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

September 12, 2023: 6:00 – 8:30 p.m.

Board Members Present:

	Andy Miller, RPH		**Lucy Miller, MD**		**Margot Kagan, PharmD**
	Bram Starr, MD		**Annie Daly, PharmD**		**Katharina Cahill, PharmD**

Board Members Absent:

	Mark Pasanen, MD		**Douglas Franzoni, PharmD**		

DVHA Staff Present:

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

Change Healthcare Staff Present:

	Jacqueline Hedlund, MD		**Laurie Brady, RPh**		**Carla Quinlivan**

Guests/Members of the Public:

Omer Aziz, Mark Douglass, Franco Casagrande, Allison Roark, Kushal Bhatt, Matthew Stryker, Paul Miner, Basmina Parmakhtiar, Claire Judkins, Beth D'Ambrosio, Dalia Moufarreg-Petosa, Frank Lanotte, Jim McCarthy, Lucie Garand, Melissa Abbott, Nicholas Boyer, Nikhil Kacker, Amy Cunningham, Ryan Miller, Collin Sinclair, Joe Ward, John Meyer, Jim Pitt, Laura Goldie, Lisa Dunn, Brett White

Executive Session:

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

Introductions and Approval of DUR Board Minutes:

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

DVHA Pharmacy Administration Update: Lisa Hurteau, PharmD, DVHA

- Introduction of new board member, Dr. Bram Starr. He recently retired from family practice.
- DVHA pharmacy administration is currently working on the Best Practices and Cost Control Report, which is a legislatively required annual report. This report focuses on the pharmacy benefit program, pharmacy spend overall, supplemental rebates, specialty medication, drug utilization, and state and federal trends. The report is due at the end of October and will be shared with the board once completed.
- DVHA is required to complete a Gold Card feasibility study as part of H222. They will look at providers that have at least 90% or more of their prior authorizations approved and see if there is a way to "gold card" them and make them exempt from the prior authorization process.
- The FDA approved the latest COVID vaccine for everyone 6 years of age and older. Many of the new NDCs are not yet in the Medispan system but should be available shortly.

Chief Medical Officer Update: Michael Rapaport, MD, DVHA

- DVHA has been part of a hypertension project to make blood pressure cuffs more available to patients at home. Availability until now was through DME and the process was cumbersome for both providers and patients. Following California's lead, DVHA will now be offering them through the pharmacy benefit beginning 9/22/23. Although we will see a cost increase, the level of care will be greatly improved.
- A new workgroup is being created to help evaluate the cost of weight loss medications versus lifestyle changes. DVHA is currently prohibited from covering these medications per state rule. An amendment to the State Plan would be required for DVHA to begin covering these medications.

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

- None at this time.

Recommendation: None needed.

Board Decision: None needed.

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

- Data Presentation: Chronic Use of Sedatives/Hypnotics

The chronic use of sedatives/hypnotic prescription drugs is seen in a large amount of the U.S. population. It is estimated that approximately 4.6% of all Americans have used legally prescribed anxiolytics, sedatives, or hypnotics in the past 30 days. There are risk factors that could lead to poor health outcomes with sedative/hypnotic use including: current or previous alcohol or substance use disorder, history of overdose, fall risk, traumatic brain injury, memory problems, sleep apnea, age > 60 and COPD. In addition, increased risk is known in those concurrently using opioids and sedatives, including respiratory depression, over-sedation, and accidental overdose. The 2014 National

Survey on Drug Use and Health estimated that 2.5% of those 12 and older used psychotherapeutic drugs for non-medical purposes, which equates to 6.5 million people. Of those, 1.9 million used tranquilizers and 330,000 used sedatives. The DSM-5 now has a specific classification labeled as Sedative, Hypnotic and Anxiolytic Use Disorder with criteria that includes a persistent desire to cut down use, or unsuccessful attempts to control use and cravings. Additionally included criteria involve spending a lot of time obtaining substance(s) and stopping or reducing important occupational social or recreational activities due to use. Sedative/hypnotic use should be restricted to short-term treatment in most cases, with attempts to use other first-line treatments such as cognitive behavioral therapy (CBT). CBT for insomnia is preferred as first-line therapy for chronic insomnia in most patients. However, CBT is not effective for all patients and is not accessible to many, either due to lack of therapists or to limitations of insurance or time. Despite these recommendations, there remains a vast number of individuals prescribed sedative/hypnotic medications chronically.

Change Healthcare used paid, non-reversed Medicaid pharmacy and medical claims from October 2021 through calendar year 2022, excluding members with Part D, VMAP and Healthy Vermonters coverage. Members with 6 months or more using sedatives/hypnotic drugs were identified. Change Healthcare then looked to see if any claims were submitted for cognitive behavioral therapy in these members. Additionally, they identified how many different prescribers of the sedative/hypnotic drugs each member had, to assess possible misuse of the drugs and monitor for potentially dangerous concurrent prescribing habits. Sedative/Hypnotic Drugs reviewed for analysis: temazepam, estazolam, flurazepam, triazolam, eszopiclone, zaleplon, zolpidem, zolpidem ER, Belsomra® (suvorexant), Dayvigo® (lemborexant), doxepin (3mg and 6mg only), Edluar® (zolpidem), Hetlioz® (tasimelteon), and ramelteon.

