BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:

Gastric Electrical Stimulation

Policy #: 148
Category: Surgery

Latest Review Date: February 2021
Policy Grade: A

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

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 December 10, 2020. 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 case series. 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 that the technology results in an improvement in the net health outcome.

For individuals who have obesity who receive GES, the evidence includes one published randomized study as well as small case series and uncontrolled trials. Relevant outcomes are change in disease status and treatment-related morbidity. The published RCT (the SHAPE trial) did not show significant improvement in weight loss with gastric electrical stimulation 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

National Institute for Health and Care Excellence

In 2014, the National Institute for Health and Care Excellence 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.

American College of Gastroenterology

The American College of Gastroenterology published a clinical practice guideline on management of gastroparesis in 2013. The recommendation was that:
"GES 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, but not in patients with IG or PSG. [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).]"

An update is in progress from the American College of Gastroenterology.

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 second.
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 policy when applicable.

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 or gastric neurostimulator pulse generator or receiver, direct or inductive coupling
64595	Revision or removal of peripheral or gastric neurostimulator pulse generator or receiver
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

REFERENCES:

1. Abell T, et al. Gastric electrical stimulation for gastroparesis improves nutritional parameters at short, intermediate, and long-term follow-up, Journal of Parenteral and Enteral Nutrition, 2003; 27(5): 386-7.
2. Abell T, et al. Gastric electrical stimulation in intractable symptomatic gastroparesis, Digestion, 2002; 66(4); 204-12. (Abstract)
3. Abell T, et al. Gastroparesis and the gastric pacemaker: A revolutionary treatment for an old disease, Journal of the Mississippi State Medical Association, 2002; 43(12): 369-75. (Abstract)

4. Abell T, McCallum R, Hocking M, et al. Gastric electrical stimulation for medically refractory gastroparesis. Gastroenterology. Aug 2003;125(2):421-428.
5. Abell TL, Johnson WD, Kedar A, et al. A double-masked, randomized, placebo-controlled trial of temporary endoscopic mucosal gastric electrical stimulation for gastroparesis. Gastrointest Endosc. Sep 2011; 74(3): 496-503 e493.
6. Anand C. Al-Juburi A, Familoni B, et al. Gastric electrical stimulation is safe and effective: a long-term study in patients with drug-refractory gastroparesis in three regional centers. Digestion. 2007; 75(2-3): 83-89.
7. Andersson S, Ringstrom G, Elfvin A, et al. Temporary percutaneous gastric electrical stimulation: a novel technique tested in patients with non-established indications for gastric electrical stimulation. Digestion. 2011; 83(1-2):3-12.
8. Bertolotti M. The "electrical way" to cure gastroparesis, American Journal of Gastroenterology, 2002; 97(8): 1874-83. (Abstract)
9. Blue Cross Blue Shield Association. Gastric Electrical Stimulation. Medical Policy Reference Manual, October 2010.
10. Brody F, Vaziri K, Saddler A, et al. Gastric electrical stimulation for gastroparesis. J Am Coll Surg, October 2008; 207(4): 533-538.
11. Brody F, Zettervall SL, Richards NG, et al. Follow-up after gastric electrical stimulation for gastroparesis. J Am Coll Surg. Jan 2015; 220(1):57-63.
12. Camilleri M, Parkman HP, Shafi MA et al. Clinical guideline: management of gastroparesis. Am J Gastroenterol 2013; 108(1): 18-37; quiz 38.
13. Chu H, Lin Z, Zhong L et al. Treatment of high-frequency gastric electrical stimulation for gastroparesis. Journal of gastroenterology and hepatology 2012; 27(6):1017-26.
14. Cigaina V, Hirschbery AL. Gastric pacing for morbid obesity: plasma levels of gastrointestinal peptides and leptin. Obes Res. Dec 2003; 11(12): 1456-1462.
15. Cigaina V. Gastric pacing as therapy for morbid obesity: preliminary results. Obes Surg. Apr 2002; 12 Suppl 1:12S-16S.
16. Cowan G SM. Gastric pacemaker for weight loss. Medscape, November 16, 2000, www.medscape.com/viewarticle/414348.
17. 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.
18. 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.
19. Elfvin A, Gothberg G, Lonroth H, et al. Temporary percutaneous and permanent gastric electrical stimulation in children younger than 3 years with chronic vomiting. J Pediatr Surg. Apr 2011; 46(4):655-661.
20. 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.

