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 **April 21, 2026** meeting of the Pharmacy and Therapeutics Advisory Committee.

SINGLE AGENT REVIEWS

Agent	Options for Consideration

New Product to Market
Palsonify™ (paltusotine)
	Non-PDL
	
	Approval Duration: 12 months initial, 12 months renewal
	
	• *Palsonify (paltusotine) is an oral somatostatin receptor agonist indicated for adults with acromegaly who had an inadequate response to surgery and/or for whom surgery is not an option.*
	
	Initial Approval Criteria:
	
	• Documented diagnosis of acromegaly requiring medical therapy; **AND**
	• Prescribed by, or in consultation with, an endocrinologist or neurosurgeon, or specialist experienced in acromegaly management; **AND**
	• Inadequate response to pituitary surgery and/or surgery is not an option; **AND**
	• Documentation of inadequate response, intolerance, or contraindication to at least one injectable somatostatin analogue (SSA) following a trial of at least one month (≥ 30 days) (e.g., octreotide, lanreotide, Sandostatin, Somatuline); **AND**
	• Historical or current IGF-1 above the upper limit of normal for age/sex, or documentation of prior elevation with ongoing requirement for somatostatin-based medical therapy; **AND**
	• Provider attestation that patient has been counseled on and is able to comply with empty-stomach administration instructions.
	
	Renewal Criteria:
	
	• Documentation (e.g., progress note) of a positive response, such as:
	  ○ IGF-1 reduced to ≤1.0 × ULN or clinically meaningful reduction from baseline; **AND**
	  ○ Improvement or stabilization of acromegaly signs and symptoms (e.g., headache, soft tissue swelling, sweating, joint pain).
	
	Age Limit: ≥ 18 years of age
	
	Quantity Limit: 2 tablets per day

New Product to Market **Voyxact® (sibeprenlimab-szsi)**	**Non-PDL** **Approval Duration**: 3 months initial, 12 months renewal • *Voyxact (sibeprenlimab-szsi) is a humanized IgG2 monoclonal antibody (mAB) that inhibits A Proliferation-Inducing Ligand (APRIL) to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk for disease progression. It blocks signaling at the B cell maturation*

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Agent	Options for Consideration

	antigen (BCMA) and transmembrane activator and calcium modulator and cyclophilin ligand interactor (TACI) receptors, which reduces levels of serum galactose-deficient immunoglobulin A1 (Gd-IgA1), which is implicated in the pathogenesis of IgAN.
	
	Initial Approval Criteria:
	
	• Diagnosis of primary immunoglobulin A nephropathy (IgAN); **AND**
	• Diagnosis is confirmed by kidney biopsy consistent with IgAN
	• Prescriber submits documentation that patient meets the definition of high risk of disease progression, defined as:
	  ○ Proteinuria greater than or equal to 0.5 g/day; **OR**
	  ○ Urine protein-to-creatinine ratio greater than or equal to 0.8 g/g
	• Prescribed by, or in consultation with, a nephrologist or other appropriate specialist in the treatment of IgAN; **AND**
	• Patient is stable on a maximally tolerated dose of angiotensin-converting enzyme inhibitors (ACEI) or angiotensin receptor blockers (ARB) unless contraindicated.
	
	Renewal Criteria:
	
	• Patient is stable on a maximally tolerated dose of angiotensin-converting enzyme inhibitors (ACEI) or angiotensin receptor blockers (ARB) unless contraindicated**; AND**
	• Prescribed by, or in consultation with, a nephrologist or other appropriate specialist in the treatment of IgAN; **AND**
	• Prescriber submits clinical documentation that the patient has experienced a clinical benefit compared to baseline**,** such as reduction in proteinuria or UPCR or stabilization or improvement in estimated glomerular filtration rate (eGFR).
	
