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

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Administrator

DRUG USE REVIEW (DUR) BOARD

Minutes
June 3, 2010

Las Vegas Chamber of Commerce
6671 Las Vegas Blvd. S., Suite 300
Las Vegas, NV 89119

First Health Services
885 Trademark Dr., Suite 150
Reno, NV 89521

Committee Members Present:
Las Vegas: Paul Oesterman, Pharm.D.; Williams Evans, MD; James Marx, MD
Reno: David England, Pharm.D; Chris Shea, Pharm.D.
Absent: Keith Macdonald, R.Ph.; Steven Rubin, MD

Others Present:
DHCFP:
Las Vegas: Gabriel Lither; Deputy Attorney General
Reno: Jennifer Matus; Pharmacy Program Specialist

First Health Services:
Las Vegas: Rob Coppola Pharm.D; Program Director, Paula Townsend Pharm.D; Clinical Manager, Shirley Hunting
Reno: Dave Wuest R.Ph.; Clinical Manager

Others:
Las Vegas: Jolan Terner-Rosenthal-Forest, Irene Camerino-Forest, Ronnie DePue-Forest, Sandy Sierawski-Pfizer, Ozlem Equils-Pfizer, John Brokers-Lilly, Helen Liao-Lilly, Sabrina Aery-BMS, Mike Crittenden-Pfizer, Mark Browning-Pfizer, Lori Horwarth-Bayer, Lisa Wilson-J&J, Stephanie Dr.erts-Acorda, Steve Farmer-Amgen
Reno: Larry Hinson-Astra Zeneca

i. Call to Order and Roll Call

Chairman Paul Oesterman called the meeting to order at 1:05 p.m.

ii. Discussion and Approval of July 30, 2009 Minutes and January 28, 2010 Minutes

MOTION: **James Marx motioned to accept the July 30, 2009 minutes as presented.**
SECOND: **David England**
VOTES: **Unanimous**
MOTION CARRIED

Gabriel Lither clarified that there are currently seven members of the DUR Board and four are present which constitutes a quorum. He asked for confirmation of the current number of members. Dave Wuest confirmed that there are currently seven members of the DUR Board.

MOTION: **James Marx motioned to accept the January 28, 2010 minutes as presented.**
SECOND: **David England**
VOTES: **Unanimous**
MOTION CARRIED

Paul Oesterman reminded the Board that the January meeting did not have a quorum of the members present. There were no action items taken at that time.

Paul Oesterman stated that agenda item XIII: Proposed Prior Approval Criteria for Zyvox® will be tabled until the next meeting.

iii. Status Update by DHCFP

Paul Oesterman said that the status update will be delivered by Dr. Coppola of First Health.

a. Introduction of new DHCFP Pharmacy Program Specialist

Dr. Coppola stated that at the January meeting, Coleen Lawrence announced that DHCFP was recruiting for a Pharmacy Program Specialist and that position has now been filled. He introduced Jennifer Matus who will be responsible for the pharmacy program for the State of Nevada Medicaid Fee-for-Service Program.

b. Legislative Updates from 26th Special Legislative Session regarding Senate Bill (SB)4

Dr. Coppola provided the following update:

- The bill removed the restriction from including the following drug classes on the PDL: atypical and typical antipsychotics, anticonvulsants, and the anti-diabetic classes. On May 3, 2010, the P&T Committee met, reviewed and took action on these classes.
- Modifications to the Medicaid Services Manual, Chapter 1200, Prescribed Drugs, based on SB4, were approved at the April 29, 2010, public hearing. The PDL exception criteria were modified to state that for atypical and typical antipsychotics, anticonvulsant and anti-diabetic medications, the recipient must demonstrate a failure of one preferred agent.
- The bill requires the following drug classes to include every therapeutic prescription drug that is classified as an anticonvulsant medication or anti-diabetic medication that is covered by Nevada Medicaid on June 30, 2010. If a therapeutic prescription drug that is included on the list of preferred prescription drugs is prescribed for a clinical indication other than the indication for which was approved as of June 30, 2010, the committee shall review the new clinical indication in accordance with regular process for new drug indications.
- The bill requires Medicaid to make available without prior authorization (PA) atypical and typical antipsychotic medications that are prescribed for the treatment of mental illness, anticonvulsant medications, and anti-diabetic medications, if the drug was prescribed before June 30, 2010, and the recipient takes the medication continuously, as prescribed on and after that date, and maintains continuous eligibility.
- The bill requires the Division of Health Care Financing and Policy to prepare a report for the legislature on the status of regulations and amounts of money saved as a result of the amended statute.
- The act becomes effective on July 1, 2010, and expires by limitation on June 30, 2011, and only applies to atypical and typical antipsychotic, anticonvulsant and anti-diabetic classes.

c. Program Updates

No update.

iv. Review of Prescribing/Program Trends

a. Top 10 Therapeutic Classes (by Payment and by Claims)

Dr. Coppola presented the Top 10 Therapeutic Classes Ranked by Payment Amount report for first quarter 2010. He pointed out that the increase in the antihemophilic factors accounts for three recipients and FHSC is in the process of conducting outreach to the prescribers of these recipients to ensure appropriate therapy. The decrease in the payment of anticonvulsants is due to the number of generic drugs released; claim volume remains the same. The skeletal muscle relaxant claims are being researched to determine the increase of approximately 13% reflecting 1,300 claims from the previous quarter. A report will be presented at the next meeting.

b. Top 50 Drugs (by Payment and by Claims)

Dr. Coppola presented the report for first quarter 2010.

