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 **January 28, 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: Cobenfy™** **Central Nervous System – Antipsychotics, Second Generation (Atypical) and Injectable: Non-Preferred** **Approval Duration: 1 year** • *Xanomeline is a M1 and M4 muscarinic acetylcholine receptor agonist in the central nervous system, influencing dopaminergic activity. Trospium is a muscarinic antagonist in the peripheral tissues, mitigating xanomeline's side effects.* **Initial Approval Criteria:** • Diagnosis of schizophrenia; **AND** • Trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications) or intolerance to one preferred agent; **AND** • Prescriber attests that liver enzymes and bilirubin were measured prior to initiation; **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 clinical signs and symptoms. **Age Limit:** 18 years of age or older **Quantity Limit:** 2 capsules per day	***Decision*** ***8 For*** ***0 Against***
2	**New Product to Market: Livdelzi®** **Gastrointestinal, Bile Salts: Non-Preferred** **Approval Duration: 1 year** • *Seladelpar decreases bile acid synthesis by activating peroxisome proliferator-activated receptor (PPAR)-delta. This causes downregulation of CYP7A1, an enzyme used to synthesize bile acids from cholesterol, through Fibroblast Growth Factor 21 (FGF21).*	***Decision*** ***8 For*** ***0 Against***

	Description of Recommendation	P&T Vote

	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 Livdelzi in addition to current therapy; **OR**
	  ○ Patient has a contraindication or intolerance to ursodiol and will take Livdelzi 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 for the provided indication.
	
	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 Livdelzi in addition to current therapy; **OR**
	  ○ Patient has a contraindication or intolerance to ursodiol and will take Livdelzi as monotherapy.
	
	Age Limit: 18 years of age or older
	Quantity Limit: 1 capsule per day	

3	**New Product to Market: Vyalev™** **Central Nervous System – Parkinson's Disease (Antiparkinson's Agents): Non-Preferred** **Approval Duration: 1 year** • *Foscarbidopa and foslevodopa are prodrugs that are converted to carbidopa and levodopa in vivo. Carbidopa inhibits peripheral levodopa from decarboxylation, allowing more levodopa to be delivered to the brain, where it is converted to dopamine.* **Initial Approval Criteria:** • Diagnosis of Parkinson's disease (PD); **AND** • Receiving PD therapy with carbidopa/levodopa; **AND** • Experiencing "off" episodes with carbidopa/levodopa for at least 2 hours per day; **AND** • Trial and failure of at least 2 adjunctive therapies, such as:	***Decision*** ***8 For*** ***0 Against***

	Description of Recommendation	P&T Vote
	○ Dopamine agonists (e.g., pramipexole, ropinirole) ○ Monoamine oxidase-B inhibitors (e.g., selegiline) ○ Catechol-O-methyltransferase inhibitors (e.g., entacapone); **AND** • Patient will not take within two weeks of a non-selective monoamine oxidase (MAO) inhibitor (e.g., phenelzine, isocarboxazid, tranylcypromine); **AND** • Patient meets the minimum age recommended by the package insert for the provided indication. **Renewal Criteria:** • Patient has clinically meaningful response of treatment (e.g., patient shows a reduction in time of "off" episodes). **Age Limit:** 18 years of age or older **Quantity Limit:** 2 vials (20 mL) per day	
4	**New Product to Market: Ebglyss™** **Immunomodulators – Atopic Dermatitis: Non-Preferred** **Approval Duration: 4 months initial, 1 year renewal** • *Lebrikizumab-lbkz is an IgG4 monoclonal antibody that binds to and allows interleukin (IL)-13 to bind to IL-13R-α1, but inhibits human IL-13 signaling. IL-13 is a cytokine involved in type 2 inflammation seen in atopic dermatitis.* **Initial Approval Criteria:** • Diagnosis of moderate-to-severe atopic dermatitis (AD) with ≥ 1 of the following: ○ Involvement of at least 10% of body surface area (BSA); **OR** ○ Scoring Atopic Dermatitis (SCORAD) score of 25 or more; **OR** Investigator's Global Assessment (IGA) with a score ≥ 3; **OR** ○ Eczema Area and Severity Index (EASI) score of ≥ 16; **OR** ○ Incapacitation due to AD lesion location (e.g., head and neck, palms, soles, or genitalia); **AND** • Prescribed by, or in consultation with, a dermatologist, allergist/immunologist, or other specialist in the treatment of atopic dermatitis; **AND** • Trial and failure, contraindication, or intolerance to ≥ 1 agent in 2 or more of the following categories (total prior agent use of ≥ 90 days): ○ Topical corticosteroid of medium to high potency (e.g., mometasone, fluocinolone) unless inappropriate for the location (e.g., face, groin); **AND** ○ Topical calcineurin inhibitor (i.e., tacrolimus or pimecrolimus); **OR**	***Decision 8 For 0 Against***

