KENNY C. GUINN
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

PHARMACY & THERAPEUTICS COMMITTEE

The Orleans Hotel
Salon A&B
4500 W. Tropicana Ave
Las Vegas, Nevada

Minutes
December 14, 2006
1:00 p.m.

Committee Members Present:
Steven Phillips, MD, Chairman
Diana Bond, R.Ph.
Judy Britt, Pharm.D.
Robert Bryg, MD
Linda Flynn, MD
Carl Heard, MD
Robert Horne, MD
Larry Pinson, Pharm.D.
Chris Shea, Pharm.D.

Absent:
Susan Pintar, MD

Others Present:
Coleen Lawrence-DHCFP, Debbie Meyers-DHCFP, Darrell Faircloth-DAG, Jeff Monaghan-FHSC, Shirley Hunting-FHSC, Dawn Daly-FHSC, Joe Tyler-NAMI, Gary Dawson-Takeda, Doug Ethel-Glaxo Smith Kline, Eric Rowe-Lilly, Joe Busby-Lilly, Judi Profant-McNeil Pediatrics, David Lindquist-Ortho-McNeil, Kele Griffiths-OMJPS, Laura Likenberger-Ortho-NcNeil Janssen, John Stockton-Genentech, Judy Varga-Sepracor, John Ostezan-Sepracor, Shanu Khanrja-Takeda, Helen Kale-Takeda, Betty Kuhn-Takeda, Gustavos Aranda-Takeda, Cindy Yeo-Takeda, Bert Jones-Glaxo Smith Kline, Dick Knosspel-Abbott, Courtney Fagan-Abbott, Karrie Marren-Sanofi-Aventis, Deanne Calvert-Sanofi-Aventis, Jeff Hille-Lilly, Don Cleveland-Astra Zeneca, T. Guerra-UNSOM, Johanna Fricke-UNSOM, Jim Goddard-Shire, Ann Childress, Joe Schwab-Novartis, Sandy Sierawski-Pfizer, Elson Kim-Forest Labs, Doug Powell-Forest Labs, Walter Dawkins-NcNeil Pediatrics, Kara Smith-Cephalon, Todd Gavin-Daiichi Sankyo, Chris Almeida-Purdue Pharma, Cynthia Dietrick-Mojave, Coni Kalinowski-Mojave, Sedrick Spencer-Roche, Wendy Fong-Abbott, Doug Rapel-Daiichi Sankyo.

I. Call to Order and Roll Call
Chairman Steven Phillips called the meeting to order at 1:00 p.m.

II. *Review and Approval of July 27thth Meeting Minutes

MOTION: Larry Pinson motioned to accept the minutes as written.
SECOND: Diana Bond
AYES: Unanimous
MOTION CARRIED

III. Public Comment
No comment.

Dr. Phillips stated that at the last meeting, there was a request to refer to the DUR Board for review issues brought up by Dr. Britt regarding Advair® (recent new warnings on long-acting beta-agonists). The issues were reviewed at the last DUR Board meeting and it was agreed to address this through the development of an educational program. Minutes of the DUR Board are available on the State's website at dhcfp.state.nv.us.

Coleen Lawrence introduced and welcomed on behalf of the State of Nevada, the Honorable Governor Kenny Guinn and Charles Duarte, Administrator of DHCFP, two new committee members. Dr. Robert Bryg is a cardiologist with the School of Medicine and has been practicing in northern Nevada for seventeen years. Dr. Chris Shea, pharmacist, owns and operates Diversified Medication Consulting and PAX Rx Pharmacy and is board certified in geriatrics.

On behalf of the Committee, Dr. Phillips welcomed both new committee members.

Dr. Phillips recognized that Dr. Robert Horne and Dr. Carl Heard have joined the meeting (1:04 p.m.).

IV. Analgesic: Long Acting Narcotics

Public Comment
No comment.

Drug Class Review Presentation – First Health Service
Jeff Monaghan stated that the drug classes being reviewed today are part of the annual review.

At the 2005 annual review, the Committee moved to approve the recommendations by FHSC moving Avinza® and Oxycontin® to non-preferred status and added Duragesic® to the Preferred Drug List (PDL) with a notation on the list that prior authorization is required. A 60-day grandfathering was allowed for patients currently undergoing therapy. He stated that over the past year, that transition has gone quite smoothly.

