

using medication information cost effectively

February 9, 2005

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

February 14, 2005 at 1:00pm

Kelly Inn Colony Room A 1800 North 12th Street Bismarck, ND

If you are unable to attend, please contact Brendan Joyce at (701) 328-4023 (sojoyb@state.nd.us).

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



North Dakota Medicaid DUR Board Meeting Agenda

February 14, 2005

- 1. Administrative items travel expenses, signature forms
- 2. Old Business
 - Review and approval of minutes of 12/13/04 meeting
 - Budget update
 - Introduction of new Prior Authorization Vendor
 - Clarification of all approved prior authorization programs per vendor
 - PhRMA presentation / response to Oregon Rx presentation
- 3. New Business
 - Identifying upcoming medications to review for prior authorization
- 4. Upcoming meeting agenda
- 5. Adjourn

Drug Utilization Review (DUR) Board Meeting Minutes December 13, 2004

Members Present: Brendan Joyce, Norm Byers, Bob Treitline, Al Samuelson, Gary Betting, Greg Pfister, Leann Ness, John Savageau, Pat Churchill, Greg Pfister, Carrie Sorrenson, Scott Setzepfandt, Cheryl Huber,

Members absent: Jay Huber

John Savageau (the chair) called the meeting to order at 1:02 pm. The chair asked for a motion to approve the meeting minutes from the 9/27/04 and 11/1/04 meetings. Pat Churchill so moved and Cheryl Huber seconded the motion for the 9/27/04 minutes. Bob Treitline moved to approve the minutes from the 11/1/04 meeting and Greg Pfister seconded this motion. The chair called for two separate voice votes on the two motions, and both passed with no audible dissenters.

The chair asked for an update on the budget. Brendan Joyce reported that for the current fiscal year (through October 2004), the Department is a few hundred thousand dollars to the good, but for the current biennium, the Department is still over budget at the moment and is projecting expenditures to exceed appropriation for pharmacy services by \$3.6 million. Norman Byers asked what is in the Department's budget proposal. Brendan Joyce had no specifics, but reported that the Governor's budget appears to fund the Department to continue to provide services with no cutbacks. The proposed budget includes the savings derived from continued expansion of the prior authorization program.

The chair moved to the next item (ACE Inhibitors). Brendan Joyce presented an algorithm that was derived based on the motion from the previous meeting. He explained that the same grandfathering would be used for these medications, but stabilization on samples would not qualify the patient for exemption from the prior authorization. Much discussion was held regarding the definition of a failure for the medications. Norman Byers suggested that a failure should be side effects or 60 days at an adequate dose without desired response. The chair asked for audience input, and none was volunteered. The chair asked for a motion to approve the algorithm. Greg Pfister moved to accept it and Norm Byers seconded the motion. The chair then asked for a motion to define failure as any side effect or inadequate blood pressure control after 60 days at an adequate dose. Bob Treitline so moved and Norm Byers seconded the motion. The chair asked for a voice vote for the first motion and all approved (no audible dissenters). The chair asked for a voice vote for the second motion and all approved (no audible dissenters). Brendan Joyce then asked the Board to consider a motion to recommend that the Department perform prior authorization on ACE Inhibitors as outlined with the algorithm. Norm Byers so moved and Pat Churchill seconded the motion. The chair asked for a voice vote and it was approved with no audible dissenters.

The chair moved to the next item (ARBs). Brendan Joyce restated the motion as written in the previous meeting's minutes. The chair asked, and no audience members asked to present

on the ARBs. Scott Setzepfandt asked if other states had required failure of one class of drugs before they could start another and if any state required it with ACEs and ARBs. Brendan Joyce responded that he was unsure if any state did this with these two classes of medications, but it has definitely been done time and again with other classes of medications (e.g. H2RAs and PPIs). Norman Byers moved to approve the motion from the previous meeting. Pat Churchill seconded the motion. The chair asked for a voice vote and all approved (no audible dissenters).

The chair moved to the next agenda item (PPIs). Brendan Joyce presented the algorithm for the proposed step therapy for PPI prior authorization. Bob Treitline moved to accept the algorithm. Greg Pfister seconded the motion. Pedro Mendoza presented comments regarding this class of medication. After discussion, the chair called for a voice vote on the motion and it passed with no audible dissenters.

The chair called for a break while John Santa with the Oregon Rx project prepared for his presentation. When the meeting reconvened, John Santa presented his information. Brendan Joyce then presented information regarding the CNS project that is in operation in ND. Copies of these presentations are available upon request.

The chair chose to delay the final agenda item until the next meeting. The next meeting was scheduled for February 14, 2005 at 1:00 pm. One agenda item will be a 30-minute PhRMA presentation regarding the Oregon Rx project. Scott Setzepfandt shared an article with the DUR Board members. Cheryl Huber moved to adjourn the meeting and Carrie Sorrenson seconded the motion. The chair adjourned the meeting at 3:22 pm.



using medication information cost effectively

Welcome

Health Information Designs. Inc., (**HID**) is the most experienced and qualified provider of drug utilization review and pharmacy benefit management services in the country. We specialize in helping our clients promote clinically appropriate and cost effective prescribing, dispensing and utilization of prescription dugs.

For 29 years, HID has worked to improve the quality and cost effectiveness of health care through clinically rational use of prescription medication. Our clients include public and private health care plans throughout the U.S. with a combined total of over 11 million covered lives.

Who We Are

Health Information Designs, Inc. was founded in 1976 and is incorporated as a C Corporation in the State of Delaware. HID's initial mission was to market drug utilization review (DUR) services nationally and since its founding it has provided DUR services for clients in approximately two-thirds of the various U.S. states. HID was sold to Value Health, Inc. in 1987 and in turn was sold to Health Data, Inc. in 1997. HID's headquarters were in Fairfax, Virginia, until they were moved to Auburn, Alabama, in January of 2000.

Who We Serve

HID has one or more clients in the following starred areas.





MEMORANDUM

| DATE: | (date?) |
|----------|--|
| TO: | Physicians Who Prescribe to Medicaid Patients |
| FROM: | Brendan K. Joyce, PharmD, Administrator Pharmacy Services |
| SUBJECT: | Prior Authorization of Specified Drug Benefits for Medicaid Patients |

The 2003 Legislative Assembly passed House Bill 1430, creating a Drug Utilization Review (DUR) Board to advise the Department of Human Services in developing a **Prior Authorization (PA)** process to help assure that beneficiaries receive appropriate medications in the most cost-effective manner, thus conserving state expenditures for drugs whenever possible. The pharmaceutical benefits segment of the Medicaid budget has been increasing dramatically for several years. For the current biennium, the Department expended \$ 59.4 million dollars (retail drug costs) for covered beneficiaries.

The DUR Board, consisting of six physicians, six pharmacists, and two non-voting members of the Department and one from the Pharmaceutical Research and Manufacturers of America, has reviewed and supports the Department's plan to implement the PA process for **Dispense as Written prescriptions** (**DAW**) This notice provides important details on how physicians and patients will continue to access Medicaid pharmaceutical benefits under the PA process for this class of drugs.

