Kentucky Department for Medicaid Services
Pharmacy and Therapeutics Advisory Committee Recommendations

The following chart provides a summary of the official recommendations made by the Pharmacy and Therapeutics (P&T) Advisory Committee at the **November 16th, 2023,** 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.

	Description of Recommendation	P & T Vote

1	**New Product to Market: Filspari™**
	
	Non-PDL Class**Length of Authorization:** 6 months initial; 1 year renewal
	• Sparsentan (Filspari) is an endothelin and angiotensin II receptor antagonist indicated to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression, generally a urine protein-to-creatinine ratio (UPCR) ≥ 1.5 g/g.
	
	Criteria for Approval:
	• Biopsy-proven primary immunoglobulin A nephropathy (IgAN); AND
	• Presence of proteinuria; AND
	• Patient is at risk of rapid disease progression, generally a urine protein-to-creatinine ratio (UPCR) ≥ 1.5 g/g; AND
	• Patient must not have hypersensitivity to any component of the product; AND
	• Patient must have had an adequate trial of an angiotensin converting enzyme (ACE) inhibitor or angiotensin II receptor blocker (ARB) at ≥ 50% of the maximum labeled dose; AND
	• Patient will avoid concomitant therapy with major interacting drugs, including:
	  ○ Renin-angiotensin-aldosterone system (RAAS) inhibitors, endothelin receptor antagonists (ERAs), and aliskiren; AND
	  ○ Strong CYP3A inhibitors; AND
	  ○ Strong CYP3A inducers; AND
	  ○ Histamine H2 receptor antagonists; AND
	  ○ Proton pump inhibitors; AND
	  ○ Sensitive substrates of P-glycoprotein (P-gp) and breast cancer resistance protein (BCRP); AND
	• Prescriber has confirmed aminotransferases (ALT, AST) are < 3x upper limit of normal (ULN)
	• Prescriber will monitor ALT, AST and total bilirubin monthly for the first 12 months after initiation, or when restarting therapy following an interruption due to elevated aminotransferases, then every 3 months for the duration of treatment; AND
	• Prescriber will monitor renal function and serum potassium regularly during treatment; AND
	• Female patients have a negative pregnancy test prior to the start of therapy; AND
		Passed
		5 For
		0 Against

	Description of Recommendation	P & T Vote
	• Patients of reproductive potential have been advised to use an effective contraceptive method during treatment; AND • Prescriber has assessed the patient's risk for hypotension and has discontinued or adjusted other antihypertensive medications as needed. **Renewal Criteria** • Patient must continue to meet the above criteria; AND • Patient must have reduction or stabilization in proteinuria; AND • Patient has not experienced any treatment-restricting adverse effects (e.g., hepatotoxicity, acute kidney injury, severe hypotension, hyperkalemia). **Quantity Limit**: 1 per day **Age Limit:** 18 years of age	

2	**New Product to Market: Joenja®**
	
	Non-PDL Class
	
	Length of Authorization: 1 year
	
	• Leniolisib (Joenja) is a kinase inhibitor indicated for the treatment of activated phosphoinositide 3-kinase delta (PI3Kδ) syndrome (APDS) in adult and pediatric patients ≥ 12 years of age.
	
	Initial Approval Criteria:
	• Patient has a confirmed diagnosis by the presence of an activated phosphoinositide 3-kinase delta (PI3Kδ) syndrome (APDS)-associated genetic PI3Kδ mutation with a documented variant in either PIK3CD or PIK3R1; AND
	  ○ Patient has nodal and/or extra-nodal lymphoproliferation, with the presence of ≥ 1 measurable nodal lesion, as measured on computed tomography (CT) or magnetic resonance imaging (MRI); OR
	  ○ Patient has clinical findings and manifestations compatible with APDS (e.g., history of repeated oto-sino-pulmonary infections, organ dysfunction [e.g., lung, liver]); AND
	• Pregnancy status will be confirmed in female patients of reproductive potential prior to initiating therapy and highly effective methods of contraception will be used during treatment; AND
	• Patient will avoid concomitant therapy with all the following:
	  ○ Coadministration with strong and moderate CYP3A4 inducers
	  ○ Coadministration with strong CYP3A4 inhibitors
	• Patient is NOT on concurrent immunosuppressive therapy.
	
