Medical Coverage Policy | Gastric Electrical Stimulation - Insertion

EFFECTIVE DATE: 12|01|2014
POLICY LAST UPDATED: 12|06|2016

OVERVIEW
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 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.

MEDICAL CRITERIA
Not applicable

PRIOR AUTHORIZATION
Not applicable

POLICY STATEMENT
BlueCHiP for Medicare and Commercial Products
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.

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

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. 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.

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 U.S. Food and Drug Administration (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."

Currently, only one gastric electrical stimulator has received approval from the FDA, the Gastric Electrical Stimulator (GES) system (now called Enterra™ 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.

The evidence on the efficacy of gastric electrical stimulation to treat gastroparesis is inadequate to permit scientific conclusions about its efficacy. Therefore, 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 of gastric electrical stimulation for the treatment of obesity. Therefore, gastric electrical stimulation as treatment for obesity is considered not medically necessary.

CODING

BlueCHiP for Medicare and Commercial Products

The following code is not medically necessary when used for gastric electrical stimulation and filed with the diagnosis codes listed below:
64590

ICD-10

E08.40	E09.43	E11.40	E66.01	E66.3
E08.43	E10.40	E11.43	E66.09	E66.8
E08.65	E10.43	E11.65	E66.1	E66.9
E09.40	E10.65	E13.43	E66.2	K91.89

The following codes are **not medically necessary**:
43647
43881
95980
95981
95982

RELATED POLICIES

Preauthorization via Web-Based Tool for Procedures
Removal of Non-Covered Implantable Devices

PUBLISHED

Provider Update, January 2017
Provider Update, February 2016
Provider Update, July 2014

Provider Update, August 2013
Provider Update, July 2012
Provider Update, August 2010
Provider Update, August 2011

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. Clinical gastroenterology and hepatology : the official clinical practice journal of the American Gastroenterological Association. Nov 2010;8(11):947-954; quiz e116. PMID 20538073
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10. Teich S, Mousa HM, Punati J, et al. Efficacy of permanent gastric electrical stimulation for the treatment of gastroparesis and functional dyspepsia in children and adolescents. J Pediatr Surg. Jan 2013;48(1):178-183. PMID 23331812