

Department of Vermont Health Access
Pharmacy Benefit Management Program
DUR Board Meeting Minutes
July 12, 2016

Board Members:

Present:

Zail Berry, MD
Janet Farina, RPh

Louise Rosales, NP
Clayton English, PharmD

James Marmar, RPh

Absent: Patrica King, MD

Staff:

Jacquelyn Hedlund, MD
GHS/Change HealthCare
Mike Ouellette, RPh, GHS/Change
HealthCare
Scott Strenio, MD, DVHA

Mary Beth Bizzari, RPh, DVHA
Jennifer Egelhof, DVHA
Stacey Baker, DVHA

Carrie Germaine, DVHA
Laurie Pedlar, RPh, GHS/Change
HealthCare

Guests:

Thomas Algozzine, Novartis
Kristen Bruno-Doherty,
Astrazeneca
Stew Hoover, UCB
Scott Williams, J & J
Randy McGinley, Bayer
Christopher Kant, Allergan

Thomas Currier, Purdue
Darren Keegan, Allergan
Megan Walsh, Abbvie
Dana Lawlor, Bayer
Rodney Francisco, Sunovion
Paul Short, Vertex

Adam Denman, GSK
Margaret Glassman, Alkermes
John Meyer, Otsuka
Joe Ward, Abbvie
John Kirby, Sanofi

1. Executive Session:

- An executive session was held from 6:00 p.m. until 6:30 p.m.

2. Introductions and Approval of DUR Board Minutes:

- Introductions were made around the table.
- The May meeting minutes were accepted as printed.

3. DVHA Pharmacy Administration Updates: Mary Beth Bizzari, DVHA:

- No update at this time.

4. Medical Director Update: Scott Strenio, MD, DVHA:

- No update at this time.

5. Follow-up Items from Previous Meetings:

6. RetroDUR/DUR: GHS/Change Healthcare Jacqueline Hedlund, MD:

- **Data Presentation: *Overuse of Butalbital Containing Medications***
Butalbital containing medications, combined with caffeine and other analgesics including aspirin, acetaminophen, and codeine are indicated for the relief of the symptom complex tension headache. Evidence supporting its efficacy and safety in the treatment of multiple recurrent headaches is unavailable. Use of these medications carries risks, such as tolerance, dependence, toxicity and the development of medication overuse headache. Tension type headache (TTH) is the most common headache in the general population. For the acute treatment of mild to moderate TTH, simple analgesics such as acetaminophen or NSAIDs can be used. Combining one of the simple analgesics with caffeine is more effective and is recommended for those unresponsive to simple analgesics alone. For the treatment of moderate to severe TTH, IM ketorolac is recommended.

Diagnoses included in our search were headaches, tension-type headaches, migraine headaches, and drug-induced headaches. We initially categorized members who received less than 18 tablets a month throughout the year and those who received more than 18 tablets a month for at least one month during the year, without any restriction on diagnoses. Due to the large number of members who were using more than 18 tablets in at least one month, we examined the distribution of use and found a large number of patients using substantially more butalbital than is recommended for headache treatment. What is notable is that there are 94 members prescribed over 250 tablets a year, several receiving over 1000.

Interestingly, many patients receiving butalbital did not have medical claims with headache as the diagnosis. We were able to search for the first 3 diagnoses for each claim, so it is possible we missed headache diagnoses for some of these members. In addition, a significant number of members in both the under 18 tablets a month and over 18 tablets are not on any other treatments for headache, either for prevention or treatment. There were 665 total distinct members using butalbital containing

medications. 493 members were identified as using greater than 18 tablets in any given 30 day period, and 172 members received less than 19 tablets in every 30 day period.

Recommendation: Require a PA for anything greater than 18 tablets per month and send out an educational letter to the prescribing provider.

Board Decision: After board discussion it was decided that GHS will further break down the data to include more detailed prescriber information.

▪ **Introduce: *Use of Naltrexone in Children***

Children with mental retardation, autism and related disorders and other behavioral disorders are prone to self-injurious behaviors (SIB). ASC (autism spectrum conditions) may result from a failure of striatal beta endorphins to diminish with maturation. Many symptoms of ASC resemble behaviors induced in humans by opiate administration, including decreased socialization, insensitivity to pain and motor hyperactivity. These behaviors are heterogeneous and are likely the consequence of a variety of environmental-brain-behavioral relationships. Opioidergic, dopaminergic and serotonergic pathways may play a role in behaviors and can be affected by medications. Studies have shown altered beta-endorphin levels in persons of all ages with SIB, therefore blocking opioid receptors with the orally available narcotic antagonist naltrexone is a treatment strategy that is employed when behavioral therapy alone is ineffective. Although studies have shown naltrexone to be relatively safe in children, there is not consensus about treatment guidelines.

