Gastric Electrical Stimulation

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DESCRIPTION

Gastric electrical stimulation (GES), also referred to as gastric pacing/gastric pacemaker, is performed using an implantable device designed to y treat chronic drug-refractory nausea and vomiting secondary to gastroparesis. Gastric electrical stimulation (GES) has also been investigated as a treatment of obesity.

Gastric Electrical Stimulation for Gastroparesis

Gastric electrical stimulation (GES) as a treatment for gastroparesis is thought to help control the chronic nausea and vomiting associated with gastroparesis by stimulating the smooth muscles of the lower stomach. 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.

Gastroparesis is a chronic disorder of gastric motility characterized by delayed gastric emptying of solids in the absence of mechanical obstruction. It can frequently result from longstanding diabetes mellitus and vagal nerve injury or can be idiopathic in nature. Gastroparesis leads to postprandial nausea and vomiting, bloating, early satiety, and discomfort. In severe cases, nausea and vomiting may cause weight loss, dehydration, electrolyte disturbances and malnutrition due to inadequate caloric and fluid intake.

- **Idiopathic** – idiopathic gastroparesis may be the most common form of gastroparesis. It is estimated that no detectable underlying abnormality is found in approximately one-half of patients with delayed gastric emptying.

- **Diabetes Mellitus** – Diabetes mellitus (DM) is the most frequently recognized systemic disease associated with gastroparesis. Gastrointestinal complications of diabetes typically occur in patients who have had the disorder for more than five years. Patients with diabetes mellitus have abnormalities at several levels in the process of gastric emptying, including abnormal postprandial proximal gastric accommodation and contraction, and difficulties with antral motor function. These abnormalities are primarily due to autonomic dysfunction or abnormal intrinsic nervous system.

  Hyperglycemia (blood glucose > 200 mg/dL) may also contribute to delayed gastric emptying.

- **Post-Surgical** – previous gastric and thoracic surgery can result in gastric stasis due to intended or accidental injury to the vagus nerve.

The evaluation of gastroparesis is to exclude mechanical obstruction and establish the diagnosis of gastroparesis by an assessment of gastric motility. If there is no evidence of mechanical obstruction on imaging or upper endoscopy, scintigraphy is typically performed to document the presence of delayed gastric emptying. Scintigraphy measures the motor function of the stomach by quantifying the emptying of a physiologic caloric meal. The technique involves incorporating a radioisotope tracer into a standard meal and tracking its passage through the stomach using a gamma camera. Images are typically gathered at 1, 2, 3, and 4 hours.

Delayed gastric emptying is defined as gastric retention of > 10 percent at 4 hours and/or > 60 percent at two hours when using a standard low- fat diet. Although the severity of symptoms doesn't always correlate with the rate of gastric emptying, delayed gastric emptying has been classified based on the extent of gastric retention on scintigraphy at four hours into the following:

- Mild 10 to 15 percent
- Moderate 15 to 35 percent
- Severe > 35 percent

Primary medical management for gastroparesis includes dietary modification and pharmacologic therapy with prokinetic agents such as metoclopramide, macrolide antibiotics such as erythromycin and antiemetic agents such as granisetron or ondansetron. Patient's refractory to treatment, are difficult to manage. Treatment may involve changing or combining medications; placement of gastrostomy or jejunostomy tube for enteral feedings, or in severe cases, total parenteral nutrition (TPN) for brief periods. Some patients, however, remain refractory to gastroparesis treatment.

Currently, only one gastric electrical stimulator has received approval from the U.S. Food and Drug Administration (FDA), the Enterra™ Therapy System, manufactured by Medtronic and it was cleared by the FDA as a humanitarian use device. This system delivers a high frequency (12 cycles per minute), low energy stimulation to the stomach. The FDA labeling for Enterra™ Therapy System indicates the use of this system is for the treatment of chronic, intractable (drug refractory) nausea and vomiting secondary to gastroparesis of diabetic or idiopathic etiology.

Humanitarian Device Exemption (HDE)
In rare instances, certain medical devices intended to be used for humanitarian purposes are evaluated by the US Food and Drug Administration (FDA) through the Humanitarian Device Exemption (HDE) process. The FDA's humanitarian use device (HUD) designation permits the use of certain medical devices when there is no comparable device available to treat or diagnose a disease or condition affecting fewer than 4,000 individuals annually. Since clinical investigation demonstrating the device's efficacy is not feasible (given the low prevalence of the disease in the population), an HDE grants manufacturers an exemption to the usual premarket approval process and allows marketing of the device only for the FDA-labeled HDE indication(s).

