



JIM GIBBONS
Governor

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

MICHAEL J. WILLDEN
Director

CHARLES DUARTE
Administrator

DRUG USE REVIEW (DUR) BOARD

Las Vegas Chamber of Commerce
6671 Las Vegas Boulevard, Suite 300
Las Vegas, Nevada

Meeting Minutes
July 30, 2009

Committee Members Present:

Paul Oesterman, Pharm.D., Chairman
David England, Pharm.D.
William Evans, MD
Brian Hall, MD (called-in)
Keith Macdonald, R.Ph.
James Marx, MD

Absent:

Steven Rubin, MD
Chris Shea, Pharm.D.

Others Present:

Mary Griffith-DHCFP, Gabriel Lither-DAG, Jeff Monaghan-FHSC, Dave Wuest-FHSC, Shirley Hunting-FHSC, Helen Liau-Lilly, Joe Busby-Lilly, Chris Jensen-Lilly, Adam Shprecler-Schering, Isam Herndon-GSK, Kenneth Grant, MD-UNR School of Medicine, M. Steelman-Pfizer, Roy Palmer-Pfizer, Doug Powell-Forest, Anoon Pazzaforest, Mike Pinocci-Pfizer, Kirk Huffaker, Schering Plough, Chase (last name illegible)-Pfizer, Kim Bohannan-PCARE, Dan Bay-Abbott, Bill (last name illegible)-CHC, Laura Litzenberger-Ortho McNeil Janssen, David Lindquist-Ortho McNeil Janssen, Lori Howarth-Bayer, Chris Almeida-Purdue, Kara Thorsfoldt-Cephalon.

I. Call to Order and Roll Call

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

He announced that Item X. Presentation by First Health Services on Proposed Changes to the Clinical Prior Authorization Criteria for Cox-2 Inhibitors will be moved to the fifth order of business and Item XI. Presentation by First Health Services on Proposed Clinical Prior Authorization Criteria for Savella® will be deferred to the next meeting at the request of Dr. Steven Rubin who is unable to attend today.

II. Discussion and Approval of April 30, 2009 Minutes

MOTION: James Marx motioned to accept the minutes as presented.
SECOND: Keith Macdonald
VOTES: Unanimous
MOTION CARRIED

III. Status Update by DHCFP

New Member

Mary Griffith stated that new board member, Chris Shea, Pharm.D., is unable to attend today. He previously served on the Pharmacy and Therapeutics Committee (P&T) for many years as well as several other medical advisory committees. He received his doctorate at Idaho University and is certified in geriatric pharmacy.

Darrell Faircloth, DAG, has new responsibilities with the Attorney General's Office and his role within Medicaid will decrease. She welcomed Gabriel Lither, DAG, who will be replacing Mr. Faircloth during the transition period.

Mary Griffith announced that she has accepted another position within Medicaid and this will be her last meeting. Board members can contact Crystal Johnson for any assistance.

On behalf of the Board, Paul Oesterman thanked Mary for all of her past and present work.

IV. Nevada Medicaid Drug Utilization Review Annual Report Federal Fiscal Year 2008

Presentation by First Health Services of the Nevada Medicaid Drug Utilization Review Annual Report

Jeff Monaghan presented an overview of the Nevada Medicaid Drug Utilization Review (DUR) Report for Federal Fiscal Year 2008. The annual report is a summarization of drug utilization review, outcomes, cost savings, number of prospective drug utilization (ProDUR) alerts experienced, retrospective drug utilization review (RetroDUR) intervention statistics and DUR Board activity. The report is prepared by First Health and submitted to DHCFP for review, approval and submission to CMS. States are required by the federal government to submit this report annually.

