Department of Vermont Health Access
Pharmacy Benefit Management Program
DUR Board Meeting Minutes
October 19, 2021

Board Members Present:

Mark Pasanen, MD
Bill Breen, RPH,
Douglas Franzoni, PharmD
Renee Mosier, PharmD,
Claudia Berger, MD,
Andy Miller, RPH
Margot Kagan, PharmD

Board Members Absent: Joseph Nasca, MD

Staff:

Laurie Brady, RPh, Change HealthCare
Nancy Hogue, Pharm D, DVHA
Mike Ouellette, RPh, Change Healthcare
Lisa Hurteau, PharmD, DVHA
Jason Pope, DVHA
Marietta Scholten, MD, DVHA
Gabrielle Gagnon, ACPHS Intern
Jacqueline Hedlund, MD, Change Healthcare

Guests:

Amy Cunningham
Camille Kerr
Erica Hintze (Abbvie)
Franco Casagrande (Abbvie)
Gene Muise (Amgen)
Jane Gou
Jessica Todd
Joe Ward (Abbvie)
Joseph Shaker
Kristen K
Lindsey Walter
Lisa Dunn (Amgen)
Megan Walsh
Mike Dowling
Nikhil Kacker (Genentech)
Patty Arcese
Paul Iswke (Teva)
Rocco Iannetta (PTC Therapeutics)
Stephanie Kennedy (Greenwich Bioscience)
Stormy Cameron
Vincent Joseph Lawler

1. Executive Session:

- An executive session was held from 5:00 p.m. until 6:00 p.m.

2. Introductions and Approval of DUR Board Minutes:

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

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

- DVHA has recently waived co-pays for HIV pre-exposure prophylaxis (PrEP) medications, effective 10/1/21. This is based on the A Grade recommendation of the Preventive Services Task Force as part of the Affordable Care Act.
- Andy Miller, board member, noted that some private insurers require a submission clarification code on the claim to indicate whether the medication is

being used for treatment or prophylaxis. Nancy Hogue advised that DVHA is not requiring that at this time, and the co-pay waiver applies to the medication regardless of indication.

4. Medical Director Update: Marietta Scholten, DVHA

- Introduction of Marietta Scholten, family medicine physician who has been contracted with DVHA as a consultant for approximately 10 years. She will be taking on additional roles since Dr. Scott Strenio is transitioning full-time to the Department of Corrections.

5. Proposed 2022 DURB Meeting Dates

February 15, 2022
April 5, 2022
May 10, 2022
June 21, 2022
September 13, 2022
October 25, 2022
December 6, 2022

6. Follow-up Items from Previous Meetings:

- RetroDUR: Codeine Use in Pediatrics was deferred until the December DUR meeting

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

- Introduce: Discussion Topics for 2022 RetroDUR Initiatives

CONCURRENT USE OF GLP-1 RECEPTOR AGONISTS AND DPP-4 INHIBITORS
Purpose: Combination therapy provides only modest improvement in glycemic control with minimal weight loss benefits, which is similar to monotherapy with either agent. Combination is unlikely to provide synergistic effects and is not cost effective.

LETROZOLE USE FOR INFERTILITY
Purpose: Medicaid does not provide coverage for infertility treatment. However, since letrozole has multiple clinical indications and is a preferred agent, there may be unintended use.

BLOOD GLUCOSE TEST STRIPS IN CGM USERS
Purpose: The expectation is that blood glucose test strip (BGS) utilization will decrease after a member starts on a continuous glucose monitor (CGM) system.

OPIOID USE FROM MULTIPLE PROVIDERS
Purpose: Asses potentially high-risk opioid prescribing practices and/or provider "shopping."

METABOLIC MONITORING FOR CHILDREN AND ADOLESCENTS ON ANTIPSYCHOTICS

Purpose: Use of antipsychotic medications in children and adolescents increases the risk of developing diabetes and high cholesterol which can extend into adulthood. The American Psychiatric Association and the American Diabetic Association recommend that patients receiving antipsychotic medications be monitored for metabolic risk factors at baseline and routinely during therapy.

APPROPRIATE USE OF ASTHMA CONTROLLER MEDICATIONS
Purpose: To evaluate use of short term beta-adrenergic (SABA) inhalers since increased use of SABA has been associated with increased risk of acute asthma exacerbation and death. GINA guidelines were updated in 2019 and recommend that all adults and adolescents should receive ICS-containing controller treatment, including patients with mild asthma. The goal is to assess compliance with these guidelines.

