

MEDICAL POLICY

POLICY TITLE	GASTRIC ELECTRICAL STIMULATION
POLICY NUMBER	MP- 2.069

Effective Date:	11/1/2023
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I. POLICY

Gastric electrical stimulation may be considered **medically necessary** when provided in accordance with the humanitarian device exemption (HDE) specifications of the U.S. Food and Drug Administration (FDA) for the treatment of chronic intractable nausea and vomiting secondary to severe gastroparesis of diabetic or idiopathic etiology when **ALL** of the following criteria are met:

- Significant delayed gastric emptying as documented by standard scintigraphic imaging of solid food. If scintigraphy is contraindicated, then breath testing is an acceptable alternative; **and**
- The individual has tried and failed dietary modifications (see policy guidelines); **and**
- Individual is refractory to or intolerant of at least two (2) anti-emetic and/or prokinetic drug classes for greater than or equal to a total of 12 weeks; **and**
- No mechanical obstruction is found on diagnostic testing; **and**
- One or more of the following:
 - Nausea or vomiting greater than or equal to seven (7) episodes per week; **or**
 - Individual requires enteral or parenteral nutrition; **or**
 - Unable to achieve glycemic control; **or**
 - Weight loss greater than or equal to 10% within a six (6) month timeframe; **or**
 - Emergency department visits or hospital admissions greater than or equal to 2 episodes within 1 year; **and**
- Individual has NO history of **ALL** below:
 - Cardiac pacemaker or implantable cardioverter defibrillator or other neurostimulators
 - Gastric resection
 - Systemic motility disorder (examples include Systemic Lupus Erythematosus, Amyloidosis, Scleroderma, Neurofibromatosis, Parkinson’s disease, Muscular Dystrophies, Thyroid Disease)

Gastric electrical stimulation is considered **investigational** for the treatment of obesity. There is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with this procedure.

Policy Guidelines

Recommended dietary modifications for individuals with gastroparesis include eating frequent, smaller sized meals, replacing solid foods with liquid nutritional supplements, and adhering to a low fat, low fiber diet. In addition to dietary modifications, cessation of alcohol and tobacco use

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is recommended, as their use is associated with slowed gastric emptying. For individuals with diabetes, glucose control should be closely monitored because hyperglycemia can aggravate gastroparesis

II. PRODUCT VARIATIONS

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This policy is only applicable to certain programs and products administered by Capital Blue Cross please see additional information below, and subject to benefit variations as discussed in Section VI below.

FEP PPO - Refer to FEP Medical Policy Manual. The FEP Medical Policy manual can be found at: <https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies>.

III. DESCRIPTION/BACKGROUND

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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. Treatment of gastroparesis includes prokinetic agents (e.g., metoclopramide) and antiemetic agents (e.g., metoclopramide, granisetron, ondansetron). Severe cases may require enteral or total parenteral nutrition.

Treatment

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.

Regulatory Status

In 2000, the Gastric Electrical Stimulator system (now called Enterra™ Therapy System; Medtronic) was approved by the U.S. Food and Drug Administration through the humanitarian device exemption process (H990014) for the treatment of gastroparesis. The GES system

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consists of 4 components: the implanted pulse generator, two 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 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.

Currently, no GES devices have been approved by the Food and Drug Administration 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.

IV. RATIONALE

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Summary of Evidence

For individuals who have gastroparesis who receive GES, the evidence includes randomized controlled trials (RCTs), nonrandomized studies, and systematic reviews. 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.

Input from the National Institute for Health and Care Excellence states that “current evidence on the efficacy and safety of gastric electrical stimulation for gastroparesis is adequate to support the use of this procedure...” Input from the American College of Gastroenterology states that “gastric electrical stimulation may be considered for compassionate treatment in patients with refractory symptoms, particularly nausea and vomiting”. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have obesity who receive GES, the evidence includes an RCT. 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 sham stimulation. The evidence is insufficient to determine the effects of the technology on health outcomes.

