

PA.215.MPC – Gastric Electrical Stimulation

Maryland Physicians Care considers **Gastric Electrical Stimulation** medically necessary for the treatment of chronic nausea and vomiting due to gastroparesis when the member meets ALL of the following criteria:

- a) Diagnosis of gastroparesis is confirmed by gastric emptying scintigraphy
- b) Member is refractory or intolerant of medical and pharmaceutical management, including dietary modification, and prokinetic and antiemetic medications
- c) Gastric electrical stimulation is used in accordance with the Humanitarian Device Exemption (HDE) conditions as outlined by the U.S. Food and Drug Administration (FDA)

Limitation

Gastric Electrical Stimulation is considered experimental and investigational for all other indications including, but not limited to:

- Treatment of obesity
- Treatment of diabetes mellitus in persons without gastroparesis
- Treatment of cyclic vomiting syndrome
- Treatment of autonomic nervous system disorder other than gastroparesis

Maryland Physicians Care does not cover experimental and investigational services.

Background

Gastroparesis is a disorder in which the stomach's motility is compromised, preventing the stomach from properly emptying its contents. Gastroparesis is caused by damage to the vagus nerve due to diabetes mellitus, or surgery to the stomach or small intestine. When functioning normally, the vagus nerve contracts the stomach muscles to move food through the digestive tract. When it is damaged, the vagus nerve is unable to pass food from the stomach to the intestines. Other causes of gastroparesis may include viral infections, nervous system diseases such as Parkinson's disease, hypothyroidism, medications such as narcotics and antidepressants, amyloidosis, and scleroderma. Symptoms of gastroparesis includes chronic heartburn, nausea and vomiting, malnutrition, early satiety, abdominal bloating, and poor blood sugar regulation. Gastroparesis may be treated with dietary modification and pharmacologic therapy. In

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extreme gases, gastroparesis may be treated by a jejunostomy tube placed in the small intestine, or a gastric venting tube to assist with relieving pressure from gastric contents.

As of March 31, 2000, the Food and Drug Administration (FDA) approved the Enterra™ gastric pacemaker unit by Medtronic, Inc. Under the Humanitarian Device Exemption (HDE) clearance, this device has been cleared for use for the treatment of gastroparesis. Enterra consists of neurostimulators laparoscopically placed in the serosa of the abdomen and are connected to a generator implanted in the subcutaneous layer. This device has been cleared by the FDA to treat intractable nausea and vomiting secondary to gastroparesis in individuals aged 18 to 70.

These codes are not intended to be all inclusive. Inclusion or exclusion of any code does not guarantee coverage.

Codes

CPT Codes / HCPCS Codes covered when the indications above are met:	
Code	Description
CPT Codes	
64595	Revision or removal of peripheral or gastric neurostimulator pulse generator or receiver
64590	Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling
43881	Implantation or replacement of gastric neurostimulator electrodes, antrum, open
43882	Revision or removal of gastric neurostimulator electrodes, antrum, open
43647	Laparoscopy, surgical; implantation or replacement of gastric neurostimulator electrodes, antrum
43648	Laparoscopy, surgical; revision or removal of gastric neurostimulator electrodes, antrum
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
HCPCS Codes	
E0765	FDA approved nerve stimulator, with replaceable batteries, for treatment of nausea and vomiting

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L8680	Implantable neurostimulator electrode, each
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
Non-Covered Codes (<i>considered experimental and investigational</i>)	
C9787	Gastric electrophysiology mapping with simultaneous patient symptom profiling

References

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<https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=37360>
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5. Krishnasamy S, Abell TL. Diabetic gastroparesis: principles and current trends in management. *Diabetes Ther*. 2018;9:S1-S42.
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6. Levinthal DJ, et al. Systematic review and meta-analysis: Gastric electrical stimulation for gastroparesis. *Auton Neurosci*. Jan 2017;202:45-55
<https://www.ncbi.nlm.nih.gov/pubmed/27085627>
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<https://www.medtronic.com/us-en/patients/treatments-therapies/neurostimulator-gastroparesis/enterra-2-neurostimulator.html>

8. Morales-Conde S, Alarcon Del Agua I, Busetto L, et al. Implanted closed-loop gastric electrical stimulation (CLGES) system with sensor-based feedback safely limits weight regain at 24 months. *Obes Surg.* 2018;28(6):1766-1774.
<https://www.ncbi.nlm.nih.gov/pubmed/29333595/>
9. National Institute of Diabetes and Digestive and Kidney Diseases. Digestive Diseases – Gastroparesis.
<https://www.niddk.nih.gov/health-information/digestive-diseases/gastroparesis>
10. Shada A, Nielsen A, Marowski S, et al. Wisconsin's Enterra Therapy Experience: A multi-institutional review of gastric electrical stimulation for medically refractory gastroparesis. *Surgery.* Oct 2018;164(4):760-765. PMID 30072246
<https://www.ncbi.nlm.nih.gov/pubmed/30072246>
11. U.S. Food and Drug Administration. Center for Devices and Radiological Health. Enterra Therapy System- H990014. Executive Summary: Pediatric Advisory Committee meeting. Sep 26, 2019.
<https://www.fda.gov/media/130826/download>
12. U.S. Food & Drug Administration (FDA). Humanitarian Device Exemption: Gastric Electrical Stimulation (GES) System - H990014. Issued: 03/31/2000.
<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfhde/hde.cfm?id=H990014>

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