Department of Vermont Health Access
Pharmacy Benefit Management Program
DUR Board Meeting Minutes
April 6, 2021

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

Board Members Present:

Zail Berry, MD
Andy Miller, RPh
Claudia Berger, MD
Margot Kagan, PharmD
Bill Breen, RPh
Renee Mosier, PharmD
Doug Franzoni, PharmD

Absent: Patricia King, MD, Mark Pasanen, MD, Joseph Nasca, MD

Staff:

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

Guests:

Gene Muise (Amgen)
Nicholas Boyer (Braeburn)
Adam Denman (Global Blood Therapeutics)
Bryan Dillon (Otsuka)
Patty Arcese (Amgen)
Mark Clark (Zogeniz)
Megan Mays (Eyofem Biosciences, INC)
Megan Walsh
Joseph Ward
Beth D'Ambrosio (Novartis)
Paul Isikwe (Teva Pharmaceuticals)
Zachary Spurlin (Abbvie)
Brooky Sherwood (Rockingham Health Center)
Brett White
Jim Pitt
Tammy Martin
Tom Letizia
Tricia Mulcahy
Lindsey Walter
David Large
Kelly Mroczka
Lee Marks
Margrett Glassman
Amy Conners
Kristen Chopas
Ling Ling Huang
Lisa Dunn
Linda Burns
Mark Finnegan
Hannah Parker
Robert Pearce

1. Executive Session:

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

2. Introductions and Approval of DUR Board Minutes:

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

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

- DVHA is in the process of preparing the annual CMS DUR Report. This is requirement for all states and covers Federal Fiscal Year (FFY) 2020 (10/1/19-9/30/20). It is shared publicly on the CMS website and can be used to form future policy decisions. The activity of the DUR board, prescription monitoring programs, fraud, waste, and abuse, and many other topics are included.
- DVHA will be starting to examine data for the fiscally oriented legislative "Cost Control and Best Practices" report which is due by the end of September. This focuses on trends, drug spend, and rebate.

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

- Dr. Strenio reported that he has recently been working as the part-time medical director of the Department of Corrections (DOC). His focus has been on aligning medical policies between DOC and Medicaid and facilitating a smoother provider transition when inmates are discharged.
- DVHA is reviewing the codes added during the public health emergency.
- A pilot project for providing Hepatitis C antiviral medications at HUB MAT clinics in moving forward.

6. Follow-up Items from Previous Meetings:

- **Cumulative Daily Maximum Morphine Milligram Equivalent (MME) Limits**
  In response to section 1004 of the SUPPORT Act, states must include in their DUR programs safety edit limitations identified by the state on the maximum daily MME for treatment of chronic pain and a claims review automated process, that indicates when an individual is prescribed an MME in excess of these limitations. The prospective safety edit must include a MME threshold.

Recommendation:

OPIOIDS: SHORT ACTING and OPIOIDS: LONG ACTING

- NOTE: As of 5/1/21, a completed safety checklist must be submitted for new patients exceeding 90 MME per day, and existing patients exceeding 120 MME per day (applies to any combination of short and/or long acting opiates).
  - Clinical criteria:
    - PA requests to exceed daily cumulative MME limits:
      - Non-Opioid alternatives (up to a maximum dose recommended by the FDA) and Non-Pharmacological Treatments have been considered, and any appropriate treatments are documented in the patient's medical records. Such treatments may include, but are not limited

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to: NSAIDs, Acetaminophen, Acupuncture, Chiropractic, Physical Therapy.

- Vermont Prescription Monitoring System (VPMS) has been queried.
- Patient education and informed consent have been obtained, and a Controlled Substance Treatment Agreement is included in the patient's medical record.
- A reevaluation of the effectiveness and safety of the patient's pain management plan, including an assessment of the patient's adherence to the treatment regimen is completed no less than once every 90 days.
- Patient has a valid prescription for or states they are in possession of naloxone.
- Patients in nursing homes, receiving or eligible for hospice services, or those with chronic pain associated with cancer or cancer treatment are exempt from these requirements.

Public Comment: No public comment

Board Decision: The Board unanimously approved the above recommendations with the following revisions to the safety checklist:

- If the prescriber indicates that the member resides in a nursing home, is receiving or eligible for hospice services, or has chronic pain associated with cancer or cancer treatment, the remainder of the safety checklist does not need to be completed.
- Replace "drug requested" with "opioid regimen."

