Medical Coverage Policy | Gastric Electrical Stimulation - Insertion

EFFECTIVE DATE: 10|01|2021
POLICY LAST UPDATED: 04|20|2022

OVERVIEW
Gastric electrical stimulation is performed using an implantable device designed to treat chronic drug-refractory nausea and vomiting secondary to gastroparesis of diabetic, idiopathic, or post-surgical etiology. Gastric electrical stimulation has also been investigated as a treatment of obesity. The device may be referred to as a gastric pacemaker. This policy is intended to document the insertion or implantation of the device as not medically necessary.

Note: For removal of the device, refer to the following policy: Removal of Non-Covered Implantable Devices

MEDICAL CRITERIA
Not applicable

PRIOR AUTHORIZATION
Not applicable

POLICY STATEMENT
Medicare Advantage Plans
Implantation of a gastric electrical stimulation device for any indication is not covered as the evidence is insufficient to determine the effects of the technology on health outcomes.

Commercial Products
Implantation of a gastric electrical stimulation device for any indication is considered not medically necessary as the evidence is insufficient to determine the effects of the technology on health outcomes.

COVERAGE
Benefits may vary between groups and contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage or Subscriber Agreement for not covered/not medically necessary benefits/coverage.

BACKGROUND
GASTROPARESIS
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 diabetic patients. While most commonly associated with diabetes, gastroparesis is also found in chronic pseudo-obstruction, connective tissue disorders, Parkinson's disease, and psychological pathologic conditions. Some cases may not be associated with an identifiable cause and are referred to as idiopathic gastroparesis. Treatment of gastroparesis includes prokinetic agents, such as metoclopramide, and antiemetic agents, such as metoclopramide, granisetron, or ondansetron. Severe cases may require enteral or total parenteral nutrition.

Treatment
Gastric electrical stimulation, 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 that are implanted during laparoscopy or open laparotomy.

In 2000, the Gastric Electrical Stimulator system (now called Enterra™ Therapy System; Medtronic) was approved by the U.S. Food and Drug Administration through the humanitarian device exemption process for the treatment of gastroparesis. The GES system consists of 4 components: the implanted pulse generator, 2 unipolar intramuscular stomach leads, the stimulator programmer, and the memory cartridge. With the exception of the intramuscular leads, all other components have been used in other implantable neurologic stimulators, such as spinal cord or sacral nerve stimulation. The intramuscular stomach leads are implanted either laparoscopically or during a laparotomy and are connected to the pulse generator, which is implanted in a subcutaneous pocket. The programmer sets the stimulation parameters, which are typically set at an "on" time of 0.1 seconds alternating with an "off" time of 5.0 seconds.

OBESITY

Gastric electrical stimulation 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 neuro-hormonal modulation and/or stomach muscle stimulation.

Currently, no GES devices have been approved by the Food and Drug Administration for the treatment of obesity. The Transcend® (Transneuronix; acquired by Medtronic in 2005), an implantable gastric stimulation device, is available in Europe for treatment of obesity.

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. Five crossover RCTs have been published. A 2017 meta-analysis of these 5 RCTs did not find a significant benefit of GES on the severity of symptoms associated with gastroparesis. Patients generally reported improved symptoms at follow-up whether or not the device was turned on, suggesting a placebo effect. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have obesity who receive GES, the evidence includes an RCT. Relevant outcomes are change in disease status and treatment-related morbidity. The SHAPE trial did not show significant improvement in weight loss using GES compared with sham stimulation. The evidence is insufficient to determine the effects of the technology on health outcomes.

CODING

The following code(s) are not covered for Medicare Advantage Plans and not medically necessary for Commercial Products:

43647 Laparoscopy, surgical; implantation or replacement of gastric neurostimulator electrodes, antrum

43881 Implantation or replacement of gastric neurostimulator electrodes, antrum, open

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

For Obesity

The following code(s) are not covered for Medicare Advantage Plans and not medically necessary for Commercial Products:

Laparoscopic procedures related to gastric stimulation electrodes for morbid obesity should be reported using code 43659 (unlisted laparoscopy procedure, stomach), and laparotomy procedures related to gastric stimulation electrodes for morbid obesity should be reported using 43999 (unlisted procedure, stomach).

