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 17, 2022** meeting of the Pharmacy and Therapeutics Advisory Committee.

Single Agent Reviews	Options for Consideration
New Product to Market: **Ztalmy®**	Non-prefer in the PDL class: *Anticonvulsants: Second Generation* **Length of Authorization:** 1 year • Ganaxolone (Ztalmy) is a neuroactive steroid gamma-aminobutyric acid (GABA) A receptor positive modulator indicated for the treatment of seizures associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD) in patients ≥ 2 years of age. **Initial Approval Criteria** • Patient is ≥ 2 years of age; AND • Patient has a diagnosis of seizures associated with cyclin dependent kinase-like 5 (CDKL5) deficiency disorder (CDD) confirmed with genetic testing; AND • Patient has tried ≥ 2 other anticonvulsant medications; AND • Patient will avoid concomitant therapy with moderate or strong CYP450 inducers (e.g., carbamazepine, phenobarbital, phenytoin, omeprazole), or if concomitant therapy is unavoidable, dose adjustments will be considered; AND • Ganaxolone is prescribed by or in consultation with a neurologist. **Renewal Criteria** • Patient must continue to meet the above criteria; AND • Prescriber attests to stabilization of disease or reduction in seizure frequency from baseline; AND • Patient has not experienced any treatment-restricting adverse effects (e.g., somnolence, pyrexia, suicidal thoughts or behavior) **Quantity Limit**: 1800mg (36mL) per day **Age Limit:** 2 years of age
New Product to Market: **Zoryve®**	Non-prefer in the PDL class: *Topical Psoriasis Agents* **Length of Authorization:** 1 year • Phosphodiesterase 4 (PDE-4) inhibitor indicated for topical treatment of plaque psoriasis, including intertriginous areas (e.g., groin folds, axillae, gluteal cleft), in patients ≥ 12 years old **Criteria for Approval:** • Patient must have an adequate trial and failure, contraindication or

Single Agent Reviews	Options for Consideration
	intolerance, of at least two preferred medications within the last 90 days **Age Limit**: ≥ 12 years **Quantity Limit**: 1 tube per 30 days
New Product to Market: **Vivjoa®**	Non-prefer in the PDL class: *Antifungals, Oral* **Length of Authorization:** 1 year • Oteseconazole (Vivjoa) is an azole antifungal indicated to reduce the incidence of recurrent vulvovaginal candidiasis (RVVC) in females with a history of RVVC who are NOT of reproductive potential. **Criteria for Approval:** **Initial Approval Criteria** • Patient has diagnosis of recurrent vulvovaginal candidiasis with ≥3 episodes of vulvovaginal candidiasis (VVC) in a 12-month period; AND • Patient is a biological female who is postmenopausal or has another reason for permanent infertility (e.g., tubal ligation, hysterectomy, salpingo-oophorectomy); AND • Patient must not have hypersensitivity to any component of the product; AND • Patient is not pregnant; AND • Patient is not lactating; AND • Patient has tried and failed or has a contraindication or intolerance to maintenance antifungal therapy with oral fluconazole x 6 months **Renewal Criteria** • Cannot be renewed for the same course of infection **Age Limit**: none **Quantity Limit**: 18 tablets per treatment course

New Product to Market: **Sotyktu®**	Non-prefer in the PDL class: *Cytokine and CAM Antagonists*
	
	Length of Authorization: 1 year
	• Deucravacitinib (Sotyktu) is a tyrosine kinase 2 (TYK2) inhibitor indicated for the treatment of adults with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy. It is not recommended for use in combination with other potent immunosuppressants.
	Criteria for Approval:
	• Diagnosis of moderate to severe plaque psoriasis; AND
	• Prescribed by, or in consultation with, a dermatologist, rheumatologist or other specialist in the treatment of psoriasis; AND
	• Symptoms persistent for ≥ 6 months with at least 1 of the following:
	  ○ Involvement of at least 3% of body surface area (BSA); OR
	  ○ Psoriasis Area and Severity Index (PASI) score of 10 or greater; OR
	  ○ Incapacitation due to plaque location (i.e., head and neck, palms, soles, or genitalia); AND

Single Agent Reviews	Options for Consideration

	• Trial and failure (at least 3 months) of ≥ 1 conventional therapy:
	  ○ Disease-modifying anti-rheumatic drug (DMARD), such as methotrexate
	  ○ Immunosuppressant (e.g., cyclosporine)
	  ○ Oral retinoid (e.g., acitretin); AND
	• NOT used in combination with any other biologic agent; AND
	• For non-preferred agents: 3-month trial and failure of, contraindication or intolerance to, ≥ 1 preferred cytokine or CAM antagonist indicated for the treatment of this condition; AND
	• Patient must meet the minimum age recommended by the package insert for this FDA-approved indication.
	Renewal Criteria:
	  • Documentation (e.g., progress note) of response to therapy compared to baseline, such as redness, thickness, scaliness, amount of surface area involvement, and/or PASI score.
	Age Limit: ≥ 18 years
	Quantity Limit: 1 per day

