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DIVISION OF HEALTH CARE FINANCING AND POLICY
NEVADA MEDICAID

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DRUG USE REVIEW (DUR) BOARD

Location of Meeting

Las Vegas Chamber of Commerce
Conference Room A/B
3720 Howard Hughes Pkwy.
Las Vegas, NV 89109

Meeting Minutes

March 31, 2005
Time: 1:00 p.m.

Committee Members Present:

David England, Pharm.D., Chairman
Keith Macdonald
Amy Schwartz
Lori Winchell (1:24 p.m.)

Steven Parker, MD (called in 1:09 p.m.)
Marjorie Uhalde, MD (called in 1:13 p.m.)

Others Present:

Coleen Lawrence DHCFP, Vickie Langdon DHCFP, Darrell Faircloth AGO, Jeff Monaghan FHSC, Shirley Hunting FHSC, Katie Johnson FHSC (called in), Ken Grant, MD University of Nevada, Duane Dorsched GSK, Angie Hull Resource Pharmacy, Robert Popovian Pfizer, Dennis Ryan Pfizer, Shawn Prince Elan, Roland Baldwin Wyeth, Laura Squartsoff Eli Lilly & Co., Kathy Yozie Cephalon, Claudia Dodge Pfizer, Kelly Wright Amgen, Kris Drewes Astra Zeneca, Alan Sloan Purdue, Jay Jennings Sanofi-Aventis, Barbee Arthur Spectrum Pharmacy, John A. Palliser BMS, Mike Gardner BMS, Elizabeth Bellocchio BMS, Chris Jensen Lilly, Dr. Upinder Singh Southwest Medical Group.

I. Call to Order and Roll Call

David England, Chairman, called the meeting to order at 1:01 p.m. Roll call was taken.

II. Discussion and Approval of December 16, 2004 Minutes

MOTION: Keith Macdonald motioned to accept the minutes as written.

SECOND: Amy Schwartz

VOTES: Unanimous

MOTION CARRIED.

III. Report on Historical Prior Authorization Request Activity and Approval Rates – First Health Services

Jeff Monaghan presented a report (attached) on historical prior authorization activity and approval rates as requested by the Committee at the last meeting. Approximately 2,000 requests (average 70 calls per day) were received by the Clinical Call Center during the month of February, 2005. Half of the requests involved clinical edits (prior authorization edit); the other half were related to the Preferred Drug List (PDL). Technicians handled two-thirds of incoming calls, approving 75% of the requests and changing therapy in 25%. Pharmacists approved approximately 50% of the requests and changed therapy in 50%. He added that Nevada experiences a higher rate in change of therapy as compared to other states. In many cases, the clinician agrees to use a different drug or use a drug on the PDL. He stated that there has been a significant cost-savings to the State as a result of high volume clinical edits, specifically PPI's and Cox-2 edits.

Dave England said that the reason the report was requested was to determine if the prior authorization process should continue since many authorizations were granted. Based on this report, he felt the prior authorization system is functional and should continue.

IV. 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 – CY2004
- B. Top 10 Therapeutic Classes by Payment Amount – CY2004
- C. Pro DUR Message Report– Nov 04 through Jan 05

Jeff Monaghan presented the ProDUR reports (attached). In comparing the top ten therapeutic classes ranked by payment amount, he noted that the drug classes with significant increases versus the previous year are the analgesic narcotics, antipsychotics, and antihemophilic factors.

Dave England asked how Nevada compares to other states.

Jeff Monaghan stated that in the antipsychotic arena, it's not uncommon in the Medicaid population to see that at or near the top. Although controls are in place, the analgesic narcotic utilization rate in Nevada is high.

Dave England asked if you look at the state based on an aging population, or based on the type of patients on analgesic narcotics, would we compare favorably to states like Florida where there's a higher geriatric population or other states with a high number of retirees.

Jeff Monaghan said that on a per capita basis, Nevada is extremely high.

Keith Macdonald added that according to DEA reports, Nevada has been high for a number of years in hydrocodone utilization as well as other products.

V. Committee Discussion of Recent FDA Public Health Advisory and Resultant FDA Advisory Committee Recommendation Concerning the Use of Non-Steroidal Anti-inflammatory Drug Products (NSAIDs), Including Those Known as COX-2 Selective Agents

Jeff Monaghan reported that on December 23, 2004, the FDA issued a Public Health Advisory recommending limited use of COX-2 inhibitors. Since then, an FDA Advisory panel has met to receive testimony and make recommendations. The panel did not recommend that any of the drugs be withdrawn from the market. The panel did feel that the warnings needed to be considerably strengthened particularly for patients with a history of cardiovascular disease and stroke and felt the drugs should be used at the lowest, safest dose. Mr. Monaghan recommended that the DUR Board review the current prior authorization criteria for COX-2's to determine if any revisions should be made or wait for FDA formal action to determine if a change in the criteria is warranted. He felt the current criteria are somewhat liberal allowing authorization for chronic or acute pain if at least one of the following is present: history of or signs and symptoms of Peptic/Gastric Ulcer Disease, Gastric Esophageal Reflux Disease or gastritis. He also suggested dose optimization or dosing limits could also be reviewed.

