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

February 7, 2023: 6:00 – 8:30 p.m.

Board Members Present:

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

Board Members Absent:

	Mark Pasanen, MD				

DVHA Staff Present:

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

Change Healthcare Staff Present:

	Jeffrey Barkin, MD		**Laurie Brady, RPh**		**Michael Ouellette, RPh**

Guests/Members of the Public:

Ed Paiewonsky (Alnylam Pharmaceuticals), Dr. John Flatt, Dan Bassoff (Sarepta Therapeutics), Gene Muise (Amgen), Jai Persico, Joe Ward, Dennis Cole, Folger Tuggle, Paul Ford, Frank Lanotte, Kristen Chopas (Gilead Sciences), Alain Nguyen, Beth D'Ambrosie, Terry Masterson, Lindsey Walter, Trent Berrier, Tina McCann, Timothy McSherry, Meagan Mitchell, Deep Patel, Shelly Nickerson, Tanya Kuzminsky, Leslie Zanetti

1. Executive Session:

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

2. Introductions and Approval of DUR Board Minutes:

- Attendance was called and introductions of DVHA and Change Healthcare staff were made.
- The December meeting minutes were accepted as printed. Margot Kagan abstained from voting since she was not in attendance at the meeting.

3. DVHA Pharmacy Administration Update: Lisa Hurteau, PharmD, DVHA

- DVHA and Change Healthcare continue to see shortages on certain medications. Amoxicillin antibiotics and oseltamivir have been intermittently

unavailable, but the helpdesk has been able to work through those and provide overrides for alternate therapies when needed. Certain preferred formulations of albuterol inhalers are on a long term backorder, alternatives including ProAir Digihaler and the Teva labeler of albuterol HFA were temporarily opened up as preferred covered options for pharmacies at the Point-of-Sale.

4. Chief Medical Officer Update: Michael Rapaport, MD, DVHA

- Buprenorphine safety checklist changes which are on the agenda tonight to be discussed.
- The federal public health emergency ends April 2023.

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

- None at this time.

Recommendation: None needed.

Board Decision: None needed.

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

- Data Presentation: Appropriate Use of Asthma Controller Medications

  The National Heart, Lung and Blood Institute has published Guidelines for the Diagnosis and Management of Asthma. An update was published in 2020 and included a recommendation for as needed low dose ICS-formoterol to be used as preferred initial treatment. Alternatively, a low dose ICS can be taken whenever SABA is taken. For anyone who requires use of a SABA more than twice a month, as-needed low dose ICS-formoterol or daily controller medication is recommended. Higher average use of SABA over a year is associated with a higher risk of severe exacerbations, and in the shorter term, increasing use of as-needed SABA is associated with an increased likelihood of a severe exacerbation in subsequent days or weeks. Therefore, the use of more than one SABA canister (e.g., albuterol 200 puffs per canister) during a one-month period most likely indicates over reliance on this drug and suggests inadequate control of asthma. Additionally, inhaled corticosteroids (ICS) are the preferred long-term maintenance therapy in asthma for all ages. Before considering a regimen with a SABA reliever, it is important to consider whether patients will likely be adherent to daily controller therapy; if not, they will be exposed to the risks of SABA-only treatment. Long-acting beta-adrenergic inhalers (LABAs) should never be used without first using ICS inhalers due to the increased risk of asthma exacerbations and death.

Change Healthcare used paid, non-reversed Medicaid pharmacy claims from January 2020 through December 2021, excluding members with Part D, VMAP, and Healthy Vermonters coverage. Members with a diagnosis of cystic fibrosis, COPD, or emphysema were also be excluded. Members were stratified by age and the number of short acting inhalers dispensed per year, and analysis was completed on whether an inhaled corticosteroid inhaler was also being prescribed. In addition, the number of members in each group who had an ER visit or hospitalization associated with an asthma diagnosis during the study period were reported.

16,322 members had claims for 12 or less SABA inhalers per year. Of those members, 33% had an ICS and 67% did not. 283 members had claims for 13-15 SABA per year. Of those, 66% had an ICS and 34% did not. 263 members had claims for 16-19 SABA per year. Of those, 66% had an ICS and 34% did not. 467 members filled prescriptions for > 19 SABA inhalers per year. Of those, 69% had an ICS and 31% did not.

Across the board, those on ICS in addition to SABA had more ED visits and hospitalizations, suggesting the providers are prescribing ICS to those who have more symptomatic asthma. In general, as the number of SABA inhalers per year increased, there is a trend toward increased ED visits and hospital admissions. Additionally, stratifying out providers who prescribed SABA without ICS, we could see that these providers only did so for a small number of members. It appears that providers generally followed the guidelines and for the most part ICS was prescribed for those using 12 or mores SABAs per year with few exceptions.

