start of Respiratory Syncytial Virus season.
Category 3 Prematurity of ≤ 35 weeks gestation Age: 0 – 24 months old Risk factor(s) as noted below are present, documented and indicated on PA form.	Category 4 33 - 35 weeks gestation Age: 0-6 months old during RSV season Risk factor(s) as noted below are present, documented an indicated on PA form. No diagnosis of CLD is required.

Coverage limitations:

- Authorization will end at age 24 months (last day of child's birthday month). Extension beyond age 24 months will be considered on an individual basis when supported by clinical documentation of extreme necessity.
- Authorization will be granted for administration between October 16 and March 31. In consultation with community clinical leaders during early March, an annual assessment will be made as to whether an extension of the season is necessary.
- Coverage will be limited to five doses. Doses administered during hospitalization will be included as part of these five covered doses.

RSV Risk Factors
For categories 3 and 4:
One of the following are considered sufficient:

- Chronic lung disease requiring medical treatment within the past six months (e.g. diuretics, systemic steroids, oxygen on a continuous basis, bronchodilators or ventilation-dependent; or
- Hemodynamically significant Congenital Heart Disease [simple, small Atrial Septal Defects (ASD), Ventricular Septal Defects (VSD), and Patent Ductus Arteriosus (PDA) are not eligible]; or
- Human Immunodeficiency Virus (HIV) or Acquired Immunodeficiency Deficiency Syndrome (AIDS)

OR

For category 4 only:
Two of the following are considered sufficient:

- Exposure to tobacco smoke in the home; and/or
- School age Siblings; and/or
- Multiple Birth; and/or
- Day Care; and/or
- Severe neuromuscular disease; and/or
- Congenital airway abnormalities

Arkansas Medicaid Prescription Drug Program
Synagis Prior Authorization (PA) Request Form (Year 2006-2007)

Prescription Drug PA Help Desk
TEL (800) 707-3854

FAX - ATTN: Pharmacy PA Center
FAX (501) 372-2971

This form **MUST** be **completed** by and **received** from the prescribing provider. Please fax the completed form to the Pharmacy PA Center for evaluation & processing. **PRESCRIBERS** – please provide pharmacy information below.

TO BE COMPLETED BY PRESCRIBER

PRESCRIBER MEDICAID PROVIDER NUMBER:	PATIENT INFORMATION
Prescriber Name:	RECIPIENT MEDICAID ID NUMBER:
Address:	Patient Name:
City: State: Zip:	Address:
Phone ( )	City: State: Zip:
FAX ( )	Patient date of birth: / /

☑ **Birth Weight:** _____ **Kg,** ☑ **Current Weight:** _____ **Kg,** ☑ **Date Measured:** ____/____/200__

☑ **Pharmacy Provider:** _____ ☑ **Fax Number:** _____

Note: Synagis must be given every 30 days during RSV Season. The 2006-07 season is November to March. Approved PA is valid for current season only. Prescribe minimum units necessary for dosage. **Compliance with all of the specific criteria listed on this page is a condition for payment by Arkansas Medicaid.**

☑ Select **ONE** of the following criteria the patient currently meets to be considered for RSV prophylaxis:

☐ 1. Chronic lung disease (CLD) **AND** < 2 years of age at ***start*** of RSV season **AND** has required medical therapy for their CLD within the past 6 months (e.g. diuretics, systemic steroids, oxygen on a continuous basis, bronchodilators, or ventilator dependent).

☐ 2. Former premature (≤ 28 weeks EGA) **AND** < 12 months of age at the ***start*** of RSV season.

☐ 3. Former premature (29 to 32 weeks EGA) **AND** ≤ 6 months of age at the ***start*** of RSV season.

☐ 4. Former premature (32 to 35 weeks EGA) **AND** < 6 months of age at the ***start*** of RSV season **WITH 2** or more additional risk factors. **(Circle all that apply):**
a) Severe neuromuscular disease
b) Congenital abnormalities of the airways
c) School age siblings
d) Daycare attendance

☐ 5. Infants ≤ 24 months of age at ***start*** of RSV season with hemodynamically significant cyanotic congenital heart disease (CHD) or hemodynamically significant acyanotic CHD.

☐ 6. Infants ≤ 12 months of age at ***start*** of RSV season with congenital heart disease **AND** one of the following **(circle all that apply):**
a) Infants receiving medication to control congestive heart failure
b) Infants with moderate to severe pulmonary hypertension
c) Infants with cyanotic heart disease

☐ 7. Severe immunodeficiency (e.g. SCID or severe acquired immunodeficiency syndrome) **AND** patient is < 2 years of age.

☑ **Prescriber Signature:** _____ **Date:** _____
(By signature, the prescriber confirms the criteria information above is accurate and verifiable in patient records)

Note: If none of the above criteria are met, an exception request may be submitted in the form of a letter by the prescriber, identifying the patient and documenting the conditions for which the exception is being requested. These letters may be faxed to the DMS Pharmacy Unit at **501-683-4124.**

Pharmacy and dosage information: Synagis dosage based on 15mg/kg. Dispense minimum units necessary for dose. Pharmacies will be subject to audit to ensure that NDC(s) dispensed will total the dosage closest to the dose required. Overbilled units are subject to recoupment. Contact PA help desk if weight change requires change in NDC.

Weight	Dosage	Dispense Units
Up to 3.3 kg	up to 49.5 mg	1 x 50 mg vial
3.4 kg to 6.6 kg	51 mg to 99 mg	1 x 100 mg vial
6.7 kg to 10 kg	100.5 mg to 150 mg	1 x 100 mg vial + 1 x 50 mg vial
10.1 kg to 13.3 kg	151.5 mg to 199.5 mg	2 x 100 mg vials
13.4 kg to 16.6 kg	201 mg to 249.5 mg	2 x 100 mg vials + 1 x 50 mg vial
16.7 kg to 20 kg	250.5 mg to 300 mg	3 x 100 mg vials

HEALTH INFORMATION DESIGNS

Prior Authorization Vendor for ND Medicaid

SYNAGIS PA Form

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

ND Medicaid requires that infants receiving Synagis must follow American Academy of Pediatrics recommendations.

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:

□ **SYNAGIS 100MG/1ML VIAL** Patient's Gestational Age(weeks and days):_____ Birth weight:_____g/kg/lbs

□ **SYNAGIS 50MG/0.5ML VIAL** Current Weight:_____g/kg/lbs Daterecorded:_____

□ CONGENITAL HEART DISEASE □ CHRONIC RESPIRATORY DISEASE ARISING IN THE PERINATAL PERIOD
□ CONGENITAL ABNORMALITY OF RESPIRATORY SYSTEM □ SECONDARY DIAGNOSIS (IF APPLICABLE):_____
□ OTHER RESPIRATORY CONDITIONS OF FETUS AND NEWBORN
□ OTHER_____

Medical Criteria:

1. Diagnosis of Chronic Pulmonary Disease (CLD/BPD) and less than 24 months of age? □ No □ Yes
   Is patient receiving medical treatment of (check all that apply and provide last date received): □ Oxygen Date:_____
   □ Corticosteroids Date:_____ □ Bronchodilator Date:_____ □ Diuretics Date:_____
2. Diagnosis of hemodynamically significant congenital heart disease and less than 24 months of age? □ No □ Yes
   Patient has the following conditions: □ Diagnosis of moderate-severe pulmonary hypertension
   □ Cyanotic heart disease □ Acyanotic heart disease □ Medications for CHD and date received:_____
3. Prematurity: □ Gestational age of less than 28 weeks and less than 12 months of age at the start of Synagis season
   □ Gestational age of 29-32 weeks and less than 6 months of age at the start of Synagis season
   □ Gestational age of 32-35 weeks AND □ less than 6 months at the start of Synagis season
   □ has two or more risk factors
   □ has no risk factors

Has the following risk factors (check all that apply)
□ Day Care □ School Age Siblings □ Severe neuromuscular disease □ Exposure to Environmental Air Pollutants
□ Congenital anomalies of airway □ None □ Other_____

Additional Clinical Information: □ Multiple Births □ Birth wt. < 2500g NICU History: □ No □ Yes
Please attach NICU Discharge Summary. Was there a NICU dose administered? □ No □ Yes Date(s):_____
Did the neonatologist recommend Synagis prior to discharge? □ No □ Yes Expected date of first/next injection:_____
Previous injections? □ No □ Yes Date(s):_____

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)	

2005 House Bill 1459

SECTION 2 A new section to chapter 50-24.1 of the North Dakota Century Code is created and enacted as follows:

Medical assistance program management-The department of human services, with respect to the state medical assistance program, shall:
6. Review and develop recommendations regarding whether to require medical assistance providers to secure prior authorization for certain high-cost medical procedures.

2005 House Bill 1459 directed the Department to review expensive medical procedures for prior authorization. To be consistent with that direction, we will ask the DUR Board to review expensive medications for prior authorization. It is common practice through insurance and Medicaid agencies to set a level at which everything beyond that level requires prior authorization. These are typically put in as 'safety edits' in claims processing systems, but we are bringing it through the Board.

We must remember that new products are coming out continuously, therefore we will not limit our review to specific products, but we will determine a level for the 'safety edit' based on cost. It is good payer practice to know when and why these expensive products are being used. It assists with utilization review, disease management, and budget planning. Also, it protects from exposure to fraud, as many of these products are billed by out of state pharmacy providers and are prescribed by specialists from out of state medical practices.

HEALTH INFORMATION DESIGNS

Prescriptions Dispensed 1/1/06 thru 12/28/06 Amount Billed Greater Than $1000.00			
NDC Number	NDC Name	Avg. Amt Billed	Avg. Amt Paid
00944294004	ADVATE	$14,726.40	$14,723.40
60258044530	ANDEHIST DM NR	$4,785.20	$1,218.49
00088120806	ANZEMET	$1,177.39	$1,064.38
55513004601	ARANESP	$2,440.22	$2,281.66
00007323411	ARIXTRA	$3,365.90	$3,029.41
59627000103	AVONEX	$2,037.79	$1,278.00
00066057760	BENZAMYCIN PAK	$2,864.70	$2,575.99
50419052325	BETASERON	$1,681.67	$1,183.61
00087611142	CAFCIT	$1,544.80	$1,388.62
00078012705	CLOZARIL	$1,162.75	$1,040.86
65649010102	COLAZAL	$9,179.45	$8,259.81
39822061501	COLISTIMETHATE SODIUM	$2,517.43	$2,307.63
61570041451	COLY-MYCIN M	$3,550.00	$3,199.85
00088115330	COPAXONE	$1,655.06	$1,299.07
67919001101	CUBICIN	$3,424.02	$2,247.15
45802042237	DESONIDE	$2,914.89	$1,157.60
51672127003	DESOXIMETASONE	$2,081.50	$1,674.20
58406042534	ENBREL	$1,983.54	$1,033.08
55513082301	EPOGEN	$1,930.29	$1,694.73
00378326694	ETOPOSIDE	$1,913.00	$1,720.55
00078047015	EXJADE	$6,711.60	$6,042.17
00013242691	FRAGMIN	$1,104.14	$1,025.16
00013264681	GENOTROPIN	$4,296.08	$1,520.99
00013265802	GENOTROPIN MINIQUICK	$2,263.93	$1,835.02
00078043815	GLEEVEC	$3,780.66	$2,308.97
00002803101	GLUCAGON EMERGENCY KIT	$1,758.80	$1,656.48
63004773101	H.P. ACTHAR	$2,864.63	$2,777.60
00053813004	HELIXATE FS	$17,790.61	$8,802.33
00074379902	HUMIRA	$1,645.63	$1,306.60
00173047800	IMITREX STATDOSE REFILL	$1,215.40	$1,089.16
67211034253	INNOHEP	$2,267.30	$1,964.15
00085117902	INTRON A	$1,881.98	$1,833.84
00074679922	KALETRA	$1,213.54	$1,079.55
55513017728	KINERET	$1,435.53	$1,305.00
00026037230	KOGENATE FS	$7,464.80	$7,443.03
00004024126	KYTRIL	$1,674.67	$1,409.87
00173052700	LAMICTAL CD	$1,223.25	$1,105.50
00045153005	LEVAQUIN LEVA-PAK	$1,731.25	$1,554.10
00173072100	LEXIVA	$1,394.76	$1,246.44
00075291501	LOVENOX	$2,817.16	$2,414.91

00310032130	MERREM IV	$3,117.26	$2,150.24
00089020025	METROGEL-VAGINAL	$4,589.50	$4,589.50
52769046001	MONARC-M	$18,267.89	$18,165.68
49735011047	NEOCATE ONE +	$1,423.50	$1,423.50
55513019001	NEULASTA	$7,713.99	$7,364.17
55513092410	NEUPOGEN	$3,788.15	$3,039.68
50242004314	NUTROPIN AQ PEN CARTRIDGE	$2,020.80	$1,457.87
60951071070	OXYCODONE HYDROCHLORIDE	$1,763.30	$1,162.32
00045034660	PANCREASE MT 20	$1,395.07	$1,118.85
59767000102	PANCRECARB MS-8	$1,767.25	$1,176.07
00004035239	PEGASYS	$1,813.62	$1,640.58
00085127901	PEG-INTRON	$1,880.73	$1,481.57
00944047180	POLYGAM S/D	$1,521.29	$1,097.66
57599881401	PRECISION XTRA MONITOR	$6,479.60	$5,831.74
59676034001	PROCRIT	$2,115.13	$1,972.21
00469061773	PROGRAF	$1,280.27	$1,012.24
50242010040	PULMOZYME	$2,088.05	$1,637.62
00085135105	REBETOL	$2,142.86	$1,112.27
44087002203	REBIF	$1,830.78	$1,670.52
49884085694	RIBASPHERE	$1,022.95	$1,005.20
00078018325	SANDOSTATIN	$1,390.05	$1,340.40
00310027460	SEROQUEL	$1,419.35	$1,150.24
00006384130	SINGULAIR	$3,385.21	$2,930.73
00003052411	SPRYCEL	$3,639.34	$3,216.06
00069098030	SUTENT	$6,981.71	$5,645.17
60574411301	SYNAGIS	$1,717.12	$1,441.52
50242006401	TARCEVA	$3,394.11	$2,865.44
00085125901	TEMODAR	$2,844.02	$1,743.92
59572020594	THALOMID	$3,454.40	$2,745.62
58468184904	THYROGEN	$3,207.84	$1,635.85
53905006501	TOBI	$3,498.74	$2,673.94
66215010106	TRACLEER	$6,100.19	$3,443.98
58914000450	ULTRASE MT20	$1,389.85	$1,147.37
00004003822	VALCYTE	$2,594.54	$2,296.09
00049318030	VFEND	$2,028.07	$1,769.75
00004110150	XELODA	$1,797.49	$1,572.85
00069314019	ZITHROMAX	$1,551.79	$1,400.95
00173044700	ZOFRAN	$1,916.96	$1,528.67
00310095130	ZOLADEX	$1,416.05	$1,273.58
00002442030	ZYPREXA	$1,264.99	$1,114.96
00002445685	ZYPREXA ZYDIS	$1,464.97	$1,227.69
00009513502	ZYVOX	$1,782.91	$1,521.70

NORTH DAKOTA MEDICAID
RETROSPECTIVE DRUG UTILIZATION REVIEW
CRITERIA RECOMMENDATIONS
2ND QUARTER 2007

Criteria Recommendations	*Approved*	*Rejected*

1. Sitagliptin / High Dose _____ _____

Alert Message: Januvia (sitagliptin) may be over-utilized. The manufacturer's recommended maximum dose is 100 mg once daily as monotherapy or in combination with metformin or a thiazolidinedione.
Conflict Code: HD – High Dose
Drugs/Disease:

Util A	Util B	Util C
Sitagliptin		

Max Dose: 100mg/day
References:
Januvia Prescribing Information, October 2006, Merck & Co., Inc.

2. Sitagliptin / Moderate Renal Impairment _____ _____

Alert Message: The recommended dose of Januvia (sitagliptin) in patients with moderate renal impairment (CrCl ≥ 30 mL/min to <50 mL/min) is 50 mg once daily. Patients with more severe renal insufficiency (CrCl < 30 mL/min) or with end-stage renal disease on hemodialysis or peritoneal dialysis should be dosed at 25 mg once daily. Assessment of renal function is recommended prior to initiation of sitagliptin and periodically thereafter.
Conflict Code: ER– Overutilization
Drugs/Disease:

Util A	Util B	Util C
Sitagliptin		Renal Impairment – No ERSD or Stage IV or V

Max Dose: 50mg/day
References:
Januvia Prescribing Information, October 2006, Merck & Co., Inc.

3. Sitagliptin / Severe Renal Impairment _____ _____

Alert Message: The recommended dose of Januvia (sitagliptin) in patients with severe renal insufficiency (CrCl < 30 mL/min) or with end-stage renal disease on hemodialysis or peritoneal dialysis is 25 mg once daily. In patients with moderate renal impairment (CrCl ≥ 30 mL/min to <50 mL/min) sitagliptin should be dosed at 50 mg once daily. Assessment of renal function is recommended prior to initiation of sitagliptin and periodically thereafter.
Conflict Code: ER– Overutilization
Drugs/Disease:

Util A	Util B	Util C	
Sitagliptin		ESRD	PhosLo
		CKD Stage IV (severe) GFR (15-29)	Renagel
		CKD Stage V GFR <15	Zemplar
		Fosrenol	

Max Dose: 25mg/day
References:
Januvia Prescribing Information, October 2006, Merck & Co., Inc.

Criteria Recommendations	*Approved*	*Rejected*

4. Sitagliptin / Type I Diabetes _____ _____

Alert Message: Januvia (sitagliptin) should not be used in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis.
Conflict Code: MC – Drug (Actual) Disease Precaution
Drugs/Disease:

Util A	Util B	Util C
Sitagliptin	Type I Diabetes	
	Diabetic Ketoacidosis	

References:
Januvia Prescribing Information, October 2006, Merck & Co., Inc.

5. Sitagliptin / Digoxin _____ _____

Alert Message: The concurrent use of Januvia (sitagliptin) and digoxin has been reported to cause increases in the AUC and Cmax of digoxin 11% and 18%, respectively. While no dosage adjustment of either agent is necessary appropriate monitoring of digoxin is recommended.
Conflict Code: DD – Drug/Drug Interaction
Drugs/Disease:

Util A	Util B	Util C
Sitagliptin	Digoxin	

References:
Januvia Prescribing Information, October 2006, Merck & Co., Inc.

