Department of Vermont Health Access
Pharmacy Benefit Management Program
DUR Board Meeting Minutes
December 1, 2020

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

Board Members Present:

Zail Berry, MD
Marc Pasanen, MD
Andy Miller, RPh
Margot Kagan, PharmD
Bill Breen, RPh
Claudia Berger, MD
Doug Franzoni, PharmD
Patricia King, MD
Renee Mosier, PharmD
Joseph Nasca, MD

Absent: N/A

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
Marietta Scholten, MD, DVHA

Guests:

Kevin Black (SK Life Science,Inc)
Karen Szydlik (Allergan/Abbvie)
Frank Lanotte (GlaxoSmithKline)
Gene Muise (Amgen)
Nicholas Boyer (Braedurn)
Kristen DiDesidero (Takeda)
Afraim Botros (Bristol Meyers Squibb)
Tom Seignious (Arbor Pharamaceuticals)
Lisa Kunze (Greenwich Biosciences)
Michaela Hedberg (Indivior)
Nicholas Primpas (Indivior)
Adam Denman (Global Blood Therapeutics)
Bryan Dillon (Otsuka)
Megan Walsh (Abbvie)
Patty Arcese (Amgen)
Franco Casagrande (Abbvie)
Beth D'ambrosio (Novartis)
Eric Sherr (Viiv)
John Jocye (Boehringer Ingelheim)
Nikhil Kacker (Genetech)
Jeffrey Olson
Susan Donnelly
Erin Booth
Matthew Wright
Teri Peck
Andrea Wilson
Brian Calaman
Brian Hall
Linda Burn

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 as printed.

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

- Introduced Marietta Scholten, MD, DVHA the associate medical director. Dr. Scholten will be filling in for Dr. Strenio at the DURB Meetings.

4. Medical Director Update: Marietta Scholten, MD, DVHA

- Dr. Scholten provided a brief background on her professional experience. She has been working with DVHA since 2008 in many capacities including VCCI and as the Associate Medical Director. She is a board-certified family medicine physician and hospice medical director.

6. Follow-up Items from Previous Meetings:

- None at this time.

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

- Introduction of RetroDUR: 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 the majority of 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 medically assisted treatment to prevent relapse. Medication consists of treatment with an opioid agonist, antagonist, or a combination. Commonly used drugs are buprenorphine (with or without naltrexone), methadone and naltrexone. 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 are more successful at abstinence. Currently the oral film, Suboxone®, is the most commonly prescribed MAT medication. Sublocade®, the SC formulation of buprenorphine, is recommended when there is continued use of illicit opioids while the person is prescribed sublingual buprenorphine. Sublocade®, while more convenient, and preferred by some people, is more expensive and therefore limited in use as a non-preferred medication on the PDL and requiring a PA for approval.

Change Healthcare will use paid, non-reversed Medicaid pharmacy and medical claims from SFY 2020, excluding members with Part D, VMAP and Healthy Vermonters coverage. They will look at 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 will identify the reasons they were prescribed Sublocade® instead of a more cost-effective sublingual buprenorphine formulation. They will

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

Recommendation: None at this time.

Public Comment: No public comment.

Board Decision: None needed.

- Data presentation: PDL COMPLIANCE

Social Security Act 1927 allows states to maintain Preferred Drug lists to maximize savings while at the same time guaranteeing access and quality. The criteria used to determine authorization for non-preferred drugs is transparent and vetted through the state Drug Utilization Review Board (DURB) and available publicly. In Vermont, the DURB serves a dual purpose. One is the drug utilization review component whereby the Board applies criteria and standards in the application of DUR activities, reviews and reports the results of DUR activities performed by DVHA and/or proposes recommended intervention programs such as educational outreach. The second portion of the DUR Board is the P&T Committee role whereby the board provides guidance on the development of the PDL for DVHA beneficiaries and performs new drug reviews focused on clinical efficacy, safety and cost. Together these functions result in more clinically appropriate prescribing and savings to Vermont's pharmacy benefit program.

Criteria for prescribing non-preferred medications are posted on the PDL. The PDL is not meant to be burdensome for providers. A well- constructed PDL should allow for prescribing of appropriate medications in most circumstances without requiring prior authorization of non-preferred medications. Evaluating the compliance with prescribing of preferred medications is a way to evaluate the rigor and adherence to criteria of the PA process. Additionally, if the PA process is sound, and many members are getting non-preferred medications appropriately, it may indicate a need to reevaluate the medication class and possible reorganization of preferred and non-preferred drug categorizations. States strive to stay current with new drugs and new indications for established medications, making PDLs fluid documents that change regularly. Auditing compliance of major drug classes is a way to monitor performance of pharmacy benefit management.

