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

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Pharmacy & Therapeutics Committee

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

Minutes
June 21, 2007
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
Chris Shea, Pharm.D.
Robert Horne, MD (called-in)

Absent:

Larry Pinson, Pharm.D.
Susan Pintar, MD

Others Present:

Coleen Lawrence-DHCFP, Debbie Meyers-DHCFP, Mary Griffith-DHCFP, Darrell Faircloth-DAG, Jeff Monaghan-FHSC, Dawn Daly-FHSC, Shirley Hunting-FHSC, Mandy Hosford-Astra Zeneca, Kirk Huffaker-Schering Plough, Teev Heinaufon-Schering Plough, Doug Powell-Forest, Johnna Nelson-Lilly, Craig Boody-Lilly, Lisa Wilson-Ortho McNeil, Laura Litzenberger-Ortho McNeil, Marisha Madhoo-Ortho McNeil, Perry Johnson-Graceway Pharma, Raza Karim-GSK, John Paulowski-GSK, Mike Bennett-GSK, Brian McManus-GSK, Bret Parker-Pfizer, Sandy Serawski-Pfizer, John Rembold-Pfizer, Eric Byrnes-Alcon, Gina Guinasso-EMD Serono, Anthony DeLeon-Shire, Lee Boyle-Shire, Debbie Dye-Shire, Jim Goddard-Shire, Mike Titus-Pratt, Shannon Lindsley-Pratt, Joseph Schwab-Novartis, Dan Bay-Abbott, David Abrahamson-Merck, Matthias Cheung-Astra Zeneca, Joann Phillips, Elizabeth Bellocchio-BMS, Bert Jones-GSK, Walter Dawkins-McNeil Ped., Vicky Viss-Suatanus, Richard Fiscella-Allergan, Robin Leth-Reliant, Roland Baldwin-Wyeth, Annette Stephra-Wyeth, Rick (last name illegible)-ISPH, Melia Loskill-Takeda, Derek Terada-Boehringer Ingelheim, Jim Griffin-Santarus, Ann Childress-Private Practice, Sedrick Spencer-Roche, Mark Alden-Roche, Lisa Durette, MD-Spring Mountain Treatment Center, A. Stanz, MD, Penny Atwood-Boehringer Ingelheim, Steve Farmer, Amgen, Jim Morgan-Novartis, Lori Howarth-Bayer.

I. Call to Order and Roll Call

Chairman Steven Phillips called the meeting to order at 1:03 p.m.

II. Review and Approval of March 22, 2007, Meeting Minutes

Dr. Heard noted the following:

- 1) Page 9, paragraph two, change externa media to otitis externa.
- 2) The minutes state that there was a request of Mr. Faircloth to report back to the committee regarding the open meeting requirement of subcommittees. This was not included on today's agenda and Dr. Heard stated that he would like for this discussion to occur at some point.
- 3) Page 13: "Dr. Pinson suggested that Dr. Heard provide the State and First Health with his questions. The State and First Health can then address them at the next meeting."

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Dr. Heard stated that he provided the questions following the last meeting and reiterated that the goal is how to contain rampant drug utilization profiles by controlling it with a PDL. He would like to know what measures can be put in place and what the impact and effect of those measures are. He noted that it's not on today's agenda and he appreciates that the agenda is very busy and requested a commitment to include this item on the next agenda.

MOTION: Diana Bond motioned to accept the minutes with corrections as noted.
SECOND: Carl Heard
AYES: Unanimous
MOTION CARRIED

Dr. Phillips made the recommendation that at the next and subsequent meetings, the PDL Quality and Outcome Indicators be agendaized until there is resolution.

III. Public Comment

Coleen Lawrence announced that Dawn Daly, First Health, is moving on to a new career opportunity. Dawn has played a key role in provider training, the development and maintaining of procedures and in keeping a strong integrity within the program. On behalf of the State, Ms. Lawrence thanked Dawn for her service.

Dr. Robert Bryg has accepted a new position and will be relocating to southern California. On behalf of the State, Ms. Lawrence thanked Dr. Bryg for his contribution to the committee.

Dr. Steven Phillips will be leaving his position on the committee. On behalf of the State, Ms. Lawrence thanked Dr. Phillips for his service on the committee. He has been a critical component in setting the tone and environment in developing the P&T process. More importantly, the leadership he has given to this committee has found a balance between delivering quality healthcare and managing State resources without compromising the integrity. She presented him with the Governor's Award of Recognition for his service and commitment to the committee.

No public comment.

ANNUAL REVIEW – DRUG CLASSES WITH PROPOSED CHANGES

IV. Antidepressants: Novel

Public Comment

Elizabeth Bellocchio, Bristol-Myers Squibb, spoke in support of EMSAM transdermal system.

Drug Class Review Presentation – First Health Services

Jeff Monaghan offered a point of clarification. Historically, monoamine oxidase inhibitors (MAOIs) have not been included in the antidepressant reviews. The SSRIs are one group, and those that affect other neurotransmitters such as serotonin and norepinephrine are the other group which we have labeled "novel" antidepressants. The MAOI class has not been addressed. The drug, EMSAM, is currently available because it has not been included in a current PDL drug class. If the committee desires, MAOIs can be included and reviewed at a future meeting.

Dr. Phillips suggested that Dr. Monaghan consult with Dr. Horne and determine if MAOIs should be considered.

Dr. Monaghan stated that criteria for drug class review at the annual meeting not only includes the release of new drugs within the class since the last annual review but can be reviewed at committee request. Dr. Horne requested review of this class.

Dr. Monaghan said that there are no new drugs to present in this class. On May 2, 2007, the black box warning on all antidepressants was expanded in terms of suicidal symptoms. Previously, it was children and adolescents. It has been expanded to include young adults up to age 24.

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 Group

MOTION: Robert Horne motioned that the agents in this class be considered therapeutic alternatives.

