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MEDICAL POLICY – 7.01.522

Gastric Electrical Stimulation

BCBSA Ref. Policy:	7.01.73	
Effective Date:	May 1, 2025	RELATED MEDICAL POLICIES:
Last Revised:	Jan. 1, 2026	1.01.507 Electrical Stimulation Devices
Replaces:	7.01.73	7.01.593 Vagus Nerve Stimulation

Select a hyperlink below to be directed to that section.

∞ Clicking this icon returns you to the hyperlinks menu above.

Introduction

Gastroparesis is a condition in which the normal movement of food from the stomach to the small intestine is drastically slowed or has stopped. This can lead to nausea and vomiting. Gastric electrical stimulation (GES) is a treatment that sends weak electrical signals to the nerves and smooth muscles in the lower stomach. This treatment helps decrease nausea and vomiting caused by gastroparesis. A small battery-powered device is surgically placed in the skin in the lower belly area. Wires are then placed in the area to be stimulated. This policy discusses when GES may be considered medically necessary. It has also been proposed as a treatment for obesity. The one published medical study that looked at using GES for obesity did not show it improved weight loss. GES for the treatment of obesity is considered investigational (unproven) because more medical studies are needed.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

Service	Medical Necessity
Gastric electrical stimulation (GES)	**Gastric electrical stimulation may be considered medically necessary in the treatment of chronic, intractable nausea and vomiting secondary to gastroparesis of diabetic or idiopathic etiology when ALL of the following criteria are met:** • Significantly delayed gastric emptying as documented by standard scintigraphic imaging (gastric emptying scan) of solid food **AND** • The individual is refractory or intolerant of prokinetic (antireflux) medications and antiemetic medications **AND** • The individual's nutritional status is sufficiently low so that total parenteral nutrition is likely to become medically necessary
Service	**Investigational**
GES for obesity and other indications	**Gastric electrical stimulation is investigational for the treatment of obesity and all other indications.**

Documentation Requirements
The medical records submitted for review should document that medical necessity criteria are met. The record should include clinical documentation of ALL of the following: • The individual has chronic, intractable nausea and vomiting secondary to gastroparesis (inability to empty food) caused by diabetes or for an unknown reason • Significantly delayed gastric emptying confirmed by standard scintigraphic imaging (gastric emptying scan) of solid food • The individual has not responded or is intolerant to the use of prokinetic (antireflux) and antiemetic (antinausea and vomiting) medications • The need for parenteral nutrition is likely to become medically necessary because of member's inadequate nutritional status

Note: Vagus nerve stimulation is addressed in separate clinical criteria. Please refer to **Related Medical Policies**.

Coding

Code	Description
CPT	
43647	Laparoscopy, surgical; implantation or replacement of gastric neurostimulator electrodes, antrum
43648	Laparoscopy, surgical; revision or removal of gastric neurostimulator electrodes, antrum
43881	Implantation or replacement of gastric neurostimulator electrodes, antrum, open
43882	Revision or removal of gastric neurostimulator electrodes, antrum, open
HCPCS	
C1607	Neurostimulator, integrated (implantable), rechargeable with all implantable and external components including charging system (new code effective 01/01/26)
C1767	Generator, neurostimulator (implantable), nonrechargeable
C1778	Lead, neurostimulator (implantable)
L8679	Implantable neurostimulator, pulse generator, any type
L8680	Implantable neurostimulator electrode, each
L8685	Implantable neurostimulator pulse generator, single array, rechargeable, includes extension
L8686	Implantable neurostimulator pulse generator, single array, nonrechargeable, includes extension
L8687	Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension
L8688	Implantable neurostimulator pulse generator, dual array, nonrechargeable, includes extension

Related Information

N/A

Evidence Review

Description

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

Background

Gastroparesis

Gastroparesis is a chronic disorder of gastric motility characterized by delayed emptying of a solid meal from the stomach. 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 diabetic individuals. While most commonly associated with diabetes, gastroparesis is also found in chronic pseudo-obstruction, connective tissue disorders, Parkinson disease, and psychological pathologic conditions. Some cases may not be associated with an identifiable cause and are referred to as idiopathic gastroparesis. Gastric electrical stimulation (GES), also referred to as gastric pacing, using an implantable device, has been investigated primarily as a treatment for gastroparesis. Currently available devices consist of a pulse generator, which can be programmed to provide electrical stimulation at different frequencies, connected to intramuscular stomach leads, which are implanted during laparoscopy or open laparotomy. (see **Regulatory Status** section).

