7.01.73 Gastric Electrical Stimulation

Section 7.0 Surgery
Effective Date 11/26/2014

Subsection
Original Policy Date December 7, 2006
Next Review Date November 2015

Description
Gastric electrical stimulation is performed using an implantable device designed to treat chronic drug-refractory nausea and vomiting secondary to gastroparesis of diabetic, idiopathic, or postsurgical etiology. Gastric electrical stimulation has also been investigated as a treatment of obesity. The device may be referred to as a gastric pacemaker.

Related Policies
- Sacral Nerve Neuromodulation/Stimulation
- Electrical Stimulation for Pain
- Neuromuscular and Functional Electrical Stimulation
- Deep Brain Stimulation
- Spinal Cord Stimulation

Policy
Gastric electrical stimulation is considered investigational for the treatment of gastroparesis of diabetic, idiopathic, or postsurgical etiology.
Gastric electrical stimulation is considered investigational for the treatment of obesity.

Policy Guidelines
There are CPT codes that are specific to insertion of the gastric stimulation device:
- 43647: Laparoscopy, surgical; implantation or replacement of gastric neurostimulator electrodes, antrum
- 43648: 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
• 64595: Revision or removal of peripheral or gastric neurostimulator pulse generator or receiver

There are also specific codes for electronic analysis and programming of gastric neurostimulator pulse generator:

• 95980: Electronic analysis of implanted neurostimulator pulse generator system (e.g., 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 reprogramming

• 95982: subsequent, with reprogramming

Prior to 2012, when the procedure was performed in the treatment of obesity, there were specific category III CPT codes:

• 0155T: Laparoscopy, surgical; implantation or replacement of gastric stimulation electrodes, lesser curvature (i.e., morbid obesity)

• 0156T: Revision or removal of gastric stimulation electrodes, lesser curvature (i.e., morbid obesity)

• 0157T: Laparotomy, implantation or replacement of gastric stimulation electrodes, lesser curvature (i.e., morbid obesity)

• 0158T: Laparotomy, revision or removal of gastric stimulation electrodes, lesser curvature (i.e., morbid obesity)

The CPT book instructs that after January 1, 2012, laparoscopic procedures related to gastric stimulation electrodes for morbid obesity should be reported using code 43659 (unlisted laparoscopy procedure, stomach), and laparotomy procedures related to gastric stimulation electrodes for morbid obesity should be reported using 43999 (unlisted procedure, stomach).

The insertion of the gastric neurostimulator pulse generator is coded with 64590 and revision or removal of the pulse generator is coded with 64595, regardless of the indication.

The following HCPCS codes may be used:

• L8680: Implantable neurostimulator electrode, each (implant requires 2 leads)

• 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
Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program (FEP)) prohibit Plans from denying Food and Drug Administration (FDA) - approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

Rationale

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's disease, and psychological pathologic conditions. Some cases may not be associated with an identifiable cause, and are referred to as idiopathic gastroparesis. 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 electrical stimulation, 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 that are implanted during laparoscopy or open laparotomy. (See “Regulatory Status” section.)

Gastric electrical stimulation 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 neuro-hormonal modulation and/or stomach muscle stimulation. There are no gastric electrical stimulation devices approved by the FDA for the treatment of obesity. The Transcend® Implantable Gastric Stimulation device, manufactured by Transneuronix Corporation and acquired by Medtronic in 2005, is currently available in Europe for treatment of obesity. Medtronic announced in December 2005 that the preliminary results of the Screened Health Assessment and Pacer Evaluation, or SHAPE trial, which was initiated by Transneuronix using the Transcend device, “did not meet the efficacy endpoint of a difference in mean excess weight loss at one year.”

Regulatory Status

Currently, only one gastric electrical stimulator has received approval from the U.S. Food and Drug Administration (FDA) (see note below), the Gastric Electrical Stimulator (GES) system (now called Entera™ Therapy System), manufactured by Medtronic, Inc.
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 second.

Note: It should be noted that The GES system received FDA approval through a humanitarian device exemption in March 2000 (HDE Approval H990014). This regulatory category was established in 1996 and only applies to devices intended to benefit fewer than 4000 patients. The approval process is similar to that of a premarket approval application (PMA) but is exempt from the effectiveness requirements of a PMA. Thus the application is not required to include results of scientifically valid clinical investigations but must contain sufficient information for the FDA to determine that the device does not pose unreasonable or significant risk of illness or injury. A humanitarian use device may only be used in facilities that have an institutional review board (IRB) to supervise clinical testing of the device.

