

Policy: MP134

Section: Medical Benefit Policy

Subject: Gastric Electrical Stimulation

I. Policy: Gastric Electrical Stimulation

II. Purpose/Objective:

To provide a policy of coverage regarding Gastric Electrical Stimulation

III. Responsibility:

- A. Medical Directors
- B. Medical Management

IV. Required Definitions

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

- a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;
- c. in accordance with current standards of good medical treatment practiced by the general medical community.
- d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
- e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

Medicaid Business Segment

Medical Necessity shall mean a service or benefit that is compensable under the Medical Assistance Program and if it meets any one of the following standards:

- (i) The service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.
- (ii) The service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or development effects of an illness, condition, injury or disability.
- (iii) The service or benefit will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for members of the same age.

DESCRIPTION:

Gastric electrical stimulation has been proposed for use in patients with gastroparesis who are refractory to medical treatment. This implanted device delivers high-frequency electrical stimulation at four times the basal rate to the stomach. The proposed use of this device is believed to reduce the symptoms of gastroparesis such as nausea and vomiting and is thought to improve gastric emptying.

Gastric pacing (gastric pacemaker) has been proposed for treatment in patients with morbid obesity. The implanted device utilizes low frequency, high-energy electrical stimulation to the stomach to entrain and pace the gastric slow waves to encourage satiety.

INDICATIONS: Requires Prior Authorization by a Plan Medical Director or Designee

Gastric electrical stimulation may be considered for coverage as a humanitarian device for the treatment of chronic, refractory nausea and vomiting secondary to diabetic or idiopathic gastroparesis when **all** of the following criteria are met:

- Diagnosis of diabetic or idiopathic gastroparesis
- Member has been symptomatic for at least one year
- Nausea and vomiting refractory to maximized treatment including:
 - dietary modification and
 - maximized pharmacotherapy, contraindications to, or significant side effects of pharmacotherapy
- Documented gastric emptying scan showing
 - Greater than 60% retention at 2 hours; or
 - Greater than 10% retention at 4 hours
- Documented absence of all of the following:
 - Organic or pseudo-obstruction
 - Primary eating or swallowing disorder
 - Chemical dependency
 - Current pregnancy
 - Poorly controlled psychiatric illness

EXCLUSIONS: The Plan does **NOT** provide coverage for Gastric Electrical Stimulation/ Gastric Pacing as a treatment for any other indication including but not limited to the treatment of obesity because it is considered **experimental, investigational or unproven**. The Geisinger Technology Assessment Committee evaluated this technology and concluded that there is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of this test on health outcomes when compared to established tests or technologies.

Note: A complete description of the process by which a given technology or service is evaluated and determined to be experimental, investigational or unproven is outlined in MP 15 - Experimental Investigational or Unproven Services or Treatment.

CODING ASSOCIATED WITH: Gastric Electrical Stimulation

The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services. Please note that per Medicare coverage rules, only specific CPT/HCPCS Codes may be covered for the Medicare Business Segment. Please consult the CMS website at www.cms.gov or the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements.

E0765	FDA approved nerve stimulator, with replaceable batteries, for treatment of nausea and vomiting
0155T	Laparoscopy, surgical, implantation or replacement of gastric stimulation electrodes, less curvature (i.e. morbid obesity)
0156T	Laparoscopy, surgical, revision or removal of gastric stimulation electrodes, less curvature (i.e. morbid obesity)
0157T	Laparotomy, surgical, implantation or replacement of gastric stimulation electrodes, less curvature (i.e. morbid obesity)
0158T	Laparotomy, surgical, revision or removal of gastric stimulation electrodes, less curvature (i.e. morbid obesity)
43647	Laparoscopy, surgical implantation or replacement of gastric neurostimulator electrodes, antrum

- 43648 Laparoscopy, surgical; revision or removal of gastric neurostimulator electrodes, antrum, open
- 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 system (eg, rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient measurements)
- 95981 Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient measurements)
- 95982 Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient measurements)

Current Procedural Terminology (CPT®) © American Medical Association: Chicago, IL

LINE OF BUSINESS:

Eligibility and contract specific benefits, limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For Medicare, applicable LCD's and NCD's will supersede this policy. For PA Medicaid Business segment, this policy applies as written.