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

- Introduction of RetroDUR: Influenza Vaccination Rates

Immunization guidelines published by the CDC recommend that everyone above the age of 6 months receive influenza vaccinations yearly unless there is a history of severe reactions to previous flu shots. Even those with egg allergies are eligible to get the vaccines, contrary to popular belief. Influenza is responsible for many thousands of deaths annually, including among children and those with chronic illnesses. It is somewhat surprising that more people are not immunized, given the many avenues available for immunization, including pharmacies, work sites, sponsored clinics, and PCP/medical specialty offices. While children are often the highest group affected by flu every year, immunization rates are lower than recommended. The federal government has the goal of vaccinating 70% of the population every year, however the data shows that less than half of Americans get the flu vaccine every year. Change Healthcare will use paid, non-reversed Medicaid pharmacy and medical claims from SFY 2019-2020 (pre-COVID), excluding members with Part D, VMAP and Healthy Vermonters coverage. They will

look at all medical and pharmacy claims for influenza vaccines for members who were eligible for vaccination in 2019 and determine the rate of vaccination for the 2019-20 flu season. Additionally, they will look at those who were prescribe oseltamivir, amantadine, rimantadine, zanamivir and baloxavir in the 2018-2019 flu season, to see if previous infection had any effect on improving vaccination rates compared to the general Medicaid population. They will also look at two high risk groups, children with asthma and adults with COPD, to see if there was a better vaccination rate given the higher likelihood of severe infection and death.

Recommendation: None at this time.

Public Comment: No public comment.

Board Decision: None needed.

- Data presentation: Sublocade Adherence

Opioid abuse and addiction are catastrophic realities in the US today. Fueled by the overuse of prescription pain medication, attempts at overcoming addiction with behavior modification and counseling alone have been disappointing. The reality is that most people who are addicted to opiates will need pharmacologic treatment with opiate agonists and/or antagonists, many for an indefinite period of time. It is best if pharmacologic therapy is coupled with counseling, however there are often not enough of those resources available in many communities. In those who are physiologically dependent on opiates, medically supervised withdrawal usually requires follow up with medication-assisted treatment (MAT) to prevent relapse. Medication consists of treatment with an opioid agonist(methadone), antagonist(naltrexone), or a partial agonist (buprenorphine with or without naloxone). Experts in the field of opioid addiction tend to prefer buprenorphine as first line treatment, due to ease of administration, safety, and ability to be given in both oral and subcutaneous formulations. Oral and IM naltrexone are reserved generally for the more mildly addicted users, who may be successful with an opioid antagonist. Currently the oral film, Suboxone®, is the most commonly prescribed MAT medication for Vermont Medicaid patients. Sublocade®, the SC formulation of buprenorphine, can be successful for some patients who have unique challenges, such as homelessness, those struggling with poor adherence, theft, or poor social supports. Sublocade® while more convenient for some, is significantly more expensive and therefore is listed as a non-preferred medication on the PDL and requires a PA for approval. This analysis intends to evaluate the clinical rationale for prescribing and measure the compliance and adherence rates for patients prescribed Sublocade® in the Vermont Medicaid population. Change Healthcare examined the number of members on all forms of MAT, including buprenorphine tablets, buprenorphine/naltrexone tablets, Suboxone® film, Sublocade® injection, and naltrexone (oral and IM). Of those on Sublocade®, they identified the reasons they were prescribed Sublocade® instead of a more cost-effective sublingual buprenorphine formulation. They also looked at

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compliance to see if members continued to receive monthly injections, if they switched back to oral forms of buprenorphine, or if they stopped MAT completely.

Only 44 members were prescribed Sublocade® representing less than 1% of all MAT prescriptions. Of those, 1/3 received only 1 or 2 doses. There were only 9 members who had a full year of Sublocade® within the time frame measured, but there were several members who were started during the year and were compliant with monthly injection schedule. Also of note, 4 patients temporarily switched from Sublocade® to Suboxone® due to pandemic concerns but were converted back to Sublocade®.

Reasons identified for starting Sublocade®: Drug Diversion: 20/44 (45.5%), Drug Adherence: 15/44 (34.1%), Drug Theft: 5/44 (11.4%), Trigger: 2/44 (4.5%), Other 2/44 (4.5%).

Reasons identified for discontinuing Sublocade®: Still on Sublocade®: 25/44 (56.8%), Unknown (no explanation): 15/44 (34.1%), Preference: 1/44 (2.3%), Transport Issue: 2/44 (4.5%), Other: 1/44 (2.3%).

