MEDICAL POLICY

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Medical Policy Title	**Gastric Electrical Stimulation**
Policy Number	**7.01.64**
Current Effective Date	**January 22, 2026**
Next Review Date	**January 2027**

Our medical policies are guides to evaluate technologies or services for medical necessity. Criteria are established through the assessment of evidence based, peer-reviewed scientific literature, and national professional guidelines. Federal and state law(s), regulatory mandates and the member's subscriber contract language are considered first in the determination of a covered service.
(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) granted Humanitarian Device Exemption (HDE) approval for the Enterra Therapy GES system (Medtronic, Inc.) in 2000. Under this exemption, the device is indicated for the treatment of chronic, intractable (drug-refractory) nausea and vomiting associated with gastroparesis of diabetic or idiopathic origin, in patients who have failed, cannot tolerate, or have contraindications to pharmaceutical therapy (FDA 2000). See Regulatory Status.

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.

Abell et al (2011) evaluated temporary GES in a randomized, placebo-controlled, crossover trial of 58 patients with gastroparesis symptoms. 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.

Levinthal et al (2017) conducted a 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 et al (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 et al (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.

Cassidy et al (2024) conducted a prospective, single-center cohort study evaluating clinical outcomes of gastric electrical stimulation (GES) in 157 adults with refractory gastroparesis managed through a

multidisciplinary preoperative optimization protocol. Patients were followed for up to five years, with outcomes assessed using the Gastroparesis Cardinal Symptom Index (GCSI), medication usage, hospitalization rates, patient satisfaction, and device-related interventions. The authors reported significant and sustained improvement in symptom severity across all GCSI domains at 1- and 5-years post-implantation ($p < 0.05$). Medication use, particularly prokinetic and antiemetic agents, decreased substantially, and gastroparesis-related hospitalizations were reduced by 91% at one year compared to baseline ($p < 0.05$). Patient satisfaction remained high (87.1% at 1 year; 79.7% at 5 years). Device-related complications, including lead dislocation and erosion, were infrequent, with explantation occurring in fewer than 3% of patients. Limitations included the lack of a randomized control group, single-center design, and potential selection bias, which reduce the certainty of evidence and limit generalizability. The study concluded that, in carefully selected and medically optimized patients, GES can provide durable symptom relief and reduce healthcare utilization, supporting its role as part of a multidisciplinary treatment approach for refractory gastroparesis.

Gastric Electrical Stimulation for the Treatment of Obesity

Shikora et al (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 et al (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 2025, Staller et al published the American Gastroenterological Association (AGA) Clinical Practice Guideline on Management of Gastroparesis, issuing a conditional recommendation against the routine

use of GES for the treatment of refractory gastroparesis. Based on a very low certainty of evidence, the AGA recommends reserving this procedure for select patients with medically refractory gastroparesis.

In 2022, 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).

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.

REGULATORY STATUS

The Enterra Therapy System (Medtronic) was granted FDA approval in 2000 under the Humanitarian Device Exemption (HDE) program and received an MRI-conditional labeling upgrade in 2024.

HDE is an FDA regulatory pathway for Class III medical devices intended to treat or diagnose conditions affecting no more than 8,000 individuals in the United States per year. Under HDE, manufacturers are exempt from demonstrating effectiveness; instead, FDA must determine that the device does not pose an unreasonable or significant risk and that the probable benefit outweighs the potential risks. As mandated by federal regulations, use of an HDE device requires approval and oversight by an Institutional Review Board (IRB) or an appropriate local committee to ensure compliance with the FDA-approved indication(s) (FDA 2019).

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.

The United States Food and Drug Administration (FDA) regulates gastric electrical stimulators as medical devices. All gastric electrical stimulators require FDA approval before marketing and use in the United States to ensure they are safe and effective for human use. Refer to the FDA Medical Device website. Available from: https://www.fda.gov/medical-devices [accessed 2025 Dec 11]

The FDA lists the most serious type of medical device recalls as well as early alert communications about corrective actions being taken by companies that the FDA believes are likely to be the most serious type of recalls. on our website by the date that the FDA posts the information on our website. Available from: https://www.fda.gov/medical-devices/medical-device-safety/medical-device-recalls-and-early-alerts [accessed 2025 Dec 11]

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
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

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
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

Code	Description
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
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	Overweight and obesity (code range)
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	Nausea and vomiting (code range)

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SEARCH TERMS

Not Applicable

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

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, 01/22/26	
Date	**Summary of Changes**
01/22/26	• Annual review, policy intent unchanged, redirected HCPCS code E0765.
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.
04/21/05	• Original effective date