Nevada Medicaid Pharmacy & Therapeutics Committee

Location of Meeting

401 South Carson Street, Room 2135, Carson City, NV

Teleconference 555 E. Washington, Room 4406 Las Vegas, NV

> MEETING MINUTES OF April 22, 2004 1:00 p.m.

Committee Members Carson City:

Committee Members in Las Vegas: Thomas Wiser, PharmD

Steven Phillips, MD, Chairman Judy Britt, PharmD Carl Heard, MD Larry Pinson, PharmD Diana Bond, RPh Alan Greenberg, MD Linda Flynn, RPh Susan Pintar, MD

Absent: Robert Horne, MD

Others Present:

Darrell Faircloth AGO, Coleen Lawrence DHFCP, Charles Duarte DHFCP, Nancy Davis DHCFP, Jeff Monaghan First Health Services Corporation, Dawn Daly First Health Services Corporation, Jamie Wyels First Health Services Corporation, Joseph Tyler, Advisory Committee, Carla Sloan AARP, Paul Pereira Tap, Sedrick Spencer Roche, Charlie Speranzo Novartis, Bert Jones GSK, Matthew Frankl Schering Plough, Slater Sparks Bertel, Doug Woelfle Novartis, Mary Ellen Snider Sepracor, Jennifer Brown Sepracor, Virginia Bose Sepracor, Joe Hennessy Purdue, Bob McElderry Purdue, Alan Sloan Purdue, Brian Hodgkins Purdue, Liz MacMenamin RAN, Jesse Deaver Aventis, Joann Phillips, Allen Christie GSK, Nader Abdel Sayed, John Andrews Pfizer, Dana Lockrey Pfizer, Barbara Tagge Clark Co. S.S, Kirk Huffaker Nevada Care, Emerald Foster Nevada Care, Mary Wherry, DHCFP

I. Call to Order and Roll Call

Chair Steven Phillips called the meeting to order at 1pm. All committee members were present.

II. Approval of Minutes of March 25th, 2004 Meeting

Correction on item V; change "with cost" to "without cost". Correction on item VI; change State RX program to Senior RX program.

Motion to Accept: Larry Pinson motioned to accept the minutes with corrections. Seconded: Carl Heard Ayes: Unanimous

Motion Carried

III. PDL Decision Process Overview and Discussion, Jeff Monaghan, FHSC

Dr. Phillips stated this item will be presented without the flow diagram that was provided. .

Charles Duarte, DFCHP announced that CMS has approved the multi-state pooling initiative for supplemental rebates and Nevada would be moving ahead with the pool versus seeking bids as a single state.

Jeff Monaghan, FHSC reviewed the PDL process, including suggested language for committee motions. Attachment.

Dr. Phillips reviewed the generic PDL criteria for prior authorization. Attachment.

Dr. Heard asked if there was another committee involved in the financial analysis. Jeff Monaghan responded that there was not another committee per se. The state and FHSC will complete the analysis and then make formal recommendations to the committee for specific drug selection within each drug class reviewed. The committee would have the ultimate decision regarding the inclusion of drugs on the Preferred List.

Diana Bond asked if they would have an opportunity to revise the drug class review decisions made by the committee. Dr. Phillips stated they could recall the origin motion and entertain a new motion.

IV. Herpetic Antivirals

Public Comment:

Dr. Nader Abdel Sayed, OB-GYN, requested that valacyclovir be placed on the preferred list, due to the epidemic proportion of genital herpes. He stated that valacyclovir reduces viral shedding which in turn decreases transmission and it also easier to dose. He stated that most patients want to know how to decrease transmission to their partners and valacyclovir reduces the risk of transmission to partners.

Carl Heard asked him to rank the three medications. He stated that in his opinion valacylovir should be number one due to the study about decreased risk of transmission and famciclovir and acyclovir are number two. Dr. Greenberg asked if the valacyclovir study compared the drug to placebo. His response was yes.

