JIM GIBBONS
*Governor*

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

MICHAEL J. WILLDEN
*Director*

CHARLES DUARTE
*Administrator*

**PHARMACY & THERAPEUTICS COMMITTEE**

**Las Vegas Chamber of Commerce**
**6671 Las Vegas Blvd. S., Suite 300**
**Las Vegas, NV 89119**

**First Health Services**
**885 Trademark Dr., Suite 150**
**Reno, NV 89521**

**Meeting Minutes**
**June 24, 2010**

**Committee Members Present:**
**Las Vegas:** Rudy Manthei, MD; Joseph Adashek, MD; Chad Luebke, Pharm.D.; Shamin Nagy, MD
**Reno**: Judy Britt, Pharm.D.; David Chan, R.Ph.; Justin Holt, Pharm.D.; Michael Hautekeet, R.Ph.,
**Absent:** Weldon Havins, MD; Constance Kalinowski, MD

**Others Present:**
**DHCFP:**
**Las Vegas:** Gabriel Lither; Deputy Attorney General
**Reno:** Coleen Lawrence, Chief, Program Services; Jennifer Matus, Pharmacy Program Specialist

**First Health Services:**
**Las Vegas:** Rob Coppola Pharm.D, Program Director; Paula Townsend Pharm.D., Clinical Manager; Shirley Hunting
**Reno:** Judy LaFleur, Kim Teixeira

**Others:**
**Las Vegas:** Sabrina Aery-BMS; Steve Fox-GSK; Karen Marchi-GSK; Mark Miller-Allergan; Michelle Threde-Ortho McNeil Janssen; Michael Weingerten-Ortho McNeil Janssen; Billy Gahagan-Ortho McNeil Janssen; Peter Berggren-Ortho McNeil Janssen; Mark Schwartz-GSK; David Case-Astellas Pharma; Jim Kooyman-Astra Zeneca; Doug Ethel-GSK; Naresh P. Singh-Pulmonary Assoc.; Damon Cox-Merz; Steve Nelson-Merck; Esther Pack-Merck; Leigh Platte-Astellas; Rob Meier-Pfizer; Sandy Sierawaski-Pfizer; Alex Mitchell-Pfizer; Michael Gilmore-Pfizer; Brett Brewer-EMD Serono; Helen Liar-Lilly; Eric Tilers-Lilly; Larry Hinson-Astra Zeneca; Joseph Sirna-ENDO; Lori Horwarth-Bayer; Robert Martin-Bayer; Julie Hubbard-EMD Serono; John Robinson-Boehringer Ingleheim; Te(illegible) Fuller-Biogen Idec; Linda Nowell-National MS Society; Jan Peterson-Novo Nordisk; Dana Cornell-Novo Nordisk; Melissa Walsh-Novartis; Sharon Cahoon-Metzger-Biogen Idec; Eric Byrnes-Alcon; Dean Donato-Alcon; Eric Eilers-Lilly; Pat Wiseman-Medimune; Raza Karim-GSK; Craig Nakamura, MD-Children's Lung Specialist; Dan Bay-Abbott; Kris Drewes-Ortho McNeil; Javier Avila, PA; Ed Luesch-person with MS; Angela Duran-MS; Guli Teffen-Eisai; Scott Brown-Teva; David Raham-(illegible); Lynn McCl(illegible)-OMJSA; John Brokers-Eli Lilly; Annie Ogostalick-ABT; Michael Casey-UNSOM; Brad Bugstahler-Elan; Victoria Dahl-MS; Cathy Kelly-MS; Kathy Chamberlain-MS; David Block-(illegible); Lisa Wilson-J&J; Tim Wilkinson-Astra Zeneca; Dr. Sterling Tanner; Dr. Gabrieda Gregory-NV Neuro Science Inst.; Chris Almeida-Purdue
**Reno:** Irene Camerino-Forest; Jessica Ferrato-Pfizer

Copies of written testimony submitted by the public were distributed to the committee.

## I. Call to Order and Roll Call

Chairman Rudy Manthei called the meeting to order at 1:01 p.m.

## II. Review and Approval of the May 3, 2010 Meeting Minutes

**MOTION:** **Shamim Nagy motioned to approve the minutes as presented.**
**SECOND:** **Chad Luebke**
**VOTES:** **Unanimous**
**MOTION CARRIED**

Dr. Manthei reminded the public that public comment is limited to five minutes per individual, organization or agency and only new information within a drug class is to be presented.

## III. New Drug Class Reviews

### A. Analgesics: Topical

**Public Comment**
No comment.

**Drug Class Review Presentation – First Health Services**

Rob Coppola stated this is a new drug class for inclusion to the PDL and the drugs in this class are diclofenac epolamine (Flector®), diclofenac sodium (Pennsaid®, Voltaren® Gel), capsaicin (Qutenza®) and lidocaine (Lidoderm®). FDA indications for these agents differ slightly. Flector® is indicated for topical treatment of acute pain due to minor strains, sprains, and contusions; Pennsaid® is approved for the treatment of signs and symptoms of osteoarthritis of the knees; Voltaren® Gel is approved for the relief of pain of osteoarthritis in joints amenable to topical treatment such as the knees and hands; Lidoderm® and Qutenza® are indicated for the relief of pain associated with post-herpetic neuralgia. These drugs are minimally absorbed systemically. There are slight differences in the absorption characteristics between the diclofenac agents. He reviewed the dosages for each agent as outlined in the drug review. Diclofenac inhibits cyclooxygenase resulting in the lessening of prostaglandins, thromboxane and prostacyclin. Lidocaine stabilizes neuronal membranes by inhibiting the ionic fluxes required for initiation and conduction of impulses. Capsaicin works to enhance stimulation of transient receptor potential vanilloid 1 (TRPV1) causing painful sensations followed by pain relief mediated by TRPV1 expressing nociceptive nerve endings. There are no significant contraindications or warnings with these products. Diclofenac products may interact with ACE inhibitors, aspirin, diuretics, lithium, methotrexate and warfarin; lidocaine should be used with caution in patients receiving Class 1 antiarrhythmics; capsaicin has no reported drug interactions. Diclofenac products share comparable adverse effect profiles; lidocaine and capsaicin have minimal reported adverse events. These topical agents have not been studied in pediatrics; lidocaine and capsaicin are Pregnancy Category B; diclofenac formulations are Pregnancy Category C. Diclofenac is not recommended in patients with advanced renal disease; lidocaine should be used cautiously in patients with severe hepatic disease. There are no head-to-head trials; indirect comparisons indicate comparable efficacy and similar adverse event profiles. 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 Identify Exclusions/Exceptions for Certain Patient Populations**

**MOTION:** **Chad Luebke motioned that the agents in this class be considered therapeutic alternatives.**
**SECOND:** **Shamim Nagy**
**VOTES:** **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. Coppola stated that it is the recommendation of DHCFP and First Health to add Voltaren® Gel to the PDL. The other agents in this class will be non-preferred.

**Committee Discussion and Approval of Drugs for Inclusion on the PDL**

**MOTION:** **Chad Luebke motioned to accept First Health's recommendation to add Voltaren® Gel as the preferred product to the PDL.**
**SECOND:** **Shamim Nagy**
**VOTES:** **Unanimous**
**MOTION CARRIED**

Dr. Adashek joined the meeting at 1:09 p.m.

