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Governor

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

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**PHARMACY & THERAPEUTICS COMMITTEE**

**Las Vegas Chamber of Commerce  
6671 Las Vegas Blvd. S., Suite 300  
Las Vegas, NV**

**Meeting Minutes  
December 17, 2009**

**Committee Members Present:**

Rudy Manthei, DO, Chairman  
Joseph Adashek, MD  
David Chan, R.Ph.  
Shamim Nagy, MD  
Weldon Havins, MD  
Michael Hautekeet, R.Ph.  
Constance Kalinowski, MD  
Judy Britt, Pharm.D.

**Absent:**

Justin Holt, Pharm.D.  
Chad Luebke, Pharm.D.

**Others Present:**

Coleen Lawrence-DHCFP, Gabriel Lither-DAG, Rob Coppola Pharm.D.-FHSC, Dave Wuest-FHSC, Paula Townsend-FHSC, Shirley Hunting-FHSC, Chris Almeida-Purdue, Rupal Naik Gupta-Shire, Laura Forte-Nephron, Gregg Polacek-Nephron, Isam Herndon-GSK, Robert Pearce-Teva, Ken Orr-Teva, Dean Donato-Alcon, Marlene Mendiola-Boehringer Ingelheim, Glenn Wright-Eisai, Guli Teffen-Eisai, Doug Powell-Forest, Chase Freiman-Primary Care, Heather Villella-Primary Care, Pat Wisemal-Medimmune, M. Shetelyk-Novo Nordisk, Dan Bay-Abbott, Penny Atwood-Boehringer Ingelheim, Marilyn Senenchuk-GSK, Doug Ethel-GSK, Lori Howarth-Bayer.

I. Call to Order and Roll Call

Chairman, Rudy Manthei, called the meeting to order at 1:04 p.m.

Coleen Lawrence introduced Rudy Manthei as the new chairman of the Pharmacy and Therapeutics Committee and new committee members Drs. Joseph Adashek, Shamim Nagy, Weldon Havins and pharmacist Michael Hautekeet. She also introduced new First Health staff, Rob Coppola, Clinical Program Manager and Paula Townsend, Clinical Account Manager.

She gave an overview of the P&T process. The role of the P&T Committee is to develop a list of preferred prescription drugs for the Medicaid program. Nevada Medicaid, unlike the private sector, has an open formulary. Drugs not included on the Preferred Drug List (PDL) are accessible. There is a prior authorization (PA) process in place to access non-PDL agents. Use of drugs in classes that have been reviewed and not included on the PDL will require a call by the prescriber to the FHSC Clinical Call Center for prior authorization (PA). PDL exception criteria (included in reference binder) must be met to grant approval of a non-PDL drug. The Call Center is required by policy to respond to PA requests within twenty-four hours of receipt.

Nevada Medicaid participates in the multi-state National Medicaid Pooling Initiative program. Different levels of drug rebates are offered to the State through this initiative.

Washoe and Clark Counties we have the Temporary Assistance for Needy Families (TANF) and Child Health Assurance Programs (CHAP) and participants in these counties are covered by a Medicaid managed care organization (MCO). Decisions made by this committee affect participants in the Nevada Medicaid fee-for-service population and not MCO participants. The MCO drug formulary process is a separate process from the fee-for-service program. The fee-for-service population comprises the rural areas (including TANF and CHAP) and state-wide for the aged, blind and disabled.

Ms. Lawrence provided an overview of the drug class review process. FHSC determines the classes to be reviewed and provides recommendations that are in the best interest of the State. Drug manufacturers have the opportunity to submit to FHSC product information for classes being reviewed prior to the meeting by the date specified and also present at the meeting. FHSC provides meeting materials to committee members in advance of the meeting. FHSC on behalf of DCHFP provides 1) an overview of the drug class to include a recommendation of therapeutic alternative, and 2) recommendation for addition and/or removal of drugs to the PDL. The committee acts upon these recommendations in two separate actions and can amend or accept the recommendations. The committee also has the option of applying restrictions when adding agents to the PDL; e.g., use of ICD-9 code(s), age restriction, etc.

Gabriel Lither stated that these meetings are held pursuant to the Open Meeting Law. Items to be discussed will be on the agenda. Issues that the committee wishes to discuss that are not included on the agenda will be agendaized for a future meeting. Deliberations and decisions by this committee need to occur during the open meeting and should not be discussed or acted upon between committee members outside of the open meeting. Ms. Lawrence added that committee members are not obligated to discuss agendaized items with the public; e.g., pharmaceutical representatives, outside of the open meeting.

Ms. Lawrence asked the public to disclose any financial affiliation with pharmaceutical manufacturers prior to presenting comment.

