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Gastric Electrical Stimulation (GES)

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Disclaimer

Carefully check state regulations and/or the member contract.
Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Legislative Mandates

EXCEPTION: For HCSC members residing in the state of Arkansas, § 23-99-419 relating to gastric pacemakers, requires coverage of gastric pacemakers, including replacement if needed. "Gastric pacemaker" means a medical device that A) uses an external programmer and implanted electrical leads to the stomach; and B) transmits low-frequency, high-energy electrical stimulation to the stomach to entrain and pace the gastric slow waves to treat gastroparesis; and "Gastroparesis" means a neuromuscular stomach disorder in which food empties from the stomach more slowly than normal. Enterra Therapy may be used only in medical centers in which an institutional review board has approved use of the device. This applies to the following: Fully Insured Group, Student, Small Group, Mid-Market, Large Group, HMO, EPO, PPO, POS. Unless indicated by the group, this mandate or coverage will not apply to ASO groups.

Coverage

Gastric electrical stimulation (GES) using the Enterra Therapy System™ **may be considered medically necessary** for the treatment of chronic, intractable (drug refractory) nausea and vomiting secondary to gastroparesis of diabetic or idiopathic etiology when **ALL** of the following criteria are met:

- Symptomatic gastroparesis ≥ one year, as documented by an initial gastric emptying test, **and**
- Refractory or intolerant to at least two anti-emetic and prokinetic drug classes, **and**
- On stable medical therapy and, if applicable, stable nutritional support during the month prior to initiation of therapy, **and**
- Delayed gastric emptying, defined by > 60% retention at two hours and > 10% retention at four hours, as measured by standardized gastric emptying testing, **and**
- As a humanitarian approved device, the Enterra Therapy System™ may only be used in facilities that have an Institutional Review Board (IRB) to supervise clinical testing of the device.

Gastric electrical stimulation **is considered experimental, investigational and/or unproven** in all other indications including but not limited to the treatment of obesity.

Policy Guidelines

None.

Description

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.

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 patients. 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. 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 Regulatory Status 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 changes in eating behavior are uncertain but may be related to neurohormonal modulation and/or stomach muscle stimulation.

Regulatory Status
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 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 second 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

This medical policy was originally created in December 2002 and was regularly updated with searches of the PubMed database. The most recent literature review was performed through December 27, 2022.

Medical policies assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function, including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be

adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice. The following is a summary of the key literature to date.

Gastric Electrical Stimulation for Gastroparesis

Clinical Context and Test Purpose

The purpose of gastric electrical stimulation (GES) is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as conservation management, medication, and enteral or total parenteral nutrition, in patients with gastroparesis.

The following PICO was used to select literature to inform this policy.

Populations

The relevant population of interest is individuals with gastroparesis.

Interventions

The therapy being considered is GES.

Comparators

Comparators of interest include conservative management, medication, enteral or total parenteral nutrition. Treatment includes diet modification and gut motility stimulation.

Outcomes

The general outcomes of interest are symptoms and treatment-related morbidity.

The existing literature evaluating GES as a treatment for gastroparesis has varying lengths of follow up, ranging from 6 to 12 months. While studies described below all reported at least one outcome of interest, longer follow-up was necessary to fully observe outcomes. Therefore, 10 years of follow-up is considered necessary to demonstrate efficacy.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess longer term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Systematic Reviews

Several systematic reviews of studies on GES for gastroparesis have been published, (1-4) the most recent of which is by Saleem et al. (2022). Saleem identified 9 studies (7 RCTs; N=730)

including a recent large (N=172) crossover study by Durcotte et al. (2020). (4) The primary outcome evaluated in this analysis was total symptom score (TSS). The included studies were deemed of moderate quality and low risk of bias. Analysis of the 7 blind RCTs found the TSS was significantly improved at the 4-day, 2-month, 4-month, and 12-month follow-up (mean difference [MD], -6.07; 95% confidence interval [CI], -4.5 to -7.65; p<.00001) but not at all follow-up time points (not further defined). These studies had high heterogeneity (I^2=70%) due to variable follow-up duration. The weekly vomiting frequency was not different between groups (MD, -1.76; 95% CI, -6.15 to 2.63; p=.43) when the blind RCTs were pooled; however, in the open trials, vomiting episodes were lower after GES (MD, 15.59; 95% CI, 10.29 to 20.9; p<.00001). The analysis is limited by the variety of scoring systems, variable time points of follow up, and relatively small sample sizes of the individual trials.