It is speculated that those who stopped Sublocade® and did not continue MAT may have discontinued it due to relapse. Alternatively, some of these patients may have been referred to a HUB for methadone treatment. Often those who started Sublocade® were in situations where their attempt at abstinence was being impacted by theft of Suboxone® or medication diversion. Many members on Suboxone® had trouble with adherence, and many of those members were successfully compliant with monthly Sublocade® injections.

Recommendation: Due to a significant percentage of non-compliance and early termination of treatment, in addition to a very high net cost to Medicaid, we recommend continuation of prior authorization with current PA criteria.

Public Comment: Brooky Sherwood RN/CARN, Rockingham Health Center discussed the advantages of Sublocade she has seen in practice. In some patients, she noted the ability to change patterns of sobriety compared to other MAT therapy. She also feels, anecdotally, that it is easier to taper off medication. She would like to see PA criteria loosened to provide more access.

Board Decision: The Board unanimously approved the above recommendation.

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

Biosimilar Drug Reviews:

- None at this time.

Full New Drug Reviews:

- Armonair Digihaler® (fluticasone propionate)

Fluticasone propionate, the active ingredient of Armonair® Digihaler, is a synthetic trifluorinated corticosteroid with anti-inflammatory activity. Inflammation is an important component in the pathogenesis of asthma. Corticosteroids have been shown to have a wide range of actions on multiple cell types (e.g. mast cells, eosinophils) and mediators (e.g. histamine, eicosanoids, leukotrienes, and cytokines) involved in inflammation. These anti-inflammatory actions of corticosteroids contribute to their efficacy in the treatment of asthma. It is indicated for the maintenance treatment of asthma as prophylactic therapy in patients 12 years of age and older. Armonair® Digihaler is not indicated for the relief of acute bronchospasm. The safety and efficacy of fluticasone propionate (Armonair® Respiclick) were assessed in 2130 patients with asthma. Armonair® Digihaler includes a QR code (on the top of the inhaler) and contains a built-in electronic module which automatically detects, records, and stores data on inhaler events, including peak inspiratory flow rate (L/min). Armonair® Digihaler may pair with and transmit data to the mobile app where inhaler events are categorized. There is no evidence the use of the app leads to improved clinical outcomes, including safety and effectiveness. Use of the app is not required for administration of fluticasone propionate to the patient.

- Airduo Digihaler® (fluticasone propionate and salmeterol)

AirDuo® Digihaler is a combination product containing fluticasone (a synthetic corticosteroid with anti-inflammatory activity) and salmeterol (a long-acting beta2-adrenergic agonist or LABA, causing relaxation of bronchial smooth muscle and inhibition of release of mediators of immediate hypersensitivity from cells, especially from mast cells). It is indicated for the treatment of asthma in patients aged 12 years and older. It should be used for patients not adequately controlled on a long-term asthma control medication such as an inhaled corticosteroid or whose disease warrants initiation of treatment with both an inhaled corticosteroid and long acting beta2-adrenergic agonist (LABA). AirDuo® Digihaler is not indicated for the relief of acute bronchospasm. AirDuo® Digihaler contains a built-in electronic module. It includes a QR code (on the top of the inhaler), and contains a built-in electronic module which automatically detects, records, and stores data on inhaler events, including peak inspiratory flow rate (L/ml). AirDuo® Digihaler may pair with and transmit data to the mobile app, where inhaler events are categorized. There is no evidence the use of the app leads to improved clinical outcomes, including safety and effectiveness. Use of the app is not required for administration of fluticasone propionate and salmeterol to the patient. The safety and efficacy of fluticasone propionate and salmeterol inhalation powder (AirDuo® Respiclick) were assessed in 3004 patients with asthma. The development program included 2 confirmatory trials of 12 weeks in duration, a 26-week safety trial, and 3 dose-ranging trials. The efficacy of AirDuo® Digihaler is based primarily on the dose-ranging trials and the confirmatory trials of AirDuo® Respiclick. AirDuo® Respiclick has been available for numerous years and has been found to be a safe and effective product.

Recommendation:

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- Add Armonair® Digihaler (fluticasone propionate) with QTY LIMIT = 3 inhalers/90 days to non-preferred. Add AirDuo® Digihaler (fluticasone/salmeterol) with QTY LIMIT: 3 inhalers/90 days to non-preferred.
    - Clinical criteria:
        - Add AirDuo Digihaler to the AirDuo Respiclick, Breo Ellipta, Fluticasone/Salmeterol (non-authorized generics) clinical criteria.

Public Comment: Paul Isikwe from Teva Pharmaceuticals: Highlighted the attributes of Armonair® and AirDuo® Digihaler.

