Department of Vermont Health Access
Pharmacy Benefit Management Program
DUR Board Meeting Minutes
June 23, 2020

NOTE: The Meeting was held via Skype due to the Governor's "Stay Home Stay Safe" order related to the COVID-19 Emergency Declaration, and as authorized by recent modifications to Vermont's Public Meeting Law.

Board Members Present:

Clayton English, PharmD
Zail Berry, MD
Louise Rosales, NP
Marc Pasanen, MD
Margot Kagan, PharmD
Bill Breen, RPh
Claudia Berger, MD
Doug Franzoni, PharmD
Patricia King, MD
Renee Mosier, PharmD
Joseph Nasca, MD

Absent:

Staff:

Laurie Brady, RPh, Change HealthCare
Carrie Germaine, DVHA
Nancy Hogue, Pharm D, DVHA
Mike Ouellette, RPh, Change Healthcare
Lisa Hurteau, PharmD, DVHA
Jason Pope, DVHA
Jacquelyn Hedlund, MD, Change Healthcare
Scott Strenio, MD, DVHA

Guests:

Josh Bishop, Allergan/Abbvie
Karen Szydlik, Allergan/Abbvie
Erica Hintze, Allergan/Abbvie
Lisa Dunn, Amgen
Gene Muise, Amgen
Chelsea Leroue, Biohaven Pharmaceuticals
David Large, Biohaven Pharmaceuticals
Brett White, Biohaven Pharmaceuticals
Elizabeth Lubelczyk, Eli Lilly and Company
Garth Wright, Genentech
Frank Lanotte, GlaxoSmithKline
Lauren Lennon, Global Blood Therapeutics
Adam Denman, Global Blood Therapeutics
Crystal Henderson, Global Blood Therapeutics
Ryan Gregg, Ironshore Pharmaceuticals
Nicole Trask, Janssen Scientific Affairs
Jessica Grussing, Neurelis
Brian Burke, Neurelis
Thomas Algozzine, Novartis Pharmaceuticals
Matt Bradley, Novartis Pharmaceuticals
Matthew Guilbault, Novartis Pharmaceuticals
Brian Dillon, Otsuka
Tina McCann, Sarepta Therapeutics
Tracy Copeland, Sarepta Therapeutics
Ryan Vogel, Sarepta Therapeutics
Lisa Borland, Sarepta Therapeutics
Laurian Sequeria, Sarepta Therapeutics
Bethany Zanrucha, Sarepta Therapeutics
Kevin Black, SK Life Science, Inc.
Eric Sheer, ViiV Healthcare
Frank Nagy, Xeris
Doug Franzoni
Laurie Webb
Katie MacDonald
Robert Shapiro (UVM Health Network)

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.
- The May meeting minutes were accepted as printed.

3. DUR Board Chair Election:

- Renee Mosier was nominated. The board voted and approved the nomination.

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

- This is the last meeting for Louise Rosales and Clayton English as their term ends on August 31, 2020. Thanks for their service to the board.
- September 1, 2020 is the start date for the new chair.
- An effort is ongoing to allow pharmacy COVID-19 testing. DVHA is working with the Department of Health and other payers in Vermont. The hope is for pharmacies to start testing next month.

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

- DVHA has opened many codes to cover telemedicine and align reimbursement with face-to-face visits. They are coordinating with Blue Cross/Blue Shield.
- DVHA is also looking into methods to reimburse both the PCP and specialist for electronic consults.
- National Institutes of Health (NIH) grant may be available to support remote alcohol abuse counseling. This would involve an app on the patient's mobile device.

6. Follow-up Items from Previous Meetings: Lisa Hurteau, PharmD, DVHA, Laurie Brady, RPH Change Healthcare, and Mike Ouellette, RPh, Change Healthcare

- Long Term Use of Antibiotics RetroDUR status update:

DVHA is currently working on pulling a select number of charts for review. Point-of-sale edits to broadly limit antibiotic duration across therapeutic classes is proving to be difficult due to the wide range of indications and dosing. The better approach would be to focus on specific antibiotics.

