Kentucky Department for Medicaid Services
Pharmacy and Therapeutics Advisory Committee Recommendations

May 21, 2020

The following chart provides a summary of the recommendations that were made by the Pharmacy and Therapeutics (P&T) Advisory Committee at the **May 21, 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: Aklief®** Non-prefer in the PDL class: *Topical Acne Agents* **Length of Authorization:** 1 year • Aklief® (trifarotene) is a retinoid indicated for the topical treatment of acne vulgaris in patients 9 years of age and older. **Criteria for Approval**: • Diagnosis of acne vulgaris; AND • Trial and failure of, or contraindication to, all preferred agents. **Age Limit**: ≥ 9 years	**Passed** 9 For 0 Against
2	**New Product to Market: Nayzilam®** Non-prefer in the PDL class: *Anticonvulsants: First Generation* **Length of Authorization:** 1 year • Nayzilam® (midazolam) nasal spray, a benzodiazepine, is indicated for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (e.g., seizure clusters, acute repetitive seizures) that are distinct from a patient's usual seizure pattern in patients ≥ 12 years old with epilepsy. **Criteria for Approval:** • Prescribed by, or in consultation with, a neurologist or epilepsy specialist; AND • Diagnosis of intermittent, stereotypic episodes of frequent seizure activity; AND • Patient is on a stable antiepileptic drug regimen; AND • Prescriber attestation that patient or caregiver has been counseled on proper identification of a seizure cluster; AND • Prescriber attestation that patient or caregiver has been counseled on proper administration and when to seek emergency medical treatment. **Renewal Criteria** • Prescriber attestation of efficacy (e.g., decreased length of seizure episodes). **Age Limit**: ≥ 12 years **Quantity Limit**: 5 boxes (10 nasal spray units)/ 30 days	**Passed** 9 For 0 Against

	Description of Recommendation	P & T Vote
3	**New Product to Market: Nurtec™ ODT** Prefer with clinical criteria in the PDL class: *Anti-Migraine: CGRP Inhibitors (* **Length of Authorization:** 1 year • Nurtec™ ODT (rimegepant) is a calcitonin gene-related peptide (CGRP) receptor antagonist indicated for the acute treatment of migraine with or without aura in adults. It is not indicated for the preventive treatment of migraine. **Criteria for Approval:** • Diagnosis of migraine, with or without aura; AND • Trial and failure, or contraindication to, 2 triptans. **Renewal Criteria:** • Attestation or documentation of resolution in headache pain or reduction in headache severity, as assessed by prescriber. **Age Limit:** ≥ 18 years **Quantity Limit:** 8 tablets (1 package) per 30 days	**Passed** 10 For 0 Against
4	**New Product to Market: Reyvow™** Non-prefer in the PDL class: *Anti-Migraine: 5-HT1 Receptor Agonists* **Length of Authorization:** 1 year • Reyvow™ (lasmiditan) is a serotonin 5-HT_{1F} receptor agonist indicated for the acute treatment of migraine with or without aura in adults. **Criteria for Approval:** • Diagnosis of migraine, with or without aura; AND • NOT have severe hepatic impairment (Child-Pugh C); AND • Trial and failure of at least one of the following: NSAID, non-opioid analgesic, acetaminophen OR caffeinated analgesic combination; AND • Trial and failure, or contraindication to, ≥ 2 triptans; AND • Prescriber attests patient has been educated about need to refrain from driving or operating machinery for ≥ 8 hours after dose. **Renewal Criteria:** • Attestation or documentation of resolution in headache pain or reduction in headache severity, as assessed by prescriber. **Age Limit**: ≥ 18 years **Quantity Limit**: 8 tablets (1 package) per 30 days	**Passed** 10 For 0 Against
5	**New Product to Market: Ubrelvy™** Non-prefer in the PDL class: *Anti-Migraine: CGRP Inhibitors* **Length of Authorization:** 1 year • Ubrelvy™ (ubrogepant) is a calcitonin gene-related peptide (CGRP) receptor antagonist indicated for the acute treatment of migraine with or without aura in adults. It is not indicated for the preventive treatment of migraine. **Criteria for Approval:** • Diagnosis of migraine, with or without aura; AND • NOT have end-stage renal disease (creatinine clearance [CrCl] < 15 mL/min); AND • Trial and failure of at least one preferred calcitonin gene-related peptide (CGRP) inhibitor used for migraine treatment (e.g., Nurtec ODT). **Renewal Criteria:** • Attestation or documentation of resolution in headache pain or reduction in headache severity, as assessed by prescriber. **Age Limit**: ≥ 18 years	**Passed** 10 For 0 Against

