Commissioner for the Department for Medicaid Services Selections for Preferred Products

The following tables provide a summary of the final Preferred Drug List (PDL) selections made by the Commissioner for 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 **January 18, 2024**, and the resulting official recommendations.

NEW PRODUCTS 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

Drug Class	Preferred Agents	Non-Preferred Agents
Antibiotics, Gastrointestinal	*Firvanq* CC	*Aemcolo*
	Metronidazole tablet	*Dificid* CC, QL
	Neomycin	*Flagyl*
	Tinidazole	*Likmez*
	Vancomycin capsule CC	*Metronidazole capsule*
	Xifaxan CC, QL	*Nitazoxamide*
		Paromomycin
		Solosec AE, CC, QL
		Vancocin
		Vancomycin solution
		Vowst AE, CC, QL

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

Drug Class	Preferred Agents	Non-Preferred Agents
Cytokine and CAM Antagonists	*Cosentyx* CC, QL	*Abrilada* CC, QL
	Enbrel CC, QL	*Actemra* CC, QL
	Humira CC, QL	*Adalimumab-aacf* CC, QL
	Otezla CC, QL	*Adalimumab-adaz* CC, QL
	Xeljanz CC, QL	*Adalimumab-adbm* CC, QL
		Adalimumab-fjkp CC, QL
		Amjevita CC, QL
		Bimzelx AE, CC, QL
		Cibinqo CC, QL
		Cimzia CC, QL
		Cyltezo CC, QL
		Enspryng AE, CC, QL
		Hadlima CC, QL
		Hulio CC, QL
		Hyrimoz CC, QL
		Idacio CC, QL
		Ilaris CC, QL
		Ilumya AE, CC, QL
		Kevzara AE, CC, QL
		Kineret CC, QL
		Olumiant AE, CC, QL
		Omvoh AE, CC, QL
		Orencia CC, QL
		Rinvoq AE, CC, QL
		Siliq AE, CC, QL
		Simponi CC, QL
		Skyrizi AE, CC, QL
		Sotyktu AE, CC, QL
		Stelara CC, QL
		Taltz CC, QL
		Tremfya AE, CC, QL
		Velsipity AE, CC, QL
		Xeljanz XR CC, QL
		Yuflyma CC, QL
		Yusimry CC, QL

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).*

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

Drug Class	Preferred Agents	Non-Preferred Agents
Cytokine and CAM Antagonists	*Cosentyx* CC, QL	*Abrilada* CC, QL
	Enbrel CC, QL	*Actemra* CC, QL
	Humira CC, QL	*Adalimumab-aacf* CC, QL
	Otezla CC, QL	*Adalimumab-adaz* CC, QL
	Xeljanz CC, QL	*Adalimumab-adbm* CC, QL
		Adalimumab-fjkp CC, QL
		Amjevita CC, QL
		Bimzelx AE, CC, QL
		Cibinqo CC, QL
		Cimzia CC, QL
		Cyltezo CC, QL
		Enspryng AE, CC, QL
		Hadlima CC, QL

Drug Class	Preferred Agents	Non-Preferred Agents
		Hulio CC, QL
		Hyrimoz CC, QL
		Idacio CC, QL
		Ilaris CC, QL
		Ilumya AE, CC, QL
		Kevzara AE, CC, QL
		Kineret CC, QL
		Olumiant AE, CC, QL
		Omvoh AE, CC, QL
		Orencia CC, QL
		Rinvoq AE, CC, QL
		Siliq AE, CC, QL
		Simponi CC, QL
		Skyrizi AE, CC, QL
		Sotyktu AE, CC, QL
		Stelara CC, QL
		Taltz CC, QL
		Tremfya AE, CC, QL
		Velsipity AE, CC, QL
		Xeljanz XR CC, QL
		Yuflyma CC, QL
		Yusimry CC, QL

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**
- 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

Drug Class	Preferred Agents	Non-Preferred Agents
Cytokine and CAM Antagonists	*Cosentyx* CC, QL	*Abrilada* CC, QL
	Enbrel CC, QL	*Actemra* CC, QL
	Humira CC, QL	*Adalimumab-aacf* CC, QL
	Otezla CC, QL	*Adalimumab-adaz* CC, QL
	Xeljanz CC, QL	*Adalimumab-adbm* CC, QL
		Adalimumab-fjkp CC, QL
		Amjevita CC, QL
		Bimzelx AE, CC, QL
		Cibinqo CC, QL
		Cimzia CC, QL
		Cyltezo CC, QL
		Enspryng AE, CC, QL
		Hadlima CC, QL
		Hulio CC, QL
		Hyrimoz CC, QL
		Idacio CC, QL
		Ilaris CC, QL
		Ilumya AE, CC, QL
		Kevzara AE, CC, QL
		Kineret CC, QL
		Olumiant AE, CC, QL
		Omvoh AE, CC, QL
		Orencia CC, QL
		Rinvoq AE, CC, QL
		Siliq AE, CC, QL
		Simponi CC, QL
		Skyrizi AE, CC, QL
		Sotyktu AE, CC, QL
		Stelara CC, QL
		Taltz CC, QL
		Tremfya AE, CC, QL

Drug Class	Preferred Agents	Non-Preferred Agents
		Velsipity AE, CC, QL
		Xeljanz XR CC, QL
		Yuflyma CC, QL
		Yusimry CC, QL

