MEDICAL POLICY

POLICY TITLE	GASTRIC ELECTRICAL STIMULATION
POLICY NUMBER	MP- 2.069

Original Issue Date (Created):	**5/9/2003**
Most Recent Review Date (Revised):	**4/20/2020**
Effective Date:	**2/1/2021**

I. POLICY

Gastric electrical stimulation may be considered medically necessary when provided in accordance with the humanitarian device exemption (HDE) specifications of the U.S. Food and Drug Administration (FDA) for the treatment of chronic intractable nausea and vomiting secondary to severe gastroparesis of diabetic or idiopathic etiology when **ALL** of the following criteria are met:

- Significant delayed gastric emptying as documented by standard scintigraphic imaging of solid food; **and**
- Individual is refractory to or intolerant of at least two (2) anti-emetic and/or prokinetic drug classes for greater than or equal to a total of 12 weeks; **and**
- No mechanical obstruction is found on diagnostic testing; **and**
- Nausea or vomiting greater than or equal to seven (7) episodes per week; **and**
- Individual's nutritional status is sufficiently low that adequate trials of dietary adjustment, oral supplements, or tube enteral nutrition have been demonstrated that the individual can receive less than or equal to 30% of his/her caloric needs orally and/or tube; **and**
- Weight loss greater than or equal to 10% within a six (6) month timeframe; **and**
- Individual has NO history of **ALL** below:
  - Cardiac pacemaker or implantable cardioverter defibrillator or other neurostimulators
  - Gastric resection
  - Systemic motility disorder (examples include Systemic Lupus Erythematosus, Amyloidosis, Scleroderma, Neurofibromatosis, Parkinson's disease, Muscular Dystrophies, Thyroid Disease)

Gastric electrical stimulation is considered **investigational** for the treatment of obesity. There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

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II. PRODUCT VARIATIONS TOP

This policy is only applicable to certain programs and products administered by Capital BlueCross please see additional information below, and subject to benefit variations as discussed in Section VI below.

FEP PPO - Refer to FEP Medical Policy Manual MP-7.01.73, Gastric Electrical Stimulation. The FEP Medical Policy manual can be found at: https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies.

III. DESCRIPTION/BACKGROUND TOP

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 4 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.

IV. RATIONALE

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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 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 Screened Health Assessment and Pacer Evaluation (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.

V. DEFINITIONS

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ANTIEMETIC refers to an agent that prevents or relieves nausea or vomiting.

ENTERAL refers to within or by way of the intestine.

ETIOLOGY refers to the cause of a disease.

IDIOPATHIC refers to conditions without a known cause.

LAPAROSCOPY refers to abdominal exploration using a type of endoscope called a laparoscope.

PROKINETIC refers to the stimulation of gastrointestinal activity.

SUBCUTANEOUS refers to beneath the skin.

TOTAL PARENTERAL NUTRITION refers to the intravenous provision of dextrose, amino acids, emulsified fats, trace elements, vitamins, and minerals to patients who are unable to assimilate adequate nutrition by mouth.

VI. BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member's health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits and which require preauthorization. There are different benefit plan designs in each product administered by Capital BlueCross. Members and providers should consult the member's health benefit plan for information or contact Capital BlueCross for benefit information.

VII. DISCLAIMER

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Capital BlueCross's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital BlueCross' Provider Services or Member Services. Capital BlueCross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

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Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

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Covered when medically necessary:

CPT Codes ®							
43647	43648	43659	43881	43882	43999	64590	64595
95980	95981	95982					

HCPCS Code	Description
L8680	Implantable neurostimulator electrode, each
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
L8688	Implantable neurostimulator pulse generator, dual array, non-rechargeable, includes extension

ICD-10-CM Diagnosis Code	Description
E08.43	Diabetes mellitus due to underlying condition with diabetic autonomic (poly)neuropathy
E08.8	Diabetes mellitus due to underlying condition with unspecified complications
E09.43	Drug or chemical induced diabetes mellitus with neurological complications with autonomic (poly)neuropathy
E09.8	Drug or chemical induced diabetes mellitus with unspecified complications
E10.43	Type 1 diabetes mellitus with diabetic autonomic (poly)neuropathy
E10.8	Type 1 diabetes mellitus with unspecified complications
E11.43	Type 2 diabetes mellitus with diabetic autonomic (poly)neuropathy
E11.8	Type 2 diabetes mellitus with unspecified complications
E13.43	Other specified diabetes mellitus with diabetic autonomic (poly)neuropathy
E13.8	Other specified diabetes mellitus with unspecified complications
K31.84	Gastroparesis
K31.89	Other diseases of stomach and duodenum
K31.9	Disease of stomach and duodenum, unspecified