You are receiving this notice because Department records indicate that you have prescribed drugs in this manner to Medicaid beneficiaries during the past 90 days. A listing of your patients who received [filled prescriptions for] these drugs during that time period is included, indicating the specific brand name drug they received. Also included is the Prior Authorization (PA) form you may utilize to direct [determine] the continuation of the drug regimen prescribed for these patients.

DIRECTIONS FOR PHYSICIANS

As noted on the PA form, the Department has determined that it is most cost effective to prescribe generic drugs whenever possible. As the prescribing physician, the next time you prescribe a "dispense as written" prescription, you must request a PA. The criteria must be met before the PA can be approved. <u>Please make additional copies of the PA Form as needed</u>. If you do not respond, PA will be required (the Department will deny the claim at the pharmacy) the first time the patient receives this prescription under a new prescription number. You will then be contacted and asked to change the prescription to a generic or to request prior authorization for the product specified on the original prescription. If you cannot be reached immediately to facilitate a PA request, the pharmacy is authorized to dispense one emergency five-day supply of the prescribed drug.

For additional information regarding the implementation of the Medicaid Prior Authorization program, please contact Brendan Joyce, PharmD, DHS Director of Pharmaceutical Services, at (701) 328-4023.

North Dakota Medicaid Dispense as Written Request Form for Prior Authorization

ND 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 MEDICAID ID NUMBER: | | | | | | |
|---|---|----------------------------------|---|--|--|--|--|--|
| Recipient | | | | | | | | |
| Date of birth: / | / | | | | | | | |
| | - | | | | | | | |
| | | | PHYSICIAN | | | | | |
| PHYSICIAN NAME: | | | MEDICAID ID NUMBER: | | | | | |
| | | | | | | | | |
| Address: | | | Phone: () | | | | | |
| | | | | | | | | |
| City: | | | FAX: () | | | | | |
| State: | Zip: | | | | | | | |
| REQUESTED DRUG: | • | Requested Do | sage: (must be completed) | | | | | |
| | | - | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | Diagnosis for t | his request: | | | | | |
| | | _ | | | | | | |
| | | | | | | | | |
| Qualifications for coverage: | | | | | | | | |
| Failed generic equiva | | art Date: d Date: | | | | | | |
| | | | Frequency | | | | | |
| Adverse Reaction to or a section to or a section to or a section. | Dose: Frequency: Adverse Reaction to generic equivalent (attach FDA Medwatch form) or Contraindicated: (provide description below) | | | | | | | |
| | generic equivalent | | watch form) of contraindicated. (provide description below) | | | | | |
| | | | | | | | | |
| I confirm that I have conside | red a generic or ot | her alternative an | d that the requested drug is expected to result in the | | | | | |
| successful medical management of the recipient. | | | | | | | | |
| | | | | | | | | |
| Physician Signature: | | | Date: | | | | | |
| Part II: TO BE COMPLETED | | | | | | | | |
| | | | ND MEDICAID | | | | | |
| PHARMACY NAME: | | | PROVIDER NUMBER: | | | | | |
| | | | | | | | | |
| Phone: | | | FAX: | | | | | |
| | | | | | | | | |
| Drug: | | NDC#: | | | | | | |
| Part III: FOR OFFICIAL USE | ONLY | | | | | | | |
| Date: | / | / | Initials: | | | | | |
| Approved - | | | | | | | | |
| Effective dates of PA: From | m: / | / | To: / / | | | | | |
| Denied: (Reasons) | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |

PLEASE FAX COMPLETED FORM TO: (866) 254-0761

MEMORANDUM

| DATE: | (date?) |
|----------|--|
| TO: | Physicians Who Prescribe to Medicaid Patients |
| FROM: | Brendan K. Joyce, PharmD, Administrator Pharmacy Services |
| SUBJECT: | Prior Authorization of Specified Drug Benefits for Medicaid Patients |

The 2003 Legislative Assembly passed House Bill 1430, creating a Drug Utilization Review (DUR) Board to advise the Department of Human Services in developing a **Prior Authorization (PA)** process to help assure that beneficiaries receive appropriate medications in the most cost-effective manner, thus conserving state expenditures for drugs whenever possible. The pharmaceutical benefits segment of the Medicaid budget has been increasing dramatically for several years. For the current biennium, the Department expended \$59.4 million (retail drug costs) for covered beneficiaries.

The DUR Board, consisting of six physicians, six pharmacists, and two non-voting members of the Department and one from the Pharmaceutical Research and Manufacturers of America, has reviewed and supports the Department's plan to implement the PA process for **Cox-II and brand name NSAIDS**. This notice provides important details on how physicians and patients will continue to access Medicaid pharmaceutical benefits under the PA process for this class of drugs.

You are receiving this notice because Department records indicate that you have prescribed drugs in this class to Medicaid beneficiaries during the past 90 days. A listing of your patients who received [filled prescriptions for] these drugs during that time period is included, indicating the specific Cox II or brand name NSAID they received. Also included is the Prior Authorization (PA) form you may utilize to direct [determine] the continuation of the drug regimen prescribed for these patients.

DIRECTIONS FOR PHYSICIANS

As noted on the PA form, the Department has determined that the most cost-effective anti-inflammatory treatment is generic NSAIDS. As the prescribing physician, the next time you prescribe a Cox II or brand name NSAID for your patient, you must request a PA. The criteria must be met in order for the PA to be approved. <u>Please make additional copies of the PA Form as needed</u>. If you do not respond, the next time the patient seeks a renewal for this prescription, the Department will deny the claim at the pharmacy. You will then be contacted and asked to change the prescription to a generic NSAID or to request prior authorization for the product specified on the original prescription. If you cannot be reached immediately to facilitate a PA request, the pharmacy is authorized to dispense one emergency five-day supply of the prescribed drug.

For additional information regarding the implementation of the Medicaid Prior Authorization program, please contact Brendan Joyce, PharmD, DHS Director of Pharmaceutical Services, at (701) 328-4023.

North Dakota Medicaid Brand Name NSAID and Cox II Request Form for Prior Authorization

ND Medicaid requires that patients 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 NSAID

