

Preferred Drug List Committee Meeting

Meeting Minutes, Open Session

September 10, 2014 10:00 a.m.

HP Enterprise Services-Capital Room

6511 SE Forbes Ave., Bldg. 283 J, Topeka, Kansas 66619

Board Members Present:

Taylor Gill, Pharm. D.
Emily Prohaska, Pharm.D., BCACP

Robert Haneke, Pharm.D.
Matthew Schlotterback, M.D.

Janet Hierl, R.Ph
Dennis Tietze, M.D

KDHE-DHCF Staff:

Kelley Melton, Pharm. D.

Liane Larson, MPH, Pharm.D.

F.E. Bustillo, III, M.D.

HP Staff Present:

Karen Kluczykowski, R.Ph

Nancy Perry, R.N.

HID Staff Present:

Nicole Ellermeier, Pharm. D.

MCOs Present:

Jennifer Murff-United Healthcare

Jonalan Smith-Sunflower

Lisa Todd-Amerigroup

Public Attendees:

Deepan Patel, NovoNordisk
Jeff Knappen, Allergan
Jodi Jensen, UCB
Julie McDavitt, Boehringer Ingelmeim
Molly Skelsey, AstraZeneca
Scott Jones, AstraZeneca
Teresa Blair, Amgen

Eddilisa Martin, Abbvie
Jennifer Stoffel, Janssen
Joe Summers, UCB
Scott Maurice, Boehringer Ingelmeim
Randy Niemeyer, AstraZeneca
Shefchyk, NNI

Jay Rarsons, Pfizer
Jim Baumann, Pfizer
Marla Wiedenmann, NovoNordisk
Mike Krug, Sunovion
Risa Rcuscher, Amgen
Susan Zalenski, J&J

Item	Facilitator (s)	Notes
Welcome and Announcements	<i>Robert Haneke, Pharm.D.</i>	<p>Dr. Haneke called the meeting to order at 10:03 am and reminded the public to provide ‘Disclosure of Interest’ forms if they intend to speak. Dr. Haneke also noted the 5 minute time limit for speakers.</p> <p>Dr. Melton provided general parking instructions for those in attendance.</p> <p>Dr. Melton introduced Liane Larson, MPH, Pharm.D. as the new Assistant Pharmacy Program Manager.</p>
Review and Approval of March 13th, 2014 Minutes	<i>Robert Haneke, Pharm.D.</i>	<p>The draft minutes from the March 13, 2014 meeting were reviewed & approved as written.</p> <p>Dr. Schlotterback moved to approve the minutes. Dr. Gill seconded the motion.</p> <p>The motion carried unanimously and the minutes were approved.</p>
Insulin Delivery Systems – Class Re-review: New Agent (Novolog FlexTouch)	<i>Robert Haneke, Pharm.D.</i>	<p>The first topic for discussion is Insulin Delivery Systems. They were last review in 2005. Dr. Melton offers to and reads the Background: The Insulin Delivery Systems class was last reviewed at the June 8, 2005 PDL meeting. Prior to this, they were reviewed at the May 2003 PDL meeting. At both meetings, it was recommended that multi dose vials should be the delivery system of choice, with pens available via the non-preferred PA process. Since that time, the state has designated some pen agents as preferred agents due to cost and ease-of-use considerations. Presented for inclusion in the class today is a new Insulin Delivery System product, Novolog FlexTouc. Novolog FlexTouch is being added to join the other Novolog products that are currently on the PDL. Included for the board’s consideration are package inserts, previous meeting minutes, and a class comparison chart.</p> <p>Public Comment: Deepan Patel spoke on behalf of Novolog FlexTouch offering samples of the pens for the board to review.</p> <p>Board Discussion: Discussion included the new pen similar to what we already have, basically keeping it the same.</p>

