



Commercial/Healthcare Exchange PA Criteria

Effective: October 7, 2020

Prior Authorization: Gimoti

Products Affected: Gimoti 15mg/actuation nasal spray

Medication Description: Metoclopramide stimulates motility of the upper gastrointestinal tract without stimulating gastric, biliary, or pancreatic secretions. The exact mechanism of action of metoclopramide in the treatment of gastroesophageal reflux and acute and recurrent diabetic gastroparesis has not been fully established. It seems to sensitize tissues to the action of acetylcholine. The effect of metoclopramide on motility is not dependent on intact vagal innervation, but it can be abolished by anticholinergic drugs.

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

Exclusion Criteria:

1. Patients with a history of tardive dyskinesia (TD) or a dystonic reaction to metoclopramide
2. In patients where stimulation of gastrointestinal motility might be dangerous (e.g., in the presence of gastrointestinal hemorrhage, mechanical obstruction, or perforation).
3. Patients with pheochromocytoma or other catecholamine-releasing paragangliomas.
4. Patients with epilepsy
5. Patients with hypersensitivity to metoclopramide.
6. Pediatric patients
7. Patients with moderate or severe hepatic impairment (Child-Pugh B or C)
8. Patients with moderate or severe renal impairment (creatinine clearance less than 60 mL/minute)
9. Concurrent use with strong CYP2D6 inhibitors due to the risk of increased drug exposure and adverse reactions

Required Medical Information:

1. Diagnosis
2. Medical history
3. Previous therapies tried

Age Restrictions: 18 years of age and older

Prescriber Restrictions: N/A

Coverage Duration: 12 weeks

Other Criteria:

- A. Patient has a diagnosis of diabetic gastroparesis with acute or recurrent symptoms; **AND**
- B. Patient has had a trial and failure to an oral metoclopramide dosage form; **OR**
- C. Patient is unable to ingest oral dosage forms due to one of the following:
 - a. i. Oral/motor difficulties; **OR**
 - b. ii. Dysphagia

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Confidential Information

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References:

1. Gimoti (metoclopramide) [prescribing information]. Solana Beach, CA: Evoke Pharma Inc; June 2020.

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	10/7/2020