Section VII. Summary of Drug Use Review Board Actions outlines Board actions taken and new clinical edits put in place in FFY 2008, which include implementation of the medically unbelievable edit for the erythropoiesis stimulating protein drug class which limits unnecessary over utilization; growth hormone prior authorization criteria; the Lock-In Program, poly-pharmacy retrospective drug utilization review project; implementation of the tamper-resistant mandate from CMS; prescriber-specialty exception for Attention Deficit Disorder prior authorizations; revision of the prior authorization criteria for proton pump inhibitors; and adoption of more stringent prior authorization criteria for transmucosal narcotic lozenges and buccal tablets.

Section VIII. Summary of Accomplishments: There was an estimated \$27,147,261 in ProDUR cost avoidance and an estimated \$133,904 in RetroDUR cost avoidance. Overall payment increased 7.8%, which was primarily driven by a 5.6% increase in utilizing recipients.

Other accomplishments include implementation of e-prescribing; a system change which allows for the capturing and payment of outpatient administered drugs based on National Drug Codes (NDC) to comply with the Medicare Modernization Act; full implementation of the National Provider Identification Program (NPI) which has also improved the identification of physicians through the RetroDUR process.

Discussion and Action by Board to Approve Nevada Medicaid Drug Utilization Review Annual Report

Paul Oesterman asked if there are any significant changes compared to last year's report.

Jeff Monaghan replied that there was a fairly significant rise in generic drug utilization which was in the low 60% range and is now at 72%. He stated that three to four years ago, drug costs for Nevada Medicaid were rising rapidly and are now flattening and credited the Board, the P&T Committee and the State for that moderation.

Dave Wuest added that one change in drug costs for the top ten therapeutic classes is the addition of the insulin class which was not previously in the top ten. Jeff Monaghan added that the new "designer insulins" are driving the cost increase.

MOTION: David England motioned to approve the Nevada Medicaid Drug Utilization Review Annual Report for Federal Fiscal Year 2008 as presented.

SECOND: James Marx

VOTES: Unanimous

MOTION CARRIED

V. Update by First Health Services on the Utilization of Psychotropic Medications in Children and Adolescents

Jeff Monaghan stated that the policy approved by this Board went into effect on April 15, 2009. Currently, there is not enough data available to provide a meaningful report, but data is continuing to be collected and the impact of this change will be presented at a future meeting. Inservices have been conducted with the major psychiatric groups.

Public Comment

No comment.

Discussion by Board

Paul Oesterman thanked First Health for the update and stated that this item will be deferred until further data is available.

VI. Update by First Health Services on the Utilization of Oral Fentanyl

Dave Wuest stated that in July 2008, the Board reviewed the utilization of oral fentanyl and adopted criteria which restricted approval for use to the FDA indication of malignant cancer. He referred to the utilization reports which were presented at that meeting (reporting period 7/1/07 through 6/30/08) which indicated that fentanyl prescriptions were not being written by oncologists. Once the policy was in place, First Health worked with individual recipients and prescribers on a beneficial treatment plan for affected recipients.

At the time the edit went into effect, thirty-one recipients were receiving oral fentanyl. Since that time, ten of the thirty-one patients continue to have a PA in place which was approved prior to the effective date of the edit. Nineteen of the thirty-one recipients have had their PA expire and re-reviewed by the Clinical Call Center for proper indication. All were denied because they did not meet criteria. Two recipients had the proper indication and continue to be on the medication.

He presented data comparing first quarter 2008 utilization and cost to first quarter 2009, and noted the decrease in first quarter 2009, which is expected to continue to trend down.

Public Comment

No comment.

Discussion by Board

Dr. Marx commented that the data is staggering when only two patients out of thirty-one had a legitimate indication with approximately \$1.7 million in payment over the reporting period. The cost savings will be significant.

VII. Update by First Health Services on the Utilization of Levaquin®.

Paul Oesterman stated that this item is being presented for informational purposes only.

Dave Wuest reported that the P&T Committee added Levaquin® to the Preferred Drug List (PDL) with the stipulation that it be limited to a five day supply per prescription. He presented flouoroquinolone utilization comparing February, March, and April, 2008 to the same period in 2009. Levaquin® average days supply increased 18.7% with no significant change in Avelox® and ciprofloxacin. Because this change may continue to impact utilization, updates will be presented to the Board for possible future action. DHCFP and First Health will not be recommending action at this time.

