Introduction

Obesity is a health hazard because it impacts the heart, lungs, muscles, and bones. Obesity also can lead to type 2 diabetes, heart disease, and high blood pressure. Changes to diet and exercise are the initial ways to treat obesity. Certain medications that make a person feel less hungry and feel fuller after eating may also be tried. When lifestyle changes do not work, some people have tried a treatment called intra-abdominal vagus nerve blocking therapy (vBloc). This treatment requires surgery to place a pacemaker-type device that sends an electrical signal to a specific nerve called the vagus nerve. The device blocks signals sent from the stomach to the brain. The goal is to promote weight loss by decreasing the feeling of hunger and increasing the feeling of fullness after eating. These types of devices are investigational (unproven). More studies are needed to see how effective they are in the long term.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.
### Procedure

**Intra-abdominal vagus nerve blocking therapy**

**Investigational**

Intra-abdominal vagus nerve blocking therapy is considered investigational in all situations, including but not limited to the treatment of obesity.

**Note:** Vagus nerve stimulation is addressed in a separate policy (see Related Policies).

### Coding

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tr>
<td>0312T</td>
<td>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</td>
</tr>
<tr>
<td>0313T</td>
<td>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</td>
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<tr>
<td>0314T</td>
<td>Vagus nerve blocking therapy (morbid obesity); laparoscopic removal of vagal trunk neurostimulator electrode array and pulse generator</td>
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<td>0315T</td>
<td>Vagus nerve blocking therapy (morbid obesity); removal of pulse generator</td>
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<td>0316T</td>
<td>Vagus nerve blocking therapy (morbid obesity); replacement of pulse generator</td>
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<td>0317T</td>
<td>Vagus nerve blocking therapy (morbid obesity); neurostimulator pulse generator electronic analysis, includes reprogramming when performed</td>
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### Related Information

N/A
Description

Vagus nerve blocking therapy for obesity consists of an implantable device that delivers electrical stimulation to branches of the vagus nerve on the anterior abdominal wall. The intent is to intermittently block signals to the intra-abdominal vagus nerve to disrupt hunger sensations and induce feelings of satiety.

Background

**Obesity**

Obesity is a common condition in the United States. A large, nationally representative survey conducted from 2009 to 2010 found that 36% of American adults age 20 years and older were obese, defined as a body mass index (BMI) of 30 kg/m² or more.¹ Fifteen percent of these adults had a BMI of 35 kg/m² or more and 6% had a BMI of 40 kg/m² or more. Among 2- to 19-year olds, 17% were obese, which is defined in this population as being at or above the 95% percentile in sex-specific BMI for corresponding age (based on the U.S. Centers for Disease Control and Prevention age growth charts).

Obesity is a major cause of premature death and is linked to serious illnesses including heart disease, type 2 diabetes, sleep apnea, osteoarthritis, and certain types of cancer. In a 2013 systematic review, being obese was associated with higher all-cause mortality and death from cardiovascular disease.² In that same year, the American Medical Association officially recognized obesity itself as a disease.

Management and Treatment

Weight loss (bariatric) surgery is a potential option for obese patients who have failed conservative treatments. Common procedures include gastric bypass surgery (open or laparoscopic approaches), sleeve gastrectomy, and laparoscopic adjustable gastric banding. Certain types of bariatric surgery have improved outcomes in select patients who choose that treatment. (Bariatric surgery is addressed separately. See Related Policies.)
Vagus nerve blocking therapy is another potential treatment option for obese patients. The vagus nerve consists of two long cranial nerves that extend from the brainstem to the viscera. The term vagus is Latin for wandering, and the vagus nerve winds through the abdomen and has branches that come in contact with the heart, lung, stomach, and other body parts. The vagus nerve plays a major role in autonomic and sympathetic nervous system functioning, including regulation of heartbeat and breathing. It is also involved in the regulation of the digestive system, although its exact role in controlling appetite and feelings of satiety is unknown. Vagus nerve blocking therapy involves intermittent blocking of signals to the intra-abdominal vagus nerve, with the intent of disrupting hunger sensations and inducing feelings of satiety.

In January 2015, the U.S. Food and Drug Administration (FDA) approved a medical device specifically designed to provide vagal nerve blocking therapy for regulation of weight in obese patients. This device, the Maestro Rechargeable System, includes a neuroblocking pulse generator that is implanted subcutaneously on the thoracic sidewall and flexible leads approximately 47 cm in length that are placed on the abdominal anterior and posterior vagal nerve trunks. External components include a mobile charger, a transmit coil, a programmable microprocessor, and customized software. The system delivers high-frequency pulses of electrical current to vagus nerve trunks; therapy parameters and the treatment schedule can be customized by a clinician. Like other surgical interventions, there is the potential for adverse effects. In addition, there may be other unintended consequences of disrupting signals to a particular portion of the vagus nerve.

Stimulation of the vagus nerve via a device implanted within the carotid artery sheath has also been evaluated as a treatment for obesity and is addressed in another policy (see Related Policies). Vagus nerve stimulation is approved by the FDA to treat epilepsy and depression, but not obesity.

**Outcomes**

To assess obesity treatments, a double-blind randomized controlled trial is optimal because these interventions require changes to patient behavior (ie, diet, exercise) that are subject to the placebo effect. Health outcomes such as mortality, cardiovascular events, and rates of type 2 diabetes would be optimal, but are difficult to use as study end points due to the need for a large sample size and long follow-up period. Cardiovascular risk factors, such as changes in blood pressure, glucose, and lipid levels, are good intermediate measures because they have been linked with these health outcomes, and would require smaller sample sizes. Weight loss outcomes, reported as absolute change in weight or BMI, or as percent excess weight loss or
percent BMI are acceptable intermediate outcome measures and are commonly used in obesity studies. Weight loss has been linked to improvements in cardiovascular risk factors. While no generally accepted threshold of percent excess weight loss is considered clinically significant, bariatric surgery trials generally define clinical success as at least 50% excess weight loss. The amount of weight loss is expected to be lower for other, less dramatic weight loss interventions.