		<p>Dr. Schlotterback made the motion to maintain the previous recommendations as clinically equivalent. Dr. Gill seconded the motion.</p> <p>The motion carried unanimously.</p>
<p>Long-Acting Insulins – Class re-review: new Agents (Levemir FlexPen, Levemir FlexTouch, LaNTUS sOLOsTAR)</p>	<p><i>Robert Haneke, Pharm.D.</i></p>	<p>Background: Long-Acting Insulins were established as a class at the December 2009 PDL meeting. Lantus and Levemir products were approved for inclusion in the class at that time, but only for their vial dosage forms. Today, we are proposing adding pen dosage forms to the class with the addition of Levemir FlexPen, Levemir FlexTouch, and Lantus SoloStar. Included for the board’s consideration are package inserts, previous meeting minutes, and a class comparison chart.</p> <p>Public Comment: Deepan Patel spoke on noting this is the same device as the prior.</p> <p>Board Discussion: Emphasized the directive as to this being different or clinically equivalent</p> <p>Dr. Schlotterback made the motion to maintain the recommendations as before and include these as clinically equivalent.</p> <p>Dr. Tietze seconded the motion.</p> <p>The motion carried unanimously.</p>
<p>Hypertriglyceridemia Agents – Class Re-review: New Agents (Epanova, Omtryg)</p>	<p><i>Robert Haneke, Pharm.D.</i></p>	<p>Background: This class was established at the March 2014 PDL meeting. Like the existing agents in class, Lovaza and Vascepa, new agents Epanova and Omtryg are indicated as an adjunct to diet to reduce triglyceride levels in adults patients with severe (>500 mg/dL) hypertriglyceridemia. Included for the board’s consideration are package inserts for all 4 agents and a class comparison chart.</p> <p>Public Comment: None</p> <p>Board Discussion: Dr. Gill noted that these 2 agents are similar to the others in performance.</p>

		<p>Dr. Gill moved to add based on clinically equivalent. Dr. Tietze seconded the motion.</p> <p>The motion carried unanimously.</p>
<p>Incretin Mimetics – Class Re-review: New Agents (Bydureon Pen, Tanzeum)</p>	<p><i>Robert Haneke, Pharm.D.</i></p>	<p>Background: This class was established at the March 2012 PDL meeting and included both Byetta and Bydureon. In March 2013 Victoza was added to the class as a preferred drug. Bydureon Pen, a new dosage form of the existing PDL Bydureon was FDA approved in March 2014 and is presented for review by the board today. In addition, Tanzeum was also FDA approved within this class in April 2014. Both drugs are approved as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Included for board consideration are previous meeting minutes, package inserts of all agents in class, and a comparison chart.</p> <p>Public Comment: Molly Skelsey, AstraZeneca provided a delivery system demonstration.</p> <p>Board Discussion: Board discussion struggles with 10 day window, with positive comments towards the delivery system. Board members were concerned over the wording ‘preferred’.</p> <p>Dr. Gill moved to add these two agents but keep Victoza as the preferred agent. Dr. Prohaska seconded the motion.</p> <p>The motion carried unanimously.</p>
<p>Combination Products for Hyperlipidemia – New Class Review (Liptruzet, Vytorin)</p>	<p><i>Robert Haneke, Pharm.D.</i></p>	<p>Background: Presented for the board’s consideration today is a new class, the fixed-dose combination products for hyperlipidemia. The two agents in this class, Liptruzet and Vytorin, each contain ezetimibe and a statin. Both are indicated to reduce elevated cholesterol levels in patients with primary or mixed hyperlipidemia, and as adjunct therapy to reduce elevated total cholesterol and LDL cholesterol in patients with homozygous familial hypercholesterolemia (HoFH). Included for the board’s consideration are package inserts of both agents and their individual components, as well as a class comparison chart.</p> <p>Public Comment: Mike Krug noted that Liptruzet is not on the market right now due to packaging not bad drug.</p> <p>Board Discussion: Clarification was offered between the administrative and criteria. Noting it is clinically equivalent. The motion to establish would also validate that</p>

