Department of Vermont Health Access
Pharmacy Benefits Management Program
DUR Board Meeting
Draft Minutes

May 9, 2023: 6:00 – 8:30 p.m.

Board Members Present:

	Andy Miller, RPH		**Lucy Miller, MD**		**Douglas Franzoni, PharmD**
	Claudia Berger, MD		**Annie Daly, PharmD**		**Katharina Cahill, PharmD**

Board Members Absent:

	Mark Pasanen, MD		**Joseph Nasca, MD**		**Margot Kagan, PharmD**

DVHA Staff Present:

	Ashley MacWalters		**Stacey Baker**		**Taylor Robichaud, PharmD**
	Lisa Hurteau, PharmD				

Change Healthcare Staff Present:

	Laureen Biczak, DO		**Laurie Brady, RPh**		**Michael Ouellette, RPh**

Guests/Members of the Public:

- Alain Nguyen, Nicholas Boyer, Zachariah Thomas, Scott Mills, Timothy McSherry, Megan Walsh, Annie Vong, Kristen Chopas, Dennis Cole, Nicholas Primpas, Joseh Ward, Deep Patel

Executive Session:

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

Introductions and Approval of DUR Board Minutes:

- Attendance was called and introductions of DVHA and Change Healthcare staff were made.
- The March meeting minutes were accepted as printed.

DVHA Pharmacy Administration Update: Lisa Hurteau, PharmD, DVHA

- The legislative season is winding down with this tentatively being the last week in session. There are potentially some changes for DVHA pharmacy if select bills are passed, specifically as it relates to over-the-counter coverage of melatonin, vitamin D, and antihistamines.

Chief Medical Officer Update:

- None at this time. Dr. Rapaport was not in attendance.

Follow-up Items from Previous Meetings:

None at this time.

RetroDUR/ProDUR: Mike Ouellette, RPh and Laurie Brady, RPh, Change Healthcare

- Introduce: Chronic Use of Sedatives/Hypnotics

The chronic use of sedatives/hypnotic prescription drugs can be seen in a large amount of the U.S. population. It is estimated that approximately 4.6% of all Americans have used legally prescribed anxiolytics, sedatives, or hypnotics in the past 30 days. There are risk factors that could lead to poor health outcomes with sedative/hypnotic use including: current or previous alcohol or substance use disorder, history of overdose, fall risk, traumatic brain injury, memory problems, sleep apnea, age > 60 and COPD. In addition, increased risk is known in those concurrently using opioids and sedatives, including respiratory depression, over-sedation and accidental overdose.

The 2014 National Survey on Drug Use and Health estimated that 2.5% of those 12 and older used psychotherapeutic drugs for non-medical purposes, which equates to 6.5 million people. Of those, 1.9 million used tranquilizers and 330,000 used sedatives. The DSM-5 now has a specific classification labeled as Sedative, Hypnotic and Anxiolytic Use Disorder with criteria that includes a persistent desire to cut down use, or unsuccessful attempts to control use and cravings. Additionally included criteria involve spending a lot of time obtaining substance(s) and stopping or reducing important occupational social or recreational activities due to use.

Sedative/hypnotic use should be restricted to short-term treatment in most cases, with attempts to use other first-line treatments such as cognitive behavioral therapy (CBT). CBT for insomnia is preferred as first-line therapy for chronic insomnia in most patients. However, CBT is not effective for all patients and is not accessible to many, either due to lack of therapists or to limitations of insurance or time. Despite these recommendations, there remains a vast amount of individuals prescribed sedative/hypnotic medications chronically. We will use paid, non-reversed Medicaid pharmacy and medical claims from October 2021 through calendar year 2022, excluding members with Part D, VMAP and Healthy Vermonters coverage. Members with 6 months or more of continual use of sedatives/hypnotic drugs will be identified. We will look to see if any claims were submitted for cognitive behavioral therapy in these members. Additionally, we will see how many different prescribers of the sedative/hypnotic drugs each member had, to assess possible misuse of the drugs and monitor for potentially dangerous concurrent prescribing habits.

Board Decision: None at this time.

