Department of Vermont Health Access
Pharmacy Benefit Management Program
DUR Board Meeting Minutes
April 7, 2020

NOTE: The Meeting was held via Skype due to the Governor's "Stay Home Stay Safe" order related to the COVID-19 Emergency Declaration, and as authorized by recent modifications to Vermont's Public Meeting Law.

Board Members Present:

Clayton English, PharmD	Margot Kagan, PharmD	Patricia King, MD
Zail Berry, MD	Bill Breen, RPh	Renee Mosier, PharmD
Louise Rosales, NP	Claudia Berger, MD	
Marc Pasanen, MD	Doug Franzoni, PharmD	

Absent: Joseph Nasca, MD

Staff:

Laurie Brady, RPh, Change HealthCare	Mike Ouellette, RPh, Change Healthcare	Jeffrey Barkin, MD, Change Healthcare
Carrie Germaine, DVHA	Lisa Hurteau, PharmD, DVHA	Scott Strenio, MD, DVHA
Nancy Hogue, Pharm D, DVHA	Jason Pope, DVHA	

Guests:

Adam Denman	Andy Hsieh	Brian O'Sullivan
David Wickard	Jessica Grussing	Jai Persico
Jeffery Olson	Cassandra Marx	Kristen Chopas
Kristin Crouch	Gene Muise	Megan Walsh
Melissa Mattice	Tyson Thompson	Paul Short
Tom Algozzine	Thomas Lahiri	Karen Szydlik
		Tyson Thompson

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 February meeting minutes were accepted as printed.

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

- Changes to the Pharmacy Benefit have been made due to the COVID-19 pandemic: Waived all copays of medications used in the treatment of COVID-19 symptoms, allowing early refills on maintenance medications, increased the number of days patients can get Suboxone, removed the requirement for mandatory 90-day fills, waived signature requirement at the pharmacy.

- Albuterol HFA shortages are being reported and DVHA has temporarily lifted the PA requirement on those drugs. As shortages arise, adjustments will be made.
- DVHA has compiled a list of Vermont Medicaid enrolled Pharmacies that deliver (either in person or mail order).

4. Medical Director Update: Scott Strenio, MD, DVHA

- Many reimbursement codes have been opened up. For example, PA requirements for high tech imaging have been removed, and telemedicine coverage has been expanded.

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

- None at this time.

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

- Introduction of RetroDUR: Concurrent Use of Opioids and Antipsychotics

The prevalence of substance use disorder is elevated among those with schizophrenia. The lifetime prevalence is estimated at 47 to 59%, compared with 16% in the overall population, although rates vary by age, gender and other factors. Opioid abuse is estimated in the schizophrenic population to be around 4-11%. Antipsychotics, used to treat schizophrenia, are also used to treat other behavioral health conditions, such as mania associated with bipolar disease, depression, PTSD, obsessive-compulsive disorder and anxiety, which are also known to have a high rate of substance abuse. The concern with co-prescribing opioids and antipsychotics is the risk of over-sedation, respiratory depression and death. CMS has highlighted the need to monitor co-prescribing of opioids and antipsychotics for side effects and adverse reactions. Section 1004 of the SUPPORT ACT adds a new section to the Social Security Act which requires states to implement drug review and utilization requirements including Opioid and Antipsychotic Concurrent Fill Reviews. According to the CMCS informational bulletin dated August 5, 2019.

This alert is supported by the FDA's warning of increased risk of respiratory and Central Nervous System (CNS) depression with concurrent use of opioid and CNS depressants such as antipsychotics or sedatives, including extreme sleepiness, slowed or difficult breathing, unresponsiveness or the possibility that death can occur. Patients concurrently prescribed opioid and antipsychotic drugs benefit from increased coordination of care. Additionally, improving treatment of comorbid mental health disorders is an important consideration when trying to reduce the overall negative impacts of opioid use disorders, and the treatment of pain. This review will encourage coordination of care for patients taking antipsychotic and opioid medication concurrently.