Recommendation: These results are similar to what was seen in the same analysis done in 2019, and outreach was targeted towards those prescribers with patients using more than 12 SABA inhalers per year without a controller medication. Additionally, Change Healthcare has done the analysis for Maine fee for service Medicaid and found similar trends. Given the still prevalent use of SABA inhalers without ICS, continued partnership with the Department of Health Asthma Advisory Panel to provide education to the provider community would be beneficial. A follow-up targeted outreach to providers prescribing 12 or more inhalers per year without a controller medication could help curb prescribing habits to align with guideline recommendations.

Board Decision: The Board discussed the benefits of doing a target mailing versus a general educational mailing. Multiple board members discussed the issue of children that are required to have multiple inhalers for different households or school. The Board and Dr. Rapaport requested we follow-up in 6 months on targeted providers to review if a change in prescribing habits and SABA use has resulted. The Board unanimously approved doing a targeted mailing to prescribers of patients with more than 12 SABA inhalers without an ICS and complete a 6 month follow up.

- Introduce: Use of Warfarin with 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 a 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 for interaction with warfarin include trimethoprim/sulfamethoxazole (TPM/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 will use paid, non-reversed Vermont Medicaid pharmacy and medical claims from 2022, excluding members with Part D, VMAP, and Healthy Vermonters coverage. They will look at all members on warfarin and determine how many were prescribed any of the antibiotics listed above that can cause a change in INR. They will identify the prescribers and then see if there are any medical claims for Emergency Department visits or hospital admissions up to 4 weeks after the antibiotic was prescribed, to determine if there were serious complications related to bleeding.

Board Decision: Doug Franzoni recommended that Change Healthcare also look to see if an INR was done within 5 days of the date of the antibiotic claim. Change Healthcare agreed to include those CPT codes in the analysis.

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

Biosimilar Drug Reviews:

- None at this time.

Full New Drug Reviews:

- Amvuttra® (vutrisiran)

Vutrisiran, the active ingredient of Amvuttra®, is a chemically modified double-stranded small interfering ribonucleic acid (siRNA) that targets mutant and wild-type transthyretin

(TTR) messenger RNA (mRNA) and is covalently linked to a ligand containing three N-acetyl galactosamine (GalNAc) residues to enable delivery of the siRNA to hepatocytes. Vutrisiran causes degradation of mutant and wild-type TTR mRNA through RNA interference, which results in a reduction of serum TTR protein and TTR protein deposits in tissues. It is indicated for the treatment of the polyneuropathy of hereditary transthyretin-mediated amyloidosis in adults. The efficacy of Amvuttra® was assessed in a randomized, open-label, clinical trial that included adult patients with polyneuropathy caused by hereditary transthyretin-mediated amyloidosis. Patients were randomized to receive 25mg of Amvuttra® SC once every 3 months (N=122) or 0.3mg/kg patisiran IV every 3 weeks (N=42) as a reference group. Treatment with Amvuttra® resulted in a statistically significant improvement in the mNIS+7 (primary endpoint), Norfolk QoL-DN total score, and 10-meter walk test at month 9 compared to placebo in the external study ($p<0.001$). IV patisiran every 3 week dosing was included as a reference group. In the full-text study by Adams et al2, TTR reduction with vutrisiran every 3 months was non-inferior to within-study patisiran every 3 weeks in the per-protocol population, assessed by mean trough serum TTR levels over 18 months. Amvuttra® provides physicians another option with once every 3-month dosing.

Recommendation:

- Add Amvuttra (vutrisiran) 25mg/0.5ml injection for subcutaneous use to non-preferred with QTY LIMIT: 1 syringe (0.5ml) every 3 months.
    - Clinical criteria:
        - Update **Amvuttra, Onpattro, Tegsedi:** The patient is ≥ 18 years of age with a diagnosis of polyneuropathy of heredity transthyretin mediated (hATTR) amyloidosis (Documentation of TTR mutation by genetic testing and the presence of amyloid deposits via tissue biopsy has been submitted) AND The medication is being prescribed by or in consultation with a neurologist AND Clinical signs and symptoms of the disease (e.g., peripheral/autonomic neuropathy, motor disability, cardiovascular dysfunction, renal dysfunction) are present and other causes of neuropathy have been excluded AND Patient is receiving vitamin A supplementation

Public Comment: Ed Paiewonsky from Alnylam Pharmaceuticals: Highlighted the attributes of Amvuttra.

