# Clinical Policy: Metoclopramide (Gimoti)

Reference Number: ERX.NPA.151
Effective Date: 12.01.20
Last Review Date: 11.22
Line of Business: Commercial, Medicaid

Revision Log

**See Important Reminder at the end of this policy for important regulatory and legal information.**

**Description**
Metoclopramide (Gimoti™) is a dopamine-2 (D2) antagonist.

**FDA Approved Indication(s)**
Gimoti is indicated for the relief of symptoms in adults with acute and recurrent diabetic gastroparesis.

Limitation(s) of use: Gimoti is not recommended for use in:
- Pediatric patients due to the risk of tardive dyskinesia (TD) and other extrapyramidal symptoms as well as the risk of methemoglobinemia in neonates
- Moderate or severe hepatic impairment (Child-Pugh B or C), moderate or severe renal impairment (creatinine clearance less than 60 mL/minute), and patients concurrently using strong CYP2D6 inhibitors due to the risk of increased drug exposure and adverse reactions

**Policy/Criteria**
*Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.*

*Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.*

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that Gimoti is **medically necessary** when the following criteria are met:

**I. Initial Approval Criteria**

**A. Diabetic Gastroparesis** (must meet all)**:**
1. Diagnosis of diabetic gastroparesis;
2. Age ≥ 18 years;
3. Documentation supports member's inability to use all formulary generic metoclopramide products (oral tablets, oral disintegrating tablets, injection);
4. Dose does not exceed one amber vial (10 mL) per month.

**Approval duration: 12 weeks**

**B. Other diagnoses/indications**
1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

**II. Continued Therapy**

**A. Diabetic Gastroparesis**
1. Re-authorization is not permitted. Members must meet the initial approval criteria.

**Approval duration: Not applicable**

**B. Other diagnoses/indications** (must meet 1 or 2)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   **Approval duration: Duration of request or 12 months (whichever is less)**; or

2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

**III. Diagnoses/Indications for which coverage is NOT authorized:**

**A.** Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – ERX.PA.01 or evidence of coverage documents.

**IV. Appendices/General Information**

*Appendix A: Abbreviation/Acronym Key*
FDA: Food and Drug Administration
TD: tardive dyskinesia

*Appendix B: Therapeutic Alternatives*
*This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.*

| Drug Name | Dosing Regimen | Dose Limit/ Maximum Dose |
|---|---|---|
| metoclopramide (Reglan®) | Continuous dosing: 10-15 mg orally 4 times a day given 30 minutes before meals and at bedtime for 4 to 12 weeks<br><br>Intermittent dosing: up to 20 mg orally as a single dose given prior to provoking situation | 60 mg/day, avoid use for longer than 12 weeks |

*Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.*

*Appendix C: Contraindications/Boxed Warnings*

- Contraindication(s): history of TD or dystonic reactions to metoclopramide; when stimulation of the gastrointestinal motility might be dangerous; pheochromocytoma, catecholamine-releasing paragangliomas; epilepsy; or hypersensitivity to metoclopramide
- Boxed warning(s): TD; the risk of developing TD increases with duration of treatment and total cumulative dosage

**V. Dosage and Administration**

| Indication | Dosing Regimen | Maximum Dose |
|---|---|---|
| Diabetic gastroparesis | 1 spray in one nostril, 30 minutes before each meal and at bedtime, for 2 to 8 weeks, depending on symptomatic response<br><br>Avoid treatment with metoclopramide (all dosage forms and routes of administration) for longer than 12 weeks because of the increased risk of developing TD with longer-term use | 4 sprays daily |

**VI. Product Availability**

Nasal spray*: 15 mg metoclopramide in each 70 microliter spray
*Gimoti is supplied in a 10 mL amber glass bottled fitted with a metered spray pump attachment, a protective cap, and a safety clip. Each bottle is sufficient for 4 weeks of 4 times a day use.

**VII. References**

1. Gimoti Prescribing Information. Solana Beach, CA: Evoke Pharma, Inc.; January 2021. Available at: https://evokepharma.com/product-focus/gimoti/. Accessed July 28, 2022.
2. American College of Gastroenterology (ACG). Clinical Guideline: Management of Gastroparesis. *Am J. Gastroenterol.* 2013; 108:18-37.

3. American Gastroenterological Association. Technical Review on the Diagnosis and Treatment of Gastroparesis. *Gastroenterol*. 2004: 127:1592-1622.
4. American Society for Gastrointestinal Endoscopy. The role of endoscopy in gastroduodenal obstruction and gastroparesis. *Gastrointestinal Endoscopy*. 2011; 74(1): 13-21.

| Reviews, Revisions, and Approvals | Date | P&T Approval Date |
|---|---|---|
| Policy created | 07.16.20 | 11.20 |
| 4Q 2021 annual review: no significant changes; references reviewed and updated. | 06.28.21 | 11.21 |
| 4Q 2022 annual review: no significant changes; references reviewed and updated. | 07.28.22 | 11.22 |

**Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.

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