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 **April 18, 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: Voquezna®** **Proton Pump Inhibitors: Non-Preferred (NPD)** **Approval Duration: *8 weeks initial approval, 6 months for renewal*** • *Vonoprazan works by suppressing basal and stimulated gastric acid secretion at the secretory surface of the gastric parietal cell through inhibition of the H^+, K^+-ATPase enzyme system in a potassium competitive manner.* **Initial Approval Criteria:** • Diagnosis of diagnostically confirmed erosive esophagitis; **AND** • Prescribed by, or in consultation with, a gastroenterologist or other specialist in the diagnosis and treatment of erosive esophagitis; **AND** • Patient has had a ≥ 2-week trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications) or intolerance to 2 preferred agents in this PDL class. **Renewal Criteria:** • Diagnosis of diagnostically confirmed erosive esophagitis; **AND** • Prescribed by, or in consultation with, a gastroenterologist or other specialist in the diagnosis and treatment of erosive esophagitis; **AND** • Patient has experienced symptom improvement or control during initial treatment course. **Age Limit:** ≥ 18 years of age **Quantity Limit:** 1 tablet per day	***Decision*** ***9 For*** ***0 Against***
2	**New Product to Market:** **Voquezna Dual Pak® (vonoprazan/amoxicillin)** **Voquezna Triple Pak® (vonoprazan/amoxicillin/clarithromycin)** **H. Pylori Treatment: Non-Preferred (NPD)** **Approval Duration: *30 days*** • *Vonoprazan works by suppressing basal and stimulated gastric acid secretion at the secretory surface of the gastric parietal cell through inhibition of the H^+, K^+-ATPase enzyme system in a potassium competitive manner. Amoxicillin and clarithromycin are antimicrobial agents that work by various mechanisms to treat bacterial infections.*	***Decision*** ***9 For*** ***0 Against***

	Description of Recommendation	P&T Vote
	Approval Criteria: • Diagnosis of diagnostically confirmed *H. pylori* infection; **AND** • Prescribed by, or in consultation with, a gastroenterologist or other specialist in the diagnosis and treatment of *H. pylori*; **AND** • Patient has had a ≥ 2-week trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications) or intolerance to Pylera. **Age Limit:** ≥ 18 years of age **Quantity Limit:** Voquezna Dual Pak: 1 carton of 28 tablets and 84 capsules per 14-day supply Voquezna Triple Pak: 1 carton of 56 tablets and 56 capsules per 14-day supply.	

3	**New Product to Market: Fabhalta®**
	
	Non-PDL
	
	Approval Duration: ***4 months for initial, 1 year for renewal***
	
	• *Iptacopan inhibits Factor B, which acts proximally in the alternative pathway of the complement cascade to control C3B-mediated intravascular and extravascular hemolysis.*
	
	Initial Approval Criteria:
	• Diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) confirmed by flow cytometry results demonstrating both of the following:
	  ○ The absence or deficiency of glycosylphosphatidylinositol (GPI)-anchored proteins (e.g., CD55, CD59) on at least two cell lineages; **AND**
	  ○ PNH granulocyte clone size ≥ 10%; **AND**
	• Prescribed by, or in consultation with, a hematologist or other appropriate specialist in the treatment of paroxysmal nocturnal hemoglobinuria (PNH); **AND**
	• Patient will not be using a C5 complement inhibitor (e.g., Soliris, Ultomiris) or a C3 complement inhibitor (e.g., Empaveli) while taking Fabhalta.
	
	Renewal Criteria:
	• Physician attestation of clinical benefit, such as reduction in number of blood transfusions needed, improvement or stabilization of hemoglobin levels, reduction in hemolysis.
	
	Age Limit: ≥ 18 years of age
	Quantity Limit: 2 capsules per day
		Decision
		9 For
		0 Against

	Description of Recommendation	P&T Vote
4	**New Product to Market: Jesduvroq®** **Erythropoiesis Stimulating Proteins: Non-Preferred (NPD)** **Approval Duration: *6 months*** • *Jesduvroq 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 4 months; **AND** • Patient is not receiving treatment with any other erythropoiesis stimulating agents. **Renewal Criteria:** • Documentation (e.g., progress note, laboratory report) demonstrating a positive response to therapy. **Quantity Limit:** 1mg one daily 2mg one daily 4mg one daily 6mg two daily 8mg three daily	***Decision*** ***9 For*** ***0 Against***

5	**New Product to Market: Wainua™**
	
	Non-PDL
	
	Approval Duration: *1 year*
	
	• *Eplontersen is a ligand-conjugated antisense oligonucleotide that degrades transthyretin (TTR) mRNA, thereby decreasing TTR protein and thus amyloid deposits in the liver.*
	
	Initial Approval Criteria:
	• Patient has a definitive diagnosis of hereditary transthyretin-mediated (hATTR) amyloidosis/FAP (familial amyloidotic polyneuropathy) as documented by:
	  ○ Amyloid deposition on tissue biopsy; **OR**
	  ○ Identification of a pathogenic TTR variant using molecular genetic testing; **AND**
	• Patient has polyneuropathy attributed to hATTR/FAP; **AND**
	• Patient has NOT received an orthotopic liver transplant (OLT); **AND**
	• Patient will not be using Wainua in combination with other TTR-reducing agents (e.g., inotersen [Tegsedi], patisiran [Onpattro], tafamidis [Vyndamax, Vyndaqel], vutrisiran [Amvuttra]).
		Decision
		9 For
		0 Against

