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Governor

Sara Gagné-Holmes
Commissioner

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TO: Maine Drug Utilization Review Board

DATE: January 9, 2026

RE: Maine DUR Board Meeting minutes from December 9, 2025

ATTENDANCE	UNEXCUSED	EXCUSED	IN-PERSON	REMOTELY
Erin Ackley, PharmD.		X		
John Deason, PharmD.				X
Michela Fiori, Pharm.D.				X
Linda Glass, MD		X		
Caitlin Morrow, PharmD.				X
Kathleen Polonchek, MD		X		
Non –Voting				
Roberta Capp, MD, Optum				X
Dan Mickool, R.Ph., M.S., Ed D, MaineCare			X	
Mike Ouellette, R.Ph., Optum		X		
Courtney Pladsen, MaineCare		X		
Jan Wright, MaineCare				
Gavin Gillespie, Pharm.D., Optum			X	

CALL TO ORDER: 6:00PM

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

MAINECARE UPDATE

Dan Mickool, R.Ph., M.S., Ed D, MaineCare

- Welcomed the Board members to the last meeting of 2025.
- Major system upgrade to Health PAS that is currently underway. The goal of the upgrade is to improve vendor integration to result in improved service for our Maine members.

PUBLIC COMMENTS

- Kyla Scarponi, DO: Presented information regarding the ADHD medication **Jornay PM®** and requested for Jornay PM® to be more accessible (Preferred) for MaineCare children with ADHD.
- Paul Isikwe, PharmD., MS, BioGen: Highlighted attributes of **Zurzuvae®** with a request for the 14-day oral PPD drug be included as a Preferred medication on the MaineCare PDL.
- Christine Dube, PharmD., BCPS, AstraZeneca: Addressed the Board regarding **Airsupra®** with a goal to align MaineCare with GINA (Global Initiative for Asthma) favoring ICS-formoterol SMART (Single Maintenance and Reliever Therapy) therapy.

OLD BUSINESS

TYENNE®: The Board discussed and recommended moving Tyenne® (biosimilar to Actemra) to Preferred status to support biosimilar strategy and pricing.

BOARD DECISION: The Board unanimously approved the recommendation as presented.

DUR MINUTES

The minutes of the 2025 Annual Drug Utilization Review Board meeting held on November 4, 2025, were accepted as submitted.

CONSENT AGENDA

NEW CANCER MEDICATIONS

BEIZRAY® (Docetaxel)
Beizray® (docetaxel) is an antineoplastic agent belonging to the taxoid family. It acts by disrupting the microtubular network in cells that is essential for mitotic and interphase cellular functions. Docetaxel binds to free tubulin and promotes the assembly of tubulin into stable microtubules while simultaneously inhibiting their disassembly. This leads to the production of microtubule bundles without normal function and to the stabilization of microtubules, which results in the inhibition of mitosis in cells. Docetaxel's binding to microtubules does not alter the number of protofilaments in the bound microtubules, a feature which differs from most spindle poisons currently in clinical use.

HERNEXEOS® (Zongertinib)
Hernexeos® (zongertinib) is a kinase inhibitor of human epidermal growth factor receptor 2 (HER2). In vitro, zongertinib inhibited phosphorylation of HER2, downstream signaling of HER2, and proliferation of lung cancer cells harboring HER2 tyrosine kinase domain activating mutations.

IBTROZI® (Taletrectinib)
Ibtrozi® (taletrectinib) is a kinase inhibitor. It is an inhibitor of tyrosine kinase ROS1, including ROS1 resistance mutations. Taletrectinib also demonstrated inhibitory effects on tropomyosin receptor kinases (TRKs) TRKA, TRKB, and TRKC. Taletrectinib inhibited growth of cancer cells expressing ROS1 fusion genes and mutations.

INLURIYO® (Imlunestrant)
Inluriyo (imlunestrant) is an estrogen receptor (ER) antagonist that binds to Erα. In vitro, imlunestrant induced degradation of Erα, leading to inhibition of ER-dependent gene transcription and cellular proliferation in ER+ breast cancer cells. Imlunestrant demonstrated in vitro and in vivo anti-tumor activity in ER+ breast cancer xenograft models, including models with ESR1 mutations.

