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

December 3, 2024: 6:00 – 8:30 p.m.

Board Members Present:

Heather Stein, MD	**Anne Daly, PharmD**	**Douglas Franzoni, PharmD**
Rima Carlson, MD	**Bram Starr, MD**	**Louise Rosales, APRN**
Julie MacDougall, PharmD		

Board Members Absent: Katharina Cahill, Andy Miller

DVHA Staff Present:

Carrie Germaine	**Lisa Hurteau, PharmD**	**Ashley MacWalters**
Michael Rapaport, MD	**Sandi Hoffman**	

Change Healthcare Staff Present:

Roberta Capp, MD	**Mike Ouellette, RPh**	**Molly Trayah, PharmD**

Guests/Members of the Public: Adam Bradshaw, Adam Denman, Bobby White, Brielle Dozier, Carmen Hinton, Elena Fernandez, Erin Booth, Jai Persico, Kevin Gaffney, Kristen Chopas, Kristin DiDesidero, Melissa Abbott, Nicole Pinkerton, Ryan Miller, Salina Yip, Susan Donnelly, Tim McSherry

Executive Session

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

Introductions

- Attendance was called and introductions to DVHA and Optum staff were made

DVHA Pharmacy Administration Updates: Lisa Hurteau, PharmD

- Introduction of new board member
  - Heather Doyle Stein, MD was introduced as a new member to the board. Heather currently works as the Associate Medical Director for the Community Health Centers of Vermont. She has a broad record of experience serving Vermont residents in family medicine, addiction medicine, healthcare management and medical education.

DVHA Chief Medical Officer Update: Michael Rapaport, MD

- Dr. Rapaport shared DVHA's drafted report on Obesity and Implications for Covering Obesity Medications, which aims to consider the potential health benefits associated with treatment of obesity using lifestyle interventions and medications with the financial impact the newer anti-obesity medications carry.
- DVHA's summary of recommendations and concerns were shared and the board

was engaged in a discussion regarding the group's experience treating obesity and use of the GLP-1 medications.
- The group acknowledged that these medications can be life-changing for patients, but the current budget cannot absorb the costs.
- DVHA and the board will continue discussions around this topic including the potential change in the clinical definition of obesity (coming soon), determining criteria for coverage, and how to best support lifestyle modifications in conjunction with medication use

Follow-up Items from Previous Meetings

- Approval of October DUR Board minutes

Board Decision: The Board unanimously approved the above recommendations.

RetroDUR/ProDUR: Molly Trayah, PharmD, Optum

- **Data Presentation: The Effect of Trikafta on the cost and quality of care of patients with cystic fibrosis**

Cystic fibrosis (CF) is a debilitating progressive, hereditary disease which causes progressive pulmonary decline resulting in untimely death. Mutations in the CF transmembrane conductance regulator (CFTR) protein can lead to impaired sodium and potassium transport across cell membranes resulting in high viscosity sputum, dehydration and impaired sputum clearance. CFTR modulator drugs have substantially decelerated disease progression, however recurrent respiratory infections and hospitalizations are still a reality for most patients. Until recently, available CFTR modulators included lumacaftor and tezacaftor. Ivacaftor (Kalydeco) is a chloride channel opener, also used to manage disease in combination with a CFTR and is approved for those ages 1 month and older. Lumacaftor/ivacaftor (Orkambi) is approved for those 1 year and older and tezacaftor/ivacaftor (Symdeko) is approved for those 6 years of age and older. The newest medication, Trikafta, is a combination of three drugs, two CFTR modulars (elexacaftor, tezacaftor) and ivacaftor and is considered a breakthrough in therapy for those who have at least one F508del mutation and for those with any other CFTR gene mutation that is responsive, based on in vitro and/or clinical trial data. Approximately 92% of people with CF in the US have a CFTR genotype that would qualify for this treatment once they are 2 years of age. Studies have shown significant benefits in improvements in FEV1, sweat chloride measurements and even significant improvements in patients with advanced disease. The costs of CF therapeutics can be significant and newer treatments, including Trikafta, come with substantially increased drug prices. However, the increased cost of CF drugs may be offset by decreases in other medical expenses, mainly hospital admissions.

