

## FEP 7.01.73 Gastric Electrical Stimulation

**Effective Date:** July 15, 2018

**Related Policies:**  
7.01.150 Vagal Nerve Blocking Therapy for Treatment of Obesity

### Gastric Electrical Stimulation

#### 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.

#### FDA 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 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 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.

#### POLICY STATEMENT

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

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

#### BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

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### RATIONALE

#### Summary of Evidence

For individuals who have gastroparesis who receive GES, the evidence includes RCTs 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.

### SUPPLEMENTAL INFORMATION

#### Practice Guidelines and Position Statements

##### National Institute for Health and Care Excellence

The National Institute for Health and Care Excellence (2014) has issued guidance on GES for gastroparesis.<sup>15</sup> The Institute made the following recommendations:

- 1.1 “Current evidence on the efficacy and safety of gastric electrical stimulation for gastroparesis is adequate to support the use of this procedure with normal arrangements for clinical governance, consent, and audit.
- 1.2 ... clinicians should inform patients considering gastric electrical stimulation for gastroparesis that some patients do not get any benefit from it. They should also give patients detailed written information about the risk of complications, which can be serious, including the need to remove the device.
- 1.3 Patient selection and follow-up should be done in specialist gastroenterology units with expertise in gastrointestinal motility disorders, and the procedure should only be performed by surgeons working in these units.

##### American College of Gastroenterology

The American College of Gastroenterology published practice guidelines on the management of gastroparesis in 2013.<sup>16</sup> The College recommended that:

“GES [gastric electrical stimulation] may be considered for compassionate treatment in patients with refractory symptoms, particularly nausea and vomiting. Symptom severity and gastric emptying have been shown to improve in patients with DG [diabetic gastroparesis], but not in patients with IG [idiopathic gastroparesis] or PSG [postsurgical gastroparesis]. [Conditional recommendation (there is uncertainty about trade-offs), moderate level of evidence (further research would be likely to have an impact on the confidence in the estimate of effect).]”

#### U.S. Preventive Services Task Force Recommendations

Not applicable.

#### Medicare National Coverage

There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

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### 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*. 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](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. 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 25, 2018.
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

### POLICY HISTORY

Date	Action	Description
September 2012	New Policy	Gastric electrical stimulation is considered not medically necessary for the treatment of gastroparesis of diabetic or idiopathic etiology. Gastric electrical stimulation is considered investigational for the treatment of obesity.
December 2013	Update Policy	Policy updated with literature review, references 1, 9, 13, 17, 18, 26 and 27 added; no changes in policy statements. Policy summary revised/clarified with no change to intent.
December 2014	Update Policy	Policy updated with literature review through July 1, 2014. References 5, 14, and 27-28 added. Rationale section reorganized. No change to policy statements.
June 2016	Update Policy	Policy updated with literature review through November 10, 2015; references 4 and 12 added. Policy statements unchanged.
June 2018	Update Policy	Policy updated with literature review through December 11, 2017; reference 1 added. Policy statements unchanged except "not medically necessary" corrected to "investigational" due to FDA HDE status.

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