# DRUG USE REVIEW (DUR) BOARD

**Airport Plaza**
**1981 Terminal Way**
**Reno, NV 89502**

## Committee Approved
**Meeting Minutes**
**April 30, 2009**

**Committee Members Present:**
Paul Oesterman, Pharm.D., Chairman
David England, Pharm.D.
William Evans, MD (called-in)
Keith Macdonald, R.Ph.
James Marx, MD (called-in)
Steven Rubin, MD
Chris Shea, Pharm.D.

**Absent:**
Brian Hall, MD

**Others Present:**
Coleen Lawrence-DHCFP, Mary Griffith-DHCFP, Crystal Johnson-DHCFP, Darrell Faircloth-DAG, Jeff Monaghan-FHSC, Dave Wuest-FHSC, Shirley Hunting-FHSC, John Stockton-Genentech, Paul Sparks-Genzyme, Chase Freman-Pfizer, Mike Steelman-Pfizer, Sandy Sierawski-Pfizer, Katie Vargas-Pfizer, Marcus Waite-Pfizer, Laurie Bresnyan-Endo, Bert Johnson-Endo.

**I. Call to Order and Roll Call**

Chairman Oesterman called the meeting to order at 1:00 p.m.

Dr. Marx requested to be excused from the meeting at 2:00 p.m. due to another commitment.

Mr. Oesterman noted that Dr. Rubin joined the meeting at 1:04 p.m.

**II. Discussion and Approval of October 23, 2008 Minutes.**

**MOTION: Keith Macdonald motioned to accept the minutes as presented.**
**SECOND: Dave England**
**VOTES: Unanimous**
**MOTION CARRIED**

Mary Griffith introduced three new board members:

Dr. Brian Hall is a pediatrician practicing in Carson City. He received his post-graduate training at Harbor-UCLA Medical Center and his doctorate of medicine at the University of California, Davis.

Dr. James Marx is board certified in anesthesiology, pain management, addiction medicine and as a medical review officer and is currently practicing in Las Vegas. He received his post-graduate training at the Mayo Clinic in Rochester, Minnesota and his doctorate of medicine at the University of Nebraska.

Dr. William Evans specializes in pediatric cardiology and is also a professor in the Department of Cardiology at the University Of Nevada School Of Medicine. He received his post-graduate training at the Children's Hospital in Los Angeles and received his doctorate at the University of California, Irvine. Dr. Evans currently practices in Las Vegas.

## III. Status Update by DHCFP

### A. Legislative Update

Coleen Lawrence said that the State's budget should be closed next week. The State is requesting that statutory language in reference to the Preferred Drug List (PDL) be changed.

Due to the recent outbreak of the Swine Flu, Ms. Lawrence noted that Relenza® and Tamifu® are covered medications for Nevada Medicaid and Nevada Check-up recipients.

### B. Lock-In Program

Mary Griffith stated that there are currently nine Medicaid recipients in the lock in program. Quarterly reports are reviewed to determine recipients meeting criteria for the program. Comparing second quarter lock-in prescriptions to first quarter prescription history indicates a significant reduction in the number of narcotic prescriptions paid for by Medicaid.

## IV. Status Update by DHCFP and FHSC

### A. July and October DUR Actions

Mary Griffith reported that at the February, 2009 public hearing, Medicaid adopted the July and October, 2008 DUR Board recommendations that included the ICD-9 codes to bypass the prior authorization (PA) requirement for PPIs. Quantity limitations were applied to Fentora® and Actiq®. Criteria were added for psychotropic medications for children 0 through 17 years of age and coverage limitations were added to Lyrica®. There was an issue with the psychotropic medication criteria for anticonvulsants for children. A pediatric neurology group was inundated with calls for PA requests because the ICD-9 code to bypass the PA requirement was not included on the prescription. To alleviate this problem, the system will be coded to bypass the PA requirement for anticonvulsants if the prescriber specialty is neurologist or pediatric neurologist.

## V. Presentation by First Health Services on the Application of Quantity Limits to Narcotic/Acetaminophen Combination Products

Paul Oesterman read the proposed criteria and stated that it's recognized that the limitation of 4gms of acetaminophen per day does have the well documented potential for hepatotoxicity.

Jeff Monaghan said that the State asked First Health to analyze how controls on narcotic analgesics could be expanded. PA requirements and quantity limits are currently in place for transdermal fentanyl (Duragesic®). Quantity limits are also in place for long acting morphine sulfate products, Oxycontin® and on the short acting transdermal fentanyl (Actiq® and the buccal form Fentora®). It is difficult to set quantity limits on narcotic analgesics due to tolerance and dose escalation. What can be defined and action taken on is to tie the narcotics being used to acetaminophen and set limits on acetaminophen to avoid hepatotoxicity.