## II. Review and Approval of June 25, 2009, Meeting Minutes

**MOTION: Judy Britt motioned to approve the June 25, 2009, minutes as presented.**  
**SECOND: Joseph Adashek**  
**VOTES: Unanimous**  
**MOTION CARRIED**

## III. New Drug Class Reviews

Rob Coppola stated that seven drug classes will be presented today five of which are new therapeutic classes to the PDL. Currently, there are fifty-five drug classes on the PDL. A high level overview of each class will be presented. Recommendations by DCHFP and First Health will be made for Committee discussion and action. In addition to the therapeutic class reviews, included in the meeting binder are the American Medical Association's definition of therapeutic alternative, the PDL exception criteria and a copy of the current PDL. Following review of the new classes, there will be a re-review of two existing PDL classes. Only new information which has become available since the last review of the class will be presented.

### A. Ulcerative Colitis Agents

#### 1. Public Comment

Rupal Naik Gupta, Shire Pharmaceuticals, spoke in support of Lialda® (mesalamine). Ulcerative Colitis is a debilitating and chronic disease. Patients are usually young and symptoms include increased stool frequency and rectal bleeding. Mesalamine is a primary treatment for ulcerative colitis; not all mesalamines are the same. Lialda® is indicated for induction of remission. Lialda® and Pentasa® are the only two mesalamines indicated for induction of remission. Induction of remission means that the patient not only receives treatment but will also get mucosal healing which differs from other agents. Lialda® has a unique delivery system which has both a lipophilic and

hydrophilic component which allows the drug to stay in the colon longer. Lialda® has the highest amount of mesalamine per tablet (1.2 gm) compared to other agents. Patients with ulcerative colitis may take up to sixteen tablets per day. Most tablets have doses of 400mg, 800mg or 0.375mg. The usual dose of Lialda® prescribed is 2.4 gm or 4.8 gm per day. Lialda® is safe and common side effects include headache and flatulence. She requested consideration of Lialda® to the PDL.

2. Drug Class Review Presentation – First Health Services

Rob Coppola stated that ulcerative colitis is a chronic disease with recurrent symptoms and significant morbidity. Precise etiology is unknown. It is characterized by diffuse mucosal inflammation of the colon, always involves the rectum and extends contiguously throughout the entire colon. Today's review will focus on aminosalicylates or mesalamine agents which are the cornerstone for treatment for mild to moderate ulcerative colitis. These agents only differ in their mode of distribution throughout the intestine and colon. The agents are broken down by three types: immediate release products (Colazal®, Dipentum®, Azulfidine®), extended release products (Asacol®, Lialda®, Pentasa®, Apriso®), and topical forms (Rowasa®, Canasa®). Generic Colazal® (balsalazide), Azulfidine® (sulfasalazine), and Rowasa® (mesalamine) enema are now available. All of the agents have similar indications; most are approved for moderate to mild active ulcerative colitis. Some have additional indications for remission. Dipentum® is only indicated for therapy of maintenance of remission for patients who are intolerant to sulfasalazine. Apriso® is only indicated for maintenance of remission in adults. The mechanism of action for all of the agents is similar and includes the inhibition of prostaglandin leukotriene synthesis, free radical scavenging, immunosuppressive activity, impairment of white cell adhesion and function, and inhibition of cytokine synthesis. Pharmacokinetics for all agents is comparable with the exception of the half-life which can range from two to fifteen hours. All products are designed to be minimally absorbed. Contraindications are similar for all. Drug interactions are not significant with these agents. Sulfasalazine has interactions with digoxin, folic acid and phenytoin. pH dependent products should not be taken with antacids. Dosing for most agents is two to three times per day. Two new agents, Lialda® and Apriso® are dosed at one time per day. Adverse effects for all agents are comparable. These drugs have not been extensively studied in the pediatric population. Sulfasalazine is approved for use in patients six years of age and older; balsalazide is approved for use in patients five years of age and older. Olsalazine is Pregnancy Category C; all other agents are Pregnancy Category B. In terms of clinical trials; there are limited quality head-to-head studies (listed in handout). Some small, short studies have been sponsored by manufacturers overseas. These drugs contain the same active ingredient, mesalamine; efficacy should be the same for all products. The 2004 Practice Guidelines of the American College of Gastroenterology stated that there is no difference in efficacy among the available agents. In 2007, the American Academy of Family Physicians released guidelines which did not support any agent as superior to others in the class. It is the recommendation of DHCFP and First Health that the agents in this class be considered therapeutic alternatives.

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

Dr. Adashek asked if there are cost differences with these products. Ms. Lawrence responded that the P&T Committee is prohibited by statute to consider cost when determining drugs for the PDL. The P&T Committee determines therapeutic equivalence and acts on recommendations by DHCFP and FHSC to add and/or remove drugs from the PDL. Once therapeutic

equivalence is determined, DHCFP and FHSC can base their recommendations based on cost, clinical information, access, etc.

Judy Britt said that all of the clinical trials did appear to be fairly similar in efficacy; however, there is one study (340 patients) which clearly showed an advantage in remission rates with Lialda®. Most of the trials did show comparable efficacy, but though small, that study did show superiority in remission with Lialda®. She asked the representative of Shire if there are larger studies.