**B. Analgesics: Tramadol Containing Products**

**Public Comment**

Peter Berggren, Ortho McNeil, spoke in support of Nucynta™ (tapentadol). He stated that Nucynta™ is not a tramadol containing product. It is a short-acting opioid and in other state systems has been reviewed within the short-acting opioid category. Nucynta™ is a Schedule II product; tramadol is not scheduled. Nucynta™ is indicated for the relief of moderate to severe acute pain in patients 18 years of age and older; Tramadol does not have an indication for severe pain. Nucynta™ compares favorably with oxycodone with regard to ability to relieve pain. Tramadol is more appropriately compared to Celebrex® or weak opioid containing products. Nucynta™ is two times less potent than morphine; tramadol is a weak agonist approximately ten times less potent than morphine. Nucynta™ has little to no serotonin reuptake inhibition. It's a relatively stronger norepinephrine reuptake inhibition; tramadol is both a serotonin and norepinephrine reuptake inhibitor. There is no bolded warning for seizure risk or serotonin syndrome for Nucynta™; tramadol has bolded warnings in both of these areas. These are two different drugs; one should not be substituted for another and should be used in different patient populations for the treatment of pain as per the FDA approved guidelines. In pivotal trials, Nucynta™ demonstrated superior reduction in pain intensity compared to placebo, was non-inferior and generally comparable to oxycodone IR. There was a lower incidence of GI adverse events versus oxycodone.

Michael Casey, general surgeon, University of Nevada School of Medicine, spoke in support of Nucynta™, as a drug used in his patient class and general surgery population, and would like to have it available. 85% of his surgery patients are Medicaid; most have difficult reconstructive hernia surgery. The lack of GI side effects with Nucynta™ is enhanced in the fact that these people do not become constipated and stress their wounds. They also do not suffer the nausea or GI upset associated with Oxycontin®, Percocet® or Lortab®. He felt that Nucynta™ is ideal for the patients he serves, polypharmacy can be decreased; the effect of antiemetics which can be costly be reduced. He requested the drug be available for the general population.

Javier Avila, physician assistant, pain management practice, spoke in support of Nucynta™. His practice manages patients post-operatively and those patients sometimes have difficulty with side effects in the use of other opioids; e.g., GI tolerability, constipation, nausea. Nucynta™ is useful in those patients that cannot tolerate other opioid type medication. He also stated that Nucynta™ is helpful in patients with hepatic disease or that admittedly consume more than three drinks of alcohol on a regular basis. He avoids acetaminophen products in these types of patients and does not have to be concerned with acetaminophen content with Nucynta™. His practice screens patients for opioid problems and prescribes this drug to patients who have a high risk of opioid use. Nucynta™ has $1/18^{th}$ of the opioid affinity versus morphine.

**Drug Class Review Presentation – First Health Services**

Dr. Coppola stated that the products being discussed today are the tramadol containing products in this class. FDA indications for Ultram® (tramadol) are the management of moderate to moderately severe pain in adults; Ultracet® is indicated for the short-term treatment of acute pain; Nucynta™ is indicated for relief of moderate to severe acute pain. Tramadol is a centrally acting synthetic opioid analgesic with dual opioid and non-opioid mechanisms. In addition to activity at opioid receptors, tramadol weakly inhibits norepinephrine and serotonin reuptake. Nucynta™ is also a centrally acting synthetic analgesic with dual opioid and non-opioid mechanisms and only inhibits norepinephrine reuptake. Nucynta™ is highly metabolized in the liver and eliminated in the urine; tramadol is 60% metabolized to active metabolites. Both have comparable kinetics with no clinically significant differences. Tramadol is a non-scheduled product; Nucynta™ is a Schedule II product. Nucynta™ is contraindicated in patients with impaired pulmonary function, in patients with paralytic ileus and patients taking MAO inhibitors in the past 14 days. Tramadol is contraindicated in patients at risk for intoxication from drugs and alcohol, in patients taking MAO inhibitors or SSRIs, and in patients with seizures. The adverse event profile is comparable with slightly more constipation and headaches with tramadol. These agents have not been studied

in pediatrics; all are Pregnancy Category C. Nucynta™ should be used with caution in patients with moderate hepatic impairment and not in patients with severe impairment. Tramadol use in patients with renal impairment requires a dose adjustment. There are no head-to-head trials between these agents; all show comparable efficacy and adverse events. It is the recommendation of DHCFP and First Health that the tramadol containing 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**

**MOTION:** **Shamim Nagy motioned that the tramadol containing agents in this class be considered therapeutic alternative**
**SECOND:** **Joseph Adashek**
Justin Holt asked if these agents are being considered therapeutic alternative to the rest of the narcotic analgesics or considered therapeutic alternatives within their own group.
Dr. Coppola replied within their group separate from the short-acting opioid analgesics.
**VOTES:** **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. Coppola stated that it is the recommendation of DHCFP and First Health that the generic products tramadol and tramadol/acetaminophen be the preferred agents on the PDL.

**Committee Discussion and Approval of Drugs for Inclusion on the PDL**

Dr. Adashek said that tramadol use with SSRIs has been associated with seizures and asked what agent would be used as an alternative for those types of patients. Also, what is the process for patients that are discharged from the hospital on Nucynta™.

Dr. Coppola replied that Nucynta™ will be available through the PDL exception process. Dr. Adashek asked how that process works. Dr. Coppola said that the Clinical Call Center is open 24 hours per day/seven days per week. The prescriber can obtain prior authorization by calling the call center, faxing the appropriate form to the call center or through the on-line Web PA mechanism. The turnaround on PA requests is 24 hours as required by federal law.

Dr. Manthei said that the issue is that if the patient has to fail, creating a bad outcome, and something has to be used secondarily, why it wouldn't be available primarily to prevent complications in the first place.

Dr. Coppola replied for those instances when it's used for severe pain following surgery, a PA would be required and approved since it meets the unique FDA indication for severe pain. Failure of another preferred agent would not be required in this situation.

**MOTION:** **Joseph Adashek motioned to add Nucynta™ to the PDL and to accept First Health's recommendation to add the generic products tramadol and tramadol/acetaminphen to the PDL.**
**SECOND:** **Shamim Nagy**
**AYES:** **Hautekeet, Holt, Chan, Adashek, Luebke, Manthei, Nagy**
**NAYES:** **Britt**
**MOTION CARRIED**

## IV. Established Drug Class Reviews

### A. Intranasal Rhinitis Agents

**Public Comment**
No comment

**Drug Class Review Presentation – First Health Services**

Dr. Coppola stated that this class was last reviewed in June, 2009. At that time, Astepro® and Veramyst® were added to the PDL. There are no new products or studies released since last year's review. 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 to Identify Exclusions/Exceptions for Certain Patient Groups**

**MOTION: Shamim Nagy motioned that the agents in this class be considered therapeutic alternatives.**
**SECOND: Chad Luebke**
**VOTES: Unanimous**
**MOTIONED CARRIED**

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

Dr. Coppola stated that it is the recommendation of DHCFP and First Health that generic fluticasone propionate, Astelin® and Astepro® be the preferred agents on the PDL.

**Committee Discussion and Approval of Drugs for Inclusion on the PDL**

Dr. Manthei asked why this recommendation. Dr. Coppola replied that the recommendation is based on the current utilization in the class and the pricing that's available at this time. The indications are the same for the products in the class and the recommended agents provide ample coverage clinically.

Dr. Manthei stated that cost cannot be considered by the Committee.

