DUR Board Meeting November 13th, 2006 1pm





September 13th, 2006

The next North Dakota Drug Utilization Review (DUR) Board Meeting will be held November 13th, 2006 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 November 13th, 2006 1pm

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- Travel vouchers
- Board Members Sign In

2. Old Business

•	Review and approval of minutes of 08/07/06 meeting	Chairman
•	Budget update	Brendan Joyce
•	Review Boniva Injectable	HID
•	Review Generic Prior Authorization	HID
•	Review Zymar and Vigamox	HID

3. New Business

•	Review Solodyn and Oracea	HID
•	Review Exubera	HID
•	Review Oxycontin	HID
•	Criteria Recommendations	Brendan Joyce
•	Upcoming meeting date/agenda February 5th, 2007	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 August 7th, 2006

Members Present: Albert Samuelson, Greg Pfister, John Savageau, Patricia Churchill, Cheryl Huber, Leann Ness, Norman Byers, Scott Setzepfandt, and Bob Treitline.

Medicaid Pharmacy Department: Brendan Joyce

HID Staff Present: Candace Rieth

Members Absent: Carrie Sorenson, Todd Twogood

Acting chair, Bob Treitline, called the meeting to order at 1:05pm. He asked for a motion to approve the minutes from the May 1st, 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 there was no updated budget information, at this time.

Review Abilify Mailing

C. Rieth reviewed the Abilify mailing that went out in March, 2006. Abilify claims totaled approximately 713,000 dollars in 2005. This was an informational mailing to physicians including initiatives that could be taken to promote cost-effective use of Abilify. Options included optimal dosing, tablet splitting and limited multiple strength prescriptions.

Review of Boniva Injectable

C. Rieth began a review of Boniva injectable. Since the injectable dosage form is given in a physician's office, pharmacy claims will not reflect usage. Scott Setzepfandt, representing Roche, recused himself from the Board discussion. There is concern that Boniva injectable will be used first line, based on feedback from 2 clinics in the area that have been detailed on this product. Appropriate utilization of the injectable dosage form includes patients intolerant to oral bisphosphonates, those with significant pill burden, those who are non-adherent with an oral bisphosphonate, those who have difficulty swallowing and those who do not want to fast prior to taking a bisphosphonate. By placing Boniva injectable on prior authorization, the Department will be able to monitor and assure appropriate utilization. There was public comment by Bryan Yeager, representing Roche. He reviewed Boniva related prescribing information with the Board. A motion was made by B. Treitline to place Boniva injectable on prior authorization. G. Pfister seconded the motion. This topic will be brought up again at the next Board meeting for finalization.

Review of Nasal Steroids

C. Rieth reviewed nasal steroid utilization data. Fluticasone, generic Flonase, became available in March, 2006. Typically, prices for generics are greater for several months after the drug is launched. This is the case with Fluticasone. In the first 4 months that Fluticasone was on the market, the Department paid almost twice as much for the generic version compared to the name brand product. The Department would like the authority to prior authorize generic versions when they are much more expensive than the brand alternatives. It was also noted that Rhinocort Aqua was twice as expensive as the other choices in the nasal steroid class. There was public comment by Loren Grad, representing Astra Zeneca. He stated that a box of Rhinocort Aqua should last 2 months instead of 1 month; therefore the price difference should not be a factor. He suggested

limiting 1 box for a 2 month supply. This can be handled through quantity limits, eliminating the need for a prior authorization on Rhinocort Aqua, at this time. The Board began discussion regarding generic versions of medications and allowing the Department to prior authorize these products based on net cost. B. Joyce stated that a new form could be developed that would be specific for pharmacy, taking the burden of this authorization away from physicians, since it is a pharmacy issue. B. Treitline also suggested an attachment letter be developed for pharmacies, explaining the purpose of this decision. C. Huber made a motion to allow the Department to prior authorize generic medications as needed, based on net cost. G. Pfister seconded the motion. This topic will be discussed at the next Board meeting for finalization.