		<p>process.</p> <p>Dr. Tietze made the motion to establish the class. Dr. Gill seconded the motion.</p> <p>The motion carried unanimously.</p>
<p>Non-Steroidal Anti-Inflammatory Drugs (Oral) – Class Re-review: New Agent (Tivorbex)</p>	<p><i>Robert Haneke, Pharm.D.</i></p>	<p>Background: Tivorbex, a newly approved NSAID, is presented to the board today for review. Tivorbex is a new dosage strength indomethacin product approved for the treatment of mild to moderate acute pain in adults. The NSAID class was reviewed in 2002, 2004, 2009, 2010, 2011. The class was last reviewed in March 2014, at which time Zorvolex was approved for PDL inclusion. Meeting minutes, package inserts, and a class comparison chart are included for your review.</p> <p>Public Comment: None</p> <p>Board Discussion: None</p> <p>Dr. Schlotterback moved to include as an equivalent and keep class unchanged. Dr. Prohaska seconded the motion.</p> <p>The motion carried unanimously.</p>
<p>Anticholinergics for the Maintenance Treatment of COPD - Class Re-review: New agents (Anoro Ellipta & Incruse Ellipta)</p>	<p><i>Robert Haneke, Pharm.D.</i></p>	<p>Background: This class was established at the March 2013 PDL meeting and currently includes Spiriva and Tudorza PressAir. Two new agents are presented today for review. Incruse Ellipta is solely an inhaled anticholinergic while Anoro Ellipta is an anticholinergic & long acting beta2-adrenergic agonist combination product. Both are indicated for the long-term, once daily, maintenance treatment of airflow obstruction in patients with COPD. Included for the board's consideration today are package inserts for all 4 agents as well as a class comparison chart.</p> <p>Public Comment: None.</p> <p>Board Discussion: Discussion around similarities and differences, that there is a precedent for going both ways. Some board members noted the combination. Dr. Prohaska suggesting a different class. Unsure how you a combo can be called a single agent. Suggestions for other classes.</p> <p>Dr. Prohaska moved include Incruse and bring the others back in March 2015 and establish a different class for them at that time.</p>

		<p>Dr. Schlotterback seconded the motion.</p> <p>The motion carried unanimously.</p>
<p>Sodium-Glucose Cotransporter 2 (SGLT2) Inhibitors – Class Re-review: New Agent (Jardiance)</p>	<p><i>Robert Haneke, Pharm.D.</i></p>	<p>Background: The Sodium-Glucose Cotransporter 2 (SGLT2) class was established at the September 2013 PDL meeting and currently includes Farxiga (dapagliflozin) and Invokana (canagliflozin). On August 1st the FDA approved Jardiance (empagliflozin) 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 all 3 products, previous meeting minutes, as well as a class comparison chart.</p> <p>Public Comment: Julie McDavid spoke on behalf of Jardiance.</p> <p>Board Discussion: None</p> <p>Dr. Schlotterback moved to add as clinically equivalent. Dr. Gill seconded the motion.</p> <p>The motion carried unanimously.</p>
<p>Biologics – Class Re-review: New Indications/Agents (Cimzia, Entyvio, Otezla, Xeljanz)</p>	<p><i>Robert Haneke, Pharm.D.</i></p>	<p>Background: The Biologics are being presented today for the addition of new agents and indications as well as a potential re-structuring of the class. Historically, the agents available for the treatment of conditions such as Psoriatic Arthritis and Adult Rheumatoid Arthritis have been biologic therapies such as Humira, Enbrel, and Remicade. However, with the release of new non-biologic therapies such as Xeljanz and Otezla, the state is proposing that the classes currently under the ‘Biologics’ heading be renamed based on indication (i.e. ‘Psoriatic Arthritis Therapies’, ‘Ankylosing Spondylitis Therapies’) to better reflect the current climate of available therapies. Should this change be approved, Xeljanz is proposed for inclusion in the ‘Adult Rheumatoid Arthritis Agents’ class, while Otezla is presented for the ‘Psoriatic Arthritis Agents’ class. Additionally, new indications of Psoriatic Arthritis and Ankylosing Spondylitis are proposed for Cimzia, while the new biologic Entyvio is proposed for inclusion for Crohn’s Disease and Ulcerative Colitis. Included for the board’s review are minutes of previous meetings, package inserts, and a class comparison chart.</p> <p>Public Comment: Phil King spoke on behalf of Xeljanz, offers to answer any questions.</p> <p>Board Discussion: Discussion concerning whether the tablet form is clinically</p>

