| BSC7.17 | Vagus Nerve Blocking Therapy for Treatment of Obesity | | |
|---|---|---|---|
| **Original Policy Date:** | September 30, 2015 | **Effective Date:** | March 1, 2023 |
| **Section:** | 7.0 Surgery | **Page:** | Page 1 of 12 |

## Policy Statement

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

**NOTE**: Refer to Appendix A to see the policy statement changes (if any) from the previous version.

## Policy Guidelines

**Coding**

***Effective January 1, 2023,*** the following specific CPT category III codes has been ***deleted***:

- **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

## 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.

## Related Policies

- Bariatric Surgery
- Gastric Electrical Stimulation

## Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

## 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 (MRI). Additional contraindications to use of the device include conditions such as cirrhosis of the liver, portal hypertension, 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 04/27/2020), the Maestro® Rechargeable System is described as "no longer marketed as of September 2018".[3.] Additionally, on the ReShape Lifesciences™ website (previously EnteroMedics), the Maestro® Rechargeable System, is not listed among their current portfolio of medical devices to treat obesity and metabolic disease.[4.] However, updates to the Maestro® Rechargeable System were noted in the FDA Premarket Approval database (P130019) subsequent to April 2020, including approval of the revised protocol which includes modification to the follow-up schedule for the post-approval study (PAS) protocol.[5.]

## Rationale

### 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 aged 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 in Blue Shield of California Medical Policy: Bariatric Surgery)

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 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. 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 (RCT) is optimal because these interventions require changes to patient behavior (i.e., 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 endpoints due to the need for 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 an 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.

## Literature Review

Evidence reviews assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are the length of life, quality of life, and ability to function–including benefits and harms. Every clinical condition has specific outcomes that are important to patients and managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of technology, 2 domains are examined: the relevance, and quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in

some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

## Vagus Nerve Blocking Therapy for Obesity

### Clinical Context and Test Purpose

The purpose of vagal nerve blocking therapy for the treatment of obesity is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this evidence review is: Does the use of vagal nerve blocking therapy for the treatment of obesity improve net health outcomes?

The following PICO was used to select literature to inform this review.

#### *Populations*

The relevant population of interest is patients with morbid obesity who have been unsuccessful with lifestyle management for weight reduction.

#### *Interventions*

The therapy being considered is vagal nerve blocking therapy for the treatment of obesity. Vagus nerve blocking therapy involves the intermittent blocking of signals to the intra-abdominal vagus nerve, with the intent of disrupting hunger sensations and inducing feelings of satiety. Patients with obesity who receive vagal nerve blocking therapy would require follow-up for 6-12 months to ascertain weight loss success and early device complications. Follow-up of maintenance of weight loss or obesity-associated conditions are life-long

#### *Comparators*

The following therapies and practices are currently being used to make decisions about the treatment of obesity; 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 events (e.g., oily stool, nausea, dizziness) associated with their use. Weight loss (bariatric) surgery is a potential option for obese patients who have failed conservative treatments.

#### *Outcomes*

The general outcomes of interest are weight reduction and maintenance of weight reduction, disease status changes such as the development of medical complications of obesity, and treatment-related morbidity.

### Study Selection Criteria

Methodologically credible studies were selected using the following principles:

a. To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
b. In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
c. To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.

Studies with duplicative or overlapping populations were excluded.

## Review of Evidence

### Randomized Controlled Trials

The published literature on vagus nerve blocking for obesity consists of 2 RCTs, both of which were industry-sponsored, multicenter, double-blind, and sham-controlled. [6,7] Although both trials included a sham treatment group, protocols differed. In the 2012 Vagal Blocking for Obesity Control (EMPOWER) trial, all participants had devices implanted and leads placed.[6] However, external controllers were programmed differently such that if the controllers were worn for 10 hours a day, the total charge delivered was 3.9 coulombs (C) to patients in the treatment group and a negligible amount (0.0014 C), to the sham group. In the 2014 trial to Evaluate the Safety and Efficacy of vBloc Therapy Delivered by the Maestro Rechargeable System for the Treatment of Obesity (ReCharge), all participants had devices implanted, but no leads were placed in the sham group.[7]

Trial characteristics and results are summarized in Tables 1 and 2, respectively.