Literature Review

Permanent Gastric Electrical Stimulation for Gastroparesis

The evidence on gastric electrical stimulation (GES) for gastroparesis consists of 3 small randomized crossover trials, and numerous case series. The case series include several that report on medium and/or long-term use (>1 year of follow-up) of the device.

Systematic Reviews

In a 2012 systematic review and meta-analysis, Chu et al evaluated 10 studies on GES for the treatment of gastroparesis. Included in the meta-analysis were 2 randomized controlled trials (RCT) by Abell et al and McCallum et al and 8 observational studies, totaling 601 patients who received GES for more than 1 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 with 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 subanalysis of 197 patients with diabetic gastroparesis, total symptom severity scores and gastric emptying at 2 and 4 hours significantly improved. In the subanalysis 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 subanalysis of 40 patients with postsurgical gastroparesis, total symptom severity scores and gastric emptying at 2 hours significantly improved but not at 4 hours. A subanalysis 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, because most studies...
analyzed were low-quality observational studies. Only 2 studies had control groups, and the control groups of these RCTs were not included in the combined analysis.

**Randomized Controlled Trials**

The data presented to the U.S. Food and Drug Administration (FDA) documenting the "probable benefit" of the GES system was based on a multicenter, double-blinded crossover study, the Worldwide Anti-Vomiting Electrical Stimulation Study (WAVESS). The study included 33 patients with intractable idiopathic or diabetic gastroparesis. The primary end point 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 to 29 episodes, respectively. However, no significant differences were found in the number of vomiting episodes between the 2 groups, suggesting a placebo effect.

The final results of the WAVESS study were reported in 2003. Among those with idiopathic gastroparesis, there was a similar drop in vomiting frequency compared with baseline regardless of whether the device was turned on or off, suggesting a placebo effect. In contrast, in those with diabetic gastroparesis, compared with baseline, there was a small drop in vomiting frequency with the device turned off, compared with a larger drop in vomiting frequency with the device turned on. In the second open-label phase of the trial, all patients had their stimulators turned on for the remainder of the 6 to 12 months' follow-up. During this period, the vomiting frequency declined in both the idiopathic and diabetic subgroups. The cause of this continuing decline is uncertain, related to either a placebo effect or some sort of long-term effect of gastric stimulation.

McCallum et al performed a multicenter prospective study to evaluate GES (Enterra therapy) in patients with chronic intractable nausea and vomiting from diabetic gastroparesis (DGP). In this study, 55 patients with refractory DGP (5.9 years of DGP) were given implants of 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 crossover 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 crossover 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.

In a later study, McCallum et al evaluated GES (Enterra system) in patients with chronic vomiting due to idiopathic gastroparesis in a randomized, double-blind crossover trial. 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% compared with baseline (17.3 episodes/week at baseline vs 5.5 episodes/week at 6
week postimplant, \( p < 0.001 \)). 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 the on phase vs 9.8 in the 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 compared with baseline (17.3 episodes/week at baseline vs 2 episodes/week at 12-month follow-up, \( p < 0.001 \)). Two subjects required surgical intervention for lead migration/dislodgement or neurostimulator migration.

**Section Summary.**

Three small, crossover RCTs have been performed on GES for gastroparesis. In addition to being small in numbers, these RCTs have methodologic limitations including the use of a crossover design that may limit the ability to maintain successful blinding. In each RCT, patients in both of the treatment groups improved, but none of the studies demonstrated differences between groups during the crossover phases. Therefore, it is not possible to determine whether the improvement was due to GES treatment or due to a placebo effect.

**Case Series**

Anand et al reported on 214 consecutive drug-refractory patients with the symptoms of gastroparesis (146 idiopathic, 45 diabetic, 23 postsurgery) who consented to participate in a variety of clinical research and clinical protocols at 3 centers from January 1992 through January 2005, resulting in 156 patients implanted with a GES device and 58 patients as controls.\(^6\) 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 who were explanted, usually for pocket infections, were later successfully reimplanted.