There were 1,297 members who had at least one claim for a sedative or hypnotic. Of these 1,297 Members, 547 had at least 1 Drug Prescribed with Total Days' Supply of 6 Months or More (180 Days). Of these 547 Members, 7 members had > 1 Drug Prescribed with Total Days' Supply of 6 Months or More (180 Days). Of these 7 Members, 5 had >1 Overlapping Drug Prescribed with Total Days' Supply of 6 Months or More (180 Days)

Recommendation: After reviewing Vermont Medicaid pharmacy claims, data shows that many members prescribed sedatives/hypnotics were taking the prescribed drugs for more than 6 months, and of those, some were prescribed more than one drug from these classes. While there were only a few who had 2 or more different drugs for more than 6 months each (7 unique members), 5 of these had the drugs prescribed at the same time. Most members got their prescriptions from only 1 or 2 prescribers, however, there were some members who had multiple prescribers. While this could be a red flag for drug seeking behavior/diversion, a further review showed that some of the prescribers were from the same medical institution. This would suggest that the drugs could have been refilled without an assessment as to whether the drug was still of benefit. A potential intervention would be to limit prescriptions from being filled for

members already taking a sedative, possibly requiring a prior authorization for justification of the need for a second sedative/hypnotic drug.

Board Decision: After board discussion, Change Healthcare will research if an edit can be placed to look back for previous drugs, in combination with accumulation, to help prevent the edit from looking at medications that have been discontinued.

- Introduce: Proposed RetroDUR topics for 2024

The Medicaid Retrospective DUR program involves ongoing and periodic examination of claims data to identify patterns of care related to therapeutic appropriateness, adverse events, appropriate use of generic products, incorrect duration of treatment, utilization, inappropriate or medically unnecessary care, gross overuse, abuse, and fraud. The State implements corrective action such as provider education or outreach when needed. Topics are developed based on several factors including, but not limited to, issues identified through utilization review, areas of interest specified by CMS, concerns related to new clinical data/FDA labeling and therapeutic areas impacted by new/pipeline medications.

CYSTIC FIBROSIS THERAPIES

Purpose: Evaluate medical cost savings after initiation of Trikafta®(elexacaftor/tezacaftor/ivacaftor).

- This is a major driver of increased specialty medication spend for DVHA; however, it may have benefits including fewer hospitalizations or ED visits.

USE OF HEMLIBRA® (Emicizumab-kxwh)

Purpose: Evaluate shift in utilization of factor since Hemlibra® (Emicizumab-kxwh) was FDA approved.

- Evaluate cost of care before and after Hemlibra® in members who switched.
- Note: Factor may be a mix of both pharmacy and medical claims. Hemlibra® should be exclusively pharmacy.

TREATMENT OF C. DIFF

Purpose: IDSA guidelines have changed.

- Can evaluate use of metronidazole (no longer recommended), vancomycin, Dificid®(fidaxomicin), and Zinplava® (bezlotoxumab) injection in members with a diagnosis of C. Diff in medical claims.
- Attempt to evaluate recurrences by looking at repeat prescriptions or change in therapy after first fill.

HEPATITIS C ADHERENCE AND CURE RATES

Purpose: Utilize information gathered from the Pharmacy Care Management (PCM) program.

- Evaluate frequency of use for 8-week, 12-week, and 16-week regimens based on genotype or other clinical parameters.

- Report cure rates for members (will only be reported for those whose MD's have sent follow up information to the program leader).
- Evaluate adherence rates.

CO-ADMINISTRATION OF PPIS AND BISPHOSPHANATES

Purpose: Long term use of PPIs may be associated with an increased fracture risk. Patients also taking bisphosphonates may be at further risk.

- Identify members with overlapping claims for PPIs and bisphosphonates.
- Look at duration and dose of PPI where possible.

AUTOFILL AND OVERFILLING SPECIALTY DRUGS LEADING TO ACCUMULATION AND WASTE

Purpose: Review prescription claims for specialty drugs to analyze days' supply dispensed. Members that have received an excessive supply of specialty medications will be included in the analysis. The number of drugs dispensed in excess of an expected annual supply will be used to determine a gross fiscal estimate for assumed waste.

- Identify members with specialty drugs dispensed with a days' supply greater than the study period (over 365 days of medication for a one-year timeframe with 7-14 day grace period). We will use the top 10 specialty drugs by both spend and claim volume.
- Determine the estimated gross cost of excessive medications dispensed and the cost savings if tighter edits are used.

CODEINE OR HYDROCODONE CONTAINING COUGH SYRUPS PRESCRIBED DURATION

Purpose: Review prescription claims for cough syrup formulations that contain opioid drugs (hydrocodone and codeine) and the duration of prescribed prescriptions.

- Determine the amount and days' supply for cough formulation containing opioids.
- Generally, 30 or 60 mL is acceptable for acute antitussive needs. If there are any prescribers writing for entire bottles or in excess of 5–10-day prescriptions, this may be a red flag.

Board Decision: The board felt that the four topics of highest interest were: Cystic Fibrosis Therapies, Use of Hemlibra® (Emicizumab-kxwh), Codeine or Hydrocodone Containing Cough Syrups Prescribed Duration, and Autofill and Overfilling Specialty Drugs. Change Healthcare will move forward with creating a schedule for the upcoming year.

Clinical Update: Drug Reviews: Jacqueline Hedlund, MD, Laurie Brady, RPh, Change Healthcare

Biosimilar Drug Reviews:

- None at this time.

