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

December 5, 2023: 6:00 – 8:30 p.m.

Board Members Present:

	Andy Miller, RPH		**Katharina Cahill, PharmD**		**Margot Kagan, PharmD**
	Bram Starr, MD		**Anne Daly, PharmD**		**Lucy Miller, MD**
	Douglas Franzoni, PharmD		**Mark Pasanen, MD**		**Louise Rosales, APRN**

Board Members Absent: N/A

DVHA Staff Present:

	Ashley MacWalters		**Taylor Robichaud, PharmD**		**Michael Rapaport, MD**
	Lisa Hurteau, PharmD		**Carrie Germaine**		

Change Healthcare Staff Present:

	Jacqueline Hedlund, MD		**Laurie Brady, RPh**		**Mike Ouellette, RPh**
	Dan Hardin, SVP				

Guests/Members of the Public:

Joseph Ward, Adam Denman, Amy Cunningham, Andrew Garcia, Anna Basoff, Bill Eicholzer, Bryan Dillon, Claire Judkins, Dennis Cole, Emily Flynn, Erin Booth, Evie Knisely, Fiona Cheung, Jamie Tobitt, Jennifer Tamburo, Jigna Bhalla, Jim Pitt, Kevin Mickune, Lauren Donovan, Lindsay Smith, Lindsey Walter, Marrisa Connor, Mike Zaborowski, Nicholas Boyer, Nikhil Kacker, Omer Aziz, Ryan Miller, Susan Donnelly, Timothy McSherry, Zpora Perry

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. Lisa Hurteau welcomed Louise Rosales, APRN back to the board. Louise is a board-certified family nurse practitioner with additional certification in adult psychiatric and mental health. She currently practices at Richmond Family Medicine.

- The October meeting minutes were accepted as printed.

DVHA Pharmacy Administration Update: Lisa Hurteau, PharmD, DVHA

- In accordance with Act H. 222 of the 2023-23 legislative session, DVHA was asked to research the feasibility and cost of administering a gold card program for substance use disorder treatments. Research required to be submitted by 12/1/23 to the DURB and CURB. By 4/1/24 the DURB and CURB each need to submit recommendations to the House Committee on Human Services and to the Senate Committee on Health and Welfare.
- A Gold Card Program is a process that exempts prescribers who order or prescribe drugs in accordance with the Preferred Drug List (preferred drugs) or have high Prior Authorization approval rates. The legislation specifies AHS would not require a prior authorization for providers with a 90% or greater approval rate.
- DVHA outlined research including experience in other states. Wyoming had draft legislation, but Medicaid was specifically excluded from participation. Texas enacted a law that permits the 'gold card' exemption, but it does not apply to Medicaid. Indiana implemented exemptions for board certified addiction medicine providers, but this was discontinued in 2018 when PA criteria was removed from preferred MAT products. In Alabama, providers are reviewed quarterly to identify prescribers who practice compliance with the preferred drug list and can be removed if they don't meet the criteria. They must have prescribed three or fewer non-preferred medications during the quarter and must have prescribed more than 220 preferred agents during the quarter. Certain drugs are excluded from the exemption and still require a PA, including monoclonal antibodies, PDE inhibitors, weight loss agents, growth hormones and biological injectables.
- In Vermont, as of October 2023, prior authorization is no longer required for most drugs for substance use disorder, including injectables (Sublocade, Brixadi, Vivitrol), Suboxone film up to 24 mg per day, buprenorphine/naloxone tablets up to 24 mg per day, and naltrexone tablets. The number of prior authorizations has dropped by more than half in the 30+ days since the change went into effect. The average determination time for opioid partial agonists in October was 31 minutes. Prior Authorization remains for a few drugs: buprenorphine sublingual tablet (buprenorphine mono), buprenorphine/naloxone (generic Suboxone film), and Zubsolv (buprenorphine/naloxone) tablets.
- Preferred formulations have a lower net cost to the state. Managing this class (having non-preferred formulas) results in significant cost saving to the state. This is a CMS approved practice.
- Prior authorization is also an important safety check and helps ensure appropriate care, prevents drug diversion, and reduces potential for fraud, waste, and misuse of program resources.
- Implementing a Gold Card Program would require significant changes to the claims processing system. It would also require a new reporting suite, including a system for notification to providers as well as to capture data historically and to show the history. It would require complex programming to bypass specific prior authorization requirements at a drug category rather than for a specific drug.

Programming to define the parameters for the exemption would also be needed. The cost for this would exceed what is in the current budget.

Board Discussion: Members of the board expressed concern that a prescription could qualify for prior authorization exemption one quarter, but not in another quarter. Patient access to their prescriptions could be negatively impacted since the claim will reject if the provider is no longer eligible for gold carding, and this could potentially increase provider burden to obtain a new prior authorization. Dr. Rapaport noted that the Vermont Medical Society will sponsor legislation to look at Gold Carding from a broader perspective. Board members noted that there are frequent changes to preferred status in the commercial space which can create confusion for providers and sometimes result in patients duplicating medications with similar mechanisms of action.

Recommendation: DVHA would like the Board members to review the provided information and submit recommendations by 4/1/24.

Chief Medical Officer Update: Michael Rapaport, MD, DVHA

- Commissioner Andrea De La Bruere accepted a position with the Agency of Digital Services. Her last day will be December 14, 2023. Both a nationwide and local search will be performed for her replacement. Deputy Commissioner Adaline Strumolo will serve as Commissioner on a temporary basis until a replacement is found.
- Introduced Optum Senior Vice President Dan Hardin and stated that former Change Healthcare medical directors Dr. Barkin and Dr. Biczak will no longer be assisting with the DUR Board. With the acquisition of Change Healthcare, Optum now provides Medicaid services in 24 states, covering more than 21 million lives.