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IX. REFERENCES

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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 April 20, 2020.*
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 [IPG48]. 2014; https://www.nice.org.uk/guidance/ipg489. Accessed April 20, 2020.*
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*
19. *Camilleri M, Talley, N, Grover S. Gastroparesis: Etiology, clinical manifestations, and diagnosis. 2018; https://www.uptodate.com/contents/gastroparesis-etiology-clinical-manifestations-and-diagnosis. Accessed April 20, 2020.*
20. *Reddymasu S, Sarosiek I, McCallum R. Severe Gastroparesis: Medical Therapy or Gastric Electrical Stimulation. 2010; https://www.cghjournal.org/article/S1542-3565(09)00893-3/fulltext. Accessed April 20, 2020.*
21. *Cederholm T, Jensen G, Correia, M et al. GLIM criteria for the Diagnosis of Malnutrition – A Consensus Report from the Global Clinical Nutrition Community. 2019; https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6438340/. Accessed April 20, 2020.*
22. *Family Practice Notebook. Lab Markers of Malnutrition. 2018. https://fpnotebook.com/pharm/lab/lbmrkrsofmlntrtn.htm#fpnContent-panel-id_3. Accessed April 20, 2020.*
23. *Hasler W, Talley N, Grover, S. Electival Stimulation for Gastroparesis. 2019. https://www.uptodate.com/contents/electrical-stimulation-for-gastroparesis. Accessed April 20, 2020.*
24. *InterQual® Level of Care Criteria 2020. Acute Care Adult. CP:Procedures Gastric Stimulation. Change Healthcare.*
25. *Ducrotte P, Coffin B, Fontaine S et al. Gastric Electrical Stimulation Reduces Refractory Vomiting in a Randomized Crossover Trial. American Gastroenterological Association. February 2020;158(3):506-514. https://www.gastrojournal.org/article/S0016-5085(19)41463-7/fulltext. Accessed May 22, 2020.*
26. *Medical Advisory Secretariat. Gastric electrical stimulation: an evidence-based analysis. Ontario Health Technology Assessment Series 2006; 6(16). https://www.ncbi.nlm.nih.gov/pubmed/23074486. Accessed May 22, 2020.*
27. *Blue Cross Blue Shield Association Medical Policy Reference Manual. 7.01.73, Gastric Electrical Stimulation. March 2020.*

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X. POLICY HISTORY

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MP 2.069	**CAC 1/28/03**
	CAC 1/25/05
	CAC 2/28/06
	CAC 2/27/07
	CAC 9/25/07
	CAC 7/29/08
	CAC 7/28/09 Consensus review
	CAC 5/25/10 Adopted BCBSA criteria
	CAC 4/26/11 Consensus review
	CAC 6/26/12 Consensus review. No changes, references updated.
	03/07/13 Administrative update. Code review
	CAC 9/24/13 Consensus review. References updated but no changes to the policy statements. Rationale added. FEP variation revised to refer to the FEP manual. Admin Code review
	CAC 7/22/14 Consensus review. No change to policy statements. References updated. Coding reviewed.
	CAC 7/21/15 Consensus review. No change to the policy statements. Background, references and rationale updated. Codes reviewed.
	12/1/16 Administrative update. Variation section reformatted.
	CAC 7/26/16 Minor revision. 'Post-surgical' added to the gastroparesis investigational policy statement. Regulatory Status, Rationale and Reference sections updated. Coding reviewed/updated to address gastric stimulation for obesity.
	CAC 9/26/17 Consensus review. No change to policy statements. References and rationale updated. Coding Reviewed.
	6/05/18 Consensus review. Policy statements unchanged. Description/Background, Rationale and Reference sections updated.
	4/9/19 Consensus review. No change to policy statements. Background reviewed. Summary of evidence and references updated.
	5/22/20 Minor review. Added GES covered for severe gastroparesis of diabetic or idiopathic etiology with criteria included. References added. Coding updated.

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