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

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PHARMACY & THERAPEUTICS COMMITTEE

Meadow Wood Courtyard
5851 S. Virginia St.
Reno, NV

Final Minutes
March 22, 2007
1:00 p.m.

Approved by P&T Committee on 6/21/2007

Committee Members Present:

Steven Phillips, MD, Chairman
Judy Britt, Pharm.D.
Robert Bryg, MD
Carl Heard, MD
Larry Pinson, Pharm.D.
Susan Pintar, MD
Chris Shea, Pharm.D.
Diana Bond, R.Ph. (called in)
Linda Flynn, R.Ph. (called in)
Robert Horne, MD (called in)

Others Present:

Coleen Lawrence-DHCFP, Debbie Meyers-DHCFP, Darrell Faircloth-DAG, Jeff Monaghan-FHSC, Shirley Hunting-FHSC, Dawn Daly-FHSC, Jeff Neumann-Lilly, Craig Boody-Lilly, Laurie Babb-EMD Serono, Gina Guinasso-EMD Serono, Karen Musso-EMD Serono, Rajiv Dass-Sepracor, Adam Lyons-Astellas, Kathleen O'Neill-Astra Zeneca, Sandy Sierawski-Pfizer, Lori Howarth-Berlex, Jonathan Lloyd-Pfizer, Matt Jackson-Astellas, Brian Streng-GSK, John Stockton-Genentech, Bert Jones-GSK, Joann Phillips, Robin Leith-Reliant, Bret Parker-Pfizer, Kathy Hollingsworth-Takeda, Shawn Prince-Elan, Vicky Viss-Santarus, Jim Griffin-Santarus, Doug Powell-Forest, Chris Almeida-Purdue Pharma.

I. Call to Order and Roll Call

Chairman Steven Phillips called the meeting to order at 1:05 p.m.

II. *Review and Approval of December 14, 2006 Meeting Minutes

Dr. Heard referred to page 6 of the minutes (Item VI. Central Nervous System: ADHD/Stimulants/Non-Stimulants). Action could not be taken on the prior authorization (PA) requirement because it was not agendaized at the December meeting. He stated that it is the DUR's position to consider PA requirements and he requested the DUR Board consider the current dilemma that every specialist that treats ADHD has to obtain a PA for every drug used.

Ms. Lawrence stated that the DUR Board did address this request and decided not to make any changes to the existing criteria at that time. They requested more data collection; primarily the physician types that are prescribing ADHD drugs. The State and First Health will be presenting a preliminary report at the April DUR Board meeting.

Dr. Heard requested a status report be presented at the next P&T meeting.

MOTION: Larry Pinson motioned to accept the minutes as written.

SECOND: Carl Heard

AYES: Unanimous

MOTION CARRIED

III. Public Comment

No Comment

Dr. Phillips stated that due to time constraints for Ms. Lawrence, Items X and XI will be taken out of order and addressed following Item III.

IV. Bladder Relaxants

Public Comment

Dr. Monaghan informed the committee that today's reviews are of new drug classes that have not been brought to the committee before.

Brian Streng, Glaxo SmithKline, spoke in support of VESicare®. He referred to the STAR and VENUS studies. He stated that VESicare®, to date, is the first and only drug that has been able to show a statistical difference in warning time for patients. Though small, the warning time for patients in this category is critical. He requested consideration be given to VESicare® as an additional choice in this category and added to the PDL.

John Lloyd, Pfizer, spoke in support of Detrol® LA. Efficacy and tolerability have been demonstrated in multiple patient populations. He referred to the IMPACT study which showed improvement in patients for whatever the patient said was their most bothersome symptom when using Detrol® LA. Overall, the study demonstrated that 80% of the patients said that their bladder condition was better. He requested consideration for maintaining Detrol® LA on the preferred list.

Drug Class Review Presentation – First Health Services

Dawn Daly presented an overview and comparison of the drugs within this class. There are five agents in this class all indicated for the treatment of urge urinary incontinence, frequency and urgency. Contraindications, warnings and adverse events are similar for all urinary antispasmodics. A key factor to consider in differentiating these agents is their extensive metabolism via the CYP450 system. In December, 2005, OHSU reviewed this class. Overall, the evidence did not demonstrate consistent differences in the objective or subjective efficacy measures especially in the target population to be treated among comparisons of tiroprium, oxybutynin (IR, ER, TD), tolterodine (IR, ER) and solifenacin. There was evidence for darifenacin only in placebo-controlled trials so no statement can be made about comparative efficacy. It is the recommendation of DHCFCP and FHSC 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. Britt commented that several of these agents have cytochrome P450 interactions specifically with 2D6 and 3A4. These would be seen as differences though therapeutically correct. They are therapeutically equivalent but there are differences in the side effect profile and the interaction profile.