In a case series of 12 patients receiving a gastric stimulation device, Abell et al reported rapid improvement in nutritional parameters (e.g., body mass index, serum albumin).\(^2\) Forster et al reported on their experience at a single institution among 55 patients with gastroparesis, as documented by gastric retention.\(^7\) While the total symptom score improved, gastric emptying did not change. The authors reported significant improvements in upper gastrointestinal symptoms, health-related quality of life, nutritional status, glucose control, and hospitalizations at 6 and 12 months in a retrospective review of 48 adult patients with diabetes who received a gastric electrical stimulation implant.\(^6\) The review also noted that gastric emptying was not significantly faster. Similarly, van der Voort et al reported that 17 patients with diabetic gastroparesis experienced a decrease in nausea and vomiting and an improvement in glucose control in a prospective case series examining the 12-month outcomes.\(^8\)

Several case series have evaluated GES in children. Teich et al reported significant improvement after GES placement in symptoms of nausea and vomiting among 16 children with functional dyspepsia and gastroparesis who failed medical therapy.\(^9\) Another case series of 24 children with functional dyspepsia and/or gastroparesis who failed medical therapy reported improvements in quality of life after GES placement.\(^10\)

The durability of GES treatment was evaluated in several publications. Lin et al reported on outcomes beyond 3 years in patients receiving GES for gastroparesis.\(^11\) Of 55 patients, 10 died of nonpacemaker-related complications, 6 had the devices removed, and 2 could not be reached. In the remaining 37 patients, symptoms, hospital days, and the use of medications had sustained reductions (from baseline) beyond 3 years. Mason et
al reported on the 20-month follow-up of 27 of 29 patients referred for gastrectomy who instead received GES for refractory gastroparesis. Three patients required additional procedures due to poor outcomes. Nutritional support was discontinued in the 19 patients who were dependent on supplemental feeding before the procedure. Gastric emptying rates improved. McCallum et al reported on long-term follow-up for 188 patients who received a GES and had at least 1 year of follow-up visits. This sample was drawn from a total of 221 patients treated with a GES system between 1 and 11 years before the study. The authors report that symptoms, hospitalizations, and medication use all improved over the time period of the study. The percent of patients with at least 50% improvement in symptoms was 58% for diabetic patients, 53% for postsurgical gastroparesis, and 48% for idiopathic disease. A total of 13 patients (7%) had their device removed due to infection. Hamson et al reported results from a cohort of 15 patients with idiopathic or diabetic gastroparesis who developed recurrent symptoms after an initial GES placement who had symptom improvement after replacement GES surgery. Recurrent symptoms developed an average of 48 months after the initial procedure. Patients demonstrated improvements in an investigator-derived gastroparesis symptoms core following device replacement compared with baseline (17.3 prereplacement vs 13.6 postreplacement, p=0.017). The magnitude of the symptom score reduction was similar to that seen in a retrospectively-identified comparison cohort of 15 patients who had a response to an initial GES implant (15.8 presurgery vs 12.3 postsurgery, p=0.011.)

GES placement using minimally invasive surgical approaches has also been evaluated in several publications. Laparoscopy has been reported in at least 2 studies as a feasible approach in placement of GES for patients with medically refractory diabetic or idiopathic gastroparesis.

Section Summary.

Numerous case series and uncontrolled studies on GES have been published. These studies generally report improvements in symptoms following treatment. However, this evidence is insufficient to draw conclusions because of the lack of control groups and the possibility that improvement is due to a placebo effect and/or other nonspecific factors.

Permanent Gastric Electrical Stimulation for Obesity

There has only been 1 RCT published on GES for the treatment of obesity: the SHAPE trial. In 2009, Shikora et al reported on a randomized controlled, double-blind study to evaluate GES for the treatment of obesity. All 190 patients participating in the study 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 diet by 500-kcal/day. At 12 month follow-up, there was no difference in excess weight loss between the treatment group (weight loss of 11.8% +/- 17.6%) and the control group (weight loss of 11.7% +/- 16.9%) using intention-to-treat analysis (p=0.717).

Small case series and uncontrolled prospective trials have reported positive outcomes in weight loss and maintenance of weight loss along with minimal complications. However, interpretation of these uncontrolled studies is limited. In conclusion, given the available evidence including the results of the SHAPE RCT, GES for the treatment of obesity is considered investigational.
**Temporary Gastric Electrical Stimulation**

Several trials were identified that evaluated the use of a temporary gastric stimulator. Temporary stimulators are intended to be used to determine whether or not a patient will respond to GES before undertaking a permanent implant. Temporary stimulators involve the endoscopic placement of a mucosal electrode, which is subsequently connected to the GES pulse generator system, which is carried externally by the patient.

