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 **November 19, 2020** 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: Fintepla®** Non-prefer in the PDL class: *Anticonvulsants: Second Generation* **Length of Authorization:** 1 Year • Fintepla® (fenfluramine) indicated for the treatment of seizures associated with Dravet syndrome in patients 2 years of age and older. **Criteria for Approval**: • Diagnosis of Dravet syndrome; AND • Prescriber is, or has a consultative relationship with, a neurology/epilepsy specialist; AND • Trial and failure (e.g., incomplete seizure control) of ≥ 2 antiepileptic drugs; AND • Used in adjunct with ≥ 1 antiepileptic drug; AND • Documentation (e.g., progress note or diagnostic report) or attestation that echocardiogram assessments will be performed in accordance with the prescribing information. **Renewal Criteria** • Documentation (e.g., progress note or diagnostic report) that echocardiogram assessments have been performed in accordance with the prescribing information; AND • Documentation (e.g., progress note) of improved seizure control. **Age Limit:** ≥ 2 years **Quantity Limit:** 12 mL per day	**Passed** 8 For 0 Against

2	**New Product to Market: Ongentys®**
	Non-prefer in the PDL class: *Parkinson's Disease*
	Length of Authorization: 1 year
	• Ongentys® (opicapone) is a catechol-O-methyltransferase (COMT) inhibitor indicated as adjunctive treatment to levodopa/carbidopa in patients with Parkinson's disease (PD) experiencing "off" episodes.
	Criteria for Approval:
	• Diagnosis of Parkinson's disease (PD); AND
	• Receiving PD therapy with carbidopa/levodopa; AND
	• Experiencing "off" episodes with carbidopa/levodopa for at least 2 hours per day; AND
	• Trial and failure of at least 2 adjunctive therapies, such as:
	  ○ Dopamine agonists (e.g., pramipexole, ropinirole);
	  ○ Monoamine oxidase-B inhibitors (e.g., selegiline)
	  ○ Catechol-O-methyltransferase inhibitors (e.g., entacapone); AND
	• NONE of the following contraindications:
		Passed
		8 For
		0 Against

	Description of Recommendation	P & T Vote
	○ Severe hepatic impairment (Child-Pugh C); OR ○ End-stage renal disease (creatinine clearance < 15 mL/min); OR ○ Use with a monoamine oxidase-B (MAO-B) inhibitor. **Renewal Criteria** • Patient has clinically meaningful response to treatment (e.g., patient shows a reduction in time of "off" episodes). **Age Limit**: ≥ 18 years **Quantity Limit**: 1 per day	
3	**New Product to Market: Enspryng™** Non-prefer in the PDL class: *Immunomodulators (Cytokine and CAM Antagonists)* **Length of Authorization:** 1 year • Enspryng™ (satralizumab-mwge) is an interleukin-6 (IL-6) receptor antagonist indicated for the treatment of neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive. **Criteria for Approval:** • Prescribed by a specialist (e.g., immunologist, neurologist, ophthalmologist, etc.) with experience in the diagnosis and treatment of neuromyelitis optica spectrum disorder (NMOSD); AND • Diagnosis of NMOSD confirmed by the following: ○ Seropositive for aquaporin-4 (AQP4) IgG antibodies; AND ○ Presence of ≥ 1 core clinical characteristic (e.g., optic neuritis, acute myelitis, area postrema syndrome, acute brainstem syndrome, symptomatic narcolepsy or acute diencephalic clinical syndrome with NMOSD-typical diencephalic MRI lesions, symptomatic cerebral syndrome with NMOSD-typical brain lesions); AND ○ Alternative diagnoses have been excluded (e.g., multiple sclerosis, sarcoidosis, cancer, chronic infection); AND • Patient meets ALL of the following conditions: ○ History of ≥ 1 relapse(s) that required rescue therapy within the prior year or ≥ 2 relapses that required rescue therapy within the prior 2 years; AND ○ Expanded Disability Status Score (EDSS) of ≤ 6.5 (e.g., requires 2 walking aids [pair of canes, crutches, etc.] to walk about 20 m without resting); AND ○ At risk of having a disabling relapse of NMOSD for which oral agents (e.g., corticosteroids and immunosuppressants such as azathioprine and mycophenolate) alone are inadequate and biologic therapy is necessary; AND ○ Screening for and absence of Hepatitis B, tuberculosis (TB), and other active infections prior to therapy initiation; AND • NOT previously treated with prolonged immunosuppressive therapy with alemtuzumab, cladribine, cyclophosphamide or mitoxantrone OR immunosuppressant procedures (e.g., bone marrow transplant, total lymphoid irradiation); AND • NOT to be used in combination with any of the following: ○ Multiple sclerosis agents (e.g., interferon, dimethyl fumarate, fingolimod, glatiramer, etc.) within 6 months of therapy initiation; AND ○ Other biologics used for the treatment of NMOSD (e.g., eculizumab, inebilizumab, rituximab). **Renewal Criteria:** ○ Disease response as indicated by stabilization/improvement in any of the following: neurologic symptoms as evidenced by a decrease in acute relapses, stability, or improvement in EDSS, reduced hospitalizations,	**Passed** 8 For 0 Against