The following code(s) is not covered for Medicare Advantage Plans and not medically necessary for Commercial Products when used for gastric electrical stimulation **AND** filed with the diagnosis codes listed below:

64590 Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling

ICD-10
E08.43
E09.43
E10.43
E11.43
E13.43
E66.01-E66.9
K31.89

RELATED POLICIES
Removal of Non-Covered Implantable Devices

PUBLISHED
Provider Update, June 2022
Provider Update, August 2021
Provider Update, June 2020
Provider Update, December 2019
Provider Update, November/December 2018
~~Provider Update, January 2018~~

REFERENCES

1. Levinthal DJ, Bielefeldt K. Systematic review and meta-analysis: Gastric electrical stimulation for gastroparesis. Auton Neurosci. Jan 2017;202:45-55. PMID 27085627
2. Chu H, Lin Z, Zhong L, et al. Treatment of high-frequency gastric electrical stimulation for gastroparesis. J Gastroenterol Hepatol. Jun 2012;27(6):1017-1026. PMID 22128901
3. Lal N, Livemore S, Dunne D, et al. Gastric electrical stimulation with the Enterra System: a systematic review. Gastroenterol Res Pract. 2015;2015:762972. PMID 26246804
4. Abell T, McCallum R, Hocking M, et al. Gastric electrical stimulation for medically refractory gastroparesis. Gastroenterology. Aug 2003;125(2):421-428. PMID 12891544
5. U.S. Food and Drug Administration. FDA Summary of Safety and Probable Benefit. 2010; http://www.accessdata.fda.gov/cdrh_docs/pdf/H990014b.pdf. Accessed January, 2017.
6. McCallum RW, Snape W, Brody F, et al. Gastric electrical stimulation with Enterra therapy improves symptoms from diabetic gastroparesis in a prospective study. Clin Gastroenterol Hepatol. Nov 2010;8(11):947-954; quiz e116. PMID 20538073
7. McCallum RW, Sarosiek I, Parkman HP, et al. Gastric electrical stimulation with Enterra therapy improves symptoms of idiopathic gastroparesis. Neurogastroenterol Motil. Oct 2013;25(10):815-e636. PMID 23895180
8. Shikora SA, Bergenstal R, Bessler M, et al. Implantable gastric stimulation for the treatment of clinically severe obesity: results of the SHAPE trial. Surg Obes Relat Dis. Jan-Feb 2009;5(1):31-37. PMID 19071066
9. Cigaina V. Gastric pacing as therapy for morbid obesity: preliminary results. Obes Surg. Apr 2002;12 Suppl 1:12S-16S. PMID 11969102
10. Cigaina V, Hirschberg AL. Gastric pacing for morbid obesity: plasma levels of gastrointestinal peptides and leptin. Obes Res. Dec 2003;11(12):1456-1462. PMID 14694209
11. D'Argent J. Gastric electrical stimulation as therapy of morbid obesity: preliminary results from the French study. Obes Surg. Apr 2002;12 Suppl 1:21S-25S. PMID 11969104

12. De Luca M, Segato G, Busetto L, et al. Progress in implantable gastric stimulation: summary of results of the European multi-center study. Obes Surg. Sep 2004;14 Suppl 1:S33-39. PMID 15479588
13. Favretti F, De Luca M, Segato G, et al. Treatment of morbid obesity with the Transcend Implantable Gastric Stimulator (IGS): a prospective survey. Obes Surg. May 2004;14(5):666-670. PMID 15186636
14. Shikora SA. Implantable gastric stimulation for the treatment of severe obesity. Obes Surg. Apr 2004;14(4):545-548. PMID 15130236
15. National Institute of Health and Care Excellence. Gastroelectrical stimulation for gastroparesis [IPG489]. 2014; https://www.nice.org.uk/guidance/ipg489. Accessed January 23, 2017.
16. Camilleri M, Parkman HP, Shafi MA, et al. Clinical guideline: management of gastroparesis. Am J Gastroenterol. Jan 2013;108(1):18-37; quiz 38. PMID 23147521