

Preferred Drug List Committee Meeting

Meeting Minutes, Open Session

September 18, 2013 10:00 a.m.

HP Enterprise Services-Capital Room

6700 SW Topeka Blvd. Bldg. 283 J, Topeka, Kansas 66619

Board Members Present:

Taylor Gill, Pharm. D.
Jonalan Smith, Pharm. D.

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

Matthew Schlotterback, M.D.
Dennis Tietze, M.D.

KDHE-DHCF Staff:

Katy Brown, Pharm. D.

Kelley Melton, Pharm. D.

Brandy Allen

HP Staff Present:

Nancy Perry, R.N.

HID Staff Present:

Nicole Ellermeier, Pharm. D.

Public Attendees:

Matthew Stafford, Merck
Bob Gustafson, Lundbeck
Heather Jones, GlaxoSmithKline
Phil King, Pfizer
Sara Nollette, Novartis
Mike Ketcher, Novo Nordisk
Kathy Conrad, Astellas
Janie Huff, Takeda
Rob Hansen, Pfizer
Adriana Sanchez, Supernus
Carol A. Curtis, Astra-Zeneca
Brieana Buckley, Biogen Idec
Mike Krug, Sunovion
Marla Wiedenmann, Novo Nordisk

Berend Koops, Merck
Joel Meyer, Novartis
Teresa Blair, Amgen
Tara Waycock, Boehringer-Ingelheim
Barbara Felt, GlaxoSmithKline
Jeff Knappen, Allergan
Lisa Borland, Vertex
Kass Gray, Takeda
Russ Wilson, J&J
Justin Crum, Gilead
Chad Tabor, Teva
Brian Strickland, Gilead
Don Larsen, Forest

Dave Sproat, Bristol-Myers Squibb
Sam Smothers, MedImmune
Eric Gardner, Vertex
Mary Shefcyk, Novo Nordisk
John Brunson
Joe Summers, UCB
Susan Zalenski, J&J
Jim Baumann, Pfizer
Carmen Oliver, Biogen Idec
Scott Edelhauser, Alcon
Kathleen Karnik, Janssen
Brian Rose, Merck
Terry McCurren, Otsuka

Item	Facilitator (s)	Notes
Welcome and Announcements	<i>Dr. Sweet, M.D.</i>	<p>Dr. Sweet called the meeting to order at 10:00 am and reminded the public to provide ‘Disclosure of Interest’ forms if they intend to speak.</p> <p>Dr. Ellermeier provided general parking instructions for those in attendance.</p> <p>Dr. Melton introduced Dr. Katy Brown, a new pharmacist with the Division of HealthCare Finance. She had previously served on the PDL Board, and started with the state in August.</p> <p>She also introduced Dr. Jonalan Smith as a new PDL board member, and introduced the MCO Directors of Pharmacy: Jennifer Murff, Lisa Todd, and Tom Kaye.</p> <p>Dr. Melton mentioned the 5 minute time limit for speakers, and re-iterated information on head-to-head studies is welcome.</p>
Review and Approval of March 13, 2013 Minutes	<i>Dr. Sweet, M.D.</i>	<p>The draft minutes from the March 13, 2013 meeting were reviewed & approved as written.</p> <p>Dr. Gill moved to approve the minutes. Dr. Sweet seconded the motion.</p> <p>The motion carried unanimously and the minutes were approved.</p>
Hepatitis C Protease Inhibitors – New Class Review (Incivek & Victrelis)	<i>Dr. Sweet, M.D.</i>	<p>Background: Approved in May of 2011, Incivek (telaprevir) and Victrelis (boceprevir) are the first protease inhibitors approved that directly target the Hepatitis C virus. Both are generally indicated for the treatment of genotype 1 chronic Hepatitis C virus (HCV) in combination with peginterferon alfa and ribavirin in adult patients with compensated liver disease, including cirrhosis, who are treatment-naive or who have been previously treated with interferon-based treatment. Included for the board’s considerations are package inserts of both medications and a comparison chart.</p> <p>Public Comment: Lisa Borland, Vertex Pharmaceuticals, addressed the committee regarding Telaprevir, which is known commercially as Incivek. It is indicated for the treatment of genotype 1 chronic Hepatitis C in adults with compensated liver disease, including those with cirrhosis. Telaprevir is indicated for those who are new to</p>