CONCURRENT USE OF OPIOIDS AND ANTIPSYCHOTICS
Purpose: CMS mandate as part of the SUPPORT Act. Increased risk of respiratory and CNS depression with concurrent use of opioids and CNS depressants. Prospective DUR edit to alert dispensing pharmacist was implemented in January 2021.

CONCURRENT USE OF OPIOIDS AND BENZODIAZEPINES
Purpose: CMS mandate as part of the SUPPORT Act. Increased risk of respiratory and CNS depression with concurrent use of opioids and CNS depressants. Prospective DUR edit to alert dispensing pharmacist was implemented in January 2021.

Recommendation: Choose 6 topics to work on next year.

Public Comment: No public comment.

Board Decision: After much discussion the board choose to move forward with these RetroDUR topics: Appropriate use of Asthma Controller Medications, Blood Glucose Test Strips in CGM Users, Concurrent Use of GLP-1 Receptor Agonists and DPP-4 Inhibitors, Letrozole Use for Infertility, Metabolic Monitoring for Children and Adolescents on Antipsychotics and Opioid Use from Multiple Providers. Change Healthcare will create a RetroDUR initiatives calendar.

- Introduce: Immunologic Therapies for Asthma

Immunologic therapies for asthma have significantly improved outcomes and quality of life for patients with moderate or severe asthma who are not controlled on chronic treatment with inhaled corticosteroids and long-acting bronchodilators. One of the goals of immunotherapy is to decrease the need for intermittent treatment with oral corticosteroids, which have numerous deleterious effects when used chronically. Benralizumab (Fasenra®) and mepolizumab (Nucala®) are IL-5 receptor antagonist monoclonal antibodies that are FDA approved for use in those 12 years of age and older with severe asthma with elevated eosinophil counts. Dupilumab (Dupixent®) is an IL-4 and IL-13 dual inhibitor for those 12 years of age or older with either an eosinophilic phenotype or who are dependent on oral

corticosteroids. GINA guidelines recommend adding immunologic anti - IL-4 or IL-5 therapy as step 5 in asthma management in adults and adolescents, in those who are dependent on high dose ICS-LABA inhalers rather than adding oral corticosteroids, with the appropriate phenotype. Of note, the GINA guidelines do recommend adding anti-IgE therapy (Xolair, omalizumab) in those 6 years of age and older with the appropriate phenotype, however Xolair was until recently only a physician administered drug and this RetroDUR is focusing on self-administered medications. We will use paid, non-reversed Medicaid pharmacy and medical claims from SFY 2021 excluding members with Part D, VMAP and Healthy Vermonters coverage. We will identify all members ages 12 and older with a diagnosis of asthma who were prescribed Nucala, Fasenra or Dupixent. We will look to see how many members were compliant with these medications and with their concurrent inhalers (ICS or ICS/LABA combinations) and the frequency at which members were prescribed oral corticosteroids.

Recommendation: No action needed.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

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

Biosimilar Drug Reviews:

- None at this time.

Full New Drug Reviews:

- None at this time.

9. New Therapeutic Drug Classes

- None at this time.

10. Therapeutic Drug Classes- Periodic Review:

- None at this time.

11. Review of Newly-Developed/Revised Criteria (all PDL changes will be effective 1/1/2022):

- **ADHD/Short Acting Stimulants**

Recommendation:

- Move Procentra® (dextroamphetamine sulfate) to preferred.
    - Clinical criteria:
        - Update Evekeo ODT, Dextroamphetamine oral solution: patient has a medical necessity for a non-solid oral dosage form. (e.g. swallowing disorder) AND

the patient has a documented intolerance to Procentra oral solution.

Public Comments: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

- **ADHD/Long-Acting Stimulants**

Recommendation:

- Move Vyvanse® (lisdexamfetamine) chew to non-preferred with grandfathering with QTY Limit of 1 tab/day.
- Move dexmethylphenidate ER caps (generic Focalin XR) to preferred.
- Move Ritalin® LA (methylphenidate SR 24 HR, IR/ER, 50:50%) and Methylphenidate SR 50:50 caps to preferred.
- Move Aptensio® XR (methylphenidate DR 24HR IR/ER, 40:60%) to non-preferred with grandfathering.
    - Clinical criteria:
        - Add Aptensio XR: patient has had a documented side effect, allergy, or treatment failure on two preferred long-acting Methylphenidate products.
        - Add Dyanavel, Vyvanse Chew: patient must be unable to tolerate Adderall XR sprinkled onto applesauce or Vyvanse mixed with yogurt, water, or orange juice.