Dave Wuest presented a three month (September, October & November, 2008) utilization of acetaminophen with narcotic agents. The review is broken down by the amount of acetaminophen in the combination drug, the number of instances, claims, recipients that received over 4gms, number of prescribing physicians and pharmacies. If a recipient had a 3gms per day dose and a prescription came in putting them over the 4gms, it counted as an exception. However, the comparison is only within each category; i.e., recipient taking Percocet® 325mg and adding on another Percocet® 325mg; a 500mg Vicodin® that would be added to the same patient would not hit in this exception. The 325mg and the 500mg combinations are the biggest offenders. He noted that over-the-counter acetaminophen is included in the proposed criteria.

Mr. Oesterman asked about the implementation process. Mr. Wuest replied that the system will accumulate the amount of acetaminophen that's entered over a certain period of time based on the day's supply entered by the pharmacy or a calculated day's supply from the system.

Dave England felt that a possible problem could be range orders. How will a dose of 1-2 q3-4h prn for pain, Vicoden® ES with 750mg acetaminophen be coded? Mr. Oesterman said that most pharmacies will enter the shortest possible day's supply. Mr. Wuest replied that the system can theoretically limit the pharmacy's ability to expand the day's supply to where they are not getting more than 4gms per day. The system will see it as an early refill and the pharmacy will be alerted with a ProDUR message. The coding will be a combination of the day's supply entered by the pharmacy plus what the computer system allows the pharmacy to enter for a day's supply.

Dr. Marx stated that a study was conducted within the last year that showed that anything over 2.5gms a day of acetaminophen can cause significant measurable liver dysfunction. He never prescribes more than 2.5gms per day and will move to a single component opioid if more than 2.5gms is needed. Patients that come to his practice on more than 2.5gms to 3gms per day have elevated liver enzymes. The implication is the patient will be moved to a more expensive opioid but considering the downside of liver dysfunction, it should be taken into consideration. He felt that more than 4gms of acetaminophen per day is too much and did not support that amount in the proposed criteria. He suggested that additional investigation go into the dosing limit.

Dr. Rubin agreed with Dr. Marx but felt that if the dosing range was dropped lower, there will be documentation that the prescribing physician is violating the recommended 2.5gms and that will raise the lawsuit initiative and tighten the noose on doctors. By leaving it at 4gms, the noose will be loosened.

Coleen Lawrence suggested implementing the 4gms per day, collect data, and reevaluate in six months.

**Public Comment**

No comment.

**Discussion and Action by Board on the Application of Quantity Limits to Narcotic/Acetaminophen Combination Products**

**MOTION:** **Dave England motioned to accept the proposed criteria of the 4gms per day limitation as presented and reevaluate in six months.**
**SECOND:** **Keith Macdonald**
**Dr. Marx offered a friendly amendment that if a patient is on 4gms per day of acetaminophen, periodic laboratory tests be required for continuing to prescribe at that level.**
**Mr. England and Mr. Macdonald accepted Dr. Marx's friendly amendment.**
Coleen Lawrence requested clarification on the frequency of lab tests.
Dr. Marx proposed 30 days initially and 90-120 days following that.
Mr. England accepted Dr. Marx's proposal.
Mr. Monaghan asked for clarification if the criteria for lab will override the 4gms.
Dr. Marx replied that it's to allow continuance.
Mr. Monaghan stated the issue is enforcement. We will only be aware of when the physician or pharmacy contacts the call center because the claim denied for exceeding 4gms. At that time, there can be discussion and education and he asked Dr. Marx if this is the point where the call center requests lab work.
Dr. Marx felt that there should be no exceptions or overrides for over 4gms per day.
Mr. Monaghan asked if there are any exception criteria that Dr. Marx would consider and Dr. Marx replied no.
Ms. Lawrence asked at what level up to 4gms should lab values be required.
Dr. Marx personally felt at 2.5gms per day but since that's not the proposal, once the 4gm level is reached, that would be the trigger.
Ms. Lawrence stated that there needs to be a value set in the system to trigger the request.
Mr. Monaghan suggested that the request for lab work not be done at the time the prescription is filled. RetroDUR can be done which identifies recipients receiving 4gms or more per day and letter the

