Department of Vermont Health Access
Pharmacy Benefit Management Program
DUR Board Meeting Minutes
September 10, 2019

Board Members:

Present:

Bill Breen, RPh
Clayton English, PharmD
Joseph Nasca, MD
Margot Kagan, PharmD
Marc Pasanen, MD
Renee Mosier, PharmD
Louise Rosales, NP
Claudia Berger, MD

Absent: Patricia King, MD, Zail Berry, MD, Jocelyn Van Opdorp, PharmD

Staff:

Laurie Brady, RPh, Change HealthCare
Jason Pope, DVHA
Scott Strenio, MD, DVHA
Stacy Baker, DVHA
Danielle Carpenter, PharmD, Change Healthcare
Jacquelyn Hedlund, MD, Change Healthcare
Lisa Hurteau, PharmD, DVHA
Nancy Hogue, PharmD, DVHA

Guests:

Shaffee Bacchus, J&J
Mark Leyden, Novo Nordisk
Denise Timmerman, Allergan
Jai Persico, Neurocrine
Michael Armlin, J&J
Nicole Trask, Janssen
Erica Hintze, Allergan

1. Executive Session:

- An executive session was held from 6:00 p.m. until 6:40 p.m.

2. Introductions and Approval of DUR Board Minutes:

- Introductions were made around the table.
- The June meeting minutes were accepted as printed.

3. DVHA Pharmacy Administration Updates: Nancy Hogue, PharmD DVHA

- October DUR Meeting is the annual review for 2020. Executive session will be from 5pm to 6pm, open session 6pm to 8:30pm.

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

- No update at this time.

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

- Presented proposed meeting dates for 2020.

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

- **Introduce: Discussion Topics for 2020 RetroDUR Initiatives**

The Medicaid Retrospective DUR program involves ongoing and periodic examination of claims data to identify patterns of fraud, abuse, gross overuse, or medically unnecessary or

inappropriate care and implements corrective action when needed. Initiatives are developed to address potential issues identified through utilization review, areas of interest specified by CMS, designated quality outcome measures (such as HEDIS), concerns related to new clinical data/FDA labeling and therapeutic areas impacted by new/pipeline medications. Below are potential topics for 2020.

- Compliance with oral contraceptives
- Influenza vaccination rates
- Prep HIV therapy prescribing rates in those who has post-exposure prophylaxis
- Sublocade adherence
- Prescriber PDL compliance
- Lost medication overrides (refill too soon)
- Chantix use
- BP med adherence and chronic NSAID use in chronic kidney disease

Nancy Hogue, DVHA presented to the board some changes that are coming from CMS from the Support Act. The state currently complies with most of these changes. Some elements are safety edits for opioids, MME edits for both acute and chronic pain. Two retrospective claims review that are required are opioids and benzodiazepine concurrent fills and opioid and antipsychotic concurrent fills. These will be reported back to CMS in the annual CMS report.

Recommendation: None at this time.

Public Comment: No public comment.

- **Board Decision**: In addition to the two topics presented by Nancy Hogue the board's top choices are Prep HIV therapy prescribing rates in those who has post-exposure prophylaxis, Prescriber PDL compliance, BP med adherence and chronic NSAID use in chronic kidney disease. Change Healthcare will review topics except for Compliance with oral contraceptives and fill in the rest of the RetroDUR calendar to present at the next meeting.

- **Data presentation: Use of Gabapentin**

The use gabapentin tripled between 2001 and 2015. While the labeled indications for gabapentin include control of seizures and pain associated with post-herpetic neuralgia, off-label uses include diabetic neuropathy, fibromyalgia, essential tremor, panic disorder, hot flashes associated with menopause or breast cancer treatment, social phobia, nystagmus, orthostatic tremor and migraine prophylaxis. For each indication the recommended doses of gabapentin vary. Additionally, the adverse effect profile of gabapentin, especially in higher doses, is significant. The FDA is currently evaluating the use of gabapentinoids in patients on opioids and other CNS depressants as adverse reactions, including respiratory depression and death, are substantial. A Canadian hospital study showed that patients co-prescribed gabapentin and opioids were 49% more likely to experience an opioid-related death and Canada has required an updated package insert to include information about the risks of respiratory depression, syncope, profound sedation and death with co-prescribing of opioids

and gabapentin. Doses of greater than 3,000mg daily pose the highest risk, but increased risk is noted between moderate dose (900-1799mg/day) and high dose (greater than 1800mg/day). There is no indication for doses greater than 3600mg total daily dose. Additionally, gabapentin is now recognized as a drug with abuse potential and street value. While not a controlled substance in the US now, the DEA may in the future change that, as it has pregabalin.