- Data Presentation: Use of Warfarin and Antibiotics

Warfarin is an effective anticoagulant but has multiple drug-drug interactions that alter its metabolism and therefore affects the degree of anticoagulation. The consequences of out-of-range INRs can leave patients vulnerable to either bleeding or clotting complications, including stroke. Antibiotics and antifungals are typically problematic group of drugs, as many of them affect the metabolism of warfarin, leading to elevated INRs and increased risk of bleeding. Antibiotics considered to be high-risk of interaction with warfarin include trimethoprim/sulfamethoxazole (TMP/SMX), ciprofloxacin, levofloxacin, metronidazole, azithromycin, clarithromycin, and the antifungal fluconazole. Although not commonly prescribed, rifampin decreases the INR, leaving patients under-anticoagulated. The manufacturer's package insert recommends closely monitoring the warfarin dose and INR when patients are prescribed these antibiotics. This monitoring should lead to dose alterations or withholding doses when necessary. In certain situations, the best course of action is to use alternative antibiotics when possible. Fortunately, pharmacists usually monitor for these interactions and contact the prescriber to be certain the drug is still warranted. Closer and more frequent monitoring of INRs is necessary during the period when patients undergo warfarin dosing adjustments. Change Healthcare used paid, non-reversed Vermont Medicaid pharmacy and medical claims from 2022, excluding members with Part D, VMAP and Healthy Vermonters coverage. They looked at all members on warfarin and determined how many were prescribed any of the antibiotics listed above that can cause a change in INR. They looked to see if an INR was done within 5 days of the antibiotic claim. We identified the prescribers and examined medical claims for ED visits and admissions up to 4 weeks after the antibiotic was prescribed, to determine if there were serious complications related to bleeding.

Of the 222 members taking warfarin, 20 were prescribed antibiotics. Of these 20, only 1 had an INR checked within 5 days of starting the antibiotic. 5 members had an ED visit or admission within 4 weeks of starting the antibiotic, but only 1 member had diagnoses possibly related to an INR increase due to antibiotic/warfarin combination. This member was diagnosed with a hemorrhagic disorder due to extrinsic anticoagulants and non-traumatic hematoma of soft tissue. This member had been placed on fluconazole for 5 days followed by ciprofloxacin for 7 days. The prescribers of the antibiotic and antifungal were different, and neither was the prescriber of warfarin, nor was an INR found for the member while on antibiotics. We do not have the INR at the time the member was seen at the hospital, that level of detail is unavailable to us in the claims system. The member was switched to Eliquis after hospitalization.

Recommendation: It appears that members on warfarin are not routinely having INRs checked after starting antibiotics, which in many cases is not being prescribed by the provider managing the INR. Given the widespread prescribing of antibiotics by all types of providers, a general mailing to the provider community reminding them of the potential interactions of antibiotics (and other drugs) with warfarin and the need to monitor INRs may be appropriate. As warfarin is used less frequently now that newer and safer anticoagulants are available, a reminder to providers may be warranted.

Board Discussion: Douglas Franzoni spoke on the importance of this notification to providers and how it would be helpful to have gentle communication and outreach regarding the possible drug interactions with warfarin.

Board Decision: The Board unanimously approved the above recommendations.

Clinical Update: Drug Reviews: Laureen Biczak, DO Change Healthcare and Laurie Brady RPh, Change Healthcare

Biosimilar Drug Reviews:

- Fylnetra® (pegfilgrastim-pbbk) biosimilar to Neulasta
- Stimufend® (pegfilgrastim-fpgk) biosimilar to Neulasta

Full New Drug Reviews:

- Auvelity® (dextromethorphan- bupropion)

Auvelity® is a combination of dextromethorphan hydrobromide (an uncompetitive NMDA receptor antagonist and sigma 1 receptor agonist) and bupropion HCl (an aminoketone and CYP450 2D6 inhibitor). The mechanism of dextromethorphan in the treatment of MDD is unclear. The mechanism of action of bupropion in the treatment of MDD is unclear; however, it is thought to be related to noradrenergic and/or dopaminergic reuptake mechanisms. Bupropion increases plasma levels of dextromethorphan by competitively inhibiting CYP2D6, which catalyzes a major biotransformation pathway for dextromethorphan. Bupropion is a relatively weak inhibitor of the neuronal reuptake of norepinephrine and dopamine and does not inhibit monoamine oxidase or the reuptake of serotonin. It is indicated for the treatment of major depressive disorder (MDD) in adults. The efficacy of Auvelity® for the treatment of MDD in adults was demonstrated in a placebo-controlled clinical study and confirmatory evidence included a second study comparing Auvelity® to bupropion HCl SR tablets. There is currently some evidence to suggest that Auvelity® may be more effective than bupropion monotherapy for the primary endpoint of mean change from baseline in MADRS score for weeks 1-6; however, there is no evidence at this time to support that Auvelity® is safer or more effective than the other currently preferred, more cost-effective medications, including using the combination of the individual components. The individual components of Auvelity® have been generically available for many years. It is therefore recommended that Auvelity® remain non-preferred and require prior authorization and be available to those who are unable to tolerate or who have failed on preferred medications.

