



Louisiana

Gastric Electrical Stimulation

Policy # 00046

Original Effective Date: 04/29/2002

Current Effective Date: 03/01/2019

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.

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
- 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.

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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

GES is performed using an implantable device designed to treat chronic drug-refractory nausea and vomiting secondary to gastroparesis of diabetic or idiopathic etiology. The device may be referred to as a gastric pacemaker.

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 diabetics. While most commonly associated with diabetes, gastroparesis is also found in chronic pseudo-obstruction, connective tissue disorders, Parkinson's disease and psychological pathologic conditions. Treatment of gastroparesis includes prokinetic agents such as metoclopramide, and antiemetic agents such as metoclopramide, granisetron or ondansetron. Severe cases may require enteral or total parenteral nutrition.

GES has also been investigated as a treatment of obesity as a technique to increase a feeling of satiety with subsequent reduced food intake and weight loss. The exact mechanisms resulting in changes in eating behavior are uncertain but may be related to neuro-hormonal 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.

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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)

One GES device received approval from the FDA, the GES system (now called Enterra™ Therapy System) †, manufactured by Medtronic. The GES system consists of four 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 neurological stimulators, such as spinal cord or sacral nerve stimulation. The intramuscular stomach leads are implanted either laparoscopically or during a 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 sec alternating with an OFF time of 5.0 sec.

There are no GES devices approved by the FDA for the treatment of obesity. However, the Transcend implantable gastric stimulation device, manufactured by Transneuronix Corporation, is currently available in Europe for treatment of obesity. Transneuronix is currently funding clinical trials in the United States, and the company hopes to obtain FDA approval in a couple of years for use of the Transcend device to promote weight loss in the management of obesity.

Note: It should be noted that the GES system received FDA approval through a “humanitarian device exemption.” This regulatory category was established in 1996 and only applies to devices intended to benefit fewer than 4,000 patients. The approval process is similar to that of a premarket approval application (PMA) but is exempt from the effectiveness requirements of a PMA. Thus the application is not required to provide results of scientifically valid clinical investigations, but must contain sufficient information for the FDA to determine that the device does not pose unreasonable or significant risk of illness or injury. A humanitarian use device may only be used in facilities that have an Institutional Review Board (IRB) to supervise clinical testing of the device.

Rationale/Source

Gastroparesis

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The evidence on GES for gastroparesis consists of one small randomized crossover trial, and numerous case series. The case series include several that report on medium and/or long-term use (greater than one year of follow-up) of the device.

The data presented to the FDA documenting the “probable benefit” of the GES system was based on a multicenter, double-blinded crossover study, the Worldwide Anti-Vomiting Electrical Stimulation Study (WAVESS). The study included 33 patients with intractable idiopathic or diabetic gastroparesis. The primary endpoint of the study was a reduction in vomiting frequency, as measured by patient diaries. In the initial phase of the study, all patients underwent implantation of the stimulator and were randomly and blindly assigned to stimulation on or stimulation off for the first month, with crossover to off and on during the second month. The baseline vomiting frequency was 47 episodes per month, which significantly declined in both on and off groups to 23 to 29 episodes, respectively. However, no significant differences were found in the number of vomiting episodes between the 2 groups, suggesting a placebo effect.

The final results of the WAVESS study were reported in 2003, which allows further review of the data. When looking individually at those with idiopathic gastroparesis, there was a similar drop in vomiting frequency compared to baseline regardless of whether the device was turned on or off, suggesting a placebo effect. In contrast, in those with diabetic gastroparesis, compared to baseline, there was a small drop in vomiting frequency with the device turned off, compared to a larger drop in vomiting frequency with the device turned on. In the second open-label phase of the trial, all patients had their stimulators turned on for the remainder of the 6 to 12 months’ follow-up. During this period, the vomiting frequency declined in both the idiopathic and diabetic subgroups. The cause of this continuing decline is uncertain, related to either a placebo effect or some sort of long-term effect of gastric stimulation.

Anand and colleagues reported on 214 consecutive drug-refractory patients with the symptoms of gastroparesis (146 idiopathic, 45 diabetic, 23 after surgery) who consented to participate in a variety of clinical research and clinical protocols at 3 centers from January 1992 through January 2005, resulting in 156 patients implanted with a GES device and 58 patients as controls. At last follow-up (median 4 years), most patients who received implants (135 of 156) were alive with intact devices, significantly reduced gastrointestinal symptoms, and improved health-related quality of life, with evidence of improved gastric emptying. Also, 90% of the patients had a response in at least 1 of 3 main symptoms. Most patients, who were explanted, usually for pocket infections, were later re-implanted successfully.

