01-91000-04

Original Effective Date: 11/15/01

Reviewed: 04/22/21

Revised: 05/15/21

Subject: Gastric Electrical Stimulation

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

DESCRIPTION:

Gastroparesis is a chronic disorder of gastric motility characterized by delayed emptying of a solid meal. Symptoms include bloating, distension, nausea, and vomiting. Severe and chronic gastroparesis can be associated with dehydration, poor nutritional status, and poor glycemic control in those with diabetes. 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 (eg, metoclopramide, granisetron, ondansetron). Severe cases may require enteral or total parenteral nutrition.

Gastric electrical stimulation (GES), also referred to as gastric pacing, uses an implantable device. Currently available devices consist of a pulse generator, which can be programmed to provide electrical stimulation at different frequencies, and connected to intramuscular stomach leads, which are implanted during laparoscopy or open laparotomy.

POSITION STATEMENT:

Gastric electrical stimulation (gastric pacing, gastric pacemaker) **meets the definition of medical necessity** when an FDA-approved device is used for the FDA-approved indication of chronic, intractable nausea and vomiting secondary to severe gastroparesis of diabetic or idiopathic etiology, and when **BOTH** of the following are met:

- Delayed gastric emptying, documented by standard scintigraphic imaging or radiopaque marker testing, **AND**
- Refractory or intolerant to diet modification and pharmaceutical therapy (e.g, prokinetic and antiemetic medications)

Revision or removal of a previously implanted stimulator/pacer **meets the definition of medical necessity** when used to treat complications associated with gastric stimulation/pacing (e.g., bowel obstruction, gastric wall perforation, infection, lead dislodgement, lead erosion into the small intestine).

Gastric electrical stimulation is considered **experimental or investigational** for all other indications, including but not limited to the treatment of obesity, as current available clinical data is inadequate to permit scientific conclusions regarding the effectiveness of this therapy.

BILLING/CODING INFORMATION:

CPT Coding:

43647	Laparoscopy, surgical; implantation or replacement of gastric neurostimulator electrodes, antrum
43648	Laparoscopy, surgical; revision or removal of gastric neurostimulator electrodes, antrum
43881	Implantation or replacement of gastric neurostimulator electrodes, antrum, open
43882	Revision or removal of gastric neurostimulator electrodes, antrum, open
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 programming
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 programming

HCPCS Coding:

E0765	FDA-approved nerve stimulator, with replaceable batteries, for treatment of nausea and vomiting

REIMBURSEMENT INFORMATION:

Refer to section entitled **POSITION STATEMENT**.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage products: No National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) were found at the time of the last guideline reviewed date.

DEFINITIONS:

Enterra™ Therapy System

RELATED GUIDELINES:

Vagus Nerve Stimulation, 02-61000-22

OTHER:

None applicable.

REFERENCES:

1. Abell T, McCallum R, Hocking M, Koch K, Abrahamsson H, Leblanc I, Lindberg G, Konturek J, Nowak T, Quigley EM, Tougas G, Starkebaum W. Gastric electrical stimulation for medically refractory gastroparesis. Gastroenterology. 2003 Aug; 125(2): 421-8.
2. Agency for Healthcare Research and Quality. National Guideline Clearinghouse. Guideline Summary NGC-9188. The role of endoscopy in gastroduodenal obstruction and gastroparesis. July 2011.
3. Agency for Healthcare Research and Quality. National Guideline Clearinghouse. Guideline Summary NGC-7460. Type 2 diabetes. The management of type 2 diabetes. May 2009.
4. American College of Gastroenterology: Clinical Guideline. Management of gastroparesis (January 2013). Accessed at https://gi.org.
5. American Diabetes Association. Gastroparesis. Accessed at http://www.diabetes.org/ on 01/28/14.
6. American Gastroenterological Association. Medical Position Statement: Diagnosis and Treatment of Gastroparesis. Gastroenterol. 2004;127:1589-91.
7. Blue Cross Blue Shield Association Evidence Positioning System®. 7.01.73 - Gastric Electrical Stimulation, 03/21.
8. Bortolotti M. Gastric electrical stimulation for gastroparesis: A goal greatly pursued, but not yet attained. World J Gastroenterol 2011 January 21; 17(3): 273-282.
9. Bouras EP. Gastroparesis and electrical stimulation: can we afford the power bill? Neurogastroenterol Motil. 2005 Feb; 17(1): 2-3.
10. Camilleri M, et al. American College of Gastroenterology Clinical Guideline: Management of Gastroparesis. Am J Gastroenterol 2013; 108:18–37.
11. ClinicalTrials.gov. Enterra Therapy Clinical Study (Gastric Stimulation for Gastroparesis). NCT00157755. Last Updated on February 23, 2010.
12. ClinicalTrials.gov. Temporary Gastric Electrical Stimulation for Drug Refractory Gastroparesis: NCT00432835. University of Mississippi Medical Center. Last updated 11/01/12.
13. Cutts TF, Luo J, Starkebaum W, Rashed H, Abell TL. Is gastric electrical stimulation superior to standard pharmacologic therapy in improving GI symptoms, healthcare resources, and long-term health care benefits? Neurogastroenterol Motil. 2005 Feb; 17(1): 35-43.
14. ECRI, Health Technology Forecast. Gastric electrical stimulation for treatment of obesity. Plymouth Meeting, PA: ECRI, December 2007.

15. ECRI, Health Technology Forecast. Gastric electrical stimulation for treating type 2 diabetes mellitus. 12/20/11.
16. ECRI Institute Health Technology Forecast: Gastric Electrical Stimulation for Treating Type 2 Diabetes Mellitus. August 2012.
17. ECRI, Target Database, Target Report 494. Gastric stimulation for medically refractory gastroparesis. Plymouth Meeting, PA: ECRI, December 2006.
18. Enweluzo C, Aziz F. Gastroparesis: a review of current and emerging treatment options. Clinical and Experimental Gastroenterology 2013:6 161–165.
19. Farmer AD, et al. Diabetic Gastroparesis: Perspectives From a Patient and Health Care Providers. J Patient Cent Res Rev. 2019 Apr 29;6(2):148-157. doi: 10.17294/2330-0698.1689. eCollection 2019 Spring.
20. Florida Medicare Part B Local Coverage Determination L29288. Noncovered Services. 02/02/09. Retired 09/30/15).
21. Florida Medicare Part B Local Coverage Determination L5780 NCSVCS The List of Medicare Non-covered Services. Retired 02/01/09.
22. Hayes, Inc. Hayes Medical Technology Directory – Gastric Electrical Stimulation Lansdale, PA: Hayes, Inc. July 2004. Updated July 2007.
23. Hayes, Inc. Health Technology Brief. Gastric Electrical Stimulation with an Implantable Gastric Stimulator (IGS) for the Treatment of Obesity. Lansdale, PA: Hayes, Inc; July 2007
24. Jayanthi NVG, Dexter SP, Sarela AI, Team TLG. Gastric electrical stimulation for treatment of clinically severe gastroparesis. Journal of minimal access surgery, 9(4), 163.
25. Keller DS, Parkman HP, Boucek DO, Sankineni A, Meilahn JE, Gaughan JP, & Harbison S. Surgical Outcomes After Gastric Electric Stimulator Placement for Refractory Gastroparesis. Journal of Gastrointestinal Surgery, 1-7.
26. Kim BJ, Kuo B. Gastroparesis and Functional Dyspepsia: A Blurring Distinction of Pathophysiology and Treatment. J Neurogastroenterol Motil. 2019 Jan 31;25(1):27-35. doi: 10.5056/jnm18162.
27. Koch K L. Gastric Electrical Stimulation and the “Eye of the Beholder” (Editorial). CLINICAL GASTROENTEROLOGY AND HEPATOLOGY 2010;8:908–909.
28. Lahr CJ, Griffith J, Subramony C, Halley L, Adams K, Paine ER, Abell T. Gastric Electrical Stimulation for Abdominal Pain in Patients with Symptoms of Gastroparesis. The American Surgeon, 79(5), 457-464.
29. Lin Z, Forster J, Sarosiek I, McCallum RW. Treatment of diabetic gastroparesis by high-frequency gastric electrical stimulation. Diabetes Care. 2004 May; 27(5): 1071-6.
30. Lin Z, Sarosiek I, Forster J, Ross RA, Chen JD, McCallum RW. Two-channel gastric pacing in patients with diabetic gastroparesis. Neurogastroenterology & Motility, 23(10), 912-e396.
31. McCallum R, Lin Z, Wetzel P, Sarosiek I, Forster J. Clinical response to gastric electrical stimulation in patients with postsurgical gastroparesis. Clin Gastroenterol Hepatology. 2005;3: 49-54.
32. McCallum RW, Sarosiek I, Parkman HP, Snape W, Brody F, Wo J, Nowak T. Gastric electrical stimulation with Enterra therapy improves symptoms of idiopathic gastroparesis. Neurogastroenterology & Motility, 25(10), 815-e636.
33. Mintchev MP. Gastric Electrical Stimulation for the Treatment of Obesity: From Entrainment to Bezoars—A Functional Review. ISRN Gastroenterology Volume 2013, Article ID 434706.
34. Mizrahi M, Ya'acov AB, Ilan Y. Gastric stimulation for weight loss. World J Gastroenterol 2012 May 21; 18(19): 2309-2319.