Provigil Mailing

C. Rieth reviewed utilization data of Provigil. A letter was developed for physicians that will cover the issue of increased utilization over the last several years of this medication. Each physician will receive a list of patients taking this medication along with a survey form to return to the Department. The Board suggested several changes to the letter, but authorized the mailing after changes are made.

Review of Zymar and Vigamox

C. Rieth reviewed utilization data of Vigamox and Zymar. A suggestion was made to prior authorize these two medications considering the availability of less expensive, therapeutic alternatives. C. Huber asked for a broader fluoroquinolone ophthalmic review. N. Byers made a motion to prior authorize Vigamox and Zymar. P. Churchill seconded the motion. This topic will be discussed at the next Board meeting for finalization.

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. P. Churchill moved to approve the new criteria and B. Treitline seconded the motion. The motion was approved by voice vote with no audible dissent

The next DUR board meeting will be November 13th, 2006. 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 at 2:45 pm.



DRUG USAGE for nd_boniva from 01/01/06 to 06/26/06 for Program						
Generic Name	Rx Num	Qty Dispensed	Total Price			
<u>Boniva</u>	72	72	\$5,023.05			
TOTAL	72	72	\$5,023.05			

Totals:

- Patients 29
- Physicians 23
- Pharmacies 27

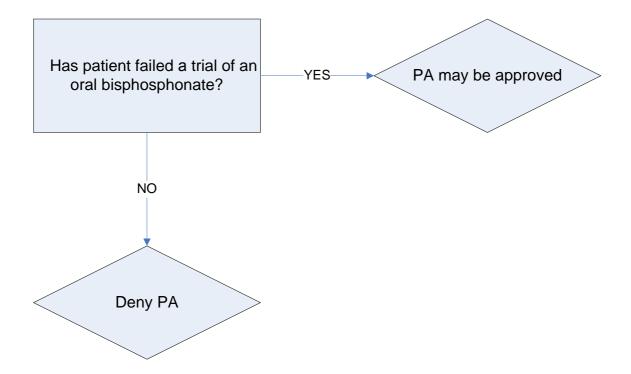


Note: ND Medicaid will not pay for Boniva injectable without documented failure of an oral bisphosphonate.

Part I: TO BE COMPLETED BY PHYSICIAN

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REQUESTED DRUG:	Dose:	Indication:		
BONIVA INJECTABLE				
□ I confirm that I have cons	ı idered an oral bisphosp	honate on thi	s patient and it will not wo	ork because
			<u>,</u>	
Physician Signature:				Date:
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Phone: () -			FAX: () -	
Drug:		NDC#:		
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Effective dates of PA: From:	1		To: /	/
Denied: (Reasons)				

North Dakota Department of Human Services Boniva Authorization Algorithm







Dear Pharmacists,

In an effort to control rapid growth in Medicaid spending, the state of North Dakota is taking a proactive step to save money. One way to accomplish this is to implement a brand mandate on certain medications when a generic is more expensive than the brand name product. One example of this is when a generic first enters the market. It is easy to assume that having a generic available would ultimately save the Department money. This is not always the case. Prices to North Dakota Medicaid for generics are occasionally greater in the first 6 months of inception than the price for the name brand products.

Attached you will find a prior authorization form for pharmacies to fill out and process through normal prior authorization channels. No physician signature will be required. This form will be used for generic products that the Department deems **NOT** to be cost effective. We hope that you will help us with this endeavor.

Sincerely,

Brendan Joyce



- North Dakota Medicaid requires a prior authorization on certain generic medications when the generic does not result
 in a cost savings. This name brand mandate will be implemented by the Department until the generic medication
 reflects a cost savings to the State.
- When generic medication is required, this form will need to be filled out by the client's pharmacy and will be processed through the existing Prior Authorization program.
- This form does not require a physician's signature.