Rupal Naik Gupta, Shire, responded that if you take all of the mesalamine agents that are available, the trial of 340 patients is the largest mesalamine trial available. The difference in all of the studies is that the Lialda® study is the only one with placebo. The Asacol® and Asacol HD® studies do not have a placebo, there are non-inferiority studies and the patient populations were very small; thirty-six patients in one arm and one-hundred seventy-six patients total. Apriso® had a placebo arm but their studies are not published and there is only the package insert to go by. Their placebo rates were in the fifty to sixty percentile. In the Lialda® studies, there were four treatment arms; placebo, Lialda® 2.4gm, Lialda® 4.8mg and mesalamine (Asacol®). The rates of each arm were compared only to placebo not to each agent. It was a superiority study and the rates were higher than placebo. In all of the studies, the induction of remission is different from treatment. The indications for all mesalamines are different. To reach induction remission, the colon has to show healing at the end of eight weeks. In the Lialda® study, at the end of eight weeks, the patient's colon was healthy and normal.

**MOTION: David Chan motioned that the agents in this class be considered therapeutic alternatives.**

**SECOND: Judy Britt**

**VOTES: Unanimous**

**MOTION CARRIED**

4. Presentation of Recommendations for Preferred Drug List (PDL) Inclusion by First Health Services and the Division of Health Care Financing and Policy

Rob Coppola stated that it is the recommendation of DHCFP and First Health for the oral agents, the two generic sulfasalazine agents (immediate release and delayed release), Pentasa® and Asacol® be added to the PDL. For the topical agents, the generic Rowasa® (mesalamine) enema and Canasa® suppository be added to the PDL.

5. Committee Discussion and Approval of Drugs for Inclusion on the PDL

Dr. Adashek asked about cost. Gabriel Lither reiterated that any discussion of cost by this committee is prohibited by statute for both action items. Ms. Lawrence clarified that recommendations by DHCFP and First Health are in the best interest of the State. DHCFP and First Health base their recommendations on clinical, access and financial considerations. Decisions made by the P&T are based on evidence of clinical efficacy and safety without consideration of the cost of the drugs.

Michael Hautekeet asked if the drugs not included on the PDL will be available. Rob Coppola replied that non-preferred drugs will be available through the PA process based on the PDL exception criteria for approval.

Judy Britt asked if PA reports can be presented to the Committee. Coleen Lawrence replied that prior authorization reports are reviewed for trends, prescribing patterns, etc., and presented to the Committee with recommendations.

Coleen Lawrence stated that there are two pharmacy committees, the Pharmacy and Therapeutics Committee and the Drug Use Review (DUR) Board which is a federal mandated board. The DUR Board is responsible for developing the prior authorization clinical criteria; e.g., step therapy, quantity limitations. The P&T Committee can make a recommendation to the DUR Board to review agents for clinical criteria.

Rob Coppola said that there are a number of things taken into consideration when recommending preferred drugs such as utilization and market share. In this particular class, agents being recommended as preferred represent 97% of current patients. Judy Britt stated that a new drug would not currently have market share but based on reported clinical efficacy, it may be a better drug.

Dave Wuest stated that all PDL drug classes are reviewed at the annual P&T meeting in June and market share changes are taken into consideration and recommendations presented to the Committee at that time.

**MOTION:**        **Joseph Adashek motioned to accept First Health’s recommendation that the oral agents, generic sulfasalazine immediate release, generic sulfasalazine delayed release, Pentasa® and Asacol®, be added to the PDL. For the topical agents, generic mesalamine enema and Canasa® suppository, be added to the PDL.**

**SECOND:**        **Michael Hautekeet**

Judy Britt recommended that this class be referred to the DUR Board and PA activity and utilization be monitored. She doesn’t want a drug withheld that may have 10% difference in efficacy for remission if gastroenterologists are asking for the drug. Perhaps the DUR Board can consider step therapy by looking for prior history of other agents in the class or at least present it again to P&T in a subsequent meeting if there tends to be a number of PAs.

Rob Coppola stated that this class will be re-reviewed in June and new clinical information will be presented at that time, if available.

(The motion was not amended to include referral to the DUR Board.)

**VOTES:**        **Unanimous**

**MOTION CARRIED**

**B. Benign Prostatic Hypertrophy (BPH) Agents**

**1. Public Comment**

Marlene Mendiola, Boehringer Ingelheim, spoke in support of Flomax®. Flomax® is indicated for the treatment and signs and symptoms of Benign Prostatic Hyperplasia (BPH). It is not indicated to treat hypertension. Flomax® is dosed once daily and does not require titration. Greater than 50% of men in their sixties and as many as 90% in their seventies and eighties have symptoms of BPH. Studies have demonstrated that Flomax® has a rapid onset of action. An open label, multi-center randomized parallel designed study assessed the early onset of symptom improvement offered by Flomax® 0.4mg or dose titration up to 5mg with moderate to severe BPH symptoms. There is a difference between Flomax® and terazosin 1mg in the change in total AUA symptom score from baseline to day five which was maintained over the entire study period. Compared to Flomax®, the terazosin group had more than twice the incidences of treatment related fatigue, 5.4% versus 2.5% with Flomax®; dizziness, 12.1% versus 5.5% with Flomax®; somnolence 3.0% versus 0.9% with Flomax®, all of which were statistically significant. There are long-term efficacy and safety data for Flomax®. She cited a six year study of 600 patients taking Flomax® which showed that Flomax® maintained improvements in symptoms and flow rate and was well tolerated. There is a potential risk for syncope. Patients beginning treatment with Flomax® should be cautioned to avoid situations where injury can result should syncope occur. During clinical trials, the incidents of clinically significant hypotension or cardiovascular events