Change Healthcare will use paid, non-reversed Medicaid pharmacy and medical claims from Calendar Year 2019, excluding members with Part D, VMAP and Healthy Vermonters coverage. They will identify members, excluding those with a cancer diagnosis, who were prescribed an opioid for at least 90 days and examine how many were given an overlapping antipsychotic

prescription along with continued use of the opioid (we will look at those with an overlap of more than 30 days). The data will be stratified by age cohorts. We will also evaluate whether members, while prescribed both types of drugs, had ED visits or hospitalizations that were not behavioral health related, and if the medications were prescribed by the same, or different, prescribers.

Recommendation:

Public Comment: No public comment.

Board Decision: None needed.

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

Biosimilar Drug Reviews:

- None at this time.

Full New Drug Reviews:

- Aklief® (trifarotene)

Trifarotene, the active ingredient of Aklief®, is a terphenyl acid derivative and is a retinoid. It is an agonist of retinoic acid receptors (RAR), with particular activity at the gamma subtype of RAR. Stimulation of RAR results in modulation of target genes, which are associated with various processes, including cell differentiation and mediation of inflammation. The exact mechanism of action by which trifarotene works for acne is not known. It is indicated for the topical treatment of acne vulgaris in patients 9 years of age and older. The safety and efficacy of use of Aklief® cream in the treatment of moderate facial and truncal acne vulgaris were assessed in 2 randomized, multicenter, parallel group, double-blind, vehicle-controlled trials of identical design. The trials included subjects 9 years of age and older (N=2420) who were treated for up to 12 weeks with either Aklief® cream or vehicle cream. Subjects were encouraged to use a moisturizer as desired, while allowing about a 1-hour period before or after the study treatment application. In 2 randomized, vehicle-controlled trials, Aklief® cream was found to be more effective than vehicle for its primary endpoints. Per the full-text study by Tan et al2, the facial and truncal success rates per the IGA and PGA, respectively, as well as the changes in inflammatory and non-inflammatory lesion counts were all significantly ($p<0.001$) in favor of trifarotene when compared with vehicle. In a long-term 52-week study by Blune-Peytavi et al3, trifarotene was found to be safe, well-tolerated, and effective in moderate facial and truncal acne.

Recommendation:

- Add Aklief® (trifarotene) 0.005% cream to non-preferred.
- Move Fabior ® (tazarotene) 0.1% foam to non-preferred.
    - Clinical criteria:

- Aklief: patient has had a documented side effect or treatment failure with a preferred topical tretinoin product and Differin.
- Fabior: patient has had a documented side effect, allergy, or contraindication with Tazorac.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

- Drizalma® Sprinkle (duloxetine capsule, delayed release)

Duloxetine, the active ingredient of Drizalma® Sprinkle, is a selective serotonin and norepinephrine reuptake inhibitor (SNRI). While the exact mechanisms of the antidepressant, central pain inhibitory and anxiolytic actions of duloxetine in humans are not known, these actions are believed to be related to its potentiation of serotonergic and noradrenergic activity in the CNS. It is indicated for the treatment of Major Depressive Disorder (MDD) in adults, Generalized Anxiety Disorder (GAD) in adults and pediatric patients 7 years to 17 years old and Diabetic Peripheral Neuropathy (DPN) in adults. It is also indicated for the management of chronic musculoskeletal pain in adults. Drizalma® has a box warning regarding the increased risk of suicidal thoughts and behaviors. The prescribing information for Drizalma® Sprinkle had the same studies included as Cymbalta®, a brand name duloxetine extended-release capsule, with the exception of fibromyalgia. Cymbalta® is indicated for fibromyalgia, whereas Drizalma® Sprinkle is not. Cymbalta® has been on the market for numerous years and has a generic version as well. While Drizalma® Sprinkle has the same doses of Cymbalta®, Drizalma® is available in an additional dose of 40mg. In addition, Drizalma® Sprinkles may be opened and the contents sprinkled over applesauce or added for nasogastric tube administration. This is unlike Cymbalta®, where the capsules should not be opened.

