Clinical Policy: Gastric Electrical Stimulation

Reference Number: CP.MP.40
Date of Last Revision: 02/24

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 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 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.[8,10]

Policy/Criteria

I. It is the policy of health plans affiliated with Centene Corporation® that gastric electrical stimulation (GES) is **medically necessary** for diabetic and idiopathic gastroparesis when all the following criteria are met:

A. Member/enrollee is ≥ 18 years of age;
B. Diagnosis of diabetic or idiopathic gastroparesis confirmed by gastric emptying scintigraphy;
C. Severe nausea and vomiting occurring at least once daily on most days of the week for the duration of more than one year;
D. Documented intolerance or failure of a trial of antiemetic, dietary modifications, and prokinetic drug therapy;
E. Not currently pregnant;
F. 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.[11]

II. It is the policy of health plans affiliated with Centene Corporation 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 health plans affiliated with Centene Corporation 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.

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.[2,4,5] The stomach is unable to contract normally and cannot crush food or propel food into the small intestine properly.[2,6]

There are numerous conditions associated with gastroparesis, but the majority of gastroparesis cases are either idiopathic or associated with diabetes.[4,6] The main symptoms of gastroparesis include nausea, vomiting, early satiety, bloating, and abdominal discomfort.[4,6] 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.[8] Nausea and vomiting also improved for at least one year after surgery.[8,11]

Gastric Electrical Stimulation for Obesity

GES is currently not supported by peer-reviewed literature as a treatment for obesity. Cha et al[7] 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 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.[7]

Lebovitz[8] 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.[8]

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, 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. 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, sacral, or gastric neurostimulator pulse generator or receiver, requiring pocket creation and connection between electrode array and pulse generator or receiver
64595	Revision or removal of peripheral, sacral, or gastric neurostimulator pulse generator or receiver, with detachable connection to electrode array
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), non-rechargeable
C1778	Lead, neurostimulator (implantable)

HCPCS Codes	Description
L8679	Implantable neurostimulator, pulse generator, any type
L8680	Implantable neurostimulator electrode, each
L8688	Implantable neurostimulator pulse generator, dual array, non-rechargeable, includes extension

Reviews, Revisions, and Approvals	Revision Date	Approval Date
References reviewed and updated. Modified language regarding trial of antiemetic and prokinetic drug therapy.	09/11	11/11
Reference reviewed and updated. Removed contraindications of alcohol dependency, dialysis, and cancer w/limited life span. Specialist review.	08/19	09/19
References reviewed and updated. Replaced "members" with "members/enrollees" in all instances.	08/20	09/20
Annual review. Updated description with no 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.	09/21	09/21
Annual review. References reviewed and updated. Updated description and background with no clinical significance.	02/22	02/22
Annual review. "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.	02/23	02/23
Annual review. Updated description and background with no clinical significance. Added I.A. "Member/enrollee is ≥ 18 years of age". Updated I.B. to include "diabetic or" in describing type of gastroparesis. Updates made to CPT code descriptions. References reviewed and updated.	02/24	02/24

References

1. Camilleri M. Treatment of gastroparesis. UpToDate. www.uptodate.com. Published August 31, 2022. Accessed January 2, 2024.
2. Health Technology Assessment. Gastric electrical stimulation for gastroparesis. Hayes. www.hayesinc.com. Published December 7, 2022. Accessed January 2, 2024.
3. Hasler WL. Electrical stimulation for gastroparesis. UpToDate. www.uptodate.com. Published September 12, 2023. Accessed January 2, 2024.
4. Camilleri M. Gastroparesis: Etiology, clinical manifestations, and diagnosis. UpToDate. www.uptodate.com. Published August 15, 2022. Accessed January 2, 2024.
5. Parkman HP, Fass R, Foxx-Orenstein AE. Treatment of patients with diabetic gastroparesis. *Gastroenterol Hepatol (N Y)*. 2010;6(6):1 through 16.
6. Camilleri M, Kuo B, Nguyen L, et al. ACG Clinical Guideline: Gastroparesis. *Am J Gastroenterol*. 2022;117(8):1197 through 1220. doi:10.14309/ajg.0000000000001874

7. 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 through 431. doi:10.4253/wjge.v6.i9.419
8. Lebovitz HE. Interventional treatment of obesity and diabetes: An interim report on gastric electrical stimulation. *Rev Endocr Metab Disord*. 2016;17(1):73 through 80. doi:10.1007/s11154-016-9350-7
9. Reddivari AKR, Mehta P. Gastroparesis. In: *StatPearls*. Treasure Island (FL): StatPearls Publishing; September 30, 2022.
10. 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.
11. 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 2, 2024.
12. Cheng LK, Nagahawatte ND, Avci R, Du P, Liu Z, Paskaranandavadivel N. Strategies to Refine Gastric Stimulation and Pacing Protocols: Experimental and Modeling Approaches. Front Neurosci. 2021;15:645472. Published April 22, 2021. Doi:10.3389/fnins.2021.645472
13. U.S. Food and Drug Administration (FDA). Humanitarian Device Exemption (HDE). Medical Device Record. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfhde/hde.cfm?id=376493. Last updated January 8, 2004. Accessed January 9, 2024.

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 developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

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 Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. 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. The Health Plan 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 the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. 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.

Note: For Medicaid members/enrollees, 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/enrollees, 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.