Board Decision: The Board unanimously approved the above recommendations.

- Alkindi® (hydrocortisone oral granules)

Hydrocortisone, the active ingredient of Alkindi® Sprinkle, is a corticosteroid, also known as cortisol. Hydrocortisone is a glucocorticoid, which cause varied metabolic effects. In addition, it modifies the body's immune responses to diverse stimuli. Naturally occurring glucocorticoids, such as hydrocortisone and cortisone, which also have salt-retaining properties, are used as replacement therapy in adrenocortical deficiency states. It is indicated as replacement therapy in pediatric patients with adrenocortical insufficiency. There are no clinical trials included in the prescribing information for this product. Following oral administration, a dose of four Alkindi® Sprinkle 5mg capsules was about 87% bioavailable when compared to IV hydrocortisone in dexamethasone-suppressed healthy adult male volunteers. In an open-label, single-dose study in 24 pediatric patients with adrenocortical insufficiency, Alkindi® Sprinkle (1-4mg based on body surface area) increased cortisol levels from baseline to median cortisol level 19.4mcg/dl (range 12.5-52.4mcg/dL) at Cmax (60 minutes post-dose). It is the first and only FDA-approved granular hydrocortisone formulation intended for children for adrenocortical insufficiency. Generic oral hydrocortisone tablets are available.

- Hemady® (dexamethasone)

Dexamethasone, the active ingredient of Hemady®, is a corticosteroid with anti-inflammatory effects and low mineralocorticoid activity. The exact mechanism of action for its approved indication is not known. Dexamethasone induces apoptosis of multiple myeloma cells. It is indicated in combination with other anti-myeloma products for the treatment of adults with multiple myeloma (MM). There were no clinical trials listed in the Hemady® prescribing information. Following oral administration of a single dose of dexamethasone tablet to healthy subjects, the decrease in mean baseline cortisol concentration was maximal by 12 hours post-dose, with mean cortisol concentrations returning to near baseline about 3 days after drug administration. Hemady® is an oral dexamethasone 20mg tablet indicated in combination with other anti-myeloma products for the treatment of adults with multiple myeloma. Generic dexamethasone tablets are available in lower strengths than Hemady®. There is no evidence to suggest that Hemady® is safer or more effective than the other currently preferred, more cost-effective medications.

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Recommendation:

- Add Alkindi® Sprinkle (hydrocortisone) granule to non-preferred.
- Add Hemady® (dexamethasone) tablets to non-preferred.
- Remove Millipred® (prednisolone) tablets, Millipred® (prednisolone sodium phos) oral solution, Millipred DP® (prednisolone) dose pack tablets, Orapred® oral solution (prednisolone sod phos), Orapred® ODT (prednisolone sod phos), and Cortisone acetate tablets from the PDL.
    - Clinical criteria:
        - The patient has a documented side effect, allergy, or treatment failure to at least two preferred medications. If a product has an AB rated generic, one trial must be the generic formulation

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

- Fintepla® (fenfluramine)

The exact mechanism of action of fenfluramine, the active ingredient of Fintepla®, is not known. Fenfluramine and its metabolite, norfenfluramine, increase extracellular levels of serotonin through interaction with serotonin transporter proteins, and exhibit agonist activity at serotonin 5HT-2 receptors. It is indicated for the treatment of seizures associated with Dravet syndrome in patients 2 years of age and older. The safety and efficacy of Fintepla® for the treatment of seizures associated with Dravet syndrome in patients 2 years of age and older were assessed in two randomized, double-blind, placebo-controlled studies. It is a Schedule IV controlled substance, and it is has a box warning regarding increased risk of valvular heart disease and pulmonary arterial hypertension. Cardiac monitoring is required before, during, and after treatment. Due to these risks, Fintepla® is available only through a restricted program under a REMS called the Fintepla® REMS. In clinical trials, the reduction in convulsive seizure frequency per 28 days was statistically significantly greater for all doses of Fintepla® as compared with placebo. Comparator studies with active treatments were not found.

Recommendation:

- Add Fintepla® (fenfluramine) oral solution to non-preferred.
    - Clinical criteria:
        - Add Fintepla: Diagnosis or indication is treatment of Dravet Syndrome AND patient has had a documented side effect, allergy, treatment failure/inadequate response or a contraindication to at least two preferred anticonvulsants and Epidiolex AND prescriber, pharmacy, and patient are registered with the REMS program AND for reapproval, the patient must have a documented decrease from baseline in seizure frequency per 28 days.

