JIM GIBBONS
Governor

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

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PHARMACY & THERAPEUTIC COMMITTEE

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

Redfield Campus
18600 Wedge Parkway, Room 102
Reno, NV

Committee Approved
Meeting Minutes
March 25, 2010

Committee Members Present:

Reno
Judy Britt, Pharm.D.
David Chan, R.Ph.
Justin Holt, Pharm.D.
Michael Hautekeet, R.Ph.

Las Vegas
Rudy Manthei, DO, Chairman
Joseph Adashek, MD
Shamim Nagy, MD
Weldon Havins, MD
Constance Kalinowski, MD
Chad Luebke, Pharm.D.

Others Present:

Reno
Coleen Lawrence-DHCFP, Jennifer Matus-DHCFP, Dave Wuest-FHSC, Paula Townsend Pharm.D.-FHSC, Shirley Hunting-FHSC, Mark Miller-Allergan, Sarah Day-VCG & Associates, Jennifer Davidson-Axcan Pharma, Jim Morgan-Novartis, Brad Burgstabler-Elan Pharmaceuticals, Larry Hinson-Astra Zeneca

Las Vegas
Gabriel Lither-DAG, Rob Coppola Pharm.D.-FHSC, Adam Browning-FHSC, Laura Litzenberger-Ortho-McNeil, Peter Berggren-OMJ, Felicia Fuller-Biogen IDEC, Carrie Stiles-Bristol Myers, George Scott Davis-Bristol Myers Squibb, Michelle Threde-Janssen, Betty Iverson-J&J, Isam Herndon-GSK, Lisa Wilson-J&J, Dan Bay-Abbott Labs, Craig Hudena-J&J, Gil Astruc(illegible), Sandy Sierawski-Pfizer, Naresh Singh, MD-Pulmonary Associates, Lori Horwarth-Bayer, Doug Powell-Forest, Cris Andeson-Otsuka

I. Call to Order and Roll Call

Chairman Rudy Manthei called the meeting to order at 1:02 p.m.

II. Review and Approval of the December 17, 2009 Meeting Minutes

MOTION: **Joseph Adashek motioned to accept the minutes as presented.**
SECOND: **Weldon Havins**
VOTES: **Unanimous**
MOTION CARRIED

III. New Drug Class Reviews

A. Bile Acid Sequestrants

1. Public Comment

No comment.

2. Drug Class Review Presentation – First Health Services

Rob Coppola stated that the bile acid sequestrant agents are primarily used for the treatment of hypercholesterolemia. WelChol® (colesevelam) carries an additional indication for Fredrickson type IIa (monotherapy or in combination with a statin). Due to the complementary mechanisms of action, these drugs are more commonly seen in combination therapy especially with other statins. These agents bind to bile acid in the intestine to form an insoluble complex which is excreted in the feces; endogenous bile acid is reduced by approximately 40%; 7 a-hydroxylase is upregulated. The overall impact is to increase clearance of LDL-C by approximately 15-30% which is similar across all the agents at the maximum doses. There is little effect on HDL-C or triglycerides. Pharmacokinetics are similar with all of the agents; they are not systemically absorbed and all are excreted in the feces. All agents are contraindicated in patients with dysbetalipoproteinemia and triglycerides greater than 400mg/dl. Colesevelam is contraindicated in patients with bowel obstruction and hypertriglyceridemia-induced pancreatitis; cholestyramine is contraindicated in patients with complete biliary obstruction. Colestipol has a Pregnancy Category C rating; colesevelam and cholestyramine carry Pregnancy Category B ratings. There is limited data available for pediatric use for cholestyramine and colestipol; colesevelam is approved for use in children 10-17 years of age. In terms of drug interactions, these agents are not systemically absorbed-not metabolized; the large molecular size of these agents prevents absorption. There are no incidences of systemic drug-drug interactions. There is impaired absorption of other drugs/nutrients therefore fat soluble vitamin supplementation may be necessary. Adverse events are comparable and most commonly include constipation and flatulence. Colesevelam has a lower incidence of constipation but a higher incidence of dyspepsia. There are no head-to-head trials with these agents. Indirect comparisons demonstrate comparable efficacy in lowering LDL and increasing HDL with a comparable effect on triglycerides. Reported ranges in change are as follows: reduction in total cholesterol of 9-13%; lowering of LDL-C of 12-30%; increase in HDL-C of 3-9%; increase in triglycerides 0-25%. 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 Populations

