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 18th, 2021,** 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: Brexafemme®** **Non-prefer in the PDL class:** *Antifungals: Oral* **Length of Authorization:** Date of Service • Ibrexafungerp (Brexafemme) is a triterpenoid antifungal indicated for the treatment of adult and post-menarchal pediatric females with vulvovaginal candidiasis (VVC). **Criteria for Approval** • Patient is post-menarchal female; AND • Diagnosis of vulvovaginal candidiasis (VVC); AND • Females of reproductive potential must have negative pregnancy test; AND • Patient must have an adequate trial and failure, contraindication, resistance, or intolerance of at least single dose 150 mg oral fluconazole. **Renewal Criteria** • Coverage is not renewable **Quantity Limit:** 4 tablets per fill	**Passed** 10 For 0 Against
2	**New Product to Market: Kerendia®** **Non-PDL drug class agent requiring PA** **Length of Authorization: 1 year** • Kerendia® (finerenone) is a non-steroidal mineralocorticoid receptor antagonist (MRA) indicated to reduce the risk of sustained estimated glomerular filtration rate (eGFR) decline, end stage kidney disease, cardiovascular death, non-fatal myocardial infarction, and hospitalization for heart failure in adult patients with chronic kidney disease (CKD) associated with type 2 diabetes (T2D). **Criteria for Approval:** **Initial Approval Criteria** • Patient has a diagnosis of type 2 diabetes; **AND** • Patient has a diagnosis of chronic kidney disease (CKD); **AND** • Patient has eGFR ≥ 25 mL/min/1.73 m^2; **AND** • Patient must NOT be concomitantly receiving strong CYP3A4 inhibitors; **AND** • Patient must NOT have adrenal insufficiency; **AND** • Patient must NOT have severe hepatic impairment (Child Pugh C); **AND** • Serum potassium is ≤ 5 mEq/L. **Renewal Criteria** • Patient must continue to meet the above criteria; **AND** • Patient must have disease improvement and/or stabilization OR improvement in the slope of decline (based on UACR or eGFR); **AND**	**Passed** 10 For 0 Against

	Description of Recommendation	P & T Vote
	• Patient has NOT experienced any treatment-restricting adverse effects (e.g., hyperkalemia). **Age Limit:** ≥18 years **Quantity Limit:** 1 per day	

3	**New Products to Market – Verquvo®**
	Non-PDL drug class agent requiring PA
	Length of Authorization: 1 year
	• Verquvo® (vericiguat), a soluble guanylate cyclase (sGC) stimulator, is indicated to reduce the risk of cardiovascular (CV) death and heart failure (HF) hospitalization following a hospitalization for HF or need for outpatient intravenous (IV) diuretics, in adults with symptomatic chronic HF and ejection fraction (EF) < 45% (HF with reduced EF [HFrEF]).
	Criteria for Approval:
	Initial Approval Criteria
	• Patient has a diagnosis of heart failure; **AND**
	• Patient's ejection fraction is < 45%; **AND**
	• Patient meets ≥ 1 of the following criteria:
	  ○ Patient has required the use of intravenous diuretics as an outpatient in the past 3 months; **OR**
	  ○ Patient was recently hospitalized for heart failure (within the last 6 months); **AND**
	• Patient is on guideline-directed therapy for heart failure, unless contraindicated (e.g., beta-blocker, angiotensin-converting enzyme [ACE] inhibitor or angiotensin II receptor blockers [ARB], and mineralocorticoid receptor antagonists/aldosterone antagonists); **AND**
	• Patient is NOT taking another soluble guanylate cyclase (sGC) stimulator or phosphodiesterase-5 (PDE-5) inhibitor; **AND**
	• If patient is of childbearing potential, patient is NOT pregnant **AND** is using contraception.
	Renewal Criteria
	• Patient continues to meet above criteria; **AND**
	• Prescriber attestation that patient is responding positively to treatment (e.g., symptom improvement, slowing of decline); **AND**
	• Patient has NOT experienced treatment-limiting adverse effects (e.g., symptomatic hypotension).
	Age Limit: ≥18 years
	Quantity Limit: 1 per day
		Passed
		10 For
		0 Against

4	**Diabetes: DPP-4 Inhibitors** • DMS to select preferred agent(s) based on economic evaluation; however, at least two 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; DPP-4 Inhibitors* class, require PA until reviewed by the P&T Advisory Committee. **Diabetes: GLP-1 Agonists** • DMS to select preferred agent(s) based on economic evaluation; however, at least one product FDA approved to reduce the risk of major adverse cardiovascular event (MACE) in patients with Diabetes 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 Agonists* class, require PA until reviewed by the P&T Advisory Committee.	**Passed** 10 For 0 Against
5	**Pulmonary Hypertension (PAH) Agents** • DMS to select preferred agent (s) based on economic evaluation; however, at least one agent representing three of the unique mechanisms of action should be	**Passed** 10 For 0 Against

