FEP Medical Policy Manual

FEP 7.01.150 Vagus Nerve Blocking Therapy for Treatment of Obesity

Effective Policy Date: July 1, 2020

Original Policy Date: June 2015

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.

OBJECTIVE

The objective of this evidence review is to determine whether the use of vagus nerve blocking therapy improves the net health outcomes for individuals treated for obesity.

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.

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.
POLICY GUIDELINES

None

BENEFIT APPLICATION

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

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 (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 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.

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, 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.
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:

1. Reversible vagal nerve blockade has been shown to result in statistically significant 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

In 2018, the U.S. Preventive Services Task Force updated recommendations for screening and management of obesity in adults. 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.

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.

REFERENCES


POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>June 2015</td>
<td>New policy</td>
<td>Intra-abdominal vagus nerve blocking therapy is considered not medically necessary in all situations, including but not limited to the treatment of obesity.</td>
</tr>
<tr>
<td>June 2016</td>
<td>Replace policy</td>
<td>Policy updated with literature review through December 13, 2015; reference 6 added. Policy statement unchanged.</td>
</tr>
<tr>
<td>June 2018</td>
<td>Replace policy</td>
<td>Policy updated with literature review through December 11, 2017; no references added. Policy statement unchanged.</td>
</tr>
<tr>
<td>June 2019</td>
<td>Replace policy</td>
<td>Policy updated with literature review through January 26, 2019; no references added; reference 9 updated. Policy statement unchanged.</td>
</tr>
<tr>
<td>June 2020</td>
<td>Replace policy</td>
<td>Policy updated with literature review through December 10, 2019; references added to Regulatory Status section (links to FDA and manufacturer websites) regarding commercial availability of device. Policy statement unchanged.</td>
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</tbody>
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