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

- Xeljanz® (tofacitinib) oral solution

Categories:
Ankylosing Spondylitis: Injectables
Rheumatoid, Juvenile & Psoriatic Arthritis: Immunomodulators
Gastrointestinal: Inflammatory Bowel Disease Biologics

Recommendation: All forms of Xeljanz must be preferred with the allowance of a step through a preferred TNF inhibitor. This will be a correction to what was proposed at the October meeting.

- Move Xeljanz® (tofacitinib) oral solution to preferred after clinical criteria are met.
  - Clinical criteria:
    - Remove for approval of oral solution, the patient must have medical necessity for a non-solid oral dosage form.

Board Decision: The Board unanimously approved the above recommendations.

- Kesimpta® (ofatumumab)

Recommendation: Revise the criteria that were proposed at the October meeting.

- Clinical criteria:
  - Patient is ≥18 years AND has a diagnosis of relapsing multiple sclerosis AND has a documented side effect, allergy, or treatment failure to one preferred drug.

Public Comments: Evie Knisely from Novartis Pharmaceuticals: Yielded time back to the committee.

Board Decision: The Board unanimously approved the above recommendations.

Antiretroviral Therapy Human Immunodeficiency Virus (HIV)

- Move Cabenuva® (cabotegravir/rilpivirine) Kit to preferred.
  - Clinical criteria:
    - Juluca: The patient has been started and stabilized on the requested medication (Note: samples are not considered adequate justification for stabilization.) OR patient is virologically suppressed (HIV-1 RNA < 50 copies per mL) on a stable oral antiretroviral regimen for at least 6 months AND 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.
    - Symfi, Symfi Lo: The patient has been started and stabilized on the requested medication. (Note: samples are not considered adequate justification for stabilization.) OR 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.

Public Comments: Lindsay Smith from UVM Medical Center advocated for expanded access to Cabenuva for her Medicaid patients. This would align with NIH guidelines and FDA approval for the medication. She has seen increased compliance in her patients that have switched from oral therapy to Cabenuva and feels it can be useful for patients with pill fatigue or high pill burdens. She stated that there is precedence on the PDL (e.g. contraception) for injectable formulations to be co-preferred with oral tablets to increase patient choice.

Zpora Perry, LICSW, UVM Medical Center advocated for expanded access to Cabenuva for her Medicaid patients. She indicated that this could help reduce the

stigma associated with taking a daily HIV medication and would lead to a direct impact on patients' physical and mental health. She also noted that Vermont commercial plans cover Cabenuva without restriction, and she feels that prior authorization by Medicaid leads to a stratification by economic status.

Board Decision: The Board unanimously approved the above recommendations.

RetroDUR/ProDUR: Jacqueline Hedlund, MD Change Healthcare and Laurie Brady, RPH Change Healthcare

Data Presentation: Co-prescribing of Opioids, Benzodiazepines, and Muscle Relaxants

The co-prescribing of opioids, benzodiazepines, and muscle relaxants is known to cause significant morbidity and has been shown to increase the likelihood of hospital admissions. A retrospective cohort study was published in 2019, examining data from the Medical Expenditure Panel Survey longitudinal dataset and the affiliated Prescribed Medicines Files from 2013-2014, weighted to reflect the actual US population. The results showed that 0.53% of the population used all three classes of medications simultaneously and compared with non-users, the odds ratio of hospitalization was 8.52 in 2013. Respiratory and CNS depression are the primary reasons for hospitalizations and deaths associated with concurrent use. A study completed in Washington State found that opioid users had a 12-fold increased rate of death when also taking a benzodiazepine and muscle relaxant. While the FDA has issued warnings about the combined use of benzodiazepines and opioids, adding a muscle relaxant contributes to the risk of hospitalization and poor outcomes. Short-term use of opioid and benzodiazepine drugs has been deemed reasonable in specific situations, although the use of triple drug therapy with opioids, benzodiazepines, and muscle relaxants, even in the short-term, is not considered appropriate patient care. FDA Warnings about the co-prescribing of benzodiazepines and opioids has brought attention to the risks; however, short-term overlapping prescriptions are sometimes seen, although less frequently over the last few years.

Change Healthcare used paid, non-reversed Medicaid pharmacy claims from Calendar Year 2022, excluding members with Part D, VMAP and Healthy Vermonters coverage. They identified members who were prescribed an opioid, benzodiazepine, and muscle relaxant with overlapping dates of service and determined if the members had the same or different prescribers. Of note, substance use disorder treatments (e.g. buprenorphine) and methadone obtained from an Opioid Treatment Program (OTP) were not included.

There were 17,095 members on any 3 of the drug classes of which 195 members had overlapping claims for opioids, benzodiazepines, and muscle relaxants (1.14%). When analyzing all members in the studied population, the average number of overlapping days was 62 for calendar year 2022. Of the 195 members prescribed triple drug overlap, 10 (5.1%) were on 3 overlapping drugs for 280 days or more, and 23 (11.8%) were on 180 days or more.

Recommendation:
There is a concern that over 44% (86 unique members) of those prescribed drugs from all three studied classes were seen by different prescribers for their prescriptions. This suggests that either incomplete histories and medication reconciliations were completed or that there is an unawareness of the risks of taking a drug from all three classes concurrently. A sample chart review by DHVA may be helpful to determine member diagnoses and to evaluate prescriber documentation that would clinically support the necessity of triple therapy in these members. Additionally, a targeted provider outreach, with the greatest priority given to prescribers in the "Different" studied population, may assist with provider notification and awareness among their patient population.

