

**Preferred Drug List Committee Meeting
Meeting Minutes, Open Session
February 17, 2011**

<p>Preferred Drug List Committee Meeting Minutes, Open Session HP Enterprise Services Capital / Cedar Crest Room Topeka, KS</p>	<p>Members Present: Michael Burke, M.D, Ph.D., Chair Robert Haneke, Pharm.D. Glenn Harte, Pharm.D. Kenneth Mishler, R.Ph., Pharm.D. Donna Sweet, M.D.</p> <p>KHPA Staff Present: Shelly Liby Margaret Smith, M.D. Marlene Shellenberger</p> <p>HP Staff Present: Nicole Churchwell, Pharm.D. Karen Kluczykowski, R.Ph. Lisa Todd, R.Ph.</p>	<p>Representatives: Carol A. Curtis – AstraZeneca Kim Lonergan – AstraZeneca Molly Skelsey – AstraZeneca April Adams – AstraZeneca Russ Wilson – OMJPI Jerry Clewell – Abbott Laboratories Amanda Berge – BMS Grant Cale – BMS Melanie Simpson – KU Med Ctr Kathleen Karnik – OMJSA Rick Barbarash – AstraZeneca Laura Nichols – GlaxoSmithKline Barbara Felt – GlaxoSmithKline Matthew Stafford – Merck Seth Nicuwauhuis – BIPI Bob Marshall – Novartis Jared Lurk – Novartis Kevin Dungey – Sanofi-Aventis Charles Pennewell – Sanoti-Aventis Melissa Wegner – Sanoti-Aventis Phil King – Pfizer Barbara Belcher – Merck Patty Minear – Eli Lilly</p>
TOPIC	DISCUSSION	DECISION AND/OR ACTION
<p>I. Welcome and Announcements</p>	<p>Dr. Burke called the meeting to order at 10:28 am. Ms. Todd provided general parking instructions for those in attendance, advised attendees of the limit of five minutes per drug for Public Comments, and requested that a Conflict of Interest Disclosure form be completed by those individuals planning to make Public Comments.</p>	
<p>II. Review and Approval of June 2, 2010, Meeting Minutes</p>	<p>The draft minutes from the June 2, 2010, meeting were reviewed and approved as written.</p>	<p>Dr. Sweet moved to approve the minutes.</p> <p>Dr. Harte seconded the motion.</p> <p>Motion carried with unanimous vote.</p>

<p>III. Fixed-Dose Combination Drugs for the Treatment of Hypertension, Diabetes, BPH, Arthritis, Hyperlipidemia, Migraines – New Class Review</p> <p>a. Public Comment</p> <p>b. Committee Discussion and Recommendations</p>	<p>Background: Fixed-Dose Combination (FDC) drugs are products that contains two or more active ingredients in a single dosage form. The products available in combination form are also available as monotherapy products, often as generics. Kansas Medicaid has, in the past, managed these products in different ways – sometimes including a FDC with one or the other primary ingredient class, sometimes creating a new class of combo products if there was more than one agent, and other times not including them at all. We are proposing that for select disease states, use of the FDC product is no more effective than using the individual products by themselves, and therefore preferred products may be selected based on cost-efficacy. FDC products for the treatment hypertension, hyperlipidemia, diabetes, BPH, migraines and arthritis have been selected. In today’s meeting packets, Board members received copies of package inserts, a table of products in each class, a DERP review of FDCs in type-II diabetes and hyperlipidemia, and a two part review article of multiple FDC classes from the National Health Service (NHS). Also included in the packets were minutes from previous meetings – December 2009 when the PDL Committee reviewed CCB/ARB combos and June 2005 when CCB/ACE combos were reviewed.</p> <p>Public Comment: Jerry Clewell, Abbott Laboratories, stated he had no specific comments but that he was available to respond to any questions from the Board. Public Comments were provided by:</p> <ul style="list-style-type: none"> • Amanda Berge, Bristol Myers Squibb; • Barbara Felt, GlaxoSmithKline; • Kim Lonergan, Astra Zeneca • Dr. Molly Skelsey, Astra Zeneca • Phil King, Pfizer • Dr. Jared Lurk, Novartis Pharmaceuticals • Matthew Stafford, Merck <p>Board Discussion: Dr. Burke stated that Board members received considerable materials to review in advance and that the FDC issue had previously been addressed by the Board. He continued that, after reviewing the UK’s Regional Drug and Therapeutic Center update, he noted that their position was that the convenience of a FDC product could lead to improved concordance (compliance) but that evidence was sparse</p>	

