Janet T. Mills
Governor

Jeanne M. Lambrew, Ph.D.
Commissioner

Maine Department of Health and Human Services
Office of MaineCare Services - Pharmacy Unit
11 State House Station
Augusta, Maine 04333-0011
Toll Free: (866) 796-2463; TTY: Dial 711 (Maine Relay)
Fax: (207) 287-8601

TO: Maine Drug Utilization Review Board
DATE: 09/15/22
RE: Maine DUR Board Meeting minutes from September 13, 2022

ATTENDANCE	PRESENT	ABSENT	EXCUSED
Linda Glass, MD	X		
Lisa Wendler, Pharm. D., Clinical Pharmacy Specialist, Maine Medical CTR	X		
Kathleen Polonchek, MD			X
Erin Ackley, PharmD.	X		
Charmaine Patel, MD	X		
Caitlin Morrow, PharmD.	X		
Non –Voting			
Mike Ouellette, R.Ph., Change Healthcare	X		
Jeff Barkin, MD, Change Healthcare	X		
Anne-Marie Toderico, PharmD MaineCare Pharmacy Director	X		

Guests of the Board: Ed Bosshart, PharmD, Fran Jensen, OMS Medical Director

CALL TO ORDER: 6:30PM

Erin Ackley called the meeting to order at 6:30 PM.

PUBLIC COMMENTS

Chikezie Okoro from Bristol Myers Squibb: Highlighted the attributes of Camzyos.

Ed Paiewonsky from Alnylam: Highlighted the attributes of Amvuttra.

Elizabeth Lubelczk from Eli Lilly: Highlighted the attributes of Mounjaro.

OLD BUSINESS

DUR MINUTES

Approval amended of March 08, 2022, DUR meeting minutes.
Approval of June 13, 2022, DUR meeting minutes

Board Decision: The Board unanimously approved the above recommendation.

MAINECARE UPDATE- ANNE-MARIE TODERICO

- Thank Lisa Wendler for her many years of service. Lisa has been a strong advocate for MaineCare and we have appreciated her expertise, compassion, attention to detail and humor. Thank you, Lisa.
- We would like to welcome 2 new board members: Dr. Caitlin Morrow and Dr. Charmaine Patel,
- Letrozole changes to DUR

    - We became aware, through pharmacy dispensing data, that short-term claims for Letrozole have been prescribed for treatment of infertility. Letrozole is a preferred agent for the treatment of breast cancer. Members will be allowed to complete their current treatment, up to 6 cycles with a PA. No subsequent rounds of treatment will be covered.
- We plan to start the RSV season Dec 5th send out emessage
    - We base it on statewide epi unless there is other data, and the current state data shows that there is currently no circulating RSV.
    - Encourage providers to report RSV cases to ME CDC for tracking purposes.
- Avastin change from Biosimilar PDL
    - We recently introduced a PDL on the medical side for biosimilar medications. One of the medications is bevacizumab, Avastin. The Department determined that Avastin biosimilars should not be used for injection into the eye. Providers intending to use Avastin for this purpose must still submit a PA, but use of Avastin in the eye will constitute appropriate medical necessity for approval.

UPDATED HEPATITIS C PA FORM

- Presented updated Hepatitis C PA form to the board.

Board Decision: None needed.

BIOSIMILAR

- Alymsys (bevacizumab-maly)- biosimilar to Avastin
- Byooviz (ranibizumab-nuna)- biosimilar to Lucentis

Recommendation: Add Alymsys and Byooviz to non-preferred on the PDL.

Board Decision: The Board unanimously approved the above recommendation.

REVISED CLINICAL CRITERIA/PREFERRED REVIEW

- None at this time.

NEW BUSINESS

INTRODUCE: 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 stepwise 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. Updated GINA guidelines state that all adults and adolescents on a SABA, even those with mild asthma, should be on an ICS controller treatment. 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 will use paid, non-reversed pharmacy claims with dates of service from 1/1/2022 through 12/31/2022 excluding members with Part D, MaineRX and TPL. Change Healthcare will review Maine paid non-reversed pharmacy claims with dates of service from 1/1/2022 through 12/31/2022 and identify the members with the diagnosis of asthma and exclude members with diagnoses of cystic fibrosis, COPD or emphysema. Members will be stratified by age and the number of short acting inhalers used per year. Additionally, we will identify how many members who were prescribed a SABA were also prescribed a controller medication, either an ICS inhaler or an ICS combination inhaler. 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.

