Baroreflex Stimulation Devices

Description

Baroreflex stimulation devices provide electrical stimulation of the baroreceptors in the carotid arteries using an implanted device. Activation of the baroreflex inhibits the sympathetic nervous system, resulting in various physiologic changes, including slowed heart rate and lower blood pressure. A device for baroreflex stimulation has been developed, but has not received U.S. Food and Drug Administration approval other than a humanitarian device exemption for patients who had previously participated in a clinical trial.

OBJECTIVE

The objective of this evidence review is to determine whether baroreflex stimulation devices improve the net health outcome in patients with treatment-resistant hypertension or heart failure.

POLICY STATEMENT

Use of baroreflex stimulation implanted devices is considered investigative in all situations, including but not limited to treatment of hypertension and heart failure.
BENEFIT APPLICATION

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

FDA REGULATORY STATUS

In 2014, the Barostim neo Legacy System (CVRx) received a humanitarian device exemption from the Food and Drug Administration for use in patients with treatment-resistant hypertension who received Rheos Carotid Sinus leads as part of the Rheos pivotal trial and were considered responders in that trial.\(^1\)

In 2015, CVRx received expedited access pathway designation from the Food and Drug Administration for Barostim Therapy to treat heart failure.\(^2\) This pathway designation does not guarantee that an application to the Food and Drug Administration will ultimately be approved.

RATIONALE

Summary of Evidence

For individuals who have treatment-resistant hypertension who receive baroreflex stimulation therapy, the evidence includes an RCT and several small uncontrolled studies. Relevant outcomes are overall survival, functional outcomes, quality of life, hospitalizations, medication use, and treatment-resistant morbidity. The uncontrolled studies have reported short-term reductions in blood pressure in patients treated with baroreflex stimulation devices, as well as adverse events such as infection, hypoglossal nerve injury, and wound complications. The RCT comparing baroreflex stimulation with continued medical management met some efficacy end points but not others as well as 2 of its 3 predefined safety end points. Additional RCTs are needed to permit conclusions on the efficacy and safety. In addition, baroreflex stimulation currently has a very narrow Food and Drug Administration approval (ie, for patients who previously participated in a pivotal trial) and broader approval or clearance is needed for wider application. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have treatment-resistant heart failure who receive baroreflex stimulation therapy, the evidence includes an RCT. Relevant outcomes are overall survival, functional outcomes, quality of life, hospitalizations, medication use, and treatment-resistant morbidity. The RCT met all 3 efficacy end points but had methodologic limitations, including lack of blinding, a relatively small sample size for a common condition and a relatively short intervention period. A second, larger, RCT designed to assess the effects of the intervention on mortality, safety, functional, and quality of life outcomes, is underway. In addition, the only baroreflex stimulation device with humanitarian device exemption approval currently has only a very narrow Food and Drug Administration approval (ie, for patients who previously participated in a pivotal trial) and broader approval or clearance is needed for wider application. The evidence is insufficient to determine the effect of the technology on health outcomes.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

National Institute for Health and Care Excellence

In 2015, National Institute for Health and Care Excellence issued guidance that stated: "Current evidence on the safety and efficacy of implanting a baroreceptor stimulation device for resistant hypertension is inadequate. Therefore, this procedure should only be used in the context of research."\(^1\)

U.S. Preventive Services Task Force Recommendations

Not applicable.

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.
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:

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<th>Date</th>
<th>Action</th>
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<tr>
<td>March 2012</td>
<td>New policy</td>
<td>Policy updated with literature review, references 2, 4, 8-11 added. No change to policy statement.</td>
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<tr>
<td>December 2013</td>
<td>Replace policy</td>
<td>Policy updated with literature review. No change to policy statement.</td>
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<tr>
<td>December 2014</td>
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<tr>
<td>December 2015</td>
<td>Replace policy</td>
<td>Policy updated with literature review through August 11, 2015; reference 6 added. Hypertension and heart failure added as examples in investigational policy statement.</td>
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<tr>
<td>September 2018</td>
<td>Replace policy</td>
<td>Policy updated with literature review through March 6, 2018; references 1-2, 8, and 10-11 added; reference 2 updated. Policy statement unchanged.</td>
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<tr>
<td>September 2019</td>
<td>Replace policy</td>
<td>Policy updated with literature review through April 2, 2019; reference added. Policy statement unchanged.</td>
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