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Governor

STATE OF NEVADA
DEPARTMENT OF HUMAN RESOURCES
DIVISION OF HEALTH CARE FINANCING AND POLICY
NEVADA MEDICAID

MICHAEL J. WILLDEN
Director

CHARLES DUARTE
Administrator

DRUG USE REVIEW (DUR) BOARD

Location of Meeting
Grant Sawyer Building
555 East Washington Avenue – Room 4401
Las Vegas, NV

Meeting Minutes
September 22, 2005

Committee Members Present:
David England, Pharm.D., Chairman
Amy Schwartz, Pharm.D.
Keith Macdonald, R.Ph.
Marjorie Uhalde, MD (called in)
Steven Parker, MD (called in)

Absent:
Lori Winchell, RNP

Others Present:
Vickie Langdon DHCFP, Darrell Faircloth AGO, Jeff Monaghan FHSC, Dawn Daly FHSC, Shirley Hunting FHSC, Chad Wolf Boehringer Ingelheim, Bruce Martz Boehringer Ingelheim, Joe Sirna Alpharma, Steve Schaerrer Astra Zeneca, Mark Lattimore Astra Zeneca, Laurie Squartsoff Eli Lilly, Ed Lewis Pfizer, John Rembold Pfizer, David Abrahamson Merck, Kirk Huffaker Schering-Plough, Sandy Sierawski Pfizer, Nancy Fairchild Sepracor, Alan Sloan Purdue, Roland Baldwin Wyeth, Mary Anne Phillips MD, Joe Duarte Cephalon

I. Call to Order and Roll Call

David England, Chairman, called the meeting to order at 12:20 p.m.

II. *Discussion and Approval of June 30, 2005 Minutes

MOTION: Steven Parker motioned to accept the minutes as written.
SECOND: Amy Schwartz
VOTES: Unanimous
MOTION CARRIED

III. *Proposal by First Health Services and Action by Board on Clinical Prior Authorization Criteria for the Following Drugs and/or Drug Classes:

A. Vytorin®- New Step Therapy Edit

Jeff Monaghan stated that at the July Pharmacy and Therapeutics Committee (P&T) meeting, this class of drugs, Lipotropics, was reviewed and simvastatin/ezetemibe (Vytorin®) was added to the Preferred Drug List. Included in that motion was Vytorin® be referred to the DUR Board for criteria review and adoption. In reviewing the utilization of this drug, some patients are on ezetemibe (Zetia®) and another statin. It's to the State's benefit as well as a convenience for the patient to be on a combination agent, which is Vytorin®. He presented proposed criteria that if a patient is receiving both ezetemibe and a statin or ezetemibe is added to an existing statin regimen, the simvastatin/ezetemibe combination will be required and the single-entity statin discontinued. A system message will prompt the pharmacy that the patient is on individual agents and the physician should be consulted to consider use of the combination product. He clarified that this is a duplicate therapy edit not a step therapy edit. Patients on high dose atorvastatin (Lipitor® 80mg) or rosuvastatin (Crestor® 40mg) will be excluded from this edit.

Amy Schwartz asked if a patient is not on simvastatin but on another statin, will a comparison chart be distributed indicating what the equivalent simvastatin dose would be if they are going to be switched to Vytorin®. Mr. Monaghan stated that a chart can be made available.

Mr. England asked if there have been movements in other states to allow the equivalent of therapeutic interchange in retail community settings as opposed to institutional care. Keith Macdonald said that, at the present time, the therapeutic interchange is not possible; it has to be a bioequivalent exchange.

Dr. Parker asked if there would be a legitimate reason the patient might be on another statin instead of simvastatin. Mr. Monaghan replied that there are PDL exception criteria in place and a patient could be on another statin. If there is record that they are on a non-preferred statin, the edit would be bypassed.

Public Comment

Chairman England announced that public comment will be limited to three minutes.

David Abrahamson, Merck, spoke in support of Vytorin®. He felt the proposed criteria may be confusing to the treating physician and asked the Committee to not apply prior authorization criteria for obtaining this drug.

He felt that Vytorin® should be available as first-line therapy for high-risk patients.

