

Corporate Medical Policy

Gastric Electrical Stimulation

File Name:	gastric_electrical_stimulation
Origination:	9/2003
Last CAP Review:	5/2019
Next CAP Review:	5/2020
Last Review:	5/2019

Description of Procedure or Service

Gastric electrical stimulation (GES), also referred to as gastric pacing 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.

Gastroparesis is a chronic disorder of gastric motility characterized by delayed emptying of a solid meal. Symptoms include bloating, distension, nausea, and vomiting. When severe and chronic, gastroparesis can be associated with dehydration, poor nutritional status, and poor glycemic control in diabetics. While most commonly associated with diabetes, gastroparesis is also found in chronic pseudo-obstruction, connective tissue disorders, Parkinson's 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 such as metoclopramide, and antiemetic agents such as metoclopramide, granisetron, or ondansetron. Severe cases may require enteral or total parenteral nutrition.

Gastric electrical stimulation has been investigated as a treatment of obesity as a technique 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.

Regulatory Status

In 2000, the Gastric Electrical Stimulator (GES) system (now called Enterra™ Therapy System; Medtronic) was approved by the U.S. Food and Drug Administration (FDA) through a humanitarian device exemption process (HDE Approval H990014) for the treatment of gastroparesis. The GES system consists of 4 components: the implanted pulse generator, 2 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.

Currently, no GES devices has been approved by FDA for the treatment of obesity. The Transcend® (Transneuronix; acquired by Medtronic in 2005), an implantable gastric stimulation device, is available in Europe for treatment of obesity.

Related Policy

Vagus Nerve Stimulation

Gastric Electrical Stimulation

*****Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

Policy

Gastric Electrical Stimulation is considered investigational for all applications. BCBSNC does not cover investigational services or procedures.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Gastric Electrical Stimulation is covered

Not applicable.

When Gastric Electrical Stimulation is not covered

Gastric Electrical Stimulation (GES) is considered investigational for the treatment of:

- gastroparesis of diabetic, idiopathic, or post-surgical etiology; or
- obesity

Policy Guidelines

The evidence for the use of gastric electrical stimulation (GES) for treatment of patients with gastroparesis includes RCTs, nonrandomized studies, and systematic review. 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 the effects of the technology on health outcomes.

The evidence for the use of GES for treatment of obesity includes 1 published randomized study (SHAPE trial). Relevant outcomes are change in disease status and treatment-related morbidity. This trial did not show significant improvement in weight loss with GES compared with sham stimulation. The evidence is insufficient to determine the effects of the technology on health outcomes.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable service codes: 43647, 43648, 43659, 43881, 43882, 64590, 64595, 95980, 95981, 95982, 43999

ICD-10 diagnosis codes: E10.40, E10.43, E10.49, E10.65, E11.40, E11.43, E11.49, E11.65, E13.43, E13.49, E66.01, E66.2, E66.3, E66.9, K31.84, K31.89

Gastric Electrical Stimulation

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

- BCBSA Medical Policy Reference Manual, 3:2002, 7.01.73
- BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.73, 12/17/2003.
- ECRI. (2002) Gastric electrical Stimulation (GES) for gastroparesis. TARGET database. Retrieved on 5/ 25/2004 from http://www.target.ecri.org/summary/detail.aspx?doc_id=483&q=Gastric+electrical+stimulation.
- Medical Policy Advisory Group - 6/2004
- BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.73, 11/9/2004
- BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.73, 9/27/2005
- Specialty Matched Consultant Advisory Panel - 4/2006
- BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.73, 2/15/2008
- Specialty Matched Consultant Advisory Panel - 4/2008
- Masaoka T, Tack J. Gastroparesis: current concepts and management. Gut Liver 2009 Sep;3(3): 166-73. Epub 2009 Sep 30.
- BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.73, 6/11/2009
- BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.73, 10/4/11
- Specialty Matched Consultant Advisory Panel - 4/18/12
- BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.73, 10/11/12
- Specialty Matched Consultant Advisory Panel - 4/2013
- BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.73, 8/8/13
- Specialty Matched Consultant Advisory Panel - 4/2014
- BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.73, 8/14/14
- Specialty Matched Consultant Advisory Panel – 5/2015
- Medical Director review 5/2015
- BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.73, 12/2015
- Specialty Matched Consultant Advisory Panel – 5/2016
- Medical Director review 5/2016
- BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.73, 2/1017
- Medical Director review 2/2017
- Specialty Matched Consultant Advisory Panel – 5/2017
- Medical Director review 5/2017
- BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.73, 2/1018
- Specialty Matched Consultant Advisory Panel – 5/2018
- Medical Director review 5/2018