Paul Oesterman asked if there are any types of patterns in terms of analgesic use.

Dr. Townsend responded that there has not been a large shift from those containing APAP; utilization is standard as seen in other states.

Dave England asked if it can be distinguished that anticonvulsants are being used as adjunct to pain relief or for treating seizures.

Dr. Townsend responded that in order to create a report with that type of data, pharmacy claims need to be bounced off of the medical claims information and the ICD-9 code pulled. The FHSC biostatistician is formulating a report to include this data.

Dr. Marx stated that it may be easier to look at those claims that have concurrent analgesics prescribed. Many times the diagnosis indicates a neuropathic component. Dr. Townsend agreed and that will be considered in the report as well.

Chris Shea referred to the top ten therapeutic classes report and pointed out that there was a 20% increase in payments for insulins, 16% increase in beta-adrenergics and 12% increase in antipsychotics and asked why. Is there a link to utilization of new medications that have been approved on the PDL?

Dr. Coppola stated that the claims payment increase is largely driven by price increases by the manufacturers. Dr. Townsend added the diabetic agents are not a managed PDL class. In accordance with the recent legislation, all drugs for diabetes have equivalent PDL status.

Dr. Coppola said that FHSC will analyze the increase in insulin payments and provide a report at the next meeting.

c. Program Trends

Dr. Coppola reported that recipient enrollment at the end of quarter one 2010, was 81,600 which is a 4% increase from the same period last year. Utilizers (recipients that used the drug benefit) were 35,500 which represents an 8% increase over the same period last year. Paid claims were 122,000, a 10% increase from the previous year, which corresponds to 3.4 claims per user which is not a change from the same period last year. Generic utilization is currently at 75% which represents 21% of the total spend. Brand utilization is at 25% and represents 79% of the total spend.

Paul Oesterman asked with the change in the do not substitute edit (DAW1 edit), is a significant drop anticipated in the amount of brand name products being utilized, and are the brands being dispensed primarily brand products where generics are not available.

Dr. Coppola replied that the generic substitution rate is approximately 90%; if a generic is available, it's being dispensed. The DAW1 edit will bring it closer to 100%.

v. Concurrent Drug Utilization Review (ProDUR)
   a. Review of Q1 2010

Dr. Coppola presented ProDUR reports for first quarter 2010. He noted that pharmacist intervention is only required for Severity Level 1 alerts and "Too Soon Clinical" alerts.

Chris Shea asked how the dollar amount is derived. Dr. Coppola replied that it's the total amount of claims aggregated.

William Evans, MD, joined the meeting at 1:28 p.m.

vi. Retrospective Drug Utilization Review (RetroDUR) UPDATE
   a. Review of Responses (Q3 & Q4 2009)

Dr. Coppola reviewed the RetroDUR Letter Response Report by Response Code for the third and fourth quarters of 2009.

Dr. Oesterman stated that response 1e ("I was not aware of other prescribers") appears frequently and with the work done by the Nevada Narcotic Task Force asked if there is a way to ensure that the prescribers and pharmacies take the time to look at the task force reports.

Dr. Coppola replied that it can be included in the RetroDUR letters and incorporated into the quarterly provider newsletter. Dave Wuest added that at the previous legislative session, there was a bill "requiring" physicians writing for narcotics to review the report prior to writing the prescription. At the end of the session, the language was modified to state "should look at".

Dr. Marx stated that the law was modified to state "should" if they suspect abuse. He added that the use of the task force has gone up expeditiously for the last several years indicating that prescribers and pharmacies are doing a good job. It's a critical issue and needs to continue to be publicized.

   b. Status of Previous Quarter (Q4 2009)

Dr. Coppola reviewed the RetroDUR Summary Report for last quarter 2009.

   c. Status of Current Quarter (Q1 2010)

Dr. Coppola reviewed the RetroDUR Summary Report for first quarter 2010 noting that this quarter is still in data collection mode.

Dr. Marx noted that on the Suboxone® criteria in February, 25 profiles were pulled and asked why no letters were sent.

Dr. Coppola stated that once the profiles are identified, they are sent to be reviewed by a pharmacist reviewer. The reviewer may have felt there was nothing significant to require a letter.

Chris Shea said that he is involved in the RetroDUR review process. Many times a profile will indicate, for example, Suboxone® and an opioid dispensed in the same month but not at the same time (the opioid dispensed prior to the Suboxone®), and there are no recurrent prescriptions of the opioid. The system flags the profile because it meets the criteria. The reviewer determines that although there is a continuation of Suboxone® therapy, there are no subsequent claims for the opioid and a letter to the prescriber is not necessary at this time.

