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

December 6, 2022: 6:00 – 8:30 p.m.

Board Members Present:

	Andy Miller, RPH		**Lucy Miller, MD**		**Douglas Franzoni, PharmD**
	Joseph Nasca, MD		**Mark Pasanen, MD**		**Claudia Berger, MD**
	Anne Daly, PharmD		**Katharina Cahill, PharmD**		

Board Members Absent: Margot Kagan, PharmD

DVHA Staff Present:

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

Change Healthcare Staff Present:

	Jacquelyn Hedlund, MD		**Laurie Brady, RPh**		**Michael Ouellette, RPh**

Guests/Members of the Public:
Adam Denman (Global Blood Therapeutics), Frank Lanotte, George Ward (Abbvie), Jai Persico (NGU/Zocrine), Kristen Chopas (Gilead Sciences), Nels Kloster, Mike Zaborowski, John Ciruso, Megan Walsh

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 October meeting minutes were accepted with the following changes to Change Healthcare staff in attendance: Removal of Carla Quinlivan and addition of Mike Ouellette, RPh.

3. DVHA Pharmacy Administration Update: Lisa Hurteau, PharmD, DVHA and Taylor Robichaud, PharmD, DVHA:

- A follow-up email was sent to board members as requested during the September meeting. It was in reference to some of the language that was proposed in bill H. 728, an act relating to opioid overdose and response services. Although Governor Scott vetoed this bill, DVHA is

working to research the provisions of the bill regardless. Information on approval and denial rates for MAT therapy and frequency of requests exceeding 16mg were included.

- Highlights of the VT MAT prescribing rule were shared with board. These were developed in 2013 and most recently updated in November 2021. This rule has three main functions:
  - Vermont Department of Health has regulatory oversight over prescribing.
  - Sets a reasonable standard of care (what is currently believed to be good practice) and ensures that monitoring for diversion is being done.
  - Intended to be for patient protection.
- Introduction of the Buprenorphine safety checklist which will need to be submitted with PA requests for Buprenorphine mono formulation (any dose), Suboxone® film or buprenorphine/naloxone combination tablets if dose > 16mg, and for patients with a co-diagnosis of both pain and SUD.
- The checklist references the VT MAT rule and ASAM guidelines. Highlights include easier approval for dose decreases from previous PA, pregnancy updates on buprenorphine mono formulation, and documentation of diversion protocols.

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

- Historical basis for the VT MAT prescribing rule provided. It was initiated after the owners of a practice shut down with no notice to patients or providers. It protects patients from being in this situation again and also protects providers from complaints if they are following the established rules.
- The rule sets standards for HUBs that sets them apart from SPOKEs. There are differences in both clinical and regulatory practice, and the rule does not provide parity between the two locations.

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

- Substance Use Disorder Treatments

Recommendation:

- Clinical criteria:
  - Update CLINICAL CONSIDERATIONS: Prescriber must have a DATA 2000 waiver ID number (“X DEA License”) in order to prescribe buprenorphine or buprenorphine/naloxone combination products used for the treatment of opioid dependence. These products are not FDA approved for alleviation of pain. For this indication, please refer to the Opioid Analgesics PDL category.

Note: As of 1/1/23, a completed Buprenorphine safety checklist must be submitted with all PA requests.