Recommendation:

- Add Auvelity™ (bupropion/dextromethorphan) with QTY LIMT: 2 tablets/day to non-preferred.
- Add Vilazodone (compare to Viibryd®) with QTY LIMIT: 1 tablet/day to non-preferred.
- Move Viibryd® (vilazodone) Tablet (Age ≥ 18 years) with FDA maximum recommended dose = 40 mg/day to preferred.

- Clinical criteria:
    - Update Aplenzin, Auvelity: The patient is ≥ 18 years of age AND The patient has had a documented side effect, allergy, or inadequate response to at least 3 different antidepressants from the SSRI, SNRI and/or Miscellaneous Antidepressant categories (may be preferred or non-preferred), one of which must be bupropion.
    - Update Nefazodone: The patient is ≥ 18 years of age AND The patient has had a documented side effect, allergy, or inadequate response to at least 3 different antidepressants from the SSRI, SNRI and/or Miscellaneous Antidepressant categories (may be preferred or non-preferred)
    - Update Trintellix The patient is ≥ 18 years of age AND The diagnosis or indication is MDD AND The patient has had a documented side effect, allergy, or inadequate response (defined by at least 8 weeks of therapy) to at least 2 different antidepressants from the SSRI, SNRI, and/or Miscellaneous Antidepressant categories (may be preferred or non-preferred).
    - Add Vilazodone: Patient is ≥ 18 years of age AND The patient has had a documented intolerance to brand Viibryd.

Public Comment: Zachariah Thomas from Axsome Therapeutics highlighted the attributes of Auvelity.

Board Discussion: Douglas Franzoni asked if any of the patients in clinical trials were undergoing CBT while getting treatment with Auvelity. Zachariah Thomas explained that outstanding treatments, such as CBT, were not allowed in this trial as is generally seen in similar drug trials.

Board Decision: The Board unanimously approved the above recommendations.

- Relyvrio® (sodium phenylbutyrate and taurursodiol)

Relyvrio® contains two active ingredients, including sodium phenylbutyrate and taurursodiol, also known as tauroursdeoxycholic acid. This latter agent is an ambiphilic bile acid and is the taurine conjugate of ursodiol, also known as ursodeoxycholic acid. The mechanism by which Relyvrio® exerts its therapeutic effects for its approved indication is not known. It is indicated for treatment of amyotrophic lateral sclerosis (ALS) in adults. The safety and efficacy of Relyvrio® for the treatment of ALS were demonstrated in a 24-week, multicenter, randomized, double-blind, placebo-controlled, parallel-group study, that included adults with ALS. Results suggested that there was a statistically significant difference in the rate of reduction in the ALSFRS-R total score from baseline to week 24 in those treated with Relyvrio® compared to placebo. This provides another treatment option for ALS and helps slow disease progression.

Recommendation:

- Add Relyvrio™ (sodium phenylbutyrate/taurursodiol) powder for suspension with QTY LIMIT: 2 packets/day to non-preferred.
    - Clinical criteria:
        - Add Relyvrio: The diagnosis is amyotrophic lateral sclerosis (ALS) AND Disease duration is ≤ 18 months AND The patient has a slow vital capacity (SVC) spirometry test of greater than 60% of predicted at screening AND Baseline ALS Functional Rating Scale-Revised (ALSFRS-R) total score has been completed AND Initial approval will be granted for 6 months. For reapproval, clinical notes must indicate there has been improved or maintained baseline functional ability as measured by ALSFRS-R scale.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

- Rolvedon® (eflapegrastim-xnst)

Eflapegrastim-xnst, the active ingredient of Rolvedon®, is a granulocyte colony-stimulating factor (G-CSF). It is a recombinant human granulocyte growth factor that binds to G-CSF receptors on myeloid progenitor cells and neutrophils, triggering signaling pathways that control cell differentiation, proliferation, migration, and survival. It has been shown to elevate neutrophil counts in healthy subjects and in cancer patients. It is indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in adult patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with clinically significant incidence of febrile neutropenia. Rolvedon® is not indicated for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation. The safety and efficacy of Rolvedon® to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs were assessed in two randomized, open-label, active-controlled, non-inferiority studies of similar design (Study 1 and Study 2) that enrolled patients (N=643) with early-stage breast cancer. Efficacy for both trials was based on the duration of severe neutropenia in Cycle 1, and results suggested that Rolvedon® was non-inferior to pegfilgrastim for this endpoint.