Dr. Shea commented on the acetaminophen >4gms re-review profiles. The profile review of these criteria began years ago and the majority of profiles required lettering. The physicians and pharmacies were both lettered. This issue was addressed more heavily with the pharmacies because the physicians were not writing prescriptions to exceed the 4gms. The patients were seeing more than one physician. Pharmacies were filling prescriptions for multiple combinations from multiple prescribers. Lettering the pharmacies resulted in a significant decrease in subsequent profiles meeting these criteria.

Dr. Marx expressed concern that 4gms is too high. Studies have shown that 2.5gms is a cause for concern due to elevations in GGT, etc.

Paul Oesterman felt that it would be appropriate to review and revise the DUR Board's standard amount of acetaminophen content.

Dr. Coppola said data will be presented at the next meeting.

d. Selection of Quarter Criteria (Q3 2010)

Dr. Townsend stated that the profile run for April is medications which may increase the risk of falls in the elderly and a future run will include topical anesthetic drugs.

Dr. Coppola said that in the past, FHSC in collaboration with DHCFP, selected the criteria which generated the profiles. For future profile runs, the Board is being asked to assist by providing recommendations for criteria to review. He reminded the Board that when selecting criteria from the exception reports presented, the number of exceptions (profiles) should be considered in order to meet the requirement of 300 profile reviews per month.

Gabriel Lither stated that because this is not identified as an action item on the agenda, the Board cannot deliberate or take any formal action on this item at this time.

Dave Wuest suggested that the current selection process be followed for the next profile run and that this item can be agendized at the next meeting for Board action. He referred to the criteria exception reports stating that the number of exceptions may change each month, but the criteria remain the same. Dr. Coppola added that the Board is not limited to the criteria listed in the report. The criteria are based on First DataBank data and proprietary algorithms developed by FHSC. There are system limitations but the Board can also suggest criteria based on their experience and practice.

e. Public Comment

No comment.

f. Discussion by Board

Dr. Oesterman stated that this item will be agendized as an action item for the next meeting.

vii. Update by First Health Services on Dispense as Written (DAW = 1) Edit

a. Public Comment

No comment.

b. Discussion by Board

Dr. Coppola reported that this was presented and approved at public hearing on May 12, 2010. The edit was implemented on the afternoon of May 12th. Data will be presented at the July meeting.

Dr. Oesterman asked if there have been any issues since implementation. Dr. Coppola replied that the call center has reported no technical or clinical issues to date.

viii. Review of Existing Fibromyalgia Prior Approval Criteria

a. Public Comment

Jolan Terner-Rosenthal, Forest Laboratories, spoke in support of Savella® (milnacipran) which is available for the management of fibromyalgia. She provided a Savella® Fact Sheet for Board review. Milnacipran is a selective serotonin and norepinephrine reuptake inhibitor (SNRI). Peer reviewed publications and a recent meta-analysis have shown that SSRIs and TCAs have limited clinical benefit in fibromyalgia. Newer more specific SNRIs show increased clinical efficacy and evidence suggests that SNRIs are the preference for norepinephrine reuptake and may play a more important role in chronic pain states. Milnacipran is reported to inhibit norepinephrine reuptake at an approximately three-fold higher potency over serotonin. It does not significantly inhibit other receptors. Milnacipran has a high oral bioavailability of 85%; demonstrates a half-life of 8-10 hours and exhibits linear kinetics. Absorption is not altered by food, has 13% protein binding and is primarily excreted through the kidneys. The clinical efficacy was determined in two clinical trials that applied a unique design approach in order to study improvements in the many symptoms a fibromyalgia patient struggles to manage. In the studies, patients were required to achieve simultaneous improvements in three areas: pain, physical function and their own personal impression of their fibromyalgia improvement. Results showed that both 100mg and 200mg per day doses of Savella® were statistically significantly superior to placebo. Savella® is safe, well-tolerated and weight neutral. It is recommended that patients on Savella® should have their blood pressure and heart rate monitored both prior to and during treatment. Savella® has a FDA class label black box warning for suicidality and serotonin syndrome. It is contraindicated in patients taking MAOIs or with uncontrolled narrow-angle glaucoma.

Dr. Shea asked what the advantage is of Savella® over Cymbalta® or venlafaxine. According to the package insert, Savella® can cause an increase in blood pressure and heart rate significantly higher than Cymbalta® or venlafaxine.

Ms. Terner-Rosenthal replied that there are no head-to-head trials comparing these different drugs. Their studies were unique looking at simultaneous improvement in three key outcomes. Since fibromyalgia is a multi-symptom condition, it's important to look at multiple outcomes. Savella's® pharmacokinetic profile differs compared to the other drugs. It does not impact the CYP450 system and it has low protein binding. Savella® does impact the cardiovascular system and this appears to be a class effect of SNRIs. It's difficult to compare because Cymbalta® has a variety of different indications and Savella® is only indicated for fibromyalgia. There is a 3mg mercury increase in blood pressure for both systolic and diastolic; duloxetine is 2mg mercury increase. Increase in heart rate with Savella® is 6-7 (beats per minute) and duloxetine is 4-5.

Dr. Shea referred to the Savella® fact sheet which indicates that increases in pulse ≥20 beats per minute occurred more frequently in Savella® patients. Ms. Terner-Rosenthal replied that is correct on average in approximately .9% of patients.

