Medical Policy
Vagus Nerve Blocking Therapy for Treatment of Obesity

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Policy Number: 644
BCBSA Reference Number: 7.01.150
NCD/LCD: Local Coverage Determination (LCD): Category III CPT® Codes (L33392)

Related Policies
- Vagus Nerve Stimulation, #474
- Medical and Surgical Management of Obesity including Anorexiants, #379
- Gastric Electrical Stimulation, #636

Policy
Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity

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

Medicare HMO BlueSM and Medicare PPO BlueSM Members

This is not a covered service.

Local Coverage Determination (LCD): Category III CPT® Codes (L33392)

For medical necessity criteria and coding guidance for Medicare Advantage members living outside of Massachusetts, please see the Centers for Medicare and Medicaid Services website for information regarding your specific jurisdiction at https://www.cms.gov.

Prior Authorization Information
Pre-service approval is required for all inpatient services for all products.
See below for situations where prior authorization may be required or may not be required.
Yes indicates that prior authorization is required.
No indicates that prior authorization is not required.
N/A indicates that this service is primarily performed in an inpatient setting.

<table>
<thead>
<tr>
<th>Outpatient</th>
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<tbody>
<tr>
<td>Commercial Managed Care (HMO and POS)</td>
<td>This is not a covered service.</td>
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</tbody>
</table>
Commercial PPO and Indemnity

This is not a covered service.

Medicare HMO BlueSM

This is not a covered service.

Medicare PPO BlueSM

This is not a covered service.

CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member’s contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following codes are included below for informational purposes only; this is not an all-inclusive list.

The following CPT codes are considered investigational for Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:

CPT Codes

<table>
<thead>
<tr>
<th>CPT codes:</th>
<th>Code Description</th>
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<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>
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<tr>
<td>0313T</td>
<td>Vagus nerve blocking therapy (morbid obesity); laparoscopic revision or replacement of vagal trunk neurostimulator electrode array, including connection to existing pulse generator</td>
</tr>
<tr>
<td>0314T</td>
<td>Vagus nerve blocking therapy (morbid obesity); laparoscopic removal of vagal trunk neurostimulator electrode array and pulse generator</td>
</tr>
<tr>
<td>0315T</td>
<td>Vagus nerve blocking therapy (morbid obesity); removal of pulse generator</td>
</tr>
<tr>
<td>0316T</td>
<td>Vagus nerve blocking therapy (morbid obesity); replacement of pulse generator</td>
</tr>
<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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Description

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 aged 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.

Lifestyle interventions, specifically changes to diet and exercise, are the first-line treatment of obesity. These interventions can be enhanced by participation in a structured weight loss program and/or by psychological interventions such as cognitive-behavioral therapy. There are also prescription weight loss medications available, most notably orlistat (which blocks digestion and absorption of fat) and lorcaserin (which decreases appetite and promotes satiety). Weight loss medications have limited evidence of efficacy and there are adverse effects (eg, oily stool, nausea, dizziness) associated with their use.
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 in policy #379.)

Vagus nerve blocking therapy is another potential treatment option for obese patients. The vagus nerve consists of 2 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 into 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 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 policy #474. Vagus nerve stimulation is approved by FDA to treat epilepsy and depression, but not obesity.)

Summary
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.

For individuals who have obesity who receive vagus nerve blocking therapy, the evidence includes 2 sham-controlled randomized trials. 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 (EWL) between groups at 12 months was 1%. In the more recent trial (ReCharge), the observed difference in EWL 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.

Policy History

<table>
<thead>
<tr>
<th>Date</th>
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<tbody>
<tr>
<td>4/2017</td>
<td>BCBSA National medical policy review.</td>
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<tr>
<td></td>
<td>Title changed from “Vagal” to “Vagus”. Policy statement unchanged.  4/1/2017</td>
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<tr>
<td>9/2015</td>
<td>New medical policy describing investigational indications. Effective 9/1/2015</td>
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References