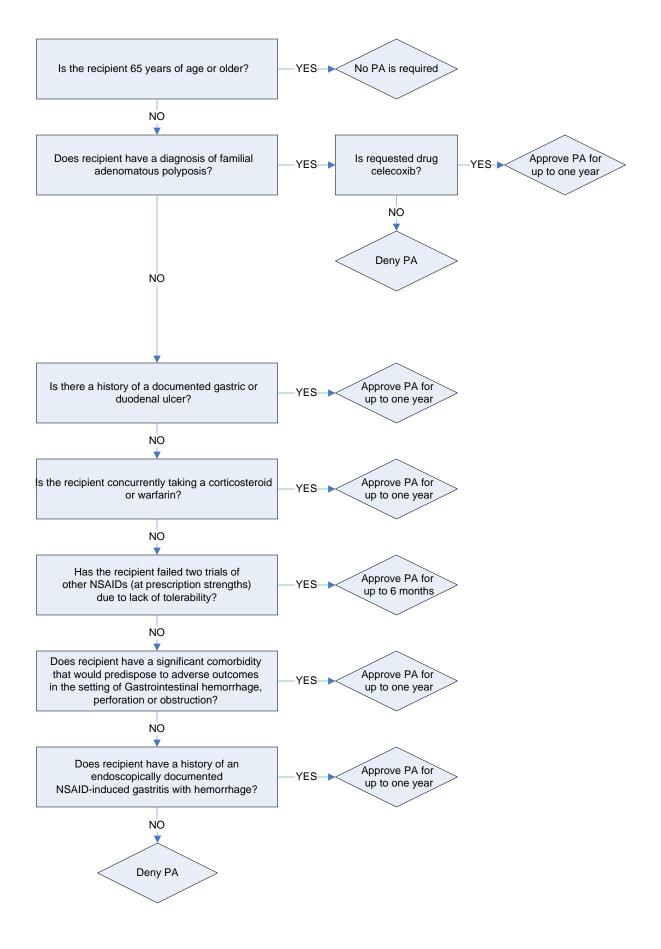
Recipient > 65 years old

Recipient has history of gastric or duodenal ulcer, or has comorbidity of GI bleed, perforation or obstruction Recipient has a 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 MEDICAID ID NUMBER: | | | | | |
|---|-------------------------------|------------|---------------|---|---------------|--------------------------------|--|--|--|
| Recipient Date of birth: / / | | | | | | | | | |
| | / / | | | | | | | | |
| PHYSICIAN NAME: | | | | PHYSICIAN MEDICAID ID NUMBER: | | | | | |
| Address: | | | | Phone: (|) - | | | | |
| City: | | | | FAX: (|) - | | | | |
| State: | Zip: | | | | | | | | |
| REQUESTED DRUG: | Request | ed Dosage: | Diagnosis for | this reque | est: | | | | |
| CELEBREX BEXTRA MOBIC | Gastric or du GI Bleed, pe | | | rticosteriod therapy uodenal ulcer erofration or obstruction ally documented NSAID gastritis with GI Bleed | | | | | |
| Qualifications for cove | | | • | | | | | | |
| Failed NSAID therap | ру | St | Start Date: | | Dose: | | | | |
| | | Er | End Date: | | Frequency: | | | | |
| Failed NSAID therapy | | | Start Date: | | Dose: | | | | |
| | | Er | End Date: | | Frequency: | | | | |
| I confirm that I have c successful medical m | | | | nd that the | requested dru | g is expected to result in the | | | |
| Physician Signature: | | | | | | Date: | | | |
| Part II: TO BE COMPL | ETED BY | PHARMACY | | | | | | | |
| PHARMACY NAME: | | | | ND MEDICAID PROVIDER NUMBER: | | | | | |
| Phone: () - | | | | FAX: (|) - | | | | |
| Drug: | | | | NDC#: | | | | | |
| Part III: FOR OFFICIAL U | JSE ONLY | | | | | | | | |
| Date: | / | / | | Initials: | | | | | |
| Approved - Effective dates of PA: | From: | / | / | To: | / | / | | | |
| Denied: (Reasons) | | | | | | | | | |

North Dakota Department of Human Services Cox-2 Inhibitor Authorization Criteria Algorithm



MEMORANDUM

| DATE: | (date?) |
|-------|--|
| TO: | Physicians Who Prescribe to Medicaid Patients |
| FROM: | Brendan K. Joyce, PharmD, Administrator Pharmacy Services |
| RE: | Prior Authorization of Specified Drug Benefits for Medicaid Patients |

The 2003 Legislative Assembly passed House Bill 1430, creating a Drug Utilization Review (DUR) Board to advise the Department of Human Services in developing a **Prior Authorization (PA)** process to help assure that beneficiaries receive appropriate medications in the most cost-effective manner, thus conserving state expenditures for drugs whenever possible. The pharmaceutical benefits segment of the Medicaid budget has been increasing dramatically for several years. For the current biennium, the Department expended \$59.4 million (retail drug costs) for covered beneficiaries.

The DUR Board, consisting of six physicians, six pharmacists, and two non-voting members of the Department and one from the Pharmaceutical Research and Manufacturers of America, has reviewed and supports the Department's plan to implement the PA process for **ACE Inhibitors**. This notice provides important details on how physicians and patients will continue to access Medicaid pharmaceutical benefits under the PA process for this class of drugs.

You are receiving this notice because Department records indicate that you have prescribed drugs in this class to Medicaid beneficiaries during the past 90 days. A listing of your patients who received [filled prescriptions for] these drugs during that time period is included, indicating the specific ACE Inhibitor they received. Also included is the Prior Authorization (PA) form you may utilize to direct [determine] the continuation of the drug regimen prescribed for these patients.

DIRECTIONS FOR PHYSICIANS

As noted on the PA form, the Department has determined that the most cost-effective treatment with ACE Inhibitors is to prescribe generic products. As the prescribing physician, the next time you prescribe a brand name ACE Inhibitor for your patient, you must request a PA. The criteria must be met before the PA can be approved. <u>Please make additional copies of the PA Form as needed</u>. If you do not respond, the next time the patient seeks a renewal for this prescription, the Department will deny the claim at the pharmacy. You will then be contacted and asked to change the prescription to a generic ACE Inhibitor or to request prior authorization for the product specified on the original prescription. If you cannot be reached immediately to facilitate a PA request, the pharmacy is authorized to dispense one emergency five-day supply of the prescribed drug.

For additional information regarding the implementation of the Medicaid Prior Authorization program, please contact Brendan Joyce, PharmD, DHS Director of Pharmaceutical Services, at (701) 328-4023.

North Dakota Medicaid ACE Inhibitor Request Form for Prior Authorization

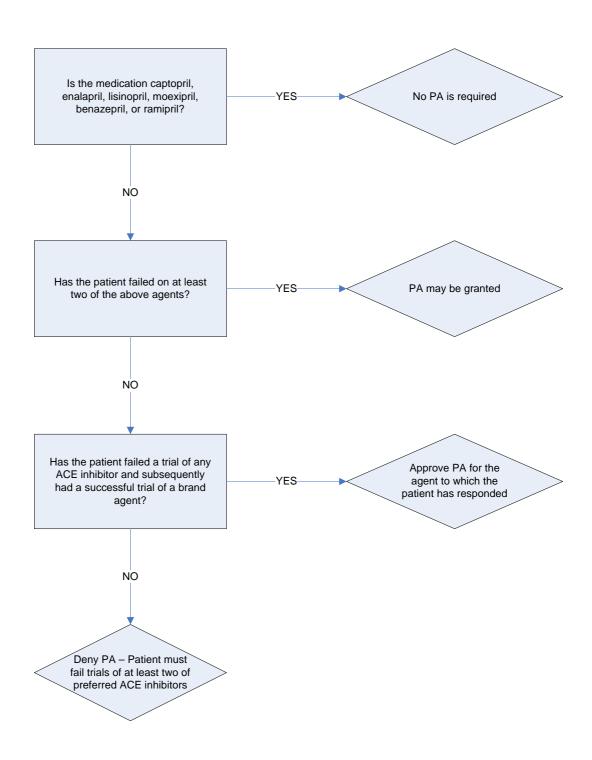
ND Medicaid requires that patients receiving an ACE Inhibitor, must use at least two generics as first line. **Note:*