physicians. The letter includes the criteria description, identifies the patient and the recommendation for lab work.
Dr. Marx agreed with the RetroDUR process and recommended the lettering be done at over 2.5gms per day.
Ms. Lawrence added that the RetroDUR process will not impact dispensing of the drug or providing the prescription to the patient and will provide data regarding how many prescribers were lettered.
Mr. Wuest stated that there are acute trauma patients receiving short-course acetaminophen combination therapy and chronic patients that get it continually. He suggested that the RetroDUR criteria define a period of time the patient is taking 2.5gms or more per day.
Dr. Rubin asked if, for example, a patient in on acetaminophen 3gms per day and lab work indicates that the ALTs are elevated, how do you distinguish it's due to the acetaminophen and not the Luvox® or Dilantin, or any drug that can elevate ALTs?
Mr. Oesterman felt that is up to the individual physician. It's a matter of making the physician aware.
Dr. Rubin stated that there seems to be an assumption that the doctors don't know what their doing with medications and that's more liability on the doctors.
Ms. Lawrence felt that it's good public policy to state that there are other ramifications of these medications and that physicians would do a complete profile on the patient and not rely specifically on this policy. This is not a requirement for the physician but awareness that the opportunity is there.
Dr. Rubin stated that works in theory but not in reality. It sets the doctor up for the liability of having ignored the counsel's advice which is great in court. Once again, there is a new policy which says the ALTs are high, it's the acetaminophen. You see narrow vision ruling out all other mitigating factors and creating another restriction on the prescribers.
David England amended his original motion.

**MOTION:** **David England motioned to accept the proposed criteria denying 4gms or more of acetaminophen per day.**
**SECOND:** **Keith Macdonald**
**AYES:** **England, Macdonald, Oesterman, Shea, Marx, Evans**
**NAYES:** **Rubin**
**MOTION CARRIED**

The Board recommended a six month review of narcotic/acetaminophen combination utilization and the generation of physician education letters through the RetroDUR process for recipients receiving greater than 2.5gms of acetaminophen per day. A report will be presented to the Board upon completion of the review.

## VI. Presentation by First Health Services on the Implementation of Clinical Prior Authorization Criteria for Patients Requiring Treatment with Topical Lidocaine Patches

### Public Comment

Laurie Bresnyan-Endo, spoke in support of Lidoderm® patches. She said that in her daily interactions with doctors, they state that Lidoderm® patches are very beneficial for their patients experiencing PHN pain.

### Presentation by First Health Services

Paul Oesterman read the proposed criteria.

Dave Wuest stated a warning letter from the FDA to Endo Pharmaceuticals regarding the Lidoderm® patch and package insert are included in the meeting binder. The proposed criteria directly reflect the package insert indications and quantity limits. Prescriptions transmitted with the appropriate ICD-9 code will bypass the PA process.

Mary Griffith stated that most ICD-9 codes are three digits and the ICD-9 code included in the proposed policy is 53. She asked if this is the ICD-9 for post-herpetic neuralgia. Mr. Wuest replied that the code is 053 through 053.9 and that condition is included in the range.

**Discussion and Action by Board on Clinical Prior Authorization Criteria for Treatment with Topical Lidocaine Patches**

**MOTION: James Marx motioned to accept the proposed criteria as presented.**
**SECOND: David England**
Dr. Rubin asked if there are alternative treatments other than lidocaine patches.
Dr. Marx replied capsaicin is the only other local topical preparation otherwise you're looking at the anticonvulsant type medications or antidepressants which are a systemic approach. He suggested a step edit if the patient fails or cannot tolerate capsaicin, allow the lidoderm.
Dave Wuest said that lidoderm is within the standard of care for first line agents. Dr. Marx agreed.
**AYES: England, Macdonald, Oesterman, Shea, Marx, Evans**
**NAYES: None**
**ABSTAIN: Rubin**
**MOTION CARRIED**

**VII. Presentation by First Health Services on Modification to the Current Clinical Prior Authorization Criteria for Cox-2 Inhibitors to Include Updated FDA Approved Diagnoses and Recently Released Expert Consensus Guidelines**