Recommendation:

- Add new sub-category Eflapegrastim Products with a note that all products require PA.
- Add Rolvedon™ (eflapegrastim-xnst) Syringe to non-preferred.
- Add Fylnetra® (pegfilgrastim-pbbk) to non-preferred.
- Add Stimufend® (pegfilgrastim-fpgk) to non-preferred.
    - Clinical criteria:

- Add Fylnetra, Rolvedon, and Stimufend to Nyvepria, Udenyca: The prescriber must provide a clinically compelling reason for the use of the requested medication including reasons why any of the preferred pegfilgrastim products would not be suitable alternatives.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

- Ryaltris® (olopatadine hydrochloride and mometasone)

Ryaltris® is a metered-dose manual nasal spray containing an aqueous suspension of a fixed-dose combination of a histamine-1 (H1) receptor inhibitor (olopatadine) and a corticosteroid (mometasone furoate). The antihistaminic activity of olopatadine has been documented in humans. Mometasone is a corticosteroid demonstrating potent anti-inflammatory activity. The precise mechanism of corticosteroid action on allergic rhinitis is not known. Corticosteroids have been shown to have a wide range of inhibitory effects on multiple cell types (e.g., mast cells, eosinophils, neutrophils, macrophages, and lymphocytes) and mediators (e.g., histamine, eicosanoids, leukotrienes, and cytokines) involved in inflammation. It is indicated for the treatment of symptoms of seasonal allergic rhinitis in adult and pediatric patients 12 years of age and older. The safety and efficacy of Ryaltris® were assessed in two multicenter, randomized, double-blind, placebo- and active-controlled trials of 2-week duration (Study 1 and Study 2) that were of similar design and enrolled patients 12 years of age and older with seasonal allergic rhinitis. In both studies, Ryaltris® resulted in a statistically significant improvement in rTNSS compared to olopatadine and to mometasone given as monotherapies, as well as to placebo (except for Study 1 comparison to mometasone). (Note that the olopatadine and mometasone comparators used the same device and vehicle as Ryaltris® but were non-US approved drugs).

Recommendation:

- Add Ryaltris® (olopatadine/mometasone) with QTY LIMIT: 1 bottle (29 gm)/30days to non-preferred.
  - Clinical criteria:
    - Add Azelastine/Fluticasone, Ryaltris: The patient has a documented side effect, allergy, or treatment failure to azelastine 0.1% AND The patient has a documented side effect, allergy, or treatment failure to a preferred nasal corticosteroid OR the patient has a documented intolerance to Dymista.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

- Xaciato® (clindamycin phosphate vaginal gel)

Clindamycin phosphate, the active ingredient of Xaciato®, is an antibacterial agent that inhibits bacterial protein synthesis by binding to the 23S RNA of the 50S subunit of the ribosome. Clindamycin is predominantly bacteriostatic. Although clindamycin phosphate is inactive in vitro, rapid in vivo hydrolysis converts it to active clindamycin. It is indicated for the treatment of bacterial vaginosis in females 12 years and older. The efficacy of Xaciato® for the treatment of bacterial vaginosis in females of 12 years of age and older (N=307) was demonstrated in a randomized, double-blind, placebo-controlled clinical study that compared a single dose of Xaciato® with a single dose of placebo vaginal gel. Results suggested that a statistically significantly greater percentage of patients experienced clinical cure, bacteriological cure, and therapeutic cure at the test of cure visit (days 21-30) in the Xaciato® arm compared to placebo. While other clindamycin products are FDA approved for the treatment of bacterial vaginosis, this is the first single use clindamycin vaginal gel.

Recommendation:

- Add Xaciato™ (clindamycin vaginal gel 2%) to non-preferred.
  - Clinical criteria:
    - Update Cleocin, Xaciato: The patient has had a documented side effect, allergy, or treatment failure to a preferred clindamycin vaginal cream.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

New Therapeutic Drug Classes

- None at this time.

Therapeutic Drug Classes- Periodic Review:

Analgesics: Short Acting Opioids

- No new drugs.
- The 2022 CDC guidelines concluded that nonopioid therapies are at least as effective as opioids for many common acute pain conditions and that clinicians should maximize the use of nonopioid pharmacologic and nonpharmacologic therapies.

Recommendation:

- Remove Hydrocodone-Acetaminophen solution 10-325 mg/15ml, Pentazocine w/acetaminophen, and Ultracet® (tramadol w/ acetaminophen) from the PDL. They have been discontinued.
- Add Tramadol oral solution 5mg/ml to non-preferred.
  - Clinical criteria:

- Add Tramadol Oral Solution: patient has a medical necessity for a non-solid oral dosage form. (e.g. swallowing disorder).

Public Comments: None at this time.

Board Decision: The Board unanimously approved the above recommendations.

Analgesics- Long Acting Opioids

- No new drugs
- No other significant clinical changes.

Recommendation:

- Remove Zohydro ER® (hydrocodone bitartrate) from the PDL. It has been discontinued.

Public Comments: None at this time.

Board Decision: None needed.