- Add Buprenorphine/naloxone films to Zubsolv clinical criteria.
- Update Buprenorphine: Patient is pregnant and is experiencing an adverse reaction or intolerance to a preferred combination product that cannot be resolved or mitigated through alternative efforts (duration of PA will be 90 days post anticipated delivery date). Other requests will be considered with clinical documentation submitted detailing a provider-observed reaction to both Suboxone films and buprenorphine/naloxone tablets severe enough to require discontinuation (documentation of measures tried to mitigate/manage symptoms is required). AND the Buprenorphine Safety Checklist has been completed documenting that there is evidence of the 3 most recent routine toxicological screens AND there is evidence of the 3 most recent random requests for medication counts.
- Update Requests to exceed quantity limits or maximum daily dose: Documentation must be submitted detailing medical necessity for requested dosage regimen AND the Buprenorphine Safety Checklist has been completed documenting that there is evidence of the 3 most recent routine toxicological screens AND there is evidence of the 3 most recent random requests for medication counts OR If the request is for a patient NEW to the treatment program, a copy of protocol for conducting toxicological screens and medication counts throughout treatment has been submitted.
- Add Requests for treatment of dual diagnosis Pain AND opioid use disorder: The Buprenorphine Safety Checklist has been completed documenting that there is evidence of the 3 most recent routine toxicological screens AND there is evidence of the 3 most recent random requests for medication counts AND other non-opioid medications and pain management modalities have been trialed prior to increasing the buprenorphine dose for pain AND split dosing (multiple daily administrations) on current dose have been trialed for pain control as recommended in the ASAM 2020practice guidelines AND clinical rationale has been provided if the request is for a dose increase > 25% the current daily dose.

Public Comment: Nels Kloster, MD, Addiction Psychiatrist, Brattleboro HUB Medical Director, Serenity House Medical Director, and Savida Healthcare Practitioner noted that he is in favor of preserving the PA as he feels it helps guide safe and appropriate

treatment. He emphasized that Buprenorphine is not a 100% safe medication and wants to reduce diversion. He noted that medication treatment by itself is not sufficient; many other supports are needed during recovery. He expressed reservations about solely telemedicine practices for challenging or complex patients. He believes his statements are shared by other HUB medical directors across the state.

Board Discussion: Douglas Franzoni expressed concern that some patients may be locked into a pharmacy by accident and would like more clarity on the Buprenorphine checklist. Additionally, Douglas Franzoni asked how we would evaluate a claim if the provider does not have a plan to decrease dose when used for acute pain control. Dr. Rapaport explained that in those cases DVHA would work with the provider to obtain this information or treatment plan. Dr. Rapaport requested that we add an attestation that the VPMS has been checked. Alternatives may be needed for medication counts such as observed dosing in situations where short duration prescriptions are provided. Dr. Pasanen requested that we ask for the 3 most recent diversion monitoring practices.

Board Decision: The Board unanimously approved the criteria changes with approval of the Buprenorphine safety checklist to be completed and final votes submitted by email.

6. RetroDUR/ProDUR: Jacquelyn Hedlund, MD and Laurie Brady, RPh, Change Healthcare

- **Data Presentation:** Antipsychotics, while effective in treating schizophrenia and other disorders, such as bipolar disorder, depression, anxiety and autism, can have significant side effects. The atypical antipsychotics have fewer severe side effects than the typical antipsychotics, however metabolic effects are still a concern. Additionally, as the use of the antipsychotic medications has increased for disorders other than schizophrenia and psychosis, there is a paucity of evidence from randomized clinical trials for use in children with such disorders. Generally, because of a lack of data showing superiority of any particular antipsychotic (other than clozapine), decisions about treatment should include the side effect profiles and risks to the particular patient. Side effects from antipsychotics as a group include extrapyramidal symptoms, significant weight gain, metabolic syndrome, liver function abnormalities, QT prolongation, and bone marrow suppression, although the drugs vary in risk profiles. Prior to starting antipsychotics, patients should have baseline studies including CBC, fasting glucose, lipid profile (including triglycerides), transaminases, HbA1c and ECG with QTc. At 4 weeks a CBC should be repeated and at 12 weeks, repeat of CBC, fasting plasma glucose and fasting lipid profiles are recommended. These labs and ECGs should all be repeated annually as well.
  Change Healthcare used paid, non-reversed Medicaid pharmacy claims from 2021, and medical claims from 1/1/21-3/31/22. Members with Part D, TPL, VMAP and Healthy Vermonters coverage were excluded. Only

