



Kansas Medical Assistance Program

Preferred Drug List Committee Meeting Minutes

<p>Preferred Drug List Committee Meeting Minutes Capitol Plaza Hotel President's Room August 23, 2006 10:00 A.M.-3:30 P.M.</p>	<p>Members Present: Robert Haneke, PharmD Brenda Schewe, M.D. Donna Sweet, M.D. Dennis D. Tietze, M.D. Kristin Fink PharmD</p> <p>KHPA Staff Present: Mary Lesperance, R.Ph. Anne Ferguson, R.Ph. Wanda Pohl Susan Wood, RN, BSN. Nialson Lee, RN, BSN, MHA</p>	<p>Public: AstraZeneca: Jim McClain, Terri Hurley, Dr. Ron Weiner, Rick Barbaresh, Patti Wingerbermink, Dan McCall Pfizer: Jim Baumann, Jacque Marinac Wyeth: Kate Kulesher Genetech: M. Patty Lassiter Roche: Jacqueline Travis, Barbara Cassenhop VBC: Ron Rhodes Merck: Barbara Belcher, Sue Smithers, Jerry Johnson, Thomas J. Pyron, Marty Mazurek Sanofi-Aventis: Rebecca Waldrip, Kevin Duhrkopf GSK: Ann Gustafson, Sandra Vail, James Osborne IVAX TSP: Jim Surface, Julie Olson, Mike Neidleman KOS: Susanne Holly King Pharmaceuticals: Danny Icenhour Eli Lilly: Richard Mesquitas Santarus: John Frey Otho McNeil Jansen: Brian Macomson Sepracor: John Nieworehriar TAP: Joe Summers, Larry Dollar 3M Pharma: Perry Johnson P&G Pharma: Mark Hoig, Robert Thomsen, James Anderson Boehringer Ingelheim: Bray Caywood</p>
<p>I. Call to Order</p>	<p>Dr. Brenda Schewe called the Meeting of the Preferred Drug List (PDL) Advisory Committee to order at 10:10a.m. with four members present and Dr. Sweet arriving shortly after the meeting was called to order. Dr. Schewe is acting as the Chair in the absence of Dr. Michael Burke.</p>	
<p>II. Announcements</p>	<p>Dr. Tietze opened the meeting with an explanation of the purpose of the PDL Committee. The Committee's role is to look at equivalency from a clinical</p>	

	<p>standpoint. The committee is interested in hearing information about comparative studies, head to head data, statistical analysis with absolute risk reduction numbers, not relative risk reduction numbers. The committee is also interested in anything that is clinically new or relevant since the last time these medications were reviewed.</p> <p>Mary Lesperance thanked the PDL Committee for their time and support. Mary welcomed the public to the meeting. Mary stated that anyone wishing to speak during the public comment period would need to fill out and sign a Conflict of Interest Disclosure form and return the form to the Chair of the Committee, or to a State representative. Mary stated that there is a five minute time limit per drug during public comment and that speakers should provide key points outlining scientifically based evidence of comparative data on drugs in the classes being reviewed. Mary also stated that non-preferred drugs can be obtained through KMAP's streamlined, reasonable PA process when medically necessary. Lastly, Mary announced that September 13th is the deadline for submission of supplemental rebate offers.</p>	
<p>III. Review minutes from February 28, 2006</p>	<p>There were no additions or corrections to the February 28, 2006 meeting minutes.</p>	<p>A motion to approve the minutes as written was made by Dr. Haneke and seconded by Dr. Fink. The motion carried unanimously by roll call of members present.</p>
<p>IV. Proton Pump Inhibitors (PPI) - Esomeprazole, Lansoprazole, Omeprazole, pantoprazole and Rabeprazole.</p> <p>A. Public Comment</p> <p>B. Committee Recommendation and Action</p>	<p>Lawrence Dollar representing (TAP) Prevacid. Mr. Dollar affirmed that all PPI's are comparable in efficacy. He highlighted the flexibility in administration options of Prevacid.</p> <p>John Frey (Santarus) Zegerid Mr. Frey gave a detailed description of drug release and availability. Dr. Tietze requested Mr. Frey present any clinical outcomes data. Mr. Frey responded that the drug is only 2 years old and therefore, this is not available.</p> <p>Dr. Schewe stated that there were no other speakers and asked for discussion from the Committee</p> <p>Dr. Sweet arrived.</p> <p>Dr. Schewe stated that the last time that the PDL Committee reviewed this class of drugs, there was no overwhelming evidence that any one of the PPI's are superior to any other and were deemed clinically equivalent</p> <p>Dr. Haneke stated that there has been relatively no change in the last few years in regards to taking with or without meals. Essentially it takes about 48 to 72 hours to see clinical effects from all of the PPI's, whether they are given with</p>	<p>Dr. Tietze made a motion to maintain the clinical equivalency recommendation for the PPI's reviewed. Dr. Sweet seconded the motion. The motion carried unanimously by roll call of members present.</p>