Board Decision: The Board unanimously approved sample chart review and asked for additional data regarding same or different pharmacies. A board member mentioned it may be beneficial to know if any of the triple threats were for chronic pain patients and have pain clinic referrals in place. The board discussed the possibility of pharmacy follow up to ensure pharmacist are contacting providers with multiple interaction medications are prescribed and documenting the response.

Clinical Update: Drug Reviews: Jacqueline Hedlund, MD, Laurie Brady, RPh, Change Healthcare

Biosimilar Drug Reviews:

- None at this time.

Full New Drug Reviews:

- Abilify Asimtufii® (aripiprazole)

Aripiprazole, the active ingredient of Abilify® Asimtufii, is an atypical antipsychotic. The mechanism of action for its approved indications is not known. The efficacy of aripiprazole could be mediated through a combination of partial agonist activity at dopamine D2 and serotonin 5-HT1A receptors and antagonist activity at 5-HT2A receptors. It is indicated for the treatment of schizophrenia in adults. Maintenance monotherapy treatment of bipolar I disorder in adults. The efficacy of Abilify® Asimtufii (once every 2 months dosing) for the treatment of schizophrenia in adults is based on adequate and well-controlled studies of Abilify® Maintena (every month dosing). The studies included in the Abilify® Asimtufii prescribing information are those of Abilify® Maintena for the treatment of schizophrenia, which includes one short-term, double-blind, placebo-controlled study and one longer-term, double-blind, placebo-controlled, randomized-withdrawal (maintenance) study.

- Uzedy® (risperidone)

Risperidone, the active ingredient of Uzedy®, is an atypical antipsychotic. The mechanism of action of risperidone in schizophrenia is unclear. The drug's therapeutic activity in schizophrenia could be mediated through a combination of dopamine Type 2 (D2) and serotonin Type 2 (5HT2) receptor antagonism. The clinical effect from risperidone results from the combined concentrations of risperidone and its major

metabolite, 9-hydroxyrisperidone (paliperidone). Antagonism at receptors other than D2 and 5HT2 may explain some of the other effects of risperidone. It is indicated for the treatment of schizophrenia in adults. The efficacy of Uzedy® for the treatment of schizophrenia in adults is based, in part, on the established effectiveness of oral risperidone as well as in a randomized withdrawal study (Study 1) with Uzedy® in adults who met the DSM-5 criteria for schizophrenia. The primary endpoint of the study was time to impending relapse. Time to relapse was statistically significantly longer in the Uzedy® treated groups compared to the placebo-group. There is no evidence at this time to support that Uzedy® is safer or more effective than the other currently preferred, more cost-effective medications.

Recommendation:

- Add Abilify Asimtufii® (aripiprazole) with QTY LIMIT: 1 syringe/56 days; FDA maximum recommended dose = 960 mg/ 2 months to preferred.
- Add Uzedy™ (risperidone) with QTY LIMIT: 250 mg (0.7 ml)/2 months to non-preferred.
    - Clinical criteria:
        - Remove Note: Prior therapy with injectable Invega Sustenna® is not considered to be started and stabilized for oral Invega. Patients transferring to oral therapy from Invega Sustenna® should transition to oral risperidone (unless patient previously failed such treatment).
        - Update Abilify Mycite: The patient has not been able to be adherent to aripiprazole tablets resulting in significant clinical impact (documentation of measures aimed at improving compliance is required) AND there is a clinically compelling reason why Abilify Asimtufii, Abilify Maintena, or Aristada cannot be used. Initial approval will be granted for 3 months. For renewal, documentation supporting use of the tracking software must be provided and pharmacy claims will be evaluated to assess compliance with therapy.
        - Update Olanzapine/fluoxetine: The patient has had a documented side effect, allergy, or treatment failure with two preferred products OR The prescriber provides a clinically valid reason for the use of the requested medication.
        - Add Uzedy: Provider must submit clinical rationale detailing why the patient is unable to use Perseris or Risperdal Consta.

Public Comments: Anna Basoff from Otsuka: Yielded time back to the committee.

Omer Aziz from Teva Pharmaceuticals: Highlighted the attributes of Uzedy™.

Board Decision: The Board unanimously approved the above recommendations.

- Inpefa® (sotagliflozin)

Sotagliflozin, the active ingredient of Inpefa®, is an inhibitor of sodium-glucose co-transporter 2 (SGLT2) and SGLT1. Inhibiting SGLT2 reduces renal reabsorption of glucose and sodium which may influence several physiological functions such as lowering both pre- and afterload of the heart and downregulating sympathetic activity. Inhibiting SGLT1 reduces intestinal absorption of glucose and sodium which likely contributes to diarrhea. The mechanism for the cardiovascular benefits of sotagliflozin has not been established. It is indicated to reduce the risk of cardiovascular death, hospitalization for heart failure, and urgent heart failure visit in adults with: Heart failure or Type 2 diabetes mellitus, chronic kidney disease, and other cardiovascular risk factors. The safety and efficacy of Inpefa® were assessed in the SOLOIST (Effects of Sotagliflozin on Clinical Outcomes in Hemodynamically Stable Patients with Type 2 Diabetes Post Worsening Heart Failure) study, a randomized, double-blind, placebo-controlled, parallel-group, multicenter study that included patients with type 2 DM who had been admitted to the hospital, a heart failure unit, infusion center, or emergency department for worsening heart failure. The primary endpoint for both studies was a composite of the total occurrence of cardiovascular death, hospitalization for heart failure, and urgent heart failure visit. In both studies, Inpefa® was superior to placebo in reducing the risk of the primary composite endpoint. It remains to be determined whether sotagliflozin or other SGLT2 inhibitors (e.g., ertugliflozin) have similar effects in patients with HFrEF without type 2 DM. Although it is likely a class effect, this has not yet been demonstrated in clinical studies.

