Gastric Electrical Stimulation

Policy # 00046
Original Effective Date: 04/29/2002
Current Effective Date: 06/08/2020

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

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 FDA or Other Governmental Regulatory Approval 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

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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

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

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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 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, Blue Cross and Blue Shield Association technology assessment program (TEC) and other non-affiliated 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.

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.

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,

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input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

2015 Input
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. Most respondents agreed that gastric electrical stimulation (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
In response to requests, input was received from 4 academic medical centers (5 reviewers) while this policy was under review in 2009. 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

National Institute for Health and Care Excellence
In 2014, the National Institute for Health and Care Excellence has 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.

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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 2013, the American College of Gastroenterology published practice guidelines on the management of gastroparesis. The College recommended that:

> "GES [gastric electrical stimulation] may be considered for compassionate treatment in patients with refractory symptoms, particularly nausea and vomiting. Symptom severity and gastric emptying have been shown to improve in patients with DG [diabetic gastroparesis], but not in patients with IG [idiopathic gastroparesis] or PSG [postsurgical gastroparesis]. [Conditional recommendation (there is uncertainty about trade-offs), moderate level of evidence (further research would be likely to have an impact on the confidence in the estimate of effect).]"

An update is in progress from the American College of Gastroenterology.

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
Ongoing			
NCT03261531[a]	Dermatome Electrical Stimulation on Individuals With Overweight and Class I Obesity	16	Dec 2019

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NCT: national clinical trial.
[a] Denotes industry-sponsored or cosponsored trial.

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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

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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
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.

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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.

Next Scheduled Review Date: 05/2021

Coding

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Code Type	Code

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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:
    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

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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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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.

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