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Medical Policy

Gastric Electrical Stimulation (Gastric Pacing)

Policy Number: 1067

Policy History			
Approve Date:	10/20/2016	Effective Date:	10/20/2016
Reviewed/Revised Date:	10/20/2017, 10/20/2018, 07/15/2019, 12/07/2020, 12/20/2021		

Preauthorization	
All Plans	Benefit plans vary in coverage and some plans may not provide coverage for certain service(s) listed in this policy. Decisions for authorization are subject to all terms and conditions of the applicable benefit plan, including specific exclusions and limitations as well as applicable state and/or federal laws. Please review the benefit plan descriptions for details.

Policy

Indications of Coverage

Health Tradition considers Gastric Electrical Stimulation medically necessary for the treatment of chronic, intractable (drug-refractory) nausea and vomiting secondary to gastroparesis of diabetic or idiopathic etiology.

I. The following criteria must be met:
   A. The member is not under the age of 18 or over the age of 70 AND
   B. The member is not pregnant AND
   C. Symptomatic gastroparesis ≥ one year, as documented by an initial gastric emptying test AND
   D. Refractory or intolerant to at least two anti-emetic and prokinetic drug classes AND
   E. On stable medical therapy and, if applicable, stable nutritional support during the month prior to initiation of therapy AND
   F. Delayed gastric emptying, defined by > 60% retention at two hours and > 10% retention at four hours, as measure by standardized gastric emptying testing AND
   G. Does not have any implanted devices that are electrically or magnetically activated (e.g. cardiac pacemakers, automatic Cardioverter defibrillators, drug infusion pumps, cochlear implants) AND
   H. Does not have ferromagnetic metal objects (e.g. cerebral aneurysms clips, intraocular metallic foreign body, prosthesis, screws) AND
   I. As a humanitarian approved device, the Enterra Therapy System™ may only be used in facilities that have an Institutional Review Board (IRB) to supervise clinical testing of the device.

II. In addition the member MUST NOT have a history of any of the following:
   A. Gastric obstruction or pseudo-obstruction AND
   B. Prior gastric resection or fundoplication AND
   C. Seizures AND
   D. Primary swallowing disorders AND
   E. Eating disorders AND
   F. Chemical dependency AND
   G. Psychogenic vomiting.

III. Health Tradition considers gastric electrical stimulation experimental and/or investigational for all other indications.

Background

Gastroparesis, also referred to as gastric stasis, is a common gastrointestinal motility disorder occurring in approximately 4% of the population in the United States. It is defined by delayed gastric emptying without evidence of mechanical obstruction. Patients may experience symptoms of frequent nausea and vomiting, early satiety, bloating, postprandial fullness, and epigastric pain and burning. The most common cause of gastroparesis is diabetes. Gastroparesis may also occur in association with viral infections, anorexia nervosa or bulimia, medications that slow contractions in the intestines (anticholinergics and narcotics), gastroesophageal reflux disease, smooth muscle disorders (e.g., amyloidosis, scleroderma), nervous system diseases (e.g., Parkinson's), and metabolic disorders (e.g., hypothyroidism). Gastroparesis may also develop after vagotomy and gastric drainage operations or may be present in the absence of other disease (idiopathic gastroparesis).

Diabetes mellitus frequently results in gastrointestinal disorders, and hyperglycemia is, in itself, a physiologic cause of delayed gastric emptying; but diabetic gastroneuropathy is a common cause of gastroparesis in diabetic patients, and is associated with damage to the vagus nerve. Gastropathy may cause persistent vomiting, which contributes to poor glycemic control, and these patients may require frequent hospitalization due to hypoglycemia or hyperglycemia, electrolyte imbalance, or other complications of their disease.

Gastroparesis interferes with the normal function of the stomach, which is made to contract and empty by the coordinated electrical and physical activity of its muscles. Recent studies demonstrated that the interstitial cells of Cajal, the pacemaker cells of the gastrointestinal system, are reduced in patients with gastroparesis. Failure of the stomach to empty substantially within the normal time interval of approximately two hours leads to the chronic nausea and repeated vomiting that are the symptoms of gastroparesis. In addition to the great physical discomfort suffered by these patients, poor nutrition, and the inability to attend work, school, or social activities severely limits their lifestyles.

The Enterra® Therapy System, formerly named Gastric Electrical Stimulation (GES) System (Medtronic Inc.), is currently the only gastric pacing system approved for marketing by the Food and Drug Administration (FDA); it is approved under a Humanitarian Device Exemption (HDE). This device delivers timed electrical impulses to the gastric muscles. These electrical impulses are intended to stimulate gastric myoelectric activity, with the goal of improving stomach emptying and relieving symptoms such as nausea and vomiting.

References

1. Abell T, McCallum R, Hocking M, et al. Gastric electrical stimulation for medically refractory gastroparesis. Gastroenterology. 2003; 125(2):421-428.
2. Abell TL, Van Cutsem E, Abrahamsson H, et al. Gastric electrical stimulation in intractable symptomatic gastroparesis. Digestion. 2002; 66(4):204-212
3. Abidi N, Starkebaum WL, Abell TL. An energy algorithm improves symptoms in some patients with gastroparesis and treated with gastric electrical stimulation. Neurogastroenterol Motil. 2006; 18(4):334-338.
4. Abrahamsson H. Severe gastroparesis: new treatment alternatives. Best Pract Res Clin Gastroenterol. 2007; 21(4):645-655.
5. Al-Juburi A, Granger S, Barnes J, et al. Laparoscopy shortens length of stay in patients with gastric electrical stimulators. JSLS. 2005; 9(3):305-310.
6. Anand C, Al-Juburi A, Familoni B, and 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. Anderson S, Lonroth H, Simren M, et al. Gastric electrical stimulation for intractable vomiting in patients with chronic intestinal pseudo obstruction. Neurogastroenterol Motil. 2006; 18(9):823-830.

