

# Preferred Drug List Committee Meeting

## Meeting Minutes, Open Session

September 9, 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  
Donna Sweet, M.D.

Robert Haneke, Pharm.D.(phone)  
Emily Prohaska, Pharm.D., BCACP

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.

### MCOs Present:

Jennifer Murff-United Healthcare

Jonalan Smith-Sunflower

Lisa Todd-Amerigroup

### Public Attendees:

Jim Baumann, Pfizer  
Deb Bock, Abbvie  
Scott Edelhauser, Alcon  
Sean Mayers, Mylan  
Amy Christensen, Novartis  
Phil King, Pfizer  
Elizabeth Ariano, Indivior  
Terry Ayers, Lilly  
Jennifer Stoffel, Janssen  
Lisa Tootle, BMS  
Scott Maurice, BI

Cassandra Johnson, Alkermes  
Scott Jones, AstraZeneca  
Berend Koops, Merck  
Joel Meyer, Novartis  
Randy Niemeyer, AstraZeneca  
Mark Edwards, Mylan  
Brian Rose, Merck  
Paul Hueseman, AstraZeneca  
Julie McDavitt, BI  
Rob Hanson, Pfizer  
Valerie Collins, BMS

Marla Wiedenmann, NovoNordisk  
Susan Zalenski, J&J  
Heather Jones, Novartis  
Michal Baird, Merck  
David Williams, Allegan  
Patty Tim, Lilly  
Deron Grothe, Tera  
Terry McCurren, Otsuka  
Nikki Moon, Abbvie  
Mary Jo Deflorio, Janssen

Item	Facilitator (s)	Notes
<b>I. Welcome and Announcements</b>	<i>Donna Sweet, M.D.</i>	Call to order at 10:01am. Reminded the public, if they want to speak, they must fill out the conflict of interest form. Dr. Sweet had all individuals at the table introduce themselves for the public attendees.
<b>II. Review and Approval of May 13, 2015 Meeting Minutes.</b>	<i>Donna Sweet, M.D.</i>	<p>Dr. Gill requested the minutes be provided on their discs. Dr. Melton noted we do send them on the disc.</p> <p>Dr. Hierl made the motion to approve the minutes as written. Dr. Prohaska seconded the motion.</p> <p>The motion carried unanimously.</p>
<b>III. Injectable Agents to treat Plaque Psoriasis – Class Re-review: New Agents (Cosentyx)</b>	<i>Donna Sweet, M.D.</i>	<p><b>Background:</b> FDA Approved in January of 2015, Cosentyx (secukinumab), is a new injectable agent for plaque psoriasis. This class was first established as part of the biologics class at the December 16, 2009 PDL meeting. Since then, the class has been renamed and split into differentiated injectable and oral classes, but no new agents have been since the original meeting. Included for the board’s consideration are package inserts of all agents in class, minutes from the 2009 meeting, and a class comparison chart.</p> <p><b>Public Comment:</b> Amy Christenson with Novartis spoke on behalf of Cosentyx.</p> <p><b>Board Discussion:</b> Board discussions included utilization and possible need to reconstitute. Ms. Christenson noted that there is not reconstitution for this medication. Dr. Haneke spoke to not seeing this particular medication as superior, at this point in time, to any other in the class.</p> <p>Dr. Gill made the motion to add Cosentyx but not make it preferred. Dr. Prohaska seconded the motion.</p> <p>The motion carried unanimously.</p>
<b>IV. Opioid-Induced Constipation Agents – New Class Review (Movantik, Relistor)</b>	<i>Donna Sweet M.D.</i>	<b>Background:</b> Both Movantik (naloxegol oxalate) and Relistor (methylnaltrexone bromide) are agents indicated for treatment of opioid-induced constipation in adult patients with chronic noncancer pain. Relistor is also indicated for treatment of opioid-induced constipation in adult patients with advanced illness (receiving palliative care) who have an inadequate response to conventional laxative regimens. Movantik is

