Kentucky Department for Medicaid Services Pharmacy and Therapeutics Advisory Committee Recommendations

The following tables provide a summary of the official recommendations made by the Pharmacy and Therapeutics (P&T) Advisory Committee at the **July 9, 2024** 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: Opsynvi®**
	
	Pulmonary Arterial Hypertension (PAH) Agents, Oral And Inhaled: Non-Preferred (NPD)
	
	Approval Duration: 1 year
	
	• *Macitentan inhibits the binding of endothelin (ET)-1 to ETA and ETB receptors to lessen vasoconstriction, fibrosis, proliferation, hypertrophy, and inflammation. Tadalafil inhibits phosphodiesterase type 5 (PDE5), increasing the concentration of cyclic guanosine monophosphate (cGMP) to relax pulmonary vascular smooth muscle cells and vasodilate the pulmonary vascular bed.*
	
	Initial Approval Criteria:
	
	• Diagnosis of pulmonary arterial hypertension (PAH) World Health Organization (WHO) Group 1; **AND**
	• Patient is WHO functional class (FC) 2 or 3; **AND**
	• Prescribed by, or in consultation with, a cardiologist, pulmonologist, or other specialist in the treatment of pulmonary arterial hypertension (PAH); **AND**
	• Patient has had at least a 30-day trial and failure, allergy, or contraindication (including potential drug-drug interactions with other medications) or intolerance of the following agents:
	  o ambrisentan; **AND**
	  o sildenafil or tadalafil; **AND**
	• Patient meets the minimum age recommended by the package insert for use in PAH; **AND**
	• Patient will not be using with other phosphodiesterase-5 inhibitors, e.g., sildenafil, tadalafil.
	
	Renewal Criteria:
	
	• Prescriber attestation of clinically significant improvement or stabilization in clinical signs and symptoms.
	
	Quantity Limit: 1 tablet per day
		Decision
		7 For
		0 Against

	Description of Recommendation	P&T Vote
2	**New Product to Market: Winrevair™** **Non-PDL** **Approval Duration: 1 year** • *Sotatercept-csrk is an activin signaling inhibitor that helps balance proliferative signaling to regulate vascular cell proliferation that leads to pulmonary arterial hypertension.* **Initial Approval Criteria:** • Diagnosis of pulmonary arterial hypertension (PAH) World Health Organization (WHO) Group 1; **AND** • Prescribed by, or in consultation with, a cardiologist, pulmonologist, or other specialist in the treatment of PAH; **AND** • Patient has had at least a 30-day trial and failure, allergy, or contraindication (including potential drug-drug interactions with other medications) or intolerance of the following agents: o Adempas; **AND** o ambrisentan; **AND** o sildenafil or tadalafil; **AND** • Patient meets the minimum age recommended by the package insert for use in PAH; **AND** • Prescriber attests that the patient's hemoglobin and platelet will be monitored. **Renewal Criteria:** • Prescriber attestation of clinically significant improvement or stabilization in clinical signs and symptoms.	***Decision*** ***7 For*** ***0 Against***
3	**New Product to Market: Voydeya™** **Non-PDL** **Approval Duration: 3 months initial, 6 months renewal** • *Danicopan selectively inhibits Factor D, a protein that is key to amplifying the complement system response. Danicopan helps control C3 fragment-mediated extravascular hemolysis.* **Initial Approval Criteria:** • Diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) with extravascular hemolysis (EVH); **AND**	***Decision*** ***7 For*** ***0 Against***

	Description of Recommendation	P&T Vote
	• Prescribed by, or in consultation with, a hematologist or other specialist in the treatment of PNH with EVH; **AND** • Patient meets the minimum age recommended by the package insert for use in PNH with EVH; **AND** • Patient will be using as add-on therapy to ravulizumab (Ultomiris) or eculizumab (Soliris). **Renewal Criteria:** • Prescriber attestation of clinically significant improvement or stabilization in clinical signs and symptoms, such as increase in hemoglobin levels. **Quantity Limit:** 50 mg tablet: 9 tablets per day 100 mg tablet: 6 tablets per day	
4	**New Product to Market: Rivfloza™** **Non-PDL** **Approval Duration: 6 months initial, 1 year renewal** • *Nedosiran is an LDHA-directed small interfering RNA indicated to lower urinary oxalate levels in children 9 years of age and older and adults with primary hyperoxaluria type 1 (PH1) and relatively preserved kidney function.* **Initial Approval Criteria:** • Patient has a diagnosis of primary hyperoxaluria type 1 (PH1); **AND** • Prescribed by, or in consultation with, a nephrologist, urologist, or other applicable specialist in the diagnosis and treatment of primary hyperoxaluria type 1 (PH1); **AND** • Patient does not have severe renal impairment (eGFR < 30 mL/min/1.73 m^2); **AND** • Patient does not have moderate or severe hepatic impairment; **AND** • Patient will not use nedosiran concomitantly with lumasiran (Oxlumo). **Renewal Criteria:** • Documentation (e.g., progress notes, labs) of reduction or stabilization in serum oxalate levels; **AND** • Patient does not have severe renal impairment (eGFR < 30 mL/min/1.73 m^2); **AND** • Patient does not have moderate or severe hepatic impairment; **AND** • Patient will not use nedosiran concomitantly with lumasiran (Oxlumo). **Age Limit:** ≥ 9 years of age	***Decision*** ***7 For*** ***0 Against***

