Janet T. Mills
Governor

Jeanne M. Lambrew, Ph.D.
Commissioner

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TO: Maine Drug Utilization Review Board
DATE:
RE: Maine DUR Board Meeting minutes from March 11, 2025

ATTENDANCE	UNEXCUSED	EXCUSED	IN-PERSON	REMOTELY
Linda Glass, MD	X			
Kathleen Polonchek, MD		X		
Erin Ackley, PharmD.		X		
John Deason, PharmD.				X
Caitlin Morrow, PharmD.	X			
Non –Voting				
Mike Ouellette, R.Ph., Optum			X	
Roberta Capp, MD, Optum				X
Jan Wright, MaineCare			X	

Guests of the Board: Gavin Gillespie PharmD, Optum

CALL TO ORDER: 6:00PM

The meeting was called to order at 6:00 PM.

PUBLIC COMMENTS

Erin Booth, Elena Fernandez, Justin Alberts, Kathleen Maignan, Brian Hall, Nikki Demaine, Mark Kosion, Adam Denman

The attritubes of Alyftrek, Duvyzat, Erzofri, Cobenfy, and Opdivo Qvantig were highlighted.

MAINECARE UPDATE - JAN WRIGHT

- Updates were provided on Temporary MaineCare payment holds:
  - As of February 26, 2025, unless there is emergency action by the State Legislature, the department would need to hold certain provider payments beginning with the payment cycle that will run on March 12, 2025
  - The providers affected will be multi-state chain, large health system, and out-of-state retail pharmacies
    - Independent pharmacies located in New Hampshire towns within 15 miles of the Maine border will continue to be paid
  - This temporary hold will not impact claims processing in the Maine Point of Purchase System (MEPOPS). Claims showing as PAID indicate the provider will receive reimbursement once funds are available
  - Pharmacies will know if their claims are temporarily held because pharmacies will not receive a Remittance Advice (RA) if their claim is not paid
  - During this time, no provider may deny services to a member for failure of a requested copayment
  - For additional information, refer to the e-message shared on March 5, 2025

OLD BUSINESS

- None at this time

CONSENT AGENDA

DUR MINUTES

Approval of December DUR meeting minutes

Board Decision: Approved by the Board as presented

NEW CANCER MEDICATIONS

Recommendations: Add Bizengri, Danziten, Imkeldi, Itovebi, Opdivo Qvantig, Vyloy, Ziihera to non-preferred.

Criteria: All non-preferred: A clinical PA is required to confirm appropriate clinical indication for the individual drug request. Specific to each drug all age, clinical testing requirements, previous step therapies, adjunctive drug therapy requirements, and response without disease progression will also be evaluated for clinical appropriateness. The standard for the appropriate indication will include the FDA label as well as current NCCN guidelines

Board Decision: Approved by the Board as presented

BIOSIMILARS

Recommendations: Add Pavblu (aflibercept-ayyh) and Hercessi (trastuzumab-strf) to non-preferred.

Board Decision: Approved by the Board as presented

NEW BUSINESS

RETRODUR

Update: Use of Stimulants in Children

An updated analysis was provided on the use of stimulant medications in children and adolescents in foster care. Children in foster care exhibit higher utilization of stimulant drugs across all age groups compared to their non-foster care counterparts. The highest utilization is observed in children aged 6-12 years. Therapy choices vary more significantly in older children, particularly those aged 6-12 years. Gender differences indicate a substantial increase in stimulant prescriptions for both males and females in foster care. A study presented in the American Academy of Pediatrics showed that children in Foster Care were three times more likely to have an ADHD diagnosis compared with non-foster care children ages 2-17. The results of the study were from 2011 and this is almost ten years later, but our results show a higher proportion than stated in the literature.

Introduce The effect of Hemlibra on the Cost of Care in Hemophilia A Patients

Hemlibra (emicizumab), a bispecific - and factor X -directed antibody is used to treat factor VIII deficient patients (hemophilia A), with or without inhibitors. It activates the coagulation cascade downstream of the factor VIII activating pathway, thereby negating the need for factor VIII for normal coagulation. It

was initially developed for patients with inhibitors to factor VIII[1], which usually develop after only a few exposures to factor products, to reduce the need for immune tolerance with very high doses of factor and to avoid the used of bypassing agents, such as NovoSeven. However, it is now routinely used as the initial prophylactic treatment in children born with hemophilia, due to the ease of subcutaneous administration and only rare incidences of inhibitor development[2]. If bleeding occurs, traditional factor replacement is used. Hemlibra may be given weekly, every other week or monthly. In children, it prevents the need for central line placement with the risks of infection and prevents in all patients the need for IV prophylaxis several times a week. The medical and scientific advisory council (MASAC) of the National Bleeding Disorders Foundation recommends Hemlibra as one possible prophylactic agent for the treatment of patients with factor VIII deficiency[3].

