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 **September 15, 2022** meeting of the Pharmacy and Therapeutics Advisory Committee.

Clinical Criteria Review	Options for Consideration
Quviviq™	Non-preferred in the PDL class: *Sedative Hypnotic Agents* **Length of Authorization:** 6 months, 1 year renewal • Daridorexant (Quviviq™) is an orexin receptor antagonist indicated in the treatment of adult patients with insomnia characterized by difficulties with sleep onset and/or sleep maintenance. **Criteria for Approval:** • Approval of non-preferred agents requires trial and therapeutic failure, allergy, contraindication (including potential drug-drug interactions with other medications) or intolerance of 2 preferred agents, unless otherwise specified **Maximum Duration:** 60 days **Age Limit:** ≥ 18 years **Quantity Limit:** 30 tablets/30 days
Igalmi™	Non-preferred in the PDL class: *Sedative Hypnotic Agents* **Length of Authorization:** 12 months • Dexmedetomidine (Igalmi™) is an alpha-2 adrenergic agonist indicated in adults for the acute treatment of agitation associated with schizophrenia or bipolar I or II disorder. **Initial Approval Criteria** • Patient has agitation associated with a confirmed diagnosis of schizophrenia or bipolar disorder, defined as meeting DSM-5 criteria for schizophrenia, schizoaffective, or schizophreniform disorder or bipolar I or II disorder; AND • Agitation is NOT due to acute intoxication; AND • Prescriber attestation that patient will be monitored by a healthcare provider, including an assessment of vital signs and alertness to prevent falls and syncope; AND • Patient is NOT taking medications known to prolong the QT interval; AND • Prescriber attestation that patient has been advised to avoid activities requiring mental alertness for at least 8 hours following administration. **Renewal Criteria** • Patient must continue to meet the above criteria; AND

Clinical Criteria Review	Options for Consideration
	• Prescriber attestation of response (patient not requiring alternative agents following treatment of mild to moderate agitation); AND • Patient has not experienced any treatment-restricting adverse effects (e.g., syncope, orthostatic hypotension, fall, QT prolongation, symptomatic bradycardia). **Age limit:** ≥ 18 years **Quantity Limit:** 120 mcg film: 2 per day 180 mcg film: 2 per day

Ibsrela®	Non-preferred in the PDL class: *GI Motility Agents*
	
	Length of Authorization: 1 year
	• Tenapanor (Ibsrela) is a locally acting, sodium/hydrogen exchanger 3 (NHE3) inhibitor indicated for irritable bowel syndrome with constipation (IBS-C) in adults.
	
	Criteria for Approval
	• Patient does NOT have known or suspected mechanical GI obstruction; AND
	• Patient does NOT have severe diarrhea; AND
	• Patient has failed on 1 of the following regimens:
	  ○ Osmotic laxatives; OR
	  ○ Antispasmodics; AND
	• Patient has had 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: ≥ 18 years
	Quantity Limit: 60 tablets/30 days

Mounjaro™	Non-preferred in the PDL class: *Diabetes: GLP-1 Receptor Agonists* **Length of Authorization:** 1 year • Tirzepatide (Mounjaro) is a glucose-dependent insulinotropic polypeptide (GIP) receptor agonist and glucagon-like peptide-1 (GLP-1) receptor agonist indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus (T2DM). **Criteria for Approval** • Diagnosis of Type II Diabetes Mellitus; AND • Trial and failure, intolerance or contraindication to metformin. OR • Diagnosis of chronic kidney disease (ICD-10 Group N18) AND trial and failure of, intolerance or contraindication to ≥ 1 SGLT2 inhibitor plus metformin; OR • Diagnosis of atherosclerotic cardiovascular disease (ASCVD); OR • Diagnosis of heart failure with reduced ejection fraction AND trial and failure of, intolerance or contraindication to ≥ 1 SGLT2 inhibitor. AND • Trial and therapeutic failure, allergy, contraindication (including potential drug-drug interactions with other medications) or intolerance of at least 3-month therapy with 1 preferred GLP-1 agent, unless otherwise specified. **Age Limit**: none **Quantity Limit**: 4 pens per 28 days
Vtama®	Non-preferred in the PDL class: *Topical Psoriasis Agents*