Obesity

GES has also been investigated as a treatment of obesity. It is used to increase the feeling of satiety with subsequent reduction in food intake and weight loss. The exact mechanisms resulting in changes in eating behavior are uncertain but may be related to neurohormonal modulation and/or stomach muscle stimulation.

Summary of Evidence

For individuals who have gastroparesis who receive gastric electrical stimulation (GES), the evidence includes randomized controlled trials (RCTs), nonrandomized studies, and systematic reviews. The relevant outcomes are symptoms and treatment-related morbidity. Several crossover RCTs have been published. A 2017 meta-analysis of five RCTs did not find a significant benefit of GES on the severity of symptoms associated with gastroparesis. Individuals generally reported improved symptoms at follow-up whether or not the device was turned on, suggesting a placebo effect. A 2022 meta-analysis did find some improvements, but interpretation of its findings are limited by inconsistent benefits across different outcomes and timepoints, high heterogeneity (I^2=70%), and inclusion of study populations not representative of the intended population. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

A Hayes Medical Technology Directory report analyzed the evidence (n=10 studies) for GES for the treatment of gastroparesis. The report evaluated controlled studies (n=7studies/18-241 individuals) and uncontrolled studies (n=3 studies/131-233 individuals). The controlled trials included RCTs (n=3 studies), prospective (n=2), and retrospective studies (n=2). Individuals were selected who had symptomatic gastroparesis refractory to medical treatment with diagnoses of diabetic gastric neuropathy or idiopathic gastroparesis. Exclusion criteria included the structural cause of symptoms, psychogenic vomiting, chemical dependency, previous gastric surgery, and pregnancy. Outcomes measured were gastroparesis symptom severity and gastric retention assessed by scintigraphy. Additional outcomes included the need for nutritional support, and changes in antiemetic and/or prokinetic medications. Follow-up timeframe varied among studies, the longest follow-up being four years. The report found poor to fair quality evidence indicating that GES may improve gastroparesis symptoms and gastric emptying as well as decrease the need for nutritional support in some individuals with refractory gastroparesis. Overall, GES was found to be safe with the device removal rate ranging from 7%-12% in most studies, primarily due to lack of symptom improvement. It was noted that despite the low quality of the supportive evidence, GES may be an option for individuals with debilitating gastroparesis that is refractory to medical treatment (Hayes, 2016 update).

Overall, the evidence for gastric electrical stimulation is not very strong. However, this policy requires that the individual has tried and failed other treatments and that their nutritional status is so depleted that total parenteral nutrition (TPN) may soon become medically necessary. TPN is invasive and not without its own risks. Therefore, even though the evidence for gastric electrical stimulation is not strong, and the Enterra Therapy System had only been approved by

the FDA under a Humanitarian Device Exemption (HDE), GES may be helpful and allow the individual to avoid the risks associated with receiving ongoing TPN.

For individuals who have obesity who receive GES, the evidence includes an RCT and several small case series and uncontrolled prospective trials. Relevant outcomes are change in disease status and treatment-related morbidity. The Screened Health Assessment and Pacer Evaluation (SHAPE) trial did not show significant improvement in weight loss using GES compared with a sham stimulation. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Ongoing and Unpublished Clinical Trials

Some currently ongoing trials that might influence this review are listed in **Table 1**.

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT03123809	Combined Gastric Electrical Stimulation (GES) and Pyloroplasty for the Treatment of Gastroparesis: Can Pyloroplasty be Effective Without GES?	50	Sep 2024
NCT05980455[a]	Randomized Study of Enterra Programming with Nocturnal Cycling in Gastroparetics	50	Dec 2025

NCT: national clinical trial.

[a] Denotes industry-sponsored or cosponsored trial.

