

## Gastric Electrical Stimulation

**Policy # 00046**

Original Effective Date: 04/29/2002

Current Effective Date: 06/01/2026

*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.*

*Investigational or experimental services are not covered. This includes any drug, device, procedure, or service provided under the investigational arm of a clinical trial or clinical study. These services are excluded from coverage under benefits.*

*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) to be **eligible for coverage\*\*** when **ALL** of the following criteria are met:

- GES is requested for one of the following indications:
  - Chronic, intractable nausea and vomiting secondary to diabetic gastroparesis; **OR**
  - Chronic, intractable nausea and vomiting secondary to idiopathic gastroparesis; **AND**
- Significantly delayed gastric emptying as documented by standard scintigraphic imaging of solid food; **AND**
- Severe nausea and vomiting are occurring on average at least once daily; **AND**
- Symptoms are refractory to treatment with prokinetic medications and antiemetic medications for at least one year in duration, or individual has been intolerant of this treatment; **AND**
- Patient's nutritional status is sufficiently low that total parenteral nutrition is likely to become medically necessary; **AND**
- The medical records support that all medical necessity criteria are met.

*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 Not Medically Necessary

The use of gastric electrical stimulation (GES) when coverage criteria are not met is considered to be **not medically necessary.\*\***

Policy # 00046

Original Effective Date: 04/29/2002

Current Effective Date: 06/01/2026

## **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) for 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 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

## Gastric Electrical Stimulation

Policy # 00046

Original Effective Date: 04/29/2002

Current Effective Date: 06/01/2026

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

## **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. 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 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 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.

## Gastric Electrical Stimulation

Policy # 00046

Original Effective Date: 04/29/2002

Current Effective Date: 06/01/2026

### 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. 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.

## **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 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,

## Gastric Electrical Stimulation

Policy # 00046

Original Effective Date: 04/29/2002

Current Effective Date: 06/01/2026

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.

### **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)."

### **American Gastroenterological Association**

In 2025, the American Gastroenterological Association (AGA) published practice guidelines on the management of gastroparesis. They recommended that "In patients with gastroparesis refractory to medical therapy, the AGA suggests against the routine use of gastric electrical stimulation". Through shared decision-making, patients and clinicians who prioritize the potential benefits of reducing nausea and vomiting over the possible risks of adverse events may reasonably choose to proceed with GES placement. For implementation considerations for this recommendation, the AGA states that this procedure should be considered only for carefully selected patients with gastroparesis that does not respond to medical therapy. When implemented, patients should be advised that GES is primarily intended to alleviate nausea and vomiting, rather than abdominal pain.

### **National Institute for Health and Care Excellence**

In 2014, NICE 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 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."

## Gastric Electrical Stimulation

Policy # 00046

Original Effective Date: 04/29/2002

Current Effective Date: 06/01/2026

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."

### 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                 | Sep 2024        |
| NCT05980455 <sup>a</sup> | Randomized Study of Enterra Programming with Nocturnal Cycling in Gastroparetics                                                              | 50                 | Dec 2025        |

NCT: national clinical trial.

<sup>a</sup> Denotes industry-sponsored or cosponsored trial.

## References

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## Gastric Electrical Stimulation

Policy # 00046

Original Effective Date: 04/29/2002

Current Effective Date: 06/01/2026

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13. Shikora SA, Bergenstal R, Bessler M, et al. Implantable gastric stimulation for the treatment of clinically severe obesity: results of the SHAPE trial. *Surg Obes Relat Dis*. 2009; 5(1): 31-7. PMID 19071066
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## Gastric Electrical Stimulation

Policy # 00046

Original Effective Date: 04/29/2002

Current Effective Date: 06/01/2026

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Original Effective Date: 04/29/2002

Current Effective Date: 06/01/2026

|            |                                                                                                                                                                                   |
|------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 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                                                                                                                                                           |
| 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.                                                                                                 |

## Gastric Electrical Stimulation

Policy # 00046

Original Effective Date: 04/29/2002

Current Effective Date: 06/01/2026

|            |                                                                                                                                                                                                    |
|------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 01/01/2017 | Coding update: Removing ICD-9 Diagnosis Codes                                                                                                                                                      |
| 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.                                                                                                                  |
| 05/02/2024 | Medical Policy Committee review                                                                                                                                                                    |
| 05/08/2024 | Medical Policy Implementation Committee approval. Coverage eligibility unchanged.                                                                                                                  |
| 05/01/2025 | Medical Policy Committee review                                                                                                                                                                    |
| 05/13/2025 | Medical Policy Implementation Committee approval. Coverage eligibility unchanged.                                                                                                                  |
| 05/07/2026 | Medical Policy Committee review                                                                                                                                                                    |
| 05/13/2026 | Medical Policy Implementation Committee approval. Added “The use of gastric electrical stimulation (GES) when patient selection criteria are not met is considered to be not medically necessary.” |

Next Scheduled Review Date: 05/2027

## **Coding**

*The five character codes included in the Louisiana Blue Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)†, copyright 2025 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.*

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## Gastric Electrical Stimulation

Policy # 00046

Original Effective Date: 04/29/2002

Current Effective Date: 06/01/2026

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CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

| Code Type        | Code                                                                                                                                       |
|------------------|--------------------------------------------------------------------------------------------------------------------------------------------|
| CPT              | 43647, 43648, 43659, 43881, 43882, 43999, 64590, 64595, 95980, 95981, 95982                                                                |
| HCPCS            | C1816, C1883, L8680, L8685, L8686, L8687, L8688<br>Add codes effective 06/01/2026: C1767, C1778<br>Delete code effective 06/01/2026: E0765 |
| 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:
  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,

## Gastric Electrical Stimulation

Policy # 00046

Original Effective Date: 04/29/2002

Current Effective Date: 06/01/2026

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.

‡ Indicated trademarks are the registered trademarks of their respective owners.

**NOTICE:** If the Patient’s health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

**NOTICE:** Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

**NOTICE:** Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.

**NOTICE:** If an authorization for an ongoing course of treatment has been provided to a member and the member changes from one health plan to another health plan (e.g., a member moves from carrier A to Louisiana Blue), Louisiana Blue may honor the previous health plan’s authorization for the same service under the same type of in-network benefit for a 90-day transition period. Documentation of the authorization for the ongoing course of treatment from the previous health plan must be provided to us by the member or their provider and the services provided for the course of treatment must otherwise be a covered service under the Louisiana Blue health plan. This provision does not apply to medications covered under the plan’s pharmacy benefit.