Dave England stated that there is a recommendation in the treatment guidelines for fibromyalgia under pharmacological treatments which includes adequate sleep, treat fatigue and depression, treat muscle spasms and adequate pain control. He asked Ms. Terner-Rosenthal where Savella® fits into this considering the product only has an indication for fibromyalgia. He would like to see guidelines developed by national groups that deal with these types of patients most often and in the event that Savella® impacts one of these criteria effectively, he would not be opposed to considering it. Fibromyalgia is a vague diagnosis; which component of the treatment will be improved or enhanced with this product; i.e., improvement in pain or depression, etc.

Ms. Terner-Rosenthal replied that Savella® is only indicated for the management of fibromyalgia. A number of different variables were looked at in clinical trials including fatigue and sleep; there was a significant impact on fatigue; depression was not included in the trials.

Sandy Sierawski, Pfizer, spoke in support of Lyrica®. Last year the DUR Board put into place prior authorization (PA) criteria for Lyrica® use. They identified that as long as Lyrica® was being used for one of the four FDA approved indications, of which fibromyalgia is one, patients could have access to the medication. Since that time, utilization has been well controlled and used for appropriate indications. Quarterly utilization went from 1,100 prescriptions to 550 per CMS data for the last three quarters of 2009. She asked that the current PA criteria be maintained.

John Brokers, Eli Lilly, spoke in support of Cymbalta®, a serotonin and norepinephrine reuptake inhibitor, which is FDA indicated for major depressive disorder (MDD), generalized anxiety disorder, diabetic peripheral neuropathic pain and fibromyalgia. Cymbalta® has a black box warning for increases in suicidal thinking in adolescents and children. 73% of fibromyalgia patients will experience a major mood disorder in their lifetime; 62% will experience depression; 55% will experience anxiety. Cymbalta® was studied in two randomized control trials (60mg once daily). Both trials studied pain reduction in fibromyalgia patients with or without MDD. In the trials, 51% and 55% of patients taking Cymbalta® 60mg daily had clinically meaningful pain relief as measured by a 30% improvement in the Brief Pain Inventory (BPI). Cymbalta® 60mg was superior over placebo in the fibromyalgia impact total score. Treatment guidelines set in 2005, recommended treatment in the areas of sleep and fatigue which is reflected in the literature. Cymbalta® has a known safety profile. It's been studied since 2005 with published data twelve months and beyond in fibromyalgia and has demonstrated significant improvement in patients with or without MDD. The most common adverse events are nausea, dry mouth, constipation, somnolence, hyperhidrosis, and decreased appetite.

Dr. Oesterman asked if Mr. Brokers is aware of any direct head-to-head studies that are currently ongoing. Mr. Brokers replied no but they have retrospective data on cost-effectiveness and utilization of healthcare resources in abstract form. He offered to provide head-to-head trials.

b. Discussion and Action by Board on the Review of the Clinical Prior Authorization Criteria for fibromyalgia agents (Lyrica®, Savella® and Cymbalta®)

Dave England said that the proposed criteria for Savella® has a diagnosis for fibromyalgia; Cymbalta® a diagnosis for diabetic peripheral neuropathy and/or fibromyalgia. It appears that if there is a diagnosis for fibromyalgia, the prescriber can prescribe for both Savella® and Cymbalta®. Is there anything that limits the classes of medications to treat fibromyalgia?

Dave Wuest stated that there is nothing that would prohibit that and FHSC can analyze this and bring recommendations to a subsequent meeting.

Dr. England said that there are a lot of disease states and though there are several medications to treat that disease, there need to be some rational as to what is to be tried first line, second line, etc.

Mr. Wuest stated that when PA criteria were originally presented in a previous meeting, step therapy was proposed and not accepted by the board. Dr. Oesterman noted that at that time, there were not a significant number of patients. Mr. Wuest suggested utilization data be presented at a future meeting.

Dr. Coppola stated that currently, Savella® is unrestricted. To ensure proper utilization of the drug, the proposal is to have all three of the FDA approved drugs have the same

criteria which is submission of an ICD-9 code, 729.1(myalgia and myositis), on the prescription and submitted by the pharmacy or the completion of the Generic Nevada Medicaid Request for Prior Authorization documenting a diagnosis of fibromyalgia and/or myalgia and myostitis. There is no proposed change for Cymbalta® or Lyrica®; Savella® is being added. Once claims volume adjusts, utilization can be analyzed and potential edits proposed.

Dr. Shea asked for clarification if it is possible for a patient to be on two SNRIs concomitantly. Dr. Coppola stated that is correct. The pharmacy will receive a ProDUR message upon submission of the claim but beyond that, there is no restriction.

Dr. Marx said that he suspects that the treatment of fibromyalgia will increase considerably. In his practice, it's consistently under diagnosed and there are various degrees of severity in fibromyalgia therefore it's not a yes or no criteria. He feels utilization of all of these drugs will go up and PhRMA will educate the prescribers to recognize this and he suspects an increase in utilization over the next one to two years.