While Hemlibra is more costly per month than traditional factor infusions, it is possible that patient quality of life improvement and the overall cost of care for patients is decreased, due to better compliance with prophylaxis (no IV required), less development of inhibitors, which are more costly to treat, and less use of medical care, such as hospitalizations for infections from central lines, bleeds, and trauma-related care.

We will use paid, non-reversed Medicaid pharmacy and medical claims from SFY 2023, excluding members with Part D, TPL and Maine RX coverage. For members taking Hemlibra during SFY 23, we will analyze medical claims, looking at number and cost of hospitalizations, ER visits, factor use and provider visits for the year prior to starting Hemlibra and 1 year after starting the medication in those who had been on traditional factor prophylaxis prior to starting Hemlibra, to see if the increased cost of Hemlibra is offset by decreased utilization of medical care, including factor use.

Board Decision: None needed.

Data Presentation: Co-Administration of PPIs and Bisphosphonates
Proton pump inhibitors are the most efficient therapeutic class currently available for suppressing gastric acid secretion and are the most extensively prescribed medications worldwide.1 PPIs are indicated for the treatment of gastro-duodenal ulcers, gastroesophageal reflux disease (GERD), heartburn, and other conditions related to gastric acid. However, long term PPI use has been linked to significant adverse drug events (ADE), including, but not limited to kidney disease, dementia, and osteoporosis.[1]

A recent systematic review highlighted the relationship between PPIs, bone mineral density, and increased risk of fractures.[2,3] A significant number of studies showed increased risk of hip and spine fractures associated with long term use of PPI, defined as use of PPI for longer than 12 months.[3]

Despite study results outlining the risks associated with long term PPI use, several studies reported overtreatment with PPI and prescriptions at higher doses or longer duration than required, and without a clear indication.[1] There is recognition from the medical community on the risks associated with PPI overuse and some provider groups successfully piloted the use of clinical decision support to identify guideline concordant vs. guideline non-concordant prescriptions to help providers decrease PPI overuse.[4] Finally, global choosing wisely campaign promoting appropriate PPI use and an ask of providers and patients to re-assess PPI use at least once a year. [5]

Patients taking bisphosphonates may be at even high risk for fractures while on long term use of PPIs and this retro DUR will evaluate current use of episodic (prescription for less than 2 months), short term

(≥ 2 months -12 months), and long term (>12 months) use of PPIs in those with highest risk for fractures, or those taking bisphosphonates.

Recommendation: No recommendation at this time but will continue to monitor concurrent utilization and adherence to recommended treatment durations.

Board Decision: Approved by the Board as presented

NEW REVISED CRITERIA

Zepbound® (tirzepatide); **PDL category-** Obstructive Sleep Apnea

Zepbound® is a glucose-dependent insulinotropic polypeptide (GIP) receptor and glucagon-like peptide-1 (GLP-1) receptor agonist indicated in combination with a reduced-calorie diet and increased physical activity to: reduce excess body weight and maintain weight reduction long term in adults with obesity or adults with overweight in the presence of at least one weight-related comorbid condition, as well as to treat moderate to severe obstructive sleep apnea (OSA) in adults with obesity. A limitation of use includes that coadministration with other tirzepatide-containing products or with any GLP-1 receptor agonist is not recommended. The backbone of treatment for adults with OSA and an AHI ≥15 events per hour of sleep is positive airway pressure (PAP) therapy.2

Zepbound® does have a box warning regarding risk of thyroid c-cell tumors. The efficacy of Zepbound® for OSA was assessed in two randomized, double-blind, placebo-controlled trials that included patients with moderate to severe OSA (apnea-hypopnea index [AHI] ≥15) with obesity (BMI ≥30kg/m2). The primary endpoint for both studies was the change from baseline in AHI at week 52, and results suggested that treatment with Zepbound® for 52 weeks resulted in a statistically significant reduction in AHI as compared with placebo.

Recommendation: Zepbound® to non-preferred.