Public Comment

No comment.

Discussion and Action by Board on Quantity Limitation Criteria for Levaquin®

No action required at this time. An updated report will be presented in six months.

VIII. Presentation by First Health Services on the Current Clinical Prior Authorization Criteria and Quantity Limitations for all Narcotic Classes

Jeff Monaghan stated that this item is being presented at the request of DHCFP. He summarized the narcotic edits: Duragesic®, fentanyl citrate buccal tablet and lozenges (Fentora® and Actiq®) currently have clinical criteria in place; Schedule II long-acting narcotics currently have quantity limits in place. He noted that these edits are in line with most other states.

Public Comment

No comment.

Discussion and Action by Board on the Clinical Prior Authorization Criteria and Quantity Limitations for all Narcotic Classes

Dr. Marx requested each criteria be addressed individually for discussion.

Duragesic® (fentanyl transdermal) Patches

Jeff Monaghan stated that Duragesic® is indicated for chronic pain in patients requiring continuous opioid analgesia that cannot be managed by lesser means such as the short-acting opioids. Dosing interval is one patch every three days; may be dosed every two days if failure to achieve pain relief is documented and provided to the Clinical Call Center. Authorization will be granted for up to six months.

Dave England asked if the criteria is in line with the black box warning. Jeff Monaghan replied the basis of the criteria is formed based on the black box warning.

Dr. Marx asked if there an edit to ensure that the patient is opioid tolerant. Jeff Monaghan responded that the request for authorization requires a discussion with the Clinical Call Center at which time that question would be asked. The Call Center has access to the patient's drug profile and are able to see the drugs the patient has been and is currently taking. Dr. Marx suggested the way to codify it would be to get it down to a minimum morphine-equivalent dose in order for criteria to be easily administered.

Dave England said that the criteria he is familiar with is an equivalent dose of 60mg of morphine per day for a minimum of seven days. Dr. Marx felt that was a reasonable number adding that most patients will develop a tolerance to respiratory depression within three or four days allowing for a good margin of safety.

Dr. Marx commented on section b. of the additional guidelines which states "Do not authorize if on long-acting narcotics." There are patients that do require fentanyl as a basal analgesic and may require additional oral opiates particularly if they have been on analgesics for a long period of time. From an expense standpoint, to get the full daily opioid equivalent, you wouldn't want to use fentanyl for their entire opioid requirement. Many patients are on 100mg to 300mg of long-acting morphine over the course of a day in addition to 100mcg to 200mcg fentanyl patches per day.

Dave England suggested for this type of use, require the prescriber to be a specialist; i.e., anesthesiologist or pain management specialist.

Dr. Marx stated that the objective is to get pain management down to the primary care level. If the patient requires a higher dose, there should be a specialist referral or consultation; have the specialist do the prior authorization and the patient can go back to the primary care physician for continuing prescriptions.

Jeff Monaghan said that the exception for long-acting narcotics will be included in the criteria and handled at the call center level.

Fentanyl Citrate Buccal Tablet and Lozenge (Fentora® and Actiq®)

Dave Wuest stated the quantity of 120 tablets or lozenges per 30 rolling days is higher than most other states are allowing; most were 60 or less.

Keith Macdonald pointed out that per the report of fentanyl utilization presented earlier, only two recipients are currently authorized for this medication and asked if these two recipients require 120 per month. Dave Wuest will follow-up.

Jeff Monaghan commented that when a patient is put on this medication, they quickly ascend to the four per day. Dr. Marx felt that four per day is not excessive and illegitimate usage will be cut by the existing edits.

The Board agreed that due to low utilization, modifications to this criteria are not necessary at this time.

Long-Acting Narcotics

Jeff Monaghan presented a table of the current quantity limits for long-acting narcotics.