Dr. Heard asked if any of those differences are strong enough to exclude them from the PDL. Dr. Britt replied no that we are looking at patient variability, especially the elderly who will be sensitive to the oxybutynin. If individuals are on drugs that would have effect on the three cytochrome P450, those individuals probably would do better to be on something that didn't interact with those drugs.

MOTION: Larry Pinson 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 DHCFCP and First Health that tolterodine long acting (Detrol® LA), darifenacin (Enablex®), short-acting oxybutynin and solifenacin (Vesicare®) be preferred.

Committee Discussion and Approval of Drugs for Inclusion in the PDL

MOTION: Carl Heard motioned to accept the recommendations of First Health that tolterodine long-acting (Detrol® LA), darifenacin (Enablex®), short-acting oxybutynin and solifenacin (Vesicare®) be preferred.

SECOND: Larry Pinson

AYES: Unanimous

MOTION CARRIED

V. Immunomodulators, Topical

Public Comment

Adam Lyons, Astellas Pharmaceuticals, spoke in support of Protopic® (tacrolimus), 0.3% and 0.1% topical ointment for the treatment of eczema. Clinical experience since its release in 2001 is 2.1 million patients in the United States and 5.4 million worldwide. To date, there have been no reports of malignancies in twenty-three comparative clinical trials, however, have recently received a label change by the FDA due to theoretical concerns. Protopic® ointment is an important treatment option for patients with atopic dermatitis. It is safe and effective when used according to the label.

Dr. Shea said that looking at the indications for either drug being reviewed, there is a second line therapy for short-term and non-continuous chronic treatment and every study listed in the review obviously was done for a different duration of time (four weeks, twenty-four weeks, one year). Under the warnings, it states to avoid long-term use of one of the drugs and then another statement says to continue until clear and asked for clarification on how long the drug should be used.

Mr. Lyons replied that what is shown is a compendium of the different studies, pre and post label change. Some of the studies were done prior to the label change from the language in the label change to non-continuous long-term use. The original label gave guidance in saying seven days after until the symptoms cleared. That was what non-continuous long-term use was interpreted by both Astellas and the FDA. The reason why you are seeing one year clinical studies is because before the label change, we continued to look at long-term patient care and side-effects of the drug.

Drug Class Review Presentation – First Health Services

Dawn Daly presented an overview and comparison of the drugs within this class, pimecrolimus (Elidel®) and tacrolimus (Protopic®). Both agents are second-line therapy for short-term and non-continuous chronic treatment of mild to moderate atopic dermatitis in non-immunocompromised patients two years and older. Both carry a black box warning regarding the long-term safety of topical administration. Contraindications, warnings, adverse drug events and drug interactions are similar and considered a class effect. It is the recommendation of DHC FP 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 to Identify Exclusions/Exceptions for Certain Patient Groups

Dr. Pintar stated that the studies for Elidel® have been done in infants. Studies in infants are included in the review yet the FDA label indication is different. By specifying two years old, are we restricting use to two years and older. Ms. Daly replied its labeled indication is two years and older. Dr. Monaghan stated that there is no age edit to preclude use.

Dr. Britt commented that when the pre-marketing studies were done, infants under two were included. After post-marketing surveillance showed that there was some association between lymphomas and malignancy and the use of this agent, the FDA required a labeling change not be used under two. It was all based on post-marketing surveillance adverse events.

MOTION: Carl Heard motioned that the agents in this class be considered therapeutic alternatives.

SECOND: Judy Britt

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 include pimecrolimus (Elidel®) and tacrolimus (Protopic®) to the Preferred Drug List.

Committee Discussion and Approval of Drugs for Inclusion in the PDL

Dr. Britt recommended both agents be referred to the DUR Board for consideration of age edits and restriction for duration of use. Dr. Phillips asked if she is accepting the recommendation of including the two but with referral to DUR and she replied that is correct.

Dr. Heard commented that management of a formulary is to contain costs and to encourage correct behavior. When trying to encourage correct behavior by putting in edits and other bureaucratic measures of obstructing the practice of medicine, then we want to discuss what that break point is. Otherwise, we bog First Health down potentially with a lot of edits that may not be changing behavior or we may overlook the opportunity to significantly change behavior in professionals and encourage a more healthy interaction with their patients. He asked Dr. Britt her thoughts on how this case is different than others this committee has debated. She stated that the FDA took action to have the labeling changed so it was serious that they intended this to be used in individuals over two. If there's a need for a child under two to use it, you will have a PA process that for medical and legal reasons is a better idea than have it open-ended.

