Department of Vermont Health Access
Pharmacy Benefit Management Program
DUR Board Meeting Minutes
February 18, 2020

Board Members:

Present:

Clayton English, PharmD	Margot Kagan, PharmD	Douglas Franzoni Jr., PharmD
Zail Berry, MD	Bill Breen, RPh	Patricia King, MD
Louise Rosales, NP	Claudia Berger, MD	

Absent: Joseph Nasca, MD, Renee Mosier, PharmD, Marc Pasanen, MD

Staff:

Laurie Brady, RPh, Change HealthCare	Mike Ouellette, RPh, Change Healthcare	Laureen Biczak, DO, Change Healthcare
Stacey Baker, DVHA	Lisa Hurteau, PharmD, DVHA	Scott Strenio, MD, DVHA

Guests:

Robert Arcot, Merck	Patty Arcese, Amgen	Christine Dube, MedImmune
Bill Eicholzier, Alexion	Elizabeth Lubelczyk, Lilly	Tina McCann, Sarepta
Joseph Miller, Novo Nordisk	Brett White, Biohaven	John Meyer, Avexis
Bryan Dillon, Otsuka	Suzanne Barrali, Sage	

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:

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

3. DVHA Pharmacy Administration Updates:

- Welcome new board member Douglas Franzoni Jr., PharmD.
- The legislature is currently in session, and a few pharmacy related initiatives are being discussed. One relates to expanding access to contraceptives, allowing pharmacists to dispense oral contraceptives without a prescription in some cases. Another involves setting a maximum monthly out of pocket expense for insulin.

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

- None at this time.

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

- None at this time.

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

- Introduction: Chronic kidney disease (CKD) is epidemic in the United States with an estimated 15% of the adult population (37 million) affected, per the CDC as of July 2019. CKD is an independent risk factor for cardiovascular disease, including strokes, CAD and death. There are many causes of kidney disease, including diabetes, hypertension (HTN), hyperlipidemia, inflammatory conditions and drug toxicities, and it is estimated that 80-95% of those with CKD have concurrent hypertension. Many of those with CKD will have multiple risk factors. Additionally, early CKD often goes undetected until the estimated glomerular filtration rate falls below 60mL/min per 1.73m2 (stage 3a), when there has been mild to moderate loss of kidney function, minimally 40%. The degree of albuminuria is also a key factor in staging CKD and is a marker of damage to the nephrons. It has been long recognized that controlling hypertension can slow the progression of disease and decrease albuminuria and there are guidelines for treatment that take into account the baseline blood pressure, stage of disease, presence or absence of albuminuria. Kidney Disease Improving Global Outcomes (KDIGO) 2012 guidelines used eGFR, presence or absence of DM and degree of albuminuria to determine both BP goals and recommended drug therapy to treat HTN. In general, first line therapies for treating HTN in CKD are ACE inhibitors and ARBs, regardless of whether there is albuminuria. If edema is present, loop diuretics are recommended and calcium channel blockers are recommended as second or third line therapy when additional therapy is needed to reach the target blood pressure (in most cases SBP <130, DBP<80).
- Change Healthcare will use paid, non-reversed Medicaid pharmacy and medical claims from SFY 2019, excluding members with Part D, VMAP and Healthy Vermonters coverage. They will identify members with Stage 3 or later CKD, including members on dialysis, and stratify each stage into those with and without hypertension. In each group, those on antihypertensive medications, including ACE, ARB, loop diuretics and CCB medications will be identified. Change Healthcare will examine this data using standard measures of compliance including the medication possession ratio (MPR).

Recommendation:

Public Comment: No public comment.

Board Decision: None needed.

- Data Presentation: Overuse of antibiotics is associated with both adverse events (C. diff diarrhea, bacterial overgrowth, etc.) and resistance. Some classes of antibiotics have idiosyncratic toxicities, such as tendon rupture with fluroquinolones. There are a few conditions for which prolonged use of antibiotics has been shown to be effective and

considered now to be standard of care (for example cystic fibrosis, severe acne, TB, MAC, recurrent UTIs). Prolonged use of antibiotics is a practice that is unsupported in conditions such as “chronic” Lyme disease.