Antipsychotics

- No new drugs
- December 16, 2022 FDA Approves Vraylar® (cariprazine) as an Adjunctive Treatment to antidepressants for the treatment of Major Depressive Disorder (MDD) in adults. In addition, it is FDA-approved to treat adults with depressive, acute manic and mixed episodes associated with bipolar I disorder, as well as schizophrenia.
  - Study 3111-301-001 is a randomized, double-blind, placebo-controlled, multicenter trial with 751 participants conducted in the United States, Bulgaria, Estonia, Germany, Hungary, Ukraine and the United Kingdom. Following a screening period of up to 14 days, patients with an inadequate clinical response to their antidepressant monotherapy (ADT) were randomized into three treatment groups (1:1:1). The first group received cariprazine 1.5 mg/day + ADT, the second group received cariprazine 3.0 mg/day + ADT, and the third group received placebo + ADT. For six weeks, the medication was given once daily in addition to the ongoing ADT treatment. Patients treated with cariprazine 3.0 mg/day + ADT demonstrated improvement in MADRS total score at week six over placebo + ADT but did not meet statistical significance.
  - Study RGH-MD-75 is a randomized, double-blind, placebo-controlled, flexible-dose, outpatient, multicenter trial with 808 participants, conducted in the United States, Estonia, Finland, Slovakia, Ukraine and Sweden. After 7-14 days of screening and washout of prohibited medications, eligible patients entered an 8-

week, double-blind treatment period in which they continued antidepressant treatment and were randomized (1:1:1) to adjunctive cariprazine 1-2 mg/day, cariprazine 2-4.5 mg/day, or placebo. Data from Study RGH-MD-75 were published in the Journal of Clinical Psychiatry.7 Patients treated with cariprazine 1-2 mg/day + ADT demonstrated improvement in MADRS total score at week eight over placebo + ADT but did not meet statistical significance.

Recommendation:

Antipsychotics/Atypical and Combination (Children <18 years old)

- Remove QTY LIMIT for preferred tablet formulations of olanzapine and aripiprazole aside from highest dosage form to correlate with the daily FDA maximum recommended dose.
- Add Lurasidone (compare to Latuda®) with FDA maximum recommended dose = 80 mg/day to preferred
- Move Quetiapine ER (compare to Seroquel® XR) with FDA maximum recommended dose = 800 mg/day to preferred.
- Move Paliperidone (compare to Invega®) with FDA maximum recommended dose = 12 mg/day to preferred.
    - Clinical criteria:
        - Update Criteria for approval of ALL drugs: Medication is being requested for one of the target symptoms or diagnoses listed above AND baseline labs including CBC, fasting glucose or HbA1C, and lipid profile have been completed AND the patient is started and stabilized on the requested medication (Note: samples are not considered adequate justification for stabilization) OR patient meets additional criteria outlined below Note: all requests for patients < 5 years will be reviewed by the DVHA medical director.
        - Update Abilify, Clozaril, Geodon, Invega, Latuda, Risperdal, Seroquel, Seroquel XR, Zyprexa: patient has a documented intolerance to the generic equivalent.
        - Update Aripiprazole ODT, Olanzapine ODT, Risperidone ODT, Zyprexa Zydis: Medical necessity for a specialty dosage form has been provided AND if the request is for Zyprexa Zydis, the patient has a documented intolerance to the generic equivalent.

Antipsychotics/Atypical and Combination (Adult)

- Remove QTY LIMIT for preferred tablet formulations of olanzapine and aripiprazole aside from highest dosage form to correlate with the daily FDA maximum recommended dose.

- Add Lurasidone (compare to Latuda®) with FDA maximum recommended dose = 160 mg/day to preferred
- Move Quetiapine ER (compare to Seroquel® XR) with FDA maximum recommended dose = 800 mg/day to preferred.
- Move Paliperidone (compare to Invega®) with FDA maximum recommended dose = 12 mg/day to preferred.
- Move Olanzapine intramuscular injection (compare to Zyprexa® IM) with FDA maximum recommended dose = 30 mg/day and Zyprexa® IM (olanzapine intramuscular injection) with FDA maximum recommended dose = 30 mg/day to preferred.
    - Clinical criteria:
        - Update Abilify, Clozaril, Geodon, Invega, Latuda, Risperdal, Seroquel, Seroquel XR, and Zyprexa: patient has a documented intolerance to the generic equivalent.
        - Update Vraylar:
            - Indication for use is schizophrenia/schizoaffective disorder: the patient has had a documented side effect, allergy or treatment failure with three preferred products (typical or atypical antipsychotics)
            - Indication for use is Bipolar I depression: the patient has had a documented side effect, allergy, or treatment failure with two preferred products (typical or atypical antipsychotics). If the prescriber feels that neither quetiapine or olanzapine/fluoxetine combination would be appropriate alternatives for the patient because of pre-existing conditions such as obesity or diabetes, the patient must have a documented side effect, allergy, or treatment failure with lurasidone.
            - Indication for use is adjunct treatment of Major Depressive Disorder (MDD): the patient has had a documented inadequate response to at least 3 different antidepressants from two different classes AND the patient has had a documented side effect, allergy, or treatment failure with two preferred atypical antipsychotic products being used as adjunctive therapy.