Larry Pinson asked how safe in early pregnancy. The response was it is in category B

Alan Christie, GSK, stated that the indications for famciclovir and valacyclovir stated on page 3 of the drug class reviews were transposed. Jeff Monaghan confirmed the transposition and stated the transposition was actually on page 2.

Doug Wolfe, Novartis gave an overview of famciclovir.

Dr. Greenberg asked if famciclovir has ever been compared to acyclovir for viral suppression. He responded that they may be able to provide some studies.

Jeff Monaghan, FHSC, gave an overview of the class.

Linda Flynn asked if they are only considering oral agents. The response was yes. Diana Bond asked for discussion on the use of these agents in CMV and in the HIV positive or immunocompromised patients. Dr. Greenberg stated these agents are generally not used for treatment or prevention of CMV in these patients. Dr. Greenberg stated that when these agents are used for herpes simplex virus for primary treatment and suppression, they are all therapeutically equivalent. In the small percentage of usage for zoster, the newer agents, famciclovir and valacyclovir, appear to have decreased incidence of post herpetic neuralgia.

Motion: Dr. Heard motion that the agents in this class be therapeutically equivalent with the inclusion of either famciclovir or valacyclovir as a preferred agent. No second.

Motion did not carry.

Dr. Greenberg stated that acyclovir 400mg twice a day is used as the herpes suppression dose.

Motion: Dr. Greenberg motioned that these agents be considered therapeutically equivalent. He also requested the availability of either famciclovir or valacyclovir with specific criteria for herpes zoster or failure on acyclovir for suppression of herpes simplex 2.

Seconded: Carl Heard No discussion Vote: Ayes: Unanimous

Motion Carried

V. Macrolides

Public Comment:

Dr. John Andrews, internist representing Pfizer, spoke in support of azithromycin. He gave an overview of azithromycin. Dr. Pintar asked to delineate the age group used in the studies. He responded for otitis media the age was from 6 months to 6 years old and for sinusitis 18 years and older.

Dr. Greenberg asked how the Thoracic and Infectious Diseases societies ranked the macrolides in the treatment of outpatient pneumonia. He responded that both azithromycin and clarithromycin are ranked equally.

Jeff Monaghan, FHSC, gave an overview of the class.

Judy Britt commented dithromycin had been discontinued and the company no longer exists. She asked if the new agent about to be released, Ketek, would be considered a macrolide.

Jeff Monaghan responded that although it was closely related to the macrolides, it was actually a ketolide. The committee may be asked to review this drug in the future.

Dr. Greenberg stated they needed one of the newer agents on the Preferred Drug list due to the intolerability of erythromycins. He also stated that the advantages of azithromycin have been clearly documented.

Judy Britt stated they need to make accommodations for the treatment of H. Pylori and the use of clarithromycin.

Diana Bond stated they need to look into the sensitivity of MAC to these drugs at the state lab level.

Motion: Dr. Greenberg motioned for these agents to be considered therapeutically equivalent with the inclusion of azithromycin on the PDL. Seconded: Linda Flynn Vote: Ayes: Unanimous

Motion Carried

VI. Second Generation Cephalosporins

Public Comment: None

Jamie Wyels, FHSC, Gave an overview of the class.

Dr. Greenberg stated that high dose amoxicillin is a better choice than most of these agents.

Motion: Dr. Greenberg motioned that the second generation cephalosporins be considered therapeutically equivalent. Seconded: Carl Heard Vote: Ayes: Unanimous

Motion carried

VII. Third Generation Cephalosporins

Public Comment: None

Jamie Wyels, FHSC, gave an overview of the class.

Dr. Greenberg stated these agents very infrequently used in the outpatient arena.

Motion: Dr. Greenberg motioned that the third generation cephalosporins be considered therapeutically equivalent. Seconded: Tom Wiser

Dr. Phillips stated Vantin suspension is used for nursing home patients or MS patients with a feeding tube who develop pneumonia.

Dr. Heard asked about the PDL implications in the inpatient population. Dr. Phillips stated the PDL would impact nursing home patients. Jeff Monaghan stated the PDL would not apply to inpatient hospital acute care patients.

