MEDICAL POLICY

Medical Policy Details	
Medical Policy Title	**Gastric Electrical Stimulation**
Policy Number	**7.01.64**
Category	**Technology Assessment**
Original Effective Date	**04/15/04**
Committee Approval Date	**04/21/05, 01/19/06, 03/15/07, 12/20/07, 10/23/08, 09/17/09, 08/19/10, 07/21/11, 06/21/12, 05/23/13, 05/22/14, 04/16/15, 03/17/16, 03/16/17, 02/15/18, 01/17/19, 01/16/20, 01/21/21, 01/20/22, 01/18/24**
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Archived Date	**N/A**
Archive Review Date	**N/A**
Product Disclaimer	• *Services are contract dependent; if a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.* • *If a commercial product (including an Essential Plan or Child Health Plus product), medical policy criteria apply to the benefit.* • *If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.* • *If a Medicare product (including Medicare HMO-Dual Special Needs Program [DSNP] product) covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.* • *If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.*

POLICY STATEMENT

Based upon our criteria and assessment of the peer-reviewed literature, gastric electrical stimulation (GES) has not been medically proven to be effective and, therefore, is considered **investigational** for the treatment of any disease or condition, including, but not limited to, gastroparesis and obesity.

Refer to Corporate Medical Policy #11.01.03 Experimental and Investigational Services

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, idiopathic, or postsurgical etiology. GES has also been investigated as a treatment of obesity. The device may be referred to as a gastric pacemaker.

Gastroparesis is a chronic disorder of gastric motility characterized by delayed emptying stomach in the absence of a mechanical obstruction. 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 diabetic patients. Although most commonly associated with diabetes, gastroparesis is also found in chronic pseudo-obstruction, connective tissue disorders, Parkinson disease, and psychological pathologic conditions. Some cases may not be associated with an identifiable cause and are referred to as idiopathic gastroparesis.

GES, also referred to as gastric pacing, using an implantable device, has been investigated primarily as a treatment for gastroparesis. Currently available devices consist of a pulse generator, which can be programmed to provide electrical stimulation at different frequencies, connected to intramuscular stomach leads, which are implanted during laparoscopy or open laparotomy.

GES has also been investigated as a treatment of obesity. It is used to increase a feeling of satiety with subsequent reduction in food intake and weight loss. The exact mechanisms resulting in changes in eating behavior are uncertain but may be related to neurohormonal modulation and/or stomach muscle stimulation.

RATIONALE

The Enterra Therapy System (Medtronic Inc.) is a high-frequency gastric electrical stimulation system that is indicated for the treatment of chronic, intractable (drug refractory) nausea and vomiting secondary to gastroparesis of diabetic or idiopathic etiology. The Enterra Therapy system received U.S. Food and Drug Administration (FDA) approval in 2000 under the Humanitarian Device Exemption (HDE). HDE allows approval of a device for conditions that are considered rare. Approval is granted with the understanding that the device is intended to benefit patients in the treatment and diagnosis of diseases and conditions that affect or are manifested in fewer than 4,000 people in the U.S. each year. A humanitarian use device may only be used in facilities that have an Institutional Review Board (IRB) to supervise clinical testing of the device.

The data presented to the FDA documenting probable benefit of the GES system were based on a multi-center, double-blind crossover study referred to as the Worldwide Anti-vomiting Electrical Stimulation Study (WAVESS). The study included 33 patients with intractable idiopathic or diabetic gastroparesis. In the initial phase of the study, all patients underwent implantation and were randomly and blindly assigned to either the ON mode or the OFF mode for the first month of the study, with crossover to the opposite mode for the second month. The baseline vomiting frequency was 47 episodes per month, which declined in both the ON mode and the OFF mode to 23 and 29 episodes, respectively. However, no statistically significant differences in the number of vomiting episodes were found between the OFF and ON groups, suggesting a placebo effect. In questioning patients as to which month of treatment they preferred (ON versus OFF), a greater number of patients preferred the month of treatment in the ON mode. In the second phase of the study, patients received stimulation consistent with their preference for the ON or OFF mode. At six- and 12-month follow-up, vomiting episodes continued to decline, although only 15 patients were available for follow-up.

