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Governor

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

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Director

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DRUG USE REVIEW (DUR) BOARD

The Division of Health Care Financing and Policy (DHCFP), Drug Use Review (DUR) Board, will conduct a public meeting on **September 21, 2006**, beginning at **2:00 p.m.** at the following location:

Las Vegas Chamber of Commerce
3720 Howard Hughes Parkway
Las Vegas, Nevada

Draft
Meeting Minutes
September 21, 2006

Committee Members Present:
David England, Pharm.D, Chairman
Keith Macdonald, R.Ph.
Marjorie Uhalde, M.D. (called-in)

Absent:
Steven Parker, M.D.
Steven Rubin, M.D.

Others Present:
Coleen Lawrence DHCFP, Debbie Meyers DHCFP, Gabriel Lither DAG, Jeff Monaghan FHSC, Dawn Daly FHSC, Shirley Hunting FHSC, Doug Powell-Forest, Doug Ethel Glaxo SmithKline, Kirk Huffaker-Schering Plough, Bert Jones-Glaxo SmithKline, Jim Goddard-Shire, Eric Rouse-Eli Lilly, Chris Almeida-Purdue, Zepu Heimausen-Glaxo SmithKline, Sandy Sierawski-Pfizer, Michelle Gile-Pfizer, Ed Lewis-Pfizer, Lori Horwarth-Berlex.

I. Call to Order and Roll Call

Chairman David England called the meeting to order at 2:00 p.m.

II. *Discussion and Approval of June 22, 2006 Minutes

MOTION: **Marjorie Uhalde motioned to accept the minutes as written.**
SECOND: **Keith Macdonald**
VOTES: **Unanimous**
MOTION CARRIED

III. Status Update on Coverage of Plan B Contraceptive for Medicaid Recipients

Coleen Lawrence stated that the FDA has approved over-the-counter (OTC) access for the contraceptive, Plan B, for women over the age of 18. Medicaid currently covers OTC products and contraceptives are a covered service. Medicaid will pay for Plan B but a prescription will be required as is currently the requirement for all OTC's.

IV. Status Update on National Provider Identifier (NPI) Initiative

Ms. Lawrence stated that DHCFP and First Health are working together on NPI. They have been looking at the MMIS and POS claims systems and it appears there will be no issues with the adjudication of pharmacy claims with NPI. Home infusion therapy provider drug billing will eventually be moved to MMIS which will eliminate split billing of drugs and supplies.

V. *Proposal by First Health Services and Action by Board on Suggested Changes to Clinical Prior Authorization Criteria for the Following Drugs and/or Drug Classes:

A. Byetta®-Add Clinical Edit

Dawn Daly presented proposed clinical PA criteria (attached) for exenatide injection (Byetta®). Byetta®, an incretin mimetic, is a new agent to the market and is only indicated for Type II diabetes. It's given twice daily by injection. This drug has been known to cause weight loss and in some instances used for that purpose. Medicaid does not cover weight loss agents.

Dave England asked since its main purpose is to lower the hemoglobin A1C levels and it's an adjunct to the other medications, what is considered adequate glycemic control? Ms. Daly responded that in the VA system, if there is less than a 10% decrease in A1C after three to six months of therapy, it will be discontinued. Currently, there are no best practices guidelines available. Mr. England suggested acceptance of the proposed criteria and requested follow-up on best practice guidelines which can be applied once available. Mr. Monaghan recommended limiting the length of the PA (3-6 months) to ensure effectiveness.

Public Comment
No comment.

MOTION: **Keith Macdonald motioned to add a six month prior authorization limitation until utilization standards are available.**
SECOND: **Marjorie Uhalde**
VOTES: **Unanimous**
MOTION CARRIED

MOTION: **Keith Macdonald motioned to accept the proposed criteria for Byetta® as amended.**
SECOND: **Marjorie Uhalde**
VOTES: **Unanimous**
MOTION CARRIED

B. Symlin-Add Clinical Edit

Dawn Daly presented proposed clinical PA criteria (attached) for pramlinitide injection (Symlin®). Symlin®, amylin analog, is a new agent indicated for use in Type I or Type II diabetes in patients who are taking insulin. It's given twice daily, slows the gastric emptying and reduces the rate in which the glucose appears in the blood stream. The agent is available in a vial and measures in micrograms versus units. A conversion chart is available but for people currently taking insulin, this may be confusing.

Ms. Lawrence suggested including as part of the PA form an acknowledgement that patient education has occurred.

Ms. Daly stated that the VA criteria includes an acknowledgement that "the patient has demonstrated proficiency and compliance of SMBG and is willing to perform self-monitoring of blood glucose pre- and postprandially and at bedtime (until stabilized on dose)." Another private insurance carrier includes the question "is the patient's care supported by the services of the diabetic educator."

Public Comment
No comment.