- Concurrent use of Opioids and Benzodiazepines RetroDUR status update:

DVHA and Change Healthcare completed a detailed review of the prescription profiles for the 5 patients that had benzodiazepine/opioid overlap and 10 or more ER/hospital visits. Their daily MME and clonazepam daily equivalents were provided to the board. Reaching out to the prescriber(s) of these 5 patients is the next step.

7. RetroDUR/ProDUR: Laurie Brady, RPh, Change Healthcare and Jacquelyn Hedlund, MD, Change Healthcare

- Introduction of RetroDUR: Prescriber PDL Compliance

The Department of Vermont Health Access Pharmacy Benefit Management Program maintains a Preferred Drug List and Drugs Requiring Prior Authorization. Act 127 passed in 2002 resolved the Commissioner for Office of Vermont Health Access shall establish a pharmacy best practices and cost control program designed to reduce the cost of providing prescription drugs, while maintaining high quality in prescription drug therapies. The program shall include: "A preferred list of covered prescription drugs that identifies preferred choices within therapeutic classes for particular diseases and conditions, including generic alternatives. "

Social Security Act 1927 allows states to maintain Preferred Drug lists to maximize savings while at the same time guaranteeing access and quality. The criteria used to determine authorization for non-preferred drugs is transparent and vetted through the state Drug Utilization Review Board (DURB) and available publicly. In Vermont, the DURB serves a dual purpose. One is the drug utilization review component whereby the Board applies criteria and standards in the application of DUR activities, reviews and reports the results of DUR activities performed by DVHA and/or proposes recommended intervention programs such as educational outreach. The second portion of the DUR Board is the P&T Committee role whereby the board provides guidance on the development of the PDL for DVHA beneficiaries and performs new drug reviews focused on clinical efficacy, safety and cost. Together these functions result in more clinically appropriate prescribing and savings to Vermont's pharmacy benefit program.

Criteria for prescribing non-preferred medications are posted on the PDL. The PDL is not meant to be burdensome for providers. A well- constructed PDL should allow for prescribing of appropriate medications in most circumstances without requiring prior authorization of non-preferred medications. Evaluating the compliance with prescribing of preferred medications is a way to evaluate the rigor and adherence to criteria of the PA process. Additionally, if the PA process is sound, and many members are getting non-preferred medications appropriately, it may indicate a need to reevaluate the medication class and possible reorganization of preferred and non-preferred drug categorizations. States strive to stay current with new drugs and new indications for established medications, making PDLs fluid documents that change regularly. Auditing compliance of major drug classes is a way to monitor performance of pharmacy benefit management.

We will use paid, non-reversed Medicaid pharmacy claims from 1Q2020 (1/1/20-3/31/20), excluding members with Part D, TPL, VMAP, and Healthy Vermonters coverage. We will evaluate the following categories to see how often the dispensed medication was preferred. Depending on the results, we will look at provider level detail to determine who is using non-preferred medications more frequently.

Asthma: Inhaled Corticosteroids (alone and in combination with a LABA)
Diabetes mellitus: incretin mimetics (GLP1 agonists and DPP-4 inhibitors)
Stimulants

MAT therapy (Buprenorphine and buprenorphine/naloxone

Recommendation: None at this time.

Public Comment: No public comment.

Board Decision: None needed.

Data presentation: Concurrent Use of Opioids and Antipsychotics
The prevalence of substance use disorder is elevated among those with schizophrenia. The lifetime prevalence is estimated at 47 to 59%, compared with 16% in the overall population, although rates vary by age, gender and other factors. Opioid Use Disorder is estimated in the schizophrenic population to be around 4-11%. Antipsychotics, used to treat schizophrenia, are also used to treat other behavioral health conditions, such as mania associated with bipolar disease, depression, PTSD, obsessive-compulsive disorder and anxiety, which are also known to have a high rate of concurrence with Substance Use Disorder. The concern with co-prescribing opioids and antipsychotics is the risk of over-sedation, respiratory depression and death. CMS has highlighted the need to monitor co-prescribing of opioids and antipsychotics for side effects and adverse reactions. Section 1004 of the SUPPORT ACT adds a new section 1902 the Social Security Act which requires states to implement drug review and utilization requirements including Opioid and Antipsychotic Concurrent Fill Reviews. According to the CMCS informational bulletin dated August 5, 2019:

This alert is supported by the FDA's warning of increased risk of respiratory and Central Nervous System (CNS) depression with concurrent use of opioid and CNS depressants such as antipsychotics or sedatives, including extreme sleepiness, slowed or difficult breathing, unresponsiveness or the possibility that death can occur.[15] Patients concurrently prescribed opioid and antipsychotic drugs benefit from increased coordination of care. Additionally, improving treatment of comorbid mental health disorders is an important consideration when trying to reduce the overall negative impacts of opioid use disorders, and the treatment of pain. This review will encourage coordination of care for patients taking antipsychotic and opioid medication concurrently. We will use paid, non-reversed Medicaid pharmacy and medical claims from Calendar Year 2019, excluding members with Part D, VMAP and Healthy Vermonters coverage. Identify members, excluding those with a cancer diagnosis, who were prescribed an opioid for at least 90 days and examine how many were given an overlapping antipsychotic prescription along with continued use of the opioid. The data will be stratified by age cohorts. We will also look to see if the members, while prescribed both types of drugs, had ED visits or hospitalizations that were not behavioral health related, and if the medications were prescribed by the same, or different, prescribers. 166 members who were taking an opiate for at least 90 days were also prescribed an overlapping antipsychotic, representing approximately 10% of that population. Of note, 20 of these members had a Quetiapine prescription of 50mg or less. 69 members had at least one hospitalization or ER visit, and the total number of ER visits or hospitalizations overall was 122.

Recommendation: Several members had a fracture or trauma diagnosis associated with their ER visit/hospitalization, although there is no way to confirm whether this was related to over-sedation or adverse effects from their medications. A chart review could be completed for these members.

DVHA and Change Healthcare will be implementing a prospective DUR edit to alert the dispensing pharmacist when the patient is prescribed an antipsychotic in combination with an opiate. This will provide additional information for patient counseling and provider outreach, if deemed necessary.

Public Comment: No public comment.

Board Decision: After much discussion, The Board unanimously approved the above recommendation of a DUR edit to alert the dispensing pharmacist. The more specific the messaging can be, the better. Change Healthcare will research if CMS has guidance on general educational letters.

8. Clinical Update: Drug Reviews: Jacquelyn Hedlund, MD, Change Healthcare and Laurie Brady RPh, Change Healthcare

Biosimilar Drug Reviews:

- None at this time.

Full New Drug Reviews:

- Adakveo® (crizanlizumab-tmca)

Defer until Sickle Cell Disease Agents Therapeutic Class Review.

Recommendation:

- Defer until Sickle Cell Disease Agents Therapeutic Class Review.

Public Comment: No public comment.

Board Decision: None needed.

- Amzeeq® (minocycline aerosol, foam)

Minocycline, the active ingredient of Amzeeq®, is a semi-synthetic derivative of tetracycline. Its mechanism of action for the treatment of acne is not known. It is indicated for the topical treatment of inflammatory lesions of non-nodular moderate to severe acne vulgaris in adults and pediatric patients 9 years of age and older. The safety and efficacy of Amzeeq® were assessed in three multicenter, randomized, double-blind, vehicle-controlled studies of 12 weeks in duration that included subjects with moderate to severe acne vulgaris. This formulation of minocycline has not been evaluated in the treatment of infections. To reduce the development of drug-resistant bacteria as well as to maintain the effectiveness of other antibacterial drugs,

Amzeeq® should be used only as indicated. Amzeeq® is the first topical minocycline available on the market, and it was found to be effective in clinical trials as compared with vehicle for treatment success and inflammatory lesion count change. The propellant in Amzeeq® is flammable and thus the patient should avoid fire, flame, and smoking during and immediately after application.