Recommendation:

- Add Inpefa® (sotagliflozin) with QTY LIMIT: 1 tab/day to non-preferred.
- Add Jardiance® (empagliflozin) to preferred.
  - Clinical criteria:
    - Add Inpefa: The patient has a documented side effect, allergy, or contraindication to Farxiga and Jardiance.

Public Comments: None at this time.

Board Decision: The Board unanimously approved the above recommendations.

- Liqrev® (sildenafil)

Sildenafil, the active ingredient of Liqrev®, is an inhibitor of cyclic guanosine monophosphate (cGMP) specific phosphodiesterase type-5 (PDE-5) in the smooth muscle of the pulmonary vasculature, where PDE-5 is responsible for degradation of cGMP. Sildenafil thus increases cGMP within pulmonary vascular smooth muscle cells resulting in relaxation. In patients with Pulmonary Arterial Hypertension (PAH), this can lead to vasodilation of the pulmonary vascular bed and, to a lesser degree, vasodilation in the systemic circulation. It is indicated for the treatment of PAH (World Health Organization [WHO] Group I) in adults to improve exercise ability and delay clinical

worsening. The clinical trials in the Liqrev® prescribing information were the same as those found in the Revatio® prescribing information, which is available as oral sildenafil tablets and powder for oral suspension and has the same FDA approved indication for adults as Liqrev®. Revatio® tablets and powder for suspension are also available as generic products. Revatio® for oral suspension is a powder that needs to be reconstituted with water, while Liqrev® is available as an opaque suspension with a strawberry flavor.

Recommendation:

- Move Revatio® (sildenafil citrate) suspension to preferred after clinical criteria are met.
- Add Liqrev® (sildenafil) suspension to non-preferred.
  - Clinical criteria:
    - Update Revatio Suspension, Sildenafil tablet, Tadalafil tablet: Clinical diagnosis of pulmonary arterial hypertension.
    - Add Liqrev suspension: Clinical diagnosis of pulmonary arterial hypertension AND medical necessity for a liquid formulation is provided AND the patient has a documented side effect, allergy, or treatment failure with Revatio and sildenafil suspension.
    - Update Tadliq: Clinical diagnosis of pulmonary arterial hypertension AND medical necessity for a liquid formulation is provided AND the patient has a documented side effect, allergy, or treatment failure with sildenafil or Revatio suspension.

Public Comments: None at this time.

Board Decision: The Board unanimously approved the above recommendations.

- Qalsody® (tofersen)

Tofersen, the active ingredient of Qalsody®, is an antisense oligonucleotide that causes degradation of SOD1 mRNA through binding to SOD1 mRNA, which results in a reduction of SOD1 protein synthesis. It is indicated for the treatment of amyotrophic lateral sclerosis (ALS) in adults who have a mutation in the superoxide dismutase 1 (SOD1) gene. This indication is approved under accelerated approval based on reduction in plasma neurofilament light chain (NfL) observed in patients treated with Qalsody®. Continued approval for this indication may be contingent upon verification of clinical benefit in confirmatory trial(s). The efficacy of Qalsody® was assessed in a randomized, double-blind, placebo-controlled study of 28-weeks in duration that included patients 23 to 78 years of age with weakness attributable to ALS and a SOD1 mutation confirmed by a central laboratory (Study 1, Part C). Patients (N=108) were randomized to Qalsody® 100mg or placebo for 24 weeks (3 loading doses followed by 5 maintenance doses). Concomitant riluzole and/or edaravone use was permitted. The primary efficacy endpoint was the change from baseline to week 28 in the ALSFRS-R total score in the mITT population. Results suggested that patients treated with

Qalsody® experienced less decline from baseline in the ALSFRS-R compared to placebo, but the results were not statistically significant. However, secondary endpoints of change from baseline at week 28 in plasma NfL and CSF SOD1 protein were nominally statistically significant.

Recommendation:

- Add Qalsody® (tofersen) injection with QTY LIMIT: 100 mg (15 ml) every 14 days x 3 doses and 100 mg (15 ml)/28 days thereafter to non-preferred.
  - Clinical criteria:
    - Add Qalsody: The diagnosis is amyotrophic lateral sclerosis (ALS) AND Documentation has been provided indicating the presence of a mutation in the superoxide dismutase 1 (SOD1) gene AND The patient is ≥ 18 years old AND Patient has a slow vital capacity (%SVC) spirometry test ≥ 50% of predicted as adjusted for sex, age, and height at screening. AND Patient is not dependent on invasive ventilation or tracheostomy AND Baseline ALS Functional Rating Scale-Revised (ALSFRS-R) total score has been completed AND Initial approval will be granted for 6 months. For re-approval there must be documented response to therapy compared to baseline as evidenced by either stable or slowing decline on ALSFRS-R rating scale. (patient has not experienced a rapid disease progression while on therapy)

Public Comments: None at this time.

Board Decision: The Board unanimously approved the above recommendations.