Full New Drug Reviews:

- Altuviiio® (antihemophilic factor (recombinant), Fc-VWF-XTEN fusion protein-ehtl)

The active ingredient in Altuviiio® is a fully recombinant fusion protein comprising a single chain B-domain deleted (BDD) analogue of human FVIII covalently fused to the Fc domain of human immunoglobulin G1 (IgG1), the FVIII-binding D'D3 domain of human von Willebrand factor (VWF), and 2 XTEN polypeptides. Altuviiio® is produced by recombinant DNA technology in a human embryonic kidney (HEK) cell line and is manufactured without addition of human- or animal-derived components and purified by a combination of multiple chromatography steps, a detergent viral inactivation step, a nano filtration step for viral clearance, and ultrafiltration steps. Altuviiio® (antihemophilic factor (recombinant), Fc-VWF-XTEN fusion protein-ehtl) temporarily replaces the missing coagulation factor VIII needed for effective homeostasis. Altuviiio® has demonstrated a 3- to 4-fold prolonged half-life relative to other standard and extended half-life FVIII products. It is indicated as a von Willebrand Factor (VWF) independent recombinant DNA-derived, Factor VIII concentrate indicated for use in adults and children with hemophilia A (congenital factor VIII deficiency) for: Routine prophylaxis to reduce the frequency of bleeding episodes, On-demand treatment and control of bleeding episodes, Perioperative management of bleeding. A limitation of use is that Altuviiio® is not indicated for the treatment of von Willebrand disease. The safety, efficacy, and pharmacokinetics of Altuviiio® were assessed in two multicenter, prospective, open-label, clinical studies (one study in adults and adolescents ≥12 years of age and one pediatric study in children <12 years of age) in previously treated patients (PTPs) with severe hemophilia A (<1% endogenous Factor VIII activity or a documented genetic mutation consistent with severe hemophilia A). All studies evaluated the efficacy of routine prophylaxis with a weekly dose of 50 IU/kg and determined hemostatic efficacy in the treatment of bleeding episodes and during perioperative management in subjects undergoing major or minor surgical procedures. In the study with adults and adolescents, routine prophylaxis resulted in a mean annualized bleed rate (ABR) of 0.7. There is no evidence at this time to support that Altuviiio® is safer or more effective than the other currently preferred, more cost-effective medications.

Recommendation:

- Add Altuviiio™ (antihemophilic factor (recombinant), Fc-VWF-XTEN fusion protein-ehtl) to non-preferred.
- Update category name to Hemophilia Treatments and subcategory Hemophilia A (Factor VIII Deficiency)
- Move Nuwiq® and Kovaltry® to preferred.
    - Clinical criteria:
        - Add Altuviiio: The patient has severe Factor VIII deficiency as evidenced by < 1% of normal circulating factor AND Patient has the following:
            - Current and continuous use of Factor VIII prophylaxis therapy for the previous 6 months

as evidenced by claims history or clinical documentation, without breaks in adherence. (Continuous use is defined as routine prophylaxis with defined frequency, e.g. twice weekly, once every two weeks) AND
    - Current or historical life-threatening hemorrhage despite use of preferred prophylaxis therapy OR Repeated, serious spontaneous bleeding episodes requiring hospitalization.
- Update Adynovate, Eloctate, Esperoct: Documentation must include why the member is unable to use the preferred extended half-life concentrate Jivi.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

- Atorvaliq® (atorvastatin calcium)

Atorvastatin, the active ingredient of Atorvaliq®, is a selective, competitive inhibitor of 3-hydroxy-3-methylglutaryl-coenzyme A (HMG-CoA) reductase, the rate-limiting enzyme that converts 3-hydroxy-3-methylglutaryl-coenzyme A to mevalonate, a precursor of sterols, including cholesterol. In animal models, atorvastatin lowers plasma cholesterol and lipoprotein levels by inhibiting HMG-CoA reductase and cholesterol synthesis in the liver and by increasing the number of hepatic LDL receptors on the cell surface to enhance uptake and catabolism of LDL; atorvastatin also reduces LDL production and the number of LDL particles. The effectiveness of Atorvaliq® has been established in adequate and well-controlled trials of atorvastatin calcium tablets, referenced as atorvastatin, in the trials included in the Atorvaliq® prescribing information. Atorvastatin tablets, under the brand name Lipitor®, have been available for numerous years as brand and generic, and have the same indications as Atorvaliq®. There is no evidence at this time to support that Atorvaliq® is safer or more effective than the other currently preferred, more cost-effective medications.

Recommendation:

- Add Atorvaliq® (atorvastatin) oral suspension to non-preferred.
    - Clinical criteria:
        - Add Atorvaliq, Ezallor: medical necessity for a specialty dosage form has been provided.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

- Austedo XR® (deutetrabenazine) extended-release tablets

Deutetrabenazine, the active ingredient of Austedo® XR (and Austedo®), is a vesicular monamine transporter 2 (VMAT2) inhibitor. Its exact mechanism of action for its approved indication is not known, but it is thought to be related to its effect as a reversible depleter of monoamines (such as dopamine, serotonin, norepinephrine, and histamine) from nerve terminals. The major metabolites of deutetrabenazine are reversible inhibitors of VMAT2, resulting in decreased uptake of monoamines into synaptic vesicles and depletion of monoamine stores.it is indicated in adults for the treatment of: Chorea associated with Huntington's disease and Tardive dyskinesia. The studies described in the Austedo®/Austedo® XR prescribing information establishing effectiveness for Huntington's disease and tardive dyskinesia were conducted with Austedo® tablets. The efficacy of Austedo® XR is based on a relative bioavailability study comparing Austedo® XR tablets administered once daily and Austedo® tablets administered twice daily. Austedo® XR is considered a safe, effective, and relatively cost-effective treatment. It is therefore recommended that Austedo® XR remain preferred but require clinical prior authorization.

