


<b>MEDICAL POLICY</b>	<b>Gastric Electrical Stimulation</b>
<b>Effective Date: 1/1/2023</b>	Medical Policy Number: 107
 1/1/2023	Technology Assessment Committee Approved Date: 2/05; 1/08; 1/2010; 2/14; 2/15; 2/16
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**See Policy CPT/HCPCS CODE section below for any prior authorization requirements**

**SCOPE:**

Providence Health Plan, Providence Health Assurance, Providence Plan Partners, and Ayin Health Solutions as applicable (referred to individually as “Company” and collectively as “Companies”).

**APPLIES TO:**

All lines of business

**BENEFIT APPLICATION**

Medicaid Members

*Oregon:* Services requested for Oregon Health Plan (OHP) members follow the OHP Prioritized List and Oregon Administrative Rules (OARs) as the primary resource for coverage determinations. Medical policy criteria below may be applied when there are no criteria available in the OARs and the OHP Prioritized List.

<p><b>POLICY CRITERIA</b></p> <p>I. Gastric electrical stimulation (GES) (i.e., gastric pacing, Enterra™ Therapy) may be considered <b>medically necessary</b> when <b>all</b> of the following criteria are met (A.-C.):</p> <ul style="list-style-type: none"> <li>A. Patient has been diagnosed with chronic, intractable nausea and vomiting secondary to gastroparesis of diabetic or idiopathic etiology (see <a href="#">Policy Guidelines</a>); <b>and</b></li> <li>B. The diagnosis has been confirmed by gastric emptying scintigraphy; <b>and</b></li> <li>C. Patient is refractory or has contraindications to the use of prokinetic and antiemetic medications.</li> </ul> <p>II. Gastric electrical stimulation is considered <b>investigational and is not covered</b> when criterion I. above is not met, including, but not limited to any of the following listed contraindications or conditions (A. – I.):</p>
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<ul style="list-style-type: none"> <li>A. Treatment of obesity</li> <li>B. Gastric obstruction or pseudo-obstruction</li> <li>C. Prior gastric resection</li> <li>D. Prior fundoplication</li> <li>E. History of eating disorders</li> <li>F. History of seizures</li> <li>G. Primary swallowing disorders</li> <li>H. Chemical dependency</li> <li>I. Psychogenic vomiting</li> </ul> <p>Link to <a href="#">Policy Summary</a></p>
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**POLICY GUIDELINES**

Possible causes of gastroparesis should be reviewed prior to consideration of GES. This includes but is not limited to: uncontrolled diabetes (A1C > 7.0), heavy smoking (> 1 pack/day cigarette use or equivalent), alcohol use at 2+ drinks per day, opioid use, and cannabis use.<sup>1</sup>

**CPT/HCPCS CODES**

All Lines of Business Except Medicare	
Prior Authorization Required	
L8680	Implantable neurostimulator electrode, each
L8685	Implantable neurostimulator pulse generator, single array, rechargeable, includes extension
L8686	Implantable neurostimulator pulse generator, single array, non-rechargeable, includes extension
L8687	Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension
L8688	Implantable neurostimulator pulse generator, dual array, non-rechargeable, includes extension
All Lines of Business	
Prior Authorization Required	
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
64590	Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling

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64595	Revision or removal of peripheral or gastric neurostimulator pulse generator or receiver
C1767	Generator, neurostimulator (implantable), non-rechargeable
C1778	Lead, neurostimulator (implantable)
C1822	Generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system
C1823	Generator, neurostimulator (implantable), non-rechargeable, with transvenous sensing and stimulation leads
C1827	Generator, neurostimulator (implantable), non-rechargeable, with implantable stimulation lead and external paired stimulation controller
C1883	Adapter/extension, pacing lead or neurostimulator lead (implantable)
C1897	Lead, neurostimulator test kit (implantable)
E0765	FDA approved nerve stimulator, with replaceable batteries, for treatment of nausea and vomiting
L8679	Implantable neurostimulator, pulse generator, any type

**No Prior Authorization Required**

95980	Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient measurements) gastric neurostimulator pulse generator/transmitter; intraoperative, with programming
95981	Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient measurements) gastric neurostimulator pulse generator/transmitter; subsequent, without reprogramming
95982	Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient measurements) gastric neurostimulator pulse generator/transmitter; subsequent, with reprogramming

**Unlisted Codes**  
All unlisted codes will be reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is billed related to services addressed in this policy then **prior-authorization is required.**

43659	Unlisted laparoscopy procedure, stomach
43999	Unlisted procedure, stomach

**Medicare Only**

**Not Covered**  
The following codes are not separately payable for Medicare Plan members. See the “Centers for Medicare & Medicaid Services (CMS)” section below for more information.

