

# Preferred Drug List Committee Meeting

## Meeting Minutes, Open Session

May 13, 2015 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. BCPS  
Dennis Tietze, M.D.

Robert Haneke, Pharm.D.  
Donna Sweet, M.D.

Janet Hierl, R.Ph

### **KDHE-DHCF Staff:**

Kelley Melton, Pharm. D.

Liane Larson, MPH, Pharm.D.

Carol Arace

### **HP Staff Present:**

Karen Kluczykowski, R.Ph

Nancy Perry, R.N.

### **HID Staff Present:**

Ariane Casey, Pharm.D.

### **MCOs Present:**

Jennifer Murff-United Healthcare

Jonalan Smith-Sunflower

Lisa Todd-Amerigroup

### **Public Attendees:**

Jeannine Alameda, Sanofi  
Jim Baumann, Pfizer  
Kendig Bergstresser, Celgene  
Deb Bock, Abbvie  
Kyle Peters, NNI  
Mike Donze, Boehringer Ingelmeim  
Scott Edelhauser, Alcon  
Trey Gardner, Silvergate  
Lee Hennisan, GSK  
Brent Hildebrand, Gilead Sciences  
Janie Huff, Takeda

Terri Hurley, AstraZeneca  
Gordan Ingle, Novartis  
Cassandra Johnson, Al Kermes  
Scott Jones, AstraZeneca  
Berend Koops, Merck  
Darrel Link, Merck  
Joel Mezel, Novartis  
Carolyn Montalvo, NNI  
Randy Niemeyer, AstraZeneca  
Keith Perkins, Shawnee Mission Med.  
Rick Pham, Gilead

Sara Philipi, Takeda  
Ashley Polce, Abbvie  
David Schlatter, Sanofi  
M. Shefchyk, NNI  
Chris Thompson, Purdue LP  
Danielle Walters, Sanofi  
Gina Westfall, Abbvie  
Marla Wiedenmann, NovoNordisk  
Phil Wiegand, Janssen  
Susan Zalenski, J&J  
Diane Hanna, Celgene

Item	Facilitator (s)	Notes
<b>Welcome and Announcements</b>	<i>Donna Sweet, M.D.</i>	Introduced Ariane Casey, Pharm.D. with HID. Reminded the public, if they want to speak, they must fill out the conflict of interest form. Public comment limited to 5 minutes and can be granted more time if the Board allows. Parking announcement was also made.
<b>Review and Approval of September 11<sup>th</sup>, 2014 Minutes</b>	<i>Donna Sweet, M.D.</i>	Dr. Tietze made the motion to approve the minutes as written. Dr. Gill seconded the motion.  The motion carried unanimously.
<b>Hepatitis C Antiviral Agents – New Class Review (Harvoni, Olysio, Sovaldi, Viekira Pak)</b>	<i>Donna Sweet, M.D.</i> <i>Taylor Gill, Pharm.D. BCPS</i>	<p>The first class presented for board consideration today is the Hepatitis C Antiviral Agents. Included for review are 4 new treatment agents; Sovaldi, Harvoni, Olysio, and Viekira Pak.</p> <p><b>Background:</b> Previously, the PDL included a class titled Hepatitis C Protease Inhibitors which included two drugs; Incivek and Victrelis. These medications are no longer in production therefore the class has been renamed to reflect the current therapy options available. If approved, the structure of this class will be somewhat different than that seen for previous classes. Harvoni and Viekira Pak will be listed as distinct entities within the class, but Sovaldi and Olysio will be listed together as combination therapy. Included for the board’s consideration are package inserts for all 4 medications and a comparison chart.</p> <p>Dr. Sweet recused herself from this agent. Dr. Gill presided over this agent.</p> <p><b>Public Comment:</b> Ashley Polce, Abbvie, offered hand outs and commentary on the Viekira Pak. The Board granted additional time for Ashley Polce.</p> <p>Rick Pham, Gilead, commented on Harvoni and Sovaldi.</p> <p>Phil Wiegand, Janssen, offered to answer questions concerning Olysio.</p> <p><b>Board Discussion:</b> Dr. Melton noted there is copy of a letter that was received from a practice in Hutchinson</p>