		<p>available as an oral tablet, while Relistor is a subcutaneous injection. Included for the board's consideration are package inserts of both agents and a class comparison chart.</p> <p><b>Public Comment:</b> None.</p> <p><b>Board Discussion:</b> Dr. Gill moved to make this a new class with these two agents as clinically equivalent. Dr. Prohaska seconded the motion.</p> <p>The motion carried unanimously.</p>
<p><b>V. Long-Acting Insulin – Class Re-review: New Agents (Toujeo)</b></p>	<p><i>Donna Sweet M.D.</i></p>	<p><b>Background:</b> Last reviewed at the September 2014 PDL meeting, the long-acting insulins class is again before the board today. Toujeo Solostar (insulin glargine), approved by the FDA in February of 2015, is indicated to improve glycemic control in adults with type 1 diabetes mellitus and type 2 diabetes mellitus and to improve glycemic control in children 6 years older with type 1 diabetes mellitus. Included for the board today are package inserts of all agents in class, prior meeting minutes, and a class comparison chart.</p> <p><b>Public Comment:</b> None.</p> <p><b>Board Discussion:</b> Dr. Gill provided review information for therapeutically equivalent.</p> <p>Dr. Gill moved to add Toujeo to this class as therapeutically equivalent. Dr. Haneke seconded the motion.</p> <p>The motion carried unanimously.</p>
<p><b>VI. Inhaled Short-Acting Beta<sub>2</sub> Agonists – Class Re-review: New Agent (ProAir Respiclick)</b></p>	<p><i>Donna Sweet M.D.</i></p>	<p><b>Background:</b> The Inhaled Short-Acting Beta<sub>2</sub> Agonists class was initially presented to the PDL committee in March of 2007, and has not been re-reviewed since that meeting. Today, a new device for ProAir (albuterol), the ProAir Respiclick, is presented for board consideration. Included for the board's consideration are package inserts, meetings from the March 2007 meeting, and a class comparison chart.</p> <p><b>Public Comment:</b> None.</p>

		<p><b>Board Discussion:</b> Dr. Hierl noted her experiences with this agent.</p> <p>Dr. Prohaska moved to add as clinically equivalent. Dr. Gill seconded the motion.</p> <p>The motion carried unanimously.</p>
<p><b>VII. Ophthalmic Antihistamine/Mast Cell Stabilizers – Class Re-review: New Agents (Pazeo)</b></p>	<p><i>Donna Sweet M.D.</i></p>	<p><b>Background:</b> Pazeo (olopatadine) was FDA approved in February of 2015, and is proposed for inclusion in the Ophthalmic Antihistamine/Mast Cell Stabilizers Class. It is indicated for treatment of the signs and symptoms of allergic conjunctivitis. This class was last reviewed at the May 2015 PDL meeting, when generic cromolyn and Alocril were added to the class. Included for the board’s consideration are previous meeting minutes, packages inserts of all agents in class, and a class comparison chart.</p> <p><b>Public Comment:</b> Scott Edelhauser with Alcon stated he was here to answer any questions if needed.</p> <p><b>Board Discussion:</b> Dr. Gill made the motion to add Pazeo to this class as therapeutically equivalent. Dr. Hierl seconded the motion.</p> <p>The motion carried unanimously.</p>
<p><b>VIII. Growth Hormone – Class Re-review: New Agent (Zomacton)</b></p>	<p><i>Donna Sweet M.D.</i></p>	<p><b>Background:</b> Zomacton (somatropin) is the first new entrant to the growth hormone class since the class was established at the February 2006 meeting. Ferring Pharmaceuticals acquired Tev-Tropin from Teva Pharmaceuticals in December 2014 and received FDA approval for a name change from Tev-Tropin to Zomacton. Like other agents in class, Zomacton is indicated for growth failure in children (this is Zomacton’s only indication, while other agents in class have expanded indications). Included for the board’s review are package inserts of all growth hormone agents in class, minutes from the February 2006 meeting, and a class comparison chart.</p> <p><b>Public Comment:</b> None.</p> <p><b>Board Discussion:</b> Questions on how much this agent is used. Dr. Melton noted that this agent is used quite a lot.</p>