**Table 1. Characteristics of RCTs Evaluating Vagus Nerve Blocking as Treatment of Morbid Obesity**

| | | | | | Interventions | |
|---|---|---|---|---|---|---|
| **Author; Study** | **Countries** | **Sites** | **Dates** | **Participants** | **Active** | **Comparator** |
| Sarr et al. (2012)[6]; EMPOWER | U.S., Australia | 15 | Nov 2005-Sep 2011 | 294 | 192 to active Maestro device plus 15 weight management counseling sessions | 102 to inactive sham Maestro device plus 15 weight management counseling sessions |
| Ikramuddin et al. (2014)[7]; ReCharge | U.S., Australia | 10 | May 2011-Jun 2013 | 239 | 162 to active Maestro device plus 17 weight management counseling sessions | 77 to inactive sham Maestro device plus 17 weight management counseling sessions |

EMPOWER: Vagal Blocking for Obesity Control; ReCharge: Evaluate the Safety and Efficacy of vBloc Therapy Delivered by the Maestro Rechargeable System for the Treatment of Obesity; RCT: randomized controlled trial.

**Table 2. Results of RCTs Evaluating Vagus Nerve Blocking as Treatment of Morbid Obesity**

| Study | Mean Percent EWL | ≥25% EWL | Serious Adverse Events, n/n (%) or % |
|---|---|---|---|
| Sarr et al. (2012)[6] | | | |
| Active | 17 | 22 | 23/192 (12%) |
| Sham | 16 | 25 | 12/102 (12%) |
| Diff (95% CI) | 1 (NR) | -3 (NR) | |
| Ikramuddin et al (2014)[7] | | | |
| Active | 24.4 | | 3.7[b] |
| Sham | 15.9 | | NR |
| Mean diff (95% CI) | 8.5 (3.1 to 13.9)[a] | | |

CI: confidence interval; diff: difference; EWL: excess weight loss (calculated as difference between pre- and posttreatment weights divided by difference between pretreatment weight and ideal body weight. Body mass index of 25 kg/m$^2$ was considered ideal); NR: not reported; RCT: randomized controlled trial.

[a] For a >10% difference.

[b] Single group comparison; FDA objective of <15% was met.

The primary efficacy outcomes were not met in either RCT. The difference in mean percent excess weight loss (EWL) was the sole primary efficacy outcome in the Vagal Blocking for Obesity Control (EMPOWER) study and a coprimary outcome in the Evaluate the Safety and Efficacy of vBloc Therapy Delivered by the Maestro Rechargeable System for the Treatment of Obesity (ReCharge) study. This outcome was evaluated in both trials using a superiority margin of 10% (i.e., the efficacy objective would be met only if there was a >10% difference between groups in EWL). U.S. Food and Drug Administration (FDA) documents have indicated the unattained 10% margin was considered to indicate a clinically meaningful difference in weight loss between active and sham treatment groups.[8]

For the ReCharge trial, however, in addition to the primary efficacy analysis, the authors conducted a post hoc analysis that evaluated the difference in EWL between groups using a 2-sided *t*-test with no superiority margin. In this post hoc analysis, the difference between groups (8.5% EWL; 95% confidence interval [CI], 3.1% to 13.9%) was statistically significant. (The difference between groups in percent EWL in the Vagal Blocking for Obesity Control (EMPOWER) study was 1%.)

