Department of Vermont Health Access
Pharmacy Benefit Management Program
DUR Board Meeting Minutes
December 7, 2021

Board Members Present:

Mark Pasanen, MD
Bill Breen, RPH
Douglas Franzoni, PharmD
Claudia Berger, MD,
Joseph Nasca, MD
Lucy Miller, MD
Andy Miller, RPH
Margot Kagan, PharmD

Absent: Renee Mosier, PharmD,

Staff:

Laurie Brady, RPh, Change HealthCare
Nancy Hogue, Pharm D, DVHA
Lisa Hurteau, PharmD, DVHA
Stacy Baker, DVHA
Jeffrey Barkin, MD, Change Healthcare
Marietta Scholten, MD, DVHA

Guests:

Adam Denman
Allison Musick Leiger (Pfizer)
Donald Nopper
Elizabeth Lubelczyk
Jai Persico
Kristin Chopas
Jamie Tobitt (Apellis Pharmaceuticals)
Kristin DiDesidero
Linda Burns
Matt McMahon
Matt Nguyen (Abbvie)
Morgan Carter
Patty Arcese
Rasheed Jandali
Rodney Francisco
Tyson Thompson

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:

- Attendance was called and introductions of DVHA and Change Healthcare staff were made. Mark Pasanen filled in as board chair in Renee Mosier's absence.
- The DUR Board welcomed new member, Lucy Miller, an internal medicine physician practicing with UVM Medical Center in Williston.
- The October meeting minutes were accepted as printed.

3. DVHA Pharmacy Administration Update: Nancy Hogue, Pharm.D., DVHA:

- The Governor announced an effort to provide statewide coverage of COVID-19 antigen tests with no patient cost share, regardless of payer. DVHA is already covering them, effective 12/1/21. A GCR notice with a list of covered tests is available on the DVHA website.
- The Annual Pharmacy Best Practices and Cost Control report has been submitted to the legislature. It includes data from State Fiscal Year 2021 (7/1/20-6/30/21). Drug spend was significantly higher for Medicaid, most of which was due to an increase in member eligibility. There was also an

increase in spend attributed to a growing percentage of specialty medication claims.
- Follow up to a question from the October meeting regarding coverage of HIV medications for post-exposure prophylaxis. Medicaid is not required to offer coverage with no member cost share for this indication.

4. Medical Director Update: Marietta Scholten, MD, DVHA

- No updates at this time.

6. Follow-up Items from Previous Meetings: Laurie Brady, RPH Change Healthcare

- Codeine Use in Pediatric Patients

Change Healthcare presented an analysis of codeine use in children at the May 2020 DUR Board Meeting. They used paid, non-reversed Medicaid pharmacy claims from calendar years 2019 and 2020, excluding members with Part D, VMAP and Healthy Vermonters coverage. They identified members, stratified by age cohort (less than 12, 12-18) with at least one prescription for a codeine containing product. They identified the total number of members with prescriptions from both medical and dental providers. They also looked at the average days prescribed and speculated if codeine was being used for acute or chronic pain management based on the classification of the drug.

Overall, prescribing of codeine in children decreased from 2019 to 2020, with 137 claims among 127 members in 2019 and 79 claims among 76 members in 2020. There were very few prescription refills. Pain management was the primary indication, and it was used infrequently for cough suppression. As such, the highest number of prescribers came from dentists, oral maxillofacial surgeons, and family practitioners. Pediatricians rarely prescribed codeine, which may be due to better education about the risks. Because there were also claims from ED providers and surgical subspecialists, it appears that most codeine use is for acute pain associated with trauma or procedures. Fortunately, the days supplied were very low, with the lengthiest days' supply being for cough suppressants that contained codeine. There were 70 individual prescribers in 2019 and 43 in 2020. It appears that overall, use of codeine in children is being done judiciously, however, the board accepted the recommendation that a minimum age edit be implemented for patients under the age of 12 due to the contraindicaton in this age group. The board asked that Change Healthcare come back with additional data on other opioids being used in the same population. Results were as follows: 129 members ages 0-11 were prescribed opioids in 2019, and 66 members ages 0-11 were prescribed opioids in 2020. 1,100 members ages 12-18 were prescribed opioids in 2019, and 720 members ages 12-18 were prescribed opioids in 2020. Hydrocodone with acetaminophen was the most frequently used opioid for both years in all age groups.

Recommendation: None at this time.

Public Comment: No public comment.

Board Decision: None at this time.