Criteria: For adults with a BMI ≥ 30 mg/kg2 and diagnosis of moderate to severe OSA, confirmed by sleep study within the last 3 years documenting AHI ≥ 15, AND in which CPAP is ineffective (AHI > 5 during therapeutic section of sleep study) or patient is unable to tolerate CPAP for at least 90 days AND for whom lifestyle modifications have been attempted for at least 3 months with failure to achieve weightloss Note: Not for patients with T1DM, T2DM

Board Decision: Approved by the Board as presented

NEW DRUG REVIEW

Alhemo® (concizumab-mtci); **PDL category-** Antihemophilic Agents

Alhemo® is a tissue factor pathway inhibitor (TFPI) antagonist indicated for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients 12 years of age and older with hemophilia A (congenital factor VIII deficiency) with FVIII inhibitors and with hemophilia B (congenital factor IX deficiency) with FIX inhibitors. While treatment with all bypassing agents can be used for breakthrough bleeds, high and/or frequent doses of bypassing agents with Alhemo® increases the risk of thromboembolism. The efficacy of Alhemo® in patients with hemophilia A and B with inhibitors was assessed in a multicenter, open-label, phase 3 study. Efficacy was assessed in hemophilia A and B patients with inhibitors when all patients in arms 1 and 2 had completed at least 24 or at least 32 weeks,

respectively, by comparing the number of treated bleeding episodes between Alhemo® prophylaxis (arm 2) and no prophylaxis (arm 1). A ratio of the annualized bleeding rates (ABR) was estimated to 0.14 ($p<0.001$) corresponding to a reduction in ABR of 86% for subjects on Alhemo® prophylaxis compared to no prophylaxis. Alhemo® is the second TFPI antagonist FDA approved. Hympavzi® (marstacimab-hncq) is a TFPI antagonist indicated for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients 12 years of age and older with hemophilia A without factor VIII inhibitors or hemophilia B without factor IX inhibitors. Alhemo® is the first FDA approved prophylaxis treatment available in a prefilled pen for subcutaneous injection for patients with hemophilia A with inhibitors and hemophilia B with inhibitors.

Recommendation: Alhemo® to non-preferred.

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.

Alyftrek® (vanzacaftor, tezacaftor, and deutivacaftor); **PDL category-** Antiasthmatic- CFTR Potentiator and Combinations

Alyftrek® is a combination of deutivacaftor, tezacaftor, and vanzacaftor indicated for the treatment of CF in patients aged 6 years and older who have at least one F508del mutation or another responsive mutation in the CFTR gene. If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to confirm the presence of at least one indicated mutation. A noted reference recommends the use of triple therapy (ELX/TEZ/IVA) instead of dual therapy or ivacaftor in patients ≥2 years of age with any disease severity and who have two F508del mutations (homozygotes). In addition, ELX/TEZ/IVA is recommended over no therapy and over dual therapy or ivacaftor in patients ≥2 years of age with any disease severity and who have one F508del mutation (heterozygotes).2 (Note that this reference has not been updated with Alyftrek® drug information.)

Alyftrek® has a box warning regarding drug-induced liver injury and liver failure; Alyftrek® should not be used in patients with severe hepatic impairment while use is not recommended in patients with moderate hepatic impairment. Liver function tests should be assessed regularly. The efficacy of Alyftrek® was assessed in two randomized, double-blind, active-controlled trials that included patients aged 12 years and older with CF who have at least one F508del mutation or a responsive mutation in the CFTR gene. The primary endpoint in both studies evaluated non-inferiority in mean absolute change in ppFEV1 from baseline through week 24, and results for this primary endpoint demonstrated non-inferiority of Alyftrek® to ELX/TEZ/IVA.

Recommendation: Alyftrek® to non-preferred.

Criteria: PA required. Will be considered for the treatment of patients 6 years and older with at least one responsive mutation, including 31 additional mutations not responsive to other CFTR modulator therapies for appropriate diagnosis

Azmiro® (testosterone cypionate injection); **PDL category-** Androgens/Anabolics

Azmiro® prefilled syringe should be administered by a healthcare professional only, and the recommended dosage is to be administered every 2 to 4 weeks. Other generic testosterone cypionate solution for injection are available, but Azmiro® is the only FDA-approved prefilled testosterone cypionate injection in a single-dose prefilled syringe (also available in a single-dose vial per the prescribing information).

