Subject: Gastric Electric Stimulation for the Treatment of Chronic Gastroparesis

Medical Policy #: 7.2

Original Effective Date: 08-22-2012

Status: Reviewed

Last Annual Review Date: 12-11-2024

Disclaimer

Refer to the member's specific benefit plan and Schedule of Benefits to determine coverage. This may not be a benefit on all plans or the plan may have broader or more limited benefits than those listed in this Medical Policy.

Description

Gastroparesis is a chronic motility disorder of the stomach characterized by gastric retention in the absence of mechanical obstruction.

The system uses the implanted neurostimulator to deliver electrical impulses to nerves in the stomach. The electrical stimulation produced by this device stimulates the stomach to contract and helps control the symptoms associated with gastroparesis, including nausea and vomiting. The Enterra Therapy System (Medtronic, Minneapolis, MN) is currently the only gastric electrical stimulator that has received approval from the U.S. Food and Drug Administration (FDA). It was cleared by the FDA as a humanitarian use device. A humanitarian use device (HUD) is a device that is intended to benefit patients by treating or diagnosing a disease or condition that affects fewer than 4000 individuals in the United States per year.

Coverage Determination

Prior Authorization is not required. Logon to Pres Online to submit a request: https://ds.phs.org/preslogin/index.jsp

PHP has determined that the Gastric Electric Stimulation for the treatment of chronic gastroparesis is a covered benefit **for Medicare, Medicaid, and Commercial members.**

PHP will consider the use of gastric pacing (gastric pacemaker) device for refractory gastroparesis that has failed other treatments. **The Medical Director will review the request submitted for consideration on a case-by-case basis.**

Indication:

- Gastric pacing (also known as gastric electrical stimulation) is a treatment for individuals with chronic, intractable or drug-refractory nausea and vomiting **secondary to gastroparesis**, which could be **caused by diabetes** or other unknown (idiopathic) reasons.
- Permanent gastric electrical stimulation (GES) **or gastric pacing** (e.g., Enterra™ Therapy) is considered medically necessary when provided in accordance with the **Humanitarian Device Exemption (HDE)** specifications of the U.S. Food and Drug Administration (FDA) for intractable nausea and vomiting secondary to gastroparesis with failure, contraindication, or intolerance of pharmaceutical therapy.
- Gastric electrical stimulation (GES) or gastric pacing for any other indication is considered experimental, investigational or unproven.
- Temporary gastric electrical stimulation (GES) is considered experimental, investigational or unproven.

See the comprehensive list of devices (such as Enterra Therapy System (Medtronic Inc., Minneapolis, MN) and their respective FDA-labeled HDE indication(s) is available at:http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfHDE/HDEInformation.cfm.

Any condition outside these conditions mentioned in Gastric Electric Stimulation for the Treatment of Chronic Gastroparesis MPM 7.2 and/or Sacral Nerve Stimulation for Urinary and Fecal Incontinence MPM 51.0 will be reviewed on case-by-case basis by a Medical Director.

Coding

The coding listed in this medical policy is for reference only. Covered and non-covered codes are within this list.

CPT	Description
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
C1767	Generator, neurostimulator (implantable), non-rechargeable
C1778	Lead, neurostimulator (implantable)
C1820	Generator, neurostimulator (implantable), with rechargeable battery and charging system
C1822	Generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system
C1883	Adaptor/extension, pacing lead or neurostimulator lead (implantable)
C1897	Neurostimulator lead test kit (implantable)
L8679	Implantable neurostimulator, pulse generator, any type
L8680	Implantable neurostimulator electrode, each
L8685	Implantable neurostimulator pulse generator, single array, rechargeable, includes extension
L8686	Implantable neurostimulator pulse generator, single array, non-rechargeable, includes extension
L8688	Implantable neurostimulator pulse generator, dual array, non-rechargeable, includes extension

