



Kansas Medical Assistance Program

Preferred Drug List Committee Meeting Minutes

<p>Preferred Drug List Committee Meeting Minutes Capitol Plaza Hotel Pioneer Room, Maner Conference Center October 07, 2004 10:00 A.M.-4:00 P.M.</p>	<p>Members Present: Michael Burke, M.D., Ph.D., Chair Kristen Fink, PharmD Robert Haneke, 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. Vicki Schmidt, R.Ph. Erica Miller</p>	<p>Representatives: Conrad Duncan (University of Kansas), Bruce Steinberg (Sanofi-Aventis), Debra Vickers (Sanofi-Aventis), Tom Rickman (Sanofi-Aventis), Bill Giltner (Pfizer), Kirk Becker (Pfizer), Colette Wunderlick (AstraZeneca), Michael Windheuser (GlaxoSmithKline), James Lieurance (TPNA), Kim Kraenow (TPNA), Danny Ottosen (Bertek Pharmaceuticals), Neal Beasley (Bristol Myers Squibb), Marguerite Enlow (Bristol Myers Squibb), Dennis Jacobson (Sanofi-Aventis), Chris Lepore (Johnson & Johnson), Cheryl Edwards (Reliant Pharmaceuticals), Candie Phipps (Boehringer Ingelheim), Patrick Byler (Novartis), Randy Blackwell (Biovail Pharmaceuticals), Mike Moratz (Merck), Dennis Bresnahan (University of Kansas Hospital – Cardiologist), James Simple (AstraZeneca), Robert Greely (Takeda), John Kiefhaber (Kansas Pharmacist Association), Joshua Lang (Novartis), Kathleen Carmody (Eli Lilly), Hal Pierce (HealthPoint), James Rider, D.O. (Geriatrics), Carol Curtis (AstraZeneca), Randy Beckner (GlaxoSmithKline), John Hawley (Reliant Pharmaceuticals), Lon Lowrey (Novartis), Scott Wilson (Andrx), Gil Preston (Watson), Matt Ackermann (Boehringer Ingelheim), Brian Michael (Novartis), Mark Ritter (Proctor & Gamble), Jason Heiderscheidt (Proctor & Gamble), Mark Hershy (Aventis), Jeffrey Fajando (Topeka Infectious Disease), Holli Hill (Sankyo Pharma), Craig Wildey (Sankyo Pharma), Barbara Boner (Novartis), Jacqueline Houston (Coventry Health Care), Elias Tawil, M.D., F.A.C.S. (Physician), Karil Bellah (Sankyo Pharma), Amy Siple, MSN, ARNP (Bio-Vail), Michael Martin (Bio-Vail)</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. Intro Comments</p>	<p>Mary thanked the PDL members for their time and commitment to the PDL Committee. Mary then reviewed the rules for public forum and the PDL process. The bids for the drug classes discussed today will be due on October 28, 2004.</p>	

