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DIVISION OF HEALTH CARE FINANCING AND POLICY
NEVADA MEDICAID

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DRUG USE REVIEW (DUR) BOARD

**The Orleans Hotel
4500 West Tropicana Ave.
Las Vegas, NV 89103**

Meeting Minutes
April 26, 2007

Approved by the DUR Board on June 21, 2007

Committee Members Present:

David England, Pharm.D., Chairman
Keith Macdonald, R.Ph.
Paul Oesterman, Pharm.D.
Steven Parker, MD (called-in)
Marjorie Uhalde, MD (called-in)

Absent: Steven Rubin, MD

Present:

Coleen Lawrence-DHCFP (called-in), Debbie Meyers-DHCFP, Joyce Ramos-DAG, Jeff Monaghan-FHSC, Dawn Daly-FHSC (called-in), Shirley Hunting-FHSC, Doug Powell-Forest Labs, Sharyl Kolmas-MGI Pharma, Craig Boody-Eli Lilly, Joe Busby-Eli Lilly, Rajiv Dass-Sepracor, John Stockton-Genentech, Bret Parker-Pfizer, Sandy Sierawski-Pfizer, Lisa Wilson-Johnson & Johnson, Lori Howarth-Bayer.

I. Call to Order and Roll Call

Chairman David England called the meeting to order at 1:05 p.m.

II. Discussion and Approval of January 25, 2007, Meeting Minutes.

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

III. Status Update by DHCFP on the National Provider Identification (NPI) Project.

Debbie Meyers reported that Point of Sale (POS) system enhancements are in place to accept pharmacy and prescriber NPI numbers for the adjudication of pharmacy claims. 99% of pharmacies and 75% of prescribers have provided First Health with their NPI numbers. Pharmacy NPI will be required on claims submitted on or after May 23, 2007. Due to HIPPA regulations, NPI numbers cannot be posted or shared until approval is granted by CMS. Therefore, for a limited time, pharmacies may submit either the prescriber NPI or legacy number.

Jeff Monaghan stated that First Health and the State are anxious to move toward the requirement of prescriber NPI submitted on the claim because of the over utilization of the prescriber dummy number. The University Of Nevada School Of Medicine has applied for individual NPI numbers for residents and interns.

IV. Inhaled Insulin (Exubera®)

Public Comment

Sandy Sierawski, Pfizer, presented three letters of public comment and spoke in support of Exubera®. She felt the prior authorization (PA) criteria are restrictive as it states that patients who are going to fail subcutaneous insulin are possible candidates. The criteria defeat the purpose of inhaled insulin because it has a unique delivery system to get patients insulin a little sooner. American Diabetic Association Guidelines recommend that after patients have failed lifestyle changes and metformin, they should go to insulin because that's the most effective treatment for lowering blood glucose. Pfizer's position on Exubera® in treating Type II diabetics as a third line pharmacotherapy for patients who are uncontrolled on the two oral agents that, possibly in place of TZDs, they could get patients on insulin sooner and the insulin shows superior efficacy to the TZDs as far as getting patients to the A1c control. Exubera® is competitively priced with the TZDs. She requested the board review the restrictive nature of the prior authorization criteria and provide patients and providers with a non-injectable insulin option.

Dave England asked when Pfizer developed this product, what was the market they were going after and how do these restrictions keep that market from getting this product. Ms. Sierawski replied that the market is Type II diabetics who have failed two oral agents. Mr. England stated that the AHCPD guidelines suggest a six month trial because it was uncertain what changes inhaled insulin can have on the structure or function of the lungs. If the two hypoglycemic agents didn't work, and the patient went on inhaled insulin and within six months they didn't achieve the A1cs, would there be any reason to continue Exubera® therapy.

Ms. Sierawski felt it would be up to the clinical judgment of the physician. The lung function issues are listed in the package insert and that is a concern with this product. Patients must have a lung function test prior to being prescribed and then checked in six months and annually thereafter. It has been studied for two years and there has been shown to be a decline in function that's very small, develops early and is non-progressive.