members with continuous Medicaid coverage were used in the analysis. We identified members 18 years and younger who were started on an antipsychotic medication in 2021 and evaluated if appropriate laboratory monitoring was done after starting therapy. We looked for CPT codes from the date of the first antipsychotic prescription fill through 3/31/22 to accommodate any patients who potentially started later in the year. The following procedure codes were included:
CBC: 85025, 85027; 85004 (blood count with automated WBC dif)
Fasting Glucose: 82947; 80053 (CMP); 80048 (BMP); 80069 (RFP); 82947 (gluc)
Lipid: 80061, 82465, 83718, 83721, 84478

The total number of members who started an antipsychotic was 302. Of those, 133 had evidence of a CBC (44%), 136 had evidence of a fasting glucose (45%), and 44 had evidence of lipid measurements (15%). The average number of days until obtaining CBC =84 (12 weeks), average number of days until obtaining fasting glucose = 88 (12.5 weeks), average number of days until obtaining lipid profile = 124 (18 weeks).

Recommendation: Data shows that providers are not overall compliant with metabolic monitoring of children and adolescents started on antipsychotic medications. Education of providers is warranted and possibly implementing PAs that require lab results for the 4th refill of medications (4th month of medication).

Board Discussion: The board expressed concern about the 4th claim rejecting and the timeframe it might take for the pharmacy to outreach the prescriber, ensure appropriate labs were completed, and obtain PA renewal. They also discussed the possibility of Academic detailing or Grand Rounds education, but Dr. Pasanen noted that this often takes significant time to implement.

Board Decision: The Board requested that Change Healthcare obtain data on prescriber specialty. They unanimously approved provider education and the addition of baseline labs to the current PA. They do not want to implement another PA after 4 fills at this time due to the risk of impacting access to care at the pharmacy. Dr. Rapaport suggested we add the required lab tests to the DVHA prior authorization form to obtain a baseline assessment before approving antipsychotics in children under 18.

- **Introduce Concurrent Use of Antipsychotics and Opioids:** 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 use disorder 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 added a new section, 1902 of 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.15 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. Vermont conducted this RetroDUR in 2020, and a drug-drug interaction ProDUR edit was added 1/13/21. While direct comparisons cannot be made given changing Medicaid eligibility, it will be interesting to look at the data from each year to see if there might be fewer members taking both antipsychotics and opiates and if there are fewer providers prescribing both concurrently. Change Healthcare will use paid, non-reversed Medicaid pharmacy and medical claims from Calendar Years 2020 and 2021, 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 look to see if the 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.

Board Decision: None needed at this time.

7. 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:

- Epsolay® (benzoyl peroxide)

Benzoyl peroxide, the active ingredient of Epsolay®, is an oxidizing agent with bactericidal and keratolytic effects, but the exact mechanism of action in the treatment of rosacea is not known. It is indicated for the treatment of inflammatory lesions of rosacea in adults. The safety and efficacy of Epsolay® were assessed in 2 multicenter, randomized, double-blind, vehicle-controlled studies that included subjects with moderate-to-severe papulopustular rosacea. Per the manufacture site, "Epsolay® cream is the first topical treatment to combine BPO (benzoyl peroxide) with innovative microencapsulation technology to treat the bumps and blemishes of rosacea." Furthermore, the microcapsules control the release of benzoyl peroxide on the skin, and "these microcapsules gradually release BPO to relieve rosacea while remaining tolerable, so you can use it daily, or as prescribed."2 The efficacy of Epsolay® was assessed in 2 randomized, double-blind studies that compared Epsolay® with vehicle cream. Treatment success, a co-primary endpoint, was obtained by more subjects with Epsolay® as compared with vehicle (NNT of 4 in study 1, NNT of 5 in study 2). A greater absolute change from baseline in inflammatory lesion counts at week 12, a coprimary endpoint, was achieved with Epsolay® as compared with vehicle cream. While generic benzoyl peroxide products are available, none are FDA approved for inflammatory lesions of rosacea.3 Epsolay® provides another treatment option for rosacea.

