



## Gastric Electrical Stimulation

**Policy #** 00046

**Original Effective Date:** 04/29/2002

**Current Effective Date:** 06/12/2023

*Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.*

*Note: Vagus Nerve Stimulation is addressed separately in medical policy 00134.*

## When Services May Be Eligible for Coverage

*Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:*

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider the use of gastric electrical stimulation (GES) in the treatment of chronic, intractable nausea and vomiting secondary to gastroparesis of diabetic or idiopathic etiology to be **eligible for coverage\*\*** when **ALL** of the following criteria are met:

### Patient Selection Criteria

Coverage eligibility will be considered when **ALL** of the following criteria are met:

- Significantly delayed gastric emptying as documented by standard scintigraphic imaging of solid food; and
- Patient has severe nausea and vomiting occurring on average at least once daily; and
- Patient is refractory to treatment with prokinetic medications and antiemetic medications for at least one year in duration, or has been intolerant of this treatment; and
- Patient's nutritional status is sufficiently low that total parenteral nutrition is likely to become medically necessary

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:

- Member has chronic, intractable nausea and vomiting secondary to gastroparesis (inability to empty food) caused by diabetes or for an unknown reason; and

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- Significantly delayed gastric emptying confirmed by standard scintigraphic imaging (gastric emptying scan) of solid food; and
- Member has not responded or is intolerant to the use of prokinetic (antireflux) and antiemetic (antinausea and vomiting) medications; and
- The need for parenteral nutrition is likely to become medically necessary because of member's inadequate nutritional status

*Note: Replacement of gastric electrical stimulation (GES) may be considered medically necessary for an individual that meets (or has met) the above medical necessity criteria and the existing stimulator is no longer under warranty and cannot be repaired.*

## When Services Are Considered Investigational

*Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.*

Based on review of available data, the Company considers the use of gastric electrical stimulation (GES) in all other indications, including but not limited to the treatment of obesity, to be **investigational**.\*

## Background/Overview

### 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 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

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electrical stimulation at different frequencies, connected to intramuscular stomach leads, which are implanted during laparoscopy or open laparotomy.

### **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.

Gastroparesis is a chronic disorder of gastric motility characterized by delayed gastric emptying of solids in the absence of mechanical obstruction. It can frequently result from longstanding diabetes mellitus and vagal nerve injury, or can be idiopathic in nature. Gastroparesis leads to postprandial nausea and vomiting, bloating, early satiety and discomfort. In severe cases, nausea and vomiting may cause weight loss, dehydration, electrolyte disturbances and malnutrition due to inadequate caloric and fluid intake.

The evaluation of gastroparesis is to exclude mechanical obstruction and establish the diagnosis of gastroparesis by an assessment of gastric motility. If there is no evidence of mechanical obstruction on imaging or upper endoscopy, scintigraphy is typically performed to document the presence of delayed gastric emptying. Scintigraphy measures the motor function of the stomach by quantifying the emptying of a physiologic caloric meal. The technique involves incorporating a radioisotope tracer into a standard meal and tracking its passage through the stomach using a gamma camera. Images are typically gathered at 1, 2, 3, and 4 hours.

Delayed gastric emptying is defined as gastric retention of  $> 10$  percent at 4 hours and/or  $> 60$  percent at two hours when using a standard low fat diet. Although the severity of symptoms do not always correlate with the rate of gastric emptying, delayed gastric emptying has been classified based on the extent of gastric retention on scintigraphy at four hours into the following:

- Mild 10 to 15 percent
- Moderate 15 to 35 percent
- Severe  $> 35$  percent

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## **FDA or Other Governmental Regulatory Approval**

### **U.S. Food and Drug Administration (FDA)**

In 2000, the Gastric Electrical Stimulator system (now called Enterra™ Therapy System; Medtronic) was approved by the U.S. 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 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 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.

## **Rationale/Source**

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

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.

### **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

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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. 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.

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 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.