Clinical Input Received from Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

2015 Input

Clinical input was sought to help determine whether the use of gastric electrical stimulation (GES) for individuals with gastroparesis would provide a clinically meaningful improvement in net health outcome and whether the use is consistent with generally accepted medical practice. In response to requests, input was received from one specialty society (two reviewers) and four academic centers while this policy was under review in 2015. For individuals who have gastroparesis who receive GES, clinical input does not support a clinically meaningful improvement in net health outcome and does not indicate this use is consistent with generally accepted medical practice. Most respondents agreed that GES should be considered investigational for gastroparesis. There was a lack of consensus whether GES should be considered medically necessary for any specific indication (e.g., diabetic gastroparesis, idiopathic gastroparesis, gastroparesis of postsurgical etiology). The reviewers were not asked about GES for treatment of obesity.

2009 Input

Clinical input was sought to help determine whether the use of GES for individuals with gastroparesis or obesity would provide a clinically meaningful improvement in net health outcome and whether the use is consistent with generally accepted medical practice. In response to requests, input was received from 4 academic medical centers (5 reviewers) while this policy was under review in 2009. For individuals who have gastroparesis or obesity who receive GES, clinical input does not support a clinically meaningful improvement in net health outcome and does not indicate this use is consistent with generally accepted medical practice. There was strong agreement among reviewers about the limited data for the use of GES to treat diabetic and idiopathic gastroparesis and about the need for randomized controlled trials (RCTs). There was strong agreement that GES is investigational for the treatment of obesity.

Practice Guidelines and Position Statements

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the policy conclusions.

Guidelines or position statements will be considered for inclusion if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are

informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American College of Gastroenterology

In 2022, the American College of Gastroenterology updated practice guidelines on the management of gastroparesis.[20] The College recommended that:

> "Gastric electric stimulation (GES) may be considered for control of GP [gastroparesis] symptoms as a humanitarian use device (HUD) (conditional recommendation, low quality of evidence)."

National Institute for Health and Care Excellence

In 2014, the National Institute for Health and Care Excellence issued guidance on gastroelectrical stimulation for gastroparesis.[21] The Institute made the following recommendations:

1. "Current evidence on the efficacy and safety of gastric electrical stimulation for gastroparesis is adequate to support the use of this procedure with normal arrangements for clinical governance, consent, and audit.
2. … clinicians should inform patients considering gastric electrical stimulation for gastroparesis that some patients do not get any benefit from it. They should also give patients detailed written information about the risk of complications, which can be serious, including the need to remove the device.
3. Patient selection and follow-up should be done in specialist gastroenterology units with expertise in gastrointestinal motility disorders, and the procedure should only be performed by surgeons working in these units."

Medicare National Coverage

There is no national coverage determination.

Regulatory Status

In 2000, the Gastric Electrical Stimulator system (now called Enterra Therapy System; Medtronic) was approved by the US Food and Drug Administration (FDA) through the humanitarian device exemption process (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 seconds alternating with an "off" time of 5.0 seconds. The Enterra II system features a no magnetic activation switch which reduces electromagnetic interference.

Currently, no GES devices have been approved by the 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.

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History

Date	Comments
01/18/01	Add to Surgery Section - New Policy
03/11/03	Replace Policy - 2002 updates added; policy statement unchanged.
05/11/04	Replace Policy - Policy revised; no change in policy statement; new HCPC code added.
06/08/04	Replace Policy - Policy replaces BC.7.01.73 due to policy statement being changed from investigational to medically necessary.
09/01/04	Replace Policy - Policy renumbered from PR.7.01.122. No changes to dates.