6. Paliperidone / High Dose _____ _____

Alert Message: Invega (paliperidone) may be over-utilized. The manufacturer's maximum recommended dose is 12 mg once daily administered in the morning.
Conflict Code: HD – High Dose
Drugs/Disease:

Util A	Util B	Util C
Paliperidone		

Max Dose: 12mg/day
References:
Invega Prescribing Information, December 2006, Janssen, L.P.

7. Paliperidone / Risperidone _____ _____

Alert Message: Invega (paliperidone) is the major active metabolite of Risperdal (risperidone) and concurrent use of these agents may result in additive paliperidone exposure and risk of adverse effects.
Conflict Code: DD – Drug/Drug Interaction
Drugs/Disease:

Util A	Util B	Util C
Paliperidone	Risperidone	

References:
Invega Prescribing Information, December 2006, Janssen, L.P.

Criteria Recommendations *Approved* *Rejected*

8. Paliperidone / Moderate to Severe Renal Impairment _____ _____

Alert Message: The maximum recommended dose of Invega (paliperidone) in patients with moderate to severe renal impairment (10 mL/min to <50 mL/min) is 3 mg once daily. Patients with mild renal impairment should receive a maximum of 6 mg once a day.
Conflict Code: ER – Overutilization
Drugs/Disease:

Util A	Util B	Util C (Inclusive)	
Paliperidone		ICD-9s & Drugs:	
		CKD Stage III (moderate) GFR (30-59)	PhosLo
		CKD Stage IIV (severe) GFR (15-29)	Renagel
		CKD Stage V GFR <15	Zemplar
		End Stage Renal Disease	Fosrenol

Max Dose: 3 mg/day
References:
Invega Prescribing Information, December 2006, Janssen, L.P.

9. Paliperidone / Mild Renal Impairment _____ _____

Alert Message: The maximum recommended dose of Invega (paliperidone) in patients with mild renal impairment (≥50 mL/min to < 80 mL/min) is 6 mg once daily. The maximum recommended dose of Invega (paliperidone) in patients with moderate to severe renal impairment (10 mL/min to <50 mL/min) is 3 mg once daily.
Conflict Code: ER – Overutilization
Drugs/Disease:

Util A	Util B	Util C
Paliperidone		CKD Stage I GFR >90
		CKD Stage II (mild) (GFR 60 - 89)
		Chronic Kidney Disease, Unspecified

Max Dose: 6 mg/day
References:
Invega Prescribing Information, December 2006, Janssen, L.P.

10. Paliperidone / Therapeutic Appropriateness _____ _____

Alert Message: The safety and efficacy of Invega (paliperidone) has not been established in patients less than 18 years of age.
Conflict Code: TA – Therapeutic Appropriateness
Drugs/Disease:

Util A	Util B	Util C
Paliperidone		

Age Range: 0 – 18 years of Age
References:
Invega Prescribing Information, December 2006, Janssen, L.P.

Criteria Recommendations *Approved* *Rejected*

11. Paliperidone / QT Prolongation _____ _____

Alert Message: Invega (paliperidone) has been shown to cause moderate increases in the corrected QT (QTc) interval. Paliperidone use should be avoided in patients with congenital long QT syndrome, a history of cardiac arrhythmias and in patients receiving any drug that prolongs the QTc interval (i.e., Class 1A & III antiarrhythmics, antipsychotics, macrolides and fluoroquinolones).

Conflict Code: DB - Drug/Drug and/or Disease Marker

Drugs/Disease:

Util A	Util B		Util C
Paliperidone	QT Prolongation	Levofloxacin	
	Cardiac Arrhythmias	Flecainide	
	Quinidine	Propafenone	
	Procainamide	Dofetilide	
	Disopyramide	Pimozide	
	Amiodarone	Ziprasidone	
	Sotalol	Erythromycin	
	Chlorpromazine	Clarithromycin	
	Thioridazine	Norfloxacin	
	Gatifloxacin		
	Moxifloxacin		

References:

Invega Prescribing Information, December 2006, Janssen, L.P.

12. Paliperidone / Seizures _____ _____

Alert Message: Invega (paliperidone) should be used with caution in patients with a history of seizures or other conditions that potentially lower the seizure threshold.

Conflict Code: DB - Drug/Drug and/or Disease Marker

Drugs/Disease:

Util A	Util B		Util C
Paliperidone	Seizures	Gabapentin	
	Epilepsy	Pregabalin	
	Phenytoin	Lamotrigine	
	Ethosuximide	Levetiracetam	
	Methsuximide	Primidone	
	Zonisamide	Tiagabine	
	Oxcarbazepine	Topiramate	
	Felbamate	Valproic Acid & Derivatives	

References:

Invega Prescribing Information, December 2006, Janssen, L.P.

13. Paliperidone / Orthostatic Hypotension _____ _____

Alert Message: Invega (paliperidone) can produce hypotension and syncope due to its alpha-blocking activity. Paliperidone should be used with caution in patients with known cardiovascular disease, cerebrovascular disease, or conditions that predispose a patient to hypotension (e.g., dehydration, hypovolemia, and antihypertensive medications).

Conflict Code: DB - Drug/Drug and/or Disease Marker

Drugs/Disease:

Util A	Util B		Util C
Paliperidone	Heart Failure	CCBs	
	Myocardial Infarction	ARBs	
	Conduction Abnormalities	Diuretics	
	Dehydration	Antiadrenergic Antihypertensives	
	Hypovolemia		
	ACE Inhibitors		
	Beta Blockers		

References:

Invega Prescribing Information, December 2006, Janssen, L.P.

14. Paliperidone / Dopamine Agonists _____ _____

Alert Message: Invega (paliperidone) may antagonize the effects of levodopa and other dopamine agonists. Monitor patients for dopamine agonist efficacy.
Conflict Code: DD – Drug/Drug Interaction
Drugs/Disease:

Util A	Util B	Util C
Paliperidone	Levodopa	
	Pramipexole	
	Ropinirole	
	Apomorphine	
	Pergolide	

References:
Invega Prescribing Information, December 2006, Janssen, L.P.

15. Paliperidone / Gastrointestinal Narrowing _____ _____

Alert Message: Invega (paliperidone) ordinarily should not be used in patients with severe pathologic or iatrogenic gastrointestinal narrowing. The agent is a non-deformable controlled-release formulation and does not appreciably change shape in the gastrointestinal tract.
Conflict Code: MC – Drug Actual Disease Precaution
Drugs/Disease:

Util A	Util B	Util C
Paliperidone	Cystic Fibrosis	
	Meckel's Diverticulum	
	Peritonitis	
	Short Bowel Syndrome	
	Achalasia	

References:
Invega Prescribing Information, December 2006, Janssen, L.P.

16. Paliperidone / Hyperprolactinemia _____ _____

Alert Message: Invega (paliperidone) like other dopamine-2 antagonists elevates prolactin levels initially and during chronic administration. The prolactin elevating effect is similar to that seen with risperidone, a drug associated with higher levels of prolactin than other antipsychotics. Prolactin elevating agents may cause galactorrhea, amenorrhea, gynecomastia, impotence, and decreased bone density.
Conflict Code: MC – Drug Actual Disease Precaution
Drugs/Disease:

Util A	Util B	Util C
Paliperidone	Galactorrhea	
	Amenorrhea	
	Gynecomastia	
	Impotence	
	Osteoporosis	

References:
Invega Prescribing Information, December 2006, Janssen, L.P.

Criteria Recommendations	*Approved*	*Rejected*

17. Rosiglitazone / Congestive Heart Failure & Fluid Retention _____ _____

Alert Message: The use of rosiglitazone-containing products is not recommended in patients with NYHA Class 3 and 4 heart failure and may cause an increase risk of cardiovascular events in patients with NYHA Class 1 and 2 heart failure. Rosiglitazone can cause fluid retention which may exacerbate or lead to heart failure.
Conflict Code: MC – Drug (Actual) Disease Precaution
Drugs/Disease

Util A	Util B	Util C
Rosiglitazone	Heart Failure	
	Fluid Retention	

References:
Avandia Prescribing Information, September 2006, GlaxoSmtihKline.
Avandamet Prescribing Information, Feb. 2007, GlaxoSmithKline.
Avandaryl Prescribing Information, Oct. 2006, GlaxoSmithKline.

18. Pioglitazone / Congestive Heart Failure & Fluid Retention _____ _____

Alert Message: Actos (pioglitazone) may cause or exacerbate fluid retention. Patients at risk for heart failure may need to be monitored for signs and symptoms. Use is not recommended for those with NYHA class 3 or 4 heart failure unless benefit outweighs the risk.
Conflict Code: MC – Drug (Actual) Disease Precaution
Drugs/Disease

Util A	Util B	Util C
Pioglitazone	Heart Failure	
	Fluid Retention	

References:
Facts & Comparisons, 2006 Updates.
Actos Prescribing Information, Nov. 2006, Takeda Pharmaceuticals American, Inc.

NORTH DAKOTA MEDICAID
RETROSPECTIVE DRUG UTILIZATION REVIEW
CRITERIA RECOMMENDATIONS
APRIL 2007

Criteria Recommendations	*Approved*	*Rejected*

1. Modafinil / Opioids _____ _____

Alert Message: Provigil (modafinil) is not approved for treatment of opioid-induced sedation. Data supporting the use of psychostimulants in the management of drug-induced sedation are lacking in clinical trials. The potential adverse effects of a psychostimulant warrant judicious prescribing in this situation. Consider identifying and eliminating other unnecessary medications that may worsen sedation.
Conflict Code: DD – Drug/Drug Interaction – Therapeutic Appropriateness
Drug/Disease:

Util A	Util B		Util C
Modafinil	Codeine	Meperidine	Narcolepsy
	Fentanyl	Methadone	Obstructive Sleep Apnea
	Hydrocodone	Morphine	
	Hydromorphone	Oxycodone	
	Levorphanol	Propoxyphene	

References:
Facts & Comparisons, 2007 Updates.
Swegle JM, Lodgemann C, Management of Common Opioid-Induced Adverse Effects, American Family Physician, October 15, 2006, Vol. 74, No. 8.

Provigil criteria currently in place:

Therapeutic duplication of stimulants may be occurring

DUR Board Meeting
August 20th, 2007
Heritage Center
Rooms A and B
1pm

HEALTH INFORMATION DESIGNS

June 13th, 2007

The next North Dakota Drug Utilization Review (DUR) Board Meeting will be held August 20th, 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
August 20th, 2007
1pm

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

2. Old Business

• Review and approval of minutes of 06/04/07 meeting	Chairman
• Budget update	Brendan
• Amrix Review	HID
• Synagis Review	HID
• Tekturna Review	HID
• Xopenex Review	HID
• Ketek Review	HID
• Review of Oral Antineoplastic Agents	HID
• Review of Antiretroviral Agents	HID
• Review of High Cost Medications	HID
• Yearly PA Review of Growth Hormone/IGF-1 Agents	HID

3. New Business

• Review of ADHD 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
June 4th, 2007

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

Chairman, C. Huber, called the meeting to order at 1:00pm. She asked for a motion to approve the minutes from the March 12th, 2007 meeting. N. Byers moved that the minutes be approved and T. Twogood seconded the motion. The chair called for a voice vote to approve the minutes, which passed with no audible dissent.

Synagis Review:
B. Joyce updated the Board regarding Synagis utilization. The Department would like to develop a patient registry for Synagis. Potential Synagis patients would be submitted to the Department by physicians. A registry would allow the Department to track Synagis patients and utilization. It would also allow the Department to track patients that should receive Synagis and do not. Currently, there is not a good system in place to track Synagis prescriptions due to billing issues. T. Twogood suggested that the Department disseminate Synagis information to primary care physicians as well as neonatologists. Dr. Rafael Ocejo spoke regarding the form type that should be used for Synagis. Dr. Ocejo also asked if the Department could work with the Health Department to determine when the Synagis season should begin. Dr. Ocejo said that doing this would prevent utilization of Synagis before the true season starts. Dr. Karen Brown spoke regarding health officials determining the beginning of the Synagis season. Dr. Brown is concerned that this would require all patients be cultured for RSV at a greater expense to the State. A motion was made by A. Samuelson to require a registry for Synagis. P. Churchill seconded the motion. This topic will be brought before the Board in August for finalization.

Budget Update:
B. Joyce had no new information to present regarding the budget.

Review of Methadone
At the March meeting A Samuelson asked for Methadone information including trends over time, the distribution of patients using methadone and patients using methadone with multiple prescribers. C. Rieth reviewed this data with the Board. T. Twogood suggested that the Department review profiles of the patients receiving Methadone from 3 or more prescribers.

Review of Qualaquin
B. Joyce informed the Board that all quinine products will eventually leave the market with Qualaquin being the only remaining product. Qualaquin is approved for malaria. At the March DUR meeting, a motion and second was made to place Qualaquin on prior authorization. A voice vote was taken with no audible dissent. Motion passed to place Qualaquin on prior authorization.

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. ACE-Inhibitors were reviewed. No action will be taken regarding the ACE-Inhibitor form or criteria. Sedative/Hypnotics were reviewed. No action will be taken regarding the Sedative/Hypnotic form or criteria.

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 two years, 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.

Review of Amrix
Amrix is a new extended release skeletal muscle relaxant containing cyclobenzaprine. B. Joyce stated that all cyclobenzaprine is for short term use, and the current immediate release product appears to be therapeutically effective. There was no public comment. A motion was made by N. Byers to require a prior authorization on Amrix. G. Pfister seconded the motion. This topic will be brought before the Board in August for finalization.

Review of Janumet
Janumet is a combination medication containing sitagliptin (Januvia) with metformin for treating type 2 diabetes. The pricing of two pills of Janumet is equivalent to one pill of Januvia; therefore this topic was tabled.

Review of Tekturna
Tekturna is a new antihypertensive medication that is the first direct rennin inhibitor approved by the FDA. Criteria for approval would be similar to the ARBs as there is no outcome data to suggest Tekturna should be used first line before ACE inhibitors or ARBs. There was public comment by Dana Meier, representing Novartis. She reviewed Tekturna related prescribing information with the Board. Randy Troxill, representing Novartis, spoke regarding pricing of Tekturna in relation to ACE-Is and ARBs. A motion was made by N. Byers to require a prior authorization on Tekturna. P. Churchill seconded the motion. This topic will be brought before the Board in August for finalization.

Review of Xopenex
The final discontinuation date for CFC inhalers is December 31, 2008. With the absence of these inhalers, HFA inhalers will be the only option for albuterol/levalb uterol in the near future. With the switch from CFC inhalers to HFA inhalers, the Department anticipates an increase in total claims cost of at least 170,000 dollars a year. The Department would like to group the albuterol HFA and levalbuterol HFA products together and choose the preferred product based on the cheapest HFA, post-rebate. Unfortunately, the Department is unable to disclose rebate dollars to the Board to show the major difference between the HFA albuterol/levalbuterol products. There was public comment by Jason Anderson, representing Sepracor. Brian Easton, representing Sepracor, spoke regarding the Xopenex standing orders given to physicians in the past. A motion was made by T. Twogood to table the issue of prior authorization for the HFA products. A. Samuelson seconded the motion. This motion did not pass (failed by two votes after post-meeting review). C. Sorenson asked if modification of the PA form is acceptable. B. Joyce said that the form and criteria could be changed and an age restriction could also be added. T. Twogood suggested that patients under the age of 16 be exempt. C. Sorenson made a motion to modify the PA form to exclude patients 16 and below. G. Pfister seconded the motion. This topic will be brought before the Board in August for finalization.

Review of Ketek
In light of recent FDA warnings, the Department would like to monitor utilization of Ketek. The Board discussed placing Ketek on prior authorization. A motion was made by C. Sorenson to place Ketek on prior authorization with an additional criterion of allergy to quinolones and tetracyclines. T. Twogood seconded the motion. This topic will be brought before the Board in August for finalization.

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. The Department would like for the Board to review utilization data and make suggestions on how best to monitor these products. This topic will come up for further discussion at a later meeting.

Criteria Recommendations
The enclosed recommended RDUR criteria are 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 C. Sorrenson seconded the motion. The motion was approved by voice vote with no audible dissent.

HIV/AIDS Review
The HIV/AIDS Review is based on the 2007 legislative session requesting information on classes of medications that currently are exempt from prior authorization. The Legislative Council gave a deadline of October, 2008 for these reviews to be completed. A periodic report will also be sent to the Council as each class is reviewed. T. Twogood suggested getting a consult from one of the Infectious Disease doctors that are currently prescribing to North Dakota Medicaid patients. C. Huber and B. Joyce will contact these physicians for guidance regarding this class of medications.

Oral Antineoplastic Review
B. Joyce reviewed utilization data of the antineoplastic medications. The Department suggests a registration process for the antineoplastic class of medications. Having a registration would allow physicians to include study information the patients are enrolled in as well as peer reviewed literature endorsing utilization of specific products. Most private insurance companies require a prior authorization process with this class of medications. A. Samuelson suggested getting a consult from one of the Oncology physicians currently prescribing to North Dakota Medicaid patients. B. Joyce will contact these physicians for guidance regarding this class of medications.

The next DUR board meeting will be August 20th, 2007. B. Joyce reviewed future agenda items. These include ADHD, HIV/AIDS and Cancer. P. Churchill made a motion to adjourn the meeting and N. Byers seconded. Chair C. Huber adjourned the meeting at 3:50 pm.

