FEP Medical Policy Manual

FEP 8.01.57 Baroreflex Stimulation Devices

Effective Policy Date: October 1, 2023

Original Policy Date: June 2012

Related Policies:

7.01.136 - Radiofrequency Ablation of the Renal Sympathetic Nerves as a Treatment for Resistant or Uncontrolled Hypertension

Baroreflex Stimulation Devices

Description

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.

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 **not medically necessary** in all situations, including but not limited to treatment of hypertension and heart failure.

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 2014, the Barostim Neo™ Legacy System received a humanitarian device exemption from the U.S. 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 2019, Barostim Neo was granted premarket approval (PMA P180050) and is indicated for the improvement of symptoms of heart failure (ie, quality of life, six-minute hall walk, and functional status) for patients who remain symptomatic despite treatment with guideline-directed medical therapy, are New York Heart Association (NYHA) Class III or Class II (with a recent history of Class III), and have a left ventricular ejection fraction less than or equal to 35% and a N-terminal pro-B-type natriuretic peptide (NT-proBNP) less than 1600 pg/ml, excluding patients indicated for Cardiac Resynchronization Therapy according to the American Heart Association/American College of Cardiology/European Society of Cardiology guidelines.

It was the first device to be granted approval via the Expedited Access Pathway.[2,3,] The Expedited Access Pathway hastens the approval of novel therapies that target life-threatening conditions.

RATIONALE

Summary of Evidence

For individuals who have treatment-resistant hypertension who receive baroreflex stimulation therapy, the evidence includes a randomized controlled trial (RCT) and several small uncontrolled studies. Relevant outcomes are overall survival (OS) , 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 endpoints but not others, as well as 2 of its 3 predefined safety endpoints. Additional RCTs are needed to permit conclusions on efficacy and safety. Baroreflex stimulation for treatment-resistant hypertension is accessible only through a Humanitarian Device Exemption for patients who previously participated in a pivotal trial. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have treatment-resistant heart failure who receive baroreflex stimulation therapy, the evidence includes 2 RCTs, a post hoc subgroup analysis of an RCT, and meta-analyses of these trials. Relevant outcomes are OS, functional outcomes, quality of life, hospitalizations, medication use, and treatment-resistant morbidity. The expedited phase of a 2019 RCT was used by the U.S. Food and Drug Administration to approve the Barostim Neo System. The trial demonstrated that the system is safe and effective for its intended use population in the short term; however, results of the extended trial are not published , and longer-term outcomes have not been determined. A 2018 RCT met all 3 efficacy endpoints but had methodologic limitations, incomplete blinding, a relatively small sample size for a common condition, and a short intervention period. Another larger RCT designed to assess the effects of the intervention on mortality, safety, function, and quality of life outcomes is underway. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information" if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Heart Association

In 2017, the American Heart Association issued a joint guideline for the management of high blood pressure in adults with the American College of Cardiology and multiple other organizations.[17,] This guideline notes that studies have not provided sufficient evidence to support the use of baroreceptor pacing for managing resistant hypertension.

In 2022, the American Heart Association, American College of Cardiology, and multiple other organizations published a guideline on management of heart failure.[18,] The guideline states that baroreceptor stimulation has produced mixed results, and data regarding mortality and hospitalization are lacking.

National Institute for Health and Care Excellence

In 2015, the NICE 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."[19,]

U.S. Preventive Services Task Force Recommendations

Not applicable.

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

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

Date	Action	Description
March 2012	New policy	
December 2013	Replace policy	Policy updated with literature review, references 2, 4, 8-11 added. No change to policy statement.
December 2014	Replace policy	Policy updated with literature review. No change to policy statement
December 2015	Replace policy	Policy updated with literature review through August 11, 2015; reference 6 added. Hypertension and heart failure added as examples in investigational policy statement.
September 2018	Replace policy	Policy updated with literature review through March 6, 2018; references 1-2, 8, and 10-11 added; reference 2 updated. Policy statement unchanged
September 2019	Replace policy	Policy updated with literature review through April 2,2019; reference added. Policy statement unchanged.
September 2020	Replace policy	Policy updated with literature review through March 9, 2020; no references added. Policy statement unchanged except "investigational" corrected to "not medically necessary".
September 2021	Replace policy	Policy updated with literature review through March 30, 2021; references added. Policy statement unchanged.
September 2022	Replace policy	Policy updated with literature review through April 1, 2022; references added. Policy statement unchanged.
September 2023	Replace policy	Policy updated with literature review through March 24, 2023; references added. Policy statement unchanged.