Recommendation:

- Add Amzeeq® (minocycline aerosol, foam) 4% foam to non-preferred.
- Note that all topical minocycline products will require PA.
- Remove non-rebateable formulations of benzoyl peroxide from the PDL.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation

- Nurtec® ODT (rimegepant tablet, orally disintegrating)

Rimegepant, the active ingredient of Nurtec® ODT, is a calcitonin gene-related peptide (CGRP) receptor antagonist. It is indicated for the acute treatment of migraine with or without aura in adults. Nurtec® ODT is not indicated for the preventive treatment of migraine. The efficacy of Nurtec® ODT for the acute treatment of migraine with or without aura in adults was assessed in a randomized, double-blind, placebo-controlled study. In a clinical trial, Nurtec® ODT was found to be significantly more effective than placebo for pain freedom at 2 hours and most bothersome symptom freedom at 2 hours. The safety and efficacy of treating more than 15 migraines per month has not been established. Nurtec® ODT is a safe and cost-effective medication if used for those who have failed a trial of two preferred triptans or for whom they are contraindicated.

Recommendation:

- Rename category Migraine Therapy: Acute Treatments
- Add subcategory Gepants.
- Add NURTEC® ODT (rimegepant) with *QTY LIMIT:* 16 tablets/30 days to preferred after clinical criteria are met.
    - Clinical criteria
        - Add Nurtec ODT: Patient has a documented side effect, allergy, or treatment failure with 2 preferred triptans, unless contraindicated.

Public Comment: Dr. Robert Shapiro, Professor of Neurological Sciences, UVM Health Network: Discussed cardiovascular risk in patients with migraine and requests access to the new acute migraine treatments for Medicaid members since they do not have CV contraindications.

Board Decision: The Board unanimously approved the above recommendations.

- Oxbryta ® (voxelotor)

Defer until Sickle Cell Disease Agents Therapeutic Class Review.

Recommendation:

- Defer until Sickle Cell Disease Agents Therapeutic Class Review.

Public Comment: No public comment.

Board Decision: None needed.

- Reyvow® (lasmiditan)

Lasmiditan, the active ingredient of Reyvow®, is a serotonin (5-HT) 1F receptor agonist. While the exact mechanism of lasmiditan is not known, it does bind with high affinity to the 5-HT 1F receptor and it presumably exerts its effects through agonist effects at this receptor. It is indicated for the acute treatment of migraine with or without aura in adults. Reyvow® is not indicated for the preventive treatment of migraine. Reyvow® is a Schedule V controlled substance, with abuse potential. Reyvow® may cause CNS depression, including dizziness and sedation. Reyvow® may cause significant driving impairment. Warn against driving and other activities requiring complete mental alertness for at least 8 hours after Reyvow® is taken. The safety and efficacy of Reyvow® in the acute treatment of migraine were assessed in 2 randomized, double-blind, placebo-controlled trials that included patients with a history of migraine with and without aura per the International Classification of Headache Disorders (ICHD-II) diagnostic criteria. In clinical trials compared with placebo, Reyvow® significantly improved the proportion achieving headache pain freedom and freedom from most bothersome symptoms at 2 hours. Comparator studies with other active agents were not found. There is no evidence at this time to support that Reyvow® is safer or more effective than the currently preferred medications.

Recommendation:

- Add subcategory Ditans.
- Add Reyvow® (lasmiditan) with QTY LIMIT: 8 tablets/30 days to non-preferred.
    - Clinical criteria
        - Add Reyvow: Patient has a documented side effect, allergy, or treatment failure with 2 preferred triptans, unless contraindicated AND patient has a documented side effect, allergy, or treatment failure with Nurtec ODT AND counseling has been documented regarding the risks of driving impairment.

Public Comment: Elizabeth Lubelczyk, PharmD from Eli Lilly: Highlighted the attributes of Reyvow.