What has stimulated review of the long acting narcotics is the release of a new agent, oxymorphone extended release tablets (brand name Opana® ER). It's available in 5, 10, 20, and 40mg tablets and dosed on a q12h basis similar to many of the other long-acting narcotics. Indications are similar to other long-acting opioids and this agent shares the same strong warnings as Avinza® in relation to the concomitant use with alcohol. It is strongly warned that co-administration be avoided due to a significant increase in drug absorption that occurs with alcohol. Opana® ER should be taken on an empty stomach due to the increased absorption seen when taken with a high-fat meal. There is nothing to distinguish this drug from the other drugs within this class. Although there is a large amount of individual opinion and anecdotal evidence, there is insufficient evidence from head-to-head studies to suggest that one long-acting opioid is superior to another long-acting opioid in terms of adverse rates, efficacy and addiction or abuse. It is the recommendation of DHCFP and First Health that the drugs in this class be considered therapeutic alternatives.

Committee Discussion and Action to Approve Clinical/Therapeutic Equivalency of Agents in Class and Identify Exclusions/Exceptions for Certain Patient Groups

MOTION: **Robert Horne motioned that the drugs in this class be considered therapeutic alternatives.**
SECOND: **Larry Pinson**
AYES: **Unanimous**
MOTION CARRIED

Presentation of Recommendations for Preferred Drug List (PDL) Inclusion by First Health Services and the Division of Health Care Financing and Policy
Dr. Monaghan stated that it is the recommendation of DHCFP and First Health that no changes be made to the PDL in this drug category and that Opana® ER be considered non-preferred.

Committee Discussion and Approval of Drugs for Inclusion in the PDL

MOTION: Larry Pinson motioned to accept First Health's recommendation that no changes be made to the PDL in this class and that Opana® ER be considered non-preferred.
SECOND: Judy Britt
AYES: Unanimous
MOTION CARRIED

V. Antidepressants: SSRIs

Public Comment

Elsin Kim, Forest Labs, spoke in support of Lexapro®.

Dr. Britt asked what the study sizes were. Mr. Kim replied that in the Lamb Study, there were 1,203 patients and the other four studies varied 150 patients per arm.

Dr. Horne asked if other indications are being pursued at this time. Mr. Kim said there are but he is not at liberty to say at this time.

Drug Class Review Presentation – First Health Services
Jeff Monaghan stated that there are no new drugs to review at this time but that recently a scientific advisory panel has recommended that the black box warning on antidepressants be expanded up to age twenty-five. The warning relates to increases in suicidal behavior for children. This is an advisory panel recommendation and no action has been taken by the FDA at this point. The other development in this category is that Zoloft® (sertraline) is now available generically. It is the recommendation of DHCFP and First Health that the drugs in this category be considered therapeutic alternatives.

Committee Discussion and Action to Approve Clinical/Therapeutic Equivalency of Agents in Class and Identify Exclusions/Exceptions for Certain Patient Groups

MOTION: Robert Horne motioned that the drugs in this class be considered therapeutic alternatives.
SECOND: Carl Heard
AYES: Unanimous
MOTION CARRIED

Presentation of Recommendations for Preferred Drug List (PDL) Inclusion by First Health Services and the Division of Health Care Financing and Policy
Dr. Monaghan stated that it is the recommendation of DHCFP and First Health that the only change to the PDL in this class is to remove the current restriction on Zoloft® for the diagnosis of OCD for children ages 6 to 17 years of age.

Committee Discussion and Approval of Drugs for Inclusion in the PDL
Dr. Horne asked for clarification that there will be no restrictions on sertraline being a preferred drug and Dr. Monaghan replied correct.