- Twyneo® (tretinoin & benzoyl peroxide)

Twyneo® cream is a combination of tretinoin and benzoyl peroxide. Tretinoin is a retinoid and benzoyl peroxide is an oxidizing agent. It is indicated for the topical treatment of acne vulgaris in adults and pediatric patients 9 years of age and older. The safety and efficacy of Twyneo cream® were assessed in two randomized, double-blind, multicenter, vehicle-controlled trials of identical design that included subjects 9 years of age and older with facial acne vulgaris. Treatment success at week 12 (one of the co-primary efficacy endpoints) was obtained more frequently with Twyneo® than vehicle (NNT of 4 for study 1 and NNT of 9 for study 2). Generic products are available for both individual ingredients of the product.

Recommendation:

- Add Epsolay® 5% cream to non-preferred.
- Add Twyneo® 0.1%-3% cream to non-preferred.
- Add Ery (erythromycin 2%) Pads and Rhofade® (oxymetazoline) 1% C to non-preferred.
- Add Clindacin (clindamycin) 1% CL, P, Swab to non-preferred.
- Remove PANOXYL; 4%, 10% Cleanser since they are no longer rebateable.
- Add qty limit to clindamycin 1% gel (Max of 60gm) to prevent the 75mL bottle from being filled. This is the generic form of Clindagel and will be non-preferred.
    - Clinical criteria:
        - Update Winlevi: patient has had a documented side effect, allergy, or treatment failure with two preferred topical acne agents.

- Add Epsolay, Rhofade: the patient has had a documented side effect, allergy or treatment failure with 2 preferred topical rosacea agents.
- Add Twyneo to Adapalene/benzoyl peroxide gel, Clindamycin/tretinoin gel, Epiduo Forte criteria.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

- Tlando® (testosterone undecanoate)

Tlando® contains testosterone undecanoate, an ester of testosterone. Endogenous androgens, including testosterone and dihydrotestosterone (DHT), are responsible for the normal growth and development of the male sex organs and for maintenance of secondary sex characteristics. It is indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone: Primary hypogonadism (congenital or acquired): testicular failure due to conditions such as cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter's syndrome, chemotherapy, or toxic damage from alcohol or heavy metals. These men usually have low serum testosterone concentrations and gonadotropins (follicle stimulating hormone [FSH], luteinizing hormone [LH]) above the normal range. Or Hypogonadotropic hypogonadism (congenital or acquired): gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency or pituitary-hypothalamic injury from tumors, trauma, or radiation. These men have low testosterone serum concentrations but have gonadotropins in the normal or low range. The safety and efficacy of Tlando® were assessed in study 16-002, a multicenter, open-label, single-arm study that included adult hypogonadal male patients who received Tlando® 225mg PO BID with food for about 24 days. The safety and efficacy in males less than 18 years of age have not been established. Tlando® is not substitutable with other oral testosterone undecanoate products. Monitor serum testosterone (8 to 9 hours after the morning dose) 3 to 4 weeks after starting Tlando®, and periodically thereafter. Tlando® has a box warning regarding blood pressure increases. The primary endpoint, the percentage of patients who achieved a 24-hour average serum testosterone concentration within the normal range of 300-1080ng/dL on the final visit of the study, was achieved by 80% of the subjects. Tlando® offers prescribers another treatment option.