- Rebyota™ (fecal microbiota, live- jslm)

Rebyota® (fecal microbiota, live-jslm) is an opaque fecal microbiota suspension for rectal administration. Rebyota™ is manufactured from human fecal matter sourced from qualified donors. The mechanism of action of Rebyota™ has not been established. It is indicated for the prevention of recurrence of Clostridioides difficile infection (CDI) in individuals 18 years of age and older following antibiotic treatment for recurrent CDI. The limitation of use is that Rebyota™ is not indicated for treatment of CDI. The efficacy of Rebyota™ was assessed using a Bayesian analysis of data from a randomized, double-blind, placebo-controlled, multicenter Phase 3 study (Study 1), which formally integrated treatment success rates from a placebo-controlled Phase 2 study. Treatment success was defined as the absence of CDI diarrhea within 8 weeks of blinded treatment. In the Bayesian analysis, the estimated rate of treatment success was significantly greater in the Rebyota™ group than in the placebo group through 8 weeks after completing blinded treatment (NNT 8).

- Vowst™ (fecal microbiota spores, live-brpk)

Vowst™ (fecal microbiota spores, live-brpk) is a bacterial spore suspension in capsules for oral administration manufactured from human fecal matter sourced from qualified donors indicated to prevent the recurrence of Clostridioides difficile infection (CDI) in individuals 18 years of age and older following antibacterial treatment for recurrent CDI (rCDI). Vowst™ is not indicated for treatment of CDI. Complete antibacterial treatment for recurrent CDI 2 to 4 days before initiating treatment with Vowst™. The efficacy of Vowst™ was assessed in a randomized, placebo-controlled study that included adult patients with a confirmed diagnosis of recurrent CDI (with a total of ≥3 episodes of CDI within 12 months). The primary efficacy endpoint was CDI recurrence through 8 weeks after completion of treatment, and results suggested that through 8 weeks after treatment, CDI recurrence in Vowst™ treated participants was lower compared to that in placebo-treated participants (12.4% vs 39.8%; NNT 4).

Recommendation:

- Add new PDL sub-category of Clostridium Difficile (C. Diff) Agents. Move Dificid® (fidaxomicin) tablet from macrolide class. Move Zinplava™ (bezlotoxumab) injection from miscellaneous class.
- Move Vancomycin (compare to Vancocin®) capsules to preferred.
- Move Firvanq™ (vancomycin HCl) powder for oral solution to preferred with QTY LIMIT: 1 bottle (150ml) per course of therapy. If more than 150ml is required, use of 300ml bottle is required.
- Add Rebyota™ (fecal microbiota, live-jslm) suspension to non-preferred with QTY LIMIT: 150 ml as a one-time dose.
- Add Vowst™ (fecal microbiota spores, live-brpk) capsule with QTY LIMIT: 12 capsules/3 day supply to non-preferred.
    - Clinical criteria:
        - Update Dificid: patient's diagnosis or indication is Clostridium difficile associated diarrhea (CDAD) AND for first time infection, the patient has had a side-effect, allergy, treatment failure or contraindication to oral vancomycin. OR patient is at high risk for relapse (age ≥ 65, immunocompromised, severe disease or Zar score ≥ 2).
        - Update Vancomycin oral solution: The patient has a documented intolerance to Firvanq.
        - Update Vancocin capsules: The patient has a documented intolerance to generic vancomycin capsules.
        - Add Rebyota: The patient is 18 years of age or older AND The patient has a diagnosis of Clostridium difficile infection (CDI) confirmed by a positive stool test AND The patient has had at least 2 episodes of CDI recurrence after a primary episode (i.e., 3 episodes of CDI) or CDI recurrence after pulse dosed fidaxomicin (200 mg orally twice daily for 5 days, followed by once every other day for 20 days) AND The patient has received at least 10 consecutive days of antibiotic therapy for the current CDI AND Rebyota will be administered within 24 to 72 hours of completion of the

current antibiotic regimen AND The current CDI is controlled (i.e. <3 unformed/loose stools/day for 2 consecutive days)

- Add Vowst: The patient is 18 years of age or older AND The patient has a diagnosis of Clostridium difficile infection (CDI) confirmed by a positive stool test AND The patient has a confirmed diagnosis of at least 2 recurrent episodes of Clostridium difficile infection within 12 months (total of ≥ 3 episodes of CDI within 12 months) AND The patient has had a treatment failure (CDI recurrence) with pulse dose fidaxomicin, Zinplava AND either Rebyota or fecal transplant AND The patient has received at least 10 consecutive days of antibiotic therapy for the current CDI AND Vowst will be administered within 2 to 4 days of completion of the current antibiotic regimen AND The current CDI is controlled (i.e. <3 unformed/loose stools/day for 2 consecutive days)

Public Comments: None at this time.

Board Decision: The Board unanimously approved the above recommendations. They asked DVHA and Change Healthcare to research whether fecal transplant should be required prior to approval of Rebyota..

- Veozah™ (fezolinetant)

Fezolinetant, the active ingredient of Veozah®, is a small-molecule neurokinin 3 (NK3) receptor antagonist that blocks neurokinin B (NKB) binding on the kisspeptin/neurokinin B/dynorphin (KNDy) neuron to modulate neuronal activity in the thermoregulatory center. It is indicated for the treatment of moderate to severe vasomotor symptoms due to menopause. The efficacy of Veozah® for the treatment of moderate to severe vasomotor symptoms due to menopause was assessed in the first 12-week, randomized, placebo-controlled, double-blind portion of each of two phase 3 clinical trials. In each of these 2 trials, after the first 12 weeks, women on placebo were then re-randomized to Veozah® for a 40-week extension to assess safety for up to 52 weeks total exposure. During therapy, perform follow-up bloodwork at 3 months, 6 months, and 9 months after initiation of therapy and when symptoms suggest liver injury. Use is contraindicated in known cirrhosis, as well as severe renal impairment or end-stage renal disease and concomitant use with CYP1A2 inhibitors. Data also demonstrated a statistically significant reduction from baseline in the severity of moderate to severe vasomotor symptoms at weeks 4 and 12 for Veozah™ 45mg compared to placebo. Head-to-head comparator studies with other active ingredients were not found at this time.

