

**Preferred Drug List Committee Meeting  
Meeting Minutes, Open Session  
March 14, 2012**

<p><b>Preferred Drug List Committee</b> Meeting Minutes, Open Session HP Enterprise Services Capital / Cedar Crest Room Topeka, KS</p>	<p><b>Members Present:</b> 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.</p> <p><b>Members Not Present:</b> Kristen Fink, Pharm.D. Matthew Schlotterback, M.D.</p> <p><b>KHPA Staff Present:</b> Kelley Melton, Pharm.D. Shelly Liby Shea Robinson Cheryl Coughlin</p> <p><b>HP Staff Present:</b> Nicole Churchwell, Pharm.D. Karen Kluczykowski, R.Ph. Lisa Todd, R.Ph.</p> <p><b>ACS Staff Present:</b> Bethany Noble, C.Ph.T</p>	<p><b>Representatives:</b> Jim Graham - J &amp; 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>
<p><b>TOPIC</b></p>	<p><b>DISCUSSION</b></p>	<p><b>DECISION AND/OR ACTION</b></p>
<p>I. Welcome and Announcements</p>	<p>Dr. Sweet called the meeting to order at 10:00 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. Melton provided general parking instructions for those in attendance. Deb Quintanilla from HP introduced Pam Girard as the new supervisor for Prior Authorization at HP. Dr. Melton introduced Dr. Terry Mills as a new board member. He currently serves as the Medical Director for Patient Care Systems at the Via Christi Clinic in Newton. Dr. Melton also introduced Kansas Medicaid's new Director, Dr. Susan Mosier. Dr. Melton announced Dr. Burke's departure from the PDL and DUR Boards, and reported that Dr. Sweet is serving as today's chairperson, with an</p>	

	<p>official election of a new chairperson to follow at the end of the meeting.</p> <p>Dr. Sweet asked all board members to introduce themselves and mention where they are currently practicing.</p>	
<p>II. Review and Approval of Sep. 14, 2011, Meeting Minutes</p>	<p>The draft minutes from the September 14, 2011, meeting were reviewed and approved as written.</p>	<p>Dr. Haneke moved to approve the 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>III. Adjunct Antiepileptics - (Class Previously Reviewed; New Agents in Class)</p> <p>a. Public Comment</p> <p>b. Committee Discussion and Recommendations</p>	<p><b>Background:</b> Onfi (clobazam) is a new agent in this class. Approved in October of 2011, Onfi is to be used as an adjunct treatment for seizures associated with Lennox-Gastaut syndrome in adults and children 2 years of age and older. Adjunct antiepileptics were reviewed at the September 2011 meeting, at which point it was determined to wait for the final package insert of Potiga before making a decision. This finalized package insert is still not available, although in December of 2011, Potiga was designated as a Schedule V medication by the FDA. Prior to this, the last review was in June of 2009, when Vimpat (lacosamide), Banzel (rufinamide), and KeppraXR (levetiracetam XR) were determined to be equivalent to existing members of this class. The class was established in February of 2006, and the minutes of both meetings are attached.</p> <p>Public Comment: No comments.</p> <p>Board Discussion: Dr. Harte questioned if Onfi should be a part of the adjunct anti-epileptic class as it is a benzodiazepine.</p> <p>Dr. Sweet stated that she considers that question to be a matter of efficacy of those agents in the anti-epileptic class, mentioning that this drug will show efficacy for seizure purposes, but not necessarily for anti-anxiety purposes. She said that this drug should be left in the anti-epileptics class, and sees nothing that would indicate it is any better, worse, or different than other agents already in the class.</p> <p>Dr. Melton reported that other benzodiazepines have quantity limits, but like clonazepam, Onfi will not have these limitations placed on it as it is to</p>	<p>Dr. Tietze made a motion to continue considering these drugs equivalent, and to add Onfi to the class.</p> <p>Dr. Haneke seconded the motion.</p> <p>The motion carried unanimously.</p>

<p>IV. Incretin Mimetics – (New Class Review)</p> <p>a. Public Comment</p> <p>b. Committee Discussion and Recommendations</p>	<p>be used for seizure indications.</p> <p><b>Background:</b> The Incretin Mimetics class of antidiabetic agents has not previously been reviewed by the PDL Committee. It includes three agents for potential PDL inclusion. Byetta (exenatide) was approved in April of 2005, while Victoza (liraglutide) followed in January of 2010. Both Byetta and Victoza are used as adjuncts to diet and exercise in patients with Type 2 Diabetes. Bydureon, an extended release form of exenatide, was approved by the FDA in January of 2012. It is given via once weekly administration, as opposed twice daily injections for Byetta and once daily injections for Victoza.