Clinical Policy: Gastric Electrical Stimulation

Reference Number: LA.CP.MP.40 Coding Implications
Date of Last Revision: ~~5/22~~4/23 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 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 ~~some~~ 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 ten 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] ~~Electrodes that are 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 been shown to benefit those with nausea and vomiting as their main symptoms.~~

Policy/Criteria

I. It is the policy of Louisiana Healthcare Connections that gastric electrical stimulation (GES) is **medically necessary** for diabetic and idiopathic gastroparesis when all of the following criteria are met:

A. Diagnosis of idiopathic 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~~ more than one year;
C. Documented intolerance or failure of~~to~~ a trial of antiemetic, dietary modifications, and prokinetic drug therapy;
D. ~~Is n~~Not currently pregnant;~~.~~
~~D.~~E. Technology is provided in accordance with the Humanitarian Device Exemption (HDE) specifications of the U.S. Food and Drug Administration (FDA).

Note:

- Current recommended combination prokinetic therapy includes metoclopramide and erythromycin, and centrally acting antidepressants used as symptom modulators.
- A humanitarian device exemption (HDE) is granted by the FDA. A humanitarian use device (HUD) is a device that is intended to benefit patients in the treatment or diagnosis of a disease or condition that affects fewer than 8,000 individuals in the United States annually. A HUD may only be used in facilities that have established a local institutional review board to supervise clinical testing of devices and after an independent review board has approved the use of the device to treat or diagnose the specific disease.~~.~~[14]

II. It is the policy of Louisiana Healthcare Connections that GES is **not medically necessary** for the reduction of pain, fullness, bloating, or acid reflux symptoms as there is no evidence to support efficacy of such therapy.

III. It is the policy of Louisiana Healthcare Connections that current evidence in peer-reviewed literature does not support the use of GES for any other indications, including, but not limited to the treatment of obesity. ~~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 ~~therefore~~ cannot crush food ~~n~~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 one~~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] ~~11~~

Coding Implications

This clinical policy references Current Procedural Terminology (CPT®). CPT® is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted 2023~~19~~, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from the current manuals and those included herein are not intended to be all-inclusive and are for informational purposes only. They are current at time of review of this policy. Inclusion or exclusion of any codes does not guarantee coverage and may not support medial necessity. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

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
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

* All non-covered codes are reviewed for medical necessity for members under 21 years old

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

* All non-covered codes are reviewed for medical necessity for members under 21 years old

~~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~~
~~K91.89~~	~~Other postprocedural complications and disorders of digestive system~~

Reviews, Revisions, and Approvals	Revision Date	Approval Date
Converted corporate to local policy.	08/15/2020	
Annual review. References reviewed and updated. Updated description and background with no clinical significance. Added “and may not support medical necessity” to Coding Implications section	5/22	
Annual review. Updated description with no impact on criteria. Added criteria that gastroparesis should be confirmed by scintigraphy. Modified criteria in I.B requiring daily vomiting to say that vomiting should happen at least once daily on *most days of the week*. “Dietary modifications” added to I.C. and “FDA specifications” added as I.E. Updated verbiage in note at the end of criteria I. and added additional note about humanitarian device exemptions. ICD-10 code table removed. References reviewed and updated. External specialist reviewed.	4/23	

References

1. Camilleri M. Treatment of gastroparesis. UpToDate. www.uptodate.com. Published August 31, 2022. Accessed January 19, 2023~~November 11, 2021. Accessed January 14, 2022~~.
2. Health Technology Assessment. Gastric electrical stimulation for gastroparesis. Hayes. www.hayesinc.com. Published October 26, 2018. (annual review December 7, 2022). Accessed January 19, 2023~~review March 09, 2021) Accessed January 18, 2022~~.
3. Hasler WL. Electrical stimulation for gastroparesis. UpToDate. www.uptodate.com. Published May 31, 2022. Accessed January 19, 2023~~May 05, 2020. Accessed January 14, 2022~~.
4. Abell TL, Van Cutsem E, Abrahamsson H, et al. Gastric electrical stimulation in intractable symptomatic gastroparesis. Digestion. 2002;66(4):204-212. doi:10.1159/000068359
5. Forster J, Sarosiek I, Lin Z, et al. Further experience with gastric stimulation to treat drug refractory gastroparesis. Am J Surg. 2003;186(6):690-695. doi:10.1016/j.amjsurg.2003.08.024
6. Camilleri M. Gastroparesis: Etiology, clinical manifestations, and diagnosis. UpToDate. www.uptodate.com. Published August 15, 2022. Accessed January 19, 2023~~September 30, 2020. Accessed January 14, 2022~~.
7. Parkman HP, Fass R, Foxx-Orenstein AE. Treatment of patients with diabetic gastroparesis. Gastroenterol Hepatol (N Y). 2010;6(6):1–16.
8. Camilleri M, Parkman HP, Shafi MA, Abell TL, Gerson L; American College of Gastroenterology. Clinical guideline: management of gastroparesis. Am J Gastroenterol. 2013;108(1):18-38. doi:10.1038/ajg.2012.373
9. Abell T, Lou J, Tabbaa M, Batista O, Malinowski S, Al-Juburi A. Gastric electrical stimulation for gastroparesis improves nutritional parameters at short, intermediate, and long-term follow-up. JPEN J Parenter Enteral Nutr. 2003;27(4):277-281. doi:10.1177/0148607103027004277
10. Cha R, Marescaux J, Diana M. Updates on gastric electrical stimulation to treat obesity: Systematic review and future perspectives. World J Gastrointest Endosc. 2014;6(9):419-431. doi:10.4253/wjge.v6.i9.419
11. ~~Lebovitz HE. Interventional treatment of obesity and diabetes: An interim report on gastric electrical stimulation. Rev Endocr Metab Disord. 2016;17(1):73-80. doi:10.1007/s11154-016-9350-7~~

11.

12. Reddivari AKR, Mehta P. Gastroparesis. In: *StatPearls*. Treasure Island (FL): StatPearls Publishing; September 30, 2022.
13. Setya A, Nair P, Cheng SX. Gastric electrical stimulation: An emerging therapy for children with intractable gastroparesis. *World J Gastroenterol*. 2019 Dec 28;25(48):6880 through 6889. doi:10.3748/wjg.v25.i48.6880. PMID: 31908392; PMCID: PMC6938723.
14. U.S. Food and Drug Administration (FDA). Humanitarian Device Exemption (HDE) Program. Guidance for Industry and Food and Drug Administration Staff. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/humanitarian-device-exemption-hde-program. Published September 2019. Accessed January 24, 2023.

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. LHCC makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable LHCC administrative policies and procedures.

This clinical policy is effective as of the date determined by LHCC. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. LHCC retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members/enrollees. This clinical policy is not intended to recommend treatment for members/enrollees. Members/enrollees should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom LHCC has no control or right of control. Providers are not agents or employees of LHCC.

This clinical policy is the property of LHCC. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members/enrollees and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members/enrollees and their representatives agree to be bound by such terms and conditions by providing services to members/enrollees and/or submitting claims for payment for such services.