		<p>equivalent to the biologics in treatment outcome. Dr. Melton noted looking to the future treatments available for the re-structuring. Dr. Tietze offered the idea to add the agents then create the class by indication with sub-class them by administration with Dr. Melton state she could bring back a mock up to the next meeting. This class would need renaming to include sub bullets. Dr. Heneke suggests naming the class ‘Immune Disease Modifying Therapy’, and then break it down into therapy class then sub break it down by injectable or oral.</p> <p>Dr. Tietze motion to re-name the class to: ‘Immune Disease Modifying Therapy’, sub-class: ‘Therapy Class’ sub-sub-classes: injectable or oral. Dr. Gill seconded the motion The first half motion carried unanimously</p> <p>Dr. Gill moved to add the Agents. Dr. Haneke seconded the motion.</p> <p>The second half motion carried unanimously.</p>
<p>Inhaled Beta2 Agonists – Long-Acting – Class Re-review: New Agent (Striverdi)</p>	<p><i>Robert Haneke, Pharm.D.</i></p>	<p>Background: Striverdi (olodaterol), a recently approved inhaled long-acting beta-adrenergic agonist, is presented to the board for review today. Striverdi is approved for long-term, once-daily maintenance bronchodilator treatment of airflow obstruction in patients with COPD, including bronchitis and/or emphysema. This class was established in March of 2007 and most recently reviewed in September 2011 when Brovana and Arcapta were added. Meeting minutes, package inserts, and a class comparison chart are included for review.</p> <p>Public Comment: Julie McDavitt, Boehringer Ingelmeim spoke on behalf of Striverdi.</p> <p>Board Discussion: None</p> <p>Dr. Gill motion to approve as therapeutically equivalent. Dr. Prohaska seconded the motion.</p> <p>The motion carried unanimously.</p>
<p>Ophthalmic Prostaglandin Analog – Class Re-review: New Agents (Izba)</p>	<p><i>Robert Haneke, Pharm.D.</i></p>	<p>Background: Izba (travoprost), a newly approved travoprost strength product for the reduction of elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension, is being proposed for inclusion in the Ophthalmic Prostaglandin Analogs PDL class. This class was established in June 2005 with its most recent</p>

		<p>review in March 2013 for the inclusion of Zioptan. For their consideration today, the board has package inserts of Ibza and all current agents, previous meeting minutes, and a comparison chart.</p> <p>Public Comment: None</p> <p>Board Discussion: Dr. Gill noted the same drug with a lower concentration.</p> <p>Dr. Schlotterback moved to add as clinically equivalent. Dr. Tietze seconded the motion.</p> <p>The motion carried unanimously.</p>
<p>Fixed Dose Combinations for Diabetes – Class Re-review: New Agent (Invokamet)</p>	<p><i>Robert Haneke, Pharm.D.</i></p>	<p>Background: Approved by the FDA in August 2014, fixed-dose combination product Invokamet (canagliflozin/metformin) is presented for the board’s consideration. This class was last reviewed at the September 2013 PDL meeting, when Kazano (alogliptin/metformin) and Oseni (Alogliptin/Pioglitazone) were approved for inclusion in the class. When reviewing fixed-dose combination classes, the board is not being asked to review equivalency between agents in the class, but between a given combination product and its individual agents. Included for consideration are previous meeting minutes, package inserts of all products in class, and a comparison chart.</p> <p>Public Comment: Jennifer Stoffel, Janssen, spoke on behalf Invokamet.</p> <p>Board Discussion: Question concerning the need to review the combination once the individual agents have already been approved. Dr. Melton will talk to the legal people to see if that is possible.</p> <p>Dr. Tietze moved to add Invokamet as equivalent to its individual components. Dr. Schlotterback seconded the motion.</p> <p>The motion carried unanimously.</p>
<p>Otic Combinations – New Class Review (Acetasol HC, A/B Otic, Cortisporin, Ciprodex, Cipro HC, Cortisporin TC)</p>	<p><i>Robert Haneke, Pharm.D.</i></p>	<p>Background: Presented for potential PDL inclusion today is the Otic Combinations class. Agents proposed for inclusion include the brand and generic versions (when available) of Acetasol HC, A/B Otic, Cortisporin, Ciprodex, Cipro HC, and Cortisporin TC. While the specifics of each agent’s indication vary, in general they are all indicated for topical treatment of acute ear infections. Included for the board’s consideration today are package inserts of each agent and a class</p>

		<p>comparison chart.</p> <p>Public Comment: None.</p> <p>Board Discussion: Dr. Melton explained the agents being brought forth as clinically efficient as well as cost effective. Dr. Gill is concerned with the AB being in the class when it doesn't seem to belong.</p> <p>Dr. Schlotterback motion to rename the class to 'Otic Anti Infective Steroid Combinations' and to remove A/B from the class and approve the rest as clinically equivalent.</p> <p>Dr. Prohaska seconded the motion.</p> <p>The motion carried unanimously.</p>
Open Public Comment		No open public comment.
Open Board Comment		Request for Oregon data. Asks Kelley to see if we can get access to the data.
Adjourn		Meeting adjourned at 11:34 a.m.