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Denied: (Reasons)			

Bacterial Conjunctivitis

Mild bacterial conjunctivitis may be self-limited and resolve spontaneously without specific treatment in immune-competent patients. The duration, recurrence rate, and morbidity associated with most common types of bacterial conjunctivitis may be decreased with topical antibacterial therapy and the choice of antibiotic is usually empirical. Since a 5-to-7 day course of a broad-spectrum topical antibiotic is usually effective, the least expensive option can be selected.¹

Fluoroquinolone Ophthalmics Included in this Review

= 1 I I			
Generic Name	Brand Name		
Levofloxacin	Quixin®		
Ofloxacin	Ocuflox®		
Moxifloxacin	Vigamox®		
Gatifloxacin	Zymar®		
Ciprofloxacin	Ciloxan®		

FDA Approved Indications²

Levofloxacin solution is indicated for the treatment of bacterial conjunctivitis caused by susceptible strains of the following organisms:

Aerobic gram-positive microorganisms:

Corynebacterium species (Efficacy for this organism was studied in fewer than 10 infections.)

Staphylococcus aureus (methicillin-susceptible strains only)

Staphylococcus epidermidis (methicillin-susceptible strains only)

Streptococcus pneumoniae

Streptococcus (groups C/F)

Streptococcus (group G)

Viridans group streptococci

Aerobic gram-negative microorganisms:

Acinetobacter lwoffii

Haemophilus influenzae

Serratia marcescens

Ofloxacin solution is indicated for the treatment of infections caused by susceptible strains of the following bacteria in the conditions listed below:

Conjunctivitis:

Gram-positive bacteria:

Staphylococcus aureus

Staphylococcus epidermidis

Streptococcus pneumoniae

Gram-negative bacteria:

Enterobacter cloacae

Haemophilus influenzae

Proteus mirabilis

Pseudomonas aeruginosa

Corneal ulcers:

Gram-positive bacteria:

Staphylococcus aureus

Staphylococcus epidermidis

Streptococcus pneumoniae

Gram-negative bacteria:

Pseudomonas aeruginosa

Serratia marcescens (efficacy for this organism was studied in fewer than 10 infections)

Anaerobic species:

Propionibacterium acnes

Moxifloxacin hydrochloride ophthalmic solution is indicated for the treatment of bacterial conjunctivitis caused by susceptible strains of the following organisms: Aerobic gram-positive microorganisms:

Corynebacterium species1

Micrococcus luteus

Staphylococcus aureus

Staphylococcus epidermidis

Staphylococcus haemolyticus

Staphylococcus hominis

Staphylococcus warneri

Streptococcus pneumoniae

Streptococcus viridans group

Aerobic gram-negative microorganisms:

Acinetobacter lwoffii

Haemophilus influenzae

Haemophilus parainfluenzae

Other microorganisms:

Chlamydia trachomatis

Gatifloxacin is indicated for the treatment of bacterial conjunctivitis caused by susceptible strains of the following organisms listed below:

Gram positive bacteria:

Cornyebacterium propinquum1

Staphylococcus aureus

S. epidermidis

Streptococcus mitis

S. pneumoniae

Gram negative bacteria:

Haemophilus influenzae

Ciprofloxacin ophthalmic solution is indicated for the treatment of infections caused by susceptible strains of the designated microorganisms in the conditions listed below:

Corneal ulcers:

Pseudomonas aeruginosa

Serratia marcescens (efficacy for this organism was studied in fewer than 10 infections)

Staphylococcus aureus

Staphylococcus epidermidis

Streptococcus pneumoniae

Streptococcus (viridans group) (efficacy for this organism was studied in fewer than 10 infections)

Conjunctivitis:

Haemophilus influenzae

Staphylococcus aureus

Staphylococcus epidermidis

Streptococcus pneumoniae

¹ American Academy of Ophthalmology Cornea/External Disease Panel, Preferred Practice Patterns Committee. Conjunctivitis. San Francisco (CA): American Academy of Ophthalmology (AAO); 2003. 25 p. [67 references]
 Drug Facts and Comparisons, Folio Views, April 2005.

