### MEDICAL POLICY – 7.01.150

**Vagus Nerve Blocking Therapy for Treatment of Obesity**

**BCBSA Ref. Policy:** 7.01.150

<table>
<thead>
<tr>
<th>Effective Date:</th>
<th>May 1, 2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Last Revised:</td>
<td>April 3, 2018</td>
</tr>
<tr>
<td>Replaces:</td>
<td>N/A</td>
</tr>
</tbody>
</table>

**RELATED MEDICAL POLICIES:**

- 7.01.20 Vagus Nerve Stimulation
- 7.01.516 Bariatric Surgery
- 7.01.522 Gastric Electrical Stimulation

---

**Introduction**

Obesity is a health hazard as 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** | **Investigational**
---|---
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)

### Coding

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT</td>
<td></td>
</tr>
<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>
</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>
</tr>
</tbody>
</table>

**Note:** CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

### Related Information

N/A
Evidence Review

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 is a common condition in the United States. A large nationally representative survey conducted in 2009 to 2010 found that 36% of American adults age 20 and older were obese, defined as body mass index (BMI) of 30 kg/m\(^2\) or more.\(^1\) Fifteen percent of the 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

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 associated adverse effects (eg, oily stool, nausea, and 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 improve outcomes in select 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 brain stem 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 systems, 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 disrupting hunger sensations and inducing feelings of satiety.

In 2015, the U.S. Food and Drug Administration (FDA) approved a medical device specifically designed to provide vagus nerve blocking therapy for weight regulation 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 vagus nerve trunks. External components include a mobile charger, a transmit coil, a programmable microprocessor, and customized software. The system delivers high-frequency pulses of 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.

Vagus nerve stimulation is approved by 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 an intervention beyond the placebo effect and for controlling for 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 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 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 December 2016 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 2016 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:

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 published recommendations for screening and management of obesity in adults in 2012. 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. The recommendations are currently being updated.

Medicare National Coverage

There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.
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 BMI of 40 to 45 kg/m² or a BMI of 35 to 39.9 kg/m² 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

<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<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>
</tr>
<tr>
<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>
</tr>
<tr>
<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>
</tr>
<tr>
<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>
</tr>
</tbody>
</table>

**Disclaimer:** This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2018 Premera All Rights Reserved.

**Scope:** Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.
Discrimination Is Against the Law

Premera Blue Cross complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. Premera does not exclude people or treat them differently because of race, color, national origin, age, disability or sex.

Premera:
- Provides free aids and services to people with disabilities to communicate effectively with us, such as:
  - Qualified sign language interpreters
  - Written information in other formats (large print, audio, accessible electronic formats, other formats)
- Provides free language services to people whose primary language is not English, such as:
  - Qualified interpreters
  - Information written in other languages

If you need these services, contact the Civil Rights Coordinator.

If you believe that Premera has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with:
- Civil Rights Coordinator - Complaints and Appeals
PO Box 91102, Seattle, WA 98111
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.


Getting Help in Other Languages

This Notice has Important Information. This notice may have important information about your application or coverage through Premera Blue Cross. There may be key dates in this notice. You may need to take action by certain deadlines to keep your health coverage or help with costs. You have the right to get this information and help in your language at no cost. Call 800-722-1471 (TTY: 800-842-5357).

Arabic (Amharic):

لا يوجد هذا الإشعار معلومات هامة. قد يوجد هذا الإشعار معلومات مفيدة لموضوع طبئ أو
المعاهدة التي تمدد الحصول عليها من خلال Premera Blue Cross. قد تكون هناك تأثير مهمة Premera Blue Cross على الحصول على بعض المعلومات المربحة المتعلقة في هذا الإشعار. يتعين أن يكون الإسم في تواريخ منتظمة للحفاظ على تواريخ موثقة صحيحة أو غير مأمونة في التأكد من بطاقة التأمين. يمكن للحصول على هذه المعلومات بالإضافة إلى القائمة التالية:
800-722-1471 (TTY: 800-842-5357).

中文 (Chinese):

本通知有重要的信息。本通知可能有关于您透过 Premera Blue Cross 提交的申请或保险的重要资讯。本通知内可能有重要日期。您可能需要在截止日期之前采取行动，以保留您的健康保险或费用补贴。您有权利免费以您的母语得到本讯息和帮助。请拨电话 800-722-1471 (TTY: 800-842-5357).

