Gastric Pacing/Gastric Electrical Stimulation

Humana

Medical Coverage Policy

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Change Summary: Updated Title, References

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Disclaimer

State and federal law, as well as contract language, including definitions and specific inclusions/exclusions, take precedence over clinical policy and must be considered first in determining eligibility for coverage. Coverage may also differ for our Medicare and/or Medicaid members based on any applicable Centers for Medicare & Medicaid Services (CMS) coverage statements including National Coverage Determinations (NCD), Local Medical Review Policies (LMRP) and/or Local Coverage Determinations. Refer to the CMS website. The member's health plan benefits in effect on the date services are rendered must be used. Clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. Clinical technology is constantly evolving, and we reserve the right to review and update this policy periodically.

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. **(Refer to Coverage Limitations section)**

For information regarding **vagus/vagal nerve blocks or vagal blocking for obesity control,** please refer to Bariatric Surgery Medical Coverage Policy.

Coverage Determination

Commercial Plan members: requests for gastric pacing require review by a medical director.

Humana members may be eligible under the Plan for **gastric pacing** when the following criteria are met:

- 18 through 70 years of age; **AND**
- 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)

Humana members may be eligible under the Plan for **gastric pacing revision or removal** of previously approved implantation for complications associated with gastric pacing (eg, bowel obstruction, gastric wall perforation, infection, lead dislodgement or lead erosion into the small intestine).

Humana members may be eligible under the Plan for **replacement of a gastric pacing device** if required for battery depletion (generally no more frequently than every 5 to 10 years).

Coverage Limitations

Humana members may **NOT** be eligible under the Plan for **gastric pacing** for any indications other than those listed above including, but may not be limited to:

- Initial treatment for gastroparesis; **OR**
- Temporary trial of gastric pacing; **OR**
- Treatment of obesity

This is considered experimental/investigational as it is not identified as widely used and generally accepted for any other proposed use as reported in nationally recognized peer-reviewed medical literature published in the English language.

Background

Additional information about **gastroparesis** may be found from the following websites:

- American College of Gastroenterology
- National Library of Medicine

Medical Alternatives

Alternatives to **gastric pacing** include, but may not be limited to, the following:

- Surgical intervention, such as the placement of a feeding tube

Physician consultation is advised to make an informed decision based on an individual's health needs.

Provider Claims Codes

Any CPT, HCPCS or ICD codes listed on this medical coverage 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	**New Code Effective 01/01/2023**
L8679	Implantable neurostimulator, pulse generator, any type	
L8680	Implantable neurostimulator electrode, each	
L8688	Implantable neurostimulator pulse generator, dual array, nonrechargeable, includes extension	

References

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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.

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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.