Optum used paid, non-reversed Vermont Medicaid pharmacy and medical claims, excluding members with Part D, VMAP and Healthy Vermonters coverage. The dates analyzed are specific to each patient and determined from the treatment initiation

period. For members taking Trikafta, medical and pharmacy claims were analyzed, looking at the number and cost of hospitalizations, emergency room visits and provider visits for the year prior to and 1 year after starting the medication. For those who have initiated Trikafta for CF, this analysis will calculate if the increased cost of the drug is offset by decreased utilization of medical care.

Recommendation: There are no recommended interventions. This analysis showed that, although more expensive, the use of Trikafta has had a positive impact on decreasing total spend for all medical and institutional services and a decrease in hospital admissions and the cost of those admissions.

Additionally, there was a decrease in the use of Pulmozyme after starting Trikafta. Now that the age at which Trikafta can be used is 2 years old, we expect better outcomes and preserved lung function and expect to see less use of Pulmozyme over time. A retroDUR again in 1-2 years is warranted to continue to monitor usage of these medications and cost of care.

Public Comment: None at this time

Board Discussion: A board member inquired about the reasons for emergency department visits and hospitalizations. Optum staff indicated that this could be investigated further. When asked if the effect of Trikafta diminishes over time, Optum staff confirmed that it does not. Additionally, there was a discussion about the impact of the COVID-19 pandemic.

Board Decision: None needed

- **Introduce: Prescribed Duration of Codeine or Hydrocodone Containing Cough Syrups** Codeine, a widely used opioid for pain relief and cough suppression, has seen a significant increase in misuse and dependence globally. This study aims to evaluate the patterns, risks, and consequences of codeine overuse. Codeine can be habit-forming. Regular use, especially in higher doses, can lead to physical dependence and addiction. Overuse can cause severe side effects, including respiratory depression, liver damage (when combined with acetaminophen), and increased risk of overdose. Paid, non-reversed Vermont Medicaid pharmacy and medical claims, excluding members with Part D, VMAP and Healthy Vermonters coverage will be used. Prescription claims will be analyzed for members taking codeine or hydrocodone containing cough syrups and we will identify members who have received prescriptions lasting 10 days or longer or contain amounts in excess of 60 mL. In addition, we will identify prescribers outliers for prescriptions written for greater than 10 days or contain amounts in excess of 60 mL.

Recommendation: None at this time

Public Comment: No public comment

Board Decision: None needed

Consent Agenda Items

- **Biosimilar Drug Reviews**
  - Tofidence™ (adalimumab-afzb)
- **Therapeutic Drug Classes – Periodic Review**
  - Smoking Cessation
  - Parathyroid Agent
  - Antihistamines (minimally sedating)
  - Leukotriene Modifiers

Recommendation:

- Add Tofidence™ (tocilizumab-bavi) biosimilar to Actemra intravenous infusion QTY LIMIT: 80 mg vial = 4 vials/28 days, 200 mg vial = 3 vials/28 days, 400 mg vial = 2 vials/28 days to non-preferred
  - Clinical criteria:
    - Update **Actemra, Kevzara, Orencia, Tofidence, and Tremfya additional criteria:** The prescriber must provide clinically valid reason why at least 2 preferred agents cannot be used. For approval of Actemra, patient has had a documented side effect, allergy, or treatment failure Tyenne.
- Remove CHANTIX® (varenicline) and GETQUIT support line information from the PDL as product has been discontinued by the manufacturer
- Remove Nicotrol Inhaler from the PDL as product has been discontinued by the manufacturer
- Remove Natpara® (parathyroid hormone) from the PDL as product has been discontinued by the manufacturer
- Remove fexofenadine suspension from the PDL as product has been discontinued by the manufacturer

Board Decision: The Board unanimously approved the above recommendations.

Review of Newly Developed/Revised Criteria

- None at this time.