Ester Pack, Merck, requested to provide public comment; Dr. Manthei accepted. Ms. Pack spoke in support of Nasonex®. She stated that all indications for these agents are not the same in terms of the age criteria as well as allergic rhinitis and perennial allergic rhinitis. Nasonex® is indicated down to age 2; the generic is indicated down to 4 years of age. It is indicated for the treatment of nasal polyps and for prophylaxis of seasonal rhinitis. Nasonex® has received a new FDA indication as the only nasal steroid indicated for the treatment of nasal congestion. Side effect profiles have not changed.

David Chan asked regarding the utilization statistics for those products being removed from the PDL.

Dr. Townsend replied that the data reflects steroid products and Astepro® and Astelin® which are significantly used are not reflected in these percentages. Fluticasone and related compounds are 35% of the market; branded Nasonex® is 55%.

Dr. Manthei asked if any of the other medications are indicated for under the age of 4 and Dr. Coppola replied no.

**MOTION: Chad Luebke motioned to include Nasonex® on the PDL and to accept First Health's recommendation that fluticasone, Astelin® and Astepro be on the PDL.**
**SECOND: Shamim Nagy**
**VOTES: Unanimous**
**MOTION CARRIED**

## B. Growth Hormone Agents

### Public Comment

Sterling Tanner, pediatric endocrinologist, stated that he is not representing anyone except for his patients. Since pediatric endocrinologists are the major prescribers for growth hormone in children, he offered to be available as a resource for questions the Committee may have. He commented that the available agents are all equal in efficacy; some have FDA approvals for certain conditions that others don't, but in general, the drugs are used interchangeably in practice. The insurance company determines which drug is used. Some drugs have different means by which the product is administered. He expressed no specific concerns regarding individual use and efficacy particularly with the current PDL agents.

Dr. Luebke asked if Dr. Tanner felt that there are any omissions from the current PDL that would be deemed to be therapeutically necessary. Dr. Tanner stated other than the mechanism of administration, there is no advantage over one drug to another.

Coleen Lawrence expressed appreciation for Dr. Tanner's time and testimony. She explained that the PDL is different from a private insurance preferred list. Medicaid's PDL is an open formulary. If a drug is not on the PDL, it does not mean that they cannot have access to it.

Sandy Sierawski, Pfizer, spoke in support of Genotropin®, which has been available on the Nevada Medicaid PDL for a number of years. Based on the 2009 CMS data, Genotropin® has accounted for 26% of the growth hormone prescriptions in Nevada Medicaid patients. Genotropin® is indicated in 95% of pediatric patients who require growth hormone therapy. It's the only FDA approved drug for the treatment of children with Prader-Willi Syndrome. Pfizer can provide comprehensive patient and parent educational materials for this condition in English and Spanish. Genotropin® has cartridges for the pens with overfill to ensure the appropriate dose. The Miniquick® device is the only single-use disposable device; no refrigeration is required and it's preservative-free. Pfizer offers a comprehensive Bridge Program, is a patient support program, which assigns a patient care consultant who serves as a liaison for the patient, physician, pharmacy, etc., and also provides in-home device training.

Julie Hubbard, EMD Serono, spoke in support of Saizen®. Saizen® is indicated for pediatric and adult growth hormone deficiency. A needle-free and needle-hidden device are available for administration and the new device, easypod®, is electronic. The easypod® device is easy to manipulate and use for children. The device tracks dosing administration and allows multiple cartridges minimizing wastage.

Shelly Mitchell, Teva Biologics, spoke in support of Tev-Tropin®. Clinical trials demonstrated Tev-Tropin® to be therapeutically equivalent to HGH of pituitary origin. It is synthesized in a strain of e-coli that has been modified by the insertion of human growth hormone gene. Tev-Tropin® is safe and effective. It stimulates human growth in linear growth in pediatric patients who lack adequate levels of endogenous growth hormone, is available in a sterile white powder intended for subcutaneous administration after reconstitution and is supplied in a 5mg vial with diluent. Tev-Tropin® is value priced with comprehensive support services (Growth Solutions) for the patient, family and doctor. The new needless device, Tjet®, has three steps for delivery: fill up to the prescribed dose; apply to injection site; reset and dial down to reset the injector button, and store for next administration.

John Brokers, Lilly, spoke in support of Humatrope®. Since 2009, three pen injection devices have been released, HumatroPen® 6mg, 12mg, and 24mg. In March, 2009, there was an FDA approval for Humatrope® for small gestational age indication. Pancreatitis in patients with Turner Syndrome has been seen with Humatrope®. Since PA is required for all of the agents, he asked that Humatrope® be treated equally with the other agents.

Dana Cornell, Novo Nordisk, spoke in support of Norditropin®. In reference to Dr. Tanner's comments, the medication itself is similar to other products but there are different devices that may make is easier for patients and allow for less wastage. Novo Nordisk's device is a prefilled, preloaded device with a 160 unique dosages as well a 0.25mg. No refrigeration is required after

initial use. Novo Nordisk has a patient support program to assist patients and providers during the initiation of the drug and duration of therapy.

**Drug Class Review Presentation – First Health Services**

Dr. Coppola stated that there has not been new information released since the class was last reviewed in 2009. The 2009 American Association of Endocrinologists Guidelines indicates no new evidence exists to support any specific growth hormone product over another. 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 to Identify Exclusions/Exceptions for Certain Patient Groups**

**MOTION: Shamim Nagy motioned that the agents in this class be considered therapeutic alternatives.**
**SECOND: David Chan**
**VOTES: 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. Coppola stated that it is the recommendation of DHCFP and First Health that the Genotropin® products and the Nutropin® products be preferred.

David Chan asked if all agents need a PA, why is there preferred and non-preferred.

Coleen Lawrence stated that all the drugs in this class require a clinical prior authorization. The agents recommended are in the best interest of the State.

**Committee Discussion and Approval of Drugs for Inclusion on the PDL**

**MOTION: Justin Holt motioned to accept First Health's recommendation that the Genotropin® products and the Nutropin® products be the preferred agents on the PDL.**
**SECOND: Judy Britt**
**VOTES: Unanimous**
**MOTION CARRIED**

**C. Respiratory: Long Acting Beta Adrenergics**

Dr. Manthei noted that review of this class will be for combination products.

**Public Comment**

Naresh Singh, pulmonologist, stated that he is on the speaker's bureau for Astra Zeneca, Pfizer, Boehringer Ingelheim and GSK. He stated that it's his recommendation that the formulary add Symbicort® in addition to Advair®. The reason is that the formoterol molecule is slightly different with a five minute onset of action. There are certain populations that he serves where severe COPD patients have a great utilization of rescue inhalers during the course of a day and use their rescue inhalers while waiting for their maintenance medication to work. Astra Zeneca has data that has shown there has been a one dose reduction in rescue inhalers. It's not necessarily for everyone, but there are certain patients that it would reduce their rescue inhaler use, provide a faster onset of action and improve their functionality. He requested that Symbicort® be added to the PDL.

Jim Kooyman, Astra Zeneca, spoke in support of Symbicort®. On June 16, 2010, Symbicort® prescribing information was revised in accordance with the FDA class labeling guidance. The updated labeling provides guidance on how these products should be prescribed for asthma. Symbicort® is indicated for the treatment of asthma in patients 12 years of age and older and

should only be used in patients not adequately controlled on long-term asthma control medication. Once asthma control is achieved and maintained, assess the patient at regular intervals and step-down therapy. The box warning and label have been revised that when used as single ingredient product, there is an increase in the risk of asthma related death based on a large placebo controlled trial with salmeterol. Currently available data are inadequate to determine whether concurrent use of ICSs or other long-term asthma control drugs mitigates increased risk of death. Symbicort® 160mcg/4.5mcg twice daily is also approved for the maintenance of airflow obstruction in patients with COPD including chronic bronchitis and emphysema. Two pivotal trials demonstrated Symbicort® significantly improved lung function in patients with COPD reversing airway obstruction within 30 minutes after receiving two inhalations of Symbicort®. He requested Symbicort® be added to the PDL.