	<p>sodium bicarbonate or not, and with or without meals.</p> <p>Dr. Tietze pointed to the OHSU report and Facts & Comparisons summary and stated that there is no compelling data to change the original determination of clinical equivalence of all the PPI's.</p>	
<p>V. Sedative Hypnotics - Eszopiclone, Zaleplon, Zolpidem A. Public Comment B. Committee Recommendation and Action</p>	<p>John Warner (Sepracor) Lunesta. At this point in time there is no comparative or head to head data between Lunesta and any of the other sedative hypnotics. Mr. Warner stated that there is no dose creep, no rebound effect and no residual effects on cognitive function with Lunesta.</p> <p>Dr. Tietze reiterated that this committee does not establish or maintain the PDL. The task of this group is to look at clinical efficacy. This committee is looking at the drugs from a clinical perspective only. This is the scientific arm of the process. Then it goes to the State for economic analyses and the DUR Board for prior authorization criteria.</p> <p>Dr. Sweet and Mary Lesperance clarified the process that occurs once the PDL committee makes their recommendation of clinical equivalences, and how drugs become preferred and non-preferred. Handouts on this process were provided at the back of the room</p> <p>Kevin Duhrkopf (Sanofi-Aventis) Ambien CR. No comparative studies are available. Dr. Schewe asked if there are studies comparing Ambien and Ambien CR. Mr. Duhrkopf responded that there is not.</p> <p>Danny Icenhaour (King Pharmaceuticals) Sonata. Information was presented stating Sonata is safe and effective for persons with insomnia with an onset of action of 30 minutes or less and a short half- life.</p> <p>Dr. Schewe expressed that the evidence for the group shows clinically equivalence even with Sonata having a reduced half- life.</p> <p>Dr. Tietze referenced the summary on page 39 of the OHSU report. There are four fair quality head to head trials between zaleplon and zolpidem that support zaleplon being more effective for sleep latency, while zolpidem is more effective for sleep duration and sleep quality. However, after going through all the information, there is no compelling data that there are clinical differences in terms of overall effects, but there is for room for clinical judgment.</p> <p>Dr. Sweet asked for a response from the pharmacist committee members regarding clinical differences due to pharmacokinetics. Dr. Sweet stated that</p>	<p>A motion was made by Dr. Sweet that the sedative hypnotics reviewed are clinically equivalent. The motion is seconded by Dr. Haneke. The motion carried unanimously by roll call of members.</p>

	<p>she sees no evidence of clinical differences in overall effects. Dr. Haneke stated that there is not much pharmacokinetic data as far as how well they bind to receptors. Most of the studies are based on subjective questionnaires.</p> <p>Dr. Fink stated that the controlled release formulation of Ambien is not superior in terms of clinical efficacy and believes the drugs in the class are clinically equivalent.</p>	
<p>VI. Antiemetics 5-HT3 Receptor Antagonist - Ondansetron, Dolasetron, Granisetron A. Public Comment B. Committee Recommendation and Action</p>	<p>Dr. Schewe stated that this class was found to be clinically equivalent at the last review.</p> <p>Sandra Vail (Glaxosmithkline) Zofran Ms. Vail stated that Zofran will become generically available later this year.</p> <p>Dr. Sweet stated that there is no new data in the evidence-based information.</p>	<p>A motion was made by Kristin Fink that the antiemetics reviewed in this class are clinically equivalent. Dr. Haneke seconded the motion. The motion passed unanimously by roll call vote.</p>
<p>VII. Inhaled Corticosteroid - Beclomethasone, budesonide, Flunisolide, Fluticasone, Mometasone, Triamcinolone A. Public Comment B. Committee Recommendation and Action</p>	<p>Dr. Schewe noted that the drugs in this class have varied indications and that many studies have been done using non-equipotent doses.</p> <p>Dr. Ron Weiner (AstraZeneca) Pulmicort, (turbohaler and respule) Asthma and Allergy Specialist.</p> <p>Pulmicort Turbohaler: Only approved steroid inhaler approved with Pregnancy category B for pregnant or potentially pregnant women. Ease of use – dry powder, breath activated and no spacer required.</p> <p>Pulmicort Respule: Only nebulized inhaled steroid approved by the FDA and the only nebulized inhaled steroid approved for children beginning at 12 months of age for daily preventative treatment of asthma.</p> <p>Dr. Weiner explained the difference between nebulized inhalers and dry powder bioavailability. He also provided health quality impact data related to the use of these products.</p> <p>Dr. Tietze acknowledged that Dr. Weiner is recognized as a national expert in pediatric asthma and a strong advocate for children in the State of Kansas. Dr. Tietze remarked that the PDL Committee is tasked with clinical decisions but that there are financial pressures that drive this process because the State spends huge amounts of money on health care. Dr. Tietze opened the floor to Dr. Weiner regarding issues with access to inhaled steroids. Dr. Weiner emphasized that “the inhaled medication that is the most effective is the one that the patient takes. In order to lessen asthma deaths in adolescents we have to give them an option that is convenient enough that it will fit in their day.”</p>	<p>A motion was made by Dr. Haneke that the inhaled corticosteroids reviewed remain clinically equivalent. The motion seconded by Dr. Sweet. The motion passed unanimously by roll call vote.</p>