Gastric Electrical Stimulation

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.73, 3/2019

Specialty Matched Consultant Advisory Panel – 5/2019

Medical Director review 5/2019

Policy Implementation/Update Information

- 9/03 Original policy issued. Code S2213 effective 10/1/2003.
- 6/10/04 Medical Policy Advisory Group review. No changes to criteria. References added. Notification given 6/10/2004. Effective date 8/12/2004.
- 10/8/05 Updated "Description of Procedure or Service" to include the name brand "Enterra™" and information related to the use of gastric electrical stimulation for the treatment of obesity. Added "for the treatment of gastroparesis of diabetic or idiopathic etiology or obesity" under "When not covered". Rationale added to "Policy Guidelines". References added.
- 5/22/06 Specialty Matched Consultant Advisory Panel review 4/20/2006. No changes to criteria. References added.
- 7/10/06 Added new 2006 CPT codes 0155T, 0156T, 0157T, and 0158T. (btw)
- 1/3/07 Added new 2007 CPT codes: 43647, 43648, 43881, 43882, 64590, 64595, and 0162T to "Billing/ Coding" section.
- 4/9/07 Removed deleted HCPCS code S2213 from "Billing/Coding" section.
- 12/31/07 Added 2008 CPT codes; "95980, 95981, and 95982" to the "Billing/Coding" section.
- 6/16/08 Specialty Matched Consultant Advisory Panel review 4/30/08. No change to policy statement. Reformatted the "When Not Covered" section, no change in content. References added.
- 1/5/09 Removed deleted CPT code 0162T from the "Billing/Coding" section. (btw)
- 6/22/10 Policy Number(s) removed (amw)
- 10/26/10 Description section revised. Specific diagnoses added to Billing/Coding section. Policy Guidelines and References updated. No change to policy statement or criteria. (adn)
- 5/10/11 Specialty Matched Consultant Advisory Panel review 4/27/11. No changes to policy statement or criteria. (adn)
- 1/1/12 CPT code 43659 added to Billing/Coding section. Deleted codes 0155T, 0156T, 0157T and 0158T. (adn)
- 2/21/12 Description section revised. No change to policy statement or criteria. Reference added. (sk)
- 5/1/12 Code 43999 added. Policy Guidelines section revised. Specialty Matched Consultant Advisory Panel review 4/18/12. No change to policy statement or criteria. (sk)
- 11/27/12 Reference added. "Post-surgical" added to investigational statement on gastroparesis. Policy Guidelines updated. Medical director review. (sk)

Gastric Electrical Stimulation

- 4/30/13 Specialty Matched Consultant Advisory Panel review 4/17/13. No change to policy statement or criteria. (sk)
- 7/1/13 ICD-10 diagnosis codes added to Billing/Coding section. (sk)
- 10/15/13 Reference added. ICD-10 diagnosis codes E13.43 and E13.49 added to Billing/Coding section. No change to policy statement or guidelines. (sk)
- 5/13/14 Specialty Matched Consultant Advisory Panel review 4/29/14. Related policy added. Summary statement updated. No change to policy statement. (sk)
- 8/14/14 Policy Guideline section updated. Reference updated. Medical Director review. (td)
- 7/1/15 Specialty Matched Consultant Advisory Panel review 5/27/2015. Medical Director review 5/2015. Policy Statements remain unchanged. (td)
- 2/29/16 Description section revised. Policy Guidelines section updated. References updated. (td)
- 7/1/16 Specialty Matched Consultant Advisory Panel review 5/25/2016. Medical Director review 5/2016. No change to policy statement or guidelines. (jd)
- 3/31/17 Minor revision to Description section and Policy Guidelines. References updated. Medical Director review 2/2017. (jd)
- 6/30/17 Specialty Matched Consultant Advisory Panel – 5/2017. Medical Director review 5/2017. (jd)
- 6/8/18 Specialty Matched Consultant Advisory Panel 5/2018. Medical Director review 5/2018. (jd)
- 5/28/19 References updated. Specialty Matched Consultant Advisory Panel 5/2019. Medical Director review 5/2019. (jd)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.