Vagus Nerve Blocking Therapy for Treatment of Obesity

**Policy Coverage Criteria**
Procedure | Investigational
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Intra-abdominal vagus nerve blocking therapy | 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).

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<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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<tr>
<td>0316T</td>
<td>Vagus nerve blocking therapy (morbid obesity); replacement of pulse generator</td>
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<tr>
<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/m$^2$ or more.¹ Fifteen percent of these adults had a BMI of 35 kg/m$^2$ or more and 6% had a BMI of 40 kg/m$^2$ 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 (EMPOWER), the observed difference in excess weight loss between groups at 12 months was 1%. In the more recent trial (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 January 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**

A position statement published by the American Society for Metabolic and Bariatric Surgery (2016) includes the following conclusions on vagus nerve blocking therapy for treatment of obesity:

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**

The U.S. Preventive Services Task Force (2018) updated recommendations for screening and management of obesity in adults. 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.

References


History

<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
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<tbody>
<tr>
<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>Comments</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>05/01/18</td>
<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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</table>

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  • Written information in other formats (large print, audio, accessible electronic formats, other formats)
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  • Qualified interpreters
  • Information written in other languages

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Toll free 855-332-4535, Fax 425-918-5592. TTY 800-842-5357
Email AppealsDepartmentInquiries@Premera.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, the Civil Rights Coordinator is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:
U.S. Department of Health and Human Services
200 Independence Avenue SW, Room S09F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)

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본 통지서에는 중요한 정보가 들어 있습니다. 즉 이 통지서는 귀하의 신청에 관하여 그리고 Premera Blue Cross를 통한 커버리지를 관할 정보를 포함하고 있습니다. 본 통지서에는 핵심이 되는 날짜들이 있을 수 있습니다. 귀하의 이전 커버리지를 계속 유지하거나 비용을 절감하기 위해서 일정한 마감일까지 조기에 취급해야 할 필요가 있을 수 있습니다. 귀하의 이러한 정보와 수동을 귀하의 안정을 비용 부담없이 얻을 수 있는 권리가 있습니다. 800-722-1471 (TTY: 800-842-5357)로 전화하십시오.

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