

SUBJECT: GASTRIC ELECTRICAL STIMULATION	EFFECTIVE DATE: 04/15/04 REVISED DATE: 04/21/05, 01/19/06, 03/15/07, 12/20/07, 10/23/08, 09/17/09, 08/19/10, 07/21/11, 06/21/12, 05/23/13, 05/22/14
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• If the member's subscriber contract excludes coverage for a specific service it is not covered under that contract. In such cases, medical policy criteria are not applied.

• Medical policies apply to commercial and Medicaid products only when a contract benefit for the specific service exists.

• Medical policies only apply to Medicare products when a contract benefit exists and where there are no National or Local Medicare coverage decisions for the specific service.

POLICY STATEMENT:

Based upon our criteria and assessment of peer-reviewed literature, gastric electrical stimulation is considered **investigational** for the treatment of any disease or condition, including, but not limited to, gastroparesis and morbid obesity.

Although other methods of electrical stimulation of the gastric wall of patients with gastroparesis are under investigation (e.g., gastric pacing, neural gastric electrical stimulation), this medical policy addresses only the medical appropriateness of high-frequency gastric electrical stimulation.

Refer to Corporate Medical Policy #11.01.03 regarding Experimental and Investigational Services.

POLICY GUIDELINES:

The Federal Employee Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

DESCRIPTION:

Gastroparesis is a gastrointestinal motility disorder defined by delayed gastric emptying without evidence of obstruction. Patients may experience symptoms of frequent nausea and vomiting, early or easy satiety, bloating and weight loss. Gastroparesis may occur in association with systemic diseases such as diabetes mellitus, scleroderma, or lupus erythematosus. Gastroparesis can also develop after vagotomy or other gastric surgeries or may be idiopathic in nature.

Gastric electrical stimulation (GES) has been developed as an alternative treatment for patients with 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.

Gastric electrical stimulation 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.

RATIONALE:

The Enterra™ Therapy System (Medtronic Inc.), a high frequency gastric electrical stimulation system, received FDA approval in 2000 under Humanitarian Device Exemption (HDE). The Enterra™ Therapy System is indicated for the treatment of chronic, intractable (drug refractory) nausea and vomiting secondary to gastroparesis of diabetic or idiopathic etiology. HDE allows approval of a device for conditions that are considered rare. Approval is granted with the understanding that the device is intended to benefit patients in the treatment and diagnosis of diseases and conditions that affect or are manifested in fewer than 4,000 people in the USA each year. A humanitarian use device may only be used in facilities that have an Institutional Review Board (IRB) to supervise clinical testing of the device.

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The data presented to the FDA documenting probable benefit of the GES system were based on a multicenter double-blind crossover study referred to as the WAVESS study (worldwide anti-vomiting electrical stimulation study). The study included 33 patients with intractable idiopathic or diabetic gastroparesis. In the initial phase of the study all patients underwent implantation and were randomly and blindly assigned to either the ON mode or the OFF mode for the first month with crossover to the opposite mode for the second month of the study. The baseline vomiting frequency was 47 episodes per month, which declined in both the ON mode and the OFF mode to 23 and 29 episodes respectively. However, no statistically significant differences in the number of vomiting episodes were found between the OFF and ON groups, suggesting a placebo effect. In questioning patients as to which month of treatment they preferred (ON vs OFF), a greater number of patients preferred the month of treatment in the ON mode. In the second phase of the study, patients received stimulation consistent with their preference to the ON or OFF mode. At 6 and 12-month follow-up, vomiting episodes continued to decline, although only 15 patients were available for follow-up.

The evidence available from studies is insufficient to prove that gastric electrical stimulation is effective for the treatment of patients with gastroparesis. Though the evidence does suggest that GES can relieve nausea and vomiting and may also reduce the need for nutritional support in some patients with intractable gastroparesis, there was no documentation of improved gastric emptying or enhanced gastric motility. The studies included small numbers of patients, limited follow-up and are inadequate to establish that GES is an effective or durable treatment for gastroparesis. Long-term results of GES need to be validated in longer-term randomized trials.

No FDA devices have received FDA approval for the treatment of obesity. Transneuronix, Inc. has developed an implantable gastric stimulator (IGS®), The Transcend® IGS, which is currently being studied in the SHAPE clinical trial in the United States. The TANTALUS® System by MetaCure is also being investigated in the treatment of obese/overweight patients with Type II Diabetes. Preliminary studies are promising for this treatment modality, but weight reduction in studies thus far has varied widely with 1/3 of patients losing no weight and others having significant weight loss.

CODES: Number Description

Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.

CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.

Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).

CPT:	43647 (E/I)	Laparoscopy, surgical; implantation or replacement of gastric neurostimulator electrodes, antrum
	43648 (E/I)	revision or removal of gastric neurostimulator electrodes, antrum
	43881 (E/I)	Implantation or replacement of gastric neurostimulator electrodes, antrum, open
	43882 (E/I)	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 peripheral or gastric neurostimulator pulse generator or receiver
	95980 (E/I)	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

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95981 (E/I) 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 (E/I) 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

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HCPCS:	E0765 (E/I)	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
	L8681	Patient programmer (external) for use with implantable programmable neurostimulator pulse generator
	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, non-rechargeable, includes extension
	L8687	Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension
	L8688	Implantable neurostimulator pulse generator, dual array, non-rechargeable, includes extension
	L8689	External recharging system for battery (internal) for use with implanted neurostimulator
ICD9:	536.3	Gastroparesis
	278.00	Obesity, unspecified
	278.01	Morbid obesity
	787.01-787.03	Nausea and vomiting (code range)
ICD10:	E66.01	Morbid obesity due to excess calories
	E66.09	Other obesity due to excess calories
	E66.8	Other obesity
	E66.9	Obesity, unspecified
	K31.84	Gastroparesis
	R11.0-R11.2	Nausea and vomiting (code range)

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KEY WORDS:

Gastric stimulation, Gastric pacing, Gastroparesis

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

Based on our review, there is no specific national or regional coverage determination addressing gastric electrical stimulation.