Dr. Marx asked if the three per day maximum for Oxycontin® (oxycodone time-release) is subject to override. He commented that the branded extended-release forms are pricey and that most patients can be managed on the less costly extended-release morphine.

Jeff Monaghan stated that there has rarely been a request to increase the quantity; requests have been to increase up to the maximum strength. Currently, there are only quantity limitations in place. To Dr. Marx's point, before authorizing oxycodone, perhaps a trial of extended-release morphine should be required. Dr. Marx felt that it's a reasonable requirement and will result in significant cost savings.

Paul Oesterman stated that many of these narcotics contain acetaminophen and asked if the 4gm per day limitation should be considered. At the last meeting, the Board moved to deny 4gms or more of acetaminophen per day.

Jeff Monaghan said that the coding is complex and extensive and First Health is continuing to analyze the best way to accomplish the edit.

Dr. Marx stated that over-utilization of acetaminophen is the number one cause of liver failure leading to liver transplant. He felt that the maximum dose should be 2.5gm per day for chronic users.

Jeff Monaghan said that it appears from the FDA hearings, they may settle at 3gm or 3.2gm per day.

Paul Oesterman felt that that quantity limits to narcotic/acetaminophen combination products should be revisited by the Board and be included on the next agenda.

MOTION: James Marx motioned that a morphine equivalent dose of 60mg of morphine per day for seven days will be the prerequisite to meet the criteria for the fentanyl patch (Duragesic®); long-acting narcotics will be authorized if a pain management consult has been obtained; a trial of long-acting morphine will be required to meet the criteria for Oxycontin®.

SECOND: David England

VOTES: Unanimous

MOTION CARRIED

IX. Presentation by First Health Services on Proposed Changes for Prescriptions with a “Dispense as Written” Designation by a Practitioner

Jeff Monaghan presented a report of prescriptions transmitted with practitioner dispense as written (DAW) fill counts for reporting period 5/1/08 through 4/30/09. DAW, under Nevada law, is a physician writing "dispense as written" on the prescription. Though Nevada is a mandatory generic state, the DAW indicates to the pharmacy that the physician is requesting that brand only be used. The extent of the use of DAW is extremely high and the fiscal impact is in the hundreds of thousands of dollars. Nevada has a "Maximum

Allowable Cost" (MAC) program with multi-source drugs, where a maximum unit cost is established based on market sampling. When a DAW1 is invoked, it overrides MAC pricing and pays at average wholesale price (AWP) which is much higher than the MAC price. Nevada is one of the only states that does not require a PA approval process for DAW1. Dave Wuest added that the DAW1 use is a widespread practice.

Gabriel Lither stated that Chapter 1200 of the Medicaid Services Manual has a provision for being able to do the DAW and policies related to that. To the extent that changes are proposed, he suggested they be presented as recommendations to DHCFP for incorporation to the policy.

Public Comment

No comment.

Discussion and Action by Board on Changes Regarding Prescriptions with a Dispense as Written Designation by a Practitioner

Keith Macdonald referred to subsection 4. of NRS 639.2583, which specifically states "...the pharmacist shall dispense the drug prescribed by brand name, unless the pharmacist is being paid for the drug by a governmental agency, in which case the pharmacist shall dispense the drug in substitution." He added that was the intent of the legislator that proposed this legislation, in part, due to cost constraints and concerns at that time. This suggests that Medicaid prescriptions should be a generic drug.

Gabriel Lither stated that in reading the entire statute as well as the policy and the history of what's occurred, DAW has been allowed by Nevada Medicaid. There are situations where a dispense as written is necessary. He felt it's not the legislature's intent to do something that is contraindicated to what would be medically necessary.

Dr. Evans felt that there was no reason why Nevada, in terms of this era of cost containment, should not have a PA system for DAW for a specific brand. He always informs patients that they will likely get a generic version which will be less costly.