		<p>Dr. Gill moved to add Zomacton as clinically equivalent. Dr. Hierl seconded the motion.</p> <p>The motion carried unanimously.</p>
<p><b>IX. Phosphate Binder Agents – Class Re-review: New Agent (Auryxia)</b></p>	<p><i>Donna Sweet M.D.</i></p>	<p><b>Background:</b> First presented at the May 2015 PDL meeting, the Phosphate Binder Agents class is being revisited today. Auryxia (ferric citrate) was mistakenly not included in the agents presented in May, but is being proposed for inclusion today. It is indicated for the control of serum phosphorus levels in patients with chronic kidney disease (CKD) receiving dialysis. Presented for the board’s consideration are package inserts of all agents in class and a class comparison chart.</p> <p><b>Public Comment:</b> None.</p> <p><b>Board Discussion:</b> Dr. Haneke motioned to add Auryxia as clinically equivalent. Dr. Gill seconded the motion.</p> <p>The motion carried unanimously.</p>
<p><b>X. Inhaled Long-Acting Beta Agonists/Anticholinergics – New Class Review (Anoro Elipta, Stiolto Respimat)</b></p>	<p><i>Donna Sweet M.D.</i></p>	<p><b>Background:</b> Two new agents are presented today as part of a new Inhaled Long-Acting Beta Agonists/Anticholinergics class. Anoro Elipta (umeclidinium/vilanterol) was approved in December 2013, while Stiolto Respimat (tiotropium/olodaterol) was approved in May of 2015. Both agents are indicated for the long-term, once-daily maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD). Included for the board’s consideration are package inserts of all agents in class and a class comparison chart.</p> <p><b>Public Comment:</b> Julie McDavitt spoke on behalf of Stiolto Respimat.</p> <p><b>Board Discussion:</b> Dr. Prohaska moved to accept the new class and add both agents. Dr. Gill seconded the motion.</p> <p>The motion carried unanimously.</p>
<p><b>XI. Immunosuppressive Agents – Class Re-</b></p>	<p><i>Donna Sweet M.D.</i></p>	<p><b>Background:</b> The immunosuppressive class was previously tabled and not approved as a class.</p>

<p><b>review: New agents (Envarsus XR, Neoral)</b></p>		<p><b>Public Comment:</b> None.</p> <p><b>Board Discussion:</b> Due to inaccurate information as this was not created as a new class at the last PDL meeting, this agenda item was tabled. Dr. Melton indicated that she will bring the data to the next PDL meeting. Dr. Gill and Dr. Prohaska offered to have unofficial consults with transplant doctors as well.</p> <p>Tabled till the next PDL meeting.</p>
<p><b>XII. Muscle Relaxants (Skeletal) – Class Re-review: New Agents (Lorzone)</b></p>	<p><i>Donna Sweet M.D.</i></p>	<p><b>Background:</b> Lorzone, a new branded version of chlorzoxazone, is being presented today for inclusion in the Skeletal Muscle Relaxants class. Lorzone is indicated as an adjunct to rest, physical therapy, and other measures for the relief or discomfort associated with acute, painful musculoskeletal conditions. This class was first reviewed at the July 2003 PDL meeting, and then re-reviewed at the March 2007 meeting. Minutes of both meetings are included, along with package inserts and a class comparison chart.</p> <p><b>Public Comment:</b> None.</p> <p><b>Board Discussion:</b> Dr. Gill made the motion to add the agent as clinically equivalent. Dr. Hierl seconded the motion.</p> <p>The motion carried unanimously.</p>
<p><b>XIII. Topical Acne Agents – Class Re-review: New agent (Epiduo Forte, Neuac)</b></p>	<p><i>Donna Sweet M.D.</i></p>	<p><b>Background:</b> The topical acne agents class was first presented at the May 2015 PDL meeting. At that time, we neglected to include Neuac (clindamycin &amp; benzoyl peroxide gel) in the products presented. Additionally, Epiduo Forte (adapalene &amp; benzoyl peroxide gel) was approved by the FDA in July of 2015. Both are indicated for the topical treatment of acne vulgaris. Presented for the board’s consideration are package inserts of all agents in class and a class comparison chart.</p> <p><b>Public Comment:</b> None.</p> <p><b>Board Discussion:</b> Dr. Gill moved to add both agents as clinically equivalent. Dr. Prohaska seconded the motion.</p>