Board Decision: The Board unanimously approved the above recommendations with a change to the criteria that the requirement of a biopsy would be left up to the neurologist. Criteria will change as follows: Documentation of TTR mutation by genetic testing OR the presence of amyloid deposits via tissue biopsy has been submitted.

- Enjaymo® (sutimlimab-jome)

Sutimlimab-jome, the active ingredient of Enjaymo®, is a classical complement inhibitor. Sutimlimab-jome is an immunoglobulin G (IgG), subclass 4 (IgG4) monoclonal antibody (mAb) that inhibits the classical complement pathway (CP) and specifically binds to complement protein component 1, s subcomponent (C1s), a serine protease which

cleaves C4. Sutimlimab-jome does not inhibit the lectin and alternative pathways. Inhibition of the classical complement pathway at the level of C1s prevents deposition of complement opsonins on the surface of red blood cells (RBCs), resulting in inhibition of hemolysis in patients with CAD. It is indicated to decrease the need for red blood cell transfusion due to hemolysis in adults with cold agglutinin disease (CAD). The safety and efficacy of Enjaymo® were assessed in an open-label, single-arm, 6-month trial (N=24; CARDINAL study). After the completion of the 6-month treatment period, patients continued to receive Enjaymo® in a long-term safety and durability of response extension phase for an additional 24 months. Efficacy was based on responder rate, which was defined as a patient with an increase from baseline in Hgb level ≥2g/dL or a Hgb level ≥12g/dL at the treatment assessment time point, no blood transfusion from week 5 through week 26, and no treatment for CAD beyond what was permitted per protocol from week 5 through week 26. The responder rate with Enjaymo® use was 54%.

Recommendation:

- Add Enjaymo™ (sutimlimab-jome) to non-preferred.
    - Clinical criteria:
        - Add **Enjaymo:** The patient has a diagnosis of cold agglutinin syndrome (CAD) AND the patient does not have an active chronic systemic infection (e.g. Hepatitis B, Hepatitis C, HIV) AND the medication is prescribed by, or in consultation with, a hematologist AND the patient has had at least one blood transfusion in the 6 months prior to starting Enjaymo AND the patient has received the pneumococcal, Haemophilus influenzae, and meningococcal vaccines at least 2 weeks prior to therapy initiation. Authorization for continued use shall be reviewed to confirm that the patient has experienced an objective response to the therapy (e.g. stabilization of hemoglobin levels, reductions in transfusions, improvement in hemolysis, etc.)

Public Comment: No public comment.

Board Decision: The Board asked about any recommendations on specific pneumococcal vaccine requirements as there are multiple formulations. Change Healthcare clarified that there are no recommendations as to a specific pneumococcal vaccine. The Board unanimously approved the above recommendations.

- Entadfi® (finasteride & tadalafil)

Entadfi® is combination of finasteride (a specific inhibitor of steroid Type II 5α-reductase, an intracellular enzyme that converts the androgen testosterone into 5α-dihydrotestosterone or DHT) and tadalafil (a selective inhibitor of cyclic guanosine monophosphate (cGMP)-specific phosphodiesterase type 5 or PDE5). It is indicated to initiate treatment of the signs and symptoms of benign prostatic hyperplasia (BPH) in

men with an enlarged prostate for up to 26 weeks. Note that Entadfi® is not recommended for more than 26 weeks because the incremental benefit of tadalafil decreases from 4 weeks until 26 weeks, and the incremental benefit beyond 26 weeks is not known. The efficacy of Entadfi® is based on an adequate and well-controlled study of tadalafil co-administered with finasteride. A double-blind, parallel-design study of 26 weeks in duration randomized men (N=696) to start either tadalafil 5mg with finasteride 5mg or placebo with finasteride 5mg in treating signs and symptoms of BPH in men with an enlarged prostate (>30 cc). The study population had a mean age of 64 years (range 46-86) and patients with multiple co-morbid conditions (such as erectile dysfunction, DM, hypertension, and other cardiovascular diseases) were included. The safety and efficacy of Entadfi® is based on an adequate and well-controlled study of tadalafil co-administered with finasteride as compared with finasteride co-administered with placebo. Results suggested that tadalafil and finasteride administered together demonstrated statistically significant improvement in the signs and symptoms of BPH compared to placebo with finasteride, as measured by the total symptom score (IPSS) at 12 weeks. However, the magnitude of the treatment difference between placebo/finasteride and tadalafil/finasteride decreased from 1.7 points at week 4 to 1.0 point at week 26. The incremental benefit of Entadfi® beyond 26 weeks is unknown.

