Pharmacy Provider Notice #315 September 2023 P&T PDL Changes

November 14th, 2023

Please be advised that the Department for Medicaid Services (DMS) is making changes to the Kentucky Medicaid Pharmacy Preferred Drug List (PDL) based on recommendations and guidance as adopted by the Commissioner of DMS of the Cabinet for Health and Family Services by order dated October 6th, 2023.

The Kentucky Medicaid Pharmacy and Therapeutics Advisory Committee (Committee) met on September 21st, 2023. The expertise, vote, and recommendations were captured within the Committee's official recommendations. DMS, through the Commissioner, reviewed the recommendations and in consultation rendered these final decisions.

On December 14th, 2023 the following changes will be effective:

Existing Drug Classes

Drug Class	The following products will **remain preferred** products:	The following products will **become preferred** products:	The following products will **become non-preferred** products and **require prior authorization (PA):**	The following products will **remain non-preferred** products and **require prior authorization (PA):**
Angiotensin Modulator + CCB Combinations	amlodipine/benazepril valsartan/amlodipine valsartan/amlodipine/HCTZ	olmesartan/amlodipine	*N/A*	*Azor™* *Exforge®* *Exforge HCT®* *Lotrel®* *olmesartan/amlodipine/HCTZ* *Tribenzor®* *telmisartan/amlodipine* *verapamil/trandolapril*
ACE Inhibitors	benazepril enalapril tablets lisinopril quinapril ramipril	enalapril solution	*N/A*	*Accupril®* *Altace®* *captopril* *Epaned™CC* *fosinopril* *Lotensin®* *moexipril* *perindopril* *Qbrelis™ CC, QL* *trandolapril* *Vasotec®* *Zestril®*
Anticoagulants	Eliquis® enoxaparin Jantoven® Pradaxa® warfarin	N/A	*Pradaxa®pellet pack*	*Arixtra™* *dabigatran* *fondaparinux* *Fragmin®* *Lovenox®*

Drug Class	The following products will **remain preferred** products:	The following products will **become preferred** products:	The following products will **become non-preferred** products and **require prior authorization (PA):**	The following products will **remain non-preferred** products and **require prior authorization (PA):**
	Xarelto®			*Savaysa™* *Xarelto® granules for suspension*
Sedative Hypnotics	temazepam 15 mg, 30 mg MD, QL zolpidem MD, QL	eszopiclone MD, QL	*N/A*	*Ambien® MD, QL* *Ambien CR® MD, QL* *Belsomra® MD, QL* *Dayvigo™ MD, QL* *Doral® MD, QL* *doxepin QL (generic Silenor®)* *Edluar® CC, MD, QL* *estazolam MD, QL* *flurazepam MD, QL* *Halcion® MD, QL* *Hetlioz® CC, QL* *Hetlioz LQ® CC, QL* *Igalmi™ AE, CC, QL* *Intermezzo® MD, QL* *Lunesta™ MD, QL* *Quviviq™ AE, CC, MD, QL* *ramelteon CC, MD, QL* *Restoril® MD, QL* *Rozerem® CC, MD, QL* *Silenor® QL* *tasimelteon CC, QL* *temazepam 7.5 mg, 22.5 mg MD, QL* *triazolam MD, QL* *zaleplon MD, QL* *zolpidem capsules MD, QL* *zolpidem ER MD, QL* *zolpidem SL MD, QL*

New Products to Market

Drugs Requiring PA	Criteria for Prior Authorization
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. **Initial Approval Criteria** • Pt has a diagnosis of bipolar disorder or schizophrenia; **AND**

Drugs Requiring PA	Criteria for Prior Authorization
	• 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. **Quantity Limit:** 1 syringe every 2 months **Age Limit:** ≥ 18 years old

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 either of the following:
	  ○ Molecular genetic testing with heterozygous methyl-CpG binding protein-2 (MECP2) pathogenic variant gene mutations to establish a new diagnosis, **OR**
	  ○ A previous diagnosis is based on clinical presentation and other causes for symptoms have been ruled out; **AND**
	• 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 (i.e., eGFR < 45 mL/min/1.73m^2)
	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)
	Quantity Limit: 8 bottles every 30 days
	Age Limit: 2 years of age or older

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.
	Initial Approval Criteria
	• Diagnosis of Type 2 Diabetes Mellitus; AND
	  ○ Diagnosis of chronic kidney disease; 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.

Drugs Requiring PA	Criteria for Prior Authorization
	Age Limit: 30 tablets per 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).
	Initial Approval Criteria
	• 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**
	• Patient does NOT have Prader-Willi syndrome with > 1 of the following:
	  ○ Severe obesity
	  ○ History of upper airway obstruction or sleep apnea
	  ○ Severe respiratory impairment
	  ○ Unidentified respiratory infection; **AND**
	• Trial and therapeutic failure, allergy, contraindication (including potential drug-drug interactions with other medications), or intolerance of 2 preferred agents.
	Renewal Criteria
	• 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. **Initial Approval Criteria** • 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 **Quantity Limit:** 1 syringe per 30 days **Age Limit:** ≥ 18 years old
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.

Drugs Requiring PA	Criteria for Prior Authorization
	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** • Patient has not experienced any treatment-restricting adverse effects (e.g., ALT or AST > 3 times the ULN). **Quantity Limit:** 30 tablets per 30 days **Age Limit:** ≥ 18 years old
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; **AND** • Patient must have tried and failed or have a contraindication or intolerance to 1 preferred CGRP antagonist **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. **Quantity Limit:** 8 nasal spray devices per 30 days **Age Limit:** ≥ 18 years old

Consent Agenda

The therapeutic classes in the table below were reviewed; no changes were made to the currently posted status for agents in these classes.

• 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)

To review the complete summary of the final PDL selections and new products to market updates and changes, please refer to the "Commissioner's Final Decisions" from September 21st, 2023 posted on the provider web portal at: https://kentucky.magellanmedicaid.com (by clicking the Provider/Resources/Documents/Committees/P&T tabs).

Thank you for helping Kentucky Medicaid members maintain access to cost effective medications by selecting drugs on the preferred drug list whenever possible. For any additional information or questions that you may have, please contact Magellan Medicaid Administration at kyproviders@magellanhealth.com for Fee-for-Service members or the Kentucky MedImpact team at KYMCOPBM@medimpact.com for Managed Care Organization (MCO) members.

Sincerely,

ShaLeigh Hammons, CPhT

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Account Manager I
kyproviders@magellanhealth.com

Kentucky Medicaid Fee-for-Service Pharmacy Program's Contact Information		
Clinical Support Center	1-800-477-3071 Sunday – Saturday 24 hours a day	Please contact the Clinical Support Center to request a prior authorization (PA) or to check the status of a request. **NOTE: The only drugs that are now required to be submitted via fax are Brand Medically Necessary.**
Pharmacy Support Center	1-800-432-7005 Sunday – Saturday 24 hours a day	Please contact the Pharmacy Support Center when claims assistance is required. Timely filing, lock-in, and early refill (ER) overrides can be obtained through this Call Center.
Provider Services	1-877-838-5085 Monday – Friday 8:00 a.m. – 4:30 p.m.	Please contact Provider Services if you have questions about enrollment or when updating your license or bank information.
Member Services	1-800-635-2570 Monday – Friday 8:00 a.m. – 5:00 p.m.	Please contact Member Services if you are a member or if you as the provider have questions regarding the member's benefits or eligibility coverage dates.