Under FDA requirements, an HUD may only be used after institutional review board (IRB) approval has been obtained for the use of the device in accordance with the FDA-labeled indication(s) under the HDE.

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

Populations
The relevant population of interest is individuals with gastroparesis. Gastroparesis is a chronic disorder of gastric motility characterized by delayed emptying of a solid meal. Symptoms include bloating, distension, nausea, and vomiting. When severe and chronic, gastroparesis can be associated with dehydration, poor nutritional status, and poor glycemic control in diabetic patients. While most associated with diabetes, gastroparesis is also found in chronic pseudo-obstruction, connective tissue disorders, Parkinson

disease, and psychological pathologic conditions. Some cases may not be associated with an identifiable cause and are referred to as idiopathic gastroparesis.

Interventions
The therapy being considered gastric electrical stimulation (GES).

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

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

The existing literature evaluating GES as a treatment for gastroparesis has varying lengths of follow-up, ranging from 6 to 12 months. Therefore, 10 years of follow-up is considered necessary to demonstrate efficacy.

Review of Evidence
Hayes completed a Health Technology Assessment December 2021 which included the following regarding gastric electrical stimulation (GES) for gastroparesis. The literature search related to this assessment included 12 studies: 3 randomized cross over trials, 6 pretreatment/post-treatment studies, 1 nonrandomized comparative study, 1 comparative cohort study and 1 case series. Although the overall quality of evidence was determined to be low-quality and did not provide consistent evidence regarding the effectiveness of gastric electric stimulation (GES) for the treatment of gastroparesis refractory to medical therapy, it may represent compassionate treatment option for individuals who have exhausted all conservative treatment options, have debilitating symptoms and want to avoid other problematic surgical therapies which includes implantation of a gastrostomy tube.

Based on UpToDate review completed May 2022 regarding electrical stimulation for gastroparesis, the gastric electrical neurostimulator (Enterra Therapy system) is not approved by the United States Food and Drug Administration for unrestricted marketing for treatment of gastroparesis but is approved as a humanitarian use device. In addition, because of probable benefit rather than established effectiveness, the device has also received humanitarian device exemption approval for treatment of refractory diabetic and idiopathic gastroparesis, documented by objective measures of delayed gastric emptying. In a systematic review looking at clinical outcomes, which included 19 studies in patients with gastroparesis that underwent gastric electrical stimulation, symptoms of nausea and vomiting were more likely to improve as compared with abdominal pain. Symptomatic improvement has been reported as soon as three days after device implantation. However, gastric electrical stimulation has not consistently demonstrated benefits in reducing other gastrointestinal symptoms including fullness, bloating, or acid reflux symptoms. Observational studies have reported associated improvements in body mass index, HbA1c, serum albumin, and reduction in the need for prokinetic medication and supplemental nutrition with gastric electrical stimulation. Gastric stimulation has also

been associated with improvements in physical and mental quality of life scores and reduction in the need for hospitalization. In a systematic review on efficacy a review of 38 studies reported smaller improvements in nausea and abdominal pain with gastric neurostimulation as compared with pyloromyotomy or pyloroplasty and less effective antiemetic effects than after pyloric surgery or gastrectomy. Although response rates to gastric neurostimulation in larger uncontrolled studies range from 50 to 92 percent with continued improvement in gastroparesis symptoms for up to 15 years, there is less convincing benefit in four published randomized controlled crossover trials.

In 2019, Abell et.al. studied 319 idiopathic or diabetic gastroparesis symptom patients from the Gastroparesis Clinical Research Consortium (GpCRC) observational studies: 238 without gastric electrical stimulation (GES) and 81 with gastric electrical stimulation (GES). They assessed the effects of GES using change in GCSI total score and nausea/ vomiting subscales between baseline and 48 weeks. Also utilized were the propensity score methods to control for imbalances in patient characteristics between comparison groups. In the NIDDK GpCRC multi-center cohort study of 319 patients with gastroparesis, of whom 81 received GES, significant improvements were observed in the GCSI, and nausea, retching, and vomiting severity in patients receiving GES versus patients not receiving GES. However, accounting for baseline gastroparesis severity and other factors, observed improvements attenuated, and only the improvement in nausea score by ≥ 1 point remained significant. Patients with greater symptoms scores at baseline improved more with GES than those with lesser symptoms. A much larger sample of patients with the GES in either a cohort study or randomized clinical trial is needed to fully evaluate symptomatic responses to GES and to precisely identify the patients more or less likely to respond.