Recommendation:

- Add Veozah™ (fezolinetant) tablet with QTY LIMIT: 1 tablet/day to non-preferred.

- Clinical criteria:
  - Add Veozah: The indication for use is moderate to severe vasomotor symptoms (VMS) associated with menopause AND documentation has been provided detailing the frequency and severity of these symptoms AND the patient has had a documented side effect, allergy, contraindication, or treatment failure, defined by at least 4 weeks of therapy, to one preferred Hormone Replacement Therapy (HRT) and two preferred nonhormonal therapies (i.e., SSRIs, SNRIs, gabapentin, pregabalin, clonidine). For re-approval, there must be a documented improvement in the frequency or severity of VMS.

Public Comments: None at this time.

Board Decision: The Board unanimously approved the above recommendations.

- Zavzpret™ (zavegepant)

Zavegepant, the active ingredient of Zavzpret™, is a calcitonin gene-related peptide (CGRP) receptor antagonist. It is indicated for the acute treatment of migraine with or without aura in adults. A limitation of use is that it is not indicated for the preventive treatment of migraine. The safety and efficacy of Zavzpret™ for the acute treatment of migraine with or without aura in adults was demonstrated in 2 randomized, double-blind, placebo-controlled trials (Study 1 and Study 2). In both studies, patients were instructed to treat a migraine of moderate to severe headache pain intensity. Results from study 1 and 2 indicated that the percentage of patients achieving headache pain freedom and MBS freedom 2 hours after a single dose was statistically significantly greater in patients treated with Zavzpret™ as compared to placebo. Zavzpret™ is the first and currently only nasal CGRP receptor antagonist and offers providers another dosage formulation.

Recommendation:

- Add Zavzpret™ (zavegepant) with QTY LIMIT: 8 units/30 days to non-preferred. Note that all nasal spray gepants require PA.
  - Clinical criteria:
    - Add Zavzpret: Patient has a documented side effect, allergy, or treatment failure with 2 preferred triptans, one of which must be sumatriptan nasal spray, unless contraindicated AND patient has a documented side effect, allergy, or treatment failure with Nurtec ODT.

Public Comments: None at this time.

Board Decision: The Board unanimously approved the above recommendations.

<u>New Therapeutic Drug Classes</u>

- Ophthalmic, Anti-VEGF and Miscellaneous Agents (new drug Syfovre® (pegcetacoplan) included)
- Anti-VEGF agents in combination with pan-retinal photocoagulation is suggested for proliferative Diabetic Retinopathy (DR) treatment in patients with high-risk and severe proliferative DR. Ranibizumab and aflibercept are two anti-VEGF agents indicated for DR; while bevacizumab is used to treat DR, it is not FDA approved and use is off-label. There is no data to support that one is more effective for reducing neovascularization, and thus treatment is selected based on other factors, such as cost, availability, and selected patient characteristics, among others.
- Anti-VEGF agents are also recommended for most with Diabetic Macular Eedem (DME) and impaired visual acuity as first line treatment. FDA approved anti-VEGF agents for DME include aflibercept, brolucizumab, and ranibizumab, while faricimab is an antibody that inhibits VEGF-A and angiopoietin-2 pathways. The use of bevacizumab would be off-label for DME. A retina specialist should select which anti-VEGF agent is to be used for each individual patient based on numerous factors, such as baseline visual acuity, anatomic characteristics, ophthalmic history, planned future treatments for other aspects of diabetic retinopathy, and cost. It should be noted that regardless of visual acuity level, an improved response may be seen if a patient switches to a different anti-VEGF (even after two switches) when there is an inadequate response to one of the agents.4
- Retinal vein occlusion (RVO) can cause vision loss in older adults, and is the second most frequent reason for vision loss from retinal vascular disease after DR. The 3 types of RVO include central retinal vein occlusion (CRVO), hemi-retinal vein occlusion (HRVO), and branch retinal vein occlusion (BRVO). Treatment is indicated for secondary complications of RVO that affect vision, including macular edema. The intent of treatment is to maintain central visual acuity by lessening the effects of chronic macular edema, as well as regression of retinal neovascularization and the prevention of neovascular glaucoma. Anti-VEGF agents are noted to be first-line treatment for macular edema from BRVO or CRVO that has caused visual loss. Aflibercept and ranibizumab are anti-VEGF agents FDA-approved for use, while bevacizumab is off-label use. Most recently, faricimab was granted FDA approval for macular edema following RVO.
- Intravitreal injection with anti-VEGF antibodies (e.g., aflibercept, brolucizumab, ranibizumab) are recommended as first-line therapy for neovascular AMD. Bevacizumab (under the brand name Avastin®) is also an anti-VEGF agent but is not FDA approved for neovascular AMD and thus use would be off-label; however, some reference sources indicate that off-label use may be considered as a cost-effective alternative treatment. In addition, faricimab is an anti-VEGF

and an angiopoietin-2 inhibitor that is FDA approved for neovascular AMD.