Antipsychotics/Typical

- No changes

Public Comments: Annie Vong from Abbvie: Highlighted the attributes of Vraylar.

Board Decision: The Board unanimously approved the above recommendations.

Epinephrine Autoinjectors

- No new drugs
- An FDA MedWatch was disseminated in late October 2015 regarding a recall of Auvi-Q® due to a potential inaccurate dosage delivery. This was a voluntary recall by the manufacturer of Auvi-Q®, Sanofi US, to include both available strengths. The FDA bulletin recommended that patients contact their healthcare provider to obtain a prescription for an alternate epinephrine auto-injector. Auvi-Q® was reintroduced in the first half of 2017 but was produced by a different manufacturer, Kaleo, Inc. This new manufacturer of Auvi-Q® was not rebateable in the Federal Medicaid program until April 2023, but is now eligible for coverage.

Recommendation:

- Add Auvi-Q® Inj 0.1mg, 0.15mg, and 0.3mg to non-preferred.
  - Clinical criteria:
    - Update Non-preferred Agents (0.15mg, 0.3mg): The patient must have a documented intolerance to a preferred epinephrine product.
    - Add Auvi-Q 0.1mg: Patient weight is 7.5kg to 15kg (16.5 to 33 lbs).

Public Comments: None at this time.

Board Decision: The Board unanimously approved the above recommendations.

Hepatitis B

- No new drugs
- No other significant clinical changes.

Recommendation:

- Remove Epivir-HBV® (lamivudine) and Hepsera® (adefovir dipivoxil) from the PDL. They are no longer available.
- Add Viread® (tenofovir disoproxil fumarate) powder to non-preferred. Note that the tablet formulation will remain preferred.
  - Clinical criteria:
    - Update Adefovir, Lamivudine HBV, Epivir-HBV: The prescriber must provide a clinically compelling reason for the use of the requested medication including reasons why any of the preferred products would not be suitable alternatives.
    - Update Baraclude suspension, Viread Powder: the patient has a medical necessity for a non-solid oral dosage form.

Public Comments: Alain Nguyen from Gilead: Highlighted the attributes of Vemlidy (tenofovir disoproxil).

Board Decision: The Board unanimously approved the above recommendations.

Hepatitis C

- No new drugs
- June 2022, The World Health Organization (WHO) published updated guidance on hepatitis C infection with new recommendations on treatment of adolescents and children. Treatment is now recommended for all adolescents and children down to age 3 years. These guidelines align existing recommended direct-acting antiviral (DAA regimens for adults (sofosbuvir/daclatasvir, sofosbuvir/velpatasvir, and glecaprevir/pibrentasvir for use in adolescents and children. This is expected to simplify procurement, promote access to treatment among children in low- and middle-income countries and contribute to global efforts to eliminate the disease. Until recently there had been less attention to addressing HCV in children and adolescents, and there were no DAA regimens approved for use in children. In 2018 there were an estimated 3.26 million children and adolescents, ages 18 years and younger, living with chronic HCV infection. Early diagnosis and treatment in adolescents and children are key to preventing long-term morbidity related to chronic hepatitis C infection.

Recommendation:

- Remove Peg-intron/Peg-intron Redipen (peginterferon alfa-2b) and Viekira PAK® (ombitasvir, paritaprevir, ritonavir tablet with dasabuvir tablet) from the PDL. They have been discontinued.
- Move Pegasys® (peginterferon alfa-2a) with QTY LIMIT: 4 vials or syringes/28 days to preferred.

Public Comments: Annie Vong from Abbvie: yielded time back to the committee.
Alain Nguyen from Gilead: yielded time back to the committee.

Board Decision: The Board unanimously approved the above recommendations.

Neuropathic Pain/Fibromyalgia

- No new drugs
- A 2022 systematic review and network meta-analysis by Farag et al included 36 randomized controlled trials (N=11,261) to assess the comparative efficacy and safety associated with pharmacological treatment options for fibromyalgia. Trials comparing the off-label use of amitriptyline and any FDA-approved doses of drugs (pregabalin, duloxetine and milnacipran) or placebo in reducing fibromyalgia symptoms were included. Doses compared included duloxetine 60mg and 120mg; pregabalin 150mg, 300mg, 450mg, and 600mg; milnacipran 100mg and 200mg; and amitriptyline. Outcomes assessed

included pain, sleep problems, depression, fatigue, quality of life, and acceptability. Rank probabilities were summarized using the surface under the cumulative ranking (SUCRA) curve.