Public Comments: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

- **ADHD/Miscellaneous**
    - Xywav: New indication is for idiopathic hypersomnia in adults, a rare condition in which patients experience excessive daytime sleepiness even when they get plenty of sleep. The effectiveness of Xywav® was evaluated in a double-blind placebo-controlled randomized-withdrawal study in 154 adult patients (ages 19 to 75 years) with IH. In the clinical study, patients who were randomized to switch from Xywav® to placebo experienced worsening on measures of sleepiness and symptoms of IH compared to patients randomized to continue treatment with Xywav®. In the clinical trial for IH, the most common adverse events as a result of the treatment observed in the study included nausea (21.4%), headache (16.2%), dizziness (11.7%), anxiety (10.4%) and vomiting (10.4%). Xywav® has a boxed warning for central nervous system depression and abuse and misuse. The active moiety of Xywav® is oxybate, also known as gamma-hydroxybutyrate

(GHB), a Schedule I controlled substance. Abuse or misuse of illicit GHB has been associated with serious side effects including seizures, trouble breathing, changes in alertness, coma, and death. Clinically significant respiratory depression and reduced level of alertness has occurred in adult patients taking sodium oxybate. Because of the potential risks associated with Xywav®, it is subject to strict safety controls on prescribing and dispensing under a program called a Risk Evaluation and Mitigation Strategy (REMS).

Recommendation:

- Move Clonidine ER with QTY Limit of 4 tabs/day to preferred.
    - Clinical criteria:
        - Revise Sunosi: patient has had a documented side effect, allergy, or treatment failure to 2 preferred agents (may be stimulant or non-stimulant)
        - Revise Xyrem, Xywav: patient has had a documented side effect, allergy, or treatment failure to 2 preferred agents (may be stimulant or non-stimulant) and Sunosi AND patient has been enrolled in the REMS program AND for approval of Xywav, the patient must have a documented intolerance to Xyrem.

Public Comments: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

- **Alzheimer's**

Recommendation:

- Move Galantamine tab, Rivastigmine tab with QTY Limit 2 capsules/day, and Exelon® (rivastigmine transdermal) patch with QTY limit 1 patch/day to preferred.
    - Clinical criteria:
        - Revise Donepezil 23mg Tablet, Galantamine ER Capsule, Razadyne ER Capsule: patient has been started and stabilized on the requested medication (Note: samples are not considered adequate justification for stabilization) OR patient had a documented side effect, allergy or treatment failure to a preferred cholinesterase inhibitor AND if the product has an AB rated generic.
        - Revise Donepezil ODT, Galantamine Oral Solution, Rivastigmine patch: medical necessity for a specialty dosage form has been provided. AND for approval of rivastigmine patch the patient has a documented intolerance to brand Exelon patch.

Public Comments: No public comment.

Board Decision: The Board unanimously approved the above recommendations with the removal of "AND if the product has an AB rated generic" from Donepezil 23mg Tablet, Galantamine ER Capsule, and Razadyne ER Capsule clinical criteria.

- **Anticoagulants/Oral**
    - Xarelto: The FDA approved an expanded peripheral artery disease (PAD) indication for rivaroxaban (Xarelto) plus Aspirin to include patients who have undergone recent lower-extremity revascularization due to symptomatic PAD.

Recommendation:

- Remove day supply max of 30 days per 180 day period for Xarelto® (rivaroxaban) 10 mg tablets.
    - Clinical criteria:
        - Revise Savaysa: creatinine clearance is documented to be < 95 ml/min AND prescriber has provided another clinically valid reason why generic warfarin, Pradaxa, Xarelto or Eliquis cannot be used. A yearly creatinine clearance is required with renewal of PA request.

