Gastric Pacing/Gastric Electrical Stimulation

INDEPENDENT CARE HEALTH PLAN

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Policy Number: WI.PA-1089-000
Line of Business: Medicare

Medical Coverage Policy

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Related Medical/Pharmacy Coverage Policies

None

Related Documents

There are no NCDs or LCDs for this service.

Description

Gastric pacing (also known as gastric electrical stimulation) is a treatment for an individual with chronic, intractable or drug-refractory nausea and vomiting secondary to gastroparesis, which could be caused by diabetes or idiopathic (unknown) reasons. A gastric pacing system delivers electrical stimulation to the gastric muscles by means of two leads that are implanted directly into the stomach and connected to a generator that is implanted into the abdominal area. The electrical impulses that are delivered to the gastric muscles are intended to stimulate gastric myoelectric activity with the goal of improving stomach emptying and relieving symptoms.[4] The device is regulated by an external programmer that noninvasively

adjusts the level of gastric stimulation and allows the device to be completely turned off at any time. Internal battery replacement is required every 5 to 10 years.
The Enterra Therapy II system is approved under a Humanitarian Device Exemption (HDE) by the US Food & Drug Administration (FDA) and is the only gastric pacing system approved for marketing.

A temporary trial of gastric pacing is being investigated to determine the response and benefit of this treatment prior to placing a permanent device. 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.

Coverage Determination

iCare follows the CMS requirements that only allows 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.

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

Gastric pacing will be considered medically reasonable and necessary when **ALL** the following criteria are met:

- Chronic, intractable nausea and vomiting secondary to gastroparesis of diabetic or idiopathic etiology; **AND**
- Diagnosis confirmed by gastric emptying scintigraphy and/or radiopaque marker testing; **AND**
- Refractory or intolerant to diet modification and pharmaceutical therapy (eg, antiemetics, prokinetics)

Gastric pacing revision or removal of previously approved implantation will be considered medically reasonable and necessary for complications associated with gastric pacing (eg, bowel obstruction, gastric wall perforation, infection, lead dislodgement or lead erosion into the small intestine).

Replacement of a gastric pacing device will be considered medically reasonable and necessary if required for battery depletion (generally no more frequently than every 5 to 10 years).

The use of the criteria in this Medicare Advantage Medical Coverage Policy provides clinical benefits highly likely to outweigh any clinical harms. Services that do not meet the criteria above are not medically necessary and thus do not provide a clinical benefit. 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

The following g**astric pacing** indications will not be considered medically reasonable and necessary:

- Initial treatment for gastroparesis; **OR**
- Temporary trial of 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 for these indications. There remains an absence of randomize, blinded clinical studies examining benefit and long-term clinical outcomes establishing the value of this service in clinical management for these indications.

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]

There is a lack of evidence to support the use of a temporary trial of gastric 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. The indications do not reference the use of a temporary trial.[9] There were no recommendations from the American College of Gastroenterology guidelines. 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 only one clinical trial of 58 subjects in which it was 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	**Not Covered**
L8688	Implantable neurostimulator pulse generator, dual array, nonrechargeable, includes extension	**Not Covered**

References

1. American College of Gastroenterology (ACG). Clinical Guideline. Management of gastroparesis. https://gi.org. Published August 2022. Accessed February 16, 2023.

2. American Gastroenterological Association (AGA). AGA clinical practice update on management of medically refractory gastroparesis: expert review. https://www.gastro.org. Published March 2022. Accessed February 16, 2023.

3. Hayes, Inc. Health Technology Brief (ARCHIVED). 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. Accessed February 15, 2023.

4. Hayes, Inc. Medical Technology Directory. Gastric electrical stimulation for gastroparesis. https://evidence.hayesinc.com. Published October 26, 2018. Updated December 7, 2022. Accessed February 15, 2023.

5. MCG Health. Gastric stimulation (electrical). 26th edition. https://www.mcg.com. Accessed February 15, 2023.

6. UpToDate, Inc. Approach to the adult with nausea and vomiting. https://www.uptodate.com. Updated January 2023. Accessed February 15, 2023.

7. UpToDate, Inc. Electrical stimulation for gastroparesis. https://www.uptodate.com. Updated January 2023. Accessed February 15, 2023.

8. UpToDate, Inc. Treatment of gastroparesis. https://www.uptodate.com. Updated January 2023. Accessed February 15, 2023.

9. US Food & Drug Administration (FDA). Summary of safety and probable benefit: Enterra therapy system. https://www.fda.gov. Published September 23, 1999. Accessed July 27, 2016.

Change Summary

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