	Description of Recommendation	P & T Vote
	reduction/discontinuation in plasma exchange treatments, and/or reduction/discontinuation of corticosteroids without relapse. **Age Limit**: ≥ 18 years **Quantity Limit**: 1 syringe (1 dose) per 28 days; allow 2 syringes (2 doses) for the first 28 days	
4	**New Product to Market: Rukobia®** Non-prefer in the PDL class: *Antiretrovirals: HIV/AIDS (HIV/AIDS)* **Length of Authorization:** 1 Year • Rukobia® (fostamsavir) is a human immunodeficiency virus type 1 (HIV-1) gp120-directed attachment inhibitor indicated for use in combination with other antiretrovirals 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**: • Diagnosis of human immunodeficiency virus (HIV); AND • Prescribed by, or in consultation with, an infectious disease specialist or HIV specialist (AAHIVS); AND • Previous treatment with at least 3 drug classes (nucleoside reverse transcriptase inhibitors [NRTI], non-nucleoside reverse transcriptase inhibitors [NNRTI], or protease inhibitor [PI]); AND • Documentation (e.g., progress note, lab report) of baseline viral load > 1,000 copies/mL on current antiretroviral regimen; AND • Used in combination with highly active antiretroviral therapy (HAART); AND • NOT have impaired liver function. **Renewal Criteria** • Documentation (e.g., progress note, lab report) of a decrease in viral load from pretreatment baseline. **Age Limit:** ≥ 18 years **Quantity Limit:** 2 per day	**Passed** 8 For 0 Against
5	**New Product to Market: Kesimpta®** Non-prefer in the PDL class: *Multiple Sclerosis Agents* **Length of Authorization:** 1 Year • Kesimpta® (ofatumumab) is a CD-20 antibody indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults. **Criteria for Approval**: • Initially prescribed by a neurologist or multiple sclerosis specialist (non-specialist may renew and refill); AND • Diagnosis of a relapsing form of multiple sclerosis (MS): relapsing-remitting MS (RRMS) active secondary progressive MS (SPMS), or clinically isolated syndrome (CIS); AND • Inadequate response to, or unable to tolerate, 1 or more preferred MS agent; AND • NOT have active Hepatitis B, or other clinically significant active infection; AND • Baseline serum immunoglobulin measurement has been or will be performed; AND • NOT used in combination with any other MS agent. **Renewal Criteria** • Documentation of response to therapy (e.g., progress note); AND • Documentation (e.g., lab results) of ongoing serum immunoglobulin monitoring. **Age Limit:** ≥ 18 years **Quantity Limit:** 0.4 mL (1 dose) per 28 days; allow 1.2 mL (3 doses) for the first 28 days	**Passed** 8 For 0 Against
6	**New Product to Market: Evrysdi™** Non-prefer in the PDL class: *Spinal Muscular Atrophy*	**Passed** 8 For