Craig Nakamura, MD, stated that he is not being compensated for appearing today and requested that Advair® remain on the PDL. As a pediatric pulmonologist, he treats many patients with moderate and severe persistent asthma. Following the guidelines, a number of these patients will be on combination therapy. Advair® is a good choice to stay on the PDL because the inhaled corticosterioid, fluticasone, is also on the PDL and when stepping down asthmatics, the steroid can be kept the same. It's available with different devices and with diskus indicated down to four years of age. He recommended that Advair® remain on the PDL.

Doug Ethel, GSK, stated that the labeling on the combination products has changed. The long-acting beta-agonists are now contraindicated as monotherapy for asthma (listed in the black box warning). Wording that was strengthened centered around step-down therapy. The terms "long-term" and "maintenance" were removed and replaced with a statement that "the patient's asthma control should be reassessed at regular intervals." It is left up to the provider what the interval times will be.

**Drug Class Review Presentation – First Health Services**

Dr. Coppola stated that this class was last reviewed in June, 2009. Today's review is based solely on the combination products, Advair® and Symbicort®. 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:** **Joseph Adashek motioned that these agents be considered therapeutic alternatives.**
**SECOND:** **Shamim Nagy**
**VOTES:** **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. Coppola said that it is the recommendation of DHCFP and First Health that Advair® Diskus, Advair® HFA and Symbicort® be preferred.

**Committee Discussion and Approval of Drugs for Inclusion on the PDL**

**MOTION:** **Shamim Nagy motioned that Advair® Diskus, Advair® HFA and Symbicort® be the preferred agents on the PDL.**
**SECOND:** **Judy Britt**
**VOTES:** **Unanimous**
**MOTION CARRIED**

## V. ANNUAL REVIEW – DRUG CLASSES BEING REVIEWED DUE TO RELEASE OF NEW DRUGS

### A. Analgesics: Long-Acting Narcotics

**Public Comment**
No comment.

**Drug Class Review Presentation – First Health Services**

Dr. Townsend stated that this class was last reviewed in June, 2009. At that time the Committee recommended that the agents in the class were therapeutic alternatives and no changes were made to the PDL at that time. Since that time, two new products have been released, Embeda® and Exalgo™; there has been a reformulation of Oxycontin®. Exalgo™ is an extended release hydromorphone in a once daily formulation with a maximum of once daily frequency. The tablets are extended release and should not be chewed, crushed or dissolved. Taking broken, chewed, dissolved or crushed tablet, leads to rapid release and absorption hydromorphone which can be extremely dangerous. The drug has a unique warning for sodium metabisulfite which is a sulfite that can cause an allergic reaction in some patients. The American Pain Society 2009 guidelines do not distinguish among the long-acting narcotics in terms of their guideline recommendations. Embeda® contains pellets of morphine and a sequestered core of naltrexone. Taken orally or sprinkled on applesauce, the morphine will be released while the naltrexone will remain sequestered in a film coating that is resistant to GI digestion. Crushing, chewing, etc., of the product will cause an immediate release of both morphine and naltrexone and will precipitate withdrawal in someone who is dependent. In those not dependent, the naltrexone will offset the morphine. There is a theoretical advantage in terms of abuse liability but to date there is no evidence demonstrating that the formulation decreases the abuse. According to the FDA, the new formulation of Oxycontin® is bioequivalent to the old formulation in terms of the amount of drug that's actually available. The reformulation was intended to make it more difficult to manipulate for intentional abuse; there is no evidence demonstrating any difference. Dissolving the reformulated tablet for injection results in a gummy mass which cannot be injected. 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 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**

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

Dr. Townsend stated that it is the recommendation of DHCFP and First Health that no changes be made to the current PDL in this drug class.

**Committee Discussion and Approval of Drugs for Inclusion on the PDL**

**MOTION:** **Joseph Adashek motioned to accept First Health's recommendation that no changes be made to the current PDL in this drug class.**
**SECOND:** **Chad Luebke**
**VOTES:** **Unanimous**
**MOTION CARRIED**

### B. Central Nervous System: Sedative Hypnotics

**Public Comment**
No comment.

**Drug Class Review Presentation – First Health Services**

Dr. Townsend stated that this class was last reviewed in June, 2009. At that time the drugs in this class were determined to be therapeutically equivalent and no changes were made to the PDL. Since that time, a new formulation of zolpidem, Edluar®, has been released. Edluar® is a sublingual tablet and should not be swallowed or taken with water. The label states that this sublingual tablet is bioequivalent to Ambien®, which is the branded oral zolpidem tablet with respect to its $C_{max}$ and AUC. The label states that similar to zolpidem, Edluar® sublingual tablets result in a pharmacokinetic profile characterized by rapid absorption. There is no label claim which states that the sublingual onset of action is faster versus the tablet and there is no data available which demonstrates a faster onset of action. The label also states that Edluar® should not be taken unless the patient can stay in bed a full 7-8 hours. 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 to Identify Exclusions/Exceptions for Certain Patient Groups**

**MOTION:** **Chad Luebke motioned that the agents in this class be considered therapeutic alternatives.**
**SECOND:** **Joseph Adashek**
**VOTES:** **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. Townsend stated that it is the recommendation of DHCFP and First Health that no changes be made to the current PDL in this drug class.

**Committee Discussion and Approval of Drugs for Inclusion on the PDL**

**MOTION:** **Chad Luebke motioned to accept First Health's recommendation that no changes be made to the current PDL in this drug class.**
**SECOND:** **Joseph Adashek**
**VOTES:** **Unanimous**
**MOTION CARRIED**

C. **Immunomodulators: Injectable**

**Public Comment**
No comment

**Drug Class Review Presentation – First Health Services**

Dr. Townsend stated that for the purpose of this review and the PDL, which primarily serves as an outpatient document, the self-injectable products are being considered today. This class was last reviewed in June, 2009. At that time, the Committee recommended no changes be made to the PDL. There are two new TNF-alpha blockers available. Cimzia® is a new drug which is indicated for both Crohn's Disease and rheumatoid arthritis. Simponi™ is also a new drug which is indicated for rheumatoid arthritis, ankylosing spondylitis, and psoriatic arthritis. Other TNF-alpha blockers include etanercept (Enbrel®), which is self-injected, infliximab (Remicaid®) which is a physician infusion, and adalimumbab (Humira®) also self-injected. Other notable changes that have occurred in the class in the past year, Raptiva® was voluntarily withdrawn from the marketplace due to reports of PML. The other labels include updates on safety data primarily strengthening the warnings and clarifying at-risk groups for adverse events. In November, 2009, a black box was added to these labels (TNF inhibitors) regarding the risk of lymphoma and other malignancies reported in children and adolescents. Cimzia® is a recombinant antibody pegylated Fab' fragment which binds the TNF-alpha. Because it's pegylated, it has a longer half-life of 14 days compared to Remicaid® or Embrel® but similar to Humira® which range from 10-20 days; Simponi™ is two weeks. It's indicated for RA and Crohn's Disease and offers an alternative to

infliximab and adalimumab for the treatment of Crohn's. Cimzia® is administered subcutaneously. The labeling currently advises that Cimzia® be administered by a health care provider but it also states that patients can self-administer; it requires less frequent administration than Humira®. Adverse reactions and efficacy appear similar with all three agents. Simponi™ is a human IgG1κ monoclonal antibody specific for TNF-alpha indicated in combination with methotrexate for treatment of moderate to severely active RA. It has no labeling for inhibition of progression of disease or structural damage or improving physical function. For psoriatic arthritis, it's indicated with methotrexate and as a sole agent in ankylosing spondylitis. It's similar to Humira® but requires less frequent administration. The FDA states that Simponi® appears to offer similar efficacy and safety to Enbrel®, Humira®, and Remicaid®; adverse drug events occurred in similar incidences and types as the other drugs. It is the recommendation of DHCFP and First Health that the self-injectable immunomodulators be considered therapeutic alternatives within their indications.