Board Decision: None at this time

PRESENTATION: OPIOID USE FROM MULTIPLE PROVIDER

Monitoring of opioid prescribing has been a focus of federal and state medical agencies for several years. Prescription monitoring systems have been instituted, and prescribers must query the database before writing an opioid prescription for patients. The database includes information about the prescriber, the dispensing pharmacy, the payment methods (including cash) and the dates, names and doses of the opioids prescribed. It is important that providers utilize the system to be sure that members are not getting multiple prescriptions of opioids inappropriately. In theory, this tracking should minimize provider shopping to get opioids beyond what has been prescribed by one provider.

Per the Chapter 11 Rule of the Maine Legislature, Rules Governing the Controlled Substances Prescription Monitoring Program and Prescription of Opioid Medications, pharmacy requirements also exist to help prevent opioid misuse. Pharmacists must review:

1. the aggregate MMEs for the patient.
2. the number of prescribers currently prescribing any controlled substances to the patient.
3. the number of pharmacies currently filling controlled substance prescriptions for the patient.
4. if the patient is from out of state.
5. if the patient pays cash.
6. if there are no opioids prescribed in the past 12 months.

The pharmacist is expected to decline filling the prescription until contact is made with the prescriber to communicate concerning information and verify that the prescriber still wants to prescribe the medication. The database includes information about the prescriber, the dispensing pharmacy, the payment methods (including cash) and the dates, names and doses of the opioids prescribed. It is important that providers utilize the system to be sure that members are not getting multiple prescriptions of opioids inappropriately. In theory, this tracking should minimize provider shopping to get opioids beyond what has been prescribed by one provider. Additionally, credentialing and quality assessment agencies, such as HEDIS, are using opioid prescribing and monitoring to measure quality and these ratings are being used by payers and the public alike. We used paid, non-reversed Medicaid pharmacy claims from calendar year 2021, excluding members with Part D, MaineRX and TPL. We identified all adult members receiving prescriptions for opioids from four or more different prescribers during the year. The analysis included prescriptions billed through Maine Medicaid. It did not include cash prescriptions. For those with multiple prescribers we looked to see if there was dose escalation and if any of the prescriptions overlapped.

Recommendation: One suggestion to ensure effective care for members with multiple prescribers is to refer them to Program Integrity. They could evaluate member specific issues and determine if the member should be "locked in" with specific providers for their opioid prescriptions. Overall, a small number of members receiving narcotics are getting their prescriptions from multiple providers.

In looking at specific members in the data, multiple provider addresses (mailing vs physical) caused duplications that we mostly eliminated. The majority of the members showed no prevalence for early refills, increase dosing frequency or strength increase that would be typical of doctor shopping. There were members that seemed to show definite moves in geographic location, example of moving from Bangor area to the Portland area but were consistent with calendar dates. Another factor was looking at pharmacy location and the members we reviewed did not show a typical pattern of moving from pharmacy to pharmacy.

Other influences on the number of prescriptions for controlled substances obtained by members are edits related to quantities that can obtained for acute short-term use before transitioning to chronic longer-term use.

Board Decision: The Board unanimously approved the above recommendation.

NEW DRUG REVIEW

Adlarity® (donepezil); **PDL category-** Alzheimer- Cholinomimetics/Others

Donepezil, the active ingredient of Adlarity®, is a reversible inhibitor of the enzyme acetylcholinesterase. Donepezil is postulated to exert its therapeutic effect by enhancing cholinergic function. This is accomplished by increasing the concentration of acetylcholine through reversible inhibition of its hydrolysis by acetylcholinesterase. There is no evidence that donepezil alters the course of the underlying dementing process. It is indicated for the the treatment of mild, moderate, and severe dementia of the Alzheimer's type. There were no clinical efficacy trials in the Adlarity® prescribing information specific to the transdermal system. The efficacy of Adlarity® is based on a relative bioavailability study in healthy subjects comparing Adlarity® transdermal system to Aricept® tablets. The clinical studies described in the Adlarity® prescribing information were conducted using donepezil tablets.

Recommendation: Adlarity® to non-preferred.