Clinical Update: Drug Reviews

Full New Drug Reviews

Beqvez™ (fidanacogene elaparvovec-dzkt)

Beqvez™ (fidanacogene elaparvovec-dzkt) is an adeno-associated virus (AAV)-based gene therapy that is based on recombinant DNA technology that consists of a recombinant viral capsid (AAVRh74var) derived from a naturally occurring AAV

serotype (Rh74) vector containing the human coagulation factor IX transgene modified to a high-specific factor IX activity variant known as FIX-R338L. The AAVRh74var capsid is derived from the Rh74 AAV, which is not known to cause disease in humans. Beqvez™ is a gene therapy designed to introduce in the transduced cells a functional copy of the factor IX gene encoding a high-activity FIX variant (FIX-R338L, hFIX Padua). The AAVRh74var capsid is able to transduce hepatocytes, the natural site of factor IX synthesis. Single IV infusion of Beqvez™ results in cell transduction and increase in circulating factor IX activity in patients with hemophilia B. It results in continuous endogenous coagulation factor IX expression. It is indicated as an adeno-associated virus vector-based gene therapy indicated for the treatment of adults with moderate to severe hemophilia B (congenital factor IX deficiency) who: Currently use factor IX prophylaxis therapy, or Have current or historical life-threatening hemorrhage, or Have repeated, serious spontaneous bleeding episodes, and, Do not have neutralizing antibodies to adeno-associated virus serotype Rh74var (AAVRh74var) capsid as detected by an FDA-approved test. The efficacy of Beqvez™ was assessed in clinical study 1, an ongoing, prospective, open-label, single-arm study that enrolled adult male patients with moderately severe to severe hemophilia B. The main efficacy outcome was a non-inferiority test of annualized bleeding rate (ABR) during the efficacy evaluation period, week 12 to data cutoff following Beqvez™ treatment, compared with baseline ABR during the lead-in period. Results suggested that the model derived mean ABR was 4.5 bleeds/year during the baseline period and 2.5 bleeds/year during post-Beqvez® efficacy evaluation period, resulting in a difference of -2.1 bleeds/year, meeting the non-inferior study success criterion. The median ABR was 0 post-Beqvez™ efficacy evaluation period.

Recommendation:

- Add Beqvez™ (fidanacogene elaparvovec-dzkt) to non-preferred.
    - Clinical criteria:
        - Add **Beqvez**: Patient is ≥ 18 years of age AND
        - Patient has a diagnosis of severe congenital Factor IX deficiency, as evidenced by < 1% of normal circulating factor IX AND
        - Patient has the following:
            - Current and continuous use of Factor IX prophylaxis therapy for the previous 6 months as evidenced by claims history or clinical documentation, without breaks in adherence. (Continuous use is defined as routine prophylaxis with defined frequency, e.g. twice weekly, once every two weeks) AND
            - Current or historical life-threatening hemorrhage despite use of preferred prophylaxis therapy OR
            - Repeated, serious spontaneous bleeding episodes requiring hospitalization AND
        - Patient has been tested and found negative for Factor IX inhibitor titers and has no prior history for factor IX inhibition AND
        - Patient must have a negative baseline anti-AAVRh74var antibody titer AND

- The patient meets one of the following:
  - Patient is not HIV positive; or Patient is HIV positive and is virally suppressed with anti-viral therapy (i.e., < 20 copies of HIV per mL or CD4+ cell count > 200 mm3) AND
- The patient is not currently using antiviral therapy for hepatitis B or C AND does not have significant liver dysfunction/significant fibrosis.
- Baseline liver function tests will be completed prior to start of therapy and continued per package insert following Beqvez administration AND
- Factor IX activity will be monitored weekly for 3 months AND
- Approval will be granted for a max one-time dose per lifetime and may not be renewed

Public Comment: None at this time

Board Decision: The Board unanimously approved the above recommendations.