	Description of Recommendation	P & T Vote
	preferred. • Agents not selected as preferred will be considered non-preferred and will require Prior Authorization. • For any new chemical entity in the *Pulmonary Arterial Hypertension (PAH)* Agents class, require a PA until reviewed by the P&T Advisory Committee.	
6	**Topical Acne Agents** • DMS to select preferred agent(s) based on economic evaluation; however, at least three 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 *Topical Acne Agents* class, require PA until reviewed by the P&T Advisory Committee.	**Passed** 10 For 0 Against
7	**Oral Antipsoriatics** • DMS to select preferred agent(s) based on economic evaluation; however, at least one 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 *Oral Antipsoriatics* class, require PA until reviewed by the P&T Advisory Committee.	**Passed** 10 For 0 Against
8	**Topical Antipsoriatics** • DMS to select preferred agent(s) based on economic evaluation; however, at least one 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 *Topical Antipsoriatics* class, require PA until reviewed by the P&T Advisory Committee.	**Passed** 10 For 0 Against
9	**Topical Steroids** • DMS to select preferred agent (s) based on economic evaluation; however, at least two agents in each of the potency categories (low, medium, high, and very high) should be preferred. • Agents not selected as preferred will be considered non preferred and require PA. • For any new chemical entity in the *Steroids, Topical* class, require PA until reviewed by the P&T Committee.	**Passed** 10 For 0 Against
10	**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** 10 For 0 Against
11	**Ophthalmic Beta Blockers** • DMS to select preferred agent(s) based upon economic evaluation; however, at least two 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 *Ophthalmic Beta Blockers* class, require PA until reviewed by the P&T Advisory Committee. **Ophthalmic Carbonic Anhydrase Inhibitors** • DMS to select preferred agent(s) based upon economic evaluation; however, at least one 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 *Ophthalmic Carbonic Anhydrase Inhibitors* class, require PA until reviewed by the P&T Advisory Committee. **Ophthalmic Combinations for Glaucoma** • DMS to select preferred agent(s) based upon economic evaluation; however, at least one unique chemical entity should be preferred. • Agents not selected as preferred will be considered non-preferred and will require	**Passed** 10 For 0 Against

	Description of Recommendation	P & T Vote
	PA. • For any new chemical entity in the *Ophthalmic Combinations for Glaucoma* class, require PA until reviewed by the P&T Advisory Committee. **Ophthalmic Prostaglandin Agonists** • DMS to select preferred agent(s) based upon economic evaluation; however, at least one 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 *Ophthalmic Prostaglandin Agonists* class, require PA until reviewed by the P&T Advisory Committee. **Ophthalmic Sympathomimetics** • DMS to select preferred agent(s) based upon economic evaluation; however, at least one 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 *Ophthalmic Sympathomimetics* class, require PA until reviewed by the P&T Advisory Committee. **Ophthalmic Glaucoma Agents (Other)** • DMS to select preferred agent(s) based upon economic evaluation; however, at least one 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 *Glaucoma Agents (Other)* class, require PA until reviewed by the P&T Advisory Committee.	

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

6	• Acne Agents, Oral
	• Antibiotics, Topical
	• Antifungals, Topical
	• Antiparasitics, Topical
	• Antivirals, Topical
	• Rosacea Agents, Topical
	• Antiemetics & Antivertigo Agents
	  ○ Anti-Emetics: Other
	  ○ Oral Anti-Emetics: 5-HT3 Antagonists
	  ○ Oral Anti-Emetics: NK-1 Antagonists
	  ○ Oral Anti-Emetics: Δ-9-THC Derivatives
	• Antispasmodics/Anticholinergics
	• Antidiarrheals
	• Anti-Ulcer Protectants
	• Bile Salts
	• GI Motility Agents
	• H. pylori Treatment
	• Histamine II Receptor Blockers
	  ○ H2Receptor Antagonists
	• Laxatives and Cathartics
	• Proton Pump Inhibitors
	• Ulcerative Colitis Agents
		Passed
		10 For
		0 Against

	Therapeutic Classes	P & T Vote

	• Immunomodulators, Atopic Dermatitis
	• Immunosuppressives, Oral
	  ○ Immunosuppressants
	• Multiple Sclerosis Agents
	• Spinal Muscular Atrophy
	• Ophthalmics, Allergic Conjunctivitis
	  ○ Ophthalmic Antihistamines
	  ○ Ophthalmic Mast Cells Stabilizers
	• Ophthalmics, Anti-inflammatories
	  ○ Ophthalmic NSAIDs
	  ○ Ophthalmic Anti-inflammatory Steroids
	• Ophthalmics, Antibiotics-Steroid Combinations
	• Ophthalmics, Antibiotics
	  ○ Ophthalmic Quinolones
	  ○ Ophthalmic Antibiotics, Non-Quinolones
	• Ophthalmics, Antivirals
	• Ophthalmic Immunomodulators
	• Ophthalmics, Mydriatics & Mydriatic Combinations
	• Ophthalmic Vasoconstrictors
	• Otic Antibiotics
	• Otics, Anti-Inflammatories
	  ○ Otic Anesthetics and Anti-Inflammatories	