AMRIX 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 try and fail generic cyclobenzaprine.
****Note:***

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

Part I: TO BE COMPLETED BY 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 cyclobenzaprine therapy	Start Date:	Dose:
	End Date:	Frequency:

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

Physician Signature: Date:

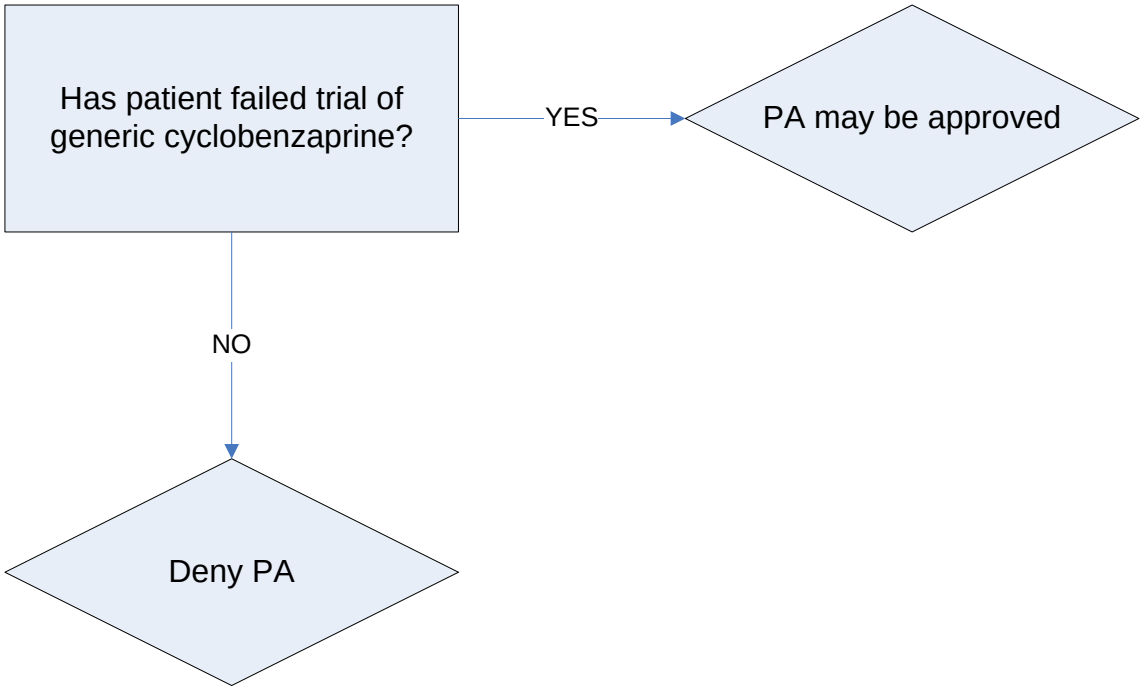
Part II: TO BE COMPLETED BY PHARMACY

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
Amrix Authorization Algorithm



AAP 2006 REDBOOK RECOMMENDATIONS FOR THE PREVENTION OF RSV

CLINICAL MANIFESTATIONS: Respiratory syncytial virus (RSV) causes acute respiratory tract illness in patients of all ages. In infants and young children, RSV is the most important cause of bronchiolitis and pneumonia. During the first few weeks of life, particularly among preterm infants, infection with RSV may produce minimal respiratory tract signs. Lethargy, irritability, and poor feeding, sometimes accompanied by apneic episodes, may be the presenting manifestations in infants. Most previously healthy infants infected with RSV do not require hospitalization, and many who are hospitalized improve with supportive care and are discharged in fewer than 5 days. Characteristics that increase the risk of severe or fatal RSV infection are preterm birth; cyanotic or complicated congenital heart disease, especially conditions causing pulmonary hypertension; underlying pulmonary disease, especially chronic lung disease of prematurity; and immunodeficiency disease or therapy causing immunosuppression at any age. The association between RSV bronchiolitis early in life and subsequent reactive airway disease remains poorly understood. After RSV bronchiolitis, many children will have episodes of recurrent wheezing, which usually diminish in subsequent years. Some children may develop wheezing at older ages or develop long-term abnormalities in pulmonary function. This association may reflect an underlying predisposition to reactive airway disease rather than a direct consequence of RSV infection.

Almost all children are infected at least once by 2 years of age, and reinfection throughout life is common. Respiratory syncytial virus infection in older children and adults usually manifests as upper respiratory tract illness, but more serious disease involving the lower respiratory tract also can develop in immunocompromised patients or in the elderly. Exacerbation of acute asthmatic bronchitis or other chronic lung conditions may occur.

ETIOLOGY: Respiratory syncytial virus is an enveloped RNA paramyxovirus that lacks neuraminidase and hemagglutinin surface glycoproteins. Two major strains (groups A and B) have been identified and often circulate concurrently. The clinical and epidemiologic significance of strain variation has not been determined, but some evidence suggests that antigenic differences may affect susceptibility to infection and that some strains may be more virulent than other strains.

EPIDEMIOLOGY: Humans are the only source of infection. Transmission usually is by direct or close contact with contaminated secretions, which may involve droplets or fomites. Respiratory syncytial virus can persist on environmental surfaces for many hours and for a half-hour or more on hands. Infection among hospital personnel and others can occur by self-inoculation with contaminated secretions. Enforcement of infection control policies is important to decrease the risk of health care-related transmission of RSV. Health care-related spread of RSV to organ transplant recipients or patients with cardiopulmonary abnormalities or immunocompromised conditions has been associated with severe and fatal disease in children and adults.

Respiratory syncytial virus usually occurs in annual epidemics during winter and early spring in temperate climates. Spread among household and child care contacts, including adults, is common. The period of viral shedding usually is 3 to 8 days, but shedding may last longer, especially in young infants and in immunosuppressed individuals, in whom shedding may continue for as long as 3 to 4 weeks.

The **incubation period** ranges from 2 to 8 days; 4 to 6 days is most common.

DIAGNOSTIC TESTS: Rapid diagnostic assays, including immunofluorescent and enzyme immunoassay techniques for detection of viral antigen in nasopharyngeal specimens, are available commercially and generally are reliable. The sensitivity of these assays in comparison with culture varies between 53% and 96%, with most in the 80% to 90% range. As with all antigen detection assays, false-positive test results are more likely to occur at the beginning or end of the RSV season when the incidence of disease is low. Therefore, antigen detection assays should not be the solitary basis on which the beginning and end of monthly prophylaxis is determined.

Viral isolation from nasopharyngeal secretions in cell cultures requires 3 to 5 days, but results and sensitivity vary among laboratories, because methods of isolation are exacting and RSV is a labile virus. Experienced viral laboratory personnel should be consulted for optimal methods of collection and transport of specimens. Serologic testing of acute and convalescent serum specimens should not be used to confirm infection; in particular, the sensitivity of serologic diagnosis of infection is low among young infants. The polymerase chain reaction assay has been used for detection of RSV in clinical specimens but is not available commercially.

TREATMENT: Primary treatment is supportive and should include hydration, careful clinical assessment of respiratory status, including measurement of oxygen saturation, use of supplemental oxygen, suction of the upper airway, and if necessary, intubation and mechanical ventilation. Ribavirin has in vitro antiviral activity against RSV, but ribavirin aerosol treatment for RSV infection is not recommended routinely. Ribavirin therapy has been associated with a small but statistically significant increase in oxygen saturation during the acute infection in several small studies. However, a consistent decrease in need for mechanical ventilation, decrease in length of stay in the pediatric intensive care unit, or reduction in days of hospitalization among ribavirin recipients has not been demonstrated. The high cost, aerosol route of administration, concern about potential toxic effects among exposed health care professionals, and conflicting results of efficacy trials have led to controversy about the use of this drug. A decision about ribavirin administration should be made on the basis of the particular clinical circumstances and experience of the physician.

BETA-ADRENERGIC AGENTS. Beta-adrenergic agents are not recommended for routine care of first-time wheezing associated with RSV bronchiolitis. Some physicians elect to use bronchodilator therapy because of concern that reactive airway disease may be misdiagnosed as bronchiolitis. Repeat doses of an inhaled bronchodilator should be

continued only in the small number of infants with well-documented improvement in respiratory function soon after the first dose.

CORTICOSTEROIDS. In hospitalized infants with RSV bronchiolitis, corticosteroids are not effective and are not indicated.

ANTIMICROBIAL AGENTS. Antimicrobial agents rarely are indicated, because bacterial lung infection and bacteremia are uncommon in infants hospitalized with RSV bronchiolitis or pneumonia. Otitis media occurs in infants with RSV bronchiolitis, but oral antibiotic agents can be used if therapy for otitis media is necessary.

PREVENTION OF RSV INFECTIONS. Palivizumab, a humanized mouse monoclonal antibody that is administered intramuscularly, is available to reduce the risk of RSV hospitalization in high-risk children. Respiratory Syncytial Virus Immune Globulin Intravenous (RSV-IGIV), a hyperimmune, polyclonal globulin prepared from donors selected for high serum titers of RSV neutralizing antibody, no longer is available. Palivizumab is licensed for prevention of RSV lower respiratory tract disease in selected infants and children with chronic lung disease of prematurity (CLD [formerly called bronchopulmonary dysplasia]) or with a history of preterm birth (<35 weeks' gestation) or with congenital heart disease. Palivizumab is administered every 30 days, beginning in early November, with 4 subsequent monthly doses (total of 5 doses). The dose of palivizumab is 15 mg/kg, administered intramuscularly. Palivizumab is not effective in the treatment of RSV disease, and it is not approved for this indication.

Recommendations by the American Academy of Pediatrics for the use of palivizumab are as follows:

- Palivizumab prophylaxis should be considered for infants and children younger than 24 months of age with chronic lung disease of prematurity who have required medical therapy (supplemental oxygen, bronchodilator or diuretic or corticosteroid therapy) for CLD within 6 months before the start of the RSV season. Patients with more severe CLD who continue to require medical therapy may benefit from prophylaxis during a second RSV season. Data are limited regarding the effectiveness of palivizumab during the second year of life. Individual patients may benefit from decisions made in consultation with neonatologists, pediatric intensivists, pulmonologists, or infectious disease specialists.
- Infants born at 32 weeks of gestation or earlier may benefit from RSV prophylaxis, even if they do not have CLD. For these infants, major risk factors to consider include their gestational age and chronologic age at the start of the RSV season. Infants born at 28 weeks of gestation or earlier may benefit from prophylaxis during their first RSV season, whenever that occurs during the first 12 months of life. Infants born at 29 to 32 weeks of gestation may benefit most from prophylaxis up to 6 months of age. For the purpose of this recommendation, 32 weeks' gestation refers to an infant born on or before the 32nd week of gestation (ie, 32 weeks, 0 days). Once a child qualifies for initiation of prophylaxis at the

start of the RSV season, administration should continue throughout the season and not stop at the point an infant reaches either 6 months or 12 months of age.

- Although palivizumab has been shown to decrease the likelihood of hospitalization in infants born between 32 and 35 weeks of gestation (ie, between 32 weeks, 1 day and 35 weeks, 0 days), the cost of administering prophylaxis to this large group of infants must be considered carefully. Therefore, most experts recommend that prophylaxis should be reserved for infants in this group who are at greatest risk of severe infection and who are younger than 6 months of age at the start of the RSV season. Epidemiologic data suggest that RSV infection is more likely to lead to hospitalization for these infants when the following risk factors are present: child care attendance, school-aged siblings, exposure to environmental air pollutants, congenital abnormalities of the airways, or severe neuromuscular disease. However, no single risk factor causes a very large increase in the rate of hospitalization, and the risk is additive as the number of risk factors for an individual infant increases. Therefore, prophylaxis should be considered for infants between 32 and 35 weeks of gestation only if 2 or more of these risk factors are present. Passive household exposure to tobacco smoke has not been associated with an increased risk of RSV hospitalization on a consistent basis. Furthermore, exposure to tobacco smoke is a risk factor that can be controlled by the family of an infant at increased risk of severe RSV disease, and preventive measures will be far less costly than palivizumab prophylaxis. High-risk infants never should be exposed to tobacco smoke. In contrast to the well-documented beneficial effect of breastfeeding against many viral illnesses, existing data are conflicting regarding the specific protective effect of breastfeeding against RSV infection. High-risk infants should be kept away from crowds and from situations in which exposure to infected individuals cannot be controlled. Participation in group child care should be restricted during the RSV season for high-risk infants whenever feasible. Parents should be instructed on the importance of careful hand hygiene. In addition, all high-risk infants and their contacts should be immunized against influenza beginning at 6 months of age.
- In the Northern hemisphere and particularly within the United States, RSV circulates predominantly between November and March. The inevitability of the RSV season is predictable, but the severity of the season, the time of onset, the peak of activity, and the end of the season cannot be predicted precisely. There can be substantial variation in timing of community outbreaks of RSV disease from year to year in the same community and between communities in the same year, even in the same region. These variations, however, occur within the overall pattern of RSV outbreaks, usually beginning in November or December, peaking in January or February, and ending by the end of March or sometime in April. Communities in the southern United States tend to experience the earliest onset of RSV activity, and Midwestern states tend to experience the latest. The duration of the season for western and northeast regions typically occurs between that noted in the South and the Midwest. In recent years, the national median duration of the RSV season has been 15 weeks and even in the South, with a seasonal duration of 16 weeks, the range is 13 to 20 weeks. Results from clinical trials indicate that palivizumab trough serum concentrations >30 days after the fifth dose will be well

above the protective concentration for most infants. If the first dose is administered in November, 5 monthly doses of palivizumab will provide substantially more than 20 weeks of protective serum antibody concentrations for most of the RSV season, even with variation in season onset and end. Changes from this recommendation of 5 monthly doses require careful consideration of the benefits and costs.

- Children who are 24 months of age or younger with hemodynamically significant cyanotic and acyanotic congenital heart disease will benefit from palivizumab prophylaxis. Decisions regarding prophylaxis with palivizumab in children with congenital heart disease should be made on the basis of the degree of physiologic cardiovascular compromise. Children younger than 24 months of age with congenital heart disease who are most likely to benefit from immunoprophylaxis include:
- Infants who are receiving medication to control congestive heart failure
- Infants with moderate to severe pulmonary hypertension
- Infants with cyanotic heart disease

Because a mean decrease in palivizumab serum concentration of 58% was observed after surgical procedures that use cardiopulmonary bypass, for children who still require prophylaxis, a postoperative dose of palivizumab (15 mg/kg) should be considered as soon as the patient is medically stable.

The following groups of infants are **not** at increased risk of RSV and generally should not receive immunoprophylaxis:

- Infants and children with hemodynamically insignificant heart disease (eg, secundum atrial septal defect, small ventricular septal defect, pulmonic stenosis, uncomplicated aortic stenosis, mild coarctation of the aorta, and patent ductus arteriosus)
- Infants with lesions adequately corrected by surgery, unless they continue to require medication for congestive heart failure
- Infants with mild cardiomyopathy who are not receiving medical therapy

Dates for initiation and termination of prophylaxis should be based on the same considerations as for high-risk preterm infants.

- Palivizumab prophylaxis has not been evaluated in randomized trials in immunocompromised children. Although specific recommendations for immunocompromised patients cannot be made, children with severe immunodeficiencies (eg, severe combined immunodeficiency or advanced acquired immunodeficiency syndrome) may benefit from prophylaxis.
- Limited studies suggest that some patients with cystic fibrosis may be at increased risk of RSV infection. However, insufficient data exist to determine the effectiveness of palivizumab use in this patient population.
- If an infant or child who is receiving palivizumab immunoprophylaxis experiences a breakthrough RSV infection, monthly prophylaxis should continue through the

RSV season. This recommendation is based on the observation that high-risk infants may be hospitalized more than once in the same season with RSV lower respiratory tract disease and the fact that more than one RSV strain often cocirculates in a community.

- Physicians should arrange for drug administration within 6 hours after opening a vial of palivizumab, because this biological product does not contain a preservative.
- Respiratory syncytial virus is known to be transmitted in the hospital setting and to cause serious disease in high-risk infants. In high-risk hospitalized infants, the major means to prevent RSV disease is strict observance of infection control practices, including prompt isolation of RSV-infected infants. If an RSV outbreak occurs in a high-risk unit (eg, pediatric intensive care unit), primary emphasis should be placed on proper infection control practices, especially hand hygiene. No data exist to support palivizumab use in controlling outbreaks of nosocomial disease.
- Palivizumab does not interfere with response to vaccines.

ISOLATION OF THE HOSPITALIZED PATIENT: In addition to standard precautions, contact precautions are recommended for the duration of RSV-associated illness among infants and young children, including patients treated with ribavirin. The effectiveness of these precautions depends on compliance and necessitates scrupulous adherence to appropriate hand hygiene practices. Patients with RSV infection should be cared for in single rooms or placed in a cohort.

CONTROL MEASURES: The control of nosocomial RSV transmission is complicated by the continuing chance of introduction through infected patients, staff, and visitors. During the peak of the RSV season, many infants and children hospitalized with respiratory tract symptoms will be infected with RSV and should be cared for with contact precautions (see Isolation of the Hospitalized Patient, p 565). Early identification of RSV-infected patients (see Diagnostic Tests, p 561) is important so that appropriate precautions can be instituted promptly. During large outbreaks, a variety of measures have been demonstrated to be effective, including the following: (1) laboratory screening of symptomatic patients for RSV infection; (2) cohorting infected patients and staff; (3) excluding visitors with respiratory tract infections; (4) excluding staff with respiratory tract illness or RSV infection from caring for susceptible infants; and (5) use of gowns, gloves, goggles, and perhaps masks.

A critical aspect of RSV prevention among high-risk infants is education of parents and other caregivers about the importance of decreasing exposure to and transmission of RSV. Preventive measures include limiting, where feasible, exposure to contagious settings (eg, child care centers) and emphasis on hand hygiene in all settings, including the home, especially during periods when the contacts of high-risk children have respiratory infections.