MOTION: Robert Horne motioned to accept First Health's recommendation that the only change to the PDL in this class is to remove the current restriction on sertraline.
SECOND: Diana Bond
AYES: Unanimous
MOTION CARRIED

VI. Central Nervous System: ADHD/Stimulants/Non-Stimulants

Public Comment

Johanna Fricke, MD, developmental behavioral pediatrician with the University Of Nevada School Of Medicine, stated she has no affiliation with any drug companies. She said that up until the twenty-first century, there were only two stimulants, the methylphenidates and amphetamines. The molecules of stimulants have not changed but the delivery system has. In a delivery system that gives an ascending level of methylphenidate with peak at 6-7 hours, the length of action does not get a child through the day, homework, and aftercare. Medium acting preparations do not help the kids as much as the longer-acting preparations. Aftercare programs in Las Vegas will not give a second dose of medication. She said that several studies have shown that the longer-acting preparations have shown to help in the evening hours with driving. The driving impairment of an untreated male teenager with ADHD is the same as that of an eight year old boy. What we need to look at is clinical efficacy and happiness for the patients. She requested access to Concerta® the oral preparation and Daytrana® the transdermal delivery system that has an ascending blood level and a twelve hour plus duration of action.

Ann Childress, board certified child analyst and adult psychiatrist in private practice, disclosed that she receives research support from Lilly, Shire and Norvatis, is on the speakers bureau for Shire and Novartis and a consultant for Shire and Novartis. She stated that she has done clinical research trials on all the stimulants both on and off the formulary, and she prescribes these medications daily. She said that she seconds Dr. Fricke's comments on Daytrana® and felt that access is needed on all of these medications because each patient is individual and one may not do well on one long-acting methylphenidate but they do well on another preparation. She had the opportunity to do clinical trials on Daytrana® before it came on the market and felt if offers a number of advantages such as for people who can't swallow oral medications. Some medications can be sprinkled but it's unsure how much is being ingested. Daytrana® can be a short or long-acting medicine depending on how long the patch is left on. If left on for nine hours, it lasts for twelve; if left on for four hours, it lasts for seven.

Dr. Heard said that her request is to have every drug within this class on the PDL. How do we get a list of medications that covers 95-98% of the patients that are in need and to do that in a way that identifies medications that we absolutely must have or medications that we cannot have on this list? He stated that she is here advocating for a drug that is a relatively new addition but there is currently a therapeutic equivalent on the list. He asked for her insight on which drugs can be moved off the list.

Dr. Phillips' invited Dr. Fricke to join Dr. Childress in addressing Dr. Heard's question.

Dr. Fricke stated that Ritalin® SR (methylphenidate extended release) could be retired and long-acting dexedrine since the amphetamine salts cause less weight loss. She added that as some drugs are becoming mono-isomers, the mixed amphetamine salts seem to be the preferred formulation. In talking with her colleagues, some find Metadate® useful in a part of the population. For children with inattentive type ADHD and no social problems or homework, Metadate® works to get them through the school day. Dr. Childress felt that Methylin® and Methylin® ER could be removed because to her knowledge, they are rarely used.

Dr. Pinson expressed concern regarding disposal of patches in terms of safety and abuse. Dr. Childress said that the patch has to stay in contact with the epidermis to release drug and the adhesive will not re-stick once removed. Drug cannot be extracted by scraping or chewing the patch once the patch is removed from the skin.

Dr. Britt asked if the ideal number of drugs were included in this class with no restrictions, what percentage of patients would be on the transdermal patch and Dr. Childress replied less than 20%.

Joe Schwab, Novartis, spoke in support of Focalin® XR.

Judy Profant, McNeil Pediatrics, spoke in support of Concerta®.

Drug Class Review Presentation – First Health Services
Dawn Daly stated that at the annual review in October 2005, the drugs in this class were considered therapeutic alternatives and no changes were made to the PDL. This class is being reviewed today due to the release of the transdermal patch, Daytrana®.

The systemic effects with the patch have been dose-related and are similar to the oral formulations. Erythema and pruritis at the application site were common in the short-term clinical studies. Contact sensitization to the patch might lead to development of systemic sensitization to other forms of methylphenidate precluding further use. In June 2006, *The Medical Letter* states that Daytrana® should be reserved for patients who cannot take oral ADHD drugs. It the recommendation of DHCFP and First Health that the drugs in this category, including the new drug formulation of methylphenidate, be considered therapeutic alternatives.

Committee Discussion and Action to Approve Clinical/Therapeutic Equivalency of Agents in Class and Identify Exclusions/Exceptions for Certain Patient Groups
Dr. Phillips asked for clarification. Did *The Medical Letter* distinguish between patients that are incapable of taking oral medications, have failed other medications, or if there truly is no gut, use the patch? Ms. Daly replied the statement is it should be reserved for patients who cannot take oral meds; e.g., young children who cannot or will not swallow oral meds.