7. RetroDUR/ProDUR: Laurie Brady, RPH and Mike Ouellette, RPH, Change Healthcare

- Data Proposal: Glucose Test Strip Usage with CGMs

The use of continuous glucose monitors (CGMs) has become accepted standard of care for both type 1 diabetes and insulin dependent type 2 diabetes mellitus. While the value of CGM in type 2 diabetics not requiring insulin is uncertain due to rare occurrence of hypoglycemia, there are studies that show improvement in A1c levels compared with conventional blood glucose monitoring. In addition, blood glucose monitoring with fingersticks has potential errors due to poor compliance, dirty or contaminated meters, improper storage of test strips, expired test strips and poor skin preparation. Initially when CGMs came on the market, conventional testing with finger sticks was recommended multiple times a day. As CGMs have evolved, however, the recommendation now is to corroborate results when the CGM reading seems inaccurate, either due to symptoms or unexplained fluctuations in the readings. Blood glucose monitoring is still required during CGM warm-up periods, to double check high and low values and sometimes for calibrating CGMs. For members using CGMs, it is expected that the increased expense of the monitors, sensors and supplies would be somewhat offset by decreased need to do fingerstick testing, and therefore decreased cost of glucose test strips. Of note, Vermont Medicaid historically covered CGM as a medical/DME benefit only. Coverage in the pharmacy Point of Sale was added October 1, 2019.
Change Healthcare will use paid, non-reversed Medicaid pharmacy claims from 10/1/19-3/31/20, excluding members with Part D, VMAP and Healthy Vermonters coverage. Members with a medical procedure code of A9276 (sensor), A9277 (transmitter), or A9278 (receiver) between 4/1/19 and 3/31/20 will be eliminated from the analysis since they are not likely new CGM users. They will be considered members who transitioned from the medical/DME channel to the pharmacy channel. Change Healhcare will look at all pharmacy claims for members who began Dexcom G6 or Freestyle Libre CGM between 10/1/19-3/31/20, excluding those that transferred from the medical/DME channel to the pharmacy channel. They will evaluate blood glucose test strip usage in the 1-year time frame prior to the CGM period (10/1/18-9/30/19) and for 1 year after the CGM period (4/1/20-3/31/21).

Recommendation: None at this time.

Public Comment: No public comment.

Board Decision: None at this time.

- Data Presentation: Use of Acute Migraine Medication in Members on CGRPs

Migraine headaches are a pervasive problem in the US population. Migraines affect 1 in 7 Americans. Notably, 10% of children suffer from migraines and up to 28% of adolescents ages 15-19. 4 million people suffer from chronic migraines with at least 15 migraine days per month. The cost to the US healthcare system is consequential. In 2015, the cost of treating chronic migraine in the US was over 5.4 billion dollars. In addition to medical costs, there are large economic costs in loss of productivity. For people who suffer from frequent migraines, preventative medications have been the mainstay of treatment, although the success in reducing migraines is variable. Historically, anticonvulsants, tricyclic antidepressants, beta-

blockers, calcium channel blockers and Botox injections have been used, with additional drug classes (NSAIDs, ergotamines, steroids, opioids) used to treat acute symptoms. The development of triptans has improved the treatment of acute migraines, but improvements in prevention have been lacking. A newer class of medications, the calcium gene-related peptide receptor antagonists (CGRPs) arrived on the scene in 2018 for migraine prevention. These monoclonal antibodies include Aimovig (erenumab), Ajovy (fremanezumab) and Emgality (galcanezumab). Each is given once monthly as subcutaneous self-administered injections. (Ajovy can also be given as 3 injections every 3 months). Vyepti is administered in a heath care setting via IV every 3 months. The CGRP antagonists are used in those who have an inadequate response to oral preventative medications. With improvement in prevention, the expectation is that use of medications for acute treatment of migraines will decrease.
Change Healthcare used paid, non-reversed Medicaid pharmacy and medical claims from SFY 2019-2020 (pre-COVID), excluding members with TPL, Part D, VMAP and Healthy Vermonters coverage. Only members with continuous eligibility were included. Using pharmacy and medical claims, they identified members who were taking a long-acting CGRP and identified the prescribing patterns of acute migraine medications for these members as well as their compliance with the long-acting injectables. Although pediatric patients were not excluded from the analysis, CGRPs are not indicated in this population, and all patients were 18 years of age or older at the time of their first CGRP claim. Since medications such as NSAIDs and opioids can be used for many indications aside from migraine treatment, it was decided to limit the analysis of acute migraine medications to triptans.

Change Healthcare specifically looked to see if use of acute migraine medication decreased in the 6-months after the initiation of the long-acting CGRP medication compared to the 6-months prior.

Total members with at least one CGRP claim between 7/1/18-6/30/20 = 79
Total members with CGRP claim and Triptan claim 6 months before or after CGRP claim = 44
Total members with CGRP claim and NO Triptan claim 6 months before or after CGRP claim = 35

Of those with a Triptan claim (44 members), there were a total of 1,117 triptan tablets filled in the 6 months prior to starting the CGRP and 990 tablets in the 6 months after starting the CGRP, for a decrease in Triptan usage of 11.4%. 13 members (29.5%) had more Triptan doses filled after starting a CGRP, 10 members (22.7%) had an equal number of Triptan doses in both time frames, and 21 members (47.7%) had less Triptan doses after starting the CGRP.

