



**Clinical Review Criteria Related to
Gastric Electrical Stimulation (GES) (Enterra Therapy System)**

I. Criteria for Approval

- A. GES therapy is a treatment for patients with chronic gastroparesis, a disorder in which there is prolonged gastric retention following the ingestion of food in the absence of mechanical obstruction. Its main symptoms include nausea, vomiting, early satiety, distention, bloating, and epigastric pain. The implanted stimulator delivers electrical impulses to the gastric muscles to stimulate gastric myoelectric activity, thereby improving stomach emptying and reducing the frequency and severity of symptoms. The Enterra Therapy System by Medtronic was developed to provide gastric electrical stimulation.
- B. Minuteman Health Insurance (MHI) covers GES when the following are met:
 - 1. The member has gastroparesis that is caused by diabetes, OR is idiopathic OR is neurogenic AND
 - 2. Is used for the treatment of gastroparesis when medical management has failed OR is contraindicated.

II. Required Documentation

- A. Letter of medical necessity or office notes documenting diagnosis, symptoms, and medical management.

III. What is Not Covered

- A. MHI considers GES therapy experimental and investigational as an initial treatment for gastroparesis, to treat diabetes mellitus, obesity, and for other indications because its effectiveness for these indications has not been established.

Coding:

Note: This list of codes may not be all-inclusive.

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	Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling

References:

NCQA Standard, UM 2, Clinical Criteria for Utilization Management Decisions, Element A

Winifred S. Hayes, Inc., Gastric Electrical Stimulation for Gastroparesis, Published 4/18/2008, latest update search, 10/10/13, annual review 10/20/15
<https://www.hayesinc.com/subscribers/displaySubscriberArticle.do?articleId=3373>
 (Last Reviewed 10/6/16)

Medtronic For Healthcare Professionals, Gastric Electrical Stimulation:
<http://professional.medtronic.com/pt/gastro/ges/index.htm>
 (Last Accessed 10/6/16)

U.S. Department of Health & Human Services, FDA U.S. Food and Drug Administration, Enterra Therapy System (formerly named Gastric Electrical Stimulation (GES System)- H990014
http://www.accessdata.fda.gov/cdrh_docs/pdf/H990014b.pdf
 (Last Accessed 10/6/16)

NHS, National Institute for Health and Clinical Excellence, Gastric electrical stimulation for gastroparesis
<http://guidance.nice.org.uk/IPG103>
 (Last Accessed 10/6/16)

Summary of Changes:
02/09/2017

- No changes