MOTION: **Keith Macdonald motioned to add a fifth criterion that the patient has received education and is competent to self-administer and perform blood glucose monitoring.**
SECOND: **Marjorie Uhalde**
VOTES: **Unanimous**
MOTION CARRIED

MOTION: **Keith Macdonald motioned to adopt a six month prior authorization review criteria.**
SECOND: **Marjorie Uhalde**
VOTES: **Unanimous**
MOTION CARRIED

MOTION: **Keith Macdonald motioned to accept the proposed criteria for Symlin® as amended.**
SECOND: **Marjorie Uhalde**
VOTES: **Unanimous**
MOTION CARRIED

C. Gabapentin-Remove Clinical Edit that had been placed on hold

Jeff Monaghan stated that the Committee had approved the criteria (attached) at a previous meeting and the meeting following it was recommended the edit be placed on hold. The criteria were not removed from Chapter 1200. At the time this was presented, there were concerns that Neurontin® was being used off-label and used as first line therapy when it should not have been. A review of this drug indicates most usage is not off-label and the recommendation is to remove the criteria.

Ms. Lawrence stated that the Committee had agreed to remove the edit but it was not documented in the minutes.

Dave England asked if there have been any serious complications or events with off-label use of this drug and Mr. Monaghan replied that he is not aware of any.

Public Comment
No comment.

MOTION: **Keith Macdonald motioned to remove the clinical edit for gabapentin.**
SECOND: **Marjorie Uhalde**
VOTES: **Unanimous**
MOTION CARRIED

VI. *Proposal by First Health Services and Action by Board to Apply/Revise Quantity Limitation Edits on the following:

A. Imitrex 4mg Injection (Creation of new quantity edit)

Jeff Monaghan stated that there are currently quantities limitations on the triptans which were approved by the Committee. The injectable sumatriptan (Imitrex®) was not included on the initial list and he recommended it be included (limit is 4 injections per month without a PA).

Mr. Macdonald asked if there have been a large number of requests for greater quantities. Ms. Daly replied that prior to implementation of the quantity edit, there were prescriptions prescribing Relpax® one tablet daily.

Public Comment
No comment.

MOTION: Marjorie Uhalde motioned to accept the quantity limitation on Imitrex® injectable as presented.
SECOND: Keith Macdonald
VOTES: Unanimous
MOTION CARRIED

VII. 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. He referred to the "Top 50 All Drugs ranked by Payment Amount" report and stated that the top five drugs listed (risperidone, olanzapine, quetiapine fumarate, aripiprazole, divalproex sodium) comprise 50% of Medicaid dollars.

He stated the one shift seen with Part D is the analgesic narcotics class. In the past, this class consistently ranked second highest by payment amount and it has now dropped to a low four. Part D has had an impact on this as well as the aggressive approach taken by the Committee and State on implementing criteria on these drug types.

Dave England stated that recently an FDA advisory has been issued on the potential triptan/SSRI interaction causing Serotonin Syndrome. He asked if there have been any issues with this and Mr. Monaghan replied that he is not aware of any but will include that criterion in the next RetroDUR run.

VIII. 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 report period 01/06 through 07/06. Criteria review was focused on excessive daily doses of acetaminophen and letters were generated to pharmacies for those profiles that fell into these exception criteria. He stated that pharmacies have been very responsive in reporting back requested information.

Dave England asked if the response rate percentage is in line with the national average for states of this size and Mr. Monaghan replied that the percentage is comparable.

IX. *Discussion and action by Board to select Retrospective Drug Utilization Criteria and Prescriber Communication Regarding Advair®-Issue referred from the Pharmacy and Therapeutics Committee based on safety concerns and FDA warnings related to long-acting beta agonist agents.

Jeff Monaghan stated that this item is being referred to the DUR Board by the Pharmacy & Therapeutics Committee (P&T). Advair® was recently added to the Preferred Drug List (PDL) and one of the P&T committee members asked that this be referred to DUR for discussion. In May of 2006, an updated FDA Public Health Advisory was released effecting not only Advair® but all of the long-acting beta agonist products including Serevent® and Foradil®. The warning states that these medications may increase the chance of severe asthma episodes and death when those episodes occur. The manufacturers have updated the product labels with the new warnings and have made available new medication guides. He noted that Advair® is highly used across the country. The issues are is Advair® being used correctly in a step-wise fashion as is recommended

in the NIH asthma management guidelines and is the education with the prescribers and the patient's adequate.

Keith Macdonald asked if a problem has been identified. Mr. Monaghan replied, not specifically. The problem that was identified was by the SMART trial; there was a statistically significant difference in the number of deaths versus placebo within the two groups that were compared. The FDA felt that this needed to be communicated and have taken steps to do that. The difficultly is trying to design something that will ensure that the drug is used correctly. Depending on the severity of the disease, it could be used first-line. It should not be used first-line for mild or moderate asthma; inhaled corticosteroid with rescue beta-agonist short-acting should be used.

Dave England asked Dr. Uhalde what criteria she follows to put a patient on a long-acting beta-agonist as opposed to continue having them use a short-acting beta-agonist. She replied if they are using it everyday, they should be on the long-acting.