Tyvaso® Tyvaso DPI™	Non-prefer in the PDL class: *Pulmonary Arterial Hypertension (PAH) Agents* **Length of Authorization:** 1 year • Treprostinil (Tyvaso® Tyvaso DPI™) is a prostacyclin mimetic indicated for the treatment of pulmonary arterial hypertension [PAH; World Health Organization (WHO) Group 1] to improve exercise ability and pulmonary hypertension associated with interstitial lung disease (PH-ILD; WHO Group 3) to improve exercise ability. **Initial Approval Criteria:** *Pulmonary Arterial Hypertension (PAH)* • Diagnosis of Pulmonary Arterial Hypertension (PAH) WHO Group 1 • Prescribed by, or in consultation with, a cardiologist or a pulmonologist • Patient has trial and therapeutic failure, allergy, contraindication or intolerance to 2 or more preferred agents for at least 1 month. *Pulmonary Hypertension Associated with Interstitial Lung Disease* • Diagnosis of Pulmonary Hypertension Associated with Interstitial Lung Disease WHO Group 3 • Prescribed by, or in consultation with, a cardiologist or a pulmonologist • Baseline forced vital capacity < 70% for patients with connective tissue disease • Patient has had a right heart catheterization [documentation required] • Results of the right heart catheterization confirm the diagnosis of WHO Group 3 interstitial lung disease associated with pulmonary hypertension **Renewal Criteria** • Patient has a documented response to therapy • Patient has not experienced any treatment limiting adverse effects

Full Class Reviews	Options for Consideration
Anticonvulsants (Anticonvulsants: First Generation)	**Anticonvulsants: First Generation** • 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 require PA. • For any new chemical entity in the *Anticonvulsants: First Generation* class, require PA until reviewed by the P&T Advisory Committee.
Antifungals, Topical	**Topical Antifungal Agents** • 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 Antifungals Agents* class, require PA until reviewed by the P&T Advisory Committee.
Anti-Emetics/ Anti-vertigo Agents, Other	**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.
Antivirals, Topical	**Topical Antiviral Agents** • 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 Antiviral Agents* class, require PA until reviewed by the P&T Advisory Committee.
GI Motility, Chronic	**GI Motility 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 require PA. • For any new chemical entity in the *GI Motility Agents* class, require PA until reviewed by the P&T Advisory Committee.
Immunomodulators, Atopic Dermatitis	**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.
Multiple Sclerosis Agents	**Multiple Sclerosis Agents**

Full Class Reviews	Options for Consideration
	• 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. • For any new chemical entity in the *Multiple Sclerosis Agents* 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 *Topical Steroids* class, require PA until reviewed by the P&T 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
• 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
• Antiparasitic, Topical
• Antipsoriatic, Oral
• Antipsoriatics, Topical
• Anti-Ulcer Protectants
• Bile Salts
• Cytokine and CAM Antagonists
• Histamine II Receptor Blockers (H2 Receptor Antagonists)
• *H. pylori* Treatment
• Immunomodulators, Asthma
• Immunosuppressives, Oral (Immunosuppressants)
• Laxatives and Cathartics
• Ophthalmics, Allergic Conjunctivitis
  ○ Ophthalmic Antihistamines
  ○ Ophthalmic Mast Cells Stabilizers
	• Ophthalmics, Antibiotics
	  ○ Ophthalmic Quinolones
	  ○ Ophthalmic Antibiotics, Non-Quinolones
	• Ophthalmics, Antibiotics-Steroid Combinations
	• Ophthalmics, Anti-inflammatories
	  ○ Ophthalmic NSAIDs
	  ○ Ophthalmic Anti-inflammatory Steroids
	• Ophthalmics, Antivirals
	• Ophthalmics, Glaucoma Agents
	  ○ Ophthalmic Beta Blockers
	  ○ Ophthalmic Carbonic Anhydrase Inhibitors
	  ○ Ophthalmic Combinations for Glaucoma
	  ○ Ophthalmic Prostaglandin Agonists
	  ○ Ophthalmic Sympathomimetics
	  ○ Ophthalmic Glaucoma Agents,Other
	• Ophthalmic Immunomodulators
	• Ophthalmics, Mydriatics & Mydriatic Combinations
	• Ophthalmic Vasoconstrictors
	• Otic Antibiotics
	• Otic Anesthetic and Anti-Inflammatories
	• Proton Pump Inhibitors
	• Proton Pump Inhibitors
	• Rosacea Agents, Topical
	• Spinal Muscular Atrophy
	• Ulcerative Colitis Agents