Change Healthcare used paid, non-reversed Medicaid pharmacy claims from 1Q2020 (1/1/20-3/31/20), excluding members with Part D, TPL, VMAP, and Healthy Vermonters coverage. They evaluated the following categories to see how often the dispensed medication was preferred.

Asthma: Inhaled Corticosteroids (alone and in combination with a LABA)
Diabetes mellitus: incretin mimetics (GLP1 agonists and DPP-4 inhibitors)
Stimulants
MAT therapy (Buprenorphine and buprenorphine/naloxone)

Prescribing of preferred agents exceeded 90% for the following therapeutic classes: inhaled corticosteroids, combination corticosteroid/LABA (sympathomimetics), stimulants, and DPP-4 Inhibitors. Prescribing of preferred agents was lower for MAT therapy (opioid partial agonists) and GLP-1 receptor agonists, 87% and 65% respectively.

The most frequently prescribed non-preferred medications were buprenorphine/naloxone tablets, buprenorphine (mono) tablets, Trulicity®, Ozempic®, and various formulations of methylphenidate (SR tablets having the highest claim count). Whenever a product has been moved to non-preferred within the stimulant class, all patients on the existing therapy have been "grandfathered." This allows the patient to continue therapy with the non-preferred medication without a rejection at the pharmacy, and no prior authorization needs to be completed by the prescriber. PA's would only need to be submitted for patients new to therapy. Utilization shifts to preferred products occur naturally over time, but it is expected that use of non-preferred products will remain high after a recent change. Examples include Daytrana® patch and methylphenidate chew tabs which moved to non-preferred 1/1/20.

Recommendation: Evaluation of Ozempic® and Trulicity® prescribing and clinical outcomes data was performed during the May 2020 DUR Board meeting. It was clear that providers were seeking a once-weekly GLP-1 RA with cardiovascular outcomes data, and Trulicity® was the most cost-effective option for DVHA. Trulicity® injection was therefore moved to preferred, effective 6/5/2020. The GLP-1 RA therapeutic class should be re-evaluated in 6mos-1 year to assess the impact of the PDL change.

Changes in net cost for Buprenorphine/naloxone tablets allowed DVHA to make them preferred in August 2020. We looked at the 20 prescribers that were identified as having > 100 claims with < 80% of these being preferred. For 3 of these prescribers, buprenorphine/naloxone tablets were the most frequently prescribed non-preferred medication. 1 prescriber, practicing at Brattleboro Retreat, frequently used non-preferred stimulants. 1 prescriber, a pulmonologist, frequently used non-preferred corticosteroid/LABA products. Buprenorphine mono tablets were prescribed in some capacity by the remaining prescribers. Further evaluation may be warranted.

Public Comment: No public comment.

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:

- Arazlo® lotion (tazarotene)

Tazarotene, the active ingredient of Arazlo®, is a member of the acetylenic class of retinoids. It is a retinoid prodrug that is converted to its active form, tazarotenic acid, the carboxylic acid of tazarotene, by de-esterification. Tazarotenic acid binds to all 3 of the retinoic acid receptor (RAR) family, including RARα, RARβ and RARγ, but shows relative selectivity for RARβ and RARγ and may modify gene expression. However, the clinical significance of these findings for the treatment of acne vulgaris is not known. It is indicated for the topical treatment of acne vulgaris in patients 9 years of age and older. The safety and efficacy of once daily use of Arazlo® for the treatment of acne vulgaris were assessed in 2 multicenter, randomized, double-blind studies that included subjects ≥9 years of age with facial acne vulgaris. Arazlo® lotion was found to be more effective than placebo in 2 clinical trials evaluating success on the EGSS and absolute changes in non-inflammatory and inflammatory lesion counts. Per the full text by Tanghetti et al2, differences between tazarotene lotion and placebo were statistically significant for reducing inflammatory and non-inflammatory lesion counts at week 12 in favor of tazarotene ($p<0.001$ for both studies), as well as for treatment success ($p<0.001$ for both studies).

Recommendation:

- Add Arazlo® (tazarotene) 0.045% Lotion to non-preferred.
    - Clinical criteria:
        - Add Arazlo to the Fabior clinical criteria.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

- Durysta® (bimatoprost implant)

Bimatoprost, the active ingredient of Durysta®, is a prostaglandin analog. It is a synthetic structural analog of prostaglandin with ocular hypotensive activity. It is believed to lower intraocular pressure in humans by increasing outflow of aqueous humor through both the trabecular meshwork (conventional) and uveoscleral routes (unconventional). Elevated intraocular pressure presents a major risk factor for glaucomatous field loss. The higher the level of intraocular pressure, the greater the likelihood of optic nerve damage and visual field loss. It is indicated for the reduction of intraocular pressure (IOP) in patients with open angle glaucoma (OAG) or ocular hypertension (OHT). The efficacy of Durysta® was assessed in two multicenter, randomized, parallel-group, controlled studies of 20 months in duration. Durysta® implant was compared to twice daily topical timolol 0.5% drops in patients with OAG or OHT. Results suggested that Durysta® demonstrated an IOP reduction of about 5-8mmHg in patients with a mean baseline IOP of 24.5mmHg. In two clinical trials, Durysta® was found to have similar reduction in IOP as compared with daily timolol ophthalmic drops at 12 weeks. There is no evidence at this time to support that Durysta® is safer or more effective than the other currently preferred, more cost-effective medications.