Mr. Monaghan stated that there is no barrier to giving Vytorin®. The edit is not a step-therapy requiring failure of statin mono-therapy. If individual agents are being used, the combination product needs to be considered.

Dr. Parker stated he was okay with this as long as it was a recommendation versus a requirement.

Dave England clarified that this does not inhibit use of the single combination anytime during therapy and Mr. Monaghan stated that is correct.

MOTION: Keith Macdonald motioned to accept the duplicate therapy edit for Vytorin®.
SECOND: Amy Schwartz
VOTES: Unanimous
MOTION CARRIED

B. Crestor®- New Step Therapy Edit

Jeff Monaghan stated that at the July P&T Committee meeting, it was determined to maintain rosuvastatin (Crestor®) on the Preferred Drug List. Previously, there was a 20mg per day dosing limit. The P&T Committee felt that 40mg could be appropriate and is recommending step-therapy be implemented requiring a trial of 20mg before moving to the 40mg strength.

Public Comment
None

MOTION: Keith Macdonald motioned to accept the step therapy edit for Crestor® as presented.
SECOND: Amy Schwartz
VOTES: Unanimous
MOTION CARRIED

C. Spirva®/Combivent®/Atrovent®- Proposal to require a specific diagnosis and apply duplicate therapy edits.

Dawn Daly informed the Committee that only the duplicate therapy edit is being proposed today. It is the recommendation of DHCFP and First Health to allow for only one inhaled anticholinergic or anticholinergic combination. She stated that there is no documentation supporting the use of more than one agent. Spiriva's® package insert states co-adminstration with other anticholinergic-containing drugs has not been studied and

therefore not recommended. She has consulted with Dr. Michael Lucia, Sierra Pulmonary, who supports the use of only one agent stating that it's a waste of resources to use more than one at a time.

Dave England asked if there is an issue of patients using a combination of MDI's or nebulizers. Ms. Daly replied that there are recipients that are on all three types and getting them filled on a monthly basis.

Public Comment

Chad Wolf, Boehringer Ingleheim, spoke in support of Spiriva®. He stated that Spiriva® is a once daily bronchodilator indicated for the long-term maintenance treatment of brochospasms associated with COPD. The use of Spiriva® with other anticholinergic agents as maintenance therapy has not been studied and therefore not recommended. His company supports the use of only one anticholinergic agent at a time.

Dave England asked that if the physician determines a patient is a candidate for long-acting, once a day dosing, yet the patient currently has an order for short-acting, will the pharmacist be prompted to contact the physician to let him know the short-acting will no longer be allowed; i.e., the patient can get one or the other but cannot get them refilled concurrently. Ms. Daly stated that is correct.

MOTION: Amy Schwartz motioned to require and apply the duplicate therapy edit to inhaled anticholinergic agents as presented.
SECOND: Keith Macdonald
VOTES: Unanimous
MOTION CARRIED

IV. *Proposal by First Health Services and Action by Board to Change Early Refill Parameters for Controlled Substances, reducing refill window from six to three days.

Jeff Monaghan stated that the current refill policy is based on an 80% rule. When 80% of the medication has been used in accordance with the day's supply that has been entered by the pharmacy, the refill can occur. This allows the ability to obtain additional doses of medications. The potential for diversion and abuse of controlled substances increases. Many states have tightened the rule for controlled substances, and some states for all medications. It is the recommendation of DHCFP and First Health to apply a 90% rule to controlled substance prescriptions. For a typical 30-day supply, instead of a six-day window, there would be a three-day window on controlled substances.

Dave England asked if this is a problem we're trying to pre-empt or have there been issues or concerns with the abuse and misuse of controlled substances. Mr.

Monaghan stated that what is being done is related to the experience other states have had when they've narrowed this window. Utilization has decreased. He added that there is an early refill override if the patient experiences severe pain and requires a dosage increase. The pharmacy can call the Call Center and get an early refill override.

Dr. Parker asked what happens on a three-day weekend. If the patient runs out of medication on Friday, they can't get the drug until Tuesday. Mr. Monaghan said the pharmacy could call the Call Center, which is available 24 hours per day, seven days per week, and get an early refill override.