Dr. Heard asked if Medicaid can endorse or pay for off-label use of medications. Dr. Monaghan said that age edits are easy to put in place and when the DUR Board discusses this, it will probably be something they consider.

Dr. Phillips said that at a previous meeting, there was a suggestion of having a drug available that was not FDA approved for that population. The committee was counseled that they could not endorse off-label use. Ms. Lawrence confirmed that the State cannot endorse off-label use.

Dr. Heard said that he is in favor of PDL inclusion and leave it to the clinician and patient to negotiate a solution and keep the strong arm of the bureaucracy out of it for now. If the DUR Board comes back with a recommendation, we debate that based on what the DUR recommendation is.

Dr. Britt responded that is why she asked that this go to the DUR Board. Not that they put the restriction on, that they consider it.

Darrell Faircloth commented that it is within DUR's power rather than the P&T's power to recommend prior authorization criteria. The function of this committee is to create the Preferred Drug List. What is being addressed here is utilization consideration and practice consideration which is more the purview of the DUR Board.

MOTION: Judy Britt motioned to include pimecrolimus (Elidel®) and tacrolimus (Protopic®) to the Preferred Drug List with referral to the DUR Board for consideration of age edits and restrictions for duration of use.

SECOND: Larry Pinson

AYES: Unanimous

MOTION CARRIED

VI. Lipotropics, Other

Prior to accepting public comment, Dr. Phillips requested that Dr. Monaghan clarify why this class is being reviewed. Dr. Monaghan stated that the Lipotropic class of statin agents was initially reviewed in 2004. In 2005, the cholesterol absorption inhibiting agents, Zetia® and Vytorin® were reviewed. Today, the other non-statin Lipotropic agents are brought to the committee for review. The drug review has included several different drug classes within this category. In his presentation, he will break these down into subclasses. He stated that public comment will be taken on any or all of the classes within the category.

Public Comment

Robin Leith, Reliant Pharmaceuticals, spoke in support of Omacor®, an omega-3 fatty acid for the indication of triglycerides over 500 with reduction of triglycerides of 45%. There are no known drug interactions. The only clinically significant adverse reaction was eructation.

Dr. Britt commented that she read that Omacor® had an approvable letter for indication for 200 to 499 triglycerides as well. Ms. Leith replied that is accurate. The FDA has to return information to the company regarding this indication by June.

Kathleen O'Neill, Astra Zeneca pharmaceuticals, spoke in support of Crestor®. She reinforced the efficacy of Crestor® (rosuvastatin calcium) as an effective first line agent for the treatment of high risk patients. Crestor® has been proven to reduce LDL by half, increase HDL by 8-14%. In pre-approval clinical trials and marketing experience, Crestor's demonstrated safety profile is in line with other statins. She respectfully requested Crestor® remain on the PDL.

Dr. Phillips stated that the statins are not being considered today therefore their status on the PDL will not be affected today.

Drug Class Review Presentation – First Health Services

Jeff Monaghan said that the overall Lipotropic class was first reviewed in 2004 and in 2005 a re-review was done. At that time, the agents Zetia® and Vytorin® were reviewed. Vytorin® was added to the PDL; Zetia® was not added but it has been available via PA for statin-intolerant patients. What is being presented today is the remainder of the non-statin Lipotropic agents for discussion. Because they are all grouped together, it could be fairly confusing to say they are therapeutic equivalents since they act differently. To add some structure to the discussion, he proposed breaking down this category into the following subclasses for discussion and action:

1. Triglyceride Lowering Agents
2. Niacin Agents
3. Cholesterol Absorption Inhibitor Agent (Zetia®)
4. Bile Acid Sequestrants (due to low utilization in this category, it will not be reviewed for action)

The current standard for treatment of elevated LDL-C is statin therapy, which as a class, can lower LDL-C by up to 55% in a dose related fashion. Statins typically only have minor effects on triglyceride and HDL-C. Each class of the non-statin lipotropics provides a unique option for use in patients who cannot reach their target on statin monotherapy or maybe don't tolerate statin therapy. For high risk patients, the NCEP guidelines recommend that fibric acid and nicotinic acid be considered either as monotherapy or in combination with statins in the presence of elevated TG and/or low HDL-C. He referenced page 9 of the Drug Class Review document for the comparative impact of these agents on serum lipids. He presented the subclasses for discussion and action.