	Renewal Criteria:
	• Patient must continue to meet the above criteria; AND
	• Patient must have disease response with treatment as defined by stabilization of or improvement of disease signs and symptoms (e.g., decrease in the frequency and/or severity of infections, decreased lymphadenopathy, increased percentage of naïve B cells, decrease in disease-related hospitalizations); AND
	• Patient has NOT experienced any treatment-restricting adverse effects (e.g.,
		Passed
		5 For
		0 Against

	Description of Recommendation	P & T Vote
	severe neutropenia: absolute neutrophil count [ANC] < 500 cells/µL). **Age Limit**: ≧ 12 years **Quantity Limit**: 2 per day	
3	**New Product to Market: Miebo™** Non-prefer in the PDL class: *Ophthalmic Immunomodulators* **Length of Authorization:** 1 year • Perfluorohexyloctane (Miebo) is a semifluorinated alkane that is indicated for the treatment of the signs and symptoms of dry eye disease (DED). **Criteria for Approval:** • Trial and failure of ≥ 1 over-the-counter ophthalmic lubricant (e.g., polyvinyl alcohol); **AND** • At least a 1 month trial and therapeutic failure, allergy, contraindication (including potential drug-drug interactions with other medications) or intolerance of 2 preferred agents **Age Limit**: none **Quantity Limit**: 0.4 mL (8 drops) per day	**Passed** **5 For** **0 Against**

4	**New Product to Market: Ngenla™**
	
	Non-prefer in the PDL class: Growth Hormones
	
	Length of Authorization: 1 year
	
	• Somatrogon-ghla (Ngenla) is a human growth hormone analog indicated for treatment of pediatric patients aged 3 years and older who have growth failure due to inadequate secretion of endogenous growth hormone.
	
	Initial Approval Criteria:
	
	• Diagnosis of growth hormone deficiency; AND
	• Patient does NOT have a hypersensitivity to somatrogon-ghla or any of the excipients; AND
	• Pediatric patient must NOT have closed epiphyses if used for longitudinal growth promotion; AND
	• Patient does NOT have active malignancy; AND
	• Patient does NOT have active proliferative or severe non-proliferative diabetic retinopathy; AND
	• Patient does NOT have Prader-Willi syndrome with > 1 of the following:
	  ○ severe obesity
	  ○ history of upper airway obstruction or sleep apnea
	  ○ severe respiratory impairment
	  ○ unidentified respiratory infection; AND
	• Trial and therapeutic failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of 2 preferred agents.
	
	Renewal Criteria
		Passed
		5 For
		0 Against

	Description of Recommendation	P & T Vote
	• Patient continues to meet the above criteria; AND • Patient has not had unacceptable toxicity from the drug; AND • Patient has a positive response compared to pre-treatment baseline **Age Limit:** ≥ 3 years **Quantity Limit:** none	
5	**New Product to Market: Olpruva™** Non-PDL Class **Length of Authorization:** 1 year • Sodium phenylbutyrate (Olpruva) is a nitrogen-binding agent indicated as adjunctive therapy to standard of care, which includes dietary management, for the chronic management of adult and pediatric patients weighing 20 kg or greater and with a body surface area (BSA) of 1.2 m^2 or greater, with urea cycle disorders (UCDs) involving deficiencies of carbamylphosphate synthetase (CPS), ornithine transcarbamylase (OTC), or argininosuccinic acid synthetase (AS). **Initial Approval Criteria:** • Patient is diagnosed with a urea cycle disorder involving deficiency of CPS, OTC, or AS; AND • Patient weighs 20 kg or greater with a body surface area ≥ 1.2 m^2; AND • Prescribed by, or in consultation with, a specialist experienced in the treatment of urea cycle disorders; AND • Requested drug is not being used for acute hyperammonemia **Renewal Criteria** • Patient has a documented response to therapy • Patient has not experienced any treatment limiting adverse effects	**Passed** **5 For** **0 Against**
6	**New Product to Market: Skyclarys™** Non-PDL Class **Length of Authorization:** 1 year • Omaveloxolone (Skyclarys) is indicated for the treatment of Friedreich's ataxia (FA) in adults and adolescents aged ≥ 16 years. **Initial Approval Criteria:** • Patient has a diagnosis of Friedreich's ataxia as confirmed by molecular genetic testing and detection of biallelic pathogenic variant in the FXN gene and clinical signs and symptoms (e.g., ataxia, speech disturbance, sensory dysfunction, etc.) that is consistent with Friedreich's ataxia; AND • Patient retains meaningful voluntary motor function (e.g., manipulate objects using upper extremities, ambulates); AND • Patient does not have pes cavus defined as having a loss of lateral support and was determined if light from a flashlight could be seen under the patient's arch when	**Passed** **5 For** **0 Against**