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Public Comment: Matthew Clark from Zogenix: Highlighted the attributes of Fintepla.

Board Decision: The Board unanimously approved the above recommendations.

- Ongentys® (opicapone)

Opicapone, the active ingredient of Ongentys®, is a peripheral, selective, and reversible catechol-O-methyltransferase (COMT) inhibitor. COMT catalyzes the transfer of the methyl group of S-adenosyl-L-methionine to the phenolic group of substrates that contain a catechol structure. Physiological substrates of COMT include catecholamines (dopamine, norepinephrine, and epinephrine) and their hydroxylated metabolites. When decarboxylation of levodopa is prevented by carbidopa, COMT becomes the major metabolizing enzyme for levodopa, catalyzing its metabolism to 3-methoxy-4-hydroxy-L-phenylalanine (3-OMD). It is indicated as adjunctive treatment to levodopa/carbidopa in patients with Parkinson's disease (PD) experiencing 'off' episodes. The efficacy of Ongentys® for the adjunctive treatment to levodopa/carbidopa in patients with PD experiencing 'off' episodes was assessed in two double-blind, randomized, parallel-group studies of 14 to 15 weeks in duration, with study 1 being placebo- and active-controlled and study 2 being placebo-controlled. In two phase 3 studies, Ongentys® significantly reduced mean absolute OFF-time as compared with placebo. In addition, both studies assessed ON-time without troublesome dyskinesia as a secondary efficacy endpoint. Only study 1 reported statistically significantly differences with Ongentys® compared with placebo, while results from study 2 were not statistically significant between Ongentys® and placebo. In addition, study 1 included an active comparator. In the full-text study by Ferreira2, adults were randomized to Ongentys® and placebo as well as entacapone (200mg with every levodopa intake; N=120). The primary endpoint of the least-squares mean change from baseline in absolute time in the off state was -1.605 in the entacapone group. Opicapone 50mg was superior to placebo and non-inferior to entacapone. Entacapone was also superior to placebo. In addition, the % of patients with a reduction of ≥1 hour in time in the off state was 70% with Ongentys® 50mg and 58% with entacapone 200mg, which was not significantly different (p=0.063). For the placebo group, the % of patients was 48%. Opicapone was significantly different from placebo (p=0.001) but entacapone was not significantly different from placebo (p=0.094).

Recommendation:

- Add Ongentys® (opicapone) to non-preferred.
  - Clinical criteria
    - Add Ongentys: The diagnosis or indication is Parkinson's disease AND The patient has had a documented side effect, allergy, or treatment failure with entacapone.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

- Phexxi ® (lactic acid, citric acid, potassium bitartrate)

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In vitro studies demonstrated that a pH lowering effect and sperm motility reduction contributed to the activity of Phexxi® in the vagina. Pharmacokinetic studies have not been performed. It is indicated for the prevention of pregnancy in females of reproductive potential for use as an on-demand method of contraception. Phexxi® is not effective for the prevention of pregnancy when administered after intercourse. The efficacy of Phexxi® for the prevention of pregnancy was assessed in a multicenter, open-label, single-arm study in the United States. Phexxi® is a first in its class, being a non-hormonal agent available via prescription that works immediately for the prevention of pregnancy. Phexxi® should be avoided with a vaginal ring. In an open-label, single-arm study, the 7-cycle cumulative pregnancy rate of Phexxi® was 13.7% and the estimated Pearl Index, calculated based on data from the 7-cycle study, was 27.5. To provide some basis for comparison, another contraceptive method, the Annovera® vaginal ring that contains segesterone acetate and ethinyl estradiol, has an overall unintended pregnancy rate (Pearl Index) of 2.98 per 100 woman-years2 and condoms are generally cited as having a Pearl Index of 3-123.

Recommendation:

- Add Phexxi™ (lactic acid, citric acid, and potassium bitartrate) vaginal gel to non-preferred. Add a new sub-category Vaginal Gel. Add link to the DVHA website for covered OTC spermicidal gels.
    - Clinical criteria:
        - Add Phexxi: Use of hormonal contraceptives is contraindicated AND the patient has a documented side effect or allergy to nonoxynol-9.

Public Comment: Megan Mays from Evofem Biosciences: Highlighted the attributes of Phexxi Vaginal Gel.

Board Decision: The Board unanimously approved the above recommendations.