SECOND: Robert Bryg

Dr. Heard asked regarding the indication for smoking cessation and whether that is within this class since it's an antidepressant class. There's currently only one agent that has a clear indication for smoking cessation and asked if this should be discussed now as therapeutic equivalency is being considered.

Dr. Monaghan felt it would not be as the antidepressant effect is being considered. Smoking cessation agents are not a category on the PDL.

Dr. Heard felt that consideration should be given to creating a smoking cessation category because the downstream benefit is huge in this population. Dr. Phillips recommended adding this to the next meeting agenda.

Ms. Lawrence stated that smoking cessation products are currently available without restrictions, other than two ninety-day supplies of any agent within a twelve-month period. She stated the policy can be found on the DHCFP website. She asked if the committee is recommending this class be reviewed for the PDL with possible restrictions.

Dr. Heard replied that a lot of clinicians are clinically casting a different glance at this to help their patients quit smoking though they may not fit the full criteria for depression. He felt there is a benefit clinically and, as the DUR Board considers financially, to Medicaid and the population being served. He would like this addressed at the next meeting.

Dr. Phillips stated that for the next meeting, First Health and the State present the current status of the smoking cessation policy for committee review and possible action.

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

It is the recommendation of DHCFP and First Health that there be no changes to the current PDL for this class.

Committee Discussion and Approval of Drugs for Inclusion in the PDL

Dr. Horne requested this class be reviewed due to the release of generic Wellbutrin® XL (bupropion). He felt the advantage to adding the XL formulation is once per day dosing which will improve compliance up to 20%. If a physician wants to start a patient on the once-a-day agent, the 150mg SR bupropion, which is currently on the PDL, could be prescribed for the first three to seven days and then prescribe the 300mg XL. The only reason for the 150mg XL to be utilized is if after a month on the 300mg XL dose there is partial response but not a remission of depression, the dose could be increased to 450mg to try and achieve complete remission. Currently, there is no 300mg sustained release available. He recommended including each strength (100mg, 150mg, 200mg) of the sustained release on the PDL.

Dr. Britt expressed concern that because there is only one strength and it's a QD dosing, she felt it would be problematic in titration because the 75mg, 100mg or 150mg would be used BID and then if a 450mg dose is needed, the extended release and sustained release would need to be combined. Until there is availability of all strengths in the extended release, she felt it would be more prudent to not include it at this time.

MOTION: Carl Heard made a motion to add the bupropion 300mg when the 150mg becomes available.

Dr. Horne asked for clarification of the motion. When the 150 and 300mg become available as a generic, the extended release would be on the PDL.

Dr. Heard said he preferred not to make a distinction between generic or trade. He would like to have sustained release 150mg and 300mg bupropion available for patient use however First Health achieves that. We do not want to tie their hands if Wellbutrin is a better price than generics though price cannot be considered by this committee.

Dr. Monaghan recommended this be addressed by the committee when the products are available on the market because of the financial side which this committee is not involved in. The availability of a generic does not ensure a price advantage.

Dr. Heard asked if the only reason this motion should not be supported is financial.

Dr. Monaghan replied no. He agreed with Dr. Britt that it's a patient safety issue. By adding the 300mg without the 150mg is potentially dangerous.

Dr. Heard said his motion is attempting to not deny access for the next three months if we can get the 150mg.

Dr. Monaghan clarified that the sustained release product is available today therefore therapy is not being withheld.

SECOND: None

MOTION: Robert Bryg motioned to accept First Health's recommendation that there be no changes to the current PDL for this class.

SECOND: Judy Britt

AYES: Bryg, Bond, Phillips, Flynn, Shea, Britt

NAYES: Heard, Horne

MOTION CARRIED

V. Anti-Migraine Agents: Triptans

Public Comment

No comment.

Drug Class Review Presentation – First Health Services

Dawn Daly stated that the Triptans were reviewed in July, 2006. The motion was to accept these agents as therapeutic alternatives. There currently is no new information to present in this class. It is the recommendation of DHCFP and First Health that these agents 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: Judy Britt motioned that the drugs in this class be considered 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

Ms. Daly stated that it is the recommendation of DHCFP and First Health to continue to include all dosage forms of sumatriptan (Imitrex®) and rizatriptan (Maxalt®) on the PDL and add eletriptan (Relpax®) to the PDL.

Committee Discussion and Approval of Drugs for Inclusion in the PDL

MOTION: Diana Bond motioned to accept First Health's recommendation to include all dosage forms of sumatriptan (Imitrex®) and rizatriptan (Maxalt®) to the PDL and add eletriptan (Relpax®) to the PDL.

SECOND: Robert Horne

AYES: Unanimous

MOTION CARRIED

VI. Cardiovascular: Antihyperlipidemics: Statins and Statin Combinations

Public Comment

Claude Lardinois, M.D., F.A.C.P., F.A.C.N., professor of medicine, UNR School of Medicine, disclosed that he is on the Speakers' Bureau for several pharmaceutical companies and participates in ongoing education programs with drug companies. He has no grant or research support from those companies. He presented a handout to the committee noting the 2006 ranking of drugs in the United States ranked Lipitor® as number one, Zocor® twenty-five, Crestor® fifty and Pravachol® one-hundred seventy-six. He stated that the group of lipid lowering agents that seem to have the most evidence is Lipitor® (atorvastatin), Zocor® (simvastatin) and niacin. Safety is of concern and there has been a lot of discussion regarding Crestor® (rosuvastatin) and proteinuria issues. He referred to his handout indicating that the 170 FDA report demonstrates that as the dose of atorvastatin, pravastatin, simvastatin, is increased, proteinuria goes down. Two companies have demonstrated reductions in albuminuria. Albuminuria is a powerful marker for cardiovascular disease. In the next ten years, it will turn out to be a greater risk factor for heart disease than hypertension. There is good outcome data for simvastatin, pravastatin and atorvastatin; there is none for Crestor®, Lescol®, Vytorin® or Zetia®. He recommended the committee include drugs on the PDL that have good safety records and good outcome efforts. He states that cost is important to him but not until there is data to show that what is given is safe and efficacious.

