

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

PA.215.MPC - Gastric Electrical Stimulation

Policy Number: PA.215.MPC
Last Review Date: 08/26/2021
Effective Date: 10/01/2021

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.

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
L8680	Implantable neurostimulator electrode, each

PA.215.MPC - Gastric Electrical Stimulation

Policy Number: PA.215.MPC
Last Review Date: 08/26/2021
Effective Date: 10/01/2021

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. American College of Gastroenterology – GI Health and Disease: Gastroparesis. Last revised December 2012. <https://gi.org/topics/gastroparesis/>
2. Busetto L, Torres AJ, Morales-Conde S, et al. Impact of the feedback provided by a gastric electrical stimulation system on eating behavior and physical activity levels. Obesity (Silver Spring). 2017;25(3):514-521. <https://www.ncbi.nlm.nih.gov/pubmed/28164463>
3. Centers for Medicare and Medicaid Services (CMS). Local Coverage Determination: L37360 – Peripheral Nerve Stimulation. Revision Effective Date: 12/01/2019. <https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=37360>
4. Hayes Medical Technology Directory. Gastric Electrical Stimulation for Gastroparesis. Oct 26, 2018. Annual Review Date: March 9, 2021.
5. Krishnasamy S, Abell TL. Diabetic gastroparesis: principles and current trends in management. Diabetes Ther. 2018;9:S1-S42. <https://www.ncbi.nlm.nih.gov/pubmed/29934758>
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>
7. Medtronic Inc. Gastroparesis: About Gastric Electrical Stimulation. Last updated: March 2018. <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/>

PA.215.MPC - Gastric Electrical Stimulation

Policy Number: PA.215.MPC

Last Review Date: 08/26/2021

Effective Date: 10/01/2021

9. National Institute of Diabetes and Digestive and Kidney Diseases. Digestive Diseases- Gastroparesis. 2019. <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>

Disclaimer:

Maryland Physicians Care medical payment and prior authorization policies do not constitute medical advice and are not intended to govern or otherwise influence the practice of medicine. The policies constitute only the reimbursement and coverage guidelines of Maryland Physicians Care and its affiliated managed care entities. Coverage for services varies for individual members in accordance with the terms and conditions of applicable Certificates of Coverage, Summary Plan Descriptions, or contracts with governing regulatory agencies.

Maryland Physicians Care reserves the right to review and update the medical payment and prior authorization guidelines in its sole discretion. Notice of such changes, if necessary, shall be provided in accordance with the terms and conditions of provider agreements and any applicable laws or regulations.

These policies are the proprietary information of Maryland Physicians Care. Any sale, copying, or dissemination of said policies is prohibited.