CLINICAL MEDICAL POLICY	
Policy Name:	Gastric Electrical Stimulation (GES)
Policy Number:	MP-102-MD-PA
Responsible Department(s):	Medical Management
Provider Notice/Issue Date:	11/01/2023; 11/01/2022; 10/15/2021; 11/23/2020; 12/09/2019
Effective Date:	12/01/2023; 12/01/2022; 11/15/2021; 12/21/2020; 12/09/2019
Next Annual Review:	09/2024
Revision Date:	09/20/2023; 09/21/2022; 09/15/2021; 09/16/2020
Products:	Highmark Wholecare℠ Medicaid
Application:	All participating hospitals and providers
Page Number(s):	1 of 7

Policy History

Date	Activity
12/01/2023	Provider Effective date
10/19/2023	PARP Approval
09/20/2023	QI/UM Committee review
09/20/2023	Annual Review: No changes to E/I stance. Updated 'Summary of Literature' and 'Reference Sources' sections.
12/01/2022	Provider Effective date
10/05/2022	PARP Approval
09/21/2022	QI/UM Committee review
09/21/2022	Annual Review: No changes to clinical criteria. Updated 'Summary of Literature' and 'Reference Sources' sections.
11/15/2021	Provider effective date
10/07/2021	PARP Approval
09/15/2021	QI/UM Committee review
09/15/2021	Annual Review: No changes to clinical criteria. Added Option #4 TAG determination information. Updated Summary of Literature and Reference Sections.
12/21/2020	Provider effective date
10/22/2020	PARP approval
09/16/2020	Annual Review: No change in noncoverage position; update Summary of Literature and Reference sections
09/16/2020	QI/UM Committee review
12/09/2019	Provider effective date

10/08/2019	PARP approval
09/18/2019	QI/UM Committee approval
08/19/2019	Initial policy developed

Disclaimer

Highmark Wholecare℠ medical policy is intended to serve only as a general reference resource regarding coverage for the services described. This policy does not constitute medical advice and is not intended to govern or otherwise influence medical decisions.

Policy Statement

Highmark Wholecare℠ does not provide coverage for the Company's Medicaid products for gastric electrical stimulation in the treatment of gastroparesis of diabetic, idiopathic, post-surgical etiology, or for the treatment of obesity. The service is considered experimental/investigational and therefore, not medically necessary.

This policy is designed to address medical necessity guidelines that are appropriate for the majority of individuals with a particular disease, illness or condition. Each person's unique clinical circumstances warrant individual consideration, based upon review of applicable medical records.

(Current applicable Pennsylvania HealthChoices Agreement Section V. Program Requirements, B. Prior Authorization of Services, 1. General Prior Authorization Requirements.)

Definitions

Prior Authorization Review Panel (PARP) - A panel of representatives from within the PA Department of Human Services who have been assigned organizational responsibility for the review, approval and denial of all PH-MCO Prior Authorization policies and procedures.

Gastroparesis - This condition is a chronic disorder of the gastric motility of the stomach evidenced by delayed emptying of a solid meal from the stomach in the absence of mechanical obstruction. Gastroparesis is associated with diabetes, connective tissue disorders, Parkinson's disease, postoperative gastric surgery, and the disease may be idiopathic.

Gastric Neurostimulator - A programmable device that generates mild electrical pulses for gastric electrical stimulation to treat chronic, intractable nausea and vomiting due to gastroparesis. This device may be referred to as a gastric pacemaker.

Humanitarian Use Device (HUD) - A device that the FDA has determined is intended to benefit patients in the treatment and/or diagnosis of conditions that affect or are manifested in fewer than 4,000 individuals in the United States. The use of an HUD within it approved labeling does not constitute research, however, the FDA requires IRB review and approval before any HUD is used.

Procedures

1. The use of gastric electrical stimulation in the treatment of gastroparesis is considered experimental and investigational, and therefore is not covered. There is currently insufficient peer-reviewed medical evidence to support coverage.

2. Post-payment Audit Statement
   The medical record must include documentation that reflects the medical necessity criteria and is subject to audit by Highmark Wholecare℠ at any time pursuant to the terms of your provider agreement.

3. Place of Service
   The proper place of service for gastric electrical stimulator procedure is in the inpatient or outpatient setting.

