POLICY: PG0235
ORIGINAL EFFECTIVE: 06/15/09
LAST REVIEW: 01/25/18

MEDICAL POLICY
Gastric Electrical Stimulation (GES)

PARAMOUNT
Affiliate of ProMedica

GUIDELINES
This policy does not certify benefits or authorization of benefits, which is designated by each individual policyholder contract. Paramount applies coding edits to all medical claims through coding logic software to evaluate the accuracy and adherence to accepted national standards. This guideline is solely for explaining correct procedure reporting and does not imply coverage and reimbursement.

DESCRIPTION
Gastric electrical stimulation (GES) is performed using an implantable device designed to treat chronic drug-refractory nausea and vomiting secondary to gastroparesis of diabetic or idiopathic etiology. The device may be referred to as a gastric pacemaker.

Gastroparesis is a chronic disorder of gastric motility characterized by delayed emptying of a solid meal. Symptoms include bloating, distension, nausea, and vomiting. When severe and chronic, gastroparesis can be associated with dehydration, poor nutritional status, and poor glycemic control in diabetics. While most commonly associated with diabetes, gastroparesis is also found in chronic pseudo-obstruction, connective tissue disorders, Parkinson disease, and psychological pathologic conditions. Treatment of gastroparesis includes prokinetic agents such as cisapride and metoclopramide, and antiemetic agents such as metoclopramide, granisetron, or ondansetron. Severe cases may require enteral or total parenteral nutrition.

GES is performed using an implantable device designed to treat chronic drug-refractory nausea and vomiting, secondary to gastroparesis of diabetic or idiopathic etiology. One gastric electrical stimulator has received approval from the U.S. Food and Drug Administration (FDA), the Gastric Electrical Stimulator system called Enterra™ Therapy System is manufactured by Medtronic. The data presented to the FDA documenting the "probable benefit" of gastric electrical stimulation (Gastric Electrical Stimulation System) were based on a multi-center double-blind cross-over study (FDA, 2000), which included 33 patients with intractable idiopathic or diabetic gastroparesis. The GES system received FDA approval through a “humanitarian device exemption” (HDE). This regulatory category was established in 1996, and only applies to devices intended to benefit fewer than 4,000 patients.

The first implantable gastric electrical stimulation device to treat obesity is now commercially available in the United States. On January 14, 2015, the Food and Drug Administration (FDA) approved the Maestro Rechargeable (RC) System (Enteromedics) to deliver vagal blocking for obesity control (VBLOC) therapy in adults who have not achieved adequate results with a supervised weight loss program and who have a body mass index (BMI) ≥ 40 to 45 kilograms per square meter (kg/m2), or a BMI ≥ 35 to 39.9 kg/m2 plus an obesity-related health condition.

The ReliefBand is a watch-like device worn on the ventral side of the wrist. When activated, the device emits a low-level electrical current across two small electrodes on its underside, stimulating the median nerve (an acupuncture point). It offers five stimulation levels from the rotary dial that one can control to provide maximum comfort and relief. Studies have shown that the ReliefBand is effective in treating chemotherapy-induced nausea and vomiting and as effective as antiemetic medications in managing nausea and vomiting following surgery. It has also been proven successful in the treatment of hyperemesis gravidarum that is unresponsive to other conservative medical therapy (e.g., change in diet, ginger capsules, vitamin B6).

POLICY
Gastric electrical stimulation (e.g., Enterra™ Therapy) (43647, 43648, 43881, 43882) for gastroparesis requires prior authorization for all product lines.

Gastric electrical stimulation devices (e.g., Maestro VBLOC Therapy) (0312T-0317T) for the treatment of obesity are non-covered for all product lines.

Transcutaneous electrical acupoint stimulation (E0765) does not require prior authorization for all product lines.

HMO, PPO, Individual Marketplace, Elite, Advantage
Paramount utilizes InterQual® criteria sets for medical necessity determinations for gastric electrical stimulation.