<p>III. Review Approval of June 16, 2004 Meeting Minutes</p>	<p>There were no additions or corrections to the June 2004 meeting minutes.</p>	<p>A motion to approve the minutes as written was made by Dr. Schewe and seconded by Dr. Haneke. The motion carried unanimously by roll call.</p>
<p>IV. Urinary Incontinence Drugs A. Public Comment B. Committee Recommendation and Action</p>	<p>Dr. Burke stated that the Urinary Incontinence (UI) drugs were last reviewed in July of 2003 and the committee consensus was that all UI drugs were clinically equivalent.</p> <p>Dr. Elias Tawil (Physician) presented information to the PDL Committee regarding his preference for extended release tablets over immediate release tablets.</p> <p>Dr. Burke asked what age Ditropan XL® was approved for. Dr. Tawil stated that Ditropan XL® is approved down to 6 years of age. Dr. Tietze asked if he could supply absolute risk reduction on extended release and immediate release UI Drugs. Dr. Tawil stated that he did not have any absolute risk reduction, but that there are more neuroeffects with immediate release than there are with extended release.</p> <p>Dr. Tawil also stated that there have been 5 hip fractures in the nursing home where he works over the past couple years, which he thinks could be due to the immediate release UI drugs. He has not had any hip fractures with patients on the extended release drugs. Dr. Haneke stated that he doesn't think there is a significant difference in the number of hip fractures with patients on extended or immediate release UI drugs.</p> <p>James Rider, D.O. (Geriatrics) stated that he is here to represent patients that are over the age of 65. Dr. Rider presented information to the PDL Committee regarding his preference for extended release UI drugs.</p> <p>Dr. Tietze asked if any of his comments were for patients under the age of 65. Dr. Rider stated that most of his presentation was for patients over the age of 65, most patients that are under the age of 65 tolerate the long acting UI drugs better.</p> <p>Dr. Tietze stated that the PDL committee isn't about formulary; this is about drugs and science. There are a number of issues to look at to decide clinical equivalency.</p>	<p>A motion was made by Dr. Haneke and seconded by Dr. Tietze that all formulations of UI drugs are clinically equivalent. The Committee also made a suggestion that molecular characteristics of tolteridine products may be associated with less adverse effects. The motion carried unanimously by roll call.</p>

	<p>Dr. Conrad Duncan (University of Kansas) presented information to the PDL Committee regarding Detrol® and stated that he is not receiving financial compensation from Pfizer.</p> <p>Dr. Tietze asked if he thinks there could be a legal liability with the State of Kansas for placing drugs on the preferred drug list and requiring prior authorization (PA) for other drugs. Dr. Conrad stated that the State does have a protective shield, but that is not absolute. Dr. Conrad stated that a lawsuit was filed when a patient taking UI drugs was driving and got into a wreck. The patient sued because they were not informed that you weren't supposed to drive.</p> <p>Dr. Burke stated these were interesting comments, but he wasn't sure of the relevance. If a patient is on a UI drug and driving this should be a discussion between the patient and the doctor. Dr. Burke also reviewed the EPC report, and stated that the EPC did find that there were more side effects with the immediate release UI drugs, but they were not significant findings. The EPCs outcome is clinical equivalence for all UI drugs.</p> <p>Dr. Burke reported on his discussion with Dr. Sweet, Dr. Sweet's position has not changed since the last time the UI drug class was reviewed. She assessed all the UI drugs to be clinically equivalent.</p> <p>Dr. Tawil asked if the EPC used randomized double blind studies. Dr. Burke answered that they do.</p> <p>With no further discussion, a motion was placed before the Committee.</p>	
<p>V. Beta Blockers A. Public Comment B. Committee Recommendation and Action</p>	<p>Dr. Burke stated that the Beta Blockers (BB) were last reviewed by the PDL Committee in November 2002. In November 2002 the committee consensus was clinical equivalence between generic and brand name BB.</p> <p>Dr. Cheryl Edwards (Reliant) presented information to the PDL Committee regarding Innopran XL®.</p> <p>Dr. Schewe asked if she had any studies comparing Innopran XL® to any other BB. Dr. Edwards stated that she did not</p>	<p>A motion was made by Dr. Tietze and seconded by Dr. Schewe that Beta Blockers are clinically equivalent to there brand name counterparts and Coreg® and Toprol XL® are preferred agents for patients with CHF. The motion carried unanimously by roll call.</p>