Recommendation:

- Add Tlando capsule to non-preferred.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

- Vyvgart® (efgartigimod alfa)

Efgartigimod alfa-fcab, the active ingredient of Vyvgart®, is a human immunoglobulin G1 (IgG1)-derived Fc fragment of the za allotype. It is a human IgG1 antibody fragment that binds to the neonatal Fc receptor (FcRn), resulting in the reduction of circulating IgG. It is indicated for the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive. The safety and efficacy of Vyvgart® were assessed in a multicenter, randomized, double-blind, placebo-controlled study of 26 weeks in duration that included adults with generalized myasthenia gravis (gMG) who were AChR antibody positive. Because Vyvgart® causes transient reduction in IgG levels, immunization with live-attenuated or live vaccines is not recommended during treatment with Vyvgart®. Assess the need to administer age-appropriate immunizations according to immunization guidelines before initiation of a new treatment cycle with Vyvgart®. In a multicenter, randomized, double-blind, placebo-controlled study that compared Vyvgart® with placebo, the primary efficacy endpoint was the comparison of the percentage of MG-ADL responders during the first treatment cycle between treatment groups in the AChR-Ab positive population. Results suggested that a statistically significant difference favoring Vyvgart® was observed in the MG-ADL responder rate during the first treatment cycle (67.7% with Vyvgart® and 29.7% with placebo; NNT calculated by CHC- 3). Vyvgart® also reduced muscle weakness as measured by the percentage of QMG responders. This product gives patients another treatment option.

Recommendation:

- Add Vyvgart capsule to non-preferred.
  - Clinical criteria:
    - Add Vyvgart: Patient is ≥ 18 years of age AND Patient has a diagnosis of generalized Myasthenia Gravis with Myasthenia Gravis Foundation of America (MGFA) clinical classification class II to IV AND Patient is anti-acetylcholine receptor (AChR) positive AND MG-Activities of Daily Living (MG-ADL) total score of ≥5 at baseline AND Patient has IgG levels of at least 6g/L AND Patient has had an inadequate response with at least 2 immunosuppressive therapies (e.g. corticosteroids, azathioprine, cyclosporine, mycophenolate) over the course of at least 12 months AND Dose does not exceed 10mg/kg weekly; maximum of four doses per 50 days. For re-approval, the patient must have had a positive response to therapy as evidenced by a 2-point reduction in the MG-ADL score.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

8. New Therapeutic Drug Classes

- None at this time.

9. Therapeutic Drug Classes- Periodic Review:

- **Antihistamines, minimally sedating**
  - No new drugs
  - No other significant clinical changes.

Recommendation:

- Move FEXOFENADINE tablets, FEXOFENADINE/PSEUDOEPHEDRINE SR 12hr 60mg/120 mg, FEXOFENADINE/PSEUDOEPHEDRINE SR 24hr 180mg/240 mg, and LORATADINE chewable tablet 5 mg to preferred.
  - Clinical Criteria:
    - Update CLARINEX TABLETS, DESLORATADINE TABLETS: The patient has had a documented side effect, allergy, or treatment failure to 2 preferred second generation antihistamines, at least one must be loratadine AND If the request is for Clarinex, the patient must also have a documented intolerance to the generic equivalent tablets.
    - Update CETIRIZINE CHEWABLE TABLETS, DESLORATADINE ODT: The patient has had a documented side effect, allergy, or treatment failure to cetirizine oral solution and one of the following loratadine formulations: chewable tablet, rapidly disintegrating tablet, or oral solution.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

- **Alzheimer's Agents (new drug Adlarity® (donepezil transdermal system) included)**
  - Donepezil, the active ingredient of Adlarity®, is a reversible inhibitor of the enzyme acetylcholinesterase. Donepezil is postulated to exert its therapeutic effect by enhancing cholinergic function. This is accomplished by increasing the concentration of acetylcholine through reversible inhibition of its hydrolysis by acetylcholinesterase. There is no evidence that donepezil alters the course of the underlying dementing process. It is indicated for the treatment of mild, moderate, and severe dementia of the Alzheimer's type. There were no clinical efficacy trials in the Adlarity® prescribing information specific to the transdermal system. The efficacy of Adlarity® is based on a relative bioavailability study in healthy subjects comparing Adlarity® transdermal system to Aricept® tablets. The clinical

studies described in the Adlarity® prescribing information were conducted using donepezil tablets.
    - No other significant clinical changes.

