The following Protocol contains medical necessity criteria that apply for this service. It is applicable to Medicare Advantage products unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. **Preauthorization is not required but is recommended if, despite this Protocol position, you feel this service is medically necessary; supporting documentation must be submitted to Use Management.** Please note that payment for covered services is subject to eligibility and the limitations noted in the patient’s contract at the time the services are rendered.

**Description**

Gastric electrical stimulation is performed using an implantable device designed to treat chronic drug-refractory nausea and vomiting secondary to gastroparesis of diabetic or idiopathic etiology. The device may be referred to as a gastric pacemaker.

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 Enterra™ Therapy System), manufactured by Medtronic. The GES system consists of four components: the implanted pulse generator, two 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.

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.

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. However, the Transcend® Implantable Gastric Stimulation device, manufactured by Transneuronix Corporation, is currently available in Europe for treatment of obesity. Transneuronix is currently funding clinical trials in the United States with hopes of obtaining FDA approval within a couple years for use of the Transcend device to promote weight loss in the management of obesity.

**Note:** It should be noted that the GES system received FDA approval through a humanitarian device exemption (HDE). This regulatory category was established in 1996 and only applies to devices intended to benefit fewer
than 4,000 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.

Corporate Medical Guideline

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

Gastric electrical stimulation is considered investigational for the treatment of obesity.

References

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.


20. National Government Services, Inc. Local Coverage Determination (LCD) for Bariatric Surgery (L28482).