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 21, 2023** meeting of the Pharmacy and Therapeutics Advisory Committee.

Clinical Criteria Review	Options for Consideration
Abilify Asimtufii®	Non-preferred in the PDL class: *Antipsychotics: Injectable* **Length of Authorization:** 1 year • Aripiprazole (Abilify Asimtufii®) is an atypical antipsychotic indicated for the treatment of schizophrenia in adults and as maintenance monotherapy treatment of bipolar I disorder in adults. **Criteria for Approval:** • Pt has a diagnosis of bipolar disorder or schizophrenia; AND • Pt has had at least a 2-week trial of ONE preferred Antipsychotic (oral or parenteral) at an appropriate dose; AND • Patient is established on oral aripiprazole with adequate response and tolerability. **Age Limit:** ≥ 18 years **Quantity Limit:** 1 syringe every 2 months

Daybue™	Non PDL Class
	
	Length of Authorization: 1 year
	• Trofinetide (Daybue) is a synthetic analog of glycine-proline-glutamate that is indicated for the treatment of Rett syndrome in adults and pediatric patients ≥ 2 years of age.
	
	Initial Approval Criteria
	• Patient has a diagnosis of classical/typical or variant/atypical Rett syndrome, as established by both of the following:
	  ○ Molecular genetic testing with heterozygous methyl-CpG binding protein-2 (MECP2) pathogenic variant gene mutations, AND
	  ○ Diagnosis is based on clinical presentation; AND
	  ○ Other causes for symptoms have been ruled out
	• Therapy will NOT be used for other genetically related (allelic) disorders; AND
	• Physician has assessed baseline disease severity of behavior and/or functionality using an objective measure or tool (e.g., Clinical Global Impression-Improvement [CGI-I] score, Motor-Behavior Assessment [MBA], Interval History Form, Clinical Severity Scale, Rett Syndrome Gross Motor Scale); AND
	• Patient does NOT have progressive weight loss prior to initiation of therapy; AND
	• Patient does NOT have moderate or severe renal impairment (e.g., eGFR < 45 mL/min/1.73m2)

Clinical Criteria Review	Options for Consideration
	Renewal Criteria • Patient must have response to therapy from pre-treatment baseline with disease stability or improvement in core symptoms as evidenced by objective measure or tool (e.g., Rett Syndrome Behavior Questionnaire [RSBQ], CGI-I, MBA, Interval History Form, Clinical Severity Scale, Rett Syndrome Gross Motor scale); AND • Patient has NOT experienced any treatment-restricting adverse effects (e.g., severe diarrhea or dehydration, significant weight loss) **Age limit:** 2 years of age or older **Quantity Limit:** 8 bottles every 30 days
Inpefa™	Non-preferred in the PDL class: *Diabetes: SGLT2 Inhibitors* **Length of Authorization**: 1 year • Sotagliflozin (Inpefa) is a sodium-glucose cotransporter 2 (SGLT2) inhibitor indicated to reduce the risk of cardiovascular (CV) death, hospitalization for heart failure (HF), and urgent HF visit in adults with HF or type 2 diabetes mellitus (T2DM), chronic kidney disease (CKD), and other CV risk factors. **Criteria for Approval** • Diagnosis of Type 2 Diabetes Mellitus; AND • Diagnosis of chronic kidney disease (ICD-10 Group N18); AND • Patient has other cardiovascular risk factors; OR • Diagnosis of heart failure; AND • Patient has had ≥ 3 month trial and therapeutic failure, allergy, contraindication (including potential drug-drug interactions with other medications) or intolerance of 1 preferred agent. **Quantity Limit**: 30 tablets/30 days
Sogroya®	Non-preferred in the PDL class: *Growth Hormones* **Length of Authorization:** 1 year • Somapacitan-beco (Sogroya) is a human growth hormone (GH) analog indicated for the replacement of endogenous growth hormone in adults with growth hormone deficiency (GHD) and the treatment of pediatric patients aged 2.5 years and older who have growth failure due to inadequate secretion of endogenous growth hormone (GH). **Criteria for Approval** • Patient will be at least 2.5 years old at the start of treatment; AND • Diagnosis of growth hormone deficiency; AND • Patient does NOT have a hypersensitivity to any somapacitan product 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, or previously had, an intracranial tumor growth as confirmed by a sellar MRI scan with contrast; AND

