Janet T. Mills
Governor

Jeanne M. Lambrew, Ph.D.
Commissioner

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TO: Maine Drug Utilization Review Board
DATE: September 29, 2025
RE: Maine DUR Board Meeting minutes from September 9, 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	
Dan Mickool, R.Ph., M.S., Ed D, MaineCare			X	
Jan Wright, MaineCare			X	
Courtney Pladsen, 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. Due to lack of a quorum, Board voting was conducted via electronic ballot and confirmed on September 29, 2025.

MAINECARE UPDATE

Dan Mickool was introduced to the members as the Associate Director of Pharmacy replacing Anne-Marie Toderico who retired at the beginning of the year.

PUBLIC COMMENTS

Alain Nguyen, PharmD, MBA from Gilead Pharmaceutical: Highlighted the attributes of Yeztugo.

Armen Khachatourian, PharmD, MBA from Sarepta Pharmaceutical: Highlighted the attributes of Elevidys.

Mae Kwong, PharmD from Soleno Pharmaceutical: Highlighted the attributes of Vykat-XR.

OLD BUSINESS

None.

CONSENT AGENDA

DUR MINUTES

Approval of June 10, 2025, DUR meeting minutes.

AVMAPKI FAKZYNJA® co-pack (Avutometinib & Defactinib)

Avmapki Fakzynja® co-pack, a combination of avutometinib and defactinib, each kinase inhibitors, is indicated for the treatment of adult patients with *KRAS*-mutated recurrent low-grade serous ovarian cancer (LGSOC) who have received prior systemic therapy. This indication is approved under accelerated approval based on tumor response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial. Select patients for the treatment of recurrent LGSOC with Avmapki Fakzynja® co-pack based on the presence of a *KRAS* mutation in tumor specimens. Conduct a comprehensive ophthalmic exam at baseline, prior to cycle 2, and every 3 cycles thereafter regardless of baseline exam findings, and as clinically indicated. In addition, with initiation of and during at least the first 2 cycles of Avmapki Fakzynja® co-pack administer topical corticosteroids and systemic oral antibiotics. The efficacy of Avmapki Fakzynja® co-pack was assessed in an open-label multicenter study that included adults with measurable *KRAS*-mutated recurrent LGSOC. The main efficacy outcome measure was overall response rate (ORR), and the confirmed ORR was 44% with patients taking Avmapki Fakzynja® co-pack.

EMRELIS® (Telisotuzumab Vedotin)

Emrelis® is a c-Met-directed antibody and microtubule inhibitor conjugate indicated for the treatment of adult patients with locally advanced or metastatic non-squamous non-small cell lung cancer (NSCLC) with high c-Met protein overexpression (≥50% of tumor cells with strong [3+] staining), as determined by an FDA-approved test, who have received a prior systemic therapy. This indication is approved under accelerated approval based on overall response rate (ORR) and duration of response (DOR). Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s). It is to be administered as an IV infusion every 2 weeks until disease progression or unacceptable toxicity. The efficacy of Emrelis® was assessed in an open-label, single-arm, multicohort study that included patients required to have locally advanced or metastatic NSCLC with c-Met protein overexpression and treatment with prior systemic therapy in the locally advanced or metastatic setting. The main efficacy outcome measure was overall response rate (ORR); the ORR with Emrelis® was 35%.

LYNOZYFIC® (Linvoseltamab-gcpt) injection, solution, concentrate

Lynozyfic® is a bispecific B-cell maturation antigen (BCMA)-directed CD3 T-cell engager indicated for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least 4 prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody. This indication is approved under accelerated approval based on response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s). Lynozyfic® has a box warning regarding risks of CRS and neurologic toxicity, including ICANS. The warning ends that because of the risk of CRS and neurologic toxicity, including ICANS, Lynozyfic® is available only through a restricted program under a REMS called the Lynozyfic® REMS. The efficacy of Lynozyfic® was assessed in an open-label, multicenter, multi-cohort study that included patients with relapsed or refractory multiple myeloma who had previously received at least 3 prior therapies, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 antibody. Efficacy was established based on objective response rate, which was 70%. The median time to first response was 0.95 months.