Systematic Reviews

Several systematic reviews of studies on gastric electrical stimulation (GES) for gastroparesis have been published, the most recent and comprehensive of which is by Levinthal et al (2017). To be selected for the Levinthal et al. review, studies had to include adults with established gastroparesis, report patient symptom scores, and administer treatment for at least 1 week. Five randomized controlled trials (RCTs) and 13 non-RCTs meeting criteria were identified. Pooled analysis of data from the 5 RCTs (N =185 patients) did not find a statistically significant difference in symptom severity when the GES was turned on versus off (standardized mean difference, 0.17; 95% confidence interval [CI], -0.06 to 0.40; p=.15). Another pooled analysis did not find a statistically significant difference in nausea severity scores when the GES was on or off (standardized mean difference, -0.143; 95% CI, -0.50 to 0.22; p=.45). In a pooled analysis of 13 open-label single-arm studies and data from open-label extensions of 3 RCTs, mean total symptom severity score decreased 2.68 (95% CI, 2.04 to 3.32) at follow-up from a mean of 6.85 (95% CI, 6.28 to 7.42) at baseline. The rate of adverse events in the immediate postoperative period (reported in 7 studies) was 8.7% (95% CI, 4.3% to 17.1%). The in-hospital mortality rate within 30 days of surgery was 1.4% (95% CI, 0.8% to 2.5%), the rate of reoperations (up to 10 years of follow-up) was 11.1% (95% CI, 8.7% to 14.1%), and the rate of device removal was 8.4% (95% CI, 5.7% to 12.2%).

Randomized Controlled Trials
Randomized crossover trials have been performed, and findings have not provided consistent evidence of effectiveness. These randomized controlled trials limitations included small size, possible confounding of blinding by sensation of gastric stimulation, a high dropout rate, and inadequate follow-up.

In 2020 Ducrotte, et. al. performed a multicenter, randomized, double-blind trial with crossover to study the efficacy of GES in patients with refractory vomiting, with or without gastroparesis. Symptoms in 172 patients with chronic refractory vomiting and with or without diabetes were assessed. A GES device (Medtronic Enterra therapy system) was implanted and left inactive for one month until patients were randomly assigned, in a double-blind manner, to groups that received 4 months of stimulation parameters (14 Hz, 5 mA, pulses of 330 μs) or no stimulation (control). Participants were then switched over to the other condition for the following 4 months and were examined at five and nine months after device implantation. At each visit, the follow-up included the assessment of symptoms, nutritional status, QOL, and anxiety and depression levels, as well as a gastric emptying study. Primary endpoints were vomiting episodes assessed on a five-point scale and the quality of life, assessed by the Gastrointestinal Quality of Life Index scoring system. The authors found that high-frequency GES, performed with standard stimulation parameters, was effective to reduce the frequency of vomiting (on average 0.4 points on a 5-point scale) in diabetic and nondiabetic patients with refractory vomiting with or without delayed gastric emptying. Quality of life, the other primary outcome, was not significantly improved

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

Shada et al. (2018) published a prospective study of patients with medically refractory gastroparesis who underwent implantation of GES between 2005 and 2016. One hundred nineteen patients (64 diabetic, 55 idiopathic), with mean follow-up of 39.0 ± 32.0 months, were included in the analysis. Before GES placement, operatively placed feeding tubes were present in 22% of diabetic and 17% of idiopathic patients; however, after GES placement, 67% of feeding tubes were removed. Due to a perceived lack of benefit, 8 patients decided to have their GES device removed after a mean time of 36 ± 29 months. Also, there was significant improvement in Gastroparesis Cardinal Symptom Index scores for both diabetic (p=.01) and idiopathic (p=.003) subgroups at ≥2 years after

implantation. The study was limited by its retrospective nature, not all patients being administered the Gastroparesis Cardinal Symptom Index before GES, and a number of patients being lost to follow-up.