Related text in Red Book:

Preterm and Low Birth Weight Infants

Red Book 2006: 67-69. [Extract] [Full Version]

American Indian/Alaska Native Children

Red Book 2006: 87-90. [Extract] [Full Version]

This topic has been referenced by these articles:

- Uzel, G., Premkumar, A., Malech, H. L., Holland, S. M. (2000). Respiratory Syncytial Virus Infection in Patients With Phagocyte Defects. *Pediatrics* 106: 835-837 [Abstract] [Full Version]
- Gavin, P. J., Katz, B. Z. (2002). Intravenous Ribavirin Treatment for Severe Adenovirus Disease in Immunocompromised Children. *Pediatrics* 110: e9-9 [Abstract] [Full Version]
- Bockova, J., O'Brien, K. L., Oski, J., Croll, J., Reid, R., Weatherholtz, R. C., Santosham, M., Karron, R. A. (2002). Respiratory Syncytial Virus Infection in Navajo and White Mountain Apache Children. *Pediatrics* 110: e20-20 [Abstract] [Full Version]
- Titus, M. O., Wright, S. W. (2003). Prevalence of Serious Bacterial Infections in Febrile Infants With Respiratory Syncytial Virus Infection. *Pediatrics* 112: 282-284 [Abstract] [Full Version]
- Thatayatikom, A., Liu, A. H. (2005). Vascular Endothelial Growth Factor (VEGF) Induces Remodeling and Enhances Th2-Mediated Sensitization and Inflammation in the Lung. *Pediatrics* 116: 556-557 [Full Version]
- Choudhuri, J. A., Ogden, L. G., Ruttenber, A. J., Thomas, D. S.K., Todd, J. K., Simoes, E. A.F. (2006). Effect of Altitude on Hospitalizations for Respiratory Syncytial Virus Infection. *Pediatrics* 117: 349-356 [Abstract] [Full Version]
- Pinto, R. A., Arredondo, S. M., Bono, M. R., Gaggero, A. A., Diaz, P. V. (2006). T Helper 1/T Helper 2 Cytokine Imbalance in Respiratory Syncytial Virus Infection Is Associated With Increased Endogenous Plasma Cortisol. *Pediatrics* 117: e878-e886 [Abstract] [Full Version]

Synagis

NDC USAGE for synagis from 08/01/05 to 05/01/06 for Program All			
NDC Code	**Rx Num**	**Total Reimb Amt**	**Label Name**
60574411101	141	$201,775.83	SYNAGIS 100 MG VIAL
60574411201	83	$59,432.00	SYNAGIS 50 MG VIAL
60574411301	35	$48,549.18	SYNAGIS 100 MG/1 ML VIAL
60574411401	20	$33,700.00	SYNAGIS 50 MG/0.5 ML VIAL
TOTAL	279	$343,457.01	
60 patients/30 physicians			

NDC USAGE for synagis from 08/01/06 to 04/27/07 for Program All			
NDC Code	**Rx Num**	**Total Reimb Amt**	**Label Name**
60574411301	237	$362,015.86	SYNAGIS 100 MG/1 ML VIAL
60574411401	114	$85,310.76	SYNAGIS 50 MG/0.5 ML VIAL
TOTAL	351	$447,326.62	
84 patients/27 physicians			

HEALTH INFORMATION DESIGNS

Synagis Prescribers 2006-2007 Season

Prescribing Physicians	Patients per Physician	Rx Num	City
11577	8	42	Bismarck
11867	8	36	Bismarck
18949	15	75	Bismarck
15372	1	6	Cando
10421	3	11	Dickinson
18565	2	4	Dickinson
11974	1	4	Fargo
13079	3	4	Fargo
13117	1	4	Fargo
13203	1	1	Fargo
13724	1	4	Fargo
14362	1	2	Fargo
14687	1	4	Fargo
14760	1	4	Fargo
11327	4	19	Grand Forks
11815	3	4	Grand Forks
12520	5	13	Grand Forks
12539	1	2	Grand Forks
13147	9	35	Grand Forks
14379	1	7	Grand Forks
15647	3	6	Grand Forks
17626	6	29	Grand Forks
19515	1	2	Grand Forks
19655	2	2	Grand Forks
13561	1	7	Rugby
14103	1	1	Wahpeton
10919	2	19	Williston

HEALTH INFORMATION DESIGNS

ARB and Renin Inhibitor PA Form

Clear Fields

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 an ARB or Renin Inhibitor, must use and fail one ACE Inhibitor.

- Angiotensin II receptor antagonists: Hyzaar, Micardis, Micardis/HCT, Teveten, Teveten/HCT, Atacand, Atacand/HCT, Avapro, Avalide, Benicar, Benicar/HCT, Cozaar, Diovan, Diovan/HCT
- Renin Inhibitor: Tekturna

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:

Qualifications for coverage:

☐ Failed ACE Inhibitor	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:

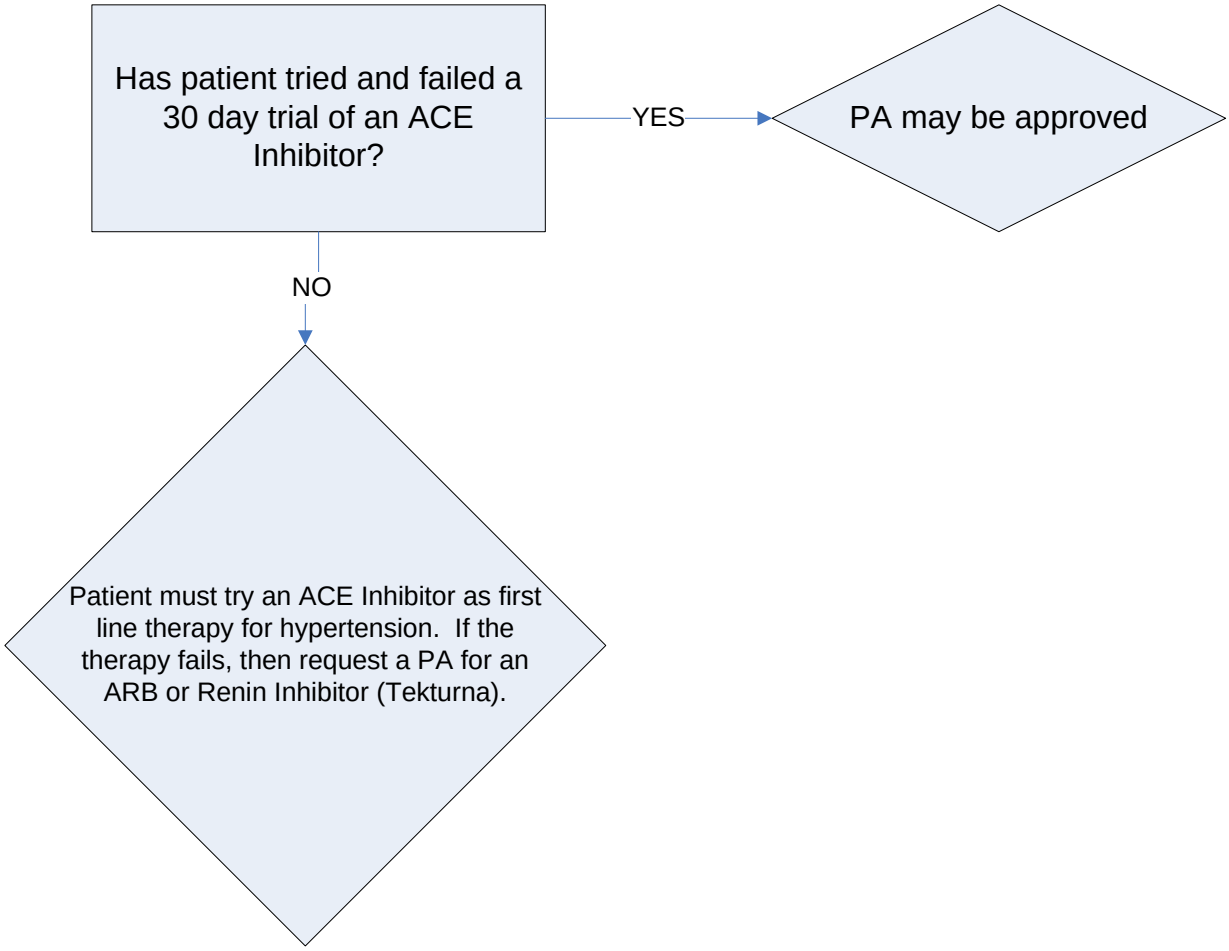
Part II: TO BE COMPLETED BY PHARMACY

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
ARB and Renin Inhibitor (Tekturna) Authorization Criteria Algorithm



Xopenex Utilization from 01/01/06 to 02/26/07

Rx Num	Total Claim Cost	Label Name
187	$10,132.42	XOPENEX HFA 45 MCG INHALER

Xopenex Prescribers by City (scripts of 2 or more)

Prescribing Physicians	Patients per Physician	Rx Num	Location
11363	8	9	Bismarck
18949	2	6	Bismarck
10332	5	5	Bismarck
16461	3	5	Bismarck
12961	1	4	Bismarck
14254	3	9	Bismarck
14301	4	4	Bismarck
14311	4	9	Bismarck
14317	1	10	Bismarck
16763	1	4	Bismarck
17583	3	7	Bismarck
18113	2	2	Bismarck
18731	2	2	Bismarck
18975	4	4	Bismarck
15348	2	2	Bismarck
12861	1	2	Bismarck
10988	2	2	Bismarck
16167	2	2	Bismarck
17583	3	7	Bismarck
17616	2	2	Bismarck
16186	2	3	Dickinson
19751	1	3	Dickinson
11510	1	2	Fargo
12281	1	2	Grand Forks
13341	3	3	Harvey
14910	1	6	In State Provider
19810	2	2	Jamestown
17845	22	39	Minot
15227	1	2	Minot
12822	1	2	Minot
53168	11	11	Out of State Provider

Xopenex Utilization age 16 and below 01/01/06 to 02/26/07

Rx Number	Total Reimb Amt	Label Name
75	$4,084.52	XOPENEX HFA 45 MCG INHALER

Prescribers of age 16 and below Xopenex scripts 01/01/06 to 02/26/07 (scripts of 2 or more)

Prescribing Physicians	Patients per Physician	Rx Num	Location
17845	8	14	Trinity Health-Minot Immunology
11363	8	9	Medcenter Peds
53168	8	9	Out of State Provider
18949	2	6	Medcenter Peds
10332	5	5	Medcenter Peds
16461	3	5	Medcenter Peds
16186	2	3	Dickinson IM/Peds
12822	1	2	Minot
13341	2	2	Harvey Family Practice
16167	2	2	St. A's Family Practice
17583	2	2	St. A's Family Practice
17616	2	2	Medcenter Family Practice
19810	2	2	Jamestown

HEALTH INFORMATION DESIGNS

Prior Authorization Vendor for ND Medicaid

Xopenex HFA PA Form

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 a new prescription for Albuterol HFA must use Proventil HFA as first line therapy.
__Note:__

- Proventil HFA does not require 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: **XOPENEX HFA**	**Requested Dosage:** (must be completed)

Qualifications for coverage:

☐ Failed Proventil HFA 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:

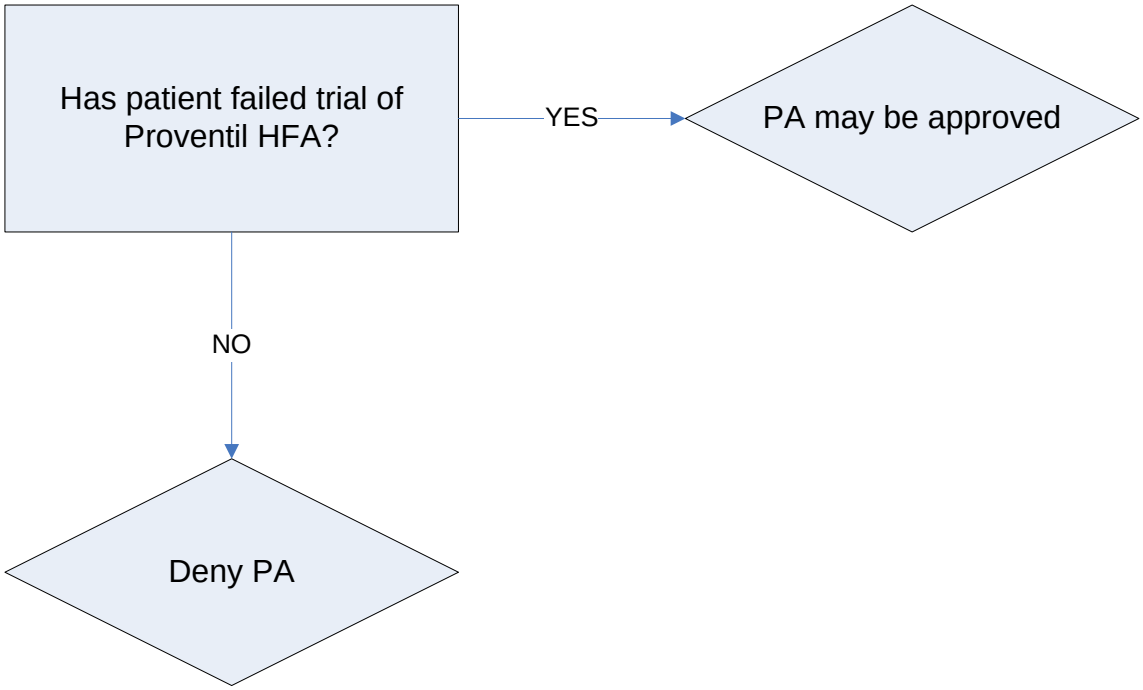
Part II: TO BE COMPLETED BY PHARMACY

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
Xopenex HFA Authorization Algorithm



HEALTH INFORMATION DESIGNS

Ketek Form

Clear Fields

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

Prior Authorization Vendor for ND Medicaid

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

ND Medicaid will cover Ketek for patients with an allergy to fluoroquinolones or tetracyclines.

Part I: TO BE COMPLETED BY PHYSICIAN

RECIPIENT NAME:	
RECIPIENT DATE OF BIRTH:	RECIPIENT MEDICAID ID NUMBER:
PHYSICIAN NAME:	PHYSICIAN MEDICAID ID NUMBER:
Address:	Phone:
City:	FAX:
State: Zip:	

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

Qualifications for coverage:

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

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

Physician Signature: Date:

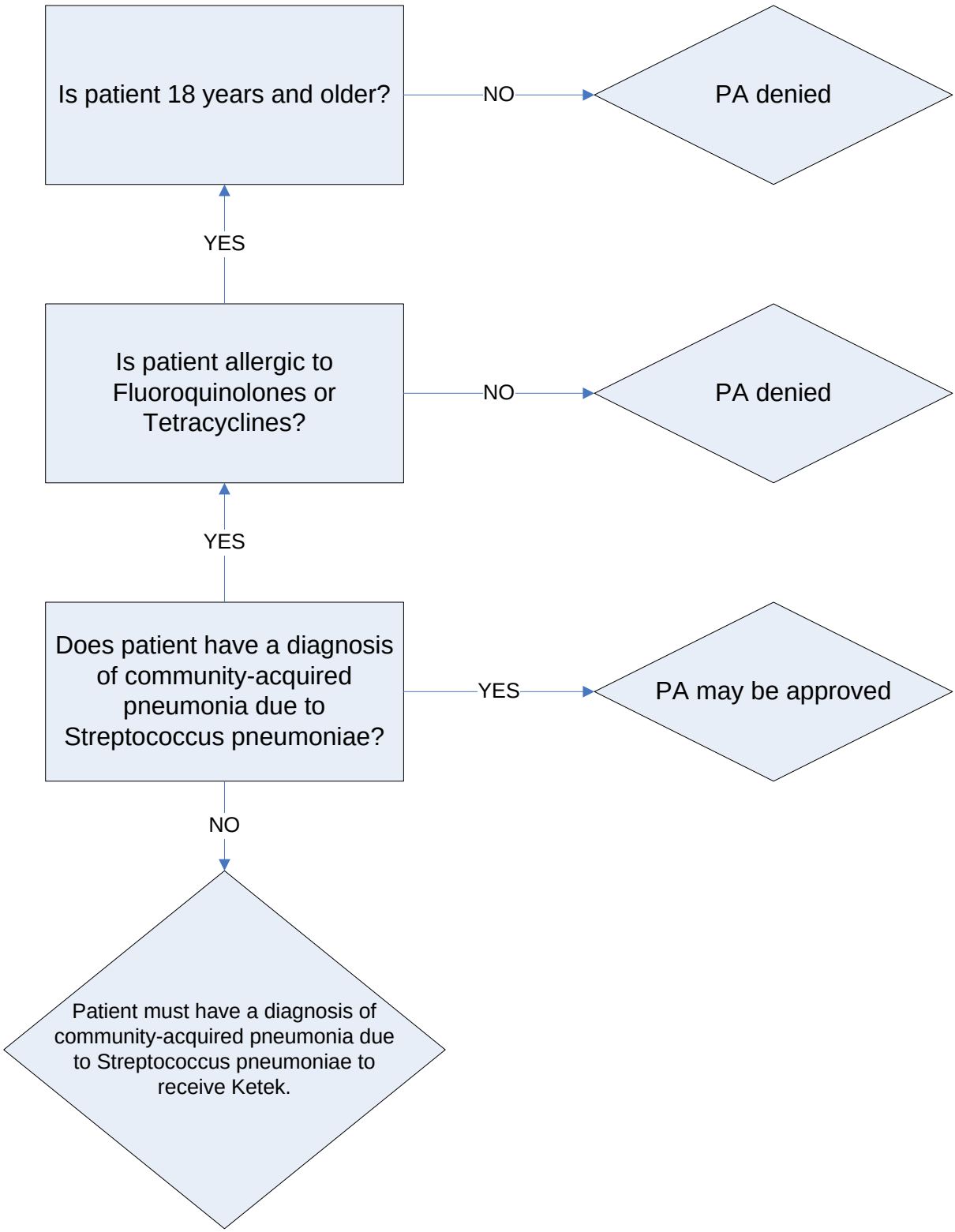
Part II: TO BE COMPLETED BY PHARMACY

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
Ketek Criteria Algorithm



North Dakota Century Code

SECTION 2 A new section to chapter 50-24.1 of the North Dakota Century Code is created and enacted as follows:

Medical assistance program management-The department of human services, with respect to the state medical assistance program, shall:
6. Review and develop recommendations regarding whether to require medical assistance providers to secure prior authorization for certain high-cost medical procedures.

2005 House Bill 1459 directed the Department to review expensive medical procedures for prior authorization. To be consistent with that direction, we will ask the DUR Board to review expensive medications for prior authorization. It is common practice through insurance and Medicaid agencies to set a level at which everything beyond that level requires prior authorization. These are typically put in as 'safety edits' in claims processing systems, but we are bringing it through the Board.

We must remember that new products are coming out continuously, therefore we will not limit our review to specific products, but we will determine a level for the 'safety edit' based on cost. It is good payer practice to know when and why these expensive products are being used. It assists with utilization review, disease management, and budget planning. Also, it protects from exposure to fraud, as many of these products are billed by out of state pharmacy providers and are prescribed by specialists from out of state medical practices.