V. DEFINITIONS

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ANTIEMETIC refers to an agent that prevents or relieves nausea or vomiting.

ENTERAL refers to within or by way of the intestine.

ETIOLOGY refers to the cause of a disease.

IDIOPATHIC refers to conditions without a known cause.

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LAPAROSCOPY refers to abdominal exploration using a type of endoscope called a laparoscope.

PROKINETIC refers to the stimulation of gastrointestinal activity.

SUBCUTANEOUS refers to beneath the skin.

TOTAL PARENTERAL NUTRITION refers to the intravenous provision of dextrose, amino acids, emulsified fats, trace elements, vitamins, and minerals to patients who are unable to assimilate adequate nutrition by mouth.

VI. BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member's health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits and which require preauthorization. There are different benefit plan designs in each product administered by Capital Blue Cross. Members and providers should consult the member's health benefit plan for information or contact Capital Blue Cross for benefit information.

VII. DISCLAIMER

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Capital Blue Cross's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice, and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital Blue Cross' Provider Services or Member Services. Capital Blue Cross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

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Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Covered when medically necessary:

Procedure Codes							
C1767	C1778	L8679	L8680	L8685	L8686	L8687	L8688
43647	43648	43881	43882	64590	64595	95980	95981
95982							

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ICD-10-CM Diagnosis Code	Description
E08.43	Diabetes mellitus due to underlying condition with diabetic autonomic (poly)neuropathy
E09.43	Drug or chemical induced diabetes mellitus with neurological complications with autonomic (poly)neuropathy
E10.43	Type 1 diabetes mellitus with diabetic autonomic (poly)neuropathy
E11.43	Type 2 diabetes mellitus with diabetic autonomic (poly)neuropathy
E13.43	Other specified diabetes mellitus with diabetic autonomic (poly)neuropathy
K31.84	Gastroparesis

IX. REFERENCES

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X. POLICY HISTORY

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	CAC 1/25/05
	CAC 2/28/06
	CAC 2/27/07
	CAC 9/25/07
	CAC 7/29/08

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CAC 7/28/09 Consensus review
CAC 5/25/10 Adopted BCBSA criteria
CAC 4/26/11 Consensus review
CAC 6/26/12 Consensus review. No changes, references updated.
03/07/13 Administrative update. Code review
CAC 9/24/13 Consensus review. References updated but no changes to the policy statements. Rationale added. FEP variation revised to refer to the FEP manual. Admin Code review
CAC 7/22/14 Consensus review. No change to policy statements. References updated. Coding reviewed.
CAC 7/21/15 Consensus review. No change to the policy statements. Background, references, and rationale updated. Codes reviewed.
12/1/16 Administrative update. Variation section reformatted.
CAC 7/26/16 Minor revision. ‘Post-surgical’ added to the gastroparesis investigational policy statement. Regulatory Status, Rationale, and Reference sections updated. Coding reviewed/updated to address gastric stimulation for obesity.
CAC 9/26/17 Consensus review. No change to policy statements. References and rationale updated. Coding Reviewed.
6/05/18 Consensus review. Policy statements unchanged. Description/Background, Rationale, and Reference sections updated.
4/9/19 Consensus review. No change to policy statements. Background reviewed. Summary of evidence and references updated.
5/22/20 Minor review. Added GES covered for severe gastroparesis of diabetic or idiopathic etiology with criteria included. References added. Coding updated.
6/3/2021 Consensus review. Updated Rationale, References, and Coding.
9/7/2021 Administrative update. New codes added K31.A0, K31.A11, K31.A12, K31.A13, K31.A14, K31.A15, K31.A19, K31.A21, K31.A22, K31.A29. Effective 10/1/2021
5/27/2022 Consensus review. Updated FEP, coding tables, and references.
3/31/2023 Minor review. Breath testing is acceptable alternative if scintigraphy is contraindicated. Dietary modifications must be tried and failed. Expanded on symptoms/treatments that can be chosen from. Added policy guidelines. Updated references. Added C1767 and C1778 to coding table.

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