Clinical Policy: Metoclopramide (Gimoti)

Reference Number: CP.PMN.252
Effective Date: 12.01.20
Last Review Date: 11.24
Line of Business: Commercial, HIM, 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 (D_2) 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.

It is the policy of health plans affiliated with Centene Corporation® 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 (e.g., oral tablets, oral disintegrating tablets, injection);
4. Dose does not exceed both of the following (a and b):
   a. 4 sprays per day;
   b. One amber vial (10 mL) per month.

Approval duration: 12 weeks

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):

a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or

2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

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. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

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 policies – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid 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 for all relevant lines of business 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 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; 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 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/wp-content/uploads/Prescribing-Information-Gimoti%E2%84%A2-metoclopramide-nasal-spray.pdf. Accessed July 16, 2024.
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. *Gastroenterology*. 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.
5. Camilleri M, Kuo B, Nguyen L, et al. ACG clinical guideline: Gastroparesis. Am J gastroenterol 2022;117:1197-1220.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	07.16.20	11.20
4Q 2021 annual review: no significant changes; references to HIM.PHAR.21 revised to HIM.PA.154; references reviewed and updated.	06.28.21	11.21
4Q 2022 annual review: no significant changes; references reviewed and updated. Template changes applied to other diagnoses/indications.	07.28.22	11.22
4Q 2023 annual review: no significant changes; references reviewed and updated.	07.06.23	11.23
4Q 2024 annual review: added maximum quantity limit of 4 sprays daily to criteria; references reviewed and updated.	07.16.24	11.24

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. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy,

contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. 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. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members, and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.