Anthem

Clinical UM Guideline

Subject: Gastric Electrical Stimulation
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Description

This document addresses gastric electrical stimulation (GES) for gastroparesis and other indications.

GES refers to the use of an implantable device to treat gastroparesis, a chronic disorder in which there is delayed gastric emptying without evidence of obstruction. Symptoms include abdominal distension, nausea, and vomiting. GES has more recently been investigated as a technique to treat obesity.

Clinical Indications

Medically Necessary:

Gastric electrical stimulation is considered **medically necessary** in the treatment of chronic intractable nausea and vomiting secondary to severe gastroparesis of diabetic or idiopathic etiology when the following criteria are met:

1. Individual is refractory, intolerant or has contraindications to the use of prokinetic and antiemetic medications; **and**
2. Delayed gastric emptying as documented by standard scintigraphic imaging of solid food.

Removal of a gastric electrical stimulator is considered **medically necessary** when ***any*** of the following criteria are met (1 ***or*** 2):

1. The individual has experienced complications associated with gastric electrical stimulation (for example, bowel obstruction, gastric wall perforation, infection, lead dislodgement or disruption, or generator site pain); **or**
2. When GES is unsuccessful after an adequate trial period, for example, one year, both the generator and the leads may be removed.

Revision or replacement of a gastric electrical stimulator is considered **medically necessary** when both of the following criteria are met (1 ***and*** 2):

1. The individual has demonstrated clinical benefit from gastric electrical stimulation; **and**
2. The device has malfunctioned.

Not Medically Necessary:

Gastric electrical stimulation is considered **not medically necessary** in all other indications, including but not limited to the treatment of obesity.

Revision, replacement, or removal of a gastric electrical stimulator is considered **not medically necessary** when the criteria above have not been met.

Coding

The following codes for treatments and procedures applicable to this guideline are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services may be Medically Necessary when criteria are met:

CPT	
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 [when specified as gastric neurostimulator]
64595	Revision or removal of peripheral, sacral, or gastric neurostimulator pulse generator or receiver, with detachable connection to electrode array [when specified as gastric neurostimulator]
95980-95982	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 [includes codes 95980, 95981, 95982]
HCPCS	
	For the following codes when specified as gastric neurostimulator:
C1767	Generator, neurostimulator, implantable, non-rechargeable
C1778	Lead, neurostimulator, implantable
L8679	Implantable neurostimulator, pulse generator, any type
L8680	Implantable neurostimulator electrode, each
L8688	Implantable neurostimulator pulse generator, dual array, non-rechargeable, includes extension
ICD-10 Procedure	
0DH60MZ	Insertion of stimulator lead into stomach, open approach

0DH63MZ	Insertion of stimulator lead into stomach, percutaneous approach
0DH64MZ	Insertion of stimulator lead into stomach, percutaneous endoscopic approach
0DP60MZ	Removal of stimulator lead from stomach, open approach
0DP63MZ	Removal of stimulator lead from stomach, percutaneous approach
0DP64MZ	Removal of stimulator lead from stomach, percutaneous endoscopic approach

ICD-10 Diagnosis

E08.00-E08.8	Diabetes mellitus due to underlying conditions
E09.00-E09.8	Drug or chemical induced diabetes mellitus
E10.10-E10.8	Type 1 diabetes mellitus
E11.00-E11.8	Type 2 diabetes mellitus
E13.00-E13.8	Other specified diabetes mellitus
K31.84	Gastroparesis
R11.0-R11.2	Nausea and vomiting
Z45.42	Encounter for adjustment and management of neuropacemaker (brain) (peripheral nerve) (spinal cord) [when specified as GES device for diabetic or idiopathic gastroparesis]

When services are Not Medically Necessary:
For the procedure and diagnosis codes listed above when criteria are not met, for the diagnoses listed below; or when the code describes a procedure designated in the Clinical Indications section as not medically necessary.

ICD-10 Diagnosis

	All other diagnoses, including but not limited to the following:
E66.01-E66.9	Overweight and obesity

Gastric stimulators of lesser curvature
When services are Not Medically Necessary:
For the following procedure codes; or when the code describes a procedure designated in the Clinical Indications section as not medically necessary.