Triglyceride Lowering Agents - Drug Class Review Presentation – First Health Services

Dr. Monaghan stated that there are two fibric acid entities to consider, fenofibrate and gemfibrozil. Fenofibrate is available in various strengths depending on the manufacturer. The fibric acid derivatives have been shown to reduce cardiovascular mortality and morbidity. They lower triglyceride levels and raise HDL-C levels to a greater extent than do the statins. The fibric acid derivatives should be considered as an alternative to the statins or as add-on therapy with a caution when used together, there is an increased risk of myopathy. Indications and adverse events are comparable for all agents. The strengths of the various fenofibrate products vary by manufacturer. They've shown at the highest available dose to produce plasma concentrations similar to the fenofibrate 200mg capsule in single dose studies. The other product in this category is the omega-3 fatty acids. There is one product to consider in this class, Omacor®. There are several forms of omega-3 fatty acids available over-the-counter, however, this is the only legend or prescription product. Omacor® is a combination of two fatty acids contained in fish oil. The mechanism of action is not completely understood. Adverse effects are minimal. Current guidelines position this product as a second line or alternative to either niacin or the fibric acid derivatives. It is the recommendation of DHCFP and First Health that the products within the triglyceride lowering agents category be considered therapeutic alternatives.

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

Dr. Bryg commented that after getting away from statins, there is surprisingly little evidence that outcomes are changed. With triglycerides over 500, we're also trying to prevent pancreatitis which is a big problem. There is no good outcome data on what to do with triglycerides from 200 to 499. These agents are used to lower cholesterol and triglyceride numbers but there is surprisingly little data once you get past gemfibrozil of changing outcomes in these patients.

Dr. Horne stated that the drug review indicates that the omega-3 fatty acid increase LDL by 45%. He said he is not in favor of reducing triglycerides by raising the bad cholesterol and would not want it to be grouped with the fibric acids.

Dr. Phillips said just looking at the triglycerides, it's a reasonable grouping with fibric acids and omega-3 in terms of therapeutic alternative. Dr. Heard added that these are specifically drugs that are therapeutic alternatives for the lowering of triglycerides. It is not intended to be something focused on the other measures. For the purpose of managing triglycerides, these are therapeutic alternatives. PDL inclusion of these agents can be considered during that discussion.

MOTION: Carl Heard motioned that the agents 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 gemfibrozil and the Tricor® brand of fenofibrate be added to the PDL.

Committee Discussion and Approval of Drugs for Inclusion in the PDL

Dr. Britt asked for clarification that niacin is not included in this subclass. Dr. Monaghan stated that is correct.

Dr. Phillips clarified that this discussion was about the subclass which includes fenofibrate, gemfibrozil and omega-3 fatty acid ethyl esters. It was agreed that these are therapeutic alternatives for the lowering of triglycerides.

MOTION: Robert Horne motioned to accept First Health's recommendation to add gemfibrozil and the Tricor® brand of fenofibrate to the Preferred Drug List.

SECOND: Robert Bryg

AYES: Unanimous

MOTION CARRIED

Niacin Products - Drug Class Review Presentation – First Health Services

Jeff Monaghan stated that immediate release niacin is generically available over the counter. To increase tolerance, the extended release niacin has been developed, Niaspan® being the most common brand name, and it's available in various strengths. Combination therapy with niacin and statins yield a significant reduction in LDL-C as well as an increase in HDL-C. There are outcome studies in the use of this drug in terms of reducing risk of cardiovascular disease both as monotherapy and in combination with statins. It is the recommendation of DHCFP and First Health that extended-release niacin agents be considered therapeutic alternatives.

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

MOTION: Robert Bryg motioned that the agents 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 to add niacin extended release and Niaspan® to the PDL under the category of niacin agents.

Committee Discussion and Approval of Drugs for Inclusion in the PDL

MOTION: Larry Pinson motioned to add niacin extended release to the PDL.

SECOND: Judy Britt

AYES: Unanimous

MOTION CARRIED

Cholesterol Absorption Inhibitors - Drug Class Review Presentation – First Health Services

Dr. Monaghan stated that there is only one agent within this drug class, ezetimibe (Zetia®). Although Zetia® was recently reviewed, it is presented for discussion again due to its inclusion in this drug review. In order to provide a full range of alternatives for patients intolerant of statins, it is recommended that Zetia® be considered for addition to the PDL as a unique agent in its own subclass, the calcium absorption inhibitors. It currently has very low utilization (2% of market share). When taken off prior authorization in other states, it has not been found to be abused or misused. This is an opportunity to remove a PA requirement and make a drug available as a statin alternative. It is the recommendation of DHCFP and First Health to add ezetimibe (Zetia®) to the PDL.

