KENTUCKY DEPARTMENT FOR MEDICAID SERVICES DRUG REVIEW AND OPTIONS FOR CONSIDERATION

TEAM KENTUCKY
CABINET FOR HEALTH AND FAMILY SERVICES

The following tables list the agenda items as well as the Options for Consideration that are scheduled to be presented and reviewed at the **July 28, 2026** meeting of the Pharmacy and Therapeutics Advisory Committee.

SINGLE AGENT REVIEWS

Agent	Options for Consideration
New Product to Market **Yuviwel® (navepegritide)**	**Non-PDL** **Approval Duration:** 1 year initial, 1 year renewal • *Yuviwel (navepegritide) is a C-type natriuretic peptide (CNP) analog. It is indicated to increase linear growth in pediatric patients 2 years and older with achondroplasia with open epiphyses. It is a prodrug of CNP and works similarly to the body's natural hormone. After release, CNP binds to natriuretic peptide receptor-B (NPR-B) and increases cyclic guanosine monophosphate (cGMP), which helps reduce the overactivity of fibroblast growth factor receptor 3 (FGFR3). Achondroplasia is caused by an overactive FGFR3, which slows normal bone growth and leads to short stature and skeletal differences. By counteracting this pathway, CNP supports more normal cartilage cell growth and maturation, promoting improved bone growth in patients with achondroplasia.* **Initial Approval Criteria:** • Diagnosis of achondroplasia confirmed by genetic testing demonstrating a mutation in the fibroblast growth factor receptor type 3 (FGFR3) gene; **AND** • Prescribed by, or in consultation with, a pediatric endocrinologist, or other appropriate specialist in the treatment of this condition; **AND** • Documentation confirms open epiphyses; **AND** • Documentation of patient's baseline body weight, growth, and physical development; **AND** • Patient has not had limb lengthening surgery in the previous 18 months; **AND** • Patient does not plan to have limb-lengthening surgery while on Yuviwel. **Renewal Criteria:** • Prescribed by, or in consultation with, a pediatric endocrinologist, or other appropriate specialist in the treatment of this condition; **AND** • Documentation of improvements in annualized growth velocity and height compared to pre-treatment baseline; **AND** • Documentation confirms open epiphyses; **AND** • Patient has not had limb lengthening surgery in the previous 18 months; **AND** • Patient does not plan to have limb-lengthening surgery while on Yuviwel. **Age Limit**: 2-18 years of age **Quantity Limit**: • 1.3 mg vial: 4 vials per 28 days • 2.8 mg vial: 4 vials per 28 days • 5.5 mg vial: 8 vials per 28 days

Agent	Options for Consideration

New Product to Market
Icotyde™ (icotrokinra)
	Immunologic and Genetic – Cytokine and CAM Antagonists: Non-Preferred
	
	Approval Duration: 6 months initial, 1 year renewal
	
	• *Icotyde (icotrokinra) is a peptide that selectively binds to the IL-23 receptor (IL-23R) with a dissociation constant of 7 pM and antagonizes the binding of IL-23. IL-23 is a naturally occurring cytokine that is involved in inflammatory and immune responses. Icotrokinra inhibits the IL-23/IL-23R-dependent release of proinflammatory cytokines.*
	
	Initial Approval Criteria:
	• Diagnosis of moderate to severe plaque psoriasis; **AND**
	• Patient weighs ≥ 40 kg; **AND**
	• Patient is a candidate for systemic therapy or phototherapy; **AND**
	• Trial and failure (at least 3 months) of ≥ 1 conventional therapy:
	  ○ Disease-modifying anti-rheumatic drug (DMARD) such as methotrexate,
	  ○ Immunosuppressant (e.g., cyclosporine),
	  ○ Oral retinoid (e.g., acitretin); **AND**
	• Trial and failure of ≥ 2 preferred biologics indicated for plaque psoriasis; **AND**
	• NOT used in combination with any other biologic agent; **AND**
	• Screening for and absence of tuberculosis (TB) and other active infections prior to therapy initiation; **AND**
	• NOT administered concurrently with live vaccines; **AND**
	• Prescribed by, or in consultation with, a dermatologist, rheumatologist or other specialist in the treatment of psoriasis.
	