A prescription profile review of the 13 members who filled more Triptans after CGRP initiation revealed the following:

- 7 members changed to a different CGRP suggesting that the initial CGRP was either not tolerated or not effective.
- 5 members had either a change to their triptan dose or switched to a different triptan (one of these members also changed their CGRP and is included in the above total).

- 1 member discontinued injectable CGRP therapy. They are currently prescribed Nurtec ODT for acute migraine treatment as well as amlodipine and divalproex (indication for use is unknown).
- 1 member had nothing in claims history to explain the increase in triptan use.

It appears that the initiation of CGRPs in members using Triptans for acute migraine treatment decreased overall usage of Triptans by about 11%, however the usage did not drop in all members. In fact, in some members the quantity of Triptans increased following the introduction of the CGRP medication. There were also 35 members who had no claims for Triptans. This may have been due to a contraindication such as vascular disease, or past Triptan use may have been ineffective.

Recommendation: The current criteria for re-approval after 6 months requires that the patient have documentation of a decrease in the number of headache days per month or decreased use of acute migraine medications such as triptans. Pharmacy claims are also evaluated to assess compliance with the medication. We suggest considering adding a requirement for renewal of PAs, that providers explain increases in triptan use when requesting the same CGRP be renewed.

Public Comment: Andy Miller indicated that many patients pay out of pocket for triptans due their low cost, particularly if they need more than quantity limits allow.

Board Decision: The Board unanimously approved the above recommendations.

8. Clinical Update: Drug Reviews: Jeff Barkin, MD, Change Healthcare and Laurie Brady RPh, Change Healthcare

Biosimilar Drug Reviews:

- None at this time.

Full New Drug Reviews:

- Elepsia XR® (Levetiracetam extended-release)

Levetiracetam, the active ingredient of Elepsia® XR, is an antiepileptic drug. The exact mechanism of action is unknown. A saturable and stereoselective neuronal binding site in rat brain tissue has been described for levetiracetam. Experimental data indicate that this binding site is the synaptic vesicle protein SV2A, thought to be involved in the regulation of vesicle exocytosis. While the molecular significance of levetiracetam binding to synaptic vesicle protein SV2A is not understood, levetiracetam demonstrated a rank order of affinity for SV2A which correlated with the potency of their antiseizure activity in audiogenic seizure-prone mice. These findings suggest that the interaction of levetiracetam with the SV2A protein may contribute to the antiepileptic mechanism of action of the drug. It is indicated as adjunctive therapy for the treatment of partial-onset seizures in patients 12 years of age and older. The efficacy of Elepsia® XR is based upon bioavailability studies. The clinical studies found in the Elepsia® XR prescribing information are the same as in the Keppra® XR prescribing information. Keppra® XR

is available as 500mg and 750mg extended-release tablets and is indicated for the treatment of partial-onset seizures in patients 12 years of age and older. Elepsia® XR tablets are available as 1000mg and 1500mg.

Recommendation:

- Add Elepsia XR® (levetiracetam) extended release to non-preferred.
  - Clinical criteria:
    - Add Elepsia XR to the Keppra XR, Lamictal XR, Lamotrigine ER, Levetiracetam ER, and Oxtellar XR criteria.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

- Empaveli® (pegcetacoplan)

Pegcetacoplan, the active ingredient of Empaveli®, is a complement inhibitor. It binds to complement protein C3 and its activation fragment C3b, thereby regulating the cleavage of C3 and the generation of downstream effectors of complement activation. In paroxysmal nocturnal hemoglobinuria, extravascular hemolysis (EVH) is facilitated by C3b opsonization while intravascular hemolysis (IVH) is mediated by the downstream membrane attack complex (MAC). Pegcetacoplan acts proximally in the complement cascade controlling both C3b-mediated EVH and terminal complement-mediated IVH. It is indicated for the treatment of adult patients with paroxysmal nocturnal hemoglobinuria (PNH). The safety and efficacy of Empaveli® in patients with PNH were assessed in a randomized, open-label, active comparator-controlled, 16-week, phase 3 study, that included patients with PNH who had been treated with a stable dose of eculizumab for at least the previous 3 months and with Hb levels less than 10.5g/dL (N=80). Due to the risk of serious infections, Empaveli® is available only through a restricted program under the Empaveli® REMS. It is recommended to vaccinate patients against encapsulated bacteria, including Streptococcus pneumoniae, Neisseria meningitidis, and Haemophilus influenzae type B at least 2 weeks prior to initiation of Empaveli® therapy per current ACIP guidelines. In an open-label, active-comparator clinical study comparing Empaveli® with eculizumab, Empaveli® was superior to eculizumab for the change from baseline in hemoglobin level at week 16, the primary outcome. Non-inferiority of Empaveli® was demonstrated in the endpoints of transfusion avoidance and change from baseline in absolute reticulocyte count (ARC). There is some evidence at this time to suggest that Empaveli® may be more effective than eculizumab for the primary outcome of change from baseline in hemoglobin level at 16 weeks in a phase 3 study, but non-inferiority was demonstrated for the endpoints of transfusion avoidance and change from baseline in ARC.