were low or did not differ from placebo. The most common side effects with Flomax® are dizziness, abnormal ejaculation and rhinitis. Flomax® is an alpha 1A adrenoceptor selective agent, dosed once daily, does not require titration, demonstrates a long onset of action, has proven long-term safety and efficacy and is on the PDL for most First Health states.

Marilyn Senenchuk, Glaxo Smith Kline, spoke in support of Avodart®. She cited the four year CombAT data which is a combination of Avodart® with Flomax®. The data is now published and available on the Clinical Trial Register at GSK.com. The data indicates that the combination of Avodart® and Flomax® provides sustained clinical benefit for patients who have BPH. Alpha blockers are designed for symptomatic control and provide rapid relief to the patient but alpha reductase inhibitors are involved in the overall disease progression. BPH is a result of enlarged prostate and the prostate grows as a result of dihydrotestosterone (DHT). The testosterone is converted to DHT through the 5-alpha reductase isoenzyme. The two 5-alpha reductase isoenzymes are Proscar® and Avodart®. Avodart® targets both the type I and type II 5alpha reductase isoenzymes whereas Proscar® targets the type II isoenzyme. DHT suppression with Avodart® is 95% which translates to 28% prostate volume reduction versus Proscar® which has a 70% DHT suppression with a 16%-18% prostate volume reduction. She felt that Proscar® and Avodart® are therefore not therapeutically equivalent and recommended the committee consider Avodart® as one of the preferred agents.

Dr. Havins asked regarding the effect of 5-alpha reductase in reducing the chance of prostate cancer. Ms. Senenchuk replied that GSK presented at the American Urological Association (AUA) meeting this year the results from the four year REDUCE Trial (available at GSK.com). The trial was designed to look at Avodart® in decreasing the risk for developing prostate cancer in men who are at high risk (men between the ages of 50-70 with a negative biopsy upon entry; PSA greater than or equal to 2.5 and less than 10; prostate volume less than 80). The study found that there was a 22% risk reduction for developing prostate cancer in that particular group of men who are at high risk.

Rob Coppola asked if it was an absolute risk reduction or relative risk reduction and also what the absolute reduction and value were. Ms. Senenchuk replied relative risk reduction. In two years, one in twenty-eight high risk men could be saved from getting prostate cancer; in four years it's one in seventeen.

## 2. Drug Class Review Presentation – First Health Services

Rob Coppola stated that there are two therapy classes in this category; alpha blockers and the alpha reductase inhibitors. The alpha blocker agents are Uroxatral®, Cardura®, Cardura XL®, Rapaflo® (the newest entry into the market), Flomax® and Hytrin®. Flomax® has received a pediatric indication and is scheduled to be available generically by the end of third quarter 2010. The 5-alpha reductase inhibitors are Avodart® and Proscar®. Proscar® is available as a generic. All alpha blockers are indicated for the treatment of the signs and symptoms of BPH. Hytrin® and Cardura® are also indicated for hypertension and both are available generically and will be listed as preferred on the PDL. Avodart® and Proscar® have similar indications. Alpha 1 blockers all share the same pharmacology. The new agents are alpha 1a specific which may result in lower cardiovascular events. The 5-alpha reductase inhibitors share similar pharmacology; inhibition of 5-alpha reductase decreases the concentration of DHT which is known to be a stimulator of prostate growth. Avodart® inhibits both type I and II isoforms of 5-alpha reductase (5-AR), however, studies have not clearly shown a clinical advantage. Proscar® inhibits type II only. Pharmacokinetics, contraindications and drug interactions are comparable with all alpha blockers. He referred to page five of the drug review which states concerns with Uroxatral® in hepatic impairment as well drug interactions with CYP3A4 inhibitors. Doxazosin ER should be used with