The outcome used in these studies was percent EWL, and modest changes in this outcome may translate to a relatively small amount of weight loss relative to total weight for patients with morbid obesity. Mean initial body weight in the Evaluate the Safety and Efficacy of vBloc Therapy Delivered by the Maestro Rechargeable System for the Treatment of Obesity (ReCharge) trial was 113 kilograms (249 pounds) in the active treatment group and 116 kilograms (255 pounds) in the sham group. Mean excess body weight was 44 kilograms (97 pounds) in the treatment group and 45 kilograms (99 pounds) in the sham group. Thus, a difference of 10% EWL, used in the primary analyses, represents a difference of only about 5 kilograms (10 pounds) in absolute weight loss and a 4% difference in absolute body weight.

The Evaluate the Safety and Efficacy of vBloc Therapy Delivered by the Maestro Rechargeable System for the Treatment of Obesity (ReCharge) study had a second primary outcome, which would have been met if at least 55% of patients in the active treatment group had achieved at least 20% EWL and at least 45% had achieved at least 25% EWL. This outcome was not achieved; the data showed that 52% of patients in the active treatment group achieved at least 20% EWL and 38% achieved at least 25% EWL. In the Vagal Blocking for Obesity Control (EMPOWER) study, groups did not differ significantly on the secondary outcome measure (percent of patients achieving at least 25% EWL).

In post hoc subgroup analysis of the Vagal Blocking for Obesity Control (EMPOWER) trial, longer duration of device use per day was associated with a larger percent EWL. However, this improvement occurred in the sham group as well as the active treatment group. For example, percent EWL among patients who used the device for less than 6 hours a day was 5% in the active treatment group and 6% in the sham group, whereas percent EWL among patients who used the device for at least 12 hours a day was 30% and 22%, respectively. This finding suggests a substantial placebo effect associated with device use.

Both trials met their primary safety outcomes, which related to serious adverse events. However, there were frequent nonserious adverse events. Rates of key adverse events (all severity levels) in the Evaluate the Safety and Efficacy of vBloc Therapy Delivered by the Maestro Rechargeable System for the Treatment of Obesity (ReCharge) trial are shown in Table 3. Most were of mild or moderate severity. The authors of the Vagal Blocking for Obesity Control (EMPOWER) trial did not report individual adverse events.

**Table 3. Most Common Adverse Events in the ReCharge Trial**

| Adverse Events | No. (%) of Patients | |
|---|---|---|
| | Treatment Group (n=162) | Sham Group (n=77) |
| Pain, neuroregulator site | 61 (38) | 32 (42) |
| Dyspepsia | 38 (23) | 3 (4) |
| Pain, other | 37 (23) | 0 |
| Pain, abdominal | 20 (12) | 2 (3) |
| Nausea | 11 (7) | 0 |
| Dysphagia | 13 (8) | 0 |
| Belching | 13 (8) | 0 |

Additional information on the Evaluate the Safety and Efficacy of vBloc Therapy Delivered by the Maestro Rechargeable System for the Treatment of Obesity (ReCharge) trial design and findings has been reported in the FDA documents.[8] The trial was designed to evaluate primary endpoints at 12 months and to follow patients to 5 years postimplant. Patients were blinded until 12 months and

unblinding began once all patients had completed the 12-month follow-up. After the 12-month follow-up, sham patients had the option to cross over into the active treatment group. At 18 months, follow-up data (n=159) were reported for 117 (72%) patients initially assigned to the active treatment group and 42 (55%) assigned to the sham treatment group. The number of patients in the sham group who crossed over to active treatment and the timing of unblinding was not reported. At 18 months, the mean percent EWL was 25.3% in the active treatment group and 11.7% in the sham group; the mean between-group difference was 13.5% (95% CI, 5.7% to 21.3%). In this analysis, the treatment group maintained the weight loss they achieved at 12 months, and the control group gained weight. Nearly half of the patients initially randomized to the sham group were not included in the 18-month analysis, which limits the ability to draw conclusions about these data. In addition, the 18-month analysis could have been biased by unblinding, which occurred after all patients completed the 12-month follow-up. In the 12-month sham intervention phase of the trial, patients in both groups experienced decreased hunger, increased cognitive restraint, and decreased food intake. It is likely that unblinding could have had an impact on these factors. The FDA documents also reported longer-term safety data. Analyses of data up to 48 months from the Vagal Blocking for Obesity Control (EMPOWER) trial and 18-month data from the ReCharge trial did not identify any deaths or unanticipated serious adverse events. There were 13 surgical explants through 12 months (5 in the active treatment group, 8 in the sham group) and an additional 16 explantations between 12 and 18 months. Reasons for explant included the patient decision, pain, and need for magnetic resonance imaging (MRI).