	Description of Recommendation	P & T Vote
	Quantity Limit: 10 tablets (1 package) per 30 days	
6	**New Product to Market: Nourianz™** Non-prefer in the PDL class: *Parkinson's Disease* **Length of Authorization:** 1 year • Nourianz™ (istradefylline) is an adenosine A2A receptor antagonist approved as adjunctive treatment to levodopa/carbidopa (LD/CD) in adults 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; AND • Trial and failure of at least 2 adjunctive therapies, such as: o Dopamine agonists (e.g., pramipexole, ropinirole); o Monoamine oxidase-B inhibitors (e.g., selegiline) o Catechol-O-methyltransferase inhibitors (e.g., entacapone); AND • NONE of the following contraindications: o Severe hepatic impairment (Child-Pugh C); OR o End-stage renal disease, including dialysis; OR o Pregnant; OR o Major psychiatric disorder. **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	**Passed** 10 For 0 Against
7	**New Product to Market: Wakix®** Non-prefer in the PDL class: *Narcolepsy Agents* **Length of Authorization:** 1 year • Wakix® (pitolisant) a histamine-3 (H3) receptor antagonist/inverse agonist, is indicated for the treatment of excessive daytime sleepiness (EDS) in adult patients with narcolepsy. **Criteria for Approval:** • Diagnosis of excessive daytime sleepiness associated with narcolepsy; AND • Prescriber is a neurologist, sleep medicine, or other specialist in the treatment of narcolepsy; AND • Documentation of a multiple sleep latency test (MSLT) confirming narcolepsy; AND • Trial and failure/intolerance of, contraindication to, a preferred agent (e.g., modafanil); trial can be waived if member has a history of substance abuse. **Age Limit**: ≥ 18 years **Quantity Limit:** 2 per day	**Passed** 10 For 0 Against
8	**Narcotics: Short-Acting** • DMS to select preferred agent(s) based on economic evaluation; however, at least 6 unique chemical entities should be preferred. • Agents not selected as preferred will be considered non-preferred and require PA. • For any new chemical entity in the *Narcotics: Short-Acting* class, require PA until reviewed by the P&T Advisory Committee.	**Passed** 10 For 0 Against

	Description of Recommendation	P & T Vote
9	**Antibiotics: GI** • 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 require PA. • For any new chemical entity in the *Antibiotics: GI* class, require PA until reviewed by the P&T Advisory Committee.	**Passed** 10 For 0 Against
10	**Antivirals: Herpes** • DMS to select preferred agent(s) based on economic evaluation; however, at least 3 unique chemical entities should be preferred. • Agents not selected as preferred will be considered non-preferred and require PA. • For any new chemical entity in the *Antivirals: Herpes* class, require PA until reviewed by the P&T Advisory Committee. **Antivirals: Influenza** • 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 require PA. • For any new chemical entity in the *Antivirals: Influenza* class, require PA until reviewed by the P&T Advisory Committee.	**Passed** 10 For 0 Against
11	**Bone Resorption Suppression and Related Agents** • 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 require PA. • For any new chemical entity in the *Bone Resorption Suppression and Related Agents* class, require PA until reviewed by the P&T Advisory Committee.	**Passed** 10 For 0 Against
12	**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 require PA. • For any new chemical entity in the *Antibiotics: Cephalosporins 1st Generation* class, require PA until reviewed by the P&T Advisory Committee. **Antibiotics: Cephalosporins 2nd 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 require PA. • For any new chemical entity in the *Antibiotics: Cephalosporins 2nd Generation* class, require PA until reviewed by the P&T Advisory Committee. **Antibiotics: Cephalosporins 3rd Generation** • 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 require PA. • For any new chemical entity in the *Antibiotics: Cephalosporins 3rd Generation* class, require PA until reviewed by the P&T Advisory Committee.	**Passed** 10 For 0 Against