Mr. Monaghan noted that COX-2 utilization has decreased by 60% in February 2005 on a per claim basis as compared to usage in August 2004. NSAID utilization is down 5%.

Coleen Lawrence referred to the PA Activity Report which indicates that the clinical prior authorizations (PA) for COX-2's accounted for only 6 PA's (less than 2% of the 50% of PA's approved).

Public Comment

Dr. Ken Grant, Rheumatologist, University of Nevada-School of Medicine, stated that based on the data he saw from the advisory committee meeting, the entire class of NSAIDs and COX-2's are open to some question with regard to cardiovascular risk and felt that long-term studies are needed. He requested the Board wait for the FDA report and perhaps they (FDA) can provide further guidance based on their analysis and proceed from there. He did not feel action was necessary at this point given utilization is down.

Dave England asked Dr. Grant if he is sponsored or has grants from drug companies.

Dr. Grant responded that he is paid by the State and has given lectures with drug companies for years but does not feel beholden to them. He stated that he has no grants from any drug companies.

Robert Popovian, Pfizer, stated that the advisory committee meeting was about the entire NSAID class and not just COX-2's. A final vote of the advisory committee on the question "is there a potential cardiovascular risk with the NSAID class", the answer was "yes" 28-0. When looking at cardiovascular

issues and recommendations for prior authorizations for COX-2's, he felt that the entire NSAID class should be considered. He referred to two studies, the Kaiser Trial and Medi-Cal Trial, citing that in both of those studies, NSAIDs such as ibuprofen and naproxen did much worse than the COX-2 inhibitors did in regard to cardiovascular risk. In lower doses of Celebrex and Bextra, studies have never shown or demonstrated any kind of cardiovascular risk in any of the studies, even the colorectal cancer study that was conducted.

Amy Schwartz asked if there could be a relationship between the increase in narcotic analgesic use and the decrease in COX-2 and NSAIDs utilization.

Jeff Monaghan stated that narcotic use is a historical issue and he felt the increase was not related to the decrease in COX-2 and NSAID use.

Dr. Upinder Singh, Chief of Geriatrics, Southwest Medical Group, stated that he sees patients who are on multiple medications and have diet and GI problems. A large number of patients have stated they would rather have adequate pain relief over the small concerns that COX-2 inhibitors and the other medications may have. Narcotic use in this patient population can cause significant problems such as increased confusion, constipation and hallucination. His concern is that most of the non-specific NSAIDs have not been proven to be any safer than the COX-2 inhibitors from the available data he's reviewed. He stated that if medicine is used within the FDA approved indications, dosage, recommendations and guidelines, the benefits outweigh the risk.

Dave England suggested that questions regarding the patient's past medical history regarding stroke and cardiovascular disease should be added to the PA but not change the current PA process until there are better guidelines issued by the FDA.

Jeff Monaghan asked if this is to be a filter in terms of the approval or denial process and Mr. England stated it was not.

Dr. Parker recommended the question not be limited to COX-2's but mention the entire drug class; e.g., has the physician discussed potential cardiac complications associated with NSAIDs including COX-2's with the patient.

Mr. Monaghan reminded the Board that PA screening is not done on regular NSAIDs only on COX-2's.

Dr. Parker did not want to leave the impression that only COX-2's had potential problems and that NSAIDs are benign. He felt NSAIDs should be included as part of the question as they have cardiac risks as well.

Keith Macdonald stated that because that question has no relevance to the filtering process, the question should not be included.

Mr. England felt it should be a factor to consider even if it's not a level of approval.

Dr. Parker stressed that his concern is patient safety and wants to make patients aware about the medications they are getting. Some discussion should take place between the patient and physician about all drugs they are put on. If the FDA has made a point of moving this to a higher level of awareness, it should be acknowledged.

Jeff Monaghan asked if every black box warning should be looked at.

Mr. England suggested that prior to the statement in the criteria “Authorization will be given if the following criteria are met and documented”, place a “warning” that based on recent information, history of cardiac disease or stroke, length of time on COX-2’s or NSAID’s should be considered but are not part of the criteria.

Dr. Parker said if there is a drug with a black box warning, should we include as part of the criteria “are you aware that the FDA has issued a black box warning with respect to this drug”.

Mr. Monaghan stated that there are some black box warnings that could be clearly incorporated into the clinical criteria.

Lori Winchell stated that the purpose of this committee is to educate providers and felt this might be a useful tool.

