

**Preferred Drug List Committee Meeting
Meeting Minutes, Open Session
March 13, 2013**

| <p>Preferred Drug List Committee Meeting Minutes, Open Session HP Enterprise Services Capital / Cedar Crest Room Topeka, KS</p> | <p>Members Present: Robert Haneke, Pharm.D. Glenn Harte, Pharm.D. Landa Colvin-Marion, M.P.H., Pharm.D. Terry 'Lee' Mills, Jr., M.D. Donna Sweet, M.D. Dennis Tietze, M.D. Katy Brown, Pharm.D. Taylor Gill, Pharm.D.</p> <p>Members Not Present: Matthew Schlotterback, M.D.</p> <p>KHPA Staff Present: Kelley Melton, Pharm.D. Brandy Allen</p> <p>HP Staff Present: Karen Kluczykowski, R.Ph. Nancy Perry, R.N.</p> <p>HID Staff Present: Nicole Elleremeier, Pharm.D.</p> | <p>Representatives: Jim Graham - J & J Micka Goodlett – KU Angela Liu - KU Rupa Shah – Purdue Pharma Teresa Blair - Amgen Barbara Felt - GlaxoSmithKline Jack Planchard – GlaxoSmithKline Mike Hauger – Genentech Jeff Himmelberg – GlaxoSmithKline Jim Bauman - Pfizer Eric Blake – Merck Kathy Conrad – Astellas Phil King -Pfizer Tone' Jones – Sunovion Lauren Bohning – Fedrico Consulting Debbie Bock – Abbott Mark Weise – Otsuka Dave Sproat – Bristol Myers Squibb Jim Russell – GlaxoSmithKline Sam Smothers – MedImmune Mike Ketcher – Novo Nordisk</p> |
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| TOPIC | DISCUSSION | DECISION AND/OR ACTION |
| <p>I. Welcome and Announcements</p> | <p>Dr. Sweet called the meeting to order at 10:04 am and reminded the public to provide 'Disclosure of Interest' forms if they plan to speak. She also mentioned that there is a time limit, but information on head-to-head studies is welcome.</p> <p>Dr. Ellermeier provided general parking instructions for those in attendance.</p> <p>Dr. Melton announced the absence Glen Harte, Linda Colvin-Marion and Kristen Fink have all left the board.</p> <p>Dr. Sweet explained the role of the PDL board and expectations.</p> <p>Dr. Melton explained that all 3 MCO's using the same PDL PA criteria as the board.</p> | |
| <p>II. Review and Approval of March</p> | <p>The draft minutes from the March 14, 2012, meeting were reviewed and</p> | <p>Dr. Haneke moved to approve the</p> |

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| <p>13,2012 Meeting Minutes</p> | <p>approved as written.</p> | <p>minutes.</p> <p>Dr. Harte seconded the motion.</p> <p>Dr. Tietze abstained from the vote.</p> <p>The motion carried and the minutes were approved.</p> |
| <p>I. Ophthalmic Prostaglandin Analog – Class Re-review: New Agents (Zioptan)</p> <p>a. Public Comment</p> <p>b. Committee Discussion and Recommendations</p> | <p>Background: Zioptan is an ophthalmic solution indicated for the treatment of open angle glaucoma and patients with ocular hypertension. Been studied in adults in 5 different clinical studies with 905 patients. The head to head data is against Timolol No contraindications. The warning precautions include things that are typical with the Prostaglandin Analogs.</p> <p>Public Comment: Matt Stafford, Merck provided public comment on Zioptan. He stated that it demonstrates powerful efficacy in reducing inner ocular pressure up to 30% for out to 2 years in clinical studies. The most common adverse experience is hyperemia. He also mentioned that Zioptan is a preservative-free solution, and that there is a discontinuation rate of less than 1%.</p> <p>Board Discussion:</p> <p>Dr. Sweet questioned why they opted to do a head to head with another class of drug as opposed to any other existing Prostaglandins.</p> <p>Dr Tietze commented that they are clinically equivalent with the only difference being the single dose container.</p> | <p>Dr. Tietze made a motion to considering this drug clinically equivalent.</p> <p>Dr, Gill seconded the motion.</p> <p>The motion carried unanimously.</p> |
| <p>II. Fixed Dose Combination Products for Hypertension– Class Re-review: New Agent (Dutoprol)</p> <p>a. Public Comment</p> <p>b. Committee Discussion and Recommendations</p> | <p>Background: The introduction of this class was established in Feb 2011 PDL meeting and then was revisited in Mar 2012. The new combination agent hypertenstion Dutoprol was approved in April 2012. It is a combination of the extended release version beta blocker Metoprolol Succinate and Hydrochlorothiazide the direutic.</p> <p>The board was provided with the package inserts for Dutoprol, minutes from the Feb 2011 and Mar 2012 as well as a comparison chart.</p> <p>No Public Comments.</p> <p>No Board Comments.</p> | <p>Dr.Haneke made a motion accept Dutoprol as clinically equivalent.</p> <p>Dr Brown seconded the motion.</p> <p>The motion carried unanimously.</p> |