Recommendation:

- Add Durysta® (bimatoprost) 10 mcg implant to non-preferred.
    - Clinical criteria:

- Add Durysta: The patient has had a documented side effect, allergy, or treatment failure with at least 2 preferred prostaglandin inhibitors OR the patient is not a candidate for topical drop therapy AND the patient does not have any of the following contraindications: History of prior corneal transplantation or endothelial cell transplants (e.g. Descemet's Stripping Automated Endothelial Kratoplasty), Diagnosis of corneal endothelial dystrophy (e.g. Fuchs' Dystrophy) , Absent or ruptured posterior lens capsule Approval will be limited to a single implant per eye without retreatment.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

- Fensolvi® (leuprolide acetate)

Leuprolide acetate, the active ingredient of Fensolvi®, is a gonadotropin releasing hormone (GnRH) agonist and acts as a potent inhibitor of gonadotropin secretion (luteinizing hormone [LH] and follicle stimulating hormone [FSH]) when given continuously in therapeutic doses. After an initial stimulation of GnRH receptors, chronic administration of leuprolide results in downregulation of GnRH receptors, reduction in release of LH, FSH, and consequent suppression of ovarian and testicular production of estradiol and testosterone respectively. This inhibitory effect is reversible upon discontinuation of drug therapy. It is indicated for the treatment of pediatric patients 2 years of age and older with central precocious puberty (CPP). The efficacy of Fensolvi® was assessed in an uncontrolled, open-label, single-arm study that included pediatric patients (62 females and 2 males, naïve to previous GnRH agonist treatment) with CPP who received at least one dose of Fensolvi® at a dosing interval of 24 weeks and who were observed for 12 months. The mean age of included patients at the start of treatment was 7.5 years (range 4 to 9 years). It is the first and only six-month subcutaneously administered leuprolide, and it demonstrated clinical efficacy in a single-arm, open-label study with suppression of peak stimulated LH concentrations achieved by 87% at month 6. Fensolvi® utilizes the ATRIGEL Delivery system, which is a polymeric (non-gelatin containing) delivery system consisting of a biodegradable poly(DL-lactide-co-glycolide) (PLG) polymer formulation dissolved in the biocompatible solvent, N-methyl-2-pyrrolidone (NMP), and leuprolide is released in a sustained and controlled manner over a six-month dosing cycle. There is no evidence at this time to support that Fensolvi® is safer or more effective than the other currently preferred, more cost-effective medications.

Recommendation:

- Add Fensolvi® (leuprolide acetate) subcutaneous injection QTY LIMIT: 1 vial every 6 months to non-preferred.
  - Clinical criteria

- Add Fensolvi: There is a documented diagnosis of Central Precocious Puberty (CPP) AND All other underlying causes have been ruled out including a brain tumor, spinal cord tumor, hypothyroidism, brain defect at birth (e.g. hematoma or hydrocephalus), injury to the brain or spinal cord, McCune-Albright syndrome, congenital adrenal hyperplasia, radiation to the spinal cord or brain AND There is a documented inability to tolerate (not due to pain) monthly injections of Leuprolide IM

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

- Isturisa ® (osilodrostat)

Osilodrostat, the active ingredient of Isturisa®, is a cortisol synthesis inhibitor. It inhibits 11beta-hydroxylase (CYP11B1), the enzyme responsible for the final step of cortisol biosynthesis in the adrenal gland. It is indicated for the treatment of adult patients with Cushing's disease for whom pituitary surgery is not an option or has not been curative. The safety and efficacy of Isturisa® were assessed in a 48-week multicenter study that consisted of 4 study periods, including: Period 1: 12-week, open-label, dose titration period, Period 2: 12-week, open-label, maintenance treatment period, Period 3: 8-week, double-blind, placebo-controlled, randomized withdrawal treatment period which provided the data for the primary efficacy endpoint, Period 4: open-label treatment period of 14 to 24 weeks duration. In a clinical trial, the percentage of complete responders for the primary endpoint was significantly higher with Isturisa® as compared with placebo. In a clinical trial, the percentage of complete responders for the primary endpoint was significantly higher with Isturisa® as compared with placebo. There is no evidence at this time to support that Isturisa® is safer or more effective than the currently preferred, more cost-effective medications.