Board Decision: The Board unanimously approved the above recommendations.

- Tosymra® (sumatriptan)

Sumatriptan, the active ingredient of Tosymra®, is a selective 5-HT1B/1D receptor agonist. It presumably exerts its therapeutic effects in the treatment of migraine headache through agonist effects at the 5-HT1B/1D receptors on intracranial blood vessels and sensory nerves of the trigeminal system, which result in cranial vessel constriction and inhibition of pro-inflammatory neuropeptide release. It is indicated for the acute treatment of migraine with or without aura in adults. Use only if a clear diagnosis of migraine has been established. If a patient has no response to the first migraine attack treated with Tosymra®, reconsider the diagnosis before Tosymra® is administered to treat any subsequent attacks. Tosymra® is not indicated for the preventive treatment of migraine and is not indicated for the treatment of cluster headache. The efficacy of Tosymra® is based on the relative bioavailability of Tosymra® nasal spray as compared to sumatriptan subcutaneous injection 4mg in healthy adults. Sumatriptan nasal spray under the brand name Imitrex® has been available for several years as 5mg and 20mg dosages, with a generic also available.

Recommendation:

- Add Tosymra® (sumatriptan) with QTY LIMIT: 6 units/30 days to non-preferred.
  - Clinical criteria
    - Add Tosymra to the Zomig Nasal Spray, Imitrex Nasal Spray, and Onzetra Xsail criteria.

Public Comment: No public comment

Board Decision: The Board unanimously approved the above recommendations.

- Ubrelvy® (ubrogepant)

Ubrogepant, the active ingredient of Ubrelvy®, is a calcitonin gene-related peptide (CGRP) receptor antagonist. It is indicated for the acute treatment of migraine with or without aura in adults. This is not indicated for the preventive treatment of migraine. The safety and efficacy of Ubrelvy® for the acute treatment of migraine were assessed in 2 randomized, double-blind, placebo-controlled trials. In both studies, patients were instructed to treat a migraine with moderate to severe headache pain intensity; a second dose of study medication, or the patient's usual acute treatment for migraine, was permitted between 2 to 48 hours after the initial treatment for a non-responding or recurrent migraine headache. There were up to 23% of patients taking preventive medications for migraine at baseline. In 2 clinical trials compared with placebo, Ubrelvy® significantly increased the proportion of patients achieving headache pain freedom and most bothersome symptom freedom at 2 hours post-dose. The safety and efficacy of treating more than 8 migraines per month has not been established. There is no evidence at this time that Ubrelvy® is safer or more effective than the currently preferred, more cost-effective medications.

Recommendation:

- Add Ubrelvy® (ubrogepant) with QTY LIMIT: 10 tablets/30 days to non-preferred.
  - Clinical criteria
    - Add Ubrelvy: Patient has a documented side effect, allergy, or treatment failure with 2 preferred triptans, unless contraindicated AND patient has a documented side effect, allergy, or treatment failure with Nurtec ODT.

Public Comment: Josh Bishop, PharmD, CHIE from Allergan/Abbvie: Highlighted the attributes of Ubrelvy.
Dr. Malik presented a letter to the board for review on behalf of Ubrelvy.

Board Decision: The Board unanimously approved the above recommendations.

- Valtoco® (diazepam spray) (Included in the Anticonvulsants TCR)

Defer until Anticonvulsants Therapeutic Class Review.

Recommendation:

- Defer until Anticonvulsants Therapeutic Class Review.

Public Comment: No public comment.

Board Decision: None needed.