Recommendation:

- Add Entadfi™ (finasteride/tadalafil) to non-preferred with QTY LIMIT: 1 capsule/day.
- Remove Statement: Current clinical guidelines recommend the use of Cialis (tadalafil) only in men with concomitant erectile dysfunction or pulmonary hypertension. Medicaid programs do not receive Federal funding for drugs used in the treatment of erectile dysfunction so Cialis will not be approved for use in BPH.
- Add new sub-category PDE-5 INHIBITORS with a note that all products require PA.
- Add Cialis® (tadalafil) and Tadalafil (compare to Cialis®) to non-preferred with QTY LIMIT:1 tablet/day
    - Clinical criteria:
        - Add Cialis, Tadalafil: The patient has a diagnosis of BPH (benign prostatic hypertrophy) AND the patient has a documented treatment failure/inadequate response to a preferred alpha blocker AND the patient has a documented treatment failure/inadequate response to a preferred 5-alpha reductase inhibitor AND for approval of Cialis, the patient must have a documented intolerance to the generic equivalent. Approval will be limited to 5mg daily for a maximum of 26 weeks.
        - Add Entadfi: The patient has a diagnosis of BPH (benign prostatic hypertrophy) AND the patient has a

documented treatment failure/inadequate response to a preferred alpha blocker AND the patient has a documented treatment failure/inadequate response to a preferred 5-alpha reductase inhibitor AND the patient has a documented treatment failure/inadequate response to tadalafil. Approval will be limited to a maximum of 26 weeks.

Public Comment: No public comment.

Board Decision: The Board asked for clarification on the maximum of 26 weeks stated in the criteria. Dr. Barkin clarified that the tadalafil benefit wears off after 26 weeks. The Board unanimously approved the above recommendations.

- Hyftor® (sirolimus)

Sirolimus, the active ingredient of Hyftor®, is an mTOR (mammalian target of rapamycin) inhibitor immunosuppressant for topical use. The mechanism of action for its approved indication is not known. Tuberous sclerosis is associated with genetic defects in TSC1 and TSC2 which leads to the constitutive activation of mTOR. Sirolimus inhibitors mTOR activation. It is indicated for the treatment of facial angiofibroma associated with tuberous sclerosis in adults and pediatric patients 6 years of age and older. The safety and efficacy of Hyftor® were assessed in a single, randomized, double-blind, vehicle-controlled, multicenter, phase 3 trial that was conducted in Japan and included adults and pediatric patients 6 years of age and older with facial angiofibroma associated with tuberous sclerosis. It is the first and only FDA-approved topical gel with this indication. A single, randomized, vehicle-controlled, double-blind study assessed the safety and efficacy of Hyftor® in 62 Japanese adult and pediatric patients 6 years of age and older. A greater number in the Hyftor®-treated group were assessed by the investigator as 'improved' or 'markedly' improved as compared with the vehicle-treated group. One noted reference source suggests that laser therapy and dermabrasion may improve disfiguring skin lesions associated with tuberous sclerosis complex.

Recommendation:

- Add Hyftor® (sirolimus) topical gel to non-preferred.
  - Clinical criteria:
    - Add **Hyftor:** The patient has 3 or more angiofibromas (≥ 2mm in diameter with redness in each) on the face, associated with tuberous sclerosis AND the patient has completed all ACIP recommended age-appropriate vaccinations prior to starting therapy. Initial approval will be granted for 3 months. For re-approval, there must be documented reduction in the size and redness of angiofibromas from baseline.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

- Korsuva® (difelikefalin)

Difelikefalin, the active ingredient of Korsuva®, is a kappa opioid receptor (KOR) agonist. The relevance of KOR activation to therapeutic effectiveness is not known. It is indicated for the treatment of moderate-to-severe pruritus associated with chronic kidney disease (CKD-aP) in adults undergoing hemodialysis (HD). Korsuva® has not been studied in patients on peritoneal dialysis and is not recommended for use in this population. The safety and efficacy of Korsuva® were assessed in two randomized, multicenter, double-blind, placebo-controlled trial that enrolled subjects 18 years of age and older undergoing HD who had moderate-to-severe pruritus. Its efficacy was assessed in 2 randomized, double-blind, placebo-controlled trials that included adults undergoing HD who had moderate-to-severe pruritus. In each trial, efficacy was assessed based on the proportion of subjects achieving a 4-point or greater improvement (reduction) from baseline in the weekly mean of the daily 24-hour WI-NRS score at week 12; and results suggested that more in the Korsuva® group achieved ≥4-point improvement from baseline in WI-NRS score compared with placebo.

