Gastric Pacing/Gastric Electrical Stimulation

INDEPENDENT CARE HEALTH PLAN

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Medicare Advantage Medical Coverage Policy

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Please refer to CMS Medicare Coverage Database for the most current applicable CMS National Coverage Determination (NCD)/Local Coverage Determination (LCD)/Local Coverage Article (LCA). Refer to CMS website for the most current applicable CMS Online Manual System (IOMs) and Transmittals.

Type	Title	Document ID Number	Jurisdiction Medicare Administrative Contractors (MACs)	Applicable States/Territories
Internet-Only	Pub. 100-02, Medicare Benefit Policy Manual, Chapter 15	§120 Prosthetic Devices		

Manuals (IOMs)				

Description

Gastroparesis is a motility disorder that causes delayed gastric emptying. Symptoms associated with gastroparesis can include abdominal pain, bloating, early satiety, nausea and vomiting. In severe cases, it can cause electrolyte imbalances, dehydration, weight loss and malnutrition due to inadequate oral intake. Management of gastroparesis typically includes diet modification and medications to increase gastric motility and decrease nausea. However, these treatments have limited efficacy for severe disease which has led to the development of new treatments including, but not limited to:

- **Gastric electrical stimulation (GES)**, also known as **gastric neurostimulation**[9], uses low-energy, high-frequency electrical impulses to relieve the nausea and vomiting associated with gastroparesis. Although the exact mechanism of action is not fully understood, GES is thought to both increase the amount of gastric distention the body can tolerate and to decrease the body's response to gastric distention (eg, vomiting), thus, helping to alleviate symptoms. The **Enterra II Therapy System** is the only device approved by the US Food & Drug Administration (FDA) for GES treatment. It consists of a battery-powered pulse generator and two intramuscular electrode leads that are surgically implanted in the abdomen. The system is controlled using a wireless programming device. The Enterra II System requires internal battery replacement every 5 to 10 years.

  A **temporary trial of GES** is being investigated to determine the response and benefit of this treatment prior to placing a permanent device. During the procedure, a cannula with an internal needle is inserted through the skin and placed in the gastric submucosa. A self-anchoring electrode is passed through the needle, which delivers electrical stimulation up to 8 weeks.

- **Gastric pacing**[9] delivers low duration impulses (30 to 500 milliseconds) using high-energy, low-frequency electrical current. Unlike GES, gastric pacing directly affects gastric motility by promoting increased gastric contractions and accelerated gastric emptying. However, this technology is still in development and not clinically available in the US. There are currently no FDA-approved devices for gastric pacing treatment.

Gastric electrical stimulation is also being explored as an alternative to gastric bypass surgery for the treatment of obesity. It is thought that GES may have the ability to decrease appetite and, consequently, lead to weight loss.[5] There are currently no FDA-approved devices for this indication.

Coverage Determination

iCare follows the Medicare requirements that only allow coverage and payment for services that are reasonable and necessary for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body member except as specifically allowed by Medicare.

iCare applies any applicable National Coverage Determination (NCD) and any applicable Local Coverage Determinations (LCDs) to the services and jurisdiction at issue. There are currently no NCDs, LCDs or LCAs that provide criteria as to when gastric electrical stimulation is considered medically reasonable and necessary.

In interpreting or supplementing the criteria above and in order to determine medical necessity consistently, iCare may consider the criteria contained in the following:

Initial Treatment

Gastric electrical stimulation (GES) ~~**pacing**~~ will be considered medically reasonable and necessary when **ALL** of the following criteria are met:

- Chronic, intractable nausea and vomiting secondary to gastroparesis of diabetic or idiopathic etiology[11]; **AND**
- Diagnosis of gastroparesis is confirmed by gastric emptying scintigraphy and/or radiopaque marker testing[7]; **AND**
- Individual is 18 through 70 years of age[11]; **AND**
- Individual is not concurrently treated with opioid medications[2,7]; **AND**
- Symptoms are refractory or intolerant to diet modification and pharmaceutical therapy (eg, antiemetics, prokinetics)[2,11]

Revision or Removal

~~**gastric pacing**~~ **Revision or removal** of a previously implanted GES device will be considered medically reasonable and necessary for **ANY** of the following indications: ~~approved implantation for complications associated with gastric pacing (eg, bowel obstruction, gastric wall perforation, infection, lead dislodgement or lead erosion into the small intestine).~~

- Inadequate symptom relief**; OR**
- Infection**; OR**
- Lead fracture**; OR**
- Lead migration**; OR**
- Loss of effectiveness/tolerance**; OR**
- Painful generator site**; OR**
- Seroma

Replacement

Replacement[3] of a ~~**gastric pacing**~~ previously implanted GES device will be considered medically reasonable and necessary for **ANY** of the following indications:

- A change in the physiological condition of the individual**; OR**

- An irreparable change in the condition of the device, or in a part of the device**; OR**

- Generator replacement* due to end of battery life (generally no more frequently than every 5 to 10 years)[3]**; OR**

- The condition of the device, or the part of the device, requires repairs and the cost of such repairs would be more than 60 percent of the cost of the replacement device, or as the case may be, of the part being replaced

*Lead and electrode replacement are not generally required at the time of generator replacement due to end of battery life.

The use of the criteria above provides clinical benefits highly likely to outweigh any clinical harms (eg, adverse effects including, but not limited to infection, lead migration or erosion, electrode penetration into the gastric mucosa, seroma and bowel obstruction[9]). Services that do not meet the criteria above are not medically reasonable and necessary and may result in unnecessary exposure to potential complications. Medically unnecessary services carry risks of adverse outcomes and may interfere with the pursuit of other treatments which have demonstrated efficacy.