- Syfovre®, a complement inhibitor to be administered by a qualified physician by intravitreal injection to each affected eye once every 25 to 60 days, is indicated for the treatment of geographic atrophy (GA) secondary to age-related macular degeneration (AMD). Its safety and efficacy were assessed in two randomized, sham-controlled studies that included patients with GA, with or without subfoveal involvement, secondary to AMD. Reduction in the mean rate of GA lesion growth was observed in both studies with Syfovre® every month and Syfovre® every other month as compared with sham. Syfovre® is the first FDA-approved treatment for GA.

Recommendation:

- Add new PDL Class Anti-VEGF and Miscellaneous Agents.
- Add Eylea® (aflibercept) and Lucentis® (ranibizumab) to preferred.
- Add Beovu® (brolucizumab-dbll), Byooviz™ (ranibizumab-nuna) biosimilar to Lucentis®, Cimerli® (ranibizumab-eqrn) biosimilar to Lucentis®, Eylea® HD (aflibercept), Susvimo® (ranibizumab) implant, Syfovre® (pegcetacoplan) with QTY LIMIT: 15mg (0.1mL) per dose (each affected eye) every 25 days, and Vabysmo® (faricimab-svoa) to non-preferred.
    - Clinical criteria:
        - Add Beovu, Vabysmo: The patient has a documented side effect, allergy, or treatment failure with Eylea and Lucentis.
        - Add Byooviz, Cimerli: Patient must be unable to use Lucentis.
        - Add Eylea HD: Patient has had a positive clinical response to Eylea AND Medical necessity for a specialty dosage form has been provided.
        - Add Susvimo: Patient has had a positive clinical response to an intravitreal formulation of ranibizumab AND Medical necessity for a specialty dosage form has been provided.
        - Add Syfovre: Medication is being used for the treatment of Geographic Atrophy (GA) secondary to age-related macular degeneration (AMD). Initial approval will be granted for 6 months. For re-approval, documentation is required showing a reduction in the mean rate of GA lesion growth.

Public Comments:
Jamie Tobitt from Apellis Pharmaceuticals highlighted the attributes of Syfovre® (pegcetacoplan).

Board Decision: The Board unanimously approved the above recommendations with the following modification to Syfovre: For re-approval, documentation is required showing no worsening in the mean rate of GA lesion growth.

Therapeutic Drug Classes- Periodic Review:

(Public comment prior to Board action)

- Gastrointestinal Ulcer Therapies (new drug Konvomep® (omeprazole and sodium bicarbonate) included)

Konvomep® is a combination of omeprazole (a proton pump inhibitor or PPI) and sodium bicarbonate (an antacid). Omeprazole belongs to a class of antisecretory compounds, the substituted benzimidazoles, that suppress gastric acid secretion by specific inhibition of the H+/K+ ATPase enzyme system at the secretory surface of the gastric parietal cell. Because this enzyme system is regarded as the acid (proton) pump within the gastric mucosa, omeprazole has been characterized as a gastric acid-pump inhibitor, in that it blocks the final step of acid production. This effect is dose related and leads to inhibition of both basal and stimulated acid secretion irrespective of the stimulus. It is indicated in adults for short-term treatment (4 to 8 weeks) of active benign gastric ulcer. Reduction of risk of upper gastrointestinal (GI) bleeding in critically ill adult patients. The efficacy of Konvomep® has been established, in part, based on studies of an oral delayed-release omeprazole product for the treatment of active benign gastric ulcer. The studies in the prescribing information for Konvomep® were the same as in the omeprazole capsules prescribing information regarding treatment of gastric ulcer. In addition, the efficacy of Konvomep® has been established, in part, based on studies of another omeprazole and sodium bicarbonate oral suspension product for the reduction of risk of upper GI bleeding in critically ill adult patients. Konvomep® offers physicians a different dosage formulation and is the only FDA-approved omeprazole formulation dispensed as an oral liquid, as it is to be reconstituted by a healthcare provider prior to dispensing.

Recommendation:

H2 Blockers:

- Remove Cimetidine and Nizatidine oral solutions. They are no longer available.
-

PPIs and Combinations:

- Remove quantity limits for preferred capsules and tablets.
- Add Dexlansoprazole (compare to Dexilant®) capsules with QTY LIMIT: 1 cap/day to non-preferred.
- Add Konvomep® (omeprazole/sodium bicarbonate) oral suspension with QTY LIMIT: 8 weeks of therapy to non-preferred.
- Add Omeprazole/Sodium bicarbonate (compare to Zegerid®) packet for oral suspension with QTY LIMIT: 1 packet/day to non-preferred.
- Add Pantoprazole (compare to Protonix®) packet with QTY LIMIT: 1 packet/day to non-preferred.

- Add Zegerid RX® (omeprazole/sodium bicarbonate) packet for oral suspension with QTY LIMIT: 1 packet/day to non-preferred.
- Move Zegerid RX® brand and omeprazole-sodium bicarbonate (oral) capsule to preferred with QTY LIMIT: 1 cap/day.
- Move Lansoprazole ODT (compare to Prevacid Solutab®) with QTY LIMIT: 1 tab/day to preferred for age < 12 years.
- Move Protonix® (pantoprazole) packet with QTY LIMIT: 1 packet/day to preferred for age < 12 years.
- Remove Aciphex® Sprinkle (rabeprazole) DR Capsules. They were discontinued by the manufacturer.
    - Clinical criteria:
        - Update Lansoprazole ODT, Nexium powder for suspension, Protonix packet (for patients ≥ 12 years old): The patient has a requirement for a non-solid oral dosage form (e.g. an oral liquid, dissolving tablet or sprinkle).
        - Update Pantoprazole packet, Prevacid Solutabs, Prilosec packet: The patient has a requirement for a non-solid oral dosage form (e.g. an oral liquid, dissolving tablet or sprinkle). AND the member has had a documented side effect, allergy, or treatment failure to two preferred specialty dosage formulations.
        - Add Dexlansoprazole: The patient has had a documented side effect, allergy, or treatment failure to three preferred PPIs AND the patient has had a documented intolerance to brand Dexilant.
        - Update Other single-ingredient non-preferred medications: The patient has had a documented side effect, allergy, or treatment failure to three preferred PPIs AND if the product has an AB rated generic, there must be a trial of the generic.
        - Add Konvomep, Omeprazole/sodium bicarb packet, Zegerid packet: The patient has a documented side effect, allergy, or treatment failure to omeprazole/sodium bicarb capsules OR patient has a medical necessity for a non-solid oral dosage form and has a documented side effect, allergy, or treatment failure with lansoprazole ODT or Nexium powder for suspension.