Recommendation:

- Add Korsuva® (difelikefalin) to non-preferred.
  - Clinical criteria:
    - Add Korsuva: The patient has a diagnosis of moderate-to-severe pruritis associated with chronic kidney disease AND the patient is receiving hemodialysis AND the patient has a documented side effect, allergy, or treatment failure with at least 1 topical and 1 systemic pruritis treatment (e.g. antihistamines, corticosteroids, gabapentin, pregabalin, capsaicin)

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

- Verkazia® (cyclosporine ophthalmic solution)

Cyclosporine, the active ingredient of Verkazia®, is a calcineurin inhibitor immunosuppressant agent when administered systemically. Following ocular administration, cyclosporine is thought to act by blocking the release of pro-inflammatory cytokines such as IL-2. The exact mechanism of action for its approved indication is not known. It is indicated for the treatment of vernal keratoconjunctivitis (VKC) in children and adults. The safety and efficacy of Verkazia® for the treatment of VKC were assessed in two randomized, multicenter, double-masked, vehicle-controlled clinical trial. Verkazia® is the only topical immunomodulator indicated for the treatment of VKC in children (≥4 years) and adults. In addition, per the manufacturer website,

"Verkazia® uses proprietary cationic ophthalmic emulsion technology to increase cyclosporine bioavailability in the cornea." Furthermore, the site indicates that "cationic ophthalmic emulsion enables rapid spread, maximization of contact, prolonged exposure, and near doubling of concentration of cyclosporine in the cornea." Other cyclosporine products are currently available at different doses. There is no evidence at this time to support that Verkazia® is safer or more effective than the other currently preferred, more cost-effective medications.

Recommendation:

- Add Verkazia® (cyclosporine ophthalmic emulsion) 0.1% single dose vials to non-preferred.
    - Clinical criteria:
        - Add **Verkazia:** The patient has a diagnosis of vernal keratoconjunctivitis (VKC) AND the patient has had a documented side effect, allergy, or treatment failure with a mast cell stabilizer (e.g. cromolyn sodium) or a dual acting antihistamine/mast cell stabilizer (e.g. olopatadine, azelastine)

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

- Vivjoa® (oteseconazole capsules)

Oteseconazole, the active ingredient of Vivjoa®, is an antifungal agent. Specifically, it is an azole metalloenzyme inhibitor targeting the fungal sterol, 14α demethylase (CYP51), an enzyme that catalyzes an early step in the biosynthetic pathway of ergosterol, a sterol required for fungal cell membrane formation and integrity. Inhibition of CYP51 results in the accumulation of 14-methylated sterols, some of which are toxic to fungi. Through the inclusion of a tetrazole metal-binding group, oteseconazole has a lower affinity for human CYP enzymes. It is indicated to reduce the incidence of recurrent vulvovaginal candidiasis (RVVC) in females with a history of RVVC who are not of reproductive potential. The safety and efficacy of Vivjoa® were assessed in two multicenter, randomized, double-blind, placebo-controlled trials (Trial 1 and Trial 2) that included adults and post-menarchal pediatric females (N=656) with RVVC (defined as ≥3 episodes of vulvovaginal candidiasis (VVC) in a 12-month period). There is also evidence that it is effective for recurring VVC episodes and results in less of a need to take VVC medication known to treat VVC during the maintenance phase and results in fewer subjects who failed clearing the infection during the induction phase compared to placebo. However, there is no evidence at this time to support that Vivjoa® is safer or more effective than the other currently preferred, more cost-effective medications. It is therefore recommended that Vivjoa® 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 Vivjoa® (oteseconazole) to non-preferred.
    - Clinical criteria:
        - Add **Vivjoa:** the patient is not of reproductive potential AND the patient has recurrent yeast infections despite a treatment course of 7-14 days with a preferred vaginal azole, a longer course of oral fluconazole (e.g. one dose every 3 days for a total of 3 doses), and Brexafemme.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

- Ztalmy® (ganaxolone suspension)

Ganaxolone, the active ingredient of Ztalmy®, is a neuroactive steroid gamma-aminobutyric acid A (GABA-A) receptor positive modulator. The exact mechanism of action by which ganaxolone exerts its therapeutic effects for its approved indication is not known, but its anticonvulsant effects are thought to result from positive allosteric modulation of the GABA-A receptor in the CNS. It is indicated for the treatment of seizures associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD) in patients 2 years of age and older. The safety and efficacy of Ztalmy® for the treatment of seizures associated with CDD were assessed in a single, double-blind, randomized, placebo-controlled study that included patients 2 to 19 years of age. The primary efficacy endpoint was the percentage change in the 28-day frequency of major motor seizures, and patients receiving Ztalmy® had a significantly greater reduction in the 28-day frequency of major motor seizures as compared to patients receiving placebo.