L8680	Implantable neurostimulator electrode, each
L8685	Implantable neurostimulator pulse generator, single array, rechargeable, includes extension

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L8686	Implantable neurostimulator pulse generator, single array, non-rechargeable, includes extension
L8687	Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension
L8688	Implantable neurostimulator pulse generator, dual array, non-rechargeable, includes extension

**DESCRIPTION**

Gastric Electrical Stimulation (GES) for Gastroparesis

Gastroparesis is a “gastrointestinal motility disorder defined by delayed gastric emptying without evidence of physical obstruction.”<sup>2</sup> The most common causes of gastroparesis include diabetes, surgery, and opioids, but up to 40% of cases remain idiopathic (i.e. gastroparesis of unknown cause).<sup>3</sup> Typically, gastroparesis produces symptoms of nausea, vomiting (usually of undigested food), and early satiety (feeling full after eating only a small amount of food). Patients with uncontrolled, chronic nausea and vomiting may eventually become severely dehydrated and malnourished; thus requiring hospitalization for fluid restoration and nutritional support. The first line treatment for gastroparesis relies on dietary modifications and pharmaceutical treatment. However, 30-40% of patients are refractory and require additional treatment options.<sup>3</sup>

Gastric electrical stimulation (GES) (i.e., gastric pacing) is a surgical treatment for chronic, intractable nausea and vomiting secondary to gastroparesis. GES works by delivering timed electrical impulses to the gastric muscles to stimulate gastric activity; therefore, improving stomach emptying and relieving symptoms. The device consists of electrodes and a pulse generator, which are implanted on to the greater curvature of the stomach (electrodes) and in an abdominal wall pocket (pulse generator). The electrodes then deliver electrical stimulation to the stomach according to pre-operatively programmed parameters in the pulse generator.

Gastric Electrical Stimulation (GES) for Obesity

Although the potential mechanism of action is unknown, GES has been purported as a surgical treatment for morbid obesity. Research indicates the electrical stimulation of the device might reduce biochemicals involved in appetite and satiety; thus producing early satiety with subsequent reduced food intake and weight loss.

**REVIEW OF EVIDENCE**

A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding 70 of gastric electrical stimulation as a treatment of chronic gastroparesis. Below is a summary of the available evidence identified through May 2022.

**Gastric Electrical Stimulation (GES) for Gastroparesis**Systematic Reviews

- In 2021, Shiu and colleagues reviewed short-term outcomes of different modalities of pyloromyotomy versus gastric electrical stimulation in the treatment of gastroparesis.<sup>4</sup> Three studies totaling 196 participants who had received 4 interventions (including single per-oral pyloromyotomy (POP), double OPO, laparoscopic pyloromyotomy, and GES) were eligible for analysis. GES showed a reduction in frequency in nausea and vomiting in diabetic and non-diabetic patients with gastroparesis-like syndrome or gastroparesis, although GES did not improve either gastric emptying or quality of life. Limited benefits from GES in patients with idiopathic gastroparesis exist due to the requirement of surgical implantation, subsequent pacemaker adjustment or battery replacement, variable clinical response rates, and device-associated removal rates, all of which are factors which may negatively affect the clinical application of GES.

The authors concluded that double POP demonstrated better clinical success with similar recurrence and complication rates. Additionally, GES displayed a borderline significance of recurrence in comparison to single POP. There were no differences in the remainder of the comparisons. Shiu et al. discussed the following limitations of the study including differing outcome differences, assessments, and follow-up periods; lack of exploration of publication bias; small sample sizes; exclusion of combination treatment studies; and sparse number of clinical trials. The authors urge that further multicenter prospective studies are needed.