35. Moga C, Harstall C. Gastric electrical stimulation (Enterra (TM) therapy system) for the treatment of gastroparesis. Edmonton: Alberta Heritage Foundation for Medical Research (AHFMR), 2006:88.

36. Myint AS, et al. Current and Emerging Therapeutic Options for Gastroparesis. Gastroenterol Hepatol (N Y). 2018 Nov;14(11):639-645.

37. National Institute for Clinical Excellence. Gastroelectrical stimulation for gastroparesis. London: National Institute for Clinical Excellence (NICE), 2004:2. Accessed at: http://www.nice.org.uk/ on 01/28/14.

38. National Institutes of Health (NIH). National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), NIH Publication No. 12–4348: Gastroparesis. June 2012. Accessed at http://www2.niddk.nih.gov/ on 01/28/13.

39. Ontario Ministry of Health and Long-Term Care. Gastric electrical stimulation: health technology policy assessment. Toronto: Medical Advisory Secretariat, Ontario Ministry of Health and Long-Term Care (MAS), 2006:77.

40. Parkman HP, Hasler WL, Fisher RS; American Gastroenterological Association. American Gastroenterological Association medical position statement: diagnosis and treatment of gastroparesis. Gastroenterology. 2004 Nov; 127(5): 1589-91. (Accessed 01/23/12).

41. Policker S, Haddad W, Yaniv I. Treatment of Type 2 Diabetes Using Meal-Triggered Gastric Electrical Stimulation. Israel Medical Association World Fellowship Conference. IMAJ Volume 11 (April 2009).

42. Sanmiguel CP, Conklin JL, Cunneen SA, Barnett P, Phillips EH, Kipnes M, et al. Gastric electrical stimulation with the TANTALUS System in obese type 2 diabetes patients: effect on weight and glycemic control. J Diabetes Sci Technol. 2009 Jul 1;3(4):964-70.

43. Shanker A, Bashashati M, Rezaie A. Gastric Electrical Stimulation for Treatment of Refractory Gastroparesis: the Current Approach to Management. Curr Gastroenterol Rep. 2021 Jan 22;23(2):2. doi: 10.1007/s11894-020-00803-0.

44. Timratana P, El-Hayek K, Shimizu H, Kroh M,Chand B. Laparoscopic Gastric Electrical Stimulation for Medically Refractory Diabetic and Idiopathic Gastroparesis. Journal of Gastrointestinal Surgery, 17(3), 461-470.

