BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:

Gastric Electrical Stimulation

Policy #: 148
Latest Review Date: February 2025
Category: GI/GU

BACKGROUND:

Blue Advantage *medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
   - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
   - *Furnished in a setting appropriate to the patient's medical needs and condition;*
   - *Ordered and furnished by qualified personnel;*
   - *One that meets, but does not exceed, the patient's medical need; and*
   - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000, which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill* ***Original Medicare* *for covered services that are related to* ***clinical trials*** *that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

POLICY:

Blue Advantage will treat **gastric electrical stimulation** as a **covered** benefit for the treatment of nausea and vomiting from **chronic gastroparesis that is refractory for medical management** when **all** of the following criteria are met:

- Diagnosis of delayed gastric emptying has been made; **AND**
- Patient is refractory or intolerant of prokinetic medications and antiemetic medications; **AND**
- Nutritional status is poor, and either enteral tube feedings or total parental nutrition is medically necessary.

Blue Advantage will treat **gastric electrical stimulation** as a **non-covered** benefit and as **investigational** for all other indications including but not limited to initial treatment of gastroparesis and treatment of obesity.

Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

DESCRIPTION OF PROCEDURE OR SERVICE:

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 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.

Treatment

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. 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.

Obesity
Gastric electrical stimulation has also been investigated as a treatment of obesity. It is used to increase a feeling of satiety with subsequent reduced 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.

KEY POINTS:
The most recent literature review was performed through January 3, 2025. The following is a summary of the key findings to date.

Summary of Evidence
For individuals with gastroparesis who receive GES, the evidence includes randomized controlled trials (RCTs), non-randomized studies, and systematic reviews. Relevant outcomes are symptoms and treatment-related morbidity. Several 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. A 2022 meta-analysis did find some improvements, but interpretation of its findings is limited by inconsistent benefits across different outcomes and time points, 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 Screened Health Assessment and Pacer Evaluation (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.

Practice Guidelines and Position Statements
American College of Gastroenterology
In 2022, the American College of Gastroenterology updated practice guidelines on management of gastroparesis. The College recommended that:

"Gastric electric stimulation (GES) may be considered for control of GP [gastroparesis] symptoms as a humanitarian use device (HUD) (conditional recommendation, low quality of evidence)."

National Institute for Health and Care Excellence
In 2014, NICE issued guidelines on gastroelectrical stimulation for gastroparesis that made the following recommendations:

- 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.

- … 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.
- 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.

U.S. Preventive Services Task Force Recommendations
Gastric electrical stimulation is not a preventive service.

KEY WORDS:
Gastric electrical stimulation (GES), gastroparesis, Enterra™ Therapy System, gastric pacemaker, gastric pacing

APPROVED BY GOVERNING BODIES:
In 2000, the Gastric electrical stimulator (GES) system (now called Enterra™ Therapy System), manufactured by Medtronic, Inc. (Minneapolis, MN) was approved by the U.S. Food and Drug Administration through the humanitarian device exemption process. 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 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 second alternating with an "off" time of 5.0 seconds. The Enterra II system features no magnetic activation switch which reduces electromagnetic interference.

There are no gastric electrical stimulation devices approved by the U.S. Food and Drug Administration (FDA) for the treatment of obesity. The Transcend® Implantable Gastric Stimulation device, manufactured by Transneuronix and acquired by Medtronic in 2005, is currently available in Europe for treatment of obesity.

BENEFIT APPLICATION:
Coverage is subject to member's specific benefits. Group-specific policy will supersede this

CURRENT CODING:
CPT Codes:
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).

43647	Laparoscopy, surgical; implantation or replacement of gastric neurostimulator electrodes, antrum
43648	Laparoscopy, surgical; revision or removal of gastric neurostimulator electrodes, antrum
43659	Unlisted laparoscopy procedure, stomach
43881	Implantation or replacement of gastric neurostimulator electrodes, antrum, open
43882	Revision or removal of gastric neurostimulator electrodes, antrum, open
43999	Unlisted procedure, stomach
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
64595	Revision or removal of peripheral, sacral or gastric neurostimulator pulse generator or receiver, with detachable connection to electrode array
95980	Electronic analysis of implanted neurostimulator pulse generator system (e.g., rate, pulse amplitude and duration, configuration of waveform, 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 waveform, 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 waveform, battery status, electrode selectability, output modulation, cycling, impedance and patient measurements) gastric neurostimulator pulse generator/transmitter; subsequent, with reprogramming

