Department of Vermont Health Access
Pharmacy Benefit Management Program
DUR Board Meeting Minutes
December 3, 2019

Board Members:

Present:

Clayton English, PharmD	Margot Kagan, PharmD	Renee Mosier, PharmD
Zail Berry, MD	Bill Breen, RPh	Marc Pasanen, MD
Joseph Nasca, MD	Claudia Berger, MD	

Absent: Louise Rosales, NP, Patricia King, MD

Staff:

Laurie Brady, RPh, Change HealthCare	David Aboelezz, PharmD, Change HealthCare	Laureen Biczak, DO, Change Healthcare
Carrie Germaine, DVHA	Mike Ouellette, RPh, Change Healthcare	Scott Strenio, MD, DVHA
Jason Pope, DVHA	Lisa Hurteau, PharmD, DVHA	Danielle Bragg, DVHA
Sandi Hoffman, DVHA		

Guests:

Thomas Algozzine, Novartis	Afraim Botros, BMS	Jai Persico, Neurocrine
Karl Magnussen, BMS	Brad King, Takeoa	Ken Skidmore, Kute Pharma
Ami Muehlberg, Amgen	Bryan Dillon, Otsuka	Frank Nagy, Xeris

1. Executive Session:

- An executive session was held from 6:00 p.m. until 6:35 p.m.

2. Introductions and Approval of DUR Board Minutes:

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

3. DVHA Pharmacy Administration Updates:

- No updates at this time.

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

- An executive summary is due soon regarding urine drug testing. This is an area of high spend for Medicaid, and the goal is to determine how much duplication of services is happening and how to better avoid this in the future. Some of the challenges have been multiple payment methods and lack of clear guidelines regarding urine drug testing. LC-MS/MS hybrid testing shows promise and may avoid the need for both an initial and confirmatory test in many instances.
- Review of the Pediatric Palliative Care Waiver Program is ongoing. They are looking at children as they age out of this program to better facilitate them into other programs.

- ACO continues to grow.

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

- Review Analgesics: Miscellaneous: Topical and Transdermal Patch.

Recommendation:

- Add Lidocaine 4% OTC Patch to preferred.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation and asked that the available NDCs be included in the 1/1/20 PDL changes newsletter

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

- Introduce: Long Term Antibiotic Use

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. The scope of overprescribing is not known and there is concern that patients may be cycling through different antibiotics continuously, which is sometimes seen in patients with sinus symptoms, for example. In addition to adverse effects, the financial burden of inappropriate antibiotic use is another factor that needs to be considered. Change Healthcare will use paid, non-reversed Medicaid pharmacy claims from State Fiscal Year 2019 (7/1/18-6/30/19), excluding members with Part D, VMAP and Healthy Vermonters coverage. Change Healthcare will review 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 supperativa. For the remaining members, we will do 2 types of analysis. The first will look at members prescribed more than 12 consecutive weeks of fluroquinolones, assessing the conditions for which the antibiotic was used. The second analysis will look at members with the diagnoses of Lyme disease, anaplasmosis or babesiosis and look at the use of antibiotics in that population, both long-term use of one antibiotic, or cycling of antibiotics. The prescribers for these members will be identified to look at providers who are possibly practicing outside of guideline recommendations, perhaps identifying those who would be appropriate for more targeted education.

Recommendation:

Public Comment: No public comment.

Board Decision: None needed.