	Age Limit: ≥ 18 years of age
	
	Quantity Limit: 1 syringe per 4 weeks

New Product to Market **Attruby™ (acoramidis)**	**Non-PDL** **Approval Duration:** 12 months initial, 12 months renewal • *Attruby (acoramidis) is an oral transthyretin stabilizer indicated for adults with cardiomyopathy of wild-type or variant transthyretin-mediated amyloidosis (ATTR-CM) to reduce cardiovascular death and cardiovascular-related hospitalization.* **Initial Approval Criteria:** • Documented diagnosis of transthyretin mediated cardiomyopathy (ATTR CM), either wild type or variant (hereditary), confirmed by appropriate diagnostic evaluation (e.g., Tc 99m PYP scan, cardiac MRI, biopsy, and/or genetic testing); **AND**

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Agent	Options for Consideration

	• Prescribed by, or in consultation with, a cardiologist, geneticist, or specialist experienced in the management of transthyretin amyloidosis; **AND**
	• Documentation of clinical features consistent with symptomatic cardiomyopathy (e.g., heart failure symptoms such as dyspnea, fatigue, lower extremity edema, or reduced exercise tolerance); **AND**
	• Documentation that patient is receiving optimized guideline-directed medical therapy (GDMT) for heart failure as clinically appropriate (e.g., beta-blocker, ACEi/ARB/ARNI, MRA, SGLT2i, diuretics), and/or documented medical reason(s) why not fully optimized.
	
	Renewal Criteria:
	
	• Documentation (e.g., progress note) that at least ONE of the following has occurred since treatment initiation:
	  ○ Stabilization or improvement in functional status (e.g., New York Heart Association [NYHA] class, 6-minute walk distance); **OR**
	  ○ Reduction in cardiovascular related hospitalization frequency versus baseline; **OR**
	  ○ Stabilization or improvement in cardiac biomarkers (e.g., NT proBNP) or echocardiographic/cardiac MRI parameters; **OR**
	  ○ Clinical impression from the cardiologist that the patient has derived meaningful benefit (slowed disease progression, improved symptoms, or improved quality of life).; **AND**
	• Prescribed by, or in consultation with, a cardiologist, geneticist, or specialist experienced in the management of transthyretin amyloidosis.
	
	Age Limit: ≥ 18 years of age
	
	Quantity Limit: 4 tablets per day

New Product to Market
Redemplo® (plozasiran)
	Non-PDL
	
	Approval Duration: 12 months initial, 12 months renewal
	
	• *Redemplo (plozasiran) is a siRNA prescription injection designed to significantly reduce high triglycerides in adults with familial chylomicronemia syndrome (FCS), used alongside a low-fat diet. It works by suppressing the apoC-III protein in the liver.*
	
	Initial Approval Criteria:
	
	• Diagnosis of familial chylomicronemia syndrome (FCS) confirmed by genetic mutations in one of the following:
	  ○ LPL gene; **OR**
	  ○ APOA5 gene; **OR**
	  ○ GPIHBP1 gene; **OR**
	  ○ LMF1 gene; **OR**
	  ○ APOC2 gene; **AND**
	• Prescribed by, or in consultation with, an endocrinologist, or other specialist in the treatment of familial chylomicronemia syndrome (FCS); **AND**

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Agent	Options for Consideration
	• 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. **Renewal Criteria:** • Prescribed by, or in consultation with, an endocrinologist, or other specialist in the treatment of familial chylomicronemia syndrome (FCS); **AND** • Documentation of clinically significant improvement or stabilization in the patient's condition such as reduction in fasting triglyceride levels, decreased frequency or severity of pancreatitis episodes**.** **Age Limit:** ≥ 18 years of age **Quantity Limit:** 1 syringe per 3 months
New Product to Market **Forzinity™ (elamipretide)**	**Non-PDL** **Approval Duration:** 12 months initial, 12 months renewal • *Forzinity (elamipretide) is a mitochondrial cardiolipin binder that localizes to the inner mitochondrial membrane and improves mitochondrial morphology and function.* **Initial Approval Criteria:** • Diagnosis of Barth Syndrome, documented by genetic test demonstrating a pathogenic variant in the tafazzin (TAZ) gene; **AND** • Patient weighs at least 30 kg; **AND** • Prescriber attestation that patient is ambulatory and able to complete a 6-minute walk test; **AND** • Documentation of baseline muscle strength (e.g., handheld dynamometry); **AND** • Prescribed by, or in consultation with, a cardiologist, hematologist, or other specialist in the diagnosis and treatment of Barth Syndrome. **Renewal Criteria:** • Clinical documentation demonstrating improvement or stabilization of muscle strength as measured by handheld dynamometry.; **AND** • Prescribed by, or in consultation with, a cardiologist, geneticist, or specialist experienced in the management of transthyretin amyloidosis. **Age Limit:** ≥ 12 years of age **Quantity Limit:** 4 vials per 28 days
New Product to Market **Aqvesme™ (mitapivat)**	**Non-PDL**

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Agent	Options for Consideration