Dr. England stated that he is not opposed to adding Savella®, but there should be a restriction that the patient can only be on one SNRI at a time. Mr. Wuest suggested that FHSC research this and report back to the Board. Dr. Oesterman agreed.

Dr. Marx said that there is an issue if you have a patient that has a diagnosis of both MDD and fibromyalgia. Savella® does not have an indication for MDD.

Dr. Oesterman stated that currently there are no restrictions on Savella® and the attempt is to place the fibromyalgia diagnosis on Savella®. He proposed that at this point, approve that and refining the criteria for the three products and their concurrent use.

Dr. Coppola said that a system edit can be put in place to prevent duplicate SNRI therapy and will present a proposal at the July meeting.

MOTION: **Dave England motioned to accept the proposed criteria for Savella® for the diagnosis of fibromyalgia.**
SECOND: **James Marx**
VOTES: **Unanimous**
MOTION CARRIED

ix. Review of Existing Onychomycosis Prior Approval Criteria

a. Public Comment

No comment.

b. Discussion and Action by Board on the Review of the Clinical Prior Authorization Criteria for onychomycosis agents (oral and topical)

Dr. Coppola stated that the criteria are written for Lamisil®, Sporanox® and Penlac®; primarily for the tablet form of the Lamisil® and the liquid Penlac®. There are a significant amount of calls received from prescribers who are confused thinking it applies to the topical preparations as well. He asked for clarification from the Board if the intent was to include the topical agents in these criteria. It is the recommendation of DHCFP and FHSC that the topicals not be included.

Dr. Oesterman clarified that the Lamisil® and Sporanox® in the oral dosage form and Penlac® topical are proposed to require the prior authorization and the topical forms, with the exception of Penlac®, will not require prior authorization.

MOTION: **James Marx motioned to accept the proposed prior authorization criteria for Lamisil® and Sporanox® in the oral dosage form and Penlac® topical. Excluded from the prior authorization**

requirement are the topical preparations, with the exception of Penlac®.
SECOND: David England
VOTES: Unanimous
MOTION CARRIED

Dr. Coppola stated that provider outreach will be conducted to clarify the issue.

x. Review of Existing Prior Approval Criteria for Cox 2 Inhibitors

a. Public Comment

Sandy Sierawski, Pfizer, spoke in support of Celebrex®. There have been a number of proposed changes to the Cox 2 Inhibitors PA criteria over the last year and a half. The changes in the proposed criteria fall in line with what was discussed at the July 30th meeting except for two points. Celebrex® is the only Cox 2 Inhibitor available in the United States and that is the major product that this involves. The FDA approved indications for Celebrex® do not include bone pain which is 1.E. in the proposed criteria. The current proposal lists a restriction (3.A.) that "patient is being treated daily with aspirin for cardioprophylaxis" will not be approved to receive Cox 2 therapy. This makes it appear that there is a contraindication to Celebrex® which isn't the case. On page 9 of the July 30th minutes, it was decided that this restriction should be removed from PA criteria. Celebrex® does not interact with the platelets and can be used with low-dose aspirin. This is listed in the package insert whereas with some of the non-selective NSAIDs that is not the case. In 2008, a white page in the American College of Rheumatology recommends that selective NSAIDs would be preferred over non-selective NSAIDs when patients are taking low-dose aspirin. She requested that the 3.A. restriction be removed from the PA criteria.

b. Discussion and Action by Board on the Review of the Clinical Prior Authorization Criteria for Cox 2 Inhibitors (Celebrex®)

Dr. Townsend stated that the purpose of this review is 1) to correct the decision tree in the currently written criteria for the call center which requires that someone with a GI bleed is required to fail two NSAIDs which is medically inappropriate and 2) bring the criteria up to date and consistent with currently recommended guidelines. She referred to the *ACG Practice Guidelines for the Prevention of NSAID-Related Ulcer Complications* which was published in March 2009. The guidelines for the call center decision tree are derived from this document. DHCFP and FHSC are recommending that the approved FDA indications be required. Upon documentation of an approved indication, authorization will be given for patients at high-risk for NSAID induced adverse GI events, as defined in section 2.; or, patient is greater than 65 years of age (it is consistently documented in multiple guidelines patients >65 years of age are at high risk of NSAID-induced ulceration); or, patient is at risk for GI complications due to the presence of any of the following concomitant drug therapies: 1) anticoagulants, 2) chronic use of corticosteroids; or, patient has documented history of inability to tolerate therapy with at least two non-selective NSAIDs. Following the ACG guidelines, Cox 2 therapy will not be approved if the patient is being treated daily with aspirin for cardioprophylaxis (the use of aspirin negates the benefit of the Cox 2); or, the patient has a documented history of a cardiac event in the past six months; or, the patient has a history of allergies to sulfonamides, aspirin or other NSAIDs. The length of authorization will be one year; the quantity limit 800mg/day (FAP dose).

Dr. Marx stated that the dose should be 400mg/day unless there is an FAP diagnosis.

Dave England asked regarding 3.A., if the daily aspirin dose is 81mg or 325mg. Dr. Townsend replied both and referred to pages 6, 9 and 10 of the ACG guidelines which addresses aspirin. The aspirin dose is not differentiated in the guidelines. Conclusions on page 9 indicate that the benefit of using a Cox 2 over another NSAID is negated by using aspirin.