Recommendation:

- Add new category Cushing's Disease with a note that all products require PA.
- Add Isturisa® (osilodrostat) tablets to non-preferred.
  - Clinical criteria:
    - Add Isturisa to the Signifor criteria.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

- Nexletol® (bempedoic acid)

Bempedoic acid, the active ingredient of Nexletol®, is an adenosine triphosphate-citrate lyase (ACL) inhibitor that lowers LDL-C by inhibition of cholesterol synthesis in the liver. ACL is an enzyme upstream of 3-hydroxy-3-methyl-glutaryl-coenzyme A (HMG-CoA) reductase in the cholesterol biosynthesis pathway. Bempedoic acid and its active metabolite (ESP15228) require coenzyme A (CoA) activation by very long-chain acyl-CoA synthetase 1 (ACSVL1) to ETC-1002-CoA and ESP15228-CoA, respectively. ACSVL1 is expressed mainly in the liver. Inhibition of ACL by ETC-1002-CoA results in decreased cholesterol synthesis in the liver and lowers LDL-C in blood via upregulation of low-density lipoprotein receptors. Bempedoic acid is also available as a combination treatment with ezetimibe. It is indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia or established atherosclerotic cardiovascular disease who require additional lowering of LDL-C. The effect of Nexletol® on cardiovascular morbidity and mortality has not been determined. The safety and efficacy of Nexletol® were assessed in two multicenter, randomized, double-blind, placebo-controlled studies (N=3009) that included adults with heterozygous familial hypercholesterolemia (HeFH) or established atherosclerotic cardiovascular disease (ASCVD) who were on maximally tolerated statin therapy. In both studies, the maximum LDL-C lowering effects occurred at week 4. The effect of Nexletol® on cardiovascular morbidity and mortality has not been determined. This is the first agent in a new class of drugs designed to lower cholesterol levels. Two studies assessed the percent change from baseline to week 12 in LDL-C with Nexletol® as compared with placebo for the primary endpoint, and the difference was highly significant in favor of Nexletol®. In a 2019 study by Ballantyne et al2, bempedoic acid plus ezetimibe fixed-dose combination was significantly more effective than either individual agent for LDL-C reduction, the primary endpoint. There is no evidence at this time to support that Nexletol® is safer or more effective than the currently preferred, more cost-effective medications.

- Nexlizet® (bempedoic acid and ezetimibe)

Nexlizet® contains bempedoic acid and ezetimibe. It is indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia or established atherosclerotic cardiovascular disease who require additional lowering of LDL-C. The effect of Nexlizet® on cardiovascular morbidity and mortality has not been determined. The safety and efficacy of Nexlizet® were assessed in a multicenter, randomized, double-blind, placebo-controlled parallel group study (N=301) that included adults with heterozygous familial hypercholesterolemia (HeFH), established atherosclerotic cardiovascular disease (ASCVD), or multiple risk factors for cardiovascular disease on maximally tolerated statins. The efficacy of Nexlizet® in patients with multiple risk factors for cardiovascular disease has not been established. The effect of Nexlizet® on cardiovascular morbidity and mortality has not been determined. A clinical study assessed the percent change from baseline to week 12 in LDL-C with Nexlizet® as compared with placebo for the primary endpoint, and the difference was highly significant in favor of Nexlizet®. In the 2019 full-text study by Ballantyne et al2, bempedoic acid plus ezetimibe fixed-dose combination was significantly more effective than either individual agent for LDL-C reduction.

Recommendation:

- Add Nexletol® (bempedoic acid) QTY LIMIT: 1 tab/day to non-preferred.
- Add Nexlizet® (bempedoic acid/ezetimibe) QTY LIMIT: 1 tab/day to non-preferred.
    - Clinical criteria
        - Add Nexletol, Nexlizet: The patient has had an inadequate response to a 3-month trial of atorvastatin or rosuvastatin OR Patient has demonstrated statin intolerability as defined by statin-related rhabdomyolysis or skeletal related muscle symptoms AND Patient (if eligible) will continue adjunct therapy with maximally tolerated high intensity statin. If patient is using simvastatin, dose should not exceed 20 mg/day; if patient is using pravastatin, dose should not exceed 40 mg/day.

Public Comment: No public comment

Board Decision: The Board unanimously approved the above recommendations.