Coverage Limitations

US Government Publishing Office. Electronic code of federal regulations: part 411 – 42 CFR § 411.15 - Particular services excluded from coverage

Services that are not medically reasonable and necessary may result in unnecessary exposure to potential complications. Medically unnecessary services carry risks of adverse outcomes and may interfere with the pursuit of other treatments which have demonstrated efficacy.

The following services will **not** be considered medically reasonable and necessary:

- Gastric pacing; **OR**
- GES for the treatment of obesity

A review of the current medical literature shows that there is **no evidence** to determine that these services are standard medical treatments. There is an absence of current, widely-used treatment guidelines or acceptable clinical literature (as defined by CMS) examining benefit and long-term clinical outcomes establishing the value of these services in clinical management.

The following ~~**gastric pacing** indications~~ services will **not** be considered medically reasonable and necessary:

- ~~Initial treatment for gastroparesis; **OR**~~
- Temporary trial of GES[2] ~~gastric pacing~~; **OR**

- ~~Treatment of obesity~~

A review of the current medical literature shows that the **evidence is insufficient** to determine that this service is standard medical treatment. There is an absence of current, widely-used treatment guidelines or acceptable clinical literature (as defined by CMS) examining benefit and long-term clinical outcomes establishing the value of this service in clinical management.

Summary of Evidence

~~A review of the current medical literature demonstrates a lack of evidence or unclear utility regarding the use of gastric pacing for the initial treatment of gastroparesis. Gastric electrical stimulation should only be used for the treatment of chronic, intractable (drug refractory) nausea and vomiting secondary to gastroparesis of diabetic or idiopathic etiology.[8,9]~~

Temporary Trial of GES

There is a lack of evidence to support the use of a temporary trial of gastric electrical stimulation ~~pacing~~. The FDA approval of the only available device (Enterra) states it is indicated for the treatment of chronic, intractable (drug refractory) nausea and vomiting secondary to gastroparesis of diabetic or idiopathic etiology[11]. The indications do not reference the use of a temporary trial. There are no recommendations from the American College of Gastroenterology.[1] The American Gastroenterological Association states temporary electrical stimulation may predict a response to gastric electrical stimulation and if available, should be offered. However, this statement was based on a single clinical trial of 58 subjects in which concluded that overall treatment effects were not significant[2].

~~There are no FDA approved gastric electrical stimulation devices for the treatment of obesity.~~

Coding Information

Any codes listed on this policy are for informational purposes only. Do not rely on the accuracy and inclusion of specific codes. Inclusion of a code does not guarantee coverage and/or reimbursement for a service or procedure.

CPT® Code(s)	Description	Comments
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	Revision or removal of peripheral or gastric neurostimulator pulse generator or receiver	
95980	Electronic analysis of implanted neurostimulator pulse generator system (eg, 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 (eg, 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 reprogramming	
95982	Electronic analysis of implanted neurostimulator pulse generator system (eg, 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 reprogramming	
CPT® Category III Code(s)	**Description**	**Comments**
No code(s) identified		
HCPCS Code(s)	**Description**	**Comments**
C1767	Generator, neurostimulator (implantable), nonrechargeable	
C1778	Lead, neurostimulator (implantable)	
C1827	Generator, neurostimulator (implantable), non-rechargeable, with implantable stimulation lead and external paired stimulation controller	
L8679	Implantable neurostimulator, pulse generator, any type	
L8680	Implantable neurostimulator electrode, each	
L8688	Implantable neurostimulator pulse generator, dual array, nonrechargeable, includes extension	

References

1. American College of Gastroenterology (ACG). ACG clinical guideline: gastroparesis. https://gi.org. Published August 2022.

2. American Gastroenterological Association (AGA). AGA clinical practice update on management of medically refractory gastroparesis: expert review. https://gastro.org. Published March 2022.

3. Centers for Medicare and Medicaid Services (CMS). Medicare Benefit Policy Manual. Covered medical and other health services. Published June 13, 2024.

4. ECRI Institute. Clinical Evidence Assessment. Enterra II therapy system (Medtronic plc.) for gastroparesis. https://www.ecri.org. Published April 7, 2004. Updated August 24, 2023.

5. Hayes, Inc. Health Technology Brief. Gastric electrical stimulation with an implantable gastric stimulator (IGS) for the treatment of obesity. https://evidence.hayesinc.com. Published July 1, 2007. Updated July 6, 2009.

6. Hayes, Inc. Medical Technology Directory. Gastric electrical stimulation for gastroparesis. https://evidence.hayesinc.com. Published October 26, 2018. Updated December 7, 2022.

7. MCG Health. Gastric stimulation (electrical). https://humana.access.mcg.com/index.

8. UpToDate, Inc. Approach to the adult with nausea and vomiting. https://www.uptodate.com. Updated July 2024.

9. UpToDate, Inc. Electrical stimulation for gastroparesis. https://www.uptodate.com. Updated July 2024.

10. UpToDate, Inc. Treatment of gastroparesis. https://www.uptodate.com. Updated July 2024.

11. US Food & Drug Administration (FDA). Summary of safety and probable benefit: Enterra therapy system. https://www.fda.gov. Published September 23, 1999.

Change Summary

01/01/2024 New Policy.
09/24/2024 Annual Review, Coverage Change. Updated Coding Information