- Captopril, Lisinopril, Moexipril, Benazepril, 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 will only be aproved 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: / / | | | | | | | | | |
| Date of birth: | / / | | | | <u> </u> | | | | |
| | | | | | PHYSICIAN | | | | |
| PHYSICIAN NAME: | | | | | | CAID ID NUMBER: | | | |
| Address: | | | | | Phone: () - | | | | |
| City: | | | | | FAX: () - | | | | |
| State: | Zip: | | | | | | | | |
| REQUESTED DRUG: | Requested Dosage (must be completed | | Diagnosis for t | his | reques | st: | | | |
| | | | Other CV Risk | Fac | tors: | | | | |
| | | | | | | | | | |
| Qualifications for cove | | | | | | | | | |
| Failed generic d | rug | Sta | rt Date: | | Dose: | | | | |
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| Failed generic drug End Da | | | Date: Frequency: | | | Frequency: | | | |
| I confirm that I have considered a generic or other alternative and that successful medical management of the recipient. | | | | | the rea | quested drug is expected to result in th | е | | |
| | | | | | | 5. | | | |
| Physician Signature: | | | | | | Date: | | | |
| Part II: TO BE COMPLI | ETED BY PHARMAC | Y | | - | | | | | |
| PHARMACY NAME: | | | | | ND MEDICAID PROVIDER NUMBER: | | | | |
| Phone: () - | | | | | FAX:() - | | | | |
| | | | | | NDC#: | | | | |
| Drug: Part III: FOR OFFICIAL USE ONLY | | | | | NDC# | τ | | | |
| | | | | | | | | | |
| Date: / / | | | | | Initials | S: | | | |
| 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.

MEMORANDUM

| DATE: | (date?) |
|----------|--|
| TO: | Physicians Who Prescribe to Medicaid Patients |
| FROM: | Brendan K. Joyce, PharmD, Administrator Pharmacy Services |
| SUBJECT: | Prior Authorization of Specified Drug Benefits for Medicaid Patients |

Last year, the 2003 Legislative Assembly passed House Bill 1430, creating a Drug Utilization Review (DUR) Board to advise the Department of Human Services in developing a **Prior Authorization (PA)** process to help assure that beneficiaries receive appropriate medications in the most cost-effective manner, thus conserving state expenditures for drugs whenever possible. The pharmaceutical benefits segment of the Medicaid budget has been increasing dramatically for several years. For the current biennium, the Department expended \$59.4 million (retail drug costs) for covered beneficiaries.

The DUR Board, consisting of six physicians, six pharmacists, and two non-voting members of the Department and one from the Pharmaceutical Research and Manufacturers of America, has reviewed and supports the Department's plan to implement the PA process for **Angiotensin II Receptor Antagonists** (**ARBs**). This notice provides important details on how physicians and patients will continue to access Medicaid pharmaceutical benefits under the PA process for this class of drugs.

You are receiving this notice because Department records indicate that you have prescribed drugs in this class to Medicaid beneficiaries during the past 90 days. A listing of your patients who received [filled prescriptions for] these drugs during that time period is included, indicating the specific ARB they received. Also included is the Prior Authorization (PA) form you may utilize to direct [determine] the continuation of the drug regimen prescribed for these patients.

DIRECTIONS FOR PHYSICIANS

As noted on the PA form, the Department has determined that the most cost-effective treatment with ARBs is to initially prescribe a generic ACE Inhibitor. As the prescribing physician, the next time you prescribe an ARB for your patient, you must request a PA. The criteria must be met before the PA can be approved. Please make additional copies of the PA Form as needed. If you do not respond, the next time the patient seeks a renewal for this prescription, the Department will deny the claim at the pharmacy. You will then be contacted and asked to change the prescription to a generic ACE inhibitor or request prior authorization for the product specified on the original prescription. If you cannot be reached immediately to facilitate a PA request, the pharmacy is authorized to dispense one emergency five-day supply of the prescribed drug.

For additional information regarding the implementation of the Medicaid Prior Authorization program, please contact Brendan Joyce, PharmD, DHS Director of Pharmaceutical Services, at (701) 328-4023.

North Dakota Medicaid ARB * Request Form for Prior Authorization

ND Medicaid requires that patients receiving an ARB, must use and fail one ACE Inhibitor.

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

| Part I: TO BE COMPLETED BY P | HYSICIAN | | | | | | | |
|---|----------|-------|--------------------------|------------------|--|--|--|--|
| RECIPIENT NAME: | | | | RECIPI MEDIC/ | ENT AID ID NUMBER: | | | |
| Recipient Date of birth: / / | | | | | | | | |
| | | | | | | | | |
| PHYSICIAN NAME: | | | | PHYSIC MEDIC/ | CIAN AID ID NUMBER: | | | |
| Address: | | | Phone: () - | | | | | |
| City: | | | | FAX: (|) - | | | |
| State: | Zip: | | | | | | | |
| REQUESTED DRUG: | | | Requested Dosage: | (must be | completed) | | | |
| | | | | | | | | |
| | | | Diagnosis for this re | quest: | | | | |
| | | | | | | | | |
| Qualifications for coverage: | | | | | | | | |
| Failed ACE Inhibitor | | Sta | rt Date: | | Dose: | | | |
| | | Enc | d Date: | Frequency: | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| I confirm that I have considered a medical management of the recip | | alter | mative and that the requ | uested dr | ug is expected to result in the successful | | | |
| | | | | | | | | |
| Physician Signature: | | | | | Date: | | | |
| Part II: TO BE COMPLETED BY F | PHARMACY | | | | | | | |
| PHARMACY NAME: | | | | ND MEI PROVII | DER NUMBER: | | | |
| Phone: (): - | | | | FAX:: () - | | | | |
| Drug: | | | NDC#: | | | | | |
| Part III: FOR OFFICIAL USE ONLY | | | | | | | | |
| Date: / | / | | | Initials: | | | | |
| Approved - Effective dates of PA: From: | / / | | | To: | | | | |
| Denied: (Reasons) | | | | | | | | |
| | | | | | | | | |

PLEASE FAX COMPLETED FORM TO: (866) 254-0761

Health Information Designs, Inc. (334) 502-3262

NORTH DAKOTA MEDICAID

02/09/2005

Program Summary

3 Month Assessment

3 Month Assessment

| Period Covered: | 04/01/04 - 06/30/04 |
|----------------------------|---------------------|
| Rx Claims Cost: | \$ 15,065,523.01 |
| Number Rx: | 303,571 |
| Total Recipients: | 30,813 |
| Avg. Recipients Per Month: | 22,391 |
| Avg Paid Per Member | |
| Over Period: | \$488.93 |
| Avg. Paid Per Member | |
| Per Month: | \$224.28 |
| Avg Paid Per Rx | \$49.63 |
| | |

| Period Covered: | 07/01/04 - 09/30/04 |
|----------------------------|---------------------|
| Rx Claims Cost: | \$ 15,178,605.71 |
| Number Rx: | 291,206 |
| Total Recipients: | 29,912 |
| Avg. Recipients Per Month: | 21,750 |
| Avg Paid Per Member | |
| Over Period: | \$507.44 |
| Avg. Paid Per Member | |
| Per Month: | \$232.62 |
| Avg Paid Per Rx | \$52.12 |