	<p>have any head to head trials.</p> <p>Dr. James Simple (AstraZeneca) presented information to the PDL Committee regarding Toprol XL®.</p> <p>Dr. Tietze asked if there was data on absolute risk reduction in any of the studies. Dr. Simple stated that he did not have that information. Dr. Tietze asked if the studies were tested with placebos. Dr. Simple confirmed that the studies he has supplied are with a placebo.</p> <p>Dr. Randy Beckner (GlaxoSmithKline) presented information to the PDL Committee regarding Coreg®.</p> <p>Dr. Bresnahan (University of Kansas – Cardiology) presented information to the PDL Committee regarding Coreg® on behalf of GlaxoSmithKline.</p> <p>Dr. Tietze asked if he was unhappy with the outcome a year ago. Dr. Bresnahan stated that he was not, and that he would like to suggest that the PDL be left as is.</p> <p>Dr. Burke stated that the EPC report states that all formulations of BB are clinically equivalent. Dr. Burke also stated that Dr. Sweet has no recommendation for changes from the previous review.</p> <p>With no further discussion, a motion was placed before the Committee.</p>	
<p>VI. Oral Hypoglycemics</p> <p>A. Thiazolidinediones</p> <ol style="list-style-type: none"> 1. Public Comment 2. Committee Recommendation and Action 	<p>Dr. Burke stated that this class was last reviewed in May of 2003 and the committee consensus was that all Thiazolidinediones were clinically equivalent.</p> <p>Kim Kraenow, PharmD (Takeda) presented information to the PDL Committee regarding Actos®.</p> <p>Michael Windheuser and Jeffrey Fajando (GlaxoSmithKline) presented information to the PDL Committee regarding Avandia®.</p> <p>Dr. Burke pointed out that there is not a lot of new information in this class of drugs.</p>	<p>A motion was made by Dr. Schewe and seconded by Dr. Haneke that all formulations of Thiazolidinediones are clinically equivalent. The motion carried unanimously by roll call.</p>

<p>B. Sulfonylureas</p> <ol style="list-style-type: none"> 1. Public Comment 2. Committee Recommendation and Action 	<p>With no further discussion a motion was placed before the Committee.</p> <p>Dr. Debra Vickers (Sanofi-Aventis) presented information to the PDL Committee regarding Amaryl®.</p> <p>Dr. Burke pointed out that this class of drugs was last reviewed in May 2003. The decision at the May 2003 meeting was clinical equivalence among the sulfonylureas; glipizide, glyburide, and glimepride. There is no significant clinical differences in single agents, and the combination agents are clinically equivalent to single agents taken together.</p> <p>Dr. Mishler asked if the first generation sulfonylureas are covered, since they are not on the PDL. Mary stated that they are a covered drug, but they are not used often.</p> <p>With no further discussion, a motion was placed before the Committee.</p>	<p>A motion was made by Dr. Schewe and seconded by Dr. Mishler that there is clinical equivalence among the sulfonylureas. There is no significant clinical differences among single agents, and the combination agents are clinically equivalent to single agents taken together. The motion carried unanimously by roll call.</p>
<p>C. Biguanides</p> <ol style="list-style-type: none"> 1. Public Comment 2. Committee Recommendation and Action 	<p>Scott Wilson (Andrx) presented information to the PDL Committee regarding Fortamet®.</p> <p>Dr. Burke pointed out that this class of drugs were last reviewed in May 2003. The decision at the May 2003 meeting was generic metformin is equivalent to extended release forms of metformin.</p> <p>Dr. Fink asked if we need to review Fortamet®, since it is a new drug and it is not listed on the PDL. Mary stated that Fortamet is a non-preferred drug on the PDL list, but the website may not be updated yet.</p> <p>With no further discussion, a motion was placed before the Committee.</p>	<p>A motion was made by Dr. Schewe and seconded by Dr. Fink that all formulations of biguanides are clinically equivalent including; glucophage®, glucophage XR®, and Fortamet®. The motion carried unanimously by roll call.</p>
<p>D. Meglitinides</p> <ol style="list-style-type: none"> 1. Public Comment 2. Committee Recommendation and Action 	<p>Dr. Brian Michael (Novartis) presented information to the PDL Committee regarding Starlix®.</p> <p>Dr. Schewe asked if they have any studies comparing Starlix® to another agent. Dr. Michael stated that he did not.</p> <p>Dr. Burke stated that this class was last reviewed in May of</p>	<p>A motion was made by Dr. Haneke and seconded by Dr. Tietze that all formulations of Meglitinides are clinically equivalent. The motion carried unanimously by roll call.</p>

