



**GASTRIC ELECTRICAL STIMULATION  
(GASTRIC PACING) FOR GASTROPARESIS  
HS-086**



*Harmony Behavioral Health, Inc.*

*Harmony Behavioral Health of Florida, Inc.*

*Harmony Health Plan of Illinois, Inc.*

*HealthEase of Florida, Inc.*

*'Ohana Health Plan, a plan offered by  
WellCare Health Insurance of Arizona, Inc.*

*WellCare Health Insurance of Illinois, Inc.*

*WellCare Health Insurance of New York, Inc.*

*WellCare Health Plans of New Jersey, Inc.*

*WellCare of Florida, Inc.*

*WellCare of Connecticut, Inc.*

*WellCare of Georgia, Inc.*

*WellCare of Kentucky, Inc.*

*WellCare of Louisiana, Inc.*

*WellCare of New York, Inc.*

*WellCare of Ohio, Inc.*

*WellCare of Texas, Inc.*

*WellCare Prescription Insurance, Inc.*

**Gastric Electrical Stimulation  
(Gastric Pacing) for  
Gastroparesis**

**Policy Number: HS-086**

**Original Effective Date: 3/2/2009**

**Revised Date(s): 3/31/2010; 3/31/2011**

**DISCLAIMER**

The Clinical Coverage Guideline is intended to supplement certain standard WellCare benefit plans. The terms of a member's particular Benefit Plan, Evidence of Coverage, Certificate of Coverage, etc., may differ significantly from this Coverage Position. For example, a member's benefit plan may contain specific exclusions related to the topic addressed in this Clinical Coverage Guideline. When a conflict exists between the two documents, the Member's Benefit Plan always supersedes the information contained in the Clinical Coverage Guideline. Additionally, Clinical Coverage Guidelines relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

**APPLICATION STATEMENT**

The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

## **BACKGROUND**

Gastroparesis, also referred to as gastric stasis, is a common gastrointestinal motility disorder occurring in approximately 4% of the population in the United States. It is defined by delayed gastric emptying without evidence of mechanical obstruction. Patients may experience symptoms of frequent nausea and vomiting, early satiety, bloating, postprandial fullness, and epigastric pain and burning. The most common cause of gastroparesis is diabetes. Gastroparesis may also occur in association with the absence of other disease (idiopathic gastroparesis).

### *Gastric Electrical Stimulation*

GES consists of a series of electric pulses, usually in a rectangular shape, with a constant current or a constant voltage. To date, there have been basically two methods of GES for treatment of gastroparesis: (i) high energy/low frequency stimulation, known as gastric pacing, which utilizes long pulse width in the order of milliseconds (ms) and stimulation frequency in the vicinity of the physiologic frequency of the gastric slow wave; or (ii) low energy/high frequency stimulation, known as neurostimulation, which uses short pulse width in the order of a few hundred microseconds (ms) or trains of short pulses and stimulation frequency much higher than the physiologic frequency of the gastric slow wave. Both methods have benefited the symptoms of gastroparesis. Improvements in gastric emptying as well as symptoms have only been achieved by pacing the stomach at its intrinsic slow wave frequency with long pulses (300 ms). However, there are no implantable devices available in the market capable of generating long pulses. On the other hand, high frequency and low energy stimulation (short pulse of 330  $\mu$ s) is employed by the FDA approved device (Enterra TM Therapy, Medtronic, Minneapolis) under Humanitarian Device Exemption (HDE) and provided as a Human Use Device (HUD), thus requiring an institutional Review Board (IRB) approval, with financial coverage provided by Medicare and all insurance carriers. The following discussion will focus on Enterra Therapy.

### *Enterra Therapy*

The implantable GES system for Enterra Therapy consists of a pair of electrodes sutured to the muscular layer of the greater curvature of the stomach and connected to a pulse generator, called the neurostimulator, implanted in a subcutaneous pocket in the abdominal wall. The pulse generator can be activated and programmed externally. It is a permanently implantable device with a battery life expectation of six to eight years and the system can be implanted by laparotomy or laparoscopy. The pulse-generator contains an electronic circuit that controls the stimulation frequency and strength. There are situations where those parameters can be adjusted to fit a patient's individual needs, such as increasing voltage if resistance or impedance increases, or increasing current if the patient is not sustaining an overall improvement of symptoms. This technique of interrogation involves placing the programmer on the skin over the implant site and, in seconds, the investigator can identify the strength and timing of the stimulation pulse and continue the program or alter it.

### *Patient Selection*

Candidates for Enterra Therapy include members with documented gastroparesis, diabetic or idiopathic, chronic, not responding to available drug therapy. Particular consideration should be given to patients who are being evaluated for enteral/parenteral nutrition because of the risk and expense associated with these types of nutrition support, and the possibility that GES might preclude the need for such intervention.

The patient-selection criteria have evolved since initial FDA approval for Enterra. For example, patients with a gastric resection of less than 50 percent or post-vagotomy (typically occurring during fundoplication) are included. Also, post-renal or -pancreas transplants are accepted. Gastric retention criteria are now  $\geq$ 50 percent at two hours

and  $\geq 6$  percent at four hours utilizing the four-hour egg beater meal as the gold standard. Symptom severity, quality of life, level of function and family assessment are some of the important subjective measures that may play a role in patient-selection criteria. Objective measures include weight loss, requirements for nutritional support, TPN and G-j tubes, as well as the number of ER visits and hospitalizations. Patients are excluded if they are pregnant, suffering from chemical dependency, undergoing peritoneal dialysis or have a limited life-span based on diagnosis of cancer.

