

01-91000-04

Original Effective Date: 11/15/01

Reviewed: 02/27/25

Revised: 10/15/25

Subject: Gastric Electrical Stimulation

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

Position Statement	Billing/Coding	Reimbursement	Program Exceptions	Definitions	Related Guidelines
Other	References	Updates			

DESCRIPTION:

Gastroparesis is a chronic disorder of gastric motility characterized by delayed emptying of a solid meal. Symptoms include bloating, distension, nausea, and vomiting. Severe and chronic gastroparesis can be associated with dehydration, poor nutritional status, and poor glycemic control in those with diabetes. While most commonly associated with diabetes, gastroparesis is also found in chronic pseudo-obstruction, connective tissue disorders, Parkinson 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 (e.g., metoclopramide) and antiemetic agents (eg, metoclopramide, granisetron, ondansetron). Severe cases may require enteral or total parenteral nutrition.

Gastric electrical stimulation (GES), also referred to as gastric pacing, uses an implantable device. Currently available devices consist of a pulse generator, which can be programmed to provide electrical stimulation at different frequencies, and connected to intramuscular stomach leads, which are implanted during laparoscopy or open laparotomy.

Summary and Analysis of Evidence: An UpToDate review “Electrical stimulation for gastroparesis” (Hasler, 2024) states “Gastric neurostimulation has no effect on basal gastric emptying or electrical activity but modifies sympathovagal activity and perception of gastric distention. Uncontrolled studies suggest clinically important benefits of gastric neurostimulation, including improvements in nausea and vomiting associated with gastroparesis. Emerging evidence from a multicenter crossover trial suggests there may be benefit from active versus sham stimulation. Patients with severe nausea and vomiting refractory to antiemetic and prokinetic drug therapy for at least one year may be candidates for gastric stimulation. In the United States, the gastric neurostimulator (Enterra Therapy system) is approved as a humanitarian exemption device only for diabetic and idiopathic gastroparesis.”

POSITION STATEMENT:

Gastric electrical stimulation (gastric pacing, gastric pacemaker) **meets the definition of medical necessity** when an FDA-approved device is used for the FDA-approved indication of chronic, intractable nausea and vomiting secondary to severe gastroparesis of diabetic or idiopathic etiology, and when **BOTH** of the following are met:

- Delayed gastric emptying, documented by standard scintigraphic imaging or radiopaque marker testing, **AND**
- Refractory or intolerant to diet modification and pharmaceutical therapy (e.g. prokinetic and antiemetic medications)

Revision or removal of a previously implanted stimulator/pacer **meets the definition of medical necessity** when used to treat complications associated with gastric stimulation/pacing (e.g., bowel obstruction, gastric wall perforation, infection, lead dislodgement, lead erosion into the small intestine).

Gastric electrical stimulation is considered **experimental or investigational** for all other indications, including but not limited to the treatment of obesity, as current available clinical data is inadequate to permit scientific conclusions regarding the effectiveness of this therapy.

BILLING/CODING INFORMATION:

CPT Coding:

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, sacral, or gastric neurostimulator pulse generator or receiver, requiring pocket creation and connection between electrode array and pulse generator or receiver
64595	Revision or removal of peripheral, sacral, or gastric neurostimulator pulse generator or receiver, with detachable connection to electrode array
95980	Electronic analysis of implanted neurostimulator pulse generator system (e.g., rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient measurements) gastric neurostimulator pulse generator/transmitter; intraoperative, with programming
95981	Electronic analysis of implanted neurostimulator pulse generator system (e.g., rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient measurements) gastric neurostimulator pulse generator/transmitter; subsequent, without programming
95982	Electronic analysis of implanted neurostimulator pulse generator system (e.g., rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient measurements) gastric neurostimulator pulse generator/transmitter; subsequent, with programming

REIMBURSEMENT INFORMATION:

Refer to section entitled [POSITION STATEMENT](#).

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage products: No National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) were found at the time of the last guideline reviewed date.

If this Medical Coverage Guideline contains a step therapy requirement, in compliance with Florida law 627.42393, members or providers may request a step therapy protocol exemption to this requirement if based on medical necessity. The process for requesting a protocol exemption can be found at [Coverage Protocol Exemption Request](#).

DEFINITIONS:

Enterra™ Therapy System

RELATED GUIDELINES:

[Vagus Nerve Stimulation, 02-61000-22](#)

OTHER:

None applicable.

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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 02/27/25.

GUIDELINE UPDATE INFORMATION:

11/15/01	New Medical Coverage Guideline
12/15/02	Review of guideline; consisting of updated references and maintaining investigational status.

04/15/03	Revision to guideline; consisting of addition of E0765.
10/01/03	4th quarter HCPCS update; consisting of addition of S2213.
11/15/03	Review of guideline; maintain investigational status.
04/15/04	Review of guideline; consisting of updated references and no change to investigational status.
03/15/05	Review of guideline; consisting of updated references and no change to investigational status.
03/15/06	Review of guideline consisting of updated references.
07/01/06	HCPCS coding update consisting of the addition of 0155T, 0156T, 0157T and 0158T.
01/01/07	Annual HCPCS coding update: added 43647, 43648, 43881, 43882, 64590, 64595 and 0162T.
03/15/07	Review and revision of guideline consisting of updated references.
04/01/07	HCPCS coding update consisting of the deletion of S2213.
06/15/07	Reformatted guideline.
01/01/08	Annual HCPCS coding update: added codes 95980, 95981 and 95982.
03/15/08	Review and revision of guideline consisting of updated references.
01/01/09	Annual HCPCS coding update: deleted code 0162T.
03/15/09	Review and revision of guideline consisting of updated references.
03/15/10	Scheduled review; update in position statement for humanitarian device exemption. Update references
01/01/12	Annual HCPCS coding update. Deleted 0155T, 0156T, 0157T and 0158T.
03/15/12	Scheduled review; position statement maintained. Updated references.
03/15/13	Scheduled review. Revised description and position statement (deleted requirement that criteria for total parenteral nutrition are met). Updated references.
03/15/14	Scheduled review. Maintained position statement. Updated program exceptions section and references.
05/11/14	Revision: Program Exceptions section updated.
10/15/19	Scheduled review. Revised description. Maintained position statement. Deleted Institutional Review Board (IRB) facility requirement and added revision/replacement coverage statement. Updated references.
05/15/21	Scheduled review. Maintained position statement and updated references.
05/15/23	Scheduled review. Maintained position statement and updated references.
05/22/23	Update to Program Exceptions section.
01/01/24	Annual HCPCS coding update. Revised 64590, 64595.
03/15/24	Scheduled review. Revised description, maintained position statement and updated references.
03/15/25	Scheduled review. Maintained position statement and updated references.
10/15/25	Revision. Deleted E0765 (refer to MCG 02-61000-04 Transcutaneous Electric Nerve Stimulation (TENS)).