ICD-10	Description
K31.84	Gastroparesis

Reviewed by / Approval Signatures

Population Health & Clinical Quality Committee: Clinton White MD
Senior Medical Director: Jim Romero MD
Date Approved: 12-11-2024

References

1. MCG Health, 28th Edition Ambulatory Care, Gastric Stimulation (Electrical), ACG: A-0395 (AC), Last Update: 3/14/2024. [Cited 10/08/2024]
2. Hayes, a TractManager Company, Health Technology Assessment, Gastric Electrical Stimulation for Gastroparesis, Oct 26, 2018, Annual Review: Dec 07, 2022. [Cited 10/08/2024]
3. UpToDate, Electrical Stimulation for Gastroparesis, Author: William L Hasler, MD, Literature review current through: Sep 2024. | This topic last updated: Sept 12, 2023. [Cited 10/08/2024]
4. New Mexico BCBC, Gastric Electrical Stimulation (GES), Policy #: SUR709.031, Effective Date: 09-15-2023 Policy End Date: 10/14/2024
5. Aetna, #0678 Gastric Pacing / Electrical Stimulation and Gastric Per Oral Endoscopic Myotomy, Effective: 02/06/2004, Next Review: 07/25/2024. [Cited 10/0/2024]
6. Cigna, # 0103, Gastric Pacing/Gastric Electrical Stimulation (GES), Effective Date: 11/15/2021, Next Review Date:11/15/2024. [Cited 10/08/2024]
7. Humana, Gastric Pacing, Effective Date: 06/23/2022, Revision Date: 09-26-2024, Review Date: 09-26-2024, Policy Number: HUM-0388-023, Effective date: 09-26-2024. [Cited 10/08/2024]
8. CMS, Billing and Coding: Sacral Nerve Stimulation for Urinary and Fecal Incontinence, LCA (A53017), Revision date: 01/01/2024, R11 [Cited 10/08/2024]

Publication History

08-22-12 Original effective date
01-29-14 Presbyterian Policy Retired
01-29-14 Presbyterian now uses Aetna # 0678
03-25-15 Annual Review and changed from Aetna #0678 to MCG A-0395
03-22-17: Annual Review. Reviewed by the Technology Assessment Committee on Feb 25, 2017. Language re: use of Milliman criteria has been removed
07-31-19: Annual Review. MCG, 23rd Edition ACG: A-0395 current role remains uncertain. Hayes and GES is an adjunct to standard care for treatment of gastroparesis.
11-18-20 Annual Review. PHP Medical Policy Committee on 10-30-20. The following were updated:

- Clarified statement: "*Gastric Electric Stimulation is a non-covered benefit; however, request submitted for consideration of the device will be reviewed on a case-by-case basis*" was replaced to say, "*PHP has determined that the Gastric Electric Stimulation for the treatment of chronic gastroparesis is a covered benefit for Medicare, Medicaid, and Commercial members*."
- CPT codes were added. Prior Authorization will be required for 43647, 43648, 43881, 43882, 64590, 64595. A Medical Director will review request submitted for consideration on a case-by-case basis.
- The device codes C1820 and C1822 are considered paired to device dependent procedure and will be set to not pay

11-17-21 Annual review. Reviewed by PHP Medical Policy Committee on 10/29/2021. Continue as case-by-case review by Medical Directors. The language in the Description section was generalized. Gastric Electric Stimulation will be considered medically necessary for Gastroparesis, diagnosis code (K31.84)

New codes added to policy: C1767, C1778, C1883 and C1897. The following codes are considered bundled to procedure by OPPS (Status Indicator-N): C1767, C1778, C1883, C1897 and L8679. Codes C1883, C1897 and L8679 will be configured as Status N for all product line. Note C1883 & C1897 also applies to MPM 51.0 and L8679 also applies to MPM 22.4