Change Healthcare used paid, non-reversed Medicaid pharmacy claims from January 2018 through March 2019, excluding members with Part D, VMAP and Healthy Vermonters coverage. They identified members on a stable dose of gabapentin for the entirety of 1 year and examine how many are refilling prescriptions early, perhaps taking a higher daily dose than prescribed, or for diversion. By starting the search in January of 2018 but evaluating use from 4/1/18 through 3/31/19, the intent was to minimize the effect of the dose escalation often done before the patient reaches control of symptoms in order to look at consistent dosing per prescription. Additionally, they identified those on greater than or equal to 3600mg/day and those who are taking concurrently an opiate or MAT medication.

There were 595 members who were prescribed gabapentin from April 2018 – March 2019. 14 of those members were on a dose of 3601mg or greater. Of the members on gabapentin who were prescribed opiates/MAT for at least 30 overlapping days: 46 members had the same prescriber of both the gabapentin and opioid/MAT consistently, 107 members had a mix of providers for both drugs, sometimes having the same prescriber, but not always, 42 members always had different prescribers for gabapentin and opioids/mat.

Recommendation: Change Healthcare recommends that we Identify the members who had more than 50 extra days of medication per calendar year and providers who had prescribed both the gabapentin and opioid/mat for more than 30 days of overlap to see if there was a clear justification, or if the findings indicate a targeted education/intervention with the provider.

Public Comment: No public comment.

Board Decision: The Board requested either a targeted communication or outreach to prescribers for those patients taking >3600mg as there is no clear indication for that dose.

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

Biosimilar Drug Reviews:

- None are this time.

Full New Drug Reviews:

a) Apadaz® (benzhydrocodone and acetaminophen)

Apadaz® is an immediate-release, fixed-dose combination of benzhydrocodone (an opioid agonist) and acetaminophen. Benzhydrocodone is a pro-drug of hydrocodone, a full opioid agonist with relative selectivity for the mu-opioid receptor. The main therapeutic action of hydrocodone is analgesia. Like all full opioid agonists, there is no ceiling effect for analgesia with hydrocodone. Acetaminophen is a non-opioid, non-salicylate analgesic. The mechanism of action has not been determined but it is thought to primarily involve central actions. Apadaz® contains benzhydrocodone, a Schedule II controlled substance. A box warning with Apadaz® indicates the risk of addiction, abuse, and misuse, as well as a risk evaluation and mitigation strategy (REMS). Apadaz® is indicated for the short-term (no more than 14 days) management of acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate. There were no clinical trials listed in the prescribing information for Apadaz®. Apadaz® met the bioequivalence criteria for hydrocodone AUC and Cmax to other immediate-release hydrocodone combination products. Benzhydrocodone was not detectable in plasma after oral administration in clinical studies, indicating that exposure to benzhydrocodone was minimal and transient. Apadaz® is not expected to deter abuse by the oral or nasal routes of administration.

Recommendation:

- Add Apadaz® (benzhydrodrocodone and acetaminophen) (Qty Limit = 12 tablets/day) and Benzhydrocodone/APAP (Qty Limit = 12 tablets/day) to non-preferred.
    - Clinical criteria:
        - No changes.

Public Comment: None at this time.