	Description of Recommendation	P&T Vote
	○ Immunosuppressive systemic agent (e.g., cyclosporine, azathioprine, methotrexate, mycophenolate mofetil); **AND** • Trial and failure, contraindication, or intolerance to at least one preferred injectable agent (Adbry or Dupixent); **AND** • Patient must meet the minimum age and weight 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 and/or stabilization based on an objective measure. **Age Limit:** 12 years of age or older **Quantity Limit:** 1 pen/syringe (2 mL) per 28 days	
5	**New Product to Market: Xdemvy™** **Non-PDL** **Approval Duration: 3 months initial, 1 year renewal** • *Lotilaner is an inhibitor of the gamma-aminobutyric acid (GABA)-gated chloride channel. This drug is selective for channels present in mites, causing a paralytic action leading to death.* **Initial Approval Criteria:** • Diagnosis of Demodex Blepharitis; **AND** • Prescribed by, or in consultation with, an ophthalmologist or other specialist for the requested condition; **AND** • Prescriber attests that the patient currently has active disease. **Renewal Criteria:** • Patient has a diagnosis of Demodex Blepharitis [H01.00]; **AND** • Prescribed by, or in consultation with, an ophthalmologist or other specialist for the requested condition; **AND** • Prescriber attests patient has experienced a response to previous therapy. **Age Limit:** 18 years of age or older **Quantity Limit:** 1 bottle (10 mL) per month	***Decision 8 For 0 Against***
6	**New Product to Market: Yorvipath™** **Non-PDL** **Approval Duration: 6 months initial, 1 year renewal**	***Decision 8 For 0 Against***

	Description of Recommendation	P&T Vote

	• *Palopegteriparatide mimics endogenous parathyroid hormone to increase serum calcium and decrease serum phosphate. This drives homeostasis and a number of downstream effects, such as maintaining appropriate laboratory levels and stimulating bone turnover.*
	
	Initial Approval Criteria:
	• Diagnosis of hypoparathyroidism; **AND**
	• Prescriber attests that this medication is NOT being prescribed for acute hypoparathyroidism post-surgery; **AND**
	• Patient has not received therapy with parathyroid hormone analogs (e.g. abaloparatide, teriparatide) for 24 months or more (lifetime cumulative); **AND**
	• Documentation that the following labs are within normal limits:
	  ○ **Corrected Serum Calcium:** 7.8-10.2 mg/dL; **AND**
	  ○ **Serum Phosphate:** 2.5-4.5 mg/dL; **AND**
	• Prescriber attestation that the patient is not well-controlled despite appropriate utilization (trial and failure of 3 months) of calcium and active forms of vitamin D; **AND**
	• Prescribed by, or in consultation with, an endocrinologist or other specialist for the requested condition.
	
	Renewal Criteria:
	• Patient continues to have the above listed diagnosis; **AND**
	• Prescribed by, or in consultation with, an endocrinologist or other specialist for the requested condition; **AND**
	• Documentation (e.g., progress note) of response to therapy.
	