Criteria: All non-preferred: A clinical Prior Authorization 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.

Recommendation: Add Avmapki Fakzynja®, Emrelis®, and Lynozyfic® to non-preferred.

BIOSIMILARS

Recommendation: Add Novolog® Biosimilar Merilog® 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.

Recommendation: Add Prolia® Biosimilars Conexxence®, Jubbonti®, and Stoboclo® 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.

Recommendation: Add Stelara® Biosimilars Imuldosa® and Selarsdi® 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.

Recommendation: Add Xgeva® Biosimilars Bomyntra®, Osenvelt, ® and Wyost® to non-preferred.

Criteria: Previous trial of Xgeva® or intolerable side effects before non-preferred biosimilar will be approved. 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: Via written consent, the Board unanimously approved the above recommendations as presented.

NEW BUSINESS

RETRODUR

Introduction: Long-Acting Antipsychotic Injection Purpose

Long-acting injectable (LAI) antipsychotics have become an increasingly important tool in the treatment of schizophrenia, particularly among Medicaid beneficiaries who often face barriers to consistent care, such as transportation challenges, housing instability, and limited access to outpatient services. LAIs offer a pharmacological advantage by maintaining steady plasma drug levels and reducing the need for daily medication decisions, which can significantly improve adherence and reduce relapse rates (Castillo & Stroup, 2015). For individuals with schizophrenia, especially those with a history of non-adherence, LAIs have

demonstrated superior outcomes in symptom control and continuity of care compared to oral antipsychotics (Lin et al., 2021). These benefits are especially relevant in the Medicaid population, where gaps in care can lead to frequent hospitalizations and emergency department visits.

Real-world evidence indicates that patients initiated on LAIs experience significantly fewer hospitalizations and emergency room admissions, which offsets the increased medication costs and results in comparable or lower overall healthcare expenditures (Lin et al., 2021). However, very little is known about the outcomes of LAIs and how they vary by their frequency schedule within and across key subclasses of drugs.

In this retro-DUR an analysis of anti-psychotic long-acting injectables will be conducted to understand adherence, discontinuation rates, and the cost benefit analysis on use of LAIs administered at different frequencies within the three available different subclasses (aripiprazole, paliperidone, and risperidone).

We will use paid, non-reversed Medicaid pharmacy and medical claims from calendar year 2022-2024, excluding members with Part D, TPL and Maine RX coverage.

This analysis will identify adults ages 18 and older who started anti-psychotic long acting injectables with a minimum of two consecutive doses of the same medication during the calendar year of 2022-2024. An evaluation of the adherence by PDC, discontinuation rates, switch practices and overall BH pharmacy costs will be conducted. For reference a PDC of 55% for the Medicaid population has been reported (Campagna et al, 2014), which is higher than the oral PDC rates of 30-35%.

Data Presentation: Biosimilar PDL Cost Saving Evaluation
MaineCare's biosimilar PDL established a preference and coordination of medical and pharmacy benefits for targeted biosimilar products. The five reference product groups are: bevacizumab, infliximab, pegfilgrastim, rituximab, and trastuzumab. The analytic plan uses paid, non-reversed Medicaid medical claims only from PDL inception; members with Part D, TPL, or Maine RX coverage are excluded. The goal is to quantify (1) the shift toward preferred biosimilars, (2) cost deltas between preferred and nonpreferred dispensing/infusion. We will use paid, non-reversed Medicaid medical claims from the inception of the Biosimilar PDL excluding members with Part D, TPL and Maine RX coverage.

PDL intent is translating into practice. Across families, the mix continues to trend toward preferred biosimilars after the policy start, not just in a single year but persistently through 2023-2024 and into 2025 YTD. That pattern is consistent with DUR's stated objective to assess utilization and savings impact from the Biosimilar PDL.

