



Kansas Medical Assistance Program

Preferred Drug List Committee Meeting Minutes

<p>Preferred Drug List Committee Meeting Minutes Capitol Plaza Hotel Emerald Room I, June 08, 2005 10:00 A.M.-4:00 P.M.</p>	<p>Members Present: Michael Burke, M.D., Ph.D., Chair Robert Haneke, PharmD Glenn Harte, PharmD Kenneth Mishler, PharmD Brenda Schewe, M.D. Dennis Tietze, M.D.</p> <p>SRS Staff Present: Nialson Lee, B.S.N, M.H.A. Mary Obley, R.Ph. Anne Ferguson, R.Ph. Erica Miller</p>	<p>Representatives: Ann Gustafson (GlaxoSmithKline), Tom Rickman (Aventis), Mike Moratz (Merck), Joshua Lang (Novartis), James Lieurance (Takeda), Lon Lowrey (Novartis), Elizabeth Stoltz (Janssen), Gina Westfall (Abbott), Patrick Byler (Novartis), Patricia Solbach (Janssen), Soraly Servera (Novo Nordisk), Shaun Genka (Novo Nordisk), Daniel Garcia (Takeda), Bryan Reichmuth (Eli Lilly), Gina Parks (Novo Nordisk), Daniel Topham (Novo Nordisk), John Niewoehner (Sepracor), Etta Fanning, M.D., Ph.D. (Sanofi Aventis), Bruce Brown, R.Ph. (Eli Lilly), Barbara Reichenau (Roche), Jacqueline Travis (Roche), Jim Baumann (Pfizer), Mark Whitehair (Eli Lilly), Tina Hartmanus (HealthPoint), Mike Manade (King), Patti Wingbermuehle (AstraZeneca), Raj Soni (Alcon Labs), Rick Reynolds (Alcon Labs), Tammy Shelor (Naploe), Brad Smoot (Roche), Tim Boldt (Pfizer), Michael Cox, M.D. (Roche), Kelly Showactek, PharmD (GlaxoSmithKline), John Gelvin, O.D. (Hunkeler Eye Institute)</p>
<p>I. Call to Order</p>	<p>Dr. Michael Burke, Chair, called the Meeting of the Preferred Drug List (PDL) Committee to order at 10:10a.m.</p>	
<p>II. Announcements</p>	<p>Dr. Burke announced that the allowed speaking time is 5 minutes per drug.</p>	
<p>III. Review Approval of February 02, 2005 Meeting Minutes</p>	<p>There were no additions or corrections to the February 2005 meeting minutes.</p>	<p>A motion to approve the minutes as written was made by Dr. Tietze and seconded by Dr. Harte. The motion carried unanimously by roll call.</p>
<p>IV. New Urinary Incontinence (UI) Drugs A. Public Comment B. Committee Recommendation and Action</p>	<p>Dr. Burke stated that the UI drugs were reviewed at the October 2004 and February 2005 PDL meeting. The PDL Committee needs to decide if Enablex[®] should be added to the clinical equivalence decision that was made at the October 2004 meeting.</p> <p>Josh Lang (Novartis) presented information to the PDL Committee regarding Enablex[®].</p>	<p>A motion was made by Dr. Haneke and seconded by Dr. Mishler that the decision of clinical equivalence of UI drugs at the October 2004 and February 2005 meeting will also include Enablex[®]. The motion carried unanimously by roll call.</p>