Recommendation:

- Add Adlarity® patch to non-preferred with QTY LIMIT: 12 patches/84 days.
- Move DONEPEZIL ODT (compare to Aricept® ODT) with QTY LIMIT: 1 tablet/day and memantine titration pack to preferred.
- Move Namenda titration pack to non-preferred.
    - Clinical Criteria:
        - Add Adlarity: medical necessity for a specialty dosage form has been provided AND the patient had a documented side effect, allergy, or treatment failure to Exelon patch.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendations (Joseph Nasca absent from voting)

- **IBS (new drug Ibsrela®(tenapanor) included)**
    - Tenapanor, the active ingredient of Ibsrela®, is a locally acting inhibitor of the sodium/hydrogen exchanger 3 (NHE3), an antiporter expressed on the apical surface of the small intestine and colon mainly responsible for the absorption of dietary sodium. In vitro and animal studies indicate its major metabolite (M1) is not active against NHE3. By inhibiting NHE3 on the apical surface of the enterocytes, tenapanor reduces absorption of sodium from the small intestine and colon, resulting in an increase in water secretion into the intestinal lumen, which accelerates intestinal transit time and results in a softer stool consistency. It is indicated for the treatment of irritable bowel syndrome with constipation (IBS-C) in adults. The safety and efficacy of Ibsrela® were assessed in two double-blind, placebo-controlled, randomized, multicenter trials that included adult patients with IBS-C (Trial 1 and Trial 2). This product does have a box warning regarding the risk of serious dehydration in pediatric patients. The warning adds that use is contraindicated in patients less than 6 years of age and should be avoided in patients 6 years to less than 12 years of age. Furthermore, the safety and efficacy of use have not been established in the pediatric population less than 18 years of age. In 2 double-blind, placebo-controlled, phase 3 studies, there were more CSBM

responders and abdominal pain responders in those treated with Ibsrela® as compared with placebo. Per the full-text study by Chey et al2 (Trial 1), a significantly greater proportion in the tenapanor treatment group were 6/12-week combined responders as compared with placebo ($p<0.001$). Per the full-text study by Chey et al3 (Trial 2), a significantly greater proportion treated with tenapanor met the primary endpoint than placebo ($p=0.020$). Head-to-head comparator studies with other active agents with the same indication were not identified.

- No other significant clinical changes.

Recommendation:

- Move TRULANCE® with QTY LIMIT: 1 tablet/day to preferred.
- Add Lubiprostone (compare to Amitiza®) with QTY LIMIT: 2 capsules/day to non-preferred.
- Add Ibsrela® to non-preferred with QTY LIMIT: 2 tablets/day.
- Add minimum age edit of 6 years for Trulance, Linzess (Linzess® and Trulance® are contraindicated in patients less than 6 years of age due to the risk of serious dehydration).
    - Clinical Criteria:
        - Update Linzess 72mcg: The patient has a diagnosis of chronic idiopathic constipation (CIC) AND the patient is unable to tolerate the 145 mcg dose.
        - Update Relistor Tablets, Symproic: The patient is current using an opiate for at least 4 weeks AND has documented opioid-induced constipation AND the patient has had a documented side effect, allergy, or treatment failure to Amitiza and Movantik.
        - Add Lubiprostone: The patient is 18 years of age or older has had a documented intolerance to brand name Amitiza.
        - Update Ibsrela, Motegrity: The patient is 18 years of age or older AND The patient has had a documented side effect, allergy or treatment failure to Amitiza and either Linzess or Trulance.
        - Update Gattex: Patient has a diagnosis of short bowel syndrome AND Patient is receiving specialized nutritional support administered intravenously (i.e. parenteral nutrition) AND Patient does not have an active gastrointestinal malignancy (gastrointestinal tract, hepatobiliary, pancreatic), colorectal cancer, or small bowel cancer. Note: Re-approval requires evidence of decreased parenteral nutrition support from baseline.
        - Update Lotronex/Alosetron: The patient is a woman and has a diagnosis of severe diarrhea-predominant irritable bowel syndrome (IBS) with symptoms lasting 6 months or longer AND has had anatomic or biochemical abnormalities of the GI tract

