KENTUCKY DEPARTMENT FOR MEDICAID SERVICES PHARMACY AND THERAPEUTICS ADVISORY COMMITTEE RECOMMENDATIONS

TEAM KENTUCKY
CABINET FOR HEALTH AND FAMILY SERVICES

The following tables provide a summary of the official recommendations made by the Pharmacy and Therapeutics (P&T) Advisory Committee at the **January 20, 2025** meeting.

Pending is the review by the Commissioner of the Department for Medicaid Services of the Cabinet for Health and Family Services of these recommendations and final decisions.

RECOMMENDATIONS

	DESCRIPTION OF RECOMMENDATION	P&T VOTE

1	**New Product to Market: Brinsupri™ (brensocatib)**
	
	Non-PDL
	
	Approval Duration: 6 months initial, 12 months renewal
	
	• *Brensocatib is an oral, competitive, and reversible dipeptidyl peptidase 1 (DPP-1) inhibitor that targets neutrophil serine proteases (NSPs). DPP-1 is an enzyme that activates proinflammatory NSPs during neutrophil maturation, which are key drivers of bronchiectasis pathophysiology and airway inflammation. Brensocatib reduces the activity of NSPs.*
	
	Initial Approval Criteria:
	
	• Provider attestation of a non-cystic fibrosis bronchiectasis diagnosis, confirmed by chest computed tomography (CT) scan; **AND**
	• Prescribed by, or in consultation with, a pulmonologist or other specialist in the treatment of this disease; **AND**
	• Prescriber attestation that the patient meets ONE of the following:
	  ○ Aged 18 years and older with ≥ 2 exacerbations; **OR**
	  ○ Aged 12 to 17 years with ≥ 1 exacerbation; **AND**
	• Patient experienced exacerbations that required antibiotic treatment in the past 12 months; **AND**
	• Provider attestation that the patient may not be a current smoker. If a smoker, they should be counseled on the harmful effects of smoking on pulmonary diseases and be informed about available smoking cessation options.
	
	Renewal Criteria:
	
	• Provider attestation that the patient has demonstrated a positive response to therapy by one of the following:
	  ○ Improvement or stabilization of symptoms; **OR**
	  ○ Reduction in or stabilization of the frequency, severity, or duration of exacerbations; **OR**
	  ○ Reduction in the decline of FEV1.
	
	Age Limit: ≥ 12 years of age
	
	Quantity Limit: 1 tablet per day
		Decision 5 For 0 Against

	DESCRIPTION OF RECOMMENDATION	P&T VOTE

2	**New Product to Market: Orlynvah™ (sulopenem etzadroxil and probenecid)**
	
	Non-PDL
	
	Approval Duration: 1 month
	
	• *Sulopenem etzadroxil and probenecid is a first-in-class oral carbapenem antibiotic consisting of sulopenem etzadroxil, a prodrug converted to the active penem sulopenem, combined with probenecid, a renal tubular transport inhibitor. Sulopenem disrupts bacterial cell wall synthesis by binding to penicillin-binding proteins and offers broad-spectrum activity against common uropathogens, including multidrug-resistant and extended-spectrum β-lactamase-producing Enterobacteriaceae. Probenecid increases sulopenem's bioavailability by inhibiting renal excretion. This medication is approved for the treatment of uncomplicated urinary tract infections (uUTIs) in adult women caused by Escherichia coli, Klebsiella pneumoniae, or Proteus mirabilis, specifically in those with limited or no alternative oral treatment options.*
	
	Approval Criteria:
	
	• Patient is female; **AND**
	• Patient is 18 years of age or older, and weighs at least 40 kg; **AND**
	• Documented clinical diagnosis of uncomplicated urinary tract (uUTI) infection with at least 2 signs/symptoms, (e.g., dysuria, urgency, frequency, lower abdominal pain, etc.); **AND**
	• Urinalysis confirming pyuria and/or positive urinary nitrites; **AND**
	• Urine culture confirming or showing high-clinical suspicion of uUTI caused by ONE of the following susceptible organisms:
	  ○ Escherichia coli; **OR**
	  ○ Klebsiella pneumoniae; **OR**
	  ○ Proteus mirabilis; **AND**
	• Documented allergy, intolerance, contraindication, or therapeutic failure to at least 2 first-line oral agents for uUTI (e.g., sulfamethoxazole/trimethoprim tablet or suspension, amoxicillin-clavulanate, cefdinir, fosfomycin, cefpodoxime, nitrofurantoin, etc.) as appropriate, based on organism susceptibilities; **AND**
	• Provider attests that Orlynvah is not being used as step-down therapy for infections that previously required IV antibiotics.
	