KEYTRUDA QLEX® (pembrolizumab and berahyaluronidase alfa-pmph)

- Keytruda QLEX (pembrolizumab and berahyaluronidase alfa) is a fixed-combination drug product.
- Pembrolizumab is a programmed death receptor-1 (PD-1) blocking antibody. It is a humanized monoclonal IgG4 kappa antibody.
- Binding of the PD-1 ligands, PD-LI and PD-L2, to the PD-1 receptor found on T cells, inhibits T cell proliferation and cytokine production. Upregulation of PD-1 ligands occurs in some tumors and signaling through this pathway can contribute to inhibition of active T-cell immune surveillance of tumors.

- Pembrolizumab binds to the PD-1 receptor and blocks its interaction with PD-L1 and PD-L2, releasing PD-1 pathway-mediated inhibition of the immune response, including the anti-tumor immune response.
- Berahyaluronidase alfa is an endoglycosidase used to enhance dispersion and permeation, which facilitates delivery of increased volume of pembrolizumab that is co-administered subcutaneously.

MODEYSO® (dordaviprone)
Modeyso (dordaviprone) is a protease activator of the mitochondrial caseinolytic protease P (ClpP). It also inhibits the dopamine D2 receptor.

PHYRAGO® (dasatinib)
Phyrago (dasatinib) is a kinase inhibitor.

JOBEVNE Biosimilar to Avastin
Jobevne® (bevacizumab-nwgd) is a vascular endothelial growth factor inhibitor.

Criteria: All non-preferred: A clinical Prior Authorization is required to confirm appropriate diagnosis and clinical indication for the individual drug request. Specific to each drug, all ages, 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 Beizray®, Hernexeos®, Ibtrozi®, Inluriyo®, Keytruda Qlex®, Modeyso®, Phyrago®, and Jobevne® to non-preferred.

BIOSIMILARS

Recommendation: Add Actemra® Biosimilar Avtozma® 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. **Additional criteria are listed on the Rheumatoid Arthritis Prior Authorization form.**

Recommendation: Add Novolog® Biosimilar Kirsty® 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® Biosimilar Bildyos® 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® Biosimilar Otulfi® 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 Tysarbri® Biosimilar Tyruko® 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® Biosimilar Bilprevda® 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: The Board unanimously approved the Consent Agenda recommendations as presented.

NEW BUSINESS

RETRODUR

Introduction: Adherence to Oral Anti-Psychotic Medications for Individuals Diagnosed with Schizophrenia and Schizoaffective Disorder

Schizophrenia and schizoaffective disorder are chronic, relapsing psychiatric disorders that impose substantial clinical and economic burdens, with antipsychotic medications remaining the cornerstone of maintenance treatment. Despite their proven efficacy in reducing positive symptoms and preventing relapse, medication nonadherence remains a major barrier to optimal outcomes, contributing to increased risk of hospitalization, relapse, and overall disease burden. Adherence rates to oral antipsychotics are suboptimal, ranging from 20% to 61% in real-world studies, and are influenced by factors such as side-effect profiles, patient preferences, and illness insight.

Recently, the state assessed adherence rates using proportion of days covered (PDC) for long acting injectables containing aripiprazole, paliperidone, or risperidone, showing underutilization of these agents despite high adherence rates.

This retrospective drug utilization review will focus on adherence rates of oral antipsychotics containing aripiprazole, risperidone, or paliperidone, in addition to Cobenfy® (xanomeline-trospium), a muscarinic receptor agonist/antagonist combination approved in 2024 as the first nondopaminergic antipsychotic. This novel mechanism of action may offer improved tolerability. The findings will inform future strategies to optimize adherence and improve long-term outcomes in this population.

Non-reversed Medicaid pharmacy and medical claims from calendar year 2024-2025, excluding members with Part D, TPL and Maine RX coverage.

This retrospective drug utilization review (RDUR) will focus on adult Maine Medicaid members, ages 18 and older, who receive at least one ICD10 diagnosis of schizophrenia or schizoaffective disorder during fiscal years 2024 and 2025. This analysis will include oral medication adherence and discontinuation rates with aripiprazole, risperidone, or paliperidone using the proportion of days covered (PDC), considering members with a PDC of 80% or higher as adherent. Discontinuation is defined as any member who does not maintain continuous medication therapy for at least 120 days.

The review specifically assesses adherence and discontinuation rates for two atypical oral antipsychotics and compares these rates to those for members receiving first-line atypical antipsychotic therapy, including Cobenfy®.