Keith Macdonald commented on the complaints related to the variability of generic drugs. Dr. Marx said that there was a recent study on levothyroxine showing a 40% to 50% variability between the various generic brands. There are a tremendous number of variables that go into the bioequivalency of these drugs.

Dave England said the policy in the Medicaid Manual states that the physician can certify the need for brand name by indicating "dispense as written" rather than document a treatment failure. There is an incongruency between the Medicaid Manual and the state law. He suggested the policy include certification must be documented by a treatment failure before the DAW can be overridden.

Jeff Monaghan said that some states require a Med Watch form be completed which is a product problem or defect report when a request for brand is made.

Paul Oesterman stated that there are a number of different products on the list some of which have a narrow therapeutic index which is an area of concern due to the variability in the amount of active ingredient, release rate, etc. With other products, there is not a significant difference particularly with the products on the report with a fill count in excessive of 3,400, the narcotic analgesics. He felt that a PA process should be implemented when a brand medically necessary is required. As suggested by First Health, the Med Watch form is being used by other states and appears to be fairly effective in limiting the amount of patients unnecessarily receiving brand name products. He proposed the implementation of a PA process for those products that do not have a narrow therapeutic index.

Point of clarification from Mary Griffith that the Med Watch form cannot be monitored by the State for submission by the physician to the FDA.

Dr. Marx commented that the issue with that is that the analgesics have a fairly narrow therapeutic index so it doesn't help with the "frequent flyers" so the problem remains.

Jeff Monaghan stated that if someone is stabilized on a generic, we cannot control if they are switched to a different generic which is common practice.

Dave England questioned if the Medicaid Manual and statute could include that the physician could request a particular generic brand product be dispensed but not specify a brand name per se. Jeff Monaghan responded that cannot be enforced at the payer level. Keith Macdonald added that another problem is that chain stores negotiate for the best price, will stock that product and there is no opportunity for the pharmacist to change the drug from what has been provided by the chain operation.

Jeff Monaghan stated that product variability can be seen in brands as well as generics.

Paul Oesterman suggested that the other option is to have a blanket policy that any DAW has a PA requirement.

Dr. Evans was excused from the meeting at 2:49 p.m.

MOTION: David England motioned that a recommendation be made to DHCFP to amend Section 1203.1.B.d of the Medicaid Services manual to state that the prescriber will be required to provide a documented adverse event in order for the brand name product to be prior authorized.

SECOND: Keith Macdonald

Dr. Marx asked what the impact will be in terms of review of the adverse events. One class of drugs alone has over 3,400 cases.

Jeff Monaghan predicted that the numbers will drop precipitously with the implementation of this policy. He commented that the term "documented adverse event" may be unclear. The Med Watch form contains the documentation and will be required to be faxed to the call center.

David England offered a friendly amendment that the documented adverse event is documented on the Med Watch form and faxed to the call center.

Paul Oesterman accepted the friendly amendment.

VOTES: Unanimous

MOTION CARRIED

X. Presentation by First Health Services on Proposed Changes to the Clinical Prior Authorization Criteria for Cox-2 Inhibitors

Public Comment

Ken Grant, MD, is a rheumatologist for the UNR School of Medicine and University Medical Center clinics. He stated that Celebrex® has been around for a long time and most practitioners have a good sense of that particular medication and he doesn't have a problem using it for the FDA-approved indications. He said it is important to be able to use the medication in cases where there are treatment failures with other non-steroidals and felt that a proton pump inhibitor (PPI) does not need to be associated with that treatment failure. Using it for patients on aspirin therapy for cardiovascular illnesses would be a useful tool because it seems that it would not block the cardio-protective effect of aspirin. For patients on cardio-protective aspirin who meet the criteria for FDA-approved indications, this would be a useful alternative. He did not support if someone takes Celebrex®, a PPI would have to be used with it. In cases of previous GI bleeding, it might be a reasonable concern but the decision should be left up to the practitioner. Literature suggests that if a PPI is used, GI risk can be reduced to almost zero in that situation.