Recommendation:

- Add Ztalmy® (ganaxolone) suspension to non-preferred with QTL LIMIT: 36mL/day
    - Clinical criteria:
        - Add **Ztalmy:** Diagnosis or indication is for the treatment of seizures associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD) confirmed by genetic testing (results must be submitted) AND patient has had a documented side effect, allergy, treatment failure, inadequate response, or a contraindication to at least TWO preferred anticonvulsants AND for reapproval, the patient must have a documented decrease from baseline in seizure frequency per 28 days.

Public Comment: Dr. John Flatt from Marinus Pharmaceuticals: Highlighted the attributes of Ztalmy.

Board Discussion: Members of the board discussed whether a step through 2 preferred agents made clinical sense for approval. Dr. Flatt responded that since Ztalmy® is only

indicated in patients 2 years of age or older, most patients have been through multiple medication trials and continue to have refractory seizures prior to being eligible for Ztalmy®.

Board Decision: The Board unanimously approved the above recommendations.

8. New Therapeutic Drug Classes

- None at this time.

9. Therapeutic Drug Classes- Periodic Review:

- **Gaucher Disease**
  - No new drugs
  - No other significant clinical changes.

Recommendation:

- Clinical Criteria:
  - Update Miglustat, Zavesca additional criteria: For patients whom enzyme replacement therapy is not a therapeutic option (e.g. due to allergy, hypersensitivity, or poor venous access) AND for approval of miglustat, the patient must have a documented intolerance to brand Zavesca.

Public Comments: None at this time.

Board Decision: The Board unanimously approved the above recommendations.

- **Hemophilia/Factor Deficiency**
  - The FDA approved the first adeno-associated virus vector-based gene therapy for the treatment of adults with Hemophilia B who current use Factor IX prophylaxis therapy or have current or historical life-threatening hemorrhage, or have repeated, serious spontaneous bleeding episodes. It will be reviewed in detail at a future meeting.
  - No other significant clinical changes.

Recommendation:

- Add a note under AHF-Factor VII sub-category and AHF- Anti-Inhibitors Coagulation Complex that all products require a PA.
- Remove Kogenate-FS® and Mononine®. They have been discontinued.

Public Comments: None at this time.

Board Decision: None needed.

- **Hereditary Angioedema**
  - No new drugs
  - No other significant clinical changes.

Recommendation: None changes.

Public Comments: None at this time.

Board Decision: None needed.

- **Muscular Dystrophy Agents**
  - No new drugs
  - Confirmatory trial data for Vyondys® 53 and Amondys® 45 is expected in 2024, and confirmatory trial data for Exondys® 51 is expected in 2026.

Recommendation:

- Clinical criteria:
  - Add to current criteria for Amondys, Exondys, Viltepso, Vyondys: Baseline documentation of the members voluntary motor and cardiac function has been provided and results have shown member retains meaningful voluntary motor function:
    Optional: 6-minute walk test (6MWT) or other timed function tests (e.g., time to stand [TTSTAND], time to run/walk 10 meters [TTRW], time to climb 4 stairs [TTCLIMB]). Brooks Upper Extremity Test, North Star Ambulatory Assessment (NSAA)
    Required: Forced Vital Capacity (FVC) percent predicted, Ejection Fraction Percentage.
    Note: Initial approval will be granted for 6 months. For re-approval after 6 months, the patient must demonstrate a response to therapy compared to baseline as evidenced by stable, improved, or slowed rate of either motor function or cardiac function degradation. Evidence may include one or more of the following (not all-inclusive): 6MWT or other timed function tests (e.g., time to stand [TTSTAND], time to run/walk 10 meters [TTRW], time to climb 4 stairs [TTCLIMB]). Brooks Upper Extremity Test, North Star Ambulatory Assessment (NSAA), Forced Vital Capacity

(FVC) percent predicted, Ejection Fraction Percentage, Improvement in quality of life.

Public Comments: Dan Basoff from Sarepta: Highlighted the attributes of Exondys 51 (eteplirsen), Vyondys 53 (golodirsen), and Amondys 45 (casimersen).

Board Decision: The Board unanimously approved the above recommendations.

- **Pancreatic Enzymes**
  - No new drugs
  - No other significant clinical changes.

Recommendation:
- Remove Pancreaze® DR Capsules. They are no longer rebateable.

Public Comments: None at this time.

Board Decision: None needed.

- **Platelet Stimulating Agents**
  - No new drugs
  - No other significant clinical changes.

