

Corporate Medical Policy

Gastric Electrical Stimulation

File Name:	gastric_electrical_stimulation
Origination:	9/2003
Last CAP Review:	4/2012
Next CAP Review:	4/2013
Last Review:	4/2012

Description of Procedure or Service

Gastric electrical stimulation (GES) is performed using an implantable device designed to treat chronic drug-refractory nausea and vomiting secondary to gastroparesis of diabetic or idiopathic etiology. The device may be referred to as a gastric pacemaker.

Currently, only one gastric electrical stimulator has received approval from the U.S. Food and Drug Administration (FDA) (see note below), the Gastric Electrical Stimulator (GES) system (now called Enterra™ Therapy System), manufactured by Medtronic. 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 neurological 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 sec alternating with an “off” time of 5.0 sec.

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. 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 (GES) has also 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. There are no gastric electrical stimulation devices approved by the FDA for the treatment of obesity. However, the Transcend implantable gastric stimulation device, manufactured by Transneuronix Corporation, is currently available in Europe for treatment of obesity. Transneuronix is currently funding clinical trials in the United States, and the company hopes to obtain FDA approval in a couple of years for use of the Transcend device to promote weight loss in the management of obesity

Note: the GES system received FDA approval through a “humanitarian device exemption.” This regulatory category was established in 1996 and only applies to devices intended to benefit fewer than 4,000 patients. The approval process is similar to that of a premarket approval application (PMA) but is exempt from the effectiveness requirements of a PMA. Thus the application is not required to provide results of scientifically valid clinical investigations, but must contain sufficient information for the FDA to determine that the device does not pose unreasonable or significant risk of illness or injury. A humanitarian use device may only be used in facilities that have an Institutional Review Board (IRB) to

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supervise clinical testing of the device.

*****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 or idiopathic etiology; or
- obesity

Policy Guidelines

The evidence on the efficacy of gastric electrical stimulation is inadequate to permit scientific conclusions. The single published randomized study on treatment of gastroparesis included only 33 patients recruited from 11 centers in the United States. There was no statistically significant improvement in symptoms for the entire study group compared to placebo, but positive results were reported for the subgroup of 17 patients with diabetic gastroparesis. The case series report improvements in symptoms, nutritional parameters, and quality of life. However, the lack of control group precludes the conclusion that these changes are due to treatment with gastric electrical stimulation, given the variable natural history of gastroparesis, and the expected placebo effect.

Several small trials of a temporary gastric stimulator have been published in attempts to select patients for permanent device implantation. The results of these trials are mixed, with some short-term improvements in symptoms noted, but this evidence is not sufficient to determine that patients selected for permanent device implantation as a result of a temporary trial have improved outcomes compared to alternative treatments.

There are no randomized controlled trials (RCTs) on GES for the treatment of obesity. Small clinical trials have reported positive outcomes in weight loss and maintenance of weight loss along with minimal complications. However, further study is needed, as the currently available data are insufficient to permit scientific conclusions.

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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

Diagnoses that are subject to medical necessity review: 250.6x, 278, 278.0, 278.00, 278.01, 278.02, 278.03, 536.3

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

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.

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- 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)

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.