June 1st, 2006

The next North Dakota Drug Utilization Review (DUR) Board Meeting will be held August 7th, 2006 at 1:00pm

Pioneer Room
State Capital
612 East Blvd
Bismarck, ND

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

North Dakota Medicaid
DUR Board Meeting
Agenda
Pioneer Room
August 7th, 2006
1pm

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

2. Old Business

• Review and approval of minutes of 05/01/06 meeting	Chairman
• Budget update	Brendan Joyce
• Abilify Mailing	HID

3. New Business

• Review Boniva Injectable	HID
• Review Nasal Steroids	HID
• Review Provigil	HID
• Review Zymar and Vigamox	HID
• Criteria Recommendations	Brendan Joyce
• Upcoming meeting date/agenda November 13th, 2006	Chairman
• Executive Session	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
May 1st, 2006

Members Present: Albert Samuelson, Greg Pfister, John Savageau, Patricia Churchill, Cheryl Huber, Leann Ness, Norman Byers, Scott Setzepfandt, Gary Betting, Bob Treitline, Todd Twogood

Medicaid Pharmacy Department: Brendan Joyce

HID Staff Present: Candace Rieth

Members Absent: Carrie Sorenson

Chair J. Savageau called the meeting to order at 1:03pm. Brendan Joyce introduced the new Board member, Dr. Todd Twogood. J. Savageau asked for a motion to approve the minutes from the February 13th, 2006 meeting. G. Pfister 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 on pre- and post- Part D data. Expenditures in September 2005 were approximately 4.6 million dollars with approximately 22,600 recipients receiving approximately 93,000 prescriptions. With the inception of Part D, March 2006 had expenditures of approximately 2.4 million dollars with approximately 18,062 recipients receiving approximately 47,600 prescriptions.

Review Sedative/Hypnotic Agents
C. Rieth reviewed the Sedative/Hypnotic class of medications. The board approved to place all Sedative/Hypnotic agents, except for Ambien, on prior authorization at the February meeting. This is the 2nd review. The suggested criteria for PA would require a failure of Ambien (Zolpidem) before other single source Sedative/Hypnotics would be covered. There was public comment by Tim Butler, Account and Leadership Development Director for Sepracor. He spoke against the board implementing a prior authorization of Sedative/Hypnotics. Gary Dawson, representing Takeda, reviewed Rozerem related information with the board. Since a motion was made and seconded at the February meeting, a voice vote was taken with one audible dissent, C. Huber. Motion passed.

Review of Growth Hormone and Related Products
C. Rieth reviewed growth hormone and related products. The board made a motion and second in February to place growth hormone products and IGF-1 products on prior authorization, allowing the Department to review each claim for clinical appropriateness. There was no public comment on Growth Hormone and related products. T. Twogood suggested that short stature alone not be covered criteria. T. Twogood made a motion to amend the current growth hormone criteria and remove the statement 'infants born small for gestational age (SGA) who have not caught up in height'. A. Samuelson seconded the motion. A voice vote was taken with no audible dissent. Since a motion was made and seconded at the February meeting to place IGF-1 products on prior authorization, a voice vote was taken with no audible dissent.

Yearly review of Prior Authorization
Legislation requires a yearly review of the status of prior authorization. C. Rieth reviewed 2 classes, ACE-Is and ARBs. Cost avoidance numbers, market share reports, and prior authorization forms and criteria were reviewed. Cost avoidance with the Prior Authorization Program through January 2006 was approximately 3.3 million dollars. C. Huber suggested that the algorithm and PA form on the ACE-I's be edited so that the list of drugs that do not require Prior Authorization match.

SROA Physician Survey:
At the November DUR meeting, the board voted to send SROA letters and surveys to physicians prescribing these opioids on what appeared to be a prn basis. C. Rieth gave the board an update on the mailing. The first week of January, 192 letters were mailed and as of April 30th, 140 surveys were returned. These surveys were reviewed and specific information will be provided in the executive session.

Review of Recommended Criteria:
B. Joyce advised the board that 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. C. Huber moved to approve the new criteria and G. Pfister seconded the motion. The motion was approved by voice vote with no audible dissent

The next DUR board meeting will be August 7th, 2006. Chair, J. Savageau asked the Board for suggested agenda items. Topics that were mentioned included Boniva injectable, Lamisil/Penlac, Nasal Steroids and Skeletal Muscle Relaxants. These topics will be reviewed for inclusion in the August agenda. C. Huber made a motion to adjourn the meeting in to executive session to discuss patient specific health information. P. Churchill seconded. Chair J. Savageau adjourned the meeting in to executive session at 2:20 pm.

Executive Session:
Board members reviewed actual physician responses to the SROA's and discussed the responses. Board members informed the Department representative that this process should be repeated because based on some responses, their prescribing patterns will change.

NDC USAGE for nd-abilify from 01/01/05 to 12/31/05 for Program non-dual

NDC Code	Rx Num	Qty Dispensed	Total Price	Label Name
59148000713	487	12169.5	$109,543.18	ABILIFY 5 MG TABLET
59148000735	1	15	$87.32	ABILIFY 5 MG TABLET
59148000813	682	18943	$173,727.07	ABILIFY 10 MG TABLET
59148000913	540	13948	$126,031.73	ABILIFY 15 MG TABLET
59148001013	330	9346	$117,863.58	ABILIFY 20 MG TABLET
59148001113	218	6634	$85,147.68	ABILIFY 30 MG TABLET
TOTAL	2258	61055.5	$612,400.56	

Totals:

- **Patients 355**
- **Physicians 117**
- **Pharmacies 117**

March Abilify Mailing:

- **Patients 345**
- **Physicians 103**

NORTH DAKOTA DEPARTMENT

Medical Services

John Hoeven, Governor
Carol K. Olson, Executive Director

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

[TODAY]

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

DEAR [tadrs1]:

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

The North Dakota DUR Board requested that Medicaid pharmacy claims be scanned to identify patients receiving Abilify. Abilify is indicated for the treatment of acute manic and mixed episodes associated with bipolar disorder. It is also indicated for the treatment of schizophrenia. Atypical antipsychotic agents are widely prescribed and have dramatically improved the quality of life for many patients. However, in 2005, the state of North Dakota spent close to $700,000 (before rebates) on Abilify prescriptions.

This letter is being sent to the top prescribers of Abilify. We are asking you to assist the North Dakota Medicaid Pharmacy Program in conserving limited resources. Several initiatives can be taken to promote the most cost-effective use of this agent such as:

1. Use of optimal cost effective dosing for this agent (for example, if a patient requires 10mg of Abilify daily, prescribing one 10mg tablet is more cost effective than prescribing two 5mg tablets)
2. Use of tablet splitting can lower the cost per day of Abilify by 40% to 50%.
3. Limit multiple strength prescriptions of Abilify. Prescribing multiple strengths of Abilify can increase costs per prescription by $360 a month.