- Twirla® (levonorgestrel and ethinyl estradiol)

Combined hormonal contraceptives (CHCs) lower the risk of becoming pregnant primarily by suppressing ovulation. Twirla® is a combination of levonorgestrel (a progestin) and ethinyl estradiol (an estrogen). It is indicated as a method of contraception for use in women of reproductive potential with a BMI <30 kg/m2 for whom a combined hormonal contraceptive is appropriate. The efficacy of Twirla® was assessed in one open-label, single arm, multicenter study in the U.S. that included women ranging in age between 18 to 60 years (N=2,031) who were healthy and sexually active with regular menstrual cycles. Consider the reduced effectiveness of Twirla® in women with a BMI ≥25 to <30kg/m2 before prescribing Twirla®. Twirla® is contraindicated in women with a BMI ≥30kg/m2. In an open-label, single-arm study that included healthy and sexually active women aged 18 to 35 years, the overall Pearl Index was 5.8; however, there were clear differences in efficacy by BMI category. The Pearl Index for women with a BMI <25kg/m2 was 3.5. There was an increase in pregnancy rate as BMI increased based on the primary analysis population (N=1,735).

Recommendation:

- Add Twirla® (levonorgestrel/ ethinyl estradiol) patch to non-preferred.
  - Clinical criteria:
    - Add Twirla: Trial with at least three preferred contraceptive products including the preferred formulation of the requested non-preferred agent.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

- Xywav® (calcium, magnesium, potassium, & sodium oxybates solution)

Xywav® is a CNS depressant that contains a mixture of calcium oxybate, magnesium oxybate, potassium oxybate, and sodium oxybate. The chemical name of oxybate is gamma-hydroxybutyrate (GHB), which is an endogenous compound and metabolite of the neurotransmitter GABA. The exact mechanism of action for its approved indication is not known, but it is hypothesized that the therapeutic effects of Xywav® are mediated through $GABA_B$ actions during sleep on noradrenergic and dopaminergic neurons, as well as at thalamocortical neurons. It is indicated for the treatment of cataplexy or excessive daytime sleepiness (EDS) in patients 7 years of age and older with narcolepsy. The efficacy of Xywav® for the treatment of cataplexy and excessive daytime sleepiness in adults with narcolepsy was established in a double-blind, placebo-controlled, randomized-withdrawal study. This study had two parts, consisting of the main study followed by an optional 24-week open label extension (OLE). The main study consisted of a 12-week open label optimized treatment and titration period, followed by a 2-week stable dose period and finally a 2-week double blind randomized-withdrawal period (DB RWP). It is a Schedule III controlled substance. Due to the risks of CNS depression, as well as abuse and misuse discussed in the box warning, Xywav® is available only through a restricted program under a REMS called the Xywav® and Xyrem® REMS. Per the manufacturer, Xywav® has 92% less sodium than sodium oxybate in each nightly dose. Xyrem® has the same indication as Xywav® but has a higher salt content. The amount of daily sodium intake in each dose of Xyrem® should be considered in patients sensitive to high salt intake, such as those with heart failure, hypertension, or renal impairment. Results of a clinical trial in adults indicated that patients taking stable doses of Xywav® who discontinued Xywav® treatment and were randomized to placebo during the double-blind, randomized-withdrawal period experienced a significant worsening in the average weekly number of cataplexy attacks and in ESS score as compared with patients randomized to continue treatment with Xywav®. The efficacy of Xywav® in pediatric patients is based upon a clinical study in patients treated with Xyrem®.

Recommendation:

- Add Xywav™ (calcium, magnesium, potassium, and sodium oxybates) solution with QTY LIMIT: 9 g (18 mL)/day non-preferred.

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- Clinical criteria
    - Revise Xyrem, Xywav: indication for use is the treatment of cataplexy or excessive daytime sleepiness in narcolepsy AND patient has had a documented side effect, allergy, or treatment failure to 2 preferred agents (may be stimulant or non-stimulant) and Sunosi AND patient has been enrolled in the REMS program AND for approval of Xywav, the patient must have a documented intolerance to Xyrem.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

9. New Therapeutic Drug Classes

- None at this time.

10. Therapeutic Drug Classes- Periodic Review:

- **Angiotensin Modulators and Heart Failure Agents**
    - Merck's Verquvo® (vericiguat) was approved in January 2021 for reduction of risk of cardiovascular death and heart Failure (HF) hospitalization following a hospitalization for HF or need for outpatient intravenous diuretics in adults with symptomatic chronic heart failure and ejection fraction less than 45%. It is the first soluble guanylate cyclase stimulator approved to treat HF. Its place in therapy is not yet defined. A New Drug Review for this medication will take place at a future DUR meeting.
    - No new significant clinical changes.