MOTION: Joseph Adashek motioned that the agents in this class be considered therapeutic alternatives.
SECOND: Shamim Nagy
Judy Britt asked if one of the agents has FDA approval for glycemic control in Type II diabetics, how that fits in with therapeutic equivalence for all the other agents.
Rob Coppola responded that there was a modest impact on HbA1c of half a point. They are not first line agents and it was not addressed with any significance in current diabetes guidelines reviewed.
Coleen Lawrence suggested that if there is a special indication for one drug, the Committee can consider an exception in determining agents for addition to the PDL.
Judy Britt agreed.
Rob Coppola added that within the exception criteria, if there is a unique indication to a non-preferred medication, it will be approved.
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 colestipol (tablets, packets, and granules), cholestyramine (powder and light powder), Welchol® (tablets and packets) and Prevalite® powder to the PDL.

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

MOTION: Joseph Adashek motioned to accept First Health's recommendation to add colestipol (tablets, packets, and granules), cholestyramine (powder and light powder), Welchol® (tablets and packets) and Prevalite® powder to the PDL.
SECOND: Chad Luebke
Dr. Adashek asked if an indication will need to be provided to obtain approval for use in pregnant women.
Rob Coppola replied that cholestyramine is recommended as a preferred drug and prior authorization will not be required.
VOTES: Unanimous
MOTION CARRIED

B. Androgenic Agents; Topical

1. Public Comment

No comment.

2. Drug Class Review Presentation – First Health Services

Adam Browning stated that this is a new category to the PDL. The agents in this category are available as brand name products only. Studies show that there are no apparent differences in the efficacy of these products for the approved indication of treatment of primary or secondary hypogonadism. A report on the current claims count for these agents indicates that 100% of claims are in Androderm® and Androgel®. 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 Populations

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

Adam Browning stated that it is the recommendation of DHCFP and First Health to add Androgel® and Androderm® to the PDL.

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

MOTION: Shamim Nagy motioned to accept First Health's recommendation to add Androgel® and Androderm® to the PDL.
SECOND: Weldon Havins
Dr. Adashek asked when these agents would be used over intramuscular testosterone.

Adam Browning replied the IM product would be used for an indication different than hypogonadism. For instance, a patient that requires testosterone supplementation for certain types of cancer that may be sensitive to testosterone receptor supplementation.
VOTES: Unanimous
MOTION CARRIED

C. Retinoid Agents; Topical

1. Public Comment

No comment.

2. Drug Class Review Presentation – First Health Services

Adam Browning stated that topical retinoids decrease keratinization, epithelial cell cohesion and inflammation. The combination of a topical retinoid and benzoyl peroxide is the preferred approach for most patients with acne. The adverse effect profiles of the topical retinoids are similar. They vary in incidence from class to class. Differin® (adapalene) and Tazorac® (tazarotene) show similar efficacy to tretinoin for primary and secondary clinical outcomes and may be associated with lower rates of adverse effects; however, tazarotene may be more irritating to the skin. Adverse effects for retinoids generally include erythema, scaling (xerosis and peeling) pruritus skin irritation, burning/stinging and photosensitivity. 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 Populations

MOTION: Chad Luebke 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

Adam Browning stated that it is the recommendation of DHCFP and First Health to add Differin®, Epiduo®, Retin-A Micro®, and Retin-A Micro® Pump to the PDL.

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

Dr. Manthei suggested that in order to assist the Committee members, drugs recommended for inclusion in the PDL by First Health be identified in the meeting material.

Rob Coppola stated that for future meetings, recommendations will be included.

MOTION: Shamim Nagy motioned to accept First Health's recommendation to add Differin®, Epiduo®, Retin-A Micro® and Retin-A Micro® Pump to the PDL.
SECOND: Judy Britt
Adam Browning noted that Retin-A® in its generic form will not be included on the PDL. Dr. Havins asked why. Adam Browning responded there may be a lower incidence of topical side effects with the micro formulation of Retin-A® versus the generic (tretinoin). Rob Coppola added that the Committee has determined that the agents in this class are therapeutic alternatives. Because there is little clinical difference between the two products, the recommendation is based on fiscal analysis and utilization.