		<p>therapy or who have received prior treatment with an interferon-based regimen. Borland stated that a boxed warning was added to the label last December for serious skin reactions, and that the appropriate management of these skin reactions is outlined in the boxed warning. She stated that telaprevir must always be used in combination with peg-interferon and ribavirin, and that the recommended dose is 750 mg given orally three times daily with food that is not low fat. A full regimen is telaprevir with pegylated interferon and ribavirin for 12 weeks for all patients, which is followed by another 12 or 36 weeks with just peg-interferon and ribavirin. The treatment duration is defined by treatment history as well as viral response at weeks 4 and 12. In Phase 3 pivotal trials, the majority of treatment naive and prior relapser patients were eligible to shorten their treatment time by half (from 48 to 24 weeks). HCV RNA levels at weeks 4 and 12 are also used to assess treatment futility. Head-to-head studies have been conducted with peg-interferon and ribavirin as the control, and have consistently demonstrated significant improvements in SVR rates over the previous standard of care of peg-interferon and ribavirin alone. Borland stated that SVR is defined as undetectable virus 24 weeks post completion of therapy, which is essentially a viral cure. Long-term studies with peg-interferon and ribavirin have demonstrated that achieving an SVR is associated with a reduction in some of the long-term liver-related consequences from chronic Hepatitis C. such as de-compensation, hepatocellular carcinoma, and liver transplantation. In pivotal Phase III studies, for the treatment naïve population, nearly 80% of patients treated with telaprevir achieved SVR, while less than half achieved SVR with peg-interferon and ribavirin alone. For the treatment experienced population, SVR rates were four to six times higher in telaprevir-treated patients. This was seen across a variety of sub populations, including those that historically had had a low response to peg-interferon and ribavirin alone, namely African Americans and cirrhotic patients. Because all 3 drugs must be used together, contraindications to peg-interferon and ribavirin also apply. Additionally, there are contraindications related to co-administration with certain drugs due to an increased risk of serious adverse reactions or reduced exposure to telaprevir. Borland stated that the adverse events that most commonly lead to discontinuation of therapy were rash, anemia, fatigue, pruritus, nausea, and vomiting.</p> <p>Matt Stafford, Merck, stated that the indications for the protease inhibitors are the same, but that Victrelis is dosed differently. Four weeks of lead-in therapy with peg-interferon and ribavirin are required, and then Victrelis therapy is started based on the response that the patient has had to lead-in therapy. This allows for potential cost savings in identifying non-responders, as about 10-15% won't respond to peg-interferon and ribavirin therapy. In this way, non-responders can be identified early on, and Victrelis therapy can be avoided. The dosing is 800 mg three times daily, and</p>
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		<p>the SVR response rate ranges from 65-75% depending on the patient population.</p> <p>Dr. Sweet asked if there were any head-to-head studies with telaprevir and boceprevir. Stafford stated that there have not been any studies. Dr. Sweet also asked what Victrelis' food requirements were. Stafford stated that dosing is with or without food. Dr. Sweet stated that this is an important difference, as Victrelis requires dosing with 20 grams of fat, and that this requires patient education as to what constitutes 20 grams of fat.</p> <p>Board Discussion: Dr. Sweet asked Dr. Melton how these drugs are currently managed. Dr. Melton stated that both drugs currently have clinical PA criteria that was revised at the July DUR meeting to make criteria more clear.</p> <p>Dr. Sweet stated that looking at data, the drugs appear to be equivalent in outcomes, and that decisions are made based on what side effects a patient can better tolerate. Dr. Sweet stated that, having used both drugs for her patients, the skin issues have not been significant, but that anemia has been an issue.</p> <p>Dr. Gill moved to consider both agents clinically equivalent. Dr. Tietze seconded the motion.</p> <p>The motion carried unanimously.</p>
<p>Non-Steroidal Anti-Inflammatory Drugs (Ophthalmic) – Class Re-review: New Agent (Ilevro)</p>	<p><i>Dr. Sweet, M.D.</i></p>	<p>Background: The Ophthalmic NSAIDs were reviewed as a new class at the February 17, 2011 PDL meeting. At that time, all proposed agents (bromfenac (Bromday/Xibrom), diclofenac (Votaren), ketorlac (Acular/Acular LS/Acuvail), nepafenac (Nevenac), flurbiprofen (Ocufen)) were approved for inclusion in the class. Presented today for the board's consideration is Ilevro (nepafenac), an agent approved in December of 2012 for the treatment of pain and inflammation associated with cataract surgery. Included for the board are minutes of the February 17, 2011 meeting, all package inserts, and a comparison chart.</p> <p>No Public Comment</p> <p>Board Discussion: Dr. Gill stated that this appeared to be very similar to Nevanac, but that it appears to be triple the concentration, and has gone from TID dosing to once daily dosing. Gill stated that her concern was if changing the dosing schedule changed the duration of action.</p>