	<p>which could show actual improved outcomes using FDCs. Dr. Burke added that his own opinion was the lack of flexibility in dosing using FDCs would also be a disadvantage.</p> <p>Dr. Burke commended today's presentations provided by the pharmaceutical representatives, noting the solid data which supported increased benefit and safety with the combination of different agents with unique mechanisms of action. He added that the PDL Board's position has been that FDC products do not appear to be superior to the co-prescribing of individual components of those products. He also clarified that he supports the review of credible data that shows combining agents of different mechanisms of action can provide superior outcomes but that he agrees with the Board's position on FDCs.</p> <p>Dr. Sweet stated that, while the fixed dose combo therapy provides ease and convenience, the focus should be what is best for the patient and there is not data suggested that outcomes are any different using a FDC product rather than taking two separate drugs at optimal dosages. For FDCs, she cited concerns with: a) difficulty with tracking a patient's medication dosage and frequency; b) a delay in dosing for a patient who switches dosage; c) potential toxicity; d) the limitation on number of brand drugs for a patient per month (however she noted there are more generics now available). She closed by stating again that there is simply not a significant difference in outcomes using FDCs.</p> <p>Dr. Haneke agreed with Dr. Sweet's comments and added that, while he appreciates that manufacturers continue to look at safety and efficacy of combination drugs, he remains on record as being against FDCs and, instead, is a proponent of optimizing a single dose instead of adding two or three additional products.</p> <p>Dr. Mishler added that there are many combo drugs that are available in generics which is a benefit.</p> <p>Dr. Burke stated that the PDL Board had already reviewed individually the products used to treat hypertension, diabetes, BPH, arthritis, hyperlipidemia, and migraines with regard to the issue of FDC. He then requested a motion which would address the FDC issue for the drug treatments for those select disease states cited in the "Background" section.</p>	<p>Dr. Haneke made a motion to include all drugs treating the disease states listed and that the Board considers the efficacy of FDC vs. individual doses as being clinically equivalent and not superior to the coprescribed individual components of the FDC product.</p> <p>Dr. Sweet seconded the motion.</p> <p>Motion carried unanimously;</p>
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IV. Short Acting Opioids (SAO) –
New Class Review
a. Public Comment
b. Committee Discussion and
Recommendations

Background: Short acting opioids have not been previously reviewed by the PDL committee. This class consists of fourteen opioids in mono and combination products – codeine, hydrocodone, hydromorphone, meperidine, morphine, opium, oxycodone, oxymorphone, pentazocine, tapentadol, tramadol and fentanyl. Board members were provided with package inserts, a DERP review of Long-Acting Opioids (sections relevant to short-acting opioids appear on pages 18-19 and 25), a morphine equianalgesic dose table, and a table of short-acting opioid dosage forms and dosing frequencies.

Ms. Todd provided background on this agenda item as summarized above.

Public Comments: Dr. Melanie Simpson, University of Kansas Hospital Center, provided comments.

Board Discussion: Dr. Burke advised that the PDL Board had already reviewed long-acting opioids and found the evidence review information contained in the Oregon Health and Science report very helpful during those discussions. He continued that today’s Board decisions would relate to the short-acting analgesics and would be used by KHPA Pharmacy staff during negotiations for placement on the Medicaid Preferred Drug List.

Ms. Todd clarified that PDL Board decisions on these products would impact outpatient treatment only and would not restrict any pain management treatment for a patient within a hospital setting.

Dr. Burke added that, while an evidence-based research report focused on short-acting agents is not available, PDL members have reviewed research on long-acting opioids and that research would periodically make reference to short-acting agents as being clinically equivalent and he reminded the members that these products should be reviewed with the primary outcome being pain relief.

Dr. Sweet, Dr. Haneke, and Dr. Mishler expressed specific concerns with the following five agents being included in this group: codeine, meperidine, opium tincture and opium/belladonna, pentazocine, and tramadol.

Additional discussion was held regarding the availability of generics for some of these agents listed, whether generics are included in the preferred drug formulary, and the supplemental rebate process for branded vs.