Recommendation:

- Add Drizalma® (duloxetine) sprinkle capsule QTY LIMIT: 2 capsules/day FDA maximum recommended dose = 120 mg/day (MDD and GAD), 60 mg/day all others to non-preferred.
  - Clinical criteria
    - Add Drizalma to the Cymbalta clinical criteria.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

- Duaklir® Pressair (aclidinium bromide and formoterol fumarate)

Duaklir® Pressair is a combination inhaler for oral inhalation that includes aclidinium bromide (an anticholinergic with specificity for muscarinic receptors) and formoterol fumarate (a selective beta2-adrenergic agonist). Aclidinium is a long-acting antimuscarinic agent, also known as an anticholinergic, that exerts its pharmacological effects through inhibition of M3 receptors at the smooth muscle leading to bronchodilation. Formoterol is a long-acting

selective beta2-adrenergic receptor agonist, also known as a LABA, that acts locally in the lung as a bronchodilator. It is indicated for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD). Duaklir® Pressair is not indicated for the relief of acute bronchospasm or for the treatment of asthma. The safety and efficacy of Duaklir® Pressair were assessed in a clinical development program that included 3 dose-ranging trials, one active and two placebo-controlled lung function trials of 24 weeks in duration, and one 28-week long-term safety extension study. There is some evidence at this time to suggest that Duaklir® Pressair is more effective than tiotropium for the endpoint of improved 1-hour post-dose FEV; however, there is no evidence to suggest it is safer or more effective than the other currently preferred medications.

Recommendation:

- Add Duaklir® Pressair (aclidinium bromide/ formoterol fumarate) QTY LIMIT: 3 inhalers/90 days to non-preferred.
- Remove UTIBRON™ NEOHALER® (indaceterol/glycopyrrolate) and Seebri Neohaler® (glycopyrrolate) from the PDL as they are no longer available.
    - Clinical criteria
        - Add Duaklir Pressair to the Stiolto Respimat clinical criteria.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

- Nayzilam® (midazolam nasal spray)

Midazolam, the active ingredient of Nayzilam®, is a compound of the benzodiazepine class. The exact mechanism of action for midazolam is not fully understood, but it is thought to involve potentiation of GABAergic neurotransmission resulting from binding at the benzodiazepine site of the GABA-A receptor. Nayzilam® is a Schedule IV controlled substance. Benzodiazepines, such as midazolam, may be subject to abuse and can cause physical dependence. It is indicated for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (i.e. seizure clusters, active repetitive seizures) that are distinct from a patient's usual seizure pattern in patients with epilepsy 12 years of age and older. The safety and efficacy of Nayzilam® were established in a randomized, double-blind, placebo-controlled study. This study enrolled patients with epilepsy on a stable regimen of antiepileptic drugs (AEDs) who were identified by their physicians as having intermittent, stereotypic episodes of frequent seizure activity that were distinct from the patient's usual seizure pattern. In a clinical study compared with placebo, a statistically significant greater number in the Nayzilam® group met the primary endpoint of treatment success. Nayzilam® is not recommended for chronic, daily use as an anticonvulsant because of the potential for development of tolerance to midazolam. It is recommended that Nayzilam® be used to treat no more than one episode every 3 days and no more than 5 episodes per month.

Recommendation:

- Add a sub-category of Nasal to Anticonvulsants.