caution in patients with mild hepatic dysfunction. 5-alpha reductase inhibitors share a similar side effect contraindication profile. Avodart® has a longer half-life compared to Proscar®; the clinical significance is not clear. 5-ARs should not be taken or handled by pregnant women or women who are to become pregnant. Avodart® should not be crushed. There are no significant drug interactions with 5-ARs. Side effects are typically transient and do not normally result in discontinuation of therapy. Common side effects include headache, syncope and asthenia. Others include hypotension, altered libido, and abnormal ejaculation. Adverse events of the 5-alpha reductase inhibitors are usually not noticeable with low incidence of occurrence and are comparable between the two products. BPH agents are not indicated or studied in the pediatric population. 5-ARs are rated Pregnancy Category X. Alpha blockers, Uroxatral®, Flomax® and Rapaflo® are Pregnancy Category B with all others rated Pregnancy Category C. The AUA guidelines state that the appropriate treatment for Lower Urinary Tract Symptoms (LUTS) secondary to BPH are alfuzosin (Uroxatrol®), doxazosin (Cardura®), tamsulosin (Flomax®) and terazosin (Hytrin®). They concluded that there were minor differences in the adverse event profiles and all alpha blockers indicated for the treatment of BPH were equal in clinical effectiveness. They also concluded that both 5-AR inhibitors were appropriate and equally efficacious. Head-to-head trials have not proven that one agent is better over another and indicate comparable efficacy and tolerability. It is the recommendation of DHCFP and First Health that the alpha blocker agents are considered therapeutic alternatives and that the 5-alpha reductase inhibitors are considered therapeutic alternatives.

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

**MOTION:** Michael Hautekeet motioned that the alpha blocker agents be considered therapeutic alternatives and that the 5-alpha reductase inhibitors be considered therapeutic alternatives.

**SECOND:** Joseph Adashek

**VOTES:** Unanimous

**MOTION CARRIED**

Michael Hautekeet asked how First Health handles situations when there is a drug shortage of a PDL drug. Mr. Coppola replied that First Health will confer with DHCFP to address the situation. Ms. Lawrence replied that when there is a shortage of a PDL drug, an administrative exception is made to assure there is access to alternate agents.

4. Presentation of Recommendations for Preferred Drug List (PDL) Inclusion by First Health Services and the Division of Health Care Financing and Policy

Rob Coppola stated that it is the recommendation of DHCFP and First Health for the alpha blocker agents to add Flomax® and the generic products doxazosin and terazosin to the PDL. The recommendation for the 5-alpha reductase inhibitors is to add Avodart® and the generic product finasteride to the PDL.

5. Committee Discussion and Approval of Drugs for Inclusion on the PDL

**MOTION:** Judy Britt motioned to accept First Health's recommendation for the alpha blocker agents to add Flomax® and the generic products doxazosin and terazosin to the PDL and for the 5-alpha reductase inhibitors to add Avodart® and the generic product finasteride to the PDL.

**SECOND:** Weldon Havins

**VOTES:** Unanimous

**MOTION CARRIED**

C. Antiviral Agents, Topical

1. Public Comment

No comment.

2. Drug Class Review Presentation – First Health Services

Rob Coppola stated that the agents in this class are Zovirax® Cream (acyclovir), Zovirax® Ointment (acyclovir), Abreva® Ointment (docosanol) OTC and Denavir® Ointment (penciclovir). The indications for the agents in this class are about the same. Zovirax® (acyclovir) Ointment is available generically and is indicated for the management of initial genital herpes whereas the other agents are indicated for herpes labialis. Acyclovir is a synthetic purine nucleoside with inhibitory activity against herpes simplex 1 and 2 and varicella-zoster virus. It works with competitive inhibition of viral DNA polymerase with incorporation into and termination of growing viral DNA chains and inactivation of viral DNA polymerase. Penciclovir is similar to acyclovir but has a higher affinity for HSV1 and HSV2 in infected cells but the clinical significance in accordance with better outcomes has not been determined. The pharmacology of docosanol is unknown but it is thought to inhibit viral replication by blocking the fusion of lipid enveloped viruses with cell membrane. Pharmacokinetics of all agents are similar with low systemic absorption. The systemic availability of all topical agents is very low. The agents are contraindicated for ophthalmic, intranasal, intraoral or intravaginal use. There are no known drug interactions and adverse effects are local and transient. Safety and efficacy have not been established in the pediatric population and all agents are Pregnancy Category B. In a randomized, double-blind active comparative study with 250 patients of acyclovir 3% (commercial availability in the U.S. is 5% not 3%) versus penciclovir 1%, the endpoint indicated the sub-therapeutic dose of acyclovir was not as effective as the therapeutic dose of penciclovir. It is the recommendation of DHCFP and First Health that the agents in this class be considered therapeutic alternatives.

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

**MOTION: Joseph Adashek motioned that the agents in this class be considered therapeutic alternatives.**

**SECOND: Shamim Nagy**

**VOTES: Unanimous**

**MOTION CARRIED**

4. Presentation of Recommendations for Preferred Drug List (PDL) Inclusion by First Health Services and the Division of Health Care Financing and Policy

Rob Coppola stated that it is the recommendation of DHCFP and First Health to add Abreva®, Denavir® and generic acyclovir ointment to the PDL.

5. Committee Discussion and Approval of Drugs for Inclusion on the PDL

Michael Hautekeet said that as a practicing pharmacist, the potential for a medication error or misfills between ointment and cream could be a problem if the doctor just writes Zovirax®. He felt it would be easier for the pharmacist if both the cream and ointment acyclovir were added to the PDL.