	<p>generics.</p> <ul style="list-style-type: none"> • Barbara Belcher with Merck stated that her understanding was the PDL Board was to review branded products for clinical equivalency and make recommendations to the State Pharmacy Team to negotiate for supplemental rebates. • Shelly Liby, KHPA, clarified that during supplemental rebate reviews, the entire class is reviewed – both branded and generics – for utilization and cost estimates. • Dr. Sweet and Dr. Burke both questioned if generics are part of the preferred drug list (PDL) without a prior authorization and whether generics are automatically placed on the preferred drug list. Dr. Churchwell confirmed that each drug included on the PDL has to be approved for Medicaid coverage, that the drugs on the PDL are either preferred or non-preferred, and for those non-preferred drugs, usually a PA is required and sometime those drugs are generic products. <p>Dr. Harte stated his concern with hydrocodone and suggested placing in with the codeine group.</p> <p>Dr. Burke questioned whether tramadol should be excluded.</p> <p>After additional discussion, the Board agreed to have the following six agents removed from the analgesic group being reviewed today: 1) codeine, 2) meperidine, 3) opium tincture and opium/belladonna, 4) pentazocine, 5) propoxyphene, and 6) tramadol. These will be discussed and reviewed by the Board at a later date.</p> <p>Dr. Churchwell confirmed that the Kansas Medicaid Program does not cover Propoxyphene and that this product should have been removed from the handout being reviewed today, as the DUR Board removed the product from the analgesic class sometime ago.</p> <p>The following products remained in the grouping for Board’s consideration of clinical equivalence at today’s meeting: Fentanyl, Hydrocodone, Hydromorphone, Morphine, Oxycodone, Oxymorphone, Tapentadol.</p>	<p>Dr. Sweet made a motion that, with the exclusion of codeine, meperidine, opium tincture and opium/belladonna, pentazocine, propoxyphene, and tramadol, the following remaining agents - Fentanyl, Hydrocodone, Hydromorphone, Morphine, Oxycodone, Oxymorphone, Tapentadol - are clinically equivalent for pain control.</p> <p>Dr. Haneke seconded the motion.</p> <p>Motion carried by unanimous vote.</p>
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<p>V. Ophthalmic NSAIDs – New Class Review</p> <p>a. Public Comment</p> <p>b. Committee Discussion and Recommendations</p>	<p>Background: The Ophthalmic NSAID class has not been previously reviewed. This class is most commonly utilized following cataract surgery or other ophthalmic surgeries to help with pain and promote healing. Agents in the class include bromfenac (Bromday/Xibrom), diclofenac (Votaren), ketorlac (Acular/Acular LS/Acuvail), nepafenac (Nevenac), flurbiprofen (Ocufen). In today’s meeting packets are copies of package inserts and a table of products with concentrations and dosing frequency. There is also a class review from the Department of Veteran Affairs.</p> <p>Public Comment: None.</p> <p>Board Discussion: Dr. Burke commented on the review provided by the Department of Veterans Affairs (2009) in which it had been reported that, in regard to primary outcome of reducing pain, there was no substantive advantage between any of the products (listed above). Dr. Sweet agreed with Dr. Burke’s statement.</p>	<p>Dr. Haneke made motion that these agents (see list in Background) are clinically equivalent.</p> <p>Dr. Mishler seconded the motion.</p> <p>Motion carried with unanimous vote.</p>
<p>VI. Combination Inhaled Corticosteroid (ICS) / Long-Acting Beta-Agonist (LABA) Inhalers – New Class Review</p> <p>a. Public Comment</p> <p>b. Committee Discussion and Recommendations</p>	<p>Background: ICS/LABA inhalers have not been previously reviewed by the PDL Committee. The class includes three products for the treatment of Asthma and COPD – Advair (fluticasone/salmeterol), Dulera (mometasone/formoterol) and Symbicort (budesonide/formoterol). Included in today’s packets are package inserts for each agent, an article and guideline from the FDA regarding the use of combination inhalers in adolescents, a DERP review of controller meds for asthma (comparison of LABA/ICS combinations specifically found on pgs. 84-88; comparisons of ICS against each other and LABA against each other are also addressed), a chart of the products with available strengths and dosing frequency for each, and minutes from the PDL Committee’s previous review of LABA and ICS monotherapy agents.</p> <p>Public Comments were provided by: Dr. Rick Barbarash with AstraZeneca, Barbara Felt with GlaxoSmithKline, and Matthew Stafford with Merck.</p> <p>Board Discussion: Dr. Burke commented the DERP report had indicated there was no reported difference between the Advair and Symbicort combinations after a head-to-head comparison was completed. He added</p>	<p>Dr. Haneke made motion that these three products were clinically equivalent.</p>

	that the findings would most likely be very similar for the Dulera product had it been included in the comparison. Dr. Sweet agreed with Dr. Burke's statement as well.	Dr. Sweet seconded the motion. Motion carried unanimously.
VII. Open Public Comment	There were no additional Public Comments.	
VIII. Adjourn	The meeting adjourned at 12:30 pm. The next PDL meeting is scheduled for June 15, 2011.	Dr. Sweet made motion to adjourn. Dr. Mishler seconded the motion. Motion carried by unanimous vote.