Recommendation: GHS will look at paid, non-reversed Medicaid pharmacy claims during SFY 2016, excluding members with Part D, VMAP, and Healthy Vermonters coverage. In the analysis we will query claims for children <18 years old to look for any utilization of naltrexone to examine the frequency and patterns of usage. We will look at the number of prescriptions over the 1 year period, divide the utilization into broad age bands (e.g. < 6 years, 6-12 years and > 12 years of age), and look at the dosage ranges. Finally, we will look at the most common diagnosis and specifically report on the frequency of any diagnosis of behavioral disorders or mental retardation.

Board Decision: None needed at this time.

7. Clinical Update: Drug Reviews: Jacquelyn Hedlund, MD GHS/Change Healthcare and Laurie Pedlar, RPh GHS/Change Healthcare

Abbreviated New Drug Reviews:

- None at this time.

Full New Drug Reviews:

- a) **Viberzi® tablets (eluxadoline)**

- Eluxadoline, the active ingredient of Viberzi[®], is a mu-opioid receptor agonist indicated for the treatment of irritable bowel syndrome with diarrhea (IBS-D). It is also a delta opioid receptor antagonist and a kappa opioid receptor agonist. Viberzi[®] is listed as a Schedule IV drug. There is no pregnancy category with this product; however, the risk summary indicates that there are no studies of use in pregnant women to inform any drug-associated risks. The safety and efficacy of use in the pediatric population have not been established. The recommended dosage is 100mg BID with food. In patients who do not have a gallbladder, are unable to tolerate the 100mg dose, are receiving concomitant OATP1B1 inhibitors, or have mild to moderate hepatic impairment, the recommended dosage of Viberzi[®] is 75mg BID with food. Viberzi[®] is contraindicated in those with severe hepatic impairment. Information regarding use in renal impairment was not found. It is recommended to discontinue treatment in patients who develop severe constipation for more than 4 days. The safety and efficacy of Viberzi[®] were assessed in two randomized, double-blind, placebo-controlled 26-week trials. Results suggested that in both studies, the proportions who were composite responders to Viberzi[®] was statistically significantly higher as compared with placebo for both doses. Contraindications and drug interactions limits its use in certain patient populations.

Recommendation: The recommendation is for Viberzi[®] to be non-preferred.

Clinical Criteria:

- Add Irritable Bowel Syndrome- Diarrhea (IBS-D) as a new subcategory to the Gastrointestinal Agents.
- Include alosetron and Lotronex[®] (alosetron) as well as Viberzi[®] on the non-preferred side of the PDL.
- Under clinical criteria:
 - **Lotronex/alosetron:** The patient is a woman and has a diagnosis of severe diarrhea-predominant irritable bowel syndrome (IBS) with symptoms lasting 6 months or longer AND has had anatomic or biochemical abnormalities of the GI tract excluded AND has not responded adequately to conventional therapies loperamide, cholestyramine, and TCA's. For approval of generic alosetron, the patient must have documented intolerance to brand Lotronex.
 - **Viberzi:** The patient has a diagnosis of IBS-D AND does not have any of the following contraindications to therapy A) known or suspected biliary duct obstruction, or sphincter of Oddi disease or dysfunction B) alcoholism, alcohol abuse, alcohol addiction, or drink more than 3 alcoholic beverages/day C) a history of pancreatitis; structural diseases of the pancreas D) severe hepatic impairment (Child-Pugh Class C) AND has not responded adequately to conventional therapies loperamide, cholestyramine, and TCA's.

Public Comment: Christopher Kant, Allergan: Highlighted attributes of Viberzi®.