Clinical Criteria Review	Options for Consideration
	Length of Authorization: 1 year • Tapinarof (Vtama) cream is an aryl hydrocarbon receptor agonist indicated for the topical treatment of plaque psoriasis in adults **Criteria for Approval** • Patient must have an adequate trial and failure, contraindication or intolerance, of at least two preferred medications within the last 90 days **Age Limit**: ≥ 18 years **Quantity Limit**: 1 tube per 30 days
Voquezna™	Non-preferred in the PDL class: *H. pylori Treatment* **Length of Authorization:** Date of Service Only • Vonoprazan is a novel potassium-competitive acid blocker (PCAB) co-packaged with the penicillin antibacterial amoxicillin (Voquezna Dual Pak), and with amoxicillin and the macrolide clarithromycin (Voquezna Triple Pak) for the treatment of Helicobacter pylori (H. pylori) infection in adults. **Criteria for Approval** • Trial and therapeutic failure of a complete course of therapy, allergy, contraindication (including potential drug-drug interactions with other medications) or intolerance of a preferred agent OR combination therapy comprised of individual, generic agents **Age Limit**: none **Quantity Limit:** Voquezna Dual Pak: 1 carton of 28 tablets and 84 capsules per 14-day supply Voquezna Triple Pak: 1 carton of 56 tablets and 56 capsules per 14-day supply
Camzyos™	Non PDL class **Length of Authorization:** 1 year • Mavacamten (Camzyos) is a reversible selective cardiac myosin inhibitor indicated for the treatment of adults with symptomatic New York Heart Association (NYHA) class 2 to class 3 obstructive hypertrophic cardiomyopathy (HCM) to improve functional capacity and symptoms. **Initial Approval Criteria** • Patient has a diagnosis of obstructive hypertrophic cardiomyopathy (oHCM) consistent with current guidelines (e.g., American College of Cardiology Foundation/American Heart Association, European Society of Cardiology guidelines); AND • Patient has New York Heart Association (NYHA) Class 2 or Class 3 disease; AND • Patient has documented left ventricular ejection fraction (LVEF) ≥ 55%; AND • Patient will be monitored for LVEF, Valsalva left ventricular outflow tract (LVOT) gradient assessment, and heart failure symptoms); AND • Patient will avoid concomitant use with moderate to strong CYP2C19 inhibitors, strong CYP3A4 inhibitors, and moderate to strong CYP2C19 and CYP3A4 inducers (e.g., carbamazepine, cimetidine, esomeprazole, omeprazole, phenobarbital, phenytoin, rifampin, St. John's wort); AND • Patient will avoid concomitant dual therapy with a beta-blocker and calcium channel blocker or monotherapy with disopyramide or ranolazine; AND

Clinical Criteria Review	Options for Consideration
	• For females of childbearing potential, a pregnancy test is performed before starting therapy; AND • Mavacamten is prescribed by or in consultation with a cardiologist; AND • Patient must have an adequate trial and failure of ≥ 1 beta-blocker. **Renewal Criteria** • Patient must continue to meet the above criteria (not including prerequisite therapy); AND • Patient must have disease improvement and/or stabilization of disease from baseline (e.g., at least 1 NYHA class decrease, ≥ 1.5 mL/kg/min in pVO2 increase or ≥ 3 mL/kg/min in pVO2 without NYHA class worsening); AND • Patient has NOT have experienced any treatment-restricting adverse effects (e.g., heart failure, LVEF < 50%); AND • Patient will continue to be monitored for LVEF, Valsalva LVOT gradient, and heart failure symptoms. **Age limit:** Patient is ≥ 18 years of age **Quantity limit:** 30 capsules/30 days

Full Class Reviews	Options for Consideration
Angiotensin Modulators **(Ace Inhibitors)**	**Ace Inhibitors** • DMS to select preferred agent(s) based on economic evaluation; however, at least 2 distinct combinations should be preferred. • Agents not selected as preferred will be considered non-preferred and require PA. • For any new chemical entity in the *Ace Inhibitors* class, require PA until reviewed by the P&T Advisory Committee.
Anticonvulsants **(Anticonvulsants: Second Generation)**	**Anticonvulsants: Second Generation** • DMS to select preferred agent(s) based on economic evaluation; however, at least 6 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: Second Generation* class, require PA until reviewed by the P&T Advisory Committee.
Antidepressants, Tricyclics	**Antidepressants: Tricyclics** • DMS to select preferred agent(s) based on economic evaluation; however, at least 3 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 *Antidepressants: Tricyclics* class, require PA until reviewed by the P&T Advisory Committee.
Antiparkinson's Agents **(Dopamine Receptor Agonists)**	**Dopamine Receptor Agonists** • 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 *Dopamine Receptor Agonists* class, require PA until reviewed by the P&T Advisory Committee.

Antipsychotics **(Antipsychotics: Injectable)**	**Antipsychotics: Injectable** • 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 *Antipsychotics: Injectable* class, require PA until reviewed by the P&T Advisory Committee.
Beta-Blockers	**Beta-Blockers** • 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 *Beta Blockers* class, require PA until reviewed by the P&T Advisory Committee.
Calcium Channel Blockers **[Calcium Channel Blockers (Non-DHP)]**	**Calcium Channel Blockers (Non-DHP)** • 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 *Calcium Channel Blockers (Non-DHP)* class, require PA until reviewed by the P&T Advisory Committee.
Movement Disorders	**Movement Disorders** • DMS to select preferred agent(s) based on economic evaluation. • Agents not selected as preferred will be considered non-preferred and will require PA. • For any new chemical entity in the *Movement Disorders* class, require PA until reviewed by the P&T Advisory Committee.
PAH Agents - Oral and Inhaled **(Pulmonary Arterial Hypertension (PAH) Agents)**	**Pulmonary Arterial Hypertension (PAH) 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 require PA. • For any new chemical entity in the *Pulmonary Arterial Hypertension (PAH) Agents* 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 currently posted Preferred Drug List (PDL) status**; these may be voted on as a group:	
• Alzheimer's Agents • Angiotensin Modulators (Angiotensin Receptor Blockers) • Angiotensin Modulator Combinations • Antianginal & Anti-Ischemic • Antiarrhythmics, Oral • Anticoagulants • Anticonvulsants: Carbamazepine Derivatives • Anticonvulsants: First Generation • Antidepressants, Other • Antidepressants, SNRI • Antidepressants, SSRI	• Antiparkinson's Agents (Parkinson's Disease) • Antipsychotics: First-Generation (oral) • Antipsychotics: Second-Generation (oral) • Anxiolytics • Bladder Relaxant Preparations • BPH Treatments • Calcium Channel Blockers (DHP) • Lipotropics, Other • Lipotropics, Statins • Platelet Aggregation Inhibitors • Stimulants and Related Agents • Tobacco Cessation Products