- Add NAYZILAM® (midazolam) nasal spray (age ≥ 12 years) QTY LIMIT: 10 units/30 days to preferred.
- Move Diastat (diazepam) rectal gel to non-preferred.
- Move Diazepam (compare to Diastat®) rectal gel to preferred.
    - Clinical criteria
        - Add Diastat: patient has had a documented intolerance to the generic equivalent.
        - Remove the Diazepam Rectal Gel criteria.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

- Nourianz® (istradefylline)

Istradefylline, the active ingredient of Nourianz®, is an adenosine receptor antagonist, which has a xanthine derivative structure. The mechanism of action by which it exerts its therapeutic effects in Parkinson disease is not known. In in vitro and in vivo animal studies, istradefylline was demonstrated to be an adenosine A2A receptor antagonist. It is indicated as an adjunctive treatment to levodopa/carbidopa in adult patients with Parkinson's disease (PD) experiencing "off" episodes. The safety and efficacy of Nourianz® for the adjunctive treatment to levodopa/carbidopa in patients with Parkinson's disease experiencing "off" episodes was shown in 4 randomized, multicenter, double-blind, placebo-controlled, 12-week studies. In clinical trials compared with placebo, patients treated with Nourianz® experienced a statistically significant decrease from baseline in percentage of daily awake "off" time.

Recommendation:

- Add subcategory ADENOSINE RECEPTOR ANTAGONIST to Parkinson's Medications with a note that all products require PA.
- Add Nourianz® (istradefylline) QTY LIMIT: 1 tablet/day to non-preferred.
- Add QTY limit 1 tab/day to Pramipexole ER (compare to Mirapex ER®).
    - Clinical criteria
        - Add Nourianz: The patient has a diagnosis of Parkinson's disease with intermittent presence of OFF episodes AND the patient is currently taking Carbidopa/Levodopa AND the patient has had a documented side effect, allergy, or treatment failure with TWO preferred medications being used as adjunct therapy.

Public Comment: No public comment

Board Decision: The Board unanimously approved the above recommendations.

- ProAir® Digihaler (albuterol sulfate)

Albuterol sulfate, the active ingredient of ProAir® Digihaler, is a beta2-adrenergic agonist. Its effects are attributable to activation of beta2-adrenergic receptors on airway smooth muscle. Albuterol relaxes the smooth muscle of all airways, from trachea to the terminal bronchioles. It is indicated for the treatment or prevention of bronchospasm in patients 4 years of age and older with reversible obstructive airway disease and for the prevention of exercise-induced bronchospasm in patients 4 years of age and older. The use of ProAir® Digihaler for these indications is supported by adequate and well-controlled studies in adults and pediatric patients of albuterol sulfate inhalation powder (ProAir® RespiClick). ProAir® RespiClick has been available for numerous years and has been found to be safe and effective. The Digihaler contains a QR code on the electronic module which is built-in to the top of the inhaler and automatically detects, records, and stores data on inhaler events. ProAir® Digihaler may pair with and transmit data to the mobile app where inhaler events are categorized. There is no evidence the use of the app leads to improved clinical outcomes, including safety and effectives.

Recommendation:

- Add ProAir® Digihaler (albuterol) to non-preferred.
- Update QTY limit on Servent diskus to 1 inhaler (60 blisters)/ 30 days.
    - Clinical criteria
        - Add ProAir Digihaler: Preferred albuterol metered dose inhalers and Xopenex HFA are on a long-term backorder and unavailable from the manufacturer.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

- Trikafta® (elexacaftor, tezacaftor, & ivacaftor kit)

Defer until Cystic Fibrosis Therapeutic Class Review.

Recommendation:

- Defer until Cystic Fibrosis Therapeutic Class Review.

Public Comment: No public comment.