Recommendation: Azmiro® to non-preferred. Remove Androderm PT24 from PDL

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. Additionally, laboratory evidence of a testosterone deficiency must be supplied. One of each dosage form should be tried (tablet, injection, and topical)

Crenessity® (crinecerfont); **PDL category-** Congenital Adrenal Hyperplasia

Crenessity® is a corticotropin-releasing factor type 1 receptor antagonist indicated as adjunctive treatment to glucocorticoid replacement to control androgens in adults and pediatric patients 4 years of age and older with classic congenital adrenal hyperplasia (CAH). Patients receiving Crenessity® should continue glucocorticoid replacement therapy for the adrenal insufficiency associated with congenital adrenal hyperplasia. In addition, androstenedione levels can be assessed beginning four weeks after Crenessity® initiation to inform reduction in glucocorticoid dosage as clinically indicated. Do not reduce the glucocorticoid dosage below that required for replacement therapy. The safety and efficacy of use were assessed in both adult and pediatric patients, in randomized, double-blind, placebo-controlled studies. The LS mean percent change from baseline in daily glucocorticoid dose for adults (primary outcome) was statistically significantly greater in the Crenessity® group than placebo ($p<0.0001$). At week 4 in the pediatric study, following a treatment period at a stable glucocorticoid dose regimen, the LS mean reduction from baseline in serum androstenedione (primary outcome) in the Crenessity® group was statistically significantly different as compared to placebo ($p=0.0002$). Crenessity® is the first FDA-approved treatment for patients with classic CAH, approved as adjunctive treatment to control androgens. Hydrocortisone is suggested as first line treatment for adults with classic CAH.2

Recommendation: Crenessity® to non-preferred.

Criteria: As adjunctive treatment to glucocorticoid replacement to control androgens in adults and pediatric patients 4 years of age and older with classic congenital adrenal hyperplasia (CAH)

Daxxify® (daxibotulinumtoxinA-lanm); **PDL category**- Neurologics, Misc.

Daxxify® is an acetylcholine release inhibitor and neuromuscular-blocking agent indicated for the treatment of cervical dystonia in adult patients. (It is also indicated for temporary improvement in the appearance of moderate to severe glabellar lines associated with corrugator and/or procerus muscle activity in adult patients but is not being reviewed here for this indication.) Daxxify® has a box warning regarding the distant spread of toxin effect, as the effects of Daxxify® and all botulinum toxin products may spread from the area of injection to produce symptoms consistent with botulinum toxin effects. These symptoms have been reported hours to weeks after injection. The potency units of Daxxify® are specific to the preparation and test method utilized. They are not interchangeable with other preparations of botulinum toxin products; thus, units of biological activity of Daxxify® cannot be compared to, or

converted into, units of any other botulinum toxin products assessed with any other specific test method. The efficacy of Daxxify® was assessed in a randomized, double-blind, placebo-controlled trial that included patients with a clinical diagnosis of cervical dystonia. The primary endpoint was the mean change in the TWSTRS total score from baseline averaged over weeks 4 and 6, and results suggested that the mean change from baseline in the total TWSTRS score was significantly greater for both dosage groups of Daxxify® than for placebo. For most patients with cervical dystonia, recommended first-line treatment is botulinum toxin injection.

Recommendation: Daxxify® to non-preferred. Remove Ruzurgi from PDL

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.

Duvyzat® (givinostat suspension); **PDL category-** Muscular Dystrophy Agents

Duvyzat® is a histone deacetylase inhibitor indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients 6 years of age and older. Obtain and assess baseline platelet counts and triglycerides prior to the start of treatment, and do not start treatment in patients with a platelet count less than 150 X 109/L. Monitor platelet counts and triglycerides as recommended during treatment to assess if dosage modifications are needed. In addition, in patients with underlying cardiac disease or taking concomitant medications that cause QT prolongation, obtain ECGs when starting treatment with Duvyzat®, during concomitant use, and as clinically indicated. The efficacy of Duvyzat® was assessed in a randomized, double-blind study that included male patients 6 years of age and older with a confirmed diagnosis of DMD who were ambulatory and on a stable dosage of corticosteroids. The primary endpoint was the change from baseline to month 18 in 4-stair climb (4SC) time for Duvyzat® as compared to placebo. Results suggested that patients treated with Duvyzat® demonstrated statistically significant less decline in the 4SC compared to placebo. Duvyzat® is the first FDA approved oral non-steroidal treatment for DMD patients 6 years of age and older irrespective of their genetic variant or ability to walk. Note that the phase 3 trial did not include patients who were not able to walk on their own.