Dr. Greenberg interjected there should be an agent available for the pediatric population with refractory ENT infections that do not respond to other therapy.

Vote: Ayes: Unanimous Motion carried

Recess

VIII. Onychomycosis Antifungals

Public Comment: None

Jamie Wyels, FHSC gave the overview for the class

Dr. Greenberg asked if Penlac solution would be considered under dermatologicals or within the category being reviewed today. Jeff Monaghan stated that today's category was addressing oral agents only.

Dr. Heard asked about the comparative side effect profile and was referred to page 4 of the drug review.

Dr. Greenberg suggested that one should confirm the diagnosis before using these agents. Dr. Phillips stated he does not use any oral agents and uses a topical agent, tea tree oil. It is not considered curative but does slow the progression. Dr. Greenberg stated that griseofulvin is no longer commonly used for onychomycosis.

Motion: Dr. Pintar moved to have the oral antifungal agents be considered therapeutically equivalent, with the exception of griseofulvin, for the treatment of onychomycosis. She also wanted this category as well as the topicals referred to the DUR board for usage criteria development. Seconded: Larry Pinson

Vote: Ayes: Unanimous

Motion carried

IX. Short Acting Beta-adrenergic (MDI and Nebs)

Public Comment:

Dawn Daly, FHSC, stated that written public comment was distributed during the recess.

Mary Ellen Snyder, Sepracor, representing Xopenex. She asked the committee not to limit to these agents and referred to an article. Attachment.

Dr. Heard asked if she was aware of any studies that documented PDL's increasing hospitalizations and decreasing patient compliance. She stated she was not aware of any studies that addressed his guestion.

Mary Wherry, DHCFP, stated the majority of children are in managed care programs and there are very few children in fee for service (FFS) Medicaid. There is an emergency policy in FFS which allows for a 72 hour supply for the drug. Dr. Pintar asked about the market share report and asked if it was all Nevada or just Medicaid. Jeff Monaghan stated the data was based on fee-for-service (FFS) Medicaid only. Coleen Lawrence, DHCFP, stated the managed care programs (MCOs) do have a restrictive formulary system and do not offer an emergency supply for non-formulary drugs.

Dr. Heard asked if there was any relationship to MCO drug policies and FFS drug policies. Mary Wherry, DHCFP, stated the two programs operate independently.

Jeff Monaghan, FHSC, gave an overview of the class.

Motion: Diana Bond moved that the short acting beta-adrenergic (MDI and Nebs) class be considered therapeutically equivalent and criteria for use be developed for Xopenex if it is not included in the final PDL.

Seconded: Dr. Greenberg

Dr. Phillips stated in the geriatric population he uses Xopenex for approximately 1 in 6 patients. These patients tend to be chronic users and are typically CHF, cardiac arrhythmia, and atrial fibrillation patients. Votes: Ayes: Unanimous

Motion Carried

X. Long Acting Beta-Adrenergics

Public Comment:

Dr. Matthew Frankel, Schering Plough, gave an overview of Foradil.

Jamie Wyels FHSC, gave an overview of the class.

Dr. Wiser asked about the black box warning for salmeterol. Jamie Wyels stated the drug has been on the market since 1994 and the black box warning was implemented in August 2003. Diana Bond stated the information in the black box was based on MDI use and not Diskus use. Also, the patients were using it as a rescue method, which is not recommended. Jeff Monaghan stated that the conservative approach would be to consider this a class effect, although this could not be documented in head to head studies.

Motion: Diana Bond moved to consider the long acting beta-adrenergic class as therapeutically equivalent. Seconded: Judy Britt Vote: Ayes: Unanimous

Motion Carried

XI. Discussion of Future Meeting Locations

Dr. Phillips stated the May 27th meeting will most likely be devoted to voting on specific drugs as well as further drug class reviews. He stated he would like the committee to meet in Carson City in May.

Diana Bond recommended the designation of a point person in Las Vegas when they are teleconferencing. Dr. Phillips agreed, and stated the committee will meet in Las Vegas in June.

XII. Public Comment:

None

XIII. Meeting adjourned at 3:30pm.