- Change Healthcare reviewed Vermont paid non-reversed pharmacy and medical claims with dates of service from 7/1/18-6/30/19 excluding members who had a diagnosis of cystic fibrosis, chronic bronchitis, chronic UTIs, rosacea, acne, or hidradenitis suppurativa. For the remaining members, 2 types of analysis were done. The first looked at members prescribed more than 12 consecutive weeks of fluroquinolones. The second analysis looked at members with the diagnoses of Lyme disease, anaplasmosis or babesiosis and evaluated the use of antibiotics in that population, both long-term use of one antibiotic or cycling of antibiotics. The prescribers for these members were identified to look at providers who are possibly practicing outside of guideline recommendations, perhaps identifying those who would be appropriate for more targeted education.
- 5 members had 12 consecutive weeks of treatment with fluoroquinolones in SFY 2019. There were 9 prescribers for these members, as some members received prescriptions from more than one doctor. Of these 5 members, one member had the diagnoses of staphylococcus, streptococcus and enterococcus infections, but the only site of infection was sinusitis. Other members had the diagnoses of skin and soft tissue infection, prostatitis, cholecystitis. None had a diagnosis of Lyme disease or other tick- borne illnesses.
- There were 29 members with the diagnosis of Lyme disease, babesiosis or anaplasmosis who took any oral antibiotics for at least 12 consecutive weeks or at least 24 total weeks (intermittently)within SFY 2019, not just fluoroquinolones. There were 22 prescribers for this group. Most of the providers wrote for one patient, but there was one prescriber with prescriptions for 10 members, one for 8 members, one for 6 members and one for 5 members. Of these prescribers with 5 or more members, three are naturopathic physicians, and one is a physiatrist. None are infectious disease specialists. Prolonged use of antibiotics for the diagnosis of “chronic” Lyme disease is not currently supported by evidence or guidelines.

Recommendation: While it is hard to link specific diagnoses to the long – term use of antibiotics in some members, there are prescribers who have a pattern of prolonged antibiotic use for a few members, and a few of them consider themselves specialists in treating Lyme disease. Targeted education for these providers about current ID guidelines on the diagnosis and treatment of tick-borne illnesses may be useful. Another intervention to prevent antibiotic overuse in other infections would be to put in an accumulator edit for fluoroquinolone use beyond 28 days within a 90 day time period (prior authorization would be required for members exceeding these limits). This hopefully would discourage inappropriate use of fluoroquinolones to treat multiple types of infections.

Public Comment: No public comment.

Board Decision: The Board would like DVHA to review a sample of medical chart records for members with a tick-borne illness diagnosis. They would like Change Healthcare to explore

what cumulative edits are possible across different antibiotic classes to limit use without a PA to 12 weeks.

7. Clinical Update: Drug Reviews: Laureen Biczak, DO, Change Healthcare and Laurie Brady RPh, Change Healthcare

Biosimilar Drug Reviews:

- None at this time.

Full New Drug Reviews:

- Adhansia® XR (methylphenidate extended-release)

Methylphenidate, the active ingredient of Adhansia® XR, is a central nervous system (CNS) stimulant. The exact mode of action in ADHD is not known. Methylphenidate blocks the reuptake of norepinephrine and dopamine into the presynaptic neuron and increase the release of these monoamines into the extra neuronal space. Adhansia® XR capsules contain multilayered beads, composed of an immediate-release layer which contains about 20% of the dose and a controlled-release layer which contains about 80% of the methylphenidate dose. Adhansia® XR is a Schedule II controlled substance. It is indicated for the treatment of attention deficit hyperactivity disorder (ADHD) in patients 6 years and older. The safety and efficacy of Adhansia® XR were established in two randomized double-blind placebo-controlled trials in adults, as well as in 2 pediatric trials. It is to be taken once daily in the morning. Some, but not all doses were found to be significantly more effective than placebo in clinical trials assessing efficacy, based on average PERMP and SKAMP scores, as well as ADHD-RS-IV scores.

