

Gastric Electrical Stimulation

Published: 06/01/2019

Next Review: 04/2020

Last Review: 04/2019

Medicare Link(s) Revised: 06/01/2019

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.

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 the Centers of Medicare and Medicaid Services (CMS) policies, when available. 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 CMS guidance for a requested service or procedure, the health plan may apply their Medical Policy Manual or MCG™ criteria, both of which are developed with an objective, evidence-based process using scientific evidence, current generally accepted standards of medical practice, and authoritative clinical practice guidelines.

Medicare and EOCs exclude from coverage, among other things, services or procedures considered to be investigational, cosmetic, or not medically necessary, and 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.

DESCRIPTION

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

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*	None
------------------------------	------

National Coverage Determinations (NCDs)*	None
Noridian Healthcare Solutions (Noridian) Local Coverage Determinations (LCDs) and Articles (LCAs)*	<p>For the Enterra® Gastric Electrical Stimulation System for use in the treatment of gastroparesis:</p> <ul style="list-style-type: none"> ✓ Retired Enterra® Gastric Electrical Stimulation System Humanitarian Device Exemption R3 (A51751) <p>Instructions: Highlight A51751, and press Control + C to copy. Click on the LCA A51751 link. Click the “Search” button provided in the list near the top, and enter (or paste) the LCA number into the “ID Search” field. The date of service can be left blank. Click the “Search Now” button.</p> <p>Note: This LCA was retired May 15, 2014; however, Noridian states, “Retirement does not mean that medical necessity has changed or that the LCD no longer reflects appropriate criteria. Rather, retirement is a reflection of the provider community’s understanding of the medical necessity criteria for the services covered by and compliance with Medicare guidelines on these LCDs.” Therefore, continue to use LCA A51751 for determining medical necessity for the Enterra® gastric electrical stimulation system.^[1]</p> <p>**Scroll to the “Public Version(s)” section at the bottom of the LCD for links to prior versions if necessary.</p>

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:

- Chart notes, medical records, or other clinical documentation that supports severe and chronic gastroparesis of diabetic or idiopathic origin, refractory to drug and other reasonable therapeutic interventions; and,
- The implanting facility's institutional review board (IRB) approval for implantation of the system for one of the specific indications listed above.

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. It 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.

CROSS REFERENCES

[Electrical Stimulation and Electromagnetic Therapy Devices](#), Durable Medical Equipment, Policy No. M-83

[Investigational \(Experimental\) Services and New and Emerging Medical Technologies and Procedures](#), Medicine, Policy No. M-149

[Vagus Nerve Stimulation \(VNS\)](#), Surgery, Policy No. M-74

[Vagus Nerve Blocking Therapy for Obesity](#), Surgery, Policy No. M-200

REFERENCES

1. LCD Retirement Clarification. [cited 4/19/2019]; Available from: <https://med.noridianmedicare.com/web/jfb/policies/lcd/retired/retirement-clarification>
2. Enterra Therapy System FDA Summary of Safety and Effectiveness Data (SSED). [cited 04/19/2019]; 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 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	; 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
	L8679	Implantable neurostimulator, pulse generator, any type
	L8680	Implantable neurostimulator electrode, each (<i>Code non-covered by Medicare – see L8679</i>)
	L8685	Implantable neurostimulator pulse generator, single array, rechargeable, includes extension (<i>Code non-covered by Medicare – see L8679</i>)
	L8686	Implantable neurostimulator pulse generator, single array, nonrechargeable, includes extension (<i>Code non-covered by Medicare – see L8679</i>)
	L8687	Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension (<i>Code non-covered by Medicare – see L8679</i>)
	L8688	Implantable neurostimulator pulse generator, dual array, nonrechargeable, includes extension (<i>Code non-covered by Medicare – see L8679</i>)

***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.