	Age Limit: 18 years of age or older
	Quantity Limit: 2 pens per month	

7	**New Product to Market: Duvyzat™** **Muscular Dystrophy Agents: Nonpreferred** **Approval Duration: 6 months initial, 1 year renewal** • *Givinostat is a histone deacetylase inhibitor. The precise mechanism by which givinostat exerts its effect in patients with DMD is unknown.* **Initial Approval Criteria:** • Diagnosis of Duchenne muscular dystrophy (DMD) [G71.01]; **AND** • Platelet count within the last 30 days equals to or is greater than 150 x 10^9/L; **AND** • Prescribed by, or in consultation with, a neuromuscular specialist with expertise in the treatment of DMD; **AND**	***Decision 8 For 0 Against***

	Description of Recommendation	P&T Vote
	• Patient is ambulatory (e.g., ability to walk with or without assistive devices, not wheelchair dependent); **AND** • Patient's baseline ambulatory function has been or will be assessed prior to therapy initiation; **AND** Patient has been on a stable systemic corticosteroid therapy for at least 6 months and will continue to be on the systemic corticosteroid therapy unless contraindicated or clinically significant adverse effects are experienced; **AND** • Prescriber provides a patient weight obtained within the past 3 months; **AND** • The requested dose meets the FDA-approved dosing recommendation. **Renewal Criteria:** • Documentation (e.g., progress note) of stabilized or improved ambulatory function from baseline; **AND** • Patient will continue systemic corticosteroid therapy unless contraindicated or clinically significant adverse effects are experienced; **AND** • Prescriber provides a patient weight obtained within the past 3 months; **AND** • The requested dose meets the FDA-approved dosing recommendation. **Age Limit:** 6 years of age or older **Quantity Limit:** 12 mL per day	
8	**New Product to Market: Nemluvio®** **Immunomodulators, Atopic Dermatitis Class: Nonpreferred** **Approval Duration: 4 months initial, 1 year renewal** • *Nemolizumab-ilto is a humanized IgG2 monoclonal antibody that inhibits IL-31 signaling by binding selectively to IL-31 RA. IL-31 is a naturally occurring cytokine that is involved in pruritus, inflammation, epidermal dysregulation, and fibrosis. Nemolizumab-ilto inhibited IL-31-induced responses including the release of proinflammatory cytokines and chemokines.* **Initial Approval Criteria:** **Atopic Dermatitis:** • Diagnosis of moderate-to-severe atopic dermatitis (AD) with ≥ 1 of the following: o Involvement of at least 10% of body surface area (BSA); **OR** o Investigator's Global Assessment (IGA) with a score ≥ 3; **OR**	***Decision 8 For 0 Against***

Description of Recommendation	P&T Vote

- Eczema Area and Severity Index (EASI) score of ≥ 16; **OR** Peak Pruritis Numeric Rating Scale (PP-NRS) score ≥ 4; **OR**
- Incapacitation due to AD lesion location (e.g., head and neck, palms, soles, or genitalia); **AND**

- Prescribed by, or in consultation with, a dermatologist, allergist/immunologist, or other specialist in the treatment of atopic dermatitis; **AND**
- Trial and failure, contraindication, or intolerance to ≥ 1 agent in 2 or more of the following categories (total prior agent use of ≥ 90 days):
  - Topical corticosteroid of medium to high potency (e.g., mometasone, fluocinolone) unless inappropriate for the location (e.g., face, groin); **AND**
  - Topical calcineurin inhibitor (i.e., tacrolimus or pimecrolimus); **OR**
  - Immunosuppressive systemic agents (e.g., cyclosporine, azathioprine, methotrexate, mycophenolate mofetil, etc.); **AND**
- Trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications) or intolerance of 1 preferred injectable (Adbry, Dupixent) agent; **AND**
- Nemluvio will be taken with topical corticosteroids and/or calcineurin inhibitors (e.g., pimecrolimus, tacrolimus); **AND**
- Patient must meet the minimum age recommended by the package insert for this FDA approved indication.