	Approval Duration: 6 months initial, 12 months renewal
	
	• *Aqvesme (mitapivat) is a pyruvate kinase activator, binds allosterically to enhance PK activity. It addresses oxidative stress from globin chain imbalances in erythropoiesis, improving energy balance, RBC lifespan, and reducing ineffective erythropoiesis and hemolysis in beta-thalassemia models.*
	
	Initial Approval Criteria:
	
	• Diagnosis of anemia with alpha or beta thalassemia; **AND**
	• Patient meets ONE of the following:
	  ○ Recent (within the last 30 days) hemoglobin level of ≤10.0 g/dL; **OR**
	  ○ Prescriber attestation that patient has required ≥ 6 red blood cell (RBC) units within the last 24 weeks; **AND**
	• Prescribed by, or in consultation with, hematologist or other specialist; **AND**
	• Patient is not on concurrent treatment with Reblozyl or Pyrukynd.
	
	Renewal Criteria:
	
	• Prescriber submits clinical documentation that the patient has experienced a clinical benefit compared to baseline.
	
	Age Limit: ≥ 18 years of age
	
	Quantity Limit: 2 tablets per day

New Product to Market **Pivya (pivmecillinam)**	**Non-PDL** **Approval Duration:** 1 month • *Pivya (pivmecillinam) is the pro-drug form of mecillinam, an amidinopenicillanic acid. When taken orally, it's well absorbed and quickly converted by non-specific esterases into mecillinam, the active antibacterial. Mecillinam, a beta-lactam antibiotic, mainly targets gram-negative bacteria by disrupting their cell wall biosynthesis. Unlike most beta-lactams, it specifically binds to penicillin-binding protein-2 (PBP-2) in gram-negative bacteria.* **Approval Criteria:** • Patient is female; **AND** • Documented clinical diagnosis of uncomplicated urinary tract (uUTI) infection with at least 2 signs/symptoms, (e.g., dysuria, urgency, frequency, lower abdominal pain, etc.); **AND** • Urinalysis confirming pyuria and/or positive urinary nitrites; **AND** • Urine culture confirming or showing high-clinical suspicion of uUTI caused by ONE of the following susceptible organisms: ○ Escherichia coli; **OR**

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Agent	Options for Consideration
	○ Proteus mirabilis; **OR** ○ Staphylococcus saprophyticus; **AND** • Documented allergy, intolerance, contraindication, or therapeutic failure to at least 2 first-line oral agents for uUTI (e.g., sulfamethoxazole/trimethoprim tablet or suspension, amoxicillin-clavulanate, cefdinir, fosfomycin, cefpodoxime, nitrofurantoin, etc.) as appropriate, based on organism susceptibilities.; **AND** • Provider attests that Pivya is not being used as step-down therapy for infections that previously required IV antibiotics. **Age Limit:** ≥ 18 years of age **Quantity Limit:** 21 tablets per 7-day course
New Product to Market **Zycubo® (copper histidinate)**	**Non-PDL** **Approval Duration**: 6 months initial, 6 months renewal • *Menkes disease is an X-linked recessive disorder caused by mutations in the ATP7A gene, affecting copper transport ATPase. This results in poor dietary copper absorption, impaired copper transport across the blood-brain barrier, and enzyme dysregulation. Zycubo (copper histidinate), a bioavailable copper therapy, is given via subcutaneous injection to bypass gastrointestinal absorption issues in Menkes disease patients.* **Initial Approval Criteria:** • Diagnosis of Menkes disease; **AND** • Patient has documented laboratory evidence of a genetic mutation in the ATP7A gene; **AND** • Patient has documented serum copper < 75 mcg/dL; **AND** • Prescriber attests to monitoring the following before initiating treatment and as clinically indicated during treatment: ○ Serum copper and ceruloplasmin levels; **AND** ○ Serum electrolytes; **AND** ○ Kidney and liver function; **AND** ○ Complete blood count (CBC); **AND** • Medication will not be used concomitantly with other copper-containing therapies; **AND** • Documentation (e.g., progress note or lab report) of response to therapy compared to baseline; **AND** • Prescribed by, or in consultation with, a pediatric neurologist, geneticist, or other specialist in the diagnosis and treatment of Menkes disease. **Renewal Criteria:** • Documentation (e.g., progress note or lab report) of response to therapy compared to baseline; **AND** • Prescribed by, or in consultation with, a pediatric neurologist, geneticist, or other specialist in the diagnosis and treatment of Menkes disease.

