Gastric Electrical Stimulation

POLICY NUMBER	LAST REVIEW
MG.MM.SU.57C4aC4	February 14, 2025

Definition

Gastric electrical stimulation (GES) has been developed as an alternative treatment for refractory gastroparesis. The device consists of 4 components: the implanted pulse generator, 2 intramuscular stomach leads, a stimulator programmer and a memory cartridge. The leads are implanted surgically using an open or laparoscopic technique and are connected to the pulse generator that is implanted in a subcutaneous pouch. The device delivers timed impulses to the gastric muscles that are intended to stimulate gastric myoelectric activity, with the goal of improving stomach emptying and relieving the symptoms of nausea and vomiting.

GES has also been proposed as an alternative to bariatric surgery for the treatment of obesity. The technique for implantation of the device is the same for treating gastroparesis but utilizes different stimulation parameters and a different location for placement of electrodes on the stomach wall. GES in the obese patient is thought to induce early satiety, but it is not known whether this is caused by stimulation of the nerves, inhibition of hormones or stimulation of the stomach muscle itself. (See Limitations/Exclusions)

Guideline

GES is considered medically necessary for the treatment of chronic, intractable (drug-refractory) nausea and

vomiting secondary to gastroparesis of diabetic or idiopathic etiology.

The following criteria must be met:

1. Significantly delayed gastric emptying as evidenced by standard scintigraphic imaging of solid food
2. Member is refractory or intolerant to both:
    - Prokinetic medications (2 out of 3 classes)
    - Antiemetic medications (2 out of 3)
3. Significantly poor nutritional status, as evidenced by weight loss of 10% of body weight (for height and age in comparison with pre-illness weight)

Table 1: Prokinetic Medications

Class	Common Examples
Cholinergic Agonists	dexpanthenol (Ilopan®), bethanechol (Urecholine®)
Motolin receptor agonists	Erythromycin
Dopamine receptor antagonists	metoclopramide (Reglan®)

Table 2: Antiemetic Medications

Class	Common Examples
Antihistamines	diphenhydramine (Benadryl®), dimenhydrinate (Dramamine®), meclizine (Antivert®), hydroxyzine (Vistaril®), trimethobenzamide (Tigan®)
Serotonin (5HT3) receptor antagonists	ondansetron (Zofran®), granisetron (Kytril®), dolasetron (Anzemet®)
Dopamine receptor antagonists	Metoclopramide (Reglan®), perphenazine (Trilafon®), prochlorperazine (Compazine®), promethazine (Phenergan®), thiethylperazine (Torecan®), cyclizine (Marezine®)

Limitations and Exclusions

1. GES is not considered medically necessary for gastrointestinal dysmotility disorders other than gastroparesis, obesity (or any other indication not listed above) due to insufficient evidence of therapeutic value.

2. The Medtronic Enterra® Therapy System, a high frequency electronic device, is currently FDA approved under the FDA's Humanitarian Device Exemption (HDE) program. No other GES system for treating gastroparesis has been approved to date. Therefore, requests for alternate GES systems (e.g., gastric pacing, neural gastric electrical stimulation) will be denied as not medically necessary due to insufficient evidence of therapeutic value.

Procedure Codes

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
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, nonrechargeable, includes extension
L8687	Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension
L8688	Implantable neurostimulator pulse generator, dual array, nonrechargeable, includes extension
L8689	External recharging system for battery (internal) for use with implantable neurostimulator, replacement only

References

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. 2003; 125(2):421-428.
3. Camilleri M, Parkman HP, Shafi MA, et al. American College of Gastroenterology. Clinical guideline: management of gastroparesis. Am J Gastroenterol. 2013; 108(1):18-37.
4. Chu H, Lin Z, Zhong L, et al. Treatment of high-frequency gastric electrical stimulation for gastroparesis. J Gastroenterol Hepatol. 2012; 27(6):1017-1026.
5. Cigaina V, Hirschberg AL. Gastric pacing for morbid obesity: plasma levels of gastrointestinal peptides and leptin. Obesity Research. 2003; 11(12):1456-1462.

6. Cutts TF, Luo J, Starkebaum W, et al. Is gastric electric stimulation superior to standard pharmacological therapy in improving GI symptoms, healthcare resources, and long-term health care benefits? Neurogastroenterol Motil. 2005; 17(1): 35-43.
7. Food and Drug Administration. Enterra Therapy System (formerly named Gastric Electrical Stimulation) – H990014. Issued March 31, 2000. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfhde/hde.cfm?id=H990014. Accessed on March 7, 2025.
8. Food and Drug Administration. Guidance for HDE Holders, Institutional Review Boards (IRBs), Clinical Investigators, and FDA Staff - Humanitarian Device Exemption (HDE) Regulation: Questions and Answers. Issued July 8, 2010. Last updated 08/27/2014. http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm110194.htm. Accessed March 7, 2025.
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. National Institute for Clinical Excellence (NICE). Gastroelectrical stimulation for gastroparesis. Interventional procedures guidance (IPG489). London, UK: NICE; May 2014. http://www.nice.org.uk/guidance/IPG489. Accessed March 7, 2025.
13. Parkman HP, Hasler WL, Fisher RS; American Gastroenterological Association. American Gastroenterological Association technical review on the diagnosis and treatment of gastroparesis. Gastroenterology. 2004; 127(5):1592-1622. http://www.gastrojournal.org/article/S0016-5085(04)01634-8/abstract. Accessed March 7, 2025.
14. Swedish Council on Technology Assessment in Healthcare (SBU). Gastric pacing (gastric electrical stimulation) for the treatment of obesity. Alert. Stockholm, Sweden: SBU; 2004.
15. van der Voort IR, Becker JC, Dietl KH, et al. Gastric electrical stimulation results in improved metabolic control in diabetic patients suffering from gastroparesis. Exp Clin Endocrinol Diabetes. 2005; 113(11):38-42.
16. Yao S, Ke M, Wang Z, et al. Retrograde gastric pacing reduces food intake and delays gastric emptying in humans: a potential therapy for obesity? Dig Dis Sci. 2005; 50(9):1569-7155.
17. Specialty-matched clinical peer review.

Revision History

Company(ies)	DATE	REVISION
EmblemHealth	Mar. 14, 2025	Transferred policy content to individual company branded template
EmblemHealth ConnectiCare	Jan. 8, 2021	Changed decrease of "≤ 90% of normal body weight" (as evidence of significantly poor nutritional status) to "weight loss of 10% of body weight"
ConnectiCare	Dec. 9, 2019	ConnectiCare adopts the clinical criteria of its parent corporation EmblemHealth