Ingrezza® (valbenazine tosylate) update: In August 2023 Neurocrine Biosciences received approval from the FDA for the treatment of adults with chorea associated with Huntington disease (HD). The agent, delivered as a once-daily capsule, is a selective vesicular monoamine transporter 2 (VMAT2) inhibitor also approved by the FDA for the treatment of adults with tardive dyskinesia. FDA approval was based on results from the KINECT-HD (NCT04102579) phase 3, randomized, double-blind, placebo-controlled study, which assessed the efficacy, safety, and tolerability of Ingrezza® in the treatment of HD-associated chorea in 128 adult participants aged 18 to 75 years from 46 Huntington's Study Group (HSG)-credentialed sites across North America. Participants received a capsule of Ingrezza® or placebo once daily for 12 weeks. The primary outcome was change from baseline in Unified Huntington's Disease Rating Scale (UHDRS) Total Maximal Chorea (TMC) score. Participants who received Ingrezza® improved by 4.6 points in UHDRS TMC scores vs 1.4 points of improvement for placebo, meeting the study's primary endpoint with significant chorea severity improvement. Common treatment-emergent adverse events (TEAEs) included somnolence, sedation, urticaria, rash, and insomnia. Ingrezza's prescribing information contains a black box warning for the risk of depression and suicidal ideation.

Recommendation:

- Add Austedo XR® (deutetrabenazine) extended-release tablets with QTY LIMIT: 6 mg and 12 mg = 1 tablet/day; 24 mg = 2 tablets/day; Starter pack = 42 tablets/28 days; Maximum 1-month supply per fill to preferred after clinical criteria are met.
  - Clinical criteria:
    - Update Austedo, Austedo XR, Ingrezza: The diagnosis or indication for the requested medication is Huntington's Disease (HD) with chorea or Tardive Dyskinesia (TD) AND the results of an Abnormal Involuntary Movement Scale

(AIMS) exam have been submitted AND the patient is ≥18 years of age. For re-approval, there must be documented clinical improvement.

Public Comment: Omer Aziz from Teva had one question before giving the time back to the board. For reapproval, he asked what the AIMS score required is. Change Healthcare stated it would be based on clinical documentation from the patient's chart. The AIMS is required for a baseline to evaluate but threshold is not set.

Board Decision: The Board unanimously approved the above recommendations.

- Brixadi® (buprenorphine extended-release injection)

Buprenorphine, the active ingredient of Brixadi®, is a partial agonist at the mu-opioid receptor and an antagonist at the kappa-opioid receptor. Brixadi® contains buprenorphine, a Schedule III substance under the Controlled Substances Act. It can be abused in a manner similar to other opioids. Buprenorphine is sought by people with opioid use disorder and is subject to criminal diversion. Monitor all patients for progression of opioid use disorder and addictive behaviors. It is indicated for the treatment of moderate to severe opioid use disorder in patients who have initiated treatment with a single dose of a transmucosal buprenorphine product or who are already being treated with buprenorphine. Brixadi® should be used as part of a complete treatment plan that includes counseling and psychosocial support. The key studies from the Brixadi® clinical development program that support its use in the treatment of moderate to severe opioid use disorder are a phase 3, double-blind, active-control (sublingual buprenorphine/naloxone), efficacy and safety study, and an opioid blockade study. Additionally, a phase 3, open-label safety study provides data to support the safety of converting from daily transmucosal buprenorphine, buprenorphine/naloxone or generic equivalents. It has a box warning regarding the risk of serious harm or death with IV administration and thus is only available through a restricted program called the Brixadi® REMS. The weekly formulation should be administered in 7-day intervals while the monthly formulation should be administered in 28-day intervals. In a phase 3 efficacy study, 16.9% of Brixadi®-treated patients (taken with SL placebo tablets) met the responder definition as compared with 14% of the SL-BPN/NX tablet-treated patients (taken with placebo injection). Brixadi® is the only FDA approved buprenorphine injectable product with a weekly and monthly dosing option.

Recommendation:

- Add Brixadi® (buprenorphine extended-release) injection WEEKLY with QTY LIMIT: 1 syringe per week; maximum days' supply 28 days (Note: Two 8 mg syringes may be approved for initial titration purposes in patients not currently receiving buprenorphine)
- Add Brixadi® buprenorphine extended-release) injection MONTHLY with QTY LIMIT: 1 syringe per month to preferred.

Commented [MA1]: I believe we leave this as is since this was recommendation, and Dr. R requested 28 days for all to be on PDL which was approved. So this should remain and PDL be changed to reflect

- Move Sublocade® (buprenorphine extended-release) injection with QTY LIMIT: 300mg 1 injection per month for a maximum of 2 months then 100mg 1 injection per month thereafter to preferred.
- Increase the maximum daily dose for buprenorphine/naloxone tablets and Suboxone® (buprenorphine/naloxone) films to 24mg per day. PA is required for over 24mg per day. Update quantity limits for 8mg tabs and films to 3 per day. Update quantity limits for 12mg films to 2 per day.
    - Clinical criteria:
        - Update Sublocade (to exceed quantity limits): A maintenance dose increase to 300mg will be considered for those patients who are able to tolerate the 100mg dose but do not demonstrate a satisfactory clinical response (including supplemental oral buprenorphine dosing, documentation of self-reported illicit opioid use, or urine drug screens positive for illicit opioid use). Once the patient is established on a maintenance dose, concurrent use of Sublocade and supplemental oral buprenorphine dosing will not be permitted. Sublocade must be dispensed directly to a healthcare provider and will not be approved for dispensing to the patient.