Data Presentation: Long-Acting Atypical Injection Adherence and Impact on ER, Hospital Utilization, and Outpatient Utilization

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. Some are administered every week, every other week, every month, every other month, or every 6 months

The purpose of this retro-DUR analysis of anti-psychotic long-acting injectables was conducted to understand adherence, discontinuation rates, and the cost benefit analysis on use of LAIs administered at different frequencies within the two available different subclasses (aripiprazole, paliperidone, and risperidone), and impact on acute hospital utilization such as hospitalizations and ER visits.

This analysis identified 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 years of 2023. There were a 6-month and a 12-month look back and forward time using data from calendar years of 2022 and 2024. LAI injectables were classified by their dose frequency of every two weeks, every month or every 2 months within their subclasses. An evaluation of 55% or greater PDC and discontinuation rates at 6 and 12 months was determined (Campagna et al, 2014). Secondly, an assessment of those with PDC >55% versus those with PDC<55% on the impact of ER, hospital utilization, and outpatient utilization was conducted, along with its total cost. Finally, an overview of common patterns of prescription changes within and across subclasses were evaluated.

The analysis of 351 Medicaid members indicates that LAIs are underutilized among potential candidates. Of the group, 64% were male and 46% were aged 30-44. The average PDC was 90% at six months and 82% at twelve months, both exceeding rates seen in other Medicaid studies and surpassing those of oral antipsychotic treatments.

Invega Sustenna was the initial treatment for 52% of patients, Abilify Maintena for 27%, and Aristada for 8%. Overall, paliperidone products were chosen first in 60% of cases, aripiprazole in 35%, and risperidone in 5%. At both 6 and 12 months, paliperidone and aripiprazole had higher average PDC rates (paliperidone: 90% at 6 months, 83% at 12 months; aripiprazole: 92% at 6 months, 82% at 12 months) compared to risperidone (74% at 6 months, 71% at 12 months).

At six months, the average proportion of days covered (PDC) was 88% for Invega Sustenna, 99% for Invega Trinza, and 100% for Invega Hafyera. At twelve months, the PDC rates were 81% for Invega Sustenna, 95% for Invega Trinza, and 99% for Invega Hafyera. However, the sample sizes for both Invega Trinza and Invega Hafyera were small, so these findings may not be broadly applicable.

Risperdal Consta was the most used Risperidone product, prescribed to 81% of unique Medicaid members within the risperidone product class. Six- and twelve-month PDC rates were both 68%. Fewer than five members received Perseris or Risperidone ER.

Abilify Maintena was the most widely used aripiprazole product, with 77% of unique Medicaid members receiving it, in aripiprazole product class. The proportion of days covered (PDC) rates were 91% at 6 months and 82% at 12 months. Aristada ranked second, used by 23% of Medicaid members in this class, with PDC rates of 93% at 6 months and 82% at 12 months.

Product switching during treatment was common. In assessing the proportion of unique Medicaid members who achieved a PDC of 55% or greater within 12 months of initiating a LAI, 83% of members met this adherence rate.

The predominant administration frequency among members was every 28 to 30 days (76%). Mean PDC adherence rates were as follows: ≤14 days—15%, 28–30 days—52%, 60 days—35%, 90 days—86%, and 180 days—81%. Extended dosing intervals were associated with increased PDC rates.

In conclusion, the analysis reveals that while long-acting injectable antipsychotics demonstrate high adherence rates among Medicaid members who initiate them, there remains significant underutilization among eligible patients. The data suggests that products with longer dosing intervals are associated with superior adherence, and most members received their injections every 28 to 30 days. Moving forward, targeted outreach and education initiatives should be implemented to increase LAI adoption, especially among populations with lower historical adherence.

Additionally, the analysis examined barriers to LAI use, including prescriber preferences and patient access, and evaluated the impact of increased LAI utilization on hospitalization and emergency department visits.

Recommendation: Based on findings, no PDL changes resulted from this RDUR analysis.

NEW/REVISED CRITERIA

FASENRA® (benralizumab): The FDA indication has been updated to include severe asthma, age 6+, with eosinophilia. A recommendation was made to accept the new criteria while maintaining its Preferred status.

AIRSUPRA® (albuterol sulfate and budesonide): This medication has been repositioned into anti-asthmatic beta-agonist class with new PA criteria that includes the patient is aged ≥ 18, AND the patient has had a documented side effect or allergy, AND treatment failure/intolerance or contraindication to Symbicort® and Dulera® SMART therapy, AND the patient is unable to use albuterol and Budesonide separately. A recommendation was made to accept the new criteria while maintaining its Non-Preferred status.