	<p>Dr. Mishler asked if he had any head to head trials. Dr. Lang stated that they have one head to head trial comparing Enablex[®] to tolteridine 2mg BID. The efficacy and adverse drug events (ADE) were comparable in both drugs.</p> <p>Dr. Burke stated that the position at the October 2004 was that all formulations of UI drugs are clinically equivalent. The position in February 2005 was that the decision of clinical equivalence would also include VESicare[®] and Sanctura[®].</p> <p>Dr. Tietze explained that the PDL Committee's goal is to decide if there is clinical equivalence within a class. The state medical department deals with the cost issues and decides what is preferred and non-preferred.</p> <p>With no further discussion, a motion was placed before the Committee.</p>	
<p>V. New Oral Bisphosphonates</p> <p>A. Public Comment</p> <p>B. Committee Recommendation and Action</p>	<p>Dr. Burke stated that the oral bisphosphonates were reviewed at the February 2005 PDL meeting. The PDL Committee needs to decide if Boniva[®] should be added to the clinical equivalence decision that was made at the February 2005 meeting.</p> <p>Jacqueline Travis (Roche) presented information to the PDL Committee regarding Boniva[®]</p> <p>Dr. Tietze asked Ms. Travis if she had any information that distinguished Boniva[®] from the other oral bisphosphonates. Ms. Travis stated that they are all the same. Dr. Tietze asked if there is a cost advantage, since it is a once a month pill. Ms. Travis stated that there should be a 7.7% savings. Dr. Tietze asked if it is difficult to manufacturer a once a month pill. Ms. Travis stated that she doesn't believe so.</p> <p>Michael Cox, M.D. (Topeka physician) presented information to the PDL Committee regarding Boniva[®] on behalf of Roche.</p> <p>Dr. Tietze asked if Dr. Cox had additional fracture data. Dr. Cox stated that he didn't. Dr. Haneke asked about nursing home patients. Dr. Cox stated that he does not have any data about nursing home patients.</p> <p>Dr. Harte asked if there is a lost pill program. Dr. Cox stated that there is at no cost to the patient.</p>	<p>A motion was made by Dr. Mishler and seconded by Dr. Haneke that the decision of clinical equivalence of oral bisphosphonate drugs made at the February 2005 meeting will also include Boniva[®]. The motion carried unanimously by roll call.</p>

	<p>Dr. Burke stated that the position at the February 2004 PDL meeting was that all formulations of Oral Bisphosphonates are clinically equivalent. Dr. Burke reviewed comments sent in by Dr. Fink and Dr. Sweet. Dr. Fink and Dr. Sweet could not find Boniva[®] superior to the other oral bisphosphonates, recommends clinical equivalence.</p> <p>With no further discussion, a motion was placed before the Committee.</p>	
<p>VI. Insulins (Re-review) A. Public Comment B. Committee Recommendation and Action</p>	<p>Dr. Burke stated that the Insulins were last reviewed in May of 2003. The position at the May 2003 meeting was that Humalog[®] and Novalog[®] products are equivalent efficacy wise and that the delivery system of choice would be the multi dose vials with a recommendation to the DUR Board that there should be a process by which a physician could access the pens for the patients who need them.</p> <p>Bruce Brown, R.Ph. (Eli Lilly) presented information to the PDL Committee regarding Humalog[®] and Humalog Mix 75/25[®].</p> <p>Soraly Servera (Novo Nordisk) presented information to the PDL Committee regarding Novolog[®].</p> <p>Dr. Burke reviewed the decision of the May 2003 meeting. He also reviewed comments made by Dr. Fink and Dr. Sweet. Dr. Fink and Dr. Sweet recommend clinical equivalence.</p> <p>Dr. Mishler asked if Humalog[®] and Novolog[®] are the only insulin agents being reviewed. Mary stated that the insulins listed on the agenda are what they are reviewing.</p> <p>Dr. Schewe stated that at this point all the delivery systems are available through PA. Dr. Schewe also showed concern, for example, if Novalog[®] becomes preferred it would become an inconvenience if in a year the state decides to change the preferred to Humalog[®]. Nialson stated that is something the state reviews before we make our decision</p> <p>With no further discussion, a motion was placed before the Committee.</p>	<p>A motion was made by Dr. Haneke and seconded by Dr. Harte that the comparable Eli Lilly and Novo Nordisk insulin products listed on this agenda are clinically equivalent. The PDL Committee would also like to recommend the DUR Board review the availability of the delivery systems. The motion carried unanimously by roll call.</p>
<p>VII. Sedative/Hypnotics (Re-review) A. Public Comment B. Committee Recommendation and Action</p>	<p>Dr. Burke stated that the Sedative/Hypnotics were last reviewed in May of 2003. The position at the May 2003 meeting was that all sedative/hypnotics are clinically equivalent. It was also recommended that there should be a quantity/duration limit on Sonata[®] and Ambien[®].</p>	<p>A motion was made by Dr. Haneke and seconded by Dr. Tietze that all formulations of sedative/hypnotics are clinically equivalent. The motion carried unanimously by roll call.</p>

