Gastric Electrical Stimulation

Published: 08/01/2025

Next Review: 04/2026

Last Review: 06/2025 ***Medicare Link(s) Revised:*** *08/01/2025*

IMPORTANT REMINDER

The Medicare Advantage Medical Policy manual is not intended to override the member Evidence of Coverage (EOC), which defines the insured's benefits, nor is it intended to dictate how providers are to practice medicine. Physicians and other health care providers are expected to exercise their medical judgment in providing the most appropriate care for the individual member, including care that may be both medically reasonable and necessary.

The Medicare Advantage medical policies are designed to provide guidance regarding the decision-making process for the coverage or non-coverage of services or procedures in accordance with the member EOC and Centers of Medicare and Medicaid Services (CMS) policies and manuals, along with general CMS rules and regulations. In the event of a conflict, applicable CMS policy or EOC language will take precedence over the Medicare Advantage Medical Policy. In the absence of a specific CMS coverage determination for a requested service, item or procedure, the health plan may apply CMS regulations, as well as their Medical Policy Manual or other applicable utilization management vendor criteria developed with an objective, evidence-based process using scientific evidence, current generally accepted standards of medical practice, and authoritative clinical practice guidelines.

Some services or items may appear to be medically indicated for an individual, but may be a direct exclusion of Medicare or the member's benefit plan. Medicare and member EOCs exclude from coverage, among other things, services or procedures considered to be investigational (experimental) or cosmetic, as well as services or items considered not medically reasonable and necessary under Title XVIII of the Social Security Act, §1862(a)(1)(A). In some cases, providers may bill members for these non-covered services or procedures. Providers are encouraged to inform members in advance when they may be financially responsible for the cost of non-covered or excluded services. Members, their appointed representative, or a treating provider can request coverage of a service or item by submitting a pre-service organization determination prior to services being rendered.

DESCRIPTION

Gastric electrical stimulation (GES) is performed using an implantable device designed to treat chronic drug-refractory nausea and vomiting secondary to gastroparesis of diabetic or idiopathic etiology. Gastric electrical stimulation is also proposed as a treatment of obesity. The device may also be referred to as a gastric pacemaker or gastric pacing.

MEDICARE ADVANTAGE POLICY CRITERIA

Note: This policy addresses *gastric* nerve stimulation. It does not address *vagus* nerve *stimulation* (VNS), nor does it address *vagus* nerve *blocking*. These procedures, and additional treatments for obesity can be found in separate Medicare Advantage medical policies (See Cross References).

CMS Coverage Manuals*	For ***removal of the gastric electrical stimulation devices only,*** as well as ***revision/replacement*** of *not medically necessary devices*: Medicare Benefit Policy Manual Chapter 16 - General Exclusions From Coverage *See Section 180 in the following link:* §180 - Services Related to and Required as a Result of Services Which Are Not Covered Under Medicare Note: Please read the applicable section, in its entirety, for complete criteria details. ***Removal only*** (without replacement) of a device may be allowed as medically necessary when the removal is required in order to treat a medical condition or complication. Even if initial placement of the device did not meet medical necessity coverage criteria and the complication or subsequent medical condition is the result of a prior non-covered service, coverage may be allowed in select circumstances for the removal of the device. However, a procedure or device that doesn't meet medical necessity criteria is non-covered and any ***revision or replacement*** to allow for the *continued* use of the non-covered device would not meet Medicare's general requirements for coverage. For ***revision/replacement*** requests of previously placed *medically necessary devices*: Medicare Benefit Policy Manual Chapter 15 – Covered Medical and Other Health Services *See Section 120 in the following link:* §120 - Prosthetic Devices, D. Supplies, Repairs, Adjustments, and Replacement[1] Note: Replacement of previously placed medically necessary devices or their components that are non-functioning and irreparable (e.g., device malfunction, etc.) may be considered medically necessary in accordance with the above Medicare reference if the stimulator continues to be medically indicated and is no longer under manufacturer warranty or if the component is not included under the warranty.[1]

National Coverage Determinations (NCDs)*	None
Noridian Healthcare Solutions (Noridian) Local Coverage Determinations (LCDs) and Articles*	None
Medical Policy Manual	*Medicare coverage guidance is not available for Gastric Electrical Stimulation. Therefore, the health plan's medical policy is applicable.* Gastric Electrical Stimulation, Surgery, Policy No. 111 *(see "NOTE" below)*

NOTE: If a procedure or device lacks scientific evidence regarding safety and efficacy because it is investigational or experimental, the service is noncovered as not reasonable and necessary to treat illness or injury. (*Medicare IOM Pub. No. 100-04, Ch. 23, §30 A*). According to Title XVIII of the Social Security Act, §1862(a)(1)(A), only medically reasonable and necessary services are covered by Medicare. In the absence of a NCD, LCD, or other coverage guideline, CMS guidelines allow a Medicare Advantage Organization (MAO) to make coverage determinations, applying an ***objective, evidence-based process, based on authoritative evidence***. (*Medicare IOM Pub. No. 100-16, Ch. 4, §90.5*). The Medicare Advantage Medical Policy - Medicine Policy No. M-149 - provides further details regarding the plan's evidence-assessment process (see Cross References).

