Pharmacy Provider Notice #301 March 2023 P&T PDL Changes

May 8th, 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 March 23, 2023.

The Kentucky Medicaid Pharmacy and Therapeutics Advisory Committee (Committee) met on March 16, 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 June 8th, 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):**
Antibiotics: Cephalosporins 1st Generation	cefadroxil capsules cephalexin capsules, suspension	N/A	*cephalexin tablets*	*cefadroxil tablets, suspension*
Antiretrovirals: HIV/AIDS	abacavir QL abacavir-lamivudine atazanavir QL Biktarvy® QL Cimduo™ QL Complera® QL Delstrigo™ QL Descovy® CC, QL Dovato QL Edurant® efavirenz efavirenz/emtricitabine/tenofovir disoproxil fumarate QL emtricitabine/tenofovir disoproxil fumarate QL Emtriva® QL Evotaz™ QL Genvoya® QL Intelence® Isentress® Juluca QL lamivudine QL lamivudine-zidovudine lopinavir-ritonavir tablets, solution	N/A	*stavudine capsules QL* *Sunlenca CC, AE, QL*	*Aptivus®* *Atripla®* *Combivir®* *Crixivan®* *didanosine DR QL* *efavirenz/lamivudine/tenofovir disoproxil fumarate QL* *emtricitabine QL* *Epivir® QL* *Epzicom®* *etravirine* *fosamprenavir* *Fuzeon®* *Invirase®* *Kaletra®* *tablets, solution* *Lexiva®* *maraviroc* *nevirapine QL* *nevirapine ER QL* *Norvir® tablets, solution QL, powder packets* *Prezcobix® QL* *Retrovir®* *Reyataz® QL*

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):**
	Odefsey® QL Pifeltro™QL Prezista® ritonavir tablets Selzentry® Stribild® QL Symfi™ QL Symfi Lo™ QL Symtuza™ QL tenofovir disoproxil fumarate tablets QL Tivicay® tablets QL Triumeq® QL Trizivir® Tybost® zidovudine syrup, tablets			*Rukobia® CC, QL* *Sustiva®* *Temixys™ QL* *Triumeq® suspension* *Tivicay® suspension* *Truvada® QL* *Viracept®* *Viramune® QL* *Viramune XR® QL* *Viread® powder packets* *Viread® tablets QL* *Vocabria™ CC, AE, QL* *Ziagen® QL* *zidovudine capsules*
Immunomodulators, Asthma	Nucala AE, QL Xolair® AE, QL	Fasenra® AE, QL	*N/A*	*Tezspire ™ CC, AE, QL*
Intranasal Antihistamines and Anticholinergics	azelastine 0.1%, 0.15% ipratropium nasal spray	olopatadine nasal spray	*N/A*	*Patanase™*
Self-Injectable Epinephrine	epinephrine 0.3 mg (generic EpiPen®, Mylan) QL epinephrine 0.15 mg (generic EpiPen Jr.®, Mylan) QL	EpiPen® QL EpiPen Jr.® QL	*epinephrine 0.3 mg (generic EpiPen®, Teva) QL* *epinephrine 0.15 mg (generic EpiPen Jr.®, Teva) QL*	*epinephrine 0.3 mg (generic Adrenaclick®) QL* *epinephrine 0.15 mg (generic Adrenaclick®) QL* *Symjepi™ QL*

New Products to Market

Drugs Requiring PA	Criteria for Prior Authorization
Amvuttra™	**Non-PDL Class** **Length of Authorization:** 1 year • Vutrisiran (Amvuttra) is a transthyretin-directed small interfering RNA indicated for the treatment of the polyneuropathy of hereditary transthyretin-mediated (hATTR) amyloidosis in adults. **Criteria for Approval:** **Initial Approval Criteria** • Patient will receive supplementation with vitamin A at the recommended daily allowance during therapy; AND • Vutrisiran must NOT be used in combination with other transthyretin (TTR) reducing agents (e.g., inotersen [Tegsedi®], tafamidis [Vyndamax®, Vyndaqel®], patisiran [Onpattro®]); AND • Patient has a definitive diagnosis of hereditary transthyretinmediated (hATTR) amyloidosis/FAP (familial amyloidotic polyneuropathy) as documented by:

Drugs Requiring PA	Criteria for Prior Authorization
	○ Amyloid deposition on tissue biopsy; OR ○ Identification of a pathogenic TTR variant using molecular genetic testing; AND • Polyneuropathy is demonstrated by ≥ 2 of the following criteria: ○ Subjective patient symptoms suggestive of neuropathy ○ Abnormal nerve conduction studies consistent with polyneuropathy ○ Abnormal neurological examination suggestive of neuropathy; AND • Patient's peripheral neuropathy is attributed to hATTR/FAP and other causes of neuropathy have been excluded; AND • Baseline strength/weakness has been documented using an objective clinical measuring tool (e.g., Medical Research Council [MRC] muscle strength); AND • Patient has NOT received an orthotopic liver transplant (OLT). **Renewal Criteria** • Patient continues to meet the above criteria; AND • Patient is absent of unacceptable toxicity from the drug. • Patient has experienced disease response compared to pretreatment baseline as evidenced by stabilization or improvement in ≥ 1 of the following: ○ Signs and symptoms of neuropathy ○ MRC muscle strength. **Quantity Limit**: 1 syringe per 3 months **Age Limit:** ≥ 18 years
Relyvrio™	**Non-PDL Class** **Length of Authorization:** 1 year • Sodium phenylbutyrate/taurursodiol (Relyvrio) is indicated for the treatment of amyotrophic lateral sclerosis (ALS) in adults. **Criteria for Approval:** **Initial Approval Criteria** • Patient has a diagnosis of amyotrophic lateral sclerosis (ALS) based on validated criteria (e.g., revised El Escorial criteria, Awaji criteria, Gold Coast criteria); AND • Patient must not have hypersensitivity to any component of the product; AND • Patient must have an adequate trial of riluzole for ≥ 8 weeks; AND • Physician has assessed baseline disease severity utilizing an objective measure/tool (e.g., Amyotrophic Lateral Sclerosis Functional Rating Scale-Revised (ALSFRS-R); AND • Patient does not require permanent assisted ventilation; AND • Prescribed by, or in consultation with, a neurologist; AND • Prescriber attests to reviewing medical history and evaluating for potential drug and disease state interactions. **Renewal Criteria** • Patient must continue to meet the above criteria; AND • Patient must have disease stabilization OR improvement in the slope of decline as demonstrated on an objective measure/tool; AND • Patient has not experienced any unacceptable toxicity from treatment (e.g., worsening hypertension or heart failure). **Age Limit:** ≥ 18 years **Quantity Limit:** 60 packets/ 30 days

Drugs Requiring PA	Criteria for Prior Authorization
Rolvedon™	**Non-preferred in the PDL class:** *Colony Stimulating Factors* **Length of Authorization:** 1 year • Eflapegrastim-xnst (Rolvedon) is a leukocyte growth factor indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in adult patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with clinically significant incidence of febrile neutropenia. **Criteria for Approval:** **Initial Approval Criteria** • The medication is being used for chemotherapy-induced neutropenia prophylaxis, to decrease the incidence of febrile neutropenia. • Patient has a nonmyeloid malignancy and is receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia. • Patient has had at least a 7-day trial and therapeutic failure, allergy, contraindication or intolerance of 2 preferred agents. **Age Limit:** ≥ 18 years **Quantity Limit:** 1 syringe per 14 days
Sunlenca™	**Non-preferred in the PDL class:** *Antiretrovirals: HIV/AIDS* **Length of Authorization:** 1 year • Lenacapavir (Sunlenca), a human immunodeficiency virus type 1 (HIV-1) capsid inhibitor, in combination with other antiretroviral(s), is indicated for the treatment of HIV-1 infection in heavily treatment-experienced adults with multidrug resistant HIV-1 infection failing their current antiretroviral regimen due to resistance, intolerance or safety considerations. **Criteria for Approval:** • Patient has a diagnosis of human immunodeficiency virus type 1 (HIV-1) infection; AND • Prescribed by, or in consultation with, an infectious disease specialist or HIV specialist (AAHIVS); AND • Patient is heavily treatment-experienced with multidrug resistance HIV-1 infection (has documented resistance to ≥ 2 antiretroviral [ARV] medications from each of at least 3 of the 4 main classes [nucleoside reverse-transcriptase inhibitors [NRTIs], non–nucleoside reverse-transcriptase inhibitors [NNRTIs], protease inhibitors [PIs], and integrase strand-transfer inhibitors [INSTI]); AND • Patient has ≤ 2 fully active ARVs remaining from the 4 main classes that can be effectively combined; AND • Documentation (e.g., progress note, lab report) of baseline viral load ≥ 400 copies/mL on current antiretroviral regimen; AND • Patient has no history of treatment failure or known or suspected resistance to lenacapavir; AND • Patient will be taking with other antiretrovirals (optimized background regimen); AND • NOT used in combination with strong CYP3A inducers **Renewal Criteria:** • Patient has been adherent to their ARV treatment regimen; AND • Patient has NOT experienced virologic failure of lenacapavir and has documented clinical improvement and/or stabilization (e.g., disease response as indicated by a decrease in viral load from pretreatment baseline; increased or stabilized CD4+ counts); AND • Patient has NOT experienced any treatment-restricting adverse effects.

Drugs Requiring PA	Criteria for Prior Authorization
	Age Limit: ≥ 18 years **Quantity Limit**: • 300 mg tablets: 5 tablets per fill • 463.5 mg/1.5 mL vial: 2 vials per 6 months

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.

• Antibiotics: Cephalosporins 2nd Generation • Antibiotics: Cephalosporins 3rd Generation • Antibiotics: Inhaled • Antibiotics: Vaginal • Antibiotics: Gastrointestinal (GI) • Antibiotics: Macrolides/ Ketolides • Antibiotics: Oxazolidinones • Antibiotics: Penicillins • Antibiotics: Pleuromutilins • Antibiotics: Quinolones • Antibiotics: Sulfonamides, Folate Antagonists • Antibiotics: Tetracyclines • Antifungals: Oral • Anti-Infectives: Hepatitis B	• Antivirals: Herpes • Antivirals: Influenza • Beta Agonists: Combination Products • COPD Agents • Hepatitis C: Direct-Acting Antiviral Agents • Hepatitis C: Interferons • Hepatitis C: Ribavirins • Inhaled Corticosteroids • Intranasal Corticosteroids • Leukotriene Modifiers • Long-Acting Beta2 Adrenergic Agonists • Minimally Sedating Antihistamines • Short-Acting Beta2 Adrenergic Agonists

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 March 16, 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.

AE – Age Edit; CC – Clinical Criteria; MD – Medications with Maximum Duration; QL – Quantity Limit; ST – Step Therapy