Molina Clinical Policy
Gastrointestinal Electrical Stimulation (GES) and Vagus Nerve Blocking Therapy (VBLOC) for Obesity: Policy No. 243

Last Approval: 10/13/2021
Next Review Due By: October 2022

DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment and clinical recommendations for the Member. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. 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 (e.g., will be paid for by Molina) for a particular Member. The Member's benefit plan determines coverage – each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their Providers will need to consult the Member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a Member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid Members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this MCP and provide the directive for all Medicare members.[1] References included were accurate at the time of policy approval and publication.

OVERVIEW

Gastrointestinal Electrical Stimulation (GES) therapy has been developed as a treatment for patients with obesity. The goal of gastric stimulation is to cause early satiety and reduce appetite causing subsequent weight loss. The exact mechanisms that result in changes in eating and behavior are uncertain. The mechanisms may be related to neuro-hormonal modulation and/or stomach muscle stimulation. There are two types of GES therapy, the first one developed called gastric neurostimulation, also known as gastric pacemaker or gastric modulation involves placement of gastric neurostimulator electrodes into the muscle of the pyloric antrum and connected to a neurostimulator that has been secured in a subcutaneous pocket in the abdomen. The implantable pulse generator then delivers electrical pulses to the stomach muscles.[3,4]

The second type of procedure developed, vagus nerve blocking therapy, also known as vagal blocking for obesity control or VBLOC, involves the insertion of a neuroregulator via laparoscope in the patient's subcutaneous tissue. Electrodes are attached to the trunk of each vagal nerve at the gastroesophageal junction and the distal ends attached to the neuroregulator. Low voltage, high frequency energy waves are sent to the vagus nerves to block the signals of hunger from the nerve to the brain.[3,4]

The Maestro Rechargeable System was FDA approved as a VBLOC treatment in January, 2015 for patients aged 18 and older who have not been able to lose weight with a weight loss program, and who have a body mass index of 35 to 45 with at least one other obesity-related condition, such as type 2 diabetes.[2]

There are no other GES devices approved by the FDA for the treatment of obesity. The Transcend™ implantable gastric stimulation device (Medtronic) is currently being studied in the SHAPE clinical trial in the United States; Transneuronix, Inc. has developed an implantable gastric stimulator (IGS®), the TANTALUS(R) System by MetaCure is also being investigated in the treatment of obese/overweight patients with Type II Diabetes.[3,4,5]

COVERAGE POLICY

Gastrointestinal Electrical Stimulation (GES) therapy and vagal blocking for obesity control **are considered experimental, investigational and unproven** for obesity due to insufficient evidence in the peer reviewed medical literature that that have not established long term safety, efficacy and effect on net health outcomes.[6]

DOCUMENTATION REQUIREMENTS. Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

SUMMARY OF MEDICAL EVIDENCE

There is insufficient published evidence to support the efficacy and safety of gastrointestinal electrical stimulation (GES) therapy for promoting weight loss among patients with morbid obesity. There are no randomized controlled trials on GES for the treatment of obesity. Small clinical trials have reported positive outcomes in weight loss and maintenance of weight loss along with minimal complications.[7-14] The best available evidence on VBLOC therapy consists of 2 published pivotal sham-controlled trials: ReCharge and EMPOWER. The primary efficacy endpoint was percent estimated weight loss (EWL) at 12 months. The study population in both trials was predominantly female (~86%) and middle-aged (mean age, 47 years). The third prospective multicenter study called the SHAPE trial evaluated the difference in the percentage of excess weight loss (EWL) between the control and treatment groups. In this study the EWL was the same for both groups. All three trials did not meet their primary efficacy endpoints.[15-17] Summaries of the most relevant studies are provided below.