		<p>Kansas asking the State for access to Harvoni and Viekira. Discussions involved retired agents, clinical equivalent, patient specific needs, and genotype.</p> <p>Dr. Tietz made the motion accept the change to the Hepatitis C class. Dr. Haneke seconded the motion. Dr. Sweet abstained.</p> <p>The motion carried.</p>
<p><b>Topical Acne Products – New Class Review</b></p>	<p><i>Donna Sweet M.D.</i></p>	<p><b>Background:</b> The Topical Acne Products are a new class presented today for the PDL committee's consideration. Agents of differing dosage forms (creams, gels, etc.) are presented for inclusion, as are agents with varying mechanisms. However, all agents are indicated for the treatment of acne vulgaris. The class chart presents agents under consideration listed first by generic ingredient, then separated by dosage form and brand names. For each generic ingredient, those dosage forms with a generic equivalent are also listed. Also included for the committee's consideration are package inserts for all agents presented in the class.</p> <p><b>Public Comment:</b> There was no public comment.</p> <p><b>Board Discussion:</b> Dr. Haneke moved to include these in the class and a motion to accept as clinically equivalent. Dr. Gill seconded the motion.</p> <p>The motion carried unanimously.</p>
<p><b>Insulin Delivery Systems – Class Re-review: New Agents (Afrezza, Apidra, Apidra Solostar, Humalog KwikPens)</b></p>	<p><i>Donna Sweet M.D.</i></p>	<p><b>Background:</b> The Insulin Delivery Systems class was last reviewed at the September 2014 PDL Meeting when Novolog FlexTouch was added to the class. Humalog KwikPens, a new dosage form of the existing PDL Humalog is presented for review by the board today. Afrezza and Afrezza Solostar are also included for consideration as new additions; both are indicated to improve glycemic control in adults and children with diabetes mellitus. In addition, Afrezza, a rapid-acting inhaled insulin which gained FDA approval in June 2014, is also presented. Included for the board's consideration are package inserts, previous meeting minutes, and a class comparison chart.</p> <p><b>Public Comment:</b> David Schlatter, Sanofi, spoke about Afrezza; adults only, portability.</p>

		<p><b>Board Discussion:</b>  It was mentioned that the dose will depend on the ability of the patient to inhale. Dr. Tietz noted that this is an option.  Dr. Sweet requests information from the MCOs on Afrezza utilizations in 6 months.</p> <p>Dr. Sweet moved to add as clinically equivalent with differences in delivery systems for specific people.  Dr. Tietze seconded the motion.</p> <p>The motion carried unanimously.</p>
<p><b>Topical Lice Treatments – New Class Review (Lindane, Natroba, Ovide, Sklice, Ulesfia)</b></p>	<p><i>Donna Sweet M.D.</i></p>	<p><b>Background:</b> Presented for the committee’s consideration is another new class, the Topical Lice products. These agents (Sklice, Natroba, Lindane shampoo, Ovide, and Ulesfia) are all indicated for, at a minimum, the treatment of head lice. Included for the committee’s review are package insert of all agents in class and a class comparison chart.</p> <p><b>Public Comment:</b>  Jeannine Alameda, Sanofi, spoke on behalf of Sklice.</p> <p><b>Board Discussion:</b>  Dr. Sweet noted the recent mandate to not use Lindane on children as it is considered unsafe. Dr. Teitz reminded the public to not read the package inserts when offering public comment. Dr. Melton will look into the state limitations on OTC.</p> <p>Dr. Sweet moved to exclude Lindane and accept the others as clinically equivalent.  Dr. Gill seconded the motion.</p> <p>The motion carried unanimously.</p>
<p><b>Long-Acting Opioids – Class Re-review: New Agents (Conzip (tramadol Hydrochloride) and Hysingla ER (hydrocodone bitartrate))</b></p>	<p><i>Donna Sweet M.D.</i></p>	<p><b>Background:</b> Two new agents are proposed for inclusion today in the Long-Acting Opioids PDL class; Conzip and Hysingla ER. Both are indicated for round the clock, long-term treatment of pain. Long-acting opioids were approved for addition to the PDL in June 2009 and were last reviewed in March 2014 when Zohydro ER (hydrocodone ER) was 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><b>Public Comment:</b>  None</p> <p><b>Board Discussion:</b>  Dr. Sweet expressed concerns of Opana. Dr. Melton noted the PDL and DUR can set</p>