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DRUG USAGE for nd_quinolone_opth from 01/01/06 to 06/26/06 for Program			
Name	Rx Num	Qty Dispensed	Total Price
CIPROFLOXACIN HCL (CILOXAN)	169	751	\$5,139.59
GATIFLOXACIN (ZYMAR)	65	325	\$3,516.24
LEVOFLOXACIN (QUIXIN)	1	5	\$55.45
MOXIFLOXACIN HCL (VIGAMOX)	411	1239	\$20,954.30
OFLOXACIN (OCUFLOX)	10	55	\$378.09
TOTAL	656	2375	\$30,043.67

DRUG USAGE for nd_quinolone_opth from 01/01/06 to 06/26/06 for Program Age 5-20			
Name	Rx Num	Qty Dispensed	Total Price
CIPROFLOXACIN HCL (CILOXAN)	37	194	\$995.21
GATIFLOXACIN (ZYMAR)	11	55	\$570.05
LEVOFLOXACIN (QUIXIN)	1	5	\$55.45
MOXIFLOXACIN HCL (VIGAMOX)	119	357	\$6,051.29
OFLOXACIN (OCUFLOX)	2	10	\$74.46
TOTAL	170	621	\$7,746.46

DRUG USAGE for nd_quinolone_opth from $01/01/06$ to $06/26/06$ for Program Age > 20			
Name	Rx Num	Qty Dispensed	Total Price
CIPROFLOXACIN HCL (CILOXAN)	36	159.5	\$888.85
GATIFLOXACIN (ZYMAR)	54	270	\$2,946.19
LEVOFLOXACIN (QUIXIN)	0	0	0
MOXIFLOXACIN HCL (VIGAMOX)	66	201	\$3,434.60
OFLOXACIN (OCUFLOX)	2	15	\$95.46
TOTAL	158	645.50	\$7,365.10



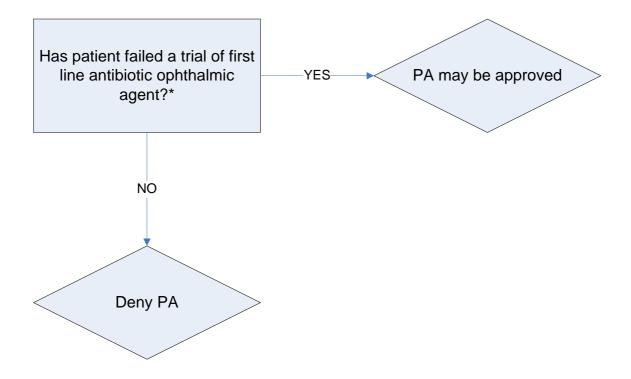
Note: ND Medicaid will not pay for Zymar or Vigamox without documented failure of a first line antibiotic ophthalmic agent.

• 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.).

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L Zymai		
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North Dakota Department of Human Services Zymar/Vigamox Authorization Algorithm



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



Patients with doxycycline, minocycline or tetracycline prescription

DRUG USAGE for nd_acne from 01/01/05 to 06/26/06 for Program				
Generic Name	Rx Num	Qty Dispensed	Total Price	
DOXYCYCLINE HYCLATE	3029	78902	\$24,551.46	
MINOCYCLINE HCL	1809	84507	\$74,992.36	
TETRACYCLINE HCL	1303	66722	\$12,320.86	
TOTAL	6141	230131	\$111,864.68	

Patients with doxycycline, minocycline or tetracycline prescription and a diagnosis of acne

DRUG USAGE for nd_acne from 01/01/05 to 06/26/06 for Program				
Generic Name	Qty Dispensed	Total Price		
DOXYCYCLINE HYCLATE	534	19962	\$5,117.66	
MINOCYCLINE HCL	987	47834	\$43,824.12	
TETRACYCLINE HCL	444	23720	\$4,343.32	
TOTAL	1965	91516	\$53,285.10	

Review of Solodyn and Oracea¹

The tetracyclines (e.g., tetracycline, doxycycline, minocycline) have been a mainstay of therapy for moderate to severe acne and persistent acne. Tetracyclines are also used in the treatment of rosacea. In May 2006, two new extended-release formulations of tetracyclines were approved by the FDA: *Solodyn* (minocycline) Extended-Release Tablets and *Oracea* (doxycycline) Capsules.