Keith Macdonald asked in terms of the Medicaid population, if there have been any prohibitions of people who could have benefited from its use but did not receive it. In his practice, he sees no use in any population. Ms. Sierawski replied that she has no data on use in the Medicaid population and that the product is being rolled out slowly by her company to ensure the education is out there and the appropriate population for use is identified.

Presentation by First Health Services on Possible Changes to Current Clinical Prior Authorization Criteria for Inhaled Insulin (Exubera®)

Mr. Monaghan presented proposed criteria for inhaled insulin (attached).

Board Discussion and Action Concerning Revisions to Clinical Prior Authorization Criteria for Inhaled Insulin

Dr. Parker asked if Medicaid has had any requests from physicians especially endocrinologists. Mr. Monaghan replied no other than the letters presented today. He referred to the National Guideline Clearinghouse (NGC) treatment guidelines which mirrors the current PA requirements. The only thing that is more specific is in the current PA guidelines, the term "an inability to self-administer." The guidelines from NGC expand upon that stating a patient that has "a marked and persistent fear of injections and meets DSM-IV criteria." The committee could consider expanding what an inability to inject is and include the term "persistent fear." The expert guidelines and the president-elect of the American Diabetes Association do not consider this as first line therapy; subcutaneous insulin is first line therapy.

Dr. Parker asked if a physician has a patient who is deathly afraid of needles, would an override be granted and Mr. Monaghan replied yes. Dr. Parker said there is a mechanism in place to obtain

the drug and felt the current guidelines are fine and can be revisited after monitoring for a year. He added that he has spoken with local endocrinologists and they are easing into use of inhaled insulin; i.e., they are not switching everyone to it.

Mr. England asked if the NGC guidelines are incorporated, will a patient be required to go through the DSM-IV criteria or can an override be granted without the diagnosis. Mr. Monaghan stated if it is recommended that the NGC guidelines are adopted, it specifically indicates that the phobia has to be diagnosed by a diabetes specialist or mental health professional. Dr. Parker preferred not to require the patient to undergo additional testing but to leave that to the judgment of the physician. Dr. Uhalde agreed adding that it does not make sense to send these patients to a psychologist for testing.

MOTION: Steven Parker motioned to accept the criteria for inhaled insulin with changes to A.1.a and A.2.c to state as follows:
A.1.a. Have an inability to self-administer injections of SC insulin or has a persistent fear of self-administration of SC insulin and do not have a caregiver who can administer SC insulin.
A.2.c. Intolerance or contra-indication to SC insulin (i.e., injection site reactions or allergic reaction) or inability to self-administer injections of SC insulin or has a persistent fear of self-administration of SC insulin and do not have a caregiver who can administer SC insulin.

SECOND: Keith Macdonald
Paul Oesterman stated to encourage both dietary changes and exercise, he would like to offer a friendly amendment to change A.2.a from “Unresponsive/intolerant to treatment with dietary changes” to “Unresponsive/intolerant to treatment with lifestyle changes.”
Mr. Macdonald accepted the amendment.

VOTES: Unanimous
MOTION CARRIED

Dave England asked when the criteria will be in effect and Ms. Meyers stated within a minimum of 90 days.

Dr. Parker asked if FHSC will monitor usage and Mr. Monaghan replied that the number of requests and the number of requests that are granted or denied will be monitored.

V. Topical Immunomodulators (requested by the Pharmacy and Therapeutics Committee)

Public Comment

No comment.

Presentation by First Health Services on Possible Adoption of Clinical Prior Authorization Criteria for Topical Immunomodulators

Jeff Monaghan stated that this drug class was reviewed by the Pharmacy and Therapeutics (P&T) Committee at the March meeting and Elidel® and Protopic® were added to the Preferred Drug List (PDL). One member, in particular, felt strongly that the DUR Board should ensure that these drugs are not used first-line and criteria should also reflect the black box warnings with these products. He referred to the FDA Public Health Advisory that warns of the potential cancer risk as shown in animal studies. The advisory also states that these agents should be used as labeled and in patients who have failed attempts with other therapies. He presented proposed criteria.