Board Decision: The Board unanimously approved the above recommendation.

b) Firdapse® (amifampridine)

Amifampridine phosphate, the active ingredient of Firdapse®, is a voltage-gated potassium channel blocker. The mechanism by which it exerts its therapeutic effects for its indication has not been fully established. Amifampridine is a broad-spectrum potassium channel blocker. It is indicated for the treatment of Lambert-Eaton myasthenic syndrome (LEMS) in adults. The safety and efficacy of Firdapse® for the treatment of LEMS were assessed in 2 randomized, double-blind, placebo-controlled discontinuation studies that included adults with a confirmed diagnosis of LEMS based on either neurophysiology studies or a positive anti-P/Q type voltage-gated calcium channel antibody test. Compared with placebo, it was found to be associated with significantly higher muscle strength scores and patient satisfaction scores.

Recommendation:

- Add Firdapse® (amifampridine) (Qty limit = 8 tablets/day) to non-preferred.
    - Clinical criteria:
        - **Firdapse:** The patient is ≥ 17 years of age AND patient has a diagnosis of Lambert-Eaton myasthenic syndrome (LEMS) AND prescription is initiated by or in consultation with a neurologist AND patient does not have a history of seizures. Initial approval will be granted for 3 months with documentation of the patient's baseline clinical muscle strength assessment using a standardized rating scale. For re-approval after 3 months, the patient must have improved or stable symptoms documented with the appropriate standardized rating scale

Public Comments: None at this time.

Board Decision: The Board unanimously approved the above recommendation.

c) Gamifant® (emapalumab-lzsg)

Emapalumab-lzsg, the active ingredient of Gamifant®, is an interferon gamma blocking antibody produced in Chinese Hamster Ovary cells by recombinant DNA technology. It is a monoclonal antibody that binds to and neutralizes interferon gamma. Nonclinical data suggest that interferon gamma plays a pivotal role in the pathogenesis of hemophagocytic lymphohistiocytosis (HLH) by being hypersecreted. It is indicated for the treatment of adult and pediatric (newborn and older) patients with primary hemophagocytic lymphohistiocytosis (HLH) with refractory, recurrent, or progressive disease or intolerance with conventional HLH therapy. The safety and efficacy of Gamifant® were assessed in a multicenter, open-label, single-arm study that included pediatric patients (N=27) with suspected or confirmed HLH with either refractory, recurrent, or progressive disease during conventional HLH therapy or who were intolerant of conventional HLH therapy. The efficacy was based on the overall response rate at the end of treatment, defined as achievement of either a complete or partial response or HLH improvement.

Recommendation:

- Add Gamifant® (emapalumab-lzsg) to non-preferred.
    - Clinical criteria:
        - **Gamifant**: the patient has a diagnosis of primary hemophagocytic lymphohistiocytosis (HLH) with refractory, recurrent, or progressive disease or intolerance with conventional HLH therapy (e.g. etoposide + dexamethasone) AND the patient is a candidate for a stem cell transplant AND Gamifant will be administered in combination with dexamethasone

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

d) Inbrija® (levodopa inhalation powder)

Levodopa, the active ingredient of Inbrija®, is the metabolic precursor of dopamine. It crosses the blood-brain barrier and presumably is converted to dopamine in the brain. This is thought to be the mechanism where levodopa relieves symptoms of Parkinson's disease. It is indicated for the intermittent treatment of OFF episodes in patients with Parkinson's disease treated with carbidopa/levodopa. The safety and efficacy of Inbrija® were assessed in a randomized, placebo-controlled, double-blind study of 12 weeks in duration. In a clinical trial compared with placebo, Inbrija® was found to have a significant change in the UPDRS Part III motor score. In addition, a significantly larger number of patients in the Inbrija® group returned to an ON state and sustained that ON state through 60 minutes post-dose as compared with placebo. Due to its high relative cost, Inbrija® should be reserved as an alternative for patients who cannot tolerate side effects of Apokyn®, such as hypotension, nausea and vomiting.

Recommendation:

- Add Inbrija® (levodopa inhalation powder) (Qty limit = 10 caps/day) to non-preferred.
    - Clinical criteria:
        - **Inbrija:** 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 Apokyn®.