	Description of Recommendation	P & T Vote
13	**Erythropoiesis Stimulating Proteins** • 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 require PA. • For any new chemical entity in the *Erythropoiesis Stimulating Proteins* class, require PA until reviewed by the P&T Advisory Committee. **New agent in the class:** Reblozyl® (luspatercept-aamt) Non-prefer in this PDL class. **Length of Authorization:** 1 year • Reblozyl® (luspatercept-aamt) is indicated for the treatment of anemia in adult patients with beta thalassemia who require regular red blood cell (RBC) transfusions. **Criteria for Approval:** • Prescribed by, or in consultation with, a hematology or oncology specialist; AND • Diagnosis of beta thalassemia requiring regular red blood cell (RBC) transfusions; OR • Diagnosis of anemia that is associated with low-to-moderate risk myelodysplastic syndromes with ring sideroblasts or myelodysplastic/myeloproliferative neoplasm with ring sideroblasts and thrombocytosis; AND • Has required 2 or more RBC units over an 8-week period; AND • Failure of an erythropoiesis stimulating agent (e.g., epoetin alfa); OR • Serum erythropoietin (EPO) > 500 mU/mL. **Renewal Criteria:** • Attestation or documentation (e.g., progress note) of a reduction in transfusion burden or other clinical benefit. **Age Limit:** ≥ 18 years	**Passed** 10 For 0 Against
14	**Glucagon Agents** • DMS to select preferred agent(s) based on economic evaluation; however, at least intramuscular (IM) glucagon should be preferred. • Agents not selected as preferred will be considered non-preferred and require PA. • For any new chemical entity in the *Glucagon Agents* class, require PA until reviewed by the P&T Advisory Committee. **Criteria for Preferred with PA agents**: At least 1 Rx for intramuscular glucagon, recombinant has been dispensed in the past 180 days.	**Passed** 10 For 0 Against
15	**Beta Agonists: Combination Products** • DMS to select preferred agent(s) based on economic evaluation; however, at least 2 unique combinations should be preferred. • Agents not selected as preferred will be considered non-preferred and require PA. • For any new chemical entity in the *Beta Agonists: Combination Products* class, require PA until reviewed by the P&T Advisory Committee. **Inhaled Corticosteroids** • DMS to select preferred agent(s) based on economic evaluation; however, at least 2 unique chemical entities should be preferred.	**Passed** 10 For 0 Against

	Description of Recommendation	P & T Vote
	• Agents not selected as preferred will be considered non-preferred and require PA. • For any new chemical entity in the *Inhaled Corticosteroids* class, require PA until reviewed by the P&T Advisory Committee.	

16	**Hepatitis C: Direct-Acting Antiviral Agents**
	• DMS to select preferred agent(s) based on economic evaluation; however, at least 1 first-line treatment regimen should be preferred.
	• Agents not selected as preferred will be considered non-preferred and require PA.
	• For any new chemical entity in the *Hepatitis C: Direct-Acting Antiviral Agents* class, require PA until reviewed by the P&T Advisory Committee.
	
	Class Criteria review:
	Current criteria subject to changes:
	• Prescriber restrictions (specialist or KHAMP training) apply for all requests.
	• Hepatitis C virus (HCV) genotype testing is required for all cases.
	• Human immunodeficiency virus (HIV) and Hepatitis B surface antigen (HBsAg) testing may be submitted as informational only.
	
	Recommended criteria changes:
	• No prescriber restrictions for PA requests that fall under simplified treatment (adult, treatment-naïve, and no cirrhosis based on FIB-4 score < 3.25) and the request is for a preferred first-line treatment regimen.
	• HCV genotype testing is no longer required for PA approval when a preferred first-line treatment regimen is requested in patients with no cirrhosis.
	• Require HIV antigen/antibody test and Hepatitis B surface antigen testing to determine simplified treatment eligibility.
	• A gastroenterologist, hepatologist, infectious disease, or transplant specialist must prescribe and HCV genotype testing is required under any of the following patient circumstances:
	  ○ Prior hepatitis C treatment
	  ○ Cirrhosis (as suggested by FIB-4 score > 3.25 or evidenced by a proprietary serologic test, transient elastography, prior liver biopsy or other clinical findings suggestive of liver dysfunction)
	  ○ HIV or HBsAg positive
	  ○ Current pregnancy
	  ○ Known or suspected hepatocellular carcinoma
	  ○ Prior liver transplantation
	
	Hepatitis C: Interferons
	• DMS to select preferred agent(s) based on economic evaluation.
	• Agents not selected as preferred will be considered non-preferred and require PA.
	• For any new chemical entity in the *Hepatitis C: Interferons* class, require PA until reviewed by the P&T Advisory Committee.
	Hepatitis C: Ribavirins
	• DMS to select preferred agent(s) based on economic evaluation; however, at least generic ribavirin tablets should be preferred.
	• Agents not selected as preferred will be considered non-preferred and require PA.
	• For any new chemical entity in the *Hepatitis C: Ribavirins* class, require PA until reviewed by the P&T Advisory Committee.
		Passed
		10 For
		0 Against

