MEDICAL POLICY

POLICY TITLE	VAGUS NERVE BLOCKING THERAPY FOR THE TREATMENT OF OBESITY
POLICY NUMBER	MP 1.146

Clinical benefit	☐ **Minimize safety risk or concern.** ☒ **Minimize harmful or ineffective interventions.** ☐ **Assure appropriate level of care.** ☐ **Assure appropriate duration of service for interventions.** ☐ **Assure that recommended medical prerequisites have been met.** ☐ **Assure appropriate site of treatment or service.**
Effective Date:	**2/1/2024**

I. POLICY

Intra-abdominal vagus nerve blocking therapy is considered **investigational** in all situations, including but not limited to the treatment of obesity. There is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with this procedure.

Cross-references:

MP 1.015 Metabolic and Bariatric Surgery
MP 1.034 Implantable Electrical Nerve Stimulators (Vagus, Autonomic Nerve, and Peripheral Nerve Stimulators
MP 2.069 Gastric Electrical Stimulation

II. PRODUCT VARIATIONS

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This policy is only applicable to certain programs and products administered by Capital Blue Cross and subject to benefit variations as discussed in Section VI. Please see additional information below.

FEP PPO: Refer to FEP Medical Policy Manual. The FEP Medical Policy manual can be found at:

https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies .

III. DESCRIPTION/BACKGROUND

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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.

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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. 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. 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.

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 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 evidence review 7.01.20. 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 is optimal because these interventions require changes to patient behavior (e.g., 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.

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. 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 09/05/2019), the Maestro® Rechargeable System is described as "no longer marketed as of September 2018." 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. However, updates to the Maestro® Rechargeable System were noted in the FDA Premarket Approval database (P130019) subsequent to September 2018, including updates to the circuit assembly and application firmware of the mobile charger (01/25/2019) and approval of modifications to the follow-up schedule for the post-approval study protocol.

IV. RATIONALE

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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.

V. DEFINITIONS

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NA

VI. BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member's health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits, and which require preauthorization. There are different benefit plan designs in each product administered by Capital Blue Cross. Members and providers should consult the member's health benefit plan for information or contact Capital Blue Cross for benefit information.

VII. DISCLAIMER

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Capital Blue Cross's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital Blue Cross' Provider Services or Member Services. Capital Blue Cross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

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Investigational; therefore, not covered:

Procedure Codes							
64999							

Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

IX. REFERENCES

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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. *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*
4. *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*
5. *U.S. Food and Drug Administration. Summary of Safety and Effectiveness Data (SSED): Maestro Rechargeable System. 2015;*
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 ReCharge Trial. J Obes. 2015;2015:365604. PMID 26246907*
7. *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. Aug 10 2016. PMID 27506803*
8. *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*
9. *U.S. Preventive Services Task Force. Obesity in Adults: Screening and Management. 2012 (Archived);*
10. *U.S. Food and Drug Administration. Weight-Loss and Weight-Management Devices. 2019;.*
11. *ReShape LifesciencesTM. Summary of Transformative Technologies for the Treatment Continuum. 2020.*
12. *U.S. Food and Drug Administration. Premarket Approval (PMA) Database: Maestro Rechargeable System (P130019). 2020.*
13. *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;3 20(11). PMID 30326502*
14. *Blue Cross Blue Shield Association Medical Policy Reference Manual. 7.01.150, Vagus Nerve Blocking Therapy for Treatment of Obesity. Archived April, 2021.*

X. POLICY HISTORY

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MP 1.146	**CAC 9/29/15 New policy adopting BCBSA.** Vagal nerve blocking therapy considered investigational in all situations. Policy coded.
	CAC 9/27/16 Consensus review. No change to policy statements. Background, rationale, and references updated. Variation reformatted. Coding reviewed.
	CAC 11/28/17 Consensus review. Changed the word "vagal" to "vagus" in title and in policy. Intent of policy unchanged. References and rationale updated. Coding reviewed.
	10/12/18 Consensus review. No change to the policy statement. Background and references reviewed. Rationale revised.
	9/3/19 Consensus review. No change to policy statements. Background and references updated. Summary of evidence reviewed.
	9/4/20 Consensus review. No change to policy statement. Coding reviewed, no changes; References reviewed and updated; Regulatory Status updated; Product Variation Statement updated.
	5/11/21 Consensus review. No change to policy statement. Coding reviewed with no changes. Product Variations updated. References reviewed and updated.
	10/20/2022 Consensus review. No change to policy statement. References updated
	12/1/2022 Admin update. Deleted codes effective 1/1/23.
	11/3/2023 Consensus review. No change to policy statement. Added code 64999. References updated.

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