Dr. Horne asked regarding Lipitor® on the PDL and Dr. Lardinois replied that his recommendation is to move Lipitor® to preferred because of the clear, emerging outcome data in the last 2-3 years.

Dr. Bryg asked regarding Crestor® and Vytorin®. Dr. Lardinois recommended leaving Crestor® on the PDL, but until albuminuria data is shown that it decreases as with the other three statins, he has serious reservations about using the agent. There is no data on Vytorin®. The inhibiting of the cholesterol in the gut is fascinating and it does help to lower LDL. The important thing is seeing outcome results to feel comfortable in using these agents.

Dr. Phillips asked about pravastatin which is non-preferred. Dr. Lardinois said there is good mortality data with pravastatin and simvastatin.

Mandy Hosford, Astra Zeneca, spoke in support of Crestor®. In response to Dr. Lardinois' concerns, she stated that there is published data on improvement of urinary albumin excretion upon high dose Crestor® versus Lipitor® therapy showing that neither is superior in attenuating albumin excretion at higher doses. Her company also has ongoing clinical trials in Type II Diabetes patients presenting with proteinuria.

David Abrahamson, Merck Schering Plough, spoke in support of Vytorin®. Dr. Heard asked if Mr. Abrahamson has literature which specifically addresses proteinuria. Mr. Abrahamson stated that are two sources of protein, tubular and glomerula. In head-to-head trials Vytorin® versus Crestor®, significant differences were noted and tubular in nature. What is known to date is that with most of the other statins, as the dose is increased, the protein levels diminish but there has not been a study in a renal population prospectively. The impact is unknown until there are outcome studies. What is known is that with most statins at higher doses, there is a decrease in protein levels. The mechanisms are unknown and the outcomes based on that finding are unknown.

Dr. Lardinois commented that albuminuria and proteinuria need to be separated. Most of the literature as referenced in the report is dipstick proteinuria not albuminuria. There are studies with Lipitor® and Zocor® as you increase the dose, albuminuria is decreased. There are LDL receptors on the mesangium of the glomerulas. When the LDL burden is reduced, the flow through the nephron is improved and albuminuria is decreased and that is seen in an increasing dose. Most patients don't need 80mg of Lipitor®. There is reduction in lower doses. The best predictor of cardiovascular disease is not the LDL cholesterol, but the total cholesterol/HDL ratio.

Sandy Serawski, Pfizer, spoke in support of Lipitor®. She stated that Lipitor® was available on the PDL in 2004-2005. During this period, the number of statin prescriptions was 50,000 or more per year and the projected 2006 numbers was 19,000. The decrease may be explained by Medicare Part D. Total prescription volume decreased by 45% whereas the statin prescription volume decreased by 65%. She indicated that there is not enough data explaining the change in utilization. This year, Pfizer applied and was approved for five new indications by the FDA (listed in Pfizer handout).

Dr. Monaghan addressed statin utilization on a per member basis which he stated has increased. The gross decrease seen is due to the reduction from Medicare Part D.

Dr. Britt stated that she works on the managed care side also. Utilization statistics from the prescription benefit manager are required to be based on the prescription per member per month otherwise it's not considered pertinent.

Drug Class Review Presentation – First Health Services

Jeff Monaghan stated that the statins have become the standard treatment for hyperlipidemia. He referred to page 13 of the First Health drug review that all agents in the class produce a dose-dependent LDL lowering. According to ATP guidelines, statins should be considered first-line drugs when LDL lowering drugs are indicated to achieve LDL lowering treatment goals. Across the board, these drugs are considered relatively well tolerated. Rhabdomyolysis can occur with any of them and a liver function test is required with all the agents. All agents are category X. He reminded the committee that when Crestor® was added to the PDL, because of the concerns with renal issues, a safeguard (step-edit) was put in place which required a trial of the 20mg Crestor® before the 40mg will be approved. In terms of drug interactions (CYP450 site), pravastatin is a drug that is probably the safest of all the statins. It is the recommendation of DHCFC and First Health that the agents 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

Dr. Heard questioned that gemfibrozil and the binding agents are not included in this category. Dr. Monaghan clarified that on the PDL, the antihyperlipidemic agents have been broken down into four subcategories: triglyceride lowering agents, niacin agents, cholesterol absorption inhibitor agents and the statins and statin combinations. Today's discussion involves statins and statin combinations as listed on the agenda. The niacin agents and the cholesterol absorption inhibitors were addressed at the last meeting.

Dr. Heard requested for future reviews, the various types of hyperlipidemia be reasonably well covered and to police the literature to confirm or refute the findings regarding proteinuria.

MOTION: Diana Bond motioned that the agents in this category be considered therapeutic alternatives.

SECOND: Robert Horne

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

Jeff Monaghan stated that it is the recommendation of DHCFC and First Health to add pravastatin to the PDL and remove Altoprev®, which is a long-acting lovastatin with very low utilization, from the PDL.

Committee Discussion and Approval of Drugs for Inclusion in the PDL

MOTION: Robert Horne motioned to accept First Health's recommendation to add pravastatin to the PDL and remove Altoprev® from the PDL

SECOND: Robert Bryg

Dr. Heard asked Dr. Bryg if further discussion should be pursued since a giant shift has been made from the number one prescribed drug. He stated that it is not known what the impact of

the shift has been on patients or practices, although that's the question that has been reinforced by the drug reps that there's been a drop in statin use and it's not known if that's meaningful or not at this point.