Board Decision: The Board unanimously approved the above recommendation.

b) Belbuca® film (buprenorphine HCl buccal film)

- Buprenorphine, the active ingredient of Belbuca®, is a partial opioid agonist at the mu-opioid receptor and an antagonist at the kappa-opioid receptor. Belbuca® is not indicated as an as-needed (prn) analgesic. Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, and because of the greater risks of overdose and death with long-acting opioid formulations, reserve Belbuca® for use in patients with whom alternative treatment options (e.g. non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain. There is no pregnancy category listed for this product; however, the risk summary indicates there are no adequate and well-controlled studies of Belbuca® or buprenorphine in pregnant women. Nevertheless, limited published data have not shown an increased risk of major malformations with the use of buprenorphine in pregnancy. The safety and efficacy of use in the pediatric population have not been established. Belbuca® is a Schedule III controlled substance. It has a box warning regarding the increased risk of addiction, abuse and misuse, which can lead to overdose and death. It is recommended to assess each patient's risk prior to prescribing the product, as well as to monitor regularly for the development of these behaviors or conditions. Three double-blind, placebo-controlled trials were performed in opioid-naïve and opioid-experienced patients to assess the safety and efficacy of Belbuca® when used for the management of moderate-to-severe chronic low back pain. One study did not demonstrate a statistically significant reduction in low back pain with Belbuca® as compared to placebo; however, two of the studies did demonstrate efficacy. Belbuca® has been shown to prolong the QTc interval in clinical trials, therefore it is recommended to avoid use in patients with a history of Long QT syndrome, in those taking Class IA or Class III antiarrhythmic medications, or other medications that prolong the QT interval.

Recommendation: The recommendation is for Belbuca® to be non-preferred.

Clinical Criteria:

- Add sub category: Buccal to the long acting opioids category.
- Quantity limits 28 films/14 days, maximum 14 day fill.
- Remove Avinza® since it is no longer on the market.
- Under clinical criteria:
 - **Belbuca Films:** patient has a diagnosis of severe pain that requires daily, around-the-clock, long-term treatment and for which alternative treatment options are inadequate AND

the patient has had a documented intolerance to Butrans patches.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

c) Enstilar® aer (calcipotriene/betamethasone dipropionate foam)

- Is included in the Therapeutic Class Review.

Recommendation: PDL placement and criteria will be recommended when TCR is reviewed.

Public Comment: No public comment.

Board Decision: Defer decision- to occur with the class review.

d) Veltassa® powder (patiomer sorbitex calcium for susp packets)

- Patiomer sorbitex calcium, the active ingredient of Veltassa®, consists of the active moiety patiomer, which is a non-absorbed potassium-binding polymer, and a calcium-sorbitol counterion. Each gram of patiomer is equivalent to a nominal amount of 2g of patiomer sorbitex calcium. Veltassa® is a non-absorbed, cation exchange polymer that increases fecal potassium excretion through binding of potassium in the lumen of the GI tract, resulting in a reduction of serum potassium levels. Veltassa® should not be used as an emergency treatment for life-threatening hyperkalemia because of its delayed onset of action. There is no pregnancy category listed with this product; however, the risk summary indicates that Veltassa® is not absorbed systemically after oral administration and maternal use is not expected to result in fetal risk. The safety and efficacy of use in the pediatric population have not been established. Start at 8.4g once daily with food. Do not heat Veltassa® (e.g. microwave) or add to heated foods or liquids. Monitor serum potassium and adjust the dose based on serum potassium levels and the desired target range up to a maximum dose of 25.2g once daily. There were no formal drug interactions studies performed in humans. However, *in vitro* studies suggested that Veltassa® was seen to bind about half of the oral medications that were tested, which could result in decreased GI absorption and loss of efficacy of the oral medications. It is recommended to administer other oral medications at least 6 hours before or 6 hours after Veltassa®. The efficacy of Veltassa® was assessed in a 4 week, two-part, single-blind, randomized withdrawal study that evaluated Veltassa® in hyperkalemic patients with chronic kidney disease (CKD) on stable doses of ≥1 renin-angiotensin-aldosterone system inhibitor (RAAS; i.e. ACE inhibitor, ARB, or aldosterone antagonist). It was also assessed in up to a

one-year open-label study, and the treatment effect on serum potassium was maintained during continued therapy.

Recommendation: The recommendation is for Veltassa® to be non-preferred.

