Kentucky Department for Medicaid Services Pharmacy and Therapeutics Advisory Committee Recommendations

The following tables provide a summary of the official recommendations made by the Pharmacy and Therapeutics (P&T) Advisory Committee at the **January 18, 2024** 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.

RECOMMENDATIONS

	Description of Recommendation	P&T Vote

1	**New Product to Market: Vowst™**
	
	Antibiotics, Gastrointestinal: Non-Preferred (NPD)
	
	Approval Duration: ***30 days (Limit to 1 fill per approval)***
	
	• *Vowst (fecal microbiota spores, live-brpk) is a bacterial spore suspension in capsules indicated for the prevention of recurrent Clostridioides difficile infection (CDI) following antibacterial treatment for recurrent CDI (rCDI).*
	
	Initial Approval Criteria:
	• Diagnosis of recurrent *Clostridioides difficile* infection (CDI); **AND**
	• Prescribed by, or in consultation with, a gastroenterologist or infectious disease specialist; **AND**
	• Patient has completed at least 3 full courses of antibiotic treatment with two or more of the following guideline recommended agents:
	  ○ Vancomycin oral
	  ○ Dificid
	  ○ Metronidazole oral; **AND**
	• Treatment with Vowst will be initiated between 48 and 96 hours of completion of the most recent course of antibiotics; **AND**
	• At least 8 hours prior to the first dose of Vowst, the patient will receive an appropriate bowel cleansing regimen (e.g., magnesium citrate or polyethylene glycol)
	
	Renewal Criteria:
	• Diagnosis of recurrent *Clostridioides difficile* infection (CDI); **AND**
	• Prescribed by, or in consultation with, a gastroenterologist or infectious disease specialist; **AND**
	• Patient had treatment failure defined as the presence of CDI diarrhea within 8 weeks of the first dose of Vowst AND a positive stool test for *C. difficile*; **AND**
	• Patient has not previously received more than 1 treatment course of Vowst; **AND**
	• Previous course of Vowst was at least 12 days ago but no more than 8 weeks ago.
	
	Age Limit: ≥ 18 years of age
	Quantity Limit: 12 capsules over 3 days
		Decision 4 For 0 Against

	Description of Recommendation	P&T Vote

2	**New Product to Market: Bimzelx®**
	
	Cytokine and CAM Antagonists: Non-Preferred (NPD)
	
	Approval Duration: *6 months initial; 1 year renewal*
	
	• *Bimekizumab-bkzx is a humanized immunoglobulin IgG1/kappa monoclonal antibody indicated for the treatment of moderate to severe plaque psoriasis.*
	
	Initial Approval Criteria:
	• Diagnosis of moderate to severe plaque psoriasis; **AND**
	• Prescribed by or in consultation with a dermatologist, rheumatologist, or other specialist in the treatment of psoriasis; **AND**
	• Symptoms persistent for ≥ 6 months with at least 1 of the following:
	  ○ Involvement of at least 3% of body surface area (BSA); **OR**
	  ○ Psoriasis Area and Severity Index (PASI) score of 10 or greater; **OR**
	  ○ Incapacitation due to plaque location (e.g., head and neck, palms, soles, or genitalia); **AND**
	• Trial and failure (at least 3 months) of ≥ 1 conventional therapy, such as:
	  ○ Disease-modifying anti-rheumatic drug (DMARD), such as methotrexate
	  ○ Immunosuppressant (e.g., cyclosporine)
	  ○ Oral retinoid (e.g., acitretin); **AND**
	• NOT used in combination with any other biologic agent; **AND**
	• 3-month trial and failure of, contraindication, or intolerance to ≥ 1 preferred cytokine or CAM antagonist indicated for the treatment of this condition.
	
	Renewal Criteria:
	• Documentation (e.g., progress note) of response to therapy compared to baseline, such as redness, thickness, scaliness, amount of surface area involvement, and/or PASI score.
	
	Age Limit: ≥ 18 years of age
	Quantity Limit: 2 injections per 28 days
		Decision
		4 For
		0 Against

3	**New Product to Market: Velsipity™** **Cytokine and CAM Antagonists: Non-Preferred (NPD)** **Approval Duration: *6 months initial; 1 year renewal*** • *Etrasimod is a sphingosine 1-phosphate (S1P) receptor modulator that binds with high affinity to S1P receptors 1, 4, and 5 indicated for the treatment of moderate to severe ulcerative colitis (UC).*	***Decision*** ***4 For*** ***0 Against***

	Description of Recommendation	P&T Vote

	Initial Approval Criteria:
	• Diagnosis of moderate to severe ulcerative colitis (UC); **AND**
	• Prescribed by, or in consultation with, a gastroenterologist or other specialist in the treatment of UC; **AND**
	• Patient has had a trial and failure of ≥ 1 of the following conventional therapies:
	  ○ Oral/rectal 5-aminosalicylic acid agents (e.g., Apriso, balsalazide, Lialda, mesalamine, sulfasalazine)
	  ○ Oral/rectal steroids (e.g., budesonide, hydrocortisone, prednisone)
	  ○ Immunosuppressant (e.g., azathioprine, mercaptopurine); **OR**
	• Patient is deemed high-risk for intestinal complications or post-operative recurrence; **AND**
	• NOT used in combination with any other biologic agent; **AND**
	• Patient has had a 3-month trial and failure of, or contraindication or intolerance to, ≥ 1 preferred cytokine or CAM antagonist indicated for the treatment of UC; **AND**
	• Patient meets the minimum age recommended by the package insert for use in UC.
	