Public Comment: Mark Douglass from Braeburn Pharmaceuticals yielded his time back to the board.

Board Discussion: As of January 2024, the legislature mandated that up to 24mg of Suboxone sublingual and buprenorphine/naloxone tablet be available without a PA. DHVA has decided to move forward with that change ahead of the January deadline. By doing that, they will have data available before the legislative session starts and be better able to address questions. They also feel that having injectable formulations preferred will help address diversion concerns for some patients. Dr. Rapaport requested that the quantity limits specify 28 days rather than monthly.

Board Decision: The Board unanimously approved the above recommendations with the modification of the quantity limit for Brixadi® and Sublocade® to be for 28 days.

- Daybue® (trofinetide solution)

The mechanism by which trofinetide, the active ingredient of Daybue®, exerts its therapeutic effects in patients with Rett syndrome is unknown. It is indicated for the treatment of Rett syndrome in adults and pediatric patients 2 years of age and older. The efficacy of Daybue® for the treatment of Rett syndrome was established in a 12-week randomized, double-blind, placebo-controlled study in patients with Rett syndrome 5 to 20 years of age. The co-primary efficacy endpoints were changes from baseline after 12 weeks of treatment in the total score of the Rett Syndrome Behavior Questionnaire (RSBQ) and the Clinical Global Impression-Improvement (CGI-I) score. Treatment with Daybue® demonstrated a statistically significant difference in favor of

Daybue® as compared to placebo for the co-primary efficacy endpoints. Daybue® is the first and only FDA approved treatment for Rett syndrome in adults and children 2 years of age and older.

Recommendation:

- Add Daybue™ (trofinetide) solution with QTY LIMIT: 120 mL/day to non-preferred.
  - Clinical criteria:
    - Add Daybue:
      - The patient is ≥ 2 years of age.
      - The prescription is initiated by or in consultation with a neurologist or other developmental specialist.
      - The patient has a diagnosis of typical Rett syndrome per the Rett Syndrome Diagnostic Criteria (must meet ALL):
        - Partial or complete loss of acquired purposeful hand skills.
        - Partial or complete loss of acquired spoken language.
        - Gait abnormalities: Impaired (dyspraxic) or absence of ability.
        - Stereotypic hand movements such as hand wringing/squeezing, clapping/tapping, mouthing and washing/rubbing automatisms.
      - The patient does not have any of the Exclusion Criteria:
        - Brain injury secondary to trauma (peri- or postnatally), neurometabolic disease, or severe infection that causes neurological problems.
        - Grossly abnormal psychomotor development in first 6 months of life.
      - The patient has a documented disease-causing mutation in the *MECP2* gene.
      - The patient is not using any insulin.
      - Detailed clinical baseline has been provided using an objective measure or tool (Rett Syndrome Behavior Questionnaire (RSBQ).
      - Initial approval will be granted for 3 months. For reapproval, the patient must have a documented clinical improvement in disease as evidenced by ≥ 10% reduction in the RSBQ questionnaire score. Patients with a baseline RSBQ score of ≤ 30 must have at least a ≥ 3-point reduction AND The patient has not experienced significant weight loss (>5% from baseline).

Public Comment: Franco Casagrande from Acadia Pharmaceuticals: Highlighted the attributes of Daybue.
Allison Roark, a parent of a child with Rett Syndrome spoke on behalf of Daybue.

Board Decision: The Board unanimously approved the above recommendations.

- Filspari™ (sparsentan)

Sparsentan, the active ingredient of Filspari™, is an endothelin and angiotensin II receptor antagonist. It is a single molecule with antagonism of the endothelin type A receptor (ETAR) and the angiotensin II type 1 receptor (AT1R). Endothelin-1 and angiotensin II are thought to contribute to the pathogenesis of IgAN via the ETAR and AT1R, respectively. It is indicated to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression, generally a urine protein-to-creatinine ratio (UPCR) ≥1.5g/g. The efficacy of Filspari™ on proteinuria was assessed in a randomized, double-blind, active-controlled, multicenter, global study that included adults with biopsy-proven IgAN, eGFR ≥30ml/min/1.73m2, and total urine protein ≥1.0g/day on a maximized stable dose of RAS inhibitor treatment that was at least 50% of maximum labeled dose. This indication is approved under accelerated approval based on a reduction of proteinuria. It has not been established whether Filspari™ slows kidney function decline in patients with IgAN. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory clinical trial. There is some evidence in a phase 3 study to suggest that Filspari™ may be more effective than irbesartan for the primary endpoint of relative change from baseline in UPCR at week 36; however, there is no evidence at this time to support that Filspari™ is safer or more effective than the other currently preferred, more cost-effective medications. It is therefore recommended that Filspari™ remain non-preferred and require prior authorization and be available to those who are unable to tolerate or who have failed on preferred medications.

