

Policy Number: PA.215.MPC Last Review Date: 11/17/2022 Effective Date: 12/01/2022

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.

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



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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: June, 2021. <u>https://gi.org/topics/gastroparesis/</u>
- 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. <u>https://www.ncbi.nlm.nih.gov/pubmed/28164463</u>
- Centers for Medicare and Medicaid Services (CMS). Local Coverage Determination: L37360 – Peripheral Nerve Stimulation. Revision Effective Date: 12/01/2019. <u>https://www.cms.gov/medicare-coverage-database/details/lcddetails.aspx?LCDId=37360</u>
- 4. Hayes Medical Technology Directory. Gastric Electrical Stimulation for Gastroparesis. Oct 26, 2018. Annual Review Date: December 8, 2021.
- 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
- Levinthal DJ, et al. Systematic review and meta-analysis: Gastric electrical stimulation for gastroparesis. Auton Neurosci. Jan 2017;202:45-55 <u>https://www.ncbi.nlm.nih.gov/pubmed/27085627</u>
- 7. Medtronic Inc. Gastroparesis: About Gastric Electrical Stimulation. Last updated: March, 2020. <u>https://www.medtronic.com/us-en/patients/treatments-</u> 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/



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- 9. National Institute of Diabetes and Digestive and Kidney Diseases. Digestive Diseases- Gastroparesis. 2019. <u>https://www.niddk.nih.gov/health-information/digestive-diseases/gastroparesis</u>
- 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. <u>https://www.fda.gov/media/130826/download</u>
- 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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