		<p>criteria to have stringent guidelines to prescribe the agents. Dr. Melton noted that the DUR can look at Opana at the next meeting in July, 2015.</p> <p>Dr. Gill made the motion to consider these agents as therapeutically equivalent. Dr. Haneke seconded the motion.</p> <p>The motion carried unanimously.</p>
<p><b>Oral Biologics for Plaque Psoriasis – Class Re-review: New Agent (Otezla)</b></p>	<p><i>Donna Sweet M.D.</i></p>	<p><b>Background:</b> An additional indication for Otezla (apremilast), Plaque Psoriasis, was approved in September 2014. At the previous PDL meeting, the committee approved changes to the structure of the biologics class that would separate agents by indication and oral/non-oral therapies. The proposal before the committee today would add Otezla to a class for ‘Oral Biologics for Plaque Psoriasis’, a class for which it would currently be the only agent. Included for the board’s consideration are prior meeting minutes, an Otezla package insert, and a class comparison chart.</p> <p><b>Public Comment:</b> Diane Hanna, Celgene, spoke on behalf of Otezla noting that it is a molecule not a biologic. Asked the Board to consider re-naming the class to ‘small molecule’.</p> <p><b>Board Discussion:</b> Dr. Melton noted a discussion had taken place concerning biologic and non-Biologic, oral and/or injectable was also discussed. The review will be in May. The re-structure of the class has not been completed.</p> <p>Dr. Gill moved that this agent be added to the Oral class. Dr. Hierl seconded the motion.</p> <p>The motion carried unanimously.</p>
<p><b>Incretin Mimetics – Class Re-review: New Agent (Trulicity (dulaglutide))</b></p>	<p><i>Donna Sweet M.D.</i></p>	<p><b>Background:</b> This class was established at the March 2012 PDL meeting and included both Byetta and Bydureon. It was last reviewed at the September 2014 meeting when Bydureon Pen and Tanzeum were approved for inclusion. Today, we are proposing adding Trulicity to the incretin mimetic class. Trulicity received FDA approval in September 2014 as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Included for the board consideration are previous meeting minutes, package inserts of all agents in this class, and a comparison chart.</p> <p><b>Public Comment:</b></p>

		<p>None.</p> <p><b>Board Discussion:</b>  Dr. Tietze motioned to accept as clinically equivalent.  Dr. Sweet seconded the motion.</p> <p>The motion carried unanimously.</p>
<p><b>Fixed Dose Combinations for Diabetes – Class Re-review: New Agent (Glyxambi (empagliflozin/linagliptin), Xigduo XR (dapagliflozin/metformin ER))</b></p>	<p><i>Donna Sweet M.D.</i></p>	<p><b>Background:</b> Approved by the FDA in October 2014, fixed-dose combination product Xigduo XR is presented for the board’s consideration. Also presented for the board’s consideration is Glyxambi, a combination of empagliflozin and linagliptin approved in February of 2015. This class was last reviewed at the September 2014 PDL meeting, when Invokamet (canagliflozin/metformin) was approved for inclusion into the class. When reviewing the fixed-dose combination class, the board is not being asked to review equivalency between agents in the class, but rather 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><b>Public Comment:</b>  Mike Donze, Boehringer Ingelheim on behalf of Glyxambi.</p> <p><b>Board Discussion:</b>  Dr. Tietz moved to add as clinically equivalent.  Dr. Gill seconded the motion.</p> <p>The motion carried unanimously.</p>
<p><b>Anticholinergics for the Maintenance Treatment of COPD – Class Re-review: New agents (Atrovent HFA (Ipratropium bromide) &amp; Spiriva Respimat (tiotropium bromide))</b></p>	<p><i>Donna Sweet M.D.</i></p>	<p><b>Background:</b> This class was established at the March 2013 PDL meeting and currently includes Spiriva, Tudorza, Anoro Ellipta &amp; Incruse Ellipta. Two possible additions to the class are presented for review today. The first is Atrovent HFA; an anticholinergic indicated for the maintenance treatment of bronchospasm associated with COPD, including bronchitis and emphysema. In addition, a new dosage form of the existing PDL Spiriva is presented today for review. Spiriva Respimat was approved in September 2014 for the long-term, once daily, maintenance treatment of bronchospasm associated with chronic obstructive pulmonary disease (COPD), and for reducing COPD exacerbations. Meeting minutes, package inserts, and a class comparison chart are included for your review.</p> <p><b>Public Comment:</b>  None</p>