</p> <p>Public Comment: Mike Ketcher, Novo Nordisk, spoke on behalf of Victoza. He said there have been numerous studies done with Victoza in Type-2 diabetes, and that several of these have been head-to-head. The LEAD-6 study compared exenatide and Victoza in patients with type-2 diabetes over 26 weeks. In that study, Mr. Ketcher stated that Victoza was shown to be statistically superior to exenatide in terms of hemoglobin A1c reduction and fasting plasma glucose reductions, while weight loss was similar. In this study, Victoza was shown to be tolerated significantly better at the end of the 26-week period. This study was published in Lancet and is part of the Victoza labeling, and is a direct, randomized, controlled head-to-head trial without bias (patients were on same background therapy, randomized with same duration of disease, and there were no differences between the populations). At the end of the 26-week study, patients who had been on exenatide had the option to switch to Victoza as part of an open-label extension study. Those who switched experienced significantly more A1c reduction, lost more weight, and their GI tolerability was similar to what it would have been had they started on Victoza therapy.</p> <p>Mr. Ketcher also described the results of a second head-to-head study of 26 weeks duration comparing Victoza to Januvia in type-2 diabetes patients on background standard therapy of metformin. Both doses (1.2 and 1.8 mg) of Victoza were shown to be clinically and statistically superior to patients that received Januvia 100 mg per day in terms of A1c, fasting plasma glucose, and weight loss. Victoza did have a higher degree of GI side effects compared to oral Januvia, but that subsided by the end of the 26-week period. An extension of this study was done out to 78 weeks and the patients continued to have favorable outcomes compared to Januvia.</p> <p>Mr. Ketcher described another study, which was funded not by Novo</p>	<p>Dr. Harte made a motion to consider Byetta and Bydureon clinically equivalent, but to table discussion of Victoza until the next meeting when the board has had a chance to review the studies.</p> <p>Dr. Tietze seconded the motion.</p> <p>The motion carried unanimously.</p> <p>Dr. Haneke suggested to Mr. Ketcher that he provide copies of the study for the next meeting to Dr. Melton, which he agreed to do.</p>
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	<p>Nordisk but by another manufacturer, and compared Bydureon to Victoza. In that study, Bydureon failed to meet their primary endpoint. Ketcher also reported that Victoza outperformed Bydureon in another sponsor study.</p> <p>Mr. Ketcher summarized that Victoza has shown superiority in those studies mentioned, and asked that the board consider Victoza for placement on the PDL.</p> <p>Dr. Sweet asked Mr. Ketcher if the black box warning is the same in terms of the thyroid tumors. Mr. Ketcher reported that the warning and safety portion of Victoza's label has been the same since launch, and added that they routinely meet with the FDA as part of post-marketing surveillance and continues to have an ongoing clinical trial program. Novo has had no change to their label or recommendations for additional monitoring since launch based on what has been seen in post-marketing and ongoing studies. He did report that the label has been updated with the LEAD-6 trial data.</p> <p>Board Discussion: Dr. Sweet stated that this is the first time the committee has seen head-to-head data done both by a drug's company and by another company. She mentioned that there has been discussion in the past regarding concerns about the thyroid cancer risk.</p> <p>Dr. Tietze stated that he has had a lot of experience with Victoza, which has generally been positive, but that the head-to-head data is something to consider. He stated he has had no experience with Bydureon, and he has concern about the delivery mechanism involved.</p> <p>Dr. Sweet stated that it will be hard to consider some agents clinically equivalent due the varied dosing of once daily versus once weekly. She asked if it was unusual to have a drug come before the board within the first six months of approval. She also asked if a drug, once meeting the rebating requirements, was on the list for the first six months.</p> <p>Dr. Melton stated that a drug does not go on the PDL until it has been before the committee.</p> <p>Lisa Todd clarified that as long as the drug has a federal rebate, that it is considered covered, and that there has been a standard to wait six months before bringing a drug to the PDL Committee in order to give clinicians some experience with it.</p>	