McCallum and colleagues performed a multicenter prospective study to evaluate GES (Enterra therapy) in patients with chronic intractable nausea and vomiting from diabetic gastroparesis (DGP). In this study, 55 patients with refractory DGP (5.9 years of DGP) were given implants of the Enterra system. After surgery, all patients had the stimulator turned on for 6 weeks and then were randomly assigned to groups that had consecutive 3-month cross-over periods with the device on or off. After this period, the device was turned on in all patients, and they were followed up unblinded for 4.5 months. During the initial 6-week phase with the stimulator turned on, the median reduction in weekly vomiting frequency (WVF) compared with baseline

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was 57%. There was no difference in WVF between patients who had the device turned on or off during the 3-month cross-over period. At 1 year, the WVF of all patients was significantly lower than baseline values (median reduction, 68%; p less than 0.001). One of the patients had the device removed due to infection; 2 patients required surgical intervention due to lead-related problems.

In a case series of 12 patients receiving a gastric stimulation device, Abell and colleagues reported rapid improvement in nutritional parameters (e.g., body mass index, serum albumin). Forster and colleagues reported on their experience at a single institution among 55 patients with gastroparesis, as documented by gastric retention. While the total symptom score improved, gastric emptying did not change. The authors reported significant improvements in upper gastrointestinal symptoms, health-related quality of life, nutritional status, glucose control, and hospitalizations at 6 and 12 months in a retrospective review of 48 adult patients with diabetes who received a GES implant. The review also noted that gastric emptying was not significantly faster. Similarly, van der Voort and colleagues reported that 17 patients with diabetic gastroparesis experienced a decrease in nausea and vomiting and an improvement in glucose control in a prospective case series examining the 12-month outcomes.

Several trials were identified that evaluated the use of a temporary gastric stimulator. Temporary stimulators are intended to be used to determine whether or not an individual patient will respond to GES prior to undertaking a permanent implant. Abell et al. performed a trial of temporary GES in 58 patients with 1 of 3 etiologies (idiopathic, diabetic, and postsurgical). A temporary device was placed in all patients with the device turned on or off for 4 consecutive days, followed by cross-over to the other group for an additional 4-day period. The frequency of vomiting decreased in both groups. At day 3, the decrease in vomiting was significantly greater for the GES group; however, by day 8, the differences between groups were no longer significant.

Andersson et al. tested a temporary GES in 27 patients with drug-refractory nausea/vomiting. Fourteen patients were treated with temporary GES in open-label fashion, and 13 had a randomized, cross-over trial in which the device was turned on for 12-14 days and off for 12-14 days. These authors reported that the majority of patients (22/27) improved following GES placement. Of the 13 patients in the randomized cross-over phase, 6 had improvement in symptoms during the on period and 7 did not. Of the 7 patients who did not improve during the on period, there was improvement with an increased intensity of stimulation.

Elfvin et al. treated three children with intractable vomiting who were younger than 3-years-old with a temporary GES. There were no adverse events of GES placement. All three children responded to the temporary GES and were implanted with a permanent device. Following permanent placement, all 3 children reported at least a 50% reduction in vomiting episodes.

The durability of GES treatment was evaluated in several publications. Lin and colleagues reported on outcomes beyond 3 years in patients receiving GES for gastroparesis. Of 55 patients, 10 died of non-pacemaker-related complications, 6 had the devices removed, and 2 could not be reached. In the remaining

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37 patients, symptoms, hospital days, and the use of medications had sustained reductions (from baseline) beyond 3 years. Mason and colleagues reported on the 20-month follow-up of 27 of 29 patients referred for gastrectomy who instead received GES for refractory gastroparesis. Three patients required additional procedures due to poor outcomes. Nutritional support was discontinued in the 19 patients who were dependent on supplemental feeding prior to the procedure. Gastric emptying rates improved. While these results are encouraging, given the findings of the WAVESS study, randomized trials are needed to determine the efficacy of GES in gastroparesis.

McCallum et al. reported on long-term follow-up for 188 patients who received a GES and had at least 1 year of follow-up visits. This sample was drawn from a total of 221 patients treated with a GES system between 1 and 11 years prior to the study. The authors report that symptoms, hospitalizations, and medication use all improved over the time period of the study. The percent of patients with at least 50% improvement in symptoms was 58% for diabetic patients, 53% for postsurgical gastroparesis, and 48% for idiopathic disease. A total of 13 patients (7%) had their device removed due to infection.

Obesity

The evidence on the efficacy of gastric electrical stimulation is inadequate to permit scientific conclusions. The single published randomized study on treatment of gastroparesis included only 33 patients recruited from 11 centers in the United States. There was no statistically significant improvement in symptoms for the entire study group compared to placebo, but positive results were reported for the subgroup of 17 patients with diabetic gastroparesis. The case series report improvements in symptoms, nutritional parameters, and quality of life. However, the lack of control group precludes the conclusion that these changes are due to treatment with GES, given the variable natural history of gastroparesis, and the expected placebo effect.

Several small trials of a temporary gastric stimulator have been published in attempts to select patients for permanent device implantation. The results of these trials are mixed, with some short-term improvements in symptoms noted, but this evidence is not sufficient to determine that patients selected for permanent device implantation as a result of a temporary trial have improved outcomes compared to alternative treatments.

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Policy History

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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
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

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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
 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.
 Next Scheduled Review Date: 12/2019

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:

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- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. 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 the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated 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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