**Public Comment**

Sandy Siewerski, Pfizer, spoke in support of Celebrex®. Celebrex is the only available Cox-2 Inhibitor. These criteria were put in place in 2005 at a time where there were safety concerns with this class because of cardiovascular safety data with Vioxx®. Since that time, Celebrex® has gone through scrutiny by the FDA who concluded that Celebrex® has cardiovascular safety equivalent to other NSAIDs. Its GI safety is better than other NSAIDs as shown in a number of trials and is safe to use with low-dose aspirin where other NSAIDs are not necessarily recommended. The use of Celebrex® in Nevada Medicaid is low (600 prescriptions per year). She asked the Board to consider if there is a need to have complicated criteria for this medication. She stated that the proposed criteria should include that it is FDA approved for ankylosing spondylitis. She felt that the proposed criteria are too restrictive requiring that all criteria under section b. must be met and requested consideration be given to changing "are" to "or" with some of these criteria depending on the indication and the actual criteria. Section b.2. states that the patient needs documented history of GI bleed or ulceration, etc. The decision to use a Cox-2 Inhibitor should be influenced by the potential to improve the safety profile and patient's risk for a GI toxicity. There are other things that may put a patient at risk such as high dose and felt the risk versus benefit should be considered. The American Pain Society has published guidelines for the management of arthritis pain in which Cox-2 Inhibitors are promoted as first-line therapy over the non-selective NSAIDs. Requiring failure of two other products may not be in the best interest of all patients or all indications and she asked for modification of Section b.3. She stated that in terms of Section b.4, there is a recent white paper by the American College of Rheumatology on the use of selective versus non-selective NSAIDs with low-dose aspirin noting that selective NSAIDs would be preferred. Studies have shown that concomitant use of naproxen or ibuprofen might weaken or limit the cardio protective effects of aspirin. In September, 2006, the FDA *MedWatch* issued a warning that ibuprofen can interfere with the anti-platelet effect of low-dose aspirin and also noted that other non-selective over-the-counter NSAIDs should be viewed as having potential to interfere with the anti-platelet effect of low-dose aspirin unless proven otherwise. Celebrex® is contraindicated in treating perioperative pain and CABG surgery and there is a box warning in the package insert regarding cardiovascular and GI risk. The April, 2005 FDA memo did note that all NSAIDs may have a similar risk and it's not possible to conclude at this point that the Cox-2 selective drugs confer an increased cardiovascular risk over non-selective NSAIDs in chronic use. To encompass all these criteria making it necessary for a patient to receive this product might be excessively restrictive. Celebrex® does provide pain relief and has a similar cardiovascular safety profile with other NSAIDs with an advantage of a better tolerated GI profile. She requested removing or modifying the restrictions allowing the physicians to weigh the risk versus the benefit on an individual patient basis.

Dr. Marx stated that he has no issue with criteria b.1 and that b.2 is appropriate but did not see the concurrency of b.3 and b.2. He disagreed with the cardioprophylaxis with aspirin (b.4) stating that his patients on Celebrex® are also taking aspirin. Criteria b.5, he stated that the relative risks have to be considered; he would not use it on a CABG patient. He did not feel that acute pain was an indication

although Celebrex® does have that indication. He felt the concurrency of all the criteria is excessively onerous and even dangerous in some cases like criteria b.3.

Dave England asked if it would be more acceptable to rank the criteria or after each criterion, put "or" so that all could be considered but not necessarily concurrently. Dr. Marx felt that would be more appropriate.

Dr. Evans asked regarding the financial impact since there would be an increase in prescriptions (Celebrex®).

Jeff Monaghan asked for clarification regarding discussion of cost and Darrell Faircloth stated that there are no restrictions with discussing cost in this sort of matter.

Mr. Monaghan replied to Dr. Evans that the product is significantly more expensive than a generic NSAID but he does not have the financial data available at this meeting.

**Presentation by First Health Services**

Jeff Monaghan said that in July, 2008, Pfizer approached First Health stating that Celebrex® has a new indication and that the drug can be given with low-dose aspirin. Celebrex® does have the new indication for juvenile RA which was added to the proposed criteria. The criteria were also modified to state that if the patient is being treated with low-dose aspirin and protective PPI therapy, a Cox-2 can be given. He suggested the proposed criteria could be modified to state that "one of the following criteria must be met" and suggested those criteria be 1) the patient has history of GI bleeding, ulceration, etc., potential for GI toxicity noting that the patient should also be receiving protective PPI therapy; 2) concurrent use of oral corticosteroids or anticoagulants with a note recommending that the patient be receiving protective PPI therapy; 3) therapeutic trial and failure of a minimum of two different non-Cox-2 NSAIDs. In terms of the limitations, no history of allergies to sulfonamides, aspirin or other NSAIDs; allow for patients being treated with daily aspirin therapy if also receiving a PPI. He stated that he is hesitant to lessen b.5 (patient does not have a documented history of cardiac events). The American Heart Association in 2007 updated their pain management recommendations for patients with unstable angina or MI. These guidelines clearly indicate that the Cox-2s have the potential for cardiac toxicity, especially at higher doses, and recommend a trial of non-selective NSAIDs before Cox-2s.

