

## MEDICAL POLICY

<b>POLICY TITLE</b>	<b>GASTRIC ELECTRICAL STIMULATION</b>
<b>POLICY NUMBER</b>	<b>MP 2.069</b>

<b>CLINICAL BENEFIT</b>	<input type="checkbox"/> MINIMIZE SAFETY RISK OR CONCERN. <input checked="" type="checkbox"/> MINIMIZE HARMFUL OR INEFFECTIVE INTERVENTIONS. <input type="checkbox"/> ASSURE APPROPRIATE LEVEL OF CARE. <input type="checkbox"/> ASSURE APPROPRIATE DURATION OF SERVICE FOR INTERVENTIONS. <input type="checkbox"/> ASSURE THAT RECOMMENDED MEDICAL PREREQUISITES HAVE BEEN MET. <input type="checkbox"/> ASSURE APPROPRIATE SITE OF TREATMENT OR SERVICE.
<b>Effective date:</b>	<b>6/1/2026</b>

### POLICY

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

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.

### PRODUCT VARIATIONS

This policy is only applicable to certain programs and products administered by Capital Blue Cross and subject to benefit variations. Please see additional information 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>.

### DESCRIPTION/BACKGROUND

#### 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.

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### 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 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.

## RATIONALE

### 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.

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.

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### DEFINITIONS

**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.

**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.

### DISCLAIMER

*Capital Blue Cross' medical policies are used to determine coverage for specific medical technologies, procedures, equipment, and services. These medical policies do not constitute medical advice and are subject to change as permitted by law or applicable clinical evidence from independent treatment guidelines. Treating providers are solely responsible for medical advice and treatment of members. These policies are not a guarantee of coverage or payment. Payment of claims is subject to a determination regarding the member's benefit program and eligibility on the date of service, and a determination that the services are medically necessary and appropriate. Final processing of a claim is based upon the terms of contract that applies to the members' benefit program, including benefit limitations and exclusions. If a provider or a member has a question concerning this medical policy, please contact Capital Blue Cross' Provider Services or Member Services.*

### CODING INFORMATION

**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.

#### Investigational, and therefore not covered:

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

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### POLICY HISTORY

<b>MP 2.069</b>	<b>05/22/2020 Minor Review.</b> Added GES covered for severe gastroparesis of diabetic or idiopathic etiology with criteria included. References added. Coding updated.
	<b>06/03/2021 Consensus Review.</b> Updated Rationale, References, and Coding.
	<b>09/07/2021 Administrative Update.</b> New codes added K31.A0, K31.A11, K31.A12, K31.A13, K31.A14, K31.A15, K31.A19, K31.A21, K31.A22, K31.A29. Effective 10/01/2021
	<b>05/27/2022 Consensus Review.</b> Updated FEP, coding tables, and references.
	<b>03/31/2023 Minor Review.</b> 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.
	<b>04/23/2024 Consensus Review.</b> No change to policy stance. Updated references.
	<b>05/22/2025 Major review.</b> Gastric electrical stimulation is now investigational, associated coding is investigational. Updated references.
	<b>09/09/2025 Administrative Update.</b> Removed Benefit Variations Section and updated Disclaimer.
	<b>02/17/2026 Consensus Review.</b> Updated references. No changes to coding.

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