Clinical Policy: Gastric Electrical Stimulation

Reference Number: PA.CP.MP.40
Effective Date: 01/18
Date of Last Review: 5/17/2022

Coding Implications
Revision Log

Description

Gastric electrical stimulation (GES) has been used as compassionate care in patients who are proven refractory to conventional treatment for gastroparesis.[1] It can be used as an alternative to surgery to reduce symptoms of gastroparesis.[2] The GES device includes a pair of leads that are placed in the muscularis propria of greater curvature of the stomach about 10 cm proximal to the pylorus.[3] The leads are connected to a pulse generator that is typically placed subcutaneously in the right or left upper quadrants of the abdomen, and an external programming device controls the gastric stimulation parameters of the GES device.[3] This stimulation has not shown a significant improvement in gastric emptying but has proven to be beneficial in those who have nausea and vomiting as primary symptoms.[4-5]

Policy/Criteria

I. It is the policy of Pennsylvania Health and Wellness® (PHW) that GES is **medically necessary** for diabetic and idiopathic gastroparesis when all of the following criteria are met:
   A. Diagnosis of gastroparesis confirmed by gastric emptying scintigraphy;
   B. Severe nausea and vomiting occurring at least once daily on most days of the week for the duration of ≥1 year;
   C. Documented intolerance or failure to a trial of antiemetic and prokinetic drug therapy;
   D. Is not currently pregnant.

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

II. It is the policy of PHW 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 PHW that GES is **investigational** for all other indications, including but not limited to, 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 (GES) 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.[2,6-7] The stomach is unable to contract normally and cannot crush food or propel food into the small intestine properly.[2,8]

There are numerous conditions associated with gastroparesis, but the majority of gastroparesis cases are either idiopathic or associated with diabetes.[6,8] The main symptoms of gastroparesis include nausea, vomiting, early satiety, bloating, and abdominal discomfort.[6-8] Nausea and vomiting may be so severe that it causes weight loss, dehydration, electrolyte disturbances, and malnutrition.[3]

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 the electrical 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.

Multiple studies on GES for gastroparesis have shown an improvement in quality of life scores, even though on average, gastric emptying did not change. Quality of life scores improved along with weight gain, and there was a reduction in hemoglobin A1C (HbA1c) and a decrease in hospitalizations.[5] Nausea and vomiting also improved for at least one year after surgery.[4-5,9]

Gastric Electrical Stimulation for Obesity

GES is currently not supported by peer-reviewed literature as a treatment for obesity. Cha et al[10] reviewed current approaches to evaluate the effect of GES on obesity and included 31 studies in their systematic review. Most of the studies showed weight loss during the first 12 months of treatment, but only a few studies performed follow-up past 1 year. Some of the evaluated GES treatments also showed positive effects in lowering HbA1c and blood pressure. The review concluded that GES is promising for the treatment of obesity, but stronger studies with longer follow-up are needed to determine long-term effects.[10]

Lebovitz[11] 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. Two randomized controlled trials failed to show a significant benefit in excess weight loss with the Transcend device. The other evaluated GES device, the DIAMOND, has been assessed in clinical trials with obese patients with type II diabetes. Findings were positive and included reduced HbA1c and weight loss, but these results varied among patients included in the treatment and seemed to be influenced by baseline HbA1c levels and triglyceride levels. Further research is needed to determine long-term effects and appropriate patient selection criteria to ensure the best outcomes.[11]

Coding Implications

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CPT® Codes	Description
43647	Laparoscopy, surgical; implantation or replacement of gastric neurostimulator electrodes, antrum

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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
95980	Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance, and patient measurements) gastric neurostimulator pulse generator/transmitter, intraoperative, with programming
95981	Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient measurements) gastric neurostimulator pulse generator/transmitter; subsequent, without reprogramming
95982	Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient measurements) gastric neurostimulator pulse generator/transmitter; subsequent, with reprogramming

HCPCS Codes	Description
C1767	Generator, neurostimulator (implantable), nonrechargeable
C1778	Lead, neurostimulator (implantable)
L8679	Implantable neurostimulator, pulse generator, any type
L8680	Implantable neurostimulator electrode, each
L8688	Implantable neurostimulator pulse generator, dual array, nonrechargeable, includes extension

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

ICD-10-CM Code	Description
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
K91.89	Other postprocedural complications and disorders of digestive system

Reviews, Revisions, and Approvals	Revision Date	Approval Date
Policy Developed	11/17	1/18
Added "gastric emptying" to scintigraphy in I.A. for clarification. Modified III. to state that GES is investigational for all other indications, including but not limited to the treatment obesity. References and codes reviewed and updated.	08/18	09/18
Reference reviewed and updated. Removed contraindications of alcohol dependency, dialysis, and cancer w/limited life span. Specialist review.	11/19	1/10/2020
References reviewed and updated. Specialist reviewed. Annual review complete.	2/18/2021	
Annual review. Updated description and background with no clinical significance or impact on criteria. Changed "review date" in the header to "date of last revision" and "date" in the revision log header to "revision date." References reviewed, reformatted, and updated. Specialist reviewed.	5/17/2022	

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