Eighteen-month follow-up data from the Evaluate the Safety and Efficacy of vBloc Therapy Delivered by the Maestro Rechargeable System for the Treatment of Obesity (ReCharge) trial were published by Shikora et al. (2015).[9] They reported on a larger proportion of the patient population than that discussed in the FDA documents: in addition to the 159 (67%) of 239 randomized patients who completed the 18-month follow-up, the 2015 analysis included 30 patients who missed the 18-month analysis but had a visit at 16 or 17 months. The additional patients included 11 from the active treatment group and 19 from the sham group, comprising 188 patients (79% of those originally randomized). At 18 months, the mean percent EWL noted was 23.5% (95% CI, 20.8% to 26.3%) in the active treatment group and 10.2% (95% CI, 6.0% to 14.4%) in the sham group. The mean between-group difference in percent EWL was 13.4% (95% CI, 8.4% to 18.4%). The authors also evaluated the potential impact of blinding on outcomes and found no statistically significant effect; their findings were similar to the analysis restricted to patients who remained blinded at 18 months. The percentages of EWL at 18 months in this 2015 analysis of ReCharge trial data were also similar to those previously reported in the FDA documents, although this sample size was larger, reducing potential bias from missing data. However, because this post hoc analysis incorporated 16- and 17-month data in addition to 18-month data, the authors considered these results preliminary or hypothesis-generating.

Twenty-four-month outcomes from Evaluate the Safety and Efficacy of vBloc Therapy Delivered by the Maestro Rechargeable System for the Treatment of Obesity (ReCharge) were published by Apovian et al. (2017).[10] The investigators noted that the sham arm was no longer a valid comparator at 24 months due to crossovers, dropouts, and patient unblinded at 12 months. There was no prespecified statistical analysis plan for assessments after the 12-month primary outcome assessment, including those in this 2017 article. A total of 103 (43%) patients of 239 randomized patients completed the 24-month follow-up. Their mean EWL was 21% (95% CI, 16% to 26%) and mean total weight loss was 8% (95% CI, 6% to 10%). No serious treatment-related adverse events were reported in the 18- to 24-month time period. The analysis lacked a blinded comparison group, and, like the 18-month data, was post hoc.

### Section Summary: Vagus Nerve Blocking Therapy for Obesity

Two sham-controlled RCTs have been published. The primary efficacy outcome (at least a 10% difference between groups) was not met for either trial. In the first trial, Vagal Blocking for Obesity Control (EMPOWER), the observed difference in EWL between groups at 12 months was 1%. In the

more recent trial, (Evaluate the Safety and Efficacy of vBloc Therapy Delivered by the Maestro Rechargeable System for the Treatment of Obesity - 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. Additional analyses of data from Evaluate the Safety and Efficacy of vBloc Therapy Delivered by the Maestro Rechargeable System for the Treatment of Obesity (ReCharge) found a difference in EWL at 18 months of approximately 13% in 79% of initially randomized patients and a mean EWL of 21% at 24 months in 43% of initially randomized patients. However, analyses beyond 12 months were post hoc, considered preliminary, and need to be replicated in other appropriately designed RCTs. In addition, the 18- and 24-month data have potential biases, including missing data and unblinding. Moreover, the 18-month analysis combined data from different follow-up visits and the 24-month analysis lacked a control group. The 2 RCTs found that vagus nerve blocking was reasonably safe in terms of serious adverse events during follow-up, although a substantial number of mild and moderate adverse events were reported.