Paramount considers gastric electrical stimulation devices experimental and investigational for the treatment of obesity. Refer to PG0237 Vagus Nerve Stimulation (VNS)

Paramount considers transcutaneous electrical acupoint stimulation (prescription version ReliefBand devices) medically necessary for:

- Treatment of post-operative nausea and chemotherapy-induced nausea that is unresponsive to antiemetics and other conservative therapies.
- Treatment of hyperemesis gravidarum that is unresponsive to other conservative medical therapy (e.g., change in diet, ginger capsules, vitamin B6).

Paramount considers transcutaneous electrical acupoint stimulation (prescription version ReliefBand devices) experimental and investigational for the following indications because their effectiveness has not been established:

- Prevention of motion sickness
- Improving pregnancy rates in women undergoing in-vitro fertilization
- Muscle spasticity following brain injury

Note: Paramount does not cover over-the-counter disposable ReliefBand devices, which are used for the treatment of motion sickness, because they do not meet Paramount's definition of durable medical equipment.

CODING/BILLING INFORMATION

The appearance of a code in this section does not necessarily indicate coverage. Codes that are covered may have selection criteria that must be met. Payment for supplies may be included in payment for other services rendered.

CPT CODES	
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 (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
95981	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; subsequent, without reprogramming
95982	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; subsequent, with reprogramming
0312T	Vagus nerve blocking therapy (morbid obesity); laparoscopic implantation of neurostimulator electrode array, anterior and posterior vagal trunks adjacent to esophagogastric junction (EGJ), with implantation of pulse generator, includes programming
0313T	Vagus nerve blocking therapy (morbid obesity); laparoscopic revision or replacement of vagal trunk neurostimulator electrode array, including connection to existing pulse generator
0314T	Vagus nerve blocking therapy (morbid obesity); laparoscopic removal of vagal trunk neurostimulator electrode array and pulse generator
0315T	Vagus nerve blocking therapy (morbid obesity); removal of pulse generator
0316T	Vagus nerve blocking therapy (morbid obesity); replacement of pulse generator
0317T	Vagus nerve blocking therapy (morbid obesity); neurostimulator pulse generator electronic analysis, includes reprogramming when performed
HCPCS CODES	
C1767	Generator, neurostimulator, implantable, non-rechargeable
C1778	Lead, neurostimulator, implantable
E0765	FDA approved nerve stimulator, with replaceable batteries, for treatment of nausea and vomiting
L8680	Implantable neurostimulator electrode, each
L8688	Implantable neurostimulator pulse generator, dual array, non-rechargeable, includes extension

TAWG REVIEW DATES:

Gastric electrical stimulation (e.g., Enterra™ Therapy) - 07/17/2013, 01/22/2016, 01/27/2017
Gastric electrical stimulation for the treatment of obesity: Maestro VBLOC Therapy **-** 01/23/2015, 01/22/2016, 01/27/2017, 01/25/2018

REVISION HISTORY EXPLANATION

09/09/14: Removed CPT codes 0155T, 0156T, 0157T, 0158T deleted 12/31/11. Policy title changed from Gastric Neurostimulator to Gastric Electrical Stimulation (GES). Policy reviewed and updated to reflect most current clinical evidence per Medical Policy Steering Committee.
01/23/15: Added CPT codes 0313T, 0314T, 0315T, 0316T, & 0317T. Policy reviewed and updated to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG).
01/22/16: PPO will now be required to do prior authorization for gastric electrical stimulation (e.g., Enterra™ Therapy) for gastroparesis. Policy reviewed and updated to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG).
01/27/17: Policy reviewed and updated to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG).
01/25/18: Policy reviewed and updated to reflect most current clinical evidence per The Technology Assessment Working Group (TAWG).

REFERENCES/RESOURCES

Centers for Medicare and Medicaid Services, CMS Manual System and other CMS publications and services
Ohio Department of Medicaid http://jfs.ohio.gov/
American Medical Association, *Current Procedural Terminology (CPT®)* and associated publications and services
Centers for Medicare and Medicaid Services, Healthcare Common Procedure Coding System, HCPCS Release and Code Sets
Industry Standard Review
Hayes, Inc.