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| | <p>Dr Melton added that the 2nd part of this conversation that took place at the meeting last March was about the fix of the combination products. It came up with the diabetes agents also. Came up with a mock up on how they plan to best structure these combo products.</p> | |
| <p>III. Long-Acting Opioids – Class Re-review: New Agents (Nucynta ER & Butrans) a. Public Comment b. Committee Discussion and Recommendations</p> | <p>Background: Long acting opioids were approved for inclusion to the PDL in June 2009; they had previously been discussed in 2004 and were not added to the PDL at that time. Board members have packet inserts and minutes from all previous meetings</p> <p>Public Comment: Mary Cook, from Perdue, mentioned that they were transdermal systems for the indication of management of moderate to severe chronic pain for patients that require opioid analgesia round the clock consistently for a long period of time. Butrans should not be used for mild or acute pain or as a PRN analgesic or post operatively unless the patient was on long acting opioids prior to surgery.</p> <p>The package insert was recently revised by the FDA & has a new box warning with regards to abuse potential, respiratory depression & risk of accidental exposure.</p> <p>Board Discussion: Dr. Tietze asked what the advantage over the transdermal fentanyl was.</p> <p>Dr. Haneke does not see any advantages over fentanyl.</p> <p>Ms. Cook explained that is really just the dosing. No head to head data just referred to chart for comparison. Really just the type and severity of the pain.</p> <p>Dr. Sweet could not find any major advantages with this compared to other medications already on the large list of drugs in this class.</p> <p>Dr. Gill agreed, adding that she was concerned with patient’s safety using more than one patch and the long half life of the patch.</p> <p>Jennifer Stffel, with Johnson & Johnson to speak about Nucynta ER, an extended release of formulation of Tapentadol , a central-acting synthetic analgesic indicated for the management of moderate to severe chronic pain. Has recently received a 2nd indication for the neuropathic pain associated with diabetic peripheral neuropathy in adult patients. It is a schedule 2 opioid analgesic and has black box warning with regards</p> | <p>Dr. Tietze made a motion to consider both clinically the equivalent.</p> <p>Dr. Haneke seconded the motion.</p> <p>The motion carried unanimously.</p> |

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| | <p>to respiratory depression, risk of addiction and misuse. This has a unique mechanism in that it has the new opioid receptor activity and also has neupenephrin reuptake infision. The schedule ER dose ranges from 50 up to 250 mg dosed twice daily for a max dose of 500 mg.</p> <p>Dr. Tietze asked if they could add access to DERP evaluations to be available</p> <p>Dr. Brown questioned the advantages of Nucynta; what makes them different?</p> <p>Ms. Stuffel: The advantages that it will have different method of actions particularly in neuropathic pain where there was a different route that it works on for the pain, so you're hitting it from 2 different aspects. Also that due to the 2nd component, you don't have to get the same amount of opioids effects to get the pain relief, potentially minimizing side effects (i.e. GI issues).</p> <p>Dr Gill & Dr. Sweet have concerns about the differences.</p> | |
| <p>IV. Intranasal Corticosteroids– Class Re-review: New Agent (Qnasl) a. Public Comment b. Committee Discussion and Recommendations</p> | <p>Background: Qnasal was approved by the FDA Mar 2012 as Beclomethasone for treatment of allergic rhinitis. This class was last reviewed in Mar 2012 when Zetonna was approved for inclusion. Prior to this the topic was before the board in June 2008 and Feb 2005. Board members have packet inserts for all agents in the class, minutes from the 06/08 & 02/05 meeting as well as a chart summarizing all agents in this class.</p> <p>Public Comments: Kristen Chau, Teva, had head to head from a major medical conference but that are not yet published. Indications for tx of nasal symptoms associated with seasonal and perennial rhinitis in adults and children ages 12 y/o & older. 80% retention after 1 minute of application. Has a counter on the applicator to keep track of usage.</p> <p>Board Discussion: Dr. Haneke questioned the head to head study if they tested the efficacy of the nasal spray or just tracked the retention of the molecules in the nasal cavity.</p> <p>Kristen stated that it was just the retention of the molecule in the nasal cavity.</p> <p>Dr. Sweet added that in previous discussions it had never been discussed as far as the efficacy, just the perfume vs. non-perfume and water vs. non-</p> | <p>Dr. Haneke made a motion</p> <p>Dr. Brown seconded the motion.</p> <p>The motion carried unanimously.</p> |