Amvuttra® (vutrisiran); **PDL category-** Neurologics- hATTR Agents

Vutrisiran the active ingredient of Amvuttra®, is a chemically modified double-stranded small interfering ribonucleic acid (siRNA) that targets mutant and wild-type transthyretin (TTR) messenger RNA (mRNA) and is covalently linked to a ligand containing three N-acetyl galactosamine (GalNAc) residues to enable delivery of the siRNA to hepatocytes. Vutrisiran causes degradation of mutant and wild-type TTR mRNA through RNA interference, which results in a reduction of serum TTR protein and TTR protein deposits in tissues. It is indicated for the treatment of the polyneuropathy of hereditary transthyretin-mediated amyloidosis in adults. The efficacy of Amvuttra® was assessed in a randomized, open-label, clinical trial that included adult patients with polyneuropathy caused by hereditary transthyretin-mediated amyloidosis. Patients were randomized to receive 25mg of Amvuttra® SC once every 3 months (N=122) or 0.3mg/kg patisiran IV every 3 weeks (N=42) as a reference group. Treatment with Amvuttra® resulted in a statistically significant

improvement in the mNIS+7 (primary endpoint), Norfolk QoL-DN total score, and 10-meter walk test a month 9 compared to placebo in the external study (p<0.001). IV patisiran every 3 week dosing was included as a reference group. In the full-text study by Adams et al2, TTR reduction with vutrisiran every 3 months was non-inferior to within-study patisiran every 3 weeks in the per-protocol population, assessed by mean trough serum TTR levels over 18 months. Amvuttra® provides physicians another option with once every 3 month dosing.

Recommendation: Amvuttra® to non-preferred.

Clinical Criteria:

- PA required for appropriate diagnosis.

Aspruzyo® Sprinkle (ranolazine granule); **PDL category**- Beta-blockers, Non-Selective

Ranolazine, the active ingredient of Aspruzyo® Sprinkle, is an antianginal agent. Its mechanism of action has not been determined. Ranolazine has anti-ischemic and antianginal effects that do not depend upon reductions in heart rate or blood pressure. It does not affect the rate-pressure product, a measure of myocardial work, at maximal exercise. Ranolazine at therapeutic levels can inhibit the cardiac late sodium current (lNa); however, the relationship of this inhibition to angina symptoms is uncertain. It is indicated for the treatment of chronic angina. May be used with beta-blockers, nitrates, calcium channel blockers, anti-platelet therapy, lipid-lowering therapy, ACE inhibitors, and angiotensin receptor blockers. he studies included in the prescribing information for Aspruzyo® Sprinkle are the same as found in the ranolazine extended-release tablets prescribing information, which have the same indication as Aspruzyo® Sprinkle and have been available for numerous years.

Recommendation: Aspruzyo® Sprinkle and Ranexa to non-preferred. Ranolazine ER tablets to preferred.

Clinical Criteria:

- DDI: Concomitant use of Aspruzyo® Sprinkle with strong CYP3A inhibitors, including ketoconazole, itraconazole, clarithromycin, nefazodone, nelfinavir, ritonavir, indinavir, and saquinavir, is contraindicated.

Camzyos® (mavacamten) **PDL category-** Antihypertensives/Cardiac- Cardiac Myosin Inhibitors

Mavacamten, the active ingredient of Camzyos®, is an allosteric and reversible inhibitor selective for cardiac myosin. Mavacamten modulates the number of myosin heads that can enter 'on actin' (power-generating) states, thus reducing the probability of force-producing (systolic) and residual (diastolic) cross-bridge formation. Excess myosin actin cross-bridge formation and dysregulation of the super-relaxed state are mechanistic hallmarks of hypertrophic cardiomyopathy (HCM). Mavacamten shifts the overall myosin population towards an energy-sparing, recruitable, super-relaxed state. In HCM patients, myosin inhibition with mavacamten reduces dynamic left ventricular outflow tract (LVOT) obstruction and improves cardiac filling pressures. It is indicated for the treatment of adults with symptomatic New York Heart Association (NYHA) class II-III obstructive hypertrophic cardiomyopathy (HCM) to improve functional capacity and symptoms. The safety and efficacy of Camzyos® were assessed in a phase 3, double-blind, randomized, placebo-controlled, multicenter, international, parallel-group study (EXPLORER-HCM) that included adults (N=251) with symptomatic NYHA class II and III obstructive HCM, LVEF ≥55%, and Valsalva LVOT peak gradient ≥50mmHg at rest or with provocation. In addition, Camzyos® is contraindicated with concomitant use of moderate to strong CYP2C19 inhibitors or strong CYP3A4

inhibitors, as well as with moderate to strong CYP2C19 inducers or moderate to strong CYP3A4 inducers. The safety and efficacy of Camzyos® were assessed in a double-blind, placebo-controlled, multicenter study that included adults with symptomatic NYHA class II or III obstructive HCM, LVEF ≥55%, and Valsalva LVOT peak gradient ≥50 mmHg at rest or with provocation. A greater proportion of patients met the primary endpoint at week 30 in the Camzyos® group compared to the placebo group (37% vs 17%, p=0.0005; NNT 6).