Solodyn

Solodyn is an extended-release formulation of minocycline (Medicis Pharmaceutical) approved for the treatment of inflammatory lesions of non-nodular moderate to severe acne in patients aged 12 years and older. It is not bioequvalent to or interchangeable with any other minocycline products. Solodyn has not been evaluated in the treatment of infections. The cost of Solodyn is about five to six times more expensive than generic minocycline. The cost for Solodyn is \$14.76 per tablet for all strengths (about \$500/month). The cost of generic minocycline is about \$1.05 per 100mg capsule (about \$70/month).

Oracea

Oracea 40 mg is a unique capsule formulation of doxycycline containing a combination of immediate- (30 mg) and delayed-release beads (10 mg). Oracea is dosed once daily and is approved for the treatment of inflammatory lesions (papules and pustules) of rosacea in adult patients. It is not bioequivalent to or interchangeable with any other doxycycline products and has not been studied for the treatment of infections. Oracea will cost about \$150/month (\$4.44 per capsule). The cost of generic doxycycline is about 10 cents per tablet (about \$4/month).

Conclusion

In addition to antibacterial effects, tetracyclines' anti-inflammatory effects are believed to play a role in the management of acne and rosacea. The new extended-release tetracycline formulations (*Oracea* and *Solodyn*) have been shown to be effective treatments for rosacea and acne, respectively. Theoretically, *Oracea* is less likely to induce antibiotic resistance than standard doses of doxycycline. *Solodyn* is significantly more expensive than generic minocycline and *Oracea* is more expensive than generic doxycycline. At this time, there is no evidence that *Solodyn* or *Oracea* are superior to their generic counterparts for treating acne or rosacea, respectively. For patients with acne or rosacea who may benefit from antibiotic treatment, generic doxycycline or minocycline are less expensive options. For patients with rosacea who require long-term antibiotic treatment, the low-dose doxycycline formulation, *Oracea*, may be considered to potentially decrease the risk of antibiotic resistance.

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¹ Pharmacist's Letter, 2006; 22(7):220709.



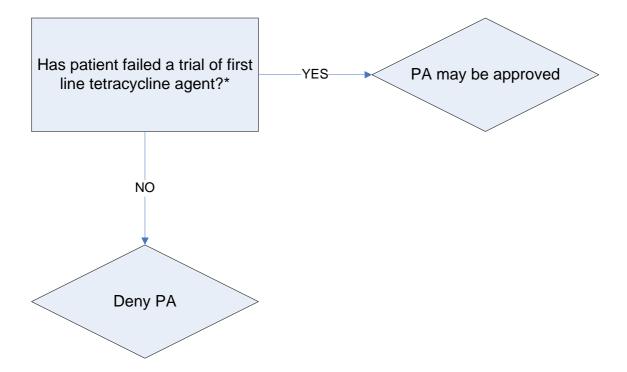
Note: ND Medicaid will not pay for Solodyn or Oracea without documented failure of a first line tetracycline agent.

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

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□ Oracea		
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North Dakota Department of Human Services Solodyn/Oracea Authorization Algorithm



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

Insulin human inhalation powder (Exubera®) Review

Inhaled insulin is a dry powder short acting recombinant regular insulin product indicated for the treatment of diabetes mellitus in adults.