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

Dr. Nagy asked if Remicaid® will be included. Dr. Townsend replied that Remicaid® is not a self-administered agent; agents administered in a physician's office are not being considered.

**MOTION: Shamim Nagy motioned to accept First Health's recommendation that the self-injectable immunomodulators be considered therapeutic alternatives.**
**SECOND: Judy Britt**
**VOTES: 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. Townsend stated that it is the recommendation of DHCFP and First Health that no changes be made to the current PDL in this drug class.

**Committee Discussion and Approval of Drugs for Inclusion on the PDL**

**MOTION: Justin Holt motioned to accept First Health's recommendation that no changes be made to the current PDL in this drug class.**
**SECOND: Michael Hautekeet**
**VOTES: Unanimous**
**MOTION CARRIED**

Dr. Adashek said if there is no public comment and First Health's recommendation is the same as the previous year's review with no change, is it necessary to go through the entire process.

Gabriel Lither, DAG, responded that it is required to complete the entire process, but perhaps does not have to be as involved in every case.

D. **Antiparkinson's Agents: Non-ergot Dopamine Agonists**

**Public Comment**

Dr John Robinson, Boehringer Ingelheim, spoke in support of Mirapex® ER, approved in 2010, is a non-ergot derived dopamine agonist, indicated for the signs and symptoms of early and advanced idiopathic Parkinson's Disease. Mirapex® ER tablets are taken orally once daily. The initial US approval for Mirapex® ER was in 1997. Parkinson's Disease is a progressive neuro-degenerative disease with debilitating and devastating motor and non-motor symptoms. The effectiveness of Mirapex® ER as monotherapy was established in clinical trials of six month's duration in early Parkinson's Disease. It significantly improved motor function and activities of daily living compared to placebo. The effectiveness of Mirapex® ER as adjunctive therapy was established in the second clinical trial of six month's duration in advanced Parkinson's Disease patients on concomitant levodopa therapy. Mirapex® ER significantly improved motor function in activities of daily living in this patient population. The profile of this drug includes slow

release of once daily Mirapex® ER with similar exposure over 24 hours as three times daily pramipexole (Mirapex®) immediate release and is thus bioequivalent. It's titrated gradually with a flexible dosing based on efficacy and tolerability to a maximum of 4.5mg per day. Titration to an effective dose may be achieved is three weeks with normal renal function with or without levodopa. Urinary excretion is the major route of elimination. Mirapex® ER has not been studied in patients with severe renal impairment or patients on hemodialysis and is not recommended in these patients. This drug may cause patients to fall asleep without perceived warning signs during activities of daily living. Hallucinations or orthostatic hypotension may occur. There have been reports of patients experiencing intense sexual urges while taking one or more of the medications including Mirapex® ER that increase central dopaminergic tone and that are generally used for the treatment of Parkinson's Disease. The most commonly reported adverse events are somnolence, nausea, dyskinesia, constipation, dizziness, fatigue and hallucinations. He requested that Mirapex® ER be considered for inclusion to the PDL for Parkinson's Disease.

**Drug Class Review Presentation – First Health Services**

Dr. Townsend stated that this class was last reviewed in June, 2009, and at that time, no changes were made to the PDL in this class. Since that time, a new product has been released, Mirapex® ER, which is indicated for early Parkinson's Disease (PD), in a once-daily formulation. It is the recommendation of DHCFP and First Health that the agents in this category be considered therapeutic alternatives.

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

**MOTION: Joseph Adashek motioned that the agents in this class be considered therapeutic alternatives.**
**SECOND: Chad Luebke**
**VOTES: 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. Townsend stated that it is the recommendation of DHCFP and First Health that no changes be made to the current PDL in this drug class.

**Committee Discussion and Approval of Drugs for Inclusion on the PDL**

**MOTION: David Chan motioned to accept First's Health recommendation that no changes be made to the current PDL in this drug class.**
**SECOND: Shamim Nagy**
Dr. Adashek requested clarification that the Requip® XL is a once-a-day extended release and Dr. Townsend replied that is correct.
**VOTES: Unanimous**
**MOTION CARRIED**

E. **Anaphylaxis: Self-Injectable Epinephrine**

**Public Comment**
No comment

**Drug Class Review Presentation – First Health Services**

Dr. Townsend stated that this class was last reviewed in December, 2009. The products in this class all contain the same drug and available doses. At that time, the Committee recommended that the drugs in this class be considered therapeutic alternatives. A new product has since been released, AdrenaClick®, which is an auto injector containing epinephrine as a single-use injection. 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: Shamim Nagy motioned that the agents in this class be considered therapeutic alternatives.**
**SECOND: Chad Luebke**
**VOTES: 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. Townsend stated that it is the recommendation of DHCFP and First Health that no changes be made to the current PDL in this drug class.

**Committee Discussion and Approval of Drugs for Inclusion on the PDL**

**MOTION: Chad Luebke motioned to accept First Health's recommendation that no changes be made to the current PDL in this drug class.**
**SECOND: Shamim Nagy**
Dr. Britt asked in the case of drug shortages which are currently being experienced within this class, is there a mechanism in place that automatically approves a non-preferred if there is a shortage of the preferred agents.
Dr. Townsend replied that shortages are tracked weekly by First Health. With respect to this class, there are two products on the preferred list. Mechanisms would be put in place if there was a shortage of both agents.
Ms. Lawrence stated that she has administrative authority to put a blanket override in place to override the PDL if there is an actual drug shortage in the state.
**VOTES: Unanimous**
**MOTION CARRIED**

F. **Ophthalmic Antihistamines**

**Public Comment**
No comment.

**Drug Class Review Presentation – First Health Services**

Dr. Townsend stated that this class was last reviewed in June, 2009. At that time, the Committee recommended no changes to the PDL in this class. A new antihistamine, Bepreve®, has been released since the last review. It's a direct H1 antihistamine for ocular itching associated with allergic conjunctivitis indicated down to age 2. Bepreve® is similar to the other agents. There have not been any comparisons other than with vehicle and there is no data to support its superiority over other available agents. Bepreve® is dosed twice daily; Pataday®, which is currently on the PDL, is dosed once daily. 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: Shamim Nagy motioned that the agents in this class be considered therapeutic alternatives.**
**SECOND: David Chan**
**VOTES: 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. Townsend stated that it is the recommendation of DHCFP and First Health that there be no changes to the current PDL in this drug class.

