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Preauthorization	No	Review Dates: 01/07, 03/08, 03/09, 01/10, 01/11, 01/12, 01/13, 01/14, 11/14, 11/15, 11/16, 11/17, 11/18, 11/19	

Preauthorization is not required.

The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient’s contract at the time the services are rendered.

Populations	Interventions	Comparators	Outcomes
Individuals: • With gastroparesis	Interventions of interest are: • Gastric electrical stimulation	Comparators of interest are: • Conservative management • Medication • Enteral or total parenteral nutrition	Relevant outcomes include: • Symptoms • Treatment-related morbidity
Individuals: • With obesity	Interventions of interest are: • Gastric electrical stimulation	Comparators of interest are: • Conservative management • Medication • Bariatric surgery	Relevant outcomes include: • Change in disease status • Treatment-related morbidity

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.

SUMMARY OF EVIDENCE

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 five 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.

POLICY

Gastric electrical stimulation is considered **investigational** for the treatment of gastroparesis of diabetic, idiopathic or post-surgical etiology.

Gastric electrical stimulation is considered **investigational** for the treatment of obesity.

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. Treatment of gastroparesis includes prokinetic agents (e.g., metoclopramide) and antiemetic agents (e.g., metoclopramide, granisetron, ondansetron). Severe cases may require enteral or total parenteral nutrition.

Treatment

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 (see Regulatory Status section).

OBESITY

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.

REGULATORY STATUS

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 (H990014) for the treatment of gastroparesis. The GES system consists of four components: the implanted pulse generator, two 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 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.

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.

RELATED PROTOCOL

Vagus Nerve Stimulation

Services that are the subject of a clinical trial do not meet our Technology Assessment and Medically Necessary Services Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment and Medically Necessary Services Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

REFERENCES

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

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*. Aug 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. Summary of Safety and Probable Benefit: Enterra™ Therapy System. 2010; http://www.accessdata.fda.gov/cdrh_docs/pdf/H990014b.pdf. Accessed January 25, 2018.
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. Laine M, Siren J, Koskenpato J, et al. Outcomes of High-Frequency Gastric Electric Stimulation for the Treatment of Severe, Medically Refractory Gastroparesis in Finland. *Scand J Surg*. Jun 2018;107(2):124-129. PMID 29268656
9. Shada A, Nielsen A, Marowski S, et al. Wisconsin's Enterra Therapy Experience: A multi-institutional review of gastric electrical stimulation for medically refractory gastroparesis. *Surgery*. Oct 2018;164(4):760-765. PMID 30072246
10. 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
11. Cigaina V. Gastric pacing as therapy for morbid obesity: preliminary results. *Obes Surg*. Apr 2002;12 Suppl 1:12S-16S. PMID 11969102
12. 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
13. 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
14. 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

15. 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
16. Shikora SA. Implantable gastric stimulation for the treatment of severe obesity. *Obes Surg.* Apr 2004;14(4): 545-548. PMID 15130236
17. National Institute of Health and Care Excellence. Gastroelectrical stimulation for gastroparesis [IPG489]. 2014; <https://www.nice.org.uk/guidance/ipg489>. Accessed January 25, 2018.
18. 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