The product recommended for the PDL currently has 50% of the market share so there will not be an impact to the patients and providers.
VOTES: Unanimous
MOTION CARRIED

D. Psoriasis Agents; Topical

1. Public Comment

No comment.

2. Drug Class Review Presentation – First Health Services

Paula Townsend stated that this is a new class to the PDL. Topical agents only will be considered for the PDL. The corticosteroids will not be considered in this class. Approximately 80% of patients with psoriasis have mild to moderate disease and the majority of these can be treated with topical agents that generally provide high efficacy and safety. Sometimes these agents are combined with systemic or phototherapy. Topical corticosteroids are the cornerstone of therapy but the duration of use can be limited by long-term local or systemic side effects. Agents currently available include anthralin (also known as dithranol) which has an unknown mechanism of action but believed to be both an anti-proliferative and anti-inflammatory. It is commonly used as short-contact therapy titrating duration of exposure, and in controlled trials, appears to have lower efficacy than more potent corticosteroids or vitamin D analogues. The most common side effects include skin irritation, staining of skin and objects touched. The second pharmacologic class include the Vitamin D_3 analogs, calcipotriene and calcitriol, which work by inhibition of keratinocyte proliferation and enhancement differentiation. Calcipotriene and calcitriol are applied twice daily and generally 70-74% of patients showed either 75% or marked improvement to clearing compared to 18-19% for placebo. Use with topical corticosteroids gives added benefit. The most common adverse effects include photosensitivity, transient irritation in the lesional and perilesional skin. There is a potential for a reversible increase in serum calcium if used in doses greater than 100gm per week. The third type of agent is tazarotene, a synthetic retinoid which modulates differentiation and proliferation of epithelial tissue and also decreases expression of some inflammatory markers. Tazarotene is applied once daily, and in a twelve week study, there was at least a 50% improvement in 63% and 50% of patients treated with 1% and 0.05% gel. Efficacy is best in combination with topical steroids. The most common adverse effects are irritation in lesional and perilesional skin and photosensitivity. Anthralin, calcipotriene and calcitriol are Pregnancy Category C; Tazarotene is Pregnancy Category X. She cited the Cochrane Systematic Review Findings and noted that data presented today were based on this and the American Academy of Dermatologists Treatment Guidelines 2009. It is the recommendation of DHCFP and First Health that these agents 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 Populations

MOTION: Shamim Nagy motioned that the agents in this class be considered therapeutic alternatives.
SECOND: Constance Kalinowski
VOTES: Unanimous (Joseph Adashek was not present during the vote)
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

Paula Townsend stated that it is the recommendation of DHCFP and First Health to add Dovonex® Cream and generic calcipotriene solution to the PDL.

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

MOTION: Shamim Nagy motioned to accept First Health's recommendation to add Dovonex® Cream and generic calcipotriene solution to the PDL.
SECOND: Weldon Havins
VOTES: Unanimous (Joseph Adashek was not present during the vote)
MOTION CARRIED

IV. Established Drug Classes for Review

A. Proton Pump Inhibitors

1. Public Comment

No comment.

2. Drug Class Review Presentation – First Health Services

Adam Browning stated that since the last review of this class, Prevacid OTC® has been released and Kapidex® has been renamed as Dexilant® because of name similarity to two other products; formulation of the drug remains the same. The manufacturers of Nexium® and Prevacid® have conducted new research to reinforce the use of PPIs for the treatment of NSAID induced ulcerations and for maintenance of healing. He referred the Committee to the drug class review which indicates that there has been a significant amount of research on this class of drugs. The research indicates that these agents are used in a similar way and have similar effects to each other in terms of healing in most types of ulcerations including esophageal. 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 Populations

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

Adam Browning stated that it is the recommendation of DHCFP and First Health that Nexium® capsules, omeprazole tablets and Prilosec OTC® be on the PDL and Prevacid® capsule be non-preferred.