In presenting this information to you, the Department recognizes that the management of each patient's drug therapy depends upon an assessment of the patient's entire clinical situation about which we are not fully aware. The Department is dedicated to improving the health and well being of our patients. We thank you for your participation in the North Dakota Medicaid Program and hope that you will assist us in making the most effective utilization of our resources as we continue to provide valuable pharmacy benefits to our patients.

Sincerely,

Brendan K. Joyce, PharmD
Administrator, Pharmacy Services
[provid]

DRUG USAGE for nd_boniva from 01/01/05 to 03/28/06 for Program non-dual			
Generic Name	**Rx Num**	**Qty Dispensed**	**Total Price**
Boniva	93	93	$6,129.51
TOTAL	93	93	$6,129.51

Totals:

- **Patients 26**
- **Physicians 26**
- **Pharmacies 23**

BONIVA® INJECTABLE 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

Note: ND Medicaid will not pay for Boniva injectable without documented failure of Boniva tablets.

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:	**Dose:**	**Indication:**	
BONIVA INJECTABLE			
□ *I confirm that I have considered Boniva tablets on this patient and it will not work because_____.*			
Physician Signature:			Date:

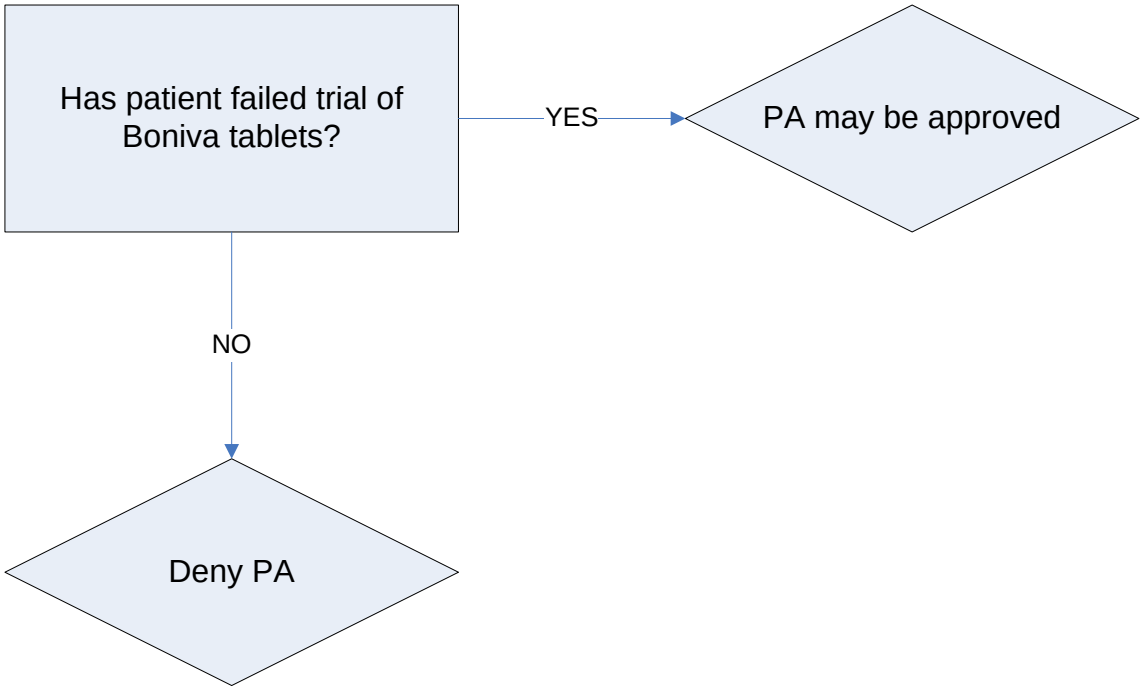
Part II: TO BE COMPLETED BY PHARMACY

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
Boniva Authorization Algorithm



HEALTH INFORMATION DESIGNS

Intranasal Corticosteroid Review

I. Overview

Intranasal corticosteroids are one of the most effective medications used to treat allergic rhinitis. These agents produce direct local anti-inflammatory effects with minimal systemic side effects when used within recommended dosing guidelines. More than 50 million Americans suffer from allergic diseases and allergic rhinitis (AR) is estimated to affect 10 to 30% of adults and up to 40% of children. The common signs and symptoms of AR include runny/itchy nose, sneezing, and congestion. Less common symptoms may include headache, impaired smell and itchy, watery eyes. Although generally thought to be a mildly disturbing malady, allergic rhinitis can actually have a significant impact on the quality of life for both adults and children, resulting in school absenteeism and decreased work productivity. Additionally, untreated or poorly controlled allergic rhinitis can lead to increased prevalence of several comorbidities. These include worsening asthma, sinusitis, otitis media, sleep disorders, and nasal polyps. It is estimated that allergies are the 6th most common chronic illness, costing the United States healthcare system about 18 billion dollars annually.

The pathophysiology of allergic rhinitis involves a complex inflammatory response including both early- and late-phase responses. Within minutes after exposure to an allergen, the early-phase response starts. The allergen interacts with the T- and B-cell lymphocytes and produces IgE antibodies. These antibodies attach to mast cells and basophils so that upon re-exposure to the same allergen, preformed mediators (histamine, leukotrienes, prostaglandin, and bradykinin) will be released. This causes the runny nose, sneezing, itching, and congestion. Several hours later, the late-phase response will occur, whereby the inflammatory cells (eosinophils, neutrophils, macrophages, basophils, and monocytes) migrate, causing a renewal of symptoms, especially nasal secretions and congestion.

Treatment of allergic and non-allergic rhinitis includes trigger avoidance, environmental modification, and pharmacologic therapy. Medication management may target symptom relief or the underlying inflammatory response. Treatment options include oral antihistamines, intranasal corticosteroids, intranasal antihistamines, oral decongestants, oral corticosteroids, intranasal cromolyn sodium, oral anti-leukotriene agents, and intranasal ipratropium bromide. Patients with severe rhinitis may benefit from allergen immunotherapy. As will be discussed, intranasal corticosteroids play a very important role in the management of allergic rhinitis. Table 1, below, lists the intranasal corticosteroids included in this review.