	Description of Recommendation	P&T Vote
	Quantity Limit: 1 syringe per month	
5	**New Product to Market: Zymfentra™** **Cytokine and CAM Antagonists: Non-Preferred (NPD)** **Approval Duration: 6 months initial, 1 year renewal** • *Infliximab-dyyb is a monoclonal antibody with specific activity for human tumor necrosis factor-alpha (TNF-alpha). Infliximab-dyyb binds with high affinity to TNF-alpha receptors and neutralizes TNF-alpha activity.* **Initial Approval Criteria:** • Diagnosis of moderate to severe Crohn's disease (CD) or ulcerative colitis (UC); **AND** • Patient has undergone induction therapy with intravenous infliximab; **AND** • Prescribed by, or in consultation with, a gastroenterologist or other specialist in the treatment of CD or UC; **AND** • Patient has had a trial and failure of ≥ 1 of the following conventional therapies: o Oral/rectal 5-aminosalicylic acid agents (e.g., Apriso, balsalazide, Lialda, mesalamine, sulfasalazine) o Oral/rectal steroids (e.g., budesonide, hydrocortisone, prednisone) o Immunosuppressant (e.g., azathioprine, mercaptopurine); **OR** • Patient is deemed high-risk for intestinal complications or post-operative recurrence; **AND** • NOT used in combination with any other biologic agent; **AND** • Patient has had a 3-month trial and failure of, or contraindication or intolerance to, ≥ 1 preferred cytokine or CAM antagonist indicated for the treatment of UC; **AND** • Patient meets the minimum age recommended by the package insert for use in CD or UC. **Renewal Criteria:** • Documentation (e.g., progress notes) of response to therapy compared to baseline. **Quantity Limit:** 2 syringes per month	***Decision 7 For 0 Against***
6	**New Product to Market: Filsuvez®** **Non-PDL**	***Decision 7 For 0 Against***

	Description of Recommendation	P&T Vote
	Approval Duration: 90 days initial, 1 year renewal • *Birch triterpenes topical gel is indicated for the treatment of wounds associated with dystrophic and junctional epidermolysis bullosa. The mechanism of action of this agent is not known.* **Initial Approval Criteria:** • Patient has a diagnosis of dystrophic or junctional epidermolysis bullosa; **AND** • Prescribed by, or in consultation with, a dermatologist or other specialist in the treatment of epidermolysis bullosa; **AND** • Patient has partial thickness wounds (does not extend beyond the dermis layer) which are clean with adequate granulation tissue, excellent vascularization, and do not appear infected; **AND** • Patient's wound has persisted for at least 3 weeks; **AND** • Patient wound size is at least 10 cm; **AND** • Patient is receiving standard-of-care wound therapy; **AND** • Patient has not received or is being considered for other gene therapy, stem cell transplant, or investigational cellular therapy; **AND** • Patient has not received immunosuppressive therapy or cytotoxic chemotherapy within the past 60 days; **AND** • Patient meets the minimum age recommended by the package insert for use in dystrophic or junctional epidermolysis bullosa. **Renewal Criteria:** • Clinical documentation showing improvement and no treatment-limiting adverse effects; **AND** • Patient must have disease response as defined by improvement (healing) of treated wound(s), reduction in skin infections, etc.; **AND** • Patient requires continued treatment for new and/or existing open wounds. **Age Limit:** ≥ 6 months of age	
7	**New Product to Market: Eohilia™** **Non-PDL** **Approval Duration: 12 weeks** • *Eohilia is a corticosteroid indicated for 12 weeks of treatment in adult and pediatric patients 11 years of age and older with eosinophilic esophagitis (EoE). The precise mechanism of corticosteroid actions on inflammation in EoE is unknown. Inflammation is an important component in the pathogenesis of EoE. Corticosteroids have a wide*	***Decision*** ***7 For*** ***0 Against***

	Description of Recommendation	P&T Vote
	range of inhibitory activities against multiple cell types and mediators involved in allergic inflammation. **Initial Approval Criteria:** • Diagnosis of eosinophilic esophagitis; **AND** • Prescribed by, or in consultation with, an allergist, immunologist, gastroenterologist, or other specialist in the treatment of eosinophilic esophagitis. **Renewal Criteria:** • Patient previously had a positive response to Eohilia; **AND** • Patient has a histologic relapse after the prior remission. **Age Limit:** 11 years or older **Quantity Limit:** 20 mL per day for 12 weeks	
8	**New Product to Market: Alvaiz™** **Thrombopoiesis Stimulating Proteins: Non-Preferred (NPD)** **Approval Duration: 6 months** • *Eltrombopag is a TPO-receptor agonist that interacts with the transmembrane domain of the human TPO-receptor (a.k.a cMpl) and initiates signaling cascades that induce proliferation and differentiation of megakaryocytes leading to increased platelet production.* **Initial Approval Criteria:** • Prescribed by, or in consultation with, a hematologist or liver disease specialist; **AND** • Patient has one of the following indications: o Diagnosis of persistent or chronic immune thrombocytopenia (ITP) with an insufficient response to corticosteroids, immunoglobulins, or splenectomy; **OR** o Used for the treatment of thrombocytopenia in patients with chronic hepatitis C (to allow the initiation and maintenance of interferon-based therapy); **OR** o Diagnosis of severe aplastic anemia with an insufficient response to immunosuppressive therapy; **AND** • Patient meets the minimum age recommended by the package insert for respective indications. **Renewal Criteria:** • Documentation (e.g., progress note, laboratory report) of response to therapy.	***Decision*** ***7 For*** ***0 Against***

