# **Medical Coverage Policy |** Gastric Electrical Stimulation - Insertion





**EFFECTIVE DATE:** 12 | 01 | 2014 **POLICY LAST UPDATED:** 11 | 18 | 2014

#### **OVERVIEW**

Gastric electrical stimulation is performed using an implantable device designed to treat chronic drugrefractory nausea and vomiting secondary to gastroparesis of diabetic, idiopathic or post-surgical etiology. Gastric electrical stimulation has also been investigated as a treatment of obesity. The device may be referred to as a gastric pacemaker. This policy is intended to document the insertion or implantation of the device as not medically necessary.

## **PRIOR AUTHORIZATION**

Not applicable.

#### **POLICY STATEMENT**

## BlueCHiP for Medicare and Commercial

Implantation of a gastric electrical stimulation device for any indication is considered **not medically necessary** because there is insufficient medical literature to support the efficacy of this treatment.

#### **MEDICAL CRITERIA**

Not applicable.

### **BACKGROUND**

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. 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.

Currently, only one gastric electrical stimulator has received approval from the U.S. Food and Drug Administration (FDA), the Gastric Electrical Stimulator (GES) system (now called Enterra<sup>TM</sup> Therapy System), manufactured by Medtronic. 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 sec alternating with an "off" time of 5.0 sec.

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 evidence on the efficacy of gastric electrical stimulation to treat gastroparesis is inadequate to permit scientific conclusions. In conclusion, gastric electrical stimulation for the treatment of gastroparesis of diabetic, idiopathic, or post-surgical etiologies is considered not medically necessary. Additionally, case series publications are limited and insufficient to draw conclusions on health outcomes gastric electrical stimulation for the treatment of obesity. Therefore, the gastric electrical stimulation as treatment for obesity is considered not medically necessary.

#### **COVERAGE**

Benefits may vary between groups/contracts. Please refer to the appropriate Evidence of Coverage or Subscriber Agreement for limitations of benefits/coverage when services are not medically necessary.

## **CODING**

BlueCHiP for Medicare and Commercial

The following code is not medically necessary when used for gastric electrical stimulation and filed with the diagnosis codes listed below:

64590

ICD-9



GES ICD 9 Codes.pdf

ICD-10



The following codes are **not medically necessary:** 

0157T, 43647, 43881, 95980, 95981, 95982

## **RELATED POLICIES**

CPT Category III Codes

Preauthorization via Web-Based Tool for Procedures

#### **PUBLISHED**

Provider Update	Jul	2014
Provider Update	Aug	2013
Provider Update	Jul	2012
Provider Update	Aug	2011
Provider Update	Aug	2010
Provider Update	Sep	2009
Provider Update	Jul	2008

#### **REFERENCES**

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- 3. McCallum RW, Snape W, Brody F et al. Gastric electrical stimulation with Enterra therapy improves symptoms from diabetic gastroparesis in a prospective study. Clin Gastroenterol Hepatol 2010; 8(11):947-54; quiz e116.
- 4. FDA Summary of Safety and Probable Benefit. Available online at: http://www.accessdata.fda.gov/cdrh\_docs/pdf/H990014b.pdf. Last accessed July 2013.
- 5. Anand C, Al-Juburi A, Familoni B et al. Gastric electrical stimulation is safe and effective: a long-term study in patients with drug-refractory gastroparesis in three regional centers. Digestion 2007; 75(2-3):83-9.
- 6. Abell T, Lou J, Tabbaa M et al. Gastric electrical stimulation for gastroparesis improves nutritional parameters at short, intermediate, and long-term follow-up. JPEN J Parenter Enteral Nutr 2003; 27(4):277-81.
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