	Description of Recommendation	P & T Vote

	Length of Authorization: 1 Year
	• Evrysdi™ (risdiplam) is a survival of motor neuron 2 (SMN2) splicing modifier indicated for the treatment of spinal muscular atrophy (SMA) in patients ≥ 2 months of age.
	Criteria for Approval:
	Infantile-onset (Type 1) Spinal Muscular Atrophy (SMA)
	• Member is ≥ 2 months of age; AND
	• Prescribed by, or in consultation with, a pediatric neurologist or other specialist in the diagnosis and treatment of spinal muscular atrophy (SMA); AND
	• Diagnosis of spinal muscular atrophy (SMA) Type 1; AND
	• Genetic test results (i.e., laboratory results) confirming SMA:
	  ○ Homozygous deletion or mutation of the survival motor neuron 1 (SMN1) gene; OR
	  ○ Compound heterozygous mutation of the SMN1 gene; AND
	  ○ At least two copies of the SMN2 gene.
	• Patient does NOT require permanent ventilation (defined as requiring a tracheostomy or more than 21 consecutive days of either non-invasive ventilation (≥ 16 hours per day) or intubation, in the absence of an acute reversible event); AND
	• Prescriber conducts, and submits documentation of an assessment of baseline motor function using at least one of the following:
	  ○ Hammersmith Infant Neurologic Exam-Part 2 (HINE-2)
	  ○ Hammersmith Functional Motor Scale Expanded (HFMSE)
	  ○ Upper Limb Module (ULM) score
	  ○ Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND); AND
	• NOT to be used in combination with Spinraza™ (nusinersen); AND
	• Patient has not received treatment with Zolgensma (onasemnogene abeparvovec-xioi).
	
	Later-onset SMA
	• Prescribed by, or in consultation with, a neurologist or other specialist in the diagnosis and treatment of spinal muscular atrophy (SMA); AND
	• Member is ≥ 2 years of age; AND
	• Diagnosis of spinal muscular atrophy (SMA) Type 2 or 3; AND
	• Prescriber attestation/opinion that patient is non-ambulatory (e.g., requires wheelchair, not able to walk unassisted, etc.); OR
	• Prescriber attestation/opinion that patient is experiencing a decline in motor function/failure to achieve motor milestones; AND
	• Documentation of baseline Motor Function Measure 32 (MFM32) score or Revised Upper Limb Module (RULM) score; AND
	• NOT to be used in combination with Spinraza™ (nusinersen); AND
	• Patient has not received treatment with Zolgensma (onasemnogene abeparvovec-xioi).
	Renewal Criteria (all requests):
	• Documentation of repeat motor function testing showing motor improvements or clinically significant improvements in SMA associated symptoms such as:
	  ○ Lack of disease progression or stabilization; OR
	  ○ Decreased decline in motor function as compared to the natural history trajectory of the disease (evident by the comparative assessment of baseline motor function measurements with current measurements using one of the assessments listed above); AND
		0 Against

	Description of Recommendation	P & T Vote
	• Individual does not require use of invasive ventilation or tracheostomy as a result of advanced SMA disease.	

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
7	• Acne Agents, Oral • Acne Agents, Topical • Antibiotics, Topical • Anticholinergics/Antispasmodics • Antidiarrheals • Anti-Emetic & Antivertigo Agents • Antifungals, Topical • Antiparasitics, Topical • Antipsoriatics, Oral • Antipsoriatics, Topical • Anti-Ulcer Protectants • Antivirals, Topical • Bile Salts • Cytokine and CAM Antagonists • GI Motility, Chronic • H. pylori Treatment • Histamine II Receptor Blockers • Immunomodulators, Atopic Dermatitis • Immunosuppressives, Oral • Laxatives & Cathartics • Multiple Sclerosis Agents • Ophthalmic Antibiotic-Steroid Combinations • Ophthalmic Antibiotics • Ophthalmics, Anti-Inflammatories • Ophthalmics, Glaucoma Agents • Ophthalmics, Immunomodulators • Ophthalmics, Antiviral • Ophthalmics for Allergic Conjunctivitis • Ophthalmics, Mydriatic • Ophthalmics, Vasoconstrictor • Otic Antibiotics • Otic Anti-Infectives, Anesthetics and Anti-Inflammatories • Proton Pump Inhibitors • Rosacea Agents, Topical • Spinal Muscular Atrophy • Steroids, Topical • Ulcerative Colitis Agents	**Passed** 8 For 0 Against