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 15, 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:** Alyftrek™
	
	Non-PDL
	
	Approval Duration: 6 months
	
	• *Vanzacaftor and tezacaftor work additively to increase the amount of cystic fibrosis transmembrane conductance regulator (CFTR) protein on the cell surface. Deutivacaftor increases the channel open probability of the CFTR protein at the cell surface. The three agents increase CFTR activity.*
	
	Initial Approval Criteria:
	• Patient has a documented diagnosis of cystic fibrosis with:
	  ○ A genetic profile (e.g., gene mutation) that is considered responsive to the product based on clinical and/or in vitro data contained in the FDA labeling; **AND**
	  ○ Confirmed by an FDA-approved diagnostic test; **AND**
	• Patient meets the FDA-approved minimum age; **AND**
	• Documentation (e.g., progress notes) of baseline functional status and baseline predicted FEV1.
	
	Renewal Criteria:
	• Patient has had disease response, as indicated by one or more of the following:
	  ○ Decreased pulmonary exacerbations, as compared to pre-treatment baseline; **OR**
	  ○ Improvement or stabilization of lung function, compared to baseline; **OR**
	  ○ Decrease in decline of lung function; **OR**
	  ○ Improvement in quality of life, weight gain, or growth.
	
	Age Limit: 6 years of age or older
	
	Quantity Limit:
	• 50-20-4 mg tablets: 3 per day
	• 125-50-10 mg tablets: 2 per day
		Decision
		7 For
		0 Against

	Description of Recommendation	P&T Vote
2	**New Product to Market: Sofdra™** **Non-PDL** **Approval Duration: 6 months** • *Sofpironium competitively inhibits acetylcholine receptors on some peripheral tissues, including sweat glands. With receptor stimulation prevented, the rate of sweating decreases.* **Initial Approval Criteria:** • Patient has a diagnosis of primary axillary hyperhidrosis; **AND** • Prescriber attests hyperhidrosis is significantly interfering with activities of daily living; **AND** • Patient meets the FDA-approved minimum age. **Renewal Criteria:** • Prescriber attestation of clinically significant improvement in clinical signs and symptoms. **Age Limit:** 9 years of age or older **Quantity Limit:** 1 bottle per 30 days	***Decision*** ***7 For*** ***0 Against***
3	**New Product to Market: Ryzumvi™** **Non-PDL** **Approval Duration:** Single fill only • *Phentolamine is a relatively non-selective alpha-1 and alpha-2 adrenergic antagonist. Muscles involved in dilating the pupil are primarily activated by these receptors to directly reduce pupil diameter, therefore reversing the mydriasis induced by specific pharmacological agents.* **Approval Criteria:** • Patient has a diagnosis of pharmacologically-induced mydriasis produced by adrenergic agonists (e.g., phenylephrine) OR parasympatholytic (e.g., tropicamide) agents; **AND** • Prescriber attests product will be used within 24 hours of the procedure; **AND** • Prescribed by, or in consultation with, an ophthalmologist or other specialist in the treatment of pharmacologically-induced mydriasis	***Decision*** ***6 For*** ***0 Against***

	Description of Recommendation	P&T Vote
	Age Limit: 3 years of age or older **Quantity Limit:** 1 single-patient-use vial per fill	
4	**New Product to Market:** Crenessity™ **Non-PDL** **Approval Duration: 6 months initial, 1 year renewal** • *Crinecerfont is a selective corticotropin-releasing factor (CRF) type 1 receptor antagonist. Crinecerfont blocks the binding of CRF to CRF type 1 receptors in the pituitary but not CRF type 2 receptors. Crinecerfont binding to CRF type 1 receptors inhibits adrenocorticotropic hormone (ACTH) secretion from the pituitary, thereby reducing ACTH-mediated adrenal androgen production.* **Initial Approval Criteria:** • Patient has a diagnosis of classic congenital adrenal hyperplasia (CAH) defined by ≥ 1 of the following: o Elevated 17-hydroxyprogesterone (17-OHP) level; **OR** o Confirmed CYP21A2 genotype; **OR** o Positive newborn screening with confirmatory second-tier testing (e.g., liquid chromatography – tandem mass spectrometry); **OR** o Cosyntropin stimulation test; **AND** • Prescribed initially by, or in consultation with an endocrinologist; **AND** • Crenessity (crinecerfont) will be used as an adjunct therapy with chronic glucocorticoid therapy for CAH (e.g., hydrocortisone, prednisone, prednisolone, methylprednisolone, dexamethasone) at a minimum glucocorticoid dose required for cortisol replacement; **AND** • If prescribed concomitantly with a moderate or strong CYP3A4 inducer (e.g., phenytoin, carbamazepine, rifampin, rifabutin, rifapentine, phenobarbital, bosentan, efavirenz, etravirine, and primidone), dosages will be modified as recommended by the package insert; **AND** • Patient meets the minimum age recommended by the package insert for the provided indication. **Renewal Criteria:** • Patient must continue to meet initial approval criteria; **AND** • Patient must have disease improvement, as indicated by ≥ 1 of the following: o Reduction in glucocorticoid daily use; **OR** o Reduction in serum androstenedione (A4) levels.	***Decision*** ***6 For*** ***0 Against***