9. Camilleri M, Prather C. Gastric stasis. In: Feldman M, Scharschmidt BF, Sleisenger MH, eds. Sleisenger & Fordtran's Gastrointestinal and Liver Disease: Pathophysiology/Diagnosis/Management. 6th ed. Philadelphia, PA: WB Saunders Co.; 1998:577-582.
10. Centers for Medicare & Medicaid Services (CMS) [website]. Medicare Coverage Database. National Coverage Determinations (NCDs). January 3, 2008. Available at: http://www.cms.hhs.gov/mcd/index_list.asp?list_type=ncd. Accessed January 27, 2013.
11. ClinicalTrials.gov [website]. Search results for gastroparesis and gastric stimulation. 2008. Available at: http://www.clinicaltrials.gov/ct2/results?term=gastroparesis+AND+gastric+stimulation. Accessed January 27, 2013.
12. Cutts TF, Luo J, Starkebaum W, et al. Is gastric electrical stimulation superior to standard pharmacologic therapy in improving GI symptoms, healthcare resources, and long-term health care benefits? Neurogastroenterol Motil. 2005; 17(1):35-43.
13. Eagon JC, Soper NJ. Gastrointestinal pacing. Surg Clin North Am. 1993; 73(6):1161-1172.
14. Ejskjaer NT, Bradley JL, Buxton-Thomas MS, et al. Novel surgical treatment and gastric pathology in diabetic gastroparesis. Diabet Med. 1999; 16(6):488-495.
15. Food and Drug Administration (FDA) [website]. FDA Talk Paper. Janssen Pharmaceutical stops marketing cisapride in the US. March 23, 2000a. Available at: http://www.fda.gov/bbs/topics/ANSWERS/ANS01007.html. Accessed January 27, 2013.
16. Food and Drug Administration (FDA) [website]. Center for Devices and Radiological Health (CDRH). H990014 – Enterra® Therapy System (formerly named Gastric Electrical Stimulation (GES) System). Updated August 22, 2000b. Available at: http://www.fda.gov/cdrh/ode/H990014sum.html. Accessed January 27, 2013.
17. Food and Drug Administration (FDA) [website]. Center for Devices and Radiological Health (CDRH). Devices@FDA. Searched for Enterra. Updated March 6, 2008a. Available at: http://www.accessdata.fda.gov/scripts/cdrh/devicesatfda/index.cfm. Accessed January 27, 2013.
18. Food and Drug Administration (FDA) [website]. Center for Devices and Radiological Health (CDRH). Humanitarian Device Exemption. Updated February 21, 2008b. Available at: http://www.fda.gov/cdrh/devadvice/hde.html. Accessed January 27, 2013.
19. Forster J, Sarosek I, Delcore MD, et al. Gastric pacing is a new surgical treatment for gastroparesis. Am J Surg. 2001; 182(6):676-681.
20. Forster J, Sarosiek I, Lin Z, et al. Further experience with gastric stimulation to treat drug refractory gastroparesis. Am J Surg. 2003; 186(6):690-695.
21. Hasler WL. Gastroparesis: symptoms, evaluation, and treatment. Gastroenterol Clin North Am. 2007; 36(3):619-647.
22. Lin Z, Forster J, Sarosiek I, McCallum RW. Treatment of diabetic gastroparesis by high-frequency gastric electrical stimulation. Diabetes Care. 2004; 27(5):1071-1076.
23. 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):1328-1334.
24. Lin Z, Sarosiek I, Forster J, McCallum RW. 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.
25. Mason RJ, Lipham J, Eckerling G, et al. Gastric electrical stimulation: an alternative surgical therapy for patients with gastroparesis. Arch Surg. 2005; 140(9):841-848.
26. McCallum RW, Chen JD, Lin Z, et al. Gastric pacing improves emptying and symptoms in patients with gastroparesis. Gastroenterology. 1998; 114(3):456-461.
27. Medtronic Inc. [website]. Enterra® Therapy. Gastric Electrical Stimulation (GES). Important Safety Information. Updated November 13, 2007. Available at: http://www.medtronic.com/neuro/enterra/disclaimer.html. Accessed January 27, 2013.
28. Miedema BW, Sarr MG, Kelly KA. Pacing the human stomach. Surgery. 1992; 111(2):143-150.
29. National Digestive Diseases Information Clearinghouse (NDDIC) [website]. Gastroparesis. July 2007. Available at: http://digestive.niddk.nih.gov/ddiseases/pubs/gastroparesis/. Accessed January 27, 2013.
30. Quigley EM, Hasler WL, Parkman HP. AGA technical review on nausea and vomiting. Gastroenterology. 2001; 120(1):263-286.
31. Rabine JC, Barnett JL. Management of the patient with gastroparesis. J Clin Gastroenterol. 2001; 32(1):11-18.
32. Shen B, Soffer EE. Diabetic gastropathy: a practical approach to a vexing problem. Cleve Clin J Med. 2000; 67(9):659-664.