	<p>Etta Fanning, M.D., Ph.D. (Sanofi Aventis) presented information to the PDL Committee regarding Ambien®.</p> <p>Dr. Burke asked if the package insert still recommends Ambien® for short term use. Dr. Fanning stated that it is still listed for short term use. There is documentation of using Ambien® for long term, but Sanofi Aventis has not tried to get the indication changed. They think all patients should be re-evaluated.</p> <p>John Niewoehner (Sepracor) presented information to the PDL Committee regarding Lunesta®.</p> <p>Dr. Burke asked about the binding to the Omega1 site. The other sedative/hypnotics have documentation of their drugs binding to the Omega1 and Lunesta® doesn't. Mr. Niewoehner stated that most sedative/hypnotics bind to the Alpha1, Lunesta® binds to the Alpha3. They are still trying to find out the difference between the Alpha1 and Alpha3.</p> <p>Dr. Mishler asked if there were any active controlled trials besides placebo trials. Mr. Niewoehner stated that there was one trial comparing Lunesta® to Zolpidem in healthy volunteers.</p> <p>Dr. Burke reviewed Dr. Fink and Dr. Sweet's comments. Dr. Fink finds the sedative/hypnotics to be clinically equivalent and would like to recommend quantity limits. Dr. Sweet also found the sedative/hypnotics to be clinically equivalent. Mary stated that there is a policy for the sedative/hypnotics regarding quantity limits, but is not sure when it will be effective.</p> <p>With no further discussion a motion was placed before the Committee.</p>	
<p>VIII. ACE/Calcium Channel Blockers</p> <p>A. Public Comment</p> <p>B. Committee Recommendation and Action</p>	<p>Dr. Burke stated that we have reviewed the ACE Inhibitors and Calcium Channel Blockers (CCB) separately, but we have never reviewed them as combo drugs. When we reviewed the CCB we decided to separate the dihydropyridines and non-dihydropyridines. The state is recommending to not split up the CCB in this class. Mary stated that the intent is to look at these 3 drugs as a group of drugs for treatment of hypertension, because they are only indicated for hypertension.</p> <p>Gina Westfall, PharmD (Abbott) presented information to the PDL Committee regarding Tarka®.</p>	<p>A motion was made by Dr. Tietze and seconded by Dr. Haneke that all formulations of ACE/Calcium Channel Blockers are clinically equivalent for the treatment of hypertension with recommendation to generic substitution of individual components when available. The motion passed unanimously by roll call.</p>

Joshua Lang, PharmD (Novartis) presented information to the PDL Committee regarding Lotrel[®].

Dr. Harte asked if there is any therapeutic difference between taking an ACE inhibitors and CCB separately or taking in a combination pill. Dr. Lang stated that there is no difference.

Dr. Burke stated that the ACE Inhibitors and the CCB were last reviewed in June of 2004. The position at the June 2004 meeting was that all formulations of ACE Inhibitors are clinically equivalent; they would also like to recommend to the DUR Board to give physicians numerous choices on the PDL. The position at the June 2004 meeting regarding CCB was that the CCB should be evaluated by separating them into two subdivisions; the dihydropyridines and the non dihydropyridines. The dihydropyridine CCB are clinically equivalent within their subdivision and the non-dihydropyridine CCB are clinically equivalent within their subdivision.

Dr. Burke reviewed the Dr. Fink and Dr. Sweet's comments. Dr. Fink found clinical equivalence in the ACE/CCB drugs. Dr. Sweet found clinical equivalence in the ACE, but isn't sure about the dihydropyridines and non-dihydropyridines in the CCB.

Dr. Schewe stated that she doesn't see how the dihydropyridine and non-dihydropyridines can be combined.

Dr. Mishler pointed out that amlodipine will be going generic and benazepril already is.

