



MASSACHUSETTS

Blue Cross Blue Shield of Massachusetts is an independent
Licensee of the Blue Cross and Blue Shield Association

Medical Policy

Vagus Nerve Blocking Therapy for Treatment of Obesity

Table of Contents

- [Policy: Commercial](#)
- [Policy: Medicare](#)
- [Authorization Information](#)
- [Coding Information](#)
- [Description](#)
- [Policy History](#)
- [Information Pertaining to All Policies](#)
- [References](#)

Policy Number: 644

BCBSA Reference Number: 7.01.150

NCD/LCD: Local Coverage Determination (LCD): Category III CPT® Codes (L33392) (A56195)

Related Policies

- Vagus Nerve Stimulation, [#474](#)
- Medical and Surgical Management of Obesity including Anorexiant, [#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.

Medical necessity criteria and coding guidance for **Medicare Advantage members living in Massachusetts** can be found through the link below.

[Local Coverage Determinations \(LCDs\) for National Government Services, Inc.](#)

Local Coverage Determination (LCD): Category III CPT® Codes (L33392) (A56195)

Note: To review the specific LCD, please remember to click “accept” on the CMS licensing agreement at the bottom of the CMS webpage.

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 at <https://www.cms.gov> for information regarding your specific jurisdiction.

Prior Authorization Information

Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** for all products if the procedure is performed **inpatient**.

Outpatient

- For services described in this policy, see below for products where prior authorization **might be required** if the procedure is performed **outpatient**.

| | Outpatient |
|--|---------------------------------------|
| Commercial Managed Care (HMO and POS) | This is not a covered service. |
| 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

| CPT codes: | Code Description |
|------------|---|
| 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

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/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.

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 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 the regulation of the digestive system, although its exact role in controlling appetite and feelings of satiety is unknown. Vagus nerve blocking therapy involves intermittent blocking of signals to the intra-abdominal vagus nerve, with the intent of disrupting hunger sensations and inducing feelings of satiety.

In January 2015, the U.S. Food and Drug Administration (FDA) approved a medical device specifically designed to provide vagal nerve blocking therapy for regulation of weight in obese patients. This device, the Maestro Rechargeable System, includes a neuroblocking pulse generator that is implanted subcutaneously on the thoracic sidewall and flexible leads approximately 47 cm in length that are placed on the abdominal anterior and posterior vagal nerve trunks. External components include a mobile charger, a transmit coil, a programmable microprocessor, and customized software. The system delivers high-frequency pulses of electrical current to vagus nerve trunks; therapy parameters and the treatment schedule can be customized by a clinician. Like other surgical interventions, there is the potential for adverse effects. In addition, there may be other unintended consequences of disrupting signals to a particular portion of the vagus nerve.

Stimulation of the vagus nerve via a device implanted within the carotid artery sheath has also been evaluated as a treatment for obesity and is addressed in policy [#474](#). 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 (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 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.

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 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 the effects of the technology on health outcomes.

Policy History

| Date | Action |
|--------|---|
| 4/2020 | BCBSA National medical policy review. Description, summary and references updated. Policy statements unchanged. |
| 4/2019 | BCBSA National medical policy review. Description, summary and references updated. Policy statements unchanged. |
| 4/2017 | BCBSA National medical policy review. Title changed from "Vagal" to "Vagus". Policy statement unchanged. 4/1/2017 |
| 9/2015 | New medical policy describing investigational indications. Effective 9/1/2015. |

Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

[Medical Policy Terms of Use](#)

[Managed Care Guidelines](#)

[Indemnity/PPO Guidelines](#)

[Clinical Exception Process](#)

[Medical Technology Assessment Guidelines](#)

References

1. Ogden CL, Carroll MD, Kit BK, et al. Prevalence of childhood and adult obesity in the United States, 2011-2012. JAMA. Feb 26 2014;311(8):806-814. PMID 24570244
2. Flegal KM, Kit BK, Orpana H, et al. Association of all-cause mortality with overweight and obesity using standard body mass index categories: a systematic review and meta-analysis. JAMA. Jan 2 2013;309(1):71-82. PMID 23280227
3. U.S. Food and Drug Administration. Weight-Loss and Weight-Management Devices. 2019; <https://www.fda.gov/medical-devices/products-and-medical-procedures/weight-loss-and-weight-management-devices> Accessed January 2, 2020
4. ReShape LifesciencesTM. Summary of Transformative Technologies for the Treatment Continuum. 2020. <https://www.reshapelifesciences.com/> Accessed January 2, 2020.
5. U.S. Food and Drug Administration. Premarket Approval (PMA) Database: Maestro Rechargeable System (P130019). 2020. <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm>. Accessed January 2, 2020.

6. Sarr MG, Billington CJ, Brancatisano R, et al. The EMPOWER study: randomized, prospective, double-blind, multicenter trial of vagal blockade to induce weight loss in morbid obesity. *Obes Surg.* Nov 2012;22(11):1771- 1782. PMID 22956251
7. Ikramuddin S, Blackstone RP, Brancatisano A, et al. Effect of reversible intermittent intra-abdominal vagal nerve blockade on morbid obesity: the ReCharge randomized clinical trial. *JAMA.* Sep 3 2014;312(9):915-922. PMID 25182100
8. U.S. Food and Drug Administration. Summary of Safety and Effectiveness Data (SSED): Maestro Rechargeable System. 2015; http://www.accessdata.fda.gov/cdrh_docs/pdf13/P130019B.pdf. Accessed December 19, 2019.
9. Shikora SA, Wolfe BM, Apovian CM, et al. Sustained weight loss with vagal nerve blockade but not with sham: 18-month results of the ReCharge Trial. *J Obes.* 2015;2015:365604. PMID 26246907
10. Apovian CM, Shah SN, Wolfe BM, et al. Two-year outcomes of vagal nerve blocking (vBloc) for the treatment of obesity in the ReCharge Trial. *Obes Surg.* Jan 2017;27(1):169-176. PMID 27506803
11. Papasavas P, El Chaar M, Kothari SN, et al. American Society for Metabolic and Bariatric Surgery position statement on vagal blocking therapy for obesity. *Surg Obes Relat Dis.* Mar-Apr 2016;12(3):460-461. PMID 26948945
12. Curry SJ, Krist AH, Owens DK et al. Behavioral Weight Loss Interventions to Prevent Obesity-Related Morbidity and Mortality in Adults: US Preventive Services Task Force Recommendation Statement. *JAMA.* 2018 Sep;320(11). PMID 30326502