Dr. Marx stated that he does not agree with that recommendation. 81mg of aspirin with a PPI is safer than putting the patient on naproxen or ibuprofen with a PPI; GI complications are much higher with the non-selective drugs.

Dr. Townsend addressed Dr. Marx's comment regarding the daily dose of 800mg/day for FAP versus 400mg/day for all other diagnoses. System limitations will not allow a quantity limit based on diagnosis which is why the daily dose was set at the maximum of 800mg/day.

Dr. Marx felt addressed eliminating the indication for bone pain, though it's not an FDA PI indication, there may be situations, for example, metastatic bone pain, where it might be appropriate and perhaps should not be eliminated.

Dave Wuest referred to the package insert for Celebrex®. In the CLASS Study, low-dose aspirin is defined as lower than or equal to 325mg per day. There was a four-fold higher rate of complicated ulcers in the group that received Celebrex® with low-dose aspirin versus those that did not receive aspirin.

Dr. Shea stated that if the drug is going to be made available to patients greater than 65, PPI use needs to be documented. Dave Wuest stated that currently, there is an auto PA edit in place for patients ≥60 years to bypass the PA requirement for a PPI if there is history of an NSAID within the past 30 days. Dr. Coppola added that patients over 65 are covered by Part D plans and Cox 2 claims would fall under Part D.

Dave England suggested that since Dr. Marx felt that there may be some rationale for using a Cox 2 for bone pain, change the verbiage eliminate "FDA Approved Indications." Dave Wuest suggested revising the statement to read: "Use is for one of these indications" and Dr. Marx agreed.

MOTION: **David England motioned to accept the proposed criteria with the following amendments:**
Section 1: strike the wording "FDA Approved"; bone pain will remain on the list of indications.
Section 3.A amended to state: "The patient is being treated daily with aspirin for cardioprophylaxis unless concurrent PPI use is documented."
SECOND: **Chris Shea**
VOTES: **Unanimous**
MOTION CARRIED

xi. Review of Existing Prior Authorization Criterion for Injectable Immunomodulator Drugs

a. Public Comment

No comment.

b. Discussion and Action by Board on the Review of the Clinical Prior Authorization Criteria for injectable immunomodulator Drugs (Amevive®, Cimzia®, Enbrel®, Humira®, Kineret®, Raptiva®, Remicade®, Simponi®, Stelara®)

Dr. Townsend clarified that the proposed criteria being discussed today have been updated from the original which was posted on the website and distributed the update criteria to the board members and public. The proposed criteria include recently approved drugs and have been updated to be consistent with recently published guidelines. The new agents being added to the criteria are Cimzia®, Simponi™ and Stelara™. Cimzia® is a pegylated recombinant antibody Fab' fragment which binds the TNF alpha, is indicated for RA and Crohn's Disease and is a self-injected product. Simponi™ is a human IgG1κ monoclonal antibody specific for TNF alpha indicated for RA in combination with methotrexate, psioratic arthritis, ankylosing spondylitis and is

self-injected. Stelatra™ is a new human IgG1κ monoclonal antibody that binds to IL-12 and IL-23 and indicated for moderate to severe plaque psoriasis and is administered under the direct care of a healthcare provider. The TNF alpha blockers include Enbrel®, Simponi™, Remicade®, Cimzia® and Humira®. Amevive® and Orencia® are CAM antagonists. Kineret® is an IL-1 receptor antagonist; Actemra® is an IL-6 receptor antagonist. All of these agents, with the exception of Kineret®, previously required a negative tuberculin test. The new guidelines are a negative test or, if positive, therapy with INH be initiated at least a month prior to the request for the drug. This is in line with the ACR guidelines and taking into account CDC recommendations. In general, patients with latent TB should begin preventive therapy before starting their anti-TNF therapy. The CDC suggests that preferred regimen for management of latent TB is the standard nine month course of isoniazid. The CDC also suggests delaying the TNF alpha therapy until INH treatment has been initiated; a time period for the delay is not specified. Observational studies suggest that anti-TNF alpha therapy can be safely started within one month of starting INH. For consistency, these guidelines have been applied to all of the disease states listed in the proposed criteria.

Criteria 1.A: Rheumatoid Arthritis
The primary guidelines used to develop RA criteria were the ACR recommendations published in 2008. Cimzia® and Simponi™ have been added to the existing list of agents within the criteria. Biologic agents are recommended for patients that have early disease (≤6months) with high disease activity; intermediate or long-term disease (≥6months) with moderate disease activity and inadequate response to DMARDs; and patients with RA ≥6 months with high disease activity. Disease activity is determined by the physician using one of six instruments as summarized in the 2008 ACR guidelines.

Dr. Marx asked how many of these disease modifying drugs are prescribed by non-rheumatologists. Dr. Townsend replied that typically, the initial consult to initiate these drugs is from a rheumatologist and continued by non-rheumatologists.