Date	Comments
01/11/05	Replace Policy - BCBSA update, scheduled review date changed. Policy statement adds obesity as investigational.
06/16/05	Device name change added - Reference to Enterra added to Gastric Electrical Stimulation System for clarification purposes only. MPC approval not needed.
01/10/06	Replace Policy - Policy reviewed with literature search; codes updated; policy statement unchanged.
02/06/06	Codes updated - No other changes.
06/06/09	Disclaimer and Scope update - No other changes.
09/18/06	Codes Updated - No other changes.
01/09/06	Replace Policy - Policy updated with literature review. No change in policy statement. Codes updated.
02/26/07	Codes Updated - No other changes.
04/02/07	Codes Updated - No other changes.
01/08/08	Replace Policy - Policy updated with literature review; no change to the policy statement.
01/13/09	Code Updates - Code S2213 deleted
09/15/09	Replace Policy - Policy updated with literature review; no change to the policy statement. References added.
02/09/10	Code Update - New 2010 codes added.
11/09/10	Replace Policy - Policy updated with literature review; no change to the policy statement. Reference added.
09/15/11	Replace Policy – Policy updated with literature review; no change in policy statement.
08/20/12	Replace Policy. Policy updated with literature review, references 21 and 22 added; no change in policy statement.
10/09/12	Update Related Policies – Add 8.03.01.
02/04/13	Code update. HCPCS code E0765 added to the policy.
02/12/13	Update Related Policies, add 1.01.507.
10/14/13	Replace policy. Policy updated with extensive literature revision. No change in policy statement. CPT codes 0155T, 0156T, 0157T and 0158T removed from policy; they were deleted effective 1/2012.
12/03/13	Coding Update. Add ICD-10 codes.
11/20/14	Annual Review. Policy updated with literature review. Policy statement remains unchanged. References 23, 26 and 27 added. All CPT codes removed except 43647, 43648, 43881 & 43882.

Date	Comments
02/25/15	Interim Update. Adding FDA Approved device. Related policy 7.01.20 added.
09/01/15	Update Related Policies. Add 7.01.150.
11/10/15	Annual Review. Policy updated with literature review through July 8, 2015; reference added. Policy statements unchanged.
02/09/16	Annual Review. Policy updated with literature review through January, 2016; reference added. Policy statements unchanged.
01/10/17	Interim review. Coding update; added CPT code 95980. Combined coding tables.
05/01/17	Annual review, changes approved April 11, 2017. Policy updated with literature review through December 22, 2016; reference 1 added. Policy statements unchanged.
08/25/17	Coding update, removed CPT code 95980. Supporting information added to Summary of Evidence section. Policy moved into new format; no change to policy statements.
05/01/18	Annual Review, approved April 3, 2018. Policy updated with literature review through December 2017; 1 reference added. Policy statements unchanged.
05/01/19	Annual Review, approved April 2, 2019. Policy updated with literature review through January 2019; references 8-9 added. Policy statements unchanged.
04/01/20	Delete policy, approved March 10, 2020. This policy will be deleted effective July 2, 2020, and replaced with InterQual criteria for dates of service on or after July 2, 2020.
06/10/20	Interim Review, approved June 9, 2020, effective June 10, 2020. This policy is reinstated immediately and will no longer be deleted or replaced with InterQual criteria on July 2, 2020.
08/01/20	Annual Review, approved July 23, 2020. Policy updated with literature review through December 2019; no references added. Policy statements unchanged.
05/01/21	Annual Review, approved April 1, 2021. Policy updated with literature review through December 10, 2020; no references added. Policy statements unchanged. Update Related Policies, removed policy 7.01.150 as it was archived.
05/01/22	Annual Review, approved April 11, 2022. Policy updated with literature review through December 31, 2021; no references added. Policy statements unchanged.
05/01/23	Annual Review, approved April 10, 2023. Policy updated with literature review through December 27, 2022; references added. Policy statements unchanged. Changed the wording from "patient" to "individual" throughout the policy for standardization.
09/11/24	Minor update to related policies. 7.01.20 was replaced with 7.01.593 Vagus Nerve Stimulation.
12/01/24	Annual Review, approved November 25, 2024. Policy updated with literature review through January 3, 2024; no references added. Policy statements unchanged. HCPCS code E0765 removed from policy as it is not a gastric stimulator and added C1767, C1778 and L8679 for Enterra device.

Date	Comments
05/01/25	Annual Review, approved April 7, 2025. Policy updated with literature review through January 3, 2025; no references added. Policy statements unchanged.
01/01/26	Coding update. Added new HCPCS code C1607, effective January 1, 2026.

Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.