Recommendation:

- Add Filspari™ (sparsentan) tablet with QTY LIMIT: 1 tablet/day to non-preferred.
  - Clinical criteria:
    - Update Filspari, Tarpeyo:
      - The patient has a diagnosis of Immunoglobulin A Nephropathy (IgAN) confirmed by biopsy AND
      - eGFR ≥ is 35ml/min/1.73m2 AND
      - The patient meets one of the following: Proteinuria ≥ 1g/day or Urine protein-to-creatinine ratio (UPCR) ≥ 1.5 g/g AND
      - The patient is on a stable dose of maximally tolerated ACE-I or ARB therapy for a minimum of 3 months AND

- The patient's kidney function has continued to decline despite treatment with a preferred oral corticosteroid AND
- Duration of therapy does not exceed 9 months (Tarpeyo only)
- The prescriber, patient, and pharmacy are enrolled in the REMS program (Filspari only)

Public Comment: Kushal Bhatt from Travere Therapeutics: Highlighted the attributes of Filspari.

Board Decision: The Board unanimously approved the above recommendations.

- Leqembi® (lecanemab-irmb injection)

Lecanemab-irmb, the active ingredient of Leqembi®, is a recombinant humanized immunoglobulin gamma 1 (IgG1) monoclonal antibody directed against aggregated soluble and insoluble forms of amyloid beta. The accumulation of amyloid beta plaques in the brain is a defining pathophysiological feature of Alzheimer's disease. It is indicated for the treatment of Alzheimer's disease. Treatment with Leqembi® should be initiated in patients with mild cognitive impairment or mild dementia stage of disease, the population in which treatment was initiated in clinical trials. The efficacy of Leqembi® was assessed in two double-blind, placebo-controlled, parallel group, randomized studies (Study 1 and Study 2) that included patients with Alzheimer's disease (patients with confirmed presence of amyloid pathology and mild cognitive impairment [64% in Study 1; 62% in Study 2] or mild dementia stage of disease [36% in Study 1; 38% in Study 2] consistent with Stage 3 and Stage 4 Alzheimer's disease). The primary endpoint was change from baseline on a weighted composite score consisting of selected items from the CDR-SB, MMSE, and ADAS-Cog 14 at week 53. Leqembi® had a 64% chance of 25% or greater slowing of progression on the primary endpoint relative to placebo at week 53, which did not meet the prespecified success criterion of 80%.

Recommendation:

- Add Leqembi® (lecanemab-irmb) IV solution to non-preferred.
  - Clinical criteria:
    - Update Aduhelm, Leqembi:
      - Patient is 50 years of age or older
      - Prescriber has assessed and documented baseline disease severity utilizing an objective measure/tool (e.g., MMSE, Alzheimer's Disease Assessment Scale-Cognitive Subscale [ADAS-Cog-13], Alzheimer's Disease Cooperative Study-Activities of Daily Living Inventory-Mild Cognitive, Impairment version [ADCS-ADL-MCI], Clinical Dementia Rating-Sum of Boxes[CDR-SB]).

Commented [MA2]: Should also add irmb on PDL

- Patient has mild cognitive impairment (MCI) due to Alzheimer's Disease or mild Alzheimer's dementia as evidenced by the following:
  - Clinical Dementia Rating (CDR) Global Score of 0.5
  - Objective evidence of cognitive impairment at screening
  - MMSE score between 24 and 30
  - PET scan is positive for amyloid beta plaque OR Cerebrospinal fluid (CSF) test is positive for amyloid
- Patient has had a recent (within 1 year) brain MRI prior to initiating treatment and prescriber attests to a repeat brain MRI as directed in the labeling (prior to the 7th infusion and 12th infusion for Aduhelm and prior to the 5th, 7th, and 14th infusion for Leqembi).
- Patient does not have any of the following within 1 year of treatment initiation: pretreatment localized superficial siderosis, 10 or more brain microhemorrhages, or brain hemorrhage >1 cm
- Patient has had a documented treatment failure, as defined by significant disease progression after 1 year of therapy, with a preferred cholinesterase inhibitor, unless contraindicated.
- Prescriber has enrolled in the voluntary Alzheimer's Network for Treatment and Diagnostics (ALZ-NET) registry.
- For re-approval, the patient must have responded to therapy compared to pre-treatment baseline as evidenced by improvement, stabilization, or slowing in cognitive or functional impairment AND patient has not progressed to moderate or severe disease (there is insufficient evidence in moderate or severe AD)

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

- Pradaxa® Oral Pellets (dabigatran etexilate pellet)

Dabigatran etexilate mesylate, the active ingredient of Pradaxa® Oral Pellets, is a direct thrombin inhibitor. Dabigatran and its acyl glucuronides are competitive, direct thrombin inhibitors. Because thrombin (serine protease) enables the conversion of fibrinogen into fibrin during the coagulation cascade, its inhibition prevents the development of a thrombus. Both free and clot-bound thrombin, and thrombin-induced platelet aggregation are inhibited by the active moieties. It is indicated for the treatment of VTE

in pediatric patients aged 3 months to less than 12 years of age who have been treated with a parenteral anticoagulant for at least 5 days. It is also indicated to reduce the risk of recurrence of VTE in pediatric patients aged 3 months to less than 12 years of age who have been previously treated. Pradaxa® capsules are indicated for the use in pediatric patients 8 to less than 18 years of age, but with the same pediatric indications as the Pradaxa® Oral Pellets (which are indicated for use in pediatric patients aged 3 months to less than 12 years of age). The pediatric studies included in the Pradaxa® Oral Pellets prescribing information are the same as those in the Pradaxa® capsules prescribing information. The Pradaxa® Oral Pellets offers physicians a different dosage formulation and an oral treatment for patients 3 months and older.