Dr. Shea asked where Vytorin® will be placed. Dr. Monaghan replied that Vytorin® was reviewed and approved with the statins. Dr. Bryg added that Zetia® can be prescribed alone for statin intolerant patients. Zetia® is not used as a first line drug. Most physicians will not use it as a sole agent because the monograph states that it has not been shown to change any outcomes.

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

There is only one agent in this drug class; no action is required.

Committee Discussion and Approval of Drugs for Inclusion in the PDL

MOTION: Larry Pinson motioned to add ezetimibe (Zetia®) to the PDL.

SECOND: Carl Heard

AYES: Unanimous

MOTION CARRIED

VII. Multiple Sclerosis Agents

Public Comment

Laurie Babb, EMD Serono, spoke in support of the inclusion of Rebif® on the Preferred Drug List. In 2002, the American Academy of Neurology published an article reviewing all disease modifying therapies in MS. The review committee came up with three efficacy parameters which were reduction in the relapse rate, delayed progression of disability and a reduction in the number of active lesions. Only Rebif® had a statistical significant effect on each of the parameters. To overturn the orphan drug status of Avonex®, Serono undertook the Evidence Trial. The end points of the Evidence Trial where Rebif® was statistically superior to Avonex® were the proportion of patients relapse-free at 48 weeks and the reduction in active lesions on MRI at 48 weeks. The Evidence Trial showed comparable side effects, adverse events, and drug discontinuation with both Rebif® and Avonex®.

Dr. Heard commented that Avonex® and Rebif® appear to be identical drugs and asked what the difference is. Ms. Babb replied because of how it works in the body with regard to being an immunosuppressant and the dosing which is three times per week versus once per day intramuscularly with Avenox®.

Karen Musso, EMD Serono, presented a letter from Frank Quaglieri, M.D., in support of Rebif® (Dr. Quaglieri was not able to attend the meeting).

Drug Class Review Presentation – First Health Services

Jeff Monaghan stated that MS is a complex human autoimmune-type inflammatory disease of the CNS resulting in nerve degeneration. Interferon beta agents (Avonex®, Rebif®, and Betaseron®) and glatiramer (Copaxone®) are immunoregulatory agents that have been shown to reduce relapse rates and possibly slow the rate of progression of the disease. Consensus guidelines for the use of MS disease-modifying therapies endorse the use of immunomodulators for all relapsing forms of MS and for consideration in the treatment of selected first-attack or high-risk patients. Questions remain as to the comparable and optimal dosages and frequencies for the various interferons. Although there is a lack of non-blinded, non-randomized studies directly comparing Copaxone® to the interferon agents, these agents appear to be similarly effective for the control of MS exacerbations. The adverse events profile indicates that Copaxone® may be better tolerated but the beta interferons may slow progression more effectively. 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 to Identify Exclusions/Exceptions for Certain Patient Groups

Diana Bond asked about preexisting patients that are stabilized on one of these agents. Dr. Monaghan replied that it would not be advisable to change someone that has a track record of success on an agent. Dr. Phillips noted that Ms. Lawrence had to leave the meeting early but felt the State would support this as well.

Dr. Phillips read Dr. Quagliari's letter supporting Rebif® for inclusion to the PDL. Dr. Quagliari wrote that "it is extremely important that patients receiving Rebif® be allowed to continue their treatment without interruption, and that new patients being considered for treatment with Rebif® or other immunomodulators be able to access these very effective medications through Nevada Medicaid."

Dr. Heard asked regarding market share. Dr. Monaghan replied that Copaxone® is at 41%, Avonex® at 33%, Rebif® at 13%, Betaseron® at 11%.

MOTION: Larry Pinson motioned that the agents in this class be considered therapeutic alternatives.

SECOND: Judy Britt

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 to add Avonex®, Betaseron®, Rebif® and Copaxone® to the PDL.

Committee Discussion and Approval of Drugs for Inclusion in the PDL

MOTION: Carl Heard motioned to accept First Health's recommendation to add Avonex®, Betaseron®, Rebif® and Copaxone® to the PDL.

SECOND: Larry Pinson

AYES: Unanimous

MOTION CARRIED

VIII. Otic Fluoroquinolones

Public Comment

No comment.

Drug Class Review Presentation – First Health Services

Dawn Daly stated that there are three fluoroquinolone formulations for use as otological medications: ofloxacin, ciprofloxacin with hydrocortisone and ciprofloxacin with dexamethasone. These agents are synthetic, broad spectrum antibacterial agents that have activity against a wide range of gram negative and gram positive microorganisms. All are indicated for the treatment of otitis externa. Ofloxacin and ciprofloxacin with dexamethasone are also indicated for acute otitis media with tympanostomy.