Table 1 Intranasal Corticosteroids Included in this Review

Generic Name	Brand Name
Beclomethasone dipropionate monohydrate	Beconase AQ®
Budesonide	Rhinocort Aqua®
Flunisolide	Nasarel®**
Fluticasone propionate	Flonase®**
Mometasone furoate monohydrate	Nasonex®
Triamcinolone acetonide	Nasacort AQ®

**Available generically.

II. FDA Approved Indications

All of the nasal corticosteroids are approved to treat allergic rhinitis. Table 2 below outlines the specific types of rhinitis and the age guidelines as outlined by the FDA.

Table 2 FDA Approved Indications for the Intranasal Corticosteroids

Generic Name	FDA Approved Indications
Beclomethasone	Seasonal, perennial, and nonallergic rhinitis; Prevention of recurrence of nasal polyps.
Budesonide	Seasonal and perennial rhinitis in patients > 6 years old.
Flunisolide	Seasonal and perennial rhinitis.
Fluticasone	Seasonal, perennial, and nonallergic rhinitis in patients > 4 years old.
Mometasone	Seasonal and perennial rhinitis in patients > 2 years old; May be used as prophylaxis of allergic rhinitis in patients > 12 years old; Treatment of nasal polyps in patients >18 years old.
Triamcinolone	Seasonal and perennial rhinitis in patients > 6 years old.

III. Pharmacology

This class of drugs has potent glucocorticoid activity and weak mineralocorticoid activity. The exact mechanisms of action of these drugs in the nasal mucosa is unknown, however, these drugs have inhibitory actions on many different types of cells (mast cells, eosinophils, neutrophils, macrophages, etc.) and mediators (histamine, leukotrienes, and cytokines) and are thought to work by stopping allergy-mediated inflammation.

IV. Drug Interactions

Concerns regarding drug-drug interactions with the inhaled nasal corticosteroids are limited due to the method of administration and relatively low systemic bioavailability with most of these agents. There is slight potential for absorption into systemic circulation which may occur through absorption in the nasal mucosa as well as through the gastrointestinal tract from swallowing the inhaled drug.

There are no significant drug interactions reported for beclomethasone, flunisolide, mometasone, or triamcinolone. Budesonide and fluticasone are both metabolized in the liver via the CYP3A system, so there is potential for these drugs to interact with other medications. Drugs which inhibit the CYP3A4 system (such as clarithromycin, ketoconazole, itraconazole, erythromycin, cimetidine, and protease inhibitors) inhibit metabolism of the steroid and significantly increase systemic exposure.

All of these medications should be used with caution when used concomitantly with oral corticosteroids. There is concern that increased systemic exposure to the steroids would induce hypercorticism and adrenal suppression.

V. Adverse Effects

The most common side effects of this class of drugs include local effects such as nasal irritation, dryness, and bleeding. Headache, lightheadedness, urticaria, nausea, epistaxis, rebound congestion, bronchial asthma, and insomnia have also been reported, although not commonly. Nasal septal perforations have been reported rarely and patients should be instructed to direct sprays away from the nasal septum during administration.

Localized *Candida albicans* infections of the nose and pharynx have been reported only rarely in users of intranasal steroids. As expected, patients receiving steroid therapy may be more susceptible to infections and these agents should be used with caution in patients with active or quiescent tuberculosis infection; untreated fungal, bacterial, or systemic viral infections; or ocular herpes simplex. Providers should also use with caution in patients with recent nasal septic ulcers, recurrent epistaxis, or nasal trauma or surgery because corticosteroids can slow the wound healing process.

A reduction in growth rate has been reported in controlled clinical trials and in post-marketing experience in pediatric patients receiving intranasal corticosteroids. When children and adolescents receive these medications, or any corticosteroid formulation, their growth rate should be closely monitored and using the lowest effective dose may help to minimize any systemic effects of these agents.

VI. Dosing and Administration

Table 3 below outlines the dosing recommendations for the intranasal corticosteroids included in this review.

Table 3 Dosing and Administration Guidelines of the Intranasal Corticosteroids

Drug	Dosing and Administration		
	Age	Recommended Daily Dose	Maximum Daily Dose
Beclomethasone	≥12 years old	1 or 2 inhalations in each nostril 2 times a day.	2 inhalations in each nostril 2 times a day. *Discontinue in 3 weeks if no improvement.
	6-12 years old	1 inhalation in each nostril 2 times a day.	
Budesonide	≥6 years old	1 spray in each nostril once daily.	**≥12 years old:** 4 sprays in each nostril once daily. **6-11 years old:** 2 sprays in each nostril once daily.
Flunisolide	>14 years old	2 sprays in each nostril 2 times a day.	**≥ 14 years old:** 8 sprays in each nostril daily. **6-13 years old:** 4 sprays in each nostril daily. *Discontinue in 3 weeks if no improvement.
	6-14 years old	1 spray in each nostril 3 times a day ***or*** 2 sprays in each nostril 2 times a day.	
Fluticasone	Adults	2 sprays in each nostril once daily or 1 spray in each nostril 2 times a day.	2 sprays in each nostril once daily. *Once symptoms are adequately controlled, reduce dosage to 1 spray in each nostril daily.
	≥4 years old to adult	1 spray in each nostril once daily.	
Mometasone	≥12 years old	2 sprays in each nostril once daily.	
	2-11 years old	1 spray in each nostril once daily.	
Triamcinolone	≥12 years old	2 sprays in each nostril once daily.	2 sprays in each nostril once daily.
	6-11 years old	1 spray in each nostril once daily.	

References

1. Wolters Kluwer Health, Inc, ed. Drugs Facts & Comparisons. St. Louis, MO. 2005.
2. Dykewicz MS, Fineman S. Diagnosis and Management of Rhinitis: Complete Guidelines of the Joint Task Force on Practice Parameters in Allergy, Asthma, and Immunology. Ann Allergy Asthma Immunol 1998; 81:478-518.
3. National Institute of Allergy and Infectious Diseases/National Institutes of Health. Allergy Statistics. August 2005. Accessed at www.niaid.nih.gov.
4. Storms W. Comorbidities of Allergic Rhinitis and Its Impact on Treatment: Impact of Nasal Steroid Therapy on Rhinitis. Symposia Highlights for the Primary Care Physician. Spring 2003. Accessed at www.cmecorner.com.
5. Bui B, Poulakos M. Management of Allergic Rhinitis. US Pharmacist 2002;27:10. Accessed at www.uspharmacist.com.

