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)

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 supercede 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


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.


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.


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.


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


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