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	<p>Dr. Melton stated that as part of Medicaid Reform, some of the proposals from drug manufacturers have proposed a requirement that a drug go through the PDL process within the first six months of their release. She stated that she was not aware of any standard that has been adhered to.</p> <p>Dr. Melton then mentioned instances where standard release products are included in the same class as regular release products, including Keppra and Keppra XR in the adjunct antiepileptics and Ambien and Ambien CR in the Sedative Hypnotics class. For diabetic agents, metformin and metformin XR are in the same class.</p> <p>Dr. Haneke stated that the mechanism of delivery has been discussed in other classes, and that discussions of extended and immediate release drugs have been had previously. He asked if the studies mentioned by Mr. Ketcher could be made available to the board, as he would like to review these.</p> <p>Mr. Ketcher said that the LEAD-6 is in the package insert, but that these studies can be made available to the board.</p> <p>Dr. Sweet asked for the committee's thoughts on what should be done in this class.</p> <p>Dr. Harte stated that he would like to review the studies for Victoza, and then stated that he would like to consider naming the agents in this class therapeutically equivalent for now, but pending the results of a review of the studies for Victoza.</p> <p>Dr. Tietze said that he would like to review studies for information such as number needed to treat, which may be able to influence the board's decision. Dr. Sweet asked Mr. Ketcher if number needed to treat information was available.</p> <p>Mr. Ketcher reported that on the LEAD 1-6 studies the number for exenatide vs. Victoza is 6.67, which means that for every 7 patients treated with Victoza instead of Byetta, one more patient will achieve the composite or endpoint goal of an A1c less than 7.0. As a comparison, when initially released, Plavix had a number needed to treat of 200.</p> <p>Dr. Tietze said that, from what he understands, a number needed to treat of 10 or below should change behavior. He also said it is reasonable to want to review the studies as it is unprecedented for the Board.</p>	
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	<p>Dr. Melton stated for now, Byetta and Bydureon could be deemed therapeutically equivalent and Victoza could be added at a later meeting if deemed to be equivalent.</p> <p>Dr. Sweet asked what would be done with Victoza in the meantime.</p> <p>Dr. Melton reported that it would not be added to the PDL for now, but that it would continue to be covered.</p> <p>Dr. Landa Colvin-Marion asked how long it would be covered for.</p> <p>Dr. Melton stated it would be covered indefinitely, as long as it was rebatable.</p> <p>Dr. Sweet said that it makes sense to add Byetta and Bydureon to the PDL while leaving Victoza off the PDL until the next meeting, at which point the Board will have reviewed the Victoza studies.</p>	
<p>V. Bile Acid Sequestrants – (New Class Review)</p> <p>a. Public Comment</p> <p>b. Committee Discussion and Recommendations</p>	<p><b>Background:</b> The Bile Acid Sequestrants class has not been previously reviewed. These agents are primarily used in treating primary hyperlipidemia as an adjunct to diet. There are three agents in this class available for consideration today: cholestyramine, with brand names of Questran and Prevalite, colesevelam (Welchol), and colestipol (Colestid).</p> <p>Public Comment: No comments.</p> <p>Board Discussion: Dr. Sweet stated that she has experience with these drugs and sees no differences.</p>	<p>Dr. Harte made a motion that these agents be considered clinically equivalent.</p> <p>Dr. Tietze seconded the motion.</p> <p>The motion carried unanimously.</p>
<p>VI. Fixed Dose Combination Products for Diabetes – (Class Previously Reviewed; New Agents in Class)</p> <p>a. Public Comment</p> <p>b. Committee Discussion and Recommendations</p>	<p><b>Background:</b> Fixed-Dose Combination (FDC) drugs are products that contain two or more active ingredients in a single dosage form. The products available in combination form are also available as monotherapy products, often as generics. Kansas Medicaid has, in the past, managed these products in different ways – sometimes including a FDC with one or the other primary ingredient class, sometimes creating a new class of combo products if there was more than one agent, and other times not including them at all. However, at the February 2011 PDL meeting, classes of Fixed-Dose Combination products were established for hypertension, hyperlipidemia, diabetes, BPH, migraines, and arthritis. Criteria has been established that for these disease states, use of the FDC product is no more effective than using the individual products by themselves, and therefore preferred products may be selected based on cost-efficacy. Proposed for inclusion in the fixed dose combinations for</p>	<p>Dr. Haneke made a motion</p> <p>Dr. Colvin-Marion seconded the motion.</p> <p>The motion carried unanimously.</p>

