Kentucky Department for Medicaid Services
Drug Review and Options for Consideration

The following tables list the Agenda items as well as the Options for Consideration that are scheduled to be presented and reviewed at the **March 18, 2021** meeting of the Pharmacy and Therapeutics Advisory Committee.

Clinical Criteria Review	Options for Consideration

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:
	  ○ History of signs or symptoms of tardive dyskinesia (TD);
	  ○ History of a dystonic reaction to metoclopramide;
	  ○ Known or suspected circumstances where stimulation of gastrointestinal (GI) motility could be dangerous (e.g., GI hemorrhage, mechanical obstruction, or perforation);
	  ○ Known or suspected pheochromocytoma or other catecholamine-releasing paraganglioma;
	  ○ Diagnosis of epilepsy or any other seizure disorder;
	  ○ Hypersensitivity to metoclopramide (e.g., angioedema, bronchospasm);
	  ○ Moderate or severe renal impairment (creatinine clearance [CrCl] < 60 mL/minute);
	  ○ 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**
	• 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

Full Class Reviews	Options for Consideration
Antibiotics, GI	**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.
Hepatitis C Agents **(Hepatitis C: Direct-Acting Antiviral Agents; Hepatitis C: Interferons; Hepatitis C: Ribavirins)**	**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.
HIV/AIDS **(Antiretrovirals: HIV/AIDS)**	**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.
Intranasal Rhinitis Agents **(Intranasal Antihistamines and Anticholinergics; Intranasal Corticosteroids)**	**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.

Consent Agenda	Options for Consideration
For the following therapeutic classes, there are **no recommended changes to the currently posted Preferred Drug List (PDL) status**; these may be voted on as a group:	
• 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