	Description of Recommendation	P & T Vote

	barefoot and weight bearing; AND
	• Patient does not have a history of clinically significant left-sided heart disease and/or clinically significant cardiac disease (Note: excludes mild to moderate cardiomyopathy associated with Friedreich's ataxia); AND
	• Patient does not have signs of very advanced disease (e.g., cardiomyopathy by transthoracic echocardiogram); AND
	• Patient B-Type Natriuretic Peptide (BNP) is ≤ 200 pg/mL prior to initiating therapy and will be monitored periodically during treatment; AND
	• Prescriber will assess the following prior to therapy initiation and periodically during therapy as recommended in the product label:
	  ○ Liver function (alanine transaminase [ALT], aspartate transaminase [AST], bilirubin); AND
	  ○ Lipid parameters; AND
	• Patient does not have severe hepatic impairment (Child-Pugh C); AND
	• Patient has the ability to swallow capsules; AND
	• Patient will avoid concomitant therapy with any of the following:
	  ○ Moderate or strong CYP3A4 inhibitors (e.g., fluconazole, itraconazole); if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; AND
	  ○ Moderate or strong CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's wort); AND
	• Patients of reproductive potential have been advised to use nonhormonal contraceptive method (e.g., non-hormonal intrauterine system, condoms) during omaveloxolone therapy and for 28 days after discontinuation.
	
	Renewal Criteria
	• Patient must continue to meet the above criteria; AND
	• Patient must have disease improvement as defined by stabilization OR slowed progression of disease signs and symptoms (e.g., bulbar function, upper/lower limb coordination, upright stability) from pretreatment baseline; AND
	• Patient has not experienced any treatment-restricting adverse effects (e.g., fluid overload, heart failure; ALT or AST >5x the ULN or >3x the ULN with signs of liver dysfunction).
	Age Limit: ≥ 16 years old
	Quantity Limit: 90 capsules per 30 days	

7	**New Product to Market: Vyjuvek™** Non-PDL Class **Length of Authorization:** 6 months initial, 1 year renewal • Beremagene geperpavec-svdt (Vyjuvek) is a herpes-simplex virus type 1 (HSV-1) vector-based gene therapy indicated for the treatment of wounds in patients ≥ 6 months of age with dystrophic epidermolysis bullosa (DEB) with mutation(s) in the collagen type VII alpha 1 chain (COL7A1) gene.	**Passed** **5 For** **0 Against**

	Description of Recommendation	P & T Vote
	Criteria for Approval: • Age ≥ 6 months; AND • Patient has not received a skin graft within the past 3 months; AND • Prescribed by, or in consultation with, a dermatologist or other specialist with expertise in the treatment of DEB; AND • Patient has a genetically confirmed diagnosis of dystrophic epidermolysis bullosa with mutation in the COL7A1 gene (documentation required); AND • Patient has cutaneous wound(s) which are clean with adequate granulation tissue, excellent vascularization, and do not appear infected; AND • Patient is receiving standard-of-care wound therapy; AND • Patient has not received or is being considered for other gene therapy, or investigational cellular therapy. **Renewal Criteria** • Patient must continue to meet the above criteria; AND • Patient has not experienced any unacceptable toxicity from the drug (e.g., severe medication reactions resulting in discontinuation of therapy); AND • Patient must have disease response as defined by improvement (healing) of treated wound(s), reduction in skin infections, etc.; AND • Patient requires continued treatment for new and/or existing open wounds. **Age Limit**: none **Quantity Limit**: 4 vials per 28 days	
8	**Anti-Emetics: Other** • DMS to select preferred agent(s) based on economic evaluation; however, at least 4 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 *Anti-Emetics: Other* class, require PA until reviewed by the P&T Committee.	**Passed** **5 For** **0 Against**
9	**Cytokine and CAM 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 require PA. • For any new chemical entity in the *Cytokine and CAM Antagonists* class, require PA until reviewed by the P&T Advisory Committee.	**Passed** **5 For** **0 Against**
10	**Ophthalmic Quinolones** • 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 require PA. • For any new chemical entity in the *Ophthalmic Quinolones* class, require PA until reviewed by the P&T Advisory Committee.	**Passed** **5 For** **0 Against**

