Clinical Policy: Gastric Electrical Stimulation

Reference Number: CP.MP.40
Effective Date: 09/09
Last Review Date: 10/16

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Gastric electrical stimulation (GES) has been used in patients who are proven refractory to conventional treatment for gastroparesis. It can be used as an alternative to surgery to reduce some symptoms of gastroparesis. Electrodes that are surgically or endoscopically attached to the stomach wall deliver timed electrical impulses to trigger stomach contractions. This stimulation has not shown a significant improvement in gastric emptying, but has shown to benefit those with nausea and vomiting as their main symptoms.

Policy/Criteria

I. It is the policy of health plans affiliated with Centene Corporation that GES is **medically necessary** for diabetic and idiopathic gastroparesis when all of the following criteria are met:
   A. Severe nausea and vomiting occurring at least once daily for the duration of ≥1 year, *and*
   B. Documented intolerance or failure to a trial of antiemetic and prokinetic drug therapy;
   C. Does not have any of the following contraindications:
      1. Pregnancy;
      2. Chemical dependency;
      3. Undergoing peritoneal dialysis;
      4. Diagnosis of cancer with a limited estimated life span.

Note: Current recommended combination prokinetic therapy includes metoclopramide and erythromycin.

II. It is the policy of health plans affiliated with Centene Corporation that GES is **not medically necessary** for reduction in pain, fullness, bloating, or acid reflux symptoms as there is no evidence to support efficacy of such therapy.

III. It is the policy of health plans affiliated with Centene Corporation that GES is **investigational** for the treatment of obesity due to a lack of evidence in the peer review literature demonstrating the long term safety and efficacy of this device.

Background

Gastric Electrical Stimulation for Gastroparesis

Gastroparesis is a disorder in which there is delayed gastric emptying following ingestion of food, in the absence of mechanical obstruction, due to abnormal or absent motility of the stomach. The stomach is unable to contract normally, and therefore cannot crush food nor propel food into the small intestine properly.

Approximately two-thirds of cases are idiopathic or associated with diabetes mellitus, but gastroparesis may also develop after gastric surgery and in other less common conditions. The main symptoms include nausea, vomiting, early satiety, bloating, and discomfort. Nausea and vomiting may be so severe that they cause weight loss, dehydration, electrolyte disturbances, and malnutrition.

It is theorized that GES works in the following ways:

1. Activation of the central mechanisms for nausea and vomiting control related to afferent nerves being stimulated by the constant high frequency current in the stomach wall.
2. Enhanced relaxation of the fundus of the stomach by this current thus providing better accommodation and decreased sensitivity to distention.
3. Augmentation of the amplitude of gastric slow wave after eating.
4. Increase in cholinergic function and decreased sympathetic functions
5. Small and unpredictable improvements in gastric emptying.

The results of a number of studies have shown an improvement in quality of life score, even though on average, gastric emptying did not change. Quality of life scores improved along with a decrease in hospital admission days, reduction in hemoglobin A1C, and weight gain. Nausea and vomiting have also showed improvements for at least one year after surgery.

Gastric Electrical Stimulation for Obesity

GES is currently under investigation as a treatment for obesity. Cha et al. (2014) reviewed current approaches to evaluate the effect GES on obesity. 31 studies were included in their systematic review. Although most of the studies showed weight loss in the treatment group, most had a follow-up duration of 12 months or less. Some of the evaluated GES treatments also showed positive effects in lowering HbA1c and blood pressure.[9] Cha et al. stated that GES holds great promise for the treatment of obesity, but stronger studies with longer follow-up are needed to determine long-term effects.[9] Lebovitz (2016) reviewed the evidence on three different methods of GES, including the Transcend® Implantable Gastric Stimulator, the Maestro™ vagal blockade device, and the DIAMOND™ gastric electrical stimulatory device.[10] Two randomized controlled trials failed to show a significant benefit in excess weight loss with the Transcend device.[10] The other evaluated GES device, the DIAMOND, has been assessed in clinical trials with obese patients with type 2 diabetes. Findings were positive but varied among the patients included in treatment. Effects included reduced HbA1c and weight loss, and seemed to be influenced by baseline HbA1c levels and triglyceride levels.[10] Further research is needed to determine long-term effects and appropriate patient selection criteria to ensure the best outcomes.

Coding Implications

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CPT®* Codes	Description
43647	Laparoscopy, surgical; implantation or replacement of gastric neurostimulator electrodes, antrum
43648	Laparoscopy, surgical; revision or removal of gastric neurostimulator electrodes, antrum
43881	Implantation or replacement of gastric neurostimulator electrodes, antrum, open
43882	Revision or removal of gastric neurostimulator electrodes, antrum, open
64590	Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling
64595	Revision or removal of peripheral or gastric neurostimulator pulse generator or receiver

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HCPCS Codes	Description
E0765	FDA approved nerve stimulator with replaceable batteries for nausea and vomiting

ICD-10-CM Diagnosis Codes that Support Coverage Criteria

ICD-10-CM Code	Description
E08.43	Diabetes mellitus due to underlying condition with diabetic autonomic (poly) neuropathy
E09.43	Drug or chemical induced diabetes mellitus with neurological complications with diabetic autonomic (poly) neuropathy
E10.43	Type I diabetes mellitus with diabetic autonomic (poly) neuropathy
E11.43	Other specified diabetes mellitus with diabetic autonomic (poly) neuropathy
E13.43	Other specified diabetes mellitus with diabetic autonomic (poly) neuropathy
K31.84	Gastroparesis

Reviews, Revisions, and Approvals	Date	Approval Date
References reviewed and updated. Modified language regarding trial of antiemetic and prokinetic drug therapy.	09/11	11/11
References reviewed and updated.	12/12	12/12
Clarified langue in bullet points under Policy/Criteria	10/13	10/13
References and coding reviewed and updated	10/14	10/14
Converted into new template References & coding reviewed and updated	10/15	10/15
Added obesity as an investigational indication; added supporting background information. Changed exclusions to contraindications in criteria.	10/16	10/16

Bibliography

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9. Cha R, Marescaux J, Diana M. Updates on gastric electrical stimulation to treat obesity: Systematic review and future perspectives. World J Gastrointest Endosc. 2014 Sep 16;6(9):419-31.
10. Lebovitz HE. Interventional treatment of obesity and diabetes: An interim report on gastric electrical stimulation. Rev Endocr Metab Disord. 2016 17: 73-80. DOI 10.1007/s11154-016-9350-7.

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

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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.

Note: For Medicare members, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs,

and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at http://www.cms.gov for additional information.