Recommendation: Based on findings, the recommendation is to continue the shift toward biosimilars.

NEW/REVISED CRITERIA

There were no new or revised criteria for review at this time.

Board Decision: Via written consent, the Board unanimously approved the above recommendations as presented.

NEW DRUG REVIEW

ANDEMBRY® (Garadacimal-gxii) Injection; **PDL Category** – Hereditary Angioedema-Prophylaxis

Andembry® is an activated Factor XII (FXIIa) inhibitor (monoclonal antibody) indicated for prophylaxis to prevent attacks of HAE in adult and pediatric patients aged 12 years and older. It is for subcutaneous use only, intended to

be self-administered by the patient or administered by a caregiver. Its efficacy was assessed in a double-blind, randomized, placebo-controlled trial that included patients with Type I or Type II HAE who experienced at least 2 investigator-confirmed HAE attacks over a 2-month period prior to randomized treatment. The primary endpoint was the monthly HAE attack rate at 6 months and results suggested that the least squares mean for the monthly HAE attack rate was significantly lower with Andembry® as compared with placebo. Plasma-derived C1 INH, lanadelumab, berotralstat, and garadacimab-gxii are recommended rather than other treatments for long-term prophylaxis in patients with severe disease.

Criteria: Non-preferred: Prior Authorization required.

Recommendation: Add Andembry® to non-preferred.

CTEXLI® (Chenodiol) Tablets; **PDL Category** – GI-Bile Acid

Ctexli® is a bile acid indicated for the treatment of cerebrotendinous xanthomatosis (CTX) in adults. Before starting Ctexli® treatment, obtain baseline liver transaminase and total bilirubin levels in all patients. Monitor levels yearly and as clinically indicated. The efficacy of Ctexli® was assessed in a randomized, double-blind, placebo-controlled, 2-period with 2-treatment crossover trial. In the trial, plasma cholestanol and urine 23S-pentol were assessed at multiple time points. With Ctexli® treatment, mean day 29 plasma cholestanol was lower than baseline while it was higher than baseline with placebo. Urine 23S-pentol increased more with placebo than Ctexli®. Per a noted reference source, chenodeoxycholic acid (chenodiol) is the backbone of CTX treatment.

Criteria: Non-preferred: Prior Authorization required to establish diagnosis and medical necessity.

Recommendation: Add Ctexli® to non-preferred.

HARLIKU® (Nitisinone) Tablets; **PDL Category** – AKU Agents

Harliku® is a hydroxyphenyl-pyruvate dioxygenase inhibitor indicated for the reduction of urine homogentisic acid (HGA) in adult patients with alkaptonuria (AKU). The efficacy of Harliku® was assessed in an open-label, single center, randomized, no-treatment controlled trial that included adults with AKU. Results suggested that Harliku® was effective at reducing levels of urinary HGA. The Harliku® group had an average percent reduction from baseline of 88% after 1 year of treatment, which was sustained through three years of treatment with an average precent reduction from baseline of 91% at year 3. In contrast, the untreated controls had an average increase of 107% from baseline to year 1 and 108% from baseline to year 3. Harliku® is the only FDA-approved treatment for HGA reduction in adults with AKU.

Criteria: Non-preferred: Prior Authorization required to establish diagnosis and medical necessity. Preferred drugs must be tried and failed due to lack of efficacy or intolerable side effects before non-preferred drugs (in step order) 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.

Recommendation: Add Harliku® to non-preferred.

HEMICLOR® (Chlorthalidone) Tablet; **PDL Category** – Diuretics

Hemiclor® is a thiazide-like diuretic indicated for the treatment of hypertension in adults, to lower blood pressure. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarction. It may be used alone or in combination with other antihypertensives. Treatment should be started with the lowest possible dose. No new clinical trials were found in the prescribing information of Hemiclor®. Chlorthalidone tablets, at currently available strengths of 25mg and 50mg, have been available for many years, and are also indicated for hypertension, among other indications. Hemiclor® offers providers and patients a new dosage option.