Dr. Bryg stated that the latest data on Lipitor® and Zocor® is that there's not much difference at the high doses in their outcome. Pfizer trumpeted a report indicating that there was a big difference and then very quietly retracted it when the FDA had them say they reevaluated and there was no real difference. A statin is a statin other than pravastatin which has differences in drug interactions and differences in the degree that it's lowered. You're aiming for a level and which one you choose doesn't matter though the preference would be to use a drug that has outcomes data versus one that doesn't. Pravastatin, Zocor®, simvastatin, and lovastatin have outcomes data. Lipitor® has less and there is none yet on Vytorin® and Crestor®. There was an article in the *Annals of Internal Medicine* three months ago where the author is questioning all the combination products used in cholesterol lowering.

AYES: Unanimous
MOTION CARRIED

Dr. Phillips requested a review of all of the drug classes and the usage per member. Ms. Bond suggested that the review include pre-Medicare Part D.

VII. Cardiovascular: Beta Blockers

Public Comment

Claude Lardinois, M.D., spoke in support of Coreg® SR. He stated that his number one goal in patients with diabetes is their blood pressure. He strives for 120 systolic and 5 mm above syncope. His first line drugs to achieve that goal are an ACE inhibitor and an ARB or thiazide diuretic. When it comes to a third agent, one of the most powerful drugs available, has tremendous outcome data in lowering blood pressure, reducing albuminuria and improving lipids is carvedilol (Coreg®). Most formularies including Nevada restrict use to congestive heart failure. Beta blockers induce insulin resistance, increase triglycerides, lower HDL, and increase visceral fat. This is consistent with most beta blockers with the exception of Coreg®. He asked the committee to consider Coreg® as a preferred drug and would have no problem having the CR as a backup, but there should be some type of Coreg® availability for those complex, hypertensive, diabetes patients.

Dr. Heard asked if Dr. Lardinois is attending at the request of a drug company. Dr. Lardinois replied no and stated that Coreg® is a GSK product and he has no affiliation with that company.

Dr. Phillips asked if the request for the addition of Coreg® to the PDL is for the diabetic or for hypertension. Dr. Lardinois stated that it's the only beta blocker that reduces insulin resistance. It would be an appropriate choice in all populations, not as a first or second line agent, but as third line.

Dr. Heard asked regarding torsades or other complications. Dr. Bryg responded that Coreg® has both alpha and beta agonism and has effects similar to labetalol. There is no data on it being cardio protective in post-MI patients. It's a good blood pressure lowering medicine when the others aren't working well.

John Paulowski, Glaxo Smith-Kline, spoke in support of Coreg® CR. He stated that the metabolic benefits from the Gemini Trial have recently been included in the new prescribing information for both Coreg® and Coreg® CR. Coreg® has also received a recommendation from the American Association of Clinical Endocrinologists as a preferred beta blocker for Type II diabetic patients. Coreg® CR was recently approved by the FDA for the same three indications as Coreg® and has a similar adverse event profile. Decreasing the number of doses taken per day increases patient adherence to medications.

Drug Class Review Presentation – First Health Services

Dr. Monaghan stated that since the last annual review, a new product, Coreg® CR, has been released. When compared to carvedilol (Coreg®) immediate release, the obvious difference is one-a-day dosing. In *Expert Opinion Pharmacotherapy*, December 2006, it was stated that the

pharmacokinetic and pharmacodynamic properties of this new formulation are equivalent to the twice daily formulation. Phase III outcomes trials are underway but currently there are no outcomes trials which indicate outcomes are equivalent. Carvedilol remains one of two beta-blockers FDA approved for the treatment of heart failure. Carvedilol is currently on the PDL with the requirement that the ICD-9 code for heart failure be included on the prescription. Interesting points about diabetes have been discussed. The data is good, however, there is no approved FDA indication for anything related to diabetes. 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 Bryg motioned that the drugs in this class be considered therapeutic alternatives.

SECOND: Diana Bond

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 Coreg® CR be added to the PDL with the requirement that the ICD-9 code (428) for heart failure be included on the prescription. The main concern is that this drug should not be used as first line beta-blocker for hypertension and he encouraged the use of some type of ICD-9 qualification.

Committee Discussion and Approval of Drugs for Inclusion in the PDL

Dr. Phillips stated that he agreed with the requirement of the ICD-9 for heart failure but would like to consider its inclusion for diabetes and not used as first line therapy in the treatment of hypertension.

Dr. Bryg agreed that it should not be used first line. As a third drug, it would be reasonable to add Coreg® CR because it is better blood pressure lowering than some of the other beta-blockers. He suggested approving inclusion for hypertension with an edit for step-therapy that the patient must also be on other hypertensive agents.

Ms. Lawrence stated that to accomplish this, you can default to the PDL exception criteria which will involve the prior authorization process. Currently, if the CHF diagnosis is included on the prescription and entered into the pharmacy system, the claim will process. The other option would be a system look back within a period of time for other prescriptions within the same therapeutic class filled, and if the qualifiers are met, the claim processes. If the request is for a step-therapy edit, it will need to be referred to the DUR Board.

Dr. Heard asked Dr. Bryg if the thinking is step-therapy or should it be a previous hypertensive is already on board and this could be a second or third drug. Dr. Bryg replied that there should be two anti-hypertensives on board and that remain on board. This is in addition to rather than replacement of.

Dr. Phillips stated that per Mr. Faircloth, as clinicians, the committee can define whether this is step-therapy or not. This is combination therapy and the committee has the ability to do that.

Ms. Lawrence said that step-therapy is defined in the State manual as “The process of beginning drug therapy for a medical condition with the safest and most effective lower risk drug therapy and progression to other drug regimens only if medically necessary. Step-therapy protocols are developed at a therapeutic class level and approved through the Drug Use Review Board based upon clinical practice guidelines without consideration of the cost of prescription drugs. Step-therapy guidelines may be implemented through a prior authorization process, prospective DUR edits and/or provider educational programs.”