	<p>Diabetes class are three new agents: Janumet XR (sitagliptin/metformin extended-release), Jentadueto (linagliptin/metformin), and Juvisync (sitagliptin/simvastatin).</p> <p>Public Comments: Eric Blake, Merck, stated that the company’s position for Juvisync is that there is an unmet need of diabetic patients who have cardiovascular risk but are not on a statin. He also stated that both Janumet XR and Juvisync are price neutral to Januvia, and that even with the introduction of these agents, patent expiry issues were not extended.</p> <p>Board Discussion: Dr. Sweet noted that the agents in this class, other than the Juvisync, are composed of two diabetic agents, noting that this is the only agent with a statin in it. Dr. Landa Colvin-Marion agreed, stating that there was a concern as to whether the same things were being treated. Dr. Sweet agreed, stated that she would have a hard time putting Juvisync in this class.</p> <p>Dr. Melton clarified that this class has not yet been placed on the PDL because how we want the PDL to actually look for these classes is undecided, but that the purpose of the Fixed-Dose Combination classes is to state that the two agents in a combination product are clinically equivalent to those same two agents used individually. For this reason, metformin and glimepiride, for example, don’t have the exact same therapeutic function, but when compared to their individual agents, they do.</p> <p>Dr. Sweet stated that in that example, both agents are still being used to treat diabetes.</p> <p>Dr. Colvin-Marion asked if we had an example in other classes where the two different agents in a combination product are being used to treat different indications.</p> <p>Dr. Sweet agreed that this is problematic in deeming these agents therapeutically equivalent to other agents in the class, as a combination product with two agents treating diabetes cannot be considered therapeutically equivalent to a product with only one agent used to treat diabetes in terms of hemoglobin A1c efficacy. Placing Juvisync in this class is essentially asking the board to sign off on a recommendation that sitagliptin alone is as effective for diabetes as sitagliptin plus metformin, which is not true.</p>	
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	<p>Dr. Melton described how the state is considering structuring the PDL for Fixed Dose Combinations, which may ameliorate some of these concerns. She suggested that mock-up could be done of this format that the board could review.</p> <p>Dr. Sweet did not think that this would help with their concerns, and Dr. Colvin-Marion stated that the concern was more that as the class itself is a Fixed Dose Diabetes class, sitagliptin may be equivalent, but not the entire product.</p> <p>Dr. Sweet stated that for the ethical and scientific rigor considerations of this committee, it would be difficult to label Juvisync as therapeutically equivalent to the other combination products.</p> <p>Dr. Melton asked that if the committee would like to take this stance, would they also want to re-review the Fixed Dose Combination products for hypertension, as we also have products in this class that also have statins.</p> <p>Dr. Mills noted that he didn't think that the drugs that cross disease states belong with other combination products treating just one disease state.</p> <p>Dr. Tietze asked if it was possible to deal with the class today by including the other proposed agents besides Juvisync.</p> <p>Dr. Sweet agreed that this was the best course of action, and stated that the board will also need to re-look at the Fixed Dose Combinations for Hypertension.</p> <p>Dr. Melton stated that we could look at both the Diabetes and Hypertension combination classes at the September meeting with the Caduet pulled out, with a mock up for the Hypertension class.</p>	