POLICY GUIDELINES

REQUIRED DOCUMENTATION

The information below **must** be submitted for review to determine whether policy criteria are met. If any of these items are not submitted, it could impact our review and decision outcome:

- For initial placement:
  - History and Physical/Chart Notes
  - Current Symptomology
  - Prokinetic and Antiemetic Medications given and response
- For replacement of irreparable devices or their components, documentation must support reason for replacement (e.g., device malfunction, etc.) and whether or not the stimulator is still under manufacturer warranty or that the component excluded from the warranty
- For revisions and removal only (without replacement): Revisions to previously placed medically necessary devices and removals do not require additional documentation.

REGULATORY STATUS

The Enterra™ Therapy System (formerly named Gastric Electrical Stimulation [GES] System; manufactured by Medtronic) is the only device approved for treatment of chronic refractory

gastroparesis. Specifically, the indication for Enterra Therapy is for treatment of chronic, resistant to medication nausea and vomiting associated with gastroparesis caused by diabetes or an unknown origin in patients aged 18 to 70 years. The Enterra system received approval for marketing from the U.S. Food and Drug Administration (FDA) in 2000 through the humanitarian device exemption (HDE) process.[2] This process requires the manufacturer to provide adequate information for the FDA to determine that the device has "probable" benefit but does not pose an unreasonable or significant risk; it does not require data confirming the efficacy of the device. The HDE process is available for devices treating conditions that affect fewer than 4,000 Americans per year.

Note, the fact a service or procedure has been issued a CPT/HCPCS code or is FDA approved for a specific indication does not, in itself, make the procedure medically reasonable and necessary. The FDA determines safety and effectiveness of a device or drug, but does not establish medical necessity. While Medicare may adopt FDA determinations regarding safety and effectiveness, CMS or Medicare contractors evaluate whether or not the drug or device is reasonable and necessary for the Medicare population under §1862(a)(1)(A).

CROSS REFERENCES

Electrical Stimulation and Electromagnetic Therapy Devices, Durable Medical Equipment, Policy No. M-83

Investigational (Experimental) Services, New and Emerging Medical Technologies and Procedures, and Other Non-Covered Services, Medicine, Policy No. M-149

Vagus Nerve Stimulation (VNS), Surgery, Policy No. M-74

REFERENCES

1. Medicare Benefit Policy Manual, Chapter 16 - General Exclusions From Coverage. [Accessed: 4/21/2025]; Available from: §40.4 - Items Covered Under Warranty
2. Enterra Therapy System FDA Summary of Safety and Effectiveness Data (SSED). [Accessed: 04/21/2025]; Available from: http://www.accessdata.fda.gov/cdrh_docs/pdf/H990014b.pdf

CODING

NOTE: HCPCS code C1823 is NOT the correct code to use for reporting these services. Please refer to the codes listed below for guidance.

Codes	Number	Description
CPT	43647	Laparoscopy, surgical; implantation or replacement of gastric neurostimulator electrodes, antrum
	43648	Laparoscopy, surgical; revision or removal of gastric neurostimulator electrodes, antrum
	43659	Unlisted laparoscopy procedure, stomach

	43881	Implantation or replacement of gastric neurostimulator electrodes, antrum, open
	43882	Revision or removal of gastric neurostimulator electrodes, antrum, open
	43999	Unlisted procedure, stomach
	64590	Insertion or replacement of peripheral, sacral, or gastric neurostimulator pulse generator or receiver, requiring pocket creation and connection between electrode array and pulse generator or receiver
	64595	Revision or removal of peripheral, sacral, or gastric neurostimulator pulse generator or receiver, with detachable connection to electrode array
	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	; subsequent, without programming
	95982	; subsequent, with reprogramming
HCPCS	C1767	Generator, neurostimulator (implantable), non-rechargeable
	C1778	Lead, neurostimulator (implantable)
	C1822	Generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system
	C1883	Adaptor/Extension, pacing lead or neurostimulator (implantable)
	C1897	Lead, neurostimulator test kit (implantable)
	E0765	FDA approved nerve stimulator, with replaceable batteries, for treatment of nausea and vomiting
	L8678	Electrical stimulator supplies (external) for use with implantable neurostimulator, per month
	L8679	Implantable neurostimulator, pulse generator, any type
	L8680	Implantable neurostimulator electrode, each *(Code non-covered by Medicare – see L8679)*
	L8685	Implantable neurostimulator pulse generator, single array, rechargeable, includes extension *(Code non-covered by Medicare – see L8679)*
	L8686	Implantable neurostimulator pulse generator, single array, nonrechargeable, includes extension *(Code non-covered by Medicare – see L8679)*
	L8687	Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension *(Code non-covered by Medicare – see L8679)*
	L8688	Implantable neurostimulator pulse generator, dual array, nonrechargeable, includes extension *(Code non-covered by Medicare – see L8679)*

***IMPORTANT NOTE:** Medicare Advantage medical policies use the most current Medicare references available at the time the policy was developed. Links to Medicare references will take viewers to external websites outside of the health plan's web control as these sites are not maintained by the health plan.*