- Data Presentation: Appropriate Use of Asthma Controller Medications

The National Heart, Lung and Blood Institute has published Guidelines for the Diagnosis and Management of Asthma. The treatment of asthma is done in a step-wise manner, and depending on disease severity, a combination of several agents may be needed. For anyone who requires use of a short acting agent > 2 days/week, a controller medication daily is recommended. The Guidelines state that the frequency of short acting beta-adrenergic inhaler (SABA) use can be clinically useful as a measure of disease activity since increased use of a SABA has been associated with increased risk for death or near death in patients who have asthma. Use of more than one SABA canister every one to two months is also associated with an increased risk of an acute exacerbation. Therefore, the use of more than one SABA canister (e.g., albuterol 200 puffs per canister) during a one-month period most likely indicates over reliance on this drug and suggests inadequate control of asthma. Additionally, inhaled corticosteroids (ICS) are the preferred long-term control therapy in asthma for all ages, although leukotriene receptor antagonists (LTRA) are listed as an alternative. Long-acting beta-adrenergic inhalers (LABAs) should never be used without first using ICS inhalers due to the increased risk of asthma exacerbations and death. Change Healthcare used paid, non-reversed Medicaid pharmacy claims from January 2018 through December 2018, excluding members with Part D, VMAP and Healthy Vermonters coverage. Change Healthcare reviewed Vermont paid non-reversed pharmacy and medical claims with dates of service from 1/1/2018 through 12/31/2018, excluding members who had a diagnosis of cystic fibrosis, COPD or emphysema. Members were stratified by age and the number of short acting inhalers used per year. In addition, the number of members in each group who had an ER visit or hospitalization associated with an asthma diagnosis during the study period were reported. The rates of ER visits and hospitalizations were compared to the rates seen in the 2015 analysis, examining whether the educational interventions provided by the Board had an impact in reducing rates of asthma exacerbations, understanding that the populations are not identical. Additional analysis was done on those using more than 12 short acting inhalers/year and sorted geographically. 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. Total of 235 members were on greater than 12 inhalers/year. Of those, 72 were not on controller medication (31%), which is the same percentage as in 2015. There is not a clear pattern of increased ER use or asthma admissions in those who are not on controller medications and are prescribed more than 12 inhalers/year, although the numbers are fairly small. Only 4 prescribers had more than 2 members using > 12 inhalers/year and not on a controller medication.

Recommendation: Global Initiative for Asthma (GINA) Guidelines have been updated for 2019 and recommend that all adults and adolescents should receive ICS-containing controller treatment, including patients with mild asthma. Complete this analysis again in 1-2 years to assess compliance with these new guidelines.

Public Comment: No public comment.

Board Decision: A targeted mailing of prescribers that have patients on >12 inhalers a year who are not on a controller medication.

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:

- Beser lotion® (fluticasone propionate)

Fluticasone propionate, the active ingredient of Beser®, is a synthetic fluorinated corticosteroid. Corticosteroids play a role in cellular signaling, immune function, inflammation, and protein regulation; however, the exact mechanism of action in atopic dermatitis is not known. It is indicated for the relief of the inflammatory and pruritic manifestations of atopic dermatitis in patients 3 months of age or older. In clinical trials, fluticasone propionate lotion was found to be superior to vehicle in the treatment of atopic dermatitis. Fluticasone lotion 0.05% generic and brand name Cutivate® have been available for several years. The clinical trials included for Beser® lotion were the same as those in the Cutivate® lotion clinical trials section of the prescribing information. Both are given once daily with the same indication.

Recommendation:

- Add Beser (fluticasone) 0.05% Lotion to non-preferred.
  - Clinical criteria: Include with all non-preferred agents to state the patient has a documented side effect, allergy, or treatment failure to at least two different preferred agents of similar potency. (If a product has an AB rated generic, one trial must be the generic.)

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

- Diacomit® (stiripentol)

Stiripentol, the active ingredient of Diacomit®, is an anticonvulsant. The exact mechanism of action is not known, but possible mechanisms of action include direct effects mediated through the gamma-aminobutyric acid $(GABA)_A$ receptor and indirect effects involving inhibition of CYP450 activity with resulting increase in blood levels of clobazam and its active metabolite. It is indicated for the treatment of seizures associated with Dravet syndrome (DS) in patients 2 years of age and older taking clobazam. There are no clinical data to support the use of

Diacomit® as monotherapy in DS. The safety and efficacy of Diacomit® were assessed in 2 multicenter, placebo-controlled, double-blind, randomized studies that included patients 3 years of age to less than 18 years of age with Dravet syndrome and inadequately controlled on clobazam and valproate. Patients had at least 4 generalized clonic or tonic-clonic seizures per month despite optimized therapy. In clinical trials as add-on to clobazam and valproate, Diacomit® significantly improved response rates and the changes in seizure frequency as compared to placebo. These were small randomized studies that included pediatric patients uncontrolled on their current regimen.