REFERENCES:

Geisinger Technology Assessment Committee Triage Group. Gastric Electrical Stimulation. December 21, 2005, April 2012

Geisinger Technology Assessment Committee Triage Group. Gastric Electrical Stimulation. May 2010., March 2012

Abell T et al. Gastric Electrical Stimulation for Medically Refractory Gastroparesis. *Gastroenterol* 2003; 125:421-428.

Abell T, Lou J, Tabbaa M, Batista O, Malinowski S, Al-Juburi A. Gastric Electrical Stimulation for Gastroparesis Improves Nutritional Parameters at Short, Intermediate and Long-Term follow-up. *J Parenter Enteral Nutr.* 2003 (a) Jul-Aug; 27(4): 277-81.

Lin Z, Forster J, Sarosiek I, McCallum RW. Treatment of Diabetic Gastroparesis by High-Frequency Gastric Electrical Stimulation. *Diabetes Care* 2004 May; 27(5): 1071-1076.

Lin Z, McElhinney C, Sarosiek I, Forster J, McCallum R. Chronic Gastric Electrical Stimulation for Gastroparesis reduces the Use of Prokinetic and/or Antiemetic Medications and Need for Hospitalizations. *Dig Dis Sci* 2005 July; 50(7): 1328-1334.

Mason RJ, Lipham J, Eckerling G, Schwartz A, DeMeester TR. Gastric Electrical Stimulation: An Alternative Surgical Therapy for Patients with Gastroparesis. *Arch Surg* 2005 Sept; 140:841-848.

American Gastroenterological Association. Medical Position Statement: Diagnosis and Treatment of Gastroparesis. *Gastroenterology* 2004; 127:1589-1591.

Medtronic Inc. (website) Accessed November 2,2005 at: <http://www.medtronic.com/neuro/enterra/>

U.S. Food and Drug Administration. Center for Devices and Radiological Health. Humanitarian Use Devices. Accessed November 2, 2005 at: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfHDE/HDEInformation.cfm>

Shikora SA. The U.S. experience with Implantable Gastric Stimulation (IGS) for the Treatment of Obesity- Update on the Ongoing Clinical Trials. *Obesity Surgery* 2004; 14:S40-S48.

Winifred S. Hayes. Medical Technology Directory-Gastric Electrical Stimulation for Gastroparesis. Updates July 30, 2007

ECRI Target Database. Gastric Stimulation for Medically Refractory Gastroparesis. Dec. 2006.

ECRI, Health Technology Forecast. Gastric electrical stimulation for treatment of obesity. Plymouth Meeting, PA: ECRI, December 2007.

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):31-37.

Policker S, Lu H, Haddad W, Aviv R, Kliger A, Glasberg O, Goode P. Electrical Stimulation of the gut for the treatment of Type 2 Diabetes: The role of automatic eating detection. *J Diabetes Sci Technol* 2008;2(5):906-912.

Bohdjalian A, Ludvik B, Guerci B, et al. Improvement in glycemic control by gastric electrical stimulation (TANTALUS) in overweight subjects with type 2 diabetes. *Surg Endosc.* 2009;23(9):1955-1960.

Brody F, Vaziri K, Saddler A, Ali A, Drenon E, et al. Gastric Electrical Stimulation for Gastroparesis. *J Am Coll Surg* 2008;207:533-538.

Maranki, JL. Lytes V, Meilahn JE, Harbison S, Friedenber FK, Fisher RS, Parkman HP. Predictive Factors for clinical improvement with Enterra Gastric Electrical Stimulation treatment for refractory gastroparesis. *Dig Dis Sci* 2008;53:2072-2078.

Bohdjalian A, Prager G, Aviv R, Policker A et al. One-year experience with Tantalus™: a new surgical approach to treat morbid obesity. *Obesity Surgery* 2009b;16:627-634.