Board Decision: N/A

- Vyndamax® (tafamidis)

Tafamidis, the active ingredient of Vyndamax®, is a selective stabilizer of transthyretin (TTR). Tafamidis binds to TTR at the thyroxine binding sites, stabilizing the tetramer and slowing dissociation into monomers, the rate-limiting step in the amyloidogenic process. (Note that Vyndaqel® is tafamidis meglumine and available as a 20mg capsule with the same indication as Vyndamax® to be taken as 80mg daily.) It is indicated for the treatment of the cardiomyopathy of wild type or hereditary transthyretin-mediated amyloidosis (ATTR-CM) in adults to reduce

cardiovascular mortality and cardiovascular-related hospitalization. The efficacy of Vyndamax® was demonstrated in a multicenter, randomized, double-blind, placebo-controlled study that included patients with wild type or hereditary ATTR-CM (N=441). Adults were randomized to receive Vyndaqel® 20mg, Vyndaqel® 80mg, or matching placebo QD for 30 months, in addition to standard of care (e.g. diuretics). Transplant patients were excluded from the study. The mean age for the pooled tafamidis group was 74.5 years and for the placebo group was 74.1 years. Compared with placebo, Vyndaqel®, a 20mg capsule of tafamidis meglumine, significantly reduced all-cause mortality, cardiovascular-related hospitalization rate, and functional decline in a 30-month clinical trial.

Recommendation:

- Defer until the Vyndaqel Drug Review.

Public Comment: No public comment.

Board Decision: N/A

- Vyndaqel® (tafamidis meglumine)

Tafamidis meglumine, the active ingredient of Vyndaqel®, is a selective stabilizer of transthyretin (TTR). Tafamidis binds to TTR at the thyroxine binding sites, stabilizing the tetramer and slowing dissociation into monomers, the rate-limiting step in the amyloidogenic process. (Note that Vyndamax® is tafamidis and available as a 61mg capsule with the same indication as Vyndaqel® to be taken as 61mg daily.) It is indicated for the treatment of the cardiomyopathy of wild type or hereditary transthyretin-mediated amyloidosis (ATTR-CM) in adults to reduce cardiovascular mortality and cardiovascular-related hospitalization. The efficacy of Vyndaqel® was assessed in a multicenter, randomized, double-blind, placebo-controlled study that included patients with wild type or hereditary ATTR-CM (N=441). Adults were randomized to receive Vyndaqel® 20mg, Vyndaqel® 80mg, or matching placebo QD for 30 months, in addition to standard of care (e.g. diuretics). Transplant patients were excluded from the study. The mean age for the pooled tafamidis group was 74.5 years and for the placebo group was 74.1 years. Compared with placebo, Vyndaqel® significantly reduced all-cause mortality, cardiovascular-related hospitalization rate, and functional decline in a 30-month clinical trial.

Recommendation:

- Add Vyndamax® (tafamidis) QTY LIMIT: 1 capsule/day and Vyndaqel® (tafamidis meglumine) QTY LIMIT: 4 capsules/day to non-preferred.
    - Clinical criteria
        - Add Vyndamax, Vyndaqel: The patient is ≥ 18 years of age with a diagnosis of cardiomyopathy of wild type transthyretin-mediated amyloidosis or heredity transthyretin mediated (hATTR) amyloidosis AND Documentation of TTR mutation by genetic testing and the presence of amyloid deposits showing cardiac involvement via tissue biopsy or imaging has been

submitted AND The medication is being prescribed by or in consultation with a cardiologist AND Initial approval will be granted for 6 months. For re-approval, the patient must have a decrease in the frequency of cardiovascular-related hospitalizations or slower progression of the disease than would otherwise be expected.

Public Comment: Tyson Thompson, PharmD, MBA highlighted the attributes of Vyndamax and Vyndaqel.

Board Decision: The Board unanimously approved the above recommendations.

- Wakix® (pitolisant)

Pitolisant, the active ingredient of Wakix®, is an antagonist/inverse agonist of the histamine-3 (H3) receptor. It is indicated for the treatment of excessive daytime sleepiness (EDS) in adults with narcolepsy. The safety and efficacy of Wakix® were assessed in 2 multicenter, randomized, double-blind, placebo-controlled studies that included adults who met the International Classification of Sleep Disorders (ICSD-2) criteria for narcolepsy and who had an Epworth Sleepiness Scale (ESS) score ≥14. Wakix® prolongs the QT interval and should be avoided in patients with known QT prolongation or in combination with other drugs known to prolong the QT interval. In 2 clinical trials compared with placebo, Wakix® demonstrated statistically significantly greater improvement on the primary endpoint, the least square mean final ESS score.