Recommendation:

- Add Adhansia ® XR (methylphenidate IR/ER 20:80%) *QTY LIMIT*: 1 capsule/day to non-preferred.
  - Clinical criteria: Add Adhansia XR and Cotempla XR ODT to the Jornay PM criteria.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

- Baqsimi® (glucagon powder)

Glucagon, the active ingredient of Baqsimi®, is an anti-hypoglycemic agent used to treat severe hypoglycemia. Glucagon increases blood glucose concentration by activating hepatic glucagon receptors, thus stimulating glycogen breakdown and release of glucose from the liver. Hepatic stores of glycogen are necessary for glucagon to produce an anti-hypoglycemic effect. It is indicated for the treatment of severe hypoglycemia in patients with diabetes ages 4 years and older. A 3mg dose is administered as one actuation of the intranasal device into one nostril. If there has been no response after 15 minutes, an additional 3mg dose from a new device may

be administered while waiting for emergency assistance. The safety and efficacy of Baqsimi® were assessed in two adult trials and one pediatric trial. The first adult trial (N=70) was a randomized, multicenter, open-label, 2-period crossover study that included adults with type 1 diabetes mellitus (DM). The efficacy of Baqsimi® was compared to a 1mg dose of IM glucagon (IMG). Insulin was used to reduce blood glucose levels to <60mg/dL. In clinical studies, intranasal glucagon was shown to be effective for severe hypoglycemia and was non-inferior to IM glucagon for treatment success in one adult study and in reversing insulin-induced hypoglycemia in another adult study. In a pediatric study, all patients in both treatment arms of intranasal glucagon and IM glucagon achieved an increase in glucose ≥20mg/dL from glucose nadir within 20 minutes of administration.

- Gvoke™ (glucagon injection)

Glucagon, the active ingredient of Gvoke™, is an anti-hypoglycemic agent used to treat severe hypoglycemia. It is indicated for the treatment of severe hypoglycemia in pediatric and adult patients with diabetes ages 2 years and above. The recommended dose for patients 12 years of age and older is 1mg administered by subcutaneous injection. The recommended dose for patients 2-12 years of age weighing less than 45kg is 0.5mg administered by subcutaneous injection. Gvoke™ is available as either a single-dose pre-filled syringe or auto-injector. The safety and efficacy of Gvoke™ were assessed in 2 multicenter, 2-way crossover studies in adult patients aged 18 to 74 years of age with type 1 diabetes. Study 1 was double-blinded (N=80) and study 2 was single-blinded (N=81). Both studies involved 2 clinic visits 7 to 28 days apart, with random assignment to receive Gvoke™ 1mg during one session and glucagon emergency kit (GEK) 1mg during the other. In clinical trials, Gvoke™ was non-inferior to glucagon emergency kit administration in adults with type 1 diabetes regarding treatment success. In a pediatric clinical trial, patients underwent insulin-induced hypoglycemia and achieved a target glucose increase of at least 25mg/dl.

Recommendation:

- Add Baqsimi® (glucagon nasal powder) 3mg and Gvoke™ (glucagon SC injection) prefilled syringe and auto-injector 0.5mg, 1mg to non-preferred.
- Add GlucaGen® HypoKit® (glucagon for injection) 1mg and Glucagon Emergency Kit (glucagon for injection) 1mg to preferred.
    - Clinical criteria
        - Add Baqsimi, Gvoke: the patient must be ≥ 4 years of age for Baqsimi or ≥ 2 years of age for Gvoke AND Patient has recurrent episodes of symptomatic or severe hypoglycemia (<55 mg/dL) requiring the assistance of another individual AND caregiver(s) is unable to reconstitute and administer IM glucagon (e.g. difficulty with manual dexterity). Convenience is not adequate justification for inability to use Glucagon IM.

Public Comment: Elizabeth Lubelczyk from Lilly: Highlighted the attributes of Baqsimi.
J.T. Mathis from Xeris: Highlighted the attributes of Gvoke.

Board Decision: The Board unanimously approved the above recommendations.

- Ezallor® Sprinkle (rosuvastatin capsule)

Rosuvastatin, the active ingredient of Ezallor® Sprinkle, is a selective and competitive inhibitor of HMG-CoA reductase, the rate-limiting enzyme that converts 3-hydroxy-3-methyglutaryl coenzyme A to mevalonate, a precursor of cholesterol. Ezallor® is indicated for:

- Hypertriglyceridemia- as adjunctive therapy to diet
- Primary Dysbetalipoproteinemia (Type III Hyperlipoproteinemia)- as adjunct to diet
- Adult Patients with Homozygous Familial Hypercholesterolemia (HFH)- as adjunctive therapy to other lipid-lowering treatments (e.g. LDL apheresis) or alone if such treatments are unavailable to reduce LDL-C, Total-C and ApoB in adults with HFH. Ezallor® Sprinkle has not been studied in Frederickson Type 1 and V dyslipidemias. The efficacy of Ezallor® Sprinkle is based from that of Crestor® tablets. Note that pediatric use information for patients 7 to 17 years of age is approved for Crestor® (rosuvastatin calcium) tablets. However, due to AstraZeneca's marketing exclusivity rights, this drug product is not labeled with that pediatric information. Ezallor® offers providers the availability of a new dosage form.