	Renewal Criteria:
	• Documentation (e.g., progress note) of response to therapy compared to baseline, such as redness, thickness, scaliness, amount of surface area involvement, and/or PASI score.
	
	Age Limit: ≥ 12 years of age
	
	Quantity Limit: 1 tablet per day

New Product to Market **Kygevvi® (doxecitine and doxribtimine)**	**Non-PDL** **Approval Duration:** 1 year initial, 1 year renewal • *Kygevvi (doxecitine and doxribtimine) is intended to incorporate the pyrimidine nucleosides, deoxycytidine and deoxythymidine, into skeletal muscle mitochondrial deoxyribonucleic acid (DNA). This action restores mitochondrial DNA copy number in TK2d mutant mice.* **Initial Approval Criteria:** • Documented clinical diagnosis of thymidine kinase 2 deficiency (TK2d) confirmed with genetic testing; **AND** • Age of symptom onset ≤ 12 years; **AND** • Documentation baseline of transaminase (e.g., alanine aminotransferase [ALT], aspartate aminotransferase [AST]) and total bilirubin; **AND**

Agent	Options for Consideration
	• Clinical documentation to verify the member's weight within the past 6 months; **AND** • Weight based dosing should not exceed 800 mg/kg/day for the maintenance phase (400 mg doxecitine and 400 mg doxribtimine); **AND** • Prescribed by, or in consultation with, a pulmonologist, neurologist, geneticist, or specialist experienced in the management of metabolic or neuromuscular disorders. **Renewal Criteria:** • Clinical documentation demonstrating improvement and/or stabilization in motor function, respiratory status, or disease progression; **AND** • Clinical documentation to verify the member's weight within the past 6 months. **Age Limit:** N/A **Quantity Limit:** 16 packets per day

New Product to Market
Nereus™ (tradipitant)
	Gastrointestinal – Antiemetics and Antivertigo Agents: Non-Preferred
	
	Approval Duration: 3 months
	
	• *Nereus (tradipitant) is an oral substance P/neurokinin 1 (NK1) receptor antagonist indicated for the prevention of vomiting induced by motion in adults.*
	
	Initial Approval Criteria:
	• Nereus is being used for prevention of vomiting induced by motion; **AND**
	• Member has been counseled on non-pharmacological interventions; **AND**
	• Member has a planned event expected to cause vomiting induced by motion; **AND**
	• Patient has tried and failed, or has an allergy, contraindication, (including potential drug-drug interactions with other medications), or intolerance of ≥ 2 preferred agents, including BOTH of the following:
	  ○ Transdermal scopolamine; **AND**
	  ○ ≥ 1 preferred or over-the-counter (OTC) first-generation antihistamine (e.g., meclizine, dimenhydrinate) verified by pharmacy claims.
	
	Renewal Criteria:
	• Not applicable.
	
	Age Limit: ≥ 18 years of age
	
	Quantity Limit: 14 capsules per fill and 36 capsules per year

New Product to Market **Idvynso™ (doravirine/islatravir)**	**Antiretrovirals – Human Immunodeficiency Virus/Acquired Immunodeficiency Syndrome (HIV/AIDS): Non-Preferred** **Approval Duration:** 1 year initial, 1 year renewal

Agent	Options for Consideration
	• *Idvynso (doravirine/islatravir) is a two-drug combination that includes doravirine, a nonnucleoside reverse transcriptase inhibitor (NNRTI), and islatravir, a nucleoside analog reverse transcriptase inhibitor (NRTI). It is used as a complete regimen for adults with HIV-1 who are already virologically suppressed (HIV-1 RNA <50 copies/mL) on a stable regimen, with no history of treatment failure and no known resistance to doravirine.* **Non-Preferred (NPD) Criteria:** • Approval of non-preferred agents requires trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of 1 preferred agent. **Age Limit**: N/A **Quantity Limit**: 1 tablet per day