Criteria: Non-preferred: Prior Authorization required. 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.

Recommendation: Add Hemiclor® to non-preferred.

IMAAVY® (Nipocalimab-aahu) Injectable; **PDL Category** – Myasthenia Gravis

Imaavy® is a neonatal Fc receptor blocker indicated for the treatment of generalized myasthenia gravis (gMG) in adult and pediatric patients 12 years of age and older who are anti-acetylcholine receptor (AChR) or anti-muscle-specific tyrosine kinase (MuSK) antibody positive. It is for IV infusion only, and the need to administer age-appropriate vaccines per immunization guidelines should be assessed before the start of Imaavy® treatment. Vaccination with live vaccines is not recommended during treatment with Imaavy®. Delay Imaavy® administration in patients with an active infection until the infection is resolved. The efficacy of Imaavy® was assessed in a randomized, double-blind, placebo-controlled trial that included patients with gMG who were anti-AChR or anti-MuSK antibody positive. Results suggested a statistically significant difference favoring Imaavy® as compared with placebo for the primary endpoint of MG-ADL total score change from baseline (p=0.002). While oral acetylcholinesterase inhibitor therapy is suggested for most patients as initial treatment for mild to moderate MG, several biologic therapies are available for MG. A reference source notes that biologics can be considered for management of gMG. Furthermore, it is noted that biologics are generally kept for patients who are refractory to standard treatments.

Criteria: Non-preferred: Prior Authorization required. 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.

Recommendation: Add Imaavy® to non-preferred.

KHINDIVI® (hydrocortisone) Viscous oral solution; **PDL Category** – Glucocorticoids/Mineralcorticolds

Khindivi® is a corticosteroid indicated as replacement therapy in pediatric patients 5 years of age and older with adrenocortical insufficiency. Limitations of use include that Khindivi® is not approved for increased dosing during periods of stress or acute events. Use a different hydrocortisone-containing drug product for stress dosing. Individualize the dose for each patient, using the lowest dosage possible. Monitor patients for symptoms of under and/or overtreatment including signs and symptoms of adrenocortical insufficiency, linear growth, and weight gain. Adjust doses accordingly. When stress dosing is needed, use a different hydrocortisone-containing drug product.

There are no new clinical studies in the Khindivi® prescribing information. Khindivi® is the only FDA-approved hydrocortisone oral solution, to offer patients a new dosage formulation.

Criteria: Non-preferred: Prior Authorization required. Trial and failure, contra-indication or intolerance to Alkindi Sprinkle is required. 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.

Recommendation: Add Khindivi® to non-preferred.

LEQSELVI® (Deuruxolitinib) Tablets; **PDL Category** – Alopecia Areata Agents

Leqselvi® is an oral Janus kinase (JAK) inhibitor indicated for the treatment of adults with severe alopecia areata (AA). Limitations of use include that Leqselvi® is not recommended for use in combination with other JAK inhibitors, biologic immunomodulators, cyclosporine, or other potent immunosuppressants. Test patients for CYP2C9 variants to determine CYP2C9 genotype. Leqselvi® is contraindicated in patients who are CYP2C9 poor metabolizers (patients with decreased CYP2C9 function). It has a box warning regarding risks of serious infections, mortality, malignancy, major adverse cardiovascular events (MACE) and thrombosis. Leqselvi® treatment is not recommended in patients with active TB or in patients with active hepatitis B or hepatitis C. The efficacy of Leqselvi® was assessed in two randomized, double-blind, placebo-controlled studies that included adults with AA, who had at least 50% scalp hair loss per the Severity of Alopecia Tool (SALT) for more than 6 months. The primary endpoint for both trials assessed the proportion of subjects who achieved at least 80% scalp hair coverage (SALT score of ≤20) at week 24. Results suggested that at week 24, a greater proportion of subjects had a SALT ≤20 response and SALT ≤10 response with Leqselvi® 8mg as compared with placebo. Per the full-text study by King et al (trial AA-1), Leqselvi® resulted in significantly higher proportions of patients achieving a SALT score ≤20 after 24 weeks of treatment as compared with placebo ($p<0.0001$). Per a noted reference source, first-line treatment is generally topical or intralesional corticosteroids for adults with limited AA. However, additional treatment should be considered for moderate-to-severe AA and JAK inhibitors, such as baricitinib, ritlecitinib, or deuruxolitinib 8mg BID are suggested for severe alopecia.