Recommendation: Camzyos® XR to non-preferred.

Clinical Criteria:

- Preferred drugs must be tried and failed due to lack of efficacy or intolerable side effects before non-preferred drugs will be approved, unless an acceptable clinical exception is offered on the Prior Authorization form, such as the presence of a condition that prevents usage of the preferred drug or a significant potential drug interaction between another drug and the preferred drug(s) exists.
- Camzyos: For the treatment of adults with symptomatic New York Heart Association (NYHA) class II-III obstructive hypertrophic cardiomyopathy (HCM) to improve functional capacity and symptoms.
- DDI: Concomitant use of Camzyos® with a moderate to strong CYP2C19 inhibitor or a strong CYP3A4 inhibitor is contraindicated.

Epsolay® (benzoyl peroxide); **PDL category**- Topical- Acne Preparations

Benzoyl peroxide, the active ingredient of Epsolay®, is an oxidizing agent with bactericidal and keratolytic effects, but the exact mechanism of action in the treatment of rosacea is not known. It is indicated for the treatment of inflammatory lesions of rosacea in adults. The safety and efficacy of Epsolay® were assessed in 2 multicenter, randomized, double-blind, vehicle-controlled studies that included subjects with moderate-to-severe papulopustular rosacea (N=733).

Recommendation: Epsolay® to non-preferred.
Additional change add Evoclin® to preferred.

Igalmi® (dexmedetomidine); **PDL category**- Antipsychotics, Atypicals

Dexmedetomidine, the active ingredient of Igalmi®, is an alpha-2 adrenergic receptor agonist. The mechanism of action of Igalmi® for its approved indication is thought to be due to activation of presynaptic alpha-2 adrenergic receptors. It is indicated for the acute treatment of agitation associated with schizophrenia or bipolar I or II disorder in adults. The safety and effectiveness of Igalmi® have not been established beyond 24 hours from the first dose. The safety and efficacy of Igalmi® were assessed in 2 randomized, double-blind, placebo-controlled, fixed-dose studies: Study 1: This study included adults (N=380) who met DSM-5 criteria for schizophrenia, schizoaffective or schizophreniform disorder. The included population was 18 to 71 years of age (mean 46 years), while 37% were female and 20% were white. Study 2: This study included adults (N=378) who met DSM-5 criteria for bipolar I or II disorder. The included population was 18 to 70 years of age (mean 47 years), while 45% were female and 41% were white. The safety and effectiveness of Igalmi® have not been established beyond 24 hours from the first dose. Results suggested that in both studies, the mean change from baseline in the PEC total score at 2 hours after the first dose in patients treated with 180mcg and 120mg of Igalmi® was statistically greater than in patients who received placebo.

Recommendation: Igalmi® to non-preferred.
Additional change add Paliperidone ER to preferred.

Lyvispah® (baclofen granule); **PDL category**- Muscle Relaxants

Baclofen, the active ingredient of Lyvispah®, is a gamma-aminobutyric acid (GABA-ergic) agonist. While the exact mechanism of action is not fully understood, baclofen inhibits both monosynaptic and polysynaptic reflexes at the spinal level, possibly by decreasing excitatory neurotransmitter release from afferent terminals, although actions at supraspinal sites may also occur and contribute to its clinical effect. Baclofen is a structural analog of the inhibitory neurotransmitter gamma-aminobutyric acid (GABA) and may exert its effects by stimulation of the GABA-B receptor subtype. Baclofen has been shown to have general CNS depressant properties, as indicated by the production of sedation with tolerance, somnolence, ataxia, and respiratory and cardiovascular depression. It is indicated for the treatment of spasticity resulting from multiple sclerosis, particularly for the relief of flexor spasms and concomitant pain, clonus, and muscular rigidity. Lyvispah® may also be of some value in patients with spinal cord injuries and other spinal cord diseases. It is not indicated in the treatment of skeletal muscle spasm resulting from rheumatic disorders. There are no clinical trials in the prescribing information for Lyvispah®. The efficacy of Lyvispah® is based upon a bioavailability study in healthy adults comparing baclofen oral tablets to Lyvispah®. Baclofen tablets have been available for numerous years and have been found to be safe and effective when used for their approved indication, which is the same as Lyvispah®. Lyvispah® offers providers a treatment option in a different dosage formulation.