Dr. Heard said one of the problems with fentanyl patches is people doubling up on patches because it had a long and large residual value. Will a similar problem be faced with this patch?

Dr. Childress stated that the Noven studies left the patch on for twenty-four hours. 40% of the drug was out at nine hours. As it's on longer, the curve drops off at twenty-four hours.

MOTION: Carl Heard motioned that the drugs in this class are therapeutic alternatives.
SECOND: Linda Flynn
AYES: Unanimous
MOTION CARRIED

Presentation of Recommendations for Preferred Drug List (PDL) Inclusion by First Health Services and the Division of Health Care Financing and Policy
Dawn Daly stated that DHCFP and First Health are recommending no changes to the PDL for this class with the exception that one failure of a long-acting agent will be required before a non-preferred drug will be approved. Currently, PDL criteria require failure of two preferred agents.

Committee Discussion and Approval of Drugs for Inclusion in the PDL
Dr. Britt asked if First Health will have the ability to determine failure electronically as in step therapy and actually look for history of another stimulant rather than calling in for a PA. Ms. Daly replied that currently there is a clinical edit in place for prior authorization (PA) which requires a call to the Call Center.

Dr. Heard stated that he supports the one drug failure rule but would it be possible to reduce the number of calls to one call, the initial ADHD authorization. When they fail that first prescription, write on the prescription the failed agent and expediting the process so the clinician and their staff don't have to make another call.

Dr. Phillips stated that the first action item to be considered is the recommendation from First Health that the PDL be maintained as is with failure of one preferred agent. The second action is requesting that the State and First Health look at streamlining, not just this class, but the entire process to make it easier for the prescribing clinician.

MOTION: Dr. Heard motioned to accept First Health's recommendation except expedite the prior authorization for the non-PDL drug.
Dr. Horne offered a friendly amendment that the preferred drug list be maintained as it is but a non-preferred agent can be prescribed after one failure instead of two failures.
SECOND: Robert Bryg

Dr. Heard stated that the motion does not address the expediting of the process. That is being put in a second motion.
Coleen Lawrence said that there are some drug classes that are authorized and coded in the system at a higher level. This hierarchy of coding will allow the checking of drugs to determine the level authorization is given. First Health and the State can present to this Committee and the DUR Board what the hierarchy is for these drugs and how they fit into the different coding classes and determine what options are available to make the process easier.
Dr. Heard stated that he does not want to lose the opportunity in this motion to simplify an already complicated process and to the extent necessary impose this administrative obstruction to the practice of clinical medicine. If you are suggesting that you will come back at the next meeting and show how the authorization process works and we can make recommendations based on that, it makes sense. In the meantime, I would rather not commit everyone that wants to go a second line drug in the treatment of ADHD to have to make a second call.
AYES: Horne, Flynn, Bond, Phillips, Shea, Pinson, Britt, Bryg
NAYES: Heard
MOTION CARRIED

Diana Bond recommended that DUR or the State reexamine the requirement for prior authorization for this class. For the two practitioners here today, almost everything in their entire practice for children requires prior authorization. As we've moved through these PDL classes, we've left them in an unfair circumstance in their practice setting.

Dr. Horne said that every medication prescribed for ADHD requires a separate prior authorization regardless of which one is used. Psychiatrists and pediatricians complain about this all the time. A greater complaint for the DUR is the requirement for an intelligence test for adult attention disorder before you can prescribe.

Dr. Phillips stated that action has been taken and the motion carried on this drug class. Action cannot be taken on the PA requirement at this meeting because it was not on the agenda.

Coleen Lawrence acknowledged the Committee's recommendation.

VII. Central Nervous System: Sedative Hypnotics

Public Comment

Judy Varga, Sepracor, spoke in support of Lunesta®.

Gary Dawson, Takeda Pharmaceuticals, spoke in support of Rozerem®.

Dr. Heard asked if Rozerem® should be within this therapeutic class, "Sedative Hypnotics". It is claimed to be a non-sedative. Is there a new class we should consider because there may be pipeline drugs that will be similar or in the same mode of pharmacologic action.