	Description of Recommendation	P&T Vote
	Age Limit: 4 years of age or older **Quantity Limit:** • 25 mg, 50 mg, and 100mg oral capsules: 2 per day • 50 mg/mL oral solution: 4 mL per day	
5	**New Product to Market: Journavx™** **Non-PDL** **Approval Duration: 3 months (Limit to 1 fill per approval)** • *Suzetrigine is a selective blocker of the NaV1.8 voltage-gated sodium channel. NaV1.8 is expressed in peripheral sensory neurons including dorsal root ganglion neurons, where its role is to transmit pain signals. By selectively inhibiting NaV1.8 channels, suzetrigine inhibits transmission of pain signals to the spinal cord and brain.* **Approval Criteria:** • Patient has a diagnosis of moderate to severe acute pain; **AND** • Journavx (suzetrigine) will be used for up to 14 days; **AND** • Prescriber attests that the member's pain is unable to be managed with an NSAID, acetaminophen, or other non-opioid analgesic; **AND** • Journavx (suzetrigine) is not being prescribed to treat chronic pain; **AND** • Journavx (suzetrigine) is not being prescribed to treat pain associated with migraine; **AND** • Patient does not have severe hepatic impairment (Child-Pugh Class C); **AND** • Patient has been counseled to avoid food or drink containing grapefruit during treatment with Journavx (suzetrigine); **AND** • Patient is not concurrently taking a strong CYP3A inhibitor; **AND** • Patient is not concurrently taking a moderate or strong CYP3A inducer; **AND** • Patients using hormonal contraceptives containing progestins other than levonorgestrel and norethindrone have been counseled regarding alternative or additional contraception, if appropriate, per product labeling; **AND** • Patient meets the minimum age recommended by the package insert for the provided indication. **Age Limit:** 18 years of age or older **Quantity Limit:** 30 tablets per 14 days	***Decision*** ***7 For*** ***0 Against***

	Description of Recommendation	P&T Vote
6	**New Product to Market: Tryngolza™** **Non-PDL** **Approval Duration: 1 year** • *Olezarsen is an APOC-III-directed antisense oligonucleotide (ASO) indicated as an adjunct to diet to reduce triglycerides in adults with familial chylomicronemia syndrome (FCS).* **Initial Approval Criteria:** • Diagnosis of familial chylomicronemia syndrome (FCS) confirmed by genetic mutations in one of the following: o LPL gene o APOA5 gene o GPIHBP1 gene o LMF1 gene o APOC2 gene; **AND** • Patient has a fasting triglyceride level greater than or equal to 880 mg/dL; **AND** • Patient will follow a low-fat diet of less than or equal to 20 grams of fat per day; **AND** • Prescribed by, or in consultation with, an endocrinologist, or other specialist in the treatment of familial chylomicronemia syndrome (FCS); **AND** • Patient meets the minimum age recommended by the package insert for the provided indication. **Renewal Criteria:** • Prescriber attestation of clinically significant improvement or stabilization in the patient's condition. **Age Limit:** 18 years of age or older **Quantity Limit:** 1 autoinjector per month	***Decision*** ***7 For*** ***0 Against***
7	**New Product to Market: Hympavzi™** **Non-PDL** **Approval Duration:** 1 year initial, renewal • *Hympavzi is a non-factor, monoclonal antibody targeting and blocking tissue factor pathway inhibitor (TFPI), an anti-clotting protein. It is the first non-factor therapy approved for both hemophilia A and B but limited to only those without inhibitors.*	***Decision*** ***7 For*** ***0 Against***

	Description of Recommendation	P&T Vote

	Initial Approval Criteria:
	• Prescribed for the prophylactic treatment in patients with one of the following:
	  ○ Hemophilia A without inhibitors to Factor 8 (FVIII); **OR**
	  ○ Hemophilia B without inhibitors to Factor 9 (FIX).
	• Documentation (e.g., an inhibitor lab result within the past year) demonstrating the absence of one of the following:
	  ○ Factor VIII inhibitors for hemophilia A; **OR**
	  ○ Factor IX inhibitors for hemophilia B; **AND**
	• Patient meets the minimum age recommended by the package insert for the provided indication.
	
