

Blue Cross Blue Shield of Massachusetts is an Independent Licensee of the Blue Cross and Blue Shield Association

Medical Policy

Gastric Electrical Stimulation

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Policy History

Policy Number: 636

BCBSA Reference Number: 7.01.73 (For Plan internal use only)

NCD/LCD: N/A

Related Policies

Meniscal Allografts and Other Meniscal Implants, #110

- Vagus Nerve Stimulation, #474
- Vagal Nerve Blocking Therapy for Treatment of Obesity, #644

Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity Medicare HMO BlueSM and Medicare PPO BlueSM Members

Gastric electrical stimulation is considered **INVESTIGATIONAL** for the treatment of gastroparesis of diabetic or idiopathic etiology.

Gastric electrical stimulation is considered INVESTIGATIONAL for the treatment of obesity.

Prior Authorization Information

Inpatient

 For services described in this policy, precertification/preauthorization <u>IS REQUIRED</u> for all products if the procedure is performed **inpatient**.

Outpatient

• For services described in this policy, see below for products where prior authorization <u>might be</u> <u>required</u> if the procedure is performed <u>outpatient</u>.

	Outpatient
Commercial Managed Care (HMO and POS)	This is not a covered service.
Commercial PPO and Indemnity	This is not a covered service.
Medicare HMO Blue SM	This is not a covered service.
Medicare PPO Blue SM	This is not a covered service.

CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following codes are included below for informational purposes only; this is not an all-inclusive list.

The following CPT codes are considered investigational for <u>Commercial Members: Managed Care</u> (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:

CPT Codes

CPT codes:	Code Description
43647	Laparoscopy, surgical; implantation or replacement of gastric neurostimulator electrodes, antrum
43881	Implantation or replacement of gastric neurostimulator electrodes, antrum, open
64590	Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct, or inductive coupling
95980	Electronic analysis of implanted neurostimulator pulse generator system (e.g., rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient measurements), gastric neurostimulator pulse generator/transmitter; intraoperative, with programming
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) gastric neurostimulator pulse generator/transmitter; subsequent, without reprogramming
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) gastric neurostimulator pulse generator/transmitter; subsequent, with reprogramming

Description

Treatment Gastroparesis

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 diabetic patients. 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 a 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

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.

For individuals who have gastroparesis who receive gastric electrical stimulation (GES), the evidence includes randomized controlled trials (RCTs), nonrandomized studies, and systematic reviews. Relevant outcomes are symptoms and treatment-related morbidity. Several crossover RCTs have been published. A 2017 meta-analysis of 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. 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.

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.

Policy History

Date	Action
4/2024	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
4/2023	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
3/2022	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
4/2021	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
4/2020	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
4/2019	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
3/2017	Annual policy review. New references added.
2/2016	Annual policy review. New references added.
12/2015	Clarified coding information.
10/2014	Annual policy review. New references added.
6/2014	Updated Coding section with ICD10 procedure and diagnosis codes. Effective 10/2015.
12/2013	Annual medical policy. Removed HCPCS codes L8680 and L8685-L8686 as they do
	not meet the intent of the policy.
10/2013	Removed CPT codes 43648, 43882 and 64595 as they do not apply to the policy.
11/2011- 4/2012	Medical policy ICD 10 remediation: Formatting, editing and coding updates. No changes to policy statements.

10/2011	Reviewed - Medical Policy Group - Gastroenterology, Nutrition and Organ
	Transplantation. No changes to policy statements.
11/2010	Reviewed - Medical Policy Group - Gastroenterology, Nutrition and Organ
	Transplantation. No changes to policy statements.
11/2009	Reviewed - Medical Policy Group - Gastroenterology, Nutrition and Organ
	Transplantation. No changes to policy statements.
7/2009	Annual policy review. No changes to policy statements.
11/2008	Reviewed - Medical Policy Group - Gastroenterology, Nutrition and Organ
	Transplantation. No changes to policy statements.
4/2008	Annual policy review. No changes to policy statements.
11/2007	Reviewed - Medical Policy Group - Gastroenterology, Nutrition and Organ
	Transplantation. No changes to policy statements.
8/2007	Annual policy review. No changes to policy statements.
1/2007	Annual policy review. No changes to policy statements.

Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

Medical Policy Terms of Use

Managed Care Guidelines

Indemnity/PPO Guidelines

Clinical Exception Process

Medical Technology Assessment Guidelines

References

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