Public Comments: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

- **Anticonvulsants/Oral**
    - Epidiolex: The FDA approved Epidiolex® (cannabidiol) [CBD] oral solution for the treatment of seizures associated with tuberous sclerosis complex (TSC) in patients one year of age and older. Epidiolex® was previously approved for the treatment of seizures associated with two rare and severe forms of epilepsy, Lennox-Gastaut syndrome (LGS) and Dravet syndrome (DS). This is the only FDA-approved drug that contains a purified drug substance derived from cannabis. It is also the second FDA approval of a drug for the treatment of seizures associated with TSC. TSC is a rare genetic disease that causes non-cancerous (benign) tumors to grow in the brain and other parts of the body like the eyes, heart, kidneys, lungs, and skin. TSC usually affects the central nervous system and can result in a combination of symptoms including seizures, developmental delay, and behavioral problems,

although the signs and symptoms of the condition, as well as the severity of symptoms, vary widely. TSC affects about 1 in 6,000 people. Epidiolex's effectiveness for the treatment of seizures associated with TSC was established in a randomized, double-blind, placebo-controlled trial where 148 patients out of a total of 224 in the study received Epidiolex®. The study measured the change from baseline in seizure frequency. In the study, patients treated with Epidiolex® had a significantly greater reduction in the frequency of seizures during the treatment period than patients who received placebo (inactive treatment). This effect was seen within eight weeks and remained consistent throughout the 16-week treatment period. The most common side effects that occurred in Epidiolex-treated patients with TSC in the clinical trial were: diarrhea, elevated liver enzymes, decreased appetite, sleepiness, fever, and vomiting. Additional side effects for patients with LGS, DS, or TSC include: liver injury, decreased weight, anemia, and increased creatinine.

Recommendation:

- Revise Epidiolex® (cannabidiol) oral solution QTY Limit to 25mg/kg/day for TSC indication.
    - Clinical criteria:
        - Add to current criteria for Epidiolex: Diagnosis or indication is Tuberous Sclerosis Complex: Serum transaminases (AST and ALT) and total bilirubin levels have been obtained prior to starting therapy and are monitored periodically thereafter AND patient has had a documented side effect, allergy, treatment failure/inadequate response or a contraindication to at least TWO preferred anticonvulsants or vigabatrin.

Public Comments: Stephanie Kennedy of Greenwich Biosciences yielded her time back to the committee.

Board Decision: The Board unanimously approved the above recommendations.

- **Antidiabetics/GLP-1 Receptor Agonists**

Recommendation:

- Add qty limit for Ozempic® (semaglutide) of 9mL/84 days.
    - Clinical criteria:

- Revise Ozempic: patient has a documented side effect, allergy, contraindication, or treatment failure with Trulicity.

Public Comments: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

- **Antidiabetics/ Insulin Long-acting**

Recommendation:
- Move Toujeo® Solostar (insulin glargine) and Tresiba® Flextouch (insulin degludec) to preferred.

Public Comments: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

- **Antiretrovirals**

Recommendation:
Single product regimens
- Move brand Atripla® to non-preferred and add the generic efavirenz/lamivudine/tenofovir DF preferred.
    - Clinical criteria:
        - Add Atripla: patient must have a documented intolerance to the generic equivalent.

Protease Inhibitors
- Move Ritonavir to preferred.

Nucleoside & Nucleotide Analog RTIs
- Move brand Truvada® to non-preferred.
- Add generic emtricitabine/tenofovir to preferred.
    - Clinical criteria:
        - Add Truvada: patient must have a documented intolerance to the generic equivalent.

Public Comments: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

- **Atopic Dermatitis**

Recommendation:
- Move brand Elidel® (pimecrolimus) to preferred after clinical criteria are met.
- Move pimecrolimus authorized generic (labeler code 68682) to non-preferred.

- Move Dupixent® (dupilumab) with QTY Limit of 4 syringes/pens the first 28 days then 2 syringes/pens every 28 days thereafter to preferred after clinical criteria are met. Revise length of initial approval to 6 months (was previously 3 months).
    - Clinical criteria:
        - Remove requirement that the patient has had a documented side effect, allergy, or treatment failure to at least one of the following systemic therapies: cyclosporine, azathioprine, methotrexate, mycophenolate, or tacrolimus from Dupixent criteria.
        - Revise Elidel, Pimecrolimus additional criteria: The patient is ≥2 years of age AND the quantity requested does not exceed 30 grams/fill and 90 grams/6 months. AND If the request is for generic forms of pimecrolimus, the patient has a documented intolerance to the brand name equivalent.

Public Comments: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

- **Cardiovascular/Beta Blockers**

Recommendation:

- Move Bystolic® (nebivolol) to preferred.
- Add Nebivolol to preferred.