The goals of GES include a significant improvement in nausea and vomiting within six months of device placement and elimination of other nutritional support, such as j-tube feeding and TPN, as well as significant decreases in medical costs related to hospitalizations and ER visits. In addition, patients with diabetic gastroparesis should experience a decrease in HbA1c, with an ability to tolerate oral medications, and can become candidates for renal and pancreas transplants. Clinically relevant symptom improvement has been defined as  $>50$  percent improvement after GES. Published data indicates that approximately 75 percent of patients achieve this. Of the remaining 25 percent, a subpopulation has no improvement in symptoms or the number of the hospitalization days. This subgroup, which is approximately 5 percent of all implanted patients, ultimately requires total gastrectomy.

## **POSITION STATEMENT**

Gastric electrical stimulation (gastric pacing) **is considered medically necessary** if ALL of the following criteria are met:

- Member is experiencing chronic intractable nausea and vomiting secondary to severe gastroparesis of diabetic or idiopathic etiology; **AND**,
- Delayed gastric emptying is documented (see background for details); **AND**,
- Conservative treatment has failed

NOTE: Particular consideration should be given to members who are being evaluated for enteral/parenteral nutrition because of the risk and expense associated with these types of nutrition support, and the possibility that gastric electrical stimulation might preclude the need for such intervention.

Gastric electrical stimulation **is contraindicated and is NOT a covered benefit** in members who are:

- Pregnant; **OR**,
- Suffering from chemical dependence; **OR**,
- Undergoing peritoneal dialysis; **OR**,
- Have a limited life-span based on diagnosis of cancer.

Gastric electrical stimulation **is considered experimental and investigational** as:

- An initial treatment for gastroparesis; **OR**,
- Treatment of obesity; **OR**,
- Treatment for other indications NOT listed above.

## **CODING**

### **Covered CPT® 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

- 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, gastric neurostimulator pulse generator/transmitter, intraoperative, with programming
- 95981** Electronic analysis of implanted neurostimulator pulse generator system, gastric neurostimulator pulse generator/transmitter, subsequent, without reprogramming
- 95982** Electronic analysis of implanted neurostimulator pulse generator system, gastric neurostimulator pulse generator/transmitter, subsequent, with reprogramming

**Covered ICD-9-CM Procedure Codes**

- 04.92** Implantation or replacement of peripheral neurostimulator lead(s)
- 04.93** Removal of peripheral neurostimulator lead(s)
- 86.95** Insertion or replacement of dual array neurostimulator pulse generator, non-rechargeable
- 86.05** Incision with removal of foreign body or device from skin and subcutaneous tissue

**Covered HCPCS Codes**

- C1767** Generator, neurostimulator, implantable, non-rechargeable
- C1778** Lead, neurostimulator, implantable
- E0765** FDA approved nerve stimulator, with replaceable batteries, for treatment of nausea and vomiting
- L8680** Implantable neurostimulator electrode, each
- L8688** Implantable neurostimulator pulse generator, dual array, non-rechargeable, includes extension

**Covered ICD-9-CM Diagnosis Codes**

- 250.60 – 250.63** Diabetic gastroparesis; must include an additional diagnosis for 536.3 Gastroparesis
- 536.2** Persistent vomiting
- 536.3** Gastroparesis
- 787.01** Nausea and vomiting

**Experimental and Investigational Not Covered:** Gastric electrical stimulation is contraindicated and NOT a covered benefit and is considered experimental and investigational as indicated in the criteria above and codes below.

**Non-Covered Category III CPT® Codes**

- 0155T** Laparoscopy, surgical, implantation or replacement of gastric stimulation electrodes, lesser curvature (i.e., morbid obesity)
- 0156T** Laparoscopy, surgical, 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)

**Non-Covered ICD-9-CM Procedure Codes - No applicable codes**

**Non-Covered HCPCS Codes - No applicable codes**

**Non Covered ICD-9-CM Diagnosis Codes - This list may not be all inclusive**

<b>140.0 – 209.30</b>	Malignant Neoplasms
<b>278.01</b>	Morbid obesity
<b>303.00 – 304.93</b>	Alcohol Dependence and Drug Dependence
<b>649.1</b>	Obesity, Complicating Pregnancy, Childbirth or the Puerperium; also requires additional code for 278.01 Morbid Obesity
<b>V22.0 - V23.89</b>	Pregnancy Status, Normal and High Risk Categories
<b>V45.11</b>	Renal Dialysis status; hemodialysis status
<b>V85.35</b>	Body Mass Index 35.0-35.9, adult
<b>V85.36</b>	Body Mass Index 36.0-36.9, adult
<b>V85.37</b>	Body Mass Index 37.0-37.9, adult
<b>V85.38</b>	Body Mass Index 38.0-38.9, adult

\*Current Procedural Terminology (CPT) 2010 American Medical Association: Chicago, IL.®©

## REFERENCES

### Peer Reviewed

1. Gastric Electrical Stimulation: An Alternative Surgical Therapy for Patients with Gastroparesis. Mason, RJ et al. Arch Surg, 140, September, 2005.
2. Hayes Inc. Hayes Directory. Gastric Electrical Stimulation for Gastroparesis. April 18, 2008.

### Government Agencies, Professional and Medical Organizations

1. American Gastroenterological Association. AGA Institute. Gastric Electrical Stimulation: A Useful Option for Gastroparesis. R.W. McCallum, MD.
2. American Gastroenterological Association. Medical Position Statement: Diagnosis and Treatment of Gastroparesis. Gastroenterology, 127. 2004.

### Other

1. UnitedHealthcare Technology Assessment. Gastric Stasis, Diagnosis and Treatment with Electrical Systems. April 19, 2007.

## HISTORY AND REVISIONS

Date	Action
12/1/2011	• New template design approved by MPC.
3/31/2011	• Approved by MPC.