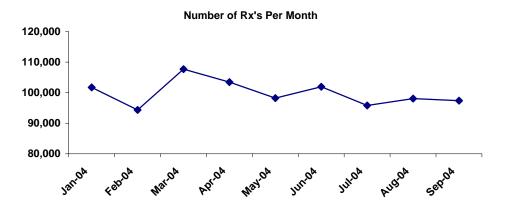
6 Month Assessment

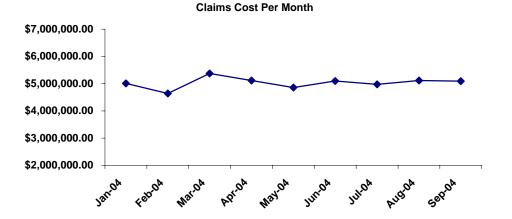
| Period Covered: | 04/01/04 | - 09/30/04 |
|----------------------------|----------|------------|
| Rx Claims Cost: | \$ 30,24 | 4,128.72 |
| Number Rx: | | 594,777 |
| Total Recipients: | | 37,639 |
| Avg. Recipients Per Month: | | 22,070 |
| Avg Paid Per Member | | |
| Over Period: | | \$803.53 |
| Avg. Paid Per Member | | |
| Per Month: | | \$228.39 |
| Avg Paid Per Rx | | \$50.85 |

Health Information Designs, Inc. (334) 502-3262

NORTH DAKOTA MEDICAID Cost Management Analysis

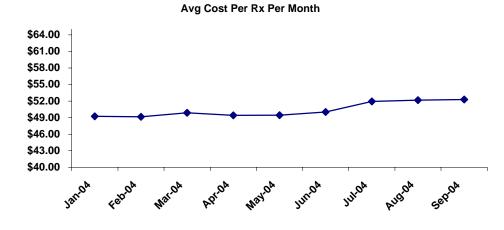
| | | | | | Cost per | | |
|----------------|------------|---------|--------------------|----|------------|----|-----------|
| | | | Rx Claims | Ν | lember Per | | |
| Period Covered | Recipients | # Rx's | Cost | | Month | С | ost/Claim |
| Jan-04 | 22,516 | 101,705 | \$ 5,009,250.74 | \$ | 222.48 | \$ | 49.25 |
| Feb-04 | 22,101 | 94,371 | \$ 4,638,277.75 | \$ | 209.87 | \$ | 49.15 |
| Mar-04 | 23,301 | 107,694 | \$ 5,372,335.23 | \$ | 230.56 | \$ | 49.89 |
| Apr-04 | 23,121 | 103,438 | \$ 5,112,708.56 | \$ | 221.13 | \$ | 49.43 |
| May-04 | 22,478 | 98,222 | \$ 4,855,222.64 | \$ | 216.00 | \$ | 49.43 |
| Jun-04 | 21,573 | 101,911 | \$ 5,097,591.81 | \$ | 236.29 | \$ | 50.02 |
| Jul-04 | 21,258 | 95,796 | \$ 4,974,887.17 | \$ | 234.02 | \$ | 51.93 |
| Aug-04 | 21,793 | 98,043 | \$ 5,113,405.31 | \$ | 234.64 | \$ | 52.15 |
| Sep-04 | 22,199 | 97,367 | \$ 5,090,313.23 | \$ | 229.30 | \$ | 52.28 |





02/09/2005





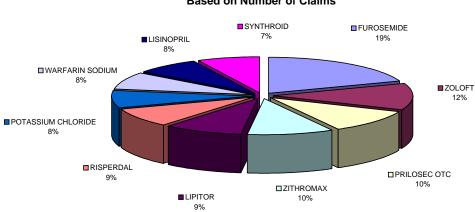
Health Information Designs, Inc.

NORTH DAKOTA MEDICAID Cost Management Analysis

02/09/2005

TOP 25 DRUGS BASED ON NUMBER OF CLAIMS FROM 07/01/2004 - 09/30/2004

| | | | | | | | % Total |
|---|---|--------|------|--------------|----|--------|---------|
| Drug | AHFS Therapeutic Class | Rx | | Paid | P | aid/Rx | Claims |
| FUROSEMIDE | DIURETICS | 8,650 | \$ | 69,654.74 | \$ | 8.05 | 2.97% |
| ZOLOFT | ANTIDEPRESSANTS | 5,326 | • | 400,389.71 | \$ | 75.18 | 1.83% |
| PRILOSEC OTC | PROTON-PUMP INHIBITORS | 4,596 | \$ | 104,608.73 | \$ | 22.76 | 1.58% |
| ZITHROMAX | MACROLIDES | 4,524 | \$ | 208,067.43 | \$ | 45.99 | 1.55% |
| LIPITOR | HMG-COA REDUCTASE INHIBITORS | 3,958 | \$ | 287,069.98 | \$ | 72.53 | 1.36% |
| RISPERDAL | ANTIPSYCHOTIC AGENTS | 3,828 | \$ | 574,088.88 | \$ | 149.97 | 1.31% |
| POTASSIUM CHLORIDE | REPLACEMENT PREPARATIONS | 3,517 | \$ | 57,763.22 | \$ | 16.42 | 1.21% |
| WARFARIN SODIUM | ANTICOAGULANTS | 3,397 | \$ | 44,681.07 | \$ | 13.15 | 1.17% |
| LISINOPRIL | ANGIOTENSIN-CONVERTING ENZYME INHIBITORS | 3,394 | \$ | 41,219.28 | \$ | 12.14 | 1.17% |
| SYNTHROID | THYROID AGENTS | 3,171 | \$ | 47,480.66 | \$ | 14.97 | 1.09% |
| HYDROCODONE W/ACETAMINOPHEN | OPIATE AGONISTS | 3,018 | \$ | 36,671.62 | \$ | 12.15 | 1.04% |
| TRAZODONE HCL | ANTIDEPRESSANTS | 2,757 | \$ | 24,532.12 | \$ | 8.90 | 0.95% |
| LORAZEPAM | BENZODIAZEPINES (ANXIOLYTIC, SEDATIV/HYP) | 2,748 | \$ | 33,820.18 | \$ | 12.31 | 0.94% |
| ALBUTEROL | SYMPATHOMIMETIC (ADRENERGIC) AGENTS | 2,687 | \$ | 40,989.22 | \$ | 15.25 | 0.92% |
| NEURONTIN | MISCELLANEOUS ANTICONVULSANTS | 2,644 | \$ | 329,759.80 | \$ | 124.72 | 0.91% |
| SEROQUEL | ANTIPSYCHOTIC AGENTS | 2,643 | \$ | 524,781.44 | \$ | 198.56 | 0.91% |
| ZYPREXA | ANTIPSYCHOTIC AGENTS | 2,525 | \$ | 764,087.16 | \$ | 302.61 | 0.87% |
| NORVASC | DIHYDROPYRIDINES | 2,470 | \$ | 118,848.28 | \$ | 48.12 | 0.85% |
| FLUOXETINE HCL | ANTIDEPRESSANTS | 2,405 | \$ | 34,348.22 | \$ | 14.28 | 0.83% |
| ATENOLOL | BETA-ADRENERGIC BLOCKING AGENTS | 2,399 | \$ | 18,391.88 | \$ | 7.67 | 0.82% |
| METOPROLOL TARTRATE | BETA-ADRENERGIC BLOCKING AGENTS | 2,355 | \$ | 20,155.27 | \$ | 8.56 | 0.81% |
| LEVOTHYROXINE SODIUM | THYROID AGENTS | 2,239 | \$ | 27,169.36 | \$ | 12.13 | 0.77% |
| HYDROCHLOROTHIAZIDE | DIURETICS | 2,202 | \$ | 14,699.64 | \$ | 6.68 | 0.76% |
| LEXAPRO | ANTIDEPRESSANTS | 2,197 | \$ | 128,377.92 | \$ | 58.43 | 0.75% |
| EFFEXOR XR | ANTIDEPRESSANTS | 2,183 | \$ | 207,341.75 | \$ | 94.98 | 0.75% |
| TOTAL TOP 25 | | 81,833 | \$ 4 | 4,158,997.56 | \$ | 50.82 | 28.10% |
| Total Rx Claims From 07/01/2004 - 09/30/2004 | 291,206 | i | | | | | |



Top 10 Drugs Based on Number of Claims

Health Information Designs, Inc.