		<p>Scott Edelhauser, Alcon, stated that Ilevro is the once-a-day formulation of Nevanac, and that what is happening in the cataract procedure marketplace is that a lot of prescribers are going to a once-a-day formulation. The once-a-day formulation has a smaller particle size, which allows for more penetration. The side effect profiles are very similar, and head-to-head studies with Nevanac have shown clinical equivalency.</p> <p>Dr. Gill asked what the duration of use was for Ilevro. Edelhauser stated that most patients will use the medication for two weeks post-cataract surgery, although some may use it for longer.</p> <p>Dr. Haneke moved to add Ilevro to the Ophthalmic NSAIDs class. Dr. Schlotterback seconded the motion.</p> <p>The motion carried unanimously.</p>
<p>Dipeptidyl Peptidase-4 Inhibitors – Class Re-review: New Agents (Nesina)</p>	<p><i>Dr. Sweet, M.D.</i></p>	<p>Background: The newest DPP-4 Inhibitor Nesina (alogliptin) was approved by the FDA in January of 2013 as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. The PDL Board last visited the DPP-4 class when Tradjenta (linagliptin) was reviewed at the September 14, 2011 meeting. Other agents in class also include Januvia (sitagliptin) and Onglyza (saxagliptin). Included in the board’s packet are previous meeting minutes, package inserts of all agents, and a comparison chart.</p> <p>Public Comment: Janie Huff, Takeda, stated that she was available to answer any questions.</p> <p>Board Discussion: Dr. Sweet stated that in her review, she did not see any significant differences from other agents in the class.</p> <p>Dr. Haneke moved to add Nesina to the DPP4 Class. Dr. Gill seconded the motion.</p> <p>The motion carried unanimously.</p>
<p>Fixed Dose Combinations for Diabetes – Class Re-review: New Agent (Oseni, Kazano)</p>	<p><i>Dr. Sweet, M.D.</i></p>	<p>Background: Approved by the FDA in January 2013 in conjunction with Nesina (alogliptin), fixed-dose combination products Oseni (alogliptin & pioglitazone) and Kazano (alogliptin & metformin) are presented for the board’s consideration. This class was last reviewed at the March 14th, 2012 PDL meeting, when Janumet XR (sitagliptin & metformin XR), Jentadueto (linagliptin & metformin), and Juvisync (sitagliptin & simvastatin) were all approved for inclusion in the class. When</p>

		<p>reviewing fixed-dose combination classes, the board is not being asked to review equivalency between agents in the class, but between a given combination product and its individual agents. Included for consideration are previous meeting minutes, package inserts of all products in class, and a comparison chart.</p> <p>Public Comment: Janie Huff, Takeda, stated that she was available to answer any questions.</p> <p>Board Discussion: Dr. Sweet stated that the drugs in the combination product are equivalent to their individual agents.</p> <p>Dr. Tietze moved to add Oseni and Kazano to the Fixed Dose Combination Products for Diabetes Dr. Smith seconded the motion.</p> <p>The motion carried unanimously.</p>
<p>Urologics: Beta-3 adrenergic agonists– New Class Review (Myrbetriq)</p>	<p><i>Dr. Sweet, M.D.</i></p>	<p>Background: Myrbetriq (mirabegron) is an overactive bladder agent with a novel mechanism of action. It is an agonist of the beta-3 adrenergic receptor, which relaxes the detrusor smooth muscle during the storage phase of the urinary bladder fill-void cycle, increasing bladder capacity. More agents within this class are in development. Presented for the board’s consideration today are Mybetriq’s package insert and a summary chart.</p> <p>Public Comment: Kathy Conrad, Astellas, stated that she was available for questions.</p> <p>Board Discussion: Dr. Tietze stated that he has used this drug for his patients and it has worked well. Dr. Sweet stated that there will be more agents coming in this class.</p> <p>Dr. Smith moved to add the Beta-3 adrenergic agonists as a new class. Dr. Haneke seconded the motion.</p> <p>The motion carried unanimously.</p>
<p>Triptans – Class Re-review: New Agent (Zecuity)</p>	<p><i>Dr. Sweet, M.D.</i></p>	<p>Background: With the January 2013 approval of Zecuity (sumatriptan iontophoretic transdermal system), patients now have another option for sumatriptan drug delivery. Approved for the treatment of acute migraine with or without aura in adults, Zecuity is a single-use battery powered patch that delivers sumatriptan through the skin. The Triptan class, initially established at the June 16, 2004 PDL meeting, was last re-visited at the September 14, 2011 PDL meeting when Alsuma, Sumavel DosePro, and</p>