Dr. Haneke stated that he has seen inappropriate use of the combination products when the dosing of a single agent is inadequate and a combination product is added on.

Mary pointed out that the ACE inhibitors and the CCB are on the PDL, but the combination drugs are not. The only other option would be to place all the ACE/CCB on PA.

Dr. Burke pointed out that federally Medicaid is not able to withhold product available. We have two questions to answer, first, are these 3 agents clinically equivalent for the treatment of hypertension. Second, are substitutions of individual components equal in efficacy to combined formulations. The PDL Committee agreed there is no advantage of combination drugs over the individual agents.

	<p>With no further discussion, a motion was placed before the Committee.</p>	
<p>IX. Anti-Virals A. Public Comment B. Committee Recommendation and Action</p>	<p>Joshua Lang (Novartis) presented information to the PDL Committee regarding Famvir®.</p> <p>Dr. Harte asked if there are any head-to-head trials. Dr. Lang stated that there has been one head-to-head trial between Zovirax® and Famvir® on HIV patients.</p> <p>Kelly Showactek, PharmD (GlaxoSmithKline) presented information to the PDL Committee regarding Valtrex®.</p> <p>Dr. Tietze asked if there is an indication for children, 6 months and up. Dr. Showactek stated that there is not.</p> <p>Dr. Burke reviewed Dr. Fink and Dr. Sweet’s comments. Dr. Fink found clinical equivalence in the anti-viral drugs. Dr. Sweet also found clinical equivalence in the anti-viral drugs, but would like to make a notation of dosing advantages between Famvir® and Valtrex®.</p> <p>With no further discussion, a motion was placed before the Committee.</p>	<p>A motion was made by Dr. Haneke and seconded by Dr. Mishler that all formulations of Anti-Viral drugs are clinically equivalent. The motion carried unanimously by roll call.</p>
<p>X. Glaucoma Agents – Ophthalmic Prostaglandin Analogs A. Public Comment B. Committee Recommendation and Action</p>	<p>Tim Boldt (Pfizer) presented information to the PDL Committee regarding Xalatan®. He also showed the Committee a device that Pfizer is providing to patients through the physicians to make the drops easier to apply.</p> <p>Dr. Haneke asked if the devices are supplied to pharmacies as well. Mr. Boldt stated that they have on occasion. Dr. Haneke stated that it would probably be helpful to supply these devices to pharmacies. Mary asked if the devices require a prescription. Mr. Boldt stated that they don’t.</p> <p>Raj Soni (Alcon Labs) presented information to the PDL Committee regarding Travatan®. Alcon Labs is also coming out with a device to make applying drop easier, but they are waiting on approval from FDA.</p> <p>Dr. Burke stated that the VA report finds clinical equivalence in this class of drugs. He then reviewed comments sent in by Dr. Fink and Dr. Sweet. Dr. Fink and Dr. Sweet find Lumigan®, Travatan® and Xalatan® clinically equivalent. Rescula® is not equivalent in efficacy</p>	<p>A motion was made by Dr. Haneke and seconded by Dr. Tietze that there is clinical equivalence among Xalatan®, Lumigan®, and Travatan®. Rescula® is not as efficacious as the others in the class. The motion passed unanimously by roll call.</p>

	<p>and has an increased dosage frequency.</p> <p>John Gelvin, O.D. (Hinkeler Eye Institute) presented information to the PDL Committee regarding Travatan® on behalf of Alcon Labs.</p> <p>Dr. Mishler asked regarding the study, what percentage of the population actually reach goal and maintain it. Dr. Gelvin stated that most do.</p> <p>Dr. Burke pointed out that this class of drugs has not been reviewed before.</p> <p>With no further discussion, a motion was place before the Committee.</p>	
<p>XI. Adjournment</p>	<p>There being no further discussion, a motion to adjourn was placed before the Committee.</p>	<p>A motion was made by Dr. Burke and seconded by Dr. Tietze to adjourn the meeting. The motion carried unanimously by roll call. The Preferred Drug List Committee meeting was adjourned at 12:15 a.m.</p>