Summary of Evidence
Based on review of the peer reviewed medical literature the evidence includes randomized crossover trials, nonrandomized controlled trials, systematic reviews and case series. The finding related to adult individuals who have symptomatic gastroparesis that is refractory to medical management has not provided consistent evidence. Studies without concurrent control groups and/or blinding have reported statistically significant improvement from baseline in symptoms of gastroparesis, gastric retention, need for enteral nutrition, jejunostomy-tube usage, quality of life, weight gain, and medication use. However, the available randomized studies have provided little confirmation of the apparent benefit seen in unblinded studies that compared outcomes at baseline versus follow-up after stimulator implantation. The Enterra Therapy System (Medtronic, Inc., Minneapolis, MN) is a gastric electrical stimulation device which received FDA marketing approval as a Class III medical device under the Humanitarian Device Exemption (HDE), it is indicated for the treatment of chronic intractable or drug-refractory nausea and vomiting secondary to paresis of diabetic or idiopathic etiology. Updated guidelines by the American College of Gastroenterology issued in 2022 on gastroparesis includes the following recommendation: "GES may be considered for control of gastroparesis (GP) symptoms as a humanitarian use device (Low quality of evidence; Conditional recommendation) and goes on to state: "Documented clinical usefulness in both idiopathic gastroparesis (IG) and diabetic gastroparesis (DG) suggests there is a role for GES in accordance with its HUD approval." The evidence may be of low quality of evidence, however, the use of gastric electrical stimulation (GES) in individuals with idiopathic gastroparesis (IG) and diabetic gastroparesis (DG) represents a compassionate treatment option for those individuals who have exhausted all conservative options, have debilitating symptoms and want to avoid other problematic surgical therapies which may include implantation of gastrostomy tube.

Gastric Electrical Stimulation for the Treatment of Obesity
Gastric electrical stimulation (GES) is currently under investigation for the treatment of obesity as a technique to increase a feeling of satiety by delaying gastric emptying with subsequent reduced food intake and weight loss. The exact mechanism of action is unclear but may be related to the following: a local enteric nervous system effect, an effect mediated by the autonomic nervous system, possible central nervous system changes, and neurohormonal changes. Optimal stimulation patterns are unknown, as is the importance of the number of leads and the location of the electrodes. Optimal screening of patients for gastric electrical stimulation (GES) for obesity has not yet been determined. Also, the best combination of behavioral, drug, device and surgical therapy has not been determined. Currently there are no GES devices approved by the U.S. Food and Drug Administration for the treatment of obesity.

Clinical Content and Therapy Purpose
The purpose of gastric electrical stimulation (GES) is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as conservative management, medication, and bariatric surgery in patients with obesity.

Populations
The relevant population of interest is individuals with obesity.

Interventions
The therapy being considered is gastric electrical stimulation (GES).

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

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

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

Review of Evidence
A single published randomized controlled trial evaluated the use of gastric electrical stimulation (GES) for the treatment of obesity: the Screened Health Assessment and Pacer Evaluation (SHAPE trial), this trial did not show any improvement in weight loss with gastric electrical stimulation (GES) compared with sham stimulation.

Summary of Evidence
For individuals who have obesity who receive gastric electrical stimulation (GES), the evidence includes a randomized controlled trial (SHAPE trial), several small call series and uncontrolled prospective trials. Optimal patient selection criteria, electrode position, lead number and stimulation patterns have not yet been determined. Additional well-designed studies are needed to demonstrate the safety and effectiveness of GES for the treatment of obesity. Based on the single published randomized controlled trial (SHAPE trial), this trial did not show significant improvement in weight loss with GES compared to sham stimulation. Currently there are no GES devices approved by the U.S. Food and Drug Administration for the treatment of obesity. The evidence is insufficient to determine the effects of this technology on net health outcomes.

Practice Guidelines and Position Statements
American College of Gastroenterology (ACG)
In 2022, the American College of Gastroenterology (ACG) updated the 2013 guideline regarding gastroparesis which summarizes the perspectives on the risk factors, diagnosis, and management of gastroparesis in adults (including dietary, pharmacological, device, and interventions directed at the pylorus), and represents the official practice recommendations of the American College of Gastroenterology.

This guideline includes the following recommendation:

- GES may be considered for control of gastroparesis (GP) symptoms as a humanitarian use device (Low quality of evidence; Conditional recommendation).

GES is approved as an HUD, as defined by the FDA for medically refractory DG or IG. The recommendation includes the use of GES in humanitarian use.