Recommendation:

- Add subcategory of Complement Inhibitors to Miscellaneous category.
- Add Empaveli™ (pegetacoplan) subcutaneous solution with QTY LIMIT: 8 vials/28 days to non-preferred.
- Add Soliris® (eculizumab) vial to non-preferred.

- Clinical criteria:
    - Add Empaveli: The patient has a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) documented by flow cytometry AND The patient has received the meningococcal vaccine at least 2 weeks prior to therapy initiation. Authorization for continued use shall be reviewed to confirm that the patient has experienced an objective response to the therapy (e.g. stabilization of hemoglobin levels, reductions in transfusions, improvement in hemolysis, etc.). Note: For patients switching from eculizumab, an additional 4 weeks of eculizumab will be approved before continuing monotherapy with Empaveli. For patients switching from ravulizumab, Empaveli will be initiated no more than 4 weeks after the last dose of ravulizumab. Ongoing combination therapy of complement inhibitors will not be approved.
    - Soliris:
      Indication for use is Atypical Hemolytic Uremic Syndrome: Dose requested must be within the FDA parameters for loading and maintenance dose.
      Indication for use is paroxysmal nocturnal hemoglobinuria (PNH): Diagnosis is documented by flow cytometry AND The patient has received the meningococcal vaccine at least 2 weeks prior to therapy initiation. Authorization for continued use shall be reviewed to confirm that the patient has experienced an objective response to the therapy (e.g. stabilization of hemoglobin levels, reductions in transfusions, improvement in hemolysis, etc.)
      Indication for use is Myasthenia Gravis: The patient is anti-aceytlcholine receptor (AchR) antibody positive AND the patient has a documented side effect, allergy, or treatment failure with at least 2 immunosuppressive therapies (e.g. corticosteroids, azathioprine, cyclosporine, mycophenolate, etc.).
    - Update Ultomiris: The patient has a diagnosis of Atypical Hemolytic Uremic Syndrome or a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) documented by flow cytometry AND The patient has received the meningococcal vaccine at least 2 weeks prior to therapy initiation. Authorization for continued use shall be reviewed to confirm that the patient has experienced an objective response to the therapy (e.g. stabilization of hemoglobin levels, reductions in transfusions, improvement in hemolysis, etc.) Note: Dose requested must be within the weight-based parameters for loading and maintenance dose.

Public Comment: Jamie Tobitt, PharmD from Apellis Pharmaceuticals: Highlighted the attributes of Empaveli (pegcetacoplan).

Board Decision: The Board unanimously approved the above recommendations.

- Exservan® (riluzole)

Riluzole, the active ingredient of Exservan®, is a member of the benzothiazole class. The mechanism by which it exerts its therapeutic effects for its approved indication is not known. It is indicated for the treatment of amyotrophic lateral sclerosis (ALS). The efficacy of Exservan® is based upon a relative bioavailability and food-effect study in healthy subjects comparing oral riluzole tablets to Exservan® oral film. A pharmacokinetic study in healthy adult subjects under fasting conditions at 50mg dose level demonstrated similar bioavailability for riluzole from Exservan® and riluzole tablets. Riluzole tablets, under the brand name of Rilutek® have been available for several years and are available generically. Exservan® provides another dosage formulation option for providers.

Recommendation:

- Add Exservan™ (riluzole) film to non-preferred.
  - Clinical criteria:
    - Add Exservan to the Tiglutik criteria.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

- Myfembree® (relugolix, estradiol, & northindrone acetate)

Myfembree® is a fixed-dose combination of relugolix (a non-peptide small molecule gonadotropin-releasing hormone [GnRH] receptor antagonist), estradiol (E2, an estrogen), and norethindrone acetate (NETA, a progestin). Relugolix is a GnRH receptor antagonist that competitively binds to pituitary GnRH receptors, thus reducing the release of luteinizing hormone (LH) and follicle-stimulating hormone (FSH), leading to decreased serum concentrations of the ovarian sex hormones estradiol and progesterone and reduced bleeding associated with uterine fibroids. Estradiol acts by binding to nuclear receptors that are expressed in estrogen-responsive tissues. The addition of exogenous estradiol may reduce the increase in bone resorption and resultant bone loss that can occur due to a decrease in circulating estrogen concentrations from relugolix alone. Progestins act by binding to nuclear receptors that are expressed in progesterone-responsive tissues. Norethindrone may protect the uterus from the potential adverse endometrial effects of unopposed estrogen. It is indicated for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal women. Use of Myfembree® should be limited to 24 months due to the risk of continued bone loss which may not be reversible. The safety and efficacy of Myfembree® were assessed in two replicate, 24-week, multinational, randomized, double-blind, placebo-controlled trials (Study LI and Study L2), that included premenopausal