DRUG USAGE for nd_nasalsteroid from 01/01/05 to 03/28/06 for Program ndu

Name Brand	Generic Name	Rx Num	Qty Dispensed	Total Price	Market Share
Beconase AQ	BECLOMETHASONE DIPROPIONATE	44	1100	$3,112.64	1.15
Rhinocort Aqua	BUDESONIDE	492	4222.6	$34,446.76	12.85
Nasarel	FLUNISOLIDE	59	1475	$2,587.96	1.54
Flonase	FLUTICASONE PROPIONATE	1615	25906	$106,199.62	42.18
Nasonex	MOMETASONE FUROATE	682	11560	$43,581.70	17.81
Nasacort AQ	TRIAMCINOLONE ACETONIDE	937	15473	$61,190.69	24.47
	TOTAL	3829	59736.6	$251,119.37	

Totals:

- **Patients 1608**
- **Physicians 473**
- **Pharmacies 182**

NASAL STEROID 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

North Dakota Medicaid requires that patients receiving a new prescription for a nasal steroid use these agents as first line:

- **Beconase AQ, Nasacort AQ, Flunisolide, Nasarel, Flonase and Nasonex do not require a PA**
- **Patients must use one of the above listed agents a minimum of 14 days for the trial to be considered a failure. Patient preference does not constitute a failure.**
- **Rhinocort Aqua and Fluticasone will 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: (circle one) **RHINOCORT AQ** **FLUTICASONE**	**Requested Dosage:** (must be completed) **Diagnosis for this request:**

Qualifications for coverage:

❑ Failed 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

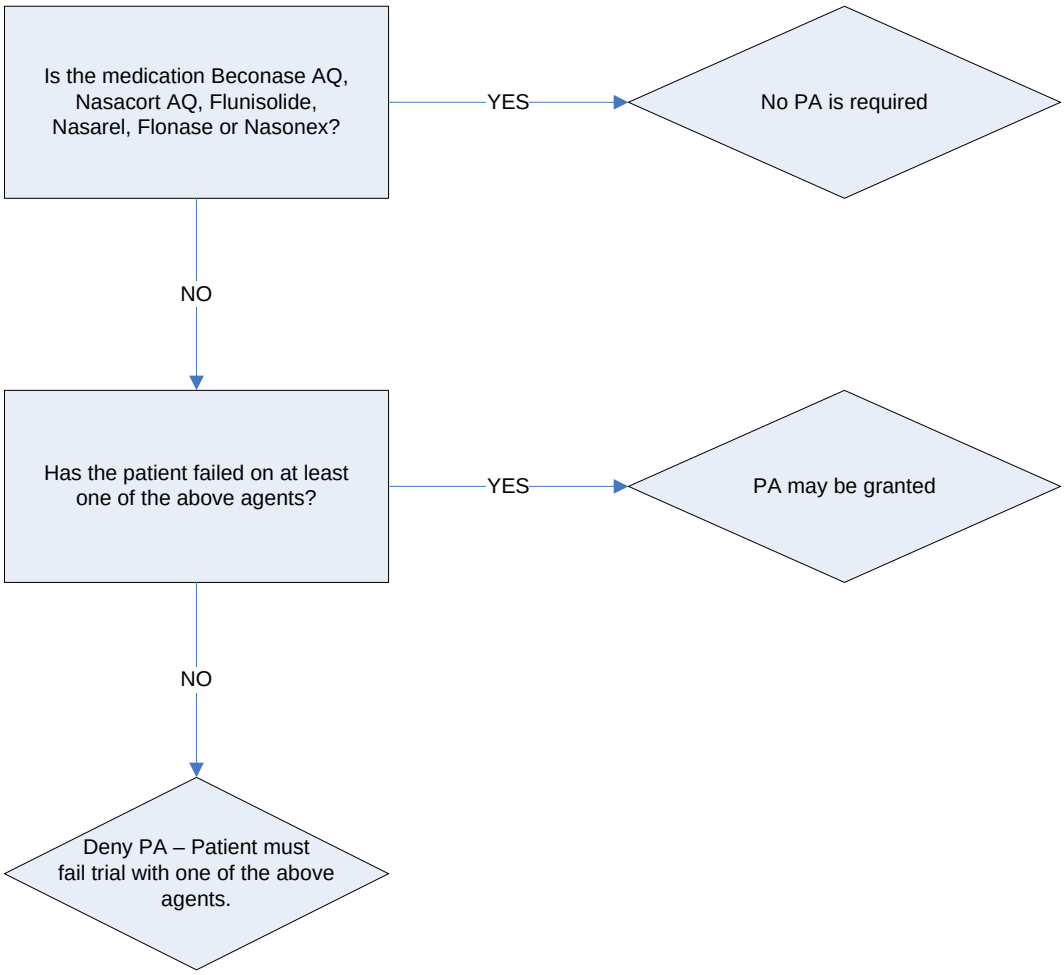
PHARMACY NAME:	ND MEDICAID PROVIDER NUMBER:
Phone:	FAX:
Drug:	NDC#:

Part III: FOR OFFICIAL USE ONLY

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

North Dakota Department of Human Services

Nasal Steroid Prior Authorization Criteria Algorithm

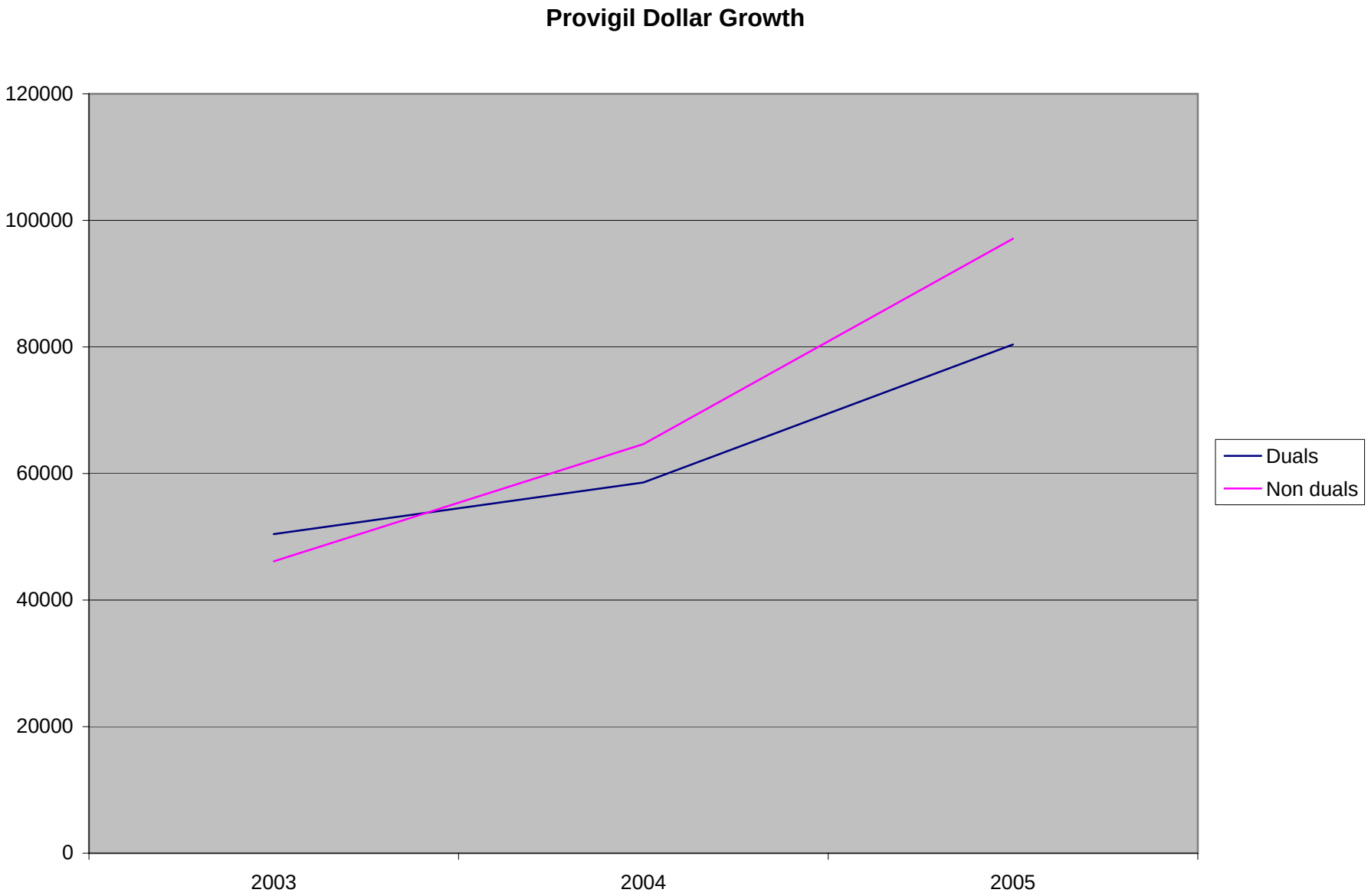


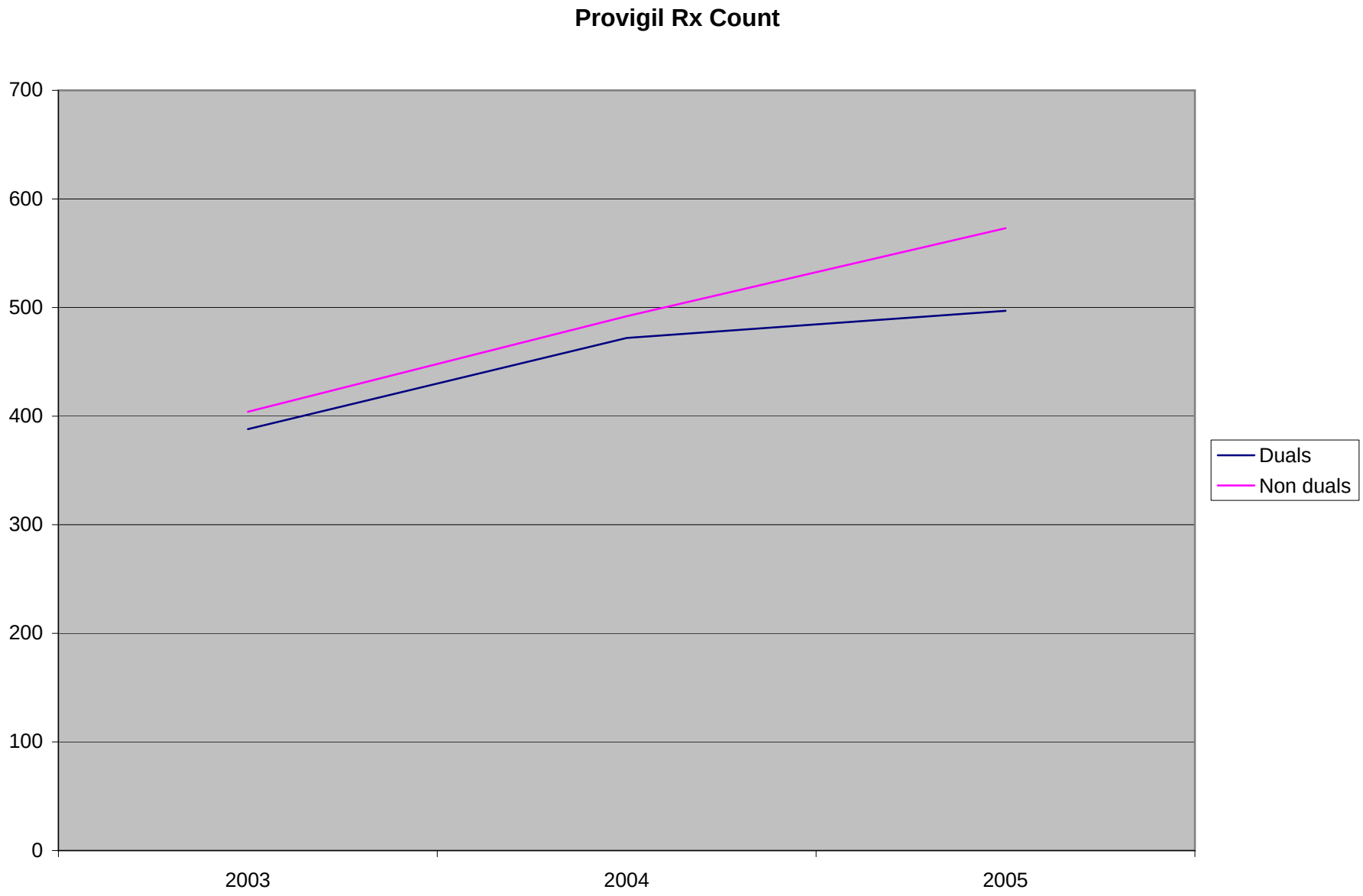
NDC USAGE for nd-provigil from 01/01/06 to 03/28/06 for Program non-dual				
NDC Code	**Rx Num**	**Qty Dispensed**	**Total Price**	**Label Name**
63459010001	0	0	$.00	PROVIGIL 100 MG TABLET
63459010101	24	720	$3,752.83	PROVIGIL 100 MG TABLET
63459020001	1	30	$243.93	PROVIGIL 200 MG TABLET
63459020101	114	3440	$22,080.87	PROVIGIL 200 MG TABLET
TOTAL	139	4190	$26,077.63	