2013, Lahr et al reported significant improvement during temporary GES (placement for at least 4 days) in 95 drug-refractory patients with symptoms of gastroparesis (abdominal pain, bloating, early satiety, nausea, vomiting). For the entire group of patients, abdominal pain decreased from a baseline of 2.95 on a 0 to 4 modified Likert scale to 1.12 after temporary GES (p<0.001). In a subset of patients reporting severe pain at baseline (n=68), as defined by a score of 3 to 4 on the pain scale, mean pain scores decreased from 3.62 to 1.29 (p<0.001). There were also reductions of similar magnitude on symptom scores for early satiety, abdominal distension, nausea, and vomiting.

Abell et al performed a trial of temporary GES in 58 patients with 1 of 3 etiologies (idiopathic, diabetic, postsurgical). A temporary device was placed in all patients with the device turned on or off for 4 consecutive days, followed by crossover to the other group for an additional 4-day period. The frequency of vomiting decreased in both groups. At day 3, the decrease in vomiting was significantly greater for the GES group; however, by day 8, the differences between groups were no longer significant.

Andersson et al tested a temporary GES in 27 patients with drug-refractory nausea/vomiting. Fourteen patients were treated with temporary GES in open-label fashion, and 13 had a randomized, crossover trial in which the device was turned on for 12 to 14 days and off for 12 to 14 days. These authors reported that most patients (22/27) improved following GES placement. Of the 13 patients in the randomized crossover phase, 6 had improvement in symptoms during the on period and 7 did not. Of the 7 patients who did not improve during the on period, there was improvement with an increased intensity of stimulation.

Elfvin et al treated 3 children with intractable vomiting who were younger than 3 years-old with a temporary GES. There were no adverse events of GES placement. All 3 children responded to the temporary GES and were implanted with a permanent device. Following permanent placement, all 3 children reported at least a 50% reduction in vomiting episodes.

Jayanthi et al selected a cohort of 71 patients with idiopathic (n=44), diabetic (n=14), or postsurgical (n=13) gastroparesis to undergo temporary GES (placement of a transvenous pacing wire at the junction of the gastric body and antrum), 51 of whom had undergone temporary GES placement at the time of publication. Of those, 39 had a good response to temporary GES placement and were referred for permanent GES, which was completed in 35 patients. Among 31 patients with available follow-up at a median of 10 months, 22 patients (71%) had at least 50% symptom improvement.

**Ongoing Clinical Trials**

A search of online database ClinicalTrials.gov identified the following studies (comparative and noncomparative) related to the use of gastric electrical stimulation that are currently enrolling subjects:
Gastric Pacemaker Implantation for Gastroparesis (HUD) (NCT00568373) – This is a noncomparative protocol for the use of the Enterra GES system under FDA’s Humanitarian Use Device (HUD). The protocol includes patients with intractable nausea and vomiting secondary to gastroparesis of diabetic or idiopathic etiology who have tried and failed conventional treatment (drug therapy and dietary modification). Enrollment is planned for 40 subjects; the planned study completion date is December 2016.

Escalating Temporary Gastric Electrical Stimulation (GES) for Severe Gastroparesis (TempGES) (NCT02164591) – This is a prospective, observational study to evaluate outcomes after placement of a temporary gastric electrical stimulation device among patients with severe gastroparesis. Enrollment is planned for 200 subjects; the planned study completion date is December 2016.

Medico-economic Evaluation of ENTERRA Therapy (NCT00903799) – This is a randomized, double-blind crossover study of gastric electrical stimulation with the Enterra device in patients with idiopathic, postsurgical, or diabetic gastroparesis with nausea and/or vomiting that is refractory to prokinetic agents. Outcomes related to health and healthcare utilization will be evaluated. Enrollment is planned for 220 subjects; the planned study completion date is November 2015.

Gastric Electrical Stimulation (GES) for the Treatment of Obesity (NCT01823705) – This is a nonrandomized safety and feasibility study to evaluate a new device, the Exilis Implantable Gastric Electrical Stimulation device, for the treatment of obesity. Enrollment is planned for 30 subjects; the planned study completion date is September 2016.

Summary

Gastric electrical stimulation is performed using an implantable device designed to treat chronic drug-refractory nausea and vomiting secondary to gastroparesis of diabetic, idiopathic or postsurgical etiology. The device may be referred to as a gastric pacemaker. Gastric electrical stimulation has also been studied for the treatment of obesity.