Mr. Dawson replied that the categorizing of sedative hypnotic is a misnomer for Rozerem® because it does not produce sedation in the classic sense. Monitors have been brought forward to address how to classify these drugs, and there are other drugs that are in Phase II and Phase III development that fall into the same category because of their mechanism of action. He stated that they follow the American Society of Hospital Pharmacists' categorization of drugs and he does not know how they will categorize these drugs.

Karrie Marren, Sanofi-Aventis, spoke in support of Ambien® CR.

Dr. Britt stated that Ambien® CR does have some benefit in sleep maintenance and if Ms. Marren acknowledges that there is a portion of patients that have more trouble with sleep onset than sleep

maintenance and that there still is a population that would benefit from regular Ambien®. Ms. Marren agreed.

Drug Class Review Presentation – First Health Services
Jeff Monaghan stated that historically what happened with this class is the Committee felt the drugs in the class were therapeutically equivalent with some exceptions. Because benzodiazepines are in Pregnancy Category X, Sonata® and Ambien® were made available for women of childbearing age. At last year's review, after much testimony, Ambien® was added to the PDL without any restrictions. This year, there are two new agents to consider, Ambien® CR and Rozerem®. There are no good clinical trials comparing Ambien® CR to the new agents or to the benzodiazepines. Ambien® CR, like Lunesta®, is approved for the treatment of insomnia versus the short-term treatment of insomnia. Even with the subtle differences in the labeling, all the drugs are controlled substances and CNS depressants, and all require close monitoring by prescribers. Rozerem® is not a controlled substance, does not create tolerance, dependence, or rebound, is not indicated for insomnia or short-term treatment of insomnia and is only approved for reducing time to sleep onset. Because of the action this drug has, it was best placed in this category. There are no trials comparing this drug to the newer sedative hypnotics or benzodiazepines. He stated that he agreed with the representative of Takeda that his drug is an alternative. There is no ideal sedative hypnotic but with the understanding that a selection should be available, it is the recommendation of DHCFP and First Health that the drugs in this class be considered therapeutic alternatives.

Committee Discussion and Action to Approve Clinical/Therapeutic Equivalency of Agents in Class and Identify Exclusions/Exceptions for Certain Patient Groups
Dr. Heard said that at some point the pharmacologic effect is what distinguishes a class not its' therapeutic result. Pharmacology is the issue. If we look at an antidepressant that is an SSRI versus a tricyclic, we consider not the antidepressant class, we consider that pharmacologic class of SSRIs. We are now entering into a drug that seems to have a remarkably different side effect profile and has a fundamentally different pharmacologic profile even though it's striving for the same therapeutic end. Is it the pharmacological association that we are dependent on for these classifications or is there some point where we would recommend splitting out of a class.

Dr. Monaghan replied that the subject of determining therapeutic alternatives is contained as a separate item within this agenda. Dr. Phillips stated that this subject will be addressed when that item is open for discussion and Dr. Heard withdrew his question until that time.

MOTION: **Carl Heard motioned that the drugs in this class are therapeutic alternatives.**
SECOND: **Larry Pinson**
AYES: **Bond, Heard, Phillips, Shea, Pinson, Britt, Bryg**
NAYES: **Horne, Flynn**
MOTION CARRIED

Presentation of Recommendations for Preferred Drug List (PDL) Inclusion by First Health Services and the Division of Health Care Financing and Policy
Dr. Monaghan stated that it is the recommendation of DHCFP and First Health that no changes be made to the PDL for the drugs in this therapeutic class.

Committee Discussion and Approval of Drugs for Inclusion in the PDL
Dr. Horne said that an agent indicated for patients with chronic insomnia is needed. The only drug he felt that was equivalent to Rozerem® in this class is trazadone. Two studies of trazadone in non-depressed patients showed it had a sleeping pill effect. Without making a prior authorization call, we need to have the option of giving patients something that has good data to support it and is not addictive. Rozerem® should be in a separate class or if you're going to put it in the class, change it to hypnotics as opposed to sedative hypnotics or put it in a separate class that does not require prior authorization. He felt an agent for long-term use for the treatment of insomnia should be added.

Dr. Heard supported Dr. Horne's recommendation with the condition that there be a non-addicting alternative on the PDL (something with no abuse or low abuse potential).