Sham controls are useful for establishing the efficacy of intervention beyond the placebo effect and for controlling other nonspecific effects of interventions including disease natural history and regression to the mean. Because there are so many existing treatment options for weight loss, if sham-controlled weight loss intervention studies are positive, trials using an active comparator, such as medication or other types of surgery, are desirable.

Summary of Evidence

For individuals with obesity who receive vagus nerve blocking therapy, the evidence includes two sham-controlled randomized trials. The relevant outcomes are change in disease status, morbid events, quality of life, and treatment-related morbidity. The primary efficacy outcome (at least a 10% difference between groups at 12 months) was not met for either trial. In the first trial, Vagal Blocking for Obesity Control (EMPOWER), the observed difference in excess weight loss between groups at 12 months was 1%. In the more recent trial to Evaluate the Safety and Efficacy of vBloc Therapy Delivered by the Maestro Rechargeable System for the Treatment of Obesity (ReCharge), the observed difference in excess weight loss between groups at 12 months was 8.5%; a post hoc analysis found this difference statistically significant, but the magnitude of change may not be viewed as clinically significant according to investigators’ original trial design decisions. Post hoc analyses of longer term data have been published and are subject to various biases, including missing data and unblinding at 12 months. The evidence is insufficient to determine the effects of the technology on health outcomes.

Ongoing and Unpublished Clinical Trials

A search of ClinicalTrials.gov in December 2019 did not identify any ongoing or unpublished trials that would likely influence this review.
Practice Guidelines and Position Statements

American Society for Metabolic and Bariatric Surgery

In 2016, a position statement published by the American Society for Metabolic and Bariatric Surgery includes the following conclusions on vagus nerve blocking therapy for treatment of obesity.11

1. “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.

2. 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 explantation rates.

3. The prospective collection of VBLOC [vagus nerve blocking] outcomes as part of the national center of excellence databases is encouraged to establish the long-term efficacy of this new technology."

U.S. Preventive Services Task Force Recommendations

In 2018, the U.S. Preventive Services Task Force updated recommendations for screening and management of obesity in adults.12 The Task Force recommended screening all adults for obesity and referring those with a body mass index of 30 kg/m² or higher to intensive, multicomponent behavioral interventions. Vagus nerve blocking therapy and other surgical interventions were not addressed in the recommendations or literature review.

Medicare National Coverage

There is no national coverage determination.

Regulatory Status

In January 2015, the Maestro® Rechargeable System (EnteroMedics, St. Paul, MN) was approved by the FDA through the premarket approval process for use in adults ages 18 years and older.
who have a BMI of 40 to 45 kg/m\(^2\) or a BMI of 35 to 39.9 kg/m\(^2\) with 1 or more obesity-related conditions such as high blood pressure or high cholesterol and have failed at least 1 supervised weight-management program within the past 5 years. Implantable components are incompatible with magnetic resonance imaging. Additional contraindications to use of the device include conditions such as cirrhosis of the liver, portal hypertension and clinically significant hiatal hernia, and the presence of a previously implanted medical device. FDA product code: PIM.

The commercial availability of the Maestro® System is unclear. On the FDA’s Weight-Loss and Weight-Management Devices webpage (content noted as current as of 09/05/2019), the Maestro® Rechargeable System is described as "no longer marketed as of September 2018". Additionally, on the ReShape LifesciencesTM website (previously EnteroMedics), the Maestro® Rechargeable System, is not listed among their current portfolio of medical devices to treat obesity and metabolic disease. However, updates to the Maestro® Rechargeable System were noted in the FDA Premarket Approval database (P130019) subsequent to September 2018, including updates to the circuit assembly and application firmware of the mobile charger (01/25/2019) and approval of modifications to the follow-up schedule for the post-approval study protocol.

References


### History

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<th>Date</th>
<th>Comments</th>
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<td>07/14/15</td>
<td>New Policy. Policy created with literature review through March 30, 2015. Vagal nerve blocking therapy considered investigational in all situations.</td>
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<td>05/01/16</td>
<td>Annual Review, changes approved April 12, 2016. Policy updated with literature review through December 13, 2015; reference 6 added. Policy statement unchanged.</td>
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<td>05/01/17</td>
<td>Annual Review, changes approved April 11, 2017. Policy updated with literature review through December 20, 2016; references 7-8 added. “Vagal” changed to “Vagus” in the policy Title and throughout the policy document when appropriate. Policy Statement unchanged.</td>
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<td>Annual Review, approved April 3, 2018. Policy updated with literature review through December 2017; no references added. Policy statement unchanged.</td>
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<td>05/01/19</td>
<td>Annual Review, approved April 2, 2019. Policy updated with literature review through January 2019; no references added; reference 9 updated. Policy statement unchanged.</td>
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<td>05/01/20</td>
<td>Annual Review, approved April 7, 2020. Policy updated with literature review through December 2019; references added to Regulatory Status section (links to FDA and manufacturer websites) regarding commercial availability of device. Policy statement unchanged.</td>
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200 Independence Avenue SW, Room 509F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)

Complaint forms are available at
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Civil Rights Coordinator
Premera Blue Cross
200 Independence Avenue SW, Room 509F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)
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