The evidence on the use of gastric electrical stimulation to treat gastroparesis is inadequate to permit conclusions about its efficacy. Three small randomized studies have been published on the treatment of gastroparesis. In one randomized study, only 33 patients recruited from 11 centers in the United States were included. There was no statistically significant improvement in symptoms for the entire study group compared with placebo, but positive results were reported for the subgroup of 17 patients with diabetic gastroparesis. In the second randomized study of 55 patients, weekly vomiting frequency was significantly lower than baseline values at one-year follow-up, but there was no difference in weekly vomiting frequency between patients who had the device turned on or off during the 3-month crossover period. The third study reported improvements in vomiting frequency at 6 weeks and 12 months of follow-up compared with baseline, but did not demonstrate differences in weekly vomiting frequency between patients who had the device turned on or off during the 3-month crossover period. The case series report improvements in symptoms, nutritional parameters, and quality of life. However, the lack of a control group precludes the conclusion that these changes are due to treatment with gastric electrical stimulation, given the variable natural history of gastroparesis, and the expected placebo effect. Therefore, gastric electrical stimulation for the treatment of gastroparesis of diabetic, idiopathic, or postsurgical etiologies is considered investigational.
There has only been 1 published randomized study on gastric electrical stimulation for the treatment of obesity (SHAPE trial), which did not show any improvement in weight loss with gastric electrical stimulation. Case series publications are limited and insufficient to draw conclusions on health outcomes. Given the results of the SHAPE trial, gastric electrical stimulation for the treatment of obesity is considered investigational.

**Practice Guidelines and Position Statements**

In 2014, the National Institute for Health and Care Excellence issued guidelines on gastroelectric stimulation for gastroparesis that made the following recommendations:

- Current evidence on the efficacy and safety of gastric electrical stimulation for gastroparesis is adequate to support the use of this procedure with normal arrangements for clinical governance, consent, and audit.
- During the consent process, clinicians should inform patients considering gastric electrical stimulation for gastroparesis that some patients do not get any benefit from it. They should also give patients detailed written information about the risk of complications, which can be serious, including the need to remove the device.
- Patient selection and follow-up should be done in specialist gastroenterology units with expertise in gastrointestinal motility disorders, and the procedure should only be performed by surgeons working in these units.
- Further publications providing data about the effects of the procedure on symptoms in the long term and on device durability would be useful.

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 evidence on GES consisted of the 2 randomized crossover trials and the case series, as previously described. The recommendation for GES was 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 DG [diabetic gastroparesis], but not in patients with IG [idiopathic gastroparesis] or PSG [postsurgical gastroparesis]. [Conditional recommendation (there is uncertainty about trade-offs), moderate level of evidence (further research would be likely to have an impact on the confidence in the estimate of effect).]”

**U.S. Preventive Services Task Force Recommendations**

Gastric electrical stimulation is not a preventive service.

**Medicare National Coverage**

There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

**References**


**Documentation Required for Clinical Review**

- History and physical including: previous treatment plan and response
- Multidisciplinary evaluation
- Operative report(s)

**Coding**

This Policy relates only to the services or supplies described herein. Benefits may vary according to benefit design; therefore, contract language should be reviewed before applying the terms of the Policy. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement.
The following services are considered investigational and therefore not covered for any indication.

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ICD Procedure

For dates of service on or after 10/01/2015

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Medical Policy

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Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

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Definitions of Decision Determinations

**Medically Necessary:** A treatment, procedure or drug is medically necessary only when it has been established as safe and effective for the particular symptoms or diagnosis, is not investigational or experimental, is not being provided primarily for the convenience of the patient or the provider, and is provided at the most appropriate level to treat the condition.

**Investigational/Experimental:** A treatment, procedure or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

**Split Evaluation:** Blue Shield of California / Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a Split Evaluation, where a treatment, procedure or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Prior Authorization Requirements

This service (or procedure) is considered **medically necessary** in certain instances and **investigational** in others (refer to policy for details).

For instances when the indication is **medically necessary**, clinical evidence is required to determine **medical necessity**.
For instances when the indication is investigational, you may submit additional information to the Prior Authorization Department.

Within five days before the actual date of service, the Provider MUST confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should also be directed to the Prior Authorization Department. Please call 1-800-541-6652 or visit the Provider Portal www.blueshieldca.com/provider.

The materials provided to you are guidelines used by this plan to authorize, modify, or deny care for persons with similar illness or conditions. Specific care and treatment may vary depending on individual need and the benefits covered under your contract. These Policies are subject to change as new information becomes available.