Public Comments: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

- **Cardiovascular/PCSK9 Inhibitors**

Recommendation:

- Move Repatha® (evolocumab) with QTY Limit 2mL (2 injections)/28 days; max of 28 days to preferred after clinical criteria are met.
- Move Repatha® (evolocumab) Pushtronix with QTY Limit 3.5mL (one single-use infusor and prefilled cartridge/28 days; max of 28 days to preferred after clinical criteria are met.
    - Clinical criteria:
        - Remove statement that for approval of Repatha, the patient must have a documented side effect, allergy, or treatment failure with Praluent.
        - Update Additional criteria for the diagnosis of homozygous familial hypercholesterolemia (Repatha only): Total cholesterol levels > 290mg/dL or LDL-C > 190mg/dL (adults) OR Total cholesterol levels > 260mg/dL or LDL-C > 155mg/dL (children < 16

years) and TG within reference range OR Confirmation of diagnosis by gene testing

Public Comments: Gene Muise of Amgen yielded time back to the committee.

Board Decision: The Board unanimously approved the above recommendations.

- **Cystic Fibrosis/Inhaled Antibiotics**

Recommendation:

- Move tobramycin inhalation solution 300mg/5mL with QTY Limit 56 vials/56 days; max of 56 days (2 vials per day for 28 days, then 28 days off) to preferred after clinical criteria are met.
    - Clinical criteria:
        - Revise TOBI, tobramycin inhalation solution (300mg/4mL): Diagnosis or indication is cystic fibrosis AND the patient has a documented failure or intolerance to two preferred formulations of tobramycin inhalation solution.
        - Add tobramycin inhalation solution (300mg/5mL) to Bethkis and Kitabis clinical criteria.

Public Comments: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

- **Cytokine Modulators (includes the following PDL classes):**
  Ankylosing Spondylitis Injectables
  Gastrointestinal Inflammatory Disease Biologics
  Psoriasis
  Rheumatoid, Juvenile, and Psoriatic Arthritis Immunomodulators

Recommendation:

Ankylosing Spondylitis Injectables

- No changes.

Gastrointestinal Inflammatory Disease Biologics

- Move Renflexis® (infliximab-abda) to preferred after clinical criteria are met.
- Move Xeljanz® (tofacitinib) with QTY Limit 2 tablets/day to preferred after clinical criteria are met.
    - Clinical criteria:
        - Add Xeljanz to Avsola, Humira, Remicade, Cimzia, Tysabri, Entyvio, Inflectra, Renflexis, and Stelara clinical criteria.

- Revise Xeljanz XR additional criteria: Patient has not been able to tolerate or adhere to twice daily dosing of immediate release Xeljanz, resulting in significant clinical impact.
- Revise Cimzia additional criteria: Patient age > 18 years AND the prescriber must provide a clinically valid reason why Humira and Remicade or Renflexis cannot be used.

Psoriasis
- Move Otezla® (apremilast) with QTY Limit: Starter Pack = 55 tablets/28 days, 30mg = 2 tablets/day to preferred after clinical criteria are met.

Rheumatoid, Juvenile, and Psoriatic Arthritis Immunomodulators
- Move Otezla® (apremilast) with QTY Limit: Starter Pack = 55 tablets/28 days, 30mg = 2 tablets/day and Kineret® (anakinra) to preferred after clinical criteria are met.
    - Clinical criteria:
        - Revise Olumiant, Rinvoq additional criteria: The patient must be ≥ 18 years of age AND The prescriber must provide a clinically valid reason why at least two preferred agents cannot be used, one of which must be Xeljanz.

Public Comments: Jane Guo from Novartis: Highlighted the attributes of Cosentyx.
Franco Casagrande from Abbvie: Highlighted the attributes of Skyrizi.
Gene Muise from Amgen yielded time back to the committee.

Board Decision: The Board unanimously approved the above recommendations.

- **Hematopoietics/Colony Stimulating Factors**

Recommendation:
- Move Neupogen® (filgrastim) syringes and Ziextenzo®(pegfilgrastim-bmez) to preferred.
- Move Granix® (tbo-filgrastim) to non-preferred.
- Add Nyvepria® (pegfilgrastim-apgf) to non-preferred.

Public Comments: Paul Isikwe from Teva Pharmaceutical: Highlighted the attributes of Granix.

Board Decision: The Board unanimously approved the above recommendations.

- **Hemophilia/Factor VIII**

Recommendation:
- Move Nuwiq® to non-preferred.
- Move Recombinate® and Esperoct® to preferred.
    - Clinical criteria:

- Add to clinical criteria for all non-preferred products: For approval of Adynovate, Eloctate, or Jivi, documentation must include why the member is unable to use the preferred extended half-life concentrate Esperoct.