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<p>VII. Fixed Dose Combination Products for Hypertension – (Class Previously Reviewed; New Agents in Class)</p> <p>a. Public Comment</p> <p>b. Committee Discussion and Recommendations</p>	<p><b>Background:</b> This class was established at the February 2011 PDL meeting, along with the previously mentioned fixed dose classes for hyperlipidemia, diabetes, BPH, migraines, and arthritis. A new combination agent for hypertension, Edarbyclor, was approved in December of 2011. This drug is a combination of the angiotensin II receptor blocker azilsartan and chlorthalidone, a diuretic. As with other fixed dose classes, the board’s role is to determine if each fixed-dose combination medication is therapeutically equivalent to its individual agents used in combination.</p> <p>Public Comments: No Comments</p> <p>Board Discussion: Dr. Colvin-Marion mentioned that this appears to be another ‘me too’ drug, while Dr. Sweet stated that she found nothing that makes this drug therapeutically superior to others in class.</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. Colvin-Marion made the motion.</p> <p>Dr. Haneke seconded the motion.</p> <p>The motion carried unanimously.</p>
<p>VIII. Non-benzodiazepine Sedative Hypnotics – (Class Previously Reviewed; New Agents Class)</p> <p>a. Public Comment</p> <p>b. Committee Discussion and Recommendations</p>	<p><b>Background:</b> Intermezzo, a sublingual Zolpidem tablet, was approved for use in insomnia characterized by middle-of-the-night waking followed by difficulty returning to sleep. This agent is being proposed for inclusion in the non-benzodiazepine sedative hypnotics class on the PDL. This class was last reviewed at the June 2010 PDL meeting, when Edluar, another sublingual form of zolpidem, was approved for inclusion. Previous reviews of drugs for insomnia were done by the PDL Committee in June 2005 and February 2006. Eszopiclone (Lunesta®), zaleplon (Sonata®), and zolpidem (Ambien, Ambien CR) were reviewed in 2005 and determined to be equivalent. Ramelteon (Rozerem®) was evaluated in 2006 for possible equivalence with the other non-benzodiazepine sleep agents. However, it was determined, in a divided vote, to not be equivalent.</p> <p>Public Comments: Rupa Shah, representing Purdue Pharma, spoke on behalf of Intermezzo. Ms. Shah noted the indication of Intermezzo, which is the treatment of insomnia when a middle-of-the-night awakening is followed by difficulty returning to sleep. Intermezzo is not indicated when the patient has less than four hours before planned time of awakening, and is contraindicated in patients with hypersensitivity to zolpidem as anaphylaxis and angioedema may occur. Ms. Shah stated that Intermezzo is the only drug FDA-approved for this specific indication, and is taken</p>	<p>Dr. Haneke made a motion</p> <p>Dr. Harte seconded the motion.</p> <p>The motion carried, with Dr. Tietze as a dissenting vote.</p>

only once per night. She reported that the recommended dose of Intermezzo is 1.75 mg for women, those taking concomitant CNS depressants, those over the age of 65, and those with hepatic impairment. The recommended dose of Intermezzo is 3.5 mg for men. Ms. Shah reported that this dosing differs because women clear zolpidem from the body at a lower rate than men. She stated that Intermezzo is a sublingual tablet and should be not taken immediately after a meal.

Ms. Shah encouraged the board to review the full warnings and precautions in the package insert, but noted that some warnings and precautions included the following: Intermezzo has CNS depressant effects and that administration with other CNS depressants increases the risk of CNS depression; use with other sedative hypnotics, including zolpidem, is not recommended; the failure of insomnia to remit after 7-10 days of treatment may be indicative of a psychiatric and/or medical illness that should be evaluated. Ms. Shah also reported that complex behaviors have been reported in both sedative hypnotic-naïve and experienced patients. Because zolpidem is a schedule IV medication, patients with a history of addiction or substance abuse of drugs or alcohol should be monitored while taking Intermezzo.

Dr. Shah also reported that Intermezzo was evaluated in two randomized, double-blind, placebo-controlled studies in patients with primary insomnia characterized by difficulty returning to sleep after middle-of-the-night awakening. In a sleep lab study with scheduled dosing, 82 adults were randomized in a three-period crossover study. Objective and subjective sleep latency after a middle-of-the-night wakening was significantly decreased with doses of 3.5 mg and 1.75 mg of Intermezzo compared with placebo. In the outpatient study with as-needed dosing, 295 adult patients were randomized to Intermezzo 3.5 mg or placebo in a 4-week study. In patients randomized to Intermezzo, time to fall back asleep after middle-of-the-night wakening was significantly shorter. Ms. Shah reported that the most common adverse events in the outpatient study were headache, nausea, and fatigue.