	Description of Recommendation	P & T Vote
11	**Antipsychotics: 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 *Antipsychotics: Injectable* class, require PA until reviewed by the P&T Committee.	**Passed** **5 For** **0 Against**
12	**COPD Agents** • DMS to select preferred agent(s) based on economic evaluation; however, at least 4 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 *COPD Agents* class, require PA until reviewed by the P&T Committee.	**Passed** **5 For** **0 Against**
13	**Diabetes: GLP-1 Receptor Antagonists** • DMS to select preferred agent(s) based on economic evaluation; however, at least 3 unique chemical entities should be preferred. • Agents not selected as preferred will be considered non-preferred and require PA. • For any new chemical entity in the *Diabetes: GLP-1 Receptor Antagonists* class, require PA until reviewed by the P&T Advisory Committee.	**Passed** **4 For** **0 Against** **1 Abstain**
14	**Glucagon 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 require PA. • For any new chemical entity in the *Glucagon Agents* class, require PA until reviewed by the P&T Advisory Committee.	**Passed** **5 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 require PA. • For any new chemical entity in the *Growth Hormones* class, require PA until reviewed by the P&T Advisory Committee.	**Passed** **5 For** **0 Against**
16	**Immunomodulators, Atopic Dermatitis** • 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 require PA. • For any new chemical entity in the *Immunomodulators, Atopic Dermatitis* class, require PA until reviewed by the P&T Advisory Committee.	**Passed** **5 For** **0 Against**
17	**Multiple Sclerosis Agents** • DMS to select preferred agent(s) based on economic evaluation; however, at least 5 unique chemical entities should be preferred. • Agents not selected as preferred will be considered non-preferred and will require PA.	**Passed** **5 For** **0 Against**

	Description of Recommendation	P & T Vote
	• For any new chemical entity in the *Multiple Sclerosis Agents* class, require PA until reviewed by the P&T Advisory Committee.	
18	**Ophthalmic Immunomodulators** • 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 require PA. • For any new chemical entity in the *Ophthalmic Immunomodulators* class, require PA until reviewed by the P&T Advisory Committee.	**Passed** **5 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

10	• Acne Agents, Oral
	• Acne Agents, Topical
	• Antibiotics, Topical
	• Anticholinergics/Antispasmodics
	• Antidiarrheals
	• Antiemetics & Antivertigo Agents
	  ○ Oral Anti-Emetics: 5-HT3 Antagonists
	  ○ Oral Anti-Emetics: NK-1 Antagonists
	  ○ Oral Anti-Emetics: Δ-9-THC Derivatives
	• Antifungals, Topical
	• Antiparasitic, Topical
	• Antipsoriatic, Oral
	• Antipsoriatic, Topical
	• Anti-Ulcer Protectants
	• Antivirals, Topical
	• Bile Salts
	• GI Motility, Chronic
	• Histamine II Receptor Blockers (H2 Receptor Antagonists)
		Passed
		5 For
		0 Against

	Therapeutic Classes	P & T Vote

	• H. pylori Treatment
	• Immunomodulators, Asthma
	• Immunosuppressives, Oral (Immunosuppressants)
	• Laxatives and Cathartics
	• Ophthalmic, Allergic Conjunctivitis
	  ○ Ophthalmic Antihistamines
	  ○ Ophthalmic Mast Cells Stabilizers
	• Ophthalmic, Antibiotics
	  ○ Ophthalmic Antibiotics, Non-Quinolones
	• Ophthalmic, Antibiotics-Steroid Combinations
	• Ophthalmic, Anti-inflammatories
	  ○ Ophthalmic NSAIDs
	  ○ Ophthalmic Anti-inflammatory Steroids
	• Ophthalmic, Antivirals
	• Ophthalmic, Glaucoma Agents
	  ○ Ophthalmic Beta Blockers
	  ○ Ophthalmic Carbonic Anhydrase Inhibitors
	  ○ Ophthalmic Combinations for Glaucoma
	  ○ Ophthalmic Prostaglandin Agonists
	  ○ Ophthalmic Sympathomimetics
	  ○ Ophthalmic Glaucoma Agents, Other
	• Ophthalmic, Mydriatics & Mydriatic Combinations
	• Ophthalmic Vasoconstrictors
	• Otic Antibiotics
	• Otic Anesthetic and Anti-Inflammatories
	• Proton Pump Inhibitors
	• Rosacea Agents, Topical
	• Steroids, Topical
	• Spinal Muscular Atrophy	

	Therapeutic Classes	P & T Vote
	• Ulcerative Colitis Agents	