**Committee Discussion and Approval of Drugs for Inclusion on the PDL**

**MOTION: Michael Hautekeet motioned to accept First Health's recommendation that no changes be made to the current PDL in this class.**
**SECOND: Shamim Nagy**
**VOTES: Unanimous**
**MOTION CARRIED**

Dr. Manthei called for a five minute recess at 2:50 p.m.
Dr. Manthei called the meeting to order at 2:59 p.m.

G. **Multiple Sclerosis Agents**

**Public Comment**

Angela Duran, stated that she is a registered nurse and an active member of the MS community in Las Vegas. She has been living well with MS for the last 16½ years and states the reason is because of the drugs that are on the PDL. She encouraged that if there needs to be change on the list, add Extavia®, but do not remove any current drugs from the list. Having a choice is imperative when it comes to patient compliance. She speaks from experience having been on the majority of the PDL drugs and the need to change is often there primarily because all of the medications are injectable and not all are pleasantly injectable. She asked the Committee to maintain the current PDL, but if there is a need to add a drug, Extavia® is the drug to add.

Dr. Manthei referred to Ms. Duran's comment "if there is a need to add" and asked if she felt that the Committee does not need to add to the current PDL.

Ms. Duran replied that Extavia® is the newest agent and very comparable to Betaseron®. If the Committee chooses to add Extavia®, great; if not, MS patients are familiar with the current drug Betaseron®.

Linda Nowell, National Multiple Sclerosis Society, referred to the Disease Management Consensus Statement by the MS Society which she submitted to the Committee. She reiterated that there is no known cure for MS and the Society's position is that any agent that has been approved for the treatment of MS should be available to physicians and their patients because of the option of increasing the quality of life. Agents work differently on different patients.

Sharon Cahoon-Metzger, Biogen Idec, spoke in support of Avonex®. The corporate policy at Biogen Idec is to strongly encourage open and equal access. MS is a heterogeneous disease. Patients do not respond the same to any individual agent. Physicians need the freedom to be able to prescribe the agent that they feel is most appropriate for the patient. Avonex® is indicated for slow disability progression reducing the number of relapses. Data suggests early treatment of MS before the damage accumulates. Avonex® is unique among the interferons due to its once weekly administration; other agents are administered from daily to 3-4 times per week. Fifteen year data indicates that there is a decreased accumulation of disability and use is safe over the long term.

**Drug Class Review Presentation – First Health Services**

Dr. Townsend stated that this class was last reviewed in June, 2009. At that time, the Committee recommended no changes to the PDL in this drug class. Since that time, two new products have been released, Extavia® and Ampyra®. Extavia® is interferon beta-1b and is the same drug as Betaseron®, marketed by a different company. Ampyra® (dalfampridine) is a selective potassium blocker indicated to improve walking in patients with MS. It's proposed to improve conduction and action potential in demyelinated nerves. The mechanism of action is not fully delineated. The compounded chemical has been used off-label for 20 years in many different neurologic conditions. The approved product is an extended release agent which differs from the compound and is dosed at 10mg twice per day. Higher doses are contraindicated due to an increased risk of seizures. There is a risk evaluation and mitigation strategy which has been developed for the product which limits distribution to specialty pharmacies, distribution of patient information and verification of doses greater than 20mg. Studies were conducted in short-term placebo control

trials using a new primary outcome measure of walking speed; the 25 foot timed walk using a responder analysis. In the two studies done, response (≥20% increase in walk speed) was seen in 35% and 43% of Ampyra-treated patients vs 8% and 9% of placebo-treated patients. So, there was a modest improvement in the minority of patients in walking speed of about 0.5 feet/sec. Durability of response is unknown and there is no effect on disease progression. 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**

Gabriela Gregory, neurologist and director of the MS clinic at the Nevada Neurosciences Institute at Sunrise, requested to provide public comment; Dr. Manthei accepted. She spoke in support of Ampyra®. Less than 50% of patients responded in the studies but there has been a response for patients in-home. Although it sounds insignificant to say half a foot per second walking speed, the change can be the difference between being able to transfer alone versus requiring assistance to transfer versus being able to walk with a walker or cane. The symptomatic relief of patients that have responded has been significant. The drug is not an immunomodulator and not a disease modulator but a drug for symptomatic relief. In this class, it does not have an equivalent or alternative which is why it has been used off-label as a compounded drug for years. The improvement in patients was significant enough that it was worth the cost. She felt there is not a drug available on the PDL that is equivalent to Ampyra® and suggested that it be added to the PDL or allow a trial of six months, and if there is no improvement, discontinue the drug.

Dr. Adashek asked if this drug is given as a primary or secondary if the primary drug does not work, or an adjunct to a primary medication. Dr. Gregory said that the primary medications are disease modulators. The primary drugs, Betaseron® or Copaxone®, are aiming at modifying the disease. Ampyra® is different in that it doesn't affect the number of attacks or the progression, but affects how well a patient can function.

Dr. Adashek asked if this Committee voted either way that in conjunction or in place of another drug would have to obtain prior approval, would that be amenable to her and fellow physicians. Dr. Gregory felt as long as there were identifiable criteria. Dr. Manthei asked if there is another drug to fail and Dr. Gregory responded no.

Dr. Adashek asked when she attends national meetings, is this a medication being used by many other neurologists in the country. She replied, yes, that it's been used prior to being approved as a tablet; it was previously available by the kilogram and compounded.

**MOTION:** **Shamim Nagy motioned that the agents in this class be considered therapeutic alternatives.**
**SECOND:** **Joseph Adashek**
**VOTES:** **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. Townsend stated that it is the recommendation of DHCFP and First Health that there be no changes to the current PDL in this drug class.

**Committee Discussion and Approval of Drugs for Inclusion on the PDL**

**MOTION:** **Rudy Manthei motioned to accept First Health's recommendation to maintain the current drugs on the PDL; in addition, add Ampyra® to the PDL.**
**SECOND:** **Michael Hautekeet**
**VOTES:** **Unanimous**
**MOTION CARRIED**

## H. Cardiovascular: Calcium Channel Blockers & Combinations

**Public Comment**

Dr. John Robinson, Boehringer Ingelheim, spoke in support of Twynsta®, a combination product of telmisartan and amlodipine. Twynsta® is indicated for the treatment of hypertension alone or with other antihypertensives. The tablets can be used as initial therapy in patients who are likely to use multiple drugs to achieve their blood pressure goals. The usual starting dose is 40/5mg once daily. Patients requiring larger blood pressure reductions may be started at 80/5mg once per day. Initial therapy is not recommended in patients 75 years and older with hepatic impairment. Studies show Twynsta® is more effective in reducing blood pressure compared to the respective monotherapies. The majority of the antihypertensive effect of the telmisartan/amlodipine combination was attained within two weeks after initiation of therapy; there were larger reductions in diastolic and systolic pressure compared to patients treated with respective monotherapy. There is a boxed warning to avoid Twynsta® use in pregnancy due to possible injury or death in the developing fetus. Correct any volume or salt depletion before initiating therapy. Observe for signs and symptoms of hypotension particularly in patients with severe aortic stenosis. In patients with heart failure or severe renal impairment, care should be exercised with dosing of Twynsta®. Use of Twynsta® with an ACE inhibitor should be avoided. In clinical trials, the most commonly reported events were peripheral edema, dizziness, clinically meaningful orthostatic hypotension and back pain. Nursing mothers should discontinue Twynsta®.