Recommendation: Duvyzat® to non-preferred.

Criteria: : The patient must meet the FDA approved age AND have a diagnosis of Duchenne Muscular Dystrophy confirmed with a confirmed mutation of the DMD gene AND

- The prescriber is, or has consulted with, a neuromuscular disorder specialist
- The patient is ambulatory AND
  The patient is currently on a stable corticosteroid dose for at least 6 months. AND
  Baseline platelet counts are > 150 x 109/L and baseline triglycerides are < 300 mg/dL

Erzofri® (paliperidone palmitate extended-release injectable suspension); **PDL category-** Antipsychotics-Atypicals

Erzofri® is an atypical antipsychotic indicated for the treatment of schizophrenia in adults. It is also indicated for treatment of schizoaffective disorder in adults as monotherapy and as an adjunct to mood stabilizers or antidepressants. The efficacy of Erzofri® is based upon adequate and well-controlled studies of another once-a-month paliperidone palmitate extended-release injectable suspension, called Invega® Sustenna. Invega® Sustenna has been FDA approved for several years and has the same indications as

Erzofri®; however, while Invega® Sustenna has a once monthly maintenance dosing, the initiation dosing is a required dose on day 1 and day 8 (with monthly maintenance dose administered 5 weeks after the first injection). With Erzofri®, the initial dose is on day 1 and the monthly dosage is administered 4 weeks after the first injection. This offers providers another treatment option.

Recommendation: Erzofri to non-preferred.

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.

Flolipid® (simvastatin suspension Cholesterol-HMG-CO); **PDL category**- Cholesterol-HMG-CoA + Absorb Inhibitors More Potent Drugs/Combinations

Flolipid is a statin indicated for reductions in risk of CHD mortality and cardiovascular events, hyperlipidemia, and adolescent patients with heterozygous familial hypercholesterolemia (HeFH). Refer to the indications section for specific information regarding these indications. There were no new clinical studies found in the Flolipid® prescribing information but rather were the same as those found in the Zocor® prescribing information, an oral tablet formulation of simvastatin. Flolipid® is the first liquid simvastatin formation and offers prescribers another prescribing option.

Recommendation: Flolipid® to non-preferred.

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.

Hympavzi® (marstacimab-hncq); **PDL category-** Antihemophilic Agents

Hympavzi® is a tissue factor pathway inhibitor (TFPI) antagonist indicated for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients 12 years of age and older with hemophilia A (congenital factor VIII deficiency) without factor VIII inhibitors, or hemophilia B (congenital factor IX deficiency) without factor IX inhibitors. It is for subcutaneous use only and may be self-injected by the patient or the patient's caregiver may administer after proper training in subcutaneous injection technique. After a loading dose, the maintenance dose is to be administered once every week. The efficacy of Hympavzi® was established in adult and pediatric patients with severe hemophilia A without FVIII inhibitors or severe hemophilia B without FIX inhibitors in an open-label, two-phase study. Hympavzi® prophylaxis demonstrated superiority over on-demand factor-based therapy in incidences of treated bleeds, spontaneous bleeds, joint bleeds, total bleeds, and target joint bleeds. Hympavzi® prophylaxis demonstrated non-inferiority to routine prophylactic factor-based therapy as measured by ABR of treated bleeds, as well as incidences of spontaneous bleeds, joint bleeds, target joint bleeds, and total bleeds.

Recommendation: Hympavzi to non-preferred.

Lodoco® (colchicine); **PDL category-** Cardiac Risk Reduction

Lodoco® is an alkaloid indicated to reduce the risk of MI, stroke, coronary revascularization, and cardiovascular death in adult patients with established atherosclerotic disease or with multiple risk factors for cardiovascular disease. It is thought to work by targeting inflammatory pathways involved in plaque formation and major cardiac events.[3] Its use is contraindicated in patients with renal failure and severe hepatic impairment, in patients with preexisting blood dyscrasias, and with concurrent use of strong CYP3A4 inhibitors or P-gp inhibitors. The efficacy of Lodoco® was assessed in a double-blind, event-driven trial that compared colchicine 0.5mg daily with placebo in patients with stable coronary artery disease. The primary endpoint was a composite of cardiovascular death, spontaneous MI, ischemic stroke, or ischemia-driven coronary revascularization (commonly referred to as major adverse cardiovascular events or MACE). Results suggested that colchicine 0.5mg daily resulted in a 31% lower relative risk of the primary composite endpoint events compared to placebo (HR 0.69, p<0.001; NNT 36). Daily colchicine treatment is suggested in patients with chronic coronary artery disease who have made appropriate lifestyle changes and are on appropriate secondary preventive medications (such as statins and aspirin and/or other antiplatelet agents) for prevention of CV disease events.2

Recommendation: Lodoco to non-preferred. Update Wegovy criteria.

