Kentucky Department for Medicaid Services
Drug Review and Options for Consideration

The following tables list the Agenda items as well as the Options for Consideration that are scheduled to be presented and reviewed at the **November 18, 2021** meeting of the Pharmacy and Therapeutics Advisory Committee.

Single Agent Reviews	Options for Consideration
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
New Product to Market: **Kerendia®**	**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**

Single Agent Reviews	Options for Consideration
	• 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** • Patient has NOT experienced any treatment-restricting adverse effects (e.g., hyperkalemia). **Age Limit**: ≥ 18 years **Quantity Limit**: 1 per day

New Product to Market:
Verquvo®
	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

Full Class Reviews	Options for Consideration
Hypoglycemics, Incretin Mimetics/Enhancers **(Diabetes: DPP-4 Inhibitors, Diabetes: GLP-1 Agonists)**	**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.
Pulmonary Hypertension (PAH) Agents	**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 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.
Acne Agents, Topical	**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.
Antipsoriatics, Oral	**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.
Antipsoriatics, Topical	**Topical Antipsoriatics** • DMS to select preferred agent(s) based on economic evaluation; however, at least one unique chemical entity should be preferred.

Full Class Reviews	Options for Consideration
	• 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.
Steroids, Topical (High, Low, Medium, Very High)	**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.
Cytokine and CAM Antagonists **(Immunomodulators)**	**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.
Ophthalmics, Glaucoma Agents **(Ophthalmic Beta Blockers, Ophthalmic Carbonic Anhydrase Inhibitors, Ophthalmic Combinations for Glaucoma, Ophthalmic Prostaglandin Agonists, Ophthalmic Sympathomimetics, Ophthalmic Glaucoma Agents [Other])**	**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 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**

Full Class Reviews	Options for Consideration
	• 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	Options for Consideration
For the following therapeutic classes, there are **no recommended changes to the Preferred Drug List (PDL) status**; these may be voted on as a group:	

• 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
	• 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