**Drug Class Review Presentation – First Health Services**

Dr. Townsend stated that this class was last reviewed in June, 2009. At that time the Committee, recommended no changes to the PDL in this class. In addition to Twynsta®, other combination products available on the market are amlodipine/olmesartan (Azor™), amlodipine/valsartan (Exforge®), amlodipine/valsartan/hydrochlorothiazide (Exforge® HCT), and valsartan/aliskiren (Valturna®); all dosed daily. Combinations all result in a greater lowering of blood pressure versus individual agents alone; all are associated with peripheral edema. Blood pressure reductions among the combination agents are similar. It is the recommendation of DHCFP and FHSC 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 Group**

**MOTION:** **Joseph Adashek motioned that the agents in this class be considered therapeutic alternatives.**
**SECOND:** **Shamim Nagy**
**VOTES:** **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. Townsend stated that it is the recommendation of DHCFP and FHSC that Exforge® and Lotrel® be maintained on the PDL and to add Exforge® HCT to the PDL. Twynsta® will be non-preferred.

**Committee Discussion and Approval of Drugs for Inclusion on the PDL**

**MOTION:** **Shamim Nagy motioned to accept First Health's recommendation that Exforge® and Lotrel® be maintained on the PDL and to add Exforge® HCT to the PDL.**
**SECOND:** **Joseph Adashek**
**VOTES:** **Unanimous**
**MOTION CARRIED**

I. **Direct Renin Inhibitors**

**Public Comment**

Melissa Walsh, Novartis, spoke in support of Valturna®. Valturna® was approved in late 2009, and combines in a single pill aliskiren and valsartan. It's indicated for the treatment of hypertension in adult patients not adequately controlled on aliskiren or ARB monotherapy and may be used as initial therapy in patients that may need multiple drugs to achieve their blood pressure goals. In a double-blind study, 1,797 patients were randomly assigned to receive dosages of aliskiren 150mg and valsartan 160mg or placebo for four weeks followed by a forced titration to double the dose to the maximum recommended dose for four weeks. From baseline to week eight, the combination of aliskiren 300mg and valsartan 320mg lowered mean sitting diastolic blood pressure by 12.2mm of mercury which was greater than monotherapy or placebo. The most common adverse events were headache, nasopharyngitis and dizziness. The combination of aliskiren and valsartan maximum recommended dose provides significantly greater reductions in blood pressure than does monotherapy with either agent in patients with hypertension and with a tolerability profile similar to either agent alone.

**Drug Class Review Presentation – First Health Services**

Dr. Townsend stated that this class was last reviewed in June, 2009. At that time, the Committee recommended no changes to the PDL in this class. Valturna is a new fixed-dose combination of aliskiren and valsartan. Both componensts are available seperately on the PDL. It is the recommendation of DHCFP and FHSC that the agents in this class be considered therapeutic alternatives.

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

**MOTION:** **Shamim Nagy motioned that the agents in this class be considered therapeutic alternatives.**
**SECOND:** **David Chan**
**VOTES:** **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. Townsend stated that it is the recommendation of DHCFP and FHSC that Tekturna® and Tekturna® HCT be maintained on the PDL and to add Valturna® to the PDL

**Committee Discussion and Approval of Drugs for Inclusion on the PDL**

**MOTION:** **Michael Hautekeet motioned to accept First Health's recommendation that Tekturna® and Tekturna® HCT be maintained on the PDL and to add Valturna® to the PDL.**
**SECOND:** **Justin Holt**
**VOTES:** **Unanimous**
**MOTION CARRIED**

J. **Otic Fluoroquinolones**

**Public Comment**
No comment.

**Drug Class Review Presentation – First Health Services**

Dr. Townsend stated that this class was last reviewed at the June, 2009 meeting. At that time, the Committee recommended that no changes be made to the PDL in this class. Since that time, a new formulation of ciprofloxacin has been released, Cetraxal® (ciprofloxacin 0.2%), indicated for otitis externa in adults and pediatric patients down to one year or older. Indications are similar to

ofloxacin 0.3% and Cipro HC® which also contains hydrocortisone. Safety and efficacy of topical fluroquinolones are well documented. There are no clinical trials suggesting superiority of one agent over the other. There is evidence to suggest that there is more rapid clearing with the hydrocortisone containing product; there is no data comparing ofloxacin versus ciprofloxacin alone. It is the recommendation of DHCFP and FHSC that the agents in this class be considered therapeutic alternates.

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

**MOTION: Shamim Nagy motioned that the agents in this class be considered therapeutic alternatives.**
**SECOND: Chad Luebke**
**VOTES: 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. Townsend stated that it is the recommendation of DHCFP and FHSC that no changes be made to the current PDL in this class.

**Committee Discussion and Approval of Drugs for Inclusion on the PDL**

**MOTION: Joseph Adashek motioned to accept First Health's recommendation that no changes be made to the PDL in this class.**
**SECOND: Chad Luebke**
**VOTES: Unanimous**
**MOTION CARRIED**

K. **Urinary Tract Antispasmodics**

**Public Comment**

Leigh Platte, Astellas, spoke in support of VESIcare®, indicated in the treatment of overactive bladder, urge urinary incontinence, urgency and frequency. It has been shown to increase warning time and to reduce episodes of urgency and severe urgency. VESIcare® improves patient reported outcomes for overactive bladder symptom bother and other quality of life and demonstrates significantly fewer dry mouth episodes and less dry mouth severity as compared to oxybutynin immediate release. In trials, VESIcare® produced no clinically meaningful change in mean heart rate or mean blood pressure. The most common adverse events across all studies included dry mouth, constipation, blurred vision, dry eye and headache. VESIcare® consistently demonstrated significant improvements in diary-based voiding symptoms, patient reported subjective symptoms and assessments and favorable tolerability across several safety parameters.

Sandy Sierawski, Pfizer, spoke in support of Toviaz™ (fesoterodine). At last year's annual review, because Toviaz™ was a new entrant to the market, FDA approved in October 2008, First Health noted that it had not been established that there was nothing to distinguish that it was superior over the other agents in the class. Since then, Pfizer is the only company that has made the investment to meet the standard substantial evidence demonstrating superiority in reducing urge urinary incontinent episodes between two antimuscarinics. Pfizer has conducted two overactive bladder (OAB) head-to-head superiority trials (copies provided to the Committee). Primary endpoint for both trials was the mean change in number of urge urinary incontinent episodes per 24 hours from baseline to week 12, and in both trials, Toviaz™ 8mg was superior to Detrol® LA 4mg. Toviaz™ 8mg was significantly better than Detrol® LA on a number efficacy and patient reported outcome endpoints such as three day diary dry rate, total health related quality of life scores and patient perception score of overall bladder condition and urgency. Nevada Medicaid CMS data shows that Detrol® LA is the highest utilized OAB product by Nevada Medicaid patients encompassing 49% of the OAB prescriptions in 2009. She recommended that Detrol® LA be maintained on the PDL and to add Toviaz™ as an additional choice.

Dr. Coppola asked if superiority was clinically and statistically significant. Ms. Sierawski replied yes but was not able to provide supporting study numbers.

Dr. (inaudible), geriatrician and professor, stated that he is speaking on behalf of his patients. Overactive bladder is a major quality of life issue for his patients. Some of the antimuscarinics agents dry up the person but mess up the person's cognition; oxybutynin is bad for cognition. He stated that he prefers not to fix one thing while messing up the other and there are very few choices in that regard. From his clinical experience, patients have failed on Detrol® but responded on Toviaz™. He requested choices on the formulary.