Recommendation:

- Add Diacomit (stiripentol) to non-preferred.
- Move Clobazam (compare to Onfi®) Quantity Limit = 3 tabs/day (10 mg) and 2 tabs/day (20 mg) to preferred.
- Move Lyrica® (pregabalin) capsules Quantity Limit = 3 capsules/day to non-preferred.
- Add Pregabalin (compare to Lyrica) Quantity Limit = 3 capsules/day to preferred.
    - Clinical criteria
        - Add Diacomit: Diagnosis or indication is treatment of Dravet Syndrome AND neutrophil and platelet counts have been obtained prior to starting therapy and are monitored periodically thereafter AND Patient is unable to tolerate or has had an inadequate response to valproate and clobazam AND medication will used concurrently with clobazam. Note: There are no clinical data to support the use of Diacomit as monotherapy.
        - Add Lyrica and Onfi to the Mysoline, Neurontin caps, tabs, sol, Tegretol tabs, Tegretol XR (200mg & 400mg), Topamax tabs, Topamax sprinkles, Trileptal tabs, Trileptal oral suspension, Zarontin, and Zonegran criteria.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

- Duobrii® (halobetasol propionate and tazarotene)

Duobrii® is a combination product containing halobetasol propionate (corticosteroid) and tazarotene. Corticosteroids play a role in cellular signaling, immune function, inflammation, and protein regulation; however, the exact mechanism of action in plaque psoriasis is not known. Tazarotene is a retinoid prodrug that is converted to its active form, tazarotenic acid. Tazarotenic acid binds to all 3 members of the retinoic acid receptor (RAR) family with relative selectivity to 2 of the 3 receptors and may modify gene expression. The clinical significance of

these findings for the treatment of plaque psoriasis is not known. It is indicated for the topical treatment of plaque psoriasis in adults. The safety and efficacy of Duobrii® were assessed in 2 prospective, multicenter, randomized, double-blind, vehicle-controlled studies that included adults ≥18 years of age with moderate to severe plaque psoriasis.

Recommendation:

- Add Duobrii (halobetasol propionate/tazarotene) lotion to non-preferred.
  - Clinical criteria
    - Add Duobrii lotion: the patient has had an inadequate response to at least 2 different preferred high or very high potency corticosteroids AND Tazorac cream or gel.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

- Evenity® (romosozumab)

Romosozumab-aqqg, the active ingredient of Evenity®, is a humanized monoclonal antibody (IgG2) produced in a mammalian cell line (Chinese Hamster Ovary) by recombinant DNA technology that binds to and inhibits the action of sclerostin. Sclerostin is a regulatory factor in bone metabolism. Evenity® increases bone formation, and to a lesser extent, decreases bone resorption. It is indicated for the treatment of osteoporosis in postmenopausal women at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy. The anabolic effect of Evenity® wanes after 12 monthly doses of therapy. Therefore, the duration of Evenity® should be limited to 12 monthly doses. If osteoporosis therapy remains warranted, continued therapy with an anti-resorptive agent should be considered. The safety and efficacy of romosozumab-aqqg were assessed in a randomized double-blind, placebo-controlled study that included postmenopausal women aged 55 to 90 years (mean age 71 years) with bone mineral density (BMD) T-score ≤ -2.5 at the total hip or femoral neck. Results suggested that Evenity® significantly reduced the incidence of new vertebral fractures through month 12 as compared to placebo. In addition, the significant reduction in fracture risk persisted through the second year in women who received Evenity® during the first year and transitioned to denosumab compared to those who transitioned from placebo to denosumab.

Recommendation:

- Add Evenity® (romosozumab-aqqg) injection Quantity Limit = 210 mg (2 syringes)/month (Lifetime max duration = 12 months) to non-preferred.
- Add new sub category Injectable Sclerostin Inhibitor noting that all products require PA.

- Clinical criteria
  - Add Evenity Injection: diagnosis or indication is postmenopausal osteoporosis AND patient has no history of stroke or MI within the previous year AND patient has had a documented side effect or treatment failure to a preferred bisphosphonate and Forteo. (Bisphosphanate treatment failure is defined as documented continued bone loss or fracture after one or more years despite treatment with an oral bisphosphonate).

Public Comment: Ami Muehtherg from Amgen: Highlighted the attributes of Evenity.

Board Decision: The Board unanimously approved the above recommendations.