CPT codes (64590 and 64595) will continue to require Prior Authorization for MPM 51.0 and MPM 7.2. For all product lines, CPT codes (64590 and 64595) will be set to only pay when submitted with those diagnoses codes listed in "Group one" in both LCA (A53017)-Billing and Coding: Sacral Nerve Stimulation for Urinary and Fecal Incontinence and LCA (A55530)-Billing and Coding: Peripheral Nerve Stimulation; in addition to these listed codes from both LCAs, diagnoses code (K31.84) will also be included.
11-16-22 Annual review. Reviewed by PHP Medical Policy Committee on 10/14/2022. No change. Continue as case-by-case review by Medical Directors. Continue configuration set for (MPM 7.2 and MPM 51.0) in 2021 since LCA (A55530) for Peripheral Nerve Stimulation and LCA (A53017) for Urine/Fecal incontinence plus ICD-10 code (K31.84) remains unchanged. New codes added to policy: L8679, L8679, L8680, L8685, L8686, and L8688. Added language regarding any condition outside these conditions mentioned in MPM 7.2 and/or MPM 51.0 will be reviewed on case-by-case basis by a Medical Director. HCPCS codes (C1767, C1778, C1820, C1883, C1897) are still considered Status N-per OPPS Addendum B (Oct 2022).
12-13-23 Annual review. Reviewed by PHP Medical Policy Committee on 10/11/2023. Additional coverage criteria added for permanent gastric pacing for treatment of with chronic, intractable or drug-refractory nausea and vomiting secondary to gastroparesis, which could be caused by diabetes or other unknown (idiopathic) reasons. Only those gastric pacing (e.g., Enterra™ Therapy) is considered medically necessary when provided in accordance with the Humanitarian Device Exemption (HDE) specifications of the U.S. Food and Drug Administration (FDA). Gastric electrical stimulation (GES) or gastric pacing for any other indication is considered experimental, investigational, or unproven. Temporary gastric electrical stimulation (GES) is considered experimental, investigational, or unproven. Updated previous configuration to add ICD-10 (G43.E11, G43.E19) related to peripheral nerve stimulation, as indicated in Group 1 of LCA (A55530).

12-11-24 Annual review. Reviewed by PHP Medical Policy Committee on 10-09-2024. No Change.

Update 03-26-2025: Reviewed by PHP Medical Policy Committee on 02-26-2025. The decision to remove PA for CPT codes (64590, 64595 43647, 43648, 43881, 43882) for ALOB was made during December 2024 cycle but was missed to be announced. The PA removal for these codes apply to MPM 53.0, MPM 51.0 (retired), and MPM 7.2. Continuation of the custom CES rule (ex PH003) configuration to map ICD-10 codes for CPT codes (64590 and 64595) using two LCAs, Noridian LCA (A55530) - Peripheral Nerve Stimulation and Sacral Nerve Stimulation for Urinary/Fecal Incontinence Noridian LCA (A53017) will continue to apply towards ALOB. In addition to the two LCAs mentioned, ICD-10 code (K31.84- Gastroparesis) will be included to be mapped with (64590 & 64595).

This Medical Policy is intended to represent clinical guidelines describing medical appropriateness and is developed to assist Presbyterian Health Plan and Presbyterian Insurance Company, Inc. (Presbyterian) Health Services staff and Presbyterian medical directors in determination of coverage. The Medical Policy is not a treatment guide and should not be used as such.

*For those instances where a member does not meet the criteria described in these guidelines, additional information supporting medical necessity is welcome and may be utilized by the medical director in reviewing the case. Please note that all Presbyterian Medical Policies are available online at: **Click here for Medical Policies***

Web links:

At any time during your visit to this policy and find the source material web links has been updated, retired or superseded, PHP is not responsible for the continued viability of websites listed in this policy.

When PHP follows a particular guideline such as LCDs, NCDs, MCG, NCCN etc., for the purposes of determining coverage; it is expected providers maintain or have access to appropriate documentation when requested to support coverage. See the References section to view the source materials used to develop this resource document.