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Medical Policy Manual

Topic: Gastric Electrical Stimulation

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Section: Surgery

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IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

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 or idiopathic etiology. Gastric electrical stimulation is also proposed as a treatment of obesity. The device may also be referred to as a gastric pacemaker.

A subcutaneously implanted pulse generator delivers electrical stimulation to the stomach via intramuscular leads that are implanted on the outer surface of the greater curvature of the stomach either laparoscopically or during a laparotomy, Stimulation parameters are typically programmed at an “on time” (ON) (e.g., 0.1 second) alternating with an “off time” (OFF) (e.g., 5.0 seconds).

Gastric Stimulation for the Treatment of Intractable Nausea and Vomiting Due to 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 diabetics. While most commonly associated with diabetes, gastroparesis is also found in chronic pseudo-obstruction, connective tissue disorders, Parkinson disease, and psychological pathology. Treatment of gastroparesis includes prokinetic agents such as metoclopramide, and antiemetic agents such as

metoclopramide, granisetron, or ondansetron. Severe cases may require enteral or total parenteral nutrition.

Gastric Stimulation for the Treatment of Obesity

GES has also been investigated as a treatment of obesity as a technique to increase a feeling of satiety with subsequent reduced 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. Presently, there are no GES devices approved by the FDA for the treatment of obesity.

Regulatory Status

The Enterra™ Therapy System (formerly named Gastric Electrical Stimulation [GES] System; manufactured by Medtronic) is the only device approved for treatment of chronic refractory gastroparesis. It received approval for marketing from the US Food and Drug Administration (FDA) in 2000 through the humanitarian device exemption (HDE) process. This process requires the manufacturer to provide adequate information for the FDA to determine that the device has "probable" benefit but does not pose an unreasonable or significant risk; it does not require data confirming the efficacy of the device. The HDE process is available for devices treating conditions that affect less than 4,000 Americans per year.

No devices have received FDA approval for use as a treatment of obesity.

MEDICAL POLICY CRITERIA

I. Gastric electrical stimulation may be considered **medically necessary** in the treatment of chronic intractable nausea and vomiting secondary to gastroparesis of diabetic, idiopathic or post-surgical etiology when all of the following criteria are met:

   A. Significantly delayed gastric emptying as documented by standard scintigraphic imaging of solid food

   B. Patient is refractory or intolerant of 2 out of 3 classes of prokinetic medications and 2 out of 3 antiemetic medications. (see Appendices for classes)

   C. Patient's nutritional status is sufficiently low that weight has decreased to 90% or less of normal body weight for a patient's height and age in comparison with pre-illness weight.

II. Gastric electrical stimulation is **investigational** for all other indications including but not limited to the treatment of obesity.

SCIENTIFIC EVIDENCE[1]

Gastric Stimulation for the Treatment of Intractable Nausea and Vomiting Due to Gastroparesis

The published literature consists of 1 randomized controlled trial and a number of nonrandomized trials.

Systematic Reviews

In a 2012 systematic review and meta-analysis, Chu and colleagues evaluated 10 studies on Gastric Electrical Stimulation (GES) for the treatment of gastroparesis.[2] Included in the meta-analysis were 2 randomized controlled trials (RCTs) by Abell[3] and McCallum[4] and 8 observational studies, totaling 601 patients that received GES for more than one month. The treatment arms of the RCTs were combined with the single arm case series to give summary estimates of treatment effect. This review did not attempt to evaluate the RCTs separately from the case series, and therefore did not attempt to make conclusions on the efficacy of GES compared to a control group.