	Description of Recommendation	P&T Vote
	Age Limit: 6 years or older **Quantity Limit:** 9 mg: 1 per day 18 mg: 1 per day 36 mg: 3 per day 54 mg: 2 per day	
9	**New Product to Market: Rezdiffra™** **Non-PDL** **Approval Duration: 1 year** • *Resmetirom is a partial agonist of the thyroid hormone receptor-beta (THR-β). THR-β is the major form of THR in the liver, and stimulation of THR-β in the liver reduces intrahepatic triglycerides.* **Initial Approval Criteria:** • Diagnosis of noncirrhotic nonalcoholic steatohepatitis (NASH) with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis); **AND** • Prescribed by, or in consultation with, a gastroenterologist or hepatologist; **AND** • Prescriber attests that member does not have excessive alcohol consumption. **Renewal Criteria:** • Documentation (e.g., progress note, laboratory report) of response to therapy and no treatment-limiting adverse effects. **Quantity Limit:** 1 tablet per day	***Decision*** ***7 For*** ***0 Against***
10	**Angiotensin-Converting Enzyme (ACE) Inhibitors + Diuretic Combinations** • 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 Angiotensin-Converting Enzyme (ACE) Inhibitors + Diuretic Combinations class, require PA until reviewed by the P&T Committee.	***Decision*** ***7 For*** ***0 Against***
11	**Angiotensin Modulator + Calcium Channel Blocker Combinations** • 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.	***Decision*** ***7 For*** ***0 Against***

	Description of Recommendation	P&T Vote
	• For any new chemical entity in the Angiotensin Modulator + Calcium Channel Blocker Combinations class, require PA until reviewed by the P&T Committee.	
12	**Antiarrhythmics, 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 Antiarrhythmics, Oral class, require PA until reviewed by the P&T Committee.	***Decision 7 For 0 Against***
13	**Antidepressants, SNRIs** • 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 Antidepressants, SNRIs class, require PA until reviewed by the P&T Committee.	***Decision 7 For 0 Against***
14	**Antidepressants, SSRIs** • 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 Antidepressants, SSRIs class, require PA until reviewed by the P&T Committee.	***Decision 7 For 0 Against***
15	**Beta Blockers** • 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 Beta-Blockers class, require PA until reviewed by the P&T Committee.	***Decision 7 For 0 Against***
16	**Calcium Channel Blockers** • 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 Calcium Channel Blockers class, require PA until reviewed by the P&T Committee.	***Decision 7 For 0 Against***
17	**Narcolepsy Agents** • DMS to select preferred agent(s) based on economic evaluation; however, at least 2 unique chemical entities should be preferred.	***Decision 7 For 0 Against***

	Description of Recommendation	P&T Vote
	• Agents not selected as preferred will be considered non-preferred and will require PA. • For any new chemical entity in the Narcolepsy Agents class, require PA until reviewed by the P&T Committee.	
18	**Pulmonary Arterial Hypertension (PAH) Agents, Oral and 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 Pulmonary Arterial Hypertension (PAH) Agents, Oral and Inhaled class, require PA until reviewed by the P&T Committee.	***Decision*** ***7 For*** ***0 Against***
19	**Sedative Hypnotics** • 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 Sedative Hypnotics class, require PA until reviewed by the P&T Committee.	***Decision*** ***7 For*** ***0 Against***
20	**Stimulants and Related 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 Stimulants and Related Agents class, require PA until reviewed by the P&T Committee.	***Decision*** ***7 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
21	• Angiotensin-Converting Enzyme (ACE) Inhibitors • Angiotensin Receptor Blockers (ARBs) • Antianginal & Anti-Ischemic • Anticoagulants • ARB + Diuretic Combinations • Direct Renin Inhibitors • Lipotropics, Other • Lipotropics, Statins • Platelet Aggregation Inhibitors • Alzheimer's Agents • Anticonvulsants • Antidepressants, Monoamine Oxidase Inhibitors (MAOIs) • Antidepressants, Other • Antidepressants, Tricyclics • Antiparkinson's Agents • Dopamine Receptor Agonists • Antipsychotics • Anxiolytics • Movement Disorders • Tobacco Cessation Products • 5-Alpha Reductase Inhibitors • Alpha Blockers for Benign Prostatic Hyperplasia (BPH) • Bladder Relaxants	***Decision*** ***7 For*** ***0 Against***