- Vyondys® 53 (golodirsen)

Golodirsen, the active ingredient of Vyondys® 53, is an antisense oligonucleotide of the phosphorodiamidate morpholino oligomer (PMO) subclass. It is designed to bind to exon 53 of dystrophin pre-mRNA resulting in exclusion of this exon during mRNA processing in patients with genetic mutations that are amenable to exon 53 skipping. Exon 53 skipping is intended to allow for production of an internally truncated dystrophin protein in patients with genetic mutations that are amenable to exon 53 skipping. It is indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the *DMD* gene that is amenable to exon 53 skipping. This indication is approved under accelerated approval based on an increase in dystrophin production in skeletal muscle observed in patients treated with Vyondys® 53. Continued approval for this indication may be contingent upon verification of a clinical benefit in confirmatory trials. The mean changes in dystrophin levels significantly increased from normal levels with Vyondys® 53 by 48 weeks of treatment. A placebo-controlled, post-marketing confirmatory trial to support accelerated approval, the ESSENCE study, is currently enrolling and expected to conclude by 2024.

Recommendation:

- Add Vyondys® 53 (golodirsen) to non-preferred.
    - Clinical criteria
        - Add Vyondys to the Exondys clinical criteria with the following modification: The patient must have a diagnosis of Duchenne Muscular Dystrophy with a confirmed mutation of the DMD gene that is amenable to exon 51 skipping (for Exondys) or exon 53 skipping (for Vyondys) (results of genetic testing must be submitted).

Public Comment: Bethany Zanrucha from Sarepta Therapeutics: Highlighted the attributes of Vyondys 53.
Laurie Webb Presented a patient testimony on behalf of Vyondys 53.
Parent Project Muscular Dystrophy letter presented to the board on behalf of Vyondys 53.

Board Decision: The Board unanimously approved the above recommendations.

- Vyepti® (eptinezumab-jjmr)

Eptinezumab-jjmr, the active ingredient of Vyepti®, is a humanized immunoglobulin G1 (IgG1) monoclonal antibody specific for calcitonin gene-related peptide (CGRP) ligand. It binds to CGRP ligand and blocks its binding to the receptor. It is indicated for the preventive treatment of migraine in adults. The efficacy of Vyepti® was assessed as a preventive treatment of episodic and chronic migraine in 2 randomized, multicenter, placebo-controlled studies, both with 6-month double-blind periods. In clinical studies compared with placebo, Vyepti® treatment demonstrated statistically significant improvements compared to placebo for the primary endpoint of the change from baseline in mean monthly migraine days over months 1-3. These studies included adults with episodic or chronic migraine. The studies were 6 months in duration, but the primary endpoint included results at 12 weeks. Comparator studies against other active treatments were not found.

Recommendation:

- Rename category Migraine Therapy: Preventative Treatments.
- Add Vyepti® (eptinezuman-jjmr) to non-preferred.
    - Clinical criteria
        - Add Vyepti to the Aimovig, Ajovy, Emgality 120mg/mL clinical criteria and the Ajovy additional criteria.

Public Comment: No public comment

Board Decision: The Board unanimously approved the above recommendations.

9. New Therapeutic Drug Classes

- Sickle Cell Disease Agents
    - Hydroxyurea is an effective treatment for SCD in children and adults and should be considered first-line therapy for the disease. This drug has

been shown to increase HbF and hemoglobin levels, reduce the rate of painful vaso-occlusive crises, and decrease blood transfusions. It is a myelosuppressive agent and is associated with side effects such as neutropenia, bone marrow suppression, and elevated liver enzymes. However, there are few complications of long-therapy, and the drug is well tolerated in most patients. It is important that prescribers work with patients on both compliance and getting them to a therapeutic level, which is 15-35mg/kg/day. These doses can be achieved for most patients with the capsule formulations.