Public Comment: from: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

e) Lexette® (halobetasol propionate)

Lexette® is a hydroethanolic aerosol foam that contains the corticosteroid halobetasol propionate. Corticosteroids play a role in cellular signaling, immune function, inflammation, and protein regulation; however, the exact mechanism of action in plaque psoriasis is not known. It is indicated for the topical treatment of plaque psoriasis in patients 18 years of age and older. The safety and efficacy of Lexette® were assessed in 2 multicenter, randomized, double-blind, vehicle-controlled studies. It was found to be more effective than a vehicle foam for overall treatment success. As Lexette® is flammable, avoid fire, flame, or smoking during and immediately following application. There is no evidence at this time that Lexette® is safer or more effective than the currently preferred, more cost-effective medications.

Recommendation:

- Add Lexette® (halobetasol) 0.05% F to non-preferred.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

f) Motegrity® (prucalopride)

Prucalopride succinate, the active ingredient of Motegrity®, is a serotonin type 4 (5-HT4) receptor agonist. It is a gastrointestinal (GI) prokinetic agent that stimulates colonic peristalsis (high-amplitude propagating contractions [HAPCs]), which increases bowel motility. In isolated GI tissues from various animal species, prucalopride facilitated acetylcholine release to enhance the amplitude of contractions and stimulate peristalsis. It is indicated for the treatment of chronic idiopathic constipation (CIC) in adults. The safety and efficacy of Motegrity® were assessed in 6 double-blind, placebo-controlled, randomized multicenter studies that included adults with CIC. It was found in clinical trials to have a significantly higher responder rate in 5 of the 6 studies, with a responder being defined as a patient with an average of ≥3 CSBMs per week, over the 12-week treatment period. A 2018 systematic review and meta-analysis by Nee et al[2] included 27 placebo-controlled trials to assess the safety and efficacy of approved treatments for OIC. The most common primary outcome was 3 or more complete SBMs a week over the trial period. Results suggested that overall, the mu-opioid receptor antagonists, lubiprostone, and prucalopride were superior to placebo for the treatment of OIC.

Recommendation:

- Add Motegrity (prucalopride) (Qty Limit = 1 tab/day) to non-preferred.
  - Clinical criteria:
    - Add Motegrity to the Trulance criteria.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

g) Nuzyra® (omadacycline)

Omadacycline tosylate, the active ingredient of Nuzyra®, is an aminomethylcycline which is a semisynthetic derivative of the tetracycline class of antibacterial drugs. Omadacycline binds to the 30S ribosomal subunit and blocks protein synthesis. It is indicated for the treatment of adult patients with community-acquired bacterial pneumonia (CABP) caused by the following susceptible microorganisms: Streptococcus pneumoniae, Staphylococcus aureus (methicillin-susceptible isolates), Haemophilus influenzae, Haemophilus parainfluenzae, Klebsiella pneumoniae, Legionella pneumophila, Mycoplasma

pneumoniae, and Chlamydophila pneumoniae OR Acute bacterial skin and skin structure infections (ABSSSI) caused by the following susceptible microorganisms: Staphylococcus aureus (methicillin-susceptible and -resistant isolates), Staphylococcus lugdunensis, Streptococcus pyogenes, Streptococcus anginosus grp (includes S. anginosus, S. intermedius, and S. constellatus), Enterococcus faecalis, Enterobacter cloacae, and Klebsiella pneumoniae. The safety and efficacy of Nuzyra® were assessed in a multinational, double-blind, double-dummy trial comparing Nuzyra® to moxifloxacin in adults with CABP. In clinical trials, treatment success rates with Nuzyra® were similar to those achieved with moxifloxacin in the treatment of CABP and were similar to those achieved with linezolid in the treatment of ABSSSI.

Recommendation:

- Add Nuzyra (omadacycline) tabs with a Max 14-day supply to non-preferred.
  - Clinical criteria:
    - **Nuzyra:** patient has been started on intravenous or oral omadacycline in the hospital and will be finishing the course of therapy in an outpatient setting OR the patient has a diagnosis of community-acquired bacterial pneumonia (CABP) or acute bacterial skin and skin structure infections (ABSSSI) AND the patient has had a documented treatment failure with two preferred antibiotics for which the microorganism is susceptible to OR to the provider submits clinical rationale as to why the preferred agents would not be appropriate for the patient.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation with the removal of "for which the microorganism is susceptible" and adding a note that preferred agents can be from any class.