		<p><b>Board Discussion:</b> Delivery system reviews.</p> <p>Dr. Sweet made the motion to accept as clinically equivalent. Dr. Gill seconded the motion</p> <p>The motion carried unanimously.</p>
<p><b>Injectable Methotrexate – New Class Review (Otrexup, Rasuvo)</b></p>	<p><i>Donna Sweet M.D.</i></p>	<p><b>Background:</b> The new drugs Otrexup and Rasuvo represent the first entrants into the proposed new class, Injectable Methotrexate Agents. Both are dosed subcutaneously on a weekly basis and both have the same indications: symptomatic control of severe, recalcitrant, disabling psoriasis in adults who are not adequately responsive to other forms of therapy and management of patients with severe, active rheumatoid arthritis and polyarticular juvenile idiopathic arthritis, who are intolerant of or had an inadequate response to first-line therapy. Include for review are package inserts of both agents and a class comparison chart.</p> <p><b>Public Comment:</b> None.</p> <p><b>Board Discussion:</b> Discussion around injectable vs. oral. Questions about the inclusion of generic.</p> <p>Dr. Sweet made the motion to accept the new class and the agents as clinically equivalent. Dr. Haneke seconded the motion.</p> <p>The motion carried unanimously.</p>
<p><b>Non-Benzodiazepine Sedative Hypnotics – Class Re-review: New agent (Belsomra (suvorexant))</b></p>	<p><i>Donna Sweet M.D.</i></p>	<p><b>Background:</b> Belsomra is an agent presented for review today to be included in the non-benzodiazepine sedative hypnotic class. Belsomra was approved by the FDA in August 2014 as an orexin receptor antagonist indicated for the treatment of insomnia, characterized by difficulties with sleep onset and/ or sleep maintenance. This class was last reviewed at the March 2012 PDL meeting when Intermezzo, a sublingual zolpidem tablet was approved for inclusion. Included for the board consideration are previous meeting minutes, package inserts of all agents in this class, and a comparison chart.</p> <p><b>Public Comment:</b> Darrel Link, Merck, spoke on behalf of Belsomra.</p>

		<p><b>Board Discussion:</b> Dr. Gill moved to add as clinically equivalent. Dr. Hierl seconded the motion.</p> <p>The motion carried unanimously.</p>
<p><b>Inhaled Corticosteroids – Class Re-review: New agent (Aerospan, Arnuity Ellipta, Asmanex Twisthaler HFA)</b></p>	<p><i>Donna Sweet M.D.</i></p>	<p><b>Background:</b> The Inhaled Corticosteroid class was developed in February 2005 and last reviewed during the June 2009 PDL meeting when Alvesco (ciclesonide) was added to the class. Today, three agents are being presented for inclusion; Aerospan, Arnuity Ellipta, and Asmanex Twisthaler HFA. All agents are indicated for the maintenance treatment of asthma as prophylactic therapy. Meeting minutes, package inserts, and a class comparison chart are included for your review.</p> <p><b>Public Comment:</b> None.</p> <p><b>Board Discussion:</b> Dr. Haneke moved to add as therapeutically equivalent. Dr. Hierl seconded the motion.</p> <p>The motion carried unanimously.</p>
<p><b>Ophthalmic Antihistamine/Mast Cell Stabilizer Combinations – Class Re-review: New Agents (Alocril (nedocromil) &amp; cromolyn sodium)</b></p>	<p><i>Donna Sweet M.D.</i></p>	<p><b>Background:</b> This class was last reviewed during the September 2011 PDL meeting when Lastacraft was reviewed and included. Two agents are presented for review today. Alocril (nedocromil) is a mast cell stabilizer ophthalmic solution indicated for the treatment of itching associated with allergic conjunctivitis. The second agent, Cromolyn sodium ophthalmic solution, is indicated in the treatment of vernal keratoconjunctivitis, vernal conjunctivitis, and vernal keratitis. Included for review are package inserts for all agents, previous meeting minutes, and a comparison chart.</p> <p><b>Public Comment:</b> None.</p> <p><b>Board Discussion:</b> Dr. Tietze and Dr. Haneke moved to accept as clinically equivalent. Dr. Gill seconded the motion.</p> <p>The motion carried unanimously.</p>