- Jornay PM® (methylphenidate extended-release)

Methylphenidate, the active ingredient of Jornay® PM, is a central nervous system (CNS) stimulant. The exact mode of action in ADHD is not known. Methylphenidate is thought to block the reuptake of norepinephrine and dopamine into the presynaptic neuron and increase the release of these monoamines into the extra neuronal space. It is indicated for the treatment of attention deficit hyperactivity disorder (ADHD) in patients 6 years and older. The safety and efficacy of Jornay® PM were established in two clinical studies that included pediatric patients 6 to 12 years of age (N=278) who met DSM-5 criteria for ADHD inattentive, hyperactive-impulse, or combined inattentive/hyperactive impulsive subtypes. It was found to be significantly more effective than placebo in clinical trials assessing efficacy, based on SKAMP scores and ADHD-RS-IV scores, with demonstrated efficacy in the morning and throughout the day.

Recommendation:

- Add Jornay PM (methylphenidate ER) capsules Qty Limit = 1 capsule/day to non-preferred.
  - Clinical criteria
    - Add Jornay PM: patient has had a documented side-effect, allergy, or treatment failure on 3 preferred long-acting Methylphenidate products.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

- Mavenclad® (cladribine)

Cladribine, the active ingredient of Mavenclad®, is a nucleoside metabolic inhibitor. The mechanism by which it exerts its therapeutic effects in patients with MS has not been fully

elucidated but is thought to involve cytotoxic effects on B and T lymphocytes through impairment of DNA synthesis, resulting in depletion of lymphocytes. It is indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include relapsing-remitting disease and active secondary progressive disease, in adults. Because of its safety profile, use of Mavenclad® is generally recommended for patients who have had an inadequate response to, or are unable to tolerate, an alternate drug indicated for the treatment of MS. Mavenclad® is not recommended for use in patients with clinically isolated syndrome (CIS) because of its safety profile. The efficacy of Mavenclad® was demonstrated in a 96-week randomized, double-blind, placebo-controlled clinical study in patients with relapsing forms of MS. There is no evidence at this time that Mavenclad® is safer or more effective than the currently preferred, more cost-effective medications. Furthermore, Mavenclad® is generally recommended for patients who have had an inadequate response to, or are unable to tolerate, an alternative drug indicated for the treatment of MS due to its safety profile.

Recommendation:

- Add Mavenclad (cladribine) tablet to non-preferred.
- Clarify Avonex (interferon 8-1a) vial, pre filled syringe and autoinjector are preferred.
    - Clinical criteria
        - Add Mavenclad: Patient is ≥ 18 years AND has a diagnosis of relapsing-remitting MS (RRMS) 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, and MRI (within the past 3 months) have been completed AND the patient is negative for HIV, Hepatitis B, and Hepatitis C infections AND the patient is not pregnant AND patient has a documented side effect, allergy, treatment failure or contraindication to at least two preferred drugs AND dosing does not exceed any of the following: 2 tablets per day, 10 tablets per cycle, 2 treatment cycles per course, 1 course per year. Following the administration of 2 treatment courses, Mavenclad may not be administered during the next 2 years.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendations with the correction that 3 preferred drugs must be tried prior to Mavenclad approval.

- Mayzent® (siponimod)

Siponimod, the active ingredient of Mayzent®, is a sphingosine-1-phosphate (S1P) receptor modulator. It binds with high affinity to S1P receptors 1 and 5 and blocks the capacity of lymphocytes to egress from lymph nodes, reducing the number of lymphocytes in peripheral blood. While the mechanism by which siponimod exerts its effect in multiple sclerosis is not known, it may involve 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 efficacy of Mayzent® was demonstrated in a randomized, double-blind, parallel-group, placebo-controlled, time-to-event study in patients with secondary progressive MS (SPMS) who had evidence of disability progression in the prior 2 years, no evidence of relapse in 3 months prior to the study, and an Expanded Disability Status Scale (EDSS) score of 3.0-6.5 at study entry. In a clinical trial, it significantly decreased the proportion of patients with confirmed disability progression at 3 months as compared with placebo; however, it did not demonstrate a significant effect on the timed 25-foot walk test. Comparator studies with other active agents indicated for MS were not found.

Recommendation:

- Add Mayzent (siponimod) tablet to non-preferred.
  - Clinical criteria
    - Add Mayzent: *Diagnosis of relapsing-remitting MS or Clinical Isolated Syndrome:* Patient is ≥ 18 years AND Patient CYP2C9 variant status has been tested to determine genotyping (required for dosing; therapy is contraindicated in CYP2C9*3/*3) AND Baseline CBC, electrocardiogram (ECG), and ophthalmic evaluation have been completed AND Patient has a documented side effect, allergy, treatment failure or contraindication to at least two preferred drugs.
      Diagnosis of Active Secondary Progressive MS (SPMS): Patient is ≥ 18 years AND Patient CYP2C9 variant status has been tested to determine genotyping (required for dosing; therapy is contraindicated in CYP2C9*3/*3) AND Baseline CBC, electrocardiogram (ECG), and ophthalmic evaluation have been completed AND Documentation is provided showing ≥ 1 relapse within the past year OR new or enlarging T2 lesions as evidenced by MRI.

