Prior Authorization Review Panel
MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

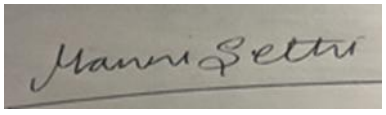
Plan: AmeriHealth Caritas Pennsylvania & Keystone First	Submission Date: 7/1/2025
Policy Number: CCP.1527	Effective Date: 7/1/2023 Revision Date: 6/2025
Policy Name: Gastrointestinal electrical stimulation for obesity	

Type of Submission:

☐ New Policy	☒ Prior Authorization Policy
☒ Revised Policy*	☐ Base Policy
☐ Annual Review- no revisions	☒ Experimental/Investigational Policy
	☐ Statewide PDL
	☐ Other:

*All revisions to the policy must be highlighted using track changes throughout the document.

Please provide any clarifying information for the policy below:

Name of Authorized Individual (Please type or print): Manni Sethi, MD, MBA, CHCQM	Signature of Authorized Individual: 

Keystone First
Family of Health Plans

Gastrointestinal electrical stimulation for obesity

Clinical Policy ID: CCP.1527

Recent review date: 6/2025

Next review date: 10/2026

Policy contains: Enterra, gastrointestinal electrical stimulation, obesity

Keystone First has developed clinical policies to assist with making coverage determinations. Keystone First's clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of "medically necessary," and the specific facts of the particular situation are considered by Keystone First, on a case by case basis, when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. Keystone First's clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. Keystone First's clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Keystone First will update its clinical policies as necessary. Keystone First's clinical policies are not guarantees of payment.

Coverage policy

Gastrointestinal electrical stimulation, also known as gastric pacemaker, for obesity, is investigational/not clinically proven and, therefore, not medically necessary.

Limitations

No limitations were identified during the writing of this policy.

Alternative covered services

- Bariatric surgery.
- Medications for appetite control.

Background

Obesity in the United States has increased rapidly in the past several decades. The prevalence from 2017 to 2020 was 19.7% for children ages 2 to 19 (Centers for Disease Control and Prevention, 2024a), and 41.9% among adults — up from 30.5% from 1999 to 2000 (Centers for Disease Control and Prevention, 2024b). Obesity is associated with common causes of preventable deaths, including heart disease, stroke, type 2 diabetes, and certain cancers.

Obesity is commonly treated with conservative measures such as dietary changes and exercise. Other treatments include medications and bariatric surgery. Intragastric balloons and gastric emptying devices offer temporary, less invasive alternatives to bariatric surgery that do not permanently alter the stomach or small intestine (National Institute of Diabetes and Digestive and Kidney Diseases, 2023).

Gastrointestinal electrical stimulation, also known as gastric pacemaker, is another less invasive procedure that uses implanted devices believed to modulate neurohormones and/or stimulate stomach muscles. Gastrointestinal electrical stimulation consists of a small electrical generator surgically implanted under the skin of the abdomen and two electrodes surgically placed into the superficial tissue of the distal stomach. Different methods apply various stimulus configurations to achieve a desired effect on satiety and gastric motility. These methods include implantable gastric stimulation, the Tantalus® system (MetaCure, Ltd, Beckenham, United Kingdom), and closed-loop gastric electrical stimulation. Physicians can adjust voltage and rate settings of the device at any time according to patient symptoms (Maisiyiti, 2019).

Stimulation can be low-frequency/high-energy with long pulse stimulation, or high-frequency/low-energy with short pulse stimulation. The latter, known as the Enterra II gastric neurostimulator (Medtronic, Minneapolis, Minnesota) is used on humans (Lal, 2015). In 2000, the U.S. Food and Drug Administration approved Enterra as a Humanitarian Device Exemption for treatment of chronic, drug-refractory nausea and vomiting secondary to gastroparesis or idiopathic etiology for persons 18 to 70 years of age; approval did not include treatment for obesity (U.S. Food and Drug Administration, 2015).

The Tantalus system is available in Europe only. The Maestro Rechargeable System (EnteroMedics, now ReShape Lifesciences, Inc., Eden Prairie, Minnesota) targets the vagus nerve but is no longer available in the United States (U.S. Food and Drug Administration, 2022). To date, the U.S. Food and Drug Administration has not approved any gastrointestinal electrical stimulation product for obesity.

