

PRIOR AUTHORIZATION CRITERIA

BRAND NAME
(generic)

GIMOTI
(metoclopramide nasal spray)

Status: CVS Caremark® Criteria
Type: Initial Prior Authorization

POLICY

FDA-APPROVED INDICATIONS

Gimoti 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 due to the risk of developing 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.

COVERAGE CRITERIA

The requested drug will be covered with prior authorization when the following criteria are met:

- The requested drug is being prescribed for the relief of symptoms in an adult with acute or recurrent diabetic gastroparesis

AND

- The patient will not use the requested drug for more than 12 consecutive weeks of therapy

AND

- The patient has experienced an inadequate treatment response or intolerance to oral metoclopramide

OR

- The patient is unable to take oral metoclopramide

REFERENCES

1. Gimoti [package insert]. Solana Beach, CA: Evoke Pharma, Inc.; January 2021.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online, Waltham, MA: UpToDate, Inc.; 2023. <https://online.lexi.com>. Accessed February 24, 2023.
3. Micromedex (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 02/24/2023).
4. Camilleri M, Parkman HP, Shafi MA, et al. Clinical guideline: Management of Gastroparesis. *Am J Gastroenterol* 2013;108(1):18-37.
5. Liu N, Abell T. Gastroparesis Updates on Pathogenesis and Management. *Gut and Liver* 2017;11(5):579-589.

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