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 **October 17, 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: Tryvio™**
	
	Non-PDL
	
	Approval Duration: 6 months initial, 1 year renewal
	
	• *Aprocitentan inhibits the binding of endothelin (ET)-1 to ETA and ETB receptors to lessen vasoconstriction, fibrosis, proliferation, and inflammation.*
	
	Initial Approval Criteria:
	• Diagnosis of treatment resistant hypertension defined as:
	  ○ Persistent blood pressure above 140/90 mmHg; **AND**
	  ○ Patient has failed optimal dosing of at least three antihypertensive medications concurrently from different classes for a minimum of 4 weeks; **AND**
	  ○ One of the tried and failed medications is diuretic; **AND**
	• Prescribed by, or in consultation with, a cardiologist, or other disease state specialist; **AND**
	• Prescriber attests that other reasons for uncontrolled hypertension (e.g., non-compliance, white coat syndrome, etc.) have been ruled out; **AND**
	• Prescriber attests that serum aminotransferase levels and total bilirubin were measured prior to initiation and will be repeated periodically during treatment; **AND**
	• Will be used in combination with at least three other antihypertensive drugs at maximally tolerated doses; **AND**
	• Patient meets the minimum age recommended by the package insert for use in treatment resistant hypertension.
	
	Renewal Criteria:
	• Prescriber attestation of clinically significant improvement or stabilization in clinical signs and symptoms; **AND**
	• Used in combination with at least three other antihypertensive drugs at maximally tolerated doses.
	
	Quantity Limit: 1 tablet per day
		Decision
		6 For
		0 Against

	Description of Recommendation	P&T Vote

2	**New Product to Market: Iqirvo®**
	
	Gastrointestinal, Bile Salts: Non-Preferred
	
	Approval Duration: 1 year
	
	• *Elafibranor is a peroxisome proliferator-activated receptor (PPAR) agonist, which activates PPAR-alpha, PPAR-gamma, and PPAR-delta in vitro. The specific mechanism of action is not known, but elafibranor is thought to work by inhibiting bile acid synthesis by activating PPAR-alpha and delta.*
	
	Initial Approval Criteria:
	• Diagnosis of primary biliary cholangitis (PBC); **AND**
	• Prescribed by, or in consultation with, a gastroenterologist, hepatologist, or other disease state specialist; **AND**
	• Patient meets one of the following:
	  ○ Patient has had a 12-month trial and failure of ursodiol, and will take Iqirvo in addition to current therapy; **OR**
	  ○ Patient has a contraindication or intolerance to ursodiol and will take Iqirvo as monotherapy; **AND**
	• Patient has an alkaline phosphatase (ALP) level greater than 200 IU/L; **AND**
	• Patient does not have decompensated cirrhosis; **AND**
	• Patient meets the minimum age recommended by the package insert.
	
	Renewal Criteria:
	• Documentation (e.g., progress notes, labs) of improvement or stabilization in alkaline phosphatase (ALP); **AND**
	• Patient meets one of the following:
	  ○ Patient has had a 12-month trial and failure of ursodiol, and will take Iqirvo in addition to current therapy; **OR**
	  ○ Patient has a contraindication or intolerance to ursodiol and will take Iqirvo as monotherapy.
	
	Quantity Limit: 1 tablet per day
		Decision
		6 For
		0 Against

3	**New Product to Market: Xolremdi™** **Non-PDL** **Approval Duration: 1 year** • *Mavorixafor is a chemokine receptor 4 (CXCR4) antagonist that blocks the binding of the CXCR4 ligand, stromal-derived factor-1 (alpha) (SDF-1 alpha)/CXC Chemokine Ligand 12 (CXCL 12). Mavorixafor inhibits the response to CXCL 12 in both wild-type and mutated CXCR4 variants associated with WHIM syndrome. Treatment with*	***Decision*** ***6 For*** ***0 Against***

	Description of Recommendation	P&T Vote
	mavorixafor results in increased mobilization of neutrophils and lymphocytes from the bone marrow into peripheral circulation. **Initial Approval Criteria:** • Diagnosis of WHIM (Warts, Hypogammaglobulinemia, Infections, and Myelokathexis) syndrome; **AND** • Diagnosis has been confirmed through genetic testing and identification of CXCR4 gene mutation; **AND** • Prescribed by, or in consultation with, a hematologist, immunologist, infectious disease specialist, or other specialist; **AND** • Patient meets the minimum age recommended by the package insert. **Renewal Criteria:** • Clinically significant improvement or stabilization in signs and symptoms **Age Limit:** 12 years of age or older **Quantity Limit:** 4 capsules per day	
4	**New Product to Market: Vafseo®** **Erythropoiesis Stimulating Proteins: Non-Preferred (NPD)** **Approval Duration: 6 months** • *Vadadustat works by increasing transcription of the HIF-responsive genes, including erythropoietin.* **Initial Approval Criteria:** • Diagnosis of chronic kidney disease (N18.9); **AND** • Pretreatment hemoglobin level ≤ 11g/dl; **AND** • Patient has been receiving dialysis for at least 3 months; **AND** • Patient does not have uncontrolled hypertension; **AND** • Patient is not receiving treatment with any other erythropoiesis stimulating agents; **AND** • Patient meets the minimum age recommended by the package insert. **Renewal Criteria:** • Documentation (e.g., progress note, laboratory report) of a positive response to therapy. **Quantity Limit:** 150 mg four tablets daily 300 mg two tablets daily	***Decision*** ***6 For*** ***0 Against***
5	**New Product to Market: Ohtuvayre™** **Respiratory, Chronic Obstructive Pulmonary Disease (COPD) Agents: Non-Preferred (NPD)**	***Decision*** ***6 For*** ***0 Against***