Recommendation:
- No changes at this time

Public Comments: None at this time.

Board Decision: None needed.

- **Prenatal Vitamins**
  - No new drugs
  - No other significant clinical changes.

Recommendation:
- Remove Pretab. It is no longer available.
- Add M-Natal Plus and Westab Plus to preferred.

Public Comments: None at this time.

Board Decision: The Board unanimously approved the above recommendations.

- **Non-biologics for Psoriasis**

- Tapinarof, the active ingredient of Vtama®, is an aryl hydrocarbon receptor (AhR) agonist. The specific mechanisms by which this cream exerts its therapeutic action in psoriasis patients is not known. It is indicated for the topical treatment of plaque psoriasis in adults. The safety and efficacy of Vtama® cream were assessed in two multicenter, randomized, double-blind, vehicle-controlled trials that included adults (N=1025) with plaque psoriasis (PSOARING 1 and PSOARING 2) who were randomized to Vtama® cream or vehicle cream once daily for 12 weeks to any lesion regardless of anatomic location. Vtama® cream is a first-in-class topical treatment that provides another treatment option for plaque psoriasis. There is no evidence at this time to support that Vtama® is safer or more effective than the other currently preferred, more cost-effective medications.
- Roflumilast, the active ingredient of Zoryve®, is a phosphodiesterase 4 (PDE4) inhibitor. Roflumilast and its active metabolite (roflumilast N-oxide) are inhibitors of PDE4. Roflumilast and roflumilast N-oxide inhibition of PDE4 (a major cyclic 3',5'-adenosine monophosphate (cyclic AMP) metabolizing enzyme) activity leads to accumulation of intracellular cyclic AMP. The specific mechanism by which roflumilast exerts its therapeutic action is not well defined. It is indicated for topical treatment of plaque psoriasis, including intertriginous areas, in patients 12 years of age and older. The safety and efficacy of Zoryve® were assessed in 2 multicenter, randomized, double-blind, vehicle-controlled trials (DERMIS-1 and DERMIS-2) that included subjects (N=881) with mild to severe plaque psoriasis and an affected body surface area (BSA) of 2% to 20%. The primary endpoint in both studies was the proportion of subjects who achieved IGA treatment success at week 8, with success being defined as a score of 'Clear' or 'Almost Clear' plus a 2-grade improvement from baseline.
- No other significant clinical changes.

Recommendation:

- Remove DOVONEX® cream (calcipotriene). There was a change in manufacturer and no longer participates in the Medicaid Drug Rebate Program.
- Move generic calcipotriene cream to preferred.
- Remove Soriatane® (acitretin) capsules. They have been discontinued.
- Remove Vectical® Ointment (calcitriol). This is no longer rebateable.

- Add Calcipotriene Foam (compare to Sorilux®), Vtama® (tapinarof) cream, and Zoryve® (roflumilast) Cream to non-preferred.
- Add Tazarotene Gel to non-preferred.
    - Clinical criteria:
        - Update **Calcipotriene Foam, Calcitriol Ointment, Sorilux, Tazarotene, Vtama, Zoryve:** The patient has a diagnosis of mild-to-moderate plaque psoriasis AND The patient has demonstrated inadequate response (defined as daily treatment for at least one month), adverse reaction or contraindication to a preferred formulation of calcipotriene.

Public Comments: None at this time.

Board Decision: The Board unanimously approved the above recommendations.

10. Review of Newly-Developed/Revised Criteria:

- **Liquid Oral Nutritional Supplements**
    - Lisa Hurteau indicated that these are not considered covered outpatient drugs and are an optional benefit under the Vermont Medicaid State Plan Agreement. DVHA is looking to establish medical necessity and better align criteria in the pharmacy and medical benefits.

Recommendation:

- **Clinical criteria:**
    - Update All Others (not including EleCare or EleCare Jr.): Requested nutritional supplement will be administered via tube feeding. OR Patient has one of the following conditions where feeding is difficult or malabsorption or maldigestion occurs: AIDS, Cancer, Cerebral Palsy, Cystic Fibrosis, Severe Dementia resulting in loss of motor skills, Neuromuscular Disease, Short Gut. OR Patient has a documented diagnosis of an inborn error of metabolism that cannot be accommodated by standard foods with a modified diet OR Patient has demonstrated nutritional deficiency identified by low serum protein levels (albumin or prealbumin levels to be provided) (albumin <3.5 g/dL /pre-albumin <15 mg/dL) OR Patient has experienced unplanned weight loss or is extremely low weight (see further definitions below)
    - Update Unplanned Weight Loss/Low Weight Table:
      Adult: Involuntary loss of > 10 % of body weight within 6 months OR Involuntary loss of > 5% of body weight within 1 month OR Loss of > 2% of body weight within one week OR BMI of < 18.5 kg/m^2 Elderly (>65): Involuntary loss of > 10 % of body weight within 6 months OR