Findings

Guidelines

No guideline on obesity from professional medical associations, including the American Association of Clinical Endocrinologists, American College of Cardiology, American College of Endocrinology, American Heart Association, and National Institute for Health and Care Excellence address gastrointestinal electrical stimulation.

Evidence review

Compared with the surgical treatment, gastrointestinal electrical stimulation is less invasive, reversible, and adjustable. Advancements in neurostimulation of the gastrointestinal tract highlight both temporary and permanent stimulation methods. Implantable gastrointestinal electrical stimulation may become an appropriate therapy for obesity for its ability to suppress food intake and induce postprandial satiety by interrupting the normal gastric pace making activity. The efficacy is insufficient to induce satiety strong enough to alter eating behaviors of patients with obesity. Long-term clinical data are not available, and ongoing clinical trials need to be completed to confirm treatment efficacy (Abell, 2015). No gastrointestinal electrical stimulator device is currently available on the market for treating obesity.

Systematic reviews on gastrointestinal electrical stimulation for obesity have been published. A systematic review examined 11 articles, and authors conclude that the procedure has potential to treat obesity, but more research is needed through clinical trials to determine optimal simulation parameters and treatment regimens (Maisiyiti, 2019). Another systematic review of 30 studies (n = 1,367) documented significant weight loss (22 studies) and appetite reduction (16 studies) in the majority of studies. However, most studies did not track patients for more than 12 months after the procedure (Cha, 2014).

Two randomized studies have been published using different gastrointestinal electrical stimulation devices, but neither supported the long-term efficacy of the intervention.

- A double-blind, multicenter trial of 190 patients with Class 2 and 3 obesity undergoing implantation with a gastric stimulator were randomized to a study group (stimulator on) and a control group (stimulator off).

All subjects consumed a diet with a 500 kilocalorie-per-day deficit and participated in monthly support group meetings. No difference in weight loss after 12 months was observed between the study group and control group (11.7% versus 11.8%), with no deaths and few complications in each group (Shikora, 2009).

- A study (n = 20) randomized morbidly obese patients undergoing gastric electrical stimulation using the Exilis system between those with the stimulator on or off. A significant reduction in weight loss ($P < .01$) occurred after weeks 4, 13, and 26, but not at week 52. No significant differences after 12 months were observed between groups in terms of gastric emptying halftime, food intake, insulin levels, and glucose levels (Paulus, 2020).

In nonrandomized studies, small sample sizes, retrospective nature, and heterogeneity in stimulation parameters prevented firm conclusions about the efficacy of various gastrointestinal electrical stimulators:

- A study (n = 47) of obese patients in four institutions followed subjects after implantation of a gastric electrical stimulator. Of 35 patients still enrolled after 24 months, mean percent total body weight loss changed only slightly, by 14.8% at month 12, and 13.3% at month 24 (Morales-Conde, 2018).
- A study (n = 34) tracked obese patients after gastrointestinal electrical stimulation. Excess weight loss, which was 28.7% after 12 months, was essentially the same after 27 months (27.5%). Improvements in body mass index, disinhibition and hunger factors, weekly physical activity, and quality of life were also observed at 12 months (Horbach, 2015).
- A study (n = 45) of obese patients documented that 12 months after gastrointestinal electrical stimulation, weight loss averaged 15.7% of baseline body weight. Significant improvements were observed in number of disallowed meals and between-meal snacks ($P < .05$), levels of physical activity ($P < .001$), and activity-based energy/calorie expenditure ($P < .001$) (Busetto, 2017).

In 2024, we updated the literature. No policy changes are warranted.

In 2025, we found no newly published, relevant literature to add to the policy. No policy changes are warranted.

References

On April 9, 2025, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were "electric stimulation therapy" (MeSH), "obesity" (MeSH), "Enterra," "gastrointestinal electrical stimulation," "gastric stimulation," "gastric pacer," and "obesity." We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

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Policy updates

6/2023: initial review date and clinical policy effective date: 7/2023

6/2024: Policy references updated.

6/2025: Policy references updated.