An older, but more inclusive meta-analysis, was published by Levinthal et al. (2017). (1) To be selected for the Levinthal review, studies had to include adults with established gastroparesis, report patient symptom scores and administer treatment for at least 1 week. Five RCTs and 13 non-RCTs meeting criteria were identified. Pooled analysis of data from the 5 RCTs (n=185 patients) did not find a statistically significant difference in symptom severity when the GES was turned on versus off (standardized mean difference [SMD], 0.17; 95% confidence interval [CI], -0.06 to 0.40; p=0.15). Another pooled analysis did not find a statistically significant difference in nausea severity scores when the GES was on or off (SMD = -0.143; 95% CI, -0.50 to 0.22; p=0.45). In a pooled analysis of 13 open-label single-arm studies and data from open-label extensions of 3 RCTs, mean total symptom severity score decreased 2.68 (95% CI, 2.04 to 3.32) at follow-up from a mean of 6.85 (95% CI, 6.28 to 7.42) at baseline. The rate of adverse events in the immediate postoperative period (reported in 7 studies) was 8.7% (95% CI, 4.3% to 17.1%). The in-hospital mortality rate within 30 days of surgery was 1.4% (95% CI, 0.8% to 2.5%), the rate of reoperations (up to 10 years of follow-up) was 11.1% (95% CI, 8.7% to 14.1%), and the rate of device removal was 8.4% (95% CI, 5.7% to 12.2%).

Randomized Controlled Trials

A summary of the larger RCTs included in the meta-analyses is presented below.

Ducrotte et al. (2020) evaluated permanent GES (Enterra) in a cross-over trial. (5) Patients (N=172) had refractory and chronic vomiting. After GES implantation, patients were randomized to receive stimulation, or no stimulation then crossed over to the other treatment after 4 months. The primary endpoints were vomiting score (range 0 to 4 where 0 is daily vomiting and 4 is no vomiting) and the Gastrointestinal Quality of Life Index. The median vomiting score with device on was 2 versus 1 with the device off (p<.002); however, over 50% of patients reported similar vomiting scores during the on and off period. There was no difference between groups in the quality-of-life measure (73.3 on the on phase and 71.1 in the off; p=.06). Delayed gastric emptying was not different in the on versus off period. Limitations of this trial include use of an unvalidated scale for the primary endpoint, inclusion of only refractory patients, and 4-month duration of treatment. Importantly, this trial was not limited to patients with gastroparesis.

Abell et al. (2003) reported findings of the Worldwide Anti-Vomiting Electrical Stimulation Study (WAVESS). (6) This double-blind crossover study, initially described in the U.S. Food and Drug Administration (FDA) materials, included 33 patients with intractable idiopathic or diabetic gastroparesis. (7) The primary end point 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. Baseline vomiting frequency was 47 episodes per month, which declined in both on and off groups to 23 to 29 episodes, respectively. However, no statistically significant differences were found in the number of vomiting episodes between the 2 groups, suggesting a placebo effect. In the second, open-label, phase of the trial, all patients had their stimulators turned on for the remainder of the 6- to 12-month follow-up. During this period, vomiting frequency declined in both the idiopathic and diabetic subgroups.