		The motion carried unanimously.
<b>XIV. Anticoagulants – Class Re-review: New agent (Savaysa)</b>	<i>Donna Sweet M.D.</i>	<p><b>Background:</b> A new entrant into the Anticoagulants class is Savaysa (edoxaban), which was FDA approved in January of 2015. Savaysa is indicated for treatment of deep vein thrombosis and pulmonary embolism following 5 to 10 days of initial therapy with a parenteral anticoagulant. This class was last reviewed in May, when Eliquis, Pradaxa, warfarin, and Xarelto were approved for inclusion in the class. Included for board consideration are package inserts of all agents in class and a class comparison chart.</p> <p><b>Public Comment:</b> None.</p> <p><b>Board Discussion:</b> Dr. Gill moved to add as therapeutically equivalent. Dr. Hierl seconded the motion.</p> <p>The motion carried unanimously.</p>
<b>XV. Anaphylaxis Agents – New Class Review (Adrenaclick, Adrenalin, Auvi-Q, Epinephrine, EpiPen, EpiPen Jr.)</b>	<i>Donna Sweet M.D.</i>	<p><b>Background:</b> A new class is proposed for the board’s consideration today. The anaphylaxis agents class is proposed to include those agents used for the emergency treatment of allergic reactions (type 1) such as anaphylaxis to insect stings or bites, allergen immunotherapy, foods, drugs, diagnostic testing substances, and other allergens, as well as idiopathic or exercise-induced anaphylaxis. Proposed for inclusion are brand name Adrenaclick, Adrenalin, Auvi-Q, EpiPen, and EpiPen Jr. along with generic epinephrine auto injectors. Included for the board’s review are package inserts and a class comparison chart.</p> <p><b>Public Comment:</b> Mark Edwards with Mylan spoke on behalf of EpiPen and EpiPen Jr.</p> <p><b>Board Discussion:</b> Dr. Gill moved to establish this class, add the agents and create the 4<sup>th</sup> criteria restriction for Prior Authorization of:</p> <ul style="list-style-type: none"> <li>• If a patient is trained on a specific device, that should be justification for them to continue using it.</li> </ul> <p>Dr. Prohaska seconded the motion.</p> <p>The motion carried unanimously.</p>

<p><b>XVI. Platelet Aggregation Inhibitors – New Class Review (Aggrenox, Brilinta, clopidogrel, dipyridamole, Effient, Plavix, ticlopidine, Zontivity)</b></p>	<p><i>Donna Sweet M.D.</i></p>	<p><b>Background:</b> Another new class presented to the board is the Platelet Aggregation Inhibitors class, with proposed agents Aggrenox, Brilinta, clopidogrel, dipyridamole, Effient, Plavix, ticlopidine, and Zontivity. While the agents in class have varying indications, all are classified as Platelet aggregation inhibitors by the American Hospital Formulary Service. Included for the boards review are package inserts and a class comparison chart.</p> <p><b>Public Comment:</b> Paul Huesman with AstraZeneca spoke on behalf of Brilinta. Michal Baihl with Merck spoke on behalf of Zontivity.</p> <p><b>Board Discussion:</b> The Board feels these agents need to be divided into two separate classes by indication of needed use. Dr. Sweet recommended to watch for possible additions. Plavix was suggested to go in both classes.</p> <p>Dr. Gill moved to table to the next PDL meeting. Dr. Haneke and Dr. Prohaska seconded the motion.</p> <p>The motion carried unanimously to table to the next PDL meeting.</p>
<p><b>XVII. Thrombopoietin (TPO) Receptor Agonists – New Class Review (Nplate, Promacta)</b></p>	<p><i>Donna Sweet M.D.</i></p>	<p><b>Background:</b> Presented today for the board’s review are two Thrombopoietin (TPO) Receptor Agonists, Nplate and Promacta. Both agents are indicated for the treatment of thrombocytopenia in patients with chronic immune thrombocytopenia (ITP) who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy. Promacta is also indicated for thrombocytopenia in patient with chronic hepatitis C to allow the initiation and maintenance of interferon-based therapy and for patients with severe aplastic anemia who have had an insufficient response to immunosuppressive therapy. Included for the board’s 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> Dr. Hierl motioned to create class and to add both agents. Dr. Prohaska seconded the motion.</p> <p>The motion carried unanimously.</p>