Dr. Townsend reviewed changes to the criteria.
1.B: Psoriatic Arthritis
Simponi™ has been added to the existing list of agents within the criteria. The guidelines were derived from the American Academy of Dermatology guidelines published in 2008 as well as the international group's recommendations which is summarized in the Medscape document included in the meeting binder. The only change to the criteria previously approved by the Board is the DMARDs that need to be tried in order to find an adequate response to reach the biologic product. Those have been changed to products that have been demonstrated to have efficacy (methotrexate, leflunomide, cyclosporine or sulfasalazine).

1.C: Ankylosing Spondylitis
Simponi™ has been added to the existing criteria. The DMARDs that need to be tried for failure are sulfasalazine, methotrexate, hydroxychloroquine, leflunomide and minocylcine.

1.D: Juvenile Rheumatoid Arthritis
No change.

1.E: Plaque Psoriasis
Stelara™ has been added to the criteria.

1.F: Crohn's Disease
Cimzia® has been added to the criteria. Criteria are based on ACG Practice Guidelines published in 2009. 1.F.1 has been modified from "Diagnosis of Crohn's Disease" to: Diagnosis of moderate to severe Crohn's Disease.

1.G: Ulcerative Colitis
Criteria are based on ACG Practice Guidelines published in 2010. "…moderate to severe ulcerative colitis" has been added to 1.G.1 and "Thiopurines" has been added to the list of drugs in 1.G.2.

Section 2 has been added:
Coverage is not provided for use of more than one biologic at a time (combination therapy).
"Coverage is not provided for use of TNF-α blocking agents (Humira®, Cimzia®, Enbrel®, Simponi™ or Remicade®) in patients with any of the following conditions:
a. Moderate or severe heart failure (NYHA Class III or IV) OR
b. History of treated lymphoproliferative disease of < 5 years in the past OR
c. Acute or chronic liver disease graded as Child-Pugh class B or C OR
d. Multiple sclerosis or other demyelinating disorder

Dr. Townsend stated that there are four primary contraindications to these drugs: moderate to severe heart failure; history of lympho-proliferative disease less than five year in the past; acute or chronic liver disease in Child Class B or C; Multiple Sclerosis or other debilitating disorder.

Dave Wuest said that Orencia® and Kineret® do not have black box warnings. Enbrel®, Remicade® and Simponi™ have warnings for lymphoma and infection. The other agents list the standard warnings for secondary infections.

Dr. England felt the warnings should be listed in the criteria on those specific agents. He felt the absolute contraindications should be included. Dr. Townsend offered another option to list them by class which is how the various groups have approached it as opposed to one brand other another brand.

MOTION: David England motioned to include the contraindications in the proposed PA criteria.
SECOND: James Marx
VOTES: Unanimous
MOTION CARRIED

MOTION: David England motioned to approve the proposed criteria with modifications as presented.
SECOND: James Marx
VOTES: Unanimous
MOTION CARRIED

xii. Proposed Prior Approval Criteria for Suboxone® and Subutex®

a. Public Comment

No comment.

b. Discussion and Action by Board on the Review of the Clinical Prior Authorization Criteria for Suboxone® and Subutex®

Dr. Coppola stated that buprenorphine is a partial opioid agonist approved by the FDA in October 2002 for the treatment of opioid dependence. It's the first agent available in the United States for office-based treatment of opioid dependence under the Drug Addiction Treatment Act of 2000 which allows qualified physicians to prescribe Schedule III to V drugs for treatment of opioid dependence in an office setting. The main objective of the law was to expand access to treatment for opioid dependence. In order to prescribe the drug for opioid dependence, physicians must be certified in addiction medicine or addiction psychiatry, have completed at least eight hours of authorized training or have been an investigator in a clinical trial leading to the approval of Suboxone® or Subutex®.

To prescribe the drug off-label; e.g., pain, certification or training is not required. Once the training has been completed, the prescriber is granted a drug treatment waiver which authorizes the physician to treat narcotic dependency without obtaining a separate DEA registration as a narcotic treatment program. The prescriber is provided a unique identification number recognized by an "X" in the first alpha-character of the DEA number. The drug is available as a single entity, Subutex®, in both 2mg and 8mg tablets and as a combination of buprenorphine/naloxone, Suboxone®, in 8mg/2mg and 2mg/0.5mg tablets. The naloxone is added to discourage the intravenous misuse of buprenorphine by crushing and injecting it. The drug is generally administered once daily; more frequent administration of divided doses can also be used and less than daily dosing is possible for maintenance therapy (3 times per week). These tablets are taken sublingually allowing 5-10 minutes for complete dissolving. Oral administration greatly reduces bioavailability of the drug to a point where it's ineffective. It's administered as a single daily dose in the range of 12mg-16mg per day. Subutex® is the preferred method for induction because it does not contain naloxone. The amount of naloxone absorbed sublingually is very small and can precipitate withdrawal in some patients. Suboxone® is the preferred treatment for maintenance therapy which includes unsupervised administration. These drugs are indicated solely for the treatment of opioid dependence. DHCFP and FHSC are recommending prior authorization for use of these drugs due to the steady increase in utilization in the past two years. He referred to the chart in the meeting material which demonstrates the increase over the period January, 2008 through November, 2009. There was an approximate four-fold increase in Suboxone® utilization during this period and the continued escalation of Subutex® claims. These drugs represent a significant amount of money for the State of Nevada's Medicaid Program as well as abuse and diversion potential. He reviewed the proposed criteria.