CPT

43659	Unlisted laparoscopy procedure, stomach [when specified as laparoscopic implantation, replacement, revision or removal of gastric stimulation electrodes, lesser curvature]
43999	Unlisted procedure, stomach [when specified as open implantation, replacement, revision or removal of gastric stimulation electrodes, lesser curvature]

ICD-10 Diagnosis

	All diagnoses, including but not limited to the following:
E66.01-E66.9	Overweight and obesity

Discussion/General Information

GES

GES involves the implantation of a neuroelectrical stimulation device into the abdomen connected to wires that are attached to the wall of the lower stomach. The device sends high frequency, low energy electrical impulses to the stomach with the intention of alleviating chronic nausea and vomiting caused by gastroparesis by stimulating the smooth muscles of the stomach.

GES for Gastroparesis

Gastroparesis is a long-lasting and recurrent disorder caused by stomach pump failure. Gastroparesis is characterized by severe epigastric pain, nausea and vomiting in the absence of mechanical obstruction. Although gastroparesis sometimes develops as a complication of diabetes, frequently the cause is unknown (idiopathic). The definitive diagnosis of gastroparesis typically is made using an isotope-labeled test meal. Treatment is addressed progressively and includes education, dietary support and pharmacologic therapy (prokinetic and antiemetic agents). For relatively mild gastroparesis, dietary modifications and a low-dose antiemetic or prokinetic agent might provide satisfactory control of symptoms. Individuals with more severe symptoms of gastroparesis (refractory vomiting, pronounced dehydration, or uncontrolled blood glucose levels), may require hospitalization, intravenous hydration, insulin for blood glucose control, nasogastric stomach decompression, and/or intravenous administration of antiemetic and prokinetic agents. GES is reserved for individuals who are refractory to medical management.

In 2000, the Enterra™ Therapy System (Medtronic, Inc., Minneapolis, MN) received U.S. Food and Drug Administration (FDA) approval through a humanitarian device exemption (HDE) as a treatment for refractory diabetic and idiopathic gastroparesis. The Enterra™ II Therapy System model received HDE approval as a treatment of chronic intractable (drug refractory) nausea and vomiting secondary to gastroparesis of diabetic or idiopathic etiology.

Several randomized crossover studies evaluating GES for treatment of gastroparesis have been published. Abell and colleagues (2003a, 2003b) conducted a randomized double-blind crossover study in 33 individuals with chronic gastroparesis (n=16 idiopathic and n=17 diabetic). Participants underwent a 1-month active stimulation period and a 1-month period with the device turned off, in random order. Following the blinded phase of the studies, all individuals received active stimulation and were evaluated at 6 and 12 months. The primary study outcome, vomiting frequency, was significantly lower in the 'on' versus 'off' crossover phase. The median overall frequency of vomiting was 6.8 episodes during the on period, compared to 13.5 episodes when the device was turned off, $p<0.05$. At the 6- and 12-month visits, vomiting frequency was significantly lower than baseline, $p<0.05$. The GES system was removed from 3 individuals due to adverse events (infection in 2 individuals and pain in 1 individual). A limitation of the study is the relatively small number of participants.

Another randomized study evaluating GES for gastroparesis was published by McCallum and colleagues in 2010. Fifty-five subjects with refractory diabetic gastroparesis were implanted with the Enterra system. After surgery, all participants had the stimulator on for 6 weeks and then were randomly assigned to groups that had consecutive 3-month crossover periods with the device either on or off. After the crossover phase of the study, the device was turned on in all participants and they were followed in an unblinded manner for 4.5 months. The primary outcome was change in weekly vomiting frequency (WVF). Thirty-two (58%) participants completed the crossover phase. There was not a significant difference in WVF between the 'on' phase and the 'off' phase. The median WVF was 3.81 episodes in the 'on' phase compared with 4.25 in the 'off' state ($p>0.05$, exact p-value not reported). At 1 year, the WVF of all participants was significantly lower than baseline values (median reduction, 68%; $p<0.001$). The study participants also had improvements in total symptom score, gastric emptying, quality of life (QOL) and median days in the hospital. One participant had the

device removed due to infection, while 2 of the study participants required surgical intervention due to lead-related problems.