**Discussion and Action by Board on the Review of the Clinical Prior Authorization Criteria for Cox-2 Inhibitors**

Dr. Marx felt that criterion b.2, "…documented history of gastrointestinal bleeding, ulceration, or perforation…" should be expanded to include some other GI criteria that might make the patient more likely to ulceration noting that he had a patient on PPIs who could not tolerate conventional non-steroidals. He recommended the criterion be modified to include a GI condition that would predispose a patient to a higher complication and Mr. Monaghan suggested adding "not relieved with concomitant PPI therapy". Dr. Marx agreed.

Dave England asked if there are ICD-9 codes that could be included in these criteria and Mr. Monaghan replied that First Health will check.

Mr. Oesterman recommended, based on this discussion, the criteria be modified and presented at the next meeting.

**MOTION: Keith Macdonald motioned to table this agenda item until the next meeting.**
**SECOND: David England**
**VOTES: Unanimous**
**MOTION CARRIED**

Dr. Marx excused himself from the meeting at 2:07 p.m.

**VIII. Presentation by First Health Services on the Utilization of Cough and Cold Medications in Children per Recent FDA Public Health Advisory**

Dave Wuest stated that in October, 2008, the FDA issued a statement on the use of cough and cold medications in children under the age of four. He presented data (reporting period 10/1/07 through 9/30/08) which, overall, indicates low utilization of these products within that age group. The data includes legend and over-the-counter medications.

**Public Comment**

No comment.

**Discussion by Board on the Utilization of Cough and Cold Medication in Children per Recent FDA Public Health Advisory**

Paul Oesterman said that he was involved in submitting documentation to the FDA hearings. The concern was that parents of these children under the age of four were replicating the active ingredients. One of the prime active ingredients is acetaminophen. Is there any data that has acetaminophen content for children that are getting non-prescription products? Mr. Wuest replied that detail can be presented at a future meeting, if requested. In the chart presented, those products are indicated in the third, fourth and fifth categories as non-narcotics which make up nineteen prescriptions for the reporting period. The data indicates low utilization.

Ms. Lawrence pointed out that Medicaid fee-for-service covers the aged, blind and disabled population. The majority of children are in the TANF and CHAP which falls under the managed care HMOs so the number is small in this population.

The data was presented for Board information. No action was required.

Dr. Marx rejoined the meeting at 2:ll p.m. (called in).

**IX. 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 drug utilization reports for calendar year 2008 and the first quarter of 2009. He referred to the top 50 drugs ranked by payment amount noting that four of the top five continue to be antipsychotics. The impact of the new PA criteria adopted in October 2008 by the Board for this drug class will be tracked. There is shifting in the antipsychotic market. Abilify® is the most highly ranked medication in the last calendar year based on cost. Drugs like risperidone that are now available generically do not get promoted and utilization decreases. He referred to the "Top 10 Therapeutic Classes Ranked by Payment Amount" graph which indicates that there is a dramatic increase in the H7T drug class (antipsychotics). He noted that in the antihemophilic factors, one or two patients can highly increase utilization. Drugs to treat MS are also rising. There is also an increase in insulin utilization particularly the designer insulins which are very expensive. He stated that a report of the top 50 drugs ranked by claim count can be generated and noted that the number one ranked drug is Vicoden® (acetaminophen/hydrocodone) which is not unique to Nevada Medicaid.

Mr. Monaghan referred to the ProDUR message report stating that the mix remains fairly constant.

Dr. Marx stated that he has a major concern regarding fentanyl citrate. It appears the oral form is grossly over utilized. Mr. Monaghan replied that more restrictive PA criteria have been approved by this Board and implemented. A high level review indicates that the impact has not been as great as expected. Data will be presented at the next meeting.

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

Results for calendar year 2008 and first quarter 2009 were included in the meeting binder for Board review.

## XI. Public Comment

Coleen Lawrence reported that in July, 2008, the State of Nevada contracted with a care management company. The web link for this program is silverstatewellness.com. The purpose is to care manage some of the high cost/high utilizer fee-for-service recipients. The State has contracted with APS Healthcare. APS is in each hospital working in the emergency room assisting with diversion, discharge planning, etc. APS finds alternate services and addresses issues such as linking Medicaid recipients with primary care physicians and medication monitoring. Their contract is a complete performance based contract which is a benefit for the State. Anyone can refer recipients to this program at no cost.

Paul Oesterman said that there was a notation in the October 23, 2008, minutes that a six month follow-up report on Lyrica® utilization will be presented at a future meeting. Mr. Monaghan stated that report will be presented at the next meeting.

## XII. Date and Location of Next Meeting

The next meeting is scheduled for July 23, 2009, in Las Vegas. Chairman Oesterman stated that he has a conflict on that date. Ms. Griffith will contact the Board regarding an alternate date.

## XIII. Adjourn

Chairman Oesterman adjourned the meeting at 2:24p.m.