- In 2021, Rajamanuri and colleagues completed a systematic review of the therapeutic role of gastric pacemakers in adults with gastroparesis.<sup>5</sup> A total of 12 studies were included in this review, comprising mostly of retrospective studies, reviews, an observational study, and three randomized control trials. The authors note that although most studies suggest a significant improvement in quality of life and GCSI scores, a few others suggest that there is no substantial change in the quality of life because of GES itself. However, the evidence supporting no difference in the quality of life seems stronger, as shown by the meta-analysis and randomized controlled trials vs. open-label trials that showed positive results for quality of life with gastric pacing. The authors conclude that the gastric pacemaker can potentially be used for managing gastroparesis, but there is currently limited supporting evidence and more research is required to harness the full ability of this device to improve the symptoms and, therefore, quality of life of patients with gastroparesis.
- In 2018 (updated 2021), Hayes published an evidence review evaluating the clinical utility of gastric electrical stimulation (GES) for gastroparesis.<sup>2</sup> The review included 12 studies (3 randomized crossover trials, 6 pretreatment/posttreatment studies, 1 nonrandomized comparative study, 1 comparative cohort study, and 1 compilation of case series). The sample sizes ranged from 18 to 233 patients and follow-up times varied from 1 month to 4.7 years. The primary outcomes of interest were gastroparesis symptom severity, gastric retention, health-related quality of life (HRQOL), body weight, need for nutritional support, medication use, hospitalization for severe symptoms, complications and mortality.

The results of the nonrandomized studies indicate GES may relieve gastroparesis symptoms, improve gastric emptying, HRQOL, jejunostomy-tube usage, weight gain, and medication use; and may eliminate or reduce the need for nutritional support. However, these studies were deemed to be of very poor to fair quality due to significant methodological limitations. In contrast, the

randomized trials (n=32-55) found no difference in GES efficacy when the device was turned on versus when it was turned off. Only one study demonstrated a statistically significant improvement in vomiting frequency, and no studies demonstrated a statistically significant improvement in HRQOL. The Hayes review theorized this could be due to lack of a washout period between the on and off phases, carryover effects, and masked GES effects. Compared to baseline, 3 studies (n=113-255) reported partial or complete relief of symptoms in 70-80% of patients, and 2 studies demonstrated statistically significant reductions in mean symptom scores (follow-up: 1.4 to 4.7 years). The same studies reported a statistically significant 91% decrease in patients' need for enteral nutrition; an 89% decrease in jejunostomy-tube usage; and a 35% improvement in mean QOL score.

Hayes rated the body's overall quality of evidence as "large in size and low in quality," due to inconsistent findings and methodological limitations in individual studies (e.g. small sample sizes, lack of control groups, high attrition rates, and inadequate follow-up periods). However, based on positive findings from the nonrandomized studies and the inconclusive results from the randomized studies, Hayes gave a "C" rating (potential but unproven benefit) for GES for the treatment of drug-refractory gastroparesis. Hayes also indicated the need for additional good-quality randomized controlled trials with a placebo or device comparator to evaluate the efficacy and safety of GES for gastroparesis.

- In 2019, ECRI conducted an evidence review assessing the safety and efficacy of the Enterra II Therapy System for the treatment of gastroparesis.<sup>6</sup> Searching the literature through April 2019, 7 studies were ultimately included for review. Outcomes of interest included symptoms, nutrition, additional treatments, and AEs at one- to five-year follow-up in patients with intractable gastroparesis. Follow-up ranged from 1 to 3 years. One systematic review was inconclusive because of low study quality and variable outcome reporting methods. Studies reported symptom relief with GES, complications in 5% to 15% of patients, and few serious adverse events. Three prospective (n = 380, n = 119, n = 151) and two retrospective (n = 266, n = 113) case series reported that 45% to 80% of patients experienced symptom relief at one- to three-year follow-up; 67% to 75% of patients with feeding aids returned to normal eating. However, 11% to 12% of patients required Enterra removal, and up to 58% required additional interventions for gastroparesis. One retrospective, nonrandomized study (n = 103) reported that more patients achieved relief with gastrectomy (87%) than with Enterra (67%). Across all studies, reported adverse event (AE) and complication rates were 5% to 15%. Investigators concluded that while many studies suggest some efficacy and symptom relief in some patients, evidence for Enterra II remains "inconclusive" given studies' lack of control groups, randomization, or blinding; retrospective design; and single-center focus.
- In 2017, Levinthal and colleagues conducted a systematic review and meta-analysis evaluating gastric electrical stimulation (GES) for gastroparesis.<sup>7</sup> Independent reviewers systematically identified eligible studies, assessed quality, and extracted data. The outcomes of interest were changes in total symptom severity (TSS) score, adverse events (AE) related to the device, perioperative mortality, and reoperations and/or device removals.