excluded AND has not responded adequately to conventional therapies such as loperamide, and TCA's. For approval of generic alosetron, the patient must have documented intolerance to brand Lotronex.
- Update Viberzi: The patient has a diagnosis of IBS-D AND does not have any of the following contraindications to therapy A) known or suspected biliary duct obstruction, or sphincter of Oddi disease or dysfunction B) alcoholism, alcohol abuse, alcohol addiction, or drink more than 3 alcoholic beverages/day C) a history of pancreatitis; structural diseases of the pancreas D) severe hepatic impairment (Child-Pugh Class C) AND has not responded adequately to conventional therapies such as loperamide, and TCA's.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendations. (Joseph Nasca absent from voting)

- **Intranasal Rhinitis**
  - No new drugs
  - No other significant clinical changes.

Recommendation:
- Remove Nasonex® (mometasone) from the PDL.

Public Comments: No public comment.

Board Decision: None needed at this time.

- **Leukotriene Modifiers**
  - No new drugs
  - No other significant clinical changes.

Recommendation:
- None at this time.

Public Comments: No public comment.

Board Decision: None needed at this time.

- **Parathyroid Agents**
  - No new drugs

- After discussions with the FDA, Takeda issued a US recall on September 5, 2019, for all doses of NATPARA® (parathyroid hormone) for Injection (25 mcg, 50 mcg, 75 mcg, and 100 mcg).
- Takeda announced its decision, made on October 3, 2022, that it will discontinue manufacturing NATPARA® (parathyroid hormone) for Injection globally at the end of 2024 due to unresolved supply issues that are specific to the product. As a result, Takeda will not re-commercialize NATPARA in the U.S. and will discontinue manufacturing NATPAR globally. Beyond 2024, Takeda intends to supply available doses until inventory is depleted or expired.

Recommendation:

- Move SENSIPAR® (cinacalcet) to non-preferred.
- Move Cinacalcet (compare to Sensipar®) to preferred.
  - Clinical Criteria:
    - Add Sensipar: the patient has a documented intolerance to the generic equivalent.

Public Comments: No public comment.

Board Decision: The Board unanimously approved the above recommendations. (Joseph Nasca absent from voting)

- **Sedative Hypnotics (new drug Quviviq® (daridorexant) included)**
  - Daridorexant, the active ingredient of Quviviq®, is an orexin receptor antagonist, and the mechanism of action for its approved indication is presumed to be through antagonism of orexin receptors. The orexin neuropeptide signaling system plays a role in wakefulness. Blocking the binding of wake-promoting neuropeptides orexin A and orexin B to receptors OX1R and OX2R is thought to suppress wake drive. Quviviq® is a Schedule IV controlled substance. It is indicated for the treatment of adult patients with insomnia, characterized by difficulties with sleep onset and/or sleep maintenance. The efficacy of Quviviq® was assessed in 2 multicenter, randomized, double-blind, placebo-controlled, parallel-group studies that included patients (N=1854) with Diagnostic and Statistical Manual of Mental Disorders, 5th edition (DSM-5th) insomnia. In study 1, patients were randomized to Quviviq® 50mg (N=310), Quviviq® 25mg (N=310), or placebo (N=310). In study 2, patients were randomized Quviviq® 25mg (N=309), Quviviq® 10mg (N=307; this is not an approved dose), or

placebo (N=308). At the end of the 3-month treatment period, both studies included a 7-day placebo run-out period, after which patients could enter a 9-month, double-blind, placebo-controlled extension study (study 3). Results suggested that Quviviq® 25mg and 50mg (in study 1) demonstrated a statistically significant improvement as compared with placebo on LPS, WASO, and sTST at month 1 and month 3. In study 2, Quviviq® 25mg demonstrated a statistically significant improvement as compared with placebo on WASO and sTST at month 1 and month 3. Comparator head-to-head studies with other active agents were not found.