women (N=768) with heavy menstrual bleeding associated with uterine fibroids. For study inclusion, women had to have uterine fibroids confirmed by ultrasound exam in which at least one fibroid met at least one of the following: Subserosal, intramural, or <50% intracavitary submucosal fibroid with a diameter ≥2cm, or Multiple small fibroids with a total uterine volume of ≥130 cm3. The primary endpoint was the proportion of women in the Myfembree® group compared with women in the placebo group, who achieved menstrual blood loss (MBL) volume of <80ml and at least a 50% reduction from baseline MBL volume over the last 35 days of treatment, as measured by alkaline hematin method. Key secondary endpoints were related to amenorrhea, MBL volume, and change in hemoglobin. It has a box warning regarding increased risk of thromboembolic disorders and vascular events. In two double-blind, placebo-controlled studies that included premenopausal women with heavy menstrual bleeding associated with uterine fibroids, relugolix 40mg +E2 1mg/NETA 0.5mg (which is the equivalent to 1 tablet of Myfembree®) was compared with placebo for 24 weeks. A statistically greater proportion of women treated with Myfembree® achieved the primary endpoint of both MBL volume of less than 80ml and at least a 50% reduction from baseline in MBL volume over the last 35 days of treatment compared with placebo. Oriahnn® (with the active ingredients of elagolix (a GnRH receptor antagonist), E2, and NETA) has the same indication as Myfembree®, but Oriahnn® is to be taken twice daily while Myfembree® can be taken once daily.

Recommendation:

- Add Myfembree® (relugolix/estradiol/norethindrone) tablet to non-preferred.
  - Clinical criteria:
    - Add Myfembree: Patient is premenopausal and is experiencing heavy menstrual bleeding associated with uterine leiomyomas (fibroids) AND patient has a documented side effect, allergy, or treatment failure to at least TWO medications from at least 2 different classes (oral contraceptives, NSAIDs, progestins) AND patient has a documented side effect, allergy, or treatment failure with Oriahnn. Approval will be limited to 1 tablet/day. Use of GnRH receptor antagonists will be limited to 2 years.
    - Update both Orillissa and Oriahnn to state Use of GnRH receptor antagonists will be limited to 2 years.

Public Comment: Allison Musick Legier, PharmD from Pfizer: Highlighted the attributes of Myfembree® (relugolix, estradiol, and norethindrone acetate).

Board Decision: The Board unanimously approved the above recommendations.

- Nextstellis® (drospirenine and estetrol)

Nextstellis® is an oral contraceptive that contains drospirenone (a synthetic progestin that is a spironolactone analogue with anti-mineralocorticoid and antiandrogenic activity) and estetrol (a synthetic analogue of a native estrogen present during pregnancy that is selective for nuclear estrogen receptor-α (ER-α) and ER-β). Combined hormonal contraceptives (CHCs) prevent

pregnancy primarily by suppressing ovulation. It is indicated for use by females of reproductive potential to prevent pregnancy. Nextstellis® may be less effective in females with a BMI ≥30kg/m2. In females with BMI ≥30kg/m2, decreasing effectiveness may be associated with increasing BMI. The efficacy of Nextstellis® was assessed in a prospective, multicenter, open-label, single-arm, one-year study in North America that included 1,674 females between the ages of 16 to 35 years. In an open-label, single-arm study, a total of 26 on-treatment pregnancies occurred in 1,524 females, contributing 12,763 at-risk cycles. The overall Pearl Index was 2.65 per 100 woman-years of use. A trend of decreasing effectiveness with increasing BMI was observed in this study. To provide some basis for comparison, another contraceptive method, the Annovera® vaginal ring that contains segesterone acetate and ethinyl estradiol, has an overall pooled unintended pregnancy rate (Pearl Index) of 2.98 per 100 woman-years[2] and condoms are generally cited as having a Pearl Index of 3-123.

Recommendation:

- Add Nexstellis (drospirenone/estetrol) to non-preferred

Public Comment: No public comment.
Board Discussion: Dr. Nasca inquired if DVHA had age limits on contraception citing age of consent for example. Laurie Brady indicated that there are not age limits currently in place.

Board Decision: The Board approved the above recommendations despite one nay vote from Dr. Nasca.

