Commissioner for the Department for Medicaid Services Selections for Preferred Products

This is a summary of the final Preferred Drug List (PDL) selections made by the Commissioner of the Department for Medicaid Services (DMS) based on the Drug Review and Options for Consideration document prepared for the Pharmacy and Therapeutics (P&T) Advisory Committee's review on **March 16, 2023,** and the resulting official recommendations.

New Products 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
- 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

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:

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

Drug Class	Preferred Agents	Non-Preferred Agents
Colony Stimulating Factors	Neupogen® CC, QL Nyvepria™ CC, QL	*Granix*® QL *Fylnetra*® QL *Fulphila*™ QL *Leukine*® QL *Neulasta*® QL *Neulasta Onpro*® QL *Nivestym*™ QL *Releuko*™ QL *Rolvedon*™ AE, CC, QL *Stimufend*® QL *Udenyca*™ QL *Zarxio*® QL *Ziextenzo*® QL

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 (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.

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

Drug Class	Preferred Agents	Non-Preferred Agents
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®	*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*

Drug Class	Preferred Agents	Non-Preferred Agents
	Juluca QL lamivudine QL lamivudine-zidovudine lopinavir-ritonavir tablets, solution Odefsey® QL Pifeltro™ QL Prezista® ritonavir tablets Selzentry® stavudine capsules QL Stribild® QL Symfi™ QL Symfi Lo™ QL Symtuza™ QL tenofovir disoproxil fumarate tablets QL Tivicay® tablets QL Triumeq® QL Trizivir® Tybost® zidovudine syrup, tablets	*Norvir® tablets, solution QL, powder packets* *Prezcobix® QL* *Retrovir®* *Reyataz® QL* *Rukobia® CC, QL* *Sunlenca™ CC, AE, 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*

Full Class Reviews

Antibiotics: Cephalosporins 1st Generation

Class Selection & Guidelines

- 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.

Drug Class	Preferred Agents	Non-Preferred Agents
Antibiotics: Cephalosporins 1st Generation	cefadroxil capsules cephalexin capsules, suspension	*cefadroxil tablets, suspension* *cephalexin tablets*

Antiretrovirals: HIV/AIDS

Class Selection & Guidelines

- 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.

Drug Class	Preferred Agents	Non-Preferred Agents
Antiretrovirals: HIV/AIDS	abacavir QL	*Aptivus®*
	abacavir-lamivudine	*Atripla®*
	atazanavir QL	*Combivir®*
	Biktarvy® QL	*Crixivan®*
	Cimduo™ QL	*didanosine DR QL*
	Complera® QL	*efavirenz/lamivudine/tenofovir disoproxil fumarate QL*
	Delstrigo™ QL	*emtricitabine QL*
	Descovy® CC, QL	*Epivir® QL*
	Dovato QL	*Epzicom®*
	Edurant®	*etravirine*
	efavirenz	*fosamprenavir*
	efavirenz/emtricitabine/tenofovir disoproxil fumarate QL	*Fuzeon®*
	emtricitabine/tenofovir disoproxil fumarate QL	*Invirase®*
	Emtriva® QL	*Kaletra® tablets, solution*
	Evotaz™ QL	*Lexiva®*
	Genvoya® QL	*maraviroc*
	Intelence®	*nevirapine QL*
	Isentress®	*nevirapine ER QL*
	Juluca QL	*Norvir® tablets, solution QL*
	lamivudine QL	*, powder packets*
	lamivudine-zidovudine	*Prezcobix® QL*
	lopinavir-ritonavir tablets, solution	*Retrovir®*
	Odefsey® QL	*Reyataz® QL*
	Pifeltro™ QL	*Rukobia® CC, QL*
	Prezista®	*Sustiva®*
	ritonavir tablets	*stavudine capsules QL*
	Selzentry®	*Temixys™ QL*
	Stribild® QL	*Triumeq® suspension*
	Symfi™ QL	*Tivicay® suspension*
	Symfi Lo™ QL	*Truvada® QL*
	Symtuza™ QL	*Viracept®*
	tenofovir disoproxil fumarate tablets QL	*Viramune® QL*
	Tivicay® tablets QL	*Viramune XR® QL*
	Triumeq® QL	*Viread® powder packets*
	Trizivir®	*Viread® tablets QL*
	Tybost®	

Drug Class	Preferred Agents	Non-Preferred Agents
	zidovudine syrup, tablets	*Vocabria™ CC, AE, QL* *Ziagen® QL* *zidovudine capsules*

Immunomodulators, Asthma

Class Selection & Guidelines

- 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.

Drug Class	Preferred Agents	Non-Preferred Agents
Immunomodulators, Asthma	Fasenra® AE, QL Nucala AE, QL Xolair® AE, QL	*Tezspire ™ CC, AE, QL*

Intranasal Antihistamines and Anticholinergics

Class Selection & Guidelines

- 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.

Drug Class	Preferred Agents	Non-Preferred Agents
Intranasal Antihistamines and Anticholinergics	azelastine 0.1%, 0.15% ipratropium nasal spray olopatadine nasal spray	*Patanase™*

Self-Injectable Epinephrine

Class Selection & Guidelines

- 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.

Drug Class	Preferred Agents	Non-Preferred Agents
Self-Injectable Epinephrine	EpiPen® QL EpiPen Jr.® QL epinephrine 0.3 mg (generic EpiPen®, Mylan) QL epinephrine 0.15 mg (generic EpiPen Jr.®, Mylan) QL	*epinephrine 0.3 mg (generic Adrenaclick®)* QL *epinephrine 0.15 mg (generic Adrenaclick®)* QL *epinephrine 0.3 mg (generic EpiPen®)* QL *epinephrine 0.15 mg (generic EpiPen Jr.®)* QL *Symjepi™* QL

Classes Reviewed by Consent Agenda

No change in PDL status:

- 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