Rob Coppola stated that a prescription which only had Zovirax® written on it would require a call to the prescriber for clarification. As with other PDL classes, if a non-preferred drug is written for, a PA will need to be obtained.



**MOTION: Michael Hautekeet motioned to add Abreva®, Denavir®, Zovirax® cream and generic acyclovir ointment to the PDL.**

**SECOND: Shamim Nagy**

Dr. Adashek said that as an OBGYN, the oral form is preferred and given exclusively unless the patient requests the topical and he felt there was no reason to differentiate between the cream and ointment.

Mr. Coppola asked Mr. Hautekeet if his concern is that the prescription comes in and the pharmacist may change it without checking with the prescriber.

Mr. Hautekeet replied that it will make it easier on the pharmacies to have both so the pharmacy does not have to call the physician to switch it from cream to ointment. It would save the pharmacy and physician a step. For safety and misfills, it would be easier to have both.

Dr. Adashek asked why both were not recommended.

Mr. Coppola reiterated that there are a number of things taken into consideration when recommending preferred drugs such as utilization, etc. Zovirax® ointment has been available for some time and is now available generically. It has a lot of acceptance in the community and is prescribed frequently.

Dr. Manthei said that for physicians not to write the correct prescription is the responsibility of the physician; i.e., write for the cream or the ointment. To assume that the physician is going to make a mistake does not make sense.

David Chan agreed. When it comes to the practice of pharmacy, pharmacists work with physicians. He felt that it makes no difference for the recommendation because the job has to be done right. A pharmacy's practice should have nothing to do with the decisions made here.

**Joseph Adashek offered a friendly amendment to accept First Health's recommendation to add Abreva®, Denavir® and generic acyclovir ointment to the PDL.**

**Michael Hautekeet accepted the friendly amendment.**

**SECOND: David Chan**

**AYES: Chan, Britt, Manthei, Kalinowski, Adashek**

**NAYES: Hautekeet, Nagy, Havins**

**MOTION FAILED**

Gabriel Lither stated that by statute, in order for the P&T Committee to take action, a majority of the members on the committee actually vote. There are ten members; six votes are needed to take action.

**Dr. Manthei called for a vote on the original motion:**

**MOTION: Michael Hautekeet motioned to add Abreva®, Denavir®, Zovirax® cream and generic acyclovir ointment to the PDL.**

**SECOND: Shamim Nagy**

**AYES: Hautekeet, Nagy, Havins**

**NAYES: Chan, Britt, Manthei, Kalinowski, Adashek**

**MOTION FAILED**

**MOTION: Weldon Havins motioned to accept First Health's recommendation to add Abreva®, Denavir® and generic acyclovir ointment to the PDL.**

**SECOND: David Chan**

**AYES: Chan, Britt, Manthei, Havins, Kalinowski, Adashek**

**NAYES: Hautekeet, Nagy**

**MOTION CARRIED**

D. Epinephrine, Self-Injectable

1. Public Comment

No comment.

2. Drug Class Review Presentation – First Health Services

Rob Coppola stated that the products in this class are Epi Pen®, Epi Pen Jr®, Twinject® and Twinject Jr®; all contain epinephrine. The Twinject® differs from the Epi Pen® by providing a second dose from one unit. The first dose from both the Epi Pen® and Twinject® are delivered via auto-injection. The Twinject® contains a second dose which is available by disassembling the unit. It is the recommendation of DHCFP and First Health that the agents in this class be considered therapeutic alternatives.

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

**MOTION: Connie Kalinowski motioned that the agents in this class be considered therapeutic alternatives.**

**SECOND: Joseph Adashek**

**VOTES: Unanimous**

**MOTION CARRIED**

4. Presentation of Recommendations for Preferred Drug List (PDL) Inclusion by First Health Services and the Division of Health Care Financing and Policy

Rob Coppola stated that it is the recommendation of DHCFP and First Health that the Epi Pen®, Epi Pen Jr®, Twinject® and Twinject Jr® be added to the PDL.

5. Committee Discussion and Approval of Drugs for Inclusion on the PDL

**MOTION: Judy Britt motioned to accept First Health's recommendation to add the Epi Pen®, Epi Pen Jr®, Twinject® and Twinject Jr® to the PDL.**

**SECOND: Weldon Havins**

**VOTES: Unanimous**

**MOTION CARRIED**

E. Progestins for Cachexia

1. Public Comment

No comment.

2. Drug Class Review Presentation – First Health Services

Rob Coppola stated that the agents in this class for review are Megace® (megestrol acetate) oral suspension which is now available generically and Megace ES® (megestrol acetate) oral suspension. Megestrol tablets have a different indication and will not be addressed in this review. Both oral suspensions are indicated for the treatment of anorexia, Cachexia or significant unexplained weight loss in patients with a diagnosis of acquired immunodeficiency syndrome (AIDS). The difference in the products is that Megace ES® is available in the NanoCrystal® dispersion technology which allows for a smaller volume of the drug to be administered with the same result; i.e., 20cc of the original formulation Megace® equals 5cc of the Megace ES®. The NanoCrystal® formulation may be beneficial for patients who have difficulty swallowing large volumes. There are no clinical trials that have been published that would indicate a clinical difference between the two products. The agents are bioequivalent at the 5cc and 20cc dose. It is the recommendation of DHCFP and First Health that the agents in this class be considered therapeutic alternatives.