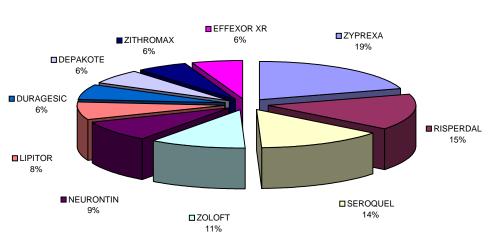
NORTH DAKOTA MEDICAID **Cost Management Analysis**

02/09/2005

TOP 25 DRUGS BASED ON TOTAL CLAIMS COST FROM 07/01/2004 - 09/30/2004

| | | | | | | | % Total |
|---|--|--------|-----|--------------|----|--------|---------|
| Drug | AHFS Therapeutic Class | Rx | | Paid | P | aid/Rx | Claims |
| ZYPREXA | ANTIPSYCHOTIC AGENTS | 2,525 | \$ | 764,087.16 | \$ | 302.61 | 0.87% |
| RISPERDAL | ANTIPSYCHOTIC AGENTS | 3,828 | \$ | 574,088.88 | \$ | 149.97 | 1.31% |
| SEROQUEL | ANTIPSYCHOTIC AGENTS | 2,643 | \$ | 524,781.44 | \$ | 198.56 | 0.91% |
| ZOLOFT | ANTIDEPRESSANTS | 5,326 | \$ | 400,389.71 | \$ | 75.18 | 1.83% |
| NEURONTIN | MISCELLANEOUS ANTICONVULSANTS | 2,644 | \$ | 329,759.80 | \$ | 124.72 | 0.91% |
| LIPITOR | HMG-COA REDUCTASE INHIBITORS | 3,958 | \$ | 287,069.98 | \$ | 72.53 | 1.36% |
| DURAGESIC | OPIATE AGONISTS | 1,343 | \$ | 240,810.62 | \$ | 179.31 | 0.46% |
| DEPAKOTE | MISCELLANEOUS ANTICONVULSANTS | 1,859 | \$ | 231,086.08 | \$ | 124.31 | 0.64% |
| ZITHROMAX | MACROLIDES | 4,524 | \$ | 208,067.43 | \$ | 45.99 | 1.55% |
| EFFEXOR XR | ANTIDEPRESSANTS | 2,183 | \$ | 207,341.75 | \$ | 94.98 | 0.75% |
| CELEBREX | NONSTEROIDAL ANTI-INFLAMMATORY AGENTS | 2,148 | \$ | 196,085.28 | \$ | 91.29 | 0.74% |
| ADVAIR DISKUS | SYMPATHOMIMETIC (ADRENERGIC) AGENTS | 1,439 | \$ | 191,861.74 | \$ | 133.33 | 0.49% |
| TOPAMAX | MISCELLANEOUS ANTICONVULSANTS | 969 | \$ | 178,273.00 | \$ | 183.98 | 0.33% |
| LAMICTAL | MISCELLANEOUS ANTICONVULSANTS | 770 | \$ | 177,823.57 | \$ | 230.94 | 0.26% |
| GEODON | ANTIPSYCHOTIC AGENTS | 827 | \$ | 165,629.05 | \$ | 200.28 | 0.28% |
| PLAVIX | MISCELLANEOUS THERAPEUTIC AGENTS | 1,438 | \$ | 163,690.69 | \$ | 113.83 | 0.49% |
| ARICEPT | PARASYMPATHOMIMETIC (CHOLINERGIC AGENTS) | 1,305 | \$ | 163,614.13 | \$ | 125.37 | 0.45% |
| ABILIFY | ANTIPSYCHOTIC AGENTS | 581 | \$ | 152,792.52 | \$ | 262.98 | 0.20% |
| SINGULAIR | MISCELLANEOUS THERAPEUTIC AGENTS | 1,807 | \$ | 145,736.28 | \$ | 80.65 | 0.62% |
| OXYCONTIN | OPIATE AGONISTS | 979 | \$ | 144,910.16 | \$ | 148.02 | 0.34% |
| TRILEPTAL | MISCELLANEOUS ANTICONVULSANTS | 912 | \$ | 128,981.51 | \$ | 141.43 | 0.31% |
| LEXAPRO | ANTIDEPRESSANTS | 2,197 | \$ | 128,377.92 | \$ | 58.43 | 0.75% |
| CONCERTA | ANOREXIGENICS;RESPIR.,CEREBRAL STIMULANT | 1,556 | \$ | 126,823.18 | \$ | 81.51 | 0.53% |
| CLOZARIL | ANTIPSYCHOTIC AGENTS | 637 | \$ | 123,706.32 | \$ | 194.20 | 0.22% |
| KEPPRA | MISCELLANEOUS ANTICONVULSANTS | 592 | \$ | 120,543.52 | \$ | 203.62 | 0.20% |
| TOTAL TOP 25 | | 48,990 | \$6 | 6,076,331.72 | \$ | 124.03 | 16.82% |
| Total Rx Claims From 07/01/2004 - 09/30/2004 | 291,206 | | | | | | |

| Total Rx Claims | 291,20 |
|------------------------------|--------|
| From 07/01/2004 - 09/30/2004 | |
| | |



Top 10 Drugs **Based on Total Claims Cost**

NORTH DAKOTA MEDICAID RETROSPECTIVE DUR CRITERIA RECOMMENDATIONS FIRST QUARTER 2005

| Criteria Recommendations | Approved | Rejected |
|--|----------|----------|
| 1. Memantine / Overutilization Alert Message: Namenda (memantine) may be over-utilized. The recommended maximum dose is 20 mg/day. Conflict Code: HD – High Dose Severity: Major Drugs: | | |
| Util A Util B Util C Memantine | | |
| Max Dose: 20mg/day References: Namenda Product Information, Oct. 2003, Forest Laboratories. | | |
| 2. Memantine / Underutilization | | |
| Alert Message: After reviewing your patient's refill frequency of Namenda (memantin we are concerned that they may be non-adherent to the prescribed dosing regimen which may lead to sub-therapeutic effects. Conflict Code: LR - Underutilization Precaution Severity: Major Drugs: | e) | |
| Util A Util B Util C Memantine | | |
| References: Namenda Product Information, Oct. 2003, Forest Laboratories | | |
| 3. Memantine / Renal Failure Alert Message: Namenda (memantine) is predominantly renally eliminated | | |

Alert Message: Namenda (memantine) is predominantly renally eliminated and dose reduction may be necessary in patients with moderate renal impairment. Memantine use has not been evaluated in patients with severe renal impairment and is therefore is not recommended. Conflict Code: ER – Overutilization Severity: Moderate Drugs: Util A Util B Util C Memantine 10mg Renal Impairment

References: Namenda Product Information, Oct. 2003, Forest Laboratories.