		<p>Imitrex StatDose were added to the class. Included for the board’s consideration are all previous meeting minutes, package inserts, and a class comparison chart.</p> <p>No Public Comment</p> <p>Board Discussion: Dr. Sweet clarified that the board is tasked with making sure that the drug component is clinically equivalent. Dr. Melton stated that this is especially true in this class, where triptan products are available through a variety of delivery systems.</p> <p>Dr. Melton also mentioned that this is not yet a covered product, as the manufacturer does not participate in drug rebate, but that the state chose to bring the product anyway in preparation for the possibility that the state would have to eventually cover the product.</p> <p>Tom Kaye, Sunflower, questioned if this would be considered a drug or a device. Dr. Brown stated that Zecuity was approved as an iontophoretic transdermal system.</p> <p>Dr. Sweet stated that there appears to be no therapeutic advantage to this delivery system, and that she considers it clinically equivalent.</p> <p>Dr. Gill moved to add Zecuity to the Triptans class. Dr. Smith seconded the motion.</p> <p>The motion carried unanimously.</p>
<p>Sodium-Glucose Cotransporter 2 (SGLT2) Inhibitors – New Class Review (Invokana)</p>	<p><i>Dr. Sweet, M.D.</i></p>	<p>Background: Another new agent with a novel mechanism of action is Invokana (canagliflozin), approved in March of 2013 as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Invokana inhibits SGLT2, a cotransporter expressed in the renal tubules that is responsible for the majority of the reabsorption of filtered glucose from the tubular lumen. By inhibiting SGLT2, Invokana reduces reabsorption of glucose and lowers the renal threshold for glucose, thereby increasing urinary glucose excretion. Included in the board’s packets today is the Invokana package insert and a summary chart.</p> <p>Public Comment: Kathleen Karnik, Janssen, stated that Invokana does have a unique mechanism of action. Invokana lowers the renal threshold, which in normal adults patients is about 180 mg/dL and in diabetic patients is about 240 mg/dL. Invokana re-sets this threshold down to 70-90 mg/dL by eliminating approximately 400 calories per day through the excretion of glucose. Unlike the other agents currently on the</p>