- There were 35 studies that assessed pain. Of these studies, the Visual Analogue Scale (VAS) was used in 18 trials, the Brief Pain Inventory in 9 trials, Numeric Rating Scale (NRS) in 7 trials, and the Fibromyalgia Impact Questionnaire (FIQ) in one trial. Compared with placebo, duloxetine 120mg was associated with the greatest pain reduction (standardized mean difference [SMD] -0.33), followed by pregabalin 450mg (SMD -0.30). Milnacipran 100mg was associated with the lowest reduction in pain (SMD -0.17). Per the SUCRA, duloxetine 120mg (99.1%) and pregabalin 450mg (86.8%) were associated with the highest probability of effectiveness for fibromyalgia pain.

Recommendation:

- Move Savella® (milnacipran) tablet and titration pack with QTY LIMIT: 2 tablets/day to preferred.
- Add Pregabalin extended release (compare to Lyrica® CR) with FDA maximum recommended dose = 330 mg/day (DPN), 660 MG/day (PHN) to non-preferred.
- Remove Lidoderm® (lidocaine) patch from the PDL. It has been discontinued.
- Move Lidocaine 5% patch (compare to Lidoderm®) QTY LIMIT: 3 patches/day to preferred.
- Remove Synera® (lidocaine/tetracaine) Patch. It is no longer rebateable.
    - Clinical criteria:
        - Update Qutenza, Ztlido: diagnosis or indication is post-herpetic neuralgia AND patient has had a documented side effect, allergy, treatment failure or contraindication to 2 drugs in the tricyclic antidepressant (TCA) class and/or anticonvulsant class as well as Lidocaine 5% patch. OR patient has a medical necessity for transdermal formulation (ex. dysphagia, inability to take oral medications) AND patient has had a documented side effect, allergy, treatment failure or contraindication to Lidocaine 5% patch.
        - Update Cymbalta and Lyrica: the patient has had a documented intolerance with the generic equivalent.
        - Update Pregabalin ER, Lyrica CR: The patient has a diagnosis of post-herpetic neuralgia (PHN) or diabetic peripheral neuropathy (DPN) patient has not been able to be adherent to a twice daily dosing schedule of pregabalin immediate release resulting in a significant clinical impact AND for approval of pregabalin ER, the patient has a documented intolerance to brand Lyrica CR.

Public Comments: None at this time.

Board Decision: The Board unanimously approved the above recommendations.

PAH

- Tadliq® (tadalafil susension): Tadalafil, the active ingredient of Tadliq®, is a selective inhibitor of cyclic guanosine monophosphate (cGMP)-specific phosphodiesterase type 5 (PDE5). Tadalafil is an inhibitor of PDE5, the enzyme responsible for the degradation of cGMP. Pulmonary arterial hypertension is associated with impaired release of nitric oxide by the vascular endothelium and consequent reduction of cGMP concentrations in the pulmonary vascular smooth muscle. PDE5 is the main phosphodiesterase in the pulmonary vasculature. Inhibition of PDE5 by tadalafil increases the concentrations of cGMP resulting in relaxation of pulmonary vascular smooth muscle cells and vasodilation of the pulmonary vascular bed. PDE5 is found in pulmonary vascular smooth muscle, visceral smooth muscle, corpus cavernosum, skeletal muscle, platelets, kidney, lung, cerebellum, and pancreas. It is indicated for the treatment of pulmonary arterial hypertension (PAH) (WHO Group 1) to improve exercise ability. Studies establishing effectiveness included predominantly patients with NYHA Functional Class II-III symptoms and etiologies of idiopathic or heritable PAH (61%) or PAH associated with connective tissue diseases (23%). There were no new studies found in the Tadliq® prescribing information. The studies in the prescribing information for Tadliq® were those found in the prescribing information of Adcirca®, brand name for tadalafil tablets. Adcirca® has been available for many years, currently has a generic available, and has the same indication as Tadliq®. Tadliq® offers prescribers a different dosage formulation.
- May 2022: The FDA approved Tyvaso DPI™ (treprostinil) inhalation powder for the treatment of pulmonary arterial hypertension (PAH; WHO Group 1) and pulmonary hypertension associated with interstitial lung disease (PH-ILD; WHO Group 3) to improve exercise ability. Tyvaso DPI represents a new formulation and inhalation device for inhaled treprostinil and is the only dry powder inhaler approved by the FDA for use in PAH and PH-ILD. FDA approval of the new drug application for Tyvaso DPI is supported by data from BREEZE, an open label study of 51 PAH patients on a stable regimen of Tyvaso Inhalation Solution who were transitioned to Tyvaso DPI. In subjects with PAH, transition from Tyvaso Inhalation Solution to Tyvaso DPI demonstrated safety and tolerance during the three-week treatment phase with significant improvements in six-minute walk distance, device preference and satisfaction, and patient reported outcomes. Top line data from BREEZE were issued in January 2021, efficacy data were presented in September 2021, long-term open-label safety data were published in April 2022, and additional long-term safety and efficacy data were presented in May 2022.