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

Drug Class	Preferred Agents	Non-Preferred Agents
Antidepressants, Other	*Bupropion*	*Aplenzin ER tablet*
	Bupropion SR tablet	*Auvelity tablet* AE, CC, QL
	Bupropion XL 150 mg, 300 mg tablet	*Bupropion XL 450 mg tablet*
	Mirtazapine ODT	*Forfivo XL tablet*
	Mirtazapine tablet	*Nefazodone tablet*
	Trazodone tablet	*Remeron Soltab*
		Remeron tablet
		Spravato spray AE, CC, QL
		Trintellix tablet
		Viibryd tablet dose pack
		Viibryd tablet
		Vilazodone tablet
		Wellbutrin SR tablet
		Wellbutrin XL tablet
		Zurzuvae CC, QL

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**
- 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

Drug Class	Preferred Agents	Non-Preferred Agents
Electrolyte Depleters	*Calcium Acetate capsule*	*Auryxia*
	Calcium Acetate tablet	*Fosrenol chewable tablet*
	Renvela powder packet	*Fosrenol powder packet*
	Renvela tablet	*Lanthanum Carbonate chewable tablet*
		Renagel
		Sevelamer Carbonate powder packet
		Sevelamer tablet
		Velphoro
		Xphozah *AE, CC, QL*

FULL CLASS REVIEWS

Cephalosporins and Related Antibiotics

Class Selection & Guidelines

- 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.

Drug Class	Preferred Agents	Non-Preferred Agents
Cephalosporins and Related Antibiotics	*Cefaclor Capsule*	*Cefaclor ER Tablet*
	Cefadroxil Capsule	*Cefaclor Suspension*
	Cefadroxil Suspension	*Cefadroxil Tablet*
	Cefdinir Capsule	*Cefixime Capsule*
	Cefdinir Suspension	*Cefixime Suspension*
	Cefprozil Suspension	*Cefpodoxime Suspension*
	Cefprozil Tablet	*Cefpodoxime Tablet*
	Cefuroxime Tablet	*Cephalexin Tablet*
	Cephalexin Capsule	*Suprax Capsule*
	Cephalexin Suspension	*Suprax Suspension*
		Suprax Chewable Tablet

Glucocorticoids, Inhaled

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 *Glucocorticoids, Inhaled* class, require PA until reviewed by the P&T Committee.

Drug Class	Preferred Agents	Non-Preferred Agents
Glucocorticoids, Inhaled	*Asmanex Twisthaler* QL	*Alvesco* QL
	Budesonide Inhalation Suspension AE, QL	*Armonair Digihaler* QL
	Flovent HFA QL	*Arnuity Ellipta* QL
	Fluticasone Propionate HFA QL	*Asmanex HFA* QL
		Flovent Diskus QL
		Fluticasone Propionate Diskus QL
		Pulmicort Respules QL
		Pulmicort Flexhaler QL
		Qvar RediHaler

Hepatitis C Agents

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 *Hepatitis C Agents* class, require PA until reviewed by the P&T Committee.

Drug Class	Preferred Agents	Non-Preferred Agents
Hepatitis C Agents	*Mavyret* AE, CC, QL	*Epclusa* AE, CC, QL
	Sofosbuvir/velpatasvir AE, CC, QL	*Harvoni* AE, CC, QL
		Ledipasvir/sofosbuvir AE, CC, QL
		Sovaldi AE, CC, QL
		Viekira Pak AE, CC, QL
		Vosevi AE, CC, QL
		Zepatier AE, CC, QL

Macrolides/Ketolides

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 *Macolides/Ketolides* class, require PA until reviewed by the P&T Committee.

Drug Class	Preferred Agents	Non-Preferred Agents
Macrolides/Ketolides	*Azithromycin Packet*	*Clarithromycin ER Tablet*
	Azithromycin Suspension	*E.E.S. 400 Tablet*
	Azithromycin Tablet	*Eryped Suspension*
	Clarithromycin Suspension	*Ery-Tab DR Tablet*
	Clarithromycin Tablet	*Erythrocin Stearate Tablet*
	E.E.S. Granules	*Erythromycin Ethylsuccinate Suspension*
	Erythromycin DR Capsule	*Erythromycin Ethylsuccinate Tablet*
	Ery-Tab DR Tablet	*Erythromycin Tablet*
		Erythromycin DR Tablet
		Zithromax Powder Packet
		Zithromax Suspension
		Zithromax Tablet
		Zithromax Tri-Pak

Oxazolidinones

Class Selection & Guidelines

- 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.

Drug Class	Preferred Agents	Non-Preferred Agents
Oxazolidinones	***Linezolid suspension*** *QL, MD*	*Linezolid suspension QL, MD*
	Linezolid tablet CC, QL, MD	*Sivextro QL*
		Zyvox suspension *QL, MD*
		Zyvox tablet QL, MD

Tetracyclines

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 *Tetracyclines* class, require PA until reviewed by the P&T Committee.

Drug Class	Preferred Agents	Non-Preferred Agents
Tetracyclines	*Demeclocycline Tablet*	*Doryx MPC DR Tablet*
	Doxycycline Hyclate Capsule	*Doryx DR Tablet*
	Doxycycline Hyclate Tablet	*Doxycycline Hyclate DR Tablet*
	Doxycycline Monohydrate 50, 100 mg Capsule	*Doxycycline IR-DR Capsule*
	Doxycycline Monohydrate Suspension	*Doxycycline Monohydrate 40, 75, 150 mg Capsule*
	Doxycycline Monohydrate Tablet	*LymePak*
	Minocycline Capsule	*Minocycline ER Tablet*
	Tetracycline Capsule	*Minocycline Tablet*
		Minolira ER Tablet
		Morgidox Capsule
		Morgidox Kit
		Nuzyra Tablet
		Solodyn ER Tablet
		Vibramycin Capsule

CONSENT AGENDA REVIEWS

For the following therapeutic classes, there were no changes in PDL status:

Therapeutic Classes
• 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