Recommendation:

- Add Ezallor® (rosuvastatin) sprinkle capsule to non-preferred.
  - Clinical criteria
    - Add Ezallor: medical necessity for a specialty dosage form has been provided.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

- Katerzia® (amlodipine)

Amlodipine benzoate, the active ingredient of Katerzia®, is a long-acting calcium channel blocker. It is a dihydropyridine calcium antagonist (calcium ion antagonist or slow-channel blocker) that inhibits the transmembrane influx of calcium ions into vascular smooth muscle and cardiac muscle. The contractile processes of cardiac muscle and vascular smooth muscle are dependent upon the movement of extracellular calcium ions into these cells through specific ion channels. Amlodipine inhibits calcium ion influx across cell membranes selectively, with a greater effect on vascular smooth muscle cells than on cardiac muscle cells. It is indicated for the treatment of Hypertension or Coronary Artery Disease (CAD). Amlodipine

tablets (under brand name Norvasc®) have been FDA approved for numerous years and have been found to be safe and effective. The exposure (Cmax and AUC) of Katerzia® oral suspension is similar to that of Norvasc® tablets. Katerzia® oral suspension has the same indications as amlodipine tablets and the same clinical trials in the prescribing information as amlodipine tablets.

Recommendation:

- Add Katerzia (amlodipine oral suspension) tablet to non-preferred.
  - Clinical criteria
    - Katerzia, Nymalize: patient has a medical necessity for a specialty dosage form (i.e. dysphagia, swallowing disorder).

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

- Rinvoq® (upadacitinib, extended-release tablet)

Upadacitinib, the active ingredient of Rinvoq®, is a Janus Kinase (JAK) inhibitor. JAKs are intracellular enzymes which transmit signals arising from cytokine or growth factor-receptor interactions on the cellular membrane to influence cellular processes of hematopoiesis and immune cell function. Within the signaling pathways, JAKs phosphorylate and activate Signal Transducers and Activators of Transcription (STATs), which modulate intracellular activity including gene expression. Upadacitinib modulates the signaling pathway at the point of JAKs, preventing the phosphorylation and activation of STATs. It is indicated for the treatment of adults with moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response or intolerance to methotrexate. Use of Rinvoq® in combination with other JAK inhibitors, biologic DMARDs, or with potent immunosuppressants such as azathioprine and cyclosporine, is not recommended. The safety and efficacy of Rinvoq® were assessed in 5 phase 3, multicenter, double-blind, randomized studies that included adults 18 years of age and older with moderately to severely active RA with the presence of at least 6 tender and 6 swollen joints and evidence of systemic inflammation based on elevation of hsCRP at baseline. Note that in the information below, upadacitinib 30mg was utilized in some studies but is not an FDA approved dose. There is some evidence in a phase 3 study to suggest that Rinvoq® may be more effective than adalimumab in RA patients when added to methotrexate; however, there is no evidence that Rinvoq® is safer or more effective than other currently available, less costly treatment options.

Recommendation:

- Add Rinvoq® (upadactinib) extended release tablet QTY LIMIT: 1 tablet/day to non-preferred.
    - Clinical criteria
        - Add Rinvoq to Olumiant additional criteria.

Public Comment: No public comment

Board Decision: The Board unanimously approved the above recommendations.