- Adakveo: Crizanlizumab-tmca is a selectin blocker humanized IgG2 kappa monoclonal antibody that binds to P-selectin and blocks interactions with its ligands, including P-selectin glycoprotein ligand 1. Binding P-selectin on the surface of the activated endothelium and platelets block interactions between endothelial cells, platelets, red blood cells, and leukocytes. It is indicated to reduce the frequency of vaso-occlusive crises (VOCs) in adults and pediatric patients aged 16 years and older with sickle cell disease. The safety and efficacy of Adakveo® were assessed in patients with sickle cell disease (SCD) in a randomized, multicenter, placebo-controlled, double-blind study of 52 weeks in duration. In the SUSTAIN study, patients treated with Adakveo® had a significantly lower median annual rate of VOC compared to placebo. In addition, more in the Adakveo® group did not experience a VOC compared with placebo (NNT 6), while the median time to the first VOC was 4.1 months with Adakveo® vs 1.4 months with placebo.
- Oxbryta: Voxelotor, the active ingredient of Oxbryta®, is a hemoglobin S (HbS) polymerization inhibitor that binds to HbS with a 1:1 stoichiometry and has preferential partitioning to red blood cells. By increasing the affinity of Hb for oxygen, voxelotor demonstrates dose-dependent inhibition of HbS polymerization. Non-clinical studies suggest that voxelotor may inhibit RBC sickling, improve RBC deformability, and reduce whole blood viscosity. It is indicated for the treatment of sickle cell disease (SCD) in adults and pediatric patients 12 years of age and older. This indication is approved under accelerated approval based on increase in hemoglobin (Hb). Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials. The safety and efficacy of Oxbryta® in SCD were assessed in a randomized, double-blind, placebo-controlled multicenter study (HOPE) that included patients with 1 to 10 vaso-occlusive crisis (VOC) events within 12 months prior to enrollment and baseline hemoglobin. In one double-blind, placebo-controlled trial, Oxbryta® had a significantly higher Hb response rate as compared with placebo.

Recommendation:

- Add Adakveo® (crizanlizumab-tmca) and Oxbryta® (voxelotor) 500 mg tablet with QTY LIMIT: 3 tablets/day to non-preferred.

- Clinical criteria:
  - Add Adakveo: Patient has a diagnosis of Sickle Cell Disease AND patient is at least 16 years of age or older AND patient has had an inadequate response to a 6-month trial of hydroxyurea dosed at 15-35mg/kg/day, unless contraindicated AND patient has experienced at least 2 vaso-occlusive crises in the previous 12 months despite compliance with hydroxyurea. Initial approval will be granted for 6 months. For re-approval, the patient must have a decrease in the frequency or severity of VOC compared to baseline. Note: Adakveo will not be approved in conjunction with Oxbryta.
  - Add Oxbryta: Patient has a diagnosis of Sickle Cell Disease AND patient is at least 12 years of age or older AND patient has a baseline hemoglobin (Hb) ≥ 5.5-10.5 g/dL AND patient has had an inadequate response to a 6-month trial of hydroxyurea dosed at 15-35mg/kg/day, unless contraindicated AND patient has experienced at least 2 vaso-occlusive crises in the previous 12 months despite compliance with hydroxyurea. Initial approval will be granted for 6 months. For re-approval, the patient must have a decrease in the frequency or severity of VOC compared to baseline. Note: Oxbryta will not be approved in conjunction with Adakveo.

Public Comments: Chris Packer from Novartis: Highlighted the attributes of Adakveo.
Lauren Lennon from Global Blood Therapeutics: Highlighted the attributes of Oxbryta.

Board Decision: The Board unanimously approved the above recommendation.

10. Therapeutic Drug Classes- Periodic Review:

- **Anticonvulsants**
  - Valtoco: Diazepam, the active ingredient of Valtoco®, is a benzodiazepine anticonvulsant. The exact mechanism of action for diazepam is not fully understood, but it is thought to involve potentiation of GABAergic neurotransmission resulting from binding at the benzodiazepine site of the GABA-A receptor. Valtoco® is a Schedule IV controlled substance. Benzodiazepines, such as diazepam, may be subject to abuse and physical dependence can develop during chronic or frequent use. It is indicated for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (i.e. seizure clusters, active repetitive seizures) that are distinct from a patient's usual seizure pattern in patients with epilepsy 6 years of age and older. The efficacy of Valtoco® is based on the relative bioavailability of Valtoco® nasal spray as compared to diazepam rectal gel

in healthy adults. The efficacy of diazepam rectal gel has been established in 2 adequate and well-controlled clinical studies in children and adults exhibiting seizure patterns. It is a controlled substance and it is recommended that patients be treated no more frequently than one episode every 5 days and no more than 5 episodes per month.