McCallum et al. (2010) reported on a crossover RCT evaluating GES (Enterra therapy) in patients with chronic intractable nausea and vomiting from diabetic gastroparesis (DGP). (8) In this study, 55 patients with refractory DGP (5.9 years of DGP) were given Enterra. After surgery, all patients had the stimulator turned on for 6 weeks and then were randomized to groups that had consecutive 3-month crossover periods with the device on or off. After this period, the device was turned on in all patients, and they were followed 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 was 57%. There was no significant difference in WVF between patients who had the device turned on or off during the 3-month crossover period. At 1 year, the WVF of all patients was significantly lower than baseline values (median reduction, 68%; $p<0.001$). One patient had the device removed due to infection; two required surgical intervention due to lead-related problems.

McCallum et al. (2013) evaluated GES (Enterra system) in patients with chronic vomiting due to idiopathic gastroparesis in a randomized, double-blind crossover trial. (9) In this study, 32 patients with nausea and vomiting associated with idiopathic gastroparesis, which was unresponsive or intolerant to prokinetic and antiemetic drugs, received Enterra implants and had the device turned on for 6 weeks. Subsequently, 27 of these patients were randomized to have the device turned on or off for 2 consecutive 3-month periods. Twenty-five of these subjects completed the randomized phase; of note, 2 subjects had the device turned on early, 2 subjects had randomization assignment errors, and 1 subject had missing diaries. During the initial 6-week on period, all subjects demonstrated improvements in their WVF, demonstrating a median reduction of 61.2% (5.5 episodes/week) compared with baseline (17.3 episodes/week; $p<0.001$). During the on-off crossover phase, subjects demonstrated no significant differences between the on and off phase in the study's primary end point, median WVF (median, 6.4 in on-phase vs 9.8 in off-phase; $p=1.0$). Among the 19 subjects who completed 12 months of follow-up, there was an 87.1% reduction in median WVF (2 episodes/week) compared with baseline (17.3 episodes/week; $p<0.001$). Two subjects required surgical intervention for lead migration/dislodgement or neurostimulator migration.

Table 1. Summary of Key RCT Characteristics

Study; Trial	Countries	Sites	Dates	Participants	Interventions	
					Active	**Comparator**
Ducrotte et al. (2020) (5)	France	19	2009-2013	Patients with refractory and chronic nausea and vomiting (N=172)	GES (stimulation on)	GES (stimulation off)
Abell et al. (2003) (6)	US, Canada, EU	11	NR	Patients with intractable idiopathic or diabetic gastroparesis (n=33)	GES (stimulation on)	GES (stimulation off)
McCallum et al. (2010) (8)	US	8	2002-2007	Patients with chronic intractable nausea and vomiting from diabetic gastroparesis (n=55)	GES (stimulation on)	GES (stimulation off)
McCallum et al. (2013) (9)	US	8	2002-2008	Patients with chronic vomiting due to idiopathic gastroparesis (n=32)	GES (stimulation on)	GES (stimulation off)

RCT: randomized controlled trial; U.S.: United States; EU: European Union; NR: Not Reported; GES: gastric electrical stimulation

Table 2. Summary of Key RCT Results

Study	Weekly Vomiting Frequency	Total Symptom Score	Vomiting Frequency Score
Ducrotte et al. (2020) (5)			
ON (mean ± SD)			2.2 ± 1.7
ON (median)			2
OFF (mean ± SD)			1.8 ± 1.7
OFF (median)			1
p-value			.0009
Abell et al. (2003) (6)			
ON	6.8	12.5±1.0	
OFF	13.5	13.9±1.1	
p-value	<.05	NR	
McCallum et al. (2010) (8)			

ON	3.81		
OFF	4.25		
P-value	0.215		
McCallum et al. (2013) (9)			
ON	6.38		
OFF	9.75		
P-value	1.0		

RCT: randomized controlled trial, NR: Not reported.

The purpose of the limitations tables (see Tables 3 and 4) is to display notable limitations identified in each study. This information is synthesized as a summary of the body of evidence following each table and provides the conclusions on the sufficiency of evidence supporting the position statement.