### 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, 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 that the technology results in an improvement in the net health outcome.

### Supplemental Information

### Practice Guidelines and Position Statements

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 the 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 1 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/$m^2$ 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. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

### Ongoing and Unpublished Clinical Trials

A search of ClinicalTrials.gov in November 2020 did not identify any ongoing or unpublished trials that would likely influence this review.

## References

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## Documentation for Clinical Review

- No records required

## Coding

*This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy.*

*The following codes are included below for informational purposes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy. Policy Statements are intended to provide member coverage information and may include the use of some codes for clarity. The Policy Guidelines section may also provide additional information for how to interpret the Policy Statements and to provide coding guidance in some cases.*

| Type | Code | Description |
|---|---|---|
| CPT® | 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 ***(Deleted code effective 1/1/2023)*** |
| | 0313T | Vagus nerve blocking therapy (morbid obesity); laparoscopic revision or replacement of vagal trunk neurostimulator electrode array, including connection to existing pulse generator ***(Deleted code effective 1/1/2023)*** |
| | 0314T | Vagus nerve blocking therapy (morbid obesity); laparoscopic removal of vagal trunk neurostimulator electrode array and pulse generator ***(Deleted code effective 1/1/2023)*** |
| | 0315T | Vagus nerve blocking therapy (morbid obesity); removal of pulse generator ***(Deleted code effective 1/1/2023)*** |
| | 0316T | Vagus nerve blocking therapy (morbid obesity); replacement of pulse generator ***(Deleted code effective 1/1/2023)*** |
| | 0317T | Vagus nerve blocking therapy (morbid obesity); neurostimulator pulse generator electronic analysis, includes reprogramming when performed ***(Deleted code effective 1/1/2023)*** |
| HCPCS | None | |

## Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

| Effective Date | Action |
|---|---|
| 09/30/2015 | BCBSA Medical Policy adoption |
| 05/01/2016 | Policy revision without position change |
| 04/01/2017 | Policy title change from Vagal Nerve Blocking Therapy for Treatment of Obesity<br>Policy revision without position change |
| 04/01/2018 | Policy revision without position change |
| 04/01/2019 | Policy revision without position change |
| 05/01/2020 | Annual review. No change to policy statement. Literature review updated. |
| 04/01/2021 | Annual review. No change to policy statement. Literature review updated. |
| 04/02/2022 | New custom policy. No change to policy statement. Literature review updated. |
| 03/01/2023 | Coding update. |

## Definitions of Decision Determinations

**Medically Necessary:** Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished

at the most appropriate level which can be provided safely and effectively to the patient; and (e) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the Member's illness, injury, or disease.

**Investigational/Experimental:** A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

**Split Evaluation:** Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

## Prior Authorization Requirements and Feedback (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at www.blueshieldca.com/provider.

We are interested in receiving feedback relative to developing, adopting, and reviewing criteria for medical policy. Any licensed practitioner who is contracted with Blue Shield of California or Blue Shield of California Promise Health Plan is welcome to provide comments, suggestions, or concerns. Our internal policy committees will receive and take your comments into consideration.

For utilization and medical policy feedback, please send comments to: MedPolicy@blueshieldca.com

*Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.*

## Appendix A

| POLICY STATEMENT<br>(No changes) | |
|---|---|
| **BEFORE** | **AFTER** |
| **Vagus Nerve Blocking Therapy for Treatment of Obesity BSC7.17**<br><br>**Policy Statement:**<br>Intra-abdominal vagus nerve blocking therapy is considered **investigational** in all situations, including but not limited to the treatment of obesity. | **Vagus Nerve Blocking Therapy for Treatment of Obesity BSC7.17**<br><br>**Policy Statement:**<br>Intra-abdominal vagus nerve blocking therapy is considered **investigational** in all situations, including but not limited to the treatment of obesity. |