Governing Bodies Approval

In 2000, the FDA approved the Gastric Electrical Stimulator (GES), which is now branded as the Enterra™ Therapy System, through a humanitarian device exemption for use in the treatment of chronic, intractable (drug refractory) nausea and vomiting secondary to gastroparesis of diabetic or idiopathic etiology in patients aged 18 to 70 years. The Enterra device is the only FDA Humanitarian Device Exemption to date.

A humanitarian use device is a medical device intended to treat or diagnose a disease or condition that affects, or is manifest in, fewer than 4,000 individuals a year in the United States. Approval is based on a determination that the device is safe and has probable benefit. Humanitarian use devices must be implanted in a medical center whose institutional review board has approved use of the device.

CMS
There were no Centers for Medicare and Medicaid Services (CMS) National Coverage Determination (NCD) or Local Coverage Determination (LCD) identified for gastric electrical stimulation at the time of this medical policy review. However, due to the humanitarian device exemption, Medicare beneficiaries have coverage for the device in the treatment of chronic, intractable, nausea and vomiting secondary to gastroparesis of diabetic or idiopathic etiology in patients age 18 to 70 years of age.

The Pennsylvania Department of Human Services Technology Assessment Group (TAG) workgroup meets quarterly to discuss issues revolving around new technologies and technologies or services that were previously considered to be a program exception. During this meeting, decisions are made as to whether or not certain technologies will be covered and how they will be covered. TAG's decisions are as follow:

- Option #1: Approved - Will be added to the Fee Schedule
- Option #2: Approved as Medically Effective - Will require Program Exception
- Option #3: Approved with (or denied due to) Limited/Minimal Evidence of Effectiveness - Will require Program Exception
- Option #4: Denied - Experimental/Investigational

In August 2006, the TAG workgroup assigned gastric electrical stimulation (GES) for gastroparesis an Option # 4, specifically for CPT codes 43647, 43648, 43881, and 43882.

Summary of Literature

It is estimated that gastroparesis occurs in up to 4% of the population in the United States, however, the prevalence may be closer to 1.8% since many underlying diseases can cause the same symptoms. While the exact etiology of gastroparesis is unknown, several conditions have been identified as potential causes including diabetes, gastric surgery with injury to the vagus nerve, medications, thyroid disease, Parkinson's disease, multiple sclerosis, amyloidosis, and scleroderma (McCallum et al. 2012).

Gastroparesis can lead to poor oral intake, a calorie-deficient diet, and deficiencies in vitamins and minerals. The choice of nutritional support depends on the severity of disease. In mild disease, maintaining oral nutrition is the goal of therapy. In severe gastroparesis, enteral or parenteral nutrition may be needed (Camilleri, Parkman, Shafi, Abell, Gerson, 2021).

Gastric electrical stimulation (GES) for treatment of gastroparesis has been in use for more than a decade. Individual response to GES remains difficult to predict. The mechanism of action of GES remains poorly understood. Stimulation parameters approved in clinical practice do not regulate gastric slow wave activity and have inconsistent effect on gastric emptying. A number of technical variables determine the effect of electrical stimulation on gut tissue. Parameters of waveform applied by the pulse generator (shape, amplitude and frequency) and consequently the energy delivered to the tissue are among the most important in determining tissue response. The electromechanical properties of the delivery system (the electrodes) are also important.

The two variations of GES are long-pulse duration which applies pulses with duration in milliseconds (usually few hundreds), at a frequency of a few cycles per minute. It is also referred to as low-frequency stimulation, or high energy stimulation, since the amount of energy delivered to the tissue depends, among others, on the product of pulse duration and its frequency. The second type of stimulus is known as a short-pulse duration, and applies pulses with duration in microseconds, at a hertz frequency (cycle/sec), therefore it is also referred to as high-frequency stimulation or low energy stimulation. Pulses can be delivered continuously, or in groups (trains). GES with trains of high frequency, short-duration pulses is currently the only type in clinical use for gastroparesis (Soffer, 2012).

Recommendations from the National Institute for Health and Care Excellence (NICE) (2014) states that:

- 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. During the consent process, 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.
- 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.
- Further publications providing data about the effects of the procedures on symptom relief in the long term and on device durability would be useful.

The American College of Gastroenterology (ACG) made recommendations in regards to GES. Accelerated gastric emptying and functional dyspepsia can present with symptoms similar to those of gastroparesis; therefore, documentation of delayed gastric emptying is recommended before selecting therapy with

prokinetics agents or gastric electrical stimulation (GES). (Strong recommendation, moderate level of evidence) (Camilleri, Parkman, Shafi, Abell, Gerson, 2021).