Clinical Criteria:

- Quantity limit 1 packet/day.
- Add Kionex® and SPS® to the preferred side of the PDL.
- Under clinical criteria:
 - **Veltassa:** The patient requires therapy for the treatment of non-emergent hyperkalemia and has a side effect, allergy, or contraindication to one preferred sodium polystyrene sulfonate product.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

e) Uptravi® tabs (selexipag)

- Selexipag, the active ingredient of Uptravi®, is a selective non-prostanoid oral prostacyclin receptor (IP receptor) agonist that is structurally distinct from prostacyclin. Selexipag is hydrolyzed to obtain its active metabolite, which is approximately 37-fold as potent as selexipag. Both selexipag and its active metabolite are selective for the IP receptor as compared with other prostanoid receptors. As an agonist of the IP receptor, it results in vasodilation of the pulmonary vascular bed. It is indicated for the treatment of pulmonary arterial hypertension (PAH, WHO Group 1) to delay disease progression and reduce the risk of hospitalization for PAH. Effectiveness was established in a long-term study in PAH patients with WHO Functional Class II-III symptoms. Included were patients with idiopathic and heritable PAH (58%), PAH associated with connective tissue disease (29%), and PAH associated with congenital heart disease with repaired shunts (10%). There is no pregnancy category listed for this product; however, the risk summary indicates that there are no adequate and well-controlled studies of use in pregnant women. The safety and efficacy of use in the pediatric population have not been established. The recommended starting dose is 200mcg BID; if taken with food, tolerability may improve. Increase the dose in increments of 200mcg BID, generally at weekly intervals to the highest tolerated dose up to 1600mcg BID. The use in patients with severe hepatic impairment should be avoided. Dose adjustments are not needed in patients with renal impairment with estimated glomerular filtration rate of $>15\text{ml}/\text{min}/1.73\text{m}^2$; however, there is no clinical experience with use in patients undergoing dialysis or in patients with glomerular filtration rates $<15\text{ml}/\text{min}/1.73\text{m}^2$. One multicenter, double-blind, placebo-controlled, parallel group, event-driven study (GRIPHON; N=1156) was performed to assess the safety and efficacy of Uptravi® when used for the treatment of patients with

symptomatic PAH (WHO Functional Class 1 [0.8%], II [46%], III [53%], and IV [1%]). The primary endpoint was the time to first occurrence up to end-of-treatment of: death; hospitalization for PAH; PAH worsening resulting in need for lung transplantation or balloon atrial septostomy; initiation of parenteral prostanoid therapy or chronic oxygen therapy; or other disease progression based on a 15% decrease from baseline in 6 minute walk distance (6MWD) test plus worsening of Functional Class or need for additional PAH-specific therapy.

Recommendation: The recommendation is for Upravi® to be non-preferred.

Clinical Criteria:

- Change sub category to Prostacyclin Agonists.
- Quantity limit 2 tablets/day.
- Under clinical criteria:
 - **Upravi:** The patient has a diagnosis of pulmonary arterial hypertension (PAH) WHO Group I with New York Heart Association (NYHA) Functional Class II or III heart failure AND the patient is unable to tolerate or has failed 2 different preferred medications, one of which must be Orenitram.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

8. Therapeutic Drug Classes – Periodic Review: Jacquelyn Hedlund, MD GHS/Change Healthcare and Laurie Pedlar, RPH GHS/Change Healthcare

a) Antiparkinson Agents

- No new drugs.
- No significant changes.
- Parkinsonism is a clinical syndrome consisting of four hallmark features: bradykinesia, resting tremor, muscular rigidity, and postural instability. The most common cause of Parkinsonism is idiopathic Parkinson's disease. Parkinson's disease is a chronic, progressive, neurodegenerative disorder that accounts for approximately 75% of all Parkinsonism. Currently, the pharmacological and non-pharmacological treatments approved for Parkinson's disease offer only symptomatic relief for patients. Levodopa, a dopamine precursor, is an effective agent for the treatment of Parkinson's disease. This medication is often given in combination with carbidopa, so as to prevent the peripheral metabolism of levodopa and allow the medication to cross the blood-brain barrier. Newer drugs that are currently being investigated are associated with better neuroprotective or disease-modifying effects. However, many of the

newer drugs have failed clinical trials due to their inability to succeed in phase III studies.

Recommendation:

- No changes at this time.