	Description of Recommendation	P&T Vote
	Renewal Criteria: • Prescriber attestation of clinically significant improvement or stabilization in clinical signs and symptoms, such as improvement in ambulation, neurologic symptoms, or activities of daily living. **Age Limit:** ≥ 18 years of age **Quantity Limit:** 1 auto-injector per 28 days	

6	**New Product to Market: Agamree®**
	
	Steroids, Oral: Non-preferred (NPD)
	
	Approval Duration: ***1 year***
	
	• *Vamorolone is a corticosteroid that acts through the glucocorticoid receptor to exert anti-inflammatory and immunosuppressive effects. The precise mechanism by which vamorolone exerts its effect in patients with Duchenne Muscular Dystrophy is unknown.*
	
	Initial Approval Criteria:
	• Diagnosis of Duchenne Muscular Dystrophy (DMD); **AND**
	• Patient is currently receiving, or planning to receive, physical therapy; **AND**
	• Patient has tried prednisone or prednisolone for at least 6 months; **OR**
	• Patient has experienced 1 of the following adverse reactions directly attributable to previous therapy with prednisone or prednisolone:
	  ○ Significant behavioral changes negatively impacting function at school, home, day care, etc.; **OR**
	  ○ Significant weight gain (e.g., crossing 2 percentiles and/or reaching 98th percentile for age and sex).
	
	Renewal Criteria:
	• Patient continues to receive physical therapy; **AND**
	• Patient has received benefit from therapy (i.e. stability, improvement or slowing of decline) in one or more of the following areas of assessment:
	  ○ Motor function (North Star Ambulatory Assessment (NSAA)
	  ○ Cardiology
	  ○ Endocrinology
	  ○ Orthopedics (e.g., scoliosis)
	  ○ Pulmonary function.
	
	Age Limit: ≥ 2 years of age
	Quantity Limit: 7.5 mL per day
		Decision
		9 For
		0 Against

	Description of Recommendation	P&T Vote

7	**New Product to Market: Zilbrysq®**
	
	Non-PDL class
	
	Approval Duration: ***Initial 3 months; Renewal 1 year***
	
	• *Zilucoplan is a complement inhibitor indicated for the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive.*
	
	Initial Approval Criteria:
	• Diagnosis of generalized myasthenia gravis (MGFA Clinical Classification Class II to IV) with positive serologic test for anti-acetylcholine receptor (AChR) antibodies; **AND**
	• Member has a baseline MG-Activities of Daily Living (MG-ADL) total score ≥ 6; **AND**
	• Patient has tried and failed at least two immunosuppressive therapies (one corticosteroid and one non-steroid immunosuppressive therapy, e.g., azathioprine, cyclosporine, mycophenolate); **AND**
	• Patient does not have unresolved Neisseria meningitidis infection.
	
	Renewal Criteria:
	• For initial renewal: Patient has disease improvement as evidenced by:
	  ○ At least 2-point reduction in MG-ADL total score from baseline; **OR**
	  ○ Improvement in signs or symptoms that impact daily function; **OR**
	• For subsequent renewal after an initial beneficial response:
	  ○ Patient is stable on therapy; **OR**
	  ○ Patient requires continuous treatment due to new or worsening disease activity.
	
	Age Limit: ≥ 18 years
	Quantity Limit: 1 syringe per day
		Decision
		9 For
		0 Against

8	**Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)** • 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 Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) class, require PA until reviewed by the P&T Committee.	***Decision*** ***9 For*** ***0 Against***
9	**Antihyperuricemics** • 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 Antihyperuricemics class, require PA until reviewed by the P&T Committee.	***Decision*** ***9 For*** ***0 Against***

	Description of Recommendation	P&T Vote
10	**Erythropoiesis Stimulating Proteins** • 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 Erythropoiesis Stimulating Proteins class, require PA until reviewed by the P&T Committee.	***Decision*** ***9 For*** ***0 Against***
11	**Steroids, 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 Steroids, Oral class, require PA until reviewed by the P&T Committee.	***Decision*** ***9 For*** ***0 Against***
12	**Pancreatic Enzymes** • 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 Pancreatic Enzymes class, require PA until reviewed by the P&T Committee.	***Decision*** ***9 For*** ***0 Against***
13	**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*** ***9 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
14	• **Narcotics, Long Acting** • **Narcotics, Short Acting** • **Narcotic Agonist/Antagonists** • **Narcotics, Fentanyl Buccal Products** • **Antimigraine Agents, Triptans** • **Antimigraine Agents, CGRP Inhibitors** • **Neuropathic Pain** • **Opiate Dependence Treatments** • **Skeletal Muscle Relaxants**	***Decision*** ***9 For*** ***0 Against***

Therapeutic Classes	P&T Vote
• Phosphate Binders • Sickle Cell Anemia Treatments • Thrombopoiesis Stimulating Proteins • Alpha-Glucosidase Inhibitors • Dipeptidyl Peptidase-4 (DPP-4) Inhibitors • Glucagon-Like Peptide (GLP-1) Receptor Agonists • Insulin & Related Agents • Meglitinides • Metformins • Sodium-Glucose Cotransporter-2 (SGLT2) Inhibitors • Sulfonylureas • Thiazolidinediones (TZDs) • Androgenic Agents • Bone Resorption Suppression & Related Agents • Glucagon Agents • Growth Hormones • Progestins for Cachexia • Uterine Disorder Treatments	