Prescriptions Dispensed 1/1/06 thru 12/28/06 Amount Billed Greater Than $1000.00

NDC Number	NDC Name	Avg. Amt Billed	Avg. Amt Paid
59148001013	ABILIFY	$1,180.08	$810.78
49502069203	ACCUNEB	$1,498.10	$706.60
00944294004	ADVATE	$14,726.40	$14,723.40
00406007101	ANAGRELIDE HCL	$1,165.50	$175.60
60258044530	ANDEHIST DM NR	$4,785.20	$1,218.49
00088120806	ANZEMET	$1,177.39	$1,064.38
55513004601	ARANESP	$2,440.22	$2,281.66
00007323411	ARIXTRA	$3,365.90	$3,029.41
59627000103	AVONEX	$2,037.79	$1,278.00
00066057760	BENZAMYCIN PAK	$2,864.70	$2,575.99
50419052325	BETASERON	$1,681.67	$1,183.61
00087611142	CAFCIT	$1,544.80	$1,388.62
00006382210	CANCIDAS	$2,372.16	$745.91
60432023730	CARBAXEFED DM RF	$4,936.80	$961.40
44206041812	CARIMUNE NF	$1,881.00	$218.75
54482014508	CARNITOR	$1,697.99	$37.86
10019009801	CEFTRIAXONE	$1,164.27	$323.31
00781932895	CEFTRIAXONE NOVAPLUS	$1,153.60	$512.75
00004026001	CELLCEPT	$1,081.75	$949.16
63304095902	CEPHALEXIN	$1,801.80	$805.60
00172436060	CLOZAPINE	$1,565.50	$485.00
00078012705	CLOZARIL	$1,162.75	$1,040.86
65649010102	COLAZAL	$9,179.45	$8,259.81
39822061501	COLISTIMETHATE SODIUM	$2,517.43	$2,307.63
61570041451	COLY-MYCIN M	$3,550.00	$3,199.85
00088115330	COPAXONE	$1,655.06	$1,299.07
00004008694	COPEGUS	$1,819.03	$999.42
67919001101	CUBICIN	$3,424.02	$2,247.15
00074568216	DEPAKENE	$1,095.95	$454.20
00074621513	DEPAKOTE	$1,065.76	$883.18
45802042237	DESONIDE	$2,914.89	$1,157.60
51672127003	DESOXIMETASONE	$2,081.50	$1,674.20
58406042534	ENBREL	$1,983.54	$1,033.08
55513082301	EPOGEN	$1,930.29	$1,694.73
00378326694	ETOPOSIDE	$1,913.00	$1,720.55
00078047015	EXJADE	$6,711.60	$6,042.17
00013242691	FRAGMIN	$1,104.14	$1,025.16
99073012050	FREESTYLE	$2,764.50	$53.32
99073011001	FREESTYLE BLOOD GLUCOSE SYSTEM	$8,027.50	$72.10

99073013001	FREESTYLE LANCETS	$1,148.44	$12.48
00172444460	GABAPENTIN	$1,022.25	$238.25
00944262004	GAMMAGARD S/D	$1,279.00	$898.00
00013264681	GENOTROPIN	$4,296.08	$1,520.99
00013265802	GENOTROPIN MINIQUICK	$2,263.93	$1,835.02
00078043815	GLEEVEC	$3,780.66	$2,308.97
00002803101	GLUCAGON EMERGENCY KIT	$1,758.80	$1,656.48
63004773101	H.P. ACTHAR	$2,864.63	$2,777.60
00053813004	HELIXATE FS	$17,790.61	$8,802.33
00002751001	HUMALOG	$1,284.34	$278.34
00074379902	HUMIRA	$1,645.63	$1,306.60
00002873059	HUMULIN N PEN	$1,257.81	$110.28
00173052300	IMITREX	$1,258.34	$174.54
00173047800	IMITREX STATDOSE REFILL	$1,215.40	$1,089.16
67211034253	INNOHEP	$2,267.30	$1,964.15
00085117902	INTRON A	$1,881.98	$1,833.84
00006384371	INVANZ	$1,372.34	$970.52
66794000260	IPRATROPIUM BROMIDE	$1,238.30	$73.21
00310048230	IRESSA	$2,737.81	$156.52
00074679922	KALETRA	$1,213.54	$1,079.55
55513017728	KINERET	$1,435.53	$1,305.00
00026037230	KOGENATE FS	$7,464.80	$7,443.03
00004024126	KYTRIL	$1,674.67	$1,409.87
60505056202	LACTULOSE	$1,302.98	$33.98
00173063302	LAMICTAL	$1,275.05	$995.07
00173052700	LAMICTAL CD	$1,223.25	$1,105.50
00093571501	LAMOTRIGINE	$1,034.32	$778.48
49348091122	LANCETS	$2,194.10	$13.23
00088222033	LANTUS	$8,383.84	$450.24
00555048527	LEUCOVORIN CALCIUM	$1,268.35	$0.00
00045153005	LEVAQUIN LEVA-PAK	$1,731.25	$1,554.10
00173072100	LEXIVA	$1,394.76	$1,246.44
00115704001	LIPRAM-PN10	$1,590.08	$615.83
00409198530	LORAZEPAM	$1,760.00	$110.15
00075291501	LOVENOX	$2,817.16	$2,414.91
00300228201	LUPRON DEPOT-PED	$1,214.41	$551.27
00310032130	MERREM IV	$3,117.26	$2,150.24
00089020025	METROGEL-VAGINAL	$4,589.50	$4,589.50
52769046001	MONARC-M	$18,267.89	$18,165.68
00074202902	MORPHINE SULFATE	$1,776.00	$423.84
00015722618	NAFCILLIN SODIUM	$1,500.00	$544.57
49735011047	NEOCATE ONE +	$1,423.50	$1,423.50
55513019001	NEULASTA	$7,713.99	$7,364.17
55513092410	NEUPOGEN	$3,788.15	$3,039.68

00766145020	NICODERM CQ	$1,271.05	$79.56
00169770511	NORDITROPIN NORDIFLEX	$1,229.04	$745.74
00169750111	NOVOLOG	$1,968.00	$13.13
00074775329	NUTRIMIX W/ELECTROLYTES	$5,735.40	$24.12
50242002220	NUTROPIN AQ	$1,181.21	$2.06
50242004314	NUTROPIN AQ PEN CARTRIDGE	$2,020.80	$1,457.87
00168003760	NYSTATIN	$1,241.50	$501.61
00574030316	ORA-PLUS	$1,783.79	$0.00
00062125115	ORTHO TRI-CYCLEN LO	$1,021.51	$47.52
00093003301	OXYCODONE HCL	$1,308.99	$893.60
60951071070	OXYCODONE HYDROCHLORIDE	$1,763.30	$1,162.32
59011010710	OXYCONTIN	$1,217.28	$950.88
00045034260	PANCREASE MT 10	$1,168.31	$575.08
00045034660	PANCREASE MT 20	$1,395.07	$1,118.85
59767000102	PANCRECARB MS-8	$1,767.25	$1,176.07
00004035239	PEGASYS	$1,813.62	$1,640.58
00085127901	PEG-INTRON	$1,880.73	$1,481.57
00944047180	POLYGAM S/D	$1,521.29	$1,097.66
57599881401	PRECISION XTRA MONITOR	$6,479.60	$5,831.74
00300304613	PREVACID	$1,512.29	$54.32
00006351458	PRIMAXIN IV	$1,902.03	$489.04
59676034001	PROCRIT	$2,115.13	$1,972.21
00469061773	PROGRAF	$1,280.27	$1,012.24
00338049906	PROSOL	$1,233.06	$928.31
00008092355	PROTONIX	$1,728.00	$841.60
00186198904	PULMICORT RESPULES	$1,080.35	$196.16
50242010040	PULMOZYME	$2,088.05	$1,637.62
00008104105	RAPAMUNE	$1,051.99	$947.54
00085135105	REBETOL	$2,142.86	$1,112.27
44087002203	REBIF	$1,830.78	$1,670.52
00069419068	REVATIO	$1,164.03	$951.11
49884085694	RIBASPHERE	$1,022.95	$1,005.20
59930152301	RIBAVIRIN	$1,473.91	$966.77
50458030811	RISPERDAL CONSTA	$1,139.81	$754.20
00004196401	ROCEPHIN	$1,226.60	$967.60
44087108801	SAIZEN	$1,544.51	$205.69
00078018325	SANDOSTATIN	$1,390.05	$1,340.40
00310027460	SEROQUEL	$1,419.35	$1,150.24
00006384130	SINGULAIR	$3,385.21	$2,930.73
60793013601	SKELAXIN	$1,373.59	$84.56
00703951403	SMZ-TMP CONCENTRATE	$1,053.91	$744.95
00338004904	SODIUM CHLORIDE	$1,163.33	$335.98
50924097110	SOFTCLIX LANCETS	$1,279.00	$14.16
10631058677	SOTRET	$1,168.61	$767.60

00003052411	SPRYCEL	$3,639.34	$3,216.06
00069098030	SUTENT	$6,981.71	$5,645.17
60574411301	SYNAGIS	$1,717.12	$1,441.52
50242006401	TARCEVA	$3,394.11	$2,865.44
00083001976	TEGRETOL	$1,145.85	$87.14
00085125901	TEMODAR	$2,844.02	$1,743.92
59572020594	THALOMID	$3,454.40	$2,745.62
58468184904	THYROGEN	$3,207.84	$1,635.85
00029657126	TIMENTIN	$1,508.00	$414.37
53905006501	TOBI	$3,498.74	$2,673.94
00703941601	TOBRAMYCIN SULFATE	$1,022.44	$493.85
00045064565	TOPAMAX	$1,075.15	$738.41
66215010106	TRACLEER	$6,100.19	$3,443.98
57664037718	TRAMADOL HCL	$1,159.69	$58.40
00008536002	TYGACIL	$1,103.71	$596.67
58914001810	ULTRASE MT18	$1,115.46	$355.39
58914000450	ULTRASE MT20	$1,389.85	$1,147.37
00004003822	VALCYTE	$2,594.54	$2,296.09
00049318030	VFEND	$2,028.07	$1,769.75
00004110150	XELODA	$1,797.49	$1,572.85
50242004062	XOLAIR	$1,069.97	$207.31
62161000820	XYREM	$1,013.70	$912.85
00069314019	ZITHROMAX	$1,551.79	$1,400.95
00173044700	ZOFRAN	$1,916.96	$1,528.67
00173056900	ZOFRAN ODT	$1,841.59	$652.36
00310095130	ZOLADEX	$1,416.05	$1,273.58
00310021020	ZOMIG	$9,404.05	$108.87
00002442030	ZYPREXA	$1,264.99	$1,114.96
00002445685	ZYPREXA ZYDIS	$1,464.97	$1,227.69
00009513502	ZYVOX	$1,782.91	$1,521.70

NDC USAGE for nd-growthhormone from 06/01/06 to 04/24/07 for Program All
Claims Type: Medicaid

NDC Code	Rx Num	Total Reimb Amt	Label Name
13264681	5	$1,012.52	GENOTROPIN 13.8 MG CARTRIDGE
13264694	4	$429.28	GENOTROPIN 13.8 MG CARTRIDGE
13265102	8	$6,582.41	GENOTROPIN MINIQUICK 0.6 MG
13265802	8	$21,625.06	GENOTROPIN MINIQUICK 2 MG
44087108801	1	$37.97	SAIZEN 8.8 MG VIAL
50242004314	2	$178.51	NUTROPIN AQ PEN CARTRIDGE
TOTAL	28	$29,865.75	6 recipients/2 prescribers

Growth Hormone 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 Growth Hormone meet one of the criteria below:

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

Part I: TO BE COMPLETED BY 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:

Criteria met:	Diagnosis Date: Drug:	Dose: Frequency:

Physician Signature: Date:

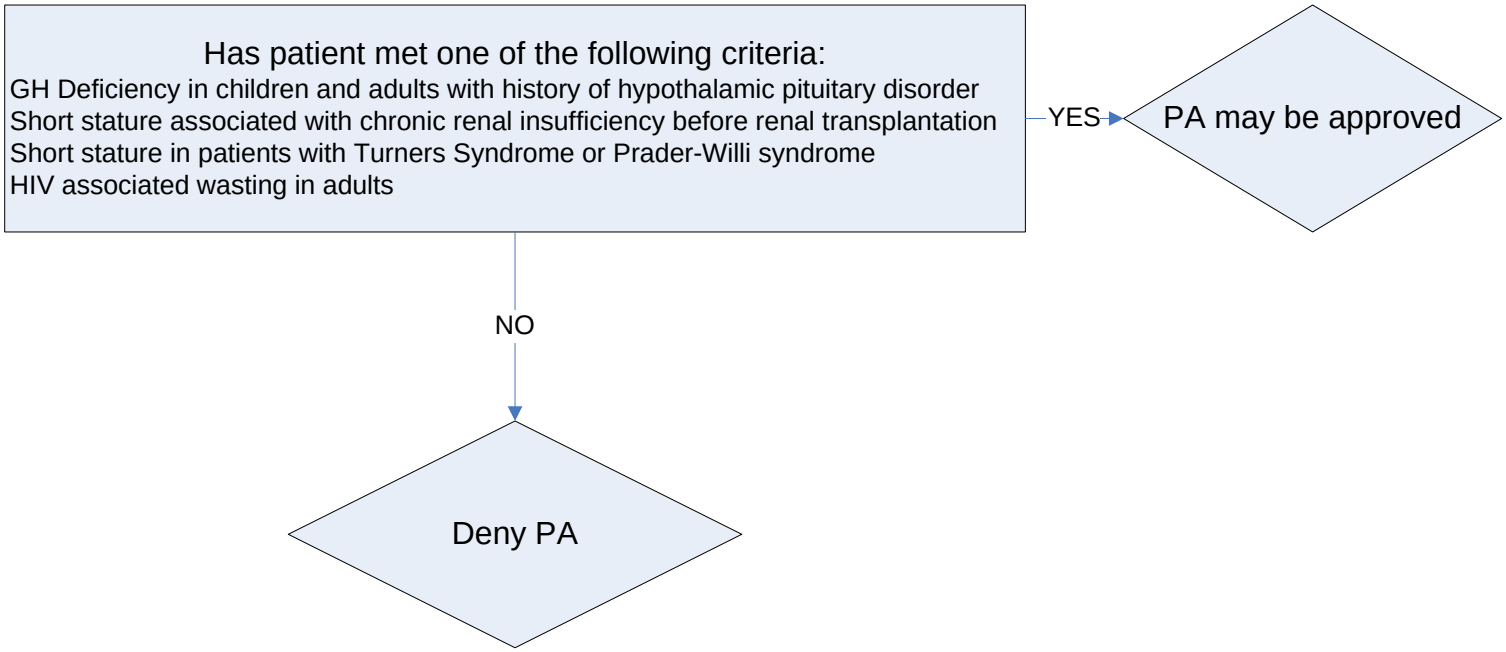
Part II: TO BE COMPLETED BY PHARMACY

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
Growth Hormone Authorization Algorithm



NORTH DAKOTA MEDICAID
RETROSPECTIVE DRUG UTILIZATION REVIEW
CRITERIA RECOMMENDATIONS
3RD QUARTER 2007

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

1. Elidel / Therapeutic Appropriateness _____ _____

Alert Message: The topical calcineurin inhibitor, Elidel (pimecrolimus), is indicated as second-line therapy for the short-term, non-continuous chronic treatment of mild to moderate atopic dermatitis in patients who are unresponsive or intolerant to other agents. Rare cases of malignancy (i.e., skin cancer and lymphoma) have been reported in patients treated with topical pimecrolimus. Application should be limited to the areas affected with atopic dermatitis.
Conflict Code: TA - Therapeutic Appropriateness
Drug/Disease:

Util A	Util B	Util C (Negating)
Pimecrolimus		High to Very High Potency Topical Corticosteroids
		Augmented Betamethasone
		Clobetasol
		Diflorasone
		Halobetasol
		Amcinonide
		Betamethasone
		Desoximetasone
		Fluocinolone
		Fluocinonide
		Halcinonide
		Triamcinolone

Day Supply: 20 days in current 90 days
Age Range: 0 – 999 years of age

References:
Facts & Comparisons, 2006 Updates.
Elidel Prescribing Information, Jan. 2006. Novartis Pharmaceuticals Corp.

2. Protopic / Therapeutic Appropriateness _____ _____

Alert Message: The topical calcineurin inhibitor, Protopic (tacrolimus), is indicated as second-line therapy for the short-term, non-continuous chronic treatment of moderate to severe atopic dermatitis in patients who are unresponsive or intolerant to other agents. Rare cases of malignancy (i.e., skin cancer and lymphoma) have been reported in patients treated with topical tacrolimus. Application should be limited to the areas affected with atopic dermatitis.
Conflict Code: TA - Therapeutic Appropriateness
Drug/Disease:

Util A	Util B	Util C (Negating)
Tacrolimus		Very High Potency Topical Corticosteroids
		Augmented Betamethasone
		Clobetasol
		Diflorasone
		Halobetasol
		Amcinonide
		Betamethasone
		Desoximetasone
		Fluocinolone
		Fluocinonide
		Halcinonide
		Triamcinolone

Day Supply: 20 days in current 90 days
Age Range: 0 – 999 years of age
References:
Facts & Comparisons, 2006 Updates.
Protopic Prescribing Information, Jan. 2006, Astellas Pharma Inc.

Recommendations	*Approved*	*Rejected*

3. Protopic & Elidel / Therapeutic Appropriateness (AGE) _____ _____

Alert Message: The topical calcineurin inhibitors, Protopic (tacrolimus) and Elidel (pimecrolimus), are not recommended for use in children less than 2 years of age. The long-term safety and effects of these agents on the developing immune system are unknown.
Conflict Code: TA - Therapeutic Appropriateness
Drug/Disease:

Util A	Util B	Util C
Tacrolimus		
Pimecrolimus		

Age Range: 0 – 1 years of age
References:
Facts & Comparisons, 2006 Updates.
Protopic Prescribing Information, Jan. 2006, Astellas Pharma Inc.
Elidel Prescribing Information, Jan. 2006, Novartis Pharmaceuticals, Inc.

4. Protopic / Therapeutic Appropriateness (AGE) _____ _____

Alert Message: The use of Protopic 0.1% ointment (topical tacrolimus) is not recommended in children less than 15 years of age. The 0.03% tacrolimus ointment is approved for use in children ages 2 to 15. Application should be limited to areas affected with atopic dermatitis. If signs and symptoms have not resolved within 6 weeks patient should be re-examined to confirm diagnosis.
Conflict Code: TA - Therapeutic Appropriateness
Drug/Disease:

Util A	Util B	Util C
Tacrolimus 0.1%		

Age Range: 2-15 years of age
References:
Facts & Comparisons, 2006 Updates.
Protopic Prescribing Information, Jan. 2006, Astellas Pharma Inc.

5. Elidel / Immunocompromised Patients _____ _____

Alert Message: Elidel (topical pimecrolimus) should not be used in immunocompromised adults and children. These patients are at risk for increased systemic exposure and adverse effects of pimecrolimus.
Conflict Code: DB – Drug-Drug Marker and/or Diagnosis
Drug/Disease:

Util A	Util B	Util C
Pimecrolimus	HIV Diagnosis	
	Antiretrovirals	
	Transplant Diagnoses	
	Immunosuppressive Agents	

Age Range: 0-999 years of age

References:
Facts & Comparisons, 2006 Updates.
Elidel Prescribing Information, Jan. 2006, Novartis Pharmaceuticals, Inc.