Criteria: Non-preferred: Clinical Prior Authorization required to establish diagnosis and medical necessity. 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.

Recommendation: Add Leqselvi® to non-preferred.

RYZNEUTA® (Efbemalenograstim alfa-vuxw) injection; **PDL Category** – Granulocyte CSF

Ryzneuta® is a leukocyte growth factor indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in adult patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia. A limitation of use includes that Ryzneuta® is not indicated for the mobilization of peripheral blood progenitor cells for hematopoietic stem cell transplantation. The efficacy of Ryzneuta® was assessed in two randomized, controlled trials. One trial was a placebo-controlled trial, with efficacy based on the mean duration of severe neutropenia in cycle 1. Results suggested that the mean duration of severe neutropenia was lower for Ryzneuta®-treated patients as compared with placebo-treated

patients (p<0.001). In addition, the incidence of febrile neutropenia was lower for the Ryzneuta® group as compared to the placebo group in cycle 1 (p=0.0016; NNT 5). The second study was an active-controlled study that compared Ryzneuta® with pegfilgrastim. Results suggested that the mean days of severe neutropenia of Ryzneuta®-treated patients did not exceed that of pegfilgrastim-treated patients by more than 0.6 days in cycle 1 of chemotherapy, and the mean days of severe neutropenia in cycle 1 were 0.2 days in both groups. One noted reference source notes that the data on the long-acting G-CSFs, including pegfilgrastim, efbemalenograstim alfa, and eflapegrastim have suggested comparable efficacy and thus the decision on which agent to use should be cased on availability and cost.

Criteria: Non-preferred: Prior Authorization required. Must be used in specified step order.

Recommendation: Add Ryzneuta® to non-preferred.

SOFDRA® (**Sofpironium Bromide**) gel; **PDL Category** –Hyperhidrosis Therapy-Axillary

Sofdra® is an anticholinergic indicated for the treatment of primary axillary hyperhidrosis in adults and pediatric patients 9 years of age and older. It is to be applied once daily at bedtime and is for topical use only. The safety and efficacy of Sofdra® were assessed in two randomized, vehicle-controlled multicenter trials that included subjects 10 years of age and older with primary axillary hyperhidrosis. The co-primary endpoints were the proportion of subjects having at least a 2-point improvement in the Hyperhidrosis Disease Severity Measure-Axillary, 7-item (HDSM-Ax-7) scale score from baseline to day 43 and the change in gravimetric sweat production (GSP) from baseline to day 43. Sofdra® was more effective than vehicle for both endpoints in both studies. Per a pooled analysis of CARDIGAN 1 and CARDIGAN 2 by Pariser et al, significantly better results were observed in the treatment group as compared with the vehicle for both co-primary endpoints (p<0.0001, p=0.0002). One noted reference prefers the use of topical antiperspirants as initial treatment for axillary hyperhidrosis, with topical glycopyrronium as an alternative first-line treatment, while another reference source suggests to consider topical nonprescription antiperspirants or prescription topical anticholinergic agents (with sofpironium listed) as first line options.

Criteria: Non-preferred: Clinical Prior Authorization is required to establish diagnosis and medical necessity. For adults and pediatric patients 9 years of age and older. Preferred drug 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 exists. Sofdra must be prescribed by a dermatologist.