Public Comment: Tom Algozzine from Novartis: Highlighted the attributes of Mayzent.

Board Decision: The Board unanimously approved the above recommendations. The Multiple Sclerosis class will be re-reviewed again in the spring.

- Oxervate™ (cenegermin-bkbj)

Cenegermin-bkbj, the active ingredient of Oxervate™, is a recombinant form of human nerve growth factor produced in E. coli. Nerve growth factor is an endogenous protein involved in the differentiation and maintenance of neurons, which acts through specific high-affinity (i.e. TrkA) and low-affinity (i.e. p75NTR) nerve growth factor receptors in the anterior segment of the eye to support corneal innervation and integrity. It is indicated for the treatment of neurotrophic keratitis. The safety and efficacy of Oxervate™ were assessed in 2 randomized, multicenter, double-masked, vehicle-controlled studies of 8 weeks in duration. In clinical trials compared with vehicle, a significantly greater number of patients treated with Oxervate® had complete corneal healing in adults with unilateral or bilateral neurotrophic keratitis. Oxervate® is the first FDA approved product approved for neurotrophic keratitis, a rare eye disease.

Recommendation:

- Add new Neurotrophic Keratitis sub-category under Ophthalmics.
- Add Oxervate™ (cenegermin-bkbj) ophthalmic solution 0.002% Qty Limit = 1 vial (1mL) per eye per day, maximum of 8 weeks therapy to non-preferred.
- Add under preferred All products require PA.
    - Clinical criteria
        - Add Oxervate: Medication is being prescribed by, or in consultation with, an ophthalmologist AND Patient has a diagnosis of Stage 2 or 3 neurotrophic keratitis (in one or both eyes) as evidenced by persistent epithelial defect or corneal ulceration AND patient has evidence of decreased corneal sensitivity in at least one corneal quadrant AND patient has failed one or more conventional non-surgical treatments such as artificial tears, gels, or ointments.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

- Qmiiz ODT® (meloxicam)

Meloxicam, the active ingredient of Qmiiz® ODT, is a nonsteroidal anti-inflammatory drug. It has analgesic, anti-inflammatory, and antipyretic properties. The mechanism of action, like that of other NSAIDs, is not completely understood but involves inhibition of cyclooxygenase (COX-1 and COX-2). Meloxicam is a potent inhibitor of prostaglandin synthesis in vitro. Prostaglandins are mediators of inflammation. Because meloxicam is an inhibitor of prostaglandin synthesis, its mode of action may be due to a decrease of prostaglandins in peripheral tissue. It is indicated for: The relief of the signs and symptoms of osteoarthritis (OA) in adults, the relief of the signs and symptoms of rheumatoid arthritis (RA) in adults, and the relief of the signs and symptoms

of pauciarticular or polyarticular course juvenile rheumatoid arthritis (JRA) in pediatric patients who weigh ≥60kg. The clinical trials section for Qmiiz® ODT included the same trials that are included in the prescribing information for Mobic® (meloxicam tablets). Mobic® and its generic equivalent have been available for numerous years and have been found to be safe and effective for its approved indications, which are the same as Qmiiz® ODT. Qmiiz® ODT has been shown to meet bioequivalence criteria for both Cmax and AUC as compared to Mobic® tablets, but the Tmax was delayed with food. There is no evidence at this time that Qmiiz® ODT is safer or more effective than the currently preferred, more cost-effective medications.