MOTION: Robert Horne motioned to maintain Ambien®, estazolam, flurazepam, temazepam and triazolam on the PDL and add Rozerem®.
SECOND: Judy Britt
Dr. Monaghan asked if Rozerem® is being added because it's non-addictive and because of long-term use and if so, is there any way to keep it focused on that population maybe by using an ICD-9 code.
Dr. Horne felt it should not be necessary to diagnosis someone with benzodiazepine dependence in order to use a non-addictive drug. He would prefer to use a non-addictive drug first versus an addictive one.
Dr. Phillips asked if there is an ICD-9 to apply to it and Dr. Monaghan replied there is an ICD-9 that refers to addiction.
Dr. Britt said that Rozerem® is a good drug for sleep onset, but if someone is looking for something for early morning awakening, it's not going to be the panacea of sleep medications.
Dr. Horne said that since price cannot be a consideration and with no recommendation with regard to cost, he suggested that First Health may want to make a recommendation in terms of long term sleep maintenance.
Dr. Monaghan said our PDL exception criteria states that if there is a drug that has a unique FDA indication, a call can be made for prior authorization or the other option is to include an ICD-9 code for chronic insomnia.
AYES: Heard, Bond, Flynn, Horne
NAYES: Bryg, Britt, Pinson, Shea, Phillips
MOTION NOT CARRIED

Dr. Heard asked to hear why on the no votes.

Dr. Phillips stated that he is not comfortable yet with Rozerem®. As a geriatrician, his prescribing practice is not to prescribe new agents for two years unless it's a life or death situation.

Dr. Shea said he also primarily practices in geriatrics and expressed concern that until we define how this drug will be placed, someone may be on both Ambien® and Rozerem®. In the drug utilization review process, we've seen people on Oxycontin® as well as morphine ER. From a pharmacist's standpoint, it's difficult to justify.

Dr. Heard said this opens an opportunity for compromise in finding resolution to this issue by saying they can only be prescribed a single sedative.

Dr. Phillips stated that he will entertain one more motion with second and vote. If acceptance is not arrived at, this item will be tabled until the next meeting.

MOTION: Larry Pinson motioned to maintain the current drug list in this class on the PDL and move Rozerem® to preferred status with the requirement of an ICD-9 code for chronic insomnia.
SECOND: Robert Horne
Dr. Heard asked First Health if a control can be put in the system to ensure more than one sleep agent is not being paid for by Medicaid and Dr. Monaghan replied yes.
Coleen Lawrence stated that depending on the DUR severity level, the system should be capturing that but if the Committee wants to institute those types of controls, a time period needs to be specified.
Dr. Monaghan said that this could be referred to the DUR Board.
Dr. Horne stated that he prefers not to refer this to the DUR Board because we will be in the same predicament that we are with ADHD drugs.
Jeff Monaghan clarified that Rozerem® is not FDA approved for chronic insomnia. It is only approved to address sleep onset problems.
Dr. Heard suggested asking First Health to come back with the appropriate ICD-9 code.

Ms. Lawrence stated that the applicable ICD-9 code can be supplied if the intent of what you're trying to accomplish is clear.
Dr. Horne said the actual indication is treatment of chronic or transient insomnia characterized by difficulty with sleep onset.
Dr. Monaghan said this can be handled administratively and the appropriate ICD-9 code will be applied.
Ms. Lawrence asked if the intent is for sleep onset or sleep maintenance.
Dr. Phillips replied chronic sleep onset is the intent.
AYES: Horne, Flynn, Bond, Heard, Pinson, Bryg
NAYES: Phillips, Shea, Britt
MOTION CARRIED

VIII. Respiratory: Inhaled Long Acting Beta Agonists

Public Comment
No comment.

Drug Class Review Presentation – First Health Services
Jeff Monaghan said that this class was on the list of drug classes with no changes. It was referred to the DUR Board because of safety concerns. As Dr. Phillips stated at the beginning of this meeting, the issues were reviewed at the last DUR Board meeting and it was agreed to address this through the development of an educational program. It is the recommendation of DHCFP and First Health that no changes be made to the current list of drugs in this class on the PDL.