- Sunosi® (solriamfetol)

Solriamfetol, the active ingredient of Sunosi®, is a dopamine and norepinephrine reuptake inhibitor (DNRI). While its exact mechanism of action is unclear, its efficacy could be mediated through its activity as a DNRI. Sunosi® is a Schedule IV controlled substance and has the potential for abuse. Physicians should carefully evaluate patients for a recent history of drug abuse, especially those with a history of stimulant or alcohol abuse, and follow such patients closely, observing them for signs of misuse or abuse of Sunosi®. It is indicated to improve wakefulness in adult patients with excessive daytime sleepiness associated with narcolepsy or obstructive sleep apnea (OSA). The safety and efficacy of Sunosi® for improving wakefulness and reducing excessive daytime sleepiness were assessed in a multicenter, randomized, double-blind, placebo-controlled, parallel-group study of 12 weeks in duration that included adults with a diagnosis of narcolepsy per ICSD-3 or DSM-5 criteria. In clinical trials, Sunosi® significantly improved changes in MWT, ESS, and PGI-C as compared with placebo at 12 weeks in patients with narcolepsy and in patients with OSA. Note that the Sunosi® 75mg dose demonstrated trends toward improvement but the changes were not statistically significant compared to placebo in patients with narcolepsy for MWT and ESS.

Recommendation:

- Add Sunosi® (solriamfetol) tablet QTY LIMIT: 1 tablet/day, FDA maximum recommended dose = 150mg/day to non-preferred.
    - Clinical criteria
        - Add Sunosi: indication for use is the treatment of excessive daytime sleepiness in narcolepsy or obstructive sleep apnea (OSA) AND patient has had a documented side effect, allergy, or treatment failure to 2 preferred agents (may be stimulant or non-stimulant).

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

- Zelnorm® (tegaserod)

Tegaserod, the active ingredient of Zelnorm®, is a serotonin-4 (5-HT4) receptor agonist. Tegaserod is an agonist of serotonin type-4 receptors that stimulates the peristaltic reflex and intestinal secretion, inhibits visceral sensitivity, enhances basal motor activity, and normalizes impaired motility throughout the GI tract. It is indicated for the treatment of adult women less than 65 years of age with irritable bowel syndrome with constipation (IBS-C). The safety and efficacy of Zelnorm® in men with IBS-C have not been established. The safety and efficacy of Zelnorm® were assessed in 3 multicenter, randomized, double-blind, placebo-controlled studies that included women (N=2470) with at least a 3-month history of IBS-C symptoms prior to the baseline period that included abdominal pain, bloating and constipation. Zelnorm® had originally been FDA approved in 2002; however, it was voluntarily removed from the drug market in the US in 2007 due to potential cardiac-related side effects. A further retrospective analysis was performed that included data from 29 placebo-controlled trials, as discussed above. Use is contraindicated in patients with a history of MI, stroke, TIA, or angina, and females should be assessed for a history of cardiovascular disease and cardiovascular risk factors prior to treatment with Zelnorm®.

Recommendation:

- Add Zelnorm® (tegaserod maleate) Qty Limit: 2 tablets/day to non-preferred.
    - Clinical criteria
        - Add Zelnorm: The patient is a female 18-64 years of age AND the patient has a diagnosis of irritable bowel syndrome with constipation (IBS-C) AND the patient has no history of MI, stroke, TIA, or angina AND the patient has had a documented side effect, allergy, or treatment failure to Amitiza and Linzess.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendations with an addition to criteria that the patient has no risk factors for developing an adverse cardiovascular event.

- Zolgensma® (onasemnogene abeparvovec-xioi)

Zolgensma® is a suspension of an adeno-associated viral vector-based gene therapy that is a recombinant self-complementary AAV9 containing a transgene encoding the human survival motor neuron (SMN) protein, under the control of a cytomegalovirus enhancer/chicken-β-actin hybrid promoter. It is a recombinant AAV9-based gene therapy designed to deliver a copy of the gene encoding the human SMN protein. Spinal muscular atrophy is caused by a bi-allelic mutation in the SMN1 gene, which results in insufficient SMN protein expression. It is indicated for the treatment of pediatric patients less than 2 years of age with spinal muscular atrophy (SMA) with bi-allelic mutations in the survival motor neuron 1 (SMN1) gene. The safety and

efficacy of repeat administration of Zolgensma® have not been evaluated. The use of Zolgensma® in patients with advanced SMA (e.g. complete paralysis of limbs, permanent ventilator-dependence) has not been evaluated. The safety and efficacy of Zolgensma® were assessed in an open-label, single-arm clinical trial (ongoing) and an open-label, single-arm ascending dose clinical trial (completed) that included pediatric patients less than 2 years of age with SMA with bi-allelic mutations in the SMN1 gene. Patients experienced onset of clinical symptoms consistent with SMA before 6 months of age. Efficacy was established on the basis of survival, and achievement of developmental motor milestones such as sitting without support. Survival was defined as time from with birth to death or permanent ventilation. Comparison of the results of the ongoing clinical trial to available natural history data provides primary evidence of the efficacy of Zolgensma®. Zolgensma® has a box warning regarding acute serious liver injury. The warning adds that prior to infusion, liver function should be assessed by clinical exam and laboratory testing. Systemic corticosteroids should be administered to all patients before and after Zolgensma® infusion, and live function should continue to be monitored for at least 3 months after infusion.