		<p>market, Invokana eliminates excess glucose. There were nine Phase III double-blind randomized, controlled, international studies with over 10,000 patients. Three of these studies were head-to-head: two against Januvia, and one against glimepiride. It was also studied as monotherapy, as dual combination therapy, as triple therapy, as combination therapy with insulin. It was also studied in patients at high risk for cardiovascular disease, older patients, and patients with moderate renal impairment. In all cases, Invokana produced clinically and statistically significant improvement in A1c, fasting blood glucose levels, 2-hour post-prandial glucose levels, systolic blood pressure, and weight. The studies also demonstrated statistically significant reductions in the primary endpoint of hemoglobin A1c at 26 and 52 weeks. Invokana 300 mg showed greater reductions in A1c from baseline compared to both sitagliptin and glimepiride. 19.8-47% achieved a goal hemoglobin A1c of less than 7 on Invokana 100 mg, and 24-64% achieved this goal with Invokana 300 mg. Patients in these studies had been stabilized on other medications prior to adding Invokana. Side effects are associated with the mechanism of action and include genital mycotic infections, urinary tract infections, and volume-related events, which cause increased hypotension and urination. Rates of hypoglycemia were similar to placebo.</p> <p>Board Discussion: Dr. Tietze asked if number needed to treat information was available. Karnik stated that she did not have this data readily available, but stated that the reductions seen with Invokana were significant in meeting goals related to hemoglobin A1c levels.</p> <p>Dr. Tietze stated that he was concerned about the excessive urination, and asked Karnik about the incidence of urinary side effects. Karnik stated that genital mycotic infections occurred in 10-11% of patients, versus 3% in the placebo group, while urinary tract infections occurred in 4.3-5.9% of Invokana patients, compared to 4% in the placebo group. She stated that genital mycotic infections were the most common side effect, and were managed with over the counter products and prescription medications.</p> <p>Dr. Tietze also asked if this would be a future weight loss drugs. Karnik stated that it would not be, as the weight loss that was seen was anywhere from 2.2-5.0 kg. Typically a weight loss agent needs to result in over 5% weight loss to be considered solely for this use. Dr. Tietze asked if weight loss continues over the duration of use of the drug. Karnik stated that the majority of weight loss is seen in the first few weeks of therapy, and the patient's weight stabilizes from that point.</p> <p>Tom Kaye, Sunflower, asked Karnik about the incidence of bone fracture seen with</p>
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		<p>Invokana. Karnik stated that there were some bone density issues seen, but that fractures were not seen. She also stated that it is not recommended for elderly patients to receive the 300 mg dose of Invokana. Dr. Sweet asked how quickly changes in bone density were seen. Karnik stated that this was seen in the 26-week trial, and that this is continuing to be monitored.</p> <p>Dr. Sweet stated that more of these drugs will be seen, so it makes sense to begin the class, but that careful attention should be paid to toxicity in this class.</p> <p>Dr. Haneke moved to establish the SGLT2 class. Dr. Tietze seconded the motion.</p> <p>The motion carried unanimously.</p>
<p>Oral Multiple Sclerosis Agents – New Class Review (Aubagio, Gilenya, Tecfidera)</p>	<p><i>Dr. Sweet, M.D.</i></p>	<p>Background: Being proposed as a new class today are the oral Multiple Sclerosis Agents Aubagio (teriflunomide), Gilenya (fingolimod), and Tecfidera (dimethyl fumarate). Aubagio and Tecfidera are indicated for the treatment of patients with relapsing forms of multiple sclerosis, while Gilenya is indicated for the treatment of patients with relapsing forms of multiple sclerosis to reduce the frequency of clinical exacerbations and to delay the accumulation of physical disability. Included for board review today are package inserts for all agents in class and a comparison chart.</p> <p>Public Comment: Brianna Buckley, Biogen Idec, stated that Tecfidera was recently approved as an oral medication to treat relapsing forms of multiple sclerosis. It is a delayed-release capsule that may be administered with or without food, and the starting dose is 120 mg twice daily for 7 days, followed by a maintenance dose of 240 mg twice daily. The mechanism by which Tecfidera exhibits its effects is unknown, but it is known that dimethyl fumarate and its metabolite, monomethyl fumarate, have been shown to activate the NRF2 pathway, which is involved in cellular response to oxidative stress. The efficacy of Tecfidera was established in two phase III clinical studies that were placebo-controlled, 2 years in duration, and included over 2,600 patients. Study 1 is known as the DEFINE study, and Study 2 is known as the CONFIRM study. Both were published in the New England Journal of Medicine in 2012. Treatment with Tecfidera significantly decreased the annual relapse rate, with a relative reduction of 53% compared to placebo in Study 1, and 44% in Study 2. There was also a significant reduction in the proportion of patients experiencing a relapse, and this relative decrease was 49% in Study 1 and 34% in Study 2. Improvement was also demonstrated in measures of disability and neuroradiologic outcomes relative to placebo. Tecfidera has no contraindications, but a decrease in lymphocyte counts was seen in patients treated with Tecfidera, as they saw a decrease in lymphocyte counts</p>