- No other significant clinical changes.

Recommendation:

- Add Quviviq™ to non-preferred with QTY LIMIT: 1 tab/day.
- Move ZOLPIDEM CR (compare to Ambien CR®) with QTY LIMIT: 1 tab/day to preferred.
- Remove Intermezzo® (zolpidem) sublingual tablet from the PDL. It is no longer available.
- Add Zolpidem sublingual tablet with QTY LIMIT: 1 tab/day to NP.
- Move Hetlioz® (tasimelteon) out of the miscellaneous section.
- Move Estazolam to non-preferred.
- Move Temazepam 7.5mg strength to preferred.
    - Clinical Criteria:
        - Update Criteria for Approval (Benzodiazepines): The patient has had a documented side effect, allergy, or treatment failure with Temazepam. If a product has an AB rated generic, one trial must be the generic.
        - Add Ambien CR to Ambien and Lunesta criteria.
        - Add Quviviq to Dayvigo criteria.
        - Add Zolpidem sublingual to Edluar criteria.
        - Update Belsomra: The patient has had a documented side effect, allergy or treatment failure to one preferred sedative/hypnotic.
        - Update Hetlioz: Patient has documentation of Non-24-Hour Sleep-Wake Disorder (Non24) or Insomnia due to Smith-Magenis Syndrome AND Patient has had a documented side effect, allergy or treatment failure with Rozerem and at least one OTC melatonin product

Public Comments: No public comment.

Board Decision: The Board unanimously approved the above recommendations. (Joseph Nasca absent from voting)

- **Smoking Cessation**
  - No new drugs
  - In July 2021, FDA announced it would not object to certain manufacturers distributing varenicline tablets containing N-nitroso-varenicline above FDA's acceptable intake limit, but below the interim acceptable intake limit of 185 ng per day, until the impurity could be eliminated or reduced to acceptable levels. The agency's current assessment shows manufacturers can adequately supply the market with varenicline at or below the acceptable intake limit of 37 ng per day.
  - Update 5/5/2022: FDA is now confident in manufacturers' ability to supply patients with varenicline containing the N-nitroso-varenicline impurity at or below the agency's acceptable intake limit of 37 ng per day. Any newly manufactured varenicline for the U.S. market should have levels of the N-nitroso-varenicline impurity at or below that limit.
  - Pfizer's branded Chantix is still in backorder status. NDCs are showing as inactive, but no official plans for discontinuation have been announced.

Recommendation:
- Move NICOTROL® NASAL SPRAY to preferred.
- Add VARENICLINE (Limited to 18 years and older) with QTY LIMIT: 2 tabs/day; Max duration 24 weeks (2x12 weeks)/365 days) to preferred.

Public Comments: No public comment.

Board Decision: The Board unanimously approved the above recommendations. (Joseph Nasca absent from voting)

10. Review of Newly-Developed/Revised Criteria:

- **Injectable Testosterone**

Recommendation:
- Clinical criteria:
  - Update Aveed, Testopel, Xyosted: The patient has had a documented side effect, allergy, or treatment failure to TWO preferred testosterone products, one of which must be an injectable formulation. Treatment failure is defined as inability to achieve testosterone values in the 300-

1,000ng/dL range despite adjustments to dose and frequency of injection.

Public Comments: No public comment.

Board Decision: The Board unanimously approved the above recommendations. (Joseph Nasca absent from voting)

11. General Announcements:

- None at this time.

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