
Medical Policy



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***Current Policy Effective Date: 7/1/21**
(See policy history boxes for previous effective dates)

Title: Vagus Nerve Blocking for the Treatment of Morbid Obesity

Description/Background

OBESITY

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/m² or more.¹ Fifteen percent of adults had a BMI of 35 kg/m² or more and 6% had a BMI of 40 kg/m² or more. Among children age 2 to 19 years, 16.9% were obese, defined in the pediatric population as 95% percentile or more in BMI for 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 meta-analyses, being obese has been associated with higher all-cause mortality and death from cardiovascular disease.² In 2013, 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 been found to improve outcomes in selected patients who choose that treatment.

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 encounter 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, 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 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, transmit coils, a programmable microprocessor and customized software. The system delivers high-frequency pulses of current to vagal 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.

Outcomes

To assess obesity treatments, a double-blind randomized controlled trial 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 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.

Regulatory Status:

FDA approved the Maestro Rechargeable System (EnteroMedics, St. Paul, MN) through the premarket approval process on January 14, 2015. The device is indicated for use in adults age 18 years and older who have a BMI of 40 to 45 kg/m² or a BMI of 35 to 39.9 kg/m² with 1 or more obesity-related comorbidities and have failed at least 1 supervised weight management program within the past 5 years. Implantable components are incompatible with magnetic resonance imaging (MRI). In addition to need for MRI, 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.

Medical Policy Statement

Vagus nerve blocking for the treatment of morbid obesity is experimental/investigational. There is insufficient documentation in medical literature to indicate that the use of this device results in improved patient clinical outcomes.

Inclusionary and Exclusionary Guidelines (Clinically based guidelines that may support individual consideration and pre-authorization decisions)

N/A

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure)*

Established codes:

N/A

Other codes (investigational, not medically necessary, etc.):

0312T

0313T

0314T

0315T

0316T

0317T

Rationale

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined health outcomes are 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 to 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 a technology, 2 domains are examined: the relevance and the 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 Therapy 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 **PICOs** were used to select literature to inform this review.

Patients

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 treatment of obesity. 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. 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 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

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 is life long. Type 1 diabetes mellitus require life-long medical monitoring of glycemic control and end-organ status.

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 longer 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.

Randomized Controlled Trials

The published literature on vagal nerve blockade for obesity consists of two RCTs, both of which were industry-sponsored, multicenter, double blind and sham controlled.^{3,4} Although both trials included a sham treatment group, protocols differed. In the 2012 EMPOWER trial, all participants had devices implanted and leads placed.³ However, external controllers were programmed differently such that if the controllers were worn for 10 hours per 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 ReCharge trial, all participants had devices implanted but no leads were placed in the sham group.⁴

Study characteristics and results of the two trials are summarized in Tables 1 and 2.

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

Author; Study	Countries	Sites	Dates	Participants	Interventions	
					Active	Comparator
Sarr et al (2011) ³ ; 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) ⁴ ; 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

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 (2011) ³			
Active	17	22	23/192 (12%)
Sham	16	25	12/102 (12%)
Diff (95% CI)	1 (NR)	-3 (NR)	
Ikramuddin et al (2014) ⁴			
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/m² 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 of the 2 RCTs. The difference in mean percent EWL was the sole primary efficacy outcome in the EMPOWER study and a coprimary outcome in the ReCharge study. This outcome was evaluated in both trials using a superiority margin of 10%, i.e., the efficacy objective would only be met if there was more than a 10%

difference between groups in EWL. U.S. Food and Drug Administration (FDA) documents state that the 10% margin, which was not attained in either trial, was considered to indicate a clinically meaningful difference in weight loss between active and sham treatment groups.⁵

For the ReCharge trial, however, in addition to the primary efficacy analysis, the authors also 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% CI, 3.1% to 13.9%) was statistically significant. (The difference between groups in percent EWL in the 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 ReCharge trial was 249 pounds in the active treatment group and 255 pounds in the sham group. Mean excess body weight was 97 pounds in the treatment group and 99 pounds in the sham group. Thus, a difference of 10% EWL, used in the primary analyses, represents only about a 10 pounds difference in absolute weight loss and a 4% difference in absolute body weight.

The Evaluate the Safety and Efficacy of vBloc Therapy Delivered by the MaestroRechargeable 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 a post hoc subgroup analysis of the EMPOWER trial, longer duration of device use per day was related to a larger percentage of EWL. This association, however, occurred in the sham group, as well as the active treatment group. For example, EWL among patients who used the device fewer than 6 hours was 5% in the active treatment group and 6% in the sham group whereas EWL among patients who used the device at least 12 h/d was 30% and 22%, respectively. This finding suggests a substantial placebo effect associated with device use.