		<p>of 30% from baseline, which was observed in the first year of the study, after which point, lymphocyte counts stabilized. The incidence of infections and serious infections was similar between Tecfidera and placebo. There were a small amount of patients who experienced a lymphocyte count below the normal range, but no difference was seen in rates of infections or serious infections when these patients were compared to those with lymphocyte counts in the normal range. A CBC is recommended prior to starting Tecfidera, and then annually and when clinically recommended. The most common adverse events were flushing, abdominal pain, nausea, and diarrhea. 40% of patients in phase III studies experienced flushing, which began soon after initiating Tecfidera, and resolved over time. Three percent of patients discontinued Tecfidera due to flushing in the clinical studies. GI events were seen earlier in the course of therapy and decreased over time. Four percent of patients discontinued Tecfidera due to these side effects in the clinical studies.</p> <p>Dr. Gill asked if patients in Tecfidera trials were treatment naïve or if they had failed other therapies in the treatment of their MS. Buckley stated that there was a mix of patients, 30% of patients in the DEFINE study were treatment naïve and 40% of patients in the CONFIRM study were treatment naïve.</p> <p>Dr. Sweet asked if any PML was seen in the Tecfidera trials. Buckley stated that there have been no cases of PML seen. She stated that in Germany, dimethyl fumarate is marketed as Fumaderm, in conjunction with monoethyl fumarate. There have been 3 cases of PML associated with Fumaderm, and another case from a compounded product. In all cases there were significant confounding factors, such as being immunosuppressed, previous treatment with Raptiva, and sarcoidosis.</p> <p>Dr. Sweet asked if Fumaderm has the same lymphocytopenia. Buckley clarified that Tecfidera does not cause lymphocytopenia, as the decrease seen in lymphocytes is still within the normal range. Dr. Sweet asked if Fumaderm causes the same lowering of lymphocytes. Buckley stated that Fumaderm does have some recommendations around CBC monitoring, but that there are no warnings calling out lymphocytopenia.</p> <p>Dr. Tietze asked if there was a good way to distinguish Tecfidera from the other agents in class. Buckley stated that there are no head-to-head studies with other proposed agent studied in this class. She stated that Tecfidera has a novel mechanism of action in multiple sclerosis, but that there is no direct comparison data.</p> <p>Dr. Tietze asked Dr. Melton why all of the proposed agents were included in the class. Dr. Melton stated that all of the agents were similarly indicated and so the class was</p>
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	<p>being reviewed for financial reasons. Dr. Sweet stated that this may not be appropriate, as the agents in class do not have similar mechanisms of action.</p> <p>Sarah Nollette, Novartis, stated that Gilenya is the first oral agent in this class, and that it is a sphingosine 1-receptor modulator. In clinical trials, Gilenya was evaluated in 2 studies, with long-term extension studies out to 7 years. It also demonstrates efficacy in a randomized, double-blind, double-dummy study. Gilenya has also been approved for 3 years now, and the safety profile has not changed during its time on the market. The efficacy of Gilenya was seen early in clinical trials, with reductions in relapse seen as early as days 82 and 64 in the FREEDOM and FREEDOM 2 trials. Long-term data shows that 59% of patients are relapse-free at year 4. Head-to-head trials versus Avonex showed a 52% reduction in annualized relapse rate at 12 months.</p> <p>Dr. Sweet asked if Nollette could cover the mechanism of action again. Nollette stated that Gilenya sequesters the lymphocyte into the lymph node system through the CCR7 receptor process. The effector memory cells on the lymphocytes aren't retained through this same process and are still circulating. Naïve and central memory cells are retained. The theory is that they are then not crossing the blood brain barrier to create the sequelae of inflammatory events. There is some pre-clinical data to indicate neuroprotection and regeneration on the axons in the brain, but this is preliminary.</p> <p>Dr. Gill asked how many patients discontinue the medication for lack of efficacy or side effects. Nollette stated that she did not have a hard number, but that side effects have presented challenges to prior DMT therapies. The adherence in clinical trials, however, was relatively high, with 70-80% of patients staying on therapy. Dr. Gill stated that she was wondering what factors may lead patients to switch from one agent to another in this class. Nollette stated that there is no standard of care in this class, so prescribing is driven by patient-specific factors.</p> <p>Board Discussion: Dr. Melton read the board the mechanism of action for Aubagio: Aubagio is a pyrimidine synthesis inhibitor indicated for the treatment of patients with relapsing forms of multiple sclerosis.</p> <p>Dr. Sweet stated that all appear to affect lymphocytes, just in different ways. Dr. Tietze stated that for the board's purposes, he did not have an objection to placing all agents in one group, as long as providers have the option to toggle between agents. Dr. Sweet asked how the three drugs are handled now. Dr. Melton stated that these drugs were taken to DUR for clinical prior authorization criteria, and for these drugs, the criteria was closely tied to the package insert. These drugs are not on PA yet,</p>
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		<p>however, as they have to go through the rules & regulations process.</p> <p>Dr. Haneke asked if the MCOs are seeing any trends in utilization of these agents. Tom Kaye stated that what they typically see are patients who have a current regiment, but are still have relapses, and are seeking to find an alternative regimen.</p> <p>The PDL PA process was discussed, including PDL PA criteria and the process for achieving approval of a non-preferred drug.</p> <p>Dr. Haneke moved to make the Oral MS agents a class based on common indications, but without stating they are necessarily clinically equivalent. Dr. Tietze seconded the motion.</p> <p>The motion carried unanimously.</p>
<p>Proton Pump Inhibitors – Class Re-review: New Agent (Aciphex Sprinkles)</p>	<p><i>Dr. Sweet, M.D.</i></p>	<p>Background: Aciphex (rabeprazole) sprinkles, a new dosage form of an existing PDL Proton Pump Inhibitor, are presented for review by the board today. Approved in March of 2013, Aciphex sprinkles are approved for the same indications as Aciphex tablets: duodenal ulcers, erosive or ulcerative gastroesophageal reflux disease, Helicobacter pylori eradication, pathological hypersecretory conditions, and treatment of symptomatic gastroesophageal reflux disease. Included for board consideration are previous meeting minutes, package inserts of all agents in class, and a comparison chart.</p> <p>No Public Comment</p> <p>Board Discussion: Dr. Sweet stated that she reviewed the class, and considered Aciphex to be Aciphex.</p> <p>Dr. Haneke moved to add Aciphex sprinkles to the PPI class. Dr. Schlotterback seconded the motion.</p> <p>The motion carried unanimously.</p>
<p>Inhaled Long-Acting Beta2-Agonists/Corticosteroids – Class Re-review: New Agent (Breo Ellipta)</p>	<p><i>Dr. Sweet, M.D.</i></p>	<p>Background: Breo Ellipta (fluticasone & vilanterol), approved by the FDA in May of 2013, is indicated for the maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema. The Inhaled Long-Acting Beta2-Agonists/Corticosteroids class was established at the February 17, 2011 meeting, at which time PDL inclusion was granted for all three agents: Advair (fluticasone & salmeterol), Dulera (mometasone & formoterol), and Symbicort (budesonide & formoterol). Included for the board are</p>