<p><b>XVIII. PCSK9-Inhibitors – New Class Review (Praluent, Repatha)</b></p>	<p><i>Donna Sweet M.D.</i></p>	<p><b>Background:</b> PCSK9 Inhibitors are a new class of drugs used to regulate LDL cholesterol. Praluent, approved in July of 2015, and Repatha, approved in August of 2015, are both indicated as adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia or clinical atherosclerotic cardiovascular disease, who require additional lowering of LDL-cholesterol. Repatha is also indicated as adjunct to diet and other LDL-lowering therapies in patients with homozygous familial hypercholesterolemia who require additional lowering of LDL-cholesterol. Presented for the board’s consideration are package inserts and a class comparison chart.</p> <p><b>Public Comment:</b> None.</p> <p><b>Board Discussion:</b> Board would like additional information and will keep a watch on this class.</p> <p>Dr. Prohaska moved to add this class and its agents. Dr. Gill seconded the motion.</p> <p>The motion carried unanimously.</p>
<p><b>XIX. Hepatitis C Antiviral Agents – Class Re-review: New Agents (Daklinza, Technivie)</b></p>	<p><i>Donna Sweet M.D. recusing Dr. Gill took the chair.</i></p>	<p><b>Background:</b> The Hepatitis C Antiviral Agents class was established in its new form at the May 2015 PDL meeting. At that time, Harvoni, Viekira, and Sovaldi plus Olysio combination therapy were approved for inclusion in the class. Since then, two new agents have been approved. Both Daklinza and Technivie were FDA approved in July of 2015. Technivie is indicated for Genotype 4 patients without cirrhosis, while Daklinza is labeled for use with sofosbuvir in Genotype 3 patients. However, Daklinza is also listed in the American Association for the Study of Liver Diseases (AASLD) Hepatitis C guidelines as a potential therapy for Genotype 1a, 1b, and 2 patients. Included for the board’s review is a chart that summarizes the AASLD Hepatitis C treatment guidelines, package inserts, and a class comparison chart.</p> <p><b>Public Comment:</b> Nikki Moon, with Abbvie spoke on behalf of Technivie. Valerie Collins, with BMS spoke on behalf of Daklinza.</p> <p><b>Board Discussion:</b> Dr. Haneke moved to accept. Dr. Hierl seconded the motion.</p>

		Dr. Sweet recused. The motion carried.
<b>XX. Combination Products for Hypertension – Class Re-review: New Agents (Prestalia)</b>	<i>Donna Sweet M.D.</i>	<p><b>Background</b> A new combination products for hypertension, Prestalia, was FDA approved in January of 2015. A combination of perindopril and amlodipine, it is indicated for the treatment of hypertension to lower blood pressure in patients not adequately controlled with monotherapy and as initial therapy in patients likely to need multiple drugs to achieve their blood pressure goals. Combination products for Hypertension were last reviewed in March of 2013. As with previous reviews, board members are asked to consider if the use of a combination product is equivalent to the concurrent use of its individual ingredients. Included for the board’s review are a class comparison chart, previous meeting minutes, and package inserts for Prestalia and its components.</p> <p><b>Public Comment:</b> None.</p> <p><b>Board Discussion:</b> Dr. Gill moved to include Prestalia. Dr. Prohaska and Dr. Haneke seconded the motion.</p> <p>The motion carried unanimously.</p>
<b>XXI. Open Public Comment</b>		None
<b>XXII. Adjourn</b>		Dr. Gill moved to adjourn. Dr. Hierl seconded the motion.  Meeting adjourned at 11:25 a.m.