Dr. Sweet asked Dr. Weiner if he understood that he could get non-preferred drugs with prior authorization. Dr. Weiner emphasized that it is not the first approved therapy in Medicaid. Dr. Sweet responded that the drug is available if he, as a provider, will take care of the paperwork. Dr. Fink and Dr. Haneke supported Dr. Sweet's statement and do not support the position that prior authorization is a barrier to access to medications.

Dr. Asha Desai (KOS Pharmaceuticals) Azmacort (Allergist from California) presented information supporting the built in spacer. No comparative information was presented.

James Osborne (GSK) Flovent HFA related that Flovent HFA Is now approved for use in children as young as 4 years of age.

Dr. Thomas Hamilton (TEVA/Ivax Labs) Q-Var. Product information review. Dr. Hamilton stated that there is a higher deposition in the lungs with Q-Var versus Flovent HFA.

Dr. Schewe asked Mary if consideration is given when the State figures cost by looking at the number of actuations and dosing per day. Mary confirmed that the State does include the number of puffs per day in cost consideration and the total cost per day of each when doing the cost analysis. Mary also confirmed that Pulmicort respules have preferred status on the PDL list for beneficiaries up to 7 years of age and prior authorization is not required for this group.

Dr. Haneke summarized that the efficacy of the corticosteroids are essentially the same in equipotent doses, but there are differences with delivery methods and patient preferences. These differences can be considered by the physician and non-preferred drugs can be accessed through prior authorization.

Dr. Sweet stated that the inhaled corticosteroids are all clinically equivalent and that there is access to non-preferred drugs, if medically necessary, through the prior authorization process.

Dr. Tietze stated that clinical equivalence is supported in the OHSU report done on this class of drugs.

A representative from AstraZeneca interjected that safety information should be considered and that Category B approval for Pulmicort has not been shown to be a "class effect". Dr. Haneke responded that we do not know if this is a "class effect" or not because the only data that has been presented to the FDA has been on budesonide. Dr. Haneke also stated that evidence suggests that women with asthma have an improvement in their asthma during pregnancy

	<p>and for a short time after delivery.</p> <p>Dr. Sweet states that as a clinician she prescribes Pregnancy Category C drugs often to sexually active women and pregnant women because there are no other choices available in many drug classes.</p>	
<p>VIII. Intranasal Corticosteroids - Beclomethasone, budesonide, Flunisolide, Fluticasone, Mometasone, Triamcinolone A. Public Comment B. Committee Recommendation and Action</p>	<p>Dr. Schewe reminded the committee and attendees that during the last review of this drug class, all were found to be clinically equivalent.</p> <p>Krishna Patel, PharmD: (Schering-Plough) Nasonex. Dr. Patel provided a brief product review.</p> <p>Dr. Ron Weiner: (AstraZeneca) Rhinocort AQ – Dr. Weiner stated that all of these drugs are considered to be effective. He also stated that there are issues of preference and convenience of dosing and drug delivery. This drug has the dose delivery in lower volume of spray. There is also less problematic taste or smell associated with it compared to the other nasal steroids.</p> <p>Mary clarified that during the prior authorization process the age of the recipient is checked to ensure the drug that is age appropriate is allowed.</p> <p>Dr. Sweet states there is no clinical difference in her practice when using the drugs in this class, but there may be patient preferences.</p>	<p>Dr. Sweet made the motion that the intranasal corticosteroids reviewed maintain clinical equivalency. Dr. Haneke seconded the motion. The motion passed unanimously by roll call vote.</p>
<p>IX. Newer Antihistamines - Cetirizine, Desloratadine, Fexofenadine, Loratadine A. Public Comment B. Committee Recommendation and Action</p>	<p>Dr. Schewe informs the committee that within the antihistamine class, the drugs within the class were found to be clinically equivalent at previous reviews. The Clarinex was reviewed at a later date than the rest of the class.</p> <p>Dr. Krishna Patel (Schering-Plough) Clarinex. A brief product review was provided. Dr. Patel stated the drug has approved for use in children as young as 6 months of age.</p> <p>Jim Baumann (Pfizer) Zyrtec. Mr. Baumann relayed that the drug is approved for use in children as young as 6 months of age.</p> <p>Dr. Sweet commented that she found no compelling evidence that desloratadine is clinically different from loratadine and has not seen differences in her practice.</p> <p>Dr. Tietze stated that the OHSU summary report on page 35 reiterates the science that goes along with our clinical experience.</p> <p>Mary confirmed for the Committee that OTC loratadine is covered by Kansas Medical Assistance Program.</p>	<p>Dr. Tietze made a motion that the newer non-sedating antihistamines reviewed are clinically equivalent, including Clarinex®. Dr. Sweet seconded the motion. The motion passed unanimously by roll call vote.</p>

