Gastric Electrical Stimulation, Gastric Pacing

Policy ID:	HHO-DE-MP-1235
Approved By:	Highmark Health Options – Market Leadership
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Products:	Medicaid
Application:	All participating hospitals and providers
Page Number(s):	1 of 4

Disclaimer

Highmark Health Options medical policy is intended to serve only as a general reference resource regarding coverage for the services described. This policy does not constitute medical advice and is not intended to govern or otherwise influence medical decisions.

POLICY STATEMENT

Highmark Health Options may provide coverage under medical surgical benefits of the Company's Medicaid products for medically necessary gastric electrical stimulation and gastric pacing.

This policy is designed to address medical necessity guidelines that are appropriate for the majority of individuals with a particular disease, illness or condition. Each person's unique clinical circumstances warrant individual consideration, based upon review of applicable medical records.

The qualifications of the policy will meet the standards of the National Committee for Quality Assurance (NCQA) and the Delaware Department of Health and Social Services (DHSS) and all applicable state and federal regulations.

DEFINITIONS

Highmark Health Options (HHO) – Managed care organization serving vulnerable populations that have complex needs and qualify for Medicaid. Highmark Health Options members include individuals and families with low income, expecting mothers, children, and people with disabilities. Members pay nothing to very little for their health coverage. Highmark Health Options currently services Delaware Medicaid: Delaware Healthy Children (DHCP) and Diamond State Health Plan Plus members.

Gastric Electrical Stimulation – Performed using an implantable device designed to treat chronic drug-refractory nausea and vomiting secondary to gastroparesis of diabetic or idiopathic etiology. The procedure may also be referred to as gastric pacing or Enterra Therapy.

Gastroparesis – A chronic disorder of gastric motility characterized by delayed emptying of a solid meal. Symptoms include bloating, distention, nausea, and vomiting. When severe, gastroparesis can be associated with dehydration, poor nutritional status, and poor glycemic control in diabetic patients.

PROCEDURES

A prior authorization is required.

Gastric Electrical Stimulation may be considered medically necessary when ALL the following criteria are met:

- The United States Food and Drug Administration (U.S. FDA) has designated the device as a Humanitarian Use Device (HUD); and
- The U.S. FDA has approved the device for marketing under the Humanitarian Device Exemption (HDE); and
- The device has local Institutional Review Board (IRB) approval; and
- Appropriate informed consent has been obtained from the individual; and
- The device is not specifically excluded from coverage.

Gastric electrical stimulation not meeting the criteria as indicated in this policy is considered experimental/investigational and therefore, non-covered because the safety and/or effectiveness of this service cannot be established by review of the available published literature.

Gastric electrical stimulation may be considered medically necessary when provided in accordance with the HDE specifications of the U.S. FDA for the treatment of chronic intractable nausea and vomiting secondary to severe gastroparesis of diabetic or idiopathic etiology when ALL of the following criteria are met:

- Significant delayed gastric emptying as documented by standard scintigraphic imaging of solid food; and
- Individual is refractory to or intolerant of at least two (2) anti-emetic and prokinetic drug classes; and
- No mechanical obstruction is found on diagnostic testing; and
- Individual's nutritional status is sufficiently low that ALL the following criteria are met:
    - Failure to meet adequate caloric needs despite adequate trials of dietary adjustment, oral supplements, or tube enteral nutrition; and
    - the individual must be in a stage of wasting as indicated by AT LEAST ONE of the following:
        - Weight loss greater than 10% within six (6) months; or
        - Serum albumin is less than 3.4 grams; or
        - Blood urea nitrogen (BUN) level is less than ten (10) mg; or
        - Phosphorus level is less than 2.5 mg (normal phosphorous is 3-4.5 mg).

Gastric electrical stimulation not meeting the criteria as indicated in this policy is considered experimental/investigational and, therefore, non-covered because the safety and/or effectiveness of this service cannot be established by review of the available published literature for all other indications including, but not limited to, initial treatment of gastroparesis and treatment of obesity.

POST-PAYMENT AUDIT STATEMENT

The medical record must include documentation that reflects the medical necessity criteria and is subject to audit by Highmark Health Options at any time pursuant to the terms of your provider agreement.

PLACE OF SERVICE: INPATIENT/OUTPATIENT

Experimental/investigational (E/I) services are not covered regardless of place of service.

Gastric Electrical Stimulation is typically an outpatient procedure which is only eligible for coverage as an inpatient procedure in special circumstances, including, but not limited to, the presence of a co-morbid condition that would require monitoring in a more controlled environment such as the inpatient setting.

CODING REQUIREMENTS

CPT code	Description
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 (e.g., 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 (e.g., 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 (e.g., 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.

COVERED DIAGNOSIS CODE FOR PROCEDURE CODES 43647, 43648, 43881 AND 43882

Codes						
K31.84	T85.518A	T85.518D	T85.518S	T85.528A	T85.528D	T85.528S
T85.598A	T85.598D	T85.598S				

REIMBURSEMENT

Participating facilities will be reimbursed per their Highmark Health Options contract.

Reference

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Shada A, Nielsen A, Marowski S, Helm M, et al. Wisconsin's Enterra therapy experience: A multiinstitutional review of gastric electrical stimulation for medically refractory gastroparesis. Surgery. 2018;164(4):760-765.

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Maisiyiti A, Chen JD. Systematic review on gastric electrical stimulation in obesity treatment. Expert Rev Med Devices. 2019;16(10):855-861.

POLICY UPDATE HISTORY

12/22/2021	Approved in Medical Policy Committee
01/2022	Approved in QI/UM
12/28/2022	Annual review; approved in Medical Policy Committee
01/03/2023	Approved in QI/UM