MEDICAL POLICY

Excellus
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Medical Policy Title	**Gastric Electrical Stimulation**
Policy Number	**7.01.64**
Current Effective Date	**January 23, 2025**
Next Review Date	**January 2026**

Our medical policies are based on the assessment of evidence based, peer-reviewed literature, and professional guidelines. Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract. (Link to Product Disclaimer)

POLICY STATEMENT(S)

Gastric electrical stimulation (GES)/gastric pacing is considered **investigational** for all indications, including, but not limited to, gastroparesis, to predict success of GES with temporary stimulation, any other gastrointestinal dysmotility disorder, and obesity.

RELATED POLICIES

Corporate Medical Policy

11.01.03 Experimental or Investigational Services

POLICY GUIDELINE(S)

The U.S. Food and Drug Administration (FDA) approved the Enterra Therapy GES system for humanitarian use under the Humanitarian Device Exemption (HDE) program. This HDE device is FDA indicated for the treatment of chronic, intractable nausea and vomiting secondary to gastroparesis with failure, contraindication, or intolerance of pharmaceutical therapy (FDA 2000).

DESCRIPTION

Gastric electrical stimulation (GES), also referred to as gastric pacing, uses electrodes implanted on the antrum of the stomach to increase gastric contractions to aid peristaltic activity and to improve gastric emptying. There are currently two methods of electrical delivery, high energy/low frequency (gastric pacing) which has had only limited use in humans, and low energy/high frequency pulsing (neurostimulation). Gastric neurostimulators can be implanted permanently via laparoscopy or laparotomy, or temporarily placed to aid in the prediction of permanent placement success.

GES has been investigated primarily as a treatment for gastroparesis, a chronic disorder of gastric motility characterized by delayed emptying stomach in the absence of a mechanical obstruction. Currently available devices consist of a pulse generator, which can be programmed to provide electrical stimulation at different frequencies, connected to intramuscular stomach leads, which are implanted during laparoscopy or open laparotomy.

GES has also been investigated as a treatment of obesity It is used to increase a feeling of satiety with subsequent reduction in food intake and weight loss. The exact mechanisms resulting in changes in eating behavior are uncertain but may be related to neurohormonal modulation and/or stomach muscle stimulation.

SUPPORTIVE LITERATURE

Gastric Electrical Stimulation for the Treatment of Gastroparesis

For individuals who have gastroparesis who receive GES, the evidence includes nonrandomized studies, randomized controlled trials (RCTs) and systematic review and meta-analysis of RCTs. Several crossover RCTs have been published. Relevant outcomes are symptoms and treatment-related morbidity.

The evidence available from studies is insufficient to support that gastric electrical stimulation is effective for the treatment of patients with gastroparesis. Though the evidence does suggest that GES can relieve nausea and vomiting and may also reduce the need for nutritional support in some patients with intractable gastroparesis, there was no documentation of improved gastric emptying or enhanced gastric motility. The studies included small numbers of patients, had limited follow-up, and were inadequate to establish that GES is an effective or durable treatment for gastroparesis. Long-term results of GES need to be validated in longer-term, randomized trials.

The data presented to the FDA documenting probable benefit of the GES system were based on a multi-center, double-blind crossover study referred to as the Worldwide Anti-vomiting Electrical Stimulation Study (WAVESS) (Abell 2003). The study included 33 patients with intractable idiopathic or diabetic gastroparesis. In the initial phase of the study, all patients underwent implantation and were randomly and blindly assigned to either stimulation ON or stimulation OFF for the first month of the study, with crossover to the opposite mode for the second month. The baseline vomiting frequency was 47 episodes per month, which declined in both the ON mode and the OFF mode to 23 and 29 episodes, respectively. However, no statistically significant differences in the number of vomiting episodes were found between the OFF and ON groups, suggesting a placebo effect. In questioning patients as to which month of treatment they preferred (ON versus OFF), a greater number of patients preferred the month of treatment in the ON mode. In the second phase of the study, patients received stimulation consistent with their preference for the ON or OFF mode. At six- and 12-month follow-up, vomiting episodes continued to decline, although only 15 patients were available for follow-up.