Dave England asked what would occur if a patient were started on twice a day dosing and a few days into the month, is moved to three times per day. When the patient takes the new prescription to the pharmacy for q8h instead of q12, how would that scenario work out? Mr. Monaghan stated that the 90% rule would apply. If it doesn't fit the day's supply entered by the pharmacy on the original prescription, it will not allow the drug to be filled without calling the Call Center for an override.

Mr. Monaghan stated that a report on the impact of the early refill override will be presented at the next meeting.

Keith Macdonald asked if patients with chronic pain are on controlled substance maintenance medications and if so, there could be a nine or ten day window with a 100 day supply. Mr. Monaghan stated that narcotics are not included on the list of maintenance medications.

Public Comment
None

MOTION: Keith Macdonald motioned to accept the recommendation to apply the 90% rule to controlled substances as presented.
SECOND: Amy Schwartz
VOTES: Unanimous
MOTION CARRIED

V. *Proposal from First Health Services to Apply/Revise Quantity Limitation Edits on the following:

A. Zomig® Nasal Spray (Creation of new quantity edit)

Jeff Monaghan stated that to keep in line with the current restrictions for anti-migraine medications, it is the recommendation of DHCFP and First Health to apply quantity limitations of 12 units per month to Zomig® Nasal Spray.

MOTION: Keith Macdonald motioned to accept the proposed quantity limitation as presented.

SECOND: Amy Schwartz
VOTES: Unanimous
MOTION CARRIED

B. Kadian® (Revision of existing quantity edit)

Jeff Monaghan stated that Kadian® currently has a dosing limit of one tablet per day. It's FDA approved for up to twice a day dosing. Average daily consumption is 1.7 or 1.8 capsules per day. The current limit is creating a number of calls to the Call Center. It is the recommendation of DHCFP and First Health to expand the quantity limits to two per day.

MOTION: Keith Macdonald motioned for adoption of the amendment as presented.
SECOND: Amy Schwartz
VOTES: Unanimous
MOTION CARRIED

VI. Presentation by First Health Services and Discussion by Board of Prospective Drug Utilization Review (Pro DUR) Reports
- A. Top 50 Drugs Ranked by Payment Amount
- B. Top 10 Therapeutic Classes by Payment Amount
- C. Pro DUR Message Report

Jeff Monaghan presented the ProDUR reports (attached). He stated that the anti-hemophyllic factors have increased significantly in the last year; otherwise, there are no significant changes to report. He added that the categories affected by the Preferred Drug List have had a definite leveling effect in terms of total expenses within those categories.

VII. Presentation by First Health Services of Retrospective Drug Utilization Review Results

Jeff Monaghan presented the results of the RetroDUR for the period 04/05 – 06/05 for Committee review.

VIII. Old Business

A. Update from First Health Services Regarding Implementation of Denials for ProDUR Severity Level One Messages

Jeff Monaghan presented the notification sent to pharmacies regarding the revisions to the prospective drug utilization review denials (attached). Conflict messages related to severity level one denials (drug-drug interaction, early refill, and drug to gender) will require the pharmacist to enter the appropriate intervention and outcome code to override the denial. Due to high volume and feedback from pharmacies, it was determined to

discontinue the denial of non-severity level one categories (high dose, low dose, etc.). The pharmacy will continue to be prompted with messages for non-severity level one categories but will not be required to enter intervention and outcome codes.

B. *Proposal by First Health Services and action by Board to revise existing Prior Authorization edits for Actiq®

This item was on the agenda and discussed at the June 30, 2005 meeting. It was tabled until this meeting for further discussion.

Jeff Monaghan stated that at the June meeting, the proposal was to come in line with the black box warning which appears on the Actiq® product literature. That warning states that "Actiq® is indicated only for the management of breakthrough cancer pain in patients with malignancies already receiving and tolerant to opioid therapy for their underlying persistent cancer pain." The proposal was then and is now that the use of this drug be restricted to the FDA approved indication. In the past, consideration has been given if there is peer reviewed literature which strongly supports the use of any drug beyond the approved labeling. There is not that base of literature to support the use of this drug beyond the black box warning. He recommended restricting the use of this drug to its' approved labeling, and if the Committee felt that they want to use this drug for pain unresponsive to other therapy, consider failure on two other short-acting narcotics for breakthrough pain before approving Actiq®.