BOARD DECISION: The Board unanimously approved the recommendations made for the RetroDUR reports and New/Revised Criteria as presented.

NEW DRUG REVIEW

ANZUPGO® (delgocitinib) Cream; **PDL Category** – Topical–Atopic Dermatitis
Anzupgo (delgocitinib) is a Janus kinase (JAK) inhibitor.

It inhibits the activity of JAK1, JAK2, JAK3, and tyrosine kinase 2 (TYK2).

- JAK signaling involves recruitment of signal transducers and activators of transcription (STATs) to cytokine receptors, and activation and subsequent localization of STATs to the nucleus, leading to the expression of cytokine-responsive genes to induce specific biological responses in target cells.

Criteria: Non-preferred: Prior Authorization required. 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.

Limitations of use include that the use of Anzupgo in combination with other JAK inhibitors or potent immunosuppressants is not recommended.

Recommendation: Add ANZUPGO® to non-preferred.

BLUJEPA® (gepotidacin); **PDL Category** – Antibiotics–Misc.
Blujepa (gepotidacin) is a triazaacenaphthylene antibacterial that inhibits Type II topoisomerases including bacterial topoisomerase II (DNA gyrase) and topoisomerase IV, thus inhibiting DNA replication.

Criteria: Non-preferred: 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.

For the treatment of patients 12 years of age and older.

Recommendation: Add BLUJEPA® to non-preferred.

BREKIYA® (dihydroergotamine mesylate); **PDL Category** – Migraine-Ergotamine Derivatives
FDA approved in 2025, Brekiya (dihydroergotamine mesylate) is an ergotamine derivative. It binds with high affinity to 5-HT1Dα and 5-HT1Dβ receptors. The therapeutic activity of dihydroergotamine in migraine is generally attributed to the agonist effects at 5-HT1D receptors.

Criteria: Non-preferred: Preferred drugs must be tried within the Migraine therapy category 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 BREKIYA® to non-preferred.

BRINSUPRI® (brensocatib); **PDL Category** – Antiasthmatic-Dipeptidyl Peptidase 1 Inhibitors (New Class)
FDA approved in 2025, Brinsupri (brensocatib) is a dipeptidyl peptidase 1 (DPP1) inhibitor. It is a competitive, reversible inhibitor of DPP1. DPP1 activates pro-inflammatory neutrophil serine proteases (NSPs) during neutrophil maturation in the bone marrow. Activated NSPs are implicated in the pathogenesis of neutrophil-mediated non-cystic fibrosis bronchiectasis inflammation. In cell-based assays, DPP1 inhibition by brensocatib reduces the activity of NSPs including neutrophil elastase, cathepsin G, and proteinase 3.

Criteria: Preferred: Clinical PA is required to establish diagnosis and medical necessity.

- Imaging confirming bronchiectasis, and no overlapping asthma/COPD
- Documented airway clearance
- Greater than 2 exacerbations requiring antibiotics therapy in the last 12 months
- Must be approved by pulmonologist

Recommendation: Add BRINSUPRI® to preferred.

BRYNOVIN® (sitagliptin); **PDL Category** – Diabetic-DPP-4 Enzyme Inhibitor
Brynovin (sitagliptin) is an orally-active inhibitor of the dipeptidyl peptidase 4 (DPP-4) enzyme. Concentrations of the active intact hormones are increased by sitagliptin, thus increasing and prolonging the action of these hormones. Incretin hormones, including glucagon-like peptide-1 (GLP-1) and glucose-dependent insulinotropic polypeptide (GIP), are released by the intestine throughout the day, and levels are increased in response to a meal. These hormones are rapidly inactivated by the enzyme, DPP-4. When blood glucose concentrations are normal or elevated, GLP-1 and GIP increase insulin synthesis and release from pancreatic beta cells. GLP-1 also lowers glucagon secretion from pancreatic cells. By increasing and prolonging active incretin levels, sitagliptin increases insulin release and decreases glucagon levels in the circulation in a glucose-dependent manner.
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 (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.

In addition to tried and failed Preferred Agents, Brynovin requires tried and failed Non-Preferred Agent Zituvio.

Recommendation: Add BRYNOVIN® to non-preferred.