Oromo (Cushite):


Français (French):


Kreyòl ayisyen (Creole):

Avi sila a gen Enfòmasyon Empòtan la. Avi sila a kapab genyen enfòmasyon empòtan konsènan aplikasyon w lan oswa konsènan kouvèti asirans lan atravè Premera Blue Cross. Kapab genyen dat ki enpòtan nan avi sila a. Ou ka gen pou pran kék aksyon avan sèten dat limit pou ka kette kouvèti asirans sante w la oswa pou yo ka ede w avèk depans yo. Se dwa w pou resewva enfòmasyon sa a ak asisants nan lang ou paale a, san ou pa gen pou peye pou sa. Rate nan 800-722-1471 (TTY: 800-842-5357).

Deutsche (German):


Hmoob (Hmong):


Iloko (Ilocano):

Daytoy a Pakdaak ket naglaon iti Napateg nga Impormasion. Daytoy a pakdaak mabalin nga adda ket naglaon iti napateg nga impormasion maipanggep iti aplikasyyon wenny coverage babaen iti Premera Blue Cross. Daytoy ket mabalin dagiti importante a petaa iti daytoy a pakdaak. Mabalin nga adda rumbeng nga aramidenyo nga addang sakbay dagiti partikular a naituding nga adda aloud tapno mapagataliayenyo to coverage tai salun-atyo wenny tungong kadagiti gastos. Adda karbenganyo a mangala iti daytoy nga impormasion ken tungong iti bukodyo a pagasassao nga awan ti bayadanoy. Tumawag ti numero nga 800-722-1471 (TTY: 800-842-5357).

Italiano (Italian):


037338 (07-2016)
Premera Blue Cross may have important dates in this notice.
This notice may contain important information about your enrollment or coverage.
If you have questions about the information in this notice, you may call 800-722-1471 (TTY: 800-842-5357).

Español (Spanish):
Este aviso contiene información importante. Es posible que este aviso contenga información importante acerca de su solicitud de cobertura a través de Premera Blue Cross. Es posible que haya fechas claras en este aviso. Es posible que deba tomar alguna medida antes de determinadas fechas para mantener su cobertura médica o ayuda con los costos. Usted tiene derecho a recibir esta información y ayuda en su idioma sin costo alguno. Llame al 800-722-1471 (TTY: 800-842-5357).

Bahasa Indonesia (Indonesian):

ไทย (Thai):
ประกาศนี้มีข้อมูลที่สำคัญเกี่ยวกับการสมัครหรือขอบเขตการประกันสุขภาพของคุณผ่านPremera Blue Cross. คุณสามารถติดต่อกับสายด่วน 800-722-1471 (TTY: 800-842-5357) เพื่อขอความช่วยเหลือ.

Português (Portuguese):
Este aviso contém informações importantes. Este aviso poderá conter informações importantes a respeito de sua aplicação ou cobertura por meio do Premera Blue Cross. Poderão existir datas importantes neste aviso.

Română (Romanian):

Русский (Russian):
Настоящее уведомление содержит важную информацию. Это уведомление может содержать важную информацию о вашем заявлении или страховом покрытии через Premera Blue Cross. В настоящем уведомлении могут быть ключевые даты. Вам, возможно, потребуется принять меры к определенным предельным срокам для сохранения страхового покрытия или помощи с расходами. Вы имеете право на бесплатное получение этой информации и помощь на вашем языке. Звоните по телефону 800-722-1471 (TTY: 800-842-5357).

Tagalog (Tagalog):

Polski (Polish):

Український (Ukrainian):
Це повідомлення містить важливу інформацію. Це повідомлення може містити важливу інформацію про Ваше звернення щодо страхувального покриття через Premera Blue Cross. Зверніть увагу на ключові дати, які можуть бути вказані у цьому повідомленні. Існує імовірність того, що Вам треба будь-які зміни в умовах страхування або отримати фінансову допомогу. У Вас є право на отримання цієї інформації та допомоги безкоштовно на Вашій рідній мові. Дзвоніть за номером телефону 800-722-1471 (TTY: 800-842-5357).

Tiếng Việt (Vietnamese):