Recommendation:

- Add new subcategory Spinal Muscular Atrophy to the Miscellaneous section of the PDL.
- Add Zolgensma® (onasemnogene abeparvovec-xioi) intravenous suspension to preferred after clinical criteria are met.
- Add Spinraza to the updated subcategory.
    - Clinical criteria
        - Remove the requirement that the prescriber is a neurologist, pulmonologist, or other physician with expertise in treating SMA AND revise the need for invasive or noninvasive ventilation (if applicable) does not exceed more than 16 hours per 24 hour period.
        - Add Zolgensma: The patient is less than 2 years of age AND The diagnosis is spinal muscular atrophy (SMA) AND The patient has bi-allelic mutations of the SMN1 gene AND The patient does not have advanced SMA (e.g. complete paralysis of limbs or permanent ventilator dependence) AND Medication is prescribed per the dosing guidelines in the package insert (recommended dose is 1.1×10^{4} vector genomes per kilogram) AND Baseline anti-AAV9 antibodies are less than 1:50 Prior to starting therapy and periodically for at least 3 months, the following laboratory tests will be conducted: Liver function (AST, ALT, total bilirubin,

prothrombin time), platelet counts, and troponin-I Note: The safety and effectiveness of repeat administration has not been evaluated. Approval is limited to a single intravenous infusion.

Public Comment: Shannon Barrett from Avexis: Highlighted the attributes of Zolgensma.

Board Decision: The Board unanimously approved the above recommendations.

- Zulresso® (brexanolone)

Brexanolone, the active ingredient of Zulresso®, is a neuroactive steroid gamma-aminobutyric acid (GABA) A receptor positive modulator that is chemically identical to endogenous allopregnanolone. The mechanism of action of brexanolone for its indication is not fully understood, but it is thought to be related to its positive allosteric modulation of GABA-A receptors. Zulresso® is a Schedule IV controlled substance. It is indicated for the treatment of postpartum depression (PPD) in adults. The safety and efficacy of Zulresso® in the treatment of PPD were established in 2 multicenter, randomized, double-blind, placebo-controlled studies (Study 1 and 2) in women aged 18 to 45 years with PPD who met the Diagnostic and Statistical Manual of Mental Disorders criteria for a major depressive episode (DSM-IV) with onset of symptoms in the third trimester or within 4 weeks of delivery. It has a box warning regarding excessive sedation and sudden loss of consciousness. Due to these risks, Zulresso® is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the Zulresso® REMS. A healthcare provider must be available on site to continuously monitor the patient, and intervene as necessary, for the duration of the Zulresso® infusion. Patients must be monitored for hypoxia and assessed for excessive sedation every 2 hours during planned, non-sleep periods. In clinical trials compared with placebo, Zulresso® titration to 90mcg/kg/hour was superior to placebo in improvement in depressive symptoms, as measured by the HAM-D total score at the end of the infusion.

Recommendation:

- Add Zulresso™ (brexanolone) intravenous solution to non-preferred.
  - Clinical criteria
    - Add Zulresso: Patient is ≥ 18 years of age and ≤ 6 months postpartum AND patient has a diagnosis of postpartum depression (PPD) with documented onset of symptoms occurring in the third trimester or within 4 weeks of delivery AND the patient has a documented treatment failure (defined by at least 8 weeks of therapy) with two different oral antidepressants unless contraindicated or documentation shows that the severity of depression would place the health of the mother or infant at significant risk AND the pharmacy,

patient, and healthcare facility are enrolled in the REMS program. Note: Zulresso™ will be approved as a medical benefit ONLY and will NOT be approved if billed through pharmacy point of sale.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

8. New Therapeutic Drug Classes

- None at this time.