Additionally, ofloxacin is indicated for chronic suppurative otitis media in patients 12 years and older. All agents are administered twice daily. The American Academy of Otolaryngology-Head and Neck Surgery Foundation in 2006, released guidelines that for the treatment of acute otitis externa, a seven day course of topical antiseptics or antibiotics should be used initially. When the tympanic membrane is perforated or the patient has tympanostomy tubes, a non-ototoxic antibiotic which includes the fluoroquinolones should be prescribed. It is the recommendation of DHCFP 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 to Identify Exclusions/Exceptions for Certain Patient Groups

Dr. Heard commented that what is being considered is a combination versus a non-combination drug (a straight antibiotic versus an antibiotic with a steroid to act with it). If you need one with steroids, it's not an alternative to one without steroids. They can be used for the same diagnosis unless there is a ruptured membrane in which case one with steroids must be used. Dr. Pintar clarified that the treatment of otitis externa was specified and Dr. Phillips agreed.

Dr. Britt stated that two of the agents are FDA approved for use in otitis media as well as otitis externa and the other is approved for only externa. It would be a problem if there is only one drug on the PDL and it's only approved for otitis externa.

MOTION: Susan Pintar motioned that the agents in this class be considered therapeutic alternatives.

SECOND: Robert Bryg

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

ABSTAINED: Heard

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 ofloxacin and ciprofloxacin with dexamethasone be added to the PDL.

Committee Discussion and Approval of Drugs for Inclusion in the PDL

MOTION: Larry Pinson motioned to accept First Health's recommendation to add ofloxacin and ciprofloxacin with dexamethasone to the PDL.

SECOND: Robert Bryg

AYES: Unanimous

MOTION CARRIED

IX. Phosphate Binders

Public Comment

No comment.

Drug Class Review Presentation – First Health Services

Jeff Monaghan stated that one of the serious complications of chronic kidney disease is hyperphosphatemia. Phosphate-binding agents decrease phosphorous absorption from the GI tract by binding dietary phosphorous. There are two types of phosphate-binding agents to consider, calcium and non-calcium containing agents. Calcium acetate, PhosLo®, is one of the most commonly used calcium salts. In addition to binding phosphorous, it also helps maintain positive calcium balance and binds to and lowers dietary phosphorous. Sevalamer, Renagel®, is a non-calcium, non-absorbable hydrogel that binds dietary phosphorous. Lanthium carbonate, Fosrenol®, is a naturally occurring earth element that has a high affinity for phosphorous and forms an insoluble lanthium phosphate in the GI tract. Phosphate-binding therapy with calcium acetate (PhosLo®) is as effective as sevalamer (Renagel®) in reducing serum phosphate levels. Hypercalcemia can occur more frequently with calcium containing agents. Some concern has been expressed based on Electron Beam Tomography (EBT) regarding an increase in vascular calcifications with calcium-based therapy. Calcium-based phosphate binders are considered first line in the pediatric population. Calcium supplementation may be required with any of the phosphate binders, but is more prevalent with the non-calcium agents. Lanthanum is another non-

calcium option but the long-term effects on bone remain unclear. 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 to Identify Exclusions/Exceptions for Certain Patient Groups

MOTION: Robert Horne 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

Dr. Monaghan stated that it is the recommendation of DHCFP and First Health that calcium acetate, PhosLo®, and sevalamer, Renagel®, be added to the PDL.

Committee Discussion and Approval of Drugs for Inclusion in the PDL

MOTION: Judy Britt motioned to accept First Health's recommendation to add calcium acetate, PhosLo®, and sevalamer, Renagel® to the PDL.

SECOND: Linda Flynn

AYES: Unanimous

MOTION CARRIED

X. Presentation by First Health Services of Policy Allowing DHCFP to change PDL Drugs from Brand to Generic

Ms. Lawrence stated that it is the goal of DHCFP and First Health to assure that there is transparency with policy creation and management of the PDL. In the past, when a generic drug has become available on the market, it has moved to where the brand is; i.e., if the brand was preferred, the generic became preferred and visa versa. A new scenario came up this past quarter whereby the brand was preferred and the generic was released on the market. It would have been in the best interest of the State to move the brand to non-preferred and prefer the generic. Upon discussing the issue with Dr. Phillips at that time, the decision was to continue to prefer the brand and move the generic to preferred. There is a mandatory generic substitution law in this state. Because the committee has considered the drugs therapeutic alternatives, the State would like to be able to have the feasibility to move a generic to non-preferred or opposite of the brand. She requested direction from the committee on how to handle this type of situation in the future.