The meta-analysis found gastric electrical stimulation significantly improved scores for total symptom severity, nausea severity and vomiting severity. Gastric emptying times at 2 and 4 hours also significantly improved. In the sub-analysis of 197 patients with diabetic gastroparesis, total symptom severity scores and gastric emptying at 2 and 4 hours significantly improved. In the sub-analysis of 65 patients with idiopathic gastroparesis, total symptom severity scores and gastric emptying at 4 hours significantly improved but not at 2 hours. In the sub-analysis of 40 patients with post-surgical gastroparesis, total symptom severity scores and gastric emptying at 2 hours significantly improved but not at 4 hours. A sub-analysis of nausea and vomiting severity scores was not presented. Infection (3.87%) was the most common complication followed by device migration (2.69%) and pain at the site of implant (0.67%). Other infrequent complications (1.18%) included peptic ulcer disease, electrode penetration of the stomach lumen, erosion of the skin after abdominal wall trauma and implant wire related small bowel obstruction. While this meta-analysis found GES provided significant benefit in gastroparesis treatment, interpretation of results must be made with caution since the majority of studies analyzed were low-quality observational studies. Only two studies had control groups, and the control groups of these RCTs were not included in the combined analysis.

Randomized Controlled Trials (RCTs)

- The data presented to the FDA documenting the "probable benefit" of the GES (Enterra™) system was based on a multicenter double-blind cross-over study referred to as the Worldwide Anti-Vomiting Electrical Stimulation Study (WAVESS).[5] The study included 33 patients with intractable idiopathic or diabetic gastroparesis. The primary endpoint of the study 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. The baseline vomiting frequency was 47 episodes per month, which significantly declined in both ON and OFF groups to 23 and 29 episodes, respectively. However, there were no significant differences in the number of vomiting episodes between the 2 groups, suggesting a placebo effect.

  After the first 2 months of therapy, patients were asked which month of the cross-over stimulation they preferred. Twenty one of the 33 patients selected the ON mode as their preferred month, compared to 7 who preferred the OFF mode, and 5 who had no preference. The greater preference for ON stimulation suggested some short-term effect that was not placebo.

  In a continuing open phase of the trial, the patients then received the stimulation consistent with their preference. However, by 4 months all patients had the device turned ON (it was not clear whether this phase was by preference or design). At 6 and 12 months' follow-up, the mean number of vomiting episodes continued to decline, although only 15 patients were followed for a period of 12 months. Data regarding quality of life were also obtained at 6 and 12 months and showed

improvement. At 6 months, there was a significant improvement in 2-hour gastric retention (from 80% retention to 60% retention), but not in 4-hour gastric retention. (Fifty percent gastric retention at 2 hours was considered the upper limits of normal.)

The results of the randomized portion of the study suggest a placebo effect. Therefore, long-term results of GES must be validated in a longer-term randomized trial. It is interesting to note that GES did not return gastric emptying to normal in the majority of the patients tested. In as much as the device is intended to improve gastric emptying, as a proof of principle, it would be interesting to investigate the correlation between the degree of gastric emptying and symptom improvement.

In an update to WAVESS, Abell and colleagues reported 12-month outcomes for all of the patients.[3] Statistically significant improvements were found for weekly vomiting frequency, total abdominal symptom score, and scintigraphic solid food emptying. At baseline the median vomiting frequency was 17.3 episodes per week with gastroparetic symptoms over a mean of 6.2 years. All patients had scintigraphic evidence of delayed gastric emptying at 2 and 4 hours, all patients were refractory to prokinetic and antiemetic medications, and 14 required some form of parenteral or enteral feedings. Results at the end of phase 1 (the blinded phase) showed a 50% decreased vomiting frequency for patients whose devices were ON compared to patients whose devices were OFF ($p=0.05$).

Symptom severity trended toward improvement in the ON versus OFF period, although these changes did not reach statistical significance in phase 1. In a second phase of the study all patients were switched to the ON position with 6- and 12- months follow-up. Vomiting at 12 months was compared to baseline; 72% for the combined group, 63% for diabetics with gastroparesis, and 83% for patients with idiopathic gastroparesis. Total symptom score improved significantly ($p<0.05$) at 6 and 12 months. Physical and mental quality of life scores improved significantly compared to baseline (p= less than 0.025). Baseline gastric retention was 78% at 2 hours. This decreased significantly with electrical stimulation to 65% at 6 months and 56% at 12 months for the combined group. The changes in 2-hour gastric emptying were not significant for the diabetic and idiopathic groups separately. Four-hour gastric emptying improved from 34% retention at baseline to 22% retention at 12 months. The difference was statistically significant for the combined group as well as the diabetic and idiopathic groups separately.