Dr. Marx stated that he had spoken with Dr. Grant and one of the concerns is under criteria 1.b.1. There may be some reason to include an additional indication addressing patients that have an underlying gastrointestinal disease which might predispose them to a higher instance of complications; e.g., GI hypomotility issues.

Jeff Monaghan asked regarding 1.b.1, if Dr. Grant would prefer a Cox-2 versus a non-selective NSAID with a PPI for that patient population. Dr. Grant responded that if the patient has a documented history of GI bleeding, ulceration or perforation of the stomach, from his experience, a Cox-2 is preferable. One area of interest is the protection of the entire GI tract and suggested consideration be given to adding

misoprostol as an alternative to a PPI. Misoprostol protects the entire GI tract whereas a PPI only protects the stomach.

Dr. Grant commented that in terms of the use of generics for rheumatoid arthritis, there are problems with the testing of some competing generic products. There are increased doctor visits for patients going out of control because one particular generic was switched for another and is not effective. Is there any way to determine if the generic products for a given drug are all therapeutically equivalent. Paul Oesterman stated that this will be discussed when the DAW component is addressed.

Roy Palmer, Pfizer, spoke in support of Celebrex®. He stated that Celebrex® is indicated for ankylosing spondylitis which was not included in section 1.a of the criteria and that degenerative joint disease, which is included, is not an approved indication for Celebrex®. Regarding the exclusionary criteria addressing cardiovascular risk and disease (section 2.b. and 2.c.), Celebrex® doesn't interfere with the anti-platelet activity of low dose aspirin and they may be used together. There may be an increased risk in GI events using these agents in combination but that's a benefit/risk calculation that the patient and physician can decide. All NSAIDs can lead to an increase in cardiovascular risk particularly in patients with existing cardiovascular disease. The available evidence does not suggest that the Cox-2 inhibitors and Celebrex® are any worse in this regard than other NSAIDs. That was the conclusion of the FDA, the American College of Rheumatology as well as others who reviewed it. The American Heart Association panel allows for the use of Celebrex® in patients who have tried and failed on non-selective NSAIDs. He respectfully requested consideration be given to removing the cardiovascular criteria. He added that there is some evidence that suggest PPIs are beneficial but when the FDA reviewed the data, they found that the evidence was not sufficient to draw a firm conclusion that PPIs should be given in combination with NSAIDs.

Dr. Evans said that speaking as a pediatric specialist and for all practitioners in the state who have had reimbursement reduced for sound clinically indicated tests and procedures, of course Pfizer would like to have this approved to increase the sale of their drug. He understands from a rheumatology standpoint that there are clinical indications but there are clinical indications for other things in which reimbursement has been reduced. His only concern is that any of these changes would increase costs because he felt that consideration is one of this Board's functions.

Dave England said that in terms of the PPI issue, he would rather have the patient on a PPI and avoid a GI bleed rather than wait for it to occur; be proactive rather than retroactive. Maybe all patients on Cox-2s do not need to be on a PPI. Is there a specific patient class that may need a PPI?

Presentation by First Health Services

Jeff Monaghan said that based on the discussion from the last meeting, the Board requested First Health provide clarity to the proposed criteria and bring back for Board review. He spoke to the comments made by the Pfizer representative regarding cardiovascular risk. He referred to the AHA Scientific Statement on the "Use of Nonsteroidal Antiinflammatory Drugs" (included in the meeting binder) which clearly indicates that Cox-2s carry a different cardiovascular risk than others. In terms of PPIs, the data shows that if there is chronic use of NSAIDs, the patient should be receiving some kind of protective therapy. Misoprostol would be fine, but PPIs appear to be the choice for most. He referred to the expert consensus document by the American College of Cardiology, the American College of Gastroenterology and the American Heart Association regarding GI risks of antiplatelet therapy and NSAID use. They are recommending that even with Celebrex®, aspirin use in a high risk patient should include PPI therapy.