The authors identified 5 publications which used a randomized double-blind cross-over design to evaluate the effect of GES on gastroparesis. Randomization was done by assigning patients to periods with and without activation of the stimulator. Follow-up duration varied from 8 days to 6 months. The authors identified an additional 13 nonrandomized studies that examined the GES

effects on gastroparesis symptoms prior to and after activation of the stimulator. The results of the randomized studies indicated no significant difference in symptoms severity between the GES on versus off states for vomiting frequency, nausea severity, satiety, and bloating. In contrast, the results of the nonrandomized studies showed statistically significant reductions in post-operative total symptoms severity scores when compared to baseline scores.

In regards to AEs, a total of 7 publications included AE data and reported rates of 8.7% during the immediate post-operative time period (within 30 days). Of 1,176 operations, the in hospital mortality rate was 1.4% within 30 days post-GES operation. Studies with longer-term follow-up also reported rates of 8.4% for device removal and 11.1% for repeated operations related to the implanted stimulator.

Strengths of this study include the systematic gathering of evidence, assessment of quality, extraction of data by several independent authors, and the assessment of heterogeneity prior to conducting a meta-analysis. Limitations were identified in the low quality of selected studies and potential publication bias due to the exclusion of non-English studies and studies before 1990. The authors noted a limitation in the conflicting results between the randomized and nonrandomized studies, and theorized this was due to bias in the nonrandomized studies. Due to the conflicting results, the authors concluded, “a call to caution is especially important considering the cost and the potential surgical complication after GES with a resulting need for repeated interventions.”<sup>7</sup>

- In 2015, Lal et al. conducted a systematic review to evaluate gastric electrical stimulation (GES) with the Enterra™ System.<sup>8</sup> Independent reviewers systematically identified eligible studies, assessed quality, and extracted data. The outcomes of interest were gastroparesis symptom scores, gastric emptying time, nutritional status, quality of life, medication usage, weight, and BMI. Due to significant heterogeneity between studies, meta-analysis was not appropriate.

The authors identified 21 studies eligible for inclusion, of which 3 were crossover studies and 18 were prospective cohort studies. Due to the nonrandomized design of most studies, overall risk of bias was determined to be medium to high. Although not always statistically significant, all studies indicated symptom improvement in patients implanted with GES. In regards to gastric emptying, seven studies reported a significant improvement in time to gastric emptying while 7 studies showed no significant change in gastric emptying time. The authors also noted that patients in some studies continued to use prokinetics during the study, which might have confounded the results. All publications reported an improvement in quality of life, especially in the physical and mental components. Although hospital admission rates were reduced after GES, only one study found a significant reduction in the post-operative use of prokinetics and antiemetics. Device related complications occurred in 5% to 14% of patients, and were commonly due to infection, migration or erosion of the device, and dislodged electrodes.

Strengths of this study include the use of PRISMA methodology for conducting the systematic collection of evidence, the assessment of bias using the Cochrane review guidelines, and quality assessment using CONSORT guidelines. Limitations were identified in the poor quality of selected studies and the inability to conduct a meta-analysis due to significant heterogeneity. The authors concluded that the current evidence shows some clinical utility; however, “high-quality, large clinical trials are needed to establish the efficacy of this therapy and to identify the patients for whom this therapy is inappropriate.”<sup>8</sup>

### Randomized Controlled Trials (RCTs)

In 2020, Ducrotte and colleagues conducted a multicenter, randomized double-blind trial with crossover to study the efficacy of gastric electric stimulation (GES) in patients with refractory vomiting, with or without gastroparesis.<sup>9</sup> In total, 172 patients were implanted with a GES device, which was left unactivated until patients were randomly assigned to groups that received 4 months of stimulation or no stimulation (control group.) Of the 172 patients, 149 patients crossed over to the other group after 4 months. Patients were examined at the end of each 4-month period (at 5 and 9 months after implantation). Primary endpoints were vomiting score, ranging from 0 (daily vomiting) to 4 (no vomiting), and the quality of life, assessed by the Gastrointestinal Quality of Life Index scoring system. Secondary endpoints were changes in other digestive symptoms, nutritional status, gastric emptying, and control of diabetes. During both phases, vomiting scores were superior in the group with the device activated (median score, 2) than the control group (median score, 1;  $P < .001$ ), in diabetic and nondiabetic patients. However, gastric emptying did not differ between groups, and the treatment group did not experience an increased quality of life. Adverse events were also common (26.1% of patients who received implants). Limitations included the use of a nonvalidated, nonlinear 5-point vomiting frequency scale, lack of patients with gastroparesis, and a lack of established patient selection criteria.