h) Qbrexza® (glycopyrronium)

Glycopyrronium, the active ingredient of Qbrexza®, is a competitive inhibitor of acetylcholine receptors that are located on certain peripheral tissues, including sweat glands. In hyperhidrosis, glycopyrronium inhibits the action of acetylcholine on sweat glands, reducing sweating. It is indicated for the topical treatment of primary axillary hyperhidrosis in adult and pediatric patients 9 years of age and older. The safety and efficacy of Qbrexza® were assessed in 2 randomized, vehicle-controlled multicenter trials that included subjects with primary axillary hyperhidrosis aged 9 years or older. It was found to be significantly more effective than vehicle for the co-primary endpoint of the proportion with a ≥4-point improvement from baseline in the weekly mean Axillary Sweating Daily Diary (ASDD), as well as a statistically significant difference favoring Qbrexza® as compared with the vehicle for mean absolute

change from baseline in sweat production in study 2. There is no evidence that Qbrexza® is safer or more effective than the currently available, more cost-effective medications.

Recommendation:

- Add sub-category Axillary Hyperhidrosis Therapy in the Dermatological Agents.
- Add Qbrexza™ (glycopyrronium) 2.4% single use pads (Qty Limit = 30 pads/month) to non-preferred.
- Add Xerac-AC (aluminum chloride) 6.25% Solution to preferred.
    - Clinical criteria:
        - **Qbrexza:** the patient has had a documented side effect, allergy, or treatment failure with a clinical strength OTC antiperspirant AND Xerac-AC.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation with the removal of requiring the clinical strength OTC antiperspirant.

i) Seysara® (sarecycline tablets)

Sarecycline, the active ingredient of Seysara®, is a tetracycline class drug. It is indicated for the treatment of inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients 9 years of age and older. The efficacy of Seysara® beyond 12 weeks and the safety beyond 12 months have not been established. Seysara® has not been evaluated in the treatment of infections. To reduce the development of drug resistant bacteria as well as to maintain the effectiveness of other antibacterial drugs, Seysara® should be used only as indicated. The safety and efficacy of Seysara® were assessed in 2 multicenter, randomized, double-blind, placebo-controlled studies that included subjects 9 years of age and older. Compared with placebo in 2 clinical trials, sarecycline was found to be significantly more effective for the co-primary efficacy endpoints per the full-length study by Moore et al[2]. There is no evidence to support that Seysara® is more effective for acne than other, significantly less costly oral tetracyclines, such as doxycycline and minocycline, although data suggests that it may be associated with a lower rate of adverse GI effects and vaginal candidiasis. Given the extremely high cost of Seysara®, its use should be reserved only for those with moderate to severe acne that cannot be adequately managed with other topical and systemic therapies and in whom lower cost tetracyclines cannot be tolerated due to significant GI effects.

Recommendation:

- Add Seysara® (saracycline tablets) (Qty limit = 1 tablet/day) to non-preferred.
    - Clinical criteria:

- **Seysara**: the patient is ≥ 9 years of age AND indication is to treat non-nodular inflammatory lesions of acne vulgaris AND the patient has had a documented side effect, allergy, or treatment failure with at least one preferred topical acne agent and both preferred systemic agents (doxycycline and minocycline).

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

j) Spravato® (esketamine nasal spray)

Esketamine, the active ingredient of Spravato®, is a non-competitive N-methyl-D-aspartate (NMDA) receptor antagonist. The mechanism by which it exerts its antidepressant effect is not known. Esketamine is the S-enantiomer of racemic ketamine. It is indicated in conjunction with an oral antidepressant for the treatment of treatment-resistant depression (TRD) in adults. The safety and effectiveness of Spravato® as an anesthetic agent have not been established. The safety and efficacy of Spravato® were assessed in a randomized, placebo-controlled, double-blind, multicenter short-term phase 3 study of 4 weeks duration that included adults 18 to <65 years of age with treatment resistant depression. Patients in the short-term study met DSM-5 criteria for MDD and in the current depressive episode had not responded adequately to at least 2 different antidepressants of adequate dose and duration. Spravato® plus a newly initiated oral antidepressant demonstrated statistical superiority for the change from baseline in the MADRS total score at the end of 4 weeks as compared with placebo nasal spray and a newly initiated oral antidepressant. Because of serious adverse outcomes from sedation, dissociation, and abuse and misuse, Spravato® is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the Spravato® REMS.

