

EFFECTIVE DATE: 10|01|2021

POLICY LAST REVIEWED: 07|17|2024

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 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, including treatment of gastroparesis of diabetic, idiopathic, postsurgical etiology or for treatment of obesity, 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, including treatment of gastroparesis of diabetic, idiopathic, postsurgical etiology or for treatment of obesity, is 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 disease, and psychological pathologic conditions. Some cases may not be associated with an identifiable cause and are referred to as idiopathic gastroparesis. Gastric electrical stimulation (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.

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. The Enterra II system features no magnetic activation switch which reduces electromagnetic interference.

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 neurohormonal 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 gastric electrical stimulation (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. 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 are limited by inconsistent benefits across different outcomes and timepoints, high heterogeneity (I²=70%), and inclusion of study populations not representative of the intended population. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have obesity who receive GES, the evidence includes an RCT and several small case series and uncontrolled prospective trials. 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 a sham stimulation. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

CODING

The following CPT 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, sacral, or gastric neurostimulator pulse generator or receiver, requiring pocket creation and connection between electrode array and pulse generator or receiver (Text revised 1/01/2024)

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

Unlisted Procedures

PUBLISHED

Provider Update, September 2024

Provider Update, May 2023

Provider Update, June 2022

Provider Update, August 2021

Provider Update, June 2020

REFERENCES

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