Recommendation:

ACE INHIBITOR/CALCIUM CHANNEL BLOCKER COMBINATIONS

- Remove Prestalia (perindopril/amlodipine) from the PDL.

ANGIOTENSIN RECEPTOR BLOCKERS (ARBs)

- Remove Eprosartan from the PDL.

ANGIOTENSIN RECEPTOR BLOCKER/DIURETIC COMBINATIONS

- Add OLMESARTAN/HYDOCHLOROTHIAZIDE (compare to Benicar HCT®) to preferred.

ANGIOTENSIN RECEPTOR BLOCKER/CALCIUM CHANNEL BLOCKER/HCTZ COMBO

- Add Olmesartan/amlodipine/hydrochlorothiazide (compare to Tribenzor®) QTY LIMIT: 1 tablet/day to non-preferred.

ANGIOTENSIN RECEPTOR BLOCKER/MISCELLANEOUS COMBINATIONS

- Remove Byvalson® (Nebivolol/Valsartan) and the category from the PDL.

Public Comments: Beth D'Ambrosio from Novartis: Highlighted the attributes of Entresto®.

Board Decision: The Board unanimously approved the above recommendations.

- **Beta-Blockers, Anti-Anginal, and Sinus Node Agents**
  - No new drugs.
  - No new significant clinical changes.

Recommendation:

ANTI-HYPERTENSIVES BETA BLOCKERS

- Move Nadolol to preferred.
- Remove Corzide® (nadolol/bendroflumethiazide) from the PDL.

CORONARY VASODILATORS/ANTIANGINALS/SINUS NODE INHIBITORS- ORAL

- Move Ranolazine tablet (compare to Ranexa®) with QTY LIMIT: 500 mg = 3 tablets/day, 1000 mg = 2 tablets/day to preferred.
- Remove NITROMIST® Lingual Spray form the PDL.
  - Clinical criteria:
    - Revise Ranexa: the patient has a documented intolerance to the generic equivalent.

Public Comments: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

- **Calcium Channel Blockers**
  - No new drugs.
  - No new significant clinical changes.

Recommendation:

- Remove Adalat® CC (nifedipine SR) and Calan® (verapamil) from the PDL.

Public Comments: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

- **Anti-Migraine Agents, Triptans & CGRP Antagonists**
  - No new drugs.
  - No new significant clinical changes.

Recommendation:

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- Add Sumatriptan/Naproxen (compare to Treximet®) with *QTY LIMIT:* 9 tablets/30 days to non-preferred.
    - Clinical Criteria:
        - Add sumatriptan/naproxen to Treximet: patient had a documented side effect, allergy, or treatment failure with 2 preferred triptans AND the patient is unable to take the individual components separately.

Public Comments: Paul Isikwe from Teva: Highlighted the attributes of Ajovy. Zach Spurlin from Abbvie: Highlighted the attributes of Ubrelvy.

Board Decision: The Board unanimously approved the above recommendations.

- **Bile Salt Agents**
    - No new drugs.
    - No new significant clinical changes.

Recommendation:

- Move Ursodiol tablets to non-preferred.
    - Clinical criteria:
        - Add ursodiol tablets to Urso, Urso Forte, Actigall: the patient must have a documented treatment limiting side effect to generic ursodiol capsules.

Public Comments: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

- **Botulinum Toxins**
    - No new drugs.
    - New indications and expanded age ranges for existing indications are frequent.

Recommendation:

- Add a note that all products require PA.
- Clinical criteria:
    - Revise Criteria for approval of ALL drugs: The medication is being prescribed for an FDA approved indication AND the patient's age is FDA approved for the given indication AND the patient meets the following additional criteria (if applicable). Initial approval will be granted for 3 months unless otherwise noted. For re-approval, the patient must have documented improvement in symptoms.
    - Additional criteria for Severe Axillary Hyperhidrosis (Botox only): the patient failed an adequate trial of topical therapy.

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- Additional criteria for Overactive bladder or detrusor overactivity (Botox only): the patient failed an adequate trial of at least TWO urinary antispasmodics (either short- or long-acting formulations)
- Additional criteria for Chronic migraine (Botox only): the patient has ≥ 15 headache days per month, of which ≥ 8 are migraine days, for at least 3 months AND the member has failed or has a contraindication to an adequate trial of at least TWO medications for migraine prophylaxis from at least two different classes (tricyclic antidepressants, SNRI's, beta-blockers, or anticonvulsants). Initial approval will be granted for 6 months. For re-approval after 6 months, the patient must have documentation of a decrease in the number of headache days per month or decreased use of acute migraine medications such as triptans.
- Additional criteria for chronic sialorrhea (Myobloc and Xeomin): the patient has a documented side effect, allergy, treatment failure, or contraindication to at least two anticholinergic agents (e.g. scopolamine, glycopyrrolate).