	Quantity Limit: 10 tablets per 5-day course
		Decision
		6 For
		0 Against

3	**New Product to Market: Dawnzera™ (donidalorsen)** **Non-PDL** **Approval Duration:** 6 months initial, 12 months renewal	**Decision** **6 For** **0 Against**

	DESCRIPTION OF RECOMMENDATION	P&T VOTE

	• Donidalorsen *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 prekallikrein (PKK) protein. Lower PKK concentration, prevents excessive bradykinin production in patients with HAE.*
	
	Initial Approval Criteria:
	
	• Diagnosis of hereditary angioedema (HAE); **AND**
	• Documentation of confirmed diagnosis of HAE by one of the following tests:
	  ○ Complement testing; **OR**
	  ○ C1 Inhibitor protein and functional tests; **AND**
	• Prescribed for prophylactic use; **AND**
	• Prescribed by, or in consultation with, an immunologist, hematologist, or other specialist in the diagnosis and treatment of HAE; **AND**
	• Patient is not on concurrent treatment with alternative prophylactic agent for HAE (e.g., Takhzyro, Haegarda, Cinryze, Dawnzera, Orladeyo); **AND**
	• Patient meets the minimum age recommended by the package insert for this FDA-approved indication.
	
	Renewal Criteria:
	
	• Prescriber attestation of improvement compared to baseline in HAE attacks (i.e., reductions in attack frequency or attack severity).
	
	Quantity Limit: 0.8mL (80 mg) per 28 days	

4	**New Product to Market: Leqembi IQLIK™ (lecanemab-irmb)** **Central Nervous System – Alzheimer's Agents: Non-Preferred** **Approval Duration:** 6 months initial, 12 months renewal • *Lecanemab-irmb is a humanized immunoglobulin gamma 1 (IgG1) monoclonal antibody directed against aggregated soluble and insoluble forms of amyloid beta. The accumulation of amyloid beta plaques in the brain is a defining pathophysiological feature of Alzheimer's Disease.* **Initial Approval Criteria:** • Patient has a diagnosis of mild cognitive impairment (MCI) due to Alzheimer's Disease (AD) or mild dementia associated with AD dementia; **AND** • Prescribed by, or in consultation with, a neurologist, geriatrician, psychiatrist, or other dementia specialist; **AND** • Patient has completed 18 months of intravenous (IV) infusions of Leqembi; **AND** • Prior to initiation of Leqembi IV, there was confirmation of beta-amyloid plaques; **AND** • Prior to initiation of Leqembi IV, there was documentation of baseline disease severity utilizing one of the following scores: ○ Mini-Mental Status Exam (MMSE); **OR**	**Decision 6 For 0 Against**

	DESCRIPTION OF RECOMMENDATION	P&T VOTE
	○ Montreal Cognitive Assessment (MoCA); **OR** ○ Clinical Dementia Rating (CDR)-Global; **AND** • Prior to initiation of Leqembi IV, there was documentation of a brain MRI; **AND** • Prior to initiation of Leqembi IV, there was genotype testing for ApoE ε4 status; **AND** • Leqembi IQLIK will not be combined with other amyloid beta-directed antibodies (e.g., aducanumab). **Renewal Criteria:** • Positive clinical response as evidenced by stabilization or slowing of disease progression as documented by ONE of the following: ○ MMSE (e.g., decline of 3 points or less per year); **OR** ○ MoCA (e.g., score of greater than or equal to 15); **OR** ○ CDR-Global Score (i.e., score of 0.5 or 1). **Age Limit:** ≥ 50 years of age and ≤ 90 years of age **Quantity Limit:** 7.2 mL per 28 days (1 syringe per week)	
5	**New Product to Market: Wayrilz™ (rilzabrutinib)** **Blood Modifiers – Thrombopoiesis Stimulating Proteins: Non-Preferred** **Approval Duration:** 6 months initial, 6 months renewal • *Rilzabrutinib is a small-molecule, covalent, reversible kinase inhibitor targeting Bruton's tyrosine kinase (BTK). In immune thrombocytopenia (ITP), rilzabrutinib has immune modulating therapeutic effects, that inhibits B cell activation, reduces the generation of autoantibody that target platelets, and reduces platelet destruction by interrupting antibody-coated cell phagocytosis.* **Initial Approval Criteria:** • Diagnosis of persistent or chronic immune thrombocytopenia (ITP); **AND** • Prescribed by, or in consultation with, a hematologist or liver disease specialist; **AND** • Documentation (e.g., progress note, laboratory report) of platelet count within the past 30 days; **AND** • Trial and failure (i.e., not achieved a platelet count ≥ 50 x 10^9/L) of at least one other therapy for persistent or chronic ITP, such as corticosteroids, IV immune globulin, RhO(D) immune globulin, thrombopoietin receptor antagonists, etc.; **AND** • Trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications) or intolerance to Promacta. **Renewal Criteria:** • Documentation (e.g., progress note, laboratory report) of response to therapy. **Age Limit:** ≥ 18 years of age **Quantity Limit:** 2 tablets per day	**Decision** **6 For** **0 Against**