Table 3. Study Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-Up[e]
Ducrotte et al. (2020) (5)	3. Study population not representative of intended use.			4. Not established and validated measurements; 5. Clinically significant difference not prespecified.	1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.
Abell et al. (2003) (6)	2. Study population is unclear.				1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.
McCallum et al. (2010) (8)	2. Study population is unclear.				1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.
McCallum et al. (2013) (9)	2. Study population is unclear.				1. Not sufficient duration for benefit; 2. Not sufficient

					duration for harms.

The study limitations stated in this table are those notable in the current literature review; this is not a comprehensive gaps assessment.

[a] Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use.

[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest.

[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.

[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not establish and validated measurements; 5. Clinical significant difference not prespecified; 6. Clinical significant difference not supported.

[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

Table 4. Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Follow-Up[d]	Power[e]	Statistical[f]
Ducrotte et al. (2020) (5)						
Abell et al. (2003) (6)	3. Allocation concealment unclear			3. High number of crossovers	1. Power calculations not reported	
McCallum et al. (2010) (8)				3. High number of crossovers		
McCallum et al. (2013) (9)				3. High number of crossovers		

The study limitations stated in this table are those notable in the current literature review; this is not a comprehensive gaps assessment.

[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.

[b] Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.

[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.

[d] Follow-Up key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).

[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.

[f] Statistical key: 1. Intervention is not appropriate for outcome type: (a) continuous; (b) binary; (c) time

to event; 2. Intervention is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4.Comparative treatment effects not calculated.

Nonrandomized Studies

Samaan et al. (2022) compared GES to laparoscopic gastrectomy in a retrospective, single-center analysis. (10) Overall, 130 refractory patients underwent GES while 51 received laparoscopic gastrectomy. Patients receiving GES were less likely to report symptom improvement compared with gastrectomy (odds ratio [OR], 0.16; 95% CI, 0.048 to 0.532) over a mean follow-up period of 35 months. However, patients receiving gastrectomy had greater in-hospital morbidity (18% vs. 5%; p=.017) and longer hospital stays (9 days vs. 3 days (p<.001).

Laine et al. (2018) published a retrospective, multicenter analysis of patients with severe, medically refractory gastroparesis who received GES. (11) Fourteen patients (11 diabetic, 1 idiopathic, and 2 postoperative) treated in Finland between 2007 and 2015 were included; median follow-up was 3 years. Eight (57.1%) patients experienced marked relief of gastroparesis symptoms, while 3 (21.4%) patients experienced partial relief. There was a median weight gain of 5.1 kg in 11 (78.6%) patients after GES implantation, and, at last possible follow-up, 5 out of 10 (50%) patients were without medication for gastroparesis.

Shada et al. (2018) published a prospective study of patients with medically refractory gastroparesis who underwent implantation of GES between 2005 and 2016. (12) One hundred nineteen patients (64 diabetic, 55 idiopathic), with mean follow-up of 39.0 ± 32.0 months, were included in the analysis. Before GES placement, operatively placed feeding tubes were present in 22% of diabetic and 17% of idiopathic patients, however, after GES placement, 67% of feeding tubes were removed. Due to a perceived lack of benefit, 8 patients decided to have their GES device removed after a mean time of 36 ± 29 months. Also, there was significant improvement in Gastroparesis Cardinal Symptom Index (GCSI) scores for both diabetic (p=0.01) and idiopathic (p=0.003) subgroups at ≥2 years after implantation.

Section Summary: Gastric Electrical Stimulation for Gastroparesis

Many nonrandomized studies and several crossover RCTs have assessed GES for treating gastroparesis. A 2017 meta-analysis of five 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. For example, there was no significant difference in the on versus off position in symptom severity or nausea severity scores. A 2022 meta-analysis did find improvement in TSS but is limited by high heterogeneity in follow-up times, and the inclusion of a crossover RCT that included those with chronic, refractory nausea/vomiting rather than limiting to patients with gastroparesis.

Gastric Electrical Stimulation for Obesity

Clinical Context and Test Purpose

The purpose of GES is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as conservative management, medication, and bariatric surgery in patients with obesity.

The following PICO was used to select literature to inform this policy.