New Product to Market
Bysanti™ (milsaperidone)
	Central Nervous System – Antipsychotics Second-Generation (Atypical): Non-Preferred
	
	Approval Duration: 1 year
	
	• *Bysanti (milsaperidone) is a newly approved atypical antipsychotic and new chemical entity that rapidly interconverts to Fanapt (iloperidone), resulting in comparable pharmacologic activity and clinical effects. It acts primarily as an antagonist at dopamine D2 and serotonin 5-HT2A receptors, with additional α1-adrenergic receptor blockade, consistent with the known profile of iloperidone and requiring dose titration to mitigate orthostatic hypotension. Bysanti is indicated for the treatment of schizophrenia and the acute treatment of manic or mixed episodes associated with bipolar I disorder in adults.*
	
	Non-Preferred (NPD) Criteria:
	• Diagnosis of one of the following conditions:
	  ○ Schizophrenia; **OR**
	  ○ Bipolar I disorder with acute mania or mixed episodes; **AND**
	• A ≥ 2-week trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of > 2 preferred antipsychotics.
	
	Age Limit: ≥ 18 years of age
	
	Quantity Limit:
	• 1 mg, 2 mg, 4 mg, 6 mg, 8 mg, 10 mg, 12 mg tablets: 2 per day
	• 1-2-4-6 mg, 1-2-6 mg, 1-2-6-8 mg tablets: 1 titration pack per 365 days

New Product to Market **Baxfendy™ (baxdrostat)**	**Non-PDL** **Approval Duration:** 1 year initial, 1 year renewal

Agent	Options for Consideration

	• *Baxfendy (baxdrostat) is an oral aldosterone synthase inhibitor (ASI) indicated for the treatment of hypertension, in combination with other antihypertensive drugs, to lower blood pressure in adults who are not adequately controlled on other agents.*
	
	Initial Approval Criteria:
	• Diagnosis of uncontrolled or treatment resistant hypertension defined as:
	  ○ Persistent blood pressure above 140/90 mmHg; **AND**
	  ○ Patient has tried and failed optimal dosing of at least TWO antihypertensive medications concurrently from different classes for a minimum of 4 weeks; **AND**
	• Patient has had a trial and failure, allergy, contraindication, (including potential drug-drug interactions with other medications), or intolerance of a mineralocorticoid receptor antagonist (e.g., spironolactone, eplerenone); **AND**
	• Prescribed by, or in consultation with, a cardiologist, nephrologist, 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 potassium and serum sodium levels were measured prior to initiation and will be repeated periodically during treatment; **AND**
	• Will be used in combination with at least two other antihypertensive drugs at maximally tolerated doses.
	
	Renewal Criteria:
	• Prescriber attestation of clinically significant improvement or stabilization in clinical signs and symptoms; **AND**
	• Used in combination with at least two other antihypertensive drugs at maximally tolerated doses.
	
	Age Limit: ≥ 18 years of age
	
	Quantity Limit: 1 tablet per day

EXISTING CRITERIA REVIEW

Agent	Options for Consideration
Vraylar® (cariprazine)	**Central Nervous System – Antipsychotics: Second Generation (Atypical) and Injectable: Preferred** **Age Limit:** ≥ 10 years: • Acute manic or mixed episodes associated with bipolar I disorder (ICD-10 Disease Group F31) **Age Limit:** ≥ 13 years: • Schizophrenic Disorders (ICD-10 Disease Group F20; ICD-10 = F60.1)