Both trials met their primary safety end points that related to SAEs. However, there were nonserious adverse events that occurred frequently. Rates of key adverse events (all severity levels) in the ReCharge trial are shown in Table 3. Most of these were of mild or moderate severity. The authors of the 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 ReCharge trial design and findings was reported in FDA documents.⁵ The study was designed to evaluate primary end points at 12 months and then to continue following patients until 5 years post implant. 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 of crossing over into the active treatment group. At 18 months, follow-up data were reported for 117 patients (72%) 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 were not reported. At 18 months, the mean percent EWL was 25.3% in the active treatment group and 11.7% in the sham group. There was a mean between-group difference of 13.5% (95% confidence interval, 5.7% to 21.3%). In this analysis, the treatment group sustained the weight loss they achieved at 12 months, and the control group gained weight. However, there are several ways the 18-month analysis may be biased. Sham patients were unblinded starting at 12 months and unblinding could influence patient beliefs, perceptions and behaviors. For example, during the 12-month sham intervention phase of the trial, patients in both groups experienced decreased hunger, increased cognitive restraint and decreased food intake. Although not reported, it is likely that unblinding could have an impact on these factors, which contributed to weight loss in the sham group during the first 12 months. Thus, due to potential biases associated with unblinding and crossover, conclusions cannot be drawn about the efficacy of vagal nerve blocking on maintenance of weight loss relative to a sham intervention. Finally, nearly half of the patients initially randomized to the sham group were not included in the 18-month analysis, which limits ability to draw conclusions about these data. FDA documents also report longer-term safety data. Analyses of data up to 48 months from the EMPOWER trial and 18-month data from the ReCharge trial did not identify any deaths or unanticipated SAEs. There were 13 surgical explants through 12 months (5 in active treatment group, 8 in sham group) and an additional 16 explants between 12 and 18 months (14 in active treatment group, 7 in sham group). Reasons for explants included patient decision, pain and need for magnetic resonance imaging.

Eighteen-month follow-up data from the ReCharge trial were published in the peer-reviewed literature by Shikora et al in 2015.⁶ The authors 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 another 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 a total of 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 and found no statistically significant impact of blinding on their findings, which were also similar when the analysis was restricted to patients who remained blinded at 18 months. The degree of EWL at 18 months in this analysis of ReCharge trial data are similar to those previously published in the FDA documents, although this sample size is larger, reducing potential bias from missing data. However, as this was a post hoc analysis that incorporated 16- and 17-month data in addition to 18-month data, results are considered preliminary or hypothesis-generating.

Twenty-four-month outcomes from the ReCharge trial were published by Apovian et al in 2016.⁷ The investigators noted that the sham arm was no longer a valid comparator at 24 months due to crossover and dropout; moreover, patients were unblinded at 12 months. There was no prespecified statistical analysis plan for analyses that occurred after the 12-month primary outcome

assessment, including the analysis in this 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 the 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 is limited by lack of a blinded comparison group, and, like the 18-month data, is a post hoc analysis.

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, the observed difference in excess weight loss (EWL) between groups at 12 months was 1%. In the more recent trial 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 the investigators' original trial design decisions. Additional analyses of data from the second trial found a difference in EWL at 18 months of approximately 13% in 79% of randomized patients and a mean EWL of 21% at 24 months in 43% of randomized patients. However, analyses beyond 12 months are post hoc analyses 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 the impact of unblinding. Moreover, the 18-month analysis combined data from different follow-up visits and the 24-month analysis lacked a control group. The two RCTs found that vagal nerve blocking was reasonably safe in terms of SAEs 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, the observed difference in excess weight loss (EWL) between groups at 12 months was 1%. In the more recent trial, 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 the investigators' original trial design decisions. Post hoc analyses of longer-term data have been published and these 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 did not identify any ongoing or unpublished trials that would likely influence this review.

SUPPLEMENTAL INFORMATION

PRACTICE GUIDELINES AND POSITION STATEMENTS

American Society for Metabolic and Bariatric Surgery (ASMBS)

A position statement published in 2016 by the ASMBS includes the following conclusions on vagus nerve blocking therapy for treatment of obesity⁸:

1. Reversible vagal nerve blockade has been shown to result in statistically significant EWL at 1 year compared with a control group in one of two 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 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.⁹ 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.

Government Regulations

National/Local:

No CMS NCD or LCD on this topic. No fees assigned to the codes for this procedure.

Local Coverage Determination (LCD) L35490, effective for services on or after 10/29/2020 addresses category III codes and coverage. Group 1 Paragraph codes are codes that CMS considers reasonable and medically necessary. The following codes are not listed in this group of codes: 0312T-0315T.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

- Vagus Nerve Stimulation
 - Bariatric Surgery
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References

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6. Shikora SA, Wolfe BM, Apovian CM, et al. Sustained weight loss with vagal nerve blockade but not with sham: 18-month results of the Re-Charge trial. *J Obes*. 2015; 2015:365604. PMID 26246907
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11. Blue Cross Blue Shield Association. Vagal Nerve Blocking Therapy for Treatment of Obesity. Medical Policy Reference Manual. Policy #7.01.150, Issue 4:2015, last review date March 2021.
12. Hayes Prognosis Overview. Vagal Blocking for Obesity Control (VBLOC®) via the Maestro® System. Lansdale, PA: HAYES, Inc. October 2012, updated February 2016. Archived February 2019; Outdated

The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through March 2021, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
9/1/13	6/18/13	6/26/13	Joint policy established
3/1/15	12/12/14	12/29/14	Routine maintenance. No change in policy status.
5/1/15	2/17/15	2/27/15	Updated FDA approval status.
7/1/16	4/19/16	4/19/16	Updated policy to mirror BCBSA policy.
7/1/17	4/18/17	4/18/17	Updated rationale and added reference #6, 7 and 8. No change in policy status.
7/1/18	4/17/18	4/17/18	Routine policy maintenance, no change in policy status.
7/1/19	4/16/19		Routine policy maintenance, no change in policy status.
7/1/20	4/14/20		Routine policy maintenance, no change in policy status.
7/1/21	4/20/21		Recommend retirement. No change in policy status.

Next Review Date: Topic is obsolete and will no longer be reviewed.

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: VAGUS NERVE BLOCKING FOR THE TREATMENT OF MORBID OBESITY

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Not covered.
BCNA (Medicare Advantage)	See government section.
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

N/A