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| <p>V. Biguanides – Class Re-review: New Agents (Riomet)</p> <p>a. Public Comment</p> <p>b. Committee Discussion and Recommendations</p> | <p>Background: Riomet is an oral solution approved for tx Type II diabetes is being proposed for inclusion in the Biguanides PDL class. Class was established May 2003, when the PDL Committee determined that immediate and extended release versions of that format were all therapeutically equivalent. Revisited in Oct 2004 & March 2007. Board has package inserts, as well as meeting minutes from 10/04 & 03/07 and a comparison chart.</p> <p>Public Comments: No Comments</p> <p>Board Discussion: Dr. Gill mentioned that in looking at the parameters, it looks very similar with regards to TMax, concentration very under the curve.</p> <p>Dr. Melton asked if the board wanted to pull the Caduet out of the class at this time. Dr. Sweet stated that they would wait to review this issue at the next meeting.</p> | <p>Dr. Haneke made the motion.</p> <p>Dr. Brown seconded the motion.</p> <p>The motion carried unanimously.</p> |
| <p>V. Combination Products for Allergic Rhinitis – New Class Review (Dymista) Reviewed; New Agents Class)</p> <p>a. Public Comment</p> <p>b. Committee Discussion and Recommendations</p> | <p>Background: Dymista was approved by the FDA in May for the treatment of seasonal allergic rhinitis in patients ages 12 & older. It is a combination and is being proposed to be included in the PDL Class of fixed dosed products for allergic Rhinitis. The PDL committee is asked to review if it is clinically equivalent to the two individual agents</p> <p>Public Comments: No Comments</p> <p>Board Discussion: Dr Tietze pointed out that it’s actually 2 classes already and he sees no difference.</p> <p>Dr. Melton pointed out that the 2 individual agents are already listed as preferred in their respective classes.</p> <p>Dr. Brown pointed out the systemic bioavailability of the fluticasone, and that the single agent is less than 2% but that in the combination it is 44% - 61% higher than mono therapy.</p> | <p>Dr. Brown made a motion</p> <p>Dr. Harte seconded the motion.</p> <p>The motion carried unanimously.</p> |
| <p>VI. Adjunct Antiepileptics – Class Re-review: New Agent (Potiga)</p> <p>a. Public Comment</p> | <p>Background: Potiga (ezogabine) is new agent to this class. It was approved in June 2011 used as adjunct therapy for partial seizures adult patients with epilepsy. It was given a Schedule 5 designation by the FDA in Dec 2011. Adjunct were reviewed by the board in March 2012, Potiga</p> | <p>Dr. Haneke made a motion to consider it clinically equivalent.</p> <p>Dr. Brown seconded the motion.</p> |