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

Judy Britt noted that Prevacid® OTC is not on the list of agents included in the drug review. Mr. Browning stated that Prevacid® OTC was considered in the review of this class and is included in the handouts presented today. The difference between the prescription Prevacid 15mg and the OTC is that the OTC does not have an indication for management. Mr. Coppola added that the therapeutic class reviews are updated once a year. This class review was updated in September 2009 and Prevacid® OTC was released after that date.

Dr. Manthei asked if the Committee can consider Prevacid OTC since it was not included in the drug review. Coleen Lawrence stated that it can be considered and Gabriel Lither

added that this is background information whether it's included in the binder or not and all drugs can immediately be considered.

Justin Holt asked if prior authorization (PA) will continue to be required for the drugs in this class. Dave Wuest responded that the clinical PA will continue to be applied.

Michael Hautekeet stated that there has been an increase in pediatric PPI use and recommended that Zegerid®, omeprazole bicarbonate, or Prevacid® Solutab be included on the PDL. The tablets and capsules are unstable when making a liquid; sodium bicarbonate must be added to make the suspension stable enough for pediatric use.

Coleen Lawrence suggested that consideration be given to adding one of the agents to the PDL and applying an age edit.

Judy Britt stated that Prevacid® Solutab has an indication down to one year old and that there is an off-label use for infants.

Dave Wuest said that there is a clinical PA for the agents in this class. When going through the process with the Clinical Call Center for the clinical PA, and it is noted that the patient cannot swallow a tablet or capsule, authorization can be given for a non-preferred agent.

MOTION: **Michael Hautekeet motioned to accept First Health's recommendation that Nexium® capsules, omeprazole tablets and Prilosec OTC® be on the PDL, Prevacid® capsule be non-preferred and to include Nexium® Powder on the PDL for pediatric use in children age 1 to 12 years old.**
SECOND: **Shamim Nagy**
VOTES: **Unanimous**
MOTION CARRIED

B. Quinolones; Systemic

1. Public Comment

Naresh Singh, MD, Director of Pulmonary Services, University Medical Center, spoke in support of Levaquin®. He stated that there are a large number of patients seen in practice that are at risk for infections. He thanked the Committee for including Levaquin® on the PDL last year. He said that Levaquin® will be available as a generic next year and asked the Committee to continue to have it available to minimize patients becoming hospitalized and expediting their recovery.

Weldon Havins asked regarding the black box warning for the increased risk of tendinitis and tendon rupture, if in Dr. Singh's experience that it's only with Levaquin® or all of the quinolones. Dr. Singh replied that he prescribes quinolones as a class quite significantly and extensively and the risk for tendinitis is a class effect.

Laura Litzenberger, Ortho-McNeil, spoke in support of Levaquin®. Levaquin® has been available in the United States since 1996 and will be going generic in June, 2011. It's approved for high dose, short-course therapy in community-acquired pneumonia, acute bacterial sinusitis, complicated UTI and acute pyelonephritis. Levaquin® has remained effective for gram-negative and gram-positive bacteria. The tracking resistance in the United States is a thirteen year study that looks at susceptibility specifically to Streptococcus pneumonaie. During those thirteen years in the state of Nevada, the susceptibility of Streptococcus pneumonaie to Levaquin® has always been greater than 99%. The safety profile of Levaquin® has been demonstrated in more than 500,000,000 patients. The most common adverse events that have lead to discontinuation of the drug have been nausea, diarrhea, insomnia and abdominal pain. Based on the broad spectrum

of activity, the broad range of indications, the demonstrated efficacy in high dose, short-course therapy, she requested that Levaquin® remain on the PDL.

2. Drug Class Review Presentation – First Health Services

Rob Coppola stated that this class was last reviewed in June, 2009. Since the last review, there are new indications for ciprofloxacin IV, nosocomial pneumonia and febrile neutropenia and a new indication for levofloxacin, nosocomial pneumonia. There is no new information or new relevant randomized trials; no changes to the disease guidelines; no significant changes to resistant patterns; no new products/line extension; no new generics. 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 Populations

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 that ciprofloxacin tablets, Cipro® Suspension, Avelox® Tablets and Avelox® ABC Pack be on the PDL.

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

Dr. Adashek asked why Levaquin® is being removed.

Rob Coppola replied the recommendation is based on utilization review as well as fiscal impact to the State.