Recommendations	*Approved*	*Rejected*

6. Protopic / Immunocompromised Patients _____ _____

Alert Message: Protopic (topical tacrolimus) should not be used in immunocompromised adults and children. These patients are at risk for increased systemic exposure and adverse effects of tacrolimus.
Conflict Code: DB – Drug-Drug Marker and/or Diagnosis
Drug/Disease:

Util A	Util B	Util C
Tacrolimus	HIV Diagnosis	
	Antiretrovirals	
	Transplant Diagnosis	
	Immunosuppressive Agents	

Age Range: 0-999 years of age

References:
Facts & Comparisons, 2006 Updates.
Elidel Prescribing Information, Jan. 2006, Novartis Pharmaceuticals, Inc.

7. Topical Immunomodulators / Therapeutic Duplications _____ _____

Alert Message: Therapeutic duplication of topical immunomodulator agents may be occurring.
Conflict Code:
Drug/Disease:

Util A	Util B	Util C
Tacrolimus		
Pimecrolimus		

References:
Facts & Comparisons, 2006 Updates.
Micromedex Healthcare Series, DRUGDEX Drug Evaluations, 2007.

8. Lisdexamfetamine / High Dose _____ _____

Alert Message: Vyvanse (lisdexamfetamine) may be over-utilized. The manufacturer's recommended maximum dose for children is 70 mg daily. Doses greater than 70 mg have not been studied in children.
Conflict Code: HD – High Dose
Drugs/Disease:

Util A	Util B	Util C
Lisdexamfetamine		

Max Dose: 70 mg/day
Age Range 6 – 12 years of age
References:
Vyvanse Prescribing Information, February 2007, New River Pharmaceuticals Inc.

9. Lisdexamfetamine / Therapeutic Appropriateness _____ _____

Alert Message: Vyvanse (lisdexamfetamine) is indicated for the treatment of Attention-Deficit/Hyperactivity Disorder (ADHD) in patients 6 to 12 years of age. This agent has not been studied in children 3 to 5 years of age. Amphetamines are not recommended for children under 3 years of age.
Conflict Code: TA – Therapeutic Appropriateness
Drugs/Disease:

Util A	Util B	Util C
Lisdexamfetamine		

Age Range: 3 – 5 years of age
References:
Vyvanse Prescribing Information, February 2007, New River Pharmaceuticals Inc.

Criteria Recommendations *Approved* *Rejected*

10. Aliskiren / Pregnancy / Pregnancy Negating _____ _____

Alert Message: When pregnancy is detected Tekturna (aliskiren) should be discontinued as soon as possible. Aliskiren is a direct renin inhibitor and drugs acting directly on the renin-angiotensin system can cause fetal and neonatal morbidity and death when administered to pregnant women. Aliskiren is FDA pregnancy category C during the first trimester and pregnancy category D during the second and third trimesters.
Conflict Code: MC – Drug (Actual) Disease Precaution (Black Box Warning)
Drugs/Disease:

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

References:
Tekturna Prescribing Information, March 2007, Novartis Pharmaceuticals Corporation.

11. Aliskiren / High Dose _____ _____

Alert Message: Tekturna (aliskiren) may be over-utilized. The usual recommended starting dose is 150 mg once daily but may be increased to 300 mg if blood pressure is not adequately controlled. Doses above 300 mg have not increased the blood pressure response but have increased the rate of diarrhea.
Conflict Code: HD – High Dose
Drugs/Disease:

Util A	Util B	Util C
Aliskiren		

Max Dose: 300 mg/day
References:
Tekturna Prescribing Information, March 2007, Novartis Pharmaceuticals Corporation.

12. Aliskiren / Severe Renal Impairment _____ _____

Alert Message: Tekturna (aliskiren) should be used with caution in patients with severe renal impairment (GFR < 30mL/min), a history of dialysis, nephrotic syndrome or renovascular hypertension. Drugs acting on the renin-angiotensin system have the potential to increase serum creatinine and blood urea nitrogen.
Conflict Code: MC – Drug/Drug or Drug/Disease Precaution
Drugs/Disease:

Util A	Util B	Util C
Aliskiren	Severe Renal Impairment	Nephrotic Syndrome
	Lanthanum	Renovascular Hypertension
	Sevelamer	Dialysis
	Paricalcitol	
	Doxercalciferol	
	Calcitriol	

References:
Tekturna Prescribing Information, March 2007, Novartis Pharmaceuticals Corporation.

13. Aliskiren / ACEIs / Diabetes _____ _____

Alert Message: The concurrent use of Tekturna (aliskiren) and an ACE inhibitor in patients with diabetes may result in increased serum potassium levels. Routine monitoring of electrolytes and renal function is indicated in this population.
Conflict Code: DD – Drug/Drug Interaction
Drugs/Disease:

Util A	Util B	Util C (Inclusive)	
Aliskiren	ACE Inhibitors	Diabetes	Dipeptidyl Peptidase-4 Inhibitor
		Insulin	Biguanide
		Sulfonylureas	Meglitinides
		Amylin Analog	Thiazolidinediones
		Incretin Mimetic	
		Alpha-Glucosidase Inhibitors	

References:
Tekturna Prescribing Information, March 2007, Novartis Pharmaceuticals Corporation.

14. Aliskiren / Furosemide _____ _____

Alert Message: The concurrent use of Tekturna (aliskiren) with furosemide has been shown to significantly reduce the blood concentrations of furosemide. Co-administration of these agents resulted in a decrease in the AUC and Cmax of furosemide by 30% and 50%, respectively. The effects of furosemide may be diminished after starting aliskiren.
Conflict Code: DD – Drug/Drug Interaction
Drugs/Disease:

Util A	Util B	Util C
Aliskiren	Furosemide	

Reference:
Tekturna Prescribing Information, March 2007, Novartis Pharmaceuticals Corporation.

15. Aliskiren / Ketoconazole _____ _____

Alert Message: The concurrent use of Tekturna (aliskiren) with ketoconazole may result in elevated aliskiren plasma levels due to inhibition of aliskiren CYP 3A4 mediated metabolism by ketoconazole. Co-administration of aliskiren with ketoconazole 200 mg twice daily has been shown to increase the plasma levels of aliskiren approximately 80%. A 400mg once-daily dose has not been studied but would be expected to increase aliskiren levels further.
Conflict Code: DD – Drug/Drug Interaction
Drugs/Disease:

Util A	Util B	Util C
Aliskiren	Ketoconazole	

Reference:
Tekturna Prescribing Information, March 2007, Novartis Pharmaceuticals Corporation.
The Medical Letter on Drugs & Therapeutics, Volume 49 (Issue 1258), April 2007.

16. Pioglitazone / Therapeutic Appropriateness _____ _____

Alert Message: Pioglitazone-containing products (Actos/ActoPlusMet/Duetact) may increase the risk of fractures in female patients. Analysis of clinical trial data revealed an increased incidence of fractures in female patients taking long-term pioglitazone therapy as compared to females taking a comparator (placebo or active). Consider the risk of fractures when initiating or treating female, type 2 diabetic patients with pioglitazone.
Conflict Code: TA – Therapeutic Appropriateness
Drugs/Disease:

Util A	Util B	Util C
Pioglitazone		

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

17. Methadone / Therapeutic Appropriateness _____ _____

Alert Msg: Methadone can cause significant toxicities. Vigilance is necessary during treatment initiation, dose titration, and drug conversion from other opioids to methadone. It is critical to understand the pharmacokinetics of methadone when converting patients to methadone. Methadone's half-life (8-59 hours) is longer than its duration of action (4-8 hours). Incomplete cross-tolerance makes conversion complex and does not eliminate the possibility of overdose.
Conflict Code: TA – Therapeutic Appropriateness
Drugs/Disease:

Util A	Util B	Util C
Methadone		

_____

DUR Board Meeting
October 1st, 2007
Heritage Center
Rooms A and B
1pm

August 31st, 2007

The next North Dakota Drug Utilization Review (DUR) Board Meeting will be held October 1st, 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
October 1st, 2007
1pm

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

2. Old Business

• Review and approval of minutes of 08/20/07 meeting	Chairman
• Budget update	Brendan
• Review of Antineoplastic Agents	HID
• Review of Antiretroviral Agents	HID
• Review of ADHD	HID
• Review of High Cost Medications	HID
• Yearly PA Review of DAW-1	HID

3. New Business

• Review of Antidepressant 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
August 20th, 2007

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

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 June 4th, 2007 meeting. A. Samuelson moved that the minutes be approved and G. Pfister seconded the motion. The chair called for a voice vote to approve the minutes, which passed with no audible dissent.

Budget Update
B. Joyce made available charts showing figures for utilizer per month and average prescription cost per month. On average, the cost per prescription per month is approximately fifty-three dollars. The average spent per member per month is approximately one-hundred and fifty dollars.

Review of Amrix
At the June meeting, a motion and second was made to place Amrix on prior authorization. No new information was presented. C. Huber called for a voice vote and the motion passed with no audible dissent. Motion passed to place Amrix on prior authorization.

Synagis Review
B. Joyce updated the Board regarding Synagis utilization. The Department would like to develop a patient registry for Synagis. Potential Synagis patients would be submitted to the Department by physicians. A registry would allow the Department to track Synagis patients and utilization. It would also allow the Department to track patients that should receive Synagis and do not. Currently, there is no system in place to track Synagis prescriptions and it appears that some patients may be getting missed in areas outside of Bismarck. At the June meeting, a motion and second was made to require a registry for Synagis patients. C. Huber called for a voice vote and the motion passed with no audible dissent. Motion passed to require a registry for Synagis. Board members requested an update on Synagis, including city data, be placed on the winter agenda for review.

Review of Tekturna
Tekturna is a new antihypertensive medication that is the first direct renin inhibitor approved by the FDA. Criteria for approval would be similar to the ARBs as there is no outcome data to suggest Tekturna should be used first line before ACE inhibitors or ARBs. There was public comment by Dana Meier, representing Novartis. She reviewed Tekturna related prescribing information with the Board and stated that new head to head trials will be available in September. K. Krohn asked for clarification regarding the wording on the PA form. She suggested that the wording on the prior authorization forms be simplified to make the forms easier to fill out. B. Treitline stated that the prior authorization forms have been the same since 2005 and he would suggest that they not change. Since the prior authorization forms and the Tekturna prior authorization are two separate topics, C. Huber called for a voice vote to place Tekturna on prior authorization. The motion passed with no audible dissent. B. Joyce said that he would review the wording included on the prior authorization forms and the Board could discuss it further at the October meeting.

Review of Xopenex HFA
The final discontinuation date for CFC inhalers is December 31, 2008. With the absence of these inhalers, HFA inhalers will be the only option for albuterol/levalbuterol in the near future. With the switch from CFC inhalers to HFA inhalers, the Department anticipates an increase in total claims cost of at least 170,000 dollars a year. The Department would like to group the albuterol HFA and levalbuterol HFA products together and choose the preferred product based on the cheapest HFA, post-rebate. Unfortunately, the Department is unable to disclose rebate dollars to the Board to show the major difference between the HFA albuterol and HFA levalbuterol products. New information was presented to the Board that showed city distribution of providers writing prescriptions for Xopenex HFA. Most prescriptions for Xopenex HFA are prescribed by one physician in Minot and in Bismarck. B. Joyce mentioned that the Department should not make a policy exemption for such small numbers of physicians. A motion was made by T. Twogood to remove the age exemption, add levalbuterol wording to the prior authorization form, and approve the prior authorization of Xopenex HFA. C. Sorenson seconded the motion. C. Huber called for a voice vote and the motion passed with no audible dissent. Motion passed to place Xopenex HFA on prior authorization.

Review of Ketek
In light of recent FDA warnings, the Department would like to monitor utilization of Ketek. A motion and second was made at the June meeting to place Ketek on prior authorization. C. Huber called for a voice vote and the motion passed with no audible dissent. Motion passed to place Ketek on prior authorization.

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 two years, 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 will contact these physicians for guidance regarding this class of medications. At this time, there is no new information to review and B. Joyce informed the Board members that this topic would be presented at a future meeting.

HIV/AIDS Review
At the June meeting, T. Twogood suggested getting a consult from one of the Infectious Disease doctors currently prescribing to North Dakota Medicaid patients. B. Joyce met with Dr. Martin, an Infectious Disease doctor in Bismarck. He works with the ND Department of Health and the Ryan White program (a federally funded program that provides HIV/AIDS medications to patients not on Medicaid). He sits on the Ryan White P&T Committee with other North Dakota Infectious Disease physicians and they have a formulary for the Ryan White program. Dr. Martin reviewed the ND Medicaid utilization data and stated that all utilization appears to follow the Ryan White formulary.

B. Joyce asked Dr. Martin if the law restricting prior authorizations on antiretrovirals was necessary, and Dr. Martin said that no law was needed if the Board had no intention of placing these medications on prior authorization. He also said such a law could keep immediate action from happening if a physician started moving away from the Ryan White formulary or practice standards. B. Joyce confirmed with Dr. Martin that the Ryan White P&T Committee would be willing to exert peer pressure on anyone prescribing in an outlier fashion (if that ever happens).

A motion was made by B. Treitline and seconded by N. Byers that the Board take the view of Dr. Martin. This would mean that the restrictions would be allowed to sunset as related to antiretrovirals and no further action would be taken by the DUR Board as the Board has no intent to prior authorize any of the medications in this class. C. Huber called for a voice vote and the motion passed with no audible dissent.

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. The Department would like for the Board to review utilization data and make suggestions on how best to monitor these products. The Board would like for more information to be provided on this topic including a minimum claim amount of three thousand dollars, strength of medication, quantities dispensed and days supply. This topic will be discussed at a later meeting.

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. Growth Hormone/IGF-1 products were reviewed. No action will be taken regarding the Growth Hormone/IGF-1 form or criteria.

ADHD Review
The ADHD 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 ADHD meds. Based on post-rebate information, Adderall XR is the most cost effective choice between Adderall XR and Vyvanse; given that Vyvanse is simply a less abusable follow-on product to Adderall XR as Adderall XR approaches its patent expiration. B. Joyce relayed information regarding the prior authorization of Sed/Hypnotics. The Board chose to leave Ambien as preferred to maintain market share in anticipation of the generic becoming available and to keep market share from shifting to the follow-on product Ambien CR and other competitors. Due to the proactive nature of this decision, the Department is saving approximately 30,000 dollars a month with generic Ambien. B. Joyce stated the logic for the suggested prior authorization of Vyvanse is the same as used for Ambien.

B. Joyce asked the Board what their overall desired actions are for ADHD medications. T. Twogood stated that there is really nothing that would predict one ADHD medication would work better than another; therefore trying the most cost effective agent first would be a very valid approach. The Board stated that they would like to broaden the prior authorization stipulations and include step therapy and asked B. Joyce to bring such an approach back to the next meeting.

B. Treitline made a motion and N. Byers seconded that the Board should recommend prior authorizing Vyvanse as presented in the packet (therefore requesting that the law should be allowed to sunset in relation to ADHD medications). C. Huber called for a voice vote and the motion passed with no audible dissent.

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. N. Byers moved to approve the new criteria and A. Samuelson seconded the motion. C. Huber called for a voice vote and the motion passed with no audible dissent.

Miscellaneous Items
Generic Zoloft is also saving the Department approximately 318,000 dollars a quarter. North Dakota Medicaid currently has a 68% generic utilization rate.

PhRMA contacting Board members
C. Sorenson and other Board members have received letters from Pfizer asking them to place smoking cessation products on the agenda for future meetings. B. Joyce stated that Pfizer has been told that current agendas are full while the Board reviews classes of medications for the legislative council and further requests of this fashion can be referred to him.

The next DUR board meeting will be October 1st, 2007. B. Joyce reviewed future agenda items. These include Antidepressants, ADHD, and Cancer. P. Churchill made a motion to adjourn the meeting and A. Samuelson seconded. Chair C. Huber adjourned the meeting at 4:15 pm.

ADHD Pricing Review

When reviewing ADHD agents, the Department takes in to account post-rebate pricing when determining the list of preferred agents. Once the net per unit cost is determined, DACON (daily average consumption) data is used to standardize all of the medications to net daily price. The following information is a result of this calculation.

Cost of Product (smallest to greatest)

Immediate Release ADHD products < Concerta < Metadate CD < Ritalin LA < Focalin XR < Concerta < Adderall XR < Metadate CD

<<< Daytrana and Strattera

391 Industry Drive • Auburn, AL 36832 • Phone: (334)502-3262 • Fax: (334) 466-6947
Auburn, Alabama • Jackson, Mississippi • Little Rock, Arkansas • Salisbury, Maryland

HEALTH INFORMATION DESIGNS

ADHD 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: Metadate CD, Adderall XR, Concerta, Focalin XR, or Ritalin LA.