Recommendation:

- Add Wakix® (pitolisant) tablet QTY LIMIT: 2 tablets/day FDA maximum recommended dose = 35.6 mg/day to non-preferred.
  - Clinical criteria:
    - Add Wakix: indication for use is the treatment of excessive daytime sleepiness in narcolepsy AND patient has no known risk factors for increased QT prolongation (e.g. cardiac arrhythmias, symptomatic bradycardia, hypokalemia, or congenital prolongation of the QT interval) AND medication is not being used in combination with other drugs known to prolong the QT interval (e.g. antipsychotics, erythromycin, tricyclic antidepressants) AND patient has had a documented side effect, allergy, or treatment failure to at least 3 agents (may be preferred or non-preferred).

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

- Xenleta® (lefamulin acetate)

Lefamulin, the active ingredient of Xenleta®, is a semi-synthetic antibacterial agent. It is a pleuromutilin derivative that inhibits bacterial protein synthesis through interactions with the A- and P- sites of the peptidyl transferase center (PTC) in domain V of the 23s rRNA of the 50S subunit. The binding pocket of the bacterial ribosome closes around the mutilin core for an induced fit that prevents correct positioning of tRNA. It is indicated for the treatment of adults with community-acquired bacterial pneumonia (CABP) caused by the following susceptible microorganisms: Streptococcus pneumoniae, Staphylococcus aureus (methicillin-susceptible isolates), Hemophilus influenzae, Legionella pneumophila, Mycoplasma pneumoniae, and Chlamydophila pneumoniae. The safety and efficacy of Xenleta® were assessed in 2 multicenter, randomized, double-blind, double-dummy, non-inferiority studies that included adults (N=1289) with CABP. In clinical trials, it was found to be comparable to moxifloxacin. Xenleta® does have the potential to prolong the QT interval in some patients, and thus should be avoided in certain patient populations, including patients receiving other drugs that prolong the QT interval.

Recommendation:

- Add sub-category Pleuromutilins to the Anti-Infective Antibiotic category with a note that all products require PA and IV form of this medication is not managed at this time.
- Add Xenleta® (lefamulin acetate) QTY LIMIT: 2 tabs/day to non-preferred.
    - Clinical criteria:
        - Xenleta: patient is completing a course of therapy which was initiated in the hospital OR patient is ≥ 18 years of age AND has a confirmed diagnosis of community-acquired bacterial pneumonia (CABP) AND culture and sensitivity (C&S) report shows isolated pathogen is a susceptible to lefamulin (If obtaining a C&S report is not feasible, provider must submit documentation.) AND patient has a documented treatment failure, intolerance, or contraindication to 2 preferred antibiotics AND patient has no known risk factors for increased QT prolongation (e.g. cardiac arrhythmias, symptomatic bradycardia, hypokalemia, or congenital prolongation of the QT interval) AND medication is not being used in combination with other drugs known to prolong the QT interval (e.g. antipsychotics, erythromycin, tricyclic antidepressants). If use of Xenleta® cannot be avoided in these patients, baseline EKG and plan for ongoing monitoring must be documented (consult with cardiology required).

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendations with the removal of the requirement for a cardiology consult.

8. New Therapeutic Drug Classes

- None at this time.