	DESCRIPTION OF RECOMMENDATION	P&T VOTE
6	**New Product to Market: Blujepa (gepotidacin)** **Non-PDL**	**Decision** **6 For** **0 Against**

Approval Duration: 1 month

- *Gepotidacin is a new clinical entity in the antibiotic category. It is the first-in-class triazaacenaphthylene bacterial topoisomerase inhibitor approved for the treatment of uncomplicated urinary tract infections (uUTIs) in adults. Unlike existing uUTI antibiotics (such as fluoroquinolones, beta-lactams, nitrofurantoin, or TMP-SMX), gepotidacin works by a unique dual-target mechanism on bacterial DNA gyrase and topoisomerase IV, overcoming the usual resistance mechanisms that affect current first-line options.*

Approval Criteria:

Uncomplicated Urinary Tract (uUTI) Infection:

- Patient is female; **AND**
- Patient is 12 years of age or older, and weighs at least 40 kg; **AND**
- Documented clinical diagnosis of uncomplicated urinary tract (uUTI) infection with at least 2 signs/symptoms, (e.g., dysuria, urgency, frequency, lower abdominal pain, etc.); **AND**
- Urinalysis confirming pyuria and/or positive urinary nitrites; **AND**
- Urine culture confirming or showing high-clinical suspicion of uUTI caused by ONE of the following susceptible organisms:
  - Escherichia coli; **OR**
  - Klebsiella pneumoniae; **OR**
  - Citrobacter freundii complex; **OR**
  - Staphylococcus saprophyticus; **OR**
  - Enterococcus faecalis; **AND**
- Documented allergy, intolerance, contraindication, or therapeutic failure to at least 2 first-line oral agents for uUTI (e.g., sulfamethoxazole/trimethoprim tablet or suspension, amoxicillin-clavulanate, cefdinir, fosfomycin, cefpodoxime, nitrofurantoin, etc.) as appropriate, based on organism susceptibilities.

Uncomplicated Urogenital Gonorrhea:

- Patient is 12 years of age or older, and weighs at least 45 kg; **AND**
- Documented clinical diagnosis of uncomplicated urogenital gonorrhea (e.g., positive Nucleic Acid Amplification Test (NAAT), culture, or Gram stain from urogenital site confirming susceptible Neisseria gonorrhoeae); **AND**
- Patient has limited or no alternative treatment options (e.g., documented allergy, intolerance, contraindication, treatment failure, or resistance to standard therapies such as intramuscular ceftriaxone plus oral azithromycin, intramuscular ceftriaxone, intramuscular gentamicin plus oral azithromycin, etc.).