U.S. Food and Drug Administration. Center for Devices and Radiological Health. Humanitarian Use Devices. Accessed Apr 11, 2010. Available at URL address: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfHDE/HDEInformation.cfm>

National Institute for Clinical Excellence (NICE). Gastroelectrical stimulation for gastroparesis. Interventional Procedure Guidance 103. London, UK: NICE; December 15, 2004. Available at: <http://www.nice.org.uk/page.aspx?o=82715>.

Parkman HP, Hasler WL, Fisher RS. American Gastroenterological Association medical position statement: Diagnosis and treatment of gastroparesis. *Gastroenterol.* 2004;127(5):1589-1591.

ECRI Institute Target Report(online) Gastric Electrical Stimulation for Medically Refractory Gastroparesis. Current as of 10/07/03.

ECRI Institute Health Technology Forecast (online) Gastric Electrical Stimulation for the treatment of obesity. Current as of 12/04/07.

Hayes Directory (online) Gastric Electrical Stimulation for Gastroparesis. Lansdale, PA: 04/11/09.

Abell TL, Van Cutsem E, et al. Gastric electrical stimulation in intractable symptomatic gastroparesis. *Digestion* 2002;66(4):204-12.

Abell T Mccallum R, et al. Gastric electrical stimulation for medically refractory gastroparesis. *Gastroenterology* 2003 Aug;125(2):421-8.

Forster J, Sarosiek I, et al. *Am J Surg* 2001 Dec;182(6):676-81

McCallum R, Snape W, et al, Gastric Electrical Stimulation With Enterra Therapy Improves Symptoms From Diabetic Gastroparesis in a Prospective Study *Clinical Gastroenterology and Hepatology* 2010November; 8(11)947-954.

McKenna D, Beverstein G, Reichelderfer M, et al. Gastric electrical stimulation is an effective and safe treatment for medically refractory gastroparesis. *Surgery.* 2008;144(4):566-572; discussion 572-574.

Soffer E, Abell T, et al. Review article: gastric electrical stimulation for gastroparesis--physiological foundations, technical aspects and clinical implications. *Aliment Pharmacol Ther.* 2009 Oct;30(7):681-94.

Gourcerol G, Leblanc I, et al. Gastric electrical stimulation in medically refractory nausea and vomiting. Eur J Gastroenterol Hepatol. 2007 Jan;19(1):29-35

Mason RJ, Lipham J, Eckerling G, Schwartz A, DeMEester TR, Gastric Electrical Stimulation An Alternative Surgical Therapy for Patients With Gastroparesis Arch Surg. 2005;140:841-848

Chu H, Lin Z, Likun Z, McCallum RW, Hou Z, A meta-analysis: The Treatment of High-Frequency Gastric Electrical Stimulation for Gastroparesis. J Gastroenterol Hepatol. 2011 Dec 1

UpToDate. Electrical Stimulation for Gastroparesis. William L. Hasler, M.D., Topic last updated March 6, 2014.

National Institute for Clinical Excellence (NICE). Interventional Procedures Guidance (IPG489), Published May 2014. Gastroelectrical Stimulation for Gastroparesis <https://www.nice.org.uk/guidance/IPG489>

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;61(1):168-175

Levinthal DJ, Bielefeldt K. Systemic review and meta-analysis: gastric electrical stimulation for gastroparesis. Auton Neurosci Jan 2017;202:45-55.

Zoll B, et al. Outcomes of surgical intervention for refractory gastroparesis: a systematic review. J Surg Res 2018 Nov;231:263-269.

Shada A, et al. Wisconsin's Enterra therapy experience: a multi-institutional review of gastric electrical stimulation for medically refractory gastroparesis. Surgery 2018 Oct;164(4):760-765.

This policy will be revised as necessary and reviewed no less than annually.

Devised: 12/2005

Revised: 05/10 (TACt Refs); 6/12, 6/13 (added obesity exclusion)

Reviewed: 12/07, 12/08, 6/14, 6/15, 6/16, 5/17, 5/18, 5/19, 5/20

Geisinger Health Plan may refer collectively to health care coverage sponsors Geisinger Health Plan, Geisinger Quality Options, Inc., and Geisinger Indemnity Insurance Company, unless otherwise noted. Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.