## **Supplemental Information**

### **Clinical Input 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 1 specialty society (2 reviewers) and 4 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 (eg, diabetic

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gastroparesis, idiopathic gastroparesis, gastroparesis of postsurgical etiology). The reviewers were not asked about the use of 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 in the treatment of obesity.

### Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' 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.

### National Institute for Health and Care Excellence

In 2014, the National Institute for Health and Care Excellence issued guidance on GES for gastroparesis. The Institute made the following recommendations:

1.1 "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."

1.2 "... clinicians should inform individuals considering gastric electrical stimulation for gastroparesis that some individuals do not get any benefit from it. They should also give individuals detailed written information about the risk of complications, which can be serious, including the need to remove the device."

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1.3 "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."

### American College of Gastroenterology

In 2022, the American College of Gastroenterology updated practice guidelines on the management of gastroparesis. 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)."

### U.S. Preventive Services Task Force Recommendations

Not applicable.

### Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

### Ongoing and Unpublished Clinical Trials

Some currently unpublished 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
<i>Ongoing</i>			
NCT03123809	Combined Gastric Electrical Stimulation (GES) and Pyloroplasty for the Treatment of Gastroparesis: Can Pyloroplasty be Effective Without GES?	50	May 15, 2023
NCT04121325	Gastric Electrical Stimulation for Treating Abdominal Pain in Individuals With Gastroparesis	20	January 1, 2028

NCT: national clinical trial.

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## **Policy History**

Original Effective Date: 04/29/2002

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12/06/2001	Medical Policy Committee review.
01/28/2002	Managed Care Advisory Council approval
06/24/2002	Format revision. No substance change to policy.
03/31/2004	Medical Director review
04/20/2004	Medical Policy Committee review. Format revision. No substance change to policy.
04/26/2004	Managed Care Advisory Council approval
04/05/2006	Medical Director review

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04/19/2006	Medical Policy Committee approval. Format revision, including addition of FDA and or other governmental regulatory approval and rationale/source. Coverage eligibility unchanged.
04/04/2007	Medical Director review
04/18/2007	Medical Policy Committee approval. No change to coverage eligibility.
04/02/2009	Medical Director review
04/15/2009	Medical Policy Committee approval. No change to coverage eligibility.
09/03/2009	Medical Policy Committee approval.
09/16/2009	Medical Policy Implementation Committee approval. Coverage eligibility changed from investigational to eligible with criteria.
09/09/2010	Medical Policy Committee review
09/15/2010	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
09/01/2011	Medical Policy Committee review
09/14/2011	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
09/06/2012	Medical Policy Committee review
09/19/2012	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
09/05/2013	Medical Policy Committee review
09/18/2013	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
09/04/2014	Medical Policy Committee review
09/17/2014	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/03/2015	Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed
12/03/2015	Medical Policy Committee review.
12/16/2015	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
12/01/2016	Medical Policy Committee review.
12/21/2016	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/01/2017	Coding update: Removing ICD-9 Diagnosis Codes

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12/07/2017	Medical Policy Committee review.
12/20/2017	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
12/06/2018	Medical Policy Committee review.
12/19/2018	Medical Policy Implementation Committee approval. Patient selection criteria revised.
12/05/2019	Medical Policy Committee review.
12/11/2019	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
05/07/2020	Medical Policy Committee review
05/13/2020	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
05/06/2021	Medical Policy Committee review
05/12/2021	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
05/05/2022	Medical Policy Committee review
05/11/2022	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
05/04/2023	Medical Policy Committee review
05/10/2023	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 05/2024

## **Coding**

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Code Type	Code
CPT	43647, 43648, 43659, 43881, 43882, 43999, 64590, 64595, 95980, 95981, 95982
HCPCS	C1816, C1883, E0765, L8680, L8685, L8686, L8687, L8688
ICD-10 Diagnosis	All related diagnoses

\*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:

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1. Consultation with technology evaluation center(s);
2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
3. Reference to federal regulations.

**\*\*Medically Necessary (or “Medical Necessity”)** - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. In accordance with nationally accepted standards of medical practice;
- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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