- McCallum and colleagues performed a multicenter prospective study to evaluate Enterra therapy in patients with chronic intractable nausea and vomiting from diabetic gastroparesis (DGP).[4] In this study, 55 patients with refractory DGP (5.9 years of DGP) were implanted with the Enterra system. After surgery, all patients had the stimulator turned ON for 6 weeks and then were randomly assigned to groups that had consecutive 3-month cross-over periods with the device ON or OFF. After this period, the device was turned ON in all patients and they were followed up 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 difference in WVF between patients who had the device turned ON or OFF during the 3-month cross-over period. At 1 year, the WVF of all patients was significantly lower than baseline values (median reduction, 68%; $P < 0.001$). One of the patients had the device removed due to infection; 2 patients required surgical intervention due to lead-related problems.

Nonrandomized Trials

- In 2013, Keller and colleagues reported complication rates and need for a second surgery in 233 patients who had GES implantation surgery over a ten year period at a single institution.[6] Additional surgery was required in 58% of patients. The majority of reoperations were due to the following complications: nutritional access (45 patients, requiring 77 procedures), subcutaneous pocket issues (n = 21), gastroparetic symptoms (n = 11), mechanical issues (n = 9) and infection (n = 4). The study reported that patient BMI was predictive of additional surgeries, with 4.45 overall increased risk of pocket revision surgery. Although 70% of patients reported improved symptoms of pain, bloating and nausea, GES had a significantly high reoperation rate due to complications associated with the initial procedure.

- Anand and colleagues reported on a study of 214 consecutive drug-refractory patients with the symptoms of gastroparesis (146 idiopathic, 45 diabetic, 23 after surgery).[7] A GES device was implanted in 156 patients. The remaining 58 patients, designated as the control group, were either on the waiting list for permanent implantation or consented to not receive a permanent implant. At last follow-up (median 4 years), most patients who received implants (135 of 156) were alive with intact devices, significantly reduced gastrointestinal symptoms, and improved health-related quality of life, with evidence of improved gastric emptying. Also, 90% of the patients had a response in at least 1 of 3 main symptoms. Most patients that explanted, usually for pocket infections, were later successfully reimplanted.

- GES placement using minimally invasive surgical approaches has also been evaluated in several publications. Laparoscopy has been reported in at least two studies as a feasible approach in placement of GES for patients with medically refractory diabetic or idiopathic gastroparesis[8,9].

- Several small case series and retrospective reviews have been reported, some with long-term outcomes up to 5 years.[8,10-22] The data indicated that GES may be associated with improvements in gastrointestinal symptom scores, nutrition and quality-of-life for patients; these improvements were sustained over time. However, gastric emptying rates were mixed.

Gastric Stimulation for the Treatment of Obesity

There are no randomized controlled trials on GES for the treatment of obesity. Small clinical trials have reported positive outcomes in weight loss and maintenance of weight loss along with minimal complications.[23-26] However, due to lack of long-term outcomes from well-designed randomized clinical trials, conclusions cannot be made concerning the safety and efficacy of chronic gastric stimulation as a treatment for morbid obesity. In addition, there are no GES devices with FDA approval for the treatment of obesity.

Clinical Practice Guidelines

American College of Gastroenterology (ACG)[27]

The American College of Gastroenterology published a clinical practice guideline on management of gastroparesis in 2013. The recommendations for this guideline were based on review of the evidence-base through 2011. The ACG concluded that GES treatment does not adequately address the clinical needs of these patients, but that, "GES may be considered for compassionate treatment in patients with refractory symptoms, particularly nausea and vomiting. Symptom severity and gastric emptying have been shown to improve in patients with diabetic gastroparesis (DG), but not in patients with idiopathic

gastroparesis (IG) or postsurgical gastroparesis (PSG). (Conditional recommendation, moderate level of evidence.)."

