BlueCross BlueShield Federal Employee Program.

FEP Medical Policy Manual

FEP 7.01.73 Gastric Electrical Stimulation

Effective Policy Date: July 1, 2022

Original Policy Date: September 2012

Related Policies:

7.01.15 - Meniscal Allografts and Other Meniscal Implants

Gastric Electrical Stimulation

Description

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, idiopathic, or postsurgical etiology. GES has also been investigated as a treatment of obesity. The device may be referred to as a gastric pacemaker.

OBJECTIVE

The objective of this evidence review is to determine whether gastric electrical stimulation improves the net health outcome for patients with gastroparesis or obesity.

POLICY STATEMENT

Gastric electrical stimulation is considered **investigational** for the treatment of gastroparesis of diabetic, idiopathic, or postsurgical etiology.

Gastric electrical stimulation is considered **investigational** for the treatment of obesity.

POLICY GUIDELINES

None

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

FDA REGULATORY STATUS

Regulatory Status

In 2000, the Gastric Electrical Stimulator system (now called Enterra™ Therapy System; Medtronic) was approved by the U.S. Food and Drug Administration (FDA) through the humanitarian device exemption process (H990014) for the treatment of gastroparesis. The GES system consists of 4 components: the implanted pulse generator, 2 unipolar intramuscular stomach leads, the stimulator programmer, and the memory cartridge. With the exception of the intramuscular leads, all other components have been used in other implantable neurologic stimulators, such as spinal cord or sacral nerve stimulation. The intramuscular stomach leads are implanted either laparoscopically or during laparotomy and are connected to the pulse generator, which is implanted in a subcutaneous pocket. The programmer sets the stimulation parameters, which are typically set at an "on" time of 0.1 seconds alternating with an "off" time of 5.0 seconds.

Currently, no GES devices have been approved by the FDA for the treatment of obesity. The Transcend (Transneuronix; acquired by Medtronic in 2005), an implantable gastric stimulation device, is available in Europe for treatment of obesity.

RATIONALE

Summary of Evidence

For individuals who have gastroparesis who receive gastric electrical stimulation (GES), the evidence includes randomized controlled trials (RCTs) , nonrandomized studies, and systematic reviews. Relevant outcomes are symptoms and treatment-related morbidity. Five crossover RCTs have been published. A 2017 meta-analysis of these 5 RCTs did not find a significant benefit of GES on the severity of symptoms associated with gastroparesis. Patients generally reported improved symptoms at follow-up whether or not the device was turned on, suggesting a placebo effect. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have obesity who receive GES, the evidence includes an RCT and several small case series and uncontrolled prospective trials. Relevant outcomes are change in disease status and treatment-related morbidity. The SHAPE trial did not show significant improvement in weight loss using GES compared with a sham stimulation. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

National Institute for Health and Care Excellence

In 2014, the National Institute for Health and Care Excellence issued guidance on GES for gastroparesis.[17,] The Institute made the following recommendations:

1.1 "Current evidence on the efficacy and safety of gastric electrical stimulation for gastroparesis is adequate to support the use of this procedure with normal arrangements for clinical governance, consent, and audit."

1.2 "... clinicians should inform patients considering gastric electrical stimulation for gastroparesis that some patients do not get any benefit from it. They should also give patients detailed written information about the risk of complications, which can be serious, including the need to remove the device."

1.3 "Patient selection and follow-up should be done in specialist gastroenterology units with expertise in gastrointestinal motility disorders, and the procedure should only be performed by surgeons working in these units."

American College of Gastroenterology

In 2013, the American College of Gastroenterology published practice guidelines on the management of gastroparesis.[18,] The College recommended that:

"GES [gastric electrical stimulation] may be considered for compassionate treatment in patients with refractory symptoms, particularly nausea and vomiting. Symptom severity and gastric emptying have been shown to improve in patients with DG [diabetic gastroparesis], but not in patients with IG [idiopathic gastroparesis] or PSG [postsurgical gastroparesis]. [Conditional recommendation (there is uncertainty about trade-offs), moderate level of evidence (further research would be likely to have an impact on the confidence in the estimate of effect).]"

An update is in progress from the American College of Gastroenterology.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

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POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

Date	Action	Description
September 2012	New policy	Gastric electrical stimulation is considered not medically necessary for the treatment of gastroparesis of diabetic or idiopathic etiology. Gastric electrical stimulation is considered investigational for the treatment of obesity
December 2013	Replace policy	Policy updated with literature review, references 1, 9, 13, 17, 18, 26 and 27 added; no changes in policy statements. Policy summary revised/clarified with no change to intent.
December 2014	Replace policy	Policy updated with literature review through July 1, 2014. References 5,14, and 27-28 added. Rationale section reorganized. No change to policy statements.
June 2016	Replace policy	Policy updated with literature review through November 10, 2015;references 4 and 12 added. Policy statements unchanged.
June 2018	Replace policy	Policy updated with literature review through December 11, 2017;reference 1 added. Policy statements unchanged except "not medically necessary€ corrected to "investigational€ due to FDA HDE status.
June 2019	Replace policy	Policy updated with literature review through January 3, 2019; references 8-9 added. Policy statements unchanged.
June 2020	Replace policy	Policy updated with literature review through December 9, 2019; no references added. Policy statements unchanged.
June 2021	Replace policy	Policy updated with literature review through December 10, 2020; no references added. Policy statements unchanged.
February 2022	Replace policy	Policy updated with literature review through December 31, 2021; no references added. Policy statements unchanged.