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

**MOTION: David Chan motioned that the agents in this class be considered therapeutic alternatives.**

**SECOND: Shamim Nagy**

**VOTES: Unanimous**

**MOTION CARRIED**

4. Presentation of Recommendations for Preferred Drug List (PDL) Inclusion by First Health Services and the Division of Health Care Financing and Policy

Rob Coppola stated that it is the recommendation of DHCFP and First Health that the generic megestrol acetate oral suspension be added to the PDL.

5. Committee Discussion and Approval of Drugs for Inclusion on the PDL

**MOTION: Michael Hautekeet motioned to accept First Health's recommendation that megestrol acetate oral suspension be added to the PDL.**

**SECOND: Judy Britt**

**VOTES: Unanimous**

**MOTION CARRIED**

#### IV. Established Drug Classes for Review

Dr. Manthei stated that the established drug classes for review were last reviewed in June 2009. Only new information since that time will be accepted for comment.

Ms. Lawrence clarified for the new committee members that the established classes being presented have been previously reviewed by this committee. The classes are being reviewed because new clinical information or due to the release of new agents within the class. Only new clinical information will be permitted for comment. Dr. Manthei added that committee members may request a re-review of a drug category prior to the annual review if new agents or clinical information has been released.

##### A. Antihistamines, Low-Sedating

1. Public Comment

No comment.

2. Presentation of Recommendation for Edit Revision by First Health Services

Rob Coppola stated that this category was last reviewed in June 2009. The new drug, Xyzal®, which is the active isomer of Zyrtec®, has a new indication for the treatment of uncomplicated skin manifestations or chronic idiopathic urticaria in adults and children six months of age and older. Zyrtec®, Allegra® and Clarinex® also have the same indication. Xyzal®, Zyrtec® and Clarinex® Syrup are indicated for the treatment of perennial rhinitis in adults and children down to six months of age. It is the recommendation of DHCFP and First Health that the agents in this class continue to be considered therapeutic alternatives.

3. Committee Discussion and Approval of Edit Revision

**MOTION: Judy Britt motioned that the agents in this class be considered therapeutic alternatives.**

**SECOND: Joseph Adashek**

**VOTES: Unanimous**  
**MOTION CARRIED**

4. Presentation of Recommendations for Preferred Drug List (PDL) Inclusion by First Health Services and the Division of Health Care Financing and Policy

Rob Coppola stated that it is the recommendation of DHCFP and First Health that Clarinex® syrup be removed from the PDL and that no other changes be made to the current PDL in this class.

Coleen Lawrence asked for clarification regarding this item as listed on the agenda. She pointed out that item IV.A.3. states “Committee Discussion and Action of Edit Revision.”

Dave Wuest stated that the edit revision is for the removal of the current edit for the PA override for Clarinex® syrup for children under age two.

Gabriel Lither stated that removal of an edit is different than removing a drug from the PDL. Ms. Lawrence added that item IV.A. is not agendized in the same process used to review drug classes and may need to be agendized for another meeting and Mr. Lither added unless this is related specifically to edit revisions.

Rob Coppola clarified that the only recommendation for change in this class is to remove the age edit from Clarinex®. Coleen Lawrence asked if the drugs on the PDL in this class will remain the same with the exception of the age edit. Mr. Coppola replied that is correct and Mr. Lither said that would be acceptable.

Dave Wuest restated the recommendation. It is the recommendation of DHCFP and First Health that the preferred agents in this class will remain the same and that the Clarinex® Syrup age edit for children less than two years of age will be removed.

5. Committee Discussion and Approval of Drugs for Inclusion on the PDL

**MOTION: David Chan motioned to accept First Health’s recommendation to remove the Clarinex® Syrup age edit for children less than two years of age.**

**SECOND: Michael Hautekeet**

**VOTES: Unanimous**

**MOTION CARRIED**

- B. Beta-Agonists, Short-Acting Inhaled

1. Public Comment

Laura Forte, Nephron, spoke in support of pediatric strength generic albuterol inhalation solution. The Nevada PDL currently only has the full strength preferred. The doctor will write for full strength and the caregiver will need to split the dose which may result in an inaccurate dose. Children are sometimes put at risk for tachycardia, tremors, increased cardiac output, excitability, etc. Nephron has generic Accuneb® in a pediatric strength. It is indicated for children ages two through twelve and is indicated for the relief of bronchospasm. She requested the pediatric strength be considered for the PDL.