Criteria: Patient must have tried and failed due to lack of efficacy or intolerable side effects of generic colchicine

Nemluvio (nemolizumab-ilto injection); **PDL category-** Topical-Atopic Dermatitis

Nemluvio® is an interleukin-31 receptor antagonist indicated for the treatment of adults with prurigo nodularis. It is also indicated for the treatment of adults and pediatric patients 12 years of age and older with moderate-to-severe atopic dermatitis in combination with topical corticosteroids and/or calcineurin inhibitors when the disease is not adequately controlled with topical prescription therapies. Complete all age-appropriate vaccinations as recommended by current immunization guidelines prior to treatment with Nemluvio®. Two randomized, double-blind, placebo-controlled trials assessed the efficacy of Nemluvio® in adults with prurigo nodularis. Efficacy was assessed with the proportion of subjects with an improvement of ≥4 from baseline in PP-NRS and the proportion of subjects with an IGA of 0 (clear) or 1 (almost clear) and a ≥2-point improvement from baseline. Nemluvio® was more effective than placebo for the endpoints assessed. Per the full-text study by Kwatra et al[2] (OLYMPIA 2), nemolizumab was significantly more effective than placebo for the primary endpoints at week 16 (p<0.001 for both comparisons). Two randomized, double-blind, placebo-controlled trials assessed the efficacy of Nemluvio® in adults and pediatric patients 12 years of age and older with moderate-to-severe AD not adequately controlled by topical treatments. The co-primary endpoints included the proportion of subjects with an IGA success (defined as an IGA of 0 [clear] or 1 [almost clear] and a ≥2-point reduction from baseline) at week 16 and the proportion of subjects with EASI-75 (≥75% improvement in EASI from baseline) at week 16. Nemluvio® was more effective than placebo for the co-primary endpoints assessed. Per the full-text by Silverberg et al[3], nemolizumab was significantly more effective than placebo for the primary endpoints. Head-to-head active comparator trials were not currently found.

Recommendation: Nemluvio to non-preferred.

Criteria: Preferred drugs also indicated for this condition, including topical steroids, cyclosporin AND calcineurin inhibitors 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. Note: If unable to use TCIs then a trial of Eucrisa could be recommended before Dupixent.

Opipza® (aripiprazole film); **PDL category-** Atypical Antipsychotics

Opipza® is an atypical antipsychotic indicated for the treatment of schizophrenia in patients ages 13 years and older, as adjunctive treatment of major depressive disorder (MDD) in adults, for irritability associated with autistic disorder in pediatric patients 6 years and older, and for the treatment of Tourette's disorder in pediatric patients 6 years and older. It has a box warning regarding increased mortality in elderly patients with dementia-related psychosis and suicidal thoughts and behaviors. Opipza® is a soluble film to be applied on the top of the tongue where it dissolves in saliva and can be swallowed in a normal manner without the need for water or other liquids. The efficacy of Opipza® for its approved indications is based on adequate and well-controlled studies of another oral aripiprazole product. Opipza® provides patients with another treatment dosage option.

Recommendation: Opipza® to non-preferred.

Criteria: Preferred drugs must be tried and failed due to lack of efficacy or intolerable side effects before non-preferred drugs will be approved (in step order), 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

Tanlor® (methocarbamol); **PDL category-** Muscle Relaxants

Methocarbamol tablets are indicated as an adjunct to rest, physical therapy, and other measures for the relief of discomfort associated with acute, painful musculoskeletal conditions. The mode of action of methocarbamol has not been clearly identified but may be related to its sedative properties. Methocarbamol does not directly relax tense skeletal muscles in man. Methocarbamol tablets have been available as 500mg and 750mg strengths for many years, but now Tanlor® offers a 1,000mg tablet strength

Recommendation: Tanlor® to non-preferred.

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.

Board Decision: Approved by the Board as presented

FDA SAFETY ALERTS

None at this time.

Board Decision: No action.

ADJOURNMENT: 7:30 PM

The next meeting will be held on June 10 2025 6 – 8p hybrid.