Recommendation:

- Add Qmiiz (meloxicam) ODT to non-preferred.
- Move DICLOFENAC (compare to Voltaren®) gel 1% and DICLOFENAC 1.5 % Topical Solution to preferred.
- Remove Voltaren® (diclofenac) 1% Gel from the PDL.
    - Clinical criteria
        - Add Qmiiz to the Vivlodex criteria.
        - Revise Flector Patch, Pennsaid: diagnosis or indication is osteoarthritis or acute pain caused by minor strains, sprains, and contusions AND patient has had a documented side effect or inadequate response to Diclofenac gel or topical solution.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

- Rocklatan® (netarsudil and latanoprost)

Rocklatan® is a fixed-dose combination ophthalmic product containing a Rho kinase inhibitor (netarsudil) and a prostaglandin F2α analogue (latanoprost). Both active ingredients decrease elevated IOP. Rocklatan® is believed to reduce IOP by increasing the outflow of aqueous humor. Elevated IOP represents a major risk factor for glaucomatous field loss. The higher the level of IOP, the greater the likelihood of optic nerve damage and glaucomatous visual field loss. It is indicated for the reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension. The safety and efficacy of Rocklatan® were assessed in 2 randomized and controlled trials that included patients with open-angle glaucoma and ocular hypertension with an IOP <36mmHg. Rocklatan® is a safe, effective, and cost-effective product.

Recommendation:

- Add Rocklatan (netarsudil/latanoprost) to preferred.
- Move Azopt® (brinzolamide 1%) to preferred.
    - Clinical criteria

- Remove the "Single Agent" criteria for the carbonic anhydrase inhibitor class.
- Revise Cosopt, Trusopt: The patient has had a documented intolerance to the generic equivalent product.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

- Ruzurgi® (amifampridine)

Amifampridine, the active ingredient of Ruzurgi®, is a potassium channel blocker. The mechanism by which it exerts its therapeutic effects for its indication has not been fully established. Amifampridine is a broad-spectrum potassium channel blocker. It is indicated for the treatment of Lambert-Eaton myasthenic syndrome (LEMS) in patients 6 years to less than 17 years of age. The safety and efficacy of Ruzurgi® for the treatment of LEMS were assessed in a randomized, double-blind, placebo-controlled withdrawal study that included patients with an established diagnosis of LEMS, confirmed by documentation and an independent neurologist review. Patients were required to be on adequate and stable dosage (30mg to 100mg daily for at least 3 months) of Ruzurgi® prior to entering the study. The randomized patients had a median age of 56 years, 66% were female, and 91% were white. Significantly fewer patients randomized to Ruzurgi® experienced a >30% deterioration in the final post-dose 3TUG test as compared with placebo (0% vs 72%). In addition, compared with Ruzurgi®, those treated with placebo showed a significantly greater decrease in the W-SAS score, indicating that patients randomized to placebo perceived a worsening of weakness compared to those on Ruzurgi®.

Recommendation:

- Add Ruzurgi® (amifampridine) Quantity Limit = 10 tablets/day to non-preferred.
  - Clinical criteria
    - Revise criteria Firdapse, Ruzurgi: The patient has a diagnosis of Lambert-Eaton myasthenic syndrome (LEMS) AND prescription is initiated by or in consultation with a neurologist AND patient does not have a history of seizures AND for approval of Firdapse, the patient must have a documented intolerance to Ruzurgi. Initial approval will be granted for 3 months with documentation of the patient's baseline clinical muscle strength assessment using a standardized rating scale. For re-approval after 3 months, the patient must have improved or stable symptoms documented with the appropriate standardized rating scale.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

- Skyrizi® (risankizumab)

Risankizumab-rzaa, the active ingredient of Skyrizi®, is a humanized immunoglobulin G1 (IgG1) monoclonal antibody produced using recombinant DNA technology. It selectively binds to the p19 subunit of human interleukin 23 (IL-23) cytokine and inhibits its interaction with the IL-23 receptor (an IL-23 antagonist). IL-23 is a naturally occurring cytokine that is involved in inflammatory and immune responses. Risankizumab-rzaa inhibits the release of pro-inflammatory cytokines and chemokines. Is it indicated for the treatment of moderate-to-severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy. The safety and efficacy of Skyrizi® were assessed in 4 multicenter, randomized, double-blind studies (ULTIMMA-1, ULTIMMA-2, IMMHANCE, and IMMVENT) that included adult subjects ≥18 years of age with moderate to severe plaque psoriasis who had a body surface area (BSA) involvement of ≥10%, a static Physician's Global Assessment (sPGA) score of ≥3 (moderate) in the overall assessment (plaque thickness/induration, erythema, and scaling) of psoriasis on a severity scale of 0 to 4, and a Psoriasis Area and Severity Index (PASI) score ≥12. Skyrizi® was found to be more effective as compared with placebo in clinical trials.