Temporary GES was evaluated in a randomized, placebo-controlled, crossover trial of 58 patients with gastroparesis symptoms (Abell 2011). The study measured the effects of 72 hours of temporary GES on gastroparesis symptoms and consisted of two consecutive 4-day sessions (session 1 and session 2). In session 1, vomiting decreased in both groups, greater with stimulation, resulting in a day 3 difference of −1.02 ($p < .001$). Scores did not return to baseline during washout, and on day 4 the difference persisted at −1.08 ($p = .005$). In session 2, vomiting slightly decreased with stimulation and slightly increased without it. At day 8, the nonactivated group had non-significantly greater vomiting ($p = .762$). An overall treatment effect of a slight, non-significant daily decrease in average vomiting scores ($p = .116$) was observed by pooling stimulation effects across sessions.

A 2017 meta-analysis of 5 RCTs (n=185) and 13 non-RCTs did not find a significant benefit of GES on the severity of symptoms associated with gastroparesis (Levinthal 2017). Patients generally reported improved symptoms at follow-up whether or not the device was turned on, suggesting a placebo effect.

Ducrotte and colleagues (2020) evaluated permanent GES, utilizing Enterra System, in a cross-over trial of 172 patients diagnosed with refractory and chronic vomiting. After GES implantation, patients were randomized to receive stimulation or no stimulation, then were crossed over to the other treatment after 4 months. The primary endpoints were vomiting score (0 is daily vomiting and 4 is no vomiting) and the Gastrointestinal Quality of Life Index. The median vomiting score with device turned on was 2, compare to a vomiting score of 1 with the device turned off (p<.002). However, over 50% of patients reported similar vomiting scores during the on and off period. There was no difference between groups in the quality-of-life measure (73.3 in the on phase and 71.1 in the off; p=.06). Delayed gastric emptying was not different in the on versus off period. Limitations of this trial include the use of an unvalidated scale for the primary endpoint, inclusion of only refractory patients, and only 4-month duration of treatment. The authors concluded that this trial showed that GES is effective in reducing the frequency of refractory vomiting and nausea in a subset of patients with chronic vomiting.

Saleem and colleagues (2024) conducted a systematic review and meta-analysis to address the limited use of gastric electrical stimulation (GES) due to conflicting results of studies. The authors aimed to assess the efficacy of GES for patients with gastroparesis and gastroparesis-like symptoms. A total of nine RCT (n=730 participants), which included seven blinded trials and a large (n=172 participants) cross over study by Durcotte and colleagues in 2020. Included studies were deemed of moderate quality and low risk of bias. Outcomes were divided into blind RCTs and open trials. Pooled blinded RCT studies showed positive significant results in total symptoms score (TSS) with the GES group compared with controls at the 4-day, 2-month, 4-month, and sustained at the 12-month follow-up (-4.5 to -7.65; p<.00001). The analysis of blinded RCT showed no significant difference between the groups in frequency of weekly vomiting episodes (WVF) (MD= 1.76; p = 0.43); in contrast, the analysis of open trials showed significant positive results in WVF (p<0.00001). The open trials analysis found significant positive results (p<0.00001) in TSS, in pre- and post-nausea symptoms severity (NSS), and in vomiting severity symptoms (VSS) at 12 months after treatment (p<0.00001). A significant positive result in gastric emptying retention after two hours or four hours after treatment. The total analysis favored post-GES compared with pre-GES (MD = 18.15% gastric retention; 95% CI, 13.05−23.35; p < 0.00001). Limitations of this analysis include significant heterogeneity among studies that could not be resolved due to high variation of follow-up durations, the use of a variety of different scoring systems which limited the number of studies that could combined into summary statistics, and the possibility of confounding effects from concurrent pharmacologic therapy that were not controlled. The authors concluded that GES appears beneficial, with significant improvement in TSS, weekly vomiting frequency, gastric emptying study and quality of life. Additional blinded RCTs could further establish the criteria for patient selection and GEST settings for optimal effects.