Doug Ethel, Glaxo Smith Kline, spoke in support of Ventolin® HFA. The NIH Asthma Guidelines recommend albuterol use as a marker for uncontrolled asthma. It’s critical now that albuterol use be monitored in patients. The devices are all HFA devices now. The old way used by filling a sink with water and float them to see if they were full can no longer be done. HFA devices have different seals and after exposure to water and dried out, there is a potential for

the seals to leak. There is no way to determine how much is left in these devices without a dose counter. GSK's dose counter gives each specific dose, not a number for every ten or twenty doses, and is the only device that has that type of dose counter. There is also a sixty dose size. Many physicians find that controlling albuterol use based on refills is easier with the smaller size rather than the two-hundred dose size.

2. Drug Class Review Presentation – First Health Services

Rob Coppola stated that this class was last reviewed in June 2009. On December 31, 2008, the FDA completed the phase out of the CFCs and only HFAs are currently on the market. The guidelines for the diagnosis and management of asthma in children five years of age and younger emphasize rapid acting bronchodilators as a treatment of choice. There is no new clinical data available for the agents in this class. It is the recommendation of DHCFP and First Health that the agents in this class continue to be considered therapeutic alternatives.

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

**MOTION: Michael Hautekeet motioned that the agents in this class be considered therapeutic alternatives.**

**SECOND: Shamim Nagy**

Judy Britt stated that when the HFAs replaced the CFCs, all the generics were lost and asked if there is any word on the status of generic production.

Rob Coppola replied that he is not aware of any updates. There is a ProAir® available that was perceived as a generic at one point. The problem was in the delivery device. It appears that a generic will not be available in the near future. Michael Hautekeet commented on the sixty doses versus the two-hundred doses. He felt there is no benefit with the sixty doses and that it will probably be more expensive versus the two-hundred doses. He recommended the two-hundred dose for the PDL.

**VOTES: Unanimous**

**MOTION CARRIED**

4. Presentation of Recommendations for Preferred Drug List (PDL) Inclusion by First Health Services and the Division of Health Care Financing and Policy

Rob Coppola stated that the recommendation for this class will be presented in two parts, inhalers and nebulizers.

For the inhalers, it is the recommendation of DHCFP and First Health to have one preferred agent on the PDL, Proventil® HFA. All other inhalers in this class, including inhalers currently on the PDL, will be non-preferred. (Mr. Coppola noted that 78% of recipients are currently using the Proventil® HFA; 78% of claims were for Proventil® HFA.)

5. Committee Discussion and Approval of Drugs for Inclusion on the PDL

**MOTION: Judy Britt motioned to accept First Health's recommendation to have one preferred inhaler on the PDL, Proventil® HFA and that all other inhalers in this class, including inhalers currently on the PDL, will be non-preferred.**

**SECOND: Joseph Adashek**

**VOTES: Unanimous**

**MOTION CARRIED**

For the nebulizers, it is the recommendation of DHCFP and First Health that the nebulizer solutions of generic Proventil® (albuterol), generic Ventolin® (albuterol) and generic Alupent® (metaproterenol), be on the PDL. Xopenex® and Accuneb®, generic or otherwise, will be non-preferred.

**MOTION:** Connie Kalinowski motioned to accept First Health's recommendation that the nebulizer solutions of generic Proventil® (albuterol), generic Ventolin® (albuterol) and generic Alupent® (metaproterenol), be on the PDL. Xopenex® and Accuneb®, generic or otherwise, will be non-preferred.

**SECOND:** David Chan

Dr. Adashek expressed concern regarding the removal of Xopenex® from the PDL. Albuterol causes more shakiness and patients may stay awake longer if taken in the middle of the night.

Rob Coppola asked what percentage of patients experience that. Xopenex® will be available through the prior authorization process.

Dr. Adashek responded that most parents of children prefer levalbuterol (Xopenex®) over albuterol because of the side effect profile especially in the middle of the night where albuterol will keep people awake longer and the shakiness sometimes increases asthma especially in children.

Dave Wuest commented that if the patient had that side effect, they could move to the Xopenex® though the PA process; the process requires the preferred drug be tried first.

Rob Coppola stated that recipients currently on Xopenex® can be grandfathered.

Judy Britt recommended that recipients currently on Xopenex® be grandfathered. Those individuals currently on Xopenex® will probably not do well going back on albuterol. Children tend to have more shakiness with albuterol so it's very individual, but for those individuals that have moved to Xopenex®, she felt would not do well if changed to albuterol.

**Connie Kalinowski offered a change of motion.**

**MOTION:** To include in the original motion to grandfather individuals already being treated with Xopenex®.

**SECOND:** David Chan

**VOTES:** Unanimous

**MOTION CARRIED**

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

Rob Coppola stated that new drugs recently released on the market within existing PDL categories are non-preferred until such time they are reviewed by the Committee. He reviewed the PDL Revisions Quarterly Report included in the meeting binder.

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

The next meeting is scheduled for March 25, 2010, at the Airport Plaza in Reno.

VII. Public Comment

No comment.

VIII. Adjournment

**MOTION:** Joseph Adashek motioned to adjourn the meeting.

**SECOND:** Weldon Havins

**VOTES:** Unanimous

**MOTION CARRIED**

**Meeting Adjourned at 3:00 p.m.**