- Ozobax® (baclofen)

Baclofen, the active ingredient of Ozobax®, is a gamma-aminobutyric acid (GABA-ergic) agonist. It's exact mechanism of action is not fully understood. Baclofen inhibits both monosynaptic and polysynaptic reflexes at the spinal level, possibly by decreasing excitatory neurotransmitter release from afferent terminals, although actions at supraspinal sites may also occur and contribute to its clinical effects. As baclofen is a structural analog of the inhibitory neurotransmitter GABA, it may exert its effects by stimulation of the GABA-B receptor subtype. It is indicated for the treatment of spasticity resulting from multiple sclerosis, particularly for the relief of flexor spasms and concomitant pain, clonus, and muscular rigidity. It may also be of some value in patients with spinal cord injuries and other spinal cord diseases. A limitation of use includes that Ozobax® is not indicated in the treatment of skeletal muscle spasm resulting from rheumatic disorders. There were no clinical trials in the prescribing information for Ozobax®. The efficacy of Ozobax® is based upon a bioavailability study in healthy adults comparing baclofen oral tablets to Ozobax®. The study included healthy adult male subjects taking a 20mg dose of oral solution and oral tablets and the results demonstrate similar bioavailability. Ozobax® may also be of some value in patients with spinal cord injuries and other spinal cord diseases. Ozobax® is not indicated in the treatment of skeletal muscle spasm resulting from rheumatic disorders. Its efficacy was based upon a bioavailability study comparing Ozobax® to oral baclofen tablets. Baclofen tablets have been available for many years and have proven to be safe and effective for their FDA approved indications, which includes being useful for the alleviation of signs and symptoms of spasticity results from

multiple sclerosis, particularly for the relief of flexor spasms and concomitant pain, clonus, and muscular rigidity. Ozobax® offers providers another dosage formulation option.

Recommendation:

- Add Ozobax® (baclofen) oral solution to non-preferred.
  - Clinical criteria:
    - Add Ozobax: Patient has a medical necessity for a non-solid oral dosage form.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

- Qelbree® (viloxazine hydrochloride)

Viloxazine, the active ingredient of Qelbree®, is a selective norepinephrine reuptake inhibitor. The mechanism of action for its approved use is not clear; however, it is thought to be mediated by inhibiting the reuptake of norepinephrine. It is indicated for the treatment of Attention-Deficit Hyperactivity Disorder (ADHD) in pediatric patients 6 to 17 years of age. The safety and efficacy of Qelbree® were assessed in three short-term, randomized, placebo-controlled, monotherapy studies that included pediatric patients 6 to 17 years of age with ADHD. It does have a box warning regarding suicidal thoughts and behaviors, thus all Qelbree®-treated patients should be closely monitored for clinical worsening, and for the emergence of suicidal thoughts and behaviors. Use is contraindicated in patients receiving concomitant treatment with MAO-inhibitors, or within 14 days following discontinuation of an MAO-inhibitor, as well as in those receiving concomitant administration of sensitive CYP1A2 substrates or CYP1A2 substrates with a narrow therapeutic range. The efficacy of Qelbree® for the treatment of ADHD in patients aged 6 to 17 years of age was assessed in 3 double-blind, placebo-controlled studies. All 3 studies demonstrated Qelbree® to have a statistically significantly greater change from baseline (reduction) in the ADHD-RS-5 total score as compared with placebo. Qelbree® is the first non-stimulant FDA approved in several years. Comparator trials with other agents approved for ADHD have not been found at this point.

Recommendation:

- Add Qelbree™ (viloxazine hydrochloride) extended-release capsule with QTY LIMIT: 100 mg = 1 capsule/day, 150 mg/200 mg = 2 capsules/day; FDA maximum recommended dose = 400 mg/day to non-preferred.
  - Clinical criteria:
    - Add Qelbree: The patient has had a documented side effect, allergy, contraindication, or treatment failure to one preferred stimulant or there is a history of substance abuse with the patient or family of the patient AND the patient has had a documented side effect, allergy, or treatment failure to atomoxetine.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

- Zegalogue® (dasiglucagon injection)

Dasiglucagon, the active ingredient of Zegalogue®, is a glucagon analog and an anti-hypoglycemic agent. It is a glucagon receptor agonist, which increases blood glucose concentration by activating hepatic glucagon receptors, thus stimulating glycogen breakdown and release of glucose from the liver. Hepatic stores of glycogen are necessary for dasiglucagon to produce an anti-hypoglycemic effect. It is indicated for the treatment of severe hypoglycemia in pediatric and adult patients with diabetes aged 6 years and above. The safety and efficacy of Zegalogue® were assessed in 3 randomized, double-blind, placebo-controlled, multicenter trials conducted in patients with type 1 DM. Its efficacy was assessed in 3 randomized, double-blind, placebo-controlled trials that also included patients randomized to glucagon for injection in 2 of the trials. The median time to plasma glucose recovery (treatment success) was the primary endpoint for all 3 studies, and the median time to plasma glucose recovery was statistically significantly shorter for Zegalogue® as compared with placebo in all 3 trials. The median time to plasma glucose recovery was 10 minutes for Zegalogue® in all 3 studies. In one adult trial and one pediatric trial, some patients were randomized to glucagon for injection. In both studies, the median time to plasma glucose recovery was numerically similar between Zegalogue® and glucagon for injection.