Recommendation: Add Sofdra® to non-preferred.

SYMBRAVO® (meloxicam & rizatriptan); tablets; **PDL Category** – Migraine-Selective Serotonin Agonists-Combinations

Symbravo® is a combination of meloxicam (an NSAID) and rizatriptan (a serotonin [5-HT] 1B/1D receptor agonist [triptan]) indicated for the acute treatment of migraine with or without aura in adults. Limitations of use include that Symbravo® should only be used where a clear diagnosis of migraine has been established. If a patient has no response for the first migraine attack treated with Symbravo®, the diagnosis of migraine should be reconsidered before Symbravo® is administered to treat any subsequent attacks. In addition, Symbravo® is not indicated for the preventive treatment of migraine attacks and is not indicated for the treatment of cluster headache. Use the shortest duration consistent with individual patient treatment goals. Symbravo® tablets are not substitutable with

other formulations of oral meloxicam or oral rizatriptan products, even if the milligram strengths are the same. Do not substitute Symbravo® with similar dose strengths of other meloxicam or rizatriptan products. After a single dose of Symbravo® under fasted conditions, the median Tmax for the meloxicam component is 0.88 hours, which is less than oral meloxicam tablets (Tmax of 4-5 hours). The efficacy of Symbravo® for the acute treatment of migraine was demonstrated in a randomized, double-blind, placebo- and active-controlled trial, with the primary efficacy analyses conducted in patients who treated a migraine with moderate to severe pain. The percentage of patients achieving headache pain freedom and MBS freedom 2 hours after a single dose was statistically significantly greater among those treated with Symbravo® as compared with placebo (co-primary endpoints; NNT 8 and NNT 8, respectively). Information regarding statistical evidence for Symbravo® vs the active comparators for the co-primary endpoints were not found in the prescribing information and the full text study has yet to be published. In study 2, the primary efficacy analyses were conducted in patients who treated a migraine with initial pain that was mild. The percentage of patients achieving headache pain freedom and MBS freedom 2 hours after a single dose was statistically significantly greater among those treated with Symbravo® as compared with placebo. Symbravo® offers prescribers a combination treatment option for acute migraine.

Criteria: Non preferred: Dosing limits apply (see Dosage Consolidation List).

Recommendation: Add Symbravo® to non-preferred**.**

TRYPTYR® (Acoltremon) solution; **PDL Category** – OP-Of Interest

Tryptyr® is a TRPM8 thermoreceptor agonist indicated for the treatment of the signs and symptoms of dry eye disease (DED). Its efficacy was assessed in two randomized, double-blind, vehicle-controlled studies that compared Tryptyr® with vehicle for 90 days. Results suggested that a statistically significant improvement in tear production favoring Tryptyr® ($p<0.01$) was observed in both studies (NNT 3 for both studies). Tryptyr® has a different mechanism of action than the currently available DED products, to increase tear production. Comparator studies with other active ingredients were not currently found.

Criteria: Non preferred: Prior Authorization required to confirm appropriate diagnosis and clinical parameters for use.

Recommendation: Add Tryptyr® to non-preferred.

VYKAT® XR (Diazoxide Choline) Tablets; **PDL Category** – Hyperphagia-Misc.

Vykat® XR is indicated for the treatment of hyperphagia in adult and pediatric patients 4 years of age and older with Prader-Willi syndrome (PWS). Prior to starting treatment, test fasting plasma glucose and HbA1c; optimize blood glucose in patients who have hyperglycemia. Do not substitute Vykat® XR with diazoxide oral suspension as the pharmacokinetic profiles differ. It is generally recommended in children and adults to restrict food intake by way of having a calorie-restricted diet and food security (restriction) to be part of the management of hyperphagia associated with PWS. The efficacy of Vykat® XR for the treatment of hyperphagia in adult and pediatric patients ages 4 years and older with PWS was assessed in a 16-week, double-blind, placebo-controlled, randomized withdrawal study period that followed an open-label study period of Vykat® XR. The primary efficacy endpoint was the change from baseline in the HQ-CT Total Score at week 16. At the end of the 16-week randomized withdrawal study period, there was statistically significant worsening of hyperphagia in the placebo group relative to the Vykat® XR group, per the HQ-CT Total Score. Vykat® XR is the only FDA-approved treatment for hyperphagia in individuals 4 years of age and older with PWS.