	Description of Recommendation	P&T Vote

	Approval Duration: 6 months initial, 1 year renewal
	
	• *Ensifentrine is a first-in-class dual phosphodiesterase (PDE) -3 and -4 inhibitor. Inhibition of PDE-4 suppresses the release of inflammatory signals, decreasing cAMP and promoting bronchial relaxation. PDE-3 regulates airway smooth muscle, influencing bronchial tone. By inhibiting both PDE-3 and -4, ensifentrine relaxes airway smooth muscle and reduces inflammation.*
	
	Initial Approval Criteria:
	• Diagnosis of moderate to severe chronic obstructive pulmonary disorder (COPD); **AND**
	• Trial and failure of at least a 2-week trial of standard care of therapy:
	  ○ Triple-ingredient therapy (inhaled corticosteroid [ICS], long-acting beta agonist [LABA], and long-acting muscarinic antagonist [LAMA]); **OR**
	  ○ Dual-ingredient therapy (long-acting beta agonist [LABA]/ long-acting muscarinic antagonist [LAMA]); **AND**
	• Patient meets the minimum age recommended by the package insert.
	
	Renewal Criteria:
	• Clinically significant improvement or stabilization in signs and symptoms
	
	Age Limit: 18 years of age or older
	Quantity Limit: 5 mL per day	

6	**Muscular Dystrophy Agents** • DMS to create a new drug class and 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 Muscular Dystrophy Agents class, require PA until reviewed by the P&T Committee.	***Decision*** ***6 For*** ***0 Against***
7	**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*** ***6 For*** ***0 Against***
8	**Antimigraine Agents, CGRP Inhibitors** • DMS to select preferred agent(s) based on economic evaluation; however, at least 2 unique chemical entities should be preferred.	***Decision*** ***6 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 Antimigraine Agents, CGRP Inhibitors class, require PA until reviewed by the P&T Committee.	
9	**Colony Stimulating Factors** • 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 Colony Stimulating Factors class, require PA until reviewed by the P&T Committee.	***Decision 6 For 0 Against***
10	**Growth Hormones** • 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 Growth Hormones class, require PA until reviewed by the P&T Committee.	***Decision 6 For 0 Against***
11	**Acne Agents, 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 Acne Agents, Oral class, require PA until reviewed by the P&T Committee.	***Decision 6 For 0 Against***
12	**Acne Agents, Topical** • 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 Acne Agents, Topical class, require PA until reviewed by the P&T Committee.	***Decision 6 For 0 Against***
13	**Antifungals, Topical** • 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 Antifungals, Topical class, require PA until reviewed by the P&T Committee.	***Decision 6 For 0 Against***
14	**Antipsoriatics, Topical** • DMS to select preferred agent(s) based on economic evaluation; however, at least 2 unique chemical entities should be preferred.	***Decision 6 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 Antipsoriatics, Topical class, require PA until reviewed by the P&T Committee.	
15	**Cytokine and CAM Antagonists** • 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 Cytokine and CAM Antagonists class, require PA until reviewed by the P&T Committee.	***Decision 6 For 0 Against***
16	**Gastrointestinal Motility, Chronic** • 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 Gastrointestinal Motility, Chronic class, require PA until reviewed by the P&T Committee.	***Decision 6 For 0 Against***
17	**Immunological and Genetic Immunomodulators, Atopic Dermatitis** • 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 Immunological and Genetic Immunomodulators, Atopic Dermatitis class, require PA until reviewed by the P&T Committee.	***Decision 6 For 0 Against***
18	**Multiple Sclerosis 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 Multiple Sclerosis Agents class, require PA until reviewed by the P&T Committee.	***Decision 6 For 0 Against***
19	**Ophthalmics, Antihistamines** • 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 Ophthalmics, Antihistamines class, require PA until reviewed by the P&T Committee.	***Decision 6 For 0 Against***

	Description of Recommendation	P&T Vote
20	**Ophthalmics, Anti-Inflammatory Steroids** • 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 Ophthalmics, Anti-Inflammatory Steroids class, require PA until reviewed by the P&T Committee.	***Decision*** ***6 For*** ***0 Against***
21	**Ophthalmics, 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 Ophthalmics, Beta Blockers class, require PA until reviewed by the P&T Committee.	***Decision*** ***6 For*** ***0 Against***
22	**Otics, Anesthetics and Anti-Inflammatories** • 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 Otics, Anesthetics and Anti-Inflammatories class, require PA until reviewed by the P&T Committee.	***Decision*** ***5 For*** ***1 Against***
23	**Steroids, Topical** • 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 Steroids, Topical 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
24	• Antiemetics & Antivertigo Agents • Anti-Ulcer Protectants • Antibiotics, Topical • Anticholinergics and Antispasmodics • Antidiarrheals • Antiparasitics, Topical • Antipsoriatics, Oral • Antivirals, Topical • Bile Salts • H. Pylori Treatment • Histamine II Receptor Blockers • Immunomodulators, Asthma • Immunosuppressives, Oral • Laxatives and Cathartics • Ophthalmics, Mast Cell Stabilizers • Ophthalmics, Antibiotic-Steroid Combinations • Ophthalmics, Antibiotics • Ophthalmics, Antivirals • Ophthalmics, Carbonic Anhydrase Inhibitors • Ophthalmics, Combinations for Glaucoma • Ophthalmics, Glaucoma Agents (Other) • Ophthalmics, Immunomodulators • Ophthalmics, Mydriatic • Ophthalmics, NSAIDs • Ophthalmics, Prostaglandin Agonists • Ophthalmics, Sympathomimetics • Otics, Antibiotics • Proton Pump Inhibitors • Rosacea Agents, Topical • Spinal Muscular Atrophy • Ulcerative Colitis Agents	***Decision*** ***6 For*** ***0 Against***