Quantity Limit: 20 tablets per 5-day course

	DESCRIPTION OF RECOMMENDATION	P&T VOTE
7	**New Product to Market: Rhapsido® (remibrutinib)** **Non-PDL** **Approval Duration:** 12 months initial, 12 months renewal • *Remibrutinib inhibits Bruton tyrosine kinase (BTK), blocking mast cell and basophil degranulation, preventing release of histamine and other pro-inflammatory mediators.* **Initial Approval Criteria:** • Diagnosis of chronic spontaneous urticaria (CSU); **AND** • Trial and failure of (≥ 14-day treatment course), contraindication, or intolerance to histamine-1 antihistamine (e.g., diphenhydramine, hydroxyzine); **AND** • ~~**Trial and failure of (≥ 1-month treatment course), contraindication, or intolerance to BOTH Xolair and Dupixent; AND**~~ • Prescribed by, or in consultation with, an allergist, immunologist, or other applicable specialist in the diagnosis and treatment of CSU; **AND** • Patient must meet the minimum age recommended by the package insert for this FDA-approved indication. **Renewal Criteria:** • Patient has experienced disease improvement and/or stabilization such as improvement in CSU symptoms, as assessed by the prescriber. **Quantity Limit:** 2 tablets per day	**Decision** **6 For** **0 Against** **Committee motioned to approve, with the removal of the third bullet point**
8	**New Product to Market: Jascayd® (nerandomilast)** **Non-PDL** **Approval Duration:** 12 months initial, 12 months renewal • *Nerandomilast is an inhibitor of phosphodiesterase 4 (PDE4). PDE4 hydrolyzes and inactivates cyclic adenosine monophosphate (cAMP). Nerandomilast exerts both anti-fibrotic and immunomodulatory effects as PDE4-B inhibition elevates intracellular cAMP levels and reduces the expression of pro-fibrotic growth factors and inflammatory cytokines, which are overexpressed in IPF and PPF.* **Initial Approval Criteria:** • Patient has a diagnosis of idiopathic pulmonary fibrosis (IPF) or progressive pulmonary fibrosis (PPF) consistent with current guidelines (e.g., American Thoracic Society/European Respiratory Society/Japanese Respiratory Society); **AND** • Provider attests that other underlying causes for pulmonary fibrosis have been ruled out; **AND** • Patient has Forced Vital Capacity (FVC) ≥ 45% of predicted normal; **AND**	**Decision** **6 For** **0 Against**

	DESCRIPTION OF RECOMMENDATION	P&T VOTE
	• Prescribed by, or in consultation with, a pulmonologist or other specialist in treating IPF, PPF, or related conditions; **AND** • Patient must meet the minimum age recommended by the package insert for the provided indication. **Renewal Criteria:** • Physician attestation that patient has experienced stability or slowing of decline based on an objective measure (e.g., absolute change from baseline in FVC). **Quantity Limit:** 2 tablets per day	
9	**New Product to Market: Exxua™ (gepirone)** **Non-PDL** **Approval Duration:** 6 months initial, 12 months renewal • *The exact mechanism of gepirone is thought to be related to its modulation of serotonergic activity in the CNS through selective agonist activity at 5-HT1A receptors.* **Initial Approval Criteria:** • Diagnosis of major depressive disorder (MDD); **AND** • Prescriber must attest to monitoring of EKG during dosage titration and periodically during treatment; **AND** • Prescribed by, or in consultation with, a psychiatrist, neurologist, or another qualified healthcare provider experienced in treating depression or related conditions; **AND** • Patient has had at least a 2-week trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance to 2 SSRIs (e.g., citalopram, escitalopram, fluoxetine), or 2 SNRIs (duloxetine, venlafaxine, desvenlafaxine); **AND** • Patient must meet the minimum age recommended by the package insert for the provided indication. **Renewal Criteria:** • Patient has experienced disease improvement and/or stabilization such as improvement in depressive symptoms, as assessed by the prescriber. **Quantity Limit:** 1 tablet per day	**Decision** **6 For** **0 Against**
10	**New Product to Market: Lynkuet® (elinzanetant)** **Non-PDL** **Approval Duration:** 3 months initial, 12 months renewal	**Decision** **6 For** **0 Against**

	DESCRIPTION OF RECOMMENDATION	P&T VOTE

	• *Elinzanetant is a neurokinin 1 (NK1) and neurokinin 3 (NK3) receptor antagonist. Inhibition of Substance P and Neurokinin B through antagonism of NK1 and NK3 receptor signaling on kisspeptin/neurokinin B/dynorphin (KNDy) neurons can modulate neuronal activity in thermoregulation associated with hot flashes.*
	
	Initial Approval Criteria:
	
	• Patient has a diagnosis of menopause with moderate to severe vasomotor symptoms; **AND**
	• Patient does not have moderate to severe hepatic impairment; **AND**
	• Patient does not have end-stage renal disease (with or without hemodialysis); **AND**
	• If female of childbearing potential, NOT pregnant or planning to become pregnant; **AND**
	• Patient will avoid concomitant therapy with strong CYP3A4 inhibitors and grapefruit juice (e.g., ketoconazole, itraconazole, clarithromycin, ritonavir, darunavir, etc.); **AND**
	• Patient will avoid concomitant therapy with moderate to strong CYP3A4 inducers (e.g., carbamazepine, phenytoin, phenobarbital, rifampin and related agents, St. John's wort, etc.); **AND**
	• Prescriber attests that baseline liver function tests have been conducted and that total and direct bilirubin, alanine aminotransferase (ALT), aspartate aminotransferase (AST), and serum alkaline phosphatase (ALP) levels are not elevated ≥ 2 times the upper limit of normal (ULN); **AND**
	• Prescriber attests that liver function testing follow-up will be conducted as outlined in prescribing information; **AND**
	• Patient has trialed and failed, or is not a candidate for, hormone therapy.
	