- Oriahnn® (elagolix, and elagolix/estradiol/norethindrone)

Oriahnn® is a combination of elagolix (a gonadotropin-releasing hormone [GnRH] receptor antagonist), estradiol (an estrogen), and norethindrone acetate (a progestin).
Elagolix is a GnRH receptor antagonist that inhibits endogenous GnRH signaling by binding competitively to GnRH receptors in the pituitary gland. Administration of elagolix results in dose-dependent suppression of luteinizing hormone (LH) and follicle-stimulating hormone (FSH), leading to decreased blood concentrations of the ovarian sex hormones estradiol and progesterone and reduces bleeding associated with uterine fibroids. Estradiol (E2) acts by binding to nuclear receptors that are expressed in estrogen-responsive tissues. The addition of exogenous estradiol may reduce the increase in bone resorption and resultant bone loss that can occur due to a decrease in circulating estrogen from elagolix alone. Norethindrone acetate (NETA) acts by binding to nuclear receptors that are expressed in progesterone-responsive tissues. As a component of Oriahnn®, NETA may protect the uterus from the potential adverse endometrial effects of unopposed estrogen. It is indicated for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal women. Use of Oriahnn® should be limited to 24 months due to the risk of continued bone loss, which may not be reversible. The efficacy of Oriahnn® in the management of heavy menstrual bleeding (HMB) associated with uterine fibroids was assessed in two randomized, double-blind, placebo-controlled studies (Study UF-1 and Study UF-2). Premenopausal women (N=790) with heavy menstrual bleeding were randomized to Oriahnn® or placebo for 6 months. In both studies, the median age of enrolled women was 43 years (range 25 to 53 years), while 68% were Black or African American and 29% were White. Due to the estrogen and progestin portion, Oriahnn® carries of a box warning regarding increased risk of thromboembolic

disorders and vascular events. In two clinical trials, significantly more women treated with Oriahnn® were responders for the primary outcome (menstrual blood loss volume less than 80ml at the final month and ≥50% reduction in menstrual blood loss volume from baseline to the final month). There is no evidence to suggest that Oriahnn® is safer or more effective than other currently preferred medications, however, is a relatively cost-effective medication.

Recommendation:

- Add ORIAHNN® (elagolix and elagolix/estradiol/norethindrone) capsules to preferred after clinical criteria are met.
  - Clinical criteria
    - Add Oriahnn: Patient is premenopausal and is experiencing heavy menstrual bleeding associated with uterine leiomyomas (fibroids) AND patient has a documented side effect, allergy, or treatment failure to at least TWO medications from at least 2 different classes (oral contraceptives, NSAIDs, progestins). Note: Approval will be limited to 2 tablets/day for a maximum length of therapy of 2 years

Public Comment: Franco Casagrande, Pharm.D. from AbbVie yielded his time back to the committee.

Board Decision: The Board unanimously approved the above recommendations.

- Trijardy® XR (empagliflozin, linagliptin, and metformin ER)

Trijardy® XR is a fixed dose combination tablet that consists of an extended-release metformin (a biguanide) core tablet that is coated with the immediate-release drug substances of empagliflozin (a sodium-glucose co-transporter 2 [SGLT2] inhibitor) and linagliptin (a dipeptidyl peptidase-4 [DPP-4] inhibitor). By inhibiting SGLT2, empagliflozin reduces renal absorption of filtered glucose and lowers the renal threshold for glucose, and thus increases urinary glucose excretion. Linagliptin is an inhibitor of DPP-4, an enzyme that degrades the incretin hormones glucagon-like peptide-1 (GLP-1). Thus, linagliptin increases the concentrations of active incretin hormones, stimulating the release of insulin in a glucose-dependent manner and decreasing the levels of glucagon in the circulation. GLP-1 increases insulin biosynthesis and secretion from pancreatic beta cells in the presence of normal and elevated blood glucose levels and also reduces glucagon secretion from pancreatic alpha cells, resulting in a reduction in hepatic glucose output. Metformin improves glucose tolerance in patients with type 2 DM, lowering both basal and postprandial plasma glucose. It decreases hepatic glucose production, decreases intestinal absorption of glucose, and improves insulin sensitivity by increasing peripheral glucose uptake and utilization. It is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 DM. Empagliflozin is indicated to reduce the risk of cardiovascular death in adults with type 2 DM and established cardiovascular disease. There were 3 clinical trials reported in the Trijardy® XR clinical trial section. Two studies were those included with the prescribing information for empagliflozin (brand name Jardiance®) and one

study was included with the prescribing information for linagliptin (brand name Tradjenta®). These agents, along with metformin, have been available for numerous years and have proven to be safe and effective for lowering HbA1c. Trijardy® XR has not been studied in patients with a history of pancreatitis. It is unknown whether patients with a history of pancreatitis are at an increased risk for the development of pancreatitis while using Trijardy® XR.

