Kentucky Department for Medicaid Services
Pharmacy and Therapeutics Advisory Committee Recommendations

The following chart provides a summary of the official recommendations made by the Pharmacy and Therapeutics (P&T) Advisory Committee at the **March 16th, 2023,** meeting.

Pending is the review by the Commissioner of the Department for Medicaid Services of the Cabinet for Health and Family Services of these recommendations and final decisions.

	Description of Recommendation	P & T Vote

1	**New Product to Market: 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:
	  ○ 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
		Passed
		5 For
		0 Against

	Description of Recommendation	P & T Vote

	• 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	

2	**New Product to Market: 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	**Passed** **5 For** **0 Against**
3	**New Product to Market: Rolvedon™** **Non-prefer in PDL Class:** *Colony Stimulating Factors* **Length of Authorization:** 1 year • Eflapegrastim-xnst (Rolvedon) is a leukocyte growth factor indicated to decrease the	**Passed** **5 For** **0 Against**

	Description of Recommendation	P & T Vote
	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	
4	**New Product to Market: 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:** • Patients 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 (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	**Passed** **5 For** **0 Against**

	Description of Recommendation	P & T Vote
	• 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 **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	
5	**Antibiotics: Cephalosporins 1st Generation** • 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 will require PA. • For any new chemical entity in the *Antibiotics: Cephalosporins 1st Generation* class, require PA until reviewed by the P&T Advisory Committee.	**Passed** **5 For** **0 Against**
6	**Antiretrovirals: HIV/AIDS** • DMS to select preferred agent(s) based on economic evaluation; however, at least 3 first-line treatment regimens should be preferred. • Agents not selected as preferred will be considered non-preferred and will require PA. • For any new chemical entity in the *Antiretrovirals: HIV/AIDS* class, require PA until reviewed by the P&T Advisory Committee.	**Passed** **5 For** **0 Against**
7	**Immunomodulators, Asthma** • 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 will require PA. • For any new chemical entity in the *Immunomodulators, Asthma,* require PA until reviewed by the P&T Advisory Committee.	**Passed** **5 For** **0 Against**
8	**Intranasal Antihistamines and Anticholinergics** • DMS to select preferred agent(s) based on economic evaluation; however, at least 2 unique chemical entities should be preferred.	**Passed** **5 For** **0 Against**

	Description of Recommendation	P & T Vote
	• Agents not selected as preferred will be considered non-preferred and will require PA. • For any new chemical entity in the *Intranasal Antihistamines and Anticholinergics* class, require PA until reviewed by the P&T Advisory Committee.	
9	**Self-Injectable Epinephrine** • 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 will require PA. • For any new chemical entity in the *Self-Injectable Epinephrine* class, require PA until reviewed by the P&T Advisory Committee.	**Passed** **5 For** **0 Against**

Consent Agenda

For the following therapeutic classes, the P&T Committee had no recommended changes to the currently posted Preferred Drug List (PDL) status.

	Therapeutic Classes	P & T Vote
10	• 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	**Passed** **5 For** **0 Against**

	Therapeutic Classes	P & T Vote
	• 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	