		<p>prior meeting minutes, all package inserts, and a class comparison chart.</p> <p>Public Comment: Barbara Felt, GSK, stated that Breo Ellipta is a combination agent with vilanterol and fluticasone furoate that is indicated for the long-term once-daily maintenance treatment of airflow obstruction in COPD patients who have either an emphysema component or chronic bronchitis component. It is also indicated to reduce exacerbations in patients who have a history of exacerbations. Three head-to-head trials are available. In the first two, Breo was compared to Advair 250/50, while in the third (which was done outside the U.S.) Breo was compared to Advair 500/50. All 3 were superiority trials, and the study designs were very similar. Improvements in FEV1 trough volume compared to the Advair 250/50 was seen in both studies, although it was only statistically significant in one study. This study is not yet published. Breo does have a boxed warning for asthma-related deaths associated with long-acting beta agonists. In terms of side effects, pneumonia, fractures, and oral candidiasis were seen with Breo at rates higher than seen with placebo groups. Breo is a once-daily medication, while other agents in the class are twice daily. Breo is also only indicated for COPD patients, and does not have an asthma indication.</p> <p>Board Discussion:</p> <p>Dr. Haneke moved to add Breo Ellipta to the Inhaled Long-Acting Beta2-Agonists/Corticosteroids Class. Dr. Tietze seconded the motion.</p> <p>The motion carried unanimously.</p>
<p>Adjunct Anti-Epileptics – Class Re-review: New Agents (Oxtellar XR)</p>	<p><i>Dr. Sweet, M.D.</i></p>	<p>Background: A new agents, Oxtellar XR (oxcarbazepine ER), was FDA approved in October of 2012 and is proposed for inclusion in the Adjunct anti-epileptic class, last reviewed at the March 13, 2013 meeting. Oxtellar XR is indicated for adjunctive therapy in the treatment of partial seizures in adults and children ages 6 to 17 years of age. Included for board consideration are prior meeting minutes, package inserts of all agents in class, and a comparison chart.</p> <p>Public Comment: Oxtellar XR Summary sheets were provided by Supernus.</p> <p>Board Discussion: Dr. Sweet stated that the drug is another dosage form of oxcarbazepine. Dr. Melton added that oxcarbazepine immediate-release was not being added to the class because it has indications for monotherapy.</p> <p>Dr. Gill moved to add Oxtellar XR to the Adjunct Anti-Epileptics class.</p>

		Dr. Smith seconded the motion. The motion carried unanimously.
Open Public Comment		No open public comment.
Adjourn		Meeting adjourned at 11:37 a.m.