9. Therapeutic Drug Classes- Periodic Review:

- **Acne Agents**
  - In October 2019, the FDA approved the first retinoid in more than 20 years, trifarotene (Alkief®). It is a first-in-class retinoid agent that works through RAR-□ selectivity which is highly expressed in the skin.
  - The Dermatological Society of Singapore produced a set of acne management guidelines in 2019.

Recommendation:

- Move Zenatane (isotrentinoin) capsules to preferred.
- Move Benzoyl Peroxide 6% CL; 5%L, 10%L to non-preferred.
- Remove Rosula® (sulfacetamide/sulfur P, W) and Rhofade™ (oxymetazoline) 1%C from the PDL.
- Move clindamycin/benzoyl peroxide pump to non-preferred.
- Add clindamycin/tretinoin 1.2/0.025% and tazarotene 0.1% C to non-preferred.
  - Clinical criteria
    - Add Clindamycin/tretinoin gel: patient has had a documented side effect or treatment failure on combination therapy with the separate ingredients of the combination product.
    - Add Clindamycin/Benzoyl peroxide pump: there must be a clinically compelling reason why clindamycin/benzoyl peroxide gel cannot be used.
    - Update Adapalene, tazarotene: patient has had a documented side effect, allergy, or treatment failure with the brand name equivalent.

Public Comments: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

- **Antibiotics, Miscellaneous**
    - In 2019, the FDA approved a semi-synthetic antibacterial, a pleuromutilin derivative, called lefamulin (Xenleta®). It is available as an IV infusion or tablet indicated for community-acquired bacterial pneumonia (CABP).

Recommendation:

- Remove Zmax® suspension (azithromycin extended release for oral suspension) and PCE Dispertab® (erythromycin base) from the PDL.
- Add Erythromycin base, delayed release (compare to Ery-tab®) to non-preferred.
- Add sub-category nitrofurantoin derivative. Add nitrofurantoin macrocrystalline capsules (compare to Macrodantin®), nitrofurantoin monohydrate macrocystalline capsules (compare to Macrobid®), and nitrofurantoin suspension (age ≤ 12 yrs) to preferred. Add Macrobid® (nitrofurantoin monohydrate macrocrystalline) capsules and Macrodantin® (nitrofurantoin macrocrystalline) capsules to non-preferred.
- Add sub-category clindamycin derivatives. Add clindamycin (compare to cleocin®) capsules and clindamycin (compare to Cleocin®) oral solution to preferred. Add Cleocin (clindamycin) Capsules and Cleocin® Ped (clindamycin) oral solution to non-preferred.
    - Clinical criteria
        - Add Macrobid, Macrodantin: the patient has a documented intolerance to the generic equivalent.
        - Add Nitrofurantoin susp (age > 12 yrs): patient must have medical necessity for a liquid formulation (i.e. swallowing disorder).
        - Add Cleocin: the patient has a documented intolerance to the generic equivalent.

Public Comments: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

- **Antivirals- Influenza, HSV, and CMV Agents**
    - No new drugs
    - No new significant clinical changes

Recommendation:

- Remove Famvir® (famciclovir) from the PDL.
    - Clinical criteria:
        - Remove Famvir criteria from the PDL.
        - Update Famciclovir, Zovirax (tabs, caps): patient has a documented side effect, allergy, or treatment failure (at least one course of ten or more days) with acyclovir or valacyclovir.

Public Comments: None at this time.

Board Decision: None needed.

- **Antivirals, Topical**
  - No new drugs
  - No new significant clinical changes. The CDC guidelines continue to recommend topical antiviral therapy is not used for the treatment of genital herpes infections due to minimal clinical benefits.

Recommendation:

- Add docosanol (compare to abreva) 10% cream to preferred.

Public Comments: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

- **Cephalosporins and Related Antibiotics**
  - No new drugs
  - No new significant clinical changes

Recommendation:

- Remove Ceftibuten suspension (compare to Cedax®), Ceftin® (cefuroxime) tablets, Ceftin® (cefuroxime) suspension, and Daxbia™ (cephalexin) capsules from the PDL.
- Move Cefaclor suspension and cefadroxil tablets to non-preferred.
- Move Cefpodoxime tablets to preferred.
  - Clinical criteria
    - Add Suprax capsule, chewable tablet: patient is completing a course of therapy which was initiated in the hospital. OR patient has had a documented side effect or treatment failure to cefdinir or cefpodoxime.
    - Remove Spectracef tablet, Cefditoren tablet, Cefpodoxime Proxetil tablets and Ceftibuten Susp clinical criteria.