Ms. Bond stated that this is not a therapeutic class discussion and the committee agreed.

Jeff Monaghan asked for guidance if the ARB is discontinued. Dr. Bryg suggested that once the patient is on Coreg® with success, not to deny it if one of the other drugs is discontinued. Coreg® would need to be included as one of the drugs in the 90 day system look-back.

MOTION: Diana Bond motioned to accept First Health's recommendation to add Coreg® CR with the requirement of ICD-9 code 428 (heart failure) on the prescription. Coreg® and Coreg® CR for hypertension will require a 90-day system look-back to verify that the recipient is currently on a diuretic and an ARB or ACEI and/or there is history of Coreg® or Coreg® CR.

SECOND: Robert Bryg

AYES: Unanimous

MOTION CARRIED

Dr. Phillips clarified that because of the system look-back for the presence of two other anti-hypertensives, the requirement of ICD-9 codes 400 through 402 would not be mandatory.

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

Public Comment

Joe Schwab, Norvartis, spoke in support of Focalin® XR. Onset of activity is 30 minutes. Duration of activity in adults is difficult to ascertain in the sense of study design. The dataset is broken down and it's all self-assessment and the spread is 8-10 hours, 10-12 hours, and greater than 12 hours. The drug is well tolerated with 25% of patients experiencing headache compared to the placebo group which experienced 19%. It's the only methylphenidate preparation indicated in the adult population.

Lisa Durette, M.D., psychiatrist, stated that she has no ties to pharmaceutical companies. Prevalence rates for ADHD are upwards of 5%-6% of the child and adolescent population and 2% of the adult population. This is a disease state that affects many patients and the number one recommendation for treatment is medications. Currently, all the medications require prior authorization which is a process which impedes our ability to provide medications to patients. It's time consuming and often times you cannot get medications to patients in a timely fashion. She requested consideration be given to removing the prior authorization process for these medications at least for the child and adolescent psychiatrists. Strattera® is on the list of the same category of the stimulants which requires prior authorization for ADHD. This medication is recommended as first-line for the treatment of ADHD for patients that have had substance abuse, tics, anxiety or difficulty with the stimulants. It's not an abuse-able drug. She requested that consideration be given to remove Strattera® from the prior authorization process.

Coleen Lawrence clarified that per State statute, the P&T Committee is responsible for the formulation of the PDL and not the establishment of prior authorization requirements and the Drug Use Review (DUR) Board develops clinical edits and prior authorization criteria. The DUR Board is currently addressing the PA requirements for ADHD drugs. She offered to provide DUR meeting information to Dr. Durette.

Dr. Heard asked what is the point between a preferred versus non-preferred drug. If you place a PA in front of preferred and non-preferred, there is no meaning of PDL versus non-PDL. Ms. Lawrence replied that when they get past the clinical edits, the drug of choice becomes the one that is on the PDL. Dr. Heard said that there still is administrative obstruction to access meds for patients whether it's on the PDL or not. Encouraging use of PDL drugs has been obviated by the DUR Board requiring a PA.

Ms. Bond commented that it's old history being reevaluated to see if there can be a different process or elimination of that process. P&T had previously requested DUR review the PA requirements for this class.

Ms. Lawrence stated from a clinician's point of view, it may seem meaningless or not useful to have a PDL, but it is of benefit to the State. By participating in the Medicaid pooling initiative,

the State receives increased rebates for drugs on the PDL. She encouraged the members and public to participate at the DUR Board meeting and offer public comment.

Ann Childress, M.D., psychiatrist stated that she does clinical research and has support from Shire, Norvartis, Lilly, and on the speakers' bureau for Shire and Norvartis. She experienced PA problems with her ADHD patients who are being prescribed stimulants and Strattera®. In some cases, requests to renew these PA's were denied or extended for only a month and she was informed existing patients would be given PA's, but new patients would not be granted PA's and questioned the committee on this type of decision. (Dr. Phillips informed Dr. Childress that these types of issues cannot be addressed by P&T and referred her to the DUR Board.) She stated that it was her understanding that after one failure, Daytrana® or Concerta® would be prior authorized but failure of two continues to be required. She requested consideration be given to adding Daytrana® to the PDL because it can be used as both a long-acting and short-acting medication.

Marisha Madhoo, Ortho-McNeil Janssen, spoke in support of Concerta®. The American Academy of Child and Adolescent Psychiatry identifies Concerta® as being less prone to abuse and diversion than methylphenidate tablets as a result of its once daily morning administration. In retrospective studies, Concerta® has been associated with longer length of therapy and lower switch rate. She requested consideration be given to adding Concerta® on the PDL.

Anthony Deleon, Shire Pharmaceuticals, spoke in support of Daytrana®. The last time Daytrana® was reviewed by the committee, there was a report by First Health that *The Medical Letter* reported that Daytrana® potentially had a higher incidence of side-effects compared to oral methylphenidate formulations. Clinical trial data did not show a significant clinical increase or difference in the instance of side-effects that were observed with oral methylphenidate products. Daytrana® is an extended release formulation administered transdermally. There are very simple and smooth increases and decreases in serum concentration which can be beneficial in patients that may be susceptible or sensitive to fluctuations in serum concentration with the oral dosage forms.

Drug Class Review Presentation – First Health Services

Jeff Monaghan stated that this drug class was reviewed in December 2006, at which time there was a fair amount of testimony from practicing pediatricians and pediatric psychiatrists. There are no new drugs or pertinent clinical information to present today and it is on the agenda today due to some recommended changes within this class. 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: Robert Bryg

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 based on input from the clinicians in the community, as well as new data, it is the recommendation of DHCFP and First Health to add Concerta® to the PDL and delete methamphetamine (Desoxyn®) from the PDL.

