Gastric Pacemakers/Gastric Electrical Stimulators

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Effective Date	6/2009
Next Review Date	9/15/2024
Coverage Policy	Surgical 95
Version	4

All requests for authorization for the services described by this medical policy will be reviewed per Early and Periodic Screening, Diagnostic and Treatment (EPSDT) guidelines. These services may be authorized under individual consideration for Medicaid members under the age of 21-years if the services are judged to be medically necessary to correct or ameliorate the member's condition. Department of Medical Assistance Services (DMAS), Supplement B - EPSDT (Early and Periodic Screening, Diagnosis and Treatment) Manual.*.

Purpose:

This policy addresses Gastric Pacemakers and Gastric Electrical Stimulators.

Description & Definitions:

Gastric electrical neurostimulators (also known as Gastric Pacemakers) consist of a pair of electrode leads, a pulse generator and a programming system. The leads are implanted generally on the grater 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 nuerostimulation 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.

Criteria:

Gastric Pacemakers/Gastric Electrical Stimulators 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 is considered **not medically necessary** for any use other than those indicated in clinical criteria, to include but not limited to:

- 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

Coding:

Medically necessary with criteria:

Coding	Description
43647	Laparoscopy, surgical; implantation or replacement of gastric neurostimulator electrodes, antrum
43881	Implantation or replacement of gastric neurostimulator electrodes, antrum, open
64590	Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling (when specified as gastric neurostimulator)

Considered Not Medically Necessary:

Coding	Description
	None

U.S. Food and Drug Administration (FDA) - approved only products only.

Document History:

Revised Dates:

- 2021: November
- 2019: November
- 2012: June

Reviewed Dates:

- 2023: September
- 2022: September
- 2020: October
- 2018: April
- 2017: January
- 2015: July
- 2014: July
- 2013: July
- 2011: June
- 2010: June

Effective Date:

- June 2009

References:

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

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(2023). Retrieved Aug 31, 2023, from CMS: https://www.cms.gov/medicare-coverage-database/search-results.aspx?keyword=gastric+neurostimulator&keywordType=starts&areaId=all&docType=NCA,CAL,NCD,MEDCAC,TA,MCD,6,3,5,1,F,P&contractOption=all

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Gastric Stimulation (Electrical) (A-0395). (2023). Retrieved Aug 31, 2023, from MCG 27th Edition: https://careweb.careguidelines.com/ed27/index.html

Special Notes: *

This medical policy express Sentara Health Plan's determination of medically necessity of services, and they are based upon a review of currently available clinical information. These policies are used when no specific guidelines for coverage are provided by the Department of Medical Assistance Services of Virginia (DMAS). Medical Policies may be superseded by state Medicaid Plan guidelines. Medical policies are not a substitute for clinical judgment or for any prior authorization requirements of the health plan. These policies are not an explanation of benefits.

Medical policies can be highly technical and complex and are provided here for informational purposes. These medical policies are intended for use by health care professionals. The medical policies do not constitute medical advice or medical care. Treating health care professionals are solely responsible for diagnosis, treatment and medical advice. Sentara Health Plan members should discuss the information in the medical policies with their treating health care professionals. Medical technology is constantly evolving and these medical policies are subject to change without notice, although Sentara Health Plan will notify providers as required in advance of changes that could have a negative impact on benefits.

The Early and Periodic Screening, Diagnostic and Treatment (EPSDT) covers services, products, or procedures for children, if those items are determined to be medically necessary to "correct or ameliorate" (make better) a defect, physical or mental illness, or condition (health problem) identified through routine medical screening or examination, regardless of whether coverage for the same service or support is an optional or limited service under the state plan. Children enrolled in the FAMIS Program are not eligible for all EPSDT treatment services. All requests for authorization for the services described by this medical policy will be reviewed per EPSDT guidelines. These services may be authorized under individual consideration for Medicaid members under the age of 21-years if the services are judged to by medically necessary to correct or ameliorate the member's condition. *Department of Medical Assistance Services (DMAS), Supplement B - EPSDT (Early and Periodic Screening, Diagnosis and Treatment) Manual.*

Keywords:

Gastric electrical stimulator, gastroparesis, neurostimulator, SHP Gastric Pacemakers, SHP Surgical 95, nausea, vomiting, diabetic gastroparesis, idiopathic gastroparesis, Laparoscopy, gastric pacemaker, low-frequency/high-energy GES, High-frequency/low-energy GES (eg. Enterra Therapy), GES, Enterra stimulator, Intestinal Stimulator, Gastric Pacing, Permanent or Temporary gastric electrical stimulation, SHP Gastric Pacemakers/Gastric Electrical Stimulators