Involuntary loss of > 5 % of body weight within 3 months OR Loss of > 2 % of body weight within one month OR BMI of < 18.5 kg/m^2
Children: Anatomic causes for malnutrition have been evaluated and treated AND clinical diagnosis and documentation supports the need for enteral nutrition: Members weight is below the 5th percentile for sex and corrected age AND weight-to-length ratio is below the 10th percentile OR Sustained decrease in growth velocity as demonstrated by weight-for-age or weight-for-length fall by two major percentiles (percentile markers 95, 90, 75, 50, 25, 10, and 5) over time (defined by the WHO for children less than 2 years of age and the CDC for children greater than 2 years of age).
Limitations: Approvals will be based on medical necessity for supplemental nutrition. Approval will NOT be granted for individuals whose need is nutritional rather than medical, including an unwillingness to consume solid or pureed foods. For non-medical needs contact WIC at 800-464-4343

Public Comments: None at this time.

Board Discussion: Dr. Nasca commented that he has submitted PA requests and although he has had no issues getting the PA approved there have been some issues with availability. He noted that although these are not drugs, the patient and pharmacy do spend a fair amount of time on these requests.

Board Decision: The Board unanimously approved the above recommendations.

- **Buprenorphine Safety Checklist**
  - Dr. Rapaport advised that the Omnibus FY23 spending package was signed into law by President Biden on December 29, 2022. This included the Mainstreaming Addiction Treatment Act (H.R. 1384/S. 445) which removes the X DEA (DATA 2000) waiver requirement. All providers with a standard DEA license number can now prescribe buprenorphine for opioid use disorder. With the removal of this requirement, the Department of Substance Use at the Vermont Department of Health supports the focus on safety with prescribing buprenorphine.
  - Both ASAM and DVHA Guidelines recommend monitoring for medication diversion and the appropriateness of continued treatment. In response to feedback and to decrease provider burden, the safety checklist has been updated for ease of use in documenting the current diversion monitoring practices utilized.

Recommendation:

- Clinical criteria:

- Update CLINICAL CONSIDERATIONS: These products are not FDA approved for alleviation of pain. For this indication, please refer to the Opioid Analgesics PDL category. Note: As of 1/1/23, a completed Buprenorphine safety checklist must be submitted with all PA requests.
- Update **Buprenorphine:** Patient is pregnant and is experiencing an adverse reaction or intolerance to a preferred combination product that cannot be resolved or mitigated through alternative efforts (duration of PA will be 90 days post anticipated delivery date). Other requests will be considered with clinical documentation submitted detailing a provider-observed reaction to both Suboxone films and buprenorphine/naloxone tablets severe enough to require discontinuation (documentation of measures tried to mitigate/manage symptoms is required). AND the Buprenorphine Safety Checklist has been completed (see PA form for detailed requirements and for documentation required).
- Update **Requests to exceed quantity limits or maximum daily dose**: documentation must be submitted detailing medical necessity for requested dosage regimen AND the Buprenorphine Safety Checklist has been completed (see PA form for detailed requirements and for documentation required).
- Update **Requests for treatment of pain AND opioid use disorder:** The Buprenorphine Safety Checklist has been completed (see PA form for detailed requirements and for documentation required) AND other non-opioid medications and pain management modalities have been trialed prior to increasing the buprenorphine dose for pain AND split dosing (multiple daily administrations) on current dose have been trialed for pain control as recommended in the ASAM 2020/CDC 2022 practice guidelines AND clinical rationale has been provided if the request is for a dose increase > 25% the current daily dose (see PA form for detailed requirements and for documentation required).

Public Comments: None at this time.

Board Discussion: DVHA stated that providers no longer have to submit monitoring results. They will now have the option to attest that the monitoring is being done. Dr. Rapaport added that based off the feedback from providers, these updates allow them to have discretion when monitoring is done on stable patients, focusing on new starts and increases rather than those on stable doses. Change Healthcare asked for clarification that even after the patient has been stable for a year or more, the provider is still required to attest that the appropriate monitoring is being done. Internal workflow is still being worked out on this, however if less than 3 diversion monitoring practices

are checked and the patient is stable and established it will be elevated to DVHA for clinical review.

Board Decision: The Board unanimously approved the above recommendations.

11. General Announcements:

- None at this time.

12. Adjourn: Meeting adjourned at 8:23 p.m.