Clinical Criteria Review	Options for Consideration
	• Patient does NOT have Prader-Willi syndrome with ≥ 1 of the following: severe obesity, have a history of upper airway obstruction or sleep apnea or have severe respiratory impairment, or unidentified respiratory infection; AND • Trial and therapeutic failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of 2 preferred agents. **Criteria for Approval** • 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 **Quantity Limit**: 4 pens per 28 days
Uzedy	Non-preferred in the PDL class: *Antipsychotics: Injectable* **Length of Authorization:** 1 year • Risperidone (Uzedy) is an atypical antipsychotic indicated for the treatment of schizophrenia in adults. **Criteria for Approval:** • Pt has a diagnosis of schizophrenia; AND • Pt has had at least a 2-week trial of ONE preferred Antipsychotic (oral or parenteral) at an appropriate dose; AND • Patient is established on oral risperidone with adequate response and tolerability **Age Limit**: ≥ 18 years **Quantity Limit**: 1 syringe per 30 days
Veozah™	Non-PDL Class **Length of Authorization:** 3 months initial, 1 year renewal • Fezolinetant (Veozah) is a neurokinin 3 (NK3) receptor antagonist indicated for the treatment of moderate to severe vasomotor symptoms (VMS) due to menopause. **Initial Approval Criteria** • Patient has a diagnosis of menopause with moderate to severe vasomotor symptoms; AND • Patient does not have cirrhosis; AND • Patient does not have severe renal impairment or end-stage renal disease; AND • Patient will avoid concomitant therapy with weak, moderate, or strong CYP1A2 inhibitors (e.g., fluvoxamine, mexiletine, cimetidine); AND • Prescriber attests that baseline liver function tests have been conducted and total bilirubin, alanine aminotransferase (ALT), and aspartate aminotransferase (AST) levels are not elevated ≥ 2 times the upper limit of normal (ULN); AND • Prescriber attests that liver function testing follow-up will be conducted as outlined in prescribing information; AND • Patient has trialed and failed, or is not a candidate for, hormone therapy. **Renewal Criteria** • Patient must continue to meet the above criteria; AND • Patient must have symptom improvement; AND

Clinical Criteria Review	Options for Consideration
	• Patient has not experienced any treatment-restricting adverse effects (e.g., ALT or AST > 3 times the ULN). **Age Limit**: ≥ 18 years **Quantity Limit:** 30 tablets per 30 days
Zavzpret™	Non-preferred in the PDL class: Anti-Migraine: CGRP Inhibitors **Length of Authorization:** 1 year • Zavegepant (Zavzpret) is a calcitonin gene-related peptide (CGRP) receptor antagonist indicated for the acute treatment of migraine with or without aura in adults. It is not indicated for the preventive treatment of migraine. **Initial Approval Criteria** • Patient has a diagnosis of migraine with or without aura; AND • Prescriber attestation will NOT be used for preventive treatment of migraine or for chronic migraine; AND • Patient must NOT have hypersensitivity to any component of the product; AND • Patient must have tried and failed or have a contraindication or intolerance to 2 triptans. **Renewal Criteria** • Patient must continue to meet the above criteria; AND • Patient must demonstrate symptom improvement (e.g., resolution in headache pain or reduction in headache severity), as assessed by the prescriber. **Age limit:** ≥ 18 years of age **Quantity limit:** 8 nasal spray devices/30 days

Full Class Reviews	Options for Consideration
Angiotensin Modulator Combinations (Angiotensin Modulator + CCB Combinations)	**Angiotensin Modulator + CCB Combinations** • 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 *Angiotensin Modulator + CCB Combinations* class, require PA until reviewed by the P&T Advisory Committee.
Angiotensin Modulators (ACE Inhibitors)	**ACE Inhibitors** • 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 *Ace Inhibitors* class, require PA until reviewed by the P&T Advisory Committee.
Anticoagulants	**Anticoagulants** • 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 *Anticoagulants* class, require PA until reviewed by the P&T Advisory Committee.
Sedative Hypnotics	**Sedative Hypnotics** • 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 Sedative Hypnotics 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, Direct Renin Inhibitors) • Angiotensin Modulators Combinations (ACEI + Diuretic Combinations, ARB + Diuretic Combinations) • Antianginal & Anti-Ischemic • Antiarrhythmics, Oral • Anticonvulsants (Anticonvulsants: First Generation, Anticonvulsants: Second Generation, Anticonvulsants: Carbamazepine Derivatives) • Antidepressants, Other (Antidepressants: Other, Antidepressants: MAOIs, Antidepressants, SNRI) • Antidepressants, SSRI • Antidepressants, Tricyclics • Antimigraine Agents, Other (Anti-Migraine: CGRP Inhibitors) • Antiparkinson's Agents (Dopamine Receptor Agonists, Parkinson's Disease)	• Antipsychotics [First-Generation (oral), Second-Generation (oral), Antipsychotics: Injectable] • Anxiolytics • Beta-Blockers (Alpha/Beta Blockers, Beta Blockers + Diuretic Combinations) • Bladder Relaxant Preparations • BPH Treatments • Calcium Channel Blockers (DHP, Non-DHP) • Lipotropics, Other (Lipotropics: Bile Acid Sequestrant, Lipotropics: Fibric Acid Derivatives, Lipotropics: Other) • Lipotropics, Statins • Movement Disorders • Narcolepsy Agents • Platelet Aggregation Inhibitors • Pulmonary Arterial Hypertension (PAH) Agents, Oral and Inhaled • Stimulants and Related Agents • Smoking Cessation (Tobacco Cessation)