Public Comments: None at this time.

Board Decision: The Board unanimously approved the above recommendations.

- H. Pylori Combination Treatments

Recommendation:

- Move Lansoprazole, Amoxicillin, Clarithromycin with QTY LIMIT: 112 caps & tabs/14 days to non-preferred.

- Add Bismuth Subcitrate, Metronidazole, Tetracycline (generic for Pylera®) with QTY LIMIT: 120 caps/10 days to non-preferred.
    - Clinical Criteria:
        - Update: The patient has a documented treatment failure with Lansoprazole, amoxicillin, clarithromycin combo package or Pylera used in combination with a PPI.

Public Comments: None at this time.

Board Decision: The Board unanimously approved the above recommendations.

- Hyperuricemia and Gout

Recommendation: No changes.

Public Comments: None at this time.

Board Decision: None needed.

- Ophthalmic, Allergic Conjunctivitis

Recommendation:

- Remove quantity limits for preferred agents.
- Remove Lastacaft® (alcaftadine). The Rx version has been discontinued. There is an OTC version available, but it is not covered due to no rebate.

- Ophthalmic, Antibiotics

Recommendation:

- Remove Ciloxan® (ciprofloxacin) solution. It is no longer available.
- Move Azasite®(azithromycin) solution to preferred.
- Move Ofloxacin (compare to Ocuflox®) solution to preferred.
- Remove Blephamide® (sulfacetamide/prednisolone acetate) suspension, Blephamide® S.O.P. (sulfacetamide/prednisolone acetate) ointment, and Bleph-10® (sulfacetamide) solution. They are all discontinued.

- Ophthalmic, Anti-Inflammatories

Recommendation:

- Move Lotemax® (loteprednol) 0.5% gel to preferred (suspension and ointment are already preferred).
- Move Nevanac® ophthalmic suspension (nepafenac 0.1%) to non-preferred.

Public Comments: None at this time.

Board Decision: The Board unanimously approved the above recommendations.

- Ophthalmic, Dry Eye Treatments

Recommendation: No changes.

Public Comments: None at this time.

Board Decision: None Needed.

- Ophthalmic, Glaucoma Agents

Recommendation:

- Add Brimonidine tartrate 0.1% to non-preferred.
- Remove Timoptic® (timolol maleate), Timoptic XE® (timolol maleate gel), Trusopt® (dorzolamide 2 %), and Isopto® Carpine (pilocarpine). They have been discontinued.
- Add Timolol maleate PF (compare to Timoptic® Ocudose) droperette and Timoptic® Ocudose (timolol maleate) preservative free droperette to non-preferred.
- Move Zioptan® (tafluprost) to preferred.
- Add Tafluprost PF solution (compare to Zioptan®) to non-preferred.
- Add Brinzolamide 1% (compare to Azopt®) to non-preferred.
- Add Dorzolamide w/timolol PF (compare to Cosopt PF®) to non-preferred.
- Add Cosopt® (dorzolamide w/timolol) to non-preferred.
- Move Phospholine iodide® (echothiophate) to non-preferred.
    - Clinical criteria:
        - Update ALPHA 2 ADRENERGIC AGENTS: Single Agent: The patient has had a documented side effect, allergy, or treatment failure with at least one preferred ophthalmic alpha 2 adrenergic agent. If the request is for brimonidine tartrate 0.1% or 0.15%, the patient must have a documented intolerance of brand name Alphagan P.
        - Update BETA BLOCKERS: The patient has had a documented side effect, allergy, or treatment failure with at least one preferred ophthalmic beta blocker OR the patient has had a documented intolerance to the preservatives in generic timolol maleate.
        - Update Bimatoprost, Tafluprost, Travoprost, Vyzulta, Xalatan, Xelpros: The patient has had a documented side effect, allergy, or treatment failure with at least 2 preferred prostaglandin inhibitors. If a product has an AB rated

preferred formulation, there must have also been a trial of the preferred formulation.
- Add Brinzolamide: the patient has a documented intolerance to a preferred carbonic anhydrase inhibitor.
- Update Cosopt PF, Dorzolamide w/timolol PF: The patient has had a documented intolerance to the preservatives in the generic combination product.

Public Comments: None at this time.

Board Decision: The Board unanimously approved the above recommendations.

- Platelet Aggregation Inhibitors

Recommendation:
- Remove Zontivity® (vorapaxar) tablets. They are no longer rebateable.

Public Comments: Jigna Bhalla from AstraZeneca Pharmaceuticals: Yielded time back to the committee.
Board Decision: None needed.

Review of Newly-Developed/Revised Criteria:
- None at this time.

General Announcements:
- None at this time

Adjourn: Meeting adjourned at 8:28 p.m.