Recommendation:

- Add SkyriziTM (risankizumab-rzaa) Quantity Limit = 4 syringes for the first month followed by 2 syringes (150 mg) every 12 weeks thereafter to non-preferred.
  - Clinical criteria
    - Add Skyrizi to the additional criteria for Ilumya, Remicade, Siliq, Stelara, Taltz and Tremfya.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the above recommendation.

8. New Therapeutic Drug Classes

- None at this time.

9. Therapeutic Drug Classes- Periodic Review:

- **Anticoagulants**
  - Xarelto has a new indication. 2.5mg taken orally twice daily in combination with aspirin is indicated for the reduction of risk of major cardiovascular events (CV Death, MI, and stroke) in patients with chronic Coronary Artery Disease (CAD) or Peripheral Artery Disease (PAD).

- Apixaban tends to have lowest bleeding rate in most studies.
- Rivaroxaban has the most data for being used for post arthroplasty.
- The 2019 AHA/ACC/HRS recommends the use of oral anticoagulants for patients with atrial fibrillation and an elevated CHA2DS2-VASc score; however, in this latest guideline, NOACs are recommended over warfarin in NOAC-eligible patients with AF, except for moderate-to-severe mitral stenosis or a mechanical heart valve.

Recommendation:

- Move Fondaparinux to non-preferred.
- Add note under Selective Factor XA Inhibitor Injectables all products require PA.
    - Clinical criteria
        - Remove current Arixtra criteria.
        - Add Arixtra, Fondaparinux, Lovenox and Fragmin: patient has a documented intolerance to generic enoxaparin AND if the request is for brand Arixtra, the patient must also have a documented intolerance to generic fondaparinux.

Public Comments: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

- **Antidepressants, Other**
    - No new drugs
    - No new significant clinical changes

Recommendation:

- Remove Parnate® (tranylcypromine), Desvenlafax ER (desvenlafaxine fumarate SR 24hr) Tablet, and Surmontil® (trimipramine) from the PDL.
- Add Deslenlafaxine succinate ER (compare to Pristiq®) FDA maximum recommended dose = 400 mg/day, Quantity Limit = 1 tablet/day (50 mg tablet only) to non-preferred.
- Move Protriptyline and Clomipramine (compare to Anafranil®) to non-preferred.
- Move venlafaxine IR FDA maximum recommended dose = 225 mg/day to preferred.
- Clarify Buproprion XL 450mg (compare to Forfivo XL®) is non-preferred and BUPROPION XL (compare to Wellbutrin XL®) 150mg, 300mg are preferred.
    - Clinical criteria
        - Add Buproprion XL 450mg to Forfivo XL: The patient is unable to take the equivalent dose as generic buproprion XL (150mg & 300mg) AND for approval of brand, the patient must have a documented intolerance to the generic equivalent.

- Revise Trintellix, Viibryd: The diagnosis or indication is MDD AND The patient has had a documented side effect, allergy, or inadequate response (defined by at least 4 weeks of therapy) to at least 2 different antidepressants from the SSRI, SNRI, and/or Miscellaneous Antidepressant categories (may be preferred or nonpreferred).
- Add Desvenlafaxine ER succinate, Pristiq to Venlafaxine ER tablet (generic), Effexor ER Capsule brand: The patient has had a documented intolerance to generic Venlafaxine ER caps AND if the request is for Pristiq, the patient has a documented intolerance to the generic.
- Revise Desvenlafaxine SR (base), Fetzima, Khedezla: The patient has had a documented side effect, allergy, or inadequate response to at least 2 different antidepressants, one of which must be venlafaxine ER capsule AND The patient has had a documented intolerance with generic desvenlafaxine succinate ER.

Public Comments: No public comment.

Board Decision: The Board unanimously approved the above recommendation with the change to Clomipramine criteria: For patients with a diagnosis of obsessive-compulsive disorder patient has had a documented side effect, allergy, or treatment failure to 2 SSRIs

- **Antidepressants, SSRIs**
  - No new drugs
  - No new significant clinical changes

Recommendation:

- No changes at this time.

Public Comments: None at this time.

Board Decision: None needed.