A recent randomized, crossover trial of ON versus OFF gastric electrical stimulation (GES) in patients with medically refractory vomiting with or without delayed GE, GES decreased the vomiting frequency. Severity of nausea and appetite improved while ON compared with OFF. However, there were no differences in GI quality of life, nutritional parameters, or GE. Randomized, crossover trials of GES for medically refractory DG or IG have shown mixed results, which may reflect the variation in trial designs with differing timing of the ON versus OFF randomization and crossover. Other modalities of electrostimulation (vagal and spinal cord) seem promising; however, larger randomized, sham-controlled trials are needed to determine the efficacy. However, documented clinical usefulness in both IG and DG suggests there is a role for GES in accordance with its HUD approval.

National Institute for Health and Care Excellence (NICE)
In 2014, the National Institute for Health and Care Excellence issued guidelines on gastroelectrical stimulation for gastroparesis that made the following recommendation:

- 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.

Regulatory Status
Currently, only the Gastric Electrical Stimulator (GES) system (now called Enterra™ Therapy System; Medtronic, Minneapolis, MN) has been approved by the U.S. Food and Drug Administration (FDA; see note below). The GES system consists of 4 components: the implanted pulse generator, 2 unipolar intramuscular stomach leads, the stimulator programmer, and the memory cartridge. Except for 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: In March 2000, the GES system was approved by FDA through a humanitarian device exemption (HDE Approval H990014), for chronic intractable or drug-refractory nausea and vomiting secondary to paresis of diabetic or idiopathic etiology. 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 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 to supervise clinical testing of the device.

Currently, no GES devices have been approved by the FDA for the treatment of obesity. The Transcend (Transneuronix; acquired by Medtronic in 2005), an implantable gastric stimulation device, is available in Europe for the treatment of obesity.

PRIOR APPROVAL

Not applicable.

POLICY

See Related Medical Policies

- 10.01.14 Humanitarian Use Devices
- 07.01.60 Vagus Nerve Stimulation (VNS) and Vagal Blocking Therapy

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

- Diagnosis confirmed by gastric emptying scintigraphy and/or radiopaque markers testing; **and**

- Individual is refractory or has contraindications to medical management including dietary modification, the use of prokinetic (anti-reflux) and antiemetic (anti-nausea and vomiting) medications.

Replacement of gastric electrical stimulation (GES) may be **considered medically necessary** for an individual that meets the above criteria and the existing stimulator is no longer under warranty and cannot be repaired.

Gastric electrical stimulation would be considered **investigational** for all other indications, including but not limited to the following because the safety and effectiveness of this service cannot be established by review of the available published medical literature:

- When the criteria above are not met
- As an initial treatment for gastroparesis
- For treatment of diabetes mellitus in persons without gastroparesis
- For the treatment of gastrointestinal dysmotility disorders other than gastroparesis as indicated above
- For the treatment of obesity

PROCEDURE CODES AND BILLING GUIDELINES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnosis codes.

- 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.
- 95980 Electronic analyses 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 programming
- 95982 subsequent with reprogramming
- C1767 Generator, neurostimulator (implantable), nonrechargeable
- C1778 Lead, neurostimulator

- C1787 Patient programmer, neurostimulator
- C1816 Receiver and/or transmitter neurostimulator (implantable)
- C1820 Generator neurostimulator (implantable), non-high frequency with rechargeable battery and charging system
- C1822 Generator neurostimulator (implantable), high frequency, with rechargeable battery and charging system
- 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
- L8680 Implantable neurostimulator electrode, each
- L8681 Patient programmer (external) for use with implantable programmable neurostimulator pulse generator, replacement only
- L8682 Implantable neurostimulator radiofrequency receiver
- L8683 Radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receiver
- L8685 Implantable neurostimulator pulse generator, single array, rechargeable, includes extension
- L8686 Implantable neurostimulator pulse generator, single array, nonrechargeable, includes extension
- L8687 Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension
- L8688 Implantable neurostimulator pulse generator, dual array, nonrechargeable, includes extension
- L8689 External recharging system for battery, (internal) for use with implantable neurostimulator, replacement only

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POLICY HISTORY

Date	Reason	Action
October 2022	Annual Review	Policy Renewed
October 2021	Annual Review	Policy Renewed
October 2020	Annual Review	Policy Renewed
October 2019	Annual Review	Policy Renewed
October 2018	Annual Review	Policy Revised
October 2017	Annual Review	Policy Revised
October 2016	Annual Review	Policy Revised
October 2015	Annual Review	Policy Revised
February 2015	Interim Review	Policy Revised
November 2014	Annual Review	Policy Revised
January 2014	Annual Review	New Policy Created

New information or technology that would be relevant for Wellmark to consider when this policy is next reviewed may be submitted to:

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Medical Policy Analyst
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