Pharmacokinetics

- Absorbed as quickly as fast-acting insulin analogs
- Average time to peak 49 minutes (range 30-90 minutes)
- Absorption of inhaled insulin is independent of body mass (unlike SC regular insulin)
- Cmax and AUC of three 1mg blisters are 30% and 40% greater than one 3mg blister
- Onset of effect 10-20 minutes, maximum effect at 2 hours, duration of effect 6 hours
- No differences in pharmacokinetics seen based on gender, advanced age, race, obesity or pregnancy; children and adolescents faster time to peak; smokers 2-5 times as much system exposure; asthma (20% lower exposure); COPD (twofold increase in systemic exposure)
- Drug interactions: bronchodilators (enhanced insulin absorption by 25-50%), agents that are associated with hyper- or hypoglycemia may have diminished or enhanced effects respectively; sympatholytic agents (e.g. beta blockers, clonidine)-hypoglycemia symptoms may be diminished

Adverse Effects

- Contraindicated in patients who have smoked in the past six months and patients with poorly controlled lung disease
- Decline in FEV1 = 20%
- Decline in DLco = 20%
- Hypoglycemia
- Chest pain
- Dry mouth
- Cough
- Pharyngitis

Cost of inhaled insulin could be 3-4 times higher than conventional injectable insulin. Because there are some good, lower-cost, branded and generic drugs for the treatment of diabetes, placing this medication on prior authorization ensures this expensive medication is only used in the small percentage of patients who do not respond to other proven therapies.



North Dakota Medicaid requires that patients receiving a new prescription for Exubera meet these guidelines for coverage:

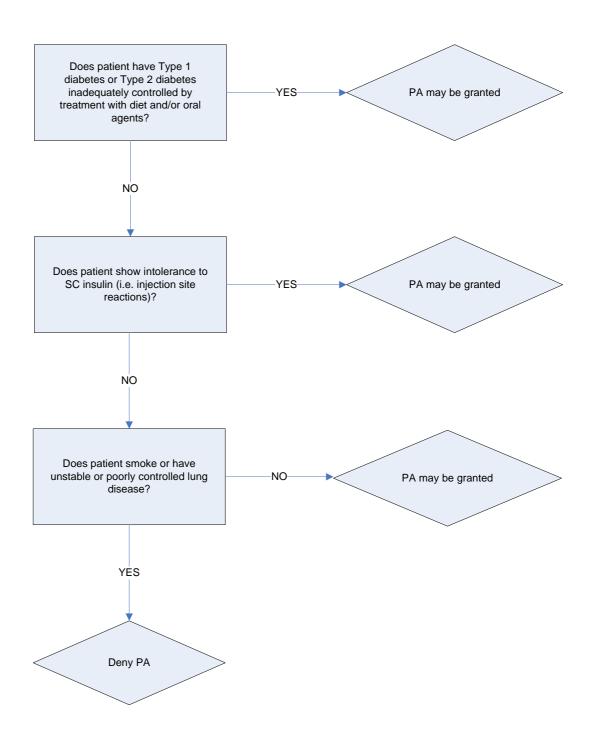
- Patient has Type 1 diabetes, or Type 2 diabetes inadequately controlled by treatment with diet and/or oral agents.
- Patient has intolerance to SC insulin (i.e. injection site reactions).
- Patient is a non-smoker with good lung function.

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Part I: TO BE COMPLETED BY PHYSICIAN				
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□ Exubera				
	Diagnosis for th	is request:		
Qualifications for coverage:				
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a railed therapy with diet and oral agents	End Date:	Frequency:		
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Denied: (Reasons)				