	Renewal Criteria:
	• Prescriber attests patient has experienced clinical benefit compared to baseline.
	• Documentation (e.g., an inhibitor lab result within the past year) demonstrating the absence of one of the following:
	  ○ Factor VIII inhibitors for hemophilia A; **OR**
	  ○ Factor IX inhibitors for hemophilia B.
	
	Age Limit: 12 years of age or older
	
	Quantity Limit: 300 mg (2mL) per week	

8	**New Product to Market: Alhemo®**
	
	Non-PDL
	
	Approval Duration: 1 year initial, renewal
	
	• *Alhemo is a non-factor, monoclonal antibody targeting and blocking tissue factor pathway inhibitor (TFPI), an anti-clotting protein. Only TFPI antagonist for use in patients WITH inhibitors.*
	
	Initial Approval Criteria:
	• Prescribed for the prophylactic treatment in patients with one of the following:
	  ○ Hemophilia A with inhibitors to FVIII; **OR**
	  ○ Hemophilia B with inhibitors to FIX.
	• Documentation (e.g., an inhibitor lab result within the past year) demonstrating one of the following:
	  ○ Factor VIII inhibitor for hemophilia A; **OR**
	  ○ Factor IX inhibitor for hemophilia B; **AND**
	• Patient meets the minimum age recommended by the package insert for the provided indication.
		Decision
		7 For
		0 Against

	Description of Recommendation	P&T Vote

	Renewal Criteria:
	• Prescriber attests patient has experienced clinical benefit compared to baseline.
	• Documentation (e.g., an inhibitor lab result within the past year) demonstrating one of the following:
	  ○ Factor VIII inhibitor for hemophilia A; **OR**
	  ○ Factor IX inhibitor for hemophilia B
	
	Age Limit: 12 years of age or older	

9	**Narcotics, Long-Acting** • 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 Narcotics, Long-Acting class, require PA until reviewed by the P&T Committee.	***Decision*** ***7 For*** ***0 Against***
10	**Colony Stimulating Factors** • 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 Colony Stimulating Factors class, require PA until reviewed by the P&T Committee.	***Decision*** ***7 For*** ***0 Against***
11	**Erythropoiesis Stimulating Proteins** • DMS to select preferred agent(s) based on economic evaluation; however, at least 2 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*** ***7 For*** ***0 Against***
12	**Phosphate Binders** • 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 Phosphate Binders class, require PA until reviewed by the P&T Committee.	***Decision*** ***7 For*** ***0 Against***
13	**Insulins & 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.	***Decision*** ***7 For*** ***0 Against***

	Description of Recommendation	P&T Vote
	• For any new chemical entity in the Insulins & Related Agents class, require PA until reviewed by the P&T Committee.	
14	**Sodium Glucose Co-Transporter 2 (SGLT2) Inhibitors** • 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 Sodium Glucose Co-Transporter 2 (SGLT2) Inhibitors class, require PA until reviewed by the P&T Committee.	***Decision*** ***7 For*** ***0 Against***
15	**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*** ***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. However, the **Glucagon Agent** therapeutic class was removed from the consent agenda pursuant to committee recommended changes.

	Therapeutic Classes	P&T Vote
16	• **Narcotic Agonist/Antagonists** • **Narcotics, Fentanyl Buccal Products** • **Narcotics, Short-Acting** • **Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)** • **Opiate Dependence Treatments** • **Antihyperuricemics** • **Sickle Cell Anemia Treatments** • **Thrombopoiesis Stimulating Proteins** • **Alpha-Glucosidase Inhibitors** • **Dipeptidyl Peptidase-4 (DPP-4) Inhibitors** • **Glucagon-Like Peptide-1 (GLP-1) Receptor Agonists** • **Meglitinides** • **Metformins** • **Sulfonylureas** • **Thiazolidinediones (TZDs)** • **Androgenic Agents** • **Bone Resorption Suppression & Related Agents** • **Pancreatic Enzymes** • **Progestins for Cachexia** • **Steroids, Oral** • **Uterine Disorder Treatments**	***Decision*** ***7 For*** ***0 Against***