Recommendation:

- Add VALTOCO® (diazepam) nasal spray (age ≥ 6 years) with *QTY LIMIT:* 20 units/30 days to preferred.
- Move Dilantin capsules and chewables to non-preferred with grandfathering of existing patients.
- Remove Depakene and Zonegran from the PDL.

Public Comments: Brian Burke from Neurelis Inc.: Highlighted the attributes of Valtoco.

Board Decision: The Board unanimously approved the above recommendations.

- **Ophthalmics: Allergic Conjunctivitis**
  - No new drugs.
  - No new significant clinical changes.

Recommendation:

- No changes at this time.

Public Comments: No public comment

Board Decision: No action needed.

- **Ophthalmics: Antibiotic & Combination Agents**
  - No new drugs.
  - No new significant clinical changes.

Recommendation:

- Move Moxeza® (moxifloxacin 0.5%) (preservative free) solution to non-preferred.
- Move all generic Moxifloxacin 0.5% solution to preferred.
  - Clinical criteria:
    - Remove criteria for the Vigamox and non-authorized moxifloxacin generics.

Public Comments: No public comment

Board Decision: The Board unanimously approved the above recommendation.

- **Ophthalmics: Anti-Inflammatories**
  - No new drugs.
  - No new significant clinical changes.

Recommendation:

- Remove Ocufen from the PDL.

Public Comments: No public comment

Board Decision: The Board unanimously approved the above recommendation.

- **Ophthalmics: Dry Eye Agents**
  - No new drugs.
  - No new significant clinical changes.

Recommendation:

- No changes at this time.

Public Comments: No public comment

Board Decision: No action needed.

- **Ophthalmics: Glaucoma**
  - No new drugs.
  - No new significant clinical changes.

Recommendation:

- Remove Betagan® (levobunolol) from the PDL.
- Add Betaxolol HCL solution to non-preferred.

Public Comments: No public comment

Board Decision: The Board unanimously approved the above recommendation.

- **Stimulants and Related Agents**
  - No new drugs.
  - The Canadian ADHD Resource Alliance (CADDRA) published practice guidelines in 2020[261]. They recommend a 4-step approach to treatment of ADHD: (1) Setting Treatment Objectives; (2) Medication Selection; (3) Titration & Monitoring; and (4) Ongoing Follow-up. First line agents are considered to be long-acting stimulants (methylphenidates and amphetamines) due to the fact that these agents lessen the need for multiple doses during the day, allowing for increased compliance, symptom coverage, and treatment response. Second line treatments are

atomoxetine, guanfacine, and short/intermediate acting psychostimulants. These agents can be used in patients who experience side effects, have suboptimal response with first time medications or don't have access to first line treatments. These agents can also be combined with first line ones for augmentation. Second-line non-stimulants can be used in cases where stimulant agents are contraindicated. Bupropion, clonidine, imipramine, and modafinil are considered to be third line options. These agents typically are used off-label, have higher risks, higher side effect or lower efficacy profile. Third line agents are generally reserved for treatment-resistant cases. The CAADRA also states that exceeding maximum recommended dosages is a third line option and can be considered after normal dosages or different options are explored.

Recommendation:

- Move Methylphenidate Solution to preferred.
    - Clinical criteria:
        - Remove duplication of the Dextroamphetamine IR, Zenzedi, Evekeo clinical criteria.

Public Comments: Ryan Gregg from Ironshore Pharmaceuticals Northeast: Highlighted the attributes of Jornay PM.

Board Decision: The Board unanimously approved the above recommendation.

11. Review of Newly Developed/Revised Criteria

- None at this time.

Recommendation:

- No changes at this time.

Public Comment: No public comment

Board Decision: None needed.

12. General Announcements:

- None at this time.

Public Comment: No public comment.

Board Decision: No action needed.

13. Adjourn: Meeting adjourned at 8:47 p.m.