Medica Central Coverage Policy

Policy Name:	**Gastric Electrical Stimulation (GES) MP9463**
Effective Date:	**09/01/2024**

Important Information – Please Read Before Using This Policy

These services may or may not be covered by all Medica Central plans. Coverage is subject to requirements in applicable federal or state laws. Please refer to the member's plan document for other specific coverage information. If there is a difference between this general information and the member's plan document, the member's plan document will be used to determine coverage. With respect to Medicare, Medicaid, and other government programs, this policy will apply unless these programs require different coverage.

Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions may call the Provider Service Center. Please use the Quick Reference Guide on the Provider Communications page for the appropriate phone number. https://mo-central.medica.com/Providers/SSM-employee-health-plan-for-IL-MO-OK-providers

Medica Central coverage policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care, and treatment.

Coverage Policy

Note: This policy is no longer scheduled for routine review of the scientific literature.

Gastric electrical stimulation therapy **is COVERED** for treating the following conditions in accordance with the U.S. Food and Drug Administration (FDA) section regarding FDA labeling and Humanitarian Device Exemption (HDE) for gastric electrical stimulation:

- Refractory diabetic gastroparesis that has failed other therapies
- Chronic, intractable (drug-refractory) nausea and vomiting secondary to gastroparesis of diabetic or idiopathic etiology when used according to U.S. Food and Drug Administration (FDA) labeled indications.

Gastric electrical stimulation is investigative and therefore **NOT COVERED** for all other indications. There is insufficient reliable evidence in the form of high quality peer-reviewed medical literature to establish the efficacy or effects on health care outcomes.

Note: The FDA has granted a humanitarian device exemption (HDE) for certain gastric electrical stimulation devices. Medica considers an FDA-approved HDE device medically necessary when all of the FDA-required criteria are met. For a current list of HDE-approved devices, refer to the FDA HDE Database at: http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/HDEApprovals/ucm161827.htm

Description

Gastroparesis is a condition in which there is abnormal or delayed emptying of the stomach following the ingestion of food. Gastric electrical stimulation, also called gastric pacing, is being investigated for use as an alternative treatment for gastroparesis, obesity and other conditions.

The Enterra® Therapy System, currently the only gastric electrical stimulation device available, consists of a neurostimulator that is implanted under the skin in the abdominal area, two intramuscular leads, and an external programmer that is used to adjust the settings of the neurostimulator. The neurostimulator delivers timed electrical impulses to the gastric muscles with the objective of improving stomach emptying and reducing symptoms such as nausea and vomiting.

FDA Approval

The Enterra® Therapy System received a Humanitarian Device Exemption (HDE) approval from the Food and Drug Administration in March 2000. The HDE allows Medtronic to market the Enterra Therapy System for the treatment of chronic, intractable (drug refractory) nausea and vomiting secondary to gastroparesis of diabetic or idiopathic etiology.

Based on FDA labeling, the Enterra device should not be used for patients with gastric obstruction or pseudo-obstruction, prior gastric resection, fundoplication, eating disorders, history of seizures, primary swallowing disorders, chemical dependency, or psychogenic vomiting. The manufacturer states that the safety of the Enterra device has not been established for patients who are pregnant or for those who are under the age of 18 or over the age of 70. In addition, the Enterra system may be affected by or adversely affect cardiac pacemakers, cardioverters/defibrillators, external defibrillators, magnetic resonance imaging (MRI), ultrasonic equipment, electrocautery, radiation therapy, and theft detectors. Diathermy is contraindicated since diathermy's energy can be transferred through the implanted system or separate components, and may result in tissue damage, severe injury or death, and/or damage to parts of the neurostimulation system.

Prior Authorization

Prior authorization is not applicable (other than via the aforementioned *Humanitarian Device Exemption* policy). Claims for this service are subject to retrospective review and denial of coverage, as investigative services are not eligible for reimbursement.

Coding Considerations

Use the current applicable CPT/HCPCS code(s). The following codes are included below for informational purposes only, and are subject to change without notice. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement.

CPT Codes:

- **43647** – Laparoscopy, surgical; implantation or replacement of gastric neurostimulator electrodes, antrum
- **43881** – Implantation or replacement of gastric neurostimulator electrodes, antrum, open

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	Committee/Source	Date(s)
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