Gimoti®
(metoclopramide)
nasal spray

Coverage Authorization Checklist for Healthcare Professionals

This checklist and sample letter of medical necessity (LMN) are intended to help you prepare an LMN for GIMOTI in the treatment of suitable patients with diabetic gastroparesis.

Patients who may need financial assistance with GIMOTI should contact EvokeAssist™

at 1-833-4-GIMOTI (1-833-444-6684), Monday to Friday from **8 AM to 7 PM Eastern Time**.

EVOKE PHARMA

Please see full Important Safety Information on page 3 and complete Prescribing Information, including Boxed Warning, and Patient Information.

Letter of Medical Necessity Checklist

Patient Information

- ☐ Patient name
- ☐ Plan identification number, group number, claim number
- ☐ Diagnosis with applicable ICD code(s)

Examples of Relevant ICD-10-CM Codes

Code	Description
E10.43	Use to specify a diagnosis of type 1 diabetes mellitus with diabetic autonomic (poly)neuropathy
E11.43	Use to specify a diagnosis of type 2 diabetes mellitus with diabetic autonomic (poly)neuropathy
K31.84	Use to specify a diagnosis of gastroparesis

Summary of Patient's Treatment History

- ☐ Age, sex
- ☐ Diagnosis and severity of current DGP condition
- ☐ Brief medical history (present-day condition, recent history of diabetic gastroparesis (DGP) symptoms and related ER visits and hospitalizations, other related medical conditions/comorbidities)
- ☐ Previous DGP therapies and outcomes (indication, duration, dosage, and reason for prescribing, rationale for why each DGP treatment was discontinued)
- ☐ Prognosis or disease progression without treatment with Gimoti® (metoclopramide) nasal spray

Enclosures

- ☐ Clinical notes and labs supporting your recommendation (include, when available, gastric emptying study, upper endoscopy, HbA1c)
- ☐ Link to the Prescribing Information (included in the LMN template)
- ☐ Link to FDA approval letter (included in the LMN template)

The sample letter is for demonstration purposes only. It is not intended to be a substitute for or to influence the independent clinical decision of the prescriber. Using this sample or the information in it does not guarantee reimbursement or coverage. Payers may have specific forms or may require additional documentation to show medical necessity.

Important Safety Information

INDICATION

Gimoti® (metoclopramide) nasal spray is indicated for the relief of symptoms in adults with acute and recurrent diabetic gastroparesis.

Limitations of Use

GIMOTI is not recommended for use in pediatric patients, in patients with moderate or severe hepatic impairment, in patients with moderate or severe renal impairment, or in patients concurrently using strong CYP2D6 inhibitors.

IMPORTANT SAFETY INFORMATION

BOXED WARNING: TARDIVE DYSKINESIA

- **Metoclopramide can cause tardive dyskinesia (TD), a serious movement disorder that is often irreversible. The risk of developing TD increases with duration of treatment and total cumulative dosage.**
- **Discontinue GIMOTI in patients who develop signs or symptoms of TD. In some patients, symptoms may lessen or resolve after metoclopramide is stopped.**
- **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.**

CONTRAINDICATIONS

GIMOTI is contraindicated in patients with a history of TD or a dystonic reaction to metoclopramide; when the stimulation of gastrointestinal motility might be dangerous (eg, in the presence of gastrointestinal hemorrhage, mechanical obstruction, or perforation); in patients with pheochromocytoma or other catecholamine-releasing paragangliomas (metoclopramide may cause a hypertensive/pheochromocytoma crisis, probably due to release of catecholamines from the tumor); in patients with epilepsy (metoclopramide may increase the frequency and severity of seizures); in patients with hypersensitivity to metoclopramide (reactions have included laryngeal and glossal angioedema and bronchospasm).

WARNING AND PRECAUTIONS

TARDIVE DYSKINESIA (TD): Metoclopramide can cause TD, a syndrome of potentially irreversible involuntary movements of the face or tongue, and sometimes of the trunk and/or extremities. The risk of developing TD and the likelihood that TD will become irreversible increases with the duration of treatment and the total cumulative dosage. The risk of developing TD is increased in the elderly, especially elderly women, and in patients with diabetes mellitus. Due to the risk of developing TD, avoid treatment with metoclopramide for longer than 12 weeks. GIMOTI is not recommended in geriatric patients as initial therapy. See Full Prescribing Information for switching geriatric patients on a stable dose of an alternative metoclopramide product to GIMOTI.

Other extrapyramidal symptoms (EPS): In addition to TD, metoclopramide may cause other EPS, parkinsonian symptoms, and motor restlessness. Advise patients to seek immediate medical attention if such symptoms occur and to discontinue GIMOTI.

