

Gimoti™ (metoclopramide nasal spray)

Policy # 00741

Original Effective Date: 04/12/2021

Current Effective Date: 04/01/2026

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Investigational or experimental services are not covered. This includes any drug, device, procedure, or service provided under the investigational arm of a clinical trial or clinical study. These services are excluded from coverage under benefits.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider Gimoti™[‡] (metoclopramide nasal spray) to be **eligible for coverage**** when the patient selection criteria are met.

Patient Selection Criteria

Coverage eligibility for Gimoti (metoclopramide nasal spray) will be considered when the following criteria are met:

- Patient has a diagnosis of diabetic gastroparesis; AND
- Patient is 18 years of age or older; AND
- Patient has tried and failed (e.g., intolerance or inadequate response) BOTH GENERIC oral erythromycin and GENERIC oral metoclopramide unless there is clinical evidence or patient history that suggests the use of these products will be ineffective or cause an adverse reaction to the patient.

*(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met)*

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of Gimoti (metoclopramide nasal spray) when the patient has not tried and failed BOTH GENERIC oral erythromycin and GENERIC oral metoclopramide to be **not medically necessary.****

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When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of Gimoti (metoclopramide nasal spray) for non-FDA approved indications OR for patients under 18 years of age to be **investigational**.*

Background/Overview

Gimoti is a dopamine 2 agonist indicated for the relief of symptoms in adults with acute and recurrent diabetic gastroparesis. The effectiveness of Gimoti was established based on studies of oral metoclopramide for the relief of symptoms in adults with acute and recurrent diabetic gastroparesis. Dosing is based on age, but the targeted dose is one spray in each nostril, 30 minutes before each meal and at bedtime for 2 to 8 weeks. The exact mechanism of action of metoclopramide has not been established in this condition, however it is known to stimulate the motility of the upper gastrointestinal tract without stimulating gastric, biliary, or pancreatic secretions. Metoclopramide is also known to increase the tone and amplitude of gastric (especially antral) contractions, relax the pyloric sphincter and the duodenal bulb, and increase peristalsis of the duodenum and jejunum resulting in accelerated gastric emptying and intestinal transit. It also increases the resting tone of the lower esophageal sphincter.

Diabetic gastroparesis is a syndrome of delayed gastric emptying of solids in the absence of a mechanical obstruction. The cardinal symptoms include nausea, vomiting, early satiety, belching, bloating, and/or upper abdominal pain. Approximately 11-18% of patients with diabetes experience gastroparesis. Patients with diabetes have abnormalities primarily caused by autonomic dysfunction or an abnormal intrinsic nervous system. These abnormalities lead to the symptoms of gastroparesis. Initial treatment includes dietary modifications (small frequent meals low in fat with soluble fibers). If dietary changes do not work, prokinetics, such as metoclopramide or erythromycin can be used. These agents are available in generic form and offer a more economical, yet equally efficacious option as compared to Gimoti, which is available as a brand product only.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Gimoti is indicated for the relief of symptoms in adults with acute and recurrent diabetic gastroparesis.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

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The effectiveness of Gimoti was established based on studies of oral metoclopramide for the relief of symptoms in adults with acute and recurrent diabetic gastroparesis. Given this information and the availability of generic options for therapy (one of which contains an identical active ingredient), there is no reason to use Gimoti over the other available treatment options.

References

1. Gimoti [package insert]. Evoke Pharma, Inc. Solana Beach, California. Updated January 2021.

Policy History

Original Effective Date: 04/12/2021

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03/04/2021	Medical Policy Committee review
03/10/2021	Medical Policy Implementation Committee approval. New policy.
03/03/2022	Medical Policy Committee review
03/09/2022	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
03/02/2023	Medical Policy Committee review
03/08/2023	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
03/07/2024	Medical Policy Committee review
03/13/2024	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
03/06/2025	Medical Policy Committee review
03/12/2025	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
03/05/2026	Medical Policy Committee review
03/11/2026	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 03/2027

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
 1. Consultation with technology evaluation center(s);

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2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
3. Reference to federal regulations.

****Medically Necessary (or “Medical Necessity”)** - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. In accordance with nationally accepted standards of medical practice;
- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient’s health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.

NOTICE: If an authorization for an ongoing course of treatment has been provided to a member and the member changes from one health plan to another health plan (e.g., a member moves from carrier A to Louisiana Blue), Louisiana Blue may honor the previous health plan’s authorization for the same service under the same type of in-network benefit for a 90-day transition period. Documentation of the authorization for the ongoing course of treatment from the previous health plan must be provided to us by the member or their provider and the services provided for the course of treatment must otherwise be a covered service under the Louisiana Blue health plan. This provision does not apply to medications covered under the plan’s pharmacy benefit.