

FEP 7.01.150 Vagus Nerve Blocking Therapy for Treatment of Obesity

Effective Date: July 15, 2018

Related Policies:
7.01.73 Gastric Electrical Stimulation

Vagus Nerve Blocking Therapy for Treatment of Obesity

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.

FDA 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/m² or a BMI of 35 to 39.9 kg/m² with 1 or more obesity-related conditions such as high blood pressure or high cholesterol and have failed at least 1 supervised weight management program within the past 5 years. Implantable components are incompatible with magnetic resonance imaging. Additional contraindications to use of the device include conditions such as cirrhosis of the liver, portal hypertension and clinically significant hiatal hernia, and the presence of a previously implanted medical device. FDA product code: PIM.

POLICY STATEMENT

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

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

RATIONALE

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

FEP 7.01.150 Vagus Nerve Blocking Therapy for Treatment of Obesity

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.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

A 2016 position statement published by the American Society for Metabolic and Bariatric Surgery includes the following conclusions on vagus nerve blocking therapy for treatment of obesity⁸:

- “1. Reversible vagal nerve blockade has been shown to result in statistically significant EWL [excess weight loss] at 1 year compared with a control group in one of 2 prospective randomized trials.
2. Reversible vagal nerve blockage has been shown to have a reasonable safety profile with a low incidence of severe adverse events and a low revisional rate in the short term. More studies are needed to determine long-term reoperation and explantation rates.
3. The prospective collection of VBLOC [vagus nerve blocking] outcomes as part of the national center of excellence databases is encouraged to establish the long-term efficacy of this new technology.”

U.S. Preventive Services Task Force Recommendations

The U.S. Preventive Services Task Force published recommendations for screening and management of obesity in adults in 2012.⁹ 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. The recommendations are currently being updated.

Medicare National Coverage

There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

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. 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; http://www.accessdata.fda.gov/cdrh_docs/pdf13/P130019B.pdf. Accessed January 19, 2018.
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*. Jan 2017;27(1):169-176. 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

FEP 7.01.150 Vagus Nerve Blocking Therapy for Treatment of Obesity

9. U.S. Preventive Services Task Force. Obesity in Adults: Screening and Management. 2012; <http://www.uspreventiveservicestaskforce.org/Page/Topic/recommendation-summary/obesity-in-adults-screening-and-management>. Accessed January 19, 2018.

POLICY HISTORY

Date	Action	Description
June 2015	New Policy	Intra-abdominal vagus nerve blocking therapy is considered not medically necessary in all situations, including but not limited to the treatment of obesity.
June 2016	Update Policy	Policy updated with literature review through December 13, 2015; reference 6 added. Policy statement unchanged.
June 2018	Update Policy	Policy updated with literature review through December 11, 2017; no references added. Policy statement unchanged.

The policies contained in the FEP Medical Policy Manual are developed to assist in administering contractual benefits and do not constitute medical advice. They are not intended to replace or substitute for the independent medical judgment of a practitioner or other health care professional in the treatment of an individual member. The Blue Cross and Blue Shield Association does not intend by the FEP Medical Policy Manual, or by any particular medical policy, to recommend, advocate, encourage or discourage any particular medical technologies. Medical decisions relative to medical technologies are to be made strictly by members/patients in consultation with their health care providers. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that the Blue Cross and Blue Shield Service Benefit Plan covers (or pays for) this service or supply for a particular member.