Dr. Heard clarified that she is requesting authorization from the committee to be able to substitute a generic for a brand or visa versa at anytime in the interim between these meetings at which time the committee would be informed of those changes. Ms. Lawrence stated that was correct. Dr. Heard stated that the challenge is that there is not always an equivalency; e.g., Coumadin®, Synthroid®.

Diana Bond stated that when generics hit the market, they do have a rating and if the brand product and generic are AB rated, this should not be a problem. Under substitution laws, if not AB rated, they would not be able to be automatically substituted. She felt this could be qualified for anything with an AB rating.

Dr. Phillips stated that his recollection of generic is there can be 10% variability. If dealing with Coumadin® for someone with atrial fibrillation, you would not want 10% more or less if they are within the window that you want. Dr. Heard added that allowing a generic substitution does not say it's a specific generic manufacturer and manufacturer lots may vary as well.

Dr. Britt stated that she assumes that First Health will be looking at the AB ratings and basing their decision on that rating. Dr. Monaghan replied yes and this is actually addressed in the existing law which specifies that generics must be AB rated.

Dr. Phillips stated that he is comfortable deferring to the experts with regard to AB rating.

At the request of Drs. Pintar and Heard, Dr. Monaghan clarified “AB” rating. The FDA publishes “The Orange Book” which lists approved drug products with therapeutic equivalence evaluations. The FDA requires certain testing when a drug comes to market and it’s compared to a reference usually the innovator product. Drugs considered bioequivalent to the brand-named original are given an “A” rating. The second letter, B, applies to the route of administration; i.e., AB means therapeutic by the oral route. Drugs with a “B” or “C” rating are not considered interchangeable.

Dr. Britt also felt this would be helpful in the situation where a generic product is available and then through litigation it is no longer available; e.g., Plavix® (clopidogrel bisulfate), Duragesic® (fentanyl), the generic can easily be removed from the PDL and the brand added without committee approval.

Dr. Heard expressed concern that even though “AB” rated, a 10% variability is significant with something like Coumadin®, and saying yes in a blanket sense to substitute a generic, it will only be found out by experience that it was not a good decision at that time.

Dr. Bond asked how many drugs on the PDL are in that narrow therapeutic index range; e.g., digoxin, warfarin, theophylline. Dr. Monaghan replied that currently those categories are not on the PDL. He added that it’s really a practice issue that this committee may not have the ability or power to deal with. If a drug is “A” rated today, no matter if you’re using a generic, and you’re talking about those narrow therapeutic index drugs, it’s really a judgment and monitoring issue at the pharmacy and physician level.

Ms. Lawrence stated that this situation has only occurred once since implementation of the PDL. It occurred this past quarter with Zoloft®. The brand was preferred and the generic was released. Typically, the generic goes wherever the brand is.

Dr. Phillips felt that there is enough support to move in this direction and have it reported as a standing item on the agenda if it’s occurred in the quarter.

Public Comment

No comment.

Committee Discussion and Action

MOTION: Dr. Heard motioned to allow generic substitution of medications in the interim which are reported to the committee at the next quarterly meeting.

SECOND: Diana Bond

AYES: Unanimous

MOTION CARRIED

Dr. Horne joined the meeting (called-in) at 1:20 p.m.

XI. Presentation by DHCFP of Policy Allowing Emergency Changes in PDL due to National Drug Shortage Situations

Coleen Lawrence stated that this is more of an administrative issue on operation of the PDL. There have been previous discussions that when an emergency shortage of a pharmaceutical has been declared, it can be at the chairman’s discretion to allow emergency changes to the PDL. She proposed including this procedure as a PDL exception criteria and distributed draft language for consideration: “Allow a PDL exception for pharmaceuticals that are deemed to be part of a National Drug Shortage as deemed by the State of Nevada.”

Dr. Pintar asked if the State of Nevada has to declare that shortage. Ms. Lawrence replied, no, the State would act when notified of shortages by a valid source.

Dr. Heard said Ms. Lawrence stated that it has to be a national drug shortage and why not say national or state drug shortage realizing it’s not likely to happen but possible. Dr. Pinson agreed and Ms. Lawrence stated that there have been regional shortages.

Public Comment

No comment.

Committee Discussion and Action

MOTION: Larry Pinson motioned to allow emergency changes in the PDL due to national or regional drug shortages as determined by the State.

SECOND: Judy Britt

AYES: Unanimous

MOTION CARRIED

XII. Update by DHCFP on PDL Quality and Outcome Indicators Project

Dr. Monaghan stated that this item was presented at the January DUR Board meeting and referred the committee to the DUR minutes (page 5) in their meeting packet. The summary of the discussion was that the DUR Board was not in favor of forming a subcommittee to address the issue. Their response was that if there are specific, concrete things that P&T would like to look at regarding specific drugs, they would be happy to pursue it. They did not see a particular value in forming a subcommittee.