Four additional RCTs were identified that evaluated gastric electrical stimulation in drug-refractory gastroparesis patients.<sup>10-13</sup> All studies were selected for inclusion in the systematic reviews described above.

### Nonrandomized Studies

- In 2016, Heckert and colleagues conducted a prospective cohort study to determine the effectiveness of gastric electric stimulation (GES) for treatment for refractory symptoms of gastroparesis, the improvement in specific symptoms of gastroparesis, and clinical factors impacting on outcome.<sup>14</sup> A total of 151 patients with refractory gastroparesis (72 diabetic, 73 idiopathic, and 6 other) were recruited to undergo GES and followed-up for 1 year. The outcomes of interest were changes in baseline symptom severity scores (measured using the PGI-SYM: Patient Assessment of Gastrointestinal Disorders Symptom Severity Index) and the therapeutic response (measured using the CPGAS: Clinical Patient Grading Assessment Scale).

A total of 13 patients were lost to follow-up. Of the 138 patients with follow-up data, 75% showed some level of improvement in CPGAS scores and 43% were at least moderately improved. Both diabetic and idiopathic patients showed clinical improvement; however, improvement was statistically significantly higher in diabetic patients when compared to idiopathic patients. The most symptom improvement after GES was seen in nausea, loss of appetite, and early satiety. The results also indicated vomiting improved in both diabetic and idiopathic patients; however, diabetic patients had a significantly greater reduction. Strengths of this study include the increased sample size and extended follow-up period. Limitations were identified in the nonrandomized observational design, lack of objective outcome measures, and losses to follow-up.

- Two additional nonrandomized studies were identified that assessed gastric electrical stimulation in drug-refractory gastroparesis patients.<sup>15,16</sup> Both studies were selected for inclusion in the systematic reviews described above.



**Gastric Electrical Stimulation (GES) for Obesity**

A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of gastric electrical stimulation as a treatment of obesity. Below is a summary of the available evidence identified through May 2022.

Systematic Reviews

- In 2021 Maisiyiti and Chen completed a systematic review on gastric electrical stimulation in obesity treatment.<sup>17</sup> A total of 11 articles covering GES use in obesity treatment were reviewed. The authors conclude that implantable gastric stimulation (IGS) is an appropriate therapy for obesity treatment as this method is designed to suppress food intake and induce satiety by interrupting the normal gastric pace-making activity and therefore inhibiting contractions and delaying gastric emptying. This device utilizes trains of short pulses and has almost no effects on gastric motility, instead acting on central neuronal and hormonal activities. However, no medical device is currently available to perform IGES and therefore no long-term clinical data is available to support that the animal data can be accurately translated into humans and IGES is indeed a viable therapy for obesity. The authors conclude that there is great potential to use GES for treating obesity, however more research and device development is needed.
- In 2014, Cha et al. conducted a systematic review to evaluate gastric electrical stimulation to treat obesity.<sup>18</sup> Independent reviewers systematically identified eligible studies, assessed quality, and extracted data. The outcomes of interest included weight loss, changes in satiety/appetite, gastric emptying rate, blood pressure, neurohormone levels or biochemical markers (e.g., ghrelin or HbA1c), and safety. Due to significant heterogeneity between studies, meta-analysis was determined to be inappropriate.

The authors identified 30 studies eligible for inclusion, most of which were nonrandomized (n=26). All studies were determined to be of poor quality due to very small sample sizes (most had fewer than 30 participants) and very high attrition rates (most had more than 50% drop-out by the end of the trial). Almost all studies indicated statistically significant weight loss during the first 12 months. Only a small proportion of studies evaluated long-term efficacy beyond one year, and found maintenance of weight loss. Significant reductions were also identified in Hb1Ac levels and blood pressure. Results were inconsistent regarding neurohormone levels or biochemical markers and gastric emptying rates. Gastric penetration was the most common complication during implantation; however, all studies reported that this was corrected immediately without any serious consequences. Other complications reported were lead dislodgement and/or lead failure and batter problems.