Recommendation:

- Move Ambrisentan (compare to Letairis®) with QTY LIMIT: 1 tablet/day to preferred.
- Move Letairis® (ambrisentan) tablet with QTY LIMIT: 1 tablet/day to non-preferred.
- Move Bosentan (compare to Tracleer®) with QTY LIMIT: 2 tablets/day to preferred.
- Move Tracleer® (bosentan) tablet (62.5 mg, 125 mg) with QTY LIMIT: 2 tablets/day to non-preferred.
- Move Tyvaso® (Treprostinil) inhalation solution and Ventavis® (iloprost) inhalation solution to non-preferred with grandfathering of existing patients.
- Add Sildenafil (compare to Revatio ®) suspension, Sildenafil (compare to Revatio®) vial, and Tadliq® (tadalafil) suspension to non-preferred.
- Add Tyvaso® DPI (treprostinil) powder for inhalation to non-preferred.
    - Clinical criteria:
        - Add Flolan, Letairis, Tracleer: patient has a documented intolerance to the generic equivalent.
        - Add Tyvaso, Ventavis: The patient has a diagnosis of pulmonary arterial hypertension (PAH) 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.
        - Update Revatio Suspension, Sildenafil Suspension: Clinical diagnosis of pulmonary hypertension AND medical necessity for a liquid formulation is provided OR the patient is unable to tolerate a 20 mg dose AND for approval of Revatio, the patient must have a documented intolerance to the generic equivalent.
        - Update Revatio IV, Sildenafil IV: Clinical diagnosis of pulmonary hypertension AND No concomitant use of organic nitrate-containing products AND The patient has a requirement for an injectable dosage form. AND Arrangements have been made for IV bolus administration outside of an inpatient hospital setting.
        - Add Tadliq: Clinical diagnosis of pulmonary hypertension AND medical necessity for a liquid formulation is provided AND the patient has a documented side effect, allergy, or treatment failure with sildenafil suspension.

Public Comments: Deep Patel from Janssen Pharmaceutical Companies of Johnson & Johnson: Highlighted the attributes of Uptravi (selexipag) and Opsumit (macitentan).

Board Decision: The Board unanimously approved the above recommendations.

Topical Corticosteroids

- No new drugs
- No other significant clinical changes.

Recommendation:
Low Potency

- Move Desonide 0.05% Cream and Ointment to preferred.
- Remove Capex® (fluocinolone) 0.01% shampoo from the PDL. It is no longer rebateable.
- Remove Desonate® (desonide) 0.05% Gel. It has been discontinued.

Medium Potency

- Remove Beser™ (fluticasone) 0.05% Lotion and Cutivate® (fluticasone) 0.05% Lotion. They have been discontinued.
- Remove Sernivo® (betamethasone dipropionate) 0.05% Spray. It is no longer rebateable.

High Potency

- Remove Amcinonide 0.1% ointment, lotion. They are no longer rebateable.
- Remove Diprolene ® AF (augmented betamethasone) 0.05% Cream, Lotion. They have been discontinued.
- Move Desoximetasone 0.05% Gel to non-preferred.

Very High Potency

- Move Clobetasol 0.05% Foam and Shampoo to preferred.
- Remove Clobex® (clobetasol propionate) 0.05% Lotion, Shampoo, Spray, Diprolene® AF 0.05% Cream, Temovate® (clobetasol propionate) 0.05% Cream, Ointment, and Ultravate® (halobetasol propionate) 0.05% Cream, Ointment. They have been discontinued.

Public Comments: None at this time.

Board Decision: The Board unanimously approved the above recommendations.

Review of Newly-Developed/Revised Criteria:

- None at this time.

General Announcements:

- FDA announces new safety label changes for opioid pain medicines https://www.fda.gov/drugs/drug-safety-and-availability/fda-announces-new-safety-label-changes-opioid-pain-medicines

- FDA Commissioner and Chief Scientist Announce Decision to Withdraw Approval of Makena https://www.fda.gov/news-events/press-announcements/fda-commissioner-and-chief-scientist-announce-decision-withdraw-approval-makena.

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