In 2020, Ducrotte and colleagues published a randomized crossover study evaluating GES in 172 individuals with chronic refractory vomiting and/or nausea for over 12 months. Individuals with morbid obesity were excluded from the study. Individuals were implanted with the Enterra system and received 4 months of active stimulation or no simulation, in random order. Clinical assessment was done at the end of each of the 4-month intervention periods. There were 2 primary endpoints: a vomiting score (ranging from 0=several episodes a day to 4=no vomiting) and a QOL score based on a self-report tool with 36 items (ranging from 0=worst QOL to 144=best QOL). The vomiting score was significantly better in the “on” phase compared with the “off” phase. The median mean score was 2.2 (SD [standard deviation], 1.7) in the on phase and 1.8 (SD, 1.7) in the off phase, p=0.0009. However, there was no significant difference between groups in the mean QOL score, p=0.15.

There are also several uncontrolled studies evaluating GES for gastroparesis (Abell, 2019; Brody, 2015; Lin, 2014; McCallum 2011). McCallum 2011 evaluated longer-term outcomes in a relatively large group of individuals. A total of 221 subjects with refractory gastroparesis were treated with the Enterra device and followed for up to 10 years. Follow-up data at 1 year or longer were available for 188 of 221 enrolled individuals (85%). They were followed for a mean of 56 months (range 12 to 131 months). At follow-up, the total symptom score (TSS) was reported to have decreased by 53% ± 32% ($p<0.001$). Additionally, all 7 individual symptom measures on the TSS were significantly reduced ($p<0.0001$). Of 119 subjects with gastric emptying data, 26% normalized their results after GES therapy ($p<0.05$). Overall weight (n=124) increased significantly from 149 ± 41 lbs. at baseline to 162 ± 43 lbs at last follow-up ($p<0.05$). The use of gastroparesis medications in all subject groups was reduced after 1 year of GES (74% at baseline vs. 56% for prokinetics, p=0.05; and 65% at baseline vs. 58% for antiemetics, p=0.025). Limitations of the study include lack of a control or comparison group and wide variability in the length of follow-up.

A 2017 systematic review and meta-analysis evaluated the published literature on GES for gastroparesis (Levinthal, 2017). The authors identified 5 published studies that included a double-blind cross-over phase, with phases lasting at least 1 month. When data from these 5 studies were pooled, there was an overall difference in GES symptom severity with devices in the ‘on’ and ‘off’ phases of 0.17 points. The difference in phases was not statistically significant, p=0.15. Data from other outcomes, including weekly vomiting frequency, could not be pooled. The authors also identified 13 uncontrolled studies that met their entry criteria and combined results with data from the open-label portions of randomized studies. When the open-label data were pooled, total symptom severity decreased from a mean of 6.85 at baseline to a mean of 2.68 at follow-up, $p<0.001$.

In 2022, the American College of Gastroenterology published a clinical guideline addressing the treatment of gastroparesis (Camilleri, 2022). Their recommendation regarding gastric electric stimulation stated that GES may be considered for compassionate treatment in individuals with refractory symptoms, particularly nausea and vomiting. They acknowledged that there are no clear guidelines on the appropriate selection of individuals to treat with GES.

In 2023 the American Society of Metabolic and Bariatric Surgery (ASMBS) published the following guideline statement regarding GES:

> The main indication for gastric electrical stimulator placement is the presence of gastroparesis (diabetic or idiopathic) with concomitant severe nausea and vomiting (1 episode daily) who are refractory to medical management for at least 1 year. Other relative indications include recurrent severe dehydration and need for parenteral/enteral nutrition. The procedure is contraindicated in patients that are not fit for a surgical intervention due to physical or mental conditions.

