

Preferred Drug List Committee Meeting

Meeting Minutes, Open Session

March 12, 2014 10:00 a.m.

HP Enterprise Services-Capital Room

6700 SW Topeka Blvd. Bldg. 283 J, Topeka, Kansas 66619

Board Members Present:

Taylor Gill, Pharm. D.

Emily Prohaska, Pharm.D., BCACP

Robert Haneke, Pharm.D.

Donna Sweet, M.D.

Janet Hierl, R.Ph

KDHE-DHCF Staff:

Kelley Melton, Pharm. D.

HP Staff Present:

Karen Kluczykowski, R.Ph

Nancy Perry, R.N.

HID Staff Present:

Nicole Ellermeier, Pharm. D.

Public Attendees:

Evie Knisley, Novartis

Dave Sproat, Bristol Myers Squibb

Berend Koops, Merck

Dennis Jacobsen, Genzyme

Jim Baumann, Pfizer

Mary Shefchyk, Novo Nordisk

Bart Brown, Eisai

Jim Fowler, AstraZeneca

Todd Herman, Merck

Phil King, Pfizer

Susan Zalenski, J&J

Brad Brekke, Biogen Idec

Molly Skelsey, AstraZeneca

Joe Summers, UCB

Brian Rose, Merck

Risa Reuscher, Genzyme

Don Larsen, Forest

Item	Facilitator (s)	Notes
Welcome and Announcements	<i>Dr. Sweet, M.D.</i>	Dr. Sweet called the meeting to order at 10:04 am and reminded the public to provide 'Disclosure of Interest' forms if they intend to speak. Dr. Ellermeier provided general parking instructions for those in attendance.

		<p>Dr. Melton introduced new board members Dr. Janet Hierl and Dr. Emily Prohaska. Dr. Jonalan Smith was introduced as the new pharmacy director for Sunflower Health Plan. Dr. F.E. Bustillo III was introduced as the state’s new Clinical Director.</p> <p>Dr. Melton mentioned the 5 minute time limit for speakers, and re-iterated information on head-to-head studies is welcome.</p>
Review and Approval of September 18, 2013 Minutes	<i>Dr. Sweet, M.D.</i>	<p>The draft minutes from the September 18, 2013 meeting were reviewed & approved as written.</p> <p>Dr. Gill moved to approve the minutes. Dr. Haneke seconded the motion.</p> <p>The motion carried unanimously and the minutes were approved.</p>
Oral Mesalamine Products – New Class Review (Apriso, Asacol HD, Delzicol, Lialda, Pentasa)	<i>Dr. Sweet, M.D.</i>	<p>Background: The first class presented for board consideration today is the Oral Mesalamine products. Included for review are Apriso, Asacol HD, Delzicol, Lialda, and Pentasa, all of which are Extended or Delayed release forms of mesalamine. All products, with the exception of Apriso, are labeled for the treatment of mildly to moderately active ulcerative colitis and for the maintenance of remission of ulcerative colitis. Apriso is labled only for the maintenance of remission of ulcerative colitis in patients 18 years and older. Included for board review are package inserts for each product and a class comparison chart.</p> <p>Public Comment: None</p> <p>Board Discussion: Dr. Sweet that the class should be labeled ‘Inflammatory Bowel Disease’ agents.</p> <p>Dr. Gill moved that the Oral Mesalamine Products be added to the PDL. Dr. Haneke seconded the motion.</p> <p>The motion carried unanimously.</p>
Carbonic Anhydrase Inhibitors – New Class Review (Azopt, Trusopt, Simbrinza)	<i>Dr. Sweet, M.D.</i>	<p>Background: Another new class presented today to the board is the Carbonic Anhydrase Inhibitors. Agents proposed for inclusion in this class are Azopt (brinzolamide), Trusopt (dorzolamide), and Simbrinza (brimonidine/brinzolamide). All three agents are indicated for the treatment of elevated intraocular pressure in patients with ocular</p>

		<p>hypertension or open-angle glaucoma. Included for board review are package inserts for each agent and a class comparison chart.</p> <p>Public Comment: None</p> <p>Board Discussion: Dr. Hierl mentioned that Trusopt is the most commonly used agent, but that all agents in the class work the same.</p> <p>Dr. Haneke moved to add Carbonic Anhydrase Inhibitors to the PDL Dr. Gill seconded the motion.</p> <p>The motion carried unanimously.</p>
<p>Hypertriglyceridemia Agents – New Class Review (Lovaza, Vascepa)</p>	<p><i>Dr. Sweet, M.D.</i></p>	<p>Background: A third new class is presented for the board’s consideration today. The new Hypertriglyceridemia Agents PDL class is proposed to include Lovaza (omega-3-acid ethyl esters) and Vascepa (icosapent ethyl). Both agents are indicated as an adjunct to diet to reduce triglyceride levels in adult patients with severe hypertriglyceridemia. Included for board review are package inserts for each agent and a class comparison chart.</p> <p>Public Comment: None</p> <p>Board Discussion: None</p> <p>Dr. Gill moved to add Hypertriglyceridemia Agents to the PDL Dr. Haneke seconded the motion.</p> <p>The motion carried unanimously.</p>
<p>Proton Pump Inhibitors – Class Re-review: New Agent (esomeprazole strontium)</p>	<p><i>Dr. Sweet, M.D.</i></p>	<p>Background: The Proton Pump Inhibitors Class was last brought to the PDL committee in September of 2013, when Aciphex Sprinkles were proposed and approved for inclusion in the class. Esomeprazole strontium delayed-release capsules, released in January, are indicated for treatment of gastroesophageal reflux disease (GERD), risk reduction of NSAID-associated gastric ulcer, H. pylori eradication to reduce the risk of duodenal ulcer recurrence, and pathological hypersecretory conditions, including Zollinger-Ellison syndrome. Included for the board’s consideration are package inserts of all agents in class, meeting minutes from previous meetings during which PPIs were reviewed, and a class comparison chart.</p> <p>Public Comment: None</p>