4. Memantine / Urine Alkalinizers

Alert Message: Namenda (memantine) should be used with caution under conditions that can alkalinize the urine (e.g., carbonic anhydrase inhibitors, sodium bicarbonate, diet, renal tubular acidosis or severe infections of urinary tract). Memantine is predominantly renally eliminated and alkalinization of urinary pH may lead to an accumulation of the drug with a possible increase in adverse effects. Conflict Code: DB - Drug/Drug Marker and/or Diagnosis Severity: Moderate Drugs: Util A Util B Util C Memantine Acetazolamide Dichlorphenamide Methazolamide **Renal Tubular Acidosis** Urinary Tract Infection

References:

Namenda Product Information, Oct. 2003, Forest Laboratories. Micromedex Healthcare Series, Drugdex Drug Evaluations, 2004.

5. Memantine / Drugs eliminated by Renal Cationic System

Alert Message: Coadministration of Namenda (memantine) and drugs that are eliminated via the renal cationic system should be done with caution. Memantine is predominantly renally eliminated and concurrent use with drugs that use the same elimination route may potentially result in altered plasma levels of both agents.

Conflict Code: DD – Drug-Drug Interaction Severity: Moderate Drugs: <u>Util A</u> <u>Util B</u> <u>Util C</u> Memantine Hydrochlorothiazide Triamterene Cimetidine

> Ranitidine Quinidine

References: Namenda Product Information, Oct. 2003, Forest Laboratories.

6. Memantine / NMDA Receptor Antagonists

Alert Message: The concurrent use of Namenda (memantine) with other N-methyl D-aspartate (NMDA) antagonists has not been evaluated and therefore should be approached with caution. Conflict Code: DD – Drug/Drug Interaction Drugs: <u>Util A</u> <u>Util B</u> <u>Util C</u> Memantine Dextromethorphan Ketamine

References: Namenda Product Information, Oct. 2003, Forest Laboratories.

7. Duloxetine / Hepatic Insufficiency

Alert Message: It is recommended that Cymbalta (duloxetine) not be administered to patients with any hepatic insufficiency. These patients experience decreased duloxetine metabolism and elimination. After a single 20 mg dose of duloxetine cirrhotic patients with moderate liver impairment had a mean plasma clearance about 15% that of age-and gender-matched healthy subjects, a 5-fold increase in AUC, and a half-life approximately three times longer. Conflict Code: MC – Drug (Actual) Disease Precaution Severity: Major Drugs:

 Util A
 Util B
 Util C

 Duloxetine
 Hepatic Insufficiency
 Util C

References:

Cymbalta Product Information, 2004, Eli Lilly and Company.

8. Duloxetine / End Stage Renal Disease

Alert Message: Cymbalta (duloxetine) is not recommended in patients with end stage renal disease. A single 60 mg dose of duloxetine resulted in Cmax and AUC values approximately 100% greater in patients with end stage renal disease receiving intermittent hemodialysis than in patients with normal renal function. Conflict Code: DB - Drug-Drug Marker and/or Diagnosis Drugs:

| Util A | Util B | Util C |
|------------|-------------------------|--------|
| Duloxetine | End Stage Renal Disease | |
| | Sevelamer | |
| | Paricalcitol | |
| | Calcitriol | |

References:

Cymbalta Product Information, 2004, Eli Lilly and Company.

9. Duloxetine / MAO Inhibitors

Alert Message: The concurrent use of Cymbalta (duloxetine) and monoamine oxidase inhibitors is contraindicated due to the risk for developing serotonin syndrome, which may include hyperthermia, tremor, myoclonus, and irritability. It is recommended that duloxetine not be used within 14 days of discontinuing treatment with an MAOI, and at least 5 days should be allowed after discontinuing duloxetine before starting an MAOI. Conflict Code: DD – Drug/Drug Interaction

Severity: Major

| Drugs: | | |
|---------------|-----------------|---------------|
| <u>Util A</u> | <u>Util B</u> | <u>Util C</u> |
| Duloxetine | Phenelzine | |
| | Isocarboxazid | |
| | Tranylcypromine | |

References: Cymbalta Product Information, 2004, Eli Lilly and Company.

10. Duloxetine / Thioridiazine

Alert Message: Cymbalta (duloxetine) and thioridiazine should not be co-administered. Duloxetine is a moderate inhibitor of CYP 2D6 and concurrent use with thioridiazine, a CYP 2D6 substrate, may increase the risk of serious ventricular arrhythmias and sudden death associated with elevated plasma levels of thioridiazine. Conflict Code: DD – Drug/Drug Interaction Severity: Major <u>Util A</u> <u>Util B</u> <u>Util C</u> Duloxetine Thiordiazine

References:

Cymbalta Product Information, 2004, Eli Lilly and Company.

11. Duloxetine / Narrow-Angle Glaucoma

Alert Message: Cymbalta (duloxetine) should be used with caution in patients with controlled narrow-angle glaucoma and is contraindicated in patients with uncontrolled narrow-angle glaucoma. In clinical trials, duloxetine has been shown to increase the risk of mydriasis. Conflict Code: MC – Drug (Actual) Disease Precaution Severity: Moderate Drugs: <u>Util A</u> <u>Util B</u> <u>Util B</u> <u>Util C</u>

Duloxetine Narrow Angle Glaucoma

References:

Cymbalta Product Information, 2004, Eli Lilly and Company.

12. Duloxetine / Fluoxetine

 Alert Message: Cymbalta (duloxetine) should be used with caution in patients receiving Luvox (fluvoxamine), a potent CYP 1A2 inhibitor. Elimination of duloxetine is mainly through hepatic metabolism involving P450 isozymes, CYP2D6 and CYP1A2. Concurrent use of these agents resulted in an approximate 6 fold increase in the AUC and a 2.5 fold increase in the Cmax of duloxetine.

 Conflict Code: DD – Drug/Drug Interaction Severity: Moderate

 Drugs:

 Util A
 Util B

 Duloxetine

References: Cymbalta Product Information, 2004, Eli Lilly and Company.

13. Duloxetine / Potent 2D6 Inhibitors

Alert Message: Cymbalta (duloxetine) should be used with caution in patients receiving potent CYP 2D6 inhibitors, (paroxetine, fluoxetine and quinidine). The concurrent use of these agents may result in elevated concentrations of duloxetine. Conflict Code: DD – Drug/Drug Interactions Severity: Moderate Drugs: Util A Util B Util C Duloxetine Paroxetine Fluoxetine Quinidine

Cymbalta Product Information, 2004, Eli Lilly and Company.