9. Therapeutic Drug Classes- Periodic Review:

- **Cystic Fibrosis**
  - New drug Trikafta® is a co-package of elexacaftor, tezacaftor, and ivacaftor fixed-dose combination tablets and ivacaftor tablets. Elexacaftor and tezacaftor bind to different sites of the cystic fibrosis transmembrane conductance regulator (CFTR) protein and have an additive effect in facilitating the cellular processing and trafficking of F508del-CFTR to increase the amount of CFTR protein delivered to the cell surface compared to either molecule alone. Ivacaftor potentiates the channel open probability (or gating) of the CFTR protein at the cell surface. The combined effect of elexacaftor, tezacaftor and ivacaftor is increased quantity and function of F508del-CFTR at the cell surface, resulting in increased CFTR activity as measured by CFTR mediated chloride transport. It is indicated for the treatment of cystic fibrosis (CF) in patients aged 12 years and older who have at least one F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene. If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to confirm the presence of at least one F508del mutation. The safety and efficacy of Trikafta® were assessed in 2 phase 3, double-blind controlled trials that included patients 12 years and older with CF. In clinical trials, Trikafta® resulted in a statistically significant treatment difference from placebo for the mean absolute change from baseline in ppFEV1 at week 4 in an interim analysis. All secondary outcomes at week 24 were statistically significantly in favor of Trikafta® when compared with placebo. In a second study with an active-comparator, treatment with Trikafta® compared to tezacaftor/ivacaftor resulted in a statistically significant improvement in ppFEV1.

Recommendation:

- Add Trikafta® (elexacaftor/tezacaftor/ivacaftor) QTY LIMIT: 84/28 days; maximum day supply = 28 days to non-preferred.
  - Clinical criteria
    - Add Trikafta to the Orkambi and Symdeko clinical criteria.
    - Update initial criteria to: Patient is ≥ 2 years of age for Orkambi or ≥ 6 years of age for Symdeko or ≥ 12 years for Trikafta. Patient must have a confirmed mutation in the CFTR gene shown to be responsive to the requested medication per FDA approval (documentation provided)

Public Comments: Melissa Mattice, PharmD, MHA, Medical Science Liaison from Vertex: Highlighted the attributes of Trikafta.

Dr. Brian O'Sullivan, Professor of Pediatrics from Geisel School of Medicine, NH Cystic Fibrosis Center Dartmouth Hitchcock Medical Center: Reports very positive results seen in clinic for patients started on Trikafta. Requesting preferred status for Trikafta.
Dr. Thomas Lahiri, Pediatric Pulmonology, Director, Cystic Fibrosis Center from UVM Children's Hospital: Reiterated Dr. Sullivan's comments that results have been very positive for Trikafta. Reduction in hospitalizations and symptom improvement have been seen. He is hoping for expansion of the ages for which Trikafta can be used.

Board Decision: The Board unanimously approved the above recommendations with a change to the ongoing approval criteria: removal of the requirement that "patient has stable or improved FEV1" and replace with "patient has clinically documented improvement in lung function (will be applied to the first renewal request only; requirement waived on subsequent renewals)."

10. Review of Newly Developed/Revised Criteria

- None at this time.

Recommendation:

- No changes at this time.

Public Comment: No public comment

Board Decision: None needed.

11. General Announcements: Michael Ouellette, RPh, Change Healthcare

Selected FDA Safety Alerts

FDA alerts patients and health care professionals of EpiPen (epinephrine) and EpiPen Jr (epinephrine) auto-injector errors related to device malfunctions and user administration
https://www.fda.gov/drugs/drug-safety-and-availability/fda-alerts-patients-and-health-care-professionals-epipen-auto-injector-errors-related-device?utm_campaign=FDA%20alerts%20patients%20and%20health%20care%20professionals%20of%20EpiPen%20auto-injector%20errors&utm_medium=email&utm_source=Eloqua

FDA Approves Three Drugs for Nonprescription Use Through Rx-to-OTC Switch Process
https://www.fda.gov/news-events/press-announcements/fda-approves-three-drugs-nonprescription-use-through-rx-otc-switch-process?utm_campaign=022420_PR_FDA%20Approves%20Three%20Drugs%20for%20Nonprescription%20Use&utm_medium=email&utm_source=Eloqua

Public Comment: No public comment.
Board Decision: No action needed.

12. Adjourn: Meeting adjourned at 8:05 p.m.