Recommendation:

- Remove quantity limits for preferred agents (Pradaxa capsules, Eliquis tablets, and Xarelto tablets)
- Add Dabigatran Etexilate (compare to Pradaxa®) capsules, Pradaxa® (dabigatran etexilate) oral pellets, and Xarelto® (rivaroxaban) oral suspension to non-preferred.
    - Clinical criteria:
        - Add Dabigatran: the patient must have a documented intolerance to brand name Pradaxa.
        - Pradaxa pellets: patient has a medical necessity for a non-solid oral dosage form and prescriber has provided a clinically valid reason why Xarelto suspension cannot be used.
        - Xarelto suspension: patient has a medical necessity for a non-solid oral dosage form (e.g. swallowing disorder).

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

New Therapeutic Drug Classes

- None at this time.

Therapeutic Drug Classes- Periodic Review:

Androgenic Agents

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

Recommendation:

- Remove Jatenzo (testosterone undecanoate) capsules. They are no longer rebateable.
- Move Testosterone 2% solution 90ml Pump Bottle to preferred.
    - Clinical criteria:

Commented [MA3]: Should we include that all nasal agents require PA since is highlighted as a change on PDL?

- Update 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 Tlando.

Public Comments: None at this time.

Board Decision: The Board unanimously approved the above recommendations.

Antiemetics

- New drug Aponvie® (aprepitant), is a substance P/neurokinin 1 (NK1) receptor antagonist. It is a selective high-affinity antagonist of human substance P/NK1 receptors, and has little or no affinity for serotonin, dopamine, and corticosteroid receptors, the targets of existing therapies for postoperative nausea and vomiting. In animal models, aprepitant has been shown to inhibit emesis via central actions. It is indicated for the prevention of postoperative nausea and vomiting (PONV) in adults. A limitation of use is that Aponvie® has not been studied for the treatment of established nausea and vomiting. The safety and efficacy of Aponvie® have been established based on adequate and well-controlled studies of a single-dose of oral aprepitant in adults. The studies included in the prescribing information for Aponvie® were the ones conducted with oral aprepitant. Oral aprepitant capsules have been available for several years and are also indicated for prevention of PONV. Aponvie® is safe, effective, and relatively cost-effective medication. It is recommended that Aponvie® be preferred and not require prior authorization.
- No other significant clinical changes.

Recommendation:

- Add Aponvie® (aprepitant) injection to preferred.
- Remove quantity limits for ondansetron tablets and ODT.
- Remove Zofran® (ondansetron) tablets, Zuplenz® (ondansetron) oral soluble films, Varubi® (rolapitant), and Cesamet® (nabilone) from the PDL. Varubi is no longer rebateable and the others have been discontinued.
- Move Palonosetron injection to preferred.
- Move Granisetron Injection to preferred.
    - Clinical criteria:
        - Update Granisetron: The patient has had a documented side effect, allergy, or treatment failure to generic ondansetron.

Public Comments: None at this time.

Board Decision: The Board unanimously approved the above recommendations.

Pulmonary Agents (will include the following class reviews: Bronchodilators: Beta Agonists, COPD Agents, Inhaled Glucocorticoids)

- No new drugs
- No other significant changes.

Recommendation:

Bronchodilators: Beta Agonists

- Remove Proventil® HFA (albuterol), Xopenex® (levalbuterol) nebulizer solution, and Albuterol ER Tablets from the PDL. They have been discontinued.
- Move Xopenex® HFA (levalbuterol) to preferred.
- Move Albuterol HFA (Teva labeler code 00093 only) to preferred.
    - Clinical criteria:
        - Revise Albuterol HFA, ProAir Digihaler: The patient has a documented side effect, allergy, or treatment failure to two preferred short acting metered dose inhalers.
        - Add Levalbuterol HFA: The patient has a documented intolerance to brand Xopenex HFA.
        - Update Levalbuterol nebulizer solution (age > 12 years): The patient must have had a documented side effect, allergy, or treatment failure to albuterol nebulizer.
        - Update Arformoterol, Brovana, Perforomist Nebulizer Solution: The patient must have a diagnosis of COPD AND The patient must be unable to use a non-nebulized long-acting bronchodilator or anticholinergic (e.g. Serevent or Spiriva) due to a physical limitation AND for approval of Brovana, Formoterol, or Perforomist, the patient must also have a documented intolerance or treatment failure with arformoterol.

COPD Agents

- Remove Lonhala® Magnair (glycopyrollate) inhalation solution from the PDL. It was discontinued.
- Update quantity limit for Incruse Ellipta to reflect 90-day maintenance supply.

Inhaled Glucocorticoids

Move Airduo Respiclick® (fluticasone/salmeterol) with QTY LIMIT: 3 inhalers/90 days to preferred.