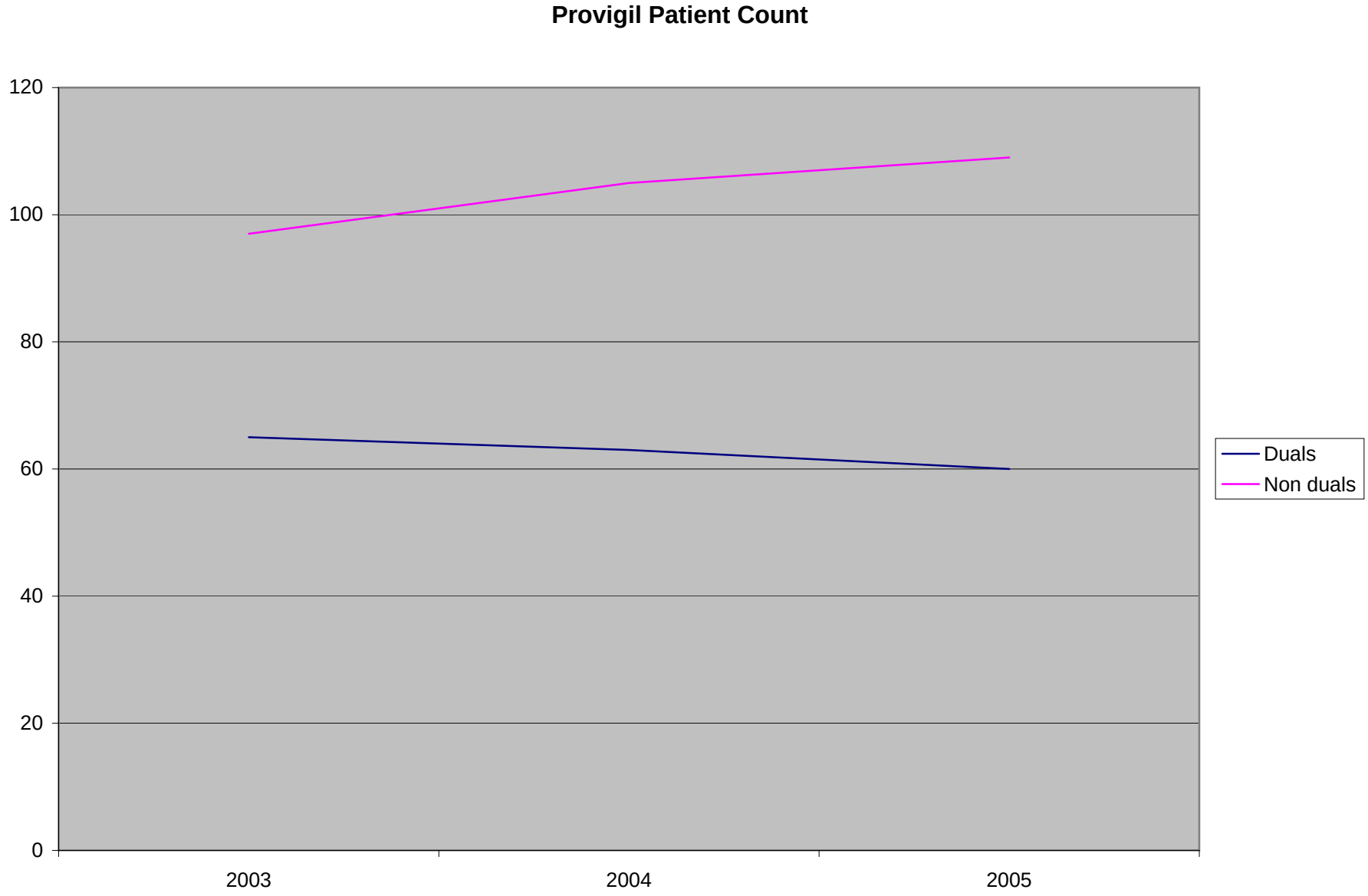
NDC USAGE for nd-provigil from 01/01/03 to 12/31/05 for Program non-dual				
NDC Code	**Rx Num**	**Qty Dispensed**	**Total Price**	**Label Name**
63459010001	146	4407	$15,309.79	PROVIGIL 100 MG TABLET
63459010101	93	2707	$13,323.86	PROVIGIL 100 MG TABLET
63459020001	629	18283	$78,397.15	PROVIGIL 200 MG TABLET
63459020101	601	17671	$100,875.21	PROVIGIL 200 MG TABLET
TOTAL	1469	43068	$207,906.01	

NDC USAGE for nd-provigil from 01/01/03 to 12/31/05 for Program duals				
NDC Code	**Rx Num**	**Qty Dispensed**	**Total Price**	**Label Name**
63459010001	101	2847	$9,863.03	PROVIGIL 100 MG TABLET
63459010101	76	1939	$6,226.81	PROVIGIL 100 MG TABLET
63459020001	667	20243	$88,426.18	PROVIGIL 200 MG TABLET
63459020101	511	14088	$84,643.38	PROVIGIL 200 MG TABLET
TOTAL	1355	39117	$189,159.40	

NDC USAGE for nd-provigil from 01/01/03 to 12/31/05 for Program All				
NDC Code	**Rx Num**	**Qty Dispensed**	**Total Price**	**Label Name**
63459010001	247	7254	$25,172.82	PROVIGIL 100 MG TABLET
63459010101	170	4672	$19,683.97	PROVIGIL 100 MG TABLET
63459020001	1296	38526	$166,823.33	PROVIGIL 200 MG TABLET
63459020101	1113	31774	$185,622.79	PROVIGIL 200 MG TABLET
TOTAL	2826	82226	$397,302.91	


Provigil Dollar Growth
120000
100000
80000
60000
40000
20000
0
2003
2004
2005
Duals
Non duals


Provigil Rx Count
700
600
500
400
300
200
100
0
2003
2004
2005
Duals
Non duals


Provigil Patient Count
120
100
80
60
40
20
0
2003
2004
2005
Duals
Non duals

NORTH DAKOTA DEPARTMENT **Medical Services**

John Hoeven, Governor
Carol K. Olson, Executive Director

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

[TODAY]

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

DEAR [tadrs1]:

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

The North Dakota DUR Board requested that Medicaid pharmacy claims be scanned to identify patients receiving Provigil. Provigil is indicated to improve wakefulness in patients with excessive sleepiness associated with narcolepsy, obstructive sleep apnea/hypopnea syndrome (OSAHS), and shift work sleep disorder (SWSD). When prescribed correctly, Provigil can improve the quality of life for many patients. However, in the past 2 years, the state of North Dakota has spent close to $400,000 (before rebates) on Provigil prescriptions.