Committee Discussion and Approval of Drugs for Inclusion in the PDL

Dr. Horne asked regarding Vyvanse®. Dr. Monaghan stated that based on its recent release date, it was not included in this drug review but will be reviewed at the September meeting.

MOTION: Robert Bryg motioned to accept the recommendation to add Concerta® to the PDL and delete methamphetamine (Desoxyn®) from the PDL

SECOND: Diana Bond

AYES: Britt, Shea, Flynn, Phillips, Bond, Bryg, Horne

ABSTAIN: Carl Heard
MOTION CARRIED

IX. Ophthalmic Antihistamines

Public Comment

Eric Brynes, Alcon, spoke in support of Pataday®, a new formulation of Patanol® for allergic conjunctivitis. Patanol® 0.1% is the gold standard in ocular allergy medications. It's BID dosed, indicated to age three, is safe and well tolerated in pediatrics, excellent efficacy with no stinging or burning which is important for compliance particularly in the pediatric population. The new formulation Pataday® is a double concentration form of Patanol® with once-a-day dosing. Once-a-day dosing provides patient benefits especially in the pediatric population. Pataday® demonstrates the same comfort and safety profile as Patanol®.

Drug Class Review Presentation – First Health Services

Jeff Monaghan stated that there are no new drug entities to discuss in this class but the current drug on the PDL, olopatadine 0.1% (Patanol®), is now available in a more concentrated form and FDA approved for once-a-day dosing (Pataday®). The other change, ketotifen (Zaditor®), has been moved from a prescription to an over-the-counter (OTC) status and is now called Zaditor® OTC. There is another OTC item available, Alaway®, which is ketotifen as well. It is the recommendation of DHCFP and First Health that the agents 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. Phillips asked for clarification if OTC items are covered by Medicaid. Dr. Monaghan stated that approved OTC items are covered but a prescription is required. OTC medications are limited to two per drug class per month.

MOTION: Diana Bond motioned that the drugs in this class be considered therapeutic alternatives.

SECOND: Judy Britt

AYES: Unanimous (Dr. Bryg was not available during the vote)

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 prescription Zaditor®, which is currently on the PDL, be deleted because the product is no longer available, retain Patanol® on the PDL, and add Pataday®, Zaditor® OTC, and Alaway® which is also an OTC product, to the PDL.

Committee Discussion and Approval of Drugs for Inclusion in the PDL

MOTION: Robert Horne motioned to accept First Health's recommendation to remove Zaditor® from the PDL, retain Patanol® on the PDL, and add Pataday®, Zaditor® OTC, and Alaway®

SECOND: Linda Flynn (Dr. Bryg was not available during the vote)

AYES: Unanimous

MOTION CARRIED

3:30 p.m. - Dr. Phillips called for a ten minute break.

Dr. Phillips called the meeting to order at 3:40 p.m.

X. Respiratory: Beta-Adrenergic Agents, Long-Acting Inhaled

Public Comment

Rajiv Dass, Sepracor, spoke in support of Brovana®. Brovana® is the first nebulized twice daily long-acting beta-agonist specifically approved for the treatment of COPD including chronic bronchitis and emphysema. Because this long-acting nebulized treatment option was not previously available, it gives patients the option to treat the disease in a manner that they will attain twelve hours of sustained symptom relief with their COPD symptoms. FDA current guidelines for treatment are focusing on medications that can prevent exacerbations, control symptoms and also control costs. In clinical studies, Brovana® has demonstrated statistically significant efficacy over placebo throughout a twelve hour dosing period with short onset of action of only 6.7 minutes when defined as an improvement of 15% in FEV₁. Studies have demonstrated sustained efficacy with minimal tolerance over long periods of time and reduction in the need for rescue medications. He requested Brovana® be included on the PDL.

Teev Heinaufon, Schering Plough, spoke in support of Foradil® inhalation powder. Foradil® is a long-acting beta-adrenergic agonist with fast onset of action causing significant bronchodilation within five minutes and extended duration of action for over twelve hours. Foradil® is indicated for maintenance therapy of bronchial constriction in patients with COPD, maintenance treatment and prevention of bronchospasm in asthma patients five years and older, prevention of exercise-induced bronchospasm administered fifteen minutes before exercise in patients five and older. In asthma, Foradil® can be added or removed from treatment regimen based upon a patient's asthma control achievement with a single entity inhaled corticosteroid. Foradil® improves respiratory function, reduces the need for rescue medication and improves quality of life.

Drug Class Review Presentation – First Health Services

Dawn Daly stated that this class is being reviewed due to the release of a new agent, arformoterol (Brovana®) inhalation solution which has the indication for long-term, twice daily maintenance in the treatment of bronchoconstriction in patients with COPD including chronic bronchitis and emphysema. It is the (R,R)-enantiomer of formoterol that has two-fold greater potency than racemic formoterol. There are comparative data to suggest that arformoterol is superior in efficacy or safety to other long-acting beta agonists. It is the recommendation of DHCFP and First Health that the agents 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: Carl Heard motioned that the agents in this class be considered therapeutic alternatives.

SECOND: Robert Bryg

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

Ms. Daly stated that it is the recommendation of DHCFP and First Health that no changes be made to the PDL in this class at this time.

Committee Discussion and Approval of Drugs for Inclusion in the PDL

MOTION: Robert Bryg motioned to accept First Health's recommendation that no changes be made to the PDL in this class.

