The following tables list the agenda items as well as the Options for Consideration that are scheduled to be presented and reviewed at the January 18, 2024 meeting of the Pharmacy and Therapeutics Advisory Committee.

SINGLE AGENT REVIEWS

Agent	Options for Consideration

New Product to Market
Vowst™ (fecal microbiota spores, live-brpk)
	Antibiotics, Gastrointestinal: Non-Preferred (NPD)
	
	Approval Duration: *30 days (Limit to 1 fill per approval)*
	
	• *The mechanism of action for Vowst has not been fully established.*
	
	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

Agent	Options for Consideration

New Product to Market
Bimzelx® (bimekizumab-bkzx)
	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 with antigen binding regions that selectively bind to human interleukin 17A (IL-17A), interleukin 17F (IL-17F), and interleukin 17-A, thereby inhibiting interaction with the IL-17 receptor complex. IL-17A and IL-17F are cytokines involved in inflammatory and immune responses. Bimekizumab-bkzx inhibits the release of proinflammatory cytokines and chemokines.*
	
	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 mL per 28 days

Agent	Options for Consideration

New Product to Market
Velsipity™ (etrasimod arginine)
	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. Etrasimod partially and reversibly blocks the capacity of lymphocytes to egress from lymphoid organs, reducing the number of lymphocytes in peripheral blood. The mechanism by which etrasimod exerts therapeutic effects in ulcerative colitis is unknown but may involve the reduction of lymphocyte migration into the intestines.*
	
	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 daily

New Product to Market Omvoh™ (mirikizumab-mrkz)	**Cytokine and CAM Antagonists: Non-Preferred (NPD)** **Approval Duration: *6 months initial; 1 year renewal***

Agent	Options for Consideration

	• *Mirkizumab-mrkz is a humanized IgG4 monoclonal antibody that selectively binds to the p19 subunit of human IL-23 cytokine and inhibits its interaction with the IL-23 receptor. Mirkizumab-mrkz inhibits the release of pro-inflammatory cytokines and chemokines.*
	
	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: 2 mL per 28 days

New Product to Market Zurzuvae™ (zuranolone)	**Antidepressants, Other: Non-Preferred (NPD)** **Approval Duration:** ***Six months with limit of 2 courses of treatment*** *(28 days)* • Mechanism of action thought related to positive modulation of GABA-A receptors.

Agent	Options for Consideration
	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
New Product to Market Xphozah® (tenapanor)	**Blood Modifiers, Phosphate Binders: Non-Preferred (NPD)** **Approval Duration:** ***1 year*** • *Tenapanor inhibits sodium/hydrogen exchanger 3 (NHE3) in the small intestine and colon to decrease phosphate absorption through the paracellular pathway, the main method of phosphate absorption.* **Initial Approval Criteria:** • Diagnosis of chronic kidney disease; **AND** • Diagnosis of elevated serum phosphorous; **AND** • Patient is on dialysis; **AND** • 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

FULL CLASS REVIEWS

PDL Class	Options for Consideration
Cephalosporins and Related Antibiotics	**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.
Glucocorticoids, Inhaled	**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.

PDL Class	Options for Consideration
	• For any new chemical entity in the Glucocorticoids, Inhaled class, require PA until reviewed by the P&T Committee.
Hepatitis C Agents	**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.
Macrolides/Ketolides	**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.
Oxazolidinones	**Oxazolidinones** • DMS to select preferred agent(s) based on economic evaluation; however, at least 1 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 Oxazolidinones class, require PA until reviewed by the P&T Committee.
Tetracyclines	**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.

CONSENT AGENDA ITEMS

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, 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**