Criteria: Non-preferred: FDA approved for the treatment of hyperphagia in adults and pediatric patients 4 years of age or older with Prader-Willi syndrome.

Recommendation: Add Vykat® XR to non-preferred.

XIFYRM® (Meloxicam) IV Solution; **PDL Category** – Cox 2 Inhibitors-Selective/Highly Selective

Xifyrm® contains meloxicam, which is an NSAID, and is indicated for use in adults for the management of moderate-to-severe pain, alone or in combination with non-NSAID analgesics. A limitation of use includes that because of delayed onset of analgesia, Xifyrm® alone is not recommended for use when rapid onset of analgesia is required. Use the shortest duration consistent with individual patient treatment goals. Xifyrm® has a box warning regarding risk of serious cardiovascular and gastrointestinal events. Its efficacy was assessed in two randomized, double-blind, placebo-controlled, multiple-dose trials that included patients with postoperative pain categorized as moderate or severe. In Study 1 (bunionectomy surgery), a statistically significant difference demonstrating efficacy was observed in the primary efficacy endpoint of the SPID48. In Study 2 (abdominoplasty surgery), a statistically significant difference demonstrating efficacy was observed in the primary efficacy endpoint of SPID24, as well as SPID48. Xifyrm® provides patients and providers with an alternate dosage form option, as this is for intravenous administration only.

A 2020 network meta-analysis by Carter et al assessed the safety and efficacy of meloxicam 30mg IV (MIV) and other IV non-opioid analgesics for moderate to severe acute postoperative pain. MIV was indirectly compared with the IV treatments that were available at the time in the US (acetaminophen, ibuprofen, and ketorolac). Results suggested that of abdominal procedures, MIV was associated with significantly greater pain reductions as compared with acetaminophen, ketorolac, other medications, and placebo. MIV was nominally more effective for pain reduction as compared with ibuprofen, but the confidence intervals did overlap. However, the surface under the cumulative ranking curve (SUCRA) suggested an 89.6% probability that MIV was the most effective treatment for abdominal procedures and a 10.4% probability for ibuprofen. For bunionectomy, MIV was significantly more effective for pain reduction as compared with all other treatment options. Per the SUCRA ranking table for SPID24, the order from best to worst was MIV, acetaminophen, ibuprofen, ketorolac, placebo, and other. In the hysterectomy procedure, MIV was the most effective treatment for pain reduction up to 24 hours postop, and the order of treatments per SUCRA was MIV, ibuprofen, ketorolac, other, acetaminophen, and placebo. Overall, MIV was associated with significant reduction in morphine milligram equivalents (MME) for all procedure categories. The authors concluded that in this indirect comparison, MIV 30mg may provide better pain reduction with similar or better safety as compared with other approved IV non-opioid analgesics

Criteria: Non-preferred: Dosing limits allowing one tablet daily of all strengths without Prior Authorization. The FDA has issued a Public Health Advisory warning of the potential for increased cardiovascular risk & GI bleeding with NSAID use.

Recommendation: Add Xifyrm® to non-preferred.