Eohilia™ (budesonide oral suspension)

Budesonide, the active ingredient of Eohilia™, is a synthetic corticosteroid; it is an anti-inflammatory corticosteroid and has a high glucocorticoid effect and a weak mineralocorticoid effect. Corticosteroids have a wide range of inhibitory activities against multiple cell types (e.g., mast cells, eosinophils, neutrophils, macrophages, and lymphocytes) and mediators (e.g., histamine, eicosanoids, leukocytes, and cytokines) involved in allergic inflammation. However, the exact mechanism of corticosteroid actions on inflammation in eosinophilic esophagitis is not known. It is indicated for 12 weeks of treatment in adult and pediatric patients 11 years of age and older with eosinophilic esophagitis (EoE). A limitation of use includes that Eohilia™ has not been shown to be safe and effective for the treatment of EoE for longer than 12 weeks. The safety and efficacy of use were assessed in two multicenter, randomized, double-blind, placebo-controlled, 12-week studies that compared Eohilia™ with placebo in patients with esophageal inflammation. Per the full text study by Dellon et al2 (Study 2), significantly more in the Eohilia™ group achieved the primary endpoint as compared with placebo. Per the full-text study by Hirano et al3 (Study 1), significantly more achieved the primary endpoint with Eohilia™. While dietary therapy, PPIs, and topical glucocorticoids are generally utilized for this diagnosis as initial treatment,4 Eohilia™ is the first FDA approved oral treatment for EoE, to be used for 12 weeks in patients 11 years and older. Budesonide oral suspension is suggested if topical glucocorticoid therapy is to be utilized.

Recommendation:

- Add Eohilia™ (budesonide oral suspension) to non-preferred.
  - Clinical criteria:
    - Add **Eohilia**: The patient has had a documented side effect, allergy,

or treatment failure with swallowed budesonide nebulizer solution or fluticasone. Note: Approval will be granted for 12 weeks of therapy.

Public Comment: None at this time.

Board Discussion: A member of the board asked if there were any head to head studies, Optum staff indicated that there were only placebo based studies.

Board Decision: The Board unanimously approved the above recommendations.

Iqirvo® (elafibranor)

Elafibranor and its main active metabolite GFT1007, the active ingredient of Iqirvo®, are peroxisome proliferator-activated receptor (PPAR) agonists. Elafibranor and GFT1007 both activate PPAR-alpha, PPAR-gamma, and PPAR-delta in vitro. However, the mechanism of action for its approved indication is not well understood. Pharmacological activity that is potentially relevant to therapeutic effects includes inhibition of bile acid synthesis through activation of PPAR-alpha and PPAR-delta. The signaling pathway for PPAR-delta was reported to include Fibroblast Growth Factor 21 (FGF21)-dependent downregulation of CYP7A1, the main enzyme for the synthesis of bile acids from cholesterol. It is indicated for the treatment of primary biliary cholangitis (PBC) in combination with ursodeoxycholic acid (UDCA) in adults who have had an inadequate response to UDCA, or as monotherapy in patients unable to tolerate UDCA. This indication is approved under accelerated approval based on reduction of alkaline phosphatase (ALP). Improvement in survival or prevention of liver decompensation events have not been demonstrated. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s). Use of Iqirvo® is not recommended in patients who have or develop decompensated cirrhosis (e.g., ascites, variceal bleeding, hepatic encephalopathy). Its efficacy was assessed in phase 3, double-blind, placebo-controlled study that included adults with PBC. Most patients in the study (95%) received study treatment in combination with UDCA. The primary endpoint was biochemical response at week 52. Results suggested that Iqirvo® demonstrated greater improvement on biochemical response and ALP normalization at week 52 as compared to placebo (NNT 3 for primary endpoint of biochemical response). Per the full-text study by Kowdley et al2, the primary endpoint of biochemical response was observed in significantly more in the Iqirvo® group as compared with placebo ($p<0.001$). Active head-to-head comparator trials were not currently found.

Recommendation:

- Add Iqirvo® (elafibranor) to non-preferred.
  - Clinical criteria:
    - Add Iqirvo**, Ocaliva**: The indication for use is the treatment of primary biliary cholangitis (PBC) AND the patient has had an inadequate response or is unable to tolerate ursodiol. For approval of Iqirvo: Patient must have documented intolerance to Ocaliva.

Public Comment: None at this time.

Board Decision: The Board unanimously approved the above recommendations.