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

The proposed criteria will be modified as follows:

1.a.

- Add diagnosis of ankylosing spondylitis

- Remove "degenerative joint disease".

Dr. Marx felt that the diagnosis of osteoarthritis encompasses most degenerative joint disease.

1.b.1.

- Change "Patient should also be receiving protective PPI therapy" to "PPI therapy or misoprostol should be considered."

Dr. Marx felt that there may be GI situations that aren't necessarily hemorrhagic and suggested including "other indications by the prescribing physician." Other criteria could be opened up on the basis of a prior authorization request for justification. Regarding PPI therapy, there are reasons not to give PPIs in some patients including side effects such as impaired calcium absorption and higher incidence of GI infections. Misoprostol is a good alternative. The use of either a PPI and/or misoprostol should be on a selective basis and if required, he felt another PA should not be required.

1.b.2.

Dr. Marx felt PPI therapy is a binding indication with the use of oral corticosteroids or anticoagulants and should not be eliminated, but he did not know the evidence of misoprostol use in this case. Jeff Monaghan stated that he will research misoprostol and if it's indicated, it will be added to this criterion.

1.b.3

- Add "adverse event": "Therapeutic trial and failure or adverse event on a minimum of two (2) different non-Cox-2 NSAIDS."

Jeff Monaghan clarified that "failure" refers to patient response to a particular NSAID. Dr. Marx felt that there should be some allowance for side effects.

1.b.4.

- Modify to state: "PPI therapy or misoprostol and low-dose aspirin should be considered

Dr. Marx felt that patients over 65 should be on low-dose aspirin for cardiac protection as well as a PPI or misoprostol.

2.b.

Remove. Addressed in 1.b.4.

3.

- Initial Coverage Period: After "FAP 400mg BID", remove "for 6 months initially, then one year."
Remove "other" from "All other indications: 1 year."

Jeff Monaghan clarified that FAP is usually discontinued after six months. Paul Oesterman proposed, for consistency, modifying the coverage period to one year.

4.

Jeff Monaghan stated that with the change in criteria, the current generic PA form will be used and the current Cox-2 PA form will be discontinued.

Dr. Evans asked if the impact on cost will be reviewed in a year. Since the criteria is being relaxed, utilization and cost will increase. It's important that when these types of changes are made, we are fiscally responsible and review the impact after a year to determine if there has been a significant change. Paul Oesterman agreed and requested a report of utilization be presented a year after the criteria has been in effect. Jeff Monaghan added that this reinforces the need to look at the science behind this also.

MOTION: Keith Macdonald motioned to approve the proposed criteria with modifications as noted above.

SECOND: James Marx

VOTES: Unanimous

MOTION CARRIED

XI. Presentation by First Health Services on Proposed Clinical Prior Authorization Criteria for Savella®

Tabled until the next meeting.

XII. 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 second quarter 2009. He referred to the "Top 50 All Drugs Ranked by Payment Amount" noting that the antipsychotics and oxycodone rank in the top ten.

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

Jeff Monaghan presented the RetroDUR Summary Report for new profile reviews and re-reviews for reporting period 1/1/09 through 4/30/09.

XIV. Public Comment

Doug Powell, Forest Pharmaceuticals, asked if the criteria for Item XI. (Savella®), which was posted on the FHSC website on July 15th, will be in place until the next meeting. He also asked how his company's involvement in the market be handled in order to provide the least amount of "trouble."

Jeff Monaghan replied that the criteria has not been adopted. Originally, it was thought that this would fall into a preferred drug list (PDL) drug category. It was realized that there is no drug category for fibromyalgia drugs on the PDL; it's been addressed with only clinical criteria. Payment was blocked because it was approached from a PDL standpoint. At this point, the block should be lifted until the Board has acted on it.

XV. Date and Location of Next Meeting

The next meeting is scheduled for October 22, 2009, in Reno.

XVI. Adjournment

Chairman Oesterman adjourned the meeting at 2:57 p.m.