A randomized, double-blind, sham-controlled clinical trial called ReCharge enrolled 239 participants who were implanted with the Maestro RC2 System. Patients were then randomized to receive either active (n=162) or inactive sham therapy (n=77). The primary efficacy endpoints were percentage excess weight loss (EWL) at 12 months. The trial's preset margin for determining device efficacy was ≥ 10% difference in mean percent EWL between active and sham VBLOC groups. The second efficacy endpoint was percentage of patients achieving ≥ 20% EWL and ≥ 25% EWL. Neither efficacy endpoint was met. The mean percent EWL was 24.4% in the active VBLOC group and 15.9% in the sham group, a difference of 8.5% that fell short of the preset 10% target. The percentage of patients in each arm achieving ≥ 20% and ≥ 25% EWL did not meet statistical difference (38% of patients in the active group and 23% of patients in the sham group achieved ≥ 25% EWL). A revision procedure was required in 8 patients; all were receiving active therapy. The authors noted that among patients with morbid obesity, the use of vagal nerve block therapy compared with a sham control device did not meet either of the prespecified coprimary efficacy objectives, although weight loss in the vagal block group was statistically greater than in the sham device group. The treatment was well tolerated, having met the primary safety objective.[15]

A randomized, double-blind, prospective, controlled trial called EMPOWER enrolled 294 patients who were implanted with an earlier version of the device used in the ReCharge trial (Maestro RF2). Patients randomized to receive active therapy had their devices turned on (n=192) and those in the sham control group had their devices turned off (n=102). The primary efficacy endpoint was percent EWL at 12 months. The secondary efficacy measure was percentage of patients that achieved > 25% EWL. Neither endpoint statistically differed between active and sham treatment groups. The percent EWL in each study arm was ~16.5%. In addition, a statistically identical proportion of patients in each arm achieved 25% EWL (22% of patients in the active VBLOC group and 25% of patients in the sham group). During the study, the device was removed from 16 patients (for an adverse event in 8 cases and due to personal decision in the other 8 cases). A revision procedure was required in 14 patients. The authors noted that VBLOC® therapy to treat morbid obesity was safe, but weight loss was not greater in treated compared to controls; clinically important weight loss, however, was related to hours of device use. Post-study analysis suggested that the system electrical safety checks (low charge delivered via the system for electrical impedance, safety, and diagnostic checks) may have contributed to weight loss in the control group.[16]

A prospective, randomized, placebo-controlled, double-blind, multicenter study called The SHAPE trial compared implantable gastric stimulation therapy with a standard diet and behavioral therapy regimen in 190 participants with obesity by evaluating the difference in the percentage of excess weight loss (EWL) between the control and treatment groups. All patients underwent implantation with the implantable gastric stimulator and were randomized to 1 of 2 treatment groups: the control group (stimulation off) or treatment group (stimulation on). The patients were evaluated on a monthly basis. All individuals who enrolled in this study agreed to consume a diet with a 500-kcal/d deficit and to participate in monthly support group meetings. The procedure resulted in no deaths and a low complication rate. The primary endpoint of a difference in weight loss between the treatment and control groups was not met. The control group lost 11.7% +/- 16.9% of excess weight and the treatment group lost 11.8% +/- 17.6% (P = .717) according to an intent-to-treat analysis. The authors noted that although implantable gastric stimulation as a surgical option for the treatment of morbid obesity is a less complex procedure than current bariatric operations, the results of the present study do not support its application. Additional research is indicated to understand the physiology and potential benefits of this therapy.[17]

A 2014 systematic review of evidence (31 studies/1367patients) was conducted to evaluate the effect of different types of gastric electrical stimulation (GES) on obesity. Published studies investigating the effect of GES using the Tantalus and Transcend devices, as well as vagus nerve stimulation, were included. Exclusion criteria for published studies were GES used for diseases other than obesity (e.g., gastroparesis); non-gastric stimulation, and non-clinical primary outcome. Studies were primarily non-randomized, with 4/31 randomized trials. In all studies, the generator was externalized and in most cases they were implanted in subcutaneous layers of the anterior abdominal wall. The electrodes connected to the generator were implanted in different locations of the stomach, depending on the type of GES. The primary outcome was weight loss, with secondary outcomes of appetite or satiety changes and biochemical marker changes. Almost all studies in each device group achieved statistically significant weight loss during the first 12 months. Only a small percentage of studies had a follow-up longer than one year and found significant weight loss maintenance. Findings were inconsistent for secondary outcomes. Gastric penetration was the most common device-related complication. In general, the level of evidence was found to be low with few studies having a large population and low loss to follow-up. Results of studies in this systematic review suggest that GES may be effective for short-term weight loss. However well-designed studies with larger patient population and long-term follow up are needed to determine safety and effectiveness of the technology for this indication.[14]