Recommendation:

- Rename sub-category Hypoglycemia Treatments
- Add Glucagon emergency kit (all other labelers except 00002) and Zegalogue® (dasiglucagon SC injection) 0.6 mg to non-preferred.
    - Clinical criteria:
        - Add Glucagon Emergency Kit (non-preferred manufacturers): Labeler 00002 must be on backorder and unavailable from the manufacturer.
        - Revise Baqsimi, Gvoke, Zegalogue: The patient's age is FDA approved for the given medication AND Patient has recurrent episodes of symptomatic or severe hypoglycemia (<55 mg/dL) requiring the assistance of another individual AND caregiver(s) is unable to reconstitute and administer IM glucagon (e.g. difficulty with manual dexterity). Convenience is not adequate justification for inability to use Glucagon IM.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

9. New Therapeutic Drug Classes

- None at this time.

10. Therapeutic Drug Classes- Periodic Review:

- **Anticoagulants**
  - No new drugs.
  - No new significant clinical changes.

Recommendation:

- Remove Coumadin® (warfarin) from the PDL.

Public Comments: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

- **Antidepressants, Other**
  - No new drugs.
  - No new significant clinical changes.

Recommendation:

- Remove Length of Authorization: Duration of Need for Mental Health Indications, 1 Year for Other Indications from the subcategory.
- Remove Khedezla® (desvenlafaxine base SR) and Tofranil® (imipramine) from the PDL.
- Revise length of therapeutic failure requirement for Trintellix and Viibryd (change from 4 to 8 weeks).

Public Comments: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

- **Antidepressants, SSRIs**
  - No new drugs.
  - No new significant clinical changes.

Recommendation:

- Move Fluoxetine® tablets to preferred.
- Remove quantity limits for sertraline tablets and escitalopram tablets.
- Add Sertraline capsules 150 mg, 200 mg with QTY LIMIT: 1 capsule/day and Paroxetine mesylate (compare to Brisdelle®) with QTY LIMIT: 1 capsule/day to non-preferred.
- Remove Sarafem® (fluoxetine pmdd) from the PDL.
  - Clinical criteria:

- Add Sertraline capsules: Prescriber must provide a clinically compelling reason why the patient is unable to use tablets.
- Revise Brisdelle, Paroxetine mesylate: The indication for use is moderate to severe vasomotor symptoms (VMS) associated with menopause. AND The patient has tried and failed generic paroxetine hydrochloride.
- Revise Paxil suspension, Escitalopram solution: The patient has a requirement for an oral liquid dosage form. AND The patient had a documented side effect, allergy, or treatment failure with 2 preferred liquid SSRI formulations.

Public Comments: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

- **Antiparkinson's Agents**
  - No new drugs.
  - No new significant clinical changes.

Recommendation:

- Remove Sinemet CR® (carbidopa/levodopa ER) and Mirapex® (pramipexole) from the PDL.

Public Comments: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

- **Gastrointestinal Agents (H2 blockers, PPIs)**
  - No new drugs.
  - The American Gastroenterological Association (AGA) published a clinical practice update (expert reviews) in 2017 of best practice advice for long-term use of PPIs by Freedberg et al. The first best practice advice included recommending the use of a PPI for short-term healing and for long-symptom control for patients with GERD and acid-related complications. It should be attempted to reduce or stop the use of PPIs in patients with uncomplicated GERD who do respond to short-term use. However, those with Barrett's esophagus and symptomatic GERD should use a PPI long-term, and those with asymptomatic Barrett's esophagus should consider long-term use. In those who use long-term PPIs, calcium, vitamin B12, and magnesium intake should not exceed the Recommended Dietary Allowance (RDA). Patients should be periodically monitored to assess they are on the lowest effective PPI dose to manage their condition. Lastly, as there is no evidence to rank PPI formulations by

risk, specific formulations utilized should not be selected based on potential risks.

Recommendation:

- Remove Zantac® (ranitidine) tablet and Pepcid® (famotidine) Oral Suspension.
- Move Cimetidine solution to non-preferred
- Revise age to ≤ 12 years for Famotidine oral suspension to be preferred. Famotidine oral suspension will remain non-preferred for patients > 12 years of age.
  - Clinical criteria:
    - Add Famotidine Oral Suspension (Age >12): Patient has a medical necessity for a liquid dosage form
    - Add Cimetidine Oral Solution, Nizatidine oral solution: Patient has a medical necessity for a liquid dosage form AND the patient has had a documented side effect, allergy, or treatment failure to famotidine oral suspension.