<p>X. Biphosphonates for Osteoporosis - Aledronate, Ibandronate, Risedronate</p> <p>A. Public Comment</p> <p>B. Committee Recommendation and Action</p>	<p>Jacqueline Travis, PharmD (Roche) Boniva presented a product history and review. The company provides a patient reminder call service and drug replacement program. Five letters of testimony were provided to the committee for support of this product and once per month dosing. There are no clinical studies supporting non-vertebral fracture risk reduction information. An IV injection is also available that would be administered in the providers' office.</p> <p>Dr. James Anderson (Proctor & Gamble) Actonel. Rheumatologist with practice in KC and Wichita. Dr. Anderson presented a product review and requested that the depth of choices not be limited. Dr. Sweet asked Dr. Anderson to confirm that Actonel now has an indication in men. This was confirmed.</p> <p>Thomas Pyron (Merck) Fosamax presented a product history and review. Mr. Pyron discussed a recently published head to head trial (double blind study) looking at the effects between Fosamax and Actonel. He stated that the second year of the study resulted in better bone mass density (BMD) with the use of Fosamax (20% higher response rate). This was not a fracture trial. Safety information is available for 10 years.</p> <p>Dr. Sweet commented that all the drugs work but only if they are taken. For certain people, the once a month dosage is not appropriate. If a person misses a single daily dose, there is less impact than if that person misses their only dose of the month.</p> <p>Dr. Tietze questions why the production of a single dose is four times more costly than the production of daily doses. He also comments that he is not certain that the single monthly dose is as efficacious as the other products.</p>	<p>Motion made by Dr. Haneke to maintain the bisphosphonates reviewed as clinically equivalent. Dr. Sweet seconded the motion. The motion passed by majority with Dr. Tietze casting an opposing vote.</p>
<p>XI. Triptans</p> <p>A. Public Comment</p> <p>B. Committee Recommendation and Action</p>	<p>Dr. Schewe reminded the committee that when these drugs were last evaluated, there were deemed clinically equivalent.</p> <p>No declaration sheet specific to Relepar. Dr. Schewe instructed Jacque Marinac (Pfizer) that she is required to sign a Conflict of Interest Disclosure form before speaking. Dr. Marinac discussed a meta-analysis comparing available triptan therapy which looked at numbers needed to treat and the doses need to treat. The results showed that Eletriptan had the lowest numbers needed to treat.</p> <p>Brian Macomsen (Johnson & Johnson) Axert Product review. No new comparative data was provided, but he stated that Axert is very well tolerated.</p>	<p>Dr. Sweet made a motion that the triptans reviewed within this class be deemed clinically equivalent and would recommend that at least one drug for each route of delivery have preferred status on the PDL. This motion was seconded by Dr. Haneke. The motion passed unanimously by roll call vote.</p>

	<p>Jerry Johnson (Merck) Maxalt. Mr. Johnson discussed changes in their package insert. One is the warning of potential risk for serotonin syndrome when any triptan is used in conjunction with SSRI's or SNRI's. He also gave an update on the new menstrual migraine data.</p> <p>Donald Frailey, PharmD: (GSK) Imitrex. Dr. Frailey requested continued open access to Imitrex. An update was given on the rapid release delivery. He reminded the Committee of the multiple formulations including injections and nasal spray. Dr. Frailey also noted that the FDA has placed a contraindication warning stating that two different triptans should not be used in a 24 hour period.</p> <p>Dr. Sweet expressed surprise that with the number of drugs within this class there is so little scientific data available.</p> <p>Dr. Tietze advised that there is little difference in efficacy; however, the various administrative routes need to be available. He asked if there is a possibility of looking at preventative measures and wondered if there is a way to flag members with utilization of triptans of more than one per month because they should be on preventative therapy.</p> <p>Dr. Sweet echoes the need to have the drugs available with alternative administration routes but that all the triptans are clinically equivalent.</p>	
<p>XII. Meeting Adjournment</p>	<p>With no further discussion, a motion to adjourn was placed before the Committee.</p>	<p>A motion was made by Dr. Tietze to adjourn the meeting. This was seconded by Dr. Haneke. The motion carried unanimously by roll call. The meeting was adjourned at 12:05 pm.</p>