		<p>Board Discussion: None</p> <p>Dr. Prohaska moved to add esomeprazole strontium to the Proton Pump Inhibitors class. Dr. Gill seconded the motion.</p> <p>The motion carried unanimously.</p>
<p>Adjunct Anti-Epileptics – Class Re-review: New Agents (Aptiom, Fycompa)</p>	<p><i>Dr. Sweet, M.D.</i></p>	<p>Background: Two new agents are proposed for inclusion in the Adjunct Anti-Epileptics PDL class: Aptiom (eslicarbazepine acetate), approved in November of 2013, and Fycompa (perampanel), approved in October of 2012. Aptiom is labeled for adjunctive treatment of partial-onset seizures, while Fycompa is labeled as adjunctive therapy for the treatment of partial-onset seizures with or without secondarily generalized seizures in patients with epilepsy who are 12 years and older. This class was last reviewed at the September 2013 PDL meeting, when Oxtellar XR (oxcarbazepine XR) was approved for inclusion. Meeting from previous minutes where the class the class was reviewed, as well as package inserts and a comparison chart, are included for board consideration.</p> <p>Public Comment: Bart Brown, Eisai, provided public comment on Fycompa.</p> <p>Board Discussion: Dr. Sweet asked Mr. Brown if any head-to-head study data was available for Fycompa, and he indicated that this was not available.</p> <p>Dr. Haneke moved to add Aptiom and Fycompa to the Adjunct Anti-Epileptics class. Dr. Gill seconded the motion.</p> <p>The motion carried unanimously.</p>
<p>Homozygous Familial Hypercholesterolemia (HoFH) Agents – New Class Review (Kynamro, Juxtapid)</p>	<p><i>Dr. Sweet, M.D.</i></p>	<p>Background: Another new class presented to the board today are the Homozygous Familial Hypercholesterolemia (HoFH) Agents. Kynamro (mipomersen), approved in January 2013, and Juxtapid (lomitapide), approved in December 2012, are both indicated as an adjunct to a low-fat diet and other lipid-lowering treatments to reduce LDL cholesterol, total cholesterol, apolipoprotein B (apo B), and non-high-density lipoprotein cholesterol (non-HDL-C) in patients with homozygous familial hypercholesterolemia. Included for the board’s consideration today are package inserts for both products and a class comparison chart.</p> <p>Public Comment: Dennis Jacobsen, Genzyme, provided public comment on Kynamro.</p>

		<p>Board Discussion: Dr. Gill asked if the clinical criteria for these agents addressed the respective REMS programs for each. Dr. Melton stated that it did not, because a limited distribution network was used for the agents, and the patient would have to complete the REMS program with their physician before these pharmacies would be able to dispense the drug.</p> <p>Dr. Haneke moved to add the HoFH Agents class to the PDL. Dr. Gill seconded the motion.</p> <p>The motion carried unanimously.</p>
<p>Inhaled Tobramycin Products – New Class Review (Bethkis, Tobi, Tobi Podhaler)</p>	<p><i>Dr. Sweet, M.D.</i></p>	<p>Background: Inhaled Tobramycin products are the newest PDL class being presented to the board. Included in this proposed class are three inhaled tobramycin products (Bethkis, Tobi, and Tobi Podhaler) that are indicated for the management of Cystic Fibrosis patients with <i>Pseudomonas aeruginosa</i>. Presented for the board’s consideration are package inserts for all products and a class comparison chart.</p> <p>Public Comment: Evie Knisley, Novartis, provided public comment on Tobi Podhaler.</p> <p>Board Discussion: Dr. Sweet mentioned that although the Podhaler may be useful, Cystic Fibrosis patients are still using inhalers for a variety of other medications.</p> <p>Dr. Haneke moved to establish the Inhaled Tobramycin products class. Dr. Gill seconded the motion.</p> <p>The motion carried unanimously.</p>
<p>Sodium-Glucose Cotransporter 2 (SGLT2) Inhibitors – Class Re-review: New Agent (Farxiga)</p>	<p><i>Dr. Sweet, M.D.</i></p>	<p>Background: The Sodium-Glucose Cotransporter 2 (SGLT2) Inhibitors class was first presented for review at the September 2013 PDL meeting, when Invokana (canagliflozin) was approved as the first agent in class. Another SGLT2 Inhibitor, Farxiga (dapagliflozin), was approved in January of 2014 and is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Included for board review are the package inserts for both Invokana and Farxiga, as well as a class comparison chart.</p> <p>Public Comment: Molly Skelsey, AstraZeneca, provided public comment on Farxiga.</p> <p>Board Discussion: None</p>