YEZTUGO® (Lenacapavir) Injection or Tablet; **PDL Category** – Antiretrovirals

Yeztugo®, a HIV-1 capsid inhibitor, is indicated for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 in adults and adolescents weighing at least 35kg who are at risk for HIV-1 acquisition. Individuals must have a negative HIV-1 test prior to starting Yeztugo®. It carries a box warning regarding risk of drug resistance with use for HIV-1 PrEP in undiagnosed HIV-1 infection. Individuals must be tested for HIV-1 infection

prior to starting Yeztugo® treatment and with each subsequent injection. Drug-resistant HIV-1 variants have been identified with the use of Yeztugo® by individuals with undiagnosed HIV-1 infection. Do not start Yeztugo® unless negative infection status is confirmed. Individuals who acquire HIV-1 while receiving Yeztugo® must transition to a complete HIV-1 treatment regimen.

There are currently two oral options for PrEP, including tenofovir disoproxil fumarate-emtricitabine (TDF-FTC; Truvada) and tenofovir alafenamide-emtricitabine (TAF-FTC; Descovy®). Cabotegravir (Apretude®) is a long-acting injectable available.

The safety and efficacy of Yeztugo® were assessed in two randomized, double-blind, active-controlled studies. In study 1, Yeztugo® demonstrated superiority with a 100% reduction in the risk of incident HIV-1 infection over Truvada® ($p<0.0001$). In study 2, Yeztugo® demonstrated superiority with an 89% reduction in the risk of incident HIV-1 infection over Truvada® ($p=0.00245$).

Criteria: Preferred.

Recommendation: Although Yeztugo® was initially presented to be included as a non-preferred drug, prior to the Committee meeting a decision was made to change the recommendation to include Yeztugo® as a preferred drug. Following discussion by those present, it was agreed to submit a separate motion for written approval to accept the addition of Yeztugo® as preferred. Add Yeztugo® as preferred.

ZELSUVMI® (Berdazimer) Gel; **PDL Category**-Topical – Antivirals

Zelsuvmi® is a nitric oxide releasing agent indicated for the topical treatment of molluscum contagiosum (MC) in adult and pediatric patients 1 year of age and older. It is for topical use only, to be applied once daily to each MC lesion for up to 12 weeks. The safety and efficacy of Zelsuvmi® was assessed in 3 multicenter, randomized, double-blind, vehicle-controlled trials that included subjects with MC. The primary efficacy endpoint was the proportion of subjects achieving complete clearance at week 12. Efficacy of Zelsuvmi® was demonstrated in Trials 1 and 2. Per the full text by Browning et al (Trial 1), significantly more in the berdazimer group achieved complete clearance of MC lesions as compared with vehicle at week 12 ($p<0.001$). Berdazimer is listed as a treatment option for MC in immunocompetent patients, along with cryotherapy, curettage, and cantharidin.

Criteria: Non-preferred: Prior Authorization required. For the topical treatment of molluscum contagiosum in adult and pediatric patients 1 year of age and older.

Recommendation: Add Zelsuvmi® to non-preferred.

Board Decision: Via written consent, the Board unanimously approved the recommendations as amended.

FDA SAFETY ALERTS

Transdermal Scopolamine Drug Safety Communication – FDA adds warning about serious risk of heat-related complications with antinausea patch – click here for the link (June 18, 2025)

FDA warning in labeling of mRNA COVID-19 vaccines regarding myocarditis and pericarditis following vaccination – click here for the link (June 25, 2025)

Expanded Safety Labeling on Extended-Release Stimulants for ADHD – click here for the link (June 30, 2025)

FDA is requiring opioid pain medicine manufacturers to update prescribing information regarding long-term use – click here for the link (July 31, 2025)

Elevidys Concerns:

- FDA investigating deaths due to acute liver failure in non-ambulatory Duchenne Muscular Dystrophy patients following Elevidys – click here for the link (June 24, 2025)
- FDA requests Sarepta Therapeutics suspend distribution of Elevidys and places clinical trials on hold for multiple gene therapy products following 3 deaths – click here for the link (July 18, 2025)

Board Decision: No action needed.

ADJOURNMENT: 8:30PM

A written Board voting ballot will be emailed for Board consent of all motions.

The next meeting will be the **Annual Meeting to be held on November 4, 2025**.