Agent	Options for Consideration
	Age Limit: ≥ 18 years: • Dementias (ICD-10 Disease Groups F01, F02, F03, F06); • Dissociative and conversion disorders (ICD-10 Disease Group F44); • Episodic Mood Disorders (ICD-10 Disease Groups F30, F39); • Huntington's disease (ICD-10 Disease Group G10); • Major depressive disorder (ICD-10 Disease Groups F32, F33); ○ **Note:** If used as adjunctive therapy for major depressive disorder (AMDD): documentation of current use of, or trial and failure of, contraindication, or intolerance to ≥ 1 antidepressant of adequate dose and duration (e.g., SSRI, SNRI, bupropion, mirtazapine). • Oppositional defiant disorder (ICD-10 = F91.3); • Pervasive developmental disorders (ICD-10 Disease Group F84); • Schizoaffective disorder (F25.9); • Tic disorder (ICD-10 Disease Group F95); • Substance use disorders and related conditions (see below for • list). **Quantity Limit:** 1 per day

FULL PDL CLASSES: SCHEDULED REVIEW WITH PROPOSED CHANGES

PDL Class	Options for Consideration
Angiotensin-Converting Enzyme (ACE) Inhibitors	• 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 class, require PA until reviewed by the P&T Committee.
Angiotensin Receptor Blockers (ARBs)	• 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 Receptor Blockers (ARBs) class, require PA until reviewed by the P&T Committee.
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.
Anticoagulants	• DMS to select preferred agent(s) based on economic evaluation; however, at least 2 unique chemical entities should be preferred.

PDL Class	Options for Consideration
	• Agents not selected as preferred will be considered non-preferred and will require PA. • For any new chemical entity in the Anticoagulants class, require PA until reviewed by the P&T Committee.
Anticonvulsants	• 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 Anticonvulsants class, require PA until reviewed by the P&T Committee.
Antidepressants, Tricyclics	• 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, Tricyclics class, require PA until reviewed by the P&T Committee.
Calcium Channel Blockers (CCBs)	• 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 (CCBs) class, require PA until reviewed by the P&T Committee.
Movement Disorders	• 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 Movement Disorders class, require PA until reviewed by the P&T Committee.
Narcolepsy Agents	• 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 Narcolepsy Agents class, require PA until reviewed by the P&T Committee.
Platelet Aggregation Inhibitors	• 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 Platelet Aggregation Inhibitors class, require PA until reviewed by the P&T Committee.
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.

PDL Class	Options for Consideration
	• 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.
Stimulants and Related Agents	• 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 Stimulants and Related Agents class, require PA until reviewed by the P&T Committee.

CONSENT AGENDA ITEMS

Consent Agenda

The following therapeutic classes have no recommended changes and may be voted on as a group under a consent agenda:

- **5-Alpha Reductase (5AR) Inhibitors**
- **ACEI + Diuretic Combinations**
- **Alpha Blockers for Benign Prostatic Hyperplasia (BPH)**
- **Alzheimer's Agents**
- **Angiotensin Modulator + Calcium Channel Blocker (CCB) Combinations**
- **Anti-anginal and Anti-Ischemic**
- **Antidepressants, Monoamine Oxidase Inhibitors (MAOIs)**
- **Antidepressants, Other**
- **Antidepressants, Serotonin-Norepinephrine Reuptake Inhibitors (SNRIs)**
- **Antidepressants, Selective Serotonin Reuptake Inhibitors (SSRIs)**
- **Antimigraine Agents, Calcitonin Gene-Related Peptide (CGRP) Inhibitors and Other Agents: Acute Treatment**
- **Antimigraine Agents, Calcitonin Gene-Related Peptide (CGRP) Inhibitors and Other Agents: Prophylaxis, Injectable**
- **Antimigraine Agents, Calcitonin Gene-Related Peptide (CGRP) Inhibitors and Other Agents: Prophylaxis, Oral**
- **Antimigraine Agents, Triptans**
- **Antiparkinson's Agents**
- **Antipsychotics**
- **Anxiolytics**
- **ARB + Diuretic Combinations**
- **Beta-Blockers**
- **Bladder Relaxants**
- **Direct Renin Inhibitors**
- **Dopamine Receptor Agonists**
- **Lipotropics, Other**
- **Lipotropics, Statins**
- **Neuropathic Pain**
- **Sedative Hypnotics**
- **Skeletal Muscle Relaxants**
- **Spinal Muscular Atrophy**
- **Tobacco Cessation Products**