Strengths of this study include the systematic review of literature following a pre-defined protocol and evaluation of methodological quality by two independent reviewers. Strength was also found in the assessment of heterogeneity to determine the appropriateness of conducting a meta-analysis. Limitations were identified in the poor quality of selected studies (small sample sizes, and high attrition rates), lack of randomized controlled trials, and the inability to conduct a meta-analysis. The authors concluded, "GES holds great promises to be an effective obesity treatment; however, stronger evidence is required through more studies with a standardized way of carrying out trials and reporting outcomes, to determine the long-term effect of GES on obesity."<sup>18</sup>

### Randomized Controlled Trials (RCTs)

Two RCTs were identified that evaluated gastric electrical stimulation for the treatment of obesity.<sup>19,20</sup> Both studies were selected for inclusion in the systematic review described above.

### Nonrandomized Studies

Five nonrandomized studies were identified that assessed gastric electrical stimulation in drug-refractory gastroparesis patients.<sup>21-26</sup> All but one of these studies<sup>26</sup> were selected for inclusion in the systematic review described above.

## CLINICAL PRACTICE GUIDELINES

### **Gastric Electrical Stimulation (GES) for Gastroparesis**

#### National Institute for Health and Care Excellence (NICE)

The 2014 NICE evidence-based clinical practice guideline on gastroelectrical stimulation for gastroparesis stated, “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.”<sup>27</sup> The NICE guideline also recommends further research on the long-term effects and durability of the procedure.

#### American College of Gastroenterology (ACG)

The 2013 ACG evidence-based clinical practice guideline (update currently in progress) for the management of gastroparesis stated, “GES may be considered for compassionate treatment in patients with refractory symptoms, particularly nausea and vomiting (conditional recommendation, moderate level of evidence).”<sup>28</sup>

The guideline also recommended documentation of delayed gastric emptying with scintigraphy (strong recommendation, high level of evidence) before treatment with gastric electrical stimulation (strong recommendation, moderate level of evidence).

### **Gastric Electrical Stimulation (GES) for Obesity**

No clinical practice guidelines were identified regarding the use of gastric electrical stimulation for the treatment of obesity.

## CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS)

As of May 25, 2022, no specific Medicare coverage policy or guidance (e.g., manual, national coverage determination [NCD], local coverage determination [LCD] article [LCA], etc.) was identified for the Company’s service area which addresses gastric electrical stimulation. In the absence of a NCD, LCD, or other Medicare policy, Medicare guidelines allow a Medicare Advantage Organization (MAO) to make coverage determinations, applying an objective, evidence-based process, based on authoritative

evidence. (*Medicare Managed Care Manual, Ch. 4, §90.5*)<sup>29,30</sup> Therefore, this Company coverage review will be applied for medical necessity decision-making.

Under Medicare, only medically reasonable and necessary services are covered (*Title XVIII of the Social Security Act, §1862(a)(1)(A)*). Procedures, devices, or other medical technologies which lack scientific evidence regarding safety and efficacy because they are investigational or experimental are considered **“not medically reasonable or necessary” for Medicare Plan members**. (*Medicare Claims Processing Manual, Ch. 23, §30 A*).

### Implantable Neurostimulator Devices

#### *Pulse Generator HCPCS Codes*

Effective January 1, 2014, HCPCS codes L8685, L8686, L8687, and L8688 (Implantable neurostimulator pulse generator codes) were removed from the 2014 DMEPOS fee schedule file to reflect the change in the coverage indicator to “invalid” for Medicare (Coverage indicator of “I”)<sup>31</sup> and thus, these HCPCS codes are considered invalid for Medicare Advantage use as well. However, HCPCS code L8679 (*Implantable neurostimulator, pulse generator, any type*) was added to the HCPCS and DMEPOS fee schedule file effective January 1, 2014 to use for billing Medicare claims that were previously submitted under L8685, L8686, L8687 and L8688. While HCPCS codes L8685, L8686, L8687 and L8688 will be denied as not separately billable for Medicare Plan members, HCPCS code L8679 can be used instead.