Dr. Phillips referred to Item X, page 10 of the December P&T minutes where it was discussed that an offer be extended to DUR to work with P&T and suggested that a subcommittee of volunteers from both P&T and the DUR Board be formed to work on this project. The DUR Board has declined and Dr. Phillips felt it was unfortunate something could not be done together as a subcommittee.

Dr. Heard commented that the process of bureaucratic obstruction is being used to manage a clinical setting between a practitioner and their patient and is there a negative or positive effect to that. What we were saying is that we would like to sit down with DUR and determine what measures are possible or feasible and hopefully already part of the stream of work that everyone is already managing and not adding to the workload. He referred to the DUR minutes and felt the question may not have been presented or understood clearly.

Dr. Phillips stated that Dr. Heard, Dr. Monaghan, Coleen Lawrence and he met several months ago to discuss this subject and it was decided to see what DUR wanted to do, not as a sanctioning body, but because both committees are responsible for formulary implementation in Nevada. It was thought that a subcommittee consisting of members from both P&T and DUR could be formed to develop quality reviews and outcome data related to the activities of both committees. He felt that P&T should move forward with this project.

Dr. Heard stated that DUR is looking at a much more significant data stream and P&T is looking at specific drug information and not getting any feedback; i.e., how many people are being turned over, what the management issues are. He added that this was in part a reaction to an announcement by the State that we had dramatically changed the course of financial burden to the State which was not pertinent to this committee but appreciated none the less. He expressed his desire to proceed with the project.

Darrell Faircloth asked what exactly is being proposed. Dr. Heard replied that instead of a subcommittee being formed with representatives of the DUR Board and P&T, a subcommittee consisting of members of P&T be formed to identify quality measures to assess the overall impact of this formulary process on patient care. Data streams already being managed by First Health will be looked at to identify the data and have that integrated into the work being done with this committee. Dr. Phillips added that it has nothing to do with determining which drugs are therapeutic alternatives or preferred or non-preferred. It's after the fact to determine the impact of DUR and P&T actions.

Mr. Faircloth stated that it is within this committee's power to form subcommittees and hold meetings of those subcommittees particularly for those things that the committee is empowered to do by statute or regulation. It is an appropriate course of action to form a subcommittee. When doing so, subcommittees are generally subject to open meeting laws and held in the same fashion as these meetings are held.

Dr. Heard asked if there is not a quorum of this committee, will the subcommittee be bound by open meeting laws. The meetings are not to conduct the business of this committee, but to obtain information

to bring back to this committee. He felt not being an open meeting would be an expeditious approach since the subcommittee will probably only meet a couple of times, find some measures and move on. Dr. Phillips added that there will be three committee volunteers to work with First Health and the State and be able to query their database.

Mr. Faircloth will research the open meeting requirement of the subcommittee and report back to the committee.

3:00 p.m. – Dr. Phillips excused himself from the meeting due to another commitment and asked Dr. Pinson to preside as chair for the remainder of the meeting.

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. He asked Mr. Faircloth if that would be appropriate since the questions would then be addressed in open meeting. Mr. Faircloth said that circumstance would be normal and added that he will look into the question of creating a subcommittee to perform the research as opposed to asking First Health to perform that research on behalf of the committee.

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

The next meeting is scheduled for June 21, 2007, 1:00 p.m. at the Orleans Hotel in Las Vegas.

XIV. Public Comment

Bert Jones, Glaxo SmithKline, asked if the next meeting will be for the annual PDL review and when the decision will be made on which categories will be re-reviewed and which will not.

Dr. Monaghan replied that the June meeting will be the start of the re-review process. An agenda of categories to be re-reviewed and those that will not be re-reviewed will be proposed next month. Requests for re-review of a category should be forwarded to Dr. Monaghan.

Mr. Jones requested a re-review of:

- 1) the beta-blocker class due to a line-extension approved in December 2006.
 - 2) the nasal steroid class due to the FDA approval of a new product being released in April
- He requested review of the triptan category be deferred until the end of the year because GSK will be releasing a new triptan in August.

Dr. Monaghan stated that Mr. Jones' requests will be taken into consideration.

Dr. Horne requested that the antidepressants be considered in June due to the release of generic Wellbutrin XL.

XV. Adjournment

MOTION: Diana Bond motioned to adjourn the meeting.

SECOND: Robert Horne

AYES: Unanimous

MOTION CARRIED

Meeting adjourned at 3:10p.m.