Darrell Faircloth stated there is no legal barrier that the physician must certify to you that they have discussed the risk of prescribing that medication.

Coleen Lawrence suggested providing education via a web announcement directing practitioners to the Pharmacy tab which in turn would provide a link to the FDA website for the most current literature for not only these agents but for all drugs.

VI. Committee Action Regarding the Implementation and/or Revision of Prior Authorization Criteria for the Non-Steroidal Anti-inflammatory (NSAIDS) Drug Class, Including Those Known as COX-2 Selective Agents

MOTION: Dr. Parker motioned for the addition of a statement to the prior authorization form to include the FDA’s warning of potential cardiac complications associated with this class of drugs, and that the length of time the patient has been on COX-2’s or NSAIDs, history of cardiac disease and history of stroke be taken into consideration and discussed with the patient prior to prescribing the medication. This is not a barrier to getting the medication if the patient meets the criteria. The reminder would be in the form of a statement for awareness purposes and not in the form of a question.

SECOND: Amy Schwartz

DISCUSSION: Keith Macdonald stated he felt that a precedent is being set and that all future PA reviews for every drug will have to

include this type of statement and therefore he did not support the motion.

Dr. Parker stated that this drug has brought this to our attention. For drugs that require prior authorization, is there other information that should be included and should this be a discussion item for a future meeting and discuss all of them at one time.

Dave England said due to time constraints and to keep to the point we are on, we can consider the review of black box warnings at the next DUR meeting.

Dr. Parker asked for a review of black box warnings for drugs that have prior authorization requirements, how those warnings are currently addressed, and that this item be placed on the agenda for the next meeting.

VOTES: Chairman England called for a roll call vote:

Dave England – Yea

Amy Schwartz – Yea

Steve Parker – Yea

Lori Winchell – Yea – however, would like to wait until FDA recommendations are released before action is taken.

Keith Macdonald – Nay

Marjorie Uhalde - Yea

MOTION CARRIED

VII. Board Discussion and Action on Changing Prior Authorization Process to Allow Pharmacists to Initiate Prior Authorization (PA) Requests

Jeff Monaghan stated that in certain cases, some states allow pharmacists to initiate PA activity. One specific sector of the profession, the long term care arena, has made a good case as the pharmacist has access to charts and patient data.

Coleen Lawrence stated that when Point of Sale was implemented, pharmacists were allowed to start the PA. When policy was changed requiring the physician to initiate the PA, there was positive feedback from pharmacists. There has been no discussion with pharmacists in the state of Nevada or the Retail Association regarding this matter. Information is a key piece of it. Also, looking at what we want to do for the goal of the patient. Is this really delaying patient care? The idea is to have discussion between the physician and Call Center prior to delivery of the drug and discuss patient medical history. There is a lot of change with prior authorizations, not all are approvals. The conversations that are occurring between the Clinical Call Center and the physician are occurring on a clinical level that is keeping within the criteria.

Dave England asked if a patient goes to a retail pharmacy and needs a medication that requires a prior authorization, the pharmacy can or cannot dispense it until it is prior authorized?

Ms. Lawrence responded they cannot.

Mr. England stated that because nothing can take place until the physician's office initiates the PA, patient care is being delayed.

Ms. Lawrence stated that it is the clinical information that we need to be aware of. Does the pharmacy have all the clinical information that the physician should have?

Mr. England said he would like to set a precedence whereby pharmacists are more involved. It will speed up the process if pharmacists have access to patient health information. He added that he did not want to set up two tiers of practice.

Dr. Uhalde stated that there already are two standards. If you see someone in the community, the chart is in the office; if you see someone in a nursing home, the chart is in the nursing home. She said she would be in favor of pharmacists initiating prior authorizations in a nursing home.

Mr. England suggested feedback be obtained from pharmacist and physician healthcare groups and this item be tabled until the next meeting.

VIII. Committee Action to Expand Current PDL Exception Criteria to Include Continuity of Care Considerations for Antidepressant Medication

Jeff Monaghan stated that the Pharmacy & Therapeutics Committee (P&T) has the authority to create the Preferred Drug List and has requested that the DUR Board review and consider adopting a revision to the exception criteria. The P&T Committee does not have the authority to revise the criteria. The concern expressed at the P&T Committee level was patients in acute mental health facilities who are stabilized on a non-preferred antidepressant and then discharged into the community. The P&T Committee is asking the DUR Board to consider revising PDL exception criteria. For those patients discharged from acute mental health facilities on a non-preferred antidepressant, consideration should be given to allow them to continue on the drug they received and responded to in the hospital.

Dave England asked if these facilities are aware that these medications are not going to be covered once the patient is discharged? What's the difference versus an HMO and Medicaid?