	Description of Recommendation	P & T Vote
17	**Antiretrovirals: HIV/AIDS** • DMS to select preferred agent(s) based on economic evaluation; however, all first-line treatment regimens should be preferred. • Agents not selected as preferred will be considered non-preferred and require PA. • For any new chemical entity in the *Antiretrovirals: HIV/AIDS* class, require PA until reviewed by the P&T Advisory Committee. **Clinical Criteria Review:** Descovy (emtricitabine/tenofovir alafenamide) *Current criteria:* Prior authorization (PA) is not required. *Recommended criteria*: • Approve for 1 year when used for treatment of HIV-1 infection; OR • Approve for 3 months when used for pre-exposure prophylaxis (PrEP) and ALL of the following are true: o Prescriber submits PA request; AND o Member is NOT a recipient of vaginal sex (not FDA-approved in this population); AND o Negative HIV-1 test immediately prior to initiating Descovy and at least every 3 months.	**Passed** 10 For 0 Against
18	**Diabetes: Injectable Insulins** • DMS to select preferred agent(s) based on economic evaluation; however, at least 1 insulin of each type (short, intermediate, long) should be preferred. • Agents not selected as preferred will be considered non-preferred and require PA. • For any new chemical entity in the *Diabetes: Injectable Insulins* class, require PA until reviewed by the P&T Advisory Committee.	**Passed** 10 For 0 Against
19	**Oral Oncology, Breast Cancer** • DMS to select preferred agent(s) based on economic evaluation; however, agents with an FDA-approved indication or guideline recommendation for use in a first-line setting should be considered for preferred status with or without clinical criteria. • Agents not selected as preferred will be considered non-preferred and require PA. • For any new chemical entity in the *Oral Oncology, Breast Cancer* class, require PA until reviewed by the P&T Advisory Committee.	**Passed** 10 For 0 Against
20	**Oral Oncology, Hematologic Cancer** • DMS to select preferred agent(s) based on economic evaluation; however, agents with an FDA-approved indication or guideline recommendation for use in a first-line setting should be considered for preferred status with or without clinical criteria. • Agents not selected as preferred will be considered non-preferred and require PA. • For any new chemical entity in the *Oral Oncology, Hematologic Cancer* class, require PA until reviewed by the P&T Advisory Committee. **New agent in the class:** Brukinsa™ Non-prefer in this PDL class. **Length of Authorization:** 1 year • Brukinsa™ (zanubrutinib) is a small molecule Bruton's tyrosine kinase (BTK) inhibitor indicated for the treatment of adult patients with mantle cell lymphoma (MCL) who have received at least one prior therapy. **Criteria for Approval:**	**Passed** 10 For 0 Against

	Description of Recommendation	P & T Vote
	• Diagnosis of mantle cell lymphoma; AND • Patient has received ≥ 1 prior therapy; AND • Patient has NOT received prior treatment with another BTK-inhibitor (e.g., ibrutinib, acalabrutinib); AND • Drug will be used as monotherapy. **Renewal Criteria:** • Evidence, such as progress report, of disease response (e.g., lack of progression or decrease in tumor size and spread). **Age Limit:** ≥ 18 years **Quantity Limit:** 4 per day	
21	**Oral Oncology, Other** • DMS to select preferred agent(s) based on economic evaluation; however, agents with an FDA-approved indication or guideline recommendation for use in a first-line setting should be considered for preferred status with or without clinical criteria. • Agents not selected as preferred will be considered non-preferred and require PA. • For any new chemical entity in the *Oral Oncology, Other* class, require PA until reviewed by the P&T Advisory Committee. **New agent in the class:** Ayvakit® Prefer with clinical criteria in this PDL class. **Length of Authorization:** 1 year • Ayvakit® (avapritinib), a tyrosine kinase inhibitor (TKI) targeting platelet-derived growth factor receptor alpha (PDGFRA) and PDGFRA D842 mutants and multiple KIT exon 11, 11/17, and 17 mutants, is approved for the treatment of adults with unresectable or metastatic gastrointestinal stromal tumor (GIST) harboring a PDGFRA exon 18 mutation, including PDGFRA D842V mutations. • Patients should be selected for treatment with avapritinib based on confirmation of the presence of a PDGFRA exon 18 mutation; however, an FDA-approved test is not currently available. **Criteria for Approval:** • Diagnosis of metastatic or unresectable gastrointestinal stromal tumors (GIST); AND • Presence of platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation, such as D842V. **Renewal Criteria:** • Evidence, such as progress report, of disease response (e.g., limited progression, lack of progression or decrease in tumor size and spread). **Age Limit:** ≥ 18 years **Quantity Limit:** 1 per day **New agent in the class:** Tazverik® Prefer with clinical criteria in this PDL class. **Length of Authorization:** 1 year • Tazverik® (tazemetostat) is indicated for the treatment of adults and pediatric patients aged 16 years and older with metastatic or locally advanced epithelioid sarcoma not eligible for complete resection. It is approved under Accelerated Approval based on overall response rate and duration of response; continued approval may be contingent upon results of confirmatory trials. • Tazemetostat inhibits EZH2 methyltransferase. EZH2 methyltransferase, a subunit of the polycomb repressive complex 2 (PRC2), catalyzes methylation of	**Passed** 10 For 0 Against