Recommendation:

- Add Trijardy® XR (empagliflozin/linagliptin/metformin ER) to non-preferred.
  - Clinical criteria:
    - Add Trijardy XR: patient has documentation of a failure of therapy with a preferred SGLT2 inhibitor, a preferred DPP-4 inhibitor and metformin/metformin XR used in combination.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

- Xcopri® (cenobamate)

Cenobamate, the active ingredient of Xcopri®, has been shown to reduce repetitive neuronal firing by inhibiting voltage-gated sodium currents. It is also a positive allosteric modulator of the γ-aminobutyric acid (GABA-A) ion channel. However, the exact mechanism by which it exerts its therapeutic effects for its approved indication is not known. Xcopri® is a Schedule V controlled substance. It is for the treatment of partial-onset seizures in adult patients. The safety and efficacy of Xcopri® were assessed for the treatment of partial-onset seizures in two multicenter, randomized, double-blind, placebo-controlled studies that included adults with partial-onset seizures with or without secondary generalization and who were not adequately controlled with 1 to 3 concomitant antiepileptic drugs (AEDs). In two clinical trials compared with placebo, Xcopri® was found to be significantly more effective than placebo for the percent change from baseline in seizure frequency per 28 days in the treatment period. Comparator studies with other active treatments were not found.

Recommendation:

- Add Xcopri® (cenobamate) tablets QTY LIMIT:200 mg = 2 tabs/day, all other strengths = 1 tab/day to non-preferred.
- Add Pregabalin oral solution (compare to Lyrica®) to non-preferred.
- Clarify Pregabalin capsules remain preferred.
  - Clinical criteria
    - Add Xcopri: the diagnosis is adjunctive therapy of partial-onset seizures AND the patient is ≥ 18 years of age AND the patient has had a documented side effect, allergy, treatment failure/inadequate response or a contraindication to at least TWO preferred anticonvulsants AND for re-approval, the

patient must have a documented decrease from baseline in seizure frequency per 28 days.
    - Add Tranxene-T to the clorazepate and Fycompa clinical criteria with the addition of: for approval of Tranxene-T the patient must have a documented intolerance to the generic equivalent.
    - Add Pregabalin oral solution to the Lyrica oral solution clinical criteria with the addition of: For approval of brand Lyrica oral solution, the patient must have a documented intolerance to the generic equivalent.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

- Zeposia® (ozanimod)

Ozanimod, the active ingredient of Zeposia®, is a sphingosine 1-phosphate (S1P) receptor modulator that binds with high affinity to S1P receptors 1 and 5. It blocks the capacity of lymphocytes to egress from lymph nodes, reducing the number of lymphocytes in peripheral blood. The mechanism by which it exerts its therapeutic effects in multiple sclerosis is not known but may involve the reduction of lymphocyte migration into the CNS. It is indicated for the treatment of relapsing forms of multiple sclerosis (MS) to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults. The safety and efficacy of Zeposia® were assessed in 2 randomized, double-blind, double-dummy, parallel-group, active comparator-controlled trials of similar design that included patients with relapsing forms of MS. In clinical trials, adults treated with Zeposia® had a statistically significantly lower ARR over 12 months in one study and at 24 months in a second study as compared with interferon beta-1a 30mcg IM in a population with relapsing MS. While MRI endpoints were also significantly improved with Zeposia® in both studies compared with interferon beta-1a, the pooled analysis of the proportion with 3 month confirmed disability progression was not significantly different between treatments.

Recommendation:

- Add Zeposia® (ozanimod) capsule QTY LIMIT: 1 capsule/day to non-preferred.
    - Clinical criteria
        - Add Zeposia: Patient is ≥ 18 years AND has a diagnosis of relapsing-remitting MS (RRMS), Clinically Isolated Syndrome or active secondary progressive MS (SPMS) AND Documentation is provided showing ≥ 1 relapse within the past year AND baseline CBC w/ diff (including lymphocyte count), liver function tests, electrocardiogram (ECG), and ophthalmic evaluation have been completed AND patient has a documented side effect, allergy,

treatment failure or contraindication to at least three drugs used to treat relapsing MS (may be preferred or non-preferred).

Public Comment: Afraim Botros from Bristol Meyers Squibb: Highlighted the attributes of Zeposia.

Board Decision: The Board unanimously approved the above recommendations.

9. New Therapeutic Drug Classes

- None at this time.

10. Therapeutic Drug Classes- Periodic Review:

- **Antihistamines, Minimally Sedating**
  - No new drugs.
  - No new significant clinical changes.