SECOND: Linda Flynn

AYES: Unanimous

MOTION CARRIED

XI. Respiratory: Glucocorticoids, Inhalers

Public Comment

Teev Heinaufon, Schering Plough, spoke in support of Asmanex®. According to the guidelines, inhaled corticosteroids are the cornerstone of persistent asthma treatment. Clinical studies have shown that continuous use of inhaled corticosteroids decrease asthma symptoms and use of rescue medications. Asmanex® is the only FDA-approved first-line inhaled corticosteroid indicated for QD administration. It's indicated for maintenance treatment of asthma in patients twelve years of age and older. Adding Asmanex® may reduce or eliminate the need for oral therapy. It is not indicated for relief of acute bronchospasm. In clinical trials, Asmanex® provided reduction in night time awakenings to 83%, provided control of asthma symptoms (coughing, wheezing and shortness of breath). 46% of patients were able to discontinue prednisone while on Asmanex®. Clinical trials showed side-effects were mild to moderate and no patients required discontinuation of therapy as a result of drug-related adverse events. Asmanex® Twisthaler does not contain a propellant so patients do not need to coordinate actuation and inhalation.

Drug Class Review Presentation – First Health Services

Ms. Daly stated that two new combination products are now available in this class, Advair® HFA (salmeterol/fluticasone), which is an aerosol formulation of the diskus product and Symbicort® HFA, the combination for budesonide/formoterol in an aerosol formulation. Symbicort® HFA and Advair® HFA are indicated for the maintenance treatment of asthma in ages twelve years and older. In previous meetings, salmeterol and formoterol have been deemed therapeutic long-acting beta-agonists and fluticasone and budesonide have been considered therapeutic alternatives as inhaled corticosteroids. 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 Bryg motioned that the agents in this class be considered therapeutic alternatives.

SECOND: Diana Bond

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

Ms. Daly stated that it is the recommendation of DHCFP and First Health to not add Symbicort® HFA and to add Advair® HFA to the PDL.

Committee Discussion and Approval of Drugs for Inclusion in the PDL

MOTION: Judy Britt motioned to add Advair® HFA to the PDL.

SECOND: Chris Shea

AYES: Unanimous

MOTION CARRIED

Due to another commitment, Dr. Britt was excused from the meeting at 4:00 p.m.

XII. Annual Review - Drug Classes without Proposed Changes

Public Comment

Bert Jones, Glaxo SmithKline, requested that the nasal steroid class be reviewed. Veramyst®, which is a new product in this category, was approved 4/27/07. He requested that this category be added for review at the September meeting.

Dr. Heard asked what is it about this drug that we must have or something that we can't have. Mr. Jones responded that the key advantages are that it's the first and only inhaled nasal steroid proven to relieve nasal and ocular symptoms. It's once-a-day dosing, low spray volume, no alcohol and

according to pediatricians, it's a kid-friendly product indicated for two years and above. It has an actuated pump which is easy to use and allows the volume to be kept low and it's non-scented.

Ms. Lawrence clarified that because this class has been reviewed, Veramyst® is considered non-preferred.

Rick Fisceler, Clinical Professor, University of Illinois, disclosed that he receives research support from Allergan and Pfizer and is on the speaker's bureau for Allergan. He stated that there are only two fourth generation fluoroquinolones commercially available, Zymar® and Vigamox® to treat infection. They are first-line, aggressive treatment for vision-threatening infections. Conjunctivitis, in general, is not considered a vision threatening infection. Fourth generation fluoroquinolones should not be used for bacterial conjunctivitis. The Academy of Ophthalmology's preferred practice patterns recommend for bacterial conjunctivitis using a cost-effective generic like polytrim or polysporin as a first line agent for most cases. There are differences when looking at Zymar® use and Vigamox® use in terms of the general population. Zymar® is prescribed by eye care practitioners 94% of the time. Vigamox® is 50% prescribed by eye care practitioners and the other 50% by pediatricians and family practitioners for bacterial conjunctivitis. Family practice physicians and pediatricians prescribe fluoroquinolones for conjunctivitis or pink eye 86% of the time. Eye care practitioners prescribe for eye surgery 43%, corneal ulcers 14%, eye trauma 11%, and conjunctivitis 14%. Inappropriate prescribing of Vigamox® for conjunctivitis may cause increased risk for developing resistance and increased cost of formularies. Data will be published in September in the *American Journal of Health System Pharmacy*.

Dr. Phillips stated that it appears the concern is the potential use for inappropriate reasons. Dr. Heard commented that this opens up the question of quality measures. If there are disproportionate primary care doctor utilization profiles that could be reviewed for this and other drugs, it would be interesting.

Dr. Monaghan stated that part of the inference here is that Zymar® should be preferred and not Vigamox®; that's one take away. The other is that maybe none should be on the PDL and if they are, there should be PA criteria applied.

Diana Bond asked if an edit can be put in place for specialty prescribing particularly with NPI. Dr. Monaghan stated that because provider information is not always submitted or captured, it is unsure how complete or accurate the provider enrollment files are. Assuming the information is in the file and accurate, an edit can be applied.

Ms. Lawrence stated that NPI is a gatekeeper into the Medicaid system. Medicaid legacy ID numbers continue to run the system. The Medicaid ID number is in the system and the sub-specialty of the prescriber is also in the system. NPI will be linked directly to the Medicaid ID and the specialty can be identified.

Lori Kamins, DEY, spoke in support of AccuNeb®. AccuNeb® is the albuterol solution for nebulization and comes in a sterile unit dose of 0.63mg. It's designed and FDA approved specifically for children two to twelve years of age. It has demonstrated efficacy at doses 50% and 75% lower than 2.5mg of adult strength albuterol, has a favorable side effect profile with less than 1% beta-agonist mediated symptoms. Both the NIH and NHLBI advisory boards say patients should use the lowest beta-2 agonist dose necessary to control symptoms. Levalbuterol is not approved for subjects two to five years old because they have more exasperations of asthma than in racemic albuterol and placebo groups. Lower doses of albuterol help avoid the side effects of tachycardia, tremors and hyperkalemia. Nebulized systems saved healthcare dollars by helping 59% avoid hospitalization, 61% avoid unscheduled office visits and 67% avoid trips to the ER.