DAWNZERA® (donidalorsen); **PDL Category** – Hereditary Angioedema-Prophylaxis
Dawnzera (donidalorsen) is a prekallikrein-directed antisense oligonucleotide (ASO) covalently linked to a ligand containing three N-acetyl galactosamine (GalNAc) residues to facilitate delivery of the ASO to hepatocytes.

It is an ASO-GalNAc conjugate that causes ribonuclease H1 (RNase H1)-mediated degradation of PKK mRNA through binding to PKK mRNA, which results in reduced production of PKK protein. PKK is a pro-enzyme for plasma kallikrein, which results in the release of bradykinin, a potent vasodilator causing swelling and pain in HAE. In patients with HAE, C1-inhibitor (C1-INH) deficiency or dysfunction leads to excessive plasma kallikrein activity, bradykinin generation, and angioedema attacks.

Donidalorsen lowers PKK concentration, preventing excessive bradykinin production in patients with HAE.

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.

For the treatment of patients ≥ 12 years of age.

Recommendation: Add DAWNZERA® to non-preferred.

EKTERLY® (sebetralstat); **PDL Category** – Hereditary Angioedema-Treatment
FDA approved in 2025, Ekterly (sebetralstat) is a plasma kallikrein inhibitor.

It is a competitive, reversible inhibitor of plasma kallikrein. Plasma kallikrein is a serine protease that cleaves high molecular weight kininogen (HK) releasing bradykinin which increases vascular permeability through activation of bradykinin receptors causing edema. Sebetralstat inhibits the cleavage of HK and reduces production of bradykinin, thus treating the clinical symptoms of an acute, episodic attack of HAE.

Sebetralstat also inhibits the positive feedback mechanism of the kallikrein kinin system by plasma kallikrein, thus reducing factor XIIa and additional plasma kallikrein generation.

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.

For the treatment of patients ≥ 12 years of age.

Recommendation: Add EKTERLY® to non-preferred.

EXXUA® (gepirone); **PDL Category** – Antidepressants-Selected SSRI's and Others
Exxua (gepirone) is an extended-release tablet for oral administration. White its exact mechanism of action is not fully understood, it is thought to be related to its modulation of serotonergic activity in the CNS through selective agonist activity at 5HT1A receptors.

Criteria: Non-preferred: Preferred drugs (including failure of at least one preferred SSRI, one SNRI and one non-SSRI/SNRI) must be tried for at least 4 weeks each 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.

For the treatment of patients ≥ 18 years of age.

Recommendation: Add EXXUA® to non-preferred.

JASCAYD® (nerandomilast); **PDL Category** – Idiopathic Pulmonary Fibrosis

FDA approved in 2025, Jascayd (nerandomilast) is a phosphodiesterase 4 (PDE4) inhibitor, with at least nine-fold preferential inhibition of the PDE4B isoenzyme over PDE4A, PDE4C, and PDE4D. PDE4 hydrolyzes and inactivates cyclic adenosine monophosphate (cAMP). Nerandomilast exerts both anti-fibrotic and immunomodulatory effects as PDE4B inhibition elevates intracellular cAMP levels and reduces the expression of pro-fibrotic growth factors and inflammatory cytokines, which are overexpressed in idiopathic pulmonary fibrosis.

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

Recommendation: Add JASCAYD® to non-preferred.

OTEZLA XR® (apremilast); **PDL Category** – Psoriasis Biologicals
FDA approved in 2025, Otezla XR (apremilast) is an oral small molecule inhibitor of phosphodiesterase 4 (PDE4) specific for cyclic adenosine monophosphate (cAMP). PDE4 inhibition results in increased intracellular cAMP levels. The specific mechanism(s) by which apremilast exerts its therapeutic action is not well defined.

Criteria: Non preferred: 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(s) exists.

For the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

Recommendation: Add OTEZLA XR® to non-preferred**.**

PIRFENIDONE® (esbriet); **PDL Category** – Idiopathic Pulmonary Fibrosis
FDA approved in 2014, Pirfenidone (esbriet) may be used to treat adults with idiopathic pulmonary fibrosis (IPF), a lung condition that causes inflammation and scarring in the lungs. Pirfenidone works by targeting multiple pathways to reduce fibrosis, primarily by inhibiting pro-fibrotic factors like TGF-β1, which blocks fibroblast proliferation and collagen production, and by reducing inflammation and oxidative stress through inhibiting cytokines (TNF-α, IL-1β) and boosting antioxidant defenses, effectively slowing tissue scarring, especially in conditions like Idiopathic Pulmonary Fibrosis (IPF).