Keith Macdonald stated that in his pharmacy the patients he sees on these drugs are established asthma patients with long-term use. He does not see first time asthma patients being placed on long-acting beta agonist agents.

Public Comment

Doug Ethel, Glaxo SmithKline, spoke in support of Advair®. He stated that through radiation skin-tography and tomography, studies conducted by a group in England have determined that salmeterol occupies about 4-6% of the beta-2 receptors. That allows 94-96% of the receptors to be unoccupied. The subsequent albuterol dose and the lack of response are not due to the fact that the receptors are tied up with salmeterol. In terms of the genetic issue, the amount of data available about polymorphisms with beta-2 receptors is limited and conflicting.

He referred to the letter submitted by Dr. Stuart Stoloff. Dr. Stoloff states that "Studies have shown that subjects who are homozygous for arginine at positions 16 (Arg/Arg 16) are more likely to experience a decline in lung function as measured by peak flow when taking regularly scheduled daily albuterol treatment than patients homozygous for glycine (Gly/Gly 16). Further studies recently identified similar findings in patients using salmeterol who were homozygous (Arg/Arg 16). However, there is no data to clearly identify that use of salmeterol combined with an inhaled corticosteroid (ICS, eg: Advair) has the same outcome...Due to the complex genetic nature of the beta2-agonist receptor and its response, the current findings are not yet definitive in identifying the functional variant responsible for this adverse effect or the number of individuals in whom this effect may occur." He recommended that "decisions be based on the present well documented benefits vs risks of each class of medications and not initial studies which can not be applied to the population at large."

(First name inaudible; did not sign-in) Hymanson, Schering Plough, spoke in support of formoterol. He stated that formoterol is a long-acting beta-agonist and involved in the controversy with the long-acting beta-agonists. It was not studied in the SMART trial but by extrapolation received a black box warning. Patients with mild, persistent asthma should be started with inhaled corticosteroids and if they fail on that treatment, they should be graduated to combination treatment or higher dose of inhaled corticosteroid. Patients should be evaluated closely. The standard of his company is that the guidelines should be followed closely. Representatives of his company have reprints of the guidelines and are presenting them to physicians.

Dave England asked that if an edit should be put in place that Advair® is only indicated for patients with moderate to severe asthma. Mr. Monaghan replied that technically to apply that in a way that would be enforceable and valuable is a challenge. The education piece has merit. It would be nice if the education that is occurring is adequate, objective, and in line with the NIH guidelines.

Keith Macdonald said that this study was one-tenth of a percent of the death rate, which is relatively small. He felt that no action should be taken at this time but at a later date if something

is recognized and the issue is raised again. Dave England agreed stating that if the FDA escalates this to a black box warning versus an advisory, the issue be addressed at that time.

Mr. Monaghan asked the representative of Glaxo SmithKline, the manufacturer of Adair®, to address what they are doing to communicate appropriate therapy.

Bert Jones, Glaxo SmithKline, stated that he has built an asthma partnership with the state of California. The goal is to drive the key stakeholders together in a work group to discuss those issues in asthma not just the medication but also air quality and as well as other things. Through those conversations were borne educational venues that helped to create the inventions you are looking for. He offered to the State and First Health to bring that best practice to Nevada. Ms. Lawrence stated that other drug manufacturers that want to participate in this initiative should contact Jeff Monaghan.

Dave England said that he is willing to table this item indefinitely until more information is available about what is occurring in the practice settings and see if education can help the practitioners and patients be more informed. His preference is to approach the issue in this manner rather than through edits.

Coleen Lawrence said that the focus for the DUR Board next year is education and recommended putting the motion into an educational stance.

Jeff Monaghan asked Mr. Jones when the representatives call on doctors about products such as Advair®, do they put as much emphasis on when to use the product and as well as when not to use it. Mr. Jones replied absolutely; with all the discussion about SMART, we have the information and package insert and we want to make sure the providers fully understand what that means, where the NIH guidelines fit and where the products fit. It is being communicated.

Kirk Huffaker, Schering Plough Pharmaceuticals, stated that his company would like to participate in this educational program.

MOTION: **Keith Macdonald motioned to develop an educational program looking into the effects of these products and incorporate the program as part of the educational initiative.**
SECOND: **Marjorie Uhalde**
VOTES: **Unanimous**
MOTION CARRIED

X. Status Report on Board's Educational Program Initiatives

Jeff Monaghan stated that the State and First Health have been meeting with the University of Nevada School (UNR) of Medicine's continuing education (CE) department to put together a program on the use of antipsychotic medications. The UNR School of Medicine's CE department is in the process of contacting manufacturers for unrestricted educational grant support. A draft agenda has been developed and CEU's will be applied for. It will be a one-day program tentatively scheduled for the spring of 2007, and conducted both in northern and southern Nevada.

XI. Public Comment

No comment.

XII. *Adjournment

MOTION: **Marjorie Uhalde motioned to adjourn the meeting**
SECOND: **Keith Macdonald**
VOTES: **Unanimous**
MOTION CARRIED
Meeting adjourned at 3:14 p.m.