<p><b>Ophthalmic NSAIDS – Class Re-review: New Agent (Prolensa (bromfenac sodium))</b></p>	<p><i>Donna Sweet M.D.</i></p>	<p><b>Background:</b> The Ophthalmic NSAID class was created during the February 2011 PDL meeting and was reviewed most recently in September 2013. The drugs within this class are most commonly utilized following cataract surgery or other ophthalmic surgeries to help with pain and promote healing. As such, Prolensa is indicated for the treatment of postoperative inflammation and reduction of ocular pain in patients who have undergone cataract surgery. Meeting minutes, package inserts, and a class comparison chart are included for your review.</p> <p><b>Public Comment:</b> None.</p> <p><b>Board Discussion:</b> Dr. Gill moved to accept as clinically equivalent. Dr. Haneke seconded the motion.</p> <p>The motion carried unanimously.</p>
<p><b>Xanthine Oxidase Inhibitors/Gout Agents – Class Re-review: New Agent (Colcrys (colchicine))</b></p>	<p><i>Donna Sweet M.D.</i></p>	<p><b>Background:</b> This class was developed during the June 2009 PDL meeting and initially included Zyloprim and Uloric. A third agent is presented for inclusion today; Colcrys (colchicine). Colcrys is an alkaloid agent indicated for the prophylaxis and treatment of gout flare. Package inserts, meeting minutes, as well as a comparison chart are presented for review.</p> <p><b>Public Comment:</b> None.</p> <p><b>Board Discussion:</b> This was brought forth through MCO suggestion. They had seen some utilization issues. With concerns about adding to this class, Dr. Tietze wondered what advantage there is; They took a tried and true from us and replaced it with a more expensive one. Dr. Sweet noted the tried and true was so old that there were no studies. Dr. Tietze said that they are used to treat two completely different clinical purposes. Dr. Sweet recommended to Dr. Melton to have this agent reviewed by the DUR.</p> <p>Dr. Sweet moved to not add the agent and let the class stand as it is. Dr. Hierl seconded the motion.</p> <p>The motion carried unanimously.</p>

<p><b>Beta-Blockers- Class Re-review: New Agent (labetalol)</b></p>	<p><i>Donna Sweet M.D.</i></p>	<p><b>Background:</b> This class was last reviewed in June 2008 when Bystolic was presented and added to the Beta-blocker class. Like the existing agents in this class, Labetalol is indicated for the management of hypertension and is therefore presented to the board for consideration. Meeting minutes, package inserts, and a class comparison chart are included for your review.</p> <p><b>Public Comment:</b> None.</p> <p><b>Board Discussion:</b> Dr. Gill moved to accept as clinically equivalent. Dr. Haneke seconded the motion.</p> <p>The motion carried unanimously.</p>
<p><b>ACE Inhibitors- Class Re-review: New Agent (Epaned (enalapril))</b></p>	<p><i>Donna Sweet M.D.</i></p>	<p><b>Background:</b> Epaned (enalapril) is an oral solution indicated for the treatment of hypertension in adults and children, symptomatic heart failure, and asymptomatic left ventricular dysfunction. Epaned is presented for inclusion into the ACE inhibitor class which was added to the PDL in June 2004 and last reviewed in March 2007. Package inserts, meeting minutes, as well as a comparison chart are presented for review.</p> <p><b>Public Comment:</b> Trey Gardner, Silvergate, spoke on behalf of Epaned.</p> <p><b>Board Discussion:</b> Dr. Haneke moved to accept as clinically equivalent. Dr. Tietze seconded the motion.</p> <p>The motion carried unanimously.</p>
<p><b>Anticoagulants –New Class Review (Eliquis, Pradaxa, Warfarin, Xarelto)</b></p>	<p><i>Donna Sweet M.D.</i></p>	<p><b>Background:</b> Presented to the board today for consideration is a new PDL class; anticoagulants. The agents proposed for inclusion are Eliquis (apixiban), Pradaxa (dabigatran), generic warfarin, and Xarelto (rivaroxaban). These agents are indicated for treatment and risk reduction of deep vein thrombosis and pulmonary embolism, and some are also indicated for postoperative uses and for risk reduction in non-valvular atrial fibrillation patients. Included for the board’s consideration are package inserts of all agents and a class comparison chart.</p> <p><b>Public Comment:</b> Keith Perkins, Shawnee Mission Med., spoke to keeping Warfarin on the list and</p>