Public Comments: No public comment

Board Decision: The Board unanimously approved the above recommendations.

- **Hepatitis C Treatments**
  - No new drugs, however pediatric formulations are now available for Harvoni® and Epclusa®.
  - The US CDC now recommends one-time hepatitis C testing of all adults (18 years and older) and all pregnant women during every pregnancy. The CDC continues to recommend people with risk factors, including people who inject drugs, be tested regularly. The CDC also recommends that any person who requests hepatitis C testing should receive it regardless of disclosure of risk.
  - This clinical area has been rapidly changing, and fortunately an evidence-based guideline has been promulgated jointly by the Infectious Disease Society of America (IDSA) and the American Association for the Study of Liver Disease (AASLD) and is updated frequently. The newest version of the guidelines just changed in late January of 2021 and is available at: http://www.hcvguidelines.org
  - Simplified pangenotypic treatment regimens exist for adults with chronic hepatitis C (any genotype) who do not have cirrhosis and have not previously received hepatitis C treatment. The recommended regimens are Glecaprevir (300 mg) / pibrentasvir (120 mg) to be taken with food for a duration of 8 weeks or Sofosbuvir (400 mg) / velpatasvir (100 mg) for a duration of 12 weeks.

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Recommendation:

- Move Epclusa® (sofosbuvir/velpatasvir) to non-preferred.
- Move SOFOSBUVIR/VELPATASVIR (compare to Epclusa®) to preferred.
- Remove RIBASPHERE 200 mg tabs, Moderiba® tablets Dose Pak (ribavirin), Ribapak Dose Pack® (ribavirin), Ribasphere 400 and 600 mg tabs (ribavirin), Pegasys Proclick (peginterferon alfa-2a), Daklinza® (daclatasvir), and PEG-INTRON REDIPEN PAK 4 (peginterferon alfa2b) from the PDL.

Public Comments: Zach Spurlin from Abbvie: Highlighted the attributes of Mayvret.

Board Decision: The Board unanimously approved the above recommendations.

- **Lipotropics, Other (Non-Statins)**
  - No new drugs.
  - No other significant clinical changes.

Recommendation:

LIPOTROPICS- BILE ACID SEQUESTRANTS
Move Prevalite powder (cholestyramine light) and powder packs to non-preferred.

LIPOTROPICS- FIBRIC ACID DERIVATIVES

- Remove Fibricor® (fenofibric acid) 35 mg, 105 mg and Triglide® (fenofibrate) 50 mg, 160 mg from the PDL.

MISC. HOMOZYGOUS FAMILIAL HYPERCHOLESTEROLEMA (HoFH) AGENTS

- Revise clinical criteria:
  - Juxtapid: Total cholesterol and LDL-C > 600 mg/dL and TG within reference range or Confirmation of diagnosis by gene testing AND Documented adherence to prescribed lipid lowering medications for the previous 90 days AND Recommended or prescribed by a lipidologist or Cardiologist AND Inability to reach goal LDL-C despite a trial of 2 or more maximum tolerated dose of statins (one of which must be atorvastatin or rosuvastatin), ezetimibe 10mg daily, and Repatha

Public Comments: Gene Muise from Amgen: Highlighted the attributes of Repatha (evolocumab).

Board Decision: The Board unanimously approved the above recommendations.

- **Lipotropics, Statins**
  - No new drugs.

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- No other significant clinical changes.

Recommendation:

STATINS

- Move Crestor® (rosuvastatin) to non-preferred.
- Update Note: All preferred agents have a quantity limit of 1 tablet/day except Lovastatin 40mg which has a quantity limit of 2 tablets/day.

MISCELLANEOUS/COMBOS

- Clinical criteria:
  - Update Vytorin, ezetimibe/simvastatin: The patient must be unable to use the individual separate agents AND If the request is for Vytorin 10/80, the patient has been taking this dose for 12 or more months without evidence of muscle toxicity.

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- Clinical criteria:
  - Revise age limits to state: The patient's age is FDA approved for the given indication.

Public Comments: no public comments.

Board Decision: The Board unanimously approved the above recommendations.

11. Review of Newly Developed/Revised Criteria

- None at this time.

12. General Announcements:

- None at this time.

13. Adjourn: Meeting adjourned at 8:46 p.m.

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