Dr. Parker asked if the package insert outside of the black box states only for cancer and no other indication. Mr. Monaghan replied that it states for breakthrough cancer pain only with no other indication and Ms. Daly added that DRUGDEX®, which lists off-label uses, lists it for only breakthrough cancer pain also.

Dave England stated that based on the information he's received, a number of pain clinics are using it on a regular basis rather than for breakthrough pain and patients are getting excessive amounts based on the FDA criteria. That's why this edit is being considered. The discussion in June brought out the point that some physicians are using this for other than breakthrough cancer pain. He stated that he has no issues with off-label use if there is peer reviewed literature to support it. The representative in June didn't appear to have peer reviewed journals or literature that stated it could be used for anything but breakthrough cancer pain. This item was tabled in order to look into this more and it appears that our research has shown there is no literature supporting use other than breakthrough cancer pain.

Public Comment

Joe Duarte, Cephalon, spoke in support of Actiq®. He stated that at the July meeting, he did not recall the motion for this decision to be tabled. He recalled that there was a motion that was entertained by the Board that no second was agreed upon and his understanding is that when a Board cannot second a motion, then the motion did not carry and the edits go to what was decided prior. In addition, this issue has been brought to the Board in June, 2004, and there was discussion about the appropriate use of this drug and again revisited at the last meeting.

Dave England asked Deputy Attorney General Darrell Faircloth if there are issues or has a violation occurred. Mr. Faircloth replied that there is no problem with bringing this item forward again on the agenda.

Dr. Mary Anne Phillips, pain management specialist, stated that her clinical rationale is that pain affects qualify of life and functioning. Treating breakthrough pain is considered standard of care. Actiq® should be used one to four times per day and no more, is convenient for the patient, effective when an ER visit is not possible and cost-effective. She stated that the current criteria of failure of other therapy is an appropriate methodology and one to four units per day is very reasonable. She supports continuation of the current criteria.

Dave England asked Mr. Monaghan if there is an increased use of more than four per day or were the four not being used for the diagnosis of cancer pain.

Mr. Monaghan stated that he received a directive from this Committee to review all of the drugs that had current clinical prior authorization (PA) criteria in place for agents containing black box warnings. In addition to the concern of the over utilization of this drug, the black box warning is being brought to the Committee's attention as directed. He recommended restricting use to breakthrough malignant cancer pain but if the decision is to use it outside the black box warning, he felt there should be failure of other short-acting, breakthrough products first.

MOTION: Keith Macdonald motioned that ActiqÒ can be used for other intractable pain on the basis of breakthrough episodes when two other short-term analgesics have failed. The current quantity limit of four per day will apply.

Dr. Parker asked what the liability to the State might be if the Board makes recommendations outside of the black box. Mr. Faircloth stated that this Committee and the State are not the ones prescribing the medication. We don't have the clinical knowledge that the individual physician has of the patient so it is not our position to oversee at that level

of detail the provision of drugs. Mr. Macdonald agreed stating that this Committee is establishing limitations for the purposes of the program and the limitation, although expanded from the black box, has no bearing on any liability by this Committee.

Amy Schwartz referred to the criteria and asked if a.2. "Diagnosis of pain unresponsive to other therapy", is currently in place. Mr. Monaghan replied no.

SECOND: Marjorie Uhalde
VOTES: Unanimous
MOTION CARRIED

C. Presentation by First Health Services and discussion by Board of Nevada Medicaid Drug Utilization Review Annual Report Federal Fiscal Year 2004 and Executive Summary of Client Report Card

Deferred until the next meeting.

IX. Public Comment

No Comment

X. *Adjourn

The next meeting will be held on December 15, 2005 in northern Nevada.

MOTION: Dr. Parker motioned for adjournment.
SECOND: Amy Schwaratz
Meeting adjourned at 1:40 p.m.