Recommendation:

- Add Spravato® (esketamine nasal spray) with Quantity Limit = not to exceed FDA recommended dose and frequency for corresponding timeframe to non-preferred.
  - Clinical criteria:
    - **Spravato:** the patient has a diagnosis of treatment resistant depression AND the patient is ≥ 18 years of age AND medication is being used as adjunct treatment with an oral antidepressant AND the patient has a documented treatment failure (defined by at least 8 weeks of therapy) with at least 2 different antidepressants from the SSRI, SNRI, and/or Miscellaneous Antidepressant categories (may be preferred or nonpreferred) AND the healthcare site and patient are enrolled in the Spravato® REMS program. Initial approval will be granted for 3 months. For re-approval after 3 months, the patient must have documented improvement in symptoms. Note: Spravato®

will be approved as a medical benefit ONLY and will NOT be approved if billed through pharmacy point of sale.

Public Comment: Shaffee Bacchus from J & J: Highlighted the attributes of Spravato.

Board Decision: The Board unanimously approved the above recommendation.

k) Symjepi® (epinephrine)

Epinephrine, the active ingredient of Symjepi®, acts on both alpha and beta-adrenergic receptors. Through its action on alpha-adrenergic receptors, epinephrine lessens the vasodilation and increased vascular permeability that occurs during anaphylaxis, which can lead to loss of intravascular fluid volume and hypotension. Through its action on beta-adrenergic receptors, epinephrine causes bronchial smooth muscle relaxation and helps alleviate bronchospasm, wheezing, and dyspnea that may occur during anaphylaxis. In addition, epinephrine alleviates pruritus, urticaria, and angioedema, and may relieve gastrointestinal and genitourinary symptoms associated with anaphylaxis due to its relaxer effects on the smooth muscle of the stomach, intestine, uterus, and urinary bladder. It is indicated in the emergency treatment of allergic reactions (Type I) including anaphylaxis to stinging insects (e.g. order Hymenoptera, which includes bees, wasps, hornets, yellow jackets, and fire ants) and biting insects (e.g. Triatoma, mosquitoes), allergen immunotherapy, foods, drugs, diagnostic testing substances (e.g. radiocontrast media) and other allergens, as well as idiopathic anaphylaxis or exercise-induced anaphylaxis. There were no clinical trials in the prescribing information of Symjepi®. Symjepi® is a pre-filled syringe for manual injection. Auto-injectable epinephrine products are available, including a generic version.

Recommendation:

- Revise category name from Epinephrine Auto Injector to Epinephrine Self-Administered.
- Add Symjepi® Inj 0.15mg (epinephrine 0.15mg/0.3ml) and Symjepi® Inj 0.3mg (epinephrine 0.3mg/0.3ml) to non-preferred.
  - Clinical criteria:
  - No changes.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

8. New Therapeutic Drug Classes

- None at this time.

9. Therapeutic Drug Classes- Periodic Review: Jacqueline Hedlund, MD, Change Healthcare and Laurie Brady, RPh, Change Healthcare

a) Androgenic Agents

- No new drugs.
- No new significant clinical changes.

Recommendation:

- Remove the Nasal sub-category.
- Remove Natesto, Android (methyltestoterone) capsule 10mgand Testred (methyltestosterone) capsule 10mg from the PDL.
- Move Androgel® Gel (testosterone 1% gel packets) Quantity limit = 2.5 gm packet (1 packet/day) 5 gm packet (2 packets/day), Androgel® Gel (testosterone 1.62% gel packets) Quantity limit = 1.25 gm packet (1.62%) (1 packet/day) 2.5 gm packet (1.62%) (2 packets/day) , Androgel® Pump (testosterone pump bottles) Quantity limit = 1.62% (2 bottles/30 days) to non-preferred.
- Move TESTOSTERONE 1% Gel Packets (compare to Androgel®) Quantity Limit = 2.5gm packet (1 packet/day) Quantity Limit= 5gm packet (2 packets/day) to preferred.
- Add TESTOSTERONE 1.62% Gel Packets Quantity limit = 1.25 gm packet (1.62%) (1 packet/day)2.5 gm packet (1.62%) (2 packets/day) , TESTOSTERONE 1.62% Gel Pump(compare to Androgel® Quantity limit = 1.62% (2 bottles/30 days) to preferred.
- Add Testosterone 1% Gel Pump (compare Vogelxo®) Quantity limit = 4 bottles/30 days to non-preferred.
    - Clinical criteria:
        - Remove the Natesto criteria.
        - Remove the Axiron, Fortesta, Testim Testosterone Gel 1%, and Testosterone Gel 2 % criteria.
        - Add **Non-preferred agents:** The patient has a documented side effect, allergy, or treatment failure to at least two preferred topical products.
        - Remove the Android, Striant, Methyltesterone, Testred criteria.
        - Add **Oral non-preferred agents:** The patient has had a documented side effect, allergy, or treatment failure to TWO preferred testosterone products (topical and/or injectable formulations) AND if the request is for Methitest or methyltestosterone, the patient has had a documented side effect, allergy, or treatment failure with Striant.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation with the change that brand Androgel 1% packets remain preferred and Testosterone 1% packets remain non-preferred.

b) Antiemetics

- No new drugs.
- No new significant clinical changes

- Varubi® injection is currently non-rebatable and has been removed from the review.

Recommendation:

- Move Cinvanti® (aprepitant) Injection to preferred.
- Add Emend® (fosaprepitant) Injection to preferred.
  - Clinical criteria
    - Remove Cinvanti criteria.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

c) Antipsychotics

- No new drugs
- New indication of Bipolar 1 Depression for Vraylar.

Recommendation:

Anti-Psychotic Atypical & Combinations (Adults ≥ 18 Years Old):

- Add Paliperidone (compare to Invega®) FDA maximum recommended dose = 12 mg/day (Qty limit = 1 tab/day (3mg, 9mg), 2 tabs/day (6mg)) to non-preferred.
  - Clinical criteria:
    - Add Paliperidone to Invega and Saphris criteria.
    - Revise **Quetiapine ER, Seroquel XR:** The patient has not been able to be adherent to a twice daily dosing schedule of quetiapine immediate release resulting in a significant clinical impact.

Anti-Psychotic Atypical & Combinations (Children < 18 Years Old):

- Add Quetiapine ER (compare to Seroquel® XR) FDA maximum recommended dose = 800 mg/day (Qty Limit = 1 tab/day (150 mg & 200 mg tablet strengths), 2 tabs/day (50 mg strength)) to non-preferred.
  - Clinical criteria:
    - Add Quetiapine XR to Seroquel XR criteria.
    - Remove Limitations criteria.

Anti-Psychotic: Typicals:

- Remove Haldol® (haloperidol) and Loxitane® (loxapine) from the PDL.
- Add Molindone to non-preferred.

Public Comment: Denise Timmerman from Allergan: Highlighted the attributes of Vraylar.

Board Decision: The Board unanimously approved the above recommendation with the change to Vraylar criteria for Bipolar depression that treatment failure with only two preferred

products (typical or atypical antipsychotics) be required unless contraindicated (mirroring criteria in place for Latuda).

d) Bronchodilators: Beta Agonists

- New Albuterol HFA generics available.
- No significant clinical changes.

Recommendation:

- Add Albuterol HFA (compare to Proventil® HFA, ProAir® HFA, Ventolin® HFA) to non-preferred.
- Remove Vospire ER® (albuterol) from the PDL.
  - Clinical criteria:
    - Add Albuterol HFA to the Levalbuterol (aerosol), Ventolin HFA, Xopenex HFA criteria.
    - Remove Vospire criteria.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

e) COPD Agents

- No new drugs.
- No significant clinical changes.
- Lonhala® magnair added in 2018 and Yupelri™ added in 2019.