Recommendation: Lyvispah® to non-preferred.
Additional change add Chlorzoxazone® 250mg to non-preferred.

Mounjaro® (tirzepatide); **PDL category**- Incretin Mimetic

Tirzepatide, the active ingredient of Mounjaro®, is a glucose-dependent insulinotropic polypeptide (GIP) receptor and glucagon-like peptide-1 (GLP-1) receptor agonist that selectively binds to and activates both the GIP and GLP-1 receptors (the targets for native GIP and GLP-1). Tirzepatide lowers fasting and postprandial glucose concentration, decreases food intake, and reduces body weight in patients with type 2 diabetes mellitus (DM). it is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 DM. It has not been studied in patients with a history of pancreatitis and is not indicated for use in patients with type 1 DM. The safety and efficacy of Mounjaro® as an adjunct to diet and exercise to improve glycemic control in adults with type 2 DM were established in 5 trials. In these trials, Mounjaro® was studied as monotherapy (SURPASS-1); as an add-on to metformin, sulfonylureas, and/or sodium-glucose co-transporter 2 inhibitors (SGLT2 inhibitors; SURPASS-2, -3, and -4); and in combination with basal insulin with or without metformin (SURPASS-5). In these trials, Mounjaro® (5mg, 10mg, and 15mg SC QW) was compared with placebo, semaglutide 1mg, insulin degludec, and/or insulin glargine. In adult patients with type 2 DM, treatment with Mounjaro® produced a statistically significant reduction from baseline in HbA1c as compared to placebo. The authors concluded that in this adjusted indirect treatment comparison, HbA1c and weight reductions were significantly greater for tirzepatide 10mg and 15mg as compared with semaglutide 2mg and were similar for tirzepatide 5mg versus semaglutide 2mg. Head-to-head studies are needed. There is some evidence at this time to suggest that Mounjaro® may be more effective than semaglutide SC 1mg (mid-range dose), insulin degludec, and insulin glargine for HbA1c reduction and weight reduction in phase 3 studies; however, there is no direct comparator

evidence at this time to support that Mounjaro® is safer or more effective than the other currently preferred, more cost-effective medications.

Recommendation: Mounjaro® to non-preferred.

Norliqva® (amlodipine); **PDL category**- Calcium Channel Blockers

Amlodipine, the active ingredient of Norliqva®, is a long-acting calcium channel blocker (CCB). 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. Serum calcium concentration is not affected by amlodipine. It is indicated for the treatment of Hypertension, to lower blood pressure in adults and children 6 years of age and older. Coronary Artery Disease (CAD): For the symptomatic treatment of chronic stable angina. Norliqva® may be used alone or in combination with other antianginal agents. For the treatment of confirmed or suspected vasospastic angina (Prinzmetal's or Variant angina). Norliqva® may be used as monotherapy or in combination with other antianginal agents. In patients with recently documented CAD by angiography and without heart failure or an ejection fraction <40%, Norliqva® is indicated to reduce the risk of hospitalization for angina and to reduce the risk of a coronary revascularization procedure. The clinical studies in the prescribing information for Norliqva® were the same as those in the prescribing information for Norvasc®, brand amlodipine tablets. Norliqva® also has the same FDA approved indications as Norvasc,® which has been available for numerous years and has an approved generic.

Recommendation: Norliqva® to non-preferred.

Quviviq® (daridorexant tablets) **PDL category**- Sedative Hypnotics- Non-benzodiazepines

Daridorexant, the active ingredient of Quviviq®, is an orexin receptor antagonist, and the mechanism of action for its approved indication 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 Quviviq® was assessed in 2 multicenter, randomized, double-blind, placebo-controlled, parallel-group studies that included patients with Diagnostic and Statistical Manual of Mental Disorders, 5th edition insomnia. Results suggested that Quviviq® 25mg and 50mg (in study 1) demonstrated a statistically significant improvement as compared with placebo on LPS, WASO, and sTST at month 1 and month 3. In study 2, Quviviq® 25mg demonstrated a statistically significant improvement as compared with placebo on WASO and sTST at month 1 and month 3. Comparator head-to-head studies with other active agents were not found. There is no evidence at this time to support that Quviviq® is safer or more effective than other currently preferred, more cost-effective medications.