21. FDA Summary of Safety and Probable Benefit: Enterra™ Therapy System. 2010; http://www.accessdata.fda.gov/cdrh_docs/pdf/H990014b.pdf. Accessed January 25, 2018.
22. Forster J, et al. Gastric pacing is a new surgical treatment for gastroparesis, American Journal of Surgery, 2001; 182(6): 676-81.
23. Forster J, Sarosiek I, et al. Further experience with gastric stimulation to treat drug refractory gastroparesis, The American Journal of Surgery 2003; 186: 690-695.
24. Harrison NS, Williams PA, Walker MR, et al. Evaluation and Treatment of Gastric Stimulator Failure in Patients with Gastroparesis. Surg Innov. Sep 20 2013; 21(3):244-249.
25. Heckert J, Sankineni A, Hughes WB et al. Gastric electric stimulation for refractory gastroparesis: A prospective analysis of 151 patients at a single center. Dig Dis Sci. 2016 Jan; 61(1):168-75.
26. Jayanthi NV, Dexter SP, Sarela AI, et al. Gastric electrical stimulation for treatment of clinically severe gastroparesis. J Minim Access Surg. Oct 2013; 9(4):163-67.
27. Lacy BE and Weiser K. Gastric motility, gastroparesis, and gastric stimulation, Surgical Clinics of North America, October 2005, Vol. 85, No. 5.
28. Lahr CJ, Griffith J, Subramony C et al. Gastric electrical stimulation for abdominal pain in patients with symptoms of gastroparesis. Am Surg 2013; 79(5): 457-64.
29. 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.
30. Lal N, Livemore S, Dunne D, et al. Gastric Electrical Stimulation with the Enterra System: A Systematic Review. Gastroenterol Res Pract. 2015; 2015:762972.
31. Levinthal DJ, Bielefeldt K. Systematic review and meta-analysis: Gastric electrical stimulation for gastroparesis. Auton Neurosci. Jan 2017; 202:45-55.
32. Lin Z, et al. Treatment of gastroparesis with electrical stimulation. Digestive Diseases and Sciences, 2003; 48(5): 837-48.
33. Lin Z, Forster J, Sarosiek I, McCallum RW. Treatment of diabetic gastroparesis by high-frequency gastric electrical stimulation. Diabetes Care 2004; 27: 1071-1076.
34. Lin Z, McElhinney C, Sarosiek I, et al. Chronic gastric electrical stimulation for gastroparesis reduces the use of prokinetic and/or antiemetic medications and the need for hospitalizations. Dig Dis Sci 2005; 50(7): 1328-34.
35. Lin Z, Sarosiek I, Forster J et al. Symptom responses, long-term outcomes and adverse events beyond 3 years of high-frequency gastric electrical stimulation for gastroparesis. Neurogastroenterol Motil 2006; 18(1):18-27.
36. Lu PL, Teich S, Do Lorenzo C, et al. Improvement of quality of life and symptoms after gastric electrical stimulation in children with functional dyspepsia. Neurogastroenterol Motil. Jul 2013; 25(7):567-e456.
37. Mason RJ, Lipham J, Eckerling G et al. Gastric electrical stimulation: an alternative surgical therapy for patients with gastroparesis. Arch Surg 2005; 140(9):841-6; discussion 847-8.

38. McCallum RW, Lin Z, Forster J et al. Gastric electrical stimulation improves outcomes of patients with gastroparesis for up to 10 years. Clin Gastroenterol Hepatol 2011; 9(4):314-19, e311.
39. McCallum RW, Sarosiek I, Parkman HP, et al. Gastric electrical stimulation with Enterra therapy improves symptoms of idiopathic gastroparesis. Neurogastroenterol Motil. Oct 2013; 25(1):815-e636.
40. 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 2010; 8(11):947-54; quiz e116.
41. National Institute for Clinical Excellence. Gastroelectrical stimulation for gastroparesis. December 2004. Available online at: www.nice.org.uk/guidance/IPG103/Guidance/pdf. Last accessed September, 2012.
42. National Institute of Health and Care Excellence. Gastroelectrical stimulation for gastroparesis [IPG489]. 2014; https://www.nice.org.uk/guidance/ipg489. Accessed December 17, 2020.
43. National Institute of Health and Care Excellence. IPG489 Gastroelectrical stimulation for gastroparesis 2014; publications.nice.org,uk/gastroelectrical-stimulation-for-gastroparesis-ipg489. Accessed January 2018.
44. Quigley E. Gastric motor disorders, Feldman, Sleisenger and Fordtran's Gastrointestinal and Liver Disease, 7th edition, Chapter 37, pp. 703-709.
45. 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.
46. Shikora SA, Bergenstal R, Bessler M et al. Implantable gastric stimulation for the treatment of clinically severe obesity: results of the SHAPE trial. Surgery for obesity and related diseases: official journal of the American Society for Bariatric Surgery 2009; 5(1):31-7.
47. Shikora SA. Implantable gastric stimulation for the treatment of severe obesity. Obes Surg 2004; 14(4):545-8.
48. Teich S, Mousa HM, Punati J et al. Efficacy of permanent gastric electrical stimulation for the treatment of gastroparesis and functional dyspepsia in children and adolescents. J Pediatr Surg 2013; 48(1): 178-83.
49. Timratana P, El-Hayek K, Shimizu H et al. Laparoscopic gastric electrical stimulation for medically refractory diabetic and idiopathic gastroparesis. J Gastrointest Surg 2013; 17(3): 461-70.
50. U.S. Food and Drug Administration. Summary of Safety and Probable Benefit: EnterraTM Therapy System. 2010; http://www.accessdata.fda.gov/cdrh_docs/pdf/H990014b.pdf. Accessed December 17, 2020.
51. Van der Voort IR, Becker JC, Dietl KH, et al. Gastric electrical stimulation results in improved metabolic control in diabetic patients suffering from gastroparesis. Exp Clin Endocrinol Diabetes. Jan 2005; 113(1): 38-42.

52. Zehetner J, Ravari F, Ayazi S et al. Minimally invasive surgical approach for the treatment of gastroparesis. Surg Endosc 2013; 27(1): 61-6.

POLICY HISTORY:

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