<p>E. Alpha-Glucosidase Inhibitors</p> <ol style="list-style-type: none"> 1. Public Comment 2. Committee Recommendation and Action 	<p>2003. The decision at the May 2003 meeting was that meglitinides are clinically equivalent.</p> <p>With no further discussion, a motion was placed before the Committee.</p> <p>No public comment.</p> <p>Dr. Burke stated that this class was last reviewed in May of 2003. This decision at the May 2003 meeting was that all Alpha-Glucosidase Inhibitors are clinically equivalent.</p> <p>With no further discussion, a motion was placed before the Committee.</p>	<p>A motion was made by Dr. Schewe and seconded by Dr. Haneke that all formulation of Alpha-Glucosidase Inhibitors are clinically equivalent. The motion carried unanimously by roll call.</p>
<p>VII. ARBs</p> <ol style="list-style-type: none"> A. Public Comment B. Committee Recommendation and Action 	<p>Dr. Burke stated that the ARBs were last reviewed in November 2002.</p> <p>Amy Siple, MSN, ARNP-B.C (Biovail) presented information to the PDL Committee regarding Teveten® and Teveten HTC®.</p> <p>Dr. Tietze asked if there are any head to head studies. Ms. Sickle stated that there aren't.</p> <p>Dr. James Simple (AstraZeneca) presented information to the PDL Committee regarding Atacand®.</p> <p>Dr. Marguerite Enlow (Bristol Myers Squibb) presented information to the PDL Committee regarding Avapro®.</p> <p>Matt Ackermann (Boehringer-Ingelheim) presented information to the PDL Committee regarding Micardis®.</p> <p>Dr. Dennis Bresnahan (University of Kansas Hospital – Cardiologist) presented information to the PDL Committee regarding Diovan® on behalf of Novartis.</p> <p>Dr. Karil Bellah (Cardiologist in Lindsberg) presented information to the PDL Committee regarding Benicar® on behalf of Sankyo Pharma.</p> <p>Dr. Schewe wanted to clarify that these drugs are available; you just have to fill out a PA for non-preferred drugs.</p>	<p>A motion was made by Dr. Tietze and seconded by Dr. Schewe that all formulations of ARBs are clinically equivalent. The motion carried unanimously by roll call.</p> <p>A motion was made by Dr. Tietze and seconded by Dr. Mishler that all combination formulation ARBs are clinically equivalent to single agents and HCTZ taken in combination. The motion carried unanimously by roll call.</p>

	<p>Dr. Tietze asked if Dr. Bellah accepts patients that have other insurances, besides Medicaid, and if so, do those insurance plans have formularies. Dr. Bellah stated that she does accept other insurances and that most have a formulary.</p> <p>Dr. Burke stated that the ARBs were last reviewed in November of 2002 and the decision at the time was that all ARBs are clinically equivalent. The EPC report stated that there is no strong head to head data. Dr. Schewe stated that it is hard to decide clinical equivalence when there is not enough information. There are no head to head studies. Dr. Haneke stated that given the available information, no one ARB is superior.</p> <p>With no further discussion, a motion was placed before the Committee.</p> <p>Dr. Burke stated that the PDL Committee also has to vote on combination agents.</p>	
VIII. Additional Comments	Dr. Bresnahan (University of Kansas – Cardiologist) presented some additional information regarding ARBs.	
IX. Meeting Adjournment	There being no further discussion, a motion to adjourn was placed before the Committee.	A motion was made by Dr. Haneke and seconded by Dr. Fink to adjourn the meeting. The motion carried unanimously by roll call. The Preferred Drug List Committee meeting was adjourned at 2:30 p.m.