American Gastroenterological Association (AGA)[28]

- The 2004 consensus statement on gastroparesis from the AGA included GES in a list of possible treatments in patients refractory to initial treatment with dietary changes and medications. However, no specific recommendations were provided and no update of this position statement was found.
- The statement noted that, "as this type of treatment evolves further delineation of the overall effectiveness, the type of patient who will likely respond, optimal electrode placement, and stimulus parameters should be explored."

The American Society for Parenteral and Enteral Nutrition (ASPEN) and the Society of Critical Care medicine (SCCM)[29]

In 2009, a joint ASPEN/SCCM guideline defined protein-calorie malnutrition as recent weight loss of >10%-15% or actual body weight <90% of ideal body weight.

Summary

There are limited studies investigating the use of gastric electrical stimulation (GES) in the treatment of patients with intractable nausea and vomiting due to gastroparesis. Although gastric emptying rates were mixed, long-term follow-up suggested improvements in gastrointestinal symptom scores, nutrition, and quality-of-life scores. Thus, given the lack of treatment options in this very specific patient population, GES may be medically necessary for the treatment of severe gastroparesis in patients with low nutritional status when other treatment modalities have failed.

The quality of the evidence remains limited regarding gastric electrical stimulation for the treatment of obesity. Well-designed, adequately powered, randomized controlled trials are needed to determine whether gastric electrical stimulation is a safe and effective treatment for obesity. In addition, there are no GES devices with FDA approval for the treatment of obesity. Therefore, GES as a treatment for obesity is considered investigational.

Appendix 1: Prokinetic Medications	
Class	**Common Examples**
Cholinergic Agonists	dexpanthenol (Ilopan®), bethanechol (Urecholine®)
Motolin receptor agonists	erythromycin
Dopamine receptor antagonists	metoclopramide (Reglan®)
Appendix 2: Antiemetic Medications	

Class	Common Examples
Antihistamines	diphenhydramine (Benadryl®), dimenhydrinate (Dramamine®), meclizine (Antivert®), hydroxyzine (Vistaril®), trimethobenzamide (Tigan®)
Serotonin ($5HT_3$) receptor antagonists	ondansetron (Zofran®), granisetron (Kytril®), dolasetron (Anzemet®)
Dopamine receptor antagonists	Metoclopramide (Reglan®), perphenazine (Trilafon®), prochlorperazine (Compazine®), promethazine (Phenergan®), thiethylperazine (Torecan®), cyclizine (Marezine®)

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CROSS REFERENCES

Bariatric Surgery; Surgery, Policy No. 58

CODES	NUMBER	DESCRIPTION
The CPT code book instructs that, after January 1, 2012, procedures related to gastric stimulation electrodes for morbid obesity should be reported using code unlisted procedure codes 43659 for laparoscopic approach and 43999 for open laparotomy approach.		
CPT	43647	Laparoscopy, surgical; implantation or replacement of gastric neurostimulator electrodes, antrum
	43648	Laparoscopy, surgical; revision or removal of gastric neurostimulator electrodes, antrum
	43659	Unlisted laparoscopy procedure, stomach
	43881	Implantation or replacement of gastric neurostimulator electrodes, antrum, open
	43882	Revision or removal of gastric neurostimulator electrodes, antrum, open
	43999	Unlisted procedure, stomach
	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
	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	; subsequent, without programming
	95982	; subsequent, with reprogramming
HCPCS	E0765	FDA approved nerve stimulator, with replaceable batteries, for treatment of nausea and vomiting
	L8679	Implantable neurostimulator, pulse generator, any type

CODES	NUMBER	DESCRIPTION
	L8680	Implantable neurostimulator electrode, each
	L8685	Implantable neurostimulator pulse generator, single array, rechargeable, includes extension
	L8686	; non-rechargeable, includes extension
	L8687	Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension
	L8688	; non-rechargeable, includes extension