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 **March 18, 2021** 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	**Clinical Criteria Review: Gimoti™** **Non-preferred in the PDL class:** *Anti-Emetics: Other* **Length of Authorization:** 8 weeks • Gimoti™ (metoclopramide) is a nasally administered dopamine-2 (D2) antagonist indicated for the relief of symptoms in adults with acute and recurrent diabetic gastroparesis. **Criteria for Approval** • Diagnosis of diabetic gastroparesis; AND • Prescribed by an endocrinologist, gastroenterologist or other specialist in the diagnosis and treatment of diabetic gastroparesis; AND • Prescriber attests that patient does NOT meet ANY of the following conditions: o History of signs or symptoms of tardive dyskinesia (TD); o History of a dystonic reaction to metoclopramide; o Known or suspected circumstances where stimulation of gastrointestinal (GI) motility could be dangerous (e.g., GI hemorrhage, mechanical obstruction, or perforation); o Known or suspected pheochromocytoma or other catecholamine-releasing paraganglioma; o Diagnosis of epilepsy or any other seizure disorder; o Hypersensitivity to metoclopramide (e.g., angioedema, bronchospasm); o Moderate or severe renal impairment (creatinine clearance [CrCl] < 60 mL/minute); o Moderate or severe hepatic impairment (Child-Pugh B or C); AND • Prescriber attests that each course of treatment, with all dosage forms and routes of administration of metoclopramide, will NOT extend beyond 12 weeks; AND • Adequate (e.g., 2-4 week) trial and failure of oral (e.g., tablet, solution, orally disintegrating tablet) or injectable (e.g., intramuscular) metoclopramide; OR • NOT a candidate for oral metoclopramide (e.g., demonstrated or documented erratic absorption of oral medications). **Renewal Criteria** (duration 8 weeks) • Must continue to meet initial authorization criteria; AND • At least 2 weeks have passed (i.e., drug holiday) since completion of a previous course of metoclopramide treatment of any dosage form; AND • Demonstrated improvement in signs and symptoms of diabetic gastroparesis (e.g., nausea, vomiting, early satiety, postprandial fullness, bloating, upper abdominal pain); AND	**Passed** 9 For 0 Against

	Description of Recommendation	P & T Vote
	• Prescriber attestation that the patient is being monitored for extrapyramidal symptoms (e.g., tardive dyskinesia, dystonia) or other serious adverse events (e.g., suicidal ideation, fluid retention). **Age Limit:** ≥ 18 years **Quantity Limit:** 1 bottle (9.8 mL) per 28 days	
2	**Antibiotics, GI** • 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 *Antibiotics, GI* class, require PA until reviewed by the P&T Advisory Committee.	**Passed** 9 For 0 Against
3	**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. **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** 9 For 0 Against
4	**Antiretrovirals: HIV/AIDS** • DMS to select preferred agent(s) based on economic evaluation; however, at least 3 first-line treatment regimens should be preferred. • Agents not selected as preferred will be considered non-preferred and will require PA. • For any new chemical entity in the *Antiretrovirals: HIV/AIDS* class, require PA until reviewed by the P&T Advisory Committee. **Note:** Allow grandfathering of members using agents moving to non-preferred.	**Passed** 9 For 0 Against
5	**Intranasal Antihistamines and Anticholinergics** • 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 *Intranasal Antihistamines and Anticholinergics* class, require PA until reviewed by the P&T Advisory Committee. **Intranasal Corticosteroids** • 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 *Intranasal Corticosteroids* class, require PA until reviewed by the P&T Advisory Committee.	**Passed** 9 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
6	• Absorbable Sulfonamides • Antibiotics, Inhaled • Antibiotics, Vaginal • Antifungals, Oral • Antihistamines, Minimally Sedating • Antivirals, Oral • Bronchodilators, Beta Agonist • Cephalosporins and Related Antibiotics • COPD Agents • Epinephrine, Self-Injected • Fluoroquinolones, Oral • Glucocorticoids, Inhaled • Hepatitis B Agents • Leukotriene Modifiers • Macrolides • Oxazolidinones • Penicillins • Pleuromutulins • Tetracyclines	**Passed** 9 For 0 Against