Recommendation:

- Move Fexofenadine tablets to non-preferred.
- Add Fexofenadine (compare to Allegra®) suspension to non-preferred.
- Remove Xyzal® (levocetirizine) 5 mg tablet, Xyzal® (levocetirizine) Solution, Clarinex® Reditabs, and Clarinex Syrup® (desloratadine).
- Move Cetirizine/Pseudoephedrine SR 12hr 5 mg/120 mg and Levocetirizine 5 mg tablet to preferred.
  - Clinical criteria:
    - Update Fexofenadine tablets, Clarinex tablets, desloratadine tablets: The patient has had a documented side effect, allergy, or treatment failure to loratadine AND cetirizine. AND If the request is for Clarinex, the patient must also have a documented intolerance to the generic equivalent tablets.
    - Update Clarinex-D: patient has had a documented side effect, allergy, or treatment failure to loratadine-D and cetirizine-D.
    - Add Fexofenadine solution to the levocetirizine solution criteria.

Public Comments: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

- **Alzheimer's Agents**
  - No new drugs.
  - No new significant clinical changes.

Recommendation:

- Clarify Donepezil 23mg is non-preferred, 5mg and 10mg continue to be preferred.
  - Clinical criteria:

- Add Donepezil 23mg to Galantamine Tablet, Galantamine ER Capsule, Razadyne Tablet, Razadyne ER Capsule, Rivastigmine capsule and update: diagnosis or indication for the requested medication is Alzheimer's disease. AND patient has been started and stabilized on the requested medication (Note: samples are not considered adequate justification for stabilization) OR patient had a documented side effect, allergy or treatment failure to a preferred donepezil product AND if the product has an AB rated generic, the patient has a documented intolerance to the generic.

Public Comments: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

- **IBS/SBS/GI Agents**
  - No new drugs.
  - No new significant clinical changes.

Recommendation:

- Remove Zelnorm® (tegaserod maleate) from the PDL. It is no longer rebateable.

Public Comments: No public comment

Board Decision: No action needed.

- **Intranasal Rhinitis**
  - No new drugs.
  - Published guidelines by the Joint Task Force on Practice Parameters for Allergy, Asthma, and Immunology discuss intranasal antihistamines, intranasal ipratropium, and intranasal corticosteroids as available pharmacologic considerations for treatment of episodic or persistent rhinitis symptoms. The guidelines further suggest that intranasal corticosteroids provide the best overall relief for controlling the symptoms of allergic rhinitis; however, there is no recommendation made for preferring one intranasal corticosteroid product over another. While the intranasal antihistamines are recommended as first-line treatment for allergic and non-allergic rhinitis, the guidelines add that they are typically less effective than the intranasal corticosteroids for allergic rhinitis
  - A 2020 practice parameter update by Dykewicz et al in the Journal of Allergy and Clinical Immunology includes a stepwise approach for management of intermittent and persistent AR. The following recommendations were made:

- Recommend the clinician not prescribe, as initial treatment, a combination of an oral antihistamine and an intranasal steroid in preference to monotherapy with an intranasal steroid in patients ≥12 years with symptoms on SAR.
- Suggest that the clinician not prescribe the combination of an oral antihistamine and an intranasal corticosteroid in preference to monotherapy with an intranasal corticosteroid in all patients with SAR and PAR.

Recommendation:

- Move AZELASTINE 0.1% Nasal Spray QTY LIMIT: 1 bottle (30 ml)/25 days and Dymista® (azelastine/fluticasone) Nasal Spray QTY LIMIT: 1 bottle (23 gm)/30 days to preferred and remove the duplication of Dymista.
- Remove Astelin® (azelastine) Nasal Spray and Astepro® (azelastine 0.15 %) Nasal from the PDL.
    - Clinical criteria:
        - Remove Astelin, Astepro, Azelastine, Azelastine/Fluticasone, Dymista, Olopatadine, Patanase, Dymista criteria.
        - Add Azelastine/Fluticasone: The patient has a documented intolerance to brand Dymista.
        - Add Azelastine 0.15%, Olopatadine, Patanase: The patient has a documented side effect, allergy, or treatment failure to Azelastine 0.1%

Public Comments: No public comment

Board Decision: The Board unanimously approved the above recommendations.

- **Leukotriene Modifiers**
    - No new drugs.
    - Brand name Zyflo® CR (zileuton extended release) is no longer rebatable and has been removed from the review.
    - No new significant clinical changes.

Recommendation:

- Indicate that Montelukast sodium 10mg tablets are preferred for ages ≥ 15.
- Update Zileuton ER, Zyflo: The diagnosis or indication for the requested medication is asthma. AND The patient has had a documented side effect, allergy, or treatment failure to Accolate/Zafirlukast or Singulair/Montelukast.

Public Comments: No public comment

Board Decision: The Board unanimously approved the above recommendations.

- **Parathyroid Agents**

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

Recommendation:

- Move Doxercalciferol (compare to Hectoral®) to non-preferred.
- Add Doxercalciferol to the clinical criteria of Drisdol, Hectoral, Rayaldee, Rocaltrol, Zemplar.

Public Comments: No public comment

Board Decision: The Board unanimously approved the above recommendations.