Ms. Shah also reported that a driving safety study was conducted to measure the effects of middle-of-the-night administration of Intermezzo on next morning driving performance. Forty healthy subjects were randomized in a double-blind, placebo-controlled, active-control trial. Results showed a statistically significant impairment when Intermezzo was dosed 3 hours prior to driving. When driving began 3 hours after taking Intermezzo, testing was terminated in one woman due to somnolence.

	<p>When driving began four hours after taking Intermezzo, statistically significant impairment was not found, but numerically Intermezzo was worse than placebo. A potential negative effect cannot be excluded in some patients four hours after taking Intermezzo.</p> <p>Board Discussion: Dr. Sweet asked Ms. Shah if she knew of any other agents that included driving information. Ms. Shah reported that she did not know of any other similar driving studies that have been conducted for Intermezzo. Dr. Sweet commented that the driving effects were worrisome compared to other agents, and that this may be difficult to help patients understand.</p> <p>Dr. Tietze noted that the sex-specific dosing is unique, and wondered why this was not a concern for other zolpidem products. Ms. Shah reported that the separation of dosing by gender was necessary due to pharmacokinetic information that came about from this specific formulation of zolpidem. She reported that she could not comment on the specific dosing of other zolpidem products. Dr. Tietze noted that the board should potentially be concerned with dosing of other zolpidem products as well. Dr. Mills noted that while men and women are different, this is the only FDA-approved drug with dosing that varies by gender. He stated that this seems like a huge potential for error.</p> <p>Dr. Sweet stated that she approached the topic thinking this would be a ‘me too’ drug with all agents the same in terms of efficacy, but now has concerns about safety given the driving data as well as the dosing.</p> <p>Dr. Haneke mentioned that the driving information may be something that is just now being teased out in the safety data, as three other products have been on the market.</p> <p>Dr. Mills mentioned that if study data in this case was able to find a metabolic difference that maybe the board needs to look more closely at the data for the other sublingual version of zolpidem. Dr. Tietze noted this may need to be done for the other forms of zolpidem.</p> <p>Dr. Nicole Churchwell noted that in the package insert for Ambien that it states that there have been reports of people getting out of bed after taking a sedative hypnotic and driving their cars while not fully awake. Dr. Sweet stated that this information is different than a situation where the number of hours recommended prior to driving is detailed.</p>	
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	<p>Dr. Tietze questioned whether there is a need for this medication to be available given that it may not have a sound clinical role in therapy, but said this is would be a clinical consideration outside of the board’s scientific scope. Dr. Sweet agreed that that is a clinical matter, but stated that looking at the pharmacokinetics and pharmacology of the drug, there is no reason for it to be placed in a separate class. She suggested that the drug be deemed equivalent, added to the class, and that utilization should be monitored. She also mentioned that dosing should be watched somehow.</p> <p>Dr. Colvin-Marion commented that although dosing was separated out based on gender, the pharmacokinetic data in the package insert was not reported separately.</p> <p>Dr. Melton mentioned that Dr. Churchwell thought review by the DUR Board to place a gender restriction on the 3.5 mg dose was possible. Dr. Haneke did not see that gender restrictions would be appropriate with only two supporting studies available.</p>	
<p>IX. Urologic Agents – (Class Previously Reviewed; New Agents in Class)</p> <p>a. Public Comment</p> <p>b. Committee Discussion and Recommendations</p>	<p><b>Background:</b> Anturol is a new topical gel form of the drug oxybutynin delivered using a metered-dose pump. Approved in early December of 2011 for the management of overactive bladder, Anturol is being proposed for inclusion in the Urologic Agents: Anticholinergics (Drugs for Urinary Incontinence) PDL Class. This class was last reviewed in June of 2009, at which point Toviaz (festerodine) and Gelnique (another topical oxybutynin product) were deemed therapeutically equivalent to existing agents in the class. Prior to that meeting, the last review was in 2005. Information provided to board members today includes package inserts for all agents in the class, as well as previous meeting minutes, and a chart summarizing all agents.</p> <p>Public Comment: No comments.</p> <p>Board Discussion: Dr. Sweet stated that she sees nothing different with these agents in terms of efficacy, and differences in dosage forms have previously been discussed in this meeting.</p>	<p>Dr. Harte moved to consider Anturol clinically equivalent.</p> <p>Dr. Tietze seconded the motion.</p> <p>The motion carried unanimously.</p>