Prurigo Nodularis:

- Diagnosis of prurigo nodularis; **AND**
- At least 20 nodular lesions; **AND**
- Other causes of pruritis have been ruled out; **AND**
- Trial and failure, contraindication, or intolerance to one of the following:
  - Moderate to super potent topical corticosteroids [e.g., betamethasone dipropionate, (augmented), fluocinonide 0.1%, flurandrenolide, betamethasone dipropionate 0.05%, clobetasol propionate 0.025%, or desoximetasone 0.05%] for a minimum of 2 weeks; **OR**
  - Narrowband ultraviolet B (NBUVB) phototherapy or psoralen plus ultraviolet A (PUVA) phototherapy; **AND**
- Trial and failure, contraindication, or intolerance to Dupixent; **AND**
- Patient must meet the minimum age recommended by the package insert for this FDA-approved indication.

	Description of Recommendation	P&T Vote
	Renewal Criteria: • Patient must continue to meet initial approval criteria; **AND** • Patient must have disease improvement and/or stabilization based on an objective measure **Quantity Limit:** 2 pens (60 mg) per 28 days	
9	**New Product to Market: Neffy®** **Self-injectable Epinephrine: Nonpreferred** **Approval Duration: 6 months initial, 1 year renewal** • *Epinephrine acts on both alpha- and beta-adrenergic receptors and is a potent vasoconstrictor via its effects on the alpha- receptors.* **Approval Criteria:** • Patient has had a trial and failure, allergy, contraindication (including potential drug-drug interactions with other medications), needle phobia, or intolerance of 1 preferred agent. **Quantity Limit:** 2 bottles per fill	***Decision 8 For 0 Against***

10	**New Product to Market: Miplyffa ™**
	
	Non-PDL
	
	Approval Duration: 6 months initial, 1 year renewal
	
	• *Miplyffa is a first-in-class oral heat shock protein (HSP) amplifier that can stabilize lysosomal membranes and improve lysosomal function so that cells can clear away waste.*
	
	Initial Approval Criteria:
	• Diagnosis of Niemann-Pick Disease Type C (NPC) [ICD-10 code E75.242]; **AND**
	• Confirmed diagnosis of NPC by ≥ 1 of the following:
	  ○ Positive genetic test for mutations on both alleles of NPC1 or NPC2; **OR**
	  ○ Positive genetic test for mutations on one allele NPC1 or NPC2; **AND**
	  ▪ Elevated biomarker; **OR**
	  ▪ Positive filipin staining; **AND**
	• Prescribed by, or in consultation with, a neurologist or geneticist or other specialist in the treatment of Niemann-Pick Disease Type C; **AND**
		Decision 8 For 0 Against

	Description of Recommendation	P&T Vote
	• Prescriber attests patient presents with at least one neurological symptom of the disease (e.g., hearing loss, ataxia, dystonia, seizures, speech delay); **AND** • Prescriber attests medication will be used in combination with miglustat; **AND** • Patient must meet the minimum age recommended by the package insert. **Renewal Criteria:** • Prescriber provides documentation (i.e., NPC Neurologic Severity Scale, cognitive function tests, motor function assessment, etc.) that patient has experienced disease improvement or stabilization or a reduction in disease progression **Age Limit:** 2 years of age or older **Quantity Limit:** 3 capsules per day	

11	**New Product to Market: Aqneursa™**
	
	Non-PDL
	
	Approval Duration: 3 months initial, 1 year renewal
	
	• *Aqneursa is modified amino acid (acetylleucine) kilograms. Once ingested, ubiquitous monocarboxylate transporters deliver Aqneursa to all tissues and is thought to serve as a neuroprotectant that reduces neuroinflammation and stabilizes the nerve cells responsible for balance and the coordination of movement.*
	