It has been noted that risks associated with GES remain exceptionally high, which limits the adoption of the procedure. Infection, bleeding, pain at the implant site, lead penetration, gastric and bowel perforation, and inflammation have occurred. These complications can result in additional surgeries. In addition to risks associated with GES, several contraindications to the procedure have been identified. This includes the inability to have diathermy and magnetic resonance imaging. Precautions noted by the manufacturer are listed as: the device has not been evaluated for use in pregnant women, use in patients under the age of 18 or over the age of 70; strong sources of electromagnetic interference such as defibrillation, cardioversion, radiofrequency/microwave ablation can result in serious injury, system damage, or operation changes (Medtronic).

Long-term GES studies report a complication rate of 7%-10%, the main one being the infection on subcutaneous pocket. Less common complications include erosion of the abdominal wall by the device, penetration of the leads through the gastric wall, or tangling of wires in the generator pocket and formation of adhesions. These complications are generally managed surgically. In case of the infection on pocket, the pulse generator needs to be removed; however, it can be reinserted once the infection is fully controlled (Camilleri, Parkman, Shafi, Abell, Gerson, 2021).

The quality of peer-reviewed scientific literature for the treatment of gastroparesis with gastric electrical stimulation remains low. While there is a large quantity of studies in this area, there is not consistent evidence on the effectiveness of GES.

A meta-analysis (Levinthal, 2017) of five random controlled studies did not find a significant benefit for gastric electrical stimulation on the severity of symptoms associated with gastroparesis. Patients reported improved symptoms at follow –up regardless whether or not the device was turned on. The evidence is insufficient to determine the effects of this technology on health outcomes.

Hayes, Inc.

- Gastric Electrical Stimulation For Gastroparesis
    - **C Rating** - For gastric electrical stimulation as an adjunct to standard care for the treatment of gastroparesis refractory to medical therapy in adult patients. Findings from a large body of overall low-quality evidence have not provided consistent evidence regarding the effectiveness of GES as treatment for gastroparesis refractory to medical therapy. A nonrandomized study that compared GES with intensive medical treatment and several studies that evaluated patients before stimulator implantation versus after extended follow-up found that GES was associated with statistically significant benefits, such as symptom relief, improved gastric emptying, and less need for nutritional support. In contrast, randomized crossover trials that involved blinded phases of GES turned on (ON phase) versus GES turned off (OFF phase) found little evidence that active GES was associated with improvement in gastroparesis symptoms. However, these randomized studies were relatively small and did not include washout periods between ON and OFF phases. Therefore, carryover effects from the ON periods may have affected results during the OFF periods and masked GES effects. GES is safe in most patients but can cause serious complications, such as infection, that may necessitate surgery to remove the stimulator. Due to inconsistent evidence that GES is beneficial, additional randomized and placebo-controlled studies are

needed to determine whether GES is a reliable therapy for gastroparesis and whether the benefits of GES treatment outweigh the potential risks.

Coding Requirements

Non-covered Procedure Codes
These procedure codes will not be reimbursed without Medical Director approval.

CPT Code	Description
43647	Laparoscopy, surgical; implantation or replacement of gastric neurostimulator electrodes, antrum
43648	Laparoscopy, surgical; revision or removal of gastric neurostimulator electrodes, antrum
43881	Implantation or replacement of gastric neurostimulator electrodes, antrum open
43882	Revision or removal of gastric neurostimulator electrodes, antrum, open
Requests for the following procedure code is to be reviewed on a case-by-case basis by a Medical Director	
64590	Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling

Reimbursement

Participating facilities will be reimbursed per their Highmark Wholecare℠ contract.

Reference Sources

Pennsylvania Department of Human Services. Technology Assessment Group (TAG) Coverage Decisions. Gastric electrical stimulation (GES) for gastroparesis. Option #4. Managed Care Operations Memorandum: OPS # 06/2015-007. Accessed on August 22, 2022.

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McCallum RW, Sarosiek I, Parkman HP, et al. Gastric electrical stimulation with Enterra therapy improves symptoms of idiopathic gastroparesis. Neurogastroenterol Not. April 18, 2012. Accessed on August 19, 2019.

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Levinthal DJ, Bielefeldt K. Systematic review and meta-analysis: Gastric electrical stimulation for gastroparesis. Auton Neurosci. January 2017. Accessed on July 29, 2020.

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Soffer EE. Gastric electrical stimulation for gastroparesis. J Neurogastroenterol Motil. April 18, 2012. Accessed on August 22, 2022.