

Corporate Medical Policy

Gastric Electrical Stimulation

File Name: gastric_electrical_stimulation
Origination: 9/2003
Last CAP Review: 5/2020
Next CAP Review: 5/2021
Last Review: 7/2020

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. The device may be referred to as a gastric pacemaker.

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

*****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

BCBSNC will provide coverage for gastric electrical stimulation when it is determined to be medically necessary because the medical criteria and guidelines noted below are met.

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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

Gastric Electrical Stimulation (gastric pacemaker) may be considered medically necessary in individuals for the treatment of chronic, intractable nausea and vomiting secondary to gastroparesis of diabetic, idiopathic, or post-surgical etiology.

When Gastric Electrical Stimulation is not covered

Gastric Electrical Stimulation (GES) is considered investigational for all other uses, including, but not limited to the treatment of obesity

Policy Guidelines

The evidence for the use of gastric electrical stimulation (GES) for treatment in individuals with gastroparesis, include two randomized controlled crossover studies. A double-blind crossover study was conducted in 33 individuals with chronic gastroparesis, 17 with diabetic and 16 with idiopathic etiologies. After implantation, stimulation was programmed to ON or OFF for a 1-month period, with the device turned OFF, in random order. After this initial phase of the studies, all individuals received active or ON stimulation and then evaluated at 6 and 12 months. The benefit in treatment, vomiting frequency, in "ON versus OFF" primarily in individuals with diabetes, decreased significantly at 6 and 12 months. Symptom severity and quality of life scores significantly improved yet gastric emptying was moderately accelerated. After an initial six weeks unblinded on treatment phase, the second controlled study did not show a difference between ON and OFF treatment periods. During the ON period, median overall frequency of vomiting was 6.8 episodes compared to 13.5 episodes when the device was programmed OFF. However, after these treatment periods, all patients had their stimulators turned to ON and improvements were noted after 12 months, with vomiting frequency significantly lower than baseline, $p < 0.05$.

A 2018 published retrospective, multicenter analysis evaluated use of GES in individuals with severe, multicenter refractory gastroparesis. There were 14 total participants (11 diabetic, 1 idiopathic, and 2 postoperative) treated between 2007 and 2015 with a mean follow-up of 3 years. Significant relief of gastroparesis symptoms was identified in 8 (57.1%) of the participants, while 3 (21.4%) experienced partial relief. Post-GES implantation showed a median weight gain of 5.1kg in 11 (78.65) participants; additionally, 5 out 10 participants (50%) upon the last follow-up were not using medication for gastroparesis treatment.

A prospective study published in 2018, evaluated individuals who underwent implantation between 2005 and 2016 secondary to medically refractory gastroparesis. There were 119 participants (64 diabetic, 55 idiopathic) included in the analysis with a mean follow-up of 39.0 ± 32.0 months. Prior to GES placement, 22% of diabetic and 17% of idiopathic participants were found to have had feeding tubes surgically placed, however, 67% of these feeding tubes were removed following GES placement. After a mean time of 36 ± 29 months, eight participants had their GES devices removed due to a perceived lack of benefit. GCSI scores were significantly improved at ≥ 2 years for both diabetic ($p=0.01$) and idiopathic ($p=0.003$) subgroups post-implantation.

Several uncontrolled studies evaluate the use of GES for gastroparesis in longer-term outcomes in a relatively large group of individuals. A 10-year follow up of 221 participants with refractory

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gastroparesis were treated with GES, specifically the Enterra device. Data at 1 year or longer in follow up were available for 85% of the participants or 188 of 221 enrolled. These individuals were followed for a mean of 56 months (range 12 to 131 months). The total symptom score (TSS) at follow-up was reported to have decreased by $53\% \pm 32\%$ ($p < 0.001$). There were 7 individual gastroparesis symptoms measured on the TSS, and all 7 measures were significantly reduced ($p < 0.0001$). There were 119 subjects with gastric emptying data which showed a 26% normalization in their results after GES treatment ($p < 0.05$). Additionally, after 1 year of GES, the use of gastroparesis medications in all subject groups was reduced (74% at baseline vs. 56% for prokinetics, $p = 0.05$; and 65% at baseline vs. 58% for antiemetics, $p = 0.025$).

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

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

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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

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

Specialty Matched Consultant Advisory Panel – 5/2019

Medical Director review 5/2019

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.73, 3/2020

Specialty Matched Consultant Advisory Panel – 5/2020

Medical Director review 5/2020

Abell T, McCallum R, Hocking M, et al. Gastric electrical stimulation for medically refractory gastroparesis. *Gastroenterology*. Aug 2003;125(2):421-428.

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

Laine M, Siren J, Koskenpato J, et al. Outcomes of High-Frequency Gastric Electric Stimulation for the Treatment of Severe, Medically Refractory Gastroparesis in Finland. *Scand J Surg*. June 2018; 107(2):124-129.

Shada A, Nielsen A, Marowski S, et al. Wisconsin's Enterra Therapy Experience: A multi-institutional review of gastric electrical stimulation for medically refractory gastroparesis. *Surgery*. Oct 2018;164(4):760-765.

Policy Implementation/Update Information

9/03 Original policy issued. Code S2213 effective 10/1/2003.

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- 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)
- 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)

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- 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)
- 3/24/20 Description section and references updated. No change to policy intent. Medical Director review 2/2020. (jd)
- 6/9/20 Specialty Matched Consultant Advisory Panel 5/2020. Medical Director review 5/2020. (jd)
- 8/11/20 Policy statement revised as follows: “BCBSNC will provide coverage for gastric electrical stimulation when it is determined to be considered medically necessary because the medical criteria and guidelines noted below are met.” When Covered section revised as follows: “Gastric Electrical Stimulation (gastric pacemaker) may be considered medically necessary in individuals for the treatment of chronic, intractable nausea and vomiting secondary to gastroparesis of diabetic, idiopathic, or post-surgical etiology.” When Not Covered section revised. Policy guidelines revised to support policy statement. References updated. Medical Director review 7/2020. (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.