****Note:***

- **Daytrana and Strattera 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:

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

Physician Signature: Date:

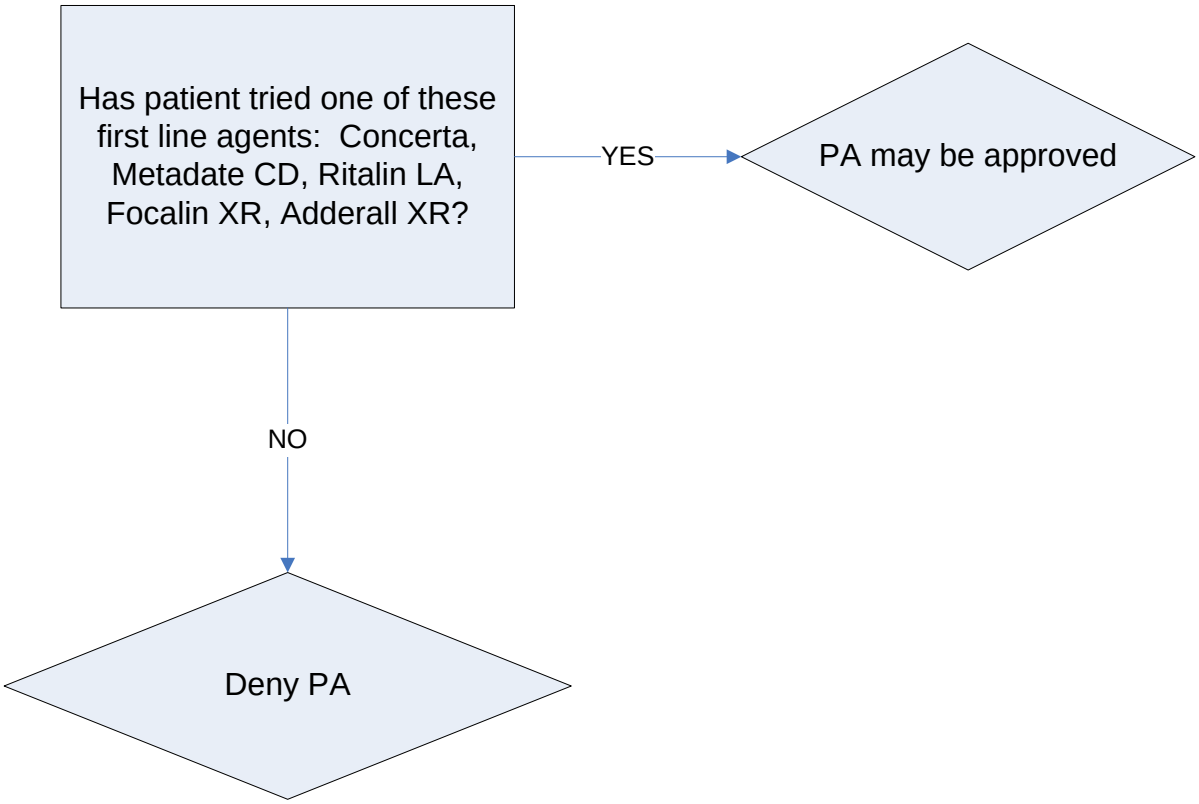
Part II: TO BE COMPLETED BY PHARMACY

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 Authorization Algorithm



Cost of Product (smallest to greatest)

Immediate Release ADHD products < Concerta

< Metadate CD < Ritalin LA < Focalin XR

< Concerta < Adderall XR < Metadate CD

<<< Daytrana and Strattera

High Cost Drugs Claims Paid 01/01/2007 thru 07/24/2007

NDC Number	NDC Name	STRENGTH	Quantity Dispensed	Days Supply	Amt Paid
00003052411	SPRYCEL	70 MG	60	30	$ 4,385.73
00003052411	SPRYCEL	70 MG	60	30	$ 4,385.73
00003052411	SPRYCEL	70 MG	60	30	$ 4,385.73
00003052411	SPRYCEL	70 MG	60	30	$ 4,732.07
00003052411	SPRYCEL	70 MG	60	30	$ 4,267.48
00003052411	SPRYCEL	70 MG	60	30	$ 4,181.83
00003052411	SPRYCEL	70 MG	60	30	$ 4,732.07
00003052411	SPRYCEL	70 MG	60	30	$ 4,732.07
00003052411	SPRYCEL	70 MG	60	30	$ 4,732.07
00003052411	SPRYCEL	70 MG	60	30	$ 4,732.07
00003052411	SPRYCEL	70 MG	60	30	$ 4,732.07
00003052411	SPRYCEL	70 MG	60	30	$ 4,732.07
00003052411	SPRYCEL	70 MG	60	30	$ 4,732.07
00003052811	SPRYCEL	70 MG	60	30	$ 4,291.44
00003052811	SPRYCEL	70 MG	60	30	$ 4,732.07
00004003822	VALCYTE	450 MG	120	30	$ 4,120.18
00009513502	ZYVOX	600 MG	60	30	$ 4,180.89
00026037230	KOGENATE FS	1 IU	9,528	30	$ 10,385.60
00026037230	KOGENATE FS	1 IU	9,756	30	$ 9,756.20
00026037230	KOGENATE FS	1 IU	9,756	30	$ 10,634.00
00026037230	KOGENATE FS	1 IU	9,756	30	$ 10,634.00
00026037230	KOGENATE FS	1 IU	9,792	28	$ 10,673.30
00053813002	HELIXATE FS	1 IU	10,728	30	$ 11,371.70
00053813002	HELIXATE FS	1 IU	8,896	1	$ 9,880.16
00053813002	HELIXATE FS	1 IU	10,024	9	$ 11,132.24
00053813004	HELIXATE FS	1 IU	13,072	2	$ 13,992.64
00053813004	HELIXATE FS	1 IU	9,008	8	$ 9,644.16
00053813004	HELIXATE FS	1 IU	9,008	8	$ 9,644.16
00053813004	HELIXATE FS	1 IU	9,008	8	$ 9,644.16
00069098038	SUTENT	50 MG	28	28	$ 6,410.19
00069098038	SUTENT	50 MG	28	28	$ 6,463.73
00069098038	SUTENT	50 MG	28	28	$ 6,546.03
00074379902	HUMIRA	40 MG/0.8 ML	6	21	$ 4,457.38
00074433906	HUMIRA	40 MG/0.8 ML	6	14	$ 4,457.37
00075062300	LOVENOX	100 MG/ML	60	30	$ 4,181.00
00075062300	LOVENOX	100 MG/ML	60	30	$ 4,389.64
00075062300	LOVENOX	100 MG/ML	60	30	$ 4,389.64
00075062300	LOVENOX	100 MG/ML	60	30	$ 4,389.64
00075062300	LOVENOX	100 MG/ML	60	30	$ 4,389.64
00078043815	GLEEVEC	400 MG	30	30	$ 3,208.53
00078043815	GLEEVEC	400 MG	30	30	$ 3,208.53
00078043815	GLEEVEC	400 MG	30	30	$ 3,208.53
00078043815	GLEEVEC	400 MG	30	30	$ 3,208.53
00078043815	GLEEVEC	400 MG	30	20	$ 3,208.53
00078043815	GLEEVEC	400 MG	45	30	$ 4,812.00
00078043815	GLEEVEC	400 MG	45	30	$ 4,459.81

00078043815	GLEEVEC	400 MG	45	30	$ 4,459.81
00078043815	GLEEVEC	400 MG	45	30	$ 4,459.81
00078043815	GLEEVEC	400 MG	45	30	$ 4,812.00
00078043815	GLEEVEC	400 MG	45	30	$ 4,812.00
00078043815	GLEEVEC	400 MG	45	30	$ 4,812.00
00078043815	GLEEVEC	400 MG	45	30	$ 4,812.00
00078043815	GLEEVEC	400 MG	45	30	$ 4,812.00
00078043815	GLEEVEC	400 MG	45	30	$ 4,812.00
00078043815	GLEEVEC	400 MG	45	30	$ 4,812.00
00085136601	TEMODAR	100 MG	30	30	$ 5,045.16
00173075200	TYKERB	250 MG	150	30	$ 3,264.10
00173075200	TYKERB	250 MG	150	30	$ 3,264.10
00173075200	TYKERB	250 MG	150	30	$ 3,264.10
00469305130	AMBISOME	50 MG	30	10	$ 5,300.35
50242010040	PULMOZYME	2.5 MG/2.5 ML	150	30	$ 3,241.60
50242010040	PULMOZYME	2.5 MG/2.5 ML	150	30	$ 3,241.60
50242010040	PULMOZYME	2.5 MG/2.5 ML	150	30	$ 3,241.60
50242010040	PULMOZYME	2.5 MG/2.5 ML	150	30	$ 3,241.60
50242010040	PULMOZYME	2.5 MG/2.5 ML	150	30	$ 3,244.60
50242010040	PULMOZYME	2.5 MG/2.5 ML	150	30	$ 3,244.60
50242010040	PULMOZYME	2.5 MG/2.5 ML	150	30	$ 3,244.60
50242010040	PULMOZYME	2.5 MG/2.5 ML	150	30	$ 3,244.60
50242010040	PULMOZYME	2.5 MG/2.5 ML	150	30	$ 3,244.60
50242010040	PULMOZYME	2.5 MG/2.5 ML	150	30	$ 3,244.60
50242010040	PULMOZYME	2.5 MG/2.5 ML	150	30	$ 3,406.60
53905006501	TOBI	60 MG/ML	280	28	$ 3,629.80
53905006501	TOBI	60 MG/ML	280	28	$ 3,629.80
53905006501	TOBI	60 MG/ML	280	30	$ 3,629.80
53905006501	TOBI	60 MG/ML	280	30	$ 3,629.80
53905006501	TOBI	60 MG/ML	280	28	$ 3,421.60
53905006501	TOBI	60 MG/ML	280	28	$ 3,626.80
53905006501	TOBI	60 MG/ML	280	28	$ 3,626.80
53905006501	TOBI	60 MG/ML	280	28	$ 3,626.80
53905006501	TOBI	60 MG/ML	280	28	$ 3,629.80
53905006501	TOBI	60 MG/ML	280	28	$ 3,629.80
53905006501	TOBI	60 MG/ML	280	28	$ 3,626.80
53905006501	TOBI	60 MG/ML	420	28	$ 5,442.40
53905006501	TOBI	60 MG/ML	560	15	$ 7,252.00
53905006501	TOBI	60 MG/ML	280	28	$ 3,626.80
59572020594	THALOMID	50 MG	56	28	$ 3,810.34
59572020594	THALOMID	50 MG	56	28	$ 3,517.33
59572020594	THALOMID	50 MG	84	28	$ 6,220.20
59572020594	THALOMID	50 MG	56	28	$ 4,422.41
59572020594	THALOMID	50 MG	84	28	$ 6,725.61
59572021015	THALOMID	100 MG	28	28	$ 3,646.89
63004773101	H.P. ACTHAR	80 U/ML	10	33	$ 3,717.62
63004773101	H.P. ACTHAR	80 U/ML	10	30	$ 3,717.62
66215010106	TRACLEER	62.5 MG	60	30	$ 3,960.48
66215010106	TRACLEER	62.5 MG	60	30	$ 3,960.48
66215010106	TRACLEER	62.5 MG	60	30	$ 3,617.29

66215010106	TRACLEER	62.5 MG	60	30	$ 3,960.48
66215010106	TRACLEER	62.5 MG	60	30	$ 3,960.48
66215010106	TRACLEER	62.5 MG	60	30	$ 3,960.48
66215010106	TRACLEER	62.5 MG	60	30	$ 3,960.48
66215010106	TRACLEER	62.5 MG	60	30	$ 4,187.85
66215010106	TRACLEER	62.5 MG	60	30	$ 4,187.85
66215010106	TRACLEER	62.5 MG	60	30	$ 4,187.85
66215010206	TRACLEER	125 MG	60	30	$ 3,960.48
66215010206	TRACLEER	125 MG	60	30	$ 3,960.48
66215010206	TRACLEER	125 MG	60	30	$ 3,960.48
66215010206	TRACLEER	125 MG	60	30	$ 3,960.48
66215010206	TRACLEER	125 MG	60	30	$ 4,187.85
66215010206	TRACLEER	125 MG	60	30	$ 4,187.85

HEALTH INFORMATION DESIGNS

DAW-1 Claims June 2007

Drug	DAW Scripts
Synthroid	8
Tegretol	5
Klonopin	4
Orapred	3
Prozac	3
Coumadin	3
Dexedrine	2
Celexa	2
Climara	2
Ultram	2
Clozaril	2
Cardizem CD	1
Pediapred	1
Xanax	1
Tenex	1
Ritalin	1
Lo-Ovral	1
Adderall	1
Corgard	1
Ortho Tri-Cyclen	1
Mestinon	1
Pred Forte	1
Lithobid	1
Tofranil	1
Zarontin	1
Halcion	1
Lasix	1
Wellbutrin SR	1
Mysoline	1

HEALTH INFORMATION DESIGNS

Prior Authorization Vendor for ND Medicaid

Dispense As Written PA Form

Clear Fields

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

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

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

Part I: TO BE COMPLETED BY 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	**Requested Dosage** (must be completed)	**Diagnosis for the request**

Qualifications for coverage:

☐ Failed generic equivalent	Start Date	End Date	Dose	Frequency
☐ Adverse reaction to generic equivalent (attach FDA Medwatch form) or contraindicated (provide description):				

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

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 STATE USE ONLY

Date Received	CSP MD ☐ Yes ☐ No CSP Pharmacy ☐ Yes ☐ No	Daily Units Bypass Units ☐ Yes ☐ No	Req App	CLM Limit
Approved - Effective dates of PA From: / / To: / /			Approved By	
Denied (Reasons)				

NORTH DAKOTA MEDICAID
RETROSPECTIVE DRUG UTILIZATION REVIEW
CRITERIA RECOMMENDATIONS
4TH QUARTER 2007

Recommendations	*Approved*	*Rejected*

1. Pregabalin / Thiazolidinediones _____ _____

Alert Message: Caution should be exercised when using Lyrica (pregabalin) and a thiazolidinedione (rosiglitazone or pioglitazone) concurrently. Both pregabalin and the thiazolidinediones have been shown to cause weight gain and peripheral edema, possibly exacerbating or leading to congestive heart failure.
Conflict Code: DD – Drug/Drug Interaction
Drugs/Disease:

Util A	Util B	Util C
Pregabalin	Pioglitazone	
	Rosiglitazone	

References:
Facts & Comparisons, 2007 Updates
Micromedex Healthcare Series, DrugDex Drug Evaluations, 2007.
Lyrica Prescribing Information, Nov. 2006, Pfizer Inc.

2. Pregabalin / Heart Failure _____ _____

Alert Message: Lyrica (pregabalin) should be used with caution in patients with New York Heart Association (NYHA) Class III or IV cardiac status. During clinical trials dose-related weight gain and peripheral edema were reported with pregabalin use. These adverse effects may exacerbate heart failure.
Conflict Code: DC – Drug (Actual Disease) Precaution
Drugs/Disease:

Util A	Util B	Util C
Pregabalin	Heart Failure	

References:
Facts & Comparisons, 2007 Updates
Micromedex Healthcare Series, DrugDex Drug Evaluations, 2007.
Lyrica Prescribing Information, Nov. 2006, Pfizer Inc.

3. Pregabalin / High Dose (Diabetic Neuropathy) _____ _____

Alert Message: Lyrica (pregabalin) may be over-utilized. The manufacturer's recommended dose for patients with diabetic peripheral neuropathy is 300 mg per day. Higher doses have not been shown to confer significant additional benefit and are less well tolerated.
Conflict Code: HD – High Dose
Drugs/Disease:

Util A	Util B	Util C (Inclusive)
Pregabalin		Diabetic Peripheral Neuropathy

Max Dose: 300 mg/day
References:
Facts & Comparisons, 2007 Updates
Micromedex Healthcare Series, DrugDex Drug Evaluations, 2007.
Lyrica Prescribing Information, Nov. 2006, Pfizer Inc.

Recommendations	*Approved*	*Rejected*

4. Pregabalin / High Dose (Postherpetic Neuralgia) _____ _____

Alert Message: Lyrica (pregabalin) may be over-utilized. The manufacturer's recommended maximum dose for patients with postherpetic neuralgia is 600 mg per day. In view of the dose-dependent adverse effects and the higher rate of treatment discontinuation caused by adverse reactions, dosing above 300 mg per day should be reserved only for those patients who have ongoing pain and are tolerating 300 mg daily.
Conflict Code: HD – High Dose
Drugs/Disease:

Util A	Util B	Util C (Inclusive)
Pregabalin		Postherpetic Neuralgia

Max Dose: 600 mg/day
References:
Facts & Comparisons, 2007 Updates
Micromedex Healthcare Series, DrugDex Drug Evaluations, 2007.
Lyrica Prescribing Information, Nov. 2006, Pfizer Inc.

5. Pregabalin / High Dose (Partial Onset Seizures) _____ _____

Alert Message: Lyrica (pregabalin) may be over-utilized. The manufacturer's recommended maximum dose for patients with partial onset seizures is 600 mg per day.
Conflict Code: HD – High Dose
Drugs/Disease:

Util A	Util B	Util C (Inclusive)
Pregabalin		Partial Onset Seizures

Max Dose: 600 mg/day
References:
Facts & Comparisons, 2007 Updates
Micromedex Healthcare Series, DrugDex Drug Evaluations, 2007.
Lyrica Prescribing Information, Nov. 2006, Pfizer Inc.

6. Pregabalin / High Dose (Renal Impairment) _____ _____

Alert Message: Lyrica (pregabalin) is primarily renally eliminated and the dose should be adjusted in patients with renal impairment. The maximum recommended dose of pregabalin in patients with a CrCl ≥ 60 mL/min is 600 mg/day while patients with a CrCl of 30 to 60 mL/min should not exceed 300 mg/day. Patients with a CrCl of 15 to 30 mL/min should not exceed 150 mg/day and patients with a CrCl of <15 mL/min should receive a maximum of 75 mg/day.
Conflict Code: HD - High Dose
Drugs/Disease:

Util A	Util B	Util C
Pregabalin		Renal Impairment

Max Dose: 75 mg/day
References:
Facts & Comparisons, 2007 Updates
Micromedex Healthcare Series, DrugDex Drug Evaluations, 2007.
Lyrica Prescribing Information, Nov. 2006, Pfizer Inc.