14. Duloxetine / Certain Tricyclic Antidepressants.

Alert Message: Cymbalta (duloxetine) should be used with caution in patients receiving certain tricyclic antidepressants (despiramine, amitriptyline, nortriptyline and imipramine). Duloxetine is a moderate inhibitor of CYP2D6 and concurrent use with these agents may result in elevated TCA plasma concentrations. TCA plasma levels may need to be monitored and TCA dose reduction may be necessary. Conflict Code: DD – Drug/Drug Interaction Severity: Moderate Drugs:

 Util A
 Util B
 Util C

 Duloxetine
 Nortriptyline
 Imipramine

References:

Cymbalta Product Information, 2004, Eli Lilly and Company.

15. Duloxetine / CYP2D6 Metabolized Drugs

Desipramine

Alert Message: Cymbalta (duloxetine) should be used with caution in patients receiving drugs that are extensively metabolized by CYP2D6 isozyme and which have a narrow therapeutic index (Type 1C antiarrhythmics and phenothiazines). Duloxetine is a moderate inhibitor of CYP2D6 and concurrent use with these agents may result in elevated plasma concentrations of the CYP2D6 substrate. Conflict Code: DD - Drug/Drug Interaction Severity: Moderate Drugs: Util A Util B Util C Duloxetine Propafenone Flecainide Chlorpromazine Fluphenazine Mesoridazine Perphenazine Prochlorperazine Trifluroperazine *Excluded thioridiazine - has individual criteria

References:

Cymbalta Product Information, 2004, Eli Lilly and Company.

16. Duloxetine / High Dose

Alert Message: Cymbalta (duloxetine) may be over-utilized. The recommended dosing range is 40 mg to 60 mg a day. There is no evidence that doses greater than 60 mg/day confer any additional benefit. Conflict Code: HD – High Dose Drugs: Util A Util B Util C Duloxetine

Max Dose: 60mg/day References: Cymbalta Product Information, 2004, Eli Lilly and Company.

17. Duloxetine / Underuse

Alert Message: After reviewing your patient's refill frequency for Cymbalta (duloxetine) we are concerned that they may be non-adherent to the prescribed dosing regimen which may lead to sub-therapeutic effects. Conflict Code: LR – Underuse Precaution Severity: Major Drugs: Util A Util B Util C Duloxetine

*Receive 65 day supply or less in 90 days. References: Cymbalta Product Information, 2004, Eli Lilly and Company.

18. Estazolam/ Azole Antifungals

Alert Message: Estazolam use is contraindicated with the potent CYP3A4 enzymes inhibitors, ketoconazole or itraconazole, due to their inhibition of estazolam metabolism. Concomitant use of these agents may result in estazolam toxicity. Conflict Codes: DD – Drug/Drug Interaction Severity: Major Drugs: <u>Util A</u> <u>Util B</u> <u>Util C</u> Estazolam <u>Ketoconazole</u> Itraconazole

References:

Micromedex Healthcare Series, Drugdex Drug Evaluations, 2004. Prosom Product Information, Jan. 2004, Abbott Laboratories.

19. Estazolam/ Certain 3A4 inhibitors (Moderate)

Alert Message: Estazolam, a CYP 3A4 substrate, should be prescribed with caution in patients receiving drugs that exhibit significant inhibition of 3A4 metabolism (e.g., nefazodone, fluvoxamine, cimetidine, diltiazem, isoniazid and some macrolide antibiotics). Concomitant therapy may result in elevated estazolam concentrations. Consideration should be given to appropriate dosage reduction of estazolam. Conflict Codes: DD - Drug/Drug Interaction Severity: Moderate Drugs: Util A Util C Util B Estazolam Nefazodone Erythromycin Fluvoxamine Clarithromycin Cimetidine Diltiazem Isoniazid

References:

Micromedex Healthcare Series, Drugdex Drug Evaluations, 2004. Prosom Product Information, Jan. 2004, Abbott Laboratories.

20. Estazolam/ CYP3A4 Inducers

Alert Message: Estazolam, a CYP 3A4 substrate, should be used with caution in patients receiving potent CYP3A4 enzymes inducers (e.g., carbamazepine, phenytoin, rifampin and barbiturates). While no in-vivo drug-drug interaction studies have been conducted between estazolam and inducers of CYP3A it would be expected that concomitant use would decrease estazolam concentrations. Monitor for signs of benzodiazepine clinical effectiveness. Conflict Codes: DD – Drug/Drug Interaction Severity: Moderate Drugs: $\underline{Util A}$ $\underline{Util B}$ $\underline{Util C}$ Estazolam Carbamazepine, Phenobarbital

| <u>ui 7 (</u> | | | <u> </u> |
|---------------|---------------|---------------|----------|
| stazolam | Carbamazepine | Phenobarbital | |
| | Phenytoin | Butalbital | |
| | Rifampin | Butabarbital | |
| | Mephobarbital | Secobarbital | |
| | Pentobarbital | | |

References:

Micromedex Healthcare Series, Drugdex Drug Evaluations, 2004. Prosom Product Information, Jan. 2004, Abbott Laboratories.

21. Celecoxib / Overutilization

Alert Message: A recent clinical trial involving the use of Celebrex (celecoxib) to prevent colon polyps was halted due to an increased risk of cardiovascular (CV) events. Patients taking 400 mg of celecoxib twice a day had a 3.4 times greater risk of CV events compared to placebo and 2.5 times greater for 200 mg twice a day. The FDA is advising that all physicians prescribing celecoxib consider the evolving information in evaluating the risks and benefits for the individual patient. Dosage reduction or alternative therapy may be necessary. Conflict Code: ER - Overutilization

| Diugs | | |
|-----------|---------------|---------------|
| Util A | <u>Util B</u> | <u>Util C</u> |
| Celecoxib | | |

Max Dose: > 400mg

References:

FDA Statement on Halting of a Clinical Trial of the Cox-2 Inhibitor Celebrex, Dec. 17, 2004.

22. Valdecoxib / Therapeutic Appropriateness

 Alert Message: Serious skin reactions have been reported in patients receiving Bextra (valdecoxib). These skin reactions are most likely to occur in the first 2 weeks of treatment, but can occur any time during therapy. In a few cases, these reactions have resulted in death. Valdecoxib should be discontinued at the first appearance of a skin rash, mucosal lesions, or any sign of hypersensitivity. Valdecoxib contains sulfa, and patients with a history of allergic reactions to sulfa may be at a greater risk of skin reactions.

 Conflict Code: TA – Therapeutic Appropriateness

 Severity: Major – Boxed Warning

 Drugs:

 Util A
 Util B

 Valdecoxib

References: Bextra Product Information, Nov. 2004, Pfizer Inc. Medwatch: FDA Safety Information and Adverse Event Reporting Program, 2004.

23. Valdecoxib / Therapeutic Appropriateness

Alert Message: Bextra (valdecoxib) is contraindicated for treatment of postoperative pain immediately following coronary artery bypass graft surgery (CABG). Patients treated with valdecoxib for pain following CABG have a higher risk for cardiovascular/thromboembolic events, deep surgical infections or sternal wound complications. Conflict Code: TA - Therapeutic Appropriateness Severity: Major Drugs: Util A Util B Util C Valdecoxib

References: Bextra Product Information, Nov. 2004, Pfizer Inc. Medwatch: FDA Safety Information and Adverse Event Reporting Program, 2004.