Debbie Dye, Shire Pharmaceuticals, spoke in support of Fosrenol®. Hyperphosphatemia is associated with increased morbidity and mortality in patients with end stage renal disease on hemodialysis. Fosrenol® has been demonstrated to control patients' serum phosphorous in prospective trials out to three years. In the last year, a new formulation of Fosrenol® was introduced into the market. 500mg doses were originally available and it's now available in 750mg and 1,000mg tablets. Using the new formulation has shown the majority of patients can

reach serum phosphorous targets with 3gm per day which correlates to 1gm or 1 tablet given with each meal three times per day. Data demonstrates that patients switched from the previous phosphate binder therapy using the 500mg tablets, there's a 30%-50% reduction in the total number of tablets that patients have to take each day. Fosrenol® is effective and has a demonstrated safety profile. There is a published prospective study that Fosrenol® was not associated with any osteomalacia. She requested that the committee consider Fosrenol® as a preferred agent.

Derek Terada, Boehringer Ingelheim Pharmaceuticals, spoke in support of Mycardis®. Clinical studies show the antihypertensive effect of Mycardis® is sustained over a full twenty-four hours (morning, nighttime and the last six hours of the dosing interval). A community based trial was recently conducted in 1,600 patients with stage one or stage two hypertension. The results showed that either starting or switching to Mycardis® gave an ambulatory blood pressure reduction of 11 over 7 which translated to an office reduction of 20 over 12. If you can reduce blood pressure by 20mm systolic over 10 diastolic, the cardiovascular event and mortality rate is cut by 50%. He stated that there is a global outcome trial which is ongoing comparing Mycardis® to ramipril and the combination of Mycardis® plus ramipril to ramipril alone in a high risk patient population similar to the HOPE Trial. The results will be presented at the American College Cardiology Conference in March 2008.

Laura Litzenberger, Ortho-McNeil Pharmaceutical, spoke in support of Levaquin®. Levaquin® is the only fluoroquinolone that is approved for two high dose, short-course respiratory tract infections. It's FDA approved for 750mg dose for five days for community-acquired pneumonia and for sinusitis and the only fluoroquinolone that has those indications. Ms. Litzenberger cited a study which demonstrated that Levaquin® has a validated cardiac safety population especially in the high risk population in contrast to Avelox® which increases the mean QTC interval. Levaquin® is safer in antibiotic associated diarrhea. Only 4% of the drug is excreted into the bile compared to Avelox® in which 25% is excreted into the bile.

Presentation of Recommendations for Preferred Drug List (PDL) Inclusion by First Health Services and the Division of Health Care Financing and Policy without Changes

1. Analgesics: Long-Acting Narcotics
2. Antibiotics: Cephalosporins Second Generation
3. Antibiotics: Cephalosporins Third Generation
4. Antibiotics: Macrolides
5. Antibiotics: Quinolones Second Generation
6. Antibiotics: Quinolones Third Generation
7. Antidepressants: SSRIs
8. Antimetics: Oral, 5-HT3s
9. Antifungals: Onychomycosis Agents
10. Antihistamines: Second Generation
11. Bone Ossification Agents: Bisphosphonates
12. Cardiovascular: ACE Inhibitors & Diuretic Combinations
13. Cardiovascular: Angiotensin II Receptor Blockers & Diuretic Combinations
14. Cardiovascular: Antihyperlipidemics: Cholesterol Absorption Inhibitors
15. Cardiovascular: Antihyperlipidemics: Niacin Derivatives
16. Cardiovascular: Antihyperlipidemics: Triglyceride Lowering Agents
17. Cardiovascular: Calcium Channel Blockers & ACEI Combinations
18. Central Nervous System: Hypnotics
19. Electrolyte Depleters
20. Gastrointestinal Agents: H2RAs
21. Gastrointestinal Agents: PPIs
22. Hepatitis C Agent
23. Herpetic Antiviral Agents
24. Immunomodulators: Injectable
25. Immunomodulators: Topical
26. Leukotriene Modifiers
27. Multiple Sclerosis Agents
28. Nasal Calcitonins

29. Ophthalmic Glaucoma Agents
30. Ophthalmic Quinolones
31. Otic Fluoroquinolones
32. Respiratory: Anticholinergic Agents, Inhaled
33. Respiratory: Beta-Adrenergic Agents, Short-Acting Inhaled
34. Respiratory: Glucocorticoids, Nasal
35. Urinary Antispasmodics

Committee Discussion and Approval of Drug Classes without changes for the PDL

Jeff Monaghan stated that it is the recommendation of DHCFP and First Health that there are no changes to the PDL for drug classes 1 through 35.

MOTION: Robert Bryg motioned to accept First Health's recommendation that there be no changes to the PDL for drug classes 1 through 35.

SECOND: Robert Horne

Dr. Phillips recommended a review of how ophthalmic quinolones are being utilized. Ms. Bond stated that she would also like to see a report on utilization and would support an edit limiting prescribing to ophthalmologists.

AYES: Unanimous (Dr. Heard was not available for the vote)

MOTION CARRIED

XIII. Report by FHSC on Brand Name Preferred Drugs Converted to Generic Status and Line Extensions

Jeff Monaghan stated that at the March meeting, the decision was made to allow the State to change the PDL to reflect the conversion of brand name drugs to their FDA approved generic equivalents and report any changes to the committee quarterly. He presented a report of changes which were put in place since the last meeting.

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

The next meeting is scheduled for September 27, 2007, 1:00 p.m., at the Meadow Wood Courtyard in Reno.

Jeff Monaghan stated that there are problems obtaining a meeting room for the December 13th meeting and will contact the committee members regarding their availability on a different date.

XV. Public Comment

No comment.

XVI. Adjournment

Dr. Phillips stated that it has been a pleasure serving on the committee and adjourned the meeting at 4:27 p.m.