	Renewal Criteria:
	• Documentation (e.g., progress notes) of response to therapy compared to baseline.
	
	Age Limit: ≥ 18 years of age
	Quantity Limit: 1 tablet per day	

4	**New Product to Market: Omvoh™**
	
	Cytokine and CAM Antagonists: Non-Preferred (NPD)
	
	Approval Duration: ***6 months initial; 1 year renewal***
	
	• *Mirkizumab-mrkz is a humanized IgG4 monoclonal antibody indicated for the treatment of moderate to severe ulcerative colitis (UC).*
	
	Initial Approval Criteria:
	• Diagnosis of moderate to severe ulcerative colitis (UC); **AND**
	• Prescribed by, or in consultation with, a gastroenterologist or other specialist in the treatment of UC; **AND**
	• Patient has had a trial and failure of ≥ 1 of the following conventional therapies:
	  ○ Oral/rectal 5-aminosalicylic acid agents (e.g., Apriso, balsalazide, Lialda, mesalamine, sulfasalazine)
	  ○ Oral/rectal steroids (e.g., budesonide, hydrocortisone, prednisone)
	  ○ Immunosuppressant (e.g., azathioprine, mercaptopurine); **OR**
		Decision
		4 For
		0 Against

	Description of Recommendation	P&T Vote
	• Patient is deemed high-risk for intestinal complications or post-operative recurrence; **AND** • NOT used in combination with any other biologic agent; **AND** • Patient has had a 3-month trial and failure of, or contraindication or intolerance to, ≥ 1 preferred cytokine or CAM antagonist indicated for the treatment of UC; **AND** • Patient meets the minimum age recommended by the package insert for use in UC. **Renewal Criteria:** • Documentation (e.g., progress notes) of response to therapy compared to baseline. **Age Limit:** ≥ 18 years of age **Quantity Limit:** 2 mL per 28 days	
5	**New Product to Market: Zurzuvae™** **Antidepressants, Other: Non-Preferred (NPD)** **Approval Duration:** ***Six months with limit of 2 courses of treatment*** *(28 days)* • *Zuranolone is a neuroactive steroid gama-aminobutyric acid $(GABA)_A$ receptor positive modulator indicated for the treatment of postpartum depression (PPD) in adults.* **Initial Approval Criteria:** • Diagnosis of Postpartum Depression (PPD) in adults • Within one year of giving birth **Quantity Limit:** maximum 14 day supply per fill, maximum 2 fills per 180 days	***Decision 4 For 0 Against***
6	**New Product to Market: Xphozah®** **Blood Modifiers, Phosphate Binders: Non-Preferred (NPD)** **Approval Duration:** ***1 year*** • *Tenapanor is a sodium/hydrogen exchanger 3 (NHE3) inhibitor used reduce serum phosphorus in adults with chronic kidney disease (CKD) on dialysis.* **Initial Approval Criteria:** • Diagnosis of chronic kidney disease; **AND** • Diagnosis of elevated serum phosphorous; **AND** • Patient is on dialysis; **AND**	***Decision 4 For 0 Against***

	Description of Recommendation	P&T Vote
	• Patient has had a trial and failure, contraindication to, intolerance, or inadequate response to at least 2 preferred phosphate binders. **Age Limit:** ≥ 18 years of age **Quantity Limit:** 2 tablets daily	
7	**Cephalosporins and Related Antibiotics** • 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 will require PA. • For any new chemical entity in the Cephalosporins and Related Antibiotics class, require PA until reviewed by the P&T Committee.	***Decision 4 For 0 Against***
8	**Glucocorticoids, Inhaled** • 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 Glucocorticoids, Inhaled class, require PA until reviewed by the P&T Committee.	***Decision 4 For 0 Against***
9	**Hepatitis C 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 will require PA. • For any new chemical entity in the Hepatitis C Agents class, require PA until reviewed by the P&T Committee.	***Decision 4 For 0 Against***
10	**Macrolides/Ketolides** • 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 Macrolides/Ketolides class, require PA until reviewed by the P&T Committee.	***Decision 4 For 0 Against***
11	**Oxazolidinones** • 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 Oxazolidinones class, require PA until reviewed by the P&T Committee.	***Decision 4 For 0 Against***

	Description of Recommendation	P&T Vote
12	**Tetracyclines** • 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 Tetracyclines class, require PA until reviewed by the P&T Committee.	***Decision*** ***4 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
15	• **Antibiotics, Gastrointestinal** • **Antibiotics, Inhaled** • **Antibiotics, Vaginal** • **Antifungals, Oral** • **Antihistamines, Minimally Sedating** • **Antiretrovirals, HIV/AIDS** • **Bronchodilators, Beta Agonist** • **Chronic Obstructive Pulmonary Disease (COPD) Agents** • **Epinephrine, Self-Injectable** • **Hepatitis B Agents** • **Intranasal Rhinitis Agents** • **Leukotriene Modifiers** • **Oral Antivirals, Herpes** • **Oral Antivirals, Influenza** • **Penicillins** • **Pleuromutulins** • **Quinolones** • **Sulfonamides, Folate Antagonist**	***Decision*** ***4 For*** ***0 Against***