	Initial Approval Criteria:
	• Diagnosis of Niemann-Pick Disease Type C (NPC) [ICD-10 code E75.242]; **AND**
	• Confirmed diagnosis of NPC by ≥ 1 of the following:
	  ○ Positive genetic test for mutations on both alleles of NPC1 or NPC2; **OR**
	  ○ Positive genetic test for mutations on one allele NPC1 or NPC2; **AND**
	  ▪ Elevated biomarker; **OR**
	  ▪ Positive filipin staining; **AND**
	• Prescribed by, or in consultation with, a neurologist or geneticist or other specialist in the treatment of Niemann-Pick Disease Type C; **AND**
	• Prescriber attests patient presents with at least one neurological symptom of the disease (e.g., hearing loss, ataxia, dystonia, seizures, speech delay); **AND**
	• Patient must meet the minimum age and weight recommended by the package insert for the provided indication
		Decision 8 For 0 Against

	Description of Recommendation	P&T Vote
	○ ≥ 4 years of age ○ ≥ 15 kg **Renewal Criteria:** • Prescriber provides documentation (i.e., NPC Neurologic Severity Scale, cognitive function tests, motor function assessment, etc.) that patient has experienced disease improvement or stabilization or a reduction in disease progression **Age Limit:** 4 years of age or older **Quantity Limit:**4 packets (4 grams) per day	
12	**Antibiotics: Gastrointestinal** • 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 Antibiotics, Gastrointestinal class, require PA until reviewed by the P&T Committee.	***Decision 8 For 0 Against***
13	**Antibiotics: Vaginal** • 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 Antibiotics, Vaginal class, require PA until reviewed by the P&T Committee.	***Decision 8 For 0 Against***
14	**Antibiotics: Penicillins** • 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 Antibiotics, Penicillins class, require PA until reviewed by the P&T Committee.	***Decision 8 For 0 Against***
15	**Antibiotics: Sulfonamides, Folate 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 Antibiotics: Sulfonamides, Folate Antagonists class, require PA until reviewed by the P&T Committee.	***Decision 8 For 0 Against***
16	**Antifungal, Oral** • DMS to select preferred agent(s) based on economic evaluation; however, at least 2 unique chemical entities should be preferred.	***Decision 8 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 Antifungal, Oral class, require PA until reviewed by the P&T Committee.	
17	**Hepatitis C Agents: Interferons and Ribavirins** • 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 Hepatitis C Agents: Interferons and Ribavirins class, require PA until reviewed by the P&T Committee.	***Decision 8 For 0 Against***
18	**Chronic Obstructive Pulmonary Disease (COPD) 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 Chronic Obstructive Pulmonary Disease (COPD) Agents class, require PA until reviewed by the P&T Committee.	***Decision 8 For 0 Against***
19	**Epinephrine, Self-Injectable** • 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 Epinephrine, Self-Injectable class, require PA until reviewed by the P&T Committee.	***Decision 8 For 0 Against***
20	**Glucocorticoids, Inhaled** • 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 Glucocorticoids, Inhaled class, require PA until reviewed by the P&T Committee.	***Decision 8 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
21	• **Antibiotics, Cephalosporins 1st Generation** • **Antibiotics, Cephalosporins 2nd Generation** • **Antibiotics, Cephalosporins 3rd Generation** • **Antibiotics, Inhaled** • **Antibiotics, Macrolides** • **Antibiotics, Oxazolidinones** • **Antibiotics, Quinolones** • **Antibiotics, Tetracyclines** • **Antihistamines, Minimally Sedating** • **Antiretrovirals, HIV/AIDS** • **Antivirals, Oral** • **Bronchodilators, Beta Agonist** • **Hepatitis B Agents** • **Hepatitis C Agents: Direct-Acting Antivirals** • **Intranasal Rhinitis Agents** • **Leukotriene Modifiers**	***Decision*** ***8 For*** ***0 Against***