Recommendations	*Approved*	*Rejected*

7. Antidepressants / Therapeutic Appropriateness _____ _____

Alert Message: All antidepressant-containing medications increase the risk of suicidal thinking and behaviors (suicidality) in children, adolescents, and young adults. Patients being treated with antidepressants for any indication should be monitored appropriately and observed closely for clinical worsening, suicidality, or unusual changes in behavior especially during the initial months of drug therapy, or at times of dose changes.
Conflict Code: TA – Therapeutic Appropriateness
Drug/Diseases

Util A	Util B	Util C
Isocarboxazid		
Phenelzine		
Tranylcypromine		
Imipramine		
Amitriptyline		
Nortriptyline		
Desipramine		
Protriptyline		
Fluvoxamine		
Amoxapine		
Trimipramine		
Doxepin		
Maprotiline		
Trazodone		
Bupropion		
Fluoxetine		
Clomipramine		
Sertraline		
Paroxetine		
Venlafaxine		
Nefazodone		
Citalopram		
Mirtazapine		
Escitalopram		
Duloxetine		

Age Range: 0 – 24 years of age

References:
FDA News: FDA Proposes New Warning About Suicidal Thinking, Behavior in Young Adults Who Take Antidepressant Medications, May 2, 2007. Available at: http://www.fda.gov/bbs/topics/NEWS/2007/NEW01624.html

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:

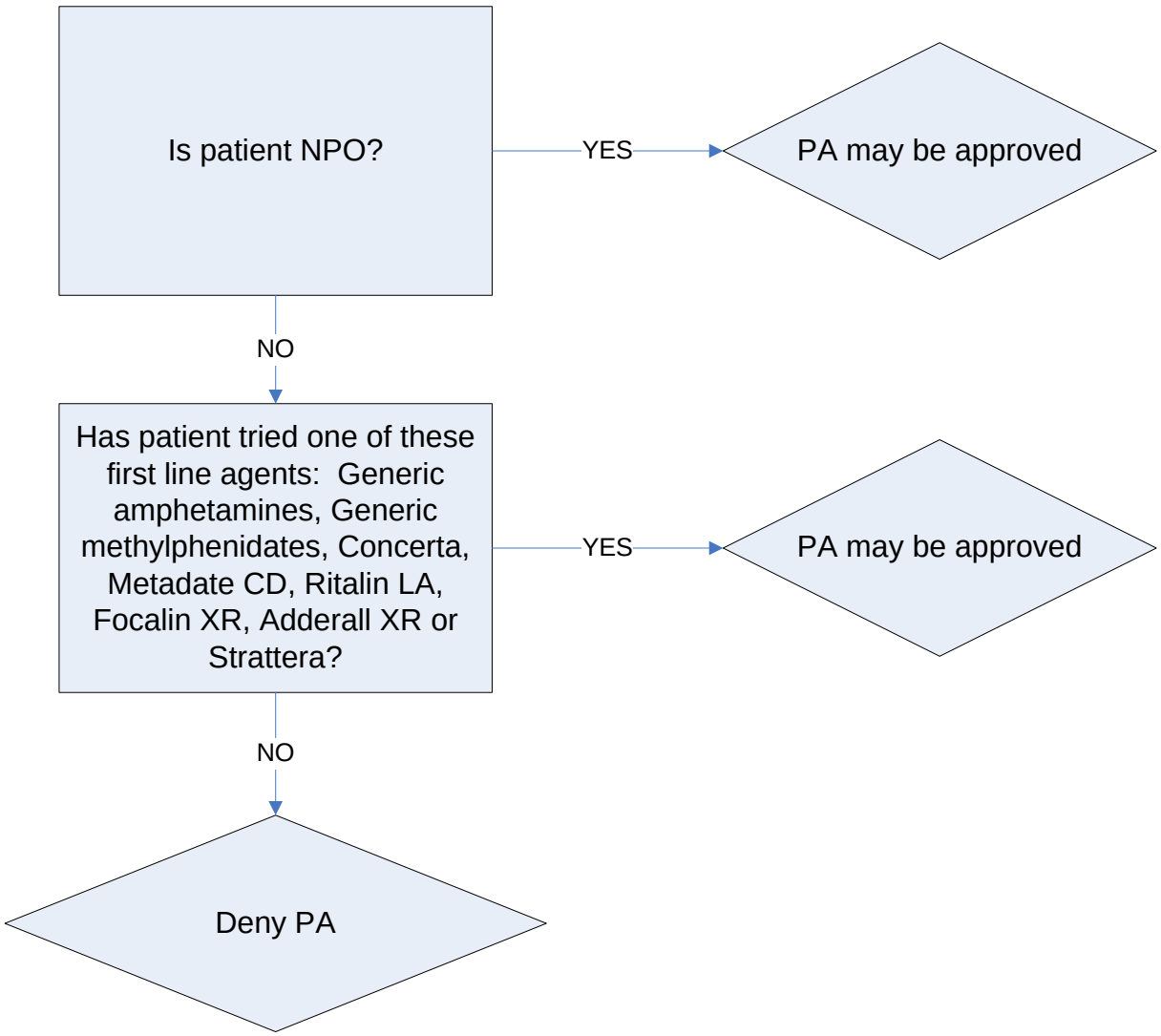
Part II: TO BE COMPLETED BY PHARMACY

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:

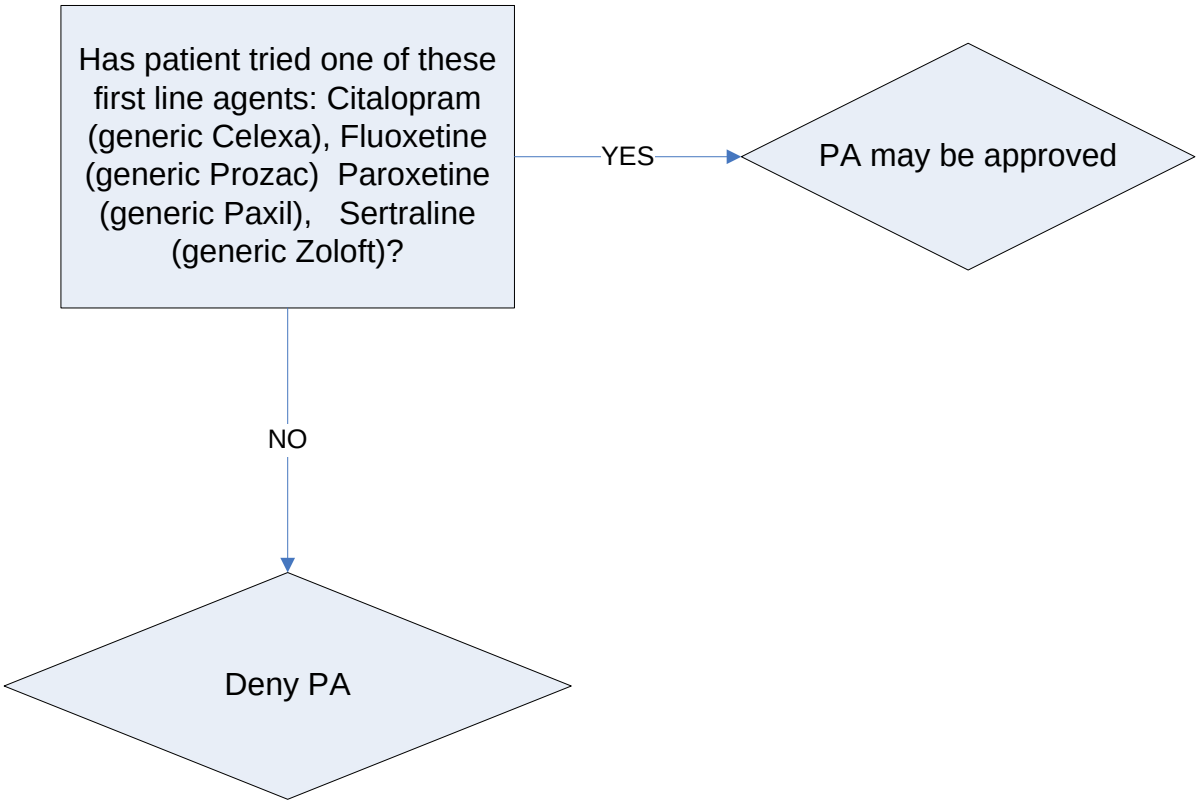
Part II: TO BE COMPLETED BY PHARMACY

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#:

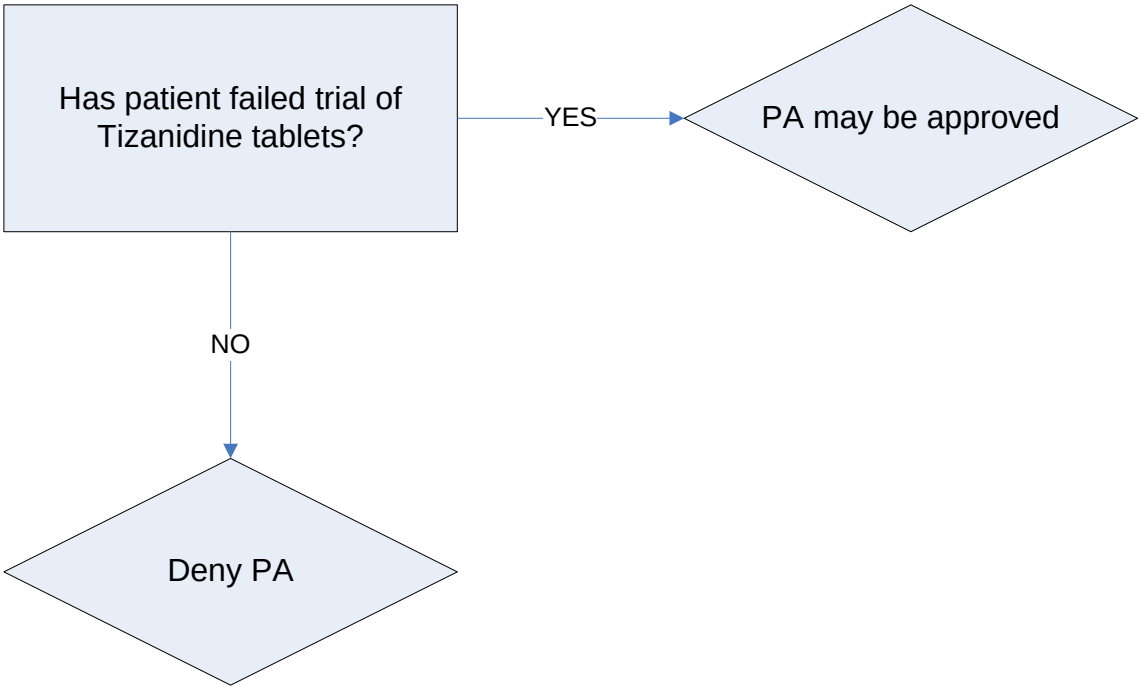
Part III: FOR OFFICIAL USE ONLY

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:

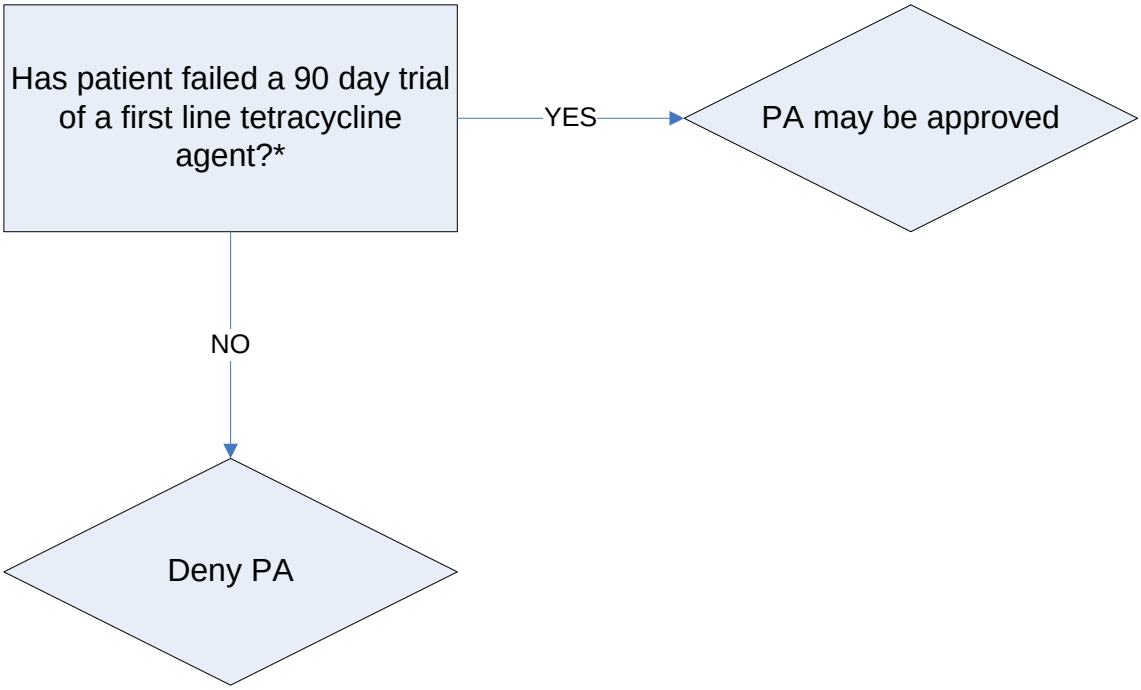
Part II: TO BE COMPLETED BY PHARMACY

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:

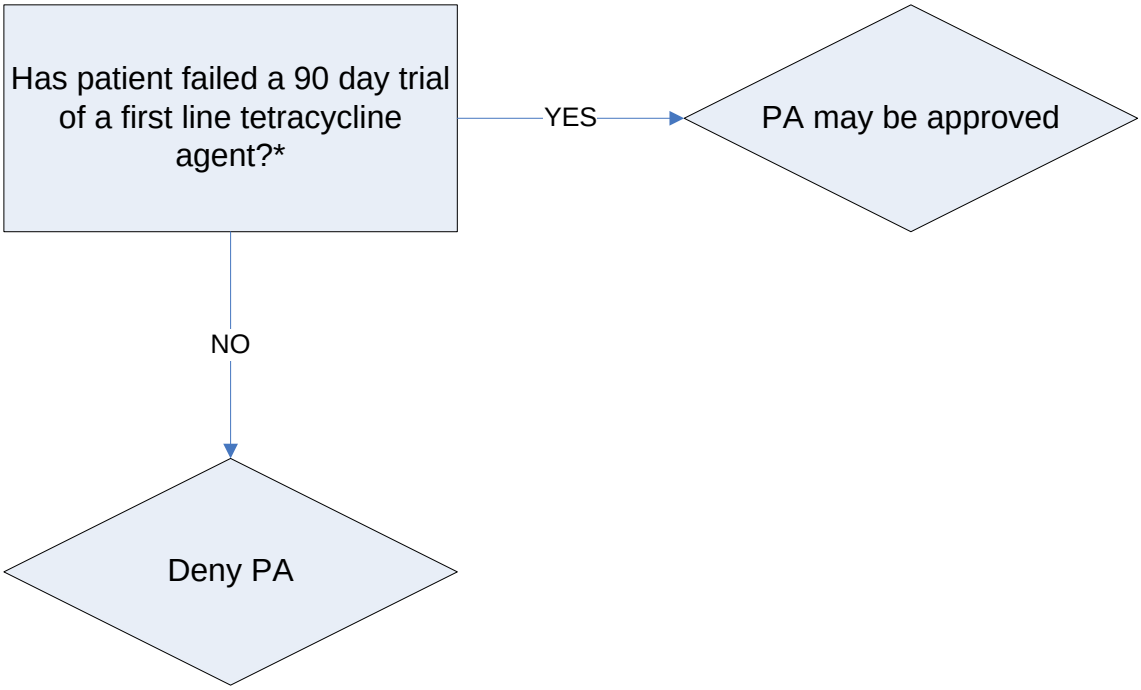
Part II: TO BE COMPLETED BY PHARMACY

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:

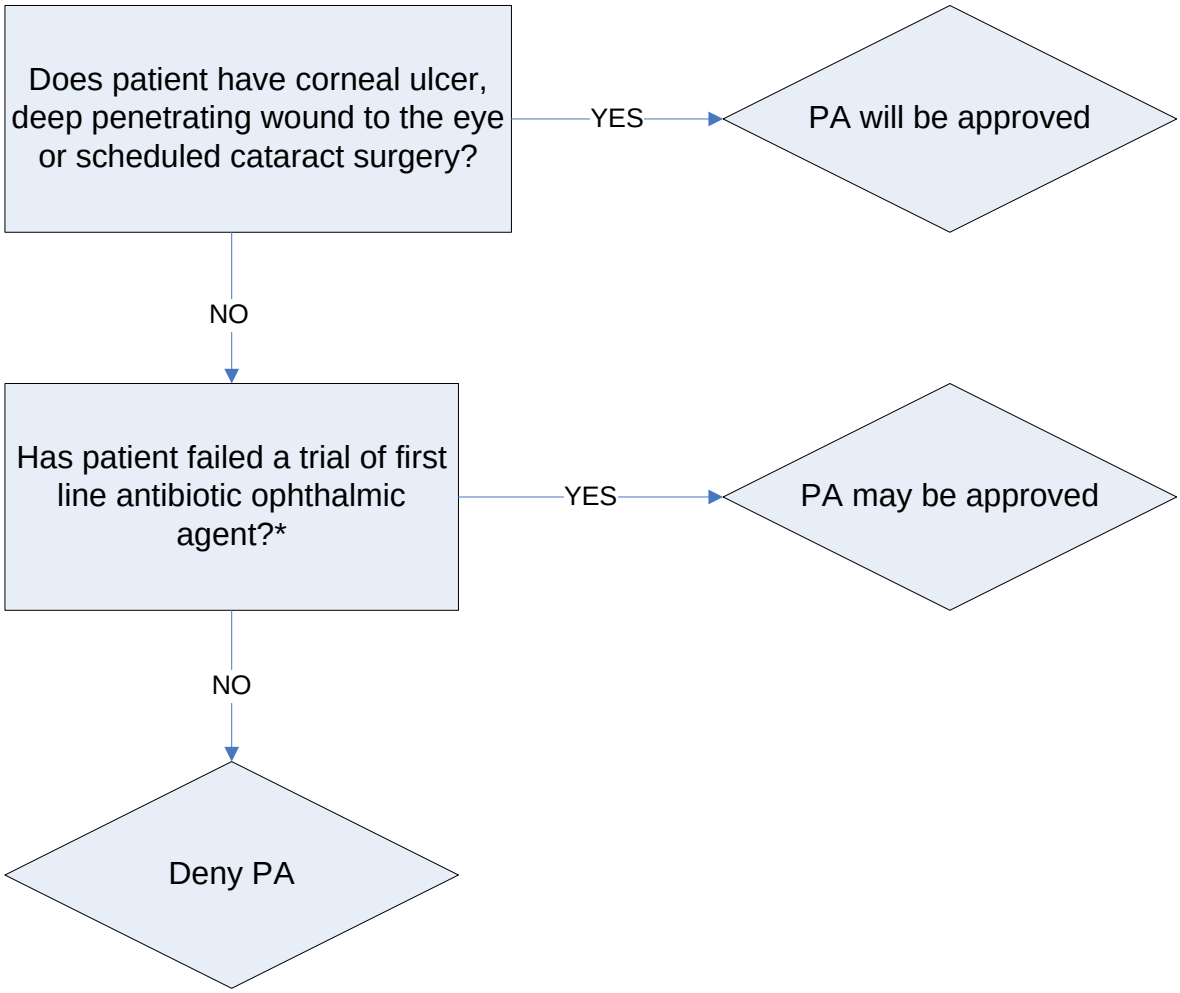
Part II: TO BE COMPLETED BY PHARMACY

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.