Dr. Oesterman referred to the requirement in the criteria which states that the "patient must not have failed two or more substantial courses of therapy…" and asked what the alternative is; the patient continues of opioids. Dr. Coppola replied that there are other alternatives such as Methadone.

Dr. Marx stated that he is certified in addiction medicine and a Suboxone® prescriber and felt that this requirement is ill-advised. He also expressed concern regarding the last criteria which requires that the "patient shows no evidence of dependence on cocaine, alcohol, or other opiates." The DSM criteria for dependence only requires dependence over a twelve month period and the proposed requirement may be overcastting a wide exclusionary net. He felt that two tablets per day may not be enough for some patients.

Dr. Coppola commented that a review of the utilization indicates that 90% falls within 16mg per day. He proposed that prescribers be required to affirm that they have reviewed the Narcotic Task Force data to confirm that there is no concurrent therapy. Dr. Oesterman agreed that it would be reasonable to include that requirement in the criteria.

Dr. Marx suggested asking the task force to initiate an unsolicited profile if a patient is on both an agonist and an antagonist such as Suboxone®. Because the drug is expensive and has street value, he recommended that the provider conduct compliance testing verifying that the patient is taking Suboxone®. The test should be conducted upon initiation of therapy, one month following and periodically there after.

Paul Oesterman stated that the motion for the proposed criteria for Suboxone® and Subutex® will be taken separately.

MOTION: **David England motioned to accept the proposed criteria for Suboxone® with the following amendments:**
Remove criteria:
-Patient must not have failed two or more substantial courses of therapy (3-5 months of therapy) in the past
-Patient shows no evidence of dependence on cocaine, alcohol, or other opiates

Add criteria that the prescriber:
-should review Narcotic Task Force patient information data
-will be required to conduct initial point-of-care verification testing; confirmatory compliance testing to be conducted one month following initiation of therapy and periodically thereafter at the physician's discretion

SECOND: **James Marx**
VOTES: **Unanimous**
MOTION CARRIED

Dr. Marx referred to Dr. Coppola's statement regarding induction therapy and commented that Subutex® has a much higher abuse potential and priced approximately 30% higher than Suboxone®. He finds in his practice if the patient is required to be in a high Clinical Opioid Withdrawal Scale (COWS) value, there is little indication for using Subutex®. Some patients claim to be allergic to the naloxone in Suboxone® but he didn't feel that to be very legitimate. He felt that Suboxone® should be preferred over Subutex® and suggested an edit for Subutex® requiring a medical indication supporting why Suboxone® cannot be taken. In terms of the induction phase, he suggested a quantity edit for Subutex® limited to a maximum two-week period.

Dr. Coppola stated that the proposed criteria for Subutex® approval lists patients that are pregnant or allergic to naloxone or medication is requested for induction therapy and asked if Dr. Marx is suggesting removing "induction therapy" for Subutex®. He is not aware of any studies done with Suboxone® in induction therapy.

Dr. Coppola noted that Subutex® is now available in generic form. Dr. Oesterman asked regarding the DAW1 edit and Subutex®. Dr. Coppola said that once enough data is available, a report will be presented to the Board.

MOTION: **David England motioned to accept the proposed criteria for Subutex® with the following amendments:**
Remove criteria:
-Patient must not have failed two or more substantial courses of therapy (3-5 months of therapy) in the past
-Patient shows no evidence of dependence on cocaine, alcohol, or other opiates
-Patient must be pregnant or patient is allergic to naloxone
Add criteria:
- that the prescriber should review Narcotic Task Force patient information data
-use will be for induction therapy limiting use to a two-week period

SECOND: **James Marx**
VOTES: **Unanimous**
MOTION CARRIED

xiii. Proposed Prior Approval Criteria for Zyvox®

Tabled until the next meeting.

a. Public Comment
b. Discussion and Action by Board on the Review of the Clinical Prior Authorization Criteria for Zyvox®

Dr. Evans was excused from the meeting at 3:28 p.m.

xiv. Public Comment

Sandy Sierawski, Pfizer, asked when the prior authorization criteria discussed today will go into effect. Dave Wuest responded that per Jen Matus, the timeframe is not known at this time. It will be posted on the DHCFP website.

Larry Hinson, Astra Zeneca, stated that his company has received FDA approval for a new product, Vimovo®, an immediate release esomeprazole with naproxen, which is indicated for osteoarthritis, rheumatoid arthritis and ankylosing spondylitis. It offers GI protection for patients at risk of stomach ulcers when taking NSAIDs. It will be released mid-June. Dave Wuest informed Mr. Hinson that this drug category is on the PDL and decisions regarding the inclusion of new drugs are addressed at the Pharmacy and Therapeutics Committee meetings.

xv. Date and Location of Next Meeting

The next meeting is scheduled for July 22, 2010, at the Grant Sawyer Building in Las Vegas with videoconferencing to the Nevada State Legislature Building in Carson City.

xvi. Adjournment

Pau Oesterman adjourned the meeting at 3:33 p.m.