MOTION: Weldon Havins motioned that ciprofloxacin tablets, Cipro® Suspension, Avelox® Tablets, Avelox® ABC Pack and Levaquin® be on the PDL.
SECOND: Joseph Adashek
Dave Wuest asked for clarification of the motion. In order to ensure appropriate usage, a five tablet quantity limit is currently in place for Levaquin® and asked if that will continue.
Dr. Havins clarified that it is not his intent to modify the current quantity limit.
AYES: Chan, Hautekeet, Holt, Britt, Adashek, Havins, Luebke, Manthei, Nagy
NAYES: Kalinowski
MOTION CARRIED

C. Combination Benzoyl Peroxide and Clindamycin Products

1. Public Comment

No comment.

2. Drug Class Review Presentation – First Health Services

Paula Townsend stated that this category was last reviewed in March, 2009. The indication for the combination products is topical treatment of inflammatory acne

vulgaris. Benzoyl peroxide is an antibacterial, keratolytic, comedolytic product. Clindamycin is an antibiotic. Combination use reduces the development of resistance. There is insufficient evidence in the literature to evaluate and compare the efficacy of different formulations. Information presented today is from the guidelines for care of acne management by the American Academy of Dermatology published in 2007. Products currently available on the PDL: DUAC® CS, which is a combination product and packaged with a non-soap cleaner/lotion; BenzaClin® is available as a benzoyl peroxide product alone and also in a care kit which includes a moisturizer; and clindamycin-benzol gel which is the generic of BenzaClin® gel. BenzaClin® is applied twice a day (morning and evening). It's mixed prior to dispensing, stored at room temperature and has a three month expiration. DUAC® is now only available as a combination product. It's applied once daily in the evening, stored at room temperature and has a two month expiration. All of the combinations have the same strength of clindamycin and benzoyl peroxide. 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 Populations

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

Paula Townsend stated that it is the recommendation of DHCFP and First Health that BenzaClin® and BenzaClin® Carekit be on the PDL and Duac® CS and clindamycin-benzol gel be non-preferred.

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

MOTION: David Chan motioned to accept First Health's recommendation that BenzaClin® and BenzaClin® Carekit be on the PDL and Duac® CS and clindamycin-benzol gel be non-preferred.
SECOND: Judy Britt
Dr. Manthei asked if the products are clinically similar.
Paula Townsend stated that they have the exact same components in terms of strength and active ingredients.
VOTES: Unanimous
MOTION CARRIED

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

Paula Townsend reviewed the PDL Revisions Quarterly Report included in the meeting binder.

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

Coleen Lawrence stated that the next meeting is scheduled for May 3, 2010, at the Las Vegas Chamber of Commerce; videoconferencing to be determined. She noted that this will be a special meeting to address the changes in the current law (SB4) which allows further modifications to the Preferred Drug List.

VII. Public Comment

Coleen Lawrence introduced Jennifer Matus, Program Specialist. Ms. Matus will be responsible for the Pharmacy Program for Nevada Medicaid.

George Davis asked what classes will be reviewed. Ms. Lawrence responded that the drug class reviews are posted on the First Health website (nevada.fhsc.com).

Dr. Havins asked if the meeting material is made available to the public per the open meeting law. He felt it should be available at the meeting and to public that requests the packet.

Rob Coppola responded that the drug class reviews are posted on the website six weeks prior to the meeting.

Coleen Lawrence clarified that in the bylaws, prior to the implementation of the P&T Committee, DHCFP and the PhRMA Association agreed that the drug class reviews will be posted forty-five days in advance of the meeting which is longer than the open meeting law requirements. Agendas are posted according to the open meeting law and are generally posted thirty days in advance. Due to limited State resources, the drug manufacturers and other public can bring their meeting materials for presentation to the meeting for dissemination. The manufacturers work prior to the meeting directly with First Health to ensure that the information and data is accurate. Minutes are posted on the Division website within 30 days of the meeting.

VIII. Adjournment

MOTION: **Weldon Havins motioned for adjournment.**
SECOND: **Joseph Adashek**
VOTES: **Unanimous**
MOTION CARRIED

Meeting adjourned at 2:41 p.m.