Public Comments: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

- **Hemophilia/Factor IX**

Recommendation:

- Move Idelvion® to preferred.
  - Clinical criteria:
    - Revise clinical criteria for all non-preferred products: 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. For approval of Rebinyn, documentation must include why the member is unable to use a preferred extended half-life concentrate, Alprolix or Idelvion.

Public Comments: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

- **Immunologic Therapies for Asthma**

Recommendation:

- Move Dupixent® (dupilumab) with QTY Limit of 4 syringes/pens the first 28 days then 2 syringes/pens every 28 days thereafter to preferred after clinical criteria are met.
- Move Cinqair® (reslizumab) to non-preferred.
- Revise length of initial approval to 6 months (was previously 3 months).
  - Clinical criteria:
    - Remove requirement for diagnosis of moderate to severe persistent asthma that the medium-high dose ICS/LABA must be given in combination with a leukotriene receptor antagonist or long-acting bronchodilator (e.g. tiotropium).
    - For approval of Cinqair or Nucala, the patient must have a documented side effect, allergy, or treatment failure with Dupixent or Fasenra.
    - Revise Dupixent: The patient must have an eosinophilic phenotype as defined by pretreatment blood eosinophil count of ≥ 150 cells per mcL within the previous 6 weeks or ≥ 300 cells per

mcL within 12 months prior to initiation of therapy OR the patient is dependent on oral corticosteroids.

Public Comments: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

- **Migraine Therapy/Acute Treatments (Gepants only)**

Recommendation:

- Update quantity limit for Nurtec® ODT (rimegepant) to a maximum of 8 tablets per 30 days

Public Comments: Franco Casagrande from Abbvie: Highlighted the attributes of Ubrelvy.

Board Decision: The Board unanimously approved the above recommendations.

- **Migraine Therapy/Preventative Treatment**

Recommendation:

- Add Nurtec® ODT (rimegepant) QTY LIMIT: 16 tablets/30 days to non-preferred.
    - Clinical criteria:
        - Add Nurtec ODT: The patient is 18 years of age or older AND patient has a diagnosis of episodic migraine (4-14 headache days per month with migraine lasting 4 hours or more) AND patient has failed or has a contraindication to an adequate trial (≥ 60 days) of at least TWO medications for migraine prophylaxis from at least 2 different classes (tricyclic antidepressants, SNRI's, beta-blockers, or anticonvulsants). Initial approval will be granted for 6 months. For re-approval after 6 months, the patient must have documentation of a decrease in the number of headache days per month or decreased use of acute migraine medications such as triptans. Pharmacy claims will also be evaluated to assess compliance with the medication.
        - Additional criteria for Aimovig, Nurtec ODT, Vyepti additional criteria: The patient must have a documented side effect, allergy, or treatment failure to Emgality and Ajovy.

Public Comments: Paul Isikwe from Teva Pharmaceutical yielded time back to the committee.

Board Decision: The Board unanimously approved the above recommendations.

- **Oncology Drugs**

Recommendation:

- Clinical criteria:
  - Update: Medication is being used for an FDA approved indication AND age, dose, duration, required concurrent therapy, and past treatment failures (if applicable) are consistent with prescribing information AND the patient does not have any contraindications prohibiting use of the medication OR medication is being used in accordance with the National Comprehensive Cancer Network® (NCCN®) Clinical Practice Guidelines. Requests outside of these parameters require medical director review. For physician-administered drugs, please refer to the Fee Schedule for which codes require a PA: http://vtmedicaid.com/#/feeSchedule.

Public Comments: No comment.

Board Decision: The Board unanimously approved the above recommendations.

13. General Announcements:

Clozapine Risk Evaluation and Mitigation Strategy (REMS) requirements will change on November 15, 2021
https://www.fda.gov/drugs/drug-safety-and-availability/clozapine-risk-evaluation-and-mitigation-strategy-rems-requirements-will-change-november-15-2021?utm_medium=email&utm_source=govdelivery

Three JAK Inhibitors Get Boxed Warnings, Modified Indications
https://www.medscape.com/viewarticle/958024?src=wnl_newsalrt_210901_MSCPEDIT&uac=2185FK&impID=3609579&faf=1

Board Discussion: The board recommends DVHA send a notification to prescribers and pharmacies alerting them to the November 15th Clozapine REMS change.

15. Adjourn: Meeting adjourned at 7:40 p.m.