Twenty-four-month outcomes from ReCharge were published by Apovian in 2016. Participants with body mass index (BMI) 40 to 45 kg/m2, or 35 to 40 kg/m2 with at least one comorbid condition were randomized to either vBloc therapy or sham intervention for 12 months. After 12 months, participants randomized to vBloc continued open label vBloc therapy and are the focus of this report. Weight loss, adverse events, comorbid risk factors, and quality of life. The results showed at 24 months, 123 (76%) vBloc participants remained in the trial. Participants who presented at 24 months (n = 103) had a mean excess weight loss (EWL) of 21 % (8 % total weight loss [TWL]); 58% of participants had ≥5 % TWL and 34 % had ≥10 % TWL. Among the subset of participants with abnormal preoperative values, significant improvements were observed in mean LDL (-16 mg/dL) and HDL cholesterol (+4 mg/dL), triglycerides (-46 mg/dL), HbA1c (-0.3%), and systolic (-11 mmHg) and diastolic blood pressures (-10 mmHg). QOL measures were significantly improved. Heartburn/dyspepsia and implant site pain were the most frequently reported adverse events. The primary related serious adverse event rate was 4.3 %. The authors concluded that vBloc therapy continues to result in medically meaningful weight loss with a favorable safety profile through 2 years. Of note the analysis lacked a blinded comparison group.[18]

Professional Society Guidelines

The **American Association of Clinical Endocrinologists (AACE)** and the **American College of Endocrinology (ACE)** published *Comprehensive Clinical Practice Guidelines for Medical Care of Patients with Obesity*. Recommendations identify that obesity is a complex, adiposity-based chronic disease – management should target weight-related complications and adiposity to improve overall health and quality of life. Decision-making should address real-world medical care including screening, diagnosis, evaluation, selection of therapy, treatment goals, and individualization of care. Ultimately the goal is to facilitate high-quality care and provide a rational, scientific approach to management that optimizes health outcomes and safety for patients with obesity.[19]

The **American Society for Metabolic and Bariatric Surgery (ASMBS)** published a position statement in 2016 that includes the following recommendations on vagus nerve blocking therapy for treatment of obesity:[20]

- Reversible vagal nerve blockade has been shown to result in statistically significant EWL [excess weight loss] at 1 year compared with a control group in one of 2 prospective randomized trials.
- Reversible vagal nerve blockage has been shown to have a reasonable safety profile with a low incidence of severe adverse events and a low revisional rate in the short term. More studies are needed to determine long-term reoperation and explanation rates.

The **National Institute for Health and Care Excellence (NICE)** published the guideline *Obesity: Identification, Assessment, and Management (CG189)*. The following recommendations were made in the last update (2014) regarding very low-calorie diets for adults, bariatric surgery for individuals with recent-onset type 2 diabetes and follow up care after bariatric surgery. Under the Dietary – Adults section, the following were added:[21]

- Very-low-calorie diets (800 kcal/day or less) to manage obesity (defined as BMI over 30) are not recognized for regular use (see 1.7.7).
- Ongoing clinical support was added for monitoring those following a very-low-calorie diet (see 1.7.8).
- Discussion about reintroduction of food following a liquid diet was added to the recommendations for topics to discuss before starting a very-low-calorie diet (see 1.7.9).
- A long-term multicomponent strategy should be provided to help the person maintain their weight after the use of a very-low-calorie diet (see 1.4.1 and 1.7.10).