REFERENCES:

1. Abell T, McCallum R, Hocking M, et al. Gastric electrical stimulation for medically refractory gastroparesis.Gastroenterology. Aug 2003; 125(2): 421-8.
2. Camilleri M, Kuo B, Nguyen L, et al. ACG Clinical Guideline: Gastroparesis. Am J Gastroenterol. Aug 01 2022; 117(8):1197-1220.
3. Chu H, Lin Z, Zhong L et al. Treatment of high-frequency gastric electrical stimulation for gastroparesis. Journal of gastroenterology and hepatology Jun 2012; 27(6):1017-26.
4. Cigaina V, Hirschberg AL. Gastric pacing for morbid obesity: plasma levels of gastrointestinal peptides and leptin. ObesRes. Dec 2003; 11(12): 1456-62.
5. Cigaina V. Gastric pacing as therapy for morbid obesity: preliminary results. Obes Surg. Apr 2002; 12 Suppl 1: 12S-16S.
6. D'Argent J. Gastric electrical stimulation as therapy of morbid obesity: preliminary results from the French study. ObesSurg. Apr 2002; 12 Suppl 1: 21S-25S.
7. 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: S33-9.
8. Ducrotte P, Coffin B, Bonaz B, et al. Gastric Electrical Stimulation Reduces Refractory Vomiting in a Randomized Crossover Trial. Gastroenterology. Feb 2020; 158(3): 506-514.e2.
9. 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): 666-70.
10. FDA Summary of Safety and Probable Benefit: Enterra™ Therapy System. 2010; www.accessdata.fda.gov/cdrh_docs/pdf/H990014b.pdf.
11. IOM (Institute of Medicine). 2011. Clinical Practice Guidelines We Can Trust. Washington, DC: The National Academies Press.
12. 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.
13. Lal N, Livemore S, Dunne D, et al. Gastric Electrical Stimulation with the Enterra System: A Systematic Review. Gastroenterol Res Pract. 2015; 2015:762972.
14. Levinthal DJ, Bielefeldt K. Systematic review and meta-analysis: Gastric electrical stimulation for gastroparesis. Auton Neurosci. Jan 2017; 202:45-55.
15. 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.
16. 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):947-54; quiz e116.
17. National Institute of Health and Care Excellence. Gastroelectrical stimulation for gastroparesis [IPG489]. 2014; www.nice.org.uk/guidance/ipg489.

18. Saleem S, Aziz M, Khan AA, et al. Gastric Electrical Stimulation for the Treatment of Gastroparesis or Gastroparesis-like Symptoms: A Systemic Review and Meta-analysis. Neuromodulation. Dec 02 2022.
19. Samaan JS, Toubat O, Alicuben ET, et al. Gastric electric stimulator versus gastrectomy for the treatment of medicallyrefractory gastroparesis. Surg Endosc. Oct 2022; 36(10): 7561-7568.
20. 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.
21. Shikora SA. Implantable gastric stimulation for the treatment of severe obesity. Obes Surg. Apr 2004; 14(4): 545-8.
22. 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. 2009; 5(1): 31-7.

POLICY HISTORY:

Adopted for Blue Advantage, March 2005
Available for comment May 1-June 14, 2005
Medical Policy Group, March 2006
Available for comment March 23-May 8, 2006
Medical Policy Group, November 2006
Available for comment November 3-December 17, 2006
Medical Policy Group, June 2009
Available for comment June 30-August 13, 2009
Medical Policy Group, October 2010
Medical Policy Group, December 2011
Medical Policy Group, January 2013
Medical Policy Group, August 2013
Medical Policy Group, August 2014
Medical Policy Group, December 2015
Medical Policy Group, February 2017
Medical Policy Group, February 2018
Medical Policy Group, February 2019
Medical Policy Group, February 2020
Medical Policy Group, February 2021
Medical Policy Group, February 2022
Medical Policy Group, February 2023
Medical Policy Group, November 2023: 2024 annual CPT coding update. Revised 64590, 64595.
UM Committee, December 2023: Policy approved by UM Committee for use for Blue Advantage business.
Medical Policy Group, February 2024
UM Committee, February 2024: Annual review of policy approved by UM Committee for use for Blue Advantage business.
Medical Policy Group, February 2025

UM Committee, February 2025: Annual review of policy approved by UM Committee for use for Blue Advantage business.

This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member's plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield's administration of plan contracts.