Gastric Electrical Stimulation for the Treatment of Obesity

Shikora and colleagues (2009) reported on a double-blind RCT that assessed GES for the treatment of obesity. In the Screened Health Assessment and Pacer Evaluation (SHAPE) trial, all participants (n=190) received an implantable gastric stimulator and were randomized to have the stimulator turned on or off. All patients were evaluated monthly, participated in support groups, and reduced their dietary intake by 500 kcal/d. At 12-month follow-up, there was no statistically significant

difference in excess weight loss between the treatment group (weight loss, 11.8%) and the control group (weight loss, 11.7%) using intention-to-treat analysis (p=.717).

Small case series and uncontrolled prospective trials (2002 to 2004) have reported positive outcomes for weight loss and maintenance of weight loss along with minimal complications (Cigaina 2002 and 2003; D'Argent 2004; De Luca 2004; Favretti 2004). However, interpretation of these uncontrolled studies is limited.

Paulus and colleagues (2020) conducted a multi-center, phase 1, open prospective clinical trial to assess the safety of the Exilis gastric electrical stimulation (GES) system and to investigate whether the settings can be adjusted for comfortable chronic use in subjects with morbid obesity. Gastric emptying and motility and meal intake were evaluated. Participants (n=20) were implanted with the Exilis and underwent two blinded baseline test days (GES ON versus OFF), after which long-term, monthly follow-up continued for up to 52 weeks. The procedure was safe, and electrical stimulation was well tolerated and comfortable in all subjects. No significant differences in gastric emptying halftime ($p > 0.05$), food intake ($p > 0.05$), insulin AUC ($p > 0.05$), and glucose AUC ($p > 0.05$) were found between GES ON and OFF. At week 4, 13, and 26, a significant ($p < 0.01$) reduction in weight loss was observed but not at week 52. The authors concluded that GES with the Exilis system was considered safe, reduction in weight loss was significant by short lasting. Further research is needed to gain insight in optimal stimulation paraments and lead localization.

PROFESSIONAL GUIDELINE(S)

In 2014, the National Institute for Health and Care Excellence (NICE) issued evidence-based guidance on GES for gastroparesis that the current evidence on the efficacy and safety of gastric electrical stimulation for gastroparesis is adequate to support the use of this procedure with normal arrangements for clinical governance, consent, and audit. NICE acknowledged that some patients do not get any benefit from GES and recommend that patients should be informed of this during the consent process.

In a 2021 consensus on gastroparesis, the effectiveness of GES is not endorsed the by the United European Gastroenterology (UEG) and European Society for Neurogastroenterology and Motility (ESNM). Lack of endorsement is based on grade B moderate evidence.

The 2022 American Gastroenterology Association (AGA) published a clinical practice update on the management of medically refractory gastroparesis. Lacy and colleagues (2022) stated that the precise mechanism of action remains unknown, and GES does not accelerate gastric emptying. GES improves refractory nausea and vomiting in some patients with gastroparesis, and may improve glycemic control, nutritional status, and quality of life, while reducing hospitalizations and medication use. Thus, GES could be a treatment option medically refractory gastroparesis, and temporary electrical stimulation may predict response to GES and should be offered if available.

The American College of Gastroenterology (ACG) Clinical Guidelines for Gastroparesis states that GES may be considered for control of gastroparesis symptoms as a humanitarian use device (conditional recommendation, low quality of evidence) (Camilleri 2022).