- Add Fluticasone furoate/vilanterol (compare to Breo Ellipta®) with QTY LIMIT: 3 inhalers (180 blisters)/90 days to non-preferred.
    - Clinical criteria:

- Update AirDuo Digihaler, Breo Ellipta, Fluticasone Furoate/Vilanterol, 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, Advair Diskus, Airduo Respiclick, Dulera, or Symbicort AND for approval of Fluticasone Furoate/Vilanterol, the patient must also have a documented intolerance to Breo Ellipta.
- Update Pulmicort Respules: medical necessity for the use of a nebulized solution has been provided AND the patient has a documented intolerance to budesonide inhalation suspension AND if the dose is 1 mg, the patient must be unable to use two 0.5 mg vials AND the patient has a documented intolerance to the generic.

PDE-4 Inhibitors

- Add Roflumilast (compare to Daliresp) tablet with QTY LIMIT: 1 tablet/day to non-preferred.
  - Clinical criteria:
    - Update Daliresp, Roflumilast: The indication for the requested medication is treatment to reduce the risk of COPD exacerbations in patients with severe COPD associated with chronic bronchitis and a history of exacerbations. AND The patient has had a documented side effect, allergy, treatment failure, or a contraindication to at least one inhaled long-acting anticholinergic AND at least one inhaled long-acting beta-agonist AND at least one inhaled corticosteroid AND for approval of brand name Daliresp, the patient has had a documented intolerance to the generic equivalent.

Public Comments: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

Immunologic Therapies for Asthma

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

Recommendation:

- Move Fasenra® (benralizumab) subcutaneous Injection, pre-filled syringe and auto-injector pen with QTY LIMIT: 1 mL every 28 days for 3 doses then 1 mL every 56 days to non-preferred with grandfathering.
- Move Nucala® (mepolizumab) auto-injector pen with QTY LIMIT: 1mL every 28 days to preferred after clinical criteria are met.
  - Clinical criteria:

- Revise For approval of Cinqair or Fasenra, the patient must have a documented side effect, allergy, or treatment failure with Dupixent or Nucala. For approval of Nucala vial or prefilled syringe, the patient must be unable to use the auto-injector.
- Add for Diagnosis of hypereosinophilic syndrome (Nucala only): For continuation of therapy after the initial 6-month authorization, the patient must continue to receive background HES therapy AND there must be documented improvement in the number or frequency of HES flares.
- Update Limitations: Dupixent®, Fasenra®, Nucala® and Cinqair® will not be considered in patients with a diagnosis of moderate to severe persistent asthma who are currently smoking or in combination with omalizumab or tezepelumab.

Public Comments: Matthew Stryker from Amgen: Highlighted the attributes of Tezspire.

Board Decision: The Board unanimously approved the above recommendations.

Growth Hormones

- New drug Somapacitan-beco, the active ingredient of Sogroya®, is a human growth hormone (hGH) analog with a single substitution in the amino acid backbone (L101C) to which an albumin-binding moiety has been attached. Somapacitan-beco is produced in Escherichia coli by recombinant DNA technology. It binds to a dimeric GH receptor in the cell membrane of target cells resulting in intracellular signal transduction and a host of pharmacodynamic effects. Some of these pharmacodynamic effects are mainly mediated by insulin-like growth factor-1 (IGF-1) produced in the liver, while others are mainly a consequence of the direct effects of somapacitan-beco. It is indicated for the treatment of pediatric patients aged 2.5 years and older who have growth failure due to inadequate secretion of endogenous growth hormone (GH). Replacement of endogenous GH in adults with growth hormone deficiency (GHD). The safety and efficacy of Sogroya® were assessed in a randomized, open-label, active-controlled, parallel-group, phase 3 study conducted in treatment-naïve, pediatric patients with growth hormone deficiency. In the adult trial, treatment with Sogroya® demonstrated superiority compared to placebo in reduction in truncal fat percentage. No formal statistical comparison between Sogroya® and daily somatropin was performed in this study. There is no evidence at this time to support that Sogroya® is safer or more effective than the other currently preferred, more cost-effective medications.
- No other significant clinical changes.

Recommendation:

- Add Sogroya® (somapacitan-beco) to non-preferred.
  - Clinical criteria:
    - Add Sogroya: The patient has a documented side effect, allergy, or treatment failure to both preferred agents AND the patient has a documented side effect, allergy, or treatment failure to Skytrofa.

Public Comments: Paul Miner from Ascendis Pharmaceuticals: Highlighted the attributes of Skytrofa.

Board Discussion: Back-order supply issues persist in this class. For Genotropin the 5mg and 12mg cartridges are available, however the pens are not. Patients not already established on this medication would need an alternative. Norditropin has intermittent supply. Change Healthcare is seeing some back and forth with this but are dealing with it case by care. Non-preferred product Nutropin has limited availability, Humatrope and Omnitrope have been available, and when necessary, those have been being approved for patients.

Board Decision: The Board unanimously approved the above recommendations.

Review of Newly-Developed/Revised Criteria:

Influenza Vaccines

- https://www.cdc.gov/flu/spotlights/2022-2023/flu-vaccination-recommendations-adopted.html
- The ACIP voted that people with egg-allergy may receive any flu vaccine (egg-based or non-egg based) that is otherwise appropriate for their age and health status. Additional safety measures are no longer recommended for flu vaccination beyond those recommended for receipt of any vaccine.

Recommendation:

- Clinical criteria:
  - Update Flucelvax Quadrivalent: Prescriber provides clinical rationale why one of the preferred influenza vaccines cannot be used.

Public Comments: None at this time.

Board Decision: The Board unanimously approved the above recommendations.

General Announcements:

- None at this time

Adjourn: Meeting adjourned at 8:30 p.m.