Pharmacy Policy Bulletin: J-1004 Gimoti (metoclopramide) nasal spray – Commercial and Healthcare Reform	
Number: J-1004	**Category:** Prior Authorization
Line(s) of Business: ☒ Commercial ☒ Healthcare Reform ☐ Medicare	**Benefit(s):** **Commercial:** **Prior Authorization (1.):** 1. Other Managed Drugs = Yes w/ Prior Authorization **Healthcare Reform:** Not Applicable
Region(s): ☒ All ☐ Delaware ☐ New York ☐ Pennsylvania ☐ West Virginia	**Additional Restriction(s):** None
Version: J-1004-008	**Original Date:** 08/05/2020
Effective Date: 10/08/2025	**Review Date:** 09/17/2025

Drugs Product(s):	• Gimoti (metoclopramide) nasal spray
FDA-Approved Indication(s):	• Relief of symptoms in adults with acute and recurrent diabetic gastroparesis

Background:	• Gimoti is a dopamine-2 (D2) antagonist that stimulates motility of the upper gastrointestinal (GI) tract without stimulating gastric, biliary, or pancreatic secretions. Gimoti increases the tone and amplitude of gastric contractions, relaxes the pyloric sphincter and the duodenal bulb, and increases peristalsis of the duodenum and jejunum resulting in accelerated gastric emptying and intestinal transit.
	• Diabetic gastroparesis is a delay in gastric emptying in the upper GI tract. It may be one of the most common GI complications of patients with diabetes. Early signs and symptoms may not be noticed by the patient or physician then progress to nausea, vomiting of undigested food, bloating, and abdominal pain.
	• For patients unable to swallow oral dosage forms, orally disintegrating tablets (ODT) may be a cost-effective alternative.
	• The systemic absorption of Gimoti after nasal administration was lower than that after oral administration given the same dose.
	• Metoclopramide is currently the only medication FDA-approved for diabetic gastroparesis. The American College of Gastroenterology (ACG) 2022 guidelines suggest treatment with metoclopramide over no treatment for management of refractory symptoms (conditional recommendation, low quality of evidence).
	• Prescribing Considerations:
	  ○ Gimoti has black box warnings for the following:
	  ▪ The risk of developing tardive dyskinesia (TD) and the likelihood that TD will become irreversible increases with duration of Gimoti treatment and total cumulative dosage. Gimoti should be discontinued in patients who develop signs or symptoms of TD.

	▪ Treatment with metoclopramide (all dosage forms and routes of administration) for longer than 12 weeks should be avoided due to the risk of developing TD with longer-term use. ○ Gimoti is contraindicated when stimulation of GI motility might be dangerous. ○ Gimoti is not recommended for use in pediatric patients due to the risk of TD and other extrapyramidal symptoms as well as the risk of methemoglobinemia in neonates. ○ Avoid Gimoti use in patients with a history of depression. ○ Gimoti is not recommended for use in moderate or severe hepatic impairment (Child-Pugh B or C) or moderate or severe renal impairment (creatinine clearance less than 60 mL/minute). ○ Gimoti is not recommended as initial therapy in adults 65 years of age and older. Geriatric patients must receive an alternative metoclopramide product titrated to a stable dosage of 10 mg four times daily and then can be switched to Gimoti. ○ Gimoti is not recommended in patients who are CYP2D6 poor metabolizers. ○ Metoclopramide-treated patients with NADH-cytochrome b5 reductase deficiency are at an increased risk of developing methemoglobinemia and/or sulfhemoglobinemia.

Approval Criteria

I. Initial Authorization

When a benefit, coverage of Gimoti may be approved when all of the following criteria are met **(A. through E.)**:

A. The member is 18 years of age or older.

B. The member has a diagnosis of diabetic gastroparesis (ICD-10: E11.43, K31.84), classified as acute or recurrent.

C. The prescriber attests the member does not have signs or symptoms of tardive dyskinesia.

D. The member meets one (1) of the following criteria **(1. or 2.)**:

1. The member has experienced therapeutic failure or intolerance to one (1) of the following plan-preferred agents **(a. or b.)**:

a. generic metoclopramide oral tablets or ODT

b. generic metoclopramide oral solution

2. The member is not a candidate for oral dosage forms.

E. If the member is 65 years of age or older, the member was titrated to a stable dose of metoclopramide oral tablets or metoclopramide oral solution at 10 mg four (4) times daily before switching to Gimoti therapy.

II. Reauthorization

When a benefit, reauthorization of Gimoti may be approved when all of the following criteria are met **(A. through E.)**:

A. The prescriber attests that the member has experienced positive clinical response to therapy.

B. The member is using Gimoti for a new episode of diabetic gastroparesis.

C. The member has undergone a 2 week drug holiday without Gimoti since its last administration.

D. The prescriber attests the member does not have signs or symptoms of tardive dyskinesia.

E. The prescriber attests that the benefits of extending therapy with Gimoti outweigh the risk of developing tardive dyskinesia.

III. An exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.

Limitations of Coverage

I. Coverage of drug(s) addressed in this policy for disease states outside of the FDA-approved indications should be denied based on the lack of clinical data to support effectiveness and safety in other conditions unless otherwise noted in the approval criteria.

II. For Commercial or HCR members with a closed formulary, a non-formulary product will only be approved if the member meets the criteria for a formulary exception in addition to the criteria outlined within this policy.

Authorization Duration

- Commercial and HCR Plans: If approved, up to a 12 week authorization may be granted.

Automatic Approval Criteria

None.

References:

1. Gimoti [package insert]. Solana Beach, CA: EvokePharma; January 2021.
2. American Diabetes Association. Standards of Medical Care in Diabetes—2024. *Diabetes Care*. 2020; 47(1).
3. Camilleri M, Kuo B, Nguyen L, et al. ACG clinical guideline: Gastroparesis. *American Journal of Gastroenterology*. 2022;117(8):1197-1220.