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| <p>b. Committee Discussion and Recommendations</p> | <p>appeared before the board previously in Sept 2011, at which time it was decided to wait for a final packet insert before making a decision. Prior to this the last review was June 2006.</p> <p>Public Comment: James Osborne, Glaxo Smith Kline, what makes this unique and different is the mechanism action. It is a first in class potassium channel opener. Opens channel earlier and stays open longer and allows potassium to flow out.</p> <p>Board Discussion: Dr.Haneke asked if they expect a black box warning.</p> <p>Mr Osborne said that Potiga had been out for over a year, so it is hard to predict that. Also noted that it is intended for neurologists & epileptologists.</p> <p>Not intended as a 1st line agent for primary care physicians and This is intended as a different option and is for patients that are already on an anti-epileptic</p> | <p>The motion carried unanimously.</p> |
| <p>VII. Incretin Mimetics – Class Re-review: New Agent (Victoza)</p> <p>a. Public Comment</p> <p>b. Committee Discussion and Recommendations</p> | <p>Background: Victoza was brought before the board in March 2012, at that time Norvo Nordisk had reported they had a head to head of Byetta and Victoza, which the board determined that they would like to review prior to considering Victoza to inclusion to this class. Was to be reviewed in September at the board meeting that was cancelled.</p> <p>Public Comment: Mike Ketcher, Norva Nordisk, reported that there were 2 studies conducted: a head to head against Byetta and one called Duration 6. In the lead 6 study of Victoza vs Byetta, it was reported that significantly more patients achieve their A1C goal of less than 7 if they were placed on Victoza relative to Byetaa. All patients are on background therapy with metformin, with or without a sulfonylurea. It was a randomized control trial published in the Lancet. At the end of 26 week period, the Byetta patients could cross over onto Victoza, they had a significant further reduction in their A1C, lost more weight, and their GI side effects came more in line with what you see with that of Victoza. The number needed to treat out of this study for a composite endpoint of achieving a hemoglobin A1C of less than 7, with no hypoglycemia and no weight gain is 6.7, or 7. Therefore out of every 7 pts treated you’re going to get 1 more patient to goal with Victoza vs. Byetta. Victoza is also once a day versus twice a day of the immediate release Byetta and has less antibody production.</p> | <p>Dr. Tietze made a motion to add Victoza to PDL and to make it preferred.</p> <p>The motion was seconded by Dr. Gill.</p> <p>The motion carried unanimously.</p> |

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| | <p>The Duration 6 study is reported on the public domain, and Mr. Kercher can only address the dosing and efficacy of Victoza. He stated that he cannot speak for Bydureon, as that data would have to be obtained from the manufacturer.</p> <p>Board Discussion: Dr. Tietze mentioned that he thinks that this is an important medication to have available and included in the class.</p> <p>Dr Sweet added to that she feels that Novo Nordisk had done what the board had asked, and has head to head documentation. She thinks this is superior and that there is evidence, perhaps to recommend it to the DUR committee.</p> <p>Dr. Melton stated that DUR has set up PA criteria around all 3 of these drugs, (Victoza, Byetta and Bydureon), with regards to a baseline A1C before they start and are appropriate for this therapy. Victoza is labeled after oral therapy. There is already a criterion for baseline and renewal A1C. The PDL board has the authority to determine if this one should be included, or if want to structure class differently or maybe to relook at how they want to do all 3.</p> <p>Dr. Ellermeier added that she thinks in the past the PDL Committee has made recommendations to a specific agent be included as a preferred agent.</p> <p>Dr. Sweet said there are 2 actions: to add Victoza to the class and also to say that there is evidence that Victoza is superior over exenatide based on head to head documentation.</p> | |
| <p>VIII. Biologics – Class Re-review: New Indication (Humira: Ulcerative Colitis)</p> <ul style="list-style-type: none"> a. Public Comment b. Committee Discussion and Recommendations | <p>Background: Biologics were added to the PDL in Dec 2009 and classes were created according to the FDA label indications. They were revisited in June 2010 when Actemra was added for adult rheumatoid arthritis agents. While Humira is already a PDL drug under other indications in the biologics class, the board is asked to include it for Ulcerative Colitis. Packet inserts and documentation provided to board members.</p> <p>No Public Comment</p> <p>No board discussion</p> | <p>Dr. Haneke motioned to add Humira to the PDL for new indication.</p> <p>Dr. Brown seconded the motion.</p> <p>The board passed unanimously.</p> |
| <p>IX. Pancreatic Enzyme Replacement Products – Class</p> | <p>Background: Pancreatic Enzyme Replacements were previously brought to the PDL only once, when the class was established June 2010. Agents</p> | <p>Dr. Haneke made the motion</p> |