Recommendation: Quviviq® to non-preferred.

Tlando® (testosterone undecanoate); **PDL category**- Androgenic Agents

Tlando® contains testosterone undecanoate, an ester of testosterone. Endogenous androgens, including testosterone and dihydrotestosterone (DHT), are responsible for the normal growth and development of the male sex organs and for maintenance of secondary sex characteristics. Tlando® is a Scheduled III controlled substance. Testosterone has been subject to abuse, typically at doses higher than recommended for the approved indication and in combination with other anabolic androgenic steroids. Anabolic androgenic steroid abuse can lead to serious cardiovascular and psychiatric adverse reactions. It is indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone: Primary hypogonadism (congenital or acquired): testicular failure due to conditions such as cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter's syndrome, chemotherapy, or toxic damage from alcohol or heavy metals. These men usually have low serum testosterone concentrations and gonadotropins (follicle stimulating hormone [FSH], luteinizing hormone [LH]) above the normal range. Hypogonadotropic hypogonadism (congenital or acquired): gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency or pituitary-hypothalamic injury from tumors, trauma, or radiation. These men have low testosterone serum concentrations but have gonadotropins in the normal or low range. The safety and efficacy of Tlando® in males less than 18 years old have not been established. The primary endpoint, the percentage of patients who achieved a 24-hour average serum testosterone concentration within the normal range of 300-1080ng/dL on the final visit of the study, was achieved by 80% of the subjects. Tlando® offers prescribers another treatment option.

Recommendation: Tlando® to non-preferred.

Vonjo® (pacritinib); **PDL category**- Cancer

Pacritinib, the active ingredient of Vonjo®, is an oral kinase inhibitor. It has activity against wild type Janus associated kinase 2 (JAK2), mutant JAK2-V617F, and FMS-like tyrosine kinase 3 (FLT3), which contribute to signaling of a number of cytokines and growth factors that are important for hematopoiesis and immune function. Myelofibrosis is often associated with dysregulated JAK2 signaling. It is indicated for the treatment of adults with intermediate or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis (MF) with a platelet count below 50 X 109/L. This indication is approved under accelerated approval based on spleen volume reduction. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s). The safety and efficacy of Vonjo® in the treatment of patients with intermediate or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) MF were assessed in a randomized controlled study. The efficacy of Vonjo® in the treatment of patients with primary or secondary MF was established based on the proportion of patients in the efficacy population receiving Vonjo® 200mg BID or BAT achieving ≥35% spleen volume reduction from baseline to week 24 as measured by MRI or computed tomography. Efficacy results for spleen volume reduction in patients with platelet count <50 X 109/L, which was adapted from the prescribing information. There is currently some evidence to suggest that Vonjo® may be more effective than best available therapy (BAT) for achieving ≥35% reduction in spleen volume in a population with baseline platelets <50 X 109/L; however, there is no evidence to suggest that Vonjo® is safer or more clinically effective than other currently preferred, more cost-effective medications.

Recommendation: Vonjo® to non-preferred.
Additional change add Zaltrap® to non-preferred.

Vtama® (tapinarof cream); **PDL category**- Topical- Antipsoriatic

Tapinarof, the active ingredient of Vtama®, is an aryl hydrocarbon receptor (AhR) agonist. The specific mechanisms by which this cream exerts its therapeutic action in psoriasis patients is not known. It is indicated for the topical treatment of plaque psoriasis in adults. The safety and efficacy of Vtama® cream were assessed in two multicenter, randomized, double-blind, vehicle-controlled trials that included adults (N=1025) with plaque psoriasis (PSOARING 1 and PSOARING 2) who were randomized to Vtama® cream or vehicle cream once daily for 12 weeks to any lesion regardless of anatomic location. The primary efficacy endpoint in both studies was the proportion of subjects who achieved treatment success, defined as a PGA score of 'clear' or 'almost clear' and at least a 2-grade improvement from baseline. Longer studies are needed. Vtama® cream is a first-in-class topical treatment that provides another treatment option for plaque psoriasis. There is no evidence at this time to support that Vtama® is safer or more effective than the other currently preferred, more cost-effective medications.

Recommendation: Vtamam® to non-preferred.

Board Decision: The Board unanimously approved the above recommendation.

FDA SAFETY ALERTS

None at this time

Board Decision: No action.

ADJOURNMENT: 8:30PM

The next meeting will be held on **November 1, 2022** 1pm-5pm hybrid.