The American College of Gastroenterology (ACG) Clinical Guidelines for Gastroparesis indicate that GES may be considered for control of gastroparesis symptoms as a humanitarian use device (conditional recommendation, low quality of evidence) (Camilleri et al., 2022).

For individuals who have gastroparesis who receive GES, the evidence includes randomized controlled trials (RCTs), nonrandomized studies, and systematic reviews. Relevant outcomes are symptoms and treatment-related morbidity. Several crossover RCTs have been published. A 2017 meta-analysis of 5 RCTs did not find a significant benefit of GES on the severity of symptoms associated with gastroparesis (Levinthal et al., 2017). Patients generally reported improved symptoms at follow-up whether or not the device was turned on, suggesting a placebo effect. A 2022 meta-analysis did find some improvements, but interpretation of its findings is limited by inconsistent benefits across different outcomes and timepoints, high heterogeneity, and inclusion of study populations not representative of the intended population (Saleem et al., 2022). The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

The evidence available from studies is insufficient to prove that gastric electrical stimulation is effective for the treatment of patients with gastroparesis. Though the evidence does suggest that GES can relieve nausea and vomiting and may also reduce the need for nutritional support in some patients with intractable gastroparesis, there was no documentation of improved gastric emptying or enhanced gastric motility. The studies included small numbers of patients, had limited follow-up, and were inadequate to establish that GES is an effective or durable treatment for gastroparesis. Long-term results of GES need to be validated in longer-term, randomized trials.

No FDA devices have received FDA approval for the treatment of obesity. Transneuronix, Inc. has developed an implantable gastric stimulator, The Transcend IGS, which was studied in the SHAPE clinical trial in the United States. The SHAPE trial did not show significant improvement in weight loss using GES, compared with sham stimulation.

CODES

- *Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.*

- *CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.*
- *Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.*
- *Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).*

CPT Codes

Code	Description
43647 **(E/I)**	Laparoscopy, surgical; implantation or replacement of gastric neurostimulator electrodes, antrum
43648 **(E/I)**	revision or removal of gastric neurostimulator electrodes, antrum
43881 **(E/I)**	Implantation or replacement of gastric neurostimulator electrodes, antrum, open
43882 **(E/I)**	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 peripheral or gastric neurostimulator pulse generator or receiver
95980 **(E/I)**	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 **(E/I)**	subsequent, without reprogramming
95982 **(E/I)**	subsequent, with reprogramming

HCPCS Codes

Code	Description
C1767	Generator, neurostimulator (implantable), nonrechargeable
C1787	Patient programmer; neurostimulator
C1820	Generator, neurostimulator (implantable), with rechargeable battery and charging system
C1822	Generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system
E0765 **(E/I)**	FDA approved nerve stimulator, with replaceable batteries, for treatment of nausea and vomiting
L8679	Implantable neurostimulator, pulse generator, any type
L8680	Implantable neurostimulator electrode, each
L8681	Patient programmer (external) for use with implantable programmable neurostimulator pulse generator, replacement only
L8682	Implantable neurostimulator radiofrequency receiver
L8683	Radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receiver
L8685	Implantable neurostimulator pulse generator, single array, rechargeable, includes extension
L8686	Implantable neurostimulator pulse generator, single array, non-rechargeable, includes extension
L8687	Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension

Code	Description
L8688	Implantable neurostimulator pulse generator, dual array, non- rechargeable, includes extension
L8689	External recharging system for battery (internal) for use with implanted neurostimulator, replacement only

ICD10 Codes

Code	Description
E66.01 – E66.9 (code range)	Overweight and obesity
E08.43	Diabetes mellitus due to underlying condition with diabetic autonomic (poly)neuropathy
E09.43	Drug or chemical induced diabetes mellitus with neurological complications with diabetic autonomic (poly)neuropathy
E10.43	Type 1 diabetes mellitus with diabetic autonomic (poly)neuropathy
E11.43	Type 2 diabetes mellitus with diabetic autonomic (poly)neuropathy
E13.43	Other specified diabetes mellitus with diabetic autonomic (poly)neuropathy
K31.84	Gastroparesis
R11.0 - R11.2 (code range)	Nausea and vomiting

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*Key Article

KEY WORDS

Gastric stimulation, Gastric pacing, Gastroparesis, Gastric pacemaker.

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

Based on our review, gastric electrical stimulation is not addressed in National or Regional Medicare coverage determinations or policies.