Libervant™ (diazepam)

Diazepam, the active ingredient of Libervant™, is a benzodiazepine anticonvulsant. The exact mechanism of action is not fully understood but is thought to involve potentiation of GABAergic neurotransmission resulting from binding at the benzodiazepine site of the GABA-A receptor. It is indicated for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (i.e., seizure clusters, acute repetitive seizures) that are distinct from a patient's usual seizure pattern in patients with epilepsy 2 to 5 years of age. The safety and efficacy of Libervant™ in pediatric patients 2 to 5 years of age are supported by evidence from adequate and well controlled studies of diazepam rectal gel in adult and pediatric patients, adult bioavailability studies comparing Libervant™ with diazepam rectal gel, adult and pediatric Libervant™ pharmacokinetic data, and an open-label safety study of Libervant™ including patients 2 years to 5 years of age. Libervant™ is the only oral, non-device diazepam-based treatment with its approved indication.

Recommendation:

- Add Libervant™ (diazepam) buccal film QTY LIMIT: 10 films/month to non-preferred.
    - Clinical criteria:
        - Add **Libervant**: The diagnosis is intermittent episodes of frequent seizure activity (i.e., seizure clusters, acute repetitive seizures) which are distinct from the patient's usual seizure pattern AND Patient is within FDA indicated age range AND the medication is prescribed by or in consultation with a neurologist AND the patient must have a documented intolerance to diazepam rectal gel

Public Comment: None at this time.

Board Discussion: A board member asked if the quantity limit was based on dosing regimen similar to diazepam rectal gel. This was confirmed by Optum staff.

Board Decision: The Board unanimously approved the above recommendations.

Xolremdi™ (mavorixafor)

Mavorixafor, the active ingredient of Xolremdi™, is an orally bioavailable CXC Chemokine Receptor 4 (CXCR4) antagonist that blocks the binding of the CXCR4 ligand, stromal-derived factor-1α (SDF-1α)/CXC Chemokine Ligand 12 (CXCL12). SDF-1/CXCR4 plays a role in trafficking and homing of leukocytes to and from the bone marrow compartment. Gain of function mutations in the CXCR4 receptor gene that occur in patients with WHIM syndrome lead to increased responsiveness to CXCL12 and retention of leukocytes in the bone marrow. Mavorixafor inhibits the response to

CXCL12 in both wild-type and for mutated CXCR4 variants associated with WHIM syndrome. Treatment with mavorixafor results in increased mobilization of neutrophils and lymphocytes from the bone marrow into the peripheral circulation. It is indicated in patients 12 years of age and older with WHIM syndrome (warts, hypogammaglobulinemia, infections, and myelokathexis) to increase the number of circulating mature neutrophils and lymphocytes. The efficacy of Xolremdi™ was assessed in a double-blind, placebo-controlled study that included patients with WHIM syndrome. The results over the 52-week period demonstrated that TAT-ANC was statistically significantly greater in patients treated with Xolremdi™ compared with placebo (15 hrs vs 2.8 hrs; p<0.0001). Xolremdi™ is the first targeted therapy FDA approved for WHIM syndrome

Recommendation:

- Add Xolremdi™ (mavorixafor) capsule to non-preferred.
  - Clinical criteria:
    - Add **Xolremdi**: The patient meets the FDA approved age AND has a diagnosis of WHIM syndrome confirmed by genetic confirmation of CXCR4 variant AND has a baseline absolute neutrophil count (ANC) ≥ 400 cells/uL

Public Comment: None at this time.

Board Decision: The Board unanimously approved the above recommendations.

New Managed Therapeutic Drug Classes

- None at this time

Therapeutic Drug Classes – Periodic Review

- Alzheimer's Agents

Recommendation:

- Move Memantine XR (compare to Namenda® XR) Oral capsule QTY LIMIT: 1 capsule/day to preferred.
- Remove Namenda XR from the PDL as product has been discontinued by the manufacturer
- Update Leqembi clinical criteria to update the patient registry verbiage to "Member and/or provider must currently be participating in a provider-enrolled patient registry that collects information on treatments for Alzheimer's disease (e.g. Alzheimer's Network for Tretment and Diagnostics (ALZ-NET)

  Public Comment: Melissa Abbott, PharmD from Eisai highlighted the attributes of Leqembi for the treatment of Alzheimer's disease. She referenced updated prescribing information and urged the board to consider removal of the

requirement for patients to have treatment failure of a cholinesterase inhibitor as it could delay access to treatment despite earlier detection of the disease, causing patients to have disease progression past the desired requirements of the medication.