You are receiving this notice because Department records indicate a patient(s), in your care, that **appears** to have received a prescription for Provigil. In presenting this information to you, the Department recognizes that the management of each patient's drug therapy depends upon an assessment of the patient's entire clinical situation about which we are not fully aware. Enclosed is a survey to fill out based on your individual treatment plan with each patient(s) listed, asking for the rationale for Provigil use. Please return the survey to the Department in the enclosed envelope within 20 business days. All information received will be used for Department purposes only and will remain confidential.

The Department is dedicated to improving the health and well being of our patients. We thank you for your participation in the North Dakota Medicaid Program and hope that you will assist us in making the most effective utilization of our resources as we continue to provide valuable pharmacy benefits to our patients.

Sincerely,

Brendan K. Joyce, PharmD
Administrator, Pharmacy Services
[provid]

ND DEPARTMENT OF HUMAN SERVICES REQUEST FOR INFORMATION: PROVIGIL

PRESCRIBER RESPONSE:

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

1. This patient was under my care during the time frame identified:
_____ Yes
_____ No (If No, stop here but please return this response.)

2. This patient has a diagnosis of:

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

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

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

Zymar Usage Less than 5 years old

NDC USAGE for nd_zymar from 01/01/05 to 12/31/05 for Program ndu				
NDC Code	**Rx Num**	**Qty Dispensed**	**Total Price**	**Label Name**
00023921805	5	25	$235.07	ZYMAR 0.3% EYE DROPS
TOTAL	5	25	$235.07	

Zymar Usage Age 5-20

NDC USAGE for nd_zymar from 01/01/05 to 12/31/05 for Program ndu				
NDC Code	**Rx Num**	**Qty Dispensed**	**Total Price**	**Label Name**
00023921805	18	90	$863.74	ZYMAR 0.3% EYE DROPS
TOTAL	18	90	$863.74	

Zymar Usage Greater than 20 years old

NDC USAGE for nd_zymar from 01/01/05 to 12/31/05 for Program ndu				
NDC Code	**Rx Num**	**Qty Dispensed**	**Total Price**	**Label Name**
00023921805	64	315	$2,607.88	ZYMAR 0.3% EYE DROPS
TOTAL	64	315	$2,607.88	

Vigamox Usage Less than 5 years old

NDC USAGE for nd_vigamox from 01/01/05 to 12/31/05 for Program ndu				
NDC Code	**Rx Num**	**Qty Dispensed**	**Total Price**	**Label Name**
00065401303	383	1149	$19,295.75	VIGAMOX 0.5% EYE DROPS
TOTAL	383	1149	$19,295.75	

Vigamox Usage Age 5-20

NDC USAGE for nd_vigamox from 01/01/05 to 12/31/05 for Program ndu				
NDC Code	**Rx Num**	**Qty Dispensed**	**Total Price**	**Label Name**
00065401303	242	734	$12,039.20	VIGAMOX 0.5% EYE DROPS
TOTAL	242	734	$12,039.20	

Vigamox Usage Greater than 20 years old

NDC USAGE for nd_vigamox from 01/01/05 to 12/31/05 for Program ndu				
NDC Code	**Rx Num**	**Qty Dispensed**	**Total Price**	**Label Name**
00065401303	130	390	$6,004.28	VIGAMOX 0.5% EYE DROPS
TOTAL	130	390	$6,004.28	

NORTH DAKOTA MEDICAID
DRUG UTILIZATION REVIEW
CRITERIA RECOMMENDATIONS
3RD QUARTER 2006

Criteria Recommendations	*Approved*	*Rejected*

1. Antara / Overutilization _____ _____

Alert Message: Antara (fenofibrate micronized) may be over-utilized. The manufacturer's recommended maximum dose is 130 mg per day.
Conflict Code: HD - High Dose
Drugs/Disease:

Util A	Util B	Util C
Antara		
43mg - gcn 23922		
130mg - gcn 23923		

Maximum Dose: 130 mg/day
References:
Antara Prescribing Information, Oct. 2005, Reliant Pharmaceuticals Inc.
Facts & Comparisons, 2006. Updates.

2. Tricor / Overutilization _____ _____

Alert Message: Tricor (fenofibrate tablets) may be over-utilized. The manufacturer's recommended maximum dose is 145 mg per day.
Conflict Code: HD - High Dose
Drugs/Disease:

Util A	Util B	Util C
Tricor Tablets		
48mg gcn - 23763		
145mg gcn - 23759		

Maximum Dose: 145 mg/day
References:
Tricor Prescribing Information, Nov. 2004, Abbott Laboratories.
Facts & Comparisons, 2006 Updates.

3. Lofibra Tablets / Overutilization _____ _____

Alert Message: Lofibra (fenofibrate tablets) may be over-utilized. The manufacturer's recommended maximum dose is 160 mg per day.
Conflict Code: HD - High Dose
Drugs/Disease:

Util A	Util B	Util C
Lofibra Tablets		
54mg - gcn 13907		
160mg - gcn 13906		

Maximum Dose: 160mg/day

References:
Lofibra Prescribing Information, July 2005, Gate Pharmaceuticals Inc.
Facts & Comparisons, 2006 Updates.

4. Lofibra Capsules / Overutilization _____ _____

Alert Message: Lofibra capsules (micronized fenofibrate) may be over-utilized. The manufacturer's recommended maximum dose is 200 mg per day.
Conflict Code: HD - High Dose
Drugs/Disease:

Util A	Util B	Util C
Lofibra Capsules 67 mg – gcn 93446 134 mg - gcn 92504 200 mg – gcn 93437		

Maximum Dose: 200mg/day

References:
Lofibra Prescribing Information, July 2005, Gate Pharmaceuticals Inc.
Facts & Comparisons, 2006 Updates.

5. Triglide / Overutilization _____ _____

Alert Message: Triglide (fenofibrate) may be over-utilized. The manufacturer's recommended maximum dose is 160 mg per day.
Conflict Code: HD - High Dose
Drugs/Disease:

Util A	Util B	Util C
Triglide 50mg - gcn 24639 160mg - gcn 12595		

Maximum Dose: 160mg/day

References:
Triglide Prescribing Information, Jan. 2005, First Horizon Pharmaceutical Corporation
Facts & Comparisons, 2006 Updates.

6. Ranolazine / High Dose _____ _____

Alert Message: Ranexa (ranolazine) may be over-utilized. The maximum recommended daily dose of ranolazine is 2000 mg (1000 mg b.i.d.). Ranolazine has been shown to prolong the QTc interval in a dose-related manner. Baseline and follow-up ECGs should be obtained to evaluate effects on QT interval.

Conflict Code: HD – High Dose
Severity: Major
Drugs/Disease

Util A	Util B	Util C
Ranolazine		

References:
Ranexa Prescribing Information, Feb. 2006, CV Therapeutics, Inc.