- **Sedative Hypnotics (new drug Dayvigo® (Lemborexant) included)**
  - Lemborexant, the active ingredient of Dayvigo®, is an orexin receptor antagonist. Its mechanism of action 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. It is indicated for the treatment of adult patients with insomnia, characterized by difficulties with sleep onset and/or sleep maintenance. The efficacy of Dayvigo® was assessed in 2 clinical trials that included patients with insomnia characterized by difficulties with sleep onset and/or sleep maintenance. Results suggested that Dayvigo® 5mg and 10mg demonstrated statistically significant superiority on the primary efficacy measure as compared with placebo, as well as the secondary endpoints of sSEF and sWASO. There is some evidence from a phase 3 study to suggest that Dayvigo® may be more effective than zolpidem extended release 6.25mg, though this is a relatively low dose for this comparator drug; however, there is no evidence at this time that to support that Dayvigo® is safer or more effective than the other currently preferred, more cost-effective medications. It is therefore recommended that Dayvigo® remain non-preferred and require prior authorization and be available to those who are unable to tolerate or who have failed on preferred medications.
  - No other significant clinical changes.

Recommendation:

- Add Dayvigo® (lemborexant) tablet QTY LIMIT: 1 tab/day to non-preferred.
- Move Eszopiclone (compare to Lunesta®) QTY LIMIT: 1 tab/day to preferred.
- Remove Sonata® (zaleplon) from the PDL.
  - Clinical criteria:
    - Add Dayvigo: The patient has had a documented side effect, allergy or treatment failure to two preferred sedative/hypnotics and Belsomra.

- Update Ramelteon, Rozerem: The patient has had a documented side effect, allergy, contraindication or treatment failure to one preferred sedative/hypnotic OR the patient has had a treatment failure after a minimum 2-week trial of melatonin OR There is a question of substance abuse with the patient or family of the patient. If the request is for Ramelteon, there must also have been a documented intolerance to brand Rozerem.
- Update Ambien, Lunesta: The patient has had a documented intolerance to the generic equivalent.
- Update Ambien CR, Belsomra, Zolpidem CR: The patient has had a documented side effect, allergy or treatment failure to two preferred sedative/hypnotics. If the request is for brand Ambien CR, there has also been a documented intolerance to the generic.
- Update Intermezzo: The patient has insomnia characterized by middle-of-the night awakening followed by difficulty returning to sleep AND The patient has had a documented inadequate response to two preferred sedative/hypnotics.
- Update Silenor: The patient has had a documented side effect, allergy, contraindication or treatment failure to two preferred sedative/hypnotics AND The patient has had a documented intolerance with generic doxepin or there is another clinically valid reason why a generic doxepin (capsule or oral solution) cannot be used.

Public Comments: No public comment

Board Decision: The Board unanimously approved the above recommendations.

- **Smoking Cessation Agents**
  - No new drugs.
  - There have been several safety concerns with oral bupropion and varenicline, and as such both had box warnings regarding the potential for increased risk of neuropsychiatric adverse events. These box warnings were removed at the end of 2016/beginning of 2017 and are now in the warnings section of the prescribing information, not as box warnings. The EAGLES study by Anthenelli et al assessed the composite measure of moderate and severe neuropsychiatric adverse events (NPAEs) between varenicline, bupropion, and nicotine patch. A significant increase was not seen with varenicline or bupropion relative to nicotine patch or placebo in NPAEs.

Recommendation:

- Remove Zyban® (bupropion SR) from the PDL.
    - Clinical criteria:
        - Update Nicotrol Inhaler, Nicotrol Nasal Spray: The patient has had a documented treatment failure with nicotine patch used in combination with nicotine gum or lozenge.

Public Comments: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

11. Review of Newly Developed/Revised Criteria

- **Ophthalmics, Anithistamines**
    - Pazeo®, Pataday®, and Patanol® will no longer be available as prescription products. All strengths of olopatadine will be available over the counter under the trade name Pataday®. The OTC formulation will not be covered by Medicaid at this time.

Recommendation:

- Remove Pazeo® (olopatadine 0.7%), Elestat® (epinastine), Emadine® (emedastine), Pataday® (olopatadine 0.2%), and Patanol® (olopatadine 0.1%) from the PDL.
- Move Olopatadine 0.2% QTY LIMIT: 1 bottle/month to preferred.
    - Clinical criteria:
        - Revise Bepreve, Epinastine: The patient has had a documented side effect, allergy, or treatment failure to a preferred Olopatadine product.

Public Comment: No public comment

Board Decision: None needed.

12. General Announcements:

- None at this time.

Public Comment: No public comment.

Board Decision: No action needed.

13. Adjourn: Meeting adjourned at 8:10 p.m.