Board Discussion: Board members and DVHA staff discussed current criteria and proposed the following changes:

- Removal of failure of cholinesterase inhibitor
- Updating MMSE score requirement to align with clinical trial (update range to 22-30)
- Remove requirement of provider or member enrollment in a registry, as this is only CMS facilitated for patient's with primary Medicare coverage

Board Decision: The Board unanimously approved the modified criteria to read as follows:

Leqembi:

- Patient is 50 years of age or older
- Prescriber has assessed and documented baseline disease severity utilizing an objective measure/tool (e.g., MMSE, Alzheimer's Disease Assessment Scale-Cognitive Subscale [ADAS-Cog-13], Alzheimer's Disease Cooperative Study-Activities of Daily Living Inventory-Mild Cognitive, Impairment version [ADCS-ADL-MCI], Clinical Dementia Rating-Sum of Boxes [CDR-SB]).
- Patient has mild cognitive impairment (MCI) due to Alzheimer's Disease or mild Alzheimer's dementia as evidenced by the following:
  - Clinical Dementia Rating (CDR) Global Score of 0.5
  - Objective evidence of cognitive impairment at screening o MMSE score between 22 and 30
  - PET scan is positive for amyloid beta plaque OR Cerebrospinal fluid (CSF) test is positive for amyloid
- Patient has had a recent (within 1 year) brain MRI prior to initiating treatment and prescriber attests to a repeat brain MRI as directed in the labeling (to the 5th, 7th, and 14th infusion for Leqembi).
- Patient does not have any of the following within 1 year of treatment initiation: pretreatment localized superficial siderosis, 10 or more brain microhemorrhages, or brain hemorrhage >1 cm
- For re-approval, the patient must have responded to therapy compared to pre-treatment baseline as evidenced by improvement, stavbilization, or slowing in cognitive or functional impairment AND patient has not progressed to moderate or severe disease (there is insufficient evidence in moderate or severe AD)

- IBS/SBS/GI Agents

Recommendation:

- Move Linzess® (linaclotide) 72mcg to preferred
- Remove Amitiza® (lubiprostone) from the PDL as product has been discontinued by the manufacturer
- Move Lubiprostone QTY LIMIT: 2 capsules/day to preferred.
    - Clinical criteria:
        - Update **Ibsrela, Motegrity**: The patient is 18 years of age or older. AND the patient has had a documented side effect, allergy, or treatment failure to lubiprostone and either Linzess or Trulance

Public Comment: None at this time

Board Decision: The Board unanimously approved the above recommendations.

- Intranasal Rhinitis

Recommendation:

- Move Mometasone QTY LIMIT: 1 inhaler (17 gm)/30 days to preferred.
- Remove Amitiza® (lubiprostone) from the PDL as product has been discontinued by the manufacturer

Public Comment: None at this time

Board Decision: The Board unanimously approved the above recommendations.

- Sedatives/Hypnotics

Recommendation:

- Add Triazolam to preferred.
- Add Tasimelteon (compare to Hetlioz®) QTY LIMIT: 1 tab/day to non-preferred.
    - Clinical criteria:
        - Update Hetlioz, **Tasimelteon**: Patient has documentation of Non-24-Hour Sleep-Wake Disorder (Non24) or Insomnia due to Smith-Magenis Syndrome AND Patient has had a documented side effect, allergy or treatment failure with ramelteon and at least one OTC melatonin product. For approval of Tasimelteon: Patient must have documented intolerance to Hetlioz.
        - Update **Ramelteon, Rozerem**: The patient has had a documented side effect, allergy, contraindication, or treatment failure to one preferred sedative/hypnotic OR the patient has had a treatment failure after a minimum 2-week trial of melatonin OR there is a question of substance abuse with the patient or family of the patient. If the request is for Rozerem, there must also have been a documented intolerance to ramelteon.

Public Comment: None at this time

Board Decision: The Board unanimously approved the above recommendations.

General Announcements

- None at this time

Adjourn **8:02 pm**