- **Antiparkinson's Agents**
  - No new drugs
  - No new significant clinical changes

Recommendation:

- Move Neupro® (rotigotine) transdermal patch Quantity Limit = 1 patch/day (2mg, 4 mg, 6 mg and 8 mg patches), Comtan® (entacapone) and Stalevo®

(carbidopa/levodopa/entacapone) to non-preferred. Grandfather existing Neupro patients.
- Move Carbidopa/Levodopa/Entacapone (compare to Stalevo®) to preferred.
- Add BENZTROPINE and TRIHEXYPHENIDYL to preferred.
    - Clinical criteria
        - Add Comtan and Stalevo to Sinemet, Sinemet CR, Mirapex, Parlodel, Requip criteria.
        - Add Neupro: The patient has a medical necessity for a specialty dosage form.

          Revise Tasmar, Tolcapone: The diagnosis or indication is Parkinson's disease AND the patient has had a documented side effect, allergy, or treatment failure with entacapone AND patient has provided written acknowledgement of risks per the package insert. For approval of brand Tasmar, the patient must have a documented intolerance to the generic equivalent.

- Restless Leg Syndrome Medications Category
    - Move Neupro® (rotigotine) transdermal patch Quantity Limit = 1 patch/day (1mg, 2 mg and 3 mg patches ONLY) to non-preferred.
        - Clinical criteria
            - Add Neupro: The patient has a medical necessity for a specialty dosage form.

Public Comments: No public comment.

Board Decision: The Board unanimously approved the above recommendation with a revision to Tasmar/tolcapone criteria.

- **Gastrointestinal Ulcer Therapies/H. Pylori Treatments**
    - No new drugs
    - No new significant clinical changes

Recommendation:

- Remove Prevpac® (lansoprazole, amoxicillin, clarithromycin) from the PDL.
- Add Nizatidine capsules and Lansoprazole ODT (compare to Prevacid Solutab®) Quantity Limit = 1 tab/day to non-preferred.
- Move Esomeprazole (compare to Nexium®) Quantity Limit = 1 cap/day to preferred.
    - Clinical criteria
        - Add Cimetidine tablet to the Nizatidine capsule, Pepcid tablet, Ranitidine capsule, Zantac tablets criteria.

- Add Aciphex Sprinkle to the Prevacid Solutabs, Prilosec packet, and Protonix packet criteria.
- Revise criteria for "Other non-preferred medications": The member has had a documented side effect, allergy, or treatment failure to ALL preferred PPIs AND if the product has an AB rated generic, there must be a trial of the generic.

Public Comments: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

- **Hyperuricemia and Gout**
  - No new drugs
  - No new significant clinical changes
  - Ironwood, the manufacturer of lesinurad products, has discontinued the US commercialization of lesinurad, effective February 2019. This would include lesinurad (Zurampic®) and lesinurad/allopurinol (Duzallo®). The manufacturer indicated the decision to remove these products from the market was a business decision and was not based on efficacy, safety, or clinical concerns.

Recommendation:

- Add Febuxostat (compare to Uloric®) Quantity Limit (40 mg tablets) = 1 tablet/day to non-preferred.
- Remove Duzallo® (lesinurad/allopurinol) and Zurampic® (lesinurad) from the PDL.
- Clarify Colchicine capsules Hikma labler code 00143 is the only preferred (all other labelers are non-preferred).
  - Clinical criteria
    - Remove Duzallo and Zurampic criteria.
    - Add Febuxostat to the Uloric criteria.

Public Comments: No public comment.

Board Decision: The Board unanimously approved the above recommendations.

- **Platelet Aggregation Inhibitors and Intermittent Claudication**
  - No new drugs
  - No new significant clinical changes

Recommendation:

- Remove Durlaza® (asprin extended release) capsules from PDL.

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

Sanofi Provides Update on Precautionary Voluntary Recall of Zantac OTC in U.S.
https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/sanofi-provides-update-precautionary-voluntary-recall-zantac-otc-us?utm_campaign=FDA%20MedWatch%20-%20Zantac%20150%2C%20Zantac%20150%20Cool%20Mint%2C%20Zantac%2075%20%28OTC%20Products%29%20by%20Sanofi&utm_medium=email&utm_source=Eloqua#recall-announcement

Public Comment: No public comment.

Board Decision: After discussion on the safety recall, the Board unanimously approved moving famotidine oral suspension to preferred for children 2 years of age and younger.

12. Adjourn: Meeting adjourned at 8:40 p.m.