Criteria: Preferred: No PA needed.

Recommendation: Add PIRFENIDONE® to preferred**.**

RHAPSIDO® (remibrutinib); **PDL Category** – Antiasthmatic / Anti-inflammary Agents–Other (New Class)
FDA approved in 2025, Rhapsido (remibrutinib) is a kinase inhibitor. It is an oral, small molecule kinase inhibitor that inhibits Bruton's tyrosine kinase (BTK). BTK is an intracellular protein expressed in mast cells, basophils, B cells, macrophages, and thrombocytes. BTK is involved in intracellular signaling via Fc epsilon receptor-1 (FcėR1), Fc gamma receptors (FcγR), and the B cell antigen receptor (BCR). Remibrutinib also inhibits the BTK-related kinases tec protein tyrosine kinase (TEC) and BMX non-receptor tyrosine kinase (BMX).

Criteria: Non preferred: Clinical PA is required to establish diagnosis and medical necessity.

For Chronic Spontaneous Urticaria – Must have had an inadequate clinical response of at least 14 days with at least two different second-generation antihistamines at 4 times standard dose.

- Must be prescribed by or in consultation with either allergist/immunologist, dermatologist, pulmonologist, or otolaryngologist.
- Must continue use of second-generation antihistamine.

Recommendation: Add RHAPSIDO® to non-preferred.

SEPHIENCE® (sepiapterin); **PDL Category** – Phenylketonuria (PKU) Treatment Agents-Oral (Aminoacidopathy Treatments)
FDA approved in 2025, Sephience (sepiapterin) is a phenylalanine hydroxylase (PAH) activator. It is a precursor of the enzymatic co-factor tetrahydrobiopterin (BH4) which activates PAH.

Criteria: Non-preferred: Clinical PA is required to establish diagnosis and medical necessity. For adults and pediatric patients one (1) month of age and older who have tried and failed or have a contraindication or intolerance to Sapropterin Dihydrochloride products.

Recommendation: Add SEPHIENCE® to non-preferred.

WAYRILZ® (rilzabrutinib); **PDL Category** – Thrombopoietin Receptor Agonists
FDA approved in 2025, Wayrilz (rilzabrutinib) is a kinase inhibitor. It is a small-molecule, covalent, reversible kinase inhibitor targeting Bruton's tyrosine kinase (BTK). Rilzabrutinib mediates its therapeutic effect in immune thrombocytopenia through immune modulation including inhibition of B cell activation and interruption of antibody-coated cell phagocytosis by Fcy receptor (FcyR) in spleen and liver. In vitro, rilzabrutinib reduced autoantibody signaling mediated through the FcyR pathway, blocked B cell signaling, and decreased autoantibody generation through effects on B cell activation.

Criteria: Non-preferred: Clinical PA is required to establish diagnosis and medical necessity. Baseline platelet count is less than 30,000/mcL and prescribed in consultation or by a hematologist/oncologist.

Recommendation: Add WAYRILZ® to non-preferred.

YUTREPIA® (treprostinil sodium); **PDL Category** – Pulmonary Anti-Hypertensives
FDA approved in 2025, Yutrepia (treprostinil sodium) is a prostacyclin mimetic. The major pharmacologic actions of treprostinil are direct vasodilation of pulmonary and systemic arterial vascular beds and inhibition of platelet aggregation.

Criteria: Non-preferred: 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 YUTREPIA to non-preferred.

ZURNAI® (nalmefene); **PDL Category** - Narcotic – Antagonists (Antidotes–Opioid Withdrawal Agents)
Zurnai (nalmefene) is an antagonist at opioid receptors. Nalmefene has no opioid agonist activity.

Nalmefene reverses the effects of natural and synthetic opioids, including respiratory depression, sedation, and hypotension.

- Pharmacodynamic studies have shown that nalmefene injection has a longer duration of action than naloxone injection at fully reversing doses.

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.

For the treatment of adult and pediatric patients 12 years of age and older

Recommendation: Add ZURNAI® to non-preferred.

BOARD DECISION: The Board unanimously approved the recommendations as presented above.

FDA SAFETY ALERTS

FDA Approves New Safety Warning and Revised Indication that Limits Use for Elevidys Following Reports of Fatal Liver Injury – link (11/14/2025)

Previous Elevidys concerns reported at the September DUR meeting:

- 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

The next meeting will be held on March 10, 2026.