Mr. Oesterman asked if consideration has been given to limiting by specialty who can prescribe these products. Mr. Monaghan stated that the committee has discussed this type of limitation in the past and has generally steered away from restricting by specialty. Mr. England added that the rationale for that is with some of the managed care organizations within the state. The process may make it difficult for someone who may need these medications to obtain them right away. In addition, the manufacturer does not recommend that type of limitation.

Mr. Macdonald noted that the third concern is geographical circumstances whereby many of our rural communities do not have specialists.

Board Discussion and Action Concerning Prior Authorization Criteria for Topical Immunomodulators

MOTION: Paul Oesterman motioned to accept the prior authorization criteria for topical immunomodulators as presented.

SECOND: Keith Macdonald

VOTES: Unanimous

MOTION CARRIED

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

Jeff Monaghan presented drug utilization reports for the first quarter of 2007. He referred to the “Top 50 All Drugs Ranked by Payment Amount” and noted that palivizumab (Synagis®), dominated the total payment for the quarter. This is normally not the number one drug but is due to a seasonal issue as the drug is only given 3-6 months a year. The report otherwise remains somewhat consistent with anti-psychotics taking up a large portion of the dollars.

Mr. England asked what is being reported as “Compound Rx”. Mr. Monaghan replied that there is a new system functionality in place (Multi-ingredient Compound) which allows the capturing of compounded drugs. FHSC is in the process of analyzing these prescriptions to see what types of drugs are being compounded and will present a report at the next meeting.

Mr. Monaghan referred to the “Top 10 Therapeutic Classes Ranked by Payment Amount” report and pointed out that in the category M4E, Lipotropics, the prescription count for this quarter compared to a year ago increased by almost 2,000 prescriptions, but the change in payment amount decreased by 36%. This is an example of what occurs when a drug like Zocor® becomes generically available.

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

Jeff Monaghan reviewed the RetroDUR Summary Report for new profile reviews and re-reviews for calendar year 2006. At the next meeting, the CMS Annual report for federal fiscal year 2006 will be presented which will include data on cost savings due to RetroDUR activity.

- VIII. Status Report on Data Collection Involving Drugs Used to Treat Attention Deficit Disorder (ADD)/Attention Deficit Hyperactivity Disorder (ADHD) in Adults and Children

Debbie Meyers stated that at the request of the Pharmacy & Therapeutics (P&T) Committee, the DUR Board re-examined the prior authorization requirements for ADHD drugs at their January meeting. Upon review and discussion, the DUR Board requested that prior to modifying the criteria, a survey be developed to determine prescriber specialty, diagnosis and the types of ADHD drugs being prescribed. Since that time, it has been determined that the data can be collected electronically through the FHSC reporting system. A report will be presented at the next DUR Board meeting.

- IX. Status Report on Upcoming CE Program: Diagnosis and Treatment of Psychiatric Symptoms

DHCFP and FHSC have been working with the University Of Nevada School Of Medicine’s continuing education department in putting together a program sponsored by DHCFP, FHSC and the DUR Board, on the use of antipsychotic medications. Mr. Monaghan stated that the program

is scheduled in Las Vegas on May 4th and in Reno on May 11th. The program mailing was sent to all physicians and pharmacists in the state.

Mr. England stated that after many discussions based on data presented to this committee, it was determined that there is a need to get information out to the practitioners. This is one of many programs that will be organized in this fashion.

- X. Next Meeting Scheduled for Thursday, August 2, 2007, at 1:00p.m. in Reno.

The next meeting is scheduled for August 2, 2007, 1:00 p.m. at the Meadow Wood Courtyard in Reno.

- XI. Public Comment

No comment.

- XII. Adjourn

MOTION: Keith Macdonald motioned to adjourn the meeting.

SECOND: Paul Oesterman

VOTES: Unanimous

MOTION CARRIED

Meeting adjourned at 1:45 p.m.