Mr. Monaghan stated that part of the problem is the dynamics of different settings and formularies. The incentive for facilities can be different for an inpatient whose medications are not being billed as outpatient prescriptions. In this case, they will have an incentive to buy through their inpatient buying group; i.e., they may be using different medications than what is on the Medicaid Preferred Drug List.

Dr. Parker asked if these patients could get these drugs anyway if they followed existing criteria.

Mr. Monaghan stated they could and read the five existing PDL Exception Criteria. He stated a sixth condition would be added that would allow an exception if the patient was discharged on this medication, stabilized and doing well. A call to the Call Center from the prescriber will be required in order for the PA exception to be granted.

Dr. Parker and Dave England both presented questions regarding why this should be an exception when the exception would not apply in the ambulatory setting.

Mr. Monaghan stated that there seems to be a different degree of illness when someone leaves an acute mental health facility versus what is experienced in ambulatory care where a patient is experiencing a more minor form of depression and is less volatile, less fragile. The practitioners in psychiatry have worked well with the existing criteria and are asking in this case, when there is a fragile, volatile patient stabilized in an acute mental health facility and released into the community, to leave him/her on that medication.

Dr. Parker stated that he has no objection to filling the medication for a month. The psychiatrist would then have to call in the following month and meet one of the five criteria. He did not feel a blanket waive should be given to any of the criteria.

Lori Winchell stated that it could take six to twelve weeks to see a provider and felt authorization should be extended to three months.

MOTION: Dr. Parker made a motion for those patients discharged from acute mental health facilities on a non-preferred antidepressant be allowed to continue on the antidepressant they received and responded to in the hospital for up to 90 days following discharge. After the 90 days, the patient must meet one of the five PDL Exception Criteria.

SECOND: Keith Macdonald

VOTES: Unanimous

MOTION CARRIED

IX. Presentation by First Health Services and Discussion by Board of Retrospective Drug Utilization Review Results

- A. Hydrocodone Compound Dose > 60mg/day
- B. Benzodiazepines Dupe w/Benzodiazepines
- C. Atypical Antipsychotics- Duplicate Therapy w/Atypical Antipsychotics
- D. Zolpidem; Duration of Therapy > 35 Days
- E. Fentanyl (Actiq) > 132 in 30 Days
- F. Cox-2's s/PPI's

Jeff Monaghan presented the results (attached) of the RetroDUR for the period 9/04 through 11/04 and noted that there has been a decrease in Actiq (Fentanyl) utilization since implementation of the 4/day limit edit.

X. Discussion by Board Regarding Areas of Focus for Future RetroDUR

Jeff Monaghan suggested that one area of review could be patients receiving COX-2's and cardiac medications.

Dave England asked what the number of hits is on the web page. He stated he's not in favor of mailings but in favor of on-line information.

Coleen Lawrence stated that Medicaid is primarily using the web. Information is available on the web for billing information and prior authorization guidelines for all provider types and is highly utilized. There is a pharmacy site on both the DHCFP and First Health sites.

The Committee agreed the focus for future RetroDUR should be black box warnings and narcotics.

XI. Old Business

- A. Update from First Health Services Regarding Implementation of Denials for Pro DUR Severity Level One Messages
- B. Discussion by Board Regarding the Limitation of Drug-Drug Interaction Denials
- C. Action by Board Regarding the Limitation of Drug-Drug Interaction Denials

Jeff Monaghan presented a draft letter which notifies pharmacy and IV therapy providers that Severity Level One ProDUR messages will require both intervention and outcome code overrides by the pharmacist. This action was recommended by the DUR Board at the last meeting. The target date for implementation is 6/15/05.

- D. Update from DHCFP Regarding the Dissemination of Informational Materials at Pharmacy Locations

Dave England requested informational flyers or signage be available at community pharmacies advising patients that the process for obtaining medications may take longer than anticipated due to pharmacist review of their medications to ensure appropriate and safe drug therapy. He felt the notification should be from the regulators establishing the criteria and include the rationale for the review process.

Coleen Lawrence stated that she will contact the Retail Association of Nevada regarding the dissemination of notification through pharmacies and that the Medicaid Fact Book for recipients can also be updated to include this message.

Mr. Monaghan will draft verbiage for presentation at the next meeting.

E. Status Report from DHCFP on Implementation of Texas/Nevada Medication Algorithm Plan

Dave England requested the Texas Medication Algorithm Plan be presented at the next meeting for discussion and action.

Mr. England clarified that he is not requesting PA criteria but guidelines for educational purposes.

F. Status Report from DHCFP and First Health Services Regarding Proposed Educational Program

Ms. Lawrence stated that there have been no funding sources identified for this program. At this time, the program is on hold.

XII. Public Comment

No Public Comment.

XIII. Adjourn

MOTION: Keith Macdonald motioned for adjournment.

SECOND: Lori Winchell

Meeting adjourned at 2:21 p.m.