Populations
The relevant population of interest are individuals with obesity.

Interventions
The therapy being considered is GES.

Comparators
Comparators of interest include conservative management, medication, and bariatric surgery. Treatment includes physical exercise, low carbohydrate dieting, and low-fat dieting.

Outcomes
The general outcomes of interest are change in disease status and treatment-related morbidity.

The existing literature evaluating GES as a treatment for obesity has varying lengths of follow up, ranging from 1 year. While studies described below all reported at least one outcome of interest, longer follow-up was necessary to fully observe outcomes. Therefore, 1 year of follow-up is considered necessary to demonstrate efficacy.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess longer term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence
A single RCT has evaluated the use of GES for the treatment of obesity: the Screened Health Assessment and Pacer Evaluation (SHAPE) trial. Shikora et al. (2009) reported on a double-blind RCT that assessed GES for the treatment of obesity. (13) All 190 trial participants received an implantable gastric stimulator and were randomized to have the stimulator turned on or off. All patients were evaluated monthly, participated in support groups, and reduced their dietary intake by 500 kcal/d. At 12-month follow-up, there was no statistically significant difference in excess weight loss between the treatment group (weight loss, 11.8%) and the control group (weight loss, 11.7%) using intention-to-treat analysis (p=0.717).

Small case series and uncontrolled prospective trials (2002-2004) have reported positive outcomes for weight loss and maintenance of weight loss along with minimal complications. (14-19) However, interpretation of these uncontrolled studies is limited.

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. Data from both nonrandomized studies and crossover RCTs that have assessed GES for treating gastroparesis have shown a decrease in weekly vomiting frequency. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have obesity who receive GES, the evidence includes a 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 sham stimulation. The evidence is insufficient to determine the effects of the technology on health outcomes.

Practice Guidelines and Position Statements

National Institute for Health and Care Excellence

In 2014, the National Institute for Health and Care Excellence issued guidance on GES for gastroparesis. (20) 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.”
- 1.3 “Patient selection and follow-up should be done in specialist gastroenterology units with expertise in gastrointestinal motility disorders, and the procedure should only be performed by surgeons working in these units.”

American College of Gastroenterology

In 2022, the American College of Gastroenterology updated practice guidelines on the management of gastroparesis (21). 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)."

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this medical policy are listed in Table 5.

Table 5. Summary of Key Trials

NCT Number	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT03123809	Gastric Electrical Stimulation (GES) and Pyloroplasty for the Treatment of Gastroparesis (GES + PP)	50	May 15, 2023
NCT04121325	Gastric Electrical Stimulation for Treating Abdominal Pain in Patients With Gastroparesis	20	January 1, 2028

NCT: national clinical trial.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	43647, 43648, 43881, 43882, 64590, 64595, 95980, 95981, 95982
HCPCS Codes	C1767, E0765, L8680, L8685, L8686, L8687, L8688

*Current Procedural Terminology (CPT®) ©2023 American Medical Association: Chicago, IL.

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Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at <https://www.cms.hhs.gov>.

Policy History/Revision	
Date	**Description of Change**
10/15/2024	Reviewed. No changes.
09/15/2023	Document updated with literature review. Coverage unchanged. References 4, 5, 10, and 21 added; some updated and others removed.
04/15/2022	Reviewed. No changes.
07/01/2021	Document updated with literature review. Coverage unchanged. No new references added.
01/01/2021	Reviewed. No changes.
05/01/2019	Policy updated with literature review. Coverage unchanged. References 8-9 added.
06/15/2018	Reviewed. No changes.
07/15/2017	Document updated with literature review. Coverage unchanged.
03/15/2016	Reviewed. No changes.
03/15/2015	Document updated with literature review. Coverage unchanged.
06/01/2011	CPT/HCPCS code(s) updated
12/15/2010	Document updated with literature review. Coverage unchanged.
07/01/2008	Revised/updated entire document
07/01/2006	Revised/updated entire document
10/01/2003	CPT/HCPCS code(s) updated
08/01/2002	New medical document