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SHP Gastric Pacemakers-Gastric Electrical Stimulators

AUTH: SHP Surgical 95 v3 (AC)

MCG Health
Ambulatory Care
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Coverage

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See the appropriate benefit document for specific coverage determination. Member specific benefits take precedence over medical policy.

Application to Products

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Policy is applicable to all products.

Authorization Requirements

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Pre-certification by the Plan is required.

Description of Item or Service

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Gastric electrical neurostimulators consist of a pair of electrode leads, a pulse generator and a programming system. The leads are implanted generally on the greater curvature of the stomach roughly 5 inches proximal to the pylorus. The leads are then connected to the pulse generator which is subcutaneously inserted in one of the upper quadrants of the abdomen. The device is then programmed externally regarding timing and degree of energy delivery. The mechanism of action of high-frequency gastric electrical neurostimulation is uncertain. It likely does NOT relate to gastric emptying. However, it has been shown to enhance slow-wave amplitude (the normal wave form associated with contractility) and propagation velocity. The device does increase the gastric volume size that can be tolerated without symptoms. There are also autonomic benefits involving sympathovagal activity as well as spinal neuron responsiveness to gastric distention.

Exceptions and Limitations

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- There is insufficient scientific evidence to support the medical necessity of gastric pacemakers/gastric electrical stimulators for the following as they are not shown to improve health outcomes upon technology review:
 - As an initial treatment for gastroparesis
 - For treatment of obesity
 - For treatment of diabetes mellitus in persons without gastroparesis
 - For the treatment of autonomic nervous system disorders other than gastroparesis
 - Second/additional Gastric electrical stimulation
 - Temporary gastric electrical stimulation
 - Rumination syndrome or eating disorders
 - Chronic usage of cannabinoid agents
 - For the treatment of cyclic vomiting syndrome (CVC)
 - Postsurgical gastroparesis (PSG)
 - Percutaneous stimulation
 - Weight loss
- There is insufficient scientific evidence to support the medical necessity of gastric pacemakers for uses other than those listed in the clinical indications for procedure section.

Clinical Indications for Treatments

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- Gastric Pacemakers are medically necessary with **ALL** of the following
 - Individual with **1 or more** of the following
 - Chronic intractable nausea and vomiting secondary to severe diabetes

- Idiopathic gastroparesis with **1 or more** of the following
 - Individual has failed the use of all standard prokinetic and antiemetic medications
 - Individual with contraindications to the use of all standard prokinetic and antiemetic medications
- Individual with testing by standard scintigraphic imaging that reveals delayed gastric emptying of solid food
- Gastric pacemakers/gastric electrical stimulators are **NOT COVERED** for **ANY** of the following
 - As an initial treatment for gastroparesis
 - For treatment of obesity
 - For treatment of diabetes mellitus in persons without gastroparesis
 - For the treatment of autonomic nervous system disorders other than gastroparesis
 - Second/additional Gastric electrical stimulation
 - Temporary gastric electrical stimulation
 - Rumination syndrome or eating disorders
 - Chronic usage of cannabinoid agents
 - For the treatment of cyclic vomiting syndrome (CVC)
 - Postsurgical gastroparesis (PSG)
 - Percutaneous stimulation
 - Weight loss

Document History

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- Revised Dates:
 - 2021: November
 - 2019: November
 - 2012: June
- Reviewed Dates:
 - 2022: September
 - 2020: October
 - 2018: April
 - 2017: January
 - 2015: July
 - 2014: July
 - 2013: July
 - 2011: June
 - 2010: June
- Effective Date: June 2009

Coding Information

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- CPT/HCPCS codes covered if policy criteria is met:
 - CPT 43647 - Laparoscopy, surgical; implantation or replacement of gastric neurostimulator electrodes, antrum
 - CPT 43881 - Implantation or replacement of gastric neurostimulator electrodes, antrum, open
 - CPT 64590 - Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling (when specified as gastric neurostimulator)
- CPT/HCPCS codes considered not medically necessary per this Policy:
 - None

References

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References used include but are not limited to the following:

Specialty Association Guidelines; Government Regulations; Winifred S. Hayes, Inc; Uptodate; Literature Review; Specialty Advisors; National Coverage Determination (NCD); Local Coverage Determination (LCD).

2014 Gastroelectrical stimulation for gastroparesis. (2014, May 28). Retrieved Aug 18, 2022, from NICE Guidelines: <https://www.nice.org.uk/guidance/ipg489>

(2022). Retrieved Aug 18, 2022, from CMS.gov: <https://www.cms.gov/medicare-coverage-database/search-results.aspx?keyword=Gastric%20Stimulator&keywordType=all&areald=all&docType=6,3,5,1,F,P&contractOption=all&hcpcsOption=code&hcpcsStartCode=43647&hcpcsEndCode=43647&sortBy=title>

2022 Gastroparesis Guideline. (2022, Aug). Retrieved Aug 18, 2022, from American College of Gastroenterology (ACG): https://journals.lww.com/ajg/Fulltext/2022/08000/ACG_Clinical_Guideline__Gastroparesis.15.aspx

Electrical stimulation for gastroparesis. (2022, May 31). Retrieved Aug 18, 2022, from UpToDate: https://www.uptodate.com/contents/electrical-stimulation-for-gastroparesis?search=Gastric%20Stimulation&source=search_result&selectedTitle=1~150&usage_type=default&display_rank=1

GASTRIC ELECTRICAL STIMULATION (GES) SYSTEM. (2022, Aug 15). Retrieved Aug 17, 2022, from Food and Drug Administration: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfhde/hde.cfm?id=H990014>

Gastric Electrical Stimulation For Gastroparesis - Annual Review: Dec 8, 2021. (n.d.). Retrieved Aug 17, 2022, from HAYES: <https://evidence.hayesinc.com/report/dir.gast0001>

Gastric Stimulation (Electrical) (A-0395). (2022). Retrieved Aug 17, 2022, from MCG 26th Edition: <https://careweb.careguidelines.com/ed26/index.html>

Procedure Fee Files & CPT Codes. (2022). Retrieved Aug 18, 2022, from Department of Medical Assistance Services: <https://www.dmas.virginia.gov/for-providers/rates-and-rate-setting/procedure-fee-files-cpt-codes/>

The Enterra II gastric neurostimulator. (2022). Retrieved Aug 17, 2022, from Medtronic: <https://www.medtronic.com/us-en/healthcare-professionals/products/digestive-gastrointestinal/gastric-electrical-stimulation-systems/enterra-ii-neurostimulator.html>

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CPT® : 43647, 43881, 64590

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