		<p>Dr. Gill moved to make add Farxiga to the SGLT2 Inhibitors class. Dr. Haneke seconded the motion.</p> <p>The motion carried unanimously.</p>
<p>Biologics – Class Re-review: New Indication (Stelara: Psoriatic Arthritis)</p>	<p><i>Dr. Sweet, M.D.</i></p>	<p>Background: Biologics were approved for inclusion on the PDL in December 2009, at which time classes were created based on FDA-labeled indications. The class was re-visited in June of 2010, when Actemra was added to the adult rheumatoid arthritis agents. The class was again re-visited in March of 2013, in order to add Humira to the agents for ulcerative colitis. Minutes of all of these minutes are included. In September of 2013, Stelara (ustekinumab) was FDA approved for treatment of psoriatic arthritis. While Stelara is already a PDL agent in the Plaque Psoriasis Biologics class, the board is asked today to consider its inclusion for psoriatic arthritis. Package inserts for Stelara and the other PDL biologics for psoriatic arthritis (Enbrel, Humira, Remicade, and Simponi) are included, as is a comparison chart.</p> <p>Public Comment: None</p> <p>Board Discussion: None</p> <p>Dr. Gill moved to add Stelara to the Psoriatic Arthritis Biologic Agents. Dr. Haneke seconded the motion.</p> <p>The motion carried unanimously.</p>
<p>Long-Acting Opioids – Class Re-review: New Agent (Zohydro ER)</p>	<p><i>Dr. Sweet, M.D.</i></p>	<p>Background: Proposed for inclusion in the Long-Acting Opioids PDL class is Zohydro ER (hydrocodone ER). Long-acting opioids were approved for addition to the PDL in June 2009. They had previously been reviewed in 2004 and were not added to the PDL at that time. Updated DERP reports were available in 2009 that showed a lack of clinical superiority for any agent. The class was also reviewed when extended-release hydromorphone (Exalgo®) was approved for inclusion at the June 2010 meeting, and additionally at the March 2013 meeting when Nucynta ER (tapentadol ER) and Butrans patches (buprenorphine) were added to the class. Today, the board has package inserts of all agents in the class, minutes from previous meetings, and a comparison chart for review.</p> <p>Public Comment: None</p> <p>Board Discussion: None</p> <p>Dr. Haneke moved to add Zohydro ER to the Inhaled Long-Acting Opioids Class.</p>

		<p>Dr. Gill seconded the motion.</p> <p>The motion carried unanimously.</p>
<p>COX II Inhibitors – New Class Review (Celebrex)</p>	<p><i>Dr. Sweet, M.D.</i></p>	<p>Background: Although Celebrex (celecoxib) has approved since late 1998, the COX II Inhibitors class has never appeared on the PDL. When NSAIDs were reviewed by the board at the May 2004 meeting, the decision was made to leave COX-II agents off of the PDL, and require a separate clinical PA. At this time, however, the state’s prerogative is to add COX-II agents to the PDL. Celebrex is the only agent currently in class and is indicated for osteoarthritis, rheumatoid arthritis, juvenile rheumatoid arthritis in patients 2 years and older, ankylosing spondylitis, acute pain, and primary dysmenorrhea. Included for board review are its package insert, minutes from the May 2004 PDL meeting, and a class chart.</p> <p>Public Comment: None</p> <p>Board Discussion: The board questioned why the COX-II Inhibitors were being reviewed now. Dr. Melton stated that this was for rebate purposes.</p> <p>Dr. Gill moved to add the COX-II Inhibitors class to the PDL. Dr. Haneke seconded the motion.</p> <p>The motion carried unanimously.</p>
<p>Non-Steroidal Anti-Inflammatory Drugs (Oral) – Class Re-review: New Agent (Zorvolex)</p>		<p>Background: Zorvolex, a newly-developed form of diclofenac, is presented to the board today for review. The NSAID class was reviewed in 2002, 2004, 2009, and 2010; all agents were determined clinically equivalent. The class was last reviewed in September 2011, at which time the PDL Committee determined that Dolobid (diflunisal) was clinically equivalent to other agents in class. Included in your packet are the minutes from the 2011, 2010, 2009, and 2004 meetings, package inserts, and a class comparison chart.</p> <p>Public Comment: None</p> <p>Board Discussion: None</p> <p>Dr. Gill moved to add Zorvolex to the Oral NSAIDs class. Dr. Haneke seconded the motion.</p> <p>The motion carried unanimously.</p>

Open Public Comment		No open public comment.
Adjourn		Meeting adjourned at 10:59 a.m.