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Originated Department	Medical Management

Gastric Pacing

Audience
Providers, Members, Brokers, MHC

Purpose

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Definition

Gastric electrical stimulation, or electrostimulation, is electrical stimulation of the stomach wall muscle. It has been approved for treating gastroparesis, a chronic gastric motility disorder characterized by nausea, vomiting, bloating, and abdominal distension. Chronic and severe gastroparesis may be associated with dehydration, poor nutritional status, and poor glycemic control in diabetics.

Gastroparesis is most commonly found as a complication of diabetes. It is also found in chronic pseudo-obstruction, connective tissue disorders, Parkinson's disease, and psychological pathology.

Prokinetic agents such as metoclopramide, erythromycin, and antiemetic agents such as metoclopramide, granisetron, or ondansetron are used to treat gastroparesis. When severe, the patient may require enteral or total parental nutrition.

The Enterra™ Therapy System manufactured by Medtronic is the only gastric electrical stimulator approved by the U.S. Food and Drug Administration (FDA) for the treatment of chronic refractory gastroparesis. The FDA has not approved any gastric pacemaker for the treatment of obesity.

Policy/Procedure

1. **Mountain Health Co-Op considers gastric pacing/gastric stimulation medically necessary when ALL of the following criteria are met:**
   - **1.1** The patient has chronic gastroparesis diagnosed by one of the following methods:
     - **a)** Gastric scintigraphy
     - **b)** Breath Testing if scintigraphy is not feasible or non-diagnostic
     - **c)** The patient is refractory to or intolerant of medical management duration, including:
       - **i.** Dietary modification for >6 months
       - **ii.** A trial of the following agents has failed to resolve all symptoms after a trial of at least 12 weeks duration:
         - Prokinetic agents (i.e. metoclopramide)
         - Antiemetic agents (i.e. ondansetron, granisetron)
         - Erythromycin
   - **1.2** Mechanical Obstruction has been excluded by endoscopy or UGI series
   - **1.3** Other medications considered noncontributory AND one of the following:
     - **a)** >2 hospital admissions or Emergency Department visits for severe vomiting and dehydration within the last 12 months
     - **b)** Unable to achieve glycemic control due to gastroparesis
     - **c)** Patient has required enteral or total parental nutrition for poor nutritional status during the past year
     - **d)** Weight loss >10% in last 6 months related to gastroparesis
     - **e)** Persistent daily nausea/vomiting for >6 months
   - **1.4** Device is FDA-approved

2. **Mountain Health Co-Op does NOT cover gastric pacing or gastric stimulation for any other indication, including for the treatment of autonomic nervous disorders, cyclic vomiting syndrome, obesity, and gastrointestinal dysmotility disorders other than gastroparesis, as they are considered experimental/investigational.**

3. Clinical Rationale

3.1 In 2015, Lal et al. conducted a systematic review of GES using the Enterra System. The final review consisted of 21 out of 53 potentially relevant studies published since 2003; eighteen were prospective cohort studies, and 3 were crossover studies. The overall risk of bias was considered medium to high in the majority of studies. The main reason was the frequency of nonrandomized trials, which tend to have a higher risk of bias. There was a variation in the methods used to assess the improvement in symptoms in the patients with GES implants. The most used measures were the Total Symptom Score (TSS), Gastroparesis Cardinal Symptom Index (GCSI), Monthly and Weekly Vomiting Frequency, Monthly and Weekly Nausea Frequency, and Gastrointestinal Symptoms Rating Scale (GSRS). All studies investigating gastric emptying used a 2-hour and 4-hour Gastric Emptying Test (GET) after a low-fat meal. The studies in this systematic review included various outcome measures and preoperative assessments, making it difficult to combine data and offer firm conclusions. The evidence base for using GES in gastroparesis is limited, with a total of just five months of blinded, randomized study that included only 83 patients. However, accepting the limitations of the evidence base, most studies reported an improvement in symptomology and quality of life with GES. An improvement in gastric emptying was seen in most studies, with only two failing to demonstrate an improvement. However, except for one study, improved gastric emptying did not correlate with improved symptomology. In conclusion, the authors found that while current evidence has shown a degree of efficacy in these patients, further high-quality, large clinical trials are needed to establish this therapy's efficacy and identify the patients for whom this therapy is inappropriate.