Recommendation:

- Move Spiriva® Respimat (tiotropium) (Qty Limit = 3 inhalers/90 days) to preferred.
  - Clinical criteria:
    - Remove Spiriva Respimat criteria.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

f) Growth Hormones

- No new drugs.
- No new significant clinical changes

Recommendation:

- No changes at this time.

Public Comment: from: No public comment.

Board Decision: None needed.

g) Inhaled Glucocorticosteriods

- Asthma Management and Prevention Guidelines from the Global Initiative for Asthma (GINA) were updated in 2019. For safety, GINA no longer recommends treatment with short-acting beta agonists alone. GINA now recommends that all adults and adolescents with asthma should receive either symptom-drive or daily low dose ICS-containing controller treatment, to reduce their risk of serious exacerbations.

Recommendation:

- Remove Armonair Respiclick® (fluticasone propionate) from the PDL.
- Add Wixela™ Inhub™ (fluticasone/salmeterol inhalation powder) (compare to Advair® diskus) (QTY LIMIT=3 inhalers/90 days) to non-preferred.
- Add FLUTICASONE/SALMETEROL inhalation powder (compare to Advair® Diskus) (authorized generic, Prasco labeler code 66993 is the only preferred form) to preferred.
- Move Advair® Diskus (fluticasone/salmeterol) (QTY LIMIT = 3 inhalers/90 days) to non-preferred.
    - Clinical criteria:
        - Add **Advair Diskus, Wixela Inhub:** A clinically compelling reason must be provided detailing why the patient is unable to use Advair HFA or Fluticasone/Salmeterol authorized generic inhalation powder.
        - Revise **AirDuo Respiclick, Breo Ellipta, Fluticasone/Salmeterol (non-authorized generics):** The patient has had a documented side effect, allergy, or treatment failure to any 2 of the following: Advair HFA, Fluticasone/salmeterol authorized generic inhalation powder, Dulera, or Symbicort.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

h) Pulmonary Arterial Hypertension

- New generics available for Remodulin, Tracleer, Letairis, and Adcirca.
- In 2019, Klinger et al[133] published, "Therapy for pulmonary arterial hypertension in adults, an update of the CHEST Guideline and Expert Panel Report." Recommendations include that for treatment-naïve PAH patients with WHO FC II and III, initial combination therapy with ambrisentan and tadalafil are suggested to improved 6MWD. For treatment-naïve PAH patients with WHO FC II symptoms who are not candidates for, or who have failed, CCB (calcium channel blockade) therapy, the authors advise that therapy be started with the combination of ambrisentan and tadalafil. Parenteral or inhaled prostanoids are not chosen as initial therapy for treatment naïve PAH patients with WHO FC II symptoms.

Recommendation:

- Add TADALAFIL (compare to Adcirca®) (QtyLimit = 2 tablets/day) and AMBRISENTAN (compare to Letairis®) (Qty Limit = 1 tablet/day) to preferred.
- Add Bosentan (compare to Tracleer) (Qty Limit = 2 tablets/day) and Treprostinil sodium injection (compare to Remodulin®) to non-preferred.
    - Clinical criteria:
        - Add tadalafil to the Sildenafil criteria.
        - Add **Bosentan:** Patient has a documented intolerance to Tracleer.
        - Add **Letairis:** patient has a documented intolerance to the generic equivalent.
        - Add **Treprostinil:** Patient has a diagnosis of pulmonary arterial hypertension AND The patient has had a documented intolerance to the brand Remodulin.
        - Revise **Opsumit:** Patient has a diagnosis of PAH with NYHA Functional Class II or III AND Patient is not pregnant AND Female patients have been enrolled in the REMS Program AND the patient has a documented side effect, allergy, or treatment failure with Tracleer or ambrisentan.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

11. General Announcements: Laurie Brady, RPh, Change Healthcare

Selected FDA Safety Alerts

- FDA approves Boxed Warning about increased risk of blood clots and death with higher dose of arthritis and ulcerative colitis medicine tofacitinib (Xeljanz, Xeljanz XR)
  https://www.fda.gov/drugs/drug-safety-and-availability/fda-approves-boxed-warning-about-increased-risk-blood-clots-and-death-higher-dose-arthritis-and

Public Comment: No public comment.

Board Decision: No action is needed.

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