North Dakota Department of Human Services

Exubera Prior Authorization Criteria Algorithm





Oxycontin Utilization

2005	Label Name	Rx Num	Qty Dispensed	Total Price	Patients	Qty/RX
January	OXYCODONE HCL	147	9163	\$29,862.94	96	62
February	OXYCODONE HCL	136	7944	\$26,096.09	93	58
March	OXYCODONE HCL	152	8571	\$30,113.26	102	56
April	OXYCODONE HCL	145	7814	\$26,147.52	95	54
May	OXYCODONE HCL	153	8539	\$29,973.45	96	56
June	OXYCODONE HCL	161	8833	\$29,111.51	107	55
July	OXYCODONE HCL	153	9344	\$30,535.42	104	61
August	OXYCODONE HCL	146	8212	\$29,065.15	97	56
September	OXYCODONE HCL	146	8798	\$29,772.86	95	60
October	OXYCODONE HCL	131	7811	\$27,216.53	96	60
November	OXYCODONE HCL	128	7936	\$26,282.22	92	62
December	OXYCODONE HCL	135	8209	\$27,396.82	89	61
2006	Label Name	Rx Num	Qty Dispensed	Total Price	Patients	Qty/RX
January	OXYCODONE HCL	127	8618	\$29,088.01	85	68
February	OXYCODONE HCL	114	7209	\$18,029.02	83	63
March	OXYCODONE HCL	119	7014	\$15,880.06	83	59
April	OXYCODONE HCL	121	6714	\$16,109.55	86	55
May	OXYCODONE HCL	143	7614	\$17,778.20	91	53
June	OXYCODONE HCL	126	7408	\$18,875.05	78	59
July	OXYCODONE HCL	109	6442	\$15,263.26	78	59
August	OXYCODONE HCL	101	6121	\$13,877.54	78	61

Since Oxycontin became available generically, the number of patients, tablets and scripts each has decreased. Since July 2005, patients obtaining a prescription for Oxycontin decreased 25%, the quantity of scripts decreased 34%, and the quantity of pills dispensed decreased 34.5%. This might indicate that obtaining the generic, in some cases, may not be as appealing as obtaining the branded product.

In light of recent court rulings stating that the generic product will become unavailable, the Department would like to implement a prior authorization status for Oxycontin. This would ensure appropriate utilization of this medication and avoid questionable brand utilization increases.

NORTH DAKOTA MEDICAID DRUG UTILIZATION REVIEW CRITERIA RECOMMENDATIONS 4th QUARTER 2006

Criteria Recommendations Approved Rejected 1. Triptans / SSRIs & SNRIs Alert Message: Coadministration of triptans and SSRIs or SNRIs should be done with caution. Concomitant use may increase the risk of serotonin syndrome. Prescribers are advised to weigh the potential risk of serotonin syndrome with the expected benefit of using the drugs in combination. Conflict Code: DD - Drug/Drug Interaction Drugs/Disease: Util A Util B Util C Naratriptan Fluvoxamine Almotriptan Fluoxetine Frovatriptan Sertraline Sumatriptan Paroxetine Zolmitriptan Venlafaxine Rizatriptan Duloxetine Eletriptan Escitalopram Citalopram References: MedWatch - The Safety Information and Adverse Event Reporting Program, 2006. *Deleting #1147 which only included SSRIs/Triptans. The MedWatch Warning includes SSRIs & SNRIs. 2. Combunox / Duration Alert Message: Combunox (oxycodone/ibuprofen) may be over-utilized. This medication is indicated for short-term (no more than 7 days) management of acute moderate to severe pain. Conflict Code: Drugs/Disease: Util A Ŭtil B Util C Combunox Duration: 8 days or more References: Facts & Comparisons, 2006 Updates. Micromedex Healthcare Series, Drugdex Drug Evaluations, 2006. Combunox Prescribing Information, March 2006, Forrest Laboratories. 3. Combunox / High Dose Alert Message: Combunox (oxycodone/ibuprofen) may be over-utilized. The manufacturer's recommended maximum dosage is 4 tablets in a 24-hour period, with use not to exceed 7 days. Conflict Code: Drugs/Disease: Util A Util B Util C Combunox Max Dose: 20mg oxycodone / day

References:

Facts & Comparisons, 2006 Updates.

Micromedex Healthcare Series, Drugdex Drug Evaluations, 2006. Combunox Prescribing Information, March 2006, Forrest Laboratories.