<p>X. Intranasal Corticosteroids – (Class Previously Reviewed: New Agent in Class)</p> <p>a. Public Comment</p>	<p><b>Background:</b> Approved by the FDA in January 2012, Zetonna (ciclesonide) is a nasal spray for the treatment of allergic rhinitis. It is being proposed today for inclusion in the Intranasal Corticosteroids PDL class. This class was last reviewed in June of 2008, when Omnaris, also</p>	<p>Dr. Mills made a motion that Zetonna is clinically equivalent to other agents in the class.</p>

<p>b. Committee Discussion and Recommendations</p>	<p>generic ciclesonide, was approved for inclusion. Prior to this, the topic was before the board at the February 2005 meeting, at which time all products presented were deemed therapeutically equivalent.</p> <p>Public Comment: No Comment.</p> <p>Board Discussion: Dr. Sweet noted that this drug is the same drug as previously added, just in a different spray form.</p>	<p>The motion was seconded by Dr. Haneke.</p> <p>The motion carried unanimously.</p>
<p>XI. Medicaid Reform</p>	<p>Dr. Melton addressed the board regard Medicaid Reform, stating that available information is somewhat limited due to the fact that the state is still in the procurement process of determining what managed care companies will be offering services to Kansas Medicaid beneficiaries. The general plan, however, is to put the majority of beneficiaries into managed care with three companies providing services. The current PDL is for the Kansas Medicaid fee-for-service population, who will be going into managed care, but the RFP for KanCare did require the MCOs to use one state-mandated PDL. This will hopefully make this an easier transition for providers in some ways. Regarding the board's role, the state plans to continue to have a PDL board, and there will continue to be an opportunity for the board members to be involved, should they wish to serve.</p> <p>Dr. Sweet wondered if there was any information on the legislature considering pushing KanCare back six months. Dr. Melton replied that they may make a resolution that makes this suggestion to the governor's office, and the state is also watching these decisions.</p> <p>Dr. Sweet also asked if there was a specific date that the RFPs have to be back by. Dr. Melton answered that the responses to the RFP were due by the end of January.</p> <p>Dr. Harte asked who would not be included in managed care plans. Dr. Melton replied that this was very limited, but included SOBRA and MediKan beneficiaries. She also stated that nursing homes were included, and that 99% of beneficiaries will be in.</p> <p>Dr. Harte also stated that he is getting many questions from nursing facilities about per diems potentially coming out for assisted living, with the concern being that facilities would have to pay for medications on a limited per diem. Dr. Melton stated that she didn't know the RFP requirements specific to nursing homes, but did state that the MCOs were required to demonstrate how they planned to manage patients currently in</p>	

	<p>nursing homes or who have the potential to be in a nursing home.</p> <p>Dr. Sweet stated that it will be interesting to see how the plan works, as fees should not be cut, outcomes improved, and the state plans to save money. Dr. Melton stated that the theory is that better coordination of care will lead to less duplication of services and less adverse outcomes that result because of lack of communication. She also mentioned the importance of having a feedback cycle so that we can receive provider input on these changes.</p>	
XII. Public Comment Policy Update	<p>Dr. Melton mentioned that potential public comment policy changes, which were discussed at the September meeting, have not yet been reviewed by the DUR Board. However, feedback has been received by representatives of PhRMA, and it seems, in general, to still be a well-received idea.</p>	
XIII. Selection of New Chairperson	<p>Dr. Sweet asked if election of a new chairperson was needed today, at which time she was informed by Dr. Melton that she had been the only board member to volunteer for the chairperson role.</p>	<p>Dr. Harte nominated Dr. Sweet as the Board Chairperson.</p> <p>The motion was seconded by Dr. Haneke.</p> <p>The motion carried unanimously, with the exception of Dr. Sweet, who abstained.</p>
XIV. Open Public Comment	<p>Jim Baumann, Pfizer, asked if members for the PDL and DUR Boards would be solicited from the companies who win the managed Medicaid contracts. Dr. Melton stated that this is currently undecided, and mentioned that this may depend upon the companies that are selected and the suggestions that they offer.</p>	
XV. Adjourn	<p>The meeting adjourned.</p>	