	Description of Recommendation	P & T Vote
	lysine 27 of histone H3, which leads to repression of gene transcription and subsequent growth of cancer cells. **Criteria for Approval:** • Diagnosis of locally advanced or metastatic epithelioid sarcoma that is not eligible for complete resection; AND • Tazverik will be used as a single agent. **Renewal Criteria:** • Evidence, such as progress report, of disease response (e.g., lack of progression or decrease in tumor size and spread). **Age Limit:** ≥ 16 years **Quantity Limit:** 8 per day	
22	**Oral Oncology, Renal Cell Carcinoma** • DMS to select preferred agent(s) based on economic evaluation; however, agents with an FDA-approved indication or guideline recommendation for use in a first-line setting should be considered for preferred status with or without clinical criteria. • Agents not selected as preferred will be considered non-preferred and require PA. • For any new chemical entity in the *Oral Oncology, Renal Cell Carcinoma* class, require PA until reviewed by the P&T Advisory Committee.	**Passed** 10 For 0 Against
23	**Antibiotics: Pleuromutulins** • DMS to select preferred agent(s) based on economic evaluation. • Agents not selected as preferred will be considered non-preferred and require PA. • For any new chemical entity in the *Antibiotics: Pleuromutulins* class, require PA until reviewed by the P&T Advisory Committee. **New agent in the class:** Xenleta (lefamulin) Non-prefer in this PDL class. **Length of Authorization:** Date of service only • Xenleta™ (lefamulin), a pleuromutilin antibacterial, is indicated for the treatment of adults with community-acquired bacterial pneumonia (CABP) caused by susceptible microorganisms. **Criteria for Approval:** • Diagnosis of community-acquired bacterial pneumonia (CABP) thought to be caused by a susceptible organism*; AND • Patient is not a candidate or has failed treatment with ≥ 2 preferred first-line options for CABP; AND • If continuing an inpatient/hospital treatment course, prescriber attests that it would be clinically inappropriate to deescalate therapy or use alternative therapy based on susceptibility results or lack of susceptibility results in conjunction with clinical picture; AND • Oral treatment duration will not exceed 5 days. **Age Limit:** ≥ 18 years **Quantity Limit:** 2 per day and 10 tablets per fill *Susceptible organisms include: *Streptococcus pneumoniae*, *Staphylococcus aureus* (methicillin-susceptible isolates), *Haemophilus influenzae*, *Legionella pneumophila*, *Mycoplasma pneumoniae*, and *Chlamydophila pneumoniae.*	**Passed** 10 For 0 Against
24	**Thrombopoiesis Stimulating Agents**	**Passed**

	Description of Recommendation	P & T Vote
	• 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 require PA. • For any new chemical entity in the *Thrombopoiesis Stimulating Agents* class, require PA until reviewed by the P&T Advisory Committee.	10 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
25	• Absorbable Sulfonamides • Analgesics, Narcotics Long • Androgenic Agents • Antibiotics, Inhaled • Antibiotics, Vaginal • Antifungals, Oral • Antihistamines, Minimally Sedating • Antihyperuricemics • Antineoplastic Agents, Topical • Bronchodilators, Beta Agonist • Colony Stimulating Factors • COPD Agents • Epinephrine, Self-Injected • Fluoroquinolones, Oral • Glucocorticoids, Oral • Growth Hormone • Hepatitis B Agents • Hypoglycemics, Alpha-Glucosidase Inhibitors • Hypoglycemics, Incretin Mimetics/Enhancers • Hypoglycemics, Meglitinides • Hypoglycemics, Metformins • Hypoglycemics, SGLT2 • Hypoglycemics, Sulfonylureas • Hypoglycemics, Thiazolidinediones (TZD) • Intranasal Rhinitis Agents • Leukotriene Modifiers • Macrolides • NSAIDs • Oncology, Oral – Lung • Oncology, Oral – Prostate • Oncology, Oral – Skin • Opiate Dependence Treatments • Oxazolidenediones • Pancreatic Enzymes • Penicillins • Phosphate Binders	**Passed** 10 For 0 Against

	Therapeutic Classes	P & T Vote
	• Progestins for Cachexia • Tetracyclines	