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 **March 16, 2023** meeting of the Pharmacy and Therapeutics Advisory Committee.

Single Agent Reviews	Options for Consideration

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 and identification of a pathogenic TTR variant using molecular genetic testing; AND
	• Polyneuropathy is demonstrated by ≥ 2 of the following criteria:
	  ○ Subjective patient symptoms are suggestive of neuropathy
	  ○ Abnormal nerve conduction studies are consistent with polyneuropathy
	  ○ Abnormal neurological examination is 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 been the recipient of 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.
	Age Limit: ≥ 18 years
	Quantity Limit: 1 syringe per 3 months

Single Agent Reviews	Options for Consideration
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 (e.g., ALSFRS-R); 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
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 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:** • 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

Single Agent Reviews	Options for Consideration
	Quantity limit: 1 syringe per 14 days
New Product to Market: **Sunlenca**	*Non-prefer in 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:** **Initial Approval Criteria** • 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 (has documented resistance to ≥ 2 antiretroviral [ARV] medications from each of ≥ 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 **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

Full Class Reviews	Options for Consideration
Cephalosporins and Related Antibiotics (Antibiotics: Cephalosporins 1st Generation)	**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.
Antiretrovirals: HIV/AIDS	**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.
Immunomodulators, Asthma	**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 *Antibiotics: Immunomodulators, Asthma*, require PA until reviewed by the P&T Advisory Committee.
Intranasal Rhinitis Agents (Intranasal Antihistamines and Anticholinergics)	**Intranasal Antihistamines and Anticholinergics** • 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 *Intranasal Antihistamines and Anticholinergics class*, require PA until reviewed by the P&T Advisory Committee.
Self-Injectable Epinephrine	**Self-Injectable Epinephrine** • DMS to select preferred agent(s) based on economic evaluation; however, at least 1 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 *Self-Injectable Epinephrine 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 Preferred Drug List (PDL) status**; these may be voted on as a group:	
• 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