Salloum and colleagues (2014) reported a small (n=15) retrospective multicenter study of individuals with recurrent symptoms after initial GES therapy who subsequently received a second GES. Twelve individuals had a preoperative diagnosis of idiopathic gastroparesis, 3 individuals had diabetic gastroparesis. Of the 15 who underwent replacement GES surgeries, recurrent symptoms developed on average 48 months after initial placement. The control group included 15 individuals with positive response to GES therapy without developing recurrent symptoms matched by 3 variables; baseline symptom scores before initial GES implantation, and etiology of disease, diabetic or idiopathic. Prior to the replacement GES procedure, individuals underwent a trial, temporary GES to assess if the replacement procedure was warranted. After 1 to 2 weeks of temporary stimulation, individuals were revaluated for symptom improvement. Positive responses were evaluated by symptoms scores for vomiting, nausea, epigastric pain, early satiety, and bloating using a modified Likert score system, 0 to 4. Total score for the replacement group decreased from 17.3 to 13.6 with a difference of 3.6, (p=0.017), compared to the control group with a preoperative symptom score of 15.8 and postoperative score of 12.3 with a difference of 3.5 (p=0.011). The results demonstrated that the control group showed a 20.3% decrease in mean total symptoms score, whereas the study group showed a 22.5% decrease. The study was limited by the small size, retrospective design, and it also lacked an explanation why the original GES therapy did not provide relief. Additionally, one of the authors was a manufacturer (Medtronic) consultant. The authors concluded that more research is needed to determine the predictors of successful and unsuccessful GES therapy.

Adams and colleagues (2020) noted complications related to GES placement include wound infections, hematomas, and seromas at the generator pouch site. Scarring of the gastric wall around the electrodes may also be correlated with decreased relief. If individuals experience a recurrence of symptoms, the generator should be interrogated to determine whether the battery is depleted. Generator leads may be damaged when replacing the generator due to disruption or dislodgement and therefore may need to be replaced at the same time. Generators may also cause severe somatic pain due to proximity to abdominal wall sensory nerves, and generators at the beltline and the costal margin may be painful with activity. Repositioning generators to a distant site can alleviate pain, rarely a generator lead may be dislodged from its gastric site, and should be replaced. When GES is unsuccessful after a trial of an adequate amount of time, for example one year, both the generator and the leads may be removed.

GES for Morbid Obesity

GES has been considered as a treatment of obesity as a technique to increase a feeling of satiety with subsequent reduced food intake and weight loss. The exact mechanisms resulting in changes in eating behavior are uncertain but may be related to neuro-hormonal modulation and/or stomach muscle stimulation (Cigaina, 2003). There are no GES devices approved by the FDA for the treatment of obesity and the Medtronic Enterra™ therapy System is not marketed for this indication. The Transcend™ implantable gastric stimulation device, manufactured by Medtronic Transneuronix, (formerly manufactured by Transneuronix Corporation), is available in Europe for treatment of obesity. In summary, GES is not considered clinically appropriate or effective for morbid obesity or any indications other than gastroparesis.

Definitions

Antiemetic drug: A drug used to treat nausea and vomiting. The principal classes of antiemetic drugs are antidopaminergics, antihistamines, anticholinergics, phenothiazines and serotonin 5-HT3 receptor antagonists. Examples of such drugs include but are not limited to: prochlorperazine, trimethobenzamide, and promethazine.

Gastric: This term refers to the stomach.

Gastroparesis: A condition where there is delayed gastric emptying due to abnormal gastric motility in the absence of obstruction.

Motility: The power to move spontaneously.

Prokinetic drug: A drug used to speed up gastric emptying time. Examples of commonly used agents include, but are not limited to, erythromycin and metoclopramide (Reglan).

Scintigraphic imaging of gastric emptying: A technique which involves incorporating a radioisotope tracer into a standard meal and tracing its passage through the stomach using a gamma camera; considered the gold standard for diagnosing delayed gastric emptying because this test quantifies the emptying of a physiologic caloric meal.

References

Peer Reviewed Publications:

1. Abell T, Lou J, Tabbaa M, et al. Gastric electrical stimulation for gastroparesis improves nutritional parameters at short, intermediate, and long-term follow-up. JPEN J Parenter Enterel Nutr. 2003a; 27(4):277-281.
2. Abell T, McCallum R, Hocking M, et al. Gastric electrical stimulation for medically refractory gastroparesis. Gastroenterology. 2003b; 125(2):421-428.
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4. Adams D, Stocker A, Lancaster W, et al. The surgeon's role in gastric electrical stimulation therapy for gastroparesis. J Gastrointest Surg. 2021 ;25(4):1053-1064.
5. Brody F, Zettervall SL, Richards NG, et al. Follow-up after gastric electrical stimulation for gastroparesis. J Am Coll Surg. 2015; 220(1):57-63.
6. Cigaina V, Hirschberg AL. Gastric pacing for morbid obesity: plasma levels of gastrointestinal peptides and leptin. Obesity Research. 2003; 11(12):1456-1462.
7. Ducrotte P, Coffin B, Bonaz B et al. Gastric electrical stimulation reduces refractory vomiting in a randomized crossover trial. Gastroenterology. 2020 Feb;158(3):506-514.
8. Levinthal DJ, Bielefeldt K. Systematic review and meta-analysis: Gastric electrical stimulation for gastroparesis. Autonomic Neuroscience: Basic and Clinical. 2017; 202:45-55.
9. Lin Z, Forster J, Sarosiek I, McCallum RW. Treatment of diabetic gastroparesis by high-frequency gastric electrical stimulation. Diabetes Care. 2004; 27(5):1071-1076.
10. McCallum RW, Lin Z, Forster J, et al. Gastric electrical stimulation improves outcomes of patients with gastroparesis for up to 10 years. Clin Gastroenterol Hepatol. 2011; 9(4):314-319.
11. McCallum RW, Snape W, Brody F, et al. Gastric electrical stimulation with Enterra therapy improves symptoms from diabetic gastroparesis in a prospective study. Clin Gastroenterol Hepatol. 2010; 8(11):947-954.
12. Salloum H, Williams P, Walker M, et al. Evaluation and treatment of gastric stimulator failure in patients with gastroparesis. Surg Innov. 2014; 21(3): 244–249.

Government Agency, Medical Society, and Other Authoritative Publications:

1. Camilleri M, Parkman HP, Shafi MA, et al. American College of Gastroenterology. Clinical guideline: management of gastroparesis. Am J Gastroenterol. 2022; 1171197-1220.
2. Food and Drug Administration. EnterraÔ Therapy System/Enterra II Therapy System (formerly named Gastric Electrical Stimulation) – H990014. Issued March 31, 2000. Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf/H990014A.pdf. Accessed on August 2, 2023.

Websites for Additional Information

1. National Digestive Diseases Information Clearinghouse (NDDIC). Gastroparesis. Available at: https://www.niddk.nih.gov/health-information/digestive-diseases/gastroparesis. Accessed on August 2, 2023.

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The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

History

Status	Date	Action
Revised	11/09/2023	Medical Policy & Technology Assessment Committee (MPTAC) review. Added MN and NMN criteria to Clinical Indications for removal, revision, or replacement of a gastric electrical stimulator. Updated Discussion and References sections. Updated Coding section with 01/01/2024 CPT changes to update descriptors for 64590, 64595; also added ICD-10-PCS codes for removal of gastric neurostimulator lead.
Reviewed	11/10/2022	MPTAC review. Updated Description, Discussion, References and Websites sections. Updated Coding section to remove ICD-10-PCS codes for stimulator generators, not specific.
Reviewed	11/11/2021	MPTAC review. Discussion/General Information, References, and Websites for Additional Information sections updated.
Reviewed	11/05/2020	MPTAC review. Discussion/General Information and References sections updated. Reformatted Coding section.
Reviewed	11/07/2019	MPTAC review. Discussion/General Information and References sections updated.
Reviewed	01/24/2019	MPTAC review. Discussion/General Information and References sections updated.
New	01/25/2018	MPTAC review. Initial document development. Moved content of SURG.00046 to new clinical utilization management guideline document with the same title.

Federal and State law, as well as contract language, and Medical Policy take precedence over Clinical UM Guidelines. We reserve the right to review and update Clinical UM Guidelines periodically. Clinical guidelines approved by the Medical Policy & Technology Assessment Committee are available for general adoption by plans or lines of business for consistent review of the medical necessity of services related to the clinical guideline when the plan performs utilization review for the subject. Due to variances in utilization patterns, each plan may choose whether to adopt a particular Clinical UM Guideline. To determine if review is required for this Clinical UM Guideline, please contact the customer service number on the member's card.

Alternatively, commercial or FEP plans or lines of business which determine there is not a need to adopt the guideline to review services generally across all providers delivering services to Plan’s or line of business’s members may instead use the clinical guideline for provider education and/or to review the medical necessity of services for any provider who has been notified that his/her/its claims will be reviewed for medical necessity due to billing practices or claims that are not consistent with other providers, in terms of frequency or in some other manner.