Committee Discussion and Action to Approve Clinical/Therapeutic Equivalency of Agents in Class and Identify Exclusions/Exceptions for Certain Patient Groups

MOTION: Carl Heard motioned that the drugs in this class are therapeutic alternatives.
SECOND: Diana Bond
AYES: Bryg, Britt, Pinson, Shea, Phillips, Heard, Bond, Flynn, Horne
MOTION CARRIED

Presentation of Recommendations for Preferred Drug List (PDL) Inclusion by First Health Services and the Division of Health Care Financing and Policy
Jeff Monaghan stated that it is the recommendation of DHCFP and the State that no changes be made to the drugs in this class.

Committee Discussion and Approval of Drugs for Inclusion in the PDL

MOTION: Carl Heard motioned for no changes to the current list of PDL drugs in this class.
SECOND: Diana Bond
AYES: Horne, Flynn, Bond, Heard, Phillips, Shea, Pinson, Britt, Bryg
MOTION CARRIED

IX. Presentation by First Health Services and Discussion by Committee of PDL Therapeutic Class Assignment

Jeff Monaghan said that this item is presented for discussion at the request of Dr. Heard. He referred to the handout which is an example of the therapeutic classes that are encompassed by the Medicare Modernization Act (MMA). This guide is derived from the USP which is the national standard setting organization for both prescription and over-the-counter drugs in the United States. In determining how the therapeutic class is chosen, we consider which drug class has a reasonable chance of being considered to have an array of therapeutic alternatives within that class. From that point, we try and put drugs in those classes for your review that you have a reasonable chance of saying are therapeutic alternatives, which then gives the State the leverage from a financial standpoint to get the best value for the drugs within that class. The MMA relies heavily on USP and if you look at our drug classes, and compare what they've done, there is a lot of similarity.

Dr. Heard said if we rely on MMA, we might be stuck with these categories for the next thirty years and that may not reflect the evolution of pharmacologics within the opportunities we have. You referred to economic ability to have a large enough class to be able to negotiate within that class and the Committee is prohibited from considering cost. What is the limit of our ability?

Ms. Lawrence stated that the classes are dependent on USP. We have adopted what USP has created for therapeutic classes. That is how First Data Bank and our system processes. The Committee is not under the restraints of the class. If, for instance, you did not feel Rozerem® was equivalent and you have a bias to not having it included in that review, you can pull the drug from the review and it's not considered and not on the PDL. The classes are set but you can maneuver around it by applying different clinical indications. How you want to handle these classes is your choice. We have adopted a national standard and other payers have adopted the same standard so it is consistent within the industry. Ms. Lawrence said that the therapeutic class labeling should not restrict the Committee from managing the PDL.

Dr. Heard asked if the Committee can choose from the MMA list of categories.

Dr. Monaghan said that the list is a guideline and that the federal government encourages Part D plans to use USP as their guideline for therapeutic classes.

Dr. Phillips added that the guidelines allow the addition of other classes or therapeutic areas (each class must have two drugs) but not the removal of classes.

Dr. Heard asked if this Committee can create other categories, and Dr. Phillips replied yes.

X. Presentation by First Health Services and Discussion by Committee of Quality and Outcome Indicators Related to the Preferred Drug List process

Coleen Lawrence stated that his item is being presented at the request of Dr. Heard. DHCFP and First Health meet with Dr. Heard and Dr. Phillips to discuss quality and outcome indicators as related to the PDL. It was decided that a subcommittee consisting of volunteer members from both P&T and the DUR Board could be created to develop quality reviews and outcome data related to the activities of these two committees. She requested that members interested in participating or providing input contact her. The subcommittee will not be a regulatory body. Based on open meetings laws, it will be a public meeting if there is a quorum of both committees.

Dr. Heard said that the Committee is there to try and represent the people actually taking care of patients and are not now being given that opportunity in an objective sense. He expressed his appreciation for this opportunity and volunteered to participate on the subcommittee.

Dr. Phillips suggested Ms. Lawrence contact both committee members via email with this information.

XI. Review of Next Meeting Location, Date, and Time

The next meeting will be March 22, 2007, in Reno.

XII. Public Comment

No comment.

XIII. *Adjournment

MOTION: Robert Bryg motioned for adjournment.
SECOND: Robert Horne
AYES: Unanimous
MOTION CARRIED

Meeting adjourned at 3:12.