7. Ranolazine / QT Prolongation _____ _____

Alert Message: Ranexa (ranolazine) may have an additive effect on the QT interval and is contraindicated in patients with known QT prolongation (including congenital long QT syndrome, uncorrected hypokalemia), known history of ventricular tachycardia and in patients receiving drugs that prolong the QTc interval (e.g. Class Ia and III antiarrhythmics and antipsychotics).

Conflict Code: DB – Drug-Drug Marker and/or Diagnosis
Severity: Major
Drugs/Disease

Util A	Util B		Util C
Ranolazine	Quinidine	QT Prolongation	Levofloxacin
	Procainamide	Ventricular Arrhythmia	Moxifloxacin
	Disopyramide	Hypokalemia	Gemifloxacin
	Dofetilide	Thioridazine	Norfloxacin
	Sotalol	Ziprasidone	Sparfloxacin
	Amiodarone	Pimozide	Clarithromycin
	Flecainide	Erythromycin	Voriconazole
	Tocainide	Propafenone	
	Mexiletine	Gatifloxacin	

References:
Ranexa Prescribing Information, Feb. 2006, CV Therapeutics, Inc.

8. Ranolazine / Hepatic Impairment _____ _____

Alert Message: Ranexa (ranolazine) is contraindicated in patients with mild, moderate or severe liver disease. Ranolazine is extensively metabolized by the liver, as well as intestine, and hepatic dysfunction may increase the QTc-prolonging effect approximately 3-fold.

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

Util A	Util B	Util C
Ranolazine	Hepatic Impairment	

References:
Ranexa Prescribing Information, Feb. 2006, CV Therapeutics, Inc.

9. Ranolazine / Potent CYP3A4 _____ _____

Alert Message: Ranexa (ranolazine) is contraindicated in patients taking potent or moderately potent CYP3A inhibitors (e.g. diltiazem, azole antifungals, verapamil, macrolides, and protease inhibitors). Ranolazine is primarily metabolized by the CYP3A pathway and inhibition will increase ranolazine plasma levels and QTc prolongation.

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

Util A	Util B			Util C
Ranolazine	Diltiazem	Erythromycin	Indinavir	
	Verapamil	Clarithromycin	Tipranavir	
	Ketoconazole	Azithromycin	Nelfinavir	
	Itraconazole	Dirithromycin	Fosamprenavir	
	Fluconazole	Ritonavir	Amprenavir	
	Voriconazole	Saquinavir	Atazanavir	

References:
Ranexa Prescribing Information, Feb. 2006, CV Therapeutics, Inc.

10. Ranolazine / / Amlodipine, Beta Blockers & Nitrates _____ _____

Alert Message: Ranexa should only be used in combination with amlodipine, beta blockers or nitrates.

Conflict Code: TA Therapeutic Appropriateness
Drugs/Disease

Util A	Util B	Util C (Negating)		
Ranolazine		Amlodipine	Nadolol	Isosorbide Dinitrate
		Atenolol	Propranolol	Isosorbide Mononitrate
		Acebutolol	Penbutolol	
		Bisoprolol	Pindolol	
		Betaxolol	Timolol	
		Metoprolol	Carteolol	

References:
Ranexa Prescribing Information, Feb. 2006, CV Therapeutics, Inc.

11. Ranolazine / Digoxin _____ _____

Alert Message: Concomitant use of Ranexa (ranolazine) and digoxin, a P-glycoprotein (P-gp) substrate, may result in 1.5-fold increase in the digoxin plasma concentrations, Ranolazine is a P-gp inhibitor and the concurrent use of these agents may result in the increased absorption and deceased elimination of digoxin. Dose reduction of digoxin may be necessary.

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

Util A	Util B	Util C
Ranolazine	Digoxin	

References:
Ranexa Prescribing Information, Feb. 2006, CV Therapeutics, Inc.

12. Ranolazine / Renal Impairment _____ _____

Alert Message: The use of Ranexa (ranolazine) should be avoided in patients with severe renal impairment. In six subjects with severe renal impairment receiving ranolazine 500 mg b.i.d. the mean diastolic blood pressure was increased approximately 10 to 15 mmHg. If ranolazine therapy is necessary monitor blood pressure regularly.

Conflict Code: MC – Drug (Actual) Disease Precaution
Drugs/Disease

Util A	Util B	Util C
Ranolazine	Chronic Renal Impairment	

References:
Ranexa Prescribing Information, Feb. 2006, CV Therapeutics, Inc.

Criteria Recommendations	*Approved*	*Rejected*

13. Ranolazine / P-gp Inhibitors _____ _____

Alert Message: Concomitant use of Ranexa (ranolazine) and P-glycoprotein (P-gp) inhibitors (e.g. ritonavir, cyclosporine, erythromycin, and amiodarone) may result in elevated ranolazine plasma concentrations. Ranolazine is a P-gp substrate and inhibition of the efflux pump may result in the increased absorption of ranolazine.

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

Util A	Util B		Util C
Ranolazine	Ritonavir	Diltiazem	Quinidine
	Cyclosporine	Felodipine	Nelfinavir
	Amiodarone	Saquinavir	Sirolimus
	Clarithromycin	Ketoconazole	Tacrolimus
	Cyclosporine	Itraconazole	Verapamil
	Erythromycin	Nicardipine	

References:
Ranexa Prescribing Information, Feb. 2006, CV Therapeutics, Inc.

14. Ranolazine / CYP2D6 Substrates _____ _____

Alert Message: The concomitant use of Ranexa (ranolazine), a CYP2D6 inhibitor, with a CYP2D6 substrate (e.g. tricyclic antidepressants, some antipsychotics) may result in increased plasma concentrations of the CYP2D6 substrate. Dose reduction of the substrate may be necessary.

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

Util A	Util B		Util C
Ranolazine	Amitriptyline	Haloperidol	
	Imipramine	Perphenazine	
	Clomipramine	Risperidone	
	Desipramine	Thioridazine	
	Nortriptyline		
	Venlafaxine		

References:
Ranexa Prescribing Information, Feb. 2006, CV Therapeutics, Inc.

15. Ranolazine / Simvastatin _____ _____

Alert Message: The concomitant use of Ranexa (ranolazine) and Zocor (simvastatin), a P-glycoprotein (P-gp) substrate, may result in a 2-fold increase in plasma concentrations of simvastatin and its active metabolite. Ranolazine is a P-gp inhibitor and the concurrent use of these agents may result in the increased absorption of simvastatin. Dose reduction of simvastatin may be necessary.

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

Util A	Util B	Util C
Ranolazine	Simvastatin	

References:
Ranexa Prescribing Information, Feb. 2006, CV Therapeutics, Inc.