	Renewal Criteria:
	
	• Patient continues to meet the above criteria; **AND**
	• Patient must have symptom improvement; **AND**
	• Patient has not experienced ANY of the following treatment-limiting adverse effects:
	  ○ ALT or AST > 5 times the ULN; **OR**
	  ○ ALT or AST > 3 times the ULN and total bilirubin > 2 times the ULN; **OR**
	  ○ Signs or symptoms that may suggest liver injury (e.g., new onset fatigue, decreased appetite, nausea, vomiting, pruritus, jaundice, pale feces, dark urine, abdominal pain, etc.).
	
	Age Limit: ≥ 18 years of age
	
	Quantity Limit: 2 capsules per day	

11	**Bronchodilators, Beta-Agonist** • DMS to select preferred agent(s) based on economic evaluation; however, at least 1 unique chemical entity should be preferred. • Agents not selected as preferred will be considered non-preferred and will require PA. • For any new chemical entity in the Bronchodilators, Beta-Agonist class, require PA until reviewed by the P&T Committee.	**Decision** **6 For** **0 Against**

	DESCRIPTION OF RECOMMENDATION	P&T VOTE
12	**Glucocorticoids, Inhaled** • DMS to select preferred agent(s) based on economic evaluation; however, at least 2 unique chemical entities should be preferred. • Agents not selected as preferred will be considered non-preferred and will require PA. • For any new chemical entity in the Glucocorticoids, Inhaled class, require PA until reviewed by the P&T Committee.	**Decision** **6 For** **0 Against**
13	**Intranasal Rhinitis Agents** • DMS to select preferred agent(s) based on economic evaluation; however, at least 2 unique chemical entities should be preferred. • Agents not selected as preferred will be considered non-preferred and will require PA. • For any new chemical entity in the Intranasal Rhinitis Agents class, require PA until reviewed by the P&T Committee.	**Decision** **6 For** **0 Against**
14	**Macrolides/Ketolides** • DMS to select preferred agent(s) based on economic evaluation; however, at least 2 unique chemical entities should be preferred. • Agents not selected as preferred will be considered non-preferred and will require PA. • For any new chemical entity in the Macrolides/Ketolides class, require PA until reviewed by the P&T Committee.	**Decision** **6 For** **0 Against**
15	**Glucagon-Like Peptide-1 (GLP-1) Receptor Agonists** • DMS to select preferred agent(s) based on economic evaluation; however, at least 2 unique chemical entities should be preferred. • Agents not selected as preferred will be considered non-preferred and will require PA. • For any new chemical entity in the Glucagon-Like Peptide-1 (GLP-1) Receptor Agonists class, require PA until reviewed by the P&T Committee.	**Decision** **0 For** **6 Against** **Committee motioned to reject recommendation**
16	**Immunosuppressives, Oral** • DMS to select preferred agent(s) based on economic evaluation; however, at least 2 unique chemical entities should be preferred. • Agents not selected as preferred will be considered non-preferred and will require PA. • For any new chemical entity in the Immunosuppressives, Oral class, require PA until reviewed by the P&T Committee.	**Decision** **6 For** **0 Against**

CONSENT AGENDA

For the following therapeutic classes, the P&T Committee had no recommended changes to the currently posted Preferred Drug List (PDL) status.

	THERAPEUTIC CLASSES	P&T VOTE
17	• Antiretrovirals, HIV/AIDS • Antibiotics, Gastrointestinal • Antibiotics, Inhaled • Antibiotics, Vaginal • Antifungals, Oral • Antihistamines, Minimally Sedating • Cephalosporins and Related Antibiotics • Epinephrine, Self-Injectable • Hepatitis B Agents • Hepatitis C Agents • Leukotriene Modifiers • Oral Antivirals, COVID-19 • Oral Antivirals, Herpes • Oral Antivirals, Influenza • Oxazolidinones • Penicillins • Quinolones • Chronic Obstructive Pulmonary Disease (COPD) Agents • Sulfonamides, Folate Antagonist • Tetracyclines	Decision 6 For 0 Against