3.2 In 2017, Levinthal and Bielefeldt published a systematic review and meta-analysis to demonstrate whether GES effectively reduces symptoms in patients with gastroparesis. Five studies randomly allocated patients to periods with or without GES. Total symptom severity (TSS) scores did not differ between these periods (0.17 [95% confidence interval: -0.06 to 0.4]; $p = 0.15$). However, sixteen open-label studies of GES showed a significant TSS decrease (2.68 [2.04-3.32]; $q = 39.0$; $p < 0.001$). Other treatment modalities similarly improved TSS by 1.97 [1.5-2.44] for medical therapy (MED), by 1.52 [0.9-2.15] for placebo arms (PLA), and by 2.32 [1.56-3.06] for botulinum toxin (BTx). There were significant differences in baseline TSS ratings among these studies (GES: 6.28 [6.28-7.42]; MED: 4.76 [4.09-5.42]; PLA: 4.59 [3.77-5.42]; BTx: 6.02 [5.3-6.74]; $q = 35.1$; $p < 0.001$). Meta-regression analysis showed these baseline differences significantly impacted TSS ratings during treatment ($q = 71.8$; $p < 0.001$). The authors concluded that independent of the treatment modality, baseline symptom severity impacts treatment results in gastroparesis, and considering the skewed population with refractory symptoms, regression to the mean likely contributes to the substantial discrepancies between the reported results of controlled and open-label GES studies.

3.3 In a 2021 systematic review of the therapeutic role of gastric pacemakers in adults with gastroparesis, Rajamanuri et al. assessed 12 studies, which included data on adults with medically refractory gastroparesis that required gastric electrical stimulation therapy, and found that the studies showed varying effects of GES on gastroparesis symptoms like nausea, vomiting, and abdominal bloating. The review

determined that there was significant weight gain noted based on the evidence in the studies they reviewed and that, while most of the studies suggested a significant improvement in the quality of life and the Gastroparesis Cardinal Symptom Index (GCSI) scores, the evidence supporting no difference in the quality of life seemed stronger, as shown by the meta-analysis and randomized controlled trials (RCTs) vs. open-label trials that showed positive results for quality of life with gastric pacing. Other beneficial effects of GES were found, including reductions in inflammatory indicators, improved metabolic hormone levels and improved mucosal electrogram frequencies over baseline sustained for over six months. The authors noted that their review was limited due to the inclusion of open-labeled studies. Therefore, further RCTs were recommended to analyze the impact of gastric pacemakers in the improvement of symptoms in patients with gastroparesis, studies that evaluate the efficacy for the different causes of gastroparesis, such as diabetes, idiopathic and post-surgical, and future studies that include the pediatric population.

3.4 In a 2016 single-center cohort case series, Heckert et al. evaluated the effectiveness of GES with Enterra® for treatment for refractory symptoms of gastroparesis, the improvement in specific symptoms of gastroparesis, and clinical factors impacting on outcome of 151 patients with refractory gastroparesis. Gastroparesis patients (n = 151; (120 females) with refractory gastroparesis (72 diabetic, 73 idiopathic, 6 other) underwent GES with Enterra® (Medtronic). Patients filled out a symptom severity questionnaire (PAGI-SYM) before insertion. At each follow-up visit, the patient filled out PAGI-SYM and assessed their therapeutic response using the Clinical Patient Grading Assessment Scale (CPGAS). The authors concluded that GES improved symptoms in 75% of patients, with 43% at least moderately improved. Response in diabetics was better than in nondiabetic patients. Nausea, loss of appetite, and early satiety responded the best. However, the unknown length of study follow-up did not allow for intermediate and long-term outcomes assessment. The lack of a comparison group limits the conclusions that can be derived from this study.

3.5 In 2020, Ducrotte et al., completed a multicenter, double-blind RCT with crossover analyzing the efficacy of GES in patients with refractory vomiting, with or without gastroparesis. Patients included in the study (n=172) had chronic vomiting and/or nausea > 12 months that was related to type 1 or 2 diabetes mellitus, related to a surgical procedure (partial gastric resection surgery and/or vagotomy), or was idiopathic. Participants had regular or delayed gastric emptying with symptoms that were refractory to treatment and severe enough to affect the patient's general condition. They also didn't have evidence of a mechanical obstruction within the digestive tract or neurologic disease. Patients were randomized to either the ON/OFF group (n=79) with four months of active stimulation followed by four months of sham stimulation or the OFF/ON group (n=93) with four months of sham stimulation followed by four months of active stimulation. They were assessed at the end of each four months (five and nine months after implantation). Primary endpoints measured were the 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 diabetes control. The final

analysis of the intention-to-treat (ITT) population was conducted on 66 patients in the ON/OFF group and 83 in the OFF/ON group. During both phases of the crossover study, vomiting scores were significantly higher in the group with the device on than in the control group ($p<0.001$) in diabetic and nondiabetic patients. Vomiting scores increased significantly when the device was ON in patients with delayed ($p<0.01$) or regular gastric emptying ($p=0.05$). Gastric emptying was not accelerated during the ON period compared with the OFF period.

