Medical Policy:
Gastric Electrical Stimulation

POLICY NUMBER	EFFECTIVE DATE	APPROVED BY
MG.MM.SU.57	2/14/2025	MPC (Medical Policy Committee)

IMPORTANT NOTE ABOUT THIS MEDICAL POLICY:

 The treating physician or primary care provider must submit to ConnectiCare, Inc. the clinical evidence that the patient meets the criteria for the treatment or surgical procedure. Without this documentation and information, ConnectiCare will not be able to properly review the request for prior authorization. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. The clinical review criteria expressed below reflects how ConnectiCare determines whether certain services or supplies are medically necessary. ConnectiCare established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer-reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). ConnectiCare, Inc. expressly reserves the right to revise these conclusions as clinical information changes, and welcomes further relevant information. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. Each benefit plan defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by ConnectiCare, as some plans exclude coverage for services or supplies that ConnectiCare considers medically necessary. If there is a discrepancy between this guideline and a member's benefits plan, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of the State of CT and/or the Federal Government. Coverage may also differ for our Medicare members based on any applicable Centers for Medicare & Medicaid Services (CMS) coverage statements including including National Coverage Determinations (NCD), Local Coverage Determinations (LCD) and/or Local Medical Review Policies (LMRP). All coding and web site links are accurate at time of publication.

Definitions

Gastric electrical stimulation (GES) has been developed as an alternative treatment for refractory gastroparesis. The device consists of 4 components: the implanted pulse generator, 2 intramuscular stomach leads, a stimulator programmer and a memory cartridge. The leads are implanted surgically using an open or laparoscopic technique and are connected to the pulse generator that is implanted in a subcutaneous pouch. The device delivers timed impulses to the gastric muscles that are intended to stimulate gastric myoelectric activity, with the goal of improving stomach emptying and relieving the symptoms of nausea and vomiting.

GES has also been proposed as an alternative to bariatric surgery for the treatment of obesity. The technique for implantation of the device is the same for treating gastroparesis but utilizes different stimulation parameters and a different location for placement of electrodes on the stomach wall. GES in the obese patient is thought to induce early satiety, but it is not known whether this is caused by stimulation of the nerves, inhibition of hormones or stimulation of the stomach muscle itself. (See Limitations/Exclusions)

Guideline

GES is considered medically necessary for the treatment of chronic, intractable (drug-refractory) nausea and vomiting secondary to gastroparesis of diabetic or idiopathic etiology.
The following criteria must be met:

- Significantly delayed gastric emptying as evidenced by standard scintigraphic imaging of solid food

- Member is refractory or intolerant to both:
  - Prokinetic medications (2 out of 3 classes)
  - Antiemetic medications (2 out of 3)
- Significantly poor nutritional status, as evidenced by weight loss of 10% of body weight (for height and age in comparison with pre-illness weight)

Table 1: Prokinetic Medications

Class	Common Examples
Cholinergic Agonists	dexpanthenol (Ilopan®), bethanechol (Urecholine®)
Motolin receptor agonists	Erythromycin
Dopamine receptor antagonists	metoclopramide (Reglan®)

Table 2: Antiemetic Medications

Class	Common Examples
Antihistamines	diphenhydramine (Benadryl®), dimenhydrinate (Dramamine®), meclizine (Antivert®), hydroxyzine (Vistaril®), trimethobenzamide (Tigan®)
Serotonin (5HT3) receptor antagonists	ondansetron (Zofran®), granisetron (Kytril®), dolasetron (Anzemet®)
Dopamine receptor antagonists	Metoclopramide (Reglan®), perphenazine (Trilafon®), prochlorperazine (Compazine®), promethazine (Phenergan®), thiethylperazine (Torecan®), cyclizine (Marezine®)

Limitations/Exclusions

1. GES is not considered medically necessary for gastrointestinal dysmotility disorders other than gastroparesis, obesity (or any other indication not listed above) due to insufficient evidence of therapeutic value.
2. The Medtronic Enterra® Therapy System, a high frequency electronic device, is currently FDA approved under the FDA's Humanitarian Device Exemption (HDE) program. No other GES system for treating gastroparesis has been approved to date. Therefore, requests for alternate GES systems (e.g., gastric pacing, neural gastric electrical stimulation) will be denied as not medically necessary due to insufficient evidence of therapeutic value.

Procedure Codes

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
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	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; subsequent, **without** reprogramming
95982	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; subsequent, **with** reprogramming
L8679	Implantable neurostimulator, pulse generator, any type
L8680	Implantable neurostimulator electrode, each
L8681	Patient programmer (external) for use with implantable programmable neurostimulator pulse generator, replacement only
L8682	Implantable neurostimulator radiofrequency receiver
L8683	Radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receiver
L8685	Implantable neurostimulator pulse generator, single array, rechargeable, includes extension
L8686	Implantable neurostimulator pulse generator, single array, nonrechargeable, includes extension
L8687	Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension
L8688	Implantable neurostimulator pulse generator, dual array, nonrechargeable, includes extension
L8689	External recharging system for battery (internal) for use with implantable neurostimulator, replacement only

References

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17. Specialty-matched clinical peer review.

Revision History

Company(ies)	DATE	REVISION
ConnectiCare	Mar. 14, 2025	Transferred policy content to individual company branded template
EmblemHealth ConnectiCare	Jan. 8, 2021	Changed decrease of "≤ 90% of normal body weight" (as evidence of significantly poor nutritional status) to "weight loss of 10% of body weight"
ConnectiCare	Dec. 9, 2019	ConnectiCare adopts the clinical criteria of its parent corporation EmblemHealth