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Agent	Options for Consideration
	Age Limit: ≤ 18 years of age **Quantity Limit:** 2 vials per day
New Product to Market **Cardamyst™ (etripamil)**	**Non-PDL** **Approval Duration:** 12 months initial, 12 months renewal • *Cardamyst (Etripamil) is an L-type calcium influx inhibitor (slow channel blocker or calcium ion antagonist). Etripamil exerts its pharmacologic effect by modulating the influx of ionic calcium across the cell membrane of the AV nodal cells as well as arterial smooth muscles and contractile myocardial cells. By interrupting reentry at the AV node, etripamil can restore sinus rhythm in patients with PSVT.* **Approval Criteria:** • Diagnosis of paroxysmal supraventricular tachycardia (PSVT) confirmed by electrocardiogram (ECG); **AND** • Prescriber attestation that the patient has a history of sustained, symptomatic episodes of PSVT (e.g., typically lasting 20 minutes or longer); **AND** • Concurrent oral medications will be used for control the ventricular rate (e.g.calcium channel blockers, digoxin, amiodarone, beta-blockers) or regulating sinus rhythm (e.g.ibutilide, flecainide, amiodarone, propafenone) as clinically appropriate.; **AND** • Medication will be used for the conversion of acute symptomatic episodes of PSVT; **AND** • Prescribed by, or in consultation with, a cardiologist, or other specialist in the diagnosis and treatment of PSVT. **Age limit:** ≥ 18 years of age **Quantity Limit:** 4 nasal spray devices per month
New Product to Market **Myqorzo™ (aficamten)**	**Non-PDL** **Approval Duration:** 6 months initial, 12 months renewal • *Myqorzo (aficamten) is a cardiac myosin inhibitor. It is used to treat adults with symptomatic obstructive cardiomyopathy (oHCM) to improve functional capacity and symptoms. It is an allosteric and reversible inhibitor of cardiac myosin motor activity that reduces the force generated by myosin at the cardiac sarcomere, which contributes to the pathophysiology of HCM. In HCM patients, myosin inhibition with aficamten reduces cardiac contractility and left ventricular outflow tract (LVOT) obstruction.* **Initial Approval Criteria:**

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Agent	Options for Consideration

	• Diagnosis of obstructive hypertrophic cardiomyopathy (oHCM); **AND**
	• Documentation of left ventricular hypertrophy based on ONE of the following:
	  ○ Maximal left ventricular wall thickness greater than or equal to 15 mm; **OR**
	  ○ Familial hypertrophic cardiomyopathy with a maximal left ventricular wall thickness greater than or equal to 13 mm; **AND**
	• Patient has New York Heart Association (NYHA) Class II or Class III symptoms of heart failure; **AND**
	• Documentation of left ventricular ejection fraction (LVEF) greater than or equal to 55%; **AND**
	• Patient has a peak left ventricular outflow tract gradient greater than or equal to 30 mmHg at rest or greater than or equal to 50 mmHg after provocation (Valsalva maneuver or post exercise); **AND**
	• Prescribed by, or in consultation with, a cardiologist, or other specialist in the treatment of oHCM; **AND**
	• Patient must have an adequate trial and failure of one of the following:
	  ○ beta blocker, **OR**
	  ○ non-dihydropyridine calcium channel blocker.
	
	Renewal Criteria:
	
	• Documentation of left ventricular ejection fraction (LVEF) ≥ 50% for renewal; **AND**
	• Prescriber submits clinical documentation that the patient has experienced a disease improvement. and/or stabilization from baseline (e.g., at least 1 NYHA class decrease, greater than or equal to 1.5 mL/kg/min in pVO2 increase or greater than or equal to 3 mL/kg/min in pVO2 without NYHA class worsening);**AND**
	• Prescribed by, or in consultation with, a cardiologist, or other specialist in the treatment of oHCM,
	
	Age Limit: ≥ 18 years of age
	
	Quantity Limit: 1 tablet per day

EXISTING CRITERIA REVIEW

Agent Subject to Criteria	Criteria for Approval
Itvisma™ (onasemnogene abeparvovec-brve) *****All PA requests must be sent to MedImpact for review.*****	**Spinal Muscular Atrophy: Non-Preferred** **Approval Criteria:** • Prescribed by or in consultation with a neurologist or other specialist experienced in the diagnosis and treatment of spinal muscular atrophy (SMA); **AND** • Must have SMA diagnosis confirmed by submission of medical records (e.g., chart notes, laboratory values, genetic testing) demonstrating:

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Agent Subject to Criteria	Criteria for Approval
	○ A mutation or deletion of genes in chromosome 5q resulting in one of the following: ▪ Homozygous gene deletion or mutation of SMN1 gene (e.g., homozygous deletion of exon 7 at locus 5q13); **OR** ▪ Compound heterozygous mutation of SMN1 gene (e.g., deletion of SMN1 exon 7 {allele 1} and mutation of SMN1 {allele 2}); **AND** • Patient is 2 years of age or older at the time of treatment ; **AND** • Has not received prior treatment with onasemnogene abeparvovec gene replacement therapy (e.g., Zolgensma); **AND** • Baseline anti–AAV9 antibody titer is ≤1:50 as measured by a validated assay (e.g., ELISA), with documentation of results; **AND** • Does not have advanced SMA characterized by any of the following: ○ Permanent invasive ventilation or chronic noninvasive ventilatory support (e.g., ≥16 hours/day) not expected to improve; **OR** ○ Complete paralysis of all extremities with no residual motor function; **AND** • Patient is clinically stable at the time of planned dosing, with no active or recent serious infection and no clinical signs or symptoms of infection on the day of injection; **AND** • Baseline laboratory assessments obtained prior to ITVISMA administration, including: ○ Liver function tests (e.g., ALT, AST, total bilirubin); **AND** ○ Creatinine and complete blood count (including hemoglobin and platelet count); **AND** ○ Baseline anti AAV9 antibody test; **AND** • Must be administered as a one-time intrathecal injection via lumbar puncture by an appropriate specialist or trained healthcare professional, with access to appropriate monitoring and supportive care; **AND** • Must be used with systemic corticosteroids (e.g., oral prednisolone/prednisone 1 mg/kg/day or equivalent) beginning 1 day prior to Itvisma and continued for at least 30 days, followed by a taper and ongoing monitoring as clinically indicated; **AND** • Provider attests that immunizations are up to date, with consideration of timing of live vaccines relative to corticosteroid use, and appropriate prophylaxis against respiratory infections (e.g., influenza, RSV) has been addressed; **AND** • Not to be used in combination with another SMN1 gene replacement therapy (no repeat or sequential AAV9-based SMN1 gene therapy including IV onasemnogene abeparvovec [Zolgensma]); **AND** • Not to be used in combination with Spinraza (nusinersen); **AND** • Not to be used in combination with Evrysdi (risdiplam). **Age Limit:** ≥ 2 years of age

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FULL PDL CLASSES: SCHEDULED REVIEW WITH PROPOSED CHANGES

PDL Class	Options for Consideration
Bone Resorption Suppression 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 Bone Resorption Suppression and Related Agents class, require PA until reviewed by the P&T Committee.
Dipeptidyl Peptidase-4 (DPP-4) 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 Dipeptidyl Peptidase-4 (DPP-4) Inhibitors class, require PA until reviewed by the P&T Committee.
Glucagon-Like Peptide-1 (GLP-1) Receptor Agonists	• 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 Glucagon-Like Peptide-1 (GLP-1) Receptor Agonists class, require PA until reviewed by the P&T Committee.

FULL PDL CLASSES: PROPOSED STRUCTURE CHANGES

PDL Class
The following therapeutic classes have recommended changes to the structure of the PDL class only: • **Colony Stimulating Factors** • **Steroids, Topical**

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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:

- **Narcotic Agonist/Antagonists**
- **Narcotics, Fentanyl Buccal Products**
- **Narcotics, Long-Acting**
- **Narcotics, Short-Acting**
- **Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)**
- **Opiate Dependence Treatments**
- **Antihyperuricemics**
- **Erythropoiesis Stimulating Proteins**
- **Phosphate Binders**
- **Sickle Cell Anemia Treatments**
- **Thrombopoiesis Stimulating Proteins**
- **Alpha-Glucosidase Inhibitors**
- **Insulins and Related Agents**
- **Meglitinides**
- **Metformins**
- **Sodium Glucose Co-Transporter 2 (SGLT2) Inhibitors**
- **Sulfonylureas**
- **Thiazolidinediones (TZDs)**
- **Androgenic Agents**
- **Glucagon Agents**
- **Growth Hormone**
- **Pancreatic Enzymes**
- **Progestins for Cachexia**
- **Steroids, Oral**
- **Uterine Disorder Treatments**

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