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| <p>Re-review: New Agents (Pertzye, Ultresa, Viokace)</p> <ul style="list-style-type: none"> a. Public Comment b. Committee Discussion and Recommendations | <p>for inclusion at that time were Creon, Pancreaze MT and Zenpep. These agents were brought to the board in response to the FDA age requirements that all Pancreatic Enzyme Replacements would have to be FDA approved by an extended deadline of 2010. Board has packet inserts for all 3 new agents, minutes of 2010 meeting as well as a comparison chart.</p> <p>Public Comment: Megan Jennings, Aptalis, stated that Viocase is non enteric coated which is the major difference, is only for adults, and in combination with a proton pump inhibitor, is indicated for the treatment of exocrine pancreatic insufficiency due to chronic pancreatitis or pancreatectomy.</p> <p>The other ones, including Ultressa, are indicated for exocrine pancreatic insufficiency due to cystic fibrosis and other conditions.</p> <p>Ultressa has 18 years of clinical usage, which used to be Ultrace.</p> <p>Board Discussion: No board discussion.</p> | <p>Dr. Tietze seconded the motion.</p> <p>The board passed unanimously.</p> |
| <p>X. Bisphosphonates – Class Re-review: New Agent (Binosto)</p> <ul style="list-style-type: none"> a. Public Comment b. Committee Discussion and Recommendations | <p>Background: Binosto is an effervescent form of alendronate approved by the FDA in March 2012 to treat osteoporosis in post menopausal in women and increase bone mass in men due to osteoporosis. Last reviewed this class in Sept 2011 when Atelvia, was approved. Prior to that the Bisphosphonates was before the board in August 2006, February & June of 2005. Board has packet inserts on agents</p> <p>Public Comment: No public comment</p> <p>Board Discussion: Dr. Sweet indicated that she didn't see any difference in Binosto compared to other similar products and the group discussed the effervescent nature of the agent and how that may or may not be tolerated by the esophageal patients.</p> | <p>Dr. Gill made the motion to add to the class of Bisphosphonates.</p> <p>The motion was seconded by Dr. Haneke.</p> <p>The motion carried unanimously.</p> |
| <p>XI. Anticholinergics for the Maintenance Treatment of COPD – New Class Review (Spiriva, Tudorza)</p> <ul style="list-style-type: none"> a. Public Comment b. Committee Discussion and Recommendations | <p>Background: Spiriva was approved by the FDA 2004 and Tudorza in 2012; both are intended for the long-term maintenance treatment of bronchial spasms associated with COPD, including chronic bronchitis and emphysema. Spiriva has an additional indication includes COPD exacerbation.</p> <p>Public Comment: Julie McDavitt, Boehringer-Engleheim, addressed Spiriva Handihaler. It is an anticholinergic indicated for the long- term,</p> | <p>Dr. Haneke made the motion to recommend new class and add both Spiriva and Tudorza.</p> <p>Dr. Gill seconded the motion.</p> <p>The motion passed unanimously.</p> |

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| | <p>once daily maintenance therapy of bronchial spasms associated with COPD and for reducing COPD exacerbation. It is a dry powder that is delivered at slow rates of 20 meters/min, so to take into consideration the lung function to inhale this product. It is he only anticholingeric that has the indication for COPD exacerbation.</p> <p>Crystal Henderson, Forrest, addressed Tudorza. Its about 6% bioavailability, with only about 6% of the agent making it to the plasma. Rapidly and extensively metabolizes to inactive products. Plasma ½ life is about 1-2 minutes. Primarily all the drug is metabolized. One inhalation twice a day. Dosage tracker on the product. No dosage adjustments with age variations.</p> <p>Board Discussion: None</p> | |
| <p>XII. KanCare Update</p> <p>XIII. Open Public Comment</p> <p>XIV. Adjourn</p> | <p>Dr. Melton advised that the supplemental information was sent out already. Stated that any problems with getting drugs through KanCare can be referred to the state for troubleshooting. MCO's can offer suggestions to new classes as well. The meeting adjourned.</p> <p>No Public Comments</p> <p>Meeting adjourned at 11:45am</p> | |