REGULATORY STATUS

The Enterra Therapy System (Medtronic Inc.) is a high-frequency gastric electrical stimulation system that is indicated for the treatment of chronic, intractable (drug refractory) nausea and vomiting secondary to gastroparesis of diabetic or idiopathic etiology. The Enterra Therapy system received U.S. Food and Drug Administration (FDA) approval in 2000 as humanitarian use device under the Humanitarian Device Exemption (HDE) program.

Humanitarian Device Exemption (HDE) is the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices. HDE approval for humanitarian use is granted with the understanding that the device is intended to benefit patients in the treatment and diagnosis of diseases and conditions that are rare. A humanitarian use device may only be used in facilities that have an Institutional Review Board (IRB) to supervise clinical testing of the device.

Currently, no GES devices have received FDA approval for any other indication, including for the treatment of obesity. Transneuronix, Inc., acquired by Medtronic in 2005, developed an implantable gastric stimulator, Transcend IGS, which is available in Europe for treatment of obesity.

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
43647 (E/I)	Laparoscopy, surgical; implantation or replacement of gastric neurostimulator electrodes, antrum
43648 (E/I)	revision or removal of gastric neurostimulator electrodes, antrum
43881 (E/I)	Implantation or replacement of gastric neurostimulator electrodes, antrum, open
43882 (E/I)	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 peripheral or gastric neurostimulator pulse generator or receiver

Code	Description
95980 (E/I)	Electronic analysis of implanted neurostimulator pulse generator system (e.g., 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 (E/I)	subsequent, without reprogramming
95982 (E/I)	subsequent, with reprogramming

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HCPCS Codes

Code	Description
C1767	Generator, neurostimulator (implantable), nonrechargeable
C1787	Patient programmer; neurostimulator
C1820	Generator, neurostimulator (implantable), with rechargeable battery and charging system
C1822	Generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system
E0765 (E/I)	FDA approved nerve stimulator, with replaceable batteries, for treatment of nausea and vomiting
L8679	Implantable neurostimulator, pulse generator, any type
L8680	Implantable neurostimulator electrode, each
L8681	Patient programmer (external) for use with implantable programmable neurostimulator pulse generator, replacement only
L8682	Implantable neurostimulator radiofrequency receiver
L8683	Radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receiver
L8685	Implantable neurostimulator pulse generator, single array, rechargeable, includes extension
L8686	Implantable neurostimulator pulse generator, single array, non-rechargeable, includes extension
L8687	Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension

Code	Description
L8688	Implantable neurostimulator pulse generator, dual array, non- rechargeable, includes extension
L8689	External recharging system for battery (internal) for use with implanted neurostimulator, replacement only

ICD10 Codes

Code	Description
E66.01 – E66.9 (code range)	Overweight and obesity
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 1 diabetes mellitus with diabetic autonomic (poly)neuropathy
E11.43	Type 2 diabetes mellitus with diabetic autonomic (poly)neuropathy
E13.43	Other specified diabetes mellitus with diabetic autonomic (poly)neuropathy
K31.84	Gastroparesis
R11.0 - R11.2 (code range)	Nausea and vomiting

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SEARCH TERMS

Not applicable

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Based on our review, gastric electrical stimulation is not addressed in National or Regional Medicare coverage determinations or policies.

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) product) covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.
- If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.

POLICY HISTORY/REVISION

Committee Approval Dates

04/21/05, 01/19/06, 03/15/07, 12/20/07, 10/23/08, 09/17/09, 08/19/10, 07/21/11, 06/21/12, 05/23/13, 05/22/14, 04/16/15, 03/17/16, 03/16/17, 02/15/18, 01/17/19, 01/16/20, 01/21/21, 01/20/22, 01/18/24, 01/23/25

Date	Summary of Changes
01/23/25	• Annual review. Policy statement revised to include clarifying terminology. Policy guideline added related to FDA HDE approval. Policy intent unchanged.
01/01/25	• Summary of changes tracking implemented.
04/15/24	• Original effective date