Public Comments: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

- **Fluoroquinolones**
  - No new drugs
  - No new significant clinical changes

Recommendation:

- Move Moxifloxacin (compare to Avelox®) to preferred.
- Remove Cipro XR® (ciprofloxacin) and Ciprofloxacin ER (compare to Cipro XR®) from the PDL.
    - Clinical criteria
        - Add Avelox, Cipro, Levaquin: the patient has had a documented intolerance to the generic equivalent.
        - Remove Cipro, Cipro XR, ciprofloxacin ER, Avelox, Moxifloxacin and Levaquin (brand) criteria.
        - Revise Ofloxacin: patient has had a documented side effect, allergy, or treatment failure to two preferred fluoroquinolones.

Public Comments: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

- **Skeletal Muscle Relaxants**
    - No new drugs
    - No new significant clinical changes
    - Friedman et al published a multicenter, randomized, double-blind parallel-group 4-arm study comparing ibuprofen three times daily plus Baclofen, metaxolone, tizanidine, or placebo in adults 18-64 presenting to the emergency department for management of non-acute, non-traumatic low back pain. Authors concluded that adding baclofen, metaxolone, or tizanidine did not appear to improve functioning or pain any more than placebo plus ibuprofen by 1 week after the ED visit.

Recommendation:

- Move Chlorzoxazone tablets QTY LIMIT: 4 tablets/day to non-preferred.
- Remove Carisoprodol, ASA (previously Soma Compound®) QTY LIMIT: 4 tablets/day from the PDL.
    - Clinical criteria:
        - Add chlorzoxazone to the Carisoprodol, carisoprodol/ASA/codeine, Lorzone, Soma, metaxolone, Skelaxin clinical criteria.
        - Remove carisoprodol/ASA clinical criteria.

Public Comments: No public comment

Board Decision: The Board unanimously approved the above recommendation.

- **Tetracyclines**
    - New drug Minolira® ER. Minocycline, the active ingredient of Minolira®, is a semi synthetic derivative of tetracycline. The mechanism of action for its indication is not known. It is indicated to

treat the inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients 12 years of age and older. This formulation of minocycline has not been evaluated in the treatment of infections. To reduce the development of drug-resistant bacteria, as well as to maintain the effectiveness of other antibacterial drugs, Minolira® should be used only as indicated. Minocycline ER tablets were found to be more effective in 2 clinical trials compared to placebo for its primary endpoints. These clinical trials were the same clinical trials found in the Solodyn® prescribing information, another minocycline ER tablet version with the same indication as Minolira®. Solodyn® has a generic version available. However, Minorlira® has a different release mechanism, in that 25% of the medicine is released immediately, while the remainder is released throughout the day.

Recommendation:

- Add Minolira® ER (minocycline extended release) tablet QTY LIMIT: 1 tablet/day, Demeclocycline 150mg, Demeclocycline 300mg tabs, Doxycycline hyclate delayed release tabs and Doryx (doxycycline hyclate) delayed release tabs to non-preferred.
- Remove Seysara® (sarecycline) tabs from the PDL.
    - Clinical criteria:
        - Remove Seysara clinical criteria from the PDL.
        - Add Minolira ER to Solodyn/Ximino criteria.

Public Comments: No public comment

Board Decision: The Board unanimously approved the above recommendation.

10. Review of Newly-Developed/Revised Criteria

- None at this time.

Recommendation:

- No changes at this time.

Public Comment: No public comment

Board Decision: None needed.

11. General Announcements: Michael Ouellette, RPh, Change Healthcare

Selected FDA Safety Alerts

FDA warns about serious breathing problems with seizure and nerve pain medicines gabapentin (Neurontin, Gralise, Horizant) and pregabalin (Lyrica, Lyrica CR)
https://www.fda.gov/drugs/drug-safety-and-availability/fda-warns-about-serious-breathing-problems-seizure-and-nerve-pain-medicines-gabapentin-neurontin?utm_campaign=FDA%20MedWatch%20-%20gabapentin%20and%20pregabalin%29%3A%20Drug%20Safety%20Communication&utm_medium=email&utm_source=Eloqua

Public Comment: No public comment.

Board Decision: No action needed.

12. Adjourn: Meeting adjourned at 8:25 p.m.