Clinical Criteria:

- No changes for Restless Leg Syndrome category.
- Rename Parkinson's: Non-Ergot Dopamine Receptor Agonist category to Parkinson's medications (1 year length of authorization).
- Remove Parcopa® and Eldepryl® as they are no longer rebateable.
- Add Tolcapone (compare to Tasmar®) to non-preferred and Amantadine syrup to the preferred side of the PDL.
- Under clinical criteria:
 - For approval of generic tolcapone, the patient must have documented intolerance to brand Tasmar.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

b) Pancreatic Enzymes

- No new drugs.
- No significant changes.
- The pancreas is an organ with two distinct components: the exocrine portion and the endocrine portion. The endocrine portion includes the islet of Langerhans cells and comprises approximately 1-2% of the organ, while the exocrine portion constitutes approximately 80-85%. This exocrine portion is made of acinar cells, which produce digestive enzymes. Examples of disorders of the exocrine pancreas include cystic fibrosis, acute and chronic pancreatitis, and neoplasms. The products in this therapeutic drug class includes: Creon®, Pancreaze®, Pertzye®, Ultresa®, Viokace®, and Zenpep®. Note that Ultresa® NDCs have an obsolete date of 1/11/2016 and generic pancrelipase 5000 has an obsolete date of 11/6/2015. Ultresa® does not have a CMS termination date and pancrelipase has a CMS termination date of 3/31/2018, thus they will remain in the review for completeness of the class. Viokace® is indicated for the treatment of exocrine pancreatic insufficiency due to chronic pancreatitis or pancreatectomy to be used in combination with a proton pump inhibitor.

Recommendation:

- No changes at this time.

Clinical Criteria:

- Remove Pancrelipase® 5,000 and Ultresa® DR.
- Under clinical criteria:
 - Replace 'All others' with Pancreaze, Pertzye, Viokace.
 - Remove criteria for Pancrelipase.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

c) Parathyroid Agents

- No new drugs.
- No significant changes.
- Hyperparathyroidism (HPT) results from the proliferation of the chief cells that secrete excess parathyroid hormone (PTH) from one or more of the four parathyroid glands. Parathyroid hormone helps the body regulate calcium homeostasis. When the parathyroid glands detect low or falling serum calcium concentration, PTH is released. This mobilizes calcium from the bones, causes the kidneys to reabsorb calcium, and stimulates GI absorption of calcium by converting 25-hydroxyvitamin D3 to the active form, 1,25 dihydroxyvitamin D3. Over-secretion of PTH, however, results in hypercalcemia. In patients with primary hyperparathyroidism, hypercalcemia is usually due to the benign enlargement of one parathyroid gland. The drugs included in this review include calcitriol (Rocaltrol®), cinacalcet (Sensipar®), doxercalciferol (Hectorol®), ergocalciferol (Drisdol®), parathyroid hormone (Natpara®), and paricalcitol (Zemplar®).

Recommendation:

Clinical Criteria:

- Add to preferred side of PDL: Calcitriol (compare to Rocaltrol®), Doxercalciferol (compare to Hectorol®), Ergocalciferol (compare to Drisdol®), Paricalcitol (compare to Zemplar®) and Sensipar® (cinacalcet)
- Add to non-preferred side of PDL: Drisdol® (ergocalciferol), Hectorol® (doxercalciferol), Rocaltrol® (calcitriol), Zemplar® (paricalcitol)
- Under clinical criteria:
 - Non-preferred agents (except Natpara): The patient must have a documented side effect, allergy, or treatment failure to two preferred agents. If a product has an AB rated generic, one trial must be the generic formulation.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

d) Phosphate Binders

- No new drugs.
- No significant changes.
- Phosphorus and calcium are important minerals that keep teeth and bones healthy and strong, as well as play a role in nerve function. The human body maintains an appropriate amount of phosphorus and calcium in the blood by managing the degree to which these minerals are absorbed from food, excreted by the kidneys, and by varying how much parathyroid hormone (PTH) is released from the parathyroid gland. Patients with chronic kidney disease (CKD) experience abnormalities in serum phosphate due to impaired phosphate excretion. This results in a condition known as hyperphosphatemia. Hyperphosphatemia has been associated with increased mortality in dialysis patients, and may also cause significant morbidity. It can also induce potentially symptomatic hypocalcemia due to calcium-phosphate precipitation into tissues. There are several ways to control hyperphosphatemia associated with CKD. Diet is one important way. Having a nutritionally complete diet is important, but those with CKD can reduce their intake of phosphorus-rich foods such as nuts and dairy products to aid with control. Dialysis is another way to help remove extra phosphorus. Lastly, since diet and dialysis may not always be sufficient to maintain appropriate phosphorus levels, pharmacologic therapy is available. Phosphate binders are one class of medications that help control hyperphosphatemia by inhibiting the absorption of dietary phosphorus from the intestine. Aluminum-based products have always been effective and were frequently used in the past; however, concerns over accumulation and unacceptable toxicities have limited their use to short durations of therapy in patients with difficult to control serum phosphate. Magnesium-based salts have also been used, but are currently not recommended in practice guidelines for CKD except in uncontrollable hyperphosphatemia, as they carry the risk of hypermagnesemia and diarrhea as a dose-limiting side effect. The drugs included in this therapeutic class review include: calcium acetate (Eliphos[®], Phoslo[®], Phoslyra[®]), lanthanum carbonate (Fosrenol[®]), sevelamer carbonate (Renvela[®]), sevelamer hydrochloride (Renagel[®]), sucroferric oxyhydroxide (Velphoro[®]), and tetraferrous tricitrate decahydrate (Auryxia[®]), also known as ferric citrate.