		<p>promoted Xarelto.  Mike Donze, Boehringer Ingelmeim, spoke on behalf of Pradaxa.  Jim Baumann, Pfizer, spoke on behalf of Eliquis.  Phil Wiegand, Janssen, spoke on behalf of Xarelto.</p> <p><b>Board Discussion:</b>  Dr. Haneke questioned the inclusion of Warfarin. Dr. Melton noted that Warfarin fits in the discussion for providing options for anticoagulants. Dr. Sweet read the letter from a local physician. Discussion around justifying clinical equality. Currently there is no criteria and these are all handled in a wide open manner. It was noted that a new agent is available, Edoxaban. Dr. Melton said in the September PDL, that this one could be reviewed.</p> <p>Dr. Tietze moved to make this a class contingent that one of the new agents must be on the preferred drug list.  Dr. Gill seconded the motion.</p> <p>The motion carried unanimously.</p>
<p><b>Immunosuppressive Agents  – New Class Review  (Astagraf XL, Azasan,  Cellcept, Gengraf, Imuran,  Myfortic, Prograf,  Rapamune, Sandimmune,  Zortress)</b></p>	<p><i>Donna Sweet M.D.</i></p>	<p><b>Background:</b> Presented for potential PDL inclusion today is the Immunosuppressive Agents Class. While the specifics of each agent’s indication vary, in general they are all oral formulations indicated for the prophylaxis or organ transplant rejection. Included for the board’s consideration today are package inserts of each agent and a class comparison chart.</p> <p><b>Public Comment:</b>  Gordan Ingle, Novartis, spoke on behalf of Zortress. Also mentioned Neoral, which is missing from class review.</p> <p><b>Board Discussion:</b>  Discussion on managing this group and pitfalls concerning limiting their use. A lot are available generically. Some use combinations. Dr. Sweet noted the need for more information from transplant specialists; utilization and use of combos. Processes for approval for a transplant. Dr. Melton requested names of individuals that the State should contact concerning transplants as related to this class.</p> <p>Dr. Sweet moved to table this class until more information is available to make a comprehensive decision.  Dr. Tietze seconded the motion.</p>

		The motion carried unanimously.
<b>Phosphate Binder Agents – New Class Review (Eliphos, Fosrenol, Phoslo, Phoslyra, Renagel, Renvela, Velphoro)</b>	<i>Donna Sweet M.D.</i>	<p><b>Background</b> Another new class presented today for board consideration is the Phosphate Binder Agents. All seven oral agents listed have a general indication for the reduction of serum phosphate in patients with either chronic kidney disease or end stage renal disease. Included for the board’s consideration today are package inserts of each agent and a class comparison chart.</p> <p><b>Public Comment:</b> None.</p> <p><b>Board Discussion:</b> Dr. Sweet moved to accept as clinically equivalent. Dr. Gill seconded the motion.</p> <p>The motion carried unanimously.</p>
<b>Open Public Comment</b>		Jim Baumann, Pfizer, thanked the Board for their time.
<b>Open Board Comment</b>		Dr. Tietze asked Dr. Melton if the Board can give the State the ability to automatically approve generics that may come. Dr. Melton said she would review the information however, she is thinking that is not possible. Dr. Sweet thanked all for participation and supporting the process.
<b>Adjourn</b>		Dr. Sweet moved to adjourn. Dr. Hierl seconded the motion.  Meeting adjourned at 12:15 p.m.