- **H. Pylori Agents**
  - No new drugs.
  - In 2017, the World Health Organization (WHO) designated clarithromycin-resistant Helicobacter pylori a high priority for antibiotic research and development. Current evidence recommends selection of alternative regimens for Helicobacter pylori eradication in settings where antibiotic resistance is higher than 15-20%. However, the distribution of antibiotic resistance is not well reported worldwide. There continues to be a need to implement surveillance networks in order to improve the eradication rate and, consequently, limit the burden of H pylori induced diseases such as gastric cancer
  - There are no clear data on the global distribution of resistance or its clinical effects. A systemic review and Meta-analysis in World Health Organization Regions was published in the Gastroenterology Journal in 2018. In a comprehensive assessment of global H pylori antibiotic resistance patterns over ten years, resistance to clarithromycin, metronidazole and levofloxacin was found to cross the threshold of 15% in the majority of WHO regions.
  - The resistance rates are higher in previously treated individuals than in patients who never received eradication treatment and higher in adults than in children. There is a significant association between antibiotic resistance and treatment failure as secondary outcome.

Recommendation:

- Revise clinical criteria for tetracycline (in antibiotics section of the PDL) to remove clarithromycin trial.

Public Comments: No public comment.

Board Decision: The board unanimously approved the above recommendations.

- **Platelet Aggregation Inhibitors**
  - No new drugs.
  - No other significant clinical changes.

Recommendation:

- Move Dipyridamole/Aspirin to preferred.
- Remove Yosprala® (aspirin/omeprazole), Aggrenox® (dipyridamole/Aspirin), and Ticlopidine from the PDL.

Public Comments: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

- **Gout Agents**
  - No new drugs.
  - No other significant clinical changes.

Recommendation:

- Move Colchicine tablets to preferred.
- Move Colchicine capsules to non-preferred.
  - Clinical criteria: Revise Colchicine capsules, Colcrys, Mitigare: the patient has a documented intolerance to generic colchicine tablets.

Public Comments: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

12. Review of Newly-Developed/Revised Criteria:

- **Hepatitis C Agents**
  - Update to American Association for the Study of Liver Disease (AASLD) & Infectious Diseases Society of America (IDSA) Guidelines for Medical Management of Acute HCV Infection
    - Recommendation is to no longer wait 6 months to see if there is spontaneous clearance.

- After the initial diagnosis of acute HCV with viremia (defined as quantifiable RNA), HCV treatment should be initiated without awaiting spontaneous resolution, using a "test and treat" strategy and according to the simplified approach, if eligible.
- Treatment scale-up, especially among those at highest risk of transmission, can reduce HCV incidence and prevalence.
- Even though 20-50% will clear spontaneously, the risk of transmission to others or losing the member to follow-up is thought to be greater than the cost of those few caught in the first 6 months after infection.

- The FDA first approved AbbVie's Mavyret® for adults in 2017 and extended the indication to children ages 12 and up in 2019. The new approval is for pediatric patients ages 3 and older without cirrhosis or with compensated cirrhosis. This approval was supported by results from the Phase II/III DORA Part 2 trial, in which 62 children ages 3 to 12 without cirrhosis were treated with Mavyret® for eight, 12 or 16 weeks, depending on their HCV genotype and prior treatment history. The overall cure rate was 98%; the one child who did not achieve SVR stopped treatment early. The approved duration is eight weeks for children being treated for the first time.The recommended dosage of Mavyret® in pediatric patients 3 to less than 12 years of age is based on weight. Mavyret® oral pellets are recommended for pediatric patients 3 to less than 12 years old weighing less than 45 kg. Mavyret® oral pellets in packets are a fixed combination drug product containing glecaprevir 50 mg and pibrentasvir 20 mg in each packet. The recommended dosage of Mavyret® in pediatric patients 12 years of age and older, or in pediatric patients weighing at least 45 kg, is three tablets taken at the same time once daily with food (total daily dose: glecaprevir 300 mg and pibrentasvir 120 mg).

Recommendation:

- Remove requirement that an infection for at least 6 months has been documented or can be reasonably inferred from the clinical criteria for Direct Acting Agents: Epclusa, Harvoni, Ledipasvir/sofosbuvir, Mavyret, Sofosbuvir/velpatasvir, Sovaldi, Viekira pak, Vosevi, Zepatier.

Public Comments: Matt Nguyen, PharmD from Abbvie: Highlighted the attributes of Mavyret® (glecaprevir/pibrentasvir).

Board Decision: The Board unanimously approved the above recommendations.

13. General Announcements:

- None at this time.

14. Adjourn: Meeting adjourned at 8:25 p.m.