#### *Electrode HCPCS Code*

Effective April 1, 2014, HCPCS code L8680 (*Implantable neurostimulator electrode, each*) was also removed from the 2014 DMEPOS fee schedule file and the coverage indicator revised to not payable by Medicare (Coverage indicator of “I”). According to Medicare, practitioners (physicians) should not report for electrode(s) in conjunction with a lead implantation procedure furnished in any setting because Medicare considers payment for electrodes to be incorporated in the allowance assigned to the surgical procedure CPT code.<sup>32</sup> Therefore, HCPCS codes L8680 will also be denied as not separately billable for Medicare Plan members.

#### *General*

Coverage indicators assigned by Medicare to HCPCS codes can be found on the [Medicare HCPCS Quarterly Updates website](#).

## POLICY SUMMARY

There is enough evidence to suggest that gastric electrical stimulation (GES) may improve chronic, intractable nausea and vomiting in patients with gastroparesis that has not responded to other methods of treatment, such as pharmaceutical management. There is a significant lack of effective treatment options for patients with debilitating gastroparesis; therefore, GES may be appropriate in carefully selected patients with gastroparesis. There is not enough evidence on the efficacy and safety of GES for treating morbid obesity. Also, GES is only FDA-approved for the treatment of chronic, intractable (drug refractory) nausea and vomiting secondary to gastroparesis of diabetic or idiopathic etiology; therefore, the use of GES for obesity would be an inappropriate use of the device.

## INSTRUCTIONS FOR USE

Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Companies reserve the right to determine the application of Medical Policies and make revisions to Medical Policies at any time. Providers will be given at least 60-days notice of policy changes that are restrictive in nature.

The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement.

## REGULATORY STATUS

### Mental Health Parity Statement

Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

### U.S. Food and Drug Administration

The Enterra Therapy System (Medtronic, Inc.) is the only gastric electrical stimulation device for gastroparesis treatment approved by the U.S. Food and Drug Administration.<sup>33</sup> The device received approval on March 31, 2000, under a Humanitarian Device Exemption (HDE).

### *Humanitarian Device Exemption (HDE)<sup>34,35</sup>*

HDE is a special FDA approval that allows a device to be marketed on a limited basis provided that:

1. The device is used to treat or diagnose a disease or condition that affects or is manifested in fewer than 4,000 individuals in the United States per year
2. The device would not be available to a person with such a disease or condition unless the exemption is granted
3. No comparable device is available to treat or diagnose the disease or condition; and
4. The device will not expose patients to an unreasonable or significant risk of illness or injury, and the probable benefit to health from using the device outweighs the risk of injury or illness from its use, taking into account the probable risks and benefits of currently available devices or alternative forms of treatment

HDE applications are not required to contain the results of scientifically valid clinical investigations demonstrating that the device is effective for its intended purpose. The application, however, must contain sufficient information for FDA to determine that the device does not pose an unreasonable or

significant risk of illness or injury. The labeling must also indicate that the effectiveness of the device for the specific indication has not been demonstrated.

Humanitarian use devices may only be used in facilities that have obtained an institutional review board (IRB) approval to oversee the usage of the device in the facility, and after an IRB has approved the use of the device to treat or diagnose the specific rare disease. The HDE holder (defined as the person who or entity that obtains the approval of an HDE from FDA) is responsible for ensuring that a device approved under an HDE is administered only in facilities having an IRB constituted and acting in accordance with the FDA's regulation governing IRBs (21 CFR Part 56), including continuing review of use of the device.

*Enterra™ Therapy System Indications/Contraindications for Use*<sup>33</sup>

Indications:

- For the treatment of chronic, intractable (drug-refractory) nausea and vomiting secondary to gastroparesis of diabetic or idiopathic etiology.

Contraindications:

- Gastric obstruction or pseudo-obstruction
- Prior gastric resection
- Prior fundoplication
- History of eating disorders
- History of seizures
- Primary swallowing disorders
- Chemical dependency
- Psychogenic vomiting

The manufacturer also states that the safety of the Enterra™ device has not been established for patients who are pregnant or for those who are under the age of 18 or over the age of 70. Also, the Enterra™ system may be affected by or adversely affect cardiac pacemakers, cardioverters/defibrillators, external defibrillators, magnetic resonance imaging (MRI), ultrasonic equipment, electrocautery, radiation therapy, and theft detectors.

Note: There is currently no U.S. FDA approved gastric electrical stimulation device for the treatment of obesity.

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