45. UpToDate. Electrical stimulation for gastroparesis. 2020. Accessed at uptodate.com.

46. Usai-Satta P, Bellini M, Morelli O, Geri F, Lai M, Bassotti G. Gastroparesis: New insights into an old disease. World J Gastroenterol. 2020 May 21;26(19):2333-2348. doi: 10.3748/wjg.v26.i19.2333.

47. U.S. Food and Drug Administration (FDA) MAUDE Adverse Event Report: MDT PUERTO RICO OPERATIONS COENTERRAINTESTINAL STIMULATOR (01/09/12). Accessed at http://www.fda.gov/.

48. U. S. Food and Drug Administration (FDA), Center for Devices and Radiologic Health. Summary of Safety and Probable Benefit, Enterra™ Therapy System (formerly named Gastric Electrical Stimulation (GES) System). Humanitarian Use Device # H990014. 03/31/00. Accessed at http://www.fda.gov/.

49. U.S. Food and Drug Administration (FDA), Center for Devices and Radiologic Health. 2016 Executive Summary for the Enterra Therapy System (HDE H990014). Summary of Safety and Probable Benefit, Enterra™ Therapy System. Accessed at http://www.fda.gov/.

50. U. S. Food and Drug Administration (FDA). FDA Dockets Management Branch re: Citizen's Petition to transfer from Humanitarian Device (HUD) to Pre-market Approval (PMA) for Enterra™ Therapy System. 02/24/04.

51. Van der Voort IR, Becker JC, Dietl KH, Konturek JW, Domschke W, Pohle T. Gastric electrical stimulation results in improved metabolic control in diabetic patients suffering from gastroparesis. *Exp Clin Endocrinol Diabetes*. 2005 Jan; 113(1): 38-42.

52. Williams PA, Nikitina Y, Kedar A, Lahr CJ, Helling TS, Abell TL. Long-Term Effects of Gastric Stimulation on Gastric Electrical Physiology. Journal of Gastrointestinal Surgery, 17(1), 50-56.

COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy & Coverage Committee on 04/22/21.

GUIDELINE UPDATE INFORMATION:

11/15/01	New Medical Coverage Guideline
12/15/02	Review of guideline; consisting of updated references and maintaining investigational status.
04/15/03	Revision to guideline; consisting of addition of E0765.
10/01/03	4th quarter HCPCS update; consisting of addition of S2213.
11/15/03	Review of guideline; maintain investigational status.
04/15/04	Review of guideline; consisting of updated references and no change to investigational status.
03/15/05	Review of guideline; consisting of updated references and no change to investigational status.
03/15/06	Review of guideline consisting of updated references.
07/01/06	HCPCS coding update consisting of the addition of 0155T, 0156T, 0157T and 0158T.
01/01/07	Annual HCPCS coding update: added 43647, 43648, 43881, 43882, 64590, 64595 and 0162T.
03/15/07	Review and revision of guideline consisting of updated references.
04/01/07	HCPCS coding update consisting of the deletion of S2213.
06/15/07	Reformatted guideline.
01/01/08	Annual HCPCS coding update: added codes 95980, 95981 and 95982.
03/15/08	Review and revision of guideline consisting of updated references.
01/01/09	Annual HCPCS coding update: deleted code 0162T.
03/15/09	Review and revision of guideline consisting of updated references.
03/15/10	Scheduled review; update in position statement for humanitarian device exemption. Update references
01/01/12	Annual HCPCS coding update. Deleted 0155T, 0156T, 0157T and 0158T.

03/15/12	Scheduled review; position statement maintained. Updated references.
03/15/13	Scheduled review. Revised description and position statement (deleted requirement that criteria for total parenteral nutrition are met). Updated references.
03/15/14	Scheduled review. Maintained position statement. Updated program exceptions section and references.
05/11/14	Revision: Program Exceptions section updated.
10/15/19	Scheduled review. Revised description. Maintained position statement. Deleted Institutional Review Board (IRB) facility requirement and added revision/replacement coverage statement. Updated references.
05/15/21	Scheduled review. Maintained position statement and updated references.