3.6 Having the GES turned on was not associated with increased quality of life. A total of 101 adverse events were reported in the study, with 45 therapy or device-related events: abdominal wall pain at the implantation site (n=28), infections at the abdominal pouch level (n=16), and hematoma (n=1). In three cases, the device-related adverse events were severe enough to prompt device removal. The authors found that GES is effective in reducing the frequency of refractory vomiting and nausea in a subset of patients with chronic vomiting. Furthermore, robust studies are needed to determine the predictive factors that lead to favorable responses.

3.7 In 2018, Hayes (updated 2022) published a Health Technology Assessment (HTA) on the safety and efficacy of GES for gastroparesis following their review of 12 studies, including 3 randomized crossover trials (RCTs), six pretreatment/post-treatment studies, one non-randomized comparative study, one comparative cohort study and one compilation of case series. The Hayes HTA stated that the effectiveness of GES for treating chronic gastroparesis remains uncertain, as findings have not provided consistent evidence. They also noted that the available randomized studies provide little confirmation of the apparent benefit seen in unblinded studies. The report stated that GES appears safe in most patients, but serious complications can occur, including the movement of the stimulator and/or the electrical leads following implantation. The device removal rates in the studies reviewed were between 7% - 12%. The overall quality of the evidence for treating gastroparesis with GES was low due to the individual study limitations and inconsistency in the findings. The authors concluded that 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.

3.8 Several specialty societies have weighed in on gastric pacing. The American College of Gastroenterology (ACG) issued updated guidelines in 2022 stating, “GES may be considered for control of gastroparesis (GP) symptoms as a humanitarian use device (HUD). Documented clinical usefulness in both idiopathic gastroparesis (IG) and diabetic gastroparesis (DG) suggests there is a role for GES following its HUD approval” as defined by the Food and Drug Administration (FDA). However, this conditional recommendation was based on a low-quality body of evidence (Camilleri, 2013, updated 2022).

3.9 Additionally, the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK): The NIDDK states that gastric electrical stimulation is only used to treat people with gastroparesis due to diabetes or unknown causes and may be effective for those people whose nausea and vomiting do not improve with dietary changes or medications (NIDDK, 2018).

3.10 The National Institute for Health and Care Excellence (NICE) stated in 2014 that it supports the use of GES for gastroparesis. They stated that current evidence on

the safety and efficacy of GES is adequate to support its use as an option for treating chronic, intractable nausea and vomiting secondary to gastroparesis, with normal arrangements for clinical governance, consent, and audit. Further publications providing data about the effects of the procedure on symptoms in the long term and on device durability would be useful.

3.11 The Enterra™ Therapy System (Medtronic Inc., Minneapolis, MN) is a GES that received U.S. Food and Drug Administration (FDA) marketing approval as a Class III medical device under the Humanitarian Device Exemption (HDE) on March 31, 2000. It is indicated for the treatment of chronic, intractable (drug refractory) nausea and vomiting secondary to gastroparesis of diabetic or idiopathic etiology. This system has not been evaluated for patients under age 18 or over 70 (FDA, 2000b). According to the FDA, HUD is a device intended to benefit patients by treating or diagnosing a disease or condition that affects fewer than 4000 individuals in the United States annually. An HDE application is not required to contain the results of scientifically valid clinical investigations demonstrating that the device is effective for its intended purpose. However, the application, must contain sufficient information for the FDA to determine that the device does not pose an unreasonable or significant risk of illness or injury and that the probable benefit to health outweighs the risk of injury or illness from its use, taking into account the likely risks and benefits of currently available devices or alternative forms of treatment. Additionally, the applicant must demonstrate that no comparable devices are available to treat or diagnose the disease or condition and that they could not otherwise bring the device to market (FDA, 2018).

Applicable Codes

CPT Codes

Possibly Covered Codes

43647	Laparoscopy, surgical; implantation or replacement of gastric neurostimulator electrodes, antrum
43648	Laparoscopy, surgical; revision or removal of gastric neurostimulator electrodes, antrum
43881	Laparoscopy, surgical; revision or removal of gastric neurostimulator electrodes, antrum
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
64595	Revision or removal of peripheral or gastric neurostimulator pulse generator or receiver

Non-Covered Codes

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
C1820	Generator, neurostimulator (implantable), with rechargeable battery and charging system
C1822	Generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system
E0765	FDA approved nerve stimulator, with replaceable batteries, for treatment of nausea and vomiting
L8679	Implantable neurostimulator, pulse generator, any type

Vendors

- **Personify**
- **HPS**

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Review/Revision/Approval History	
Date	Description
06/01/2024	**New Policy**
3/16/2026	**Revised by Mountain Health CO-OP Policy Committee**

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