Recommendation:

Clinical Criteria:

- Move Renvela[®] to preferred.
- Remove Sevelamer carbonate.
- Remove criteria for Renvela and Sevelamer.

Public Comment: No public comment

Board Decision: The Board unanimously approved the above recommendation.

e) Non Biologics for Psoriasis-Topical & Oral

- New drug **Enstilar[®] aer (calcipotriene/betamethasone dipropionate foam)**
- No significant changes.
- Psoriasis is a skin condition that affects approximately 0.6-4.8% of people worldwide and approximately 3.8% in the United States. In general, it occurs with a bimodal age distribution, with an earlier and a later peak. With psoriasis, the rate of cell turnover is affected. Typically, skin cells develop deep in the skin, and they gradually emerge to the skin's surface. This process of cell turnover generally takes about a month. In the case of psoriasis, this process can take only a few days, resulting in the skin cells emerging to the skin surface too fast, causing a mass on the skin surface. This quicker cell turnover rate is thought to be initiated by an immune system response. In psoriasis, T cells, a type of white blood cell, are erroneously put into action, which also leads to other immune responses being triggered. As a result of these events, swelling and faster skin cell turnover thus occurs. Psoriasis is considered a chronically recurring skin disease typified by scaling and inflammation affecting the scalp, skin, and inflammation that can also affect the joints. This disease can range in severity from mild to severe, with those experiencing the moderate to severe forms facing a dramatic decline in quality of life. With mild or localized psoriasis, topical treatments are generally regarded as the mainstay. Phototherapy or systemic therapy either alone or in combination with topical treatments may be used for mild forms of psoriasis in those that fail to respond to topical treatments alone.

Recommendation: The recommendation is for Enstilar[®] aer to be non-preferred.

Clinical Criteria:

- Move Calcipotriene cream to preferred.
- Add 8-MOP[®] (methoxsalen) to preferred.
- Move Dovonex[®] cream to non-preferred.
- Under clinical criteria:
 - Remove criteria for Calcipotriene cream and Dovonex Solution.
 - Add **Dovonex Cream:** The patient has a documented intolerance to the generic equivalent.
 - Criteria for Enstilar[®] will be the same as for Taclonex and calcipotriene/betamethasone ointment or scalp suspension.

Public Comment: No public comment

Board Decision: The Board unanimously approved the above recommendation.

9. New Managed Therapeutic Drug Classes

- None at this time.

10. Review of Newly-Developed/Revised Clinical Coverage Criteria and/or Preferred Products

11. General Announcements: Mike Ouellette, RPh GHS/Change Healthcare

- Selected FDA Safety Alerts

FDA advises health care professionals that counterfeit BiCNU has been discovered in some foreign countries

http://www.fda.gov/Drugs/DrugSafety/ucm500705.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

Information on Clozapine

http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm497790.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

Canagliflozin (Invokana, Invokamet): Drug Safety Communication - Clinical Trial Results Find Increased Risk of Leg and Foot Amputations

http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm501565.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

FDA Drug Safety Communication: FDA warns about new impulse-control problems associated with mental health drug aripiprazole (Abilify, Abilify Maintena, Aristada)

http://www.fda.gov/Drugs/DrugSafety/ucm498662.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

Brintellix (vortioxetine): Drug Safety Communication - Brand Name Change to Trintellix, to Avoid Confusion With Antiplatelet Drug Brilinta (ticagrelor)

http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm498607.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

Fluoroquinolone Antibacterial Drugs: Drug Safety Communication - FDA Advises Restricting Use for Certain Uncomplicated Infections

http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm500665.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery

Nizoral (ketoconazole) Oral Tablets: Drug Safety Communication - Prescribing for Unapproved Uses including Skin and Nail Infections Continues; Linked to Patient Death

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm502073.htm>

12. Adjourn: Meeting adjourned at 8:15p.m.