Neuroleptic malignant syndrome (NMS): Metoclopramide may cause a potentially fatal symptom complex called NMS. Clinical manifestations of NMS include hyperpyrexia, muscle rigidity, altered mental status, and manifestations of autonomic instability (irregular pulse or blood pressure, tachycardia, diaphoresis, and cardiac arrhythmias). Additional signs may include elevated creatine phosphokinase, myoglobinuria (rhabdomyolysis), and acute renal failure. Patients with such symptoms should be evaluated immediately. Avoid GIMOTI in patients receiving other drugs associated with NMS, including typical and atypical antipsychotics.

Depression: Depression has occurred in metoclopramide-treated patients with and without a history of depression. Symptoms have included suicidal ideation and suicide. Avoid GIMOTI use in patients with a history of depression.

Hypertension: Metoclopramide may elevate blood pressure and should be avoided in patients with hypertension or in patients taking monoamine oxidase inhibitors (MAOIs). Discontinue GIMOTI in any patient with a rapid rise in blood pressure.

Fluid Retention: Because metoclopramide produces a transient increase in plasma aldosterone, patients with cirrhosis or congestive heart failure may be at risk of developing fluid retention and volume overload. Discontinue GIMOTI if any of these adverse reactions occur.

Important Safety Information (cont'd)

Hyperprolactinemia: As with other dopamine-D_2 receptor antagonists, metoclopramide elevates prolactin levels and may suppress pituitary gonadotropin secretion. This may inhibit reproductive function by impairing gonadal steroidogenesis in both female and male patients. Galactorrhea, amenorrhea, gynecomastia, and impotence have been reported with prolactin-elevating drugs, including metoclopramide.

Effects on the ability to drive and operate machinery: Metoclopramide may impair the mental and/or physical abilities required for the performance of hazardous tasks such as operating machinery or driving a motor vehicle. Concomitant use of CNS depressants or drugs associated with EPS may increase this effect (eg, alcohol, sedatives, hypnotics, opiates, and anxiolytics). Avoid GIMOTI or the interacting drug, depending on the importance of the drug to the patient.

ADVERSE REACTIONS

The most common adverse reactions in patients treated with GIMOTI are dysgeusia, headache, and fatigue. In patients receiving an equivalent oral dose of metoclopramide, the most common adverse reactions were restlessness, drowsiness, fatigue, and lassitude. Adverse reactions involving the nervous system occurred after stopping oral metoclopramide, including dizziness, nervousness, and headaches.

DRUG INTERACTIONS

Avoid concomitant use with antipsychotics, MAOIs, and central nervous system (CNS) depressants. Concomitant use with strong CYP2D6 inhibitors (eg, quinidine, bupropion, fluoxetine, paroxetine) is not recommended. Use with caution with dopaminergic agonists and drugs that increase dopamine concentration. Monitor for reduced therapeutic effect when used with drugs that may have opposing effects on gastrointestinal motility (eg, antiperistaltics, anticholinergics, opiates). Monitor patients receiving GIMOTI for increased blood glucose and adjust insulin dose regimen as needed.

USE IN SPECIFIC POPULATIONS

Pregnancy: Published studies do not report a consistent pattern or a consistently increased risk of pregnancy-related adverse outcomes with oral use of metoclopramide during pregnancy. There are potential risks to the neonate during delivery following exposure to metoclopramide in utero.

Lactation: Breastfed infants exposed to metoclopramide have experienced gastrointestinal adverse reactions, including intestinal discomfort and increased intestinal gas formation. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for GIMOTI and any potential adverse effects on the breastfed child from GIMOTI or from the underlying maternal condition.

Pediatric: Metoclopramide is not recommended for use in pediatric patients due to the risk of TD and other EPS as well as the risk of methemoglobinemia in neonates.

Geriatric: Elderly patients are more likely to have decreased renal function and may be more sensitive to the therapeutic or adverse effects of metoclopramide, especially older women. GIMOTI is not recommended as initial therapy.

Renal impairment: GIMOTI is not recommended in patients with moderate and severe renal impairment.

Hepatic impairment: GIMOTI is not recommended in patients with moderate or severe hepatic impairment.

NADH-cytochrome b_5 reductase deficiency: Metoclopramide-treated patients with NADH-cytochrome b_5 reductase deficiency are at an increased risk of developing methemoglobinemia and/or sulfhemoglobinemia.

CYP2D6 poor metabolizers: GIMOTI is not recommended in patients who are CYP2D6 poor metabolizers.

Please see complete Prescribing Information, including Boxed Warning, and Patient Information.

You may report side effects related to Evoke Pharma products by calling 1-833-4-GIMOTI (1-833-444-6684) or emailing GIMOTImedinfo@evokepharma.com. If you prefer to report side effects to the FDA, either visit www.FDA.gov/medwatch or call 1-800-FDA-1088.

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