Dr. Manthei asked if the doctor uses Toviaz™ as a primary or secondary agent. The doctor replied that he uses all the different agents but he does not have the choice of Toviaz™ because it's not on the Medicaid formulary. There are several good agents and the more agents he has available, the better it is. He does use Toviaz™ as a primary agent because of better efficacy and less side effects as compared to Detrol®.

Dr. Coppola how frequently the doctor has to switch his patients from Detrol® LA to Toviaz™. The doctor responded that he has had to switch 50% to a different agent not necessarily Toviaz™.

**Drug Class Review Presentation – First Health Services**

Dr. Townsend stated that this class was last reviewed in June, 2009. At that time, the Committee recommended no changes be made to the PDL in this class. There are currently a broad range of agents available for OAB on the PDL. This class is being reviewed today due to the release of a new oxybutynin product, Gelnique®, a topical gel applied once a day to the abdomen, upper shoulder or thigh, rotating sites; transdermal application similar to the Oxytrol® patch. There are less anticholinergic adverse reactions than with oral oxybutynin. One study in the drug review listed dry mouth, which is a common anticholinergic side effect (6.9% versus 3% with placebo), however, there is an increase in application site reactions in both the topical products. Gelnique® has not distinguished itself clinically over the other agents currently on the PDL. It is the recommendation of DHCFP and First Health that the agents in this category be considered therapeutic alternatives.

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

Dr. Coppola asked Ms. Sierawski, Pfizer, if the second study that she referenced in her comments has been published. She said no the second study has not been published but that it has been submitted for publication. She added that by having the two studies, it meets the FDA regulations for claiming superiority.

Dr. Adashek asked if fesoterodine is considered an antispasmodic for pyridium for bladder infections. Dr. Coppola replied that it's a topical anesthetic and not absorbed systemically. Dr. Adashek asked what class pyridium falls into. Dr. Townsend responded that it's not currently a managed class on the PDL and Dr. Coppola added that pyridium is currently a covered agent.

**MOTION:** **Joseph Adashek motioned that the agents in this class be considered therapeutic alternatives.**
**SECOND:** **Shamim Nagy**
**VOTES:** **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. Townsend said that it is the recommendation of DHCFP and First Health that no changes be made to the PDL in this drug class.

**Committee Discussion and Approval of Drugs for Inclusion on the PDL**

**MOTION: Joseph Adashek motioned to accept First Health's recommendation that no changes be made to the PDL in this class.**
**SECOND: David Chan**
Shamim Nagy offered a friendly amendment to add Toviaz™ to the PDL.
No second was offered.
**VOTES: Unanimous**
**MOTION CARRIED**

David Chan was excused from the meeting at 3:55 p.m.

## VI. ANNUAL REVIEW – Drug Classes without Proposed Changes

**Public Comment**
No comment.

**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. Acne Agents: Topical: Retinoid Agents and Combinations
2. Acne Agents: Topical: Benzoyl Peroxide and Clindamycin Combinations
3. Alzheimer's Agents
4. Androgenic Agents: topical
5. Antibiotics: Cephalosporins 2nd Generation
6. Antibiotics: Cephalosporins 3rd Generation
7. Antibiotics: Macrolides
8. Antibiotics: Quinolones 2nd Generation
9. Antibiotics: Quinolones 3rd Generation
10. Anticoagulants: Injectable
11. Antidepressants: SSRIs
12. Antidepressants Other
13. Antiemetics: Oral, 5-HT3s
14. Antifungals: Onychomycosis Agents
15. Antihistamines: 2nd Generation
16. Anti-Migraine Agents: Triptans
17. Benign Prostatic Hyperplasia (BPH) Agents: Alpha-blockers
18. Benign Prostatic Hyperplasia (BPH) Agents: 5-alpha-reductase Inhibitors
19. Bone Ossification Agents: Bisphosphonates
20. Cardiovascular: ACE Inhibitors & Diuretic Combinations
21. Cardiovascular: Angiotensin II Receptor Blockers & Diuretic Combinations
22. Cardiovascular: Antihyperlipidemics: Bile Acid Sequestrants
23. Cardiovascular: Antihyperlipidemics: Cholesterol Absorption Inhibitors
24. Cardiovascular: Antihyperlipidemics: Statins & Statin Combinations
25. Cardiovascular: Antihyperlipidemics: Niacin Agents
26. Cardiovascular: Antihyperlipidemics: Triglyceride Lowering Agents
27. Cardiovascular: Beta Blockers
28. Central Nervous System: ADHD/Stimulants
29. Electrolyte Depleters
30. Erythropoiesis Stimulating Proteins
31. Gastrointestinal Agents: H2Ras
32. Gastrointestinal Agents: PPIs
33. Gastrointestinal Agents: Ulcerative Colitis
34. Hepatitis C Agents
35. Herpetic Antiviral Agents
36. Herpetic Antiviral Agents : Topical
37. Immunomodulators: Topical
38. Impetigo Agents: Topical
39. Leukotriene Modifiers
40. Nasal Calcitonins
41. Ophthalmic Glaucoma Agents

42. Ophthalmic Non-Steroidal Anti-Inflammatory Agents
43. Ophthalmic Quinolones
44. Platelet Aggregation Inhibitors
45. Progestins for Cachexia
46. Psoriasis Agents: Topical
47. Pulmonary Arterial Hypertension Agents - Endothelin Receptor Antagonists
48. Respiratory: Inhaled Anticholinergic Agents
49. Respiratory: Inhaled Corticosteroids/Nebs
50. Respiratory: Short-Acting Beta Adrenergic -Inhalers/Nebs
51. Skeletal Muscle Relaxants

Dr. Townsend stated that there has been no new information in the remaining classes (listed above) for recommended changes at this time. It is the recommendation of DHCFP and First Health that there be no changes to the PDL for the drug classes listed as 1 through 51.

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

**MOTION: Justin Holt motioned to accept First Health's recommendation that there be no changes to the PDL in classes listed as 1 through 51.**
**SECOND: Michael Hautekeet**
**VOTES: Unanimous**
**MOTION CARRIED**

## VII. Report by FHSC on New Drugs to Market, New Generic Drugs to Market, and New Line Extensions

Dr. Townsend referred to the report in the meeting packet stating that the list of new drugs or dosage forms will be presented for Committee action at a future meeting.

## VIII. Review of Next Meeting Location, Date, and Time

Dr. Manthei stated that he understands that there are fiscal issues, however, he recommended consideration be given to having all Committee members, DHCFP and First Health staff in attendance at the same location for the annual review meeting of the PDL. Videoconferencing is acceptable if financial resources are not available.

The next meeting is scheduled for September 23, 2010. The meeting will be held at the Nevada State Legislature Building in Carson City and will be videoconferenced to the Grant Sawyer Office Building in Las Vegas.

## IX. Public Comment

Larry Hinson, Astra Zeneca, referred to section IV of the PDL Revisions Quarterly report. He stated Vimovo® is listed as a PPI; although it contains esomeprazole, it's has a different indication than the PPIs. It's a pain medication with GI protection. Dr. Townsend responded that the drug will be considered in a new therapeutic class; the designation of the class has not been finalized.

## X. Adjournment

**MOTION: Joseph Adashek motioned to adjourn the meeting.**
**SECOND: Michael Hautekeet**
**VOTES: Unanimous**
**MOTION CARRIED**
**Meeting adjourned at 4:00 p.m.**