The NICE guidelines added the following regarding bariatric surgery for people with recent-onset type 2 diabetes:

- Offer an expedited assessment for bariatric surgery to people with a BMI of ≥35 if they are also receiving or will receive assessment in a tier 3 service (or equivalent) (see 1.11.1).
- Consider an assessment for people with a BMI of 30 – 34.9 as long as they are also receiving or will receive assessment in a tier 3 service (or equivalent) (see 1.11.2).
- Consider an assessment for people of Asian family origin with a lower BMI than other populations if they are also receiving or will receive assessment in a tier 3 service (or equivalent). (see 1.11.3).

Information about professionally led or peer-support groups was also added to the existing recommendations for Follow-Up Care (see 1.12.1). A recommendation was also added regarding discharge from bariatric surgery service follow-up – individuals should be offered at least annual monitoring of nutritional status and appropriate supplementation according to need following bariatric surgery, as part of a shared care model of chronic disease management (see 1.12.2).[21]

NICE guidelines also note that the following overall changes were made (without an evidence review):[21]

- Reflected changes to national standards, how blood glucose is measured, the definition of a very-low-calorie diet, use of BMI and z scores, and current practice to ensure safe prescribing.
- Recommendations better reflect the needs of people with learning disabilities.
- Strengthened the alignment between recommendations for adults and children.
- Included cross references to the NICE guideline on waist circumference, the 'Weight Wise' campaign, the NHS Choices healthy eating website, and the National Bariatric Surgery Register.
- Removed 'life-threatening' and examples of severe life-threatening comorbidities as they were considered to be unhelpful in clinical practice.
- Removed reference to sibutramine as marketing authorization was suspended for this drug.
- Highlighted that the use of orlistat in children and young people is outside its marketing authorization.

SUPPLEMENTAL INFORMATION

None.

CODING & BILLING INFORMATION

CPT Codes

CPT	Description
0312T	Vagus nerve blocking therapy (morbid obesity); laparoscopic implantation of neurostimulator electrode array, anterior and posterior vagal trunks adjacent to esophagogastric junction (EGJ), with implantation of pulse generator, includes programming
0313T	Vagus nerve blocking therapy (morbid obesity); laparoscopic revision or replacement of vagal trunk neurostimulator electrode array, including connection to existing pulse generator
0314T	Vagus nerve blocking therapy (morbid obesity); laparoscopic removal of vagal trunk neurostimulator electrode array and pulse generator
0315T	Vagus nerve blocking therapy (morbid obesity); removal of pulse generator

0316T	Vagus nerve blocking therapy (morbid obesity); replacement of pulse generator
0317T	Vagus nerve blocking therapy (morbid obesity); neurostimulator pulse generator electronic analysis, includes reprogramming when performed
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

HCPCS Codes

HCPCS	Description
L8679-80-85-86	Implantable neurostimulator pulse generator codes
C1767	Generator, neurostimulator (implantable), non-rechargeable

CODING DISCLAIMER. Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

APPROVAL HISTORY

10/13/2021	Policy reviewed, no changes to criteria; updated the Summary of Medical Evidence section, references.
9/18/2019, 9/16/2020	Policy reviewed, no changes.
12/19/2018	Policy reviewed, no changes to criteria. Updated Description of Devices, Summary of Medical Evidence, and References sections.
12/16/2015, 12/14/2016, 6/22/2017	Policy reviewed, no changes.
7/8/2015	Policy created.

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Government Agencies

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2. Food and Drug Administration. Obesity treatment devices. https://www.fda.gov/medicaldevices/productsandmedicalprocedures/obesitydevices/default.htm.Published 2018. Updated April 27, 2020. Accessed August 15, 2021.

Peer Reviewed Publications

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National and Specialty Organizations

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APPENDIX

Reserved for State specific information *(to be provided by the individual States, not Corporate). Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.*